APPARATUS FOR MONITORING, REGULATING, OR CONTROLLING FLUID FLOW

The present application is a Non-Provisional Application which claims the benefit of U.S. Provisional Patent Application Serial No. 62/288,132, filed January 28, 2016 and entitled **System, Method, and Apparatus for Monitoring, Regulating, or Controlling Fluid Flow** (Attorney Docket No. R06) and of U.S. Provisional Patent Application Serial No. 62/341,396, filed May 25, 2016 and entitled **System, Method, and Apparatus for Monitoring, Regulating, or Controlling Fluid Flow** (Attorney Docket No. R68), which is hereby incorporated herein by reference in its entirety.

BACKGROUND

Relevant Field

[0001] The present disclosure relates to monitoring, regulating, or controlling fluid flow. More particularly, the present disclosure relates to a system, method, and apparatus for monitoring, regulating, or controlling fluid flow, for example, for use in medical applications such as intravenous infusion therapy, dialysis, transfusion therapy, peritoneal infusion therapy, bolus delivery, enteral nutrition therapy, parenteral nutrition therapy, hemoperfusion therapy, fluid resuscitation therapy, or insulin delivery, among others.

Description of Related Art

[0002] In many medical settings, one common mode of medical treatment involves delivering fluids into a patient, such as a human, animal, or pet. The need may arise to rapidly infuse fluid into the patient, accurately infuse the fluid into the patient, and/or slowly infuse the fluid into the patient. Saline and lactated ringers are examples of commonly used fluids. Such fluids may be used to maintain or elevate blood pressure and promote adequate perfusion. In the shock-trauma setting or in septic shock, fluid resuscitation is often a first-line therapy to maintain or improve blood pressure.

[0003] Delivery of fluid into the patient may be facilitated by use of a gravity-fed line (or tube) inserted into the patient. Typically, a fluid reservoir (e.g., an IV bag) is hung on a pole and is connected to the fluid tube. The fluid tube is sometimes coupled to a drip chamber for trapping air and estimating fluid flow. Below the fluid tube may be a manually actuated valve used to adjust the flow of fluid. For example, by counting the number of drops formed in the drip chamber within a certain amount of time, a caregiver can calculate the rate of fluid that flows through the drip chamber and adjust the valve (if needed) to achieve a desired flow rate.

[0004] Certain treatments require that the fluid delivery system strictly adhere to the flow rate set by the caregiver. Typically, such applications use an infusion pump, but such pumps may not be used in all situations or environments.

SUMMARY

[0005] Briefly, and in general terms, the present disclosure relates to a system, method, and apparatus for monitoring, regulating, or controlling fluid

flow, for example, for use in medical applications such as intravenous infusion therapy, dialysis, transfusion therapy, peritoneal infusion therapy, bolus delivery, enteral nutrition therapy, parenteral nutrition therapy, hemoperfusion therapy, fluid resuscitation therapy, or insulin delivery, among others. More particularly, the present disclosure relates to a fluid flow meter for monitoring the flow of fluids associated with a patient, a valve for regulating the flow of fluid associated with the patient, and/or a fluid flow meter coupled to a valve (e.g., arranged in a closed-loop, open-loop, or feedback configuration) to monitor, regulate and/or control the use of fluid associated with the patient.

[0006] In an embodiment of the present disclosure, an apparatus for infusing fluid into a patient includes a housing, a tube-contact member, a rotating arm, and a tube-retention cover. The housing has an opening on a front side of the housing. The opening is sized to receive a drip chamber having an inlet tube and an outlet tube. The tube-contact member contacts one of the inlet tube and the output tube of the drip chamber when inserted into the opening. The rotating arm is coupled to the tube-contact member and is configured to rotate along an axis. The tube-retention cover is configured to close when the drip chamber is initially loaded into the opening.

[0007] In exemplary embodiments, the rotating arm may be a split-rotating arm. The split-rotating arm may comprise an arm portion and a tube-engagement portion. the tube-engagement portion may include the tube-contact member. The arm portion may include first and second catches.

[0008] The apparatus may include a carriage having a pin configured to engage with the first and second catches. The carriage may be coupled to the tube-retention cover to open or close the tube-retention cover in accordance with actuation of the carriage. A torsion spring may rotationally bias the tube contacting portion against the arm portion of the split-rotating arm. The apparatus may include a slide-clamp keyhole such that when the drip chamber is initially loaded, the rotating arm rotates to a first direction.

[0009] A backlight may be positioned behind the drip chamber to direct a light toward an opening of the drip chamber. The backlight shines light through the drip chamber and out of the opening of the housing.

[0010] A background pattern may be disposed on an inner wall within the opening of the housing and a background light may be configured to illuminate the background pattern. A backlight may be positioned behind the drip chamber to direct a light toward an opening of the drip chamber. A modulation circuit may be configured to module the background light and the backlight. The background light and the backlight may be modulated out of phase with each other.

[0011] The apparatus may include a top light disposed on a top of the apparatus. The top light may be a diffuse light forming a layer on the top of the apparatus. The apparatus may include a window disposed on the housing, and a flag configured for display in the window when the tube-retention cover is closed to retain the drip chamber.

[0012] In some embodiments, the apparatus includes a dock configured to retain the housing. A battery may be disposed within the housing. The dock

may include a magnetic coupler and the battery is coupled to a charging coupler, and the dock is configured to communicate energy from the magnetic coupler to the charging coupler when the housing is docked within the dock.

[0013] The dock may further include a power supply coupled to A/C power via an A/C cord the magnetic coupler to communicate energy from the magnetic coupler to the charging coupler. The dock may include a transceiver configured to communicate wirelessly and may include a tilt sensor to determine a tilt of the dock and communicate the tilt to a processor within the apparatus.

[0014] In accordance with an embodiment of the present disclosure a drip chamber may comprise a housing defining fluid chamber. The drip chamber may comprise a top cap coupled to the housing and a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber as well as an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port. The drip chamber may comprise a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the housing. The drip chamber may also comprise a sleeve disposed adjacent to a section of the downstream tube including a plurality of parallel wires disposed within the sleeve.

[0015] In some embodiments, the sleeve may be disposed on an outer periphery of the downstream tube. In some embodiments, the sleeve may be disposed on an inner periphery of the downstream tube. In some embodiments,

the plurality of wires may be parallel to the downstream tube. In some embodiments, the plurality of wires may be metallic. In some embodiments, the plurality of wires may be non-metallic. In some embodiments, the plurality of wires may be embedded within the sleeve.

[0016] In accordance with another embodiment of the present disclosure a drip chamber may comprise a housing defining fluid chamber and a top cap coupled to the housing. The drip chamber may comprise a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber. The drip chamber may comprise an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port. The drip chamber may comprise a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the housing. The drip chamber may also comprise a sleeve disposed adjacent to a section of the downstream tube including a coiled wire disposed within the sleeve.

[0017] In some embodiments, the sleeve may be disposed on an outer periphery of the downstream tube. In some embodiments, the sleeve may be disposed on an inner periphery of the downstream tube.

[0018] In accordance with another embodiment of the present disclosure a drip chamber may comprise a housing defining a fluid chamber. The drip chamber may comprise a top cap coupled to the housing and a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The

drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber as well as an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port. The drip chamber may comprise a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the housing. The drip chamber may also comprise an anti-pinch member disposed on a portion of the downstream tube and configured to prevent point contacts from forming within the downstream tube.

[0019] In some embodiments, the anti-pinch member may be disposed on an outer periphery of the downstream tube. In some embodiments, the anti-pinch member may be disposed on an inner periphery of the downstream tube.

[0020] In accordance with another embodiment of the present disclosure a drip chamber may comprise a housing defining a fluid chamber. The drip chamber may comprise a top cap coupled to the housing and a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber as well as an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may also comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port and a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the housing. A section of the downstream tube may include a plurality of elongated threads disposed within the section of the downstream tube.

[0021] In some embodiments, the plurality of elongated threads may be formed by extrusions. In some embodiments, the plurality of elongated threads may be disposed along an internal wall of the section of the downstream tube.

[0022] In accordance with yet another embodiment of the present disclosure, a drip chamber may comprise a housing defining a fluid chamber. The drip chamber may comprise a top cap coupled to the housing and a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber as well as an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port. The drip chamber may comprise a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the housing. A plurality of tapering channels may be formed on an internal surface of the downstream tube.

[0023] In some embodiments, each of the tapering channels taper to a point.

[0024] In accordance with still another embodiment of the present disclosure an apparatus for infusing fluid into a patient may comprise a housing having an opening on a front side of the housing. The opening may be sized to receive a drip chamber and define an internal volume. The apparatus may comprise a coupler to secure the drip chamber to the housing. The apparatus may comprise a screen disposed on a first side of the internal volume

configured to display a background pattern. The apparatus may comprise an image sensor positioned to view the screen and the drip chamber.

[0025] In some embodiments, the screen may be an e-ink screen. In some embodiments, the screen may be configured to display a streaming detecting pattern for a first period of time and a drop detecting pattern for a second period of time. In some embodiments, the screen may be configured to adaptively display the drop detecting pattern in areas of interest determined by a processor using data from the image sensor.

[0026] In accordance with another embodiment of the present disclosure a drip chamber may comprise a housing defining a fluid chamber. The drip chamber may comprise a top cap coupled to the housing, the top cap having a first notch disposed concentrically on a first side of the top cap and a second notch disposed concentrically on a second side of the top cap. The first side may be opposite to the second side. The drip chamber may comprise a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber as well as an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may also comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port.

[0027] In some embodiments, the first and second notches may define spring fingers. In some embodiments, an end of the first notch generally may define a hollow circle. In some embodiments, an outer periphery of the top cap adjacent to the first notch may define an inwardly projecting notch configured to

cooperatively mate with a securing protrusion of a coupler. In some embodiments, an outer periphery of the top cap adjacent to the first notch may define a pressure-release notch configured to allow at least a portion of the outer periphery to bend to thereby reduce a cross-sectional size of the first notch. In some embodiments, the top cap may be configured to be released from the coupler when rotated along a transverse axis. The transverse axis may be parallel to a top surface of the top cap.

[0028] In accordance with another embodiment of the present disclosure an apparatus for infusing fluid into a patient may comprise a housing having an opening on a front side of the housing. The opening may be sized to receive a drip chamber and define an internal volume. The apparatus may comprise a coupler disposed on an upper portion of the opening. The drip chamber may also comprise a drip chamber having a top cap. The top cap may comprise a horizontal surface, a guide disposed on the top of the horizontal surface, and two arms extending out of a first end of the guide. Each of the two arms may extend toward a second end of the guide. Each of the two arms may include a respective living hinge proximate to the first end.

[0029] In some embodiments, the two arms may be a predetermined distance from the horizontal surface. In some embodiments, each of the arms may comprise a barb extending outward from the arms. In some embodiments, the barb may define first and second ramps configured for snap-fitting the drip chamber into the coupler. In some embodiments, the coupler may include two pins configured to cooperate with the two arms, respectively. In some embodiments, the first end of the guide may be rounded. In some

embodiments, the first end may be rounded and coextensive with a portion of an outer periphery of the horizontal surface. In some embodiments, the opening may define a track to receive the two arms.

[0030] In accordance with another embodiment of the present disclosure, a drip chamber may comprise a top cap. The top cap may comprise a horizontal surface, a guide disposed on the top of the horizontal surface, and two arms extending out of a first end of the guide. Each of the two arms may extend toward a second end of the guide. Each of the two arms may include a respective living hinge proximate to the first end.

[0031] In some embodiments, the two arms may be a predetermined distance from the horizontal surface. In some embodiments, each of the arms may comprise a barb extending outward from the arms. In some embodiment, the barb may define first and second ramps configured for snap-fitting the drip chamber into a coupler.

[0032] In accordance with another embodiment of the present disclosure a drip chamber may comprise a housing defining fluid chamber. The drip chamber may comprise a top cap coupled to the housing. The drip chamber may comprise a bottom cap coupled to the housing at an opposite end of the housing from the top cap. The drip chamber may comprise an inlet port coupled to the top cap and in fluid communication with the fluid chamber. The drip chamber may comprise an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber. The drip chamber may comprise a drip orifice coupled to the top cap and fluidly coupled to the inlet port. The drip chamber may comprise a downstream tube coupled to the bottom cap and in

fluid communication with the fluid chamber of the housing. The drip chamber may also comprise an anti-pinch member disposed on a portion of the downstream tube and configured to prevent point contacts from forming within the downstream tube.

[0033] In some embodiments, the anti-pinch member may be a section of the downstream tube having a plurality of parallel conduits. In some embodiments, the anti-pinch member may be a section of the downstream tube having a plurality of teardrop-shaped conduits each having a point pointed toward a center axis of the downstream tube. In some embodiments, the anti-pinch member may be a section of the downstream tube having a central conduit with a plurality of side conduits in fluid communication with the central conduit. In some embodiments, each of the side conduits may have a rounded end at an opposite end to the central conduit. In some embodiments, each of the side conduits may have a flat end at an opposite end to the central conduit.

[0034] In accordance with yet another embodiment of the present disclosure an apparatus for infusing fluid into a patient may comprise a motor having a linear shaft for actuation between an extended position and a retracted position. The apparatus may comprise a lever having a first and a second end. The linear shaft may be in sliding engagement with the first end. The apparatus may comprise a plunger having an end effector and a driven end. The driven end may be in sliding engagement with the second end of the lever.

[0035] In some embodiments, the first end of the lever may include a first guide. In some embodiments, the first guide may be a slot. In some embodiments, the linear shaft may include a pin disposed within the slot to

thereby be in sliding engagement with the slot. In some embodiments, the driven end of the plunger may include a second guide. In some embodiments, the second guide may be a slot. In some embodiments, the lever may include a pin on the second end disposed within the slot to thereby be in sliding engagement with the slot.

[0036] In some embodiments, the apparatus may further comprise a housing defining a hole, and a filler disposed within the housing. In some embodiments, the plunger may be configured to engage the filler within the housing through the hole to thereby operatively deform the filler within the housing when engaging the filler. In some embodiments, the filler may have at least two differing stiffness layers. In some embodiments, the at least two differing stiffness layers of the filler may include first, second, third, and fourth layers. In some embodiments, the first and second layers may be within a first portion of a cavity formed by the housing. In some embodiments, the third and fourth layers may be within a second portion of the cavity formed by the housing.

[0037] In accordance with another embodiment of the present disclosure a drip chamber may comprise a top cap having an inlet port configured to couple to a fluid line, a valve fluidly coupled to the medication inlet port, and a fluid port. The drip chamber may comprise a cylindrical chamber coupled to the top cap. The fluid port may be in fluid communication with the cylindrical chamber.

[0038] In some embodiments, the valve may be a volcano valve. In some embodiments, the volcano valve may include an inlet port, an outlet port, and a

membrane over the inlet port and the outlet port. In some embodiments, the fluid port may be configured to couple to one of a piston pump, an air pump, and a bellow. In some embodiments, the cylindrical chamber may be coupled to a medication outlet port. In some embodiments, a fluid line may be coupled to the medication output port and receive a downstream occluder. In some embodiments, the downstream occluder may be a check valve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] These and other aspects will become more apparent from the following detailed description of the various embodiments of the present disclosure with reference to the drawings wherein:

[0040] Fig. 1 shows a block diagram of a system for regulating fluid flow in accordance with an embodiment of the present disclosure;

[0041] Fig. 2 shows a flowchart diagram of a method for exposing an image sensor in accordance with an embodiment of the present disclosure;

[0042] Fig. 3 shows a timing diagram illustrating an embodiment of the method of Fig. 2 in accordance with an embodiment of the present disclosure;

[0043] Figs. 4A-4B show illustrations of image data (i.e., images) captured by a flow meter of a drip chamber to illustrate an embodiment of the method for exposing an image sensor of Fig. 2 in accordance with the timing diagram of Fig. 3 in accordance with an embodiment of the present disclosure;

[0044] Fig. 5 shows a diagram of a flow meter and valve that are integrated together for coupling to a drip chamber and an IV bag in accordance with an embodiment of the present disclosure;

[0045] Fig. 6 is a block diagram of an imaging system of a flow meter for imaging a drip chamber in accordance with an embodiment of the present disclosure;

[0046] Fig. 7 is a graphic illustration of an image captured by the image sensor of the system of Fig. 6 in accordance with an embodiment of the present disclosure;

[0047] Fig. 8 is a block diagram of an imaging system of a flow meter for imaging a drip chamber utilizing a background pattern in accordance with an embodiment of the present disclosure;

[0048] Fig. 9 is a graphic illustration of an image captured by an image sensor of a flow meter disclosed herein when a free flow condition exists in accordance with an embodiment of the present disclosure;

[0049] Fig. 10 is a graphic illustration of an image captured by an image sensor of a flow meter for use as a background image in accordance with an embodiment of the present disclosure;

[0050] Fig. 11 is a graphic illustration of an image captured by an image sensor when drops are being formed within a drip chamber in accordance with an embodiment of the present disclosure;

[0051] Fig. 12 is a graphic illustration of an image captured by an image sensor for use as a background image in accordance with an embodiment of the present disclosure;

[0052] Fig. 13 is a graphic illustration of a difference between the images of Figs. 11 and 12 with additional processing in accordance with an embodiment of the present disclosure;

[0053] Fig. 14 is a graphic representation of some of the image processing performed using Figs. 11-13 to determine if a free flow condition exists in accordance with an embodiment of the present disclosure;

[0054] Fig. 15 is a graphic illustration of an image captured by the image sensor when a free flow condition exists in accordance with an embodiment of the present disclosure;

[0055] Fig. 16 is a graphic illustration of an image captured by the image sensor for use as a background image in accordance with an embodiment of the present disclosure;

[0056] Fig. 17 is a graphic illustration of a difference between the images of Figs. 15 and 16 with some additional processing for use in detecting a free flow condition in accordance with an embodiment of the present disclosure;

[0057] Fig. 18 is a graphic representation of some of the image processing performed using Figs. 15-17 to determine if a free flow condition exists in accordance with an embodiment of the present disclosure;

[0058] Fig. 19 illustrates a template for pattern matching to determine if a free flow condition exits in accordance with an embodiment of the present disclosure;

[0059] Fig. 20 is a graphic illustration of a difference between a reference image and an image containing a stream processed with edge detection and line detection for use in detecting a free flow condition in accordance with an embodiment of the present disclosure;

[0060] Fig. 21 is a graphic illustration of an image of a drip chamber captured by an image sensor when a free flow condition exists in accordance with an embodiment of the present disclosure;

[0061] Fig. 22 is a block diagram of an imaging system for use with a flow meter having a background pattern with stripes and a light source shining on the stripes from an adjacent location to an image sensor in accordance with an embodiment of the present disclosure;

[0062] Fig. 23 is a block diagram of an imaging system for use with a flow meter having a background pattern with stripes and a light source shining on the stripes from behind the background pattern relative to an opposite end of an image sensor in accordance with an embodiment of the present disclosure;

[0063] Fig. 24 illustrates an image from an image sensor when a drop distorts the background pattern of Fig. 23 in accordance with an embodiment of the present disclosure;

[0064] Fig. 25 is a block diagram of an imaging system for use with a flow meter having a background pattern with a checkerboard pattern and a light source shining on the stripes from behind the background pattern relative to an opposite end of an image sensor in accordance with an embodiment of the present disclosure;

[0065] Fig. 26 shows an image from the image sensor of Fig. 25 when a drop distorts the background pattern in accordance with an embodiment of the present disclosure;

[0066] Figs. 27-28 show a flow chart illustration of a method for estimating a volume of a drop within a drip chamber in accordance with an embodiment of the present disclosure;

[0067] Figs. 29-31 illustrate images used or generated by a flow meter to estimate a volume of a drop within a drip chamber using the method illustrated by Figs. 27-28 in accordance with an embodiment of the present disclosure;

[0068] Fig. 32 shows pseudo code for identifying a plurality of pixels of interest in accordance with the method of Figs. 27-28 in accordance with an embodiment of the present disclosure;

[0069] Figs. 33-36 illustrate additional images used or generated by a flow meter to estimate a volume of a drop within a drip chamber using the method illustrated by Figs. 27-28 in accordance with an embodiment of the present disclosure;

[0070] Fig. 37 shows pseudo code for determining a subset of pixels within the plurality of pixels of interest that corresponds to a drop in accordance with an embodiment of the present disclosure;

[0071] Fig. 38 shows a ray diagram illustrating the diameter of a blur circle to illustrate aspects of an image sensor of an imaging system disclosed herein in accordance with an embodiment of the present disclosure;

[0072] Fig. 39 is a graphic illustrating a calculated blur circle for a variety of lens-to-focal plane separations and lens-to-image separations for an image sensor of an imaging system disclosed herein in accordance with an embodiment of the present disclosure;

[0073] Fig. 40 is a graphic illustrating a blur circle divided by a pixel size when a 20 millimeter focal length lens of an image sensor of an imaging system disclosed herein is used in accordance with an embodiment of the present disclosure;

[0074] Fig. 41 is a graphic illustrating a blur circle divided by a pixel size when a 40 millimeter focal length lens of an image sensor of an imaging system disclosed herein is used in accordance with an embodiment of the present disclosure;

[0075] Fig. 42 shows a table illustrating the corresponding fields of view about the optical axis for the corners of two configurations of an imaging system disclosed herein in accordance with an embodiment of the present disclosure;

[0076] Fig. 43 shows a flow meter coupled to a drip chamber in accordance with an embodiment of the present disclosure;

[0077] Fig. 44 shows the flow meter and drip chamber of Fig. 43 with the door open in accordance with an embodiment of the present disclosure;

[0078] Fig. 45 shows a flow meter coupled to a drip chamber in accordance with an embodiment of the present disclosure;

[0079] Fig. 46 shows a flow meter and a pinch valve coupled to the body of the flow meter to control the flow of fluid into a patient in accordance with an embodiment of the present disclosure;

[0080] Fig. 47 shows a close-up view of the pinch valve that is coupled to the body of the flow meter of Fig. 46 in accordance with an embodiment of the present disclosure;

[0081] Fig. 48 shows a flow meter and a pinch valve wherein the flow meter includes two image sensors in accordance with another embodiment of the present disclosure;

[0082] Fig. 49 shows a flow meter and a valve including two curved, elongated support members to control the flow of fluid into a patient in accordance with an embodiment of the present disclosure;

[0083] Figs. 50A-50B show close-up views of the valve of Fig. 49 in accordance with an embodiment of the present disclosure;

[0084] Figs. 51A-51D show several views of a flow meter with a monitoring client, a valve, a drip chamber, an IV bag and a fluid tube wherein the flow meter includes a receiving portion to receive the valve in accordance with an embodiment of the present disclosure;

[0085] Figs. 52A-52D show several views of another flow meter with a valve, a drip chamber, and a tube wherein the flow meter has a receiving portion to receive the valve in accordance with an embodiment of the present disclosure;

[0086] Fig. 53A shows another view of the valve of Figs. 51A-51D and 52A-52D in accordance with an embodiment of the present disclosure;

[0087] Figs. 53B-53C show two exploded views of the valve of Fig. 53A in accordance with an embodiment of the present disclosure;

[0088] Fig. 54 shows the valve of Fig. 53 in manual use in accordance with an embodiment of the present disclosure;

[0089] Fig. 55 shows a valve that includes two flexible members in accordance with an embodiment of the present disclosure;

[0090] Figs. 56A-56C show several views of a valve having two curved, elongated support members with one of the elongated support members having a plurality of ridges adapted to engage a tube in accordance with an embodiment of the present disclosure;

[0091] Figs. 57A-57C show several views of a valve having a ratchet that engages a connecting member in accordance with an embodiment of the present disclosure;

[0092] Figs. 57D-57E show two exploded views of the valve of Figs. 57A-57C in accordance with an embodiment of the present disclosure;

[0093] Figs. 58A-58D show several views of a valve having two elongated support members, a connecting member, and a screw-type actuator in accordance with another embodiment of the present disclosure;

[0094] Figs. 59A-59C show several views of a body of a valve in accordance with an embodiment of the present disclosure;

[0095] Figs. 59D-59G show several views of a knob for use with the body shown in Figs. 59A-59C in accordance with an embodiment of the present disclosure;

[0096] Fig. 59H shows the assembled valve that includes the body shown in Figs. 59A-59C coupled to the knob of Figs. 59D-59G in accordance with an embodiment of the present disclosure;

[0097] Fig. 60 shows a valve having a guiding protrusion in accordance with an embodiment of the present disclosure;

[0098] Fig. 61 shows a motor and a valve-securing structure for coupling to the valve of Fig. 60 in accordance with an embodiment of the present disclosure;

[0099] Fig. 62 shows the valve of Fig. 60 secured to the motor and the valve-securing structure of Fig. 61 in accordance with an embodiment of the present disclosure;

[00100] Fig. 63 shows another motor and valve-securing structure for coupling to the valve of Fig. 60 in accordance with an embodiment of the present disclosure;

[00101] Fig. 64A shows a valve having a collar and several fingers for regulating fluid flow through a fluid line in accordance with an embodiment of the present disclosure;

[00102] Fig. 64B shows a cross-sectional view of the valve of Fig. 64A in accordance with an embodiment of the present disclosure;

[00103] Fig. 65 shows a cross-sectional view of a valve having two curved surfaces for positioning a fluid tube therebetween to regulate fluid flow through the fluid tube in accordance with an embodiment of the present disclosure;

[00104] Figs. 66A-66G show several views of a valve having a knob to move a connecting member which is locked into position after movement of the knob in accordance with an embodiment of the present disclosure;

[00105] Fig. 67 shows a graphic that illustrates actuation vs. flow rates for a valve in accordance with an embodiment of the present disclosure;

[00106] Fig. 68A shows a flow meter that uses binary optics in accordance with an embodiment of the present disclosure;

[00107] Fig. 68B shows the circuit for use with Fig. 68A in accordance with an embodiment of the present disclosure;

[00108] Figs. 69A-69I show several views of a safety valve that may be used with a flow meter in accordance with an embodiment of the present disclosure;

[00109] Fig. 70 shows a flow chart diagram illustrating a method of estimating drop growth and/or flow within a drip chamber in accordance with an embodiment of the present disclosure;

[00110] Figs. 71A-71E show images taken by a flow meter with a template overlaid therein to illustrate the method of Fig. 70 in accordance with an embodiment of the present disclosure;

[00111] Fig. 72 shows a modulateable backlight assembly in accordance with an embodiment of the present disclosure;

[00112] Figs. 73A-73C show several views of a tube-restoring apparatus in accordance with an embodiment of the present disclosure;

[00113] Fig. 74 shows a system for regulating fluid flow using a valve having two flexible strips in accordance with an embodiment of the present disclosure;

[00114] Fig. 75 shows the valve of Fig. 74 in accordance with an embodiment of the present disclosure;

[00115] Fig. 76A shows a valve that utilizes a fluid-based bladder in accordance with an embodiment of the present disclosure;

[00116] Fig. 76B shows a cross-sectional view of the assembled valve of Fig. 76A with two elastomeric fillers in accordance with an embodiment of the present disclosure;

[00117] Fig. 77 shows a system for regulating fluid flow using a valve having two flexible strips actuateable by a linear actuator in accordance with an embodiment of the present disclosure;

[00118] Fig. 78 shows the system of Fig. 77 with the valve actuated in accordance with an embodiment of the present disclosure;

[00119] Fig. 79 shows a close-up view of the valve of Figs. 77-78 in accordance with an embodiment of the present disclosure;

[00120] Fig. 80 shows a close-up view of the valve as actuated in Fig. 78 in accordance with an embodiment of the present disclosure;

[00121] Fig. 81 shows several images for use to illustrate a method of estimating drop growth and/or fluid flow illustrated in Figs. 82A-82B in accordance with an embodiment of the present disclosure; and

[00122] Figs. 82A-82B show a flow chart diagram illustrating a method of estimating drop growth and/or fluid flow in accordance with an embodiment of the present disclosure;

[00123] Fig. 83 shows a flow chart diagram of a method for reducing noise from condensation in accordance with an embodiment of the present disclosure;

[00124] Fig. 84 shows another valve for use with a flow meter in accordance with an embodiment of the present disclosure;

[00125] Fig. 85A shows a perspective view of another valve in an open position in accordance with an embodiment of the present disclosure;

[00126] Fig. 85B shows a perspective view of the valve of Fig. 85A in a closed position in accordance with an embodiment of the present disclosure;

[00127] Fig. 85C shown a view of the valve of Fig. 85A with the valve housing and plunger guide removed in accordance with an embodiment of the present disclosure;

[00128] Fig. 86 shows a cross-sectional view of the valve housing of Figs. 85A-85C and filler when in a closed position in accordance with an embodiment of the present disclosure;

[00129] Fig. 87A show a front view of an apparatus with the door closed, the apparatus is used to control fluid flow through a drip chamber connected to a tube in accordance with an embodiment of the present disclosure;

[00130] Fig. 87B shows a perspective view of the apparatus of Fig. 87A with the door open, highlighting the valve in accordance with an embodiment of the present disclosure;

[00131] Fig. 87C shows a perspective view of the apparatus of Fig. 87A with the door open, highlighting the safety cutoff mechanism in accordance with an embodiment of the present disclosure;

[00132] Fig. 87D shows a bottom view of the apparatus of Fig. 87A in accordance with an embodiment of the present disclosure;

[00133] Fig. 88A shows a perspective view of another apparatus used to control fluid flow through a drip chamber connected to a tube, wherein the apparatus has the door open, in accordance with an embodiment of the present disclosure;

[00134] Fig. 88B shows a perspective view of only the valve from Fig. 88A in accordance with an embodiment of the present disclosure;

[00135] Fig. 88C shows the inner workings of the valve from Fig. 88B in accordance with an embodiment of the present disclosure;

[00136] Fig. 88D shows a simplified diagram illustrate the operation of the valve cutoff mechanism in a door closed position in accordance with an embodiment of the present disclosure;

[00137] Fig 88E shows a simplified diagram to illustrate the valve cutoff mechanism in the door open position in accordance with an embodiment of the present disclosure;

[00138] Figs. 89A-89B show a flow chart diagram of a method for controlling fluid flow through a drip chamber in accordance with an embodiment of the present disclosure;

[00139] Fig. 90 shows a diagram of a system for controlling fluid flow through a drip chamber in accordance with an embodiment of the present disclosure;

[00140] Fig. 91 shows an apparatus configured to control fluid flow through a drip chamber connected to a tube and communicate with an RFID interrogator in accordance with an embodiment of the present disclosure;

[00141] Fig. 92 shows an obstructed drip chamber that may render difficult the obtainment of an accurate image of the drip chamber by an image sensor in accordance with an embodiment of the present disclosure;

[00142] Fig. 93 shows a flow chart diagram of a method for obtaining an image of a drip chamber in accordance with an embodiment of the present disclosure;

[00143] Fig. 94 shows a graphical representation of drops, as seen by an image sensor, as each drop grows within a drip chamber and subsequently falls in accordance with an embodiment of the present disclosure;

[00144] Fig. 95 shows a graphical representation of a system to convey the status of a device in accordance with an embodiment of the present disclosure;

[00145] Figs. 96A-96X show several views of an apparatus to control fluid flow in accordance with an embodiment of the present disclosure;

[00146] Figs. 97A-97AC show several views of an apparatus to control fluid flow in accordance with an embodiment of the present disclosure;

[00147] Fig. 98 shows a top perspective view of a snap-fit drip chamber that may be used by the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure;

[00148] Fig. 99 shows a top view of the drip chamber of Fig. 98 in accordance with an embodiment of the present disclosure;

[00149] Fig. 100 shows a top sectional view of the drip chamber of Fig. 99 being inserted into the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure;

[00150] Fig. 101 shows a top sectional view of the drip chamber of Fig. 99 secured within the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure;

[00151] Fig. 102 shows a close-up view of the top cap of the drip chamber of Fig. 98 being inserted into an opening of the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure;

[00152] Fig. 103 shows a cross-sectional view of the apparatus of Figs. 97A-97G with the top cap of the drip chamber being secured therein accordance with an embodiment of the present disclosure;

[00153] Figs. 104-105 show a cross-sectional view of the apparatus of Figs. 97A-97G with the top cap of the drip chamber to illustrate release of the drip chamber from the apparatus in accordance with an embodiment of the present disclosure;

[00154] Fig. 106 shows an embodiment of the drip chamber that uses mechanical resonance for drop detection in accordance with an embodiment of the present disclosure;

[00155] Fig. 107 shows an embodiment of the drip chamber that uses an optical light source and cantilever beam for drop detection in accordance with an embodiment of the present disclosure;

[00156] Fig. 108A shows a drip chamber with an inner sleeve having parallel wires as an anti-pinch member in accordance with an embodiment of the present disclosure;

[00157] Fig. 108B shows a cross-sectional view of the anti-pinch member of Fig. 108A in accordance with an embodiment of the present disclosure;

[00158] Fig. 109A shows a drip chamber with an outer sleeve having parallel wires as an anti-pinch member in accordance with an embodiment of the present disclosure;

[00159] Fig. 109B shows a cross-sectional view of the anti-pinch member of Fig. 109A in accordance with an embodiment of the present disclosure;

[00160] Fig. 110A shows a drip chamber with an outer sleeve having a spiral wire as an anti-pinch member in accordance with an embodiment of the present disclosure;

[00161] Fig. 110B shows a cross-sectional view of the anti-pinch member of Fig. 110A in accordance with an embodiment of the present disclosure;

[00162] Fig. 111A shows a drip chamber with an inner sleeve having a spiral wire as an anti-pinch member in accordance with an embodiment of the present disclosure;

[00163] Fig. 111B shows a cross-sectional view of the anti-pinch member of Fig. 111A in accordance with an embodiment of the present disclosure;

[00164] Fig. 112 shows a drip chamber with an section of tubing being an anti-pinch member in accordance with an embodiment of the present disclosure;

[00165] Figs. 113-116 show several cross-sectional views of several embodiments of the section of tubing being an anti-pinch member of Fig. 112 in accordance with several embodiments of the present disclosure;

[00166] Figs. 117-120 show several views of a snap-fit drip chamber in accordance with an embodiment of the present disclosure;

[00167] Figs. 121-122 show the snap-fit drip chamber of Figs. 117-120 secured within a flow meter in accordance with an embodiment of the present disclosure;

[00168] Fig. 123 shows a drip chamber having a fiducial for an image sensor to determine the location of the drip chamber in accordance with an embodiment of the present disclosure;

[00169] Fig. 124 shows a close-up view of the opening of the drip chamber of Fig. 123 in accordance with an embodiment of the present disclosure;

[00170] Fig. 125 shows a drip chamber having wings each of which includes a fiducial in accordance with an embodiment of the present disclosure;

[00171] Figs. 126-127 show a drip chamber having lighting elements configured to internally light the chamber walls of the drip chamber in accordance with an embodiment of the present disclosure;

[00172] Fig. 128 shows a drip chamber with a solid stripe in accordance with an embodiment of the present disclosure;

[00173] Fig. 129 shows a drip chamber with a wing having a 2-D barcode embedded thereon in accordance with an embodiment of the present disclosure;

[00174] Figs. 130-131 show a drip chamber that is keyed and includes a background pattern that is illuminated via light shined in through an edge of the background pattern in accordance with an embodiment of the present disclosure;

[00175] Fig. 132 shows a drip chamber having a barbed spike in accordance with an embodiment of the present disclosure;

[00176] Fig. 133 shows a drip chamber having a cylindrically-shaped chamber with lighting elements to illuminate a background pattern in accordance with an embodiment of the present disclosure;

[00177] Fig. 134 shows a drip chamber having a rectangular-shaped chamber with lighting elements to illuminate a background pattern in accordance with an embodiment of the present disclosure;

[00178] Figs. 135A-135C show a top cap with a pumping mechanism in accordance with an embodiment of the present disclosure;

[00179] Fig. 136 shows a drip chamber having a plurality of lighting elements in accordance with an embodiment of the present disclosure;

[00180] Fig. 137 shows a drip chamber having a plurality of internal ridges to facilitate liquid flow of condensation on the internal wall of the drip chamber in accordance with an embodiment of the present disclosure;

[00181] Fig. 138 shows a flow meter coupled to a bag via a spring in accordance with an embodiment of the present disclosure;

[00182] Fig. 139 shows a cross-section section of a drip chamber in accordance with an embodiment of the present disclosure;

[00183] Fig. 140 shows a flow meter coupled to a drip chamber in accordance with an embodiment of the present disclosure;

[00184] Figs. 141A-141B show a drip chamber having a fiducial on a wing and within the drip chamber in accordance with an embodiment of the present disclosure;

[00185] Fig. 142A shows a drip chamber with a bar code in accordance with an embodiment of the present disclosure;

[00186] Fig. 142B shows several exemplary barcodes that may be used on the drip chamber in accordance with an embodiment of the present disclosure;

[00187] Fig. 143 shows a drip chamber with an RFID tag in accordance with an embodiment of the present disclosure;

[00188] Fig. 144 shows a schematic drawing of a shuttle pump using duckbill check valves in accordance with an embodiment of the present disclosure;

[00189] Fig. 145 shows a schematic drawing of a shuttle pump in accordance with an embodiment of the present disclosure;

[00190] Fig. 146 shows a schematic drawing of a shuttle pump using an eccentric cam coupled to a motor in accordance with an embodiment of the present disclosure; and

[00191] Fig. 147 shows a drip chamber using a piston pump and check valves in accordance with an embodiment of the present disclosure.

[00192] DETAILED DESCRIPTION

[00193] Fig. 1 shows a block diagram of a system 1 for regulating fluid flow in accordance with an embodiment of the present disclosure. For example, system 1 may regulate, monitor, and/or control the flow of fluid into a patient 3. The system 1 includes a fluid reservoir 2 for infusing fluid contained therein into the patient 3. The fluid reservoir 2 is gravity fed into a drip chamber 4 via a fluid tube 5. The fluid reservoir 2, the drip chamber 4, and the patient 3 may be considered as part of the system 1 or may be considered as separate or optional work pieces for the system 1 (e.g., any fluid reservoir 2 and drip chamber 4 may be used to treat any patient 3).

[00194] A flow meter 7 monitors the drip chamber 4 to estimate a flow rate of liquid flowing through the drip chamber 4. The fluid from the drip chamber 4 is gravity fed into a valve 6. The valve 6 regulates (i.e., varies) the flow of fluid from the fluid reservoir 2 to the patient 3 by regulating fluid flow from the drip chamber 4 to the patient 3. The valve 6 may be any valve as described herein, including a valve having two curved-shaped members, a valve having two flexible sheets, a valve that pinches (or uniformly compresses) on the tube over a significant length of the tube, or the like. The valve 6 may be an inverse-Bourdon-tube valve that works in an opposite way of a Bourdon tube in that a deformation of the fluid path causes changes in fluid flow rather than fluid flow causing deformation of the fluid path.

[00195] In alternative embodiments, the system 1 optionally includes an infusion pump 414 (e.g., a peristaltic pump, a finger pump, a linear peristaltic pump, a rotary peristaltic pump, a cassette-based pump, a membrane pump, other pump, etc.) coupled to the fluid tube 5. The outlined box designated as 414 represents the optional nature of the infusion pump 414, e.g., the infusion pump may not be used in some embodiments. The infusion pump 414 may use the flow meter 7 as feedback to control the flow of fluid through the fluid tube 5. The infusion pump 414 may be in wireless communication with the flow meter 7 to receive the flow rate therefrom. The infusion pump 414 may use a feedback control algorithm (e.g., the control component 14 of Fig. 1) to adjust the flow of fluid, such as a proportional–integral–derivative (“PID”), bang-bang, neural network, and/or fuzzy logic control system. In this specific exemplary embodiment (i.e., an embodiment having the infusion pump 414), the valve 6 is

optional. However, in other embodiments, the valve 6 may or may not be used, and/or is optional. The infusion pump 414 may adjust the rotation of a cam and/or a motor in accordance with measurements from the flow meter 7, such as flow rate, volume infused, total volume infused, etc. Additionally or alternatively, the infusion pump 414 may stop fluid flow (e.g., by stopping the pumping action) when the flow meter 7 communicates to the infusion pump 414 that a free flow condition exists. In yet additional embodiments, the monitoring client 8 controls the operation of the infusion pump 414 (e.g., via a wireless connection) and receives feedback from the flow meter 7.

[00196] In some embodiments, the fluid reservoir 2 is pressurized to facilitate the flow of fluid from the fluid reservoir 2 into the patient 3, e.g., in the case where the fluid reservoir 2 (e.g., an IV bag) is below the patient 3; The pressurization provides sufficient mechanical energy to cause the fluid to flow into the patient 3. A variety of pressure sources, such as physical pressure, mechanical pressure, and pneumatic pressure may be applied to the inside or outside of the fluid reservoir 2. In one such embodiment, the pressurization may be provided by a rubber band wrapped around an IV bag.

[00197] The flow meter 7 and the valve 6 may form a closed-loop system to regulate fluid flow to the patient 3. For example, the flow meter 7 may receive a target flow rate from a monitoring client 8 by communication using transceivers 9, 10. That is, the transceivers 9, 10 may be used for communication between the flow meter 7 and the monitoring client 8. The transceivers 9, 10 may communicate between each other using a modulated signal to encode various types of information such as digital data or an analog

signal. Some modulation techniques used may include using carrier frequency with FM modulation, using AM modulation, using digital modulation, using analog modulation, or the like.

[00198] The flow meter 7 estimates the flow rate through the drip chamber 4 and adjusts the valve 6 to achieve the target flow rate received from the monitoring client 8. The valve 6 may be controlled by the flow meter 7 directly from communication lines coupled to an actuator of the valve 6 or via a wireless link from the flow meter 7 to onboard circuitry of the valve 6. The onboard electronics of the valve 6 may be used to control actuation of the valve 6 via an actuator coupled thereto. This closed-loop embodiment of the flow meter 7 and the valve 6 may utilize any control algorithm including a PID control algorithm, a neural network control algorithm, a fuzzy-logic control algorithm, the like, or some combination thereof.

[00199] The flow meter 7 is coupled to a support member 17 that is coupled to the drip chamber 4 via a coupler 16. The support member 17 also supports a backlight 18. The backlight 18 includes an array of LEDs 20 that provides illumination to the flow meter 7. In some specific embodiments, the backlight 18 includes a background pattern 19. In other embodiments, the backlight 18 does not include the background pattern 19. In some embodiments, the background pattern 19 is present in only the lower portion of the backlight 18 and there is no background pattern 19 on the top (e.g., away from the ground) of the backlight 18.

[00200] The flow meter 7 includes an image sensor 11, a free flow detector component 12, a flow rate estimator component 13, a control

component 14, an exposure component 29, a processor 15, and a transceiver 9. The flow meter 7 may be battery operated, may be powered by an AC outlet, may include supercapacitors, and may include on-board, power-supply circuitry (not explicitly shown).

[00201] The image sensor 11 may be a CCD sensor, a CMOS sensor, or other image sensor. The image sensor 11 captures images of the drip chamber 4 and communicates image data corresponding to the captured images to the processor 15.

[00202] The processor 15 is also coupled to the free flow detector component 12, the flow rate estimator component 13, the control component 14, and the exposure component 29. The free flow detector component 12, the flow rate estimator component 13, the control component 14, and the exposure component 29 may be implemented as processor-executable instructions that are executable by the processor 15 and may be stored in memory, such as a non-transitory, processor-readable memory, ROM, RAM, EEPROM, a harddisk, a harddrive, a flashdrive, and the like.

[00203] The processor 15 can execute the instructions of the free flow detector component 12 to determine if a free flow condition exists within the drip chamber 4 by analyzing the image data from the image sensor 11. Various embodiments of the free flow detector component 12 for detecting a free flow condition are described below. In response to a detected free flow condition, the processor 15 can make a function call to the control component 14 to send a signal to the valve 6 to completely stop fluid flow to the patient 3. That is, if the free flow detector component 12 determines that a free flow condition exists,

the flow meter 7 may instruct the valve 6 to stop fluid flow, may instruct the monitoring client 8 to stop fluid flow (which may communicate with the valve 6 or the pump 414), and/or may instruct the pump 414 to stop pumping or occlude fluid flow using an internal safety occluder.

[00204] The flow rate estimator component 13 estimates the flow rate of fluid flowing through the drip chamber 4 using the image data from the image sensor 11. The processor 15 communicates the estimated flow rate to the control component 14 (e.g., via a function call). Various embodiments of estimating the flow rate are described below. If the flow rate estimator component 13 determines that the flow rate is greater than a predetermined threshold or is outside a predetermined range, the flow meter 7 may instruct the valve 6 to stop fluid flow (which may communicate with the valve 6 or the pump 414), may instruct the monitoring client 8 to stop fluid flow (which may communicate with the valve 6 or the pump 414), and/or may instruct the pump 414 to stop pumping or occlude fluid flow using an internal safety occluder.

[00205] The processor 15 controls the array of LEDs 20 to provide sufficient light for the image sensor 11. For example, the exposure component 29 may be used by the processor 15 or in conjunction therewith to control the array of LEDs 20 such that the image sensor 11 captures image data sufficient for use by the free flow detector component 12 and the flow rate estimator component 13. The processor 15 may implement an exposure algorithm stored by the exposure component 29 (see Fig. 2) to control the lighting conditions and/or the exposure of the image sensor 11 when generating the image data. Additionally or alternatively, the exposure component 29 may be implemented

as a circuit, an integrated circuit, a CPLD, a PAL, a PLD, a hardware-description-language-based implementation, and/or a software system.

[00206] The control component 14 calculates adjustments to make to the valve 6 in accordance with the estimated flow rate from the flow rate estimator component 13. For example and as previously mentioned, the control component 14 may implement a PID control algorithm to adjust the valve 6 to achieve the target flow rate.

[00207] The monitoring client 8, in some embodiments, monitors operation of the system 1. For example, when a free flow condition is detected by the free flow detector component 12, the monitoring client 8 may wirelessly communicate a signal to the valve 6 to interrupt fluid flow to the patient 3.

[00208] The flow meter 7 may additionally include various input/output devices to facilitate patient safety, such as various scanners, and may utilize the transceiver 9 to communicate with electronic medical records, drug error reduction systems, and/or facility services, such as inventory control systems.

[00209] In a specific exemplary embodiment, the flow meter 7 has a scanner, such as an RFID interrogator that interrogates an RFID tag attached to the fluid reservoir 2 or a barcode scanner that scans a barcode of the fluid reservoir 2. The scanner may be used to determine whether the correct fluid is within the fluid reservoir 2, it is the correct fluid reservoir 2, the treatment programmed into the flow meter 7 corresponds to the fluid within the fluid reservoir 2 and/or the fluid reservoir 2 and flow meter 7 are correct for the particular patient (e.g., as determined from a patient's barcode, a patient's RFID tag, or other patient identification).

[00210] For example, the flow meter 7 may scan the RFID tag of the fluid reservoir 2 to determine if a serial number or fluid type encoded within the RFID tag is the same as indicated by the programmed treatment stored within the flow meter 7. Additionally or alternatively, the flow meter 7 may interrogate the RFID tag of the fluid reservoir 2 for a serial number and the RFID tag of the patient 3 for a patient serial number, and also interrogate the electronic medical records using the transceiver 9 to determine if the serial number of the fluid reservoir 2 within the RFID tag attached to the fluid reservoir 2 matches the patient's serial number within the RFID tag attached to the patient 3 as indicated by the electronic medical records.

[00211] Additionally or alternatively, the monitoring client 8 may scan the RFID tag of the fluid reservoir 2 and the RFID tag of the patient 3 to determine that it is the correct fluid within the fluid reservoir 2, it is the correct fluid reservoir 2, the treatment programmed into the flow meter 7 corresponds to the fluid within the fluid reservoir 2, and/or the fluid reservoir 2 is correct for the particular patient (e.g., as determined from a patient's barcode, RFID tag, electronic medical records, or other patient identification or information). Additionally or alternatively, the monitoring client 8 or the flow meter 7 may interrogate the electronic medical records database and/or the pharmacy to verify the prescription or to download the prescription, e.g., using the serial number of the barcode on the fluid reservoir 2 or the RFID tag attached to the fluid reservoir 2.

[00212] Fig. 2 shows a flow chart diagram of a method 21 for exposing an image sensor, e.g., the image sensor 11 of Fig. 1, in accordance with an

embodiment of the present disclosure. The method 21 includes acts 22, 23, 24, and 25. Method 21 may be implemented by the processor 15 of Fig. 1 (e.g., as the exposure component 29) and may be implemented as a processor-implemented method, as a set of instructions configured for execution by one or more processors, in hardware, in software, the like, or some combination thereof.

[00213] Act 22 selects a region of interest. For example, referring again to Fig. 1, the image sensor 11 includes a field of view that includes the drip chamber 4. However, the drip chamber 4 may not occupy the entire field of view of the image sensor 11. Act 22 selects only the pixels of the image sensor 11 that show, for example, the drip chamber 4.

[00214] Act 23 determines if a pixel is within the region of interest 23. If the pixel of act 23 is a pixel that images, for example, the drip chamber 4, then act 23 determines that it is within the region of interest. Likewise, in this example, if the pixel of act 23 is a pixel that does not image the drip chamber 4, act 23 determines that the pixel is not within the region of interest.

[00215] Act 24 activates a backlight, e.g., the backlight 18 of Fig. 1, if the pixel is within the region of interest. Pixels of an image sensor may be exposed during different times. Thus, the backlight 18 may be activated only when pixels within the region of interest are being exposed. For example, some image sensors include vertical and horizontal sync signals. The backlight may be synchronized with these signals to turn on when a pixel of interest is being exposed.

[00216] In some embodiments of the present disclosure, a subset of LEDs of the backlight (e.g., a subset of the LED array 20, which may be a 2-dimensional array) may be turned on. The subset may be a sufficient subset to sufficiently illuminate the pixel being exposed if the pixel is within the region of interest.

[00217] Act 25 exposes the pixel. If in act 23 it was determined that the pixel is within the region of interest, the pixel will be exposed with at least a portion of the backlight turned on in act 25. Additionally, if in act 23 it was determined that the pixel is not within the region of interest, the pixel will be exposed without at least a portion of the backlight turned on in act 25.

[00218] Fig. 3 shows a timing diagram 29 illustrating an embodiment of the method of Fig. 2 in accordance with an embodiment of the present disclosure. The timing diagram 29 includes traces 26, 27, and 28. Trace 26 is a vertical sync signal from an image sensor and trace 27 is a horizontal sync signal from the image sensor (e.g., image sensor 11 of Fig. 1). A circuit or software routine (e.g., the exposure component 29 found in the flow meter 7 of Fig. 1) may use the sync traces 26, 27 to generate a backlight-enable signal 28 that is used to activate a backlight or a subset thereof.

[00219] Figs. 4A-4B show illustrations of image data of a flow meter 7 illustrating an embodiment of the method of Fig. 2 in accordance with the timing diagram of Fig. 3 in accordance with an embodiment of the present disclosure. Fig. 4A illustrates the image data taken by a flow meter, such as the flow meter 7 of Fig. 1, without the use of the exposure algorithm illustrated in Figs. 2 and 3; Fig. 4B illustrates the image data taken by the flow meter with the use of the

exposure algorithm illustrated in Figs. 2 and 3. Less power is needed to provide illumination during the capture of the image of Fig. 4B than to provide illumination for the capture of the image of Fig. 4A because of less use of the backlight.

[00220] Fig. 5 shows a diagram of a flow meter 67 and a valve 71 that are integrated together for coupling to a drip chamber 409 and an IV bag 69 in accordance with an embodiment of the present disclosure. The flow meter 67 includes an optical drip counter 68 that receives fluid from the IV bag 69. The optical drip counter 68 may be an image sensor, a pair of image sensors, a capacitive drip counter, and/or the like. The flow meter 67 is coupled to a tube 70 coupled to a roller clamp 71 that is controlled by a motor 72. The motor 72 is coupled to a lead screw mechanism 73 to control a roller clamp 71 via interaction with interacting members 74.

[00221] The motor 72 may be a servo motor and may be used to adjust the flow rate through the tube 70. That is, the flow meter 67 may also function as a flow meter and regulator. For example, a processor 75 within the flow meter 67 may adjust the motor 72 such that a desired flow rate is achieved as measured by the optical drip counter 68. The processor 75 may implement a control algorithm using the optical drip counter 68 as feedback, e.g., a PID control loop with the output supplied to the motor 72 and the feedback received from the optical drip counter 68.

[00222] In alternative embodiments, the motor 72, the lead screw mechanism 73, and the roller clamp 71 may be replaced and/or supplemented by an actuator that squeezes the tube 70 (e.g., using a cam mechanism or

linkage driven by a motor) or they may be replaced by any sufficient roller, screw, or slider driven by a motor. For example, in some embodiments of the present disclosure, the roller clamp 71 may be replaced by any valve as described herein, including a valve having two C-shaped members, a valve having two curve-shaped support members, a valve having two flexible sheets, a valve that pinches on the tube over a significant length of the tube, or the like.

[00223] The flow meter 67 may also optionally include a display. The display may be used to set the target flow rate, display the current flow rate, and/or provide a button, e.g., a touch screen button to stop the flow rate.

[00224] Fig. 6 is a block diagram of an imaging system 78 of a flow meter for imaging a drip chamber in accordance with an embodiment of the present disclosure. The imaging system 78 as shown in Fig. 6 may be used within any flow meter described herein, including the flow meter 7 of Fig. 1 and/or the flow meter 67 of Fig. 5.

[00225] The imaging system 78 of Fig. 6 includes an image sensor 63, a uniform backlight 79 to shine light at least partially through the drip chamber 59, and an infrared ("IR") filter 80 that receives the light from the uniform backlight 79.

[00226] System 78 also includes a processor 90 that may be operatively coupled to the image sensor 63 and/or the uniform backlight 79. The processor 90 implements an algorithm to determine when a free flow condition exists and/or to estimate a flow rate (e.g., using the free flow detector component 12 or the flow rate estimator component 13 of Fig. 1). The processor 90 may be in operative communication with a processor-readable memory 91 (e.g., a non-

transitory, processor-readable memory) to receive one or more instructions to implement the algorithm to determine if a free flow condition exists and/or to estimate the flow rate. The one or more instructions from the processor-readable memory 91 are configured for execution by the processor 90.

[00227] The uniform backlight 79 may be an array of light-emitting diodes ("LEDs") having the same or different colors, a light bulb, a window to receive ambient light, an incandescent light, and the like. In some embodiments, the uniform backlight 79 may include one or more point-source lights.

[00228] The processor 90 may modulate the uniform backlight 79 in accordance with the image sensor 63. For example, the processor 90 may activate the uniform backlight 79 for a predetermined amount of time and signal the image sensor 63 to capture at least one image, and thereafter signal the uniform backlight 79 to turn off. The one or more images from the image sensor 63 may be processed by the processor 90 to estimate the flow rate and/or detect free flow conditions. For example, in one embodiment of the present disclosure, the system 78 monitors the size of the drops being formed within the drip chamber 59, and counts the number of drops that flow through the drip chamber 59 within a predetermined amount of time; the processor 90 may average the periodic flow from the individual drops over a period of time to estimate the flow rate. For example, if X drops each having a volume Y flow through the drip chamber in a time Z, the flow rate may be calculated as (X*Y)/Z.

[00229] Additionally or alternatively, the system 78 may determine when the IV fluid is streaming through the drip chamber 59 (i.e., during a free flow

condition). The uniform backlight 79 shines light through the drip chamber 59 to provide sufficient illumination for the image sensor 63 to image the drip chamber 59. The image sensor 63 can capture one or more images of the drip chamber 59.

[00230] Other orientations and configurations of the system 78 may be used to account for the orientation and output characteristics of the uniform backlight 79, the sensitivity and orientation of the image sensor 63, and the ambient light conditions. In some embodiments of the present disclosure, the processor 90 implements an algorithm that utilizes a uniformity of the images collected by the image sensor 63. The uniformity may be facilitated by the uniform backlight 79. For example, consistent uniform images may be captured by the image sensor 63 when a uniform backlight 79 is utilized.

[00231] Ambient lighting may cause inconsistencies in the images received from the image sensor 63; for example, direct solar illumination provides inconsistent lighting because the sun may be intermittently obscured by clouds and the sun's brightness and angle of illumination depend upon the time of the day. Therefore, in some embodiments of the present disclosure, an IR filter 80 is optionally used to filter out some of the ambient light to mitigate variations in the images captured by the image sensor 63. The IR filter 80 may be a narrow-band infrared light filter placed in front of the image sensor 63; and the uniform backlight 79 may emit light that is about the same wavelength as the center frequency of the passband of the filter 80. The IR filter 80 and the uniform backlight 79 may have a center frequency of about 850 nanometers. In some embodiments, the imaging system 78 may be surrounded by a visually

translucent, but IR-blocking, shell. In alternative embodiments, other optical frequencies, bandwidths, center frequencies, or filter types may be utilized in the system 78.

[00232] In some embodiments, the processor 90 may use a template to perform a template match of the pool of water within the drip chamber 59. Any preprocessing may be performed prior to the template match operation. Additionally, if the camera 63 is disposed higher than a preferred position, a mirror may be used so that the camera's 63 view is of a preferable view of the drip chamber 59. The position of the peak template match may be correlated to the pool's position and hence the pool's volume.

[00233] If the pool is too low, the apparatus may trigger a safety valve (described below) because water is leaving the pool and is draining toward the patient at an unsafe rate. The backlight 79 may be on or off, depending on the embodiment. The oscillations of the top of the pool may be monitored to determine the resonance frequency of the water. The resonance of the top of the pool as the drops hit the pool may be correlated with the volume of the pool. In other embodiments, the sudden change of the pool may be correlated with a drop hitting the pool such that the processor 90 can count the number of drops per unit time and estimate the fluid flow therethrough.

[00234] In some embodiments, autofocus may be used to find the line of water. That is, a focal line may be focused to ensure the entire image is focused.

[00235] In some embodiments, the processor 90 may be coupled to a wire etched onto a PCB board making it a software radio. This allows the processor

90 to communicate information to another device capable of operating at the sufficient frequencies.

[00236] Fig. 7 is a graphic illustration of an image 81 captured by the image sensor 63 of the system 78 of Fig. 6 in accordance with an embodiment of the present disclosure. The image 81 is an image of a drip chamber 59 having condensation 82 and a stream 83 caused by a free flow condition therein. Edge detection may be used to determine the position of the stream 83 and/or the condensation 82, in some embodiments. Additionally or alternatively, a background image or pattern may be used.

[00237] Fig. 8 is a block diagram of an imaging system 84 of a flow meter for imaging a drip chamber in accordance with an embodiment of the present disclosure. The imaging system 84 may be used with any flow meter disclosed herein, including the flow meter 7 of Fig. 1 and the flow meter 67 of Fig. 5.

[00238] System 84 includes an array of lines 85 that are opaque behind the drip chamber 59. System 84 uses the array of lines 85 to detect a free flow condition. The free flow detection algorithm (e.g., the free flow detector component 12 of Fig. 1) may use the presence or absence of drops for determining whether or not a streaming condition (e.g., a free flow condition) exists.

[00239] In some specific embodiments, the lines 85 are only present on a fraction of the image (e.g., the background pattern only occupies a fraction of the backlight 18 or the binary optics only causes the pattern to appear in a fraction of the image, such as the lower or upper half). For example, a lower fraction of the image may include a background pattern of stripes.

[00240] Referring now to Fig. 9, a graphic illustration of an image 86 is shown as captured by the image sensor 63 of Fig. 8 when a free flow condition exists in the drip chamber 59 in accordance with an embodiment of the present disclosure. The image 86 illustrates the condition in which the drip chamber 59 experiences a free flow condition and illustrates the effect that the stream of fluid 87 acts as a positive cylindrical lens. That is, as shown in Fig. 9, the array of lines 85 as captured in an image by the image sensor 63 are shown as a reversed line pattern 88 from the array of lines 85 as compared to a non-free flow condition. The appearance of the reversed line pattern 88 is caused by changes to the light when the light passes through the stream of fluid 87 as the light approaches the image sensor 63.

[00241] In some embodiments of the present disclosure, illumination by light having an optical wavelength of about 850 nanometers may be used to create the image 86. Some materials may be opaque in the visible spectrum and transparent in the near IR spectrum at about 850 nanometers and therefore may be used to create the array of lines 85. The array of lines 85 may be created using various rapid-prototyping plastics. For example, the array of lines 85 may be created using a rapid-prototype structure printed with an infrared-opaque ink or coated with a metal for making the array of lines 85. Additionally or alternatively, in some embodiments of the present disclosure, another method of creating the array of lines 85 is to create a circuit board with the lines laid down in copper. In another embodiment, the array of lines 85 is created by laying a piece of ribbon cable on the uniform backlight 79; the wires in the ribbon cable are opaque to the infrared spectrum, but the insulation is

transparent such that the spacing of the wires may form the line for use during imaging by the image sensor 63 (see Fig. 8). In yet additional embodiments, a piece of thin EDMed metal may be utilized. Metal is opaque to light and the spaces between the metal material deposits may be very finely controlled during manufacture to allow the IR light to pass through the spaces.

[00242] The processor 90 implements an algorithm to determine when a free flow condition exists (e.g., using the free flow detector component 12 of Fig. 1). The processor 90 may be in operative communication with a processor-readable memory 91 (e.g., a non-transitory, processor-readable memory) to receive one or more instructions to implement the algorithm to determine if a free flow condition exists. The one or more instructions from the processor-readable memory 91 are configured for execution by the processor 90.

[00243] Referring again to Fig. 8, blood may be used by the system 84. For example, system 84 may determine when a free flow condition of blood exists when utilizing the image sensor 63, the IR filter 80, and the uniform backlight 79 configured, for example, for use using optical light having a wavelength of 850 nanometers or 780 nanometers, e.g., when using bovine blood. The blood may appear opaque compared to the images taken using water.

[00244] The following algorithm implemented by the processor 90 and received from the processor-readable memory 91 may be used to determine when a free flow condition exists: (1) establish a background image 89 (see Fig. 10); and (2) subtract the background image 89 from the current image. Additionally processing may be performed on the resulting image.

[00245] In some embodiments of the present disclosure, the background image 89 of Fig. 10 may be dynamically generated by the processor 90. The dynamic background image may be used to account for changing conditions, e.g. condensation or splashes 82 on the surface of the drip chamber 59 (see Fig. 7). For example, in one specific embodiment, for each new image captured by the image sensor (e.g., 63 of Fig. 8), the background image has each pixel multiplied by .96 and the current image (e.g., the most recently captured image) has a respective pixel multiplied by .04, after which the two values are added together to create a new value for a new background image for that respective pixel; this process may be repeated for all of the pixels. In yet another example, in one specific embodiment, if a pixel of the new image is at a row, x, and at a column, y, the new background image at row, x, and column, y, is the value of the previous background image at row, x, and column, y, multiplied by .96, which is added to the value of the pixel at row, x, and column, y of the new image multiplied by .04.

[00246] When the system 84 has no water flowing through the drip chamber 59 (see Fig. 8) the resulting subtraction should be almost completely back, i.e., low pixel magnitudes, thereby facilitating the algorithm to determine that the drip chamber 59 has no water flowing therethrough.

[00247] Fig. 11 shows an image 92 from the image sensor 63 when there is a drop within the drip chamber 59 (see Fig. 8). Fig. 12 shows a background image 93 used by the system 84. When the system 84 has a drop as shown in image 92 of Fig. 11, the system 84 of Fig. 8 has a few high contrast-spots where the image of the array of lines is warped by the lensing of the droplet as

illustrated by an image 94 of Fig. 13. Image 94 of Fig. 13 is generated by taking, for each respective pixel, the absolute value of the subtraction of the image 92 of Fig. 11 from image 93 of Fig. 12, and converting each respective pixel to a white pixel if the value is above a predetermined threshold or otherwise converting the pixel to a black pixel when the value is below the predetermined threshold. Each white pixel within the image 94 of Fig. 13 is a result of there being a difference for that pixel location between the images 92 and 93 that is greater than a predetermined threshold.

[00248] For example, consider three respective pixels of Figs. 11, 12, and 13 having a location of row x and column y. To determine the pixel of row x and column y for the image 94 of Fig. 13, the pixel at row x and column y of image 92 of Fig. 11 is subtracted from the pixel at row x and column y of image 93 of Fig. 12, then the absolute value of the result of the subtraction is taken; and if the absolute value of the result is above a predetermined threshold (e.g., above a grayscale value of 128, for example), the pixel at the location of row x and column y of image 94 of Fig. 13 is white, otherwise the pixel at the location of row x and column y of image 94 of Fig. 13 is black.

[00249] When it is determined that a few high-contrast spots exist within the image 94 of Fig. 13, the processor 90 of system 84 (see Fig. 8) determines that drops are being formed within the drip chamber 59 and no free flow condition exists. The images of the drops may be utilized to determine the size of the drops to estimate a flow rate as described herein.

[00250] Fig. 14 is a graphic representation of some of the image processing that may be performed using Figs. 11-13 to determine if a free flow

condition exists in accordance with an embodiment of the present disclosure. Referring to Figs. 14 and 13, all of the white pixels for each row are summed together, and are illustrated in Fig. 14 as results 183. The y-axis represents the row number, and the x-axis represents the summed number of white pixels for each respective row.

[00251] Referring now to only Fig. 14, as previously mentioned, the number of white pixels for each row is summed together and is illustrated as results 183, which are used to determine if or when a free flow condition exists. In some specific embodiments, the processor 90 of system 84 (see Fig. 8) determines that a free flow condition exists when a predetermined number of contiguous values of the summed rows of the results 183 exists above a threshold 184. For example, within the results 183, a range of a plurality of contiguous rows represented generally by 185 has a total value above the threshold 184. When greater than a predetermined number of contiguous summed rows is determined to exist within the results 183 above a predetermined threshold (e.g., threshold 184), a free flow condition is determined to exist by the processor 90 of Fig. 8. For example, as shown in Fig. 14, the range of the plurality of contiguous summed rows 185 is below the predetermined number of contiguous summed rows (i.e., the range 185 is not wide enough) and therefore a free flow condition is determined to not exist.

[00252] Fig. 15 shows an image 95 showing a stream as captured by the image sensor 63 of Fig 8 when a free flow condition exists. Fig. 16 shows a background image 96. Fig. 17 shows an image 97 formed by the absolute value of the difference between the image 96 of Fig. 16 and the image 95 from

Fig. 15 when the absolute value is converted either to a white pixel (when the absolute value of the difference is above a threshold) or to a black pixel (when the absolute value of the difference is below the threshold). As shown in Fig. 17, high-contrast spots caused by the reverse orientation of the lines in the stream that run from top to bottom are detectable by the processor 90. The processor 90 of Fig. 8 can use the image 97 to determine if a free flow condition exists using the algorithm described above.

[00253] That is, as shown in Fig. 18, results 186 are shown as having a contiguous range 187 of the results 186 that are above a threshold 188. Because the contiguous range 187 of summed rows is greater than a predetermined threshold number of contiguous values above the threshold 188, a free flow condition is determined to exist by the processor 90 (see Fig. 8). That is, the contiguous range of the results 186 above the threshold 188 is greater than a predetermined threshold range of contiguous values; therefore, the processor 90 determines that a free flow condition exists when using the results 186 of Fig. 18.

[00254] In yet an additional embodiment of the present disclosure, the intensity, the intensity squared, or other function may be used to produce the results 183 of Fig. 14 and/or the results 186 of Fig. 18. In yet an additional embodiment, one or more data smoothing functions may be used to smooth the results 183 and/or 186, such as a spline function, a cubic spline function, a B-spline function, a Bezier spline function, a polynomial interpolation, a moving average, or other data smoothing function.

[00255] For example, an image of the image sensor 63 of Fig. 8, e.g., image 95 of Fig. 15, may be subtracted from a background image, e.g., the image 96 of Fig. 16, to obtain intensity values. That is, a pixel of row x and column y of Fig. 15 may be subtracted from a pixel of row x and column y of the image 96 of Fig. 16 to create an intensity value at row x and column y; this may be repeated for all pixel locations to obtain all of the intensity values. The intensity values of each row may be summed together to obtain the results 183 and/or 186 (see Figs. 14 and 18, respectively), such that the processor 90 may determine that a free flow condition exists when the summed rows of the intensity values has a contiguous range of summed rows above a threshold. In some embodiments, the intensity values are converted to absolute values of the intensity values, and the summed rows of the absolute values of the intensity values are used to determine if a contiguous range of summed rows of the absolute values is above a threshold range of contiguous values. Additionally or alternatively, the intensity may be squared and then the processor 90 may sum the squared intensity rows and determine if a contiguous range of summed rows of the intensity squared values exists beyond a threshold range of contiguous values to determine if a free flow condition exists.

[00256] In some embodiments, a predetermined range of contiguous values above a threshold (e.g., min and max ranges) of the summed rows of intensity values or intensity squared values may be used by the processor 90 to determine if a drop of liquid is within the image. For example, each row of the rows of the intensity values (or the intensity squared values) may be summed together and a range of the summed values may be above a threshold number;

if the range of contiguous values is between a minimum range and a maximum range, the processor 90 may determine that the range of contiguous values above a predetermined threshold is from a drop within the field of view of the image sensor 63 (see Fig. 8). In some embodiments of the present disclosure, the summed rows of intensity values or intensity squared values may be normalized, e.g., normalized to have a value between 0 and 1.

[00257] The following describes a smoothing function similar to the cubic spline (i.e., the cubic-spline-type function) that may be used on the summed rows, the summed rows of intensity values, or the summed rows of the intensity values squared prior to the determination by the processor 90 to determine if a free flow condition exits. In some specific embodiments, the cubic-spline-type function may be used to identify blocks, as described *infra*, which may facilitate the processor's 90 identification of free flow conditions.

[00258] The cubic-spline-type function is an analog to the cubic spline, but it smoothes a data set rather than faithfully mimics a given function. Having data sampled on the interval from $[0,1]$ (e.g., the summation along a row of intensity squared or intensity that is normalized) the processor 90 (see Figs. 6 or 8) may find the best fit set of cubic functions on the intervals $[x_0, x_1],[x_1, x_2],\ldots,[x_{N-1}, x_N]$ with $x_0 = 0$ and $x_N = 1$where the total function is continuous with continuous derivatives and continuous curvature.

[00259] The standard cubic spline definition is illustrated in Equation (1) as follows:

[00260] $$\chi(x) = A_i(x)\, y_i + B_i(x)\, y_{i+1} + C_i(x)\, y_i'' + D_i(x)\, y_{i+1}'' \quad x_i \le x \le x_{i+1} \quad (1),$$

[00261] with the functions A_i, B_i, C_i, D_i defined as in the set of Equations (2):

[00262]
$$A_i(x) = \frac{x_{i+1} - x}{x_{i+1} - x_i} = \frac{x_{i+1} - x}{\Delta_i}, \qquad B_i = \frac{x - x_i}{x_{i+1} - x_i} = \frac{x - x_i}{\Delta_i}$$
$$C_i(x) = \frac{\Delta_i^2}{6}\left(A_i^3(x) - A_i(x)\right), \qquad D_i = \frac{\Delta_i^2}{6}\left(B_i^3(x) - B_i(x)\right) \quad (2).$$

[00263] The Equations (1) and (2) guaranty continuity and curvature continuity. The only values which can be freely chosen are y_i, y_0'' and y_N''. Please note that Equation (3) is chosen as follows:

[00264]
$$y_0'' = y_1'' = 0 \quad (3),$$

[00265] i.e., the function is flat at 0 and 1. The remaining y_i'' must satisfy the following set of Equations (4):

[00266]
$$\begin{aligned}
\frac{y_1 - y_0}{\Delta_0} + \frac{y_1''\Delta_0}{3} &= \frac{y_2 - y_1}{\Delta_1} - \frac{y_1''\Delta_1}{3} - \frac{y_2''\Delta_1}{6} \\
\frac{y_2 - y_1}{\Delta_1} + \frac{y_1''\Delta_1}{6} + \frac{y_2''\Delta_1}{3} &= \frac{y_3 - y_2}{\Delta_2} - \frac{y_2''\Delta_2}{3} - \frac{y_3''\Delta_2}{6} \\
\frac{y_3 - y_2}{\Delta_2} + \frac{y_2''\Delta_2}{6} + \frac{y_3''\Delta_2}{3} &= \frac{y_4 - y_3}{\Delta_3} - \frac{y_3''\Delta_3}{3} - \frac{y_4''\Delta_3}{6} \\
&\vdots \\
\frac{y_{N-2} - y_{N-3}}{\Delta_{N-3}} + \frac{y_{N-3}''\Delta_{N-3}}{6} + \frac{y_{N-2}''\Delta_{N-3}}{3} &= \frac{y_{N-1} - y_{N-2}}{\Delta_{N-2}} - \frac{y_{N-2}''\Delta_{N-2}}{3} - \frac{y_{N-1}''\Delta_{N-2}}{6} \\
\frac{y_{N-1} - y_{N-2}}{\Delta_{N-2}} + \frac{y_{N-2}''\Delta_{N-2}}{6} + \frac{y_{N-1}''\Delta_{N-2}}{3} &= \frac{y_N - y_{N-1}}{\Delta_{N-1}} - \frac{y_{N-1}''\Delta_{N-1}}{3}
\end{aligned}$$
(4).

[00267] The set of Equations (4) can be rewritten as the set of Equations (5) as follows:

$$\frac{\Delta_0+\Delta_1}{3}y_1''+\frac{\Delta_1}{6}y_2''=\frac{y_0}{\Delta_0}-\left[\frac{1}{\Delta_0}+\frac{1}{\Delta_1}\right]y_1+\frac{y_2}{\Delta_1}$$

$$\frac{\Delta_1}{6}y_1''+\frac{\Delta_1+\Delta_2}{3}y_2''+\frac{\Delta_2}{6}y_3''=\frac{y_1}{\Delta_1}-\left[\frac{1}{\Delta_1}+\frac{1}{\Delta_2}\right]y_2+\frac{y_3}{\Delta_2}$$

$$\frac{\Delta_2}{6}y_2''+\frac{\Delta_2+\Delta_3}{3}y_3''+\frac{\Delta_3}{6}y_4''=\frac{y_2}{\Delta_2}-\left[\frac{1}{\Delta_2}+\frac{1}{\Delta_3}\right]y_3+\frac{y_4}{\Delta_3}$$

$$\vdots$$

$$\frac{\Delta_{N-4}}{6}y_{N-3}''+\frac{\Delta_{N-3}+\Delta_{N-2}}{3}y_{N-2}''+\frac{\Delta_{N-2}}{6}y_{N-1}''=\frac{y_{N-3}}{\Delta_{N-3}}-\left[\frac{1}{\Delta_{N-3}}+\frac{1}{\Delta_{N-2}}\right]y_{N-2}+\frac{y_{N-1}}{\Delta_{N-2}}$$

$$\frac{\Delta_{N-1}}{6}y_{N-2}''+\frac{\Delta_{N-2}+\Delta_{N-1}}{3}y_{N-1}''=\frac{y_{N-2}}{\Delta_{N-2}}-\left[\frac{1}{\Delta_{N-2}}+\frac{1}{\Delta_{N-1}}\right]y_{N-1}+\frac{y_N}{\Delta_{N-1}}$$

[00268]

(5).

[00269] In turn, this becomes the matrix Equation (6):

$$\begin{bmatrix}
\frac{\Delta_0+\Delta_1}{3} & \frac{\Delta_1}{6} & 0 & & 0 & 0 & 0 \\
\frac{\Delta_1}{6} & \frac{\Delta_1+\Delta_2}{3} & \frac{\Delta_2}{6} & \cdots & 0 & 0 & 0 \\
0 & \frac{\Delta_2}{6} & \frac{\Delta_2+\Delta_3}{3} & & 0 & 0 & 0 \\
 & \vdots & & \ddots & & \vdots & \\
0 & 0 & 0 & & \frac{\Delta_{N-4}+\Delta_{N-3}}{3} & \frac{\Delta_{N-3}}{6} & 0 \\
0 & 0 & 0 & \cdots & \frac{\Delta_{N-3}}{6} & \frac{\Delta_{N-3}+\Delta_{N-2}}{3} & \frac{\Delta_{N-2}}{6} \\
0 & 0 & 0 & & 0 & \frac{\Delta_{N-2}}{6} & \frac{\Delta_{N-2}+\Delta_{N-1}}{3}
\end{bmatrix}
\begin{Bmatrix} y_1'' \\ y_2'' \\ y_3'' \\ \vdots \\ y_{N-3}'' \\ y_{N-2}'' \\ y_{N-1}'' \end{Bmatrix}$$

$$=\begin{bmatrix}
\frac{1}{\Delta_0} & -\frac{1}{\Delta_0}-\frac{1}{\Delta_1} & \frac{1}{\Delta_1} & & 0 & 0 & 0 \\
0 & \frac{1}{\Delta_1} & -\frac{1}{\Delta_1}-\frac{1}{\Delta_2} & \cdots & 0 & 0 & 0 \\
0 & 0 & \frac{1}{\Delta_2} & & 0 & 0 & 0 \\
 & \vdots & & \ddots & & \vdots & \\
0 & 0 & 0 & & \frac{1}{\Delta_{N-3}} & 0 & 0 \\
0 & 0 & 0 & \cdots & -\frac{1}{\Delta_{N-3}}-\frac{1}{\Delta_{N-2}} & \frac{1}{\Delta_{N-2}} & 0 \\
0 & 0 & 0 & & \frac{1}{\Delta_{N-2}} & -\frac{1}{\Delta_{N-2}}-\frac{1}{\Delta_{N-1}} & \frac{1}{\Delta_{N-1}}
\end{bmatrix}
\begin{Bmatrix} y_0 \\ y_1 \\ y_2 \\ y_3 \\ \vdots \\ y_{N-3} \\ y_{N-2} \\ y_{N-1} \\ y_N \end{Bmatrix} \quad (6)$$

[00270] The matrix Equation (6) may be rewritten as the set of Equations (7) as follows:

$$\mathbf{F}\mathbf{y}_{\mathbf{dd}}=\mathbf{G}\mathbf{y}$$

[00271]

$$\mathbf{y}_{\mathbf{dd}}=\mathbf{F}^{-1}\mathbf{G}\mathbf{y}=\mathbf{H}\mathbf{y} \quad (7).$$

[00272] Choosing the values in the vector **y** using a least squares criterion on the collected data is shown in Equation (8) as follows:

[00273]
$$E = \sum \left[\psi_k - A_{i_k}(\xi_k) y_{i_k} - B_{i_k}(\xi_k) y_{i_k+1} - C_{i_k}(\xi_k) y''_{i_k} - D_{i_k}(\xi_k) y''_{i_k} \right]^2 \quad (8).$$

[00274] Equation (8) is the minimum deviation between the data and the spline, i.e., Equation (8) is an error function. The y values are chosen to minimize the error as defined in Equation (8). The vector of predicted values can be written as illustrated in Equation (9) as follows:

[00275]
$$\begin{aligned} \hat{\mathbf{y}} &= \left(\mathbf{A}_{\{k\}} + \mathbf{B}_{\{k\}} \right) \mathbf{y} + \left(\mathbf{C}_{\{k\}} + \mathbf{D}_{\{k\}} \right) \mathbf{y}_{\mathbf{dd}} \\ &= \left(\mathbf{A}_{\{k\}} + \mathbf{B}_{\{k\}} \right) \mathbf{y} + \left(\mathbf{C}_{\{k\}} + \mathbf{D}_{\{k\}} \right) \mathbf{H}\mathbf{y} \\ &= \left[\mathbf{A}_{\{k\}} + \mathbf{B}_{\{k\}} + \mathbf{C}_{\{k\}}\mathbf{H} + \mathbf{D}_{\{k\}}\mathbf{H} \right] \mathbf{y} \\ &= \mathbf{A}\mathbf{y} \end{aligned} \quad (9).$$

[00276] The elements of the matrix in brackets of Equation (9) depend upon the *x*-value corresponding to each data point (but this is a fixed matrix). Thus, the final equation can be determined using the pseudo-inverse. In turn, the pseudo-inverse only depends upon the x-locations of the data set and the locations where the breaks in the cubic spline are set. The implication of this is that once the geometry of the spline and the size of the image are selected, the best choice for **y** given a set of measured values $\mathbf{y_m}$ is illustrated in Equation (10) as follows:

[00277]
$$\mathbf{y} = \left(\mathbf{A}^T \mathbf{A} \right)^{-1} \mathbf{A} \cdot \mathbf{y}_{\mathbf{m}} \quad (10).$$

[00278] The cubic spline through the sum intensity-squared function of the image will then be given by Equation (11) as follows:

[00279] $$\mathbf{y}_{\mathbf{cs}} = \mathbf{A} \cdot \mathbf{y} \quad (11).$$

[00280] Because the maximum values of the cubic spline are of interest, the derivative of the cubic spline is determined and utilized to determine the maximum values of the cubic spline. The cubic spline derivative is given by Equation (12) as follows:

[00281]
$$\begin{aligned}\chi'(x_k) &= A'_{i_k}(x_k)\,y_{i_k} + B'_{i_k}(x_k)\,y_{i_k+1} + C'_{i_k}(x_k)\,y''_{i_k} + D'_{i_k}(x_k)\,y''_{i_k+1} \\ &= -\frac{y_{i_k}}{\Delta_{i_k}} + \frac{y_{i_k+1}}{\Delta_{i_k}} - \frac{\Delta_{i_k} y''_{i_k}}{6}\left(3A_{i_k}^2(x_k) - 1\right) + \frac{\Delta_{i_k} y''_{i_k+1}}{6}\left(3B_{i_k}^2(x_k) - 1\right)\end{aligned}$$

(12).

[00282] Equation (12) can be written as Equation (13) as follows:

[00283]
$$\begin{aligned}\mathbf{y}'_{\mathbf{cs}} &= \left(\mathbf{A}'_{\{k\}} + \mathbf{B}'_{\{k\}}\right)\mathbf{y} + \left(\mathbf{C}'_{\{k\}} + \mathbf{D}'_{\{k\}}\right)\mathbf{y}_{\mathbf{dd}} \\ &= \left[\mathbf{A}'_{\{k\}} + \mathbf{B}'_{\{k\}} + \mathbf{C}'_{\{k\}}\mathbf{H} + \mathbf{D}'_{\{k\}}\mathbf{H}\right]\mathbf{y} \\ &= \mathbf{A}'\mathbf{y}\end{aligned} \quad (13).$$

[00284] Once the current values of **y** are found, the cubic spline, $\mathbf{y}_{\mathbf{cs}}$, and its derivative, $\mathbf{y'}_{\mathbf{cs}}$, can be calculated. The cubic spline data may include "blocks" of data that includes values above a predetermined threshold. A pipe block is formed by the liquid flowing out of the tube into the drip chamber 59 and a pool block is formed as the liquid collects at the gravity end of the drip chamber 59 (see Fig. 8).

[00285] The following algorithm may be applied to the cubic spline data: (1) determine the local maxima of the cubic spline data using the derivative

information; (2) determine the block surrounding each local maxima by including all points where the cubic spline value is above a threshold value; (3) merge all blocks which intersect; (4) calculate information about the block of data including the center of mass (intensity), the second moment of the mass (intensity), the lower x-value of the block, the upper x-value of the block, the mean value of the original sum of intensity squared data in the block, the standard deviation of the original sum of intensity squared data in the block, and the mean intensity of a high-pass filtered image set in the block; and (5) interpret the collected data to obtain information about when drops occur and when the system is streaming.

[00286] The mean intensity of a high-pass filtered image set in the block is used to determine if the block created by each contiguous range of spline data is a result of a high frequency artifact (e.g., a drop) or a low frequency artifact. This will act as a second background filter which tends to remove artifacts such as condensation from the image. That is, all previous images in an image memory buffer (e.g., 30 previous frames, for example) are used to determine if the data is a result of high frequency movement between frames. If the block is a result of low frequency changes, the block is removed, or if it is a result of high frequency changes, the block is kept for further analysis. A finite impulse response filter or an infinite impulse response filter may be used.

[00287] Each block is plotted over its physical extent with the height equal to the mean value of the data within the block. If a block has a mean value of the high-pass filtered image less than the threshold, it is an indication that it has been around for several images and thus may be removed.

[00288] Free flow conditions may be determined by the processor 90 (see Figs. 6 or 8) to exist using the blocks when the pipe block extends nearly to the pool block, the pipe block and the pool block merge together, and/or the summed range of widths of the pool and pipe blocks (or all blocks) is greater than a predetermined threshold, e.g., the total extent of the blocks exceeds 380 pixels in width. The processor 90 may detect a drop when the transition of the pipe block from a larger width to a shorter width occurs as a result of a drop formation in the tube and as the drop leaves the pipe (i.e., tube) opening of the drip chamber 59. The processor 90 may detect this by looking at the ratio of the current pipe block width to the previous image's pipe block width, e.g., an image where the ratio is less than 0.9 as is also a local minima may be considered by the processor 90 to be an image formed immediately after a drop has formed.

[00289] Various filtering algorithms may be used to detect condensation or other low frequency artifacts, such as: if a block has a low mean value in the high-pass filtered image, then it may be condensation. This artifact can be removed from consideration. Additionally or alternatively, long blocks (e.g., greater than a predetermined threshold) with a low high-pass mean value are possibly streams because stream images tend to remain unchanging; the processor 90 may determine that long blocks greater than a predetermined threshold corresponds to a streaming condition. Additionally or alternatively, an algorithm may be used on the current image to detect free flow conditions.

[00290] The processor 90 may, in some specific embodiments, use the block data to count the drops to use the system 84 as a drop counter. The processor 90 may also use width changes in the pool block as a drop disturbs

the water to determine if a bubble formed when the drop hits the pool. For example, the processor 90 may determine that blocks that form below the pool block are from bubbles that formed when the drop hit the water. The bubble may be filtered out by the processor 90 when determining if a predetermined value of total block ranges indicates that a free flow condition exists.

[00291] In some embodiments of the present disclosure, the depth of field of the system 84 may have a narrow depth of field to make the system 84 less sensitive to condensation and droplets on the chamber walls. In some embodiments, a near focus system may be used.

[00292] Referring now to Fig. 19, in another embodiment of the present disclosure, a template 189 is used to determine if a free flow condition exists. The template 189 is used by the processor 90 of Fig. 8 to determine a pattern match score 190 when performing a template match algorithm on an image, e.g., the image 94 of Fig. 13. For example, the template 189 may be compared to the image 94 to determine if a portion or all of the image 94 closely matches the template 189. As previously mentioned, the image 94 of Fig. 13 is a difference between a background image and an image captured by the image sensor 63 of Fig. 8 that has each pixel converted to either a black pixel if the difference value for that pixel is below a threshold value or a white pixel if the difference value for that pixel is above a threshold value. All pixels of the image 94 will be either a white pixel or a black pixel. If the pattern match score 190 is above a predetermined threshold, a free flow condition is determined to exist. The template matching method may utilize a template matching algorithm as found in the Open Source Computer Vision ("OpenCV") library. For example,

the template 189 may be used with the matchTemplate() function call of the OpenCV library using the CV_TM_CCOEFF method or the method of CV_TM_CCOEFF_NORMED. The CV_TM_CCOEFF method uses the pattern matching algorithm illustrated in Equation (14) as follows:

[00293] $$R(x,y) = \sum_{x',y'} (T'(x',y') \cdot I'(x+x',y+y')) \quad ,(14)$$, where:

[00294] $$T'(x',y') = T(x',y') - 1/(w \cdot h) \cdot \sum_{x'',y''} T(x'',y'')$$
$$I'(x+x',y+y') = I(x+x',y+y') - 1/(w \cdot h) \cdot \sum_{x'',y''} I(x+x'',y+y'')$$

; The I denotes the image, the T denotes the template, and the R denotes the results. The summation is done over the template and/or the image patch, such that: $x' = 0...w-1$ and $y' = 0...h-1$.

[00295] The results R can be used to determine how much the template T is matched at a particular location within the image I as determined by the algorithm. The OpenCV template match method of CV_TM_CCOEFF_NORMED uses the pattern matching algorithm illustrated in Equation (15) as follows:

[00296] $$R(x,y) = \frac{\sum_{x',y'} (T'(x',y') \cdot I'(x+x',y+y'))}{\sqrt{\sum_{x',y'} T'(x',y')^2 \cdot \sum_{x',y'} I'(x+x',y+y')^2}} \quad (16).$$

[00297] In another embodiment of the present disclosure, the template matching algorithm uses a Fast Fourier Transform ("FFT"). In some embodiments, any of the methods of the matchTemplate() function of OpenCV may be used, e.g., CV_TM_SQDIFF, CV_TM_SQDIFF_NORMED, CV_TM_CCORR, and/or CV_TM_CCORR_NORMED.

[00298] The CV_TM_SQDIFF uses the pattern matching algorithm illustrated in Equation (17) as follows:

[00299]
$$R(x,y) = \sum_{x',y'} (T(x',y') - I(x+x',y+y'))^2 \quad (17).$$

[00300] CV_TM_SQDIFF_NORMED uses the pattern matching algorithm illustrated in Equation (18) as follows:

[00301]
$$R(x,y) = \frac{\sum_{x',y'} (T(x',y') - I(x+x',y+y'))^2}{\sqrt{\sum_{x',y'} T(x',y')^2 \cdot \sum_{x',y'} I(x+x',y+y')^2}} \quad (18).$$

[00302] CV_TM_CCORR uses the pattern matching algorithm illustrated in Equation (19) as follows:

[00303]
$$R(x,y) = \sum_{x',y'} (T(x',y') \cdot I(x+x',y+y')) \quad (19).$$

[00304] CV_TM_CCORR_NORMED uses the pattern matching algorithm illustrated in Equation (20) as follows:

[00305]
$$R(x,y) = \frac{\sum_{x',y'} (T(x',y') \cdot I'(x+x',y+y'))}{\sqrt{\sum_{x',y'} T(x',y')^2 \cdot \sum_{x',y'} I(x+x',y+y')^2}} \quad (20).$$

[00306] In yet another embodiment of the present disclosure, a template of a grayscale image of a free flow condition is compared to an image taken by the image sensor 63 of Fig. 8 to determine if a free flow condition exists. In some embodiments, the template matching function within the OpenCV library may be utilized.

[00307] Refer now to Figs. 20 and 21; in yet an additional embodiment of the present disclosure, the algorithm to determine when a free flow condition exists, e.g., as executed by the processor 90 of Fig. 8, may utilize an algorithm

to determine if a template pattern matches an array of pixels utilizing edge detection followed by line detection. As shown in Fig. 20, an image 98 is formed from an image 99 of Fig. 21, by using edge detected followed by line detection. The resulting lines may be utilized by the processor 90 to determine that a free flow condition exists. As shown in Fig. 20, the feature which shows up after this processing by the processor 90 are lines that have a different slope than the expected 45° slope of the background reference image. The lines having the angle of the background image may be filtered out of Fig. 20, in some embodiments. The lines may be detected as edges using a Canny algorithm as found in the OpenCV library. The Hough algorithm also found in the OpenCV library may be used to determine the slope of the lines.

[00308] One type of Hough transfer uses an algorithm described in *Progressive Probabilistic Hough Transform* by J. Matas, C. Galambos, and J. Kittler in 1998 ("Algorithm 1"). However, the following "Alternative Hough" transform may be utilized and is shown in pseudo code form in Table 1 ("Algorithm 2"). Algorithm 2 selects two pixels at random and calculates the Hough transform of the line passing through these two points. Algorithm 2 is shown in Table 1 as follows:

Table 1

Alternative Hough Transform Pseudocode

1. If the image is empty, then exit.
2. Randomly select two pixels and update the accumulator
    a. Required Operations
        i. Two random numbers

ii. One inverse tangent

3. Check if the new location is higher than the threshold *l*. If not, goto 1

a. Operations

i. One logical operation

4. Look along a corridor specified by the peak in the accumulator, and find the longest segment of pixels either continuous or exhibiting a gap not exceeding a given threshold.

5. Remove the pixels in the segment from the input image.

6. Unvote from the accumulator all the pixels from the line that have previously voted.

7. If the line segment is longer than the minimum length add it to the output list

8. Goto 1.

[00309] If the line comprises a proportion, *p*, of the total points, then the likelihood that we will see a result in the representative (r,θ)-bin is *p* for Algorithm 1 and p^2 for Algorithm 2. Generally, in some embodiments, a proportion test has at least 5 positive results and 5 negative results. Assuming that it is more likely to see negative results than positive results, in some embodiments, the Algorithms 1 and 2 continue to search for lines until there are at least 5 positive results in a particular bin.

[00310] The probability of seeing a fifth positive result in Algorithm 1 after $N \geq 5$ tests is shown in Equation (21) as follows:

[00311] $$p_1(5 \text{ on } N) = p(4 \text{ in } N-1) \cdot p = \frac{(N-1)!}{4!(N-5)!} p^5 (1-p)^{N-5} \quad (21),$$

[00312] and the probability in Algorithm 2 is shown in Equation (22) as follows:

[00313] $$p_2(5 \text{ on } N) = p(4 \text{ in } N-1) \cdot p^2 = \frac{(N-1)!}{4!(N-5)!} p^{10} (1-p^2)^{N-5} \quad (22).$$

[00314] Table 2, shown below, shows the number of tries to have a 50% chance of seeing 5 successes, $p_{1,50}$ and $p_{2,50}$, as well as the number of tries to have a 90% chance of seeing 5 successes, $p_{1,90}$ and $p_{2,90}$.

TABLE 2

p	$p_{1,50}$	$p_{1,90}$	$p_{2,50}$	$p_{2,90}$	r_{50}	r_{90}
0.5	9	14	20	31	2.22	2.21
0.25	19	30	76	127	4	4.23
0.125	39	62	299	511	7.67	8.24
0.0625	76	127	1197	2046	15.75	16.11

[00315] Table 2 shows that the increase in the number of tries between Algorithm 1 and Algorithm 2 to see 5 positive results is approximately $1/p$. There should be 1 positive result in $1/p$ trials when the proportion is p.

[00316] Algorithm 2's computationally expensive operation is, in some embodiments, the arc tangent function, which may be about 40 floating point CPU operations. There are approximately 2N floating point operations in Algorithm 1's equivalent step. The Hough transform of a 640×480 pixel image with full resolution has N equal to 2520, while the Hough transform of a 1080×1920 pixel image has N equal to 7020. This implies that Algorithm 2 has

a speed advantage over Algorithm 1 when *p* is greater than 0.008 for a 640×480 image and when *p* is greater than 0.003 for a 1080×1920 image.

[00317] In some embodiments, it is assumed that every bin in the Hough transform space is equally likely to be occupied in the presence of noise. This simplification speeds up the thresholding decision; however, in some embodiments, this assumption is not true. The primary effect of the simplification is to underestimate the probability that is seen in values greater than one in the Hough transform with a corresponding likelihood of falsely declaring that a line exists. For a particular combination of image size and Hough transform bin arrangement, the true probabilities can be pre-computed. This allows the false alarm rate to be minimized without a corresponding increase in computation. With additional restrictions on the type of imagery, even more accurate estimates of the probability of seeing a value in a bin of the Hough transform is possible.

[00318] There are additional forms of the Hough transform which parameterizes different features. For example, there is a three-element parameterization of circles, (x,y,r), where x and y specify the center and r is the radius. Algorithm 2 can work using these parameterizations as well. For the circle example, Algorithm 2 would select three pixels at random and calculate the circle passing through them.

[00319] Algorithm 2 would have a similar speed advantage for features comprising a suitably large portion of the total pixels considered. It would also have a significant advantage in storage required, since the Hough transform

could be stored in a sparse matrix, while the Algorithm 1's analog would require a full-size matrix.

[00320] Referring now to Figs. 22-26, which illustrate various background patterns that may be used to detect a free flow condition or estimate the size of a drop of liquid. The image sensor 103 may be used with the background patterns of Figs. 22-26 and may be the image sensor 11 of Fig. 1, the image sensor 68 of Fig. 5, the image sensor 63 of Fig. 6, or the image sensor 63 of Fig. 8, each of which may be coupled to a respective processor for processing the images from the image sensor, such as the processor 15 of Fig. 1 or the processor 90 of Fig. 8.

[00321] Fig. 22 is a block diagram of an imaging system 100 for use with the drip chamber 104 (e.g., a drip chamber 4 of Fig. 1) having a background pattern 101 with stripes and a light source 102 shining on the stripes from an adjacent location to an image sensor 103 in accordance with an embodiment of the present disclosure. Any drops or free flow streams within the drip chamber 104 distorts the image taken by the image sensor 103. A processor coupled to the image sensor 103 (e.g., processor 15 of Fig. 1) can use the distortions of the background pattern 101 as captured by the image sensor 103 to estimate a flow rate and/or detect free flow conditions.

[00322] Fig. 23 is a block diagram of an imaging system 105 for use with the drip chamber 104 having a background pattern 101 with stripes and a light source 102 shining on the stripes from behind the background pattern 101 relative to an opposite end to an image sensor 103 in accordance with an embodiment of the present disclosure. Fig. 24 shows an image from the image

sensor 103 of Fig. 23 when a drop distorts the background pattern 101 of Fig. 23 in accordance with an embodiment of the present disclosure. Note that as shown in Fig. 24, the background pattern's 101 stripes are distorted by the drop (or will be distorted by a free flow stream) in the drip chamber 104 as captured in images by the image sensor 103. This distortion may be used to estimate the drop size, to calculate the flow rate through a drip chamber, or to determine if a free flow condition exists within the drip chamber.

[00323] Fig. 25 shows a block diagram of an imaging system 106 for use with a flow meter having a background pattern 107 with a checkerboard pattern and a light source 102 shining on the stripes from behind the background pattern 107 relative to an opposite end to an image sensor 103 in accordance with an embodiment of the present disclosure. Fig. 26 shows an image from the image sensor 103 of Fig. 25 when a drop distorts the background pattern 107 of Figs 25-26 in accordance with an embodiment of the present disclosure. In yet another embodiment of the present disclosure, a background pattern having a plurality of random dots and/or circles may be utilized by an imaging system disclosed herein.

[00324] Referring to Figs. 22-26, the "lensing" of a drop (i.e., the distortion of the background pattern from the view of an image sensor) may be used to measure the radius of the drop. The radius of the drop corresponds to how much and what effect the drop has on any light passing through it. By measuring the change to the calibration grid (i.e., the background pattern) as seen through the drop, the radius, and hence the volume of the drop, can be calculated. For example, the magnification of a test grid of known size as seen

through the drop could be measured optically and the radius inferred from this measurement. In some embodiments of the present disclosure, the relationship between the radius and the drop may be calculated and/or may be determined using a lookup table that has been generated empirically.

[00325] Figs. 27-28 show a flow chart diagram illustrating a method for estimating a volume of a drop within a drip chamber in accordance with an embodiment of the present disclosure. That is, Figs. 27-28 illustrate a method 214. Method 214 will be also described with reference to Figs. 29-37. Figs. 29-31 and 33-36 illustrate images used or generated by a flow meter to estimate a volume of a drop within a drip chamber in accordance with an embodiment of the present disclosure. Figs. 32 and 37 illustrate pseudo code that may be used by the method 214 of Figs. 27-28.

[00326] The method 214 of Figs. 27 and 28 may be implemented by the flow meter 7 of Fig. 1, the flow meter 67 of Fig. 5, the imaging system 78 of Fig. 6, the imaging system 84 of Fig. 8, or other flow meter of an imaging system disclosed herein (each with or without a background pattern and/or with or without active illumination).

[00327] The method 214 includes acts 200-213. Act 200 determines a baseline of a drop forming at an opening of a drip chamber. Act 201 captures a first image. The first image may be captured using a uniform backlight. In some embodiments, the first image may be captured using a background pattern and/or an exposure algorithm as described herein. Acts 200 and 201 may be performed simultaneously. Fig. 29 shows an image with the baseline 215 overlaid. The baseline 215 may be a predetermined group of pixels or may

be generated using fiducial markers disposed on the opening of the drip chamber and/or on a background pattern (not shown in Fig. 29). The first image is used by the method 214 to initialize a background image, $\mu_{i,j}$, a variance array, $s_{i,j}$, and an integer array, $I_{i,j}$. The background image may have i by j pixels, while the variance array and the integer array may be 2-D arrays that also have a size of i by j.

[00328] Act 202 identifies the drop within the first image and a predetermined band near an edge of the drop (e.g., the band may be a predetermined number of pixels beyond the edge of the drop). Act 203 initializes a background image by setting each pixel to the same value as the first image (for that respective location) unless it is within the identified drop or a predetermined band near the edge of the drop. Act 204 sets pixels within the region of the drop or within the predetermined band to a predetermined value. Fig. 30 shows an example background image created after initialization. In the exemplary image of Fig. 30, the area of the drop and of a band beyond the edge of the drop, designated generally as 216, is set to a predetermined value, e.g., 140.

[00329] For example, when the method creates the first background image, every pixel in the background image that is part of the drop or a band outside of an edge of the drop is set to a default threshold value, e.g. 140 out of an intensity range of 0-255.

[00330] Act 205 initializes the integers of the array of integers to zeros. Act 206 initializes the values within the array of variances to zeros. The integer array is the same size as the image. The integer array counts how often each

pixel of the background image has been updated with new information and is initialized to all zeros. The array of variances (e.g., an array of the data type "double") is also the same size as the background image and contains an estimate of the variance of the intensity of each pixel within the background image.

[00331] Act 207 captures another image, and act 208 identifies the drop in the another image and another predetermined band near an edge of the drop. Act 209 updates the background image, the array of integers, and the array of variances.

[00332] As additional images are captured, the background image may be updated. For example, when an image is collected by the system, the background algorithm evaluates every pixel. If a pixel is considered part of the drop or its guard band, then its value in the background image is not altere*d*.

[00333] If a pixel is not considered part of the drop or its guard band: (1) if the pixel's corresponding integer in the integer array is zero, the pixel's value in the background image is set equal to the pixel's value in the input image; or (2) if the pixel's count is greater than 0, then the background image value for that pixel is updated using a low pass filter. In some embodiments, any style of filter may be used, such as a high pass filter, a bandpass filter, etc. One low pass filter that may be used is illustrated in Equation (23) as follows:

[00334] $$P_{\text{background},i,j} = P_{\text{background},i,j}\left(1-\alpha_{\text{background}}\right)+\alpha_{\text{background}}P_{\text{input},i,j} \quad (23).$$

[00335] In addition, the variance array may be updated using Equations (24) as follows:

$$\sigma^2_{\text{temp}} = \left(P_{\text{background},i,j} - P_{\text{input},i,j}\right)^2$$

[00336] $$\sigma^2_{\text{background},i,j} = \sigma^2_{\text{background},i,j}\left(1-\beta_{\text{background}}\right) + \beta_{\text{background}}\sigma^2_{\text{temp}} \quad (24).$$

[00337] Note that the filter used for both operations is an exponential filter; however, in additional embodiments, other suitable filters may be used, such as other low-pass filters. The variance estimate can be performed in any known way or using a stand in for the estimate, e.g., using standard deviation.

[00338] The new estimates of each pixel's background intensity (mean value), the number of images used to update each pixel's mean and variance, and each pixel's variance (e.g., an approximation to the true variance and/or a value that is proportional to the variance) are used to update the arrays. That is, each additional image captured may be used to update the background image, the array of integers, and the array of variances. After several images have been processed, the background image may appear as Fig. 31. Note that this image still has a region (the uniformly medium gray area, designated generally as 217) where the pixels have never changed from the initial threshold value. This region has been considered part of the drop or its guard band in every image.

[00339] Act 210 compares the another image (e.g., current or most recent image) to the background image and identifies a plurality of pixels of interest. Act 211 determines a subset of pixels within the plurality of pixels of interest that corresponds to a drop.

[00340] The comparison of act 210 compares the another image pixel-by-pixel to the background image. Out of this comparison comes an array the same size as the image where every pixel has a value of zero or not zero (255).

[00341] Act 210 may be implemented by the pseudo code shown in Fig. 32. That is, the determination of this threshold value is made in accordance with the following: If the input pixel is to the left or right of the baseline in the image, then its output value is set to zero (Line 1); if the input pixel's background count array indicates that fewer than a pre-determined number of images (e.g., 100) have been used to make this pixel's background value (Line 2), then: if the input pixel's intensity is less than the threshold intensity (e.g., 140 in a range of 0-255), then set the pixel's output value to not-zero (255) (Line 2a); or if the input pixel's intensity is greater than or equal to the threshold intensity, then set the pixel's output value to zero (Line 2b); and if the input pixel's background count array is greater than the pre-determined number of images (Line 3), then: if the square of the difference between the input pixel intensity and the background pixel intensity is greater than the pixel's estimate of background variance times a constant γ^2, then set the pixel's output value to not-zero (255) (Line 3a) (that is, if the difference between current pixel value and the background image is more than γ, then the pixel is distinct); or if the square of the difference between the input pixel intensity and the background pixel intensity is less than or equal to the pixel's estimate of background variance times a constant γ^2, then set the pixel's output value to zero (see Line 3b). Line 3 captures portions of the image that are altered by the presence of a drop, but which are made a higher intensity.

[00342] When act 210 is implemented as an algorithm, the algorithm is initialized, and the input and output of this thresholding algorithm will look like the images in Figs. 33 and 34, respectively. Because the number of images

used in estimating the background image is initially small, the only criterion applied are shown as lines (1) and (2) above because there have not been enough images used for the integer array to have a value beyond the threshold for certain respective pixels. This may result in many low-intensity regions being identified as distinct, including poorly illuminated edges and condensation on the chamber walls.

[00343] After enough images have been gathered such that most (or all) of the pixels of the background image have been generated with a sufficient number of pixels, lines (3), (3a), and (3b) of Fig. 32 are utilized. After thresholding, the background is largely black with an occasional noisy pixel exceeding the variance threshold, as shown in Figs. 35 and 36 (which show an image captured by the camera and the results of the comparison algorithm described above, respectively).

[00344] As previously mentioned, after act 210, act 211 determines which of a subset of pixels within the plurality of pixels of interest corresponds to a drop. Act 211 may be implemented by the pseudo code shown in Fig. 37. That is, the threshold image is passed to an algorithm which finds the connected component representing the drop as illustrated by the pseudo code of Fig. 37.

[00345] The binary image after processing the pseucode of Fig. 32 is evaluated to find the binary component which occupies the space given by the drop. The algorithm is passed the location of a pixel on the baseline which is white (or it is passed the center pixel of the longest stretch of contiguous white pixels on the line).

[00346] Once the algorithm has an initial white pixel, it performs the algorithm illustrated by the pseudo code shown in Fig. 37. The pseudo code determines locations that include white pixels that have a path to the baseline (i.e., a white pixel path). Line 1 pushes the location of the first pixel onto a stack. Line 2 performs a while loop while the stack is not empty. The while loop includes lines (2a)-(2d). Line 2a pops the next location (i,j) off of the stack. Line 2b makes the output pixel value at (i,j) white. Line 2c examines the eight pixels adjacent to (i,j). Line (2ci) is an "if statement," and if the adjacent input pixel (ι,φ) is white, but the output pixel (ι,φ) is black, line 2c adds the location (ι,φ) to the stack. Line 2d return to line 2 to continue the while loop (if the stack remains empty).

[00347] This algorithm will set to white all output-pixel locations which can be connected to the input pixel's location by a continuous path of white input pixels. The left boundary of the drop is found by stepping through each row of pixels from the left edge until the algorithm hits a white pixel. The right boundary is found by stepping from the right edge of the image until it hits a white pixel. The first row where it is possible to step from the left edge to the right edge without hitting a white pixel is where the drop is considered to end.

[00348] The pseudo code shown in Fig. 37 is a one-pass version of a connected-component labeling algorithm. However, other connected-component labeling algorithms or other suitable algorithms may be used to determine which pixels correspond to the drop.

[00349] Act 212 of Fig. 28 performs a rotation operation on the subset of pixels. Act 213 estimates a volume of the drop within the drip chamber by counting the number of pixels within the rotated subset of pixels. The total number of pixels within the 3-D version of the drop is counted; and because each pixel corresponds to a distance, the number of pixels may be used to estimate the volume of the drop.

Imaging System Optics

[00350] Figs. 38-42 facilitate the following description of the optics of an imaging system disclosed herein. For example, an image sensor disclosed herein may be an image sensor cube manufactured by OmniVision of 4275 Burton Drive, Santa Clara, California 95054; and, for example, the image sensor cube may be one manufactured for phone image sensor applications. In some embodiments of the present disclosure, an image sensor disclosed herein may use a fixed focus and have a depth of field ("DOF") from 15 centimeters to infinity.

[00351] The image sensor may have the blur circle of a point imaged in the range of the image sensor entirely contained within the area of a single pixel. The focal length of the image-sensor lens may be 1.15 millimeters, the F# may be 3.0, and the aperture of the lens of the image sensor may be 0.3833 millimeter. A first order approximation of the optical system of one or more of the image sensors may be made using matrix equations, where every ray, r, is represented as the vector described in Equation (25) as follows:

[00352] $$r = \left\{ \frac{h}{\theta} \right\} \quad (25).$$

[00353] In Equation (25) above, h is the height of the ray at the entrance to the image sensor, and θ is the angle of the ray. Referring to Fig. 38, when imaging a hypothetical point at a distance d_{im} from the lens of one of the image sensors (which has focal length f) and the lens is a distance d_{fp} from the focal plane, the corresponding matrix, M_{cam} ,describing the image sensor is described by Equation (26) as follows:

[00354] $$M_{cam} = \begin{bmatrix} 1 & d_{fp} \\ 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & 0 \\ -\frac{1}{f} & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & d_{im} \\ 0 & 1 \end{bmatrix} \quad (26).$$

[00355] To find the place on the focal plane, fp, where the ray strikes, a matrix multiplication as described in Equation (27) as follows may be used:

[00356] $$\begin{Bmatrix} h_{fp} \\ \theta_{fp} \end{Bmatrix} = M_{cam} \cdot \begin{Bmatrix} h_{im} \\ \theta_{im} \end{Bmatrix} \quad (27).$$

[00357] As illustrated in Fig. 38, the diameter of the blur circle, D_{blur}, is shown as approximately the distance between the two points illustrated in Fig. 38. This distance is found by tracing rays from the point, $d_{im,}$ away from the lens on the optical axis to the edges of the lens and then to the focal plane. These rays are given by the vectors shown in (28) as follows:

[00358] $$\begin{Bmatrix} 0 \\ \pm \tan^{-1} \frac{D_{lens}}{2 * d_{im}} \end{Bmatrix} \quad (28).$$

[00359] As shown in Fig. 39, the blur circle, D_{blur}, is calculated and shown for a variety of lens-to-focal plane separations and lens-to-image separations.

A contour map 77 is also shown in Fig. 39. The x-axis shows the distance in microns between the focal plane and a point located a focal length away from the lens of an image sensor. The y-axis shows the distance in meters between the lens and the point being imaged. The values creating the contour map 77 is the blur size divided by the pixel size; therefore, anything about 1 or less is sufficient for imaging. As shown in Fig. 39, the focal plane is located a focal length and an additional 5 micrometers away from the lens.

[00360] The image sensor may utilize a second lens. For example, an image sensor may utilize a second lens to create a relatively larger depth of field and a relatively larger field of view. The depth of field utilizing two lenses can be calculated using the same analysis as above, but with the optical matrix modified to accommodate for the second lens and the additional distances, which is shown in Equation (29) as follows:

[00361] $$M_{sys} = \begin{bmatrix} 1 & d_{fp} \\ 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & 0 \\ -\frac{1}{f_{cam}} & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & d_{lens} \\ 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & 0 \\ -\frac{1}{f_{lens}} & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & d_{im} \\ 0 & 1 \end{bmatrix}$$

(29).

[00362] Figs. 40 and 41 illustrate the field changes with the separation between the lens and the image sensor and the corresponding change in the focus of the image sensor. Figs. 40 and 41 show the blur circle divided by the pixel size. Fig. 40 shows the blur circle divided by pixel size when a 20 millimeter focal-length lens is used. Fig. 41 shows the blur circle divided by pixel size when a 40 millimeter focal length lens is used. The corresponding fields of view about the optical axis for the corners of the two configurations of Figs. 40 and 41 are shown in the table in Fig. 42.

[00363] As shown in Fig. 42, in some embodiments, the image sensor may utilize a 40mm to 60mm focal-length lens; this configuration may include placing an image sensor about 2 inches from the focus. In other embodiments of the present disclosure, other configurations may be used including those not shown in Fig. 42.

[00364] For example, the following analysis shows how the depth of field can be set for an image sensor using a lens of focal length, f, a distance, z, from the focal plane, and a distance, d, from a point in space; a matrix of the system is shown in Equation (30) as follows:

[00365] $$M = \begin{bmatrix} 1 & z \\ 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & 0 \\ -\frac{1}{f} & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & d \\ 0 & 1 \end{bmatrix} \quad (30).$$

[00366] Equation (30) reduces to Equation (31) as follows:

[00367] $$M = \begin{bmatrix} 1 & z \\ 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} 1 & d \\ -\frac{1}{f} & 1-\frac{d}{f} \end{bmatrix} \quad (31).$$

[00368] Equation (31) reduces to Equation (32) as follows:

[00369] $$M = \begin{bmatrix} 1-\frac{z}{f} & d+z-\frac{dz}{f} \\ -\frac{1}{f} & 1-\frac{d}{f} \end{bmatrix} \quad (32).$$

[00370] Considering the on-axis points, all of the heights will be zero. The point on the focal plane where different rays will strike is given by Equation (33) as follows:

[00371] $$\left(d+z-\frac{dz}{f} \right)\theta \quad (33).$$

[00372] As shown above in (33), θ is the angle of the ray. The point in perfect focus is given by the lens maker's equation given in Equation (34) as follows:

[00373] $$\frac{1}{f}=\frac{1}{z}+\frac{1}{d} \qquad (34).$$

[00374] Equation (34) may be rearranged to derive Equation (35) as follows:

[00375] $$d=\frac{1}{\frac{1}{f}-\frac{1}{z}}=\frac{fz}{z-f} \qquad (35).$$

[00376] Inserting d from Equation (35) into Equation (33) to show the striking point results in Equation (36) as follows:

[00377] $$\left[\frac{fz}{z-f}+z-\frac{\frac{fz}{z-f}z}{f}\right]\theta=\frac{f^2z+fz^2-f^2z-fz^2}{f(z-f)}\theta=0 \qquad (36).$$

[00378] All rays leaving this point strike the focal plane at the optical axis. As shown in Equation (37), the situation when the image sensor is shifted by a distance δ from the focus is described as follows:

[00379] $$\left[\frac{fz}{z-f}+\delta+z-\frac{\left[\frac{fz}{z-f}+\delta\right]z}{f}\right]\theta=\frac{f^2z+fz\delta-f^2\delta+fz^2-f^2z-fz^2-\delta z^2+f\delta z}{f(z-f)}\theta$$

[00380] $$=\frac{fz-f^2-z^2+fz}{f(z-f)}\delta\theta=-\frac{(z-f)^2}{f(z-f)}\delta\theta$$

[00381] $= \frac{f - z}{f} \delta\theta$ (37).

[00382] Equation (37) shows that by properly positioning the lens of the image sensor with respect to the focal plane, we can change the depth of field. Additionally, the spot size depends upon the magnitude of the angle θ. This angle depends linearly on the aperture of the vision system created by the image sensor.

[00383] Additionally or alternatively, in accordance with some embodiments of the present disclosure, an image sensor may be implemented by adjusting for various parameters, including: the distance to the focus as it affects compactness, alignment, and sensitivity of the vision system to the environment; the field of view of the system; and the lens-focal plane separation as it affects the tolerances on alignment of the system and the sensitivity of the system to the environment.

Embodiments of the flow meter with or without valves connected thereto

[00384] Referring to the drawings, Figs. 43 and 44 show a flow meter 58 coupled to a drip chamber 59. As described *infra*, the flow meter 58 may optionally include a free flow detector component 12 (see Fig. 1) in accordance with an embodiment of the present disclosure. Additionally, alternatively, or optionally, the flow meter 58 may include a flow rate estimator component 13 (see Fig. 1) in accordance with some embodiments of the present disclosure. Fig. 43 shows the flow meter 58 with a shut door 62, and Fig. 44 shows the flow meter 58 with an open door 62. The flow meter 58 may be the flow meter 7 of Fig. 1 with a valve 6 or with no valve. The flow meter 58 includes a start button

60 and a stop button 61. Additionally or optionally, the flow meter 58 may include a backup valve to stop fluid from flowing therethrough or may signal another valve to stop the fluid from flowing in response to error conditions.

[00385] The flow meter 58 optionally includes image sensors 63 and 64 that can estimate fluid flow and/or detect free flow conditions. Although the flow meter 58 includes two image sensors (e.g., 63 and 64), only one of the image sensors 63 and 64 may be used in some embodiments. The image sensors 63 and 64 can image a drop while being formed within the drip chamber 59 and estimate its size. The size of the drop may be used to estimate fluid flow through the drip chamber 59. For example, in some embodiments of the present disclosure, the image sensors 63 and 64 use an edge detection algorithm to estimate the outline of the size of a drop formed within the drip chamber 59; a processor therein (see processor 15 of Fig. 1, processor 75 of Fig. 5, or processor 90 of Figs. 6 or 8) may assume the outline is uniform from every angle of the drop and can estimate the drop's size from the outline. In the exemplary embodiment shown in Figs. 43 and 44, the two image sensors 63 and 64 may average together the two outlines to estimate the drop's size. For example, the algorithm may average the measured outlines of the two image sensor 63 and 64 to determine the size of the drop. The image sensors 63 and 64 may use a reference background pattern to facilitate the recognition of the size of the drop as described herein.

[00386] In another embodiment of the present disclosure, the image sensors 63 and 64 image the fluid to determine if a free flow condition exists. The image sensors 63 and 64 may use a background pattern to determine if the

fluid is freely flowing (i.e., drops are not forming and the fluid streams through the drip chamber 59). As previously mentioned, although the flow meter 58 includes two image sensors (e.g., 63 and 64), only one of the image sensors 64 and 64 may be used in some embodiments to determine if a free flow condition exists and/or to estimate the flow of fluid through the drip chamber.

[00387] Additionally or alternatively, in some embodiments of the present disclosure, another image sensor 65 monitors the fluid tube 66 to detect the presence of one or more bubbles within the fluid tube. In alternative embodiments, other bubble detectors may be used in place of the image sensor 65. In yet additional embodiments, no bubble detection is used in the flow meter 58.

[00388] Referring now to the drawings, Fig. 45 shows a flow meter 218 coupled to a drip chamber 219 in accordance with an embodiment of the present disclosure. The drip chamber 219 is secured to the flow meter 218 via couplers 410. A backlight 220 shines light through the drip chamber toward the image sensor 221 (shown in outlined form).

[00389] The flow meter 218 may electronically transmit a flow rate to a monitoring client 8 (see Fig. 1). Additionally or alternatively, in some optional embodiments, the flow meter 218 may include a display that displays a flow rate (e.g., a touch screen, an LED display, and the like). The flow meter 218 may be coupled to a pole 223 via clamps 222.

[00390] In some embodiments, the flow meter 218 may be coupled to an actuator which is coupled to a valve (not shown in Fig. 45) to form a closed-loop system (e.g., the control component 14 of Fig. 1, such as a PID, bang-bang,

neural network, or fuzzy logic control system) to regulate the flow of fluid through the drip chamber 219.

[00391] The flow meter 218 may use any flow algorithm described herein and may include any imaging system described herein. Additionally or alternatively, the flow meter 218 may include a free flow detector component (e.g., the free flow detector component 12 of Fig. 1).

[00392] Fig. 46 shows a flow meter 224 and a pinch valve 225 coupled to the body 226 of the flow meter 224 to control the flow of fluid to a patient in accordance with an embodiment of the present disclosure. The flow meter 224 includes an image sensor 227 and a backlight 228.

[00393] The image sensor 227 images a drip chamber 229 and can receive illumination from the backlight 228. The flow meter 224 includes a support member 230 coupled to a coupler 231 that couples the drip chamber 229 to the flow meter 224.

[00394] The flow meter 224 may implement any flow rate estimator described herein (e.g., the flow rate estimator component 13 of Fig. 1) and/or a free flow detector disclosed herein (e.g., the free flow detector component 12 of Fig. 1). The flow meter 224 may use the pinch valve 225 in a close-loop fashion to control the flow of fluid to a patient (e.g., using a control component 14 as shown in Fig. 1).

[00395] The pinch valve 225, as is more easily seen in Fig. 47, is coupled to a shaft 233 which is coupled to an actuator 234. The actuator 234 may be a solenoid or any actuator that can move the pinch valve 225 toward a tube 335.

[00396] Fig. 48 shows a flow meter 336 and a pinch valve 225 in accordance with an embodiment of the present disclosure. The flow meter includes two image sensors 337 and 338. The flow meter 336 may use the pinch valve 225 in a closed-loop feedback configuration. The flow meter 336 may implement a volume estimation algorithm described herein using both image sensors 337 and 338 to estimate the flow of fluid through the drip chamber 229. For example, the flow meter 336 may average the two volumes together for use in the feedback loop.

[00397] Fig. 49 shows a flow meter 339 and a valve 340 coupled to an actuator 341 to control the flow of fluid into a patient in accordance with an embodiment of the present disclosure. The flow meter 339 of Fig. 49 is similar to the flow meter 224 of Fig. 46; however, the flow meter 339 of Fig. 49 includes a valve 340 that has curved, elongated support members 342 and 343 (see Figs. 50A-50B).

[00398] The flow meter 339 includes an image sensor 227 and a backlight 228. The image sensor 227 images a drip chamber 229 and can receive illumination from the backlight 228. The flow meter 339 includes a support member 230 coupled to a coupler 231 that couples the drip chamber 229 to the flow meter 339.

[00399] The flow meter 339 can implement any flow rate estimator described herein (e.g., the flow rate estimator component 13 of Fig. 1) and/or a free flow detector disclosed herein (e.g., the free flow detector component 12 of Fig. 1). The flow meter 339 may use the valve 340 in a close-loop fashion to

control the flow of fluid into a patient (e.g., using the control component 14 of Fig. 1).

[00400] The flow meter 339 may actuate the actuator 341 to actuate the valve 340, which thereby regulates the fluid flowing through the IV tube 335 in a feedback (i.e., closed-loop) configuration using any control algorithm.

[00401] Referring now to Figs. 50A-50B, which shows close-up views of the valve 340 of Fig. 49 in accordance with an embodiment of the present disclosure. The valve 340 includes an inner curved, elongated support member 343 and an outer curved, elongated support member 342. The tube 335 is positioned between the support members 342 and 343.

[00402] The inner support member 343 includes a barrel nut 344. The outer support member 342 is coupled to the barrel nut 344 via hooks 345. In some embodiments, the barrel nut 344 is not coupled to the valve 340 and the inner support member 342 includes a hole for the threaded rod or screw 347 to slide through. The outer support member 342 also has hooks 348 to secure it to a frame 349 of the actuator 341. The actuator 341 includes a shaft 346 coupled to a screw 347. As the actuator 341 rotates the shaft 346, the screw 347 can rotate to push the barrel nut 334 toward the actuator 341. That is, the hooks 345 and the barrel nut 334 move toward the hooks 348 and the frame 349 because the inner and outer support members 342 and 343 are flexible.

[00403] As the support members 342 and 343 are compressed, the tube 335 becomes compressed because it is positioned between the support members 342 and 343. Compression of the tube 335 restricts the flow of fluid

through the tube 335. The valve 340 compresses a length of the tube 335 that is substantially greater than the diameter of the tube 335.

[00404] Figs. 51A-51D show several views of a flow meter 350 with a monitoring client 358, a valve 352, a drip chamber 357, an IV bag 411, and a fluid tube 412 in accordance with an embodiment of the present disclosure. The flow meter 350 includes a receiving portion 351 to receive the valve 352. The valve 352 includes two curved, elongated support members 353 and 354.

[00405] The flow meter 350 includes an image sensor 355 and a backlight 356 that can monitor drops formed within the drip chamber 357. The flow meter 350 may use the image sensor 355 to implement a flow rate estimator algorithm described herein (e.g., the flow rate estimator component 13 of Fig. 1) and/or to implement a free flow detector disclosed herein (e.g., the free flow detector component 12 of Fig. 1).

[00406] The flow meter 350 includes a base 359 that can form a dock to receive the monitoring client 358. The monitoring client 358 may be a smart phone, or other electronic computing device (e.g., an Android-based device, an Iphone, a tablet, a PDA, and the like).

[00407] The monitoring client 358 may contain software therein to implement a free flow detector, a flow rate estimator, a control component, an exposure component, etc. (e.g., the free flow detector component 12, the flow rate estimator component 13, the control component 14, the exposure component 29 of Fig. 1) and may contain one or more transceivers (e.g., the transceiver 9). Additionally or alternatively, the base 359 of the flow meter 350 may implement these items.

[00408] For example, the flow meter 350 may implement a free flow detector, a flow rate estimator, a control component, an exposure component, etc. using internal software, hardware, electronics, and the like. The flow meter 350 may implement a closed-loop feedback system to regulate the fluid flowing to a patient by varying the fluid flowing through the valve 352.

[00409] As is easily seen in Fig. 51B, the valve 352 includes an inner support member 354 and an outer support member 353. The inner support member 354 is coupled to a barrel nut 360 and to a barrel 361. In some embodiments, the barrel nut 360 is not coupled to the inner support member 354, and the inner support member 354 includes a hole for the threaded shaft 362 to slide through.

[00410] A threaded shaft 362 (e.g., a screw) spins freely within a bearing located within the barrel 361 and engages a threaded nut within the barrel nut 360 to push or pull the barrel nut 360 relative to the barrel 361 by rotation of the knob 363 (e.g., the actuator is a lead screw having a knob to actuate the lead screw.). The knob 363 may be manually rotated.

[00411] Additionally or alternatively, the valve 352 may be snapped into the receiving portion 351 which includes a rotating member 364 that engages the knob 363 within the receiving portion 351 (see Fig. 51C). The rotating member 364 engages the rotating knob 363 to actuate the valve 352. The rotating member 364 may be coupled to an electric motor which rotates the rotating member 364. The electric motor (not explicitly shown) may be controlled by the flow meter 350 in a closed-loop configuration to achieve a target flow rate of fluid flowing into a patient.

[00412] Figs. 52A-52D show several views of another flow meter 365 with a valve 352, a drip chamber 357, and a fluid tube trench 413 having a receiving portion 351 to receive a valve 352 in accordance with an embodiment of the present disclosure. The flow meter 365 of Figs. 52A-52D is similar to the flow meter 350 of Figs. 51A-51D; however, the base 359 holds the monitoring client 358 in an "upright" position. Additionally, the receiving portion 351 is on an opposite side of the base 359 from the monitoring client 358 (see Figs. 52B and 52C).

[00413] Fig. 52D shows a close-up view of the valve 352 engaging the receiving portion 351. The knob 363 engages a rotating member that is internal to the base 359 (not shown in Fig. 52D) that is coupled to a motor (also not shown in Fig. 52D).

[00414] Fig. 53A shows another view of the valve 352 of Figs. 51A-51D and 52A-52D, and Figs. 53B-53C show two exploded views of the valve of Fig. 53A in accordance with an embodiment of the present disclosure.

[00415] As shown in Figs. 53A-53C, the valve 352 includes an inner support member 354 and outer support member 353. A tube may be inserted through holes 366 and 367 to position the tube between the support members 354 and 353.

[00416] The knob 363 may be turned to turn the screw 362. Rotation of the screw 362 causes the barrel nut 360 to move toward the partial barrel 363 to compress a tube positioned between the support members 353 and 354. The partial barrel 363 includes two sides, however, there is a space to hold the end 600 (e.g., the cap) of the screw 362 securely within the space (e.g., a

complementary space). Fig. 54 shows the valve 352 in manual use and coupled to a tube 368.

[00417] Fig. 55 shows a valve 369 that includes two flexible members 370 and 371 in accordance with an embodiment of the present disclosure. The flexible members 370 and 371 may be two flexible sheets. The flexible member 371 may include holes 373 and 374 for a tube 372 to be positioned between the flexible members 370 and 371.

[00418] The flexible members 370 and 371 are coupled together via two connector members 377 and 378. The connector members 377 and 378 are coupled to coupling members 376 and 375, respectively.

[00419] Actuation of the valve 369 may be by a linear actuator that pulls the coupling members 375, 376 toward each other or away from each other. The linear actuator (not explicitly shown) may be a screw-type actuator, a piston actuator, or other actuator. In some embodiments, one of the coupling members 375 and 376 may be coupled to a stationary support while the actuator is coupled to the other one of the coupling members 375 and 376 and another stationary support for pulling the coupling members 375 and 376 together or apart.

[00420] Figs. 56A-56C show several views of a valve 380 having two curved, elongated support members 381 and 382 with one of the elongated support members 381 having a plurality of ridges 387 adapted to engage a tube positioned between the support members 381 and 382, in accordance with an embodiment of the present disclosure.

[00421] The valve 380 has both support members 381 and 382 coupled to a coupling member 383 at a first end and a second coupling member 384 at another end. That is, the coupling member 384 surrounds a screw 385, and the coupling member 383 includes internal threads for pulling the coupling member 383 toward or away from a knob 386 when the screw 385 is rotated with rotation of the knob 386. Fig. 56B shows the valve 380 when actuated to close fluid flowing through a tube coupled between the support members 381 and 382. Fig. 56C shows the support member 381 having two holes 388 and 389 to receive a tube. Also note that the support members 381 and 382 hold a tube off center from an axis of the screw 385, which is easily seen in Fig. 56C. Holding the tube off-center from the screw's 385 axis facilitates free movement of the tube.

[00422] Figs. 57A-57C show several views of a valve 390 having a ratchet 394 that engages a connecting member 393 of the valve 390 in accordance with an embodiment of the present disclosure, and Figs. 57D-57E show two exploded views of the valve 390 of Figs. 57A-57C. The ratchet 394 engages the connecting member 393 by interacting with a gear rack 397 disposed thereon. A finger 602 (see Figs. 57D and 57E) interacts with a gear rack 397 to provide the ratcheting action. That is, the finger 602 may hold the gear rack 397 against an engaging finger on a side opposite of the retaining finger 602. The valve 390 includes a support member 391 having an end coupled to the ratchet 394 and another end pivotally coupled to a hinge 395. The valve 390 also includes a support member 392 having hooks 398 that can couple to the body of the ratchet 394.

[00423] As shown in Fig. 57C, a tube 396 can be positioned between the support members 391 and 392, the hooks 398 can then be fastened to the body of the ratchet 394, and the connecting member 393 can be inserted into the ratchet 394 (as shown in Fig. 57B). As shown in Fig. 57C, the tube 396 is positioned against the support member 391 via openings 399 and 400.

[00424] The ratchet 394 engages the gear rack 397 such that the ratchet 394 can be manually moved toward the hinge 395 for course fluid flow adjustments. Thereafter, a knob (not shown) may be coupled to the ratchet 394 to make fine adjustments to the distance between the ratchet 394 and the hinge 395. Additionally or alternatively, the ratchet 394 may include a release button (not shown) to release the ratchet from the connecting member 393.

[00425] Figs. 58A-58D show several views of a valve 401 having two elongated support members 403 and 404, a connecting member 405, and a screw-type actuator 407 in accordance with another embodiment of the present disclosure.

[00426] The support members 403 and 404 may be permanently molded together at their ends with the ends of the connecting member 405. A tube 402 may be positioned between the support members 403 and 404.

[00427] As the knob 408 is turned, the screw-type actuator 407 expands or contracts because of engagement with a threaded rod 406. Fig. 58A shows the valve in an open position while Fig. 58B shows the valve in a closed position. Note that the tube 402 is squeezed along a substantial length of the tube 402. Figs. 58C-58D show the valve 401 in the open position and the closed position, respectively, from a perspective view.

[00428] Figs. 59A-59C show several views of a body 501 of a valve 500 (see Fig. 59H for the assembled valve 500) in accordance with an embodiment of the present disclosure. The body 501 includes a first curved, elongated support member 502 and a second curved, elongated support member 503. The first support member 502 includes raised holes 504, 505 to hold a tube between the support members 502 and 503.

[00429] The body 501 also includes a first connector 506 that is coupled to the support members 503, 504 at an end, and a second connector 507 that is coupled to the other ends of the support members 503, 504.

[00430] The first connector 506 is coupled to an end of the support members 503, 504 and to a first end 508 of a connecting member 509. The second connector 507 includes a hole 510 for positioning the second end 511 of the connector member 509 therethrough (as is easily seen in Fig. 59B).

[00431] When a tube is positioned between the support members 502, 503, movement of the second connector 507 toward the first connector 506 compresses the tube disposed between the support members 502, 503. As the second connector 507 moves towards the first connector, the hole 510 of the second connector 507 allows the second end 511 of the connector member 509 to freely slide therein.

[00432] Figs. 59D-59G show several views of a knob 512 for use with the body 501 shown in Figs. 59A-59C in accordance with an embodiment of the present disclosure. The knob 512 includes a ratchet 513 defined by four fingers 514. Each of the fingers 514 includes a threaded surface 515 to engage a threaded connecting member 509. The fingers 514 are arched toward a hole

516 at the center of the knob 512. The knob 512 also includes fingers 517 that engage the second connector 507 (see Fig. 59H). In some embodiments, the body 501 includes a recess 510 to receive the fingers 517 on the second connector 508.

[00433] Fig. 59H shows an assembly valve 500 that includes the body 501 shown in Figs. 59A-59C coupled to the knob 512 of Figs. 59D-59G in accordance with an embodiment of the present disclosure. The knob 512 is slid onto the threads of the connecting member 509. The fingers 514 engage the threads of the connecting member 509 and ratchet onto the connecting member 509. That is, the knob 512 is freely moveable towards the first end 508 of the connecting member 509 along the threads of the connecting member 509, but cannot be moved away from the first end 508 of the connecting member 509 without rotating the knob 512. That is, the knob 512 may be placed onto the connecting member 509 to provide a coarse adjustment of the valve 500 by coarsely moving the connectors 507, 508 toward each other to close the valve 500. Because the threaded surfaces 515 of the four fingers 514 engage the threads of the connecting member 509, rotation of the knob 512 either reduces or increases fluid flow within a tube. Each of the fingers 514 includes a threaded surface 515 to engage the threads of the connecting member 509 such that rotation of the knob 512 moves the second connector 507 toward or away from the first connector 506 to thereby control the flow of fluid of a tube positioned between the support members 502, 503.

[00434] Fig. 60 shows a valve 520 having a guiding protrusion 521 in accordance with an embodiment of the present disclosure. The valve 520 is

similar to the valve 500 of Fig. 59H, but includes the guiding protrusion 521 and a knob 522 having first and second collars 523, 524. The knob 522 also includes internal threads (not shown) to engage threads 525 of a connecting rod 526. In some embodiments, the internal threads may be ratcheting, and in other embodiments, the internal threads may be fixed without providing a ratcheting action.

[00435] Fig. 61 shows a motor 536 and a valve-securing structure 537 for coupling to the valve 520 of Fig. 60 in accordance with an embodiment of the present disclosure. The valve-securing structure 537 includes securing fingers 528, 529, 530, 531 each having a curved portion 533 for snapping onto collars 523, 524 of a knob 522 (see Fig. 62) into respective collar-guiding portions 534.

[00436] Referring now to Figs. 60, 61, and 62, once the collars 523, 524 are sufficiently secured, the knob 522 is free to rotate. That is, the collar 523 may be secured between the securing fingers 528 and 530 within their respective collar-guiding portion 534 allowing the knob 522 to rotate. Likewise, the collar 524 may be secured between the securing fingers 529 and 531 within their respective collar-guiding portion 534 allowing the knob 522 to rotate.

[00437] When the valve 520 is secured to the valve-securing structure 537, rotation of the wheel 1537 (caused by the motor 536) rotates the knob 522 of the valve 520. As the valve 520 flexes, the protrusion 521 freely moves within the protrusion guide 535 or adjacent to the protrusion guide 535. Fig. 62 shows the valve of Fig. 60 secured to the motor 536 via the valve-securing structure 537.

[00438] Fig. 63 shows another motor 538 and valve-securing structure 539 for coupling to the valve of Fig. 60 in accordance with an embodiment of the present disclosure. The valve-securing structure 539 includes a protrusion guide 540 adjacent to the motor 538. The motor 538 is coupled to the wheel 541 to engage the knob 522 (see Fig. 60).

[00439] Fig. 64A shows a valve 542 having a slidable collar 545 and several compressing fingers 544 for regulating fluid flow through a fluid line 543 in accordance with an embodiment of the present disclosure. The base 546 is connected to all of the fingers 544. As the slidable collar 545 is moved over the compressing fingers 544, the compressing fingers 544 compress the tube 543 to impede fluid flow therewithin.

[00440] The fingers 544 are coupled to a base 546 such that the base 546 and fingers 544 surround the tube 543. The collar 545 is slidable away from the base 546 such that the fingers 544 compress the tube 543 which thereby reduces an internal volume of the tube 543 as the collar is moved. The reduction of the internal volume of the tube 543 reduces the fluid flow through the tube. An actuator (not shown) may be coupled to the collar 545 to control the position of the collar 545 (e.g., a linear actuator may be coupled to the collar 545 and to the base 546). Fig. 64B shows a cross-sectional view of the valve 542 of Fig. 64A. Note that the fingers 544 may be shaped away from the tube near an opposite end of the base

[00441] Fig. 65 shows a valve 547 having two curved surfaces 549 and 550 for positioning a fluid tube 548 therebetween to regulate fluid flow through the fluid tube 548 in accordance with an embodiment of the present disclosure.

As the surfaces 549, 550 are compressed together, the tube 548 is compressed therebetween. The two curved surfaces 549 and 550 may be compressed together using an actuator. The tube 548 may be wrapped several times around the surface 549.

[00442] Figs. 66A-66G show several views of a valve 551 having a knob 552 to move a connecting member 553, which is locked into position after movement of the knob 552, in accordance with an embodiment of the present disclosure.

[00443] The valve 551 includes an inner curved, elongated support member 554 and an outer curved, elongated support member 556. A knob 552 is pivotally coupled to the outer support member 556 via a pin 578. A connecting member 553 engages teeth 576 of the knob 552.

[00444] The connecting member 553 may be inserted into a hole of an end 555 of the support member 556 such that rotation of the knob 552 frictionally locks an engaging finger 700 (see Fig. 66G) into the gear rack 558 of the connecting member 553. The engaging finger 700 may engage the teeth 576 to lock the knob 552 to thereby prevent rotation of the knob 552 unless sufficient torque overcomes the locking action of the engaging finger 700. A retaining finger 577 is positioned on the other side of the hole 571 to press the connecting member 552 against the teeth 576 of the knob 552.

[00445] The inner support member 554 can pivot out away from the outer support member 556 such that a tube can be loaded via raised portions 559 and 560 (see Fig. 66C) . The inner support member 554 pivots away from the outer support member 556 via dog bone linkers 561, 562, 701, and 702 as

shown in Fig. 66C. Thereafter, the inner support member 554 pivots back towards the support member 556 as shown in Fig. 66D. The connecting member 553 is then inserted into an end 555 of the outer support member 556 (a close up of the insertion is shown in Fig. 66E) that includes the engaging finger 700 that locks onto the teeth 576 of the knob 552 which temporarily immobilizes the connecting member 553 (see fig. 66G). The other end 581 of the connecting member 553 is locked into a hole 582 of an end 557 of the support member 556. The connecting member 553 may be pivotally connected to the end 557. The knob 552 includes teeth 576 to move the connecting member 553 in or out of the end 555. However, when the knob 552 is not moved, the engaging finger 700 locks the movement of the knob 552 unless a predetermined amount of torque clicks the finger 700 to the next tooth of the teeth 576 of the inner portion of the knob 552.

[00446] As previously mentioned, the support member 554 can swing away from the outer support member 556 as is shown in Fig. 66C, which is facilitated by the dog bone linkers 561, 562, 701, and 702. The dog bone linker 561 includes a pivot hole 572 that couples to a pivot 563 and a pivot hole 573 that couples to a pivot 565. The dog bone linker 562 includes a pivot hole 575 that couples to a pivot 566 and a pivot hole 574 that coupled to a pivot 566. The dog bone linker 701 couples to pivots 567 and 570, and the dog bone linker 702 couples to pivots 568 and 569 so that the end of the support member 556 also swings away from the inner support member 554.

[00447] Fig. 67 shows a graphic 408 that illustrates actuation vs. flow rates for a valve in accordance with an embodiment of the present disclosure. The

graphic 408 shows the operation of a valve having elongated support members, such as, for example, the valve 340 of Figs. 49 and 50A-50B, the valve 352 of Figs. 51A-54, the valve 369 of Fig. 55, the valve 380 of Figs. 56A-56C, the valve 380 of Figs. 57A-57E, the valve 401 of Figs. 58A-58D, the valve 500 of Fig. 59H, the valve 520 of Figs. 60-60, the valve 542 of Figs. 64A-64B, the valve 547 of Fig. 65, and/or the valve 551 of Figs. 66A-66G . The x-axis of the graphic 408 shows the displacement between the ends of the support members of the valve, and the y-axis shows the flow rate (e.g., caused by gravity and/or a pressure source). The response of the valve is a nonlinear function, such as an S-curve, a sigmoid curve, a Gompertz curve, or a generalized logistic function. These functions may be adjusted to match the valve and/or the valve may be adjusted to match one of the curves or functions.

[00448] Fig. 68A shows a flow meter 703 that uses binary optics 705 in accordance with an embodiment of the present disclosure. The flow meter 703 includes a camera 355 that captures one or more images to estimate a flow rate of fluid through a drip chamber 357 using any sufficient method, e.g., the methods disclosed herein. The flow meter 703 includes a laser 704 that directs a laser beam onto a binary-optics assembly 705. The binary-optics assembly 705 thereafter redirects and reforms the laser beam through the drip chamber 357 and onto the image sensor 355 such that the image sensor 355 sees a pattern, e.g., the array of lines 85 shown in Fig. 8 which may form stripes as shown in the background pattern 89 of Fig. 10. The binary-optics assembly 705 may form the stripes by using a plurality of ovals.

[00449] The image sensor 355 may include a filter to filter out all frequencies except for the frequency of the laser 704. For example, the image sensor 355 may include an optical, band-pass filter that has a center frequency equal to (or about equal to) the optical frequency (or center frequency of the optical frequency) of the laser 704.

[00450] The monitoring client 358 may be electrically coupled to the laser 704 to modulate the laser 704. For example, the monitoring client 358 may turn on the laser 704 only when predetermined pixels are being exposed and may turn off the laser 704 when other pixels besides the predetermined pixels are being exposed.

[00451] The flow meter 703 optionally includes a first electrode 800 and a second electrode 801. The monitoring client 358 may be electrically coupled to the first and second electrodes 800, 801 to measure a capacitance defined therebetween. In streaming conditions, the capacitance changes because the relative permittivity is different for air and water. The monitoring client 358 may monitor the changes that results from a streaming condition with the drip chamber 357 by monitoring the capacitance between the first and second electrodes 800, 801 and correlate increases and/or decreases of the capacitance beyond a threshold as corresponding to either a streaming condition and/or a non-streaming condition. For example, if the capacitance between the first and second electrodes 800, 801 is higher than a threshold, a processer within the monitoring client 358 may determine that the drip chamber 357 is undergoing a streaming condition.

[00452] In an alternative embodiment, the first and second electrodes 800, 801 are loop antennas. The monitoring client 358 uses a transceiver to monitor the magnetic coupling between the loop antennas 800, 801. For example, the transceiver may transmit a coded message from one loop antenna of the antennas 800, 801, to another one of the loop antennas 800, 801 and then determine if the coded message was successfully received. If so, then a received signal strength indication ("RSSI") measurement may be made from the transceiver. See Fig. 68B for an exemplary circuit. The RSSI may be used to monitor the magnetic coupling between the antennas 800, 801. If the magnetic coupling is above a threshold, then the monitoring client 358 may determine that a streaming condition exists within the drip chamber 357. In some embodiments a change of magnetic coupling or a change of capacitive coupling may be determined to be an indication that a streaming condition has occurred .

[00453] The flow meter 703 may also include a safety valve 706. Figs. 69A-69F show several views of the safety valve 706 that may be used with a flow meter, such as the flow meter 703 of Fig. 68, in accordance with an embodiment of the present disclosure.

[00454] Figs. 69A-69B show exploded views of a safety valve 706. The safety valve may also be referred to as a safety cutoff in this application. The safety valve 706 includes a solenoid 707, an interface structure 708, a tube housing 709, a spring 720, a faceplate 712, a first axle 713, a second axle 714, a first occluding arm 710, and a second occluding arm 711. The faceplate 712

includes a hole 715, and the tube housing 709 also includes a hole 819. The holes 715, 819 allow the axle 713 to slide within the holes 715, 819.

[00455] Referring to Fig. 69C, a tube may be placed in location 820 within the tube housing 709 which places the tube in the location 820 next to the first and second occluding arms 710, 711, which are easily seen in Fig. 69D. A spring 720 keeps the first and second occluding arms 710, 711 retracted when in the retracted state (as shown in Fig. 69D), but stores energy such that a predetermined amount of movement of the first and second occluding arms 710, 711 towards the tube 810 causes the spring 720 to discharge its stored mechanical energy to cause the first and second occluding arms 710, 711 to extend out and occlude the tube in location 820.

[00456] The spring may be connected to the first and second axles 713, 714. The spring 720 pulls the first and second axles 713, 714 toward each other. The first and second occluding arms 710, 711 are pivotally connected together. Because the first and second occluding arms 710 and 711 are pivotally together at a pivot point that is off center from the axles 713, 714, the spring 720 pulling on the axles 713, 714 toward each other will remain stable in the retracted states (as shown in Fig. 69D) until the solenoid 707 causes the arms 710, 711 to extend outwards beyond a predetermined amount. As is easily seen in Fig. 69E, a shaft 718 of a solenoid 707 can actuate through a hole 719 to push on the arms 710, 711 which causes the spring 720 to release its energy and occlude the tube in location 820 (see Fig. 69F for the case when the where the first and second occluding arms 710, 711 are in the occluding position).

[00457] Referring to Fig. 69G, in some embodiments, a current responsive material 717 may be coupled to the solenoid 707. The current responsive material 717 may be configured to the solenoid such that the solenoid may engage the first occluding arm 710 and the second occluding arm 711 when the current responsive material 717 changes shape due to exposure to a change in current. When the current responsive material 717 is exposed to a change in current, the current responsive material 717 will apply force to the solenoid 707. Thereafter, the solenoid 707 may apply force to the trigger mechanism to release the occluding arms.

[00458] In another embodiment, as shown in Fig 69H, the first and second occluding arms may be retained by magnetic force. In some embodiments, first and second magnets 722, 723 may be oriented with opposite magnetic poles aligned (e.g. north and south poles). The arms 710, 711 may be held in the retracted states using this attractive magnetic force. One of the two magnets may be rotated such that the magnets are reoriented so that the first and second magnets are oriented with like magnetic poles aligned (e.g. north and north poles or south and south poles). The like pole alignment causes the magnets to repel one another. The magnetic repelling force may be used to cause the arms 710, 711 to extend outwards. In other embodiments, a permanent magnet 724 may be placed within a coil 725, as shown in Fig. 69I. In these embodiments, the arms 710, 711 may be retained in the retracted state using the magnetic force created by the magnet 724 and coil 725. The magnetic force may be overcome by using a solenoid or some other element, causing the arms 710, 711 to be engaged and extend outward beyond a predetermined

amount. Fig. 70 shows a flow chart diagram illustrating a method 728 of estimating drop growth and/or flow within a drip chamber in accordance with an embodiment of the present disclosure. The method 728 includes acts 729-735. Figs. 71A-71E show images taken by a flow meter with a template overlaid therein to illustrate the method of Fig. 70. Note that the template 727 is sued to determine a position of the edge of the drop in the X and Y dimensions.

[00459] Act 729 captures an image of a drip chamber. The image captured may be the image 721 of Fig. 71A. Act 730 positions a template within the captured image to a first position. For example, as shown in Fig. 71A, a template 727 may be positioned within a predetermined position. Act 731 averages all of the pixels within the template 727. Act 732 moves the template to a second position. For example, the template 727 in Fig. 71A may move the template in the Y direction (e.g., down as seen in Fig. 71A).

[00460] In act 733, the pixels within the template are used to determine a second average. In act 734, if a difference between the second average and the first average is greater than a predetermined threshold value, determine that the template is located at an edge of a drop. For example, referring to Fig. 71A, the template may be slowly lowered down in the Y direction, until the template 727 transitions from the edge of a drop to a portion of the image that doesn't contain the drop, in which case the average value of the pixels will transition abruptly to a dark average to a lighter average. When this transition occurs, the Y position of the template 727 is considered to be at the edge of the drop (e.g., Y_1 of Fig. 71A). In act 735, the second position of the drop is correlated with a volume of the drop. For example, the Y_1 value may be associated with a

volume of a drop in a lookup table. In some embodiments of the present disclosure, multiple movements of the template 727 are needed to until the edge of the drop is detected. For example, the template 727 may be moved in the y-direction one pixel at a time (or several pixels at a time) and several template 727 movements may be needed such that the edge of the drop is detected. By monitoring the edge of the drop, the growth of the drop may be controlled by the flow meter to achieve a target flow rate (e.g., the rate of the transition between Y1 of Fig. 71A to Y2 of Fig. 71B may be controlled by a PID control loop within a flow meter). Fig. 71B shows a location, Y_2, that corresponds to a growth in the drop relative to the location, Y_1, of Fig. 71A. Figs. 72C-73E show how the sequential growth of a drop may be monitored.

[00461] Fig. 72 shows a modulateable backlight assembly 740 in accordance with an embodiment of the present disclosure. The assembly 740 may be the backlight 18 of Fig. 1 or may be used as a backlight for any sufficient flow meter disclosed herein. The assembly 740 includes a first circuit board 738, a second circuit board 739, a first backlight diffuser 736, and a second backlight diffuser 737.

[00462] The first circuit board 738 includes embedded light sources 822 that extend along the interface between the first backlight diffuser 736 and the first circuit board 738. The embedded light sources 822 shine light into the first backlight diffuser 736 which is directed outwards as indicated by 821. The light 821 may be directed towards an image sensor. The first backlight diffuser 736 only diffuses light with no “pattern” formed when viewed by an image sensor.

[00463] The second circuit board 739 includes embedded lights 823 which are shined into the second backlight diffuser 737. The second backlight diffuser 737 creates a pattern of stripes that shows up in the light 821 when viewed by an image sensor. Therefore, a monitoring client (e.g., the monitoring client 358 of Fig. 51A) and/or a flow meter (e.g., the flow meter 7 of Fig. 1) can select between a striped background pattern (by activating the embedded lights 823) and a non-striped background pattern (by activating the embedded lights 822).

[00464] For example, referring now to Figs. 1 and 72, the flow meter 7 may use the backlight assembly 740 in some specific embodiments; The flow meter 7 may use a non-striped backlight pattern (by activating the embedded LEDs 822 without activating the embedded LEDs 823) to monitor the growth of drops and may switch to a striped background pattern (by activating the embedded LEDs 823 without activating the embedded LEDs 822) to detect streaming conditions.

[00465] Figs. 73A-73C show several views of a tube-restoring apparatus 741 in accordance with an embodiment of the present disclosure. The apparatus 741 includes a drive gear 744 that is coupled to a first restoring gear 742. The first restoring gear 742 is mechanically coupled to a second restoring gear 743. A tube may be placed between the first and second restoring gears 742, 743. Portions of the first and second restoring gears 742, 743 define a space 745 in which a tube may be positioned. Rotation of the first and second restoring gears 742, 743 closes the distance between the space 745 when the tube is positioned between the first and second restoring gears 742, 743. The transition from a non-restoring position to a restoring position is shown in Fig.

73B to Fig. 73C. For example, a tube may be positioned such that an occluder presses against the tube from the bottom up (as shown in Fig. 73B). If the tube becomes distorted over time, a motor connected to the driving gear 744 rotates the gears 743 and 744, to press against the walls of the tube (as shown in Fig. 73C) to restore the tube such that a cross-section of the tube has a general circular shape by compressing on the wall portions of the tube that are expanded beyond a center axis of the tube such that the tube is distorted into an oval shape, for example.

[00466] Fig. 74 shows a system for regulating fluid flow 746 using a valve 747 having two flexible strips 753 and 754 (see Fig. 75); And Fig. 75 shows the valve 746 of Fig. 74 in accordance with an embodiment of the present disclosure. Optionally, a motor may be attached to the valve 746 for control by a flow meter in one embodiment.

[00467] As shown in Fig. 75, the valve 747 includes two flexible strips 753, 754 in which a tube may be disposed therebetween, a guiding shaft 752, two guidable members 749, 750, a screw 791, and a knob 748.

[00468] When the knob 748 is turned, the screw 791 rotates. Rotation of the screw 791 pulls the distal guiding member 750 toward the proximal guiding member 749 (because the distal guiding member 750 includes internal threads and the screw 791 spins freely within the proximal guiding member 749). The guide 752 guides the movement of the distal guiding member 750. The guide 752 is coupled to the proximal guiding member 749.

[00469] Fig. 76A shows a valve 755 that utilizes a fluid-based bladder 758 in accordance with an embodiment of the present disclosure. The valve 755

includes two clamshells 756, 757, a bladder 758, and a piston 759. The piston 759 may be any fluid source. The bladder 758 may be placed within a cavity 764 and a tube may be placed across the bladder 758 and positioned within the throughways 760 and 761. Thereafter, the clamshell 757 may be placed over the bladder 758 such that the cavity 765 is placed over the bladder 758. The two clamshells 756, 757 may then be ultrasonically welded together, temporarily compressed together, and/or sufficiently held together. Thereafter, an actuator (e.g., an actuator controlled by a flow meter disclosed herein) may be actuated to move fluid in and out of the bladder 758 via the piston 759.

[00470] Fig. 76B shows a cross-sectional view of the assembled valve 755 of Fig. 76A with two elastomeric fillers 1002, 1004 in accordance with an embodiment of the present disclosure. The elastomeric fillers 1002, 1004 help hold the tube 1000 into position and help restore the tube 1000 when the bladder 758 is deflated.

[00471] Fig. 77 shows a system 766 for regulating fluid flow using a valve 769 having two flexible strips 771, 772 (see Fig. 79) actuateable by a linear actuator 822 in accordance with an embodiment of the present disclosure. Fig. 78 shows the linear actuator 822 actuating the valve 769 to impeded fluid flow through a tube 775. The valve 769 is coupled to two couplers 767 and 768. The proximal coupler 768 moves with the linear actuator 822 while the distal coupler 767 is fixed relative to a non-moving end of the linear actuator 822.

[00472] Fig. 79 shows a close-up of the valve 769 of Figs. 77-78. The valve 769 includes two strips 771, 772 (which may be metallic strips) in which the tube 775 may be disposed. The two strips 771, 772 of the valve 769 may

be coupled to a first end structure 773 and a second end structure 774. The first end structure 773 may be coupled to the distal coupler 767 and the second end structure 774 may be coupled to the proximal coupler proximal coupler 768 (see Figs. 77-78). A string 770 or membrane may be wrapped around the tube 775 such that, when the strips 771, 772 are straightened out, the string 770 presses against the side walls of the tube 775 to help round the tube 775. The membrane may be a flexible, but not stretchable, material (or minimally stretchable material). Fig. 80 shows a close-up of the valve as actuated in Fig. 78. Note the holes 776 and 778 that the string 770 is threaded through. The string 770 (which may metallic) is spiraled around the tube 775 such that when the valve 769 opens, the string 770 restores the tube 775.

[00473] Fig. 81 shows several images for use to illustrate a method of estimating drop growth and/or fluid flow illustrated in Figs. 82A-82B in accordance with an embodiment of the present disclosure. Fig. 81 shows images 771-777 which are referred to below regarding Figs. 82A-82B.

[00474] Figs. 82A-82B show a flow chart diagram illustrating a method 803 of estimating drop growth and/or fluid flow. The method 803 includes acts 804-818.

[00475] Act 804 captures a first image (e.g., image 771 of Fig. 81). The first image may be a grey scale image of the drip chamber. The drip chamber may be uniformly lit with a striped pattern on the bottom of the chamber (i.e., there is no back pattern on the top portion of the drip chamber).

[00476] Act 805 creates a first thresholded image using the first image. The first thresholded image may be the image 774 of Fig. 81. The first

thresholded image may be made by comparing each pixel from the first image to a threshold value (e.g., setting a respective pixel of the thresolded image to 0 if the respective pixel of the first image is above the threshold or setting a respective pixel of the thresholded image to 1 if the respective pixel of the first image is below the threshold). This act is to highlight areas where there is water in front of the background.

[00477] In some specific embodiments, the threshold level is updated every time a new image is taken to ensure a predetermined ratio of 1 to 0 pixels is maintained to highlight the drop. The ratio may be updated for use by act 805 when used again or the update may adjust the threshold until a predetermined ratio of 1 to 0 pixels is made and then use the first thresholded image for the rest of the method 803.

[00478] Act 806 determines a set of pixels within the first thresholded image connected to a predetermined set of pixels within the first thresholded image. The predetermined set of pixels may be determined by fiducials marked on the drip chamber or an opening in which drops are formed. The predetermined set of pixels may be a predetermined set of x, y values that correspond to pixels. Act 806 may use a connected component image analysis algorithm.

[00479] Act 807 filters all remaining pixels of the first thresholded image that are not within the set of pixels. The filter operates on a pixel-by-pixel basis within the time domain to generate a first filtered image. The first filtered image is an estimate of a non-active (e.g., a result from features not of interest in the

image) portion of the first thresholded image (image 774 of Fig. 81). The filter may be any filter, e.g., any filter described herein.

[00480] Act 808 removes pixels determined to not be part of a drop from the first thresholded image using the first filtered image to generate a second image (e.g., image 775 of Fig. 81). A pixel within the second image will be set to 1 if a respective pixel in the first thresholded image is 1 and a respective pixel in the first filtered image is less than 0.5; otherwise, the pixel will be set to 0.

[00481] Act 809 determines a second set of pixels within the second image connected to a predetermined set of pixels within the second image to generate a third image (e.g., the image 776 of Fig. 81). The third image identifies the second set of pixels within the second image. Act 809 finds the set of "lit" pixels in the second image connected to the predetermined set of pixels (e.g., pixels representing the opening in which drops are formed).

[00482] Act 810 determines a first length of the drop by counting the number of rows containing pixels corresponding to the second set of pixels within the third image. That is, the drop length is determined to be equal to the last "lit" row in the set of pixels found in Act 809. The first length corresponds to a first estimated drop size.

[00483] Act 811 updates a background image using the first image. A low-pass filter may be used to update each pixel's value in the background image. An infinite impulse response filter may be used to update the background image using the first image. A pixel is only updated in the background image for rows below the first length plus a predetermined safety zone. A pixel in the

background image is updated by low pass filtering the value from the corresponding pixel in the first image.

[00484] Act 812 creates a second thresholded image (e.g., image 772 of Fig. 81) by comparing the first image with the background image. That is, the first image has the background image subtracted from it, and on a pixel-by-pixel basis, the absolute value of each pixel is set to 1 if it is above a second threshold value and is set to a 0 if it is below the second threshold value to generate the second thresholded image.

[00485] Act 813 sums the rows of the second thresholded image to create a plurality of row sums (see image 773 of Fig. 81). Each row sum corresponds to a row of the second thresholded image.

[00486] Act 814 starts at a row position of the second thresholded image having a first sum of the plurality of sums that corresponds to the first length. The row position is incremented in act 815. Act 816 determines whether the present row position correspond to a corresponding row sum that is below a threshold, e.g., zero. If no, then act 815 is preformed again until the present row position corresponds to a corresponding row sum that is zero and then the method 803 proceeds to act 817.

[00487] Act 817 determines a second length is equal to the present row position. The second length corresponding to a second estimated drop size. Act 818 averages the first and second lengths to determine a average length. The average length corresponding to a third estimated drop size. By using the first and second lengths to determine an average length, the effects of condensation on the inner walls of the drip chamber are mitigated. That is, the

purpose of creating two estimates of drop length is to compensate for how each length is affected by the presence of condensation. The first length tends to underestimate drop length if a drop of condensation intersects the growing drop from the spigot. The second length tends to overestimates the drop length if the drop of condensation intersects the growing drop from the spigot. Their average provides a better estimate when condensation is present. In the absence of condensation, the estimates are almost equal. In other embodiments, only either the first or second length is used to estimate the drop size.

[00488] Fig. 83 shows a flow chart diagram of a method 900 for reducing noise from condensation in accordance with an embodiment of the present disclosure. Method 900 includes acts 902-910.

[00489] Act 902 captures an image of a drip chamber. Act 904 performs a canny, edge-detection operation on the image to generate a first processed image. Act 906 performs an AND-operation on a pixel on a first side of an axis of the first processed image with a corresponding mirror pixel on the second side of the axis of the first processed image. That is, Act 902 defines an axis in the first process image, and performs an AND on each pixel on one side with a pixel on the other side, such that the pixel on the other side is symmetrical with the pixel on first side. For example, a 40 (X-axis) by 40 (Y-axis) image may have an axis defined between pixel columns 19 and 20. The top, left pixel would be pixel (1,1) A pixel at location (1, 5) would be AND-ed with a pixel at (40,5). The resulting pixel would be used for both locations (1, 5) and (40,5) to generate the second processed image.

[00490] After act 906 is performed, act 908 determines whether all of the pixels have been processed. Act 908 repeats act 906 until all pixels have been processed. Act 910 provides a second processed image that is the results of all of the AND operations.

[00491] Fig. 84 shows another valve 2000 for use with a flow meter in accordance with an embodiment of the present disclosure. The valve 2000 is coupled to a portion of an inlet fluid line 2001 and a portion of an outlet fluid line 2002. A section of flexible tube 2003 is coupled between the portion of an inlet fluid line 2001 and a portion of an outlet fluid line 2002 within a rigid cylinder 2004. A fluid pump 2005 is coupled to the rigid cylinder 2004 to pump fluid into and out of the rigid cylinder 2004. The rigid cylinder 2004 may include a fluid disposed therein, e.g., a liquid.

[00492] An actuator 2007 controls a plunger 2008 of the pump 2005 to use the fluid within the rigid cylinder 2004 to compress the flexible tube section 2003 to control the flow of fluid between the portion of an inlet fluid line 2001 and a portion of an outlet fluid line 2002. The actuator 2007 may be controlled by a processor (e.g., the processor 15 of Fig. 1). By collapsing the flexible tube section 2003, flow of fluid flowing within the flexible tube section 2003 may be controlled by actuation of the actuator 2007.

[00493] Figs. 85A-85C show another valve **8500** for use with a flow meter in accordance with an embodiment of the present disclosure. This embodiment uses a plunger **8512** and a substantially incompressible filler **8621** (the filler was left out of Figs. 85A-85C for clarity and is shown in Fig 86) to deform a flexible tube in which flow is being controlled. The flexible tube may be an IV tube and

may be disposed thorough holes 8518 (see Fig. 85B) on the first clamshell portion 8504 and/or the second clamshell portion 8502. The substantially incompressible filler **8621** (see Fig. 86) is contained within a rigid casing comprising a first clamshell portion **8504** and a second clamshell portion **8502**. The first clamshell portion **8504** and second clamshell portion **8502** are connected by a hinge **8505** that allows a user to open the casing to insert and remove a flexible tube in which fluid flow is being controlled therethrough by the valve 8500. The plunger **8512** engages the substantially incompressible filler **8621** through a hole **8511** in the first clamshell portion **8504**, ultimately deforming the tube.

[00494] The first clamshell portion **8504** and second clamshell portion **8502** are secured in a closed position by a latch (8503, 8506) once the flexible tube is positioned in the housing. The latch comprises a male component **8503** on the second clamshell portion **8502** and a female component **8506** on the first clamshell portion **8504**. The male component **8503** extends out from second clamshell portion **8502** on the side opposite the pivot as multiple fingers. The female component **8506** is a lever with an input end **8506a** and an output end **8506b**. The latch secures the clamshell 8502, 8504 closed by positioning the output end **8506b** of the female component **8506** over the male component **8503,** and rotating the female component **8506** onto the top of the second clamshell portion 8502 as depicted in Fig 85B. The connecting members 8501 connect the female portion **8506** to the first clamshell portion 8504 such that when the female component of the latch is rotated closed, the output end **8506b** of the female component's 8506 rounded edge (i.e., the output end 8506b is a

rounded edge) compresses against the male component 8503 of the latch 8503, 8506. This feature creates a force on the male component **8503** when the female portion **8506** is rotated, which squeezes the first clamshell portion **8504** and second clamshell portion **8502** together.

[00495] The plunger **8512** is guided into the first clamshell portion 8504 by a guide **8508** attached to the first clamshell portion 8504 and is powered by a linear actuator **8510**. The guide **8510** aligns the plunger **8512** with the hole **8511** in the first clamshell portion 8504. The actuator **8510** is attached to the guide **8508** on an end of the guide 8508 that is opposite to the end of the guide 8508 attached to the first clamshell portion 8504.

[00496] Fig. 85C shows a portion of the valve 8500 with parts removed for clarity. As shown in Fig. 85C, the plunger **8512** is connected to the output shaft **8520** on the actuator **8510** which drives the plunger **8512** in and out of the first clamshell portion 8504. Springs **8516** are placed in-between the plunger stabilizing arms **8514** and the actuator **8510** to urge the plunger **8512** away from the actuator **8510**. The springs 8516 help counter act the force put on the plunger by the filler 8621 (see Fig. 86) allowing an actuator 8510 that exerts less peak force.

[00497] In some embodiments of the present disclosure, the plunger head **8512a** has a smaller area than the longitudinal cross-section of the tube within the valve housing 8502, 8504. The smaller head 8512a results in a smaller change in pressure when compared to similar displacement with a larger head. In some embodiments, this may allow for more precise changes in tube deformation by the actuator **8510**.

[00498] The first clamshell portion **8504** and second clamshell portion **8502** have semicircular cutouts on the sides adjacent the hinged side to create the holes 8518 (see Fig. 85B). The cutouts are positioned to align when the casing is in the closed position, creating the hole **8518.** The hole **8518** allows a flexible tube (such as a PVC IV tube) to go through the closed rigid casing 8502, 8504 without being deformed.

[00499] Fig 86 shows a cross-sectional view of the valve housing with the substantially incompressible filler **8621** enclosed therein. The substantially incompressible filler **862 is** enclosed in the first and second clamshell portions 8502, 8504. The first layer **8628** and second layer **8626** lay within the first clamshell portion **8504**, while the third layer **8624** and fourth layer **8622** lay within the second clamshell portion **8502**. The second layer **8626** and third layer **8624** lay in the middle when the casing is closed and form a conduit **8618**, in which the tube is placed, to aid in consistent deformation of the tube. The conduit **8618** connects the holes **8618** defined by the closed clamshell portions 8502, 8504.

[00500] The materials used to make some flexible tubes may be susceptible to creep, which affects the tube's ability to rebound back to its original shape after multiple deformations. The second layer **8626** and third layer **8624** are stiffer than the first layer **8628** and fourth layer **8622** in order to consistently reform the tube when creep starts to affect the shape of the tube. The stiffer second layer **8626** and third layer **8624** are affected less by creep than the tube and will reform back to their original shape after many

deformations. Therefore, when the filler **8621** is trying to reform the original shape of the conduit 8618, it will reform the tube within the conduit.

[00501] Also, in some embodiments, the tube has a tendency to stick to its self when deformed to a point where the inner surfaces of the tube contact each other. This makes it difficult to control very low drip rates when the tube is almost completely closed. The stiff layers surrounding the tube **8624, 8626** apply forces sufficient to overpower the sticking forces, which thereby results in the tube opening uniformly.

[00502] The first layer **8528** and fourth layer **8522** fill the space between the second layer **8526** and third layer **8524**, and the clamshell portions **8502, 8504**. The second layer **8526** and the third layer **8524** are softer in order to spread the force of the plunger 8512 evenly throughout the whole section of tube within the clamshell portions **8602, 8504**. Instead of translating the force directly to the area of the tube immediately above the plunger 8512, the plunger 8512 increases the pressure in the clamshell portions 8602, 8504. This causes substantially uniform deformation of the enclosed section of the tube. Uniform deformation is advantageous because frictional forces between the liquid and the tube help with the valves flow rate precision. A longer deformed section imparts more frictional force on the liquid flowing through, slowing its flow rate. Extending the section of the tube being valved allows for a low flow rate with a larger, more manageable lumen diameter.

[00503] The soft layers 8622, 8628 preferably have a shore OO hardness from about 20 to about 25. The hard layers preferably have a shore A hardness

of about 15. In some embodiments, preferred materials for the filler include silicone, urethane, viton, or nitrile.

[00504] Figs. 87A-87D show a flow control apparatus **8700** in accordance with an embodiment of the present disclosure. The flow control apparatus **8700** includes an apparatus casing **8702** which encloses a valve **8732** and a safety cutoff **8734** (see Fig. 87B). As is easily seen in Fig. 87B, the casing **8702** includes a door **8702b** and a body **8702a**. A drip chamber holster **8714** having a top component **8714a** and a bottom component **8714b** is attached to the body 8702a and is configured to orient the drip chamber vertically. A laser **8708** and diffracting device **8716** are attached to the body 8702a of the casing 8702 and are aligned to diffract the laser light so it creates a pattern on a drip chamber loaded in the drip chamber holster **8714** (drip chamber not shown in fig 87). An image sensor **8710**, having the drip chamber and diffraction patterns in its field of view, is also attached to the apparatus casing 8702.

[00505] In some embodiments, the laser beam is first split by a beam splitter into first and second beams such that a first beam is directed toward an upper diffracting device 8716a and the second beam is directed toward a lower diffracting device 8716b. The beam splitter may be part of the laser beam exit lens.

[00506] The upper diffracting device 8716a directs its pattern at an upper section of the drip chamber and the lower diffracting device 8716b directs its pattern at a lower section of the drip chamber. The diffracting devices 8716a, 8716b may use, in some embodiments, binary-optic films to redirect and reform the laser beams into patterns. The upper film of the upper diffracting device

8716a converts the beam into an array of dots, or in some embodiments, a single dot. This creates the contrast for the image sensor **8710** to track the growth of the drop developing at the top of the drip chamber. The lower film of the lower diffracting device 8716b converts the beam into a pattern of horizontal stripes. The stripes create the contrast for the image sensor **8710** to determine if the fluid is streaming instead of dripping.

[00507] As is easily seen in Fig. 87B, this embodiment has a valve closing arm **8720** connected to the door **8702b** of the casing **8702** and to the input end **8722a** of the female latch component 8722. When the door **8702b** is opened, the closing arm **8720** pulls on the input end 8722a of the female latch component **8722** causing it to rotate up and away from the valve 8732. This releases the pressure put on the valve 8732 from the output end 8722b of the female latch component **8722**. Once the female latch component **8722** disengages the male latch component **8728**, the closing arm **8720** pulls open the valve casing clamshells **8732a, 8732b** by pulling the female latch component **8722** away from the valve **8732**. When the door **8702b** is completely open, the clamshells **8732a, 8732b** are open far enough for an operator to remove or insert a tube being valved into the valve 8732 (the open position is shown in Fig. 87B). Once a tube is placed in the valve 8732, an operator closes the door **8702b**. Closing the door **8702b** causes the closing arm **8720** to engage the female latch component 8722 such that the output end 8722b of the female latch component **8722** mates with the male latch component **8728** whereby further actuation rotates the female latch **8722** component into a secured position (similar to the position of the valve 8500 shown in Fig. 85B).

The closing arm **8720** adds efficiency to the process of rigging the apparatus **8700** and improves safety by insuring the valve **8732** is securely closed when the door **8702b** is closed.

[00508] The operator lays the tube through the safety cutoff **8734** (physical mechanics of the safety cutoff are described with regards to Fig 69) along with the valve **8732** when rigging the apparatus **8700** (refer to Fig 87C). The safety cutoff **8734** uses spring powered occluding arms **8739a, 8739b** to compress the tube into a backstop **8741** when triggered. A solenoid applies the force to trigger the mechanism and release the occluding arms **8739a, 8739b**. Once the occluding arms **8739a, 8739b** are released, they substantially cutoff flow through the tube, and ultimately to the patient, by compressing the tube against the back stop **8741**. The safety cutoff **8734** is triggered by a processor which uses a safety sensor to sense unplanned events. The unplanned events may include power loss, the apparatus 8700 falling over, the fluid streaming through the drip chamber, or the flow rate not properly correlating to the valve's 8732 position. The latter of these examples may address a situation where the tube is kinked at some point between the apparatus and the patient.

[00509] A safety cutoff resetting arm 8735 may be attached to the door 8702b and is configured to reset the safety cutoff valve 8734 to the free flow position by opening the door 8702b of the casing 8702. The safety cutoff valve 8734 used in this embodiment is similar to the valve described in Fig 69. However, in Fig. 87, the occluding arm **711 in Fig 69** is extended past the screw **714 of Fig 69** creating a tab projecting out of the bottom. The safety cutoff valve 8734 of Fig. 87B includes this tab **8740 as shown in Fig. 87C.**

[00510] Referring to Fig. 87C, the resetting arm 8735 includes three members 8736, 8738, 8742. A first member **8736** of the resetting arm 8735 is attached to the door **8702b** and to a second member **8738** of the resetting arm 8735. The second member **8738** of the resetting arm 8735 is attached to a third member **8742** of the resetting arm 8735. Opening the door **8702b** actuates the first member **8736,** which in turn actuates the second member **8738** and the third member **8742**. The third member **8742** has a projection configured to engage the tab **8740** and urge it back to the non-engaging parallel position (as shown in Fig 69D) when it engages the tab 8740. In additional embodiments, resetting the safety cutoff **8734** can be accomplished with less or more members if desired.

[00511] Fig 87D shows an embodiment of the present disclosure designed to stop fluid flow through the valved tube when the door **8702b** is in an open position. A compression tab **8744** may be used to substantially cutoff flow through the tube being valved when the apparatus casing door **8702b** is open. When installing a tube, an operator inserts the tube into the slit **8745** between the compression tab **8744** and the casing body **8702a**. When the door is open, the full force of the compression tab **8744** is exerted onto the tube, substantially cutting off flow by deforming the tube. When the door **8704b** is closed, a wedge **8746** attached to the door **8702b** is forced into the slit **8745** and wedges the compression tab **8744** open. Wedging open the tab **8744** allows the tube to reopen permitting fluid flow. This feature is used as a safety mechanism to make sure no liquid from the drip chamber is administered to the patient when an operator is rigging the apparatus.

[00512] Actuating the valve 8732 causes minor pressure changes in the apparatus casing **8702.** An array of holes **8748** may be defined in the apparatus casing body **8702a**. These holes allow the pressure inside the casing to equalize the pressure outside the casing 8702, which may increase accuracy in some embodiments.

[00513] Referring again to Fig. 87A, in some embodiments of the present disclosure, a status light **8718** may be used to visually display the status of the flow control apparatus 8700. The light **8718** is attached to the flow control apparatus 8700 at a location that can readily be seen by a nearby person. In some embodiments, the status light 8718 will emit a first color when the fluid is flowing and a second color when flow has stopped. In other embodiments, the status light 8718 will emit a first color when the flow control apparatus 8700 is operating properly, a second color when the flow control apparatus 8700 has detected a problem, and a third color when the flow control apparatus 8700 is paused. The status light 8718 may also be configured to flash ever time a drop falls in the drip chamber. This feature allows an operator to see the drip rate from a distance where it would not be possible to read the display 8704.

[00514] Certain embodiment of the present disclosure may use a battery as a power source. Other embodiments can us a combination of a battery and an AC wall adapter, or just and AC wall adapter.

[00515] In another embodiment of the present disclosure, the apparatus 8700 includes input buttons **8706** and a display **8704**. The input buttons **8706** can be used to control the flow of liquid through the drip chamber. This allows an operator to set the flow rate initially and adjust the flow rate when desired. In

other embodiments, input buttons **8706** may be configured to adjust any adjustable parameter of the apparatus 8700. The input buttons **8706** may be lit up in different colors to aid a user. For example, a green input button of the input buttons 8706 may be used to increase or decrease the flow rate, the a yellow button of the input buttons 8706 may be used to pause the flow, and a red button of the input buttons 8706 may be used to stop the flow of fluid. The display **8704** can display infusion information including the current flow rate and set flow rate, to inform an operator. The display **8704** may also display information regarding the patient, the device, or the fluid being delivered by the device. For example, the status of the batteries, any alarms, or the patient's identification sequence.

[00516] A processor may also be in communication with a status light **8718**. The processor may tell the status light **8718** to emit a first color when fluid is flowing and a second color when flow has stopped. The status light **8718** may also emit a first color light when the pump is operational and a second color light when a problem has been detected. The first color will likely be green and the second color will likely be red.

[00517] Certain embodiments may use an audio output device to communicate with an operator. For example, this device may signal an error, update an operator on the status of the pump, or guide an operator through a set up of the flow control apparatus 8700.

[00518] Referring now to Figs. 88A-88E: Fig. 88A shows a perspective view of a fluid flow apparatus 8800 used to control fluid flow through a drip chamber 8820 connected to a tube 8821, wherein the apparatus 8800 has the

casing door 8809b open; Fig. 88B shows a perspective view of only the valve 8801 from Fig. 88A; Fig. 88C shows the inner workings of the valve 8801 from Fig. 88B; Fig. 88D shows a simplified diagram illustrate the operation of the valve cutoff mechanism in a door 8809b closed position; and Fig 88E shows a simplified diagram to illustrate the valve cutoff mechanism in the door 8809b open position in accordance with an embodiment of the present disclosure.

[00519] The flow control apparatus 8800 impedes flow through a tube 8821 within the valve 8801 when the casing door **8809b** is open. The casing door 8809b is pivotally coupled to the casing body 8809a In this embodiment, the actuator **8802** and attached plunger **8816 (see Fig. 88c)** are connected to the valve 8801 by cutoff springs **8806** (see Fig. 88B) that urge the plunger **8816** into the filler disposed within the valve 8801 housing. The plunger **8816** is attached to the actuator **8802** by a threaded driveshaft **8812**, and, in some embodiments, is able to freely rotate on the drive shaft 8812. This allows the plunger **8816** to keep a constant orientation while the driveshaft **8812** rotates. A half-nut **8811** on the end of engaging member **8810** is operatively connected to the fluid flow apparatus 8800 such that the half-nut 8811 has the ability to engage and disengage the threaded driveshaft **8812** with the threads of the threaded half nut 8811.

[00520] When the apparatus casing door **8809b** (see Fig. 88A) is closed, the half-nut **8811** (see Fig. 88C) is engaged with the driveshaft **8812** to allow the actuator **8802** to control the position of the plunger **8816** by rotating the threaded driveshaft 8812. Opening the apparatus casing door **8809b** (see Fig. 88A) disengages the half-nut **8811** (see Figs. 88B-88C) from the drive shaft

8812 (by actuating the half nut 8811 away from the drive shaft), leaving only the cutoff springs **8806** to control the position of the plunger **8816**. The cutoff springs **8806** drive the plunger **8816** into the filler with enough force to substantially cutoff fluid flow through the tube 8821 coupled to the drip chamber 8820 (also see Fig. 88A). This mechanism may serve the same purpose as the compression tab described in Fig 87.

[00521] Figs. 88D-88E illustrate the mechanism that engages and disengages the half-nut **8811** with the threaded driveshaft **8812**. An engaging member **8810** has a half-nut **8811** at one end and pivotally connected to a pivoting member 8803 at the other end. The pivoting member **8803** is anchored by a hinge **8818** (coupled to the casing body 8809a) and is positioned to be engaged by an urging component **8805** connected to the casing door **8809b**. The urging component 8805 is coupled to the door 8809b (shown in Fig. 88A).

[00522] Fig 88D shows the position of the mechanism when the casing door **8809b** is closed. In this position, the urging component **8805** is not engaged with the pivoting member **8803**, leaving only the force of the spring 8814 to influence the position of the pivoting **8803** and connected engaging **8810** members. The spring 8814 biases the pivoting member 8803 to rotate in the counter clockwise direction, with respect to the view of in Fig. 88D. The rotational force translates to a force pushing on the engaging member **8810** into the threaded driveshaft **8812** due to the hinge **8818**.

[00523] Fig 88E shows the position of the mechanism when the casing door **8809b** is open. Opening the door **8809b** causes the urging component 8805 to rotate and engage the pivoting member **8803**. This counteracts the

force of the spring **8814** and rotates the pivoting member **8803** clockwise, with respect to the view of Fig. 88E. The clockwise rotation of the pivoting member **8810** disengages the engaging member **8803** from the threaded driveshaft **8812**.

[00524] Fig 89 shows a method for controlling fluid flow through a drip chamber in accordance with an embodiment of the present disclosure. The method includes an installation act **8902**. During the installation act **8902** a flexible tube in fluid communication with a drip chamber is substantially deformed while being installed in a fluid flow control apparatus by an operator. At reformatting act **8904**, the tube is reformed to substantially it initial size once the installation process is complete. At imaging act **8906**, images are captured of the drip chamber in fluid communication with the tube. At estimating act **8908**, the images from the previous act are used to estimate flow rate through the drip chamber. At communicating act **8910**, the estimated flow rate is communicated to a fluid monitoring client. At receiving act **8912**, a desires flow rate is received from a used. The user may be a fluid monitoring client or a device operator. At comparing act **8914**, the estimated flow rate is compared to the desired flow rate and a difference is produce. At determining act **8916**, the magnitude and direction of valve actuation to achieve the desired flow rate are determined using the difference from the previous act.

[00525] Referring now to Fig. 89B, at actuating act **8918**, the valve is actuated in accordance with the determined magnitude and direction to achieve the desired flow rate. Valve actuation may be achieved by increasing pressure around a defined section of the tube which deforms the tube and modifies the

shape of the lumen within the tube. Pressure adjustment may be achieve by disposing a rigid housing around a defined section of the tube and engaging a plunger with a substantially incompressible filler material enclosed within the housing. The filler material translates the the engaging plunger to pressure within the housing thereby deforming the tube.

[00526] At lighting act **8920**, a light is emitted to indicate the status of the apparatus performing this method. A first color of light may be emitted to indicate fluid is flowing and a second light may be emitted to indicate flow has stopped. A first color of light may be used to indicate the apparatus is functioning properly and a second light may be used to indicated a problem has been detected.

[00527] At monitoring act **8922**, the method monitors for unplanned events. Unplanned events may be power loss or an apparatus performing this method falling over. At cutoff act **8924**, fluid flow through the drip chamber is stopped when an unplanned event is detected by the monitoring act. At removing act **8926**, the tube is deformed to substantially reduce its lumen size while it is being removed from an apparatus performing this method.

[00528] As shown in Fig 90, a system 9000 is shown. The system 9000 may be used with the flow control apparatus 8700 of Figs. 81A-87D or the flow control apparatus 8800 of Figs. 87A-87D. The system 9000 includes a processor **9002** in communication with the image sensor **9006** and the valve actuator **9004**. The processor **9002** receives image data from the image sensor **9006**. Once the processor **9002** has received the image data from the image sensor **9006**, the processor uses the data to estimate a flow rate. The processor

9002 then compares the estimated flow rate to a desired flow rate, and produces a difference between the two values. The processor **9002** adjusts the valve actuator **9004** based on the value to achieve the desired flow rate.

[00529] The processor **9002** may also be in communication with a safety sensor **9008** and the safety cutoff **9010**. In this embodiment, the processor **9002** receives data from the safety sensor **9008** and determines when fluid flow should be stopped based on predetermined criteria (such as power loss, streaming, or device malfunction). Once the processor determines fluid flow should be stopped, it triggers the safety cutoff **9010**.

[00530] The processor **9002** may also be in communication with the input buttons **9012**. The processor **9002** receives data from the input buttons **9012** and uses that data to control the valve actuator **9004** or trigger the safety cutoff **9010**. For example, when the operator presses the increase flow button **9012** the processor **9002** receives a signal from the button **9012** and adjusts the valve actuator **9004** accordingly, or when the operator presses the stop button **9012** the processor **9002** receives a signal and directs the safety cutoff **9010** to trigger. The processor **9002** may also send data to the input buttons **9012**, such as data related to which color the button should light up.

[00531] The processor **9002** may also be in communication with the display **9014**. The processor **9002** receives data from the various components of the apparatus such as the valve actuator **9004**, the safety sensor **9008**, the image sensor **9006**, or the input buttons **9012** and then output the data in human readable form on the display **9014**. For example, the processor **9002**

receives data from the image sensor **9006**, estimates a flow rate, and displays the estimated flow rate on the display **9014**.

[00532] The processor **9002** may also be in communication with the status light **9018**. The processor **9002** receives data from various components of the apparatus such as the valve actuator **9004**, the safety sensor **9008**, the image sensor **9006**, or the input buttons **9012**, creates a signal for sending to the status light **9018** based on the data, and outputs the signal to the status light **9018**. Examples include, blinking the light **9018** every time a drip drops in the drip chamber, turning the light **9018** green when the pump is operational, turning the light **9018** yellow when the pump is paused, or turning the light **9018** red when the pump is not operating correctly.

[00533] The processor **9002** may also be in communication with a power supply or battery **9016**. The processor **9002** receives data from power supply or battery **9016** regarding power output. For example, receiving voltage from the battery **9016** to estimate how much charge it has. The processor **9002** may also send data to the power supply **9016** to adjust its power output.

[00534] Fig. 91 shows an apparatus 9100 configured to control fluid flow through a drip chamber connected to a tube and communicate with an RFID interrogator in accordance with an embodiment of the present disclosure. The apparatus 9100 may transmit data to and from a commercially available radio frequency identification (RFID) interrogator without the use of a dedicated RFID tag.

[00535] As shown in Fig. 91, a first metallic structure **9102** is coupled to a second metallic structure **9104**. Preferably, the first metallic structure **9102** and

the second metallic structure **9104** are pre-existing components of the assembly. For example, the first metallic structure **9102** could be a first clamshell **9106** and the second metallic structure **9104** could be a second clamshell. Alternatively, the first metallic structure **9102** could be a first metal geometry **9110**, such as a metallic housing of a solenoid, and the second metallic structure **9104** could be a second metal geometry **9112**, such as a ground plane of a PCB circuit board. While it is preferable that the first metallic structure **9102** and the second metallic structure **9104** be pre-existing components of the assembly, in some specific embodiments, these structures could be added to the assembly solely for this use.

[00536] At least one impedance-matching structure **9116**, such as an inductor or capacitor, may be coupled with the first metallic structure **9102** and the second metallic structure **9104** to match the impedance of the apparatus to the interrogator frequency. In some embodiments, more than one impedance matching structure **9116** may be used in combination, such as a combination of an inductor and a capacitor (e.g., in either a parallel or series configuration, to form a tank circuit).

[00537] At least for the purpose of ground continuity, a low pass filter **9114** is preferably coupled with the first metallic structure **9102** and the second metallic structure **9104**. The low pass filter **9114** preferably has a cutoff frequency sufficiently below the frequency (approximately 900 MHz) of a commercially available RFID interrogator **9122**.

[00538] The apparatus 9100 operates by performing at least two functions. In a first function, the apparatus 9100 is impedance matched at the interrogator

frequency using the at least one impedance-matching structure **9116**, limiting or essentially prohibiting reflection of the interrogator frequency. In a second function, the metallic structures **9102**, **9104** are shorted together using a shorting mechanism **9118**, such as a transistor or switch. The shorting can be controlled by a microprocessor **9120**. This shorting momentarily eliminates the impedance matching and causes a change in reflection. The transition from the first function to the second function causes a shift in the reflection coefficient of the coupled first metallic structure **9102** and second metallic structure **9104**. By shorting the metallic structures **9102**, **9104** together as desired, data can be transmitted to a commercially available RFID interrogator **9122**, coded in the resulting reflection gamma.

[00539] In some embodiments, an obstruction (e.g., condensation or droplets due to splashing) may render obtaining an accurate image of a drip chamber by an image sensor (e.g., the drip chamber 4 and the image sensor 11 of Fig. 1) difficult. Fig. 92 is an image of such an obstructed drip chamber 9200. The drip chamber **9202** includes a fluid drop **9204** and an obstruction **9206**. The obstruction **9206** may include fluid droplets from condensation or splashing in some embodiments. Fig. 93 shows a flow chart diagram of a method 9300 for obtaining an image of a drip chamber in accordance with an embodiment of the present disclosure. The method 9300 includes acts **9302**, **9304**, **9306**, and **9308**. Method 9300 may be implemented by the processor **15** of Fig. 1 and may be implemented as a processor-implemented method, as a set of instructions configured for execution by one or more processors, in hardware, in software, the like, or some combination thereof.

[00540] Act **9302** of method 9300 includes capturing an image of a drip chamber. Act **9304** of method 9300 includes determining that the image of the drip chamber includes a visual obstruction. The visual obstruction may be similar to the visual obstruction shown in Fig. 92 in some embodiments. Act **9306** of method 9300 includes applying a blurring function to the captured image of Act **9302** upon a determination that the captured image of Act **9302** contains a visual obstruction. The blurring function may be any function that decreases the amount or eliminates an amount of detail in the captured image of Act **9302**. In some embodiments, the blurring function may be applied without regard to a determination that the captured image of Act **9302** contains a visual obstruction, i.e., the blurring function is always applied to the captured image of Act **9302**.

[00541] In some embodiments, the blurring function of Act **9306** may include applying a low-pass filter to the captured image of Act **9302**. The low-pass filter or other blurring function may be applied in either a horizontal direction (e.g., an X-direction in Cartesian coordinates) of the captured image of Act **9302**, or a vertical direction (e.g., a Y-direction in Cartesian coordinates) of the captured image of Act **9302**. In some embodiments, the low pass filter or blurring function may be applied in both a horizontal and vertical direction (e.g., in both an X and Y direction in Cartesian coordinates) of the captured image of Act **9302**.

[00542] In some embodiments, the blurring function of Act **9306** may include applying a Gaussian Blur function to the captured image of Act **9302**. If the blurring function or the low pass filter is applied in either a vertical or a

horizontal direction, as described above, the low pass filter or blurring function may then include a one-dimensional Gaussian Blur function in some embodiments. If the blurring function or the low pass filter is applied in both a vertical and a horizontal direction, as described above, the low pass filter or blurring function may then include a two-dimensional Gaussian Blur function in some embodiments.

[00543] After the blurring function is applied, enough detail should be eliminated from the captured image such that Act **9308** can be carried out. Act **9308** includes determining if the captured image of Act **9302** contains a match to a template. In some embodiments, a processor (e.g., the processor **15** of Fig. 1) may use a template matching function to determine if the captured image of Act **9302** contains a match to the template. In some embodiments, the template matching function may be an OpenCV template matching function. The template may include at least a partial image of a fluid drop. In some embodiments, the template may include at least a partial image of a fluid drop being backlit by a lighting source. In yet a further embodiment, the lighting source may include an LED array (e.g., the LED array **20** of Fig. 1).

[00544] Fig. 94 is a graphical representation 9400 of an embodiment featuring a plurality of drops successively growing within a drip chamber until each falls, as seen by an image sensor (e.g., the drip chamber **4** and image sensor **11** of Fig. 1). The image sensor communicates an output signal to a processor (e.g., the processor **15** of Fig. 1), the processor configured to determine from the output signal when a fluid drop has fallen within the drip chamber. The curve **9408** to the left of time marker **9406** represents the image

sensor's output signal prior to application of a blurring function (e.g., the blurring function of Act **9206** of Fig. 92). Similarly, the curve **9410** to the right of time marker **9406** represents the image sensor's output signal after the application of the blurring function. According to the curve **9408** and the curve **9410** of Fig. 94, application of the blurring function may reduce the amount of noise in the image sensor's output signal. This reduction of noise in the output signal allows the processor to more efficiently identify, from the image sensor's output signal, when a drop of fluid has fallen inside the drip chamber.

[00545] In some embodiments, the processor is configured to recognize that a drop has fallen within the drip chamber, but only if certain current events and prior events have occurred, i.e. the processor performs a hysteresis function. In one embodiment, the processor will recognize that a drop has fallen within the drip chamber when the curve crosses a lower threshold limit **9404**, but only if the curve has previously crossed an upper threshold limit **9402** since the previous crossing of the lower threshold limit **9404**. This hysteresis function may be used to avoid the processor erroneously registering that a drop has fallen due to noise in the image sensor's output signal.

[00546] Referring now to **FIG. 95**, in some embodiments, it may be desirable to rely on some means other than or in addition to an audible noise or visual indicator to convey the status of a device **9500**. This may be desirable where a device **9500** is used in an environment with high levels of ambient noise and or high level of ambient light respectively. This may in some embodiments, be cheaply accomplished using a signature analyzer **9502**.

[00547] During normal device **9500** function, EM emissions will be created. These emissions are a natural artifact of how digital functions are executed by the device **9500**. Additionally, specific digital functions of the device **9500** will produce EM signatures in a predictable manner. That is, when a digital function is performed by the device **9500**, an EM emission corresponding to that function may occur. In **FIG. 95**, the device **9500** includes a component **9504** which may perform a digital function. This component may, for example, be a microprocessor, clock, etc.

[00548] The EM signatures of specific functions may be empirically determined. A signature analyzer **9502** may monitor the EM emissions of the device **9500**. A received EM signature may be matched to its empirically determined meaning. In this manner, a signature analyzer **9502** may divine what digital functions are being performed by the device **9500** using the EM emissions from the device **9500**.

[00549] In a specific example, the device **9500** may be a medication delivery device. A medication delivery device may generate an occlusion alarm during operation. The generation of this occlusion alarm will cause a specific EM signature to be emitted from the medication delivery device. A signature analyzer **9502** monitoring emissions from the medication delivery device may receive and analyze this specific emission signature and thereby determine that the medication delivery device is issuing an occlusion alarm.

[00550] Various components which create EM emissions may be contained within an EM shield **9506**. This shield **9506** may suppress emissions from the device **9500** such that the device **9500** does not interfere with other

devices (not shown) in the vicinity and conforms to any local requirements. The shield **9506**, however, will not totally eliminate emissions from the device **9500**. Reduced amplitude frequency emissions **9508** which satisfy regulatory compliance levels will still occur. In one embodiment which uses a signature analyzer **9502** to monitor the EM signature of a device **9500**, the signature analyzer **9502** may be suitably positioned outside of the shield **9506** and may monitor these reduced amplitude frequency emissions **9508**. In such embodiments, the signature analyzer **9502** may be an RF receiver such as a narrowband receiver. Such a receiver is capable of being tuned to very specific and reduced emission frequencies. Additionally, using a narrowband receiver may be desirable because such a receiver is relatively cheap.

[00551] In some embodiments, a medical pump device may keep track of the number of infusion sets that the medical pump device administers. The medical pump device may keep track of the infusion sets by utilizing a software radio, operably connected to the medical pump device. The software radio may include a coiled wire operably engaged with a microchip in the medical pump device, such that the microchip can transmit signals via the coiled wire. The software radio, in some embodiments, may be used to transmit a communication signal to a handheld device that is configured to receive the signal. The communication signal may be a number of infusion sets that the medical pump device has administered.

[00552] Further, in some embodiments, the medical pump device may communicate with the handheld device via a speaker on the handheld device configured to receive an acoustic or audio signal from the medical pump device.

The audio signal, in some embodiments, may include digital data that is encoded in the audio signal.

[00553] In some embodiments, the medical pump device may communicate with a handheld device by utilizing a motion sensor in the handheld device. The motion sensor may receive motion input from a motion generator included in the medical pump device. The motion generator, in some embodiments, may be a stepper motor, and, further, in some embodiments, the motion sensor may be an accelerometer. The handheld device may be configured to determine a number of infusion sets that the medical pump device has administered from the motion input received by the motion sensor.

[00554] The medical pump device may be configured to pair with a handheld device in order to establish wireless communication with the handheld device. In some embodiments, the medical pump device may establish a Blue Tooth connection with the handheld device. In yet other embodiments, the medical pump device may establish a wireless communication signal with the handheld device by utilizing near-field communication (NFC) signals.

[00555] In some embodiments, the medical pump device may communicate with a handheld device by utilizing a camera that is included in the handheld device. More specifically, the camera of the handheld device may be configured to detect a visual modulation signal. In some embodiments, the visual modulation signal may come from a dome light included in the medical pump device. The handheld device may use the visual modulation signal to determine a number of infusion sets that has been administered by the medical pump device.

[00556] Figs. 96A-96X show several views of an apparatus 9600 to control fluid flow in accordance with an embodiment of the present disclosure. Referring to Fig. 96A, the apparatus 9600 includes a body 9602 having a door 9604 pivotally coupled to the body 9602. The apparatus 9600 also includes a coupler 9606 to coupled to an drip chamber (not shown in Fig. 96A). The coupler 9606 positions a drip chamber such that the camera assembly 9614 can view the drip chamber with a background pattern 9608 behind the drip chamber.

[00557] The door 9604 is pivotally coupled to the body 9602 such that the door 9604 may be opened for insertion of a drip chamber coupled to an IV line. The door 9604 may be opened by a slide occluder coupled to the drip chamber. That is, the slide occluder may serve as a key to open the door 9604 by inserting the slide occluder into a keyhole 9610.

[00558] The apparatus 9600 also includes a strap 9612 so that the apparatus can be easily carried and hung, such as on a hook of a pole. A keyhole 9610 can receive a slide occluder (not shown) so that the door 9604 may be opened.

[00559] Fig. 96B shows a front view of the apparatus 9600. Note that the background pattern 9608 and camera assembly 9614 are at an angle to facilitate easy healthcare provider viewing of a drip chamber.

[00560] As is easily seen in Figs. 96C-96D, an upper coupler 9616 secures a drip chamber to the coupler 9606. In Fig. 96E, the camera assembly 9614 is easily viewable. In Figure 96F-96G, the bottom and top, respectively, of

the apparatus 9600 is viewable in which the attachment of the door 9604 to the body 9602 is easily viewable.

[00561] Fig. 96H shows a close-up view of the background pattern 9608. The background pattern 9608 includes fiducials 9636 to help the image sensor determine the alignment of the drip chamber when secured to the coupler 9606. The background pattern also has a stripped pattern to help it detect streaming conditions. Also, through the center there is a divider where the left side is white while the right side 9638 is black to help provide contrast to the drop.

[00562] In some embodiments, no fudicuals 9636 are used and a template match is used to match the template to area 9650. The area 9650 is designated by the doted-lined box and is not part of the background pattern 9608 shown in Fig. 96H. But rather, a template may be used by the processor 15, 90 to determine the location designated by area 9650 and use that area to orient the image sensor so that the image sensor can identify the background pattern's 9608 approximate center.

[00563] Referring to Fig. 96I, the upper coupler 9616 is easily seen in relation with the slot 9620. The slot 9620 allows a tube of the drip chamber to be received therein such that the upper coupler 9616 secures the drip chamber to the coupler 9606. Fig. 96J shows the camera assembly's 9614 view.

[00564] Referring now to Fig. 96K, the apparatus is shown with the door 9604 in an open position. Also viewable in Fig. 96K is the lower coupler 9618.

[00565] When the door 9604 is in the open position, an arm 9640 pulls open a valve casing 9642 of a valve 9644, as is seen in Fig. 96L. A latch 9622

can secure the door in the closed position and may be opened by placing a key (e.g., a keyed slide clamp) into the keyhole 9610.

[00566] Fig. 96M shows a close-up view of the valve 9644 so that it is easily seen how the arm 9640 opens the valve casing 9642 to allow insertion of a infusion tube. Fig. 96N shows a close-up view of the keyhole 9610 and the latch 9622.

[00567] Fig. 96O shows a top view of the latch 9622 with a cover of the door 9604 removed. The latch 9622 is connected to a lever 9626, which is pivotable along a pivot 9630. A protrusion 9628 engages with the lever 9626 to release the latch 9622. A spring 9634 biases the latch 9622 toward the latch receiver 9624 shown in Fig. 96P. The spring 9634 is secured to the lever 9626 via a collar 9632. The latch receiver 9624 is configured to engage with the latch 9622, and the latch 9622 is likewise configured to engage with the latch receiver 9624. Fig. 96Q shows the latch receiver 9624 in cross-sectional view while Fig. 96R shows the latch 9622 engaged with the latch receiver 9624 when the door 9604 is closed and secured. The spring 9634 keeps the latch 9622 securely engaged with the latch receiver 9624 and prevents unlatching of the latch 9622 unless a key (e.g., slide occluder) is inserted into the keyhole 9610.

[00568] Fig. 96S shows the internal workings of the apparatus 9600. The body 9602 shown in Figs. 96A-96R has been removed in Figs. 96S-96X to more clearly show the internal workings of the apparatus 9600.

[00569] In Fig. 96S, the apparatus 9600 includes a motor 9834 that is attached to a shaft 9836. The motor 9834 actuates the shaft 8836 linearly between a retracted position and an extended position. That is, the motor 9834

moves the shaft 9836 into and out of the motor 9834 in a direction parallel to a central axis of the shaft 9836. The shaft 9836 is mechanically coupled to the slotted lever 9840. The shaft 9836 includes a pin 9838 that is disposed within a slot 9854 of the slotted lever 9840 such that the slot 9854 forms a guide to guide the pin 9838 within the slot 9854.

[00570] The slotted lever 9840 pivots along a pivot 9842. The pivot 9842 may include a pin, a bearing, and/or any other know way to pivot along a point or axis. Activation of the motor 9834 to move the shaft 9836 causes the pin 9838 to slide within the slot 9854 of the slotted lever 9840 which causes the slotted lever 9840 to pivot along the pivot 9842 of the slotted lever 9840. The slotted lever 9840 is also mechanically coupled to the plunger 4844 effecting its movement.

[00571] The slotted lever 9840 includes a pin 9846 that is disposed within a slot 9856 of the plunger 9844. The plunger 9844 actuates into and out of the filler as described above as the slotted lever 9840 pivots along the pivot 9842.

[00572] Fig. 96T shows the guide 9850 that allows the plunger 9844 (see Fig. 96S) to slide toward or away from the filler within the valve 9644 (see Fig. 96V). The guide 9850 is part of the valve cover 9848 (see Fig. 96U). The movement of the plunger 9844 can compress or decompress the filler which thereby compresses or decompresses the tube as described above to impede or increase the flow of fluid through the tube, respectively.

[00573] Figs. 96U-96V show the cover 9852 removed (refer to Fig. 96S for a view of the cover). Fig. 96V shows a close up of the internal portions of the valve including the valve casing 9642. When the door 9604 is shut, the arm

9640 actuates the valve casing 9642 into a closed position to thereby surround a tube disposed within the valve 9644. When the valve 9644 is shut, the plunger 9844 can actuate into and out of the valve 9644 to compress the filler against the tube disposed therein to control the flow of fluid through the tube and thus into a patient.

[00574] Fig. 96W shows a side view of the internal workings of the apparatus 9600. As can be easily seen in Fig. 96W, actuation of the motor 9834 causes actuation of the plunger into and out of the valve. Fig. 96X shows the valve cover 9848 removed.

[00575] Figs. 97A-97AC shown several views of an apparatus 9700 to control fluid flow in accordance with an embodiment of the present disclosure. Referring now to Fig. 97A, the apparatus includes a body 9702 and a dock 9704. The body 9702 includes an opening 9708 configured to receive a drip chamber 9706. The body 9702 may house and/or contain the flow meter 7 of Fig. 1, the flow meter 67 of Fig. 5, the imaging system 78 of Fig. 6, the imaging system 84 of Fig. 8, or other flow meter of an imaging system disclosed herein (each with or without a background pattern and/or with or without active illumination), or some combination thereof.

[00576] The dock 9704 may include one or more batteries, secondary batteries, or other electronics. The dock 9704 may include a WiFi transceiver, Bluetooth transceiver, or other communications transceiver. In some embodiments, the dock 9704 solely provides one of these functions for the apparatus.

[00577] For example, the dock 9704 may include a wireless coupling (e.g., magnetic coupling) between the dock 9704 and the housing 9702 to communicate therebetween so that components within the housing 9702 may use the dock 9704 and/or power may be transferred from one or more batteries within the dock 9704 to circuitry and/or batteries within the housing 9702.

[00578] In some embodiments of the present disclosure, the dock 9704 includes an AC-to-DC converter to charge one or more batteries of the dock, charge one or more batteries within the housing 9702, and/or power the electronics within the dock 9704 and/or housing 9702. In yet additional embodiments, the dock 9704 transfers AC power to circuitry inside the housing 9702 (e.g., via electrical contacts, via magnetic coupling, etc.); The AC power may be AC-to-AC converted prior to transfer, may have a frequency, phase, and/or voltage changed during the AC-to-AC conversion.

[00579] Fig. 97B shows the dock 9704 without the housing 9702 docked therein, Fig. 97C shows a user docking the housing 9702 within the dock 9704, and Fig. 97D shows the housing 9702 prior to docking into the dock 9704. The dock 9704 has an alignment lip 9710 facilitating the sufficient alignment of the housing 9702 with the dock 9704 prior to complete docking. The housing 9702 includes a notch 9712 that is aligned with a notch 9714 on the dock so that the fluid line 9716 may pass through the notches 9712, 9714.

[00580] In some embodiments of the present disclosure, the dock 9704 includes a tilt sensor configured to determine a tilt of the dock 9704. The dock 9704 may communicate the tilt to a processor in the housing 9702 which can (e.g., when the housing 9702 is docked in the dock 9704) use the tilt

information. For example, if the dock 9704 communicates a tilt that is greater than a predetermined threshold, the apparatus 9700 may occlude fluid flow through the tube and/or sound an alarm.

[00581] Fig. 97E shows the housing 9702 docked into the dock 9704. On the top of the housing 9702, the apparatus 9700 includes a light bar 9716. The light bar 9716 may include a plurality of Light Emitting Diodes ("LEDs") embedded into a diffuser. The light bar 9716 also includes a notch 9718 to allow the fluid line to pass through.

[00582] In some embodiments, a backlight may be disposed behind the 9706 to shine a light where the drops are formed. The light may be used to create a point light when the drops form thereby allowing a user to see the dropping action at some distance. That is, a "shimmer" of light forms in accordance with the forming of the drops and dripping of the drops.

[00583] The drip chamber 9706 includes a top cap 9720 that can interface into a coupler 9722, which is easily seen in Fig. 97F. The coupler 9722 receives the drip chamber top cap 9720. The coupler 9722 includes securing protrusions 9724 (a type of latch). The coupler 9722 also includes a guide 9726 that guides a top cap 9720 to be secured within the coupler 9722. The guide 9726 may be upwardly sloping to more easily allow insertion of the top cap 9720. Referring to Fig. 97G, the securing protrusions 9724 are easily seen when the coupler 9722 is viewed from a perspective view.

[00584] Figs. 97H-97O show the flow meter 9700 in an unloaded position with Figs. 97I-97O showing the flow meter 9700 with portions removed in accordance with an embodiment of the present disclosure.

[00585] Fig. 97H shows the flow meter 9700 with a light 9901 to illuminate a drip chamber inserted into the flow meter 9700. The light 9901 may be a diffusion light and/or may be LED based. As previously mentioned, the light 9901 is positioned to illuminate an opening of a loaded drip chamber where the drops form such that a "flicker" or bright-point is formed as the drops drip through the drip chamber. This flicker can be seen from some distance and helps a caregiver visually note the drop rate from a distance. Also, the opening 9708 allows the drip chamber to be partially optically-shielded (by virtue of the drip chamber being in a recessed space) to reduce optical noise that an internal image sensor receives within the flow meter 9700.

[00586] The light 9901 may be modulated such that it is not active when the backlight mentioned above is illuminated. That is, they may be modulated such that only one of the light 9901 and the backlight is active at a time (e.g., using PWM modulation) such that the two lights alternatively switch on.

[00587] A retracted tube-retention cover 9902 is partially visible in Fig. 97H. Also shown in Fig. 97H is a tube-contact member 9904. When a drip chamber is inserted into the opening 9708, a tube of the drip chamber contacts the tube-contact member 9904. Fig. 97I shows a close-up view of the tube-contact member 9904.

[00588] Fig. 97J shows the internal mechanism of the flow meter 9700, e.g., with the housing removed. A tube engagement portion 9912 is shown and is connected to the tube-contact member 9904. When a tube is inserted into the opening 9708 (Fig. 97H shows the opening 9708), the tube engages with the tube-contact member 9904 which is coupled to the tube-engagement

portion 9912. The force on the tube-engagement portion 9912 causes it to rotate along a rotational axis.

[00589] Also shown in Fig. 97J, is a tube retention cover 9902 is coupled to a flag 9903. The flag 9903 may be visible within a window 9916 (refer to Figs. 97H-97I) when the tube-retention cover 9902 is in the closed position (described below). However, in some embodiments, no flag is used and no window for the flag is needed.

[00590] Referring again to Fig. 97J, as previously mentioned, the tube can press against the tube-contact member 9904 which causes a force on the tube-engagement portion 9912 thereby imparting a rotational force on the split-rotating arm 9910 (see Fig. 97K). As shown in Fig. 97K, the split-rotating arm 9910 includes an arm portion 9911 and tube engagement portion 9912. A torsion spring 9909 biases the tube-engagement portion 9912 against the arm portion 9911. An extension may be added to the tube-engagement portion 9912 to help cover an inserted tube.

[00591] A carriage 9914 can slide along a direction parallel to the center axis of a shaft 9918. That is, the shaft 9918 allows the carriage 9914 to actuate toward or away from a shaft bearing 9920 which in turn allows a slide 9907 to cooperate with a pin 9922. The carriage 9914 also includes a carriage pin 9913 that can move into a catch 9924 to retain the arm 9905 into a particular position.

[00592] An arm 9905 has a magnet 9906 that can be used by a Hall-Effect sensor (not shown) on a circuit board (also not shown) so that the position of the arm 9905 may be determined. That is, the arm 9905 actuates outward and/or inward as the arm portion 9911 of the split-rotating arm 9910 rotates.

[00593] Fig. 97L shows an angled view of the arm portion 9911 engaging with the tube-engagement portion 9912. The surface 9926 of the arm portion 9911 is in contact with the surface 9928 of the tube-engagement portion 9912. Note that in the unloaded position shown in Fig. 97L, the arm 9905 is in a retracted position thus keeping the magnet 9906 away from a hall-effect sensor (not shown).

[00594] Fig. 99M shows a top view of the internals of the flow meter 9700. Fig. 97N shows a close-up view of the tube-engagement portion 9912 having the tube-contact member 9904. Also, the torsion spring 9909 is shown as biasing the arm portion 9911 of the split-rotating arm 9910 against the tube engagement portion 9912 of the split-rotating arm 9910.

[00595] In Fig. 97O, a slide-clamp keyhole 9930 is shown that can accept a slide clamp. A slide clamp can be used to unload the tube from the flow meter 9700.

[00596] Figs. 97P-97W show the flow meter 9700 in an loaded position with Figs. 97Q-97W showing the flow meter 9700 with portions removed in accordance with an embodiment of the present disclosure.

[00597] As shown in Fig. 97P, after a drip chamber is inserted, a tube-retention cover 9901 closes over the IV tube and a flag 9903 is visible in window 9916. The tube-retention cover 9902 prevents a user from pulling a tube out of the flow meter 9700.

[00598] Fig. 97Q shows a close-up view of the tube-contact member 9904 (which will be pushed in by a tube), the tube-retention cover 9902, and the flag 9903. The flag 9902 is mechanically coupled to the tube-retention cover 9902.

[00599] Fig. 97R shows the flow meter 9700 with portions removed, such as the housing. Note that as previously mentioned, the flag 9903 is mechanically coupled to the tube-retention cover 9902. As the tube-retention cover 9902 pivots to a closed position along a pin 9923, the flag 9903 also pivots. When the tube retention cover 9902 is in the fully closed position, the flag 9903 is visible to the user.

[00600] As shown in Fig. 97S, the tube has pressed against the tube-contact member 9904 causing the tube-engagement portion 9912 to rotate the split-rotating arm 9910 as shown in Fig. 97T. The rotation has rotated the magnet 9906 to actuate toward a Hall-Effect sensor (not shown) so that a processor can determine that the tube-retention cover 9902 is in the closed position. The rotation has also cause the carriage 9914 to actuate the place the carriage pin 9913 into a catch 9934 and move such that the slide 9907 cooperates with the pin 9922 to close the tube-retention cover 9902. The tube-retention cover 9902 is pivotable along a pin 9932 (see Fig. 97S).

[00601] Referring now to Figs. 97U-97V, the extended position of the arm 9905 and the magnet 9906 is easily viewable. A balance spring 9908 holds the carriage 9914 in its position by friction of the carriage pin 9913 in the catch 9934. The position of the magnet 9906 is easily seen in Fig. 97W.

[00602] Figs. 97X-97AC show the flow meter 9700 in an loaded position and having the tube-retention cover 9902 open with Figs. 97Y-97AC showing the flow meter 9700 with portions removed in accordance with an embodiment of the present disclosure.

[00603] When a slide-clamp 9938 is inserted, the tube-retention cover 9902 is retracted. As shown in Fig. 97Y, when the slide-clamp 9938 is inserted, the carriage 9914 is actuated toward the shaft bearing 9920, which in turn actuates the slide 9907 such that the pin 9922 coupled to the tube-retention cover 9902 actuates the tube-retention cover 9902 into a retracted position.

[00604] Also, because the carriage 9914 is actuated toward the shaft bearing 9920, the carriage pin 9913 pushes the arm portion 9911 such that it rotates the magnet 9906 away from the Hall-Effect sensor (not shown). Referring to Fig. 97Z, please note that because the tube-contact member 9904 is still in contact with the tube, the arm portion 9911 actuates while the tube-engagement portion 9912 remains stationary. Thus, the surface 9926 of the arm portion 9911 actuates away from the surface 9928 of the tube-engagement portion 9912. The split-rotating arm 9910 is biased to rotate the surface 9928 of the tube-engagement portion 9912 toward the surface 9926 of the arm portion 9911.

[00605] Referring to Figs. 97AA- 97AC, once the tube is pulled out, the tube-contact member 9904 may actuate such that the surface 9926 of the arm portion 9911 actuates toward the surface 9928 of the tube-engagement portion 9912.

[00606] Fig. 98 shows a top perspective view of a drip chamber 9706 that may be used by the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure. The top cap 9720 is shown and includes notches 9728 that define spring fingers 9730. Optionally, the top cap 9720 may include hollow circles 9732 within the notches 9728 to allow sufficient flexibility

of the spring fingers 9730. Also optionally, the spring fingers 9730 may include a pressure-release notch 9736 that further allows the spring fingers 9730 to bend inward. Fig. 99 shows a top view of the drip chamber of Fig. 98. The spring fingers 9730 may flex inwardly when the drip chamber 9706 is inserted into the coupler 9722 (See Figs. 97A-97G).

[00607] Fig. 100 shows a top sectional view of the drip chamber 9706 of Fig. 99 being inserted into the apparatus 9700 of Figs. 97A-97G in accordance with an embodiment of the present disclosure. As shown, the spring fingers 9730 may be inwardly bowed by securing protrusions 9724 as the drip chamber 9706 is inserted into the coupler 9722. That is, the securing protrusions 9724 can cause the spring fingers 9730 to flex until the top cap 9720 of the drip chamber 9706 is secured in the coupler 9722. Pressure-release notches 9736 allow spring fingers 9730 to bend more to thereby reduce a cross-sectional size of the notches 9728 so that the spring fingers 9730 can flex inwardly. Fig. 101 shows the top cap 9720 in a secured position secured in the coupler 9722. Note that the inwardly projecting notch 9734 cooperatively mates with the securing protrusions 9724.

[00608] Fig. 102 shows a close-up view of the top cap of the drip chamber of Fig. 98 being inserted into an opening of the apparatus of Figs. 97A-97G in accordance with an embodiment of the present disclosure. Note that arms 9738 surround the top of the top cap 9720. The arms 9738 may snap around the top of the top cap 9720 to better secure them therein.

[00609] Fig. 103 shows a cross-sectional view of the apparatus of Figs. 97A-97G where the top cap of the drip chamber is secured therein in

accordance with an embodiment of the present disclosure. The securing protrusion 9727 is easily seen as being disposed within the inwardly projecting notch 9734. When the top cap 9720 is secured within the apparatus 9700, the securing protrusion 9724 prevents the drip chamber from being removed by a horizontal force out of the apparatus 9700.

[00610] However, with rotation of the bottom of the drip chamber 9706, the top cap 9720 is released. Figs. 104-105 show a cross-sectional view of the apparatus of Figs. 97A-97G with the top cap 9720 of the drip chamber 9706 to illustrate the release of the drip chamber 9702 from the apparatus 9700. As is seen in Figs. 104-106, rotation of the bottom of the drip chamber 9702 out of the apparatus 9700 allows the inwardly projecting notch 9734 to slide out away from the securing protrusion 9727. A similar process happens on both sides of the drip chamber 9706 to release the drip chamber 9702 from the apparatus 9700.

[00611] In some embodiments, the securing latches 9724 (or ribs) in Figs. 100, 101, 103 - 105 that capture and lock the notches (9734) in place may be metal (or any durable material for wear), such as a narrow strip of sheet metal or spring steel so that the drip chamber is the sacrificial material and the rib will last the life of the device.

[00612] Fig. 106 shows an embodiment of the drip chamber 9704 that uses mechanical resonance for drop detection in accordance with an embodiment of the present disclosure. The drip chamber 9704 includes a flaccid tube 8742. A resonance detector 9744 can detect a mechanical resonance of the flaccid tube 9742.

[00613] As a drop forms at the end of the flaccid tube 9742, the flaccid tube 9742 become a pendulum that has an increasing length as the drop forms at the end of the flaccid tube 9742. The resonance detector 9744 may have a vibration generator to cause the flaccid tube 9742 to swing. This swing may be measured to estimate the volume of the drop, the growth of the drop, and/or the growth rate of the drop. The resonance detector 9744 may include a camera to monitor the swing or may detect how the vibrations of the vibration generator are affected by the flaccid tube 9742 (e.g., using a microphone, piezoelectric senor, etc.). The vibration generator may be one or more of a speaker, a vibration motor, a piezoelectric device, linear actuator, etc.

[00614] Fig. 107 shows an embodiment of the drip chamber 9746 that uses an optical light source 9750 and a cantilever beam 9748 for drop detection in accordance with an embodiment of the present disclosure. As drops hit the cantilever beam 9748, the beam is deflected as a function of the size of the drop. A light beam 9750 is reflected off of the cantilever beam 9748 toward a receiver 9826. The receiver 9826 estimates the bend of the cantilever beam and correlates that bend with a drop size and/or when the drop hits the cantilever beam 9748. The receiver 9826 may be a linear CCD sensor configured to correlate the CCD pixel that receives the light beam to the cantilever beam's 9748 bend angle.

[00615] Fig. 108A shows a drip chamber 9752 having an anti-pinch member 9754 in accordance with an embodiment of the present disclosure. As is seen in Fig. 108B, a cross-sectional view of the anti-pinch member 9754 of Fig. 108A is shown. The anti-pinch member 9754 includes an inner sleeve

9756 that is internal to the tube 9758. The inner sleeve 9756 includes a plurality of wires 9760. The wires distribute the force from a pinch valve to along the length of the tube 9758 thereby causing the tube to collapse along a length of the tube in response to a pinch valve. A pinch valve applies a force along a narrow section of the tube 9758. The pinch valve may have a plunger with an edge that contacts the tube 9758 orthogonal to a central axis defined by the tube 9758 along its length.

[00616] Instead of causing the tube to collapse directly around the area where the plunger contacts the tube 9758, the plurality of parallel wires 9760 cause the tube to collapse along a longer section of the tube, preferably in some embodiments, along the entire length of the anti-pinch member 9754. By increasing the section of tubing 9759 that collapses when engaged by an anti-pinch member, the flow rate has a response that is more linearized than without an anti-pinch member thereby facilitating a control system to control fluid flow through the tube 9758.

[00617] The plurality of wires 9760 may be solid, threaded, flexible, rigid, semi-flexible, or some combination thereof. That is, some of the wires 9760 (or some subsections) may be rigid wires while wires 9760 (or subsections) may be flexible or semi-rigid, etc.

[00618] Fig. 109A shows a drip chamber 9762 with an outer sleeve 9766 (see Fig. 109B) having parallel wires 9760 as an anti-pinch member 9764 in accordance with an embodiment of the present disclosure. The anti-pinch member 9764 works in a similar manner as the anti-pinch member 9754 of Figs. 108A-108B.

[00619] Fig. 110A shows a drip chamber 9768 having an anti-pinch member 9770 in accordance with an embodiment of the present disclosure. As is easily seen in the anti-pinch member 9770 in cross-sectional view of Fig. 110B, the anti-pinch member 9770 of Figs. 110A-110B includes an outer sleeve 9772 having a spiral wire 9774. The spiral wire 9744 more uniformly distributes the pinch force along the length of the anti-pinch member 9770.

[00620] Fig. 111A shows a drip chamber 9776 with an inner sleeve 9780 having a spiral wire 9774 as an anti-pinch member 9778 in accordance with an embodiment of the present disclosure. Fig. 111B shows a cross-sectional view of the anti-pinch member 9778 of Fig. 111A. The anti-pinch member 9778 works in a similar manner as the anti-pinch member 9770 of Figs. 110A-110B.

[00621] Fig. 112 shows an drip chamber 9782 having an anti-pinch member 9784. The anti-pinch member 9784 may include different tube geometries in accordance with several embodiments of the present disclosure. That is, Figs. 113-116 show several cross-sectional views of several embodiments of the section of tubing being an anti-pinch member of Fig. 112 in accordance with several embodiments of the present disclosure.

[00622] Fig. 113 shows a cross-sectional view of an embodiment of the anti-pinch member 9782, designated generally as 9786. The anti-pinch member 9786 includes a plurality of teardrop-shaped conduits 9794 each having a point pointed toward a center axis of the downstream tube.

[00623] Fig. 114 shows a cross-sectional view of an embodiment of the anti-pinch member 9782, designated generally as 9788. The anti-pinch member 9788 has a central conduit 9796 with a plurality of side conduits 9798 in fluid

communication with the central conduit 9796. Each of the side conduits 9798 has a flat end at an opposite end to the central conduit.

[00624] Fig. 115 shows a cross-sectional view of an embodiment of the anti-pinch member 9782, designated generally as 9790. The anti-pinch member 9790 has a central conduit 9796 with a plurality of side conduits 9800 in fluid communication with the central conduit 9796. Each of the side conduits 9800 has a rounded end at an opposite end to the central conduit 9796.

[00625] Fig. 116 shows a cross-sectional view of an embodiment of the anti-pinch member 9782, designated generally as 9792. 64. The anti-pinch member 9782 is a section of the downstream tube having a plurality of parallel conduits 9802.

[00626] Figs. 117-120 show several views of a snap-fit drip chamber 9804 in accordance with an embodiment of the present disclosure. The drip chamber 9804 includes a top cap 9806 having a top surface 9808 that is orientated in a generally horizontal direction when in an upright position. The top cap 9806 includes a guide 9810 with a vent end 9816 and a rounded end 9814. Two arms 9812 extend out of the rounded end 9814 and toward the vent end 9816.

[00627] The top cap 9806 is configured to fit into a snap-fit coupler of a flow chamber. As shown in Fig. 118, the drip chamber 9804 includes two arms 9812 extending from a rounded end 9814 toward the vent end of the guide 9810. The arms 9812 are coupled to the rounded end 9814 via living hinges 9818.

[00628] The arms 9812 includes barbs 9820 approximately half way between the end 9814, 9816 of the guide 9810. Each of the barbs 9820

includes ramps 9822, 9824. The ramps 9822, 9824 control the amount of force need to snap in the drip chamber 9804 into a flow meter. As is easily seen in Figs. 119-120, the arms 9812 are shown and are a predetermined distance from the top surface 9808.

[00629] Figs. 121-122 show the snap-fit drip chamber 9804 of Figs. 117-120 secured within a flow meter in accordance with an embodiment of the present disclosure. The drip chamber 9804 may be inserted into the flow meter 9832. The arms 9812 may fit into complementary tracks 9828 to guide the drip chamber 9804 into the body of the flow meter 9832. As is easily seen in Fig. 122, the arms 9812 may snap secure to the pins 9830. Note that the shape and/or angle of the ramps 9822, 9824 control the force needed to insert the drip chamber 9804 into and out of the flow meter 9832.

[00630] Fig. 123 shows a drip chamber 10000 having a fiducial 10004 (Fig. 10004 shows a close-up of the fiducial 10004) for an image sensor to determine the location of the drip chamber in accordance with an embodiment of the present disclosure. An image sensor may take advantage of the fidicual 10004 by using it to calculate the position of the drip chamber 10000. Fig. 125 shows a drip chamber 10006 having wings 10008 each of which includes a fiducial 10010 in accordance with an embodiment of the present disclosure. The wings 10008 may be used to position the drip chamber 10006 within an opening of a flow meter (e.g., as disclosed herein). The fidicuals 10010 and/or 10004 of Figs. 123-125 may be molded into the base material.

[00631] Figs. 126-127 show a drip chamber 10012 having lighting elements 10014 configured to internally light the chamber walls of the drip

chamber in accordance with an embodiment of the present disclosure. The internal lighting elements 10014 may shine light into the walls of the drip chamber 10012 or into the internal cavity of the drip chamber 10012. A LED-light bar 10026 may also be present to illuminate the chamber and/or the periphery of the LED-light bar 10026.

[00632] Fig. 128 shows a drip chamber 100016 with a solid stripe 10018 in accordance with an embodiment of the present disclosure. The solid stripe 10018 may be used by the image sensor to determine the level of the liquid. That is, the solid stripe may optically shift from the perspective of the camera (e.g., toward the left or right of the drip chamber relative to the non-immersed side of the stripe 10019). This shift may be used to estimate the level of the liquid.

[00633] Fig. 129 shows a drip chamber 10020 with a wing 10022 with a 2-D barcode 10024 embedded thereon in accordance with an embodiment of the present disclosure. The barcode 10024 may be on one or more of the wings 10022. The 2-D barcode may be unique to each administration set coupled to the drip chamber 10020.

[00634] Figs. 130-131 show a drip chamber 10028 that is keyed and includes a background pattern 10032 that is illuminated via light shined in through an edge of the background pattern 10032 in accordance with an embodiment of the present disclosure. Fig. 131 shows the top cap 10030, while Fig. 130 shows the top cap 10030 removed. The flat shape of the background pattern 10032 provides a key for the drip chamber is that when it is inserted into a complementary flow meter only one orientation is possible. In

some embodiments, the background pattern 10032 only uses ink that is visible in the Infrared spectrum range.

[00635] Fig. 132 shows a drip chamber 10034 having a barbed spike 10036 in accordance with an embodiment of the present disclosure. The barbed spike 10036 keeps the drip chamber 10034 secured within a container (e.g., glass fluid container).

[00636] Fig. 133 shows a drip chamber 10038 having a cylindrically-shaped chamber with lighting elements 10042 to illuminate a background pattern in accordance with an embodiment of the present disclosure. Because of the round shape of the chamber, the background pattern is viewable from any angle. The background pattern may use optical piping 10044 to illuminate the background pattern. The spiral optical piping 10044 (i.e., light pipe) may or may not be part of the background pattern.

[00637] Fig. 134 shows a drip chamber 10040 having a rectangular-shaped chamber with lighting elements 10042 to illuminate a background pattern in accordance with an embodiment of the present disclosure. The background pattern is viewable on all four walls of the drip chamber allowing the drip chamber 10040 to be positioned in any of four orientations in a cooperating flow meter. Light pipes 10046 may be positioned on the drip chamber to direct light from the lighting element 10042. The light pipes 10046 may or may not be part of the background pattern.

[00638] Figs. 135A-135C show a top cap with 10048 a pumping mechanism in accordance with an embodiment of the present disclosure. Referring to Figs. 135A-135B, the top cap 10048 includes a volcano valve

10050 (however any fluid valve may be used) and a fluid port 10056. A pump coupled to the fluid port can pump fluid (e.g., air) into our or out of the port 10056. Also, a pressure sensor may be coupled to the port 10056 to measure the internal pressure of the drip chamber. The pump (not shown) may be a piston pump or a bellow-based pump.

[00639] A thin film or membrane may be placed onto the valve 10050 such that a force (pneumatic force, fluid force, or physical device) pressed against the valve 10050 closes fluid flow from an inlet port 10052 of the valve 10050 to the outlet port 10054 of the valve 10050.

[00640] The top cap 10048 may be part of any drip chamber know to one of ordinary skill in the relevant art and/or one disclosed herein. As shown in the cross-sectional drawing in Fig. 135C, the top cap 10048 may coupled to a cylindrical chamber through interface 10058. Fig. 135C views a cross-sectional view along the section A-A shown in Fig. 135B. Downstream of the drip chamber formed by the top cap 10048 may be a downstream occluder. However, in some embodiments, an upstream occlude may used.

[00641] The pumping action may operate as follows. The downstream occluder is closed and the valve 10050 is opened. Then, air is sucked out via the fluid port 10056. The valve 10050 is then closed. The downstream occluder is then opened. The air is then put into the fluid port 10056. In some embodiments, the air placed back into through the fluid port 10056 is by equal volume of the air sucked out. The volume of fluid discharged downstream may be characterized by: $V_{water} = V_{stroke} + c\Delta P/P1P2$.

[00642] In some embodiments, a piston coupled to the port 10056 drives back and forth causing pressure swings in the drip chamber. When the pressure drops, a drop is pulled out. When the pressure is raised, fluid is forced out the bottom. In some embodiments, a check valve is used, however, an active valve or valves may used. The volume displaced by the piston may be determined. A flow rate can be calculated based on monitoring the pressure (e.g., Vwater = Vstroke + c∆P/P1P2). Using this, the system can be set up such that we have two independent means of measuring flow rate – watching drops as described herein using the image sensor and/or using the pressure change. In some embodiments, using these two methods, calibration runs at set intervals with known fluids may be utilized to increase accuracy. In some embodiments, a class of fluid (drop size varies slightly based upon a class (type of fluid (e.g., viscolity-based fluids) a comparison of the number of drops to amount of fluid measured using pressure may be used to classify the fluid.

[00643] In some embodiments, an infusion using both methods may be used, but if one method is unavailable, the system may switch to the operating one to continue the infusion. In yet some additional embodiments, the valves can be switched to allow the device to pump backwards. By pumping backwards, if can be determined whether or not an infusion is getting consistent flow (connection to the vein is good), no flow exists (stuck in the person but not in a vein, or vein collapsed), or too much flow exists (lost all connection, pulling on air). In some embodiments, one or more active valves may be used.

[00644] Fig. 136 shows a drip chamber 10060 having a plurality of lighting elements 10062 in accordance with an embodiment of the present disclosure.

The lighting elements 10062 may be LEDs. The lighting elements 10062 may illuminate outside the cylindrical chamber, inside the cylindrical chamber, or on an edge of the cylindrical chamber to guide light along the wall of the cylindrical chamber. A contact 10064 may interface with a electrical contacts of a flow meter to power the plurality of lighting elements 10062. In some embodiments, the contact 10064 is instead a inductive coil that receives electrical energy remotely from the flow meter via inductive coupling, which is then used to power the lighting elements 10062.

[00645] Fig. 137 shows a drip chamber 10066 having a plurality of internal ridges 10068 to facilitate liquid flow of condensation on the internal wall of the drip chamber in accordance with an embodiment of the present disclosure. The internal ridges 10068 facilitate drop formation from inner wall condensation and help guide the liquid in a vertical direction toward the downstream tube.

[00646] Fig. 138 shows a flow meter 10070 coupled to a bag via a spring 10072 in accordance with an embodiment of the present disclosure. A coupled bag may be hung on a pole with the flow meter coupled to the bag via the spring 10072.

[00647] Fig. 139 shows a cross-section section of a drip chamber in accordance with an embodiment of the present disclosure. The chamber includes a first side 10074 having a pattern printed by a first ink and a second side 10076 having a pattern printed by a second ink. The two inks may be responsive to different wavelengths of light (e.g., photo-fluorescent) . A lighting structure 10078 may shine a light into the chamber based upon which ink is desired to show up in the image's sensor's field of view.

[00648] Fig. 140 shows a flow meter 10080 coupled to a drip chamber via latches 10082 in accordance with an embodiment of the present disclosure. There is a connection between the chamber and the fluid bag via a connection 10084. The drip chamber can snap-into the flow meter 10080 at the bottom of a drip chamber.

[00649] Figs. 141A-141B show a drip chamber having a fiducial 10088 on a wing and a fiducial 10090 within the drip chamber 70086 in accordance with an embodiment of the present disclosure. The liquid within the drip chamber 70086 can cause the fiducial 10090 to optically shift in position when the level of liquid is above the fiducial 10090. This change in optical position (from Fig. 141A to Fig. 141B) can be used by the image sensor as an indication that the liquid is above the fiducial 10090. The fiducial 10088 may be used by the image sensor to determine the position of the drip chamber 10086.

[00650] Fig. 142A shows a drip chamber 10092 with a bar code 10094 in accordance with an embodiment of the present disclosure. Fig. 142B shows several exemplary barcodes 10096 that may be used on the drip chamber. Fig. 143 shows a drip chamber with an RFID tag 10100.

[00651] Fig. 144 shows a schematic drawing of a shuttle pump 10102 using duckbill check valves 10104, 10106 in accordance with an embodiment of the present disclosure. Any mechanical pulsing between the valves 10104, 10106 back and forth will cause fluid to flow in a direction as allowed by the valves. The pulsing pushes the fluid through the correction direction through the unidirectional valve when the pulse pushes the liquid in that direction. The

shaking can occur away from a drip chamber preventing the drops from shaking too much.

[00652] Fig. 145 shows a schematic drawing of a shuttle pump 10108 in accordance with an embodiment of the present disclosure. There are two one-way valves 10110, 10112, and a shuttle 10114 subject to pulsing. Pulsing causes fluid to go in a direction as allowed by the valves 10110, 10112.

[00653] Fig. 146 shows a schematic drawing of a shuttle pump 10116 using an eccentric cam 10120 coupled to a motor 10118 accordance with an embodiment of the present disclosure. As the motor actuates the cam 10120, it causes the shuttle 10116 to pulse as shown by the arrow. The back and force allows two one-way valves to pulse fluid through the shuttle as indicated by the flow arrows.

[00654] Fig. 147 shows a drip chamber 10122 using a piston pump 10124 and check valves 10126, 10128 in accordance with an embodiment of the present disclosure. As the piston pump 10124 actuates, the check valves 10126, 10128 pump fluid downward.

[00655] In alternative embodiments, a slug or sponge may be added to the chamber 10122 at the bottom of the chamber a slug or sponge that has a one way valve, only allowing flow “down”. This will float or absorb to the top of the prime level. Using an electromagnet in the device, the slug can be pushed down, forcing the fluid out the bottom of the drip chamber and pulling more fluid in from the spout. This allows us to integrate the pumping mechanism into the drip chamber and monitor the drops with the image sensor mentioned here.

This may replace and/or supplement the check valves 10126, 10128. The drop chamber 10122 may be used within autopriming.

[00656] In some embodiments, the correct drug may be cross checked by using laser diffraction through the drop. When the first drop is acquired in the start up process, the flow can be halted temporarily and laser diffraction done on the solution. By characterizing these it can be determine what the solution that is about to be infused is prior to infusing.

[00657] Identification of the fluid may be done by density. By adding small rings in the drip chamber that are free floating and of different densities, the image sensor can observe which rings float to the top of the prime and which sank to the bottom to determine the fluid density. The rings are correlated with density of the fluid. The identification of the fluid may be done on a drop size basis using the image sensor.

[00658] Various alternatives and modifications can be devised by those skilled in the art without departing from the disclosure. Accordingly, the present disclosure is intended to embrace all such alternatives, modifications and variances. Additionally, while several embodiments of the present disclosure have been shown in the drawings and/or discussed herein, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. And, those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto. Other elements, steps, methods and techniques that are insubstantially

different from those described above and/or in the appended claims are also intended to be within the scope of the disclosure.

[00659] The embodiments shown in the drawings are presented only to demonstrate certain examples of the disclosure. And, the drawings described are only illustrative and are non-limiting. In the drawings, for illustrative purposes, the size of some of the elements may be exaggerated and not drawn to a particular scale. Additionally, elements shown within the drawings that have the same numbers may be identical elements or may be similar elements, depending on the context.

[00660] Where the term "comprising" is used in the present description and claims, it does not exclude other elements or steps. Where an indefinite or definite article is used when referring to a singular noun, e.g., "a," "an," or "the," this includes a plural of that noun unless something otherwise is specifically stated. Hence, the term "comprising" should not be interpreted as being restricted to the items listed thereafter; it does not exclude other elements or steps, and so the scope of the expression "a device comprising items A and B" should not be limited to devices consisting only of components A and B. This expression signifies that, with respect to the present disclosure, the only relevant components of the device are A and B.

[00661] Furthermore, the terms "first," "second," "third," and the like, whether used in the description or in the claims, are provided for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances (unless clearly disclosed

otherwise) and that the embodiments of the disclosure described herein are capable of operation in other sequences and/or arrangements than are described or illustrated herein.

What is claimed is:

1. A drip chamber, comprising:

a drip-chamber housing defining a fluid chamber;

a top cap coupled to the drip-chamber housing;

a bottom cap coupled to the drip-chamber housing at an opposite end of the drip-chamber housing from the top cap;

an inlet port coupled to the top cap and in fluid communication with the fluid chamber;

an outlet port coupled to the bottom cap and in fluid communication with the fluid chamber;

a drip orifice coupled to the top cap and fluidly coupled to the inlet port;

a downstream tube coupled to the bottom cap and in fluid communication with the fluid chamber of the drip-chamber housing the tube having a first length; and

an anti-pinch member disposed on a portion of the downstream tube in spaced relation to the drip-chamber housing, the anti-pinch member defining a second length, the anti-pinch member configured to collapse the tube along the second length of the anti-pinch member to thereby impede fluid flow therethrough, the first length being greater than the second length.

2. The drip chamber according to claim 1, wherein the anti-pinch member is disposed on an inner periphery of the downstream tube.

3. The drip chamber according to claim 1, wherein the anti-pinch member is a sleeve disposed adjacent to a section of the downstream tube including a plurality of parallel wires disposed within the sleeve.

4. The drip chamber according to claim 1, wherein the anti-pinch member is a sleeve disposed on an inner periphery of the downstream tube.

5. The drip chamber according to claim 1, wherein the anti-pinch member is a sleeve having a plurality of wires that are parallel to the downstream tube.

6. The drip chamber according to claim 5, wherein the plurality of wires are metallic.

7. The drip chamber according to claim 5, wherein the plurality of wires are non-metallic.

8. The drip chamber according to claim 5, wherein the plurality of wires are embedded within the sleeve.

9. The drip chamber according to claim 1, wherein the tube is configured to collapse along substantially an entirety of the second length upon application of a force thereto.