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Change History

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SECTION 1 Descriptive Information

The Plum A+ Volumetric Infusion System is designed to meet the fluid delivery requirements of today's evolving healthcare environments. The infuser is a cassette based multi-function infusion system. The Plum A+ allows two lines in and one line out. The infuser can be used for standard, piggyback, or concurrent delivery. Programming modes include:

- · Standard Infusions
- Multistep Programming
- Loading Dose
- Dose Calculation

The Plum A+ is designed to deliver parenteral, enteral, or epidural infusions over a broad range of infusion rates from multiple fluid container types.

The Plum A+ is designed to be used in most areas of patient care, including, but not limited to:

General Floor	Labor/Delivery/ Post Partum	• Burn Unit
 Medical/Surgical 	 OR/Anesthesia 	 Hemodialysis
• ICU/CCU	 Post Op/Recovery 	 Oncology
• Pediatrics	• Cardiac Cath Lab	• Mobile Intensive Care
 Neonatology 	Emergency	 Nutritional

Product Description

The system includes a pumping module (hereafter called the infuser) and an assortment of disposable IV sets (hereafter called a set), optional accessories, and this operator's manual.

The Plum A+ host device contains a Connectivity Engine peripheral module that provides wired Ethernet and wireless

802.11b local area networking capabilities. This allows the Hospira MednetTM networked application software for drug library downloads and Auto-programming to the infuser.

Indications for Use

USER QUALIFICATION

The Plum A+ is intended for use at the direction or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of the infuser and the administration of parenteral, enteral, and epidural fluids and drugs and whole blood or red blood cell components. The training should emphasize preventing related IV complications, including appropriate precautions to prevent accidental infusion of air. The epidural route can be used to provide anesthesia or analgesia.

WARNING-

ADMINISTER ONLY ANESTHETICS/ANALGESICS APPROVED FOR EPIDURAL ADMINISTRATION (AS INDICATED OR ALLOWED BY THE DRUGS' FDA APPROVED LABELING). EPIDURAL ADMINISTRATION OF DRUGS OTHER THAN THOSE INDICATED FOR EPIDURAL USE COULD RESULT IN SERIOUS INJURY TO THE PATIENT.

Conventions

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

CONVENTION	APPLICATION	EXAMPLE
Italic	Reference to a section, figure, or table Function or mode specific instructions	(See Figure 3-1, Priming Cassette) Primary Only: Attach an empty container.

CONVENTION	APPLICATION	EXAMPLE
[BRACKETED ALL CAPS]	Keys or buttons on the device are displayed in [BRACKETED ALL CAPS] or with a graphic.	[START] or START
▲ [Italic]	Softkey Options	▲ [Choose]
Initial Caps lowercase	Screen displays and device labels (as appropriate)	Program Dose Calculation
Bold	Emphasis	sets are supplied Sterile and are for

WARNINGS, CAUTIONS, AND NOTES

Alert messages used throughout this manual are described below. Pay particular attention to these messages.

WARNING-

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

CAUTION: A CAUTION USUALLY APPEARS IN FRONT OF A PROCEDURE OR STATEMENT. IT CONTAINS INFORMATION THAT COULD PREVENT IRREVERSIBLE PRODUCT DAMAGE OR HARDWARE FAILURE. FAILURE TO OBSERVE A CAUTION COULD RESULT IN SERIOUS PATIENT OR USER INJURY.

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



This symbol directs the user to consult accompanying documents.

When visible on the display, this symbol informs the user to use CAUTION because the specified drug has NOT been programmed with specified safety limits.

NOTE: Figures are rendered as graphic representations to approximate the actual product. Therefore, figures may not exactly reflect the product.

Precautions

The Plum A+ has been designed and manufactured to be safe, reliable, and easy to use. This section details precautions and possible hazards.

For safe operation of the Plum A+, observe the following precautions and hazards.

HEALTHCARE PROFESSIONALS AND PATIENT RELATED

- In vitro studies have suggested that packed red blood cells with unusually high hematocrit be diluted with bloodcompatible fluids, such as 0.9% sodium chloride injection, to decrease hemolysis and increase flow rate.
- Setting the primary rate greater than the secondary rate will result in a more rapid infusion of any residual secondary drug remaining in the line and the cassette.
- Consult drug labeling to confirm drug compatibility, concentration, delivery rates, and volumes are all suitable for secondary, concurrent and piggyback delivery modes.
- Arrange tubing, cords, and cables to minimize the risk of patient strangulation or entanglement.
- Before opening the door, close clamp on the primary line or remove the secondary container from the secondary port to prevent mixing of primary and secondary fluids.

- Although unlikely, failure of certain robust mechanical components such as the anti-free flow mechanism or valve control springs could cause fluid delivery limited to the contents of the fluid container. Single fault failure of certain electronic/motor control components would result in no more than 5 mL of unexpected fluid delivery.
- A small amount of fluid is expelled from the set (less than 0.05 ml) each time the door is opened or closed with a set installed. If potent drugs are being used, take appropriate action to guard against overmedication of the patient.
- Before disconnecting a syringe from the cassette, pull up the plunger slightly to avoid spilling the fluid. For rigid containers, close the upper slide clamp, open the cassette door, then remove and invert the cassette (ports down).
- Air bubbles may form distal to the cassette as result of normal outgassing of dissolved air in the fluid. This may occur if chilled solution is in use, if the infuser is mounted significantly above the patient, or when using certain fluids known to routinely outgas. In these cases, an air eliminating filter may be used.
- Repeated opening and closing of the door may defeat the proximal air-in-line alarm and may cause a distal air-in-line alarm, requiring repriming.
- The screen displays the VTBI (volume to be infused) in integers when value is above 99.9. Any fraction of a milliliter delivered is not displayed, but is retained in memory.

CONCURRENT FLOW GUIDELINES

When delivering short half-life critical drugs (see Critical Drugs, this section) using the Plum A+ in the Concurrent mode, the following delivery rate guidelines should be observed:

• If the critical drug (with half-life less than 6 minutes) is to be infused at less than 2.0 mL/hr, the other infusion should be no faster than 5 times the critical drug's rate. Dopamine, for example, delivered at 1.5 mL/hr should not be accompanied by an infusion programmed any faster than 7.5 mL/hr.

- If the critical drug (with half-life less than 6 minutes) is to be infused at 2.0 to 5.0 mL/hr the other infusion should be no faster than ten times the critical drug's rate. Dopamine, for example, delivered at 3.5 ml/hr should not be accompanied by an infusion programmed any faster than 35 mL/hr.
- If the critical drug (with half-life less than 6 minutes) is to be infused at 5.1 mL/hr or greater, the other infusion can be programmed at any desired rate.

NOTE: The total of the primary rate plus the secondary rate cannot exceed 500 mL/hr.

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

DELIVERY RATE GUIDELINES		
SHORT HALF-LIFE (LESS THAN 6 MINUTES) CRITICAL DRUG INFUSION RATE	MAXIMUM RATE OF ACCOMPANYING INFUSION	
0.5 - 1.9 mL/hr	5 Times the Critical Drug Rate	
2.0 - 5.0 mL/hr	10 Times the Critical Drug Rate	
5.1 or Greater	Any Desired Ratio	

CRITICAL DRUGS

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

Dobutamine Lidocaine

Dopamine Nitroglycerin

Epinephrine Nitroprusside

Epoprostenol Norepinephrine

Esmolol Oxytocin

Isoproterenol Procainamide

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

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

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

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

EPIDURAL ADMINISTRATION

- Recommended use of the epidural route is to provide anesthesia or analgesia for periods up to 96 hours.
- This device can be used to administer only those anesthetics/ analgesics approved for epidural administration (as indicated or allowed by the drugs' FDA approved labeling). Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- For epidural administration, the use of Hospira catheters, Plum sets without Y-sites, and "epidural" stickers indicating ongoing epidural administration are recommended.

- Administration of drugs via the epidural route should be limited to personnel familiar with associated techniques and patient management problems. Proper epidural placement of the catheter is essential since catheter migration could result in intravascular or intrathecal administration. Facilities practicing epidural administration must be equipped with resuscitative equipment, oxygen, naloxone, and other resuscitative drugs. Adequate monitoring equipment (e.g., Oximetry) is recommended for continuous monitoring of the patient during epidural administration. Patients must be observed frequently for side effects in a fully-equipped and staffed environment for at least 24 hours following completion of drug administration by the epidural route. DELAYED RESPIRATORY DEPRESSION FOLLOWING CONTINUOUS EPIDURAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE HAS BEEN REPORTED.
- The epidural space has 58 openings through which fluid can exit. Pressure buildup during administration is transient. However, if a large volume of fluid is administered over a short time period, the pressure will take longer to return to normal. If overdelivery occurs during administration, observe the patient closely for signs of spinal cord compression (disorientation, headache, transient neuralgias) and drug overdose.

BATTERY OPERATION

- When the battery is removed from the Plum A+, do not operate on patients. Use of a properly maintained and charged battery helps confirm proper operation.
- The battery may not be fully charged upon receipt. Connect the infuser to AC power for at least six hours.
- Use AC power whenever possible. Connect to AC power during storage to ensure a fully charged battery for emergencies. If the quality of the earth grounding source is in doubt, use battery power.
- If the low-battery alarm sounds, connect the infuser to AC power immediately.

SETS AND ACCESSORIES

- Only compatible LifeCare PlumSets can be used with the Plum A+. See individual set instructions for additional information.
- Administration sets should be changed per CDC guidelines or healthcare provider policy. Discard after use.
- LifeCare IV infusion sets with integral nonblood filters are not for use in the administration of blood, blood products, emulsions, suspensions, or any medications not totally soluble in the solution being administered. These medications may be administered through the lower Yinjection site, below the filter.
- When infusing at low delivery rates (5.0 mL/hr or less) the use of thick-walled microbore PlumSets is recommended. This will reduce the amount of the fluid bolus that may be delivered when a distal line occlusion is released.
- Syringes must be larger than 3 cc. Use syringe adapter (List 11986-48) when using syringes smaller than 10cc. Some 10cc syringes may require use of a syringe adapter. Syringes larger than 10cc may be attached directly to the secondary port of the cassette. Use of a syringe adapter may decrease the occurrence of proximal occlusion alarms.
- Use a 19-gauge or larger needle or catheter at the venipuncture site for viscous fluids if operating at rates greater than 500 ml/hr.

See Section 10 for information on sets and accessories.

BACKPRIMING

- Backpriming is not recommended for reconstituting secondary containers containing dry powders.
- To avoid pressurization when backpriming into a syringe, the user must confirm there is sufficient empty space to accept the backprimed fluid.

GENERAL

 Possible explosion hazard exists if used in the presence of flammable anesthetics.

- Do not place Plum A+ in service if it fails the self-test.
- Do not operate the Plum A+ with the case opened.
- Keep the cassette door securely closed while the infuser is not in use, to avoid cassette door damage.
- Values beyond a fields maximum hard limit will be diplayed as dashes (-- -- --). The user must clear these fields using the [CLEAR] key prior to entering new values.

CLEANING

For more information on cleaning the infuser, see Section 8.

- To avoid mechanical or electronic damage, do not immerse the Plum A+ in any fluids or cleaning solutions.
- Do not spray cleaning solutions toward any opening in the instrument.
- Certain cleaning and sanitizing solutions may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Hospira 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 infuser.
- Do not sterilize by heat, steam, ethylene oxide (ETO), or radiation.
- To avoid infuser damage, cleaning solutions should only be used as directed. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

BOLUS RELATED

Use the following procedure to avoid the administration of a bolus following a distal occlusion (i.e., a closed distal clamp):

- If a secondary container is in use, clamp proximal tubing before opening cassette door.
- Open cassette door and remove the cassette.

- Open the flow regulator briefly to dissipate the pressure and then close it.
- Eliminate the source of occlusion (closed clamp).
- · Reinsert the cassette and close the cassette door.
- · Open all clamps and resume infusion.

NOTE: When troubleshooting an occlusion where all clamps are in the OPEN position, use care to avoid delivery of a bolus by opening the flow regulator to release any built-up pressure. Close the clamp between the cassette and the patient before opening the flow regulator to relieve the pressure. See Section 7, Alarms and Troubleshooting, for more information.

ARTIFACTS

- Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infusion device instead of some other source in the environment, set the infusion device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by the electronic noise generated by the infusion device. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring equipment system documentation for setup and maintenance instructions.
- The Plum A+ system is designed to operate normally in the presence of most encountered electromagnetic interference (EMI) conditions. In the event of extreme levels of interference, such as encountered next to an electrosurgical generator, it is possible that the normal operation of a sensor

- or microcomputer might be disrupted. Even in this event, the outcome would likely be a false alarm or detected system malfunction and would not result in a hazard to patient or operator.
- This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and IEC/EN 60601-1-2:2001). These 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 (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 device
 - Increase the separation between the equipment
 - Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected
 - Consult the manufacturer or field service technician for help
- Portable and mobile RF communications equipment, such as cellular telephones, 2-way radios, Bluetooth devices, microwave ovens, in close proximity to this device may affect wireless and wired communications with the Infusion pump and/or the operation of the Infusion pump. Special precautions need to be exercised regarding EMC, These include:
 - Use of a shielded Ethernet cable (CAT5 STP or better) for plugging into the RJ45 Ethernet connector. Using an unshielded Ethernet cable may result in increased emissions.

- Maintaining a minimum separation distance of 2 ½ ft between the Infusion pump system and portable/ mobile RF communications equipment
- List Numbers 12391 and 11971 are compliant to IEC/EN 60601-1-2 (1993)

List Number 20679 is compliant to IEC/EN 60601-1-2 (2001) and have been tested and found to comply with EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2:2001).

Guidance on EMC Compatibility

- 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 precautions regarding electromagnetic compatibility and needs to be installed and used according to the electromagnetic compatibility information provided in this manual.
- The device is suitable for use in all establishments, including domestic establishments. If extended operation during power mains interruption is needed, use battery power.
- · Always manage the electromagnetic environment.
- The guidance included in this manual provides information needed to:
 - Determine the device's suitability for use in the intended environment.
 - Manage the electromagnetic environment to permit the device to perform as intended without disturbing other equipment.
- Separate the device from all other electronic equipment. If the device must be used near other electrical equipment, monitor the equipment to ensure there is no electromagnetic interference.
- Devices should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked

- with other equipment, monitor the devices to verify normal operation.
- USE ONLY components specifically labeled for use with the Plum A+ Infusion System to help ensure the device operates as intended.
- If you suspect external RF sources or other equipment are influencing device operation, contact the biomedical engineering department for additional guidelines concerning electromagnetic immunity.
- Contact the biomedical engineering department for additional information in the technical service manual concerning operating devices near RF sources.

FCC Information



U.S. Pat. No. 5,681,285 IC: 5627A-20677

US FCC (FEDERAL COMMUNICATIONS COMMISSION) STATEMENT

This device complies with part 15 of the FCC Rules.
 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 this device.

FCC Interference Statement

• 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. If not installed and used in accordance with the instructions, it 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

FCC ID: STJ-20677

to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which thereceiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by Hospira could void the user's authority to operate the equipment.

RADIO FREQUENCY EXPOSURE STATEMENT

- The Wireless LAN radio device in the Connectivity Engine peripheral board with this infusion device has been evaluated and found compliant to the requirements of the following Radio Frequency exposure standards:
 - Federal Communications Commission, OET Bulletin 65 (Edition 97-01), Supplement C (Edition 01-01), Evaluating Compliance with FCC Guidelines for Human Exposure to Radio frequency Electromagnetic Fields, July 2001.
 - Industry Canada, Evaluation Procedure for Mobile and Portable Radio Transmitters with respect to Health Canada's Safety Code 6 for Exposure of Humans to Radio Frequency Fields, Radio Standards Specification RSS-102 Issue 1 (Provisional): September 1999.
 - Federal Communications Commission, OET Bulletin 65 (Edition 97-01), Supplement C (Edition 01-01), Evaluating Compliance with FCC Guidelines for Human Exposure to Radio frequency Electromagnetic Fields, July 2001.
- The radiated output power of this Wireless LAN device is far below the FCC radio frequency exposure limits. The Wireless

LAN device has been evaluated with zero inches separation of human body from the antenna and found to be compliant with FCC RF exposure limits.

Section 2 Principles of Operation

Features

The Plum A+ is a dual-line volumetric infusion system designed to meet the growing demand for hospital-wide, as well as alternate site and home healthcare, standardization. With its primary line, secondary line, and piggyback fluid delivery capability, the Plum A+ is suited for a wide range of medical/surgical and critical care applications. Full compatibility with LifeCare Plum Series administration sets and accessories and the LifeShield® and CLAVE® needleless protection systems, makes the Plum A+ a convenient and cost-effective infusion system.

PROGRAMS

- · Standard Programming
- Loading Dose
- Multistep Programming

LINE PROGRAMMING OPTIONS

- Drug List
- Nurse Call Back
- Delayed Start/Standby Setting
- Concurrent delivery
- Titration
- Micro 0.1-99.9 mL/hr (in 0.1 mL increments) flow rate range for both lines
- Macro 100-999 mL/hr (in 1 mL increments) flow rate range for both lines
- Automated Secondary drug delivery (Piggyback)

PLUMSET CAPABILITIES

- Anti Free-Flow Protection
- · Direct Connection for syringe delivery

AIR MANAGEMENT

- Air Trap
- Air Removal/Backpriming
- · Air Detection-Proximal
- · Air Detection-Distal

BATTERY

- Battery Gauge
- · Less than 8-Hour Battery Recharge Time
- Long battery life (3 hours) for emergency backup and temporary portable operation

BIOMEDICAL

- Upgradability (Field)
- Variable Rate Cap
- Alarm History
- Nurse Call Relay Connector

OPTIONS

- Volumes Infused (A, B, Total Volume)
- KVO at dose end (1 ml/hr or less depending on delivery rate) or Continue Rate (CR) to continue at the current rate
- Variable Distal Pressure Settings

OTHER FEATURES

- Nonpulsatile volumetric accuracy
- Microprocessor control
- Large liquid crystal display (LCD) screen

- · Panel back illumination on mains power
- Lockout switch
- Standard syringe use
- · Parenteral and nonparenteral (enteral) fluid delivery
- · Blood and blood products delivery
- Wide range of Standard and Specialty administration sets
- · Password protected keypad lock

COMMUNICATION

- Networked Communication (Ethernet & Wireless)
- Autoprogramming
- Drug Library Download

Definitions

TERM	DEFINITION
Administration Set	The sterile, disposable assembly with flexible tubing that connects to a source fluid container for input to the Cassette pumping chamber and to some output device for administration to the patient.
Alarm	A condition requiring operator intervention that invokes both audible and visible alarm indicators. Confirmation of the condition usually is required.
Alert	While entering a program, a visual warning that informs the clinician of the violation of a hospital-defined rule set, e.g., a dose limit for a specific drug.
Alternate Units	Dose Rate units that may be selected. Alternate Units are any units other than mL/hr.
Alternate Units Parameters	Drug Amount, Diluent, Patient Weight (if applicable), and Dose Rate.

TERM	DEFINITION
Auto-Program	A physician order sent to the infuser.
Auto-Program (new)	An auto-program is considered "new" if either of the following conditions are met: A) There is no program on the associated line. B) The drug and concentration in the auto-program is different from a currently-programmed drug and concentration.
Auto-Program (titration)	An auto-program is considered a "titration" if the drug and concentration in the auto-program match the currently-programmed drug and concentration. Non-promotion titration programs include some subset of the following: Rate, Dose, Duration. Promotion titration programs include some subset of the following: Rate, Dose, Duration, Patient Weight, Dosing Units, Drug Amount, Drug Units, Diluent Amount.
Awake CE	The CE is considered awake when the infuser is powered on with battery power and the battery is above the low battery threshold or is plugged into AC.
Backpressure	Resistance to fluid flow on the Distal or output portion of the Administration Set, usually expressed as PSIG.
Backprime	Removal of air or fluid from the proximal tubing and Cassette air trap by rapid pumping of fluid from Line A to an output receptacle on Line B. No fluid delivered distal to the cassette during a Backprime.
Basic Delivery	A single-step delivery specifying rate, VTBI, and duration only. Drug name may or may not be specified.
Biomed Mode	The name for the non-delivery or service mode of Infuser operation.

TERM	DEFINITION
Bolus	A single uninterrupted discrete volume of fluid delivered over a discrete period of time.
Cassette	A Hospira standard Plum Macro Cassette that contains the actual pumping chamber with inlet and outlet valves. It also contains access ports to diaphragms for proximal and distal line pressure sensing and chambers for air trapping and air quantity measurement.
Caution	Contains information which could prevent hardware failure, irreversible damage to equipment, or loss of data.
Channel	Distal Line output to the patient.
Cleared Program	Same as Cleared Settings, but restricted to the program delivery settings for an individual line.
Cleared Settings	Programmed delivery settings for both lines and the general control parameters are at their default values.
Clinical Care Area (CCA)	An area of the hospital for which authorized hospital staff has allowed use of up to 149 specific drugs, plus No Drug Selected. The clinician selects a CCA after turning on the Infuser. The hospital may create from one to eighteen CCA's.
Concentration	For Dose Calculation based Line A or B delivery programming of premixed drugs, the concentration consists of Drug Amount (in micrograms [mcg], milligrams [mg], grams, milliequivalents [mEq], millimols [mmols], or units [USP Units]) and Diluent (Volume in milliliters [mL]). Abbreviated on screen displays as "Conc".

TERM	DEFINITION
Concurrent Delivery	Simultaneous delivery of two fluids at independent flow rates.
Concurrent Mode	The Line B control selection mode that allows either Line A or Line B (or both) of the Mechanism to be programmed for delivery that completes with KVO or CR. Line A operation is unaffected by Line B delivery.
Connectivity Engine (CE)	A component of the infuser that controls ethernet and wireless communication between the MMU and Infuser processor.
Continue Rate (CR)	An option used to provide fluid delivery at the current fluid delivery rate when the VTBI becomes zero.
Default Drug Library (DDL)	A drug list of 99 drug names, default units and default concentrations, plus 'No Drug Selected'. Does not contain Soft or Hard Limits. The DDL is a subset of Plum A+ Version 11.3 drug list. The Infuser functions initially with the DDL.
Deliver Together	A Biomed Delivery option setting, which selects default of Piggyback or Concurrent delivery mode.
Delivery Mode	The normal operational mode for the Infuser, either Concurrent or Piggyback, during which fluid delivery may occur.
Delivery Rate	The delivery rate (as Volume/Time) assigned by the operator or calculated from other delivery parameters.
Device	The Plum A+ IV Infusion Device (Infuser), not including the disposable administration sets.
Diluent (Volume)	The volume of fluid used with the Diluent Unit (e.g., 250 mL), which dilutes the drug to be infused.

TERM	DEFINITION
Distal	Downstream (output) from the Cassette portion of the Administration Set.
Door	The lever-operated, bottom-hinged, Cassette holder on the front of the Mechanism.
Dose (Rate)	Delivery rate times drug concentration.
Dose Calculation	Allows programming Dose Rates in alternative units of measure. Dose Calculation can be used in Simple Delivery, Loading Dose, and Multistep.
Drug Amount	The mass or quantity of the drug premixed with a Diluent to express the Concentration for the Line being programmed.
Drug Library	Drug names available for use with the Infuser in the selected CCA, and each drug's concentration, units of measure, and dose limits, as determined by authorized hospital staff. The Drug Library is based on hospital-defined best practices. The Drug Library is customized and downloaded into the Infuser by authorized hospital personnel using Hospira MedNet Networked software.
Duration	The time period used to deliver a VTBI at an existing Delivery Rate or as set by the operator.
Enteral	Delivery via an intestinal route.
Error	A condition resulting in an audible warning and often an accompanying message, such as an invalid key press, resulting from an operator attempt to make an input that is not valid for the current operational context. Not a Malfunction.

TERM	DEFINITION
Filling Head Height (FHH)	The gravity induced Proximal Line pressure due to fluid height in source container above the Distal Line output level.
Flow Rate	The resulting rate of fluid flow. (See Rate and Dose.)
Fluid Delivery Begin	The time required, measured from the initial start of a keypad press, for a digit in the third decimal place of a scale measuring grams to change when pumping water, the delivery tube is fluid filled, and the end of the delivery tube is immersed.
Hard Limit	The dosing amount (upper and/or lower amount) that when assigned to a drug cannot be overridden. Defined by the hospital for each drug in its Drug Library. The hard limits for a particular drug may vary across different CCAs.
Infuser	A Plum A+ device, not including the disposable administration set.
Initialized Position	The plunger is in the Plunger Park Position, and each valve is in the Valve Home Position.
Key	Any of the marked locations on the front panels intended for user input via a pressing action.
KVO	(Keep Vein Open) Internally selected minimal delivery rate, the lesser of 1.0 mL/Hr or actual Rate, intended to provide sufficient fluid flow to decrease the potential for clotting at the IV infusion site.
Line A	Inlet tubing on the top center of Cassette when viewed after it has been loaded in Mechanism Door.

TERM	DEFINITION
Line B	Inlet connector on the top right of Cassette when viewed after it has been loaded in Mechanism Door.
Loading Dose	Allows programming of an initial infusion rate for a specific volume, followed automatically by a maintenance rate from the same container (e.g., a fluid challenge). If Dose Calc is used, the Loading Dose and Maintenance Dose are in the same unit of measure, over the same period of time (mcg/min), from the same container.
Macro Cassette	The Plum Cassette as part of an Administration Set whose attainable delivery performance is for general purpose uses.
Malfunction	One of a number of conditions that indicate a failure of the Infuser. These conditions usually require a repair action.
Mechanism	The provider of the physical activities of: 1) valve control for Line selection and inlet to or outlet from the Cassette; 2) Plunger extension and retraction for changing fluid volume of the Cassette pumping chamber.
MedNet software	Networked application software used to define and download the custom drug library to the Infuser.

TERM	DEFINITION
Multistep	Allows a sequential program to deliver up to 10 steps; fluid volumes and delivery rates may be programmed for each step. The program may be entered based on Rate and Volume or Volume and Time. If Dose Calc is used, the delivery steps are in the same unit of measure, over the same period of time, from the same container.
MMS	Medication Management Suite- a product suite that will be used to support safe and efficient caregiver administration of intravenous medications.
ММИ	Medication Management Unit- the MMU is a product of the MMS and provides external communications with infusers and other systems supporting medication management. It supports drug library downloads and status/log updates to the infusers. MMU also delivers a variety of pre-built and custom reports related to the infuser activities.
Network-Enabled Module	The hardware that facilitates communication between the infuser and the network.
Note	A Note explains something new, gives tips on performing an activity, or provides a reminder of necessary preparations.
Override	The clinician acknowledges an Alert, confirms and proceeds with a program containing a parameter that falls outside the hospital-defined Soft Limits.
Parenteral	Delivery via other than an intestinal route, such as intravenous (IV) injection.

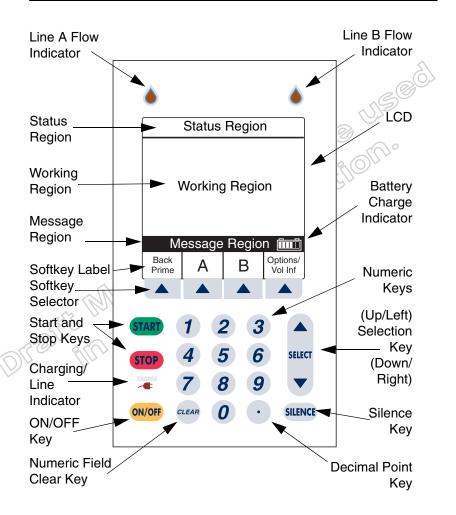
TERM	DEFINITION
Patient Weight	The Alternate Units Parameter whose value entry is required with Dose rates (quantity/time) having the third parameter of weight, such as mcg/kg/min.
Piggyback Delivery	Infusion will stop Line A and infuse Line B until VTBI completes.
Piggyback Mode	The Line B control selection mode that requires Line A delivery suspension while Line B delivers and then its resumption when Line B VTBI completes. If Line A is not programmed and started, Line B delivery just stops when its VTBI completes. Line A operation is delayed for duration of its interruption by Line B.
Plunger Park Position	The position of the pumping plunger that allows the cassette to be withdrawn from the Infuser without restriction, with an opened Door.
POST	Power On Self Tests. Startup initialization and test of critical hardware modules and software functions, to determine Infuser readiness for its Intended Use.
Power On	When the power is first applied to the Infuser processor. It occurs when Infuser is in the off condition and the AC power is applied or during battery operation when the ON/OFF key is pressed.
Pressure	The measured fluid pressure for Proximal Line A, Proximal Line B, or the Distal line when a fully primed administration set is loaded into a Mechanism with the Cassette Door closed.

TERM	DEFINITION
Programs	A Concentration-based extension to basic Volume/Rate delivery for Dose Rate applications. Softkey-selected types are: 1) Standard Program for single rate delivery; 2) Loading Dose for up to two steps of delivery at differing rates; 3) Multistep for up to ten steps of delivery at differing rates. Loading Dose and Multistep include the basic Delivery Rate option.
Protocol	In the medical field, hospital-approved procedures. For devices with an electronic communications interface, the format and content of messages being exchanged.
Proximal	Upstream (input, as Line A and/or B) with respect to the Cassette portion of the Administration Set.
Rate	See Delivery Rate
Rounding	To round-off to the closest whole number (e.g., 25.5 would round to 26, but 25.4 would round to 25).
Rule Sets	The compilation of Soft and Hard Limits associated with a drug entry.
Screen	That active portion of the LCD assigned to a delivery or other user interactive display operation.
Softkey	A front panel key whose function label is on the bottom portion of the display screen just above its location, so that label may be changed to indicate differing key functions within the operational context of the defined screens.

TERM	DEFINITION
Soft Limit	The dosing amount (upper and/or lower amount) that when assigned to a drug can be overridden based on confirmation. Defined by the hospital for each drug in its Drug Library. The soft limits for a particular drug entry may vary across CCAs.
Standard Programming	(see Basic Delivery)
Standby	A delivery program state that resembles a delayed start for a line in all respects, but status display of STANDBY instead of DELAYED. A press of the START key (and a Start Softkey if necessary) will begin the programmed delivery.
System	The Plum A+ Infuser system with its associated accessories and Administration Sets.
Tall-Man Lettering	Tall-Man lettering uses upper-case letters in combination with lower-case letters to help clinicians differentiate among sound-alike or look-alike drug names. Certain Hospira Default Library drug names are displayed in Tall-Man lettering.
Truncate	To round-down to the last whole number (e.g., 103.7 would be 103).
Units	A Drug Amount (without a quantity of mass referent) adopted as the United States Pharmacopoeia (USP) standard of measure for use in a Concentration.
VI	Volume Infused.
VTBI	Volume To Be Infused – The volume of fluid or IV solution (remaining) for delivery by a program or Therapy step from a Line.

TERM	DEFINITION
Warning	Audible indication at the defined Warning sound level, often accompanied by a brief message, to advise operator that: 1. Input was attempt to use a function in wrong sequence, with wrong values, or at wrong time (resulting in an Invalid Key Warning); 2. Input was properly related to a function (resulting in a Valid Key Warning). (The Low Battery Warning is an exception, using the Alarm Indication sound level.)
Weight	The Alternate Units Parameter whose value entry is required with Alternate Units for Dose that include /kg/.

Equipment Description



Front Panel Display and Keypad

Operating Keys

The [ON/OFF] key is used to control the power of the Plum A+.

NOTE: All deliveries must be stopped in order to turn the power off.

NOTE: To confirm proper shutdown of infuser, do not unplug until "double beep" is heard (approximately 5 seconds). If "double beep" is not heard, the infuser will turn itself back ON sensing the AC power was lost and revert to battery back-up power.

The [START] key is used to begin infusion. It brings up the Confirmation screen. If all informtion appears correct, select

[Yes] to start program.



ON/OFF

ET FEO DO TUIS COLL SERVING FER POINTS

The [STOP] key is used to stop the current delivery on one line; used in conjunction with soft keys to stop delivery on both lines.



The [SILENCE] key is used to silence an audible alarm during actions to correct its cause.



The [SELECT] key (or steet) is used to move the highlighting cursor between the programming fields.



SELECT



The numeric keys are used to enter values for any highlighted field requiring numeric data.

The [CLEAR] key will cause a highlighted numeric field to be cleared in preparation for data entry. It is also used to clear the displayed dashes (-- -- --) that occur when entering values

1

2

3

4

5

6

7

8

9

CLEAR

0

•

The [DECIMAL POINT] key is used to manually enter numbers other than whole numbers (i.e., 1.2 mL).

beyond the pre-programmed hard limits. It WILL NOT clear the entire

program.

Softkeys are located at the bottom of the main display and serve a variety of functions. What each key does is indicated by the text in the display above the actual softkey.



Indicators

The Charge/Line Indicator is illuminated to indicate the battery is currently charging.

NOTE: If the device is plugged into AC power, with a battery installed, and the Charge Indicator is not illuminated, contact technical support.

The fluid drop symbol, when flashing, indicates an active infusion on Line A and/or Line B.





Display Symbols

Battery Capacity Symbol (located on right side of message region on display) indicates relative charge with number of white boxes from left to right.

Cautionary Symbol is displayed to alert the user that the infuser is being operated without rule sets (soft or hard limits). Read the drug package insert for information on proper usage.



Soft Limit Override Symbol indicates the programmed soft limits upper (up arrow) or lower (down arrow) have been overridden.

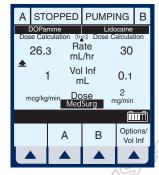


NOTE: The infuser will display the rule set icon from the first step in a situation where a 2-step process is completed and the infuser is stopped after going to KVO.

The "Wireless Connection Available" icon is displayed when the device is receiving a wireless signal. The infuser will connect to the network if a wireless network access point is recognized.



It may appear on any Main Delivery Screen whether pumping or stopped. It also may appear regardless of Auto-Programming. However, in a wireless network environment, Auto-Programming will not be successful if the icon is not visible during the Auto-Program transfer. If wireless Auto-Programming is desired and the icon is not displayed on the Main Delivery Screen, try relocating the pump



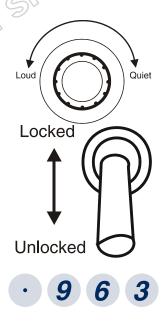
towards the wireless access point until the icon is displayed. The icon will not be displayed if the infuser is communicating via an ethernet connection.

Rear Case Controls

The audio level rotary knob, located on the back, adjusts the alarm audio level.

The toggle switch, located below the audio level control, activates the lockout function when the lever is placed in the "up" position, disabling all front panel keys except [STOP].

Password Protected Keypad Lock may also be used. It both locks and unlocks the keypad by pressing the decimal key, followed by 9, 6, & 3.

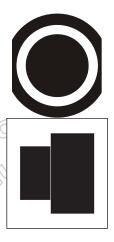


NOTE: Pressing of a key while lockout is active results in the display of the lockout enabled message. This action is recommended to confirm each lockout activation.

NOTE: If the lockout switch is put in the "Locked" position while the infuser is off, the [ON/OFF] key allows the unit to turn on.

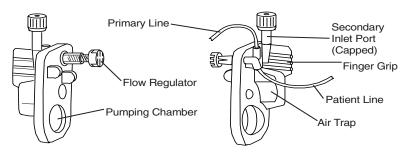
The connector located below the lockout switch is the Nurse Call Relay Connector, for providing remote notification of a nurse call event.

The Ethernet port is used to connect to a local area connection.



Administration Sets

The Plum A+ is compatible with a wide range of LifeCare Plum series administration sets. Become familiar with the set components before preparing the administration set.



Preparing the Administration Set

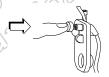
NOTE: For detailed instructions, see administration set packaging.

WARNING-

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

Use the aseptic technique to prepare the administration set for priming, then proceed as follows:

1 Make sure flow regulator is closed.



2 Insert piercing pin into container outlet with a twisting motion.



3 Fill Drip chamber to about 1/2 full or to the score mark. Do not completely fill.

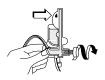


NOTE: To avoid getting Distal Air Alarms, confirm the fluid bag is positioned higher than the infuser. This should be set up prior to priming the cassette.

Priming the Administration Set



1Invert the cassette.

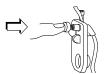


2Turn the flow regulator counter-clockwise until a drop of fluid is seen in the pumping chamber.

3 Turn the cassette upright, then prime the remainder of the administration set.



4 Push in the flow regulator to close. Confirm there is no flow.



Loading the cassette

To load the primed cassette into the plum A+, proceed as follows.

1 Open the cassette door by lifting up the handle.





2Insert cassette into door guides. Close the cassette door. Confirm there is no flow and no kinks appear in tubing.

NOTE: If flow is observed, close the tubing clamps and replace the administration set.

NOTE: The administration set should be changed per CDC guidelines or healthcare provider policy. Discard after use.

Preparing the Secondary Line

CAUTION: CONSULT THE DRUG LABELING TO CONFIRM DRUG COMPATIBILITY, CONCENTRATION, DELIVERY RATES, AND VOLUMES ARE ALL SUITABLE FOR CONCURRENT DELIVERY OR PIGGYBACK DELIVERY (SECONDARY FOLLOWED AUTOMATICALLY BY PRIMARY) MODES.

The Plum A+ features concurrent or piggyback delivery modes when program requires administering more than one fluid.

In addition to standard containers, the Plum A+ can use syringes on the secondary port. The secondary line can be prepared without removing or repriming the cassette.

Before preparing the secondary line, observe the following quidelines:

- · Review the backpriming function.
- Attach the secondary container using an 18- or 19gauge, 31 mm (or shorter) needle, if the cassette secondary inlet port has a piercing reseal.
- Syringes must be larger than 3 cc. Use syringe adapter (List 11986-48) when using syringes smaller than 10cc. Some 10cc syringes may require use of a syringe adapter. Syringes larger than 10cc may be attached directly to the secondary port of the

- cassette. Use of a syringe adapter may decrease the occurrence of proximal occlusion alarms.
- When using a syringe adapter, retract the plunger to draw approximately 1 mL of fluid into the syringe to clear air from the adapter filter.

To prepare the secondary line, use aseptic technique and proceed as follows:

 With cassette door closed: Loosen and remove white cap, then discard. Add secondary tubing or syringe.



- Open all proximal clamps before pressing [START].
- 3 Set up per operating instructions. (See Sections 4 - 6 of this manual.)



4 Syringe: Secure the container to the cassette door using the optional container support arm (List 12095-03).

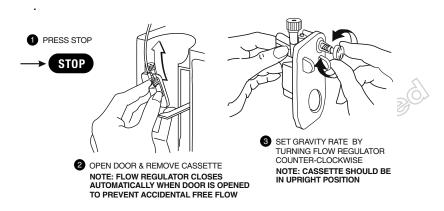


Discontinuing Electronic Flow Control & Setting Gravity Flow

CAUTION: BEFORE OPENING DOOR, CLOSE CLAMP ON PRIMARY OR SECONDARY SET OR REMOVE SECONDARY CONTAINER FROM SECONDARY PORT TO PREVENT MIXING OF PRIMARY AND SECONDARY FLUIDS.

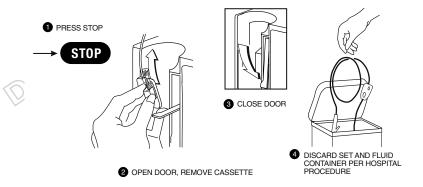
If electronic flow needs to be stopped, the precision flow regulator on the cassette can be used to manually set and

maintain fluid flow in a gravity mode (see the following graphics).



NOTE: IF DOOR OPEN ALARM OCCURS, TURN PUMP OFF

Discontinuing Fluid Administration



Basic Operation

Getting Started

UNPACKING

CAUTION: PRODUCT DAMAGE MAY OCCUR UNLESS PROPER CARE IS EXERCISED DURING UNPACKING AND INSTALLATION. DO NOT USE THE PLUM A+ IF IT APPEARS DAMAGED IN ANY WAY. THE BATTERY MAY NOT BE CHARGED UPON RECEIPT.

Inspect the Plum A+ packaging for possible shipping damage. If damage is found, contact the delivery company immediately.

Use care when unpacking the infuser. Retain the packing slip and save all packing material in case the infuser is damaged or fails the infuser self-test and has to be returned to Hospira.

Inspect thoroughly for damage.

CAUTION: IF THE PLUM A+ APPEARS TO BE DAMAGED, CONTACT HOSPIRA, INC.

To set up, connect the AC (mains) cord to a properly grounded receptacle, unless temporary battery operation is desired.

NOTE: Use AC (mains) power whenever possible. Store the infuser connected to AC (mains) to confirm a fully charged battery for emergencies.

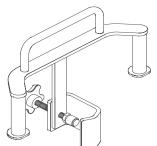
NOTE: If the quality of the earth grounding source is in doubt, use battery power.

CAUTION: THE PLUM A+ SYSTEM IS DESIGNED TO OPERATE NORMALLY IN THE PRESENCE OF MOST ENCOUNTERED ELECTROMAGNETIC INTERFERENCE (EMI) CONDITIONS. IN THE EVENT OF EXTREME LEVELS OF INTERFERENCE, SUCH AS ENCOUNTERED NEXT TO AN ELECTROSURGICAL GENERATOR, CELLULAR TELEPHONES, OR 2-WAY RADIOS, IT IS POSSIBLE THAT THE NORMAL OPERATION OF A SENSOR OR MICROCOMPUTER MIGHT

BE DISRUPTED. OPERATION OF THE INFUSER UNDER THESE CONDITIONS SHOULD BE AVOIDED.

TANDEM CARRIER INSTRUCTIONS

The Plum A+ may be safely and conveniently mounted on an IV stand or on a tandem carrier mounted on an IV stand.



Always mount the tandem carrier (List# 12270-01) to the pole before attaching the infuser(s) to the tandem carrier.

Make sure tandem carrier clamp is attached firmly to pole.

Make sure infusers are firmly attached to tandem carrier.

This section details the Plum A+

instrument setup procedures.

SYSTEM SELF-TESTS

The infuser performs a suite of System Self-Tests when power is applied to confirm readiness for use.

Failure during the Self-Tests is reported as a Malfunction Condition.

CAUTION: DO NOT PLACE THE PLUM A+ IN SERVICE IF IT FAILS THE SYSTEM SELF-TESTS.

Connect the AC power (mains) cord to an AC power receptacle, then confirm that the Charging/Line indicator illuminates (above the [ON/OFF] key on the front panel).

A systematic self-testing of the processing, delivery, and safety systems is performed whenever the Plum A+ is turned on, to verify readiness for operation.

NOTE: If the quality of the earth grounding source is in doubt, use battery power.

Press the [ON/OFF] key to turn the power on. Check screen display and listen for a beep to indicate the audio is working. Wait for the self-tests to complete. If successful, put a fully primed macro cassette into the cassette door and close the door. See *Loading Cassette* in *Section 3* for details of correct procedure.

When the Charging/Line indicator is off and the battery symbol on the display is flashing, this indicates that the Plum A+ is operating on low battery power and should be recharged.

CAUTION: WHEN THE BATTERY IS REMOVED FROM THE PLUM A+, DO NOT OPERATE ON PATIENTS. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS CONFIRM PROPER OPERATION.

To confirm battery is fully charged, connect the Plum A+ to AC (mains) power for a minimum of six hours while in the OFF mode.

If an alarm occurs during the power on self-test, identify the alarm message, then take corrective action (see *Section 7*, *Alarms and Troubleshooting*).

Turn infuser OFF, then back ON. If the self-test alarm recurs, remove the infuser from service and contact the local Hospira representative.

The infuser performs a suite of System Self-Tests when power is applied to confirm readiness for use.

Failure during the Self-Tests is reported as a Malfunction Condition.

DATA RETENTION

Delivery program settings and programming option selections are retained in non-volatile memory. If the Plum A+ has been turned off for longer than four hours, all delivery settings are cleared and programming option selections are restored to their default selections for next use.

Power On

1 Press ON/OFF to Power On the Plum A+ and the System Self-Tests Screen is displayed.

After self-testing successfully completes, the display will proceed to the next screen.

Programming the infuser may begin during the cassette check phase of the start-up testing.



NOTE: If battery is missing or defective, a "Battery not installed" message with a "Continue without battery" prompt will appear (AC power only).

CAUTION: When the BATTERY IS REMOVED FROM THE PLUM A+, DO NOT OPERATE ON PATIENTS. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS CONFIRM PROPER OPERATION.

To set up the Plum A+, insert selected Plum Set and close cassette holder door lever.

NOTE: If cassette is already inserted, this screen is skipped. If Infuser ID Entry screen appears, consult your hospital's biomed personnel.



The Area Selection screen will appear if your system has been programmed with the Hospira

MedNet accessory. Use to choose. If only one CCA has been entered, it becomes the default and this screen is skipped.



NOTE: To change the CCA while infusing, see Section 6.8, Changing CCA While Infusing.

If not using MedNet, the display will go straight to the "Clear Settings?" option.

Example of Clear Settings Screen

The on-screen message "Clear Settings?" may appear. Select ▲ [Yes] to clear all settings.

Clear ALL settings when changing patients or multiple programming parameters.



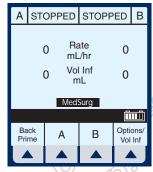
NOTE: This clears all delivery parameters, such as Rate and VTBI on both lines, as well as setting items, such as the KVO and Nurse Callback options, to their default values.

NOTE: If no settings currently exist or all settings are zero, this screen will be bypassed.

Simple Delivery

Example of MedNet Main Delivery Screen (with cleared settings). The selected area is displayed at the bottom.

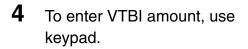
**SCREENS SHOWN IN THIS MANUAL
ARE EXAMPLES ONLY AND DON'T
NECESSARILY REFLECT CURRENT
ACTUAL PRACTICE**



NOTE: For clarity, whole number font sizes will appear larger than fractional

number font sizes (numbers on the right-side of the decimal).

- 1 To Program a delivery rate, select ▲ [A].
- To enter delivery rate, use numeric keypad.
- 3 Use to move down to the VTBI field.



NOTE: While the VTBI is being entered, the duration is automatically computed. If the computed value is greater than 99:59, dashes (- -) appear in place of hours.





5 Use to move down to the DURATION field.

If auto-calculated Duration is acceptable, skip to step 9.

6 Use keypad to change/enter the hours part of duration if desired.

NOTE: When all parameters are displayed, changing any one parameter will result in other parameters automatically being computed. To understand the Automatic Calculation feature, see



Section 6.7 Examples of Automatic Calculation.

7 Use to move from hours to minutes.

NOTE: The maximum hours allowed is 99 and the maximum minutes is 59.

- 8 Use keypad to enter minutes.
- 9 Press (START).

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

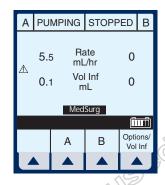
Program Confirmation screen will appear. If correct, press ▲ [Yes] to begin infusion.



Example of Main Delivery Screen just after being programmed and started.

NOTE: The Line A Fluid Flow Indicator also will flash to indicate pumping.

NOTE: VTBI (volume *to be* infused) values over 100 mL are displayed *truncated*. This means that the

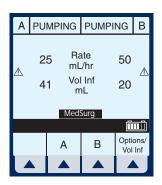


number displayed *rounds-down* to the last whole number (e.g., 105.7 would be displayed as 105). An example would be the Programming or Pumping screens.

NOTE: VI (volume infused) values over 100 mL are displayed *rounded*. This means that the number displayed rounds-off to the *nearest* number (e.g., 105.7 would be displayed as 106, but 105.3 would be displayed as 105). An example would be the Program Options screen.

Titration

1 Select Line ▲ [A] (or ▲ [B]) at the Main Delivery Screen.



2 Enter the desired Rate using the keypad.

NOTE: When Rate is changed, the duration is automatically recomputed using the current VTBI. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.



PROGRAM

Delivery will be:

No Drug Selected

15 mL/hr

50 mL

Confirm Program?

Drua

Rate

VTBI

Yes

MedSurg

 Λ

Nο

3 Press START

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Program Confirmation screen will appear. If correct, press

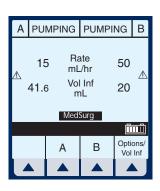
[Yes] to begin infusion.

NOTE: During Titration, infuser continues to deliver at previous parameters until new program is confirmed.

Example of Main Delivery Screen after being titrated.

NOTE: Volume Infused is an incrementing value which is cleared in **A** [Options/Vol Inf].

The following 3 screens are examples of changed values.



Example of changed rate.

- 4 From the Main Delivery Screen, select ▲ [A].
- 5 Use keypad to change the RATE value.



NOTE: The display time is only accurate to \pm one minute. As shown in this example, the delivery shows 3 hours and 20 minutes (not 3 minutes and 20 seconds).

6 Press (START).

Program Confirmation screen will appear. If correct, press \blacktriangle [Yes] to begin infusion.

NOTE: [START] accepts the change. Delivery is changed to the new RATE and DURATION and display returns to Main Delivery Screen.

Example of Changed VTBI value.

- 7 Use to highlight the VTBI field.
- **8** Use the keypad to change the VTBI value.



NOTE: When the VTBI is changed, the Duration is recomputed with respect to the current Rate. To understand the Automatic

Calculation feature, see Section 6.7 Examples of Automatic Calculation.

9 Press START .

Program Confirmation screen will appear. If correct, press ▲ [Yes] to begin infusion.

NOTE: [START] accepts the change. Delivery is changed to the new VTBI and DURATION and the display brings up the Confirmation screen before returning to the Main Delivery Screen.

Example of changed DURATION field.

10 Use to highlight the Duration field, then use the keypad to change its value.

NOTE: When DURATION is changed, RATE is automatically recomputed using the current VTBI value. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.



11 Press START

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Program Confirmation screen will appear. If correct, press ▲ [Yes] to begin infusion.

NOTE: [START] accepts the change. Delivery is changed to the new DURATION and RATE and the display brings up the Confirmation screen before returning to the Main Delivery Screen.

Piggyback Delivery

PIGGYBACK DELIVERY-Infusion will stop Line A and infuse Line B until VTBI completes. Line A will automatically restart.

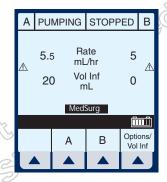
1 With Line A pumping, to program a Piggyback delivery, select ▲ [B].

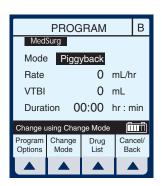
The Delivery Mode field is highlighted.

NOTE: If an entry was previously programmed, RATE is highlighted. If no previous entries, MODE is highlighted.

2 If field reads "Concurrent", select

▲ [Change Mode] to switch to "Piggyback".





- 3 Select to highlight the RATE field.
- 4 To enter delivery rate, use numeric keypad.
- 5 Use to move down to the VTBI field.
- **6** To enter VTBI amount, use keypad.

NOTE: While the VTBI is being entered, the duration is automatically computed. If the computed value is greater than 99:59, dashes (--) appear in place of hours. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.





7 Use to move down to the DURATION field.

(Optional) Use keypad to change duration.

When all parameters are displayed, changing any one parameter will result in other parameters automatically being computed.



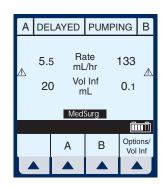
8 Press START .

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Program Confirmation screen will appear. If correct, press **A** [Yes] to begin infusion.

NOTE: If Line A has a Delay Start remaining or is stopped, a message will appear warning of a possible non-delivery (see section 6.4).

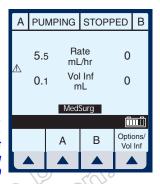
Example of Main Delivery Screen just after being programmed and started.



Concurrent Delivery

CONCURRENT DELIVERY-Simultaneous delivery of two fluids at independent flow rates.

CAUTION: CONSULT DRUG LABELING TO CONFIRM DRUG COMPATIBILITY, CONCENTRATION, DELIVERY RATES, AND VOLUME ARE ALL SUITABLE FOR CONCURRENT AND PIGGYBACK DELIVERY MODES. SEE SECTION 8 FOR INFORMATION ON CONCURRENT FLOW, SEE SECTION 9 FOR DELIVERY RATE RANGES.



NOTE: In concurrent mode with certain alarm conditions, one line may stop while the other line may continue to deliver.

1 With pumping started on line A, to program a Concurrent delivery rate, select ▲ [B].

The Delivery Mode field is highlighted.

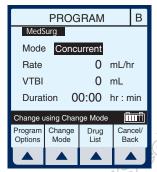
NOTE: If an entry was previously programmed, RATE is highlighted. If no previous entries, MODE is highlighted.

If field reads "Piggyback", select ▲ [Change Mode] to switch to "Concurrent".



Verify change to "Concurrent" mode.

2 Use to highlight Rate field.



To enter delivery rate, use numeric keypad.

NOTE: When Rate for Line A plus Rate for Line B is greater than valid rate ranges, a "Concurrency violation" message will explain why second line did not start. See Section 9.3 for valid delivery rate ranges.



NOTE: "Concurrency violation" may not be displayed if unit is displaying "VTBI Complete". The device will not start and an invalid keypress sound will occur when [START] is pressed.

- 4 Use to move down to the VTBI field.
- **5** To enter VTBI amount, use keypad.

NOTE: While the VTBI is being entered, the duration is automatically computed. If the computed value is greater than 99:59, dashes (- -) appear in place of hours. To



understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.

6 Use to move down to the DURATION field.

(Optional) Enter values for desired hours and minutes.

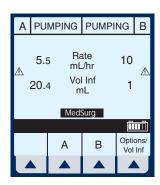
NOTE: When Duration is entered, Rate is automatically computed.

7 Press START).

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Program Confirmation screen will appear. If correct, press ▲ [Yes] to begin infusion.

Example of a concurrent delivery.



Stop and Start with only 1 Line Pumping

1 Press (STOP) at the Main Delivery Screen.

NOTE: If ▲ [A] (or ▲ [B]) is selected prior to pressing [STOP], the display will return to the programming screen. Select

▲ [Cancel/Back] to return to the Main Delivery screen.

A PUMPING STOPPED B

100 Rate mL/hr
8.5 Vol Inf mL

Medsurg

Back Prime A B Options/
Vol Inf

Example of STOPPED delivery.

- To discontinue infusion, press

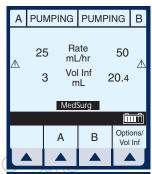
 (ON/OFF).
- **3** Clamp secondary tubing if connected.



4 Open door, remove set and close door. Or, press START to resume infusion.

Stop and Start with Both Lines pumping

1 Press STOP at the Main Delivery Screen.



2 Select ▲ [Stop A], ▲ [Stop B], or ▲ [Stop All].

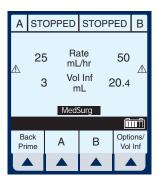
NOTE: If ▲ [A] (or ▲ [B]) is selected prior to [STOP], the display will show the programming screen. Select ▲ [Cancel/Back] to return to the Main Delivery screen.



Example of stopped infusion.

NOTE: This is an example using **▲** [Stop All].

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.



- To resume infusion, press (START).
- 4 Select ▲ [Start A],
 ▲ [Start B], or ▲ [Start All].
 Or, to discontinue infusion,
 press (ON/OFF).



- **5** Clamp secondary tubing if connected.
- 6 Open door, remove set and close door.

Backpriming

BACKPRIMING- Removal of air or fluid from the proximal line and cassette airtrap.

To initiate a backprime, select

▲ [Back Prime].

NOTE: Backpriming is available only when all delivery is stopped. Secondary container is necessary to receive the air.



2 Select and hold

▲ [Back Prime] until fluid pumped from line A to line B has expelled the air from cassette air trap into Secondary container.

NOTE: Fluid flow is at maximum rate possible.



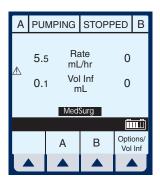
3 Upon release of ▲ [Back Prime], the cassette test is performed to confirm readiness for pumping.

Pressing (START) will resume programmed delivery.

Clearing Settings

1 Press (STOP) at the Main Delivery Screen.

Clear ALL settings when changing patients or multiple programming parameters.



2 Select Line ▲ [A] (or B if active) from the stopped Main Delivery Screen.

NOTE: If Line A or B is programmed with a Therapy (i.e., Dose Calculation), Rate, VTBI and Duration will not display values. The values to be cleared may be viewed in applicable programming screen under ▲ [Drug List].



3 Select ▲ [Yes].

Clear ALL settings when changing patients or multiple programming parameters.

Example screen of "Cleared Settings".

4 Select ▲ [Cancel/Back] to return to the Main Delivery screen or program new settings.



Updating Drug Library

If a new Drug Library is available, the New Drug Library Install screen will be displayed.

Select ▲ [Yes] to begin the installation (It may take up to an hour).
Select ▲ [No] to skip the installation and continue using the current library.

Example screen of Library Installing.





NOTES

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Section 5 Advanced Programs

Standard Program	(Dose Calculation) Allows programming Dose Rates in alternative units of measure. Dose Calculation can be used in Simple Delivery, Loading Dose, and Multistep.
Loading Dose	Allows programming of an initial infusion rate for a specific volume, followed automatically by a maintenance rate from the same container (e.g., a fluid challenge). If Dose Calc is used, the Loading Dose and Maintenance Dose are in the same unit of measure, over the same period of time (mcg/min), from the same container.
Multistep	Allows a sequential program to deliver up to 10 steps; fluid volumes and delivery rates may be programmed for each step. The program may be entered based on Rate and Volume or Volume and Time. If Dose Calc is used, the delivery steps are in the same unit of measure, over the same period of time, from the same container.

NOTE: During programming, user must identify desired drug with softkey Drug List prior to setting program parameters.

Use drug manufacturer recommendations for IV administration when using the Plum A+ infuser.

Dose Calc (mcg/kg/min on A)

DOSE CALCULATION- Allows programming Dose Rates in alternative units of measure. Dose Calculation can be used in Simple Delivery, Loading Dose, and Multistep.

Clear ALL settings when changing patients or multiple programming parameters.

The Area Selection screen will appear if your system has been programmed with the MedNet accessory.

Use to select CCA and bring you to the Main Delivery Screen.



NOTE: To change the CCA while infusing, see Section 6.8, Changing CCA While Infusing.

1 Select ▲ [A] at the Main Delivery Screen.

SCREENS SHOWN IN THIS MANUAL ARE EXAMPLES ONLY AND DON'T NECESSARILY REFLECT CURRENT ACTUAL PRACTICE



The Line A Programming screen appears.

2 Select ▲ [Drug List] for Dose Calculation programming.

The Drug List Screen appears, in mainly alphabetical order.

NOTE: Default entry is "No Drug Selected".

3 Use to highlight desired drug name.

When list does not contain desired generic drug name or group name select

▲ [Page Down] (or ▲ [Page

■ [Page Down] (or ■ [Page Up]) until it shows, then use

to highlight choice.

A PROGRAM

MedSurg

Rate 0 mL/hr

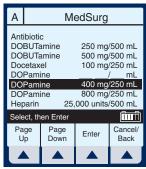
VTBI 0 mL

Duration 00:00 hr : min

Enter Value using keypad

Program Options Drug Cancel/ Back





4 Select ▲ [Enter] to indicate selection and advance to the Therapy selection screen.

Based on this selection, assume the hospital has set the following rules for the Med/Surg Area:

Soft upper limit of 8 mcg/kg/min Hard upper limit of 12 mcg/kg/min

NOTE: The SOFT and HARD limits are not displayed. However, the limit is provided if a value is programmed outside the acceptable range. Typically, the pharmacy will set the limit.

The Select Therapy screen for Line A appears.

5 Select ▲ [Choose] to select Standard Program (Dose Calc) and continue.

If selected drug has been programmed with established dosing units and concentration, skip to step 8.

The Program Dose Calc screen appears.

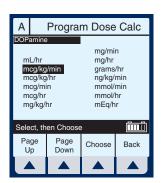
NOTE: Cursor defaults to package insert (or hospital) recommended dose units associated with the selected drug.

6 Select ▲ [Choose] to continue.

Or, use to change the units to use in the delivery.

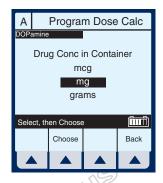
If desired, select ▲ [Page Down] to see more units of measure.





The Container Concentration Selection screen appears whenever the selected Dose Units are gram-based (e.g., grams, mg, mcg, or ng), otherwise this screen is skipped.

NOTE: Cursor defaults to package insert (or hospital) recommended concentration units associated with the selected drug.



7 Select ▲ [Choose] to continue. Or, use to change the Container Concentration units to use in the delivery.

The next page of the Program Dose Calc screen appears to provide for entry of delivery program parameters.

The Concentration and Volume fields are filled in per drug selection.



8 Use keypad to enter desired

values. Once each value is entered, use to highlight the next programming field.

NOTE: The Concentration elements and weight value must be entered before the [SELECT] key allows access to remaining fields.

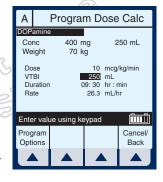
9 Continue to enter values using the keypad, and advancing to the next field using .

NOTE: As the Dose value is entered, the Rate is automatically calculated. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.



- 10 Use to scroll down to the VTBI field.
- **11** Enter a value for VTBI using the keypad.

NOTE: As the VTBI value is entered or changes, Duration is automatically updated.



NOTE: At this point, programming is complete unless [Program Options] are desired. See Section 6, Additional Features, for more information.

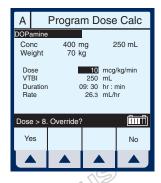
12 Press START).

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Because the Dose falls outside the soft limits, the infuser beeps three times (Invalid Key Warning), and generates the error message:

"Dose > 8. Override?"

13 Select ▲ [Yes].

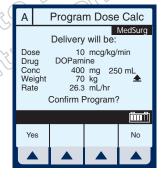


NOTE: A SOFT limit override will be recorded in the History Events Log.

This will bring up the PROGRAM CONFIRMATION screen.

14 If Dose, Drug, Conc., Weight & Rate appear correct, select ▲ [Yes] to begin program.

NOTE: If the selected drug has been pre-programmed with dosing units and concentration, the concentration

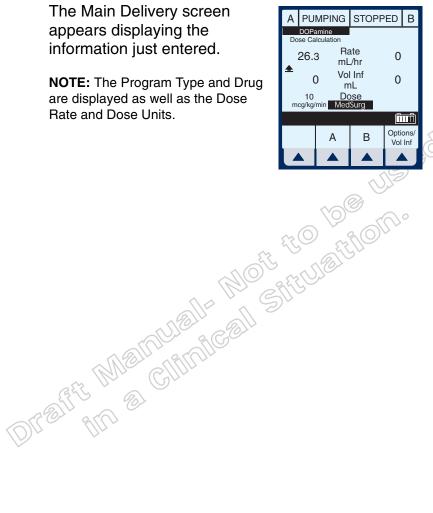


drug amount or diluent volume cannot be changed whether delivering or stopped. The only way to change to a different concentration is to clear the program.

However, if selected drug has not been pre-programmed (or still operating with the DDL), the concentration can be changed for a program.

The Main Delivery screen appears displaying the information just entered.

NOTE: The Program Type and Drug are displayed as well as the Dose Rate and Dose Units.

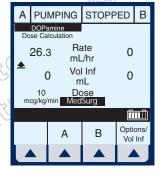


Dose Calc (mg/min on B)

DOSE CALCULATION- Allows programming Dose Rates in alternative units of measure. Dose Calculation can be used in Simple Delivery, Loading Dose, and Multistep.

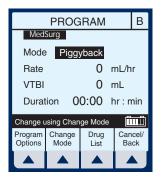
Clear ALL settings when changing patients or multiple programming parameters.

Select ▲ [B] at the Main Delivery Screen.



The Line B Programming screen appears.

2 Select ▲ [Drug List].



The Drug List Screen appears, in mainly alphabetical order.

NOTE: Default entry is "No Drug Selected".

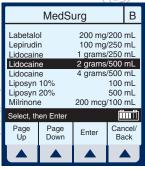


Use to highlight desired drug name.

When list does not contain desired generic drug name or group name select

- ▲ [Page Down] (or <</p>
- ▲ [Page Up]) until it shows,

then use to highlight choice.



4 Select A [Enter] to indicate selection and advance to the Program Selection screen.

The Select Program screen for Line B appears.

5 Select ▲ [Choose] to continue.



If selected drug has been programmed with established dosing units and concentration, skip to step 8.

The Program Dose Calc screen appears.

NOTE: Cursor defaults to package insert (or hospital) recommended dose units associated with the selected drug.



Or, use to change the units to use in the delivery.



If desired, select A [Page Down] to see more units of measure.

The Container Concentration Selection screen appears whenever the selected Dose Units are gram-based (e.g., grams, mg, mcg, or ng) otherwise this screen is skipped.

NOTE: Cursor defaults to package insert recommended concentration units associated with the selected drug.



7 Select ▲ [Choose] to continue. Or, use to change the Container Concentration units to use in the delivery.

The next page of the Program Dose Calc screen appears to provide for entry of delivery program parameters.

We keypad to enter desired values. Once entered, use to highlight the next field.



NOTE: If selected drug has established Rule Sets (e.g., nonblank concentration), the Mode field will be highlighted upon entry to this screen.

9 To change the Piggyback Delivery Mode default, scroll down to Mode using ↓, then select ▲ [Change Mode].

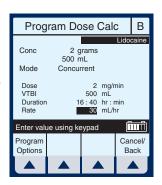
NOTE: Delivery Mode Option is available on Line B, its default is Piggyback, and the Weight field is gone.

10 Continue entering desired values using the keypad. Use



to advance to the next field.

NOTE: When entering the RATE, with a VTBI value entered, the DOSE and DURATION fields are automatically updated. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.



NOTE: The Duration field temporarily changes to dashes when the computed value is larger than what can be displayed.

11 Continue entering the RATE value, if desired.

NOTE: As Rate is entered, the Duration and Dose are automatically adjusted as individual numbers are entered.

NOTE: If the Duration value is changed, the Rate and Dose are automatically adjusted.

NOTE: At this point, programming is complete unless ▲ [Program Options] are desired. See Section 6, Additional Features, for more information.

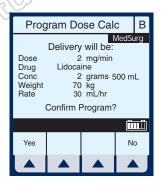
CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

12 To start the delivery, press

(START).

This will bring up the PROGRAM CONFIRMATION screen.

13 If Dose, Drug, Conc., Weight, & Rate appear correct, select ▲ [Yes] to begin program.

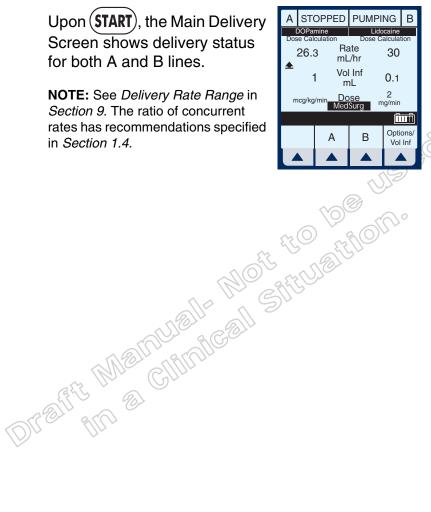


NOTE: If the selected drug has been pre-programmed with dosing units and concentration, the concentration drug amount or diluent volume cannot be changed whether delivering or stopped. The only way to change to a different concentration is to clear the program.

However, if selected drug has not been pre-programmed (or still operating with the DDL), the concentration can be changed for a program.

Upon (START), the Main Delivery Screen shows delivery status for both A and B lines.

NOTE: See Delivery Rate Range in Section 9. The ratio of concurrent rates has recommendations specified in Section 1.4.



Loading Dose

LOADING DOSE- Allows programming of an initial infusion rate for a specific volume, followed automatically by a maintenance rate from the same container (e.g., a fluid challenge). If Dose Calc is used, the Loading Dose and Maintenance Dose are in the same unit of measure, over the same period of time (mcg/min), from the same container.

Clear ALL settings when changing patients or multiple programming parameters.

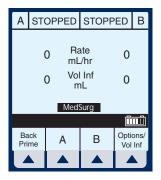
The Area Selection screen will appear if your system has been programmed with the MedNet accessory.

Use to select CCA and bring you to the Main Delivery Screen.



NOTE: To change CCA while infusing, see Section 6.8, Changing CCA While Infusing.

Select ▲ [A] (or ▲ [B]) at the Main Delivery screen.



The selected Line (A or B) Programming screen appears.

2 Select ▲ [Drug List].

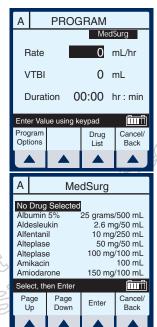
The Drug List Screen appears, in mainly alphabetical order.

NOTE: Default entry is "No Drug Selected". This process will guide you through a "fluid challenge", so "No Drug Selected" will be entered.

3 Select ▲ [Enter] to indicate selection and advance to the Program selection screen.

The Select Program screen for Line A (or B) appears.

NOTE: This example shows line A being programmed.





- 4 Use to scroll down to Loading Dose.
- 5 Select ▲ [Choose] to continue.



Program Loading Dose

mcg/kg/min

mcg/kg/hr mcg/min

mg/min mg/hr grams/hr

ng/kg/min

mmol/min

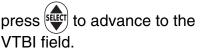
The next page of the Program Loading Dose screen appears.

6 Select ▲ [Choose] to continue. Or, use (steet) to change the units to use in the delivery.

> If desired, select ▲ [Page Down to see more units of measure.

The Loading Dose Programming screen appears.

The default field is Rate. Since a "Fluid Challenge" is being performed in this example, press (see to advance to the





Enter value using keypad

Program

Options

السائل

Cancel/

Back

8 Enter value using keypad.

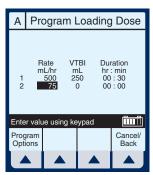


- 9 Use to highlight the next field.
- 10 Enter Duration using keypad.
 The Rate value is automatically calculated. To understand the Automatic Calculation feature, see Section 6.7 Examples of Automatic Calculation.



After the values for loading dose Step-1 are entered, use to highlight the maintenance dose, Step-2.

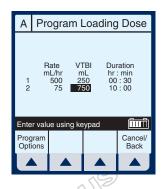
NOTE: The Loading Dose program has two steps. The first is the loading dose followed by the maintenance dose. These words will appear on the main screen as each step is delivered.



- **12** Enter the set of desired values for Step-2 of the program.
- **13** Select ▲ [Program Options] to select a Delayed Start or Standby.

NOTE: At this point, programming is complete unless ▲ [Program Options] are desired. See Section 6, Additional Features, for more information.

NOTE: Nurse Callback enables an alarm when a change in the delivery on a line occurs such as completing Step-1 and starting Step-2. Or on line B, a piggyback delivery is completed and line A is starting its delivery.





14 Enter a delay time (less than 24 hours) using the keypad.

NOTE: Not available if a delivery is taking place on the line.

NOTE: Nurse Callback cannot be changed while a delivery is taking place on the line.



15 Select ▲ [Enter] to accept the changes and return to the Program Loading Dose screen.

NOTE: ▲ [Cancel/Back] returns the fields to their original value and displays the previous screen.

16 To start the delivery, press START

This will bring up the PROGRAM CONFIRMATION screen.

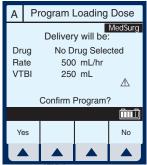
CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

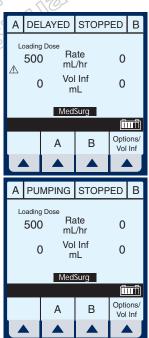
17 If Drug and Rate appear correct, select ▲ [Yes] to begin program.

The Main Delivery Screen appears.

NOTE: The words "DELAYED" and "Loading Dose" appear in the upper-left corner. These indicate the options which have been selected.

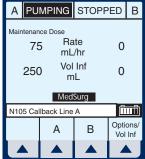
After the programmed delay period has expired, the Plum A+ starts "Pumping". This is indicated where "Delayed" previously was displayed.





After the Step-1 has completed, the Main Delivery Screen changes to the second step.

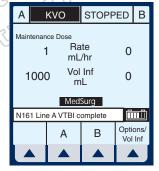
NOTE: A flashing "Callback Line A" message and the audio alarm sound indicates activation of that option.



18 The user should acknowledge the Callback message and stop the audio alarm by pressing (SILENCE).

Upon completion of delivery, the screen shows a flashing "Line A VTBI complete" message and the audible alarm sounds.

NOTE: The KVO rate will change to the rate of 1.0 mL/hr or less depending on delivery rate and "Pumping" mode changes to "KVO". If



Continue Rate option was selected, pumping continues at original rate.

19 Press (SILENCE) to stop alarm sound.

NOTE: Warning message continues to flash and audio alarm will return after a two minute period of silence, unless delivery is stopped or VTBI of last line is changed.

Multistep Programming

MULTISTEP- Allows a sequential program to deliver up to 10 steps; fluid volumes and delivery rates may be programmed for each step. The program may be entered based on Rate and Volume or Volume and Time. If Dose Calc is used, the delivery steps are in the same unit of measure, over the same period of time, from the same container.

Clear ALL settings when changing patients or multiple programming parameters.

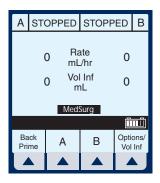
The Area Selection screen will appear if your system has been programmed with the MedNet accessory.

Use to select CCA and bring you to the Main Delivery Screen.



NOTE: To change CCA while infusing, see Section 6.8, Changing CCA While Infusing.

Select ▲ [A] at the Main Delivery screen.



The Line A Programming screen appears.

2 Select ▲ [Drug List].



The Drug List Screen appears, in mainly alphabetical order.

NOTE: Default entry is "No Drug Selected".

3 Use to highlight desired drug name.

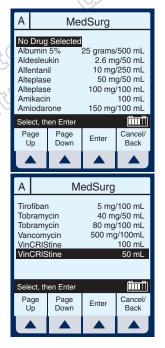
When list does not contain desired drug name or drug class name, select

▲ [Page Down] (or ▲ [Page

▲ [Page Down] (or ▲ [Page Up]) until it shows, then use



Select ▲ [Enter] to indicate selection and advance to the Program Selection screen.



The Select Program screen for Line A (or B) appears.

NOTE: This example shows line A being programmed.

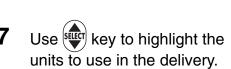


- 5 Use (see to scroll down to Multistep.
- 6 Select ▲ [Choose] to continue. If selected drug has been programmed with established dosing units and concentration, skip to step 9.

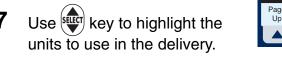
The Program Multistep screen appears.

NOTE: Cursor defaults to package insert recommended dose units associated with the selected drug.

units to use in the delivery.

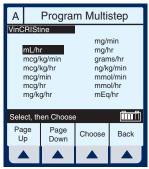






If desired, select ▲ [Page Down] to see more units of

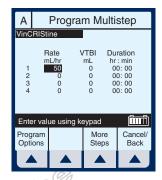




measure.

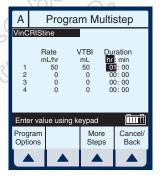
The Multistep Programming screen appears.

9 Rate is the default field. Enter value using keypad.

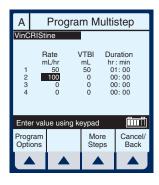


10 Use to highlight the Duration or VTBI field.

NOTE: The VTBI value is automatically computed when the Duration value is entered. If VTBI is entered, the Duration value is automatically computed.



- 11 Use to drop down to Step-2, Rate field.
- 12 Enter the set of desired values for Step-2 of the program.
 Continue process for each additional Step.



NOTE: When Step-4 is programmed, using [SELECT] to advance will highlight another item on this screen.

13 When Step-4 is programmed, select

▲ [More Steps] to program up to 10 Steps.

NOTE: Using [SELECT] will not advance you to the additional steps.

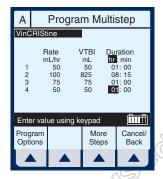
14 To set up Steps 5 through 10, enter desired values as performed for Steps 1 through 4.

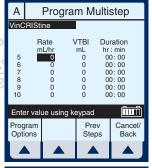
To see the previous steps, select ▲ [Prev Steps].

15 To start the delivery, press (START).

This will bring up the Confirmation screen.

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.





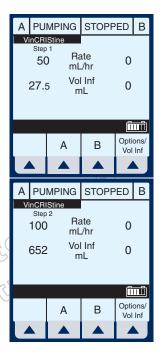


The Main Delivery Screen displays Step-1 in the upper-left corner.

NOTE: In units other than mL/hr, the Dose rate and units also will be displayed.

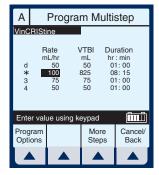
Example of Multistep Screen Pumping on Step-2.

16 To change a program parameter while pumping, select **▲** [A].



NOTE: The "*" in a Step number field indicates the step is delivering or "d" indicates each completed step.

17 Enter a value using the keypad.



If Rate value is changed, the Duration will automatically change.

NOTE: Only the current delivering step and future steps can be changed.

18 To start the delivery, press (START).

This will bring up the Confirmation screen.

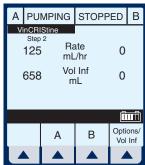
CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

NOTE: The Values are now updated on the Main Delivery Screen.

The infuser reverts to KVO when last Step completes.

The last step can be restarted by entering a new VTBI value.



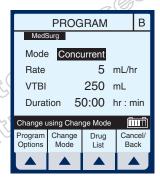


Section 6 Additional Features

Simple Delivery Using Delayed Start

Before or after entering the simple delivery program, select ▲ [Program Options].

NOTE: To program a Delayed Start using an advanced program (i.e., Dose Calc) you must first select which line you want (A or B), next select ▲ [Drug List], and then ▲ [Program Options]. If you program the Delayed Start first, it will be cleared upon entry into Select Program mode.



The Default screen for Program Options appears.



- 2 Enter values for desired hours and/or minutes.
- 3 Select ▲ [Enter] to confirm delayed start.

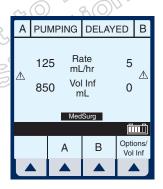
CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

4 Press (START) to confirm programming.

Line B is delayed for the time entered.

NOTE: Delayed line drip indicator is solid, not flashing. It will begin flashing when actually pumping.

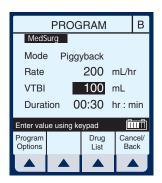




Piggyback with Nurse Callback

1 After programming in desired values for both lines, select ▲ [Program Options].

NOTE: To set a nurse callback, the infuser must be stopped. This function can be selected either before or after entering the Piggyback delivery program.



The default screen for Program Options appears.

Use steet to highlight "Callback" field and select ▲ [Yes/No], if necessary to obtain "Yes", then select

Program Options B

Delay Start for 00:00 hr:min
Callback Yes

Change using Yes/No Tenter Cancel/Back

A A A A

▲ [Enter].

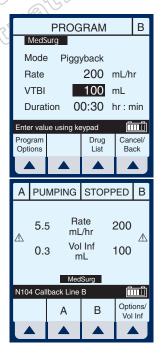
NOTE: Callback default of Yes or No is a biomedical setting and must be configured using the Hospira MedNet accessory.

CAUTION: VERIFY ALL VALUES BEFORE STARTING INFUSION.

Press START to confirm program setting and return to Main Delivery screen.

At end of Piggyback delivery, with Callback enabled for the line, Callback alarm is issued.

3 Press (SILENCE) to clear alarm.



Possible Non-Delivery Programmed

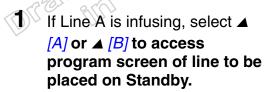
NOTE: Whenever a valid [START] key is pressed, the device checks the delivery program(s) for non-delivery conditions (such as Line B Piggyback without Line A or delayed start) that could permit a period of non-delivery. If so, the display presents this warning screen.

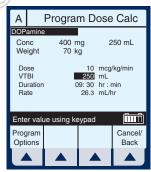


Select ▲ [Yes] to continue with delivery. Or, select ▲ [No] to cancel

Using the Standby Feature

Standby is a feature that enables the clinician to program the infuser up to 23: 59 minutes in advance of Starting.





- 2 Select ▲ [Program Options].
- 3 Select ▲ [Standby].

4 Confirm the information displayed is correct, then select ▲ [Yes] to place program on Standby mode.

NOTE: This example screen shows a Dose Calculation Program with a Standby. It looks similar to the Program Confirmation screen with the substitution of "Put delivery in Standby" replacing "Confirm Program". Selecting

[Yes] confirms both the Program and the Standby.

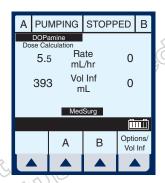
Program Dose Calc Delivery will be: Dose 10 mcg/kg/min Drug DOPamine Conc 400 mg 250 mL Weight 70 kg 26.3 mL/hr Rate Put delivery in Standby? Yes No

5 Press START to remove Standby and start the infusion.



Select Option- Volumes Infused, Pressure/Post Infusion Rate, and Lighting/Contrast

1 To select Options Screen, select ▲ [Options/Vol Inf].



- 2 Use to highlight an option.
- 3 Select ▲ [Choose] to select the Volumes Infused screen.

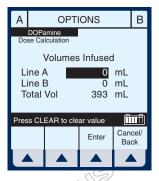
This will bring up the Volumes Infused screen which defaults to Total Volume.

4 Use to scroll to Line A or B.



- To reset Line A (or B) Volume Infused, use to highlight and press (CLEAR).
- **6** To restore the cleared quantity, select ▲ [Cancel/Back].
- 7 To reset all volumes, use to highlight Total Vol, then press
- 8 To restore all quantities, select

 ▲ [Cancel/Back] softkey.





- **9** When clearing of quantities is completed, select ▲ *[Enter]* to return to the Main Delivery screen.
- **10** Select ▲ [Options/Vol Inf] from the Main Delivery screen to return to the Options screen.
- 11 Use to highlight the Pressure/Post Infusion Rate option.



OPTIONS

Pressure/Post Infusion Rate

6 psi

ĬIII I

Cancel/

Dose Calculation

Continue Rate

Distal Pressure Limit Distal Pressure

Change using KVO/Rate

KVO/

12 Select ▲ [Choose] to continue:

NOTE: Prior to changing Pressure/Post Infusion Rate, infuser must be stopped.

- 13 Use to highlight Continue
 Rate or Distal Pressure Limit
 field.
- 14 Continue Rate allows a choice when VTBI is completed. Select
 - ▲ [KVO/Rate].



- KVO- The infuser will revert to a fixed KVO of 1 mL/hr or the last programmed Rate, whichever is less.
- Rate- The infuser will continue at the Rate programmed.

NOTE: Option will be for both line A and line B selections.

15 To change Distal Pressure Limit when highlighted,

enter value between 1.0 and 15.0 psi.

16 Select ▲ [Enter] to keep changes and return to the Main Delivery screen, or ▲ [Cancel/Back] to restore original values and return to the Options screen.

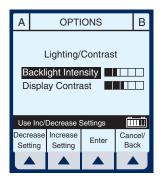
NOTE: Continue Rate default of KVO or Rate must be configured using the Hospira MedNet software.

- 17 Select ▲ [Options/Vol Inf] from the Main Delivery screen to return to the Options screen.
- 18 Use to highlight Lighting, Contrast Option.
- Volumes Infused
 Pressure/Post Infusion Rate
 Lighting/Contrast
 Any Hospital, USA
 MM/DD/YY XXYYZZ-123456
 Select, then Choose
 Change
 CCA
 Choose
 Back

OPTIONS

Release 13.x - xx/xx/xx

- **19** Select **△** [Choose] to continue.
- 20 Press to highlight Backlight Intensity or Display Contrast.
- 21 While viewing display for desired effect, select either ▲ [Increase Setting] or ▲ [Decrease Setting] to change level.



22 Select ▲ [Enter] to keep change(s) and return to the Main Delivery screen, or ▲ [Cancel/Back] to restore previous settings and return to the Options screen.

Variable Rate Cap

NOTE: Variable Rate Cap is used to set the maximum rate values to be accepted by the device. The clinician cannot change it once it has been programmed. It must be configured using the Hospira MedNet software.

Examples of Automatic Calculation At Startup

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

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

WHILE RUNNING (TITRATION)

Changing two parameters after startup of the infusion will allow for the re-calculation of the third parameter.

NOTE: VTBI will not be re-calculated if the Rate and Duration are changed. VTBI must be cleared and then the new VTBI reentered. The new VTBI will automatically calculate a new Rate.

1st Action	2nd Action	[AUTOCALC]
change RATE	keep VTBI	[DURATION]
change RATE	change VTBI	[DURATION]
change VTBI	keep RATE	[DURATION]
change DURATION	keep VTBI	[RATE]
change VTBI	change DURATION	[RATE]
change RATE	change DURATION	Recalculates [RATE] based on previous VTBI and new DURATION

AT KVO

Audible KVO alarm will sound, clinician will need to re-set the appropriate settings.

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

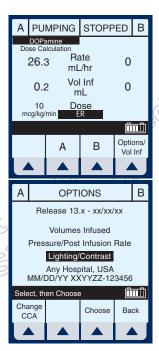
Changing CCA While Infusing

1 Select ▲ [Options/Vol Inf] from the Main Delivery screen.

2 Select ▲ [Change CCA].

Press to highlight desired CCA, then select ▲ [Enter] to confirm the change.

The delivery continues until VTBI equals zero, or you stop the program and clear the settings.

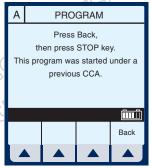




The message bar informs the user of the changed CCA.

STOPPED **PUMPING** DOPamine Dose Calculation Rate 26.3 0 mL/hr Vol Inf 0 0.3 ml 10 Dose mcg/kg/min ICU Line A using prior CCA اأستا Options/ Α В Vol Inf

When VTBI reaches zero (infusion is competed), VTBI may no longer be incremented. To program, the user must first select **A** [Back], then press the **STOP** key.



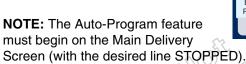
Auto-Programming

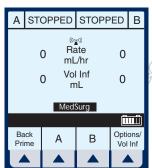
Auto-Programming is a new feature for the Hospira Plum A+ line of infusion pumps. It can only be used if the feature has been installed in conjunction with your Hospital Information System (HIS) and Barcode Point-Of-Care (BPOC) Unit. It works by scanning barcode labels for the patient, pump, and IV bag using a BPOC Unit, such as a PDA. This information is then transferred to the pump utilizing either it's wireless antenna or RJ-45 Ethernet connector. The feature reduces the number of steps needed to program an infusion.

NOTE: If the physician's order for an auto-program therapy exceeds the capabilities of the pump or is above a hospital defined hard drug limit, the infusion parameters for auto-programming will be rejected and the order will need to be rechecked.

NOTE: It is important that biomed personnel ensure that the barcode identification label affixed to each infuser corresponds to the correct Connectivity Engine Identification Number. This way the correct order will be sent to the appropriate infuser.

- **1** Power On the pump as described in Section 4.2.
- **2** After the CCA has been selected, the pump is ready for auto-programming.





- Following your hospital's procedure, activate your BPOC Unit.
- 4 Scan the patient wristband to pull up the patient's task list on the BPOC Unit.
- Scan the IV bag. IV Task and documentation with Order Details is displayed on the BPOC.

NOTE: If the scanned medication does not exist in the Hospira MedNet Rx Rules medication library, that medication will display on the pump as "No Drug Selected".

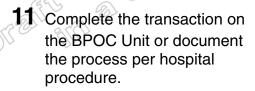
6 Scan the barcode of the available pump channel that is not currently infusing (A or B).

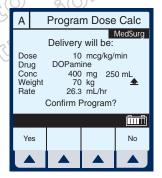
- 7 Programming screen is autofilled.
- **8** Verify ALL parameters. If changes are desired, the infusion parameters can be manually changed using the keypad on the pump.



- 9 Press START to display the Confirmation screen.
- 10 Select ▲ [Yes] to confirm programming and begin infusion.

The BPOC will reconfirm that the pump parameters match the order.





NOTES

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SECTION 7 Alarms and Troubleshooting

Warning Messages

MESSAGE Stop delivery then turn off	Possible Cause Attempting to turn the infuser off while a delivery is in progress.	CORRECTIVE ACTION Stop all lines, then turn infuser off.
Warning: Replace Battery	The battery current charge is greater than 200 mA/hr. The battery voltage is less than the depleted threshold and charge level is higher than the low charge threshold.	Replace battery.
Warning: Charger Service	The charging circuitry is not behaving as expected (charge voltage is not changing) and can reduce battery life.	Silence key is pressed.
Warning: Low Battery	Pump not plugged in to AC power.	Plug into AC power, only about 30 minutes of battery life remains.

NOTE: Other error and warning messages will occur when appropriate for the current selection context. For instance, when a change to a required parameter would result in clearing some delivery settings, the warning message will appear when that field is selected. When an input error has just been made, the three quick beeps of an Invalid Key Warning will sound and an appropriate warning message will be shown to explain the

problem. All such messages will be cleared or replaced by another message upon the next valid input key press.

Response to Alarms

- 1 Disable Lockout by confirming back switch is in the down position or press the decimal key followed by 9, 6, & 3 on the
- 2
- 3
- 4
- 5 Press [START] to resume infusion.

Correct Alarm condition (see following tables).

Press [START] to resume infusion

NOTE: Alarm materials and tracking the second tracking purposes only. If troubleshooting does not correct the problem, record the code number and contact technical support.

General Alarms

CODE	MESSAGE	Possible Cause	CORRECTIVE ACTION
N100	Unrecognized cassette	Attempting to use unrecognized cassette.	Turn off or insert recognized cassette.
N101	No Action Alarm	Pump programming incomplete.	Press [START] or continue programming.
N102	Infuser Idle 2 Minutes	Pump is ON without operator input.	Begin programming or turn infuser OFF.
		Standby time has elapsed.	Re-enter all programmed data.
N103	Memory Failure	The infuser did not accept the previous programmed data.	Re-enter all programmed data.
N230	Prox Air, Backprime	When the total proximal air detected exceeds the limit.	Check for clamps, or empty containers on line A or B. Correct as necessary. Backprime into line B tubing or syringe.
N180, N181, N186	Distal Occlusion	Distal line kinked, IV site clotted or positional, pressure limit set too	Check distal tubing, check IV site, reset pressure limit.
		low.	See page 1-14 for detailed instructions for avoiding a bolus following a distal occlusion.
N187	Neg Distal Occlusion	Pump too high above patient or defective set.	Lower infuser or replace set.
N233, N234	Distal Air	When air is detected at the distal sensor and exceeds the limit.	Remove and reprime cassette using standard technique.

CODE	Message	Possible Cause	CORRECTIVE ACTION
N250	Door open while pumping	Pump door opened while operating.	Close door with cassette inserted.
N251	Cassette Test Failure	Faulty cassette, proximal or distal occlusion or air in cassette detected at start up.	Check clamps, manually reprime set, close door. Backprime into line B tubing or syringe if appropriate. If alarm recurs on retest, replace set. If alarm repeats, replace infuser.
N252	Depleted Battery	Too much time on battery power.	Plug into AC (mains) power.
N253	Hard lockout Violation	The use of the [STOP] key during delivery, or opening the door, while lockout is enabled.	Unlock lockout switch.
N254	Hard lockout Enabled	Pressing of any key except [STOP] during delivery while any alarm is active and lockout is enabled.	Unlock lockout switch.
N255	Soft lockout Violation	The use of the [STOP] key during delivery, or opening the door, while lockout is enabled.	Unlock lockout by pressing the decimal key, followed by 9, 6, & 3 on the keypad.
N256	Soft lockout Enabled	Pressing of any key except [STOP] during delivery while any alarm is active and lockout is enabled.	Unlock lockout by pressing the decimal key, followed by 9, 6, & 3 on the keypad.

Line A Alarms

CODE	Message	Possible Cause	CORRECTIVE ACTION
N105	Callback Line A	Alarm programmed by user. Change in delivery for Loading Dose to Maintenance Step or for any step in "Multistep" program provided the step is not the last step.	Press [SILENCE].
N161	Line A VTBI complete	VTBI complete on line A.	Program new VTBI.
N185	Prox Occl A At Startup	Proximal line obstructed, line A container (or syringe) disconnected or obstructed during non-delivery (startup).	Examine line A for kinks or closed clamps. If there are closed clamps, open the clamps. Then, open and close door. Continue programming. Replace set if problem persists.
PEIFF			If clamps are not opened prior to completion of cassette test, peak proximal occlusion may recur.
			For syringe, select ▲ [Backprime].

N184, N190, N191 N232 Prox Air A, Backprime Prox Occl A / Air Proximal line obstructed, line A container disconnect or obstruction. When proximal air detected exceeds the limit for the line. Check for clamps, or empty container. Correct as necessary. Backprime into line B tubing or syringe.	CODE	MESSAGE	Possible Cause	CORRECTIVE ACTION
Backprime detected exceeds the limit for the line. empty container. Correct as necessary. Backprime into line B	N190,		obstructed, line A container disconnect or	kinks, closed clamps,
TEARTH INNER CHAINING AND SAFETURE FROM TO THE PARTY OF T		Backprime	detected exceeds the limit for the line.	empty container. Correct as necessary. Backprime into line B
TE AFFE INDESTRUMENTS OF THE INDESTRICT OF THE INDESTRUMENTS OF THE INDE			detected exceeds the limit for the line.	empty container. Correct as necessary. Backprime into line B
TERIFIED EN ENTRINE EN ENTRINE EN E				A define a sur as intra la company
TERRIFE INNERINGERILE IN SITE			A COLORER	
TO STORINGS		4	Mall- Me Sit	90
		Main		
- // / - / / / / /				

Line B Alarms

CODE	Message	Possible Cause	CORRECTIVE ACTION
N104	Callback Line B	Alarm programmed by user. Change in delivery for piggyback delivery, Loading Dose to Maintenance Step, or for any step in "Multistep" program provided the step is not the last step.	Press [SILENCE].
N160	Line B VTBI complete	VTBI complete on line B.	Program new VTBI.
N183	Prox Occl B At Startup	Proximal line obstructed, line B container (or syringe) disconnected or obstructed during non- delivery (startup).	Examine line B for kinks or closed clamps. If there are closed clamps, open the clamps. Then, open and close door. Continue programming. Replace set if problem persists.
			If clamps are not opened prior to completion of cassette test, peak proximal occlusion may recur.
			For syringe, select [Backprime].

CODE	MESSAGE	Possible Cause	CORRECTIVE ACTION
N182, N188, N189	Prox Occl B / Air	Proximal line obstructed, line B container disconnected	Examine line B for kinks, closed clamps, or air in cassette.
		or obstructed.	Occlusion caused by empty container, backprime into line B tubing or syringe.
N231	Prox Air B, Backprime	When proximal air detected exceeds the limit for the line.	Check for clamps, or empty container. Correct as necessary. Backprime into line B tubing or syringe.

Malfunctions

CODE	MESSAGE	Possible Cause	CORRECTIVE ACTION
E300 or higher	Malfunction	A failure has occurred in the infuser's internal systems.	Record Malfunction error code. Pump must be turned OFF to clear malfunction. If alarm malfunction repeats, replace infuser.

General Messages

Message	Possible Cause	CORRECTIVE ACTION
Cannot Standby in Piggyback	Selection of [Standby] when Line B is in Piggyback Mode.	Select ▲ [Cancel/ Back].
Cannot Standby with Delay	Selection of [Standby] when Delay time was entered for program.	▲ [Cancel/Back].
Changing CCA clears program	Displays when other than last-used Care Area is highlighted.	N/A COLO
Change Conc clears entries	A program delivery which has been stopped and drug amount value is selected. This is displayed before any screen or field message.	User can enter new Concentration using keypad, or press [CLEAR] then make new entry.
Change units clears entries	A program delivery which has been stopped and user highlights another concentration unit for the same line.	User can select ▲ [Back] to exit, or use [SELECT] arrows to highlight a new value.
Change Vol clears entries	A program delivery which has been stopped and diluent value is selected. This is displayed before any screen or field message.	User can enter new Concentration volume using keypad, or press [CLEAR] then make another entry.

MESSAGE	Possible Cause	CORRECTIVE ACTION
Concurrency alert	Attempt to start a multistep or loading dose delivery whose later steps would exceed concurrent delivery limit if delivery proceeds.	User can enter new values using number keypad, or use [SELECT] arrows to move to another field to change the entry. User can also press [CLEAR]
Concurrency violation	Attempt to start a second line with a delivery rate that would exceed concurrent delivery upper limit immediately. Or, concurrent delivery attempt and rate for the second line is less than concurrent delivery lower limit. Takes precedence over "Rate must be > n mL/hr" message. The combined delivery rate must fall within the range of 1.0 mL/hr – 500 mL/hr or CCA-specific Maximum Volumetric Rate, with 0.5 mL/hr minimum per line.	User can enter new values using number keypad, or use [SELECT] arrows to move to another field to change the entry. User can also press [CLEAR].
Decimal point not allowed	Attempt to input Decimal point when either not used in field or a threedigit whole number already input.	Press [CLEAR] Hardkey.

		CORRECTIVE
Message	Possible Cause	ACTION
Dose > [X.xx]. Override?	Attempt to start program with parameter that has caused the Dose (or Rate, if mL/hr program) to be greater than the upper soft limit [uuuuuuuu] for the selected drug and CCA. Also includes placing program in Standby, and re-starting a stopped program.	May be overridden by selecting ▲ [Yes]. Cleared by pressing of [NUMERIC KEYS], [.], [SELECT], [CLEAR] or [STOP] hard keys, or ▲ [Yes/No] softkeys. Also cleared by the [ON/OFF] key when the line is stopped.
Dose < [X.xx]. Override?	Attempt to start program with parameter that has caused the Dose (or Rate, if mL/hr program) to be less than the lower soft limit [IIIIIIII] for the selected drug and CCA. Also includes placing program in Standby, and re-starting a stopped program.	May be overridden by selecting ▲ [Yes]. Cleared by pressing of [NUMERIC KEYS], [.], [SELECT], [CLEAR] or [STOP] hard keys, or ▲ [Yes/No] softkeys. Also cleared by the [ON/OFF] key when the line is stopped.
Hard Lockout Enabled	The Lockout Switch has been enabled, no Alarm is active, and any key besides Stop is pressed.	Disable the Lockout switch located on the back of the device. (See Section 3)
Illegal when Line Delivering	Attempt to select program other than Dose Calculation while a Basic program is delivering on this line.	Select ▲ [Cancel/ Back] or press [CLEAR]. Pressing [CLEAR] invokes another message.

Message	Possible Cause	CORRECTIVE ACTION
Input digits > max allowed	Attempt to input digit that would exceed the number of decimal places allowed for defined value except Dose and Rate.	Press [CLEAR] hardkey.
Input value > max allowed	Attempt to input number that would cause field to exceed its defined limit. In the Drug amount, Diluent amount, VTBI, Duration, Patient Weight, Distal pressure, and Delayed Start time fields, the Software shall display '', and the user must press the Clear hard key and input a valid value.	Press [CLEAR] hardkey
Maximum value reached	The display contrast/ intensity has reached its maximum value.	User can select ▲ [Enter] or ▲ [Cancel/Back].
Minimum value reached	The display contrast/ intensity has reached its minimum value.	User can select ▲ [Enter] or ▲ [Cancel/Back].
No delivery programmed	Delivery attempt at Main Delivery Screen when A and B have both Rate and VTBI equal to zero (no delivery programmed).	Select a line to program, or • [Options] or • [Backprime].
Rate must be > 0 mL/hr	Delivery attempt when VTBI is non-zero but rate is zero.	Use number keypad to enter a value.

MESSAGE Soft Lockout Enabled	POSSIBLE CAUSE While the Soft Lockout is	CORRECTIVE ACTION Disable the Soft
Soft Edekout Eliabled	enabled and no Alarm is active, either 1) any key besides Stop is pressed during delivery, or 2) any key is pressed while stopped.	Lockout. (See Section 3)
VTBI must be > 0	Delivery attempt when rate is non-zero but VTBI is zero.	Use number keypad to enter a value.
Value is too high	Attempt to move cursor from field whose input value is too high.	Use number keypad to enter a value.
Value is too low	Attempt to move cursor from field requiring a non-default value.	Use number keypad to enter a value.
Weight change affects Line A/B	Selecting the weight field on line while a weight- based program is entered on other line.	Use number keypad to enter a value.
Minimum Dose X.xx	Attempt to start program with Dose less than lower hard Dose limit n.nn.	Use number keypad to enter a value.
Maximum Dose X.xx	Attempt to start program with Dose greater than upper hard Dose limit n.nn.	The Software will display '', and the user must press the [CLEAR] hard key and input a valid
	Attempt to input a Dose greater than the upper Hard Limit.	value.

MESSAGE	Possible Cause	CORRECTIVE ACTION
Minimum Rate X mL/hr	Attempt to start mL/hr program with Rate less than lower hard Dose limit nn.n.	Use number keypad to enter a value.
Maximum Rate X mL/hr	Attempt to start mL/hr program with Rate greater than the upper Hard Limit or CCA Maximum Volumetric Rate n.	The Software will display '', and the user must press the [CLEAR] hard key and input a valid value.
	Attempt to input a Rate greater than the upper Hard Limit or CCA Maximum Volumetric Rate n.	

Section 8 Cleaning, Maintenance, and Storage

The cleaning, maintenance, and storage of the Plum A+ are described in this section.

CLEANING AND SANITIZING

For proper maintenance of the Plum A+, observe the following cleaning and sanitizing guidelines.

Establish a routine weekly schedule for cleaning the infuser. To clean, proceed as follows:

- Turn the Plum A+ off using the [ON/OFF] switch
- Disconnect from AC (mains) power

The exposed surfaces of the Plum A+ may be cleaned with a lint-free cloth dampened by one of the recommended cleaning solutions in the following list or mild, nonabrasive soapy water.

Clean the cassette door with a soft, lint-free cloth, dampened with one of the cleaning agents listed in the following table, or a mild solution of soapy water. Use a small non-abrasive brush to aid in cleaning the infusion system housing and subsystem chassis components. To thoroughly clean the cassette receptacle, disengage the cassette door from the door latch by pressing the door release tab.

CAUTION: DO NOT ALLOW CLEANING SOLUTIONS TO SATURATE THE AIR-IN-LINE DETECTORS OR ENTER THE DEVICE WHEN CLEANING THE AIR-IN-LINE DETECTORS.

CLEANING SOLUTION	Manufacturer	PREPARATION
Coverage TM HBV	Steris Corporation, A division of Calgon Vestal Laboratories	Per manufacturer's recommendation
Formula C TM	Diversey Corporation	Per manufacturer's recommendation
Dispatch [®]	Caltech Industries	Per manufacturer's recommendation
Precise [®]	Caltech Industries	Per manufacturer's recommendation
Household bleach	Various	Per hospital procedures; do not exceed one part bleach in ten parts water
Manu-Klenz®	Calgon Vestal Laboratories	Per manufacturer's recommendation
Sporicidin [®]	Sporicidin International	Per manufacturer's recommendation
Super Edisonite®	S. M. Edison Co.	Per manufacturer's recommendation

On a routine basis, clean all of the elements behind the cassette door using cotton-tipped swabs saturated with cleaning solution. The cassette door may be unlatched from the door handle to facilitate cleaning.

To unlatch the cassette door from its handle, tilt the device back, open the cassette door, then push the door release tab to open the door fully.

CAUTION: TO AVOID MECHANICAL OR ELECTRONIC DAMAGE, DO NOT IMMERSE THE PLUM A+ IN ANY FLUIDS OR CLEANING SOLUTIONS.

CAUTION: DO NOT SPRAY CLEANING SOLUTIONS TOWARD ANY OPENING IN THE INSTRUMENT.

CAUTION: CERTAIN CLEANING AND SANITIZING SOLUTIONS MAY SLOWLY DEGRADE COMPONENTS MADE FROM SOME PLASTIC MATERIALS. USING ABRASIVE CLEANERS OR CLEANING SOLUTIONS NOT RECOMMENDED BY HOSPIRA MAY RESULT IN PRODUCT DAMAGE, DO NOT USE COMPOUNDS CONTAINING COMBINATIONS OF ISOPROPYL ALCOHOL AND DIMETHYL BENZYL AMMONIUM CHLORIDE.

CAUTION: NEVER USE SHARP OBJECTS SUCH AS FINGERNAILS, PAPER CLIPS, OR NEEDLES TO CLEAN ANY PART OF THE INFUSER.

CAUTION: DO NOT STERILIZE BY HEAT, STEAM, ETHYLENE OXIDE (ETO), OR RADIATION.

CAUTION: TO AVOID INFUSER DAMAGE, CLEANING SOLUTIONS SHOULD ONLY BE USED AS DIRECTED. THE DISINFECTING PROPERTIES OF CLEANING SOLUTIONS VARY; CONSULT THE MANUFACTURER FOR SPECIFIC INFORMATION.

BATTERY MAINTENANCE

CAUTION: DO NOT OPERATE THE INFUSER ON PATIENTS WITH THE BATTERY REMOVED. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS CONFIRM PROPER OPERATION.

CAUTION: IF THE LOW-BATTERY ALARM SOUNDS, CONNECT TO AC (MAINS) POWER IMMEDIATELY.

The Plum A+ is battery powered for emergency backup and temporary portable operation. A fully charged, new battery provides 3 hours of operation at 125 mL/hr, or delivers 250 mL total volume if pumping at a rate of 126 mL/hr or greater, whichever occurs first.

NOTE: For optimum battery life, the Plum A+ should be operated on battery power for three continuous hours at least once every six months and then charged for a minimum of six hours.

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

As a general rule, the more often the battery is partially discharged and recharged, the sooner it will need to be replaced. Consult a qualified biomedical technician for battery replacement if necessary.

To maintain maximum battery charge and to prolong battery life, connect the infuser to AC (mains) power whenever possible.

When the infuser is used without wireless, the operation times may be proportionally longer.

STORAGE

To prolong the life of the Plum A+, observe the following storage precautions:

- · Store the away from excessive heat, cold, and humidity
- Store connected to AC (mains) power
- Switch the infuser OFF using the [ON/OFF] key

SERVICE

All servicing or adjustments to the Plum A+ should be referred to qualified technical personnel. A technical service manual may be ordered from the local Hospira sales office.

SECTION 9

Specifications

Physical

Dimensions: Approximately 8" X 8" X 6", excluding pole clamp

protrusion and power cord storage.

Weight: Approximately 9.5 lbs. with battery.

Casing: High-impact plastic.

Electrical

Power 120 V~, 50-60 Hz, 35 VA. Meets UL 60601-1.

Requirements:

Fuses: F1, F2, 250V~, 0.5 A. (internal)

Power Cord: Hospital-grade AC cord. 10 ft long, with

transparent plug and retainer plate.

Battery: One sealed, lead-acid, rechargeable 6 V battery,

internal to device.

Battery Life: With a new fully charged battery, the infuser

operates for a minimum of three hours at 125 mL/hr or less, or delivers 250 mL if > 126 mL/hr. (Time is measured from initial pumping to Depleted

Battery Alarm)

Recharge: The battery charges whenever the infuser is

connected to AC power. The recharge time is approximately six hours with the device operating

at 125 mL/hr on one line.

Electrical Meets IEC 60601-1 standard: Medical Electronic

Leakage: Equipment, Part 1: General Requirements for

Safety.

NURSE-CALL NURSE-CALL alarm is factory set for Normally-

System: Open (NO)

Contact the Technical Services Center to make an internal adjustment to change the device from Normally-Open (NO) to Normally Closed (NC)

system.

Circuitry Voltage-30 VDC Max
Ratings: Current 0.35 Amos A

gs: Current- 0.25 Amps Max

Contact Rating- 3 Watts Max

Wireless Lan Device

Standards: IEEE802.11b

Radio Technology: IEEE802.11b Direct Sequence

Spread Spectrum

Data Transfer 11, 5.5, 2, 1 Mbps (auto sense)

Rate:

FREQUENCY 2412 - 2462 MHz

RANGE

IEEE802.11b

Channels: 1-11 (FCC)

Transmit Power: 100mW (+20dBm) max

Antenna: Integrated surface mount antenna
Certifications: FCC Part 15.247 for US, IC

VTBI Range

VTBI Range: 0.1 to 99.9 mL (in 0.1 mL increments)

100 to 9999 mL (in 1 mL increments)

Environment

Operating 5° to 40° C

Temperature:

Storage -20° to 60° C

Temperature:

Atmospheric 0 - 10,000 feet (0 - 3,000m) or equivalent

Pressure: pressure

Relative Humidity: 10 - 90% (40° C Max)

Delivery Rate Range

Lines A and B: 0.1 - 99.9 mL/hr (in 0.1 mL increments)

100 - 999 mL/hr (in 1 mL increments)

Concurrent 0.5 mL/hr minimum for each line

Delivery: 500 mL/hr cumulative (A+B) maximum

PlumSet:

KVO: 1.0 mL/hr or the last primary delivery rate,

whichever is less

Air-in-Line Alarm

PlumSet (Distal): Bolus 0.1 mL (100 microliters) or larger for

delivery rates less than 500 mL/hr.

Bolus 0.5 mL (500 microliters) or larger for delivery rates equal to or greater than 500 mL/

hr.

Cumulative 0.25 mL out of 2.6 mL for delivery

rates less than 500 mL/hr.

Cumulative 0.50 mL out of 5.3 mL for delivery

rates equal to or greater than 500 mL/hr.

PlumSet Bolus at 0.5 mL, Total 1.0 mL

(Proximal):

Occlusion Alarm and Limits

Distal Occlusion: The DISTAL OCCLUSION alarm sounds after

the distal set tubing or set outlet fitting

becomes occluded.

Proximal The PROXIMAL OCCLUSION alarm sounds if **Occlusion:** the tubing proximal to the cassette becomes

occluded.

Distal Pressure

Limit

(without alarm):

Maximum Infusion

Pressure:

1 to 15 psig. The maximum pressure is userselectable. Factory default setting is 6 psig.

20 psig

Time To Detect Downstream Occlusions

RATE	OCCLUSION ALARM PRESSURE SETTING	TYPICAL TIME TO ALARM (MACRO)	MAXIMUM TIME TO ALARM (MACRO)
25 mL/hr	6 psig	38 seconds	47 seconds
	15 psig	98 seconds	106 seconds
1 mL/hr	6 psig	17 minutes	22 minutes
	15 psig	45 minutes	49 minutes

^{*} Baseline backpressure is 0 psig *

Bolus Volume Released After Downstream Occlusions Are Corrected

RATE	OCCLUSION ALARM PRESSURE SETTING	TYPICAL BOLUS VOLUME (MACRO)	Maximum Bolus Volume (Macro)
25 mL/hr	6 psig	0.23 mL	0.28 mL
	15 psig	0.55 mL	0.63 mL
1 mL/hr	6 psig	0.24 mL	0.30 mL
	15 psig	0.59 mL	0.70 mL

^{*} Baseline backpressure is 0 psig *

Delivery Accuracy

The Plum A+ Infuser was designed and manufactured to maintain a volumetric delivery rate error of the total fluid delivered of less than or equal to \pm 5% over the course of 48 hours at a programmed rate of 1 to 999 mL/hr during normal operating conditions. For use of the device at rates below 1 mL/hr, the delivery rate error is less than or equal to \pm 10%.

Backpressure Effect- Positive backpressure on the distal line may affect delivery accuracy by no more than 0.5% per psig (2% per psig for rates between 0.1 and 0.9 mL/hr) for backpressures up to 15 psig. A typical deviation under these conditions is 0.3%. Negative backpressure may affect delivery accuracy no more than 2% for pressures up to -2 psig (56 inches of water). A typical deviation under these conditions is 0.3%.

Filling Head Effect- Variations in filling head (such as container height) may affect delivery accuracy by no more than 2% for variations in the range -15 to +28 inches. A typical deviation under these conditions is 0.5%.

Concurrent Delivery Effect- When both lines (A & B) are delivering, the ratio of delivery for the fluid with the lowest rate may be affected by as much as 5% for ratios up to 9 to 1. For higher ratios, the absolute percentage of delivery for the lowest rate may be affected by no more than 0.5%. When air is present in the bubble trap, the absolute percentage of delivery for the lowest rate may be affected by up to 2.0%. When variations in container height are present, the absolute percentage of delivery for the lowest rate may be affected by up to 2.5% for up to 24 inches of container height differences.

Enteral & High Viscosity Fluids Effects

System delivery accuracy limits for each Enteral and High Viscosity Fluid, such as those listed in the following table, can be degraded by an additional maximum of 5%. System accuracy for Enteral Fluids is defined only for rates of 1 to 200 mL/hr, with no

suspended air in the solution, and using an Hospira Plum enteral set.

ENTERAL/HIGH VISCOSITY FLUIDS
Dextrose 20% to 50% concentration
Isomil Powder
Similac Powder
Ensure Plus HN
Twocal HN
Jevity

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: 1998, Sub-Clause 50.102. Refer to this standard for detailed information.

How to read a Trumpet Curve Graph (Refer to example on the following page): The graphs following the Example plot flow rates at 30 second intervals for the first 2 hours and for the 96th hour of delivery. The graph plots mean delivery rate error (Average of 3 infusers) for the 2nd hour and the 96th hour as a straight line. The graph also presents maximum and minimum average delivery rate error for this interval plotted by averaging delivery errors over intervals of 2, 5, 11, 19 and 31 minutes ("Trumpet Curve").

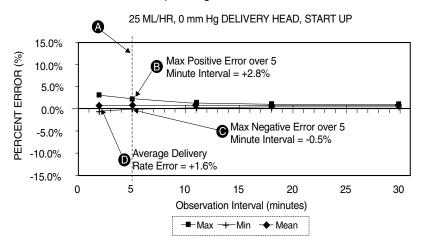
EXAMPLE

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

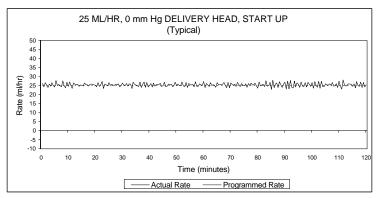
the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

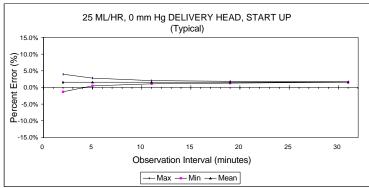
For other time intervals look at other points at the horizontal axis and determine corresponding limits as above.

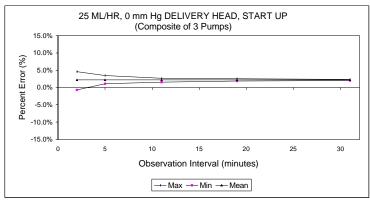


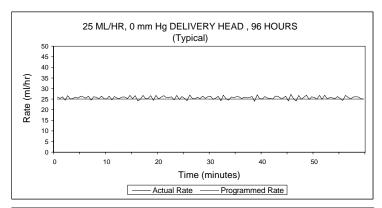
A trained professional can use the resulting graphs to select a infuser with the appropriate startup and flow characteristics to suit the clinical application.

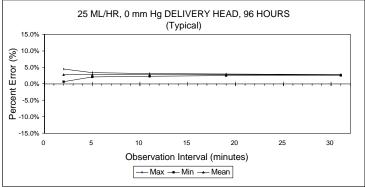
NOTE: As an example of how the trumpet curves can be used, consider the maximum and minimum deviations at the 5 minute average interval. The upper curve provides the maximum expected delivery rate error over a 5 minute interval, the lower curve provides the minimum expected delivery rate error over a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

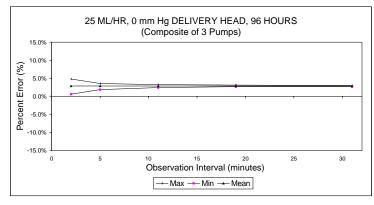




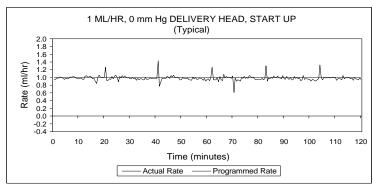


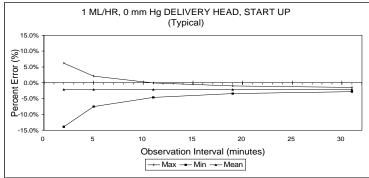


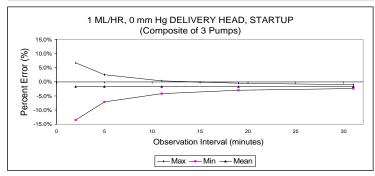


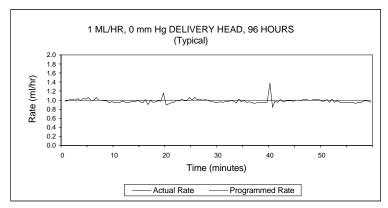


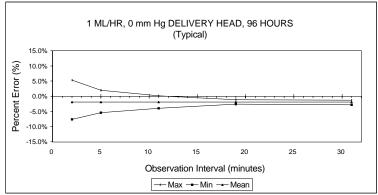
Plum A+ Infusion System

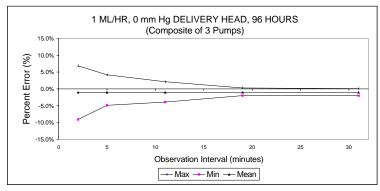












SECTION 10

Supplies and Accessories

Administration Fluids

ADMINISTRATION FLUIDS

- · All parenteral fluids
- Whole Blood
- Blood fractions

ENTERAL AND HIGH VISCOSITY FLUIDS

- Dextrose 20% to 50% concentration
- Isomil Powder
- Similac Powder
- Ensure plus HN
- TwoCal HN
- Packed red cells

CONTAINERS

- Dual Chamber Parenteral flexible container (Nutrimix)
- Large Volume Parenteral flexible plastic containers, including premixed
- Large Volume Parenteral glass containers, including premixed and nutritional
- Part Fill Parenteral flexible plastic containers, including ADD-Vantage
- Part Fill Parenteral glass containers
- Small Volume Parenterals
- Syringes (may require special adapters)
- Top Filled Enteral bags
- · Ready to hang Enteral solution containers

Accessories

GENERAL

- Syringe Adapter- List# 11986-48
- Mini Pole- List# 12096-04
- Secondary Container Support- List# 12095-03
- Tandem Carrier- List# 12270-01

NETWORKED APPLICATION

- Hospira MedNet[™] Medication Management Server Suite (MMSS)
 List# 20676-04
- *Hospira MedNet[™] Plug 'n Play Module List# 20677
- * = For use with Hospira Plum A+ Infusers Lists 11971-04-03 & above, 12391-04, & 20679-04

NOTE: Contact Technical Support Operations at **1-800-241-4002** for current listing of accessories.

Section 11 Warranty

Subject to the terms and conditions herein, Hospira, Inc., herein referred to as Hospira, warrants that (a) the product shall conform to Hospira's standard specifications and be free from defects in material and workmanship under normal use and service for a period of one year after purchase, and (b) the replaceable battery shall be free from defects in material and workmanship under normal use and service for a period of 90 days after purchase. Hospira makes no other warranties, express or implied, as to merchantability, fitness for a particular purpose, or any other matter.

Purchaser's exclusive remedy shall be, at Hospira's option, the repair or replacement of the product. In no event shall Hospira's liability arising out of any cause whatsoever (whether such cause be based in contract, negligence, strict liability, other tort, or otherwise) exceed the price of such product, and in no event shall Hospira be liable for incidental, consequential, or special damages or losses or for lost business, revenues, or profits. Warranty product returned to Hospira must be properly packaged and sent freight prepaid.

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, "major repair or other service" means any repair or service other than the

replacement of accessory items such as batteries and detachable mains power cords.

In providing any parts for repair or service of the product, Hospira shall have no responsibility or liability for the actions or inactions of the person performing such repair or service, regardless of whether such person has been trained to perform a. ing all and the property of the street of such repair or service. It is understood and acknowledged that

Default Drug Library (DDL)

NOTE: This list is only accurate if no custom drug library has been developed using the Hospira MedNetTM accessory. Once a custom drug library has been developed, this list will no longer be accessable. Only Hospira personnel can re-install the DDL.

The information contained in this manual is current as of 11/01/02. User must assure themselves that drug prescribing information has not changed since the publication of this manual.

Use drug manufacturer recommendations for IV administration when using the Plum A+ infusion infuser.

Drug Name	DEFAULT DOSE RATE	DEFAULT CONCENTRATION
No Drug Selected	mL/hr	N/A
Abciximab	mcg/kg/min	mg/mL
Acyclovir	mL/hr	N/A
Albumin	mL/hr	N/A
Aldesleukin	mL/hr	N/A
Alfentanil	mcg/kg/min	mcg/mL
Alteplase (rt-PA)	mg/kg/hr	mg/mL
Amikacin	mL/hr	N/A
Aminophylline	mg/hr	mg/mL
Amiodarone	mg/min	mg/mL
Amphotericin B	mL/hr	N/A
Ampicillin	mL/hr	N/A
Atracurium	mL/hr	N/A
Azithromycin	mL/hr	N/A

Drug Name	DEFAULT DOSE RATE	DEFAULT CONCENTRATION
Bleomycin	mL/hr	N/A
Blood Products	mL/hr	N/A
Bretylium	mg/min	mg/mL
Carboplatin	mL/hr	N/A
Cefazolin	mL/hr	N/A
Cefepime	mL/hr	N/A
CefoPERAZONE	mL/hr	N/A
CefoTAXIME	mL/hr	N/A
CefoTETAN	mL/hr	N/A
CefoXITIN	mL/hr	N/A
CeftAZIDime	mL/hr	N/A
CeftIZOXime	mL/hr	N/A
Ceftriaxone	mL/hr	N/A
Cefuroxime	mL/hr <	N/A
Cimetidine	mL/hr	N/A
Ciprofloxacin	mL/hr	N/A
Cisplatin	mL/hr	N/A
Clindamycin	mL/hr	N/A
Cotrimoxazole	mL/hr	N/A
Cytarabine	mL/hr	N/A
Diltiazem	mg/hr	mg/mL
DOBUTamine	mcg/kg/min	mg/mL
Docetaxel	mL/hr	N/A
DOPamine	mcg/kg/min	mg/mL
DOXOrubicin	mL/hr	N/A
Epinephrine	mcg/min	mg/mL
Epoprostenol	ng/kg/min	mg/mL
Eptifibatide	mcg/kg/min	mg/mL

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DRUG NAME	DEFAULT DOSE RATE	DEFAULT CONCENTRATION
Erythromycin	mL/hr	N/A
Esmolol	mcg/kg/min	mg/mL
Etoposide	mL/hr	N/A
Famotidine	mL/hr	N/A
Fentanyl	mL/hr	N/A
Fluconazole	mL/hr	S N/A
Flumazenil	mL/hr	N/A
Fluorouracil	mL/hr	N/A
Furosemide	mL/hr	N/A
Gatifloxacin	mL/hr	N/A
Gentamicin	mL/hr	N/A
Heparin	units/kg/hr	units/mL
Hydromorphone	mL/hr	N/A
Ifosfamide	mL/hr	N/A
Insulin	units/hr	units/mL
Labetalol	mg/min	mg/mL
Lepirudin	mg/kg/hr	mg/mL
Leucovorin	mL/hr	N/A
Levofloxacin	mL/hr	N/A
Lidocaine	mg/min	grams/mL
Lorazepam	mL/hr	N/A
Magnesium	grams/hr	grams/mL
Mannitol	grams/hr	grams/mL
Mesna	mL/hr	N/A
MethoHEXITAL	mL/hr	N/A
MethoTREXATE	mL/hr	N/A
Metoclopramide	mL/hr	N/A
Metronidazole	mL/hr	N/A

DRUG NAME	DEFAULT DOSE RATE	DEFAULT CONCENTRATION
Midazolam	mL/hr	N/A
Milrinone	mcg/kg/min	mg/mL
Morphine	mg/hr	mg/mL
Nafcillin	mL/hr	N/A
NitroGLYCERIN	mcg/min	mg/mL
NitroPRUSSIDE	mcg/kg/min	mg/mL
Norepinephrine	mcg/min	mg/mL
Ofloxacin	mL/hr	N/A
Ondansetron	mL/hr	N/A
Oxacillin	mL/hr	N/A
Oxytocin	mUn/min	units/mL
Paclitaxel	mL/hr	N/A
Pantoprazole	mg/min	mg/mL
Penicillin	mL/hr	N/A
Pentobarbital	mIJhr	N/A
Phenylephrine	mcg/min	mg/mL
Piperacillin	mL/hr	N/A
Potassium	mEq/hr	mEq/mL
Procainamide	mg/min	grams/mL
Propofol	mcg/kg/min	mg/mL
Ranitidine	mL/hr	N/A
STREPTOkinase	units/hr	units/mL
Theophylline	mg/kg/hr	mg/mL
Ticar-clavulanate	mL/hr	N/A
Tirofiban	mcg/kg/min	mg/mL
Tobramycin	mL/hr	N/A
UROkinase	mL/hr	N/A
Vancomycin	mL/hr	N/A

Drug Name	DEFAULT DOSE RATE	DEFAULT CONCENTRATION
Verapamil	mL/hr	N/A
VinCRIStine	mL/hr	N/A

Drafft IManigual Chinheal Shitulathorn.

NOTES

Drafft IMainulally Aleal Strulation.

Plum A+ Infusion System

For customer service within the United States, contact:

1-877-9-HOSPIRA (1-877-946-7747)

For technical assistance, product return authorization, and to order parts, accessories, or manuals within the United States, contact Hospira, Inc. Technical Support Operations:

1-800-241-4002

To order parts using the online eCatalog, download technical publications, technical training courses, and additional services, visit the website at:

www.hospiraparts.com

After authorization, ship prepaid product returns to the following address:

Hospira, Inc.
Technical Support Operations
755 Jarvis Drive
Morgan Hill. CA 95037

Outside the U.S., contact your local Hospira, Inc. sales office.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS INFUSER TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER LICENSED PRACTITIONER.

WARNING-

POSSIBLE EXPLOSION HAZARD EXISTS IF THE INFUSER IS USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

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Equipment providing adequate degree of protection against electrical shock and suitable for application to patient

Type CF

IPX1 Drip Proof Medical Equipment

Protected against dripping water

Class 1

Mains supply equipment using protective earth



The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL, i.e. 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.