

For use with List Number 20678-04

# **Technical Service Manual**

Hospira, Inc. 275 North Field Drive Lake Forest, IL 60045 USA



## **Change History**

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Update revision number on front cover

Update cover art and add Hospira address on front cover Global - add symbols to Warnings and Cautions, change ® to TM, use TM after the first or most prominent occurrence of a Hospira or a third-party product name, delete <sup>©</sup>Hospira, Inc., and delete copyright and trademark statements

Update graphics in Sections 1 and 5

Update distal air-in-line test procedure in Section 5 Delete Morgan Hill return address information, add replace CPU PWA corrective actions, and add unrestricted flow procedure with unrestricted flow warning and regulator

closer caution (Section 6.4.1) in Section 6

Update update fluid shield procedure with regulator closer and unrestricted flow steps, warnings, and cautions in

Section 7

Update air-in-line Air in Line Alarm for single air bolus and

cumulative air bolus in Section 8

Update IEC symbols/descriptions and add "All Rights

Reserved" on back page



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## Section 1

# INTRODUCTION

The Plum  $A+^{\mathsf{TM}}3$  with Hospira MedNet  $^{\mathsf{TM}}$  Software is an advanced medication management system designed to meet the growing demand for hospital wide device standardization. The infusion system consists of three component infusers, designated Line 1, Line 2, and Line 3. By incorporating three lines into one unit, the infusion system provides three primary lines, three secondary lines, and piggyback fluid delivery capabilities. Features include advanced clinical capabilities, autoprogramming, networked communication, and a plug-and-play platform.

The host device contains a Communication Engine (CE) that provides wired Ethernet and wireless 802.11 a/b/g local area networking capabilities. Hospira MedNet networked application software is designed to allow a facility to customize and download a Drug Library for use with the infusion system.

Before using the software, see the  $Hospira\ MedNet^{^{TM}}\ System\ Installation\ and\ Configuration\ Guide,$  and the  $Hospira\ MedNet^{^{TM}}\ Software\ User\ Guide.$ 

# 1.1 **SCOPE**

This manual is organized into the following sections:

Section 1	Introduction
Section 2	Warranty
Section 3	System Operating Manual
Section 4	Theory of Operation
Section 5	Maintenance and Service Tests
Section 6	Troubleshooting
Section 7	Replaceable Parts and Repairs
Section 8	Specifications
Section 9	Section
Appendix	
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Technical	Service Bulletins

If a problem in device operation cannot be resolved using the information in this manual, *contact Hospira* (see Section 6.1).

Specific instructions for operating the device are contained in the *Plum*  $A + {}^{TM}$  *and Plum*  $A + {}^{TM}$  *3 Infusion System for use with Hospira MedNet Software System Operating Manual.* 

For device configuration and compatible module list numbers, *contact Hospira*.

The terms "infusion system", "infuser", and "device" are used interchangeably throughout the manual.

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

Screen representations are examples only, and do not necessarily reflect the most current software version.

# 1.2 **CONVENTIONS**

The conventions listed in *Table 1-1* are used throughout this manual.

Table 1-1. Conventions				
Convention	Application	Example		
Italic	Reference to a section, figure, table, website, or publication	(see Section 6.1)		
[ALL CAPS]	In-text references to keys, touchswitches, and display messages	[START] CASSETTE TEST IN PROGRESS		
Bold	Emphasis	CAUTION: Use proper ESD grounding techniques when handling components.		
	Screen displays	Select Set Time and Date.		

Throughout this manual, warnings, cautions, and notes are used to emphasize important information as follows:



WARNING: A WARNING CONTAINS SPECIAL SAFETY EMPHASIS AND MUST , BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING MAY RESULT IN PATIENT INJURY AND BE LIFE-THREATENING.



CAUTION: A CAUTION usually appears in front of a procedure or statement. It contains information that could prevent hardware failure, irreversible damage to equipment, or loss of data.



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

## 1.3 COMPONENT DESIGNATORS

Components are indicated by alpha-numeric designators, as follows:

Battery	BT	Diode	D	Resistor	R
Capacitor	C	Fuse	F	Switch	sw
Crystal	Y	Integrated Circuit	U	Transistor	Q

The number following the letter is a unique value for each type of component (e.g., R1, R2).



Note: Alpha-numeric designators may be followed with a dash (-) number that indicates a pin number for that component. For example, U15-13 is pin 13 of the encoder chip [U15] on the interface PWA.

# 1.4

## **ACRONYMS AND ABBREVIATIONS**

Acronyms and abbreviations used in this manual are as follows:

- A Ampere
- **AC** Alternating current
- A/D Analog-to-digital
- ADC Analog-to-digital converter
- APP Air, pressure, and pin
- CCA Clinical care area
- **CCFT** Cold cathode fluorescent tube
  - **CE** Communication engine
- CMOS Complementary metal-oxide semiconductor
  - **CPU** Central processing unit
  - **DAC** Digital-to-analog converter
    - DC Direct current
  - DIP Dual in-line package
- **DMA** Direct memory access
- **DMM** Digital multimeter
- **DPM** Digital pressure meter
- ECG Electrocardiograph
- **EEG** Electroencephalogram
- **EEPROM** Electrically erasable/programmable read-only memory
  - **EMC** Electromagnetic compatibility
  - EMG Electromyogram
  - EMI Electromagnetic interference
  - ESD Electrostatic discharge

- ETO Ethylene oxide
- FPGA Field programmable gate array
  - FSR Force sensing resistor
    - hr Hour
    - Hz Hertz
    - **ID** Identification
  - I/O Input/output
  - IPB Illustrated parts breakdown
  - **IV** Intravenous
  - KB Kilobyte
  - Kg Kilogram
  - kHz Kilohertz
- KVO Keep vein open
  - lbs Pounds
- LCD Liquid crystal display
- LED Light emitting diode
- L/S Line select
- mA Milliampere
- MAC Media access control
  - MB Megabyte
- mcg Microgram
- MHz Megahertz
- min Minute
- mL Milliliter
- mL/hr Milliliter per hour
- mmHg Millimeter of mercury
- MMIO Memory-mapped input/output
- MOSFET Metal-oxide semiconductor field-effect transistor
  - ms Millisecond
  - nF Nanofarad
  - ng Nanogram
  - pF Picofarad
  - PROM Programmable read-only memory
    - **PVT** Performance verification test
    - PWA Printed wiring assembly
  - PWM Pulse width modulator
  - RAM Random-access memory
    - rms Root-mean-square
  - RTC Real-time clock

SCC Serial communication controller

**SCP** Serial communication port

SLA Sealed lead acid

SMT Surface mount technology

SPI Serial peripheral interface

SRAM Static random access memory

TQFP Thin quad flat pack

V Volt

VAC Volts AC

V<sub>CC</sub> Collector supply voltage

VCO Voltage-controlled oscillator

 $V_{DC}$  Volts DC

 $V_{rms}$  Volts root mean square

**VSC** 5 V<sub>DC</sub> supply circuitry

VSO Voltage sweep oscillator

VTBI Volume to be infused

WDI Watchdog input

WiFi Wireless fidelity

μA Microampere

μL Microliter

μV Microvolt

usec Microsecond

# 1.5 USER QUALIFICATION

The Plum A+3 must be used at the direction of or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of the infusion system and the administration of parenteral and enteral fluids and drugs, and whole blood or red blood cell components. Training should emphasize preventing related IV complications, including appropriate precautions to prevent accidental infusion of air. The epidural route can be used to provide anesthesia or analgesia.

# 1.6 ARTIFACTS

Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals.

To determine if the abnormality in the monitoring equipment is caused by the infuser instead of some other source in the environment, set the device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by electronic noise generated by the infuser. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring system documentation for setup and maintenance instructions.

# 1.7 **ELECTROMAGNETIC COMPATIBILITY**

The Plum A+3 with Hospira MedNet Software has been tested and found to comply with electromagnetic compatibility (EMC) limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and 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 (see the *System Operating Manual*).



CAUTION: Portable and mobile RF communications equipment, such as cellular telephones, two-way radios, Bluetooth™ devices, and microwave ovens in close proximity to the infusion system may affect wireless and wired communications and degrade performance of the system. Operation of the infusion system under such conditions should be avoided.

There is a shared responsibility between manufacturers, customers, and users to assure that medical equipment and systems are designed and operated as intended. Medical electrical equipment requires special precautions regarding electromagnetic compatibility.

The electromagnetic environment should be managed to permit the infusion system to perform as intended without disturbing other equipment. The infusion system 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 equipment to assure there is no electromagnetic interference, and verify normal infuser operation.

Use of a shielded Ethernet cable (CAT5 STP or better) for plugging into the RJ-45 connector is required. Using an unshielded Ethernet cable may result in increased emissions.

✓EN-2 Indicates International Electrotechnical Commission (IEC) compliance.

# 1.8 FCC

The device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15C, 15E of the FCC rules. These limits are designed to provide reasonable protection against harmful interference.

The wireless LAN device in the CE has been evaluated and found to be compliant with the requirements of FCC radio frequency exposure standards.

## 1.9

# INSTRUMENT INSTALLATION PROCEDURE



CAUTION: Infusion system damage may occur unless proper care is exercised during product unpacking and installation.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., 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 assuring that the system complies with the requirements of IEC 60601-1-1. If in doubt, *contact Hospira*.

## 1.9.1 UNPACKING

Inspect the shipping container, and, if any damage is found, contact the delivering carrier immediately.

Use care when unpacking the infusion system. Retain the packing slip and save all packing material in the event it is necessary to return the infusion system to the factory. Verify the shipping container contains a copy of the System Operating Manual.

## 1.9.2 INSPECTION



CAUTION: Inspect the infuser for evidence of damage. Do not use the device if it appears to be damaged. Should damage be found, contact Hospira.

Inspect the infusion system periodically for signs of defects such as worn accessories, broken connections, or damaged cable assemblies. Replace any damaged or defective external parts. Inspect the infuser after repair or during cleaning.

## 1.9.3 SELF TEST

When performing the self test, line 1, line 2, and line 3 must be tested. However, if appropriate, the test may be performed on all lines concurrently.



CAUTION: Do not place the infuser in service if the self test fails.

If an alarm condition occurs during the self test, cycle the power and repeat the self test. If the alarm condition recurs, note the message and take corrective action (see Section 6). Repeat the self test. If the alarm condition continues to recur, remove the infuser from service and contact Hospira.

- Note: Records prior to the date the infuser is received may be from the manufacturing process. Disregard any events from dates prior to receipt of the infuser.
- Note: Do not place the infuser in service if the battery is not fully charged. To make certain the battery is fully charged, connect the infuser to AC power for six hours.
- Note: When plugging the device into an AC power outlet, grasp the AC power cord plug and use a forward motion into the socket. Do not use a sideways motion. When unplugging the device, grasp the AC power cord plug and pull straight out. Do not pull out using the power cord cable and do not pull out at an angle.

To perform the self test see *Figure 1-1*, then proceed as follows:

- 1. Connect the AC power cord to a grounded AC outlet. Verify the **Charge/Line** indicator **CHARGE** illuminates and an alarm tone sounds.
- 2. Without a cassette installed, press [ON/OFF] to turn on the infuser.
- 3. The LCD screen briefly displays the **SELF TEST** screen (see Figure 1-1). If the **SELF TEST** screen does not appear, contact Hospira.
  - Note: The device may display a clinical care area (CCA) selection screen. Choose a CCA and press [ENTER].
- 4. After the self test is complete, the message INSERT PLUM SET CLOSE LEVER appears.
- 5. Verify the time and date. To set the time and date, see *Section 1.10.2*.
- 6. Open the cassette door and insert a primed cassette. Close the cassette door. The cassette test is complete when the **CASSETTE TEST IN PROGRESS** message disappears.
  - Note: The message MECHANISM INITIALIZATION IN PROGRESS will briefly appear prior to the CASSETTE TEST IN PROGRESS message.
- 7. A **NEW PATIENT?** message may appear. Press the **[YES]** softkey.
- 8. Press [ON/OFF] to turn off the infuser.

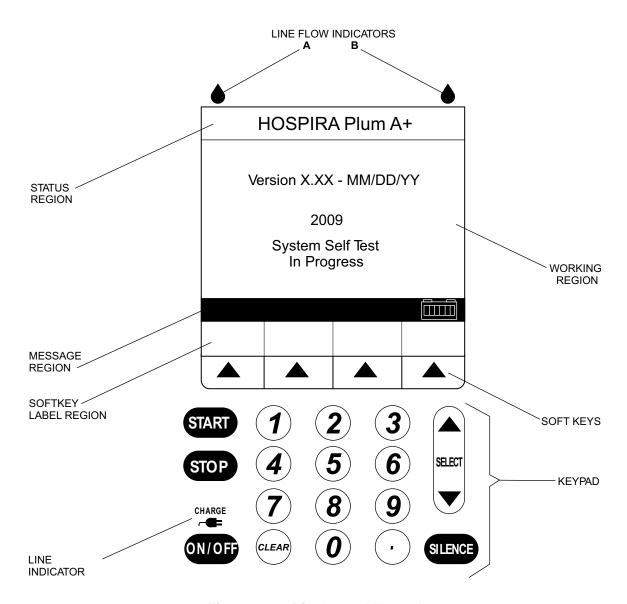


Figure 1-1. Display and Keypad

# 1.10 BIOMED SETTINGS

The **BIOMED SETTINGS** screens contain the following options that can be changed or reviewed by qualified personnel:

- Alarms log
- Set time and date

All infusers (new or refurbished) are shipped with factory settings (see Table 1-2).

- Note: Biomed screens do not time out for the Infuser Idle alarm or No Action alarm.
- Note: The battery will not be detected in the Biomed service mode.
- Note: Upon entry to Biomed mode, any Drug Library waiting for installation will be installed, and the infuser will power off at completion.

To access the Biomed settings, proceed as follows:

- 1. Open the door and turn on the device. The infusion system will perform a self test.
- 2. After the self test is complete, the message INSERT PLUM SET CLOSE LEVER appears. Press the decimal [.] key, then [START], and verify the BIOMED SETTINGS screen is displayed (see Figure 1-2).
  - **Note:** The device may display a CCA screen. Choose a CCA and press [ENTER].

Table 1-2. System Configuration Data				
Data	Options Range	Factory Setting		
Maximum macro IV mode delivery rate	0.1 - 99.9 mL/hr and 100 - 999 mL/hr	999 mL/hr		
Macro Distal Occlusion alarm (pressure level)	1 to 15 psi	6 psi		
Deliver Together enable	Concurrent or Piggyback	Piggyback		
Delayed Start/Standby enable	Yes or No	Yes		
Continue Rate	Rate or KVO	KVO		
Nurse Callback default	Yes or No	No		
Time	(24 hr) 00:00 - 23:59 in one minute increments	Factory time		
Date	1/1/2002 - 12/31/2098	Factory date		

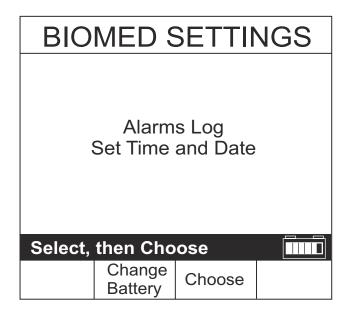


Figure 1-2. Biomed Settings

## 1.10.1 ALARMS LOG

The Alarms Log retains the latest 40 alarm and malfunction codes, listed in order from the most current to the oldest.

To view the Alarms Log, see *Figure 1-3*, then proceed as follows:

- 1. Access the **BIOMED SETTINGS** screen as described in *Section 1.10*.
- 2. Select Alarms Log, and press [CHOOSE]. Use the [PAGE UP] and [PAGE DOWN] softkeys to view the Alarms Log.
- 3. Press [BACK] to exit the Alarms Log and return to the main BIOMED SETTINGS screen.

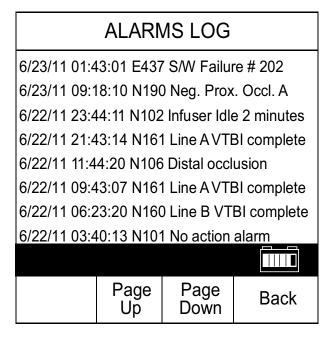


Figure 1-3. Alarms Log

## **1.10.2**

## SETTING THE TIME AND DATE

Note: The infuser will automatically display February 29 on leap year.

Note: Daylight savings and time zone changes must be made manually.

To set the time and date, see *Figure 1-4*, then proceed as follows:

- 1. Access the **BIOMED SETTINGS** screen as described in *Section 1.10*.
- 2. Select Set Time and Date, and press [CHOOSE].
- 3. Select the parameter to be changed, then enter the desired value.
- 4. Repeat step 3 for each parameter to be changed.
- 5. Verify the time and date are correct, then press **[ENTER]** to return to the **BIOMED SETTINGS** screen.
- 6. If there are no other changes to the Biomed settings, turn off the infuser.

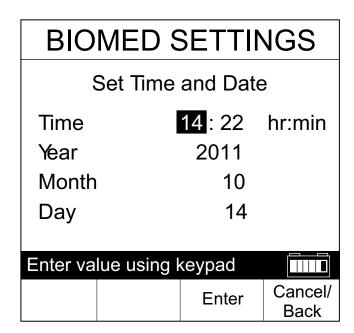


Figure 1-4. Setting the Time and Date

# 1.11 CONNECTIVITY CHECK

To check infusion system connectivity, see *Figure 1-5* and *Figure 1-6*, and proceed as follows:

- 1. To check connectivity in a wireless network environment, verify the **Wireless Connection Available** icon appears on the main delivery screen *(see Figure 1-5)*. The icon is displayed when the device is receiving a wireless signal. The infuser will connect to the network if a wireless network access point is recognized.
  - Note: The icon will not be displayed if the infuser is communicating via an Ethernet connection.
- 2. To check connectivity in an Ethernet network configuration, verify that a shielded Ethernet cable is plugged into the RJ-45 connector, and assure the green LED on the CE module is illuminated (see Figure 1-6).
  - Note: Some cable connectors are configured with tabs to prevent cable tangling. Once inserted, connectors with this configuration cannot be easily removed from the RJ-45 connector on the CE module.

If the **Wireless Connection Available** icon does not appear, or the green light on the CE module is not illuminated, contact the local IT representative, or *contact Hospira*.

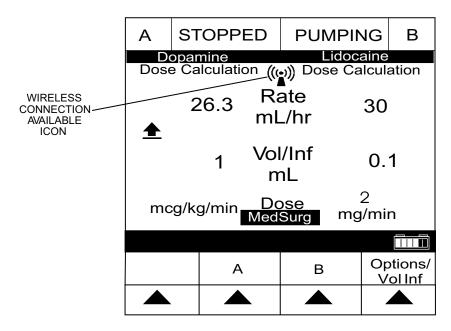


Figure 1-5. Main Delivery Screen

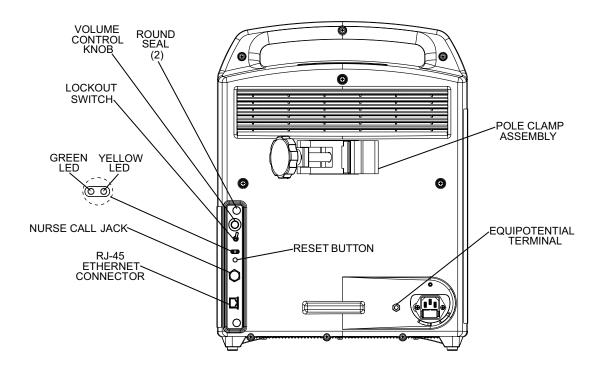


Figure 1-6. Rear View

# 1.12 SERIAL NUMBER ENTRY

The following procedure specifies how to enter the serial number for each Plum A+3 line. For additional information, *contact Hospira*.

To enter the serial number for all three lines, proceed as follows:

- 1. Connect the infuser to AC power.
- 2. Turn on Line 1, Line 2, or Line 3.
- 3. At the **SETUP** screen, enter the serial number of the infuser. The serial number is found on the **Product Identification Label** (*see Figure 1-7*).
- 4. Turn off Line 1, then repeat step 2 and step 3 for Line 2 and Line 3, incrementing the serial number by one for each channel. For example, if an infuser serial number is 15541001, Line 1 serial number is 15541001, Line 2 is 15541002, and Line 3 is 15541003.

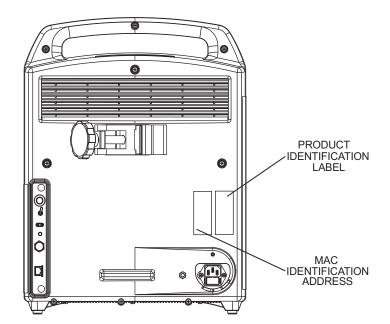


Figure 1-7. Rear Labels

## Section 2

# WARRANTY

Subject to the terms and conditions herein, Hospira, Inc., hereinafter 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, and specifically disclaims the implied warranties of merchantability and fitness for a particular purpose.

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 or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, "major repair or other service" means any repair or service other than the replacement of accessory items such as batteries and detachable AC 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 a Hospira representative performing repair or service is not an authorized agent of Hospira.

SECTION 2 WARRANTY

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## **Section 3**

# **SYSTEM OPERATING MANUAL**

A copy of the System Operating Manual is included with every Plum A+3 infusion system. If a copy is not available, contact Hospira *(see Section 6.1)*.



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## Section 4

# THEORY OF OPERATION

This section describes the theory of operation for the Plum A+3 infusion system. The theory of operation details the general description, electronic subsystem overview, printed wiring assemblies, remote mounted peripherals, and mechanical overview of the infuser.

## $\overline{4.1}$

## **GENERAL DESCRIPTION**

The infusion system includes the following features:

- Dose calculation

- Loading dose

- Multistep programming

- Therapy selection

- Nurse call

- Delayed Start setting

- Standby mode

- Drug Library

- Piggyback/concurrent delivery modes

- Titration

- 0.1-99.9 mL/hr flow rate range for both lines (in 0.1 mL/hr increments)

- 100-999 mL/hr flow rate range for both lines (in 1 mL/hr increments)

- Anti free-flow protection

- Battery gauge

- Networked communications

- Air detection (proximal/distal)

- Air removal/backpriming

- Alarm history

- Volumes infused (A, B, total volumes)

 KVO at dose end (1 mL/hr) or less depending on delivery rate) or Continue Rate to continue

- Variable distal pressure setting

- Nonpulsatile volumetric accuracy

- Microprocessor control

- Large LCD

- Panel back illumination on mains power

- Lockout switch

- Standard fullfill, partfill, syringe, and vial use

- Enteral/parenteral fluid delivery

- Blood/blood product delivery

Alarms include the following:

- Distal Occlusion

- Proximal Occlusion

- Proximal Air-in-Line

- Distal Air-in-Line

- Low Battery

- Door Opened While Pumping

- Lockout Violation

- VTBI Complete

- Valve/Cassette Test Failure

- Nurse Call

- No Action

- Infuser Idle for Two Minutes

## 4.2

## **ELECTRONIC SUBSYSTEM OVERVIEW**

This section describes the function and electronic circuitry of three main subsystems in the infusion system: CPU subsystem, power supply subsystem, and mechanism subsystem. This section also includes the Communication Engine (CE).

1

Note: An asterisk (\*) denotes an active low or negative true logic signal.

#### 4.2.1

## **CPU SUBSYSTEM**

The CPU subsystem contains the main microcontroller that is responsible for controlling the display/keyboard interface, external communications interfaces, and system management.

The CPU subsystem provides the following functions:

- External memory devices access
- LCD interfaces
- Real-time clock generator interface
- System watchdog
- Analog-to-digital and digital-to-analog converter interface
- Keypad interfaces
- Control and monitor status signals, such as LEDs, audible alarms, volume control, nurse call switch, and lockout switch
- Power supply subsystem interface
- Mechanism subsystem interface

## 4.2.1.1

# CPU

The central processing unit is a Motorola MC68302 CPU. The CPU has a closely coupled 16 bit data bus and 24 bit address bus, MC68000 microprocessor core, a system integration block for peripherals, and an RISC communications processor. The MC68302 is packaged in a 144 pin thin quad flat pack (TQFP) package and operates from a 3.3  $\rm V_{DC}$  power supply.

The on-chip peripheral devices are isolated from the system through the dual port RAM. The 1152 byte dual port RAM has 576 bytes of system RAM and 576 bytes of parameter RAM that contains various peripheral registers, parameters, and the buffer descriptors for each of the three serial communication controller (SCC) channels and the serial communication port (SCP) channels. The 24 bit address bus is capable of accessing up to 16 MB of data.

## SYSTEM MEMORY ADDRESS MAP

The CPU has a 24 bit address bus when combined with UDS\*/A0. The address bus is a bi-directional, three state bus capable of addressing 16 MB of data that is configured as 16 bits per word (including the IMP internal address space). Each of the four programmable chip-select lines has two registers that define the starting address of a particular address space and the block size.

#### 4.2.1.3

#### PROGRAMMABLE READ-ONLY MEMORY

The CPU subsystem has two 512 K x 8 bit programmable read-only memory (PROM) memory devices that provide a total of 1024 KB. The PROM space is expandable up to 2 MB. The PROM memory devices operate off the 3.3  $V_{DC}$  supply. The CPU chip-select 0 pin (CSO\*), is connected to the PROM chip-enable (CE\*) pin (signal CSROM\*). This special chip-select signal can support bootstrap operation after reset.

The interface to the CPU is the 16 bit data bus, and a 19 bit address bus. The address bus is connected to the ADDR<19:1> lines, and the data bus is connected to the DATA<15:0> lines.

#### 4.2.1.4

## STATIC RANDOM ACCESS MEMORY

There are two 512 K x 8 bit CMOS static random access memory (SRAM) devices that provide a total of 1024 KB of data memory. During an SRAM read or write cycle, the chip-enable (CE\*) is controlled by the CPU chip-select pin 1 (CS1\*, signal name (CSRAM\*). The SRAM space is expandable up to 2 MB. The SRAM operates off the 3.3  $V_{DC}$  supply. The CPU subsystem includes the additional SRAM for video buffer and real-time clock.

#### 4.2.1.5

#### CONTROL LOGIC

The CPU PWA uses field programmable gate arrays (FPGA) that are high density, high speed, I/O intensive general purpose devices. They are used to implement all the digital control functions; memory-map address decoding, memory read-write enable, direct memory access (DMA) request, I/O status signals, chip-select control, motor control, sensor select, and power up/system reset control.

## LCD CONTROLLER

The liquid crystal display (LCD) controller is used to interface the LCD to the CPU. The device displays layered text and graphics, scrolls the display in any direction, and partitions the display into multiple screens. It stores bit-mapped graphic data in external frame buffer memory. The display controller functions include transferring data from the controlling microprocessor to the buffer memory, reading memory data, converting data to display pixels, and generating timing signals for the buffer memory and LCD panel. The LCD controller accesses 32 KB of frame buffer SRAM (video) via the controller's video address and data busses (VA<14:0> and VD<7:0>). The LCD controller external clock frequency is 8 MHz. The LCD controller and the display memory are operated off the 3.3  $\rm V_{DC}$  supply. The output signal levels are shifted up to 5  $\rm V_{DC}$  by buffers for interface with the 5  $\rm V_{DC}$  LCD panel.

The interface to the CPU is through the lower 8 bits of the data bus that is connected to DATA<7:0> lines, address line A1, and LCD chip-select signal CSLCD\* (CS2\*). This controller is also configured as 8080 family compatible interface device with all the control signals, such as WRLCD\* (WR\*) and RDLCD\* (RD\*), generated by the FPGA logic.

#### 4.2.1.7

## LCD BACKLIGHT CONTROL

The LCD panel is backlit by a cold cathode fluorescent tube (CCFT) lamp. The CCFT lamp requires  $300\,V_{rms}$  to operate; a current controlled DC to AC voltage inverter circuit is used to deliver a current regulated sine wave to the lamp. A switching regulator regulates the CCFT current by monitoring feedback pin 3, and varies its output duty cycle to drive a DC/AC inverter. Intensity control is achieved by superimposing a DC control signal with the feedback signal. The DC control signal is sourced by a voltage divider consisting of a digitally controlled non-volatile potentiometer and three series diodes.

The CPU can adjust LCD backlight intensity by selecting the digitally controlled non-volatile potentiometer and controlling TUBU/D and TUBINC\* signals. The potentiometer has a five bit up/down counter with non-volatile memory. It is used to store one of 31 settings of the potentiometer. Each count represents 323  $\Omega$  with a range of 323 to 10 K $\Omega$ . The current counter value is stored in non-volatile memory after CSTUB\* is returned high while the TUBINC\* input is also high. The current counter value is not stored if CSTUB\* is returned high and TUBINC\* is low. The CCFT intensity is directly proportional to the CCFT current, where 0 mA $_{\rm rms}$  is minimum intensity and 5 mA $_{\rm rms}$  is maximum intensity. The CCFT current is inversely proportional to the counter value.

#### 4.2.1.8

#### LCD CONTRAST CONTROL

A digitally adjustable LCD bias supply is used to control the LCD contrast over a range of -24 to -8  $V_{DC}$ . It is digitally adjustable in 64 equal steps by an internal digital-to-analog converter (DAC). The CPU provides two signals, LCDADJ (ADJ) and LCDCTL (CTL), to interface with this device. On power up or after a reset, the counter sets the DAC output to the mid-range value. Each rising edge of LCDADJ increments the DAC output. When incremented beyond full scale, the counter rolls over and sets the DAC to the minimum value. Therefore, a single pulse applied to LCDADJ increases the DAC set point by one step, and 63 pulses decrease the set point by one step.

#### REAL-TIME CLOCK

The watchdog timekeeper chip includes a complete real-time clock/calendar (RTC), watchdog timer, alarm, and interval timer. The time/date information includes hundredths of seconds, seconds, minutes, hours, date, month, and year. The date at the end of the month is automatically adjusted for months with less than 31 days, including correction for leap year. The watchdog timekeeper operates in either 24-hour or 12-hour format with an AM/PM indicator. The device can be programmed to set up an interval timer, and it can generate an alarm every day, hour, or minute. These alarm functions may be used to schedule real-time related activities. A parallel resonant 32.768 kHz crystal oscillator drives the internal time base.

The external interface is a separate (non-multiplexed) 8 bit data bus and 6 bit address bus, with a contiguous address space of 64 bytes. When system power is turned off, a battery voltage input is available that makes the RTC data non-volatile. The address bus is connected to the ADDR<6:1> lines, and the data bus is connected to DATA<7:0> lines. Since the CPU accesses are 16 bits wide, the RTC data is on the lower byte of the word. The RTC chip-enable pin (CE\*) is active low enabled for read and write operations. It is driven by the FPGA control logic, chip-select RTC signal (CSRTC\*) that involves address decoding circuitry.

#### 4.2.1.10

### **VOLTAGE MONITOR WATCHDOG TIMER**

It is important to protect the system during power transitions. The CPU is reset after the  $V_{CC}$  power supply is applied. The microprocessor supervisory circuit generates an automatic reset output during power up, power down, or brownout conditions. When the  $V_{CC}$  falls below the reset threshold voltage of 2.9  $V_{DC}$ , the reset signal (RESET\*) goes low and holds the microprocessor in reset for approximately 200 ms after  $V_{CC}$  rises above the threshold. The supervisory circuit includes a chip-select inhibit circuit that is used to disable access to the real-time clock's non-volatile SRAM during power transitions and power down mode.

This device also provides a watchdog timer function to monitor the activity of the microprocessor. To service the watchdog timer immediately after reset, the device has a longer time-out period (1.6 second minimum) right after a reset. The normal time-out period (70 ms minimum) is effective after the first transition of watchdog input (WDI) after RESET\* is inactive. If the microprocessor does not toggle WDI within the time-out period, both RESET\* and watchdog out (WDO\*) outputs are asserted low. The RESET\* remains active low for a minimum of 140 ms and it resets the CPU. The WDO\* remains low as long as the WDI remains either high or low for longer than the watchdog time-out period. After a reset, the software reads this memory-mapped bit to determine if the latest reset was a watchdog time-out.

#### ANALOG-TO-DIGITAL CONVERTER

The analog-to-digital converter (ADC) monitors the proximal pressure sensor, distal pressure sensor, proximal air sensor, distal air sensor, battery charge/discharge current, battery voltage, buzzer test signal, LCD contrast voltage, CCFT test signal, and two chopper motor drive reference voltages. The ADC is an advanced 10 bit accurate, 11 channel, switched-capacitor, successive-approximation device. It has three inputs and a three-state output (chip-select, I/O clock, address input, and data out) that provide a direct four-wire interface to the serial communication port of the CPU. The ADC is designed to be used in conjunction with multiple serial devices on a common bus; consequently, the data-out pin is driven only when the chip-select (CS\*) pin is asserted. *Figure 4-1* illustrates the serial interface between the ADC and the CPU.

In addition to a high-speed ADC and versatile control capability, this device has an on-chip 14 channel multiplexer that can select any one of 11 analog inputs or any one of three internal self test voltages. The sample-and-hold function is automatic. The end-of-conversion (EOC) output goes high to indicate that conversion is complete. The CPU polls the EOC signal.

Channel selection and conversion results are transferred through the SCP pins. A serial transfer synchronizing clock (SPCLK) must be fed into the I/O clock input pin when the CS\* pin is driven low. The address to be converted is serially transmitted into the address pin, and the conversion results are serially shifted out the data-out pin. Typical access time is 21  $\mu sec$ . The APP PWA is the source of the 2.5  $V_{DC}$  reference voltage. The analog inputs are selected by the channel multiplexer according to the input address (see Table 4-3). The input multiplexer is a break-before-make type to reduce input-to-input noise injection resulting from channel switching.

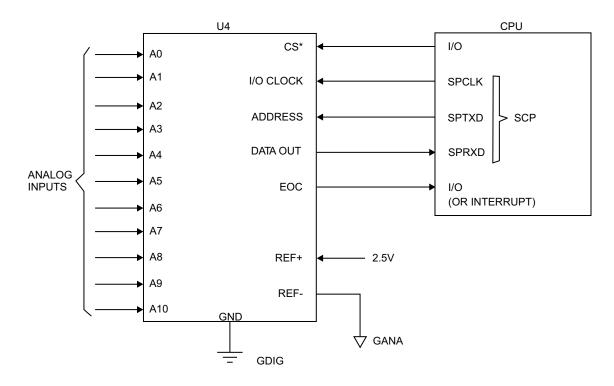


Figure 4-1. Serial Interface to ADC

	Table 4-	1. Analog Inputs	
Signal Name	Analog Input	Address (HEX)	Description
PRPRS	A0	\$00	Proximal pressure sensor
DIPRS	A1	\$01	Distal pressure sensor
PXAIR	A2	\$02	Proximal air sensor
DIAIR	А3	\$03	Distal air sensor
IBATT	A4	\$04	Battery current
VBATT	A5	\$05	Battery voltage
BUZTST	A6	\$06	Buzzer test voltage
LCDTST	A7	\$07	LCD contrast test voltage
TUBTST	A8	\$08	CCFT intensity test voltage
MI_STA	A9	\$09	Motor current A control
MI_STB	A10	\$0A	Motor current B control
		\$0B	(V <sub>ref(+)</sub> - V <sub>ref(-)</sub> ) / 2
		\$0C	V <sub>ref(-)</sub>
		\$0D	V <sub>ref(+)</sub>

#### 4.2.1.12

#### DIGITAL-TO-ANALOG CONVERTER

The dual 8 bit digital-to-analog converter (DAC) generates two analog signals to control the phase A and phase B motor coil currents. The interface between the DAC device and the CPU is the 8 bit data bus that is connected to DATA15:8. All the control signals for this DAC are generated by FPGA logic devices. Buffer amplifier/ground compensation circuits (U6 and U7) condition the DAC outputs.

#### 4.2.1.13

#### FRONT PANEL KEYPAD MATRIX

A  $5 \times 5$  membrane switch keypad matrix is located on the front panel. The keypad column lines (COL4:0) are driven by open collector type memory mapped input ports, while the keypad row lines (ROW4:0), are read by memory mapped input ports (see Table 4-2). The keypad strobing, scanning, and switch de-bouncing is accomplished by software. The keypad interface is designed with ESD protection.

	Table 4-2. Keypad Map				
	COL 0	COL 1	COL 2	COL 3	COL 4
Row 4	Softkey 1	Softkey 2	Softkey 3	Softkey 4	
Row 3	Start	1	2	3	[5]
Row 2	Stop	4	5	6	
Row 1		7	8	9	[6]
Row 0	On/Off	Clear	0	•	Silence

#### 4.2.1.14

## FRONT PANEL [ON/OFF] KEY

The <code>[ON/OFF]</code> key on the front panel provides a start up (STRTUP) signal to wake up the power supply when the system is shutdown. When activated during normal operation, the <code>[ON/OFF]</code> key interrupts (STRUPD\*) the CPU, signaling a request for shutdown.

#### 4.2.1.15

# FRONT PANEL LED INDICATORS

The CPU drives the three light emitting diode (LED) indicators embedded in the front panel. Two memory mapped I/O signals activate the two LED lights used to indicate which channel is in delivery mode (LEDAE\*, LEDBE\*). The AC power on LED indicates the status of AC power (LEDAC) and that the system is in the battery charge mode. A buffered AC on signal (BACON) drives the LED and is active only when AC power is present.

#### 4.2.1.16

#### KEYPAD LOCKOUT INTERFACE

A lockout switch (SW1) on the CE module indicates the front panel keypad is locked. A memory mapped input port (LOTSW\*) reads the switch. The switch serves as a lockout request and software performs the lockout.

#### 4.2.1.17

#### NURSE CALL INTERFACE

A nurse call relay switch on the CE module indicates alarm conditions to a remote operator. A memory-mapped output signal (NURSE) activates the relay during alarm conditions. The relay has both normally open and normally closed contacts. A jumper on the CE module selects the contact type. The factory setting is normally open.

#### 4.2.1.18

#### **AUDIBLE INDICATORS**

There are two audible indicators on the CPU subsystem. Three loud, main audible indicators are mounted on the main chassis. This main alarm is used to alert the operator to alarm conditions. A keypad beeper, with lower power and a distinctly different tone, is used to provide audible feedback to the operator. The keypad beeper is driven by a memory-mapped output (KEYALM). It is used to indicate keypad activation, and confirmation to the operator.

The main alarm has an adjustable volume control on the CE module, mounted on the rear of the device. The main alarm can be activated by either a memory-mapped control (MAINALM), the reset pulse(s), or by a power failure alarm latch. The main alarm will sound a chirp for every reset pulse sent by the watchdog timer IC. Continuous chirping indicates a stuck processor.

The alarm is activated continuously during power failure. If the control software does not shut down power in a proper sequence, a latch on the CPU PWA, powered by a backup supply (0.1 F supercap), will activate a continuous alarm. This continuous alarm sounds until either the backup supply is discharged or the user resets the latch by pressing the <code>[ON/OFF]</code> key. Reliable operation of the main alarm is assured by software monitoring of a buzzer test signal (FBUZTST) via the ADC.

#### 4.2.1.19

#### POWER SUPPLY INTERFACE

The CPU subsystem interfaces the power supply subsystem by providing the MMIO signals needed for power control and battery management. Additionally, the CPU subsystem measures the battery terminal voltage and charge/discharge current via the ADC.

See *Table 4-3* for CPU-power supply interface signals.

Table 4-3. CPU-Power Supply Interface		
Signal Name	Type	Description
PWRHLD	D, O	Holds system power on
STRTUP	A, I	Startup pulse from the [ON/OFF] key
STRUPD*	D, I	Digital startup pulse, used as interrupt to the CPU
V3_3	Р	3.3 V system power
V5_0/VANA	Р	5 V analog and interface power
VMOT	Р	Raw, unregulated charger voltage or battery voltage
V2_7	Р	2.7 V backup power for RTC and non-volatile SRAM
VSC	Р	Full time 5 V supply, backed up by supercap
V12_0	Р	12 V, low current supply for audio alarm
OVRVLT*	D, I	Signal that indicates overvoltage, regulation problem on the power supply main regulator
BACON	D, I	Buffered AC on signal
IBATT	A, I	Voltage proportional to integration of battery charge/discharge current
VBATT	A, I	Divided battery terminal voltage
CHG*	D, O	Battery charger enable
VFLOAT*	D, O	Set the main regulator voltage to battery float charge level
ITGRST	D, O	Reset the charge current integrator

**Legend: P** = Power **A** = Analog **D** = Digital **I** = Input **O** = Output

#### 4.2.1.20

# **MECHANISM INTERFACE**

The CPU subsystem provides the MMIO ports for interface to the mechanism subsystem, in addition to the analog interface referenced in *Section 4.2.1.11* and *Section 4.2.1.12*.

See *Table 4-4* for CPU-mechanism interface signals.

Table 4-4. CPU-Mechanism Interface Signals			
Signal Name	Туре	Description	
MI_STA	A, O	Motor current set for phase A	
MI_STB	A, O	Motor current set for phase B	
GDAC	A, O	Ground signal from chopper (for compensation)	
M_PHA	D, O	Motor phase A	
M_PHB	D, O	Motor phase B	
M_SEL1, M_SEL0	D, O	Motor select bits	
FLCAME	D, O	I/O and L/S cam flag sensors enable	
FLPINE	D, O	L/S pin motion detectors enable	
FLPLE	D, O	Plunger motor sensor pair enable	
FLLS_C	D, I	Flag, L/S valve cam sensor	
FLIO_C	D, I	Flag, I/O valve cam sensor	
FLLS_A	D, I	Flag, L/S valve A pin detector	
FLLS_B	D, I	Flag, L/S valve B pin detector	
FLPLRO	D, I	Flag, plunger rotation sensor	
FLPLTR	D, I	Flag, plunger translation sensor	
PXPRE	D,O	Proximal pressure sensor enable	
PXPRS	A, I	Proximal pressure sensor	
DIPRE	D, O	Distal pressure sensor enable	
DIPRS	D, O	Distal pressure sensor	
PXARE	D, O	Proximal air sensor enable	
PXAIR	A, I	Proximal air sensor	
DIARE	D, O	Distal air sensor enable	
DIAIR	A, I	Distal air sensor	
CASPR*	D, I	Cassette present	
CASS2*, CASS1*, CASSO*	D, I	Cassette type coding: Macro (111), Micro (010) All others are invalid	
SPCLK	D, O	SCP clock output	
SPRXD	D, I	SCP receive data	
SPTXD	D, O	SCP transmit data	

Table 4-4. CPU-Mechanism Interface Signals			
Signal Name Type		Description	
CSSEP*	D, O	Chip select, EEPROM	
V5_0	Р	5 V supply for interface power	
V3_3	Р	3.3 V supply for logic power	
GDIG	Р	Digital ground	
VANA P 5 V		5 V supply for analog power	
GANA P Analog ground		Analog ground	
VMOT, GMOT	Р	Motor power is directly from power supply PWA	
V2_5	A, I	Reference voltage for ADC and DAC	

**Legend:** P = Power A = Analog D = Digital I = Input O = Output

# $\overline{4.2.2}$

# POWER SUPPLY SUBSYSTEM

The power supply subsystem provides DC power to system circuits and interface software controlled power and battery management.

The power supply subsystem provides for the following functions:

- Main switching regulator

- AC power detection

- Main regulator fault detection

- System power (secondary regulators)

- Auxiliary supplies

- Power control

- Battery charging circuitry

- Battery terminal voltage measurement

- Battery charge/discharge current measurement

# MAIN SWITCHING REGULATOR

The main source of power for the infuser is the AC line. The main switching regulator is a pulse width modulated, AC-to-DC converter that provides the system an isolated DC voltage of 6.9  $V_{DC}$  (or 7.5  $V_{DC}$  in battery charger boost mode). The main regulator is preceded by line fuses F1 and F2, surge suppressor VR1, and a line filter. The bridge rectifier U14 and capacitors C52 and C53 provide the DC voltage required for the switching circuit. Voltage regulator U13 provides the pulse width modulator (PWM) device U12 startup supply voltage. After startup, supply voltage for U12 is supplied by half wave rectifier circuitry CR14, R76, and C51.

The PWM oscillation frequency is approximately 40 kHz, determined by external resistor R72 and capacitor C45. U12 controls the power delivered by varying the duty cycle of the power metal-oxide-semiconductor field-effect transistor (MOSFET) Q9 that drives T2. A half-wave rectifier rectifies the transformer's secondary voltage that provides the raw DC voltage for the battery charger and system power.

There are three feedback mechanisms that maintain control: a main loop for normal control, a secondary loop for overvoltage protection, and a current limit loop.

#### 4.2.2.1.1

# Main Loop

The main loop uses an optical feedback path to regulate the charger voltage (BATPOS) at 6.9  $V_{DC}$  (except during boost charge, when the limit is raised to 7.5  $V_{DC}$  by software control of the VFLOAT\* line). A shunt regulator and opto-isolator provide feedback to the PWM error amplifier.

#### 4.2.2.1.2

# Secondary Loop

Diode CR10 and opto-isolator U10 provide overvoltage protection. CR10 conducts and activates U10 when secondary voltage exceeds approximately 10  $\rm V_{DC}$ . The duty cycle of U12 is reduced until the excessive voltage is removed.

#### 4.2.2.1.3

# Current Limit Loop

The current limit loop is activated when the primary current, sensed by R71, exceeds 3 A. Resistor R70 and capacitor C46 filter the voltage across R71 and feed it back to the current sense input (1.5  $\rm V_{DC}$  threshold) of U12. The duty cycle of U12 is reduced until the excessive load is removed.

#### 4.2.2.2

# MAIN REGULATOR FAULT DETECTION

If the switching regulator's main loop fails, the secondary voltage limit loop takes over. However, the battery charger and motors must be disabled, and an alarm must be generated. A comparator is used to monitor the raw DC (+BUSS) for overvoltage. A 3.3  $\rm V_{DC}$  logic signal (OVRVLT\*) is provided to the CPU subsystem.

#### **SYSTEM POWER**

Along with the unregulated VMOT supply, a secondary switching regulator provides system power. The secondary switching regulator includes IC U4, transformer T1, and transistors Q4 and Q5. The regulator is a triple output, wide supply range, fly-back converter that provides regulated  $3.3\,V_{DC}$ ,  $5\,V_{DC}$ , and  $12\,V_{DC}$  outputs from the five winding transformer T1. The regulator operates over an input range of 4 to  $10\,V_{DC}$  and provides output current limit as well as voltage overshoot limit. Primary feedback is metered through a bias arrangement on transistor Q3. A Schottky rectifier diode CR4 provides feedback in the event of V3\_3 or V12\_0 failure, and transistor Q10 provides feedback in the event of V5\_0 failure. The positive terminal of the battery provides the raw DC voltage, VMOT, for the motors and backlight of the display.

#### 4.2.2.4

#### **AUXILIARY SUPPLIES**

The power supply subsystem provides full time 5  $V_{DC}$  and 2.7  $V_{DC}$  supplies that are active when battery or AC voltage is present. The full time 5  $V_{DC}$  supply (VSC) uses a linear low dropout voltage regulator U6, whose power source is directly from the battery and is backed up by a 0.1 F capacitor. VSC is used for the on/off switch and a power failure alarm latch. The full time 2.7  $V_{DC}$  supply (V2\_7) is derived from VSC and is used to supply the ultra-low current needed to power the real-time clock and non-volatile SRAM during shutdown.

#### 4.2.2.5

#### **POWER CONTROL**

The infuser will operate in one of three modes: normal, standby, or shutdown. During normal operation, the user interface is active and either on battery or AC line power. During standby mode the user interface is inactive while the CPU is still operating, servicing the battery management and waiting for a startup interrupt. Shutdown mode is when system power is off. Shutdown mode only occurs during battery operation; otherwise, +BUSS holds the system power on.

The infuser is activated when the <code>[ON/OFF]</code> key is pressed or the AC line is plugged in. The <code>[ON/OFF]</code> key activates the STRTUP signal, triggering a three second one-shot circuit that will temporarily turn the system power on. This three second one-shot period allows the CPU enough time to power up, initialize, and turn on the PWRHLD signal. The CPU monitors the STRTUP signal, via interrupt, to signal a user request for turning off the infuser.

*Figure 4-2* illustrates the system startup/shutdown sequence while battery powered. System power is always on while AC powered.

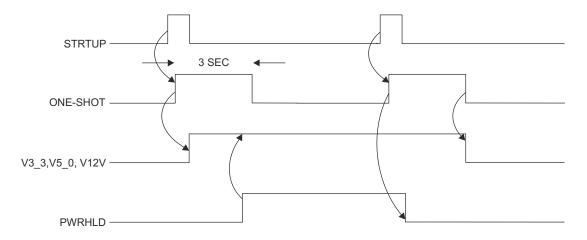


Figure 4-2. System Startup and Shutdown Timing, Battery Powered

#### BATTERY VOLTAGE MEASUREMENT

The battery terminal voltage (BATPOS - BATNEG) is measured with a differential amplifier consisting of U1, R1, R2, R4, R7, and R8. It has a gain of 0.317 to generate a single ended VBATT signal. The VBATT signal is then provided to the CPU A/D converter as input for the battery management algorithms.

#### 4.2.2.7

#### BATTERY CHARGE/DISCHARGE CURRENT MEASUREMENT

The battery management algorithms measure battery charge/discharge current for battery capacity estimation and charger control. The charge/discharge current is measured by integrating the voltage across current sense resistor R57. An operational amplifier (op-amp) integrator circuit, consisting of U2, C5, R12, R13, R19, and R20, provides a voltage proportional to the integration of battery current (IBATT) over a CPU controlled measurement period. The IBATT signal is fed to the CPU A/D converter, where it is sampled at the end of the measurement period. The battery management algorithm further accumulates the charge/discharge current for battery capacity estimation.

The op-amp integrator is reset by the CPU system at the beginning of each measurement period by parallel analog switches U3, controlled by the CPU's ITGRST signal. The battery management algorithm periodically calibrates the op-amp integrator.

#### **BATTERY CHARGER**

The software battery management algorithm controls the battery charger. The charging scheme is a current limit/two stage voltage limit charger. The charge current is limited to 1.3 A and the voltage is limited to either 6.9  $V_{DC}$  or 7.5  $V_{DC}$ .

The source of the charge current is power MOSFET transistor Q7 operating in the linear mode. Charge current passes through a current sense resistor R57, where it develops a feedback signal for the charger control amplifier consisting of U7, Q6, and associated parts. The feedback signal is compared against a  $2.5\,\rm V_{DC}$  voltage reference U8. A  $0.5\,\rm A$  fuse protects against damage due to a short circuit. The battery management algorithm maintains on/off control of the charger by the charger enable signal CHG\*. When set high, CHG\* activates a comparator U7 that overrides the feedback signal and disables the charger. Excessive voltage on the BATNEG terminal indicates there is a shorted battery cell, and will disable the charger through the same comparator.

#### 4.2.3

# **MECHANISM SUBSYSTEM**

The mechanism subsystem includes the electronics and electromechanical components that interface the infuser pumping mechanism.

The mechanism subsystem provides the following functions:

- Chopper motor drive for three stepper motors (plunger, L/S valve, I/O valve)
- Four motor position sensors (flag detectors)
- Precision voltage reference
- Two air sensors (distal, proximal)
- Two pressure sensors (distal, proximal)
- Cassette presence and type detection
- Serial electrically erasable PROM (EEPROM)

See *Table 4-4* for mechanism interface signals.

#### 4.2.3.1

# **MOTORS/MOTOR DRIVE**

The infuser uses three stepper motors for pumping: one for fluid displacement and two for cassette valve actuation. The stepper motors are driven, under step-by-step control from software, by a unipolar chopper drive.

# 4.2.3.1.1 Stepper Motors

Each motor is named by its function:

- Plunger motor for driving the plunger screw
- I/O valve motor for moving the input-output valve pins
- L/S valve motor for moving the line select valve pins A and B

All three motors are four phase stepper types. One electrical revolution is accomplished after four motor steps (phases) are completed. The step-angle (the number of steps per shaft revolution) resolutions are 3.6°/step (100 steps/rev) for the plunger motor, and 7.5°/step (48 steps/rev) for the I/O and L/S valve motors.

The unipolar motor windings have a center tap connected on each of the two coils (see Figure 4-3). Unidirectional current enters the center tap and is steered to one end of the coil or the other end by the driver electronics, creating positive or negative flux lines in the motor coil. With two coils each with a choice of flux polarity, four electrical combinations or phases are possible.

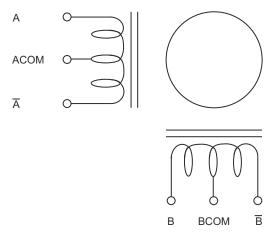


Figure 4-3. Stepper Motor Coils

# 4.2.3.1.2 Chopper Motor Drive

The infuser stepper motor drive is a chopper drive that is a pulse width modulation of the coil current in each motor winding. Current is switched on and off to maintain a predetermined coil current independent of supply voltage and motor speed. The motor winding inductance acts as a filter to smooth out the switching currents, slowing the current rise when turned on and storing a decaying current when turned off. Each motor coil is modulated independently, allowing different coil currents in the two motor windings. The coil current is sensed and compared to a reference input for each winding. Modulation circuits correct for any error between the sensed current and the reference. This reference input can be changed to set a different coil current.

#### 4.2.3.2

#### MOTOR POSITION SENSORS

Motor position is estimated by counting the motor steps, relative to a position reference. Optical switches and flags serve as position references that are used to find the motor home positions and to verify proper motion. Flag positions are anticipated by software.

Optical switch flag sensors are used for tracking the following:

- Plunger motor rotational position (coupler flag)
- Plunger translational (linear) position
- I/O valve motor rotational position (cam flag)
- L/S valve motor rotational position (cam flag)

Each optical switch consists of an infrared LED that shines through a rectangular aperture, across a slot, to illuminate a photo-transistor. The photo-transistor is activated as long as the beam is on and not blocked (by a flag in the slot). The optical switches are distributed throughout the mechanism, near their associated flags. The motor rotational optical switches are mounted on the driver PWA along with the control circuitry. The plunger translational optical switch is mounted remotely on the switch PWA. The switches are used intermittently to save power.

There are two control signals that enable associated switch pairs:

- FLCAME flag valve motor cam sensor enable
- FLPLE flag plunger motor rotation and translation sensors enable

Each of these control signals enables a constant current source that turns on the associated switch's infrared LEDs. The photo transistor states are sensed by Schmidt trigger inverters (U11 on driver PWA) that provide a 3.3 V logic high when the optical path is blocked or a logic low when the optical path is clear. The Schmidt trigger output is high when the sensor is disabled.

The following output signals are provided to the CPU subsystem:

- FLIO\_C flag I/O valve motor cam sensor
- FLLS\_C flag L/S valve motor cam sensor
- FLPLRO flag plunger motor rotation sensor
- FLPLTR flag plunger motor transition sensor

#### 4.2.3.3

# **V2 5 REFERENCE VOLTAGE**

A precision  $2.5\,\mathrm{V_{DC}}$  reference voltage is generated on the APP PWA for use by the pressure sensor excitation circuits, the air sensor amplifier circuits, and the ADC and DAC reference voltage. The precision  $2.5\,\mathrm{V_{DC}}$  reference is buffered by a voltage follower. The signal name is V2\_5.

#### 4.2.3.4

#### AIR SENSORS

The mechanism subsystem includes two air sensors, used to detect air passage into (proximal) or out of (distal) the cassette. Both sensors are piezoelectric crystal transmitter receiver pairs. Liquid between the transmitter and receiver will conduct the ultrasonic signal, while air will not (see Figure 4-4).

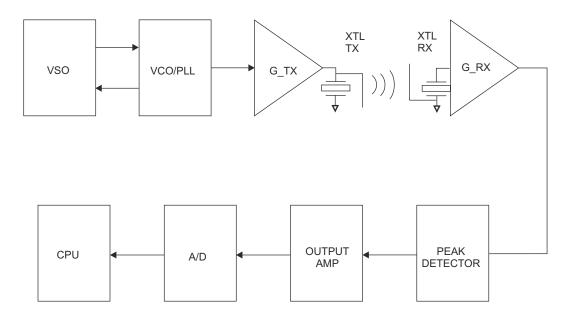


Figure 4-4. Air Sensor Block Diagram

# 4.2.3.4.1 Transmitter Circuitry

The transmitter circuitry consists of a voltage sweep oscillator, a voltage-controlled oscillator (VCO), and a transmitter amplifier, and are located on the APP PWA.

The voltage sweep oscillator circuit oscillates at approximately 12 kHz at 50 percent duty cycle. The output of the sweep oscillator is between +2  $V_{DC}$  and +3  $V_{DC}$ , and is used to sweep the VCO. The VCO sweeps through the sensor's peak coupling frequency that is between 3 MHz and 6 MHz. A resistor and capacitor are used to configure the VCO center frequency. The VCO is enabled when the CPU asserts either DIARE or PXARE control signals.

The transmitter amplifier consists of a push-pull, emitter-follower, complementary pair of transistors. The transmitter amplifier drives both proximal and distal sensors simultaneously.

#### 4.2.3.4.2

# Receiver Circuitry

When the cassette's test port is filled with fluid, the transmitted signal will be coupled to an identical piezoelectric crystal, where it is amplified and detected by the receiver circuitry. The receiver circuitry consists of an amplifier, a peak detector, and an adjustable gain buffer stage. There is a separate, symmetrical receiver circuit for each channel (proximal and distal). Component references called out in this design description will be made to the distal channel only.

The first amplifier includes two, directly coupled common emitter stages, biased from the V2\_5 supply. DIARE and PXARE are used to enable the distal and proximal sensors, respectively. The detector stage consists of an emitter follower, charging a 400 microsecond time constant, refreshed every 40 microseconds (twice per VCO sweep).

The peak detector output is buffered by an op-amp configured as a basic non-inverting amplifier with a trimming potentiometer for gain adjustment. Each sensor has an independent gain adjustment. The two air sensor, gain-trimming potentiometers are accessible for calibration in an assembled mechanism.

These final signals are read by the CPU subsystem via the ADC:

PXAIR proximal air sensor outputDIAIR distal air sensor output

#### 4.2.3.5

## PRESSURE SENSORS

The mechanism subsection contains two strain gauge-type pressure sensors, one at the proximal and the other at the distal cassette ports. Electrically, the strain gauge is a Wheatstone bridge made of four strain gauge resistors. When the bridge is electrically excited, the bridge will output a millivolt level signal proportional to the applied pressure. The output signal is amplified and offset adjusted before being read by the ADC. Each pressure sensor circuit includes an excitation voltage supply, sensor amplifiers, and a low pass filter. The pressure sensor circuitry is on the APP PWA. Each of the two channels has an identical topology, but different gain and filter response.

A block diagram of this circuit is shown in *Figure 4-5*. Component references are made to the distal channel only.

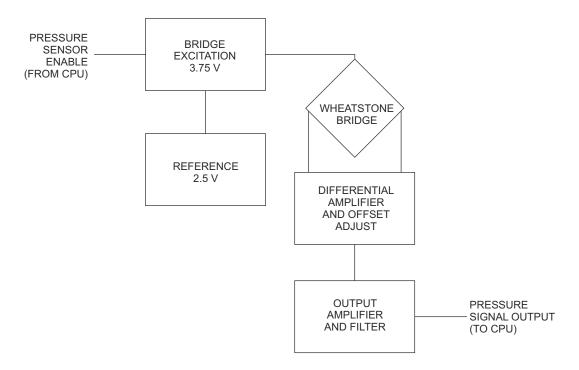


Figure 4-5. Pressure Sensor Excitation and Amplifier Block Diagram

#### 4.2.3.5.1

# **Bridge Excitation Supply**

The bridge excitation voltage is  $3.75\,V_{DC}$ , and is derived from the  $2.5\,V_{DC}$  reference signal (V2\_5), gained 1.5 times by an amplifier. The CPU subsystem may independently enable power to each pressure sensor bridge.

These enable signals are active high 3.3 V logic level inputs:

PXPRE proximal pressure sensor enableDIPRE distal pressure sensor enable

#### 4.2.3.5.2

# Amplifier and Low Pass Filter

The pressure sensor amplifiers include a high gain differential pre-amplifier, followed by a second stage non-inverting amplifier with low gain. A trimming potentiometer is adjusted to minimize any offset in the impedance of the bridge.

A two-pole filter is used to filter the pressure signals. The first pole is formed by a capacitor (C39, multiplied by 230 due to Miller effect) and a Thevenin resistance (seen at U4-2). The second pole is the RC filter at the ADC input that is located on the CPU PWA.

These output signals to the A/D converter in the CPU PWA are:

- PXPRS proximal pressure signal- DIPRS distal pressure signal

#### 4.2.3.6

#### PRESSURE SENSOR CALIBRATION

Pressure sensors are calibrated for offset and gain during mechanism calibration. A trimming potentiometer is used to adjust the initial, zero pressure offset. The proximal and distal pressure sensors have independent offset adjustments. The final system gain (cassette pressure to corrected amplifier output) is adjusted in software. During mechanism calibration, each channel's gain (amplifier output/cassette pressure) will be measured, and stored in the serial EEPROM on the driver PWA.

#### 4.2.3.7

## CASSETTE TYPE/PRESENCE SELECTION

The mechanism subsystem includes four force sensing resistor (FSR) switches that are coupled to the cassette. Three FSRs are used for cassette type decoding and one is used for cassette present detection.

The FSR is a polymer thick film device that exhibits a decrease in resistance with any increase in force applied to the active surface. The FSRs have a resistance that is either very large (> 1 M $\Omega$ ) or relatively small (< 100 K $\Omega$ ). The large resistance is defined as a logical '0', and the small resistance is defined as logical '1'. Each FSR is arranged in a voltage divider configuration with a fixed resistor, followed by a comparator with hysteresis. The comparator circuits are located on the CPU PWA. The comparators are designed to trip as the FSR's resistance falls below 120 K $\Omega$ .

#### 4.2.3.8

#### **SERIAL EEPROM**

The driver PWA holds the 8 K x 8 bit, serial EEPROM that is used to store event, alarm, malfunction, and calibration data specific to the pumping mechanism. It is accessed through a serial peripheral interface (SPI) compatible interface that is a high-speed serial interface to the CPU. The CPU PWA accesses this device through its SCP serial interface. This interface is a subset of the SPI, and consists of clock (SPCLK), data in (SPRXD), and data out (SPTXD) pins. This device is in the driver PWA to allow the calibration data to stay with the mechanism.

#### 4.2.4

# **COMMUNICATION ENGINE**

The CE has 16-bit flash memory  $(4M \times 16)$  and 32-bit SDRAM, and is a combination of a digital processor module and an 802.11 a/b/g wireless module.

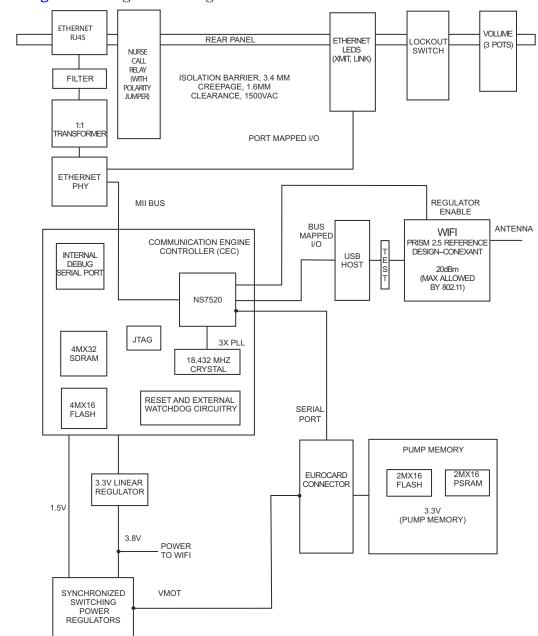
CE processor circuitry includes:

Digital processor
 Memory devices
 Reset control

- RS-232 interface - LED indicators

- USB interface - Power regulation

- Ethernet interface and isolations



See *Figure 4-6* for general configuration of the CE.

Figure 4-6. CE Module Block Diagram

# 4.2.4.1 ETHERNET

The CE supports external wired communications based on IEEE 802.3 specifications. The connector on the rear of the enclosure is a standard RJ-45 Ethernet connector. The speed of the data is 10 MHz or 100 MHz based on the 10BaseT and 100BaseT standards respectively. The Ethernet port meets the IEEE 802.3 specification of a minimum DC isolation of 1500  $V_{\rm rms}.$ 

#### 4.2.4.2

#### WIRELESS MODULE

The wireless module consists of 802.11 a/b/g circuitry, high frequency shielding, integrated surface mount antennae, and media access control (MAC) address.

The 802.11 a/b/g circuitry consists of a MAC processor, RAM and Flash memory, oscillators, and high frequency components required to implement the radio function. The 802.11 a/b/g WiFi radio is interfaced to the Communication Engine processor via an internal USB interface that supports the USB 2.0 standard to 12 Mbps.

# 4.3

# PRINTED WIRING ASSEMBLIES

Infusion system electronics are packaged into eight printed wiring assemblies (PWA) and two remote mounted peripherals (see Section 4.4). The following sections provide a brief description of the functional interfaces of each PWA.

#### 4.3.1

# POWER SUPPLY PWA

The power supply PWA contains the following functions of the power supply subsystem:

- Main switching regulator - Auxiliary supplies

- AC power detection - Power control

- Main regulator fault detection - Battery management

- System power

The power supply PWA is a four layer board, with primarily surface mount technology (SMT) components. The board is fully testable from the bottom side. An insulating tape covers the back of the power supply PWA. Open system troubleshooting should be done under battery power. If connection to the AC line is required, an isolation transformer should be used since AC line potentials are present on the power supply PWA.

See *Table 4-5* for power supply PWA interface connections.

Table 4-5. Power Supply PWA Interface Connections			
Connector	Туре	Interface	
P2	30 pin receptacle	Board-to-board connection to CPU PWA	
J16	4 pin header	Motor power connection to driver PWA	
J21	3 pin receptacle	AC power cord connection	
J22	2 pin header	Battery cable connection	

# 4.3.2 CE PWA

The CE PWA is the peripheral interface PWA, and contains the communication engine and rear user controls. The peripheral interface assembly is a plug-and-play module designed to be field replaceable to facilitate software upgrades or additional external interfaces. The module interfaces via data and address buses on the CE PWA to the CPU PWA via a board-to-board connector, and communicates with a host computer via either a wired or wireless network interface. The peripheral interface assembly is capable of supporting the interconnection of the infuser with a variety of external systems for the purpose of establishing bi-directional communication between the infuser and external systems.

#### 4.3.3

## **ANTENNA PWA**

Two antenna PWAs are housed in the upper front enclosure, and connected to the CE PWA by cable assemblies. All wireless communications are performed via the antennae according to IEEE 802.11 a/b/g specifications.

# 4.3.4 PERIPHERAL PWA

The peripheral PWA contains part of the CPU subsystem circuitry, including system program and data memories (PROM and SRAM), and external communication interface circuits. The peripheral PWA is designed to be field replaceable, to facilitate software upgrades or additional external interfaces.

The peripheral PWA is a four layer board, including one ground plane, one power plane, and two signal layers. In its initial configuration, all of the components are mounted on the top side.

# 4.3.5

# **CPU PWA**

The CPU PWA contains most of the CPU subsystem functions, with the exception of main memory and communications ports that are located on the peripheral PWA. The CPU PWA also accommodates system interconnect.

The CPU PWA is an eight layer board, with one ground plane, one power plane, and six signal layers. The CPU PWA primarily contains SMT components. Most of the components are on the top side, while the bottom side holds wave-solder compatible SMT resistors and capacitors.

See *Table 4-6* for CPU PWA interface connections.

Table 4-6. CPU PWA Interface Connections			
Connector	Туре	Interface	
J7	96 pin header	Connection to peripheral PWA (CPU bus, rear panel I/O, and communication ports)	
J2	30 pin header	Connection to power supply PWA	
J3	50 pin SMT	Ribbon cable connection to driver PWA (mechanism)	
J4	21 pin header	Front panel connector (keypad, LEDs, On/Off switch)	
J5	14 pin SMT	Flat flex cable to LCD panel	
J6	4 pin header	Lockbox connector	
J20	4 pin header	CCFT backlight connector	

# 4.3.6 DRIVER PWA

The driver PWA contains the mechanism subsystem's motor drive circuitry, motor position sensors, and serial EEPROM. The driver PWA is mounted in the mechanism sub-chassis.

The driver PWA is a four layer board, with one ground plane, one power plane, and two signal layers. The driver PWA primarily uses SMT components. Most of the components are located on the top side of the board, while the bottom side holds wave-solder compatible resistors and capacitors.

See *Table 4-7* for driver PWA interface connections.

Table 4-7. Driver PWA Interface Connections			
Connector	Туре	Interface	
J7	6 pin header	Plunger motor	
J8	6 pin header	Input/output motor	
J9	6 pin header	Line select motor	
J10	20 pin SMT	Flat flex cable to APP PWA	
J11	50 pin header	Ribbon cable to CPU PWA	
J12	6 pin SMT	FSR flex circuit	
J13	4 pin header	Motor power from power supply PWA	
J14	8 pin SMT	Flat flex cable to switch PWA	

#### 4.3.7

## **SWITCHES PWA**

The switches PWA contains the plunger translation position sensor that is one of four position sensors in the system. The switches PWA is located at the side of the mechanism sub-chassis, and connects to the driver PWA.

#### 4.3.8

## APP PWA

The APP (air, pressure, and pin) PWA is mounted in the mechanism sub-chassis, and contains the following mechanism subsystem circuitry:

- Proximal and distal air sensors and circuitry
- Proximal and distal pressure sensor amplifiers and excitation
- V2\_5 precision voltage reference
- Pin detector optical switch module

The APP PWA is a four layer board, with one ground plane, one power plane, and two signal layers. The APP PWA uses SMT components, mounted on both sides of the board. The air sensors and the pin detector module are board mounted.

See *Table 4-8* for APP PWA interface connections.

Table 4-8. APP PWA Interface Connections			
Connector	Туре	Interface	
J15	20 pin SMT	Flat flex cable to driver PWA	
J11	10 pin SMT	Pressure sensor connector	

# $\overline{44}$

# REMOTE MOUNTED PERIPHERALS

The major remote mounted peripherals are the LCD and sealed lead acid battery.

# 4.4.1 LCD

The infuser uses a graphic LCD module with a CCFT. The CCFT provides a backlight source for the LCD. The LCD requires a nominal -16  $V_{DC}$  supply for contrast control that is controlled by the CPU. The infuser's graphic display data is shifted out to the LCD by the CPU LCD controller that interfaces directly with the CPU (see Section 4.2.1.6). The display is configured as a 240 x 240 dot matrix with a viewing angle of approximately  $60^{\circ}$ .

#### 4.4.2

# SEALED LEAD ACID BATTERY

The infuser uses a nominal 6  $V_{DC}$  rechargeable sealed lead acid battery with a four amp-hour capacity.

# 4.5

# MECHANICAL OVERVIEW

The principal mechanical elements of the infuser include the cassette and the mechanism assembly. When a cassette is locked into the operating position and the <code>[ON/OFF]</code> switch is pressed, the infuser performs a self test to verify the integrity of the internal systems. The operation of the mechanism assembly moves a plunger, causing a pumping action. A valve motor selects the A or B valve, depending on the command. An additional valve motor alternately opens and closes an inlet valve and outlet valve to control fluid flow through the cassette pumping chamber.

The following sections detail the cassette and the mechanism assembly.

# 4.5.1 CASSETTE

The cassette (see Figure 4-7 and Figure 4-8) operates on a fluid displacement principle to volumetrically deliver fluid. See the System Operating Manual for a description of the major cassette functions.

The pumping cycle begins when the outlet valve is opened and the inlet valve is closed. The plunger extends to deflect the cassette diaphragm and expel fluid. At the end of the pumping stroke, the outlet valve is closed, the inlet opens, the appropriate A or B valve opens, and the plunger retracts to allow fluid to refill the pumping chamber. After the pumping chamber is filled, the inlet and outlet valves are reversed, the A and B valves are closed, and the cycle repeats.

The cassette contains two chambers: an upper air trap chamber and a pumping chamber. The two chambers are separated by an inlet valve and operate together to detect air. The air trap chamber receives fluid from the intravenous (IV) container through either the A or B valve. The air trap chamber collects air bubbles from the IV line and container to prevent them from entering the pumping chamber and can collect a substantial amount of air.

A proximal air-in-line sensor (bubble detector) is located between the A/B valves and the upper air-trap chamber. The proximal air-in-line sensor detects air entering the upper air-trap chamber and initiates an audible alarm if the predetermined air collection threshold is exceeded. Similarly, a second air-in-line sensor located distal to the pumping chamber initiates an audible alarm if a predetermined amount of air is detected.

The pumping chamber receives fluid from the upper air-trap chamber through an inlet valve. A pressure sensor located in the upper air-trap chamber monitors pressure on the proximal side of the cassette. When the diaphragm covering the pumping chamber is deflected by the plunger, the pumping chamber expels fluid through an outlet valve. A pressure sensor located distal to the pumping chamber monitors pressure on the distal side of the cassette.

A flow regulator is incorporated into the cassette distal end. This flow regulator is used to manually control flow when the cassette is not inserted in the infuser. When the cassette is properly inserted into the infuser and the door is closed, a mechanism opens the flow regulator to allow the infuser to control fluid flow. When the door is opened, the same mechanism closes the flow regulator to disable fluid flow.

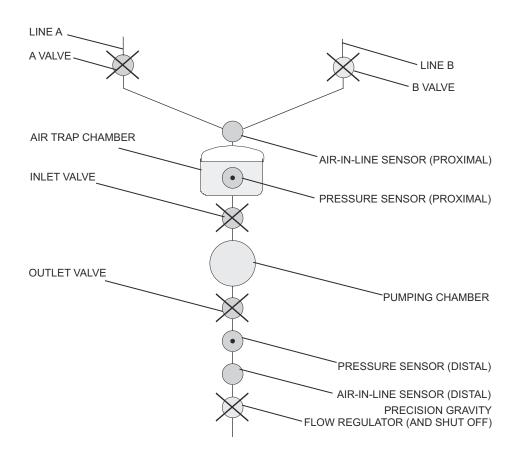


Figure 4-7. Major Elements of the Dual-Channel Cassette

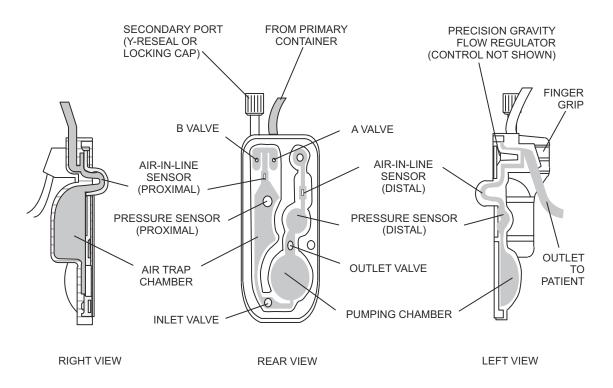


Figure 4-8. Fluid Path in the Cassette

#### 4.5.2

### MECHANISM ASSEMBLY

The mechanism assembly is a fully self-contained unit consisting of the motor and valve assemblies, A/B valve subsystem, inlet/outlet valve subsystem, plunger drive subsystem, air bubble (ultrasonic) sensor assemblies, cassette door, and pressure sensor assemblies. The motor and valve assemblies, A/B valve subsystem, inlet/outlet valve subsystem, and plunger drive subsystem are detailed in the following sections.

During infuser operation, the mechanism assembly plunger motor drives a lead screw that is coupled to the plunger. The motor action and lead screw move the plunger forward to cause the delivery of approximately 0.33 mL of fluid per cycle. The plunger motion is synchronized to the valve motors to provide controlled fluid delivery.

See *Figure 4-9* for mechanism valve pins and sensor locations.

#### 4.5.2.1

#### MOTOR AND VALVE ASSEMBLIES

The mechanism assembly pumping action is controlled by three stepper motors. The first stepper motor, in conjunction with an associated valve assembly, activates the A or the B valve of the cassette, depending on the command. The second stepper motor alternately opens and closes the inlet and outlet valve to control fluid delivery through the cassette pumping chamber. A third stepper motor controls plunger movement.

#### 4.5.2.2

#### A/B VALVE SUBSYSTEM

The A/B valve subsystem includes a motor designed to rotate a cam. When the cam is positioned at top-dead-center (home position), both valves are closed. Clockwise rotation (when viewed from the motor side) from the home position opens the A valve, while the B valve remains closed. Counterclockwise rotation opens the B valve, while the A valve remains closed.

The A/B valve subsystem consists of a stepper motor with attached cam and integral cam flag, A and B rockers and valve pins, and a pin detector assembly. The cam flag passes through an interrupter module as it rotates with the cam. Valve home position is determined by this cam flag/interrupter module combination through predetermined factory calibration data. During operation, if the cam flag passes through the interrupter module at the incorrect time sequence, a motor phase loss is detected. The rocker is the connecting link between the cam and the valve pin.

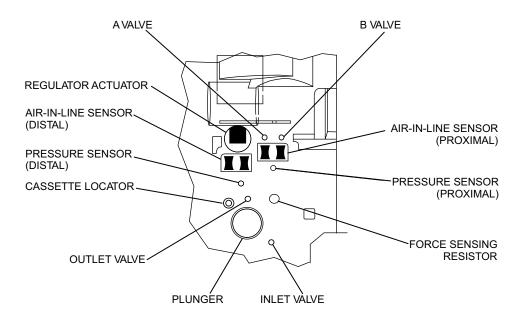


Figure 4-9. Mechanism Valve Pins and Sensor Locations

# 4.5.1.3 INLET/OUTLET VALVE SUBSYSTEM

The inlet/outlet valve subsystem is similar in function and build to the A/B valve subsystem (see Section 4.5.1.2).

# 4.5.1.4 PLUNGER DRIVE SUBSYSTEM

The main components of the plunger drive subsystem are plunger, lead screw and coupler, and stepper motor. When the infuser is turned on, the plunger moves from the retracted, PARK position to the HOME position. The cassette diaphragm is engaged. The stepper motor rotates approximately 1 2/3 revolutions per infuser cycle to permit a 0.33 mL fluid displacement every infuser cycle. The stepper motor then reverses and the plunger returns to HOME position. This cycle repeats for the duration of fluid administration.

The screw/coupler assembly links the motor and the plunger. This assembly includes a flag that passes through an interrupter module. This screw/coupler, flag/interrupter module combination is used in conjunction with predetermined factory calibration data to determine the plunger position. During operation, if the screw/coupler flag passes through the interrupter module at the incorrect time sequence, a motor phase loss is detected.

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#### Section 5

# MAINTENANCE AND SERVICE **TESTS**

A complete maintenance program promotes infusion system longevity and trouble-free operation. Such a program should include routine maintenance, periodic maintenance inspection, and the Performance Verification Test.

# 5.1 ROUTINE MAINTENANCE

Routine maintenance consists of basic inspection and cleaning procedures. As a minimum requirement, inspect and clean the infuser after each use. In addition, establish a regular cleaning schedule for the device.

# 5.1.1 CLEANING AND SANITIZING

Practice the cleaning and sanitizing guidelines in this section. Follow hospital protocol for establishing the infuser cleaning schedule.

Before cleaning, turn off the infuser and disconnect from AC power.

Clean the exposed surfaces of the infuser with a soft, lint-free cloth moistened with one of the cleaning solutions recommended in *Table 5-1*, or with a mild solution of soapy water. Remove soap residue with clear water. Use a small, non-abrasive brush to aid in cleaning the cassette door.



WARNING: DISCONNECT THE INFUSER FROM AC POWER PRIOR TO CLEANING THE DEVICE. FAILURE TO COMPLY WITH THIS WARNING COULD RESULT IN ELECTRICAL SHOCK.



CAUTION: To avoid mechanical or electronic damage, do not immerse !\text{!\text{!}} 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.

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

Table 5-1. Cleaning Solutions			
Cleaning Solution	Cleaning Solution Manufacturer		
Coverage <sup>TM</sup> HB	Steris	Per manufacturer's recommendation	
Dispatch <sup>TM</sup> Hospital Cleaner Disinfectant with Bleach	Caltech Industries	Per manufacturer's recommendation	
Manu-Klenz <sup>TM</sup>	Steris	Per manufacturer's recommendation	
Precise <sup>TM</sup> Hospital Foam Cleaner Disinfectant	Caltech Industries	Per manufacturer's recommendation	
Sani-Cloth <sup>TM</sup> HB Wipe	Professional Disposables	Per manufacturer's recommendation	
Sani-Cloth <sup>TM</sup> Bleach Wipe	Professional Disposables	Per manufacturer's recommendation	
Sporicidin <sup>TM</sup>	Sporicidin	Per manufacturer's recommendation	
Household Bleach (Sodium Hypochlorite)	Various	Use per hospital procedures  Do not exceed one part bleach in ten parts water	

Note: At the time of printing, Hospira recommends only the cleaning solutions in *Table 5-1*. For updated listings of approved cleaners, please visit www.hospiraparts.com.

# PERFORMANCE VERIFICATION TEST

The Performance Verification Test (PVT) consists of the tests described in the following sections. The PVT is designed to assure the infusion system is operating properly, and can also be used for diagnostic purposes during troubleshooting. The PVT should be used for performance verification before an infuser is placed back in service after repair.



Note: Perform the PVT exactly as described in this manual to assure effective and reliable product evaluation information.

If any malfunction is detected as a result of the PVT, see **Section 6**.

# 5.2.1 EQUIPMENT REQUIRED

The PVT requires the following equipment and materials, or equivalents:

- Graduated cylinder, 25 mL, with 0.2 mL graduations (Class A)
- Sterile water or tap water in an IV bag/container
- Digital Pressure Meter (DPM), 0 to 50 psi (Fluke<sup>TM</sup> Biomedical DPM3)
- Three-way stopcock, latex-free (List No. 3233-01)
- IV Set (List No. 11419)
- Secondary Piggyback Set (List No. 1832)
- 21-gauge butterfly needle, latex-free (List No. 4492-01), or 18-gauge blunt cannula
- Safety Analyzer (Fluke<sup>TM</sup> Biomedical 232D)
- Digital Multimeter (DMM) (Fluke<sup>TM</sup> 187)
- Nurse Call test cable (P/N 561-88416-001)

# 5.2.2 INSPECTION

Inspect the infusion system periodically for signs of defects such as worn accessories, broken connections, or damaged cables. In addition, inspect the infusion system after repair or during cleaning. Replace any damaged or defective external parts.

Inspect the following areas for missing or damaged parts:

- Labels
- AC power cord, retainer, and straps
- Rubber foot pads
- Door assembly and handle
- Keypad and display
- LEDs

- External screws
- Pole clamp assembly
- Front and rear enclosures
- Battery doors
- Peripheral interface assembly and components

# TEST SETUP



WARNING: A PATIENT SHOULD NEVER BE CONNECTED TO THE INFUSER DURING DEVICE TESTING.

To set up the infusion system for the PVT, proceed as follows:

- 1. Confirm the infuser and appropriate accessories are assembled.
- 2. Hang two sterile water containers at a height of  $18 \pm 6$  inches above the pumping chamber of the infuser.
- 3. Connect the infuser to AC power, and press [ON/OFF] to turn on the device.
- 4. Verify the infuser is in the unlocked mode. Toggling the [LOCKOUT] switch alternates between unlocked [DOWN] and locked [UP] modes.
- 5. Turn off the infuser.

#### 5.2.4

# **SELF TEST**



!\ CAUTION: Do not place the infuser in service if the self test fails.

Conduct all tests with the infuser connected to AC power unless otherwise specified.

If an alarm condition occurs during the self test, cycle the power and repeat the self test. If the alarm condition recurs, note the message and take corrective action (see Section 6). Repeat the self test. If the alarm condition continues to recur, remove the infuser from service and *contact Hospira*.

To perform the self test, see *Figure 5-1*, and proceed as follows:

- 1. Connect the AC power cord to a grounded AC outlet. Verify the charge/line indicator CHARGE illuminates and an alarm tone sounds.
- 2. Without a cassette installed, turn on the infuser.
- 3. The LCD screen briefly displays the SELF TEST screen (see Figure 5-1).
  - Note: The device may display a CCA selection screen. Choose a CCA and press [ENTER].
- 4. After the self test is complete, the message INSERT PLUM SET CLOSE LEVER appears.
- 5. Verify the time and date. To set the time and date, see Section 1.10.2.
- 6. Open the cassette door and insert a primed cassette. Close the cassette door. The cassette test is complete when the CASSETTE TEST IN PROGRESS message disappears.
  - Note: The message MECHANISM INITIALIZATION IN PROGRESS may briefly appear prior to the CASSETTE TEST IN PROGRESS message.
- 7. A **NEW PATIENT?** message may appear. Press **[YES]**, then turn off the device.

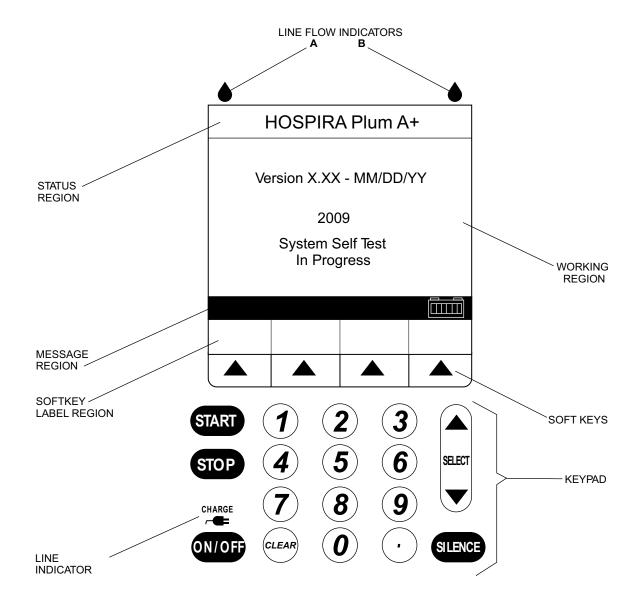


Figure 5-1. Display and Keypad

## CASSETTE ALARM TEST

To perform the cassette alarm test, proceed as follows:

- 1. Verify the infuser is on. Insert an empty cassette and close the door.
  - **Note:** The infuser may display a CCA selection screen. Choose a CCA and press [ENTER].
- 2. Verify the **CASSETTE TEST FAIL** message is flashing on the display and the alarm sounds after the cassette test is complete.
- 3. Open the door and remove the cassette.
- 4. Turn off the infuser.

#### 5.2.6

## FREE FLOW TEST

To perform the free flow test, proceed as follows:

- 1. With a primed cassette installed, turn on the infuser.
  - **Note:** The infuser may display a CCA selection screen. Choose a CCA and press **[ENTER]**.
  - 2. A **NEW PATIENT?** message may appear. Press **[YES]**.
  - 3. Place the distal end of tubing into a collection container a minimum of 36 inches below the cassette.
  - 4. With the cassette door closed, check the distal end of the tubing for fluid flow. Verify a minimal flow of fluid occurs (a few drops maximum).
  - 5. Open the cassette door and check the distal end of the tubing for fluid flow. Verify a minimal flow of fluid occurs (a few drops maximum).
    - Note: A small amount of fluid may be expelled from the cassette when opening or closing the door.
  - Close the cassette door.

#### 5.2.7

# **DISPLAY TEST**

To perform the display test, see *Figure 5-1*, and proceed as follows:

- 1. Verify the LCD backlight is illuminated and the display is clearly legible at eye level from approximately 18 inches.
- 2. With the infuser in the **DELIVERY** screen, press the **[OPTIONS/VOL INF]** softkey to select the **OPTIONS** screen.
- 3. Select Lighting/Contrast, and press [CHOOSE].
- 4. Use the [DECREASE SETTING] and [INCREASE SETTING] softkeys to change backlight intensity. Verify backlight intensity decreases and increases.
- 5. Select **Display Contrast**.

- 6. Press [DECREASE SETTING] and [INCREASE SETTING] to change display contrast. Verify the display contrast decreases and increases.
- 7. Press the **[CANCEL]** softkey to return to the **OPTIONS** screen.
- 8. Press the [BACK] softkey to return to the **DELIVERY** screen.

# KEYPAD VERIFICATION/FUNCTIONAL TEST

Note: The infuser may display override messages or hard limit restrictions, dependent on the current CCA selected. Select a different CCA, if necessary, to complete the keypad verification/functional test.

To perform the keypad verification/functional test, see *Figure 5-1*, and proceed as follows:

- 1. With the infuser in the **DELIVERY** screen, press the [A] softkey to select line A.
- 2. Verify the **PROGRAM** screen is displayed.
- 3. Enter a rate of 123 mL/hr and VTBI of 4567.
- 4. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 5. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 6. Press [STOP], then press and hold the [BACKPRIME] softkey.
- 7. Verify the BACKPRIMING and RELEASE BACKPRIME TO STOP messages are displayed, and verify the infuser is actually backpriming.
- 8. Release the [BACKPRIME] softkey, press [START], and verify normal pumping operation.
- 9. Press the [B] softkey.
- 10. Verify PIGGYBACK is the displayed delivery mode. If necessary, change the delivery mode by pressing the [CHANGE MODE] softkey.
- 11. Enter a rate of 890 mL/hr and VTBI of 2 mL.
- 12. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 13. Verify fluid is pumping, the message **PUMPING** is displayed in the line B status bar, and the line B LED flashes.
- 14. After 20 seconds, verify pumping has switched to line A.
- 15. Press [STOP].
- 16. Press [OPTIONS/VOL INF]. Select Volume Infused and press [CHOOSE].
- 17. Select line A.
- 18. Press [CLEAR]. Verify line A volume is 0 mL and press [ENTER].

# **ALARM LOUDNESS TEST**

To perform the alarm loudness test, proceed as follows:

- 1. Press the [A] softkey to select line A.
- 2. Enter a rate of 400 mL/hr and VTBI of 1 mL.
- 3. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 4. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 5. Verify the alarm sounds when the dose has been delivered.
- 6. Turn the volume control knob between **HIGH** and **LOW** (see Figure 5-2). Verify the alarm loudness changes.
- 7. Press the [SILENCE] key, and verify the alarm is silenced.
- 8. Press [STOP].

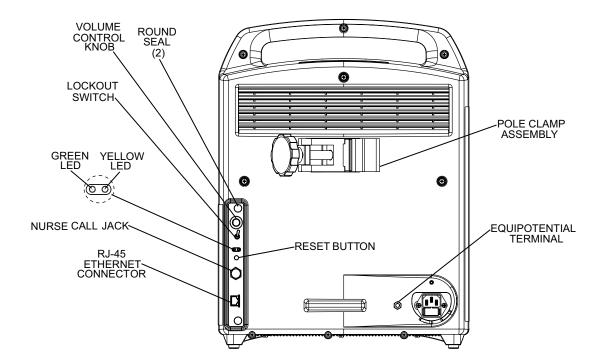


Figure 5-2. Rear View

## LOCKOUT SWITCH TEST

To perform the lockout switch test, proceed as follows:

- 1. Press the [A] softkey to select line A.
- 2. Enter a rate of 400 mL/hr and VTBI of 50 mL.
- 3. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 4. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 5. Toggle the lockout alarm switch up (ON) to engage the alarm (see Figure 5-2).
- 6. Press any key except [STOP], and verify an alarm sounds and the HARD LOCKOUT ENABLED message is displayed. Confirm the infuser continues to operate until [STOP] is pressed.
- 7. Press [STOP] and verify the HARD LOCKOUT VIOLATION message appears.
- 8. Toggle the lockout alarm switch down (OFF). Verify the **HARD LOCKOUT VIOLATION** message disappears and the alarm stops.
- 9. Press [START].
- 10. Open the door and verify the **DOOR OPEN WHILE PUMPING** message is displayed and the audio alarm activates.
- 11. Close the cassette door.
- 12. Press [NO] at the NEW PATIENT? prompt.

#### 5.2.11

## PROXIMAL OCCLUSION TEST

To perform the proximal occlusion test, proceed as follows:

- 1. Press the [A] softkey to select line A.
- 2. Enter a rate of 400 mL/hr and VTBI of 50 mL.
- 3. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 4. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 5. After several pumping cycles, clamp line A tubing proximal to the cassette. Verify the PROX OCCL A/AIR message flashes and the alarm sounds before three pumping cycles are completed.
- 6. Press **SILENCE** and verify the alarm stops while the message on the display continues to flash.
- 7. Unclamp the proximal line and press [START]. Verify pumping resumes.
- 8. Press [STOP].

# PROXIMAL AIR-IN-LINE TEST

To perform the proximal air-in-line test, see *Figure 5-3*, and proceed as follows:

- 1. Install the special cassette marked **proximal**, and close the cassette door.
  - Note: Confirm the special cassette proximal bubble sensor tips are removed.
- 2. A **NEW PATIENT?** message may appear. Press **[YES]**.
- 3. Press the [A] softkey to select line A.
- 4. Enter a rate of 400 mL/hr and VTBI of 50 mL.
- 5. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 6. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 7. Before 1 mL of fluid is delivered, verify the alarm sounds and the **PROX AIR A. BACKPRIME** message is flashing on the display.
- 8. Open the door and remove the special cassette.

#### 5.2.13

# **DISTAL AIR-IN-LINE TEST**

To perform the distal air-in-line test, see *Figure 5-3*, and proceed as follows:

- 1. Install the special cassette marked **distal**, and close the cassette door.
  - Note: Confirm the special cassette distal bubble sensor tips are removed.
- 2. A NEW PATIENT? message may appear. Press [YES].
- 3. Press the [A] softkey to select line A.
- 4. Enter a rate of 400 mL/hr and VTBI of 50 mL.
- 5. Press **[START]** and verify the **CONFIRM PROGRAM?** message is displayed. If rate and VTBI are correct, press **[YES]**.
- 6. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 7. Before 1 mL of fluid is delivered, verify the alarm sounds and the **N234 DISTAL AIR** message is flashing on the display.
  - Note: Older versions of the Plum A+3 may display the E234 DISTAL AIR message.
- 8. Open the door and remove the special cassette.

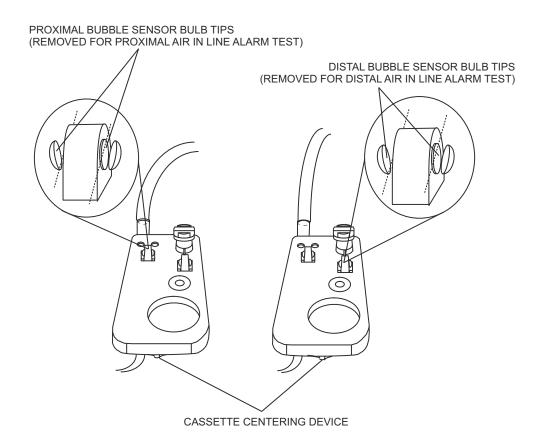


Figure 5-3. Special Cassettes with Bubble Sensor Tips Removed

#### DISTAL OCCLUSION TEST

To perform the distal occlusion test, see *Figure 5-4*, and proceed as follows:

- 1. Install the cassette and connect the distal tubing to the DPM through a three-way stopcock as illustrated in *Figure 5-4*. Close the cassette door.
  - Note: A reflux valve may be attached between the stopcock and the DPM to keep moisture out of the DPM.
  - **Note:** The height of the DPM must be  $0 \pm 12$  inches from the midline of the pumping chamber.
- 2. Turn on the infuser.
  - Note: The infuser may display a CCA selection screen. Choose a CCA and press [ENTER].
- 3. A NEW PATIENT? message appears. Press [YES].
- 4. Press [OPTIONS/VOL INF] to select the OPTIONS screen.
- 5. Select Pressure/Post Infusion Rate, and press [CHOOSE].
- 6. Verify the distal pressure limit is set at 6 psi. If the pressure limit is not 6 psi, enter 6, and press [ENTER].
- 7. Press the [A] softkey to select line A.
- 8. Enter a rate of 40 mL/hr and a VTBI of 50 mL.
- 9. Open the three-way stopcock to air.
- 10. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 11. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 12. Set the three-way stopcock to measure pressure.
- 13. Verify the distal occlusion audible alarm occurs at 6 psi  $\pm$  3 psi. Confirm the **DISTAL OCCLUSION** message is flashing on the screen.
- 14. Open the three-way stopcock to air.
- 15. Open and close the door. Press [NO] at the NEW PATIENT? prompt.
- 16. Press [OPTIONS/VOL INF] to select the OPTIONS screen.
- 17. Select Pressure/Post Infusion Rate and press [CHOOSE].
- 18. Select **Distal Pressure Limit**. Enter 10 psi, and press **[ENTER]**.
- 19. Set the three-way stopcock to measure pressure, then press [START].
- 20. Verify the distal occlusion audible alarm occurs at  $10 \text{ psi} \pm 3 \text{ psi}$ . Confirm the **DISTAL OCCLUSION** message is flashing on the screen.
- 21. Open the door and remove the cassette.

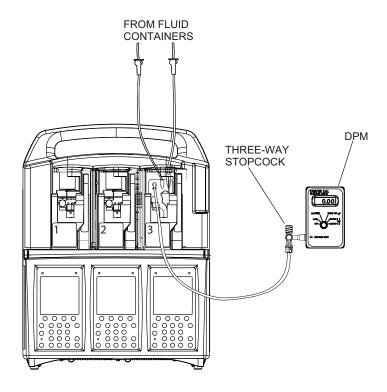


Figure 5-4. Distal Occlusion Test Setup

#### DELIVERY ACCURACY TEST

Accuracy testing is for informational purposes only, and is not to be used as a re-release test. If there is any concern as to infuser accuracy, *contact Hospira*.



!\ CAUTION: Do not remove the protective cover from the 21-gauge needle.

To perform the delivery accuracy test, see Figure 5-4, and proceed as follows:

- 1. Open the cassette door and insert a primed cassette. Close the cassette door.
- 2. The **NEW PATIENT?** message appears. Press [YES].
- 3. Install an 18-gauge blunt cannula or a 21-gauge needle to the distal end of the tubing. Verify the fluid container is 18 to 24 inches above the pumping chamber. Verify all lines are unclamped.
- 4. Place the distal output end of tubing into the graduated cylinder.
- 5. Press the [A] softkey to select line A.
- 6. Enter a rate of 200 mL/hr and VTBI of 10 mL.
- 7. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 8. Verify fluid is pumping, the message **PUMPING** is displayed in the line A status bar, and the line A LED flashes.
- 9. Press the [B] softkey to select line B.
- 10. Verify the infuser is in the PIGGYBACK delivery mode. If necessary, press [CHANGE MODE] to change the delivery mode.
- 11. Enter a rate of 200 mL/hr and VTBI of 10 mL.
- 12. Press [START] and verify the CONFIRM PROGRAM? message is displayed. If rate and VTBI are correct, press [YES].
- 13. Verify fluid is pumping, the message **PUMPING** is displayed in the line B status bar, and the line B LED flashes.
- 14. Verify the KVO message flashes on the display and an audible alarm sounds when total delivery is complete on line A.
- 15. Press [STOP] and verify the volume delivered is 20 mL  $\pm$  1 mL.

#### NURSE CALL TEST

The nurse call test may be bypassed if the nurse call function is not used.

To perform the nurse call test, attach the nurse call test cable and proceed as follows:

- 1. Set the primary delivery rate to 400 mL/hr and the primary dose limit to 1 mL.
- 2. Connect the DMM to the nurse call test cable.
- 3. Press [START] and verify pumping action.
- 4. After **DOSE END** and **KVO** appear on the display, observe a short circuit on the DMM (approximately 1  $\Omega$  on a scale of 0 to 100  $\Omega$ ).

#### 5.2.17

#### ELECTRICAL SAFETY TEST

**Note:** The electrical safety test must be performed in accordance with the instructions contained in the safety analyzer user's guide.

To perform the electrical safety test, see *Table 5-2*, and proceed as follows:

- 1. Connect the infusion system AC power cord to a safety analyzer.
- 2. Connect the safety analyzer ground lead to the ground test-point screw located on the rear of the infuser.
- 3. Check the leakage current with the safety analyzer. Leakage current must not exceed specifications in *Table 5-2*.
- 4. Measure the resistance of the AC (mains) connector ground lug with the safety analyzer. Resistance should not exceed specifications in *Table 5-2*.
- 5. Connect the device to AC power and ensure the AC indicator is lit.

Table 5-2. Electrical Safety Measurements	
Measurement	Not to Exceed
Enclosure leakage current normal condition (ground intact)	300 μΑ
Enclosure leakage current (open)	500 μΑ
Earth leakage current (ground intact)	500 μΑ
Earth leakage current (open)	1000 μΑ
Chassis ground resistance	0.2 Ω

### 5.2.18 END OF THE PVT

If any tests fail, see Section 6, or contact Hospira.

If all Performance Verification Tests have been successful, proceed as follows:

- 1. Press [OPTIONS/VOL INF]. Select Volume Infused and press [CHOOSE].
- 2. Press [CLEAR] to clear the volume infused, then press [ENTER].
- 3. Press the [A] softkey.
- 4. Press [YES] at the CLEAR LINE A SETTINGS? prompt.
- 5. Press the [CANCEL/BACK] softkey to return to the delivery screen.
- 6. Press the [B] softkey.
- 7. Press [YES] at the CLEAR LINE B SETTINGS? prompt.
- 8. Reset the infuser to the original configuration.
- 9. Turn off the infuser, and return the device to service.

## 5.3

## PERIODIC MAINTENANCE INSPECTION

Periodic maintenance inspections should be performed per hospital procedures for compliance to accreditation requirements. It is recommended that JCAHO and/or hospital protocol be followed for establishing a periodic maintenance inspection schedule. Product specifications for this inspection are listed in *Section 8*.

To perform the periodic maintenance inspection, complete the PVT in Section 5.2.

## **BATTERY OPERATION OVERVIEW**

The infusion system is intended to operate on battery power on an exception basis only, such as emergency backup or temporary portable operation. Examples of emergency backup include AC power failure and inadvertent disconnection of the AC power cord. An instance of temporary portable operation includes patient transfer from one location to another.

The device should be connected to AC power whenever possible to allow the battery to remain fully charged. The line power indicator turns off when the infuser is operating on battery power. The backlight extinguishes after approximately one minute of operation on battery power.

Factors that most commonly affect battery life are the depth and frequency of discharge and the length of the recharge period. As a general rule, the more often the battery is discharged and recharged, the sooner it will need replacement.

The primary cause of damage is leaving the battery in a less than fully charged state for any period of time. Battery damage can occur in a matter of hours and cause a permanent loss of battery capacity. The amount of lost capacity depends on the degree of discharge, the storage temperature, and the length of time the battery was stored in a discharged state.

**Note:** A permanently damaged battery cannot be recharged to full capacity.

When the battery discharges below the acceptable level while the infuser is operating, the audio indicator is activated and the WARNING: LOW BATTERY message displays. Although it is not recommended to continue operating the infuser on battery power at this point, the battery continues providing power until it is depleted. When the battery is depleted, delivery stops, a continuous alarm tone sounds, and, after three minutes, the infuser automatically turns off.



CAUTION: As soon as the low battery alarm occurs, connect the infuser

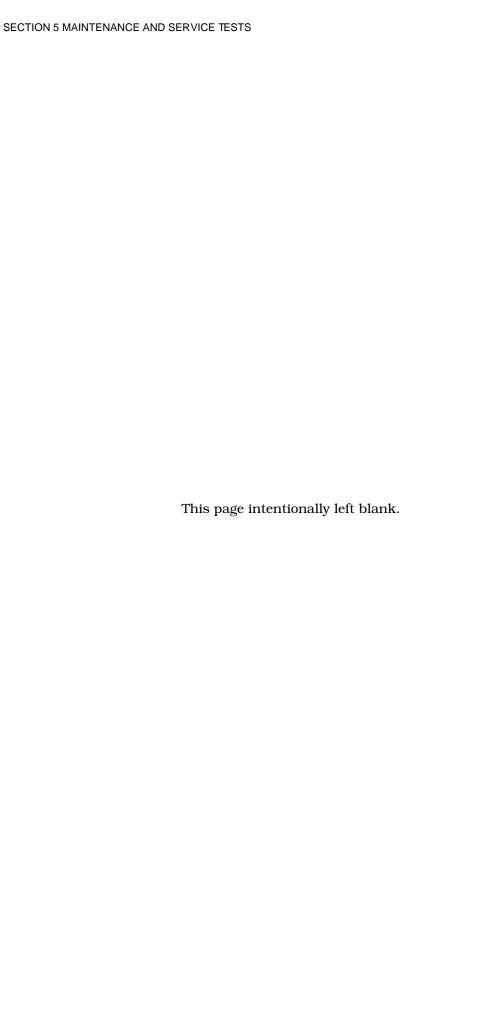
When the infuser detects that the battery has reduced capacity, it will register a **Replace Battery** condition. For the first two occurrences of a Replace Battery condition, the WARNING: LOW BATTERY message will appear and the audio indicator will activate. The message and audio indicator can be cleared only when the device is plugged in or turned off. For the third and subsequent occurrences, the WARNING: REPLACE BATTERY message will appear, and the audio indicator will activate and persist over power cycles.

The message and audio indicator are cleared by replacing the battery, accessing the Biomed Settings screen, and pressing the [CHANGE BATTERY] softkey.

Recharging can occur any time the infuser is connected to AC power. It is recommended that the infuser be connected to AC power whenever practical to maximize available battery charge during transport or ambulation. The infuser does not have to be on for the battery to recharge.



Note: The infuser should be operated on battery power for three continuous hours at least once every six months for optimum battery performance and life.



#### Section 6

## TROUBLESHOOTING

This section contains information on technical assistance, warning messages, alarm messages and error codes, and troubleshooting procedures.

### 6.1

## TECHNICAL ASSISTANCE

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 technical assistance, technical training, and product information, visit the website at *www.hospira.com*.

For technical assistance, product return authorization, and to order parts, accessories, or manuals from outside the United States, contact the nearest Hospira sales office.

## 6.2

## WARNING MESSAGES

*Table 6-1* lists warning messages, possible causes, and corrective actions. These warning messages are captured in the Error Log.

Note: When the infuser detects that the battery has reduced capacity, it will register a Replace Battery condition. For the first two occurrences of a Replace Battery condition, the WARNING: LOW BATTERY message will appear and the audio indicator will activate. The message and audio indicator can be cleared only when the device is plugged in or turned off. For the third and subsequent occurrences, the WARNING: REPLACE BATTERY message will appear, and the audio indicator will activate and persist over power cycles. The message and audio indicator are cleared by replacing the battery, accessing the Biomed Settings screen, and pressing the [CHANGE BATTERY] softkey.

**Note:** If the device is not plugged in, and turned on with a previously depleted battery, the infuser will display a **DEPLETED BATTERY** message for 12 seconds ± 3 seconds, then power off.

	Table 6-1. Warning Messages			
Message	Possible Cause Corrective Action			
Stop delivery, then turn off	Attempting to turn off the infuser while a delivery is in progress	Stop all lines, then turn off the infuser		
Warning: Low Battery	Battery is discharged so that only approximately 30 minutes of battery life remain	Plug into AC power		
Warning: Replace Battery	Battery service needed  Battery voltage is less than the depleted threshold and the charge level is higher than the low charge threshold	Replace the battery (see Section 7.2.4)		
Warning: Charger Service	A hardware problem with the battery charging circuit is detected  Charging circuitry is not behaving as expected	Press [SILENCE]		

6.3

## **ALARM MESSAGES AND ERROR CODES**

Under most alarm conditions the infuser ceases normal operation, generates an audible alarm, and displays an alarm message or error code on the LCD screen.

There are two types of alarm conditions:

- alarm codes that can be cleared by the operator
- error codes that require qualified service personnel

#### 6.3.1

#### OPERATIONAL ALARM MESSAGES

*Table 6-2* lists infuser alarm codes that can be cleared by the operator. Also listed in *Table 6-2* are the alarm messages, descriptions, possible causes, and corrective actions.

Note: Operational alarm messages are displayed on the LCD screen. Associated error codes are displayed in the Alarms Log (see Section 1.10.1).

	Table 6-2. Opera	ational Alarm Messages	s and Corrective Acti	ons
Alarm Code	Alarm	Description	Possible Cause	Corrective Action
<b>N100</b> (URC)	Unrecognizable cassette	Incorrect cassette type	An incorrect cassette is inserted	Insert proper cassette
<b>N101</b> (NAA)	No action	No operator action and no delivery for two minutes during delivery parameters entry	Interruption or a partial change to a program	Complete programming
<b>N102</b> (RL)	Infuser idle 2 minutes	Infuser in reset or idle for over two minutes	Programming set without start for two minutes	Press [START]
N103 (SEEP CRC)	NV RAM lost thrpy data	Therapy data is lost	Infuser did not complete the previous non-volatile memory write successfully	Re-enter all programmed data
N104 (NC2)	Nurse callback B	Delivery line B has changed (if alarm is enabled)	End of delivery step on line B other than VTBI complete while callback is enabled	Press [SILENCE]
<b>N105</b> (NC1)	Nurse callback A	Delivery line A has changed (if alarm is enabled)	End of delivery step on line A other than VTBI complete while callback is enabled	Press [SILENCE]
N160 or E160 (VTB2)	Line B VTBI complete	Programmed VTBI completed on line B	VTBI complete on line B	Press [SILENCE], replace IV bag, and restart line B
N161 or E161 (VTB1)	Line A VTBI complete	Programmed VTBI completed on line A	VTBI complete on line A	Press [SILENCE], replace IV bag, and restart line A
N180 or E180 (OD1)	Distal Occl	Peak distal occlusion, non-delivery	Distal occlusion detected during non-delivery	Backprime the cassette and restart the infuser
N181 or E181 (OD1)	Distal Occl	Negative distal occlusion, non-delivery	Distal occlusion detected during non-delivery	Backprime the cassette and restart the infuser
N182 or E182 (OP2)	Prox. Occl B, Air or Prox. Occl B	Negative proximal occlusion B, non-delivery	Proximal occlusion detected on line B during non-delivery	Backprime the cassette and restart line B or Stop all lines, backprime the cassette, and restart all lines

	Table 6-2.	Opera	tional Alarm Messages	and Corrective Acti	ons
Alarm Code	Alarm		Description	Possible Cause	Corrective Action
N183 or E183 (OP2)	Prox. Occl B, or Prox. Occl B	Air	Peak proximal occlusion B, non-delivery	Proximal occlusion detected on line B during non-delivery	Backprime the cassette and restart line B or Stop all lines, backprime the cassette, and restart all lines
N184 or E184 (OP1)	Prox. Occl A, or Prox. Occl A	Air	Negative proximal occlusion A, non-delivery	Proximal occlusion detected on line A during non-delivery	Backprime the cassette and restart line B or Stop all lines, backprime the cassette, and restart all lines
N185 or E185 (OP1)	Prox. Occl A, or Prox. Occl A	Air	Peak proximal occlusion A, non-delivery	Proximal occlusion detected on line A during non-delivery	Backprime the cassette and restart line A or Stop all lines, backprime the cassette, and restart all lines
N186 or E186 (OD1)	Distal Occl		Peak distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser
N187 or E187 (OD1)	Distal Occl		Negative distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser
N188 or E188 (OP2)	Prox. Occl B,	Air	Negative proximal occlusion B, delivery	Proximal occlusion detected during delivery on line B	Fix occlusion, and restart line B or Stop all lines, fix occlusion, and restart the infuser
N189 or E189 (OP2)	Prox. Occl B,	Air	Peak proximal occlusion B, delivery	Proximal occlusion detected during delivery on line B	Fix occlusion, and restart line B or Stop all lines, fix occlusion, and restart the infuser
N190 or E190 (OP1)	Prox. Occl A,	Air	Negative proximal occlusion A, delivery	Proximal occlusion detected during delivery on line A	Fix occlusion, and restart line A or Stop all lines, fix occlusion, and restart the infuser

	Table 6-2. Opera	tional Alarm Messages	s and Corrective Acti	ons
Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N191 or E191 (OP1)	Prox. Occl A, Air	Peak proximal occlusion A, delivery	Proximal occlusion detected during delivery on line A	Fix occlusion, and restart line A or Stop all lines, fix occlusion, and restart the infuser
N230 or E230 (APT)	Prox. Air total	Proximal air-in-line total	500 μL of air has entered the cassette	Backprime the cassette and restart the infuser or Remove and manually reprime the cassette, and restart the infuser
N231 or E231 (APB)	Prox. Air on B, backprime	Proximal air-in-line on line B	500 μL of air has entered the cassette on line B	Backprime the cassette and restart line B or Remove and manually reprime the cassette and restart the infuser
N232 or E232 (APA)	Prox. Air on A, Backprime	Proximal air-in-line on line A	500 μL of air has entered the cassette on line A	Backprime the cassette and restart line A or Remove and manually reprime the cassette and restart the infuser
N233 or E233 (ADC)	Distal air cumulative	Distal air cumulative	500 μL of air detected in the last 5.3 mL of fluid delivered	Remove and manually reprime the cassette and restart the infuser
N234 or E234 (ADB)	Distal air bolus	Distal air bolus	100 μL bolus of air detected at distal sensor	Remove and manually reprime the cassette and restart the infuser
N250 or E250 (DCO1)	Door opened while pumping	Door opened while pumping	Door opened while pumping	Turn off the infuser or Insert the cassette and close the door
N251 or E251 (CS1)	Valve/cass test fail	Valve/cassette test failure	Valve/cassette fails leak test	Backprime and retest or Replace the cassette and retest or Replace the mechanism

	Table 6-2. Operational Alarm Messages and Corrective Actions				
Alarm Code	Alarm	Description	Possible Cause	Corrective Action	
N252 or E252 (BDP)	Depleted battery	Low battery	Battery terminal voltage is less than 5.45 V	Connect the infuser to AC power or Recharge or replace the battery	
N253 or E253 (LOV)	Lockout Violation	Hard lockout violation	The use of the [STOP] key or an attempt to open the door while lockout switch is locked	Unlock the lockout switch	
<b>N254</b> or <b>E254</b> (FPL)	Lockout Enabled	Keypad locked	Any action not resulting in stopping of delivery while lockout switch is locked	Unlock the lockout switch	
<b>N255</b> (SLV)	Lockout violation	Soft lockout violation	The use of the [STOP] key or an attempt to open the door while lockout switch is locked	Unlock the software lockout switch	
<b>N256</b> (SLE)	Lockout enabled	Soft lockout enabled	Any action not resulting in stopping of delivery while lockout switch is locked	Unlock the software lockout switch	
-	No alarm	Unrestricted flow	If the regulator closer is disengaged and the door opens, you may experience unrestricted flow	Remove mechanism     Remove flow shield     Visually inspect regulator closer     Verify regulator closer is completely engaged     Test. If unrestricted flow persists, replace the mechanism	

#### 6.3.2

## ERROR CODES REQUIRING TECHNICAL SERVICE

*Table 6-3* lists infusion system error codes that require technical service. Also listed in *Table 6-3* are malfunction descriptions, possible causes, and corrective actions.



CAUTION: Peripheral interface assembly replacement should be performed only after receiving approval from Hospira.

	Table 6-3.	Error Codes Requiring Technical	Service
Error Code	Malfunction	Possible Cause	Corrective Action
E300	ADC failure	Analog to digital converter failure	Replace CPU PWA (see Section 7.2.14)  Reset time and date, if required (see Section 1.10.2)
E301	Audio alarm failure	Piezo is off but sensed on or Piezo is on but sensed off	Turn power off, then on, to reset the infuser  Replace piezo alarm (see Section 7.2.14.7)  Replace CPU PWA (see Section 7.2.14.6)  Reset time and date, if required (see Section 1.10.2)
E302	Backlight failure	Backlight (CCFT tube) is not at the expected range	Turn power off, then on, to reset the infuser  Replace display assembly (see Section 7.2.14.3)  Reset time and date, if required (see Section 1.10.2)
E320	Battery charge current out of range	Battery charge current is out of range after 8 hours	Replace battery (see Section 7.2.4)  Replace power supply PWA (see Section 7.2.14.1)  Reset time and date, if required (see Section 1.10.2)
E321	Battery not charging	Battery charging timed out Complete battery discharge has occurred	Charge battery for additional eight hours  Replace battery (see Section 7.2.4)
E322	Battery current calibration value out of range	Battery integrator calibration value is out of range	Replace power supply PWA (see Section 7.2.14.1) Reset time and date, if required
E323	Battery trickle charge current out of range	Battery trickle charge current is out of range	(see Section 1.10.2)
E324	Supply overvoltage	An overvoltage condition is detected in the charging circuit	
E325	Battery overvoltage	An overvoltage condition is detected in the battery	

	Table 6-3.	Error Codes Requiring Technical	Service
Error Code	Malfunction	Possible Cause	Corrective Action
E326	Battery disconnected	Battery disconnected while the infuser is on	Check for loose battery connections  Replace battery (see Section 7.2.4)
			Reset time and date, if required (see Section 1.10.2)
E327	Brownout condition	Brownout condition detected	Replace power supply PWA (see Section 7.2.14.1)
			Reset time and date, if required (see Section 1.10.2)
E340	Critical instruction failure	Power-up CPU register test failed (no malfunction message	Replace CPU PWA (see Section 7.2.14.6)
		displayed)	Reset time and date, if required (see Section 1.10.2)
E341	Critical data memory failure	Critical data memory failure	Replace mechanism assembly (see Section 7.2.14.8)
			Reset time and date, if required (see Section 1.10.2)
E342	Display failure	Defective display	Replace display assembly (see Section 7.2.14.3)
			Reset time and date, if required (see Section 1.10.2)
E343	Distal air sensor failure 1	With the cassette removed, the distal air sensor self test detects liquid	Replace mechanism assembly (see Section 7.2.14.8)  Reset time and date, if required
E344	Distal air sensor failure 2	With the cassette inserted, the distal air sensor self test detects sensor out of range	(see Section 1.10.2)
E345	Distal pressure sensor failure 1	Distal pressure sensor failed while the infuser is off	
E346	Distal pressure sensor failure 2	Distal pressure sensor failed while the infuser is on	
E347	Hardware watchdog	Hardware watchdog failure	Replace CPU PWA (see Section 7.2.14.6)
	failure		Reset time and date, if required (see Section 1.10.2)
E378	I/O valve phase loss	Generic I/O valve failure	Turn power off, then on, to reset the infuser
			Replace CPU PWA (see Section 7.2.14.6)
			Replace mechanism assembly (see Section 7.2.14.8)
			Reset time and date, if required (see Section 1.10.2)

	Table 6-3. Error Codes Requiring Technical Service				
Error Code	Malfunction	Possible Cause	Corrective Action		
E379	L/S valve phase loss	Generic L/S valve failure	Turn power off, then on, to reset the infuser		
E380	Plunger motor phase loss	Generic plunger motor failure	Replace CPU PWA (see Section 7.2.14.6)  Replace mechanism assembly		
			(see Section 7.2.14.8)		
			Reset time and date, if required (see Section 1.10.2)		
E430	Proximal air sensor failure 1	Proximal air sensor ongoing test detects liquid with cassette	Replace mechanism assembly (see Section 7.2.14.8)		
		removed	Reset time and date, if required		
E431	Proximal air sensor failure 2	Proximal air sensor self test detects liquid with cassette removed	(see Section 1.10.2)		
E432	Proximal pressure sensor 1	Proximal pressure sensor failed while the infuser is off			
E433	Proximal pressure sensor 2	Proximal pressure sensor failed while the infuser is on			
E434	RAM failure	RAM failure	Turn power off, then on, to reset the infuser		
			Replace peripheral interface assembly (see Section 7.2.9)		
			Reset time and date, if required (see Section 1.10.2)		
E435	RTC failure	Real-time clock failure	Turn power off, then on, to reset the infuser		
			Replace CPU PWA (see Section 7.2.14.6)		
			Reset time and date, if required (see Section 1.10.2)		
E436	ROM failure	ROM checksum failure	Turn power off, then on, to reset the infuser		
			Replace peripheral interface assembly (see Section 7.2.9)		
			Reset time and date, if required (see Section 1.10.2)		

	Table 6-3. Error Codes Requiring Technical Service					
Error Code	Malfunction	Possible Cause	Corrective Action			
E437	Software failure	Generic software failure	Turn power off, then on, to reset the infuser			
<b>E437</b> Sub- Category	Processor reset or restarted while in the <b>ON</b> state	AC power removed when the battery is disconnected or completely depleted	Replace CPU PWA (see Section 7.2.14.6)			
13		Hardware or software failure disrupts the operation of the processor or causes the watchdog timer to restart the processor while the device is in operation	Reset time and date, if required (see Section 1.10.2)			
		Peripheral interface assembly is removed while the device is turned on				
E438	Stack out-of-range failure	Stack out-of-range failure				
E439	Stuck key	A key is sensed as pressed for over two minutes	Replace keypad (see Section 7.2.14.2)			
E440	Power hold stuck	Power hold signal stuck Power cannot be turned off	Reset time and date, if required (see Section 1.10.2)			
E443	LCD failure	LCD bias is out of range	Replace display assembly (see Section 7.2.14.3)			
			Reset time and date, if required (see Section 1.10.2)			
E444	CPU timebase inaccurate	CPU timer 2 and RTC measured times disagree	Turn power off, then on, to reset the infuser			
			Replace CPU PWA (see Section 7.2.14.6)			
			Reset time and date, if required (see Section 1.10.2)			
E445	RTC memory failure	Real-time clock memory corrupt	Turn power off, then on, to reset the infuser			
			Reset time and date, if required (see Section 1.10.2)			
E446	CPU timer failure	CPU timer 1 and timer 2 measured times disagree	Replace CPU PWA (see Section 7.2.14.6)			
E447	Battery ADC reading failure	16 consecutive readings have been either all zero or max value	Reset time and date, if required (see Section 1.10.2)			
E448	SEEP write failure	SEEP data write failed	Replace mechanism assembly (see Section 7.2.14.8)			
E449	SEEP calibration data corrupted	Calibration data block corrupted	Replace CPU PWA (see Section 7.2.14.6)			
			Replace CPU/driver cable (see Section 7.2.14.4)			
			Reset time and date, if required (see Section 1.10.2)			

Table 6-3. Error Codes Requiring Technical Service			
Error Code	Malfunction	Possible Cause	Corrective Action
E450	MMIO port read/write failure	I/O port read/write failure	Replace CPU PWA (see Section 7.2.14.6) Reset time and date, if required (see Section 1.10.2)
E451	Inaccurate delivery	Over/under delivery detected	Turn power off, then on, to reset the infuser
E452	Software failure	Miscellaneous software failures	Reset time and date, if required (see Section 1.10.2)  If error codes recur, contact Hospira
E453	Two SEEP CRC errors	NVRAM data block corrupted	Replace mechanism assembly (see Section 7.2.14.8)
E454	NVRAM over capacity	Software trying to write into non-existent NVRAM space	Replace CPU PWA (see Section 7.2.14.6)  Replace CPU/driver cable (see Section 7.2.14.4)  Reset time and date, if required (see Section 1.10.2)
E455	Invalid device configuration	Incorrect flash memory on peripheral PWA	Turn power off, then on, to reset the infuser Replace peripheral PWA (see Section 7.2.11)
E456	Invalid drug library	A drug library install was started but not completed successfully	Attempt to reinstall the drug library (see the System Operating Manual)  Replace peripheral interface assembly (see Section 7.2.9)
E457	Drug library corrupted	CRC failure on drug library	Reload the library (see the System Operating Manual)

The following error codes are not generated in the Biomed service mode.

E320	E323	E326	E346	E373	E376	E379	E431	E441
E321	E324	E343	E371	E374	E377	E380	E432	E447
E322	E325	E345	E372	E375	E378	E430	E433	



Note: Some error codes include sub-ID codes. These sub-ID codes are intended for Hospira internal use only, and should be included when contacting Hospira.

### 6.4

## TROUBLESHOOTING PROCEDURES

This section details recommended procedures for problems not associated with malfunction alarms.

Note: See Section 6.4.1 for unrestricted flow.

Before performing any troubleshooting procedure, turn the infuser off, then on.

Allow the self test to complete and proceed as follows:

- 1. If a malfunction exists, carefully inspect the infuser for damage as described in Section 5.2.2.
- 2. If an infuser inspection has not disclosed a malfunction, perform the PVT in Section **5.2.** See *Table 6-4* for section reference, probable cause, and corrective actions.
- 3. If after completing step 1 and step 2, a malfunction has not been located, or if the infuser persistently fails, contact Hospira.

CAUTION: Peripheral interface assembly replacement should be performed only after receiving approval from Hospira.

Table 6-4. Troubleshooting with the PVT			
Test Failure	Probable Cause	Corrective Action	
Self Test	Cassette not properly installed	Reseat cassette	
(Section 5.2.4)	Defective CPU PWA	Replace CPU PWA (see Section 7.2.14.6)	
Cassette Alarm Test	Cassette not properly seated	Reseat cassette	
(Section 5.2.5)	Defective cassette	Replace cassette	
Free Flow Test	Cassette not properly seated	Reseat cassette	
(Section 5.2.6)	Defective cassette	Replace cassette	
	Defective or dirty valve pins	Clean valve pins	
		Replace mechanism assembly (see Section 7.2.14.8)	
Display Test (Section 5.2.7)	Defective display assembly	Replace display assembly (see Section 7.2.14.3)	
Keypad Verification/Functional Test	Defective keypad	Replace keypad (see Section 7.2.14.2)	
(Section 5.2.8)			
Alarm loudness test (Section 5.2.9)	Defective CPU	Replace CPU PWA (see Section 7.2.14.6)	
	Defective peripheral interface PWA	Replace peripheral interface assembly (see Section 7.2.9)	
	Defective piezo alarm assembly	Replace piezo alarm assembly (see Section 7.2.14.7)	

Table 6-4. Troubleshooting with the PVT			
Test Failure	Probable Cause	Corrective Action	
Lockout Switch Test (Section 5.2.10)	Defective peripheral interface PWA	Replace peripheral interface assembly (see Section 7.2.9)	
Proximal Occlusion Test	Closed proximal clamp	Open clamp	
(Section 5.2.11)	Cassette not properly primed	Re-prime cassette	
	Defective cassette	Replace cassette	
	Dirty sensor pin	Clean sensor pin	
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.14.8)	
Proximal Air-in-Line Test	Defective special cassette	Replace special cassette	
(Section 5.2.12)	Dirty sensors	Clean sensors	
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.14.8)	
Distal Air-in-Line Test	Defective special cassette	Replace special cassette	
(Section 5.2.13)	Dirty sensors	Clean sensors	
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.14.8)	
Distal Occlusion Test	Cassette not properly primed	Re-prime cassette	
(Section 5.2.14)	Defective cassette	Replace cassette	
	Dirty sensor pin	Clean sensor pin	
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.14.8)	
Delivery Accuracy Test	Set not properly primed	Re-prime cassette	
(Section 5.2.15)	Damaged or faulty cassette	Replace cassette	
	Defective mechanism assembly	Replace mechanism assembly (see Section 7.2.14.8)	
Electrical Safety Test	Defective AC power cord	Replace AC power cord (see Section 7.2.5)	
(Section 5.2.16)		(See Section 7.2.3)	

6.4.1

### **UNRESTRICTED FLOW**



WARNING: UNRESTRICTED FLOW MAY BE LIFE-THREATENING.



CAUTION: Prevent unrestricted flow by ensuring that the regulator closer is properly seated. If unable to ensure this, discontinue use and contact Hospira.

Unrestricted flow may occur if the infuser's regulator closer is not seated correctly and the cassette is removed from the device without ensuring that the roller clamp or slide clamp on the administration set is in the closed position.

To prevent an unrestricted flow event, see *Figure 6-1*, and proceed as follows:

- 1. Remove the mechanism and fluid shield as described in *Section 7.2.14.8* and *Section 7.2.14.9*.
- 2. Visually inspect the regulator closer and verify the regulator closer is completely seated.
- 3. If the regulator closer is not completely seated, discontinue use and contact Hospira.
- 4. If the regulator closer is completely seated, reassemble the device and perform the PVT in *Section 5.2*.

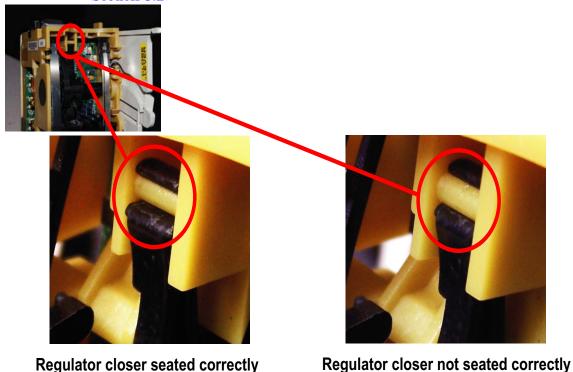


Figure 6-1. Regulator Closer

#### 6.4.2

## RESETTING THE ETHERNET IP ADDRESS AND SUBNET MASK

This section applies to List Number 20791-04 and above, and List Number 20677-04 and above.

If the CE has been misconfigured and WebConfig cannot communicate with the CE, the **Reset** button can be used to reset the Ethernet IP address (192.168.0.100) and Subnet Mask (255.255.0.0) to the factory default (see Figure 6-2).

To reset the Ethernet IP address and Subnet Mask, proceed as follows:

- 1. Turn on the infuser, and connect to Ethernet.
- 2. Confirm the configuration is **not** the factory default.
- 3. Turn off the infuser, disconnect from AC power, and wait two minutes.
- 4. Press and hold the **Reset** button.
- 5. Connect the infuser to AC power and start the timer.
- 6. Release the **Reset** button after a measured 20 seconds.
- 7. Wait two minutes for the CE to completely reboot.
- 8. Verify that the infuser network is now set to the factory default.

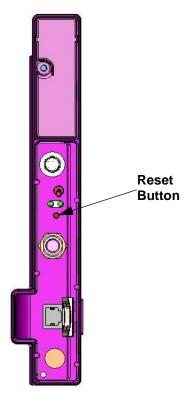


Figure 6-2. Reset Button

#### Section 7

## REPLACEABLE PARTS AND REPAIRS

This section itemizes all parts and subassemblies of the infusion system that are repairable within the scope of this manual. In addition, this section details replacement procedures for all listed parts.

## 7.1

## REPLACEABLE PARTS

Replaceable parts for the infusion system are itemized in the Illustrated Parts Breakdown (IPB) and are identified in *Figure 9-1*. *Table 9-2* identifies each part by an index number that correlates to *Figure 9-1*.

To view the online replacement parts list, visit the website at www.hospiraparts.com.

## 7.2

## REPLACEMENT PROCEDURES

This section contains safety and equipment precautions, required tools and materials, and step-by-step procedures for replacing parts in the infuser. Unless otherwise stated, always perform the PVT after a replacement procedure.

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

#### 7.2.1

## SAFETY AND EQUIPMENT PRECAUTIONS

Before opening the front enclosure of the infuser, take all necessary precautions for working on high-voltage equipment.



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



WARNING: UNLESS OTHERWISE INDICATED, DISCONNECT THE INFUSER FROM AC POWER BEFORE PERFORMING ADJUSTMENT OR REPLACEMENT PROCEDURES.



CAUTION: Use proper ESD grounding techniques when handling ! components. Wear an antistatic wrist strap and use an ESD-protected workstation. Store PWAs in antistatic bags before placing on any surface.

## REQUIRED TOOLS AND MATERIALS

The following tools and materials, or equivalents, are required for the replacement procedures in this section. In addition, the beginning of each procedure lists tools and materials recommended for that specific procedure.

- Set of flat blade screwdrivers

- Set of Phillips screwdrivers

- Set of standard and metric nutdrivers

- Set of Allen wrenches

- Metric 10 mm wrench

- Battery cable connector tool (P/N 519-89318-001) - Lint-free cloth

- Custom nutdriver (P/N 519-95056-001)

- Long needle nose pliers

- Wide-head pliers

- Diagonal cutters

- X-acto® knife

- Mild solvent

### 7.2.3

### RUBBER FOOT PAD REPLACEMENT

The recommended tool for this procedure is a #2 Phillips screwdriver.

Replacement parts for this procedure are:

Pad, Rubber Foot Screw, 6-32 x 1/2, Pan Head, Phillips Washer, Lock, #6

To replace a rubber foot pad, see *Figure 7-1*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Place the infuser face down on a soft flat surface.
- 3. Using the Phillips screwdriver, remove the screw and lock washer that secure the rubber foot pad.
- 4. Install the replacement rubber foot pad in the exact reverse order of removal.

Replacement of a rubber foot pad is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during the procedure, perform the PVT in **Section 5.2**.

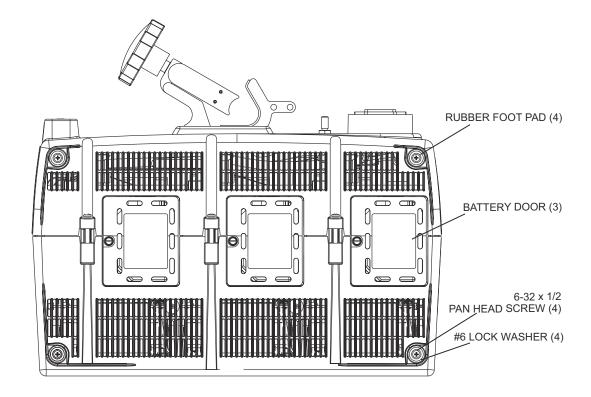


Figure 7-1. Bottom View

## BATTERY, WIRE HARNESS, DOOR, AND DOOR PAD REPLACEMENT

Recommended tools for this procedure are:

- Medium size flat blade screwdriver
- Long needle nose pliers
- X-acto knife
- Battery cable connector tool (P/N 519-89318-001), or equivalent
- Mild solvent
- Lint-free cloth

Replacement parts for this procedure are:

Assembly, Battery Assembly, Wire Harness, Battery Door, Battery Pad, Door Ring, Retaining Screw, 6-32 x 1/2, Hex Head, Slotted, with Washer

To replace a battery, wire harness, door, or door pad, see Figure 7-2, then proceed as follows:

1. Turn off the infuser and disconnect the device from AC power. The AC LED indicator will turn off.



Note: Wait five minutes for the microprocessor to save data and complete the turn off sequence before unplugging the battery.

- 2. Place the infuser face down on a soft flat surface.
- 3. Using the flat blade screwdriver, remove the screw and retaining ring that attaches the battery door to the infuser, and remove the door.
- 4. Inspect the battery door and replace, if required.
- 5. If the battery door pad is defective, remove it and clean the door with mild solvent. Dry the battery door thoroughly, and install the replacement pad on the door.
- 6. Disconnect the battery harness from the charger circuit cable. Carefully pull the battery harness wires and connector outside the enclosure, and remove the battery.
- 7. Using the needle nose pliers, remove the wire harness connectors from the battery terminals.
- 8. Using the battery cable connector tool, install the wire harness connectors onto the terminals of the replacement battery. Confirm the red wire is installed on the positive (+) terminal next to the red marker on top of the battery, and the black wire is installed on the negative (-) terminal.



/ CAUTION: Do not allow the terminals to come into contact with each other.

- 9. Connect the replacement battery harness to the charger circuit cable, and insert the replacement battery into the enclosure. The cable connectors are keyed so that cables cannot be connected incorrectly.
  - **Note:** Confirm the battery harness is not pinched between the battery and the enclosure.
- 10. Replace the battery door using the screw and retaining ring that were removed in step 3.
- 11. Press **[ON/OFF]** with the infuser disconnected from AC power, and verify the front panel battery symbol illuminates.
- 12. Access the **BIOMED SETTINGS** screen and press [CHANGE BATTERY].

Replacement of the battery door and door pad is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in *Section 5.2*.

## AC POWER CORD, RETAINER, AND VELCRO STRAP **REPLACEMENT**

Note: The AC power cord and power cord retainer must be compatible, based on part number pairings. contact Hospira for compatible part numbers.

The recommended tool for this procedure is a #2 Phillips screwdriver.

Replacement parts for this procedure are:

Cordset, AC Power, Hospital Grade, Detachable Retainer, AC Power Cord Strap, Velcro, AC Power Cord Screw, 4-40 x 3/8, Pan Head, Phillips

To replace the AC power cord, retainer, or Velcro strap, see *Figure 7-2*, then proceed as follows:

- 1. Turn off the infuser, and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Using the Phillips screwdriver, remove the screw from the AC power cord retainer. Turn the retainer approximately 1/8 turn counterclockwise.
- 4. Unplug the power cord, and slide the plug through the retainer.
  - Note: Remove the AC power cord from its receptacle by grasping the plug. Do not pull the cord.
- 5. Remove the Velcro strap from the power cord. Inspect the Velcro strap for wear and replace the strap, if required. Attach the strap to the replacement power cord.
- 6. Install the replacement AC power cord in the exact reverse order of removal.
- 7. Reinstall the batteries and connect the infuser to AC power.
- 8. Press [ON/OFF] and verify the infuser powers on.

Replacement of the AC power cord, retainer, and Velcro strap is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.2.

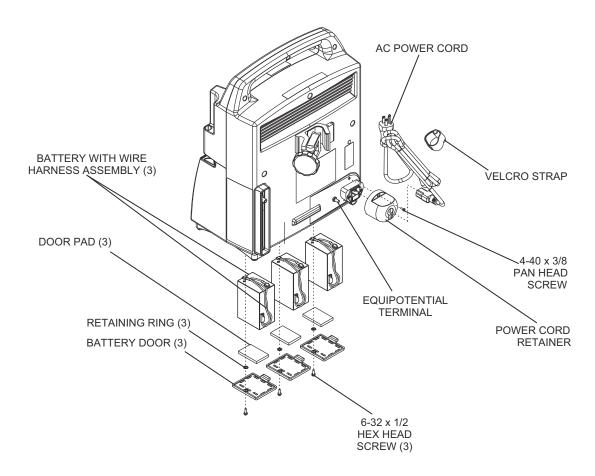


Figure 7-2. AC Power Cord Assembly and Battery Assembly

# SEPARATING THE FRONT ENCLOSURE, REAR ENCLOSURE, AND MAIN CHASSIS ASSEMBLY

The front enclosure consists of an upper assembly and a lower assembly. The main chassis assembly consists of an upper chassis and a lower chassis.

The recommended tool for this procedure is a #2 Phillips screwdriver.

Replacement parts for this procedure are:

Enclosure, Upper Front Enclosure, Lower Front Enclosure, Rear Chassis, Upper

Chassis, Lower

Screw,  $6-32 \times 1/2$ , Pan Head, Phillips

Screw, 6-32 x 1 1/4, Pan Head, Phillips

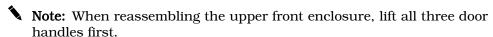
Screw, 6-32 x 2 3/4, Pan Head, Phillips

Screw, 8-32 x 3 1/2, Pan Head, Phillips

Washer, Flat, #6 Washer, Flat #8

To separate the front enclosure, rear enclosure, and main chassis assembly, see *Figure 7-3*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery doors and batteries as described in *Section 7.2.4*.
- 3. Remove the AC power cord and retainer as described in Section 7.2.5.
- 4. Using the Phillips screwdriver, remove the screws from the rear enclosure.
- 5. Remove the rear enclosure by lifting it up and to the side.
- 6. Disconnect the three internal power connectors.
- 7. Using the Phillips screwdriver, remove the screws from the bottom corners of the center mechanism.
- 8. Carefully disconnect the antenna cables.
- 9. Place the infuser upright and remove the upper front enclosure by carefully pulling it away from the upper chassis.
- 10. Remove the lower front enclosure by tilting the infuser back approximately 10 degrees, and pull the lower front enclosure away from the lower chassis.
- 11. Reassemble the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of disassembly. Follow the screw placement sequence as illustrated in *Figure 7-4*.



To verify successful assembly, perform the PVT in Section 5.2.

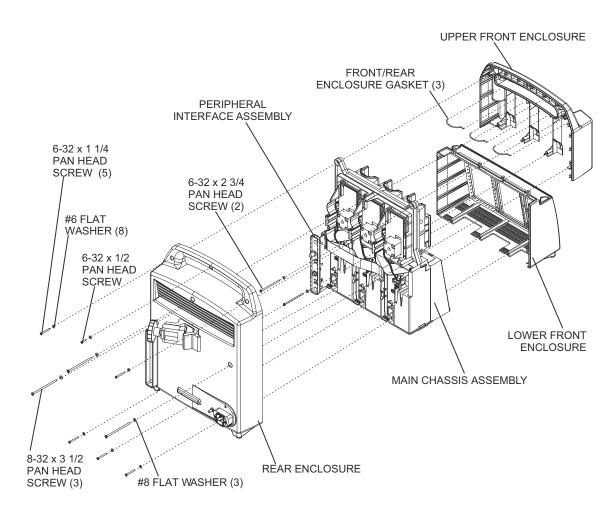


Figure 7-3. Front Enclosures, Rear Enclosure, and Main Chassis

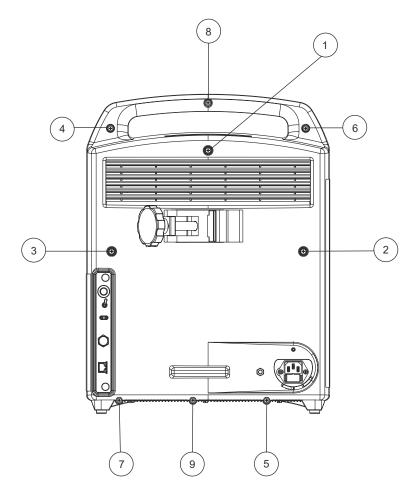


Figure 7-4. Screw Placement Sequence

#### 7.2.6.1

#### FRONT/REAR ENCLOSURE GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

The replacement part for this procedure is:

#### Gasket, Front/Rear Enclosure

To replace a front/rear enclosure gasket, see *Figure 7-3*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in *Section 7.2.4*.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the needle nose pliers, remove the front/rear enclosure gasket from the upper front enclosure as shown in *Figure 7-3*.
  - **Note:** Clean and remove any foreign matter on the replacement gasket or in the spaces where the replacement gasket is to be installed.
- 5. Install the replacement front/rear gasket in the exact reverse order of removal.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful front/rear enclosure gasket replacement, perform the PVT in *Section 5.2*.

#### 7.2.6.2

#### CONDUCTIVE GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

The replacement part for this procedure is:

#### Gasket, Conductive

To replace the conductive gasket, see *Figure 7-5*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6.*
- 4. Using the needle nose pliers, remove the conductive gasket from the upper front enclosure as shown in *Figure 7-5*.
- 5. Install the replacement conductive gasket in the exact reverse order of removal.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful conductive gasket replacement, perform the PVT in Section 5.2.

#### $\overline{7.2.7}$

#### ANTENNA PWA REPLACEMENT

The antenna PWAs are located in the upper front enclosure, as illustrated in *Figure 7-5*. The recommended tool for this procedure is needle nose pliers.

Replacement parts for this procedure are:

PWA, Antenna, with 18 in. Cable PWA, Antenna, with 22 in. Cable Pad, Antenna PWA

To replace the antenna PWAs, see *Figure 7-5*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Note the routing of the cables down and through the enclosure handle to the peripheral interface assembly, then disconnect the antenna cables.
- 5. Carefully remove the antenna PWAs from the antenna pads.
- 6. Inspect the antenna PWA pads, and replace, if required.
- 7. Insert the replacement antenna PWAs into the notches in the antenna pads.
- 8. Connect the antenna cables to the USB adaptor.
- 9. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 10. Reinstall the batteries and connect the infuser to AC power.
- 11. Turn on the infuser, and perform the connectivity check in *Section 1.11*.

To verify successful antenna PWA replacement, perform the PVT in Section 5.2.

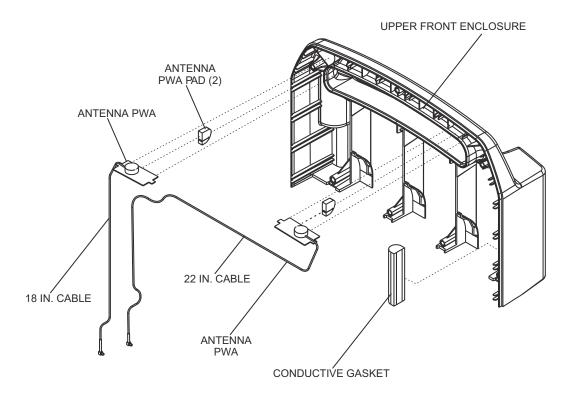


Figure 7-5. Antenna PWA Replacement

# LOWER FRONT ENCLOSURE GASKET REPLACEMENT

Lower front enclosure replacement includes the replacement of the following:

- EMI gaskets
- EMI D-Shape gaskets
- Keypad gaskets
- Top seal gaskets
  - Note: Clean and remove any foreign matter on the replacement gaskets or in the spaces where the replacement gaskets are to be installed.

To replace the lower front enclosure gaskets, see *Figure 7-6*, then proceed as detailed in the following sections.

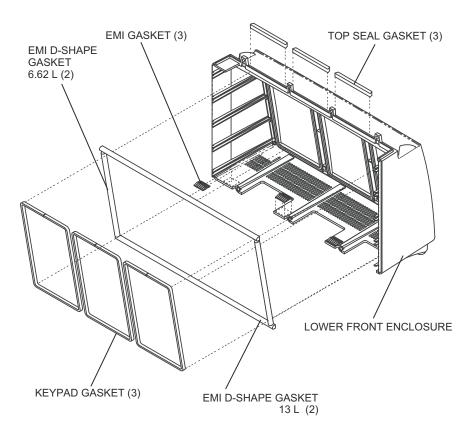


Figure 7-6. Lower Front Enclosure Gaskets

#### 7.2.8.1

# EMI GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

The replacement part for this procedure is:

#### Gasket, EMI

To replace an EMI gasket, see *Figure 7-6*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in *Section 7.2.4*.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the EMI gasket from the lower front enclosure.
- 5. Remove the backing from the replacement EMI gasket to expose the adhesive and press the gasket into place on the lower front enclosure.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful EMI gasket replacement, perform the PVT in Section 5.2.

#### 7.2.8.2

# EMI D-SHAPE GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

Replacement parts for this procedure are:

Gasket, EMI, D-Shape, 6.62 in. Gasket, EMI, D-Shape, 13 in.

To replace an EMI D-shape gasket, see Figure 7-6, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the needle nose pliers, remove the EMI D-shape gasket.
- 5. Remove the backing from the replacement EMI D-shape gasket to expose the adhesive and press the gasket into place on the lower front enclosure.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful EMI D-shape gasket replacement, perform the PVT in Section 5.2.

#### 7.2.8.3

# KEYPAD GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

The replacement part for this procedure is:

#### Gasket, Keypad

To replace a keypad gasket, see *Figure 7-6*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in *Section 7.2.4*.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the needle nose pliers, remove the keypad gasket.
- 5. Install the replacement keypad gasket in the gasket grooves. The gasket gap created by the ends of the gasket must be placed at the top of the keypad window.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful keypad gasket replacement, perform the PVT in Section 5.2.

#### 7.2.8.4

# TOP SEAL GASKET REPLACEMENT

The recommended tool for this procedure is an X-acto knife.

The replacement part for this procedure is:

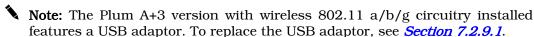
#### Gasket, Top Seal

To replace a top seal gasket, see *Figure 7-6*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the X-acto knife, remove the top seal gasket.
- 5. Remove the backing from the replacement top seal gasket to expose the adhesive and press the gasket into place on the lower front enclosure.
- 6. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful top seal gasket replacement, perform the PVT in Section 5.2.

# PERIPHERAL INTERFACE ASSEMBLY REPLACEMENT





CAUTION: Peripheral interface assembly replacement should only be performed after receiving approval from Hospira.



CAUTION: When replacing the peripheral interface assembly, carefully check the Ethernet MAC address on the PWA label to assure it matches the infuser barcode.



CAUTION: Carefully remove the peripheral interface assembly from the infuser to avoid damaging CE PWA components.

The replacement part for this procedure is: Assembly, Peripheral Interface

To replace the peripheral interface assembly, proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
  - Note: After disconnecting from AC power, wait at least five minutes for the CE to power down and the microprocessor to save data, then proceed to step 2.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Carefully place the infuser face down.
- 4. Disconnect the antenna cables.
- 5. Disconnect the peripheral cables from the peripheral interface assembly. Note the location of the cable ties and mounts (see Figure 7-9).
- 6. Depress the retention clip and carefully pull the peripheral interface assembly away from the infuser *(see Figure 7-8)*. Note the placement guides where the CE PWA rests.
- 7. Perform a visual inspection of the last three characters of the Ethernet MAC address on the replacement peripheral interface assembly, and compare the characters to the last three characters on the infuser barcode.
- 8. Install the replacement peripheral interface assembly in the exact reverse order of removal. Verify the CE PWA is placed properly between the guides and fits correctly into the CPU PWA.
- 9. Replace all cable ties and mounts in the locations shown in *Figure 7-9*.
- 10. Connect the antenna cables to the USB adaptor.
- 11. Reinstall the batteries and connect the infuser to AC power.
- 12. Turn on the infuser. An **E453** malfunction may occur (*see Table 6-3*), or a message may appear asking for the infuser serial number to be re-entered. This is part of normal device operation, and will occur only once.
- 13. Power cycle the infuser again, and verify completion of the self test (see Section 1.9.3).
- 14. Perform the connectivity check in *Section 1.11*.

To verify successful peripheral interface assembly replacement, perform the PVT in Section 5.2.

7.2.9.1

# **USB ADAPTOR**



Note: The USB adaptor is present only on the Plum A+3 version with wireless 802.11 a/b/g circuitry installed.



!\ CAUTION: A new MAC address may affect network connectivity.

There are no recommended tools for this procedure.

The replacement part for this procedure is:

#### Adaptor, USB

To replace the USB adaptor, proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
  - Note: After disconnecting from AC power, wait at least five minutes for the CE to power down and the microprocessor to save data, then proceed to step 2.
- 2. Remove the peripheral interface assembly as described in *Section 7.2.9*.
- 3. Install the foot of the adaptor's rubber support into the large slot in the CE PWA.
  - Note: Move one side of the foot into the small slot in the PWA before pressing the other end into place.
- 4. Attach the antenna cables to the adaptor, then install the adaptor over the rubber support and into the USB port on the CE PWA.
- 5. Install the free end of the adaptor into the slot of the rubber support.
  - Note: Fold back and slide the rubber support in place over the adaptor.
- 6. Reinstall the peripheral interface assembly.
- 7. Reinstall the battery and connect the infuser to AC power.
- 8. Turn on the infuser and verify completion of the self test (see Section 1.9.3).
- 9. Perform the connectivity check in *Section 1.11*.

To verify successful USB adaptor replacement, perform the PVT in Section 5.2.

# PERIPHERAL INTERFACE ASSEMBLY COMPONENT REPLACEMENT

Peripheral interface assembly component replacement includes the replacement of the volume control knob and peripheral cover.

To replace peripheral interface assembly components, see *Figure 7-7*, then proceed as detailed in the following sections.

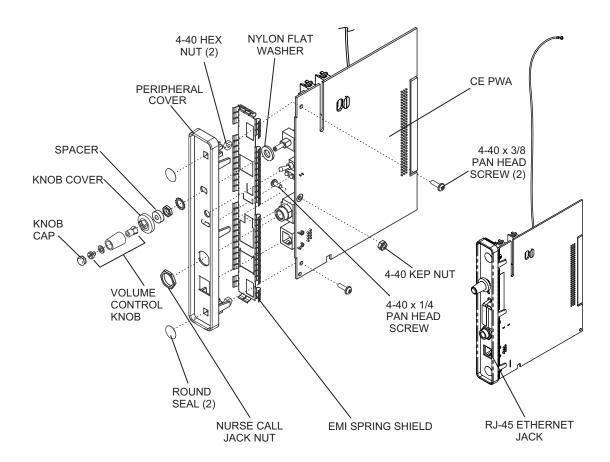


Figure 7-7. Peripheral Interface Assembly Components

#### 7.2.10.1

# VOLUME CONTROL KNOB REPLACEMENT

Recommended tools for this procedure are an X-acto knife, a medium size flat blade screwdriver, and long needle nose pliers.

Replacement parts for this procedure are:

Assembly, Volume Control Knob Cap, Knob Cover, Knob Spacer, Nylon

To replace the volume control knob, see *Figure 7-7*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Remove the peripheral interface assembly as described in Section 7.2.9.
- 4. Using the X-acto knife, lift the volume control knob end cap away from the gray knob, exposing a flat head screw.
- 5. Using the flat blade screwdriver, remove the screw that secures the knob.
- 6. Using long needle nose pliers, remove the knob cap, knob cover, and spacer.
- 7. Install the replacement volume control knob in the exact reverse order of removal.
- 8. Install the peripheral interface assembly in the exact reverse order of removal.
- 9. Reinstall the batteries and connect the infuser to AC power.

Replacement of the volume control knob is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in *Section 5.2*.

#### 7.2.10.2

# PERIPHERAL COVER REPLACEMENT

Recommended tools for this procedure are a #2 Phillips screwdriver, 5/16 nutdriver, custom nutdriver, and long needle nose pliers.

Replacement parts for this procedure are:

Cover, Peripheral
Shield, Spring, EMI
Seal, Round, Purple
Screw, 4-40 x 3/8, Pan Head, Phillips
Nut, 4-40, Hex
Nut, Hex, Nurse Call Jack
Washer, Flat, #4, Nylon

To replace the peripheral cover, see *Figure 7-7*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Carefully place the infuser face down.
- 4. Remove the peripheral interface assembly as described in *Section 7.2.9*.
- 5. Remove the volume control knob as described in *Section 7.2.10.1*.
- 6. Using the 5/16 nutdriver, remove the nut that secures the potentiometer to the peripheral cover. Using the needle nose pliers, remove the lock washer.
- 7. Using the custom nutdriver, remove the hex nut that secures the nurse call jack to the peripheral cover.
- 8. Using the Phillips screwdriver, remove the screws that secure the CE PWA to the peripheral cover.
  - Note: Note the position of the two hex nuts installed in the PWA mounting brackets located on the peripheral cover. Retain the nuts for re-assembly.
- 9. Inspect the round seals and replace, if required.
- 10. Inspect the EMI shield and replace, if required.
- 11. Install the replacement peripheral cover in the exact reverse order of removal.
- 12. Install the volume control knob and nurse call jack nut in the exact reverse order of removal.
- 13. Install the peripheral interface assembly as described in *Section 7.2.9*.
- 14. Reinstall the batteries, and connect the device to AC power.
- 15. Turn on the infuser, and verify completion of the self test (see Section 1.9.3).

To verify successful peripheral cover replacement, perform the PVT in Section 5.2.

# PERIPHERAL PWA REPLACEMENT

Note: Replacing a peripheral PWA does not change the existing Biomed settings.

The recommended tool for this procedure is a #2 Phillips screwdriver.

Replacement parts for this procedure are:

PWA, Peripheral Cable, Peripheral #1 Cable, Peripheral #2 Mount, Cable Tie Tie, Cable

To replace a peripheral PWA, see *Figure 7-8*, *Figure 7-9*, and *Figure 7-10*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Remove the rear enclosure as described in *Section 7.2.6*.
- 4. To replace peripheral PWA #1, disconnect peripheral cable #1, depress the retention clip, and carefully pull the peripheral PWA away from the infuser. Note the location of the cable ties and mounts.
- 5. Replace peripheral PWA #1 in the exact reverse order of removal. Verify the PWA is placed properly between the guides and fits correctly.
- 6. To replace peripheral PWA #2, disconnect peripheral cable #2, depress the retention clip, and carefully pull the peripheral PWA away from the infuser. Note the location of the cable ties and mounts.
- 7. Replace peripheral PWA #2 in the exact reverse order of removal. Verify the PWA is placed properly between the guides and fits correctly.
- 8. Replace all cable ties and mounts in the locations shown in *Figure 7-9*.
- 9. Reinstall the batteries and connect the infuser to AC power.

To verify successful peripheral PWA replacement, perform the PVT in Section 5.2.

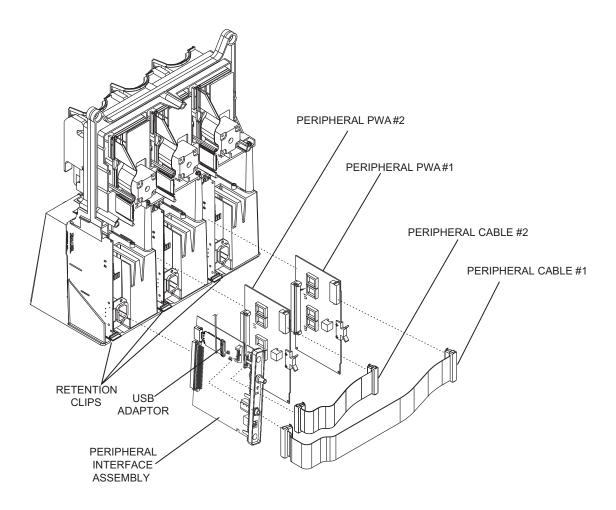
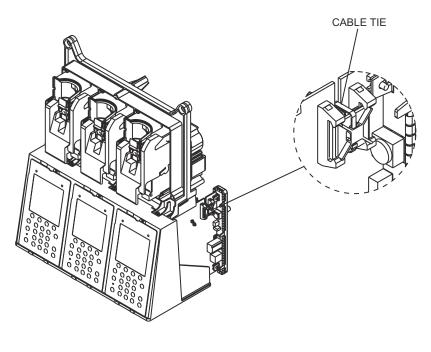


Figure 7-8. Peripheral PWA Replacement



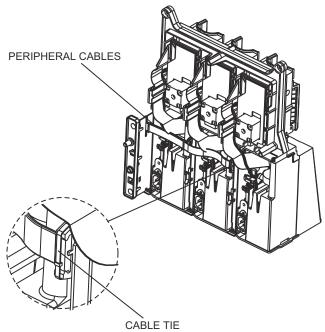


Figure 7-9. Cable Ties and Mounts

# REAR ENCLOSURE ASSEMBLY COMPONENT REPLACEMENT

Rear enclosure assembly component replacement includes replacement of the following:

- Rear enclosure gaskets
- Pole clamp assembly, backing plate, and insulator
- Equipotential terminal
- Internal AC power cord
- AC connector
- Fuses

To replace the rear enclosure assembly components, see *Figure 7-10* and *Figure 7-11*, then proceed as detailed in the following sections.

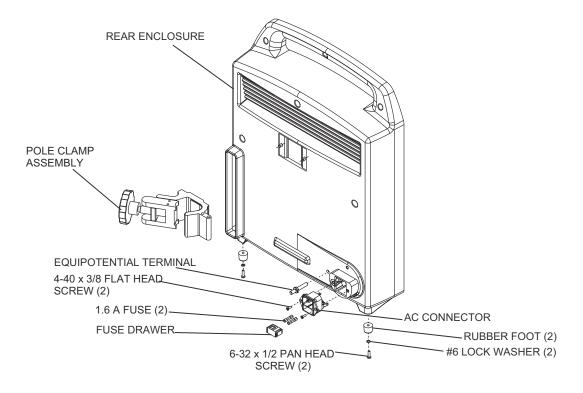


Figure 7-10. External Rear Enclosure Assembly Components

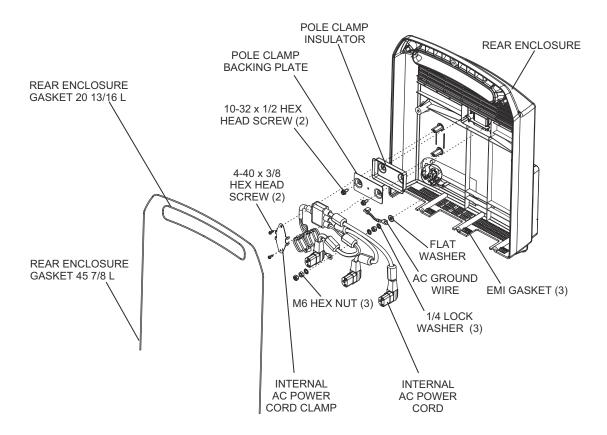


Figure 7-11. Internal Rear Enclosure Assembly Components

# REAR ENCLOSURE GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

Replacement parts for this procedure are:

Gasket, Rear Enclosure, 20 13/16 in. Gasket, Rear Enclosure, 45 7/8 in.

To replace a rear enclosure gasket, see *Figure 7-11*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the rear enclosure and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the needle nose pliers, remove the rear enclosure gasket.
- 5. Install the replacement rear enclosure gasket by pressing it into the gasket channel.
- 6. Join the front enclosure and rear enclosure in the exact reverse order of separation.
- 7. Reinstall the batteries and connect the infuser to AC power.

To verify successful rear enclosure gasket replacement, perform the PVT in Section 5.2.

# POLE CLAMP ASSEMBLY AND BACKING PLATE REPLACEMENT

Recommended tools for this procedure are a medium size flat blade screwdriver, 10 mm wrench, and mild solvent.

Replacement parts for this procedure are:

Assembly, Pole Clamp
Plate, Backing, Pole Clamp
Insulator, Pole Clamp
Terminal, Equipotential
Screw, 10-32 x 1/2, Hex Head, Slotted, with Washer

To replace the pole clamp assembly and backing plate, see *Figure 7-10* and *Figure 7-11*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front and rear enclosures as described in Section 7.2.6.
- 4. Using the 10 mm wrench, remove and inspect the equipotential terminal and replace, if required.
- 5. Using the flat blade screwdriver, remove the screws that secure the pole clamp assembly, backing plate, and pole clamp insulator, and remove the pole clamp, backing plate, and insulator from the rear enclosure.
- 6. Inspect the pole clamp insulator and replace, if required.
- 7. Install the replacement pole clamp assembly and backing plate, using the screws that were removed in step 5.
- 8. Reinstall the batteries and connect the infuser to AC power.

To verify successful pole clamp assembly and backing plate replacement, perform the PVT in *Section 5.2*.

# INTERNAL AC POWER CORD REPLACEMENT

Recommended tools for this procedure are a medium size flat blade screwdriver, needle nose pliers, and 10 mm nutdriver.

Replacement parts for this procedure are:

Cord, Internal, AC Power Clamp, Internal Power Cord Wire, Ground, AC Power Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer

To replace the internal AC power cord, see *Figure 7-11*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front and rear enclosures as described in *Section 7.2.6*.
- 4. Using the flat blade screwdriver, remove the screws from the internal power cord clamp.
- 5. Using the needle nose pliers, remove the wires from the AC connector.
- 6. Using a 10 mm nutdriver, remove the hex nuts and washers that secure the AC ground wire to the equipotential terminal.
- 7. Inspect the ground wire and replace, if required.
- 8. Install the replacement internal AC power cord in the exact reverse order of removal.
- 9. Join the front enclosure and rear enclosure in the exact reverse order of separation.
- 10. Reinstall the batteries and connect the infuser to AC power.

To verify successful internal AC power cord replacement, perform the PVT in Section 5.2.

# AC CONNECTOR REPLACEMENT

Recommended tools for this procedure are needle nose pliers and a #2 Phillips screwdriver.

Replacement parts for this procedure are:

Connector, AC Power Screw, 4-40 x 3/8, Flat Head, Phillips

To replace the AC connector, see *Figure 7-10*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the rear enclosure and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the AC power cord retainer and AC power cord as described in *Section 7.2.5*.
- 5. Using the needle nose pliers, remove the internal power cord wires and the AC ground wire from the AC connector.
- 6. Using the Phillips screwdriver, remove the screws that secure the AC connector to the rear enclosure.
- 7. Install the replacement AC connector in the exact reverse order of removal.
- 8. Join the rear enclosure and main chassis assembly in the exact reverse order of separation.
- 9. Reinstall the batteries and connect the infuser to AC power.

To verify successful AC connector replacement, perform the PVT in Section 5.2.

# **FUSE REPLACEMENT**

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CAUTION: Confirm the replacement fuse rating is identical to the rating indicated on the fuse drawer.

Recommended tools for this procedure are a #2 Phillips screwdriver and a small flat blade screwdriver.

Replacement parts for this procedure are:

Fuse, 1.6 A, 250 V Drawer, Fuse

To replace the fuses, see *Figure 7-10*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Separate the rear enclosure and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the power cord retainer and power cord as described in Section 7.2.5.
- 5. Locate the fuse drawer directly below the AC power receptacle. Insert the flat blade screwdriver between the right locking tab of the fuse drawer and the AC connector housing. Press the tab toward the center of the fuse drawer to release it. Verify the fuse drawer moves slightly outward.
- 6. Repeat step 5 to release the left locking tab. Grasp both locking tabs and remove the fuse drawer from the AC connector.
- 7. Inspect the fuse drawer and replace, if required.
- 8. Remove the fuses and replace with approved fuses only *(see Section 8)*. Do not use any other fuse types.
- 9. Insert the fuse drawer into the receptacle, then press the fuse drawer into the AC connector until it clicks into position.
- 10. Reinstall the power cord retainer and power cord in the exact reverse order of disassembly.
- 11. Reinstall the batteries and connect the infuser to AC power.

To verify successful fuse replacement, perform the PVT in see Section 5.2.

# MINIPOLE ASSEMBLY REPLACEMENT

The minipole assembly is an accessory that attaches to the infuser through two holes in the pole clamp extrusion and is held in place by a cotter ring. The cotter ring passes through a hole near the end of the longer of the two vertical rods on the bag hanger, and prevents the removal of the minipole from the holes in the pole clamp.

There are no recommended tools for this procedure.

Replacement parts for this procedure are:

Assembly, Minipole Ring, Cotter

To replace the minipole assembly, see *Figure 7-12*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Place the infuser face down on a soft surface.
- 3. Grasp the cotter ring with thumb and finger. Twist, rotate, and remove the cotter ring from the rod hole.
- 4. Remove the bag hanger from the pole clamp rod holes, and remove the minipole.
- 5. Install the replacement minipole assembly in the exact reverse order of removal.

Replacement of the minipole assembly is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during the procedure perform the PVT as described in *Section 5.2*.

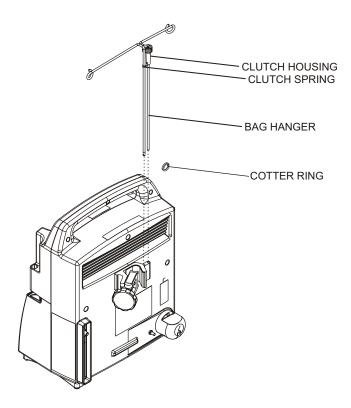


Figure 7-12. Minipole Assembly

# MAIN CHASSIS ASSEMBLY COMPONENT REPLACEMENT

Main chassis assembly component replacement includes the replacement of the following:

Power supply PWA
 CPU PWA
 Keypad
 Piezo alarm
 Display
 Mechanism assembly
 Opener handle

To replace the main chassis assembly components, see *Figure 7-13*, then proceed as detailed in the following sections.

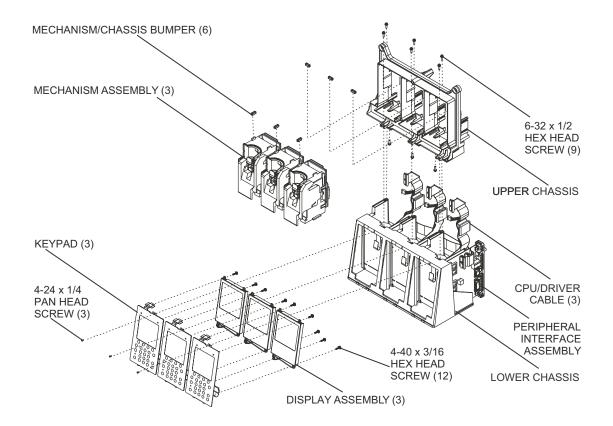


Figure 7-13. Main Chassis Assembly Components (1 of 2)

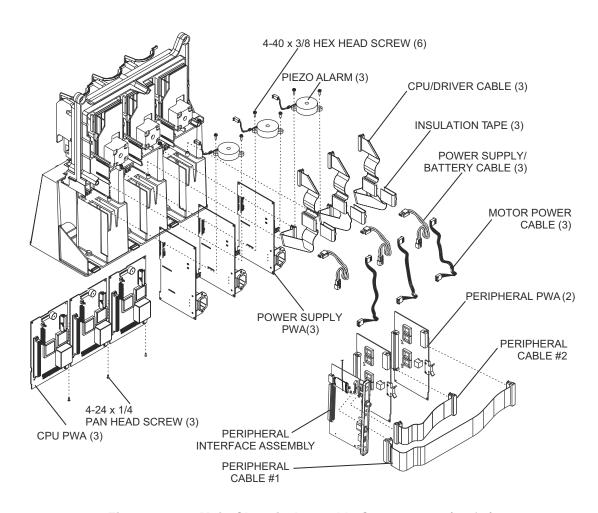


Figure 7-13. Main Chassis Assembly Components (2 of 2)

# POWER SUPPLY PWA REPLACEMENT

The recommended tool for this procedure is a medium size flat blade screwdriver.

Replacement parts for this procedure are:

PWA, Power Supply
Assembly, Cable, Power Supply/Battery

To replace a power supply PWA, see *Figure 7-13 (2 of 2)*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the rear enclosure from the main chassis as described in Section 7.2.6.
- 4. Disconnect the battery cable from the power supply PWA.
- 5. Disconnect the peripheral interface cables from the peripheral PWAs.
- 6. Remove the power supply PWA by pressing down on the finger tab at the bottom front of the power supply PWA. Slide the power supply PWA away from the CPU PWA.
- 7. Install the replacement power supply PWA in the exact reverse order of removal. Verify the power supply PWA connects to the CPU PWA correctly to avoid misalignment.
  - Note: If an alarm sounds, press [ON/OFF] to deactivate the alarm.
- 8. Join the rear enclosure and main chassis assembly in the exact reverse order of separation.
- 9. Reinstall the batteries and connect the infuser to AC power.

To verify successful power supply PWA replacement, perform the PVT in Section 5.2.

# **KEYPAD REPLACEMENT**

Recommended tools for this procedure are a #2 Phillips screwdriver, medium size flat blade screwdriver, and an X-acto knife.

Replacement parts for this procedure are:

Assembly, Keypad Screw, 4-24 x 1/4, Pan Head, Phillips Screw, 4-40 x 3/16, Hex Head, Slotted, with Washer

To replace a keypad, see *Figure 7-13 (1 of 2)*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Disconnect the flex ribbon cable assembly from the CPU PWA.
- 5. Using the X-acto knife, lift the white insulation tape that secures the grounding tab to the lower main chassis.
- 6. Using the Phillips screwdriver, remove the screw that secures the keypad and display to the lower main chassis.
- 7. Carefully disconnect the flex ribbon cable from the display by pushing the connector locking tabs down.
- 8. Using the flat blade screwdriver, separate the keypad and display by removing the screws that secure the keypad to the display.
- 9. Install the replacement keypad in the exact reverse order of removal.
- 10. Install the keypad and display in the exact reverse order of removal.
- 11. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 12. Reinstall the batteries and connect the infuser to AC power.

To verify successful keypad replacement, perform the PVT in Section 5.2.

# **DISPLAY REPLACEMENT**

Recommended tools for this procedure are a #2 Phillips screwdriver and a medium size flat blade screwdriver.

Replacement parts for this procedure are:

# Assembly, Display

Screw, 4-40 x 3/16, Hex Head, Slotted, with Washer

To replace a display assembly, see *Figure 7-13 (1 of 2)*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the keypad as described in Section 7.2.14.2.
- 5. Disconnect the display cable from the CPU PWA and remove the display.
- 6. Install the replacement display in the exact reverse order of removal.
- 7. Reassemble the keypad and display.
- 8. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 9. Reinstall the batteries and connect the infuser to AC power.

To verify successful display replacement, perform the PVT in Section 5.2.

# CPU/DRIVER CABLE REPLACEMENT

The recommended tool for this procedure is an X-acto knife.

Replacement parts for this procedure are:

Assembly, Cable, CPU/Driver Tape, Ferrite Tape, Insulation

To replace a CPU/driver cable, see *Figure 7-13 (2 of 2)*, *Figure 7-14*, and *Figure 7-15*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in *Section 7.2.4*.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the peripheral interface assembly as described in Section 7.2.9.
- 5. Remove the peripheral PWAs as described in *Section 7.2.11*.
- 6. Remove the power supply PWA as described in *Section 7.2.14.1*.
- 7. Disconnect the CPU/driver cable from the mechanism assembly.
- 8. Remove the insulating tape that secures the CPU/driver cable and ferrite to the center tab (see Figure 7-15).
- 9. Remove both ends of ferrite tape from the center tab. Cut off the adhesive strip on one side of the ferrite tape and pull through the ferrite (*see Figure 7-15*).
- 10. Remove the CPU/driver cable from the center tab.
- 11. Remove the CPU PWA as described in Section 7.2.14.6.
- 12. Disconnect the CPU/driver cable from the CPU PWA.
- 13. Insert ferrite tape through the ferrite of the replacement CPU/driver cable. Confirm the adhesive side is facing away from the cable.
- 14. Position the ferrite between the two line marks on the cable.
- 15. Route the cable around the tabs as shown in *Figure 7-14*. Assure the pin 1 stripe of the cable faces the front of the infuser. Ferrite should be on the left side of the center tab and between the cable markings.
- 16. Remove the backing to expose the adhesive and apply both ends of tape completely to the surface of the center tab *(see Figure 7-15)*.
- 17. Wrap insulation tape around the ferrite and center tab (see Figure 7-15).
- 18. Connect the CPU/driver cable to the mechanism assembly.
- 19. Reassemble the infuser in the exact reverse order of disassembly.
- 20. Reinstall the batteries and connect the infuser to AC power.

To verify successful CPU/driver cable replacement, perform the PVT in Section 5.2.

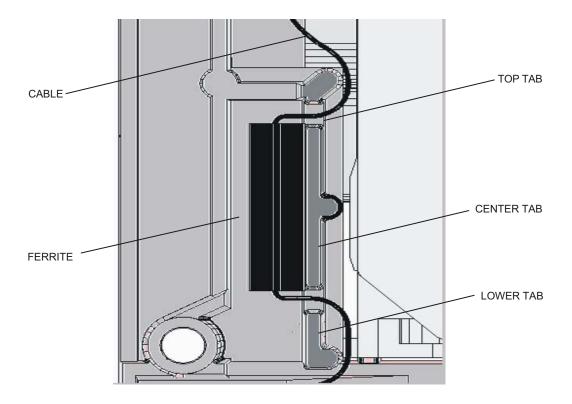
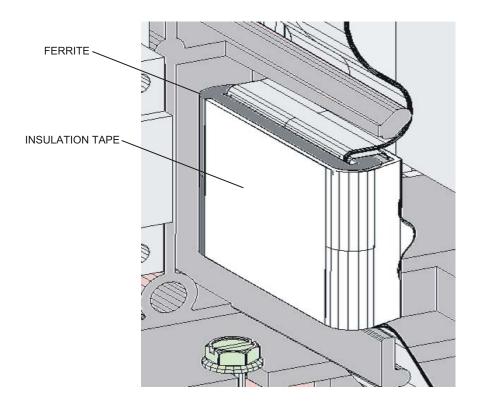


Figure 7-14. CPU/Driver Cable Routing



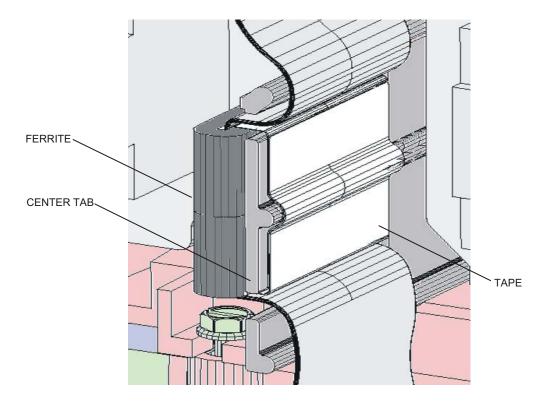


Figure 7-15. Ferrite Tape Positioning

# MOTOR POWER CABLE REPLACEMENT

The recommended tool for this procedure is a medium size flat blade screwdriver.

The replacement part for this procedure is:

#### Assembly, Cable, Motor Power

To replace a motor power cable, see Figure 7-13 (2 of 2), then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in *Section 7.2.4*.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Disconnect the motor power cable from the CPU PWA.
- 5. Remove the mechanism assembly as described in *Section 7.2.14.8*.
- 6. Disconnect the motor power cable from the mechanism assembly.
- 7. Install the replacement motor power cable in the exact reverse order of removal.
- 8. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 9. Reinstall the batteries and connect the infuser to AC power.

To verify successful motor power cable replacement, perform the PVT in Section 5.2.

# 7.2.14.6

# **CPU PWA REPLACEMENT**

Recommended tools for this procedure are a medium size flat blade screwdriver and No. 2 Phillips screwdriver.

Replacement parts for this procedure are:

#### PWA, CPU

#### Screw, 4-40 x 1/4, Hex Head, Slotted, with Washer

To replace a CPU PWA, see Figure 7-13 (2 of 2), then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the peripheral interface assembly as described in *Section 7.2.9*.
- 5. Remove the peripheral PWAs as described in Section 7.2.11.
- 6. Remove the power supply PWA as described in Section 7.2.14.1.
- 7. Disconnect the keypad ribbon cable from the CPU PWA.
- 8. Disconnect the display cable from the CPU PWA.
- 9. Disconnect the CPU/driver cable from the mechanism assembly (see Section 7.2.14.4).

- 10. Disconnect the piezo alarm cable from the CPU PWA.
- 11. Using the Phillips screwdriver, remove the screw from the bottom of the lower main chassis assembly.
- 12. Slide the CPU PWA out of the main chassis until J5 on the CPU PWA is accessible.
- 13. Using the flat blade screwdriver, release the locking tabs that secure the flex cable to the CPU PWA.
- 14. Install the replacement CPU PWA in the exact reverse order of removal.
- 15. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 16. Reinstall the batteries and connect the infuser to AC power.

To verify successful CPU PWA replacement, perform the PVT in Section 5.2.

#### 7.2.14.7

# PIEZO ALARM ASSEMBLY REPLACEMENT

The recommended tool for this procedure is a medium size flat blade screwdriver.

Replacement parts for this procedure are:

Assembly, Piezo Alarm

Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer

To replace the piezo alarm assembly, see *Figure 7-13 (2 of 2)*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Using the flat blade screwdriver, separate the upper and lower main chassis assemblies by removing the screws from the upper main chassis.
- 5. Expose the piezo alarm by lifting the upper main chassis. Place the chassis on the work surface.
- 6. Using the flat blade screwdriver, remove the screws that secure the piezo alarm to the lower main chassis assembly.
- 7. Disconnect the piezo alarm cable from the CPU PWA.
  - **Note:** When installing, route the piezo alarm cable above the CPU/driver cable.
- 8. Install the replacement piezo alarm assembly in the exact reverse order of removal.
- 9. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 10. Reinstall the batteries and connect the infuser to AC power.

To verify successful piezo alarm assembly replacement, perform the PVT in Section 5.2.

# MECHANISM ASSEMBLY REPLACEMENT

Note: Replacing the mechanism changes the biomed settings to those stored in the replacement mechanism assembly.

Recommended tools for this procedure are a medium size flat blade screwdriver and #2 Phillips screwdriver.

Replacement parts for this procedure are:

Assembly, Mechanism Bumper, Mechanism/Chassis Screw, 6-32 x 1/2, Hex Head, Slotted, with Washer

To replace a mechanism assembly, see *Figure 7-13 (2 of 2)*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in Section 7.2.6.
- 4. Disconnect the CPU/driver cable from the mechanism assembly.
- 5. Disconnect the motor power cable from the power supply PWA.
- 6. Using the flat blade screwdriver, separate the upper and lower main chassis assemblies by removing the screws from the upper main chassis.
- 7. Lift the upper main chassis assembly and place it on the work surface.
- 8. Using the flat blade screwdriver, remove the screw that secures the mechanism assembly to the upper main chassis assembly. Slide the mechanism assembly away from the main chassis assembly.
- 9. Disconnect the motor power cable from the mechanism assembly.
- 10. Inspect the mechanism/chassis bumpers and replace, if required.
- 11. Install the replacement mechanism assembly in the exact reverse order of removal.
- 12. Join the upper and lower main chassis assembly in the exact reverse order of separation.
- 13. Using fingers, tighten the remaining front screws.
- 14. Using the flat blade screwdriver, tighten the remaining front screws another 1/4 to 3/8 turn.
- 15. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 16. Reinstall the batteries and connect the infuser to AC power.

To verify successful mechanism assembly replacement, perform the PVT in Section 5.2.

# CASSETTE DOOR AND FLUID SHIELD REPLACEMENT



WARNING: UNRESTRICTED FLOW MAY BE LIFE-THREATENING.



CAUTION: To ensure that the fluid shield tab does not obstruct or unseat the regulator closer, the fluid shield tab must be visually inspected. If the fluid shield tab is bent, contact Hospira for a fluid shield assembly replacement.

Recommended tool for this procedure is a medium size flat-blade screwdriver.

Replacement parts for this procedure are:

Assembly, Cassette Door (if required)
Assembly, Fluid Shield
Cap, Door Pivot
Gasket, .75 in.
Gasket, 1.09 in.
Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer

To replace a cassette door and fluid shield, see *Figure 7-19* and *Figure 7-20*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in **Section 7.2.4**.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the mechanism assembly as described in Section 7.2.14.8.
- 5. Using the flat blade screwdriver, remove the screw that secures the door pivot cap to the mechanism assembly.
- 6. Disengage the cassette door from the opener handle assembly, and remove the door.
- 7. Disengage the clips on the back side of the fluid shield that retain the upper portion of the fluid shield to the mechanism assembly.
- 8. Lift the locking pins to release the fluid shield/driver flex connector, and disconnect the flex connector from the driver PWA.
- 9. Pull the shield away from the top of the mechanism assembly at an approximate 15-degree angle. Pull the shield up and away, clearing the mechanism assembly pins and plunger. Note the location of the gaskets (see Figure 7-19).
  - **Note:** Fluid shield gaskets may not be present in older versions of the Plum A+3.
- 10. Inspect and replace the fluid shield gaskets, if required.

11. Ensure that the regulator closer is seated properly (see Section 6.4.1).

If the fluid shield tab is bent or damaged, the regulator closer cannot be seated properly and may cause unrestricted flow (see Section 6.4.1). When this occurs, replace the fluid shield assembly.

If the regulator closer is disengaged or not seated properly, discontinue use and *contact Hospira*.

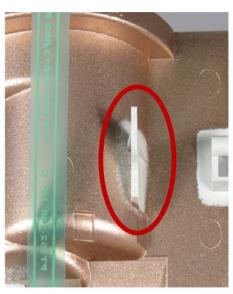
12. Inspect the fluid shield tab and ensure that it is not bent or damaged (see Figure 7-16).

If the fluid shield tab is bent or damaged (see Figure 7-16), replace the fluid shield assembly.



CAUTION: If the fluid shield tab is damaged, snapping the fluid shield assembly in place may unseat the regulator closer, which may result in unrestricted flow.

Do not attempt to fix the fluid shield tab. Replace the entire fluid shield assembly.





NORMAL

BENT

Figure 7-16. Fluid Shield Tab

13. Align the mechanism assembly pins, then install the replacement fluid shield in the exact reverse order of removal.



CAUTION: If the fluid shield assembly is misaligned, snapping the fluid shield assembly in place may unseat the regulator closer, which may result in unrestricted flow.



CAUTION: Use extreme caution when aligning the mechanism assembly pins and installing the replacement fluid shield.

14. Ensure that the fluid shield tab is aligned during installation of the fluid shield assembly. *Figure 7-17* shows the fluid shield tab that can be seen before the fluid shield is fully seated (left) and once the assembly is seated (right).





Figure 7-17. Normal Fluid Shield Tab Before and After Assembly is Seated

- 15. Once the fluid shield assembly is installed, the aligned fluid shield tab is visible from the open corner of the mechanism assembly (*see Figure 7-18*). Continue replacement of the cassette door.
- 16. If the fluid shield tab is not visible from the open corner of the mechanism assembly or if the fluid shield tab appears bent (*see Figure 7-18*), then the fluid shield tab may be bent or damaged.

Inspect the fluid shield assembly. If the regulator closer is seated properly and if the fluid shield tab is damaged, replace the fluid shield assembly.

If the regulator closer is not seated properly, discontinue use and *contact Hospira*.

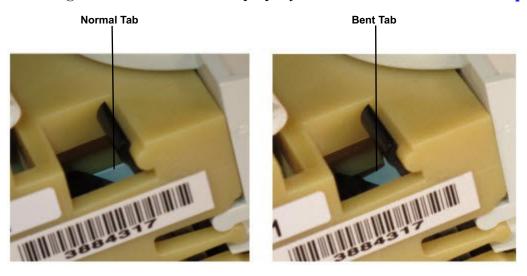


Figure 7-18. Close-up Views of Normal (left) and Bent (right) Fluid Shield Tab

- 17. Install the replacement cassette door in the exact reverse order of removal.
- 18. Replace the mechanism assembly in the exact reverse order of removal.
- 19. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 20. Reinstall the batteries and connect the infuser to AC power.

To verify successful cassette door and fluid shield replacement, perform the PVT in *Section 5.2*.

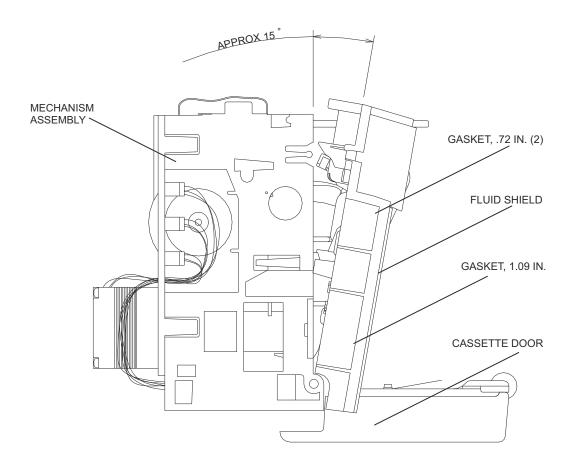


Figure 7-19. Fluid Shield Replacement

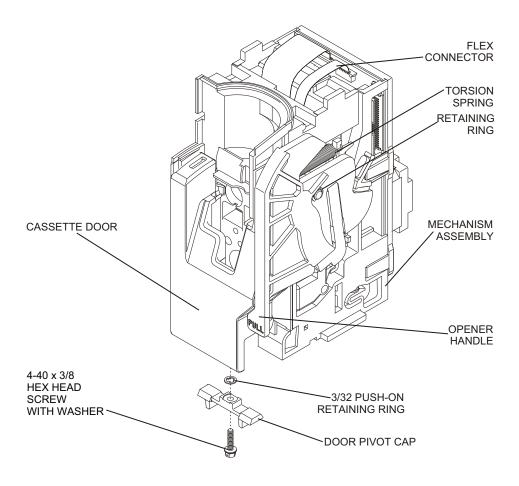


Figure 7-20. Cassette Door and Opener Handle Assembly

# OPENER HANDLE ASSEMBLY REPLACEMENT

The recommended tool for this procedure is a medium size flat blade screwdriver.

Replacement parts for this procedure are:

Assembly, Opener Handle Link, Door Ring, Retaining, Push-On

To replace an opener handle assembly, see *Figure 7-20*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the batteries as described in Section 7.2.4.
- 3. Separate the front enclosure, rear enclosure, and main chassis assembly as described in *Section 7.2.6*.
- 4. Remove the mechanism assembly as described in Section 7.2.14.8.
- 5. Open the cassette door. Disengage and fully open the cassette door from the opener handle assembly.
- 6. Close the opener handle assembly.
- 7. Remove and inspect the retaining ring and replace, if required.
- 8. Remove and inspect the door link and replace, if required.
- 9. Insert the flat blade screwdriver between the opener handle assembly and the mechanism assembly. Carefully pry the assemblies apart.
- 10. Install the replacement opener handle assembly in the exact reverse order of removal. Confirm the opener handle is aligned properly.
- 11. Replace the mechanism assembly in the exact reverse order of removal.
- 12. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 13. Reinstall the batteries and connect the infuser to AC power.

To verify successful opener handle assembly replacement, perform the PVT in Section 5.2.

#### **Section 8**

### **SPECIFICATIONS**

The following specifications apply to the Plum A+3 with Hospira MedNet Software.

**PHYSICAL** 

**Dimensions:** Approximately 19 H x 15 W x 14 D inches

(excluding pole clamp and power cord storage)

Weight: Approximately 28 lbs (with batteries)

Casing: High-impact plastic

**ELECTRICAL** 

**Power Requirements:** 95-132 V<sub>AC</sub>; 47-62 Hz; 90 W

Power Cord: Hospital-grade AC cord; 10 feet;

with transparent plug and retainer plate

Fuses:  $0.5 \text{ A}, 250 \text{ V}_{AC}$ 

Battery: Three; sealed lead acid; rechargeable; 6 V; internal

Battery Operation: A fully charged new battery provides approximately three

hours of operation at 125 mL/hr, or delivers 250 mL

if > 126 mL/hr.

Operation time is measured from initial pumping

to the Depleted Battery alarm.

The infuser should be operated on battery power for three continuous hours every six months for optimum

performance and battery life.

Recharge: The battery charges whenever the infuser is connected

to AC power.

If the infuser is operating at 125 mL/hr on one line, a full

recharge takes less than six hours.

**Self-Discharge:** 50 % of charge is retained for a minimum of one month when

the infuser is not connected to AC power or is not operating.

Nurse Call System: Default: Normally open (NO)

*Contact Hospira* to make an internal adjustment to change the device from normally open to normally closed (NC).

**ENVIRONMENT** 

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

Transporting and Storage: -4° to 140° F (-20° to 60° C); 10 % to 90 % relative humidity

**Atmospheric Pressure:** 0 - 10,000 feet (0 - 3000 meters)

or equivalent atmospheric pressure

Relative Humidity: 10 - 90 % (104° F max)

**DELIVERY RATE RANGE** 

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

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

**Concurrent Delivery:** 0.5 mL/hr minimum for each line

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

**KVO:** 1 mL/hr or the last primary delivery rate, whichever is less

**VTBI RANGE:** 0.1 to 99.9 mL (in 0.1 mL/hr increments)

100 to 9999 mL (in 1 mL/hr increments)

OCCLUSION ALARM AND

LIMITS

Distal: The distal occlusion alarm sounds after the distal tubing

or set outlet fitting becomes occluded

Proximal: The proximal occlusion alarm sounds within two pumping

cycles when the tubing proximal to the cassette becomes

occluded

**Distal Pressure Limit (Without** 

Alarm): 1 to 15 psi; maximum pressure limit is user-selectable;

factory setting is 6 psi

Maximum Infusion Pressure: 20 psi

AIR-IN-LINE ALARM

PlumSet (Distal): Bolus: 0.1 mL of air or larger

Cumulative: 0.25 mL of air out of 4.9 mL of fluid

PlumSet (Proximal): Bolus at 0.5 mL, total 1 mL (0.5 mL concurrent)

**COMMUNICATION** 

**Ethernet LAN:** Shielded Ethernet cable plugged into an RJ-45 connector

Wireless LAN: Device name: Hospira MedNet Wireless 802.11 a/b/g Module

Standards: IEEE 802.11 a/b/g

Transmit Power: 802.11 b/g - 17.6 dBm; 802.11 a - 19 dBm

Antenna: Integrated Surface Mount Antenna

Certification: FCC Part 15.247, 15.407; IC RSS-210, RSS-102

FCC ID: STJ-80411396001, IC: 5627A-80411396

**Ethernet IP Address:** 192.168.0.100

**Subnet Mask:** 255.255.0.0

# Section 9 **DRAWINGS**

*Figure 9-1* through *Figure 9-9* show the Illustrated Parts Breakdown (IPB) and assembly diagrams. *Table 9-1* lists drawings by figure number and title. *Table 9-2* identifies parts by index numbers which correlate to *Figure 9-1*.

Drawings in Section 9 are provided as information only, and may not exactly reflect current product configuration.

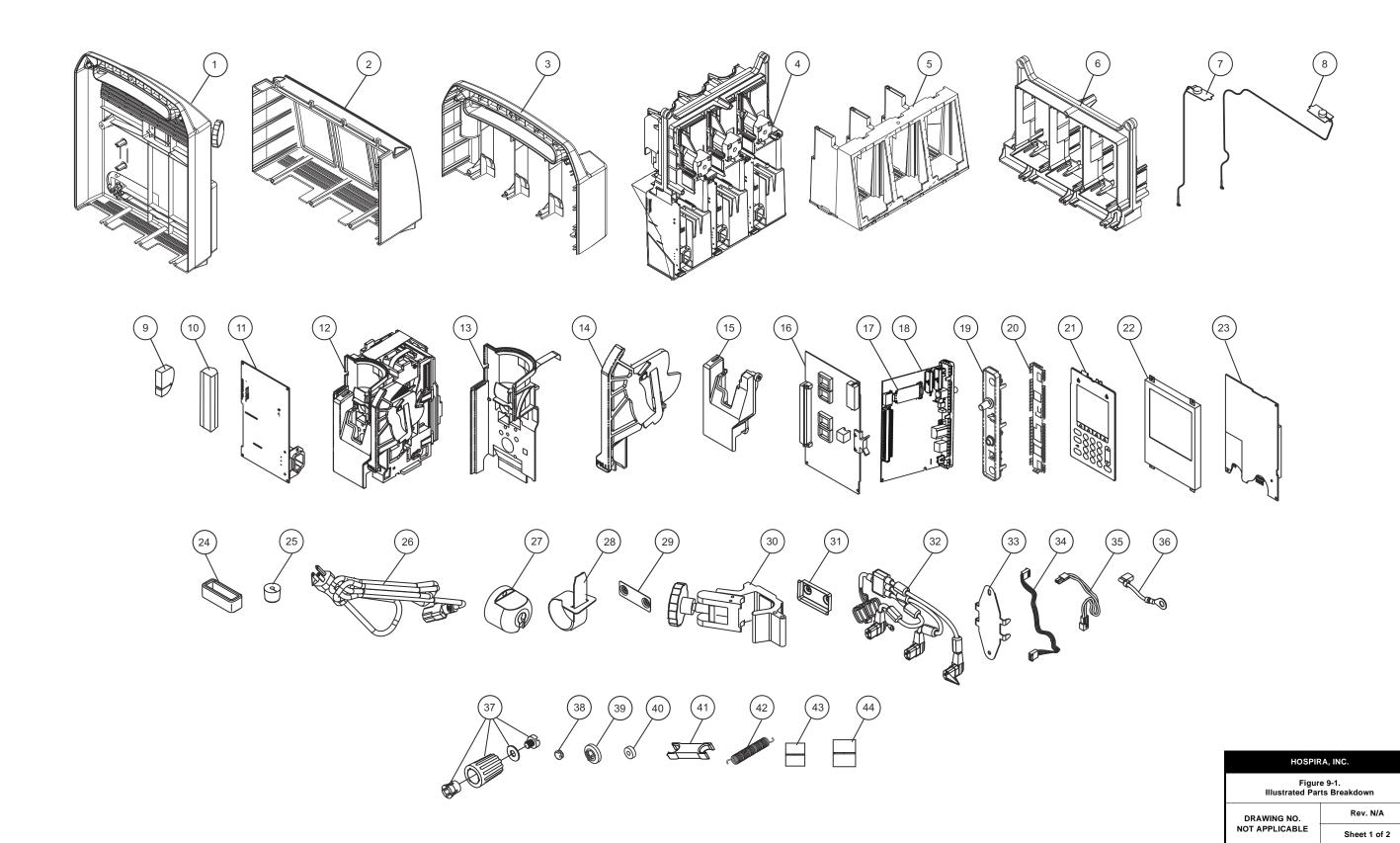
Table 9-1. Drawings		
Figure Number	Title	
9-1	Illustrated Parts Breakdown (2 Sheets)	
9-2	Front Enclosures, Rear Enclosure, and Main Chassis	
9-3	Front Enclosure Assemblies	
9-4	Rear Enclosure Assembly (2 Sheets)	
9-5	Antenna PWAs	
9-6	Peripheral Interface Assembly	
9-7	Main Chassis Assembly (2 Sheets)	
9-8	AC Power Cord Assembly and Battery Assembly	
9-9	Mechanism Assembly	

Table 9-2. IPB for the Infuser		
Index Number	Nomenclature	Replacement Procedure
1	Enclosure, Rear	see Section 7.2.6
2	Enclosure, Lower Front	see Section 7.2.6
3	Enclosure, Upper Front	see Section 7.2.6
4	Assembly, Main Chassis	see Section 7.2.6
5	Chassis, Lower	see Section 7.2.6
6	Chassis, Upper	see Section 7.2.6
7	PWA, Antenna, with 18 in. Cable	see Section 7.2.7
8	PWA, Antenna, with 22 in. Cable	see Section 7.2.7
9	Pad, Antenna PWA	see Section 7.2.7

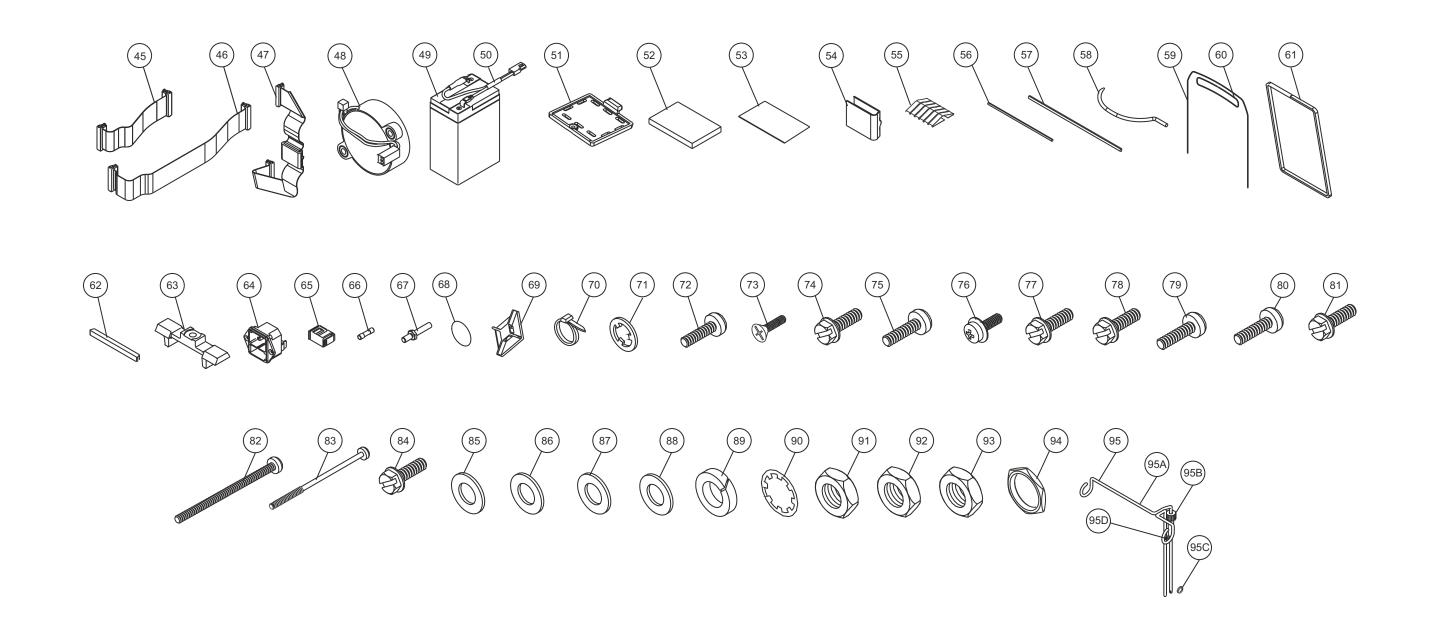
Table 9-2. IPB for the Infuser			
Index Number	Nomenclature	Replacement Procedure	
10	Gasket, Conductive	see Section 7.2.6.2	
11	PWA, Power Supply	see Section 7.2.14.1	
12	Assembly, Mechanism	see Section 7.2.14.8	
13	Assembly, Fluid Shield	see Section 7.2.14.9	
14	Assembly, Opener Handle	see Section 7.2.14.10	
15	Assembly, Cassette Door	see Section 7.2.14.9	
16	PWA, Peripheral	see Section 7.2.11	
17	Adaptor, USB	see Section 7.2.9.1	
18	Assembly, Peripheral Interface	see Section 7.2.9	
19	Cover, Peripheral	see Section 7.2.10.2	
20	Shield, Spring, EMI	see Section 7.2.10.2	
21	Assembly, Keypad	see Section 7.2.14.2	
22	Assembly, Display	see Section 7.2.14.3	
23	PWA, CPU	see Section 7.2.14.6	
24	Bumper, Mechanism/Chassis	see Section 7.2.14.8	
25	Pad, Rubber Foot	see Section 7.2.3	
26	Cordset, AC Power, Hospital Grade	see Section 7.2.5	
27	Retainer, Power Cord	see Section 7.2.5	
28	Strap, Velcro, 1 3/4 in. x 10 in., Black	see Section 7.2.5	
29	Plate, Backing, Pole Clamp	see Section 7.2.12.2	
30	Assembly, Pole Clamp	see Section 7.2.12.2	
31	Insulator, Pole Clamp	see Section 7.2.12.2	
32	Cord, AC Power, Internal	see Section 7.2.12.3	
33	Clamp, Internal AC Power Cord	see Section 7.2.12.3	
34	Assembly, Cable, Motor Power	see Section 7.2.14.5	
35	Assembly, Cable, Power Supply/Battery	see Section 7.2.14.1	
36	Wire, Ground, AC Power	see Section 7.2.12.3	
37	Assembly, Volume Control Knob	see Section 7.2.10.1	
38	Cap, Knob	see Section 7.2.10.1	
39	Cover, Knob	see Section 7.2.10.1	

Table 9-2. IPB for the Infuser		
Index Number	Nomenclature	Replacement Procedure
40	Spacer, Nylon	see Section 7.2.10.1
41	Link, Door	see Section 7.2.14.10
42	Spring, Extension	see Section 7.2.14.9
43	Gasket, Fluid Shield, .75	see Section 7.2.14.9
44	Gasket, Fluid Shield, 1.09	see Section 7.2.14.9
45	Assembly, Cable, Peripheral #2	see Section 7.2.11
46	Assembly, Cable, Peripheral #1	see Section 7.2.11
47	Assembly, Cable, CPU/Driver	see Section 7.2.14.4
48	Assembly, Piezo Alarm	see Section 7.2.14.7
49	Battery	see Section 7.2.4
50	Assembly, Wire Harness, Battery	see Section 7.2.4
51	Door, Battery	see Section 7.2.4
52	Pad, Door	see Section 7.2.4
53	Tape, Insulation	see Section 7.2.14.4
54	Tape, Ferrite	see Section 7.2.14.4
55	Gasket, EMI	see Section 7.2.8.1
56	Gasket, EMI, D-Shape, 6.62 in.	see Section 7.2.8.2
57	Gasket, EMI, D-Shape, 13 in.	see Section 7.2.8.2
58	Gasket, Front/Rear Enclosure	see Section 7.2.6.1
59	Gasket, Rear Enclosure, 45 7/8 in.	see Section 7.2.12.1
60	Gasket, Rear Enclosure, 20 13/16 in.	see Section 7.2.12.1
61	Gasket, Keypad	see Section 7.2.8.3
62	Gasket, Top Seal	see Section 7.2.8.4
63	Cap, Door Pivot	see Section 7.2.14.9
64	Connector, AC	see Section 7.2.12.4
65	Drawer, Fuse	see Section 7.2.12.5
66	Fuse, 1.6 A, 250 V	see Section 7.2.12.5
67	Terminal, Equipotential	see Section 7.2.12.2
68	Seal, Round	see Section 7.2.12.2
69	Mount, Cable Tie	see Section 7.2.11

Table 9-2. IPB for the Infuser			
Index Number	Nomenclature	Replacement Procedure	
70	Tie, Cable	see Section 7.2.11	
71	Ring, Retaining	see Section 7.2.4	
72	Screw, 4-24 x 1/4, Pan Head, Phillips, SS	As applicable	
73	Screw, 4-40 x 3/8, Pan Head, Phillips, SS	As applicable	
74	Screw, 4-40 x 1/4, Hex Head, Slotted, with Washer	As applicable	
75	Screw, 4-40 x 1/4, Pan Head, Phillips, SS	As applicable	
76	Screw, 4-40 x 3/8, Pan Head, Phillips, SS	As applicable	
77	Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer	As applicable	
78	Screw, 4-40 x 3/16, Hex Head, Slotted, with Washer	As applicable	
79	Screw, 6-32 x 1 1/4, Pan Head, Phillips, SS	As applicable	
80	Screw, 6-32 x 1/2, Pan Head, Phillips, SS	As applicable	
81	Screw, 6-32 x 1/2, Hex Head, Slotted, with Washer	As applicable	
82	Screw, 6-32 x 2 3/4, Pan Head, Phillips, SS	As applicable	
83	Screw, 8-32 x 3 1/2, Pan Head, Phillips, SS	As applicable	
84	Screw, 10-32 x 1/2, Hex Head, Slotted, with Washer	As applicable	
85	Washer, Flat, #4	As applicable	
86	Washer, Flat, #6	As applicable	
87	Washer, Flat, #8	As applicable	
88	Washer, Flat, Nylon	As applicable	
89	Washer, Lock, Split, #6	As applicable	
90	Washer, Lock, 1/4, Internal Tooth	As applicable	
91	Nut, Hex, 4-40	As applicable	
92	Nut, KEP, 4-40	As applicable	
93	Nut, Hex, 6-32	As applicable	
94	Nut, Hex, Nurse Call Jack	see Section 7.2.10.2	
95	Assembly, Minipole A: Hanger, Bag B: Housing, Clutch C: Ring, Cotter D: Spring, Clutch	see Section 7.2.13	



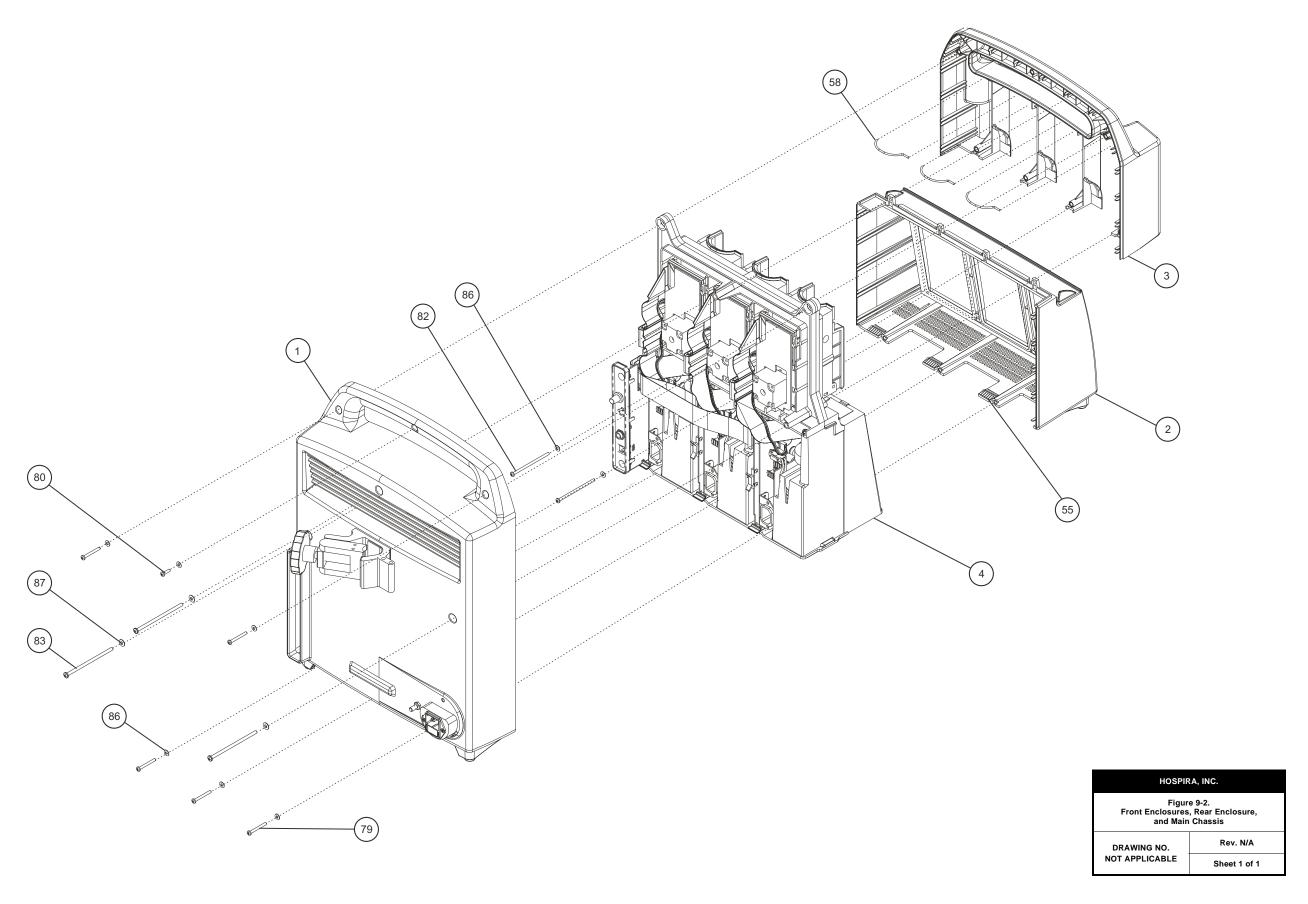
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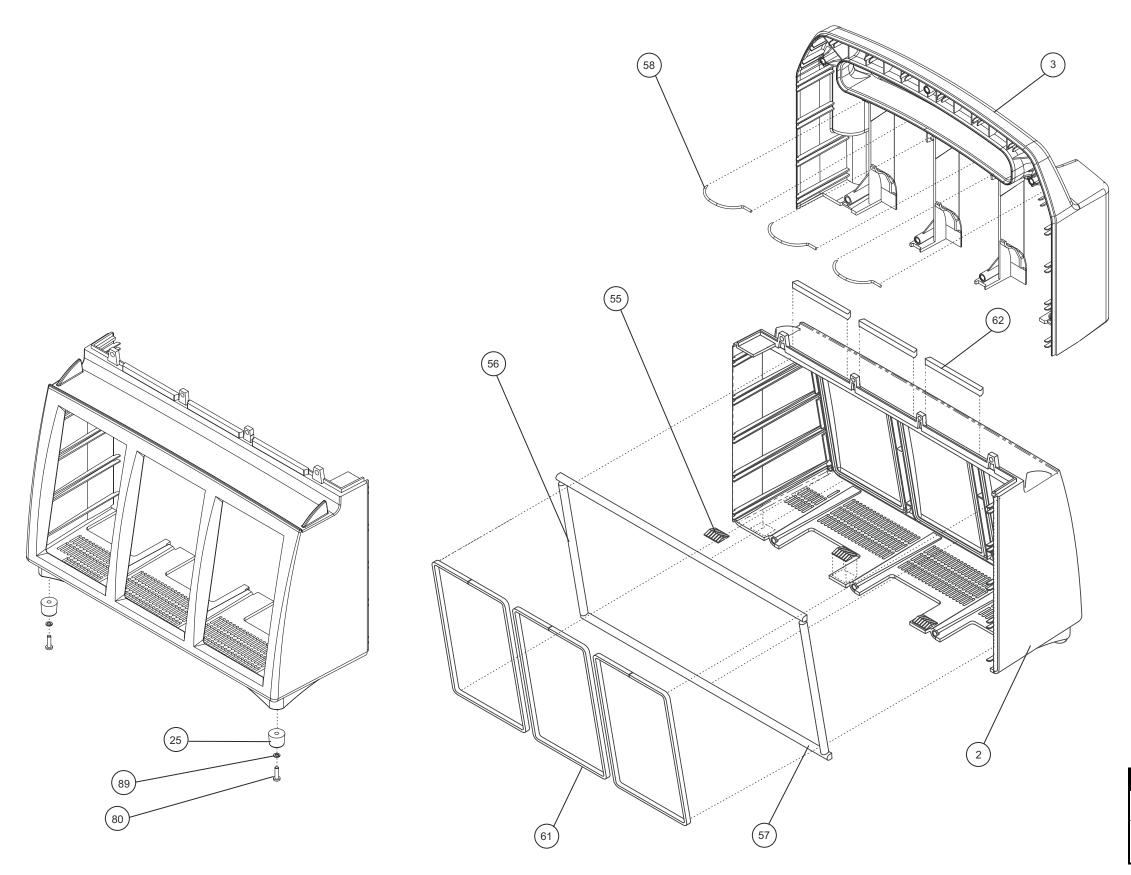
HOSPIRA, INC.	
Figure 9-1. Illustrated Parts Breakdown	
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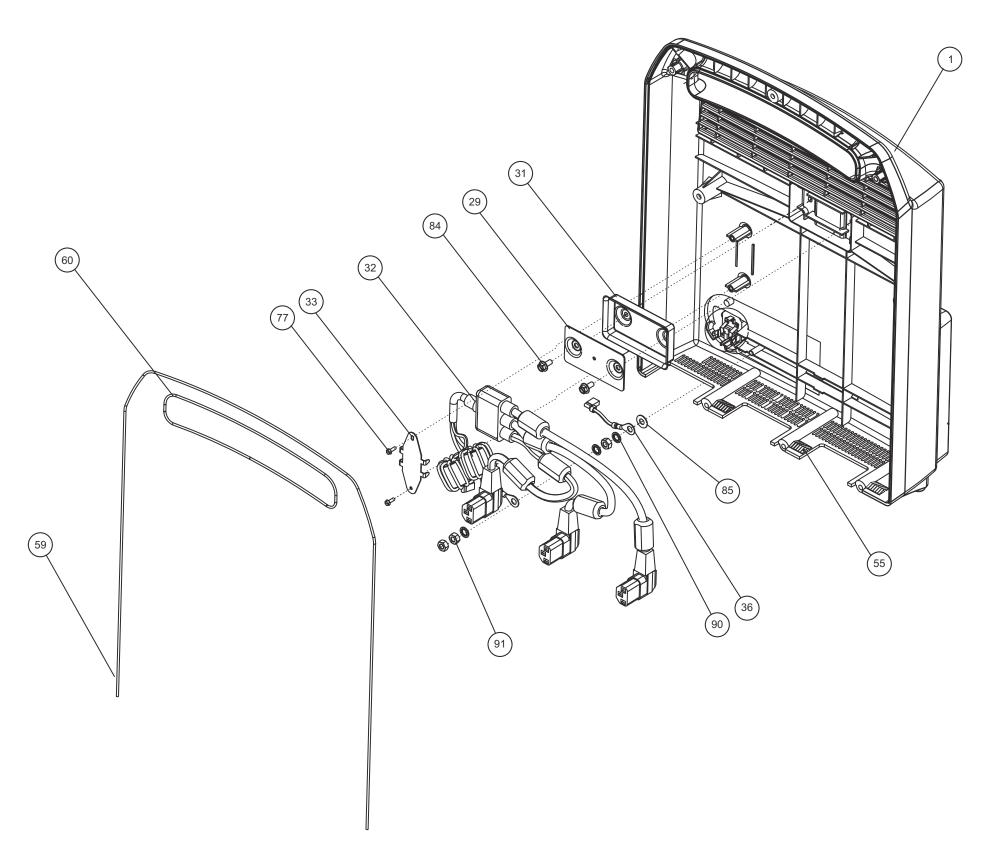


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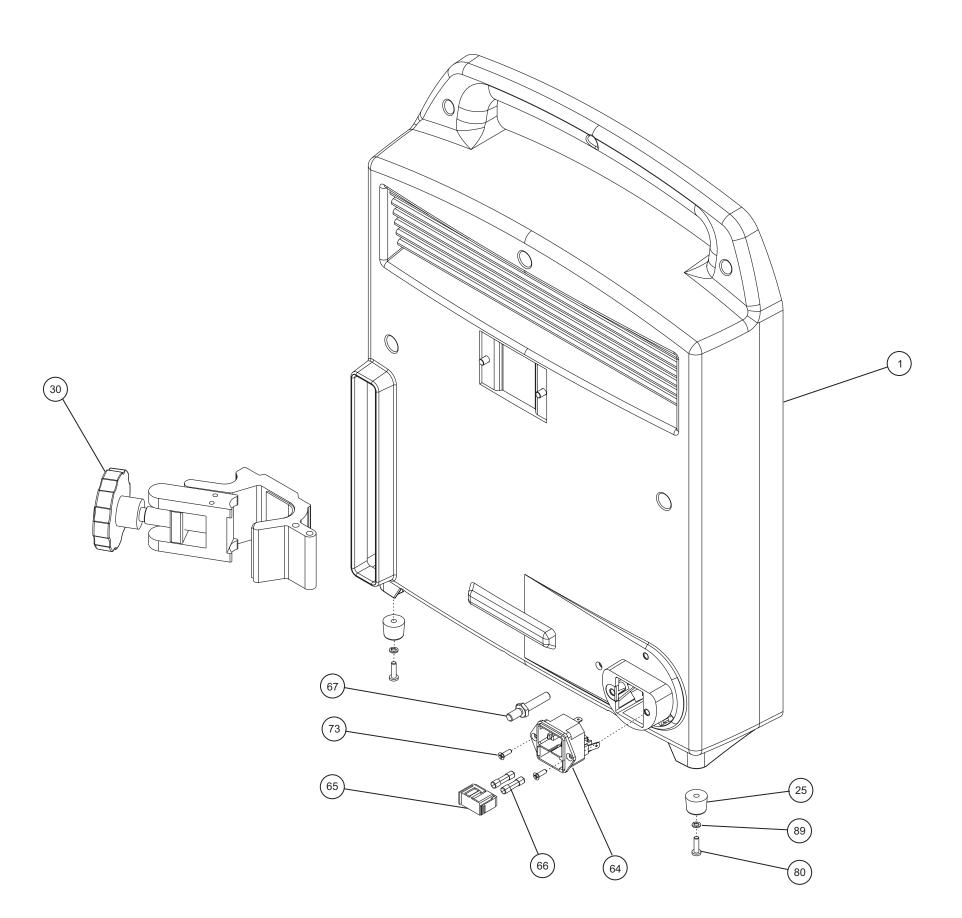
HOSPIRA, INC.		
Figure 9-3. Front Enclosure Assemblies		
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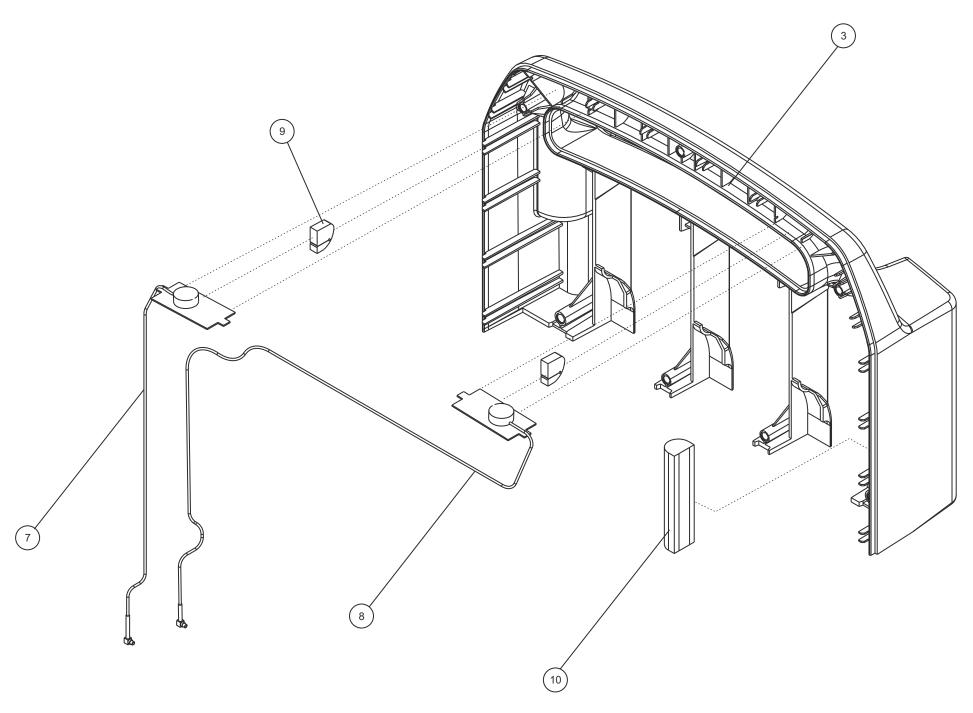
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Figure 9-4. Rear Enclosure Assembly	
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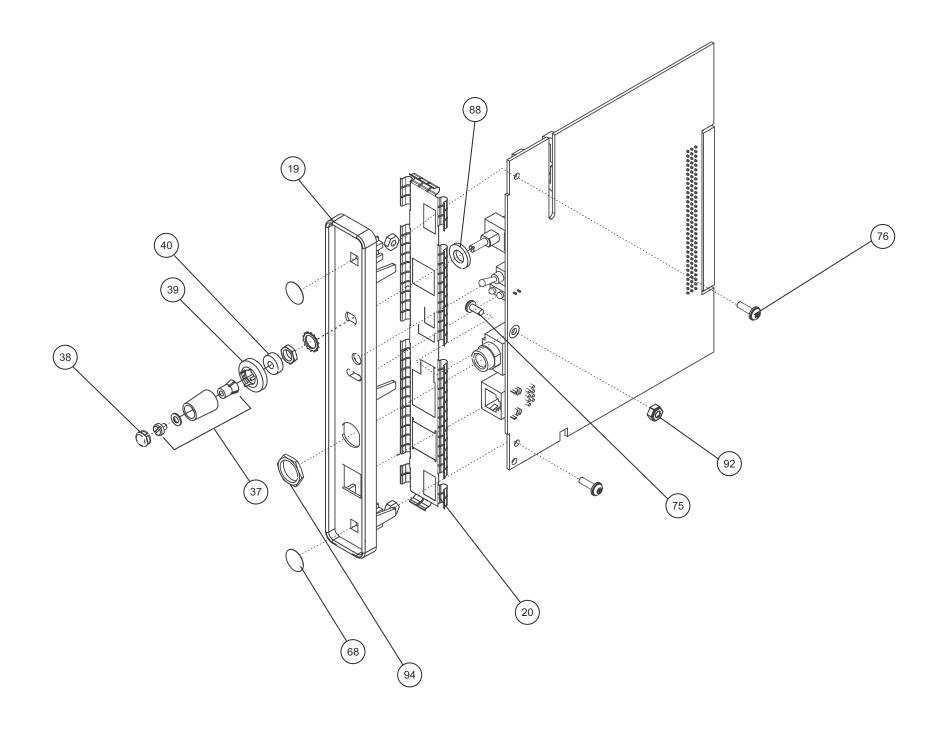
	HOSPIRA, INC.	
	Figure 9-4. Rear Enclosure Assembly	
	DRAWING NO. NOT APPLICABLE	Rev. N/A
		Sheet 2 of 2

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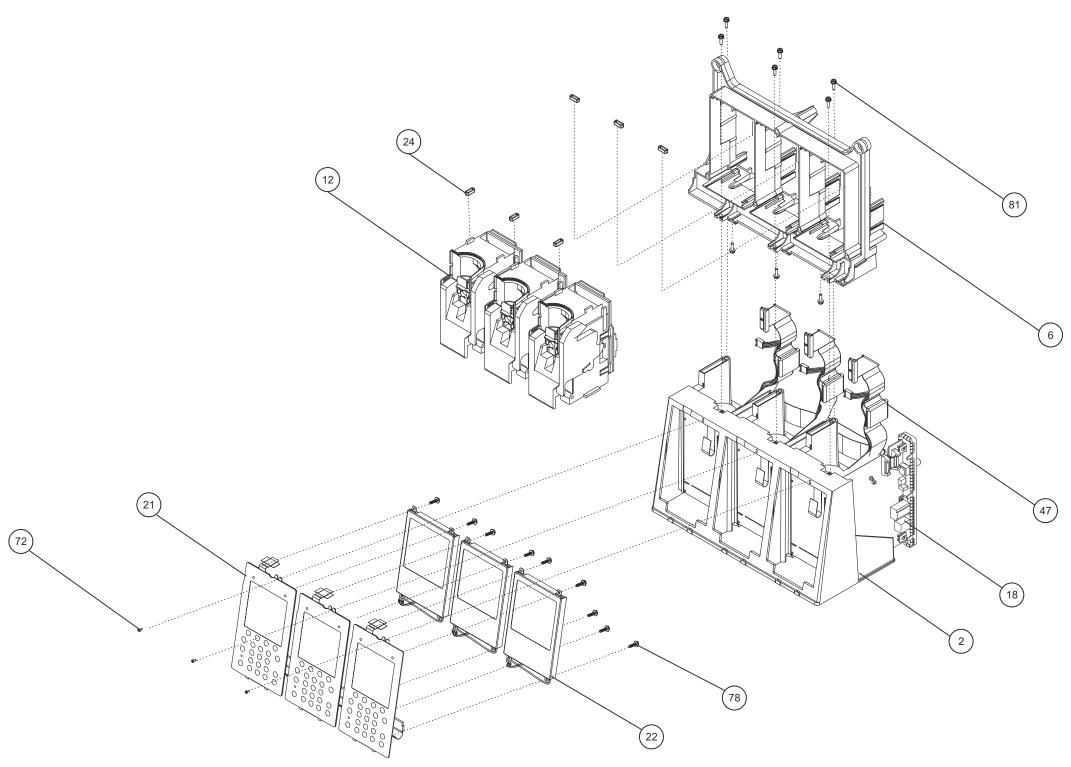
HOSPIRA, INC.		
Figure 9-5. Antenna PWAs		
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	Sheet 1 of 1	

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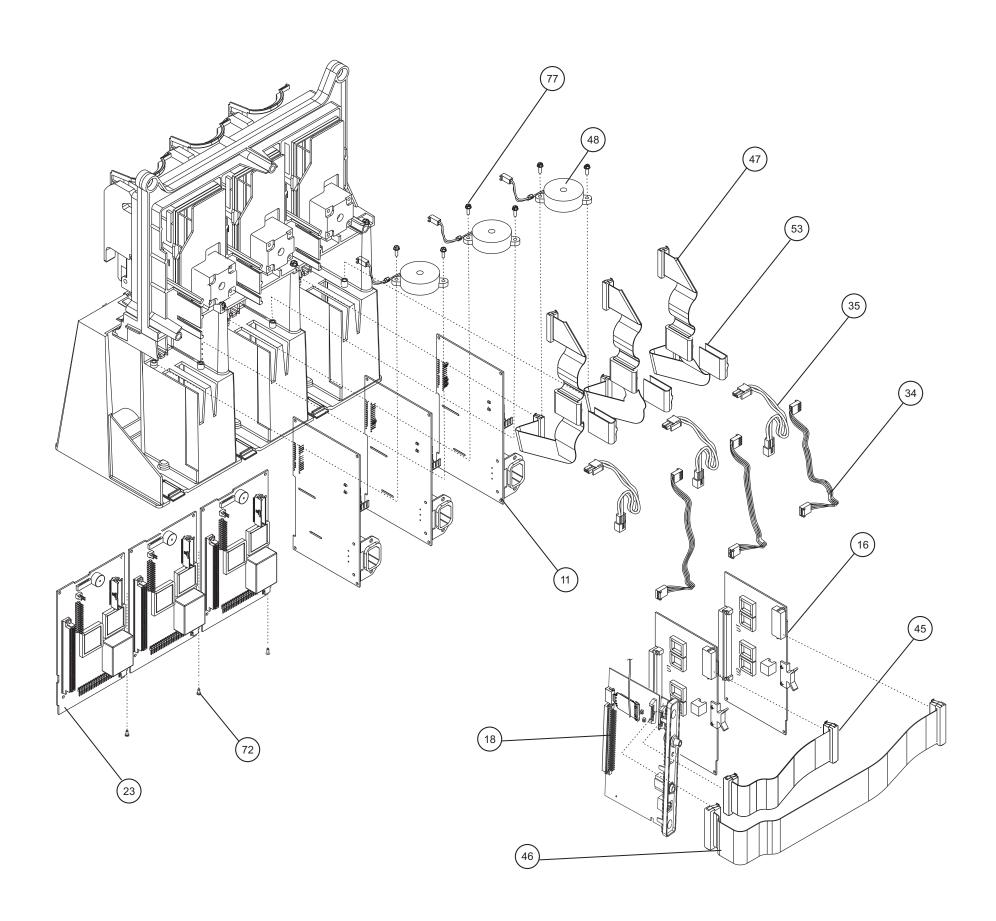
HOSPIRA, INC.	
Figure 9-6. Peripheral Interface Assembly	
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	HOSPIRA, INC.	
	Figure 9-7. Main Chassis Assembly	
	DRAWING NO. NOT APPLICABLE	Rev. N/A
		Sheet 1 of 2

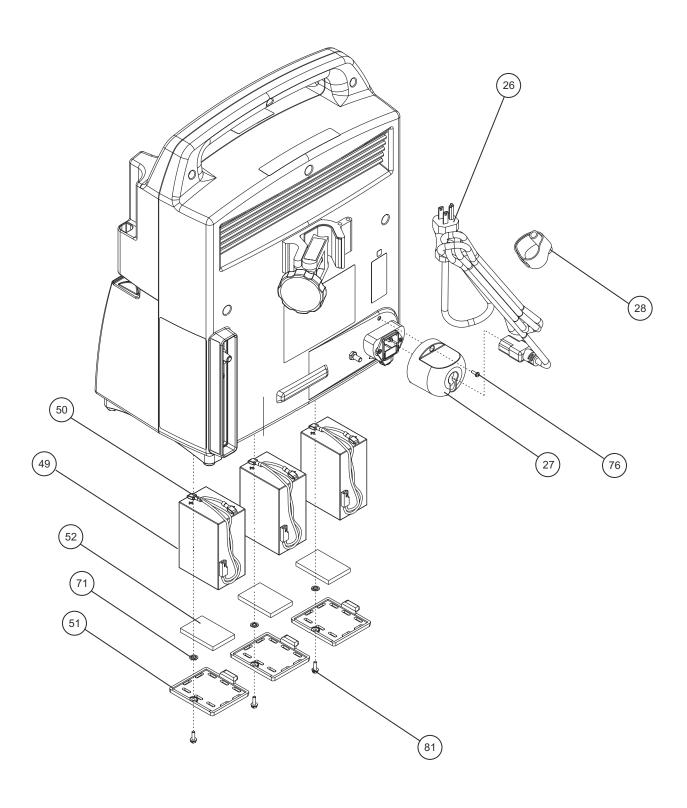
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HOSPIF	RA, INC.	
Figure 9-7. Main Chassis Assembly		
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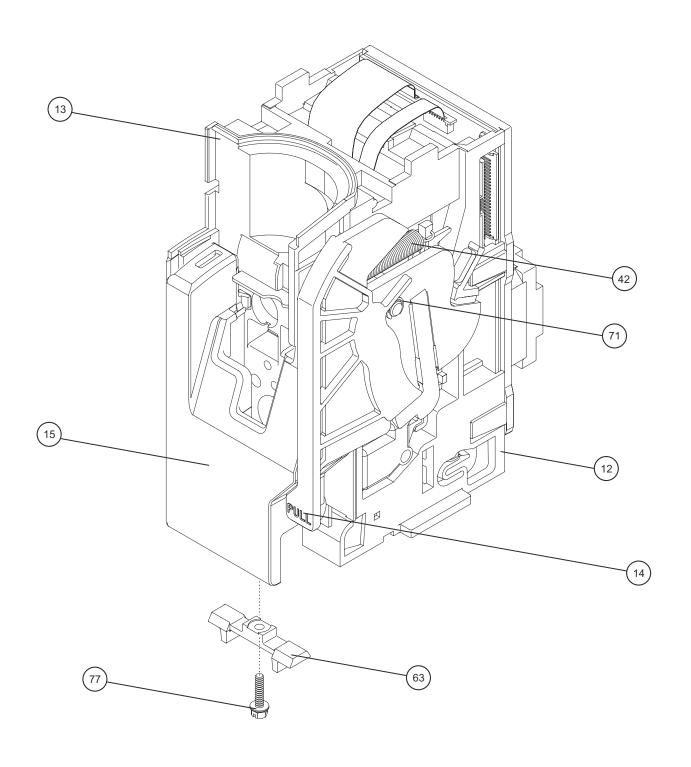
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HOSPIRA, INC.			
Figure 9-8. AC Power Cord Assembly and Battery Assembly			
DRAWING NO.	Rev. N/A		
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HOSPIRA, INC.			
Figure 9-9. Mechanism Assembly			
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### **APPENDIX**

## USE OF THE INFUSION SYSTEM IN ELECTROMAGNETIC ENVIRONMENTS

EN-2 The Plum A+3 with Hospira MedNet Software is intended for use in the electromagnetic environment specified in *Table A-1*, *Table A-2*, *Table A-3*, and *Table A-4*. The user of the infusion system should assure that it is used only in the appropriate environment.

#### **ELECTROMAGNETIC EMISSIONS**

Table A-1 details electromagnetic emissions compliance and guidance.

Table A-1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions			
Emissions Test	Compliance	Electromagnetic Enforcement - Guidance	
RF Emissions CISPR11	Class B	The infuser is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network	
Harmonic Emissions IEC 61000-3-2	Class B	that supplies buildings used for domestic purposes	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies		

#### **ELECTROMAGNETIC IMMUNITY**

*Table A-2* details guidance for the electromagnetic environment.

Table A-2. Guidance and Manufacturer's Declaration - Electromagnetic Immunity				
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete, or ceramic tile  If floors are covered with synthetic material, relative humidity should be at least 30%	
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	environment	
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U <sub>r</sub> (>95% dip in U <sub>r</sub> ) for 0.5 cycle  40% U <sub>r</sub> (60% dip in U <sub>r</sub> ) for 5 cycles  70% U <sub>r</sub> (30% dip in U <sub>r</sub> ) for 25 cycles  5% U <sub>r</sub> (>95% dip in U <sub>r</sub> ) for 5 seconds	<5% U <sub>r</sub> (>95% dip in U <sub>r</sub> ) for 0.5 cycle  40% U <sub>r</sub> (60% dip in U <sub>r</sub> ) for 5 cycles  70% U <sub>r</sub> (30% dip in U <sub>r</sub> ) for 25 cycles  5% U <sub>r</sub> (>95% dip in U <sub>r</sub> ) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment  If the user of the infusion system requires continued operation during power mains interruptions, it is recommended that the infuser be powered from an uninterruptible AC mains power supply or the battery	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment	

 $\boldsymbol{U}_{\boldsymbol{r}}$  is the AC Mains voltage prior to application of the test level.

Compliance levels are tested to IEC 60601-2-24 requirements, which are more stringent than IEC 61000-4-2 and IEC 61000-4-8.

## ELECTROMAGNETIC IMMUNITY FOR LIFE-SUPPORTING EQUIPMENT AND SYSTEMS

*Table A-3* provides guidance for use of the infusion system near communications equipment.

Table A-3. Guidance and Manufacturer's Declaration - Electromagnetic Immunity for Life-Supporting Equipment and Systems					
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Immunity Guidance		
			Portable and mobile RF communications equipment should be used no closer to any part of the infusion system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter		
Conducted RF	3 V <sub>rms</sub>	[V <sub>1</sub> ] V	Recommended separation distance		
IEC 61000-4-6	150 kHz to 80 MHz outside ISM bands <sup>a</sup>		$d = \left[\frac{3, 5}{V_1}\right] \sqrt{P}$		
	10 V <sub>rms</sub>	[V <sub>2</sub> ] V			
	150 kHz to 80 MHz in ISM bands <sup>a</sup>		$d = \left[\frac{12}{V_2}\right] \sqrt{P}$		
Radiated RF	10 V/m	[E <sub>1</sub> ] V/m	Recommended separation distance:		
IEC 61000-4-3	80 MHZ to 2.5 GHz		$d = \left[\frac{12}{E_1}\right] \sqrt{P}  80 \text{ MHz to } 800 \text{ MHz}$		
			$d = \left[\frac{23}{E_1}\right] \sqrt{P}  800 \text{ MHz to } 2.5 \text{ GHz}$		
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m) <sup>b</sup>		
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range <sup>d</sup>		
			Interference may occur in the vicinity of equipment marked with the following symbol		
			(( <u>@</u> ))		

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

At 80 MHz and 800 MHz, the higher frequency range applies.

- $^{\mathbf{a}}$  The industrial, scientific and medical (ISM) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.660 MHz to 40.700 MHz.
- <sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- <sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular and/or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the infuser is used exceeds the applicable RF compliance level above, the infuser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the infuser.
- $^{f d}$  Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V $_1$ ] V/m.

#### RECOMMENDED SEPARATION DISTANCES FOR COMMUNICATIONS EQUIPMENT

The infusion system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The recommendations provided in *Table A-4* help the user of the infusion system to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the infuser, according to the maximum output power of the communications equipment.

Table A-4. Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Infusion System					
Rated Maximum Output Power of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (Meters)				
	150 kHz to 80 MHZ 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.5 outside ISM bands in ISM bands				
	$d = \left[\frac{3, 5}{V_1}\right] \sqrt{P}$	$d = \left[\frac{12}{V_2}\right] \sqrt{P}$	$d = \left[\frac{12}{E_1}\right] \sqrt{P}$	$d = \left[\frac{23}{E_1}\right] \sqrt{P}$	
0.01	0.035	0.12	0.12	0.23	
0.1	0.11	0.38	0.38	0.73	
1	0.35	1.2	1.2	2.3	
10	1.1	3.8	3.8	7.3	
100	3.5 12 12 23				

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.



Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

The ISM bands between 150 kHz and 80 MHz are 6.765 MHz to 6.695 MHz: 13.553 MHz to 13.567 MHz: 26.957 MHz to 27.283 MHz: and 40.660 MHz to 40.700 MHz.

An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

$$V_1$$
=10  $V_{rms}$ ,  $V_2$ =10  $V_{rms}$ , and  $E_1$ =10 V/meter

APPENDIX

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Ţ	Fragile, Handle with Care		Temperature limitation
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