

# **System Operating Manual**



**For Use With List 20709-04**



**430-04685-005 (Rev. 06/2007)**

## **Section 1**

## **Descriptive Information**

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The latest patient controlled analgesia (PCA) offered by Hospira, LifeCare PCA® Infusion System with Hospira MedNet® Software, allows clinicians to administer, or patients to self-administer analgesia, safely and effectively within clinician programmed limits and/or hospital-defined medication limits.

The LifeCare PCA® Infusion System is used in a wide range of clinical settings that includes but is not limited to the following:

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

## **Product Description**

The primary drug safety features of the LifeCare PCA® Infuser device are the Hospira MedNet® Software and the bar code reader that are designed to enhance patient safety and automate drug identification. Other enhancements include new programming features and the ability to read pharmacy-generated bar codes.

The PCA Infusion System includes a microprocessor based infusion device with keypad controls, patient pendant, a bar coded drug vial, and a compatible administration set (*see Administration Equipment on page 2-5 for list of compatible sets*). The infuser has an Ethernet port for computer or printer connections.

## ***Descriptive Information***

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.

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

The vials are single-use, bar coded, and prefilled with a prescription drug by Hospira/Abbott, or the vials are sterile and empty to be custom-filled by the hospital pharmacy.

The PCA Infuser offers the following modes of delivery:

- PCA ONLY
- CONTINUOUS ONLY
- PCA+CONTINUOUS

The PCA Infuser is able to store frequently used prescriptions called protocols. The protocols are available for Hospira/Abbott 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).

## **Indications for Use**

The LifeCare PCA® Infusion System with Hospira MedNet® Software is intended for accurate, volumetric, infusion of analgesic drugs by continuous or patient demanded intravenous administration. It is intended for short-term continuous (less than 96 hours) epidural administration of analgesic drugs.

**WARNING**

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**For epidural use, administer only anesthetics/ analgesics approved for epidural administration (as indicated or allowed by the drugs' FDA approved labeling). Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**

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**PATIENT SELECTION**

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

**WARNING**

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**Patient Pendant Is only to be pressed by the patient.**

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**USER QUALIFICATIONS**

All clinicians should be appropriately trained to program the PCA Infuser prior to use. The 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 drugs, 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.

## **Contraindications For Use**

The 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.

Drugs not compatible with silicone rubber or PVC plastic, or drugs not stable under infusion conditions should not be used with this system.

# Conventions

This section describes the conventions used throughout this manual:

Convention	Application	Example
ITALIC	REFERENCE TO A SECTION, FIGURE, OR TABLE.	(See <i>Front Panel</i> on page 3-2.)
[BRACKETED ALL-CAPS]	KEYS OR BUTTONS ON THE DEVICE ARE DISPLAYED IN [BRACKETED ALL-CAPS] OR WITH A GRAPHIC.	[ON/OFF] OR 
ITALIC SMALLCAPS>	SOFTKEY OPTIONS	<i>PREVIOUS&gt;</i>
INITIAL CAPS LOWERCASE	SCREEN DISPLAYS AND DEVICE LABELS (AS APPROPRIATE)	SELECT DELIVERY MODE
BOLD	EMPHASIS	...SETS ARE SUPPLIED STERILE AND ARE FOR....

## WARNINGS, CAUTIONS, AND NOTES

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

### **WARNING**

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**A Warning Message contains special safety emphasis and must be observed at all times. Failure to observe a Warning Message is potentially life threatening.**

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

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

## ***Descriptive Information***



This symbol directs the user to consult accompanying documents.

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

# **Definitions (General and Clinical)**

TERMS	DEFINITION
<b>Accuracy</b>	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 (see <i>Section 9 Specifications</i> on page 9-1).
<b>Autoprogramming</b>	Complete or partial program received from a bar code enabled Point-of-Care System requiring clinician confirmation prior to administration.
<b>Battery Fault</b>	A battery that will not accept a full charge.
<b>Bolus</b>	A fixed amount of drug delivered in a short amount of time. A PCA dose.
<b>Button</b>	A hard key on the front panel or on the patient pendant.
<b>Clinical Care Area (CCA)</b>	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 CCA's.
<b>Connectivity Engine (CE)</b>	A component of the infuser that controls Ethernet and wireless communication between the network server and infuser.
<b>Continuous</b>	Infusion program characterized by a constant, fixed-rate dose.

## ***Descriptive Information***

TERMS	DEFINITION
<b>Custom Syringe or Vial</b>	A bar coded Hospira/Abbott sterile empty vial that is custom-filled by a pharmacy.
<b>Default Drug Library (DDL)</b>	A pre-programmed drug library embedded in the infuser software. The infuser uses the DDL until a User-defined Drug Library is installed and supersedes the DDL.
<b>Dose Limit</b>	User-programmable parameter specifying the maximum amount of drug that can be administered via PCA dose and continuous delivery in a programmable rolling time period consisting of discrete accumulation periods of 6 minutes. <b>NOTE:</b> Dose Limit periods are specified as 1 and 4 hours on an infuser with the DDL; on infusers with a User-defined Drug Library, the dose limit periods can be defined as 1, 4, 6, or 12 hours.
<b>Drug Library Download</b>	The process of moving the User-defined Drug Library from the network server to the infuser.
<b>Drug Library Installation</b>	The process of moving the User-defined Drug Library from the CE to the infuser.
<b>History</b>	Displays Rx Settings, PCA Summary and the Event Log.
<b>Hospira MedNet® Software</b>	Network based application software used to upload event logs and download the user-defined drug library to the infuser.

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TERMS	DEFINITION
<b>Infusing</b>	The infuser is ON and a DELIVERY SCREEN is displayed. The infusing mechanism may or may not be actually infusing at any given time.
<b>LCD</b>	Liquid Crystal Display
<b>LED</b>	Light Emitting Diode
<b>Loading Dose</b>	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. For more information <i>see Loading Dose on page 4-30</i> .
<b>Lockout Interval</b>	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 lock out interval are denied.
<b>Muting Period</b>	The period between the silencing of an alarm by pressing the [SILENCE] key and the resumption of the alarm.
<b>Occlusion</b>	A blockage in the PCA Infuser set that prevents the infuser from pumping fluid into the patient. Possible causes of occlusions are kinked or plugged non-patent IV tubing.
<b>Occlusion Pressure</b>	The maximum pressure produced as a result of an occlusion in the PCA Infuser set.

## ***Descriptive Information***

TERMS	DEFINITION
<b>On</b>	The infuser is turned on using either A/C or battery power. The infuser is not necessarily pumping when <b>ON</b> .
<b>Patient Pendant</b>	A hand held pendant connected to the infuser that allows the patient to request a PCA dose (bolus) by pressing a button.
<b>PCA Mode</b>	Infusion therapy characterized by bolus doses administered on patient demand subject to a lockout interval and, optionally, a dose limit.
<b>PCA Set</b>	Tubing connecting the PCA Vial to the patient.
<b>PCA Vial</b>	Vial compatible with the infuser that is either prefilled with drug by Abbott or Hospira (standard vial) or filled by the hospital pharmacy (custom vial).
<b>Prime</b>	Manually removing air from the syringe and line.
<b>Purge</b>	The process during which the pumping mechanism is run to remove air from the PCA set.
<b>Rule Set</b>	A list of upper, lower, soft and/or hard limits for delivery parameters. Rule sets reside in the User-Defined Drug Library and are associated with a specific vial within a CCA.

## **LifeCare PCA® Infusion System**

TERMS	DEFINITION
<b>Rx Settings</b>	The current programmed therapy. Includes PCA Dose, PCA Lockout Interval, Continuous Rate, Loading Dose and Dose Limit amount.
<b>Soft Keys</b>	The five keys to the right of the device's LCD display. Each key's function is dependent on the screen displayed data.
<b>Stored Protocols</b>	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.
<b>Standard Syringe</b>	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.
<b>User-defined Drug Library</b>	A drug library that contains hospital defined clinical care areas (CCAs) and rule sets created with Hospira MedNet® Software.
<b>Warning</b>	An indication to advise the clinician of a possible dangerous condition.

# **Precautions and Warnings**

## **UNPACKING**

Product damage may occur unless proper care is exercised during the unpacking and setup process. The battery may not be fully charged upon receipt.

## **GENERAL**

This section addresses general safety and operational procedures.

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

## **WARNING**

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

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- Potent analgesic medications are used with this device. Refer to drug package insert for precautions and possible adverse reactions.
- Refer to analgesic package enclosure for possible incompatibility with fluid or drug being delivered through the IV line.
- Coupling together of more than one infuser into one patient line may significantly affect the infusion rate of at least one of the infusers.
- Do not use sharp objects such as pens, scissors, or fingernails to press keys. Such objects may damage keys and cause a malfunction.
- Arrange tubing, cords, and cables to minimize the risk of patient strangulation or entanglement.
- Failure to use Hospira/Abbott vials and Hospira/Abbott PCA Infuser sets with the integral anti-siphon valve may cause an inaccurate dose delivery to the patient.
- The system must be primed prior to purging. Remove all air from vial before placing it into the infuser.

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- Always close the slide clamp on the PCA Infuser administration set before removing or the replacing syringe, and before discontinuing infusion.
- Patient must be disconnected from the PCA Infuser set before the purge cycle.
- Vial and injector must be securely locked into the infuser before beginning delivery.

## **PROGRAMMING**

This section presents known infuser programming cautions.

### **WARNING**

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**For custom syringes, confirm that the displayed concentration (mg/mL) or (mcg/mL) exactly matches the concentration value and drug name on the syringe. If they do not match, under/overdosage may result.**

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- In the CONTINUOUS and PCA+CONTINUOUS modes, if a purge is not performed after a syringe change, the infuser automatically performs a small system compliance step to remove slack when the [START/PAUSE] 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 purged.
- Selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values.

## **LOADING DOSE/DOSE LIMITS**

This section presents Loading Dose and Loading Dose information and cautions.

- 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 PCA Infuser when delivering medication with the door open.
- Patient Pendant is only to be pressed by the *intended patient*.

**WARNING**

**Patient Pendant is only to be pressed by the patient.**

**OPERATION**

This section presents operational information and cautions.

- Perform close assessment and monitoring of patients receiving potent analgesic medication for possible adverse reactions.
- The PCA Infuser is not intended to be used for frequent, long-term portable operation. Keep 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.

**MAINTENANCE**

This section addresses infuser maintenance.

- Always confirm that the bar code reader window is clean. Blood, fingerprints, condensation, and other elements may obstruct the view of the bar code reader. Elements on the window (other than scratches) can be cleaned by using one of the recommended cleaning solutions. *See Section 8 Maintenance on page 8-1.*
- Window scratches cannot be wiped clean and will probably lead to window replacement.
- To avoid mechanical or electrical damage, do not immerse the infuser in any fluids or cleaning solutions.
- Some cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Hospira may result in product damage. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.
- Do not sterilize by heat, steam, ETO, or radiation.
- Do not place the PCA Infuser in service if it fails the self-test.
- 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; the

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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.

## **ALARMS**

This section presents alarm information.

- If the MALFUNCTION Alarm Message is seen and sounds, press the [ON/OFF] key to turn the infuser off. Then turn the infuser back on. If the malfunction alarm repeats, remove the infuser from service.

## **EPIDURAL ADMINISTRATION**

This section contains epidural administration information.

- Recommended use of the epidural route is to provide anesthesia or analgesia for periods up to 96 hours.
- It is strongly recommended that the epidural 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.
- This device can be used to administer only those anesthetics/analgesics approved for epidural administration (as indicated or allowed by the drugs' FDA approved labeling). Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.
- For epidural administration, the use of infuser sets without Y-sites, and epidural stickers indicating ongoing epidural administration are recommended.
- Administration of drugs via the epidural route should be limited to personnel familiar with associated techniques and patient management problems. Proper epidural placement of the catheter is essential since catheter migration could result in intravascular or intrathecal administration. Facilities practicing epidural administration must be equipped with resuscitative equipment, oxygen, naloxone, and other resuscitative drugs.

## ***Descriptive Information***

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 drug administration by the epidural route.

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

- The epidural space has 58 openings through which fluid can exit. Pressure buildup during administration is transient. However, if a large volume of fluid is administered over a short time period, the pressure will take longer to return to normal. If over delivery occurs during administration, observe the patient closely for signs of spinal cord compression (disorientation, headache, transient neuralgias) and drug overdose.

## **BATTERY OPERATION**

This section documents battery information.

### **WARNING**

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**Unplug the AC power cord before removing the battery door.**

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### **CAUTION: WHEN THE PCA INFUSER IS CONNECTED TO A PATIENT, DO NOT OPERATE THE PCA 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 PCA Infuser to AC power for at least **16** hours.
- Use AC power whenever possible. Connect to AC power during storage to ensure a fully charged battery during a power outage.
- Always connect the infuser to a properly grounded receptacle unless battery operation is desired. If quality earth grounding source is in doubt, use battery power.
- If the low-battery alarm sounds, connect to AC power immediately.

### **WARNING**

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**The infuser cannot communicate via the network if the Low Battery Warning alarm has sounded.**

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### **SETS AND ACCESSORIES**

Use Hospira/Abbott LifeCare PCA® Set List 6517 whenever the infuser is in CONTINUOUS or PCA+CONTINUOUS Modes.

- When using PCA or PCA+CONTINUOUS Mode, another fluid line may be attached to the distal backcheck Y site. Use Hospira/Abbott LifeCare PCA® Infuser set, List 3559, 6516, or a combination of List 6514 and 6517.
- It is recommended that highly viscous solutions and drugs, colloidal suspensions, and emulsions should not be delivered through the inline backcheck valve of the PCA Infuser set. Valve functionality may be compromised by the presence of residue.
- Refer to vial and set package inserts for precautions and information on proper handling.

### **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 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,

## ***Descriptive Information***

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 for the Medical Device Directive 93/42/EEC (EN 55011 Class B and IEC/EN 60601-1-2:2001). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment 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
  - Consult the manufacturer or field service technician for help
- Portable and mobile RF communications equipment, such as cellular telephones, 2-way radios, Bluetooth devices, microwave ovens, in close proximity to this device may affect wireless and wired communications with the infusion pump and/or the operation of the infusion pump. Special precautions need to be exercised regarding EMC. These include:
  - Use of a shielded Ethernet cable (CAT5 STP or better) for plugging into the RJ45 Ethernet connector. Using an unshielded Ethernet cable may result in increased emissions.
  - Maintaining a minimum separation distance of 2 1/2 ft between the infusion pump system and portable/mobile RF communications equipment
  - List Number 20709 is compliant to IEC/EN 60601-1-2 (2001) and have been tested and found to comply with EMC limits for

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the Medical Device Directive 93/42/EEC (EN 55011 Class B and IEC/EN 60601-1-2:2001).

For more information *see Contact Information on back.*

### **INTERCONNECTING OF EQUIPMENT**

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

## ***Descriptive Information***

- 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 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 Biomedical Engineering Department for additional information in the 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 may cause undesired operation of this device.

### **FCC INTERFERENCE STATEMENT**

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception,

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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 801.11a/b/g device usage in the 5150-5250 MHz band is limited to indoor use to reduce potential for harmful interference to co-channel mobile satellite systems.
- In the 5250-5350 MHz and 5650-5850 MHz frequency bands, high power radars are allocated as primary users and these radars could cause interference and/or damage to LE-LAN devices.
- Operation is subject to the following two conditions: (1) the wireless device may not cause interference, and (2) the wireless device must accept any interference, including interference that may cause undesired operation of the wireless device.

## **RADIO FREQUENCY EXPOSURE STATEMENT**

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

## Wireless LAN Module

<b>Device Name:</b>	Hospira MedNet 802.11 a/b/g Wireless (Upgrade) Module
<b>Standards:</b>	IEEE802.11a/b/g
<b>Transmit Power:</b>	802.11 b/g- 17 dBm 802.11 a- 16 dBm
<b>Antenna:</b>	Integrated surface mount antenna
<b>Certifications:</b>	FCC Part 15.247, 15.407 IC RSS-210, RSS-102 FCC ID: STJ-80411396001 IC: 5627A- 80411396 Model: CUSTOM DWL-AG132