

# LifeCare PCA™

Infuser

## System Operating Manual

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Compatible with:

ICU Medical MedNet™

For use with list number 20837-04 and  
list number 20709-04 upgraded with 7.x software

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# Change History

Title	Description of Change
<b>430-97354-002</b> <b>(A, 2017-01)</b>	<i>Added information for handling a suspected cybersecurity event or threat (Chapter 1)</i> <i>Updated manual priming instructions (Chapter 4)</i> <i>Updated cleaning and disinfecting instructions throughout the manual</i> <i>Updated contact information throughout the manual</i>
<b>430-97354-003</b> <b>(A, 2017-09)</b>	<i>Updated entire manual to reflect new ICU Medical corporate identity</i>

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**NOTES**

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# Chapter 1

## Introduction

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### Indications for Use

The LifeCare PCA™ infuser is intended for intravenous or epidural administration of analgesic medications that are delivered by a continuous rate of infusion and/or with patient demand doses.

**WARNING**



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

The LifeCare PCA infuser allows patients to self-administer analgesics with defined parameters using a push-button pendant attached to the device.

The LifeCare PCA is intended for the hospital environment and not for home use.

A primary feature of the LifeCare PCA infuser is the bar code reader, which is designed to automate medication and concentration identification. The bar code reader identifies all LifeCare PCA pre-filled medication vials. The ICU Medical MedNet™ Software allows the LifeCare PCA infuser to read pharmacy-generated bar codes on custom-filled vials. The vials are single-use and barcoded, and are either pre-filled with a medication, or are sterile empty vials which can be custom-filled by the hospital pharmacy ([see Appendix A Generating Bar Code Labels \(ICU Medical MedNet Software Enabled\)](#)).

All LifeCare PCA vials must have a bar code label that is read by the LifeCare PCA infuser. There is no ability to bypass the bar code reader and manually enter the medication into the LifeCare

## **Introduction**

PCA infuser ([see Appendix A Generating Bar Code Labels \(ICU Medical MedNet Software Enabled\)](#)).



**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER PRACTITIONER LICENSED BY THE LAW OF THE STATE IN WHICH HE/SHE PRACTICES TO USE OR ORDER THE USE OF THE DEVICE.**

## **LifeCare PCA Infusion System without ICU Medical MedNet Software**

As a standalone infuser, the LifeCare PCA infuser uses the Default Drug Library (DDL) to program therapies. The default drug library uses a single set of predefined rules for all medication settings ([see Appendix D Default Drug Library and Prescription Delivery Limits](#)).

## **LifeCare PCA Infusion System with ICU Medical MedNet Software**

The LifeCare PCA infusion system is used in conjunction with the server-based ICU Medical MedNet safety software. ICU Medical MedNet Software facilitates networked communication between the server and ICU Medical MedNet-compatible infusers.

The ICU Medical MedNet software enables facilities to define a drug library based on hospital best practices. A default drug library is active until a new drug library is downloaded to the infuser with ICU Medical MedNet Software. The customized drug library is downloaded into the infuser by authorized hospital personnel. Hospital personnel determine and select medications, concentrations, units of measure, lock-out intervals, dose, dose limits, and rule sets (upper and lower delivery parameters) available within a selected Clinical Care Area (CCA).

A hospital-defined drug library can define up to a maximum of 18 CCAs which can include up to 25 medication entries per CCA. The infuser requires a CCA to be selected prior to programming a dose. When the CCA is selected, the medication rule sets are configured for that CCA.

# List Number 20709-04 Upgraded to 7.x Software

Legacy LifeCare PCA infusion systems list number 20709-04 upgraded to 7.x software are substantially equivalent with list number 20837. Any differences associated with list number 20709-04 upgraded to 7.x software are documented in [Chapter 11 Information for Legacy LifeCare PCA Infusers Upgraded with 7.x Software](#).

## Conventions

The conventions listed in [Table 1-1](#) are used throughout this manual.

Table 1-1. Conventions		
Convention	Application	Example
ITALIC	Reference to a chapter, figure, or table	<i>(See Appendix A)</i>
[BRACKETED ALL CAPS]	Keys or buttons on the device are displayed in [BRACKETED ALL CAPS]	[ON/OFF]
<i>ITALIC SMALL CAPS</i> >	Softkey options	<i>PREVIOUS</i> >
SMALL CAPS WITH INITIAL UPPERCASE	Screen displays and device labels	SELECT DELIVERY MODE
<b>BOLD</b>	Emphasis	...SETS ARE SUPPLIED <b>STERILE</b> AND ARE FOR...

The following conventions are used to call attention to warnings, cautions, and notes:

**WARNING**

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

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## Introduction



**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.

Figures and graphics are rendered as representations to approximate the actual product, and may not exactly reflect the product.

## Product Description

The LifeCare PCA infuser features three infusion modes:

- Patient-Controlled Analgesia (PCA)
- PCA Plus Continuous
- Continuous

An optional dose (loading dose) can be programmed by the clinician at any time during therapy for additional pain relief.

The LifeCare PCA infuser is used in a wide range of clinical settings that include but are not limited to the following:

MEDICAL	LABOR/DELIVERY/ POST PARTUM	BURN UNIT
SURGICAL	OPERATING ROOM	ONCOLOGY
CRITICAL CARE UNITS	POST ANESTHESIA CARE UNIT (PACU)	PEDIATRICS

Features of the LifeCare PCA infuser include:

- Microprocessor-based infusion device with keypad controls
- Patient pendant
- Barcoded medication vial
- Compatible administration set

**Note:** The LifeCare PCA infuser contains a Connectivity Engine module that provides wired Ethernet and wireless 802.11 a/b/g local area networking capabilities. This allows the ICU Medical MedNet networked application software to download drug libraries to the infuser and enable the auto-programming feature.

- Ethernet port for computer or printer connections
- Nurse call interface

See [Appendix B Administration Sets and Accessories](#) for a list of compatible LifeCare PCA administration sets.

The LifeCare PCA infuser is intended to operate on AC power, and an internal battery is provided to maintain operation for short periods of time when AC power is not available.

The LifeCare PCA infuser is able to store frequently used prescriptions called protocols ([see Chapter 10 Protocols](#)). The protocols are available for LifeCare PCA pre-filled vials and custom-filled vials. The protocols must be set up by a hospital-designated authority in the Biomed Mode or through ICU Medical MedNet Software (if enabled).

## Patient Selection

Patients selected to use the LifeCare PCA infuser should be able to understand the relationship between pain and pushing the LifeCare PCA infuser patient pendant button for pain relief. Patients selected for the use of the LifeCare PCA infuser should be able to physically self-administer a PCA dose using the patient pendant.



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### WARNING

**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

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### WARNING

**EXERCISE CAUTION WHEN THE PATIENT IS AMBULATORY WHILE CONNECTED TO THE INFUSER.**

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## **Contraindications For Use**

The LifeCare PCA infuser should not be used for patient-controlled analgesia by patients who do not have the cognitive ability to understand the use of self-administered pain medication, nor have the physical capacity to operate the patient pendant, if required.

Medications that are not compatible with silicone rubber or PVC plastic, or are unstable under infusion conditions should not be used with this system.

Do not use medications that are contraindicated for use with the LifeCare PCA infuser (for example, blood products, enteral feedings and lipids, cytotoxic drugs, and high-viscosity fluids).

## **User Qualifications**

All clinicians should be appropriately trained to program the LifeCare PCA infuser prior to use. The LifeCare PCA infuser is intended for use at the direction or under the supervision of licensed physicians or certified health care professionals. Clinicians must be trained in infuser use, administration of parenteral and epidural fluids and medications, and the prevention of related IV complications and precautions to prevent accidental infusion of air. Training should emphasize the assessment and monitoring of patients receiving potent analgesic medications, and the appropriate treatment for possible adverse reactions.

## **Viewing the Display**

When operating the infuser, position yourself at a distance of no more than 39 inches (1 meter) from the display. Ensure you are directly in front of the display, or at an angle of no more than 25 degrees off this position.



## LifeCare PCA Pre-Filled Vials

LifeCare PCA pre-filled vials are available for standalone infusers and ICU Medical MedNet-enabled infusers. The LifeCare PCA infuser's bar code reader identifies the bar code and displays the medication name and concentration of that pre-filled vial.

The following LifeCare PCA pre-filled medication vials are FDA approved for use with the LifeCare PCA infuser:

- Morphine Sulfate 1 mg/mL
- Morphine 5 mg/mL
- Meperidine Hydrochloride 10 mg/mL

### **WARNING**

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**FAILURE TO USE A COMPATIBLE LIFECARE PCA VIAL, INJECTOR, AND ADMINISTRATION SET WITH AN INTEGRAL PRESSURE ACTIVATED VALVE MAY CAUSE AN INACCURATE DOSE DELIVERY TO THE PATIENT.**

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The LifeCare PCA pre-filled sterile empty vials are made of USP Type 1 glass with a silicone rubber stopper.



**CAUTION: FOR ADMINISTRATION OF A MEDICATION VIA A STERILE EMPTY VIAL, REVIEW THE MEDICATION PACKAGE INSERT TO ENSURE VIAL COMPATIBILITY AND STABILITY OF THE MEDICATION FOR THE DURATION OF ADMINISTRATION. CONSULT WITH PHARMACY.**

## **Pharmacy-Filled (Custom) Vials**

Custom vials are sterile empty 30 mL vials which are filled by the hospital pharmacy and labeled with a unique bar code. A pharmacy-filled (custom) vial offers your facility the flexibility to infuse medications per your facility's practice.

### **For standalone infusers without ICU Medical MedNet Software**

The LifeCare PCA infuser reads the bar code on the custom-filled vial, displays the medication name as **OTHER DRUG**, and prompts the clinician to enter the concentration.

### **For infusers using ICU Medical MedNet Software**

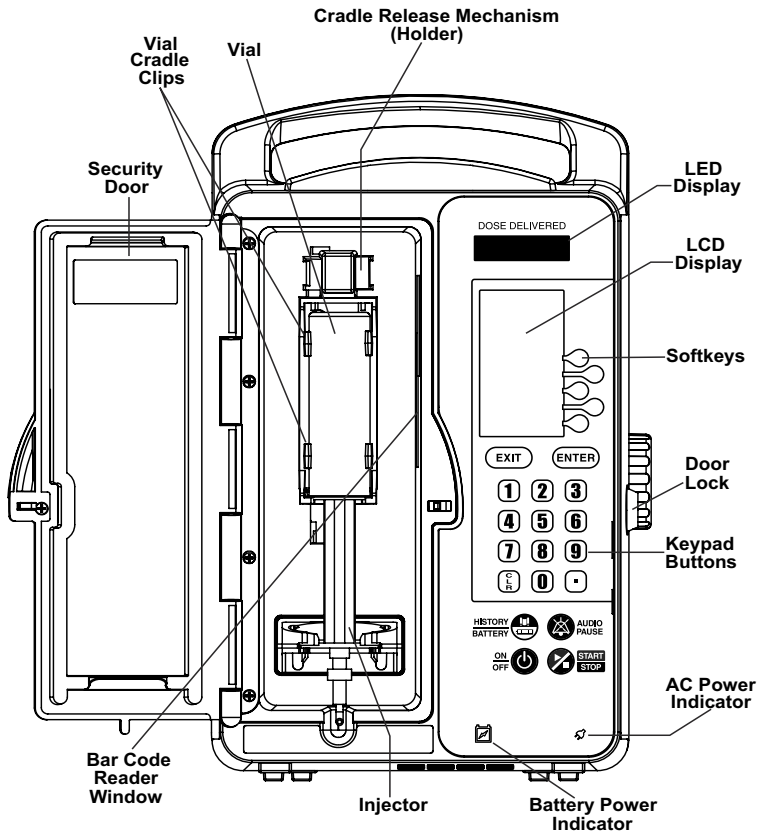
ICU Medical MedNet Software allows the LifeCare PCA infuser to read the pharmacy-generated bar code on the custom-filled vial. The bar codes are linked to the rule sets within the ICU Medical MedNet Software. This ensures that when the custom-filled vial is inserted into the infuser, the displayed medication and concentration are linked to the corresponding rule set.

# Equipment Description

This section shows the front view, vial cradle assembly, rear view, and buttons and keys of the infuser.

## Front View

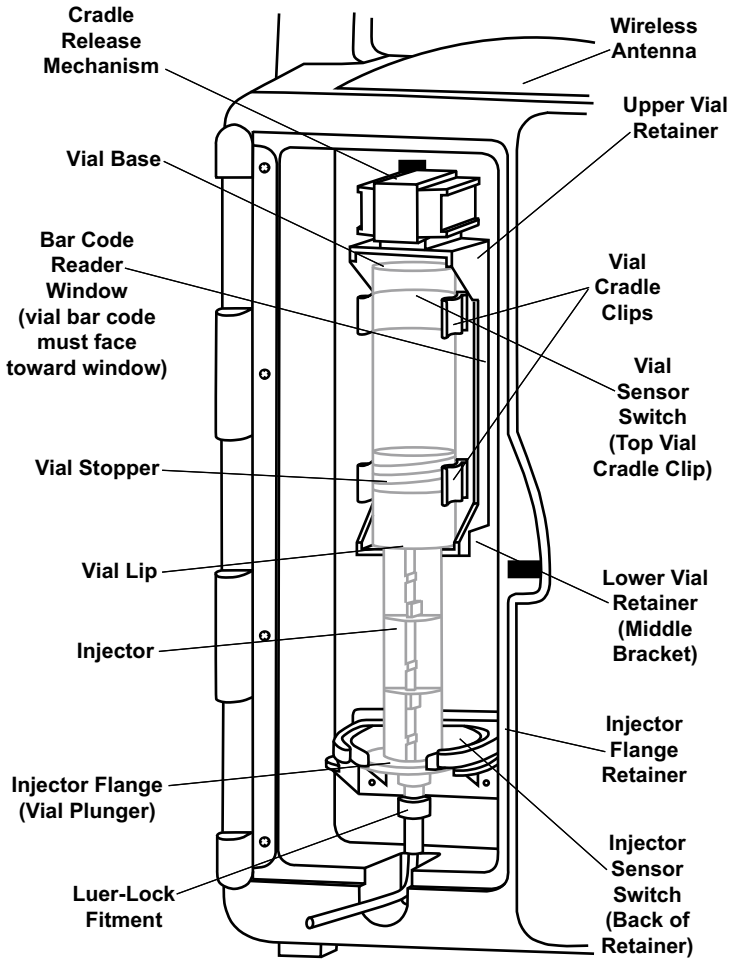
**Figure 1-1** shows the front view of the LifeCare PCA infuser.



**Figure 1-1. Front View**

# Vial Cradle Assembly

**Figure 1-2** shows a detailed view of the LifeCare PCA vial cradle assembly.



**Figure 1-2. Vial Cradle Assembly**

## Rear View

Figure 1-3 shows the rear view of the LifeCare PCA infuser.

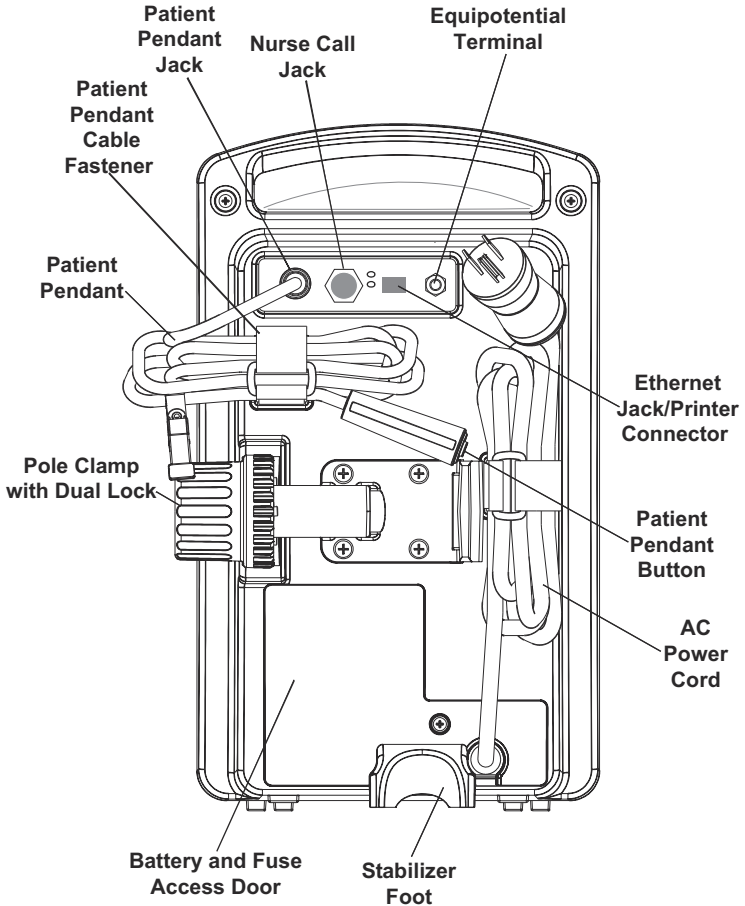


Figure 1-3. Rear View

**Note:** The pole clamp is locked when the security door is closed and locked. The infuser cannot be removed from an IV pole without a key.

# Equipotential Terminal

The equipotential terminal (*see Figure 1-3*) is used to ensure that the infuser is at the same electric potential (voltage) as the other devices in the treatment location. Ideally, the electrical potential is at zero volts, so that no current can inadvertently flow from one device to another through a patient.

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

Disconnect the power cord from the wall outlet for complete isolation from mains power.

## Patient Pendant

The LifeCare PCA patient pendant (*see Figure 1-4*) is used by the patient to deliver medication upon the press of the button.

If the patient pendant button is partially pressed, a **PENDANT FAULT** message will appear. This can be corrected by releasing the button. A PCA bolus will not be delivered during a Pendant Fault condition.

### **WARNING**

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**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

---

### **WARNING**

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**BEFORE CONNECTING THE PATIENT PENDANT TO THE UNIT, CHECK THE CONDITION OF THE PATIENT PENDANT CORD FOR DAMAGE AND CONFIRM THAT THE CONNECTOR IS NOT BENT. WHEN REMOVING THE PATIENT PENDANT CORD FROM THE UNIT, FIRMLY GRASP THE CONNECTOR AND PULL STRAIGHT OUT. DO NOT USE IF DAMAGED.**

---



**CAUTION: USE ONLY THE LIFE CARE PCA PATIENT PENDANT (BLUE HANDLE). THE LIFE CARE PCA PLUS II PATIENT PENDANT (WHITE HANDLE) WILL NOT WORK WITH THIS DEVICE.**

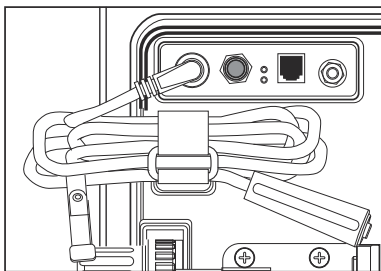


Figure 1-4. Patient Pendant



**CAUTION: DO NOT BEND THE PATIENT PENDANT CORD NEAR THE PATIENT PENDANT OR CONNECTOR JACK AT AN ANGLE OF 90° OR GREATER.**

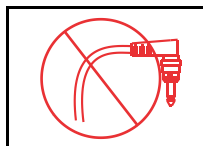
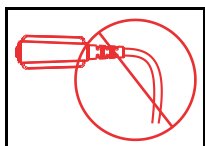


Figure 1-5.  
Patient Pendant Cord and Connector Jack

## Buttons and Keys

**Table 1-2** describes LifeCare PCA infuser buttons and keys.






Table 1-2. Buttons and Keys	
 The icon shows the text "ON" above "OFF" next to a power button symbol.	The <b>[ON/OFF]</b> button controls the power of the LifeCare PCA infuser
 The icon shows the letters "CLR" in a vertical stack inside a rounded rectangular button.	The <b>[CLEAR]</b> button is used to clear an entry
 The icon shows the word "ENTER" in a rounded rectangular button.	The <b>[ENTER]</b> button is used to select and accept various screen options
 The icon shows the word "EXIT" in a rounded rectangular button.	The <b>[EXIT]</b> button is used to return to the main display from non-programming screens
 The icon shows a bell symbol with a diagonal line through it, next to the text "AUDIO PAUSE".	The <b>[AUDIO PAUSE]</b> button is used to temporarily silence an alarm



Table 1-2. Buttons and Keys




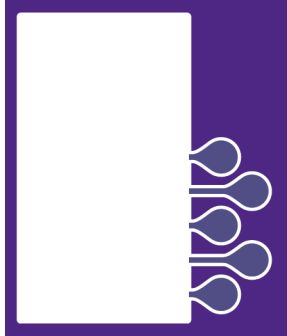



 <p>The image shows a square button with a light purple background. On the left is a circular icon with a green play button symbol and a red stop symbol. To the right of the icon, the word 'START' is written in white on a green rectangular background, and the word 'STOP' is written in white on a red rectangular background.</p>	<p>The <b>[START/STOP]</b> button is used to start or stop a continuous infusion or PCA bolus</p>
 <p>The image shows a square button with a light purple background. On the left, the words 'HISTORY' and 'BATTERY' are stacked vertically in blue, underlined text. On the right is a circular icon containing a battery strength indicator (four bars) and a wireless signal strength indicator (three curved lines).</p>	<p>When pressed, the <b>[HISTORY/BATTERY]</b> button displays the battery strength icon and wireless strength icon</p> <p>In addition, <b>[HISTORY/BATTERY]</b> is used to display parameter settings, dose history, review Rx, and review the event log</p> <p>This button also provides access to the <i>PRINT HISTORY</i> softkey</p> <p><b>Note:</b> Print History is available for standalone infusers without ICU Medical MedNet</p>
 <p>The image shows a purple numeric keypad. At the top are two buttons labeled 'EXIT' and 'ENTER'. Below them are three rows of three buttons each, labeled with numbers 1 through 9. At the bottom left is a button labeled 'CLR' (with 'C' above 'L' above 'R') and a button with a decimal point symbol '.'.</p>	<p>The <b>numeric buttons</b> are used to enter values for any field requiring numeric data</p> <p>The <b>[DECIMAL POINT]</b> button is used when entering numbers with a decimal point (such as 10.5 mg)</p>







Table 1-2. Buttons and Keys

	<p>When pressed, the <b>softkeys</b> to the right of the main display perform a variety of functions correlating to the description displayed on the screen</p>
	<p>The <b>battery indicator</b> illuminates continuously when the infuser is running on battery power</p>
	<p>The <b>AC (mains) power indicator</b> illuminates when the infuser is plugged into AC power</p>
	<p>LED displays the <b>dose delivered</b>. A vertical “walking stick” appears on the right side of the display when a dose is delivered in micrograms The walking stick appears on the left side of the display when a dose is delivered in milligrams</p>

## Battery Charge Level

To access the battery charge level indicators, press the [HISTORY/BATTERY] button.






**Table 1-3** describes each battery indicator icon and its associated battery life, power level, and alarm state.

Table 1-3. Battery Charge Levels		
Indicator	Description	Alarm State
	<b>Fully Charged</b> - 76% to 100% capacity	<b>None</b>
	<b>Three-fourths</b> - 51% to 75% capacity	<b>None</b>
	<b>Half</b> - 26% to 50% capacity	<b>None</b>
	<b>5 Minutes</b> - 1% to 25% capacity Plug in the AC power cord immediately; infuser is about to shut down	<b>Low</b>
	<b>Empty</b> - 0% capacity Empty indicator is displayed when the <b>Low Battery</b> alarm occurs, until the infuser shuts down due to depleted battery	<b>High</b>
	<b>No Battery Installed</b> The <b>Battery Fault</b> alarm displays when no battery is installed	<b>High</b>

## Wireless Strength

To access the wireless strength indicators, press the [HISTORY/BATTERY] button.

**Table 1-4** describes the wireless strength indicator icons.

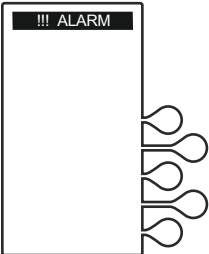
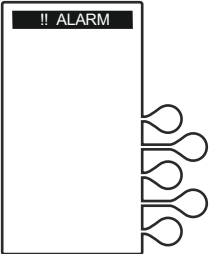
<b>Table 1-4. Wireless Strength Indicators</b>	
	<b>Excellent strength</b>
	<b>Good strength</b>
	<b>Fair strength</b>
	<b>Poor strength</b>
	<b>No signal available</b>

## Alarm Treatment

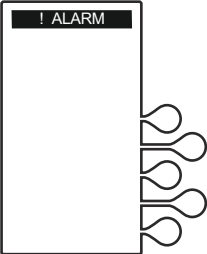
Alarms are defined as High, Medium, and Low priority. High, medium, and low priority alarm screens display three, two, or one exclamation points, respectively, to indicate alarm priority.

**Note:** The alarm message text will alternate its display over the currently displayed screen. When an alarm is cleared, the infuser returns to the screen that was displaying when the alarm occurred.

**Table 1-5** describes the high, medium, and low priority alarm indicators.

<b>Table 1-5. Alarm Priority Indicators</b>		
	<p><b>High Priority</b></p> <p>The screen flashes rapidly and the infuser emits an audible alarm of ten beeps, with an interval of approximately 4 seconds between each audible sequence</p> <p>The 3 exclamation marks (to the left of the centered screen name <b>ALARM</b>) represent a high priority alarm</p>	<p><b>High</b></p>
	<p><b>Medium Priority</b></p> <p>The screen flashes at a moderate pace, and the infuser emits an audible alarm of three beeps, with an interval of approximately 5 seconds between each audible sequence</p> <p>The 2 exclamation marks (to the left of the centered screen name <b>ALARM</b>) represent a medium priority alarm</p>	<p><b>Medium</b></p>

**Table 1-5. Alarm Priority Indicators**

	<p><b>Low Priority</b></p> <p>The screen flashes at a slower pace, and the infuser emits an audible alarm of two beeps, with an interval of approximately 15 seconds between each audible sequence</p> <p>The 1 exclamation mark (to the left of the centered screen name <b>ALARM</b>) represents a low priority alarm</p>	<p><b>Low</b></p>
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## Epidural Administration



**CAUTION: FOLLOW THE GUIDELINES IN THIS SECTION ALONG WITH HOSPITAL POLICY AND PROCEDURES FOR EPIDURAL ADMINISTRATION.**

Recommended use of the epidural route is to provide anesthesia or analgesia for periods up to 96 hours.

It is strongly recommended that the infusion system be prominently identified as **EPIDURAL**. Failure to identify the infusion system as epidural could result in incorrect administration of intravenous rather than epidural formulations. In addition, failure to identify the epidural infusion system could result in confusion with other infusion systems delivering concomitant intravenous formulations.

When used for epidural administration, this device can only be used to administer those anesthetics/analgesics approved for epidural administration (as indicated or allowed by the medications' FDA approved labeling or Health Canada approved labeling). Epidural administration of medications other than those indicated for epidural use could result in serious injury to the patient.

For epidural administration, the use of administration sets without Y-sites and labeled FOR EPIDURAL USE, indicating ongoing epidural administration, are recommended.

Administration of medications via the epidural route should be limited to personnel familiar with associated techniques and patient management. 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 medications. Adequate monitoring equipment 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 medication administration by the epidural route.



**CAUTION: DELAYED RESPIRATORY DEPRESSION FOLLOWING CONTINUOUS EPIDURAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE HAS BEEN REPORTED.**

Pressure buildup during epidural 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 over delivery occurs during administration, observe the patient closely for signs of spinal cord compression (disorientation, headache, transient neuralgias) and medication overdose.

# **Electrical Artifacts**

This section addresses electrical artifacts and their remedies.

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 LifeCare PCA Infusion 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 those 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 the patient or clinician.

This equipment has been tested and found to comply with the EMC limits as specified in IEC 60601-1-2:2007. 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 causes harmful interference with radio, television, or other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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



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



**CAUTION: USE 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.**



**CAUTION: MAINTAIN A MINIMUM SEPARATION DISTANCE OF 2 1/2 FEET BETWEEN THE INFUSION SYSTEM AND PORTABLE/ MOBILE RF COMMUNICATIONS EQUIPMENT.**

List number 20837 has been tested and found to comply with EMC limits as specified in IEC/EN 60601-1-2:2007.

For more information, see [Contact Information](#).

## **Interconnecting of Equipment**

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC Standards (for example, IEC 60950 for data processing equipment and IEC 60601-1 for Medical Equipment). If in doubt, consult the technical service department or your local representative.

## **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 requires precautions regarding electromagnetic compatibility, and must 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 the following 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 LifeCare PCA 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 Biomed for additional information in the **LifeCare PCA Technical Service Manual** concerning operating devices near RF sources.

## **FCC Information**



### **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 which 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.



**CAUTION: IF NOT INSTALLED AND USED IN ACCORDANCE WITH THE INSTRUCTIONS, THE INFUSER MAY CAUSE HARMFUL INTERFERENCE TO RADIO COMMUNICATIONS AND/OR OTHER DEVICES.**

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try 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 the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by ICU Medical could void the user's authority to operate the equipment.

## **Wireless Device Caution**

The wireless 802.11 a/b/g device usage in the 5150-5250 MHz band is limited to indoor use to reduce potential for harmful interference to co-channel mobile satellite systems.

In the 5250-5350 MHz and 5650-5850 MHz frequency bands, high power radars are allocated as primary users and these radars could cause interference and/or damage to LE-LAN devices.

Operation is subject to the following two conditions:

- (1) The wireless device may not cause interference,  
and
- (2) The wireless device must accept any interference,  
including interference that may cause undesired  
operation of the wireless device.

## **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.

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 inch human body separation from the antenna and it was found to be compliant with FCC RF exposure limits.

# **Suspected Cybersecurity Event or Threat**

The section contains information on the recommended procedure upon detecting a suspected cybersecurity event or threat.

1. Contact hospital and/or follow hospital guidelines to report the suspected cybersecurity event or threat.

Attempts to exploit a remote vulnerability on an infusion device would require penetration of several layers of network security enforced by the hospital, including firewalls. These measures serve as the primary defense against tampering with a medical device.

2. **Contact ICU Medical** to report the suspected cybersecurity event or threat.

## Warnings and Precautions

ICU Medical will be responsible for the safety effect, reliability, and performance of this device only if adjustments, modifications, or repairs are performed by persons authorized by ICU Medical, electrical setup at the point of use complies with appropriate local requirements, and the device is used in accordance with the instructions for use identified in this operating manual.

Hospital policies and guidelines must always be followed to ensure patient safety and to minimize the potential for patient hazards.

The LifeCare PCA infuser is not intended to be used for frequent, long-term portable operation. Keep the device plugged into a properly grounded AC receptacle whenever possible, and reserve battery power for temporary portable operation and emergency backup. If the AC receptacle is in doubt, use battery power.

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**WARNING**



**EXPLOSION HAZARD EXISTS IF THE INFUSER IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES.**

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**WARNING**



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

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**WARNING**



**DO NOT USE THE INFUSER IN AN MRI ENVIRONMENT OR IN THE PRESENCE OF STRONG MAGNETIC FIELDS. SERIOUS INJURY OR DAMAGE TO EQUIPMENT MAY RESULT.**

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## Introduction

### WARNING



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

### WARNING



DO NOT EXPOSE THE INFUSER DIRECTLY TO X-RAYS OR ULTRASOUND. PERMANENT DAMAGE TO THE INFUSER'S ELECTRONIC CIRCUITRY MAY OCCUR.

### WARNING



POTENT ANALGESIC MEDICATIONS ARE USED WITH THIS DEVICE. REFER TO THE MEDICATION PACKAGE INSERT FOR PRECAUTIONS, POSSIBLE ADVERSE REACTIONS, AND/OR INCOMPATIBILITY WITH FLUID OR MEDICATION BEING DELIVERED THROUGH THE IV LINE. PERFORM CLOSE ASSESSMENT AND MONITORING OF PATIENTS RECEIVING POTENT ANALGESIC MEDICATION FOR POSSIBLE ADVERSE REACTIONS.

### WARNING



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

### WARNING



THE PATIENT MUST BE DISCONNECTED FROM THE INFUSER BEFORE THE PRIME CYCLE.

### WARNING



MODIFICATION OF THIS EQUIPMENT IS PROHIBITED AND MAY IMPACT DEVICE PERFORMANCE.



**CAUTION:** USE PROPER CARE DURING UNPACKING AND INSTALLATION TO PREVENT DAMAGE. CONTACT ICU MEDICAL AND DO NOT USE THE INFUSER IF IT APPEARS DAMAGED IN ANY WAY.



**CAUTION:** DO NOT PLACE THE LIFECARE PCA INFUSER IN SERVICE IF IT FAILS THE SELF TEST.



**CAUTION:** COUPLING TOGETHER OF MORE THAN ONE INFUSER INTO ONE PATIENT LINE MAY SIGNIFICANTLY AFFECT THE INFUSION RATE OF AT LEAST ONE OF THE INFUSERS.





**CAUTION: DO NOT USE SHARP OBJECTS SUCH AS PENS, SCISSORS, OR FINGERNAILS TO PRESS KEYS. SUCH OBJECTS MAY DAMAGE KEYS AND CAUSE A MALFUNCTION.**



**CAUTION: REMOVE ALL AIR FROM THE VIAL AND ADMINISTRATION SET PRIOR TO PLACING THEM INTO THE INFUSER.**



**CAUTION: ALWAYS CLOSE THE SLIDE CLAMP ON THE INFUSER ADMINISTRATION SET BEFORE REMOVING OR REPLACING THE SYRINGE, AND BEFORE DISCONTINUING INFUSION.**



**CAUTION: THE VIAL AND INJECTOR MUST BE SECURELY LOCKED INTO THE INFUSER BEFORE BEGINNING DELIVERY.**

## **Malfunction Alarm**

If the **MALFUNCTION** alarm message displays and an audible alarm sounds, press the **[ON/OFF]** button to turn off the infuser, then turn the infuser back on. If the **MALFUNCTION** alarm repeats, remove the infuser from service and send it to Biomed.

# Battery Operation



**WARNING**

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**UNPLUG THE AC POWER CORD BEFORE REMOVING THE BATTERY DOOR.**

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**CAUTION: WHEN THE LIFECARE PCA INFUSER IS CONNECTED TO A PATIENT, DO NOT OPERATE THE INFUSER WITH THE BATTERY REMOVED. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS ENSURE PROPER OPERATION.**

The battery may not be fully charged upon receipt. Connect the LifeCare PCA infuser to AC power for at least 16 hours.

Use AC power whenever possible. Connect to AC power during storage to ensure a fully charged battery during a power outage.

Always connect the infuser to a properly grounded receptacle unless battery operation is desired. If quality earth grounding source is in doubt, use battery power.

If the low battery alarm sounds, connect to AC power immediately.



**WARNING**

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**THE INFUSER CANNOT COMMUNICATE VIA THE NETWORK IF THE LOW BATTERY WARNING ALARM HAS SOUNDED.**

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## Chapter 2

# Setup and Operation

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This chapter describes general setup and operation of the LifeCare PCA infuser, including attaching the infuser(s) to an IV pole, configuring infusers on an IV pole, priming a vial and a LifeCare PCA administration set, loading a vial, removing or changing a vial, and powering the infuser on and off.

## Prior to First Use

Before placing the infuser into service for the first time, the only preparation needed is to have a biomedical technician customize the default settings according to the facility's needs, clean the infuser, and then fully charge the battery. See the *LifeCare PCA Infuser Technical Service Manual* for more information.

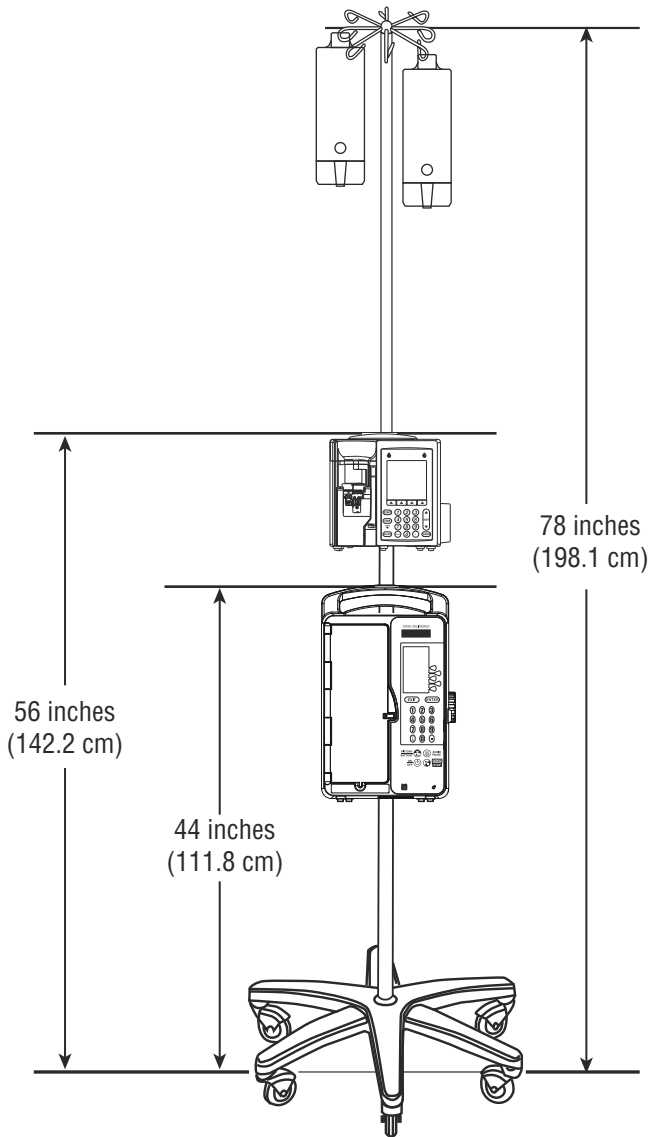
## Infuser Configurations on an IV Pole

A heavy duty IV Pole with locking casters (list number 39001-21) has been tested for stability according to the requirements of IEC 60601-1:2012. An IV pole with six locking casters should be used on inclined surfaces ([see Appendix B Administration Sets and Accessories](#)).

To maintain the stability of the pump configuration, the LifeCare PCA infuser and a general infusion IV pump are mounted on an IV pole at the maximum mounting heights shown in [Figure 2-1](#). Verify stability before use.

**Note:** After attaching the LifeCare PCA infuser to the IV pole, check to ensure the infuser is stable. Tighten the pole clamps and check the mounting heights and the extension height of the IV pole until the assembly is stable.

**Setup and Operation**



**Figure 2-1. Infuser Configurations on an IV Pole**

## Attaching an Infuser to an IV Pole

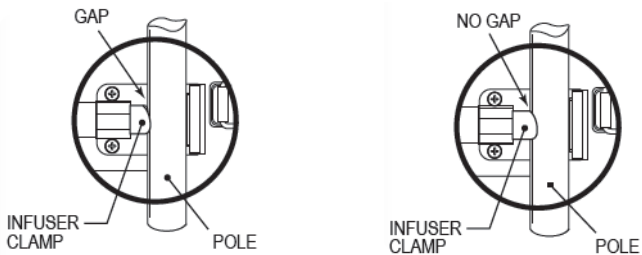
The LifeCare PCA infuser uses a locking pole clamp to prevent unauthorized removal of the infuser from the IV pole. The PCA key must be placed in the lock and turned to the unlocked position for attaching and removing the infuser from an IV pole.



**CAUTION: TO PREVENT PERSONAL INJURY OR PRODUCT DAMAGE, ENSURE THE POLE CLAMP IS TIGHTENED PROPERLY AND THE INFUSER IS SECURELY ATTACHED. DO NOT USE TOOLS TO TIGHTEN THE POLE CLAMP.**

To attach an infuser to an IV pole:

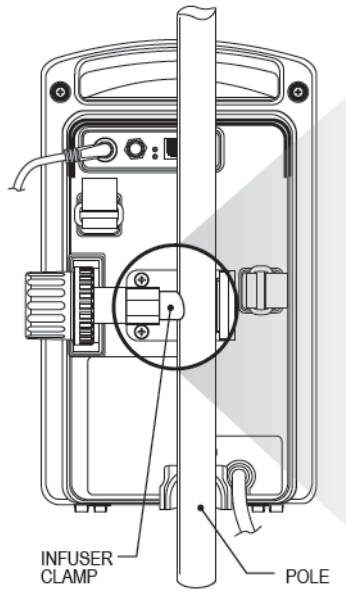
1. Ensure that the IV pole is assembled correctly, the wheels are locked, and the pole is on a flat surface.
2. Ensure that the infuser is unplugged and that the security door is unlocked.
3. Grasp the infuser by the handle, then place the IV pole inside the infuser's pole clamp.
4. Support the infuser with one hand and use your other hand to turn the pole clamp knob clockwise. Secure the infuser against the IV pole and tighten the clamp. Make sure that there is no gap between the pole and the infuser clamp (*see Figure 2-2*).



**Figure 2-2. Attaching an Infuser to an IV Pole**

## Setup and Operation

5. Press down and pull up on the infuser to confirm that it is clamped tightly to the IV pole with no vertical or rotational slippage (see [Figure 2-3](#)). If the infuser is not clamped tightly, realign the infuser with the IV pole and tighten the pole clamp knob.



**Figure 2-3. Clamping an Infuser to an IV Pole**

**Note:** Once the door is locked, the pole clamp locks the infuser to the IV pole, preventing the infuser from being removed from the IV pole without the key.

## **Removing an Infuser from an IV Pole**

To remove an infuser from an IV pole:

1. Ensure that the tubing and LifeCare PCA administration set is disconnected from the patient.
2. Verify that the security door is unlocked.
3. Ensure that the infuser is unplugged. Grasp the infuser by the handle and turn the pole clamp knob counterclockwise.
4. With the pole clamp retracted, remove the infuser from the pole.

## **Administration Sets**

LifeCare PCA administration sets are disposable and designed for single-patient use. Fluid pathways and surfaces beneath unopened protective covers are sterile and nonpyrogenic in intact packaging marked sterile.

Follow hospital procedures for disposing and handling of administration sets. Do not discard administration sets with regular trash.

For a complete list of compatible administration sets for use with the LifeCare PCA infusion system, see [\*Appendix B Administration Sets and Accessories\*](#).

**WARNING**

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**FAILURE TO USE A COMPATIBLE LIFECARE PCA VIAL, INJECTOR, AND ADMINISTRATION SET WITH AN INTEGRAL PRESSURE ACTIVATED VALVE MAY CAUSE AN INACCURATE DOSE DELIVERY TO THE PATIENT.**

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**WARNING**

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**ICU MEDICAL RECOMMENDS THAT HIGHLY VISCOUS SOLUTIONS AND MEDICATIONS, COLLOIDAL SUSPENSIONS, AND EMULSIONS SHOULD NOT BE DELIVERED THROUGH THE INLINE BACKCHECK VALVE OF THE LIFECARE PCA INFUSER SET. VALVE FUNCTIONALITY MAY BE COMPROMISED BY THE PRESENCE OF RESIDUE.**

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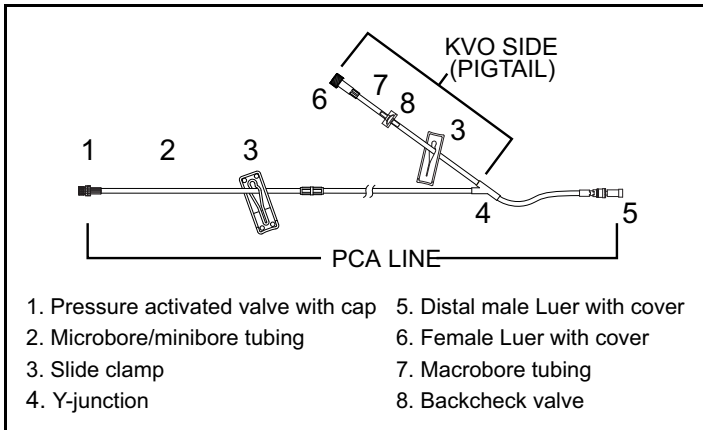


**CAUTION: INSPECT THE CONNECTION BETWEEN THE ADMINISTRATION SET AND ANY ACCESSORIES, AND BETWEEN THE ACCESSORIES OR ADMINISTRATION SET TO THE PATIENT, TO ENSURE THERE ARE NO LEAKS.**

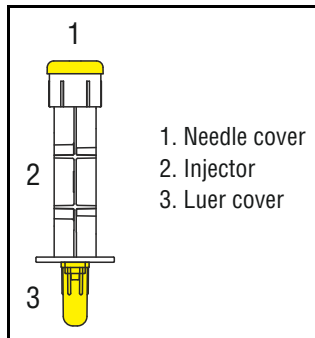


## LifeCare PCA Infusion System

The LifeCare PCA administration set shown in **Figure 2-4** is available in varying configurations and can be used in any delivery mode. **Figure 2-5** shows the injector assembly.



**Figure 2-4. LifeCare PCA Administration Set**



**Figure 2-5. Injector Assembly**

# Priming the Administration Set



**CAUTION: ALWAYS PRIME THE ADMINISTRATION SET TO REMOVE AIR FROM THE SET PRIOR TO CONNECTING TO THE PATIENT.**

## Manually Priming the Administration Set

Prior to priming, inspect the vial for damage, including leaks and cracks, and inspect the administration set for anomalies and/or irregularities.

Use aseptic technique with all fluid path connections when handling or priming the administration set to assist with contamination prevention.

To manually prime the administration set, see [Figure 2-4](#) and [Figure 2-5](#), and proceed as follows:

1. Remove the yellow caps from the vial and the needle cover of the injector.
2. Attach the injector to the vial, turning clockwise until secure.
3. Remove the luer cover from the injector and slowly depress the flange on the injector to remove excess air from the vial.
4. Connect the Pressure Activated Valve (PAV) female end of the set to the injector.
5. Close the green slide clamp on the KVO (Keep Vein Open) side of the LifeCare PCA administration set ([see Figure 2-4](#)).

**Note:** Prime the KVO side per administration set instructions.

6. Invert the vial and administration set, holding the vial vertically on a flat surface, with the administration set pointing up from the top of the syringe.
7. Using two hands, slowly depress the flange on the injector and prime past the Y on the administration set.

8. Close the orange (or white) slide clamp on the PCA side of the administration set.
9. To prime the KVO side of the set, ensure that the orange (or white) side clamp is closed on the PCA side. Open the green slide clamp on the KVO side. Attach the primed administration set or pre-filled syringe to the female adapter and prime the KVO side until fluid is observed at the distal end of the administration set.

**Note:** If the cap at the end of the set becomes wet, it must temporarily be removed to continue priming.

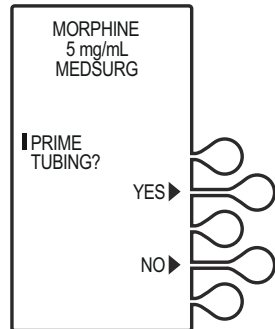
## **Priming the Administration Set on the Infuser**

To prime an administration set using the infuser's **Prime** feature, complete programming, then close and lock the door to begin the priming sequence.

The tubing will prime at a rate of 250 mL per hour.

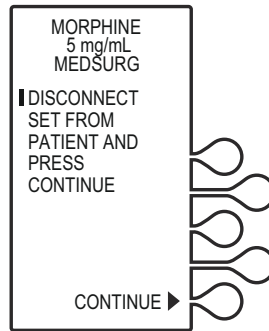
1. Ensure that the door is closed and locked. The **PRIME TUBING?** screen displays. Select **YES>**.

If **NO>** is selected, the infuser will prompt you to press the **[START]** button to begin delivery.



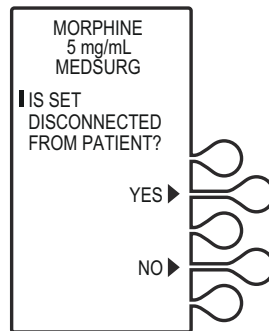
## Setup and Operation

- The **DISCONNECT SET FROM PATIENT** screen displays. Disconnect administration set from patient and press **CONTINUE**.

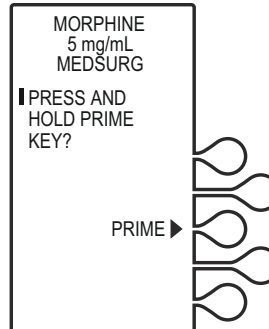


- Confirm the administration set is disconnected from the patient, then select **YES**.

If **NO** is selected, the infuser will prompt you to disconnect the set from the patient.



- Press and hold the **PRIME** key until fluid is seen at the distal end of the tubing.

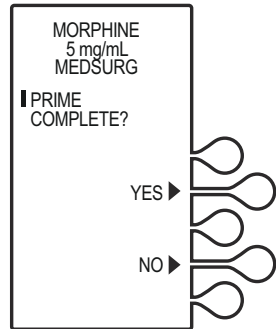


5. The **PRIME COMPLETE?** screen displays.

Priming is complete when all air has been removed and fluid is observed at the end of the administration set.

If prime is complete, select **YES>** to continue.

If air is observed in the administration set, select **NO>** to return to previous screen and continue priming.

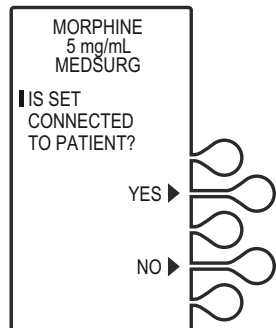
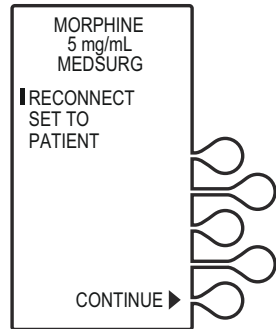


6. Once air is removed from the tubing and priming is complete, the **RECONNECT SET TO PATIENT** screen displays. Reconnect the set to the patient and press **CONTINUE>**.

**Note:** Prime the pigtail of the LifeCare PCA set per administration set instructions prior to connecting the set to the patient.

7. Confirm the administration set is connected to the patient, then select **YES>**.

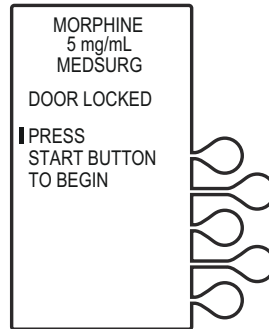
If **NO>** is selected, the infuser will prompt you to connect the set to the patient.



## Setup and Operation

8. The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.

If a loading dose was programmed, the loading dose will infuse. Once the loading dose is delivered, the infuser prompts the user to press **[START]** to begin delivery of the Continuous Only or PCA + Continuous program.



## Loading a Vial

To load a vial, see [Figure 2-6](#), and proceed as follows:

1. Squeeze the cradle release mechanism together at the top of the holder and move to the uppermost position.



**CAUTION: GRASP THE CRADLE RELEASE MECHANISM AND SQUEEZE COMPLETELY. CONTINUE TO SQUEEZE THE RELEASE MECHANISM DURING MOVEMENT OF THE CRADLE. A GRINDING SOUND SHOULD NOT BE AUDIBLE AND THE RELEASE MECHANISM SHOULD SLIDE FREELY TO PREVENT DAMAGE.**

**Note:** Always verify that the bar code reader window is clean before inserting the vial.

2. Insert the bottom of the glass vial into the middle black bracket, ensuring that the bar code label faces the bar code reader on the right side of the vial compartment.



**CAUTION: DO NOT POSITION THE VIAL INTO THE UPPER VIAL CLIP FIRST. THE VIAL LIP MAY CRACK OR CHIP.**

3. Gently press the upper end of the glass vial into the upper black bracket.

4. Squeeze the top of the cradle release mechanism and move down until the vial injector snaps into the bottom bracket.



**CAUTION: GRASP THE CRADLE RELEASE MECHANISM AND SQUEEZE COMPLETELY. CONTINUE TO SQUEEZE THE RELEASE MECHANISM DURING MOVEMENT OF THE CRADLE. A GRINDING SOUND SHOULD NOT BE AUDIBLE AND THE RELEASE MECHANISM SHOULD SLIDE FREELY TO PREVENT DAMAGE.**

5. Select **CONTINUE>**.
6. If the vial bar code is not read by the infuser, slowly rotate the vial and position it with the bar code on the right until the bar code has been read.



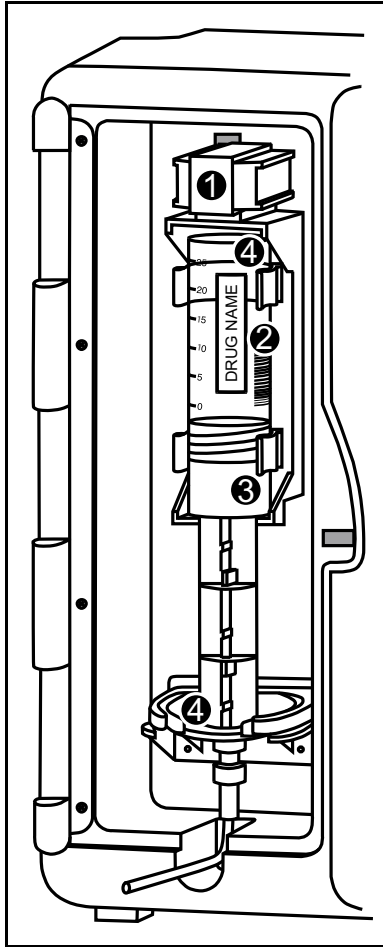
**CAUTION: VIAL AND INJECTOR MUST BE SECURELY LOCKED INTO THE INFUSER BEFORE BEGINNING DELIVERY.**



**WARNING** \_\_\_\_\_  
**CRACKED VIALS MAY NOT SHOW EVIDENCE OF LEAKAGE UNTIL DELIVERY PRESSURE IS APPLIED.**

---

**Note:** If the device is off, improper loading of the syringe turns on the device and activates a non-silenceable **CHECK INJECTOR** alarm within 30 seconds after **CONTINUE>** is selected. Proper loading (engaging injector flange) silences the alarm.



**Figure 2-6. Loading a Vial**



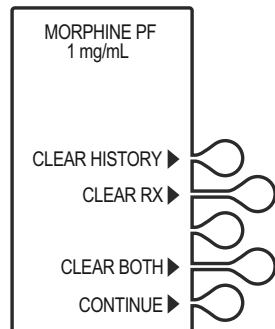
# Vial Changes and Discontinuing Therapy

This section applies to both standalone infusers and ICU Medical MedNet enabled devices.



## Changing or Removing a Vial with the Same Medication and Concentration

1. When the vial is empty, the alarm message **EMPTY SYRINGE** appears along with the statement **REPLACE SYRINGE**.
2. Press the **[START/STOP]** button to pause the infusion. The screen displays that the infusion has stopped.
3. Close the slide clamp on the LifeCare PCA administration set prior to handling the vial, then unlock the door.
4. Remove the old vial by firmly grasping the vial on both sides and pulling straight out.
5. Load the new vial (*see [Loading a Vial](#)*).
6. The screen displays options to **CLEAR HISTORY**, **CLEAR RX**, **CLEAR BOTH**, or **CONTINUE**. Press **CONTINUE>**.

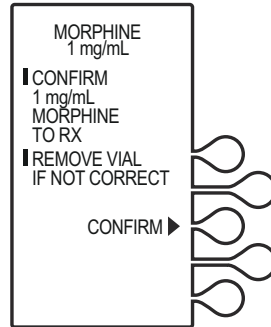


## Setup and Operation



**CAUTION: VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**

7. Verify the medication and concentration, then select **CONFIRM>**.
8. Close and lock the door and press **[START]**.



## Changing or Removing a Vial with Different Medication and/or Concentration

1. When the vial is empty, the alarm message **EMPTY SYRINGE** appears along with the statement **REPLACE SYRINGE**.

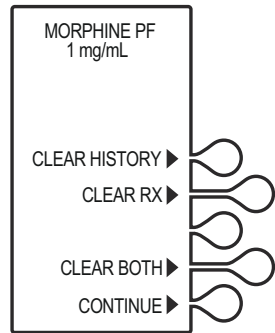
**Note:** The vial may or may not be empty when changing to a different medication and/or concentration.

2. Press the **[START/STOP]** button to pause the infusion. The screen displays that the infusion has stopped.
3. Close the slide clamp on the LifeCare PCA administration set prior to handling the vial, then unlock the door.
4. Remove the old vial by firmly grasping the vial on both sides and pulling straight out.
5. Load the new vial ([see Loading a Vial](#)).

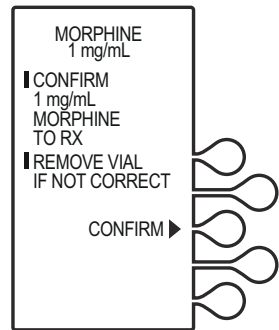
- The screen displays options to **CLEAR HISTORY**, **CLEAR RX**, **CLEAR BOTH**, or **CONTINUE**. Press **CONTINUE**> to automatically clear the current program.

**Note:** Press **CLEAR HISTORY**> to clear stored infusion events.

**CAUTION:**  
 **VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



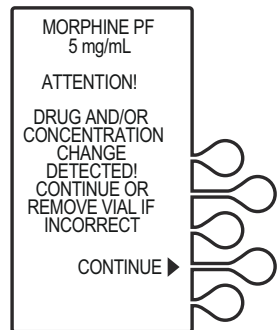
- Verify the medication and concentration, then select **CONFIRM**>.



- The **ATTENTION! DRUG AND/OR CONCENTRATION CHANGE DETECTED!** screen appears, indicating a vial is loaded with a new medication and/or concentration.

**Note:** Remove the vial if incorrect.

- Press **CONTINUE**>.
- Program according to the new physician order.



## Discontinuing a PCA Therapy

1. Stop the infuser by pressing the [START/STOP] button.
2. Close the slide clamp on the LifeCare PCA administration set.



**WARNING** —————  
**ALWAYS CLOSE THE SLIDE CLAMP ON THE LIFECARE PCA ADMINISTRATION SET BEFORE REMOVING OR REPLACING THE SYRINGE, AND BEFORE DISCONTINUING INFUSION.**  
—————

3. Unlock the door.
4. Press the [ON/OFF] button.
5. Disconnect the medication and administration set from the patient.

**Note:** Discard vial and administration set per hospital protocols.

6. Remove the vial by firmly grasping the glass vial on both sides and pulling straight out, and dispose per facility policy.
7. Clean and store the infuser.



**CAUTION: TO PROLONG THE LIFE OF THE LIFECARE PCA INFUSER, ICU MEDICAL RECOMMENDS STORING THE INFUSER CONNECTED TO AC (MAINS) POWER.**

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# Chapter 3

## Modes of Delivery

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### Modes of Delivery

The LifeCare PCA infuser delivers analgesia in one of three modes:

- **PCA ONLY**
- **CONTINUOUS ONLY**
- **PCA + CONTINUOUS**

To program these modes for LifeCare PCA infusers using ICU Medical MedNet Software, see [Chapter 4 Programming Infusers with ICU Medical MedNet Software](#).

To program these modes for standalone LifeCare PCA infusers, see [Chapter 5 Programming Infusers without ICU Medical MedNet Software](#).

### PCA Only

A patient-initiated dose may be administered using the patient pendant when the **PCA AVAILABLE** message appears. After completing the dose, the infuser enters either the preset **Lockout Interval** or the **Dose Limit Reached** state (if a dose limit has been entered). Further delivery is prohibited in both of these conditions.



**WARNING**

**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

Interrupting delivery by pressing **[START/STOP]**, opening the door, loss of power, reaching the dose limit, emptying the vial, or a malfunction alarm may result in partial doses.

## ***Modes of Delivery***

The screen message alerts the user that the LifeCare PCA infuser is not available, and a different audible tone occurs if the patient pendant button is pressed (unless deactivated in Biomed Mode).

**Note:** On infusers with the default drug library, dose limit periods are specified as 1 and 4 hours. On infusers with a user-defined drug library, dose limit periods may be defined as 1, 4, 6, or 12 hours.

## **Continuous**

A programmed Continuous infusion is started by pressing **[START/STOP]** after the door is closed and locked. The patient pendant is disabled in the Continuous mode. Upon reaching the dose limit, if entered, the infuser stops drug delivery, and displays the designated **HR LIMIT REACHED** message.

**Note:** On infusers with the default drug library, dose limit periods are specified as 1 and 4 hours. On infusers with a user-defined drug library, dose limit periods may be defined as 1, 4, 6, or 12 hours.

**Note:** In Continuous or PCA + Continuous modes, the **[START/STOP]** button must be pressed within 30 seconds of locking the door or the infuser sounds an alarm.

## **PCA + Continuous**

A programmed PCA + Continuous infusion is started by pressing [START/STOP] after the door is closed and locked. Once the **PCA AVAILABLE** message appears, the patient may initiate a PCA dose by pressing the patient pendant button.



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**WARNING**

**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

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When the patient-initiated dose is activated, the PCA dose is delivered prior to the Continuous infusion rate. After the PCA dose is completed, the infuser enters the lockout interval. While in the lockout period, the Continuous infusion remains in progress, but the patient-initiated dose cannot be activated. If a dose limit has been reached, the infuser stops all drug delivery.

**Note:** On infusers with the default drug library, dose limit periods are specified as 1 and 4 hours. On infusers with a user-defined drug library, dose limit periods may be defined as 1, 4, 6, or 12 hours.

**Note:** In Continuous or PCA + continuous modes, the [START/STOP] button must be pressed within 30 seconds of locking the door or the infuser sounds an alarm.

## Dose Limit

To program a dose limit, see [Chapter 4 Programming Infusers with ICU Medical MedNet Software](#) or [Chapter 5 Programming Infusers without ICU Medical MedNet Software](#).

The dose limit is a value prescribed by the physician to limit the total dosage delivered in a 4-hour or 1-hour period. This optional feature provides added safety that limits the total drug delivered in all three delivery modes.

**Note:** On infusers with the default drug library, dose limit periods are specified as 1 and 4 hours, or as No Dose Limit. On infusers with a user-defined drug library, dose limit periods may be defined as 1, 4, 6, or 12 hours, or as No Dose Limit.

The LifeCare PCA Infuser is factory set to program a 4 hour dose limit. For the purpose of simplifying this section, examples are written for a 4 hour dose limit program.

When the sum of all doses (PCA dose, Continuous dose, and any applicable loading or supplemental loading dose) in a rolling 4 hour period equals or exceeds the 4 hour dose limit, the patient's requests for PCA doses are denied, and a **4 HR LIMIT REACHED** message appears. In all modes, the infuser stops delivery when the 4 hour dose limit is reached, except during administration and delivery of a supplemental loading dose.



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# Chapter 4

## Programming Infusers with ICU Medical MedNet Software

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This chapter describes how to program the LifeCare PCA infuser with the ICU Medical MedNet custom drug library. The drug library is based on hospital-defined best practices and is customized and downloaded into the infuser by authorized hospital personnel.

Programming instructions will be provided for the following:

- Loading Dose
- PCA Only
- PCA + Continuous
- Continuous Only

For more information on each of the delivery modes and dose limits, see [Chapter 3 Modes of Delivery](#).

The following is consistent throughout all programming:

- To correct an entry during programming, press [CLR], re-enter the value, then press [ENTER].
- During initial programming, select **PREVIOUS>** to return to the preceding display and enter the desired setting. Each time **PREVIOUS>** is selected, the message display reverts to the previous setting, until the first setting is displayed.
- Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.

# Warnings and Cautions

This section presents known infuser programming cautions.

## **WARNING**

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**FOR CUSTOM SYRINGES, CONFIRM THAT THE DISPLAYED CONCENTRATION (mg/mL) OR (mcg/mL) EXACTLY MATCHES THE CONCENTRATION VALUE AND MEDICATION NAME ON THE SYRINGE. IF THEY DO NOT MATCH, UNDER/OVERDOSAGE MAY RESULT.**

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- In the Continuous and PCA + Continuous modes, if the system is not primed after a syringe change, the infuser automatically performs a small system compliance step to remove slack when the [START/STOP] key is pressed (with the door locked).
- Although fluid is not normally delivered to the patient during the compliance step, under some conditions up to 0.3 mL of fluid may be delivered. If 0.3 mL of fluid represents a hazard to the patient, disconnect the set during this operation.
- At flow rates less than 0.5 mL/hr, there may be a significant delay before flow is established if the system is not primed.
- Selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values.
- Perform close assessment and monitoring of patients receiving potent analgesic medication for possible adverse reactions.
- The LifeCare PCA infuser is not intended to be used for frequent, long-term portable operation. Keep the device plugged into a properly grounded AC receptacle whenever possible, and reserve battery power for temporary portable operation and emergency backup. If the AC receptacle is in doubt, use battery power.

## Loading Dose/Dose Limits

- The loading dose is always included in the total dose delivered.
- Setting a new dose limit will not erase the previous dose history.

## Patient Pendant



**CAUTION: DO NOT BEND THE PATIENT PENDANT CORD NEAR THE PATIENT PENDANT OR CONNECTOR JACK AT AN ANGLE OF 90° OR GREATER.**

Use only the LifeCare PCA blue patient pendant.



**WARNING** \_\_\_\_\_  
**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

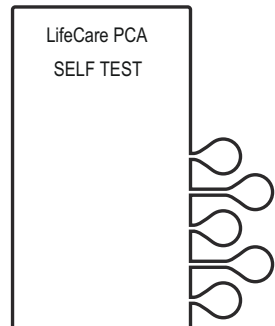
## System Settings

Select **SYSTEM SETTINGS** to change display contrast and time and date. **SYSTEM SETTINGS** is available at power on.

Once the system settings are changed, the infuser retains the new settings.

1. Press **[ON/OFF]** to turn on the infuser.

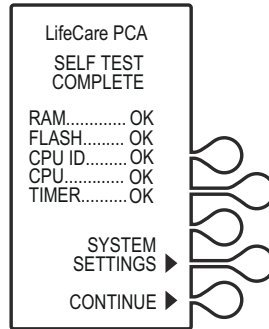
Upon initial start up, the self test begins.



## Programming Infusers with ICU Medical MedNet Software

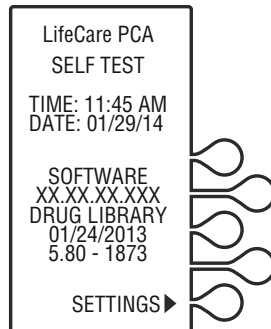
### 2. If the infuser is running 7.01 software:

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **SYSTEM SETTINGS>** to view the **SELECT SETTING TO CHANGE** menu.

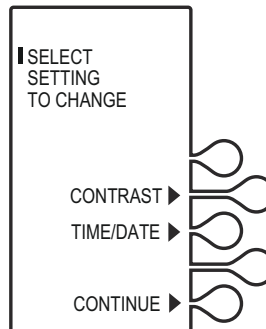


### If the infuser is running 7.02 software or higher:

The Software Version screen will display instead of the **SELF TEST COMPLETE** screen and will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

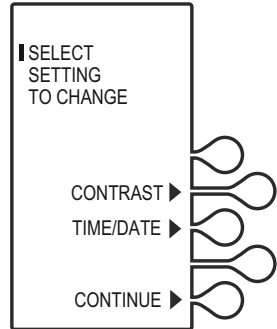


### 3. Select the **CONTRAST>** or **TIME/DATE>** softkey to adjust the setting.

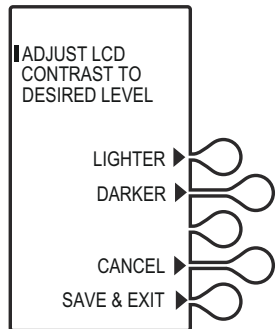


## Adjusting Contrast of Main Display

1. Select **CONTRAST**.



2. Press the **LIGHTER** or **DARKER** softkey repeatedly until contrast is optimized for viewing, then select **SAVE & EXIT**.



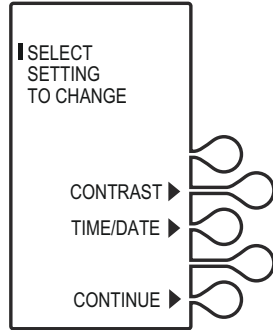
## Adjusting Time and Date

**WARNING**

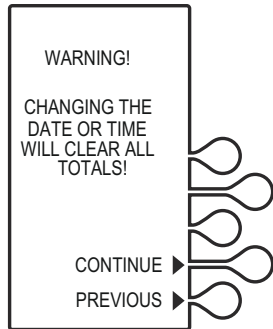


**CHANGING THE TIME OR DATE WILL CLEAR ALL TOTALS. THE CURRENT PROGRAM WILL REMAIN INTACT WHEN THE TIME/DATE FUNCTION IS ACCESSED. LOCKOUTS OR LIMITS IN PLACE WHEN THE TIME/DATE IS CHANGED WILL REMAIN IN EFFECT.**

1. Select **TIME/DATE**>, then select **CONTINUE**>.



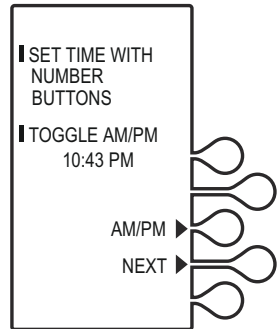
2. A **WARNING!** screen indicates that changing the date or time will clear all totals. When the **WARNING!** screen appears, select **CONTINUE**>.



- Using the numeric keypad, set the time in four-digit format (HH:MM). For example, enter 10:43 PM as 10:43.

Select **AM/PM** to alternate between AM and PM.

Time may be displayed using the 12 or 24 hour clock. The default setting is the 12 hour clock. The clock selection option is available in the **Biomed Mode**.

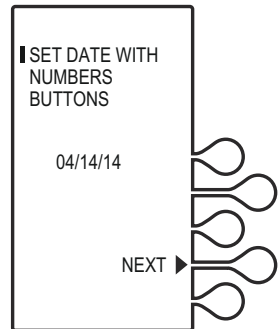


- After setting the time, select **NEXT** to set the date.

- Using the numeric keypad, set the date in MM/DD/YY format. For example, enter April 14, 2014 as 04/14/14.

The current setting for the date will flash.

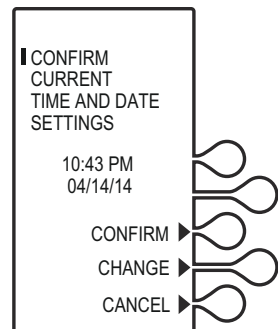
Date must be entered in MM/DD/YY sequence.



- Select **NEXT** again after changing to the desired date.

The confirmation screen appears. Select **CONFIRM** to verify the changed settings.

- Select **CONTINUE** to exit the **SELECT SETTING TO CHANGE** menu and display the vial confirmation screen (if the vial is loaded properly).



# Programming a PCA Therapy

For detailed startup information including vial insertion, clearing settings, and setting a Loading Dose, see [Loading a Vial](#).

## Turning On the Infuser

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the [ON/OFF] button,

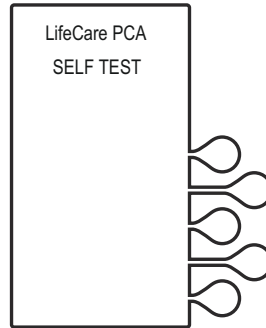
or

Loading the medication vial into the cradle will automatically power on the infuser ([see Loading a Vial](#)).

## Programming a Loading Dose

1. Power on the infuser. Upon initial start up, the self test begins.

This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.

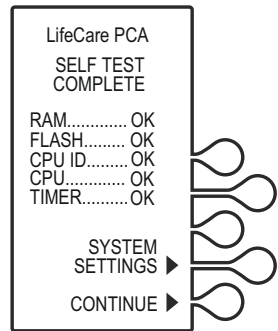




2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



**If the infuser is running 7.02 software or higher:**

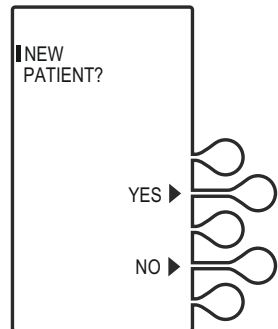
The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.

If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and Rx settings are retained.

In this example, the **YES>** option is selected.



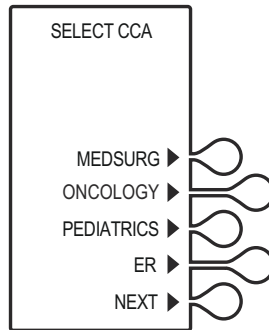
**Note:** The **SELECT CCA** (Clinical Care Area) screen displays if a drug library is installed with more than one CCA. Select the option appropriate for the patient. If there is only one CCA, this screen will not display.

## Programming Infusers with ICU Medical MedNet Software

4. Select the softkey next to the desired CCA (for example, **MEDSURG>**).


If the desired CCA is not displayed, select **NEXT>** to view additional CCAs.

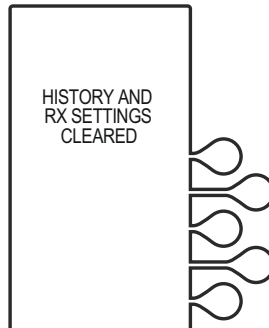
**Note:** If the wrong CCA is unintentionally chosen, turn the infuser off, then on, and select the correct CCA.



For changing a CCA and selecting a CCA when using protocols, see [Changing the CCA](#).

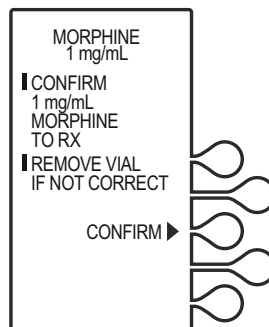
Once the CCA is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

 **CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



5. Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

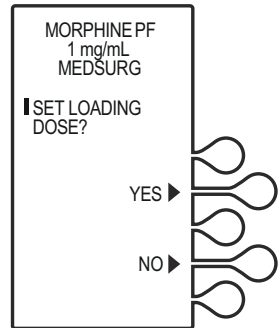
**Note:** If the medication is not correct, remove the vial and insert the correct vial.



- Set loading dose (if desired) by selecting **YES>**.

In this example, **YES>** is selected.

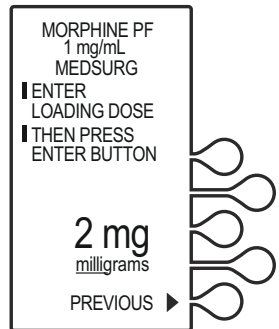
If no loading dose is desired, select **NO>** to proceed with programming.



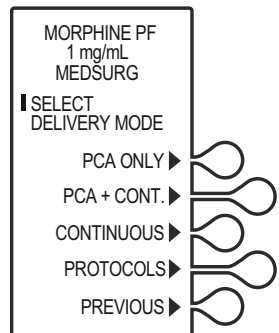
- Using the numeric keypad, enter a loading dose, then press **[ENTER]** to continue.

To correct an entry, press **[CLR]**, re-enter the value, then press **[ENTER]**.

**Note:** Select **PREVIOUS>** to return to the preceding screen if programming changes need to be made.

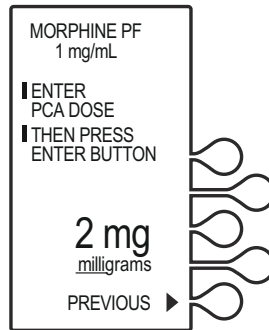


- The **SELECT DELIVERY MODE** screen appears. Select **PCA ONLY>** to continue ([see Modes of Delivery](#)).

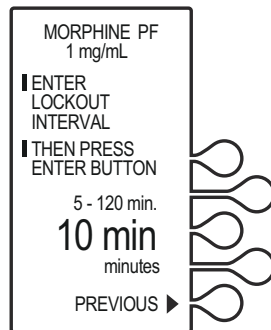


## Programming Infusers with ICU Medical MedNet Software

- Using the numeric keypad, enter the desired PCA dose, then press [ENTER].

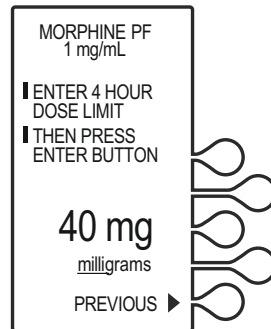


- Enter a lockout interval value. The lockout interval displays on the screen.



- Using the numeric keypad, enter the dose limit, then press [ENTER].

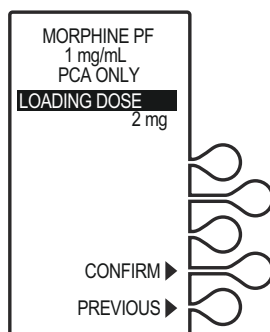
**Note:** The Drug Library Dose Limit periods may be defined as 1, 4, 6, or 12 hours, or as No Dose Limit. See [Dose Limit](#) for complete information on this feature.





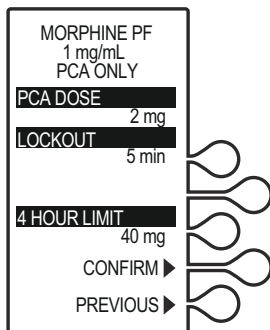
**CAUTION: VERIFY PROGRAM VALUES.**

- Verify loading dose settings, then select **CONFIRM>**.



- Verify program values, then select **CONFIRM>**.

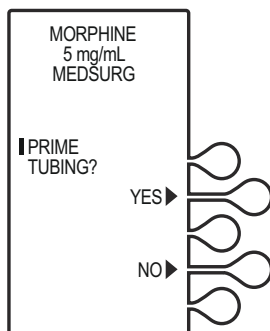
- Close and lock the door.  
Place the key in a secure location.



- Once the door is closed and locked, the **PRIME TUBING?** screen displays.

In this example, **NO>** is selected.

**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).

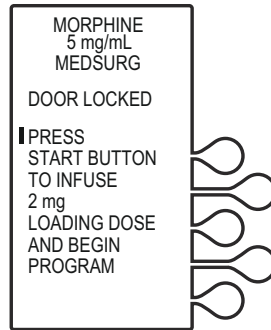


## Programming Infusers with ICU Medical MedNet Software

16. The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.

**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.

Press **[START]** to infuse the loading dose. Once the loading dose is complete, the infuser enters the PCA lockout interval. After the lockout time has elapsed, the PCA bolus will become available. The PCA dose is delivered when the patient presses the PCA patient pendant button.



**WARNING**

---

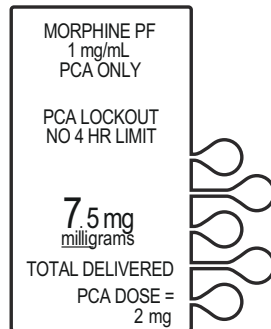
**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

---

**Note:** The infuser will deliver medication only when the door is closed and locked.

17. After the PCA dose is delivered, the infuser enters the PCA lockout interval. After the lockout time has elapsed, the next PCA dose is available.

If the patient pendant button is partially pressed, a **PENDANT FAULT** message appears. This is corrected by releasing the patient pendant button.



A message is displayed when the dose limit has been reached.

**Note:** To stop a PCA dose delivery in progress, press the **[START/STOP]** button.

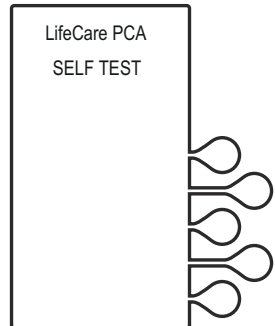
# Programming a PCA + Continuous Therapy

For detailed startup information including priming the LifeCare PCA administration set and loading a vial, see [Loading a Vial](#).

## Programming a Loading Dose

1. Open the security door and power on the infuser. Upon initial startup, the self test begins.

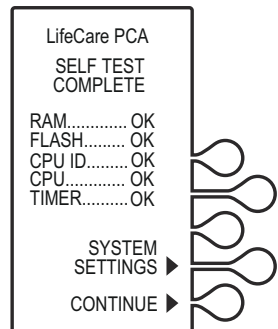
This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see [System Settings](#).



**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

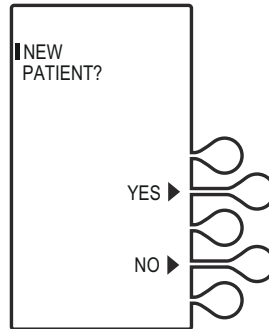
## Programming Infusers with ICU Medical MedNet Software

3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.

If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and Rx settings are retained.

In this example, the **YES>** option is selected.

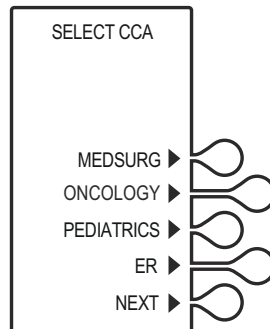


**Note:** The **SELECT CCA** (Clinical Care Area) screen displays if a drug library is installed with more than one CCA. Select the option appropriate for the patient. If there is only one CCA, this screen will not display.

4. Select the softkey next to the desired CCA (for example, **MEDSURG**).

If the desired CCA is not displayed, select **NEXT>** to view additional CCAs.

**Note:** If the wrong CCA is unintentionally chosen, turn the infuser off, then on, and select the correct CCA.



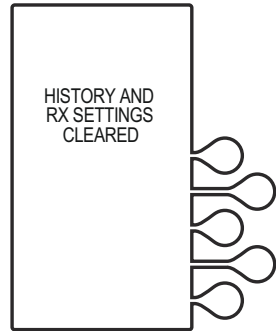
For changing a CCA and selecting a CCA when using protocols, see [Changing the CCA](#).



Once the CCA is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

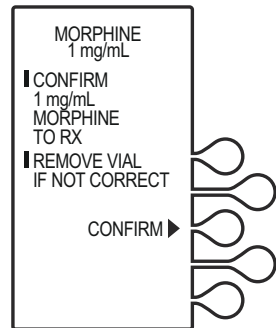


**CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



5. Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

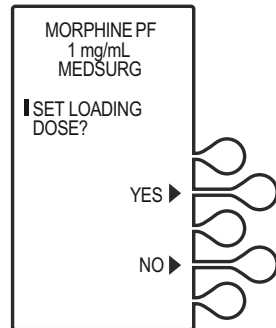
**Note:** If the medication is not correct, remove the vial and insert the correct vial.



6. Set loading dose (if desired) by selecting **YES>**.

In this example, **YES>** is selected.

If no loading dose is desired, select **NO>** to proceed with programming.

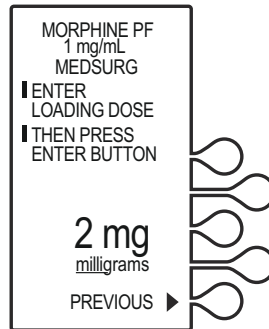


## Programming Infusers with ICU Medical MedNet Software

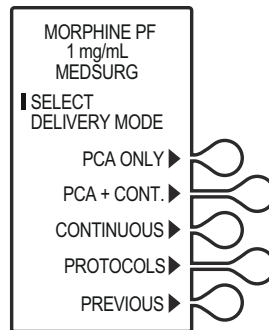
- Using the numeric keypad, enter a loading dose, then press **[ENTER]** to continue.

To correct an entry, press **[CLR]**, re-enter the value, then press **[ENTER]**.

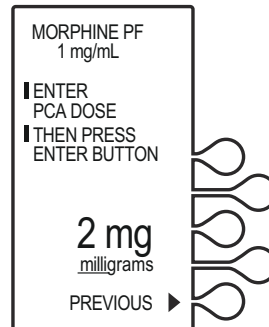
To make programming changes, select **PREVIOUS>** to return to the preceding screen.



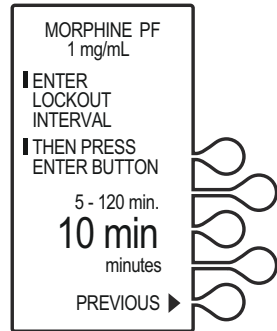
- The **SELECT DELIVERY MODE** screen appears. Select **PCA+CONT.>** to continue.



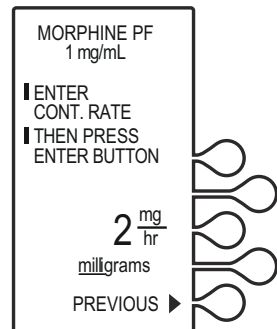
- Using the numeric keypad, enter the PCA dose.



- Using the numeric keypad, enter the lockout interval value. The lockout interval displays on the screen.

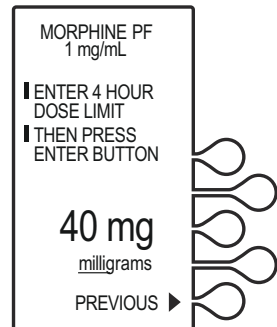


- Enter a Continuous rate, then press [ENTER].



- Using the numeric keypad, enter the dose limit, then press [ENTER].

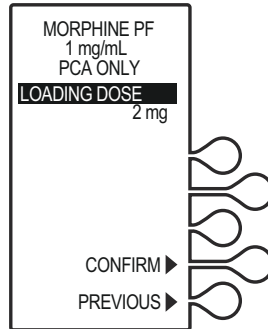
**Note:** The Drug Library dose limit periods may be defined as 1, 4, 6, or 12 hours, or as No Dose Limit. See [Dose Limit](#) for complete information on this feature.



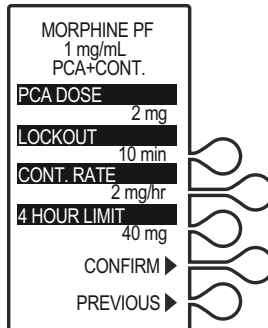


**CAUTION: VERIFY PROGRAM VALUES.**

13. Verify Loading Dose settings, then select **CONFIRM>**.



14. Verify program settings, then select **CONFIRM>**, or select **PREVIOUS>** to return to the preceding screen.

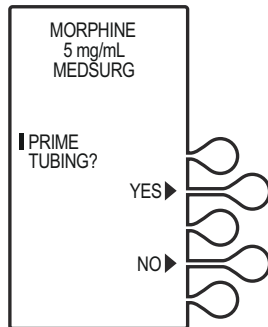


15. Close and lock the door. Place the key in a secure location.

16. Once the door is closed and locked, the **PRIME TUBING?** screen displays.

In this example, **NO>** is selected.

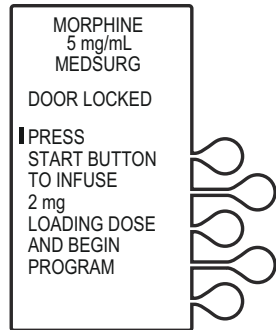
**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).



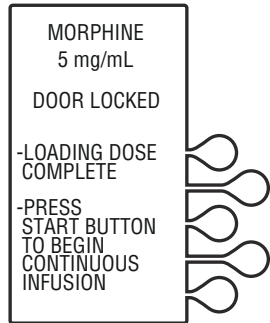
17. The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.

**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.

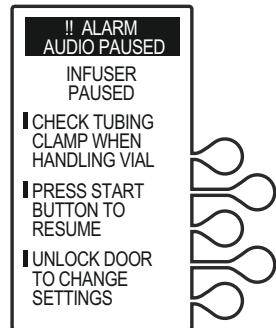
If a loading dose was programmed, the loading dose will infuse first.



18. Once the loading dose is delivered, the infuser displays a **LOADING DOSE COMPLETE** message and prompts the user to press **[START]** to deliver the Continuous program.



**Note:** If the **[START]** button is not pressed within 30 seconds, the infuser will alarm, prompting the user to either press **[START]** to resume, or unlock the door to change settings.



## Programming Infusers with ICU Medical MedNet Software

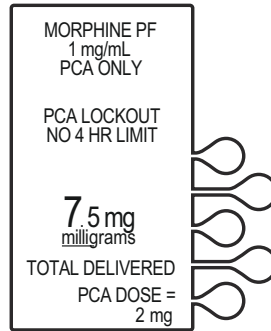
The dose is delivered when the patient presses the patient pendant button. If the patient pendant button is partially pressed, a **PENDANT FAULT** message appears. This is corrected by releasing the patient pendant button.

**Note:** The infuser will deliver medication only when the door is closed and locked.

After the PCA dose is delivered, the infuser enters the PCA lockout interval. After the lockout time has elapsed, the next PCA dose is available.

A message is displayed when the dose limit has been reached.

**Note:** To stop a PCA dose delivery in progress, press the **[START/STOP]** button.



## Programming a Continuous Therapy

For detailed startup information including vial insertion, clearing settings, purging, and setting a loading dose, see [Loading a Vial](#).

For information on adjusting systems settings such as contrast, time, and date, see [Updating the Drug Library](#).

## Turning On the Infuser

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the **[ON/OFF]** button,

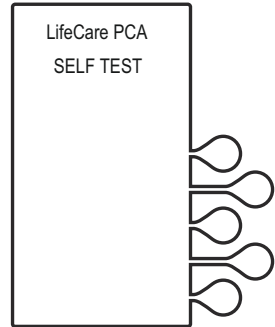
or

Loading the medication vial into the cradle will automatically power on the infuser ([see Loading a Vial](#)).

## Programming a Loading Dose

1. Power on the infuser. Upon initial startup, the self test begins.

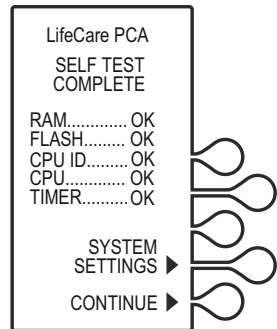
This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

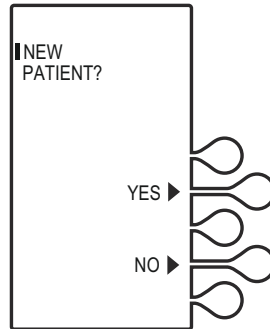
## Programming Infusers with ICU Medical MedNet Software

3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.

If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and Rx settings are retained.

In this example, the **YES>** option is selected.

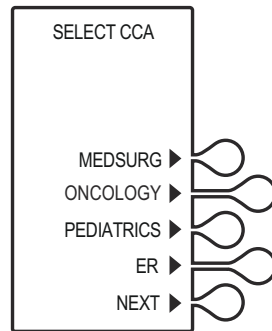


**Note:** The **SELECT CCA** (Clinical Care Area) screen displays if a drug library is installed with more than one CCA. Select the option appropriate for the patient. If there is only one CCA, this screen will not display.

4. Select the softkey next to the desired CCA (for example, **MEDSURG>**).

If the desired CCA is not displayed, select **NEXT>** to view additional CCAs.

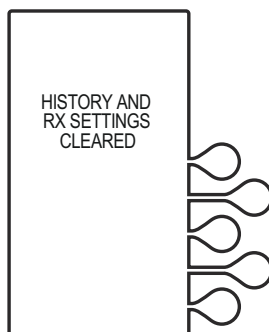
**Note:** If the wrong CCA is unintentionally chosen, turn the infuser off, then on, and select the correct CCA.



For changing a CCA and selecting a CCA when using protocols, see [Changing the CCA](#).



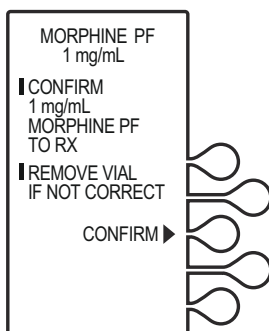
Once the CCA is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.



**CAUTION: VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**

5. Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

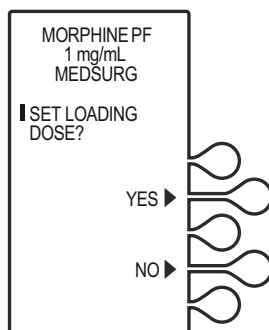
**Note:** If the medication is not correct, remove the vial and insert the correct vial.



6. Set the loading dose (if desired) by selecting **YES>**.

In this example, **YES>** is selected.

If no loading dose is desired, select **NO>** to proceed with programming.

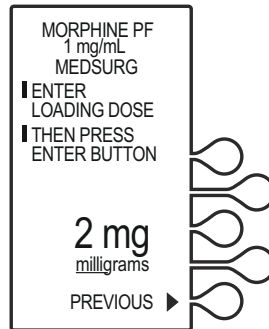


## Programming Infusers with ICU Medical MedNet Software

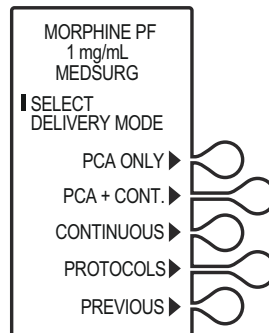
- Using the numeric keypad, enter a loading dose, then press **[ENTER]** to continue.

To correct an entry, press **[CLR]**, re-enter the value, then press **[ENTER]**.

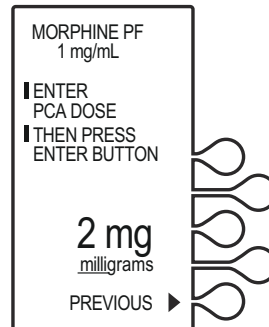
To make programming changes, select **PREVIOUS>** to return to the preceding screen.



- The **SELECT DELIVERY MODE** screen appears. Select **CONTINUOUS>** to continue.



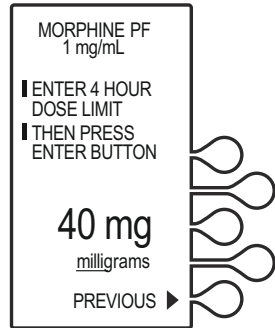
- Using the numeric keypad, enter a Continuous rate, then press **[ENTER]**.



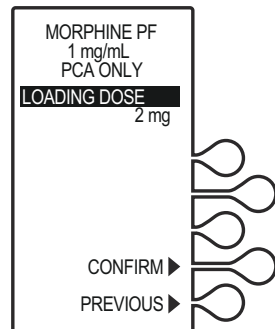
- Using the numeric keypad, enter the dose limit, then press [ENTER].

**Note:** The Drug Library dose limit periods may be defined as 1, 4, 6, or 12 hours, or as No Dose Limit. See **Dose Limit** for complete information on this feature.

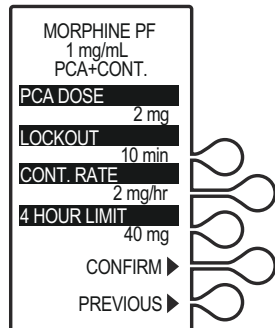
 **CAUTION:**  
**VERIFY PROGRAM VALUES.**



- Verify loading dose settings, then select **CONFIRM>**.



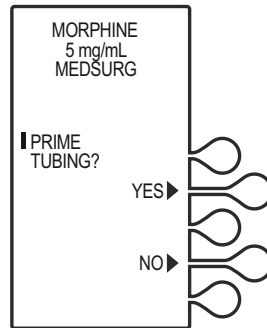
- Verify program settings, then select **CONFIRM>**, or, select **PREVIOUS>** to return to the preceding screen.
- Close and lock the door.  
Place the key in a secure location.



## Programming Infusers with ICU Medical MedNet Software

14. Once the door is closed and locked, the **PRIME TUBING?** screen displays. For this example, **NO** is selected.

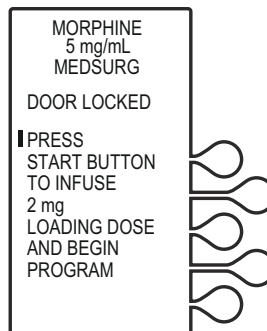
**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).



15. The **DOOR LOCKED** screen displays and the infuser indicates to press the Start button to infuse.

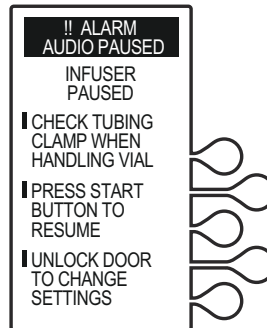
**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.

If a loading dose was programmed, the loading dose will infuse first.



16. Once the loading dose is delivered, the infuser prompts the user to press **[START]** to deliver the Continuous program.

**Note:** If the **[START]** button is not pressed within 30 seconds, the infuser will alarm, prompting the user to either press **[START]** to resume, or unlock the door to change settings.



**Note:** The infuser will deliver medication only when the door is closed and locked.

**Note:** To stop a Continuous delivery in progress, press the **[START/STOP]** button.

## Drug Library: Soft Limit, Hard Limit, and Rule Set

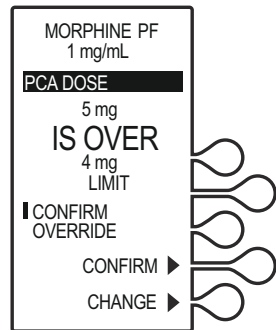
ICU Medical MedNet Software provides the ability to build a drug library based on hospital-defined best practices. The customized drug library is downloaded into the infuser by authorized hospital personnel. Hospital personnel determine and select the medications, concentrations, units of measure, dose, and dose limits available for use with the LifeCare PCA infuser in the selected CCA.

A soft limit or hard limit provides feedback comparing the infuser's programmed parameters (such as concentration, lockout intervals, dose) with these hospital-defined rule sets. If the value is programmed outside the rule set established by the facility, a soft limit override or hard limit violation message displays.



### Soft Limit Override

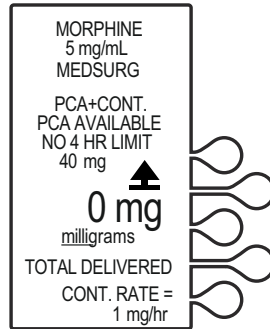
During programming, if a value is entered that exceeds the soft limit rule set determined in the drug library, the **SOFT LIMIT OVERRIDE** message displays.

1. Review the display for the exceeded parameter.
2. Select **CONFIRM>** to override the programmed soft limit, or select **CHANGE>** to enter the correct parameter.



All soft limit overrides made during programming are indicated on the infusion screen with an appropriate upper or lower limit arrow.

The **Upper**  and **Lower**  soft limit override symbols are displayed during delivery to inform the user that one or more soft limits have been overridden.

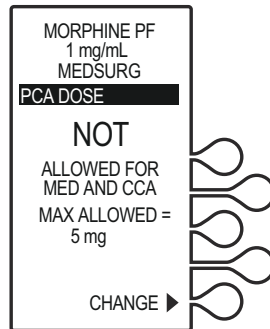


## Hard Limit Violation


During programming, if a value is entered that exceeds the hard limit rule set determined in the drug library, the **HARD LIMIT VIOLATION** screen displays.

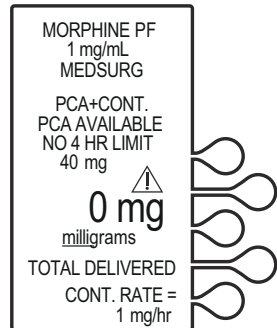
Hard limits cannot be overridden. Select **CHANGE>** to enter a new parameter.

1. The infuser displays the exceeded parameter and indicates a programmed parameter not allowed.
2. Select **CHANGE>** to enter the correct parameter.
3. Using the numeric keypad, enter the correct value, then press **[ENTER]** to proceed with programming.



## Rule Sets Caution

The **Caution** symbol  is displayed on the infusion screen to advise the user to program with caution because the established rule set does not have any soft or hard safety limits.



## Changing the CCA

1. Stop the infuser by pressing the [START/STOP] button. The **INFUSER STOPPED** screen displays. Unlock and open the door.

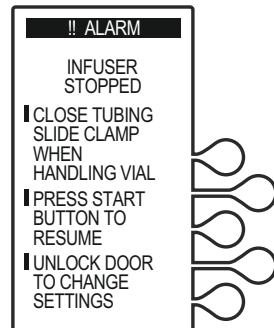


**WARNING**

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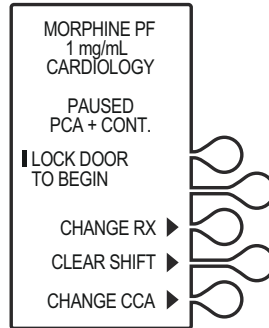
**CLOSE THE TUBING  
SLIDE CLAMP WHEN  
HANDLING THE VIAL.**

---



## Programming Infusers with ICU Medical MedNet Software

2. Select **CHANGE CCA>** to change the setting.



3. The **ATTENTION!** screen displays, indicating that changing the CCA will clear the Rx settings. Select **CONTINUE>** to advance to the **SELECT CCA** screen.

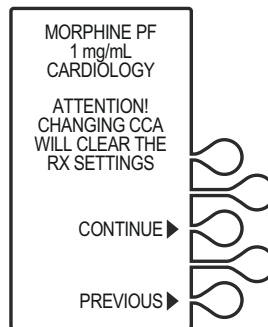


**WARNING**

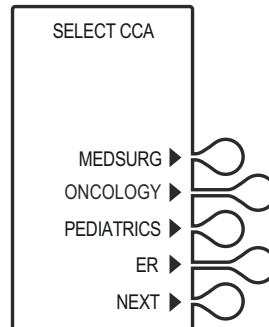
---

**CHANGING THE CCA  
CLEARS THE RX  
SETTINGS.**

---



4. Select the desired CCA, then press **CONTINUE>** to proceed with programming.





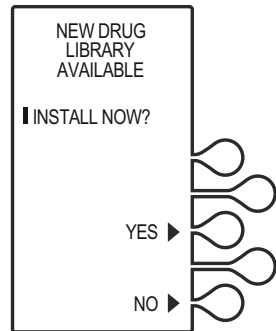
## Updating the Drug Library

A hospital has the flexibility to make changes and/or updates to its drug library as required to meet changing clinical practice. New drug libraries are available for installation when turning off the infuser.

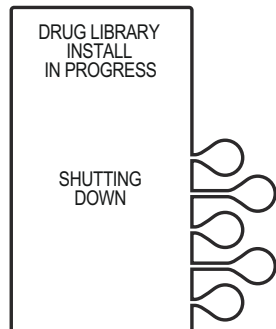
**Note:** If communication is lost with ICU Medical MedNet, a new drug library will not be able to be downloaded.

The following section describes how to accept a new drug library on the infuser.

1. Press **[ON/OFF]** to turn off the infuser. If a new user-defined drug library is available for installation, the **NEW DRUG LIBRARY AVAILABLE** screen displays.
2. Select **NO>** to skip the installation and continue using the current library. The infuser will then turn off.
3. Select **YES>** to install the new drug library. The **DRUG LIBRARY INSTALL IN PROGRESS** screen flashes the words **IN PROGRESS** on the screen.



**CAUTION: WHEN A NEW DRUG LIBRARY IS INSTALLING, ENSURE THE AC POWER CORD IS PLUGGED IN UNTIL THE PROCESS IS COMPLETE.**



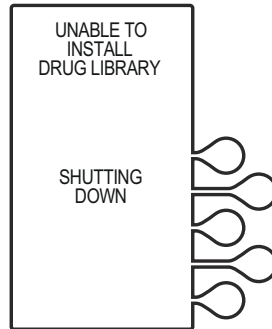
After the library has been installed successfully, the **DRUG LIBRARY INSTALL SUCCESSFUL** screen displays, and the infuser will power off automatically.

The new library will be active when the infuser is turned on.

## Programming Infusers with ICU Medical MedNet Software

If the Drug Library is not installed within 15 minutes, or if it fails to install, the **UNABLE TO INSTALL DRUG LIBRARY** screen displays, and the infuser will power off automatically.

The previous library will be active when the infuser is re-started.



## Auto-Programming

Auto-programming is available through ICU Medical MedNet Software (*see the ICU Medical MedNet Software User Guide*).

Auto-programming can only be used if the feature has been licensed and installed in conjunction with your Electronic Medical Record's (EMR) bar code medication administration functionality unit. Patient and medication order information is acquired by scanning bar code labels for the patient, the medication vial, and the infuser, and is transferred to the infuser, reducing the number of steps needed to program an infusion.

The functionality of the infuser remains the same as if the infuser was manually programmed. For example, if a soft limit violation is encountered, proceed as in manual programming.

**Note:** If communication is lost with ICU Medical MedNet, the infuser will not be able to receive auto-programs and report events or alarms to the HIS/EMR system until the connection is re-established. Other than the potential delay in therapy due to the inability to receive an auto-program there will be no effect on the patient.

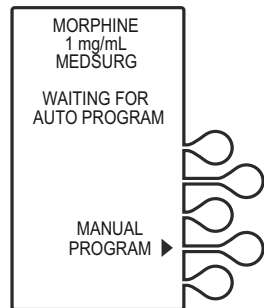
The Wireless symbol indicates that the LifeCare PCA infuser is connected to the wireless network. It does not indicate if data is currently being sent or received.

To view wireless connectivity, press the [HISTORY/BATTERY] button, and see [Table 1-4](#).

To use the auto-programming feature, proceed as follows:

1. Open the security door, power on the infuser, and select the CCA.
2. Log in to the EMR and scan or select the patient and view the active medication orders.
3. Follow the bar code scanning workflow to administer the PCA medication.
4. After scanning the PCA medication vial, load the vial into the infuser.
5. Use the **Program Pump** or similar command in EMR to transfer the medication order to the infuser.
6. The programming screen is automatically populated with the ordered infusion parameters.

**Note:** If the scanned medication does not exist in the drug library, an invalid bar code alarm will be activated.



**CAUTION: VERIFY PROGRAM VALUES.**

7. Verify all infusion parameters, then select **CONFIRM>**.

## **Programming Infusers with ICU Medical MedNet Software**

8. Close and lock the door. Place the key in a secure location.
9. Press **[START]** to begin the program.

Once the program has started, the infuser sends the program values (medication, concentration, dose, etc.) back to the EMR which in turn may present the clinician with this information to confirm against the order. The EMR will also document the start of the PCA infusion.



### **WARNING**

**THE INFUSER CANNOT COMMUNICATE VIA THE NETWORK IF THE LOW BATTERY WARNING ALARM HAS SOUNDED.**

**Note:** If the physician's order for an auto-program therapy exceeds the capabilities of the infuser, or is above a hospital defined hard drug limit, the infusion parameters for auto-programming will be rejected, and the order cannot be programmed as written and must be rechecked. The infuser allows the clinician to change soft limits by changing the value when the **SOFT LIMIT VIOLATION** screen appears.

For more information on hard and soft limits, see [Soft Limit Override](#) and [Hard Limit Violation](#).

## **Resending an Auto-Program After Changing an Empty Vial**

To resend an auto-program for a vial change (vial empty) only:

1. When the vial is empty, the alarm message **EMPTY SYRINGE** appears along with **REPLACE SYRINGE**.
2. Close the slide clamp on the LifeCare PCA administration set prior to handling the vial, then unlock the door.
3. Remove the old vial by firmly grasping the vial on both sides and pulling straight out.

4. Load the new vial (see [Loading a Vial](#)).

The screen displays options to **CLEAR HISTORY**, **CLEAR RX**, **CLEAR BOTH**, or **CONTINUE**.

5. Select **CLEAR RX**>.

**Note:** To clear both the Rx and History, select **CLEAR BOTH**>.

6. Select **CONFIRM**> to confirm clearing the prescription settings.

7. Verify the medication and concentration, then select **CONFIRM**>.

The **WAITING FOR AUTO-PROGRAM** screen displays.

8. Perform auto-program sequence (see [Auto-Programming](#)).

**Note:** This procedure is used to replace an empty vial and then reprogram the infuser with the same prescription, and to change the prescription with a new auto-program.

## Rejected Auto-Program

Should you scan a medication vial which does not match the physician order entry, the infuser displays the following:

Message: **Med does not match order**. Remove the vial and insert the correct vial.

Corrective Action: Remove the incorrect medication vial. Scan the correct vial, then load the vial into the infuser.

## Switching from Auto-Programming to Manual Programming

Should auto-programming fail, the infuser displays the following:

Message: **Unable to auto-program**. Press the **MANUAL PROGRAM** key to continue.

Corrective Action: Press the **MANUAL PROGRAM** key to manually program the infuser. Wireless connectivity may be disrupted or unavailable.

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**NOTES**

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# Chapter 5

## Programming Infusers without ICU Medical MedNet Software

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This chapter describes how to program the LifeCare PCA infuser using the default drug library and a ICU Medical pre-filled and pharmacy-filled (custom) vial. Programming instructions will be provided for the following:

- Loading Dose
- PCA Only
- PCA + Continuous
- Continuous Only

For more information on each of the delivery modes and dose limits, see [Chapter 3 Modes of Delivery](#).

The following is consistent throughout all programming:

- To correct an entry during programming, press [CLR], re-enter the value, then press [ENTER].
- During initial programming, select **PREVIOUS>** to return to the preceding display and enter the desired setting. Each time **PREVIOUS>** is selected, the message display reverts to the previous setting, until the first setting is displayed.

# Warnings and Precautions

## **WARNING**

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**FOR CUSTOM SYRINGES, CONFIRM THAT THE DISPLAYED CONCENTRATION (mg/mL) OR (mcg/mL) EXACTLY MATCHES THE CONCENTRATION VALUE AND MEDICATION NAME ON THE SYRINGE. IF THEY DO NOT MATCH, UNDER/OVERDOSAGE MAY RESULT.**

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- In the Continuous and PCA + Continuous modes, after a syringe change the infuser automatically performs a small system compliance step to remove slack when the [START/STOP] key is pressed with the door locked.
- Although fluid is not normally delivered to the patient during the compliance step, under some conditions up to 0.3 mL of fluid may be delivered. If 0.3 mL of fluid represents a hazard to the patient, disconnect the set during this operation.
- At flow rates less than 0.5 mL/hr, there may be a significant delay before flow is established.
- Selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values.
- Perform close assessment and monitoring of patients receiving potent analgesic medication for possible adverse reactions.
- The LifeCare PCA infuser is not intended to be used for frequent, long-term portable operation. Keep the device plugged into a properly grounded AC receptacle whenever possible, and reserve battery power for temporary portable operation and emergency backup. If the AC receptacle is in doubt, use battery power.



## Loading Dose/Dose Limits

- The loading dose is always included in the total dose delivered.
- Setting a new dose limit will not erase the previous dose history.
- Always monitor the LifeCare PCA infuser when delivering medication with the door open.

## Patient Pendant



**CAUTION: DO NOT BEND THE PATIENT PENDANT CORD NEAR THE PATIENT PENDANT OR CONNECTOR JACK AT AN ANGLE OF 90° OR GREATER.**

Use only the LifeCare PCA blue patient pendant.



**WARNING** \_\_\_\_\_  
**THE PATIENT PENDANT BUTTON IS TO BE PRESSED ONLY BY THE INTENDED PATIENT.**

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## System Settings

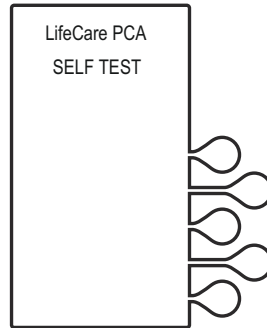
Select **SYSTEM SETTINGS** to change display contrast and time and date. **SYSTEM SETTINGS** is available at power on.

Once the system settings are changed, the infuser retains the new settings.

## Programming Infusers without ICU Medical MedNet Software

1. Open the security door and press **[ON/OFF]** to turn on the infuser.

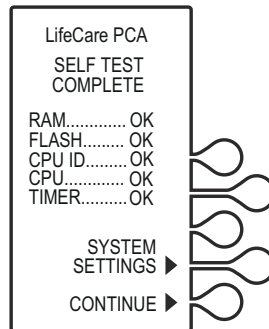
Upon initial startup, the self test begins.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

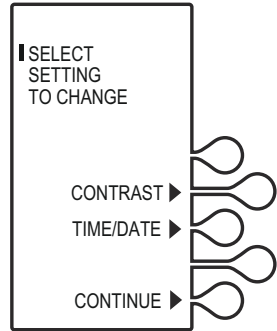
**Note:** To change contrast and/or time and date, see **System Settings**.



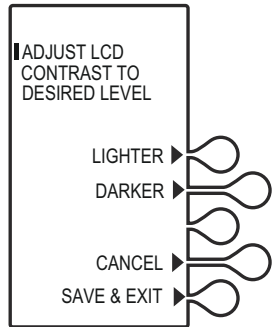
**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

3. Select the **CONTRAST>** or **TIME/DATE>** softkey to adjust the setting.



4. Select **CONTRAST>**. Press the **LIGHTER>** or **DARKER>** softkey repeatedly until contrast is optimized for viewing, then select **SAVE & EXIT>**.



## Adjusting Time and Date

### **WARNING**



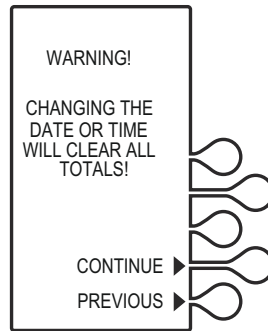
**CHANGING THE TIME OR DATE WILL CLEAR ALL TOTALS. THE CURRENT PROGRAM WILL REMAIN INTACT WHEN THE TIME/DATE FUNCTION IS ACCESSED. LOCKOUTS OR LIMITS IN PLACE WHEN THE TIME/DATE IS CHANGED WILL REMAIN IN EFFECT.**

1. Select **TIME/DATE>**, then select **CONTINUE>**.

A warning screen indicates that changing the date or time will clear all totals.

## Programming Infusers without ICU Medical MedNet Software

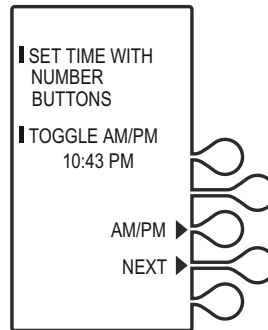
- When the **WARNING!** screen appears, select **CONTINUE>**.



- Using the numeric keypad, set the time in four-digit format (HH:MM). For example, enter 10:43 PM as 10:43.

Select **AM/PM>** to alternate between AM and PM.

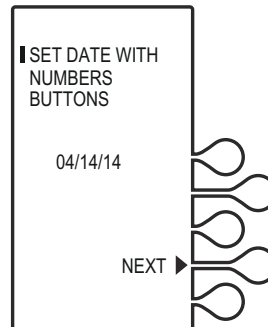
Time may be displayed using the 12 or 24 hour clock. The default setting is the 12 hour clock. The clock selection option is available in the Biomed mode.



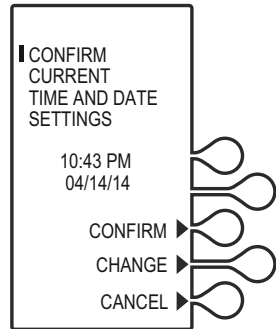
- After setting the time, select **NEXT>** to set the date.

- Using the numeric keypad, set the date in MM/DD/YY sequence. For example, enter April 14, 2014 as 04/14/14.

The current setting for the date will flash.



6. Select **NEXT>** again after changing to the desired date. The **CONFIRMATION** screen appears. Select **CONFIRM>** to verify the changed settings.
7. Select **CONTINUE>** to exit the **SELECT SETTING TO CHANGE** menu and to display the **VIAL CONFIRMATION** screen (if the vial is loaded properly).



## Programming a PCA Therapy

For detailed startup information including priming the LifeCare PCA administration set, loading a vial, and programming a Loading Dose, see [Loading a Vial](#).

For information on adjusting system values such as contrast, time, and date, see [System Settings](#).

## Turning On the Infuser

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the **[ON/OFF]** button,

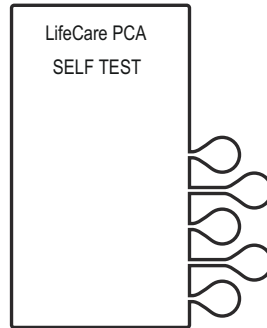
or

Loading the medication vial into the cradle will automatically power on the infuser ([see Loading a Vial](#)).

## Programming Infusers without ICU Medical MedNet Software

1. Power on the infuser. Upon initial startup, the self test begins.

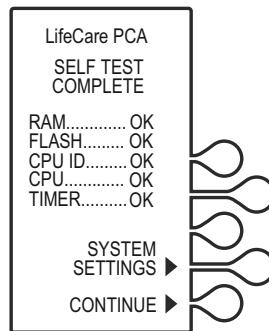
This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



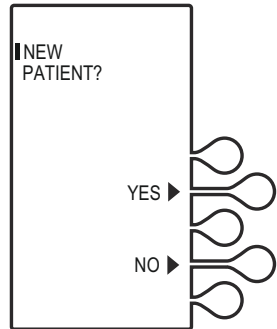
**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

- The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.

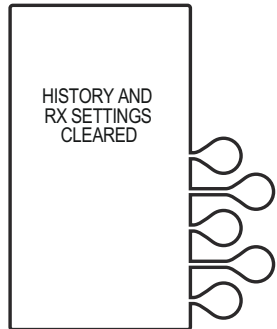
If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and Rx settings are retained.



In this example, the **YES>** option is selected. The **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

 **CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



- Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

**Note:** If the medication is not correct, remove the vial and insert the correct vial.

- Set the loading dose (if desired) by selecting **YES>**. If no loading dose is desired, select **NO>** to proceed with programming.

In this example, **YES>** is selected.

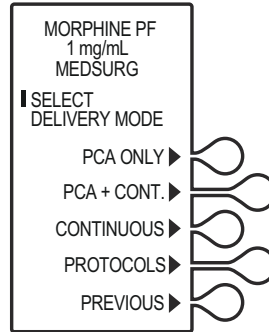
- Using the numeric keypad, enter a loading dose, then press **[ENTER]** to continue.

Select **PREVIOUS>** to return to the preceding screen if programming changes need to be made.

## Programming Infusers without ICU Medical MedNet Software

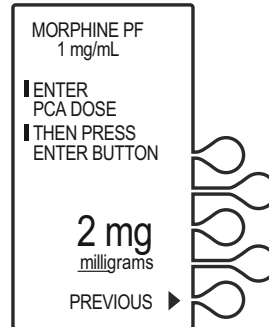
**Note:** The default drug library value range will display and will vary, depending on the concentration.

- The **SELECT DELIVERY MODE** screen appears. Select **PCA ONLY** to continue.

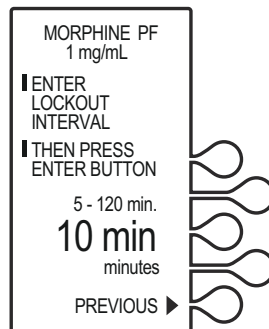


- Using the numeric keypad, enter the desired PCA dose, then press **[ENTER]**.

To correct an entry, press **[CLR]**, re-enter the value, then press **[ENTER]**.



- Using the numeric keypad, enter a desired lockout interval value, then press **[ENTER]**.

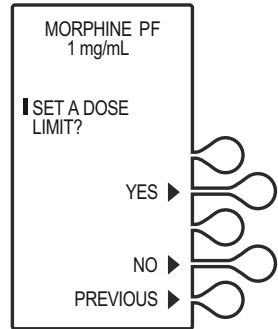




- The **SET A DOSE LIMIT?** screen displays. Set a specific dose limit by selecting **YES>** and advance to the **DOSE LIMIT ENTER VALUE** screen.

**Note:** Select **NO>** to choose no dose limit.

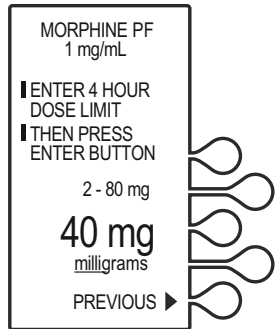
See **Dose Limit** (1 or 4 hour) for complete information about this feature.



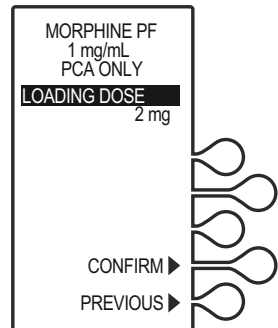
- Using the numeric keypad, enter the dose limit value (the range is displayed on the screen), then press **[ENTER]**.

The dose limit periods may be defined as 1, 4, or No Dose Limit. See **Dose Limit** for complete information about this feature.

 **CAUTION:**  
**VERIFY PROGRAM VALUES.**



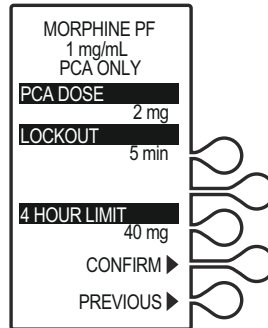
- Verify loading dose value, then **CONFIRM>**.



## Programming Infusers without ICU Medical MedNet Software

13. Verify program values, then select **CONFIRM>**.

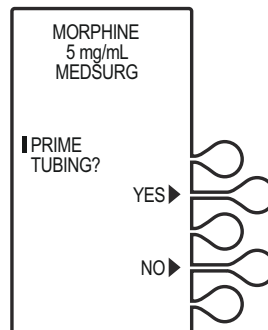
14. Close and lock the door.  
Place the key in a secure location.



15. Once the door is closed and locked, the **PRIME TUBING?** screen displays. For this example, **NO>** is selected.

**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).

**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.



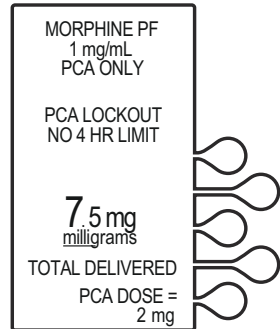
16. Press **[START]** to infuse the loading dose. Once the loading dose is complete, the PCA bolus will become available. The PCA dose is delivered when the patient presses the PCA patient pendant button.

**Note:** The infuser will deliver medication only when the door is closed and locked.

Approximately 10 seconds after the door is locked, the **DOOR LOCKED** message disappears.

After a PCA dose is delivered, the infuser enters the **PCA LOCKOUT** interval. After the lockout time has elapsed, the next PCA dose is available.

If the patient pendant button is partially pressed, a **PENDANT FAULT** message appears. This is corrected by releasing the patient pendant button.



A message is displayed when the dose limit has been reached.

**Note:** To stop a PCA dose delivery in progress, press the [START/STOP] button.

## Programming a PCA + Continuous Therapy

For detailed startup information including priming the LifeCare PCA administration set, loading a vial, and programming a Loading Dose, see [Loading a Vial](#).

For information on adjusting system values such as contrast, time, and date, see [System Settings](#).

## Turning On the Infuser

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the [ON/OFF] button,

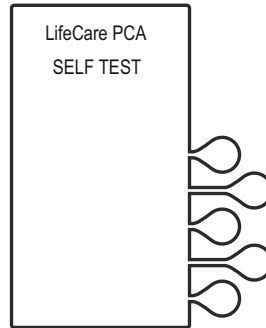
or

Loading the medication vial into the cradle will automatically power on the infuser ([see Loading a Vial](#)).

## Programming Infusers without ICU Medical MedNet Software

1. Power on the infuser. Upon initial startup, the self test begins.

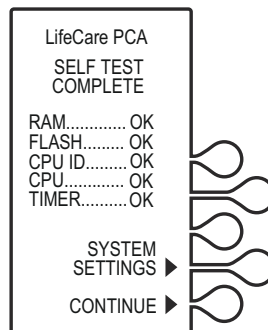
This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



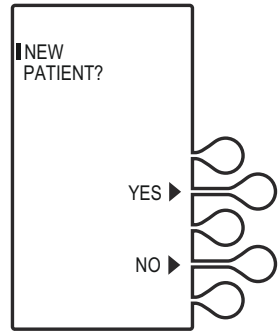
**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.


3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.

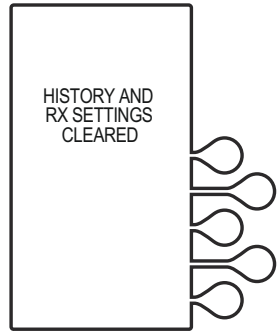
If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and Rx settings are retained.



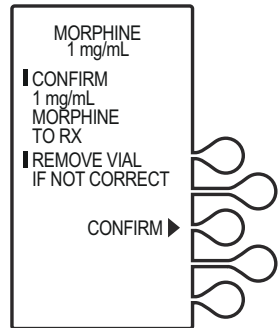
If the **YES>** option is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

**CAUTION:**  
 **VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



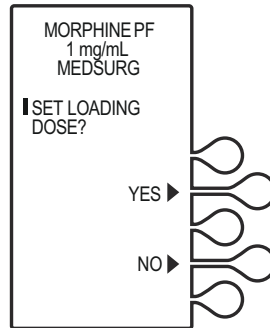
4. Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

**Note:** If the medication is not correct, remove the vial and insert the correct vial.



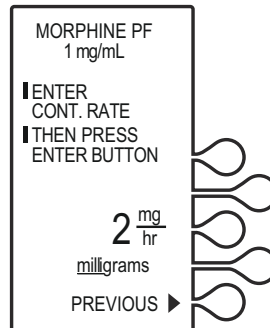
## Programming Infusers without ICU Medical MedNet Software

- Set loading dose (if desired) by selecting **YES>**, then continue to Step 7.  
  
If no loading dose is desired, select **NO>** to proceed with programming.
- Using the numeric keypad, enter a loading dose, then press **[ENTER]** to continue.



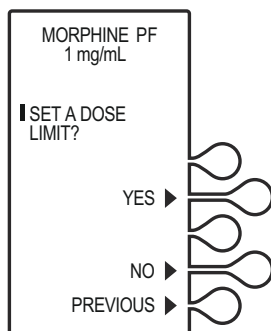
**Note:** The default drug library value range will display and will vary, depending on the concentration.

- The **SELECT DELIVERY MODE** screen appears. Select **PCA + CONT.>** to continue ([see Modes of Delivery](#)).
- Using the numeric keypad, enter the desired PCA dose, then press **[ENTER]**.
- Using the numeric keypad, enter a desired lockout interval value, then press **[ENTER]**.
- Using the numeric keypad, enter a Continuous rate, then press **[ENTER]**.



- The **SET A DOSE LIMIT** screen displays. Set a specific dose limit by selecting **YES**> and advance to the **DOSE LIMIT ENTER VALUE** screen (see [Dose Limit](#)).

**Note:** Select **NO**> to choose no dose limit.

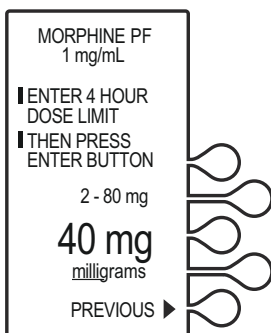


- Using the numeric keypad, enter the dose limit value (the range is displayed on the screen), then press **[ENTER]**.

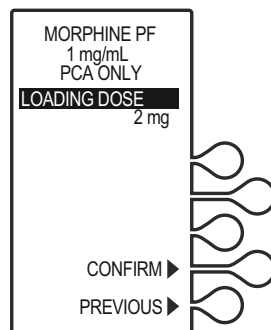
The dose limit periods may be defined as 1, 4, and No Dose Limit (see [Dose Limit](#)).



**CAUTION:**  
**VERIFY PROGRAM VALUES.**

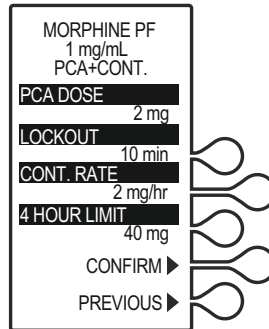


- Verify the loading dose value, then **CONFIRM**>.



## Programming Infusers without ICU Medical MedNet Software

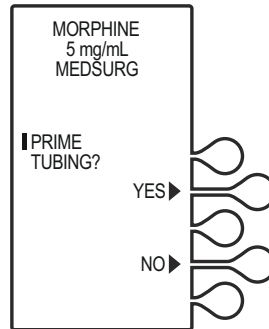
- Verify program values, then select **CONFIRM>**, or, select **PREVIOUS>** to return to the preceding screen.
- Close and lock the door. Place the key in a secure location.



- Once the door is closed and locked, the **PRIME TUBING?** screen displays. For this example, **NO>** is selected.

**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).

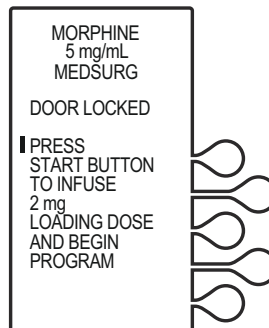
**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.



- The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.

If a loading dose was programmed, the loading dose will infuse first.

Once the loading dose is delivered, the infuser prompts the user to press **[START]** to deliver the Continuous program.

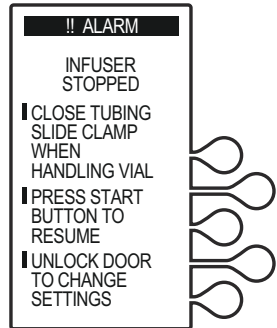




18. If the [START] button is not pressed within 30 seconds, the infuser will alarm, prompting the user to either press [START] to resume, or unlock the door to change settings.



**WARNING**  
**CLOSE THE TUBING  
 SLIDE CLAMP WHEN  
 HANDLING THE VIAL.**



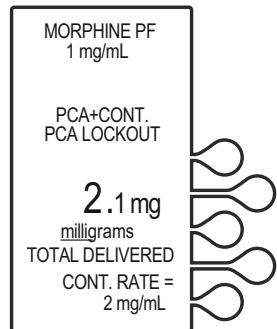
**Note:** The infuser will deliver medication only when the door is closed and locked.

**Note:** To stop a continuous mode delivery in progress, press the [START/STOP] button.

When the patient presses the PCA patient pendant button, the PCA dose is delivered.

After the PCA dose is delivered, the infuser enters the **PCA Lockout** interval. After the lockout time has elapsed, the next PCA dose is available.

If the patient pendant button is partially pressed, a **PENDANT FAULT** message appears. This is corrected by releasing the patient pendant button.



A message is displayed when the dose limit has been reached.

**Note:** To stop a PCA dose delivery in progress, press the [START/STOP] button.

# Programming a Continuous Therapy

For detailed startup information including priming the LifeCare PCA administration set, loading a vial, and programming a Loading Dose, see [Loading a Vial](#).

For information on adjusting system settings such as contrast, time, and date, see [System Settings](#).

## Turning On the Infuser

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the [ON/OFF] button,

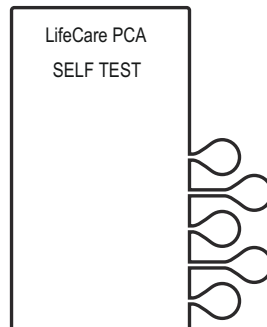
or

Loading the medication vial into the cradle will automatically power on the infuser ([see Loading a Vial](#)).

## Programming a Loading Dose

1. Power on the infuser. Upon initial startup, the self test begins.

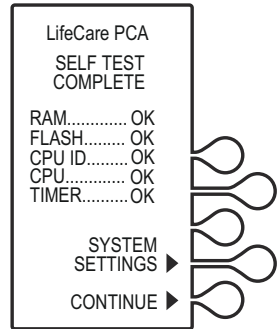
This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



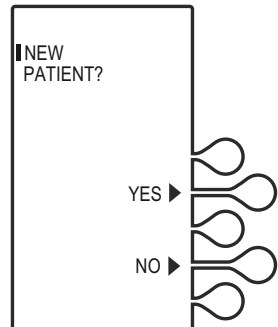
**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.


If **YES>** is selected, the History and Rx settings are cleared.

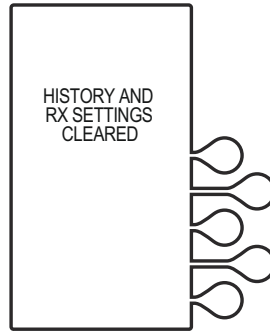
If **NO>** is selected, the History and Rx settings are retained.



## Programming Infusers without ICU Medical MedNet Software

In this example, the **YES>** option is selected. The **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

 **CAUTION:**  
**VERIFY MEDICATION AND  
CONCENTRATION WITH  
PHYSICIAN ORDER.**



4. Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

**Note:** If the medication is not correct, remove the vial and insert the correct vial.

5. Set loading dose (if desired) by selecting **YES>**, then continue to Step 7.

If no loading dose is desired, select **NO>** to proceed with programming.

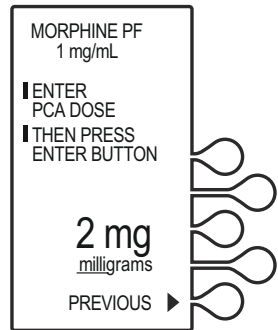
6. Using the numeric keypad, enter a loading dose, then press the **[ENTER]** button to continue.
7. The **SELECT DELIVERY MODE** screen appears.  
Select **CONTINUOUS>** to continue ([see Modes of Delivery](#)).

Select **PREVIOUS>** to return to the preceding screen if programming changes need to be made.

8. Using the numeric keypad, enter the Continuous rate, then press [ENTER].

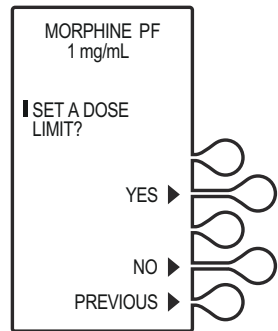
To correct an entry, press [CLR], re-enter the value, then press [ENTER].

To make programming changes, select **PREVIOUS>** to return to the preceding screen.



9. The **SET A DOSE LIMIT** screen displays. Set a specific dose limit by selecting **YES>** and advance to the **DOSE LIMIT ENTER VALUE** screen.

**Note:** Select **NO>** to choose No Dose Limit ([see Dose Limit](#)).

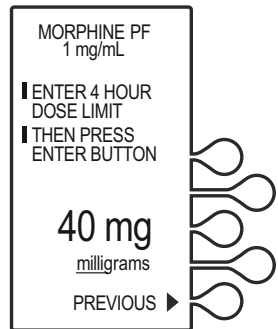


10. Using the numeric keypad, enter the dose limit value (the range is displayed on the screen), then press [ENTER].

The dose limit periods may be defined as 1, 4, and No Dose Limit ([see Dose Limit](#)).



**CAUTION:**  
**VERIFY PROGRAM VALUES.**



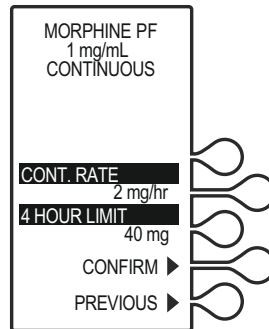
11. Verify loading dose value, then select **CONFIRM>**.

## Programming Infusers without ICU Medical MedNet Software

12. Verify program values, then select **CONFIRM>**.

**Note:** Select **PREVIOUS>** to return to the preceding screen.

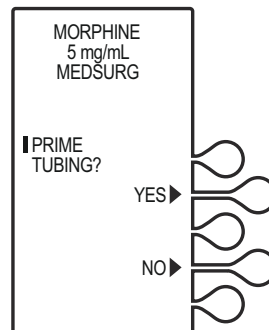
13. Close and lock the door.  
Place the key in a secure location.



14. Once the door is closed and locked, the **PRIME TUBING?** screen displays. For this example, **NO>** is selected.

**Note:** To prime the administration set on the infuser, see [Chapter 2 Setup and Operation](#).

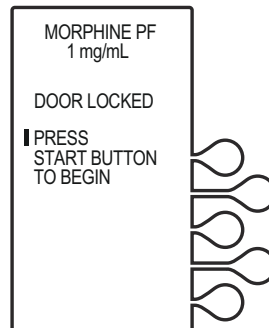
**Note:** Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.



15. Select **NO>**. The **DOOR LOCKED** screen displays and the infuser indicates to press the Start button to infuse.

If a loading dose was programmed, the loading dose will infuse first.

Once the loading dose is delivered, the infuser prompts the user to press **[START]** to deliver the **Continuous** program.



**Note:** If the [START] button is not pressed within 30 seconds, the infuser will alarm, prompting the user to either press [START] to resume, or unlock the door to change settings.

**Note:** The infuser will deliver medication only when the door is closed and locked.

**Note:** To stop a continuous mode delivery in progress, press the [START/STOP] button.

A message is displayed when the dose limit has been reached.

## **Programming with a Pharmacy-Filled (Custom) Vial**

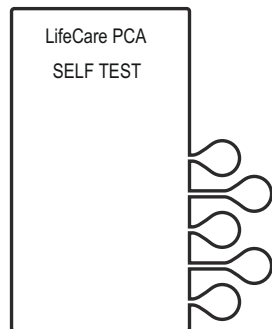
A custom vial is a LifeCare PCA sterile empty vial which is filled by the hospital pharmacy. Custom vials without a pharmacy-generated bar code can only be used with the default drug library (without ICU Medical MedNet software).

**OTHER DRUG** displays, indicating that the custom vial is filled by the hospital pharmacy.

1. Open the security door and press the [ON/OFF] button to turn on the infuser.

Upon initial startup, the self test begins.

This screen is followed by a self test information screen that includes time, date, software version, and drug library. During the self test, the infuser reads the bar code label.

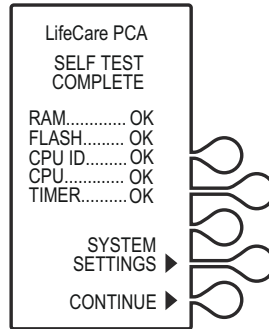


## Programming Infusers without ICU Medical MedNet Software

### 2. If the infuser is running 7.01 software:

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see **System Settings**.



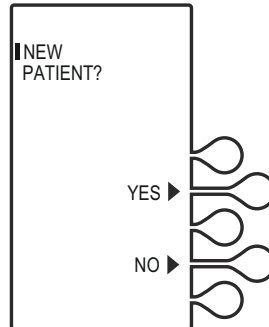
### If the infuser is running 7.02 software or higher:

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

### 3. The **NEW PATIENT?** screen displays if the infuser has been off for 5 hours or less. Select **YES>** or **NO>**.


If **YES>** is selected, the History and Rx settings are cleared.

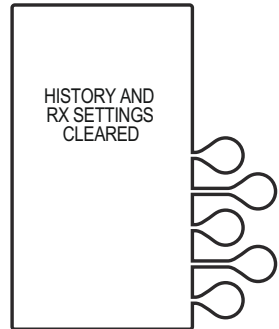
If **NO>** is selected, the History and Rx settings are retained.





In this example, the **YES>** option is selected. The **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

 **CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



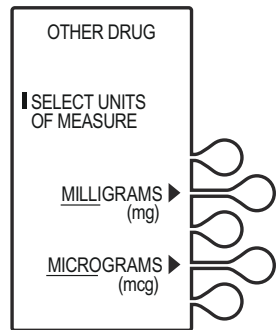
4. Verify the medication and concentration matches the physician order.

**Note:** If the medication is not correct, remove the vial and insert the correct vial.

After verifying medication and concentration, select **CONFIRM>**.

5. Select desired units of measure. For demonstration purposes **MILLIGRAMS>** is selected.

**Note:** When using **micrograms** (mcg), only whole numbers may be entered. If a decimal entry is attempted, the display will inform the user that the decimal point is not allowed. Press **[CLR]** to zero the value, then enter a whole value within the displayed range.



## Programming Infusers without ICU Medical MedNet Software

6. Enter the desired drug concentration within the displayed range, then press [ENTER].



**CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**

OTHER DRUG

ENTER DRUG CONCENTRATION  
THEN PRESS ENTER BUTTON

0.1 - 10 mg/mL

0 mg/mL

milligrams

PREVIOUS ▶

7. After verifying medication and concentration, select **CONFIRM**>.

OTHER DRUG  
10 mg/mL

CONFIRM  
10 mg/mL  
CONCENTRATION  
TO  
PHYSICIAN RX

CONFIRM ▶

PREVIOUS ▶

8. Set the loading dose (if desired) by selecting **YES**>. If no loading dose is desired, select **NO**> to proceed with programming.

OTHER DRUG  
10 mg/mL

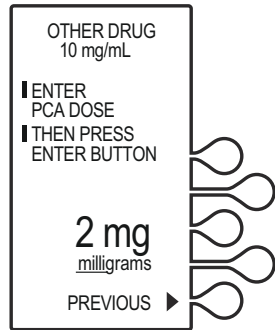
SET LOADING DOSE?

YES ▶

NO ▶

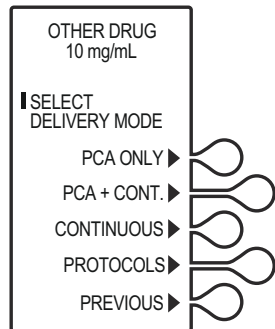
9. Using the numeric keypad, enter a loading dose, then press [ENTER] to continue.

See **PCA**, **PCA + Continuous**, or **Continuous** only for programming instructions.



10. The **SELECT DELIVERY MODE** screen displays.

See **PCA**, **PCA + Continuous**, or **Continuous** only for programming instructions.



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**NOTES**

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## Chapter 6

# Reviewing and Changing Rx Supplemental Loading Dose

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The following is consistent throughout all programming:

- To correct an entry during programming, press [CLR], re-enter the value, then press [ENTER].
- During initial programming, select **PREVIOUS>** to return to the preceding display and enter the desired setting. Each time **PREVIOUS>** is selected, the message display reverts to the previous setting, until the first setting is displayed.

## Reviewing the Current Program

Program settings may be reviewed while the infuser is running or stopped.

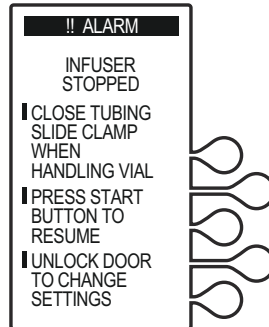
1. Press the [HISTORY/BATTERY] button twice to view current program settings.
2. Press [EXIT] to return to main menu, or, select **PREVIOUS>** to return to the preceding display.

## Changing the Current Program

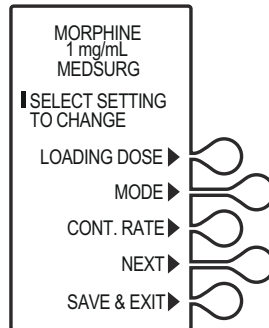
1. Stop the infuser by pressing the [START/STOP] button. The **INFUSER STOPPED** screen displays. Unlock and open the door.



**WARNING**  
**CLOSE THE TUBING  
SLIDE CLAMP WHEN  
HANDLING THE VIAL.**



2. Select **CHANGE RX>** to advance to change desired program settings. The **SELECT SETTING TO CHANGE** screen displays.
3. Select the desired setting to change:
  - Loading Dose
  - Mode (PCA, PCA + Continuous, Continuous)



**Note:** If the mode of delivery is changed, the display prompt for reprogramming uses the same steps outlined in the programming chapters.

- Cont. Rate
- Next
- Save & Exit

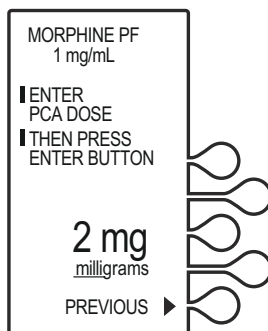
Select **NEXT>** to display additional options:

- PCA Dose
- Lockout
- Dose Limit

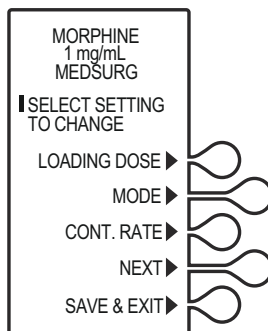
- Once the desired setting has been selected (in this example, PCA Dose), using the numeric keypad, enter the desired PCA dose, then press [ENTER].

To make additional programming changes, select **PREVIOUS>** to return to the preceding screen.

**Note:** The value range is displayed on the screen for devices without ICU Medical MedNet Software.

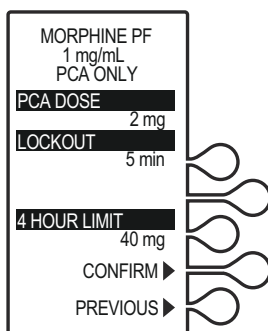


- Press **SAVE & EXIT>** to advance to the confirmation screen.



 **CAUTION:**  
**VERIFY PROGRAM VALUES.**

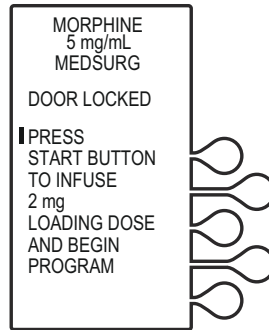
- Verify the program, then select **CONFIRM>** to accept the new program.



## Reviewing and Changing Rx Supplemental Loading Dose

- The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.

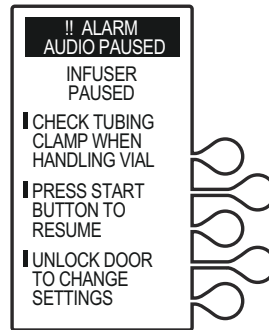
If a loading dose was programmed, the loading dose will infuse first.



- Once the loading dose is delivered, the infuser prompts the user to press **[START]** to deliver the Continuous program.

**Note:** The infuser will deliver medication only when the door is closed and locked.

**Note:** To stop a delivery in progress, press the **[START/STOP]** button.





# Programming a Supplemental Loading Dose

A supplemental loading dose (clinician-activated bolus) can be programmed anytime after initiation of PCA therapy. After a loading or supplemental loading dose delivery, the patient cannot receive any additional patient-requested boluses until the lockout interval has elapsed, assuming the dose limit has not been exceeded ([see Dose Limit](#)).

1. Stop the infuser by pressing **[START/STOP]**. The **INFUSER STOPPED** screen displays. Unlock and open the door.

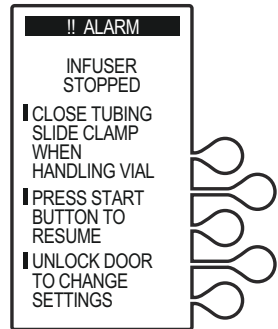


**WARNING**

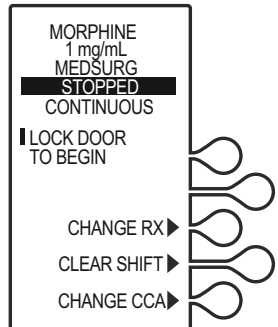
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**CLOSE THE TUBING SLIDE CLAMP WHEN HANDLING THE VIAL.**

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2. Select **CHANGE RX** to advance to change desired program settings.

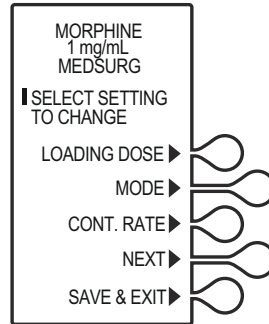


## Reviewing and Changing Rx Supplemental Loading Dose

3. The **SELECT SETTING TO CHANGE** screen displays. Select the desired setting to change:

### Loading Dose

- Loading Dose
- Mode (PCA, PCA + Continuous, Continuous)
- Cont. Rate
- Next
- Save & Exit



**Note:** If the mode of delivery is changed, the display prompt for reprogramming uses the same steps outlined in the programming chapters.

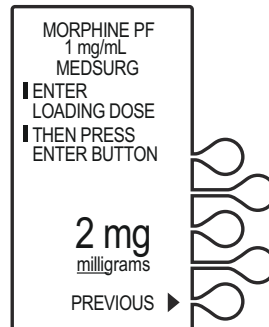
Select **NEXT>** to display additional options:

- PCA Dose
- Lockout
- Dose Limit

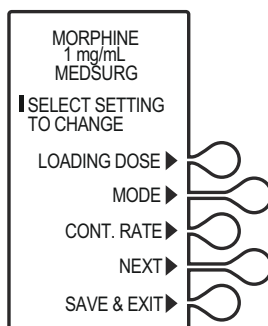
4. Once the loading dose has been selected, using the numeric keypad, enter the desired dose, then press **[ENTER]**.

To make additional programming changes, select **PREVIOUS>** to return to the preceding screen.

**Note:** The value range is displayed on the screen for devices without ICU Medical MedNet Software.

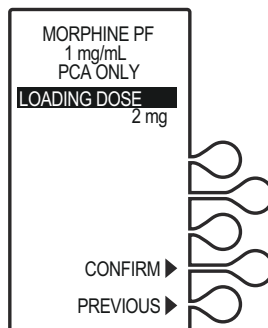


5. Press **SAVE & EXIT**> to advance to the Confirmation screen.



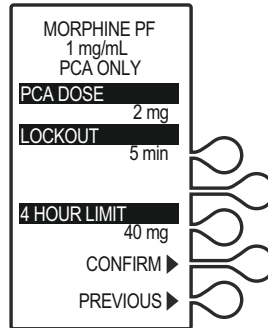
**CAUTION: VERIFY PROGRAM VALUES.**

6. Verify loading dose entry, then select **CONFIRM**>.

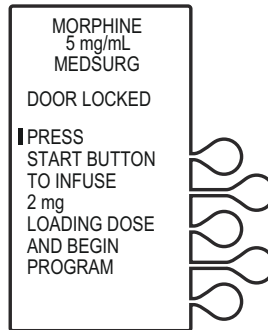


## Reviewing and Changing Rx Supplemental Loading Dose

- Verify program settings, then select **CONFIRM**>, or select **PREVIOUS**> to return to the preceding screen.



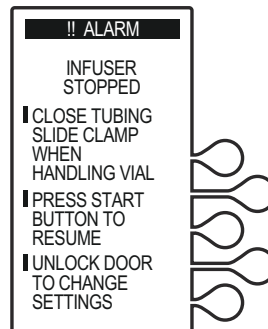
- Close and lock the door.  
Place the key in a secure location.
- The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse the loading dose.



- If the mode of delivery is PCA + Continuous or Continuous, once the loading dose is delivered the infuser prompts the user to press **[START]** to deliver the Continuous program.

**Note:** The infuser will deliver medication only when the door is closed and locked.

**Note:** To stop a loading dose in progress, press the **[START/STOP]** button.



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## Chapter 7

# Battery and Wireless Status History and Event Log

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The LifeCare PCA infuser stores data on current program settings, quantity and/or number of doses delivered, and has the capacity of recording up to 20,000 events. The infuser displays a chronological record of 400 of the most recent events occurring during infusion by pressing the [HISTORY/BATTERY] button.

These events include PCA dose as requested, amount delivered, program changes, the opening or closing of the security door, start or stop of continuous infusion. All event descriptions are preceded with time of occurrence. A **NEW DAY** event is logged to indicate the transition from one day to the next day.

**Note:** The LifeCare PCA infuser uses an internal lithium coin cell battery to ensure that History and Event Log information is maintained even if the infuser's backup battery is removed while the infuser is connected to AC power. The History and Event Log maintains the most recent 20,000 records, and deletes the oldest records if the total number of records reaches its maximum.

**Note:** For facilities using ICU Medical MedNet Software, the data is stored both on the infuser and on the facility's server.

For more information on reporting capabilities, see the **ICU Medical MedNet Meds User Guide**.

## ***Battery and Wireless Status History and Event Log***

The **[HISTORY/BATTERY]** button is used to display the following events:

- Battery strength indicator and wireless strength indicator status
- Current program settings for the clinician to review and verify the current physician order
- Shift totals, 1-hour totals, 24-hour totals
- Hour-by-hour PCA dose history (completed, partial, denied)
- Event Log (the change of any settings, the opening or closing of the security door, start or stop of continuous infusion, and alarm conditions)

When the infuser is configured for the **LAST 1 & 24 HOUR** history format, PCA activity totals in the last hour and in the last 24 hours are displayed.

When the infuser is configured for the **HOURLY-BY-HOURLY** history format, the number of PCA injections, partial doses, and patient demands occurring in each one-hour period during the last 24 hours may be displayed or printed. Only the one-hour periods with PCA activity are displayed.

The **HOURLY-BY-HOURLY** and the **LAST 1 & 24 HOUR** history totals represent a dynamic summation of past delivery of drugs and events. Data is accumulated in 5-minute increments.

- **HOURLY-BY-HOURLY** measures from the top of the hour to the next (for example, 08:00A-09:00A; 09:00A-10:00A). The infuser displays the PCA history (completed, partial, and denied attempts)
- A **LAST 1 HOUR** total consists of data from approximately the last 55 to 59 minutes without regard for when that hour began.
- A **LAST 24 HOUR** total consists of data from approximately the last 23 hours and 55 minutes to 24 hours.

**Note:** PCA requested doses (patient demands) as recorded in the history display and event log may not reflect the total number of demands. (Maximum of 100 patient demands per 10-minute interval.)

## Data Retention

Delivery program settings and programming option selections are retained in memory unless erased.

The LifeCare PCA infuser will automatically erase the program and the history if the infuser is turned off for more than four hours. If the infuser is restarted after being off for four hours or less, the **NEW PATIENT?** screen allows the clinician to either keep the current program and history, or erase the program and history.

After 24 hours the data in the infuser's short-term memory must be cleared. To clear the memory, see [Clearing Shift Totals](#).

## Infusers without ICU Medical MedNet Software

The LifeCare PCA infuser stores data on current program settings, quantity and/or number of doses delivered, and has the capacity of recording up to 20,000 events. The infuser displays a chronological record of 400 of the most recent events occurring during infusion. All event descriptions are preceded with time of occurrence.

The LifeCare PCA infuser has the capability to print the stored event history. Should your facility choose to use this feature, see [Appendix E Network Printer Setup](#) for more information on printing data.

## **Battery and Wireless Status History and Event Log**

The **[HISTORY/BATTERY]** button is used to display the following events:

- Current program settings for the clinician to review and verify the current physician order
- Shift totals, 1-hour totals, 24-hour totals
- Hour-by-hour PCA dose history (completed, partial, denied)
- Event log (the change of any settings, the opening or closing of the security door, start or stop of continuous infusion, and alarm conditions)

Pressing the **[HISTORY/BATTERY]** button displays the patient information and also provides access to the **PRINT HISTORY>** softkey.

Pressing the **PRINT HISTORY>** softkey generates a hard copy printout of the data ([Appendix E Network Printer Setup](#)).

When the infuser is configured for the **HOURLY** history format, the number of PCA injections, partial doses, and patient demands occurring in each one-hour period during the last 24 hours may be displayed or printed. Only the one-hour periods with PCA activity are displayed and printed.

When the infuser is configured for the **LAST 1 & 24 HOUR** history format, PCA activity totals in the last hour and in the last 24 hours are displayed and printed.



The **HOURLY-BY-HOURLY** and the **LAST 1 & 24 HOUR** history totals represent a dynamic summation of past delivery of drugs and events. Data is accumulated in 10-minute increments.

- **HOURLY-BY-HOURLY** measures from the top of the hour to the next (for example, 08:00A-09:00A; 09:00A-10:00A). The infuser displays the PCA history (completed, partial, and denied attempts)
- A **LAST 1 HOUR** total consists of data from approximately the last 55 to 59 minutes without regard for when that hour began.
- A **LAST 24 HOUR** total consists of data from approximately the last 23 hours and 55 minutes to 24 hours.

**Note:** PCA requested doses (patient demands) as recorded in the history display and event log may not reflect the total number of demands (maximum of 100 patient demands per 10-minute interval).

**Note:** Events occurring while printing is in progress are stored in memory, but not included in the current printout.

**Note:** If the lithium coin cell battery, the microcontroller unit, or the electronics assembly have been replaced, the serial number will not display on printouts.

**Note:** See [Figure 7-1](#) for a sample History printout (in the **PCA + CONTINUOUS** mode).

# Battery and Wireless Status History and Event Log

```
*****
*                               LifeCare PCA                               *
*                               PATIENT RECORD                             *
*****

SERIAL NUMBER: 00000143
SOFTWARE VERSION: 7.0
PATIENT NAME:

-----

DRUG ADMINISTERED:

-----

PM 04:52 MAY 17 2014

MODE: PCA + CONTINUOUS

                SETTINGS:
MORPHINE PF                1 mg/mL
CCA :
PCA DOSE                    3 mg
PCA LOCKOUT                 15 min
CONTINUOUS RATE            1 mg/hr
4 HOUR LIMIT                55 mg

                SHIFT TOTALS:
LOADING DOSE                5 mg
4 HOUR DOSE                 32.3 mg
TOTAL                       69.9 mg

                LAST 1 HOUR:
PCA COMPLETED              1
PCA PARTIAL                 1
PCA DENIED                  2

LOADING DOSE                0 mg
TOTAL                       5.6 mg

                LAST 24 HOURS:
PCA COMPLETED              18
PCA PARTIAL                 2
PCA DENIED                  21

LOADING DOSE                5 mg
TOTAL                       69.0 mg

                EVENT LOG:
04:52P SET 4 HR LIMIT      55 mg
04:52P SET CONT. RATE     1 mg/hr
04:52P SET PCA LOCKOUT    15 min
04:52P SET PCA DOSE       3 mg
04:52P SET PCA + CONT. MODE
04:52P RX SETTINGS RETAINED
04:52P CONFIRM MORPHINE PF 1 mg/mL
```

04:51P	CHECK SYRINGE ALARM	
04:51P	CHECK INJECTOR ALARM	
04:51P	CHECK SYRINGE ALARM	
04:51P	CHECK VIAL ALARM	
04:51P	BAR CODE NOT READ ALARM	
04:51P	CHECK VIAL ALARM	
04:50P	BAR CODE NOT READ ALARM	
04:50P	CHECK SYRINGE ALARM	
04:50P	BAR CODE NOT READ ALARM	
04:50P	CHECK SYRINGE ALARM	
04:50P	CHECK VIAL ALARM	
04:50P	DOOR OPENED	
04:50P	CHECK SETTINGS ALARM	
04:50P	DOOR LOCKED	
04:50P	BAR CODE NOT READ ALARM	
04:50P	CHECK VIAL ALARM	
04:49P	CHECK SYRINGE ALARM	
04:49P	CHECK VIAL ALARM	
04:49P	BAR CODE NOT READ ALARM	
04:49P	CHECK VIAL ALARM	
04:49P	BAR CODE NOT READ ALARM	
04:49P	CHECK VIAL ALARM	
04:49P	BAR CODE NOT READ ALARM	
04:49P	CHECK VIAL ALARM	
04:48P	CHECK SYRINGE ALARM	
04:48P	CHECK VIAL ALARM	
04:48P	DOOR OPENED	
04:48P	START INFUSION	
04:48P	PCA STOP	1.7 mg
04:48P	EMPTY SYRINGE ALARM	
04:47P	USING A/C	
04:43P	USING BATTERY	
04:22P	PCA DENIED	
04:10P	PCA END	3 mg
03:59P	PCA DENIED	
03:52P	USING A/C	
03:46P	USING BATTERY	
03:46P	PCA END	3 mg
03:35P	PCA DENIED	
03:34P	PCA DENIED	
03:22P	PCA END	3 mg
03:01P	PCA END	3 mg
02:59P	USING A/C	
02:44P	USING BATTERY	
02:43P	PCA END	3 mg
02:33P	PCA DENIED	
02:26P	PCA END	3 mg
01:46P	PCA END	3 mg
01:22P	PCA END	3 mg
01:12P	PCA DENIED	
12:59P	PCA END	3 mg
12:57P	PCA DENIED	
12:57P	PCA DENIED	
12:45P	PCA DENIED	
12:43P	PCA DENIED	
12:38P	PCA END	3 mg
12:23P	PCA DENIED	

## Battery and Wireless Status History and Event Log

12:14P	START INFUSION	
12:14P	DOOR LOCKED	
12:14P	CONFIRM 4 HR LIMIT	55 mg
12:14P	CONFIRM CONT. RATE	1 mg/hr
12:14P	CONFIRM PCA LOCKOUT	15 min
12:14P	CONFIRM PCA DOSE	3 mg
12:14P	CONFIRM PCA + CONT. MODE	
12:14P	MORPHINE PF	1 mg/mL
12:14P	SET 4 HR LIMIT	55 mg
12:14P	SET CONT. RATE	1 mg/hr
12:14P	SET PCA LOCKOUT	15 min
12:14P	SET PCA DOSE	3 mg
12:14P	SET PCA + CONT. MODE	
12:14P	RX SETTINGS RETAINED	
12:13P	CONFIRM MORPHINE PF	1 mg/mL
12:13P	CHECK INJECTOR ALARM	
12:12P	CHECK SYRINGE ALARM	
12:12P	CHECK VIAL ALARM	
12:12P	DOOR OPENED	
12:12P	PCA STOP	1.4 mg
12:12P	EMPTY SYRINGE ALARM	
11:51A	PCA END	3 mg
11:43A	PCA DENIED	
11:39A	PCA DENIED	
11:37A	PCA DENIED	
11:37A	PCA DENIED	
11:30A	PCA END	3 mg
11:06A	PCA END	3 mg
10:45A	PCA DENIED	
10:44A	PCA END	3 mg
10:18A	PCA DENIED	
10:10A	PCA END	3 mg
10:04A	PCA DENIED	
09:52A	PCA END	3 mg
09:17A	PCA END	3 mg
09:12A	PCA DENIED	
08:58A	PCA END	3 mg
08:42A	PCA DENIED	
08:27A	START INFUSION	
08:27A	LOAD DOSE END	5 mg
08:25A	USING A/C	
08:24A	START LOADING DOSE	
08:24A	DOOR LOCKED	
08:23A	CONFIRM 4 HR LIMIT	55 mg
08:23A	CONFIRM CONT. RATE	1 mg/hr
08:23A	CONFIRM PCA LOCKOUT	15 min
08:23A	CONFIRM PCA DOSE	3 mg
08:23A	CONFIRM PCA + CONT. MODE	
08:23A	MORPHINE PF	1 mg/mL
08:22A	SET 4 HR LIMIT	55 mg
08:22A	SET CONT. RATE	1 mg/hr
08:22A	SET PCA LOCKOUT	15 min
08:21A	SET PCA DOSE	3 mg
08:21A	SET PCA + CONT. MODE	
08:21A	SET LOADING DOSE	5 mg
08:20A	CONFIRM MORPHINE PF	1 mg/mL
08:20A	CHECK VIAL ALARM	
08:20A	CHECK INJECTOR ALARM	
08:20A	CHECK SYRINGE ALARM	

```
08:20A NEW PATIENT NOT SELECTED
08:19A BATTERY AVAILABLE
08:19A USING BATTERY
08:19A CHECK INJECTOR ALARM
08:19A POWER ON MAY 17
08:18A POWER OFF MAY 17
08:18A DOOR OPENED
08:18A CHECK SETTINGS ALARM
08:18A DOOR LOCKED
08:18A DOOR OPENED
08:18A CHECK SETTINGS ALARM
08:18A DOOR LOCKED
08:18A BATTERY AVAILABLE
08:17A POWER ON MAY 17
08:17A USING BATTERY
08:13A USING BATTERY
08:13A POWER OFF MAY 17
08:13A NEW PATIENT NOT SELECTED
08:12A USING A/C
08:12A POWER ON MAY 17
08:12A POWER OFF MAY 17
08:11A CONFIRM MORPHINE PF          1 mg/mL
08:11A NEW PATIENT NOT SELECTED
08:11A USING A/C
08:11A POWER ON MAY 17
08:11A POWER OFF MAY 17
08:10A HISTORY CLEARED

*****
VERIFIED BY:
*****
*****
*                END OF RECORD                *
*****
```

**Figure 7-1. History Printout**

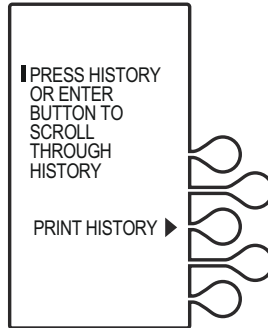
# Checking History and Settings

The history can be viewed by pressing the [HISTORY/BATTERY] button during delivery or when the device is stopped.

1. To check history or the current pump program, press the [HISTORY/BATTERY] button.
2. Press [HISTORY/BATTERY] or [ENTER] to scroll through history, or select **PRINT HISTORY>** to print.

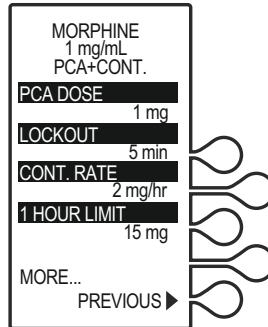
**Note:** The **Print History** option is only available for infusers without ICU Medical MedNet Software.

**Note:** See the **ICU Medical MedNet User Guide** to generate reports.



3. If **MORE** is displayed, continue to press [HISTORY/BATTERY] or [ENTER] to view additional information.

- Current pump program (shown)
- Shift totals (including total drug delivered toward the dose limit)
- Last one-hour information (if configured)
- Last 24-hour information (if configured)
- Hour by hour information (if configured)
- Event Log (start infusion, door locked, door open). The Event Log shows all events since the last **Clear History**. Up to 400 events are shown.



**Note:** Partial boluses can be the result of interrupting delivery by pressing [START/STOP] (PCA + Cont.), opening the door (PCA Only), loss of power, reaching the dose limit, emptying the vial, or a malfunction alarm.

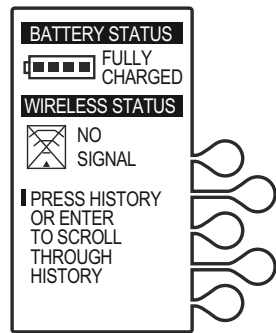
4. Press [EXIT] to return to the **MAIN DELIVERY** screen. If [EXIT] is not pressed, the infuser will automatically return to the **MAIN DELIVERY** screen.

## Clearing Shift Totals

1. Press the [HISTORY/BATTERY] button to display the battery and wireless strength indicators.

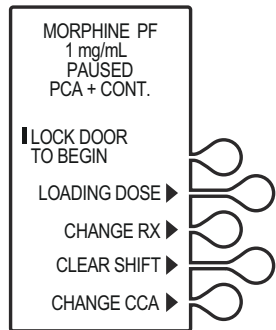
Press [HISTORY/BATTERY] a second time to review the current program.

Press [HISTORY/BATTERY] a third time to review and record shift totals.



2. Press [START/STOP] to stop delivery and unlock the door. The infuser will be paused.

**CHANGE CCA>** will only display if ICU Medical MedNet Software is enabled.



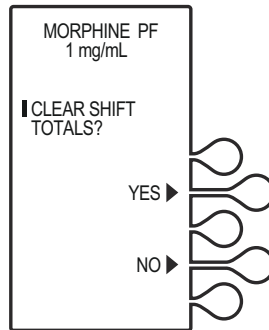
## Battery and Wireless Status History and Event Log

3. Select **CLEAR SHIFT**> to display the **CLEAR SHIFT TOTALS?** screen.

Select **YES**> to clear shift totals and return to the previous screen.

Select **NO**> to return to previous screen.

Selecting **YES**> clears the shift totals and total dose delivered. The dose limit data is not cleared.



**Note:** The 24-hour totals retain the patient information for the previous 24 hours.

4. Close and lock the door. Place the key in a secure location.
5. Press **[START/STOP]** to begin therapy. Approximately 10 seconds after door is locked and **[START/STOP]** is pressed, the **DOOR LOCKED** message disappears.



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# Chapter 8

## Maintenance

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This chapter addresses the following:

- Cleaning and Disinfecting
- Cleaning Spills
- Battery Maintenance
- Service
- Product Handling and Disposal
- Storage

## Cleaning and Disinfection

Clean and disinfect the LifeCare PCA infuser prior to the first patient use and between each patient use. In addition, the infuser should be thoroughly cleaned and disinfected once a month or according to facility protocol.

The following sections describe how to clean and disinfect the LifeCare PCA infuser. These instructions should also be used to prepare the infuser for storage, repair, or preventive maintenance.

Cleaning and disinfecting the infuser prevents build-up of contaminants from normal use and indirect patient contact. For example, organic soil can be transferred when clinicians who set up and program the infuser touch other surfaces and other patients. Thorough cleaning and effective disinfection are important steps in maintaining the infuser and preventing the spread of disease.

**Do not use the infuser if the enclosure, keypad, or display are damaged or cracked. Replace the infuser if damage or cracks are found.**

**WARNING**

---



**DISCONNECT THE INFUSER FROM AC POWER PRIOR TO OPENING THE DEVICE, CHANGING THE BATTERY, OR CLEANING THE DEVICE. FAILURE TO COMPLY WITH THIS WARNING COULD RESULT IN ELECTRICAL SHOCK.**

---

**WARNING**

---



**FAILURE TO CLEAN THE INFUSER'S OUTSIDE SURFACES AFTER PATIENT USE MAY SPREAD INFECTION. HOSPITAL INFECTION CONTROL POLICIES SHOULD BE FOLLOWED.**

---

**CAUTION: FOR PROPER FUNCTIONING OF THE BAR CODE READER, KEEP THE BAR CODE READER WINDOW CLEAN. FOR CLEANING, USE RECOMMENDED CLEANTEX™ CT 811 OPTICPAD™ OPTIC SURFACE CLEANER OR A SOFT, LINT-FREE CLOTH MOISTENED WITH A STREAK-FREE OPTICAL GLASS CLEANER. TO PREVENT FLUID INGRESS, DO NOT SPRAY FLUIDS OR CLEANING SOLUTIONS ON THE BAR CODE READER WINDOW AND PRESS LIGHTLY ON THE BAR CODE READER WINDOW WHILE CLEANING.**



**CAUTION: TO AVOID MECHANICAL OR ELECTRONIC DAMAGE, DO NOT IMMERSE THE INFUSER IN FLUIDS OR CLEANING SOLUTIONS. DO NOT SPRAY CLEANING SOLUTIONS TOWARD ANY OPENINGS IN THE DEVICE, OR DIRECTLY ON THE DEVICE.**



**CAUTION: USE ONLY RECOMMENDED CLEANING SOLUTIONS AND FOLLOW MANUFACTURERS' RECOMMENDATIONS. USING CLEANING SOLUTIONS NOT RECOMMENDED BY ICU MEDICAL MAY RESULT IN PRODUCT DAMAGE. DO NOT USE COMPOUNDS CONTAINING COMBINATIONS OF ISOPROPYL ALCOHOL AND DIMETHYL BENZYL AMMONIUM CHLORIDE.**



**CAUTION: NEVER USE SHARP OBJECTS SUCH AS FINGERNAILS, PAPER CLIPS, OR NEEDLES TO CLEAN ANY PART OF THE INFUSER. USE ONLY SOFT CLOTHS OR SPONGES. DO NOT STERILIZE BY HEAT, STEAM ETHYLENE OXIDE (ETO), OR RADIATION, AS THESE METHODS MAY CAUSE THE INFUSER TO MALFUNCTION.**



**CAUTION: DO NOT SPRAY FLUIDS ONTO THE INFUSER.**



**CAUTION: ALLOW ALL CLEANING FLUIDS APPLIED TO THE INFUSER TO DRY COMPLETELY BEFORE PLUGGING INTO AC OUTLETS AND BEFORE USE.**



## Cleaning

Follow the instructions in this section to sequentially clean all parts of the infuser to reach a visibly clean endpoint. The first step in the process is to clean the infuser to remove visible dirt, organic soil, and residue from spilled fluid. Thorough cleaning is essential to prepare the infuser for disinfection.

### Approved Cleaning Solutions

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

To clean the LifeCare PCA infuser, follow the instructions in this chapter, using the approved cleaning product in [Table 8-1](#).

Table 8-1. Cleaning Solution		
Class of Cleaning Solution	Manufacturer	Preparation
Enzymatic Detergent	ASP Enzol™	Use per manufacturer's recommendations and instructions in this manual

**Note:** At the time of publication, ICU Medical recommends only the cleaning solution in [Table 8-1](#). For updated listings of approved cleaners, visit [www.icumed.com](http://www.icumed.com).

## **Maintenance**

### **Cleaning Supplies**

To clean the infuser, use clean, soft, lint-free cloths moistened with an approved cleaning solution or commercial wipes (see [Table 8-1](#)).

To remove soil from hard-to-reach areas, use cotton-tipped or foam-tipped swabs.

**Note:** If using cotton-tipped swabs, ensure they do not leave a fiber residue.

To removed dried-on soil, use a soft, non-abrasive brush (see [Table 8-2](#)).

### **Preparing the Infuser for Cleaning**

To prepare the infuser for cleaning, proceed as follows:

1. Unplug the infuser and remove the administration sets.
2. Release the power cord from the Velcro strap.
3. Release the patient pendant cord from the Velcro strap.
4. Inspect the infuser enclosure for cracks and damage.
5. Remove all accessories.

**Note:** Administration sets must be removed by authorized personnel and disposed of per facility policy before cleaning the infuser.

**Note:** If the infuser enclosure is cracked or damaged, return the infuser to the Biomed.

## General Cleaning Instructions

To clean the infuser, use the methods shown in [Table 8-2](#).

<b>Table 8-2. Cleaning Methods</b>	
<b>Type of Cleaning Instrument</b>	<b>Method</b>
<b>Lint-Free Cloth</b>	<ol style="list-style-type: none"> <li>1. Wearing gloves, dampen the cloth with the approved cleaning solution and wipe in an outward spiral pattern on the desired surface(s).</li> <li>2. When the cloth becomes soiled, start wiping with the unsoiled part of the cloth. Replace the cloth as needed.</li> <li>3. Continue wiping until all visible soil, organic dirt, or spilled fluid is completely removed.</li> </ol>
<b>Disposable Cleaning Wipe</b>	<ol style="list-style-type: none"> <li>1. Wearing gloves, unfold the wipe completely, and use in an outward spiral pattern on the desired surface(s).</li> <li>2. When the cleaning wipe becomes soiled, start wiping with the unsoiled part of the cleaning wipe. Replace the wipe as needed.</li> <li>3. Continue wiping until all visible soil, organic dirt, or spilled fluid is completely removed.</li> </ol>

**Table 8-2. Cleaning Methods**

<b>Type of Cleaning Instrument</b>	<b>Method</b>
<b>Foam or Cotton-Tipped Swab</b>	<ol style="list-style-type: none"><li>1. Wearing gloves, dip a swab in an approved cleaning solution.</li><li>2. Press the tip against the solution container to remove excess fluid.</li><li>3. Use the swab to clean hard to reach areas. Change swabs as needed.</li><li>4. Use a cloth dampened in the cleaning solution to remove any fiber residue left behind by the cotton swab.</li><li>5. Continue swabbing until all visible soil, organic dirt, or spilled fluid is completely removed.</li></ol>
<b>Non-Abrasive Brush</b>	<ol style="list-style-type: none"><li>1. Wearing gloves, dampen the brush in the cleaning solution and gently brush seams and dried soil.</li><li>2. Use a cloth dampened in the cleaning solution or cleaning wipe to clean any residue left behind by the brush.</li><li>3. Continue brushing until all visible soil, organic dirt, or spilled fluid is completely removed.</li></ol>
<p>Follow these general instructions during cleaning and disinfection:</p> <ul style="list-style-type: none"><li>• Always wear gloves when using the cleaning solution.</li><li>• Use a spiral pattern when wiping, moving from the inner to outer edges to avoid recontaminating the areas you just cleaned.</li><li>• Do not allow cleaning fluid to run into the internal parts of the infuser.</li></ul>	

**Table 8-3** describes time intervals, in minutes, for cleaning.

<b>Table 8-3. Time Intervals for Cleaning</b>				
<b>Enzol Wiping Time (min)</b>	<b>Enzol Brushing Time (min)</b>	<b>Enzol Swabbing Time (min)</b>	<b>Tap Water Rinsing Time (min)</b>	<b>Total Dry Time (min)</b>
10	10	1/surface	5	15
Wiping, Brushing, Rinsing, and Dry time is per infuser. Brushing is to remove dried soil and swabbing is to access hard to reach areas.				

## Cleaning Exterior Surfaces

For each cleaning method, use the steps described in [Table 8-2](#). Ensure each area of the infuser is thoroughly clean and free from all visible soil before proceeding to the next step.

**Note:** Do not pour or spray fluid onto the infuser.

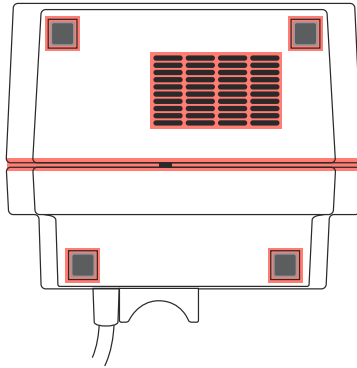
**To clean the exterior surfaces of the infuser, proceed as follows:**

1. Rest the infuser on one side to expose the bottom ([see Figure 8-1](#)).
2. Use a brush to remove debris then moist swabs to clean any openings or hard to reach areas highlighted in [Figure 8-1](#).
3. Using lint-free cloths dampened in the approved cleaning solution or wipes, wipe the bottom surface.
4. Lift the infuser. Using a lint-free cloth dampened in the approved cleaning solution or wipes, wipe the surface where it was resting, and place it upright.

## Maintenance

- Using lint-free cloths dampened in the approved cleaning solution or wipes, wipe the top and side surfaces. Use a combination of brush and swab as needed to clean the seam that joins the front and rear parts of the infuser case highlighted in **Figure 8-1**.

**Note:** Do not allow fluid into any ports or vents on the infuser.



**Figure 8-1.**  
**Bottom View - Cleaning the Bottom of the Infuser**

**To clean the back of the infuser, proceed as follows:**

- Turn the infuser upright to view the back (**see Figure 8-2**).
- Using lint-free cloths dampened in the approved cleaning solution or wipes, wipe the infuser handle and back surface.
- Using a combination of brushing, swabbing, and wiping (either with a lint-free cloth dampened in the approved cleaning solution or wipes), clean the threaded pole clamp shaft by rotating the knob back and forth, and clean the knob highlighted in **Figure 8-2**.
- Use a brush to remove debris and moist swabs to clean any openings or hard to reach areas highlighted in **Figure 8-2**.

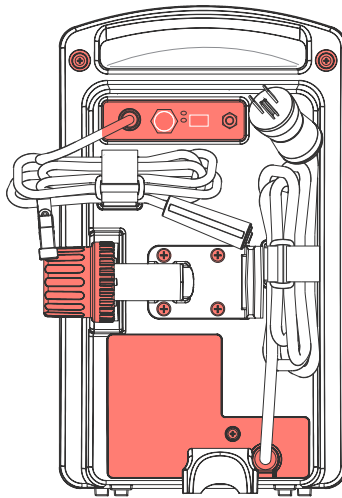


**Note:** Do not allow fluid into any ports or vents on the infuser.

**Note:** Do not allow fluid to flow behind the pole clamp knob.

5. Using a lint-free cloth dampened in the approved cleaning solution or wipes, wipe areas around the power cord outlet, the power cord, and the plug, including prongs.
6. Using a lint-free cloth dampened in the approved cleaning solution or wipes, wipe areas around the patient pendant, pendant cord, and the button at the end of the pendant cord.

**Note:** Do not allow fluid to flow into the crevices near the button.

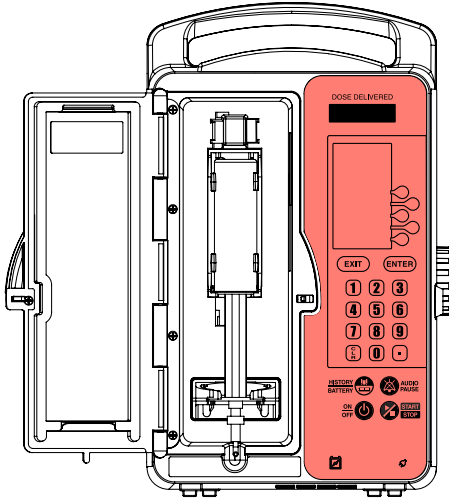


**Figure 8-2.**  
**Rear View - Cleaning the Back of the Infuser**

## Maintenance

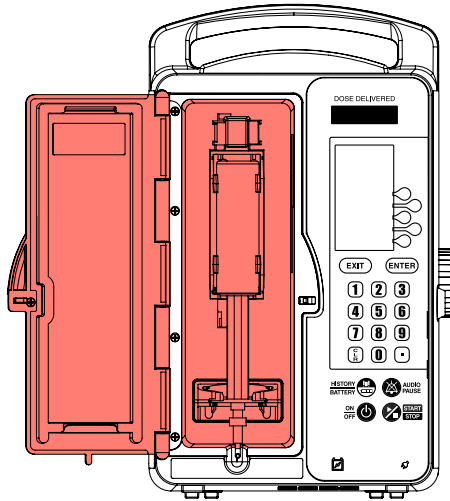
To clean the front of the infuser, proceed as follows:

1. Turn the infuser upright to view the front of the infuser (see [Figure 8-3](#)).
2. Using a lint-free cloth dampened in the approved cleaning solution or wipes, carefully wipe the keypad and display screen highlighted in [Figure 8-3](#).



**Figure 8-3.**  
**Front View - Cleaning the Keypad**

- Using a lint-free cloth dampened in the approved cleaning solution (*see Table 8-1*) or wipes, wipe the vial compartment door, including the door hinge, all interior and exterior surfaces, and the infuser housing vial door recess highlighted in *Figure 8-4*.



**Figure 8-4.**  
**Cleaning the Vial Compartment Door**

- Use a brush to remove debris, and use moist swabs to clean any openings or hard to reach areas highlighted in *Figure 8-4*.

**Note:** Do not allow cleaning fluid to flow into the door lock opening or vial cradle track opening.

## **Maintenance**

### **Cleaning the Vial Compartment**

Spilled fluid that is not cleaned properly and promptly at the patient site may accumulate and dry. If sticky or high-viscosity fluids are spilled in the vial compartment, clean the infuser as soon as possible.

Dried, built-up residue from these types of fluids can affect the operation of the vial sensor pin, injector sensor pin, and cradle mechanism. Dried fluid on the injector flange retainer can also affect the way the injector fits. Fluid or contaminants on the infuser's bar code reader window can prevent the bar code reader from operating.

The precision mechanisms located behind the vial door include parts and sensors that can be damaged by rough handling and fluid ingress. For this reason, the components in the vial compartment should only be cleaned as follows:

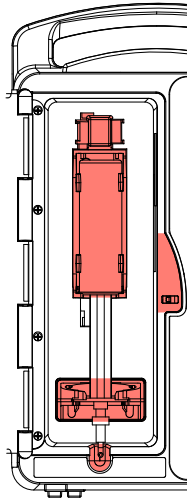
1. When cleaning the bar code reader, use recommended CleanTex CT 811 OpticPad Optic Surface Cleaner, or a soft, lint-free cloth moistened with a streak-free optical glass cleaner.



**CAUTION: TO AVOID FLUID INGRESS, DO NOT SPRAY FLUIDS OR CLEANING SOLUTIONS ON THE BAR CODE READER WINDOW AND PRESS LIGHTLY ON THE BAR CODE READER WINDOW WHILE CLEANING.**

2. Carefully handle the cradle release mechanism to prevent fluid ingress during cleaning.

**Note:** Do not allow fluid into any openings in the infuser case.



**Figure 8-5.**  
**Cleaning the Vial Compartment**

3. Turn the infuser upright and open the vial compartment door.
4. Clean the bar code reader window.
  - Use recommended CleanTex CT 811 OpticPad Optic Surface Cleaner or a soft, lint-free cloth moistened with a streak-free optical glass cleaner for cleaning, and wipe until visibly clean.
  - To avoid fluid ingress, do not spray fluids or cleaning solutions on the bar code reader window, and press lightly on the bar code reader window while cleaning.

## **Maintenance**

5. Using swabs, carefully clean the cradle release mechanism, vial cradle, vial cradle clips, and injector flange retainer, including the vial and injector sensor pins, without tilting the infuser backwards. See highlighted region in [Figure 8-5](#).

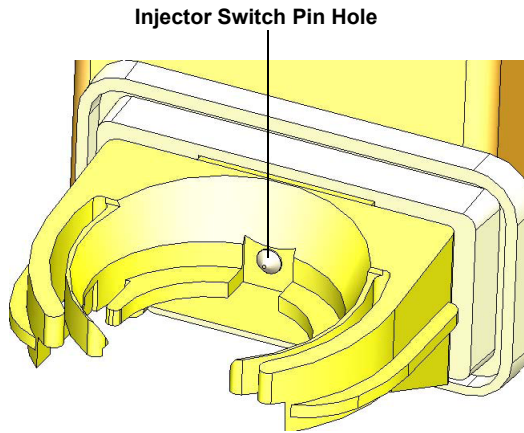
**Note:** If a sensor pin is damaged or broken off, return the infuser to the Biomed.

6. Using lint-free cloths dampened in the approved cleaning solution ([see Table 8-1](#)) or wipes, clean the interior surface of the vial compartment.
7. Use a brush to remove debris and then moist swabs to clean any openings or hard to reach areas.

### **Cleaning the Injector Switch Pin**

Spilled fluid can accumulate around the injector switch pin and injector pin hole ([see Figure 8-6](#)), which is part of the mechanism assembly.

The spilled fluid can become sticky or harden, which may retard or stop the spring action at the back of the injector switch pin, causing the pin to become stuck. This can cause the infuser to indicate that the injector flange is inserted in the injector flange retainer after the injector has been removed.



**Figure 8-6.**  
**Injector Switch Pin Location**

When a syringe is loaded into the infuser with the injector flange outside of the injector flange retainer and the **CHECK INJECTOR** alarm message does not display, inspect the injector switch pin to determine if spilled fluid has accumulated ([see Figure 8-7](#)).



**Figure 8-7.**  
**Injector Switch Pin with Accumulated Fluid Spillage**

## **Maintenance**

Recommended tools and materials for this procedure are cotton swabs and a brush. See [Table 8-3](#) for cleaning time intervals.

### **To clean the injector switch pin, proceed as follows:**

1. Using a cotton swab, clean any fluid spillage from around the injector flange retainer.
2. Tilt the infuser forward.
3. Use a brush and moist swab to loosen/remove the debris from inside the switch pin hole.
4. Using the wooden rod end of the cotton swab, carefully apply pressure on the injector switch pin, attempting to move it in and out of the injector hole. Use the rod end to scrape any remaining sticky material from the wall of the injector hole.
5. Use additional cotton swabs until all traces of the fluid/debris are gone. Wipe the area dry after cleaning.

**Note:** Repeat steps 1 through 5 as needed. When the debris has been cleared, the spring at the back of the switch pin will cause it to pop out. The pin will be able to move freely in and out of the hole.

After successful cleaning, the **CHECK INJECTOR** alarm displays when there is no injector present in the injector flange retainer.

## **Cleaning the Power Cord Strap**

To clean the power cord strap, proceed as follows:

1. Soak the power cord strap in cleaning fluid until the dried soil is softened.
2. Use a cloth or brush to dislodge soil if needed.
3. Wipe off excess cleaning fluid, and let the strap air dry.

## **Cleaning the Patient Pendant Strap**

To clean the patient pendant strap:

1. Soak the patient pendant strap in cleaning fluid until the dried soil is softened.



2. Use a cloth or brush to dislodge soil if needed.
3. Wipe off excess cleaning fluid, and let the strap air dry.

## **Cleaning Infuser Accessories**

Use the cleaning supplies, and follow the general cleaning instructions in [Table 8-2](#) to clean the infuser accessories.

## **Rinsing the Infuser**

To rinse the infuser after cleaning, use the rinse time interval indicated in [Table 8-3](#) and proceed as follows:

1. Dampen a lint-free cloth with tap water.
2. Wipe each surface with the moist cloth for the entire rinse time interval.
3. For hard to reach areas, dip the swab into the water and press the tip against the container to remove excess water, and rinse the areas.

**Note:** Do not allow fluid into any ports or vents.

## **Drying the Infuser**

To dry the infuser after cleaning, refer to the drying time indicated in [Table 8-3](#) and proceed as follows:

1. Allow the infuser and accessories to air dry.
2. Inspect all surfaces and recessed areas for moisture.
3. When no moisture is detected, close the vial compartment door.

**Note:** Allow to air dry completely before beginning disinfections.

**Note:** After the vial compartment door receptacle is dry, close the vial compartment door to avoid damage when moving the infuser.

To obtain additional information on cleaning the infuser, [contact ICU Medical](#).

## Maintenance

### Disinfection

Before disinfection, ensure the infuser is thoroughly cleaned and completely dry.



**CAUTION: DO NOT SPRAY FLUIDS ONTO THE INFUSER.**



**CAUTION: DO NOT ALLOW FLUIDS TO ENTER OPENINGS OR SEAMS IN THE INFUSER'S CASE.**



**CAUTION: WEAR PPE (PERSONAL PROTECTIVE EQUIPMENT) DURING THE DISINFECTION PROCEDURES.**

### Approved Disinfection Solutions

To disinfect the LifeCare PCA infuser, follow the instructions in this section, using the recommended disinfecting solution in [Table 8-4](#).

**Table 8-4. Disinfecting Solution**

<b>Class of Disinfecting Solution</b>	<b>Manufacturer</b>	<b>Preparation</b>
Household Bleach	Clorox™ Germicidal Bleach (8.25 % concentration)	Do not exceed 1 part bleach in 10 parts water

**Note:** At the time of publication, ICU Medical recommends only the disinfecting solution in [Table 8-4](#). For updated listings of approved cleaners, visit [www.icumed.com](http://www.icumed.com).

## **Disinfection Supplies**

To disinfect the infuser, use clean, soft, lint-free cloths moistened with an approved disinfectant, or disposable commercial wipes (*see Table 8-4*).

To disinfect hard-to-reach areas, use cotton-tipped or foam-tipped swabs.

**Note:** If using cotton-tipped swabs, ensure they do not leave a fiber residue.

## **Preparing the Infuser for Disinfection**

To prepare the infuser for the disinfection process, proceed as follows:

1. Unplug the infuser.
2. Ensure that all visible soil was removed during cleaning and that the infuser and accessories are completely dry.
3. Inspect the enclosure for cracks and damage. If cracked or damaged, return the infuser to the Biomed.

## **General Disinfection Instructions**

*Table 8-5* describes the methods for disinfecting the infuser. Specific instructions on disinfecting each part of the infuser using these methods are described in the following sections.

**Table 8-5. Disinfection Methods**

<b>Type of Disinfection Instrument</b>	<b>Method</b>
<b>Lint-Free Cloth</b>	<ol style="list-style-type: none"><li>1. Wearing gloves, dampen the cloth with the approved disinfecting solution (<a href="#">see Table 8-4</a>) and wipe in an outward spiral pattern on the desired surfaces.</li><li>2. When the cloth becomes soiled, start wiping with the unsoiled part of the cloth. Replace the cloth as needed.</li></ol>
<b>Disposable Disinfectant Wipe</b>	<ol style="list-style-type: none"><li>1. Wearing gloves, unfold the wipe completely, and use in an outward spiral pattern on the desired surfaces.</li><li>2. When the disinfectant wipe becomes soiled, start wiping with the unsoiled part of the disinfectant wipe. Replace the wipe as needed.</li></ol>

**Table 8-5. Disinfection Methods**

<b>Type of Disinfection Instrument</b>	<b>Method</b>
<b>Foam or Cotton-Tipped Swab</b>	<ol style="list-style-type: none"> <li>1. Wearing gloves, dip a swab in the approved disinfecting solution (<i>see Table 8-4</i>).</li> <li>2. Press the tip against the solution container to remove excess fluid.</li> <li>3. Use the swab to clean hard to reach areas. Change swabs as needed.</li> <li>4. Dampen a lint-free cloth with the approved disinfecting solution to remove any fiber residue left behind by the cotton swab.</li> </ol>
<b>Non-Abrasive Brush</b>	<ol style="list-style-type: none"> <li>1. Wearing gloves, dampen the brush in the disinfecting solution and gently brush seams and dried soil.</li> <li>2. Use a cloth dampened in the disinfecting solution or disinfectant wipe to clean any residue left behind by the brush.</li> </ol>
<p>Follow these general instructions during disinfection:</p> <ul style="list-style-type: none"> <li>• Always wear gloves when using the disinfecting solution.</li> <li>• Do not allow disinfecting fluid to run into the internal parts of the infuser.</li> </ul>	

**Table 8-6. Minimum Time Intervals for Disinfecting**

Brushing/swabbing (hard to reach areas): 15 minutes

Wiping: 15 minutes

Rinsing with purified water (PURW): 3 minutes

Brushing/swabbing, wiping, and rinsing times are per infuser. Apply disinfectant as often as needed to keep surfaces visually moist/wet during disinfection.

### Disinfecting Exterior Surfaces

For each disinfection step, use the methods described in [Table 8-5](#). Ensure each area of the infuser has been completely wiped or swabbed with disinfectant before proceeding to the next step.

To disinfect the infuser, proceed as follows:

1. Rest the infuser on one side to expose the bottom, as shown in [Figure 8-1](#).
2. Use brushes and swabs to disinfect hard to reach areas highlighted in [Figure 8-1](#).
3. Using lint-free cloths dampened in the approved disinfecting solution ([see Table 8-4](#)) or wipes, wipe the bottom surface.
4. Lift the infuser. Using a lint-free cloth dampened in the approved disinfecting solution or wipes, wipe the surface where it was resting, and place the infuser in the upright position.
5. Using lint-free cloths dampened in the approved disinfecting solution or wipes, wipe the top and side surfaces.
6. Turn the infuser to expose the back, as shown in [Figure 8-2](#).
7. Using lint-free cloths dampened in the approved disinfecting solution or wipes, wipe the infuser handle and back surface.
8. Using a combination of brushing, swabbing, and wiping, disinfect the threaded pole clamp shaft by rotating the knob back and forth, and disinfect the knob.

9. Use brushes and swabs to disinfect hard to reach areas highlighted in **Figure 8-2**.
10. Using a lint-free cloth dampened in the approved disinfecting solution or wipes, wipe areas around the power cord outlet, the power cord, power cord strap, and the plug.
11. Using a lint-free cloth dampened in the approved disinfecting solution (**see Table 8-4**) or wipes, wipe the areas around the patient pendant, pendant cord, and the button at the end of the pendant cord.  
**Note:** Do not allow fluid to flow into the crevices near the button.
12. Turn the infuser upright to view the front of the infuser as shown in **Figure 8-3**.
13. Using a lint-free cloth dampened in the approved disinfecting solution or wipes, carefully wipe the keypad and display screen, swabbing the keypad recess highlighted in **Figure 8-3**.
14. Using a lint-free cloth dampened in the approved disinfecting solution or wipes, wipe the area around the vial compartment door.
15. Use brushes and swabs to disinfect the hard to reach areas highlighted in **Figure 8-4**.

## **Disinfecting the Vial Compartment**

**Note:** The precision mechanisms located behind the vial compartment door include pins and sensors that can be damaged by rough handling. For this reason, the components in the vial compartment (**see Figure 8-5**) should only be disinfected by personnel who are aware of how the infuser operates and can take proper precautions.



**CAUTION: TO PREVENT FLUID INGRESS, DO NOT SPRAY FLUIDS OR DISINFECTING SOLUTIONS ON THE BAR CODE READER WINDOW AND PRESS LIGHTLY ON THE BAR CODE READER WINDOW WHILE DISINFECTING. CAREFULLY HANDLE THE CRADLE RELEASE MECHANISM TO PREVENT FLUID INGRESS DURING DISINFECTION.**

## **Maintenance**

To disinfect the vial compartment door and receptacle, proceed as follows:

1. Open the vial compartment door.
2. Clean the bar code reader window.
  - Using CleanTex CT 811 OpticPad Optic Surface Cleaner or a streak-free optical glass cleaner, clean the bar code reader window. Wipe until visibly clean. Use additional tissues as needed.
  - To prevent fluid ingress, do not spray fluids or solutions on the bar code reader window, and press lightly on the bar code reader window while disinfecting.
3. Using swabs, carefully disinfect the cradle release mechanism, vial cradle, vial cradle clips, and injector flange retainer, including the vial and injector sensor pins, without tilting the infuser backwards ([see Figure 8-5](#)).

**Note:** If a sensor pin is damaged or broken off, return the infuser to the Biomed.
4. Using a lint-free cloth dampened in the approved disinfecting solution ([see Table 8-4](#)) or wipes, disinfect the interior surface of the vial compartment.

## **Disinfecting the Power Cord Strap**

To disinfect the power cord strap, proceed as follows:

1. Soak the power cord strap in disinfecting fluid.
2. If necessary, use a lint-free cloth to force disinfectant into the fabric.
3. Using a clean, lint-free cloth, wipe off excess disinfecting fluid and let the strap air dry.

## **Disinfecting the Patient Pendant Strap**

To disinfect the patient pendant strap:

1. Soak the patient pendant strap in disinfecting fluid.



2. If necessary, use a lint-free cloth to force disinfectant into the fabric.
3. Using a clean, lint-free cloth, wipe off excess disinfecting fluid and let the strap air dry.

## **Disinfecting Accessories**

Use the disinfection supplies, and follow the general disinfecting instructions in [Table 8-5](#) to disinfect all infuser accessories.

## **Rinsing the Infuser**

To rinse the infuser after cleaning, proceed as follows:

1. Dampen a lint-free cloth with purified water (PURW).
2. Wipe each surface with the moist cloth for the entire rinse time interval.
3. For hard to reach areas, dip the swab into the water and press the tip against the container to remove excess water, and rinse the areas.

**Note:** Do not allow fluid into any ports or vents.

## **Drying the Infuser**

To dry the infuser, proceed as follows:

1. Allow the infuser and accessories to air dry for a minimum of 15 minutes.
2. Inspect all surfaces and recessed areas for moisture. If moisture is still present, a sterile cloth may be used for drying.
3. When no moisture is detected, return the infuser to service.

**Note:** Ensure the power cord and plug are completely dry before plugging the infuser into AC (mains) power.

To obtain additional information on disinfecting the infuser, [contact ICU Medical](#).

# Cleaning Spills During the Course of Patient Care

The following procedure describes how to clean non-hazardous spills or soil from the infuser during the course of patient care.

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

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

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



**CAUTION: DO NOT USE THE INFUSER IF THE ENCLOSURE, KEYPAD, OR DISPLAY IS DAMAGED OR CRACKED. IF DAMAGE OR CRACKS ARE FOUND, REPLACE THE INFUSER.**

2. With gloves on, remove a wipe from the dispenser and unfold it to expose the maximum surface area before wiping, or spray an approved cleaning solution on a clean, lint-free cloth ([see Table 8-1](#)).



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

3. Wipe up the spill.
  - Use a spiral pattern when wiping, moving from the inner to outer edges of each surface to avoid recontaminating the areas you have already wiped.
  - When part of the cleaning cloth or wipe becomes soiled or saturated, start wiping with an unused part.
  - Change cloths or wipes as needed to avoid spreading the spill from one area of the infuser to another.
  - Do not allow cleaning fluid to run into internal parts of the infuser.

- When wiping the vial compartment, take care to avoid damaging the cradle mechanism.

**Note:** If sticky or high-viscosity fluids are spilled in the vial compartment, replace the infuser as soon as possible so that it can be thoroughly cleaned. Dried, built-up residue from these type of fluids can affect the operation of the vial sensor pin, injector sensor pin, and cradle mechanism.

To obtain additional information on cleaning the infuser, [\*\*contact ICU Medical.\*\*](#)

## **Battery Maintenance**

The LifeCare PCA infuser is battery powered for emergency backup and temporary portable operation. If the batteries are to be stored for more than 6 months, they should be charged to prevent damage (sulfation) to the batteries during low charge conditions. When the battery is first put into use, or has been out of use for one or more months, it will not have full capacity. The battery will need conditioning.

Condition a battery for optimal performance by fully charging and discharging the battery three times. A fully charged conditioned battery shall provide at least 3 hours of continuous operation from the start of delivery at 5 mL/hr to **Dead Battery** state.

The battery charges whenever the LifeCare PCA infuser is connected to AC (mains) power. If the infuser is switched off, a recharge takes approximately 16 hours. The recharge takes longer if the LifeCare PCA infuser is turned on. To maintain maximum battery charge and to prolong battery life, connect the LifeCare PCA infuser to AC (mains) power whenever possible.

## Maintenance

See the *LifeCare PCA Infuser Technical Service Manual* for additional information on battery maintenance.

**Note:** Consult a qualified Biomedical technician for battery replacement.



**WARNING**  
**UNPLUG THE AC POWER CORD BEFORE REMOVING THE BATTERY DOOR.**



**CAUTION: DO NOT OPERATE THE LIFE CARE PCA INFUSER ON PATIENTS WITH THE BATTERY REMOVED. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS ENSURE PROPER OPERATION.**



**CAUTION: IF THE LOW BATTERY ALARM SOUNDS, CONNECT THE LIFE CARE PCA INFUSER TO AC (MAINS) POWER.**

- The battery may not be fully charged upon receipt. Connect the LifeCare PCA infuser to AC power for at least 16 hours.
- Always connect the infuser to a properly grounded receptacle unless battery operation is desired. If quality earth grounding source is in doubt, use battery power.



**WARNING**  
**THE INFUSER CANNOT COMMUNICATE VIA THE NETWORK IF THE LOW BATTERY WARNING ALARM HAS SOUNDED.**

## Service

**Service Life:** 10 years with an exception of the drive mechanism (rated for 5 years) and SLA battery (rated for 2 years).

All servicing or adjustments to the LifeCare PCA infuser should be referred to qualified technical personnel. A technical service manual may be ordered from the local ICU Medical sales office.

## **Product Handling and Disposal**

Comply with local disposal and recycling regulations as appropriate for disposal of batteries, rechargeable battery packs, medical electronic components, and administration sets.

At the end of the lead acid battery's service life, dispose of the lead acid battery by delivering it to an authorized lead acid battery recycler.

At the end of the lithium coin cell battery's service life, dispose of the battery by following your facility's disposal policy for lithium coin cell batteries.

At the end of the infuser's serviceable life, the infuser parts must be recycled by an authorized electronic waste handler.

## **Infuser Storage**

To prolong the life of the LifeCare PCA infuser, observe the following storage precautions:

- Store the LifeCare PCA infuser away from excessive heat, cold, and humidity
- Store the LifeCare PCA infuser connected to AC (mains) power
- Open the door then press the [ON/OFF] button to turn off the infuser

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**NOTES**

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# Chapter 9

## Specifications

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This system operating manual complies with 21 CFR 807.87(e), 21 CFR Part 801, and 21 CFR 801.109.

<b>Administration Sets:</b>	Use only compatible LifeCare PCA administration sets with Integral Pressure Activated Valves
<b>Atmospheric Pressure:</b>	0 - 9,840 feet (0 - 3,000 meters) or equivalent pressure
<b>Battery:</b>	One sealed lead acid; 8 V; rechargeable; internal to the device Accessible for ease of field replacement with color-coded leads and polarized connector
<b>Battery Life:</b>	A fully charged conditioned battery provides at least three hours of continuous operation from the start of delivery at 5 mL/hr to infuser shutdown due to a dead battery after a maximum 5 minute Power On Self Test (POST)/delivery programming operation is completed  The LifeCare PCA infuser provides a low battery warning at least 30 minutes prior to shutdown  The LifeCare PCA infuser provides a <b>DEAD BATTERY</b> alarm at least 3 minutes prior to shutting down due to a dead battery.

## Specifications

- Casing:** High-impact plastic
- Dimensions:** Approximately 8 in. W x 13 in. H x 6 in. D (excluding pole clamp and power cord)
- Weight:** Approximately 13 lbs. with battery

### Delivery Rates:

**Table 9-1. Delivery Rates**

Mode	Delivery Rate
PCA	Approximately 1 mL in 35 seconds
CONTINUOUS	Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr)
PCA + CONT.	Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr) + PCA dose (mg)



**Electrical Safety:** Meets IEC 60601-1 standard

<b>Table 9-2. Electrical Safety</b>	
<b>Specification</b>	<b>Description</b>
<b>Class 1</b>	AC (mains) supply equipment using protective earth
<b>Type BF</b>	Type BF applied parts are those parts suitable for direct patient connections  Type BF parts are not suitable for direct cardiac application
<b>Type CF</b>	Type CF applied parts complying with the higher degree of protection against electric shock  Type CF Applied Parts are those parts suitable for direct cardiac application
<b>IPX2</b>	The case is disinfectable and protected against vertically falling water drops
<b>Electromagnetic Interference (EMI) and Radio Frequency Interference (RFI)</b>	The LifeCare PCA infuser is designed to perform in the typical hospital environment  The LifeCare PCA infuser has been tested to comply with IEC 60601-1-2:2007  A qualified service technician should verify performance in any environment where EMI or RFI levels are excessive

## **Specifications**

<b>Electrical Leakage:</b>	Risk current limits meets standard IEC 60601-1
<b>Fuse:</b>	1.6 A, 250 V; Slo-Blo
<b>Lockout Interval Range:</b>	5 to 120 minutes in 1-minute increments
<b>Maximum Infusion Pressure:</b>	45 psi
<b>Maximum Overinfusion:</b>	The maximum overinfusion under single fault conditions is 25%
<b>Occlusion Alarm Pressure:</b>	12.5 psi +2.5/-3.5 psi
<b>Occlusion Bolus Volume:</b>	1 mL for fully primed set (max.)
<b>Operating Temperature:</b>	41° to 104° F (5° to 40° C); 10% to 90% relative humidity
<b>Patient Pendant:</b>	6 feet ± 6 inches (66 - 78 inches); with blue handle
<b>Power Cord:</b>	Hospital-grade AC cord; 10 feet; with transparent plug and retainer plate
<b>Power Requirements:</b>	120 V; 60 Hz; 50 VA max.
<b>Ethernet Port:</b>	Connection to IEC 60601-1 or IEC 60950 equipment
<b>Nurse Call:</b>	Connection to IEC 60601-1 or IEC 60950 equipment

- Recharge:** The battery charges whenever the infuser is connected to AC power  
After discharge to the **LOW BATTERY** operative limit, the battery will recharge to at least 80% of its full charge capacity within 16 hours, provided it is plugged into rated AC power  
The infuser will operate on AC power in the event the battery is open or shorted
- Self-Discharge:** A fully charged battery will retain a minimum 20% of the initial charge for six months when the infuser is not connected to AC power or is not operating, and is stored at 20° C
- Storage Temperature:** -4° to 140° F (-20° to 60° C)  
10% to 90% relative humidity

## *Specifications*

# Wireless LAN Module

<b>Device Name:</b>	802.11 a/b/g Wireless Module
<b>Standards:</b>	IEEE 802.11 a/b/g
<b>Transmit Power:</b>	802.11 b/g - 17 dBm 802.11 a - 16 dBm
<b>Antenna:</b>	Integrated surface mount antenna
<b>Certifications:</b>	FCC Part 15.247, 15.407 IC RSS-210, RSS-102 FCC ID: STJ-80411396001 IC: 5627A- 80411396 Model: CUSTOM DWL-AG132

## Stored Occlusion Volume

<b>Table 9-3. Stored Occlusion Volume</b>		
<b>Delivery Rate</b>	<b>Pressure Limit (Average)</b>	<b>Stored Volume (Average)</b>
0.1 mL/hr	11.4 psi	0.77 mL
5 mL/hr	11.6 psi	0.81 mL
20 mL/hr	11.6 psi	0.80 mL
PCA Dose (100 mL/hr)	11.4 psi	0.78 mL

## Time from Occlusion to Alarm

<b>Table 9-4. Time from Occlusion to Alarm</b>		
<b>Delivery Rate</b>	<b>Pressure Limit (Average)</b>	<b>Time to Occlude (Average)</b>
0.1 mL/hr	11.4 psi	10 hours
5 mL/hr	11.6 psi	10 minutes
20 mL/hr	11.6 psi	2 minutes, 30 seconds
PCA Dose (100 mL/hr)	11.4 psi	40 seconds

## **Delivery Rate Accuracy**

Delivery accuracy is  $\pm 5\%$  at continuous delivery rates greater than 1 mL/hr. This accuracy is valid within the operating temperature range stated in this chapter. For accuracy data at other flow rates, see the typical trumpet curves shown in [Figure 9-2](#).

The under-delivery that may occur at rates less than 0.5 mL/hr or bolus volumes less than 0.5 mL may be substantially greater than 5%, and is due primarily to the variability of friction between the syringe plunger and barrel. This under-delivery may include periods of no delivery. Note that at extremely low flow rates the accuracy error rate can be up to  $\pm 15\%$  from 0.5 to 1.0 mL/hr and  $\pm 30\%$  from 0.1 to 0.5 mL/hr.

If multiple partial PCA doses are delivered, the accumulated total reflected in the history totals may be higher than the sum of the PCA doses logged in the event log. This is because only a portion of the next 0.1 mg (or 1 mcg) may have been delivered at the time any of the PCA doses were interrupted. As these portions accumulate, their combined total may account for 0.1 mg (or 1 mcg).

## **Trumpet Curves**

The typical trumpet curve graphs shown in [Figure 9-2](#) show representative maximum and minimum percent flow rate deviation from the programmed rate over time. This information was developed in accordance with IEC 60601-2-24:2012, Sub-Clause 201.12.1.102. Refer to this standard for detailed information.

Refer to the example shown in [Figure 9-1](#) to read a trumpet curve graph. The graphs shown in [Figure 9-2](#) plot flow rates at 30-second intervals for the first hour after the startup period. The graph depicts mean delivery rate error (average of 36 infusers) as a straight line. The graph 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”).

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

As an example of how the trumpet curves may 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 morphine administered at 5 mL/mg. At 5 minutes, the average drug delivery error would be within the range of +2.8% and -0.5% of the expected nominal rate. For example, if morphine is administered at 5 mL/mg, at 5 minutes the average drug delivery error would be within the range of +2.8% and -0.5% of the expected nominal rate.

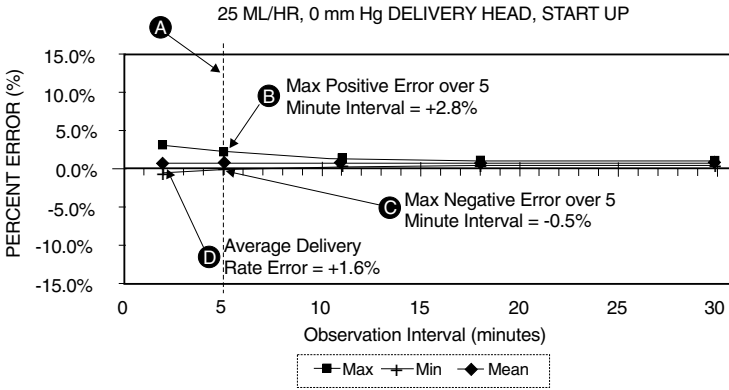
## Specifications

### Example

From the trumpet curve graph example (see [Figure 9-1](#)), 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).

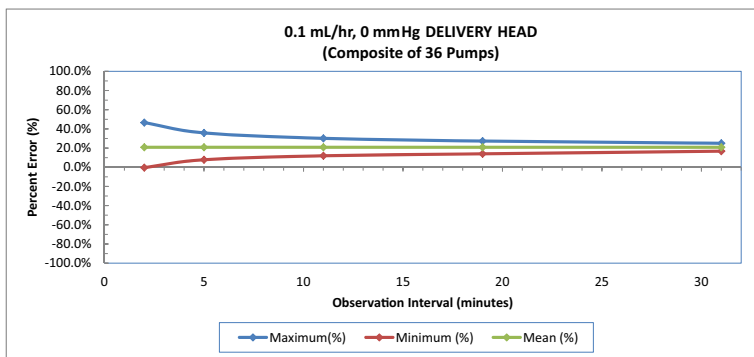
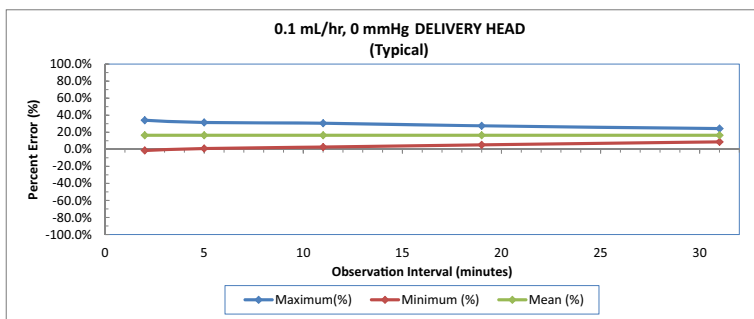
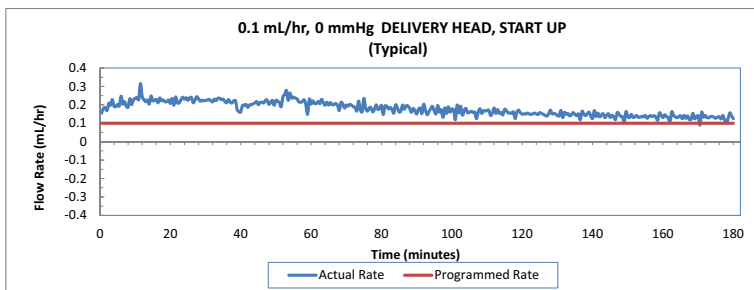
For other time intervals, look at other points at the horizontal axis and determine corresponding limits as above.



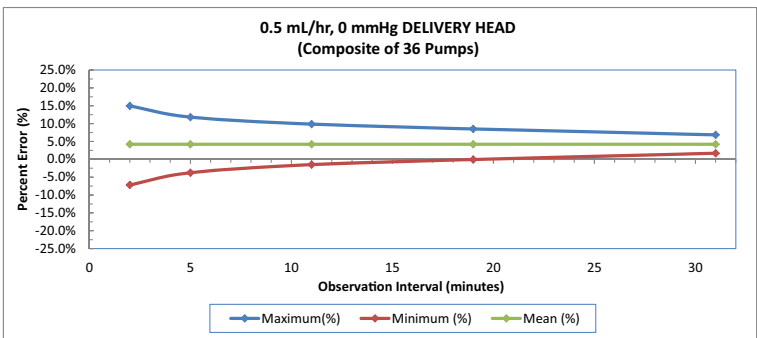
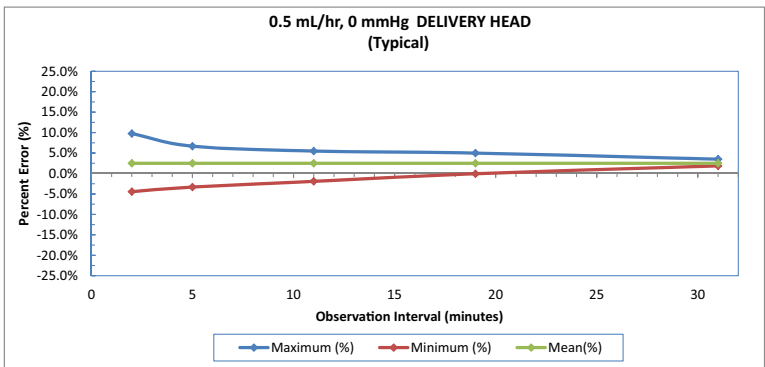
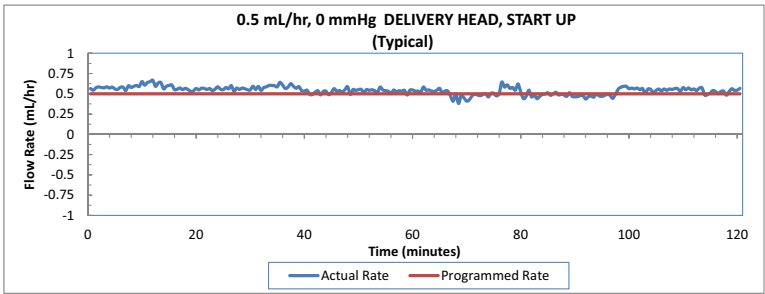
**Figure 9-1. Example of a Trumpet Curve**

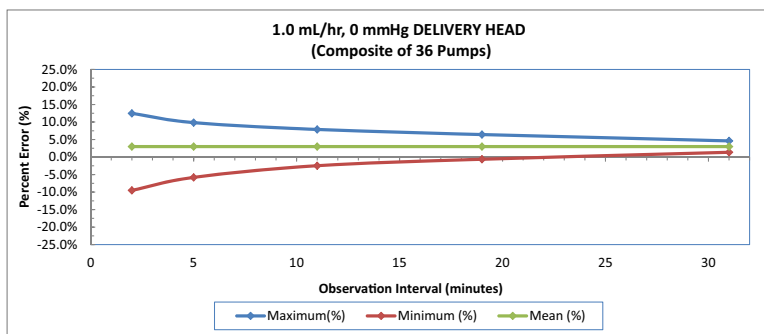
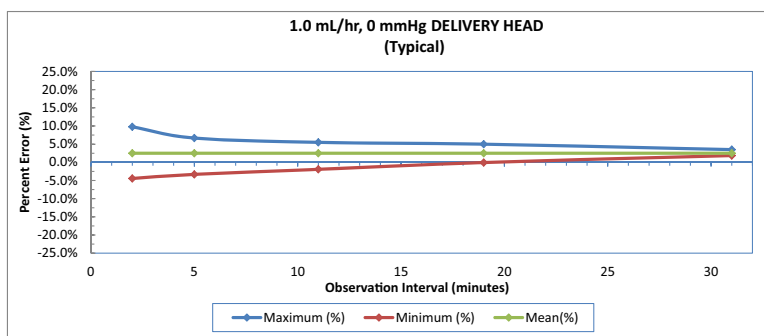
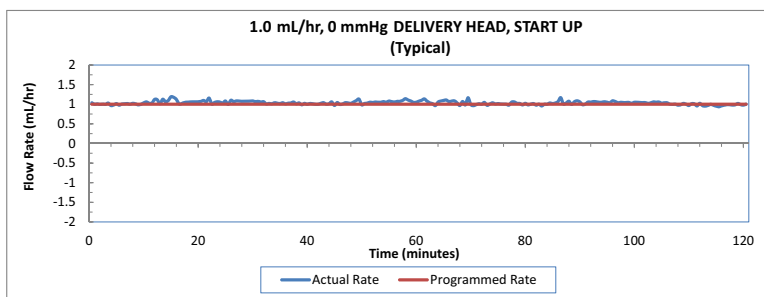


# Trumpet Curves

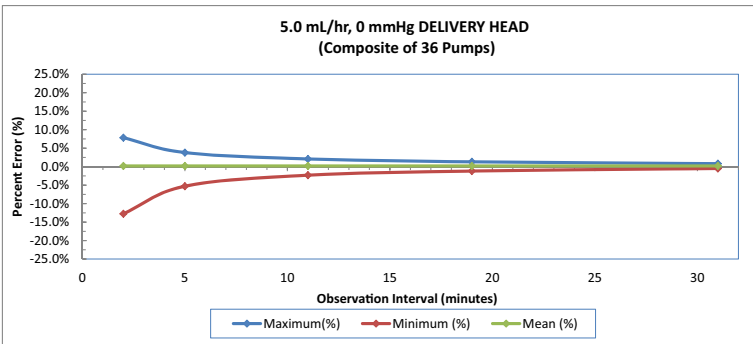
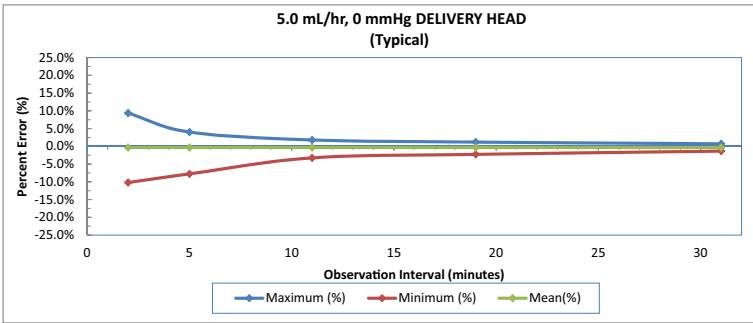
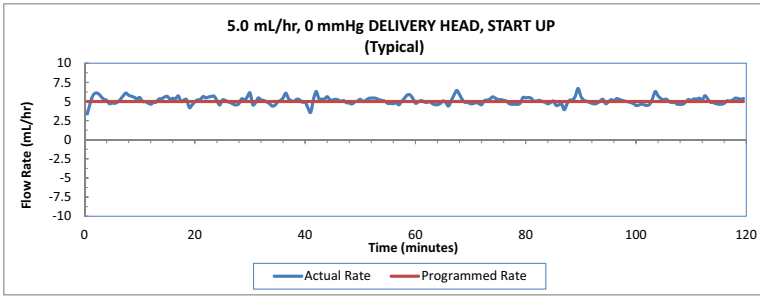


# Specifications





# Specifications



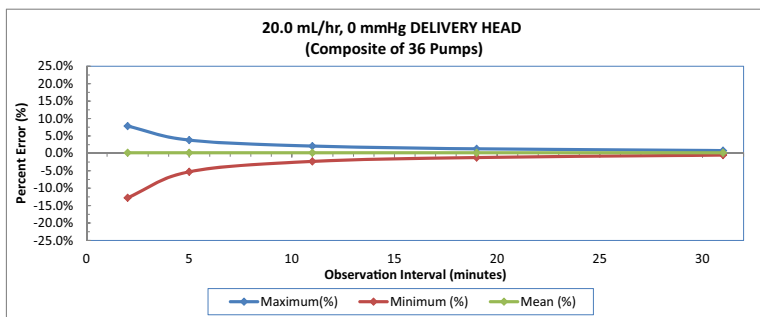
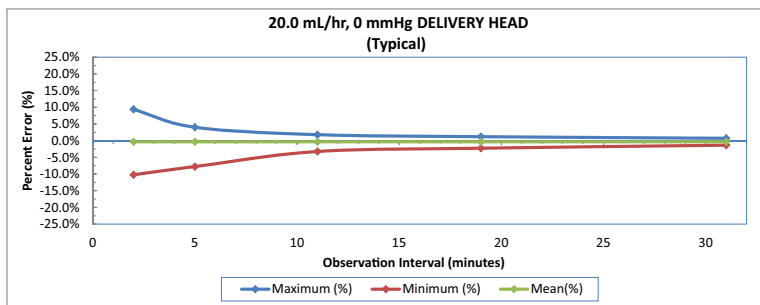
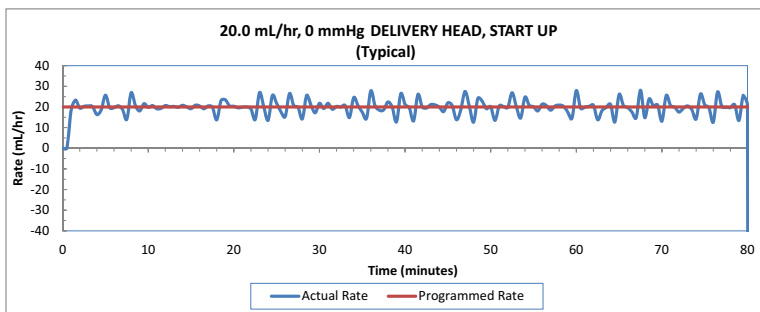


Figure 9-2. Trumpet Curves

## Specifications

**Table 9-5. Bolus Delivery Accuracy**

<b>Set Value (Bolus Volume in mL)</b>	<b>Calculated % Average Deviation from Set Value</b>	<b>Maximum % Positive Deviation from Set Value</b>	<b>Maximum % Negative Deviation from Set Value</b>	<b>Administration Set Tested</b>
Minimum: 0.1 mL	3.176%	10.4%	-8.3%	List Number 14277
Maximum: 5 mL	-0.545%	0.1%	-1.3%	List Number 14279

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# **Chapter 10**

## **Protocols**

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Protocols are program settings that are stored in the infuser's memory for frequent user access. A protocol can be recalled, making it unnecessary for the clinician to program the same therapy setting each time.

Should your facility choose to use protocols, hospital personnel will determine the protocol parameters (drug, dose, mode of delivery, etc.).

Protocols can be used for LifeCare PCA pre-filled drug vials and pharmacy-filled (custom) vials.

Only protocols associated with the inserted drug vial will be available.

## **ICU Medical MedNet Software Infusers**

ICU Medical MedNet Software allows for protocol programming from the ICU Medical MedNet™ Meds™ application. Infusers can store up to 90 protocols (5 per CCA).

For detailed startup information including priming an administration set and loading a vial, see [\*Chapter 2 Setup and Operation\*](#).

See [\*Chapter 4 Programming Infusers with ICU Medical MedNet Software\*](#), for detailed information regarding modes of delivery (PCA, PCA + Continuous, and Continuous, etc.).

## Programming Protocols

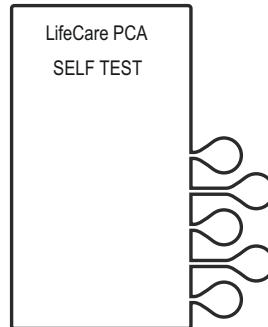
The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the [ON/OFF] button,

or

Loading the medication vial into the cradle will automatically power on the infuser ([see Chapter 2 Setup and Operation](#)).

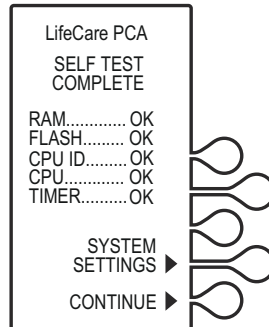
1. Power on the infuser. Upon initial start up, the self test begins.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see [System Settings](#).



**If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

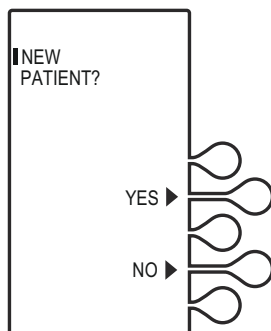


3. The **NEW PATIENT?** screen displays.  
Select **YES>** or **NO>**.

If **YES>** is selected, the History and Rx settings are cleared.

If **NO>** is selected, the History and RX settings are kept.

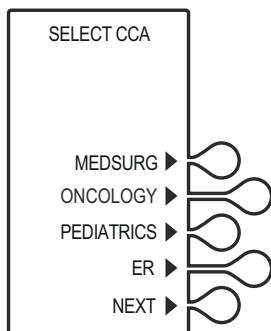
**Note:** The **NEW PATIENT?** screen will not display if the infuser has been powered off for more than five (5) hours.



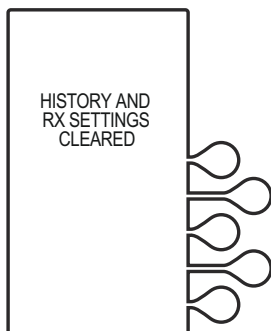
4. Select the softkey next to the desired CCA (for example, PACU).

If the desired CCA is not displayed, select **NEXT>** to view additional CCAs.

**Note:** If only one CCA has been created, that CCA becomes the default CCA, and this screen does not appear.



If the **YES>** option is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.



## Protocols

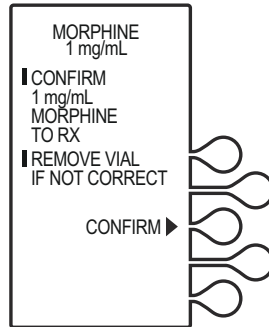


**CAUTION: VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**

- Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

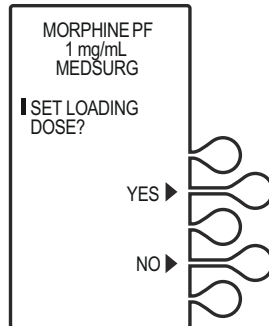
**Note:** If the medication is not correct, remove the vial and insert the correct vial.

The **TOTALS CLEARED** screen displays briefly, then transitions to the **SET LOADING DOSE** screen.



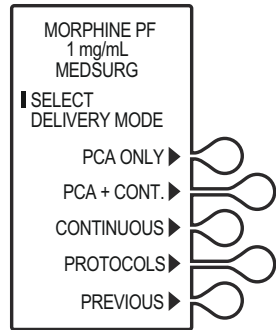
- Select **NO>** to continue.

If a loading dose is desired, see [Chapter 4 Programming Infusers with ICU Medical MedNet Software](#) and [Chapter 5 Programming Infusers without ICU Medical MedNet Software](#).



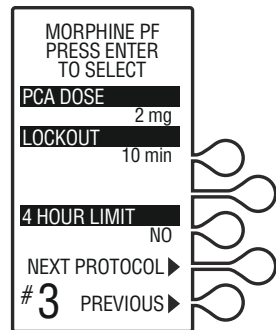
- The **SELECT DELIVERY MODE** screen appears. Select **PROTOCOLS>** to continue.

**Note:** Select **PREVIOUS>** to return to the preceding screen if programming changes need to be made.

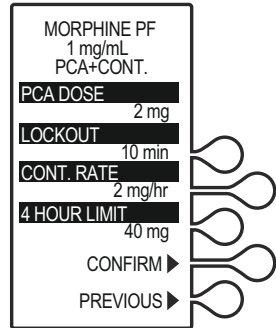


- The protocol displays. Press **[ENTER]** to accept protocol, or select **NEXT PROTOCOL>** or **PREVIOUS>** to view other stored protocols (if available).

 **CAUTION:**  
**VERIFY PROGRAM VALUES.**

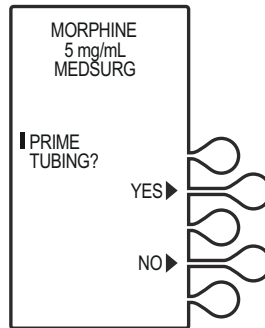


- Verify the chosen protocol settings, then select **CONFIRM>**, or select **PREVIOUS>** to return to the preceding screen.
- Close and lock the door. Place the key in a secure location.



## Protocols

11. Once the door is closed and locked, the **PRIME TUBING?** screen displays. To prime the administration set on the infuser, select **YES>** (see [Chapter 2 Setup and Operation](#)).
12. After the door is locked, if a PCA bolus is part of the protocol, it will be available for infusion. The patient presses the pendant button to initiate PCA dose.



**Note:** The infuser will deliver medication only when the door is closed and locked.

Approximately 10 seconds after the door is locked, the **DOOR LOCKED** message disappears.

## Infusers without ICU Medical MedNet

Protocols are created in Biomed mode for LifeCare PCA pre-filled drug vials and pharmacy-filled (custom) vials, for infusers without ICU Medical MedNet Software.

Should your facility choose to use protocols, hospital personnel will determine the protocol parameters (drug, dose, mode of delivery, etc.).

Ten stored protocols are available.

For detailed startup information, including priming an administration set and loading a vial, see [Chapter 2 Setup and Operation](#).

See [Chapter 5 Programming Infusers without ICU Medical MedNet Software](#) for detailed information regarding modes of delivery (PCA, PCA + Continuous, and Continuous, etc.).

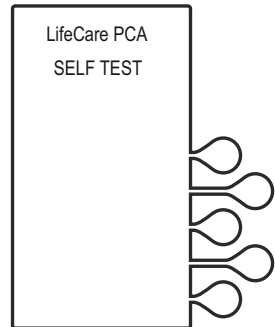
## Programming Protocols

The LifeCare PCA infuser can be turned on in either of two ways after opening the security door:

Press the [ON/OFF] button,  
or

Loading the medication vial into cradle will automatically power on the infuser ([see Chapter 2 Setup and Operation](#)).

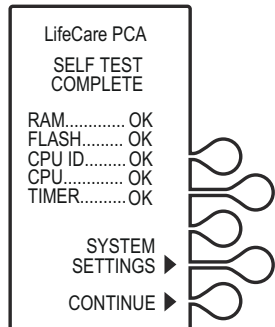
1. Power on the infuser. Upon initial startup, the self test begins.



2. **If the infuser is running 7.01 software:**

When the self test is complete, the **SELF TEST COMPLETE** screen will display. Select **CONTINUE>** to advance to the next screen.

**Note:** To change contrast and/or time and date, see [System Settings](#).



- If the infuser is running 7.02 software or higher:**

The Software Version screen shown on page 4-4 will display instead of the **SELF TEST COMPLETE** screen. There is no **CONTINUE>** option on this screen; it will automatically transition to the next screen after 5 seconds. Select **SETTINGS>** on this screen to view the **SELECT SETTING TO CHANGE** menu.

## Protocols

- The **NEW PATIENT** screen displays.  
Select **YES>** or **NO>**.

If **YES>** is selected, the History and RX settings are cleared.

If **NO>** is selected, the History and RX settings are kept.

**Note:** The **NEW PATIENT** screen will not display if the infuser has been powered off for more than five (5) hours.

If the **YES>** option is selected, the **HISTORY AND RX SETTINGS CLEARED** screen displays briefly, then transitions to the medication confirmation screen.

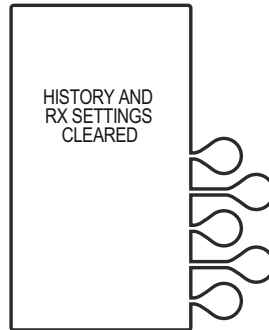
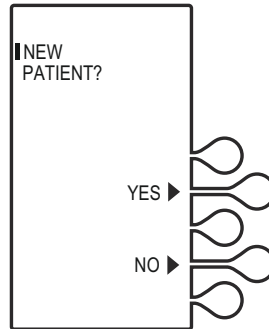
**CAUTION:**  
**VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**



- Verify that the displayed medication and concentration are correct, then select **CONFIRM>**.

**Note:** If the medication is not correct, remove the vial and insert the correct vial.

The **TOTALS CLEARED** screen displays briefly, then transitions to the **SET LOADING DOSE** screen.



5. Select **NO>** to continue.

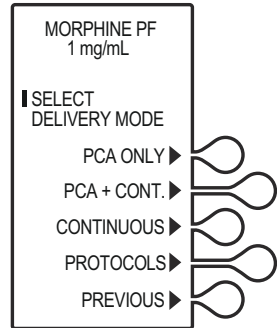
For more information on loading dose, see [Chapter 4 Programming Infusers with ICU Medical MedNet Software](#) and [Chapter 5 Programming Infusers without ICU Medical MedNet Software](#).

In this example, **NO>** is selected.

6. The **SELECT DELIVERY MODE** screen appears. Select **PROTOCOLS>** to continue.

**Note:** Select **PREVIOUS>** to return to the preceding screen if programming changes need to be made.

7. The protocol displays. Press **[ENTER]** to accept protocol, or select **NEXT PROTOCOL>** to view other stored protocols associated with the inserted drug and concentration (if available).



Select **PREVIOUS>** to return to the preceding screen.

Only protocols associated with the inserted drug vial will be available.

## Protocols



**CAUTION: VERIFY PROGRAM VALUES.**

- Verify the chosen protocol settings, then select **CONFIRM>**, or select **PREVIOUS>** to return to the preceding screen.
- Close and lock the door. Place the key in a secure location.

MORPHINE PF 1 mg/mL PCA+CONT.	
PCA DOSE	2 mg
LOCKOUT	10 min
CONT. RATE	2 mg/hr
4 HOUR LIMIT	40 mg
CONFIRM ▶	
PREVIOUS ▶	

- Once the door is closed and locked, the **PRIME TUBING?** screen displays. To prime the administration set on the infuser, select **YES>** ([see Chapter 2 Setup and Operation](#)).

MORPHINE 5 mg/mL MEDSURG	
PRIME TUBING?	
YES ▶	
NO ▶	

- The **DOOR LOCKED** screen displays and the infuser indicates to press the **[START]** button to infuse.  
  
Press **[START/STOP]** to deliver protocol.

MORPHINE 5 mg/mL MEDSURG	
DOOR LOCKED	
PRESS START BUTTON TO INFUSE 2 mg LOADING DOSE AND BEGIN PROGRAM	



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# Chapter 11

## Information for Legacy

### LifeCare PCA Infusers

### Upgraded with 7.x Software

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Legacy LifeCare PCA infusion systems with list number 20709-04 upgraded to 7.x software are substantially equivalent with list number 20837. When the software is upgraded, only the keypad and front enclosure labeling are upgrading to ensure alignment with the software.

Details of performance related to the legacy hardware that differs from list number 20837 are included in this section. See [Table 11-1](#) for a list of applicable topics and their related sections.

<b>Table 11-1. Section Reference for Upgraded Pumps</b>		
<b>Topic</b>	<b>Instead of...</b>	<b>See this section for information applicable to an upgraded infuser...</b>
IEC 60601-1 Compliance	Back cover	<a href="#">IEC 60601-1 Compliance</a>
IEC 60601-1-2 Compliance	<a href="#">Electrical Artifacts</a> and <a href="#">Table 9-2</a>	<a href="#">IEC 60601-1-2 Compliance</a>
Fluid Ingress Protection Rating	<a href="#">Table 9-2</a> and Back cover	<a href="#">Fluid Ingress Protection Rating</a>
Specifications (including Stored Occlusion Volume and Time from Occlusion to Alarm)	<a href="#">Chapter 9 Specifications</a> , including <a href="#">Table 9-3</a> and <a href="#">Table 9-4</a>	<a href="#">Specifications</a> (including subsections)
CSA Mark	Back cover	<a href="#">CSA Mark</a>

## **IEC 60601-1 Compliance**

Instead of evaluation to IEC 60601-1:2012 Edition 3.1 as indicated on the back cover of this manual, the following statement applies:

Infuser has been evaluated to IEC 60601-1:1998  
Edition 2 - Medical Electrical Equipment - Part 1: General  
Requirements for Basic Safety and Essential Performance.

## **IEC 60601-1-2 Compliance**

Instead of compliance with IEC 60601-1-2:2007, compliance with IEC 60601-1-2:2001 applies.

Replace the reference in **Electrical Artifacts** with:

List number 20709 has been tested and found to comply with EMC limits as specified in IEC 60601-1-2:2001

Replace the reference in **Table 9-2** with:

<b>Electromagnetic Interference (EMI) and Radio Frequency Interference (RFI)</b>	The LifeCare PCA infuser is designed to perform in the typical hospital environment The LifeCare PCA infuser has been tested to comply with IEC 60601-1-2:2001 Edition 2 A qualified service technician should verify performance in any environment where EMI or RFI levels are excessive
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## **Fluid Ingress Protection Rating**

Instead of the rating of IPX2, the rating of IPX1 applies.

Replace the reference in **Table 9-2** with:

<b>IPX1</b>	The case is disinfectable and protected against dripping water
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Replace the reference on the back cover of this manual with:

**IPX1** Protected against dripping water

## Specifications

Information provided in **Chapter 9 Specifications** applies with the exceptions included below and in the following subsections.

<b>Fuse:</b>	Fuse, 0.5 A, 250 V, Slo-BlO
<b>Occlusion Alarm Pressure:</b>	15 psi +/- 5 psi
<b>Occlusion Bolus Volume:</b>	2 mL for fully primed set (max.)

### Stored Occlusion Volume

Instead of the information in **Table 9-3**, the following information applies:

<b>Delivery Rate</b>	<b>Pressure Limit (Average)</b>	<b>Stored Volume (Average)</b>
0.1 mL/hr	13.7 psig	1.34 mL
5 mL/hr	13.7 psig	1.37 mL
20 mL/hr	13.8 psig	1.36 mL
PCA Dose (100 mL/hr)	13.7 psig	1.31 mL

## Time from Occlusion to Alarm

Instead of the information in [Table 9-4](#), the following information applies:

Delivery Rate	Pressure Limit (Average)	Time to Occlude (Average, hh:mm:ss)
0.1 mL/hr	13.7 psig	15:04:59
5 mL/hr	13.7 psig	0:16:57
20 mL/hr	13.8 psig	0:04:07
PCA Dose (100 mL/hr)	13.7 psig	0:00:56

## CSA Mark

Instead of the mark shown on the back cover of this manual, the following mark/description applies:



The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL (National Recognized Testing Laboratory), is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

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# Appendix A

## Generating Bar Code Labels (ICU Medical MedNet Software Enabled)

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ICU Medical recommends that the hospital or pharmacy department develop clear policies and procedures for the following:

- Generating bar code labels
- Applying generated bar code labels to pharmacy-filled (empty sterile/custom) vials
- Validating correctly filled and labeled vials
- Filling LifeCare PCA sterile empty vials

Incorrect labels and/or incorrectly filled vials may lead to significant and potentially fatal adverse events.

The following are general specifications for producing labels with pharmacy-generated bar codes for the sterile empty vials filled by pharmacy. These labels should cover the entire existing sterile empty vial bar code.

Sterile empty vials contain 30 mL in volume with 1 mL graduated scales which provide direct reading of the residual volume remaining in the sterile empty vial reservoir.

The proper placement of the pharmacy-generated bar code label on the sterile empty vial is shown in the label diagram ([see Figure A-1](#)).

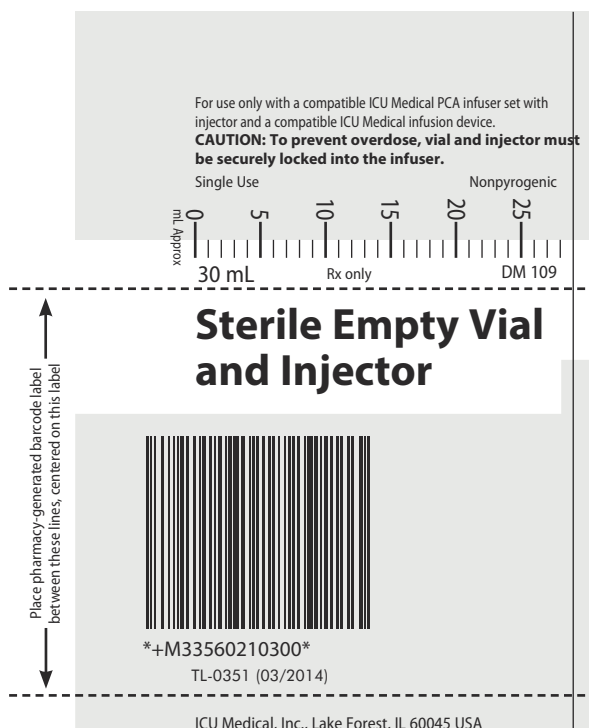
Correct placement of the pharmacy-generated bar code on the sterile empty vial helps ensure proper reading of the bar codes by the LifeCare PCA infuser.

## **Equipment Needed to Print a Pharmacy-Generated Bar Code**

1. Bar code thermal printer (300 DPI or higher)
2. Bar code label software capable of producing labels:
  - ANSI X3.182-1990
  - EAN/UCC Code 128, Code Set C (numeric characters only)
  - ANSI Grade C or better
  - 7.5 mil (0.0075 in.) pitch minimum
  - Bar code height is 1 inch
  - 18 Characters max
3. Water and smudge-resistant, opaque polyester (non-paper) labels are recommended.

## Label Diagram

**Figure A-1** depicts the area where the pharmacy-generated bar code is to be applied to the sterile empty vial. Ensure the pharmacy-generated bar code label is placed between the dotted lines and centered on the vial label.



**Figure A-1. Pharmacy-Generated Bar Code Label**

# Validation of the Pharmacy-Generated Bar Code

The label diagram shown in [Figure A-1](#) represents ICU Medical's recommendation for placement of the bar code and drug name/concentration on a 3 inch x 2 inch label.

The guidelines ensure the device's integral bar code reader will align correctly with the bar code on the LifeCare PCA sterile empty vial. Your institution may choose to use a different format for placement of the medication name and concentration based on your specific hospital guidelines or size of the label. However, it is recommended that the system be validated before use.

## Filling the LifeCare PCA Sterile Empty Vial

The following are instructions to manually fill a LifeCare PCA sterile empty vial.

Using aseptic technique:

1. Remove the vial and injector from the packaging.  
**Note:** Inspect the vial for cracks or other damage prior to use. Discard the vials with cracks, leaks, and/or other damage per hospital policy.
2. Attach the injector to the blue vial stopper, rotating the injector clockwise about three turns to ensure the injector is fully engaged with the vial stopper.
3. Remove and discard the luer cover. Attach a needle or transfer device of choice to the male luer lock. Using transfer method of choice, fill the vial to prescribed volume. Remove excess air, using caution not to expel medication from the vial.

**Note:** If using an automated device, refer to the manufacturer's operating manual.



4. Detach the needle or transfer device, and remove the injector by rotating it counterclockwise from the stopper. Dispose the needle or transfer device and injector per facility protocol. Cover the vial with a yellow cap for use with vial (list number 19361).
5. Label the vial according to facility protocol. Do not obscure graduations or bar code.
6. Adhere to storage requirements of added medications.

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**NOTES**

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# Appendix B

## Administration Sets and Accessories

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This appendix outlines the list numbers and descriptions of administration sets and accessories available for use with the LifeCare PCA infuser.

For a current list of accessories and approved administration sets, contact your local ICU Medical representative.

Refer to vial and administration set package inserts for precautions and information on proper handling.

## Administration Sets

The administration sets described in [Table B-1](#) may be used in the delivery modes as specified. The administration sets have a sterile fluid path. They should not be placed on a sterile field. LifeCare PCA sets are for single use only and are not to be resterilized.

It is recommended that highly viscous solutions and drugs, colloidal suspensions, and emulsions should not be delivered through the inline backcheck valve of the LifeCare PCA administration set. Valve functionality may be compromised by the presence of residue.

Follow hospital procedures for disposing and handling of administration sets. Do not discard administration sets with regular trash.



**CAUTION: CHANGE THE ADMINISTRATION SET AT LEAST EVERY 96 HOURS.**

## Administration Sets and Accessories

**Table B-1. Administration Sets**

<b>List Number</b>	<b>Description</b>
<b>14277</b>	LifeCare PCA Set, 67 in./170 cm Mini-Bore tubing with integral PAV and injector assembly Approximate priming volume 2.3 mL Non-DEHP; manufactured without latex For use in PCA, Continuous, and PCA + Continuous modes via intravenous route
<b>14278</b>	LifeCare PCA Extension Set, 10 in./25 cm; with backcheck valve Approximate priming volume 1.1 mL Non-DEHP; manufactured without latex For use in conjunction with administration set 14280
<b>14279</b>	LifeCare PCA Set, 86 in./218 cm Mini-Bore tubing with integral PAV and injector assembly Y-connector Approximate priming volume 2.6 mL Non-DEHP; manufactured without latex For use in PCA, Continuous, and PCA + Continuous modes via intravenous route when extra length is needed
<b>14280</b>	LifeCare PCA Set, 80 in./203 cm Mini-Bore tubing with integral PAV and injector assembly Approximate priming volume 1.5 mL Non-DEHP; manufactured without latex For use in PCA, Continuous, and PCA + Continuous modes via intravenous and epidural route

## Accessories

The accessories described in [Table B-2](#) are available for use with the LifeCare PCA infuser. Contact your local ICU Medical representative for accessories available in your area.

<b>Table B-2. Accessories</b>	
<b>List Number</b>	<b>Description</b>
<b>04831</b>	Injector
<b>06021</b>	Sterile empty vial and injector
<b>19361</b>	Yellow cap for use with vial
<b>12230</b>	Heavy duty IV pole with 6 locking casters
<b>13113</b>	Locking casters for IV stand

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**NOTES**

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# **Appendix C**

## **Troubleshooting**

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The LifeCare PCA infuser is programmed to display informational, status, and alarm messages. It will sound a series of audible tones for alarm conditions and a single tone for informational messages. These messages and alarm conditions are described in the following sections.

- Infuser Alarm System
- Occlusion Alarm
- Network Connectivity
- Status Messages
- Alarms and Messages
- Informational Messages

## **Infuser Alarm System**

Alarms on the LifeCare PCA infuser have three priority levels: high, medium, and low, which occur based on the severity of the alarm condition. Alarms are generated when values for parameters monitored by the infuser move out of a preset range.

The infuser has an intelligent alarm system that handles more than one alarm at a time. If two alarms occur at the same time, the highest priority alarm will be activated first, and the lower priority alarm will be activated after the highest priority alarm has been resolved. If two alarms occur at the same time that have the same priority, the alarm which was identified first will be activated and the second alarm identified will be activated after the first alarm has been resolved.

Alarms on the LifeCare PCA infuser have two components: a message that appears on the display and an audible signal.

## Troubleshooting

There are different indicators for high, medium, and low priority alarms, as described in [Table C-1](#).

<b>Table C-1. Alarm Priority Levels</b>			
<b>Alarm Priority</b>	<b>Visual Indicator Display</b>	<b>Visual Indicator Backlight</b>	<b>Audible Indicator Number of Beeps</b>
<b>High</b>	<b>!!! + Message</b>	Flashing rapidly between High and Normal intensity	10
<b>Medium</b>	<b>!! + Message</b>	Flashing slowly between High and Normal intensity	3
<b>Low</b>	<b>! + Message</b>	Normal intensity for 30 seconds (no flashing)	2*

\*For informational low priority alarms (**CHECK PRINTER**), no audible indicator beeps.

The sound pressure level of all audible alarms is at least 45 dBA when the volume is set to medium or high.

**Note:** If a nurse call interface cable is connected to the facility's nurse call system, the infuser also sends a signal to that system each time an alarm is activated.

During an alarm condition, the system performs the following actions:

- The current display message is saved to the Event Log.
- A flashing alarm message appears on the display.
- A repetitive, audible tone sounds with all malfunction alarms except **PENDANT FAULT**, which is a single tone with continuous visual flashing.



The infuser stops delivery when any of following alarms occur:

- CHECK INJECTOR
- CHECK VIAL
- CHECK SYRINGE
- EMPTY SYRINGE
- OCCLUSION
- DEAD BATTERY
- MALFUNCTION

## **Invalid Keypress**

The LifeCare PCA infuser emits a single sound of four notes when an invalid keypress occurs.

## **Malfunction Alarm**

**MALFUNCTION** alarms are high priority alarms. A malfunction alarm activates when electromechanical or software issues occur.

If the malfunction alarm sounds, press **[ON/OFF]** to turn off the infuser.

Turn on the infuser. If the malfunction alarm persists, remove the infuser from service, and return it to the Biomed for inspection (see the *Technical Service Manual*).

## **Responding to an Alarm**

During an alarm the display flashes and shows the alarm message until the alarm condition is resolved.

Review the display for the alarm message, resolve the alarm condition, then press **[START]** to resume the infusion.

**Note:** The alarm resumes if it is not resolved.

# Adjusting the Audio Alarm Volume

The alarm volume can only be adjusted in Biomed mode. Contact the Biomed to adjust alarm volume.

### WARNING

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**ENSURE THAT THE ALARM VOLUME LEVEL IS APPROPRIATE FOR THE CURRENT PATIENT AND BACKGROUND NOISE LEVEL BEFORE USE ON THE PATIENT.**

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## Silencing an Alarm

To silence an alarm, press [AUDIO PAUSE], then follow the displayed messages. All alarms except **MALFUNCTION**, **CHECK VIAL**, **CHECK INJECTOR**, and **CHECK SYRINGE** can be muted.

Clear the cause of the alarm, and press [START/STOP] to resume operation for **Continuous** or **PCA + Continuous** modes. The original display message will be restored.

**Note:** In the event two or more alarm conditions simultaneously occur, the alarm with the shortest muting period will take priority and be displayed first. If the alarm is muted and a second alarm condition occurs during the muting period, an audible alarm signaling the new condition will immediately occur.

## Testing the Alarm System

To test the alarm system before using on a patient, proceed as follows:

1. Load a LifeCare PCA vial and injector into the infuser ([see Loading a Vial](#)).
2. Squeeze the cradle release mechanism together at the top of the holder and move to the uppermost position.

**Note:** Always verify that the bar code reader window is clean before inserting the vial.

3. When inserting the bottom of the glass vial into the middle black bracket, ensure that the bar code label faces the bar code reader on the right side of the vial compartment.



**CAUTION: DO NOT POSITION THE VIAL INTO THE UPPER VIAL CLIP FIRST. THE VIAL LIP MAY CRACK OR CHIP.**

4. Gently press the upper end of the glass vial into the upper black bracket.
  - If the infuser was off, the infuser will run its self test. If the infuser is running 7.01 software, the user will need to press **CONTINUE>**. If the infuser is running 7.02 software or higher, there is no **CONTINUE>** option; the display will automatically transition to the next screen after 5 seconds.
  - The user selects **NEW>** or **PREVIOUS>** patient and the infuser immediately initiates a high priority visual **CHECK INJECTOR** alarm.
  - After the high priority visual **CHECK INJECTOR** alarm has been displayed for 30 seconds, a high priority audio alarm will be generated.
  - The **CHECK INJECTOR** alarm will continue until the user squeezes the top of the cradle release mechanism and moves the vial and injector down to snap the injector into the bottom bracket.

If the visual and audio high priority **CHECK INJECTOR** alarm were observed by the user, then the infuser has passed the alarm test. The vial loading procedure can be completed and the infuser is approved for patient use.

## Occlusion Alarm

An occlusion may be the result of constricted or kinked tubing, such as a closed slide clamp, or other conditions.

To clear an occlusion alarm, proceed as follows:

1. Obtain the key, and unlock and open the door.
2. Squeeze the cradle release mechanism ([see Equipment Description](#)) to relieve the residual syringe pressure.



**CAUTION: IF THE CRADLE RELEASE MECHANISM IS NOT RELEASED, AN UNINTENTIONAL BOLUS OF UP TO 1 mL MAY OCCUR WHEN THE OCCLUSION IS RELEASED.**

3. Check tubing for kinks, constriction, closed slide clamp, or other condition to clear distal occlusion.

## Network Connectivity

The reliability of a wireless connection between the infuser and ICU Medical MedNet depends upon many complex issues related to the overall configuring of the facilities network. If the infuser has recurring issues with its network connection, both the infuser and the network should be checked by the Biomed for proper operation.

# Status Messages


**WARNING**

**CLOSE THE TUBING SLIDE CLAMP WHEN HANDLING THE VIAL.**

Displayed status messages are defined in [Table C-2](#).

<b>Table C-2. Status Messages</b>	
<b>Message Displayed on the Screen</b>	<b>Definition</b>
<b>4 HR LIMIT REACHED</b>	<p>Message displayed if a dose limit has been programmed and has been reached</p> <p>Message will display the actual length of the dose limit period (1, 4, 6, 8, or 12 hours) depending on how the infuser or drug library is configured</p>
<b>CONTINUOUS</b>	Message displayed when infuser is in CONTINUOUS mode
<b>DOOR LOCKED</b>	<p>Message indicates the security door is closed and locked</p> <p>Message displays for 30 seconds and disappears</p>
<b>INFUSER STOPPED</b>	Message displayed when infuser is stopped
<b>PCA + CONT.</b>	Message displayed when infuser is in PCA + CONTINUOUS mode
<b>PCA AVAILABLE</b>	Message indicates patient can initiate a dose in PCA ONLY or PCA + CONTINUOUS mode
<b>PCA LOCKOUT</b>	<p>Message appears only in the PCA ONLY or PCA + CONTINUOUS mode</p> <p>Message remains until the lockout interval elapses and is displayed after a successful patient-originated dose delivery</p>
<b>PCA ONLY</b>	Message displayed when the infuser is in PCA ONLY mode

# Alarms and Messages

**Table C-3** lists high priority infuser alarms that can be cleared by the operator taking appropriate action.

<b>Table C-3. Alarms and Messages</b>				
<b>HIGH PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>DEAD BATTERY</b>	<b>DEAD BATTERY PLUG INFUSER INTO POWER OUTLET OR BATTERY MAY BE DAMAGED</b>	None	A discharged battery is detected and the infuser is operating on battery power  <b>Note:</b> The <b>DEAD BATTERY</b> alarm will activate at least 3 minutes prior to shutting down due to a dead battery.	Plug the infuser into AC power outlet

**Table C-3. Alarms and Messages**


<b>HIGH PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>CHECK SYRINGE</b>	<b>CHECK SYRINGE</b> <b>CLOSE TUBING SLIDE CLAMP IMMEDIATELY</b> <b>CHECK SYRINGE PLACEMENT</b>	Initial 30 second mute period if door is unlocked	The syringe (vial and injector) is not detected to be properly loaded	Properly install the syringe by inserting the bottom of the glass vial into the middle black bracket, ensuring that the bar code label faces the bar code reader on the right side of the vial  Gently press the upper end of the vial into the upper black bracket

**Table C-3. Alarms and Messages**

<b>HIGH PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>CHECK VIAL</b>	<b>CHECK VIAL CLOSE TUBING SLIDE CLAMP IMMEDIATELY CHECK VIAL PLACEMENT</b>	Initial 30 second mute period if door is unlocked	An Injector is detected and no vial is detected as properly loaded	Properly install the vial by inserting the bottom of the glass vial into the middle black bracket, ensuring that the bar code label faces the bar code reader on the right side of the vial  Gently press the upper end of the vial into the upper black bracket
<b>CHECK INJECTOR</b>	<b>CLOSE TUBING SLIDE CLAMP IMMEDIATELY CHECK INJECTOR OR PLACEMENT</b>	Initial 30 second mute period if door is unlocked	A vial is detected and a valid bar code is read, but injector is not detected as being properly loaded during setup or detected as dislodged during running	Install the injector by squeezing the top of the cradle release mechanism and move down until the vial injector snaps into the bottom bracket/ injector flange retainer



**Table C-3. Alarms and Messages**

<b>HIGH PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>OCCLUSION</b>	<b>OCCLUSION OPEN DOOR SQUEEZE CRADLE RELEASE TO CLEAR ALARM THEN CHECK TUBING AND CLEAR DISTAL OCCLUSION</b>	1 minute	An occlusion is detected during infusion or during the infuser prime sequence	Open the door Squeeze the cradle release mechanism to relieve residual syringe pressure  Check the tubing for kinks or closed slide clamp to clear the distal occlusion
 <b>CAUTION: IF THE CRADLE RELEASE MECHANISM IS NOT RELEASED, AN UNINTENTIONAL BOLUS OF UP TO 1 ML MAY OCCUR.</b>				
<b>EMPTY SYRINGE</b>	<b>EMPTY SYRINGE CLOSE TUBING SLIDE CLAMP IMMEDIATELY REPLACE SYRINGE</b>	2 minutes	The syringe is detected to be empty	Replace the syringe, or if therapy is discontinued, remove and discard the syringe then turn off the infuser

**Table C-3. Alarms and Messages**

<b>HIGH PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>BATTERY FAULT</b>	<b>BATTERY FAILURE</b> <b>SHORT DETECTED</b> <b>OVER DISCHARGED</b> <b>NO BATTERY DETECTED</b> <b>SEND PUMP TO BIOMED</b>	2 minutes	The battery may be defective or the battery is not properly connected	Send the infuser to the Biomed for servicing or press <b>[AUDIO PAUSE]</b> to silence the alarm and proceed with programming  The <b>BATTERY FAULT</b> alarm will annunciate every two minutes with the infuser connected to AC power  <b>Note:</b> The infuser will automatically power off if disconnected from AC power.  Check battery connection  Replace battery  Requires service
<b>CHARGER FAULT</b>	<b>BATTERY CHARGER FAILURE</b> <b>SEND PUMP TO BIOMED</b>	2 minutes	The battery charger is defective	Requires service

**Table C-4** lists medium priority infuser alarms that can be cleared by the operator taking appropriate action.

<b>Table C-4. Alarms and Messages</b>				
<b>MEDIUM PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>BAR CODE NOT READ</b>	<b>BAR CODE NOT READ ROTATE OR RAISE VIAL CLEAN WINDOW OR REPLACE VIAL REMOVE VIAL AND REINSERT OR REPLACE VIAL</b>	1 minute	The infuser is turned on or a new syringe has been inserted and the vial is not correctly positioned and the bar code has not been read	Slowly rotate the vial and position it with the bar code on the right until the bar code has been read  Remove the vial and reinsert the vial into the middle black bracket, ensuring that the bar code label faces the bar code reader  Clean the bar code reader window

**Table C-4. Alarms and Messages**

<b>MEDIUM PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>INVALID BAR CODE</b>	<b>INVALID BAR CODE CUSTOM VIAL USE DISABLED SEND PUMP TO BIOMED</b>	1 minute	A custom DDL vial is inserted, the default drug library is installed, and the custom DDL vial used has been disabled in Biomed mode	Power off the infuser  Remove syringe  Send the infuser to Biomed to enable custom vial
<b>INVALID BAR CODE</b>	<b>INVALID BAR CODE MED NOT IN LIBRARY VERIFY DRUG IF CORRECT DRUG, SEND PUMP TO BIOMED</b>	1 minute	A bar code is read which is not in the drug library	Power off the infuser  Remove syringe  Return the device to Biomed to update the drug library

**Table C-4. Alarms and Messages**

<b>MEDIUM PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>CHECK SETTINGS</b>	<b>CHECK SETTINGS</b> <b>OPEN THE DOOR</b> <b>COMPLETE OR CORRECT PUMP SETTINGS</b>	1 minute	The door is unlocked and no key has been pressed for 2 minutes  The door is locked and no key has been pressed for 30 seconds  Door locked prior to programming completed	Unlock and open the door to complete programming
<b>CHECK SETTINGS</b>	<b>LOADING DOSE NOT COMPLETED</b> <b>PRIMING NOT COMPLETED</b> <b>PRESS ANY KEY TO CONTINUE</b>	None	The door is locked and no key has been pressed for 30 seconds	Press any key, then complete the operation

**Table C-4. Alarms and Messages**

<b>MEDIUM PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>OPEN DOOR</b>	<b>DOOR OPEN CLOSE TUBING SLIDE CLAMP WHEN HANDLING VIAL CLOSE AND LOCK DOOR</b>	None	The infuser is on and the door has been left open or unlocked and no key has been pressed for more than 2 minutes  The door is unlocked during the infuser prime sequence	Close and lock the door

**Table C-4. Alarms and Messages**

<b>MEDIUM PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>INFUSER STOPPED</b>	<b>INFUSER STOPPED</b>  <b>CLOSE TUBING SLIDE CLAMP WHEN HANDLING VIAL</b>  <b>PRESS START BUTTON TO RESUME</b>  <b>UNLOCK DOOR TO CHANGE SETTINGS</b>	2 minutes	Infusion paused for more than 2 minutes	Press [START/STOP] to resume infusion
<b>PENDANT FAULT</b>  <b>Note:</b> Pendant refers to the patient button	<b>CHECK PENDANT</b>  <b>INSERT OR REPLACE PENDANT TO CLEAR ALARM</b>  <b>SEND PUMP TO BIOMED</b>	2 minutes	A shorted connection is detected for 800 milliseconds or more  An open connection is detected  Pendant is missing	Insert the patient pendant to the infuser and tighten the locking mechanism by turning to the right. If the alarm does not clear, send the infuser to Biomed for service

## Troubleshooting

**Table C-5** lists low priority infuser alarms that can be cleared by the operator taking appropriate action.

<b>Table C-5. Alarms and Messages</b>				
<b>LOW PRIORITY ALARMS</b>				
<b>Alarm Name</b>	<b>Message Displayed on the Screen</b>	<b>Muting Time</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<b>LOW BATTERY</b>	<b>LOW BATTERY PLUG INFUSER INTO POWER OUTLET</b>	10 minutes	Battery life has less than thirty minutes remaining and the infuser is currently operating on battery power	Connect to AC power  Failure to connect to AC power may cause battery damage
<b>CHECK PRINTER</b>	<b>CHECK PRINTER VERIFY PRINTER IS POWERED ON, ATTACHED AND ON LINE  REQUEST HISTORY PRINT AGAIN</b>	None	A history print has been requested and the printer is not attached or is off line	Ensure the printer is powered on and connected to the infuser



# Informational Messages

Displayed informational messages are defined in [Table C-6](#).

<b>Table C-6. Informational Messages</b>	
<b>Message Displayed on the Screen</b>	<b>Definition</b>
<b>LOADING DOSE COMPLETE</b>	Message displayed when a loading dose has completed delivery and the current program setting is Continuous or PCA + Continuous.  One informational tone sounds when the message starts displaying.

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**NOTES**

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## Appendix D

# Default Drug Library and Prescription Delivery Limits

The default drug library contains the drug name and concentration only, and is replaced by the user-defined drug library when connected to ICU Medical MedNet.

**Table D-1** lists the LifeCare PCA default drug library.

<b>Medication (Pre-Filled Vials)</b>	<b>Dosing Units</b>	<b>Default Concentration</b>
<b>Morphine Sulfate PF</b>	mg/hr	1 mg/mL
<b>Morphine Sulfate PF</b>	mg/hr	5 mg/mL
<b>Meperidine HCl</b>	mg/hr	10 mg/mL
<b>Sterile Empty Vial (Pharmacy-Filled Vial)</b>	N/A	N/A

Prescription delivery limits for the loading dose, PCA dose, dose limit, and continuous delivery rate parameters vary with the concentration selected. See the tables in this section for listings of the lower and upper limits.

**Note:** Concentration selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values. Minimum delivery rate is 0.1 mL/hr for concentrations between 0.1 and 1 mg/mL.

**Table D-2** lists prescription delivery limit ranges.

**Table D-3** shows an example of prescription delivery limit ranges.

# Default Drug Library and Prescription Delivery Limits

**Table D-2. Prescription Delivery Limit Ranges**

Drug	Conc. (C) (units/mL)	Loading Dose	PCA Dose min-max	Cont. Rate (units/hr) min-max	1 hr Limit min-max	4 hr Limit min-max	6 hr Limit min-max	12 hr Limit min-max
mg units	0.1-10	[0.1-10] x C	[0.1-5] x C	[0.1-20] x C	[0.1-20] x C	[0.1-80] x C	--	--
mcg units	1-100	[0.1-10] x C	[0.1-5] x C	[0.1-20] x C	[0.1-20] x C	[0.1-80] x C	--	--

**Notes:** Infuser will reject values < 0.1 mg as well as those < 1 mcg

Lockout interval range is 5 to 120 minutes (increments of 1 minute)

C = Concentration Value

See current product sales catalog for available drugs

**Table D-3. Example of Prescription Delivery Limit Ranges**

Conc. (mg/mL)	Loading Dose (mg)	PCA Dose (mg) min-max	Cont. Rate (mg) min-max	1 hr Limit (mg) min-max	4 hr Limit (mg) min-max	6 hr Limit (mg) min-max	12 hr Limit (mg) min-max
1	0.1-10	0.1-5	0.1-20	0.1-20	0.1-80	0.1-120	0.1-240
5	0.5-50	0.5-25	0.5-100	0.5-100	0.5-400	0.5-600	0.5-999.9 <sup>1</sup>
10	1-100	1-50	1-200	1-200	1-800	1-999.9 <sup>1</sup>	1-999.9 <sup>1</sup>

**Notes:** <sup>1</sup>Infuser will reject values > 999.9

Infuser will reject values < 0.1 mg

Lockout interval range is 5 to 120 minutes (increments of 1 minute)

Conc. = Concentration Value

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# Appendix E

## Network Printer Setup

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This appendix provides information about the LifeCare PCA infuser printing function. The infuser history Event Log can be printed to a network printer or to a personal computer (PC) program. The network printer can be directly connected to the infuser with an Ethernet network cable, or it can be connected through a router on a wired network. The sections below describe how to configure the connectivity engine (CE) and network printer or PC for this purpose.



**WARNING**

**DISCONNECT THE INFUSER FROM THE PATIENT BEFORE CONNECTING THE INFUSER TO A PRINTER OR COMPUTER.**

---

## Directly Connected Printer

This section describes how to configure the infuser and a directly connected network printer. It is assumed that the network printer is connected with an Ethernet network cable.

### Equipment Needed

- Infuser
- Computer meeting the printer setup requirements
- Ethernet network cable

### Preparation

Connect the Ethernet network cable from the network printer to the computer. Connector the printer to AC power and turn on the printer.

Only equipment certified to IEC 60950 or IEC 60601-1 should be connected to the Ethernet port on the infuser.

# Setup Procedure

1. Using the printer operating instructions, configure the printer Ethernet interface with a static IP address, subnet mask, and TCP/IP port (*see Figure E-1*).
  - IP address: 192.168.0.222 (arbitrary)
  - Subnet mask: 255.255.0.0 (required)
  - Port: 9100 (must be between 9000 to 9999)
2. Connect the Ethernet network cable from the network printer to the computer, then connect the infuser to AC power.
3. Test the printer configuration.
4. Configure the infuser connectivity engine settings so that the printer IP address and printer port settings match the values in Step 1.

The screenshot displays the 'Connectivity Configuration' web interface. On the left is a navigation menu with categories: Status, Ethernet, Wireless, Security, Certificates, HMSS, Service, and Administration. The main area is titled 'Service Properties' and contains the following settings:

Print Enabled:	<input checked="" type="checkbox"/>
Printer Host/IP-Address:	192.168.0.222
Printer Port:	9100
Terminal Port:	8889
Directly Connected Printer:	<input type="checkbox"/>
Scan List Size:	64
SSID Filtering:	<input checked="" type="checkbox"/>
WLAN QBSS Station Threshold:	12
WLAN QBSS Channel Load Threshold:	95
WLAN Bad AP Status Retry Timeout:	300
WLAN Bad AP Statistics Retry Timeout:	300
Roam RSSI Threshold:	34
Roam 11a/g Rate Threshold:	12000
Roam 11b Rate Threshold:	5000
Background Scan Period:	90
On Channel Time:	1000
Disable Web-Configuration:	<input type="checkbox"/>

At the bottom of the interface are navigation buttons: '< Previous', 'Reset', 'Finish', and 'Next >'.

**Figure E-1.**  
**Connectivity Configuration for Directly Connected Printer**

- Print Enabled: Checked
- Printer Host/IP Address: 192.168.0.222

- Printer Port: 9100
  - Directly Connected Printer: Checked
5. Save the infuser configuration changes and restart the CE.
  6. Connect the Ethernet network cable from the infuser to the network printer.

The infuser and printer are now set up for directly connected printing with a Ethernet network cable.

## Printing Procedure



### **WARNING**

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**DISCONNECT THE INFUSER FROM THE PATIENT BEFORE CONNECTING THE INFUSER TO A PRINTER OR COMPUTER.**

---

**Note:** After the infuser A/C power is applied or the CE is restarted by changing the Ethernet cable, allow 2 to 3 minutes for the infuser CE to complete the startup initialization before attempting to print the Event Log.

**Note:** After the infuser is turned on to initiate printing, allow 2 to 3 minutes for the infuser to complete startup before attempting to print the Event Log.

1. Load the printer with paper.
2. Turn on the infuser and confirm drug and concentration.
3. Press the [HISTORY/BATTERY] button to view the history on the display.
4. Press the **PRINT HISTORY**> softkey to print the history log.

# Network Printer

This section describes how to configure the infuser for a network printer that is connected through a network switch, hub, or router.

**Note:** The infuser must be connected with a wired Ethernet cable as the printing function is disabled when the CE wireless network is active.

## Equipment Needed

- Infuser
- Computer meeting the infuser setup requirements
- Ethernet network cable

## Preparation

Connect the Ethernet network cable from the infuser to the computer, then connect the infuser to AC power.

## Setup Procedure

1. Identify the network printer IP address or host name and TCP/IP port, as follows:
  - Printer Host/IP address: 192.168.0.222  
(host name or static IP address)
  - Port: 9100 (must be between 9000 to 9999)
2. Test the network printer configuration.
3. Configure the infuser connectivity engine settings so that the printer IP address or host name and printer port settings match the values in Step 1 ([see Figure E-2](#)).



**Connectivity Configuration**

**Service Properties**

Print Enabled:

Printer Host/IP-Address: 192.168.0.222

Printer Port: 9100

Terminal Port: 8889

Directly Connected Printer:

Scan List Size: 64

SSID Filtering:

WLAN QBSS Station Threshold: 12

WLAN QBSS Channel Load Threshold: 95

WLAN Bad AP Status Retry Timeout: 300

WLAN Bad AP Statistics Retry Timeout: 300

Roam RSSI Threshold: 34

Roam 11a/g Rate Threshold: 12000

Roam 11b Rate Threshold: 5000

Background Scan Period: 90

On Channel Time: 1000

Disable Web-Configuration:

< Previous   Reset   Finish   Next >

**Figure E-2.**  
**Connectivity Configuration for Networked Printer**

- Print Enabled: Checked
  - Printer Host/IP Address: 192.168.0.222
  - Printer Port: 9100
  - Directly Connected Printer: Unchecked
4. Save the infuser configuration changes and restart the CE.
  5. Connect the infuser to the network with an Ethernet network cable between the infuser and the network printer.

The infuser is now set up for network printing on a wired Ethernet network.

## Printing Procedure



### WARNING

**DISCONNECT THE INFUSER FROM THE PATIENT BEFORE CONNECTING THE INFUSER TO A PRINTER OR COMPUTER.**

**Note:** After the infuser A/C power is applied or the CE is restarted by changing the Ethernet cable, allow 2 to 3 minutes for the infuser CE to complete the start-up initialization before attempting to print the Event Log.

**Note:** After the infuser is turned on to initiate printing, allow 2 to 3 minutes for the infuser to complete start-up before attempting to print the Event Log.

1. Load the printer with paper.
2. Turn on the infuser and confirm drug and concentration.
3. Press the **[HISTORY/BATTERY]** button to view the history on the display.
4. Press the **PRINT HISTORY>** softkey to print history log.

**Note:** If the entire log is not successfully printed (for example, the header is missing), select **PRINT HISTORY>** again to reprint the log.

## Downloading Logs to a PC

This section describes how to configure the infuser and personal computer program to download log events to the PC.

**Note:** The infuser must be connected with a wired Ethernet cable as the printing function is disabled when the CE wireless network is active.

## **Equipment Needed**

- Infuser
- Personal computer with a terminal program (for example, Tera Term, etc.)
- Ethernet network cable
- Ethernet network crossover cable (for configuration)

## **Preparation**

Connect the Ethernet network cable from the infuser to the computer, then connect the infuser to AC power.

## **Setup Procedure**

1. On WebConfig, under the **Service Properties** menu, identify the wired network settings required for your setup).
2. Configure the infuser connectivity engine settings as shown in [Figure E-3](#).
  - Print Enabled: Checked
  - Terminal Port: 8999 (must be between 8000 and 8999)

## Network Printer Setup

The screenshot displays the 'Connectivity Configuration' web interface. On the left is a navigation menu with the following items: Status, Ethernet, Wireless, Security, Certificates, HMSS, Service (highlighted), and Administration. The main content area is titled 'Service Properties' and contains the following settings:

Print Enabled:	<input checked="" type="checkbox"/>
Printer Host/IP-Address:	192.168.0.222
Printer Port:	9100
Terminal Port:	8889
Directly Connected Printer:	<input type="checkbox"/>
Scan List Size:	64
SSID Filtering:	<input checked="" type="checkbox"/>
WLAN QBSS Station Threshold:	12
WLAN QBSS Channel Load Threshold:	95
WLAN Bad AP Status Retry Timeout:	300
WLAN Bad AP Statistics Retry Timeout:	300
Roam RSSI Threshold:	34
Roam 11a/g Rate Threshold:	12000
Roam 11b Rate Threshold:	5000
Background Scan Period:	90
On Channel Time:	1000

At the bottom of the settings area, there is a 'Disable Web-Configuration:' checkbox which is currently unchecked. Below the settings area is a navigation bar with buttons for '< Previous', 'Reset', 'Finish', and 'Next >'.

**Figure E-3. Connectivity Engine Settings**

- On WebConfig, under the **Ethernet Properties** menu, configure the infuser as shown in [Figure E-4](#) and [Figure E-5](#).
  - Ethernet DHCP Enabled: [required by your setup]
  - Ethernet IP Address: [required by your setup]
  - Ethernet Subnet Mask: [required by your setup]
  - Ethernet Default Gateway: [required by your setup]
  - HMSS Host/IP Address: [must be blank]

**Note:** The PC terminal printing function is disabled in the CE if HMSS host name or IP address is configured.

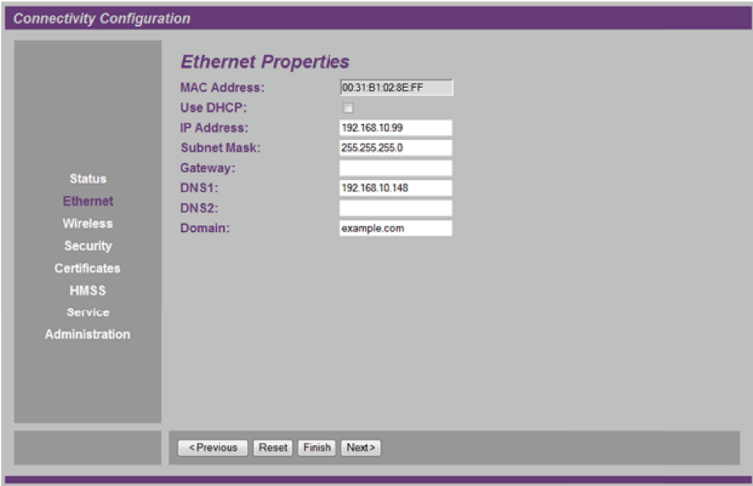


Figure E-4. Ethernet Properties

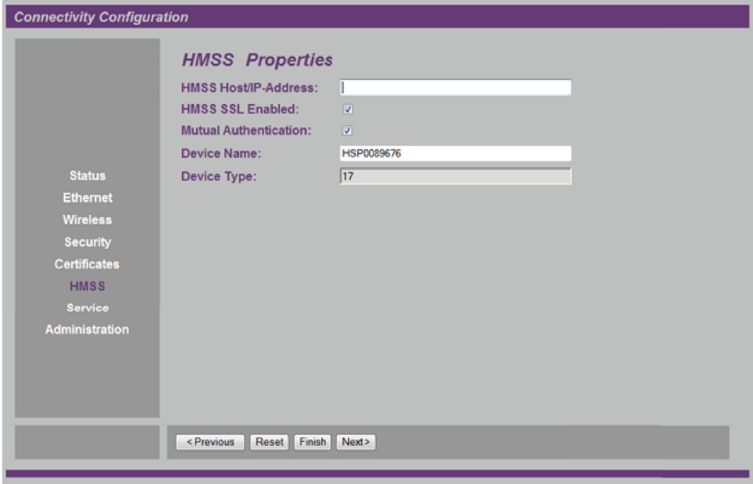
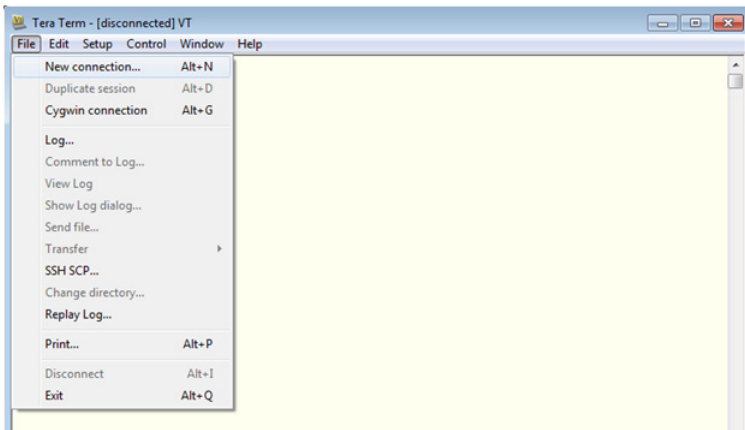


Figure E-5. HMSS Properties

## Network Printer Setup

4. Save the infuser configuration changes and restart the infuser CE.
5. Connect the infuser to the wired network. Identify the infuser DHCP assigned IP address (if applicable).
6. Connect the PC to the wired network.
7. Start the PC terminal program. Open a new TCP/IP connection.

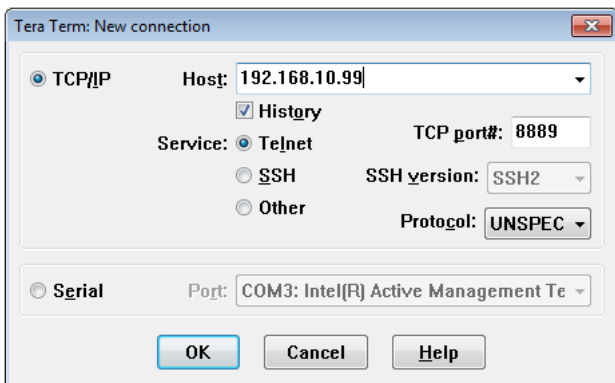
**Figure E-6** shows an example of the Tera Term option for a new connection. It is, however, not required to use Tera Term only. Any other terminal supported on the PC that allows Telnet connectivity should also be acceptable.



**Figure E-6.** Tera Term Option

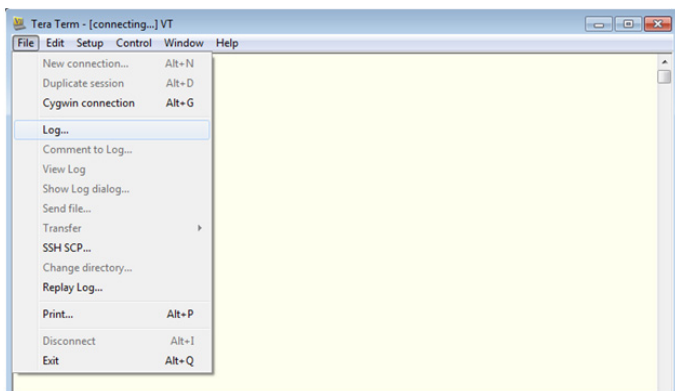
- Specify the infuser IP address and TCP/IP port configured on the infuser in Step 2 (or the DHCP assigned IP address from Step 4) and start the new connection.

**Figure E-7** shows Tera Term options for a new connection.



**Figure E-7.**  
**Tera Term Options for a New Connection**

- [Optional] Select the option to capture the terminal output to a log file, if desired ([see Figure E-8](#)).



**Figure E-8. Tera Term Log Option**

## Network Printer Setup

The infuser and terminal program are now set up and ready for PC terminal printing on a wired Ethernet network.

**Note:** The Tera Term terminal program window will close after the printing session is completed because the TCP/IP socket is disconnected.

## Printing Procedure



### **WARNING**

**DISCONNECT THE INFUSER FROM THE PATIENT BEFORE CONNECTING THE INFUSER TO A PRINTER OR COMPUTER.**

**Note:** After the infuser A/C power is applied or the CE is restarted by changing the Ethernet cable, allow 2 to 3 minutes for the infuser CE to complete the start-up initialization before attempting to print the Event Log.

**Note:** After the infuser is turned on to initiate printing, allow 2 to 3 minutes for the infuser to complete start-up before attempting to print the Event Log.

1. Load the printer with paper.
2. Turn on the infuser and confirm drug and concentration.
3. Press the [HISTORY/BATTERY] button to view the history on the display.
4. Press the **PRINT HISTORY**> softkey to print history log.

**Note:** If the entire log is not successfully printed (for example, the header is missing), select **PRINT HISTORY**> again to reprint the log.



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# Appendix F

## Glossary

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This appendix lists definitions of general and clinical terms and acronyms used in this manual.

<b>Term</b>	<b>Definition</b>
<b>Accuracy</b>	<p>The degree to which the instrument is capable of delivering the volume of analgesic drug that is displayed or targeted to be delivered</p> <p>Accuracy shall be specified as the maximum allowable delivery error from a targeted or displayed value</p>
<b>Autoprogramming</b>	<p>Complete or partial program received from a bar code enabled Point-of-Care System requiring clinician confirmation prior to administration</p>
<b>Battery Fault</b>	<p>A battery that will not accept a full charge</p>
<b>Bolus</b>	<p>A fixed amount of drug delivered in a short amount of time</p> <p>A PCA dose</p>
<b>Button</b>	<p>A hard key on the front panel or the patient pendant</p>
<b>Clinical Care Area (CCA)</b>	<p>An area of the hospital that authorized hospital staff is permitted to use specific drugs</p> <p>The clinician selects a CCA after turning on the infuser</p> <p>The hospital may create from one to eighteen CCAs</p>

## Glossary

Term	Definition
<b>Connectivity Engine (CE)</b>	A component of the infuser that controls Ethernet and wireless communication between the network server and infuser
<b>Continuous</b>	Infusion program characterized by a constant, fixed-rate dose
<b>Custom Syringe or Vial</b>	A bar coded LifeCare PCA sterile empty vial that is custom-filled by a pharmacy
<b>Default Drug Library (DDL)</b>	A pre-programmed drug library embedded in the infuser software  An infuser with ICU Medical MedNet Software uses the DDL until a user-defined drug library is installed and supersedes the DDL
<b>Dose Limit</b>	User-programmable parameter specifying the maximum amount of drug that can be administered via PCA dose and continuous delivery in a programmable rolling time period consisting of discrete accumulation periods of 6 minutes  <b>Note:</b> Dose limit periods are specified as 1 and 4 hours on an infuser with the DDL. On infusers with a user-defined drug library, the dose limit periods can be defined as 1, 4, 6, or 12 hours.
<b>Drug Library Download (ICU Medical MedNet only)</b>	The process of moving the user-defined drug library from the network server to the infuser.
<b>Drug Library Installation (ICU Medical MedNet only)</b>	The process of moving the user-defined drug library from the CE to the infuser

<b>Term</b>	<b>Definition</b>
<b>History/Battery</b>	<p>The History function displays Rx Settings, PCA Summary, and the Event Log</p> <p>The Battery function accesses the Battery Charge indicator and the Wireless Strength indicator</p>
<b>ICU Medical MedNet Software</b>	<p>Network based application software used to upload event logs and download the user-defined drug library to the infuser</p>
<b>Infusing</b>	<p>The infuser is on and a delivery screen is displayed</p> <p>The infusing mechanism may or may not be actually infusing at any given time</p>
<b>LCD</b>	<p>Liquid Crystal Display</p>
<b>LED</b>	<p>Light Emitting Diode</p>
<b>LifeCare PCA Set</b>	<p>Tubing connecting the PCA vial to the patient</p>
<b>Loading Dose</b>	<p>An optional dose programmed during setup before entering the program</p> <p>The loading dose can be administered at any time by the clinician during the programmed therapy</p>
<b>Lockout Interval</b>	<p>A programmed time interval specifying the minimum time that must pass after a loading dose or PCA dose (bolus) is administered</p> <p>This time interval specifies when the next PCA dose can begin infusing</p> <p>Bolus requests made during the lockout interval are denied</p>

## Glossary

<b>Term</b>	<b>Definition</b>
<b>Muting Period</b>	The period between the silencing of an alarm by pressing the <b>[AUDIO PAUSE]</b> key and the resumption of the alarm
<b>Occlusion</b>	A blockage in the administration set that prevents the infuser from pumping fluid into the patient  Possible causes of occlusions are kinked or plugged non-patient IV tubing
<b>Occlusion Pressure</b>	The maximum pressure produced as a result of an occlusion in the administration set
<b>Patient Pendant</b>	A hand held pendant connected to the infuser that allows the patient to request a PCA dose (bolus) by pressing a button
<b>PCA Mode</b>	Infusion therapy characterized by bolus doses administered on patient demand subject to a lockout interval and, optionally, a dose limit
<b>PCA Vial</b>	Vial or syringe that is compatible with the LifeCare PCA infuser, which is either pre-filled and bar coded (standard) or filled and bar coded by the hospital pharmacy (custom)
<b>Prime</b>	Removing air from the syringe and administration set
<b>Rule Set (ICU Medical MedNet only)</b>	A list of upper, lower, soft, and/or hard limits for delivery parameters  Rule sets reside in the user-defined drug library and are associated with a specific vial within a CCA

<b>Term</b>	<b>Definition</b>
<b>Rx Settings</b>	<p>The current programmed therapy</p> <p>Includes PCA Dose, PCA Lockout Interval, Continuous Rate, Loading Dose, and Dose Limit amount</p>
<b>Softkeys</b>	<p>The five keys to the right of the device's display</p> <p>Each key's function is dependent on the screen displayed data</p>
<b>Stored Protocols</b>	<p>Frequently used therapy settings stored in the infuser's memory</p> <p>Stored protocols can be recalled again, making it unnecessary for the operator to program the same therapy settings each time they are needed</p> <p>Stored protocols are determined by the health care facility</p>
<b>Standard Syringe</b>	<p>A pre-filled bar coded drug vial in which the infuser identifies the drug and concentration</p> <p>The drug and concentration are found in the drug library by using the bar code on the vial</p> <p>Standard syringes are also known as pre-filled drug vials</p>
<b>User-Defined Drug Library (ICU Medical MedNet only)</b>	<p>A drug library that contains hospital-defined clinical care areas (CCAs) and rule sets created with ICU Medical MedNet Software</p>
<b>Warning</b>	<p>An indication to advise the clinician of a possible dangerous condition</p>

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**NOTES**

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# **Appendix G**

## **Warranty**

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Subject to the terms and conditions herein, ICU Medical, Inc., herein referred to as ICU Medical, warrants that (a) the product shall conform to ICU Medical'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. ICU Medical 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 ICU Medical's option, the repair or replacement of the product. In no event shall ICU Medical'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 ICU Medical be liable for incidental, consequential, or special damages or losses or for lost business, revenues, or profits. Warranty product returned to ICU Medical 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 ICU Medical's judgment, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.

## ***Warranty***

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 ICU Medical and using ICU Medical 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, ICU Medical 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 such repair or service. It is understood and acknowledged that any person other than an ICU Medical representative performing repair or service is not an authorized agent of ICU Medical.



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# Contact Information

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## **United States**

For customer service, contact:

**1-877-946-7747**

For technical assistance, product return authorization, and to order parts or manuals, contact ICU Medical Technical Support Center:

**1-800-241-4002**

Parts orders can be submitted by email:

[\*\*parts@icumed.com\*\*](mailto:parts@icumed.com)

or by fax:

**1-408-284-7130**

To review replacement parts lists, technical service manuals, and alternate cleaning agents, or for additional technical resources, operating manuals, and technical training courses, visit:

[\*\*www.icumed.com\*\*](http://www.icumed.com)

For inquiries on reprocessing (cleaning/disinfecting), email Tech Support Client Solution Specialists at:

[\*\*supportservices@icumed.com\*\*](mailto:supportservices@icumed.com)

## **Canada**

For customer service, contact the Pump Repair Center:

**1-866-488-6088**

or by email:

[\*\*canadapumpsupport@icumed.com\*\*](mailto:canadapumpsupport@icumed.com)

To order parts, contact Spare Parts Customer Service:

**1-866-488-6088**

or by email:

[\*\*pumppartsservices@icumed.com\*\*](mailto:pumppartsservices@icumed.com)

## **All Other Countries**

For technical assistance, contact your local ICU Medical sales office.

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**NOTES**

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**WARNING**



**EXPLOSION HAZARD EXISTS IF THE INFUSION SYSTEM IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES.**



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



Caution



Warning

Class I

Mains supply equipment using protective earth

IPX2

Protection against vertically falling water drops



Fragile, Handle with Care



Temperature limitation



This Way Up



Keep dry



Mandatory Action



Follow Instructions for Use



Equipotential Terminal provided for electrical safety testing and as a means for connection of a potential equalization conductor. Using the equipotential terminal for anything but grounding purposes may contribute to damage of the device.



Device includes an RF transmitter that complies with IEEE 802.11 a/b/g



A certification mark employed on electronics products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission

## LifeCare PCA Infusion System

Rx Only

Indicates that Federal (USA) law restricts this device to sale by or on the order of a physician or other license



TYPE BF

The patient pendant handle and button are applied parts for the LifeCare PCA infuser. The patient pendant handle and button are Type BF applied parts complying with the higher degree of protection against electric shock, as defined in IEC 60601-1:2012. Type BF Applied Parts are those parts suitable for direct patient connections. Type BF parts are not suitable for direct cardiac application.



Type CF

The vial, injector, and administration set, which comprises the infusion liquid pathway, are applied parts for the LifeCare PCA infuser. The vial, injector, and administration set are Type CF applied parts complying with the higher degree of protection against electric shock, as defined in IEC 60601-1:2012. Type CF Applied Parts are those parts suitable for direct cardiac application.



The 'C' and 'US' indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/AAMI Standards, for use in Canada and the U.S., respectively. This 'US' indicator includes products eligible to bear the 'NRTL' indicator. NRTL (National Recognized Testing Laboratory), is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.

The infuser has been evaluated to IEC 60601-1:2012 Edition 3.1 - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.