For Use with List Number 20837-04, and for List Number 20709-04
Upgraded with 7.x Software

Compatible with Hospira MedNet™ Software
## Change History

<table>
<thead>
<tr>
<th>Title</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>430-97354-001 (E, 2015-05)</td>
<td>Initial Release</td>
</tr>
<tr>
<td>430-97354-001 (F, 2016-02)</td>
<td>Added information for upgraded pumps (Cover, Chapter 1, Chapter 11)</td>
</tr>
<tr>
<td></td>
<td>Updated Programming a Loading Dose instructions (Chapter 5)</td>
</tr>
<tr>
<td></td>
<td>Updated Clearing Shift Totals instructions (Chapter 7)</td>
</tr>
<tr>
<td></td>
<td>Added cleaning/disinfecting instructions for the patient pendant strap (Chapter 8)</td>
</tr>
<tr>
<td></td>
<td>Updated Appendix C to clarify alarm information</td>
</tr>
</tbody>
</table>
Contents

CHAPTER 1
INTRODUCTION .......................... 1-1
INDICATIONS FOR USE .................... 1-1
LIFECARE PCA INFUSION SYSTEM
   WITHOUT HOSPIRA MEDNET SOFTWARE .... 1-2
LIFECARE PCA INFUSION SYSTEM
   WITH HOSPIRA MEDNET SOFTWARE ........ 1-2
LIST NUMBER 20709-04 UPGRADED TO 7.x SOFTWARE .... 1-3
CONVENTIONS .................................. 1-3
PRODUCT DESCRIPTION ...................... 1-4
PATIENT SELECTION ........................ 1-5
   CONTRAINDICATIONS FOR USE .......... 1-6
   USER QUALIFICATIONS .................. 1-6
VIEWING THE DISPLAY ...................... 1-6
HOSPIRA PRE-FILLED VIALS .................. 1-7
PHARMACY-FILLED (CUSTOM) VIALS ............ 1-8
EQUIPMENT DESCRIPTION .................... 1-9
   FRONT VIEW ................................ 1-9
   VIAL CRADLE ASSEMBLY ................ 1-10
   REAR VIEW ................................ 1-11
   EQUIPOTENTIAL TERMINAL ............. 1-12
   PATIENT PENDANT ...................... 1-12
   BUTTONS AND KEYS .................... 1-14
   BATTERY CHARGE LEVEL ............... 1-17
   WIRELESS STRENGTH .................... 1-18
   ALARM TREATMENT ..................... 1-19
EPIDURAL ADMINISTRATION ................... 1-20
ELECTRICAL ARTIFACTS ..................... 1-22
   INTERCONNECTING OF EQUIPMENT ....... 1-24
GUIDANCE ON EMC COMPATIBILITY .......... 1-24
FCC INFORMATION .......................... 1-25
   US FCC (FEDERAL COMMUNICATIONS COMMISSION)
   STATEMENT ................................ 1-25
   FCC INTERFERENCE STATEMENT .......... 1-26
Contents

WIRELESS DEVICE CAUTION .......................... 1-27
RADIO FREQUENCY EXPOSURE STATEMENT ....... 1-27
WARNINGS AND PRECAUTIONS .................... 1-28
MALFUNCTION ALARM ................................. 1-30
BATTERY OPERATION ................................. 1-31

CHAPTER 2
SETUP AND OPERATION .............................. 2-1
INFUSER CONFIGURATIONS
ON AN IV POLE ...................................... 2-1
ATTACHING AN INFUSER TO AN IV POLE ......... 2-3
REMOVING AN INFUSER
FROM AN IV POLE .................................... 2-5
ADMINISTRATION SETS ............................... 2-5
PRIMING THE ADMINISTRATION SET ............... 2-8
MANUALLY PRIMING THE ADMINISTRATION SET 2-8
PRIMING THE ADMINISTRATION SET ON THE INFUSER 2-9
LOADING A VIAL ....................................... 2-12
VIAL CHANGES
AND DISCONTINUING THERAPY ..................... 2-15
CHANGING OR REMOVING A VIAL WITH THE SAME
MEDICATION AND CONCENTRATION .............. 2-15
CHANGING OR REMOVING A VIAL WITH DIFFERENT
MEDICATION AND/OR CONCENTRATION ......... 2-16
DISCONTINUING A PCA THERAPY .................... 2-18

CHAPTER 3
MODES OF DELIVERY ............................... 3-1
MODES OF DELIVERY ............................... 3-1
PCA ONLY ........................................... 3-1
CONTINUOUS ........................................... 3-2
PCA + CONTINUOUS ................................. 3-3
DOSE LIMIT ........................................... 3-4
CHAPTER 4
PROGRAMMING INFUSERS WITH
HOSPIRA MEDNET SOFTWARE ............... 4-1
Warnings and Cautions ....................... 4-2
Loading Dose/Dose Limits ................... 4-3
Patient Pendant .............................. 4-3
System Settings .............................. 4-3
  Adjusting Contrast of Main Display .... 4-5
  Adjusting Time and Date ................. 4-6
Programming a PCA Therapy .................. 4-8
  Turning On the Infuser .................... 4-8
  Programming a LOADING DOSE .......... 4-8
Programming a PCA + Continuous Therapy .... 4-15
  Programming a LOADING DOSE .......... 4-15
Programming a Continuous Therapy .......... 4-22
  Turning On the Infuser .................... 4-22
  Programming a LOADING DOSE .......... 4-23
Drug Library: Soft Limit, Hard Limit,
  and Rule Set ............................... 4-29
  Soft Limit Override ...................... 4-29
  Hard Limit Violation ..................... 4-30
  Rule Sets Caution ....................... 4-31
Changing the CCA ............................ 4-31
Updating the Drug Library .................. 4-33
Auto-Programming ............................ 4-34

CHAPTER 5
PROGRAMMING INFUSERS WITHOUT
HOSPIRA MEDNET SOFTWARE ............... 5-1
Warnings and Precautions .................. 5-2
Loading Dose/Dose Limits .................. 5-3
Patient Pendant ............................ 5-3
System Settings ............................ 5-3
  Adjusting Time and Date ............... 5-5
Programming a PCA Therapy .................. 5-7
  Turning On the Infuser .................. 5-7

System Operating Manual
Contents

PROGRAMMING A PCA + CONTINUOUS THERAPY ............ 5-13
  TURNING ON THE INFUSER. .......................... 5-13
PROGRAMMING A CONTINUOUS THERAPY ............... 5-19
  TURNING ON THE INFUSER. ......................... 5-20
  PROGRAMMING A LOADING DOSE ...................... 5-20
PROGRAMMING WITH A PHARMACY- FILLED
  (CUSTOM) VIAL ...................................... 5-24

CHAPTER 6
REVIEWING AND CHANGING RX SUPPLEMENTAL
LOADING DOSE ........................................ 6-1
REVIEWING THE CURRENT PROGRAM .................... 6-1
CHANGING THE CURRENT PROGRAM ...................... 6-2
PROGRAMMING A SUPPLEMENTAL LOADING DOSE ........ 6-5

CHAPTER 7
BATTERY AND WIRELESS STATUS
HISTORY AND EVENT LOG ............................ 7-1
DATA RETENTION ...................................... 7-3
INFUSERS WITHOUT HOSPIRA MEDNET SOFTWARE .... 7-3
CHECKING HISTORY AND SETTINGS ................... 7-10
CLEARING SHIFT TOTALS ............................... 7-11

CHAPTER 8
MAINTENANCE .......................................... 8-1
CLEANING AND DISINFECTION .......................... 8-1
  CLEANING ........................................... 8-3
  DISINFECTION ....................................... 8-18
CLEANING SPILLS ..................................... 8-26
BATTERY MAINTENANCE ................................ 8-27
SERVICE .............................................. 8-28
PRODUCT HANDLING AND DISPOSAL ..................... 8-28
INFUSER STORAGE .................................... 8-29
CHAPTER 9
SPECIFICATIONS ............................... 9-1
WIRELESS LAN MODULE ...................... 9-6
STORED OCCLUSION VOLUME ................... 9-7
TIME FROM OCCLUSION TO ALARM ............ 9-7
DELIVERY RATE ACCURACY .................... 9-8
TRUMPET CURVES .............................. 9-9
EXAMPLE ........................................ 9-10
TRUMPET CURVES ................................ 9-11

CHAPTER 10
PROTOCOLS ....................................... 10-1
HOSPIRA MEDNET SOFTWARE INFUSERS ........ 10-1
PROGRAMMING PROTOCOLS ..................... 10-2
INFUSERS WITHOUT HOSPIRA MEDNET ............ 10-6
PROGRAMMING PROTOCOLS ..................... 10-7

CHAPTER 11
INFORMATION FOR LEGACY
LIFECARE PCA INFUSERS UPGRADED
WITH 7.X SOFTWARE ............................ 11-1
IEC 60601-1 COMPLIANCE ....................... 11-2
IEC 60601-1-2 COMPLIANCE ..................... 11-2
FLUID INGRESS PROTECTION RATING ............ 11-2
SPECIFICATIONS ................................ 11-3
STORED OCCLUSION VOLUME .................... 11-3
TIME FROM OCCLUSION TO ALARM ............ 11-4
CSA MARK ......................................... 11-4
APPENDIX E
NETWORK PRINTER SETUP. E-1
DIRECTLY CONNECTED PRINTER E-1
EQUIPMENT NEEDED E-1
PREPARATION E-1
SETUP PROCEDURE E-2
PRINTING PROCEDURE E-3
NETWORK PRINTER E-4
EQUIPMENT NEEDED E-4
PREPARATION E-4
SETUP PROCEDURE E-4
PRINTING PROCEDURE E-6
DOWNLOADING LOGS TO A PC E-6
EQUIPMENT NEEDED E-7
PREPARATION E-7
SETUP PROCEDURE E-7
PRINTING PROCEDURE E-12

APPENDIX F
GLOSSARY F-1

APPENDIX G
WARRANTY G-1
Chapter 1
Introduction

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 Hospira-approved prefilled medication vials. The Hospira 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 prefilled with a medication by Hospira, or are sterile empty vials which can be custom-filled by the hospital pharmacy (see Appendix A Generating Bar Code Labels (Hospira 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
Introduction

code reader and manually enter the medication into the LifeCare PCA infuser (see Appendix A Generating Bar Code Labels (Hospira 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 Hospira 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 Hospira MedNet Software

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

The Hospira 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 Hospira 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>
<thead>
<tr>
<th>Convention</th>
<th>Application</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ITALIC</strong></td>
<td>Reference to a chapter, figure, or table</td>
<td>(See Appendix A)</td>
</tr>
<tr>
<td>[BRACKETED ALL CAPS]</td>
<td>Keys or buttons on the device are displayed in [BRACKETED ALL CAPS]</td>
<td>[ON/OFF]</td>
</tr>
<tr>
<td><strong>ITALIC SMALL CAPS&gt;</strong></td>
<td>Softkey options</td>
<td>PREVIOUS&gt;</td>
</tr>
<tr>
<td><strong>SMALL CAPS WITH INITIAL UPPERCASE</strong></td>
<td>Screen displays and device labels</td>
<td>SELECT DELIVERY MODE</td>
</tr>
<tr>
<td><strong>BOLD</strong></td>
<td>Emphasis</td>
<td>...SETS ARE SUPPLIED STERILE AND ARE FOR....</td>
</tr>
</tbody>
</table>

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

**WARNING**

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

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:

<table>
<thead>
<tr>
<th>MEDICAL</th>
<th>LABOR/DELIVERY/ POST PARTUM</th>
<th>BURN UNIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>SURGICAL</td>
<td>OPERATING ROOM</td>
<td>ONCOLOGY</td>
</tr>
<tr>
<td>CRITICAL CARE UNITS</td>
<td>POST ANESTHESIA CARE UNIT (PACU)</td>
<td>PEDIATRICS</td>
</tr>
</tbody>
</table>

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 Hospira 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 Hospira prefilled vials and custom syringes. The protocols must be set up by a hospital-designated authority in the Biomed Mode or through Hospira 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.

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

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

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.
Hospira Pre-Filled Vials

Hospira pre-filled vials are available for standalone infusers and Hospira 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 Hospira pre-filled medication vials are FDA approved for use with the LifeCare PCA infuser:

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

**WARNING**

**FAILURE TO USE HOSPIRA-APPROVED VIALS, INJECTORS, AND LIFECASTE PCA ADMINISTRATION SETS WITH INTEGRAL PRESSURE ACTIVATED VALVES MAY CAUSE AN INACCURATE DOSE DELIVERY TO THE PATIENT.**

The LifeCare PCA sterile empty vial is made of USP Type 1 glass with a silicone rubber stopper and is the same composition as the Hospira prefilled vials.

**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.**
**Introduction**

**Pharmacy-Filled (Custom) Vials**

For standalone infusers without Hospira MedNet Software

Custom vials are sterile empty 30 mL vials which are filled by the hospital pharmacy. A pharmacy-filled (custom) vial offers your facility the flexibility to infuse medications per your facility’s practice. 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 Hospira MedNet Software

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.

Hospira 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 Hospira 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.

![Front View Diagram]

---

System Operating Manual

1-9
Introduction

Vial Cradle Assembly

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

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

**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.
**Introduction**

**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**

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

**WARNING**

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
**Introduction**

**Buttons and Keys**

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

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ON/OFF]</td>
<td>The [ON/OFF] button controls the power of the LifeCare PCA infuser.</td>
</tr>
<tr>
<td>[CLEAR]</td>
<td>The [CLEAR] button is used to clear an entry.</td>
</tr>
<tr>
<td>[ENTER]</td>
<td>The [ENTER] button is used to select and accept various screen options.</td>
</tr>
<tr>
<td>[EXIT]</td>
<td>The [EXIT] button is used to return to the main display from non-programming screens.</td>
</tr>
<tr>
<td>[AUDIO PAUSE]</td>
<td>The [AUDIO PAUSE] button is used to temporarily silence an alarm.</td>
</tr>
</tbody>
</table>
Table 1-2. Buttons and Keys

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>[START/STOP] button</td>
<td>The [START/STOP] button is used to start or stop a continuous infusion or PCA bolus</td>
</tr>
<tr>
<td>[HISTORY/BATTERY] button</td>
<td>When pressed, the [HISTORY/BATTERY] button displays the battery strength icon and wireless strength icon. In addition, [HISTORY/BATTERY] is used to display parameter settings, dose history, review Rx, and review the event log. This button also provides access to the PRINT HISTORY softkey. Note: Print History is available for standalone infusers without Hospira MedNet.</td>
</tr>
<tr>
<td>Numeric buttons</td>
<td>The numeric buttons are used to enter values for any field requiring numeric data. The [DECIMAL POINT] button is used when entering numbers with a decimal point (such as 10.5 mg).</td>
</tr>
</tbody>
</table>
### Table 1-2. Buttons and Keys

<table>
<thead>
<tr>
<th>Button/Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Softkeys</td>
<td>When pressed, the softkeys to the right of the main display perform a variety of functions correlating to the description displayed on the screen.</td>
</tr>
<tr>
<td>Battery Indicator</td>
<td>The battery indicator illuminates continuously when the infuser is running on battery power.</td>
</tr>
<tr>
<td>AC (mains) Power Indicator</td>
<td>The AC (mains) power indicator illuminates when the infuser is plugged into AC power.</td>
</tr>
<tr>
<td>Dose Delivered</td>
<td>LED displays the dose delivered. 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.</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Alarm State</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>Fully Charged</strong> - 76% to 100% capacity</td>
<td>None</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>Three-fourths</strong> - 51% to 75% capacity</td>
<td>None</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>Half</strong> - 26% to 50% capacity</td>
<td>None</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>5 Minutes</strong> - 1% to 25% capacity</td>
<td>Low</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>Empty</strong> - 0% capacity</td>
<td>High</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td><strong>No Battery Installed</strong></td>
<td>High</td>
</tr>
</tbody>
</table>

*Table 1-3. Battery Charge Levels*
Introduction

Wireless Strength

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

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

<table>
<thead>
<tr>
<th>Table 1-4. Wireless Strength Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Icon] Excellent strength</td>
</tr>
<tr>
<td>![Icon] Good strength</td>
</tr>
<tr>
<td>![Icon] Fair strength</td>
</tr>
<tr>
<td>![Icon] Poor strength</td>
</tr>
<tr>
<td>![Icon] No signal available</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Table 1-5. Alarm Priority Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Priority</strong></td>
</tr>
<tr>
<td>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. The 3 exclamation marks (to the left of the centered screen name <strong>ALARM</strong>) represent a high priority alarm.</td>
</tr>
<tr>
<td><strong>Medium Priority</strong></td>
</tr>
<tr>
<td>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. The 2 exclamation marks (to the left of the centered screen name <strong>ALARM</strong>) represent a medium priority alarm.</td>
</tr>
</tbody>
</table>
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 Hospira or field service technician for help

**CAUTION: PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT, SUCH AS CELLULAR TELEPHONES, 2-WAY RADIOS, BLUE TOOTH 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*. 
Introduction

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 Hospira 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:


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.
Warnings and Precautions

Hospira 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 Hospira, 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.

---

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

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

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.
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 HOSPIRA 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.
Introduction

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
UNPLUG THE AC POWER CORD BEFORE REMOVING THE BATTERY DOOR.

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
THE INFUSER CANNOT COMMUNICATE VIA THE NETWORK IF THE LOW BATTERY WARNING ALARM HAS SOUNDED.
Chapter 2
Setup and Operation

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.

Infuser Configurations on an IV Pole

The Hospira 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.

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.
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](image)
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

Hospira 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

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

WARNING

HOSPIRA 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.

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.
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**

1. Pressure activated valve with cap
2. Microbore/minibore tubing
3. Slide clamp
4. Y-junction
5. Distal male Luer with cover
6. Female Luer with cover
7. Macrobore tubing
8. Backcheck valve

**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 caps from the vial and the injector.
2. Attach the injector to the vial, turning clockwise till secure.
3. Slowly depress the flange on the injector to remove excess air from the vial.
4. Remove the sterile tip protector from the proximal (female) end of the administration set and attach the set to the injector.
5. Close the slide clamp on the KVO (Keep Vein Open) side of the LifeCare PCA administration set *(see Figure 2-4)*.

**Note:** Prime the pigtail 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 until all air is removed from the administration set. Stop when you see fluid at the distal end of the administration set.
8. Close the orange slide clamp on the PCA side of the administration set.

9. To prime the KVO side of the set, close the slide clamp below the vial and open the clamp on the KVO side. Attach the primed administration set to a female adapter and prime the KVO side until all air is removed and 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

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

3. 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.

4. 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 Hospira MedNet enabled devices.

WARNING

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

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

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).

CAUTION: VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.
6. 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**.

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

8. 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.

9. Press **CONTINUE**.

10. 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, HOSPIRA RECOMMENDS STORING THE INFUSER CONNECTED TO AC (MAINS) POWER.
Chapter 3
Modes of Delivery

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 Hospira MedNet Software, see *Chapter 4 Programming Infusers with Hospira MedNet Software*.

To program these modes for standalone LifeCare PCA infusers, see *Chapter 5 Programming Infusers without Hospira 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.

WARNING
THE PATIENT PENDANT BUTTON IS TO BE PRESSSED ONLY BY THE INTENDED PATIENT.

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.
**Modes of Delivery**

**Dose Limit**

To program a dose limit, see *Chapter 4 Programming Infusers with Hospira MedNet Software* or *Chapter 5 Programming Infusers without Hospira 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.
Chapter 4
Programming Infusers with Hospira MedNet Software

This chapter describes how to program the LifeCare PCA infuser with the Hospira 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**

---

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.

---

- 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. It may take several seconds for the Hospira logo to appear on the screen.
2. When the self test is complete, select **SYSTEM SETTINGS** 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**

2. A **WARNING** screen indicates that changing the date or time will clear all totals. When the **WARNING** screen appears, select **CONTINUE**.
3. 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**.

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

5. 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.

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 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.

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select **CONTINUE>** to advance to the next screen.

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

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 \textit{YES}>.

   In this example, \textit{YES}> is selected.

   If no loading dose is desired, select \textit{NO}> to proceed with programming.

7. Using the numeric keypad, enter a loading dose, then press [\texttt{ENTER}] to continue.

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

   \textbf{Note:} Select \textit{PREVIOUS}> to return to the preceding screen if programming changes need to be made.

8. The \textbf{SELECT DELIVERY MODE} screen appears. Select \textit{PCA ONLY}> to continue (see \textit{Modes of Delivery}).
9. Using the numeric keypad, enter the desired PCA dose, then press [ENTER].

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

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

**Note:** The Hospira MedNet Software/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.
12. Verify loading dose settings, then select CONFIRM>.

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.

In this example, NO> is selected.

Note: To prime the administration set on the infuser, see Chapter 2 Setup and Operation.
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 PCA bolus will become available. The PCA dose is delivered when the patient presses the PCA patient pendant button.

![Screen with Door Locked]

**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.

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select *CONTINUE* to advance to the next screen.
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.
7. 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.

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

9. Using the numeric keypad, enter the PCA dose.
10. Using the numeric keypad, enter the lockout interval value. The lockout interval displays on the screen.

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

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

Note: The Hospira MedNet Software/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.
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 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.
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,
- 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.

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select **CONTINUE** to advance to the next screen.

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.
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.

7. 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.
8. The **SELECT DELIVERY MODE** screen appears. Select **CONTINUOUS** to continue.

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

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

   **Note:** The Hospira MedNet Software/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.**
11. Verify loading dose settings, then select CONFIRM>

12. Verify program settings, then select CONFIRM>, or, 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.*
Programming Infusers with Hospira MedNet Software

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

Hospira 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.
Programming Infusers with Hospira MedNet Software

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
CLOSE THE TUBING SLIDE CLAMP WHEN HANDLING THE VIAL.

MORPHINE PF
1 mg/mL
MEDSURG
PCA+CONT.
PCA AVAILABLE
NO 4 HR LIMIT
40 mg
0 mg
milligrams
TOTAL DELIVERED
CONT. RATE =
1 mg/hr

!! ALARM
INFUSER STOPPED
I CLOSE TUBING SLIDE CLAMP WHEN HANDLING VIAL
I PRESS START BUTTON TO RESUME
I UNLOCK DOOR TO CHANGE SETTINGS
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 Hospira 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** 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 Hospira 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 Hospira MedNet Software *(see the Hospira 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 Hospira 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 is displayed to inform the user that the LifeCare PCA infuser has an active connection to the wireless network.

The wireless icon is only displayed on the **WAITING FOR AUTO PROGRAM** screen.

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.
Programming Infusers with Hospira MedNet Software

**Note:** If the scanned medication does not exist in the Hospira MedNet™ Meds™ medication library, or if the custom drug is disabled in Biomed mode, an invalid bar code alarm will be activated

⚠️ **CAUTION: VERIFY PROGRAM VALUES.**

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

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**.
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.
Chapter 5
Programming Infusers without Hospira MedNet Software

This chapter describes how to program the LifeCare PCA infuser using the default drug library and a Hospira 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 \texttt{PREVIOUS} to return to the preceding display and enter the desired setting. Each time \texttt{PREVIOUS} is selected, the message display reverts to the previous setting, until the first setting is displayed.
Warnings and Precautions

**WARNING**
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.

- 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.

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

Upon initial startup, the self test begins. It may take several seconds for the Hospira logo to appear on the screen.

2. When the self test is complete, select SYSTEM SETTINGS> 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.

2. When the **WARNING!** screen appears, select **CONTINUE**.
3. 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.

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

5. 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 Hospira MedNet Software

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

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select **CONTINUE** to advance to the next screen.

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 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 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.

6. 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.

**Note:** The default drug library value range will display and will vary, depending on the concentration.
7. The **SELECT DELIVERY MODE** screen appears. Select **PCA ONLY** to continue.

8. 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]**.

9. Using the numeric keypad, enter a desired lockout interval value, then press **[ENTER]**.
10. 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.

11. 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.**

12. Verify loading dose value, then **CONFIRM >**.
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)*.
1. Power on the infuser. Upon initial startup, the self test begins.

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select **CONTINUE>** to advance to the next screen.

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.

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 [ENTER] to continue.

   **Note:** The default drug library value range will display and will vary, depending on the concentration.
7. The **SELECT DELIVERY MODE** screen appears. Select **PCA + CONT.** to continue (*see Modes of Delivery*).

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

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

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

11. 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.
12. 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.

13. Verify the loading dose value, then CONFIRM>.

14. Verify program values, 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. 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.

17. 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.
LifeCare PCA Infusion System

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.

   It may take several seconds for the Hospira logo to appear on the screen.

   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. Once the self test is complete, select **CONTINUE** to advance to the next screen.
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 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.
12. Verify program values, then select \texttt{CONFIRM>}.

\textbf{Note:} Select \texttt{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 \textbf{PRIME TUBING?} screen displays. For this example, \texttt{NO>} is selected.

\textbf{Note:} To prime the administration set on the infuser, see \textit{Chapter 2 Setup and Operation}.

\textbf{Note:} Open the slide clamp on the LifeCare PCA administration set prior to starting the therapy.

15. Select \texttt{NO>}. The \textbf{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 \textbf{Continuous} program.
Programming Infusers without Hospira MedNet Software

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 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 Hospira 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. It may take several seconds for the Hospira logo to appear on the screen.

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. Once the self test is complete, select **CONTINUE>** to advance to the next screen.

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.

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

**CAUTION:** Verify medication and concentration with physician order.

7. After verifying medication and concentration, select **CONFIRM**.
8. Set the loading dose (if desired) by selecting **YES**. If no loading dose is desired, select **NO** to proceed with programming.

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

   ![Diagram of loading dose input](image)

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

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

    ![Diagram of delivery mode selection](image)

    See **PCA**, **PCA + Continuous**, or **Continuous** only for programming instructions.
Chapter 6
Reviewing and Changing Rx
Supplemental Loading Dose

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](image)
   **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
4. 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 Hospira MedNet Software.

5. Press SAVE & EXIT> to advance to the confirmation screen.

⚠️ **CAUTION:** VERIFY PROGRAM VALUES.

6. Verify the program, then select CONFIRM> to accept the new program.
Reviewing and Changing Rx Supplemental Loading Dose

7. 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.

8. 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**
   CLOSE THE TUBING SLIDE CLAMP WHEN HANDLING THE VIAL.

2. Select **CHANGE RX** to advance to change desired program settings.
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 Hospira MedNet Software.
5. Press **SAVE & EXIT** to advance to the Confirmation screen.

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

**CAUTION: VERIFY PROGRAM VALUES.**
Reviewing and Changing Rx Supplemental Loading Dose

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

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

9. The DOOR LOCKED screen displays and the infuser indicates to press the [START] button to infuse the loading dose.

10. 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.
Chapter 7
Battery and Wireless Status
History and Event Log

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 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 Hospira MedNet Software, the data is stored both on the infuser and on the facility’s server.

For more information on reporting capabilities, see the *Hospira 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 HOUR-BY-HOUR 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 HOUR-BY-HOUR 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.

- HOUR-BY-HOUR 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 Hospira 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 HOUR-BY-HOUR 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 HOUR-BY-HOUR 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.

- **HOUR-BY-HOUR** 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 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).
**HOSPIRA 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:**

<table>
<thead>
<tr>
<th>DRUG</th>
<th>CONCENTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORPHINE PF</td>
<td>1 mg/mL</td>
</tr>
</tbody>
</table>

**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
04:50P CHECK VIAL ALARM
04:50P BAR CODE NOT READ ALARM
04:50P CHECK SYRINGE ALARM
04:50P CHECK VIAL ALARM
04:50P BAR CODE NOT READ ALARM
04:50P CHECK SETTINGS ALARM
04:50P CHECK VIAL ALARM
04:50P CHECK SYRINGE ALARM
04:50P CHECK VIAL ALARM
04:50P BAR CODE NOT READ ALARM
04:50P CHECK SETTINGS ALARM
04:50P CHECK VIAL ALARM
04:49P BAR CODE NOT READ ALARM
04:49P CHECK VIAL ALARM
04:49P CHECK SYRINGE ALARM
04:49P CHECK VIAL ALARM
04:49P BAR CODE NOT READ ALARM
04:49P CHECK SYRINGE ALARM
04:49P CHECK VIAL ALARM
04:49P BAR CODE NOT READ ALARM
04:49P CHECK VIAL ALARM
04:48P CHECK SETTINGS ALARM
04:48P CHECK VIAL 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
04:48P USING A/C
04:47P USING BATTERY
04:42P PCA END 3 mg
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
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 SYRING 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
Battery and Wireless Status History and Event Log

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 Hospira MedNet Software.

Note: See the Hospira 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 Hospira MedNet Software is enabled.
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.
Chapter 8
Maintenance

This chapter addresses the following:

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

Cleaning and Disinfection

Clean and disinfect the LifeCare PCA infuser 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 Hospira MAY RESULT IN PRODUCT DAMAGE. DO NOT USE COMPOUNDS CONTAINING COMBINATIONS OF ISOPROPYL ALCOHOL AND DIMETHYL BENZYL AMMONIUM CHLORIDE.

CAUTION: NEVER USE SHARP OBJECTS SUCH AS FINGERNAILS, PAPER CLIPS, OR NEEDLES TO CLEAN ANY PART OF THE INFUSER. 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>
<thead>
<tr>
<th>Class of Cleaning Solution</th>
<th>Manufacturer</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymatic Detergent</td>
<td>ASP Enzol™</td>
<td>Use per manufacturer's recommendations and instructions in this manual</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Table 8-2. Cleaning Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Cleaning Instrument</strong></td>
</tr>
<tr>
<td>Lint-Free Cloth</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Disposable Cleaning Wipe</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Table 8-2. Cleaning Methods

<table>
<thead>
<tr>
<th>Type of Cleaning Instrument</th>
<th>Method</th>
</tr>
</thead>
</table>
| Foam or Cotton-Tipped Swab           | 1. Wearing gloves, dip a swab in an approved cleaning solution.  
                                         2. Press the tip against the solution container to remove excess fluid.  
                                         3. Use the swab to clean hard to reach areas. Change swabs as needed.  
                                         4. Use a cloth dampened in the cleaning solution to remove any fiber residue left behind by the cotton swab.  
                                         5. Continue swabbing until all visible soil, organic dirt, or spilled fluid is completely removed. |
| Non-Abrasive Brush                    | 1. Wearing gloves, dampen the brush in the cleaning solution and gently brush seams and dried soil.  
                                         2. Use a cloth dampened in the cleaning solution or cleaning wipe to clean any residue left behind by the brush.  
                                         3. Continue brushing until all visible soil, organic dirt, or spilled fluid is completely removed. |

Follow these general instructions during cleaning and disinfection:

- Always wear gloves when using the cleaning solution.
- Use a spiral pattern when wiping, moving from the inner to outer edges to avoid recontaminating the areas you just cleaned.
- Do not allow cleaning fluid to run into the internal parts of the infuser.
Table 8-3 describes time intervals, in minutes, for cleaning.

<table>
<thead>
<tr>
<th>Enzol Wiping Time (min)</th>
<th>Enzol Brushing Time (min)</th>
<th>Enzol Swabbing Time (min)</th>
<th>Tap Water Rinsing Time (min)</th>
<th>Total Dry Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>10</td>
<td>1/surface</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

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

5. 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](image)

To clean the back of the infuser, proceed as follows:

1. Turn the infuser upright to view the back (see Figure 8-2).

2. Using lint-free cloths dampened in the approved cleaning solution or wipes, wipe the infuser handle and back surface.

3. 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.

4. 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
3. 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

4. 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.
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 contaminates 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.
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.
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 8-6. Injector Switch Pin Location

Figure 8-7. Injector Switch Pin with Accumulated Fluid Spillage
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.
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>
<thead>
<tr>
<th>Class of Disinfecting Solution</th>
<th>Manufacturer</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household Bleach</td>
<td>Clorox™ Germicidal Bleach (8.25% concentration)</td>
<td>Do not exceed 1 part bleach in 10 parts water</td>
</tr>
</tbody>
</table>

**Note:** At the time of publication, Hospira recommends only the disinfecting solution in *Table 8-4.* For updated listings of approved cleaners, visit [www.hospiraparts.com](http://www.hospiraparts.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

<table>
<thead>
<tr>
<th>Type of Disinfection Instrument</th>
<th>Method</th>
</tr>
</thead>
</table>
| **Lint-Free Cloth**             | 1. Wearing gloves, dampen the cloth with the approved disinfecting solution ([see Table 8-4](#)) and wipe in an outward spiral pattern on the desired surfaces.  
2. When the cloth becomes soiled, start wiping with the unsoiled part of the cloth. Replace the cloth as needed. |
| **Disposable Disinfectant Wipe** | 1. Wearing gloves, unfold the wipe completely, and use in an outward spiral pattern on the desired surfaces.  
2. When the disinfectant wipe becomes soiled, start wiping with the unsoiled part of the disinfectant wipe. Replace the wipe as needed. |
## Table 8-5. Disinfection Methods

<table>
<thead>
<tr>
<th>Type of Disinfection Instrument</th>
<th>Method</th>
</tr>
</thead>
</table>
| Foam or Cotton-Tipped Swab      | 1. Wearing gloves, dip a swab in the approved disinfecting solution *(see Table 8-4)*.  
2. Press the tip against the solution container to remove excess fluid.  
3. Use the swab to clean hard to reach areas. Change swabs as needed.  
4. Dampen a lint-free cloth with the approved disinfecting solution to remove any fiber residue left behind by the cotton swab. |
| Non-Abrasive Brush              | 1. Wearing gloves, dampen the brush in the disinfecting solution and gently brush seams and dried soil.  
2. Use a cloth dampened in the disinfecting solution or cleaning wipe to clean any residue left behind by the brush. |

Follow these general instructions during disinfection:

- Always wear gloves when using the disinfecting solution.
- Do not allow disinfecting fluid to run into the internal parts of the infuser.
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.

### Table 8-6. Minimum Time Intervals for Disinfecting

<table>
<thead>
<tr>
<th>Method</th>
<th>Time Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brushing/swabbing (hard to reach areas)</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Wiping</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Rinsing with purified water (PURW)</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>
| Brushing/swabbing, wiping, and rinsing | per infuser. Apply disinfectant as often as needed to keep surfaces visually moist/wet during disinfection.
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.
Maintenance

Cleaning Spills

The following procedure describes how to clean non-hazardous spills or soil 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.

1. 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 (see Table 8-1) on a clean, lint-free cloth.

2. 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 that have already been 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 to another.
   - Do not allow cleaning fluid to run into internal parts of the infuser.
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.

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.
Maintenance

- 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 Hospira 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 battery’s service life, dispose of the battery by following your facility’s disposal policy for lithium 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
Chapter 9
Specifications

This system operating manual complies with 21 CFR 807.87(e), 21 CFR Part 801, and 21 CFR 801.109.

Administration Sets: Use only compatible Hospira LifeCare PCA administration sets with Integral Pressure Activated Valves

Atmospheric Pressure: 0 - 9,840 feet (0 - 3,000 meters) or equivalent pressure

Battery: One sealed lead acid; 8 V; rechargeable; internal to the device Accessible for ease of field replacement with color-coded leads and polarized connector

Battery Life: 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 DEAD BATTERY 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>
<thead>
<tr>
<th>Mode</th>
<th>Delivery Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCA</td>
<td>Approximately 1 mL in 35 seconds</td>
</tr>
<tr>
<td>CONTINUOUS</td>
<td>Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr)</td>
</tr>
<tr>
<td>PCA + CONT.</td>
<td>Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr) + PCA dose (mg)</td>
</tr>
</tbody>
</table>
### Electrical Safety: Meets IEC 60601-1 standard

<table>
<thead>
<tr>
<th>Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>AC (mains) supply equipment using protective earth</td>
</tr>
<tr>
<td>Type BF</td>
<td>Type BF applied parts are those parts suitable for direct patient connections</td>
</tr>
<tr>
<td></td>
<td>Type BF parts are not suitable for direct cardiac application</td>
</tr>
<tr>
<td>Type CF</td>
<td>Type CF applied parts complying with the higher degree of protection against electric shock</td>
</tr>
<tr>
<td></td>
<td>Type CF Applied Parts are those parts suitable for direct cardiac application</td>
</tr>
<tr>
<td>IPX2</td>
<td>The case is disinfectable and protected against vertically falling water drops</td>
</tr>
<tr>
<td>Electromagnetic Interference (EMI) and Radio Frequency Interference (RFI)</td>
<td>The LifeCare PCA infuser is designed to perform in the typical hospital environment</td>
</tr>
<tr>
<td></td>
<td>The LifeCare PCA infuser has been tested to comply with IEC 60601-1-2:2007</td>
</tr>
<tr>
<td></td>
<td>A qualified service technician should verify performance in any environment where EMI or RFI levels are excessive</td>
</tr>
</tbody>
</table>
Specifications

**Electrical**

- **Leakage:** Risk current limits meets standard IEC 60601-1

**Fuse:**

- 1.6 A, 250 V; Slo-Blo

**Lockout Interval Range:**

- 5 to 120 minutes in 1-minute increments

**Maximum Infusion Pressure:**

- 45 psi

**Maximum Overinfusion:**

- The maximum overinfusion under single fault conditions is 25%

**Occlusion Alarm Pressure:**

- 12.5 psi +2.5/-3.5 psi

**Occlusion Bolus Volume:**

- 1 mL for fully primed set (max.)

**Operating Temperature:**

- 41° to 104° F (5° to 40° C);
- 10% to 90% relative humidity

**Patient Pendant:**

- 6 feet ± 6 inches (66 - 78 inches);
- with blue handle

**Power Cord:**

- Hospital-grade AC cord; 10 feet;
- with transparent plug and retainer plate

**Power Requirements:**

- 120 V; 60 Hz; 50 VA max.

**Ethernet Port:**

- Connection to IEC 60601-1
- or IEC 60950 equipment

**Nurse Call:**

- 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

Device Name: Hospira MedNet 802.11 a/b/g Wireless Module

Standards: IEEE 802.11 a/b/g

Transmit Power: 802.11 b/g - 17 dBm
               802.11 a - 16 dBm

Antenna: Integrated surface mount antenna

Certifications: 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

Table 9-3. Stored Occlusion Volume

<table>
<thead>
<tr>
<th>Delivery Rate</th>
<th>Pressure Limit (Average)</th>
<th>Stored Volume (Average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mL/hr</td>
<td>11.4 psi</td>
<td>0.77 mL</td>
</tr>
<tr>
<td>5 mL/hr</td>
<td>11.6 psi</td>
<td>0.81 mL</td>
</tr>
<tr>
<td>20 mL/hr</td>
<td>11.6 psi</td>
<td>0.80 mL</td>
</tr>
<tr>
<td>PCA Dose (100 mL/hr)</td>
<td>11.4 psi</td>
<td>0.78 mL</td>
</tr>
</tbody>
</table>

Time from Occlusion to Alarm

Table 9-4. Time from Occlusion to Alarm

<table>
<thead>
<tr>
<th>Delivery Rate</th>
<th>Pressure Limit (Average)</th>
<th>Time to Occlude (Average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mL/hr</td>
<td>11.4 psi</td>
<td>10 hours</td>
</tr>
<tr>
<td>5 mL/hr</td>
<td>11.6 psi</td>
<td>10 minutes</td>
</tr>
<tr>
<td>20 mL/hr</td>
<td>11.6 psi</td>
<td>2 minutes, 30 seconds</td>
</tr>
<tr>
<td>PCA Dose (100 mL/hr)</td>
<td>11.4 psi</td>
<td>40 seconds</td>
</tr>
</tbody>
</table>
Specifications

Delivery Rate Accuracy

Delivery accuracy is ± 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 ± 15% from 0.5 to 1.0 mL/hr and ± 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

0.1 mL/hr, 0 mmHg DELIVERY HEAD, START UP
(Typical)

0.1 mL/hr, 0 mmHg DELIVERY HEAD
(Typical)

0.1 mL/hr, 0 mmHg DELIVERY HEAD
(Composite of 36 Pumps)
Specifications

0.5 mL/hr, 0 mmHg DELIVERY HEAD, START UP
(Typical)

[Graph showing flow rate vs. time for actual and programmed rates]

0.5 mL/hr, 0 mmHg DELIVERY HEAD
(Typical)

[Graph showing percent error vs. observation interval]

0.5 mL/hr, 0 mmHg DELIVERY HEAD
(Composite of 36 Pumps)

[Graph showing percent error vs. observation interval]
Specifications

5.0 mL/hr, 0 mmHg DELIVERY HEAD, START UP
(Typical)

Flow Rate (mL/hr) vs. Time (minutes)

- Actual Rate
- Programmed Rate

5.0 mL/hr, 0 mmHg DELIVERY HEAD
(Typical)

Percent Error (%) vs. Observation Interval (minutes)

- Maximum (%)
- Minimum (%)
- Mean (%)

5.0 mL/hr, 0 mmHg DELIVERY HEAD
(Composite of 36 Pumps)

Percent Error (%) vs. Observation Interval (minutes)

- Maximum (%)
- Minimum (%)
- Mean (%)

9-14 System Operating Manual
Figure 9-2. Trumpet Curves
## Specifications

### Table 9-5. Bolus Delivery Accuracy

<table>
<thead>
<tr>
<th>Set Value (Bolus Volume in mL)</th>
<th>Calculated % Average Deviation from Set Value</th>
<th>Maximum % Positive Deviation from Set Value</th>
<th>Maximum % Negative Deviation from Set Value</th>
<th>Administration Set Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum: 0.1 mL</td>
<td>3.176%</td>
<td>10.4%</td>
<td>-8.3%</td>
<td>List Number 14277</td>
</tr>
<tr>
<td>Maximum: 5 mL</td>
<td>-0.545%</td>
<td>0.1%</td>
<td>-1.3%</td>
<td>List Number 14279</td>
</tr>
</tbody>
</table>
Chapter 10
Protocols

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 Hospira pre-filled drug vials and pharmacy-filled (custom) vials.

Only protocols associated with the inserted drug vial will be available.

Hospira MedNet Software Infusers

Hospira MedNet Software allows for protocol programming from the Hospira 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 Hospira 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.

   It may take several seconds for the Hospira logo to appear on the screen.

2. Once the self test is complete, select \textit{CONTINUE>} to advance to the next screen.
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.
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.

The TOTALS CLEARED screen displays briefly, then transitions to the SET LOADING DOSE screen.

6. Select NO> to continue.

If a loading dose is desired, see *Chapter 4 Programming Infusers with Hospira MedNet Software* and *Chapter 5 Programming Infusers without Hospira MedNet Software*. 

---

**CAUTION: VERIFY MEDICATION AND CONCENTRATION WITH PHYSICIAN ORDER.**
7. 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.

8. 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.**

9. Verify the chosen protocol settings, then select **CONFIRM**, or select **PREVIOUS** to return to the preceding screen.

10. Close and lock the door. Place the key in a secure location.
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 Hospira MedNet**

Protocols are created in Biomed mode for Hospira pre-filled drug vials and pharmacy-filled (custom) vials, for infusers without Hospira 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 Hospira 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.

   It may take several seconds for the Hospira logo to appear on the screen.

2. Once the self test is complete, select CONTINUE> to advance to the next screen.
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.

   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.

   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 Hospira MedNet Software* and *Chapter 5 Programming Infusers without Hospira 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.

8. Verify the chosen protocol settings, then select CONFIRM>, or select PREVIOUS> to return to the preceding screen.

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

10. 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).

11. The Door Locked screen displays and the infuser indicates to press the [START] button to infuse. Press [START/STOP] to deliver protocol.
Chapter 11
Information for Legacy LifeCare PCA Infusers Upgraded with 7.x Software

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.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Instead of...</th>
<th>See this section for information applicable to an upgraded infuser...</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1 Compliance</td>
<td>Back cover</td>
<td>IEC 60601-1 Compliance</td>
</tr>
<tr>
<td>IEC 60601-1-2 Compliance</td>
<td>Electrical Artifacts and Table 9-2</td>
<td>IEC 60601-1-2 Compliance</td>
</tr>
<tr>
<td>Fluid Ingress Protection Rating</td>
<td>Table 9-2 and Back cover</td>
<td>Fluid Ingress Protection Rating</td>
</tr>
<tr>
<td>Specifications (including Stored Occlusion Volume and Time from Occlusion to Alarm)</td>
<td>Chapter 9 Specifications, including Table 9-3 and Table 9-4</td>
<td>Specifications (including subsections)</td>
</tr>
<tr>
<td>CSA Mark</td>
<td>Back cover</td>
<td>CSA Mark</td>
</tr>
</tbody>
</table>
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

IEC 60601-1-2 Compliance


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:

<table>
<thead>
<tr>
<th>Electromagnetic Interference (EMI) and Radio Frequency Interference (RFI)</th>
<th>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</th>
</tr>
</thead>
</table>

Fluid Ingress Protection Rating

Instead of the rating of IPX2, the rating of IPX1 applies.

Replace the reference in *Table 9-2* with:

<table>
<thead>
<tr>
<th>IPX1</th>
<th>The case is disinfectable and protected against dripping water</th>
</tr>
</thead>
</table>
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.

**Fuse:**
Fuse, 0.5 A, 250 V, Slo-Blo

**Occlusion Alarm Pressure:**
15 psi +/- 5 psi

**Occlusion Bolus Volume:**
2 mL for fully primed set (max.)

Stored Occlusion Volume

Instead of the information in *Table 9-3*, the following information applies:

<table>
<thead>
<tr>
<th>Delivery Rate</th>
<th>Pressure Limit (Average)</th>
<th>Stored Volume (Average)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mL/hr</td>
<td>13.7 psig</td>
<td>1.34 mL</td>
</tr>
<tr>
<td>5 mL/hr</td>
<td>13.7 psig</td>
<td>1.37 mL</td>
</tr>
<tr>
<td>20 mL/hr</td>
<td>13.8 psig</td>
<td>1.36 mL</td>
</tr>
<tr>
<td>PCA Dose (100 mL/hr)</td>
<td>13.7 psig</td>
<td>1.31 mL</td>
</tr>
</tbody>
</table>
Time from Occlusion to Alarm

Instead of the information in Table 9-4, the following information applies:

<table>
<thead>
<tr>
<th>Delivery Rate</th>
<th>Pressure Limit (Average)</th>
<th>Time to Occlude (Average, hh:mm:ss)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mL/hr</td>
<td>13.7 psig</td>
<td>15:04:59</td>
</tr>
<tr>
<td>5 mL/hr</td>
<td>13.7 psig</td>
<td>0:16:57</td>
</tr>
<tr>
<td>20 mL/hr</td>
<td>13.8 psig</td>
<td>0:04:07</td>
</tr>
<tr>
<td>PCA Dose (100 mL/hr)</td>
<td>13.7 psig</td>
<td>0:00:56</td>
</tr>
</tbody>
</table>

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.
Appendix A
Generating Bar Code Labels
(Hospira MedNet Software Enabled)

Hospira 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.
Generating Bar Code Labels

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.

![Label Diagram](image)

*Figure A-1. Pharmacy-Generated Bar Code Label*
Generating Bar Code Labels

Validation of the Pharmacy-Generated Bar Code

The label diagram shown in Figure A-1 represents Hospira’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 “Yellow Cap for use with Hospira PCA Vial”.

5. Label the vial according to facility protocol. Do not obscure graduations or bar code.

6. Adhere to storage requirements of added medications.
Appendix B
Administration Sets and Accessories

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, contact a Hospira sales representative, or visit the website:

www.hospira.com/products_and_services/index

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.
<table>
<thead>
<tr>
<th>List Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14277</td>
<td>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</td>
</tr>
<tr>
<td>14278</td>
<td>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</td>
</tr>
<tr>
<td>14279</td>
<td>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</td>
</tr>
<tr>
<td>14280</td>
<td>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</td>
</tr>
</tbody>
</table>
Accessories

The accessories described in *Table B-2* are available for use with the LifeCare PCA infuser.

<table>
<thead>
<tr>
<th>List Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04831</td>
<td>Injector</td>
</tr>
<tr>
<td>06021</td>
<td>Sterile empty vial and injector</td>
</tr>
<tr>
<td>19361</td>
<td>Yellow cap for use with vial</td>
</tr>
<tr>
<td>39001-21</td>
<td>Heavy duty IV pole with 6 locking casters</td>
</tr>
<tr>
<td>39009-01</td>
<td>Locking casters for IV stand</td>
</tr>
</tbody>
</table>
Appendix C  
Troubleshooting

The LifeCare PCA infuser is programmed to display status and alarm messages and to sound an audible tone for alarm conditions. These messages and alarm conditions are described in the following sections.

- Infuser Alarm System
- Occlusion Alarm
- Network Connectivity
- Status Messages
- Alarms and 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.

There are different indicators for high, medium, and low priority alarms, as described in Table C-1.
Troubleshooting

Table C-1. Alarm Priority Levels

<table>
<thead>
<tr>
<th>Alarm Priority</th>
<th>Visual Indicator Display</th>
<th>Visual Indicator Backlight</th>
<th>Audible Indicator Number of Beeps</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>!!! + Message</td>
<td>Flashing rapidly between High and Normal intensity</td>
<td>10</td>
</tr>
<tr>
<td>Medium</td>
<td>!! + Message</td>
<td>Flashing slowly between High and Normal intensity</td>
<td>3</td>
</tr>
<tr>
<td>Low</td>
<td>! + Message</td>
<td>Normal intensity for 30 seconds (no flashing)</td>
<td>2*</td>
</tr>
</tbody>
</table>

*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
ENSURE THAT THE ALARM VOLUME LEVEL IS APPROPRIATE FOR THE CURRENT PATIENT AND BACKGROUND NOISE LEVEL BEFORE USE ON THE PATIENT.

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 and require the user to press **CONTINUE>.**
   - 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.
Troubleshooting

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 Hospira 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.
Displayed status messages are defined in *Table C-2*.

### Table C-2. Status Messages

<table>
<thead>
<tr>
<th>Message Displayed on the Screen</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4 HR LIMIT REACHED</strong></td>
<td>Message displayed if a dose limit has been programmed and has been reached. 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.</td>
</tr>
<tr>
<td><strong>CONTINUOUS</strong></td>
<td>Message displayed when infuser is in CONTINUOUS mode.</td>
</tr>
<tr>
<td><strong>DOOR LOCKED</strong></td>
<td>Message indicates the security door is closed and locked. Message displays for 30 seconds and disappears.</td>
</tr>
<tr>
<td><strong>INFUSER STOPPED</strong></td>
<td>Message displayed when infuser is stopped.</td>
</tr>
<tr>
<td><strong>PCA + CONT.</strong></td>
<td>Message displayed when infuser is in PCA + CONTINUOUS mode.</td>
</tr>
<tr>
<td><strong>PCA AVAILABLE</strong></td>
<td>Message indicates patient can initiate a dose in PCA ONLY or PCA + CONTINUOUS mode.</td>
</tr>
<tr>
<td><strong>PCA LOCKOUT</strong></td>
<td>Message appears only in the PCA ONLY or PCA + CONTINUOUS mode. Message remains until the lockout interval elapses and is displayed after a successful patient-originated dose delivery.</td>
</tr>
<tr>
<td><strong>PCA ONLY</strong></td>
<td>Message displayed when the infuser is in PCA ONLY mode.</td>
</tr>
</tbody>
</table>

**WARNING**

CLOSE THE TUBING SLIDE CLAMP WHEN HANDLING THE VIAL.
Alarms and Messages

*Table C-3* lists high priority infuser alarms that can be cleared by the operator taking appropriate action.

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEAD BATTERY</td>
<td>DEAD BATTERY</td>
<td>None</td>
<td>A discharged battery is detected and the infuser is operating on battery power</td>
<td>Plug the infuser into AC power outlet</td>
</tr>
<tr>
<td></td>
<td>PLUG INFUSER INTO POWER OUTLET</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
<td><strong>Note:</strong> The DEAD BATTERY alarm will activate at least 3 minutes prior to shutting down due to a dead battery.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>BATTERY MAY BE DAMAGED</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### HIGH PRIORITY ALARMS

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHECK SYRINGE</td>
<td>CHECK SYRINGE</td>
<td>Initial 30 second mute period</td>
<td>The syringe (vial and injector) is not detected to be properly loaded</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>CLOSE TUBING SLIDE CLAMP IMMEDIATE</td>
<td>if door is unlocked</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>CHECK SYRINGE PLACEMENT</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Troubleshooting

**Table C-3. Alarms and Messages**

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHECK VIAL</td>
<td>CHECK VIAL CLOSE TUBING SLIDE CLAMP IMMEDIATELY CHECK VIAL PLACEMENT</td>
<td>Initial 30 second mute period if door is unlocked</td>
<td>An Injector is detected and no vial is detected as properly loaded</td>
<td>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.</td>
</tr>
<tr>
<td>CHECK INJECTOR</td>
<td>CLOSE TUBING SLIDE CLAMP IMMEDIATELY CHECK INJECTOR OR PLACEMENT</td>
<td>Initial 30 second mute period if door is unlocked</td>
<td>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</td>
<td>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.</td>
</tr>
</tbody>
</table>
An occlusion is detected during infusion or during the infuser prime sequence.

**Corrective Action:**
- 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

**CAUTION:** IF THE CRADLE RELEASE MECHANISM IS NOT RELEASED, AN UNINTENTIONAL BOLUS OF UP TO 1 ML MAY OCCUR.

**EMPTY SYRINGE**
- The syringe is detected to be empty

**Corrective Action:**
- Replace the syringe, or if therapy is discontinued, remove and discard the syringe then turn off the infuser
### Troubleshooting

**Table C-3. Alarms and Messages**

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>BATTERY FAULT</td>
<td>BATTERY FAILURE</td>
<td>2 minutes</td>
<td>The battery may be defective or the battery is not properly connected</td>
<td>Send the infuser to the Biomed for servicing or press [AUDIO PAUSE] to silence the alarm and proceed with programming</td>
</tr>
<tr>
<td></td>
<td>SHORT DETECTED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>OVER DISCHARGED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NO BATTERY DETECTED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SEND PUMP TO BIOMED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHARGER FAULT</td>
<td>BATTERY CHARGER FAILURE</td>
<td>2 minutes</td>
<td>The battery charger is defective</td>
<td>Requires service</td>
</tr>
<tr>
<td></td>
<td>SEND PUMP TO BIOMED</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** The infuser will automatically power off if disconnected from AC power. Check battery connection. Replace battery. Requires service.

- Requires service
Table C-4 lists medium priority infuser alarms that can be cleared by the operator taking appropriate action.

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAR CODE NOT READ</td>
<td>BAR CODE NOT READ&lt;br&gt;ROTATE OR&lt;br&gt;RAISE VIAL&lt;br&gt;CLEAN WINDOW OR&lt;br&gt;REPLACE VIAL&lt;br&gt;REMOVE VIAL AND REINSERT OR REPLACE VIAL</td>
<td>1 minute</td>
<td>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</td>
<td>Slowly rotate the vial and position it with the bar code on the right until the bar code has been read&lt;br&gt;Remove the vial and reinsert the vial into the middle black bracket, ensuring that the bar code label faces the bar code reader&lt;br&gt;Clean the bar code reader window</td>
</tr>
</tbody>
</table>
## Table C-4. Alarms and Messages

### MEDIUM PRIORITY ALARMS

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| INVALID BAR CODE   | INVALID BAR CODE
CUSTOM VIAL
USE DISABLED
SEND PUMP TO BIOMED | 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 |
| INVALID BAR CODE   | INVALID BAR CODE
MED NOT IN LIBRARY
VERIFY DRUG IF CORRECT DRUG, SEND PUMP TO BIOMED |
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>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| CHECK SETTINGS   | CHECK SETTINGS  
OPEN THE DOOR  
COMPLETE OR CORRECT PUMP SETTINGS                                                                | 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                                                  |
| CHECK SETTINGS   | LOADING DOSE NOT COMPLETED  
PRIMING NOT COMPLETED  
PRESS ANY KEY TO CONTINUE                                                                  | None        | The door is locked and no key has been pressed for 30 seconds                  | Press any key, then complete the operation                                          |
## Troubleshooting

### Table C-4. Alarms and Messages

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPEN DOOR</td>
<td>DOOR OPEN CLOSE TUBING SLIDE CLAMP WHEN HANDLING VIAL CLOSE AND LOCK DOOR</td>
<td>None</td>
<td>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</td>
<td>Close and lock the door</td>
</tr>
</tbody>
</table>
### Table C-4. Alarms and Messages

#### MEDIUM PRIORITY ALARMS

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
</table>
| INFUSER STOPPED| INFUSER STOPPED  
CLOSE TUBING  
SLIDE CLAMP  
WHEN HANDLING  
VIAL  
PRESS START  
BUTTON TO RESUME  
UNLOCK DOOR  
TO CHANGE SETTINGS | 2 minutes   | Infusion paused for more than 2 minutes                                                  | Press [START/STOP] to resume infusion                                               |
| PENDANT FAULT  | CHECK PENDANT  
INSERT OR REPLACE PENDANT TO CLEAR ALARM  
SEND PUMP TO BIOMED | 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                  |

Note: Pendant refers to the patient button.
Troubleshooting

Table C-5 lists low priority infuser alarms that can be cleared by the operator taking appropriate action.

<table>
<thead>
<tr>
<th>Alarm Name</th>
<th>Message Displayed on the Screen</th>
<th>Muting Time</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOW BATTERY</td>
<td>LOW BATTERY PLUG INFUSER INTO POWER OUTLET</td>
<td>10 minutes</td>
<td>Battery life has less than thirty minutes remaining and the infuser is currently operating on battery power</td>
<td>Connect to AC power. Failure to connect to AC power may cause battery damage</td>
</tr>
<tr>
<td>CHECK PRINTER</td>
<td>CHECK PRINTER VERIFY PRINTER IS POWERED ON, ATTACHED AND ON LINE REQUEST HISTORY PRINT AGAIN</td>
<td>None</td>
<td>A history print has been requested and the printer is not attached or is off line</td>
<td>Ensure the printer is powered on and connected to the infuser</td>
</tr>
</tbody>
</table>
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 Hospira MedNet.

*Table D-1* lists the LifeCare PCA default drug library.

<table>
<thead>
<tr>
<th>Medication (Pre-Filled Vials)</th>
<th>Dosing Units</th>
<th>Default Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulfate PF</td>
<td>mg/hr</td>
<td>1 mg/mL</td>
</tr>
<tr>
<td>Morphine Sulfate PF</td>
<td>mg/hr</td>
<td>5 mg/mL</td>
</tr>
<tr>
<td>Meperidine HCl</td>
<td>mg/hr</td>
<td>10 mg/mL</td>
</tr>
<tr>
<td>Sterile Empty Vial (Pharmacy-Filled Vial)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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.
## Table D-2. Prescription Delivery Limit Ranges

<table>
<thead>
<tr>
<th>Drug</th>
<th>Conc. (C) Range (units/mL)</th>
<th>Loading Dose</th>
<th>PCA Dose min-max</th>
<th>Cont. Rate (units/hr) min-max</th>
<th>1 hr Limit min-max</th>
<th>4 hr Limit min-max</th>
<th>6 hr Limit min-max</th>
<th>12 hr Limit min-max</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg units</td>
<td>0.1-10</td>
<td>[0.1-10] x C</td>
<td>[0.1-5] x C</td>
<td>[0.1-20] x C</td>
<td>[0.1-20] x C</td>
<td>[0.1-80] x C</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>mcg units</td>
<td>1-100</td>
<td>[0.1-10] x C</td>
<td>[0.1-5] x C</td>
<td>[0.1-20] x C</td>
<td>[0.1-20] x C</td>
<td>[0.1-80] x C</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Conc. (mg/mL)</th>
<th>Loading Dose (mg)</th>
<th>PCA Dose (mg) min-max</th>
<th>Cont. Rate (mg) min-max</th>
<th>1 hr Limit (mg) min-max</th>
<th>4 hr Limit (mg) min-max</th>
<th>6 hr Limit (mg) min-max</th>
<th>12 hr Limit (mg) min-max</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.1-10</td>
<td>0.1-5</td>
<td>0.1-20</td>
<td>0.1-20</td>
<td>0.1-80</td>
<td>0.1-120</td>
<td>0.1-240</td>
</tr>
<tr>
<td>5</td>
<td>0.5-50</td>
<td>0.5-25</td>
<td>0.5-100</td>
<td>0.5-100</td>
<td>0.5-600</td>
<td>0.5-999.9¹</td>
<td>0.5-999.9¹</td>
</tr>
<tr>
<td>10</td>
<td>1-100</td>
<td>1-50</td>
<td>1-200</td>
<td>1-200</td>
<td>1-800</td>
<td>1-999.9¹</td>
<td>1-999.9¹</td>
</tr>
</tbody>
</table>

**Notes:**
- ¹Infuser 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
Appendix E
Network Printer Setup

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. Connect 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).

   ![Connectivity Configuration](image)

   **Figure E-1. Connectivity Configuration for Directly Connected Printer**
   - IP address: 192.168.0.222 (arbitrary)
   - Subnet mask: 255.255.0.0 (required)
   - Port: 9100 (must be between 9000 to 9999)

2. Test the printer configuration.

3. Connect the Ethernet network cable from the network printer to the computer, then connect the infuser to AC power.
4. Configure the infuser connectivity engine settings so that the printer IP address and printer port settings match the values in Step 1.
   - 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**

**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 Setup

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).
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)
3. 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. Hospira MedNet Server Suite 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](image)
8. 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.

![Tera Term Options for a New Connection](image)

*Figure E-7. Tera Term Options for a New Connection*

9. [Optional] Select the option to capture the terminal output to a log file, if desired *(see Figure E-8)*.

![Tera Term Log Option](image)

*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.
# Appendix F
## Glossary

This appendix lists definitions of general and clinical terms and acronyms used in this manual.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
</table>
| **Accuracy**             | The degree to which the instrument is capable of delivering the volume of analgesic drug that is displayed or targeted to be delivered  
                           | Accuracy shall be specified as the maximum allowable delivery error from a targeted or displayed value                                             |
| **Autoprogramming**      | Complete or partial program received from a bar code enabled Point-of-Care System requiring clinician confirmation prior to administration                                                                 |
| **Battery Fault**        | A battery that will not accept a full charge                                                                                                                                                             |
| **Bolus**                | A fixed amount of drug delivered in a short amount of time  
                           | A PCA dose                                                                                                                                                                                               |
| **Button**               | A hard key on the front panel or the patient pendant                                                                                                                                                     |
| **Clinical Care Area**   | An area of the hospital that authorized hospital staff is permitted to use specific drugs  
                           | The clinician selects a CCA after turning on the infuser  
                           | The hospital may create from one to eighteen CCAs                                                                                               |
### Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connectivity Engine (CE)</td>
<td>A component of the infuser that controls Ethernet and wireless communication between the network server and infuser</td>
</tr>
<tr>
<td>Continuous</td>
<td>Infusion program characterized by a constant, fixed-rate dose</td>
</tr>
<tr>
<td>Custom Syringe or Vial</td>
<td>A bar coded Hospira sterile empty vial that is custom-filled by a pharmacy</td>
</tr>
<tr>
<td>Default Drug Library (DDL)</td>
<td>A pre-programmed drug library embedded in the infuser software</td>
</tr>
<tr>
<td></td>
<td>An infuser with Hospira MedNet Software uses the DDL until a user-defined drug library is installed and supersedes the DDL</td>
</tr>
<tr>
<td>Dose Limit</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> 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.</td>
</tr>
<tr>
<td>Drug Library Download (Hospira MedNet only)</td>
<td>The process of moving the user-defined drug library from the network server to the infuser.</td>
</tr>
<tr>
<td>Drug Library Installation (Hospira MedNet only)</td>
<td>The process of moving the user-defined drug library from the CE to the infuser.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>History/Battery</td>
<td>The History function displays Rx Settings, PCA Summary, and the Event Log. The Battery function accesses the Battery Charge indicator and the Wireless Strength indicator</td>
</tr>
<tr>
<td>Hospira MedNet Software</td>
<td>Network based application software used to upload event logs and download the user-defined drug library to the infuser</td>
</tr>
<tr>
<td>Infusing</td>
<td>The infuser is on and a delivery screen is displayed. The infusing mechanism may or may not be actually infusing at any given time</td>
</tr>
<tr>
<td>LCD</td>
<td>Liquid Crystal Display</td>
</tr>
<tr>
<td>LED</td>
<td>Light Emitting Diode</td>
</tr>
<tr>
<td>LifeCare PCA Set</td>
<td>Tubing connecting the PCA vial to the patient</td>
</tr>
<tr>
<td>Loading Dose</td>
<td>An optional dose programmed during setup before entering the program. The loading dose can be administered at any time by the clinician during the programmed therapy</td>
</tr>
<tr>
<td>Lockout Interval</td>
<td>A programmed time interval specifying the minimum time that must pass after a loading dose or PCA dose (bolus) is administered. This time interval specifies when the next PCA dose can begin infusing. Bolus requests made during the lockout interval are denied</td>
</tr>
</tbody>
</table>
### Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muting Period</td>
<td>The period between the silencing of an alarm by pressing the <strong>[AUDIIO PAUSE]</strong> key and the resumption of the alarm</td>
</tr>
<tr>
<td>Occlusion</td>
<td>A blockage in the administration set that prevents the infuser from pumping fluid into the patient</td>
</tr>
<tr>
<td></td>
<td>Possible causes of occlusions are kinked or plugged non-patent IV tubing</td>
</tr>
<tr>
<td>Occlusion Pressure</td>
<td>The maximum pressure produced as a result of an occlusion in the administration set</td>
</tr>
<tr>
<td>Patient Pendant</td>
<td>A hand held pendant connected to the infuser that allows the patient to request a PCA dose (bolus) by pressing a button</td>
</tr>
<tr>
<td>PCA Mode</td>
<td>Infusion therapy characterized by bolus doses administered on patient demand subject to a lockout interval and, optionally, a dose limit</td>
</tr>
<tr>
<td>PCA Vial</td>
<td>Vial compatible with the infuser that is either prefilled with drug by Hospira (standard vial) or filled by the hospital pharmacy (custom vial)</td>
</tr>
<tr>
<td>Prime</td>
<td>Removing air from the syringe and administration set</td>
</tr>
<tr>
<td>Rule Set (Hospira MedNet only)</td>
<td>A list of upper, lower, soft, and/or hard limits for delivery parameters</td>
</tr>
<tr>
<td></td>
<td>Rule sets reside in the user-defined drug library and are associated with a specific vial within a CCA</td>
</tr>
</tbody>
</table>
## Term | Definition
--- | ---
Rx Settings | The current programmed therapy
Includes PCA Dose, PCA Lockout Interval, Continuous Rate, Loading Dose, and Dose Limit amount

Softkeys | The five keys to the right of the device’s display
Each key’s function is dependent on the screen displayed data

Stored Protocols | Frequently used therapy settings stored in the infuser’s memory
Stored protocols can be recalled again, making it unnecessary for the operator to program the same therapy settings each time they are needed
Stored protocols are determined by the health care facility

Standard Syringe | A prefilled bar coded drug vial in which the infuser identifies the drug and concentration
The drug and concentration are found in the drug library by using the bar code on the vial
Standard syringes are also known as prefilled drug vials

User-Defined Drug Library (Hospira MedNet only) | A drug library that contains hospital-defined clinical care areas (CCAs) and rule sets created with Hospira MedNet Software

Warning | An indication to advise the clinician of a possible dangerous condition
Appendix G
Warranty

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

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

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.
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 Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, “major repair or other service” means any repair or service other than the replacement of accessory items such as batteries and detachable mains power cords.

In providing any parts for repair or service of the product, Hospira shall have no responsibility or liability for the actions or inactions of the person performing such repair or service, regardless of whether such person has been trained to perform such repair or service. It is understood and acknowledged that any person other than an Hospira representative performing repair or service is not an authorized agent of Hospira.
Contact Information

For customer service within the United States, contact:

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

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

1-800-241-4002

For additional services and technical training courses, visit the website:

www.hospira.com

For technical assistance and services outside the United States, contact the local Hospira sales office.
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
- Mains supply equipment using protective earth

Warning
- Protection against vertically falling water drops

Class I

IPX2

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.
Indicates that Federal (USA) law restricts this device to sale by or on the order of a physician or other license.

The patient pendant handle and button are applied parts for the LifeCare PCA infuser. The patient pendant handle and button are Type CF 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.

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.