Plum Solo™

Infusion Pump

System Operating Manual

For use with list number REF 40001

Compatible with:
LifeShield™ Infusion Safety Software Suite

IFU0000499 (01, 2023-11)

icumedical
human connections

Change History

Part Number	Description of Change
IFU0000499 (01, 2023-11)	Initial Release

NOTES:

Contents

Introduction

Plum Solo is a large volume infusion pump capable of delivering fluids for a variety of therapies through clinically acceptable routes of administration, limited to intravenous, intra-arterial, subcutaneous, epidural, and enteral routes of infusions by licensed healthcare professionals. Plum Solo is for use in a hospital environment and other outpatient healthcare facilities where infusion therapy is needed for a range of patients such as adult, pediatric (including infants and children), and neonatal populations.

The Plum Solo infusion pump can deliver fluids over a broad range of infusion rates and is capable of concurrent delivery from one or more rigid or flexible fluid containers.

Plum Solo is a member of the Plum Device family, featuring an innovative design that automates many aspects of concurrent and piggyback infusions. The unique proprietary design of the cassette allows up two lines to be delivered at independent rates and prevents free flow conditions. The infusion pump does not require a hanger to lower the primary line to deliver a secondary infusion. With piggyback mode functionality, the secondary line draws medication directly from the secondary container and is not dependent on head height. The flush feature enables the clinician to flush the downstream tubing volume of a piggyback therapy. The programmed flush volume is delivered from the Primary Line container at the piggyback therapy rate after the piggyback therapy completes. In addition, the infusion pump allows the clinician to program loading dose and bolus on the primary or secondary line. The Plum Solo infusion pump also enables fluid pathway troubleshooting, such as removing upstream air in line, without disconnecting the patient line.

The Plum Solo infusion pump is fully compatible with Plum™ Series administration sets and accessories, and the Clave™ needleless connection systems, providing a convenient and cost-effective infusion pump.

The Plum Solo can act as a standalone infusion pump, or in conjunction with ICU Medical LifeShield™ Infusion Safety Software Suite to provide medication safety software at the point of care, with

customized drug libraries to support hospital defined protocols by clinical care area.

LifeShield™ Infusion Safety Software Suite connectivity is optional. For the list of features available with the version of LifeShield™ Infusion Safety Software Suite installed at your facility, contact your local rep.

Intended Use

The Plum Solo Infusion System is intended for parenteral fluids and medications through clinically acceptable routes (limited to intravenous, intra-arterial, subcutaneous, enteral, and epidural therapies). Plum Solo Infusion System is also indicated for the administration of whole blood and blood products.

The Plum Solo Infusion System is intended for use in clinical settings within the hospital environment and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion pumps and the administration of therapies consistent with the intended use of Plum Solo pumps. In addition, the healthcare professionals are trained in the administration of whole blood and blood products.

The Plum Solo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations.

Patient Population

The Plum Solo Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations. Special consideration and attention should be given to those who are medically fragile as described in this section.

Medically fragile patient populations may include a range of patients with a combination of factors (age, illness, weight, etc.) that place them at higher risk of harm. These include certain pediatric patients, such as those with low birth weight and those born premature (neonate), who require special attention when infusing at low flow

rates. Consider the following when using the Plum Solo infusion pump with medically fragile patients:

WARNING: AIR BUBBLES MAY FORM DOWNSTREAM TO THE CASSETTE AS THE RESULT OF NORMAL OUTGASSING OF DISSOLVED AIR IN THE FLUID IN ONE OR MORE OF THE FOLLOWING CASES:

- **CHILLED SOLUTION IS IN USE.**
- **CERTAIN FLUID KNOWN TO ROUTINELY OUTGAS ARE IN USE.**
- **THE INFUSION PUMP IS MOUNTED SIGNIFICANTLY ABOVE THE PATIENT. MINIMIZE THE PUMP HEIGHT ABOVE THE PATIENT WHEN OUTGASSING IS A CONCERN.**
- **THE INFUSION PUMP IS INFUSING AT VERY LOW RATES BETWEEN 0.1 AND 5 mL/HR.**

TO AVOID THESE AIR BUBBLES POTENTIALLY BEING INFUSED TO THE PATIENT AND THE NEED FOR REPRIMING, USE OF AN AIR ELIMINATING FILTER IS RECOMMENDED WHEN CLINICALLY APPROPRIATE.

WARNING: THE INFUSION PUMP CAN DETECT AIR AT A LIMIT OF 50, 100 OR 250 +20/-0% mcL BASED ON THE LIMIT DEFINED IN THE DRUG LIBRARY AND THE USE OF AN AIR ELIMINATING FILTER IS RECOMMENDED WHEN CLINICALLY APPROPRIATE.

- The cassette air trap catches small bubbles. The downstream air sensor detection is configurable for each Clinical Care Area (CCA); it can be set to detect a single air bolus of 50, 100, or 250 mcl and the cumulative of 250 mcl of air out of 4.9 mL of fluid delivered. Consider setting downstream air detection to 50 mcl as well as using an air eliminating filter as needed to prevent air embolisms in this patient group.

- The drug library can support configurations through medication rulesets and Clinical Care Area (CCA) settings that support the needs of various patient profiles. Dosing limits, concentration limits, maximum rate, volume to be infused, downstream occlusion pressure limit, downstream occlusion number of resets, detection of a single Air-in-line bolus from 50 mcl to 250 mcl, and

post infusion settings may be configured to accommodate the needs of various patient profiles and groups.

- Consider the criticality of the medication, as well as the appropriate use and limitation of a large volume pump on medically fragile patients. Special consideration is required regarding start up and accuracy needs at the intended flow rates as described in ***Delivery Accuracy*** and ***Delivery Accuracy and Start-up Delay Time Results***.

- When placing the Plum Solo infusion pump on an I.V. pole, consider its position relative to the patient. If the infusion pump is *too high above the patient*, be aware of its impact on accuracy at flow rates. At flow rates less than 1 mL/hr, the Plum Solo infusion pump should not be positioned higher than 24 inches above the patient. For information on low flow rate, accuracy, and the position of the pump above the patient, see ***Negative Backpressure (Pump Height) at Low Flow Rates***.

WARNING: DELIVERY ACCURACY MAY POTENTIALLY BE AFFECTED BY USE CONDITIONS SUCH AS FLUID VISCOSITY, BACKPRESSURE, FILLING HEAD HEIGHT, TEMPERATURE, AND CONCURRENT DELIVERY. FOR INFORMATION ON THOSE INDIVIDUAL AFFECTS, AS WELL AS WORST CASE CLINICALLY RELEVANT COMBINATIONS OF THESE FACTORS, SEE *Delivery Accuracy*.

- Typical start-up delay time for rates of 0.1 to 999 mL/hr is less than 1 minute for viscosity, temperature, ambient pressure, and filling head height conditions tested. Variation in temperature, ambient pressure (at or above sea level), fluid viscosity, and filling head heights do not impact system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

- If a Bolus or Loading Dose is to be given, see ***Bolus Delivery Accuracy*** for volume and ***Loading and Bolus Dose Volumetric***

Accuracy Results for factors to consider with a fragile patient group.

- See ***Maximum Unintended Bolus Volume Released After Downstream Occlusion is Resolved*** to determine the flow rate, downstream occlusion pressure alarm limit setting, and tubing type for the potential unintended volume released.

- See ***Steps to Avoid Unintended Bolus*** for the procedure to avoid an unintended bolus that may occur when clearing a downstream occlusion alarm. See ***Maximum Unintended Bolus Volume Released After Downstream Occlusion is Resolved*** for the typical and maximum unintended bolus volume.

WARNING: CLOSE ALL CLAMPS ON THE PRIMARY AND SECONDARY LINES, OR REMOVE THE SECONDARY CONTAINER, BEFORE OPENING THE CASSETTE DOOR TO PREVENT THE MIXTURE OF PRIMARY AND SECONDARY FLUIDS AND TO PREVENT UNRESTRICTED FLOW.

WARNING: A SMALL AMOUNT OF FLUID IS EXPELLED FROM THE SET (LESS THAN OR EQUAL TO 0.1 mL) EACH TIME THE DOOR IS OPENED OR CLOSED WITH A SET INSTALLED. IF POTENT DRUGS ARE BEING USED, TAKE APPROPRIATE ACTION TO GUARD AGAINST OVER-MEDICATION OF THE PATIENT.

WARNING: THERE IS A POTENTIAL FOR AN UNINTENDED BOLUS VOLUME TO BE DELIVERED AFTER AN OCCLUSION IS CLEARED, DEPENDING ON THE FLOW RATE, DOWNSTREAM OCCLUSION PRESSURE LIMIT, DOWNSTREAM TUBING LENGTH, AND TUBING TYPES USED. CONSIDER THESE FACTORS WHILE SETTING UP THE THERAPY TO MINIMIZE THE RISK OF UNINTENDED BOLUS.

WARNING: A SMALL AMOUNT OF FLUID MAY BE EXPELLED FROM AN INSERTED CASSETE (LESS THAN OR EQUAL TO 0.2 mL) WHEN THE INFUSION PUMP IS POWERED ON. IF POTENT DRUGS ARE BEING USED, TAKE APPROPRIATE ACTION TO GUARD AGAINST OVER-MEDICATION OF THE PATIENT.

WARNING: CLOSE ALL CLAMPS BEFORE OPENING THE CASSETTE DOOR.

- Close clamps when connected to a patient while the infusion pump is being powered on, during cassette check, and when stopping lines and opening the cassette door. If clamps are not closed, a volume of 0.2 mL or less may be delivered.

WARNING: DELIVERING MEDICATIONS IN CONCURRENT MODE WITH A SHORT HALF-LIFE OF LESS THAN 6 MINUTES PAUSES THE FLOW CONTINUITY OF SHORT HALF-LIFE MEDICATIONS, WHICH MAY IMPACT THE PHYSIOLOGIC RESPONSE.

NOTE: The following guidelines apply only when infusing short half-life critical drugs in Concurrent mode using a single channel. Individual patient responses may vary requiring adjustment of delivery rates.

- If a critical drug (with half-life less than 6 minutes) is to be infused at less than 2 mL/hr, the other infusion should be no faster than 5 times the critical drug's rate. Dopamine, for example, delivered at 1.5 mL/hr should not be accompanied by an infusion programmed any faster than 7.5 mL/hr.

- If a critical drug (with half-life less than 6 minutes) is to be infused at 2-5 mL/hr the other infusion should be no faster than ten times the critical drug's rate. Dopamine, for example, delivered at 3.5 mL/hr should not be accompanied by an infusion programmed any faster than 35 mL/hr.

- If a critical drug (with half-life less than 6 minutes) is to be infused at 5.1 mL/hr or greater, the other infusion can be programmed at any desired rate.

PRECAUTION: THE MAXIMUM COMBINED RATE OF THE PRIMARY AND SECONDARY LINES ON THE SAME CHANNEL IN CONCURRENT MODE IS 500 mL/HR, THE MINIMUM RATE IS 0.5 mL/HR PER LINE.

Conventions

This section describes the conventions used throughout this manual, as follows:

Convention	Application	Example
Italic	Function or mode specific instructions, or disclaimer	Primary Only: Attach an empty container.
Italic, bold, blue	Reference to a section, figure, or table	(See ***Button***)
ALL CAPS	Buttons in the user interface are displayed in ALL CAPS or with a graphic.	START or 
Initial Caps lowercase	Screen displays and device labels (as appropriate)	Program Dose Calculation
Bold	Emphasis	...sets are supplied **Sterile** and are for....

WARNING: INFORMATION THAT ALERTS THE USER TO POSSIBLE INJURY, DEATH OR OTHER SERIOUS ADVERSE REACTIONS OR RESIDUAL RISKS ASSOCIATED WITH THE USE OR MISUSE OF THE DEVICE.

PRECAUTION: INFORMATION THAT ALERTS THE USER OF ANY SPECIAL CARE TO BE EXERCISED FOR THE SAFE AND EFFECTIVE USE OF THE DEVICE.

NOTE: A Note highlights information that helps explain a concept or procedure.

Use Environment Exclusions

The Plum Solo infusion pump should not be used hyperbaric or oxygen-rich environments, nor should it be directly exposed to x-rays or ultrasound.

WARNING: DO NOT USE THE INFUSION PUMP IN ANY HYPERBARIC OR OXYGEN-RICH ENVIRONMENT. SERIOUS INJURY OR DAMAGE TO EQUIPMENT MAY RESULT.

WARNING: DO NOT EXPOSE THE INFUSION PUMP DIRECTLY TO X-RAYS OR ULTRASOUND; PERMANENT DAMAGE TO THE INFUSION PUMP'S ELECTRONIC CIRCUITRY MAY OCCUR.

See ***Environment*** for recommended environmental conditions and ***Electromagnetic Compatibility*** for electromagnetic compatibly.

MRI Environment

The Plum Solo infusion pump is not indicated for use in an MRI environment.

WARNING: DO NOT USE THE INFUSION PUMP IN A MRI ENVIRONMENT OR IN THE PRESENCE OF STRONG MAGNETIC FIELDS. SERIOUS INJURY OR DAMAGE TO EQUIPMENT MAY RESULT.

Plum administration sets can be used in an MRI environment in gravity mode only.

Transport Outside the Facility

The Plum Solo infusion pump is not intended for use in helicopters, ambulances, or any transport outside a healthcare facility.

Reporting Serious Incidents

Serious incidents associated with the use of this product should be reported to:

- ICU Medical using the “Contact Us” link at ***www.icumed.com***, and
- the relevant regulatory/competent authority of the country in which the user and/or patient is established (where required).

Training

ICU Medical offers a complete range of training and education to help new users and experienced personnel acquire the knowledge and confidence to operate the Plum Solo infusion pump properly and efficiently.

Training is available at the time of infusion pump purchase. Supplemental training can be purchased throughout the device’s service life. Training content is tailored to the needs of the medical facility and is presented by clinical personnel. ICU Medical works with hospital staff to identify training needs, including duration and frequency of training. Training is mandatory for new device implementation.

Contact your ICU Medical Representative for more information about available training programs.

Definitions

Term	Definition
Administration Set	The cassette with flexible tubing assembly that connects a source fluid container to a patient access device for fluid administration.
Air-In-Line Detection Limit	The sensitivity of downstream air-in-line detection of a single air bolus which causes a downstream air-in-line alarm. This is configured at the CCA level in the CDL and can be set to either 50, 100, or 250 mcl.
Air Trap	A component of the cassette that allows trapping and removal of upstream air.
Alarm	A condition that invokes audible and/or visible alarm indicators requiring operator attention.
Alert	A visual signal (with an audible tone) that provides information to you or prompts further action. As an example, an alert may occur during programming to inform the user that the entry exceeds a limit that was defined by the institution. The alert details may be presented in a dialog box or below a programming field.
Alternate Units	The Dose Rate units that may be selected. Alternate Units are any units other than mL/hr.
Alternate Units Parameters	Drug Amount, Diluent Amount, Patient Weight, Height for ***BSA*** (manually or calculated if applicable), and Dose Rate.

Term	Definition
Auto-backprime	An automatic 6-second ***Backprime*** that occurs following a secondary infusion using the ***Infuse to Empty*** feature. Auto-backprime clears any air from the air trap before the primary infusion resumes to prevent downstream air. During an auto-backprime, the fluid is pumped at a rate of approximately 1mL every 5 seconds.
Automatic Light Sensor	A sensor in the pump that detects light levels in the surrounding environment and adjusts the brightness of the screen. This can be turned off.
Auto-Programming	Also known as Smart Pump Programming (SPP), this refers to the ability to take an I.V. medication order from the electronic medical record (EMR) and translate it into program settings that can automatically populate the infusion pump. Clinician review and confirmation before starting are still required.
Backpressure	The resistance to fluid flow on the downstream or output portion of the ***Administration Set***, usually expressed as pounds per square inch (psi).
Backprime	The use of fluid in ***Primary Line 1 (R1)*** to move upstream air or fluid into a receptacle attached to ***Secondary Line 2 (R2)***. No fluid is delivered downstream to the cassette during a backprime.
Biomed Mode	Name for the non-delivery mode of pump operation for hospital technicians (Biomeds) who have access to technical information such as delivery parameter limits and displays default settings.

Term	Definition
Bolus Dose	A rapid infusion of a relatively large volume of fluid or dose of a drug, being administered (typically the same medication, concentration, and dosing family) to enhance a therapeutic response.
BSA	Body Surface Area, in m^2, for calculation of medication doses that require a patient's height and weight.
Button	A physical key or UI icon allowing users to control and interact with the device.
CAIR™	Trade name of ICU Medical's enhanced performance roller clamp.
Callback	A setting that configures the infusion pump to emit an alarm when a step completes and transitions to the next infusion. Callback occurs at the completion of a piggyback, bolus dose, loading dose, or a step in a multistep (excluding the last step), when another program follows. The Plum Solo can also be configured to continue the infusion or stop with the callback.
Cassette	A component of an administration set specifically designed to work with the Plum Solo infusion pump that facilitates two lines in and one line out, allowing primary and secondary delivery rates to be controlled separately.
CCA	Clinical Care Area. The CCA is a defined physical or virtual area in the hospital for a specific patient population that comprises rules for infusion pump settings and which drugs can be used along with their associated delivery limits.

Term	Definition
CDL	Custom Drug Library. A drug library that is based on hospital-defined practices and customized settings, using LifeShield™ Infusion Safety Software Suite.
Channel	The downstream line of an administration set that connects to the patient.
Cleared Settings	When programmed delivery settings for an individual line or both lines are reset to their default settings.
Clinical Advisories	A Clinical Advisory is defined in the drug library and used to provide additional information the clinician needs to consider when addressing medication administration according to the hospital's policy or practice. This advisory will display when the associated medication is selected while manually programming the infusion pump and must be acknowledged before programming can continue.
Clinical Use	The clinical use attributed to a medication entry. It is a setting that allows the user to define the use of a medication ruleset (for example, Standard, Cardiac, Renal, etc.).
Concentration	Concentration refers to the ratio of ***Drug Amount*** (in mg, for example) to diluent (in mL).
Concentration Entry	Also known as Wildcard or Variable entry, this is a method for inputting the drug amount and/or volume for an infusion.
Concentration Limits	The alert that occurs when a user enters a wildcard concentration value that exceeds the limits for the entry.
Concurrent Delivery	Simultaneous delivery of fluids on ***Primary Line 1 (R1)*** and ***Secondary Line 2 (R2)***.

Term	Definition
Concurrent Mode	A mode that enables the user to program ***Secondary Line 2 (R2)*** for Concurrent delivery.
Continue Rate	The pump will continue to infuse the selected line at the same rate as the programmed infusion when VTBI completes.
Continuous Infusion	An infusion that delivers at a prescribed rate or dose rate. There may be an option to deliver a Loading Dose or Bolus, as configured through the CDL.
Delay Start	A pending delivery program that will automatically start and not require operator action at the delay time programmed.
Deliver Alone Mode	A mode that disables access to the ***Secondary Line 2 (R2)***, making concurrent and piggyback mode unavailable.
DERS	Dose Error Reduction Software. Features on an infusion pump, configured by safety software, that assist clinical users by warning of potentially incorrect programming and calculation errors during medication delivery. Infusion pumps that have this software are also called “Smart Infusion Pumps”.
Device	The infusion pump, not including the disposable administration sets.
Diluent (Volume)	Volume of fluid in which a medication is diluted.
Distal	The portion of the ***Administration Set*** downstream from the ***Cassette’s*** pumping chamber.

Term	Definition
Dose	A volume of medication to be delivered on a continuous basis.
Dosing Unit	Unit of measure for a drug to be delivered.
Downstream	Also known as distal, or below the pump or cassette mechanism. Refers to a portion of the ***Administration Set*** tubing from the ***Cassette's*** pumping chamber to the patient.
Drug Amount	The mass or quantity of medication to be delivered before being mixed with a diluent.
Duration	The time period required to deliver a programmed infusion.
Electronic Medical Record (EMR)	An electronic (digital) collection of medical information about a patient, such as diagnoses, medications, and treatment plans.
Enteral	Route of administration via the gastrointestinal tract.
Epidural	Route of administration via the space around the dura mater of the spinal cord.
Expected Service Life	The amount of time from the date of implementation that the manufacturer will provide technical service to the device. Technical service involves repairs, technical support questions and troubleshooting, and replacement parts.
Filling Head Height (FHH)	The height difference between the supply container and the pump mechanism.
Haptics	A physical sensation, such as a vibration, from the pump that indicates a touch occurred on the user interface on an inactive region.

Term	Definition
Hard Limit	The upper- and lower-dosing limits associated with a drug, in the drug library, that cannot be overridden by the operator.
Hard Limit Alert	An alert on the infusion pump presented to the clinician when a hard limit is exceeded.
High Alert Medication	A drug that can cause significant patient harm if delivered incorrectly.
Infiltration	Unintentional fluid migration into the tissues surrounding a venipuncture site.
Infuse to Empty	A feature that allows intermittent piggyback infusions programmed on the secondary line to deliver overfill volume (up to an additional 15% of container volume) to ensure the entire dose is delivered. This feature is only available if enabled in the CDL.
Infuser	See ***Device*** and ***Infusion Pump***.
Infusion Pump	A medical device used to deliver fluids into a patient's body in a controlled manner.
Initial Value	A programming value defined at the ruleset that automatically populates the programming field on the infusion pump screen for dose, rate, or time (duration) and can be changed by the user during programming.
Intermittent Infusion	An infusion that may be programmed by a dose or volume over a duration, or by rate and volume. When configured through the drug library within a ruleset, the infusion cannot be configured with a Loading Dose or Bolus. Additional features may be available, such as ***Infuse to Empty***.

Term	Definition
I.V. Push	The act of manually pushing on the syringe plunger to deliver the contents of medication through access at a Y-site of an administration set.
KVO Rate	Keep Vein Open rate. The post infusion setting that provides a minimal delivery rate that is configured by LifeShield™ Infusion Safety Software Suite. It is intended to provide sufficient fluid flow to decrease the potential for clotting at the patient (IV) access site. The KVO rate default is configured by the CCA at a fixed rate from 1 to 20 mL / hr. This rate is used when KVO is configured for the post infusion behavior by the medication ruleset, but Continue or Stop is NOT a selected configuration. KVO rate will never exceed the programmed rate.
LifeShield™ Infusion Safety Software Suite	LifeShield™ Infusion Safety Software Suite provides healthcare professionals with the capability to send, receive, and store information from infusion pumps. The bi-directional communication between the hospital medication safety software and infusion pumps includes infusion parameters, infusion pump default configurations, infusion pump location, history, events, trending, alarms, and status.
Limits Range Bar	A graphic on the user interface that shows the medication-configured rule set from the library of upper, lower, hard, and soft limits.

Term	Definition
Loading Dose	Administered only at the initial start of an infusion. A rapid infusion of a relatively large volume of fluid or dose of a drug, being administered (typically the same medication, concentration, and dosing family) to enhance a therapeutic response.
Malfunction	One of a number of alarm conditions that indicate a failure of the infusion pump.
Maximum Dose	The highest dose at which the infusion pump can be configured to be programmed to run. It can be configured for Dose, Loading Dose, and Bolus Dose.
Maximum Rate	The highest dose rate at which the infusion pump can be configured to be programmed to run for a CCA.
Maximum VTBI	The largest VTBI that can be programmed for a single line or piggyback delivery.
ME Equipment	Medical Electrical Equipment.
Mode	A type of secondary infusion, either Piggyback or Concurrent.
Multistep	A sequential program that can deliver up to 10 steps from one container at different rates, doses, ***VTBI***, and durations using the same dosing unit.
Non-Time-Based Dosing Unit	A dosing unit that does not include a time component (for example, grams). These are generally intermittent infusions.
Outgassing	The release of a gas that was dissolved, trapped, frozen or absorbed in a material.
Override	An action by a clinician that acknowledges and confirms an alert and then proceeds with a program containing a parameter that falls outside the hospital-defined ***Soft Limits***.

Term	Definition
Parenteral	Delivery via other than an intestinal route, such as intravenous (I.V.) injection.
Piggyback Flush	A feature that enables the clinician to flush the downstream tubing volume of a piggyback therapy. The programmed Flush volume is delivered from the ***Primary Line 1 (R1)*** container at the Piggyback therapy rate after the Piggyback therapy completes.
Piggyback Mode	The delivery mode that suspends ***Primary Line 1 (R1)*** delivery while ***Secondary Line 2 (R2)*** delivers. The primary line resumes when the secondary line delivery completes.
Post Infusion Rate	The delivery rate the infusion pump switches to after a therapy completes. The default is configured in the ***CDL*** at the drug ruleset. It can be configured to KVO, CONTINUE at rate or STOP delivery.
Primary Line 1 (R1)	The upstream Primary tubing attached to the primary line of the cassette.
Prime	The action of filling the Plum ***Administration Set***, Plum ***Cassette***, and all connected tubing with the fluid to be infused.
Proximal	Upstream (input, as ***Primary Line 1 (R1)*** and/or ***Secondary Line 2 (R2)*** with respect to the ***Cassette*** pumping chamber portion of the Administration Set.
Rate	The amount of fluid pumped to the patient over a given period of time, expressed in mL/hr.

Term	Definition
Rule Set	The programmed ***Soft Limit*** and ***Hard Limit*** associated with a drug entry from the ***CCA*** in the drug library.
Secondary Line 2 (R2)	The upstream secondary line/syringe attached to the secondary port of the cassette.
Service Mode	A non-therapeutic mode used for configuring the infusion pump and changing default settings.
Soft Limit	The upper- and lower-dosing limits associated with a drug, in the drug library, that can be overridden by the operator.
Standby	A pending delivery program that requires operator action to begin the infusion.
Tall-Man Lettering	Uses uppercase letters in combination with lowercase letters to help clinicians differentiate among look-alike drug names.
Time-Based Dosing	A dosing unit that includes a time component (for example, g/min).
Titration	A change in ***Dose***, ***Rate***, ***Duration***, and/or ***VTBI*** in a currently running or programmed infusion.
Unintended Bolus	A single, unintended volume of fluid delivered.
Unit of Measure	One of a variety of terms used to describe a drug amount, such as grams, mg, or units.
Upstream	Also known as proximal or above the pump or cassette mechanism. Refers to a portion of the ***Administration Set*** tubing (input, as Line 1 and/or Line 2) from the ***Cassette's*** pumping chamber to the container attachment.

Term	Definition
VI	Volume Infused. The volume of fluid or IV solution that has been delivered by a program or therapy step from a line.
VTBI	Volume To Be Infused. The volume of fluid or I.V. solution (remaining) for delivery by a program or therapy step from a line.

Labeling Symbol Glossary

This section describes the symbols used in the labeling for the Plum Solo infusion pump:

Symbol	Description	Standards	Symbol Identifier
	Manufacturer	BS EN ISO 15223-1	Clause 5.1.1
	Date of manufacture	BS EN ISO 15223-1	Clause 5.1.3
	Catalogue Number	BS EN ISO 15223-1	Clause 5.1.6
	Serial Number	BS EN ISO 15223-1	Clause 5.1.7
	Fragile, Handle with Care	BS EN ISO 15223-1	Clause 5.3.1
	Keep Dry	BS EN ISO 15223-1	Clause 5.3.4
	Temperature Limitation	BS EN ISO 15223-1	Clause 5.3.7

Symbol	Description	Standards	Symbol Identifier
	Humidity Limitation	BS EN ISO 15223-1	Clause 5.3.8
	Atmospheric Pressure Limitation	BS EN ISO 15223-1	Clause 5.3.9
	Precaution	BS EN ISO 15223-1	Clause 5.4.4
	Equipotential Terminal (Ground)	IEC 60417	Ref no. 5021
	Dangerous Voltage	IEC 60417	Ref no. 5036
	Non-ionizing electromagnetic radiation. To indicate generally elevated, potentially hazardous levels of non-ionizing radiation, or to indicate equipment or systems in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC 60417	Ref no. 5140

Symbol	Description	Standards	Symbol Identifier
	The administration set, which comprises the infusion liquid pathway, is an applied part for the infusion pump. The administration set is a Type CF Applied Part complying with the higher degree of protection against electric shock. Type CF Applied Parts are those parts suitable for direct cardiac application.	IEC 60417	Ref no. 5335
	Stand By Power	IEC 60601-1	29, Table D.1
IPX2	Protection against vertically falling water drops	IEC 60601-2-24	Clause 201.11.6.5
	This Way Up	ISO 7000	Ref no. 0623
	Refer to Instructions	ISO 7010	Ref no. M0021
	Warning	ISO 7010	Ref no. W001
	Dangerous Voltage	ISO 7010	Ref no. W012

Symbol	Description	Standards	Symbol Identifier
	Federal (USA) law restricts this device to sale by or on the order of a doctor or other licensed practitioner	FDA 21 CFR 801.109	N/A
	Complies with limits for Class B digital device established by FCC Rules, Part 15	FCC 47 CFR	15.19
	Waste from Electrical and Electronic Equipment	EN 50419	Clause 4
	Regulatory Compliance Mark	Australian Communications and Media Authority (ACMA) wireless regulatory authority AS/NZS 4417.1	Clause 3.2

Symbol	Description	Standards	Symbol Identifier
	The 'US' indicator adjacent to the CSA Mark signifies that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in the U.S. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL (National Recognized Testing Laboratory), is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.	CSA International	N/A
	Complies with the Independent Communications Authority of South Africa (ICASA) Electronic Communications Act, Act No 36 of 2005	Electronic Communications Act, Act No 36 of 2005	N/A
	Items marked with this label should not enter the MRI scanner room.	ASTM F2503-20	MR Unsafe
	Lithium Ion Battery Recycling Symbol	N/A	N/A

Symbol	Description	Standards	Symbol Identifier
	CE Mark	EU Medical Device Directive/ Regulation	N/A
	Underwriter Laboratory Recognized Component Mark	N/A	N/A

Illustrations, Screen Displays, and Software Messages

Illustrations and screen examples in this manual are **graphic depictions**, not exact representations of the product.

Warnings and Precautions

The Plum Solo infusion pump has been designed and manufactured to be safe, reliable, and easy to use. For safe operation of the pump, observe the Warnings, Precautions, and recommendations in the following sections.

General Warnings and Precautions

WARNING: POSSIBLE EXPLOSION HAZARD EXISTS IF THE PLUM SOLO INFUSION PUMP IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES, INCLUDING ANESTHETICS.

WARNING: TO AVOID THE RISK OF ELECTRIC SHOCK, THE EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

WARNING: TO AVOID THE RISK OF ELECTRIC SHOCK, DO NOT OPEN THE CASE. REFER TO QUALIFIED SERVICE PERSONNEL.

WARNING: NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

WARNING: NO ADDITIONAL DEVICES CAN BE CONNECTED TO THE INFUSION PUMP THAT HAVE NOT BEEN SPECIFIED AS COMPATIBLE WITH THE INFUSION PUMP BY ICU MEDICAL.

WARNING: ARRANGE TUBING, CORDS, AND CABLES TO MINIMIZE THE RISK OF PATIENT STRANGULATION OR ENTANGLEMENT.

WARNING: DO NOT USE THE INFUSION PUMP IN A MRI ENVIRONMENT OR IN THE PRESENCE OF STRONG MAGNETIC FIELDS. SERIOUS INJURY OR DAMAGE TO EQUIPMENT MAY RESULT.

WARNING: DO NOT USE THE INFUSION PUMP IN ANY HYPERBARIC OR OXYGEN-RICH ENVIRONMENT. SERIOUS INJURY OR DAMAGE TO EQUIPMENT MAY RESULT.

WARNING: DO NOT EXPOSE THE INFUSION PUMP DIRECTLY TO X-RAYS OR ULTRASOUND; PERMANENT DAMAGE TO THE INFUSION PUMP'S ELECTRONIC CIRCUITRY MAY OCCUR.

WARNING: THE INFUSION PUMP DOES NOT HAVE THE CAPABILITY TO DETECT INFILTRATION TO THE PATIENT.

WARNING: INSPECT PLUM ADMINISTRATION SET PACKAGING BEFORE USE. IF PACKAGING IS BREACHED, DISCARD AND USE A DIFFERENT ADMINISTRATION SET.

WARNING: EXERCISE CAUTION WHEN THE PATIENT IS AMBULATORY WHILE CONNECTED TO THE INFUSION PUMP.

WARNING: CLOSE THE CLAMP ON THE UPSTREAM LINE TO PREVENT FLUID SPILL IF THE CAPPED PORT ON THE SECONDARY MUST BE REMOVED.

WARNING: DELIVERING MEDICATIONS IN CONCURRENT MODE WITH A SHORT HALF-LIFE OF LESS THAN 6 MINUTES PAUSES THE FLOW CONTINUITY OF SHORT HALF-LIFE MEDICATIONS, WHICH MAY IMPACT THE PHYSIOLOGIC RESPONSE.

WARNING: READ THE SYSTEM OPERATING MANUAL AND INSPECT THE DEVICE PRIOR TO PATIENT CARE. IMPROPER USE OR USE OF A DAMAGED DEVICE MAY LEAD TO THE FOLLOWING SYSTEM HAZARDS: AIR EMBOLISM, ALLERGIC/ CAUSTIC RESPONSE, DELAY OF THERAPY, EMBOLISM, ELECTRIC SHOCK, EXSANGUINATION, HAZARDS TO ENVIRONMENT, INCORRECT THERAPY, INFECTION, OVERDOSE, TRAUMA, UNDERDOSE. THE HARMS POTENTIALLY ASSOCIATED WITH THESE SYSTEM HAZARDS VARY BY PATIENT AND CLINICAL CONDITION AND MAY INCLUDE REVERSIBLE INJURY, PERMANENT INJURY, OR DEATH.

NOTE: Single fault failure of certain electronic/motor control components would result in no more than 5 mL of unexpected fluid delivery.

NOTE: If the infusion pump fails the Self Test, restart the infusion pump once. If it fails the Self Test again, send the pump for service.

Secondary Infusion Guidelines for Piggyback and Concurrent Deliveries

Primary and secondary fluids are delivered to the patient through a common cassette and downstream line. Observe the following guidelines during Piggyback and Concurrent deliveries.

WARNING: CLOSE ALL CLAMPS ON THE PRIMARY AND SECONDARY LINES, OR REMOVE THE SECONDARY CONTAINER, BEFORE OPENING THE CASSETTE DOOR TO PREVENT THE MIXTURE OF PRIMARY AND SECONDARY FLUIDS AND TO PREVENT UNRESTRICTED FLOW.

WARNING: IF THE RATE OF THE PRIMARY LINE IS DIFFERENT THAN THE SECONDARY LINE, THEN THE RESIDUAL FLUID FROM THE SECONDARY LINE WILL BE GIVEN AT THE RATE OF THE PRIMARY LINE. THIS APPLIES WHEN THE PIGGYBACK FLUSH FEATURE IS NOT USED.

WARNING: IF THE RATE OF THE SECONDARY LINE IS DIFFERENT THAN THE PRIMARY LINE, THEN THE RESIDUAL FLUID FROM THE PRIMARY LINE WILL BE GIVEN AT THE RATE OF THE SECONDARY LINE.

Concurrent Delivery of Critical Drugs

WARNING: ENSURE MEDICATIONS THAT ARE DELIVERED CONCURRENTLY, OR IN PIGGYBACK, ARE COMPATIBLE.

WARNING: DELIVERING MEDICATIONS IN CONCURRENT MODE WITH A SHORT HALF-LIFE OF LESS THAN 6 MINUTES PAUSES THE FLOW CONTINUITY OF SHORT HALF-LIFE MEDICATIONS, WHICH MAY IMPACT THE PHYSIOLOGIC RESPONSE.

PRECAUTION: THE MAXIMUM COMBINED RATE OF THE PRIMARY AND SECONDARY LINES ON THE SAME CHANNEL IN CONCURRENT MODE IS 500 mL/HR, THE MINIMUM RATE IS 0.5 mL/HR PER LINE.

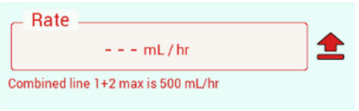
- If a critical drug (with half-life less than 6 minutes) is to be infused at less than 2 mL/hr, the other infusion should be no faster than 5 times the critical drug's rate. Dopamine, for example, delivered at 1.5 mL/hr should not be accompanied by an infusion programmed any faster than 7.5 mL/hr.

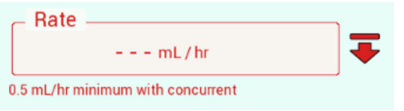
- If a critical drug (with half-life less than 6 minutes) is to be infused at 2-5 mL/hr the other infusion should be no faster than ten times the critical drug's rate. Dopamine, for example, delivered at 3.5 mL/hr should not be accompanied by an infusion programmed any faster than 35 mL/hr.

- If a critical drug (with half-life less than 6 minutes) is to be infused at 5.1 mL/hr or greater, the other infusion can be programmed at any desired rate.

These guidelines apply *only* when infusing **short half-life critical drugs in Concurrent mode using a single channel. Individual patient responses may vary requiring adjustment of delivery rates.**

NOTE: The total of the primary rate plus the secondary rate in Concurrent mode (Line 1 + Line 2) cannot exceed 500 mL/hr. The rate of either line in Concurrent mode cannot be less than 0.5 mL/hr. This is the case for all drugs. A hard limit alert will be displayed if any concurrency limits are exceeded. For example, the following alerts will display when the combined rate of both lines exceeds 500 mL/hr, or when a line is programmed for less than 0.5 mL/hr in concurrent mode.





Delivery Rate Guidelines	
Short Half-life (less than 6 minutes) Critical Drug Infusion Rate	**Maximum Rate of Accompanying Infusion**
0.5-1.9 mL/hr	5 Times the Critical Drug Rate
2-5 mL/hr	10 Times the Critical Drug Rate
5.1 mL/hr or Greater	Any Desired Ratio

Examples of drugs with a short half-life (approximately 6 minutes or less when given intravenously) include:

Dobutamine	Epoprostenol	Nitroprusside
Dopamine	Isoproterenol	Norepinephrine
Epinephrine	Nitroglycerin	Oxytocin

For these drugs, the Concurrent flow guidelines should be followed when the infusion rate of the drug will be 5 mL/hr or less.

NOTE: The list of critical drugs is not intended to be all-inclusive of critical drugs or drugs with a short half-life.

The clinician should become familiar with the pharmacodynamics of any critical drug before administration.

Guidelines When Opening the Cassette Door

WARNING: A SMALL AMOUNT OF FLUID IS EXPELLED FROM THE SET (LESS THAN OR EQUAL TO 0.1 mL) EACH TIME THE DOOR IS OPENED OR CLOSED WITH A SET INSTALLED. IF POTENT DRUGS ARE BEING USED, TAKE APPROPRIATE ACTION TO GUARD AGAINST OVER-MEDICATION OF THE PATIENT.

Opening the cassette door will stop the infusion on one or both lines of the channel.

- To prevent unrestricted flow and mixing fluids in the primary and secondary lines, close all clamps, or remove the secondary container, before opening the cassette door.

- Keep the cassette door securely closed while the infusion pump is not in use to avoid cassette door damage.

Administration Sets and Accessories Guidelines

Plum Solo infusion pump operation requires single-use Plum series administration sets (PlumSets). See ***Administration Sets*** for a representative list of Plum administration sets.

- Use only compatible PlumSets with the Plum Solo infusion pump. See individual set instructions for additional information.

- Administration sets should be changed at least every 96 hours or as per facility protocol, whichever is sooner. Discard after use.

- I.V. infusion sets with integral nonblood filters are not for use in the administration of blood, blood products, emulsions, suspensions, or any medications not totally soluble in the solution being administered. These medications may be administered through the lower Y-injection site, below the filter.

WARNING: THERE IS A POTENTIAL FOR AN UNINTENDED BOLUS VOLUME TO BE DELIVERED AFTER AN OCCLUSION IS CLEARED, DEPENDING ON THE FLOW RATE, DOWNSTREAM OCCLUSION PRESSURE LIMIT, DOWNSTREAM TUBING LENGTH, AND TUBING TYPES USED. CONSIDER THESE FACTORS WHILE SETTING UP THE THERAPY TO MINIMIZE THE RISK OF UNINTENDED BOLUS.

- For information on the effect these factors have on unintended bolus delivery, see the following points. See ***Steps to Avoid Unintended Bolus*** for information on avoiding unintended bolus delivery.

WARNING: MICROBORE SETS ARE NOT RECOMMENDED FOR FLOW RATES ABOVE 500 mL/HR. USE OF MICROBORE SETS FOR FLOW RATES GREATER THAN 500 mL/HR MAY REQUIRE ADJUSTING THE DOWNSTREAM OCCLUSION PRESSURE LIMIT SETTING TO PREVENT UNINTENDED DOWNSTREAM OCCLUSION ALARMS.

- Before disconnecting a line with a rigid container from the cassette, close the upper slide clamp or clamp upstream tubing, open the cassette door, and then remove and invert the cassette (ports down) to avoid spilling the fluid.

Steps to Avoid Unintended Bolus

In addition to the following procedure, refer to ***Maximum Unintended Bolus Volume Released After Downstream Occlusion is Resolved***.

PRECAUTION: THERE IS A POSSIBILITY OF AN UNINTENDED BOLUS OCCURRING WHEN CLEARING A DOWNSTREAM OCCLUSION. USE THE FOLLOWING PROCEDURE TO AVOID ADMINISTRATION OF AN UNINTENDED BOLUS TO THE PATIENT WHILE CLEARING A DOWNSTREAM OCCLUSION.

1. If the administration set does not have a clamp downstream to the cassette, disconnect the tubing from the patient while eliminating the downstream occlusion.

   If the administration set has a clamp on the downstream line, ensure that the clamp is closed (even if the closed clamp caused the downstream occlusion alarm).

2. Close all clamps on the primary and secondary lines.
3. Open the cassette door and remove the cassette.
4. Gently pull out the flow regulator on the cassette to dissipate the pressure for a brief moment, and then push in on the flow regulator to close it.
5. Eliminate the source of occlusion, unless it was caused by a closed downstream clamp. (The downstream clamp must remain closed until Step 8.)
6. If the downstream line was removed, reattach it to the patient access device.
7. Reinsert the cassette and close the cassette door.
8. Open all clamps and resume infusion.

For other conditions that may cause an unintended bolus to be administered, see ***Guidelines When Opening the Cassette Door*** and ***Administration Sets and Accessories Guidelines***.

Guidelines to Avoid Air in the Patient Line

WARNING: REPEATED OPENING AND CLOSING OF THE CASSETTE DOOR MAY DEFEAT THE UPSTREAM AIR-IN-LINE ALARM AND MAY CAUSE A DOWNSTREAM AIR-IN-LINE ALARM, REQUIRING REPRIMING.

WARNING: AIR BUBBLES MAY FORM DOWNSTREAM TO THE CASSETTE AS THE RESULT OF NORMAL OUTGASSING OF DISSOLVED AIR IN THE FLUID IN ONE OR MORE OF THE FOLLOWING CASES:

- **CHILLED SOLUTION IS IN USE.**
- **CERTAIN FLUID KNOWN TO ROUTINELY OUTGAS ARE IN USE.**
- **THE INFUSION PUMP IS MOUNTED SIGNIFICANTLY ABOVE THE PATIENT. MINIMIZE THE PUMP HEIGHT ABOVE THE PATIENT WHEN OUTGASSING IS A CONCERN.**
- **THE INFUSION PUMP IS INFUSING AT VERY LOW RATES BETWEEN 0.1 AND 5 mL/HR.**

TO AVOID THESE AIR BUBBLES POTENTIALLY BEING INFUSED TO THE PATIENT AND THE NEED FOR REPRIMING, USE OF AN AIR ELIMINATING FILTER IS RECOMMENDED WHEN CLINICALLY APPROPRIATE.

WARNING: THE INFUSION PUMP CAN DETECT AIR AT A LIMIT OF 50, 100 OR 250 +20/-0% mcL BASED ON THE LIMIT DEFINED IN THE DRUG LIBRARY. THE USE OF AN AIR ELIMINATING FILTER IS RECOMMENDED WHEN CLINICALLY APPROPRIATE.

WARNING: WHEN USING A SYRINGE ADAPTER, RETRACT THE PLUNGER TO DRAW APPROXIMATELY 1 mL OF FLUID INTO THE SYRINGE TO CLEAR AIR FROM THE ADAPTER FILTER.

PRECAUTION: RUNNING THE BAG DRY MAY RESULT IN STUCK FLUID DROPLETS INTERFERING WITH THE UPSTREAM AIR SENSOR, RESULTING IN A POTENTIAL FAILURE TO DETECT UPSTREAM AIR.

Guidelines During Backpriming

- Backpriming is not recommended for reconstituting secondary containers containing dry powders.
- To avoid pressurization when backpriming into a syringe, confirm that there is sufficient empty space to accept the backprimed fluid before beginning a backprime.
- During a backprime, fluid is pumped from the container on the primary line to a line or syringe attached to the secondary port (secondary line) at a rate of approximately 1 mL every 5 seconds.
- To accept the backprimed air and/or fluid, a line with a container or a syringe needs to be attached to the secondary port.
- After backpriming, the infusion pump performs a cassette check. This process temporarily stops delivery.
- The backpriming volume is deducted from the primary container volume to be infused (VTBI); this applies to fluids allowed to be interrupted by a piggyback and delivered in mL/ hr. Non-time based (intermittent) infusions do not accommodate the deduction of backprime volume to avoid impacting the dose being delivered.

NOTE: During cassette check, the START button will be accessible to queue the start of delivery after the cassette check completes. Delivery will not start if air, occlusion, or cassette issues are detected (an alarm will occur specific to the issue).

NOTE: The approximate backprime volume used can be viewed under Settings on the Volume Infused page.

Battery Guidelines

WARNING: USING THE INFUSION PUMP ON A PATIENT WITHOUT A BATTERY INSTALLED IS NOT RECOMMENDED.

- If the low-battery, very low battery, or depleted-battery alarm sounds, connect the infusion pump to AC (mains) power immediately.
- Use AC (mains) power whenever possible. Connect to AC (mains) power during storage to ensure a fully charged battery for emergencies.
- It is not recommended to use the Plum Solo infusion pump for an extended period of time when the pump indicates for a battery change. Use of a correctly maintained and charged battery helps to ensure proper operation.
- The battery may not be fully charged upon receipt. Connect the infusion pump to AC (mains) power for at least eight hours.
- If the quality of the earth grounding source is in doubt, use battery power.

Guidelines During Cleaning

- The infusion pump must be cleaned prior to first use on a patient.
- To avoid mechanical or electronic damage, do not immerse the Plum Solo infusion pump in any fluids or cleaning solutions.
- Do not spray cleaning solutions or disinfecting agents directly onto the instrument.
- Certain cleaning and sanitizing solutions may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by ICU Medical may result in product damage. Do not use compounds containing

combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

- Never use sharp objects such as fingernails, paper clips, or needles to clean any part of the infusion pump.
- Do not sterilize by heat, steam, ethylene oxide (ETO), or radiation.
- To avoid infusion pump damage, cleaning solutions should only be used as directed. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

For more information, see ***Cleaning and Disinfecting the Infusion Pump*** and the *Plum Solo Technical Service Manual*.

Artifacts

Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals.

To determine if the abnormality in the monitoring equipment is caused by the infusion device instead of some other source in the environment, set the infusion device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by the electronic noise generated by the infusion device. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring equipment system documentation for setup and maintenance instructions.

The Plum Solo infusion pump is designed to operate normally in the presence of most encountered electromagnetic interference (EMI) conditions. The Plum Solo has been tested for electromagnetic immunity compliance in accordance with professional healthcare

environment immunity requirements of IEC/EN 60601-1-2 Edition 4 standard.

This equipment has been tested and found to comply with the EMC limits for its classification of medical device. Those limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into a power outlet that is on a circuit different from that to which the other device(s) is connected
- Consult the manufacturer or field service technician for help

PRECAUTION: PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT, SUCH AS CELLULAR TELEPHONES, 2-WAY RADIOS, BLUETOOTH™ DEVICES, MICROWAVE OVENS, IN CLOSE PROXIMITY TO THIS DEVICE MAY AFFECT WIRELESS COMMUNICATIONS WITH THE INFUSION PUMP AND/OR THE OPERATION OF THE INFUSION PUMP.

If wireless connectivity is interrupted due to electromagnetic interference, it may take up to 50 seconds to recover after the electromagnetic interference is removed.

The Battery icon may indicate incorrect charge or discharge status due to electromagnetic interference and may take up to 6 seconds to recover after the electromagnetic interference is removed.

Interconnecting of Medical Equipment

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC Standards (for example, IEC 60950 for data processing equipment and IEC 60601-1 for Medical Equipment). Any person who connects additional equipment to the signal input or output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of Standard IEC/EN 60601-1.

Suspected Cybersecurity Event or Threat

Connection of the Plum Solo infusion pump to an IT network could result in previously unidentified risks to patients, operators, or third parties. The organization that makes those connections must identify and control those risks. This section contains information on the recommended procedure upon detecting a suspected cybersecurity event or threat.

1. Contact hospital and/or follow hospital guidelines to report the suspected cybersecurity event or threat.
   Attempts to exploit a remote vulnerability on an infusion device would require penetration of several layers of network security enforced by the hospital, including firewalls. These measures serve as the primary defense against tampering with a medical device.
2. Contact ***ICU Medical*** to report the suspected cybersecurity event or threat.

NOTES:

LifeShield™ Infusion Safety Software Suite

LifeShield™ Infusion Safety Software Suite is a cloud-based software platform that enables clinicians to manage IV infusion information with compatible ICU Medical infusion pumps. The LifeShield™ Infusion Safety Software Suite provides a means for the Plum Device to configure a variety of features and capabilities, depending on availability, that includes the following:

- Configurable parameters for medications, clinical care areas, and drug library management
- The ability to view information about supported devices, as well as schedule drug library and software updates
- Enables Auto-programming and Auto-documentation, if licensed

NOTE: The use of LifeShield™ Infusion Safety Software Suite with the Plum Solo infusion pump is optional. The Plum Solo can meet its intended clinical use without LifeShield™ Infusion Safety Software Suite.

NOTE: For software version and device compatibility approved by country, refer to the ICU Medical LifeShield Compatibility Matrix available through your local ICU Medical sales office.

Clinical Care Areas

For the list of features available with the version of LifeShield™ Infusion Safety Software Suite installed at your facility, contact your local representative.

LifeShield™ Infusion Safety Software Suite uses Clinical Care Areas (CCAs) to organize drug libraries around the facility or health

system's delivery of care, or common clinical/patient needs. CCAs determine drug and infusion pump parameters, such as:

- Maximum rate and limits
- KVO rate default of 1-20 mL/hr
- Enabling of Delay Start, Standby, and Callback Notifications
- Passcode locking enabled/disabled
- Patient Parameter limits for weight, height, and BSA.
- Occlusion Pressure limit and number of occlusion restart retry attempts
- Configuring the color of the user interface displayed during enteral infusions
- Downstream air-in-line detection limit
- No Drug Selected/Basic drug ruleset within the CCA, such as bolus availability, line availability, post-infusion configuration, and the ability to expand dosing units available or limit to just mL/hr
- Default infusion pump settings, such as alarm volume and initial screen brightness

Certain parameters are set at the ruleset level, such as:

- Clinical advisory messages
- Clinical use
- Limiting a route of administration to epidural or enteral delivery
- Hard and soft dosing limits
- Percentage Dose Change Limits (Titration limits)

- Initial values (including Loading Dose and Bolus)
- Availability of Loading Dose, Bolus, and Multistep programming
- Maximum dose and dosing units
- Post-infusion settings, such as post-infusion rate of KVO, Continue, or Stop
- Mode availability, including concurrent, piggyback, and deliver alone (secondary line disabled)
- Availability of Infuse to Empty for piggyback delivery for a medication defined as an intermittent in the drug library
- Ability to disable the VTBI Complete alarm in concurrent mode for a medication defined as an intermittent in the drug library

If there are questions about parameters set at the CCA or ruleset levels, or about configurations in general, contact your LifeShield™ Infusion Safety Software Suite administrator.

Loss of Communication

If the Plum Device loses communication with LifeShield™ Infusion Safety Software Suite, it will continue to infuse without interruption. However, pump status and logs will not be sent and auto-programs and software/drug library updates will not be received until communication is restored. Loss of communication can be caused by a number of factors, such as low Wi-Fi connectivity or a disruption between LifeShield™ Infusion Safety Software Suite and your hospital's network. For low Wi-Fi connectivity, relocating the pump may be sufficient to reestablish connection. If relocating does not reestablish connection, or if the cause is something besides low Wi-Fi connectivity, contact your hospital's IT department.

NOTES:

Mounting the Infusion Pump to the Pole

Mounting a Single Infusion Pump to an I.V. Pole

PRECAUTION: FOR STABILITY AND TO RESIST TIPPING, MOUNT THE INFUSION PUMP TO THE I.V. POLE PER THE PROVIDED INSTRUCTIONS. VERIFY STABILITY BEFORE USE.

The Plum Solo infusion pump pole clamp is designed to be mounted on an IV pole with a diameter from 0.625-1.375 inches (1.6 cm to 3.5 cm).

To mount the pump:

1. Make sure the pole is assembled correctly, rests on a stable surface, and is placed where infusion pump operations will not be affected by other equipment.
2. While facing the pole clamp, turn the clamp knob counterclockwise until the gap between the pole clamp and the pole clamp screw is wide enough to fit the I.V. pole.
3. Grasp the infusion pump by the handle and position the clamp around the I.V. pole.
4. Rest the pole against the pump's pole support.
5. With your other hand, turn the pole clamp knob clockwise to secure the infusion pump to the pole.

NOTE: The Plum Solo infusion pump pole clamp has a ratchet mechanism that produces an audible click when properly tightened.

PRECAUTION: MAKE SURE THE POLE CLAMP IS TIGHTENED PROPERLY AND THE INFUSION PUMP IS SECURELY ATTACHED TO THE POLE, TO PREVENT PERSONAL INJURY OR DAMAGE TO THE PUMP.

6. Push down and pull up on the infusion pump to confirm that it is tightly clamped to the I.V. pole, without vertical or rotational slippage.
   If you detect slippage, loosen the pole clamp screw, realign the pole clamp, tighten the pole clamp screw, and then check again.

Mounting Multiple Infusion Pumps to an I.V. Pole

PRECAUTION: MAKE SURE THE POLE CLAMP IS TIGHTENED PROPERLY AND THE INFUSION PUMP IS SECURELY ATTACHED TO THE POLE, TO PREVENT PERSONAL INJURY OR DAMAGE TO THE PUMP.

The I.V. pole may not have more than four (4) infusion pumps mounted to the pole, may not be extended higher than 68 inches (173 cm) from the floor, and may not have more than 2000 mL of solution hanging from the I.V. pole hangers.

To mount multiple infusion pumps to an I.V. pole, follow the instructions for ***Mounting a Single Infusion Pump to an I.V. Pole*** for each pump. Placing I.V. poles with multiple infusion pumps adjacent to each other does not affect device performance.

After mounting pumps, check the I.V. pole/infusion pump assembly for stability and tight mounting connections. **If the assembly is NOT STABLE, check the mounting heights and the extension height of the I.V. pole. Adjust those settings until the assembly is stable.**

I.V. Pole

An I.V. Pole (ICU Medical, List Number ICU3000) has been tested for stability according to the requirements of IEC 60601-1:2012. The I.V. Pole can be used in transport and stationary situations.

An I.V. Pole is not provided by ICU Medical as part of the infusion pump. For optimal performance, ensure the selected heavy-duty I.V. Pole has the following features.

- 6-leg base with casters
- Minimum 25" (63.5 cm) base
- 0.625”-1.375” (1.6-3.5 cm) pole diameter

The pump/I.V. Pole system was tested using 2 one-liter I.V. bags at a height of 68 inches (173 cm) and the infusion pumps mounted at 65, 55, 45, and 35 inches (165, 140, 114, and 89 cm) above the floor. Those values represent the maximum settings for the system to comply with the stability requirements of IEC 60601-1:2012.

NOTE: The infusion pump mounting height is measured from the floor to the top of the pump.

NOTES:

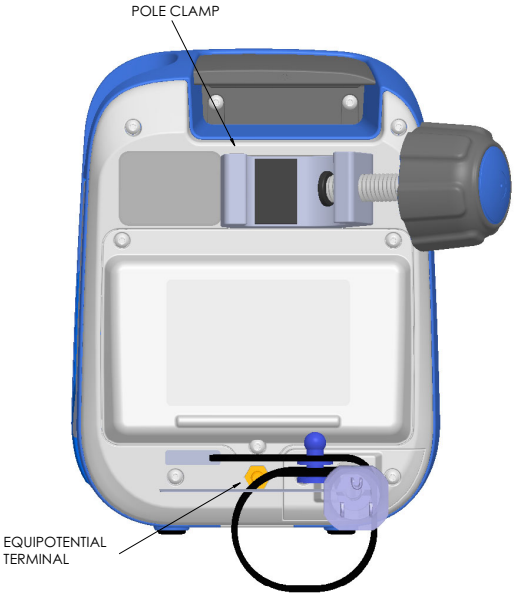
Infusion Pump Overview

Before placing the infusion pump into service for the first time, a biomedical technician should process the pump as described in the *Plum Solo Technical Service Manual*.

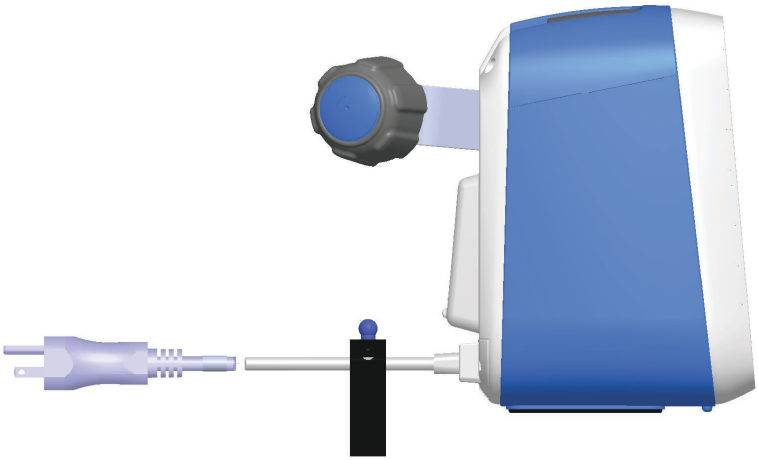
Each infusion requires a disposable, single-use Plum administration set to provide the fluid path between the fluid container and the patient access device. Each administration set includes a proprietary cassette that works with the pumping mechanism on the infusion pump to provide accurate fluid delivery and air management. See ***List of Administration Sets*** for a representative list of administration sets.

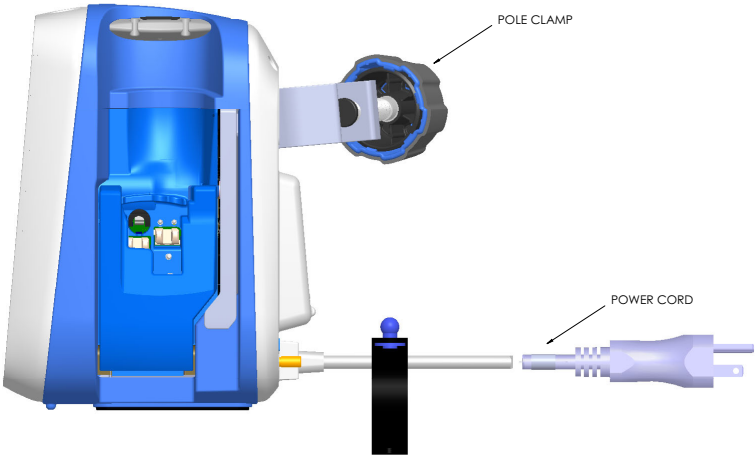
Front

Back



Sides





NOTE: The Plum Solo infusion pump has one channel on the right side of the pump with labeled tubing guides that denote the two lines, R1 and R2.

Powering On

Each time you turn the power on, the infusion pump performs a System Self Test to check the operation of critical systems and alarms. If a cassette is inserted, the pump performs a cassette test that checks for air bubbles and verifies the integrity of the cassette's pumping components.

Cassette test failure can be caused by improper cassette priming. In that case, perform backpriming to resolve the problem.

NOTE: If the test still fails, replace the administration set with a properly primed set. If the failure persists, replace the infusion pump.

WARNING: A SMALL AMOUNT OF FLUID MAY BE EXPELLED FROM AN INSERTED CASSETE (LESS THAN OR EQUAL TO 0.2 mL) WHEN THE INFUSION PUMP IS POWERED ON. IF POTENT DRUGS ARE BEING USED, TAKE APPROPRIATE ACTION TO GUARD AGAINST OVER-MEDICATION OF THE PATIENT.

1. To turn power on, make sure the power cord is plugged into AC (mains) power and that the infusion pump is mounted securely on an I.V. pole or located on a stable surface.
   The Mains On Indicator will light up green when the pump is plugged into AC (mains) power, and will not light up if the infusion pump is unplugged.

NOTE: Ensure that access to the mains plug is not blocked while using the infusion pump so that the plug can be disconnected from the mains power receptacle in the event of an emergency.

PRECAUTION: INSPECT CORD BEFORE USE. WHEN PLUGGING IN, USE STRAIGHT FORWARD MOTION.

PRECAUTION: INSPECT CORD AFTER USE. WHEN UNPLUGGING, GRASP PLUG AND PULL STRAIGHT OUT. DO NOT PULL CABLE TO UNPLUG.

PRECAUTION: DO NOT PLACE THE INFUSION PUMP ON AN UNSTABLE SURFACE.

2. Press the POWER button and wait for the user interface to respond.
   The infusion pump will display software and drug library version during power up. The pump checks for a cassette and then begins the System Self Test, followed by the cassette test.
3. Quickly release the button.

NOTE: The POWER button is on the top of the pump, and displays Symbol IEC 60417-5009, which indicates the power state of the pump by glowing green when the pump is in its operational state and glowing blue when it's in its standby state. When unplugged, the standby state duration is four hours; then, it transitions to power off.

Powering Off

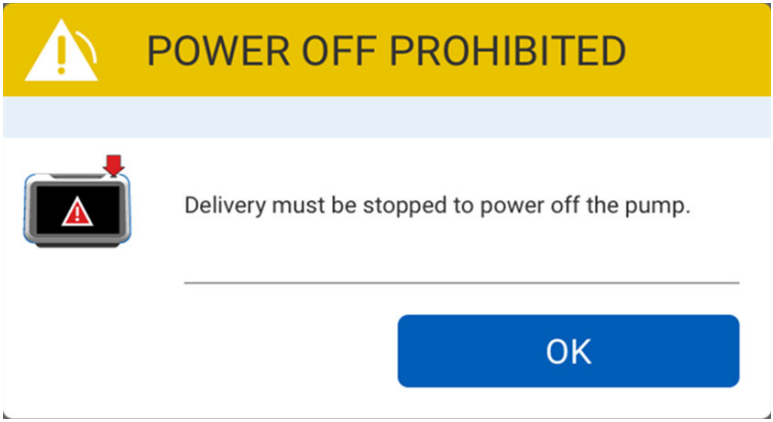
NOTE: Always turn the infusion pump off when not in use, to avoid idle alarms and to reduce the consumption of electrical energy.

You can only turn power off if all programmed infusions are Stopped.

1. To turn power off, stop all active deliveries.
2. Press the POWER button.
   If patient and/or programming data remains on the pump, you must select whether to save the data or clear it with power off. You will hear the infusion pump mechanism power down and see the display turn off.
3. Quickly release the button.

NOTE: If the Plum Solo infusion pump is turned off for 5 hours and if there are no programs delayed or on standby, all delivery and alarm settings are restored to their default selections for its next use.

NOTE: If the power button is pressed during an active infusion, an alert will be displayed prohibiting power off until the delivery is stopped.



Drug Library/Settings Updates

Drug Library and Settings downloads and updates occur at any time the infusion pump is connected to Wi-Fi and scheduled by LifeShield™ Infusion Safety Software Suite when drug library parameters are modified by the healthcare facility. An update can be downloaded while the infusion pump is in use and will not impact therapy.

If patient data is on pump on the power is off, an alert will pop up to indicate there is an update pending, and a prompt to save or clear patient data. If data was cleared it will update and be available on power on. If patient data was saved it will not update unless 5 hours has elapsed and the patient data is cleared, or at the next power off. There is no downtime of the infusion pump during this process. While not in use, and when stored with sufficient battery capacity, the infusion pump will download and activate the drug library update without user interaction.

The download and activation status of Plum Solo drug library/settings and software updates can be viewed though LifeShield™ Infusion Safety Software Suite.

Drug Library/Settings and Software Update Notification

Updates, including software, drug library, and settings changes, are downloaded to the infusion pump without disrupting current use. When an update is pending, the Settings icon will display with a yellow arrow.

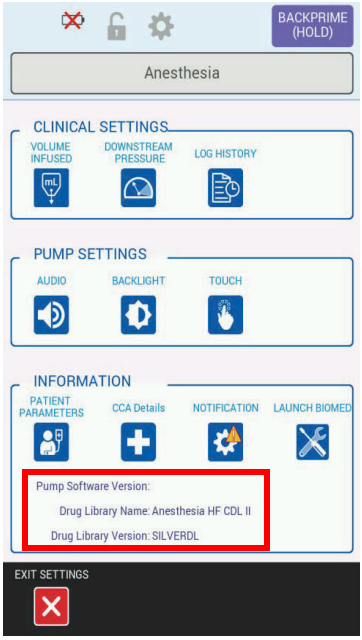
Updates are activated when the pump is not in use. If an update fails, the system will roll back to allow for the continued use of the pump with non-updated software or settings and display a message to alert the user of the failure. Although continued use is possible, the pump should be sent for service as soon as convenient.

If a pump update fails, the settings icon will display with a red alert icon.

In order to redisplay the alert message, tap the Settings button to open the Settings page and then tap the Notification button.

Drug Library Versions

The current Drug Library version is displayed on startup, as well as under Settings.



Drug Library/Settings Update Failure

Drug Library and Settings updates may fail. A message will display informing the user if the pump can still be used. If the Drug Library update fails, the pump should be sent to your biomed department for service as soon as possible.

Software Updates

Software updates may be downloaded at any time the device is connected to WiFi and scheduled by LifeShield™ Infusion Safety

Software Suite, without impacting patient therapy. Software download and activations can occur while the infusion pump is stored with adequate battery power.

Software updates are activated during pump shutdown. A message will display asking if there is programming data that needs to be retained. If the clinician selects yes, the software update will be postponed. If not, the pump will download the newest software version and clear programming data. While not in use, and when stored with sufficient battery capacity, the infusion pump will download and activate software updates without user interaction. The overall downtime of the device to activate a software update is a duration of less than five minutes. The pump displays a status estimating the remaining duration during activation.

The download and activation status of Plum Solo drug library/settings and software updates can be viewed though LifeShield™ Infusion Safety Software Suite.

Software Versions

The current software version is displayed on startup, as well as under Settings.

Software Update Failure

A software update may fail. A message will display informing the user if the pump can still be used. If the software update fails, the pump should be sent to biomed department for service as soon as possible.

Inability to Activate a Software Update Due to Low Battery

A pump may be unable to activate a software update if the battery capacity is low.

Touchscreen Display Overview

Except for the POWER button, the Plum Solo infusion pump uses a touchscreen for user interaction. When operating the pump, position yourself at a distance of no more than 39 inches (1 m) from the display. Make sure you are directly in front of the display, or at an angle of no more than 20 degrees off this position.

Use the following gestures to navigate the device:

Tap

- Lightly tap buttons to select them.
- Tap the programming keyboard to enter characters or numbers.

Drag

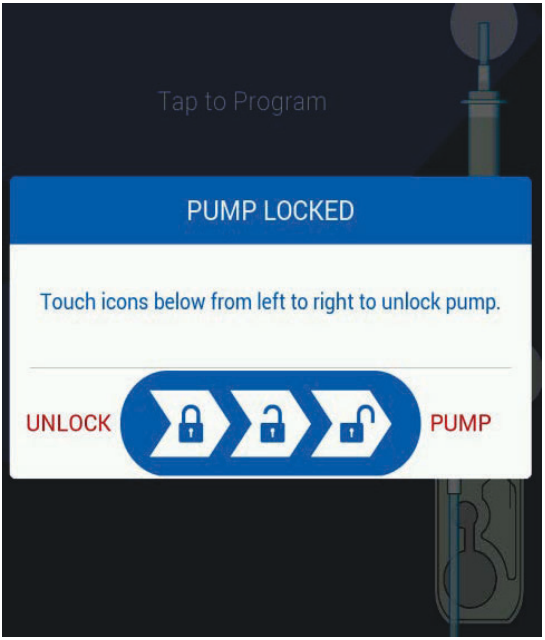
- Lightly drag your finger on lists to scroll through them.

The following elements appear on the user interface:

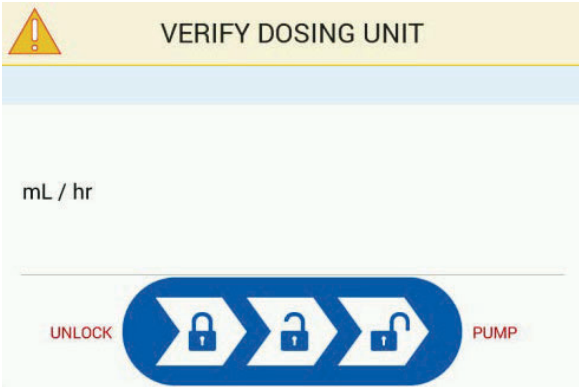
- Action Buttons - Allow for control of the pump mechanism, such as START and STOP.
- Navigation Buttons - Allow for movement through menus or pages.
- Indicators - Non-interactive icons that communicate information, such as battery power or connection to safety software.
- Scrollable Lists - Contains various options for selection, such as Delay Start times and CCAs.
- Keypads - Input values to program an infusion or set a password.
- Keyboard - Search for a drug in the drug library.

Screen Lock (Inadvertent Touch Protection)

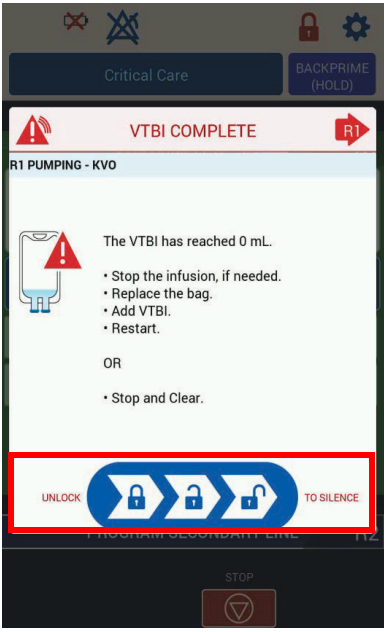
The Plum Solo infusion pump uses a screen lock feature to prevent the user interface from activating due to inadvertent touches. The Screen Lock will display when first touched after the preconfigured time (20-45 seconds) since the last interaction. To unlock the pump, touch from left to right along the arrows.



If a period of inactivity occurs while an alert is present on the screen, the unlock region will be viewed in the alert pop-up.

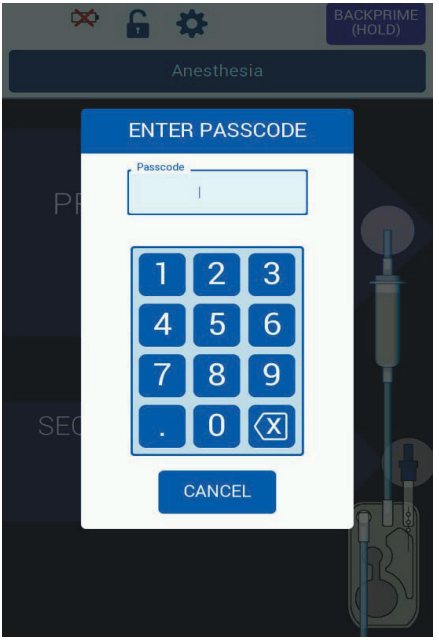


When an alarm occurs, the unlock region will also be a part of the pop-up as seen in the picture below. Interacting with the unlock region will silence the alarm temporarily.

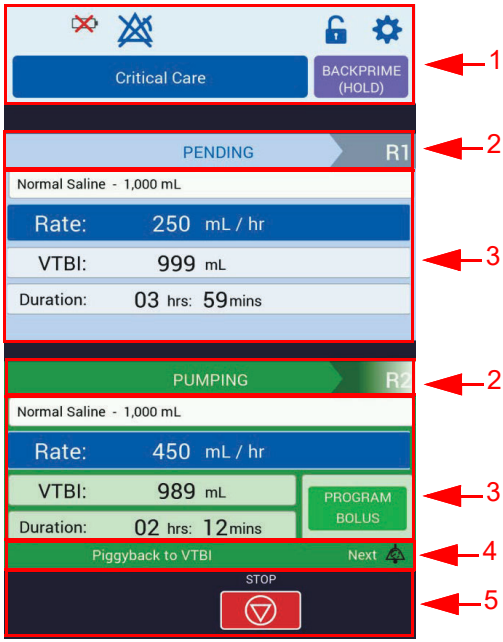


Passcode Lock

The Plum Solo infusion pump uses a passcode lock feature to prevent tampering with the user interface and programmed settings due to inadvertent touches or unauthorized users. The passcode is configured by the Biomed per facility, and the passcode lock timeout value should be set accordingly. To lock the infusion pump, tap the lock icon located on the top right and enter the four-digit passcode. To unlock the infusion pump, tap anywhere on the user interface to bring up the passcode keypad and enter the four-digit passcode.



Main Delivery Page Overview



When infusing, the Main Delivery page has a number of buttons and indicators organized into specific areas of the page, which include the following:

1. Status Bar - Displays various indicators related to the battery and Wi-Fi connectivity, as well as buttons for selecting the CCA, navigating to the Settings page and Passcode Lock, Disabled Alarms list, and backpriming.
2. Infusion Status - Displays infusion status. This includes, but is not limited to, PENDING, PUMPING, STOPPED, COMPLETED, BACKPRIMING, and VTBI COMPLETE.
3. Infusion Information - Displays information for programmed infusions, such as Rate, VI (Volume Infused) or VTBI (Volume to be Infused) as configured in the drug library, and Duration. Tapping the drug name field will navigate to the Review page, while tap-

ping the Rate, VI, or Duration fields will navigate to the Programming page.

4. Footer Messages - Displayed below Infusion Information, footer messages provide additional details, such as the mode (Piggyback, Multi-Step) of the programmed infusion, and when VTBI alarm is turned off.
5. Button Tray - Depending on the state of the primary and secondary lines, the bottom row of the Main Delivery page may display buttons such as STOP, START, and STANDBY.

Action Buttons

START - Tap to begin delivery.

STOP - Tap to stop delivery.

If the primary and secondary lines are pumping when you press STOP, you must tap one of the following: CANCEL, R1 or R2, or BOTH in response to a prompt to specify which line(s) to stop.

CONFIRM - Tap to confirm program.

CANCEL or EXIT SETTINGS - Tap to cancel a programmed infusion on the Programming or Review pages. Alternatively, tap to exit back to the Main Delivery page when on a Settings page.

REVIEW - Tap to review a multi-step infusion with 3 or more steps on the primary line, or 2 or more steps on the secondary line.

CLEAR PROGRAM - Tap to clear a programmed infusion after it's been stopped.

DELETE STEP - Tap to clear a specific step in a programmed bolus, loading dose, or multistep infusion.

CANCEL DELAY - Tap to cancel a delayed start of the line early.

CLEAR BOLUS - Tap to clear a bolus from the line.

CLEAR FLUSH - Tap to clear a flush from the line.

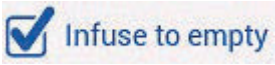
CLEAR LOAD - Tap to clear a Loading Dose from the line.

BACKPRIME - Press and hold to backprime. Monitor fluid and air movement to ensure removal or air as needed.

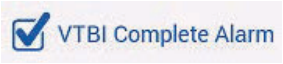
STANDBY - Tap to open the Standby pop-up. Standby time is defined here.

SILENCE (Audio Pause) - Tap to temporarily silence all audio output for any active alarm for two minutes.

DOWNSTREAM PRESSURE ARROWS - Tap to raise or lower the downstream occlusion alarm pressure limit.



INFUSE TO EMPTY - Tap to check this box to enable Infuse to Empty for a secondary infusion in piggyback mode.



VTBI COMPLETE ALARM - Tap to un-check this box to disable the VTBI Complete alarm for a secondary infusion in concurrent mode. This alarm is ON (checked) by default.

SILENCED ALARM - Tap to display the information of an alarm that has been viewed and the audio has been silenced for two minutes.

DISABLED ALARMS - Tap to display a list of alarms that are off, either by default as configured in the drug, or turned off by the pump user.

Navigation Buttons

BACK - Tap to move back to the previously viewed page.

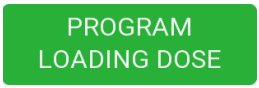
NEXT - Tap to move to the next page, usually when viewing an already confirmed infusion.

SETTINGS - Tap to open the Settings page.

LOCK SCREEN - Tap to open the lock screen keypad. The lock will turn red and appear closed if the screen is locked by the Screen Lock or Keypad Lock.

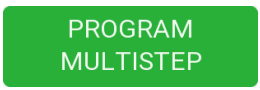
OPTIONS - Tap to open the Programming Options page. Options include: Delay Duration, Callback Alarm, Near End of Infusion Alarm, and Post Infusion Rate.

PROGRAM PRIMARY INFUSION - Tap to navigate to the Programming page for a primary infusion.

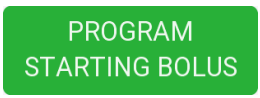


PROGRAM LOADING DOSE - Tap to navigate to the Programming page for a loading dose infusion.

NOTE: The availability of Loading Dose is defined by the medication ruleset in the drug library.



PROGRAM MULTISTEP - Tap to navigate to the Programming page for a multistep delivery infusion.

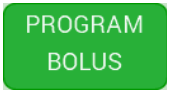


PROGRAM STARTING BOLUS - Tap to navigate to the Programming page for a starting bolus infusion.

NOTE: The availability of Starting Bolus is defined by the medication ruleset in the drug library.

PROGRAM PIGGYBACK - Tap to navigate to the Programming page for a piggyback infusion.

PROGRAM CONCURRENT - Tap to navigate to the Programming page for a concurrent infusion.



PROGRAM BOLUS - Tap to navigate to the Programming page for a bolus infusion.

ADD LINE FLUSH - Appears on the Review and Main Delivery pages. Tap to navigate to the Programming page for a line flush.

VOLUME INFUSED - Found in the Settings page, tap to view and clear infusion totals as needed.

DOWNSTREAM PRESSURE - Found in the Settings page, tap to view and edit the downstream occlusion alarm limit.

LOG HISTORY - Found in the Settings page, tap to view a historical log of event messages.

AUDIO - Found in the Settings page, tap to view and change Alarm Volume and General Volume settings.

BACKLIGHT - Found in the Settings page, tap to view and change the pump's backlight level, as well as toggle auto-brightness.

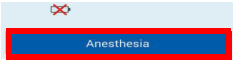
TOUCH - Found in the Settings page, tap to view and toggle touch feedback.

CCA DETAILS - Found in the Settings page, tap to view details of the current CCA.

NOTIFICATION - Found in the Settings page, tap to view a log of pump notifications.

PATIENT PARAMETERS - Found in the Settings page, tap to view all patient parameters programmed for on all lines.

LAUNCH BIOMED - Found in the Settings page, tap to launch Biomed Mode. This will reboot the pump and clear all programming data.



CCA - Tap to change a CCA, available only on Main Delivery Screen

Indicators

Battery Power - Displays the current charge of the infusion pump battery.

The remaining battery power is also displayed in a percentage. A fully charged battery displays as 100%.

If a functioning battery is not present, a red x appears on the icon.

AC Power - Displays if the infusion pump is plugged into AC (mains) power. A lightning bolt appears in the Battery Power icon when the pump is plugged into AC (mains) power and charging. During this time, the battery charges continuously when a functional battery is installed.

If the infusion pump is unplugged, the AC Indicator (lightning bolt) disappears within seconds, indicating that the infusion pump is operating on battery power.

NOTE: If the device is plugged into AC (mains) power with a battery installed, and the AC indicator does not appear, contact technical support.

Alarm - Displays when the pump alarms and the alarm message has been closed. Tapping the icon reopens the alarm message.

The color of the icon is determined by the priority of the alarm. Red for high, yellow for medium, and cyan for low.

Wireless - Displays the status of the pump's wireless connection. The current strength of the connection is displayed by the number of blue bars. This indicator does not appear if the wireless connection is lost.

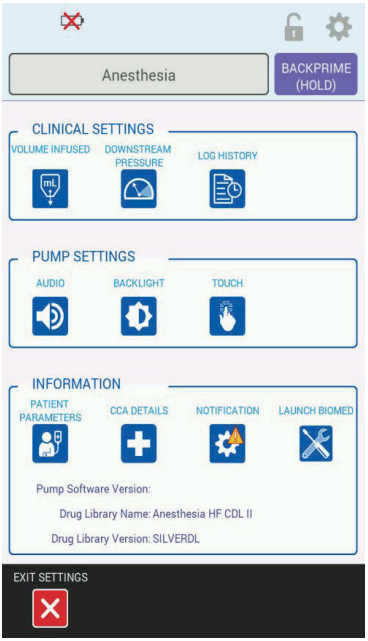
LifeShield - Displays if the pump is connected to LifeShield™ Infusion Safety Software or not. It will display as blue if it is connected, and red if not.

Status Bar - Appears on the main delivery page and describes infusion status. Includes, but is not limited to, PUMPING, PENDING, STANDBY, BACKPRIMING, BOLUS, LOADING DOSE, and VTBI COMPLETE - KVO.

High Alert - Appears when there is a condition the user should be advised about. These include programming without a ruleset (No Drug Selected) and programming under a different CCA.

Information - Appears next to the solution name when there is a Clinical Advisory.

Pump Settings



The Plum Solo infusion pump has a number of configurable settings at the CCA and infusion pump levels. To view the Settings page, tap the gear icon in the top right of the Main Delivery page. For a detailed description of each setting, see ***Running H/F 2***.

Display Symbols

Soft Limit Override - Appears on the display to inform the clinician that the specific value is outside the soft limits for that drug. The direction of the arrow indicates which soft limit, upper or lower, is being overridden.

Hard Limit Exceeded - Appears on the display to inform the clinician that the specific value is outside the drug's hard limits. The direction of the arrow indicates which hard limit, upper or lower, is being exceeded.

Limit Bar - Appears on the display to indicate the range of acceptable values for the selected drug. Soft limits are denoted by the two inner numbers, and hard limits by the two outer numbers.

Pole Clamp, Power Cord, and Equipotential Terminal

Pole Clamp - adjusts to fit round I.V. poles from 0.5-1.5 inches (1.2 cm to 3.8 cm) in diameter. When the pole clamp is tight enough, a ratcheting sound indicates that the clamp is being over-tightened.

Power Cord - plugs into AC (mains) power to provide power, charges the battery, and grounds the infusion pump. The power cord connection to the infusion pump is protected by a power cord retainer to prevent accidental disconnection. The power cord can be replaced if damaged (See the *Plum Solo Technical Service Manual*).

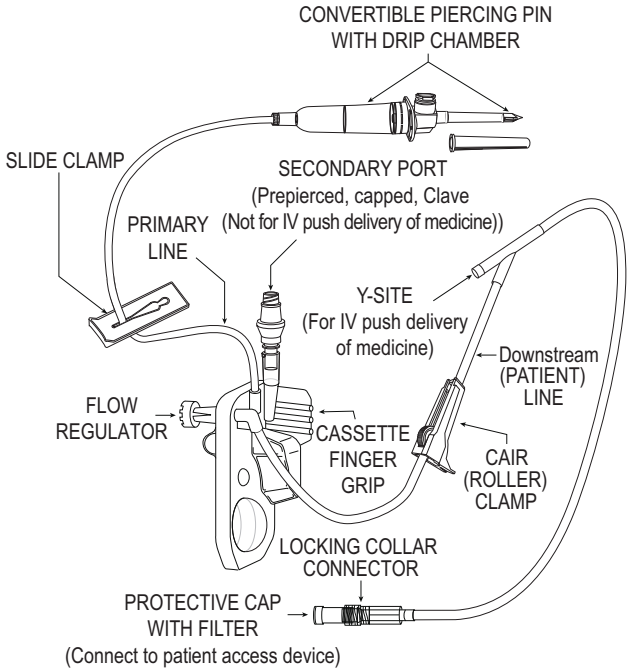
Equipotential Terminal - is used to ensure that the infusion pump is at the same electric potential (voltage) as the other devices in the treatment location. Ideally the electrical potential is at zero volts, so that no current can inadvertently flow from one device to another through a patient.

Administration Sets

Plum Solo infusion pump operations require the use of ICU Medical Plum Administration Sets. The infusion pump is intended for parenteral use (limited to intravenous, intra-arterial, subcutaneous, epidural, and enteral therapies), as well as the administration of whole blood and blood products. Intravenous and blood sets are supplied sterile. Some sets have additional features such as burettes, filters, or special tubing.

WARNING: PLUM ADMINISTRATION SETS ARE NOT FOR USE WITH HIGH-PRESSURE INFUSIONS.

The following illustration shows the parts of a typical primary administration set.

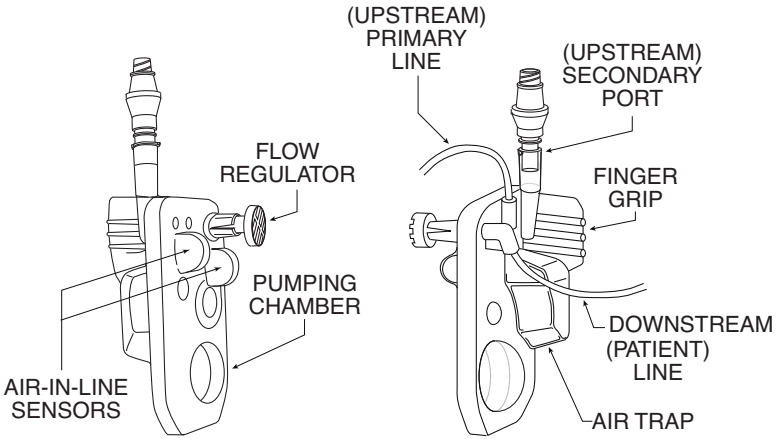


Administration sets have a 96-hour performance limit. Refer to the packaging or facility policy for guidelines on when to change the set. Follow facility guidelines when disposing of administration sets and other consumables.

The following sections describe the most common features of an administration set. For a representative list of sets, see ***List of Administration Sets***.

The Cassette

Each set includes a proprietary cassette that works with the device's pumping mechanism to provide fluid delivery, air management, and occlusion detection. The following figure shows the parts of the cassette.

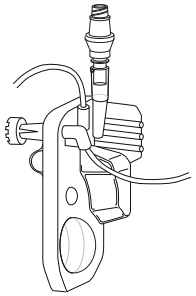


The air trap can hold a maximum of 2 mL of air. Single air bolus and cumulative air bolus alarm thresholds are defined in the alarm table (See ***List of Alarms and Corrective Actions***). To remove air bubbles from the air trap, backprime. See ***Backprime*** for instructions.

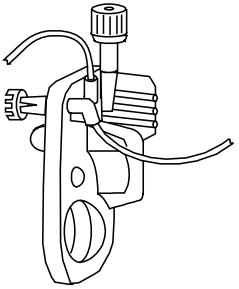
The priming volume of the cassette is 3.5 mL. Most administration sets include the cassette volume in the total volume distal (downstream) priming volume.

Review the administration set labeling. If the cassette volume is not listed on the administration set, include the cassette volume as part of the distal (downstream) priming volume used in calculating a flush volume when precision delivery is needed.

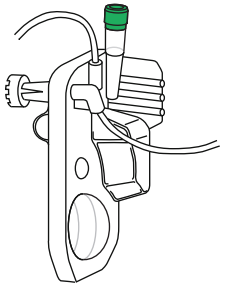
Most sets include a secondary port for attaching a line or syringe for Piggyback or Concurrent fluid delivery. The secondary port has one of these connectors:



Clave™ secondary ports are compatible with sets or syringes that employ male luer adapters for connection. Clave™ secondary ports are incompatible with needles. The Clave™ needle-less design provides a mechanically and microbiologically-closed fluid path.



Capped secondary ports are also compatible with secondary sets or syringes that employ male luer adapters for connection. Capped ports are incompatible with needles.



Prepierced secondary ports accept a locking blunt cannula attached to a secondary line or syringe.

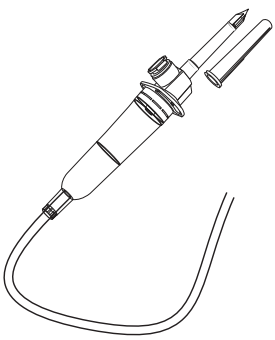
Cassettes also have the following features:

- A **finger grip** to assist placing the cassette in the correct position, to guide and load it into the door tracks of the cassette door.
- A **pumping chamber** that works with the pumping mechanism on the infusion pump to pump fluid to the patient.
- An **air trap** that collects air bubbles from the I.V. upstream primary and secondary lines. Air trap capacity is 2 mL of air that can be removed by backpriming.
- **Air-in-line sensor bulbs** that work with the upstream and downstream air-in-line detectors in the infusion pump to check for air bubbles that may be entering or leaving the cassette.
- A **flow regulator** that can be used to manually control flow during priming or when using gravity flow to deliver fluid. When you insert the cassette into the infusion pump and close the cassette

door, a mechanism opens the flow regulator to allow the pump to control fluid flow. When you open the cassette door, the same mechanism closes the flow regulator to prevent unrestricted flow from the downstream line.

Other Administration Set Features

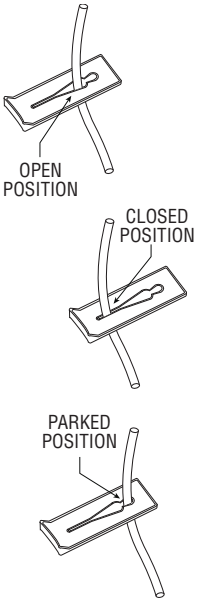
Most administration sets have some combination of the following features. For complete information about all the features of a particular administration set, refer to the label on the administration set packaging.



The **convertible piercing pin** spikes the seal on the fluid container and secures the administration set tubing to the container.

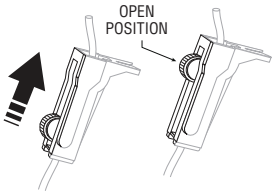
The piercing pin has a built-in filter vent that allows use with flexible or rigid fluid containers, and an integrated drip chamber with score mark for monitoring fluid flow.

If using a rigid fluid container (glass bottle, for example), open the filter vent cover above the drip chamber. If using a flexible plastic container, make sure this vent cover is closed.



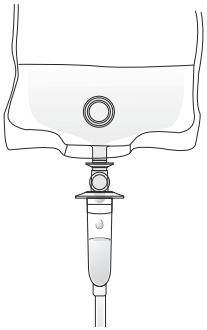
Slide clamps can be placed anywhere on the tubing. The shape of the cutout provides three clamp positions:

- **Open** position, in the middle of the cutout, allows fluid to flow and also allows the clamp to slide freely on the tubing.
- **Closed** position, at the narrow end of the cutout, clamps the line, preventing fluid flow. The closed clamp stays in a fixed position on the tubing.
- **Parked** position, at the wide end of the cutout, also allows fluid to flow, but keeps the clamp in a fixed position on the tubing to prevent movement.

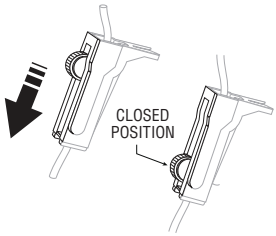


Roller clamps allow controlled fluid flow.

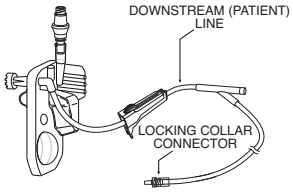
- To gradually increase fluid flow, slide the roller towards the fully **Open** position.



- Observe the fluid drops in the drip chamber.



- To gradually decrease and then stop fluid flow, slide the roller towards the fully **Closed** position.



The **downstream line** (patient line) runs from the cassette to the patient.

The **connector** that attaches the downstream line to the patient access device has a locking collar that prevents accidental disconnection.

NOTE: The cap on the connector has a filter that allows the set to be primed while the cap is on and remains dry. The cap is a sterile fluid path barrier when in place.

Gravity Flow

PRECAUTION: CONSULT INDIVIDUAL ADMINISTRATION SET INSTRUCTIONS FOR USE FOR ANY RESTRICTIONS REGARDING GRAVITY USE.

Gravity flow allows you to temporarily continue fluid delivery without the Plum Solo infusion pump.

NOTE: Gravity flow is supported for only one line. When using gravity flow to deliver fluid, only deliver from one fluid container at a time.

Stopping Fluid Flow

WARNING: CLOSE ALL CLAMPS BEFORE OPENING THE CASSETTE DOOR.

To discontinue fluid flow:

1. Tap STOP.
2. If only one line is pumping, confirm.
   If both lines are pumping, select both lines to stop
3. Press the POWER button to turn off the infusion pump.
   If programming data remains on the pump, a pop-up will be displayed to select whether to clear or save the data; then the pump will power off.
4. Close all clamps.
5. Open the cassette door and remove the cassette.

Setting Gravity Flow

To set gravity flow:

1. Discontinue fluid flow (See ***Stopping Fluid Flow***).
2. If only 1 line was pumping, open all clamps.
   If 2 lines were pumping, you must choose one line for gravity flow. Open the clamps on that upstream line and on the downstream line. Make sure one upstream line stays clamped.

3. Holding the cassette upright, set gravity flow by turning the flow regulator counter-clockwise.

NOTE: If the line is equipped with a roller clamp, you can use the clamp to control the flow rate. To do this, close the roller clamp, open the flow regulator completely, and then gradually open the roller clamp to adjust the flow.

4. Check the drip chamber to measure the flow rate. Refer to the administration set package for the number of drops/mL.

Resuming Delivery With a Replacement Pump

To resume delivery with a replacement infusion pump:

1. Close all clamps.
2. Insert the cassette into the pump and close the door.
3. Open all clamps.
4. Check the drip chamber to ensure that there is no flow.
5. If you see flow, close all clamps and replace the set. If you still see flow from a replacement set, replace the infusion pump.
6. Turn on the pump.
7. Program the delivery.
8. Start the delivery.

Syringe Delivery

WARNING: CLOSE ALL CLAMPS BEFORE OPENING THE CASSETTE DOOR.

NOTE: Access ports on the Plum cassette are NOT for I.V. push delivery of medication. Ports are only for infusion pump-controlled delivery of medication.

- When attaching a syringe to the primary (Line 1) port, use standard clinical practices to ensure the syringe is secure.
- Syringes must be between 3 mL (minimum) to 60 mL (maximum). Syringes greater than 10 mL may be directly attached to the secondary port of the cassette.

WARNING: IN ORDER TO ENSURE DELIVERY ACCURACY AND REDUCE UPSTREAM OCCLUSION ALARMS, A VENTED SYRINGE ADAPTER SHOULD BE USED FOR SYRINGE SIZES FROM 3-10 mL WHEN ATTACHED TO THE SECONDARY LINE, AND FOR SYRINGE SIZES FROM 3-60 mL WHEN ATTACHED TO THE PRIMARY LINE.

- Before disconnecting a syringe from the cassette, pull up the plunger slightly to avoid spilling the fluid.

You can attach a syringe to the secondary port on a Plum cassette for Piggyback or Concurrent delivery of a secondary fluid. Follow these guidelines:

Syringe sizes accepted on the primary line with specialty set:	3 mL - 60 mL All require a syringe adapter.
Syringe sizes accepted on the secondary line:	3 mL - 60 mL Small volume syringes, i.e., 3-10 mL, require a vented syringe adapter to ensure delivery accuracy and reduce upstream occlusion alarms. Syringes greater than 10 mL do not require a syringe adapter.