Plum Duo™
Infusion Pump

System Operating Manual

For use with list number REF 40002

Compatible with:
LifeShield™ Infusion Safety Software Suite

IFU0000224 (01, 2021-01)

icumedical
human connections

Change History

Part Number	Description of Change
IFU0000224 (01, 2021-01)	Initial Release

Contents

Introduction

Plum Duo is a large volume infusion pump capable of delivering fluids for a variety of therapies such as parenteral, enteral, or epidural infusions. The Plum Duo 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.

The Plum Duo infusion pump features an innovative design that automates many aspects of concurrent, secondary, 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. As the Duo can accommodate two cassettes, one pump can support up to four lines. The Plum Duo 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 can be programmed to deliver the secondary medication at the same rate through the downstream tubing. Also, the infusion pump allows the clinician to program loading dose and bolus on the primary or secondary line. The Plum Duo infusion pump also enables fluid pathway troubleshooting, such as removing upstream air in line, without disconnecting the patient line.

The Plum Duo 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 Duo can act as a standalone infusion pump, or in conjunction with the ICU LifeShield™ software to provide medication safety software at the point of care, with customized drug libraries to support hospital defined protocols by clinical care area. The Plum Duo and ICU LifeShield™ software wirelessly interface with other hospital systems such as Electronic Health Records, Electronic Medication Administration Records, Bar Code Point of Care, and other systems designed to create efficiency and consistency in managing patient information and clinical workflows.

Intended Use

The Plum Duo infusion pump is intended for parenteral, enteral, and epidural therapies and the administration of whole blood and blood products. The Plum Duo infusion pump is intended for use in clinical environments at the direction or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of the infusion pump and the administration of parenteral, enteral, and epidural therapies and the administration of whole blood and blood products.

Patient Population

The Plum Duo infusion pump is intended for adult, pediatric, and neonatal care.

Use Environment Exclusions

The Plum Duo infusion pump should not be used in the following environments or conditions:

- MRI Environment- In or near the magnetic field

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.

- Hyperbaric or Oxygen rich environment

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

- Directly exposed to x-rays or ultrasound

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.

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 Duo 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.

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: A WARNING MESSAGE CONTAINS SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING MESSAGE IS POTENTIALLY LIFE-THREATENING.

PRECAUTION: A PRECAUTION CONTAINS INFORMATION THAT COULD PREVENT IRREVERSIBLE PRODUCT DAMAGE OR HARDWARE FAILURE. FAILURE TO OBSERVE A PRECAUTION COULD RESULT IN SERIOUS USER OR PATIENT INJURY.

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

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 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 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 modal 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.
Auto-Program	Auto-programming refers to the ability to receive a remotely configured therapy. Also known as SPP or Smart Pump Programming.
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 (L/R 1)*** to move upstream air or fluid into a receptacle attached to ***Secondary Line 2 (L/R 2)***. No fluid is delivered downstream to the cassette during a backprime.
BCMA	Bar Code Medication Administration. An inventory control system that uses barcodes to prevent human errors in the distribution of prescription medications.
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.
Bolus	A rapid infusion of a relatively large volume of fluid or dose of the drug currently being administered (same medication, concentration, and dosing unit) to enhance a therapeutic response. Also see ***Unintended Bolus***.

Term	Definition
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 audible tone. The Plum Duo 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 Duo infusion pump that facilitates two lines in and one line out, allowing primary and secondary I.V. 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.
CDL	Custom Drug Library. A drug library that is based on hospital-defined practices and customized settings, using the ICU Medical Safety Software.
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.

Term	Definition
Concurrent Delivery	Simultaneous delivery of fluids on ***Primary Line 1 (L/R 1)*** and ***Secondary Line 2 (L/R 2)***.
Concurrent Mode	A mode that enables the user to program ***Secondary Line 2 (L/R 2)*** for Concurrent delivery.
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 line 2, 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.
Dose	A volume of medication to be delivered on a continuous basis.
Dosing Unit	Unit of measure for a drug to be delivered.
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.
Enteral	Delivery using a gastrointestinal tract route.
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.
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 (L/R 1)*** container at the Piggyback therapy rate after the Piggyback therapy completes.
Hard Limit	The upper- and lower-dosing limits associated with a drug, in the drug library, that cannot be overridden by the operator.

Term	Definition
Hard Limit Alert	An alert on the infusion pump presented to the clinician when a hard limit is exceeded.
Infiltration	Unintentional fluid migration into the tissues surrounding a venipuncture site.
Infuser	See ***Device*** and ***Infusion Pump***.
Infusion Pump	A medical device used to deliver fluids into a patient's body in a controlled manner.
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	Keep Vein Open. The Post Infusion Rate setting that provides a minimal delivery rate that is configured by LifeShield Infusion Safety Software™ that is configurable by CCA from 1-20 mL/hr or the actual programmed rate if less than the default rate. It is intended to provide sufficient fluid flow to decrease the potential for clotting at the patient (IV) access site.
LifeShield Infusion Safety Software™	LifeShield Infusion Safety Software™ 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.
Loading Dose	A bolus that is administered only at the initial start of an infusion. Like bolus, it is a rapid infusion of a relatively large volume of fluid or dose of a drug that is the same medication, concentration, and dosing unit as the continuous to enhance therapeutic response.
Malfunction	One of a number of alarm conditions that indicate a failure of the infusion pump.
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.

Term	Definition
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***.
Parenteral	Delivery via other than an intestinal route, such as intravenous (I.V.) injection.
Piggyback Flush	The amount of fluid programmed to be delivered from the primary after the piggyback completes, at the same rate the piggyback was programmed to ensure the medication is deliveed in its entirety from the downstream tubing.
Piggyback Mode	The delivery mode that suspends ***Primary Line 1 (L/R 1)*** delivery while ***Secondary Line 2 (L/R 2)*** delivers. The primary line resumes when the secondary line delivery completes.
Primary Line 1 (L/R 1)	The upstream Primary tubing attached to the Left or Right 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 (L/R 1)*** and/or ***Secondary Line 2 (L/R 2)***) 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.
Rule Set	The programmed ***Soft Limits*** and ***Hard Limits*** associated with a drug entry from the CCA in the drug library.
Secondary Line 2 (L/R 2)	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 sound-alike or look-alike drug names.
Time-Based Dosing	A dosing unit that includes a time component (for example, g/min).
Titration	A change in ***Rate***, Dose ***Duration***, and/or ***VTBI*** in a currently running or programmed infusion.

Term	Definition
Unintended Bolus	A single, unintended volume of fluid delivered. Also see ***Bolus***.
Unit of Measure	One of a variety of terms used to describe a drug amount, such as grams, mg, or units.
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 Duo infusion pump:

Symbol	Description	Standards	Symbol Identifier
	Manufacturer	BS EN ISO 15223-1	Clause 5.1.1
	Authorized Representative in the European Community	BS EN ISO 15223-1	Clause 5.1.2
	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
	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

Symbol	Description	Standards	Symbol Identifier
	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
 Type CF	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
	Wired Ethernet Interface Port	IEC 60417	Ref no. 5988
	Mains supply equipment using protective earth	IEC 60601-1	Clause 6.2
	Refer to Instruction Manual/Booklet	IEC 60601-1:2005	Clause 7.2.3
IPX2	Protection against vertically falling water drops	IEC 60601-2-24	Clause 201.11.6.5
	This Way Up	ISO 7000	Ref no. 0623
	Follow Instructions for Use	ISO 7010	Ref no. M002
	Warning	ISO 7010	Ref no. W001
	Dangerous Voltage	ISO 7010	Ref no. W012
℞ Only	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

Symbol	Description	Standards	Symbol Identifier
	Regulatory Compliance Mark	Australian Communications and Media Authority (ACMA) wireless regulatory authority AS/NZS 4417.1	Clause 3.2
C US MCN 160992	The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. 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
ICASA	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
	National Communications Commission of Taiwan (NCC) Wireless Registration	Radio Wave Regulatory	Articles 12 & 14
MR	No MRI Usage	ASTM F2503-13	MRI Unsafe
MD	Medical Device	N/A	N/A

Illustrations, Screen Displays, and Software Messages

There may be minor language differences between software messages shown in this manual and the infusion pump's user interface. Illustrations and screen examples in this manual are **graphic depictions**, not exact representations of the product.

Warnings and Precautions

The Plum Duo 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 DUO 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: ADMINISTER ONLY ANESTHETICS/ANALGESICS APPROVED FOR EPIDURAL ADMINISTRATION (AS INDICATED OR ALLOWED BY THE DRUGS' FDA APPROVED LABELLING OR HEALTH CANADA APPROVED LABELLING). EPIDURAL ADMINISTRATION OF DRUGS OTHER THAN THOSE INDICATED FOR EPIDURAL USE COULD RESULT IN SERIOUS INJURY TO THE PATIENT.


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 OXYGENRICH 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: CONSULT DRUG LABELING TO CONFIRM DRUG COMPATIBILITY, CONCENTRATION, DELIVERY RATES, AND VOLUMES ARE ALL SUITABLE FOR SECONDARY, CONCURRENT AND PIGGYBACK DELIVERY MODES.


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.

NOTE: Although unlikely, failure of certain robust mechanical components such as the anti-free flow mechanism or valve control springs could cause fluid delivery limited to the contents of the fluid container.

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

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

Piggyback, Concurrent, and Secondary Delivery Guidelines

Primary and secondary fluids are delivered to the patient through a common cassette and downstream line. Observe the following guidelines during Piggyback, Concurrent, and Secondary 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. THIS APPLIES WHEN THE PIGGYBACK FLUSH FEATURE IS NOT USED.

Concurrent Delivery of Critical Drugs

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

WARNING: WHEN DELIVERING SHORT HALF-LIFE CRITICAL DRUGS USING ONE CHANNEL (RIGHT OR LEFT) IN CONCURRENT MODE, THE FOLLOWING DELIVERY RATE GUIDELINES SHOULD BE OBSERVED:

- If the 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 the 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 the 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.

NOTE: The total of the primary rate plus the secondary rate on a single channel (Line 1 + Line 2 on the same side) cannot exceed 500 mL/hr.

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.**

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 or Greater	Any Desired Ratio

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

Dobutamine	Esmolol	Nitroprusside
Dopamine	Isoproterenol	Norepinephrine
Epinephrine	Lidocaine	Oxytocin
Epoprostenol	Nitroglycerin	Procainamide

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.

This information is presented to inform clinicians of a rare situation that could be misinterpreted if they are unfamiliar with this phenomenon.

Guidelines When Opening the Cassette Door

Opening the one of the cassette doors will stop the infusion on one or both lines of that 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.

- 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.

- 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 Duo 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 Duo infusion pump. See individual set instructions for additional information.

- Administration sets should be changed at least every 96 hours. 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: WHEN INFUSING AT LOW DELIVERY RATES (5 ML/HR OR LESS) USE THICK-WALLED MICROBORE PLUMSETS. THIS WILL REDUCE THE AMOUNT OF THE UNINTENDED FLUID BOLUS THAT MAY BE DELIVERED WHEN A DOWNSTREAM OCCLUSION IS RELEASED.

- The use of microbore sets will reduce the time to detect a downstream occlusion when downstream pressure alarm limits are set high.

- Microbore PlumSets are not recommended at flow rates above 100 mL/hr. Use of microbore sets for flow rates greater than 100 mL/hr may require adjusting the downstream occlusion pressure limit setting to prevent unintended downstream occlusion alarms.

WARNING: USE OF MICROBORE SETS AT RATES GREATER THAN 100 ML/HR MAY INCREASE THE LIKELIHOOD OF DOWNSTREAM OCCLUSIONS RESULTING IN DELAY OF THERAPY, AND REDUCE SYSTEM ACCURACY

- When infusing at delivery rates of 0.1 to 999 mL/hr, macrobore PlumSets may be used.

- When attaching a syringe to the primary port, use standard clinical practices to ensure the syringe is secure in order to reduce the chances of creating a proximal occlusion.

- Syringes must be between 3 mL (minimum) to 60 mL (maximum). Syringes larger than 10 mL may be directly attached to the secondary port of the cassette. Small volume syringes, i.e.,

- 3-10mL, require a vented syringe adapter to ensure delivery accuracy and reduce proximal occlusion alarms. For syringe sets on the primary line, use a vented syringe adapter with all syringes from 3 mL to 60 mL.
- Before disconnecting a syringe from the cassette, pull up the plunger slightly to avoid spilling the fluid.
- Before disconnecting a rigid container from the cassette, close the upper slide clamp or clamp proximal tubing, open the cassette door, and then remove and invert the cassette (ports down) to avoid spilling the fluid.

Precautions to Avoid Unintended Bolus

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

Use the following procedure to avoid the administration of an unintended bolus following 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 downsream 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

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 fluids known to routinely outgas are in use.
- The infusion pump is mounted significantly above the patient. Minimize this differential (head height) when outgassing is a concern.
- The infusion pump is infusing at very low rates between 0.1 and 5 mL/hr.

NOTE: In these cases, an air-eliminating filter may be used when clinically appropriate.

- Repeated opening and closing of the door may defeat the proximal air-in-line alarm and may cause a downstream air-in-line alarm, requiring repriming.
- 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.

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.

Battery Guidelines

- If the low-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.
- Do not operate the Plum Duo infusion pump on patients when the battery is removed. Use of a properly 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 Duo 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 Duo 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 Duo infusion pump is designed to operate normally in the presence of most encountered electromagnetic interference (EMI) conditions. The Plum Duo has been tested for electro-

magnetic 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 an outlet 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 AND WIRED COMMUNICATIONS WITH THE INFUSION PUMP AND/OR THE OPERATION OF THE INFUSION PUMP.

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 Duo 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.

LifeShield

LifeShield™ Infusion Safety Software Suite is a cloud-based software platform that provides guidance to healthcare clinicians by managing IV infusion information with compatible ICU Medical infusion pumps. The LifeShield suite of products provides the following:

- Configurable parameters for medications, clinical care areas, and drug library management
- The ability to view clinical information regarding active infusions
- The ability to view information about supported devices, as well as schedule drug library and software updates

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

Clinical Care Areas

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:

- Hard and soft limits
- Clinical advisory messages
- Titration limits
- Initial values
- Availability of load, bolus, and multistep programming
- Post infusion settings, such as post infusion rate
- KVO rate
- Mode availability, including concurrent, piggyback
- Default pump settings, such as volume, initial screen brightness

If there are questions about parameters set at the CCA level (not every parameter is set at the CCA level) or about configurations in general, contact your LifeShield administrator.

Clinical Reports

LifeShield Infusion Safety Software Suite provides the ability to generate and review clinical reports containing infusion information from compatible devices. For example, a clinical compliance report provides information about infusion programs, such as infusions that violated a limit, infusions that were edited following a limit violation, and infusions that were programmed without using a medication ruleset defined in the drug library.

LifeShield delivers standard performance reports that enable hospital staff to:

- Analyze drug library use to enhance patient safety
- Assess medication infusion practices in the hospital
- Track clinician drug library utilization or compliance
- Identify I.V. administration practices that can be improved
- Assess rule set (hard/soft limits) alignment with clinical practice

Loss of Communication

If the Plum Duo infusion pump loses communication with LifeShield, it will continue to infuse without interruption. However, log content and status 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 wifi connectivity or a disruption between LifeShield and your hospital's network. For low wifi connectivity, relocating the pump may be sufficient to reestablish connection. If relocating does not reestablish connection, or if the cause is something besides low wifi connectivity, contact your hospital's IT department.

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 Duo infusion pump pole clamp is designed to be mounted on an I.V. pole with a diameter from 0.5 - 1.5 inches (1.2 cm to 3.8 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 Duo 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 three (3) infusion pumps mounted to the pole, may not be extended higher than 68 inches from the floor, and during mobile use 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.

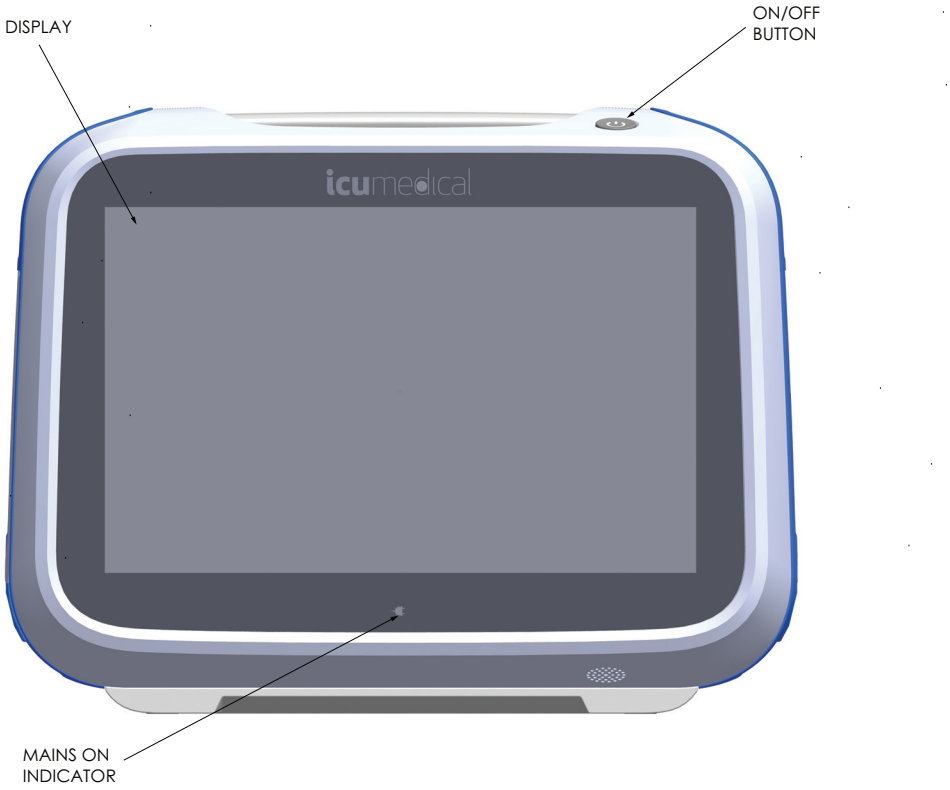
After mounting pumps, check the I.V. pole/infusion pump assembly for stability and tight mounting connections. **If the assembly is NOT STABLE, check the mounting heights and the extension height of the I.V. pole. Adjust those settings until the assembly is stable.**

Infusion Pump Overview

Before placing the infusion pump into service for the first time, a biomedical technician should process the pump, ensuring the pump is clean and the battery fully charged. See the *Plum Duo Technical Service Manual* for more information.

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



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 and hold the ON/OFF 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.

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. Programmed infusions will be saved for the next time the pump is powered on.

1. To turn power off, stop all active deliveries.
2. Press the ON/OFF button.
   You will hear the infusion pump mechanism power down and see the display turn off.
3. Quickly release the button.

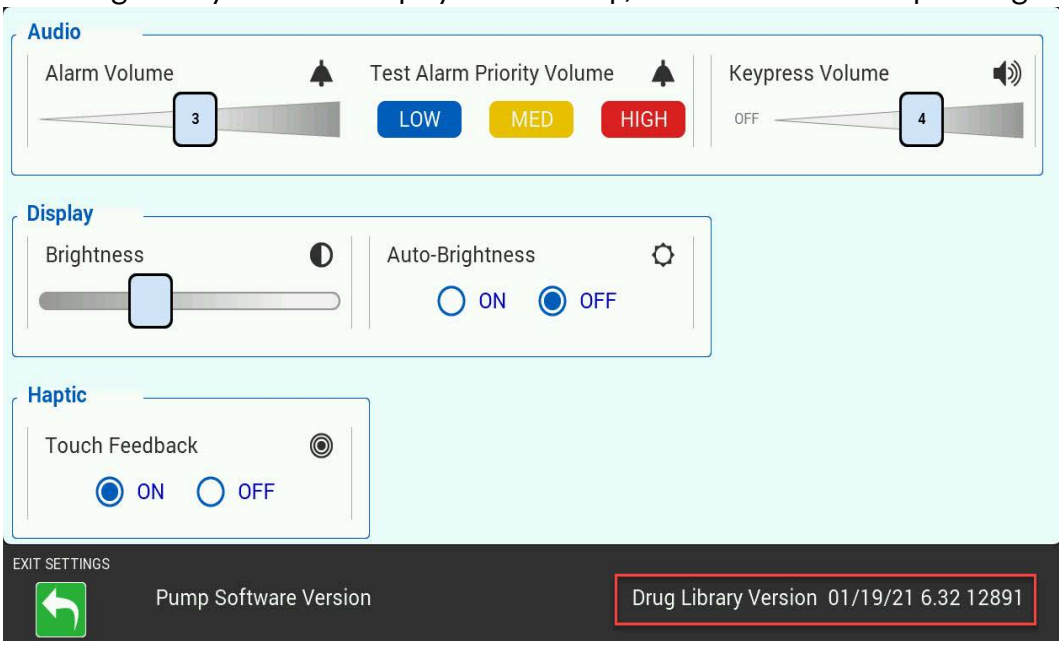
Drug Library/Settings Updates

When Updates Occur

Drug Library and Settings updates occur when the drug library parameters are modified by the healthcare facility.

Drug Library Versions

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

NOTE: All content under this Software Update section is applicable for Plum Duo 1.1 and future releases.

Software updates are activated during pump shutdown. A message will display asking if there is programming data that needs to be retained. If yes, the software update will be postponed. If not, the pump will download the newest software version and clear programming data.

Software Versions

NOTE: All content under this section is applicable for Plum Duo 1.1 and future releases.

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

Software Update Failure

A software update may fail. Most often, the user will be notified and be able to use the pump. It should still be sent for service as soon as possible. Rarely, a software update may fail and render the pump unusable.

Inability to Activate a Software Update Due to Low Battery

A pump may be unable to activate a software update if the battery charge is too low and it is not plugged into AC (mains) power.

Touchscreen Display Overview

Except for the ON/OFF button, the Plum Duo 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.

Swipe

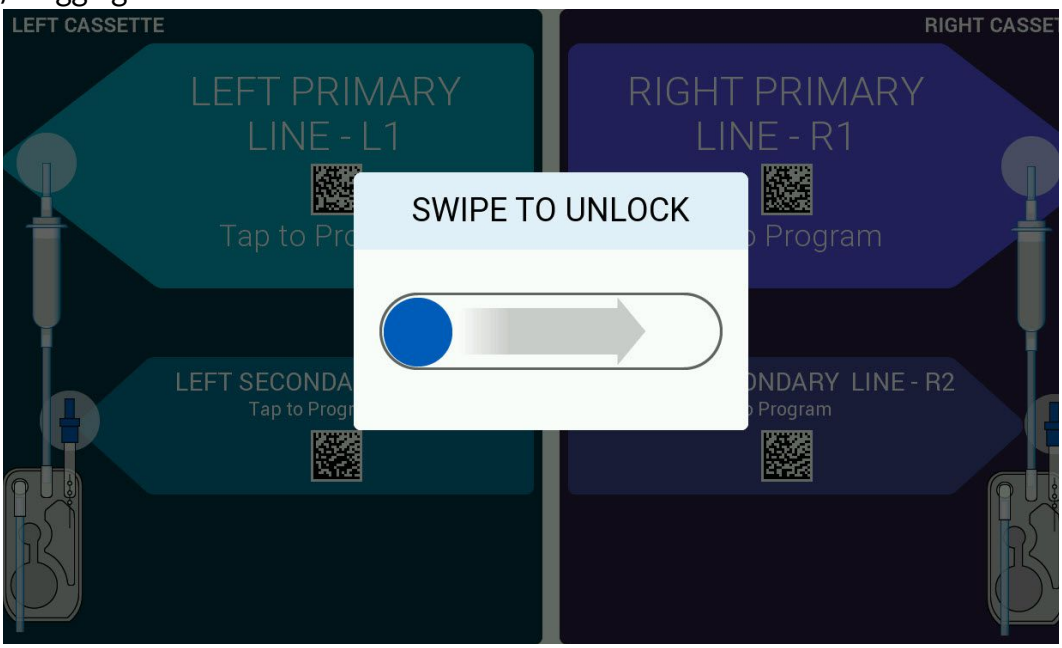
- Lightly drag your finger on lists to scroll through them.
- Swipe to unlock the screen.

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.

Swipe Lock

The Plum Duo infusion pump uses a swipe lock feature to prevent the user interface from activating due to inadvertent touches. After the preconfigured time (20-45 seconds) since the last interaction, it will display the Swipe Lock when first touched. To unlock the pump, swipe from left to right, dragging the circle.



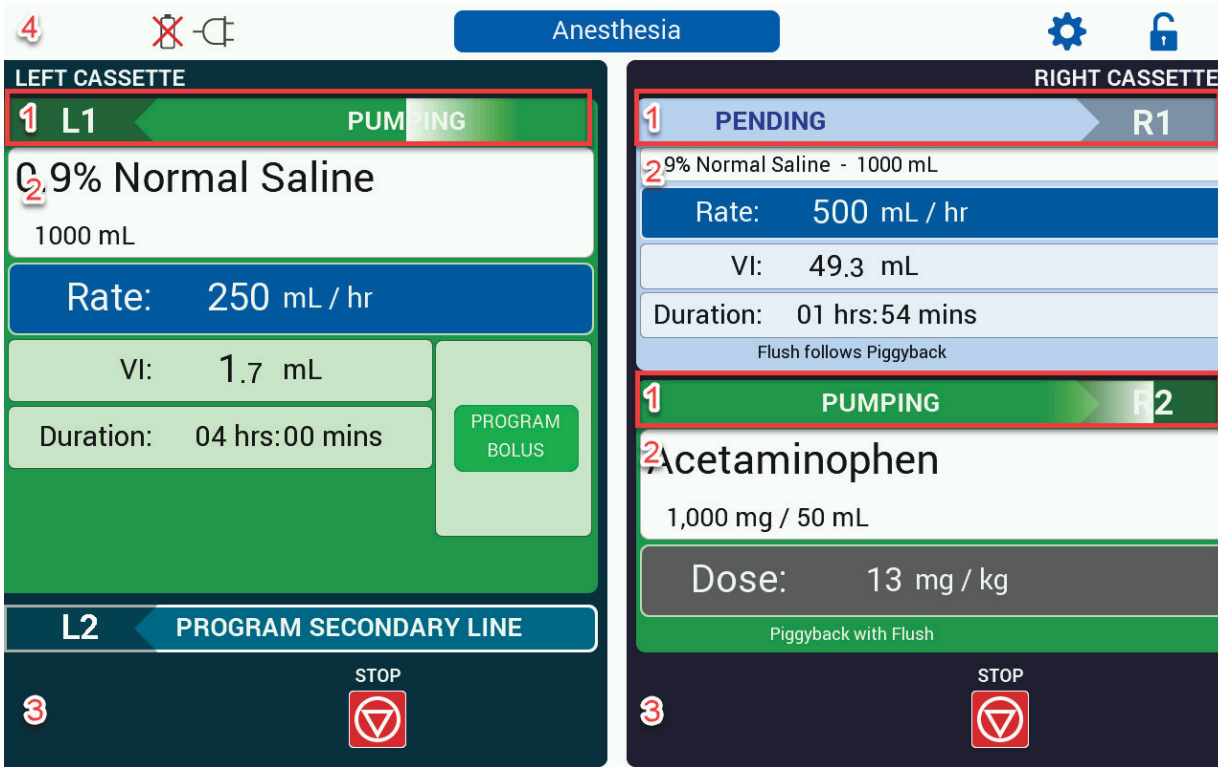
Main Delivery Page Overview

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 the infusion status. This includes, but is not limited to, PENDING, PUMPING, STOPPED, BACKPRIMING, and VTBI COMPLETE.
2. Infusion Information - These buttons display information for programmed infusions, such as Rate, VI (Volume Infused), and Duration. They are also used to navigate to different pages

when tapped. Tapping the drug name will navigate to the Review page, while tapping the Rate, VI, or Duration fields will navigate to the Programming page.

3. Bottom Row - 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, STANDBY, and BACKPRIME.
4. Top Row - The top row of the Main Delivery page displays various indicators related to the battery and wifi connectivity, as well as buttons for selecting the CCA and navigating to the Setting pages and Lock Screen keypad.



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, (Side)1, (Side)2, or BOTH in response to a prompt to specify which line(s) to stop.

CONFIRM - Tap to confirm program.

CANCEL - Tap to cancel a programmed infusion on the Programming or Review pages.

CLEAR PROGRAM - Appears on the Review and Main Delivery pages.

- On the Main Delivery page - Appears as a rectangular red button. Tap to clear a programmed infusion after it's been stopped.
- On the Review page - Appears as a red trashcan. 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 programmed flush settings from the line.

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

BACKPRIME - Tap to backprime.

STANDBY - Tap to open the Standby pop-up.

CALLBACK - Tap to set a nurse callback alarm to go off prior to end of infusion and

Navigation Buttons

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

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

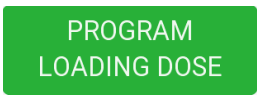
SETTINGS - Tap to open the list of Setting menus.

LOCK SCREEN - Tap to open the lock screen keypad.

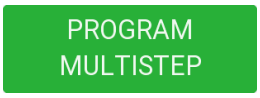
DELAY - Tap to open the Delay Start Program menu.

REVIEW- Tap to return to the first step in a Multistep infusion in the Review page.

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



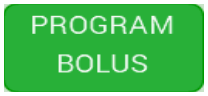
PROGRAM LOADING DOSE - Tap to navigate to the Programming page for a loading dose infusion.



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

PROGRAM PIGGYBACK - Tap to navigate to the Programming page for a loading dose 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 Clinical Settings page, tap to view the volume infused on each line.

POST INFUSION - Found in the Clinical Settings page, tap to view post infusion information for each line.

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

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

Indicators

Battery Power - Displays the current charge of the infusion pump battery. A lightning bolt appears in the icon when the pump is plugged into AC (mains) power and charging.

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. During this time, the battery charges continuously when a functional battery is installed.

If the infusion pump is unplugged, the AC Indicator 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.

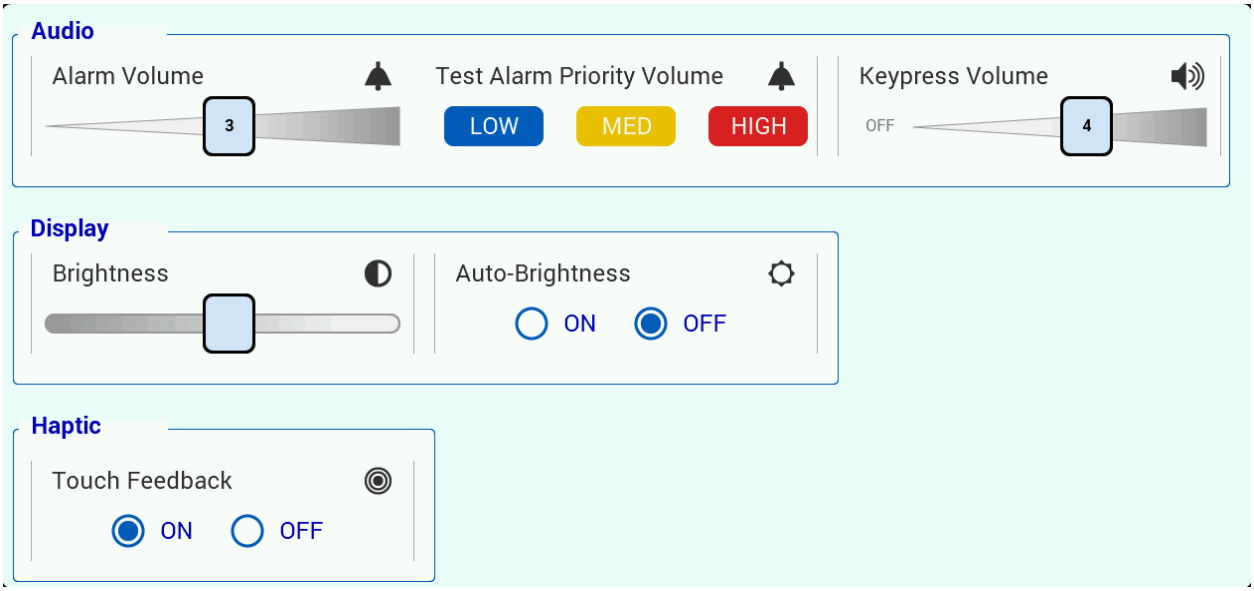
Wireless - Displays the status of the pump's wireless connection. The current strength of the connection is displayed by the number of blue bars. This indicator does not appear if the wireless connection is lost.

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

Pump Settings



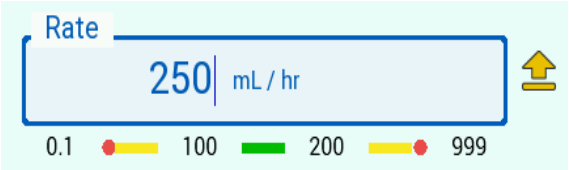
The Pump Settings page allows you to configure the following:

- Alarm Volume - Use the slider to adjust the volume of pump alarms. For patient safety, alarms cannot be muted.
- Test Alarm Priority Volume - Use these three buttons to play a Low, Medium, or High priority alarm in order to test the infusion pump's volume.
- Keypress Volume - Use the slider to adjust the volume of the keypress sound. Slide it all the way to the left to turn off keypress sounds.
- Brightness - Use the slider to adjust screen brightness.
- Auto-Brightness - Select "ON" to cause the pump to automatically adjust screen brightness based on the pump's surroundings.

- Touch Feedback - Select "ON" to enable haptic feedback, which causes the screen to lightly vibrate when buttons are tapped.

NOTE: Tones for alerts, infusion start, and infusion stop cannot be turned off.

Display Symbols



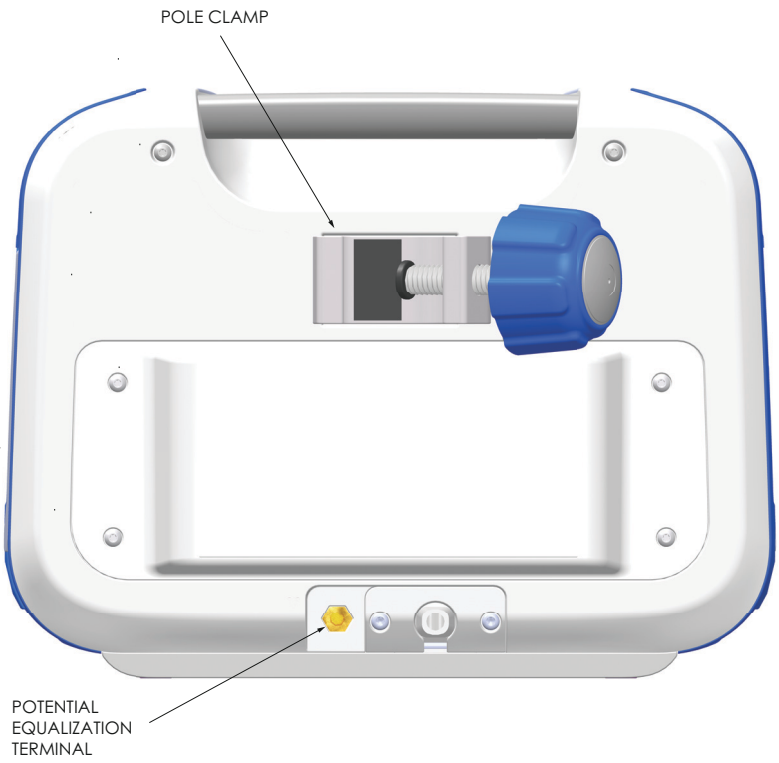
Alert Field - Appears on the Programming page and displays relevant icons, such as the particular drug's Limit Bar.

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.

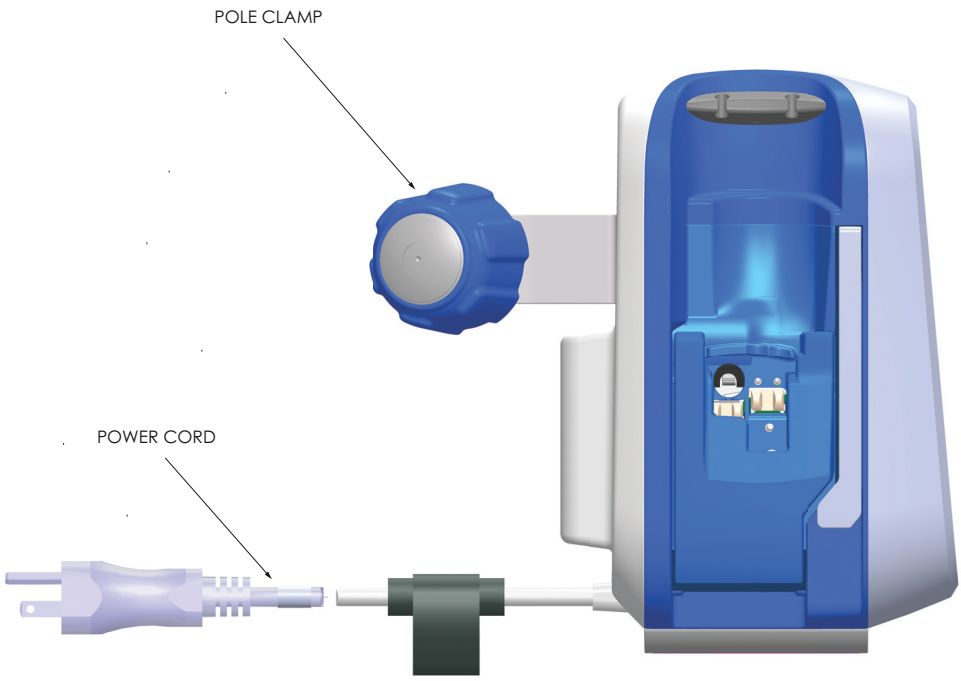
Hard Limit Exceeded - Appears on the display to inform the clinician that the specific value is outside the drug's hard limits. The direction of the arrow indicates which hard limit, upper or lower, is being exceeded.

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.

Back



Sides



NOTE: The Plum Duo infusion pump is identical on both sides.

Pole Clamp, Power Cord, and Potential Equalization 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, charge the battery, and ground the infusion pump enclosure and chassis. The power cord connection to the infusion pump is protected by an enclosure to prevent accidental disconnection. The power cord can be replaced if damaged (see the *Silver Technical Service Manual*).

Potential Equalization 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.

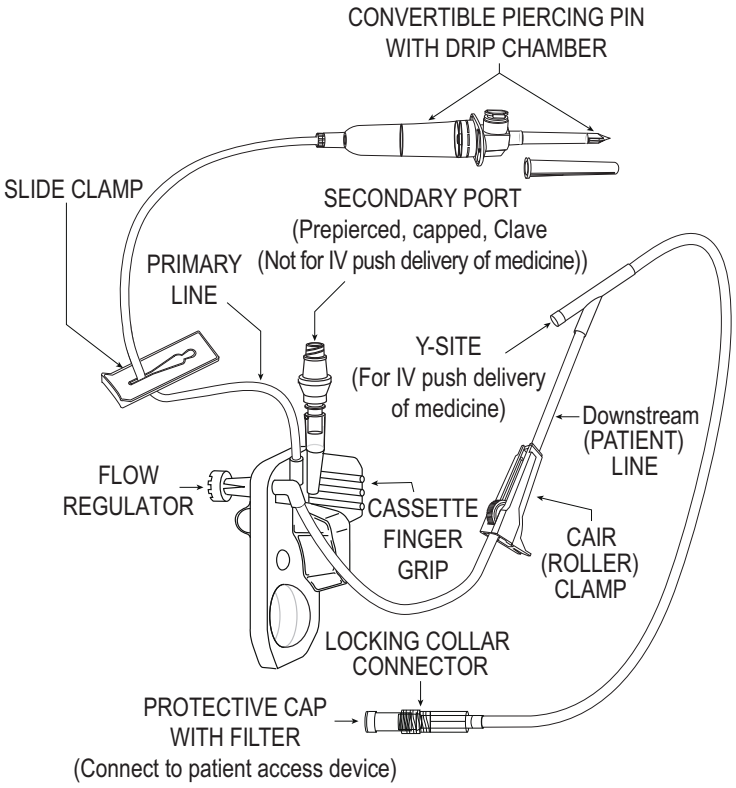
When the infusion pump's power cord is connected to an AC (mains) outlet, the grounding wire of the power cord forces the infusion pump enclosure and chassis to be at zero volts. If the pump power cord is not connected to the mains outlet, a separate grounding cord should be connected from the Potential Equalization Terminal to a grounding terminal in the treatment location.

Administration Sets

Plum Duo infusion pump operations require the use of ICU Medical Plum Administration Sets. The infusion pump is intended for parenteral, enteral, and epidural therapies and the administration of whole blood and blood products. Intravenous, epidural, and blood sets are supplied sterile. Some sets have additional features such as burettes, filters, or special tubing.

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

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

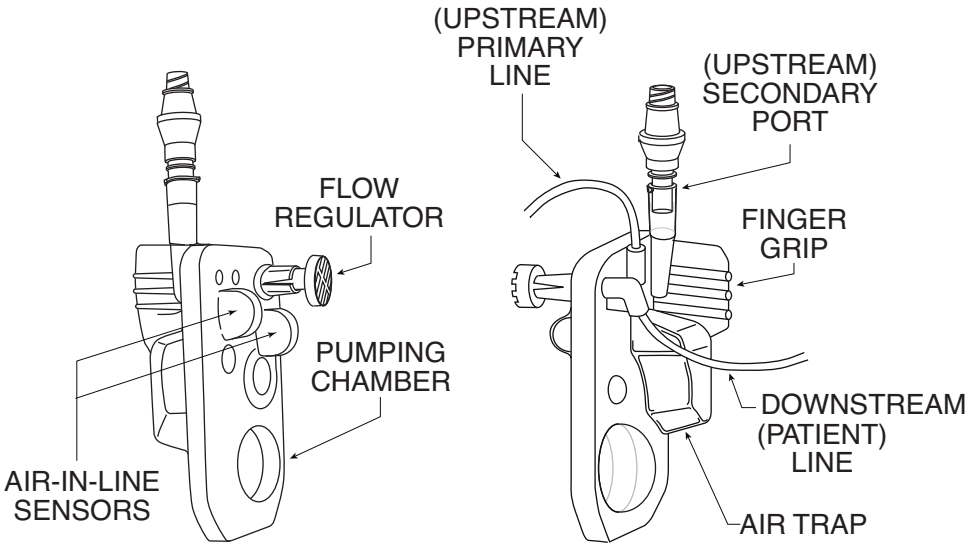


Administration sets have a 96-hour performance limit. Refer to the packaging or facility policy for guidelines on when to change the set. Follow facility guidelines when disposing of administration sets and other consumables.

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

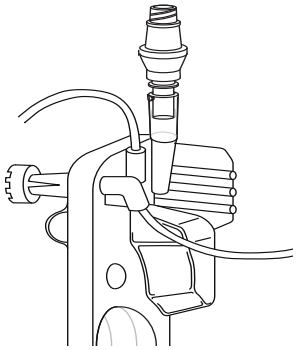
The Cassette

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.

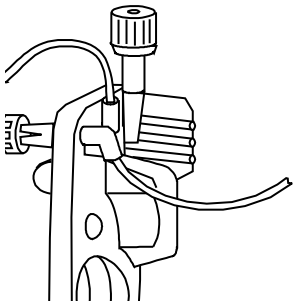


The air trap allows 1 mL of air before the infusion pump sounds a cassette alarm. To remove air bubbles from the air trap, backprime. See ***Backprime*** for instructions.

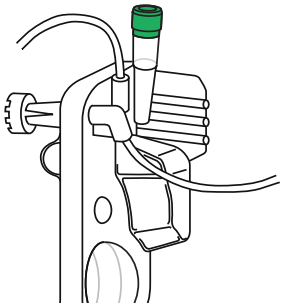
Most sets also include a secondary port for attaching a line or syringe for Piggyback or Concurrent fluid delivery. The secondary port has one of these connectors:



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.

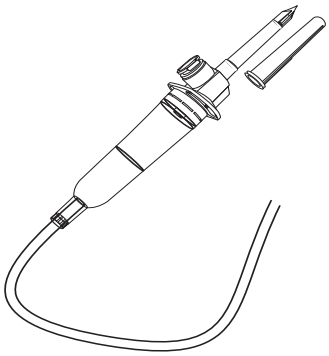
Cassettes also have the following features:

- 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

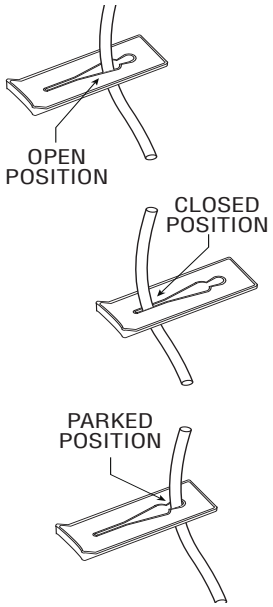
Most administration sets have some combination of the following features. For complete information about all the features of a particular administration set, refer to the label on the administration set packaging.



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

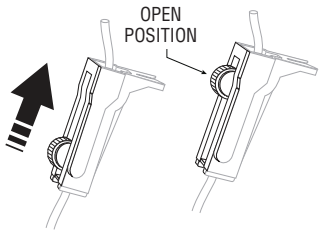
The piercing pin has a built-in filter vent that allows use with flexible or rigid fluid containers, and an integrated drip chamber with score mark for monitoring fluid flow.

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.



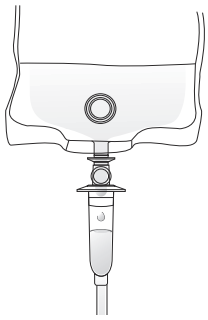
Slide clamps can be placed anywhere on the tubing. The shape of the cutout provides three clamp positions:

- **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.

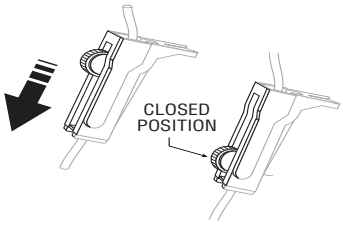


Roller clamps allow controlled fluid flow.

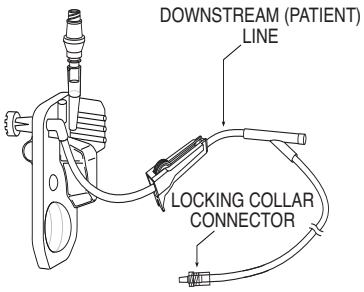
- To gradually increase fluid flow, slide the roller towards the fully **Open** position.



- 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 Duo 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.

WARNING: CLOSE ALL CLAMPS BEFORE OPENING THE CASSETTE DOOR.

To discontinue fluid flow and set gravity flow:

1. Tap STOP.
   If both the left and right channels are infusing, tap STOP on both sides.
2. If only one line on a side is pumping, confirm.
   If both lines on a side are pumping, select both lines to stop
3. Press the ON/OFF button to turn off the infusion pump.
4. Close all clamps.
5. Open the cassette door and remove the cassette.
6. 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.
7. 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.

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

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.

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:	3 mL - 60 mL Small volume syringes, i.e., 3-10 mL, require a vented syringe adapter to ensure delivery accuracy and reduce proximal occlusion alarms. Syringes larger than 10 mL do not require a syringe adapter.
Attaching to a Clave or capped secondary port:	Attach the syringe directly to the port. If using a syringe adapter, attach the adapter to the syringe and prime the adapter before attaching the syringe/adapter assembly to the port.
Attaching to a prepierced secondary port:	Fit the syringe with a locking blunt cannula before attaching to the port. If using a syringe adapter, attach the adapter to the syringe and prime the adapter, and then attach the locking blunt cannula to the adapter before attaching the syringe/adapter/cannula assembly to the port.

You do not need to remove the primary administration set from the infusion pump or the patient before attaching a syringe to the secondary port.

List of Administration Sets

The following is a list of representative administration sets that are available for use with the Plum Duo infusion pump. Administration sets are non-DEHP and latex free. PE lined tubing are generally thicker walled, in comparison to PVC. For more details, refer to the labeling on the administration set packaging. Some administration sets may not be available in your region. For information about additional compatible administration sets, contact your local sales representatives.

Table 1: Primary IV Sets

List Number	Description
12338	Microbore Conversion PlumSet, 2 Clave Y-Sites, 76in
14242	Primary PlumSet, Clave Y-Site, 104 Inch
14243	Primary PlumSet, 2 Clave Y-Sites, Secure Lock, 104 Inch
14247	Primary PlumSet, Clave Y-Site, Distal Microbore Tubing, Secure Lock, 104 Inch
14251	Primary PlumSet, Piggyback, Backcheck Valve, 2 Clave Y-Sites, Secure Lock, 103 Inch
14679	Primary PlumSet, Prepierced Y-Site, Secure Lock, 104 Inch
14687	Primary PlumSet, Clave Secondary Port, Clave Y-Site, Secure Lock, 103 Inch

Table 2: Burettes

List Number	Description
14271	Plum 150 mL Burette Set, Clave Injection Site, Clave Port, 0.2 Micron Filter, (3)Clave Y-Sites, SL, 140in
14273	Plum 150 mL Burette Set, Clave Injection Site, 2 Clave Y-Sites, SL, 114in

Table 3: Blood Sets

List Number	Description
14210	Primary Plum Blood Set, 100 mL Burette with Prepierced Additive Port, 170 Micron Filter, Prepierced Secondary Port, Non-Vented, Secure Lock, 105 Inch
14211	Primary Plum Blood Set, CLAVE Secondary Port, 200 Micron Filter, Secure Lock, 110 Inch
14212	Primary Plum Y-Type Blood Set, 200 Micron Filter, CLAVE Secondary Port, Secure Lock, 110 Inch
14220	Primary Plum Y-Type Blood Set, 200 Micron Filter, CLAVE Secondary Port, CLAVE Y-Site, Non-Vented, Secure Lock, 110 Inch

Table 4: Enteral Sets

List Number	Description
14257	Primary Enteral PlumSet, 98 Inch, Non-DEHP
14258	Primary Enteral PlumSet, 40 mm Screw Cap, 98 Inch

Priming

Priming fills the cassette, tubing, and any other special features of the set with fluid, displacing air. Proper priming is an important part of air management.

Sterile administration sets are indicated on the administration set packaging. Refer to the packaging for the method of sterilization.

The following procedure gives the general steps for priming a Plum administration set. Refer to the administration set packaging for complete instructions on how to prime the set.

WARNING: DO NOT PRIME THE ADMINISTRATION SET WHILE IT IS CONNECTED TO A PATIENT.

To prime an administration set:

1. Inspect the administration set packaging. If the packaging is not intact, discard it and use a new set.

2. Open the package and remove the administration set.

3. Press the cassette flow regulator in to make sure it is closed and confirm that there is no flow during priming.

PRECAUTION: BE CAREFUL WHEN PIERCING THE SOLUTION CONTAINER TO AVOID PUNCTURING IT.

4. Insert the piercing pin into the outlet on the fluid container using a twisting motion.

PRECAUTION: DO NOT INSERT THE PIERCING PIN WHILE THE CONTAINER IS HANGING ABOVE THE INFUSION PUMP.

5. Suspend the container on an IV pole with the bag elevated approximately 12-24 inches above the cassette/pump.

PRECAUTION: CHECK THE CONTAINER FOR LEAKS. IF ANY PART OF THE CONTAINER IS LEAKING, REPLACE IT.

6. Squeeze the drip chamber to the score mark. Do not completely fill the drip chamber.

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

8. Invert the cassette so that the secondary port is pointing down.

9. Slowly open the flow regulator by turning it counter-clockwise while holding the cassette in the inverted position, to allow the fluid to flow into the cassette at a controlled rate.

NOTE: To quickly stop the flow at any time, push in on the flow regulator.

10. When the first drop appears in the pumping chamber, turn the cassette upright.

11. Continue to slowly prime the set until all air is removed from the cassette and the remainder of the tubing. Tap the cassette and tubing to dislodge air bubbles.

NOTE: Invert and tap each Y-site to fill it with fluid, then turn the Y-site upright.

NOTE: If the filter cap at the downstream (patient) end of the tubing gets wet, you must temporarily remove the cap to continue priming.

12. Once priming is complete, push the flow regulator "in" to close it.

13. Check the drip chamber and the tubing to confirm that there is no flow and that no kinks appear in the tubing.

PRECAUTION: WHEN PRIMING IS COMPLETE AND THE CASSETTE FLOW REGULATOR IS CLOSED, ENSURE THAT FLUID IS NOT FLOWING FROM THE DOWNSTREAM END OF THE ADMINISTRATION SET. DO NOT USE THE ADMINISTRATION SET IF FLUID FLOW IS OBSERVED.

Loading a Cassette

Opening the Cassette Door

Infusion pump components located behind the cassette door interact with the cassette to control fluid flow, preventing primary and secondary fluids from mixing, and allowing fluid to reach the patient only when the infusion pump is pumping. The fluid regulator closes to prevent fluid flow to a patient.

When you open the cassette door, infusion pump components are no longer in contact with the cassette. **Always close all clamps before you open the cassette door** so that fluid does not flow into drip chambers.

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

If any administration set caps fall into the door recesses, open the door completely before removing them.

To open the cassette door:

1. Make sure that all slide clamp and lower CAIR (roller) clamps are closed before opening the cassette door.
2. Lift the cassette door lever.
3. Press the door release tab on the lower part of the door lever to disengage the cassette door from the door latch, and then gently press the cassette door down until it opens completely.

Closing the Cassette Door

Keep the cassette door closed while not in use to avoid damage to the cassette door.

To close the cassette door, press down on the cassette door lever.

If the infusion pump is turned on when you close the cassette door with a cassette installed, the cassette test begins automatically.

Loading a Cassette

To load a primed cassette into the infusion pump:

1. Lift the lever to open the cassette door.
2. Grasp the cassette by the finger grip.
3. Slide the cassette between the cassette door and the door guides at a 45 degree angle.
4. Press the lever down to close the cassette door.

5. Insert the upstream line into the tubing guide.
6. Ensure all clamps are open.

PRECAUTION: CHECK THE DRIP CHAMBER AND THE DOWNSTREAM END OF THE TUBING TO CONFIRM THAT THERE IS NO FLOW AND THAT NO KINKS APPEAR IN THE TUBING. IF YOU OBSERVE FLOW OR LEAKS, CLOSE ALL CLAMPS AND REPLACE THE ADMINISTRATION SET.

7. Press and hold the ON/OFF button to turn on the infusion pump.
   The infusion pump initiates its startup sequence.
8. Connect the Plum Set to the patient.
9. Program a delivery on the Primary Line 1.
   Infusions may be programmed during the startup sequence, but will only begin once the Self Test has successfully completed.

NOTE: An infusion pump may be programmed without a cassette to facilitate treatment. If an infusion is programmed without a cassette, perform a line trace to the program before starting infusion.

Preparing a Secondary Delivery from an Administration Set

The following procedure gives the general steps for preparing a secondary administration set for a Piggyback or Concurrent delivery. Refer to the set packaging for complete instructions on how to prime the administration set you are about to use.

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

WARNING: USE ONLY ICU MEDICAL PLUM ADMINISTRATION SETS WITH A CASSETTE SPECIFIED FOR USE WITH THE PLUM DUO INFUSION PUMP. USE OF NON-PLUM CASSETTES CAN RESULT IN IMPROPER FUNCTIONING OF THE INFUSION PUMP OR INACCURATE DELIVERY.

WARNING: DO NOT RESTERILIZE ADMINISTRATION SETS. RESTERILIZATION MAY RESULT IN INACCURATE DELIVERY, INFECTION, AND ALLERGIC REACTION.

WARNING: DO NOT REUSE ADMINISTRATION SETS. REUSE RAISES THE RISK OF INFECTIONS AND ALLERGIC REACTIONS. REUSE MAY ALSO RESULT IN INACCURATE FLOW RATES.

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

PRECAUTION: USE ASEPTIC TECHNIQUE WITH ALL FLUID PATH CONNECTIONS TO PREVENT CONTAMINATION. REMOVE CAPS WHEN REQUIRED AND SECURE ALL CONNECTIONS.

NOTE: You do not need to remove the primary administration set from the infusion pump or detach it from the patient before attaching a primed secondary administration set.

To prime a secondary administration set:

1. Prime per the administration set packaging.

PRECAUTION: CHECK THE SECONDARY CONTAINER FOR LEAKS. IF ANY PART OF THE CONTAINER IS LEAKING, REPLACE IT.

2. Attach the line to the secondary port.
3. Insert the secondary line into the Line 2 tubing guide.

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

Connecting a Secondary Line or Syringe

A primary PlumSet may have a Clave or a prepierced connector on the secondary port. The following sections describe how to attach a secondary line or syringe to each secondary port type.

NOTE: Accepted syringe sizes are 3-60mL. Small volume syringes, i.e., 3-10 mL, require a vented syringe adapter to ensure delivery accuracy and reduce upstream occlusion alarms.

Connecting to a Clave Port

The Clave is a needle-free connector with an internal design that prevents leakage from the top of the connector. The secondary line or syringe can be attached directly to the port. Avoid twisting or bending the port during attachment to prevent damage or breakage.

To connect a line or syringe to a Clave secondary port:

1. Grasp the base of the Clave connector to support it, and then insert the end of the secondary line or syringe into the Clave.
2. Secure the connection:
   If attaching a secondary line, continue to support the Clave with one hand as you move the locking collar over the port with the other hand and twist the collar clockwise to secure the line.
   If attaching a Luer-Lok syringe or syringe adapter, continue to support the Clave connector with one hand as you twist the Luer-Lok or adapter connector clockwise with the other hand to lock the connection in place.

Connecting to a Prepierced Port

The prepierced port requires the use of a locking blunt cannula to provide needle-free access and a secure connection.

To connect a line or syringe to a prepierced port:

1. Remove the protective sleeve from the locking blunt cannula.

2. Insert the connector on the secondary line or syringe into the locking blunt cannula, and then twist the locking collar on the line to secure the connection.

NOTE: If using a syringe adapter, attach the adapter to the syringe and then attach the locking blunt cannula to the adapter.

3. Center the cannula over the prepierced secondary port and push until the cannula clicks into place.
4. Gently pull the connection between the secondary line or syringe and the locking blunt cannula to confirm that all connections are secure.

Priming the Syringe Adapter

NOTE: Small volume syringes, i.e., 3-10 mL, require a vented syringe adapter to ensure delivery accuracy and reduce upstream occlusion alarms.

To prime the syringe adapter:

1. Fill the syringe with solution.
2. Attach the vented syringe adapter by inserting the vent into the syringe and secure.
3. Press on the syringe plunger until the vented syringe adapter fills up and fluid is seen at the open end of the syringe adapter.
4. Refill the syringe as needed.

Removing a Secondary Line or Syringe

The following procedure describes how to disconnect a secondary line or syringe from the Plum cassette.

NOTE: You do not need to disconnect the set from the patient during this procedure.

NOTE: You do not need to stop Line 1 during this procedure.

To remove a secondary line or syringe during delivery:

⚠ **PRECAUTION: USE ASEPTIC TECHNIQUE WITH ALL FLUID PATH CONNECTIONS TO PREVENT CONTAMINATION. REMOVE CAPS WHEN REQUIRED AND SECURE ALL CONNECTIONS.**

1. Press STOP and then select Line 2.
2. Remove the syringe or line as follows:
   To remove a secondary line from a Clave secondary port - Clamp the line, twist counterclockwise to release the locking collar, and then pull up to disconnect the line.

To remove a syringe from a Clave secondary port - Pull up the plunger slightly to avoid spilling fluid. Twist counterclockwise to disconnect a Luer-Lok or syringe adapter, if present, and remove the syringe from the port.

To remove a secondary line or syringe from a prepierced secondary port - Pull up the plunger slightly to avoid spilling fluid. Clamp the secondary line (if present), fully depress the levers on the locking blunt cannula, and then pull upward.

3. Discard the secondary line or syringe (with fluid container, if present) per hospital procedure.

Discontinuing Fluid Administration

The following procedure describes how to remove a primary administration set from the patient, either to discontinue fluid delivery, or to change the set.

PRECAUTION: DO NOT USE A PLUM ADMINISTRATION SET FOR LONGER THAN 96 CONTINUOUS HOURS. CHANGE SETS PER SET PACKAGE LABELING OR FACILITY POLICY. ADMINISTRATION SETS ARE SINGLE-PATIENT USE ONLY.

To discontinue fluid delivery:

1. Press STOP. If two lines are pumping, select the line(s) to discontinue.
2. Press and hold the ON/OFF button to turn off the infusion pump.
3. Close all clamps.
4. Detach the downstream line from the patient access device.
5. Open the cassette door and remove the cassette by grasping the finger grips.
   The cassette door must be fully opened to remove the cassette if it is stuck in the door.
6. Close the cassette door.
7. Discard the set and fluid container per hospital procedure.

Changing Administration Sets

Plum administration sets should be changed per facility policy or every 96 hours, whichever is less.

PRECAUTION: DO NOT USE A PLUM ADMINISTRATION SET FOR LONGER THAN 96 CONTINUOUS HOURS. CHANGE SETS PER SET PACKAGE LABELING OR FACILITY POLICY. ADMINISTRATION SETS ARE SINGLE-PATIENT USE ONLY.

To change the administration set:

PRECAUTION: USE ASEPTIC TECHNIQUE WITH ALL FLUID PATH CONNECTIONS TO PREVENT CONTAMINATION. REMOVE CAPS WHEN REQUIRED AND SECURE ALL CONNECTIONS.

1. Stop the infusion pump, close all clamps, and then remove and discard the old set. See ***Discontinuing Fluid Administration*** for instructions.
2. Prepare and install a new administration set. See ***Priming*** for instructions.

Programming

This section will describe the various paths and interactions that may be encountered while programming an infusion. These are:

- ***Getting Started***
- ***Primary/Single Step Infusion***
- ***Secondary Infusion: Concurrent and Piggyback***
- ***Multi-Step***
- ***Loading Dose***
- ***Bolus***
- ***VTBI Complete Alarm***
- ***Stopping an Infusion***
- ***Titration***
- ***Standby***
- ***Delay Start***

Getting Started

Programming With and/or Without a Cassette

The Plum Duo infusion pump can be programmed with and/or without a Plum administration set inserted.

NOTE: It is recommended to insert the cassette before programming.

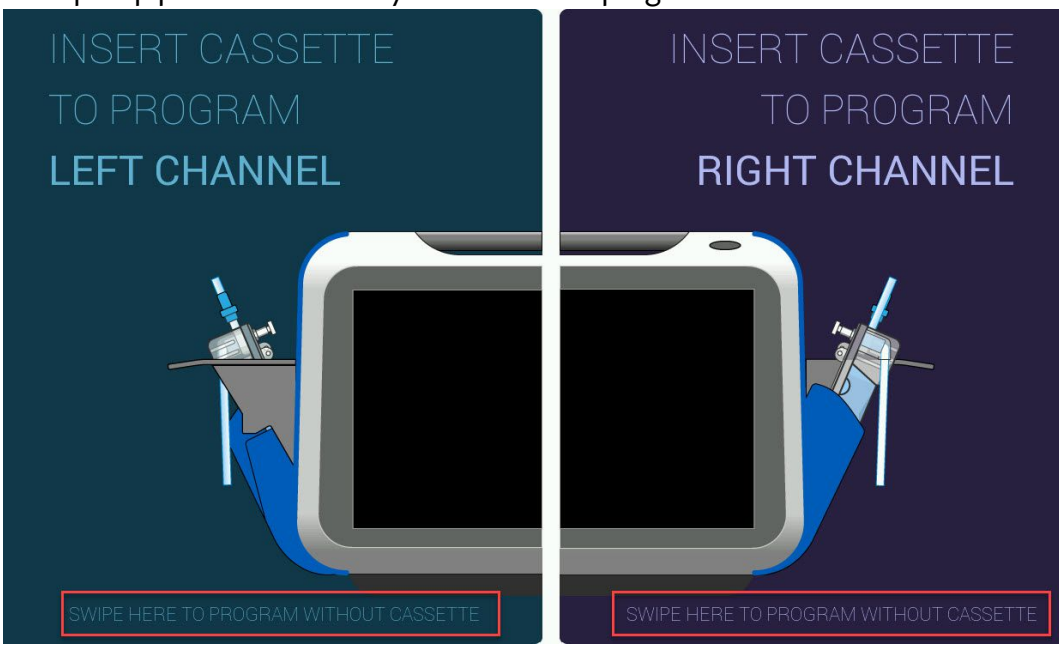
Programming With a Cassette

See ***Loading a Cassette*** for instructions on inserting an administration set into the pump.

After loading a cassette into the infusion pump, the mask will open on that side of the pump and the appropriate Primary Line icon will flash designating it is ready to be programmed.

Programming Without a Cassette

The infusion pump provides the ability for the user to program without a cassette.



Swipe the bottom of the screen on the desired side to enable programming. A popup message will be displayed. Tap CONTINUE to confirm programming without a cassette.

New Patient

When turning on an infusion pump within five hours of the last shutdown, the pump prompts “New Patient?” to give you the option to clear all settings on all lines.

Select yes to clear the settings and programming for all lines. Select no to retain the settings and programming for all lines.

Current CCA and Changing a CCA

The system CCA determines the drugs available for programming, as well as certain parameters for individual drugs, such as hard and soft limits. The current system CCA is displayed at the top of the screen.

When initially programming the pump, the last CCA used will be retained and act as the current CCA.

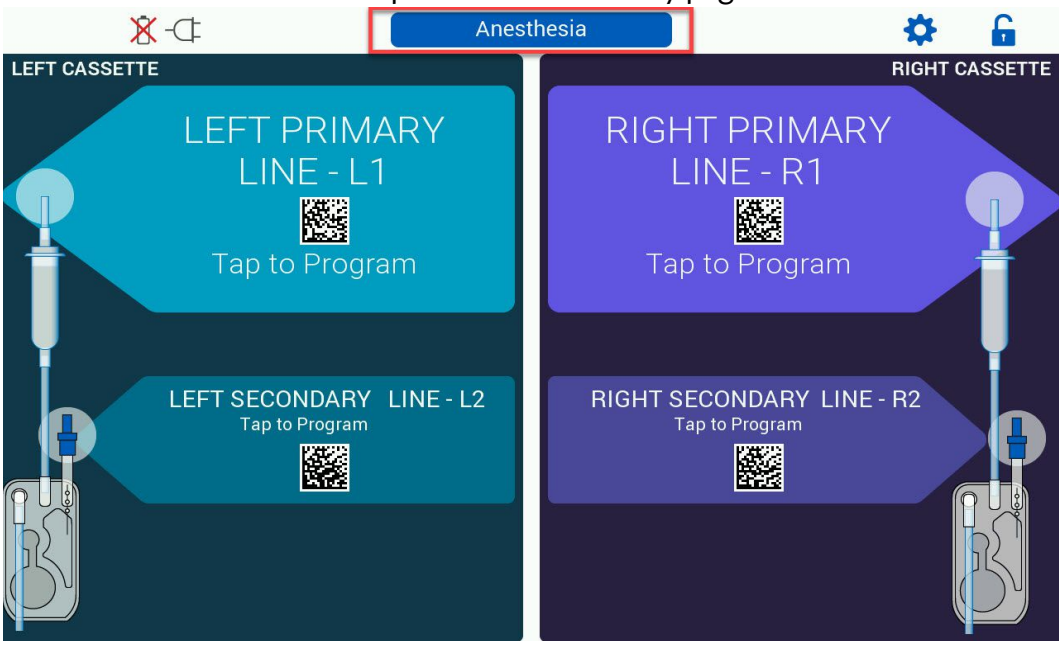
If a currently infusing line was programmed under a different CCA, the previous CCA will display on that line’s Programming and Review pages.

Changing a CCA

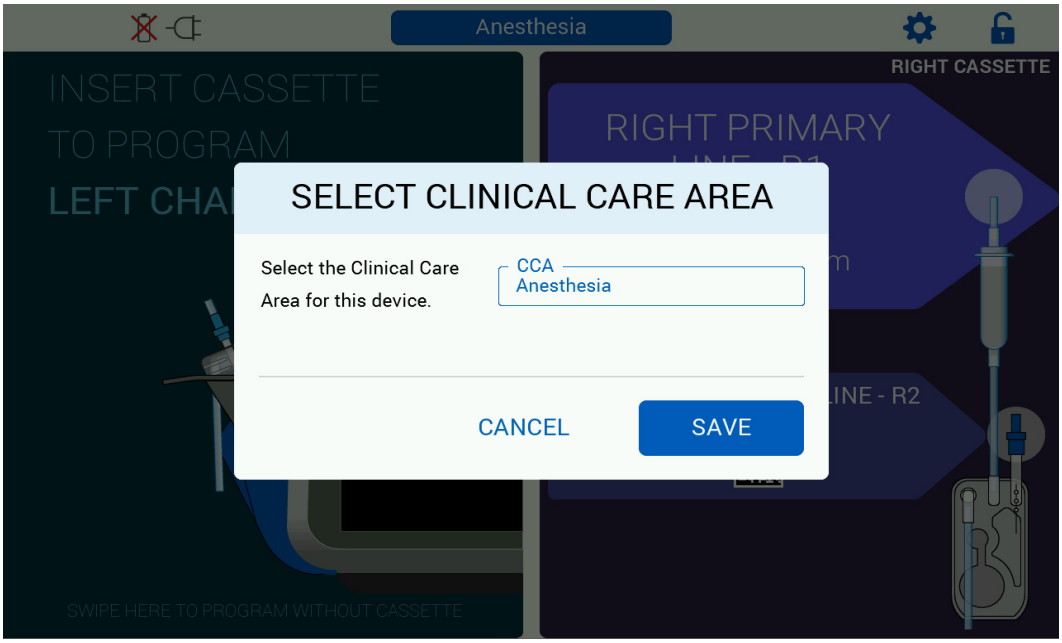
You may change the current system CCA before, during, or after an active infusion.

To change the current system CCA:

1. Tap the name of the CCA at the top of the Main Delivery page.



The CCA selection popup appears.

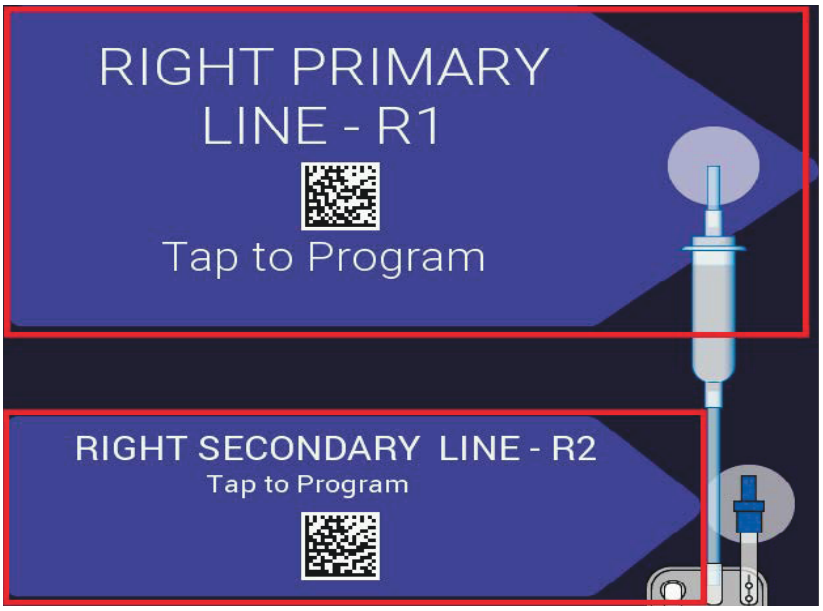


2. Tap the CCA selection field.
   Only a few CCAs are visible at one time. To navigate the list, drag your finger vertically.
3. Select the desired CCA in the drop-down list.
   The name of the selected CCA appears at the top of the screen and is now the current system CCA for all four lines.

Changing the system CCA does not affect current infusions programmed prior to the change. Settings for previously programmed infusions, such as hard and soft limits, are still determined by the previous system CCA.

When the Delivery page displays, the infusion pump will inform the user that line is delivering under a prior CCA. Until a VTBI Complete alarm occurs for the line, you can still titrate the infusion on that line under the old CCA.

Selecting a Line to Program

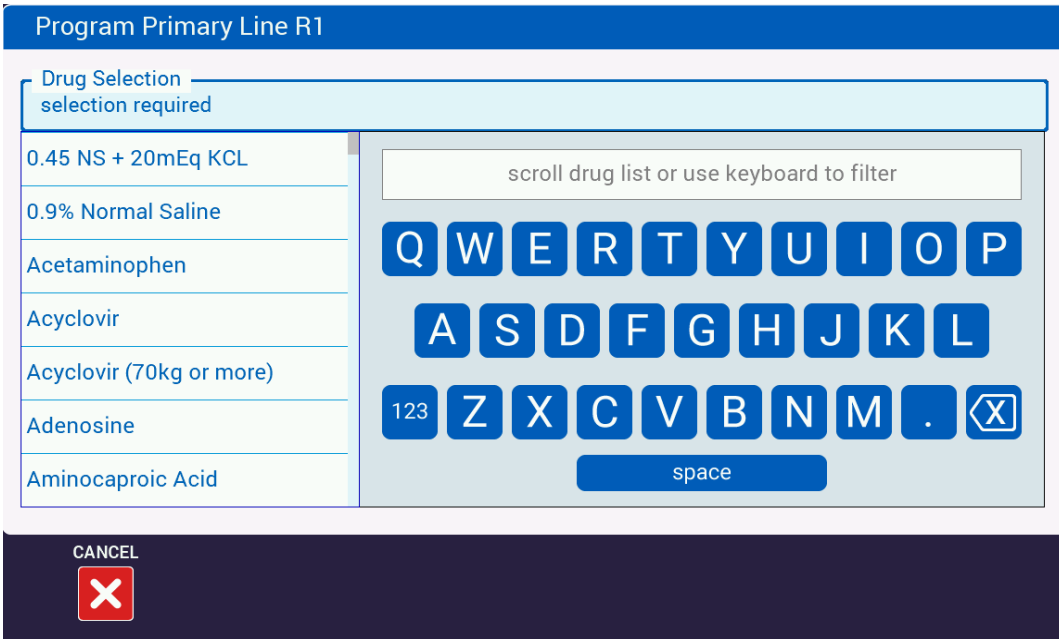


When a cassette is inserted the line selection option will be presented to the user. To select a line for programming, tap the highlighted area of the line to navigate to the Drug Selection page.

If a secondary line is selected without an infusion present on the primary line, the infusion pump will display a popup asking if this was intended.

The Plum Duo infusion pump can run up to four concurrent infusions simultaneously, depending on drug compatibility.

Selecting a Drug

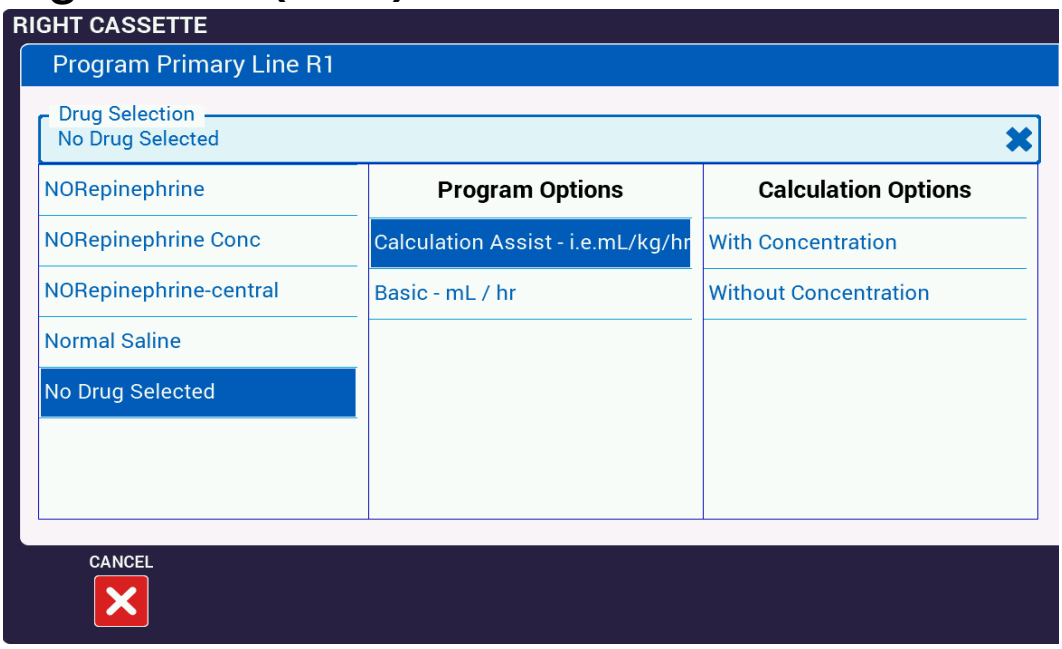


The current CCA determines the list of available drugs, as well as their configuration. Depending on how the drug is configured, the option to select a clinical use, delivery unit of measure, or concentration will be available.

Search for the drug or fluid by entering the name using the keyboard. The list will filter as you enter characters. Tap the backspace button to clear characters. You can also search numerically (example "0.9% NaCl") by tapping the 123 button in the lower left of the keyboard.

You can also search for the drug or fluid by scrolling through the medication list. Swipe your finger vertically to scroll.

No Drug Selected (Basic)



No Drug Selected (Basic) is available for when the drug of choice is not within the drug library. When utilizing this option, the clinician can program the medication, although no hard or soft limits will be applied to the infusion except for those determined by the pump's flow rate limitations.

When selecting No Drug Selected, a pop-up will appear asking if the user has searched for the drug under alternate names. Tap either button to continue.

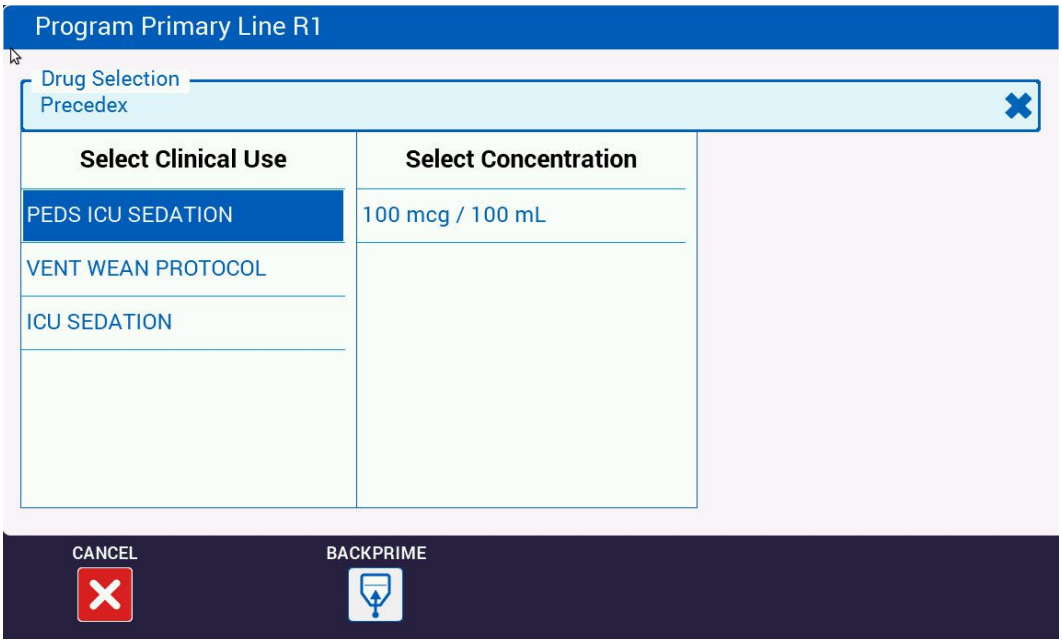
WARNING: THERE ARE NO MEDICATION LIMITS IN PLACE WHILE USING THE "NO DRUG SELECTED" OPTION.

There are two program options for No Drug Selected:

- Calculation Assist - i.e. mL/kg/hr: Choose this if you require the pump's assistance in calculating the dose. You can then choose to use the concentration in the calculation or proceed without doing so.

- Basic - mL/hr: Choose this when mL/hr or duration can be used for programming.

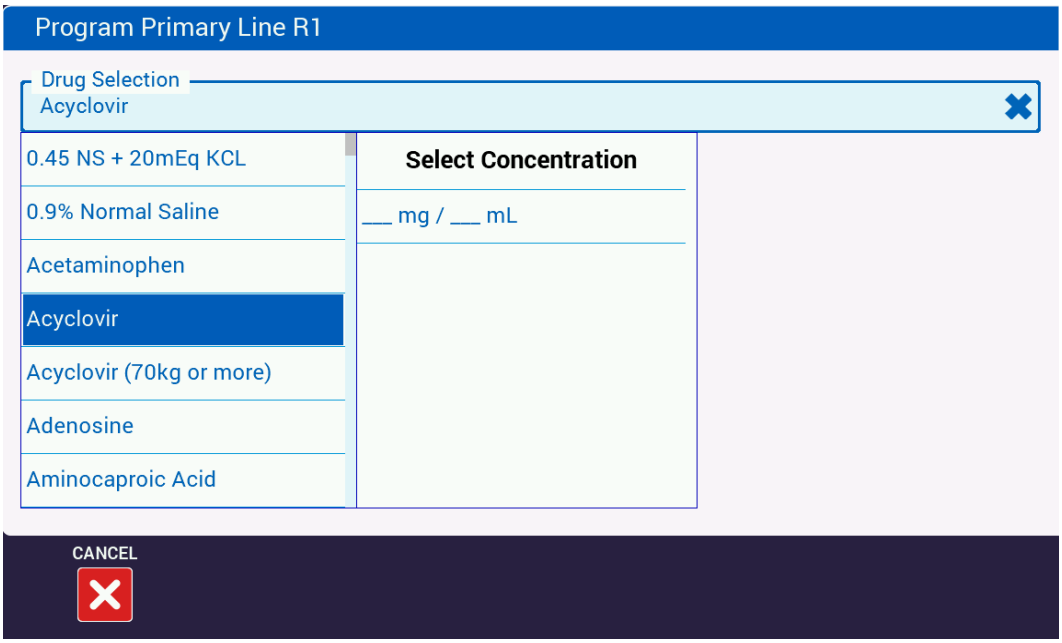
Selecting Clinical Use



An option may be presented for the indication of therapy. There may be different limits to each clinical use. Clinical uses are configured by the pharmacy based on the facility's best practices.

Example- Selecting the medication Dopamine could open a list of different clinical uses, for example Renal or Cardiac. These specific clinical uses may then display multiple concentrations.

Selecting a Concentration and/or a Unit of Measure



Medications may or may not have a predetermined concentrations and units of measure. In most custom drug library entries, these values are already predefined and will not require manual programming.

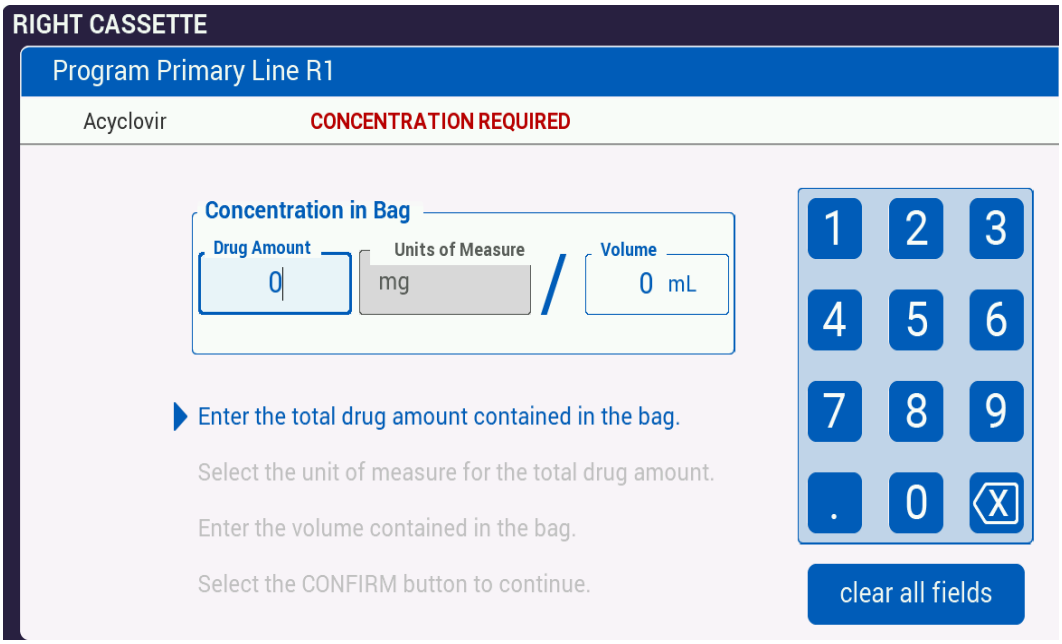
When a medication does not have a concentration and/or unit of measure, the user has the ability to enter these values.

Concentration Entry

The Plum Duo infusion pump allows the user to input custom values (drug amount and diluent volume) for medications whose values are not specified in the custom drug library. Drug amount and diluent volume may have hard limits determined by the custom drug library.

To program medications whose values are not specified in the drug library:

1. From the drug list, tap the Concentration option of the desired unit of measure (for example, "__mg/__mL" or "__mg/100mL").

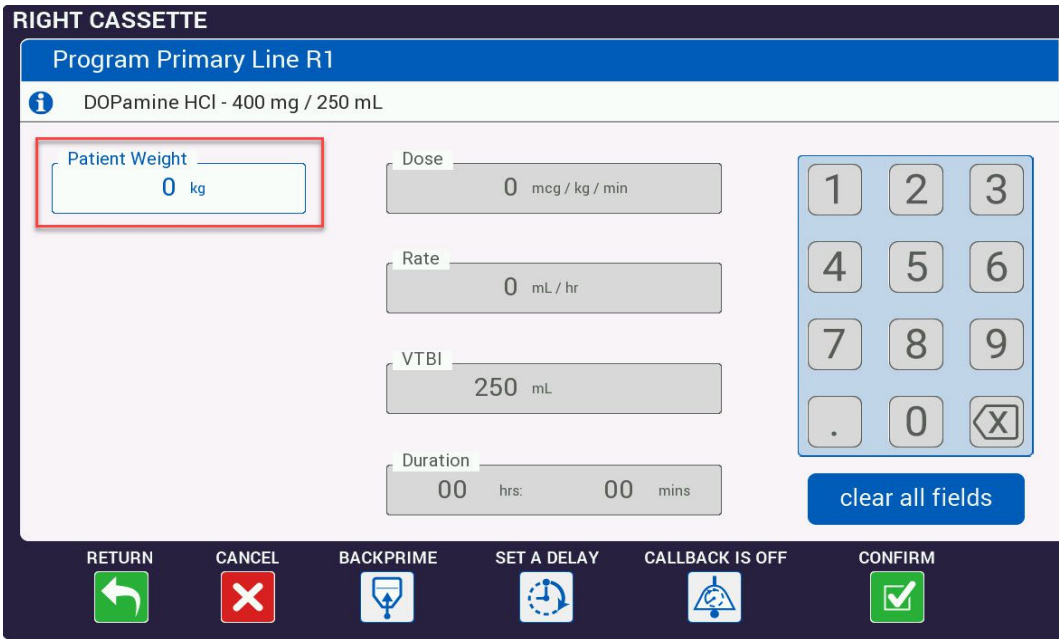


2. Enter the Drug Amount.

NOTE: Depending on the drug's configuration, certain values (such as Units of Measure) may not be editable.

3. Enter Volume if it is not pre-filled.
4. Tap CONFIRM.
   A pop-up appears to verify the concentration.
5. Tap CONTINUE if the concentration is correct or EDIT to change it.
6. See ***Programming*** for programming options.

Setting Patient Parameters



Depending on drug selection and therapy, the user may be required to input patient parameters to deliver the infusion. The required parameters will be highlighted. Enter values (for example patient weight, patient height, and BSA) using the keypad on the right. These parameters may have limits based on the CCA.

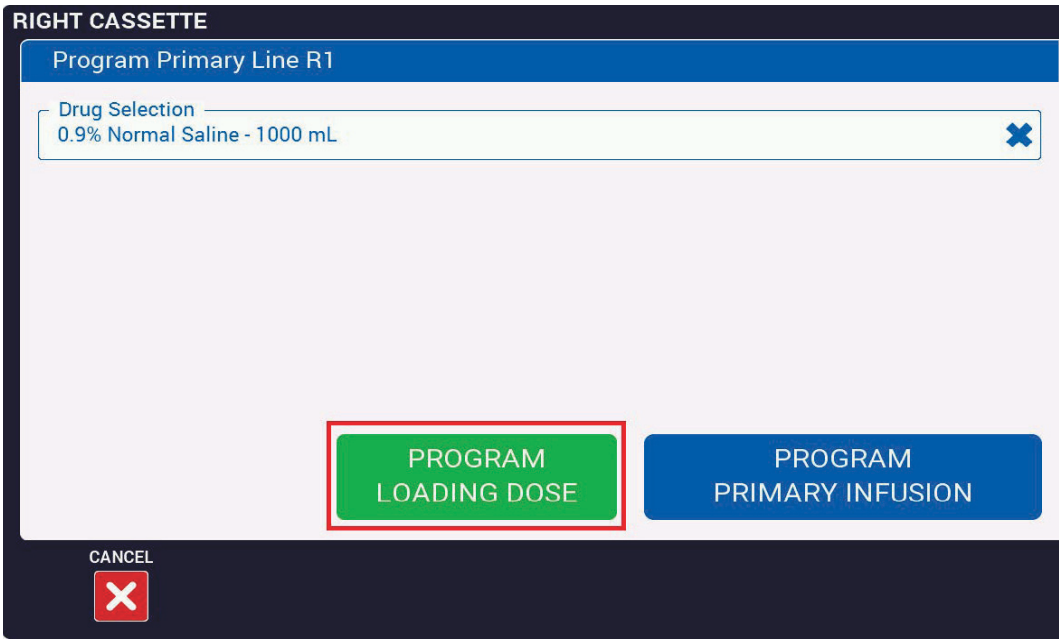
Changing Patient Parameters

In order to change patient parameters, active infusions must be stopped.

The infusion pump can have up to two different patient weights. If the difference between the weights is greater than 5%, the pump will prompt the user to continue or cancel. When the patient weight is changed, the affected rate or dose will be recalculated to reflect the new parameter.

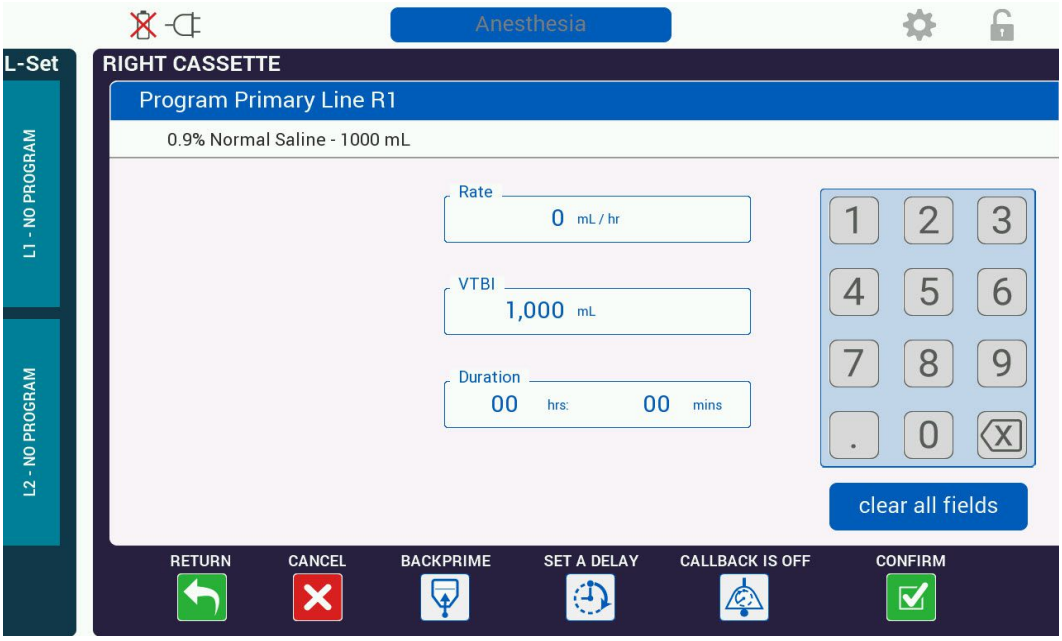
BSA can be entered manually or, if a weight and height is entered, will be automatically calculated using the DuBois method.

Setting Method of Delivery

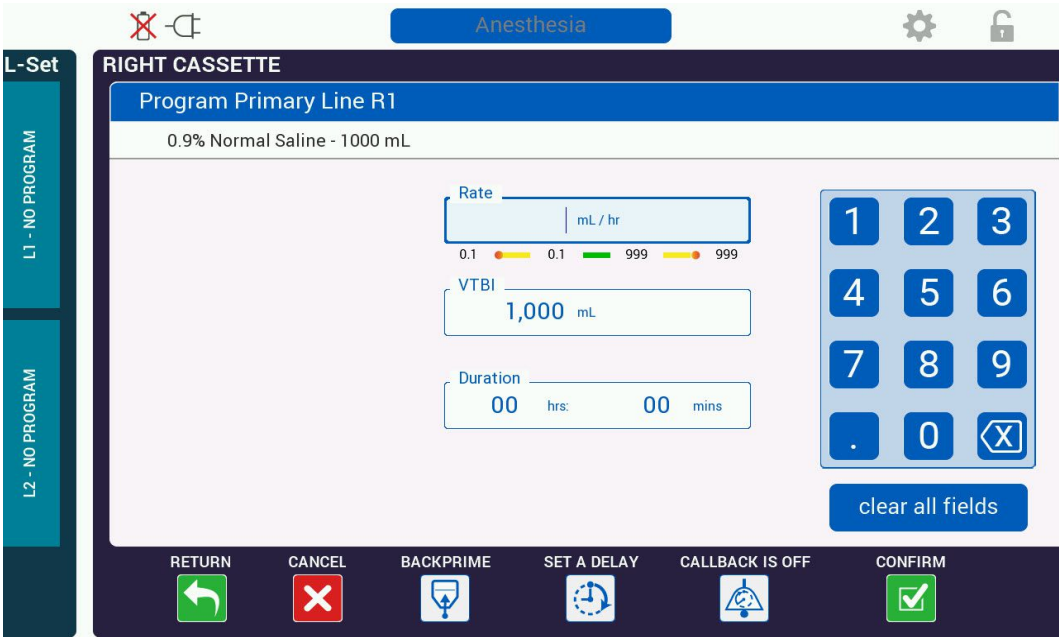


Depending on how the medication is configured through the drug library, the user may have the option to configure with a Loading Dose or Multistep, along with a Primary Infusion. If the drug ruleset is configured for Bolus, then Bolus will be available during delivery. Tap one of the options to select it.

Setting Values Through the Programming Page



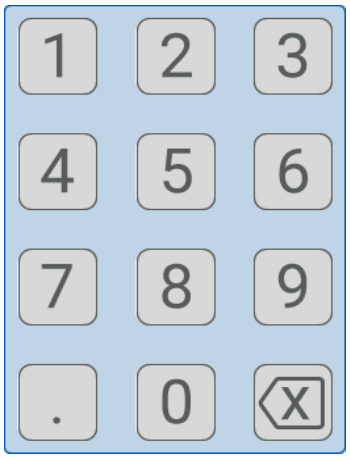
The Programming page is used to set values for an infusion, such as Dose, Rate, VTBI, and Duration. You can select a field by tapping it. When you have done so, the field will change color, the value's limit bar will appear, and the keypad on the right will unlock.



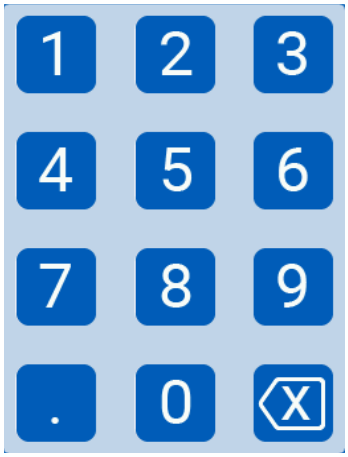
NOTE: You must touch the hours and minutes fields separately when programming duration.

Keypad Interactions

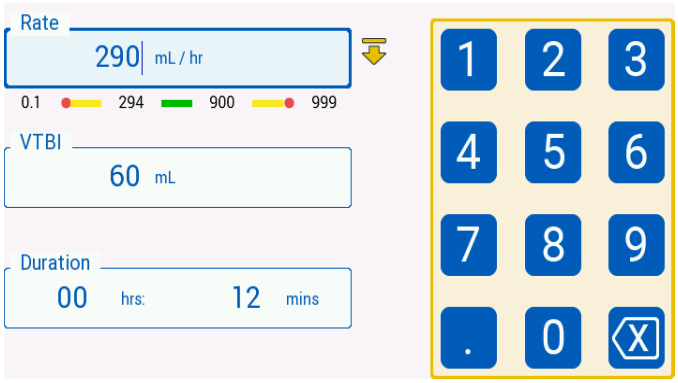
The keypad on the Programming page will display differently depending on user interactions.



The keypad will appear grayed out when first navigating to the programming page and before selecting a programming field (Dose, Rate, VTBI). The keypad cannot be interacted with in this state.



The keypad will change colors once a programming field has been selected. It can now be interacted with.



The keypad background will turn yellow, and a yellow arrow will appear, when a value falls below or above a soft limit. The direction of the arrow, as well as the value's limit bar, indicates if it is an upper or lower soft limit.

Example: the yellow arrow here indicates that the Rate of 290 mL/hr falls below the soft limit of 294 mL/hr.

The keypad background will turn red, and a red arrow will appear, when a value falls below or above a hard limit. The direction of the arrow, as well as an alert message below the relevant field, indicates if it is an upper or lower hard limit. The keypad will gray out except for the backspace button, which must be pressed to clear the field that triggered the hard limit. Once the field has been cleared, a value within the drug's hard limit may be entered.

Dose Calculation

Initial programming allows the clinician to enter two of the three programming parameters (Rate, VTBI, or Duration) and the third is automatically calculated.

1st Action	2nd Action	[AUTOCALC]
enter RATE	enter VTBI	DURATION
enter VTBI	enter DURATION	RATE
enter RATE	enter DURATION	VTBI

Recalculation Alert

There are three conditions that can trigger a Recalculation Alert.

1. Anytime a pump does a calculation that drives the VTBI higher than the selected concentration, a recalculation alert displays.

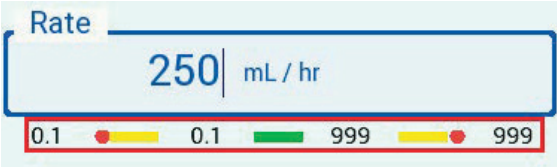
2. If a recalculation occurs on the dose of a non-time-based infusion, a Recalculation Alert will be displayed.
3. If you change the Duration of a confirmed mL/hr or non-time-based dosing unit program and tap START to confirm the titration, a Recalculation Alert will be displayed indicating that the rate has been recalculated due to the duration change.

When the alert appears, tap CONTINUE to continue to the Review page or tap EDIT to remain on the Programming page.

The Recalculation Alert will not occur for initial programming or programming after a VTBI Complete alarm.

Understanding Limits

Medications may have hard and soft limits configured through the drug library. These limits will be displayed using the limit bar under the relevant field on the Programming page.



If the user programs outside a drug's soft limits, the soft limit override icon appears and the keypad turns yellow. After tapping CONFIRM, the infusion pump will notify them to accept or edit the programmed infusion

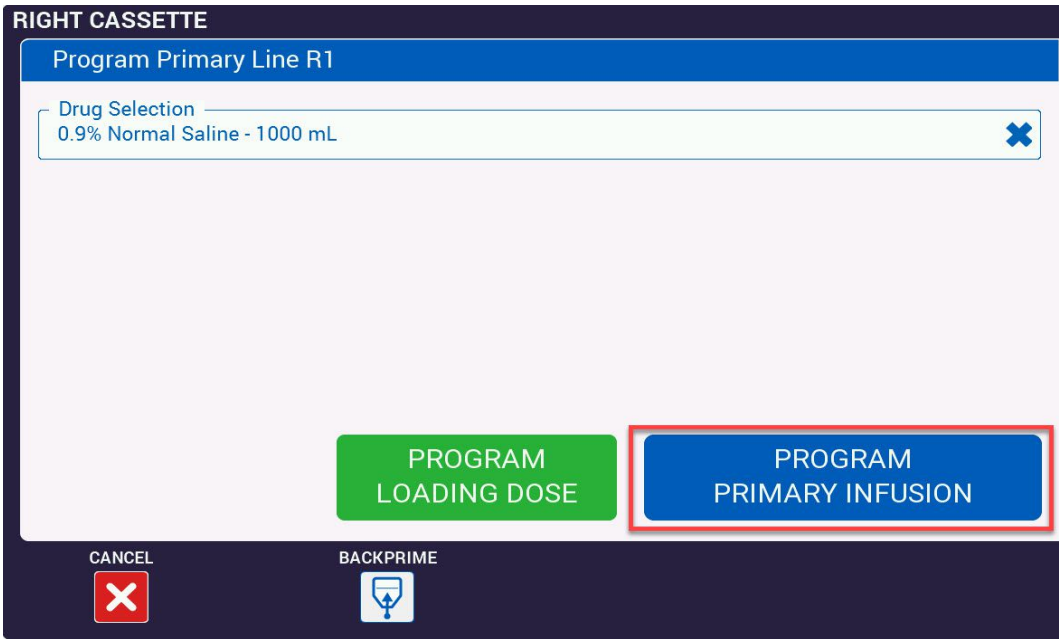
If the user programs outside a drug's hard limit, the relevant field turns red and is cleared. The pump will then notify them to edit within the approved limits. Tap the backspace button to clear the entry and enter a new value.

Primary/Single Step Infusion

To program a primary infusion:

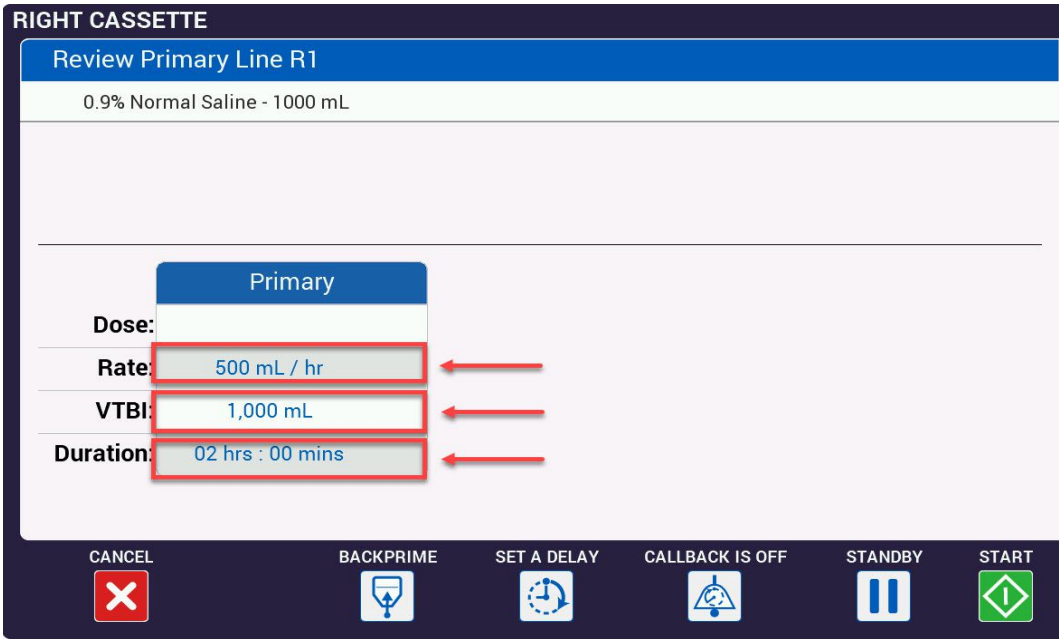
1. Tap LEFT LINE PRIMARY - L1 or RIGHT LINE PRIMARY - R1, depending on which side the cassette has been inserted into.
2. Locate the drug in the Drug Selection page by scrolling through the alphabetized list, or by typing the name of the drug. The selection of drugs will narrow as you tap each letter.
3. Tap the drug and container volume.

4. Select PROGRAM PRIMARY INFUSION.



5. Input the rate, VTBI, and/or duration of infusion using the keypad.

6. Tap CONFIRM and review the program on the Review page.
   If the program requires editing, tap the relevant field to be directed back to the Programming page.



WARNING: CONFIRM AND VERIFY ALL THERAPY VALUES BEFORE TAPPING START.

7. Tap START to begin infusing.

Secondary Infusion: Concurrent and Piggyback

The Plum Duo infusion pump allows for a secondary infusion on both channels. There are two delivery modes for a secondary infusion: Concurrent and Piggyback. During Concurrent delivery, both lines will infuse at the same time. Bolus and Loading Dose are prohibited with Concurrent delivery. Concurrent delivery is prohibited if the max flow rate of both lines would exceed 500 mL/hr, or if the minimum flow rate of both lines would fall below 0.5 mL/hr.

Piggyback delivery suspends the primary line delivery while the secondary line infuses. By default, the primary line resumes when the secondary line completes. Piggyback delivery may only be used if the drug on the primary line is configured to be interruptible in the safety software. Additionally, the drug to be piggybacked must be configured to be deliverable in this mode.

NOTE: For Plum Duo release 1.1, a drug may be configured in the safety software for Primary Only delivery. This allows the primary infusion to be delivered alone, prohibiting selection of the secondary line for delivery.

Backprime

WARNING: HERE IS A POSSIBILITY OF THE SECONDARY SOLUTION BEING DILUTED WITH THE PRIMARY SOLUTION DURING BACKPRIMING.

WARNING: BACKPRIMING SHOULD NOT BE PERFORMED FOR RECONSTITUTING SECONDARY CONTAINERS CONTAINING DRY POWDERS.

Backpriming resolves upstream air-in-line alarms on primary and secondary lines without the need to disconnect the administration set from a patient. Backpriming can also relieve built-up pressure in the cassette caused by some occlusion conditions, resolving the occlusion alarms while the patient is still connected to the set. However, backpriming is not necessary to clear alarms. See ***List of Alarms and Corrective Actions*** for alarms that can be resolved by backpriming and their corrective actions.

During a backprime, fluid is pumped from the container on the primary line to a line or syringe attached to the secondary port at a rate of approximately 1 mL every 5 seconds. In the process, air is cleared from the cassette air trap and upstream line(s). The pump closes valves to ensure that the backprimed fluid never reaches the patient.

Preparing to Backprime

To accept the backprimed air and/or fluid, a line with a container or syringe must be attached to the secondary port. This attachment prevents upstream occlusion alarms on the secondary line during the backprime operation.

NOTE: If you are using a syringe adapter, you must open and close the lever before you will be able to backprime.

NOTE: A small amount of fluid may be expelled from the set (less than or equal to 0.05 mL) after backpriming. If potent drugs are being used, take appropriate action to guard against over-medication of the patient.

Setup for Backpriming into a Secondary Line

If you already have a delivery set up for the secondary line, you can backprime into the secondary line fluid container. This setup will resolve an upstream air-in-line alarm for either lines.

NOTE: Since the Plum Duo infusion pump delivers the exact VTBI that is programmed for a line, you may need to adjust the VTBI on the secondary line to account for the extra volume from backprimed fluid.

Setup for Backpriming into a Syringe

If you do not have a delivery set up on the primary line, or you need to avoid pumping air and fluid from the primary line into the secondary, you can attach a syringe to the secondary port to accept the fluid and/or air from the primary line and the cassette when backpriming.

NOTE: Before you begin a backprime, ensure that the syringe has enough free space to accept the backprimed fluid. Backpriming into a full syringe will trigger an upstream occlusion alarm.

Backpriming Procedure

Before you begin a backprime, ensure that there is a line or syringe on the secondary port and a secondary container to accept the backprimed fluid and expelled air.

To backprime:

1. Stop any active infusions on the relevant side of the pump.
2. Press and hold BACKPRIME until fluid pumped from the primary line to the secondary line clears air from the cassette and from the secondary line (if present).
   When you release the BACKPRIME button, the infusion pump performs a cassette test.
3. If the cassette test detects that there is still air in the line, repeat Step 2 until the cassette test is successful.
4. Tap START to restart the delivery.

NOTE: If the cassette test fails, tap BACKPRIME to close the pop-up, and then hold down BACKPRIME as described above to clear air from the cassette.

Flush

The Flush feature enables the clinician to flush the downstream tubing volume after a piggyback therapy. The programmed Flush volume is delivered from the primary line container at the piggyback therapy rate after the Piggyback therapy completes.

A flush can be programmed under the following conditions:

- the primary line is programmed with a medication that is interruptible
- the primary line cannot be in Delayed Start, Standby, or programmed as a Multistep delivery
- the primary line VTBI must be greater than the Flush volume
- the secondary line delivery mode is Piggyback

Flush duration and volume are not considered when the infusion pump is checking for Hard Limit or Soft Limit violations for the primary or secondary line programs.

To program a flush with a new Piggyback delivery under the conditions listed above:

1. On the Review page, tap CLICK TO ADD LINE FLUSH.
2. Input the flush VTBI using the keypad.
3. Tap CONFIRM.
   The Review page appears.
4. Tap START.

You can also add flush to an infusion from the Delivery page. To do so, tap ADD FLUSH on the secondary delivery and follow steps 2-4 above.

When the Piggyback VTBI reaches 0, the flush will be delivered from the primary line container at the secondary line Piggyback delivery rate until the flush has been delivered. The primary line will display FLUSHING LINE.

Multi-Step

Multistep delivery is a sequential program that can deliver up to 10 steps from one container at different rate/dose/VTBI and durations using the same dosing unit and concentration. Multi-step delivery is available for drugs not configured for bolus.

NOTE: For Plum Duo release 1.1, multi-step delivery is only available when configured for the drug at the ruleset.

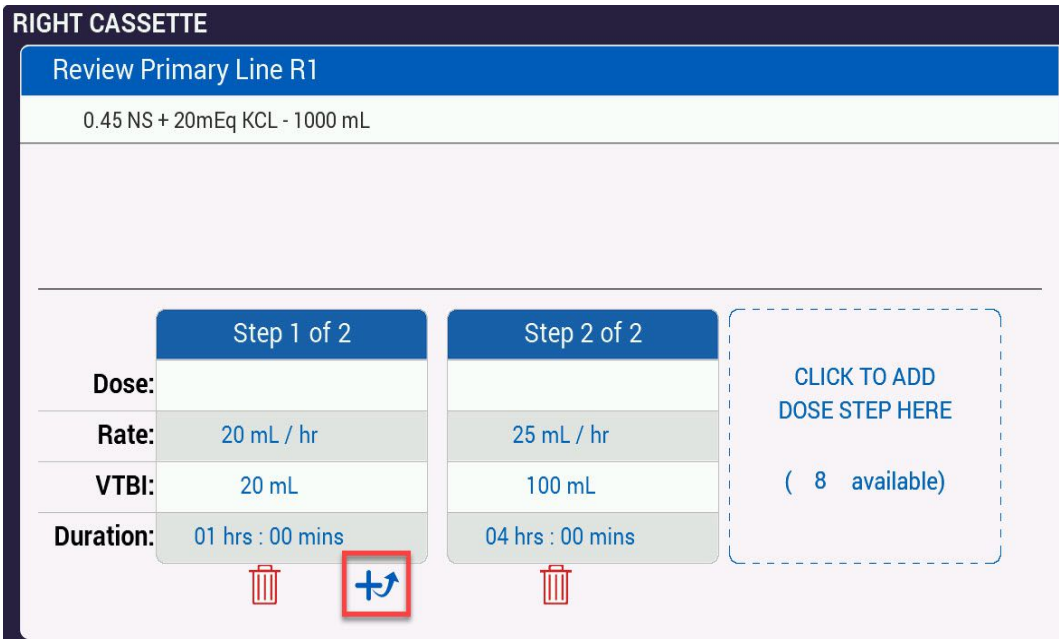
To program a Multi-Step infusion:

1. Tap Program Multi-step.
2. See ***Setting Patient Parameters*** and ***Titration*** for inputting values.
3. On the Review page, tap CLICK TO ADD DOSE STEP HERE to add a step.
   The Programming page for the step appears.

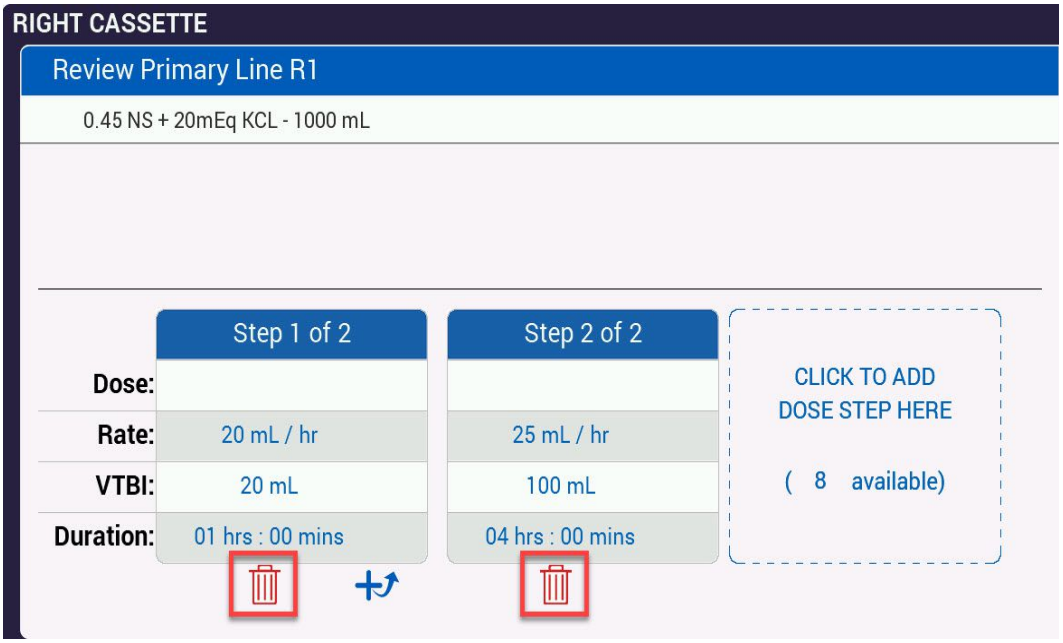
NOTE: The currently selected step number is displayed at the top of the Programming page.

4. Follow steps 2-3 as necessary.

5. To insert a step between other steps, tap the plus icon below the previous step.



6. To delete a step, tap the red trash icon below the relevant step.



7. If a certain number of steps are added (3 or more on the primary line, 2 or more on the secondary line) the START button will turn into a REVIEW button, and a review of all steps is required prior to starting. Once the steps have been reviewed, the REVIEW button will turn back into a START button.

8. Tap START to begin infusing.

NOTE: The current step number is displayed on the Main Delivery page.

NOTE: Steps may be added, edited, or deleted on a running infusion. However, you cannot delete an active step.

Adding VTBI to Multistep Program After VTBI Complete Alarm Activates

During a Multistep delivery, after the VTBI Complete alarm activates and post-infusion rate delivery has begun, as long as the post-delivery rate infusion has not been stopped you can add more VTBI to the last delivery step, if needed. If you stop infusion after VTBI has completed, you can add more VTBI, but you must add it to all delivery steps before restarting the program.

NOTE: For Plum Duo release 1.1, a stopped infusion may be restarted by adding VTBI to the last step only.

To add VTBI to a Multi-step program:

1. Select the line.
2. Navigate to the VTBI for the last step. Step display indicators will have returned to the step number, indicating it is editable.
3. Enter a VTBI.

To stop the post-infusion rate and add more VTBI to all steps:

1. Stop the line running the program to which you want to add more VTBI.

NOTE: When adding VTBI, you can also update other step parameters if necessary.

2. Tap the drug name to navigate to the Review page.
3. Tap the step to be edited.
   The Program screen for that step appears.
4. Enter the VTBI and confirm.

NOTE: You must add VTBI to all steps.

5. Repeat as needed for all steps
6. Press START to restart infusion.

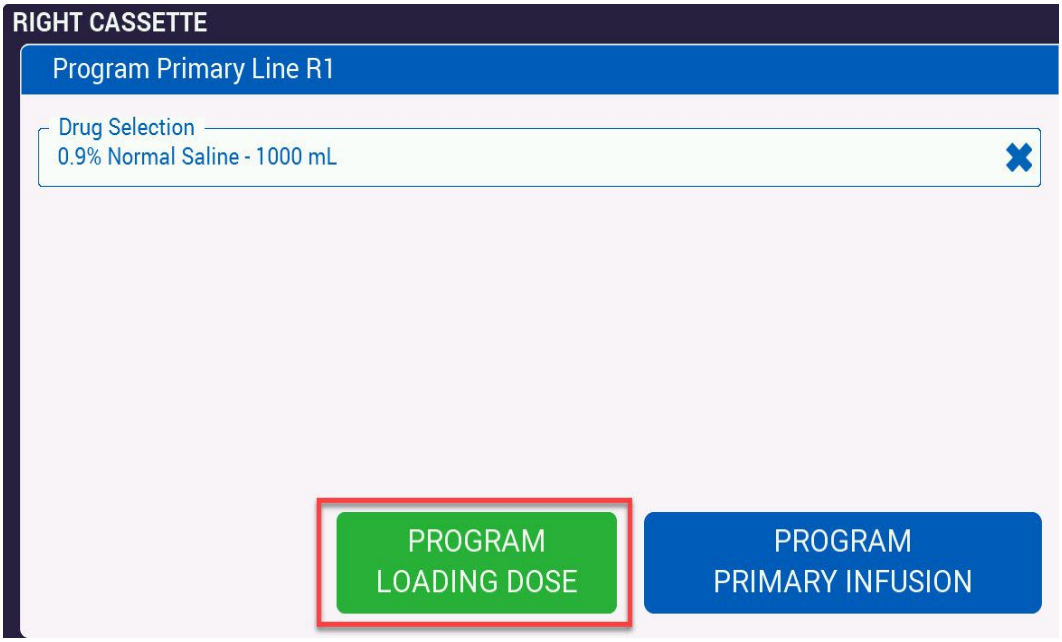
Loading Dose

A Loading Dose delivery is defined as a rapid infusion of a relatively large volume of fluid or dose of the drug currently being administered (same medication, concentration, and dosing unit) to magnify a therapeutic response. A stand-alone loading dose of a new medication can be delivered. Loading Dose is available when Bolus is configured for a drug and the two delivery methods will have the same limits. Additionally, the device must be in Piggyback mode (not Concurrent mode) if the Loading Dose is to be delivered on the secondary line. A Loading Dose cannot be repeated, and is not available once the continuous infusion has started.

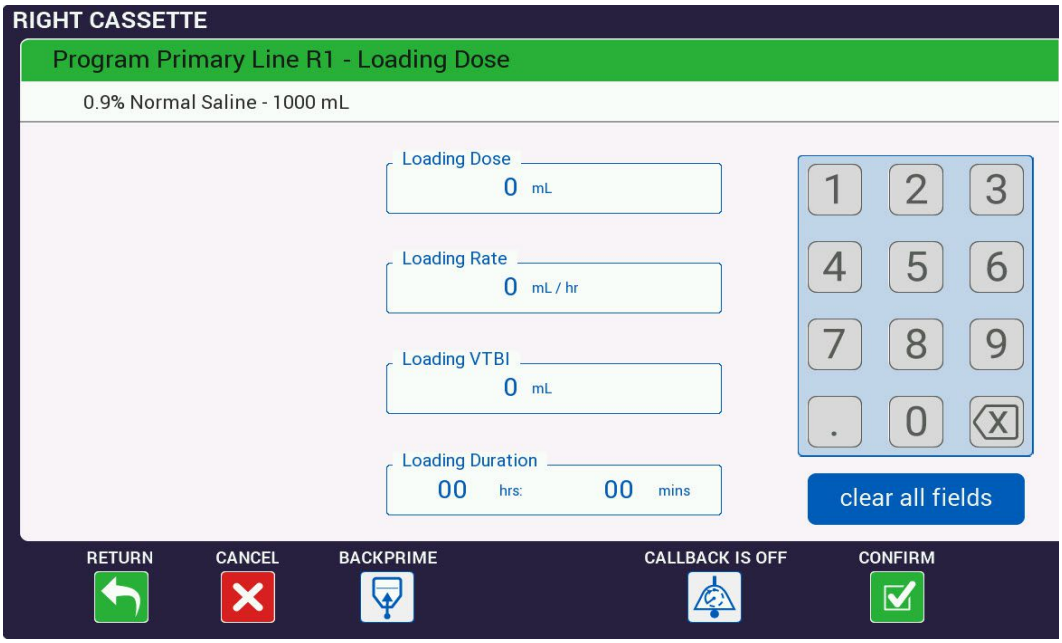
NOTE: For Plum Duo release 1.1, Loading Dose will only be available when configured for a drug at the ruleset. It may also have separate limits from a Bolus delivery.

To program a Loading Dose Delivery:

1. Tap PROGRAM LOADING DOSE.



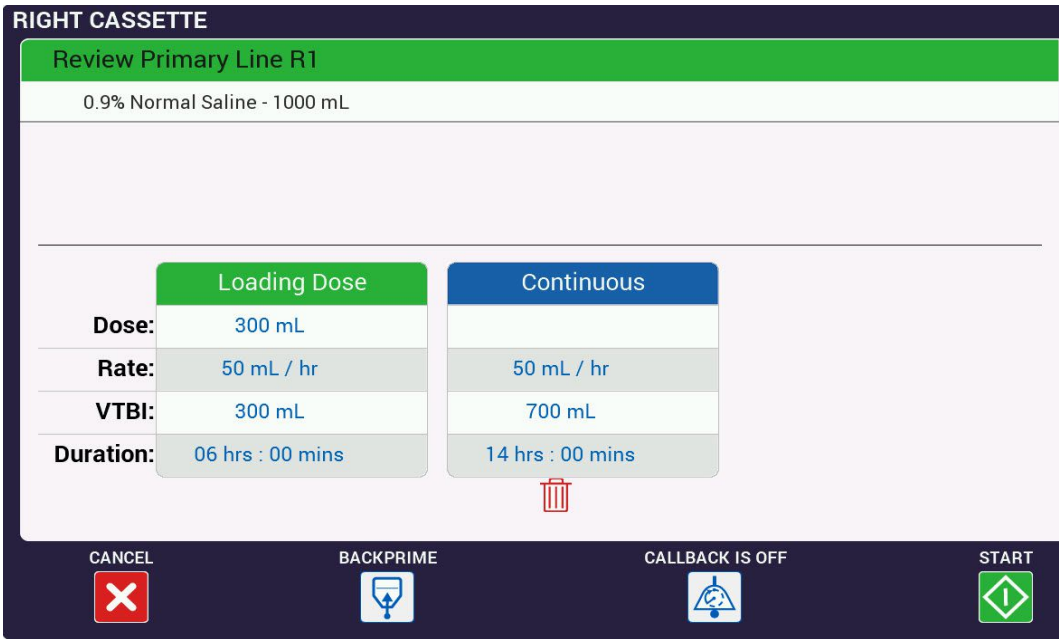
2. Input Dose, Rate, VTBI, and Duration.



NOTE: Some values will auto-calculate as you fill certain fields.

3. Tap CONFIRM.
   The Review page appears.
4. To program the continuous infusion, tap CLICK TO ADD CONTINUOUS.
5. Input Dose, Rate, VTBI, and Duration for the continuous infusion.
6. Tap CONFIRM.
   The Review page appears.

7. Review the parameters.



8. Tap START to begin infusion.

Bolus

A Bolus delivery is defined as a rapid infusion of a relatively large volume of fluid or dose of the drug currently being administered (same medication, concentration, and dosing unit) to magnify a therapeutic response. A stand-alone bolus dose of a new medication cannot be delivered. Bolus can be delivered from the primary or secondary line (the latter only while in piggyback mode). Those medications which can be delivered by bolus will have dose, time, and bolus limits defined in the drug library.

NOTE: For Plum Duo release 1.1, a stand-alone bolus dose of a new medication can be delivered.

A Bolus can be completed only if the following conditions are present:

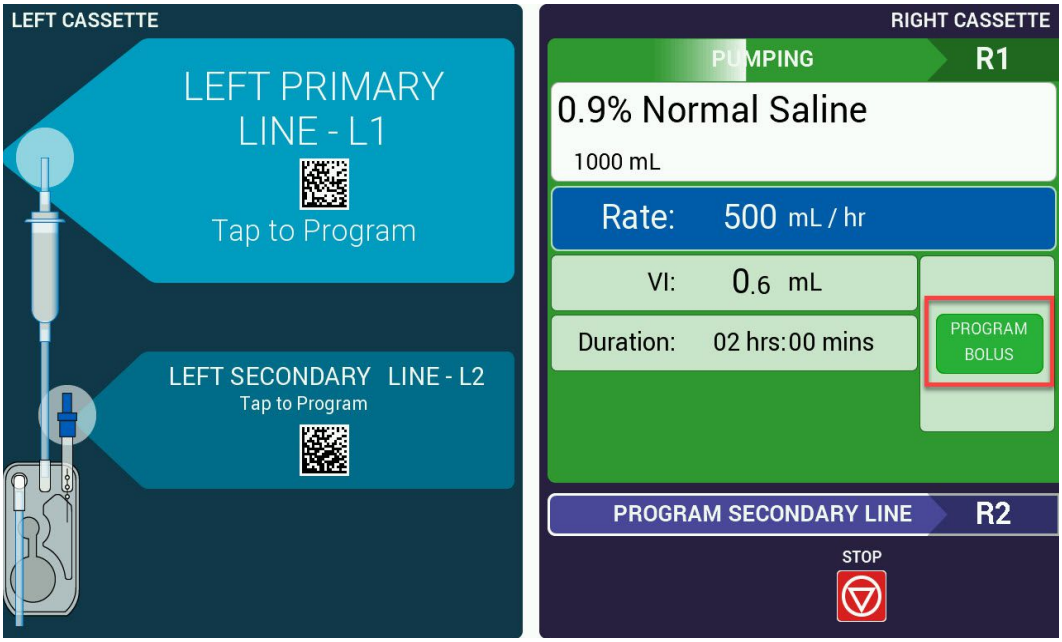
- Bolus Dose is enabled within the medication's selected profile at the ruleset level,
- there is adequate VTBI of the medication to complete the bolus dose, and
- the device is in Piggyback mode (not Concurrent mode) if the bolus is to be delivered on the secondary line

Bolus can be delivered as a standalone infusion (not requiring the continuous infusion), but continuous infusion may be added during or after the bolus delivery.

Programming a Bolus Dose

To program a Bolus Dose:

1. For a Bolus Dose from a continuous infusion, tap PROGRAM BOLUS on the relevant infusion.



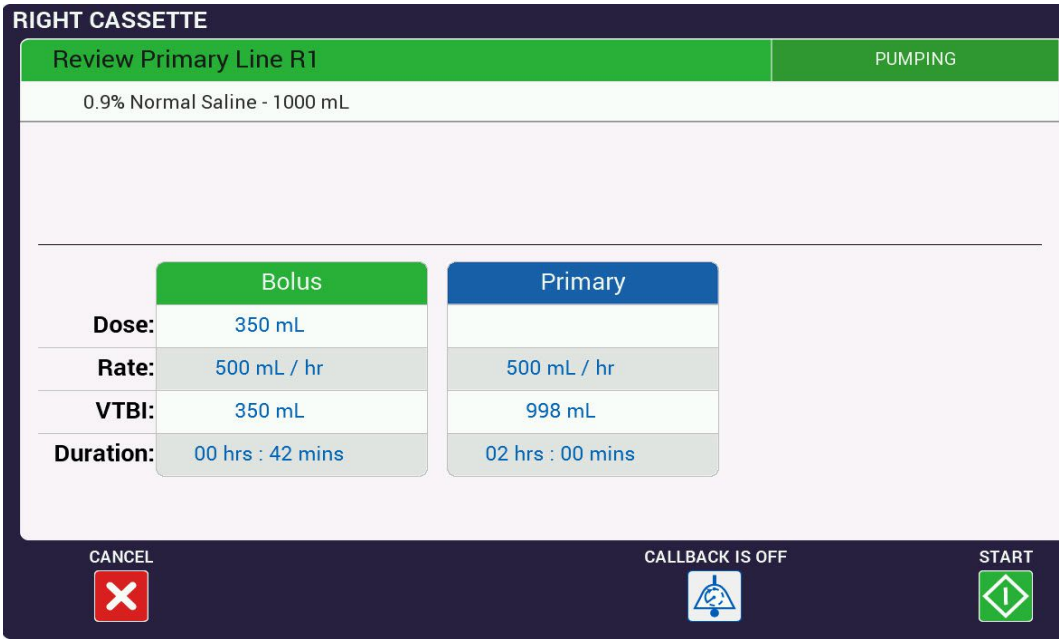
   The Programming page appears.

2. Input Dose, Rate, VTBI, and Duration.

NOTE: Some values will auto-calculate as you fill certain fields.

3. Tap CONFIRM.

   The Review page appears.

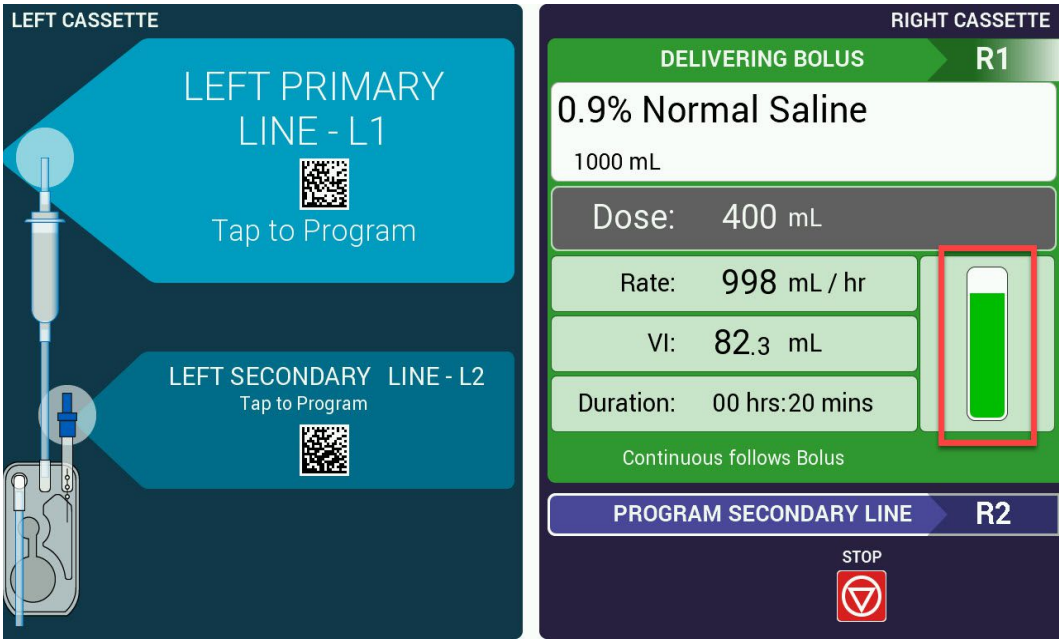


4. Review the parameters.

5. Tap START to begin infusion.

NOTE: If a bolus is delivered on the secondary line, the Main Delivery screen will show BOLUS on the secondary line. Upon completion, the infusion pump will resume the piggyback which was previously infusing and the nurse callback alarm will activate if configured. If the primary line was previously in a PENDING state, it will remain in PENDING until the bolus and the underlying piggyback are complete.

To help the clinician monitor bolus status, the percentage of remaining Bolus VTBI is reflected in the status bar on the Main Delivery page.



Stopping and Clearing a Loading or Bolus Dose Delivery

Once a Loading Dose or Bolus has started, the Loading Dose or Bolus cannot be modified. The continuous infusion may be added and/or modified during Bolus or Load delivery.

To stop and clear a Loading Dose or Bolus:

1. Tap STOP on the Main Delivery page.
2. Tap CLEAR LOAD or CLEAR BOLUS as applicable.
   A confirmation prompt appears.
3. Confirm the clearing.
   The Loading Dose or Bolus is cleared and the continuous infusion displays.
4. You may now clear the continuous infusion by tapping CLEAR PROGRAM, edit it by tapping one of the values, or start the continuous infusion by tapping START.

Callback and Near End of Infusion Alarm

Callback

You can program a Callback Alarm to alert you to each interim step of a Loading Dose, Bolus, or Multistep delivery, or to notify you that a Piggyback delivery has ended. You may also program a near-end of infusion alarm to alert you before an infusion completes.

A Callback Alarm is a medium priority alarm that must be acknowledged by the clinician.

To add a callback alarm to a Loading Dose, Bolus, Multistep, or Piggyback, delivery:

1. Tap the CALLBACK button on the Programming or Review pages.
   The Select Callback Alarms pop-up appears.
2. Select the action to occur after the dose completes and then tap CONFIRM.
   Selecting Stop Delivery will stop delivery and alarm.

To add a near end of infusion alarm:

1. Tap the CALLBACK button on the Programming or Review pages.
2. Tap the Alarm Prior to End of Infusion field.
3. Select the Alarm 10 minutes Prior option from the drop-down.

NOTE: For Plum Duo release 1.1, callback alarm defaults may be configured via the CCA. Additionally, near end of infusion alarm options may be configured at the ruleset.

VTBI Complete Alarm

Upon completion of delivery, the screen will display a "VTBI Complete" message and an alarm will sound. The line will KVO (Keep Vein Open), continue, or stop as defined at the ruleset level. Each CCA may define the KVO rate from 1-20 mL/hr.

1. If a VTBI Complete alarm sounds, you may pause the audio to stop the alarm sound.
2. Tap CLOSE to close the message.
   A confirmation popup appears.
3. Follow the instructions for ***Titration*** to add a new VTBI, or follow the instructions for ***Stopping an Infusion*** and clear the program.

Stopping an Infusion

One or more infusions may be stopped from the Main Delivery page at any time.

To stop one or two infusions on the same side of the pump:

1. Tap STOP at the bottom of the Main Delivery page on the same side as the infusion.
   If only one infusion is running on that side, the infusion will cease.
   If more than one line on a side is currently infusing, a popup appears.

   Alternatively, tap STOP on the Review page to stop that particular infusion.
2. Select the line(s) to stop.
   Infusion on the selected line(s) will cease.

To clear the program, tap CLEAR PROGRAM in the stopped infusion. To edit the program, follow the instructions for ***Titration***. To restart the program, see ***Restarting an Infusion***.

WARNING: CLOSE ALL CLAMPS BEFORE OPENING THE CASSETTE DOOR.

Alternatively, you may stop the infusion on one or both lines of a channel by opening the cassette door on that side of the pump.

Restarting an Infusion

To restart a stopped infusion:

1. Tap START on the Main Delivery page.
   If only one infusion on that side is stopped, infusion restarts.

   Alternatively, tap START on the Review page to restart that particular infusion.
2. If more than one line on the same side is stopped, select which line(s) you wish to restart.

Changing Delivery Modes on the Secondary Line

You can change the delivery mode of the Secondary Line from the Review page.

To change the delivery mode on the Secondary Line:

1. Navigate to the Review page of the relevant infusion.
2. Tap the Piggyback-Concurrent widget to change selections.
3. Tap CONFIRM.

NOTE: See ***Secondary Infusion: Concurrent and Piggyback*** for concurrent flow rate parameters.

Titration

Titration is a change in Dose/Rate, Duration, and/or VTBI in a running infusion.

To titrate a line:

1. Tap the field to be changed (Rate, VI, or Duration) on the Main Delivery page.
   The Programming page appears and the relevant field will be selected.

   Alternately, tap the name of the drug to navigate to the Review page, and then tap the field to be changed.
   The Programming page appears and the relevant field will be selected.
2. Edit one or more fields by tapping them and using the keypad.
3. Confirm the change by tapping CONFIRM.

4. Review the edited infusion and then tap START.

NOTE: Titration cannot be performed on a bolus or load after it has started. Titration can be performed on a continuous infusion during a load or bolus delivery.

Titration with Multistep Delivery

In a Multistep delivery, titration may be performed on any steps where VTBI is not complete, including the step currently infusing. To titrate a Multistep delivery, follow the instructions for ***Titration***, selecting the relevant steps from the Review page. You may scroll through the steps by swiping your finger horizontally. A review of all steps is required to start the infusion.

Standby

Standby allows you to postpone delivery start for a maximum of 24 to 72 hours. The default setting is 72 hours. The maximum standby time is configured by the Biomed technician or safety software and is defined by the currently programmed CCA. If a line is on standby and the maximum time expires, the program on the line is cleared and the infusion pump alarms 2 minutes later if there has been no interaction on either line. Standby is only available during initial infusion programming and on stopped infusion.

Putting a Line on Standby from the Review Page

To put a line on Standby from the Review page:

1. Program a line. See ***Programming*** for options..
2. Once you reach the Review page, tap STANDBY.
   A confirmation pop-up appears.
3. Tap YES to confirm and place the line on standby.
   The line is now on standby, as displayed on the Main Delivery page.

Putting 1 or 2 Lines on Standby During Active Infusion

To put lines on Standby during an active infusion:

1. Tap STOP on the Main Delivery page.
2. If both lines on the same side are infusing, select the line(s) you wish to place on standby.

NOTE: You must stop a line before it can be put on standby.

3. Tap STANDBY on the Main Delivery page.
4. Select the line(s) you wish to place on standby.
   The line(s) are now on standby, as displayed on the Main Delivery page.

Cancel Standby on 1 or 2 Lines

To cancel Standby:

1. From the Main Delivery page, tap START or STOP.
2. Select one or both lines to START or STOP.

Delay Start

To program a line with a delayed start:

1. Program the line. See ***Programming*** for options.
2. Once you reach the Review page, tap SET A DELAY.
3. Tap the hours and minutes fields under Delay Duration.
4. Scroll through the hours and minute drop down by swiping your finger and tap the desired hours and minutes, which can be any period between 1 minute and 23 hours and 59 minutes.
5. Tap CONFIRM.
6. Tap SET DELAY.
   You may view the remaining delay duration on the Main Delivery page, next to START DELAYED. Once the delay duration ends, the line will begin infusing.

Editing Delay Duration

To edit the duration of a delayed start:

1. Tap the programmed drug on the Main Delivery page.
   The Review page appears.
2. Tap DELAY IS SET.
3. Set a new duration by tapping the hours and minutes fields under Delay Duration.
4. Tap CONFIRM.
5. Tap SET DELAY.
   Delay duration is edited and now appears on the Main Delivery page, next to START DELAYED. Once the delay duration ends, the selected line begins infusing.

Ending a Delay Early

To end a delayed start early:

1. Tap CANCEL DELAY on the Main Delivery page.
2. The delay will be canceled, and the infusion will be set to STOPPED.
3. Tap START to begin the infusion.

Smart Pump Auto-Programming

NOTE: Smart Pump Auto-Programming is a Plum Duo 1.1 feature.

Smart Pump Auto-Programming, also known as Auto-Programming (AP) or Smart Pump Programming (SPP), is the ability to take an I.V. medication order from the Bar Code Medication Administration (BCMA) system and translate it into operational settings that can automatically populate the infusion pump. Order taking is done by using the BCMA application and its bar code scanner to scan the patient's identification, the medication container, and the pump. Scanned information is transferred to the infusion pump via its wireless antenna.

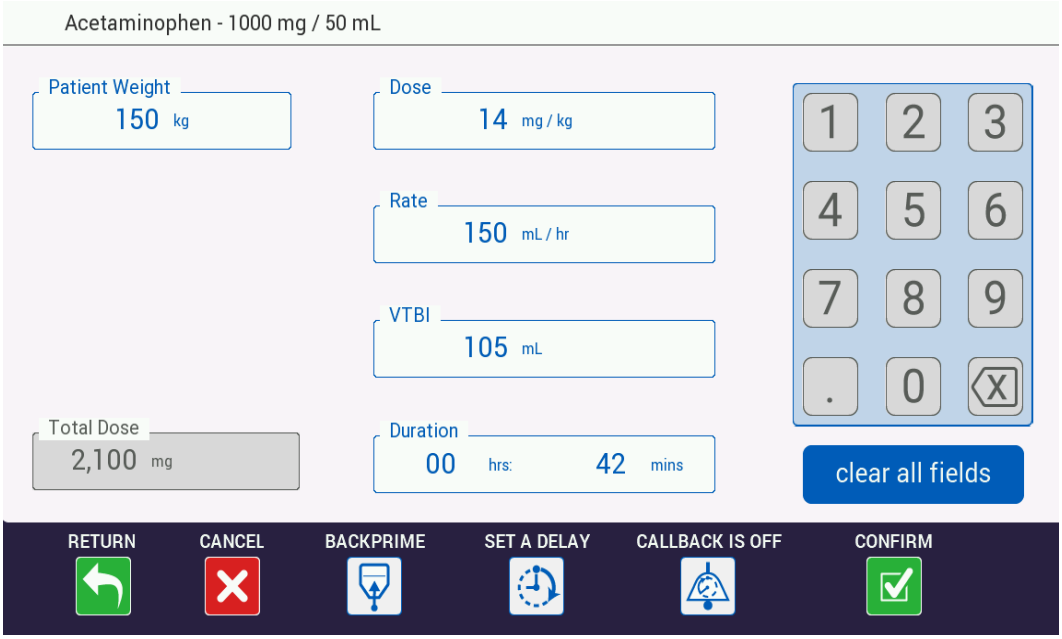
Smart Pump Auto-Programming with the Plum Duo Infusion Pump

Before you begin programming, make sure a cassette is installed in the infusion pump.

To perform Smart Pump Auto-Programming:

1. Press the ON/OFF button.
   The infusion pump begins its startup process.
2. Answer the New Patient prompt on the pump screen.
3. Select a CCA.
4. Follow your hospital's procedure to activate your BCMA device.
5. Scan the patient wristband to retrieve the patient's task list on the device.
6. Scan the medication. The I.V. task and documentation with order details are displayed on the device.
7. Scan the data matrix code (the white box containing black squares) for the desired line on the pump's user interface.

The programming page will appear on the pump screen, with the fields automatically filled.



NOTE: If the scanned medication does not exist in the drug library, no medication will be displayed on the infusion pump and "No Drug Selected" will be shown on the subsequent screens.

NOTE: If you have difficulty scanning the pump's data matrix code, you may tap the barcode to reveal the pump's barcode number. Input this number into your facility's BCMA device/EHR to facilitate order transfer.

8. Verify ALL parameters. If changes are desired, you can manually change the infusion parameters using the keypad.
9. When all values are completed, tap CONFIRM on the pump screen to confirm the program with the received order.
10. Tap START on the pump screen to begin delivery.
    The BCMA will confirm the program with the original order.
11. Complete the transaction on the BCMA unit or document the process per hospital procedure.

Smart Pump Auto-Programming Rejections

If a physician's order for an automatically programmed therapy exceeds the capabilities of the infusion pump or is above a hospital-defined hard drug limit, the order will be rejected. If your order is rejected, recheck the order.

The following table is a list of smart pump auto-programming rejection messages and operator actions to respond to rejections.

Message	Action
The incoming program was rejected because there is no custom drug library installed.	Tap OK or wait for the screen to automatically dismiss.
The incoming program received did not contain all required information.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected due to invalid data.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected by LifeShield due to drug library incompatibility.	Tap OK or wait for the screen to automatically dismiss.
The incoming program is for a line which is in Standby. Clear the line and resubmit the incoming program.	Tap OK or wait for the screen to automatically dismiss.
The incoming program is for a line which is in Delay Start. Clear the line and resubmit the incoming program.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the dosing units do not match the medication units.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected for Line 2 The medication delivering on Line 1 cannot be interrupted and concurrent delivery is not possible. Either the combined rate of Line 1 and 2 was greater than 500 mL/hr or less than 0.5 mL/hr for each line.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the combined rate of Line 1 and Line 2 cannot exceed 500 mL/hr in concurrent mode.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the rate on each line must be greater than 0.5 mL/hr while in concurrent mode.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it is a titration for a line that has no confirmed program.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because titration is not allowed on a "No Drug Selected" program.	Tap OK or wait for the screen to automatically dismiss.

Message	Action
The incoming program was rejected because the medication cannot be infused as a Piggyback.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the duration cannot be changed.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the medication on Line 1 cannot be interrupted.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it is for a different medication / concentration than is currently infusing.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the line is currently delivering.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the selected line has an unconfirmed existing program. Resubmit the program to resolve.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it contained a titration parameter that is not allowed for this type of infusion.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected due to the inability to accommodate a Multistep program.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the pump is alarming. Clear alarm and resubmit the incoming program.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because a passcode is required.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the received parameters will not result in a valid dose.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected for Line 1. The medication in the incoming program is not interruptible and Line 2 is delivering a Piggyback infusion.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the line is currently delivering a load or bolus.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because there is no cassette installed.	Tap OK or wait for the screen to automatically dismiss.

Message	Action
The incoming program was rejected by LifeShield due to incomplete or corrupt data.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the line has a pending CCA change.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it contained a medication which is different from what is delivering on the programmed line.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it exceeds a pump limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it exceeded a CCA limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because it exceeded a hard limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the patient BSA exceeds the pump limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program was rejected because the patient height exceeds the pump limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program received contains a value that exceeds a system limit or the values cause a calculated parameter to exceed a system limit.	Tap OK or wait for the screen to automatically dismiss.
The incoming program contains duration programming, but duration titration is prohibited for this dosing unit.	Tap OK or wait for the screen to automatically dismiss.

Alarms and Troubleshooting

The Plum Duo infusion pump has an intelligent alarm system that handles more than one alarm simultaneously. An alarm condition is determined by a number of variables, including time. Alarms have two components, a message that appears on the display and an audible signal. You can distinguish the priority (high, medium, or low) by the number of beeps and/or the alarm color.

Priority	Number of Beeps	Alarm Color
High	Repeating 10-note melody	Red
Medium	Single three-note melody	Yellow
Low	Single two-note melody	Blue

The alarm sound pressure range is from 45 dBa to 70 dBa, depending on the setting of the alarm loudness control located in the Pump Settings page.

The alarm sound pressure is measured in accordance with IEC 60601-1-8:2012.

WARNING: SETTING THE ALARM SOUND PRESSURE LEVEL LOWER THAN THE AMBIENT SOUND PRESSURE LEVEL CAN IMPEDE OPERATOR RECOGNITION OF ALARM CONDITIONS.

NOTE: Any triggered alarm during an infusion in the Right Channel does not cause the Left Channel to stop pumping, or vice versa, as they are independent delivery mechanisms.

Alarms

Responding to an Alarm

1. If the pump user interface is locked and requires a passcode, tap the touchscreen. Or, if inadvertent touch protection is active, swipe to unlock.
2. If the pump user interface was locked using a passcode, enter the passcode to gain access to the alarm pop-up.
3. Check the display for the alarm message.
4. Tap SILENCE to silence the audible part of an alarm for 2 minutes. The alarm symbol on the display flashes when the alarm is active.

5. Tap CLOSE to remove the alarm message from view, but with the ability to recall it during alarm resolution.
   Or, tap CLEAR to clear the current alarm from the infusion pump.
6. If you selected CLOSE, tap the alarm button to recall alarm messaging if needed.
   The alarm icon flashes until the alarm condition is resolved.

NOTE: The Low Battery alarm is silenced for 15 minutes.

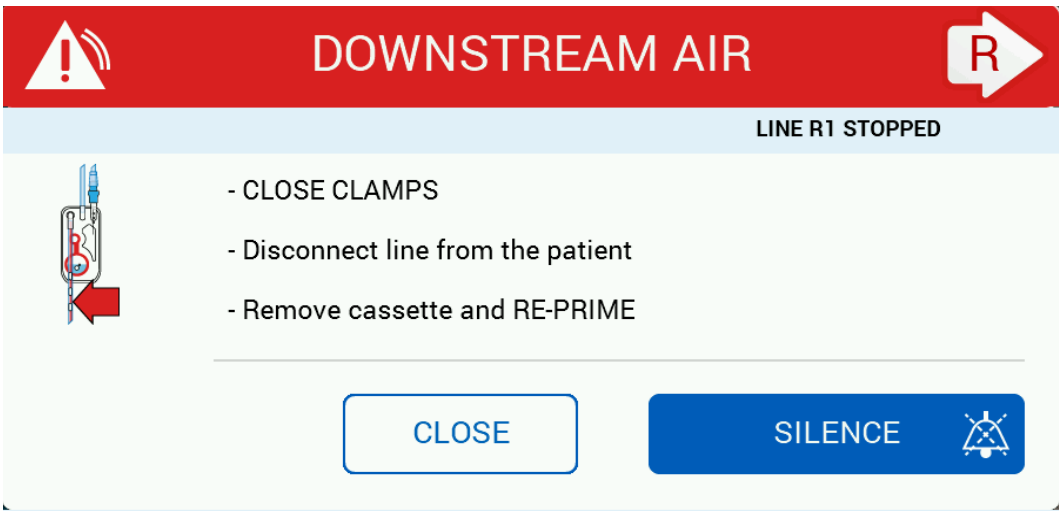
NOTE: Alarm sounds resume after the silence period expires, but can be paused again if resolving the alarm condition takes more time.

7. Correct the alarm condition (see ***List of Alarms and Corrective Actions***).
8. Press START to resume infusion. If more than one line is programmed, tap the line you wish to resume, or BOTH.

NOTE: Each alarm puts an entry in the logs. If troubleshooting does not correct the problem, contact the Biomedical department, who can check the logs and further isolate the problem.

NOTE: A malfunction alarm may prompt you to turn off the infusion pump and restart it. This may resolve the alarm condition. If the alarm continues, replace the infusion pump.

Example Alarm Message



Plum Duo alarm messages indicate the alarm's name at the top of the message. The severity of the alarm is shown by the color of the top bar. The affected channel and line(s) are indicated with an arrow in the top left or right corner and a line of text below it. A series of corrective actions is listed below the alarm name. A graphic indicates the possible site of the alarm's cause (for example, if the alarm is triggered by an air bolus in a downstream line, a red arrow will point to a downstream line in the graphic). The direction of the arrow in the graphic does **not** indicate which channel or line(s) are affected.

List of Alarms and Corrective Actions

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
STOPPED WHILE LOCKED **High** **N255**	While the touchscreen user interface was passcode-protected locked, someone pressed the stop or opened the cassette door during delivery.	Primary or Secondary Line	Enter valid key code to unlock.
POWER CYCLE PUMP **High** **Various E### Alarms**	When an issue has been detected that may be resolved with a power cycle.	N/A	Power off the pump, then on. Send for service if the alarm returns.
PUMP MALFUNCTION **High** **Various E### Alarms**	A malfunction has been detected.	N/A	Power off the pump. Close all clamps and remove the cassette(s). Send for service.
PUMP MALFUNCTION **High** **Various E### Alarms**	When a malfunction has been detected to only one channel on the pump.	Right or Left Channel	Send for service when possible. The other channel may be used until a replacement can be obtained. Close all clamps and remove the cassette from malfunctioning channel.
DEPLETED BATTERY; PLUG IN NOW! **High** **N252**	The infusion pump is running on battery power and the battery voltage is below the depleted battery threshold.	N/A	Plug into AC (mains) power source.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
DOOR OPENED **High** **N250**	The Cassette door was opened during deliver yor cassette test.	Right or Left Channel	Close Upstream Clamps to prevent backflow. Stop infusion before opening door. Close cassette door with cassette inserted, if needed to continue. Refrain from opening door during cassette test.
DOWNSTREAM AIR **High** **N234, N233**	The single air bolus or the cumulative air detected at the downstream sensor exceeds the air detection threshold.	Primary or Secondary Line	Close all clamps. Disconnect downstream line from the patient. Remove cassette and re-prime to remove air. Open and close the cassette door. Also see ***Resolving a Downstream Air-in-Line Alarm***.
UPSTREAM AIR **High** **N230, N231**	The single air bolus detected at the upstream sensor in the Primary Line exceeds the air detection threshold. Or The cumulative air detected at the Upstream sensor in Primary Line exceeds the air detection threshold.	Primary Line	Check for empty container on the PRIMARY Line. Backprime into secondary line or syringe to remove air. See ***Backprime***. Press and hold Back Prime. Check the syringe size. See ***Administration Sets and Accessories Guidelines***.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
UPSTREAM AIR **High** **N231**	The single air bolus detected at the upstream sensor in the Secondary Line exceeds the air detection threshold.	Secondary Line	Check for empty container on the SECONDARY Line. Backprime into secondary line or syringe to remove air. See ***Backprime***. Press and hold Back Prime. Check the syringe size. See ***Administration Sets and Accessories Guidelines***.
UPSTREAM OCCLUSION **High** **N188, N189**	An upstream occlusion or air detected on the Primary Line during delivery	Primary Line	Check the Primary upstream line for clamps or kinks and correct any found. Vent any rigid containers. If the occlusion is caused by a closed clamp, open the clamp. If all clamps are open, the alarm may be caused by excessive air that is creating backpressure in the cassette. Backprime into secondary line or syringe to remove air. See ***Backprime***. Check the syringe size. See ***Administration Sets and Accessories Guidelines***.
UPSTREAM OCCLUSION **High** **N189, N188**	An upstream occlusion detected on the Secondary Line during delivery.	Secondary Line	Check the Secondary upstream line for clamps or kinks and correct any found. Make sure the Secondary Line or syringe is attached to the secondary port. Vent any rigid containers.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
PUMP HIGH ABOVE PATIENT **High** **N187**	A downstream occlusion is detected during delivery due to too much backpressure.	N/A	Resolve the increased pressure by lowering the pump on the pole to place it closer to the level of the patient's heart (see ***Delivery Accuracy***) and then resume delivery. **NOTE:** The alarm can also be cleared by clearing the confirmed programs on any programmed line. If this does not resolve, the set may need to be replaced.
DOWNSTREAM OCCLUSION **High** **N186**	A downstream occlusion is detected and either the maximum auto restarts have occurred for the infusion or auto restart was set to zero. Or The Medium Priority Downstream Occlusion (N192) alarm has been active for 60 seconds without the pressure dropping below the downstream occlusion pressure threshold.	Right or Left Channel	Check the downstream line for clamps or kinks and correct any found. Check the patient access. Restart the delivery.
DOWNSTREAM OCCLUSION **High** **N180**	A downstream occlusion was detected during backprime or during the cassette check.	Right or Left Channel	Check the downstream line for clamps or kinks. Resolve the downstream Occlusion. Check patient access. Continue to backprime, as needed. Otherwise, open and close the cassette door.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
PUMP AUDIO FAILURE **High** **E301**	A speaker or audio failure is detected	N/A	Close all the clamps and remove cassette (s) Power off the pump. Send to biomed for service.
CASSETTE CHECK FAILURE **High** **N251**	A faulty cassette, upstream occlusion, or air in cassette detected during cassette integrity test	Right or Left Channel	Close all clamps, remove cassette and re-prime Also, open and close cassette door. Check for and resolve any upstream occlusions. Backprime into a secondary container. Replace administration set if not resolved.
VTBI COMPLETE IN PRIOR CCA **High** **N160**	The Primary Line was programmed under a different CCA than the system one being used and delivery is complete. Or A secondary line in concurrent or in piggyback mode with no primary to follow was programmed under a different CCA and delivery is complete.	Primary or Secondary Line	Stop and clear the delivery on the Primary Line or Secondary Line. Open and close the cassette door. Re-program under current system CCA if the program is needed to continue.
LOAD COMPLETE **High** **N160**	A Loading Dose delivery is complete with a VTBI=0 and no continuous delivery was programmed.	Primary or Secondary Line	Clear the line the Loading Dose was programmed on or program and start a continuous therapy as needed. Open and close the cassette door.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
BOLUS COMPLETE **NOTE:** This alarm is a Plum Duo 1.1 feature. **High** **N160**	A Bolus Dose delivery is complete with a VTBI=0 and no continuous delivery was programmed.	Primary or Secondary Line	Clear the line the Bolus Dose was programmed on or program and start a continuous therapy as needed. Open and close the cassette door.
CALLBACK WITH DELIVERY STOP **High** **N105**	A clinician configured a callback and stop after a Loading Dose, Bolus, or Piggyback; or a step in a Multi-step delivery that completes the infusion and stops with no KVO.	Primary or Secondary Line	Press clear. Clear the delivery on the line or and start the next program, as needed. Open and close the cassette door.
BOLUS COMPLETE IN PRIOR CCA **High** **N160**	The Bolus was programmed under a different CCA than the one being used and delivery is complete.	Primary or Secondary Line	Stop and clear the delivery on the Line. Open and close the cassette door.
LOAD COMPLETE IN PRIOR CCA **High** **N160**	The Loading Dose was programmed under a different CCA than the one being used and delivery is complete.	Primary or Secondary Line	Stop and clear the delivery on the Line. Open and close the cassette door.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
ACTION REQUIRED **High** **N102**	A pop-up is displayed which has not obtained required user interaction within the specified time period. Specified time frames include when no user interaction for: 15 seconds when the user has attempted to stop or start a delivery when both lines are delivering by pressing STOP, but not selecting a line (1, 2 or 1 & 2) or selecting Cancel to complete the action 30 seconds when any alert or dialog message is displayed, such as a soft limit override, when a titrated, bolus, or load program is waiting to be confirmed or started. 2 minutes and a soft limit override alert occurs when a new program is waiting to be confirmed, or when the infusion was stopped, clear was selected, and the pop-up dialog was abandoned.	Primary or Secondary Line	Press Clear. Respond to the pop-up displayed. If the line has not stopped after stop requested: Press BOTH, L/R 1, L/R 2, or CANCEL. If the line was not started after start was requested: Press BOTH, L/R 1, L/R 2, or CANCEL.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
ACTION REQUIRED **High** **N102**	The user has not interacted with the pump within the specified time frame when in the program & review workflows. 30 seconds: When a line is titrated during infusion and CONFIRM or START has not been pressed. When bolus programming initiated and CONFIRM or START has not been pressed. 2 minutes: When a new program has been confirmed and waiting to be started, or placed into standby or delayed start on the review page	Primary or Secondary Line	Press Clear. Review the programming and continue or cancel the programming changes on the line. If on the programming page, confirm or cancel the programming changes. If on the review page, start, cancel the programming changes.
PROGRAM INACTIVITY **High** **N102**	When there has been no interaction for 2 minutes when any Line has been stopped and it has not been cleared or restarted.	Primary or Secondary Line	Press Clear. Review and re-start the program or clear the programming for that line as needed.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
VTBI COMPLETE **High** **N160**	The primary line delivery is complete and line was programmed under the CCA that is currently being used or A Concurrent delivery on the secondary line is complete and the line was programmed under the current CCA.	Primary or Secondary Line	Replace the container (bag). Add VTBI on primary or secondary line, if needed. Or Stop and clear delivery. Open the cassette door.
UNSAFE BATTERY TEMPERATURE **High** **E463**	The battery sensor has detected a high temperature above the threshold.	N/A	Stop and clear delivery immediately. Close all clamps and remove cassettes. Disconnect infusion pump from AC power (mains). Power off. Remove from patient room. Call biomed immediately.
PROGRAMMING LOST **High** **N103**	Software issue detected and the pump is unable to retain delivery parameters.	N/A	The pump can still be used. Reprogram as needed.
DOOR OPENED - DELAYED START **Medium** **N249**	Cassette door was opened while the infusion was in Delayed Start.	Right or Left Channel	Close cassette door with cassette inserted or clear the program.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
UPSTREAM OCCLUSION **Medium** **N184, N183**	Upstream occlusion detected on the Primary Line during backprime or cassette integrity test.	Primary Line	Examine the Primary Line for clamps or kinks. Resolve the occlusion. Vent any rigid containers. Continue backprime or open and close the cassette door. Check the syringe size. See ***Administration Sets and Accessories Guidelines***.
UPSTREAM OCCLUSION **Medium** **N183**	An upstream occlusion detected on Line 2 during cassette integrity test.	Secondary Line	Check the Secondary Line (Line 2) for clamps or kinks. Vent any rigid containers. Make sure a line or syringe is attached to the secondary port and that the line is unclamped or the syringe has enough free space to accept the backprimed fluid. Either backprime or open and close the cassette door. See ***Backprime***. Backprime into secondary line or syringe to remove air. Check the syringe size. See ***Administration Sets and Accessories Guidelines***.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
DOWNSTREAM OCCLUSION **Medium** **N192**	A downstream occlusion is detected and auto-restart is configured, and the maximum number of auto resets have not occurred for the infusion within the last 15 minutes.	Right or Left Channel	Check the downstream line for clamps or kinks and correct any found. No action is necessary if the patient can resolve the alarm condition within 60 seconds of activation (for example, moving an arm to eliminate the occlusion) before the maximum retry number is reached. Check patient access site for patency. Open and close the cassette door.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
CALLBACK **Medium** **N104**	A Callback Alarm was programmed for the secondary line, which is in Piggyback mode, the primary line is programmed to resume when the secondary completes, and the VTBI for secondary line reaches 0 for a Piggyback therapy or step in a multistep therapy. OR A Callback Alarm was programmed for the secondary line, which is in Piggyback mode, the primary line is not programmed to resume when the secondary line completes, and the VTBI for the secondary line reaches 0 for any step in a multistep therapy except the last step. OR A Callback Alarm was programmed for the secondary line, which is in Concurrent mode, and the VTBI for the secondary line reaches 0 for any step in a multistep therapy, except the last step. Or A Callback Alarm was programmed for Line 1, and the VTBI for Line 1 reaches 0 or any step in a multistep therapy except the last step.	Primary or Secondary Line	Press Clear.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
CALLBACK **Medium** **N104**	A Bolus or Loading Dose delivery completed on Line 1 and a Bolus Nurse Callback was configured, with a continuous to follow. Or A Bolus or Loading Dose delivery completed on Line 2 and a Bolus Nurse Callback was configured with a continuous to follow.	Primary or Secondary Line	Press Clear.
ACTION REQUIRED **Low** **N101**	No user interaction for 5 minutes after powered on, in clinical mode.	Right or Left Channel	Press clear. Select a line to program or Power off infusion pump. Remove the cassette if not in use.
ACTION REQUIRED **Low** **N101**	One channel in use while the other has a cassette inserted, but the first has been left idle for 5 minutes on line selection screen.	Right or Left Channel	Press clear. Select a line to program or Power off infusion pump. Remove the cassette if not in use.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
PROGRAM INACTIVITY **Low** **N101**	No user interaction for 2 minutes with a pop-up dialog displayed and on a new, unconfirmed program. When the infusion pump is powered on and left idle for 5 minutes on mask or line selection screen with a popup dialog message displayed. Also, there is no active infusion on either channel, though a cassette is inserted.	Primary or Secondary Line	Press clear. Review program and continue or CANCEL programming.
ACTION REQUIRED **Low** **N101**	No user interaction for 2 minutes when a line is selected for programming but not yet confirmed.	Primary or Secondary Line	Press clear. Review program and continue or CANCEL programming.
NEAR END OF INFUSION **Low** **N159**	A program has been configured an alarm to inform the user that an infusion is about to end. The alarm is triggered at a specific time prior to the VTBI reaching 0.	Primary or Secondary Line	Press clear. Check for a near empty container.
LOW BATTERY **Low** **N58**	The battery charge level is low.	N/A	Plug into AC (mains) power.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
BATTERY NEEDS SERVICE **Low** **E326, N57, N56, E321,**	The battery charge circuity needs servicing.	N/A	The pump may shutdown unexpectedly if unplugged from AC (mains). Keep the pump plugged in to AC and obtain a replacement as soon as possible. Power off the infusion pump. Send to biomed for service.

NOTE: Alarm log information is available in Biomed Mode as well as the *Plum Duo Technical Service Manual*.

Setting the Downstream Pressure Alarm Limit

The downstream pressure limit sets the threshold for the downstream occlusion alarm. When the pump detects a downstream pressure in the cassette sensor area greater than the set pressure limit, ± 3 psi, the pump issues an alarm.

WARNING: THE INFUSION PUMP CAN DETECT THE DOWNSTREAM OCCLUSION PRESSURE WITH THE ACCURACY OF +/- 3 PSI. USERS SHOULD ACCOUNT FOR THIS ACCURACY TO HELP REDUCE NUISANCE ALARMS AND THE TIME TO DETECT OCCLUSION ALARMS.

The infusion pump checks the downstream pressure and updates the reading every second. You can view the downstream pressure reading on the same page where you set the downstream pressure limit.

To view the current downstream pressure reading and set the downstream pressure limit:

1. On the Main Delivery page, tap the Settings button to display the menu options.
2. Tap CLINICAL SETTINGS.
3. Tap DOWNSTREAM PRESSURE at the bottom of the page.
   The current downstream pressure reading for each channel is displayed on the relevant side.

To change the Downstream Pressure Alarm Limit:

1. Tap the Settings button to display the menu options.
2. Tap CLINICAL SETTINGS.
3. Tap DOWNSTREAM PRESSURE at the bottom of the page.
4. Using the + or - button for the appropriate channel, change the limit to the desired PSI value between 3 and 12 (between 155 and 634 mmHg).

Restarting the Delivery Automatically After a Downstream Occlusion Alarm

When the infusion pump detects a downstream occlusion, delivery stops immediately and the infusion pump issues an alarm. The Plum Duo infusion pump can restart the delivery automatically if the downstream occlusion clears within 60 seconds. This gives time to resolve the occlusion without the need to restart the delivery manually by pressing START. During the 60 seconds, the pump monitors pressure, the delivery screen displays the status PAUSED, and the pump issues a medium priority alarm. As soon as the pressure drops below 50% of the Downstream Occlusion Alarm Limit, the alarm clears and delivery restarts immediately.

If the occlusion is not resolved within 60 seconds, or the maximum number of restarts is exceeded, the delivery status changes to STOPPED. The alarm priority changes from medium to high. The change in the audible alarm cadence alerts you that you must intervene to resolve the alarm

When two lines are delivering, if either line exceeds the maximum number of restarts, the priority changes to high and the alarm must be resolved manually by pressing START. If ICU LifeShield software is installed, each CCA can be configured to allow up to 10 restart attempts per infusion. Without LifeShield software, the number of restarts can be configured by the Biomedical staff for the CCA.

Troubleshooting

Resolving a Downstream Air-in-Line Alarm

Use the following procedure to remove air from the downstream (patient) line following a downstream air-in-line alarm.

⚠ **PRECAUTION:** USE ASEPTIC TECHNIQUE WITH ALL FLUID PATH CONNECTIONS TO PREVENT CONTAMINATION. REMOVE CAPS WHEN REQUIRED AND SECURE ALL CONNECTIONS.

1. Close all clamps. If a secondary line is attached, clamp the downstream Line 2 to avoid mixing fluids.
2. Disconnect the administration set from the patient.
3. Open the cassette door and remove the cassette.
4. Unclamp the upstream tubing of the line you want to use to prime the downstream line.
5. Reprime the administration set to remove the downstream air (see ***Priming***).
6. Insert the cassette into the infusion pump, close the cassette door, and then open all clamps (see ***Loading a Cassette***).
7. Reattach the administration set to the patient and restart delivery.

NOTE: If there have been multiple downstream air-in-line alarms, a biomedical technician may need to clean the cassette's air sensors. For the correct cleaning method, see the *Plum Duo Technical Service Manual*.

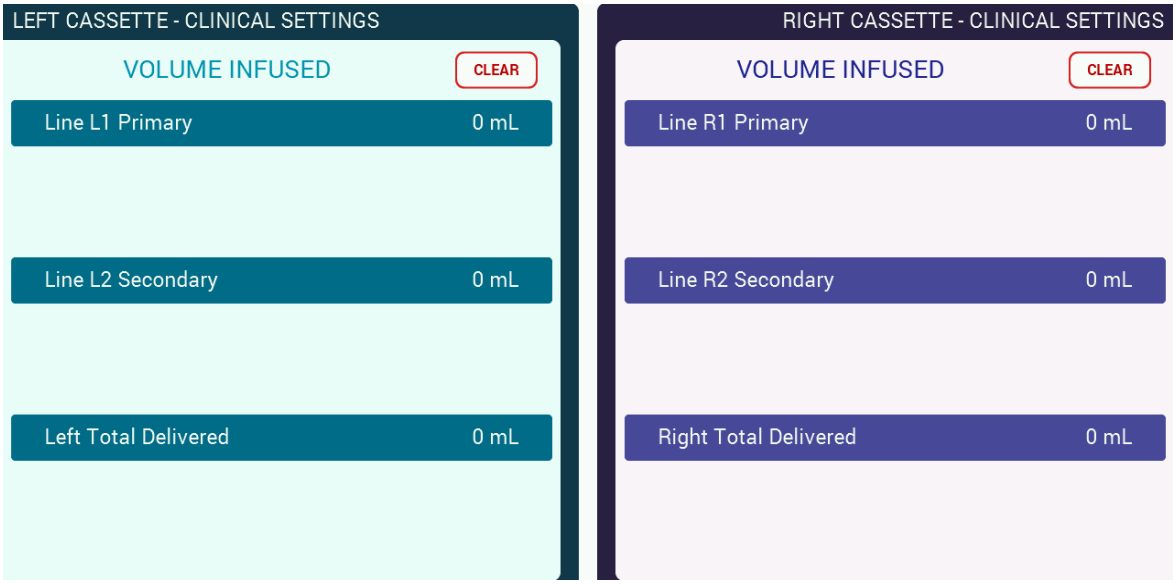
Settings

The Plum Duo infusion pump has a number of configurable settings at the CCA and infusion pump levels. CCA settings determine the default for many infusion pump settings. To view settings, tap the gear icon in the top right of the Main Delivery page. To exit settings, tap the gear icon and tap EXIT SETTINGS.

Clinical Settings

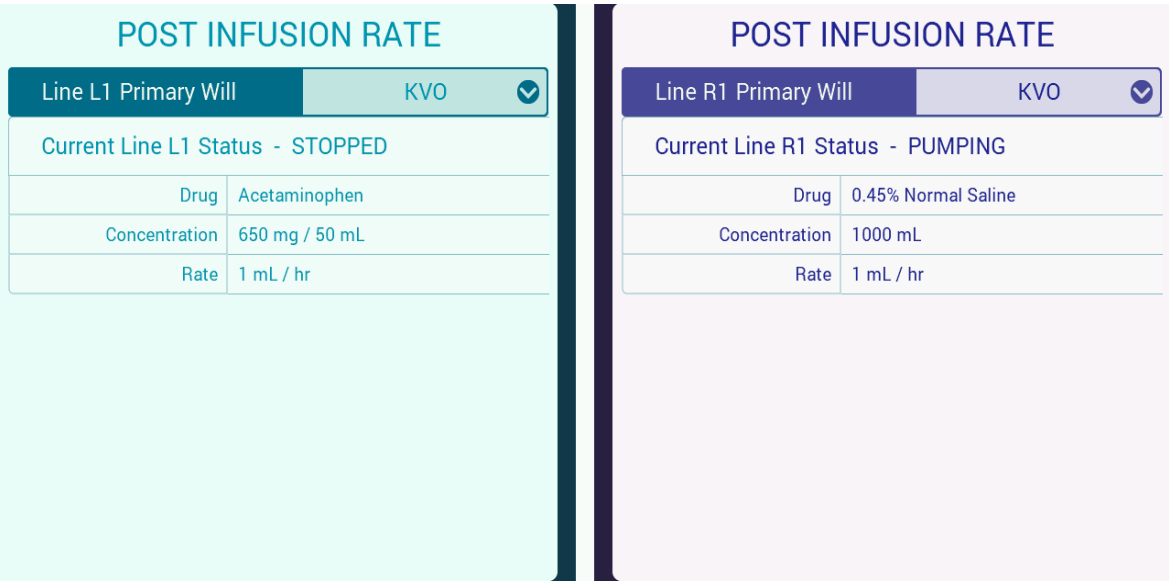
Clinical settings provide information and configurable settings related to volume infused, post infusion rate, downstream line pressure, and certain infuser related events.

Volume Infused



The Volume Infused page provides information on the volumes infused on the right and left channels. Volume infused information may be cleared by tapping CLEAR and then selecting the appropriate line(s). Volume infused is also cleared by the new patient prompt on startup.

Post Infusion

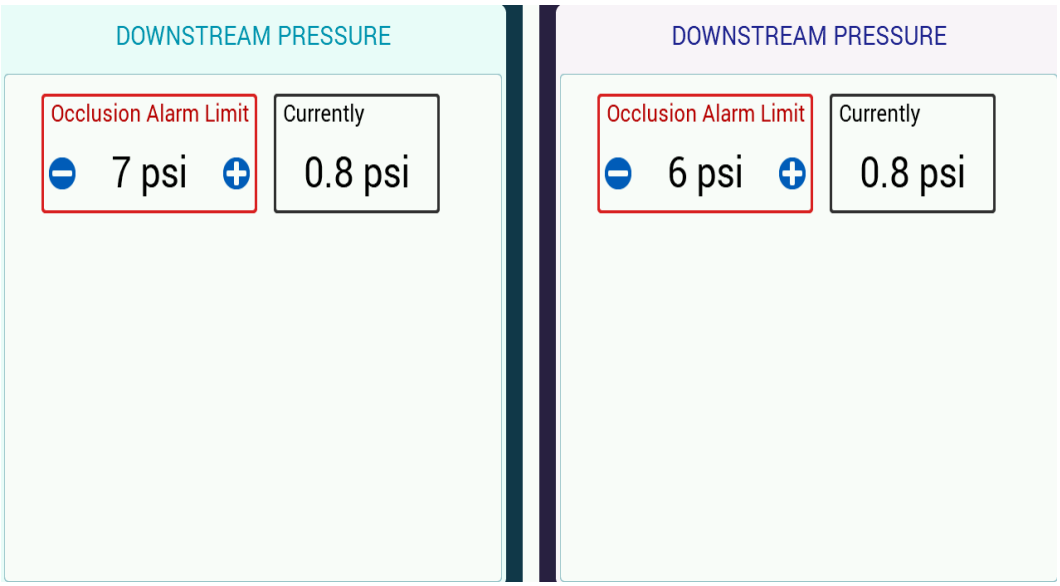


After the programmed VTBI is delivered, the infuser issues a VTBI Complete alarm and begins delivering a post infusion rate. The Post Infusion page provides the currently programmed post infusion rate for each line. Each line will display the currently programmed infusion on that line, including the line status, drug name, concentration, and post infusion rate. Post infusion rate options are configured at the ruleset and CCA level. To reveal the different post infusion rate options, tap the field next to the name of the line. You may change the post infusion rate to one of the following:

- KVO (Keep Vein Open) - The pump will continue to infuse at the CCA's KVO rate after the programmed infusion has ended.
- CONTINUE RATE - The pump continues to infuse the selected line at the same rate as the programmed infusion.
- STOP - The pump will stop infusing on that line after the programmed infusion has ended.

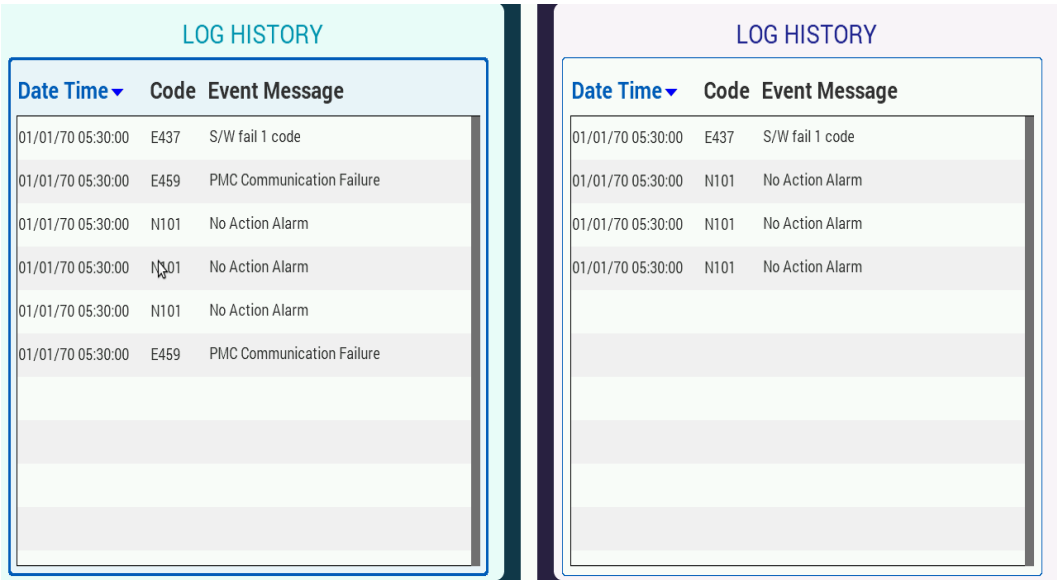
The Rate field for the line will change to reflect your choice of post infusion rate.

Downstream Pressure



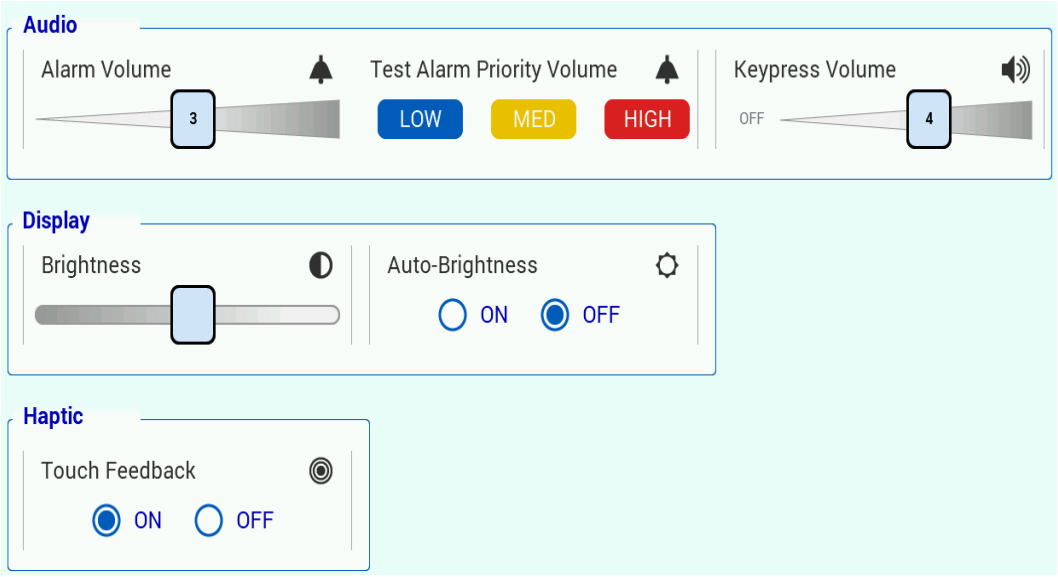
The Downstream Pressure page shows the current combined pressure of the line(s) on either side of the infuser, measured in psi. It also displays the psi at which the Occlusion Limit Alarm will sound. By tapping the + or - icons, you can raise or lower the limit. A confirmation prompt will then appear when exiting Clinical Settings. The default alarm limit is set by the current CCA.

Log History



The Log History page provides a record of significant pump interactions and events, such as alarms and alerts, that occurred during delivery to each patient and is cleared with each new patient. Each log entry contains a date and time that the event began, as well as an event message. Events are ordered by date and time, and the order may be reversed via the widget at the top of the Date column.

Pump Settings



Pump setting defaults are determined by the system CCA, but settings displayed here are user configurable.

Audio

Alarm volume may be adjusted via the slider. It has a total of 6 settings, with 5 (representing 70 dB) as the maximum and MIN (representing 45 dB) as the minimum. You can test the volume of alarms at different priority levels via the buttons LOW, MED, and HIGH.

NOTE: For patient safety, alarms may not be muted.

Keypress volume controls the volume of positive tones (activated when touching an interactive part of the pump) and may be adjusted via the slider. It has a total of 6 settings, with 5 as a maximum and OFF as a minimum. If you slide it to OFF, a prompt will appear asking you to confirm the choice.

WARNING: CHECK THAT THE ALARM THRESHOLD IS APPROPRIATE FOR THE CURRENT PATIENT PRIOR TO USE ON EACH PATIENT.

Display

The pump display brightness may also be adjusted via a slider or by using the Auto-Brightness feature. Auto-Brightness adjusts the screen's brightness relative to the light of the surrounding environment.

Haptics

The Haptics feature provides screen vibration when a negative tone is sounded. It also activates when touching a non-interactive part of the screen. Haptics may be turned off or on by tapping the appropriate icon.

CCA Details

CCA/Infuser settings set defaults and limits that are appropriate for the patient population of each Clinical Care Area (CCA) or per facility preference.

CCA Settings	Description
Maximum Rate	The highest rate that you can program for a single line or Piggyback delivery. For Concurrent delivery, the total rate for both Channels <= 999 mL/hr. If this exceeds the maximum rate per line, then the maximum rate is enforced.
Maximum VTBI	The largest VTBI that you can program for a single line or Piggyback delivery. The Maximum VTBI is defined in the drug library.
Maximum Patient Weight **Minimum Patient Weight**	Together, these display the allowable patient weight range for the CCA when you program a weight-based or BSA-based delivery.
Maximum Patient Height **Minimum Patient Height**	Together, these display the allowable patient height range for the CCA when you program a weight-based or BSA-based delivery.
Maximum Patient BSA **Minimum Patient BSA**	Together, these display the allowable patient BSA range for the CCA when you program a BSA-based delivery.
Default Downstream (Distal) Alarm Pressure	Displays the normal Downstream Alarm Pressure Limit for the CCA. You can change this value for a delivery, when needed.

CCA Settings	Description
Downstream (Distal) Alarm Resets	Displays the number of times that the infusion pump will restart delivery automatically when a downstream occlusion is resolved within 60 seconds. Set by a biomedical technician or the CCA. Default setting is 0. This feature is disabled for the CCA if Distal Alarm Resets = 0.
Allow Standby	If Allow Standby = Yes, deliveries can be put into Standby up to the configured Maximum Standby Time which is between 24 and 72 hours. (Default is 72 hours.) If Allow Standby = No, the Standby button will not be available for programming.
Allow Delayed Start	If Allow Delayed Start = Yes, you can program a Delayed Start of up to 23:59 hh:mm for deliveries. If Allow Delayed Start = No, the Delay Start button will not appear for programming.
Default End of Infusion	Sets the rate of infusion after VTBI is delivered to either KVO (Keep Vein Open), Continue Rate, or Stop.

Infusion Settings	Description
Default Mode Line 2	Sets the initial Line 2 delivery mode to Piggyback or Concurrent. Default is Piggyback.
Default Nurse Callback	When Default Nurse Callback = Yes, a medium priority alarm will be issued automatically at the end of: • any step but the last step of Multistep delivery, • a Loading Dose delivery, • a Piggyback infusion, or • a Bolus delivery. The user can change the Callback setting from the default setting of Yes. When Default Nurse Callback = No, a Callback Alarm must be set manually, if needed, for each of these.
Maximum Standby Time	This is the maximum time that a delivery can remain in Standby before the infuser issues a high priority Inactivity alarm. The Maximum Standby Time is defined in the drug library. The available range is 24 to 72 hours, with a default of 72 hours.

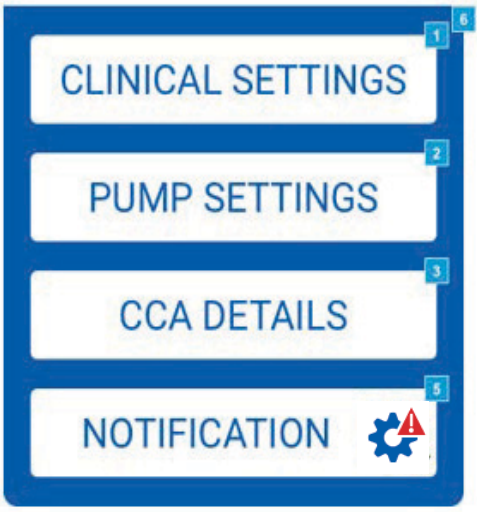
Notification

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 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 dropdown and then tap the Notification button.



Cleaning, Maintenance, Storage, and Service

Cleaning and Disinfecting the Infusion Pump

The Plum Duo infusion pump should be cleaned and disinfected prior to first patient use, between each patient use, and prior to performing repairs and preventive maintenance. For detailed instructions, see the *Plum Duo Technical Service Manual*.

PRECAUTION: DO NOT SATURATE THE AIR-IN-LINE DETECTORS BEHIND THE CASSETTE DOOR WITH CLEANING OR DISINFECTING SOLUTIONS.

PRECAUTION: DO NOT STERILIZE THE INFUSION PUMP BY HEAT, STEAM, ETHYLENE OXIDE (ETO), OR RADIATION.

PRECAUTION: DO NOT USE SHARP OBJECTS TO CLEAN ANY PART OF THE INFUSION PUMP.

PRECAUTION: TO AVOID MECHANICAL OR ELECTRONIC DAMAGE, DO NOT IMMERSE THE INFUSION PUMP IN ANY FLUID.

Cleaning Procedure

The following procedure describes how to clean nonhazardous spills or soil from the infusion pump during the course of patient care.

- **Non-hazardous** fluid spills should be wiped up as soon as possible, and not allowed to dry on the infusion pump.
- **Hazardous** spills (such as blood or chemotherapy drugs) should be processed per facility policy.

NOTE: When cleaning the pump, use approved cleaning solutions to minimize the potential for corrosion of the screen and case.

To clean non-hazardous spills or soil at the patient site:

1. Inspect the infusion pump enclosure and display for visible cracks or damage that may allow fluid to reach internal components.

PRECAUTION: DO NOT USE THE INFUSION PUMP IF THE ENCLOSURE, POWER BUTTON, OR DISPLAY IS DAMAGED OR CRACKED.

PRECAUTION: IF THE INFUSION PUMP HOUSING, POWER BUTTON, OR DISPLAY ARE CRACKED OR DAMAGED, REMOVE THE INFUSION PUMP FROM SERVICE AND RETURN IT TO THE BIOMED TECHNICIAN FOR REPLACEMENT

2. With gloves on, remove a wipe from the dispenser and unfold it to expose the maximum surface area before wiping, or spray an approved cleaning solution on a clean, lint-free cloth.

PRECAUTION: DO NOT SPRAY CLEANING SOLUTIONS OR DISINFECTING AGENTS DIRECTLY ONTO THE INFUSION PUMP.

3. Wipe up the spill.

- Use a spiral pattern when wiping, moving from the inner to outer edges of each surface to avoid recontaminating the areas you have already wiped.
- When part of the cleaning cloth or wipe becomes soiled or saturated, start wiping with an unused part.
- Change cloths or wipes as needed to avoid spreading the spill from one area of the infusion pump to another.
- Do not allow cleaning fluid to run into internal parts of the infusion pump.
- When wiping behind the cassette door, take care to avoid damaging the precision parts of the pumping mechanism.

NOTE: If sticky or high-viscosity fluids such as TPN are spilled behind the cassette door, replace the infusion pump as soon as possible so it can be thoroughly cleaned. Dried, built-up residue from these type of fluids can damage the pumping mechanism.

Cleaning Supplies

To clean the infusion pump, use clean, soft, lint-free cloths moistened with an approved cleaning solution or commercial wipes.

PRECAUTION: PREPARE CLEANING SOLUTIONS AS SPECIFIED BY THE MANUFACTURER TO AVOID INFUSION PUMP DAMAGE.

NOTE: Disinfecting properties of cleaning solutions vary, and not all cleaning solutions are sanitizers. Check product labeling or consult the manufacturer for specific information.

Approved Cleaning Solutions		
Class of Cleaning Solution	**Manufacturer**	**Preparation**
Enzymatic Detergent	ASP Enzol™ ASP Cidezyme™	Use per manufacturer's recommendations and instructions in this manual.

Disinfecting Procedure

Before disinfecting, make sure the infusion pump is thoroughly cleaned and completely dry.

To disinfect the infusion pump:

1. Inspect the infusion pump enclosure and display for visible cracks or damage that may allow fluid to reach internal components.

PRECAUTION: DO NOT USE THE INFUSION PUMP IF THE ENCLOSURE, POWER BUTTON, OR DISPLAY IS DAMAGED OR CRACKED.

PRECAUTION: IF THE INFUSION PUMP HOUSING, POWER BUTTON, OR DISPLAY ARE CRACKED OR DAMAGED, REMOVE THE INFUSION PUMP FROM SERVICE AND RETURN IT TO THE BIOMED TECHNICIAN FOR REPLACEMENT.

2. With gloves on, remove a wipe from the dispenser and unfold it to expose the maximum surface area before wiping, or spray an approved disinfecting solution on a clean, lint-free cloth.

PRECAUTION: DO NOT SPRAY CLEANING SOLUTIONS OR DISINFECTING AGENTS DIRECTLY ONTO THE INFUSION PUMP.

3. Wipe in an outward spiral pattern on the desired surface(s), replacing the cloth or wipe as needed.

Disinfecting Supplies

To disinfect the infusion pump, use clean, soft, lint-free cloths moistened with an approved disinfectant or commercial wipes.

Approved Disinfecting Solutions		
Class of Disinfecting Solution	**Manufacturer**	**Preparation**
Household Bleach	Clorox™ Germicidal Bleach (8.25% concentration)	Use per manufacturer's recommendations and instructions in this manual.

Infusion Pump Maintenance

The Plum Duo infusion pump requires preventive maintenance every two years that is performed by qualified service personnel. There is no clinician required maintenance. See the *Plum Duo Technical Service Manual* for instructions.

Battery Maintenance

WARNING: DISPOSE OF BATTERIES PER LOCAL GUIDELINES FOR BATTERY DISPOSAL (I.E., BY DISPOSING AT AN APPROPRIATE RECYCLER, COLLECTION POINT).

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

The battery maintenance cycle is intended to be run when general preventive maintenance is performed. See the *Plum Duo Technical Service Manual* for instructions. Additionally, there are specific storage conditions for the battery. There is no clinician-required battery maintenance.

The Plum Duo infusion pump is battery-powered for emergency backup and temporary portable operation. The typical battery operating time with a new and fully charged battery is 5 hours when infusing at 25 mL/hr, and TBD hours at 999 mL/hr.

The battery charges whenever connected to AC (mains) power. If the infusion pump is switched OFF, recharge takes approximately four hours. Recharge takes longer if the pump is turned ON.

To maintain maximum battery charge and to prolong battery life, connect the pump to AC (mains) power whenever possible. Connect to AC (mains) power to continually charge the battery for emergency use.

Storage

WARNING: CONNECT THE AC (MAINS) CORD TO A PROPERLY GROUNDED RECEPTACLE.

WARNING: TO PREVENT BATTERY LEAKAGE, REMOVE THE BATTERY BEFORE STORING THE INFUSION PUMP FOR AN EXTENDED PERIOD OF TIME.

Clean the infusion pump before storing it. Store the infusion pump connected to AC (mains) power, with the pump switched OFF using the ON/OFF button.

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.

For storage conditions, including extended storage conditions that can affect battery life, see ***Environment***.

Service

The infusion pump has no user-serviceable parts. In addition:

- Servicing and adjustments must only be performed by ICU Medical personnel or trained, authorized service representatives. Service training is available from ICU Medical. Contact your ICU Medical representative.

- Replacement of the power cord or other parts must only be performed by ICU Medical personnel or trained, authorized service representatives. Servicing by unauthorized personnel may invalidate the pump's warranty. See the *Plum Duo Technical Service Manual* for repair and replacement procedures.

- Circuit diagrams and repair parts lists are available for trained, authorized service representatives. See the *Plum Duo Technical Service Manual* for more information.

- See the *Plum Duo Technical Service Manual* for more information for all battery removal and storage information, component part lists, descriptions, and calibration instructions.

- The Plum Duo infusion pump can be disconnected from the mains supply by removing the power cord from the wall socket.

Supplies and Accessories

Contact your ICU Medical sales representative for supplies and accessories available in your area.

I.V. Pole

An I.V. Pole with locking casters has been tested for stability according to the requirements of IEC 60601-1:2012. The I.V. Pole can be used in mobile and non-mobile situations. Follow these directions to ensure stability in mobile use.

- The I.V. Pole may not have more than three (3) infusion pumps mounted to the pole, may not be extended higher than 68 inches from the floor, and may not have more than 2000 mL of solution hanging from the I.V. Pole hangers.

- 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.**

The pump/I.V. Pole system was tested to a maximum mobile load of 24.0 kilograms using 2 one-liter I.V. bags at a height of 68 inches (173 cm) and the infusion pumps mounted at 60, 50.5, and 41 inches (152, 128, and 104 cm) above the floor. Those values represent the maximum settings for the system to comply with the mobile stability requirements of IEC 60601-1:2012.

Specifications

The following specifications apply to the Plum Duo Infusion Pump.

Physical

Dimensions:	Approximately 9 H x 11.75 W x 6.5 D inches (23 cm H x 30 cm W x 17 cm D) (excluding pole clamp extrusion and power cord storage)
Mass:	Approximately 10.6 lbs (4.8 kilograms) with battery
Casing:	High-impact plastic.
Expected Service Life:	10 years **NOTE:** Expected Service Life is defined as 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. **NOTE:** At the end of the infusion pump's serviceable life, the pump's parts and accessories must be recycled by an authorized electronic waste handler. Inappropriate disposal of the device can result in Hazards to the Environment. Contact the ICU Medical Service Center at ***www.icumed.com*** or follow your facility procedure for proper disposal of the device.

Electrical

Power Requirements:	100 - 120 VAC; 50-60 Hz; 122 VA 220 - 240 VAC; 50-60 Hz; 160 VA
Power Cord:	Hospital-grade AC cord.
Fuses:	Internal and non-replaceable
Electrical Leakage:	Meets IEC 60601-1:2012 Medical Electronic Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
Battery Type:	Lithium Iron Phosphate; 12.8 V; internal; rechargeable. Use only ICU Medical-approved replacement batteries. **NOTE:** Unapproved batteries will not be recognized or accepted by the infusion pump and could impact the safe use of the product. Contact ICU Medical to obtain a replacement battery.
Battery Operation:	The typical battery operating time with a new and fully charged battery is 5 hours when infusing at 25 mL/hr on both channels, and TBD hours at 999 mL/hr.
Recharge:	The battery charges whenever the infusion pump is connected to AC (mains) power and it is below its maximum capacity. The recharge time is up to 8 hours.
RoHS:	The infusion pump meets the requirements of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Environment

Operating Temperature:	41°F to 104°F (5°C to 40°C); See notes 1, 2, and 4.
Storage Temperature:	-4°F to 104°F (-20°C to 60°C); See notes 2 and 3.
Atmospheric Pressure:	0 to 10,000 feet (0 to 3000 meters) or equivalent atmospheric pressure
Relative Humidity:	10% to 90% (maximum dew point of 30°C); See Note 4.

NOTE 1:	Batteries operate on electrochemical reaction, which converts chemical energy to electrical energy. The electrochemical reaction is reduced as the temperature lowers and available discharge capacity is reduced.
NOTE 2:	The cycle life (number of cycles) of the battery is related to the ambient temperature. The expected life of the battery will decrease by one-half with each rise in temperature of 10°C. Therefore, careful consideration must be taken not to use or store the battery at high temperature. The battery contains temperature protections that when triggered will permanently fail the battery.
NOTE 3:	The ambient temperature range of storage shall be 0°C to 40°C. For short term storage (up to 2 weeks), the temperature range of -20°C to 0°C or 40°C to 60°C is permissible. For long-term storage (up to 12 months), the required temperature range is 18°C to 28°C. Recharge the battery at the intervals recommended in the following table, depending on ambient temperature. Avoid storing the battery for more than 12 months, either in the infusion pump or in spares inventory.
NOTE 4:	To maintain battery safety, battery charging is inhibited when the internal temperature of the battery reaches 45°C. This is important to consider when operating at high ambient temperatures.

Storage Temperatures:	Refresh Charge Interval:
-20°C to 0°C	1 week
0°C to 18°C	2 months
18°C to 28°C	12 months
28°C to 40°C	2 months
40°C to 60°C	1 week

If any of the above conditions are not or cannot be met during storage, replace the battery before use.

NOTE 4:	The optimal relative humidity for storage or operation is 45% to 85%. For short durations (up to 2 weeks), operation or storage at a relative humidity in the range of 10% to 90% is permissible.

Communication

Wireless LAN:	Standards: IEEE 802.11 a/b/g/n/ac Transmit Power: 802.11a + 12.5dBm (max), 802.11b + 20.5dBm (max), 802.11g + 19dBm (max), 802.11n/ac + 19dBm @ 2.4GHz (max), 802.11n/ac +13.5dBm @ 5.0 GHz (max)
Frequency Band:	802.11a (5.0 GHz), 802.11ac (5.0 GHz), 802.11b (2.4 GHz), 802.11g (2.4 GHz), 802.11n/ac (2.4 GHz and 5.0 GHz)
Certification:	FCC Part 15.247, 15.407; IC RSS-210, RSS-102
FCC ID:	TBD
IC No:	TBD
Ethernet LAN (if option module is installed):	DHCP assigned IP address, Subnet Mask, Gateway, DNS1, and DNS2

Near Field Communication

Frequency Band:	13.56 MHz
Antenna:	Adhesive flex antenna mounted underneath the middle of the display.
Standards:	TBD
FCC ID:	TBD

VTBI Range

NOTE:	The Plum Duo infusion pump has two independent delivery mechanisms (Left Channel and Right Channel). Information described in this section is provided for each separate mechanism.
VTBI Range:	0.1 to 99.9 mL (in 0.1 mL increments) 100 to 9999 mL (in 1 mL increments)

Delivery Rate Range and Duration

Delivery Modes:	Primary, Piggyback, Concurrent, Loading Dose, Bolus, and Multistep
Lines 1 and 2:	0.1 to 99.9 mL/hr (in 0.1 mL/hr increments) 100 to 999 mL/hr (in 1 mL/hr increments)
Concurrent Delivery:	0.5 mL/hr minimum for each line 500 mL/hr cumulative (Line 1 + Line 2 on the same side) maximum
KVO:	1.0 mL/hr or the last primary delivery rate, whichever is less
Bolus Delivery:	1.0 to 99.9 mL/hr (in 0.1 mL/hr increments) 100 to 999 mL/hr (in 1 mL/hr increments)
Maximum Programmable Duration:	1500:00 hh:mm

Air-in-Line Alarm

PlumSet (Downstream)	Air Bolus: 0.1 mL of air or larger Cumulative: 0.25 mL of air out of 4.9 mL of fluid
PlumSet (Upstream):	Air Bolus: 0.5 mL of air or larger Cumulative: 1 mL of air (0.5 mL of air per Line for concurrent delivery)

Occlusion Alarm

Length, temperature, and type of administration set affect the maximum downstream occlusion detection time and bolus volume released after a downstream occlusion is resolved.

NOTE:	Any triggered alarm during an infusion in the Right Channel does not cause the Left Channel to stop pumping, or vice versa, as they are independent delivery mechanisms.
Downstream Occlusion:	The downstream occlusion alarm sounds after the downstream tubing or set outlet fitting becomes occluded or a vacuum occurs.
Upstream Occlusion:	The upstream occlusion alarm sounds if the tubing upstream to the cassette becomes occluded or pressurized.
Downstream Pressure Limit (Without Alarm):	Maximum pressure limit: user-selectable Factory default setting: 6 psi (310 mmHg) Selectable range: 1 to 15 psi (52 to 776 mmHg) with display accuracy ±3 psi (±155 mmHg). **NOTE:** With installation of the International English language pack, the Downstream Pressure Limit units change from psi to mmHg.
Maximum Infusion Pressure:	20 psi (1034 mmHg)

Time to Detect Downstream Occlusions

Flow Rate	Downstream Pressure Alarm Limit Setting	Downstream Tubing Type	Maximum Time to Detect Downstream Occlusion
.1 mL/hr	1 psi (52 mmHg)	Microbore	TBD
.1 mL/hr	15 psi (776 mmHg)	Microbore	TBD
1 mL/hr	1 psi (52 mmHg)	Microbore	TBD
1 mL/hr	15 psi (776 mmHg)	Microbore	TBD
25 mL/hr	1 psi (52 mmHg)	Microbore	TBD
25 mL/hr	15 psi (776 mmHg)	Microbore	TBD
.1 mL/hr	1 psi (52 mmHg)	Macrobore	TBD
.1 mL/hr	15 psi (776 mmHg)	Macrobore	TBD
1 mL/hr	1 psi (52 mmHg)	Macrobore	TBD
1 mL/hr	15 psi (776 mmHg)	Macrobore	TBD
25 mL/hr	1 psi (52 mmHg)	Macrobore	TBD
25 mL/hr	15 psi (776 mmHg)	Macrobore	TBD
Baseline backpressure is 0 psi (0 mmHg)			

Maximum Unintended Bolus Volume Released After Downstream Occlusion is Resolved

Flow Rate	Downstream Pressure Alarm Limit Setting	Downstream Tubing Type	Maximum Unintended Bolus Volume Released	Typical Unintended Bolus Volume Released
1 mL/hr	1 psi (52 mmHg)	Microbore	TBD	TBD
1 mL/hr	15 psi (776 mmHg)	Microbore	TBD	TBD
25 mL/hr	1 psi (52 mmHg)	Microbore	TBD	TBD
25 mL/hr	15 psi (776 mmHg)	Microbore	TBD	TBD
1 mL/hr	1 psi (52 mmHg)	Macrobore	TBD	TBD
1 mL/hr	15 psi (776 mmHg)	Macrobore	TBD	TBD

Flow Rate	Downstream Pressure Alarm Limit Setting	Downstream Tubing Type	Maximum Unintended Bolus Volume Released	Typical Unintended Bolus Volume Released
25 mL/hr	1 psi (52 mmHg)	Macrobore	TBD	TBD
25 mL/hr	15 psi (776 mmHg)	Macrobore	TBD	TBD
Baseline backpressure is 0 psi (0 mmHg)				

Delivery Accuracy

This table defines the standard conditions for delivery accuracy.

Delivery Accuracy	
0.1 to 0.9 mL/hr (in 0.1 mL/hr increments)	±5%
1 to 999 mL/hr (in 1 mL/hr increments)	±5%

Delivery accuracy testing was performed in accordance with IEC 60601-2-24:2012. Tests were performed using Administration Set List Numbers TBD, TDB, and TBD. Tests were performed at 22°C ± 5°C, with backpressure of 0 psi (0 mmHg), using sterile water, and at 12"-24" (30.5 to 61 cm) filling head height. See the following sections for more details on accuracy-affecting conditions.

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

Bolus Delivery Accuracy

Bolus delivery accuracy testing was performed in accordance with IEC 60601-2-24:2012. Refer to this standard for detailed information.

Bolus Delivery Accuracy data was generated using a representative sample of administration sets from the Plum set portfolio. Tests were performed using Administration Set List Number TBD.

Bolus Delivery Accuracy				
Tested Bolus Rate (in mL/hr)	Tested Bolus Volume (in mL)	Calculated % Average Deviation from Set Bolus Volume	Maximum % Positive Deviation from Set Bolus Volume	Maximum % Negative Deviation from Set Bolus Volume
1 mL/hr	4 mL	TBD %	TBD %	TBD %
25 mL/hr	100 mL	TBD %	TBD %	TBD %

Enteral or High Viscosity Fluids Effects

System delivery accuracy limits for enteral or high viscosity fluids can be degraded by up to 5%. System delivery accuracy for enteral fluids is defined only for rates of 1 to 200 mL/hr, with no suspended air in the solution, and using a Plum enteral set.

Backpressure Effect

At 25 mL/hr flow rate, backpressures of +/- 2 psi (103 mmHg) on the downstream line do not affect system delivery accuracy. Connection of other infusion system or accessories may impact accuracy depending on backpressure.

Filling Head Effect

At 25 mL/hr flow rate, filling head variations of -15 and +35 inches (-38 and +89 cm) of water (such as container height) do not affect system delivery accuracy.

Concurrent Delivery Effect

When both lines (primary and secondary) are delivering, the concentration deviation for the lower rate may be affected by up to 2.5%.

If the volume of air in the cassette air trap is greater than 0.05 mL, the total system flow rate accuracy may be affected by up to 2.0%.

When variations in container height are present, the concentration deviation for the lower rate may be affected by up to 4.0% for up to 24 inches (61 cm) of container height differences.

Effect of Clinically Relevant Combination of Factors

The system delivery accuracy limits can be degraded by up to TDB%, under the following clinically relevant conditions which are intended to represent the worst-case combination of factors:

- Dextrose 20% infused at 999 mL/hr, at a temperature of 90.5°F (32.5°C) for 1hr, using a 125 inches (318 cm) long microbore burette PlumSet (Administration Set List Number 14955). Fluid bag hanging at the level of the pump cassette.

- Dextrose 20% infused at 5 mL/hr, at a temperature of 59°F (15°C) for 24 hours, using a 125 inches (318 cm) long microbore burette PlumSet (Administration Set List Number 14955). Fluid bag hanging at the level of the pump cassette.

Trumpet Curves

The Trumpet Curve graphs following the example show representative maximum and minimum percent flow rate deviation from the programmed rate over time. This information was developed in accordance with IEC 60601-2-24:2012. Refer to this standard for detailed information.

How to read a Trumpet Curve Graph (Refer to example on the following page): The graphs following the Example plot flow rates at 30 second intervals for the first 2 hours and for the 48th and 96th hour of delivery. The graph plots mean delivery rate error for the 2nd hour and the 48th and 96th hour as a straight line. The graph also presents maximum and minimum average delivery rate error for this interval plotted by averaging delivery errors over intervals of 2, 5, 11, 19, and 31 minutes ("Trumpet Curve").

Trumpet Curve data was generated using a representative sample of administration sets from the Plum set portfolio. Tests were performed using Administration Set List Numbers TBD, TBD, and TBD

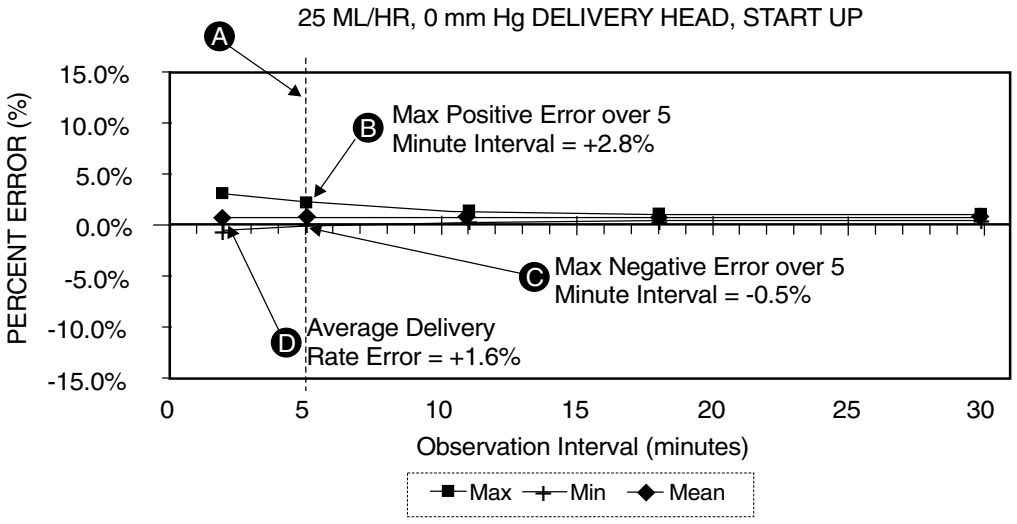
Note that at extremely low flow rates (that is, 0.1–0.3 mL/hr) and at non-standard negative back pressures (-1 psi or -52 mmHg), the accuracy error rate can be up to ±25%.

Example

From the Trumpet Curve Graph sample that follows, find the 5 minute interval (A) at the horizontal axis and read the corresponding points (B) and (C) on the vertical axis. The values are approximately +2.8% and −0.5%.

This means that at the rate of 25 mL/hr the average maximum flow rate fluctuation for any 5 minute time interval during the 2nd hour of operation was within the limits of +2.8% and −0.5% from the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

For other time intervals look at other points at the horizontal axis and determine corresponding limits as above.



A trained professional can use the resulting graphs to select an infusion pump with the appropriate startup and flow characteristics to suit the clinical application.

NOTE: As an example of how the trumpet curves can be used, consider the maximum and minimum deviations at the 5 minute average interval. The upper curve provides the maximum expected delivery rate error over a 5 minute interval, the lower curve provides the minimum expected delivery rate error over a 5 minute interval. An example would be Dopamine administered at 5 µgm/kg/min. At 5 minutes, the average drug delivery error would be within the range of +2.8% and −0.5% of the expected nominal rate.

Plum Duo trumpet curves TBD.

Appendix

FCC Information

US FCC (Federal Communications Commission) Statement (United States Only)

The device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15C, 15E of the FCC rules. These limits are designed to provide reasonable protection against harmful interference.

Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including that may cause undesired operation of these devices.

FCC Interference Statement (United States Only)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, 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 antenna
- Increase the separation between the equipment and receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/television technician for help

This device and its antenna(s) must not be co-located or operated in conjunction with any other antenna or transmitter.

Department of the Minister of Innovation, Science, and Economic Development (Canada Only)

The Class B digital apparatus complies with Canadian ICES-003.

Radio Frequency Exposure Statement

The Wireless LAN radio device in the Connectivity Engine peripheral assembly with this infusion device has been evaluated and found compliant to the requirements of the following Radio Frequency exposure standards.

FCC Rules, Part 15/Industry Canada

This device complies with Part 15 of FCC Rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference, including interference that may cause undesired operation of this device.

This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET65 and RSS-102 of the IC radio frequency (RF) Exposure rules.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This radio transmitter (identify the device by certification number, or model number if Category II) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

For product available in the USA/Canada market, only channels 1-11 can be operated. Selection of other channels is not possible.If this device is to be operated in the 5.15~5.25 GHz frequency range, it is restricted to indoor environments only.

Antenna:	Proprietary
Antenna Gain Information:	Embedded Antenna: 4.2dBi (2.4 GHz), 5.1dBi (5 GHz)
Frequency Tolerance:	±20ppm

Radio Equipment Directive

Hereby, ICU Medical, Inc. declares that the radio equipment type Wireless Local Area Network is in compliance with Directive 2014/53/ EU.

The full text of the EU declaration of conformity is available at the following internet address:

http://www.icumed.com/about-us/qualityregulatory-certificates

RoHS

ICU Medical, hereby declares that this Plum Duo Infusion Pump is in compliance with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Electromagnetic Compatibility

The Plum Duo infusion pump has been tested to the requirements of the standards in the following table:

Standard
AIM Standard 7351731 Rev. 2.00 2017-02-23
IEC 60601-1-2:2014 Edition 4 EN 60601-1-2:2015 Edition 4
IEC 60601-1:2012 EN 60601-1:2013
IEC 60601-2-24:2012 EN 60601-2-24:1998

The Plum Duo device has been evaluated and tested for safety and essential performance under the scope and requirements of IEC/EN 60601-1-2 Edition 4 (as defined in the table above) under the professional healthcare environment immunity category for following electromagnetic tests and found to be compliant:

- Radiated and Conducted Emissions (CISPR 11 Group 1 Class A)
- Voltage Fluctuation and Flicker (IEC 61000-3-3)
- ESD Immunity (IEC 61000-4-2)
- Radiated RF Field Immunity (IEC 61000-4-3)
- Proximity Fields from wireless transmitters (IEC 61000-4-3)
- Electrical Fast Transients (IEC 61000-4-4)
- Surge Immunity (IEC 61000-4-5)
- Conducted Immunity (IEC 61000-4-6)
- Conducted Immunity to ISM band (IEC 61000-4-6)
- Magnetic Field Immunity (IEC 61000-4-8)

- Voltage Dips and Interruptions (IEC 61000-4-11)

The infusion pump has been evaluated and tested for safety and essential performance under the scope and requirements of AIM 7351731 Standard for Medical Electrical Equipment and System Electromagnetic Immunity for Exposure to Radio Frequency Identification Readers (RFID) typically found in Professional Healthcare Environment.

Plum Duo found to be compliant to following RFID electromagnetic tests:

- Radiated Radio Frequency Immunity
- Electromagnetic Field Immunity

The infusion pump is suitable for use in clinical professional healthcare environments in accordance with the provisions of IEC 60601-1-2:2014 Edition 4/EN 60601-1-2:2015 Edition 4 Medical Electrical equipment standard for basic safety and essential performance for electromagnetic disturbances. The infusion pump is suitable for use in all establishments, excluding domestic establishments. The infusion pump is Group 1 Class A Medical Electrical equipment for electromagnetic disturbance emissions purposes.

WARNING: THIS EQUIPMENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY. THIS EQUIPMENT/SYSTEM MAY CAUSE RADIO FREQUENCY INTERFERENCE OR MAY DISRUPT THE OPERATION OF NEARBY EQUIPMENT, DEVICES, OR SYSTEMS USING RF ELECTRICAL ENERGY FOR THEIR OPERATION. THE USER MIGHT NEED TO TAKE MITIGATION MEASURES, SUCH AS RELOCATING OR RE-ORIENTING THE PLUM DUO EQUIPMENT OR SHIELDING THE LOCATION.

The essential performance of a Plum Duo device consists of:

- Delivery accuracy
- Free flow avoidance under single-fault condition
- Alarm generations and conditions

If the essential performance of the infusion pump is affected due to an electromagnetic disturbance event or if you suspect external RF sources or other equipment are influencing device operation, stop usage of the device and contact the biomedical engineering department for additional guidelines concerning electromagnetic immunity. Contact the biomedical engineering department for additional information in the *Plum Duo Technical Service Manual* concerning operating devices near RF sources or sources of electromagnetic disturbance.

Refer to the *Plum Duo Technical Service Manual* for further details of the EMC testing procedures and compliance levels. There is a shared responsibility between manufacturers, customers and users to ensure that Medical Equipment and Systems are designed and operated as intended. Medical electrical equipment needs special cautions regarding electromagnetic compatibility and needs to be installed and used according to the electromagnetic compatibility information provided in this manual.

Always manage the electromagnetic environment.

The guidance included in this manual provides information needed to:

- Determine the device's suitability for use in the intended environment.
- Manage the electromagnetic environment to permit the device to perform as intended without disturbing other equipment.

Separate the device from all other electronic equipment. If the device must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.

WARNING: DEVICES SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF THE DEVICE MUST BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT, MONITOR THE DEVICES TO VERIFY NORMAL OPERATION.

WARNING: USE ONLY COMPONENTS AND ACCESSORIES SPECIFICALLY LABELED FOR USE WITH THE PLUM DUO INFUSION PUMP TO HELP ENSURE THE DEVICE OPERATES AS INTENDED. USE OF UNAUTHORIZED ACCESSORIES, CABLES, TRANSDUCERS AND EQUIPMENT MAY HAVE A RISK OF AFFECTING THE EMISSIONS AND IMMUNITY COMPLIANCE REQUIREMENTS OF THE INFUSION PUMP.

To review replacement part lists, technical service manuals, and alternative cleaning agents, or for additional technical resources, operating manuals, safety software installation, product return authorization, and technical training courses, visit:

www.icumed.com

WARNING: **POSSIBLE EXPLOSION HAZARD EXISTS IF THE INFUSER IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES, INCLUDING ANESTHETICS.**

MD

EC REP

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