Medfusion™ 5000
Infusion Pump

System Operating Manual

For use with list number REF 50000401

Compatible with:
LifeShield™ Infusion
Safety Software Suite

IFU0000605 (01, 2024-08)

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Change History

Part Number	Description of Change
IFU0000605 (01, 2024-08)	Initial Release

NOTES:

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Introduction

Medfusion™ 5000 Infusion System is a small, light-weight and portable syringe infusion pump capable of delivering fluids for a variety of therapies through clinically acceptable routes of administration, to include intravenous, intra-arterial, subcutaneous, epidural, intrathecal and enteral routes of infusions by licensed healthcare professionals. Medfusion™ 5000 Infusion System is for use in a hospital environment and other outpatient healthcare facilities where infusion therapy is needed for a range of patients such as adult, pediatric (including infants and children), and neonatal populations.

The Medfusion™ 5000 Infusion System can deliver fluids over a broad range of infusion rates and is capable of delivery from specified syringe sizes and brands.

FlowSentry is a comprehensive array of pressure-related safety features, including rapid occlusion alarm response and reduction of false alarms. Pressure trending is shown on the user interface, allowing earlier opportunities for intervention, as well as a post-occlusion bolus reduction feature.

The Medfusion™ 5000 Infusion System in conjunction with ICU Medical LifeShield™ Infusion Safety Software Suite to provide medication safety software at the point of care, with customized drug libraries to support hospital defined protocols by clinical care area.

Persistent LifeShield Infusion Safety Software Suite connectivity is optional but LifeShield is required to initialize pumps and to receive libraries, syringe configurations or software updates. For the list of features available with the version of LifeShield Infusion Safety Software Suite installed at your facility, contact your local representative.

Intended Use

The ICU Medical Medfusion 5000 Infusion System is intended for parenteral (limited to intravenous, intra-arterial, and subcutaneous), enteral, intrathecal, and epidural administration of fluids and medications requiring precisely controlled infusion rates including the administration of whole blood and blood products.

The Medfusion 5000 Infusion System is intended for use in clinical environments in the hospital (i.e. critical care, anesthesia) and other outpatient healthcare facilities by licensed healthcare professionals. These healthcare professionals are trained in the use of the infusion system and the administration of therapies consistent with the intended use.

The Medfusion 5000 Infusion System is intended for neonatal, pediatric (including infants, children, and adolescents), and adult populations.

Patient Population

The Medfusion™ 5000 Infusion System is intended for adult, pediatric (including infants and children), and neonatal patient populations. Special consideration and attention should be given to those who are medically fragile as described in this section.

Medically fragile patient populations may include a range of patients with a combination of factors (age, illness, weight, etc.) that place them at higher risk of harm. These include certain pediatric patients, such as those with low birth weight and those born premature (neonate), who require special attention when infusing at low flow rates. Consider the following when using the Medfusion™ 5000 Infusion System with medically fragile patients:

- Consider the criticality of the medication, as well as the appropriate use and limitation of a syringe pump on medically fragile patients. Special consideration is required regarding start up and accuracy needs at the intended flow rates as described in Delivery Accuracy and Delivery Accuracy and Start-up Delay Time Results.
- When placing the Medfusion™ 5000 syringe infusion pump on an I.V. pole, consider its position relative to the patient. If the infusion pump is too high above the patient, be aware of its impact on accuracy at low flow rates. At flow rates less than 1 mL/hr, the Medfusion™ 5000 infusion pump should not be positioned higher than ? inches above the patient. For information on low flow rate, accuracy, and the position of the pump above the patient, see Negative Backpressure (Pump Height) at Low Flow Rates.
- Typical start-up delay time for rates of 0.01 to 1200 mL/hr is less than x minute for viscosity, temperature, ambient pressure, and head height conditions tested. Variation in temperature, ambient pressure (at or above sea level), fluid viscosity, and head heights do not impact system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.
- If a Bolus or Loading Dose is to be given, see Bolus Delivery Accuracy for volume and Loading and Bolus Dose Volumetric Accuracy Results for factors to consider with a fragile patient group.
- See Maximum Unintended Bolus Volume Released After Occlusion is Resolved to determine the flow rate, occlusion pressure alarm limit setting, and tubing type for the potential unintended volume released.
- See Steps to Avoid Unintended Bolus for the steps to avoid an unintended bolus that may occur when clearing a occlusion alarm. See Maximum Unintended Bolus Volume Released After Occlusion is Resolved for the typical and maximum unintended bolus volume.
- Close clamps when connected to a patient while the infusion pump is being powered on, during Pump Initialization, and when stopping the infusion and installing /removing the syringe. If clamps are not closed, a volume of x mL or less may be delivered.

Conventions

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

Table 1-1. Conventions		
Convention	**Application**	**Example**
Blue, Bold, Italic	Reference to a section, figure, table, website, or publication	(*see Section 6.1*)
ALL CAPS	In-text references to buttons, and display messages	PUMP INITIALIZATION IN PROGRESS
Bold	Emphasis	**PRECAUTION: Use proper techniques when handling components.**
	Screen names or displays	Select Set **Time** and **Date**.

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

PRECAUTION: Information that alerts the user of any special care to be exercised for the safe and effective use of the device.

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

Use Environment Exclusions

The Medfusion™ 5000 syringe infusion pump should not be used in any hyperbaric or oxygen-rich environments, nor should it be directly exposed to x-rays or ultrasound.

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

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

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

MR Environment

The Medfusion™ 5000 infusion pump and pole clamp are designed to be “MR Conditional” when positioned outside the 150 Gauss line when running on battery power and secured to a non-movable object.

WARNING: THE PUMP AND POLE CLAMP MUST BE POSITIONED IN A MR ENVIRONMENT SUCH THAT IT IS SECURED TO A NON MOVABLE OBJECT AND THE MAGNETIC FRINGE FIELD DOES NOT EXCEED 150 GAUSS. EXPOSING THE MEDFUSION™ 5000 PUMP TO MAGNETIC FIELDS THAT EXCEED 150 GAUSS PRESENTS A RISK OF IT BECOMING A PROJECTILE HAZARD AND CAN LEAD TO POSSIBLE PATIENT INJURY OR DEATH. IRREVERSIBLE DAMAGE TO THE PUMP CAN ALSO OCCUR, RENDERING IT INOPERABLE.

WARNING: THE AC ADAPTER IS MR UNSAFE, AND SHOULD NOT BE USED IN AN MR ENVIRONMENT OR PRESENCE OF STRONG MAGNETIC FIELDS. WHEN USING THE PUMP IN A MR ENVIRONMENT USE ON BATTERY POWER ONLY.

PRECAUTION: Do not use the infusers in a stacked configuration within a MR environment.

Transport Outside the Facility

The Medfusion™ 5000 syringe infusion pump is not certified for use in helicopters, ambulances, or any transport outside a healthcare facility.

Reporting Serious Incidents

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

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

Training

ICU Medical offers a complete range of training and education to help new users and experienced personnel acquire the knowledge and confidence to operate the Medfusion™ 5000 syringe infusion pump properly and efficiently.

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

Training is mandatory for new device implementation.

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

Definitions

Term	Definition
Alarm	A condition that invokes audible and/or visible alarm indicators requiring operator attention.
Alert	A visual signal (with an audible tone) that provides information or prompts further action. As an example, an alert may occur during programming to inform the user that the entry exceeds a limit that was defined by the institution. The alert details may be presented in a dialog box or below a programming field.
Auto-Programming	Also known as Smart Pump Programming (SPP), this refers to the ability to take a medication order from the electronic medical record (EMR) and translate it into program settings that can automatically populate the infusion pump. Clinician review and confirmation before starting are still required.
Backpressure	The resistance to fluid flow on the downstream of the Extension Set , usually expressed as pounds per square inch (psi).
Biomed Mode	Name for the non-delivery mode of pump operation for hospital technicians (Biomeds) who have access to technical information such as pump performance data for evaluation, calibration and maintenance of the pump.
Bolus Dose	A rapid infusion of a programmed volume of fluid or dose of a drug, being administered to enhance a therapeutic response.
BSA	Body Surface Area, in m2.
Button	A physical key or icon allowing users to control and interact with the device.
Callback	A setting that configures the infusion pump to emit an alarm when a step completes. Callback occurs at the completion of a bolus, loading dose, or a step in a Multistep (excluding the last step), when another program follows. The infusion pump can also be configured to continue the infusion or stop when the Callback alarm occurs.
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 LifeShield Infusion Safety Software Suite.
Cleared Settings	When programmed delivery settings for an individual infusion 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.

Term	Definition
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 rule set (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.
Continuous Infusion	An infusion that delivers at a prescribed rate or dose rate. There may be an option to deliver a Loading Dose or Bolus, as configured through the CDL.
Delay Start	A pending delivery program that will automatically start and not require operator action at the end of the program delay time.
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 syringe and extension sets.
Diluent (Volume)	Volume of fluid in which a medication is diluted.
Dose	A volume of medication to be delivered.
Dosing Unit	Unit of measure for a drug to be delivered.
Drug Amount	The mass or quantity of medication to be delivered (mixed with a diluent).
Duration	The time period required to deliver a programmed infusion.
EMC	Electromagnetic Compatibility, the ability of electrical equipment to function in their designated environment without issue.
Electronic Medical Record (EMR)	An electronic (digital) collection of medical information about a patient, such as diagnoses, medications, and treatment plans.
Enteral	Route of administration via the gastrointestinal tract.
Epidural	Route of administration via the space around the dura mater of the spinal cord.
Extension Set	The tubing assembly that connects a syringe to a patient access device for fluid administration.
FlowSentry™	Defines if the FlowSentry™ pressure monitoring (for rapid occlusion detection) feature is enabled.
Hard Limit	The upper- and lower-dosing limits associated with a drug rule set, in the drug library, that cannot be overridden by the operator.
Hard Limit Alert	An alert on the infusion pump presented to the clinician when a hard limit is exceeded.
High Alert Medication	A drug that can cause significant patient harm if delivered incorrectly.

Term	Definition
Infiltration	Unintentional fluid migration into the tissues surrounding a venipuncture site.
Infusion Pump	A medical device used to deliver fluids into a patient's body in a controlled manner.
Initial Value	A programming value defined at the rule set that automatically populates the programming field on the infusion pump screen for dose, rate, or time (duration) and can be changed by the user during programming.
Intermittent Infusion	An infusion that may be programmed by a dose or volume over a duration, or by rate and volume. When configured through the drug library within a rule set, the infusion cannot be configured with a Loading Dose or Bolus.
LifeShield Infusion Safety Software Suite	LifeShield Infusion Safety Software Suite provides healthcare professionals with the capability to send, receive, and store information from infusion pumps. The bi-directional communication between the hospital medication safety software and infusion pumps includes infusion parameters, infusion pump default configurations, infusion pump location, history, events, trending, alarms, and status.
Limits Range Bar	A graphic on the user interface that shows the medication-configured rule set of upper, lower, hard, and soft limits.
Loading Dose	Administered only at the initial start of an infusion. A rapid infusion of a relatively large volume of fluid or dose of a drug, being administered to enhance a therapeutic response.
Malfunction	One of a number of alarm conditions that indicate a failure of the infusion pump.
Maximum Dose	The highest dose which the infusion pump can be programmed for weight-based and BSA-based infusions. It can be configured for Dose, Loading Dose, and Bolus Dose.
Maximum Rate	The highest rate at which the infusion pump can be configured to be programmed to run for a CCA.
ME Equipment	Medical Electrical Equipment.
Multistep	A sequential program that can deliver up to 10 steps at different rates, doses, VTBI, and durations using the same dosing unit.
Non-time-based units	Dose units based on mass or volume.
Outgassing	The release of a gas that was dissolved, trapped, frozen or absorbed in a material i.e. solutions or medications.
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, titration limits.
Parenteral	Delivery via other than an intestinal route, such as intravenous (I.V.) injection.
Prime	The removal of air from an extension set.
Pump Initialization	When a syringe is installed in the pump, the pump prepares the mechanism by removing any mechanical slack to achieve an optimal pre-load on the syringe plunger.

Term	Definition
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.
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.
Support 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.
Tall-Man Lettering	Uses uppercase letters in combination with lowercase letters to help clinicians differentiate among look-alike drug names.
Time-Based Dosing	A dosing unit that includes a time component (for example, g/min).
Titration	A change in Dose, Rate, and/or VTBI in a currently running or programmed infusion.
Unintended Bolus	A single, unintended volume of fluid delivered.
Unit of Measure	One of a variety of terms used to describe a drug amount, such as grams, mg, or units.
VI	Volume Infused. The volume of fluid that has been delivered by a program or therapy step.
VTBI	Volume To Be Infused. The volume of fluid (remaining) for delivery by a program or therapy step.

Labeling Symbol Glossary

This section describes the symbols used in the labeling for the Medfusion™ 5000 infusion pump:

Symbol	Description	Standards	Symbol Identifier
	**Warning**	ISO 7010	Ref no. W001
	**Precaution**	ISO 15223-1	Symbol 0434A
	Follow Instructions for Use	IEC 60601-1	Symbol 1641
	Catalog Number	ISO 15223-1	Symbol 2493
	Serial Number	ISO 15223-1	Symbol 2498
	Date of Manufacture Country of manufacture	IEC 60417	Symbol 6049
	Manufacturer	ISO 15223-1	Symbol 3082
	Not made with natural rubber latex	ISO 15223-1	symbol 2725 combined with ISO 7000 symbol 6287
	Type CF applied part	IEC 60417	Symbol 5335
	Class II equipment	IEC 60417	Symbol 5172
	Class II equipment with functional earthing	IEC 60417	Symbol 6092
	Medical Device	ISO 15223-1	Symbol 5.7.7
	Non-ionizing electromagnetic radiation	IEC 60417	Symbol 5140
	MR Conditional	ASTM F2503	N/A
	MR Unsafe	ASTM F2503	N/A
	Electrostatic sensitive devices (ESD)	ISO 7000	Symbol 5134
	Equipotentiality	ISO 7000	Symbol 5021
IP32	*Infusion pump* Ingress Protection Protected against solid foreign objects of 2.5 mm Ø and greater Protection against vertically falling water drops when ENCLOSURE tilted up to 15°	IEC 60601 and IEC 60529	N/A
IP22	*AC Adapter* Ingress Protection Protected against solid foreign objects of 12.5 mm Ø and greater Protection against vertically falling water drops when ENCLOSURE tilted up to 15°	IEC 60601 and IEC 60529	N/A
	Temperature Limit	ISO 15223-1	Symbol 0632

Symbol	Description	Standards	Symbol Identifier
	Humidity Limitation	ISO 15223-1	Symbol 2620
	Atmospheric pressure limitation	ISO 15223-1	Symbol 2621
	Packaging Unit	ISO 7000	Symbol 2794
	Do not use if package is damaged and consult instructions for use	ISO 7000	Symbol 2606
	Keep dry	ISO 15223-1	Symbol 0626
	Fragile, handle with care	ISO 15223-1	Symbol 0621
	This way up	ISO 7000	Symbol 0623
	Collect separately	DIRECTIVE 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)	
Rx ONLY	**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician	FDA alternative to Certain Prescription Device Labeling Requirements Document Issued on: 21/Jan/2000. Written statement is taken from 21 CFR 801.109	
	General symbol for recovery/recyclable	ISO 7000	Symbol 1135
	Complies with limits for Class B digital device established by FCC Rules, Part 15	FCC 47 CFR	15.19
	The 'US' indicator adjacent to the CSA Mark signifies that the product has been evaluated to the applicable CSA and ANSI/ UL Standards, for use in the U.S. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL (National Recognized Testing Laboratory), is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.	CSA International	N/A
	Stand By	IEC 60417	5009

Illustrations, Screen Displays, and Software Messages

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

Warnings and Precautions

The Medfusion™ 5000 syringe 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.

WARNING: ALWAYS CONFIRM DATA WITH THE PUMP AND THE PATIENT, DO NOT SOLELY RELY UPON THE ISMS REPORT.

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: NEVER PRIME WHILE CONNECTED TO A PATIENT INFUSION SITE, AS THIS MAY CAUSE INFUSION OF AIR OR OVERINFUSION OF MEDICATION, WHICH COULD RESULT IN SERIOUS INJURY OR DEATH.

WARNING: ALWAYS USE AN EXTENSION SET WITH A FUNCTIONAL CLAMP.

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

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

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

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

WARNING: SYSTEM DELIVERY ACCURACY CAN BE AFFECTED BY THE HEIGHT ABOVE OR BELOW THE PATIENT ACCESS SITE. IF MULTIPLE INFUSION PUMPS ARE UTILISED IT IS ADVISED TO ENSURE HIGH RISK OR LIFE-SUSTAINING MEDICATIONS ARE KEPT AS CLOSE TO LEVEL WITH THE PATIENT ACCESS AS POSSIBLE. WHEN MULTIPLE LIFE-SUSTAINING OR HIGH RISK MEDICATIONS ARE BEING INFUSED, PLACE THE ONES INFUSING AT THE LOWEST RATE AS CLOSE TO THE PATIENT ACCESS SITE AS POSSIBLE.

WARNING: IF THE PUMP IS USED TO DELIVER LIFE-SUSTAINING MEDICATIONS, AN ADDITIONAL PUMP MUST BE AVAILABLE FOR SITUATIONS WHERE AN INTERRUPTION IN INFUSION COULD BE DANGEROUS.

WARNING: APPLICATION OF AN RFID DEVICE OUTSIDE THE RECOMMENDED AREA ON THE INFUSER MAY AFFECT OPERATION OF THE PUMP, PLEASE CONFIRM FUNCTIONALITY WITH BIOMED PRIOR TO USE.

WARNING: ALWAYS READ RESPECTIVE MANUFACTURER'S INSTRUCTIONS FOR MEDICATIONS, FLUIDS, SYRINGES, AND EXTENSION SETS TO BE USED WITH THE INFUSION PUMP. USE OF UNAPPROVED MEDICATIONS, FLUIDS, SYRINGES, AND EXTENSION SETS MAY LEAD TO THE FOLLOWING HAZARDS: AIR EMBOLISM, ALLERGIC/CAUSTIC RESPONSE, DELAY OF THERAPY, EXSANGUINATION, HAZARDS TO THE ENVIRONMENT, INFECTION, OVERDOSE, TRAUMA, AND UNDERDOSE. THE HARMS POTENTIALLY ASSOCIATED WITH THESE HAZARDS VARY BY PATIENT AND CLINICAL CONDITION AND MAY INCLUDE REVERSIBLE INJURY, PERMANENT INJURY, OR DEATH.

WARNING: AVOID THE USE OF MANIFOLDS WITH HIGH PRESSURE VALVES. HIGH PRESSURE VALVES REQUIRE ADDITIONAL PRESSURE (E.G., 7 KPA-27 KPA [50-200 MMHG]) TO OPEN AND ALLOW FLUID FLOW. THESE HIGH PRESSURE VALVES MAY CAUSE A SIGNIFICANT DELAY IN THERAPY FOLLOWED BY A SUDDEN BOLUS ONCE THE VALVE IS OPENED, PARTICULARLY AT LOW INFUSION RATES (E.G., LESS THAN 5 ML PER HOUR, AND ESPECIALLY FLOW RATES LESS THAN 0.5 ML PER HOUR).

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

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

WARNING: THE PUMP AND POLE CLAMP MUST BE POSITIONED IN A MR ENVIRONMENT SUCH THAT IT IS SECURED TO A NONMOVEABLE OBJECT AND THE MAGNETIC FRINGE FIELD DOES NOT EXCEED 150 GAUSS. EXPOSING THE MEDFUSION™ 5000 PUMP TO MAGNETIC FIELDS THAT EXCEED 150 GAUSS PRESENTS A RISK OF BECOMING A PROJECTILE HAZARD AND CAN LEAD TO POSSIBLE PATIENT INJURY OR DEATH. IRREVERSIBLE DAMAGE TO THE PUMP CAN ALSO OCCUR, RENDERING IT INOPERABLE.

WARNING: THE AC ADAPTER IS MR UNSAFE, AND SHOULD NOT BE USED IN AN MR ENVIRONMENT OR PRESENCE OF STRONG MAGNETIC FIELDS. WHEN USING THE PUMP IN A MR ENVIRONMENT USE ON BATTERY POWER ONLY.

WARNING: THE UNAUTHORIZED MODIFICATION OF THIS PRODUCT MAY CONSTITUTE A SAFETY HAZARD, WHICH COULD LEAD TO PATIENT INJURY OR DEATH, AS WELL AS THE POTENTIAL FOR PROPERTY DAMAGE (INCLUDING THE RISK OF FIRE). USE ONLY ICU MEDICAL SUPPLIED SERVICE/ REPLACEMENT PARTS, INCLUDING THE BATTERY PACK. UNAUTHORIZED MODIFICATION AND/OR THE USE OF UNAUTHORIZED SERVICE/REPLACEMENT PARTS WILL ALSO VOID THE LIMITED WARRANTY.

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: 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 MEDFUSION™ MODEL 5000 EQUIPMENT OR SHIELDING THE LOCATION.

WARNING: A PE LINED EXTENSION SET SHOULD BE USED WHEN DELIVERING AT LOW RATES (LESS THAN 1 ML/HR), TO AVOID UNDER DELIVERY DUE TO EVAPORATION.

WARNING: CONSIDER PRIMING, LOADING, BOLUS, AND FLUSH RATES WHEN SELECTING AN INFUSION SET, TO AVOID EXCESSIVE Backpressure AT THE DESIRED FLOW RATE.

WARNING: TO AVOID UNINTENDED BOLUS OR REVERSE FLOW DURING SYRINGE LOADING AND SYRINGE UNLOADING AND SYRINGE INITIALIZATION, THE EXTENSION SET SHOULD BE CLAMPED OR DISCONNECTED FROM THE PATIENT.

WARNING: ENSURE AIR IS REMOVED FROM TUBING PRIOR TO CONNECTION TO THE PATIENT.
TO REDUCE STARTUP TIME EITHER PRIME USING THE PRIME FEATURE OR SYRINGE INITIALIZATION IS PERFORMED BY THE INFUSER, WHEN INSTALLING A SYRINGE.

WARNING: VERIFY THAT THE PLUNGER HOLDERS SECURELY CAPTURE THE SYRINGE PLUNGER. MAKE SURE TO CAPTURE THE SYRINGE BARREL AND FLANGE. FAILURE TO PROPERLY SECURE THE SYRINGE COULD RESULT IN UNCONTROLLED FLUID FLOW TO THE PATIENT.

WARNING: USE THE APPROPRIATE SYRINGE FOR THE INTENDED ADMINISTRATION ROUTE TO AVOID POSSIBLE CONNECTION ISSUES.

WARNING: PERIODICALLY CHECK THE FLUID PATHWAY AND ALL CONNECTIONS (INCLUDING THE CATHETER/ EXTENSION SET CONNECTION) FOR LEAKS. LEAKS IN THE SYSTEM MAY CAUSE FLUID LOSS RESULTING IN UNDER-DELIVERY, AS WELL AS ALLOWING AN OPENING FOR CONTAMINATION.

WARNING: USE THE SMALLEST SYRINGE SIZE NECESSARY TO DELIVER THE FLUID OR MEDICATION. USING A LARGE SYRINGE AT VERY LOW RATES (BELOW MINIMUM RECOMMENDED RATE FOR THE SYRINGE) MAY CAUSE IMPROPER PUMP OPERATION, DELAYED OCCLUSION SENSING, LARGER POST OCCLUSION BOLUS AT HIGHER OCCLUSION LIMIT SETTINGS, DELIVERY INACCURACIES, IMPACT THERAPEUTIC RESPONSE OF SHORT HALF-LIFE DRUGS, OR OTHER POTENTIAL HAZARDS.

WARNING: ONLY USE SYRINGES SUPPORTED FOR USE WITH THIS INFUSER, SEE ***"Medfusion 5000 Approved Syringe List" on page 128***.

WARNING: ALWAYS CONFIRM THE BRAND AND SIZE OF SYRINGE SELECTED ON SCREEN MATCHES THE SYRINGE INSTALLED IN THE INFUSER.

WARNING: DROPPING THE INFUSER ON THE SYRINGE PLUNGER COULD RESULT IN AN UNINTENDED BOLUS.

WARNING: ENSURE THAT THE ACCURACY SPECIFICATION IS TAKEN INTO ACCOUNT WHEN PROGRAMMING THE PUMP AND/OR SELECTING AND FILLING A SYRINGE. FAILURE TO DO SO MAY RESULT IN MEDICATION IN THE SYRINGE BECOMING DEPLETED SOONER OR LATER THAN EXPECTED. REFER TO TABLE *"Delivery Accuracy" on page 131*.

WARNING: CARE SHOULD BE TAKEN WHEN ENGAGING THE SYRINGE PLUNGER TO AVOID UNINTENDED BOLUS. ALWAYS ENSURE THAT DOWNSTREAM CLAMPS ARE CLOSED OR TUBING IS DISCONNECTED FROM THE PATIENT BEFORE LOADING OR UNLOADING A SYRINGE.

WARNING: IF A SELECTED MEDICATION CONTAINS MORE THAN ONE CLINICAL USE, CHOOSE THE APPROPRIATE CLINICAL USE FOR THE INFUSION AS IT DETERMINES THE MEDICATION RULESETS FOR THAT INFUSION.

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

WARNING: CONFIRM AND VERIFY ALL THERAPY VALUES BEFORE STARTING THE INFUSION.

WARNING: PROGRAMMING A LOADING DOSE OR BOLUS DOSE BELOW THE MINIMUM RECOMMENDED VOLUME COULD IMPACT DELIVERY ACCURACY OF THE LOADING DOSE OR BOLUS DOSE.

WARNING: PROGRAMMING A DELIVERY RATE BELOW THE MINIMUM RECOMMENDED RATE COULD IMPACT DELIVERY ACCURACY, STARTUP PERFORMANCE, AND TIME TO DETECT OCCLUSION.

WARNING: CHECK THAT THE OCCLUSION ALARM LIMIT IS APPROPRIATE FOR THE CURRENT PATIENT PRIOR TO USE.

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

WARNING: DIFFERENT ALARM SETTINGS USED WITHIN A SINGLE AREA OF THE FACILITY COULD LEAD TO FAILURE TO RECOGNIZE AN ALARM.

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

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.

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

WARNING: SERVICING ON THE MEDFUSION™ 5000 INFUSION PUMP IS TO BE PERFORMED ONLY BY TRAINED, AUTHORIZED PERSONNEL.

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

WARNING: TO AVOID ELECTRIC SHOCK, USERS SHOULD NEVER OPEN THE PUMP CASE OR BATTERY COMPARTMENT FOR ANY REASON. SERVICE PERSONNEL SHOULD ALWAYS DISCONNECT THE AC ADAPTER BEFORE SERVICING THE PUMP.

WARNING: TO AVOID ELECTRIC SHOCK, BEFORE CLEANING, ALWAYS SWITCH ELECTRICALLY OPERATED EQUIPMENT OFF AND DISCONNECT FROM AC POWER SOURCE.

WARNING: NEVER USE A DROPPED OR OBVIOUSLY DAMAGED PUMP. WITHDRAW IT FROM SERVICE UNTIL A TRAINED BIOMEDICAL TECHNICIAN CAN TEST IT.

WARNING: USE ONLY COMPONENTS AND ACCESSORIES SPECIFICALLY LABELED FOR USE WITH THE MEDFUSION™ 5000 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.

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

WARNING: ECMO USE: DO NOT USE ON THE INLET SIDE OF EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) SYSTEMS WHERE THE NEGATIVE PRESSURE IS GREATER THAN NEGATIVE 100MM HG AS THE HIGH NEGATIVE PRESSURES CAN RESULT IN UNCONTROLLED FLUID FLOW.

NOTE: Single fault failure of certain electronic/motor control components would result in no more than 0.3 mL of unexpected fluid delivery.

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

Guidelines When Inserting and Removing a Syringe

Movement of the barrel clamp or activating the clutch lever will stop the infusion.

- To prevent flow to the patient, close all clamps, slide Plunger Head away from the syringe prior to removing the syringe.

Extension Sets and Accessories Guidelines

Medfusion™ 5000 syringe infusion pump operation requires single-use extension sets.

- Non-Enteral Extension sets should be changed at least every 96 hours or as per facility protocol, whichever is sooner. Discard after use.
- Enteral Extension Sets should be changed at least every 8 hours or as per facility protocol, whichever is sooner. Discard after use.

I.V. infusion sets with integral non-blood 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.

Steps to Avoid Unintended Bolus

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

⚠ PRECAUTION: There is a possibility of an unintended bolus occurring when clearing an occlusion. Use the following procedure to avoid administration of an unintended bolus to the patient while clearing a downstream occlusion.

1. If the extension set has a clamp, ensure that the clamp is closed (even if the closed clamp caused the occlusion alarm).
2. Disconnect the tubing from the patient while eliminating the occlusion.
3. Press and hold the clutch lever, move the plunger head away from the syringe plunger, lift the barrel clamp and remove the syringe.
4. Eliminate the source of occlusion, unless it was caused by a closed clamp.
5. Open downstream clamp to ensure any unintended bolus is released and close clamp again.
6. Reinsert the syringe into the pump.
7. Reattach it to the patient access device.
8. Open all clamps and resume infusion.

For other conditions that may cause an unintended bolus to be administered, see ***"Guidelines When Inserting and Removing a Syringe" on page 15*** and ***"Extension Sets and Accessories Guidelines" on page 16***.

Battery Guidelines

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

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.

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

- If the low-battery, very low battery, or depleted-battery alarm sounds, connect the infusion pump to AC (mains) power immediately.
- Use AC (mains) power whenever possible. Connect to AC (mains) power during storage to ensure a fully charged battery for emergencies.
- It is not recommended to use the Medfusion™ 5000 infusion pump for an extended period of time when the pump indicates a battery change; send the infuser for service. Use of a correctly maintained and charged battery helps to ensure proper operation.
- The battery may not be fully charged upon receipt. Connect the infusion pump to AC (mains) power for at least eight hours prior to initial use.

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 Medfusion™ 5000 syringe infusion pump in any fluids or cleaning solutions.
- Do not spray cleaning solutions or disinfecting agents directly onto the infusion pump.
- 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 Medfusion™ 5000 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 Medfusion™ 5000 syringe infusion pump is designed to operate normally in the presence of most encountered electromagnetic interference (EMI) conditions. The Medfusion™ 5000 has been tested for electromagnetic immunity compliance in accordance with professional healthcare environment immunity requirements of IEC/EN 60601-1-2 Edition 4 standard.

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

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

⚠ PRECAUTION: Portable and mobile RF communications equipment, such as cellular telephones, 2-way radios, Bluetooth™ devices, microwave ovens, in close proximity to this device may affect wireless communications with the infusion pump and/or the operation of the infusion pump.

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

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

Interconnecting of Medical Equipment

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

Suspected Cybersecurity Event or Threat

Connection of the Medfusion™ 5000 syringe 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™ Infusion Safety Software Suite

LifeShield Infusion Safety Software Suite is a cloud-based software platform that enables clinicians to manage IV infusion information with compatible ICU Medical infusion pumps. The LifeShield Infusion Safety Software Suite provides a means for the Medfusion 5000 Device to configure a variety of features and capabilities, depending on availability, that includes the following:

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

NOTE: The persistently connected use of LifeShield Infusion Safety Software Suite with the Medfusion™ 5000 syringe infusion pump is optional. The Medfusion™ 5000 syringe can meet its intended clinical use without LifeShield Infusion Safety Software Suite as long as a drug library has been installed.

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

Clinical Care Areas

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

LifeShield Infusion Safety Software Suite is utilized to develop the drug library for the Medfusion™ 5000 Clinical Care Areas (CCAs) are used to organize drug names, concentrations, dose modes, soft and hard limits per the facility or health system's delivery of care, or common clinical/ patient needs. CCAs are also used to determine infusion pump parameters, such as:

- Maximum rate limits
- Enabling of Delay Start, Standby, and Callback Notifications
- Require Patient Parameter double entry (example- enter weight twice)
- Allow 1 mL syringe use
- Require Total Dose Entry for intermittent dose over duration infusions
- Enable flush option for intermittent dose over duration infusions
  - Maximum flush volume
- Bolus and Loading Dose Options
  - Allow Total Dose Entry
  - Allow Dose entry in mL
  - Enable Bolus Programming
  - Allow overall program to be placed into Standby
- Patient Parameter limits for weight and BSA
- Occlusion Pressure limit
  - Enable FlowSentry™
- Default infusion pump settings, such as alarm volume, key-press volume and initial screen brightness
- Display of Volume as VTBI or VI on Main Delivery screen

- Configuring the color of the user interface displayed during enteral infusion
- Passcode and locking enabled/disabled
- Require Passcode to Use a CCA
- Syringe Types (brands and sizes) to be used within the CCA
- No Drug Selected/Basic drug rule set within the CCA such as
  - bolus availability
  - the ability to configure the dosing units available or limit to just mL/hr
  - Near End of Infusion Alarm time.

Medication and Medication Rule set

Certain parameters are set at the Medication Rule set level, such as:

- Display name
- Concentration
- Concentration Entry Limits (when concentration is not defined)
- Clinical advisory messages
- Clinical use
- Limiting a route of administration to epidural or enteral delivery
- Hard and soft dosing limits
- Percentage dose change limits (Titration limits)
- Initial values (including Dose, Loading Dose and Bolus)
- Availability of Loading Dose, as well as dose units and limits
- Availability of Bolus, as well as bolus units and limits
- Availability of, Multistep programming, units and limits
- Maximum dose and max dose-units
- Near End of Infusion enablement and alarm time.
- High Alert medication enablement

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

Loss of Communication

If the Medfusion Device loses communication with LifeShield Infusion Safety Software Suite, it will continue to infuse without interruption. However, pump status and logs will not be sent and auto-programs and software/drug library updates will not be received until communication is restored. Loss of communication can be caused by a number of factors, such as low Wi-Fi connectivity or a disruption between LifeShield Infusion Safety Software Suite and your hospital’s network , the pump being placed in airplane mode.

For low Wi-Fi connectivity, relocating the pump may be sufficient to reestablish connection. If relocating does not reestablish connection, or if the cause is something besides low Wi-Fi connectivity, contact your hospital’s IT department.

Mounting the Infusion Pump to an I.V. Pole

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

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

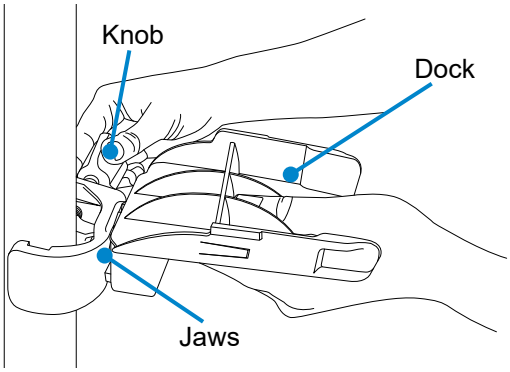
PRECAUTION: For stability and to resist tipping, mount the infusion pump to the I.V. Pole per the provided instructions. Verify stability before use.

The Medfusion™ 5000 syringe infusion pump pole clamp is designed to be mounted on an I.V. pole with a diameter from 0.625-1.375 inches (1.6 cm to 3.5 cm).

To mount the pump:

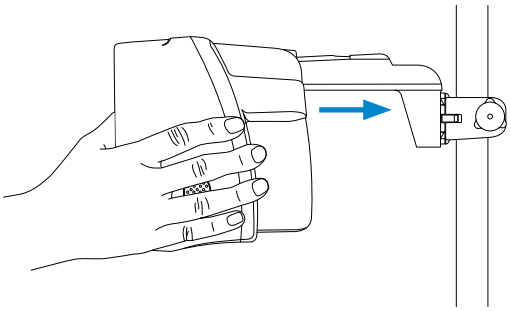
1. Make sure the pole is assembled correctly, rests on a stable surface, and is placed where infusion pump operations will not be affected by other equipment.
2. While facing the pole clamp, turn the clamp knob counterclockwise until the gap between the clamp and the pole clamp screw is wide enough to fit the I.V. pole.

   NOTE: If pole clamp is already attached to the infusion pump, remove it before attaching the clamp to the pole.



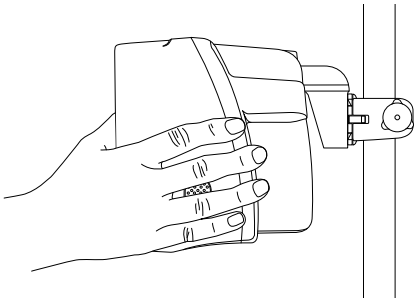
3. Grasp the pole clamp by the dock and position the clamp around the I.V. pole. With your other hand, turn the pole clamp knob clockwise to secure the infusion pump to the pole.

   NOTE: The Medfusion™ 5000 syringe infusion pump pole clamp has a ratchet mechanism that produces an audible click when properly tightened.



4. Push the infusion pump straight back onto the pole clamp dock until you hear the lever click into place.

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.



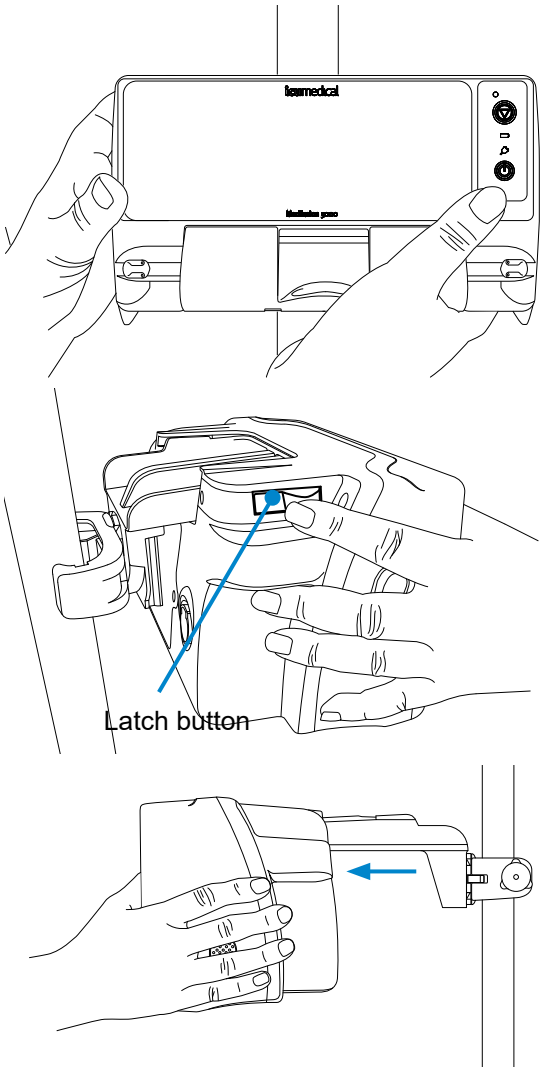
5. Push down and pull up on the infusion pump to confirm that it is tightly clamped to the I.V. pole, without vertical or rotational slippage.
   If you detect slippage, loosen the pole clamp knob, realign the pole clamp, tighten the pole clamp knob, and then check again.

When mounting a single Medfusion 5000 infusion pump to an IV pole the pump may be oriented horizontally (or landscape orientation) or may be oriented vertically (portrait orientation) or oriented at an angle by rotating the pole clamp.

Removing The Infusion Pump from an I.V. Pole

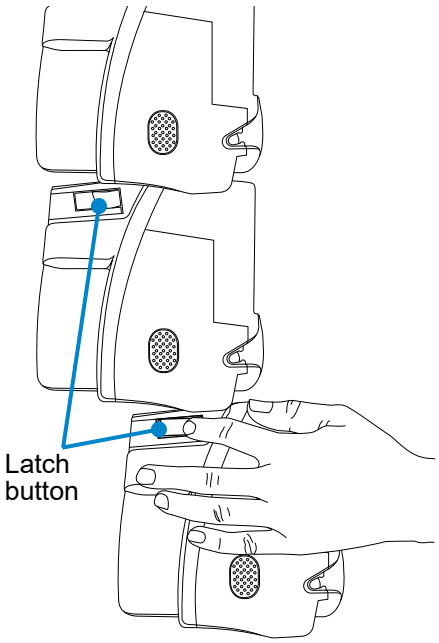
To remove the infusion pump from the I.V. pole clamp:

1. Support the infusion pump with your right hand, with your left hand reach around the left of the pump to access and press the release latch button.
2. Pull the infusion pump towards yourself, supporting the weight of the pump.
3. Remove the pole clamp from the I.V. pole and store with the infusion pump.



Mounting Multiple Infusion Pumps to an I.V. Pole in a Stacked Configuration

⚠ 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.



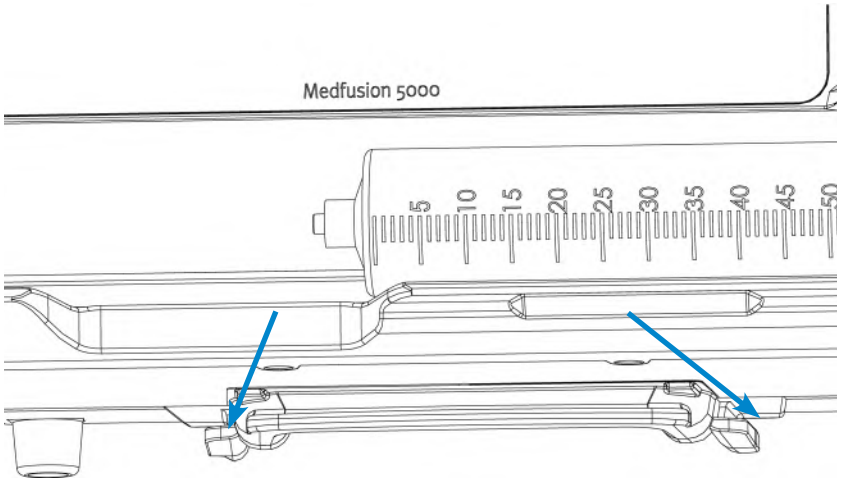
The I.V. pole may have up to four (4) infusion pumps mounted to the pole, using a single pole clamp, may not be extended higher than 68 inches (173 cm) from the floor.

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 subsequent pumps slide the handle/latch mechanism over the latching extrusion on the base of the previous pump. Placing I.V. poles with multiple infusion pumps adjacent to each other does not affect device performance.

After mounting pumps, check the I.V. pole/ infusion pump assembly for stability and tight mounting connections.

If the assembly is **NOT STABLE**, check the mounting heights and the extension height of the I.V. pole. Adjust those settings until the assembly is stable.



I.V. Pole

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

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

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

The pump/I.V. Pole system was tested using X at a height of 68 inches (173 cm) and the infusion pumps mounted at 60, 50, and 40 inches (152, 127, and 102 cm) above the floor. Those values represent the maximum settings for the system to comply with the stability requirements of IEC 60601-1:2012.

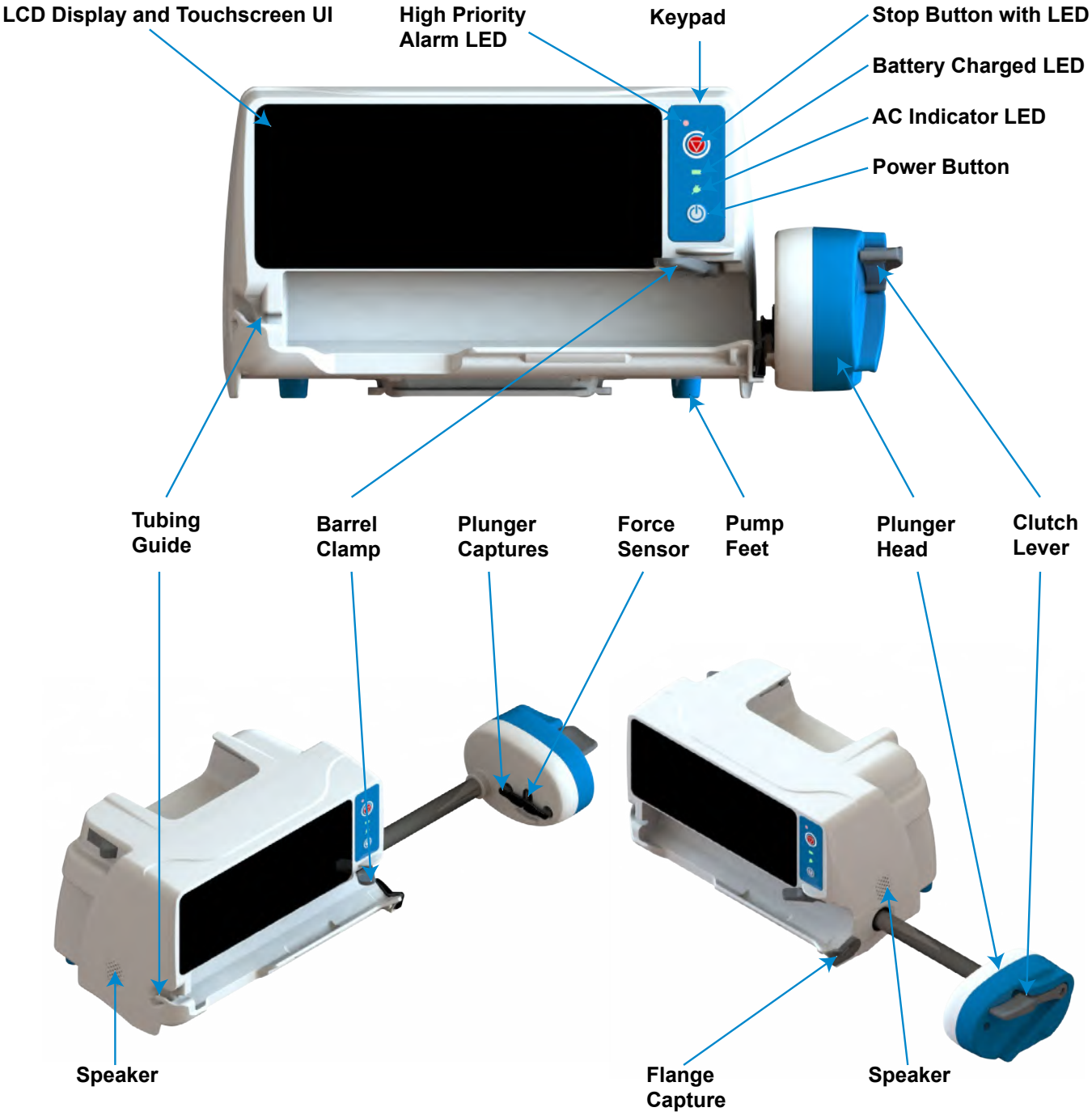
NOTE: The infusion pump mounting height is measured from the floor to the top of the pump.

Syringe Infusion Pump Overview

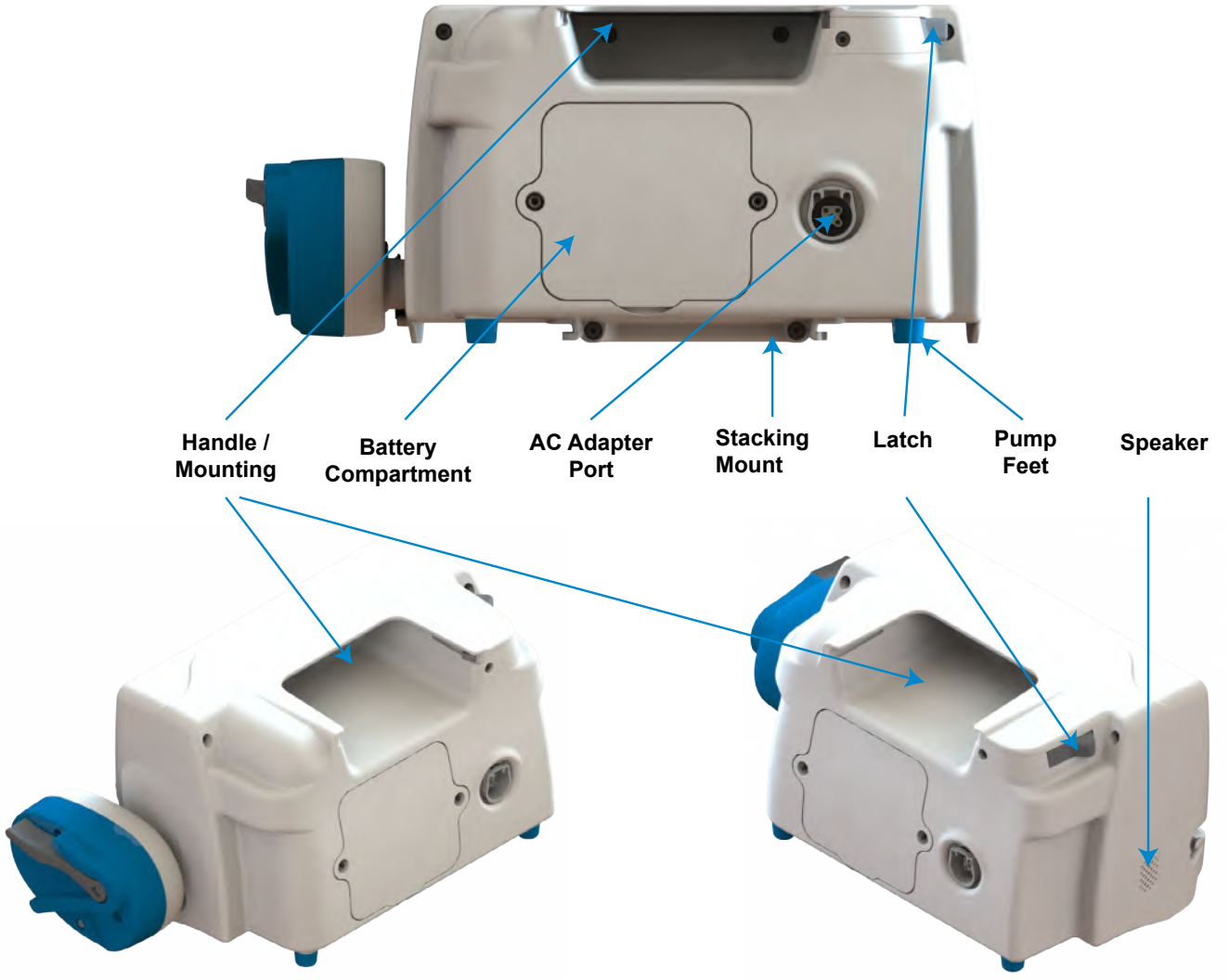
Before placing the infusion pump into service for the first time, a biomedical technician should complete the Device Implementation process as described in the Medfusion™ 5000 Technical Service Manual.

Each infusion requires a disposable, single-use extension set and syringe.

Front

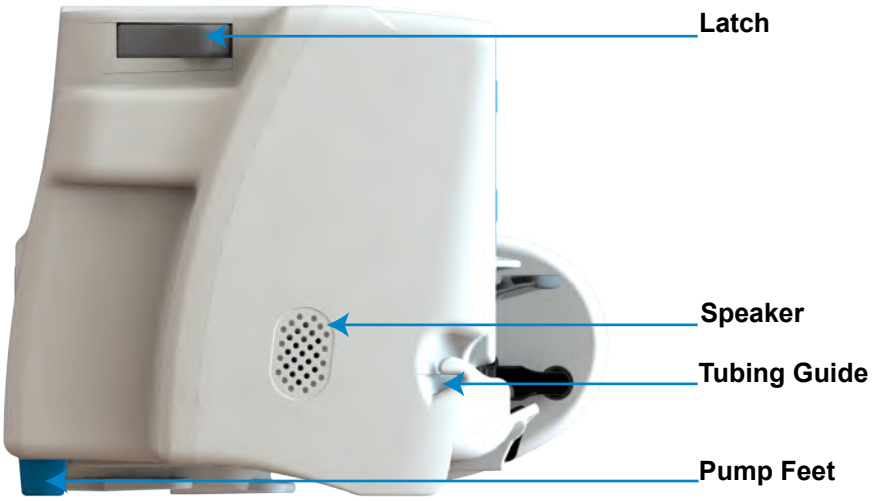


Back

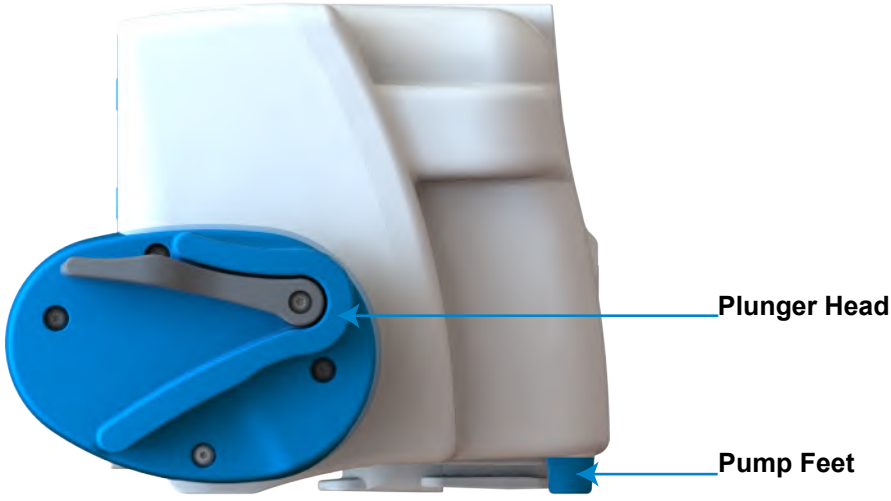

Handle / Mounting
Battery Compartment
AC Adapter Port
Stacking Mount
Latch
Pump Feet
Speaker

Sides

Left



Right



Powering On

Each time you power on, the infusion pump performs a System Self Test to check the operation of critical systems and alarms.

1. To turn power on, make sure the AC Adapter is securely connected to the pump and 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 AC 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 AC Adapter 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 AC Adapter before use. When plugging in, use straight forward motion.

⚠ PRECAUTION: Inspect AC Adapter after use. When unplugging, grasp plug and pull straight out. Do not pull the cable to unplug.

⚠ PRECAUTION: Do not place the infusion pump on an unstable surface.

2. Press the **POWER** button and release the button. Wait for the user interface to respond. The infusion pump will display software and drug library version during power up, followed by the System Self Test.

   NOTE: The POWER button located on the face of the pump, displays the IEC 60417-5009 symbol. The white ring LED surrounding the stop button is on during power up, when the pump display is active the LED light switches off.

Powering Off

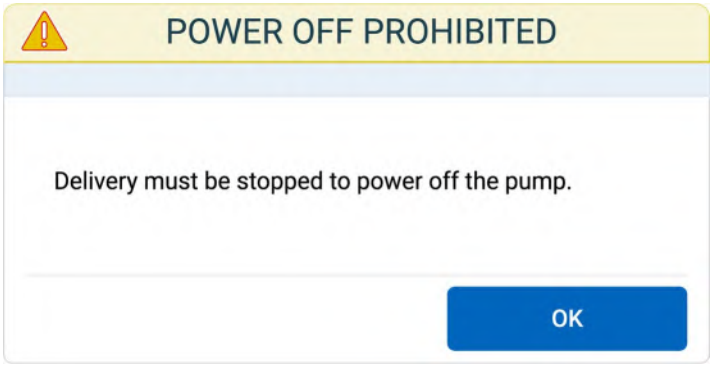
NOTE: Always turn the infusion pump off when not in use, to avoid idle alarms and to reduce the consumption of electrical energy.

You can only turn power off if the programmed infusion is **Stopped**.

1. To turn power off, stop delivery.
2. Press and hold the **POWER** button.
   If patient and/or programming data remains on the pump, you must select whether to save the data or clear it with power off.
   You will see the display turn off.
3. Release the button once display is powered down.

NOTE: If the Medfusion™ 5000 syringe infusion pump is turned off for 5 hours or more and if there are no programs entered in standby, all delivery and alarm settings are cleared for its next use.

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



Drug Library/Settings Updates

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

The infusion pump will automatically activate the library when patient delivery is stopped or completed, programming is cleared, and the infusion pump is powered off. If patient data is on the pump during the power off, an alert will pop up to indicate there is an update pending with a prompt to save or clear patient data. If patient data was cleared, the Drug Library will be updated and the new library will be available on power on. If patient data was saved, the Drug Library will not be updated unless 5 hours has elapsed and the patient data is cleared, or at the next power off. There is no downtime of the infusion pump during this process.

While not in use, and when stored with sufficient battery capacity, the infusion pump will download and activate the drug library update without user interaction.

The download and activation status of Medfusion™ 5000 syringe drug library/settings and software updates can be viewed though LifeShield Infusion Safety Software Suite.

Drug Library/Settings and Software Update Notification

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

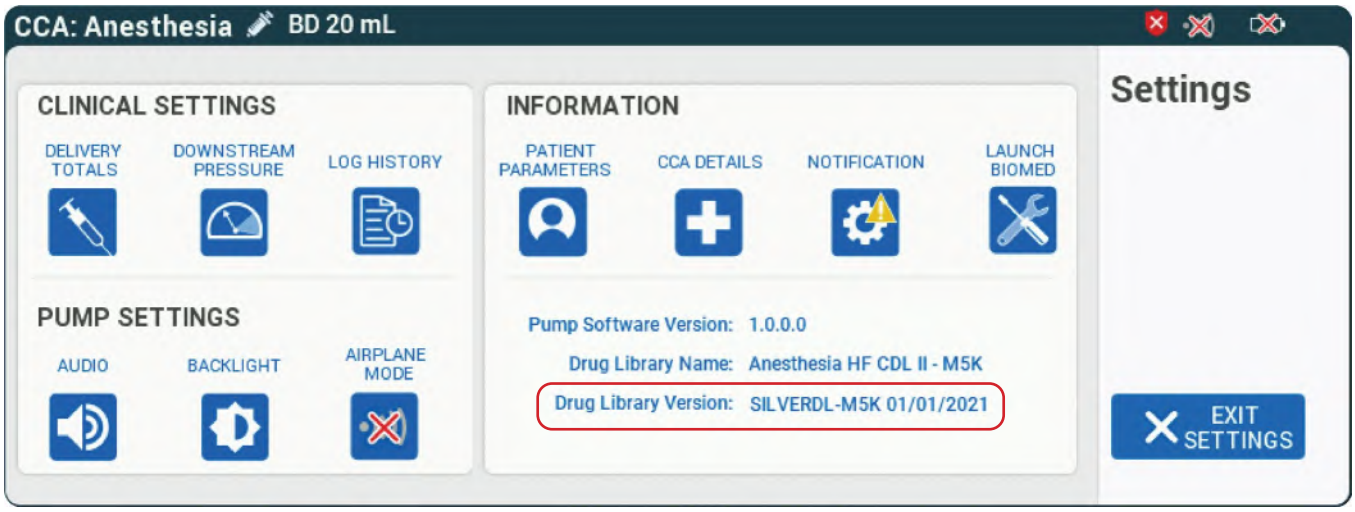
Updates are activated when the pump is not in use. If an update fails, the system will roll back to allow for the continued use of the pump with non-updated software or settings and display a message to alert the user of the failure. Although continued use is possible, the pump should be sent for service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

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

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

Drug Library Versions

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



Drug Library/Settings Update Failure

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

Software Updates

Software updates may be downloaded at any time the device is connected to Wi-Fi and scheduled by LifeShield Infusion Safety Software Suite, without impacting patient therapy. Software download and activations can occur while the infusion pump is stored with adequate battery power.

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

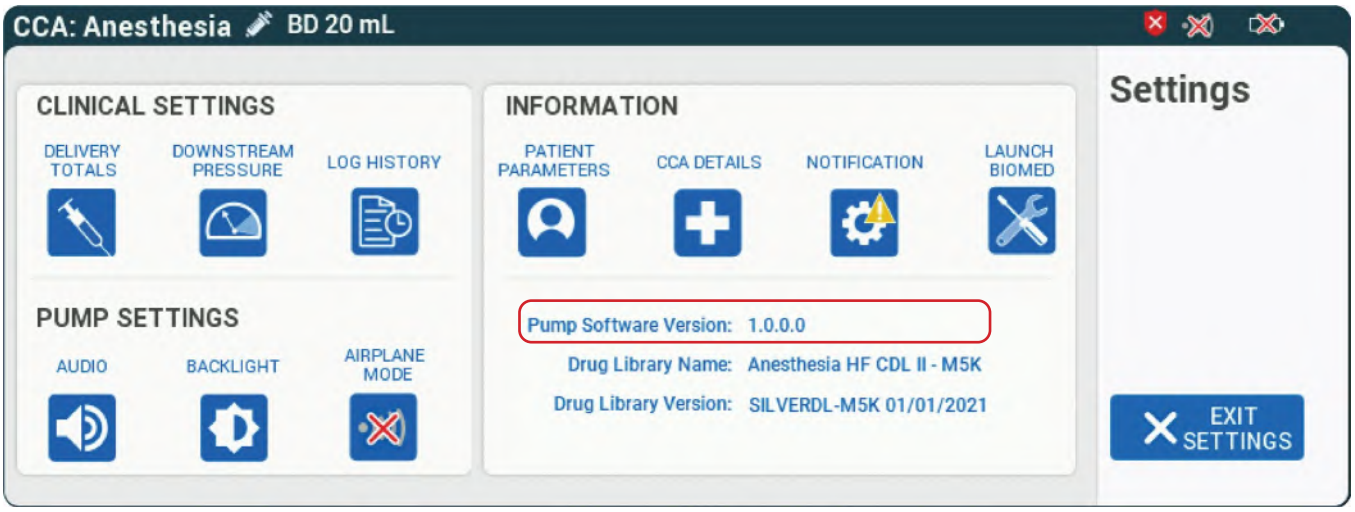
The download and activation status of Medfusion™ 5000 syringe drug library/settings and software updates can be viewed through LifeShield Infusion Safety Software Suite.

Software Versions

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

Software Update Failure

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



Inability to Activate a Software Update Due to Low Battery

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

Touchscreen Display Overview

Except for the **POWER** and **STOP** buttons on the keypad, the Medfusion™ 5000 syringe infusion pump uses a touchscreen for user interaction. When operating the pump, position yourself directly in front of the display.

Use the following gestures to navigate the device:

Tap:

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

Drag:

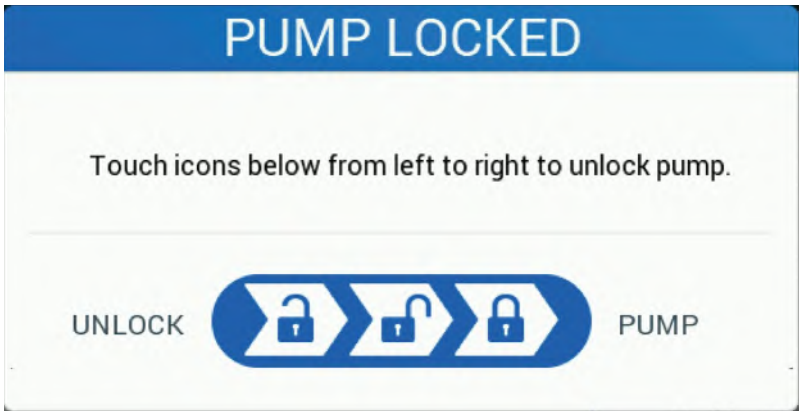
- Lightly drag your finger on lists to scroll through them.

The following elements appear on the user interface:

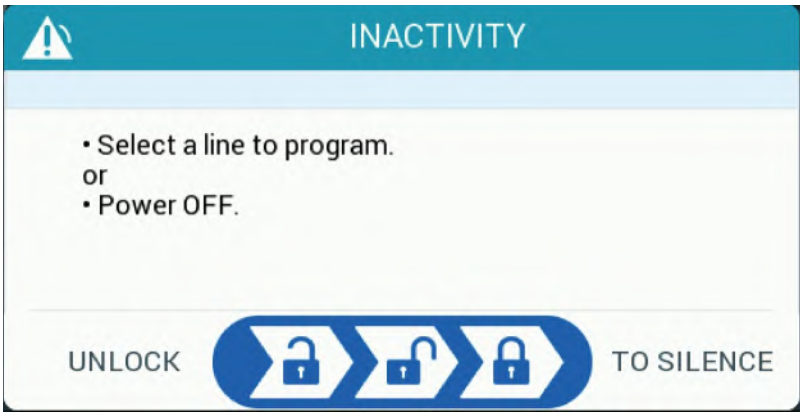
- Action Buttons - Allow for control of the pump mechanism, such as **START** and **STOP**
- Navigation Buttons - Allow for movement through menus or pages
- Indicators - Non-interactive icons that communicate information, such as battery power or connection to safety software
- Scrollable Lists - Contain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

Screen Lock (Inadvertent Touch Protection)

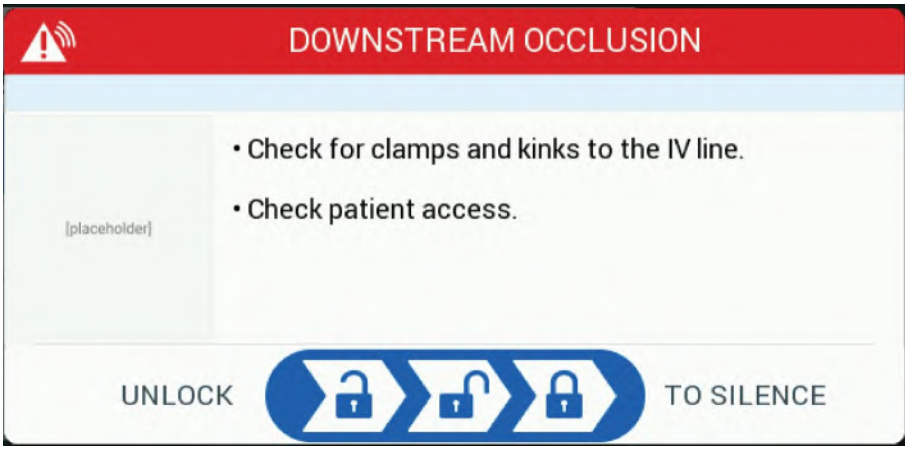
The Medfusion™ 5000 infusion pump uses a screen lock feature to prevent the user interface from activating due to inadvertent touches. The Screen Lock will display when first touched after the preconfigured time (20-45 seconds) since the last interaction. To unlock the pump, slide your finger across the symbols, left to right.



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



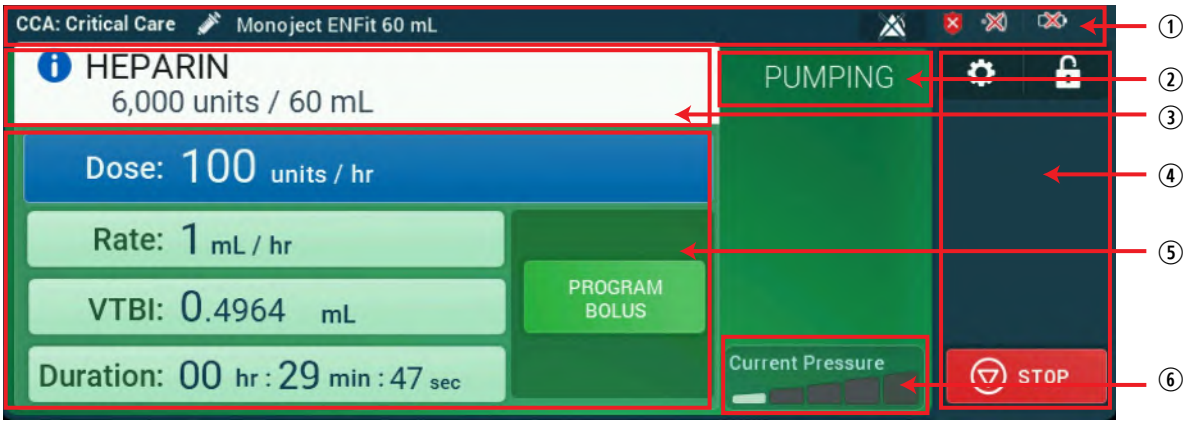
When an alarm occurs, the unlock region will also be a part of the pop-up as seen in the picture below. Interacting with the unlock region will silence the alarm temporarily.



Passcode Lock

The Medfusion™ 5000 syringe infusion pump uses an optional passcode lock feature to prevent tampering with the user interface and programmed settings due to unauthorized users. A passcode may be required to gain access to a particular CCA. The passcode is configured with in the custom drug library by pharmacist per facility. If the pump is configured to automatically passcode lock with the period of inactivity, the timeout value should be set accordingly. To lock the infusion pump manually, tap the lock icon located on the top right and enter the four-digit passcode. To unlock the infusion pump, tap anywhere on the user interface to bring up the passcode keypad and enter the four-digit passcode.

Main Delivery Page Overview



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

1. **Status Bar** - Displays various indicators related to the LifeShield connectivity, battery and Wi-Fi connectivity, as well as viewing disabled alarms list, selected CCA and syringe.
2. **Infusion Status** - Displays infusion status. This includes, but is not limited to, **PUMPING**, **STOPPED**, **STANDBY**, **DELAYED START** and for Multistep infusions it will display which step is in progress (for example Step 1 of 2).
   Tapping the Infusion Status will navigate to the Review page.
3. **Drug Information** - Displays drug name, concentration and any clinical advisories. Tapping the drug name field will navigate to the Review page.
4. **Button Panel** - Depending on the state of delivery, the button panel on the Main Delivery page may display buttons such as **STOP**, **START**, and **STANDBY**, as well as buttons for **Settings** and **Passcode lock**.
5. **Infusion Information** - Displays information for programmed infusions, such as Rate, VI (Volume Infused) or VTBI (Volume to be Infused) as configured in the drug library, and Duration. Tapping the Rate, VI/VTBI, or Duration fields will navigate to the Programming page , if configured in the CCA and the drug rule set there may be the button to **PROGRAM BOLUS**.
6. **FlowSentry™ Status** - Displays the status of flow sentry from Startup, Stabilization, Increasing, Stable and show a pressure chart of the current pressure of the infusion, to analyze and detect occlusions earlier.

Action Buttons

START - Tap to begin delivery.

STOP - Tap to stop delivery.

If the program is pumping when you press STOP, you must tap YES or NO to confirm the stop.

CONFIRM - Tap to confirm program.

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

REVIEW - Tap to review a Multistep infusion with 3 or more steps in the program.

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

INSERT STEP - Tap to add step to Multistep infusion.

DELETE STEP - Tap to clear a specific step in a Multistep infusion.

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

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

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

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

STANDBY - Tap to place pump in standby.

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

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

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

Navigation Buttons

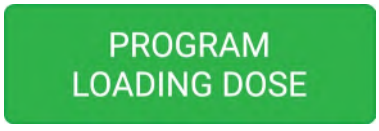
BACK - Tap to move back to the previously viewed page.

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

SETTINGS - Tap to open the Settings page.

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

OPTIONS - Tap to open the Programming Options menu. Options include: Delay Start, Callback, Near End of Infusion, Display VTBI/VI, Downstream pressure and Prime using pump.

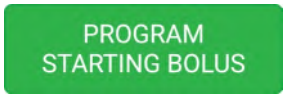


PROGRAM LOADING DOSE - Tap to navigate to the Programming page for a loading dose infusion.

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

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

NOTE: The availability of Multistep is defined by the medication rule set in the drug library.



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

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

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

NOTE: The availability of Bolus is defined by the medication rule set in the drug library.

PROGRAM INFUSION - Tap to navigate to the Programming page for Intermittent infusion.

PROGRAM CONTINUOUS - Tap to navigate to the Programming page for programming a Continuous infusion.

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

NOTE: The availability of Flush is defined by the medication rule set in the drug library or by the CCA setting.

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

DOWNSTREAM PRESSURE - Found in the Settings page, tap to view and edit the downstream occlusion alarm limit (this menu can also be reached via the options menu on the Review screen).

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

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

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

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

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

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

LAUNCH BIOMED - Found in the Settings page, tap to launch Biomed Mode. This will reboot the pump as well as clear all programming data and pending Software/Drug Library updates.

CCA - Tap to change a CCA, available only on Home screen.

Indicators

BATTERY POWER - Displays the current charge of the infusion pump battery.

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

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

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

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

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

BATTERY NEEDS SERVICE - Displays when there is a battery malfunction that can result in the pump´s unexpected shutdown if unplugged from AC (mains).

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

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

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

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

STATUS BAR - Appears on the main delivery page and describes infusion status.

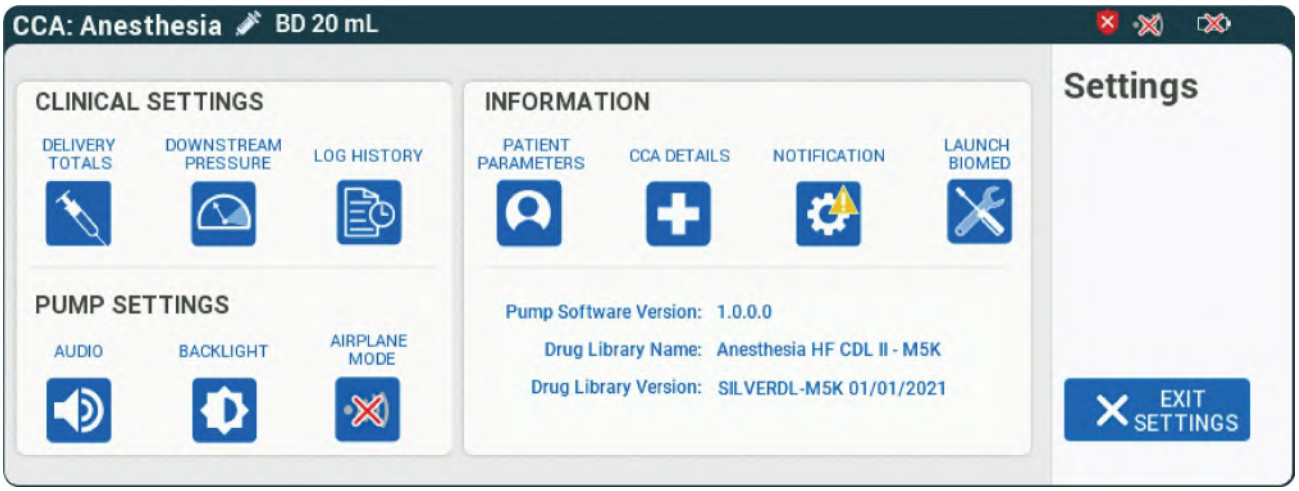
Includes, but is not limited to, PUMPING, LOADING DOSE, DELIVERING BOLUS, STANDBY, and STOPPED.

HIGH ALERT - Appears when there is a condition the user should be advised about.

These include programming without a rule- set (No Drug Selected) and programming under a different CCA.

INFORMATION - Appears next to the medication name when there is a Clinical Advisory.

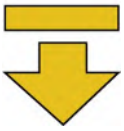
Pump Settings



The Medfusion™ 5000 syringe infusion pump has a number of configurable settings at the CCA and infusion pump levels. To view the Settings page, tap the gear icon in the top right of the Main Delivery page. For a detailed description of each setting, see ***Settings***.

Display Symbols

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



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

LIMIT BAR - Appears on the display to indicate the range of acceptable values for the selected drug. Soft limits are denoted by one or two inner numbers, when applicable, and hard limits by the two outer numbers.

Accessories

Pole Clamp and AC Adapter

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 securely tightened.

AC Adapter - Plugs into AC (mains) power to provide electrical power, charges the battery, and grounds the infusion pump. The AC Adapter can be replaced if damaged (See the Medfusion™ 5000 Technical Service Manual).

Extension Sets

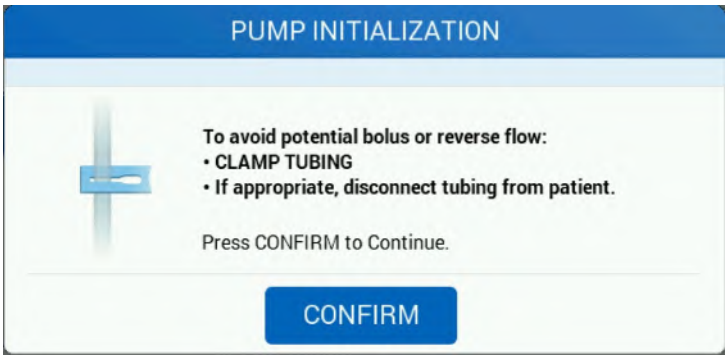
Select the appropriate extension set based on the intended route of administration so that the set can be connected to the patient access site. Always take patient, infusion needs, priming volume, delivery rate, and extension set internal diameter in to consideration when selecting an extension set.

Pump Features

Pump Initialization

Pump Initialization is performed by the pump if the prime feature is not utilized. This feature removes the mechanical slack in the system, to reduce startup delay and increase delivery accuracy.

NOTE: If pumps Prime feature is used then Pump Initialization is not carried out due to priming removing the mechanical slack in the system.



FlowSentry

FlowSentry™ pressure monitoring is an internal program unique to Medfusion™ pumps that monitors and analyzes delivery pressure. When activated, FlowSentry™ pressure monitoring alerts to the existence of an occlusion much more rapidly than conventional occlusion alarm systems. The sensitivity of the FlowSentry™ pressure monitoring setting is determined by the selection in the Custom Drug Library (CDL).

During startup and during the stabilization period following a rate change a  will appear above of the pressure trend graph. The presence of the FlowSentry above the pressure graph indicates FlowSentry™ pressure monitoring is active, and that the delivery pressure is stabilizing.

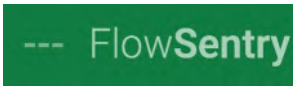
NOTE: FlowSentry™ pressure monitoring is disabled at rates greater than roughly 1/3 of the syringe size per hour. See the table at right for more information.

FlowSentry™ pressure monitoring is automatically disabled when the delivery rate for a syringe size is exceeded as indicated in the following table:

Syringe Size	FlowSentry™ maximum infusion rate
60 mL	20 mL/hr
50 mL	20 mL/hr
35 mL	12 mL/hr
30 mL	10 mL/hr
20 mL	6.6 mL/hr
12 mL	3.3 mL/hr
10 mL	3.3 mL/hr
6 mL	1.65 mL/hr
5 mL	1.65 mL/hr
3 mL	1 mL/hr

NOTE: If FlowSentry™ pressure monitoring is disabled, the bar graph is still shown, however none of the status icons will appear on screen.

FlowSentry Status Icons

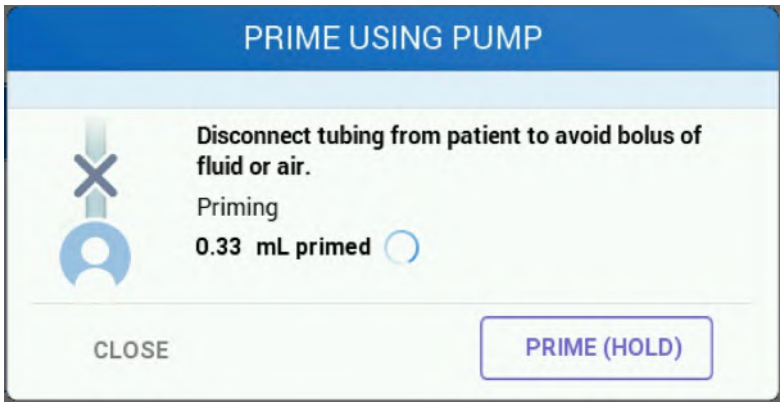
	FlowSentry Stabilizing
	FlowSentry Pressure Increasing
	FlowSentry Stable

Priming with PRIME Pump Feature

The PRIME feature is available at the beginning of programming a therapy and when delivery is stopped. If the extension set is not primed manually before the syringe is inserted into the pump, the PRIME button must be used before connecting the extension set to the patient. If the PRIME button is used at the beginning of programming, the pump initialization process will be skipped. The use of the PRIME button removes the mechanical slack that significantly reduces the start-up time and improves delivery accuracy.

To prime an administration set using the PRIME feature:

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 extension set.
3. Attach the extension set to the syringe
4. Insert the syringe into the pump. (see ***"Loading a Syringe" on page 48***)
5. Ensure the clamps are open.
6. When prompted, press and hold the **PRIME** button. The volume used for priming is calculated and displayed. Prime volume is not added to the total volume delivered.



7. Once priming is complete, close the clamp.

Priming Manually

Priming fills the tubing extension set, and any other components attached to the set with fluid, displacing air. Proper priming is an important part of air management and must be done prior to starting therapy either manually or using the **PRIME** button.

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

The following procedure gives the general steps for priming an extension set. Refer to the set packaging for complete instructions on how to prime the set.

To prime an extension set manually:

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 extension set.

PRECAUTION: Inspect the set, for leakage prior to use.

3. Connect filled syringe to the extension set.
4. Purge air from the syringe by holding extension set distal end up while activating the plunger.

PRECAUTION: Check the connections for leaks. If any part is leaking, replace it.

5. Ensure the clamps are open and gently push on the plunger to remove all the air from the extension set.
6. Once priming is complete, close the clamp.

Loading a Syringe

The following procedure describes how to insert a syringe into the pump.

1. Press and hold the clutch lever and pull the plunger head to the right to allow enough space for the syringe to be loaded. Open the barrel clamp, by lifting and twisting it to the left.

   NOTE: Ensure the syringe and extension set are primed and clamps are closed at this stage if priming manually (see *"Priming Manually" on page 47*).

2. Insert the syringe onto the syringe tray, ensuring the syringe flange is in the flange capture and the extension set tubing is fed through the tubing guide on the left.
3. Lower the barrel clamp onto the syringe, ensuring the syringe is held firmly.
4. Press and hold the clutch lever and slide the plunger head until the end of the syringe plunger is captured/secured in the plunger capture levers (flippers) and touches the sensor.
5. Release the clutch lever to capture the plunger of the syringe.

   NOTE: During loading the pump displays red indicators on screen to ensure correct placement of syringe.

6. Confirm syringe make, model and size on the screen and use the prime feature if not manually primed prior to inserting the syringe (see *"Priming with PRIME Pump Feature" on page 46*).

⚠ PRECAUTION: Use aseptic technique with all fluid path connections to prevent contamination. Remove caps when required and secure all connections.

Stopping Fluid Flow

To discontinue fluid flow:

1. Tap **STOP** on screen.
2. Confirm the **STOP**.

   NOTE: Alternatively, press the ***Stop*** button on the keypad, in case of unresponsive touchscreen or urgent stop of infusion required, this will not require confirmation and will stop the infusion immediately.

3. Press the **POWER** button to turn off the infusion pump.
   If programming data remains on the pump, a pop-up will be displayed to select whether to clear or save the data, then the pump will power off.
4. Close all clamps.
5. Press and hold the Clutch release lever and move the Plunger Head away from the syringe plunger.
6. Lift and rotate the barrel clamp lever to the left and remove the syringe.

Stopping an Infusion

The infusion may be stopped from the Main Delivery page at any time.

To stop an infusion on the pump:

1. Tap **STOP** at the bottom right of the Main Delivery page. A popup appears.
2. Select **YES** to stop.

   NOTE: The Stop button on the keypad can be pressed to stop an infusion if the touchscreen is unresponsive or if infusion needs to be stopped urgently, this will not require confirmation to stop.

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" on page 49***.

NOTE: When STOP is tapped, the infusion pump will alarm after 15 seconds if you don’t confirm the STOP by answering YES or NO.

Restarting an Infusion

To restart a stopped infusion:

1. Tap **START** on the Main Delivery page.
   Alternatively, tap **START** on the Review page to restart the infusion.

Removing the Syringe

The following procedure describes how to remove a syringe from the pump.

⚠ PRECAUTION: Use aseptic technique with all fluid path connections to prevent contamination. Remove caps when required and secure all connections.

NOTE: This procedure can only be carried out after an infusion is stopped, see ***"Stopping an Infusion" on page 49***.

1. Close clamps on the extension set.
2. Disconnect from the patient access site.
3. Press and hold the clutch lever (Ensuring the plunger capture levers (flippers) open fully) and slide the plunger head away from the syringe plunger.
4. Lift the barrel clamp and twist to the left.

NOTE: The barrel clamp will remain in an upright position.

5. Remove the syringe and dispose of per facilities policy and procedures.

Resuming Delivery with a Replacement Pump

To resume delivery with a replacement infusion pump:

1. Close all clamps.
2. Insert the syringe (see ***"Loading a Syringe" on page 48***)
3. Confirm the Syringe on screen.
4. Confirm tubing set clamp is closed for initialization.
5. Program the delivery.
6. Open all clamps.
7. Start the delivery.

Programming

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

- ***Getting Started***
- ***Continuous / Intermittent Infusion***
- ***Multistep***
- ***Loading Dose***
- ***Bolus***
- ***Options***
- ***VTBI Complete Alarm***
- ***Stopping an Infusion***
- ***Flushing***
- ***Titration***
- ***Standby***
- ***Clearing a Program***

Getting Started

New Patient

Press **ON/OFF** button to power on the infusion pump the NEW PATIENT? Screen may appear.

NOTE: New patient displays when the pump has been powered off for 5 hours or less, the pump retains the previous program if saved prior to powering off. (need help here AM)

Select **YES** to clear programming and settings, to start with CCA presets.

Select **NO** to retain previously programmed parameters (weight or BSA) for the same patient.

During Power Off, if there is uncleared programming, the pump prompts to ***CLEAR PATIENT*** or ***SAVE PATIENT*** to proceed with the power off process.

Current CCA and Changing a CCA

The CCA determines the drug names, concentration, dose units, delivery mode soft and hard limits available for programming. The current 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 until/unless it is changed.

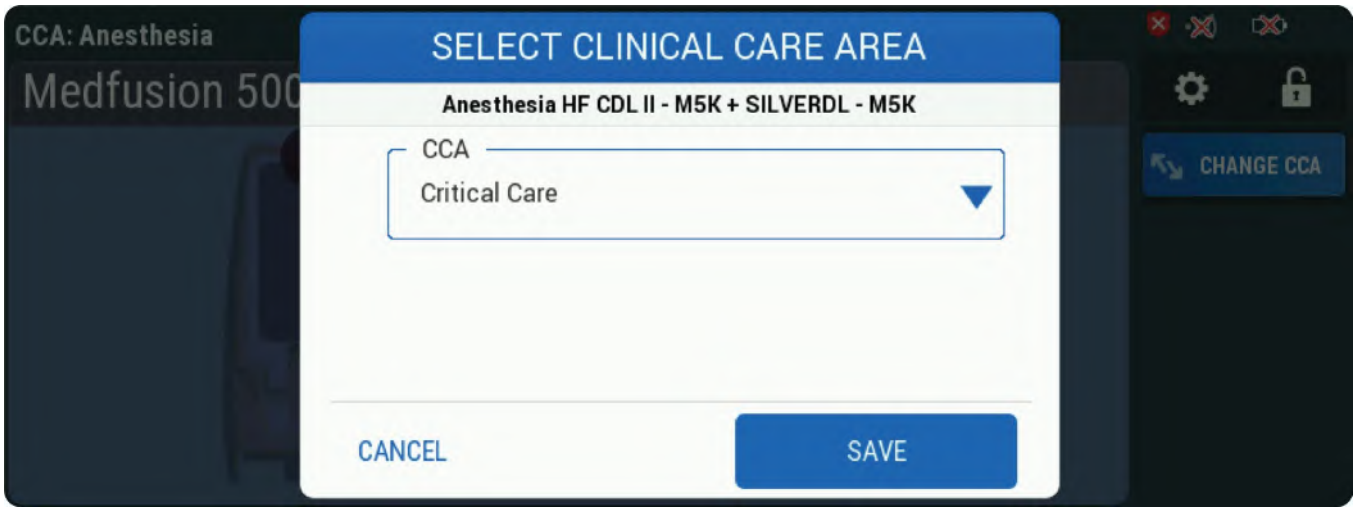
Changing a CCA

You may change the CCA before programming an infusion.

To change the current CCA:

1. Tap the ***Change CCA*** button on the right of the home screen.

The CCA selection popup appears.

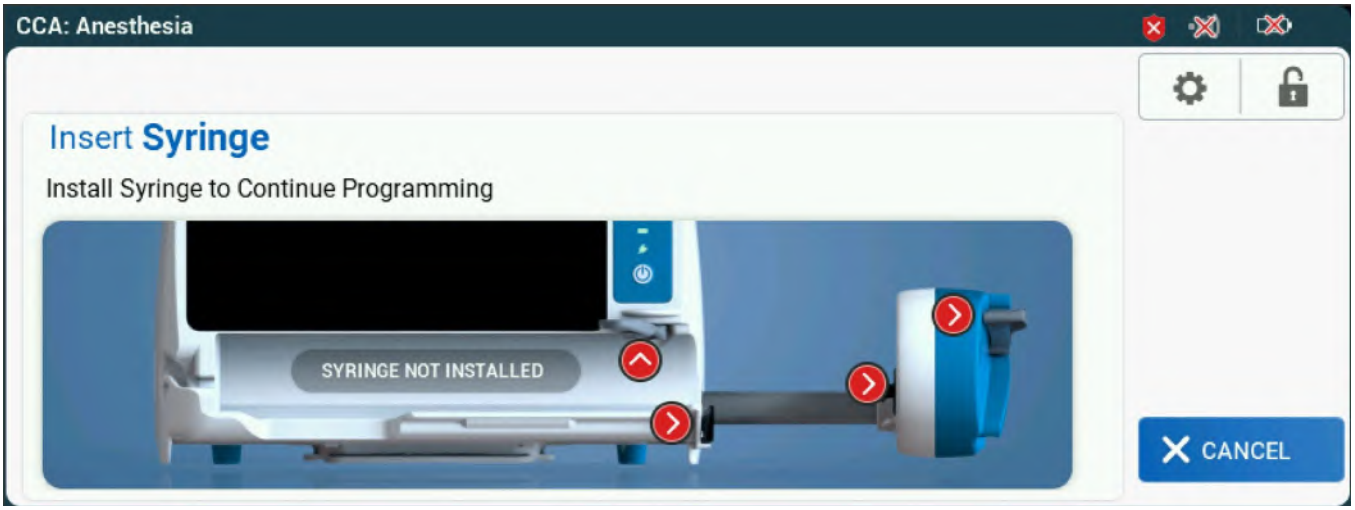


2. Tap the ***CCA*** selection field.
   Only a few CCAs are visible at one time. To navigate the list, drag your finger vertically to scroll through the list.
3. Select the desired CCA in the drop-down list, and press ***SAVE***.
   The name of the selected CCA appears at the top of the screen and is now the current system CCA. Once the CCA is selected programming can begin.

Begin Programming

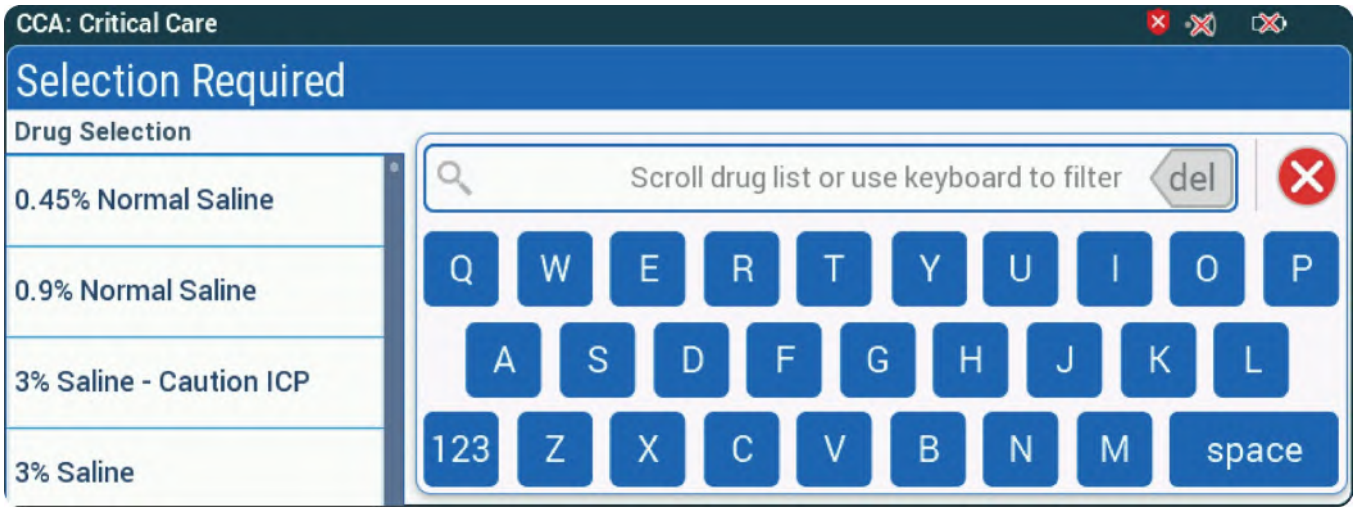
To begin programming, tap the screen to navigate to the Drug Selection screen.

If no syringe is loaded into the infusion pump, the Insert Syringe screen will appear.



Load syringe and confirm it to proceed to the Drug selection screen.

Selecting a Drug



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

Use one of the following methods to search for a drug or solution:

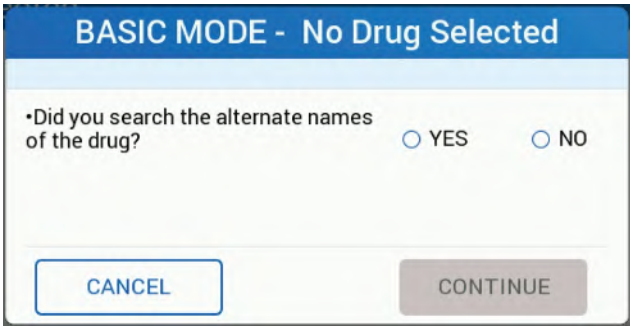
- Enter the name using the keyboard. The list will filter as you enter characters. Tap the **del** button to clear characters.
- Search numerically (example “0.9% NaCl”) by tapping the 123 button in the lower left of the keyboard.
- Scroll through the medication list manually. Drag your finger vertically through the list to scroll.

When applicable a Clinical advisory for a medication will display when the associated drug is selected while manually programming the infusion pump, and must be acknowledged before programming can continue.

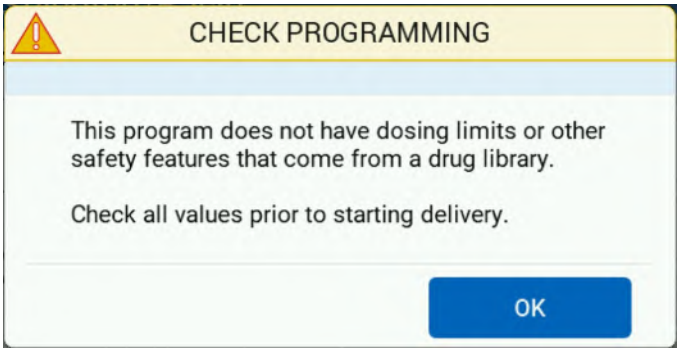
No Drug Selected (Basic)

No Drug Selected (Basic) is available when the drug of choice is not within the CCA. 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 syringe, the CCA, and the pump's flow rate limitations. The available dosing units for programming this feature are determined by the drug library, and the dosing units may be limited.

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



No Drug Selected (Basic) offers only mL/hr programming, as well as a limited selection of dosing unit options if enabled by the drug library for each CCA. When programming parameters are entered, a "**CHECK PROGRAMMING**" alert will appear. Carefully review all parameters before starting delivery.



Selecting Clinical Use

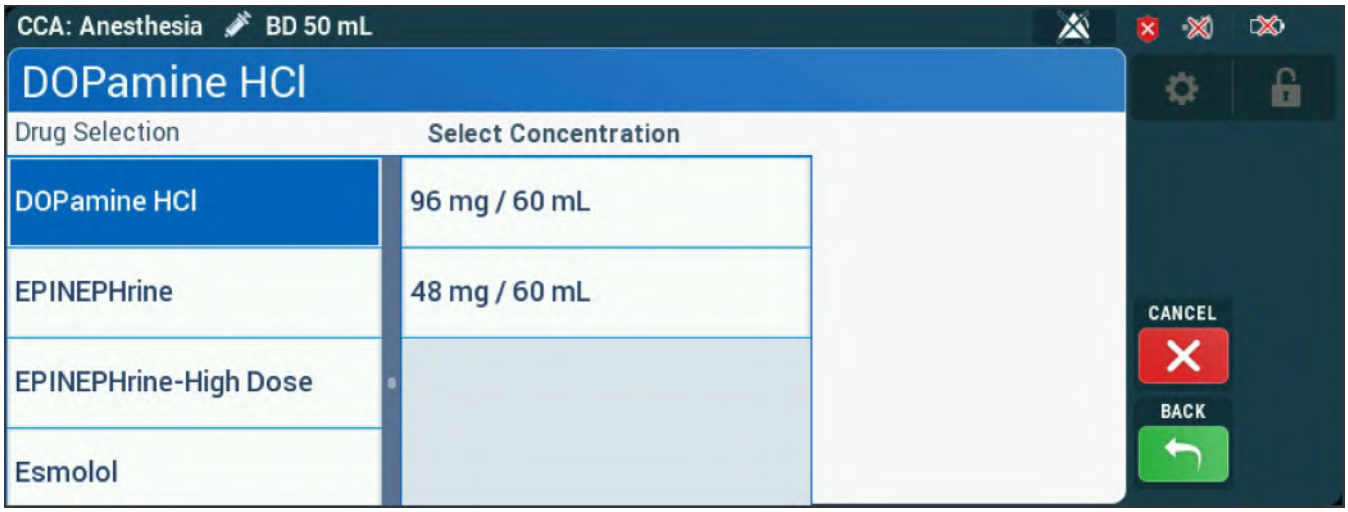
Options may be presented for a fluid or drugs clinical use. There may be different dosing units, limits, and/or other configurations assigned to each clinical use. Clinical uses are configured by the pharmacy based on the facility's best practices.

Example: selecting the medication Dopamine could open a list of different clinical uses, for example Renal or Cardiac. These specific clinical uses may display multiple concentration options.

Selecting a Concentration and/or a Unit of Measure

Medications may or may not have predefined 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 predefined concentration and/or unit of measure, the user has the ability to enter these values.



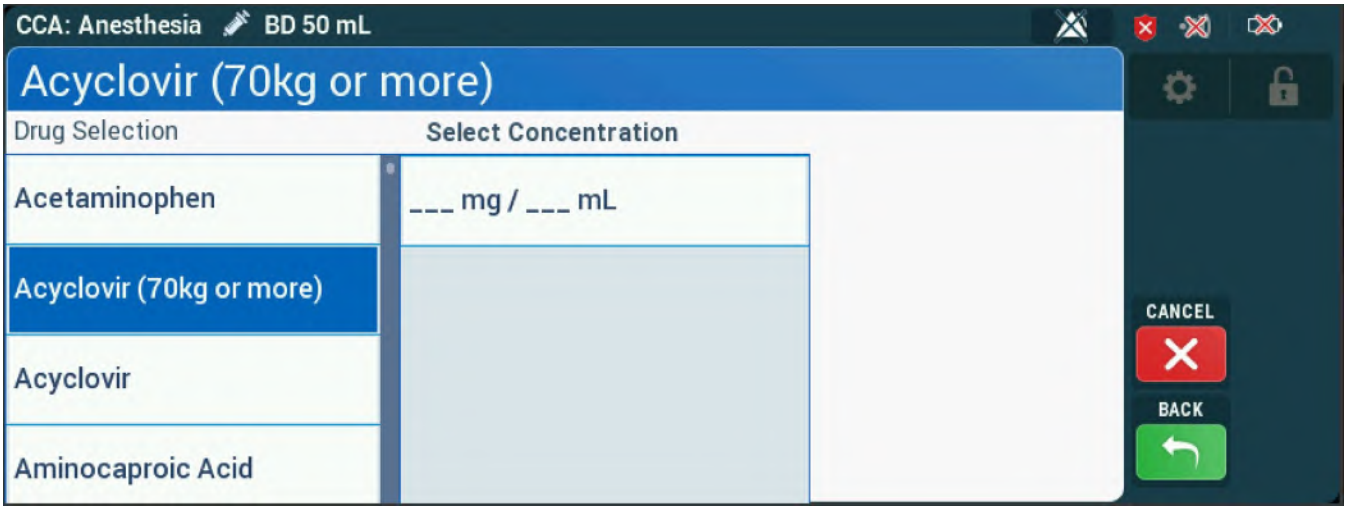
Concentration Entry

The Medfusion™ 5000 infusion pump allows the user to input custom values (drug amount and/or diluent volume) or a standard concentration (drug amount per mL) for medications whose values are not specified in the custom drug library. Drug amount and diluent volume may be subject to concentration limits determined by the custom drug library.

To program medications whose custom 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/ 50 mL” or "1 mg/ __mL").
2. Enter the total Drug Amount if it is not populated.

   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-populated.
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.



Pump Initialization

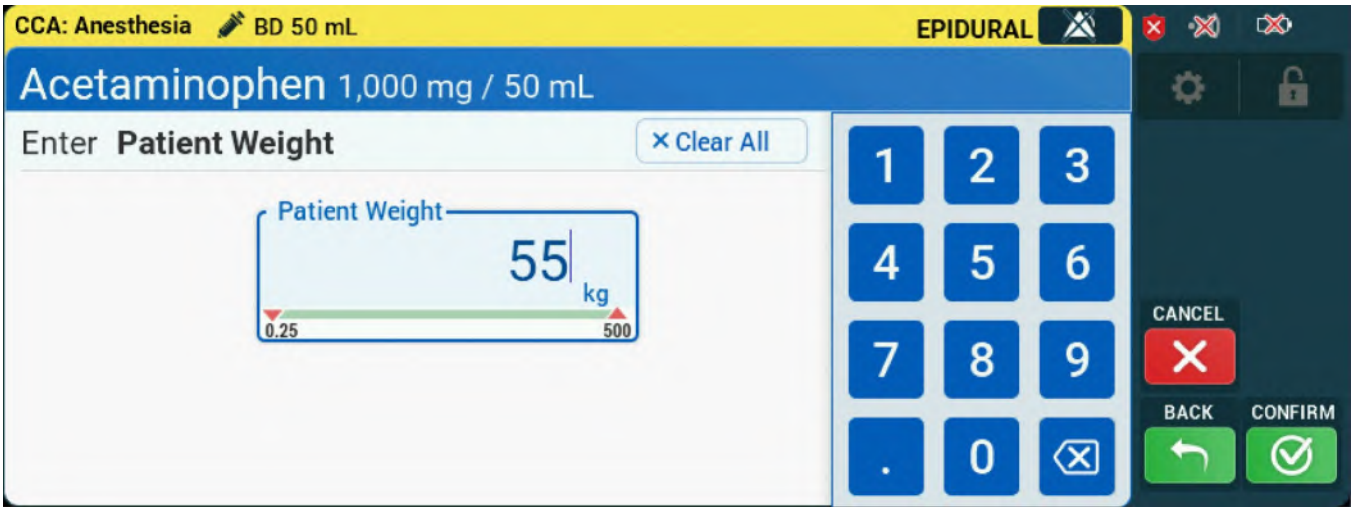
Pump Initialization is a process by which the device can reduce the mechanical slack and optimize the performance of the infusion pump. The process engages the mechanism of the device to the detected syringe, exercising the plunger head to absorb mechanical slack and ensure proper registration of the mechanism for fluid delivery. Initialization is short in duration when the tubing is securely clamped.

It is recommended to use the pump Prime feature, if the prime feature of the pump is not used due to manually priming the set, pump initialization feature will automatically occur upon confirmation of syringe inserted. Initialization or the use of the pump priming process ensures delivery accuracy and minimizes startups delays, particularly at low flow rates. The process should be done every time a syringe is inserted into the device.

Selecting Delivery Method

Once pump initialization completed, the delivery method selection screen will be displayed. Depending on how the medication is configured through the drug library, the user may have the option to program a Loading Dose, Bolus Dose (available at the start or during delivery), a Continuous Infusion, Intermittent Infusion or Multistep Infusion. Tap a delivery method to select it.

Setting Patient Parameters

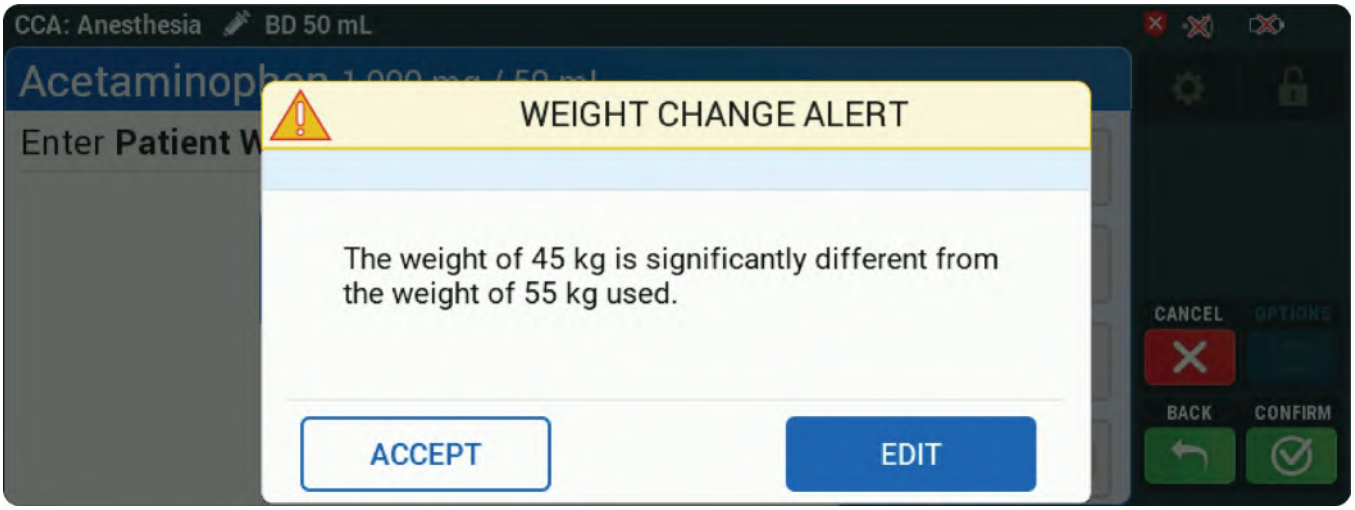


Depending on drug selection and therapy, the user may be required to input patient parameters to deliver the infusion. These parameters may have limits based on the CCA. To enter values (for example patient weight and BSA), use the keypad on the right and then tap **NEXT.**

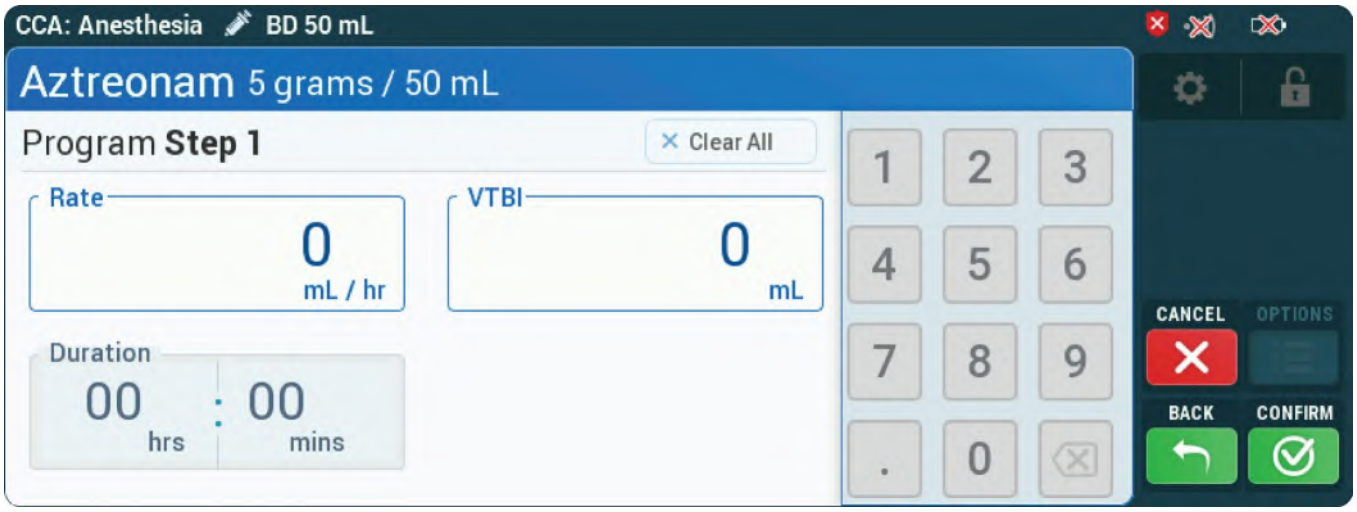
On the confirmation screen re-enter the patient parameters and tap **CONFIRM.**

Changing Patient Parameters

The infusion pump will pre-populate weight or BSA if those parameters were already programmed for the same patient on previous programs. These patient values can be changed. When the patient weight or BSA is changed, the affected rate or dose will be recalculated to reflect the new parameter. When the change in weight or BSA is greater than 10%, the clinician is alerted to confirm the change is correct.



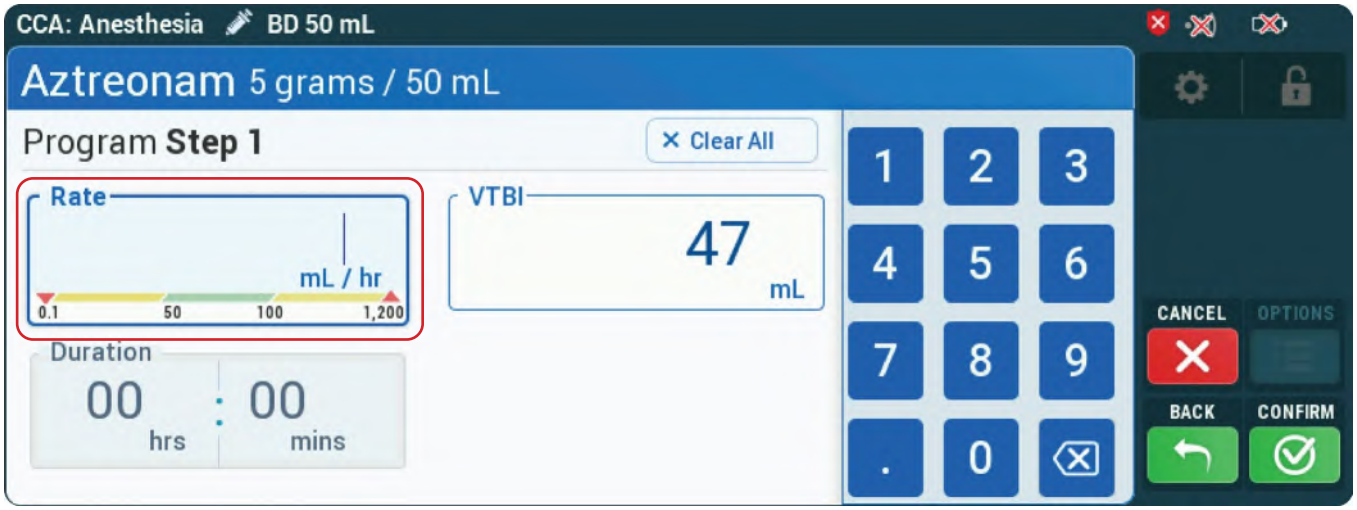
Setting Values Through the Programming Page



The Programming page is used to set values for an infusion, such as Dose, Total Dose, Rate, VTBI, and Duration. Available fields are shown with white backgrounds, unavailable fields are shown in gray and an active field is shown in light blue with a highlighted boundary. You can select an available field by tapping it. Any initial values provided by the medication rule set will pre-populate in the appropriate field.

The VTBI field on Intermittent infusions will be populated once dose is entered. The VTBI field on Continuous infusions will be prefilled based on an approximation of volume in the syringe that is detected by the pump and should be visually confirmed prior to starting.

Select the parameter field to edit as needed. When you have done so, the field will turn blue, the value's limit bar will appear, and the keypad on the right will turn blue and available for use. Once all parameters are entered tap the **CONFIRM** button.



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

NOTE: If a field is grayed out, it is not available for programming.

NOTE: If the extension set is not yet primed, you can tap the **PRIME USING PUMP** within the Options menu from the review screen. When the priming screen is displayed, ensure the tubing is disconnected from the patient, then press and hold the prime button until line is fully primed. The volume used to prime will be displayed.

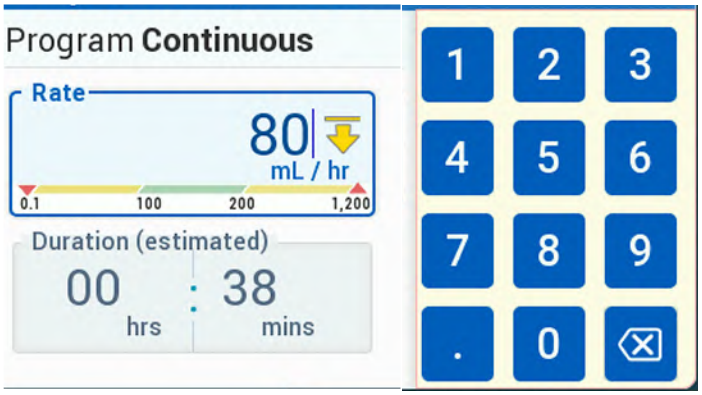
Keypad Interactions

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

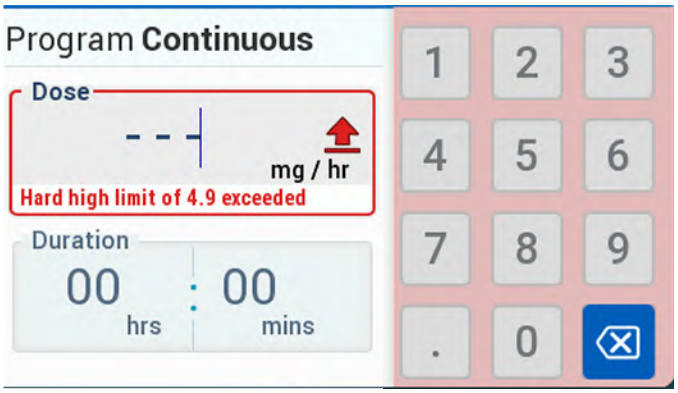
The keypad will appear grayed out when first navigating to the programming page and before selecting a programming field (Dose, Total Dose, Rate, VTBI). The keypad cannot be interacted with in this state.

The keypad will change to blue 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 80 mL/hr falls below the lower soft limit of 100 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. Tap the relevant field or the backspace button to clear and then re-enter values.



Dose Calculation

There are three ways that the Medfusion™ 5000 syringe pump performs auto-calculations:

- In a time-based continuous dosing unit such as mL/hr or mg/kg/hr, where entering the dose calculates the rate and entering the VTBI (or the pre-populated pump approximation of volume) calculates the duration.
- In intermittent dosing units such as mg/kg, where entering the dose or total dose calculates the VTBI, and entering the rate calculates the duration. Calculated VTBIs are rounded to the nearest 0.01 mL resolution.
- In mL/hr, where there is no dose value entry.

See *"Examples of Automatic Calculation" on page 150* for additional information on how the infusion pump performs auto-calculations.

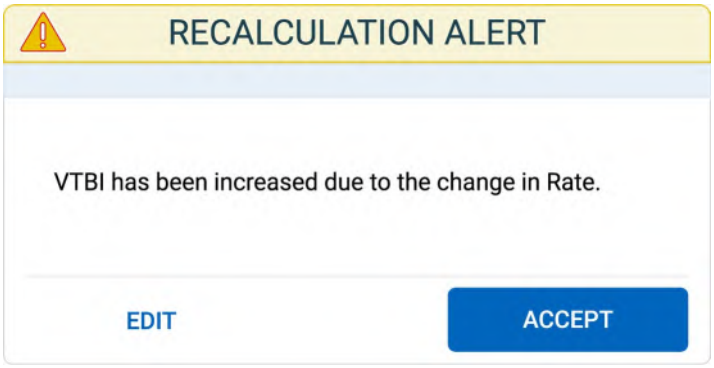
Total Dose Calculation

With intermittent dose/volume over time infusions that use weight or BSA dosing units, the Medfusion™ 5000 Syringe infusion pump will display the dose and the total dose field for entry. The following is an example:

Medfusion™ 5000 Syringe will calculate the corresponding field by using the entered dose value multiplied by the patient unit of measure. For example, if the Total Dose field is selected for programming and 105 mcg is entered, the pump will display the calculated dose of 3 mcg/ kg, assuming a 45 kg patient. Any limits for this type of program are configured for the dose per patient value.

Recalculation Alert

There are three conditions that can trigger a Recalculation Alert on an intermittent dose/volume over time infusion:



1. Anytime the pump performs a calculation that drives the VTBI higher than the detected syringe volume, 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 dis- played indicating that the rate has been recalculated due to the duration change.

When the alert appears, tap **ACCEPT** to continue to the Review screen or tap **EDIT** to remain on the Programming screen.

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 , pump limits based on syringe selected or CCA limits. 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, see *"Keypad Interactions" on page 62*. 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 to edit within the approved limits. Tap the backspace button to clear the entry and enter a new value.

Continuous Infusion

Continuous infusion is programmed by setting a flow rate in mL/hr.

To program an continuous infusion:

1. Tap the screen to begin programming. The drug selection list will be displayed, see *"Selecting a Drug" on page 55*.
2. Tap the drug and select the clinical use and/or concentration.
3. Load the syringe and confirm the brand and size (See *"Loading a Syringe" on page 48*)
4. Select the delivery method.

5. Input parameters such as dose, total dose (if available as configured), 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.

7. Tap **START** to begin infusing.

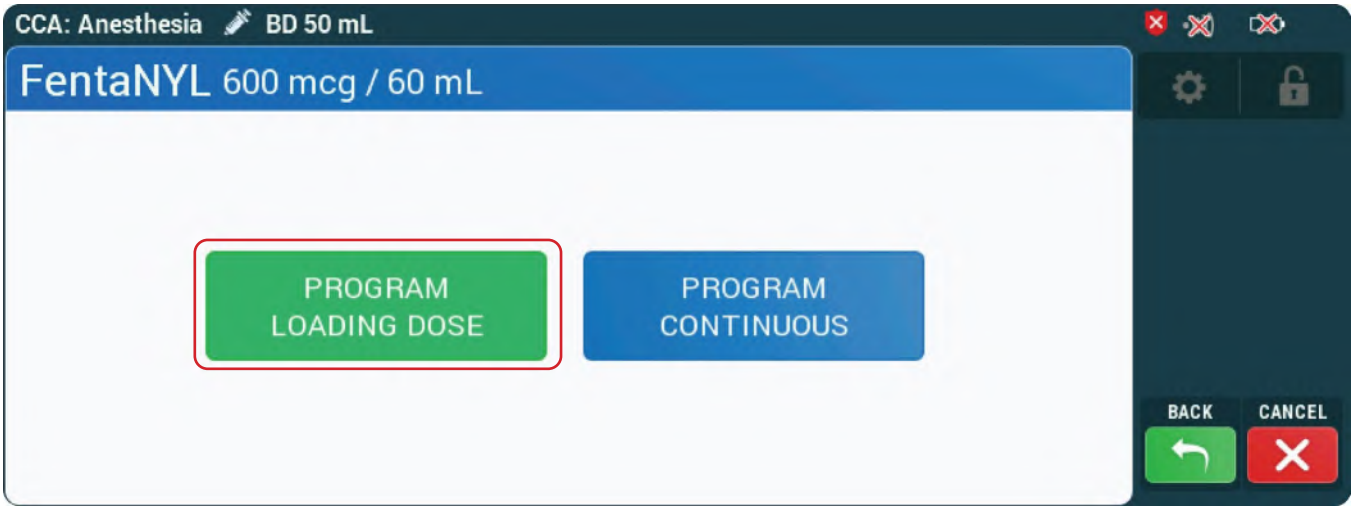
Loading Dose

A Loading Dose delivery is defined as a dose of fluid or medication at the initial onset of delivery, and may be followed by a continuous infusion from the same syringe or supported by a subsequent syringe. Loading Dose is only available when enabled for the medication rule set. The dose units and configurable limits may differ from Bolus. A stand-alone loading dose of a new medication can be delivered.

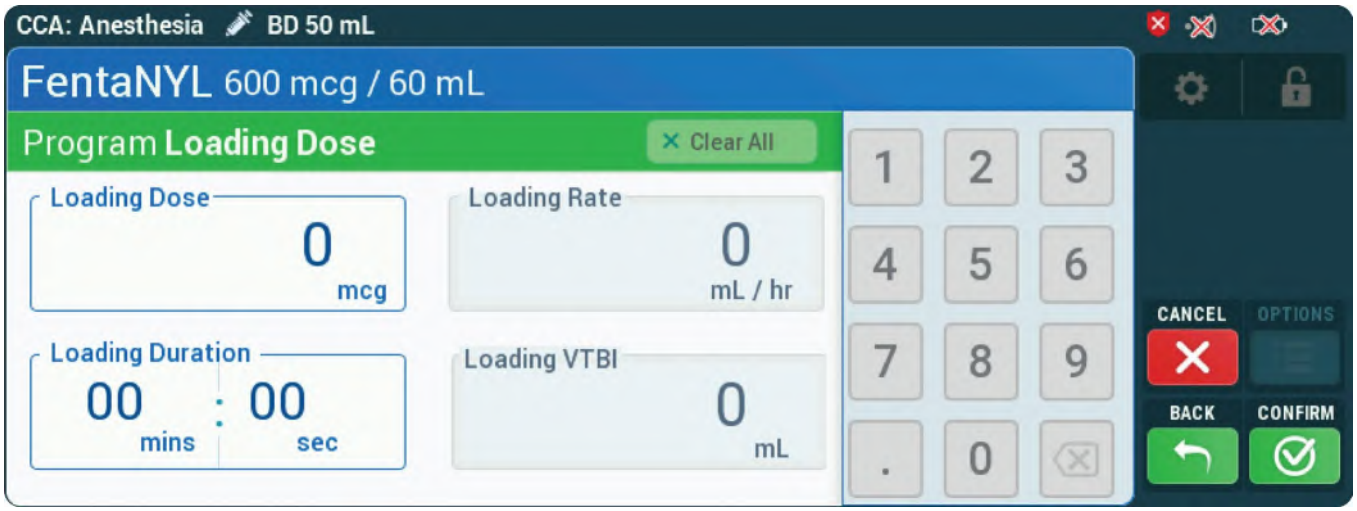
A Loading Dose cannot be repeated and is not available once the continuous infusion has started. If a loading dose is programmed without a continuous infusion, upon completion delivery will **STOP** while alarming for Loading Dose Complete. Those medications which can be delivered by Loading Dose may have dose, time, and duration Loading Dose soft/hard limits defined in the drug library. Additionally they may include initial values from the rule set that will pre-populate Loading Dose programming fields.

To program a Loading Dose Delivery:

1. Tap the screen to begin programming. The drug selection list will be displayed, see *"Selecting a Drug" on page 55*.
2. Tap the drug and select the clinical use and/or concentration.
3. Load the syringe and confirm the brand and size (See *"Loading a Syringe" on page 48*)
4. Tap **PROGRAM LOADING DOSE**.

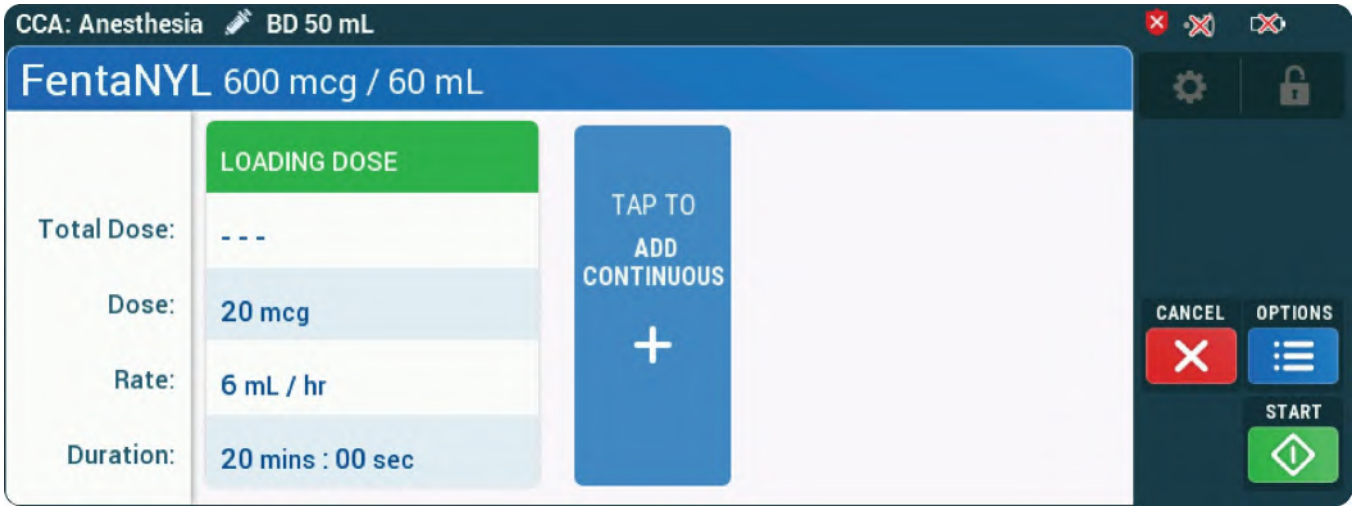


5. Input Dose, Rate, VTBI, and Duration.

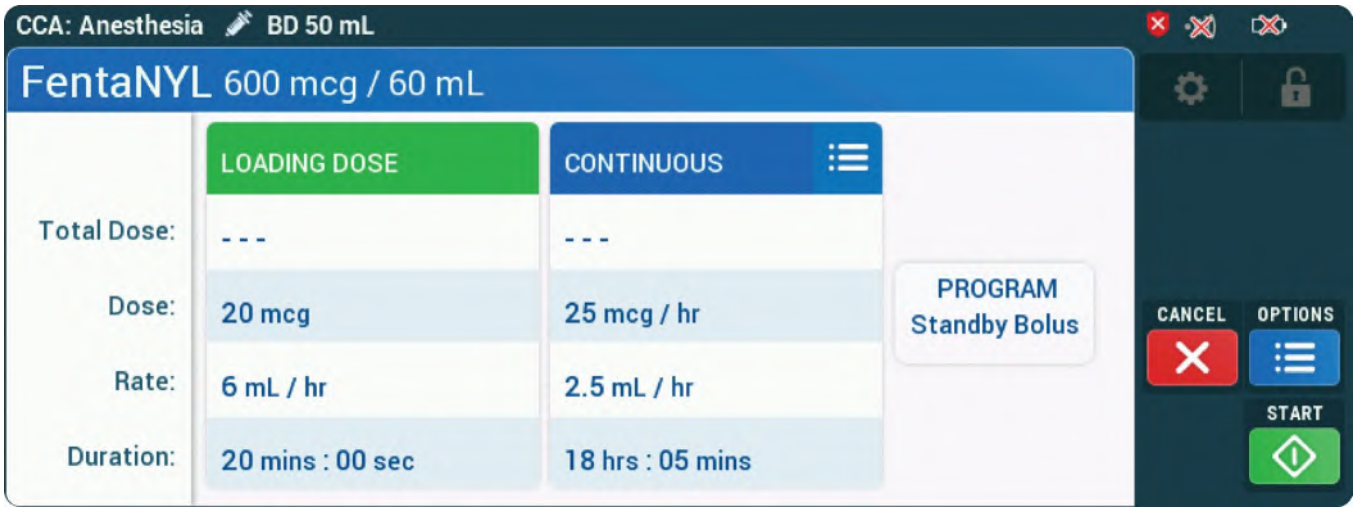


NOTE: Values will auto-calculate as you program.

6. Tap **CONFIRM**.
   The Review screen appears.
7. To program the continuous infusion, tap **TAP TO ADD CONTINUOUS**.



8. Program the continuous infusion.
9. Tap **CONFIRM**.
   The Review page appears.
10. Review the parameters, for loading dose and continuous program.



11. Tap **START** to begin infusion.

NOTE: Once Loading Dose has completed the Callback alarm will sound and the Continuous program will begin to infuse.

NOTE: Multistep delivery is not available for therapies that have Loading Dose delivery enabled.

NOTE: Standby is not available for therapies that have Loading Dose deliveries enabled.

Bolus Dose

A Bolus delivery is defined as a rapid infusion of a single or repeated delivery of fluid, or dose, of the drug currently being administered (same medication, concentration, and dosing unit). Bolus medications, will be defined in the drug library along with dosing units and soft/hard limits for dose, duration and rate. Additionally they may include initial values from the rule set that will pre-populate Bolus programming fields.

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

- Bolus Dose is enabled within the medication's selected profile at the rule set level
- There is adequate VTBI of the medication to complete the bolus dose, though changing a syringe may be required.

Programming a Bolus Dose

To program a Bolus Dose:

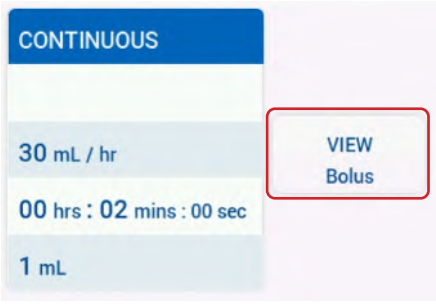
1. For a Bolus Dose from a continuous infusion, tap **PROGRAM Bolus** on the relevant infusion.

The Programming screen displays.

2. Enter Dose, Total Dose Rate, VTBI, and Duration.

   NOTE: Some values will auto-calculate as fields are programmed.

3. Tap **CONFIRM**.
   The Review page appears.
4. Review the parameters, to view Bolus parameters, tap **VIEW Bolus** button.



5. Tap **START** to begin infusion.

   NOTE: If a Loading Dose or Bolus has been programmed without a continuous, an alert will be presented.

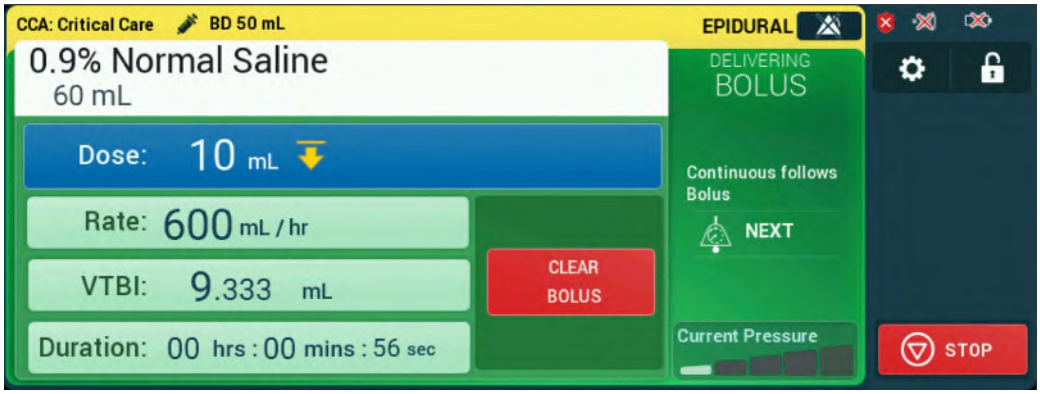
   NOTE: Multistep delivery is not available for therapies that have Bolus delivery enabled.

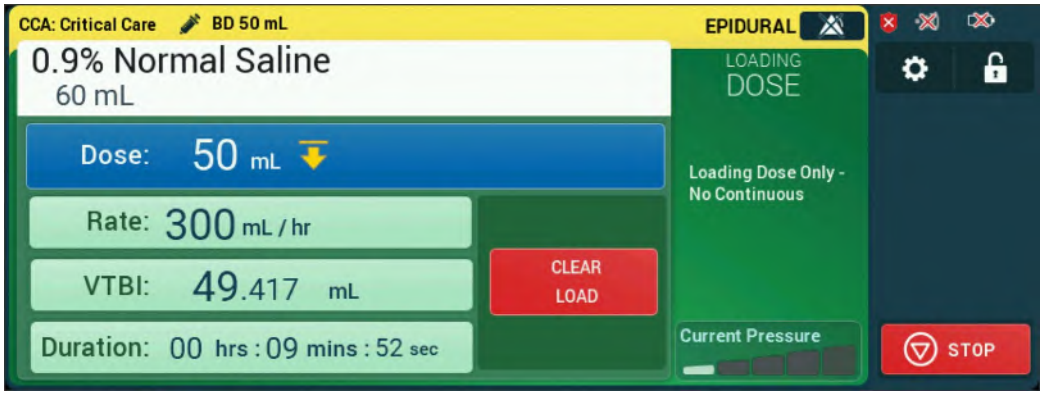
Stopping and Clearing a Loading or Bolus Dose Delivery

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

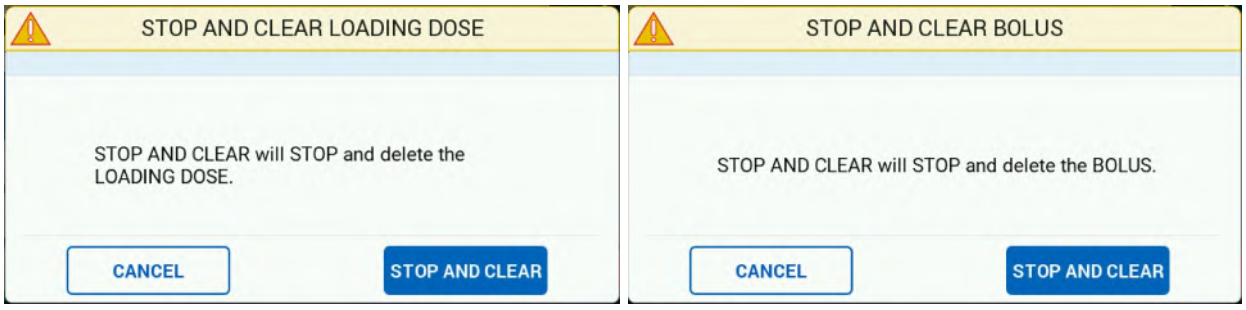
To stop and clear a Loading Dose or Bolus:

1. Tap **CLEAR LOAD** or **CLEAR BOLUS** on the Main Delivery page. A confirmation prompt appears.





2. Tap **STOP AND CLEAR** to confirm.
   The Loading Dose or Bolus is cleared, and the continuous infusion (if programmed) is displayed.



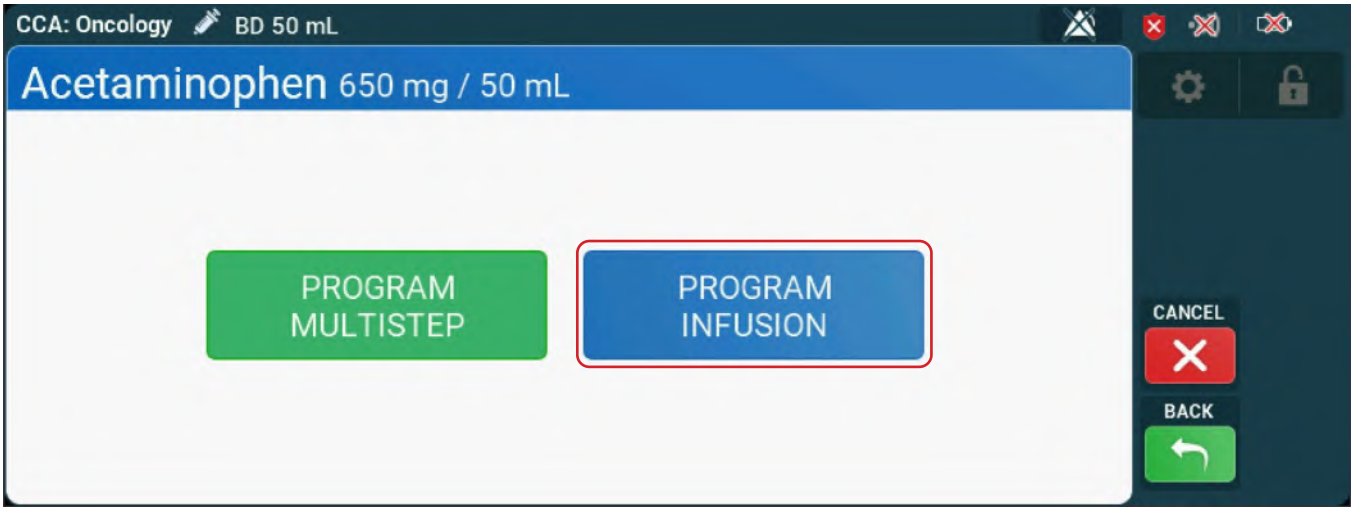
3. The continuous infusion can be cleared by tapping **CLEAR PROGRAM**, edit it by tapping one of the values, or start the continuous infusion by tapping **START**.

Intermittent Infusion

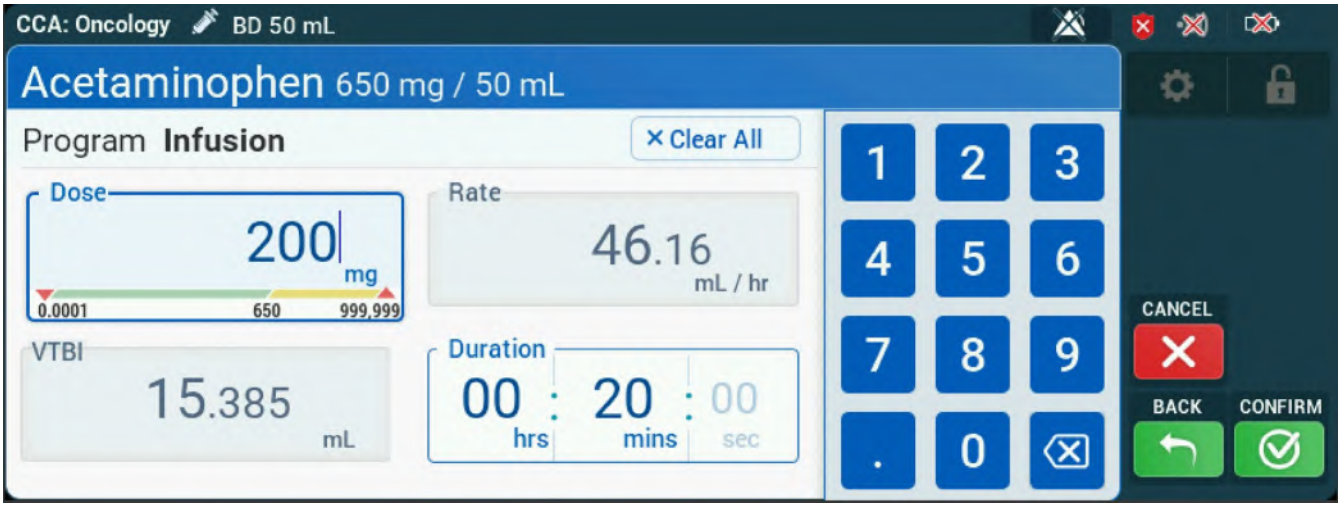
Below are the steps for programming an Intermittent Volume or Dose / Time infusion.

To program an intermittent infusion:

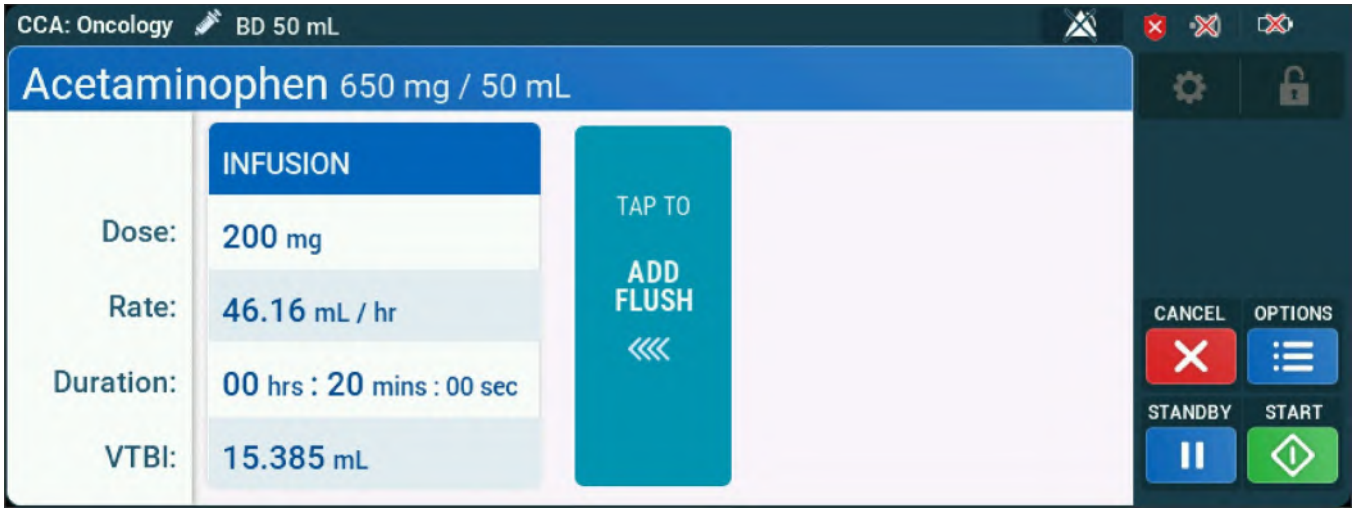
1. Tap the screen to begin programming. The drug selection list will be displayed, see *"Selecting a Drug" on page 55*.
2. Tap the drug and select the clinical use and/or concentration.
3. Load the syringe and confirm the brand and size (See *"Loading a Syringe" on page 48*)
4. Select the delivery method.



5. Input parameters such as dose, total dose (if available as configured), and duration of infusion using the keypad (VTBI will be calculated based on the dose and duration)



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.



7. On the review screen a Flush dose can be added by tapping the **ADD FLUSH** button or the infusion can be started by tapping **START**.

Flush

The Flush feature enables the clinician to deliver the residual volume in the downstream tubing after a dose/volume over time intermittent therapy.

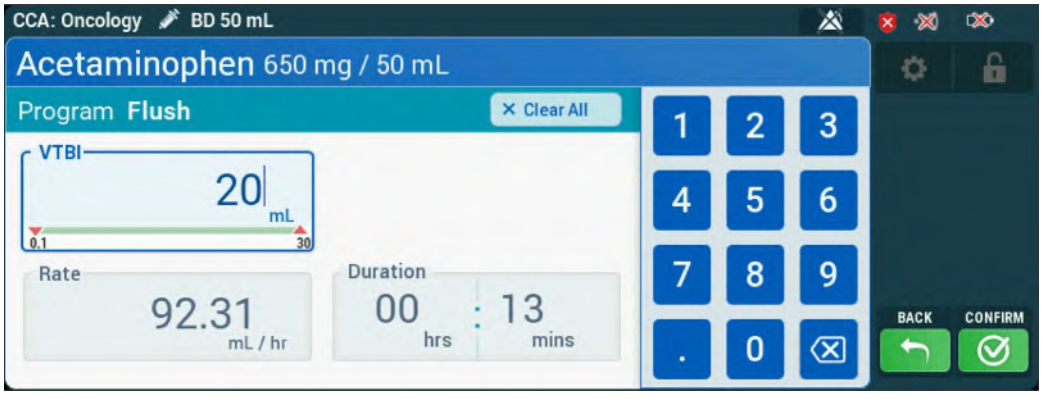
When the infusion reaches infusion complete, or syringe empty an audible alarm sounds the flush option displays. If a flush is required remove the empty syringe and load the flush syringe.

The programmed Flush volume is delivered at the rate of the dose over time intermittent therapy.

The allowable range for a flush is 0.1 to 30 mL, though the maximum allowed flush volume is configured for the CCA. Filters and other add on components should also be considered when determining and programming the flush volume.

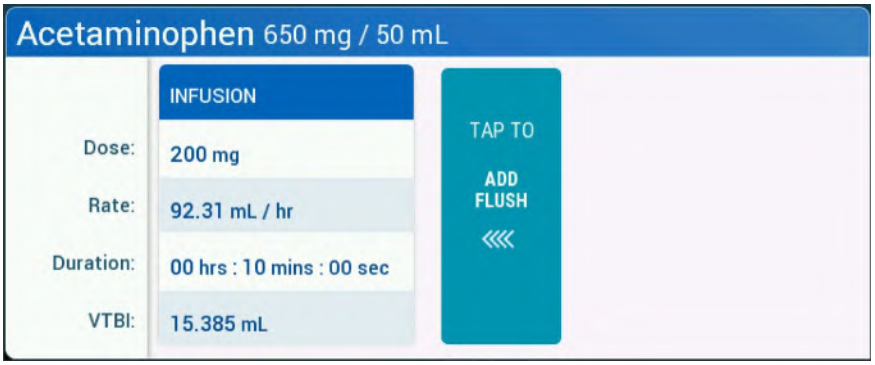
A flush can be programmed under the following conditions:

- The program must be defined as an intermittent infusion.
- Flush has to be enabled in the CCA.
- The program cannot be in Delayed Start, Standby, or programmed as a Multistep delivery, after infusion complete.
- Before starting the infusion or during delivery, it cannot be added after Infusion Complete.



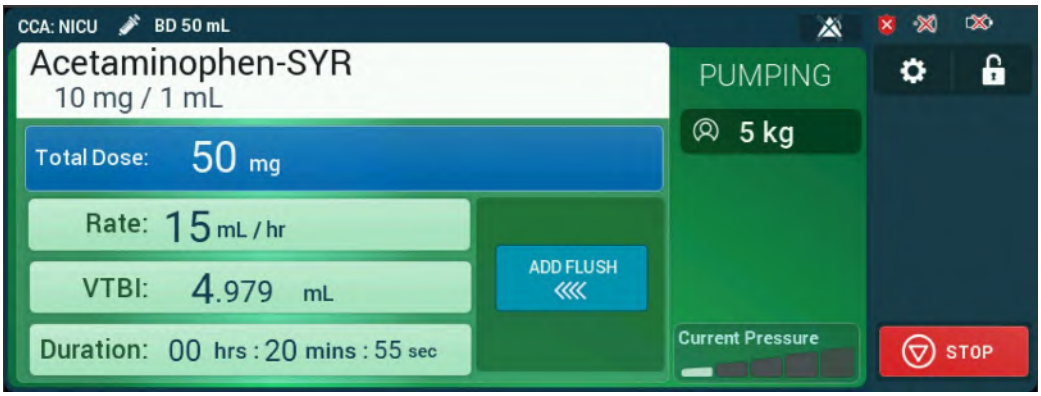
Flush duration and volume are not considered when the infusion pump is checking for Hard Limit or Soft Limit violations for the programs.

To program a flush with a new intermittent dose/ over time delivery under the conditions listed above:



1. On the Review page of an intermittent infusion, tap the **TAP TO ADD FLUSH** button.
2. On the Flush programing screen input the flush VTBI.
3. Tap **CONFIRM**.
   The Review page appears.
4. Tap **START**.

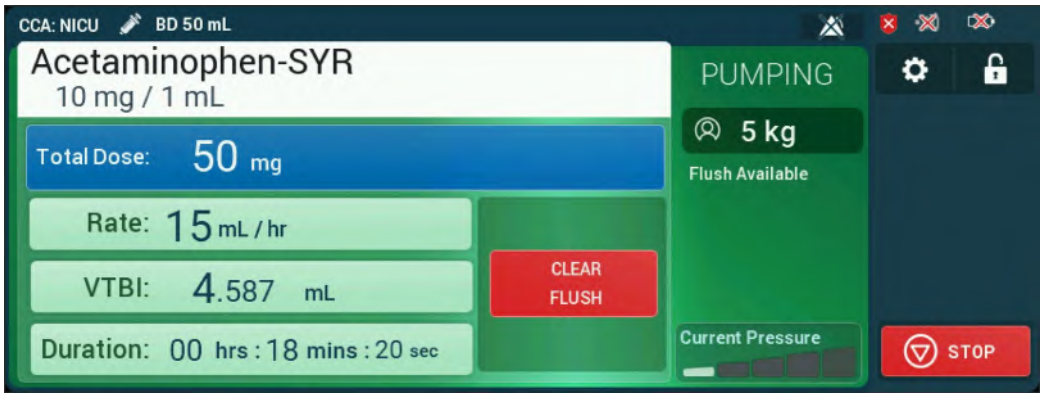
You can also add flush to an infusion from the Delivery page. To do so, tap **ADD FLUSH** and follow steps 2-4 above.



When the Intermittent dose/volume over time program completes and the syringe empty alarm occurs, load the flush syringe and press start. The flush will deliver at the intermittent programmed rate. The name of the medication will continue to display and indicate **FLUSHING** on the screen.

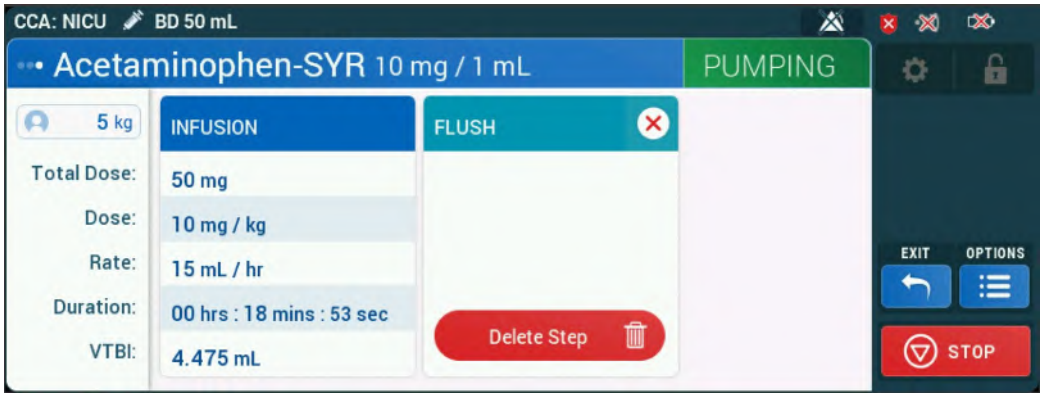
Clear Flush

To clear a flush from the Main Delivery page:



1. Tap **CLEAR FLUSH**.
2. Tap **CLEAR**.

Alternatively, to cancel a flush from the Review page:



1. Tap the Options icon on the top right of the Flush infusion.
2. Tap the trash can icon underneath the flush delivery.
3. Tap **CLEAR**.

Multistep

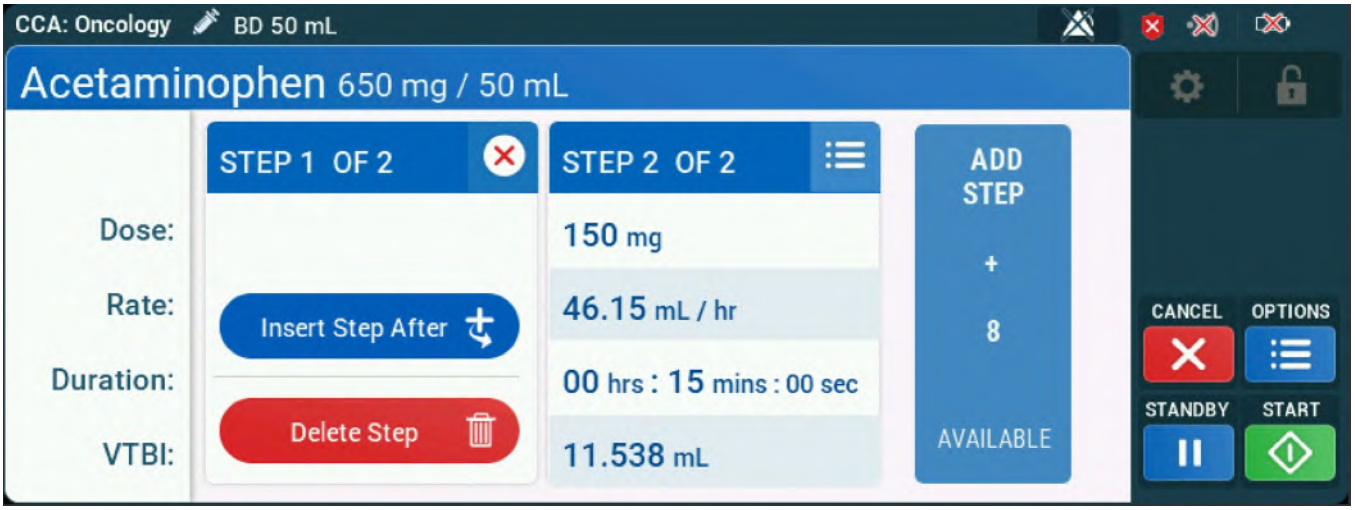
Multistep delivery is a sequential program that can deliver up to 10 steps at different rate/dose/VTBI and durations using the same dosing unit and concentration.

Multistep programming is available when enabled for the medication rule set.

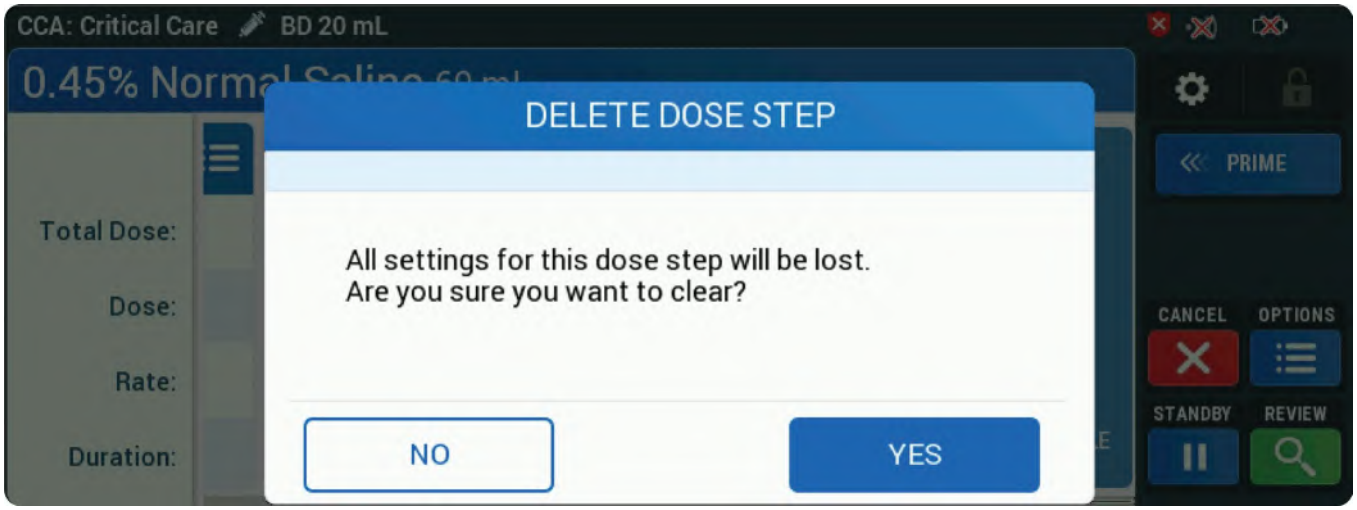
To program a Multistep infusion:

1. Tap **PROGRAM Multistep**.
2. See *"Setting Patient Parameters" on page 60* and *"Titration" on page 76* for inputting values.
3. On the Review page, select tap **ADD STEP** 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 menu button on the top right of the previous step, and select the **Insert Step After+** button, which will add the **ADD STEP** button between the two steps.



6. To delete a step, tap the menu button on the top right of the step, and select the red trash icon **Delete Step**, and confirm the deletion by selecting **YES**.



7. If more than (2) steps are added the **START** button will turn into a **REVIEW** button, and a review of all steps is required prior to starting , by swiping the step reviews to the left. 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.

NOTE: Bolus and Loading dose deliveries are not available for therapies that have Multistep delivery enabled.

Adding VTBI to Multistep Program After VTBI Complete Alarm

During a Multistep delivery, after the VTBI Complete alarm activates, and the last step of the Multistep delivery has not stopped, additional VTBI can be added to the last delivery step. Once VTBI has been completed and the pump has been stopped VTBI can be added to the last step.

To add VTBI to a Multistep program:

1. Tap the medication name to navigate to the review page.
2. Tap the last step card.
3. Navigate to the VTBI for the last step.
4. Enter a VTBI.
5. Tap **CONFIRM**.
6. Tap **REVIEW** and review steps, if necessary.
7. Tap **START** to restart infusion.

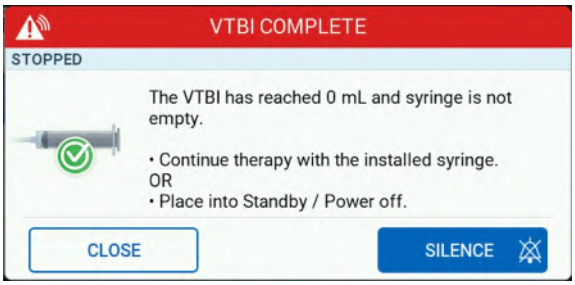
NOTE: When adding VTBI to the last step, you can also update other parameters if necessary.

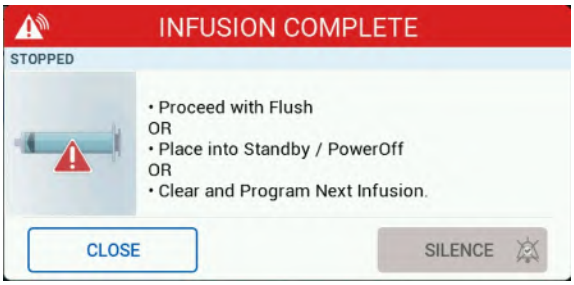
VTBI/Infusion Complete Alarm

Upon completion of delivery, the screen will display a “VTBI COMPLETE” or "INFUSION COMPLETE" message and an alarm will sound, depending on the type of infusion programmed.

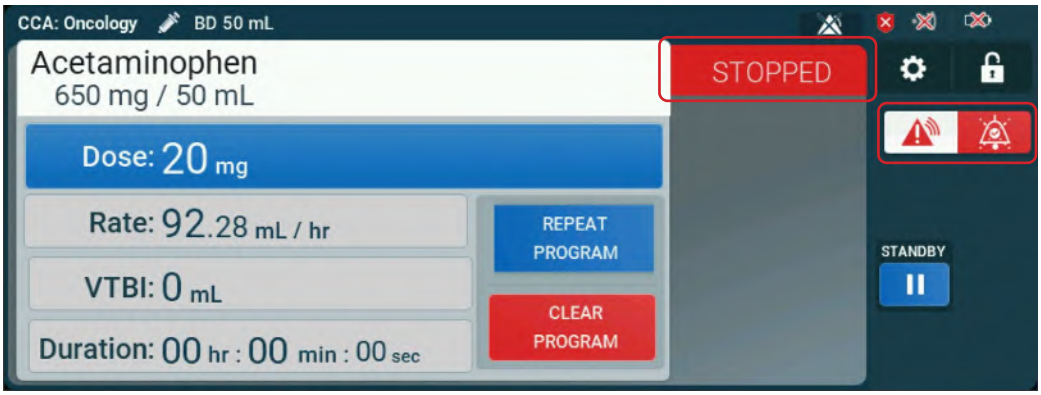
NOTE: The VTBI Complete alarm can be turned off with intermittent concurrent programs (See ***"Callback and Near End of Infusion Alarm" on page 79***).

1. If a VTBI/Infusion Complete alarm sounds, press silence to stop the audible alarm.
2. Tap **CLOSE** to close the message.





NOTE: Alarm will still flash on screen, along with the **STOPPED** status.



3. Follow the instructions for **Titration** to add a new VTBI, or follow the instructions for Stopping an Infusion and clear the program.

Titration

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

To titrate a program:

1. Tap the field to be changed (Rate, VI/VTBI, or Duration) on the Main Delivery page. The Programming page appears and select the field to be changed.
   Alternately, tap the name of the drug or any space 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 the field and use the keypad to program the entry.
3. Confirm the change by tapping **CONFIRM**.
4. Review the infusion and tap **START**.

NOTE: Titration cannot be performed on a bolus or load after it has started. Titration can be performed on a continuous infusion while a loading dose or bolus is infusing.

NOTE: Medication rule sets may define percent dose change limits, that will alert the pump user to confirm large iteration changes are intended.

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 active steps is required to start the infusion.

Routes

Depending on how the medication is configured through the drug library, the route of delivery may have been specified, and assigned a color for route identification. The color cannot be changed by the clinical pump user. For example, for an epidural delivery, the pump user interface will be configured to include yellow top banner and accents. For enteral delivery, the pump user interface will be accented by either purple or orange as configured in the drug library.

Options

The Options page provides a number of editable infusion options, depending on drug library configuration. These options may include: Delay Start, Callback, Near End of Infusion, Display VTBI/VI, Downstream Pressure and Prime Using Pump.

Any alarms that are turned off or default to off are included under an icon called Disabled Alarms. These can include the Near End of Infusion and Callback alarms found under Options.

To navigate to the options page, program the infusion and tap **OPTIONS** on the Review page.

Delay Start

Once programmed the infusion start can be delayed from 1 minute to 4 hours.

To program a delayed start:

1. Program the infusion and tap **CONFIRM**.
2. On the Review page, tap **OPTIONS**.
3. Tap the hours and minutes fields under Delay Start.
4. Scroll through the hours and minute drop down by dragging your finger and tap the desired hours and minutes, which can be any period between 1 minutes and 4 hours.
5. Tap **CONFIRM**.
6. Tap **START DELAY**.

You may view the remaining delay duration on the Main Delivery page, below **START DELAYED**. Once the delay duration ends, the program will begin infusing.

Editing Delay Duration

To edit the duration of a delayed start:

1. Tap the name of the programmed drug on the Main Delivery page. The Review page appears.
2. Tap **OPTIONS**.
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 program automatically begins infusing.

NOTE: There is no alarm to indicate the delay has begun or alarm to indicate infusion has begun.

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.

Callback and Near End of Infusion Alarm

The pump will always alarm at the end of an infusion or upon syringe empty. An optional Callback alarm can be configured via CCA settings, and modified by the bedside clinician, to alarm at the completion of interim steps within a programmed infusion. Programmed to alarm at the completion of a Loading Dose, Bolus, or steps within a Multistep infusion, when a subsequent infusion is programmed.

The Callback alarm is a medium priority alarm and occurs at the completion of a step under the following conditions:

- After a Loading Dose or Bolus completes and the continuous starts.
- After each step of a Multistep delivery, except after the last step when an Infusion Complete or Syringe Empty alarm occurs.

  NOTE: In the instance that a second step in a Multistep delivery is not configured, a Callback alarm will not occur and an Infusion Complete or Syringe Empty alarm will occur.

A high priority Callback and STOP alarm can also be configured for the same conditions above, with delivery stopping before proceeding to the next step.

Additionally, a Near End of Infusion alarm (low priority) can be configured in the medication rule set to occur with various selectable durations prior to delivery ending. The clinician also has the ability to change the configuration per clinical need.

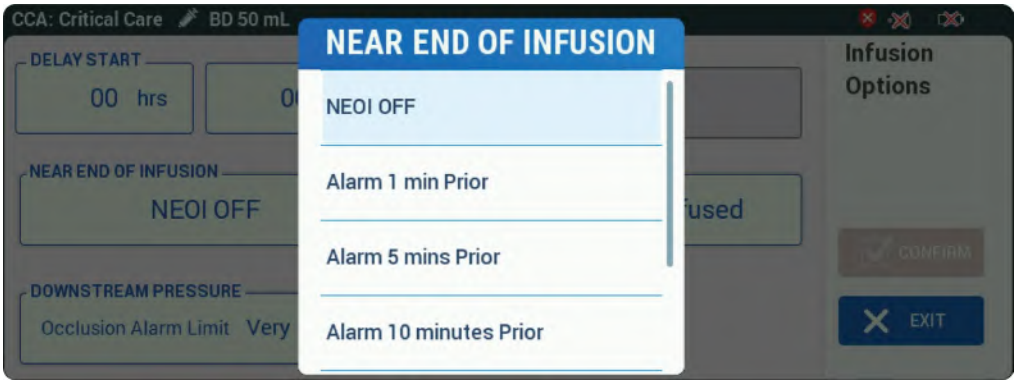
NOTE: Any alarms that are turned off or default to off are listed under the **DISABLED ALARMS -** Tap to display a list of alarms that are off, either by default as configured in the drug, or turned off by the pump user. 

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

1. Tap **OPTIONS** on the Review page.
   The Options screen appears.
2. Tap the **CALLBACK**.
   The Callback list appears.
3. Drag your finger to scroll through the list and then tap the action to occur after the dose completes.
4. Tap **CONFIRM**.

To add a near end of infusion alarm:

1. Tap **OPTIONS** on the Review page.
   The Options page appears.
2. Tap the **NEAR END OF INFUSION**.
   The Near End of Infusion list appears.
3. Select from the list the desired minutes prior to completion option from the drop-down.
4. Tap **CONFIRM**.

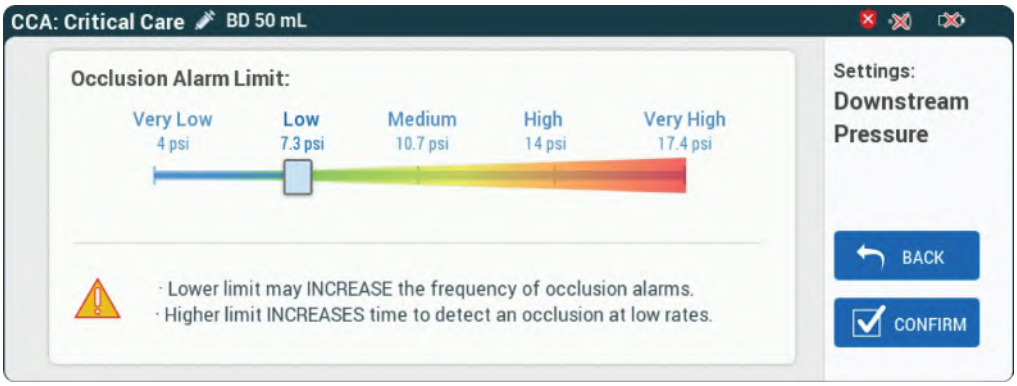


Downstream Pressure

The Downstream Pressure is the setting for the sensitivity of the downstream occlusion alarm. A higher limit increases the time to detect an occlusion at low flow rates. Setting the Downstream pressure at a lower limit may increase the frequency of occlusion alarms. It can be adjusted via Options or Settings. For setting the Downstream Pressure limit via the Settings page, see ***"Clinical Settings" on page 108***.

To adjust the Downstream Pressure limit using the Options page:

1. Tap **OPTIONS** on the Review page. The Options page appears.
2. Use the slider under **DOWNSTREAM PRESSURE** to raise or lower the limit.
3. Tap **CONFIRM**.



Standby

Standby allows you to postpone the start of delivery. The maximum standby time is defined by the CCA. The range of the standby duration is from 5 minutes to 72 hours. If a program is in standby and the programmed time expires, the pump will display a Standby Expired alarm.

Standby is only available during initial infusion programming and on stopped infusion.

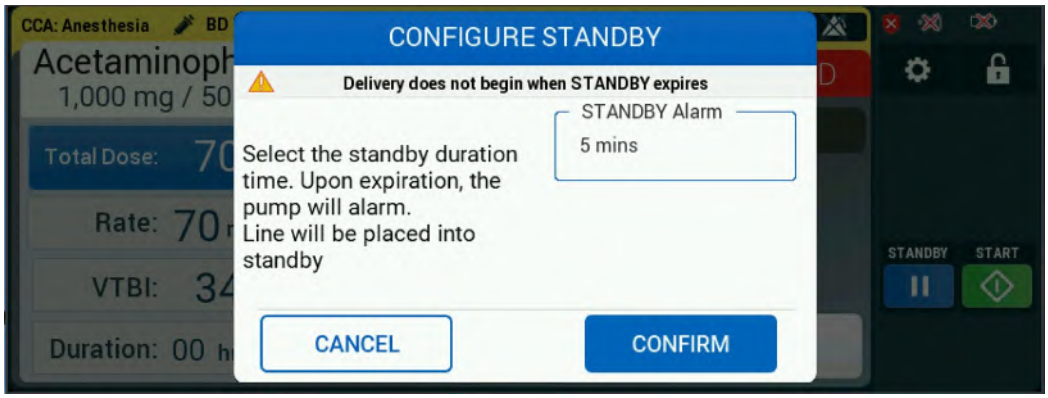
Putting a Program on Standby from the Review Page

To put a program on Standby from the Review page:

1. Program the pump. See Programming for options.
2. Once you reach the Review page, tap **STANDBY**.
   A pop-up appears to configure the standby duration.
3. Select the desired standby duration and tap **CONFIRM**.

The program is now on standby, as displayed on the Main Delivery page.

NOTE: The time until standby expires flashes on the Main Delivery page.



Putting a Program on Standby During Active Infusion

NOTE: Pump must be in stopped state to program a standby.

To program a Standby during an active infusion:

1. Tap **STANDBY** on the delivery screen.
   A screen appears to configure the standby duration.
2. Select the desired standby duration in the **STANDBY** Alarm box.
3. Tap **CONFIRM** to place on standby.

The program is now on standby, as displayed on the Main Delivery page.

NOTE: The time until standby expires displays on the Main Delivery page and counts down until expired.

When Standby Expires

When the configured standby time expires, the pump will display a Standby Expired alarm. Clear the alarm and tap **START** to start the infusion.

NOTE: If delivery was never started, the Standby Expired alarm priority is low. If the delivery had been started prior to standby, the priority of the alarm is medium.

Cancel Standby

To cancel Standby:

1. From the Main Delivery page, tap **START** or **STOP** or the **CANCEL STANDBY** button.

Clearing a Program

When you clear a program, all the prior programmed settings are cleared except the patient weight or BSA which can be used for a subsequent program. The Volume Infused reading for that program is not cleared.

Each time you turn the infusion pump on, the pump prompts “New Patient?” to give you the option to clear all settings. This is a safety feature to ensure that a patient does receive an infusion that was programmed for the previous patient. Tap **YES**, to clear all programming and Volumes Infused data, and return the pumps settings to the defaults.

Auto-Programming

LifeShield Infusion Safety Software Suite connectivity for Auto-Programming and auto-documentation is a licensable feature. For the list of features, such as Auto-Programming, available with the version of LifeShield Infusion Safety Software Suite installed at your facility, contact your local representative.

Auto-Programming (AP) is the ability to take an I.V. medication order from the electronic medical record (EMR) and translate it into program settings that can automatically populate the infusion pump. The programmable settings can include the medication name, concentration, dose, rate, and volume to be infused.

The process is facilitated by the physician's order in the EMR and verified by pharmacy. The clinician then utilizes the EMR bar code scanner to scan the barcodes for patient identification, medication container, and infusion pump. The physician’s order is transferred to the infusion pump wirelessly and is confirmed or modified by the clinician. After starting the infusion, delivery information is documented automatically in the EMR.

Auto-Programming with the Medfusion™ 5000 Syringe Infusion Pump

For optimal use, ensure the device is plugged in and at the brightest setting before you begin programming. While the pump can receive an order and Auto-Program without a syringe installed, the program needs to be confirmed, syringe validated and started within a defined time-frame of the system.

Check for the presence of the Wi-Fi signal and the LifeShield Infusion Safety Software Suite icon visible on the top of the pumps user interface to indicate connectivity to the system.

To perform Auto-Programming:

1. Press the ON/OFF button.
   The infusion pump begins its startup process.
2. Attach the syringe to the extension set and prime, see ***"Priming with PRIME Pump Feature" on page 46***.
3. Initiate the EMR/ hospital workflow to program the Medfusion™ 5000 syringe infusion pump.
4. Answer the New Patient prompt on the pump screen.
5. Select a CCA.
6. Scan the barcode on the patient wristband.

7. Scan the syringe barcode on the medication label.
8. Review the order details that are displayed on the EMR.
9. Scan the barcode for the intended syringe infusion pump.

   NOTE: The barcode can be enlarged by tapping it to ease the scanning. Alternatively, you may input the numbers below the barcode into your facility's EMR to facilitate order transfer. Having the user interface brightness to the highest (brightest) setting will optimize the ability to scan the barcode.

The programming page will appear on the pump screen, with the fields automatically filled when the pump barcode is scanned.

NOTE: The Auto-Program will map to a medication rule set within the selected CCA. 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.

10. Verify ALL parameters. If changes are required, you can manually change the infusion parameters per clinical need.
11. When all values are completed, tap **CONFIRM** on the pump screen to confirm the program with the received order.
12. Tap **START** on the pump screen to begin delivery.
    The EMR will confirm the program with the original order.
13. Complete the workflow in the EMR and document the process per hospital procedure.

NOTE: Loading Dose, Bolus, Multistep, and Flush are not accommodated by auto-programming. Program these deliveries manually.

NOTE: Any changes or titrations to the original EMR auto-programmed order do not arrive on the pump automatically. The Auto-Program process needs to be repeated, or manual programming needs to occur, depending on EMR vendor and hospital facility procedure.

Auto-Programming Rejections

There are a number of reasons for an automatically programmed therapy to be rejected. These include the following:

- The automatically programmed therapy exceeds the capabilities of the infusion pump or limits of the syringe size or brand.
- The therapy is above a hospital-defined hard drug limit.
- The infusion pump is not in a state to receive Auto-Programming (alarming).
- The connection between the pump and the facility's wireless network has been interrupted.

When an automatically programmed therapy is rejected, the infusion pump will display an alert stating the reason. If your order is rejected, recheck the order with the pharmacy or ordering physician. Alternatively, you may manually program the order to proceed.

NOTE: The Auto-Programming rejection will auto clear after a certain amount of time has passed as configured in the CDL.

Alarms and Troubleshooting

The Medfusion™ 5000 syringe 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. There is the possibility that the display is disabled; in such case, the only visual indication will be the alarm LED flashing red. The priority of the alarms (high, medium, or low) can be distinguished by the number of audio pulses and/or the alarm color.

Priority	Number of Audio Pulses	Alarm Color
High	Ten-note melody	Red
Medium	Three-note melody	Yellow
Low	Two-note melody	Cyan

The alarm sound pressure range is from 45 dBa to 67 dBa, depending on the setting of the alarm loudness control located in the Pump Settings page. If power is interrupted for

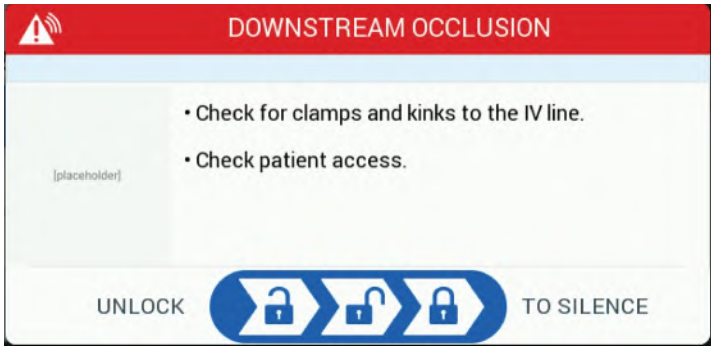
≤ 30 seconds, the alarm settings previous to the interruption are automatically restored. See ***Audio*** for instructions on how to adjust alarm volume.

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

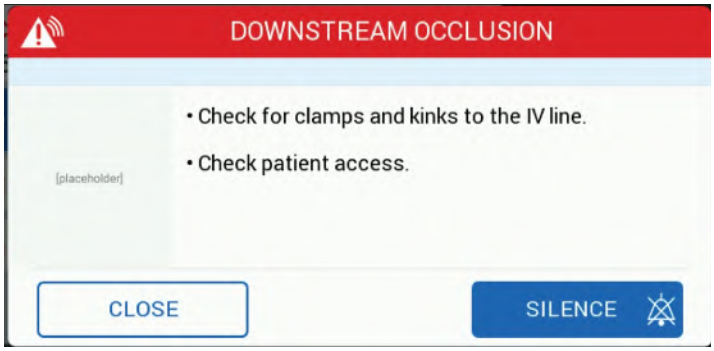
Alarms

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, slide your finger from left to right to unlock and silence.



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 and troubleshooting details.
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.

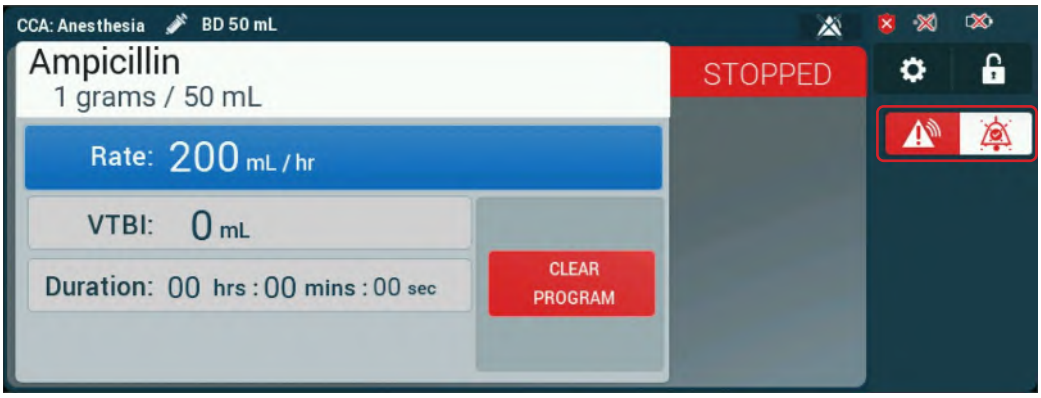


5. Tap **CLOSE** to remove the alarm message from view, but with the ability to recall it during alarm resolution.
   Or, tap **CLEAR** to clear the current alarm from the infusion pump.

   NOTE: Tapping **CLOSE** allows the clinician to troubleshoot the issue, such as removing the pop-up to enter more volume for an Infusion Complete alarm. **CLOSE** also temporarily silences the alarm.

   NOTE: CLEAR is an action used for specific alarms, such as Near End of Infusion alarms, where the only clearing condition is that the user acknowledges their return to 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 and low priority Replace Battery alarms are silenced for 15 minutes, and repeats every 15 minutes.

NOTE: An alarm that is not cleared will reassert with alarm audio and display the troubleshooting pop-up message after 2 minutes. Alarm sounds resume after the silence period expires, and can be paused again if resolving the alarm condition takes additional time.

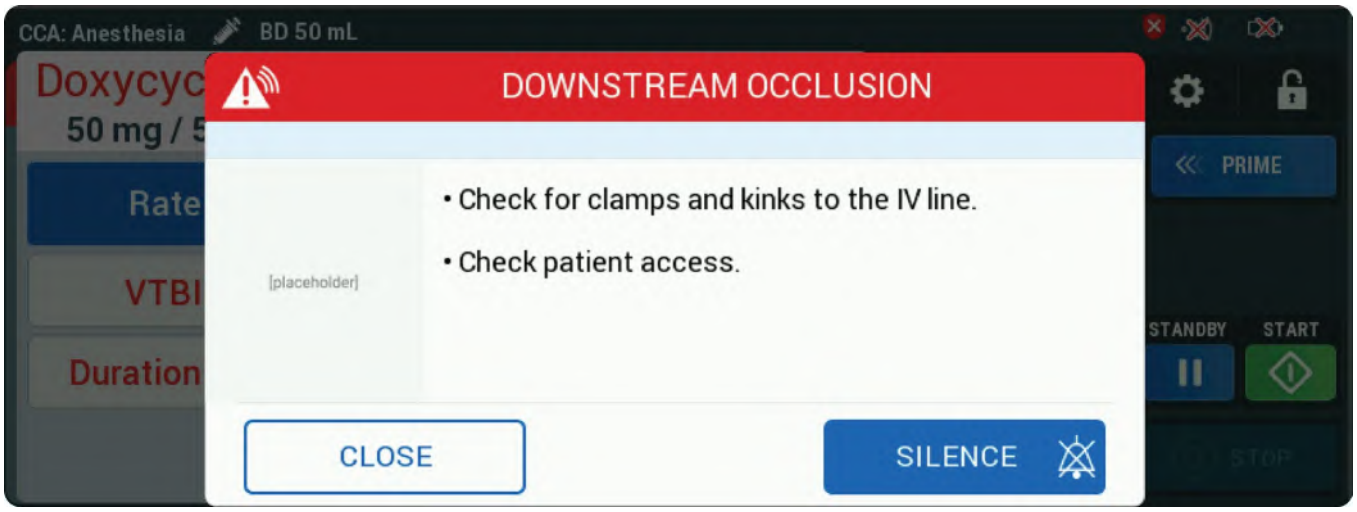
7. Correct the alarm condition (See ***"List of Alarms and Corrective Actions" on page 91***).
8. Tap **START** to resume infusion.

NOTE: When a low, very low, or depleted battery alarm occurs, connect to AC power immediately.

NOTE: Each alarm puts an entry in the logs. If troubleshooting does not correct the problem, replace the pump and then 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



Medfusion™ 5000 syringe pump 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. 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 occlusion in the extension set, a red arrow will indicate it in the graphic).

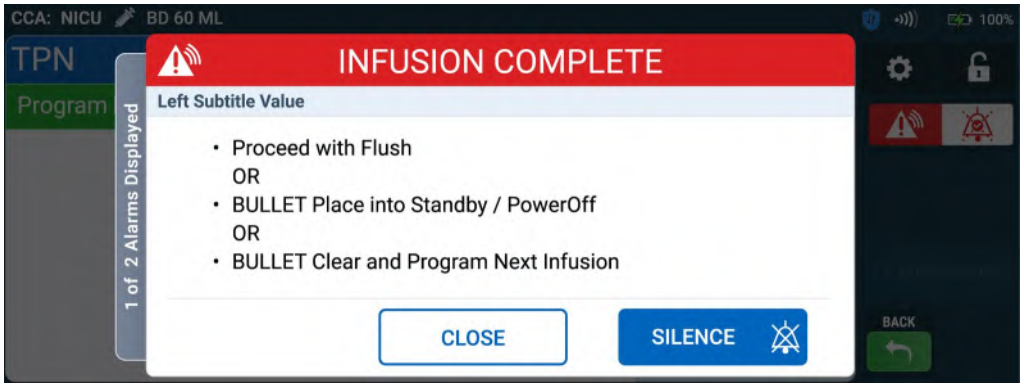
If **CLOSE** is tapped, the pop-up will temporarily be removed. The alarm icon will flash until the condition is resolved.

NOTE: If there is a touchscreen failure, to stop an infusion, use the **STOP** button on the keypad to the right of the touchscreen. Clamp the extension set to the patient and remove the syringe from the device.

Displaying Multiple Alarms

If more than one alarm condition occurs at the same time, the number of alarms to be viewed will be displayed in a tab above the alarm pop-up. The alarms are displayed in order of priority from the highest to the lowest. To view the stacked alarms, **CLEAR** or **CLOSE** the alarm in view.

NOTE: Pressing **SILENCE** will silence all the alarms on the pump. Any alarm that is not cleared will sound and display the pop-up alarm in 2 minutes.



Disabled Alarms

When alarms such as Near End of Infusion, Call Back, are disabled, the Disable Alarms icon will be displayed at the top of the pump user interface. To view disabled alarms, tap the icon to open the list. The Disabled Alarms are ordered with the highest priority on the top.

The following alarms can be disabled:

- Medium priority Callback alarm - May be disabled by configuration through the drug library, by default, or by the pump user.
- Low priority Near End of Infusion alarm – May be disabled by default as defined in the drug library or by the pump user.

See ***Callback and Near End of Infusion Alarm*** to enable Callback and Near End of Infusion alarms.

List of Alarms and Corrective Actions

NOTE: The error code is not displayed on the alarm window, this can be retrieved from the logs after the alarm is silenced, see *"Log History" on page 109*.

Alarm Message and Priority	Possible Cause	Corrective Action
PUMP AUDIO FAILURE **High** E257	Open circuit (low ADC count on the current sense line) on both primary speakers OR Short circuit (high ADC count on the current sense line) on both primary speakers OR Open circuit on a single primary speaker AND short circuit on the other single primary speaker OR Short circuit in the amplifier OR I2C communication error with the audio codec.	A hardware issue was detected. The pump can still be used pending replacement. Send to biomed for service.
PUMP MALFUNCTION **High** E300	ADC test error during power on self test and initialization	CLOSE ALL CLAMPS AND REMOVE Syringe. Power Off and then power on pump, if alarm persists, power off pump and send to biomed for service.
PUMP MALFUNCTION **High** E302	Current out of range indicates total backlight failure	CLOSE ALL CLAMPS AND REMOVE Syringe. Power Off and then power on pump, if alarm persists, power off pump and send to biomed for service.
PUMP AUDIO FAILURE **High** E303	I2C communication error with the audio code or short circuit detected in the speaker driver circuit	CLOSE ALL CLAMPS AND REMOVE Syringe. Power Off and then power on pump, if alarm persists, power off pump and send to biomed for service.

Alarm Message and Priority	Possible Cause	Corrective Action
PUMP MALFUNCTION **High** E305	UIC Die temp >= UIC Die temp threshold Or UIC Silicon temp >= UIC Silicon temp threshold	CLOSE ALL CLAMPS AND REMOVE Syringe. Power off the infusion pump and allow pump to come to room temperature. Power on the pump. If the alarm code E305 does not reappear, infusion pump may be put back in use. If the alarm persists, Power off the pump and send to Biomed for service.
PUMP MALFUNCTION **High** E307	Backlight background test fails	CLOSE ALL CLAMPS AND REMOVE Syringe. Power Off and then power on pump, if alarm persists, power off pump and send to biomed for service.
PUMP MALFUNCTION **High** E310	PMC SW reports that the Processor's internal die temperature is too high. **NOTE:** this is presented when the pump cannot be used.	CLOSE ALL CLAMPS AND REMOVE Syringe. Power Off and then power on pump, if alarm persists, power off pump and send to biomed for service.
BATTERY NEEDS SERVICE **High** E320	Average battery current is out of range	The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
BATTERY NEEDS SERVICE **High** E321	After 12 hours of charging, the battery has not reached Valid Charge Termination (VCT)	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.

Alarm Message and Priority	Possible Cause	Corrective Action
BATTERY NEEDS SERVICE **High** E325	Battery cell voltage greater than expected limit	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
BATTERY NEEDS SERVICE **High** E326	Battery not detected	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
BATTERY NEEDS SERVICE **High** E329	Battery has permanent damage	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
BATTERY NEEDS SERVICE **High** E330	Battery authentication failure.	The pump may shutdown unexpectedly if unplugged from AC (mains). Keep the pump plugged in to AC and obtain a re-placement as soon as possible. Power off the infusion pump. Close all clamps and remove the syringe. Send to biomed for service.
BATTERY NEEDS SERVICE **High** E331	Battery authentication failure/ unable to authenticate during an active infusion **NOTE:** This alarm does not get escalated/de-escalated to other levels based on infusion status.	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.

Alarm Message and Priority	Possible Cause	Corrective Action
BATTERY NEEDS SERVICE **High** E332	The Gauge detects battery short circuit during charge or discharge.	CLOSE ALL CLAMPS AND REMOVE Syringe. The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
POWER CYCLE PUMP **High** E341	Critical data verify error	CLOSE ALL CLAMPS AND REMOVE syringe. Power off the infusion pump, then on, to reset it. If alarm persists, Power off infusion pump and send to Biomed for service.
PUMP MALFUNCTION **High** E345	A Syringe Force Sensor self-test results in a fault. Fault occurs from any of the following: Syringe Force Sensor is outside the valid range Communication with the Syringe Force Sensor has been lost Syringe Force Sensor component reports a fault condition	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off infusion pump and then on to reset it. If alarm persists, power off infusion pump, and send to Biomed for service.
POWER CYCLE PUMP **High** E347	Watchdog time limit out of range during power on self-test	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
PUMP MALFUNCTION **High** E380	Various plunger motor errors	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off infusion pump and then on to reset it. If alarm persists, power off infusion pump, and send to Biomed for service.
POWER CYCLE PUMP **High** E434	RAM failure during PMC background test.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service

Alarm Message and Priority	Possible Cause	Corrective Action
POWER CYCLE PUMP **High** E436	ROM Checsum Error during CBIT (Continuous Built in Test)	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
POWER CYCLE PUMP **High** E437	Various fatal software failures including but not limited to uncontrolled shutdown.	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
POWER CYCLE PUMP **High** E438	Software stack memory overflow	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
PUMP MALFUNCTION **High** E440	Power button pressed and held for 30 Seconds or longer AND pump is not infusing. **NOTE:** if it is POST it will be for Future.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
PUMP MALFUNCTION **High** E443	During POST or when transitioning from any state (except battery wake up state) to operational, LCD Power Good GPIO pin indicates failure or Display ID check indicates failure	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
POWER CYCLE PUMP **High** E444	CPU and RTC clock frequencies mismatch during power on self test for PMC.	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
POWER CYCLE PUMP **High** E446	STL Test Failed for PMC	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump for service if alarm returns.
PUMP MALFUNCTION **High** E447	Background LCD display test fails.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
POWER CYCLE PUMP **High** E448	Persistent Storage Write verification error	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.

Alarm Message and Priority	Possible Cause	Corrective Action
PUMP MALFUNCTION **High** E449	Mechanism calibration data CRC error	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
PUMP MALFUNCTION **High** E451	Volume infused and program delivery rate mismatch	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
POWER CYCLE PUMP **High** E453	Persistent Storage verification error	There is an issue with the pump. Power OFF, then back ON to try to resolve. Send the pump to Biomed for service if alarm returns.
PUMP MALFUNCTION **High** E455	Invalid FLASH non-volatile memory type	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
PUMP MALFUNCTION **High** E459	Inter-Processor Communication (IPC) timeout between PMC and UIC.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
PUMP MALFUNCTION **High** E460	Voltage Input is too High (VIN_15) over 1 minute sliding window	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
PUMP MALFUNCTION **High** E461	Efuse output out of range	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off pump Send pump to Biomed for service
BATTERY NEEDS SERVICE **High** E464	Battery Gauge is reporting too high or too low temperature **NOTE:** If on Battery, the pump will have uncontrolled shutdown.	The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.
BATTERY NEEDS SERVICE **High** E465	The communication to battery driver or gauge has been lost	The pump can SHUTDOWN unexpectedly if unplugged from AC and should be replaced immediately. Keep plugged in until replacement obtained. Send to Biomed for service.

Alarm Message and Priority	Possible Cause	Corrective Action
POWER CYCLE PUMP **High** E466	During POST, Infuser detects a failure during touchscreen profile test or communication failure	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power OFF, then back ON to try to resolve. If alarm persists, send the pump to Biomed for service.
POWER CYCLE PUMP **High** E468	Background touchscreen diagnostic test fails	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power OFF, then back ON to try to resolve. If alarm persists, send the pump to Biomed for service.
ACTION REQUIRED **High** N102	No user interaction for 2 minutes when programming is started, but not yet confirmed. Or No user interaction for 2 minutes with a pop-up dialog displayed and on a new, unconfirmed program.	Press clear. Review program and continue or CANCEL programming.
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 delivering by pressing STOP, but not confirming STOP 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.	Press Clear. Respond to the pop-up displayed. If the infusion has not stopped after stop requested: Press STOP or CANCEL. If the infusion was not started after start was requested: Press START or CANCEL.

Alarm Message and Priority	Possible Cause	Corrective Action
ACTION REQUIRED **High** N102	No operator input for 30 seconds after line is titrated for programming but not completed, confirmed, or started. OR No operator action for 30 seconds when a bolus is programmed on top of a confirmed underlying Therapy, and is not Confirmed*. ***NOTE:** Confirmed refers to a Therapy that has been started or put into standby.	Review program and continue. or CANCEL
BOLUS CANCELED **High** N102	The reduced bolus rate is less than 25% of the original bolus rate OR The bolus dose duration based on the reduced bolus dose rate exceeds the maximum allowed bolus dose duration for the infusion OR The reduced bolus dose rate is less than or equal to the main infusion rate OR The reduced bolus rate is less than minimum programmable rate for the rule set.	Restricted flow was detected, and the BOLUS has been canceled. The RATE could not be maintained. The continuous has resumed.
LOADING DOSE CANCELED **High** N102	The reduced loading dose rate is less than 25% of the original loading dose rate OR The loading dose duration based on the reduced loading dose rate exceeds the maximum allowed loading dose duration for the infusion OR The reduced loading dose rate is less than or equal to the main infusion rate, if applicable OR The reduced loading dose rate is less than minimum programmable rate for the rule set.	Restricted flow was detected, and the LOADING DOSE has been canceled. The RATE could not be maintained. The continuous has resumed.

Alarm Message and Priority	Possible Cause	Corrective Action
BOLUS RATE REDUCED **High** N102	While delivering a bolus when the delivery pressure reaches the maximum occlusion pressure trip point for the installed syringe.	Restricted flow was detected, and the BOLUS RATE was reduced to maintain delivery. If disconnecting line, STOP pump. Check the line for clamps and kinks. Check patient site.
LOADING DOSE RATE REDUCED **High** N102	While delivering a loading dose when the delivery pressure reaches the maximum occlusion pressure trip point for the installed syringe.	Restricted flow was detected, and the LOADING DOSE RATE was reduced to maintain delivery. If disconnecting line, STOP pump. Check the line for clamps and kinks. Check patient site.
ACTION REQUIRED **High** N102	The following modals were not acknowledged after 15 seconds: - Stop confirmation dialog - Power Hard Key pressed during delivery	Required decision pending.
SYRINGE EMPTY **High** N1024	During active delivery, if the plunger position is <= to the HardHeightStop position as defined in the SyringeConfigurationData for the installed syringe.	The syringe is empty. Replace the syringe and resume delivery OR Clear and Power off.
BOLUS CANCELED **High** N1028	The pump is delivering a standalone bolus AND The reduced bolus rate is less than 25% of the original bolus rate OR The bolus dose duration based on the reduced bolus dose rate exceeds the maximum allowed bolus dose duration for the infusion OR The reduced bolus rate is less than minimum programmable rate for the rule set.	Restricted flow was detected, and the BOLUS has been canceled. Check the patient line for kinks or closed clamps. Confirm bolus rate is appropriate for the extension set used. Make necessary corrections and reprogram bolus if required.

Alarm Message and Priority	Possible Cause	Corrective Action
LOADING DOSE CANCELED **High** N1028	The pump is delivering a standalone loading dose AND The reduced loading dose rate is less than 25% of the original loading dose rate OR The loading dose duration based on the reduced loading dose rate exceeds the maximum allowed loading dose duration for the infusion OR The reduced loading dose rate is less than minimum programmable rate for the rule set.	Restricted flow was detected, and the LOADING DOSE has been canceled. Check the patient line for kinks or closed clamps. Confirm bolus rate is appropriate for the extension set used. Make necessary corrections and reprogram Loading Dose if required.
PROGRAMMING LOST **High** N103	Software issue detected and the pump is unable to retain delivery parameters.	The pump can still be used. Reprogram as needed.
CALLBACK WITH DELIVERY STOP **High** N105	A clinician configured a callback and stop after a Loading Dose, Bolus, or a step in a Multistep delivery that completes the infusion and stops.	Press clear. Clear the delivery and/or start the next program, as needed.
LOAD COMPLETE **High** N160	A Loading Dose delivery is complete with a VTBI=0 and no continuous delivery was programmed.	Close clamps and remove the syringe the Loading Dose was programmed on or program and start a continuous therapy as needed.
BOLUS COMPLETE **High** N160	A Bolus Dose delivery is complete with a VTBI=0 and no continuous delivery was programmed.	Close clamps and remove the syringe the Bolus Dose was programmed on or program and start a continuous therapy as needed.
VTBI COMPLETE **High** N160	When VTBI = 0 for continuous infusions with volume remaining in syringe	Add VTBI to the infusion if needed. Or Stop and Clear delivery. Close all clamps and remove the syringe.
INFUSION COMPLETE **High** N160	When VTBI=0 for intermittent infusions with volume remaining in syringe	The delivery has completed. Replace the syringe and Program Next Infusion OR Close all clamps and remove the syringe.

Alarm Message and Priority	Possible Cause	Corrective Action
DOWNSTREAM OCCLUSION **High** N186	Post occlusion bolus reduction complete and syringe is still installed.	Post occlusion bolus reduction is complete. Check for closed clamps and kinks to the IV line and correct any found. Check patient access. Restart the delivery.
VERY LOW BATTERY **High** N248	The infusion pump is running on battery power and there is approximately 26 minutes or less of battery life remaining.	The pump battery is getting VERY LOW. Plug into AC (mains) power source immediately. **NOTE:** If not resolved, the alarm will assert again after 2 minutes.
SYRINGE NOT DETECTED **High** N250-1	Syringe is not detected during therapy (running or delayed start).	The SYRINGE may have been removed. CLOSE ALL CLAMPS! Confirm the syringe is installed properly and restart delivery.
FLANGE NOT IN PLACE **High** N250-2	Flange error detected during therapy (running or delayed start)	The FLANGE is not in place Confirm the syringe flange is installed properly and restart delivery.
BARREL CLAMP NOT IN PLACE **High** N250-3	Barrel clamp error during therapy (running or delayed start)	The BARREL CLAMP is not in place Confirm the barrel clamp is installed properly and restart delivery.
SYRINGE INSTALLATION ERROR **High** N250-4	Plunger error detected during therapy (running or delayed start).	The PLUNGER is not secured by the holders CLOSE ALL CLAMPS! Confirm the syringe plunger is installed properly and restart delivery.
DEPLETED BATTERY! **High** N252	The infusion pump is running on battery power and the battery voltage is below the depleted battery threshold.	Plug into AC (mains) power source immediately. The pump is about to shutdown. Delivery has been stopped. Resume infusion as necessary.
STOPPED WHILE LOCKED **High** N255	While the touchscreen user interface was passcode-protected locked, someone pressed the stop or opened the Plunger release lever, or barrel clamp.	Infusion is stopped. Enter passcode to unlock the pump to address alarm.

Alarm Message and Priority	Possible Cause	Corrective Action
BATTERY NEEDS SERVICE **High** N57	The battery or the charger circuit needs servicing.	The pump may shutdown unexpectedly if unplugged from AC (mains). Keep plugged in until replacement is obtained. Discontinue use immediately. Send for service.
PUMP MALFUNCTION **High** E1324	A Plunger Position Sensor self-test results in a failure. The output of the plunger position sensor must be between 10 and 4080; otherwise, self-test failure.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off Send pump to Biomed for service
PUMP MALFUNCTION **High** E1325	A Plunger Capture Sensor self-test results in a fault. When the sensor light is turned off/sensor is disabled, the signal to PMC should be low, which corresponds to no syringe installed and is the default signal; otherwise, self-test fails Take note: when the plunger is fully in/collapsed, the syringe capture flippers will rest on the flange capture features. This should not independently trigger a self-test failure.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off Send pump to Biomed for service

Alarm Message and Priority	Possible Cause	Corrective Action
PUMP MALFUNCTION **High** E1325	Any Sensor Combination Fault Test results in a fault. If the plunger head is fully inserted into the pump, there cannot be a syringe present, and as such, if the Syringe Flange Sensor indicates that there is a syringe present, one of the sensors must be faulty. Syringe Flange Sensor indicating that syringe is present should correspond to it reading high. For this self-test, the failure threshold for the Plunger Position Sensor would correspond to when the sensor reading is at or below the value when the plunger head is fully inserted into the pump.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off Send pump to Biomed for service
PUMP MALFUNCTION **High** E1326	A Syringe Flange Sensor self-test results in a failure. When the sensor light is turned off/ sensor is disabled, the signal sent to the PMC should be low, which corresponds to no syringe installed and is the default signal; otherwise, self-test failure.	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off Send pump to Biomed for service
PUMP MALFUNCTION **High** E1327	A Syringe Barrel Diameter Sensor self-test results in a failure. The output of the syringe barrel diameter sensor must be between 10 and 3900; otherwise, self-test fails	CLOSE ALL CLAMPS AND REMOVE SYRINGE. Power Off Send pump to Biomed for service
OCCLUSION - BOLUS REDUCTION **High** N1032	Downstream occlusion detected while: Delivering the main or flush infusion OR During delivery of a bolus or loading dose and pressure does not drop below the BRR Dwell Pressure. OR Syringe is not empty	Occlusion detected. Pump reducing built-up pressure to avoid bolus! Wait! Do not address occlusion until reduction completes. OR Press Stop, clamp line, and disconnect to avoid bolus.

Alarm Message and Priority	Possible Cause	Corrective Action
PRESSURE INCREASING **Medium** N1026	The following are true: - FlowSentry is enabled for the current infusion per the CCA - FlowSentry is valid for the installed syringe - The pump is delivering at a rate for which FlowSentry is active - Per the FlowSentry algorithm the pump has reached or exceeded the pressure increasing threshold.	Downstream Pressure is increasing. If disconnecting syringe, STOP pump. Check the line for clamps and kinks. Check patient site.
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 with a continuous to follow. Or A VTBI reaches 0 or any step in a Multistep therapy except the last step.	Press Clear.
STANDBY EXPIRED **Medium** N108	When the standby timer expires, and the infusion has started	The standby setting has expired. Start delivery or other action required
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 syringe confirmation screen with a pop-up dialog message displayed. Also, there is no active infusion , though a syringe is inserted.	Press clear. Review program and continue or CANCEL programming.
INACTIVITY **Low** N101	No user interaction for 5 minutes after powered on, in clinical mode.	Press clear. Select a program or Power off infusion pump. Remove the syringe if not in use.
STANDBY EXPIRED **Low** N106	When the standby timer expires, and infusion has been programmed but infusion is never started	The standby setting has expired. Start delivery or other action required

Alarm Message and Priority	Possible Cause	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.	Press clear. Check for a near empty syringe.
BATTERY NEEDS SERVICE **Low** N56	The battery has reduced capacity.	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.
LOW BATTERY **Low** N58	The battery charge level is low, less than or equal to 57 min.	Plug into AC (mains) power immediately. **NOTE:** If not resolved, the alarm will assert again after 15 minutes.

Regardless of the power state, all alarms are maintained 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 Medfusion™ 5000 Syringe Pump Technical Service Manual.

Setting the Occlusion Alarm Limit

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

The infusion pump checks the downstream pressure and updates the reading every second. You can view the current pressure reading on the main delivery screen, the pressure graph is constantly updating through the duration of the infusion.

To set the occlusion pressure limit from main delivery screen:

1. On the Main Delivery page, tap the Settings button on the right of the screen to display the menu options.
2. Under **CLINICAL SETTINGS**.
3. Tap **DOWNSTREAM PRESSURE** on the left of the screen.
4. Adjust slider to desired limit between 4 psi and 17.4 psi, tap **CONFIRM** and **CONFIRM** or **EDIT** on the popup screen.
5. Tap **EXIT SETTINGS** to return to the main delivery screen.

To change the Occlusion Pressure Alarm Limit from home screen Settings:

1. Tap the Settings button on the top right of the screen. The Settings page appears.
2. Tap **DOWNSTREAM PRESSURE,** under **CLINICAL SETTINGS**.
3. Change the limit to the desired psi value between 4 and 17.4 (between 207 and 900 mmHg) using the slider.
4. Tap **CONFIRM**.

NOTE: Occlusion Alarm Limit can only be set if a syringe is loaded and confirmed in the infusion pump.

Troubleshooting

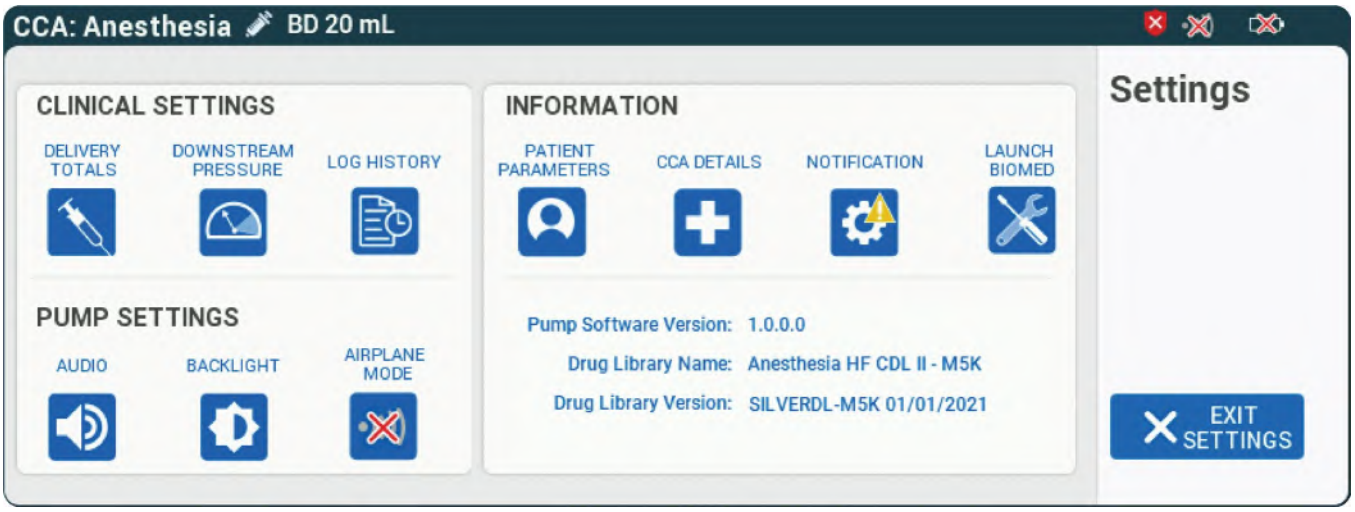
Resolving Air-in-Line

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. Unclamp the upstream tubing of the line you want to use to prime the downstream line.
4. Reprime the administration set to remove the downstream air (See Priming).
5. Initialize the syringe in the infusion pump.
6. Reattach the administration set to the patient and restart delivery.

Settings

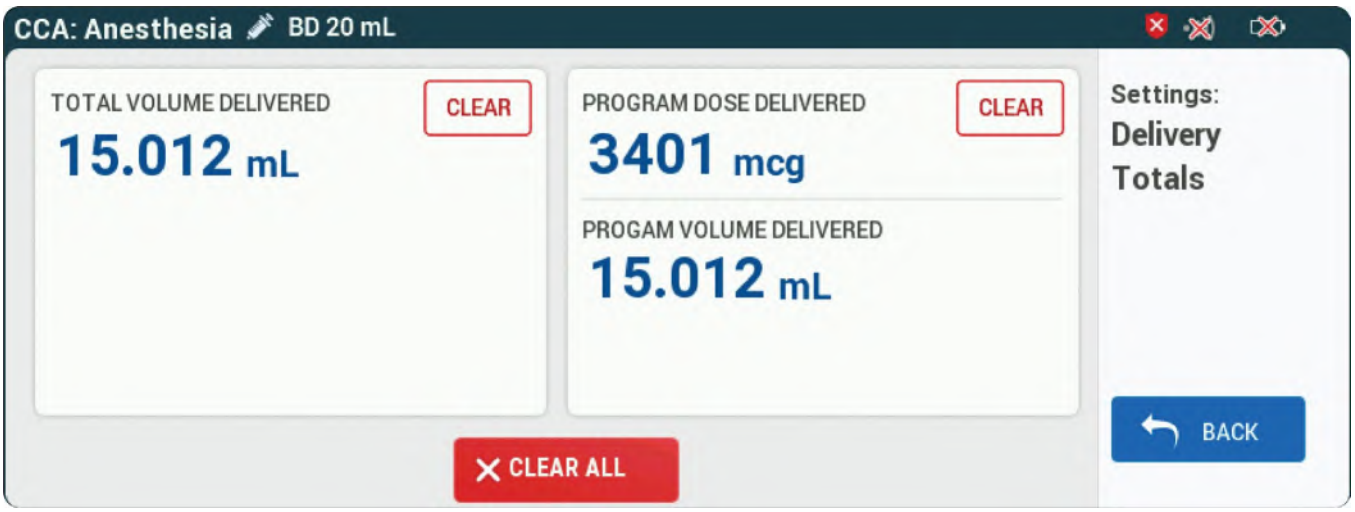


The Medfusion™ 5000 syringe infusion pump has a number of configurable settings at the CCA and infusion pump levels. CCA settings determine the default for many infusion pump settings. To view settings, tap the gear icon at the top right of the Main Delivery page. To exit settings, tap **EXIT SETTINGS**.

Clinical Settings

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

Delivery Totals



The Delivery Totals page provides information on the total volume, program volume and program dose delivered. Volume and dose delivered information may be cleared by tapping **CLEAR** or **CLEAR ALL**.

Volume and dose delivered are 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 volume used for priming with the in-pump Prime feature can be viewed on the Volume Infused page and will be cleared anytime the Primary Volume Infused is cleared.

NOTE: The Prime volume is decremented from the approximated VTBI.

To navigate to the Volume Infused page, tap the Settings icon at 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 at 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.

NOTE: Occlusion Alarm Limit can only be set if a syringe is loaded and confirmed in the infusion pump.

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 is date and time stamped when the event began, and includes an event message. Events are ordered by date and time, and the order may be reversed via tapping the column header 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 at the top right of the home screen and then tap **LOG HISTORY**, under **CLINICAL SETTINGS**.

Pump Settings

Pump setting defaults are determined by CCA, settings displayed 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 **MIN** as a minimum, which turns off key press volume other than START and STOP. 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**.

Backlight

The pump display brightness may also be adjusted via a slider

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

Airplane mode

Airplane Mode enables or disables communication to and from the pump. This can be configured as **OFF** or **ON**.

Information

Patient Parameters

The Patient Parameters screen offers a high-level look at the patient parameters (including weight and/or BSA) entered for a program.

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 settings  button 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.
Maximum Flush	Controls the maximum volume that can be entered for the flush volume within the CCA and may be further constrained by the syringe in use.
Maximum Patient Weight Minimum Patient Weight	Together, these display the allowable patient weight range for the CCA when you program a weight-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.
Require Patient Parameter Confirmation	When enabled, the patient value must be entered twice to confirm accuracy.
Require Total Dose Entry For Intermittent:	When the medication is configured as an intermittent infusion, a total dose entry may be required in place of a weight or BSA based dose, when required by the CCA.
Allow Programming Below Recommended Rate:	When enabled allows programming at rates below recommended for loaded syringe.
Allow Standby Bolus	When enabled allows user to pre-program a Bolus for later in advance, without starting when offered by the CCA.
Allow Standalone Load and Bolus	When enabled allows loading dose or bolus to be programmed without an associated continuous infusion required.

CCA and Pump Settings	Description
Allow Bolus Dose Entry in Total Dose	When the medication is configured for Loading Dose or Bolus, enablement allows programming in defined dose units (which are weight or BSA based) or in total dose units.
Allow Bolus Dose Entry in mL	When the medication is configured for Loading Dose or Bolus, enablement allows programming in defined dose units or mL.
Allow Flush	When enabled and the medication is configured as an intermittent, a flush option is made available.
Allow 1 mL Syringe	When enabled allows 1 mL syringes to be available to the pumps user if they are included in the CCA syringe list.
Default Downstream Pressure Occlusion Alarm Limit	Configures the normal Downstream Alarm Pressure Limit for the CCA. The pump user can change this value for a delivery, when needed.
Default Downstream Pressure Occlusion Alarm Limit 1 mL	Configures the 1 mL syringe Downstream Alarm Pressure Limit for the CCA. The pump user can change this value for a delivery, when needed.
Allow FlowSentry	When enabled, an alarm specific to FlowSentry may occur when a pressure increase in the extension set is detected.
Standby Allowed	If Standby Allowed is enabled, deliveries can be put into Standby up to the configured Maximum Standby Time which is between 24 and 72 hours and is configured in the CDL for the pump. If Standby Allowed is disabled, the Standby button will not be available for programming.
Delayed Start Allowed	If Delayed Start Allowed is enabled, you can program a Delayed Start of between 1 minute and 4 hours for deliveries. If Delayed Start Allowed is disabled, the Delay Start button will not appear for programming.

CCA and Pump Settings	Description
Callback Notification Allowed	When Callback Notification is configured to occur, 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 Bolus delivery. The pump user can change the Callback setting from the default setting. When Callback Notification is NOT configured, a Callback Alarm must be set manually, if needed, for each of these.
General Volume	Configures the volume level of positive tones. The pump user can change this value, as needed.
Alarm Volume	Configures the volume level of alarms. The pump user can change this value, as needed. Unlike General Alarm, there is no OFF value.
Screen Brightness	Configures the brightness of the infusion pump screen. You can raise or lower this value, as needed.
Allow Far View Screen	When configured, the pump will display the Far View after a period of time for enhanced visibility from a distance, by the CCA.
Enteral color	Indicates the color of the programming and delivery screen display highlights to specify the enteral route of administration. It can be configured as either orange or purple.
Volume Infused Display	Displays the volume as either Volume Infused (VI) or Volume to be Infused (VTBI). Set by Biomed technician or the CCA. The pump user can modify this setting.
Passcode Auto-Lock Inactivity Timeout	If Inactivity Timeout is enabled, the infusion pump will automatically lock after a certain period of inactivity and will require a passcode to unlock. If Inactivity Timeout is disabled, a passcode lock must be set manually, if needed.
Passcode Required for CCA Access	When configured, a passcode is required to obtain access to the CCA.
Infusion Pump Settings	

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). This is a master library setting shared for all associated CCA's.

Notifications

Notifications screen displays all warning and alert messages in date and time order. The order of the list can be reversed by tapping the column header at the top of the date column.

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 Medfusion™ 5000 Syringe Infusion Pump Technical Service Manual.

Cleaning, Maintenance, Storage, and Service

Cleaning and Disinfecting the Infusion Pump

The Medfusion™ 5000 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 Medfusion™ 5000 Syringe Infusion Pump Technical Service Manual.

⚠ PRECAUTION: Do not saturate the air-in-line sensors 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 Medfusion™ 5000 Technical Service Manual for a full list of cleaning and disinfecting solutions.

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

1. Power down and unplug the Medfusion™ 5000 infusion pump. Remove the pump from the pole clamp, by pressing the latch on the infuser handle and carefully pull the infuser off the pole clamp and place on a flat and stable surface.
2. 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, keypad, and display for damage. If damaged remove the infusion pump from service and return it to the biomed technician for replacement.

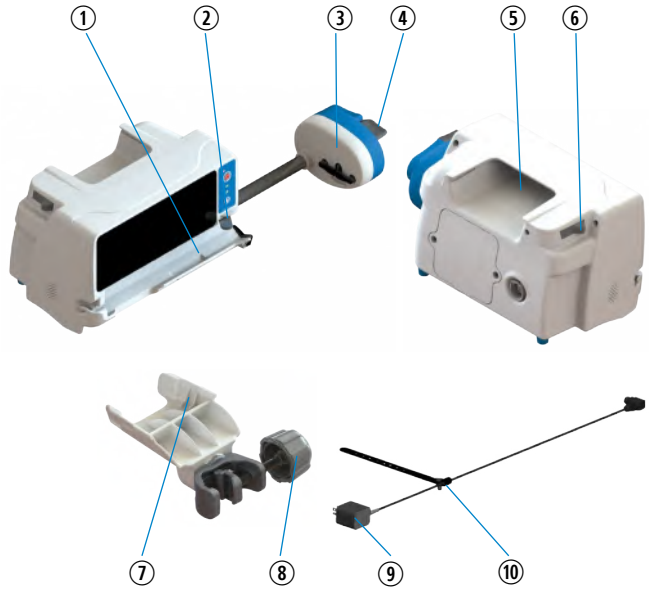
3. With gloves on, remove a wipe from the dispenser and unfold it to expose the maximum surface area before wiping, or dampen a lint-free cloth with an approved diluted cleaning solution.

⚠ PRECAUTION: Do not spray cleaning or disinfecting solutions directly onto the infusion pump.

4. Thoroughly wipe all surfaces of the infusion pump, replacing the cloth for a clean one as needed.

- Use a spiral pattern when wiping, moving from the inner to outer edges of each surface to avoid recontamination of 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 the infusion pump avoid areas with lubricant on them such as the plunger tube and barrel clamp tube.

5. Dampen a lint-free cloth with water and wipe the pump for no more than 4 minutes, replacing the cloth for a clean one as needed.
6. 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, paying particular attention to areas highlighted in the diagram below.



① Syringe Tray
② Barrel Clamp
③ Plunger Head
④ Clutch Lever
⑤ Handle
⑥ Latch Lever
⑦ Pole Clamp flat surfaces
⑧ Pole Clamp knob
⑨ AC Adapter
⑩ AC Adapter cord and strap

7. 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 near the seals, replace the infusion pump as soon as possible so it can be thoroughly cleaned. Dried, built-up residue from viscous 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.

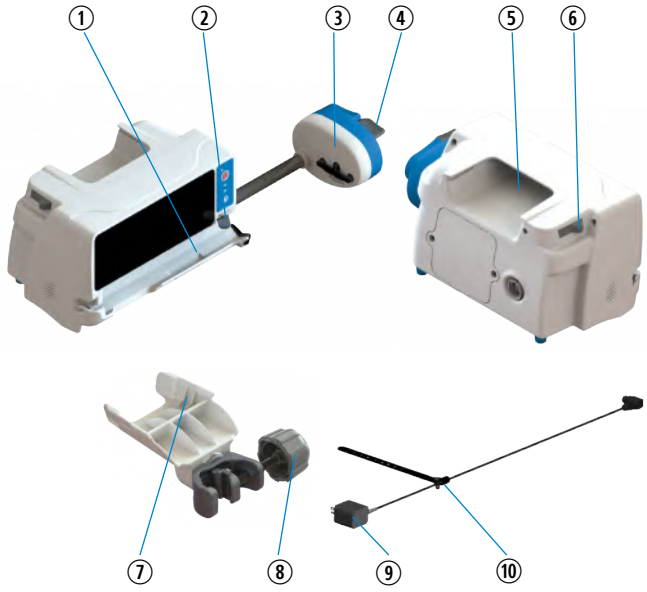
⚠ PRECAUTION: If the infusion pump housing, keypad, or display are cracked or damaged, remove the infusion pump from service and return it to the biomed technician for replacement.

2. With gloves on, remove a wipe from the dispenser and unfold it to expose the maximum surface area before wiping, or spray/dampen an approved disinfecting solution on a sterile, 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. Ensure the surface remains wet for a minimum of 7 minutes, paying particular attention to the area in the diagram below.

   NOTE: Use sterile swabs wetted with disinfectant to access hard to reach areas of the device.



① Syringe Tray
② Barrel Clamp
③ Plunger Head
④ Clutch Lever
⑤ Handle
⑥ Latch Lever
⑦ Pole Clamp flat surfaces
⑧ Pole Clamp knob
⑨ AC Adapter
⑩ AC Adapter cord and strap

4. Dampen a sterile lint-free cloth with sterile water and wipe all surfaces for no more than 4 minutes, replacing the cloth or wipe as needed.

   NOTE: Do not allow water to run into internal parts of the infusion pump.

5. 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.
Household Bleach	CaviWipes RTU Wipes	Use per manufacturer's recommendations and instructions in this manual.

Infusion Pump Maintenance

The Medfusion™ 5000 infusion pump requires preventive maintenance every two years that is performed by qualified service personnel. There is no clinician required maintenance. See the Medfusion™ 5000 Technical Service Manual for instructions.

Battery Maintenance

The battery reconditioning cycle is intended to be run when general preventive maintenance is performed. See the Medfusion™ 5000 Syringe Infusion Pump 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

⚠ 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 the cable to unplug.

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

Service

The infusion pump has no clinician-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 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 Medfusion™ 5000 Technical Service Manual for repair and replacement procedures.
- Circuit diagrams and repair parts lists are available for trained, authorized service representatives. See the Medfusion™ 5000 Technical Service Manual for more information.
- See the Medfusion™ 5000 Technical Service Manual for more information for all battery removal and storage information, component part lists, descriptions, and fuse replacement.
- The Medfusion™ 5000 infusion pump can be disconnected from the mains supply by removing the AC Adapter from the wall socket.

Specifications

The following specifications apply to the Medfusion™ 5000 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.
Support Life:	7 years **NOTE:** Support 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:** 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
AC Adapter:	ICU Medical AC Adapter (PN 22-5000-01)
Fuses:	Internal and non-replaceable
Electrical Leakage:	Meets IEC 60601-1:2020 Medical Electronic Equipment, Part 1: General Requirements for Basic Safety and Essential Performance
Electrical Standard:	Class I, Type CF
Battery Type:	Lithium-ion; 7.2 V; 9,045 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 LifeShield 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 12 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:	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 5:	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-NFCMF5K
IC ID No:	5627A-NFCMF5K

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:	Deliver Alone (if the version of LifeShield Infusion Safety Software supports this feature)
Delivery Methods:	Continuous, Loading Dose, Bolus, Flush, Intermittent 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)
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

Occlusion Alarm

Length and type of extension 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 becomes occluded. Refer to ***Restarting Delivery Automatically After a Downstream Occlusion Alarm*** to obtain more information.
Downstream Pressure Limit (Without Alarm):	Maximum pressure limit: user-selectable Factory default setting: 6 psi (310 mmHg) Selectable range: 4 psi (x mmHg) to 17.4 psi (x mmHg)
Maximum Infusion Pressure:	20 psi (1034 mmHg)

Medfusion 5000 Approved Syringe List

The table below provides a list of syringes available with syringe configuration which can be used with the Medfusion™ 5000 infusion pump. (Information regarding syringe flow rate and minimum volume for these syringes can be found on the next page).

Model (Manufacturer)	Syringe Model/Sizes
B-D® (Becton-Dickinson)	1, 3, 10, 20 and 50 mL (Luer Lok™)
	3 and 20 mL Enteral
Monoject® (Covidien)	60 mL ENFit Enteral

The critical volume (maximum) which could be infused in the event of a single point failure is 1/100th of the syringe size by volume.

Flow rate & minimum volume by manufacturer & size - Standard syringes

Please see the tables below for information regarding the lowest recommended rates for each syringe size.

The table below is provided for convenience. Should changes to the listed syringes occur, the values shown here may be superseded (see the Instructions for Use provided with the Medfusion™ Standard Syringes, Series 2.)

Model (Manufacturer)	Size	Min. Rate	Max. Rate	Minimum volume to infuse	Minimum recommended rate	
	mL	mL/hr	mL/hr	mL	mL/hr	
					FlowSentry™ disabled***	FlowSentry™ enabled
B-D® (Becton-Dickinson)						
Tuberculin (Slip tip)	1	0.01	29	0.0016	0.033	N/A*
Luer Lok™	1	0.01	29	0.0016	0.033	N/A*
	3	0.01	98	0.005	0.1	0.03
	5	0.03	191	0.0083	0.17	0.05
	10	0.05	277	0.0166	0.33	0.1
	20	0.1	483	0.0333	0.67	0.2
	30	0.1	622	0.05	1	0.3
	60	0.1	944	0.1	2	0.6
Monoject® (Covidien)						
Tuberculin (Slip tip)	1**	0.01	29	0.0016	0.033	N/A*
Luer Lock	3**	0.01	105	0.005	0.1	0.03
	6**	0.03	213	0.01	0.2	0.06
	12**	0.05	325	0.02	0.4	0.12
	20**	0.1	536	0.0333	0.67	0.2
	35	0.1	735	0.0583	1.2	0.35
	60	0.1	944	0.1	2	0.6
Terumo® (Terumo® Medical)						

Model (Manufacturer)	Size	Min. Rate	Max. Rate	Minimum volume to infuse	Minimum recommended rate	
	mL	mL/hr	mL/hr	mL	mL/hr	
					FlowSentry™ disabled***	FlowSentry™ enabled
Tuberculin (Slip tip)	1	0.01	29	0.0016	0.033	N/A*
Luer Lock	3	0.01	106	0.005	0.1	N/A*
	5	0.03	225	0.0083	0.17	N/A*
	10	0.05	333	0.0166	0.33	N/A*
	20	0.1	541	0.0333	0.67	N/A*
	30	0.1	712	0.05	1	N/A*
	60	0.11	1130	0.1	2	N/A*
BB Perfusor® (B. Braun)						
Luer Lock	20	0.1	481	0.0333	0.67	0.2
	50	0.1	1042	0.0833	1.7	0.5
BB Omnifix™ (B. Braun)						
Luer Lock	5	0.03	207	0.0083	0.17	0.05
	10	0.05	338	0.0166	0.33	0.1
	20	0.1	537	0.0333	0.67	0.2
	50	0.1	1042	0.0833	1.7	0.5

* FlowSentry™ pressure monitoring is not available with 1 mL and Terumo® syringes.

** Rigid Pack

*** The flow rate accuracy may not be maintained below minimum recommended rates due to syringe plunger flexibility. See warning below.

Time to Detect Downstream Occlusions

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
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.

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)		
	0.1 to 999 mL/hr	0.1 mL/hr	1 mL/hr	10 to 999 mL/hr
Standard Conditions (up to 96 hours)	-0.7% / 4.4%	-0.7±1.8	0.0±0.8	-0.4 ±1.0
Ambient Temperature: 41°F (5°C) (up to 96 hours)	-0.2% / 4.6%	-5.8 ±4.1		0.1 ±0.2
Ambient Temperature: 104°F (40°C) (up to 96 hours)	-1.4% / 5.6%	3.3 ±2.6		0.0 ±1.0
Ambient Pressure: 15 psia 0 feet above sea level (0 meters)	-2.6% / 5.6%	-1.7 ±3.3		0.0 ±0.9
Ambient Pressure: 10 psia 10,000 feet above sea level (3,000 meters)	-3.2% / 5.2%	1.9 ±2.4		-0.1 ±0.4
50% Dextrose Solution (high viscosity)	-1.5% / 4.4%	-0.7 ±2.1		0.0 ±1.1
70% Dextrose Solution (high viscosity)	-1.7% / 3.2%	0.7 ±2.5		0.3 ±0.1
Filling Head Height: -20 inch (-51 cm)	-1.5% / 4.2%	-1.0 ±1.8		0.0 ±1.0
Filling Head Height: +35 inch (+89 cm)	-1.3% / 4.6%	1.1 ±1.5		0.0 ±0.1

Tested Configuration	Flow Rate Error (%)	Start-up Delay Time (minutes)		
	0.1 to 999 mL/hr	0.1 mL/hr	1 mL/hr	10 to 999 mL/hr

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. Flow rate error (%) results represent the Lower and Upper Tolerance Interval Limits of the 30-sample size tested. The startup delay time results represent the mean and standard deviations from the 30 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 70% Dextrose solution
- 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

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

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 30 extension 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
1 mL/hr	4 mL	1.19%	1.48%	0.27%
25 mL/hr	100 mL	1.36%	2.17%	0.77%

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

NOTE: Loading Dose was tested with similar results reported.

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

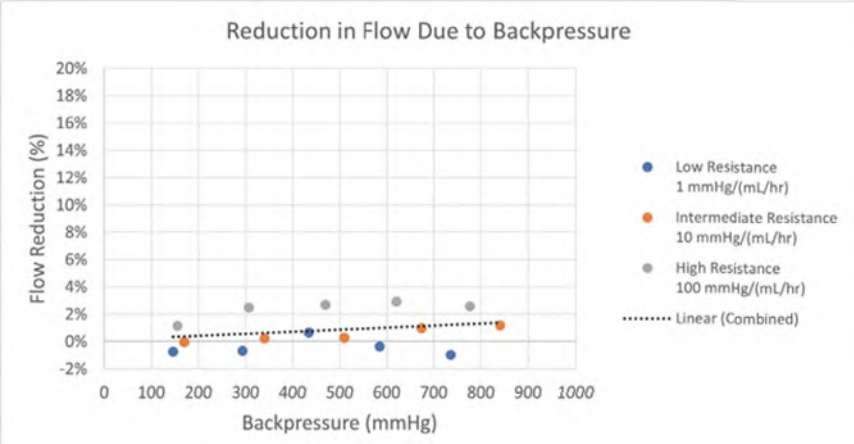
At 0.1 to 999 mL/hr flow rates, atmospheric pressure of 0 to 10,000 feet (3,000 meters) does not affect system delivery accuracy. Testing was performed in accordance with test methods and test matrix defined in AAMI TIR101:2021.

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 (30 mechanisms).



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

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	+21.7 / +/-6	+36.2 / +/-11.0
0.5	+5.5 / +/-1.2	+11.2 / +/-2.1
1.0	+4.0 / +/-0.8	+6.9 / +/-1.0
2.0	+3.0 / +/-0.5	+4.1 / +/-0.7
3.0		+3.6 / +/-0.7

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 30-sample size tested.

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.

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”).

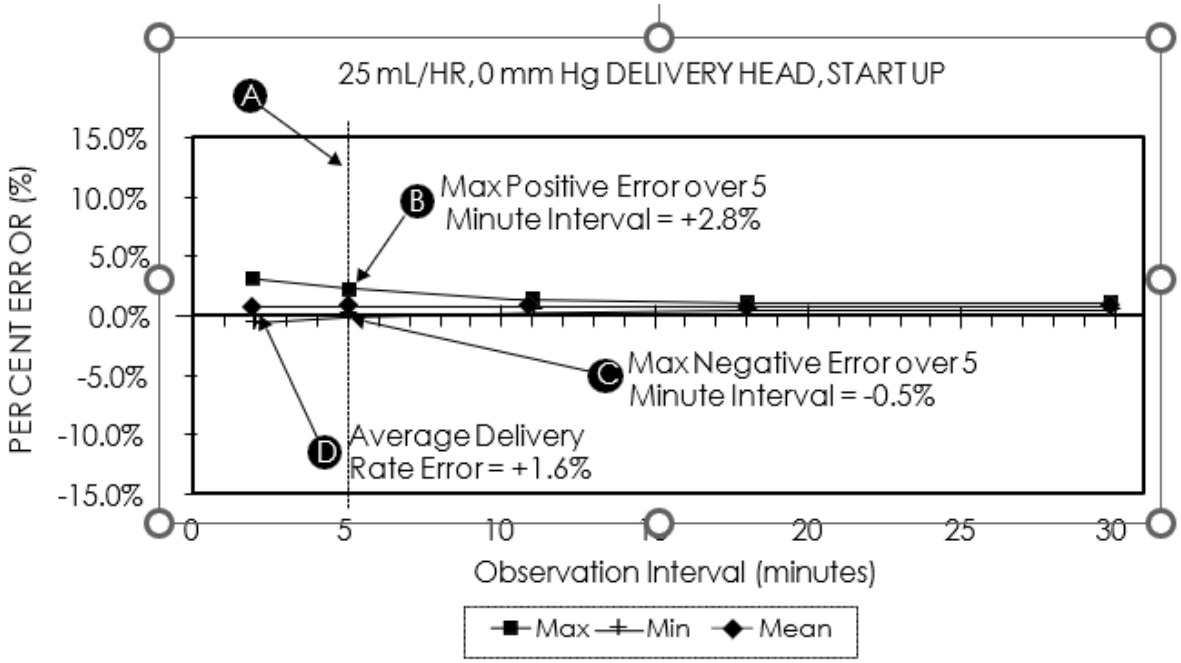
Trumpet Curve data for each rate was generated using a representative sample of 15 infusion pumps (30 mechanisms). Tests were performed using Administration Set List Numbers 14247 and 14687 from the Plum set portfolio.

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%.

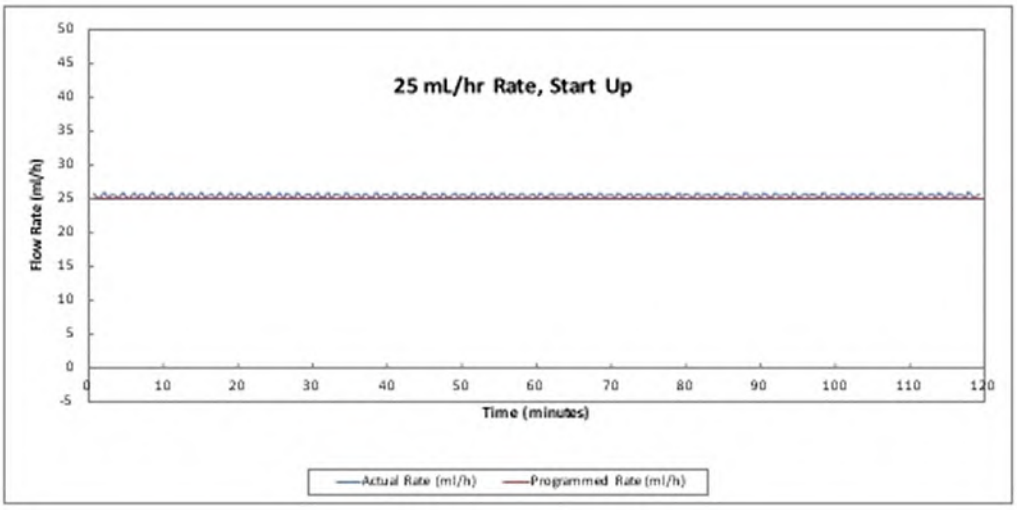
This means that at the rate of 25 mL/hr the average maximum flow rate fluctuation for any 5 minute time interval during the 2nd hour of operation was within the limits of +2.8% and –0.5% from the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

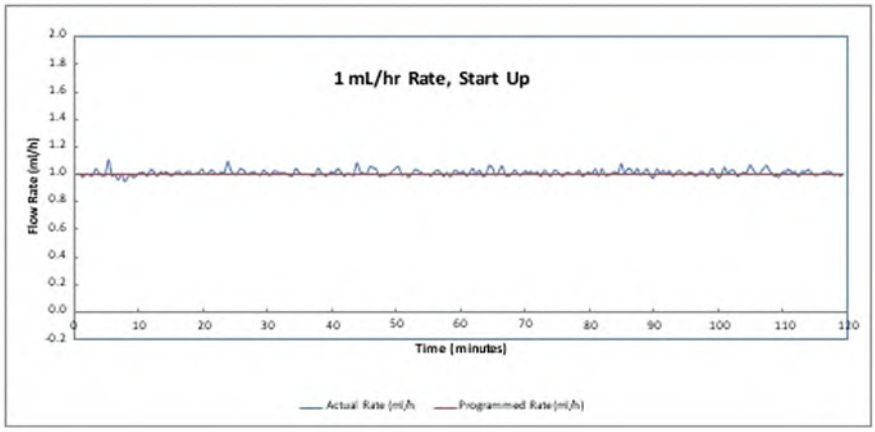
For other time intervals look at other points at the horizontal axis and determine corresponding limits as above.

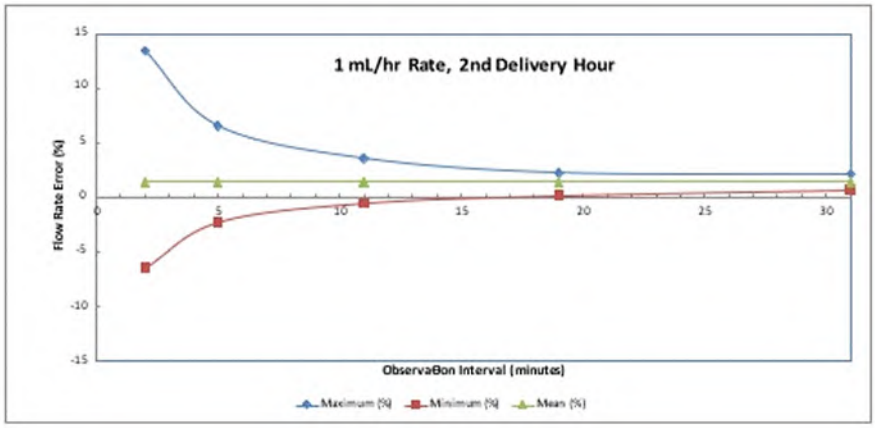


A trained professional can use the resulting graphs to select an infusion pump with the appropriate startup and flow characteristics to suit the clinical application.

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.




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 (%)
Observation Interval (minutes)
Maximum (%)
Minimum (%)
Mean (%)

NOTES:

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 thisinfusion device has been evaluated and found compliant to the requirements of the followingRadio 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). Operation is subject to the following twoconditions:

(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.

Cet appareil est conforme à la partie 15 des règles de la FCC et aux RSS sans licence d'Innovation, Sciences et Développement économique Canada. L'exploitation est assujettie aux deux conditions suivantes :(1) Cet appareil ne doit pas causer d'interférences nuisibles, et(2) Cet appareil doit accepter toute interférence, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de cet appareil.

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 CategoryII) 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 again 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 the5.15~5.25 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 Medfusion™ 5000 infusion pump.

Electromagnetic Compatibility

The Medfusion™ 5000 infusion pump has been tested for Basic Safety, Essential Performance, and Performance to the requirements of the standards in the following table:

Standard
ANSI C63.27-2017
IEC 60601-1-2:2014+AMD1:2020 Edition 4.1 EN 60601-1-2:2015+A1:2021 Edition 4.1
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 Medfusion™ 5000 device has been evaluated and tested for safety and essential performance under the scope and requirements of IEC/EN 60601-1-2 Edition 4.1 (as defined in the table above) under the professional healthcare environment immunity category for the 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)
- Radiated fields in close proximity Immunity (IEC 61000-4-39)

The infusion pump is suitable for use in clinical professional healthcare environments in accordance with the provisions of IEC 60601-1-2:2014+AMD1:2020 Edition 4.1/EN 60601-1-2:2015+A1:2021 Edition 4.1 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 interfere with radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The essential performance of a Medfusion™ 5000 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 Medfusion™ 5000 Technical Service Manual concerning operating devices near RF sources or sources of electro- magnetic 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 lifeshield. In the event of a network interruption, transmission of drug library/ software updates and auto-programming from lifeshield to the infusion system, and transmission of clinical status information from the infusion system to lifeshield, 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.

These effects are acceptable and the Medfusion™ 5000 can continue to operate as intended. These effects can be minimized by relocating or re-orienting the Medfusion™ 5000 equipment.

Refer to the Medfusion™ 5000 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 Medfusion™ 5000 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.

Wireless Coexistence

The ICU Medical Medfusion™ 5000 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 C63.27-2021 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 (LTE) Transmitter		
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 Medfusion™ 5000 and LifeShield may occur because of changes in your wireless network's Quality of Service (QoS). Medfusion™ 5000 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 Medfusion Model 5000 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 Medfusion Model 5000 and LifeShield.

When Medfusion™ 5000 is infusing in clinical mode, infusion status data is transmitted to LifeShield. The frequency of the infusion status data transmission by Medfusion™ 5000 is configurable (between 30 seconds and 5 minutes).

All outgoing data is buffered by Medfusion™ 5000 in the event of a network failure or a decline in service that hinders the transmission of the data. Medfusion™ 5000 will store up to 6 months' worth of clinical logs, 2 months' worth of diagnostic logs, and 2 months' worth of audit logs. Medfusion™ 5000 will continually check the network's connectivity and attempt to send data from its buffer. When connectivity is restored, Medfusion™ 5000 sends data that was previously buffered.

Medfusion™ 5000 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 lifeshield. In the event of a network interruption, transmission of drug library/ software updates and auto-programming from lifeshield to the infusion system, and transmission of clinical status information from the infusion system to lifeshield, 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 Medfusion™ 5000 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.

Dosing Units and Allowable Ranges

The following table lists the dosing units available with the Medfusion™ 5000 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	nanog, nanog/min, nanog/hr, nanog/day, nanog/kg, nanog/kg/min, nanog/kg/hr, nanog/kg/day, nanog/m2, nanog/m2/min, nanog/m2/hr, nanog/m2/day, mcg, mcg/min, mcg/hr, mcg/day, mcg/kg, mcg/kg/min, mcg/kg/hr, mcg/kg/day, mcg/m2, mcg/m2/min, mcg/m2/hr, mcg/m2/day, mg, mg/min, mg/hr, mg/day, mg/kg, mg/kg/min, mg/kg/hr, mg/kg/day, mg/m2, mg/m2/min, mg/m2/hr, mg/m2/day	0.0001-0.9999	0.0001
		1.000 - 99.999	0.001
		100.0-999.9	0.1
		1000 - 999,999	1
	g, grams/min, grams/hr, grams/day, grams/kg, grams/kg/min, grams/kg/hr, grams/kg/day, grams/m2, grams/m2/hr, grams/m2/day, grams/m2/min	0.0001 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.9	0.1
		1000 - 9,999	1
mEq	mEq, mEq/min, mEq/hr, mEq/day, mEq/kg, mEq/kg/min, mEq/kg/hr, mEq/kg/day, mEq/m2, mEq/m2/min, mEq/m2/hr, mEq/m2/day	0.0001-0.9999	0.0001
		1.000-99.999	0.001
		100.0-999.9	0.1
		1000-9999	1

Category	Dosing Units	Range	Increment
mL	mL/hr	0.010 - 9.999	0.001
		10.00 - 99.99	0.01
		100.0 - 999.9	0.1
		1000 - 1200	1
	mL, mL/min, mL/kg, mL/kg/min, mL/kg/hr, mL/kg/day, mL/m2, mL/m2/hr, mL/m2/min, mL/m2/day	0.0010 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.9	0.1
		1000 - 9999	1
mmol	mmol, mmol/min, mmol/hr, mmol/day, mmol/kg, mmol/kg/min, mmol/kg/hr, mmol/kg/day, mmol/m2, mmol/m2/min, mmol/m2/hr, mmol/m2/day	0.0001 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.9	0.1
		1000 - 9999	1
Units	milliUnits, milliUnits/min, milliUnits/hr, milliUnits/day, milliUnits/kg, milliUnits/kg/min, milliUnits/kg/hr, milliUnits/kg/day, milliUnits/m2, milliUnits/m2/min, milliUnits/m2/hr, milliUnits/m2/day units, units/min, units/hr, units/day, units/kg, units/kg/min, units/kg/hr, units/kg/day, units/m2, units/m2/min, units/m2/hr, units/m2/day	0.0001 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.9	0.1
		1000 - 99999999	1
Million Units	Million Units, Million Units/kg, Million Units/kg/min, Million Units/kg/hr, Million Units/min, Million Units/hr, Million Units/m2, Million Units/m2/min, Million Units/m2/hr	0.0001 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.0	0.1
mgPE	mgPE, mgPE/kg	0.0001 - 0.9999	0.0001
		1.000 - 99.999	0.001
		100.0 - 999.9	0.1
		1000 - 9999	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 the BSA directly.

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
BSA (m2)	0.025 to 0.999	0.001
	1.00 to 7.07	0.01

Examples of Automatic Calculation

Continuous (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]
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.

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]

Intermittent (dose or volume over time duration) 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]
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]

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 mL	
	5 mL	
-2 psi (-100 mmHg) backpressure	0.1 mL	
	1 mL	
+2 psi (+100 mmHg) backpressure	0.1 mL	
	1 mL	
20% Dextrose Solution	0.1 mL	
	1 mL	
70% Dextrose Solution	0.1 mL	
	1 mL	

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 Medfusion™ 5000 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 not withstanding 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

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www.icumed.com

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