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(54) **Title:** SYSTEMS AND METHODS FOR AIR-IN-LINE DETECTION IN INFUSION PUMPS

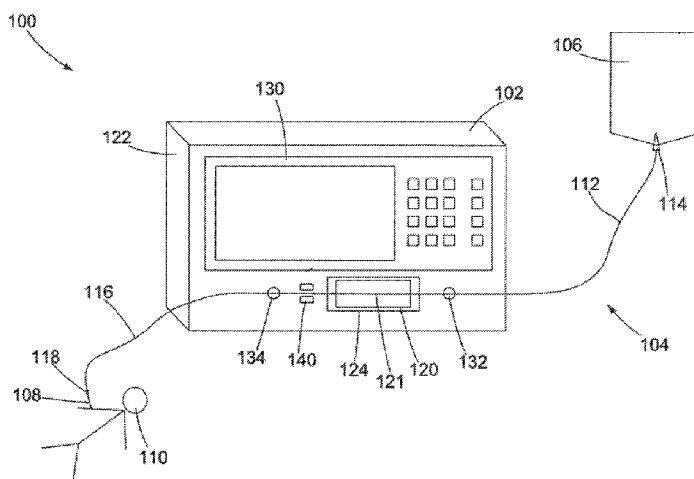


FIG. 1

(57) **Abstract:** An infusion pump is configured to deliver fluid in an infusion line. The infusion pump can include a first air-in-line detector (AILD) configured to provide signals indicating air present or air not present in the infusion line at a first location, a second AILD configured to provide signals indicating air present or air not present in the infusion line at a second location downstream from the first location, and a controller configured to receive signals from the first AILD and the second AILD. The controller can be programmed and configured to perform lowest-volume calculations of air in the infusion line based upon the signals from both the first AILD and the second AILD, and to annunciate air-in-line alarms based upon the lowest-volume calculations.

SYSTEMS AND METHODS FOR AIR-IN-LINE DETECTION IN INFUSION PUMPS

CROSS REFERENCE TO RELATED APPLICATION

The present application claims the benefit of US Provisional Application No. 62/311,204, filed on March 21, 2016, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

This disclosure relates to systems and methods for air-in-line detection in infusion pumps, and more particularly, to air-in-line detection with a plurality of detectors.

BACKGROUND

In view of the importance of avoiding introduction of gas (air or other) into the vasculature of patients, infusion pumps typically incorporate (and in many cases are required to incorporate) an air-in-line detector (AILD) to sense the presence of unwanted or deleterious gas in lines or tubes that deliver medicaments and other infusates to patients. (In the present disclosure, the term “air” is used colloquially and interchangeably with “gas” to describe any gas that may exist in an infusion line, regardless of chemical composition.) Many AILDs utilize ultrasonic sensing, exploiting the differing acoustic properties (e.g., transmission and reflection) of portions of a line filled with liquid, gas, or a mixture of the two. In some cases, an infusion pump can announce an air detection alarm when predetermined conditions are met in regard to AILD sensing, alerting a caregiver to the possibility of an air-in-line condition that may call for remediation.

Implementing a useful AILD system can require, or benefit from, careful arrangement and adjustment of hardware, and judicious choice of the predetermined conditions or parameters that define when an alarm is to be annunciated. A system that is less well-implemented - that may be, for example, adversely affected by slow-moving or “stuck” gas or air bubbles as described in greater detail below - may fail to alarm when an air-in-line condition exists, or may provide excessive false alarms. The latter case can contribute to the annoyance of caregivers and even more problematic “alarm fatigue” (desensitization to possibly valid alarms). In some cases, a poorly-implemented AILD system may be deactivated or overridden by a practitioner, eliminating any possible benefit from the system

and any associated alarms. It would therefore be desirable to provide improved systems and methods for air-in-line detection for infusion pumps.

SUMMARY

5 This disclosure relates to systems and methods for air-in-line detection in infusion pumps, and more particularly, to air-in-line detection with a plurality of detectors.

 In an illustrative but non-limiting example, the disclosure provides an infusion pump configured to deliver fluid in an infusion line. The infusion pump can include a first air-in-line detector (AILD) configured to provide signals indicating air present or air not present in
10 the infusion line at a first location, a second AILD configured to provide signals indicating air present or air not present in the infusion line at a second location downstream from the first location, and a controller configured to receive signals from the first AILD and the second AILD. The controller can be programmed and configured to perform lowest-volume calculations of air in the infusion line based upon the signals from both the first AILD and the
15 second AILD, and to annunciate air-in-line alarms based upon the lowest-volume calculations.

 In some cases, the controller can be programmed and configured to calculate a first volume of a detected bubble based at least in part upon signals from the first AILD, calculate a second volume of the detected bubble based at least in part upon signals from the second
20 AILD, and annunciate a single-bubble alarm if both the first volume and the second volume each exceeds a predetermined single-bubble limit.

 In some cases, the controller can be programmed and configured to modify a first air accumulation such that the first air accumulation represents a volume of air passing the first AILD during a specified preceding time interval, modify a second air accumulation such that
25 the second air accumulation represents a volume of air passing the second AILD during the specified preceding time interval, and annunciate an accumulated air alarm only if both the first air accumulation and the second air accumulation each exceeds a predetermined accumulated air limit.

 In some cases, the controller is programmed and configured to calculate a quantity
30 related to a travel time of the bubble from the first AILD to the second AILD based at least in part upon signals from the first AILD and the second AILD relating to detection of the bubble at the first AILD and the second AILD. In some of these cases, a single-bubble alarm is annunciated only if the travel time of the bubble from the first AILD to the second AILD is

within a predetermined range of time relative to an infusate travel time from the first AILD to the second AILD.

In some cases, the controller is programmed and configured to calculate a quantity related to a travel time of the bubble from the first AILD to the second AILD based at least in part upon signals from the first AILD and the second AILD relating to detection of the bubble at the first AILD and the second AILD. In some of these cases, performing lowest-volume calculations of the volume of air in the infusion line by the controller includes calculating at least one of a first volume of the detected bubble at the first AILD and/or a second volume of the detected bubble at the second AILD based in part upon the quantity related to the travel time of the bubble from the first AILD to the second AILD.

In another illustrative but non-limiting example, the disclosure provides an infusion pump configured to deliver fluid in an infusion line that includes a first air-in-line detector operatively coupled to the infusion line and a second air-in-line detector operatively coupled to the infusion line. The infusion line at the first air-in-line detector can be oriented along a first axis, and the infusion line at the second air-in-line detector can be oriented along a second axis oriented differently from the first axis. In some cases, the first axis and the second axis are oriented differently by an angle of at least 45 degrees.

In some cases, the pump can include a pump housing, and the first air-in-line detector can have a fixed position and a fixed orientation in relation to the pump housing, and the second air-in-line detector can have a fixed position and a fixed orientation in relation to the pump housing.

In some cases, the pump can include a pump housing, and the first air-in-line detector can have a fixed position and a fixed orientation in relation to the pump housing, and the second air-in-line detector can have a fixed position and a selectively changeable orientation in relation to the pump housing.

In some cases, one of the first axis and the second axis is substantially vertical when the pump is in a standard orientation.

In yet another illustrative but non-limiting example, the disclosure provides a method for providing information about gas in an infusion line. The method can include attempting to detect a bubble in an infusion line at a first air-in-line detector (AILD), and if the bubble is detected at the first AILD, calculating a first volume of the bubble based at least in part upon signals from the first AILD. The method can also include attempting to detect the bubble in the infusion line at a second AILD, where the second AILD is located downstream of the first

AILD, and if the bubble is detected at the second AILD, calculating a second volume of the bubble based at least in part upon signals from the second AILD. If both the first volume and the second volume each exceeds a predetermined single-bubble limit, the method can include annunciating a single-bubble alarm.

5 In some cases of the method, calculating the first volume can be based in part upon a quantity related to a first transit time of the bubble past the first AILD, and calculating the second volume can be based in part upon a quantity related to a second transit time of the bubble past the second AILD.

10 In some cases of the method, calculating at least one of the first volume and the second volume can be based in part upon a quantity related to a travel time of the bubble from the first AILD to the second AILD. In some of these cases, the quantity related to the travel time of the bubble from the first AILD to the second AILD can be calculated at least in part from signals from the first AILD and the second AILD relating to detection of the bubble at the first AILD and the second AILD.

15 In some cases of the method, a single-bubble alarm can be annunciated only if a measured travel time of the bubble from the first AILD to the second AILD is within a predetermined range of time relative to an infusate travel time from the first AILD to the second AILD.

20 Some examples of the method can further include modifying a first air accumulation such that the first air accumulation represents the volume of air passing the first AILD during a specified preceding time interval, modifying a second air accumulation such that the second air accumulation represents the volume of air passing the second AILD during the specified preceding time interval, and annunciating an accumulated air alarm only if both the first air accumulation and the second air accumulation each exceeds a predetermined accumulated air
25 limit.

 In still another illustrative but non-limiting example, the disclosure provides a method for providing information about gas in an infusion line. The method can include detecting a bubble in an infusion line at a first air-in-line detector (AILD), including recording signals produced by the first AILD and detecting the bubble in the infusion line at a second AILD,
30 including recording signals produced by the second AILD, where the second AILD is located downstream of the first AILD. The method also can include calculating a calculated air flow rate in the infusion line based at least in part upon signals from the first AILD and the second AILD and performing a lowest-volume calculation of a volume of the bubble based upon the

signals from both the first AILD and the second AILD. If the volume of the bubble from the lowest-volume calculation exceeds a predetermined single-bubble limit, the method can include annunciating a single bubble alarm. In some cases, performing the lowest-volume calculation can be based in part upon the calculated air flow rate.

Some examples of the method can include modifying an air accumulation such that the air accumulation represents the volume of air passing the first AILD and the second AILD during a specified preceding time interval. Modifying the air accumulation can include adding the volume of the bubble from the lowest-volume calculation to the air accumulation. If the air accumulation exceeds a predetermined accumulated air limit, the method can include annunciating an accumulated air alarm.

In some cases of the method, performing the lowest-volume calculation can include calculating a first volume of the bubble at the first AILD and calculating a second volume of the bubble at the second AILD. In some of these cases, a selected one of calculating the first volume and calculating the second volume can be based in part upon the calculated air flow rate.

The above summary is not intended to describe each and every example or every implementation of the disclosure. The Description that follows more particularly exemplifies various illustrative embodiments.

BRIEF DESCRIPTION OF THE FIGURES

The following description should be read with reference to the drawings. The drawings, which are not necessarily to scale, depict examples and are not intended to limit the scope of the disclosure. The disclosure may be more completely understood in consideration of the following description with respect to various examples in connection with the accompanying drawings, in which:

Figure 1 is a schematic illustration of an example of an infusion pump system;

Figure 2 is a flow diagram of a method that can be executed by a controller of the pump system of Figure 1 to determine whether and when to annunciate air-in-line alarms;

Figure 3A is a schematic illustration of an example of an infusion pump that has a plurality of air-in-line detectors;

Figure 3B is a schematic illustration of another example of an infusion pump that has a plurality of air-in-line detectors;

Figure 3C is a schematic illustration of another example of an infusion pump that has a plurality of air-in-line detectors;

Figure 3D is a schematic illustration of another example of an infusion pump that has a plurality of air-in-line detectors;

5 Figure 3E is a schematic illustration of example of an infusion pump that has a plurality of air-in-line detectors configured to detect air bubbles in a hybrid infusion line;

Figure 3F is a close in partial perspective illustration of a portion of the hybrid infusion line of Figure 3E.

10 Figure 4 is a flow diagram of a method that can be an independent sub-process for each air-in-line detector in a propose/confirm method of operation;

Figure 5 is a flow diagram of a method that can be a combination process for evaluating information from the sub-processes of Figure 4 in a propose/confirm method of operation;

15 Figure 6 is a flow diagram of a method for incorporating information from a plurality of air-in-line detectors to determine whether and when to annunciate air-in-line alarms; and

Figure 7 is a flow diagram of a method for providing information about gas in an infusion line that can include the use of calculated air flow rates.

DESCRIPTION

20 The following description should be read with reference to the drawings, in which like elements in different drawings may be numbered in like fashion. The drawings, which are not necessarily to scale, depict selected examples and are not intended to limit the scope of the disclosure. Although examples of construction, dimensions, and materials may be illustrated for the various elements, those skilled in the art will recognize that many of the examples
25 provided have suitable alternatives that may be utilized.

Figure 1 is a schematic illustration of an example of an infusion pump system 100 that includes a pump 102 and an administration set 104 operatively coupled to the pump. Administration set 104 can be a disposable component of infusion pump system 100 and can be structured and configured to reversibly couple to the pump 102. While the example of
30 infusion pump system 100 can be considered a “large volume” infusion pump, systems and methods of the present disclosure are not necessarily limited to large volume infusion pumps, and may be practiced with any suitable infusion pump that may benefit from improved air-in-line detection, including ambulatory infusion pumps.

Administration set 104 can provide a fluidic pathway via infusion lines (tubes) from an IV bag 106 or other infusate reservoir to an infusion set 108 that ultimately delivers infusate(s) to a patient 110. Administration set 104 can include upstream tubing 112 that can extend from IV bag 106 or other reservoir to pump 102. Upstream tubing 112 can terminate
5 in a bag spike 114 or other connector. Administration set 104 can also include downstream tubing 116 that can extend from pump 102 to infusion set 108. Downstream tubing 116 can be fluidically coupled to infusion set 108 or other catheter with connector 118 such as a Luer-type connector or any other suitable connector. In some embodiments, administration set 104 can include mating hardware 120 that can facilitate operative coupling of administration set
10 104 to pump 102. Mating hardware 120 can include, but is not limited to, elements for mechanically coupling administration set 104 to the pump such as clips, brackets, latches, and the like, and can also include pumping mechanism elements of infusion pump system 100, such as (but not limited to) a pump tube 121 fluidically coupled to upstream tubing 112 and downstream tubing 116, a pressure plate, and any other suitable hardware.

Pump 102 can include a housing 122 and receiving hardware 124 configured to couple to mating hardware 120 of administration set 104. Receiving hardware 124 can include elements of the pumping mechanism of the infusion pump system 100 (not illustrated). In some embodiments that incorporate a peristaltic pumping mechanism, for example, receiving hardware 124 can include peristaltic tube-engaging members that engage
20 pump tube 121 of mating hardware 120. In the present disclosure, use of the terms “mating hardware” 120 and “receiving hardware” 124 should not necessarily be construed in a limiting manner as including all elements of administration set 104 that may in any sense “mate” with pump 102, and all elements of pump 102 that may in any sense “receive” any part or portion of administration set 104, respectively. Irrespective of a particular
25 embodiment, and irrespective of specific illustration in Figure 1, it is to be appreciated and understood that pump system 100 provides a fluidic path for infusate(s) from IV bag or other infusate reservoir 106 to selectively reach and be infused into patient 110.

Pump 102 typically can include a user interface 130 (that can include, for example, a display screen, keypad, loudspeaker, and any other suitable user interface components) for
30 relaying commands to a control system or controller (not illustrated) of pump 102, and/or for communicating from the controller to users. User interface 130 generally can allow a user to enter various parameters, including but not limited to names, drug information, limits, delivery shapes, information relating to hospital facilities, as well as various user-specific

parameters (e.g., patient age and/or weight) along with so-called "five rights" verification or inputs. Pump 102 can include any appropriate wired or wireless input/output (I/O) interface port and/or protocol (including, but not limited to, USB, Ethernet, WiFi, NFC, Bluetooth, ZigBee, IrDA, and the like) for connecting pump 102 to a network or computer (not
5 illustrated) having software designed to interface with pump 102.

User inputs to pump 102 can be provided by programming from an authorized user, such as a patient, pharmacist, scientist, drug program designer, medical engineer, nurse, physician, or other authorized medical practitioner or healthcare provider. User inputs may utilize direct interfacing (via, e.g., keyboards, touch screens, or other touch-based inputs) as
10 shown, and/or user inputs may utilize indirect or "touchless" interfacing (i.e., gestures; voice commands; facial movements or expressions; finger, hand, head, body and arm movements; or other inputs that do not require physical contact such as cameras, sensors of electric field, capacitance, or sound). User inputs generally can be interfaced, communicated, sensed, and/or received by operator input mechanisms of user interface 130.

15 In the present disclosure, a controller of a pump can be any suitable controller, microcontroller, microprocessor, or the like. Such a controller can include and/or be operatively coupled to any other hardware or software resource needed for its function, such as any suitable memory of any suitable capacity, containing any suitable software, firmware, operating parameters, and so on. The controller can be configured and programmed to
20 execute, command, and/or perform any suitable actions, tasks, steps, and/or methods for controlling the pump. The pump can include a plurality of physically and/or logically distinct controllers, such as application-specific processors. In the present disclosure, a plurality of such controllers of a pump may be referred to collectively in the singular as the controller of the pump. As mentioned elsewhere herein, methods of the present disclosure can be
25 implemented by the controller of a pump, and/or in some instances by another controller, such as by a controller of another pump, a system of pumps, a controller implemented on a server, or any other appropriate controller. As such, any reference in the present disclosure to a controller in the singular should not be interpreted as strictly limiting to a single physical or logical controller (unless explicitly limited to a single controller), but rather, can include
30 systems and/or methods in which controller functions are provided by one or more controllers.

Power to infusion pump 102 can be provided via an AC or DC power cord, from an internally provided battery source (not illustrated), or by any other suitable means. Embodiments can also include a wireless power source (not illustrated).

Pump 102 can include sensors configured to measure, detect, or otherwise sense
5 conditions in or pertaining to infusion lines of administration set 104 (infusion lines can include upstream tubing 112, downstream tubing 116, and pump tube 121 of mating hardware 120). Pump 102 can include an upstream occlusion detector 132 and/or a downstream occlusion detector 134. Occlusion detectors 132, 134 can include force sensors that bear against a portion of infusion line (upstream tubing 112, downstream tubing 116,
10 pump tube 121, or any other suitable portion of line/tubing). Interpretation of readings or data obtained from occlusion sensors 132, 134 can depend on knowledge of physical properties of the infusion line where it is contacted by the sensor, and possibly other characteristics of the infusion system upstream or downstream from pump 102.

In this example embodiment of Figure 1, pump 102 can include an air-in-line detector
15 (AILD) 140. AILD 140 can employ any suitable air-detection technology, which can be ultrasonic, capacitive, optical, or another technology, or a combination of technologies. AILD 140 can surround the infusion line in whole, or more commonly, in part. AILD 140 can be structured with a groove or channel within which a segment of infusion line can reside when administration set 140 is operatively coupled to pump 102. AILD 140 can include at least one
20 ultrasonic transducer located immediately adjacent to or in the groove or channel. In an embodiment, AILD 140 can be an ultrasonic detector with an acoustic transmitter positioned on one side of the infusion line, and an acoustic receiver positioned on the other side of the infusion line.

Without necessarily relying upon any particular theory of air-in-line detection that
25 would limit the scope of the disclosure or the claimed subject matter, a discussion of ultrasonic air-in-line detection is provided. The acoustic impedance of the portion of infusion line located proximal to an AILD can vary depending on whether the tube contains liquid, gas, or a mixture of the two. Generally, a liquid-filled tube can transmit acoustic waves more efficiently than a tube containing gas (which can be regarded, relatively, as an acoustic open
30 circuit). A tube containing a mixture of liquid and gas can present an acoustic impedance between the all-liquid and all-gas cases. In practice, an ultrasonic AILD can be effectively “tuned” or calibrated (*e.g.*, by adjusting threshold values used to evaluate measured quantities related to detected acoustic properties, such as the acoustic transmissivity across the infusion

line between transmitter and receiver). The tuning or calibration can depend on the characteristics of the particular portion of infusion tube proximal the AILD, such as material, diameter, and wall thickness. In some embodiments, an ultrasonic AILD can be tuned or calibrated to provide a binary signal to indicate “air” or “no air.” In reality, in some
5 circumstances an infusion line or portion thereof can contain a mixture of liquid and gas, and given uncertainties in the interpretation of ultrasonic acoustical measurements, such an “air” or “no air” binary signal may not necessarily be indicative of an essentially entirely or predominantly air-filled vs. liquid-filled tube.

With respect to the foregoing discussion, AILD 140 of pump 102 can be configured to
10 provide a binary signal to indicate “air” or “no air.” The controller of pump 102 can be programmed and configured to handle information from AILD 140, including such a binary signal, in any suitable manner and for any suitable purposes, including determinations of whether and when to annunciate air-in-line alarms. Air-in-line alarms are not necessarily annunciated with every signaled indication of air by AILD 140. In some cases, for example,
15 small volumes of air in the infusion line can be essentially ignored as they may present negligible risk of harm to patient 110. If not ignored, their detection can result in, for example, relatively frequent annunciation of air-in-line alarms that a caregiver may, over time, learn to or be responsively conditioned to disregard (the so-called effect of “alarm fatigue”), potentially leading to the hazard of the caregiver disregarding a more serious alarm.

Annunciation of an alarm in any system or method of the present disclosure can be
20 any appropriate communication of an alarm. Annunciation of an alarm can include, for example, a visible, audible, tactile, etc. notification to a user via a user interface such as user interface 130, and/or can include an electronic or other machine-to-machine communication such as (but not limited to) a message via a protocol such as Ethernet, WiFi, Bluetooth, IrDA,
25 etc.

Figure 2 is a flow diagram of a method 200 that can be executed by the controller of pump 102 to calculate a volume of a gas or air bubble in the infusion line based at least in part upon signals from AILD 140, and determine whether and when to annunciate air-in-line alarms. As used in the present disclosure, a “bubble” or “single bubble” can refer to a volume
30 of air or gas in the infusate line as detected by an AILD, where the “bubble” is considered to start when the AILD senses or indicates “air,” and end when the AILD senses or indicates “no air,” irrespective of the appearance or actual physical reality of the contents of the infusate line. For example, an AILD may lack the resolving power to distinguish between

individual members of a tightly-packed group of bubbles, but rather, might only indicate “air” at the beginning of the group, and then indicate “no air” at the end of the group, with no intervening indications between adjacent bubbles. In the present disclosure, this example of a tightly-packed group can be referred to as a single bubble.

5 At 210 of method 200, when air is detected at AILD 140, the controller can record a transit time of a bubble passing the AILD (measured between AILD indications of “air” and “no air”). At 220, the controller can calculate the volume of the bubble based at least in part upon, for example, the recorded transit time of the bubble and the infusate flow rate. At 230, based upon comparison of the calculated volume of the single bubble with a predetermined
10 single-bubble volume limit, the controller can determine whether to annunciate an air-in-line alarm. If the limit is exceeded, a single-bubble alarm can be annunciated at 240. At 250 the controller can add the single-bubble volume to an air accumulation that can be a sum of a plurality of different single-bubble volumes. As the risk or acceptability of accumulated air in an infusion line can depend on the time span over which such an accumulation is aggregated,
15 at 250 the controller can be programmed and configured also to compensate for such time considerations. For example, the controller can subtract from the air accumulation any volume previously added that is older than a predetermined age, such as, for example, fifteen minutes, so that the air accumulation represents the volume of air passing AILD 140 during a most recent time interval (*e.g.*, fifteen minutes). At 260, the controller can determine whether
20 to annunciate an air-in-line alarm at 270 based upon whether the air accumulation exceeds a predetermined accumulated air limit. The method can then return to 210.

Some aspects of air-in-line bubble dynamics can complicate air detection and render the aforementioned air volume calculations less accurate, with potentially undesirable and/or deleterious consequences for annunciation of air-in-line alarms. Some bubbles, particularly
25 relatively small bubbles that do not bridge, span, or otherwise extend across the entire cross-sectional area of the infusion line/tube, can become “stuck” in the tube (remaining stationary, or otherwise moving substantially slower than the bulk flow of liquid). Without necessarily relying upon any particular theory of fluid and/or bubble dynamics that would limit the scope of the disclosure or the claimed subject matter, it is believed that the propensity of bubbles to
30 become stuck can depend on factors such as the physical characteristics of the infusate, adhesive and cohesive forces, bubble size, tube size, tube orientation, infusate flow rate, and so on. If a bubble that is sufficiently large to cause a detector such as AILD 140 to indicate “air” becomes stuck or slow as it transits or otherwise passes by or is present at the AILD, the

observed transit time of the bubble past the AILD can be significantly greater than that of a hypothetical bubble that transits the AILD more quickly while entrained in flowing infusate at the speed of the infusate (or close to the infusate speed). A calculation of bubble volume by the pump controller that (erroneously) assumes that the bubble is flowing at the infusate speed, rather than the slower actual bubble speed, can then result in a substantial over-estimate of bubble volume, which can, in turn, result in over-annunciation of air-in-line alarm(s).

Again, without necessarily relying upon any particular theory of fluid and/or bubble dynamics that would limit the scope of the disclosure or the claimed subject matter, it is believed that bubbles that bridge a tube generally can be moved downstream by liquid flow in the tube and generally can be less susceptible to becoming stuck. Bubbles that do not completely bridge a tube can leave a path around the side(s) of the bubble for infusate flow, and therefore infusate speed in the tube can be greater than bubble speed. However, it is also thought that bubbles that substantially bridge the entire cross section of a tube may also travel slower than the infusate in which they are entrained, in some instances. Although a bubble may substantially entirely bridge a tube, there still can be a thin layer of liquid along the tube walls around the bubble periphery, and some liquid flow around the bubble can occur via this thin liquid layer. The rate of such flow may be influenced by tube orientation, in particular in relation to infusate flow direction (upward flow, downward flow, level flow, etc.) It is conceivable, in the case of upward flow, that buoyant forces could result in a bubble speed greater than the liquid flow speed.

In the present disclosure, systems and methods that involve more than one air-in-line detector are proposed to improve estimates and/or calculations of volumes of gases in infusion lines, and consequently reduce the number of nuisance and/or false air bubble alarms annunciated by infusion pumps. Features of the present disclosure include, in various embodiments and without limitation, use of a plurality of AILDs, judicious placement of AILDs in infusion pump systems, and methods with improved algorithms for calculating volumes of gases in infusate lines and determining whether alarm conditions are met. As discussed further herein, incorporating a plurality of AILDs in infusion pumps can enable confirming with an AILD that an air alarm condition suggested by another AILD actually exists. In some embodiments, AILDs are provided with different physical conditions such that the propensity for stuck or slow bubbles at one AILD may be significantly different at another AILD, reducing the chances of providing overestimates and/or erroneous calculations

of bubble volumes when interpreting information from a plurality of AILDs. In some embodiments, improved algorithms for calculating volumes can consider signals from a plurality of AILDs to provide refined estimates of the volume of air bubbles. In some cases, the algorithms can result in lowest-volume calculations of the volume of air in an infusion
5 line (e.g., when the AILD signals can be interpreted as corresponding to a plurality of possible volumes, a lowest-volume calculation can return the lowest reasonable volume of air consistent with the data from all AILDs considered altogether).

Figures 3A-3D are schematic illustrations of example embodiments of infusion pumps 302a-302d of the present disclosure that each have a plurality of (as illustrated, e.g., two)
10 AILDs. Each of pumps 302a-302d can include features alike or similar to those described in relation to pump 102 of Figure 1, as well as any other features of other known infusion pumps, to the extent that the features of the pumps are not incompatible with the features of pumps 302a-302d described herein. The schematic representations of pumps 302a-302d of Figures 3A-3D are greatly simplified and do not show various features such as user interface,
15 occlusion detectors, and so on, but lack of illustration of such features is merely for clarity of illustration and does not imply the omission of any features from any of the pumps.

Pump 302a of Figure 3A can include a first AILD 350a and a second AILD 360a downstream of the first AILD. First AILD 350a can be structured and positioned relative to other pump components, such as housing 322a, such that a portion 352a of infusion line 305a
20 at first AILD 350a can be oriented along a first axis 354a, and second AILD 360a can be structured and positioned relative to other pump components such that a portion 362a of infusion line 305a at second AILD 360a can be oriented along a second axis 364a. As illustrated in Figure 3A, first axis 354a and second axis 364a can be oriented substantially similar to each other relative to overall dimensions of pump 302a. In some cases, axes 354a
25 and 364a that are oriented substantially similar to each other can be co-linear axes. In other cases axes 354a and 364a that are oriented substantially similar to each other can be parallel but not co-linear axes.

In Figure 3A, first AILD 350a is illustrated as upstream of receiving hardware 324a that includes the pumping mechanism of the pump (not illustrated), and second AILD 360a is
30 downstream of the pumping mechanism. (In the Figures of the present disclosure, flow in pumps is arbitrarily illustrated as being from right-to-left, upstream to downstream, unless otherwise noted.) In some other embodiment, both detectors can be upstream or both can be downstream of the pumping mechanism. In pump systems where the pumping mechanism

can generate air or outgassing from the infusate, it generally may be preferable to place both AILDs downstream of the pumping mechanism.

Pump 302b of Figure 3B can include a first AILD 350b and a second AILD 360b downstream of first AILD 350b, with both AILDs being downstream of receiving hardware/
5 pumping mechanism 324b. First AILD 350b can be structured and positioned relative to other pump components, such as housing 322b, such that a portion 352b of infusion line 305b at first AILD 350b can be oriented along a first axis 354b, and second AILD 360b can be structured and positioned relative to other pump components such that a portion 362b of infusion line 305b at second AILD 360b can be oriented along a second axis 364b. As
10 illustrated in Figure 3B, first axis 354b and second axis 364b can be oriented significantly differently relative to each other. As illustrated in Figure 3B, first axis 354b and second axis 364b may be substantially orthogonal or perpendicular. In some embodiments, first axis 354b and second axis 364b can make an angle relative to each other of at least 80 degrees, 70 degrees, 60 degrees, 45 degrees, or any other angle (and also such as orthogonal or
15 perpendicular as aforementioned) that may intentionally result in different propensity, characteristics, or sensed occurrences for or of stuck or slow bubbles at AILDs 350b, 360b.

Pump 302c of Figure 3C can include a first AILD 350c and a second AILD 360c downstream of the first AILD, with both AILDs being downstream of receiving hardware/
20 pumping mechanism 324c. First AILD 350c can be structured and positioned relative to other pump components, such as housing 322c, such that a portion 352c of infusion line 305c at first AILD 350c can be oriented along a first axis 354c, and second AILD 360c can be structured and positioned relative to other pump components such that a portion 362c of infusion line 305c at second AILD 360c can be oriented along a second axis 364c. As
25 illustrated in Figure 3C, first axis 354c and second axis 364c can be oriented significantly differently relative to each other, as similarly described in relation to first and second axes 354b, 364b of Figure 3B. A relatively close proximity of first and second AILDs 350c, 360c to each other could, in some embodiments, have advantages for cost, manufacturing, and/or other commercial considerations. In some embodiments, for example, first and second AILDs 350c, 360c could efficiently be provided on a single subassembly. In some embodiments, first
30 and second AILDs 350c, 360c could share an ultrasonic transceiver. In some embodiments, first and second AILDs 350c, 360c could share electronic components other than an ultrasonic transceiver, for example, with multiplexed or other shared operation.

Pumps 302a-c can be structured and configured with respective AILDs 350a-c, 360a-c having fixed positions and orientations in relation to other pump components, such as respective pump housings 322a-c. In each of Figure 3A-C, pumps 302a-c are illustrated in a standard orientation, with a top portion of the pump toward a top margin of each Figure. In
5 Figures 3B and 3C, second axis 364b of second AILD 360b of pump 302b and first axis 354c of first AILD 350c of pump 302c are, respectively, substantially vertical when pumps 302b-c are in standard orientation. With infusate flow through these AILDs 360b, 350c being substantially in a vertically upward direction (when in standard orientation), buoyant forces may assist propagation of gas bubbles along with liquid flow and therefore may result in
10 fewer stuck or slow bubbles, compared with horizontal or substantially non-vertical AILD configurations. It is possible, however, that in some cases pumps can be operated in orientations other than such standard or "upright" orientation. In some such cases, having differently oriented AILDs, as in pumps 302b and 302c of Figures 3B and 3C, can be advantageous if at least one of the AILDs is oriented so that directions of flow and bubble
15 buoyancy coincide. For example, if either pump 302b or 302c is operated in a "sideways" orientation with its left side higher than its right side (not illustrated), then first AILD 350b or second AILD 360c, respectively, would be so oriented accordingly.

If any of pumps 302a-c is operated lying on its back (with the front panel illustrated in the Figures facing upward) (not illustrated) then it may be that none of the AILDs are
20 oriented along a vertical or upright axis. To accommodate this possibility, a pump similar to one of pumps 302a-c could further include another or third AILD that is oriented substantially orthogonal to the first and second AILDs. Such a third AILD could be located, for example, on a side surface of the pump. In some embodiments, three AILDs of a pump can be oriented along substantially orthogonal axes, such that one of the AILD axes is close
25 to being vertical in any of the orientations in which the pump is most likely to be operated. In another example embodiment, pump 302d of Figure 3D can include a first AILD 350d on a front surface and a second AILD 360d on a side surface of the pump housing 322d. One of the AILDs 350d, 360d can be rotatably mounted such that its orientation can be selectively changeable in relation to the pump housing 322d (as illustrated in Figure 3D, second AILD
30 360d is rotatable via a rotating mount 366, but this is only one way that orientation of an AILD could be made to be selectively changeable and is not limiting). In this configuration, at least one of AILDs 350d, 360d can be vertically oriented in the most likely operational

orientations of the pump (possibly requiring a rotation of the rotatable second AILD 360d to provide such orientation).

We note, however, that a pump with two AILDs oriented similarly (such as pump 302a of Figure 3A) can still provide advantageous air detection capabilities compared to a pump having only one AILD. As aforementioned, physical properties other than orientation can differ at different AILDs with attendant differences in propensity, characteristics, or sensed occurrences for or of slow or stuck bubbles. Also, as discussed further herein, air presence and/or volume calculations incorporating information from two AILDs can yield better air volume estimates and/or calculations than those relying upon a single AILD.

The internal diameter of an infusion line 305 can have an effect on the measurement of air by the AILDs 350, 360. For example, in a standard sized infusion line having an internal diameter of approximately 2.54 mm, a spherical bubble having a volume of about 8.5 mL can substantially bridge, span, or otherwise extend across the entire cross-sectional area of the infusion line. Bubbles that completely obstruct the line are often pushed through the line by pressure exerted on the upstream side of the bubble, and therefore travel through the line at the speed of the fluid. By contrast, in a high-volume infusion line having an internal diameter of approximately 4.06 mm, a bubble having the same volume (8.5 mL) is generally not large enough to span across the entire cross-sectional area of the high-volume infusion line. Rather, the bubble can become “stuck” in the line, so as to remain stationary or otherwise move substantially slower than the bulk of the flow of the liquid. The persistence of a bubble stuck in a portion 352, 362 of infusion line 305 where it is detected by an AILD 350, 360 can result in an erroneous report of the presence of the same single bubble multiple times, giving an appearance of a significantly larger volume of gas in the tube.

False alarms as a result of air bubbles moving slower than the flow of fluid within an infusion line are more likely to occur in larger internal diameter infusion lines. Nevertheless, a larger internal diameter infusion line may be needed in certain medical procedures in order to enable a higher infusate delivery rate. Published PCT Application No. 2016/186955, titled “SYSTEMS AND METHODS FOR IMPROVED AIR-IN-LINE DETECTION FOR INFUSION PUMPS,” presently having an assignee in common with the present disclosure, the contents of which are incorporated by reference herein, describes, among other things, improved air-in-line detection with a hybrid infusion line having different diameters.

Hybrid infusion line 305e of Figures 3E-F, can present a generally larger internal diameter, high-volume infusion line, with one or more necked down portions 352e, 362e

having a generally smaller internal diameter, for the positioning of an AILD 350e, 360e for the detection of air bubbles. Accordingly, hybrid infusion line 305e can provide improved performance of air in line detection (comparable to that of a standard size infusion line), while also providing high infusate delivery rates (comparable to that of a high-volume
5 infusion line).

Hybrid infusion line 305e can include a relatively larger diameter first portion 368e, a relatively smaller diameter second portion 352e, and a transition portion 370e between the first portion 368e and the second portion 352e. Hybrid infusion line 305e can further include a larger diameter third portion 372e, and a transition portion 374e between the second portion
10 352e and the third portion 372e. In some embodiments, the third portion 372e can have an inner and outer diameter similar to, or the same as the first portion 368e. In some embodiments, first portion 370e can have a first inner and outer diameter similar to, or the same as, the inner and outer diameters of a high-volume infusion line (4.06 mm and 5.79 mm, respectively). In some embodiments, second portion 352e can have a second inner and outer
15 diameter of a standard infusion line (2.54 mm and 4.17 mm, respectively). In some embodiments, the first portion 370e can have a first wall thickness that is within about 10% of a second wall thickness of the second portion 352e. In some embodiments, other dimensions can be used for the first and the second inner and outer diameters, provided that they function together satisfactorily for a particular embodiment of a hybrid infusion line as
20 described by example or otherwise contemplated herein.

In some example embodiments of the present disclosure, portions 352e, 362e of infusion line 305e at first and second AILDs 350e, 360e can have inner and outer diameters similar to, or the same as, one another. For example, portions 352e and 362e can both be configured with a relatively smaller internal diameter relative to other portions of the infusion
25 line 305e. In other example embodiments, portions 352e and 362e of infusion line 305e can have different inner and outer diameters. For example, portion 352e can be configured with a relatively smaller inner diameter, while portion 362e can be configured with a relatively larger inner diameter, or vice versa. Changes in other physical and/or functional characteristics are also contemplated. Relevant physical characteristics for portions 352e,
30 362e of infusion line 305e at AILDs 350e, 360a can include (but are not limited to) tube material, surface finish, cross-sectional area, and/or cross-sectional shape. The cross-sectional shape can be a characteristic of the tube itself, but can also be influenced with respect to how the tube interfaces with the AILD (for example, an AILD groove or channel into which the

tube is seated or placed) and thus different AILD configurations can lend themselves to different physical characteristics for portions 352e, 362e of infusion line 305e at AILDs 350e, 360e. As stated elsewhere herein and without necessarily relying upon any particular theory of fluid and/or bubble dynamics that would limit the scope of the disclosure or the claimed subject matter, it is believed that at least some of these physical characteristics can affect the propensity of bubbles to stick or slow in the relevant portions of tube. As such, having different physical characteristics at first and second AILDs 350e, 360e can reduce the possibility of stuck or slow bubbles occurring at both AILDs, and hence, reduce the possibility that both AILDs produce signals that lead to overestimates or erroneous calculations of the volumes of gas in the infusion line.

In some example embodiments of the present disclosure, a controller can be programmed and configured to provide information about gas in an infusion line being used with a pump, such as, *e.g.*, one of pumps 302a-d, based upon signals from a plurality of AILDs. The controller can be a controller of the pump operatively coupled to or in communication with the infusion line and the plurality of AILDs, but the method is not necessarily so restricted and the controller could be a controller of a system of pumps, a controller implemented on a networked server, and so on.

Figures 4 and 5 are flow diagrams that describe aspects of what may be called a “propose/confirm” method for considering signals from a plurality of AILDs to calculate air volumes in an infusion line and determine whether and when to annunciate air-in-line alarms. While the method is described by example with regard to two AILDs, its extension to more than two AILDs should be straightforward by those of skill in the art after appreciation of the method as described herein. In some embodiments of a propose/confirm method, a sub-process for each AILD can calculate air volumes for its AILD independently of information from the other AILD, then a combination process can consider information from the sub-processes to determine whether and when to annunciate air-in-line alarms. Without limitation, in the combination process an air-in-line alarm can be annunciated if, for example, two AILDs indicate that criteria for an alarm are satisfied, including that both AILDs detect a bubble meeting minimum volume requirements, and/or that both AILDs detect a plurality of bubbles whose combined volume meet minimum accumulated volume requirements.

Figure 4 is a flow diagram of an example of a method 400 that can be an independent sub-process for each AILD in the propose/confirm method. Method 400 is analogous in some aspects to method 200 of Figure 2 for an infusion pump with a single AILD. At 410, the

method can include attempting to detect a bubble at the AILD, which can include monitoring and recording “air”/“no air” signals from the AILD. Said signals can in effect record a transit time of the bubble passing the AILD. At 420, the controller can calculate the volume of the bubble based upon the recorded transit time and other information. For example, the product of transit time and a flow rate for the bubble can yield a calculated bubble volume. At 430, based upon whether the calculated volume of the single bubble exceeds a predetermined single-bubble volume limit, the controller can determine whether to indicate that the single-bubble alarm criterion has been met. When such an indication is made at 440 by the sub-process for a first or upstream AILD (such as one of first AILDs 350a-d or one of pumps 302a-d), it can be said, colloquially or informally, that a single-bubble alarm has been “proposed” by the first AILD. When such an indication is made at 440 by the sub-process for a second or downstream AILD (such as one of second AILDs 360a-d), it can be said, colloquially or informally, that the single-bubble alarm has been “confirmed” by the second AILD. Note that the sub-processes for the first and second AILDs can be executed independently of each other, so that, for example, the process for the second AILD can “confirm” (indicate) a single-bubble alarm whether or not the first AILD has “proposed” (indicated) such an alarm. That is, “propose” and “confirm” do not necessarily indicate a temporal sequence, and are merely labels to help understand a possible sequence of the propose/confirm method. (Method 500 of Figure 5, discussed below, describes how the controller can handle the proposed/confirmed single-bubble air alarm indications from 440.)

At 450 the controller can update an air accumulation for the AILD by adding the single-bubble volume to the air accumulation. In the present disclosure, an air accumulation can be a sum of a plurality of different single-bubble volumes. Also at 450, the controller can update the air accumulation. For example, the air accumulation determination can be modified by the controller to represent a volume of air passing an AILD during a specified preceding time interval (*e.g.*, the most recent fifteen minutes), for example, by subtracting from the air accumulation older previously added single-bubble volume(s). At 460, the controller can determine whether to indicate/propose/confirm an accumulated air-in-line alarm at 470 based upon whether the air accumulation exceeds a predetermined accumulated air limit. The method can then return to 410.

Figure 5 is a flow diagram of an example of a method 500 that can be a combination process executed by a controller (or controllers) that can evaluate information from the sub-processes of method 400 for each AILD to determine whether and when to annunciate air-in-

line alarms. At 510, the method can monitor for whether/when the sub-process for the first/upstream AILD indicates/proposes (via, *e.g.*, 440 of method 400) a single-bubble alarm. If not, the method can proceed to 540; but if so, then at 520 the method can monitor for whether the sub-process for the second/downstream AILD indicates/confirms (via, *e.g.*, 440 of method 400) a single-bubble alarm, and if so, such an alarm can be annunciated at 530. For a single-bubble air-in-line alarm to be annunciated, the method at 520 can require that the sub-process for the second/downstream AILD indicate/confirm a single-bubble alarm within a predetermined range of time after the indication/proposal of the single-bubble alarm by the sub-process for the first AILD. The time interval between proposal and confirmation of a single-bubble alarm can be considered to be a measurement of the travel time of the bubble from the first AILD and the second AILD. The pre-determined range of time can be calculated relative to an overall infusate travel time from the first AILD to the second AILD, and can represent an anticipated range of time for an air bubble to travel from the first AILD to the second AILD, allowing for the possibility that the bubble may travel at a speed faster or slower than that of the infusate flow.

Requiring that proposals and confirmations of single-bubble alarms occur within a predetermined range of time can be a way that method 500 attempts to increase the probability that bubble indications from different AILDs originate from the same bubble. For example, a very short time interval between a proposal and a confirmation could suggest that the indications resulted from two separate bubbles rather than an (unrealistically) fast bubble, with the bubble that produced the confirmation alarm having propagated in the infusion line ahead of the bubble that produced the proposal alarm. Expressed another way, this hypothetical short time interval could result from mis-matched bubble indications. In addition to (in some embodiments) requiring proposals and confirmations to occur within a predetermined range of time relative to an infusate travel time, method 500 and other methods of the present disclosure can include the use of any suitable algorithms to attempt to correlate signals from a plurality of AILDs with particular bubbles in the infusion line. Such algorithms can include, for example, comparing and matching patterns of signals from AILDs resulting from the passage of pluralities of bubbles and can allow for the possibility of bubbles merging and/or splitting, and so on.

At 540, method 500 can monitor for whether the sub-process for the first/upstream AILD indicates/proposes (via, *e.g.*, 470 of method 400) an accumulated air-in-line alarm. If not, the method can return to 510; but if so, then at 550 the method can monitor for whether

the sub-process for the second/downstream AILD indicates/confirm (via, *e.g.*, 470 of method 400) an accumulated air-in-line alarm, and if so, such an alarm can be annunciated at 560. Analogously to other bubble alarms described by example herein, the method at 550 can require confirmation of the proposed accumulated air alarm within a predetermined range of time. The predetermined range of time can be calculated relative to an infusate travel time from the first AILD to the second AILD, and/or any other criteria. The method can then return to 510.

The AILD propose/confirm method of methods 400 and 500 of Figures 4 and 5, when compared with single AILD alarm annunciation methods such as method 200 of Figure 2, can advantageously reduce nuisance air-in-line alarms. The method can require that signals from multiple AILDs indicate that the bubble exceeds a predetermined bubble volume limit, thereby reducing the chances that an overestimate of bubble volume due to, for example, a stuck or slow bubble, will lead to a nuisance alarm that might not have not been triggered had a more accurate bubble volume been calculated. Requiring that an alarm confirmation occur within a predetermined range of time after an alarm proposal is another way to reduce the chances that slow bubbles will lead to nuisance alarms, since slow bubbles can lead to inaccurately large bubble volume calculations.

In the foregoing description, the propose/confirm data processing and communication techniques of the example methods 400 and 500 of Figures 4 and 5 are described as two sub-processes (method 400), one for each of two AILDs, in combination with a combination process (method 500) that considers information from the two sub-processes. Essentially the same propose-confirm model can alternately be described or framed as an example of a method 600 of Figure 6 that can be executed by a controller (or controllers) in an infusion pump system having a plurality of AILDs. Method 600 can include at 610 attempting to detect a bubble in an infusion line at a first/upstream AILD, which can include recording “air” and “no air” signals produced by the detector. At 620, the method can include calculating a first volume of the bubble (if detected) based at least in part upon the signals from the first AILD. The signals from the first AILD can, in effect, record a quantity related to the transit time of the bubble. At 630, the method can include attempting to detect the bubble in the infusion line at a second/downstream AILD, which also can include recording “air” and “no air” signals. If detected at the second AILD, at 640 a second volume of the bubble can be calculated based at least in part upon signals from the second AILD. At 650, the method can include determining whether bubble alarm criteria have been met, which can

include determining whether both the first volume and the second volume each exceeds a predetermined bubble limit, and if so, annunciating a bubble alarm at 660. In some embodiments, the bubble alarm is annunciated only if a travel time of the bubble from the first to the second AILD is within a predetermined range of time relative to the infusate travel time between the AILDs.

At 670, the method can include updating first and second air accumulations by adding the first and second volumes respectively, as well as modifying the air accumulations so that they each represent the volume of air passing their respective AILD during a specified preceding time interval. At 680, the method can include determining whether accumulated air alarm criteria have been met, which can include determining whether both the first air accumulation and the second air accumulation each exceeds a predetermined accumulated air limit, and if so, annunciating an accumulated air alarm at 690. Analogously to other bubble alarms described by example herein, in some embodiments the accumulated air alarm is only annunciated if both air accumulations exceed the predetermined accumulated air limit within a predetermined range of time. The predetermined range of time can be determined relative to the infusate travel time between the AILDs. The method can then return back to the start.

As aforescribed, calculations of bubble volumes such as at 420, 620, and 640 of methods 400, and 600 can be based upon the recorded transit time of the bubble past an AILD and the infusate flow rate. Such a calculation may rely upon an assumption that the air flow rate past the AILD is reflected by the (liquid) infusate flow rate. To the extent that the air flow rate differs from the infusate flow rate, the accuracy of such an air volume calculation may be affected adversely. Slow bubbles (*e.g.*, those that move more slowly past the AILD than the infusate) can exhibit a transit time past the detector greater than that of an identical volume of infusate, but if the air volume calculation simplistically assumes an air flow rate that is identical to the infusate flow rate, the calculated air volume can exceed the actual air volume significantly, potentially resulting in more nuisance alarms. Accordingly, if more accurate air flow rates can be determined, using such air flow rates could result in more accurate air volume calculations and fewer nuisance alarms.

The present disclosure contemplates that more accurate air flow rates can, in some embodiments, be determined from AILD signals resulting from the passage of a bubble past two (or more) AILDs separated by a distance. (While the method is described with regard to two AILDs, its extension to more than two AILDs should be straightforward by those of skill in the art after appreciation of the method as described herein.) The speed of bubble flow

between two AILDs can be calculated by dividing the distance between the AILDs by the difference in time between the arrivals of the bubble at each detector (*i.e.*, the start of an “air” signal at each AILD). The air flow rate can be calculated from the speed of bubble flow and the cross-sectional area of the infusion line between the AILDs. This calculated air flow rate
5 can then be used in air volume calculations to provide potentially more accurate bubble volumes.

Any appropriate criteria can be used to evaluate the suitability of a calculated air flow rate for use in air volume calculations. In some embodiments, a calculated air flow rate could be deemed unsuitable if its variance from the infusate flow rate exceeds a maximum
10 anticipated variance. In another example, a calculated air flow rate could be deemed unsuitable if analysis of signals from the AILDs from which the air flow was calculated suggest that the signals used to calculate the calculated air flow rate could have resulted from mis-matched bubbles, rather than from the same bubble propagating between AILDs.

The suitability for use of a calculated air flow rate (based upon measurement of the speed of a bubble between two AILDs) in an air volume calculation at a single AILD (using
15 the measured bubble transit time past the single AILD) generally can be greater when the air flow rate between the AILDs is thought to be similar to the air flow rate at the single AILD. If flow conditions in the portion of infusion line at the single AILD differ from those in the infusion line between the AILDs, then the calculated air flow rate may not be suitable for air
20 volume calculations. As aforementioned, infusion line characteristics that may affect air propagation can include (but are not limited to) tube material, surface finish, cross-sectional area, cross-sectional shape, and/or tube orientation. Using a calculated air flow rate can be more appropriate when more of these characteristics are similar when comparing the infusion line between AILDs with the portion of infusion line at the single AILD. With regard to
25 example embodiments of infusion pumps 302a-302d of Figure 3A-3D:

In pump 302a of Figure 3A, first and second AILDs 350a, 360b are oriented along axes 354a and 364a that can be substantially similar, and as illustrated, infusion line 305a between the AILDs can share a similar orientation with portions 352a, 362a of infusion line 305a at AILDs 350a, 360b. Thus, with regard to line/tube orientation, pump 302a may be a
30 suitable or good candidate for using calculated air flow rates in air volume calculations.

Whether tube characteristics such as material, surface finish, cross-sectional area, and/or cross-sectional shape are similar at the AILDs when compared to the length, portion, or run of infusion line between the AILDs can further inform whether using calculated air

flow rates in air volume calculations may be advantageous. In some scenarios, at least one of the AILDs operatively couples to a portion of line that shares similar line or tube characteristics with the length, portion, or run of infusion line between AILDs, and a calculated air flow rate can be used advantageously for air volume calculations at least at that
5 AILD. In some configurations, due to similar tube characteristics, a calculated air flow rate can be used advantageously for air volume calculations at a plurality of AILDs. In some other configurations, a calculated air flow rate can be used advantageously for air volume calculations only at one AILD.

In pump 302b of Figure 3B as illustrated, a majority of infusion line 305b between
10 AILDs 350b and 360b can be substantially aligned with first axis 354b of first AILD 350b, but not with second axis 364b of second AILD 360b. Based on orientation considerations, it may be appropriate to use a calculated air flow to improve the accuracy for air volume calculations for first AILD 350b, but not for second AILD 360b. As discussed elsewhere, other considerations, such as tube characteristics of portion 352b of infusion line 305b at
15 AILD 350b compared with tube characteristics of line 305b between AILDs can also impact the suitability of the calculated air flow rate for air volume calculations.

Figure 7 is a flow diagram of an example of a method 700 for providing information about air or gas in an infusion line that can include the use of calculated air flow rates. Method 700 can include at 710 detecting a bubble in an infusion line at a first/upstream
20 AILD, which can include recording “air” and “no air” signals produced by the detector. At 720, the method can include detecting the bubble in an infusion line at a second/downstream AILD, which also can include recording “air” and “no air” signals. At 730, a calculated air flow rate can be calculated by the pump controller based at least in part upon the recorded signals from the first and second AILDs.

At 740, method 700 can include calculating a volume for the detected air bubble in
25 the infusion line. The calculation at 740 can be a lowest-volume calculation of the volume of air in the infusion line, meaning that when the data from the first and second AILDs can be interpreted as corresponding to a plurality of possible volumes, the calculation algorithm can return the lowest reasonable volume consistent with the data. As discussed herein, the volume
30 at a single AILD can be calculated from the product of the transit time of the bubble at the detector and the air flow rate for the bubble. In some cases, the air flow rate used for the bubble can be the same as the infusate flow rate, and in some cases, it can be the calculated air flow rate from 730. As discussed elsewhere herein, whether a calculated air flow rate is

considered to be more appropriate for use in air volume calculations can depend on various factors, such as the orientation of the infusion line at and between the AILDs, and the other physical characteristics of the infusion line at and between the AILDs. In some cases, the calculated air flow rate is lower than the infusate flow rate, and is considered to be the appropriate air flow rate at both AILDs. In such a case, then the lowest-volume calculation can be based upon the calculated air flow rate and the lesser of the transit times of the bubble at each of the two AILDs. In some cases, the calculated air flow rate is considered to be the appropriate air flow rate at one AILD, but at the other AILD, the infusate flow rate is considered to be the appropriate air flow rate. In such a case, then an air volume calculation can be performed for each AILD with the corresponding air flow rate and transit time, and the lower of the two air volumes can be a the result of the lowest-volume calculation. A lowest-volume calculation does not necessarily return the lowest possible volume that might be calculated arithmetically. For example, the product of a calculated air flow rate with a transit time at a particular AILD may correspond to the lowest calculable air volume, but if the calculated air flow rate is considered inappropriate for use with that AILD, then the air volume resulting from such a calculation can be excluded as a result from the air bubble volume calculation.

At 750, based upon comparison of the calculated volume of the bubble (from 740) with a predetermined single-bubble volume limit, the controller can determine whether to annunciate an air-in-line alarm. If the limit is exceeded, a single-bubble alarm can be annunciated at 760. At 770 the controller can update an air accumulation by adding the calculated volume to the air accumulation. Also at 770, the controller can update the air accumulation by modifying the air accumulation so that it represents the volume of air passing the AILDs during a specified preceding time interval (*e.g.*, the most recent fifteen minutes), for example, by subtracting from the air accumulation older previously added volume(s). At 780, the controller can determine whether to annunciate an air-in-line alarm based upon whether the air accumulation exceeds a predetermined accumulated air limit and if so, an accumulated air alarm can be annunciated at 790. The method can then return to the start.

Methods of the present disclosure other than method 700 of Figure 7 can incorporate calculated air flow rates in order to , potentially, provide more accurate volume estimates. For example, in method 600 of Figure 6, calculations of a first volume of a bubble at 620 and of a second volume of the bubble at 640 can be modified to incorporate calculated air flow rates.

Also, in a modified propose/confirm method, a modified version of the sub-process of method 400 of Figure 4 for each AILD could incorporate calculated flow rates in the calculation of bubble volume at 420. In such a modified propose/confirm method, the sub-processes for each AILD would not necessarily run entirely independently, but could depend
5 on the other AILD sub-process(es) for information to calculate the air flow rate(s). Another way to modify the propose/confirm method could be to provide a preliminary volume calculation for the first AILD (upon which an alarm proposal can be based) before there is a volume calculation for the second AILD, then once there are signals from the second AILD, the volume calculation for the first AILD could be revised based upon a calculated flow rate,
10 if appropriate.

Persons of ordinary skill in arts relevant to this disclosure and subject matter hereof will recognize that embodiments may comprise fewer features than illustrated in any individual embodiment described by example or otherwise contemplated herein. Embodiments described herein are not meant to be an exhaustive presentation of ways in
15 which various features may be combined and/or arranged. Accordingly, the embodiments are not mutually exclusive combinations of features; rather, embodiments can comprise a combination of different individual features selected from different individual embodiments, as understood by persons of ordinary skill in the relevant arts. Moreover, elements described with respect to one embodiment can be implemented in other embodiments even when not
20 described in such embodiments unless otherwise noted. Although a dependent claim may refer in the claims to a specific combination with one or more other claims, other embodiments can also include a combination of the dependent claim with the subject matter of each other dependent claim or a combination of one or more features with other dependent or independent claims. Such combinations are proposed herein unless it is stated that a
25 specific combination is not intended. Furthermore, it is intended also to include features of a claim in any other independent claim even if this claim is not directly made dependent to the independent claim.

Any incorporation by reference of documents above is limited such that no subject matter is incorporated that is contrary to the explicit disclosure herein. Any incorporation by
30 reference of documents above is further limited such that no claims included in the documents are incorporated by reference herein. Any incorporation by reference of documents above is yet further limited such that any definitions provided in the documents are not incorporated by reference herein unless expressly included herein.

For purposes of interpreting the claims, it is expressly intended that the provisions of Section 112, sixth paragraph of 35 U.S.C. are not to be invoked unless the specific terms “means for” or “step for” are recited in a claim.

CLAIMS

What is claimed is:

1. An infusion pump configured to deliver fluid in an infusion line, comprising:
a first air-in-line detector (AILD) configured to provide signals indicating air present
5 or air not present in the infusion line at a first location;
a second AILD configured to provide signals indicating air present or air not present
in the infusion line at a second location downstream from the first location; and
a controller configured to receive signals from the first AILD and the second AILD,
the controller programmed and configured to perform lowest-volume calculations of air in the
10 infusion line based upon the signals from both the first AILD and the second AILD, and to
annunciate air-in-line alarms based upon said lowest-volume calculations.
2. The pump of claim 1, wherein the controller is programmed and configured to:
calculate a first volume of a detected bubble based at least in part upon signals from
15 the first AILD;
calculate a second volume of the detected bubble based at least in part upon signals
from the second AILD; and
annunciate a single-bubble alarm if both the first volume and the second volume each
exceeds a predetermined single-bubble limit.
20
3. The pump of claim 1, wherein the controller is programmed and configured to:
modify a first air accumulation such that the first air accumulation represents a
volume of air passing the first AILD during a specified preceding time interval;
modify a second air accumulation such that the second air accumulation represents a
25 volume of air passing the second AILD during the specified preceding time interval; and
annunciate an accumulated air alarm only if both the first air accumulation and the
second air accumulation each exceeds a predetermined accumulated air limit.
4. The pump of claim 1, wherein:
30 the controller is programmed and configured to calculate a quantity related to a travel
time of the bubble from the first AILD to the second AILD based at least in part upon signals
from the first AILD and the second AILD relating to detection of the bubble at the first AILD
and the second AILD; and

a single-bubble alarm is annunciated only if the travel time of the bubble from the first AILD to the second AILD is within a predetermined range of time relative to an infusate travel time from the first AILD to the second AILD.

5 5. The pump of claim 1, wherein:

the controller is programmed and configured to calculate a quantity related to a travel time of the bubble from the first AILD to the second AILD based at least in part upon signals from the first AILD and the second AILD relating to detection of the bubble at the first AILD and the second AILD; and

10 performing lowest-volume calculations of the volume of air in the infusion line by the controller includes calculating at least one of a first volume of the detected bubble at the first AILD and/or a second volume of the detected bubble at the second AILD based in part upon the quantity related to the travel time of the bubble from the first AILD to the second AILD.

15 6. An infusion pump configured to deliver fluid in an infusion line, comprising:

a first air-in-line detector operatively coupled to the infusion line, the infusion line at the first air-in-line detector oriented along a first axis; and

a second air-in-line detector operatively coupled to the infusion line, the infusion line at the second air-in-line detector oriented along a second axis oriented differently from the
20 first axis.

7. The pump of claim 6, wherein the first axis and the second axis are oriented differently by an angle of at least 45 degrees.

25 8. The pump of claim 6, further comprising a pump housing, wherein:

the first air-in-line detector has a fixed position and a fixed orientation in relation to the pump housing; and

the second air-in-line detector has a fixed position and a fixed orientation in relation to the pump housing.

30

9. The pump of claim 6, further comprising a pump housing, wherein:

the first air-in-line detector has a fixed position and a fixed orientation in relation to the pump housing; and

the second air-in-line detector has a fixed position and a selectively changeable orientation in relation to the pump housing.

10. The pump of claim 6, wherein one of the first axis and the second axis is substantially
5 vertical when the pump is in a standard orientation.

11. A method for providing information about gas in an infusion line, comprising:
attempting to detect a bubble in an infusion line at a first air-in-line detector (AILD);
if the bubble is detected at the first AILD, calculating a first volume of the bubble
10 based at least in part upon signals from the first AILD;
attempting to detect the bubble in the infusion line at a second AILD, wherein the
second AILD is located downstream of the first AILD;
if the bubble is detected at the second AILD, calculating a second volume of the
bubble based at least in part upon signals from the second AILD; and
15 annunciating a single-bubble alarm if both the first volume and the second volume
each exceeds a predetermined single-bubble limit.

12. The method of claim 11, wherein:
calculating the first volume is based in part upon a quantity related to a first transit
20 time of the bubble past the first AILD; and
calculating the second volume is based in part upon a quantity related to a second
transit time of the bubble past the second AILD.

13. The method of claim 11, wherein:
25 calculating at least one of the first volume and the second volume is based in part
upon a quantity related to a travel time of the bubble from the first AILD to the second AILD.

14. The method of claim 13, wherein the quantity related to the travel time of the bubble
from the first AILD to the second AILD is calculated at least in part from signals from the
30 first AILD and the second AILD relating to detection of the bubble at the first AILD and the
second AILD.

15. The method of claim 11, wherein a single-bubble alarm is annunciated only if a measured travel time of the bubble from the first AILD to the second AILD is within a predetermined range of time relative to an infusate travel time from the first AILD to the second AILD.

5

16. The method of claim 11, further comprising:

modifying a first air accumulation such that the first air accumulation represents the volume of air passing the first AILD during a specified preceding time interval;

modifying a second air accumulation such that the second air accumulation represents the volume of air passing the second AILD during the specified preceding time interval; and

10 annunciating an accumulated air alarm only if both the first air accumulation and the second air accumulation each exceeds a predetermined accumulated air limit.

17. A method for providing information about gas in an infusion line, comprising:

15 detecting a bubble in an infusion line at a first air-in-line detector (AILD), including recording signals produced by the first AILD;

detecting the bubble in the infusion line at a second AILD, including recording signals produced by the second AILD, wherein the second AILD is located downstream of the first AILD;

20 calculating a calculated air flow rate in the infusion line based at least in part upon signals from the first AILD and the second AILD;

performing a lowest-volume calculation of a volume of the bubble based upon the signals from both the first AILD and the second AILD; and

25 annunciating a single bubble alarm if the volume of the bubble from the lowest-volume calculation exceeds a predetermined single-bubble limit.

18. The method of claim 17, further comprising:

modifying an air accumulation such that the air accumulation represents the volume of air passing the first AILD and the second AILD during a specified preceding time interval, including adding the volume of the bubble from the lowest-volume calculation to the air accumulation; and

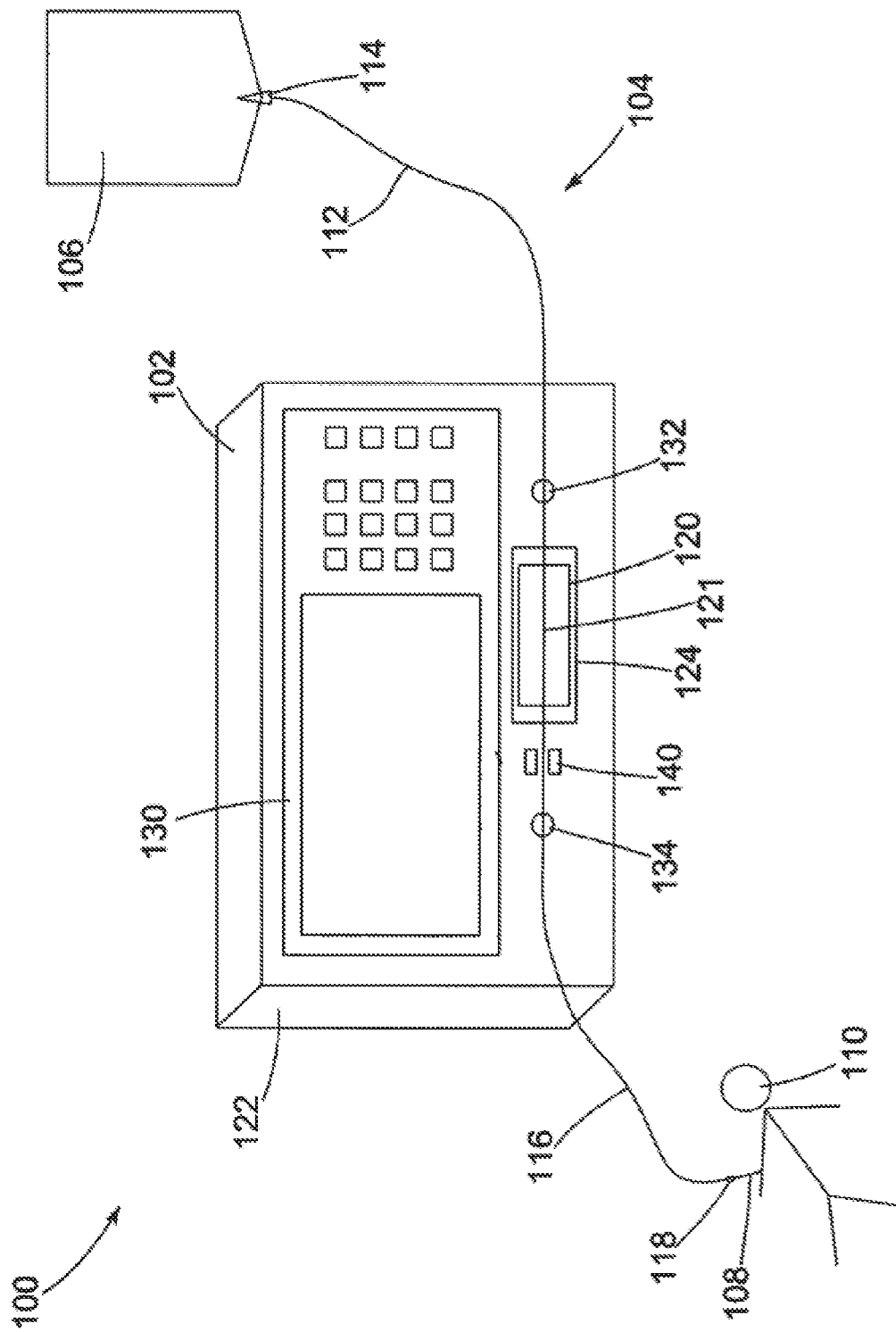
30 annunciating an accumulated air alarm if the air accumulation exceeds a predetermined accumulated air limit.

19. The method of claim 17, wherein performing the lowest-volume calculation is based in part upon the calculated air flow rate.

5 20. The method of claim 17, wherein performing the lowest-volume calculation includes:
calculating a first volume of the bubble at the first AILD; and
calculating a second volume of the bubble at the second AILD.

21. The method of claim 20, wherein a selected one of calculating the first volume and
10 calculating the second volume is based in part upon the calculated air flow rate.

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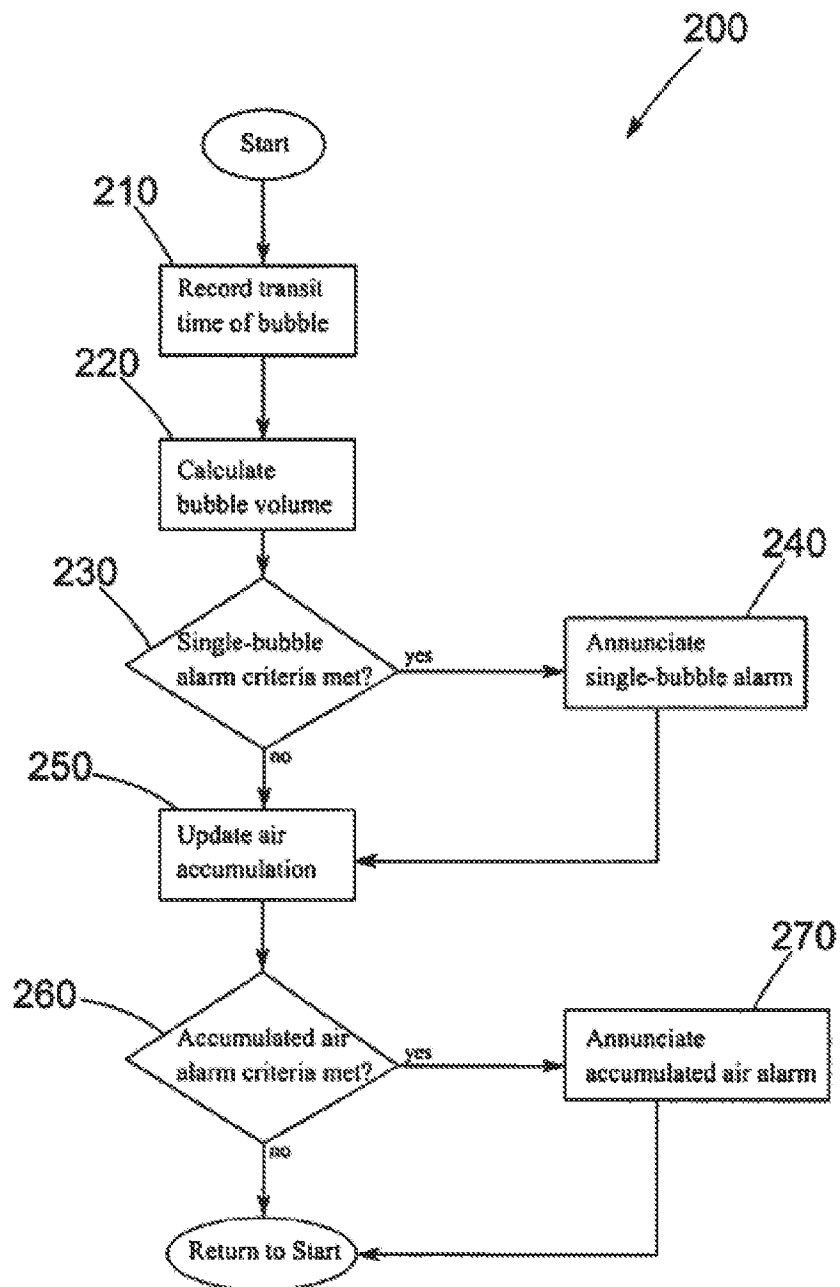


FIG. 2

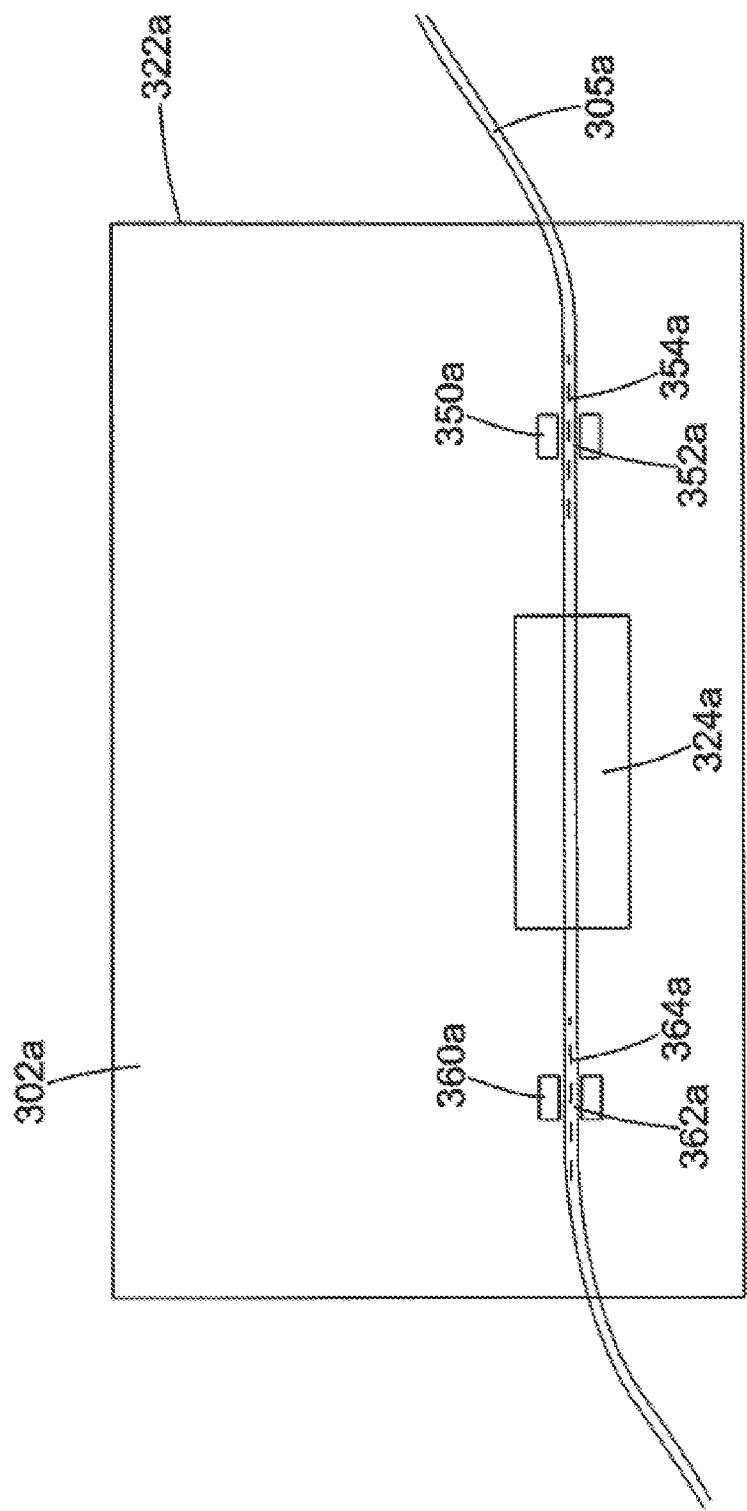


FIG. 3A

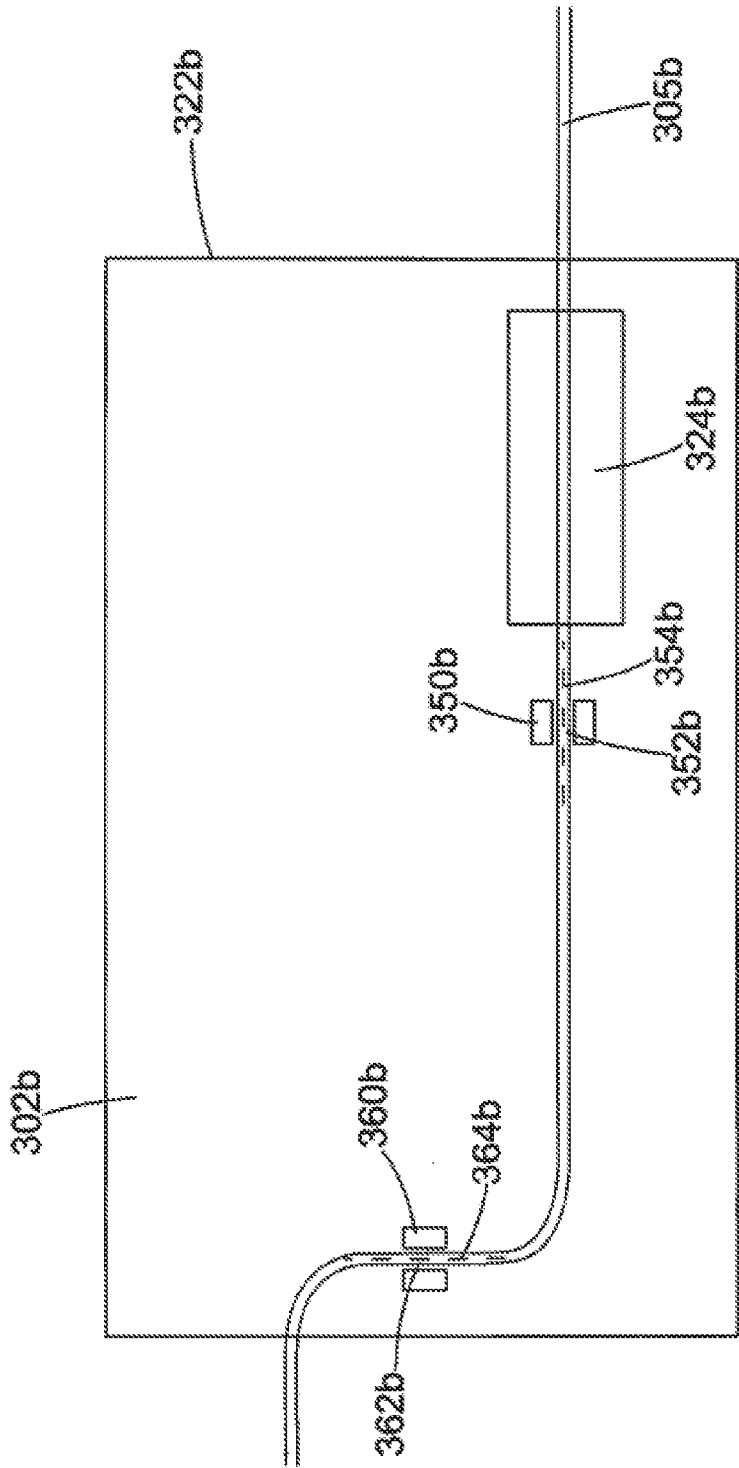


FIG. 3B

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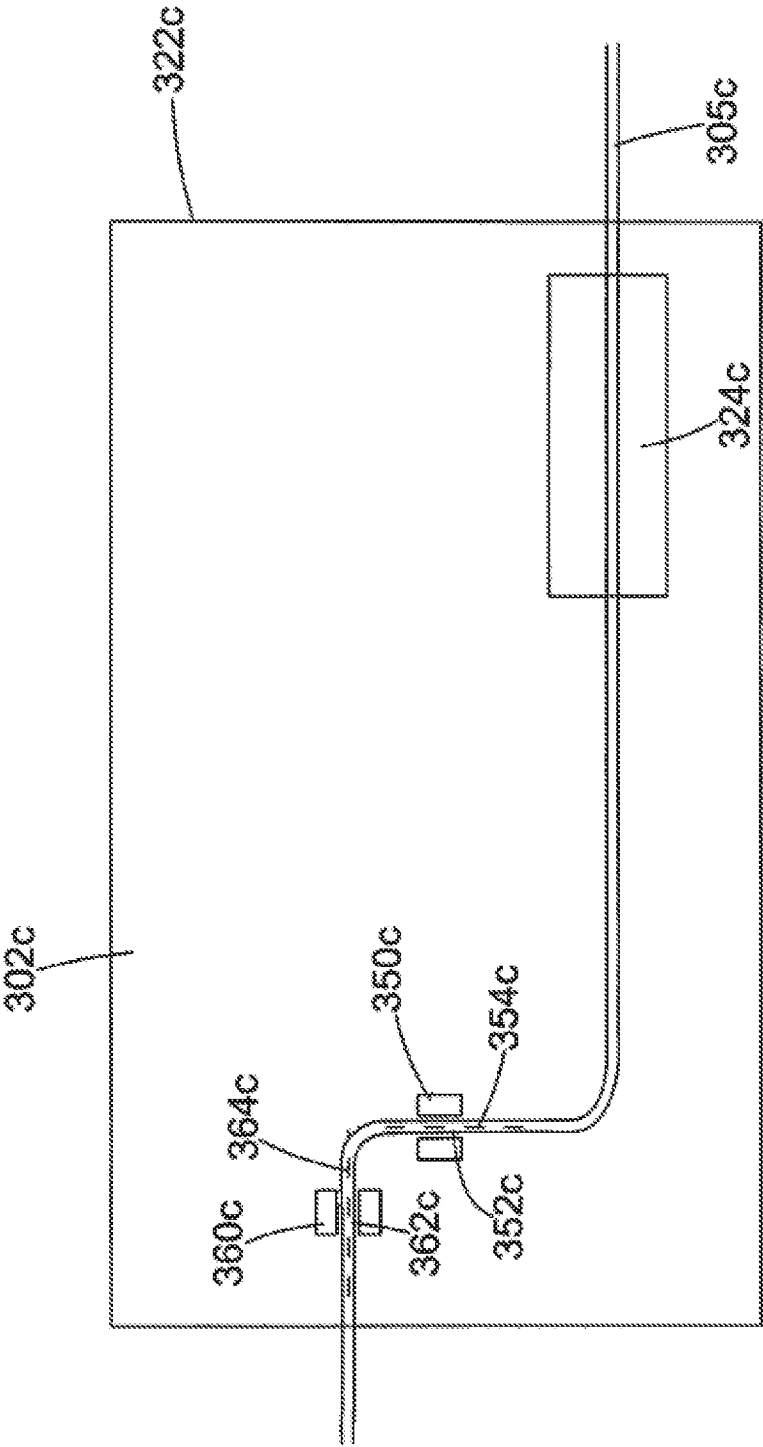


FIG. 3C

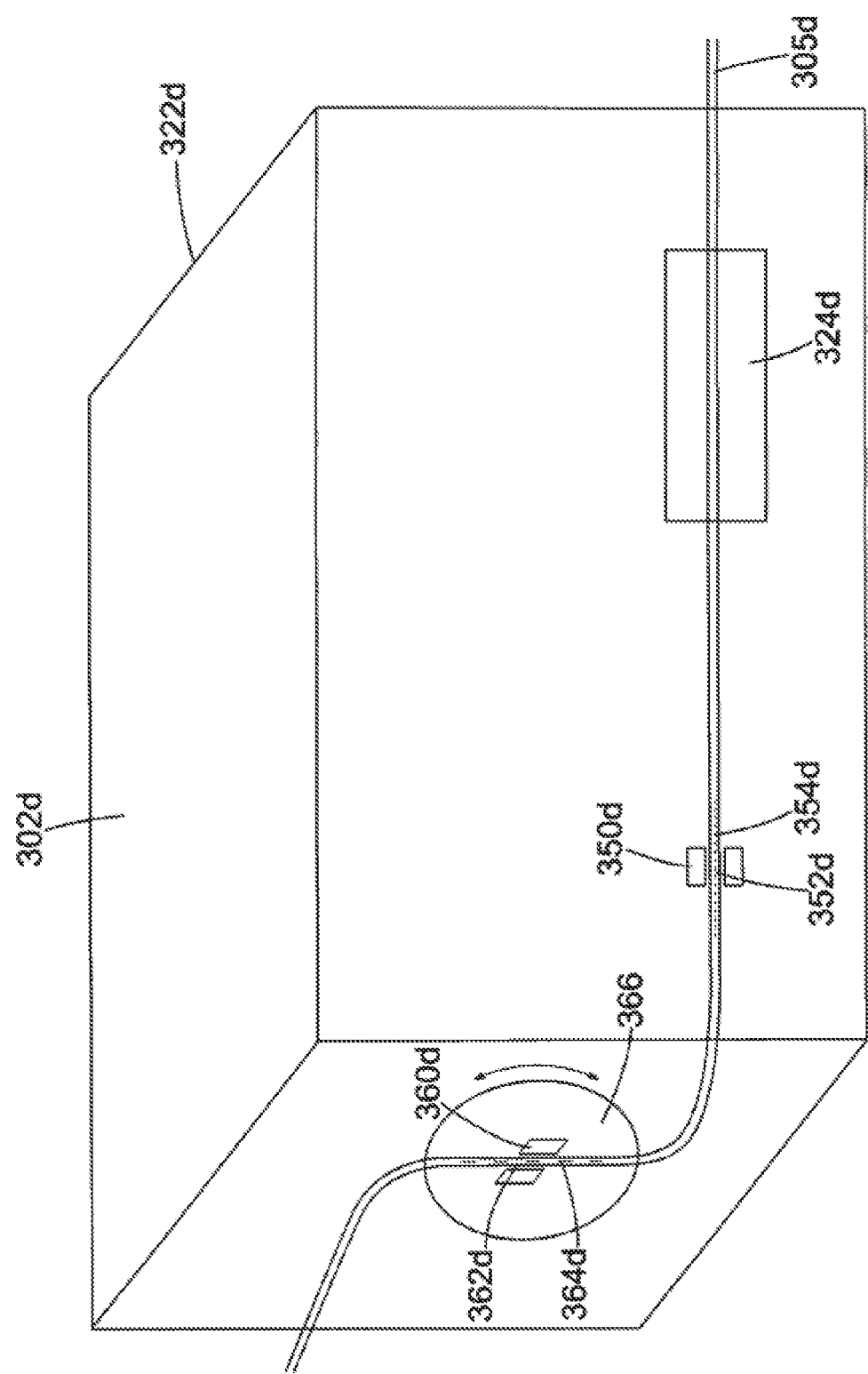


FIG. 3D

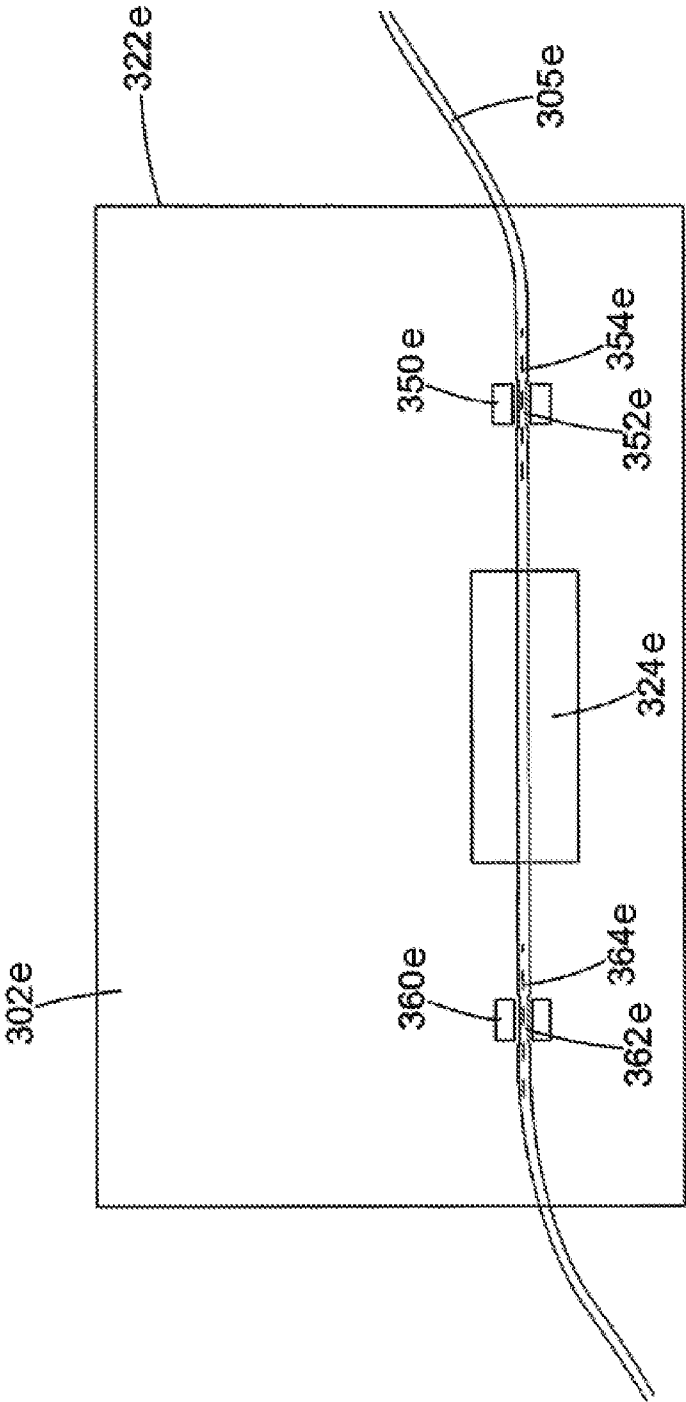


FIG. 3E

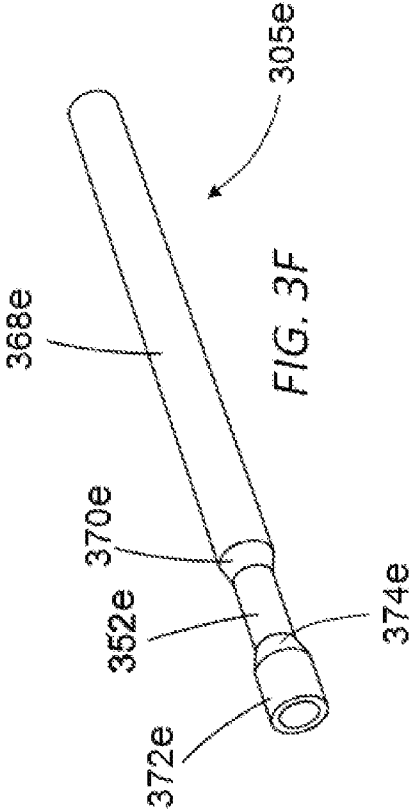


FIG. 3F

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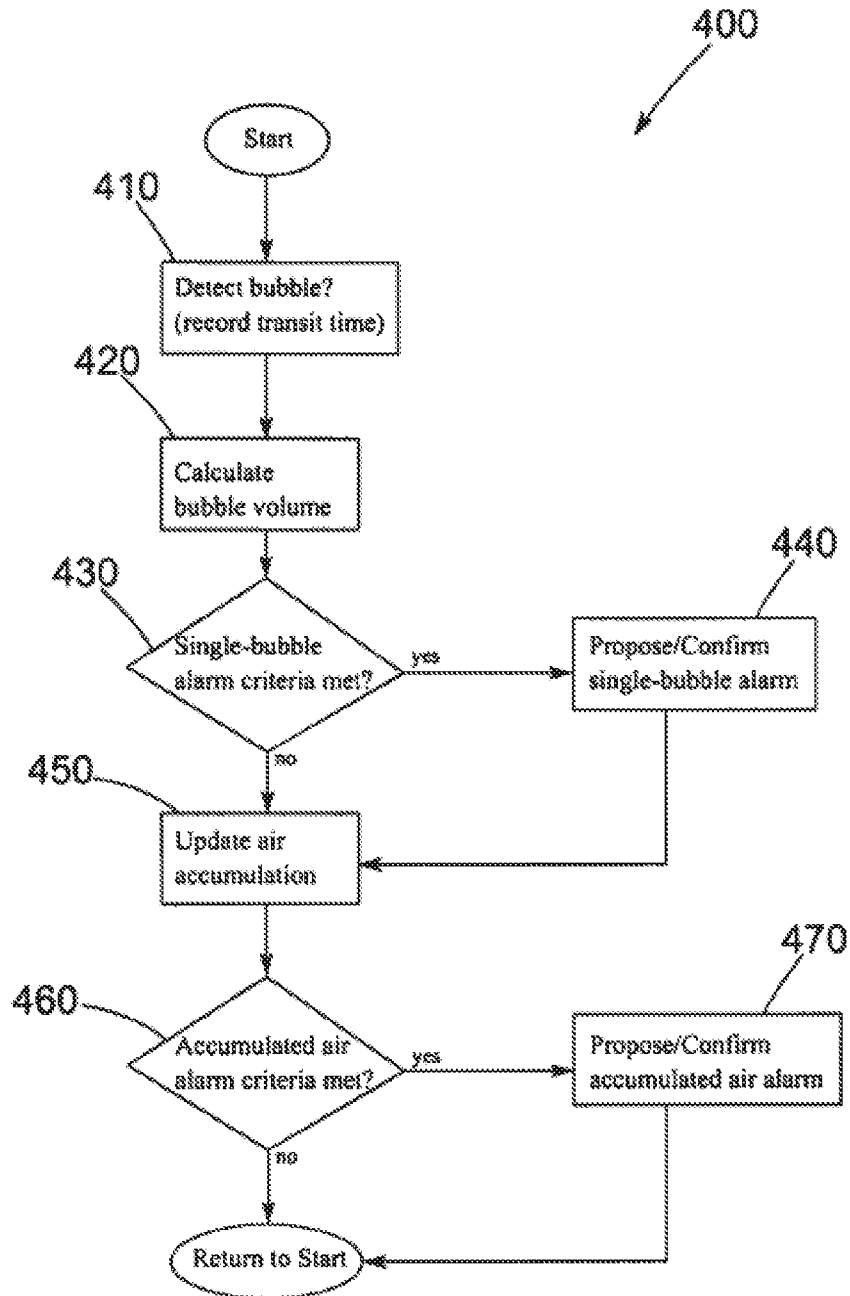


FIG. 4

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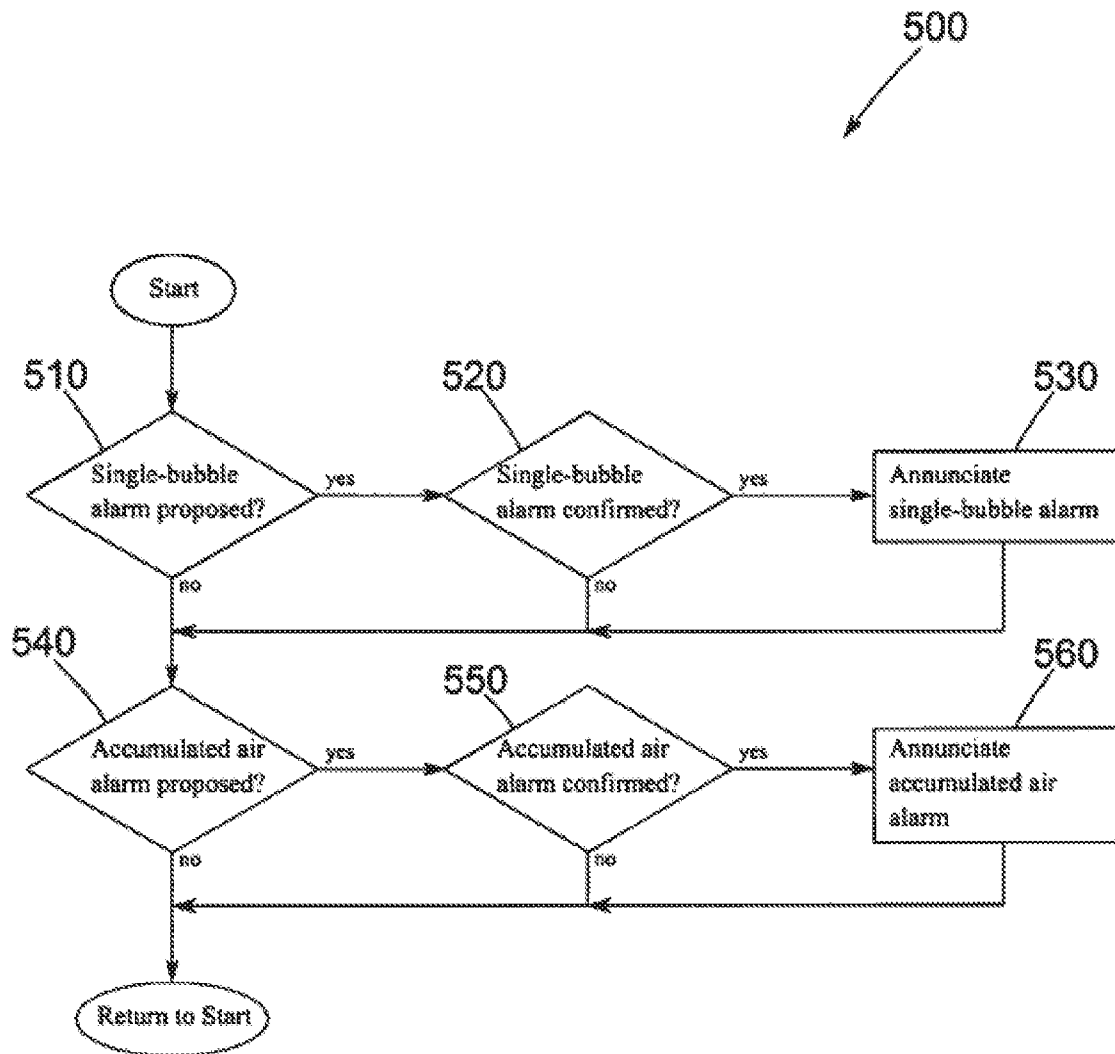


FIG. 5

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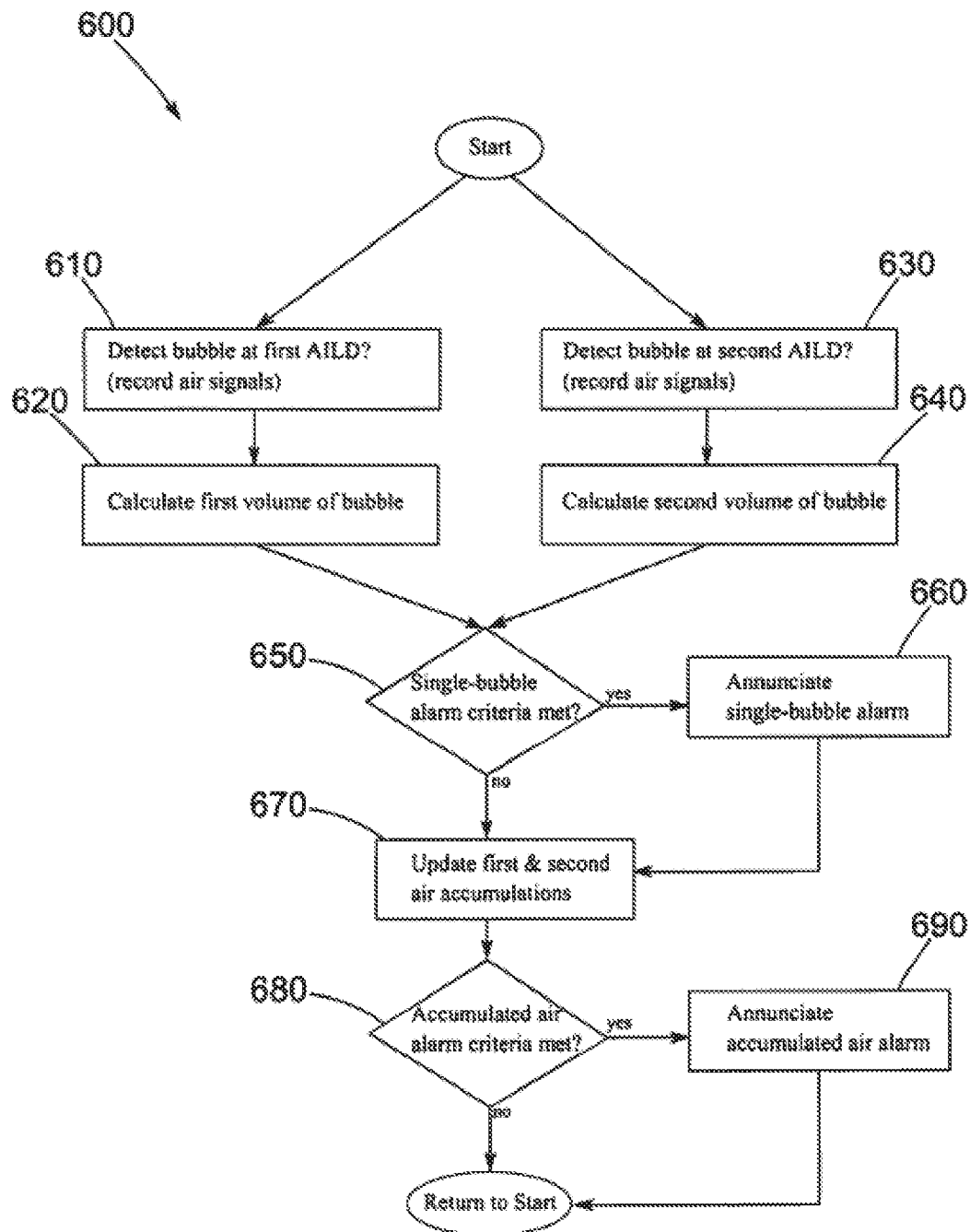


FIG. 6

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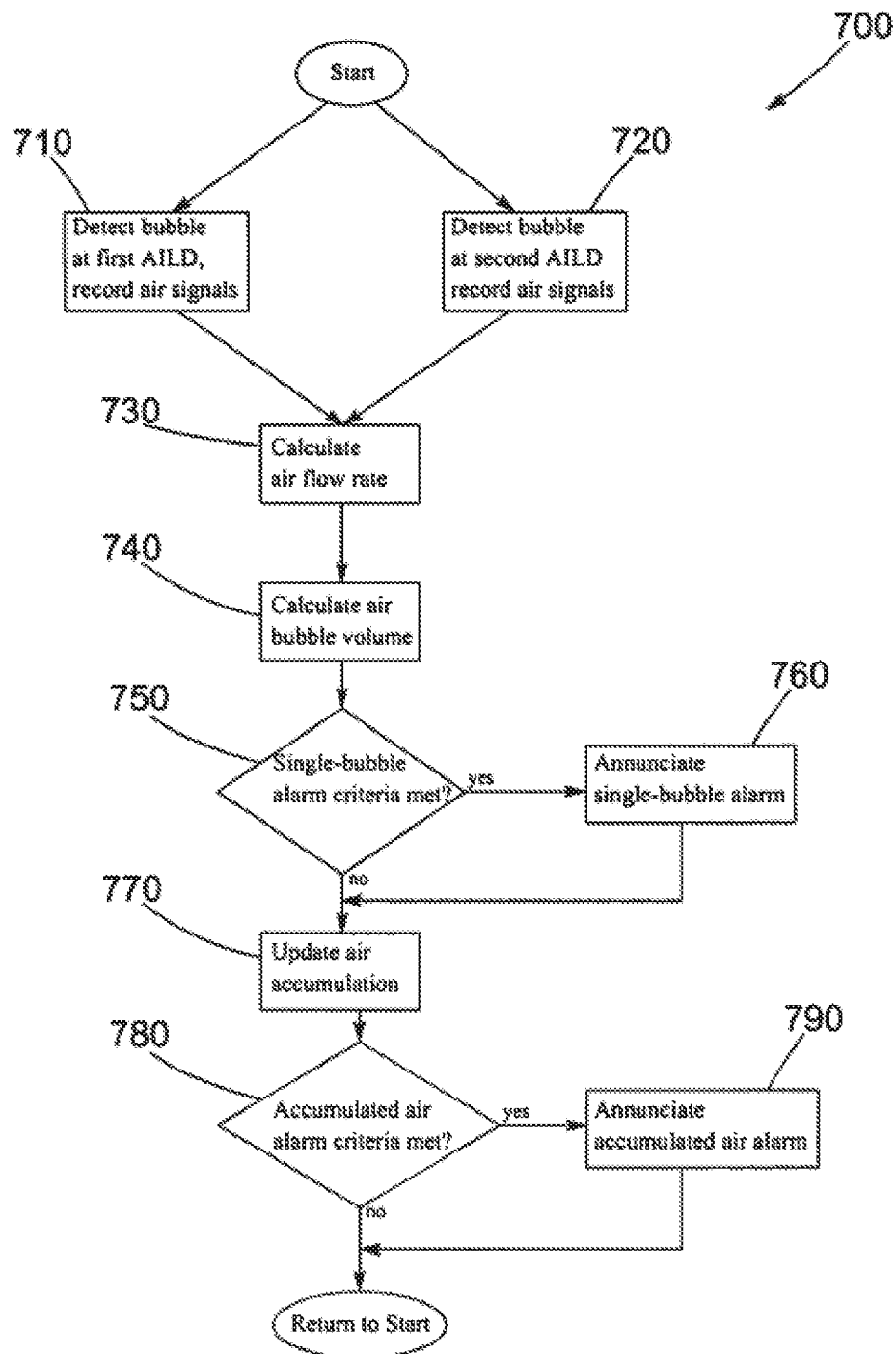


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/023145**A. CLASSIFICATION OF SUBJECT MATTER****A61M 5/36(2006.01)i, A61M 5/142(2006.01)i, A61M 5/168(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M 5/36; A61M 5/142; A61M 31/00; F04B 43/02; A61M 1/00; A61M 5/168

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & keywords: infusion pump, bubble, air, gas, line, detector, alarm

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2013-0226129 A1 (UNVERDORBEN, M.) 29 August 2013 See claims 1-21; and figures 2-3.	1-21
A	WO 02-13890 A1 (ABBOTT LABORATORIES) 21 February 2002 See the whole document.	1-21
A	US 7338470 B2 (KATZ, H. H. et al.) 04 March 2008 See the whole document.	1-21
A	US 2013-0345658 A1 (BROWNE, A. et al.) 26 December 2013 See the whole document.	1-21
A	WO 98-14234 A1 (IMED CORPORATION) 09 April 1998 See the whole document.	1-21



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

03 July 2017 (03.07.2017)

Date of mailing of the international search report

04 July 2017 (04.07.2017)

Name and mailing address of the ISA/KR

International Application Division

Korean Intellectual Property Office

189 Cheongsa-ro, Seo-gu, Daejeon, 35208, Republic of Korea



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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2017/023145

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