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(54) **SELECTIVELY CONTROLLING FLUID FLOW THROUGH A FLUID PATHWAY**

(71) Applicant: **CRISI Medical Systems, Inc.**, San Diego, CA (US)

(72) Inventors: **Stephen Michael Prince**, La Jolla, CA (US); **Walter John Bochenko**, Encinitas, CA (US); **Winthrop De Childers**, San Diego, CA (US)

(73) Assignee: **CRISI Medical Systems, Inc.**, Franklin Lakes, NJ (US)

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See application file for complete search history.

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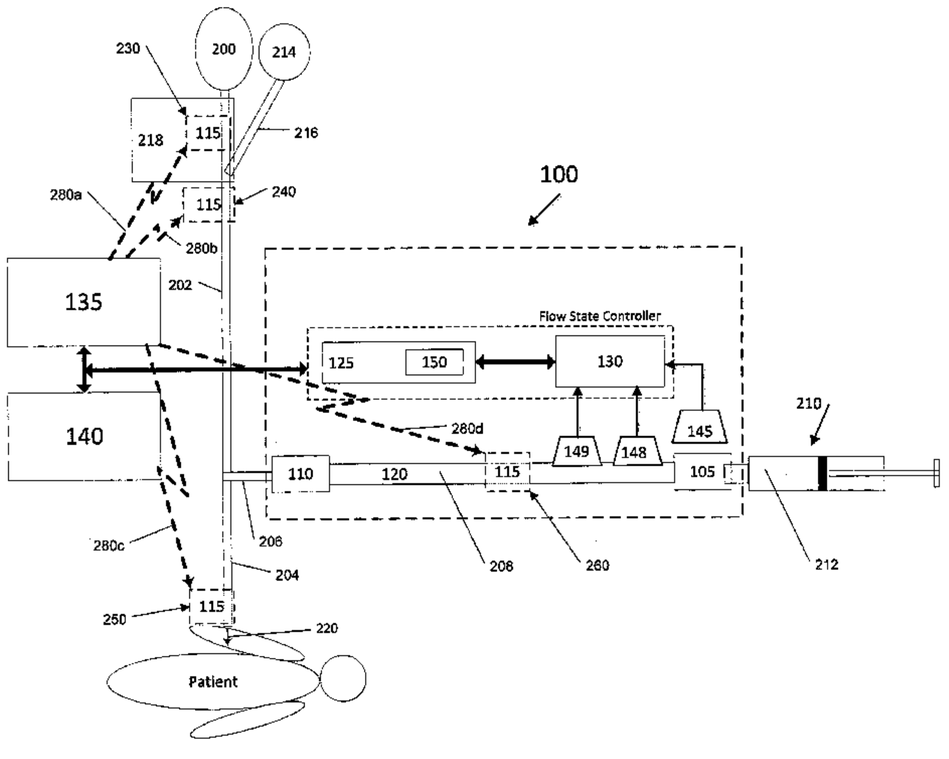
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Primary Examiner — Imani Hayman
Assistant Examiner — Nilay Shah
(74) *Attorney, Agent, or Firm* — The Webb Law Firm

(57) **ABSTRACT**

Systems and methods for controlling fluid delivery via a manually administrable medication container to a patient through a fluid delivery pathway are provided. The systems and methods described herein incorporate rules-based clinical decision support logic to drive a flow control valve within a flow pathway based on a determination of whether or not an IV fluid connected to an input port on the pathway is appropriate for patient administration by considering such factors as patient-specific clinical circumstances, current medical orders, and accepted delivery protocols. Related apparatus, systems, methods and articles are also described.

65 Claims, 10 Drawing Sheets



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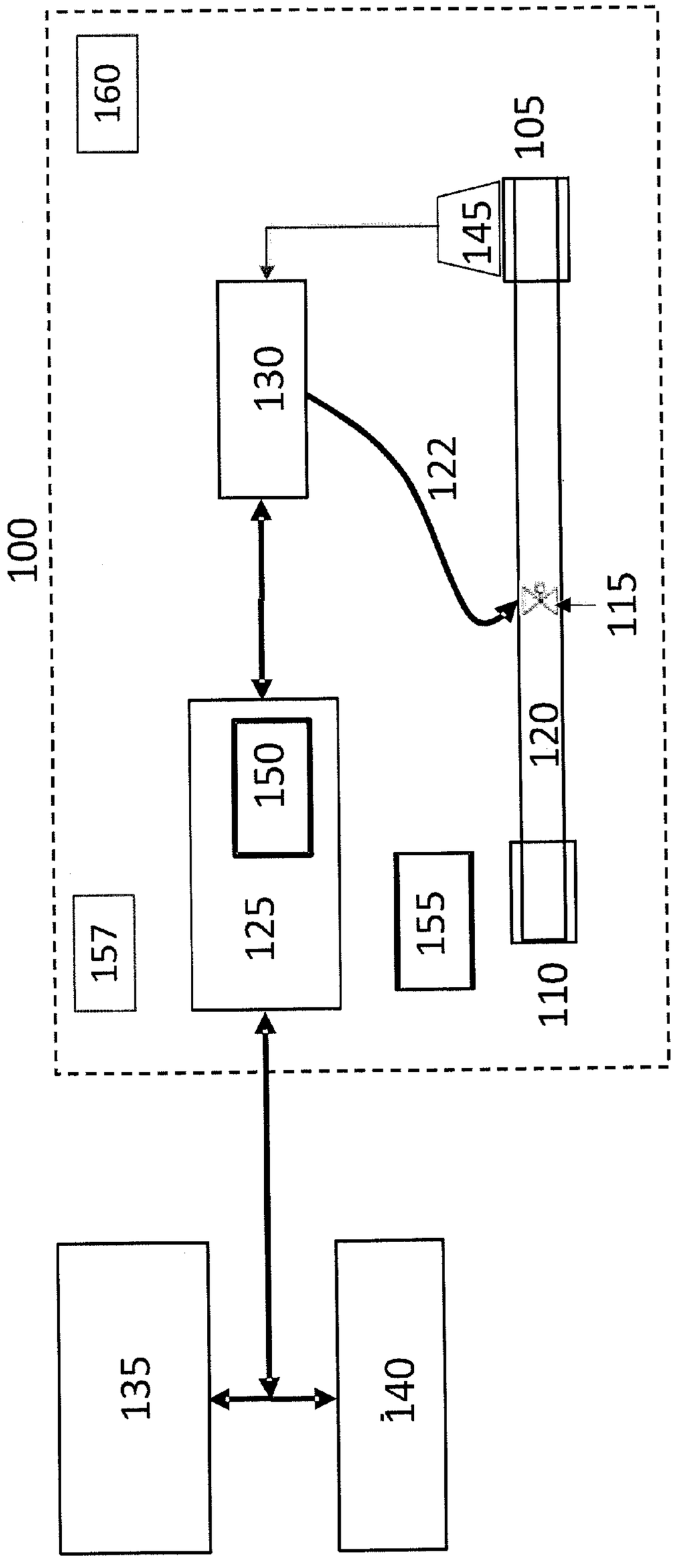


FIG. 1

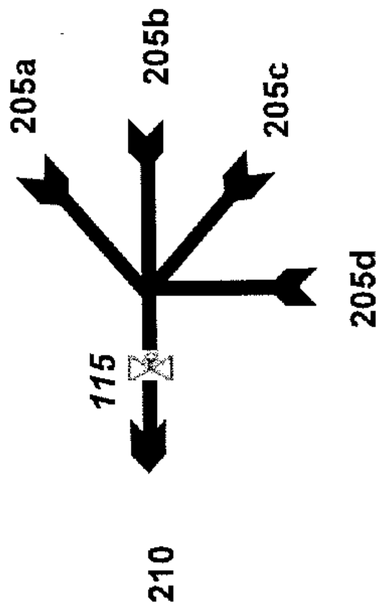


FIG. 2E

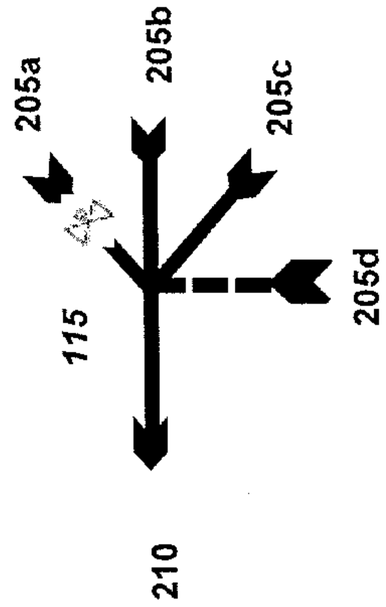


FIG. 2F

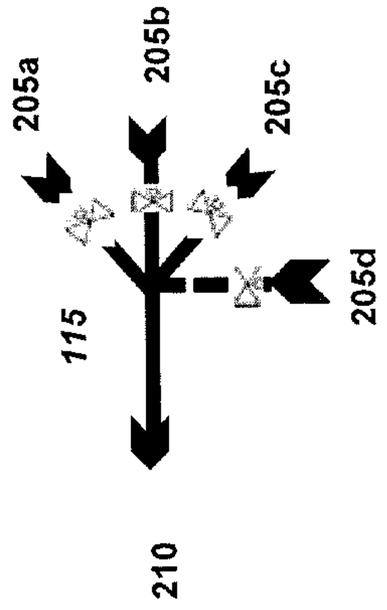


FIG. 2G

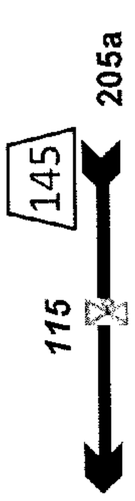


FIG. 2A

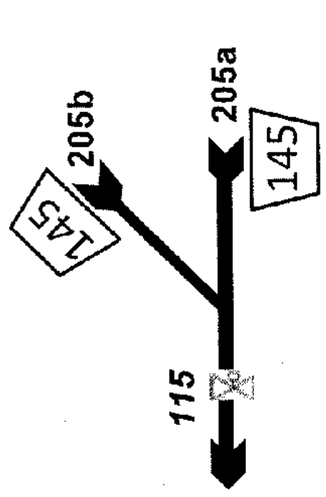


FIG. 2B

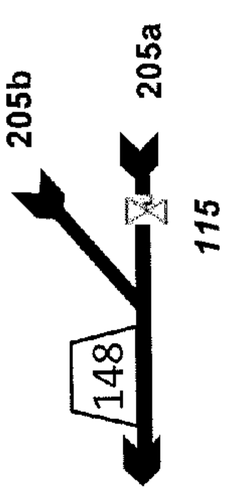


FIG. 2C

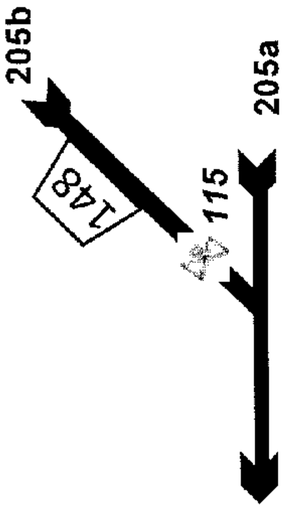


FIG. 2D

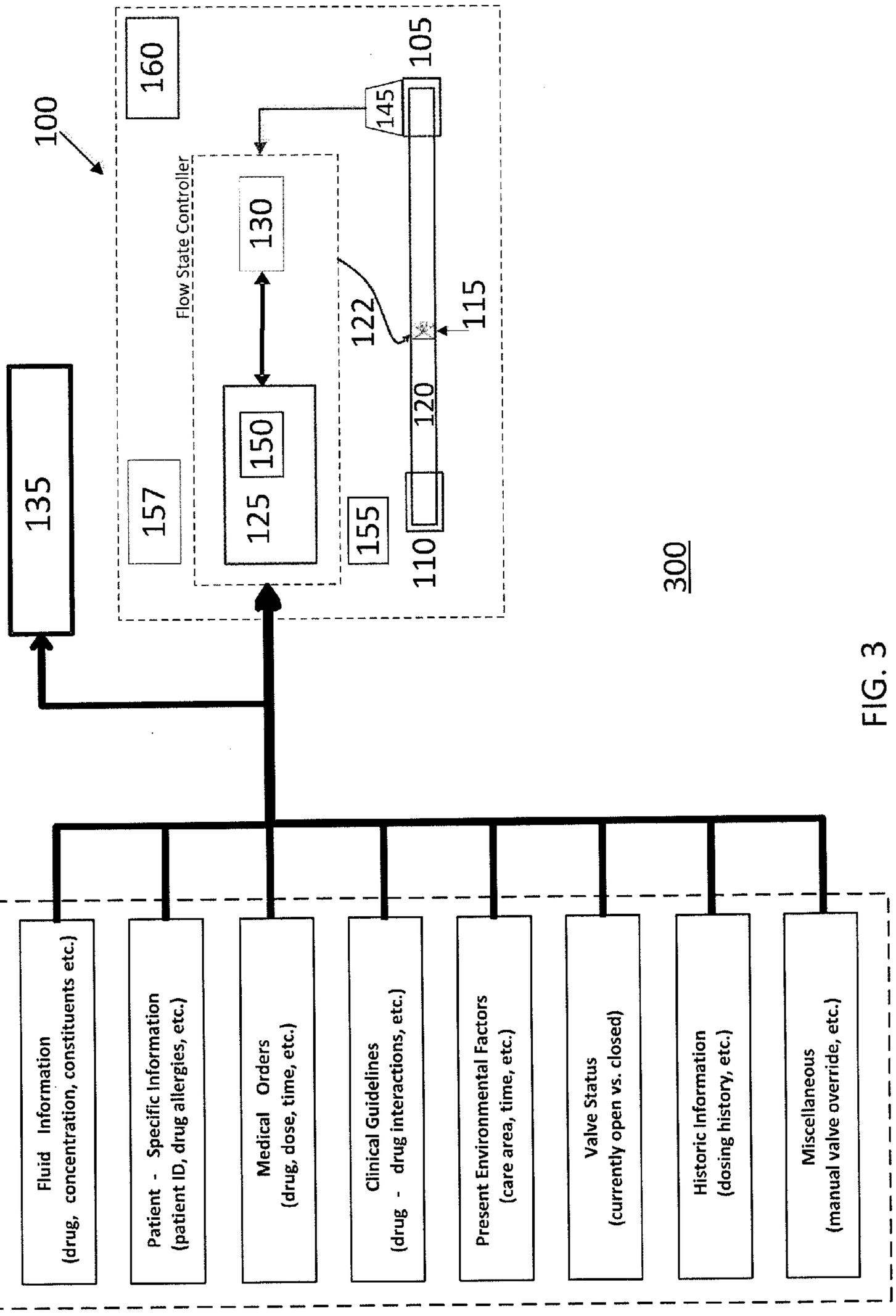

100
160
105
145
Flow State Controller
130
122
115
120
135
157
125
150
155
110
300
140
Flow Control Input Data
Fluid Information
(drug, concentration, constituents etc.)
Patient - Specific Information
(patient ID, drug allergies, etc.)
Medical Orders
(drug, dose, time, etc.)
Clinical Guidelines
(drug - drug interactions, etc.)
Present Environmental Factors
(care area, time, etc.)
Valve Status
(currently open vs. closed)
Historic Information
(dosing history, etc.)
Miscellaneous
(manual valve override, etc.)

FIG. 3

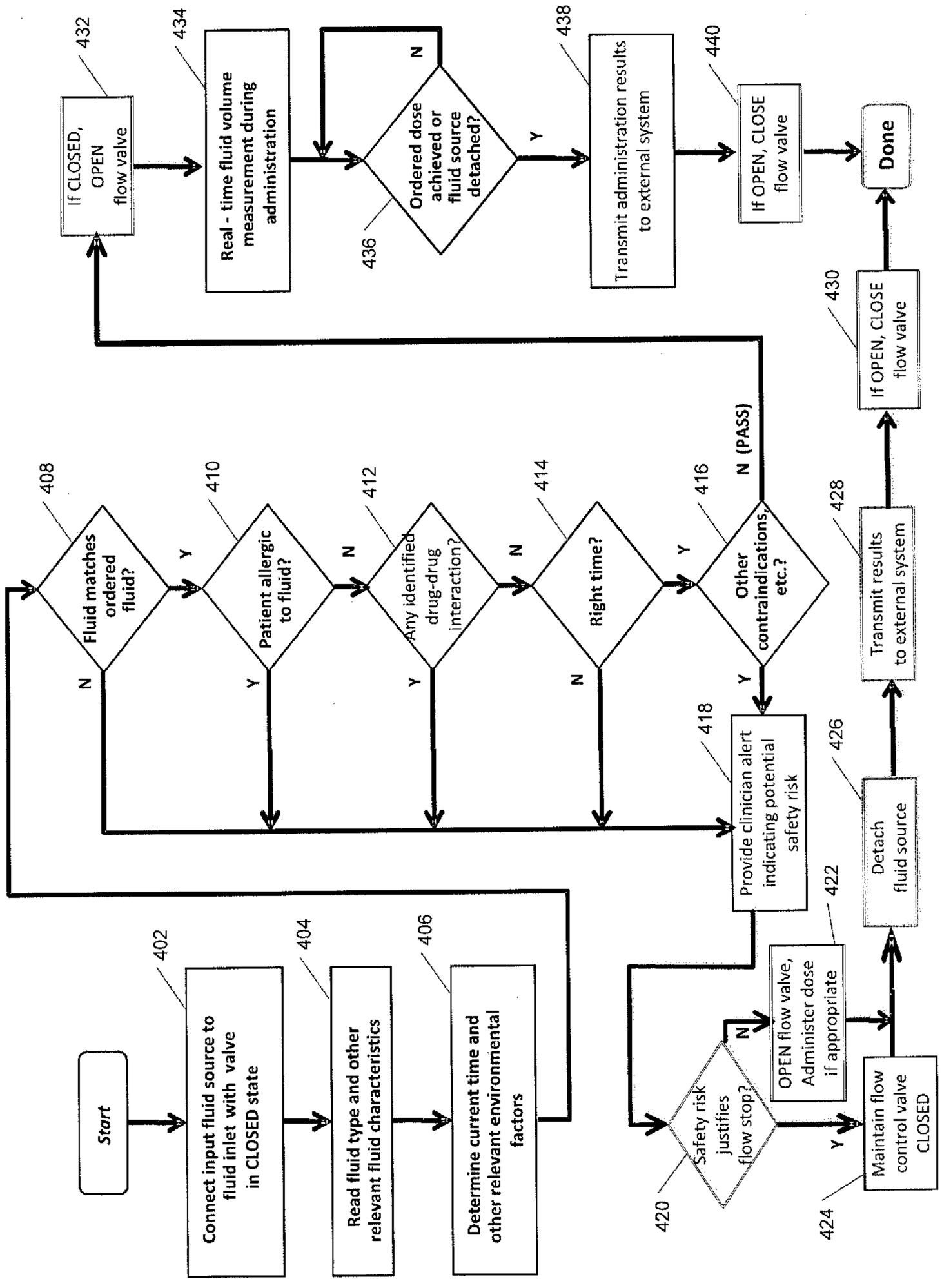

Start
402
Connect input fluid source to fluid inlet with valve in CLOSED state
404
Read fluid type and other relevant fluid characteristics
406
Determine current time and other relevant environmental factors
408
Fluid matches ordered fluid?
410
Patient allergic to fluid?
412
Any identified drug-drug interaction?
414
Right time?
416
Other contraindications, etc.?
N (PASS)
418
Provide clinician alert indicating potential safety risk
420
Safety risk justifies flow stop?
422
OPEN flow valve, Administer dose if appropriate
424
Maintain flow control valve CLOSED
426
Detach fluid source
428
Transmit results to external system
430
If OPEN, CLOSE flow valve
432
If CLOSED, OPEN flow valve
434
Real - time fluid volume measurement during administration
436
Ordered dose achieved or fluid source detached?
438
Transmit administration results to external system
440
If OPEN, CLOSE flow valve
Done
Y
N
400

FIG. 4

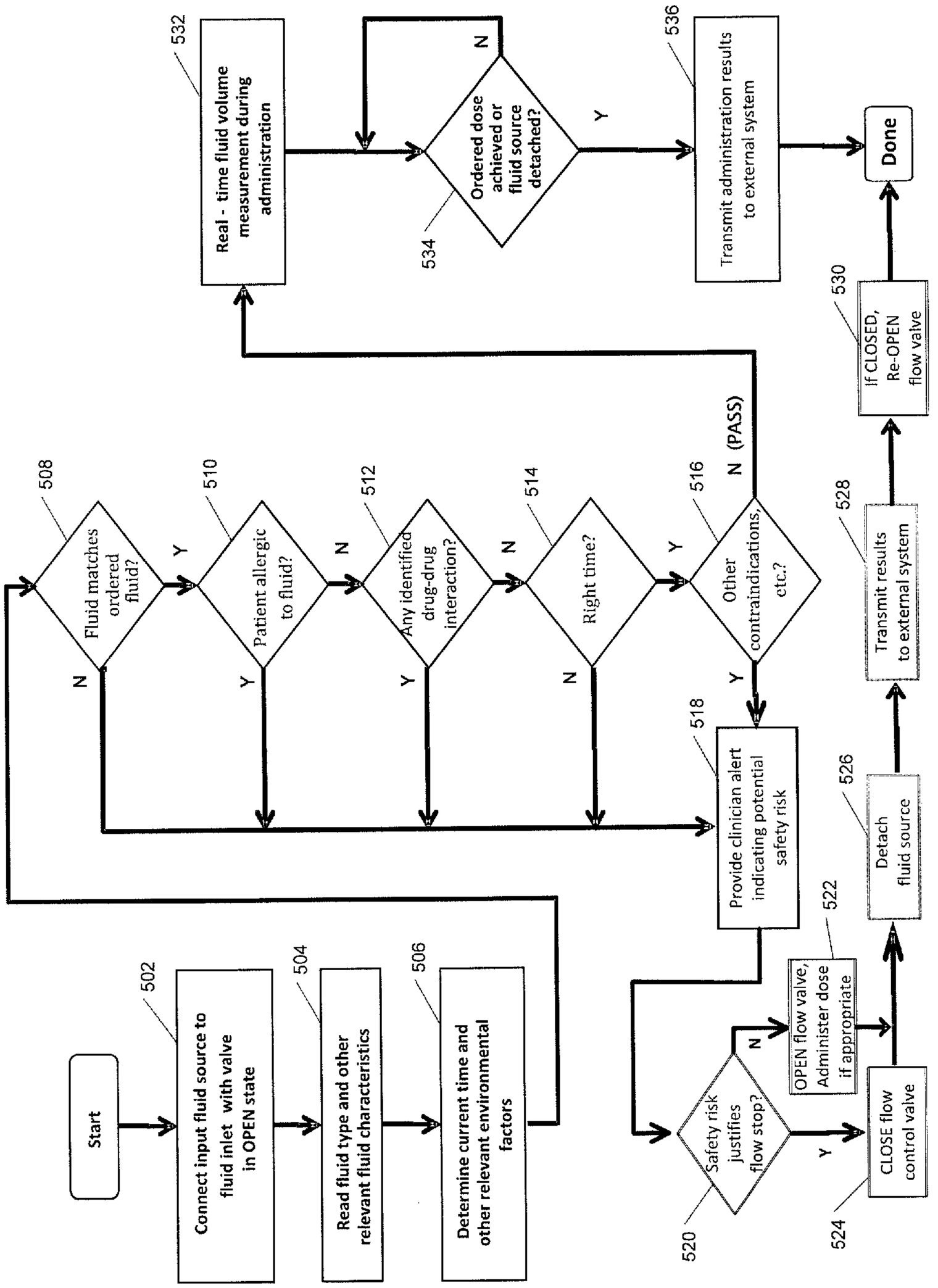

Start
502
Connect input fluid source to fluid inlet with valve in OPEN state
504
Read fluid type and other relevant fluid characteristics
506
Determine current time and other relevant environmental factors
Real - time fluid volume measurement during administration
532
Fluid matches ordered fluid?
508
Patient allergic to fluid?
510
Any identified drug-drug interaction?
512
Right time?
514
Other contraindications, etc.?
516
N (PASS)
Y
N
Provide clinician alert indicating potential safety risk
518
Safety risk justifies flow stop?
520
OPEN flow valve, Administer dose if appropriate
522
CLOSE flow control valve
524
Detach fluid source
526
Transmit results to external system
528
If CLOSED, Re-OPEN flow valve
530
Ordered dose achieved or fluid source detached?
534
Transmit administration results to external system
536
Done
500

FIG. 5

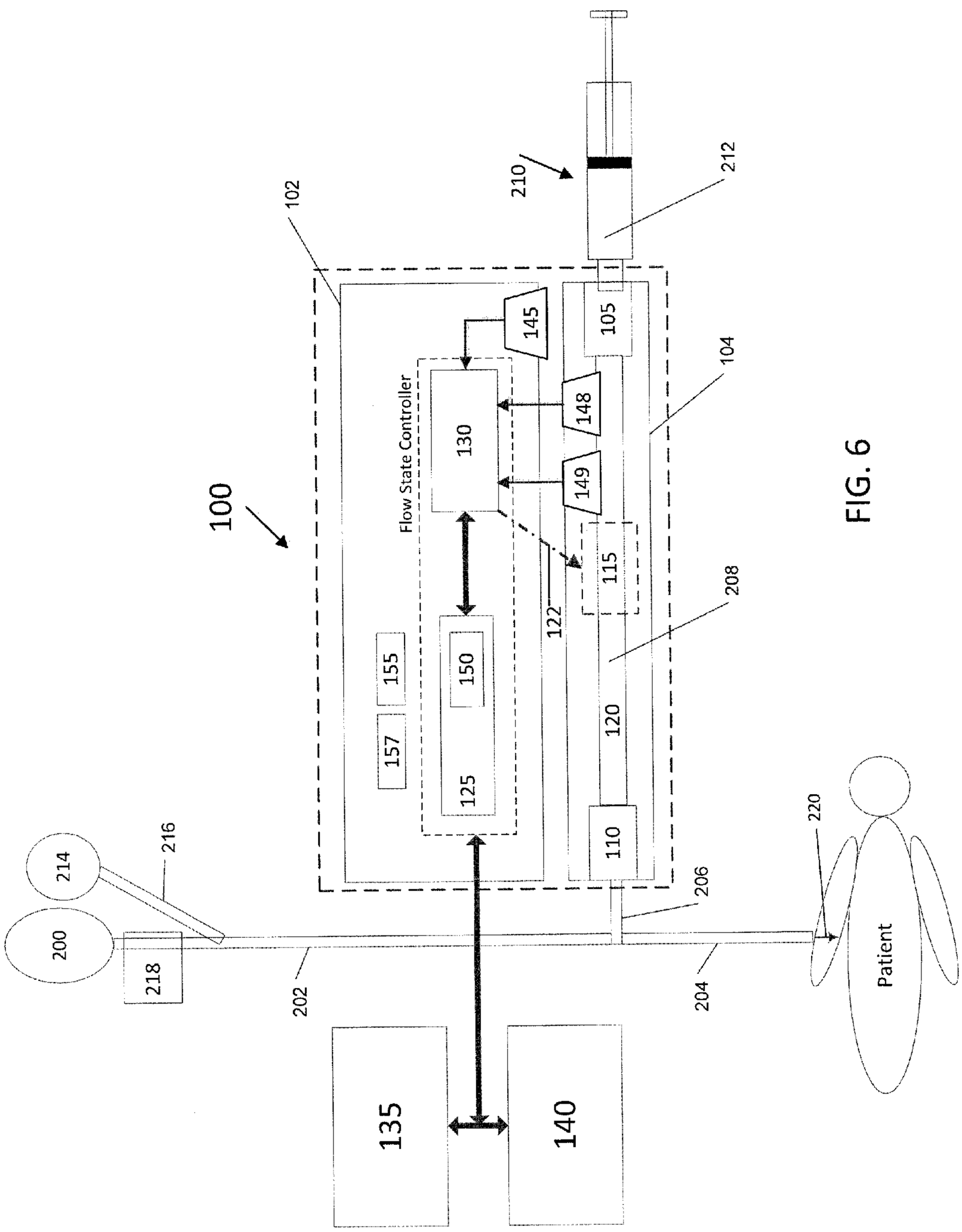

100
102
210
212
105
145
104
148
130
149
Flow State Controller
115
122
208
155
150
157
125
120
110
206
216
214
200
218
202
204
220
Patient
135
140

FIG. 6

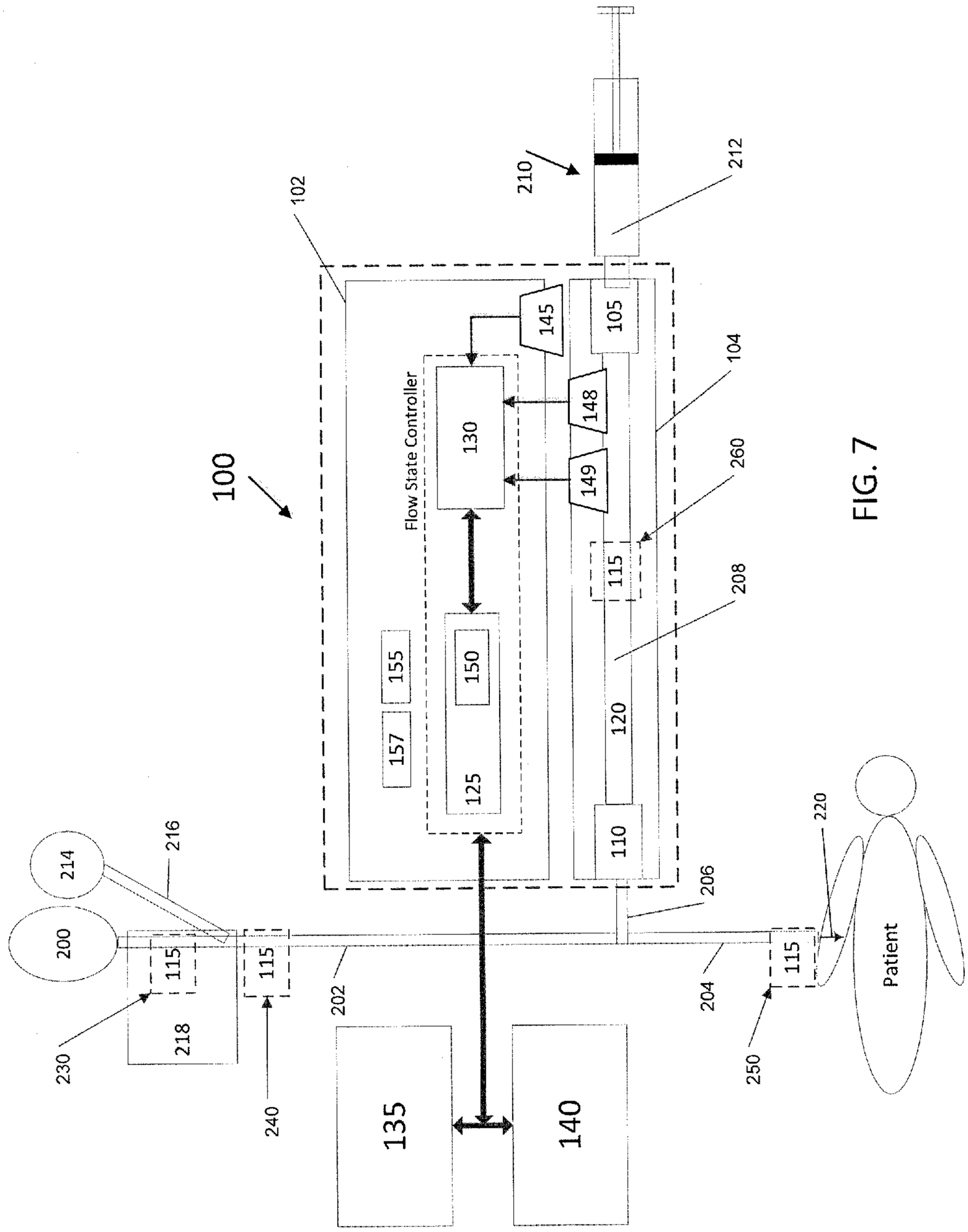

100
102
210
212
104
105
145
148
149
130
Flow State Controller
260
115
208
120
155
150
157
125
110
206
214
216
200
115
115
218
230
202
204
115
250
240
135
140
220
Patient

FIG. 7

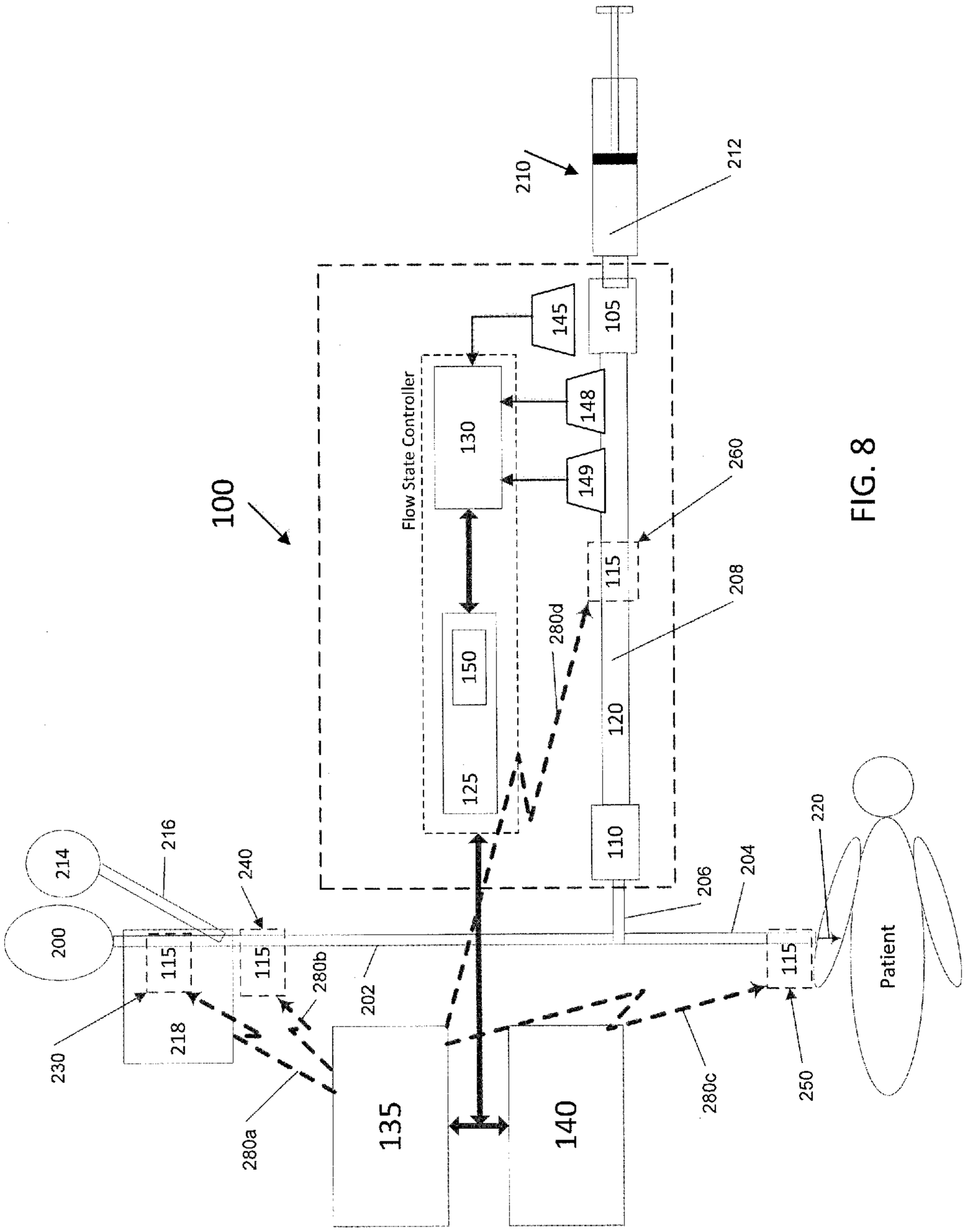

100
Flow State Controller
130
145
148
149
105
115
150
125
120
110
135
140
280d
280a
280b
280c
208
260
210
212
214
216
240
200
218
230
202
206
204
220
250
Patient

FIG. 8

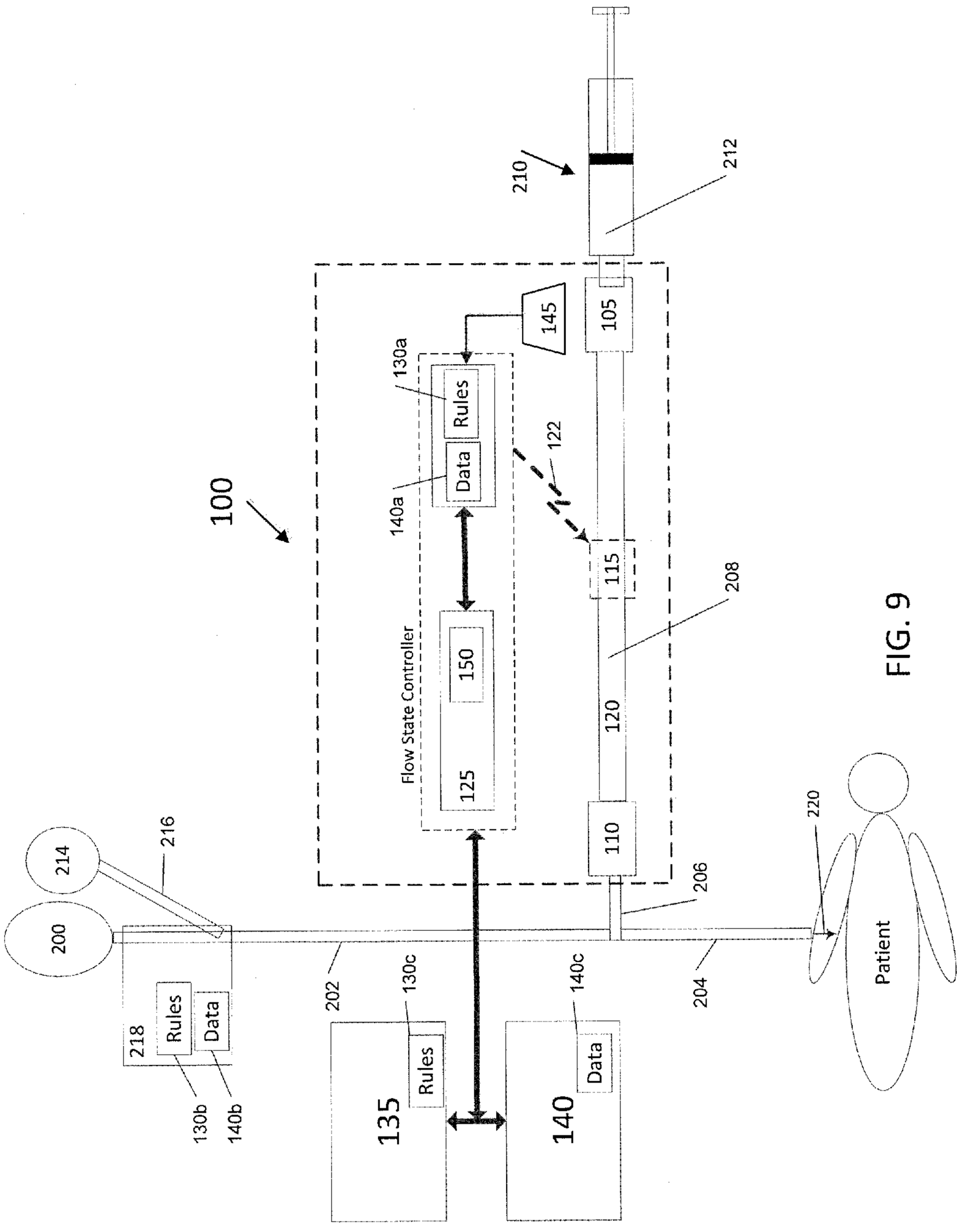

100
210
212
105
145
130a
Rules
Data
140a
122
115
208
Flow State Controller
150
125
120
110
206
214
216
200
218
Rules
Data
130b
140b
202
130c
Rules
135
140c
Data
140
204
220
Patient

FIG. 9

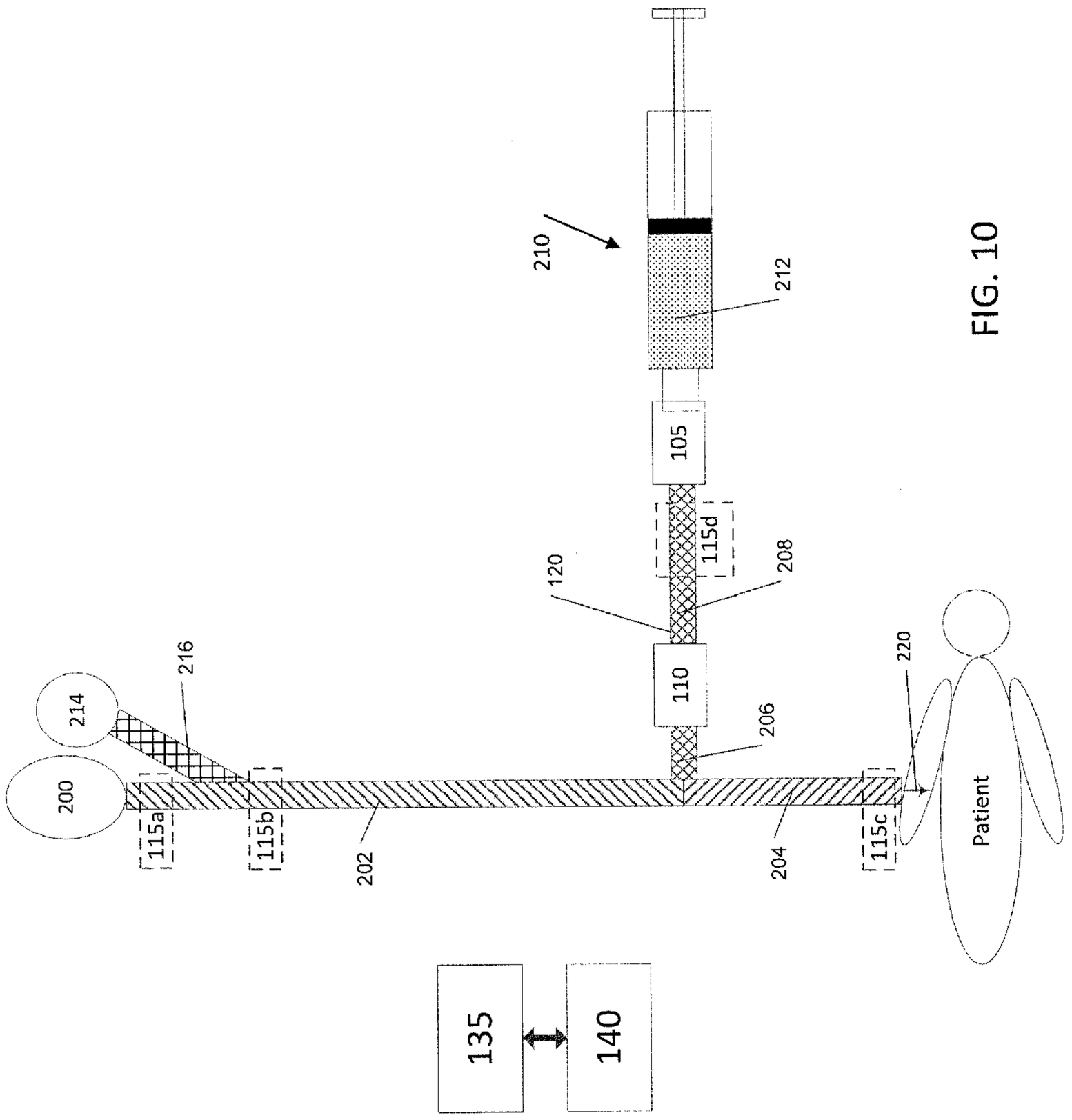

135
140
200
214
216
115a
115b
202
110
120
115d
208
105
210
212
206
204
115c
220
Patient

FIG. 10

SELECTIVELY CONTROLLING FLUID FLOW THROUGH A FLUID PATHWAY

RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 13/529,876 filed on Jun. 21, 2012, and additionally, priority is also claimed to U.S. Pat. App. Ser. No. 61/500,073, filed on Jun. 22, 2011. Each of the aforementioned patent applications are entitled: "Selectively Controlling Fluid Flow Through a Fluid Pathway", and are hereby fully incorporated by reference.

FIELD

The subject matter described herein relates to systems and methods for controlling fluid flow to a patient through a fluid pathway.

BACKGROUND

There are a number of patient clinical settings including in-hospital, outpatient, in-home care and emergency medical services (EMS) that require fluid administration to a patient. Standard clinical best practice is to label fluids intended to be delivered to patients to reduce the potential for errors. However, mistakes in compatibility of fluids with a particular patient, incorrect dose measurements, inappropriate sequence of medications, incorrect transfer of labeling information and other factors continue to be major obstacles to overcome in providing safe patient care

SUMMARY

The systems, apparatus, methods, and articles described herein provide mechanisms for preventing and/or mitigating patient fluid administration errors.

In one aspect, a system is provided that includes a fluid port, at least one sensor, a flow controller, and a flow control valve. The fluid port can include a fluid channel, a fluid inlet at a first end of the fluid channel configured to couple to an outlet of a manually administrable fluid source, and a fluid outlet at a second end of the fluid channel configured to deliver fluid from the manually administrable fluid source to a fluid pathway that provides fluid to a patient. The at least one sensor characterizes at least one attribute of the fluid from the manually administrable fluid source. The flow controller is in communication with the at least one sensor and generates at least one flow modification signal in response to the characterized at least one attribute matching at least one condition specified by at least one rule. The flow control valve is in communication with the flow controller and positioned along the fluid pathway at a location separate and distinct from the fluid port. The flow control valve changes a level of flow restriction of fluid from the manually administrable fluid source passing therethrough in response to receiving the at least one flow modification signal.

The at least one sensor can characterize at least one attribute of the fluid from the manually administrable fluid source (i) when the manually administrable fluid source is being coupled to the fluid inlet, (ii) when the manually administrable fluid source is coupled to the fluid inlet, and/or (iii) when fluid is passing through the fluid channel.

The at least one sensor can be integral or coupled to the fluid port. In other variations, the at least one sensor can be separate and distinct from the fluid port. In addition, multiple flow control valves at different points along the fluid pathway can be implemented in some variations. In addition, the flow control valve can be on the fluid pathway downstream from the fluid port and/or upstream from the fluid port.

Changing a level of flow restriction of fluid from the manually administrable fluid source passing through the flow control valve can include (i) stopping all fluid from passing through the flow control valve, and/or (ii) adjusting a current flow rate of fluid passing through the flow control valve to a higher or lower flow rate.

The flow controller can include or be in communication (e.g., via a computer network, via a wireless network, etc.) with a rules engine (which can be software and/or hardware implemented). Such a rules engine can use a plurality of rules to determine whether the at least one attribute matches the at least one condition specified by the at least one rule. The flow controller can, in some variations, poll at least one remote data source to obtain at least a portion of the rules. The rules engine, when applying the rules, can use (i) the at least one attribute, (ii) manually-entered user input, and (iii) flow control input data selected from a group consisting of: fluid information, patient-specific information, medical order information, clinical guideline information, environmental factors, flow control valve status, and historical information in order to determine whether there is a match for the at least one condition.

The fluid port can include a wireless transceiver for transmitting and receiving data to and from the flow controller, and the flow controller further comprises a wireless transceiver for transmitting and receiving data to and from the fluid port. In addition, the flow controller can transmit data to an external device other than the fluid port characterizing a state of the flow control valve.

The outlet of the manually administrable fluid source can include fluid source information encoded thereon. In such cases, the at least one sensor can include an identification sensor that detects the manually administrable fluid source information when the manually administrable fluid source is being coupled or is coupled to the fluid port inlet. The fluid source information can be a code or identifier used to reference a secondary data set that is characteristic of the fluid contained within the manually administrable fluid source. This secondary data set can be stored in memory (which can optionally form part of the fluid port). The secondary data set can be stored in a remote data source coupled to the flow controller via a communications network. The remote data source can form part of a medical device and/or a medical information system. The at least one flow modification signal can be generated using a rules engine that processes the detected fluid source information.

The at least one sensor can be a fluid composition sensor that characterizes a composition of fluid. The fluid composition sensor can be located along the fluid channel between the fluid inlet and fluid outlet. The at least one attribute can be indicative of at least one constituent present in fluid flowing through the channel. The at least one flow modification signal can be generated using a rules engine that processes the result of the sensed fluid composition information.

Contents from the manually administrable fluid source do not reach the patient for at least a time T**1** after the manually administrable fluid source begins fluid delivery into the fluid inlet. To accommodate this arrangement, the flow controller and the flow control valve can be configured to restrict flow in the fluid pathway within a time T**2**<T**1** after the manually administrable fluid source begins fluid delivery into to the fluid inlet.

Various elements forming part of the system may have wireless transmitters, receivers, and/or transceivers. A wireless transmitter can be provided to transmit data from the at least one sensor to the flow controller. A wireless transceiver can be coupled to the flow controller to receive and transmit data relating to operation of the flow control valve. A wireless receiver can be coupled to the flow control valve to receive a flow modification signal from the flow controller. A wireless transmitter can be coupled to the flow control valve to send information to the flow controller indicative of a change in the level of fluid flow restriction being applied to fluid passing through the flow control valve in response to receiving the at least one flow modification signal from the flow controller.

The at least one sensor can be any of a variety of sensors including identification sensors, flow sensors, and composition sensors.

The fluid can be a medication and the at least one attribute can characterize one or more: medication type, medication concentration, medication volume, medication expiration date, a dosage form of the medication, dose instructions for the medication, administration instructions for a specific patient, medication formulation, medication manufacturer information, a re-packager of the medication, a distributor of the medication, medication package form, medication package size, medication package serial number, medication lot number, blood type, an RxNorm identification code, an NDC code (National Drug Code), a segment of an NDC code identifying a corresponding medication product, a segment of an NDC code identifying a corresponding medication package, a unique identifier code, a human readable alphanumeric string, and a machine readable code.

The at least one flow modification signal can be automatically initiated and executed by the flow controller without user intervention. The at least one flow modification signal can be automatically initiated and executed by the flow controller as a result of coupling the outlet of the manually administrable fluid source to the fluid inlet and/or as a result of sensing the start of fluid flow into the fluid inlet.

An interface (e.g., display, GUI, etc.) can be included that provides audio and/or visual feedback to a user characterizing the at least one attribute and/or fluid contained within the manually administrable fluid source. The interface can provide an indication to the user of a state of the flow control valve. The interface can allow a user to input information to be used by the flow controller, in combination with information from the at least one sensor, to determine whether to generate the at least one flow modification signal. In cases in which the fluid is medication, the interface can display administration information and/or instructions associated with the medication. Such administration information and/or instructions can be stored within memory forming part of the system. A communications module can be provided to transmit and/or receive the administration information and/or instruction to/or from a remote data source. The interface can be adjacent to the fluid port or remote from the fluid port. The interface can display information about various aspects of fluid flow such as flow rate, composition, and the like.

A manual override element can be provided, which when activated by a user, causes the flow controller to cause the flow control valve to stop fluid flow in a first state or to allow fluid to flow in a second state.

A communications module can be provided to transmit and/or receive flow control input data, rules engine output data and/or data characterizing the fluid source to or from a remote data processing system.

There can be a plurality of fluid inlets such that each is configured to couple to an outlet of one of a plurality of manually administrable fluid sources. There can be a corresponding number of flow control valves that are coupled to the flow controller to selectively prevent fluid flowing from at least one of the plurality of fluid inlets.

The flow controller can receive data specifically relating to the patient that can be used, in combination with information from the at least one sensor and/or information manually-entered by the user, to determine whether to generate the at least one flow modification signal. Data relating to the patient can include at least one medication order. The at least one medication order can be used to confirm whether the fluid in the manually administrable fluid source matches the at least one condition specified by the at least one rule specified by the at least one medication order. The data characterizing the patient can include a patient identifier and the flow controller can poll at least one remote data store using the patient identifier to obtain reference information to determine whether to generate the at least one flow modification signal.

The at least one sensor can be a fluid flow sensor. Fluid flow information sensed by the fluid flow sensor can cause the flow controller to generate a first flow modification signal to cause the flow control valve to transition to a first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, cause the flow controller to generate a second flow modification signal to cause the flow control valve to transition to a second state different than the first state.

The at least one sensor can be an identification sensor that generates the at least one attribute using one or more technologies selected from a group including: optical, magnetic, mechanical, conductive, switchable, infrared, switchable RFID, and proximity sensors.

The at least one sensor can be a composition sensor that generates the at least one attribute using one or more technologies selected from a group including: photometric analysis, electrometric analysis, chromatography, mass spectroscopy, physical property measurements, or parametric analysis based on a combination of technologies.

The at least one sensor can be a fluid flow sensor that generates the at least one attribute using one or more technologies selected from a group including: a paddle wheel flow meter, a turbine flow meter, a thermal flow meter, an ultrasonic flow meter, a pressure sensor, a differential pressure sensor, an optical sensor, an ultrasonic sensor, a coriolis flow meter, a displacement sensor.

Some or all of the system can be enclosed by a housing. The housing can take different shapes and sizes. In some implementations, the housing envelopes at least a portion of each of the fluid inlet, the fluid outlet, the flow controller, and the at least one sensor. The housing can have a shape and size allowing a user to hold the housing in a first hand while coupling the manually administrable fluid source in a second hand. A self-contained power source can be provided within the housing to power the at least one sensor and/or other components. The fluid pathway can be an intravenous (IV) fluid line and the housing can be suspended on the IV fluid line.

The housing can include a reusable sub-housing and a disposable sub-housing. The reusable sub-housing can be operatively coupled to the disposable sub-housing and the reusable sub-housing is intended for use by a plurality of patients and the disposable sub-housing is intended for use by a single patient. In some variations, the at least the fluid

inlet, fluid outlet, and flow channel can be enclosed by the disposable sub-housing. The disposable sub-housing can be included in a sterile pouch enveloping the disposable sub-housing. Memory can be placed within the disposable sub-housing for storing data used by the flow controller to determine whether to generate the at least one flow modification signal.

The manually administrable fluid source can be of any variety of medication containers/delivery mechanisms. Examples include, but are not limited to, syringes, IV bags, disposable medication cartridges, disposable medication pouches, and IV tubing.

In an interrelated aspect, a system includes a fluid port, at least one sensor, a controller, and a transmitter. The fluid port includes a fluid channel, a fluid inlet at a first end of the fluid channel configured to couple to an outlet of a manually administrable fluid source, a fluid outlet at a second end of the fluid channel configured to deliver fluid from the manually administrable fluid source to a fluid pathway that provides fluid to a patient. The at least one sensor characterizes at least one attribute of the fluid from the manually administrable fluid source. The controller is in communication with the at least one sensor and it generates at least one operation modification signal in response to the characterized at least one attribute matching at least one condition specified by at least one rule. The transmitter wirelessly transmitting the operation modification signal to at least one device such that the operation modification signal, when received by the at least one device, causes the at least one device to modify at least one operating parameter. With this variation, different types of devices can be used other than a flow controller (although the operation modification signal can also act to cause a flow controller to modify some parameter relating to fluid flow). For example, a medical device interacting with the fluid pathway can cause the fluid flow within the fluid pathway to be adjusted and/or other non-fluid flow operating parameters of a medical device can be modified.

In another variation, different types of external devices (e.g. infusion pumps, syringe pumps, etc.) can receive operation modification signals from the flow controller and take appropriate actions. For example, a medical device interacting with the fluid pathway can, in response to an operation modification signal, cause the fluid flow within the fluid pathway to be stopped. Alternatively, other non-fluid flow operating parameters of a medical device, such as the posting of an alert or the logging of a flow rate, can be modified (i.e. acted upon) based on receipt of an operation modification signal.

In a further interrelated aspect, data is received that is generated by at least one sensor of a fluid port characterizing at least one attribute of fluid within a manually administrable fluid source. The fluid port includes a fluid channel, a fluid inlet at a first end of the fluid channel configured to couple to an outlet of the manually administrable fluid source, and a fluid outlet at a second end of the fluid channel configured to deliver fluid from the manually administrable fluid source to a fluid pathway that provides fluid to a patient, and the at least one sensor. Thereafter, it can be determined that the at least one attribute in the received data matches at least one condition specified by at least one rule. In response, at least one flow modification signal is generated. The at least one flow modification signal, when received by a flow control valve, causes the flow control valve to change a level of fluid flow restriction being applied to fluid passing through the flow control valve.

In another aspect, an apparatus includes a fluid inlet, a fluid outlet, a flow control valve, an identification sensor, and a flow controller. The fluid inlet is configured to couple to an outlet of a manually administrable fluid source having fluid source information encoded thereon. The fluid outlet is configured to deliver fluid from the manually administrable fluid source to a fluid line (pathway) leading to a patient. The flow control valve is disposed between the fluid inlet and the fluid outlet that prevents fluid flow in a first state and permits fluid flow in a second state. The identification sensor is positioned to detect the fluid source information when the manually administrable fluid source is being coupled or is coupled to the fluid inlet. The flow controller selectively causes the flow control valve to transition between the first state and the second state based on the fluid source information detected by the identification sensor.

The flow controller can use a plurality of rules to determine whether to transition the current state of the flow control valve to the other state. Some or all of the rules can be obtained from a remote data source polled by the flow controller. A rules engine (i.e., software and/or hardware for applying the rules, etc.) can take into account the fluid source information, flow control input data, and one or more attributes of the patient and their history, clinical circumstances, environmental factors, clinical best practices and the like. The rules engine can be configurable and programmable according to one or more of user-inputted specifications (via for example, an interface on the apparatus or via a remote computing system/interface, etc.), patient specific data, and/or medication specific data.

A fluid composition sensor can be additionally incorporated to characterize a composition of the fluid when the manually administrable fluid source is coupled to the fluid inlet. In some cases, the fluid composition sensor can be used in place of the identification sensor while in other implementations it is used in combination with the identification sensor. In either arrangement, the flow controller can further selectively cause the flow control valve to transition between the first state and the second state based on the fluid composition detected by the fluid composition sensor.

The flow controller can transmit data characterizing the fluid source information detected by the identification sensor to a remote rules engine that sends a signal indicating whether to change a current state of the flow control valve. The fluid source information can be indicative of a characteristic of the fluid (e.g., medication, etc.) contained therein and can include one or more of an RxNorm identification code, NDC code (National Drug Code), a segment of the NDC code identifying the drug product, a segment of the NDC code identifying the drug package, a unique identifier code, a human readable alphanumeric string, a machine readable code, a name of the medication, a manufacturer of the medication, a re-packager of the medication, a distributor of the medication, a strength of the medication, a dosage form of the medication, dose instructions for the medication, administration instructions for a specific patient, medication formulation, medication package form, medication package size, medication contained volume, medication package serial number, medication lot number, and medication expiration date, fluid type, and blood type. The fluid source information can include a code or identifier used to reference a secondary data set that is characteristic of the fluid contained therein (i.e., a reference to a lookup table, a database object, a URL, etc.). The apparatus can include memory that stores the secondary data set locally and/or a remote data store can be coupled to the flow controller that

stores the secondary data set. The remote data store can form part of a medical device or medical information system.

The transition between states can be automatically initiated and executed by the flow controller without user intervention. The transition between states can be automatically initiated and executed by the flow controller as a result of coupling the fluid source outlet to the fluid inlet.

An interface can be included to provide audio and/or visual feedback to a user characterizing one or more of the fluid source information, volume of fluid administration, rules engine information, and/or rules engine output. The interface can provide an indication to the user when the flow control valve is in the first state, an indication to the user of one or more rules used by a rules engine causing a flow control valve state transition, and/or an indication to the user without a flow control valve state transition. The interface can be adjacent to the fluid inlet and/or it can be remote from the fluid inlet (e.g., a display monitor wirelessly coupled to the flow controller, etc).

The interface can display medication administration information associated with the fluid. Such medication administration information can be stored on local memory. A communications module can be included to transmit and/or receive the medication administration information to or from a remote data source. The interface can be adjacent to or remote from the fluid inlet.

A manual override element, which when activated by a user, can cause the flow controller to cause the flow control valve to transition from the first state to the second state.

A communications module can be included to transmit and/or receive data to or from a remote data source characterizing one or more of the flow control input data, fluid source, the rules or a portion of the rules, and/or the patient.

In some implementations, there can be a plurality of fluid inlets that are each configured to couple to an outlet of one of a plurality of manually administrable fluid sources each having fluid source information thereon. In these arrangements, there can be a plurality of flow control valves that are each coupled to the flow controller to selectively prevent fluid flow in at least one of the plurality of fluid inlets.

The flow control valve can be maintained in the first state until it is determined, by using the fluid source information, to transition the flow control valve to the second state. The flow control valve can be maintained in the second state until it is determined, by using the fluid source information, to transition the flow control valve to the first state. The flow controller can receive data characterizing the patient that is used, in combination with the fluid flow source information, to determine whether to transition the current state of the flow control valve. The data characterizing the patient can include, for example, a medication order that is used to confirm whether the fluid in the fluid source matches one or more parameters specified by the at least one medication order. The data characterizing the patient can include a patient identifier that the flow controller uses to poll at least one remote data store using the patient identifier to obtain reference information for the flow controller to determine whether to transition the current state of the flow control valve.

A fluid flow sensor can be utilized that measures how much fluid has been delivered from the fluid source into the fluid inlet. The flow controller can cause the flow control valve to transition from the second state to the first state when a pre-determined volume has been delivered as measured by the fluid flow sensor. An interface can provide audio and/or visual feedback indicating how much fluid has been delivered as measured by the fluid flow sensor. The flow controller can cause the flow control valve to transition from the second state to the first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, can cause the flow control valve to transition from the first state to the second state. The rules can utilize flow control input data information such as fluid information, patient-specific information, medical order information, clinical guideline information, contraindications, environmental factor information including time, flow control valve status, and historical information.

The identification sensor can detect the fluid source information using one or more technologies selected from a group consisting of: optical, magnetic, mechanical, conductive, switchable, infrared, switchable RFID and proximity sensors. In some cases, the identification sensor includes an optical element which detects an identifier encoded on a tip/outlet of the manually injectable medication container.

A housing can envelope at least a portion of each of the fluid inlet, the fluid outlet, the flow control valve, the identification sensor, and the flow controller. Such a housing can have a compact form/shape and size that allows a user to hold the housing in a first hand while activating the manually injectable medication container in a second hand. The housing can also include a self-contained power source within the housing powering the flow control valve, the identification sensor, and the flow controller and the fluid line can be an intravenous (IV) fluid line. The compact housing can, for example, be suspended from the IV fluid line.

The housing can be subdivided into reusable sub-housing and a disposable sub-housing. The reusable sub-housing can be operatively coupled to the disposable sub-housing with the reusable sub-housing being intended for use by a plurality of patients and the disposable sub-housing being intended for use by a single patient. The disposable sub-housing can contain at least the fluid inlet, fluid outlet, flow channel, and flow control valve. The disposable sub-housing can be part of a kit including a sterile pouch enveloping the disposable sub-housing. The disposable sub-housing can include memory for storing data that can include flow stop configuration information, flow sensor calibration information and/or a serial number or a unique identification number.

In an interrelated aspect, fluid source information of a manually administrable fluid source is detected by an identification sensor of a fluid delivery device, Thereafter, it is determined, using the detected fluid source information, whether to transition the current state of the flow control valve to the other state. A flow controller of the fluid delivery device then causes a flow control valve to transition to the other state (e.g., open or closed) if it is determined that the flow control valve should transition to the other state. Otherwise, the current state of the flow control valve is maintained if it is not determined that the flow control valve should transition to the other state.

In another variation a self-contained fluid port includes a fluid inlet for receiving manually administered medication, a fluid outlet for delivering the manually administered medication to a tubing segment leading to a patient, one or more sensors that sense one or more aspects of the injection of the medication, and electronics that wirelessly communicate the sensor information to external electronics. The one or more sensors may include one or more of a fluid source identification reader, a composition sensor, and a fluid flow sensor. The self-contained fluid port may be one integrally housed unit or it can include an electronics portion

and a fluid portion. The electronics portion includes the electronics and may include a sensor such as a reader. The fluid portion may also include a fluid flow sensor.

In another variation, a fluid flow arrestor (flow control valve) can be physically separated from the self-contained fluid injection port and/or the fluid identification sensor and/or the fluid composition sensor. The fluid flow arrestor can be located upstream or downstream of the fluid injection port. The fluid flow arrestor can be within an external device like an infusion pump. A flow controller and/or a rules engine can be included to determine the appropriate state of the fluid flow arrestor (open or closed). The flow control valve can be responsive to a command from the flow controller and/or rules engine based on information provided by the fluid identification sensor and/or the fluid composition sensor. The flow control valve can be wirelessly connected or wired to the flow controller. The flow control valve can control the flow rate in a binary manor (open or closed) or it can restrict flow and limit the flow rate to a specific level. The flow controller and/or the rules engine can be external to the system and/or be distributed across several system elements. If distributed, the logic could cascade across systems (e.g.: if an outside rule is met AND an inside rule is met, THEN a trigger flow control command can be activated). The flow control valve can be powered by a self contained power source or connected to an external power source. The flow control valve can be a one-time activated device or can be resettable enabling repeat activation. The flow controller command signal can be published as an open-source such that any appropriate command could activate the flow control valve.

In another variation, the flow control valve can be part of a system to protect a patient from an inappropriate fluid administration. The system can include fluid flow paths with known volumes and flow rates. When a known volume of fluid is injected into a flowing fluid pathway the time for the injected fluid to reach the patient can be calculated. The flow control valve can be activated before the inappropriate fluid can reach the patient. A safety confirmation of fluid stop can be provided to the patient caregivers. Additionally, the fluid volume downstream from the injection port can be measured by fluid withdrawal into a syringe (pulling on an empty syringe connected to the injection port and withdrawing fluid into the syringe) with the upstream fluid pathway occluded (pinched off). The withdrawn downstream fluid volume can be measured manually by inspection of the syringe graduations or measured automatically by a fluid volume measurement sensor within the injection port apparatus. The measured downstream volume can be communicated to and stored in the rules engine. The downstream volume can then be used as an input to the flow controller.

In yet another variation, the fluid flow arrestor can include and/or be distributed between a disposable subsection and a reusable subsection. The interface between these subsections can be electrical, magnetic, mechanical, hydraulic, optical, capacitive. The disposable subsection can include the flow control valve only and the reusable subsection can include all the other components. Alternatively, the disposable subsection can include all the components including the flow control valve, power supply, wireless or wired communications and fluid path. In one variation, the disposable subsection includes portions of the fluid flow arrestor that are contacted with fluid and the reusable subsection includes portions of the fluid flow arrestor that do not contact fluid in order to minimize an expense of replacing the reusable subsection.

Computer program products are also described that comprise non-transitory computer readable media storing instructions, which when executed by at least one data processor of one or more computing systems, causes the at least one data processor to perform operations herein. Similarly, computer systems are also described that may include one or more data processors and a memory coupled to the one or more data processors. The memory may temporarily or permanently store instructions that cause at least one processor to perform one or more of the operations described herein. In addition, methods can be implemented by one or more data processors either within a single computing system or distributed among two or more computing systems. For example, the rules engine can be software-based or a combination of software-hardware based.

DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, show certain aspects of the subject matter disclosed herein and, together with the description, help explain some of the principles associated with the disclosed embodiments. In the drawings:

FIG. **1** is a diagram illustrating a system for controlling flow in a fluid delivery pathway;

FIGS. **2**A-**2**G are diagrams illustrating alternative configurations of a fluid delivery pathway having one or more flow control valves and sensors;

FIG. **3** is a diagram illustrating examples of flow control input data for the system of FIG. **1**;

FIG. **4** is a flow chart illustrating an implementation of an operating mode of a system for controlling flow in a fluid delivery pathway; and

FIG. **5** is a flow chart illustrating another implementation of an operating mode of a system for controlling flow in a fluid delivery pathway.

FIG. **6** is a diagram illustrating one configuration of fluid delivery tubing connected to a patient.

FIG. **7** is a diagram illustrating a physically separated flow control valve in various positions on the fluid delivery tubing in FIG. **6**.

FIG. **8** is a diagram illustrating various alternatives for origination of a flow control command.

FIG. **9** is a diagram illustrating various alternative locations of rules and data.

FIG. **10** is an illustration of various volume and flow rate components of the fluid delivery pathway.

Like reference symbols in the various drawings indicate like or similar elements.

DETAILED DESCRIPTION

Described herein are systems and methods for controlling fluid delivery to a patient through a fluid delivery pathway. The systems and methods described herein incorporate rules-based clinical decision support logic to drive a flow control valve along a fluid flow pathway leading to patient based on a determination of whether or not a fluid connected to an input port is appropriate for delivery to a specific patient (consistent with medical orders, accepted delivery protocols, patient-specific characteristics, etc.). In an alternative configuration, decision logic used to control the flow valve along the fluid pathway can be based on whether or not a specific volume of fluid has been delivered through the input port to the patient, rather than, or in addition to, a determination that the fluid is appropriate for patient administration.

Independent of the rules and flow-stop criteria used to actuate the flow control valve, the flow control valve can be physically located anywhere along the fluid pathway, including but not limited to within the fluid port itself, such that closure of the flow control valve will prevent fluid entering the fluid port from reaching the patient. Moreover, the flow control valve can be an integral part of the systems described herein, or it can be associated with an external device and/or system (e.g. infusion pump, wireless, IV tubing clamp, etc.) that actuates the valve in response to a trigger signal received from the systems described herein.

It should be appreciated that use of the term "fluid" herein is not limited to any specific fluid and can include any type of therapeutic fluid. Fluids as used herein can include, but are not limited to medications, blood-based products, nutritional solutions, electrolytes, buffer solutions, lactated Ringer's solutions, sodium bicarbonate, crystalloids, colloids, saline solutions. Blood-based products can include, but are not limited to, any component of the blood for use in blood transfusions, whole blood, fresh frozen plasma, cryoprecipitate, blood substitutes, artificial blood, oxygen-carrying substitutes. Medications can include any therapeutic fluid that can be administered intravenously or via another appropriate parenteral route of administration such as intra-arterial, intraosseous, intracerebral, intracardiac, subcutaneous, or intraperitoneal.

It is standard practice to query patients and place in the patient file medical record information such as blood type, known drug allergies, drugs patient is currently taking, dietary restrictions, etc. This data provides a caregiver with information regarding potential adverse reactions a particular patient may experience upon administration of such fluids. In an in-hospital setting this patient-specific information typically is entered into an Admission, Discharge and Transfer (ADT) system or other clinical documentation system when the patient is first admitted to the hospital and used throughout their length of stay to help ensure safe care. Clinical guidelines and best practices also support a host of non-patient-specific medical information that can be routinely taken into consideration by prescribers of IV medications/fluids such that administering clinicians can avoid inducing patient adverse events. This information can include, but is not limited to drug-drug interactions, blood type matching, appropriate drug dosing limits, impact of current vital signs on treatments, metabolic factors and/or lab results.

Fluids can be delivered according to a medical order defined by a prescribing physician. Delivery orders can specify information such as type of fluid, medication dose, frequency of dose, administration route, etc. In an in-hospital setting these orders can originate from and/or be accessible through a Computerized Physician Order Entry (CPOE) system, Pharmacy Information System (PIS), Blood Bank Information System (BBIS), or Operating Room Information System (ORIS). Safe delivery of medications or other fluids to patients can require clinicians to execute according to the prescribed medical orders, while simultaneously taking into consideration patient-specific health characteristics (e.g. blood type) and history (e.g. medications previously administered, allergies), drug-specific clinical guidelines, and a host of environmental circumstances such as current vital signs, time, etc.

Turning now to FIG. **1**, the system **100** can include a fluid delivery inlet **105** connected to a fluid delivery outlet **110** and one or more programmable flow control valves **115** (flow control valves) positioned within a fluid flow pathway **120** between the inlet **105** and the outlet **110**. The system **100** can include a microprocessor **125** that interacts bi-directionally with a configurable rules engine **130**. The configurable rules engine **130** can send flow state commands **122** to the flow control valve **115** in the fluid flow pathway **120**. The microprocessor **125** also can communicate with an internal memory **150** and be powered by a power source **155**. The system **100** also can include a transmitter/receiver **157**. As shown in FIG. **7** (described further in a later section), one or more flow control valves **115** can reside external to fluid flow pathway **120** in a number of alternative fluid tubing locations, each having a flow path leading to the patient.

The microprocessor **125** can communicate with one or more external systems **135**. Communication between the system **100** described herein and the one or more external systems **135** can include wired or wireless communication methods. The nature of the one or more external systems **135** can be in the form of tangible medical devices and/or systems such as IV infusion pumps, or software applications, including but not limited to, healthcare information systems such as PIS, BBIS, ORIS, or ADT systems. The system **100** can include a fluid source reader **145** coupled to the inlet **105** and configured to detect one or more information sources carried by the fluid source connected to the inlet **105**. Information detected by the fluid source reader **145** can be indicative of a characteristic of the fluid contained within the associated fluid source container, such as type, volume, concentration, expiration, manufacturer's information regarding contents, etc. The information can be detected by the fluid source reader **145** according to a variety of methods, including but not limited to, optical, magnetic, mechanical, conductive, switchable, proximity sensors, IrDA, RFID, etc. Communication systems between inlets, fluid source readers and fluid source identification systems are described in detail in U.S. Patent Publication Nos. 2011/0112473, filed Nov. 6, 2009; 2011/0111794, filed Apr. 22, 2010; and 2011/0112474, filed Nov. 2, 2010, which are each incorporated by reference herein in their entirety.

The communication between the microprocessor **125** and the one or more external systems **135** can be bi-directional such that the microprocessor **125** can both receive and transmit flow control input data **140**. Flow control input data **140** can include, but are not limited to, 1) information about the fluid source such as type of fluid, volume of fluid, concentration of fluid, etc.; 2) constant patient-specific information such as patient identification number, drug allergies, blood type, etc.; 3) variable patient-specific information such as patient vital signs, lab results, current disease states and/or clinical diagnoses, drugs previously administered, etc.; 4) medical orders such as drug, dose, route of administration, treatment schedule, etc.; 5) clinical guidelines such as known drug-drug interactions, recommended treatment protocols, dosing limits, etc.; 6) environmental factors such as the care area where treatment is being delivered, time of day, date, temperature, etc.; 7) valve status such as currently open (second state), currently closed (first state) or clinician initiation of a manual override; 8) historic patient information such as disease state, clinical diagnosis, dosing history, etc.; and 9) any other relevant information applicable to determining whether or a not a particular fluid administration is safe and appropriate for a patient. Communication between the system **100** and the one or more external systems **135** is discussed in more detail below.

The systems described herein are generally small and light-weight systems that can reduce the risk of serious medical errors and deaths by controlling flow through a fluid delivery pathway. It should be appreciated that the systems described herein can be applied to any care environment

where fluids are delivered to patients, including hospitals, clinics, outpatient surgery centers, doctor's offices, home health settings, EMS, ambulances, etc.

The system **100** described herein can be enclosed by a small plastic housing such that fluid inlet **105** and outlet **110** are available for external connections. The housing can enclose the fluid flow path **120**, one or more flow control valves **115**, and a power source **155**. The housing can additionally enclose one or more of a microprocessor **125**, a memory **150**, a transmitter/receiver **157**, a rules engine **130**, a fluid source reader **145**, and a fluid flow sensor **149** and/or composition sensor **148** (described later). The housing can be a low-cost, single-patient use, sterile, disposable assembly. Alternatively, the housing can include most or all of the system components and be reusable and rechargeable. System **100** can include a user interface **160**, located adjacent to the fluid inlet or remote from the fluid inlet, to provide information to/from a user regarding a fluid and/or medication, audio/visual feedback, status of the flow stop valve **115** and other care related details. Any one or more of the components of the system **100** can be included or excluded from the housing in any number of alternative implementations.

In some implementations, system **100** can be subdivided and have components distributed such that a portion resides within a disposable sub-housing and the remainder resides outside the disposable sub-housing. The disposable sub-housing **104** (see FIG. **6**) can be packaged sterile and be provided in a protective pouch. In one variation, for example, a first reusable sub-housing **102** (see FIG. **6**) enclosing a power source **155**, a microprocessor **125**, a memory **150**, a transmitter/receiver **157**, a rules engine **130**, and a fluid source reader **145** can mate with and attach to a second disposable sub-housing **104** enclosing a fluid flow pathway **120** and a flow control valve **115**. Additionally, the disposable sub-housing **104** can include a subset of memory **150** storing characteristics of the components within the disposable sub-housing **104** relevant for proper operation (e.g. flow path characteristics, number of fluid inlets, number and arrangement of flow control valves, serial number, etc.) when the disposable and reusable sub-housings are combined to form a complete system **100**.

As mentioned above, the system **100** can include a flow control valve **115** positioned within the fluid flow pathway **120** between the inlet **105** and the outlet **110**. The flow control valve **115** can be a programmable valve that can toggle between two states in response to flow state commands **122** from the configurable rules engine **130**. Flow control valve **115** can be limited to two operating modes, the first being an all-on "OPEN" state and the second being an all-off "CLOSED" state. Alternatively, flow control valve **115** can have multiple operating modes, including but not limited to, variable and intermittent flow control modes. Specific types of valves used can include, but are not limited to, gate valves, globe valves, T valves, butterfly valves, ball valves, check valves, plug valves, pinch valves, diaphragm valves, and the like.

FIG. **1** illustrates one of many potential component configurations (see FIG. **7** for possible alternate configurations) wherein a single flow control valve **115** can be positioned upstream from a single fluid outlet **110** and downstream from a single fluid inlet **105**. FIGS. **2**A-**2**G illustrate various alternative variations wherein one or more flow control valves **115** can be positioned within one or more tubing segments of fluid flow pathway **120**, wherein such tubing segments are collectively referred to as a fluid administration "set", regardless of configuration. The fluid delivery pathway **120** can have a variety of configurations consistent with commonly used fluid administration sets including, for example, fluid flow pathway **120** configured as a single flow path extension set (FIG. **2**A), a "Y-site" fluid set (FIGS. **2**B-**2**D), a multiple-input to single-output fluid set (e.g. triple lumen IV catheter) (FIGS. **2**E-**2**G), upstream or downstream from the fluid port as shown in FIG. **7** and others as are known in the art.

A flow control valve **115** can be positioned within a single fluid flow pathway **120** between an input fluid connector **205***a* and an output fluid connector **210** (see FIG. **2**A). The flow control valve **115** can be positioned within the single fluid flow pathway **120** downstream of the Y-site with input **205***b* (see FIG. **2**B). The flow control valve **115** can be positioned within the single fluid flow pathway **120** upstream of the Y-site with input **205***b* near input **205***a* (see FIG. **2**C). The flow control valve **115** can be positioned within the Y-site near input **205***b* (see FIG. **2**D). The flow control valve **115** can be positioned within a single fluid flow pathway **120** upstream of output **210** and downstream of multiple-inputs **205***a*, **205***b*, **205***c*, **205***d* (see FIG. **2**E). The flow control valve **115** can be positioned upstream of the single fluid flow pathway **120** and downstream of one or more of the multiple-inputs **205***a*, **205***b*, **205***c*, **205***d* (see FIGS. **2**F and **2**G).

Similarly, the fluid source reader **145** (and/or composition sensor **148**) can be positioned on various segments of the fluid flow pathway **120** depending on the configuration of the components in the set. In some implementations, the fluid source reader **145** can be positioned in an upstream location along the same flow path as the flow control valve **115** (FIG. **2**A). In some implementations, the fluid source reader **145** can be positioned along a different portion of the fluid flow pathway **120** as the flow control valve **115**. For example, in a "Y-site" configuration such as shown in FIG. **2**B, the flow control valve **115** can be positioned within the single fluid flow pathway **120** upstream of output **210** and downstream of the Y-site. In this implementation, the fluid source reader **145** can be positioned upstream of the flow control valve **115** in the same fluid flow pathway **120** or a different flow path upstream of the Y-site. The fluid source reader **145** can also be positioned upstream of the flow control valve **115** in the same fluid flow pathway **120** downstream of the Y-site. Alternately, composition sensor **148** (or fluid source reader **145**) can be positioned downstream of the Y-site as shown in FIG. **2**C or positioned upstream on the Y-site as shown in FIG. **2**D. Any number of component position combinations can be constructed for specific applications.

The microprocessor **125** can include a flow control valve software application in combination with rules engine **130** that evaluates combinations of flow control input data **140** against configurable logic for determining the proper state of the flow control valve **115** at any given time prior to or during a treatment regimen or fluid delivery protocol (see the diagram **300** of FIG. **3**). Microprocessor **125**, rules engine **130** and any associated flow control valve software application and/or configurable rules used by the rules engine **130** can sometimes be collectively referred to as a "flow controller". Access to the relevant flow control input data **140** allows the system **100** to support, guide, dictate, or perform clinical decisions relating to whether or not a particular fluid coupled to the system **100** should be allowed to flow through the fluid flow pathway **120** to a patient. As described above, the flow control input data **140** can be any data, whether patient-specific or non-patient-specific applicable to determining, for example, whether or a not a

particular fluid administration is safe and appropriate for a patient. The data **140** can be stored in a medical information system, medical database, manually entered, input from an external device and/or system (e.g. vital signs monitor, laboratory information system, temperature sensor, etc.) or based on feedback from the system **100** or external system **135**. The data **140** can be static or dynamic. Generally, the data **140** are applicable to and can provide support for making decisions on the appropriateness and/or safety of delivering a fluid to a patient.

The system **100** can be configured to operate in different operative modes. In some implementations, the system **100** can operate in a normally CLOSED mode where the baseline state of the flow control valve **115** is closed (first state) and the fluid flow pathway **120** is opened during a fluid delivery and then closed again upon completion of the delivery (see FIG. **4**). The normally CLOSED mode can be advantageous in higher risk scenarios, for example, in instances in which a caregiver is less experienced or has limited decision-making authority regarding delivery of care; fluid administrations that requires more checks, involves fluid delivery of higher cost treatments, or administration of fluid treatments where mistakes have dire consequences such as infusion of incompatible blood products; or where highly potent and/or toxic substances (e.g. chemotherapy) are involved. In other implementations, the system **100** also can operate in a normally OPEN mode where the baseline state of the flow control valve **115** is open (second state) and closes only when there is an identified potential safety risk (see FIG. **5**). The normally OPEN mode can be desirable or advantageous in scenarios such as, for example, instances in which a caregiver is more experienced or desires more manual control over fluid delivery, or the fluid administration and time-frame requires fewer checks. It should be appreciated that the system **100**, regardless of operating mode, can include a manual override mechanism such that at any time during a particular fluid administration the clinician can override the system and force flow control valve **115** to an OPEN state allowing them to perform a conventional fluid administration as if the system **100** were not in place in the patient fluid line. The override mechanism can be reset manually by the clinician or automatically by the flow controller based on a timeout or other applicable rule.

As shown in the process flow diagram **400** of FIG. **4**, the normally CLOSED mode is characterized by the flow control valve **115** normally in a closed state and temporarily opened to allow a fluid to pass through the fluid flow pathway **120**. A fluid source can be connected with fluid inlet **105** while the valve **115** is in a closed state (**402**). Various relevant characteristics of the fluid source can be identified by the system **100** (**404**). The current time and other environmental factors can be determined (**406**). A series of safety checks can be performed by the flow-control software application to assess, for example, whether the fluid coupled to the inlet **105** matches a current medical order to deliver that fluid to the patient (**408**), the patient is allergic to the fluid connected to the fluid inlet **105** (**410**), whether any drug-drug interactions exist (**412**), whether the current time is the correct time for the administration of the attached fluid (**414**), or whether any other contraindications to administering the fluid to the patient exist (**416**). If the system **100** fails one or more of the safety checks, a determination can be made whether the safety risk justifies flow stop (**420**). If the risk does not justify the flow stop, then the flow valve can be opened and the caregiver can administer the dose (**422**), otherwise the flow control valve **115** is maintained in a closed position (**424**) by sending, for example, a flow state command **122** indicating that valve **115** should remain closed. Thereafter, the fluid source can be detached (**426**), results can be transmitted (**428**) to an external system **135**, and if the valve is opened, the valve can be closed (**430**). In addition, the safety check can trigger an alert or warning to the clinician (**418**). Information associated with a resultant alert or warning (e.g. potential safety risk) can also be transmitted to an external system **135**. If the system **100** passes all the safety checks, a flow state command **122** can be sent to the flow control valve **115** to open and allow fluid delivery to the patient.

If the system **100** does not fail one or more of the safety checks, the flow control valve **115**, if closed, can be changed from a closed state to an open state (**432**). In some implementations, the system **100** can measure fluid volume in real-time during delivery of the fluid (**434**) and calculate the actual dose delivered and compare it to the ordered dose (**436**). The ordered "dose" can include a specific fluid volume (e.g. 1 liter of blood) or a quantity calculated by multiplying fluid volume by a fluid source concentration (e.g. 2 mL of 1 mg/mL concentration of morphine fluid source). Once the ordered dose is reached, the system **100** detects the fluid source is detached from the system **100**, or fluid flow has stopped for a period long enough that the fluid flow controller can consider the dose administration to be complete, a flow state command **122** can be sent to close flow control valve **115** (**440**) in preparation for the next fluid administration. The administration conditions and results can be communicated to the system memory **150** and/or an external system **135** for recording (**438**).

In some implementations, the rules engine **130** logic can be defined such that triggering an alert or warning message to alert the clinician is an independent event from sending a flow state command **122** to flow control valve **115**. Rules logic can generate tiered messages and/or flow state commands **122** using multiple trigger thresholds based on the severity of a potential safety risk. For example, if the physician-ordered dose for a fluid is 100 mL, the rules engine **130** can send a warning message to the clinician without closing the flow control valve **115** when the dose administered reaches 105 mL of fluid. However, if dose administration continues and the cumulative dose volume reaches 110 mL of fluid, the rules engine can send an alert message to the clinician while simultaneously sending a flow state command **122** to close flow control valve **115**. The rules engine can poll remote data stores to obtain rules and/or flow control input data. This polling process may involve directly or indirectly utilizing sub-elements of flow control input data as reference parameters for accessing relevant external data. Such flow control input data can include, but not limited to, patient identifier information.

Referring now to the process flow diagram **500** of FIG. **5**, the normally OPEN mode is characterized by the flow control valve **115** normally in an open position to allow fluid to pass through the fluid flow pathway **120**. A fluid source can be connected with a fluid inlet **105** while the flow control valve **115** is in the open state (**502**). Various relevant characteristics of the fluid source can be identified by the system **100** (**504**) as well as current time and environmental factors (**506**). A series of safety checks (**508-516**) similar to those described in connection with FIG. **4** can be performed by the flow controller software application using current flow control input data **140** as described above with respect to FIGS. **3-4**. If one or more of the safety checks fail, an alert can be sent to the clinician (**518**), and if the safety risk justifies preventing fluid flow to the patient (**520**), then a

flow state command **122** can be sent to close the flow control valve **115** (**524**). The fluid source can then be detached (**526**), results can be transmitted to an external system **135** (**528**), and the state of flow control valve **115** can be switched back to an open position (**530**). If one or more safety checks identify a potential risk but the risk does not justify closing flow control valve **115**, then the fluid can be administered (**522**), the syringe can be detached (**526**), and the results can be transmitted to external system **135**.

If no safety checks are triggered, fluid volume can be measured in real-time during administration (**532**). Once it is determined that the ordered dose has been achieved, the fluid source is detached, or fluid flow has stopped for a period long enough that the fluid flow controller can consider the dose administration to be complete (**534**), then results can be transmitted to external system **135** (**536**).

As described above, the rules engine can also trigger messages independent of flow state command **122** which can include transmitting data to record the condition in memory **150** of system **100** and/or to one or more external systems **135**. Such triggers can also drive inputs and outputs on user interface **160**. For example, outputs to the user through user interface **160** can include audio feedback, changes to status indicators, fluid source information, fluid composition information, volume of fluid administered, information associated with the fluid (e.g. medication) administration, rules engine information and/or output, error messages, feedback on the state of the flow control valve, or other similar parameters. Similarly, inputs from the user can include, but are not limited to, confirming an action, confirming recognition of an alert, entry of a manual override request for the flow control valve, or a reset of the valve.

While the set and sequence of safety checks utilized in FIGS. **4-5** illustrate one implementation of how elements of flow control input data **140** can be used by the system **100** flow controller to determine appropriateness of delivering a fluid to a patient, other implementations can include any mix and/or subset of flow control input data **140**, with such data elements being operated on in any sequence of decision logic steps. In addition, although the decision logic represented in FIGS. **4-5** can be based on a linear sequence of simple binary decision checks, further implementations can include complex algorithms involving simultaneous consideration of multiple data elements and/or probability-based decision logic with fixed or configurable thresholds used to determine the proper flow state command **122** to send to flow control valve **115**.

FIG. **6** is a diagram showing various illustrative arrangements of fluid delivery tubing **202**, **204**, **206** and **216** connected to a patient for the delivery of appropriate fluids. Primary fluid source **200** can be connected through tubing segment **202** and tubing segment **204** to a patient. Segment **204** can be attached to a patient by access device **220** such as a catheter or needle. Additionally, tubing segment **206** can be joined to upstream segment **202** and downstream segment **204** in between fluid source **200** and the patient. System **100** can be attached to segment **206** for the delivery of manually administered fluids. Fluid source **210**, for example, can be a manually injectable syringe. Fluid **212** contained within fluid source **210** can be injected through fluid flow path **120**, into segment **206**, into segment **204** and finally through patient access device **220** and thereby administered to a patient. A fluid delivery pump **218** can be connected to segment **202** for continuous infusion of fluid. A secondary fluid source **214** can be connected to tubing segment **216**. Tubing segment **216** can be joined with segment **202** for delivery of intermittent secondary fluids. System **100** can be separated into reusable subsection **102** and disposable subsection **104**. Flow control valve **115** is shown within the disposable subsection **104**.

In certain variations, certain elements of system **100** can be referred to as a housed and self contained fluid port **100**. The elements of fluid port **100** minimally include fluid inlet **105**, fluid flow pathway **120**, at least one sensor (fluid identification sensor **145**, and/or composition sensor **148**, and/or fluid flow sensor **149**), and wireless transmission electronics **157** that interface and/or communicate with the sensor **145** and/or **148** and/or **149** and communicate with systems that are external to the fluid port **100** in order to enable the actuation of a flow control valve **115**. Fluid flow control valve **115** can be external to fluid port **100** as illustrated in FIG. **7**. Certain portions of a flow controller that can include microprocessor **125**, memory **150**, and rules engine **130** can also be contained in fluid port **100**. Thus in certain variations a self-contained fluid port **100** can include some or all of the elements depicted for system **100**. Fluid port **100** can serve as a compact, self-contained port for manual injection of medications and other fluids into fluid inlet **105** and then into tubing segment **204** that leads to patient access device **220**. Fluid port **100** can be small and light enough to enable fluid port **100** to be suspended from tubing **202**. Fluid port **100** can include a reusable subsection **102** and a disposable subsection **104**. A compact housing (combination of **102** and **104**) can contain all the elements of port **100**.

FIG. **6** illustrates the use of three discrete sensor types: fluid identification sensor **145**, fluid composition sensor **148**, and fluid flow sensor **149**. Variations can include a single sensor type or a mix of sensors. In variations involving multiple sensors, the sensors can be used independently or in tandem to provide input to rules engine **130**. In one example, a system **100** can include only a composition sensor **148** that, following the start of fluid delivery from a manually administrable fluid source, enables the flow controller to determine the nature of flow state command **122** based on confirmation that the types and relative concentrations of fluid constituents sensed by composition sensor **148** are appropriate for administration to a patient. Composition sensor **148** can incorporate a variety of technologies, including but not limited to, photometric analysis, electrometric analysis, chromatography, mass spectroscopy, physical property measurements, or it can utilize a parametric analysis based on a combination such technologies. In another example, a system **100** can include an identification sensor **145** and fluid flow sensor **149**, where the identification sensor **145** is used to confirm a correct fluid type for the patient and fluid flow sensor **149** is used to determine when flow control valve **115** should be closed based on a prescribed fluid dosage. Fluid flow sensor **149** can be based on technologies, including but not limited to: a paddle wheel flow meter, a turbine flow meter, a thermal flow meter, a pressure sensor, a differential pressure sensor, an optical sensor, an ultrasonic sensor, a coriolis flow meter, a displacement sensor.

It should be appreciated that the use of multiple sensor types, used separately or in parallel, are fully applicable to the various fluid delivery set configurations described in FIGS. **2**A-**2**G. Furthermore, the flow control valves **115** illustrated in the FIGS. **2**A-**2**G can be integrated within the fluid sets, external to the sets while still existing as subcomponents of system **100**, or independent of, but in communication with system **100**. In FIG. **2**B, for example, the "Y-site" inlets **205***a* and **205***b* can each contain identification sensors **145**, that when used to identify the fluid coupling of

an inappropriate fluid source to either inlet, can enable the flow controller to communication with an external system containing a flow control valve **115** to initiate a flow rate change or shutdown of fluid flow in the pathway leading to the patient. In some implementations, flow control valve **115** can communicate (e.g. via wireless transmitter associated with the valve) changes in valve status to the flow controller to provide feedback in response to having received a flow state command **122**.

FIG. **7** is a diagram illustrating a physically separated flow control valve **115** in various positions on the fluid delivery tubing. The flow control valves **115** in this system may be in one or more of the illustrated (dashed) locations with respect to this fluid delivery arrangement. In this variation, flow control valve **115** can be physically separated from system **100**. The flow control valve **115** can be located upstream (positions **230** and **240**) or downstream (position **250**) of segment **206** and fluid port **100**. The flow control valve **115** can be within an external device **218** like an infusion pump (position **230**). Alternatively, flow control valve **115** can be below a "Y" site (position **240**) and control both primary fluid source **200** and secondary source **214**. Alternatively, flow control valve **115** can be positioned close to the patient (position **250**) and control primary fluid source **200**, secondary fluid source **214** and fluid source **210** (a syringe for injection into inlet **105**). Alternatively, flow control valve **115** can be within system **100** as discussed in FIG. **6** connected between tubing segment **206** and fluid source **210**.

FIG. **8** is a diagram illustrating various alternatives for the origination of a flow control command **122** from external devices/systems **135**. A flow controller and/or a rules engine **130** can be included to determine the appropriate state of the flow control valve **115** (open or closed). The flow controller and/or the rules engine **130** can be external to the system and/or be distributed across several system elements. If distributed, the logic could cascade across systems (e.g.: IF an outside rule is met AND an inside rule is met, THEN a trigger flow control command **280** can be activated). The flow control valve **115** can be responsive to a command **280** from the flow controller and/or rules engine **130** based on information provided by the fluid identification sensor **145** and/or a fluid composition sensor **148**, and/or flow sensor **149**. The flow control valve **115** can be wirelessly connected or wired to the external system **135**, flow controller and/or rules engine **130**. One alternative can include flow state command **280***a* controlling flow valve **115** in position **230**. A second alternative can include flow state command **280***b* controlling fluid flow control valve **115** in position **240**. A third alternative can include flow state command **280***c* controlling flow control valve **115** in position **250**. A fourth alternative can include flow state command **280***d* controlling flow valve **115** in position **260**. A fifth alternative can include flow state command **280** (commands **280***a*, **280***b*, **280***c*, or **280***d* not shown) originating from microprocessor **125**. Other alternatives can be envisioned for positioning fluid flow control valve **115** in various flow path segments and controlled by various flow controller commands **280**.

In some variations, flow control valve **115** can control the flow rate in a binary manner (open or closed) or in other variations it can partially restrict flow and thus limit the flow rate to a specific flow rate level. The flow control valve **115** can be powered by a self-contained power source or connected to an external power source. The flow control valve **115** can be a one-time activated device or can be resectable enabling repeat activation. The flow controller command signal **280** can be published as an open-source such that any appropriate system or device could send command **280** and activate flow control valve **115**.

FIG. **9** is a diagram illustrating various alternative locations of rules and data. Rules engine **130** (**130***a*, **130***b*, **130***c*) can reside at various locations and/or be distributed having some rules inside system **100** and some rules outside system **100**. In one alternative, rules engine **130***a* can be inside system **100**. In another alternative, rules engine **130***b* can be inside an external device (infusion pump) **218**. In another alternative, rules engine **130***c* can be inside external system **135**. If distributed, the rules logic can cascade across systems and activate flow control valve **115**. Similarly, flow control data **140** (**140***a*, **140***b*, **140***c*) can be distributed across systems. In one alternative, flow control data **140***a* can be in the flow controller. In a second alternative, flow control data **140***b* can be in the external device (infusion pump) **218**. In a third alternative, flow control data **140***c* can be in external flow control data source **140**.

FIG. **10** is an illustration of various volume and tubing components of the fluid delivery pathway. The tubing system can include flow paths with known volumes and flow rates. Primary tubing segment **202** has a known volume V**1** and a flow rate R**1**, side tubing segment **206** volume plus fluid flow pathway **120** (volume **208**) has a known volume of V**2** and a flow rate R**2** (speed of injection using syringe **210**) and lower tubing segment **204** has a known volume V**3** and a flow rate R**3** (sum of R**1** plus R**2**). When a known volume of fluid **212** is injected into a flowing fluid pathway **202**/**204** the time T**1** for the injected fluid to reach the patient can be calculated. Flow control valve **115** (**115***a*, **115***b*, **115***c* or **115***d*) can be activated before an inappropriate fluid **212** can reach the patient. A safety confirmation of fluid stop can be provided to the patient caregivers by user interface **160**.

An example of the time calculations follows:

- tubing segment **202** could contain V**1**=10 mL of fluid volume and be flowing at a rate of R**1**=60 mL/hour.
- tubing segment **206** plus tubing segment **208** (fluid flow pathway **120**) is typically small and could contain V**2**=1 mL of fluid volume.
- tubing segment **204** is moderately sized and could contain V**3**=3 mL of fluid volume flowing at a rate R**3**=R**1** prior to and after injection of fluid volume **212** and R**1**+R**2** during injection of volume **212**.
- fluid injection volume **212**=V**4**=3 mL of fluid volume and is injected at a rate of 3 mL/3 sec=R**2**=1 mL/sec.=60 mL/min.
- flow rate R**3** will return to=R**1** when syringe **210** has been fully injected.

Therefore, calculating the time $t_x=t_1+t_2$ for injection fluid **212** to reach the patient:

- where t_1=time for injection volume to get into the primary tubing segment **202**
  - t_1=Volume/Rate=(V**2**+V**3**)/R**2**=(1 mL+3 mL)/60 mL/min=4 mL/60 mL/min
  - t_1=1/15 minutes=4 seconds
- where t_2=time for injection volume **212** to flow into the patient thru segment **204**
  - t_2=V**3**/R**1**=3 mL/(60 mL/hour)=3 mL/1 mL/min=3 minutes
- time $t_x=t_1+t_2$=4 seconds+3 minutes=184 seconds for all of fluid **212** to reach the patient.

It should be noted that some of the fluid reaches the patient earlier and that the response time for flow control valve **115** is important to limit patient exposure to inappropriate fluid administration. Positioning of flow control valve **115** near the patient is thus important. Additionally, early detection of an inappropriate fluid is also important to

protect the patient. Operation of identification sensor **145** to detect fluid source **210** at the time of attachment to fluid inlet **105**, before manual administration fluid flow, is preferred. Alternatively, composition sensor **148** can identify fluid **212** and/or flow sensor **149** can measure fluid volume **212** providing data for the flow controller.

Additionally, fluid volume V**2**+V**3** downstream from the injection port can be measured by fluid withdrawal into a syringe **210** (pulling on an empty syringe connected to the injection port and withdrawing fluid into the syringe) with the upstream fluid pathway **202** occluded (pinched off). The withdrawn downstream fluid volume V**230** V**3** can be measured manually by inspection of the syringe graduations or measured automatically by a fluid volume measurement sensor **149** within the injection port apparatus (if so enabled to detect reversed flow). The measured downstream volume can be communicated to and stored in the rules engine. The downstream volume can then be used as an input to the flow controller.

In yet another variation, flow control valve **115** can be distributed between a disposable subsection and a reusable subsection. The interface between these subsections can be electrical, magnetic, mechanical, hydraulic, optical, and/or capacitive. The disposable subsection can include the flow control valve **115** and fluid flow pathway **120** only and the reusable subsection can include all the other operational components. In this configuration the valve actuator is in the reusable subsection coupled to the disposable subsection valve **115** mechanism with fluid flow pathway **120**. Alternatively, the disposable subsection can include all the components including the flow control valve **115**, power supply, wireless or wired communications, and fluid path.

It should be appreciated that the systems described herein can, but need not transmit data to an external system **135** for recording and logging data. For example, the system **100** can incorporate the intelligent flow control features of the programmable flow control valve **115** and provide user feedback (such as alarms and other alert messages to user interface **160**) without transmitting, and/or recording the data to an external system **135**.

The system **100** can be programmed with information downloaded into the system memory **150** prior to use, in real-time, using on-demand connectivity with the external systems **135** or a combination of the two. In some implementations, the system **100** can be pre-programmed according to a subset of static flow control data **140** (e.g. patient blood type, known drug allergies, dose limits, etc.) prior to or upon connection to a patient's fluid line. The system **100** can be programmed using a dockable cradle, wireless communications interface or a wired connector. In some implementations, a low-cost, non-wireless version of the system **100** can be pre-programmed with only non-patient-specific rules such as drug-drug interactions, hard dosing limits, etc. for generic use with any patient. The system **100** can be provided to a buyer including the pre-programmed with non-patient-specific information or according to published clinical guidelines and standards. The non-patient-specific information can be programmed prior to clinical use by a manufacturer, care provider or by a hospital pharmacist, or other care setting based on provider-specific rules and operating procedures.

In some implementations, the system **100** can be programmed and/or communicate information in real-time to the one or more external systems **135** using a wireless transmission **157**. A variety of wireless transmission hardware and protocols can be used such as RF, IrDA (infrared), Bluetooth, Zigbee, Continue, Wireless USB, Wibree, IEEE 802 relevant standards (e.g., 802.11, 802.15, or 802.16, etc.), Direct Sequence Spread Spectrum; Frequency Hopping Spread Spectrum; cellular/wireless/cordless telecommunication protocols, wireless home network communication protocols, paging network protocols, magnetic induction, satellite data communication protocols, wireless hospital or health care facility network protocols, and other methods. The data transmissions can, in some implementations, be encrypted in order to ensure patient privacy and/or to comply with various laws relating to handling of medical data. The transmitter can have such encryption capabilities or one or more additional chipsets can be incorporated within a region of the system **100** to provide such encryption.

In some implementations, the configurable rules engine **130** can run on a microprocessor **125** remote to the system **100**. The flow state commands **122** or **280** can be sent to the system **100** in a wireless or wired manner to the flow control valve **115** instructing the flow control valve **115** to open or close.

The system **100** described herein can include one or more mechanisms configured for receiving input from a user via user interface **160** to control operation of the system **100** and/or providing feedback to a user from the system **100**. For example, the user interface **160** can incorporate one or more user inputs such as one or more keys, buttons, switches, dials, or touch-screens. The user interface **160** can incorporate one or more user feedback mechanisms such as one or more LEDs, graphical displays, sounds, speech synthesis technology or vibration mechanisms. The visual, tactile or auditory feedback can include a sequence of notifications such as volume, color, number, intensity, or other feature of the particular feedback mechanism is varied to indicate a particular state of the system **100**. Information provided by a user via user interface **160** can be used by the flow controller in determining an appropriate flow state command **122** to flow control valve **115**. In some implementations, one or more of the user inputs and/or feedback mechanisms of user interface **160** can be remote to the system **100**, such as on a computing device in communication with the system **100** such as by a wired or wireless connection using the transmitter/receiver **157**.

The power source **155** can include a self-contained power source such as a battery, single-use or rechargeable battery, battery array or other type of power source known in the art. Where the battery is rechargeable, there can be a connector or other interface for attaching the device to an electrical outlet, docking station, portable recharger, or so forth to recharge the battery.

In some implementations, the system **100** can include an internal fluid composition sensor **148** that can be configured to allow the fluid composition and concentration of the fluid source to be empirically determined. The sensor **148** can be positioned downstream of the fluid inlet **105** and upstream of flow control valve **115**. The internal fluid composition sensor **148** can be the sole source of fluid type detection. In some implementations, the composition sensor **148** can be a supplement to fluid source information carried by the fluid source container and detected by a fluid source reader **145**.

The system **100** can accommodate a variety of volumes and doses, including fractional doses, or multiple fluid source connections to fulfill the desired treatment protocol of a single patient medical order. For example, a physician can order a 2 mg dose of morphine for a patient. The nurse can connect one 4 mg syringe of morphine, intending to deliver half the syringe to the patient and discard the other half. In this example, the system **100** can alert the clinician

that a 4 mg syringe is connected to the system **100** and the potential dose to be delivered to the patient is too high. The system **100** can also prevent overdose by sending a flow state command **122** or **280** to close the flow control valve **115** after the firstf 2 mg of morphine have been delivered to the patient to prevent delivery of remaining 2 mg of morphine. Alternatively, a physician can order 2 mg of morphine for a patient. The care provider can fulfill the order by first connecting a 1 mg syringe of morphine to the system **100** and delivering the full contents of the syringe to the patient and then connecting a second 1 mg syringe of morphine to the system **100** and delivering the full contents of the second syringe to the patient. In either scenario, the physician order for 2 mg have been fulfilled and the system **100** would not provide an alert or constrain fluid flow unless a further morphine syringe is coupled to the system **100**.

In some cases, different flow restriction mechanisms can be used other than a flow control valve. In such cases an operation modification signal can be generated (based on attributes detected by the sensor(s) as applied to various rules) which causes one or more devices to change an operational parameter which directly or indirectly affects fluid flow within the fluid pathway(s) (at various points along the fluid pathway(s)). In other variations, a fluid port can generate an operation modification signal (based on attributes detected by the sensor(s) as applied to various rules) which causes other operational parameters of an external device to change. Such operational parameters need not necessarily affect fluid flow through the fluid pathway(s).

Similarly, the systems described herein can use any sort of manually administered fluid source and are not limited to a specific IV fluid source type and can include syringes, IV bags, disposable medication cartridges or pouches, IV tubing, etc.

It should be appreciated that the systems described herein can be used for delivery of fluids by a variety of routes of administrations. Unless otherwise specified the terms injection, administration, or delivery as they relate to introducing a fluid to a patient is not intended to be limiting to a particular route of manual administration (i.e., administration effected by a human being as opposed to a pump).

Various aspects of the subject matter described herein may be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof. These various implementations may include implementation in one or more computer programs that are executable and/or interpretable on a programmable system including at least one programmable processor, which may be special or general purpose, coupled to receive data and instructions from, and to transmit data and instructions to, a storage system, at least one input device (e.g., mouse, touch screen, etc.), and at least one output device.

These computer programs, which can also be referred to programs, software, software applications, applications, components, or code, include machine instructions for a programmable processor, and can be implemented in a high-level procedural and/or object-oriented programming language, and/or in assembly/machine language. As used herein, the term "machine-readable medium" refers to any computer program product, apparatus and/or device, such as for example magnetic discs, optical disks, memory, and Programmable Logic Devices (PLDs), used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term "machine-readable signal" refers to any signal used to provide machine instructions and/or data to a programmable processor. The machine-readable medium can store such machine instructions non-transitorily, such as for example as would a non-transient solid state memory or a magnetic hard drive or any equivalent storage medium. The machine-readable medium can alternatively or additionally store such machine instructions in a transient manner, such as for example as would a processor cache or other random access memory associated with one or more physical processor cores.

These computer programs, which can also be referred to programs, software, software applications, applications, components, or code, include machine instructions for a programmable processor, and can be implemented in a high-level procedural language, an object-oriented programming language, a functional programming language, a logical programming language, and/or in assembly/machine language. As used herein, the term "machine-readable medium" refers to any computer program product, apparatus and/or device, such as for example magnetic discs, optical disks, memory, and Programmable Logic Devices (PLDs), used to provide machine instructions and/or data to a programmable processor, including a machine-readable medium that receives machine instructions as a machine-readable signal. The term "machine-readable signal" refers to any signal used to provide machine instructions and/or data to a programmable processor. The machine-readable medium can store such machine instructions non-transitorily, such as for example as would a non-transient solid state memory or a magnetic hard drive or any equivalent storage medium. The machine-readable medium can alternatively or additionally store such machine instructions in a transient manner, such as for example as would a processor cache or other random access memory associated with one or more physical processor cores.

To provide for interaction with a user, the subject matter described herein can be implemented on a computer having a display device, such as for example a cathode ray tube (CRT) or a liquid crystal display (LCD) monitor for displaying information to the user and a keyboard and a pointing device, such as for example a mouse or a trackball, by which the user may provide input to the computer. Other kinds of devices can be used to provide for interaction with a user as well. For example, feedback provided to the user can be any form of sensory feedback, such as for example visual feedback, auditory feedback, or tactile feedback; and input from the user may be received in any form, including, but not limited to, acoustic, speech, or tactile input. Other possible input devices include, but are not limited to, touch screens or other touch-sensitive devices such as single or multi-point resistive or capacitive trackpads, voice recognition hardware and software, optical scanners, optical pointers, digital image capture devices and associated interpretation software, and the like.

The subject matter described herein may be implemented in a computing system that includes a back-end component (e.g., as a data server), or that includes a middleware component (e.g., an application server), or that includes a front-end component (e.g., a client computer having a graphical user interface or a Web browser through which a user may interact with an implementation of the subject matter described herein), or any combination of such back-end, middleware, or front-end components. The components of the system may be interconnected by any form or medium of digital data communication (e.g., a communications net-

work). Examples of communications networks include a local area network ("LAN"), a wide area network ("WAN"), and the Internet.

The computing system may include clients and servers. A client and server are generally remote from each other and typically interact through a communications network. The relationship of client and server arises by virtue of computer programs running on the respective computers and having a client-server relationship to each other.

The implementations set forth in the foregoing description do not represent all implementations consistent with the subject matter described herein. Instead, they are merely some examples consistent with aspects related to the described subject matter. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Although a few variations have been described in detail above, other modifications or additions are possible. In particular, further features and/or variations can be provided in addition to those set forth herein. For example, the implementations described above can be directed to various combinations and sub-combinations of the disclosed features and/or combinations and sub-combinations of several further features disclosed above. In addition, the logic flows and steps for use described herein do not require the particular order shown, or sequential order, to achieve desirable results. Other embodiments can be within the scope of the claim.

What is claimed is:

1. A system comprising:

a fluid port comprising:

a fluid channel;

a fluid inlet at a first end of the fluid channel configured to couple to an outlet of a manually administrable fluid source;

a fluid outlet at a second end of the fluid channel configured to deliver fluid from the manually administrable fluid source to a fluid pathway that provides fluid to a patient;

at least one sensor configured to determine at least one attribute of the fluid from the manually administrable fluid source;

a flow controller in communication with the at least one sensor that generates at least one flow modification signal in response to the determined at least one attribute matching at least one condition specified by at least one rule; and

a flow control valve in communication with the flow controller and positioned within the fluid pathway at a location separate and distinct from the fluid port, the flow control valve changing a level of flow restriction of the fluid from the manually administrable fluid source passing therethrough in response to receiving the at least one flow modification signal, wherein changing the level of flow restriction of the fluid from the manually administrable fluid source passing through the flow control valve comprises adjusting a current flow rate of the fluid passing through the flow control valve to a higher or lower flow rate, wherein the flow control valve partially restricts the fluid passing through the flow control valve at the higher or lower rate,

wherein the at least one sensor is configured to automatically measure a withdrawn downstream fluid volume, wherein the withdrawn downstream fluid volume is a total volume of the fluid downstream of the fluid inlet and still within the fluid channel after fluid flow through the fluid pathway is stopped, and

wherein the at least one sensor comprises a fluid flow sensor, and wherein sensed fluid flow information causes the flow controller to generate a first flow modification signal to cause the flow control valve to transition to a first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, causes the flow controller to generate a second flow modification signal to cause the flow control valve to transition to a second state different than the first state.

2. The system as in claim **1**, wherein the at least one sensor determines the at least one attribute of the fluid from the manually administrable fluid source when the manually administrable fluid source is being coupled to the fluid inlet.

3. The system as in claim **1**, wherein the at least one sensor determines the at least one attribute of the fluid from the manually administrable fluid source when the manually administrable fluid source is coupled to the fluid inlet.

4. The system as in claim **1**, wherein the at least one sensor determines the at least one attribute of the fluid from the manually administrable fluid source when the fluid is passing through the fluid channel.

5. The system as in claim **1**, wherein the at least one sensor is integral or coupled to the fluid port.

6. The system as in claim **1**, wherein the at least one sensor is separate and distinct from the fluid port.

7. The system as in claim **1**, wherein changing the level of flow restriction of the fluid from the manually administrable fluid source passing through the flow control valve comprises stopping all fluid from passing through the flow control valve.

8. The system as in claim **1**, wherein the flow controller comprises or is in communication with a rules engine, the rules engine using a plurality of rules to determine whether the at least one attribute matches the at least one condition specified by the at least one rule.

9. The system as in claim **8**, wherein the flow controller polls at least one remote data source to obtain at least a portion of the rules.

10. The system as in claim **8**, wherein the rules engine, when applying the rules, uses (i) the at least one attribute and (ii) flow control input data selected from a group consisting of: fluid information, patient-specific information, medical order information, clinical guideline information, environmental factors, flow control valve status, and historical information.

11. The system as in claim **1**, wherein the outlet of the manually administrable fluid source comprises fluid source information encoded thereon, and the at least one sensor comprises an identification sensor that detects the manually administrable fluid source information when the manually administrable fluid source is being coupled or is coupled to the fluid port inlet.

12. The system as in claim **11**, wherein the fluid source information is a code or identifier used to reference a secondary data set that is associated with the fluid contained within the manually administrable fluid source.

13. The system as in claim **12**, further comprising a memory that stores the secondary data set.

14. The system as in claim **12**, further comprising: a remote data source coupled to the flow controller via a communications network that stores the secondary data set.

15. The system as in claim **11**, wherein the at least one flow modification signal is generated using a rules engine that processes the detected fluid source information.

16. The system as in claim 1, wherein: the at least one sensor comprises a fluid composition sensor that determines a composition of the fluid, the fluid composition sensor is located along the fluid channel between the fluid inlet and the fluid outlet, and the at least one attribute is indicative of at least one constituent present in the fluid flowing through the channel.

17. The system as in claim 16, wherein the at least one flow modification signal is generated using a rules engine that processes the result of the sensed fluid composition information.

18. The system as in claim 1, wherein the flow control valve is on the fluid pathway downstream from the fluid port.

19. The system as in claim 1, wherein the flow control valve is on the fluid pathway upstream from the fluid port.

20. The system as in claim 1, wherein: contents from the manually administrable fluid source do not reach the patient for at least a time T1 after the manually administrable fluid source begins fluid delivery into the fluid inlet, the flow controller and the flow control valve are configured to restrict flow in the fluid pathway within a time T2 <T1 after the manually administrable fluid source begins the fluid delivery into the fluid inlet.

21. The system as in claim 1, further comprising: a wireless transmitter to transmit data from the at least one sensor to the flow controller.

22. The system as in claim 1, further comprising: a wireless transceiver coupled to the flow controller to receive and transmit data relating to operation of the flow control valve.

23. The system as in claim 1, further comprising: a wireless receiver coupled to the flow control valve to receive the at least one flow modification signal from the flow controller.

24. The system as in claim 23, further comprising: a wireless transmitter coupled to the flow control valve to send information to the flow controller indicative of a change in the level of fluid flow restriction being applied to the fluid passing through the flow control valve in response to receiving the at least one flow modification signal from the flow controller.

25. The system as in claim 1, wherein the at least one sensor is selected from a group consisting of: identification sensors, flow sensors, and composition sensors.

26. The system as in claim 1, wherein the fluid is medication and the at least one attribute includes one or more of a group consisting of: medication type, medication concentration, medication volume, medication expiration date, a dosage form of the medication, dose instructions for the medication, administration instructions for a specific patient, medication formulation, medication manufacturer information, a re-packager of the medication, a distributor of the medication, medication package form, medication package size, medication package serial number, medication lot number, blood type, an RxNorm identification code, an NDC code (National Drug Code), a segment of an NDC code identifying a corresponding medication product, a segment of an NDC code identifying a corresponding medication package, a unique identifier code, a human readable alphanumeric string, and a machine readable code.

27. The system as in claim 1, wherein the fluid port further comprises a wireless transceiver for transmitting and receiving data to and from the flow controller, and the flow controller further comprises a wireless transceiver for transmitting and receiving data to and from the fluid port.

28. The system as in claim 27, wherein the flow controller transmits data to an external device other than the fluid port controlling a state of the flow control valve.

29. The system as in claim 1, wherein the at least one flow modification signal is automatically initiated and executed by the flow controller without user intervention.

30. The system as in claim 29, wherein the at least one flow modification signal is automatically initiated and executed by the flow controller as a result of coupling the outlet of the manually administrable fluid source to the fluid inlet.

31. The system as in claim 29, wherein the at least one flow modification signal is automatically initiated and executed by the flow controller as a result of sensing the start of fluid flow into the fluid inlet.

32. The system of claim 1, further comprising:

an interface to provide at least one of audio and visual feedback to a user associated with at least one of the at least one attribute and the fluid contained within the manually administrable fluid source.

33. The system as in claim 32, wherein the interface provides an indication to the user of a state of the flow control valve.

34. The system as in claim 33, wherein the interface allows a user to input information to be used by the flow controller, in combination with information from the at least one sensor, to determine whether to generate the at least one flow modification signal.

35. The system as in claim 34, wherein the fluid is medication and the interface displays at least one of administration information and instructions associated with the medication.

36. The system of claim 35, further comprising a memory that stores the at least one of the administration information and the instructions associated with the medication.

37. The system as in claim 36, further comprising: a communications module to at least one of transmit and receive the at least one of the administration information and the instruction to/or from a remote data source.

38. The system as in claim 32, wherein the interface is adjacent to the fluid port.

39. The system as in claim 32, wherein the interface is remote from the fluid port.

40. The system as in claim 1 further comprising: a manual override element, which when activated by a user, causes the flow controller to cause the flow control valve to stop fluid flow in a first state or to allow the fluid to flow in a second state.

41. The system of claim 1, further comprising: a communications module to at least one of transmit and receive at least one of flow control input data, rules engine output data and data on the fluid source to or from a remote data processing system.

42. The system of claim 41, wherein the remote data processing system forms part of at least one of a medical device and a medical information system.

43. The system of claim 1, wherein there are a plurality of fluid inlets, each configured to couple to an outlet of one of a plurality of manually administrable fluid sources.

44. The system as in claim 43, wherein there are a plurality of flow control valves, each flow control valve being coupled to the flow controller to selectively prevent the fluid flowing from at least one of the plurality of fluid inlets.

45. The system as in claim 1, wherein the flow controller receives data relating to the patient that is used, in combi-

nation with information from the at least one sensor, to determine whether to generate the at least one flow modification signal.

46. The system as in claim **45**, wherein the data relating to the patient comprises at least one medication order, the at least one medication order being used to confirm whether the fluid in the manually administrable fluid source matches the at least one condition specified by the at least one rule specified by the at least one medication order.

47. The system as in claim **45**, wherein the data relating to the patient comprises a patient identifier and the flow controller polls at least one remote data store using the patient identifier to obtain reference information to determine whether to generate the at least one flow modification signal.

48. The system as in claim **1**, wherein the at least one sensor comprises a fluid flow sensor, and wherein the system further comprises: an interface providing at least one of audio and visual feedback indicating how much of the fluid has been delivered as measured by the fluid flow sensor.

49. The system as in claim **1**, wherein the at least one sensor comprises an identification sensor that generates the at least one attribute using one or more technologies selected from a group consisting of: optical, magnetic, mechanical, conductive, switchable, infrared, switchable RFID, and proximity sensors.

50. The system as in claim **1**, wherein the at least one sensor comprises a composition sensor that generates the at least one attribute using one or more technologies selected from a group consisting of: photometric analysis, electrometric analysis, chromatography, mass spectroscopy, physical property measurements, or parametric analysis based on a combination of technologies.

51. The system as in claim **1**, wherein the at least one sensor comprises a fluid flow sensor that generates the at least one attribute using one or more technologies selected from a group consisting of: a paddle wheel flow meter, a turbine flow meter, a thermal flow meter, an ultrasonic flow meter, a pressure sensor, a differential pressure sensor, an optical sensor, an ultrasonic sensor, a coriolis flow meter, a displacement sensor.

52. The system as in claim **1**, wherein at least the fluid inlet, the fluid outlet, and the fluid channel are disposed within a disposable sub-housing.

53. The system as in claim **52**, wherein the disposable sub-housing is included in a sterile pouch enveloping the disposable sub-housing.

54. The system of claim **1** further comprising: a housing enveloping at least a portion of each of the fluid inlet, the fluid outlet, the flow controller, and the at least one sensor.

55. The system as in claim **54**, wherein the housing has a shape and size allowing a user to hold the housing in a first hand while coupling the manually administrable fluid source in a second hand.

56. The system as in claim **55**, further comprising: a self-contained power source within the housing powering the at least one sensor.

57. The system as in claim **55**, wherein the fluid pathway is an intravenous (IV) fluid line and the housing is suspended on the IV fluid line.

58. The system as in claim **1**, wherein the manually administrable fluid source is selected from a group consisting of: syringes, IV bags, disposable medication cartridges, disposable medication pouches, and IV tubing.

59. The system as in claim **1**, wherein the at least one sensor polls a remote data source or data processing system to generate the at least one attribute.

60. The system as in claim **1**, wherein the flow controller polls at least one remote data source or data processing system to determine whether the at least one attribute matches the at least one condition specified by the at least one rule.

61. A system comprising:

a fluid port comprising:

a fluid channel;

a fluid inlet at a first end of the fluid channel configured to couple to an outlet of a manually administrable fluid source; and

a fluid outlet at a second end of the fluid channel configured to deliver fluid from the manually administrable fluid source to a fluid pathway that provides the fluid to a patient, the fluid pathway having a known volume and a known flow rate;

at least one sensor configured to determine at least one attribute of the fluid from the manually administrable fluid source, wherein the at least one sensor is configured to automatically measure a withdrawn downstream fluid volume, wherein the withdrawn downstream fluid volume is a total volume of the fluid downstream of the fluid inlet and still within the fluid channel after fluid flow through the fluid pathway is stopped;

a controller in communication with the at least one sensor that generates at least one operation modification signal in response to the determined at least one attribute matching at least one condition specified by at least one rule and based on the known volume and the known flow rate, wherein the controller determines a time for the injected fluid to reach the patient from the fluid source based on the known volume and the known flow rate to generate the at least one operation modification signal; and

a transmitter for wirelessly transmitting the operation modification signal to at least one device, the operation modification signal, when received by the at least one device, causing the at least one device to modify at least one operating parameter,

wherein the at least one sensor comprises a fluid flow sensor, and wherein sensed fluid flow information causes the controller to generate a first operation modification signal to cause a flow control valve to transition to a first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, causes the controller to generate a second operation modification signal to cause the flow control valve to transition to a second state different than the first state.

62. The system as in claim **61**, wherein the at least one device comprises a medical device.

63. The system as in claim **61**, wherein the medical device causes fluid flow through the fluid pathway to be restricted.

64. A method comprising:

receiving data generated by at least one sensor of a fluid port including at least one attribute of fluid within a manually administrable fluid source, the fluid port comprising: a fluid channel, a fluid inlet at a first end of the fluid channel configured to couple to an outlet of the manually administrable fluid source, and a fluid outlet at a second end of the fluid channel configured to deliver the fluid from the manually administrable fluid source to a fluid pathway that provides the fluid to a patient, the fluid pathway having a known volume and a known flow rate and the at least one sensor, wherein the at least one sensor comprises a fluid flow sensor;

determining that the at least one attribute in the received data matches at least one condition specified by at least one rule;

generating at least one flow modification signal, which causes a change in the fluid passing through the fluid flow pathway based on the known volume and the known flow rate, wherein the generating the at least one flow modification signal comprises determining a time for the fluid to reach the patient based on the known volume and the known flow rate;

receiving data generated by the at least one sensor of the fluid port including a withdrawn downstream fluid volume, wherein the withdrawn downstream fluid volume is a total volume of the fluid downstream of the fluid inlet and still within the fluid channel after fluid flow through the fluid pathway is stopped; and

generating, based on sensed fluid flow information from the fluid flow sensor, a first flow modification signal to cause a flow control valve to transition to a first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, generating a second flow modification signal to cause the flow control valve to transition to a second state different than the first state.

65. A method comprising:

receiving data generated by at least one sensor of a fluid port, the data including at least one attribute of fluid within a manually administrable fluid source, the fluid port comprising: a fluid channel, a fluid inlet at a first end of the fluid channel configured to couple to an outlet of the manually administrable fluid source, and a fluid outlet at a second end of the fluid channel configured to deliver the fluid from the manually administrable fluid source to a fluid pathway that provides the fluid to a patient, the fluid pathway having a known volume and a known flow rate, wherein the at least one sensor comprises a fluid flow sensor;

determining that the at least one attribute in the received data matches at least one condition specified by at least one rule;

generating, by a controller in communication with the at least one sensor, at least one operation modification signal in response to the at least one attribute matching at least one condition specified by at least one rule and based on the known volume and the known flow rate, wherein the generating the at least one operation modification signal comprises determining a time for the fluid to reach the patient from the fluid source based on the known volume and the known flow rate; and

wireless transmitting, by a transmitter, the operation modification signal to at least one device, the operation modification signal, when received by the at least one device, causes the at least one device to modify at least one operating parameter;

receiving data generated by the at least one sensor of the fluid port, the data including a withdrawn downstream fluid volume, wherein the withdrawn downstream fluid volume is a total volume of the fluid downstream of the fluid inlet and still within the fluid channel after fluid flow through the fluid pathway is stopped; and

generating, based on sensed fluid flow information from the fluid flow sensor, a first operation modification signal to cause a flow control valve to transition to a first state when a first pre-determined volume has been delivered as measured by the fluid flow sensor, and after a pre-determined span of time, generating a second operation modification signal to cause the flow control valve to transition to a second state different than the first state.

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