Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
UPSTREAM OCCLUSION **High** **N189, N188**	An upstream occlusion detected on the Secondary Line during delivery. The upstream occlusion pressure limit of 7 PSI (362 mmHg) is fixed and cannot be adjusted.	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 negative pressure.	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.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
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. The occlusion pressure limit is configured by the drug library for a CCA.	Right Channel	Check the downstream line for clamps or kinks and correct any found. Check the patient access. Restart the delivery.

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 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.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
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 **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 and/or 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.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
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.
ACTION REQUIRED HIGH **N102**	No user interaction for 2 minutes when a line is selected for programming, but not yet confirmed. Or No user interaction for 2 minutes with a pop-up dialog displayed and on a new, unconfirmed program.	Primary or Secondary Line	Press clear. Review program and continue or CANCEL programming.

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	Primary or Secondary Line	Press Clear. Respond to the pop-up displayed. If the line has not stopped after stop requested: Press BOTH, R1, R2, or CANCEL. If the line was not started after start was requested: Press BOTH, R1, R2, or CANCEL.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
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.	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, R1, R2, or CANCEL. If the line was not started after start was requested: Press BOTH, R1, R2, 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 and re-start the program or clear the programming for that line as needed.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
ACTION REQUIRED **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. Or The user has not interacted with the pump for 30 seconds, and a line is programmed, such as a bolus or titration, with a continuous therapy delivering and is not confirmed.	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 or cancel the programming changes.

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. Or A piggyback delivery VTBI reaches 0, and no delivery is programmed on the primary.	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.
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.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
BATTERY NEEDS SERVICE **High** **E330**	Battery authentication failure.	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. Close all clamps and remove the cassette(s). Send to biomed for service.
DOOR OPENED - DELAYED START **Medium** **N249**	Cassette door was opened while the infusion was in Delayed Start.	Right Channel	Close cassette door with cassette inserted or clear the program.

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. The number of retry attempts is configured by the drug library for a CCA.	Right 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 can be configured by the drug library or enabled/ disabled by pump user. When callback is enabled and: A bolus or loading dose delivery completes on Line 1 with a continuous to follow. Or A VTBI for Line 1 reaches 0 or any step in a multistep therapy except the last step. Or Line 2 is in piggyback mode with a bolus or loading dose	Primary or Secondary Line	Press Clear.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
CALLBACK **Medium** **N104**	delivery, and VTBI reaches 0 with a continuous or Line 1 to follow. Or Line 2 is in Piggyback mode, and Line 1 is programmed to resume, and the VTBI for Line 2 reaches 0 for a step in a multistep therapy. Or Line 2 is in Piggyback mode, and Line 1 is not programmed to resume when Line 2 VTBI reaches 0 for 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**	Or Line 2 is in Concurrent mode, and the VTBI for Line 2 reaches 0 for 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 callback can be configured by the drug library or enabled/ disabled by pump user. When callback is enabled and: 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.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
STANDBY EXPIRED **Medium** **N109**	The configured standby duration has expired.	Primary or Secondary Line	Press dismiss. Start or Clear the program. Trace lines prior to starting the infusion.
INACTIVITY **Low** **N101**	No user interaction for 5 minutes after powered on, in clinical mode.	Right Channel	Press clear. Select a line to program or Power off infusion pump. Remove the cassette if not in use.
INACTIVITY **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 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
INACTIVITY **Low** **N101**	No user interaction for 2 minutes with a pop-up dialog displayed. 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 the channel, though a cassette is inserted.	Primary or Secondary Line	Press clear. Review program and continue or CANCEL programming.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
NEAR END OF INFUSION **Low** **N159**	A program has been configured with 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. The alarm is configured by the clinician.	Primary or Secondary Line	Press clear. Check for a near empty container.
STANDBY EXPIRED **Low** **N106**	The configured standby duration has expired for a line that has not been started yet.	Primary or Secondary Line	Press dismiss. Start or Clear the program. Trace lines prior to starting the infusion.
LOW BATTERY **Low** **N58**	The battery charge level is low.	N/A	Plug into AC (mains) power immediately. **NOTE:** If not resolved, the alarm will assert again after 15 minutes.

Alarm Message and Priority	Possible Cause	Line Applicable	Corrective Action
BATTERY NEEDS SERVICE **Low** **N56**	The battery has reduced capacity.	N/A	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.

Regardless of the power state, all alarms are maintained in a log until viewed by Biomed and are maintained until a Biomed clears them. If the log reaches capacity and another alarm occurs, the system deletes the oldest entry to ensure the new alarm is recorded. Timestamps for when the infusion pump is powered down are not captured in the log. After a total loss of power, there is a 5 second period in which last alarm entries may be lost.

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

Setting the Downstream Occlusion Pressure Alarm Limit

The downstream occlusion 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 occlusion pressure limit.

To view the current downstream pressure reading and set the downstream occlusion 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 the channel is displayed on the relevant side.

You can set the Downstream Pressure Alarm Limit from the Settings or Options pages.

To change the Downstream Occlusion Pressure Alarm Limit via Settings:

1. Tap the Settings button. The Settings page appears.
2. Tap DOWNSTREAM PRESSURE.
3. Using the arrow buttons, change the limit to the desired psi value between 1 and 15 (between 52 and 776 mmHg).
4. Tap CONFIRM.

To change the Downstream Occlusion Pressure Alarm Limit via Options:

1. Program an infusion.
2. On the Review page, tap OPTIONS.
   The Options page appears.
3. Using the arrow buttons, change the limit to the desired PSI value between 1 and 15 (between 52 and 776 mmHg).

Restarting 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 Solo 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 Medical LifeShield™ Infusion Safety Software Suite is installed, each CCA can be configured to allow up to 10 restart attempts per infusion. Without LifeShield™ Infusion Safety Software Suite, 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.

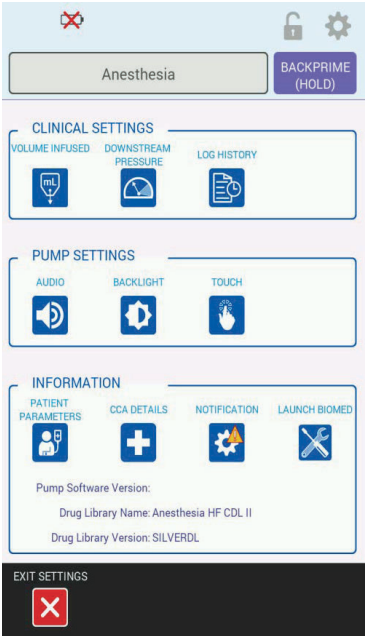
PRECAUTION: USE ASEPTIC TECHNIQUE WITH ALL FLUID PATH CONNECTIONS TO PREVENT CONTAMINATION. REMOVE CAPS WHEN REQUIRED AND SECURE ALL CONNECTIONS.

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 Solo Technical Service Manual*.

NOTES:

Settings

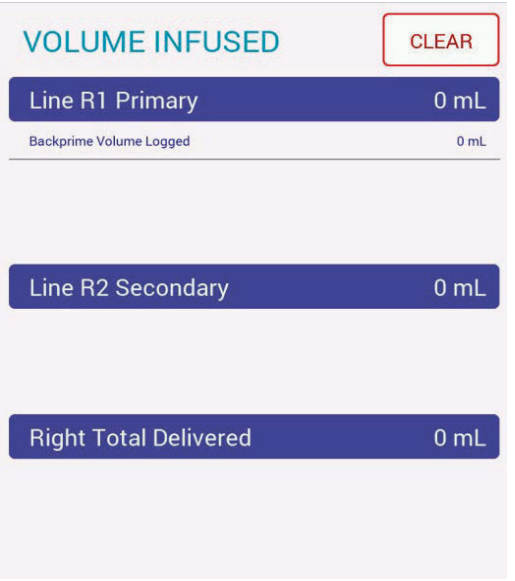


The Plum Solo infusion pump has a number of configurable settings at the CCA and infusion pump levels. CCA settings determine the default for many infusion pump settings. To view settings, tap the gear icon in the top right of the Main Delivery page. To exit settings, tap EXIT SETTINGS.

Clinical Settings

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

Volume Infused



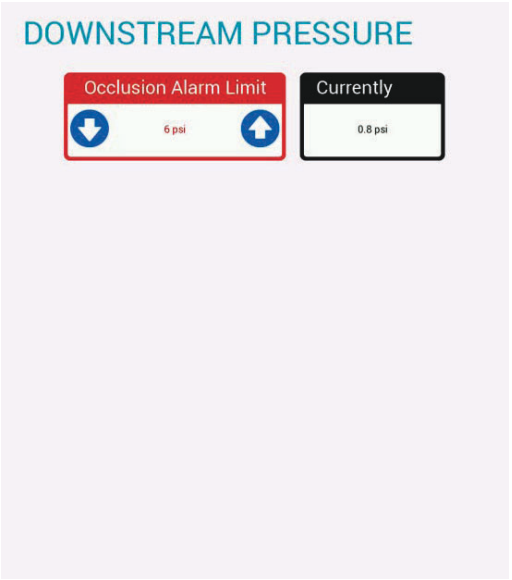
The Volume Infused page provides information on the volumes infused on the channel. Volume infused information may be cleared by tapping CLEAR and then selecting the appropriate line(s). Volume infused is also cleared by selecting CLEAR PATIENT on power off, answering YES to the New Patient prompt on startup, or after five hours of the infusion pump being off. Clearing the volume-infused totals on this page also clears the associated volume-infused total(s) on the main delivery page.

The approximate volume used for backprime can be viewed on the Volume Infused page and will be cleared anytime the Primary Volume Infused is cleared.

NOTE: The backprime volume is only decremented from a fluid on the primary line that is defined as to allowed to be interrupted by a piggyback and given in mL / hr. The backprime volume is not added to the secondary volume since air and fluid can be co-mingled and not precise.

To navigate to the Volume Infused page, tap the Settings icon in the top right of the screen and then tap Volume Infused.

Downstream Pressure

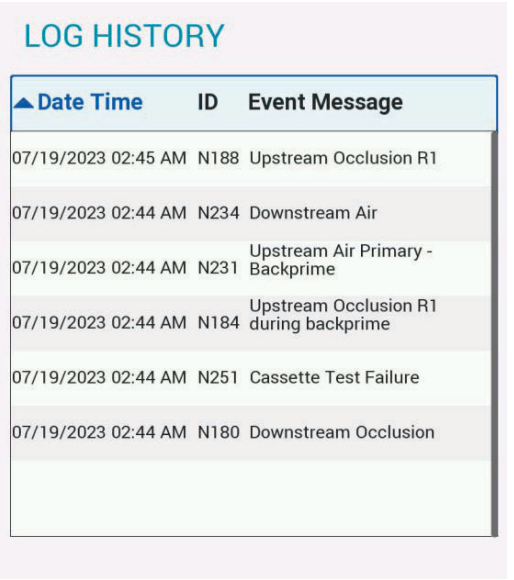


The Downstream Pressure page shows the current combined pressure of the line(s) on either side of the infuser, measured in psi. It also displays the psi at which the Occlusion Limit Alarm will sound. The default alarm limit is set by the current CCA.

To adjust the Downstream Occlusion Alarm Limit:

1. Tap the Settings icon in the top right of the Main Delivery page.
2. Tap Downstream Pressure.
3. Raise or lower the limit by tapping the arrows on the appropriate line(s).
4. Tap CONFIRM to confirm the change and exit the Downstream Pressure page.

Log History



The Log History page provides a record of significant pump interactions and events that occurred during delivery to each patient and is cleared with each new patient. The Log History includes, but is not limited to, alarms, alerts, and infusion events such as the beginning and end of an infusion. 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. Logs are cleared if the infusion pump is turned off for more than five hours. Time and date of startup and shutdown are not recorded in the log.

NOTE: After a total loss of power, there is a 5-second period in which last alarm log entries may be lost.

To navigate to the Log History page, tap the Settings icon in the top right of the screen and then tap Log History.

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. Changes to Alarm Volume affect the volume of all alarms (Low, Medium, and High). 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.

General 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. You can test the volume by tapping KEYPRESS, START STOP, or ALERTS. If you slide it to OFF, a prompt will appear asking you to confirm the choice.

To navigate to the Audio page, tap the Settings icon in the top right of the screen and then tap Audio.

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

Backlight

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. To turn the Auto-Brightness feature off or on, tap OFF or ON under Auto-Brightness.

To navigate to the Backlight page, tap the Settings icon in the top right of the screen and then tap Backlight.

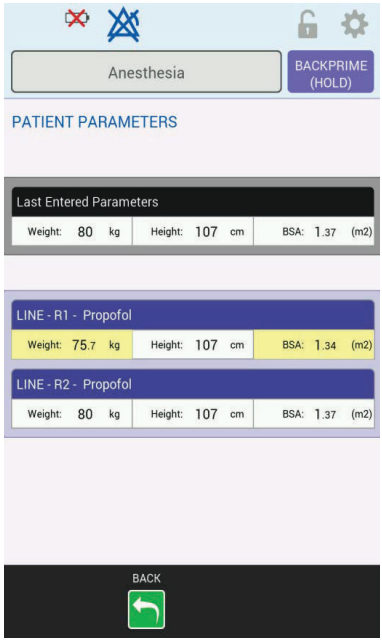
Touch

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

Information

Patient Parameters

The Patient Parameters screen offers a high-level look at the patient parameters (including weight, height, and/or BSA) entered for each line infusing a weight/BSA-based program. The most recent parameters used are displayed under Last Entered Parameters and the oldest parameters are highlighted in yellow.



CCA Details

NOTE: LifeShield™ Infusion Safety Software Suite connectivity is optional. For the list of features, such as the CCA Details page, available with the version of LifeShield™ Infusion Safety Software Suite installed at your facility, contact your local representative.

To navigate to the CCA Details page, tap the gear settings icon and then tap CCA Details.

CCA/Pump settings are configured through the LifeShield™ Infusion Safety Software Suite and by the facility biomed administrator. The settings are downloaded to all pumps over the network through a wireless connection. CCA/Pump settings set defaults and limits that

are appropriate for the patient population of each Clinical Care Area (CCA) or per facility preference.

CCA and Pump 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 the Right channel <= 500 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 if the version of LifeShield™ Infusion Safety Software Suite has the capability to configure the maximum.
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.

CCA and Pump Settings	Description
Default Downstream Pressure Occlusion Alarm Limit	Displays the normal Downstream Alarm Pressure Limit for the CCA. You can change this value for a delivery, when needed.
Downstream Occlusion Auto-Restart	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.
Air Detection	Displays the downstream air-in-line detection setting for a single bolus of air. It can be configured to 50, 100 or 250 mcl. Set by a biomedical technician or the CCA.
Standby Allowed	If Standby Allowed = Yes, deliveries can be put into Standby up to the configured Maximum Standby Time which is between 24 and 72 hours. If Standby Allowed = No, the Standby button will not be available for programming.

CCA and Pump Settings	Description
Delayed Start Allowed	If Delayed Start Allowed = Yes, you can program a Delayed Start of between 1 minute and 4 hours for deliveries. If Delayed Start Allowed = No, the Delay Start button will not appear for programming.
Default KVO Rate	Sets the KVO (Keep Vein Open) rate that can be selected for use after an infusion completes.
Callback Notification Allowed	When Callback Notification Allowed = 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. You can change the Callback setting from the default setting of Yes. When Callback Notification Allowed = No, a Callback Alarm must be set manually, if needed, for each of these.
General Volume	Controls the volume level of positive tones. You can change this value as needed.
Alarm Volume	Controls the volume level of alarms. You can change this value, as needed. Unlike General Alarm, there is no OFF value.

CCA and Pump Settings	Description
Touch Feedback Enabled	Controls the use of Touch Feedback. If enabled, the pump will vibrate when a negative tone sounds or when a non-interactive part of the screen is touched. You can enable or disable Touch Feedback, as needed.
Screen Brightness	Controls the brightness of the infusion pump screen. You can raise or lower this value, as needed.
Auto-brightness Enabled	Controls the use of Auto-Brightness. If enabled, the screen will automatically adjust its brightness relative to the surrounding environment. You can enable or disabled Auto-Brightness, as needed.
Volume Displayed on Main Delivery Screen	Displays the volume as either Volume Infused (VI) or Volume to be Infused (VTBI). Set by Biomed technician or the CCA. Default is set to VI.
Enteral Infusion Display Color	Indicates the color of the programming and delivery screen display to specify the enteral route of administration. It can be configured as either orange or purple by the drug library.
Passcode Auto-Lock Inactivity Timeout	If Inactivity Timeout = Yes, the infusion pump will automatically lock after a certain period of inactivity and will require a passcode to unlock. If Inactivity Timeout = No, a passcode lock must be set manually, if needed.

CCA and Pump Settings	Description
Maximum Standby Time	This is the maximum time that a delivery can remain in Standby before the infusion pump issues a high priority Inactivity alarm. The Maximum Standby Time is defined in the drug library. The available range is 24 to 72 hours.
Screen Lock Timeout	Displays the length of time the infusion pump may be inactive before being locked via the Screen Lock (Inadvertent Touch Prevention) for the CCA.

Launch Biomed

This application is used by biomed engineers to conduct maintenance on the pump. Biomed mode cannot be opened when an infusion is running and requires a passcode to enter. For further information, see the *Plum Solo Technical Service Manual*.

Cleaning, Maintenance, Storage, and Service

Cleaning and Disinfecting the Infusion Pump

The Plum Solo 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 Solo 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 OR DISINFECT ANY PART OF THE INFUSION PUMP.

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

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

Cleaning Procedure

PRECAUTION: USE CLEANING OR DISINFECTING SOLUTIONS AS SPECIFIED BY THE MANUFACTURER TO AVOID INFUSION PUMP DAMAGE.

PRECAUTION: THOROUGHLY CLEAN AND DRY THE DEVICE. FAILURE TO THOROUGHLY CLEAN AND DRY THE DEVICE MAY PREVENT ADEQUATE DISINFECTION.

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

NOTE: When cleaning spills during the course of patient care, it is recommended to lock the user interface using a passcode.

- **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 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. See the *Plum Solo Technical Service Manual* for a full list of cleaning and disinfecting solutions.

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: INSPECT THE INFUSION PUMP HOUSING, POWER BUTTON, OR DISPLAY FOR DAMAGED. IF ANY IS FOUND 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 OR DISINFECTING SOLUTIONS DIRECTLY ONTO THE INFUSION PUMP.

3. Thoroughly clean the infusion pump.

- 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.

4. Inspect the infusion pump. If the device is not visibly clean at the end of the cleaning procedure, continue to repeat the cleaning procedure until visibly clean.
5. Allow the infusion pump to air dry for up to 30 minutes, or towel dry until there is no visible moisture before disinfecting.

NOTE: Failure to thoroughly clean and dry the device may prevent adequate disinfection.

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. **Important:** The screen may become cloudy if the correct concentration is not used.

Disinfecting Procedure

PRECAUTION: USE CLEANING OR DISINFECTING SOLUTIONS AS SPECIFIED BY THE MANUFACTURER TO AVOID INFUSION PUMP DAMAGE.

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 OR DISINFECTING SOLUTIONS DIRECTLY ONTO THE INFUSION PUMP.

3. Wipe in an outward spiral pattern on the desired surface(s), replacing the cloth or wipe as needed.
4. Allow all surfaces to remain wet with disinfectant for a minimum of 6 minutes.
5. Dampen a sterile lint-free cloth with tap water and wipe all surfaces.
6. Allow the infusion pump to air dry for up to 30 minutes, or towel dry until there is no visible moisture before use.

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. **Important:** The screen may become cloudy if the correct concentration is not used.
Household Bleach	PDI Sani-Cloth Bleach Germicidal Disposable Wipe	Use per manufacturer's recommendations and instructions in this manual.
Quaternary	Metrex CaviWipes	Use per manufacturer's recommendations and instructions in this manual.

Infusion Pump Maintenance

The Plum Solo infusion pump requires preventive maintenance every two years that is performed by qualified service personnel. There is

no clinician required maintenance. See the *Plum Solo Technical Service Manual* for instructions.

WARNING: DO NOT PERFORM MAINTENANCE OR SERVICE ON THE INFUSION PUMP WHILE IT IS IN USE WITH A PATIENT.

Battery Maintenance

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

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

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 IN THE INFUSION PUMP, CONTACT THE BIOMEDICAL DEPARTMENT TO REMOVE THE BATTERY BEFORE STORING THE INFUSION PUMP FOR AN EXTENDED PERIOD OF TIME.

PRECAUTION: DO NOT STORE OR USE THE BATTERY OUTSIDE OPERATING OR STORAGE CONDITIONS, AS IT MAY SHORTEN THE LIFE EXPECTANCY OF THE BATTERY.

PRECAUTION: THE INFUSION PUMP INHIBITS CHARGING OF THE BATTERY IF THE BATTERY IS OPERATING AT A TEMPERATURE OF 0 C OR LOWER, 45 C OR HIGHER, AND REDUCES THE CHARGING IF THE BATTERY IS OPERATING AT A TEMPERATURE BETWEEN 0 C AND 10 C.

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

WARNING: SERVICING ON THE PLUM SOLO INFUSION PUMP IS TO BE PERFORMED ONLY BY TRAINED, AUTHORIZED PERSONNEL.

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 will invalidate the pump's warranty. See the *Plum Solo Technical Service Manual* for repair and replacement procedures.

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

- See the *Plum Solo Technical Service Manual* for more information for all battery removal and storage information, component part lists, descriptions, and fuse replacement.

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

NOTES:

Specifications

The following specifications apply to the Plum Solo Infusion Pump.

Physical

Dimensions:	Approximately 8.5 H x 6.5 W x 6.5 D inches (21.6 cm H x 16.5 cm W x 16.5 cm D) (excluding pole clamp extrusion and power cord storage)
Mass:	Approximately 7 lbs (3.2 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:	100-240 VAC; 50-60 Hz; 160VA
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
Electrical Standard:	Class I, Type CF
Battery Type:	Lithium Iron Phosphate; 12.8 V; 2,500 mAh; 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:

This table defines the typical operating time of a new and fully charged battery under different conditions.

Rate	Active Channels	Battery Operating Time (hh:mm)	
		Nominal Brightness	Max Brightness
25 mL/hr	1	06:15	05:55
	2	05:35	05:35
999 mL/ hr	1	03:20	03:20
	2	02:10	02:10

NOTE: All conditions tested while connected to ISMS via the Wireless Interface.

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.

Environment

Operating Temperature:	41°F to 104°F (5°C to 40°C); See notes 1, 2, and 4.
Storage Temperature:	-4°F to 140°F (-20°C to 60°C); See notes 2, 3 and 5.
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 6.
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.

Storage Temperature	Recharge Intervals (for both loose and inserted batteries)
-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: To maintain battery safety, battery charging is inhibited when the internal temperature of the battery reaches 45°C or higher, and is reduced when battery temperature is between 5°C and 10°C. This is important to consider when operating at temperature extremes.

NOTE 5:	Avoid storing batteries at charge levels below 20%. Storage at very low charge can lead to a condition where safety mechanisms permanently disable the battery.
NOTE 6:	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
CONTAINS FCC ID:	STJ-SDMAC
CONTAINS IC ID No:	5627A-SDMAC

Near Field Communication

Frequency Band:	13.56 MHz
Antenna:	Adhesive flex antenna mounted underneath the middle of the display.
Standards:	FCC Part 15C (15.225) RSS-210
FCC ID:	STJ-NFCS
IC ID No:	5627A-NFCS

VTBI Range

VTBI Range:	0.1 to 99.99 mL (in 0.01 mL increments) 100 to 9999 mL (in 1 mL increments)

Delivery Rate Range and Duration

Delivery Modes:	Piggyback and Concurrent Deliver Alone (if the version of LifeShield™ Infusion Safety Software supports this feature)
Delivery Methods:	Continuous, Loading Dose, Bolus, Flush, and Multistep
Rate Entry:	0.10 to 9.99 mL/hr (in 0.01 mL/hr increments) 10.0 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) maximum
KVO:	1.0 mL/hr or the last primary delivery rate, whichever is less **NOTE:** KVO may be configured by CCA to have a default setting of 1-20 mL/hr
Bolus Rate Entry:	0.10 to 9.09 mL/hr (in 0.01 mL/hr increments) 10.0 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: Configured for each CCA as 50, 100, or 250 mcL 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 and type of administration set affect the maximum downstream occlusion detection time and bolus volume released after a downstream occlusion is resolved.

Downstream Occlusion:	The downstream occlusion alarm sounds after the downstream tubing or set outlet fitting becomes occluded or a vacuum occurs. When the Downstream Occlusion Alarm Auto-Restarts (DOAR) detects a downstream occlusion, delivery stops immediately and the infusion pump issues an alarm. The Plum Solo infusion pump can restart the delivery automatically if the downstream occlusion clears within 60 seconds. Refer to ***Restarting Delivery Automatically After a Downstream Occlusion Alarm*** to obtain more information.
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).
Maximum Infusion Pressure:	20 psi (1034 mmHg)

Time to Detect Downstream Occlusions

WARNING: THERE IS A POTENTIAL FOR DELAY IN DETECTING DOWNSTREAM OCCLUSIONS, DEPENDING ON THE FLOW RATE, DOWNSTREAM OCCLUSION PRESSURE LIMIT, DOWNSTREAM TUBING LENGTH, AND TUBING TYPES USED. CONSIDER THESE FACTORS WHILE SETTING UP THE THERAPY TO MINIMIZE THE RISK OF DELAY IN DETECTING OCCLUSIONS.

WARNING: OCCLUSION ALARMS MAY OCCUR WHEN INFUSING HIGHLY VISCOUS FLUIDS AT HIGHER FLOW RATES, ESPECIALLY WITH MICROBORE OR FILTERED ADMINISTRATION SETS.

Flow Rate	Downstream Pressure Alarm Limit Setting	Downstream Tubing Type	Maximum Time to Detect Downstream Occlusion
0.1 mL/hr	1 psi (52 mmHg)	Microbore	4 minutes
0.1 mL/hr	15 psi (776 mmHg)	Microbore	3 hours
1 mL/hr	1 psi (52 mmHg)	Microbore	1 minute
1 mL/hr	15 psi (776 mmHg)	Microbore	12 minutes
25 mL/hr	1 psi (52 mmHg)	Microbore	3 seconds
25 mL/hr	15 psi (776 mmHg)	Microbore	25 seconds
0.1 mL/hr	1 psi (52 mmHg)	Macrobore	8 minutes
0.1 mL/hr	15 psi (776 mmHg)	Macrobore	8 hours
1 mL/hr	1 psi (52 mmHg)	Macrobore	3 minutes
1 mL/hr	15 psi (776 mmHg)	Macrobore	40 minutes
25 mL/hr	1 psi (52 mmHg)	Macrobore	5 seconds
25 mL/hr	15 psi (776 mmHg)	Macrobore	2 minutes

Flow Rate	Downstream Pressure Alarm Limit Setting	Downstream Tubing Type	Maximum Time to Detect Downstream Occlusion
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
0.1 mL/hr	1 psi (52 mmHg)	Microbore	0.00 mL	0.00 mL
0.1 mL/hr	15 psi (776 mmHg)	Microbore	0.15 mL	0.11 mL
1 mL/hr	1 psi (52 mmHg)	Microbore	0.00 mL	0.00 mL
1 mL/hr	15 psi (776 mmHg)	Microbore	0.16 mL	0.13 mL
25 mL/hr	1 psi (52 mmHg)	Microbore	0.00 mL	0.00 mL
25 mL/hr	15 psi (776 mmHg)	Microbore	0.12 mL	0.10 mL
0.1 mL/hr	1 psi (52 mmHg)	Macrobore	0.00 mL	0.00 mL
0.1 mL/hr	15 psi (776 mmHg)	Macrobore	0.45 mL	0.40 mL
1 mL/hr	1 psi (52 mmHg)	Macrobore	0.00 mL	0.00 mL
1 mL/hr	15 psi (776 mmHg)	Macrobore	0.46 mL	0.42 mL
25 mL/hr	1 psi (52 mmHg)	Macrobore	0.00 mL	0.00 mL
25 mL/hr	15 psi (776 mmHg)	Macrobore	0.30 mL	0.26 mL
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 14254 and 14009. 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.

Fluid viscosity, positive backpressure, filling head height, temperature, and atmospheric pressure conditions do not affect system delivery accuracy specification. See the following sections for additional details.

Delivery Accuracy and Start-up Delay Time Results

These tables define the delivery accuracy performance across various clinical use conditions.

Typical start-up delay time for 0.1 to 999 mL/hr rates is less than 1 minute for viscosity, temperature, ambient pressure, and filling head height conditions tested. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

Variations in temperature, ambient pressure (at or above sea level), fluid viscosity, and filling head height do not impact system delivery accuracy.

Tested Configuration	Flow Rate Error (%)	Start-up Delay Time (minutes)		Tested Configuration
	0.1 to 999 mL/hr	0.1 mL/hr	1 mL/hr	
Standard Conditions (up to 96 hours)	-2.6% / 1.7%	-0.3±0.9	0.0±0.2	0.1 ±0.1

NOTE: For Notes and Conditions Tested information, see the following table.

Tested Configuration	Flow Rate Error (%)	Start-up Delay Time (minutes)	
	0.1 to 999 mL/hr	0.1 mL/hr	10 to 999 mL/hr
Ambient Temperature: 41°F (5°C) (up to 96 hours)	-3.1% / 2.3%	-5.8±3.0	-0.1±1.1
Ambient Temperature: 104°F (40°C) (up to 96 hours)	-2.1% / 4.3%	3.0±2.4	0.0±1.0
Ambient Pressure: 15 psia 0 feet above sea level (0 meters)	-2.2% / 3.0%	0.5±3.0	0.0±1.0
Ambient Pressure: 10 psia 10,000 feet above sea level (3,000 meters)	-2.9% / 3.2%	2.4±2.2	0.0±0.5
50% Dextrose Solution (high viscosity)	-2.9% / 1.4%	-1.2±1.5	0.0±0.1
Peptamen 1.5	TBD	TBD	TBD
Filling Head Height: -20 inch (-51 cm)	-3.2% / 2.0%	-0.3±1.1	0.0±0.1
Filling Head Height: +35 inch (+89 cm)	-2.5% / 1.9%	0.5±1.0	0.1±0.2

NOTE: Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

NOTE: Results were established with a confidence and reliability of 95% / 95% using a sample size of 15. Flow rate error (%) results represent the Lower and Upper Tolerance Interval Limits of the 15-sample size tested. The startup delay time results represent the mean and standard deviations from the 15 samples tested.

NOTE: Start-up delay time is a measure of the lag time observed from the initiation of fluid delivery at a given rate to the effective start of delivery at that rate. Start-up delay time duration can be influenced by factors such as pumping mechanism, compliance of administration sets, and backpressure. A negative value for start-up delay time indicates that the infusion initially starts at a higher rate before settling into steady-state flow.

Conditions Tested:

- **Flow Rate:** 0.1 to 999 mL/hr
- **Filling Head Height:** -20 to +35 inch (-51 to +89 cm)
- **Viscosity:** Sterile Water up to TBD(Peptamen?)
- **Ambient Temperature:** 41 to 104˚F (5 to 40˚C)
- **Ambient Pressure:** 10 to 15 psia
- **Administration Set:** macrobore and microbore sets (List Numbers: 14009, 14254, and 14687)
- **Duration:** up to 96 hr

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 15 administration sets from the Plum set portfolio. Tests were performed using Administration Set List Numbers 14254 and 14009.

Bolus Delivery Accuracy				
Tested Bolus Rate (in mL/hr)	**Tested Bolus Volume (in mL)**	**Calculated % Deviation from Set Bolus Volume**	**Maximum % Positive Deviation from Set Bolus Volume**	**Maximum % Negative Deviation from Set Bolus Volume**
999 mL/hr	0.1 mL	TBD%	TBD%	TBD%
999 mL/hr	100 mL	TBD%	TBD%	TBD%

Bolus testing was also performed in accordance with test methods and test matrix defined in AAMI TIR101:2021. Bolus volumes of 0.1, 1, and 5 mL given at 999 mL/hr under various operating condition do not affect system delivery accuracy. Refer to ***Loading and Bolus Dose Volumetric Accuracy Results*** for conditions tested.

Tested Configuration	Bolus Dose Volume (mL)	Volumetric Accuracy (%)
Standard Test Conditions	0.1 mL	-0.7% / 3.9%
	1 mL	-1.0% / 1.0%
	5 mL	-2.3% / 0.7%
-2 psi (-100 mmHg) backpressure	0.1 mL	-0.7% / 4.6%
	1 mL	-2.0% / 0.7%
+2 psi (+100 mmHg) backpressure	0.1 mL	-0.2% / 4.8%
	1 mL	-2.1% / 1.1%
20% Dextrose Solution	0.1 mL	-2.5% / 1.9%
	1 mL	-3.7% / -0.2%
70% Dextrose Solution	0.1 mL	0.2% / 2.4%
	1 mL	-4.9% / -0.7%

NOTE: Device start-up does not affect Bolus Dose volume accuracy.

NOTE: Loading Dose was tested with similar results reported.

Enteral Fluids

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. Enteral fluids do not affect system delivery accuracy.

High Viscosity Fluids

At 0.1 to 999 mL/hr flow rates, high viscosity fluids (70% Dextrose) does not affect system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

Atmospheric Pressure

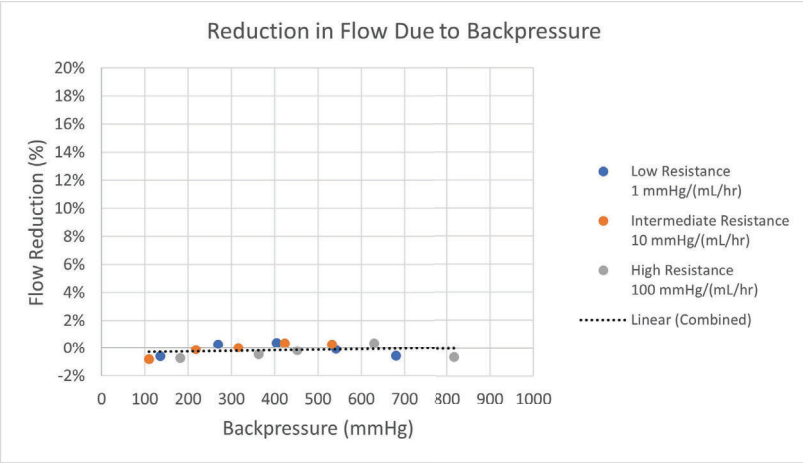
At 0.1 to 999 mL/hr flow rates, atmospheric pressure of 0 to 10,000 feet (3,000 meters) does not affect system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

Backpressure

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.

Flow resistance due to inline resistance and backpressure up to 15 psi do not affect system delivery accuracy. Flow reduction due to inline resistance (backpressure) was evaluated in accordance with test methods defined in AAMI TIR101:2021.

The following chart shows the flow reduction as a percentage of target rate versus backpressure. Represented are averaged results from 15 infusion pumps.



Typical clinical conditions that can cause backpressure include administration set tubing and catheter resistance, resistance from additional elements installed in the fluid path, fluid viscosity, pump to patient elevation, and partial tubing obstruction.

Negative Backpressure (Pump Height) at Low Flow Rates

WARNING: DELIVERY ACCURACY AT LOW FLOW RATES CAN BE AFFECTED BY THE HEIGHT OF THE INFUSION PUMP RELATIVE TO THE PATIENT. FOR BEST ACCURACY PERFORMANCE AT LOW FLOW RATES, KEEP THE INFUSION PUMP CLOSE TO THE LEVEL OF THE PATIENT.

Low flow rates and pump height relative to the patient can result in delivery accuracy variation. The following table defines the delivery accuracy performance for -50 mmHG backpressure (pump 27 inches above patient) and -100 mmHg backpressure (pump 54 inches above patient) at low flow rates.

Flow Rate (mL/hr)	Delivery Accuracy (%) at 27 Inches Above Patient Average Data / StDev	Delivery Accuracy (%) at 54 Inches Above Patient Average Data / StDev
0.1	21.0 / ±8.2	58.0 / ±3.4
0.5	2.3 / ±1.4	6.7 / ±2.9
1.0	1.3 / ±0.9	2.5 / ±1.2
2.0	-0.2 / ±1.0	0.8 / ±1.0
3.0		0.4 / ±0.8

NOTE: Testing was performed in accordance with test methods defined in AAMI TIR101:2021. Flow rate error (%) results represent the average and standard deviation of the 15-sample size tested

Filling Head Height

At 0.1 to 999 mL/hr flow rates, filling head variations of -20 and +35 inches (-51 and +89 cm) of water (such as container height) do not affect system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

Ambient Temperature

At 0.1 to 999 mL/hr flow rates, ambient temperatures of 5°C to 40°C do not affect system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

Concurrent Delivery

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 infusion system was tested under the following clinically relevant conditions, which are intended to represent the worst-case combination of factors. Under these conditions, the system delivery accuracy is maintained within specification.

- Sterile Water infused at 999 mL/hr, at a temperature of 104°F (40°C) for 1 hr, using 112 inches (284 cm) long macrobore PlumSet (Administration Set List Number 14254), attaching a catheter (SP20201) of 22 gauge and 1.5 inches long. Fluid bag hanging at the level of 35 inches above the pump cassette.

- Dextrose 50% infused at 200 mL/hr, at a temperature of 41°F (5°C) for 1 hr, using 107 inches (272 cm) long microbore PlumSet (Administration Set List Number 14009), attaching a catheter (SP20201) of 22 gauge and 1.5 inches long. Fluid bag hanging at the level of -20 inches below the pump cassette.

- Sterile Water infused at 500 mL/hr, at a temperature of 104°F (40°C) for 1 hr, using 112 inches (284 cm) long microbore PlumSet (Administration Set List Number 14009), attaching a catheter (SP20201) of 22 gauge and 1.5 inches long. Fluid bag hanging at the level of 35 inches above 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 of delivery. The graph plots mean delivery rate error for the 2nd 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”).

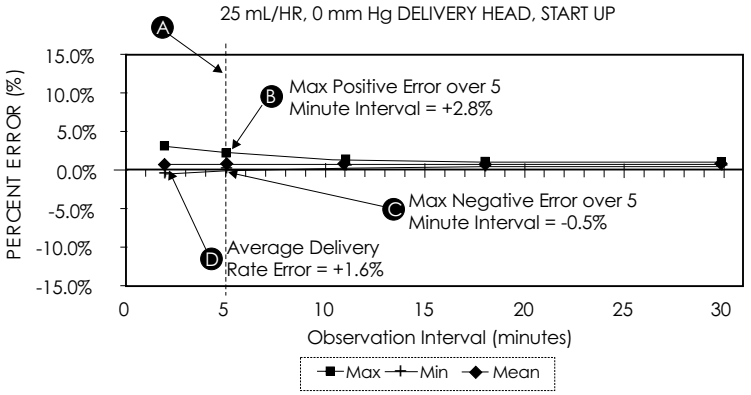
Trumpet Curve data for each rate was generated using a representative sample of 15 infusion pumps (30 mechanisms). Tests were performed using Administration Set List Numbers 14247 and 14687 from the Plum set portfolio.

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%.

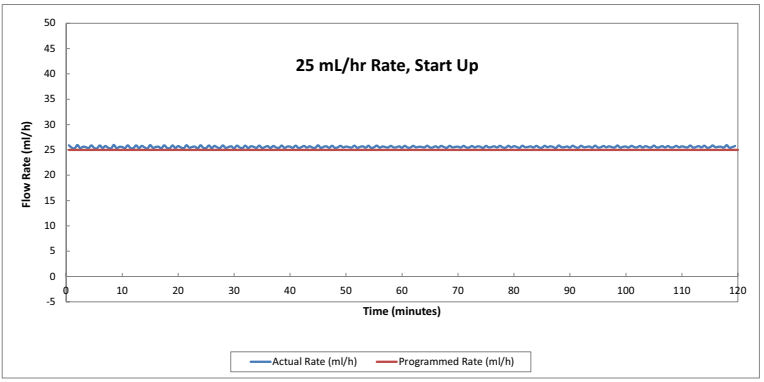
This means that at the rate of 25 mL/hr the average maximum flow rate fluctuation for any 5 minute time interval during the 2nd hour of operation was within the limits of +2.8% and –0.5% from the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

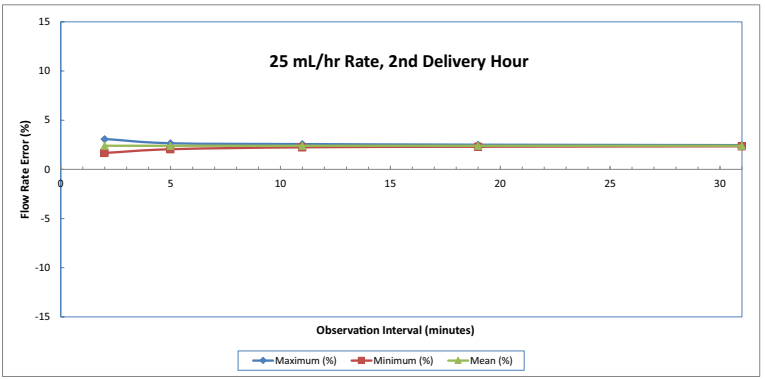
For other time intervals look at other points at the horizontal axis and determine corresponding limits as above.

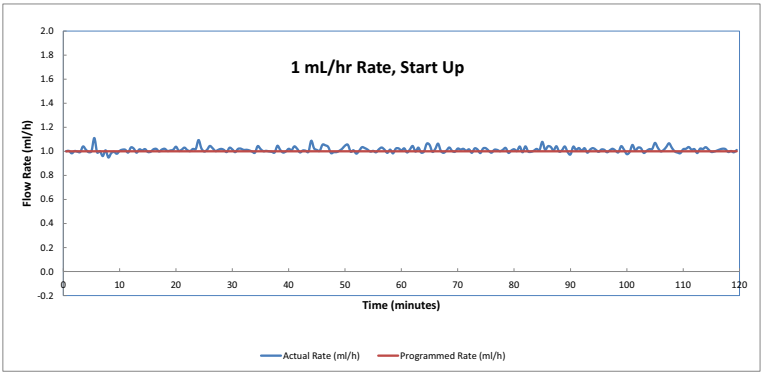


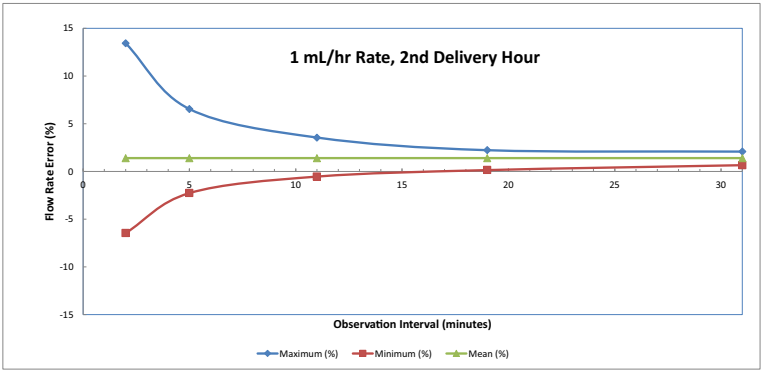
A trained professional can use the resulting graphs to select an infusion pump with the appropriate startup and flow characteristics to suit the clinical application.

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.


25 mL/hr Rate, Start Up
Flow Rate (ml/h)
Time (minutes)
Actual Rate (ml/h)
Programmed Rate (ml/h)


25 mL/hr Rate, 2nd Delivery Hour
Flow Rate Error (%)
Observation Interval (minutes)
Maximum (%)
Minimum (%)
Mean (%)


1 mL/hr Rate, Start Up
Flow Rate (ml/h)
Time (minutes)
Actual Rate (ml/h)
Programmed Rate (ml/h)


1 mL/hr Rate, 2nd Delivery Hour
Flow Rate Error (%)
15
10
5
0
-5
-10
-15
0
5
10
15
20
25
30
Observation Interval (minutes)
Maximum (%)
Minimum (%)
Mean (%)

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/Innovation, Science and Economic Development Canada

This device complies with Part 15 of FCC Rules and Innovation, Science and Economic Development Canada's licence-exempt RSS(s) 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 IC radiation exposure limits set forth for an uncontrolled environment and meets the RSS-102 of the IC radio frequency (RF) Exposure rules.

Under Innovation, Science and Economic Development Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Innovation, Science and Economic Development 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 Innovation, Science and Economic Development 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: 3.00dB (2.4 GHz), 4.45dB (5 GHz)
Frequency Tolerance:	±20ppm

Unauthorized changes or modifications to the wireless system voids the user’s authority to operate the wireless system of the Plum Solo infusion pump.

Electromagnetic Compatibility

The Plum Solo 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
ANSI C63.27-2017
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 60601-2-24:2015
IEC TR 60601-4-2 Edition 1.0 2016-05

The Plum Solo 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 Solo 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.

NOTE: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

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 SOLO EQUIPMENT OR SHIELDING THE LOCATION.

The essential performance of a Plum Solo 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 Solo Technical Service Manual* concerning operating devices near RF sources or sources of electromagnetic disturbance.

PRECAUTION: FLUCTUATIONS IN THE QUALITY OF SERVICE (QOS) OF THE WIRELESS NETWORK MAY RESULT IN TRANSMISSION DELAYS TO AND FROM THE INFUSION SYSTEM AND ISMS. IN THE EVENT OF A NETWORK INTERRUPTION, TRANSMISSION OF DRUG LIBRARY/ SOFTWARE UPDATES AND AUTO-PROGRAMMING FROM THE ISMS TO THE INFUSION SYSTEM, AND TRANSMISSION OF CLINICAL STATUS INFORMATION FROM THE INFUSION SYSTEM TO ISMS, MAY BE IMPACTED. HOWEVER, THE INFUSION SYSTEM CAN CONTINUE TO OPERATE AS INTENDED.

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

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

Refer to the *Plum Solo 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.

When using multiple Plum Solo devices, see ***Mounting Multiple Infusion Pumps to an I.V. Pole*** for proper spacing of infusion pumps stacked with each other. Multiple I.V. poles in this configuration may be directly adjacent to each other. Separate the device from any other electronic equipment. If the device must be used near any other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.

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

WARNING: USE ONLY COMPONENTS AND ACCESSORIES SPECIFICALLY LABELED FOR USE WITH THE PLUM SOLO 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 PERFORMANCE OF THE INFUSION PUMP.

Wireless Coexistence

The ICU Medical Plum Solo infusion pump has been evaluated in order to assess its ability to maintain wireless communication in the presence of other devices with Wi-Fi transmitters on adjacent channels, co-channels, or LTE adjacent channels. The evaluation was performed according to ANSI C63.27-2017 tier 2 tests with the unintended transmitter (EIRP 20 dBm or 0.1 W for Wi-Fi, and 17 dBm or 0.05 W for LTE) being placed at 1 meter separation from the device to maintain wireless coexistence performance for both the 2.4 GHz and 5 GHz bands.

PRECAUTION: PROXIMITY OF OTHER WIRELESS PRODUCTS TO THE INFUSION SYSTEM MAY IMPACT WIRELESS COEXISTENCE. USE THE FOLLOWING RECOMMENDATIONS TO MINIMIZE WIRELESS COEXISTENCE ISSUES.

If the EIRP of the unintended transmitter on adjacent channel or co-channel is different from 20 dBm (0.1 W) for Wi-Fi or 17 dBm (0.05 W) for LTE, the unintended transmitter will need to be kept at a minimum separation distance according to its EIRP as shown by the examples in the following table.

Nearby WiFi or LTE Transmitter		
Wi-Fi EIRP in W (LTE)	**EIRP in dBm (LTE)**	**Minimum Separation**
4 (2)	36 (33)	6.3 m (250 in)
1 (0.5)	30 (27)	3.2 m (130 in)
0.1 (0.05)	20 (17)	1.0 m (39 in)
0.01 (0.005)	10 (7)	0.32 m (13 in)

Wireless Network Quality of Service

Transmission delays to and from Plum Solo and LifeShield™ may occur because of changes in your wireless network's Quality of Service (QoS). Plum Solo and LifeShield™ processes are built to be

tolerant of network congestion by buffering data and resending it as required. The perceived responsiveness of network communications can be significantly impacted by network congestion, retransmissions, and service availability. Even though these network delays may cause the transmission to or from Plum Solo to be delayed, the infusion pump will continue to function normally. The following paragraphs contain more details about the different types of data transmitted between Plum Solo and LifeShield™.

When Plum Solo is infusing in clinical mode, infusion status data is transmitted to LifeShield™. The frequency of the infusion status data transmission by Plum Solo is configurable (between 30 seconds and 5 minutes).

All outgoing data is buffered by Plum Solo in the event of a network failure or a decline in service that hinders the transmission of the data. Plum Solo will store up to 6 months' worth of clinical logs, 2 months' worth of diagnostic logs, and 2 months' worth of audit logs. Plum Solo will continually check the network's connectivity and attempt to send data from its buffer. When connectivity is restored, Plum Solo sends data that was previously buffered.

Plum Solo is connected to LifeShield™ via Wi-Fi. The minimum supported stream data rate for LifeShield™ is 6 Mbits/second. On a 6 Mbit/s connection, throughput for the most frequent or time-sensitive messages is as follows:

- Average infusion data transmitted over a 6 Mbit/second connection will take less than 300 milliseconds.
- A nominal software update (approximately 188 MB) transmitted over a 6 Mbit/second connection will take roughly 14 minutes to transmit.
- A nominal Drug Library Update (approximately 1.5 MB) transmitted over a 6 Mbit/second connection will take less than 16 seconds.
- A nominal Auto Program transmitted over a 6 Mbit/second connection will take less than 600 milliseconds to transmit.

- Irregular events data (alarms) transmitted over a 6Mbit/second connection will take less than 300 milliseconds

PRECAUTION: FLUCTUATIONS IN THE QUALITY OF SERVICE (QOS) OF THE WIRELESS NETWORK MAY RESULT IN TRANSMISSION DELAYS TO AND FROM THE INFUSION SYSTEM AND ISMS. IN THE EVENT OF A NETWORK INTERRUPTION, TRANSMISSION OF DRUG LIBRARY/ SOFTWARE UPDATES AND AUTO-PROGRAMMING FROM THE ISMS TO THE INFUSION SYSTEM, AND TRANSMISSION OF CLINICAL STATUS INFORMATION FROM THE INFUSION SYSTEM TO ISMS, MAY BE IMPACTED. HOWEVER, THE INFUSION SYSTEM CAN CONTINUE TO OPERATE AS INTENDED. USE THE FOLLOWING DATA TO PLAN AND ALLOCATE NETWORK INFRASTRUCTURE TO MINIMIZE IMPACT TO WIRELESS QUALITY OF SERVICE.

To aid in the planning and allocation of network infrastructure, the following data estimations are provided. The following can be expected to be trafficked by Plum Solo infusion pumps connected to the same access point and/or subnet. Estimates are based on a use model of 13 hours per day, 7 days per week, and 46 weeks per year.

Number of Infusion Pumps	Data Traffic (bytes per second)
1	16
10	160
100	1600

NOTE: The results for 10 and 100 pumps are determined by extrapolating the data obtained for 1 pump.

Time-Based Dose Calculation (for example, mg/min) - Initial Programming

1st Action	[AUTOCALC]	2nd Action	[AUTOCALC]
enter DOSE	[RATE]	enter DURATION	[VTBI]
enter DOSE	[RATE]	enter VTBI	[DURATION]
enter RATE	[DOSE]	enter DURATION	[VTBI]
enter RATE	[DOSE]	enter VTBI	[DURATION]
enter VTBI	N/A	enter DOSE	[RATE], [DURATION]
enter VTBI	N/A	enter RATE	[DOSE], [DURATION]
enter DURATION	N/A	enter DOSE	[RATE], [VTBI]

1st Action	[AUTOCALC]	2nd Action	[AUTOCALC]
enter DURATION	N/A	enter RATE	[DOSE], [VTBI]
enter DURATION	N/A	enter VTBI	[RATE], [DOSE]

Once the VTBI is > 0, then the Duration cannot be changed, even during initial programming. This prevents the Dose/Rate from being calculated or recalculated when the Duration is changed.

Time-Based Dose Calculation (for example, mg/min) - After VTBI Complete Alarm

1st Action	[AUTOCALC]	2nd Action	[AUTOCALC]
enter DURATION (if VTBI = 0)*	[VTBI]	keep DOSE	keep RATE
enter VTBI	[DURATION]	keep DOSE	keep RATE
enter DURATION (if VTBI = 0)*	[VTBI]	keep RATE	keep DOSE
enter VTBI	[DURATION]	keep RATE	keep DOSE

NOTE: If VTBI is > 0, then the Duration cannot be changed.

Dosing Units and Allowable Ranges

The following table lists the dosing units available with the Plum Solo infusion pump, the allowable input ranges, and the increment values for each range. Input ranges are determined by the hard and soft limits assigned to each drug.

Category	Dosing Units	Range	Increment
grams	mcg, mg, g, mcg/min, mcg/hr, mcg/day, mcg/kg, mcg/kg/min, mcg/kg/hr, mcg/kg/day, mcg/m^2, mcg/m^2/min, mcg/m^2/hr, mcg/m^2/day, mg/min, mg/hr, mg/day, mg/kg, mg/kg/min, mg/kg/hr, mg/kg/day, mg/m^2, mg/m^2/min, mg/m^2/hr, mg/m^2/day, grams/min, grams/hr, grams/day, grams/kg, grams/kg/min, grams/kg/hr, grams/kg/day, grams/m^2, grams/m^2/hr, grams/m^2/day, grams/m^2/min, ***nanog***, nanog/min, nanog/hr, nanog/day, ***nanog/kg***, nanog/kg/min, nanog/kg/hr, nanog/kg/day, ***nanog/m^2***, nanog/m^2/min, nanog/m^2/hr, nanog/m^2/day	0.001-9.999	0.001
		10.00-99.99	0.01
		100-999.999	1

Category	Dosing Units	Range	Increment
Liters	liters/m^2/day, liters/m^2/hr, liters/m^2/min	0.001-9.999	0.001
		10.00-99.99	0.01
		100-9999	1
mEq	***mEq***, mEq/min, mEq/hr, mEq/day, ***mEq/kg***, mEq/kg/min, mEq/kg/hr, mEq/kg/day, ***mEq/m^2***, mEq/m^2/min, mEq/m^2/hr, mEq/m^2/day	0.001-0.999	0.001
		1.00-9.99	0.01
		10.0-99.9	0.1
		100-9999	1
mL	mL/hr	0.1-99.9	0.1
		100-999	1
	mL, mL/min, mL/kg, mL/kg/min, mL/kg/hr, mL/kg/day, ***mL/m^2***, mL/m^2/hr, mL/m^2/min, mL/m^2/day	0.001-9.999	0.001
		10.00-99.99	0.01
		100-9999	1
mmol	***mmol***, mmol/min, mmol/hr, mmol/day, mmol/kg, mmol/kg/min, mmol/kg/hr, mmol/kg/day, ***mmol/m^2***, ***mmol/m^2/min***, ***mmol/m^2/hr***, ***mmol/m^2/day***	0.001-0.999	0.001
		1.00-9.99	0.01
		10.0-99.9	0.1
		100-999	1

Category	Dosing Units	Range	Increment
Units	***milliUnits***, milliUnits/min, milliUnits/hr, milliUnits/day, milliUnits/kg, milliUnits/kg/min, milliUnits/kg/hr, milliUnits/kg/day, ***milliUnits/m^2***, milliUnits/m^2/min, milliUnits/m^2/hr, milliUnits/m^2/day ***units***, units/min, units/hr, units/day, units/kg, units/kg/min, units/kg/hr, units/kg/day, units/m^2, units/m^2/min, units/m^2/hr, units/m^2/day	0.001-0.999	0.001
		1.00-9.99	0.01
		10.0-99.9	0.1
		100-999999 99	1
Million Units	***Million Units***, ***Million Units/kg***, ***Million Units/kg/min***, ***Million Units/kg/hr***, Million Units/min, Million Units/hr, Million Units/m^2, ***Million Units/m^2/min***, ***Million Units/m^2/hr***	0.001-0.999	0.001
		1.00-9.99	0.01
		10.0-99.9	0.1
		100-999	1

Patient Data Limits

When you program a delivery for a weight-based dosage (mg/kg/hr, for example), you must enter the patient's weight. When programming a BSA (Body Surface Area)-based delivery (grams/m2/min, for example), you must enter either the patient's height and weight, or enter the BSA directly.

NOTE: If you enter the height and weight, the BSA is computed using the DuBois method.

The following table shows the valid ranges for patient weight, height, and BSA, and the increments for each range.

Patient Data	Range	Increment
Weight (kg)	0.25 to 7.999	0.001
	10.00 to 99.99	0.01
	100.0 to 500.0	0.1
Height (cm)	12.7 to 305.0	0.1
BSA (m^2)	0.025 to 0.999	0.001
	1.00 to 7.07	0.01

Examples of Automatic Calculation

mL/hr - Initial Programming

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

mL/hr - After VTBI Complete Alarm

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

Non-Time Based Dose Calculation (for example, mL) - Initial Programming

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

1st Action	[AUTOCALC]	2nd Action	[AUTOCALC]
enter VTBI	[DOSE]	enter DURATION	[RATE]
enter VTBI	[DOSE]	enter RATE	[DURATION]
enter DURATION	N/A	enter DOSE	[RATE], [VTBI]
enter DURATION	N/A	enter RATE	[DOSE], [VTBI]
enter DURATION	N/A	enter VTBI	[RATE], [DOSE]
enter RATE	N/A	enter DOSE	[DURATION], [VTBI]
enter RATE	N/A	enter DURATION	[DOSE], [VTBI]
enter RATE	N/A	enter VTBI	[DURATION], [DOSE]

Non-Time Based Dose Calculation (for example, mL) - After VTBI Complete Alarm

With the exception of the entry of the VTBI auto-calculating the Dose and the entry of the Dose auto-calculating the VTBI, all auto-calculation for a non-time-based program is the same as auto-calculation for an mL/hr program after a VTBI Complete alarm.

Loading and Bolus Dose Volumetric Accuracy Results

Bolus dose volumetric accuracy performance was tested in accordance with AAMI TIR101:2021.

Tested Configuration	Bolus Dose Volume (mL)	Volumetric Accuracy (%)
Standard Test Conditions	0.1 mL	1.8% / 4.8%
	1 mL	0.4% / 3.3%
	5 mL	0.1% / 2.9%
-2 psi (-100 mmHg) backpressure	0.1 mL	-0.7% / 3.2%
	1 mL	-0.4% / 2.5%
+2 psi (+100 mmHg) backpressure	0.1 mL	-0.5% / 6.8%
	1 mL	-0.1% / 3.7%
20% Dextrose Solution	0.1 mL	-1.2% / 2.5%
	1 mL	0.0% / 2.8%
70% Dextrose Solution	0.1 mL	-0.5% / 3.2%
	1 mL	-1.7% / 0.9%

NOTE: Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

NOTE: Results were established with a confidence and reliability of 95% / 95% using a sample size of 30. Volumetric Accuracy (%) results represent the Lower and Upper Tolerance Interval Limits of the 30-sample size tested.

NOTE: -2 psi (-100 mmHg) backpressure corresponds to the infusion pump being 54 inches higher than the patient access site.

Conditions Tested:

- **Number of Boluses:** 25 back-to-back boluses with 5 min delay time in between
- **Bolus Flow Rate:** 999 mL/hr (maximum programmable)
- **Underlying (Basal) Flow Rate:** None
- **Backpressure:** -2 to +2 psi (-100 to +100 mmHg)
- **Filling Head Height:** +18 inch (+46 cm)
- **Viscosity:** Sterile Water up to 70% Dextrose solution
- **Ambient Temperature:** 72˚F (22˚C)
- **Ambient Pressure:** 15 psia
- **Administration Set:** macrobore sets (List Number: 14254)

Warranty

Product Warranty. ICU Medical, Inc. (“ICU Medical”) warrants that the Plum Solo infusion pump (the “Device”) sold by ICU Medical to Purchaser:

1. meets ICU Medical’s specifications, and will be manufactured in accordance with all current Good Manufacturing Practices and other applicable laws in effect at the time of manufacture,
2. is free of defects in workmanship and material, and

3. complies with applicable laws and meet stated standards and regulations.

This warranty does not apply to any administration sets or other disposables or consumables sold for use with the Device, or to services rendered in connection with the Device.

Warranty Periods. This warranty shall apply as follows:

1. For the Device (except for the battery): for a period of twelve (12) months from the date of shipment to Purchaser; or
2. For the battery: for a period of ninety (90) days from the date of delivery to Purchaser.

Warranty obligations for Products. All warranty repairs, replacements or refunds shall be limited to Device or battery issues which are, as reasonably determined by ICU Medical, due and traceable to defects covered by these warranties. Warranty Device returned to ICU Medical must be properly packaged and sent freight prepaid.

Purchaser's sole and exclusive remedy, and ICU Medical's sole obligation, under these warranties shall be for ICU Medical to:

1. Repair or replace the Device or battery under warranty; or
2. If, in ICU Medical's sole opinion, the Device or battery cannot be repaired or replaced, in particular where such actions would not be commercially reasonable or feasible, refund or credit any sums paid by Purchaser to ICU Medical for the Device or battery under warranty.

Voiding of Warranties. The warranties set out herein shall not apply and shall be void if, and to the extent that, the corresponding Device or battery has been:

1. damaged, misused, neglected or subjected to improper storage while in Purchaser's possession;
2. used, handled, maintained, or installed other than in accordance with its Device instructions for use, package inserts, Device labelling, and Device packaging (together, the "Product Documentation"), such prohibited uses including but not limited to:
    a. use of the Device with any administration sets or other disposables or consumables other than those explicitly

authorized by ICU Medical and as stated in the Product Documentation,

b. cleaning, modification, fitting or repair of the Device or battery with non-ICU Medical approved (i) replacement parts, (ii) accessories or components, or (iii) cleaning agents.

3. altered by Purchaser, including the alteration, defacement or removal of serial numbers;
4. subject to installation, repair or attempted repair by unauthorized personnel;
5. resold, leased or otherwise transferred possession to the benefit of a third party;
6. damaged due to unsuitable power sources or other environmental conditions;
7. used by Purchaser notwithstanding the fact that Purchaser knew or ought to have known the Device or battery was defective or damaged.

Exclusion of other Warranties. EXCEPT FOR THE WARRANTIES SET FORTH ABOVE, ICU MEDICAL DISCLAIMS ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. THE REMEDIES SPECIFIED HEREIN ARE THE SOLE AND EXCLUSIVE REMEDIES AND APPLY REGARDLESS OF WHETHER ANY REMEDY SET FORTH HEREIN FAILS OF ITS ESSENTIAL PURPOSE. ICU Medical shall not be obligated to pay any costs or charges incurred by Purchaser or any other party except as may be agreed upon in writing in advance by ICU Medical.

NOTES:

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.

ICU Medical, Inc.
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Lake Forest, Illinois, 60045
USA