PLUM A+™

INFUSION SYSTEM

with

Hospira MedNet™

For use with the following list numbers:

11971 12391 20679 20792

Technical Service Manual

Hospira, Inc.
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Lake Forest, IL 60045 USA

430-95551-011 (A, 2015-03)

Hospira

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Change History

Part Number	Description of Change
430-95551-010 (A, 2014-08)	Tenth Issue Update front and back covers, table of contents, and lists of figures and tables. Make various clerical corrections. Section 5 - Add instruction to Section 5.2.4, Door Roller Inspection and Test - Update Figure 5-47 - Update Section 5.3.5, Unrestricted Flow Test - Revise step 6 in Section 5.3.9, Keypad Lockout Switch Test - Update Figure 5-50 for control arm position. - Update Figure 5-53, relocate it and the following step in Section 5.3.13, Distal Occlusion Test Section 7 - Add replacement procedure, including eleven new figures, for CPU/driver cable assembly to Section 7.2.12.4, CPU PWA Replacement - Add new procedure: “Section 7.2.12.6.1 Enter the serial number.” - Add Note regarding gasket tape in Section 7.2.12.8, Cassette Door and Fluid Shield Replacement Section 8 - Update Proximal Occlusion Alarm specification Section 9 - Revise “Section 9” reference link; should not be bold and blue. It is not a hyperlink. Back Cover - Remove “All Rights Reserved.” - Remove “Printed in USA” for consistency with other Plum technical service manuals.
430-95551-011 (A, 2015-03)	Eleventh Issue Section 7 - Add Cautions about regulator closer inspection and revise fluid shield replacement instructions

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Section 1

INTRODUCTION

The Plum A+™ with Hospira MedNet™ Software is an advanced medication management system designed to meet the growing demand for hospital wide, alternate site, and home healthcare device standardization. Advanced clinical capabilities, autoprogramming, networked communication, and a plug-and-play platform make the Plum A+ with Hospira MedNet Software a convenient and cost-effective multipurpose, multimode, flexible infusion system.

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 Software Installation and Configuration Guide,* and the *Hospira MedNet 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 Drawings
- ❑ Appendix
- ❑ 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+ and Plum A+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 configuration.

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] **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 alphanumeric 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: Alphanumeric designators may be followed by 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
DMA	Direct memory access
DMM	Digital multimeter
DPM	Digital pressure meter
ECG	Electrocardiogram
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
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
mmHg	Millimeter of mercury
MMIO	Memory-mapped input/output
MOSFET	Metal-oxide semiconductor field-effect transistor
ms	Millisecond
ng	Nanogram
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
V_{AC}	Volts AC
V_{CC}	Collector supply voltage
VCO	Voltage-controlled oscillator
V_{DC}	Volts DC
V_{rms}	Volts root mean square
VSC	5 V_{DC} supply circuitry
VSO	Voltage sweep oscillator
VTBI	Volume to be infused
WDI	Watchdog input
WiFi	Wireless fidelity
μA	Microampere
μL	Microliter
μV	Microvolt
μsec	Microsecond

1.5 USER QUALIFICATION

The Plum A+ 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

List numbers **20679** and **20792** are compliant with IEC/EN 60601-1-2 (2001), and have 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 *(see the System Operating Manual)*.

List numbers **11971** and **12391** are compliant with IEC/EN 60601-1-2 (1993).

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 that 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 is configuring 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

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: 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: 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: 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** may briefly appear prior to the **CASSETTE TEST IN PROGRESS** message.

7. A **NEW PATIENT?** message may appear. Press **[YES]**.
8. Press **[ON/OFF]** to turn off the infuser.

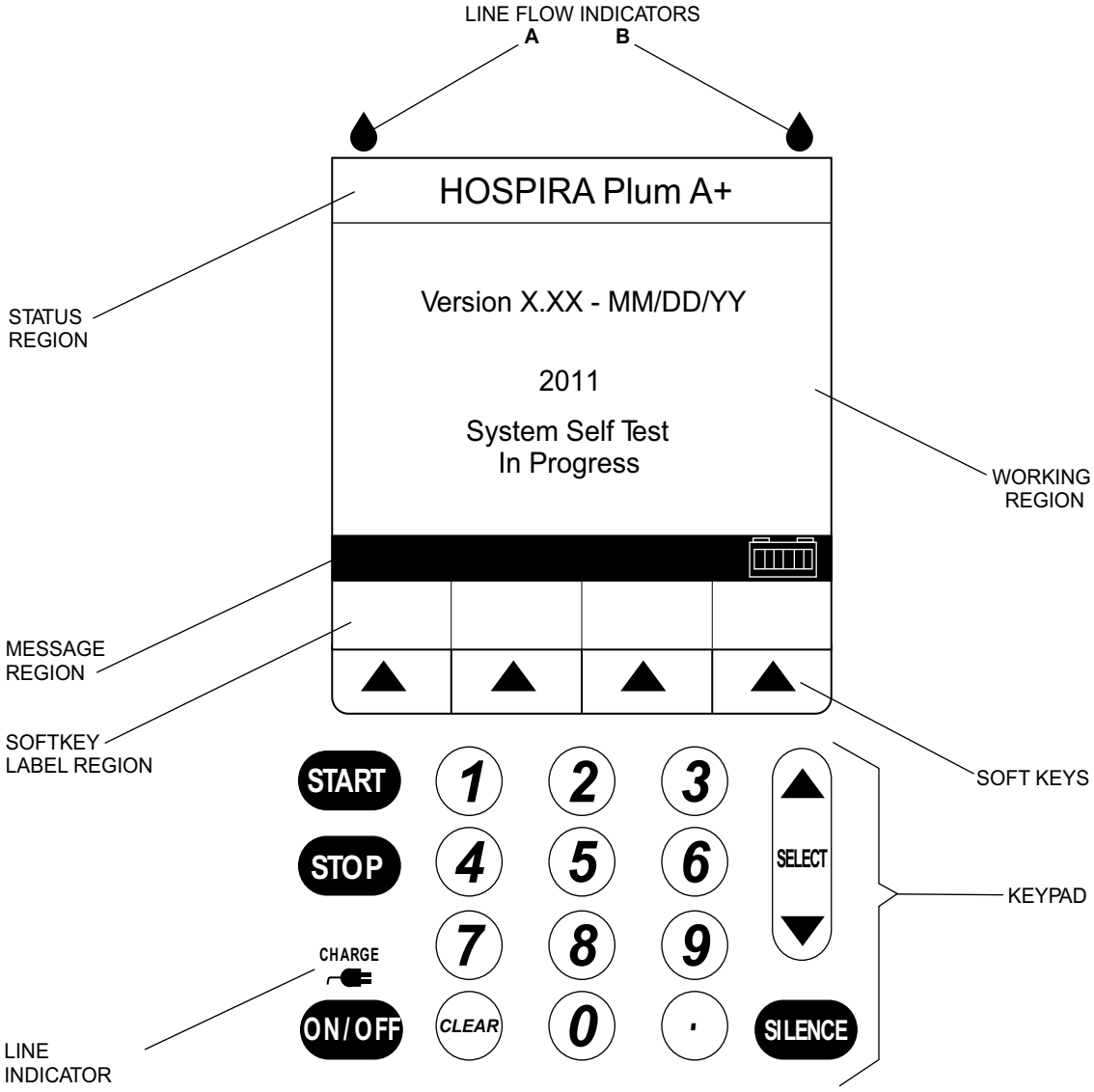

Figure 1-1. Display and Keypad

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)*.

Biomed screens do not time out for the **Infuser Idle** alarm or **No Action** alarm.

The battery will not be detected in Biomed mode.

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

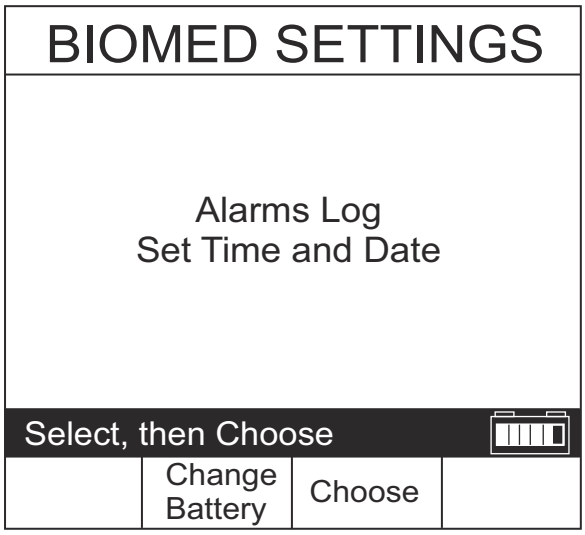

Figure 1-2. Biomed Settings

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]** to view the Alarms Log.
3. Press **[BACK]** to exit the Alarms Log and return to the main **BIOMED SETTINGS** screen.

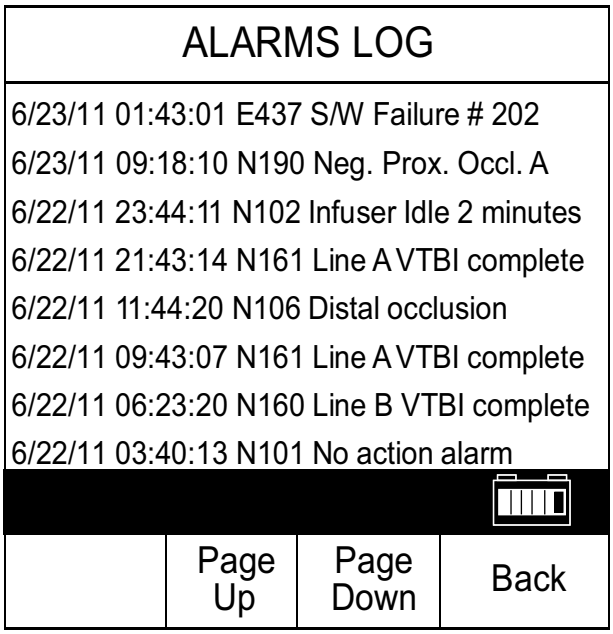

Figure 1-3. Alarms Log

1.10.2
SETTING THE TIME AND DATE

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

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 further changes to the Biomed settings, turn off the infuser.

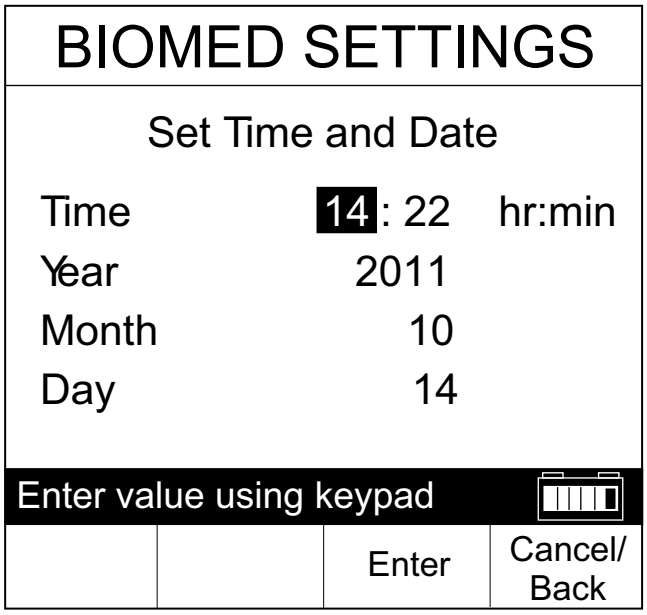

Figure 1-4. Setting the Time and Date

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 that 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***.

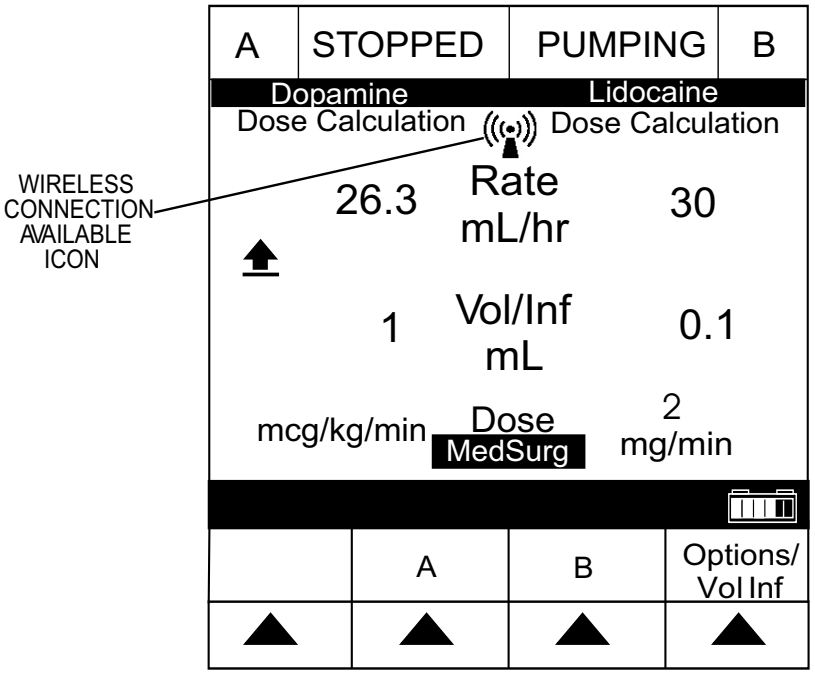

Figure 1-5. Main Delivery Screen

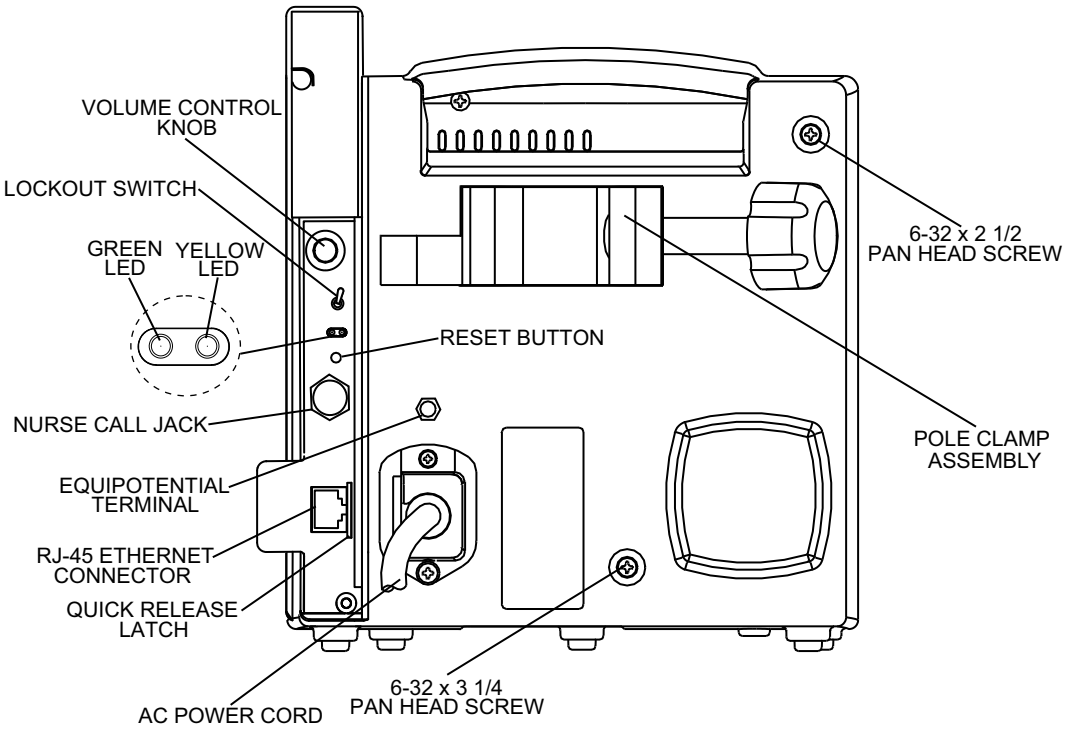

Figure 1-6. Rear View

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.

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Section 3

SYSTEM OPERATING MANUAL

A copy of the System Operating Manual is included with every Plum A+ 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+ infusion system. The theory of operation details the general description, electronic subsystem overview, printed wiring assemblies, LCD, and mechanical overview of the infuser.

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).

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 (CPU) is a Motorola MC68302. The CPU has a closely coupled 16 bit data bus and 24 bit address bus, an 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 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 contain 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.

4.2.1.2
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 (CS0*), 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.

4.2.1.6
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 V_{DC} supply. The output signal levels are shifted up to 5 V_{DC} by buffers for interface with the 5 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 Ω with a range of 323 to 10 KΩ. 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_{rms} is minimum intensity and 5 mA_{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.

4.2.1.9
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 timeout period (1.6 second minimum) right after a reset. The normal timeout 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 timeout 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 timeout period. After a reset, the software reads this memory-mapped bit to determine if the latest reset was a watchdog timeout.

4.2.1.11
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 μsec. 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 4-1)***. The input multiplexer is a break-before-make type to reduce input-to-input noise injection resulting from channel switching.

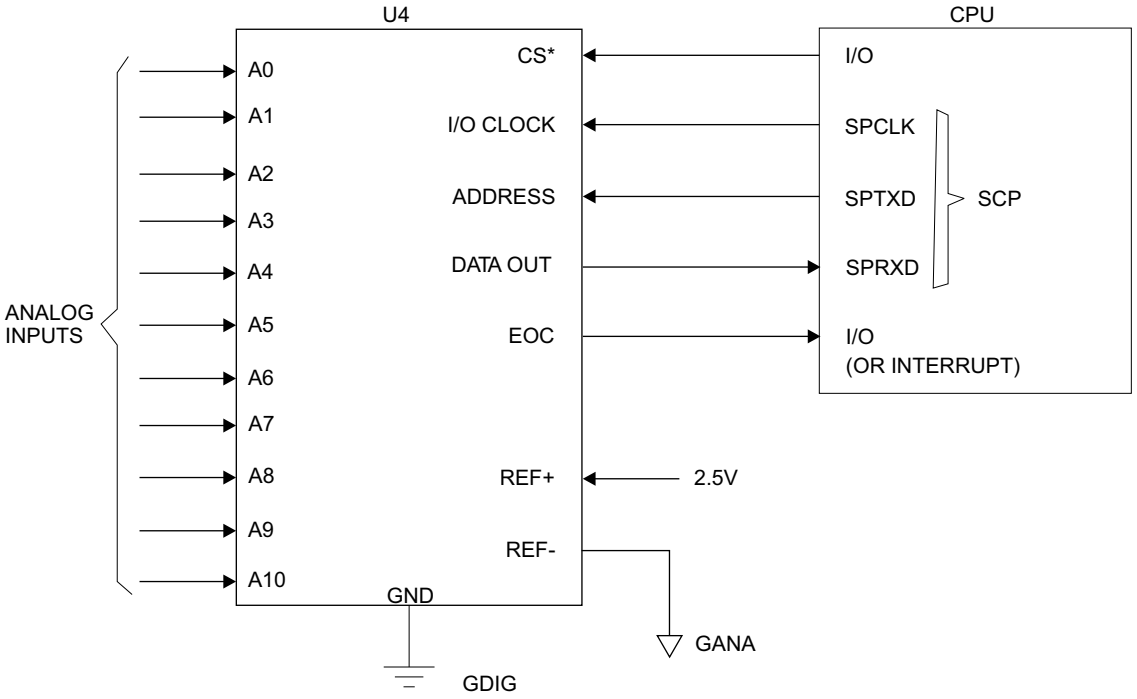

Figure 4-1. Serial Interface to ADC

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	A3	$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	$(V_{ref(+)} - V_{ref(-)}) / 2$
		$0C	$V_{ref(-)}$
		$0D	$V_{ref(+)}$

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 condition the DAC outputs.

4.2.1.13
FRONT PANEL KEYPAD MATRIX

A 5 x 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	[▲]
Row 2	Stop	4	5	6	
Row 1		7	8	9	[▼]
Row 0	On/Off	Clear	0	.	Silence

4.2.1.14
FRONT PANEL ON/OFF KEY

The **[ON/OFF]** 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 **[ON/OFF]** 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 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. A loud, main audible indicator is 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 **[ON/OFF]** 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	**P**	3.3 V system power
V5_0/VANA	**P**	5 V analog and interface power
VMOT	**P**	Raw, unregulated charger voltage or battery voltage
V2_7	**P**	2.7 V backup power for RTC and non-volatile SRAM
VSC	**P**	Full time 5 V supply, backed up by supercap
V12_0	**P**	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	Type	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

Table 4-4. CPU-Mechanism Interface Signals		
Signal Name	**Type**	**Description**
SPCLK	**D, O**	SCP clock output
SPRXD	**D, I**	SCP receive data
SPTXD	**D, O**	SCP transmit data
CSSEP*	**D, O**	Chip select, EEPROM
V5_0	**P**	5 V supply for interface power
V3_3	**P**	3.3 V supply for logic power
GDIG	**P**	Digital ground
VANA	**P**	5 V supply for analog power
GANA	**P**	Analog ground
VMOT, GMOT	**P**	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

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

4.2.2.1
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 6.74 V_{DC} (or 7.35 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 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: main loop for normal control, 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 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 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 V_{DC} logic signal (OVRVLT*) is provided to the CPU subsystem.

4.2.2.3
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 [ON/OFF] key is pressed or the AC line is plugged in. The [ON/OFF] 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.

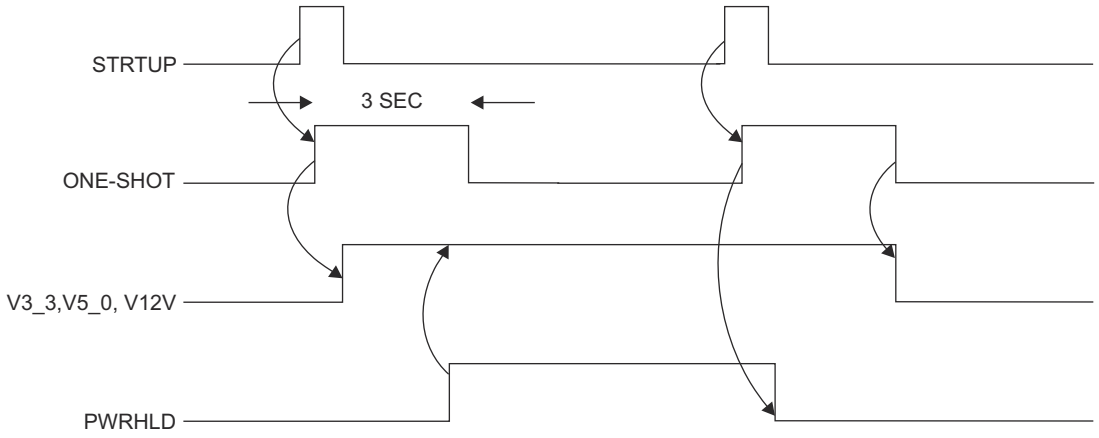

Figure 4-2. System Startup and Shutdown Timing, Battery Powered

4.2.2.6
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.

4.2.2.8
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 6.74 V_{DC} or 7.35 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 V_{DC} voltage reference U8. A 0.5 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.

4.2.2.9
BATTERY

The battery employed by the Plum infuser is a sealed lead acid (SLA) type rated at 6 volts DC and a current capacity of at least 4.0 ampere-hours.

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 infuser 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. After five minutes of operation on battery power, the infuser switches its display backlight intensity to a low intensity mode to conserve battery power.

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.

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.

4.2.3
MECHANISM SUBSYSTEM

The mechanism subsystem includes the electronics and electromechanical components that interface with 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 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 degrees/step (100 steps/rev) for the plunger motor, and 7.5 degrees/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.

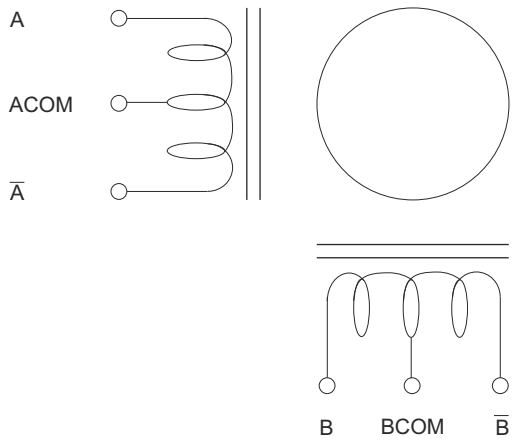

Figure 4-3. Stepper Motor Coils

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:

- 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 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 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)*.

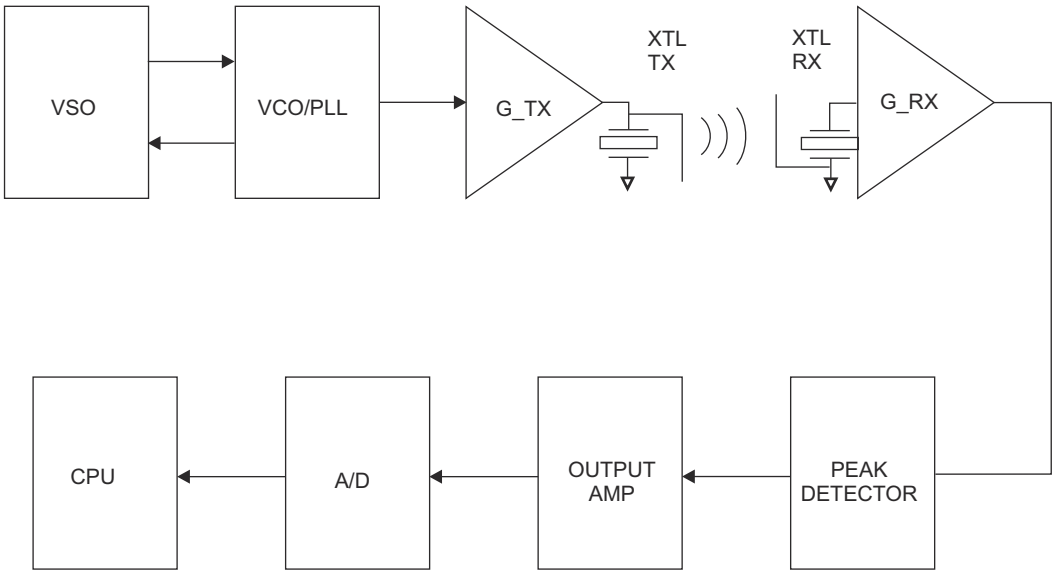

Figure 4-4. Air Sensor Block Diagram

4.2.3.4.1
Transmitter Circuitry

The transmitter circuitry consists of a voltage sweep oscillator (VSO), 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, which 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 output
- DIAIR 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.

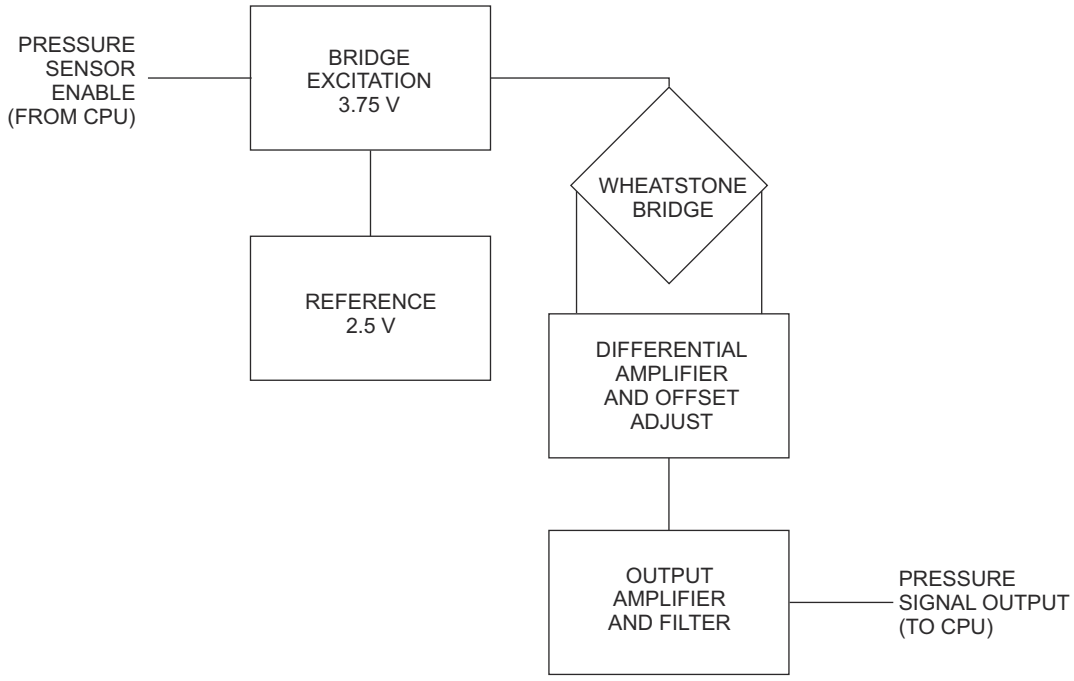

Figure 4-5. Pressure Sensor Excitation and Amplifier Block Diagram

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 enable
- DIPRE 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 PRESENCE SELECTION

The mechanism subsystem includes one force sensing resistor (FSR) switch that is coupled to the cassette and is used for cassette presence 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 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 KΩ.

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 x 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
- RS-232 interface
- USB interface
- Ethernet interface and isolations
- Clock oscillators
- Reset control
- LED indicators
- Power regulation

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

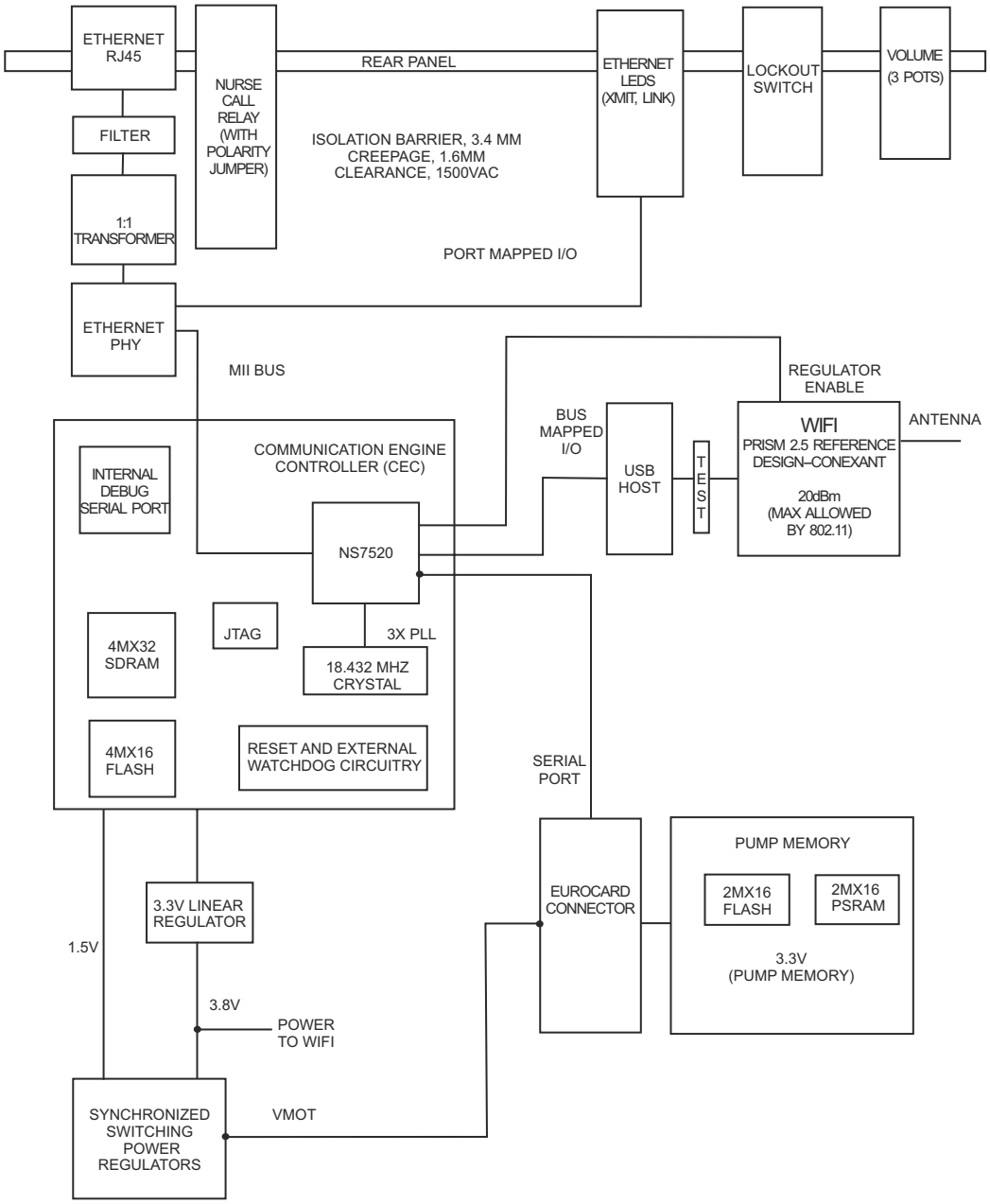

Figure 4-6. CE Module Block Diagram

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_{rms}.

4.2.4.2
WIRELESS MODULE

The wireless module consists of the 802.11 a/b/g circuitry, high frequency shielding, integrated surface mount antenna, 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 six printed wiring assemblies (PWA). 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
- AC power detection
- Main regulator fault detection
- System power
- Auxiliary supplies
- Power control
- Battery management

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	Type	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
PERIPHERAL PWA

The peripheral PWA is the CE module PWA, and contains the communication engine and rear user controls. The CE module is a plug-and-play module designed to be field replaceable to facilitate software upgrades or additional external interfaces.

The CE module interfaces via data and address buses on the peripheral 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 CE module 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.

The peripheral PWA is a four layer board, including one ground plane, one power plane, and two signal layers.

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

Table 4-6. Peripheral PWA Interface Connections

Connector	Type	Interface
P1	96 pin receptacle	Board-to-board connection to CPU PWA
J2	Block connector	Antenna cable assembly
J28	3 pin phone jack	Nurse call jack

4.3.3
ANTENNA PWA

The antenna PWA is housed in the CE module cover, and connected to the peripheral PWA by a cable assembly. All wireless communications are performed via the antenna according to IEEE 802.11 a/b/g specifications.

4.3.4
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 CE module. 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 4-7*** for CPU PWA interface connections.

Table 4-7. CPU PWA Interface Connections

Connector	Type	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
J24	2 pin header	Main audible alarm connector

4.3.5
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 4-8*** for driver PWA interface connections.

Table 4-8. Driver PWA Interface Connections

Connector	Type	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

4.3.6
SWITCH PWA

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

4.3.7
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 4-9*** for APP PWA interface connections.

Table 4-9. APP PWA Interface Connections

Connector	Type	Interface
J15	20 pin SMT	Flat flex cable to driver PWA
J11	10 pin SMT	Pressure sensor connector

4.4
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 degrees.

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 **[ON/OFF]** 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 into 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.

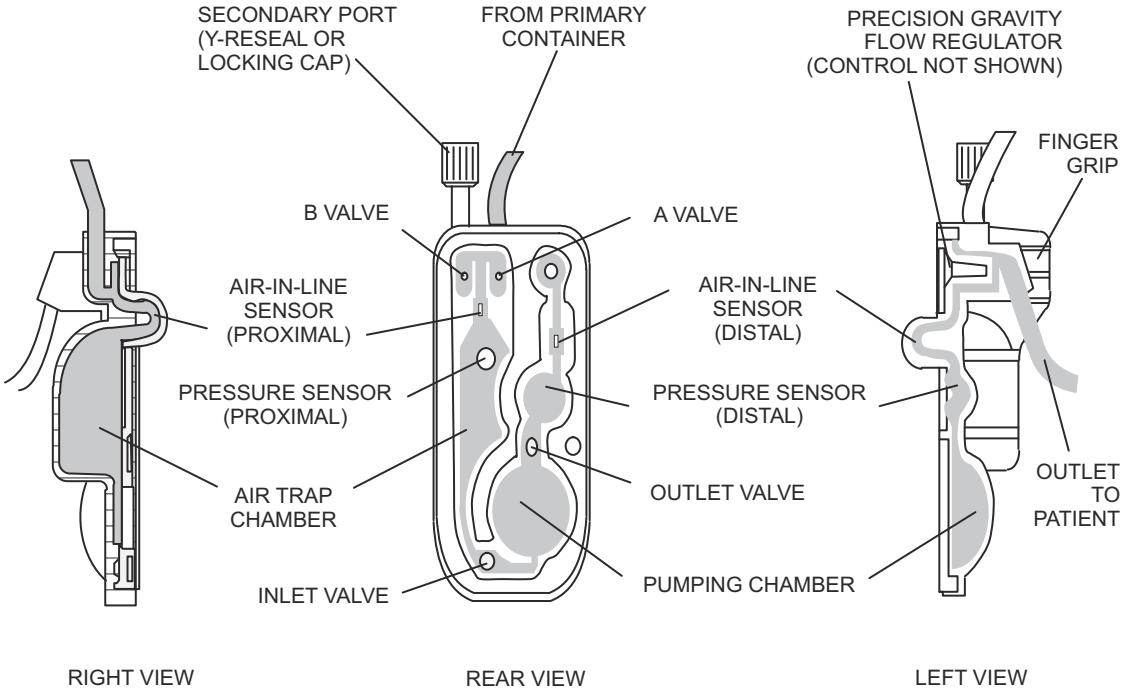

Figure 4-7. Fluid Path in the Cassette

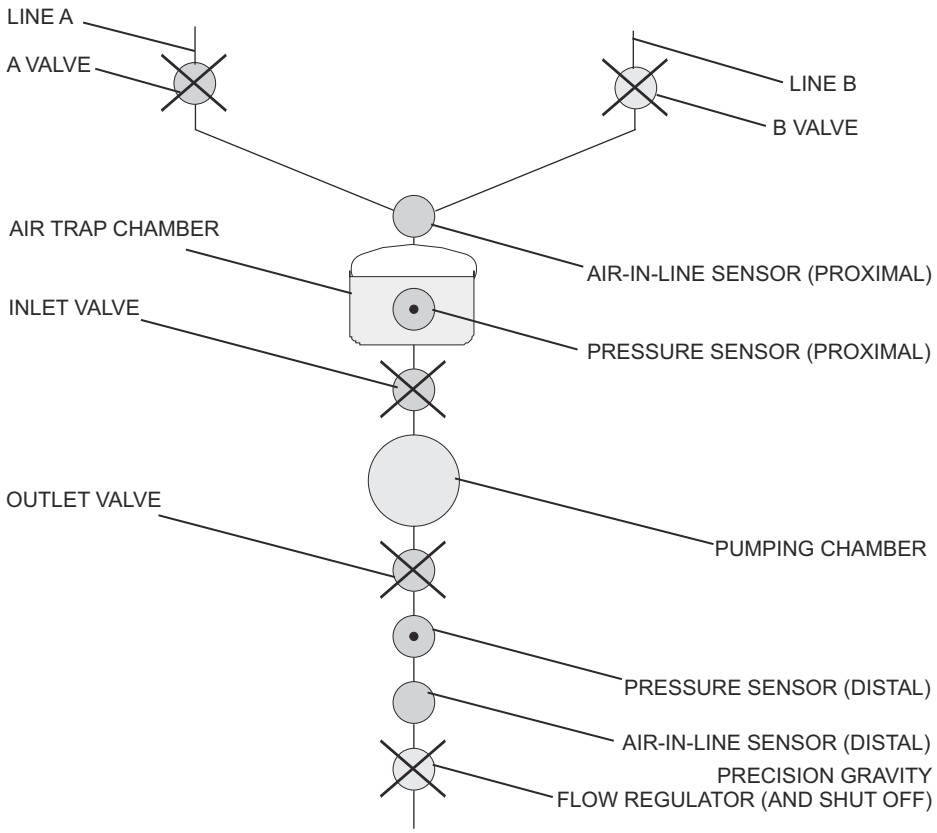

Figure 4-8. Major Elements of the Dual-Channel Cassette

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 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.

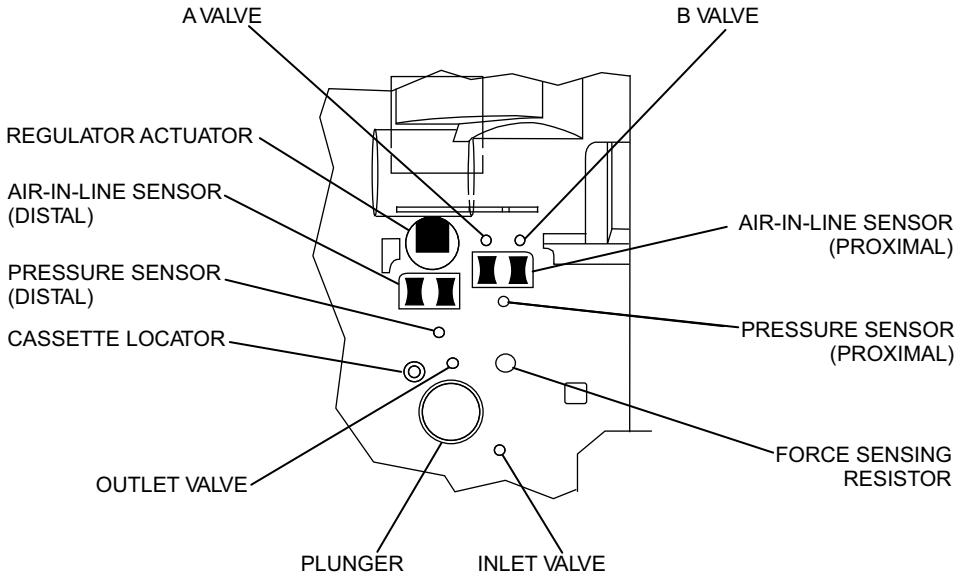

Figure 4-9. Mechanism Valve Pins and Sensor Locations

4.5.2.3
INLET/OUTLET VALVE SUBSYSTEM

The inlet/outlet valve subsystem is similar in function and build to the A/B valve subsystem *(see Section 4.5.2.2)*.

4.5.2.4
PLUNGER DRIVE SUBSYSTEM

The following are the main components of the plunger drive subsystem: 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 pump cycle to permit a 0.33 mL fluid displacement every pump 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.

Section 5

MAINTENANCE AND SERVICE TESTS

A complete maintenance program promotes infusion system longevity and trouble-free operation. Such a program should include cleaning, Preventive Maintenance, and the Performance Verification Test (PVT).

5.1 CLEANING AND SANITIZING

As a minimum requirement, inspect and clean the infuser after each use. In addition, establish a regular cleaning schedule for the device.

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 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 regarding dilution. 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	Manufacturer	Preparation
Dispatch™ Hospital Cleaner Disinfectant with Bleach	The Clorox Company	Per manufacturer's recommendation
Precise™ Hospital Foam Cleaner Disinfectant	The Clorox Company	Per manufacturer's recommendation
Sani-Cloth™ HB Wipe	Professional Disposables, Inc.	Per manufacturer's recommendation
Sani-Cloth™ Bleach Wipe	Professional Disposables, Inc.	Per manufacturer's recommendation
Sporicidin™	Sporicidin International	Per manufacturer's recommendation
Household Bleach	Various	Per hospital procedures; do not exceed one part bleach in ten parts water

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

5.2
PREVENTIVE MAINTENANCE

Hospira requires that preventive maintenance be performed at least once every 12 months. Replace components as required by visual inspection and test results.

Complete the ***Preventive Maintenance Checklist*** in ***Section 5.2.14***.

- **Note:** Perform the Performance Verification Test along with the visual Inspections as part of the preventive maintenance process at least once every12 months.
- **Note:** The distal and proximal pressure pins must be inspected at least once every 12 months and each time the infuser is serviced.
- **Note:** The sealed, lead-acid battery must be replaced at least once every 12 months.

Perform the preventive maintenance inspections and tests in the following sequence:

1. ***Section 5.2.1, Labels Inspection***
2. ***Section 5.2.2, AC Power Cord, Retainer, and Velcro Strap Inspection***
3. ***Section 5.2.3, Front Enclosure, Rear enclosure, Cassette Door, and Door Lever Inspection and Test***
4. ***Section 5.2.4, Door Roller Inspection and Test***
5. ***Section 5.2.5, Fluid Shield Inspection***
6. ***Section 5.2.6, Distal Pressure Pin Inspection***
7. ***Section 5.2.7, Proximal Pressure Pin Inspection***
8. ***Section 5.2.8, Rubber Foot Pad Inspection***
9. ***Section 5.2.9, Pole Clamp Inspection and Test***
10. ***Section 5.2.10, Battery Inspection and Replacement***
11. ***Section 5.2.11, Keypad Inspection***
12. ***Section 5.2.12, Display and Indicators Inspection***
13. ***Section 5.2.13, Keypad Lockout Switch Inspection***
14. ***Section 5.2.14, Preventive Maintenance Checklist***

5.2.1
LABELS INSPECTION

Visually inspect the infuser labels at least once every 12 months.

To inspect the labels, see ***Figure 5-1***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Confirm that the following labels are present:
   - Close Lever Label (Lever Door Open)
   - Close Lever w/Arrow Label
   - Rear Caution Label
   - Battery Label (Internal)
   - Caution Label
   - Logo Label
   - Service Revision Level Label (Driver)
   - Product I.D. Label (Driver)
   - Product ID Label (Module)
   - Switchport Label
   - (2) MAC Address Labels (Wireless)
   - Push Label (Wireless)
   - Side Labels
3. Inspect the labels for legibility and peeling. To replace a label, ***contact Hospira***.

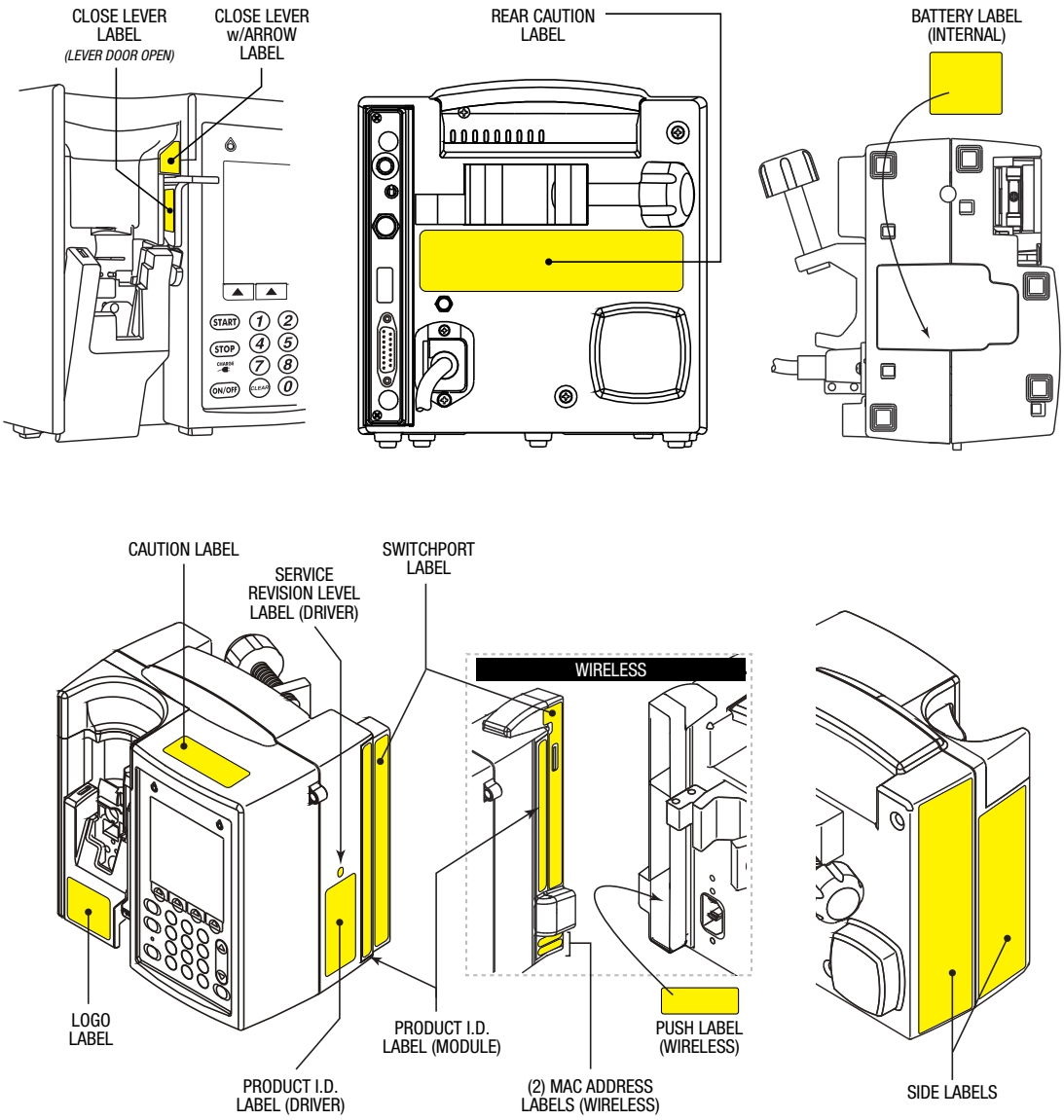

Figure 5-1. Infuser Labels

5.2.2

AC POWER CORD, RETAINER, AND VELCRO STRAP INSPECTION

Inspect the power cord, power cord retainer, and Velcro strap at least once every 12 months.

To inspect the power cord and retainer, see ***Figure 5-2***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the retainer and power cord as described in ***Section 7.2.5***.
3. Inspect the retainer for cracks, breaks, or missing parts of the retainer body. If any damage is found, replace the retainer.
4. Inspect both ends of the power cord for any signs of electrical arcing, burn marks, or heat scorching or melting. If any damage is observed, replace the power cord.
5. Inspect the plug end of the power cord for bent blades or a bent or missing ground pin. If any damage is observed, replace the power cord.
6. Inspect the Velcro strap for damage. If any damage is observed, replace the strap.
7. When inspections are completed, reassemble the power cord to the infuser as described in ***Section 7.2.5***.
8. Connect the infuser to AC power and confirm the AC indicator is lit.

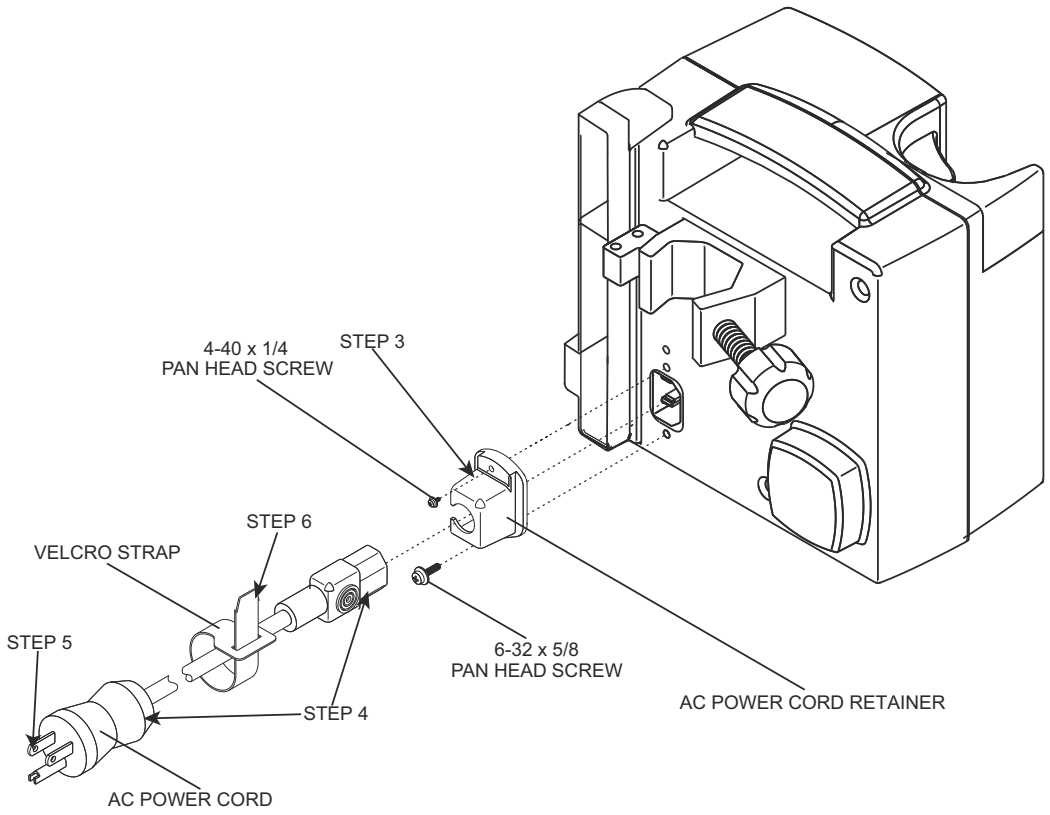

Figure 5-2. Power Cord, Retainer, and Velcro Strap

5.2.3

FRONT ENCLOSURE, REAR ENCLOSURE, CASSETTE DOOR, AND DOOR LEVER INSPECTION AND TEST

Visually inspect and test the front and rear enclosures at least once every 12 months.

To inspect the enclosures, cassette door, and door lever, see ***Figure 5-3***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Inspect the front and rear enclosures for cracks, chips, and gouges. If an enclosure is cracked, or has a significant chip or gouge, replace the damaged part ***(see Section 7.2.8*** *and* ***Section 7.2.9)***.
3. Inspect the enclosures for stains and discolorations. If the stain or discoloration is significant, replace the damaged part ***(see Section 7.2.9)***.
4. Inspect the rear enclosure for the presence and tightness of the six assembly screws. Tighten any loose screws and replace any missing screws.

   Note: Newer versions of the Plum A+ infuser will have five assembly screws (***see Figure 7-9***).

5. Inspect the cassette door for cracks and chips. Replace the door if it is damaged ***(see Section 7.2.12.8)***.
6. Inspect the door lever for cracks. Replace the door lever if it is damaged ***(see Section 7.2.12.9)***.

To test the door lever, proceed as follows:

1. Move the door lever to the OPEN position. Confirm that the door opens smoothly. If the door does not open smoothly, check for debris or dried fluid buildup. Clean the mechanism as described in ***Section 5.1***.
2. Move the door lever to the CLOSED position. Confirm smooth operation as described in Step 1.

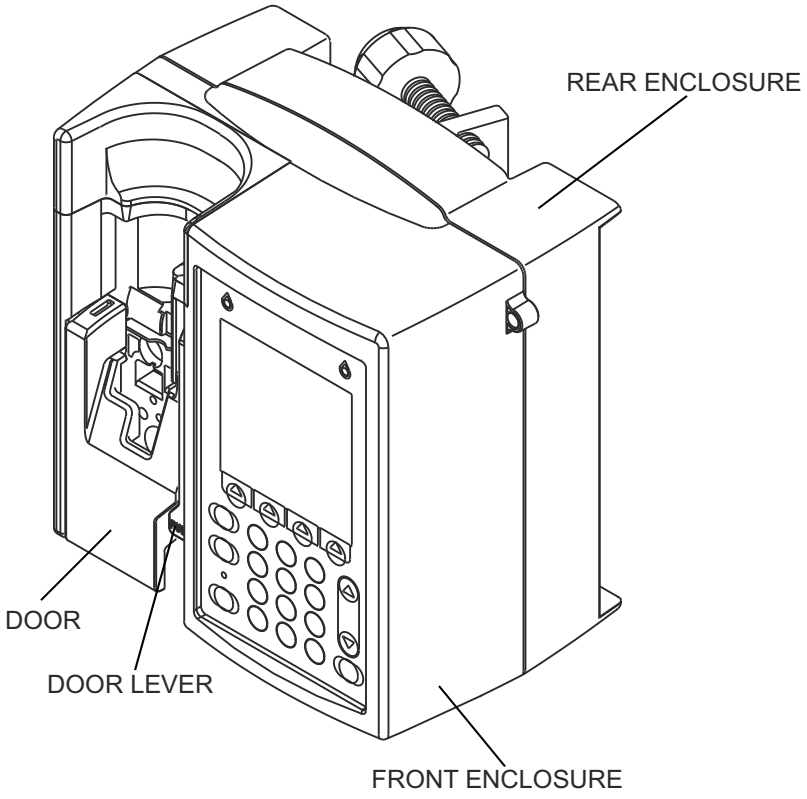

Figure 5-3. Front Enclosure, Rear Enclosure, Cassette Door, and Door Lever

5.2.4 DOOR ROLLER INSPECTION AND TEST

Inspect and test the door roller at least once every 12 months.

To inspect and test the door roller, see ***Figure 5-4***, and proceed as follows:

1. Open the cassette door.
2. Push the door release tab to the right to unlatch the door.
3. Verify that the retaining ring that secures the roller wheel to the pin is seated properly and the pin is not bent.
4. Ensure the door roller spins smoothly with a finger touch. If the roller does not spin smoothly, replace the door as described in ***Section 7.2.12.8***.

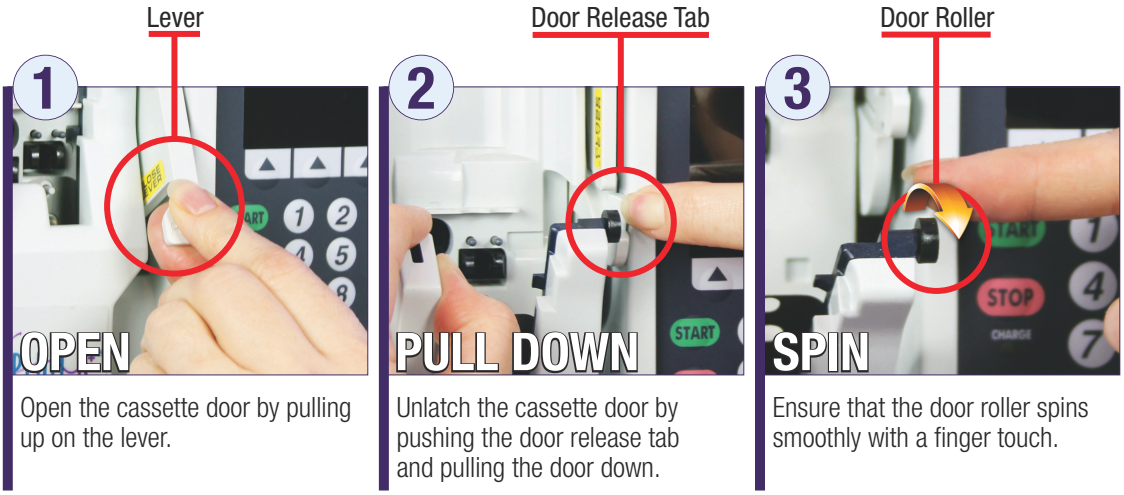

Figure 5-4. Door Roller Inspection

5.2.5 FLUID SHIELD INSPECTION

Visually inspect the Plum fluid shield least once every 12 months.

Equipment required for the fluid shield inspection is a 0.025 inch (0.65 mm) feeler gauge (plastic or metal),

To inspect the fluid shield, see ***Figure 5-5***, ***Figure 5-6***, and ***Figure 5-7***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way ***(see Figure 5-5)***.
3. Attempt to insert the feeler gauge (held perpendicular to the fluid shield) into both gaps between the mechanism assembly and the fluid shield ***(see Figure 5-6)***.
   - If you are not able to insert the feeler gauge into the gaps between the mechanism assembly and the fluid shield, the fluid shield is in an acceptable condition.

- If you are able to insert the gauge into the gaps between the mechanism assembly and the fluid shield, the fluid shield must be cleaned or replaced ***(see Section 7.2.12.8)***.

4. Inspect the sensor and control pins for damage and built-up contamination around each pin ***(see Figure 5-7)***. If any pins are broken or chipped, ***contact Hospira*** for repair. If there is accumulation of dried fluids around any pins, clean the area around the pin following the guidelines of ***Section 5.1***.
5. Inspect the cassette presence detector boot for damage ***(see Figure 5-7)***. If the boot is torn, cracked, or missing, ***contact Hospira*** for repair.

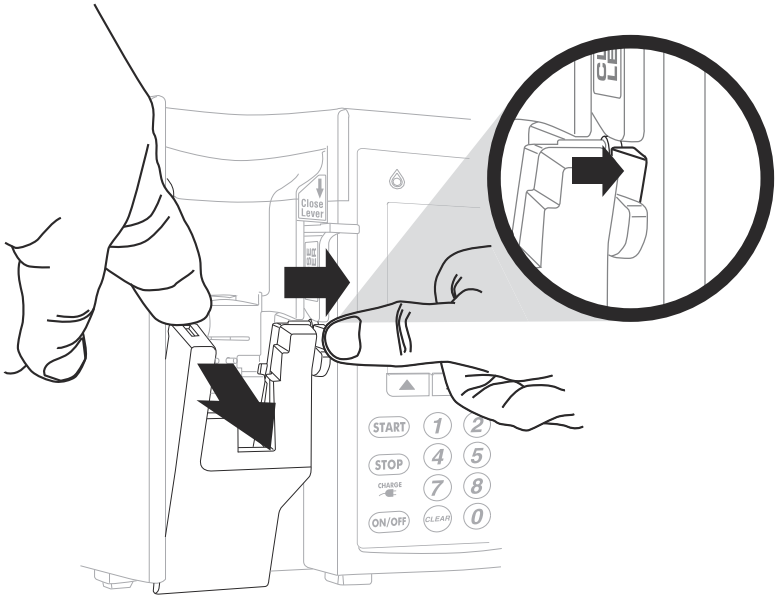

Figure 5-5. Releasing the Cassette Door

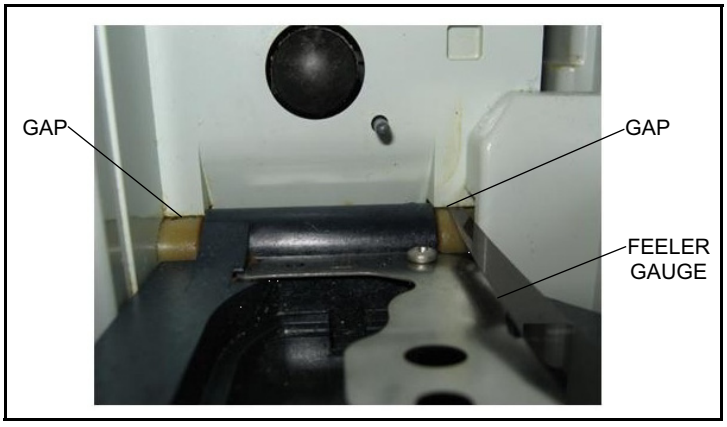

Figure 5-6. Inspecting the Fluid Shield with Feeler Gauge

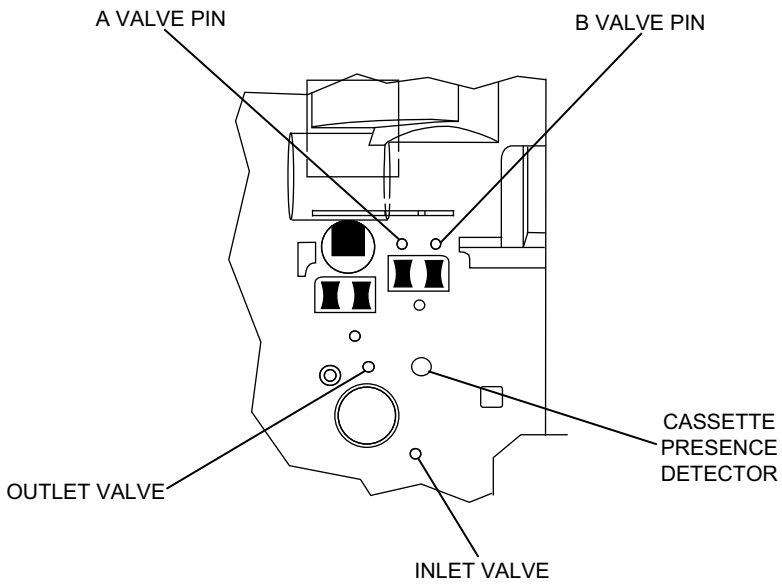

Figure 5-7. Mechanism Valve Pins and Cassette Presence Detector

5.2.6

DISTAL PRESSURE PIN INSPECTION

Visually inspect the distal pressure pin at least once every 12 months, **and** each time the infuser is serviced.

Note: The distal pressure pin is the black pin ***(see Figure 5-8)***.

To inspect the distal pressure pin, proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way ***(see Figure 5-5)***.
3. Inspect the distal pressure pin to determine that it is not damaged or broken.

4. To replace the pin if it is damaged or broken, ***contact Hospira***.

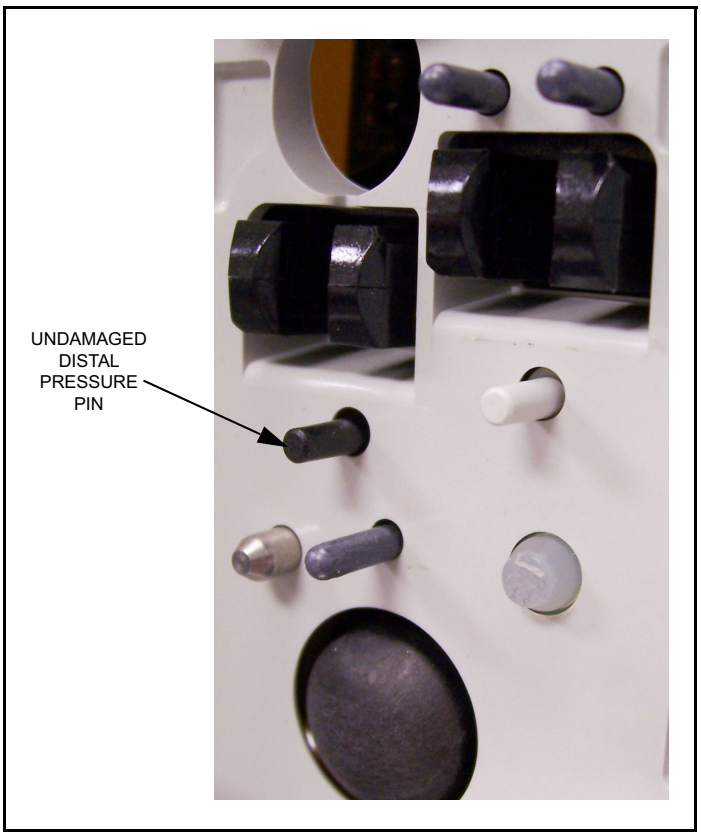

Figure 5-8. Distal Pressure Pin

5.2.7
PROXIMAL PRESSURE PIN INSPECTION

Visually inspect the proximal pressure pin at least once every 12 months **and** each time the infuser is serviced.

Note: The proximal pressure pin is the white pin ***(see Figure 5-9)***.

To inspect the proximal pressure pin, proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Release the door so that it lays flat. Press the door release tab to the right and open the cassette door all the way ***(see Figure 5-5)***.
3. Inspect the pin to determine that it is not damaged or broken.

4. To replace the pin if it is damaged or broken, ***contact Hospira***.

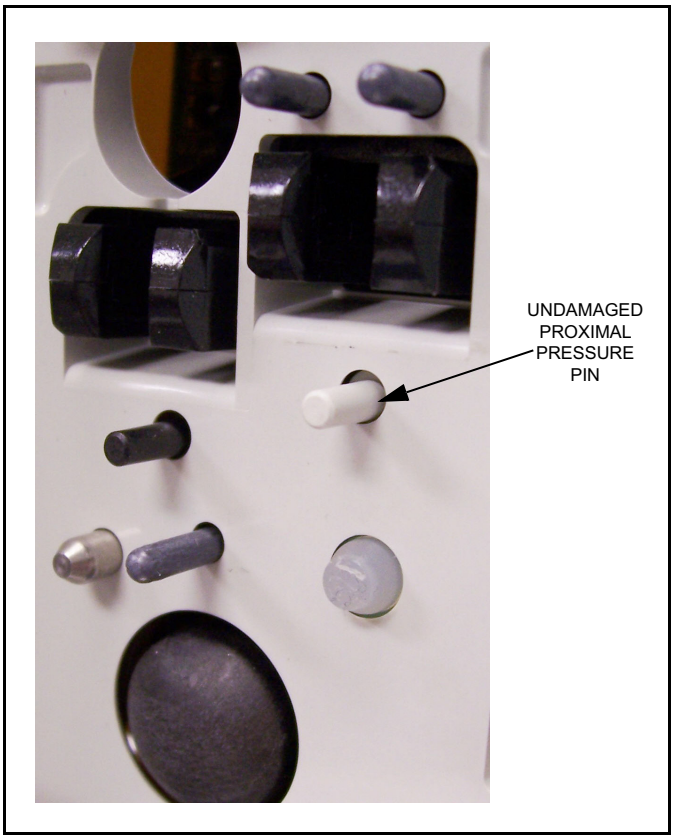

Figure 5-9. Proximal Pressure Pin

5.2.8

RUBBER FOOT PAD INSPECTION

Perform a visual inspection of the rubber foot pads at least once every 12 months.

Note: Some versions of the Plum A+ do not have rubber foot pads.

To inspect the rubber foot pads, see ***Figure 5-10***, and proceed as follows:

1. Inspect for missing or loose rubber foot pads, and rubber foot pads that are starting to peel away from the enclosure. Replace or install as described in ***Section 7.2.3***

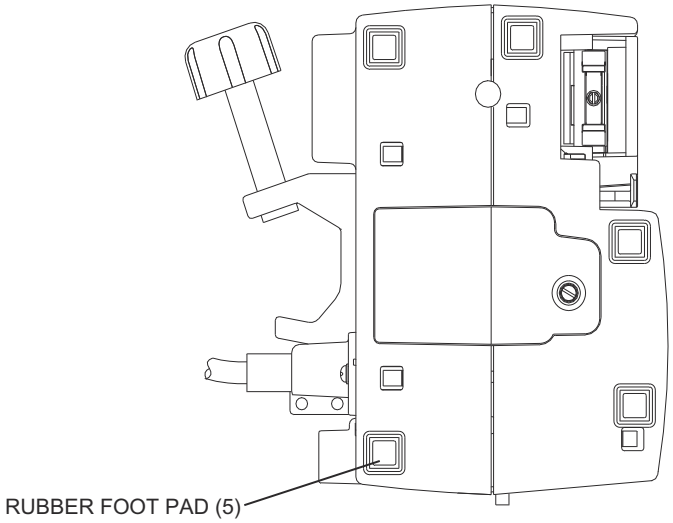

Figure 5-10. Rubber Foot Pads

5.2.9

POLE CLAMP INSPECTION AND TEST

Visually inspect and test the pole clamp at least once every 12 months.

To inspect the pole clamp, see ***Figure 5-11*** and ***Figure 5-12***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Confirm that the pole clamp assembly is securely attached to the rear of the enclosure. Tighten the assembly if it is loose ***(see Section 7.2.10.1)***.
3. Confirm that the rubber pad (wireless devices only) is present on the inside surface of the pole clamp extrusion. If the pad is missing, replace the extrusion ***(see Section 7.2.10.1)***.

   Note: Rubber pads are not present on non-wireless Plum A+ infusers.

4. Confirm that the plastic shaft tip is present at the end of the threaded pole clamp shaft. Install a replacement tip if it is damaged or missing ***(see Section 7.2.10.2)***.
5. Tighten and loosen the threaded pole clamp shaft so that it moves through the entire length of the threads. Confirm that the shaft moves smoothly and does not bind along its length. Replace the shaft/knob assembly if it binds or is difficult to tighten. If it continues to bind after replacement, replace the extrusion.

6. Mount the infuser on an IV pole and fully tighten the clamp. Ensure that the infuser is held firmly and does not slide on the IV pole. If the clamp cannot hold the infuser securely, replace the clamp.

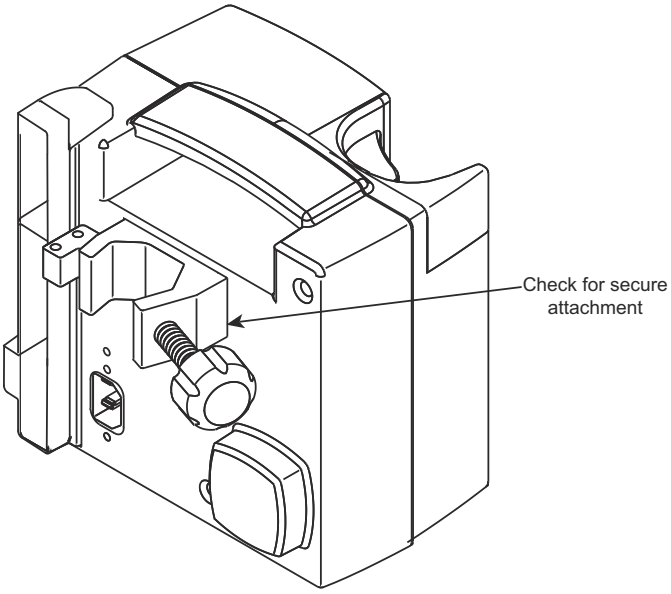

Figure 5-11. Pole Clamp and Extrusion

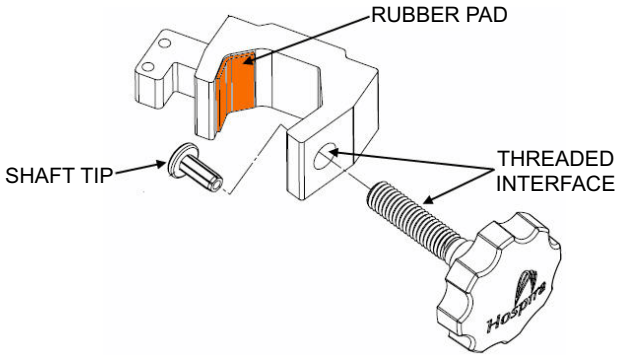

Figure 5-12. Pole Clamp Assembly

5.2.10

BATTERY INSPECTION AND REPLACEMENT

Note: The sealed, lead-acid battery **must** be replaced at least once every 12 months.

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

To inspect and replace the battery, see ***Figure 5-13*** and ***Figure 5-14***, and proceed as follows.

1. Turn off the infuser and disconnect the device from AC power. The **Charge/Line** indicator LED on the keypad 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 on its side.
3. Using the flat blade screwdriver, remove the screw that attaches the battery door to the infuser, and remove the door.
4. Carefully pull the battery and wire harness assembly out of the enclosure and disconnect it from the infuser's internal wiring at the inline connector.
5. Inspect the battery compartment for any debris. If debris is present, wipe or brush the debris out of the compartment.
6. Inspect the battery door and replace, if damaged or cracked.
7. Inspect the battery door pad on the battery door to ensure the pad is attached and is not damaged. If the pad is damaged, replace either the pad or the complete battery door assembly.
8. Inspect the battery door gasket on the battery door to ensure that the gasket is attached and is not damaged.

   Note: The battery gasket may not be present on some versions of the infuser.

9. Connect the replacement battery and wire harness assembly to the infuser's internal wiring harness at the inline connector. The inline connector is keyed so that the cables cannot be incorrectly connected.

   Note: Use only Hospira-approved replacement batteries.

10. Carefully insert the battery and wire harness assembly into its compartment with the terminals facing upward.

    Note: Confirm the battery harness is not pinched between the battery and the enclosure.

11. Reinstall the battery door using the screw that was removed in Step 3, and return the infuser to its upright position.
12. Connect the device to AC power and verify that the **Charge/Line** indicator LED on the keypad is lit.
13. Access the **BIOMED SETTINGS** screen ***(see Section 1.10)*** and press the **[CHANGE BATTERY]** softkey.

    Note: The infuser does not provide a confirmation message when the **[CHANGE BATTERY]** softkey is pressed.

14. Verify that the battery charge level indicator on the LCD display shows at least one, but not more than three white bars. If the indicator shows more than three bars, press the **[CHANGE BATTERY]** softkey again. If the indicator still shows more than three bars or shows zero bars, repeat the steps in this section.

15. Press **[ON/OFF]** to turn off the infuser.

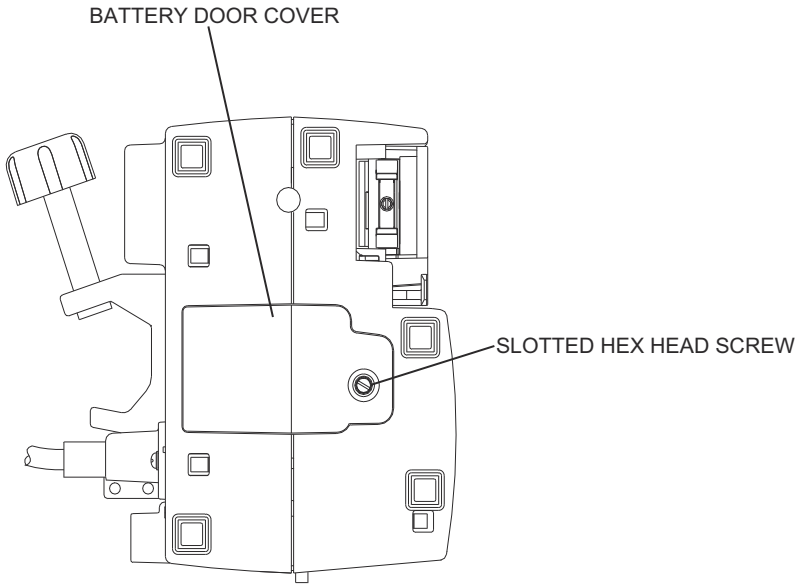

Figure 5-13. Battery Door

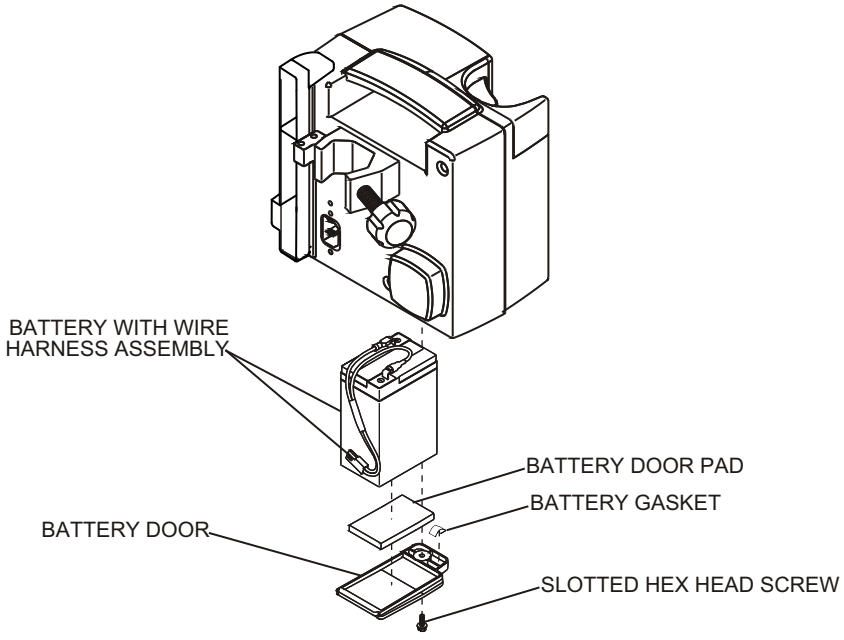

Figure 5-14. Removing the Battery

5.2.11
KEYPAD INSPECTION

Visually inspect the keypad at least once every 12 months.

To inspect the keypad, see ***Figure 5-15***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Inspect the keypad for tears, cracks, or edges lifting away from the infuser. If damage is observed, replace the keypad ***(see Section 7.2.12.2)***.
3. Inspect the keypad for worn or illegible numbers or letters. If letters or numbers are not readable, replace the keypad.
4. Inspect the keypad domes by pressing each number, word, and symbol to confirm that the domes have mechanical strength and provide tactile feedback. If any domes are weak or fatigued, replace the keypad.
5. Confirm that the green **[START]** button, red **[STOP]** button, and yellow **[ON/OFF]** button have retained their color. If any of the buttons have faded or worn color, replace the keypad.

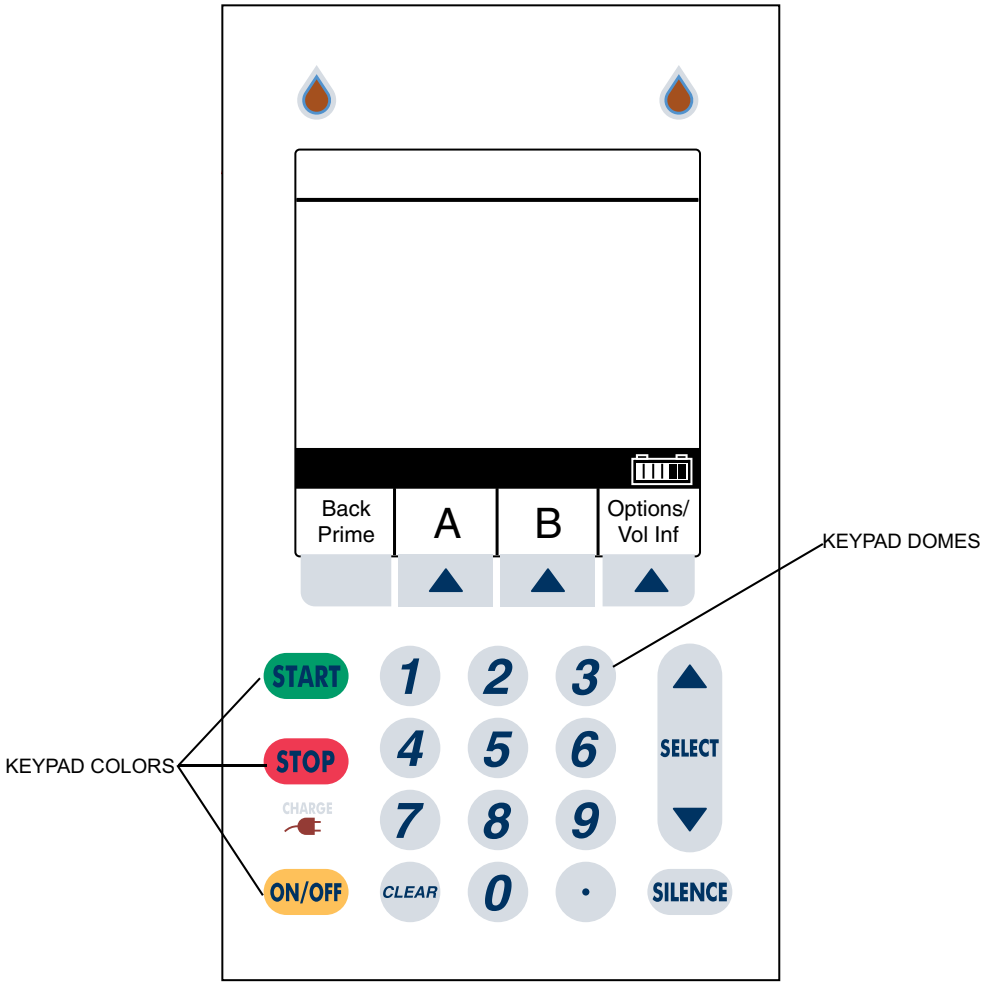

Figure 5-15. Keypad

5.2.12

DISPLAY AND INDICATORS INSPECTION

Visually inspect the display and indicators at least once every 12 months.

To inspect the display and indicators, see ***Figure 5-16***, and proceed as follows:

1. Place the infuser on a flat, stable surface.
2. Connect the power cord to the mains supply, and confirm that the **CHARGE LED** is lit.
3. Rotate the infuser so that the rear of the device is facing to the front.
4. Confirm that the keypad lockout switch is in the **OFF** (down) position.
5. Rotate the infuser back to its original position so that the display is facing forward.
6. Press the **[ON/OFF]** key to power on the infuser, and observe the infuser as it performs its self test.
7. Confirm that the two line flow LEDs flash, and that there are two audible sounds - one at the beginning of the self test and one at the end of the self test.
8. If the audible sounds do not occur, replace the piezo alarm assembly ***(see Section 7.2.12.5)***.
9. Observe the display area. Confirm that the display is clear and readable.
10. If any of the LEDs are not operating, replace the keypad ***(see Section 7.2.12.2)***.
11. If the display is not clear or pixels appear to be damaged, replace the display ***(see Section 7.2.12.3)***.

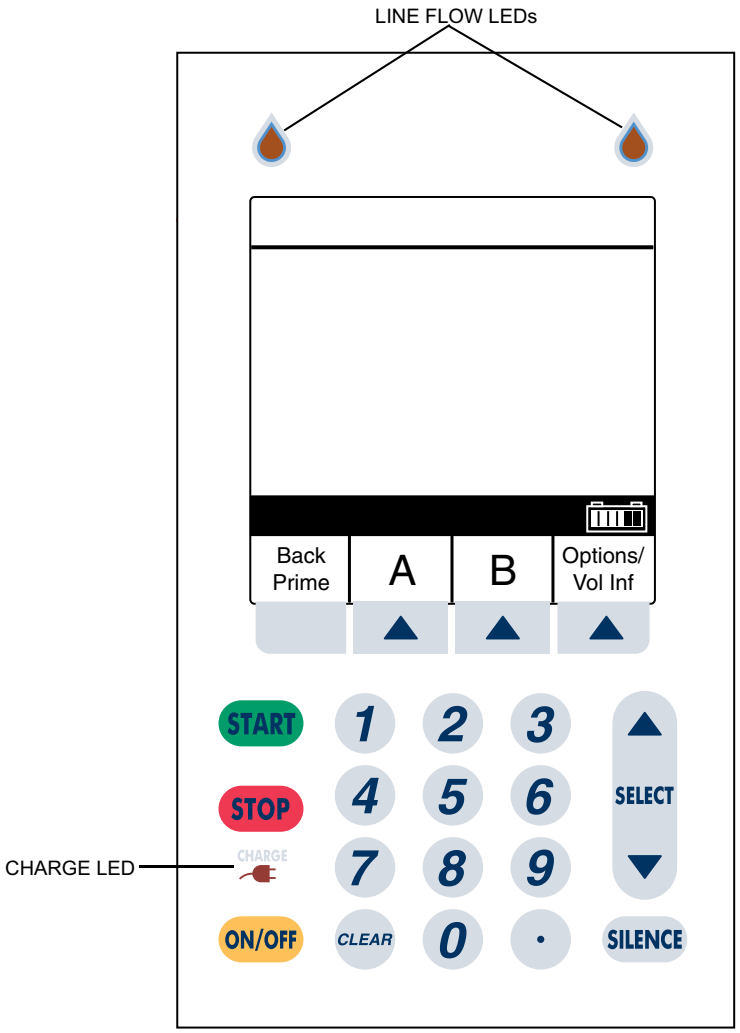

Figure 5-16. Display and Indicators

5.2.13

KEYPAD LOCKOUT SWITCH INSPECTION

Inspect the keypad lockout switch at least once every 12 months. The keypad lockout switch is located on the CE module on the rear of the infuser.

To inspect the keypad lockout switch, see ***Figure 5-17*** and proceed as follows:

1. Inspect for the presence of the keypad lockout switch and ensure the switch is not broken.
2. Inspect for a loose or dislodged switch. If the switch is loose or not in place, replace the CE module or ***contact Hospira***.

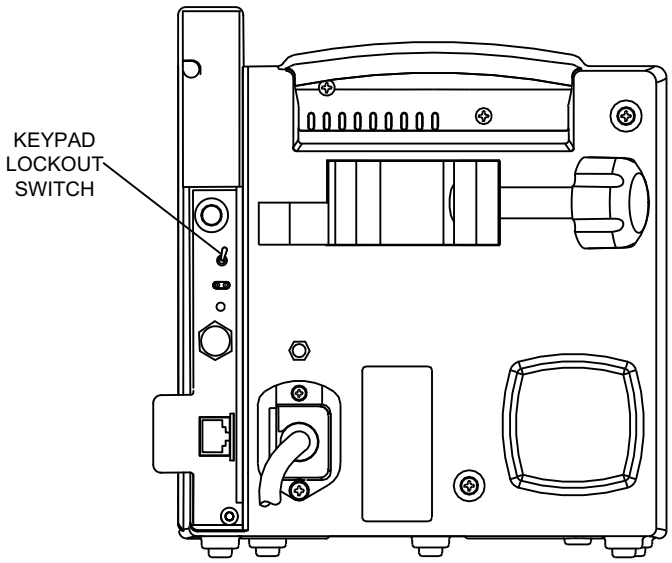

Figure 5-17. Keypad Lockout Switch

5.2.14

PREVENTIVE MAINTENANCE CHECKLIST

Hospira

Plum A+ Infusion System

Preventive Maintenance Checklist

Note: ***The Preventive Maintenance process must be performed at least once every 12 months to ensure proper performance of the Plum infuser.***

- Circle **PASS** or **FAIL** in the respective box after each inspection or test is performed.
- Enter the device model and serial number in the space provided.
- Sign and date this form in the space provided.

Item	Inspection	Test
Labels Inspection	PASS / FAIL	
AC Power Cord, Retainer, and Velcro Strap Inspection	PASS / FAIL	
Front Enclosure, Rear Enclosure, Cassette Door, and Door Lever Inspection and Test	PASS / FAIL	PASS / FAIL
Door Roller Inspection and Test	PASS / FAIL	PASS / FAIL
Fluid Shield Inspection	PASS / FAIL	
Distal Pressure Pin Inspection	PASS / FAIL	
Proximal Pressure Pin Inspection	PASS / FAIL	
Rubber Foot Pad Inspection	PASS / FAIL	
Pole Clamp Inspection and Test	PASS / FAIL	PASS / FAIL
Battery Inspection and Replacement (*indicate battery replacement below*)	PASS / FAIL	
Keypad Inspection	PASS / FAIL	
Display and Indicators Inspection	PASS / FAIL	
Keypad Lockout Switch Inspection	PASS / FAIL	
Self Test		PASS / FAIL
Cassette Alarm Test		PASS / FAIL
Unrestricted Flow Test		PASS / FAIL
Display Test		PASS / FAIL
Keypad Verification/Functional Test		PASS / FAIL
Alarm Loudness Test		PASS / FAIL
Keypad Lockout Switch Test		PASS / FAIL
Proximal Occlusion Test		PASS / FAIL
Proximal Air-in-Line Test		PASS / FAIL
Distal Air-in-Line Test		PASS / FAIL
Distal Occlusion Test		PASS / FAIL
Delivery Accuracy Test		PASS / FAIL
Nurse Call Test		PASS / FAIL
Electrical Safety Test		PASS / FAIL
	Battery Replaced?	YES / NO

TECHNICIAN	INFUSER
Signature: _____	**Model:** _____
Date: _____	**Serial Number:** _____

5.3
PERFORMANCE VERIFICATION TEST

The Performance Verification Test (PVT) consists of the tests described in this Section.

Use the PVT for the following:

- **Preventive maintenance** – Perform the PVT at least once every 12 months as part of Preventive Maintenance, which also includes the visual inspections in ***Section 5.2***. This ensures that the infusion system is operating properly. If an infuser fails any part of the test, troubleshoot using the instructions in ***Section 6***.
- **Troubleshooting** – For diagnostic purposes during troubleshooting, perform the PVT as directed in ***Section 6***.
- **Performance verification** – Before placing an infuser back in service after repair.

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

For preventive maintenance and performance verification, the following sequence is suggested. When necessary, individual tests may be performed out of sequence.

1. ***Section 5.3.3, Self Test***
2. ***Section 5.3.4, Cassette Alarm Test***
3. ***Section 5.3.5, Unrestricted Flow Test***
4. ***Section 5.3.6, Display Test***
5. ***Section 5.3.7, Keypad Verification/Functional Test***
6. ***Section 5.3.8, Alarm Loudness Test***
7. ***Section 5.3.9, Keypad Lockout Switch Test***
8. ***Section 5.3.10, Proximal Occlusion Test***
9. ***Section 5.3.11, Proximal Air-In-Line Test***
10. ***Section 5.3.12, Distal Air-In-Line Test***
11. ***Section 5.3.13, Distal Occlusion Test***
12. ***Section 5.3.14, Delivery Accuracy Test***
13. ***Section 5.3.15, Nurse Call Test***
14. ***Section 5.3.16, Electrical Safety Test***
15. ***Section 5.3.17, End of the PVT***

5.3.1
PVT EQUIPMENT LIST

To complete all the performance verification tests, the following equipment and materials, or equivalents, are required:

- Two IV Bags containing sterile or tap water
- IV pole or IV stand
- Primary IV PlumSet with Clave port (List Number 12538-28, or equivalent) or Primary IV PlumSet with capped port (List Number 14679-28, or equivalent)
- Secondary IV Set (List Number 12182-65, or equivalent)
- Three Run-in Cassettes (List Number ORD45-04-01)
- Collection container (any type, to catch fluid from the distal line)
- 18-Gauge Blunt Cannula (List Number 11302-01, or equivalent)
- Graduated Cylinder, 25 mL, with 0.2 mL graduations (Class A, any brand)
- Nurse Call Test Cable (Part Number 561-88416-001)
- Three-Way Stopcock, latex-free (List Number 03233-01, or equivalent)
- Digital Pressure Meter (DPM), 0 to 50 psi (Fluke™ Biomedical DPM3, or equivalent)
- Safety Analyzer (Fluke Biomedical LT544DLite, or equivalent)
- Digital Multimeter (DMM) (Fluke 187, or equivalent)
- X-Acto knife (or equivalent)
- Permanent marker (any brand)

Disposable equipment used during testing should be replaced on the following schedule:

- Primary IV PlumSets must be destroyed and discarded at the end of each business day.
- Run-in cassettes and secondary IV sets must be destroyed and discarded quarterly, unless there are signs of leakage, wear, or damage. Run-in cassettes and secondary IV sets should be labeled and dated as appropriate prior to use.

5.3.2
TEST SETUPS

The following sections describe the test setups required to complete the PVT, including a single ***Basic Test Setup*** that can be used for most tests in the PVT, a ***Proximal Air-in-Line Test Setup*** that is used only for the Proximal Air-in-Line test, a ***Distal Air-in-Line Test Setup*** that is used only for the Distal Air-in-Line test, and a ***Distal Occlusion Test Setup***, which is a modification of the Basic test setup.

5.3.2.1
BASIC TEST SETUP

The Basic test setup consists of primed primary and secondary lines attached to fluid bags. The cassette is inserted into the infuser and the distal (patient) end of the tubing is placed in a collection container. The Basic test setup is shown in ***Figure 5-18***:

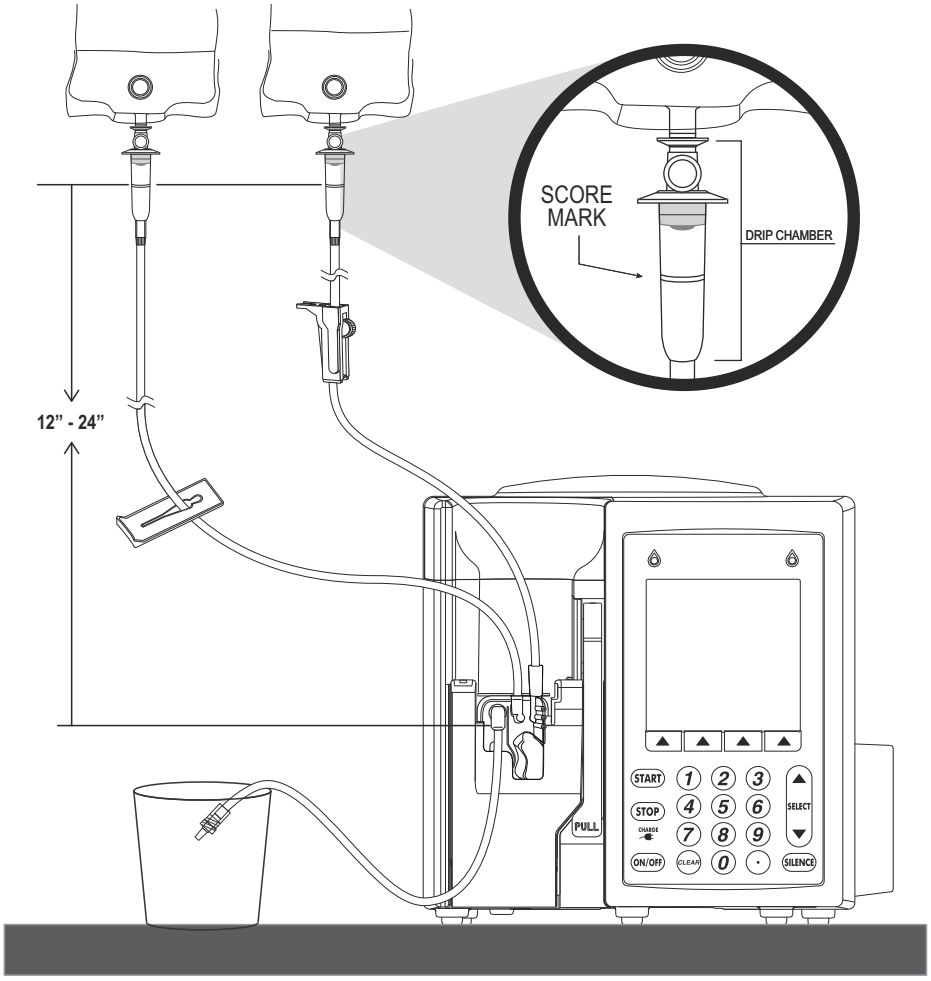

Figure 5-18. Basic Test Setup

The following tests can be performed using one Basic test setup. Not all tests will use every part of the setup.

- ***Section 5.3.3, Self Test***
- ***Section 5.3.5, Unrestricted Flow Test***
- ***Section 5.3.6, Display Test***
- ***Section 5.3.7, Keypad Verification/Functional Test***
- ***Section 5.3.8, Alarm Loudness Test***
- ***Section 5.3.9, Keypad Lockout Switch Test***
- ***Section 5.3.10, Proximal Occlusion Test***
- ***Section 5.3.13, Distal Occlusion Test***
- ***Section 5.3.14, Delivery Accuracy Test***

5.3.2.1.1

Equipment Required for This Setup

The Basic test setup uses the following equipment from the list in ***Section 5.3.1***:

- Two IV Bags (or glass IV containers) containing sterile or tap water
- IV pole or IV stand
- Primary IV PlumSet
- Secondary IV Set
- Collection container

For the Delivery Accuracy Test in ***Section 5.3.14***, add the 18-gauge blunt cannula and the graduated cylinder. For the Nurse Call Test in ***Section 5.3.15***, add the nurse call test cable.

The setup for the Distal Occlusion test in ***Section 5.3.13*** adds a three-way stopcock and DPM to the end of the distal tubing of the Basic test setup, as described in ***Section 5.3.2.5***.

5.3.2.1.2

Preparing the Primary Line

To prepare the primary line, proceed as follows to fill the cassette and tubing on the primary PlumSet with liquid (that is, *prime* it), eliminating all air, and then load the cassette into the infuser.

1. Place the infuser on a bench or attach it to an IV pole.
2. Press the cassette flow regulator in to make ensure it is closed (***see Figure 5-19***).

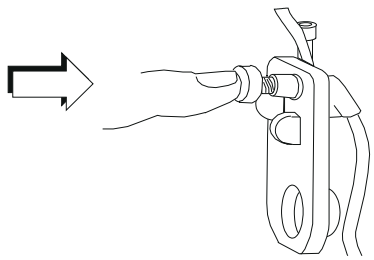

Figure 5-19. Closing the Flow Regulator

3. If using a glass IV container, open the filter vent cover above the drip chamber. If using a plastic IV container, ensure that the filter vent cover is closed (***see Figure 5-20***).

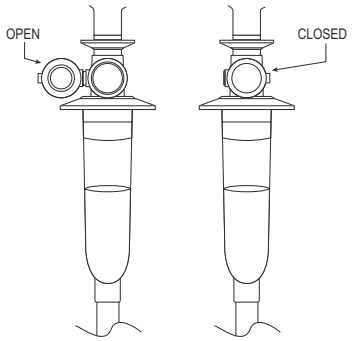

Figure 5-20. Filter Vent Cover

4. Using a twisting motion, insert the piercing pin into the outlet on a water container (***see Figure 5-21***).

   Note: Do not position the container above the infuser while inserting the piercing pin.

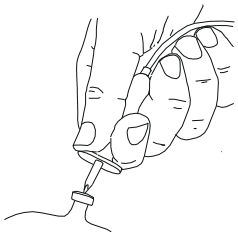

Figure 5-21. Inserting the Piercing Pin

5. Suspend the container on an IV pole.
6. Check for leaks. If any part of the container is leaking, replace it.
7. Squeeze the drip chamber to fill it about 1/2 full or to the score mark (***see Figure 5-22***). Do not completely fill the drip chamber.

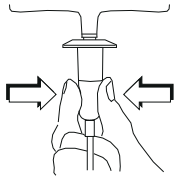

Figure 5-22. Squeezing the Drip Chamber

8. Invert the cassette so that the secondary port is pointing down (***see Figure 5-23***).

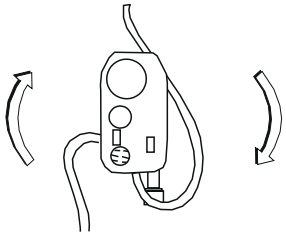

Figure 5-23. Secondary Port

9. **Slowly** open the flow regulator by turning it counter-clockwise (***see Figure 5-24***). When the first drop appears in the pumping chamber, turn the cassette upright.

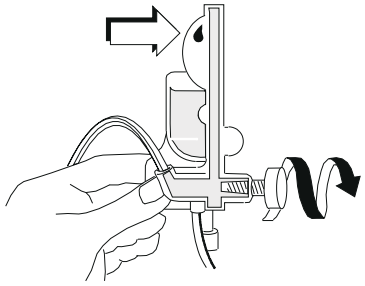

Figure 5-24. Opening the Flow Regulator

10. Tap and clear air from the cassette, Y-site, and tubing to remove all air from the remainder of the administration set (***see Figure 5-25***).

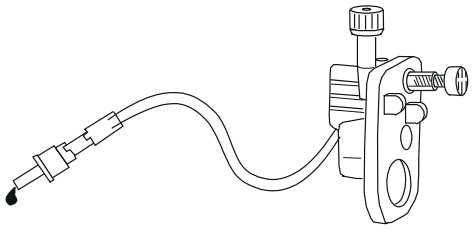

Figure 5-25. Removing Air from the Administration Set

11. Push in the flow regulator to close it (***see Figure 5-26***). Check the distal end of the tubing to confirm that there is no flow.

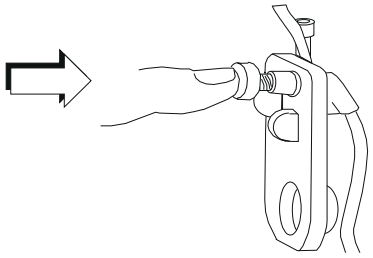

Figure 5-26. Closing the Flow Regulator

NOTE: If there is flow or leaks, close all clamps and replace the administration set.

12. Close all clamps on the proximal and distal lines.

5.3.2.1.3

Loading the Cassette

To load the primed cassette into the infuser, proceed as follows:

1. Lift the lever to open the cassette door (***see Figure 5-27***).

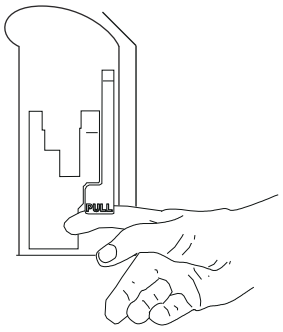

Figure 5-27. Opening the Cassette Door

2. Grasp the cassette by the finger grip (***see Figure 5-28***).

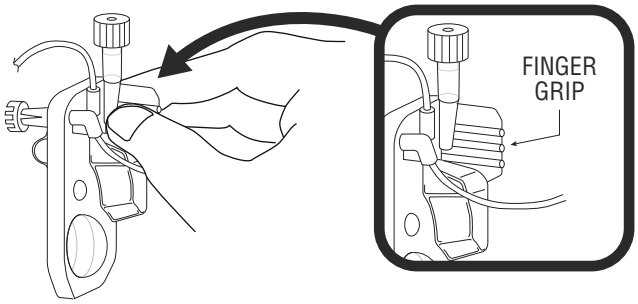

Figure 5-28. Cassette Finger Grip

3. Slide the cassette into the door guide (***see Figure 5-29***).

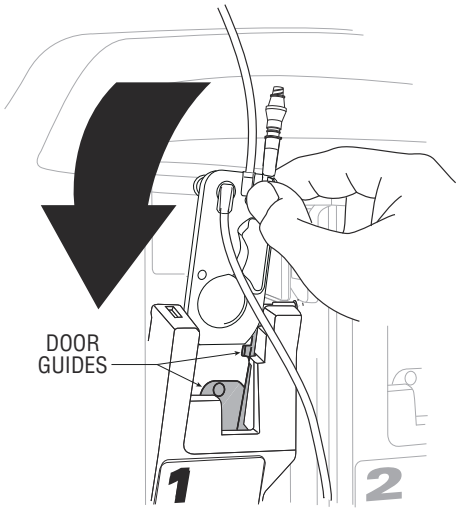

Figure 5-29. Cassette and Door Guide

4. Press the lever down to close the cassette door.
5. Open all clamps.
6. Check the distal end of the tubing to confirm that there is no flow and that no kinks appear in the tubing.

Note: If there is flow or leaks, close all clamps and replace the administration set.

7. Ensure that the score mark on the drip chamber is 12 to 24 inches higher than the cassette.
8. Place the distal end of the tubing in the collection container. Go to ***Section 5.3.2.1.4,*** to attach and prime the secondary line.

5.3.2.1.4

Preparing the Secondary Line

To prepare the secondary line, proceed as follows to prime the line and attach it to the cassette:

1. Insert the piercing pin into the secondary container outlet using a twisting motion (***see Figure 5-30***).

   Note: Do not position the container above the infuser while inserting the piercing pin.

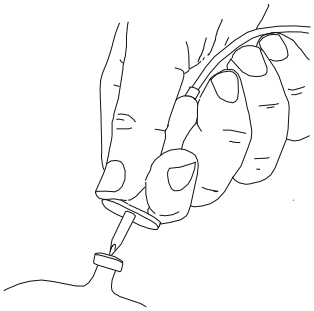

Figure 5-30. Inserting the Piercing Pin

2. Suspend the container on an IV pole.
3. Check the secondary container for leaks. If any part of the container is leaking, replace it.
4. Squeeze the drip chamber to fill it about 1/2 full or to the score mark (***see Figure 5-31***). Do not completely fill the drip chamber.

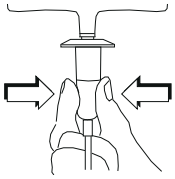

Figure 5-31. Squeezing the Drip Chamber

5. **Slowly** open the roller clamp to allow fluid to flow into the secondary tubing (***see Figure 5-32***).

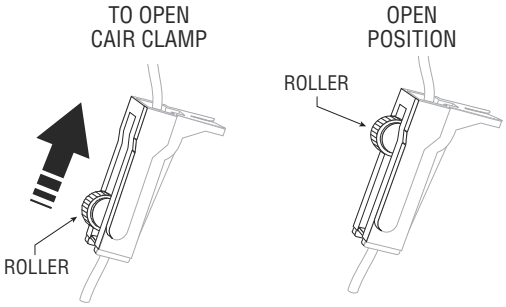

Figure 5-32. Opening the Roller Clamp

6. After all air is removed, close the roller clamp (***see Figure 5-33***).

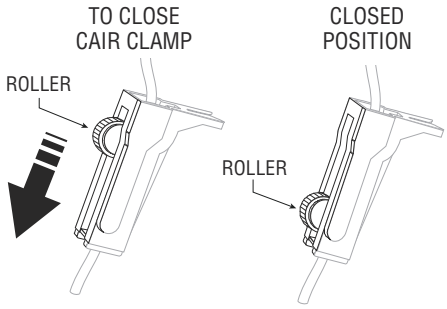

Figure 5-33. Closing the Roller Clamp

7. Attach the line to the secondary port on the cassette as follows:

   - **If the cassette has a Clave secondary port:** Insert the end of the secondary line into the Clave. Move the Option-Lok collar over the Clave and twist clockwise to secure the line to the port (***see Figure 5-34***).

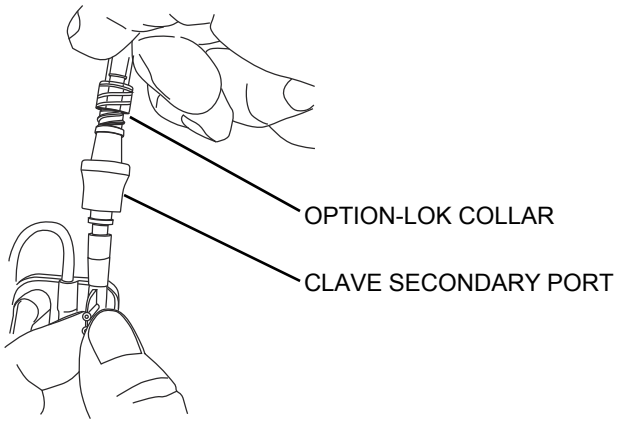

Figure 5-34. Option-Lok Collar and Clave Secondary Port

- **If the cassette has a capped secondary port:** Confirm that the cassette door is closed, and then loosen and remove the white cap. Discard the cap. Insert the end of the secondary line into the port and twist clockwise to secure the line to the port (***see Figure 5-35***).

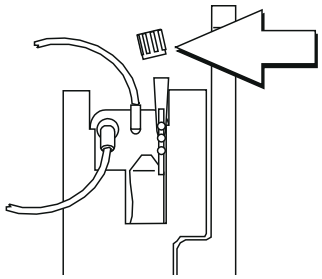

Figure 5-35. Capped Secondary Port

Note: To open the cassette door to gain better access to the white cap, first close all clamps on the primary and secondary lines to avoid spilling fluid when the cap is removed, and then lift the lever to open the cassette door (***see Figure 5-27***). Remove and discard the cap, attach the secondary line, close the cassette door and then open all clamps.

8. Arrange the fluid container so that the score mark on the drip chamber is 12 to 24 inches higher than the cassette.

Note: The secondary container does not need to be higher than the primary container for accurate delivery of a piggyback infusion.

The test setup is complete, as shown in ***Figure 5-36***.

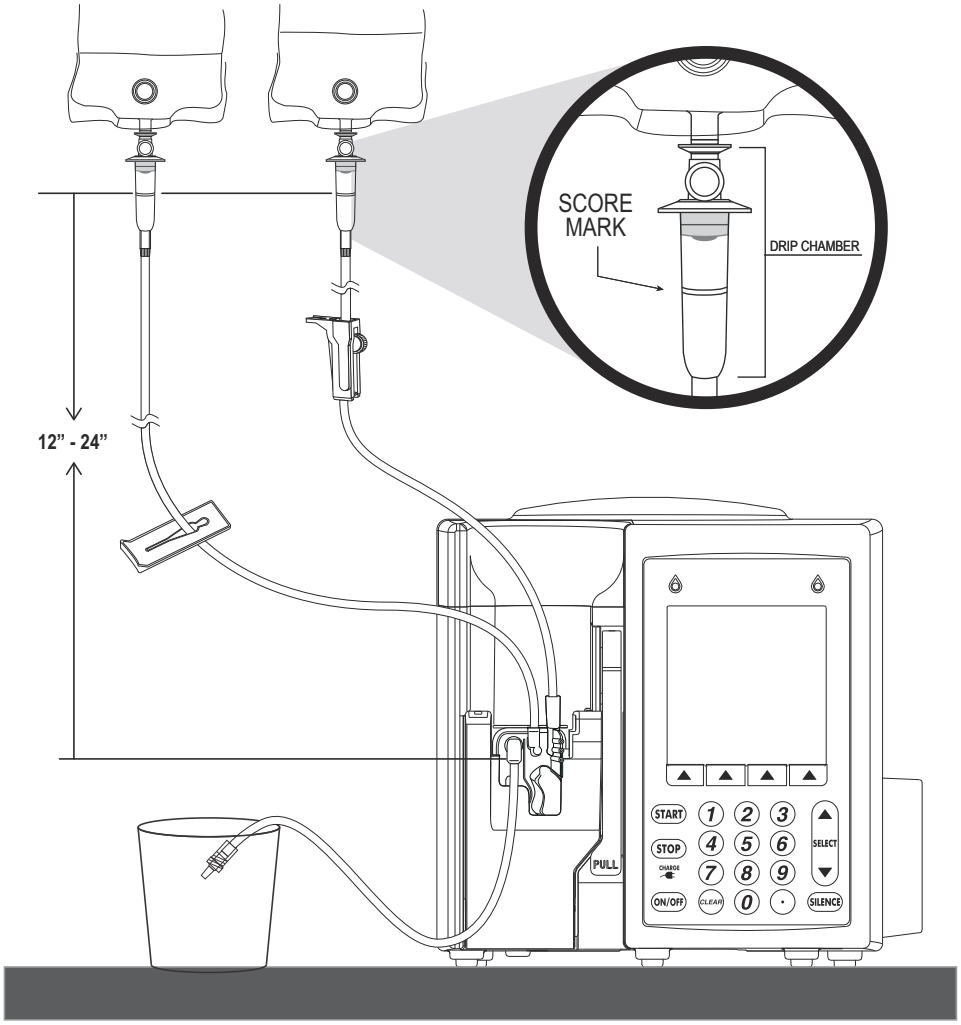

Figure 5-36. Complete Basic Test Setup

5.3.2.2

PROXIMAL AIR-IN-LINE TEST SETUP

This section describes the steps for the proximal air-in-line test setup, including modifying a run-in cassette, priming it, and loading the cassette into the infuser. This setup is used for the proximal air-in-line test in ***Section 5.3.11***.

5.3.2.2.1

Equipment Required for the Proximal Air-in-Line Test Setup

- Run-in cassette
- Sterile or tap water
- X-Acto knife or equivalent
- Permanent marker

5.3.2.2.2

Preparing the Run-in Cassette for the Proximal Air-in-Line Test

1. Using the X-Acto knife, remove the proximal bubble sensor bulb tips as shown in ***Figure 5-37***. Keep the knife parallel with the plastic to avoid cutting too far into the sensor bulb, which may cause leakage.

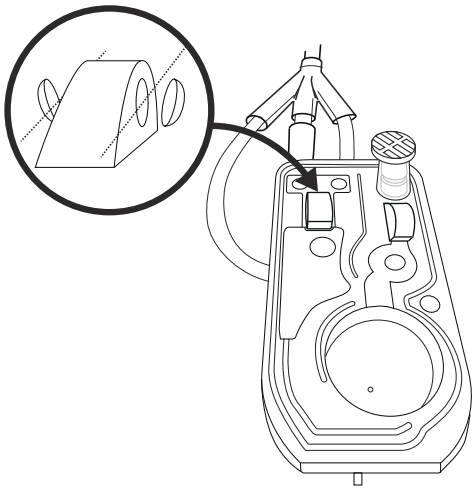

Figure 5-37. Preparing the Proximal Run-In Cassette

2. Using the permanent marker, write “Proximal” and the date on the drip chamber.
3. Follow the instructions for priming a run-in cassette assembly in ***Section 5.3.2.4***.

5.3.2.3

DISTAL AIR-IN-LINE TEST SETUP

This section describes the steps for the Distal Air-in-Line test setup, including modifying a run-in cassette, priming it, and loading the cassette into the infuser. This setup is used for the Distal Air-in-Line test in ***Section 5.3.12***.

5.3.2.3.1

Equipment Required for the Distal Air-in-Line Test Setup

- Run-in Cassette
- Sterile or tap water
- X-Acto knife or equivalent
- Permanent marker

5.3.2.3.2

Preparing the Run-in Cassette for the Distal Air-in-Line Test

1. Using the X-Acto knife, remove the distal bubble sensor bulb tips as shown in ***Figure 5-38***. Keep the knife parallel with the plastic to avoid cutting too far into the sensor bulb, which may cause leakage.

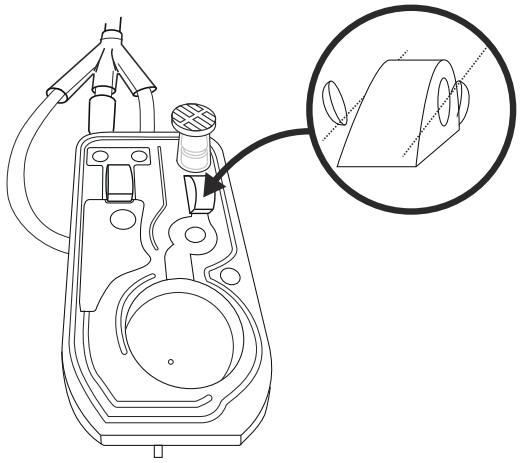

Figure 5-38. Preparing the Distal Run-In Cassette

2. Using the permanent marker, write “Distal” and the date on the drip chamber.
3. Follow the instructions for priming a run-in cassette assembly in ***Section 5.3.2.4***.

5.3.2.4

PRIMING A RUN-IN CASSETTE ASSEMBLY

Primed run-in cassettes are required for Proximal Air-in-Line and Distal Air-in-Line tests. The run-in cassette has tubing that is arranged so that fluid is pumped in a continuous loop, as shown in ***Figure 5-39***.

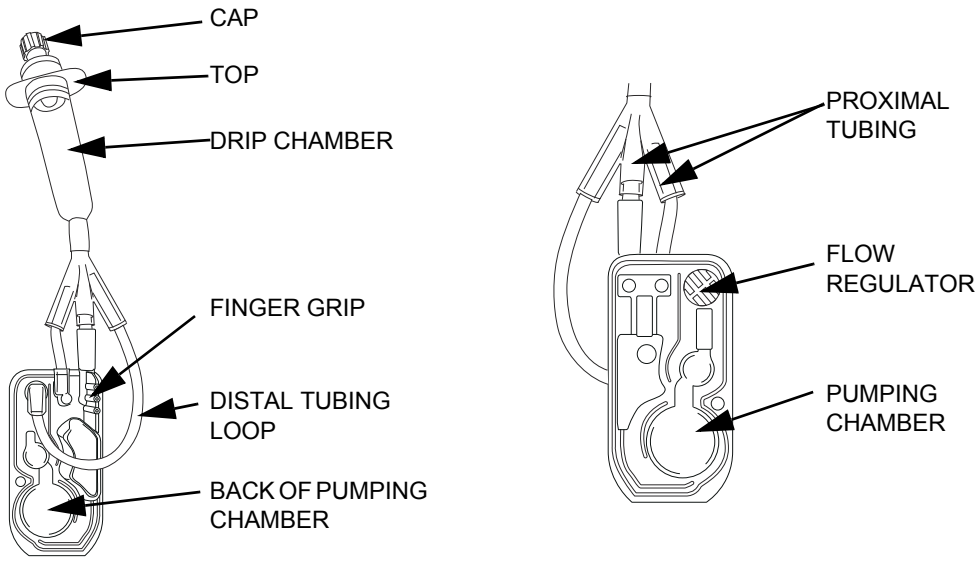

Figure 5-39. Parts of a Run-In Cassette

The proximal and distal portions of the run-in cassette must be primed separately, using two different procedures. The following sections describe the priming process.

5.3.2.4.1

Priming the Run-In Cassette and Proximal Tubing

This section describes how to prime the cassette and proximal tubing parts of the run-in cassette assembly using the Backprime feature of the infuser. During backpriming, the white cap is off to allow air to escape as fluid fills the cassette and tubing.

To prime the cassette and proximal tubing of a run-in cassette assembly, proceed as follows:

1. Remove the top from the run-in cassette, fill the drip chamber about 2/3 full, and then put the top back on.

   Note: Do not fill the drip chamber any more than 2/3 full or water may spill out the top of the cassette during backpriming in Step 5.

2. Insert the run-in cassette into the infuser and close the door.
3. Remove the white cap on the run-in cassette, taking care not to spill any water into the infuser. The run-in cassette is now installed in the infuser with the white cap off.
4. Turn on the infuser. During the self test, the infuser will issue a cassette test failure alarm.

5. Press and hold [BACKPRIME] to pump water from the drip chamber into the proximal lines and cassette.
6. When bubbles are no longer being pushed into the drip chamber, release the [BACKPRIME] key. The cassette test will proceed.
7. If the cassette test fails again, repeat Steps 5 and 6.
8. When the cassette test completes with no alarms, replace the white cap.

5.3.2.4.2

Priming the Distal Tubing Loop

After the cassette and proximal tubing are primed, the cassette test will succeed. A distal air alarm may occur the first time a test infusion is run, however, because Backprime only affects tubing that is proximal to the cassette. The following procedure describes how to manually pump air out of the distal tubing.

To prime the distal tubing of a run-in cassette, proceed as follows:

1. Open the cassette door and remove the run-in cassette. Close the cassette door.
2. Remove the top of the run-in cassette and add water to bring the level in the drip chamber to about 2/3 full. Replace the top.
3. Check the run-in cassette for leaks, especially around the sensor bulbs that were cut. If there is any leakage, replace the run-in cassette.
4. Keeping the cassette upright, remove the white cap.
5. Pull out the flow regulator (***see Figure 5-40***).

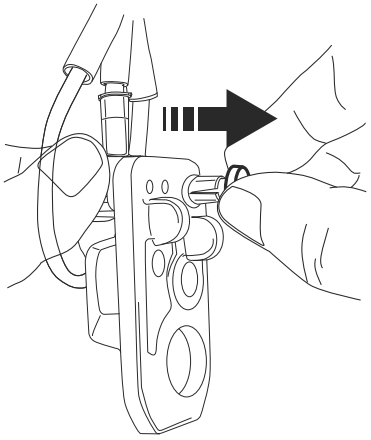

Figure 5-40. Pulling Out the Flow Regulator

6. Press in firmly on the pumping chamber to pump air out of the chamber (***see Figure 5-41***)

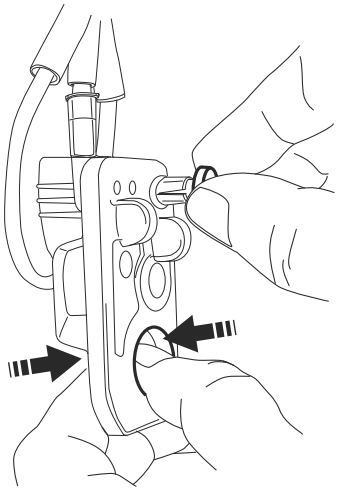

Figure 5-41. Pressing the Pumping Chamber

7. Continue to press on the pumping chamber as you use your other hand to push the flow regulator closed (***see Figure 5-42***). This prevents the air from returning to the pumping chamber.

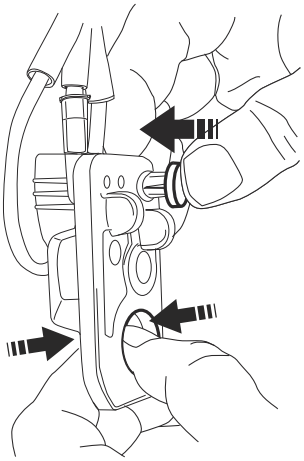

Figure 5-42. Preventing Air from Returning to the Pumping Chamber

8. Release the pumping chamber and flow regulator.
9. Repeat Steps 6 through 8 until all distal air is pumped out of the tubing.
10. Replace the cap. The run-in cassette is now ready for use.
11. Remove the cassette from the infuser.

5.3.2.5
DISTAL OCCLUSION TEST SETUP

This section describes the distal occlusion test setup, including adding a stopcock and Digital Pressure Meter (DPM) to the distal tubing on the Basic test setup. The distal occlusion test setup is shown in ***Figure 5-43***.

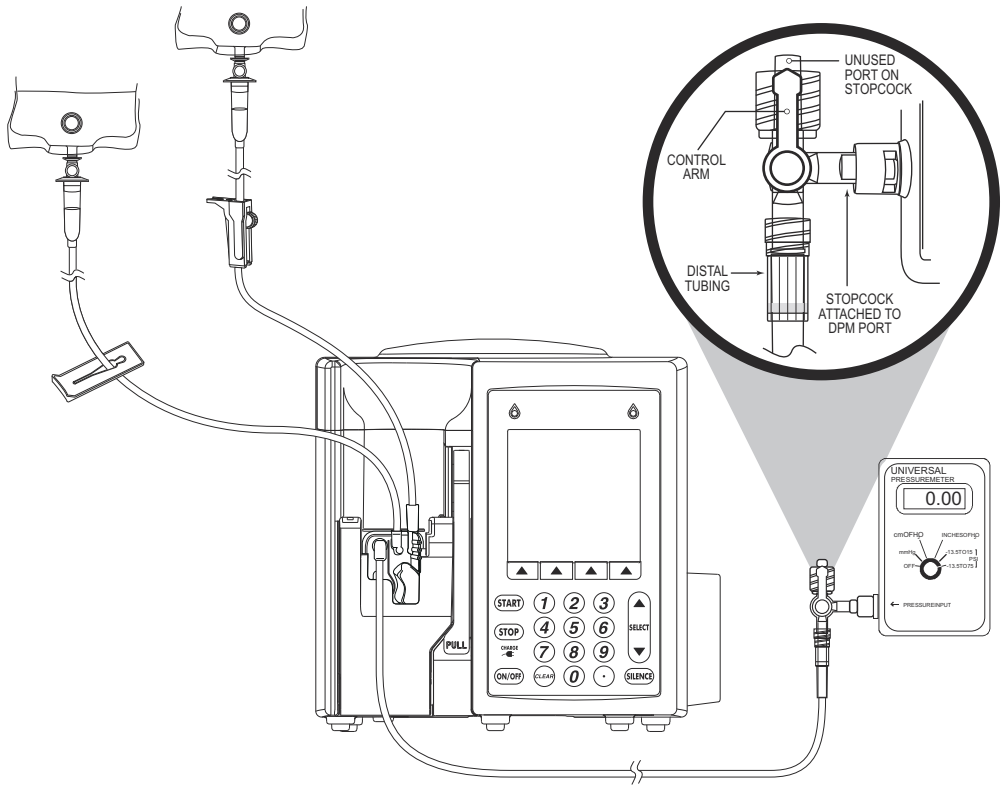

Figure 5-43. Distal Occlusion Test Setup

This setup is used to run the Distal Occlusion test in ***Section 5.3.13***.

5.3.2.5.1
Equipment Required for the Distal Occlusion Test Setup

- Required equipment as listed for the Basic test setup in ***Section 5.3.2.1***.
- Three-way stopcock
- Digital Pressure Meter (DPM)
- Cloth or paper towel to catch drips. (Small amounts of water may be released from the stopcock during testing.)

5.3.2.5.2

Setup Procedure

The three-way stopcock has two ports that are opposite each other. in addition to a third, perpendicular port for attachment to the DPM, as shown in ***Figure 5-44***.

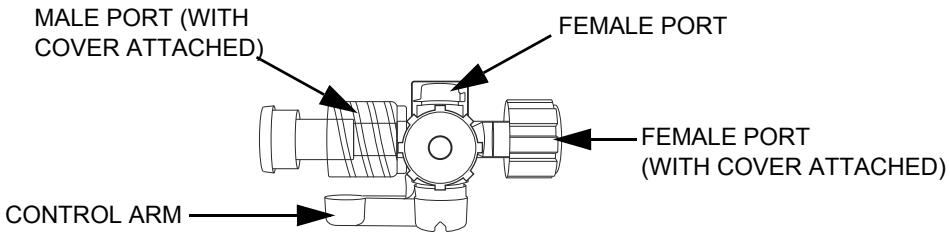

Figure 5-44. Three-Way Stopcock Ports

1. Remove the protective caps from the stopcock ports.
2. Attach the pressure sensor connector on the DPM to a compatible port (male or female) on the three-way stopcock (***see Figure 5-45***).

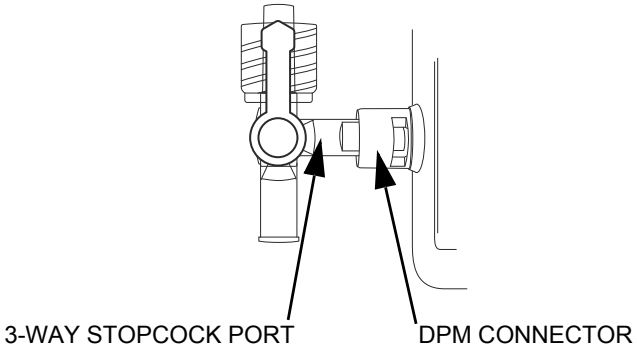

Figure 5-45. Attaching the Three-Way Stopcock to the DPM

3. Insert the distal tubing on the Basic test setup into a female port on the three-way stopcock and turn the Option-Lok connector clockwise to secure the tubing to the port (***see Figure 5-46***).

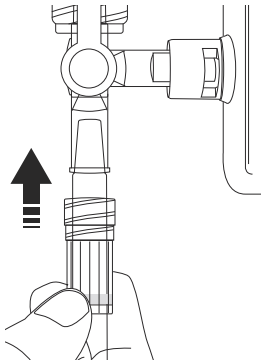

Figure 5-46. Securing the Distal Tubing to the Three-Way Stopcock

4. Place the DPM connector at a height of 0 ± 12 inches from the midline of the pumping chamber on the cassette (***see Figure 5-47***).

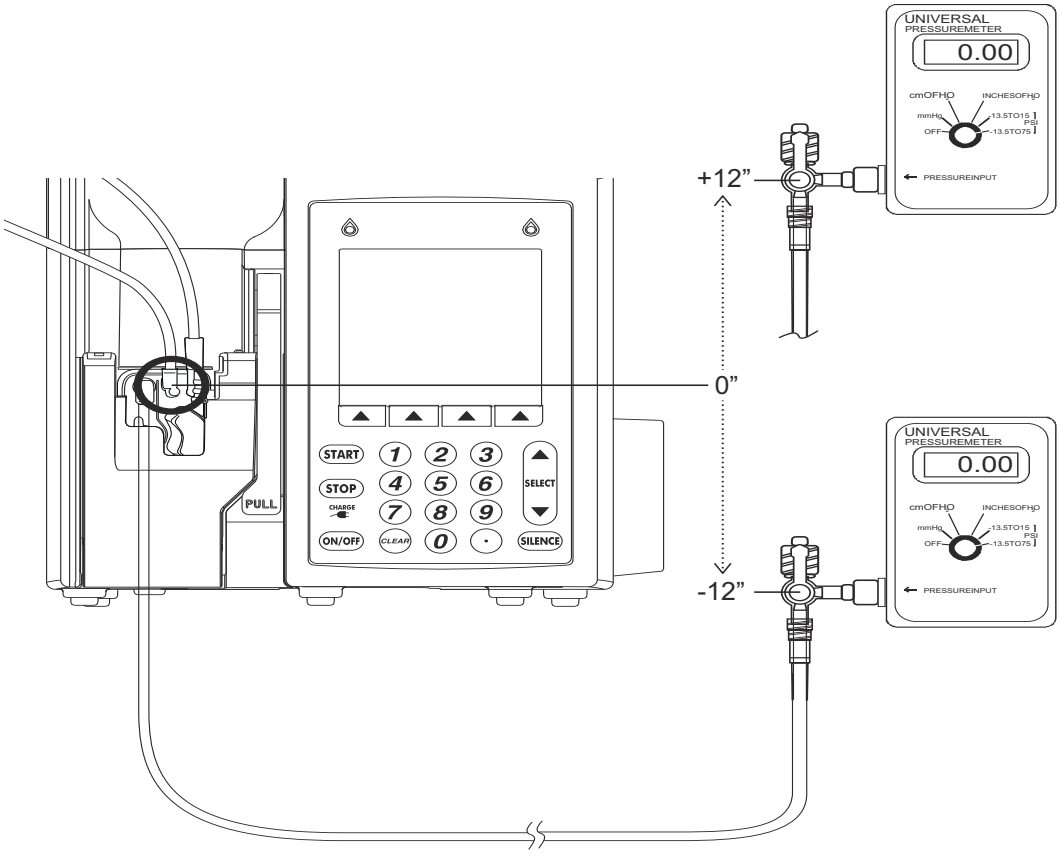

Figure 5-47. DPM Connector Height

5.3.3
SELF TEST

The self test procedure uses the Basic test setup in ***Section 5.3.2.1***.

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

To perform the self test:

1. Plug the power cord into a grounded AC outlet. Verify that the charge/line indicator is lit and an alarm sounds.
2. Without a cassette installed, press [ON/OFF] to turn on the infuser. The LCD screen briefly displays the SELF TEST screen.

   ✎ **Note:** If the SELF TEST screen does not appear, ***contact Hospira***.

3. If MedNet is installed, an Area Selection or CCA Selection screen appears. Choose a care area and press [ENTER]. (If MedNet is not installed, skip this step.)
4. After the self test is complete, the message INSERT PLUM SET CLOSE LEVER appears. Open the cassette door and insert the primed cassette from the Basic test setup in ***Section 5.3.2.1***.
5. Close the cassette door. The infuser will begin a cassette test. If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [YES].
6. When the CASSETTE TEST IN PROGRESS message disappears from the DELIVERY screen, the self test is complete. Open the door and remove the cassette.
7. Proceed to the Cassette Alarm test in ***Section 5.3.4***.

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***.

5.3.4
CASSETTE ALARM TEST

To perform the Cassette Alarm test, use an empty (not primed) run-in cassette and proceed as follows:

1. If the infuser is not on, press [ON/OFF] to turn it on. If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER].
2. Insert the empty run-in cassette and close the cassette door. The CASSETTE TEST IN PROGRESS message appears.
3. After the cassette test is complete, verify that CASSETTE TEST FAILURE is flashing on the display and that the alarm sounds.
4. Open the door and remove the cassette.

5.3.5
UNRESTRICTED FLOW TEST

To perform the unrestricted flow test, use the Basic test setup in ***Section 5.3.2.1*** and proceed as follows:

1. Insert the primed cassette into the infuser and close the cassette door.
2. If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER]. Otherwise, skip this step.
3. With the cassette door closed, check the distal end of the tubing for fluid flow. Verify that no fluid is flowing or that fluid stops after a few drops (maximum) are released from the end of the distal tubing.
4. Clamp the secondary line and open the cassette door and check the distal end of the tubing for fluid flow. Verify that no fluid is flowing or that fluid stops after a few drops (maximum) are released from the end of the distal tubing.
5. Close the cassette door.

5.3.6
DISPLAY TEST

To perform the display test, use the Basic test setup in ***Section 5.3.2.1*** and proceed as follows:

1. Verify that the LCD backlight is illuminated and the display is clearly legible at eye level from approximately 18 inches.
2. On the DELIVERY screen, press [OPTIONS/VOL INF] 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 that the backlight intensity decreases and increases.
5. Select DISPLAY CONTRAST.
6. Press [DECREASE SETTING] and [INCREASE SETTING] to change display contrast. Verify that the display contrast decreases and increases.
7. Press [CANCEL/BACK] to return to the OPTIONS screen.
8. Press [BACK] to return to the DELIVERY screen.

5.3.7
KEYPAD VERIFICATION/FUNCTIONAL TEST

To perform the keypad verification/functional test, use the Basic test setup in ***Section 5.3.2.1*** and proceed as follows:

1. While the infuser displays the DELIVERY screen, press [A] to select Line A.
2. Verify that the PROGRAM screen is displayed. Enter a rate of 123 mL/hr and VTBI of 4567.

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

3. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
4. Verify that fluid is pumping; the message PUMPING is displayed in the Line A status bar, and the LED over Line A flashes.
5. Press [STOP].
6. Press and hold [BACKPRIME]. Verify that the BACKPRIMING and RELEASE BACKPRIME TO STOP messages are displayed, and confirm that the infuser is actually backpriming.
7. Release the [BACKPRIME] softkey.

   Note: Wait for cassette test to finish, before continuing to next step.

8. Press [START], and verify that Line A is pumping again.
9. Press [B].
10. Verify that PIGGYBACK is the displayed delivery mode. If necessary, change the delivery mode by pressing [CHANGE MODE].
11. Enter a rate of 890 mL/hr and VTBI of 2.1 mL.
12. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
13. Verify that fluid is pumping, the message PUMPING is displayed in the Line B status bar, and the LED over Line B flashes.
14. After the display shows that Line B has pumped 2 mL, verify that pumping has switched to Line A.
15. Use a hemostat to clamp IV tube on distal side of the cassette to produce an occlusion fault, press [SILENCE] to silence the alarm, and remove the hemostat.
16. Press [OPTIONS/VOL INF]. Highlight VOLUME INFUSED and press [CHOOSE].
17. Use the [UP ARROW] button on the keypad to select Line A.
18. Press the [CLEAR] key on the keypad. Verify that Line A volume is 0 mL and then press [ENTER].

5.3.8
ALARM LOUDNESS TEST

To perform the alarm loudness test, use the Basic test setup in ***Section 5.3.2.1*** and proceed as follows:

1. Press [A] to select Line A.
2. If the message CLEAR LINE A SETTINGS appears, press [YES].
3. Enter a rate of 400 mL/hr and VTBI of 1 mL.
4. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
5. Verify that fluid is pumping; the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
6. Verify that the alarm sounds and the message LINE A VTBI COMPLETE appears when the dose has been delivered.
7. Turn the volume control knob on the back of the infuser clockwise and counterclockwise (***see Figure 5-48***). Verify that the alarm loudness changes.

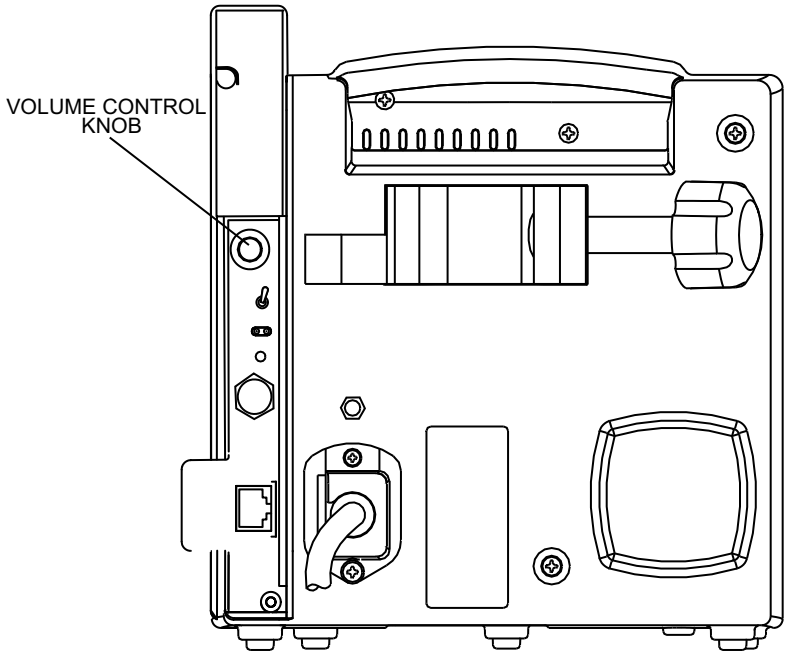

Figure 5-48. Volume Control Knob

8. Press the [SILENCE] key, and verify that the alarm is paused.
9. Press [STOP].

5.3.9
KEYPAD LOCKOUT SWITCH TEST

To perform the keypad lockout switch test, use the Basic test setup in ***Section 5.3.2.1*** and proceed as follows:

1. Press [A] to select Line A. If the message CLEAR LINE A SETTINGS appears, press [YES].
2. Enter a rate of 400 mL/hr and VTBI of 50 mL.
3. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
4. Verify that fluid is pumping; the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
5. Move the keypad lockout switch on the back of the infuser to the up (ON) position to disable the keypad (***see Figure 5-49***).

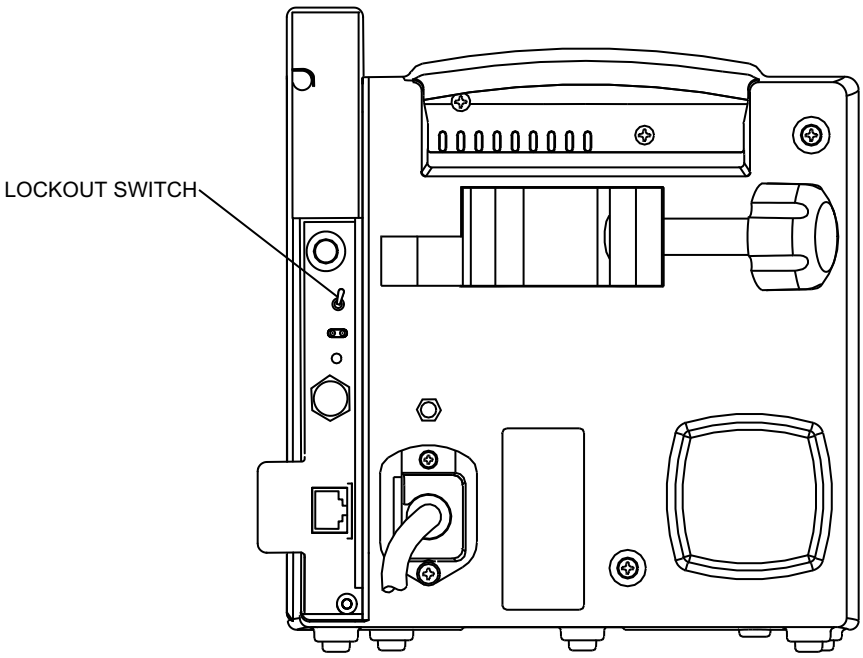

Figure 5-49. Keypad Lockout Switch

6. Press any key except [STOP], and verify that an invalid key press audio alert is generated and the HARD LOCK ENABLED message is displayed. Confirm that the infuser continues to operate.
7. Press [STOP]. Verify that an alarm sounds, the HARD LOCKOUT VIOLATION message appears, and pumping stops.
8. Move the keypad lockout switch to the down (OFF) position. Verify that the HARD LOCKOUT VIOLATION message disappears and the alarm stops.
9. Press [START].
10. Open the cassette door and verify that an alarm sounds and the DOOR OPEN WHILE PUMPING message is displayed.
11. Close the cassette door.
12. Press [NO] at the NEW PATIENT? or CLEAR SETTINGS? prompt.

5.3.10
PROXIMAL OCCLUSION TEST

To perform the proximal occlusion test, use the Basic test setup in ***Section 5.3.2.1*** and the programming from the Keypad Lockout Switch test in ***Section 5.3.9***, and proceed as follows:

> **Note:** If performing this section as a standalone test, select Line A and enter a rate of 400 mL/hr and a VTBI of 50 mL. Go to Step 1.

1. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
2. Verify that the LED above Line A flashes.
3. After several pumping cycles, clamp the Line A tubing proximal to the cassette.
4. Verify that the PROXOCCL A/AIR message flashes and the alarm sounds before three pumping cycles are completed.
5. Press [SILENCE] and verify that the alarm stops while the message on the display continues to flash.
6. Unclamp the proximal line and press [START]. Verify that pumping resumes.
7. Press [STOP].
8. Open the cassette door and remove the cassette.

5.3.11
PROXIMAL AIR-IN-LINE TEST

The Proximal Air-in-Line test uses the Proximal Air-in-Line test setup in ***Section 5.3.2.2*** and the programming from the Proximal Occlusion test in ***Section 5.3.10***.

> **Note:** If performing this section as a standalone test, insert the test cassette prepared in ***Section 5.3.2.2***, select Line A, and enter a rate of 400 mL/hr and a VTBI of 50 mL. Go to Step 4.

1. Insert the proximal test cassette into the infuser and close the cassette door.
2. If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [NO].
3. Make a note of the Volume Infused (Vol Inf mL) displayed on the Main Delivery screen for Line A. You will need this value for Step 6.
4. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
5. Verify that fluid is pumping; the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
6. Before 1 mL of fluid is delivered, verify that pumping stops, the alarm sounds, and the N232 PROX AIR A, BACKPRIME message is flashing on the display.
7. Open the cassette door and remove the test cassette.

5.3.12
DISTAL AIR-IN-LINE TEST

The Distal Air-in-Line test uses the Distal Air-in-Line test setup in ***Section 5.3.2.3*** and the programming from the Proximal Air-in-Line test in ***Section 5.3.11***.

> **Note:** If performing this section as a standalone test, insert the test cassette prepared in ***Section 5.3.2.3***, select Line A, and enter a rate of 400 mL/hr and a VTBI of 50 mL. Go to Step 4.

1. Insert the distal test cassette into the infuser and close the cassette door.
2. If a NEW PATIENT? or CLEAR SETTINGS? message appears, press [NO].
3. Make a note of the Volume Infused (Vol Inf mL) displayed on the Main Delivery screen for Line A. You will need this value for Step 6.
4. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
5. Verify that fluid is pumping, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
6. Before 1 mL of fluid is delivered, verify that pumping stops, the alarm sounds and the N234 DISTAL AIR message is flashing on the display.

> **Note:** Older versions of the Plum A+ may display the E234 DISTAL AIR message.

7. Open the cassette door and remove the test cassette.

5.3.13
DISTAL OCCLUSION TEST

For the distal occlusion test, proceed as follows:

1. Insert the cassette from the Basic test setup into the infuser and close the cassette door. The infuser will proceed with the cassette test.
2. Attach the stopcock and DPM to the distal end of the tubing as shown in the Distal Occlusion test setup in ***Section 5.3.2.5***. Position the collection container beneath the stopcock to catch water that is released during the test.
3. Turn the DPM on.
4. When the CLEAR SETTINGS? or NEW PATIENT? message appears on the infuser display, press [YES].
5. Press [OPTIONS/VOL INF] to select the Options screen.
6. Select Pressure/Post Infusion Rate, and press [CHOOSE].
7. Verify that the distal pressure limit is set at 6 psi. If the pressure limit is not 6 psi, highlight the Distal Pressure Limit and enter 6.
8. Press [ENTER].
9. Press [A] to select Line A.
10. Enter a rate of 40 mL/hr and a VTBI of 50 mL.

11. Position the control arm of the three way stopcock over the DPM connector (***see Figure 5-50***).

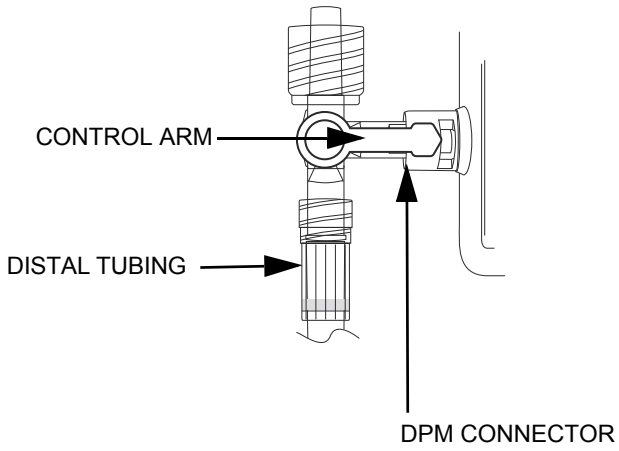

Figure 5-50. Positioning the Control Arm Over the DPM Connector

12. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
13. Verify that fluid is pumping from the open port on the stopcock, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.
14. Set the three-way stopcock to measure pressure by positioning the control arm over the open port (***see Figure 5-51***). As the infuser pumps, pressure will build up on the distal line.

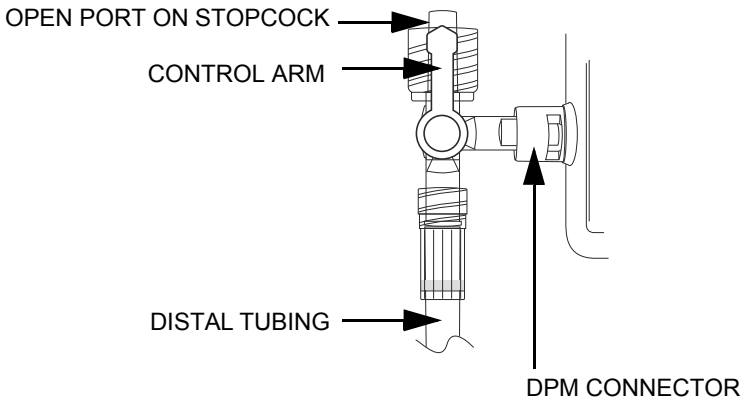

Figure 5-51. Positioning the Control Arm to Measure Pressure

15. Verify that the distal occlusion audible alarm occurs at 6 psi ± 3 psi on the DPM. Confirm that the DISTAL OCCLUSION message is flashing on the screen.

16. Open the three-way stopcock to air by positioning the control arm over the distal tubing (***see Figure 5-52***). This releases the pressure that was built up during the test.

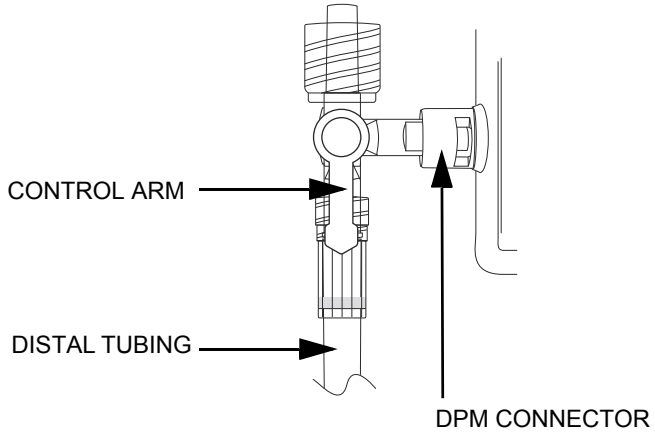

Figure 5-52. Opening the Three-Way Stopcock to Air

17. Position the control arm of the three way stopcock over the DPM connector (***see Figure 5-53***).

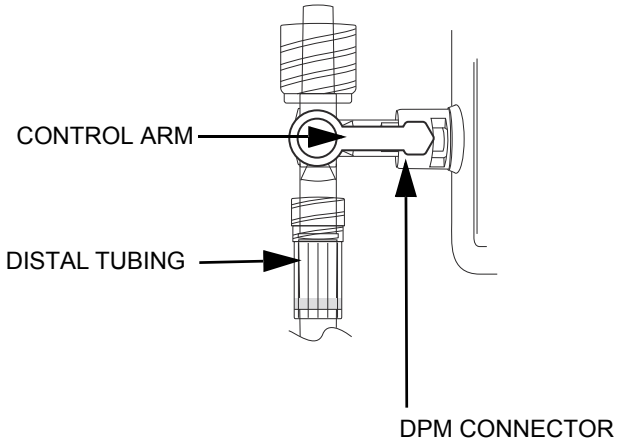

Figure 5-53. Positioning the Control Arm Over the DPM Connector

18. Open and close the cassette door to clear the distal occlusion alarm. Press [NO] at the CLEAR SETTINGS? or NEW PATIENT? prompt.
19. Press [OPTIONS/VOL INF] to select the OPTIONS screen.
20. Select Pressure/Post Infusion Rate and press [CHOOSE].
21. Select Distal Pressure Limit. Enter 10 psi, and press [ENTER].
22. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
23. Verify that fluid is pumping from the open port on the stopcock, the message PUMPING is displayed in the Line A status bar, and the LED above Line A flashes.

24. Set the three-way stopcock to measure pressure by positioning the control arm over the open port (***see Figure 5-54***).

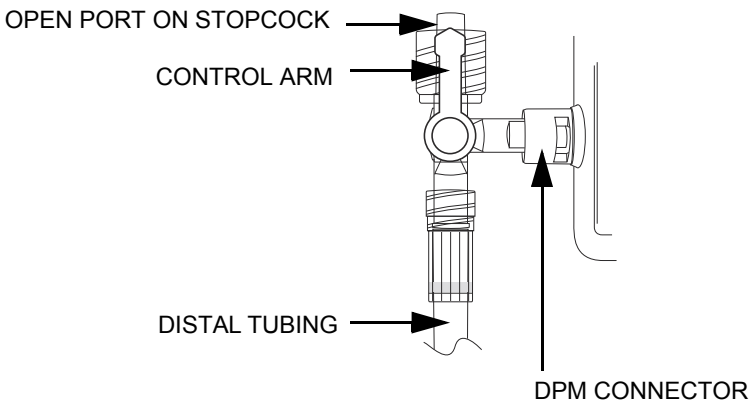

Figure 5-54. Positioning the Control Arm to Measure Pressure

25. Verify that the distal occlusion audible alarm occurs at 10 psi ± 3 psi. Confirm that the DISTAL OCCLUSION message is flashing on the screen and that pumping is stopped.
26. Turn off the Infuser.
27. Remove the distal tubing from the three-way stopcock and turn off the DPM.

5.3.14
DELIVERY ACCURACY TEST

The Delivery Accuracy Test uses the Basic test setup in ***Section 5.3.2.1*** with the following changes: a blunt cannula is attached to the end of the distal tubing, and a 25 mL graduated cylinder is used in place of the collection container.

> **Note:** Accuracy testing is for verification purposes only. If there is any concern as to infuser accuracy, ***contact Hospira***.

To perform the delivery accuracy test, proceed as follows:

1. Attach the 18-gauge blunt cannula to the distal end of the tubing and place the cannula into the graduated cylinder. Make sure the score marks on the Line A and Line B drip chambers are 12 to 24 inches above the cassette and that all lines are unclamped (***see Figure 5-55***).

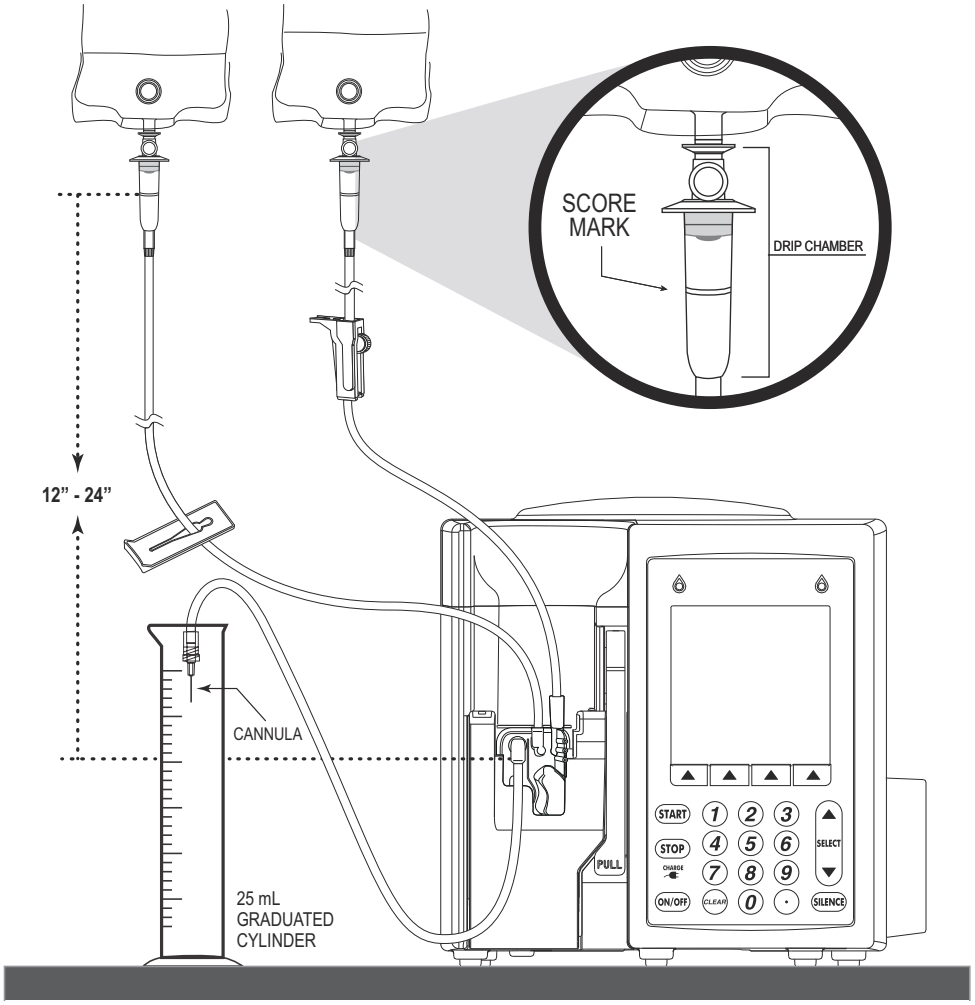

Figure 5-55. Delivery Accuracy Test Setup

2. Turn on the infuser.
3. If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER].

4. Press [YES] at the CLEAR SETTINGS? or NEW PATIENT? prompt.
5. Press [A] to select Line A.
6. Enter a rate of 200 mL/hr and VTBI of 10 mL.
7. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
8. Verify that fluid is pumping; the message PUMPING is displayed in the Line A status bar, and the LED over Line A flashes.
9. Press [B] to select Line B.
10. Verify that Piggyback delivery mode is selected. If necessary, press [CHANGE MODE] to change the delivery mode.
11. Enter a rate of 200 mL/hr and a VTBI of 10 mL.
12. Press [START]. If a CONFIRM PROGRAM? message appears, confirm that the rate and VTBI are correct, and then press [YES].
13. Verify that fluid is pumping; the message PUMPING is displayed in the Line B status bar, and the LED over Line B flashes.

    Note: Line A will be stopped (DELAYED) while Line B is pumping, and will resume pumping when Line B delivery is complete.

14. When total delivery is complete on Line A, verify that the KVO message flashes on the display and an audible alarm sounds.
15. Press [STOP] and verify that the volume delivered into the graduated cylinder is 20 mL ± 1 mL.

    Note: The pumping chamber in a test cassette can become fatigued after repeated tests are run. If an infuser fails the delivery accuracy test, run the test again with a new primary administration set, to ensure that the issue is with the infuser, not the test setup.

5.3.15
NURSE CALL TEST

Bypass this test if the nurse call function is not used.

The nurse call test requires the Basic test setup in ***Section 5.3.2.1***, the nurse call test cable, and the digital multimeter (DMM).

To perform the nurse call test, proceed as follows:

1. Attach the 2-prong lead on the nurse call test cable to the ports on the DMM that are marked for measuring resistance.
2. Attach the other lead to the nurse call jack on the back of the infuser (***see Figure 5-56***).

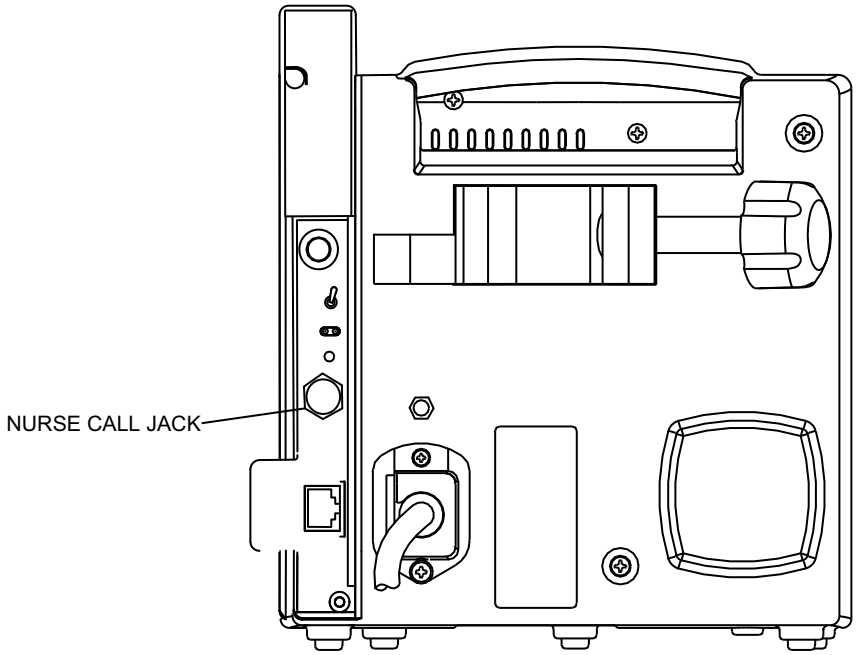

Figure 5-56. Nurse Call Jack

3. Turn on the DMM and set it to measure resistance.
4. On the infuser, press [A] to select Line A. If a CLEAR SETTINGS? or NEW PATIENT? prompt appears, press [YES].
5. Set the delivery rate to 400 mL/hr, and the VTBI to 1 mL.
6. Press [START] and verify that the infuser is pumping.
7. After KVO flashes and the LINE A VTBI COMPLETE message appears, check for a short circuit on the DMM (approximately 1 Ω on a scale of 0 to 100 Ω). If the short circuit appears, the test is successful.
8. Press [STOP], and then turn off the infuser.

5.3.16
ELECTRICAL SAFETY TEST

The electrical safety test uses the safety analyzer specified in the equipment list in ***Section 5.3.1***. Refer to the safety analyzer user's guide for specific instructions on how to set up and use the safety analyzer.

To perform the electrical safety test, proceed as follows:

1. Connect the safety analyzer to a power source.
2. Unplug the infuser's power cord from the outlet and connect it to the safety analyzer.
3. Connect the safety analyzer ground lead to the ground test-point screw/post located on the back of the infuser. (The infuser has a label that points to the location of the ground test screw.)

   Note: If the infuser does not have a ground test screw/post, connect the analyzer ground lead to one of the screws that secures the power cord retainer.

4. Check the leakage current with the safety analyzer. Leakage current must not exceed the specifications in ***Table 5-2***.
5. Measure the resistance of the AC (mains) connector ground lug with the safety analyzer. Resistance should not exceed the specifications in ***Table 5-2***.
6. Connect the infuser to AC power and ensure that the AC indicator is lit.

Table 5-2. Electrical Safety Measurements

Measurement	Not to Exceed
Enclosure leakage current (NC - ground intact)	100 µA
Enclosure leakage current (SFC - open neutral or open ground)	300 µA
Earth leakage current (NC - open ground)	500 µA
Earth leakage current (SFC - open ground and open neutral)	1000 µA
Chassis ground resistance (with cord connected)	0.2 Ω

NC = NORMAL CONDITION, SFC = SINGLE-FAULT CONDITION

5.3.17
END OF THE PVT

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

If the infuser passed all performance verification tests, follow these instructions to clear all programming and prepare the device to be put back into service:

1. Turn on the infuser.
2. If an Area Selection or CCA Selection screen appears, choose a care area and press [ENTER].
3. In response to the NEW PATIENT? or CLEAR SETTINGS? prompt, press [YES].
4. Remove the cassette and close the cassette door.
5. Turn off the infuser.
6. Make sure the keypad lockout switch on the back of the infuser is in the DOWN position (lockout disabled).
7. Return the infuser to service.

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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. Operational Alarm Messages and Corrective Actions

Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N100	Unrecognizable cassette	Incorrect cassette type	An incorrect cassette is inserted	Insert proper cassette
N101	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
N102	Infuser idle 2 minutes	Infuser in reset or idle for over two minutes	Programming set without start for two minutes	Press **[START]**
N103	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	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]**
N105	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**	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**	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**	Distal Occl	Peak distal occlusion, non-delivery	Distal occlusion detected during non-delivery	Backprime the cassette and restart the infuser
N181 or **E181**	Distal Occl	Negative distal occlusion, non-delivery	Distal occlusion detected during non-delivery	Backprime the cassette and restart the infuser
N182 or **E182**	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. Operational Alarm Messages and Corrective Actions

Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N183 or **E183**	Prox. Occl B, Air or Prox. Occl B	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**	Prox. Occl A, Air or Prox. Occl A	Negative 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
N185 or **E185**	Prox. Occl A, Air or Prox. Occl A	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**	Distal Occl	Peak distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser
N187 or **E187**	Distal Occl	Negative distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser
N188 or **E188**	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**	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**	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. Operational Alarm Messages and Corrective Actions

Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N191 or **E191**	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**	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**	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**	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**	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**	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**	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**	Valve/cass test fail	Valve/cassette test failure	Valve/cassette fails the 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**	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**	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
N254 or **E254**	Lockout Enabled	Keypad locked	Any action not resulting in stopping of delivery while lockout switch is locked	Unlock the lockout switch
N255	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
N256	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, unrestricted flow may occur	1. Remove mechanism 2. Remove fluid shield 3. Visually inspect regulator closer 4. Verify regulator closer is completely engaged 5. Test If unrestricted flow persists, replace the mechanism

6.3.2
ERROR CODES REQUIRING TECHNICAL SERVICE

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

Note: Perform corrective actions in the order listed in the Corrective Action Column.

CAUTION: CE module 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 7.2.12.4)*** 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 ***(Section 7.2.12.5)*** Replace CPU PWA ***(see Section 7.2.12.4)*** 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 7.2.12.3)*** Reset time and date, if required ***(see Section 1.10.2)***
E320	Battery charge/ discharge current out of range	Current limiting circuitry in power supply board has failed Other hardware failure causing excessive current draw	Replace power supply PWA ***(see Section 7.2.12.1)*** Replace CPU PWA ***(see Section 7.2.12.4)*** Replace mechanism assembly ***(see Section 7.2.12.6)*** 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
E321	Failure of charging current to drop below end of charge current threshold within eight hours of charging, or below one ampere within six hours of charging	Defective or worn out battery	Turn power off, then on to clear the error on the device and remove the infuser from service. While the infuser is out of service, discharge the battery until the battery charge indicator on the display shows five or fewer bars, then complete an eight hour charging cycle by plugging the device into AC power and placing it into Standby mode *(see the Plum A+ System Operating Manual)* If the **E321** error code does not reappear after the charging cycle, the infuser may be returned to service If the **E321** error code reappears after the charging cycle, replace the battery ***(see Section 7.2.4)*** Reset time and date, if required ***(see Section 1.10.2)***
E322	Battery current calibration value out of range	Defective charge current measurement circuitry	Replace power supply PWA ***(see Section 7.2.12.1)*** Reset time and date, if required ***(see Section 1.10.2)***
E323	Battery trickle charge current out of range	Defective or worn out battery Sensing circuit defective	Replace battery ***(see Section 7.2.4)*** Replace power supply PWA ***(see Section 7.2.12.1)*** Reset time and date, if required ***(see Section 1.10.2)***
E324	Supply overvoltage	Defective charging circuit	Replace power supply PWA ***(see Section 7.2.12.1)*** Reset time and date, if required ***(see Section 1.10.2)***
E325	Battery overvoltage	Battery is wrong voltage Defective sensing circuit	Replace battery ***(see Section 7.2.4)*** Replace power supply PWA ***(see Section 7.2.12.1)*** 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
E326	Battery disconnected while the infuser is on or battery voltage is too low	Connectors not seated properly on battery terminals Conductor caught or pinched in frame and pulled from battery Corrosion on terminals Defective battery cable Defective or worn out battery	Check for loose battery connections Check for battery conductors caught in enclosure Check for corrosion on battery terminals Check continuity of battery cable Replace battery ***(see Section 7.2.4)*** Reset time and date, if required ***(see Section 1.10.2)***
E340	Critical instruction failure	Power-up CPU register test failed (no malfunction message displayed)	Replace CPU PWA ***(see Section 7.2.12.4)*** 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 7.2.12.6)*** Reset time and date, if required ***(see Section 1.10.2)***
E342	Display failure	Defective display	Replace display assembly ***(see Section 7.2.12.3)*** 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 7.2.12.6)*** Reset time and date, if required ***(see Section 1.10.2)***
E344	Distal air sensor failure 2	With the cassette inserted, the distal air sensor self test detects sensor out of range	
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 failure	Hardware watchdog failure	Replace CPU PWA ***(see Section 7.2.12.4)*** 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 7.2.12.4)*** Replace mechanism assembly ***(see Section 7.2.12.6)*** 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 Replace CPU PWA ***(see Section 7.2.12.4)*** Replace mechanism assembly ***(see Section 7.2.12.6)*** Reset time and date, if required ***(see Section 1.10.2)***
E380	Plunger motor phase loss	Generic plunger motor failure	
E430	Proximal air sensor failure 1	Proximal air sensor ongoing test detects liquid with cassette removed	Replace mechanism assembly ***(see Section 7.2.12.6)*** Reset time and date, if required ***(see Section 1.10.2)***
E431	Proximal air sensor failure 2	Proximal air sensor self test detects liquid with cassette removed	
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 CE module ***(see Section 7.2.6)*** 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 7.2.12.4)*** 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 CE module ***(see Section 7.2.6)*** Reset time and date, if required ***(see Section 1.10.2)***
E437	Software failure	Generic software failure	Turn power off, then on, to reset the infuser Replace CPU PWA ***(see Section 7.2.12.4)*** Reset time and date, if required ***(see Section 1.10.2)***
E438	Stack out-of-range failure	Stack out-of-range failure	

Table 6-3. Error Codes Requiring Technical Service

Error Code	Malfunction	Possible Cause	Corrective Action
E439	Stuck key	A key is sensed as pressed for over two minutes	Replace keypad *(see Section 7.2.12.2)* Reset time and date, if required *(see Section 1.10.2)*
E440	Power hold stuck	Power hold signal stuck Power cannot be turned off	
E443	LCD failure	LCD bias is out of range	Replace display assembly *(see Section 7.2.12.3)* 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 7.2.12.4)* 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 7.2.12.4)* Reset time and date, if required *(see Section 1.10.2)*
E447	Battery ADC reading failure	16 consecutive readings have been either all zero or max value	
E448	SEEP write failure	SEEP data write failed	Replace mechanism assembly *(see Section 7.2.12.6)* Replace CPU PWA *(see Section 7.2.12.4)* Replace CPU/driver cable *(see Section 7.2.12.4)* Reset time and date, if required *(see Section 1.10.2)*
E449	SEEP calibration data corrupted	Calibration data block corrupted	
E450	MMIO port read/ write failure	I/O port read/write failure	Replace CPU PWA *(see Section 7.2.12.4)* 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 Reset time and date, if required *(see Section 1.10.2)* If error codes *recur,* ***contact Hospira***
E452	Software failure	Miscellaneous software failures	

Table 6-3. Error Codes Requiring Technical Service

Error Code	Malfunction	Possible Cause	Corrective Action
E453	Two SEEP CRC errors	NVRAM data block corrupted	Replace mechanism assembly ***(see Section 7.2.12.6)***
E454	NVRAM over capacity	Software trying to write into non-existent NVRAM space	Replace CPU PWA ***(see Section 7.2.12.4)*** Replace CPU/driver cable ***(see Section 7.2.12.4)*** 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 CE module ***(see Section 7.2.6)***
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 CE module ***(see Section 7.2.6)***
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, then 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 5.3***. See ***Table 6-4*** for section reference, probable cause, and corrective actions.

If after completing step 1 and step 2, a malfunction has not been located, or if the infuser persistently fails, ***contact Hospira***.

CAUTION: CE module 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 *(Section 5.3.3)*	Cassette not properly installed	Reseat cassette
	Defective CPU PWA	Replace CPU PWA *(see Section 7.2.12.4)*
Cassette Alarm Test *(Section 5.3.4)*	Cassette not properly seated	Reseat cassette
	Defective cassette	Replace cassette
Unrestricted Flow Test *(Section 5.3.5)*	Cassette not properly seated	Reseat cassette
	Defective cassette	Replace cassette
	Defective or dirty valve pins	Clean valve pins
		Replace mechanism assembly *(see Section 7.2.12.6)*
Display Test *(Section 5.3.6)*	Defective display assembly	Replace display assembly *(see Section 7.2.12.3)*
Keypad Verification/ Functional Test *(Section 5.3.7)*	Defective keypad	Replace keypad *(see Section 7.2.12.2)*
Alarm Loudness Test *(Section 5.3.8)*	Defective CPU	Replace CPU PWA *(see Section 7.2.12.4)*
	Defective peripheral PWA	Replace CE module *(see Section 7.2.6)*
	Defective piezo alarm assembly	Replace piezo alarm assembly *(see Section 7.2.12.5)*

Table 6-4. Troubleshooting with the PVT

Test Failure	Probable Cause	Corrective Action
Keypad Lockout Switch Test *(Section 5.3.9)*	Defective peripheral interface PWA	Replace CE module *(see Section 7.2.6)*
Proximal Occlusion Test *(Section 5.3.10)*	Closed proximal clamp	Open clamp
	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 7.2.12.6)*
Proximal Air-in-Line Test *(Section 5.3.11)*	Defective special cassette	Replace special cassette
	Dirty sensors	Clean sensors
	Defective APP PWA	Replace mechanism assembly *(see Section 7.2.12.6)*
Distal Air-in-Line Test *(Section 5.3.12)*	Defective special cassette	Replace special cassette
	Dirty sensors	Clean sensors
	Defective APP PWA	Replace mechanism assembly *(see Section 7.2.12.6)*
Distal Occlusion Test *(Section 5.3.13)*	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 7.2.12.6)*
Delivery Accuracy Test *(Section 5.3.14)*	Set not properly primed	Re-prime cassette
	Damaged or faulty cassette	Replace cassette
	Defective mechanism assembly	Replace mechanism assembly *(see Section 7.2.12.6)*
Electrical Safety Test *(Section 5.3.16)*	Defective AC power cord	Replace AC power cord *(see Section 7.2.5)*

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 7.2.12.6*** and ***Section 7.2.12.8***.
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 5.3***.

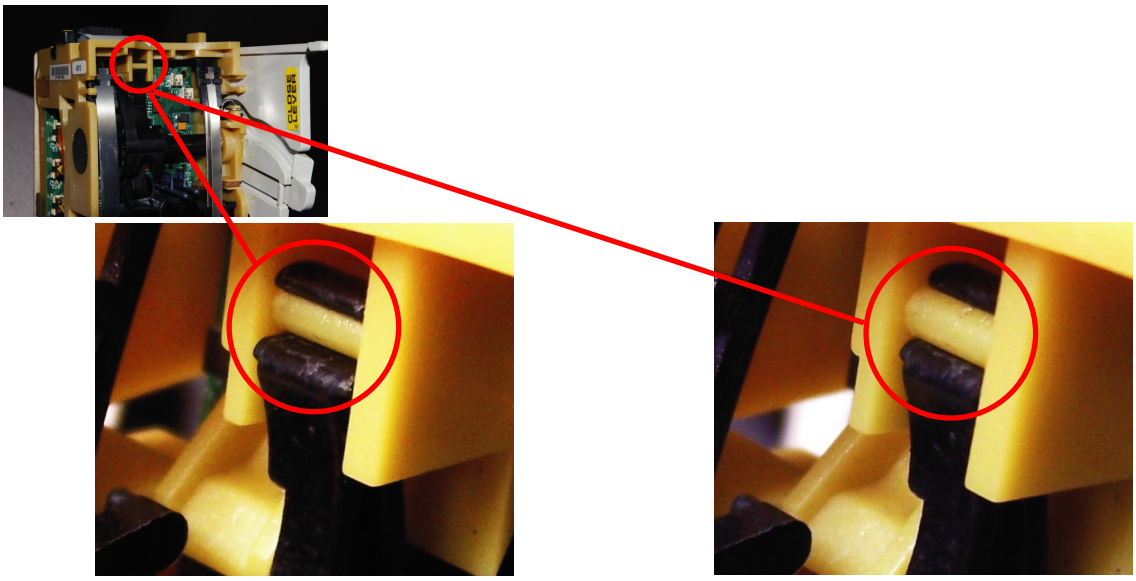

Figure 6-1. Regulator Closer

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.

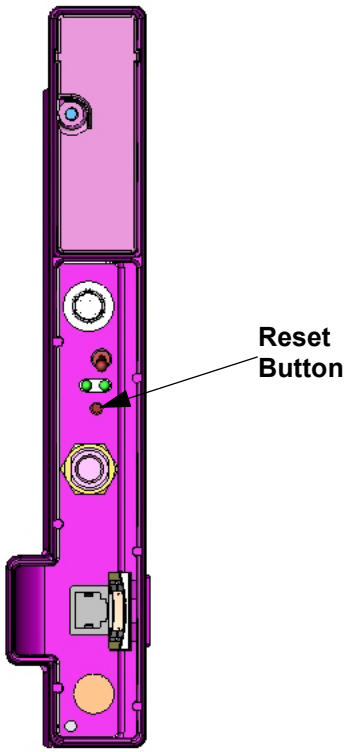

Figure 6-2. Reset Button

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 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.

7.2.2
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)
- Custom nutdriver (P/N 519-95056-001)
- Long needle nose pliers
- Wide-head pliers
- Diagonal cutters
- X-acto™ knife
- Mild solvent
- Lint-free cloth

7.2.3
RUBBER FOOT PAD REPLACEMENT

Recommended tools for this procedure are an X-acto knife, mild solvent, and lint-free cloth.

The replacement part for this procedure is:

Pad, Rubber Foot

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

1. Turn off the infuser and disconnect the device from AC power.
2. Place the infuser on its side.
3. Using the X-acto knife, remove the rubber foot pad and scrape the enclosure recess to remove adhesive residue.

   Note: Each adhesive-backed rubber foot pad is bonded in its recess. Do not damage the recess.
4. Using mild solvent and a lint-free cloth, clean any adhesive residue from the enclosure recess.
5. Remove the protective backing from the self-adhesive surface of the replacement foot pad and press the pad in place.
6. After approximately five minutes, verify the foot pad is secure.

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 these procedures, perform the PVT in ***Section 5.3***.

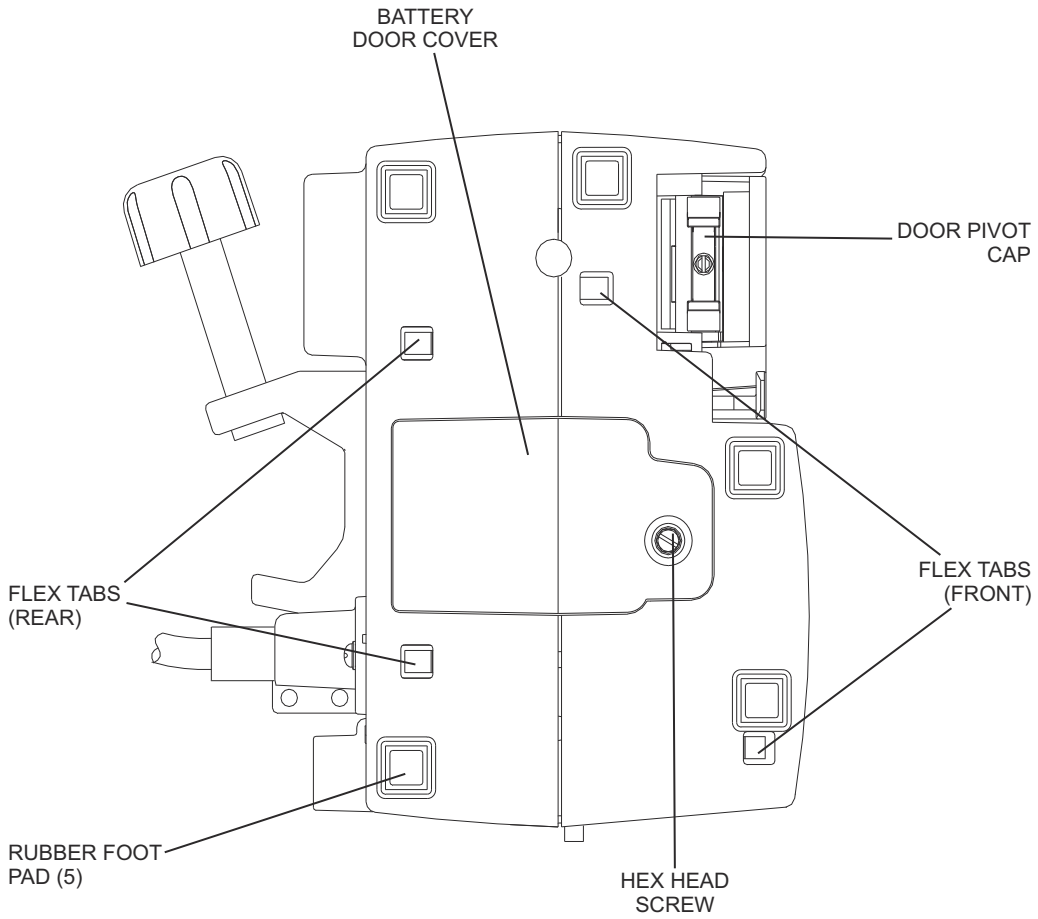

Figure 7-1. Bottom View

7.2.4
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

The replacement parts for this procedure are:

Battery
Assembly, Wire Harness, Battery
Door, Battery
Pad, Door
Gasket, Battery
Screw, 6-32 x 3/8, Hex Head, Slotted, with Washer

To replace the battery, battery door, or door pad, see ***Figure 7-2***, and 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 on its side.
3. Using the flat blade screwdriver, remove the screw 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. Inspect the gasket and replace, if required.

   Note: The battery gasket may not be present on some versions of the device.

7. Disconnect the battery harness from the charger circuit cable. Carefully pull the battery harness wires and connector outside the enclosure, and remove the battery.
8. Using the needle nose pliers, remove the wire harness connectors from the battery terminals.
9. 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.

10. 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.

11. Replace the battery door using the screw that was removed in step 3.
12. Press **[ON/OFF]** with the infuser disconnected from AC power, and verify the front panel battery symbol illuminates.
13. Access the **BIOMED SETTINGS** screen and press **[CHANGE BATTERY]**.

Replacement of the battery door, pad, and gasket 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 5.3***.

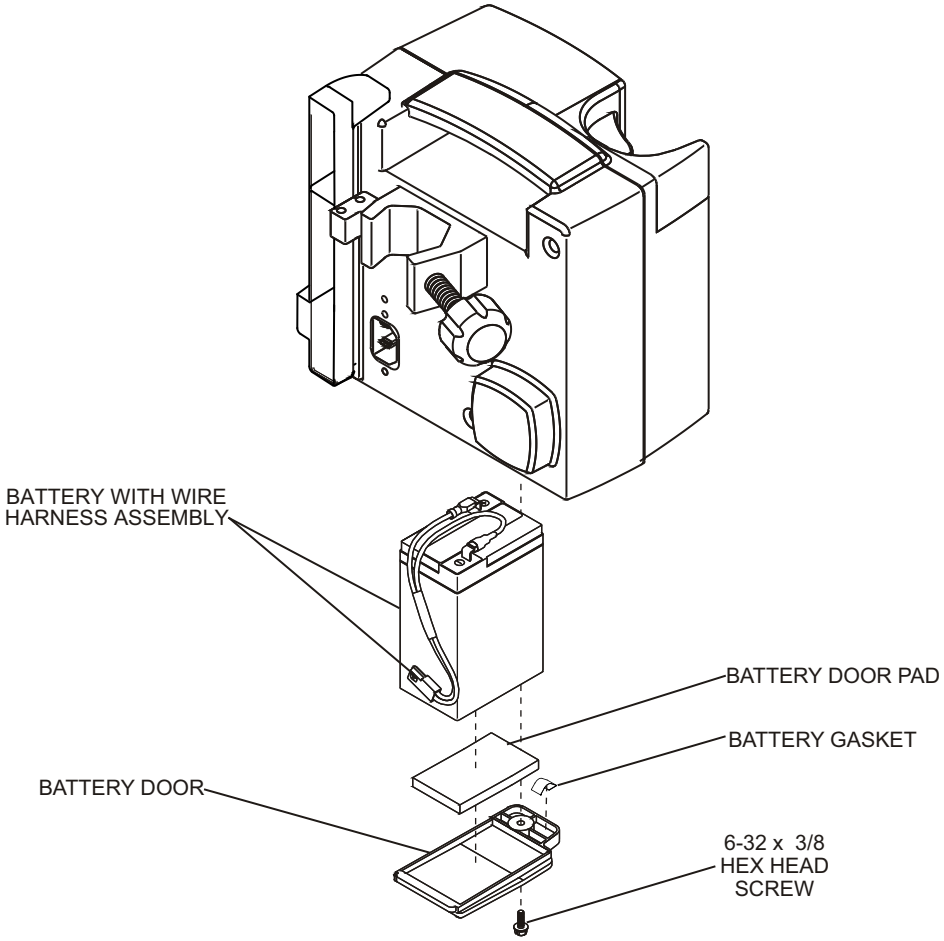

Figure 7-2. Battery Assembly

7.2.5
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 tools for this procedure are a #2 Phillips screwdriver and a 10 mm wrench.

The replacement parts for this procedure are:

Cordset, AC Power, Hospital Grade, Detachable
Retainer, AC Power Cord
Strap, Velcro, AC Power Cord
Terminal, Equipotential
Screw, 4-40 x 1/4, Pan Head, Phillips
Screw, 6-32 x 5/8, Pan Head, Phillips, with Washer
Screw, Jack, 4-40 x 7/16
Washer, Flat, .566 x .255 x .030 Thk.
Washer, Lock, #4

To replace the AC power cord, power cord retainer, or Velcro strap, see ***Figure 7-3***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Using the Phillips screwdriver, remove the screws from the AC power cord retainer.
4. Using the 10 mm wrench, remove and inspect the equipotential terminal, and replace, if required.
5. Unplug the power cord and slide the plug through the retainer.
6. 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.
7. Install the replacement AC power cord in the exact reverse order of removal.
8. Reinstall the battery and connect the infuser to AC power.
9. 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 the procedure, perform the PVT in ***Section 5.3***.

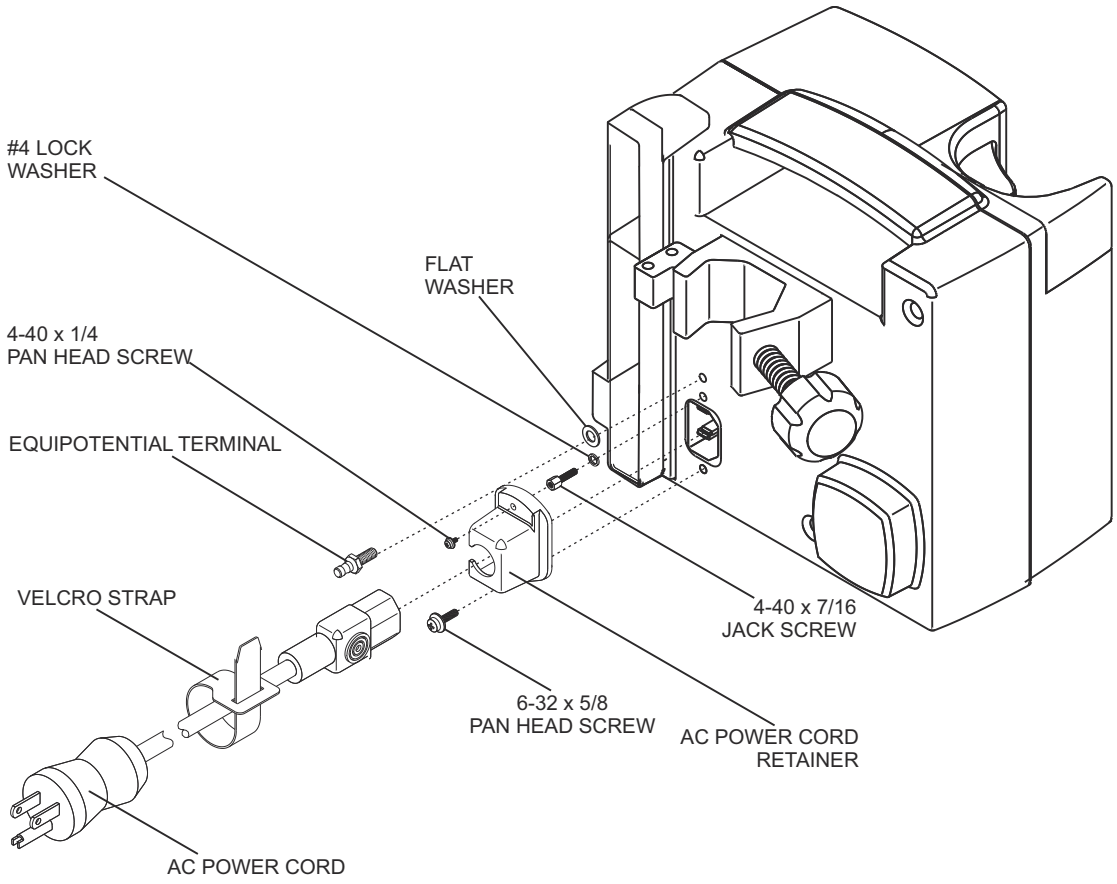

Figure 7-3. AC Power Cord Assembly

7.2.6
CE MODULE REPLACEMENT

Note: The Plum A+ version with wireless 802.11 a/b/g circuitry installed features a USB adaptor. To replace the USB adaptor, see ***Section 7.2.6.1***.

CAUTION: CE module replacement should only be performed after receiving approval from Hospira.

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

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

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

Replacement parts for this procedure are:

CE Module
Screw, 4-40 x 5/8, Pan Head, Phillips, with Washer

To replace the CE module, 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 battery as described in ***Section 7.2.4***.
3. Carefully set the infuser face down.
4. Using the Phillips screwdriver, remove the screws from the CE module.
5. Carefully pull the CE module away from the infuser.

   Note: When removing the CE module, note the placement guides where the peripheral PWA rests.

6. Perform a visual inspection of the last three characters of the Ethernet MAC address on the replacement CE module, and compare the characters to the last three characters on the infuser barcode.
7. Install the CE module in the exact reverse order of removal.

   Note: Verify the peripheral interface PWA is placed properly between the guides and fits correctly into the CPU PWA.

8. Reinstall the battery and connect the infuser to AC power.
9. Turn on the infuser and verify completion of the self test ***(see Section 1.9.3)***.
10. Perform the connectivity check in ***Section 1.11***.

To verify successful CE module replacement, perform the PVT in ***Section 5.3***.

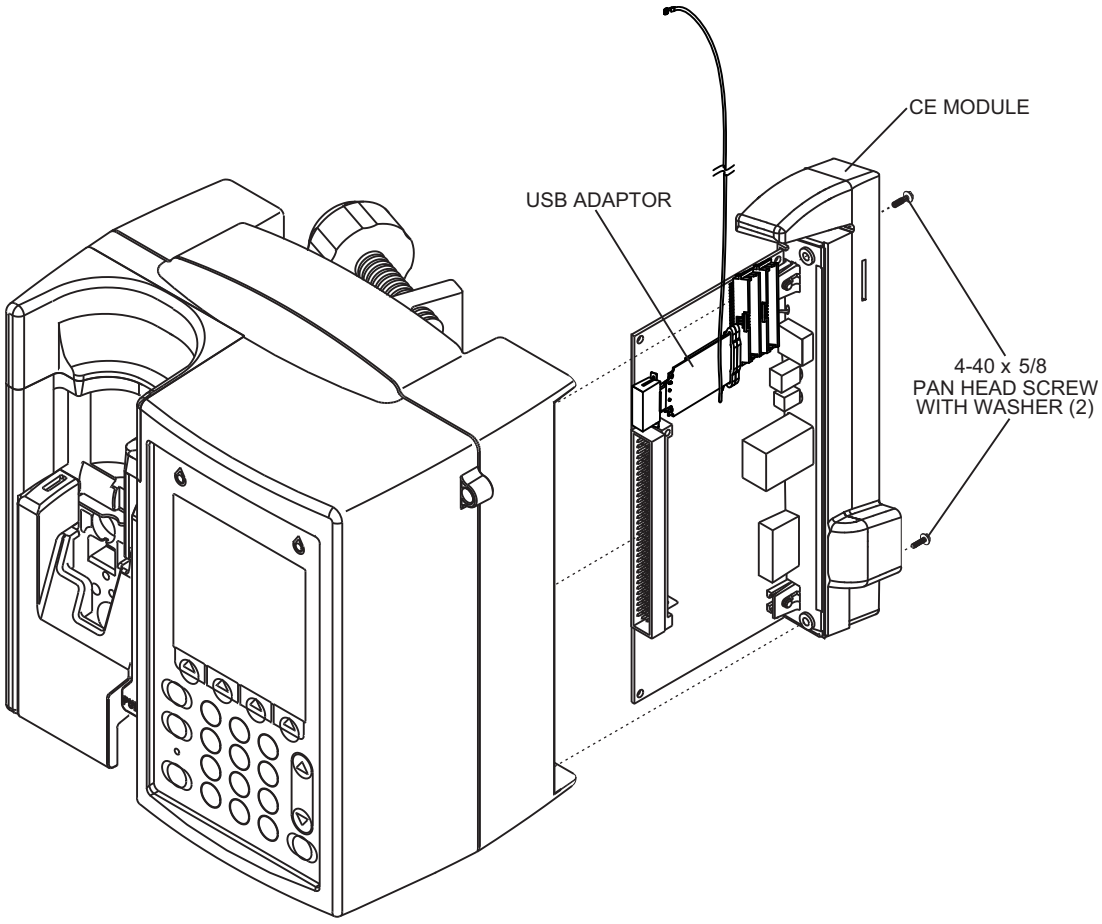

Figure 7-4. CE Module with USB Adaptor

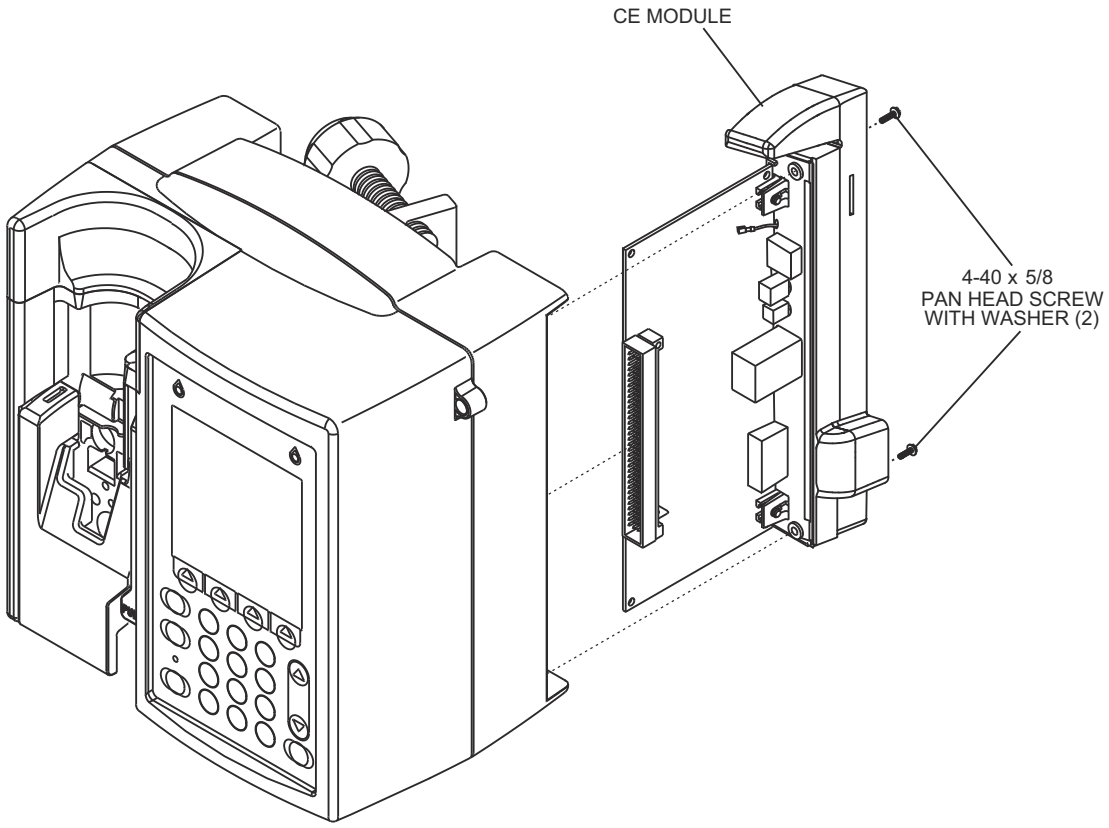

Figure 7-5. CE Module without USB Adaptor

7.2.6.1
USB ADAPTOR

Note: The USB adaptor is present only on the Plum A+ 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 CE module as described in ***Section 7.2.6***.
3. Install the foot of the adaptor's rubber support into the large slot in the peripheral interface 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 cable to the adaptor, then install the adaptor over the rubber support and into the USB port on the peripheral interface 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 CE module.
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 5.3***.

7.2.7
CE MODULE COMPONENT REPLACEMENT

CE module component replacement includes the replacement of the volume control knob, Ethernet quick release latch, antenna PWA, and CE module cover.

To replace CE module components, see ***Figure 7-6***, ***Figure 7-7***, and ***Figure 7-8***, and proceed as described in the following sections.

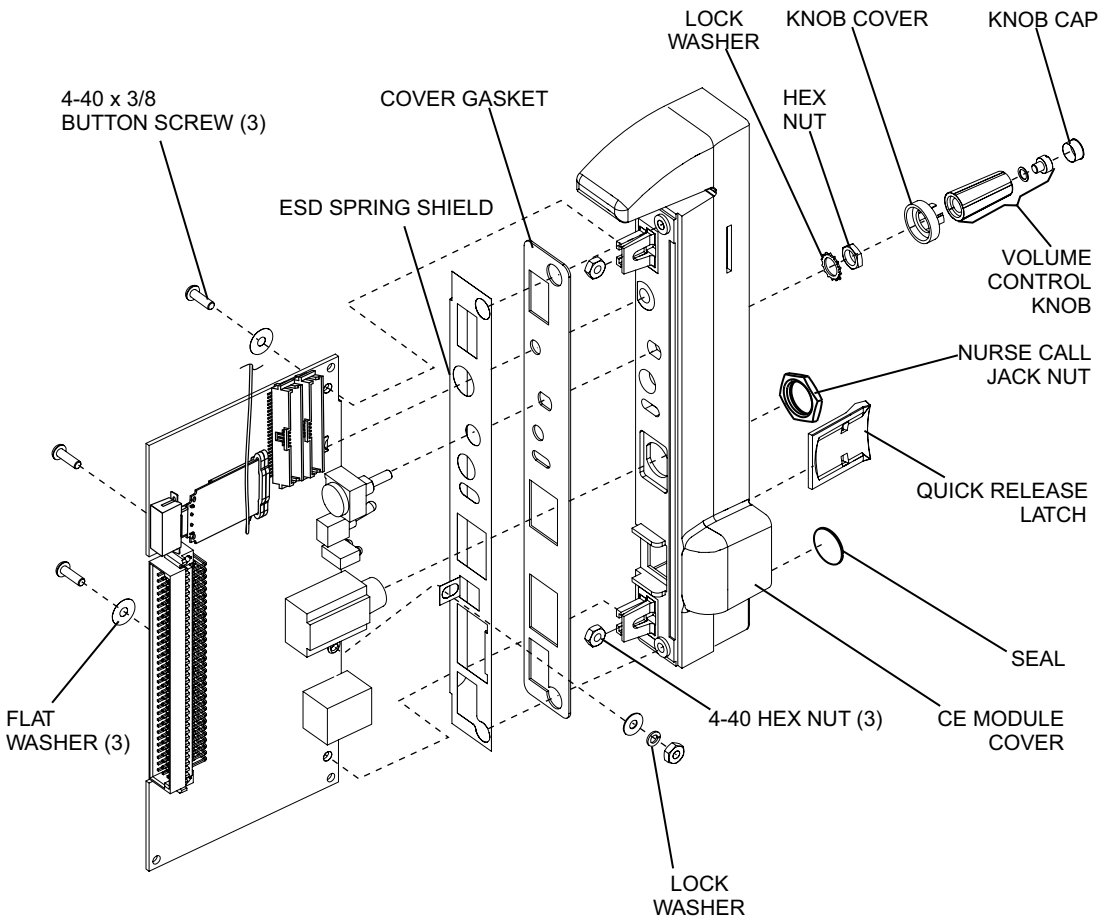

Figure 7-6. CE Module Components

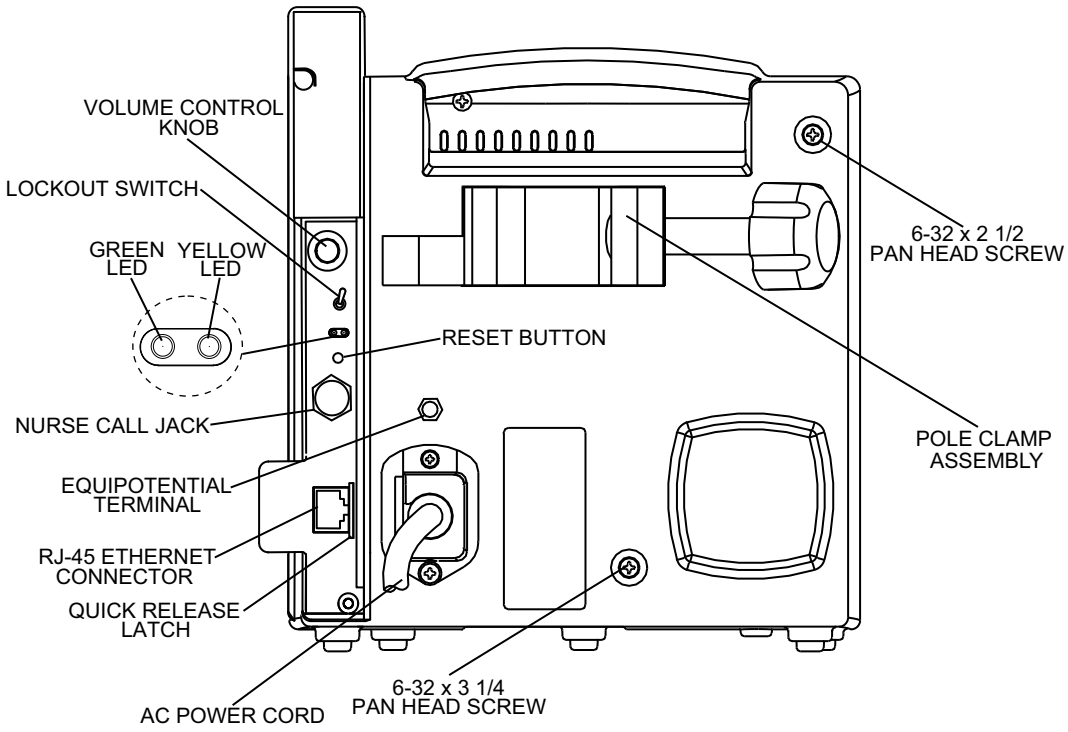

Figure 7-7. Rear View

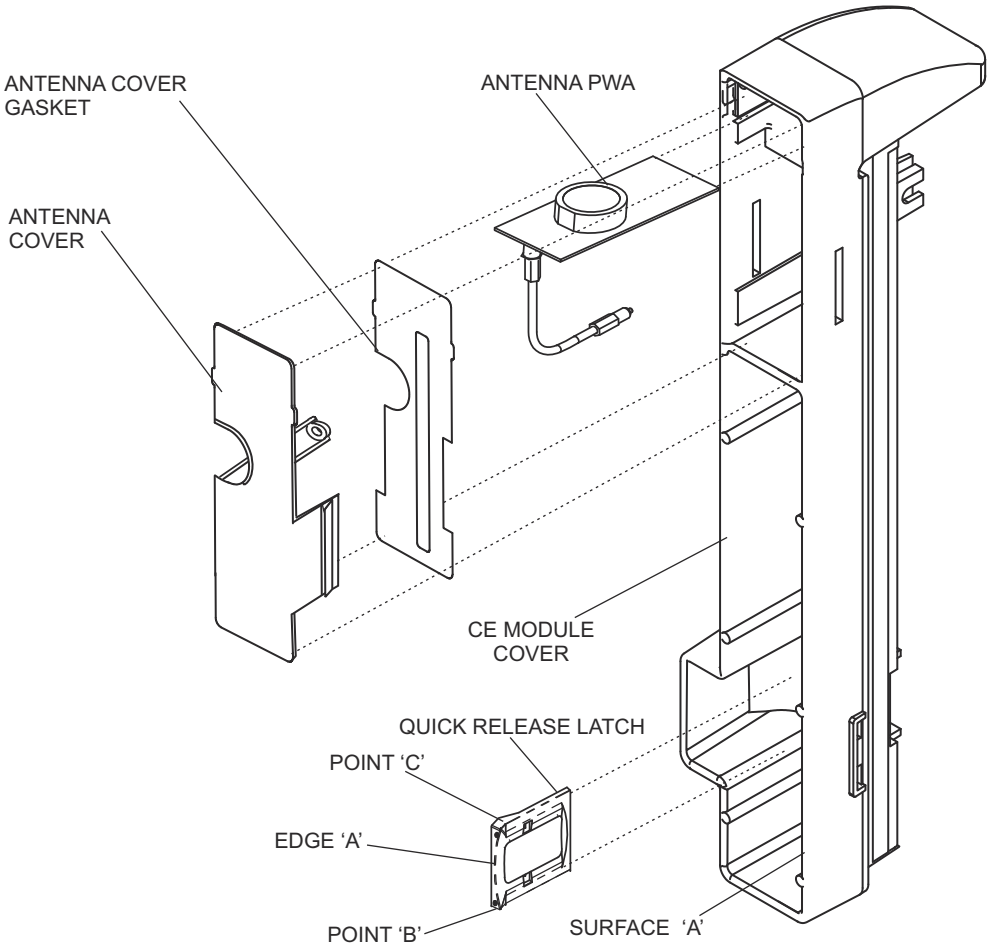

Figure 7-8. Antenna PWA and Ethernet Quick Release Latch Replacement

7.2.7.1

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.

The replacement parts for this procedure are:

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

To replace the volume control knob, see ***Figure 7-6*** and ***Figure 7-7***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Remove the CE module as described in ***Section 7.2.6***.
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, nut cover, and spacer.

   Note: The nylon spacer may not be present in some volume control knob assemblies.
7. Install the replacement volume control knob in the exact reverse order of removal.
8. Replace the CE module in the exact reverse order of removal.
9. Reinstall the battery 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 5.3***.

7.2.7.2

ETHERNET QUICK RELEASE LATCH REPLACEMENT

The recommended tool for this procedure is long needle nose pliers.

Note: The quick release latch may not be present on some versions of the device.

The replacement part for this procedure is:

Latch, Quick Release, Ethernet

To replace the Ethernet quick release latch, see ***Figure 7-8***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Unplug the Ethernet cable from the RJ-45 jack.
4. Carefully set the infuser face down.
5. Remove the CE module as described in ***Section 7.2.6***.
6. Note the position of the quick release latch in relation to the RJ-45 jack.
7. Using the long needle nose pliers, remove the quick release latch from the CE module cover.
8. Install the replacement quick release latch into the CE module cover ***(see Figure 7-8)***.

   Note: The latch should be positioned so edge “A” lays against inside surface “A”, while pushing at point “B” to install the lower snap before pushing at point “C” to install the upper snap.

   Note: Installing either the upper or lower snap first makes no difference as long as both snaps are not installed simultaneously.
9. Replace the CE module in the exact reverse order of removal.
10. Reinstall the battery and connect the infuser to AC power.
11. Plug in the Ethernet cable.
12. Turn on the infuser and perform the connectivity check in ***Section 1.11***.

7.2.7.3

ANTENNA PWA REPLACEMENT

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

The replacement parts for this procedure are:

PWA, Antenna
Cover, Antenna
Gasket, Antenna Cover
Assembly, Cable, Wireless

To replace the antenna PWA, see ***Figure 7-8***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Carefully set the infuser face down.
4. Remove the CE module as described in ***Section 7.2.6***.
5. Remove the antenna cover by pressing in on the tabs through the slots on each side of the CE module cover. Inspect the antenna cover and replace, if required.
6. Inspect the antenna cover gasket and replace, if required.
7. Disconnect the antenna cable from the USB adaptor.
8. Remove the antenna PWA. Install the replacement antenna PWA in the exact reverse order of removal.
9. Connect the antenna cable to the USB adaptor.
10. Install the antenna cover by pressing the tabs into the slots provided on the CE module cover.
11. Replace the CE module in the exact reverse order of removal.
12. Reinstall the battery and connect the infuser to AC power.
13. Turn on the infuser and perform the connectivity check in ***Section 1.11***.

7.2.7.4

CE MODULE COVER REPLACEMENT

Recommended tools for this procedure are a set of nutdrivers, long needle nose pliers, small Allen wrench, and custom nutdriver.

The replacement parts for this procedure are:

Cover, CE Module
Gasket, Cover
Shield, Spring, EMI
Seal, Round
Screw, 4-40 x 3/8, Socket, Button Head
Nut, 4-40, Hex
Nut, Hex, Nurse Call Jack
Washer, Flat, Mica, #4
Washer, Lock, #4

To replace the CE module cover, see ***Figure 7-6*** and ***Figure 7-7***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Carefully set the infuser face down.
4. Remove the CE module as described in ***Section 7.2.6***.
5. Remove the volume control knob as described in ***Section 7.2.7.1***.
6. Using a nutdriver, remove the nut that secures the potentiometer to the CE module cover. Remove the lock washer with needle nose pliers.
7. Using the custom nutdriver, remove the hex nut that secures the nurse call jack to the CE module cover.
8. Remove the Ethernet quick release latch as described in ***Section 7.2.7.2***.
9. Inspect the round seal and replace, if required.
10. Carefully unplug the antenna cable from connector J2 on the peripheral PWA, and remove the antenna PWA as described in ***Section 7.2.7.3***.
11. Using the Allen wrench, remove the screws that secure the peripheral PWA to the CE module cover and EMI shield.
12. Note the position of the two hex nuts installed in the PWA mounting brackets located on the CE module cover. Retain the nuts for reassembly.
13. Inspect the CE module cover gasket and replace, if required.
14. Inspect the EMI shield and replace, if required.
15. Install the replacement CE module cover in the exact reverse order of removal.
16. Install the antenna PWA as described in ***Section 7.2.7.3***. Carefully plug the antenna cable into connector J2 on the peripheral PWA.

17. Install the Ethernet quick release latch as described in ***Section 7.2.7.2***.
18. Install the volume control knob and phone jack nut in the exact reverse order of removal.
19. Install the CE module as described in ***Section 7.2.6***.
20. Reinstall the battery and connect the infuser to AC power.
21. Turn on the infuser and perform the connectivity check in ***Section 1.11***.

7.2.8
SEPARATING THE FRONT ENCLOSURE, REAR ENCLOSURE, AND MAIN CHASSIS

The recommended tools for this procedure are a #2 Phillips screwdriver, medium size flat blade screwdriver, and 3/16 nutdriver.

To separate the front enclosure, rear enclosure, and main chassis, see ***Figure 7-9***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Using the Phillips screwdriver, remove the screws from the CE module, and carefully pull the assembly away from the infuser ***(see Section 7.2.6)***.
4. Remove the AC power cord and retainer, and the equipotential terminal as described in ***Section 7.2.5***.
5. Using the nutdriver, remove the jack screw and lock washer ***(see Figure 7-3)***.
6. Using the Phillips screwdriver, remove the remaining screws from the upper right corner and lower center of the rear enclosure.
7. Carefully place the infuser face down.
8. Using the flat blade screwdriver, press the flex tabs ***(see Figure 7-1)*** while lifting up the rear enclosure, and remove the enclosure.
9. Using the Phillips screwdriver, remove the screws in the infuser handle, and remove the shoe from the front enclosure.

   Note: Older versions of the Plum A+ include a separate shoe that attaches to the front enclosure ***(see Table 9-2)***.
10. Using the flat blade screwdriver, press the flex tabs ***(see Figure 7-1)*** while lifting up the front enclosure, and remove the enclosure.

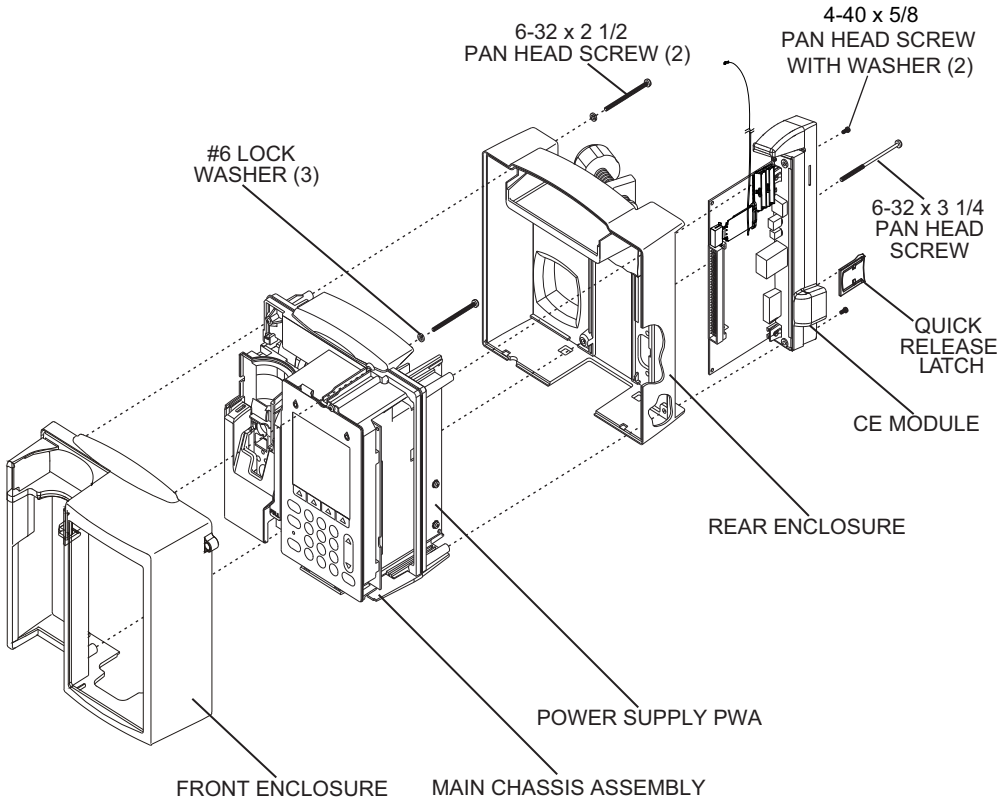

Figure 7-9. Separating the Front Enclosure, Main Chassis, and Rear Enclosure

7.2.9
FRONT ENCLOSURE, REAR ENCLOSURE, OR MAIN CHASSIS REPLACEMENT

The recommended tools for this procedure are a #2 Phillips screwdriver, medium size flat blade screwdriver, 3/16 nutdriver, and an X-acto knife.

The replacement parts for this procedure are:

Enclosure, Front
Enclosure, Rear
Assembly, Main Chassis
Shoe, Front Enclosure
Screw, 6-32 x 1/2, Pan Head, Phillips
Screw, 6-32 x 2 1/2, Pan Head, Phillips
Screw, 6-32 x 3 1/4, Pan Head, Phillips
Washer, Lock, Helical, #6
Gasket, Conductive, 6.5 L
Gasket, Conductive, 1.04 L
Gasket, Conductive, .060 x .150 x 6.5
Gasket, Conductive, .129 x .188 x 1.04
Gasket, Conductive, .129 x .188 x 1.6
Gasket, Conductive, .129 x .188 x 2.7

Note: Older versions of the Plum A+ include a separate shoe that attaches to the front enclosure.

To replace the front enclosure, rear enclosure, or main chassis, see ***Figure 7-9***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. To replace the front enclosure, remove the gaskets described in ***Section 7.2.9.1*** and ***Section 7.2.9.2***.
5. To replace the rear enclosure, remove the specific components described in ***Section 7.2.10***.
6. To replace the main chassis, remove the specific components described in ***Section 7.2.12***.
7. Inspect the conductive gaskets located on the main chassis and replace, if required ***(see Figure 7-10)***.

   Note: Main chassis conductive gaskets may not be present on some versions of the device.

8. Reassemble the front enclosure, rear enclosure, and/or main chassis components.

   Note: Assure that the CPU/driver cable is positioned completely above and to the side of the battery enclosure prior to joining the rear enclosure to the main chassis.

9. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.

10. Reinstall the battery and connect the infuser to AC power.

To verify successful front enclosure, rear enclosure, or main chassis replacement, perform the PVT in ***Section 5.3***.

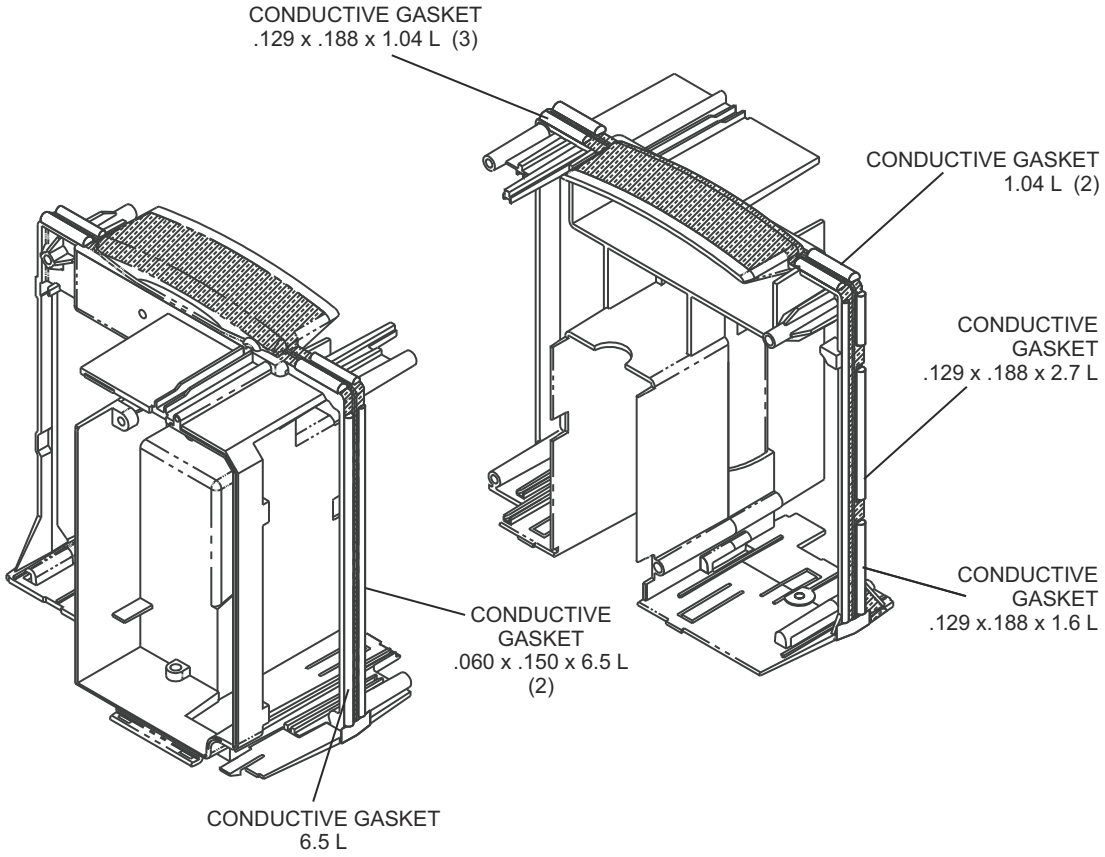

Figure 7-10. Main Chassis Conductive Gaskets

7.2.9.1

SHOE GASKET REPLACEMENT

Note: Shoe gaskets will not be present on newer versions of the device.

The recommended tool for this procedure is needle nose pliers.

The replacement part for this procedure is:

Gasket, Shoe

To replace the shoe gaskets, see ***Figure 7-11***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the shoe gaskets from the front and back of the front enclosure as shown in ***Figure 7-11***.
5. Install the replacement shoe gaskets in the exact reverse order of removal.
6. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
7. Reinstall the battery and connect the infuser to AC power.

To verify successful shoe gasket replacement, perform the PVT in ***Section 5.3***.

7.2.9.2

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 the front/rear enclosure gaskets, see ***Figure 7-11***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Using the needle nose pliers, remove the front/rear gasket from the front enclosure.
5. Install the replacement front/rear gasket in the exact reverse order of removal.
6. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
7. Reinstall the battery and connect the infuser to AC power.

To verify successful front/rear enclosure gasket replacement, perform the PVT in ***Section 5.3***.

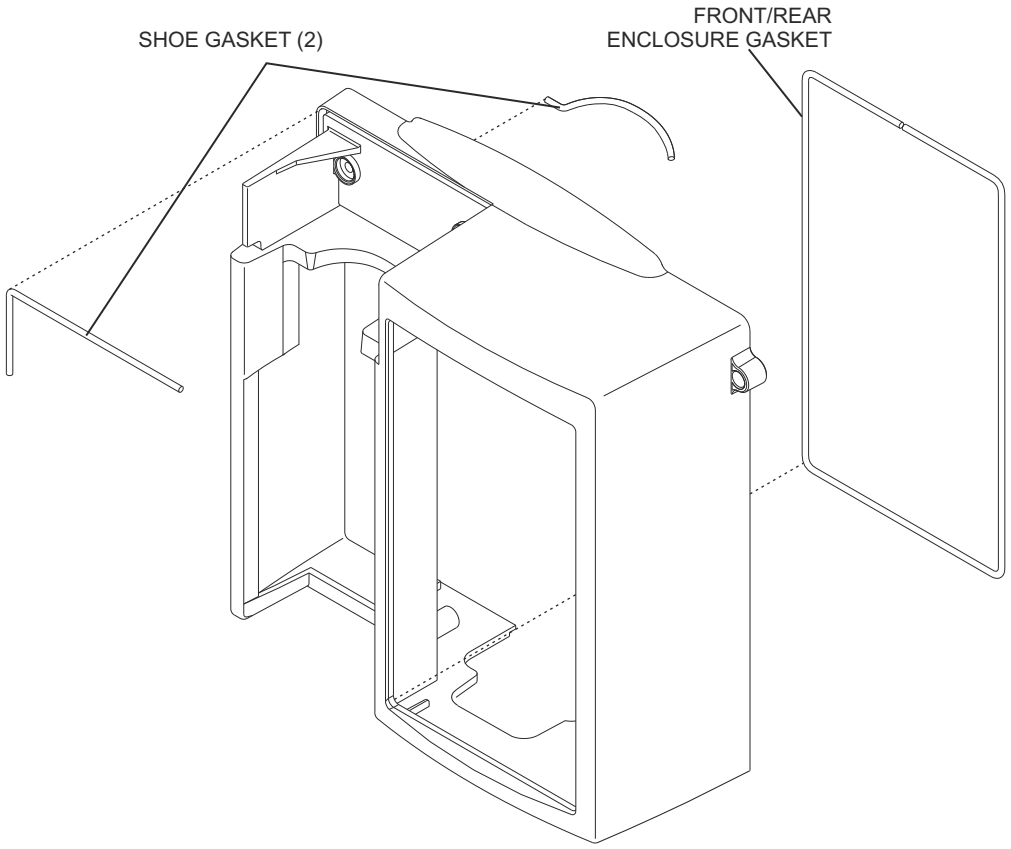

Figure 7-11. Front Enclosure Gaskets

7.2.10
REAR ENCLOSURE COMPONENT REPLACEMENT

Rear enclosure component replacement includes the replacement of the following:

- Pole clamp extrusion, backing plate, and insulator
- Pole clamp shaft/knob assembly and shaft tip
- Rear enclosure and handle gaskets

To replace the rear enclosure components, see ***Figure 7-12***, and proceed as detailed in the following sections.

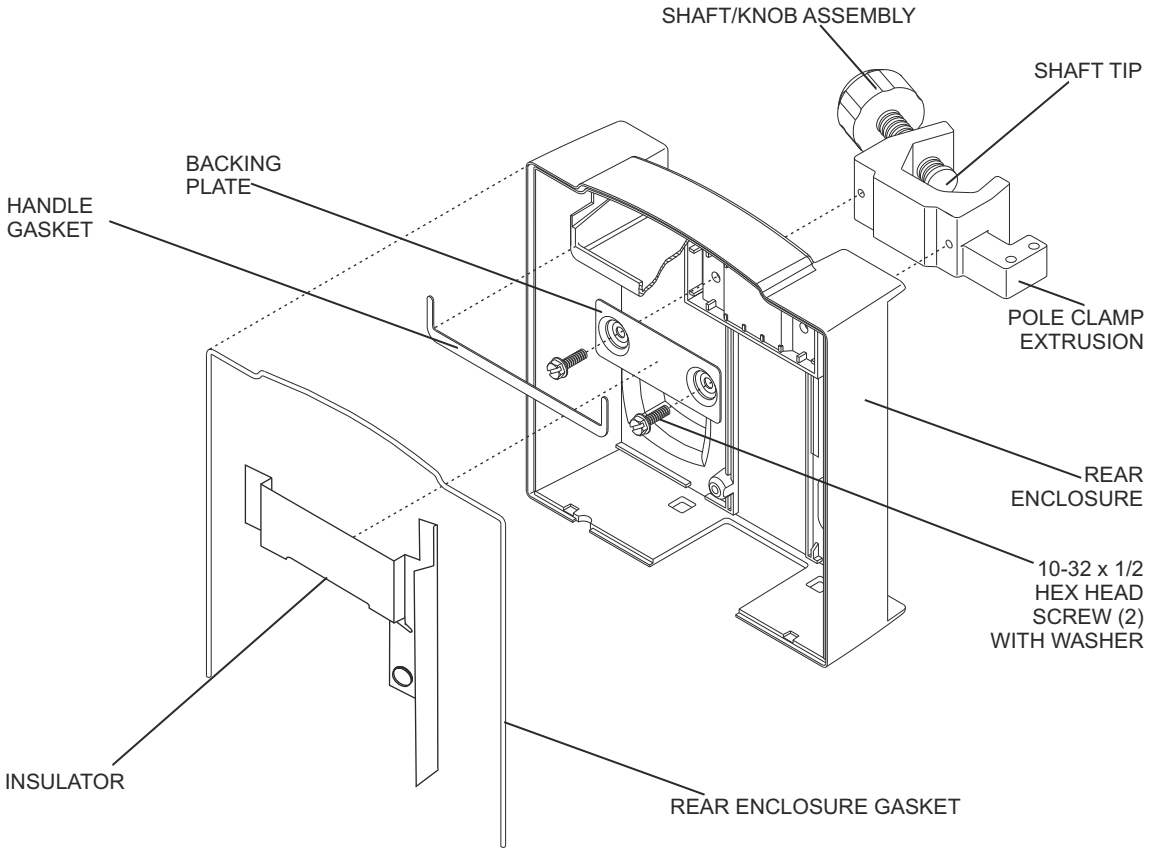

Figure 7-12. Rear Enclosure Components

7.2.10.1

POLE CLAMP EXTRUSION, BACKING PLATE, AND INSULATOR REPLACEMENT

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

The replacement parts for this procedure are:

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

To replace the pole clamp extrusion, backing plate, and insulator, see ***Figure 7-12***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Using the flat blade screwdriver, remove the screws that secure the pole clamp backing plate to the pole clamp extrusion, and remove the backing plate, insulator, and pole clamp from the rear enclosure.
5. Install the replacement backing plate and extrusion, using the screws that were removed in step 4.
6. Install the replacement insulator onto the backing plate.

   ⚠ **CAUTION: Assure that the insulator covers the entire backing plate. If the backing plate is exposed, the power supply PWA may be damaged when power is applied to the infuser.**

7. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
8. Reinstall the battery and connect the infuser to AC power.

To verify successful pole clamp extrusion, backing plate, and insulator replacement, perform the PVT in ***Section 5.3***.

7.2.10.2

POLE CLAMP SHAFT/KNOB ASSEMBLY AND SHAFT TIP REPLACEMENT

The recommended tool for this procedure is wide-head pliers.

The replacement parts for this procedure are:

Assembly, Shaft/Knob, Pole Clamp
Tip, Shaft, Pole Clamp

To replace the pole clamp shaft/knob assembly and the pole clamp shaft tip, see ***Figure 7-12***, and proceed as follows:

1. Turn the pole clamp shaft/knob assembly counterclockwise to remove it from the pole clamp extrusion, and loosen the pole clamp shaft tip from the shaft/knob assembly.

   Note: The pole clamp shaft tip has a long shaft that is pressed into the threaded pole clamp shaft/knob assembly.

2. Turn the pole clamp shaft/knob assembly back into the pole clamp extrusion. Using the wide-head pliers, remove and inspect the pole clamp shaft tip and replace the tip, if required.

3. Install the replacement pole clamp shaft/knob assembly into the pole clamp extrusion by turning the shaft/knob assembly clockwise into the extrusion until the threaded portion is visible.

4. Press the pole clamp shaft tip into the screw hole recess on the shaft/knob assembly and turn the shaft/knob assembly clockwise until the shaft tip is secure against the pole clamp extrusion.

Replacement of the pole clamp shaft/knob assembly and the pole clamp shaft tip 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 5.3***.

7.2.10.3
REAR ENCLOSURE AND HANDLE GASKETS REPLACEMENT

There are no recommended tools for this procedure.

The replacement parts for this procedure are:

Gasket, Rear Enclosure
Gasket, Handle

To replace the rear enclosure and handle gaskets, see ***Figure 7-12***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the rear enclosure gasket and handle gaskets from the rear enclosure.
5. Install the replacement gaskets in the exact reverse order of removal.
6. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
7. Reinstall the battery and connect the infuser to AC power.

To verify successful rear enclosure and handle gaskets replacement, perform the PVT in ***Section 5.3***.

7.2.11
MINIPOLE ASSEMBLY REPLACEMENT

The minipole assembly is an accessory (List Number 12096-04-01) that attaches to the infuser through two holes in the pole clamp extrusion and is held in place by a hairpin clip. The clip 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.

The replacement parts for this procedure are:

Assembly, Minipole
Clip, Hairpin

To replace the minipole assembly, see ***Figure 7-13***, and 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 hairpin clip with thumb and finger, and remove the clip 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 5.3***.

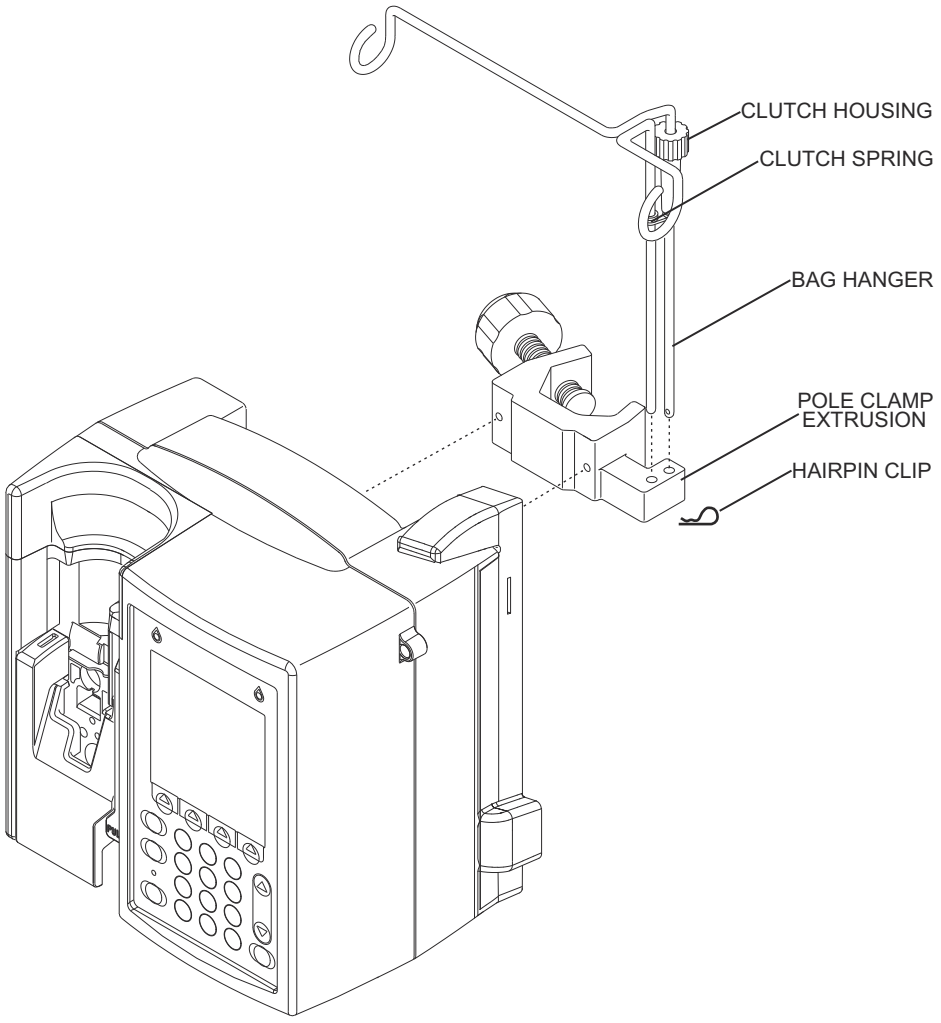

Figure 7-13. Minipole Assembly

7.2.12
MAIN CHASSIS ASSEMBLY COMPONENT REPLACEMENT

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

- Power supply PWA
- Keypad
- Display assembly
- CPU PWA
- Piezo alarm assembly
- Mechanism assembly
- Cassette door
- Fluid shield
- Opener handle assembly

To replace the main chassis assembly components, see ***Figure 7-14***, and proceed as detailed in the following sections.

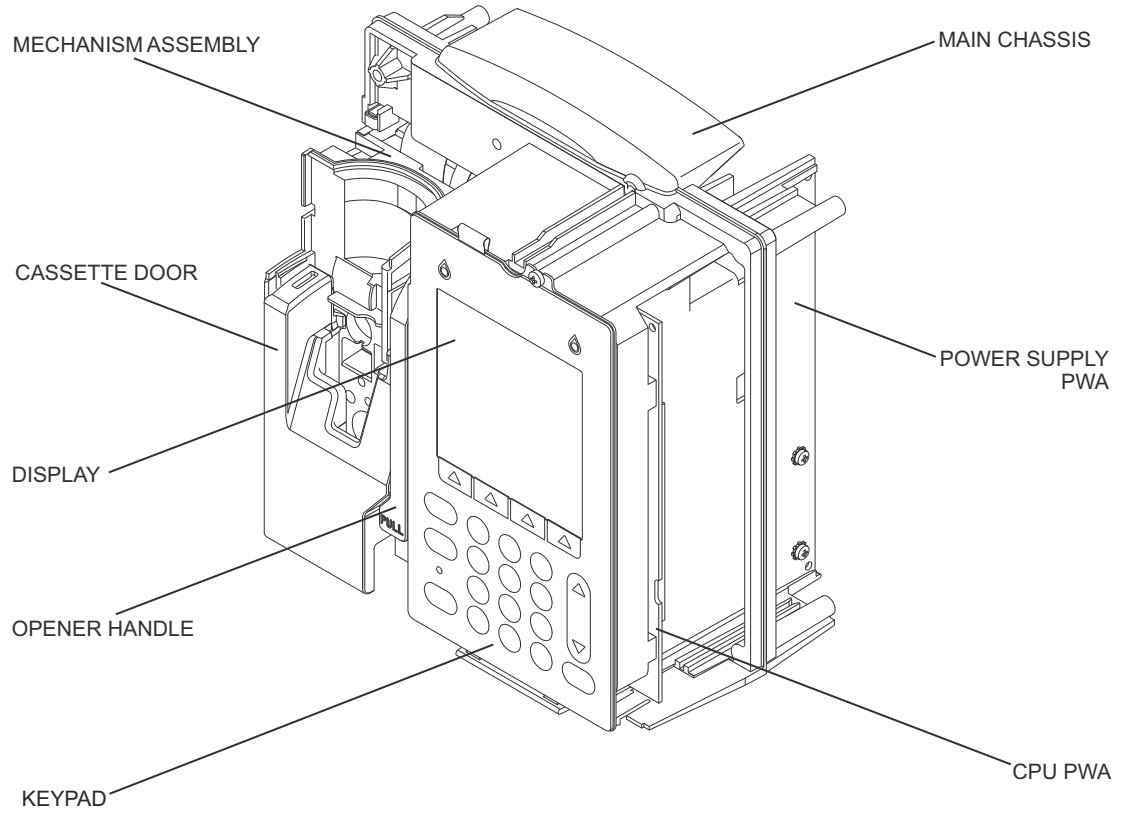

Figure 7-14. Main Chassis Assembly Components

7.2.12.1

POWER SUPPLY PWA REPLACEMENT

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

The replacement parts for this procedure are:

PWA, Power Supply
Assembly, Cable, Power Supply/Battery
Assembly, Cable, Motor Power
Wrap, Spiral

To replace the power supply PWA, proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Note the location and position of the cables, then disconnect the cables from the power supply PWA.
5. Remove the power supply PWA by sliding the board away from the CPU PWA.
6. Replace or install the spiral wrap around the motor power cable.

   Note: Position the spiral wrap so the top partially covers the bottom of the label on the motor power cable.

7. Install the replacement power supply PWA in the exact reverse order of removal.

   Note: Verify the replacement power supply PWA connects to the CPU PWA correctly to avoid misalignment.

8. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
9. Reinstall the battery and connect the infuser to AC power.

To verify successful power supply PWA replacement, perform the PVT in ***Section 5.3***.

7.2.12.2

KEYPAD AND GROUND GASKET REPLACEMENT

Note: Devices with shielded cases require the keypad ground gasket. Devices without shielded cases do not require the keypad ground gasket.

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

The replacement parts for this procedure are:

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

To replace the keypad and gasket, see ***Figure 7-15***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
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 main chassis.
6. Using the Phillips screwdriver, remove the screw that secures the keypad and display assembly to the main chassis ***(see Figure 7-14)***.
7. Lift the locking pins to release the fluid shield/driver flex connector, and disconnect the flex connector from the driver PWA.
8. Carefully disconnect the flex ribbon cable assembly from the display assembly by pushing the connector locking tabs down.
9. Using the flat blade screwdriver, separate the keypad, gasket, and display assembly by removing the screws and spacers that secure the keypad to the display.
10. Inspect the keypad ground gasket and replace, if required.
11. Install the replacement keypad in the exact reverse order of removal.
12. Install the keypad and display assembly in the exact reverse order of removal.
13. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
14. Reinstall the battery and connect the infuser to AC power.

To verify successful keypad and ground gasket replacement, perform the PVT in ***Section 5.3***.

7.2.12.3

DISPLAY ASSEMBLY REPLACEMENT

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

The replacement parts for this procedure are:

Assembly, Display

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

To replace the display assembly, see ***Figure 7-15***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the keypad and gasket as described in ***Section 7.2.12.2***, then remove the display assembly.
5. Install the replacement display assembly in the exact reverse order of removal.
6. Install the keypad and gasket in the exact reverse order of removal.
7. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
8. Reinstall the battery and connect the infuser to AC power.

To verify successful display assembly replacement, perform the PVT in ***Section 5.3***.

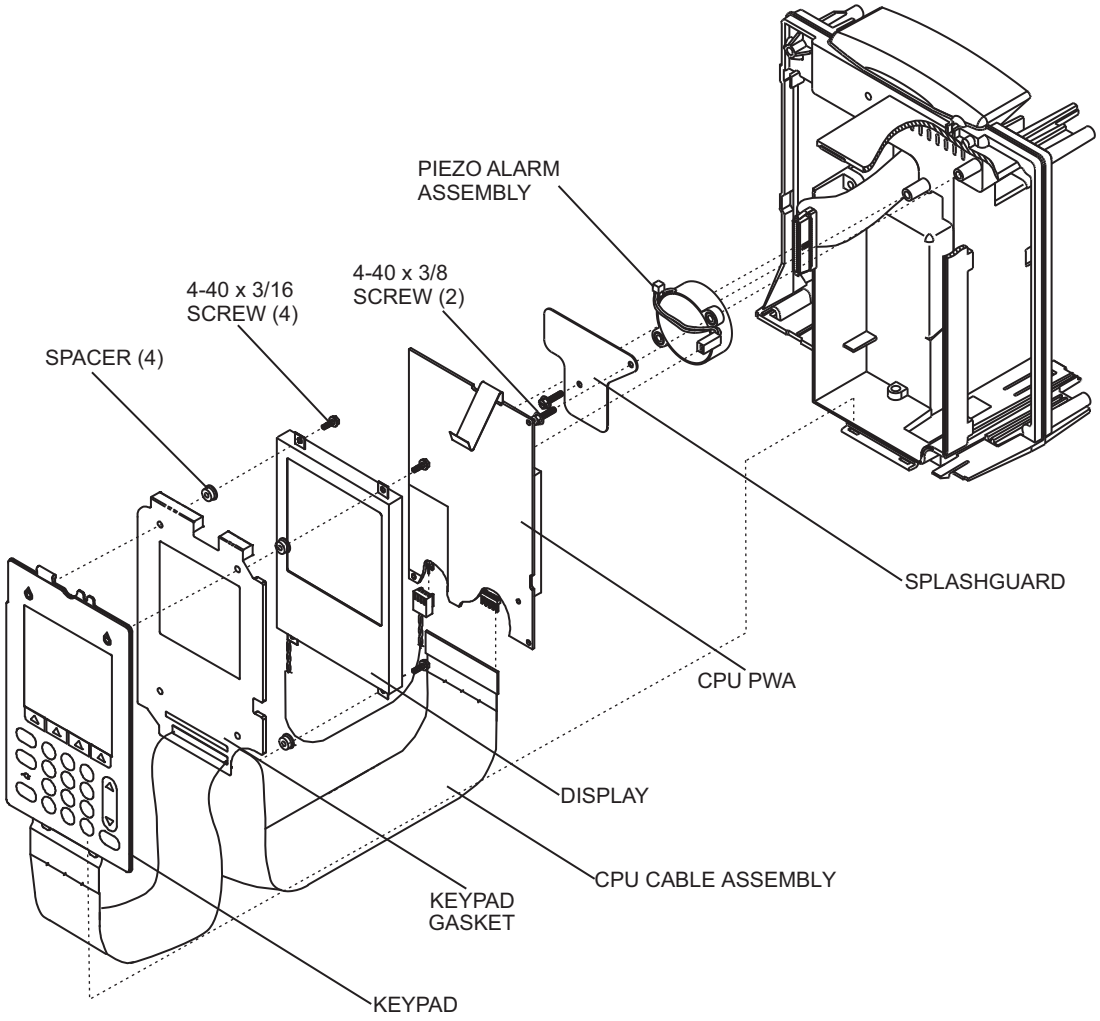

Figure 7-15. Keypad, Display, CPU PWA, and Piezo Alarm

7.2.12.4

CPU PWA REPLACEMENT

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

The replacement parts for this procedure are:

PWA, CPU
Insulator, CPU
Assembly, Cable, CPU/Driver
Screw, 4-40 x 1/4, Hex Head, Slotted, with Washer

To replace the CPU PWA, proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the power supply PWA as described in ***Section 7.2.12.1***.
5. Remove the keypad and display assembly as described in ***Section 7.2.12.2*** and ***Section 7.2.12.3***.
6. Using the flat-blade screwdriver, remove the screws that secure the CPU PWA.
7. Using the flat blade screwdriver, remove the insulator (splash shield) to the main chassis. Inspect the insulator (splash shield) and replace, if required.
8. Remove the mechanism, and inspect the CPU/Drive cable assembly, and replace, if required.
9. Route the CPU/Driver cable through the opening of the main chassis ***(see Figure 7-16*** and ***Figure 7-17)***.

   Note: Verify that the cable is free of damage on the insulation and that none of the wires are exposed.

   Note: The cable's black or red edge (pin 1) should be pointed up.

Figure 7-16.
Front and Rear View of CPU/Driver Cable Routed Through Main Chassis

10. Install the insulator (splash shield).

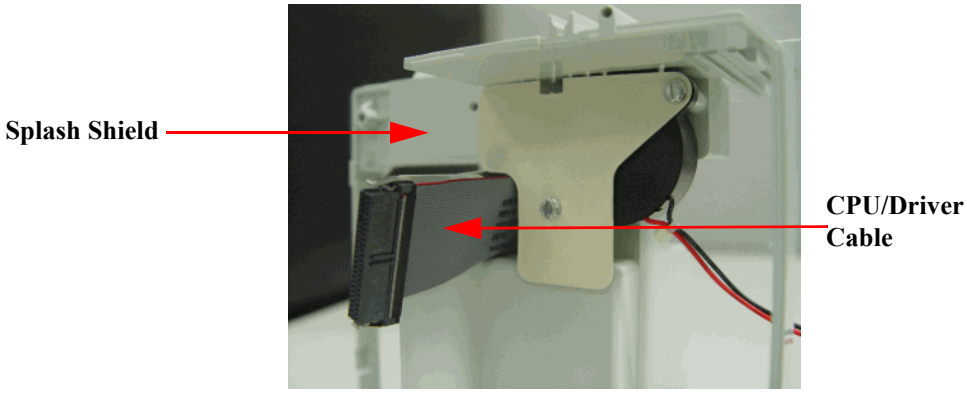

Figure 7-17. CPU/Drive Cable Routed Through Main Chassis

11. Connect the CPU/Driver cable to its matching connector on the CPU PWA. Ensure the female connector on the CPU/Driver cable mates completely to the male connector on the CPU PWA board ***(see Figure 7-18*** and ***Figure 7-19)***.

Note: Verify that the locking pins on the female cable connector are not damaged or bent.

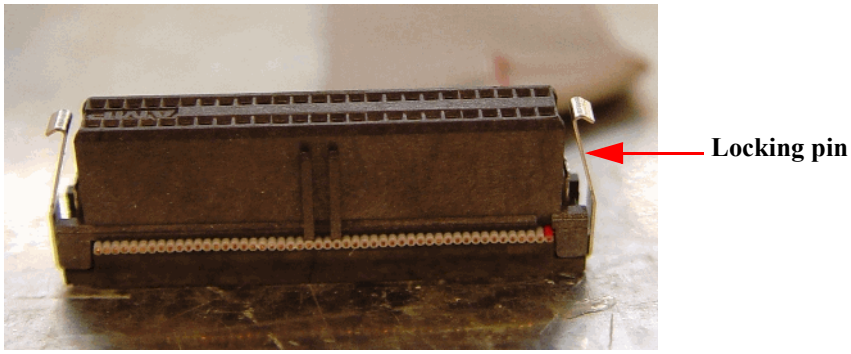

Figure 7-18. Female Cable Connector on the CPU/Driver Cable

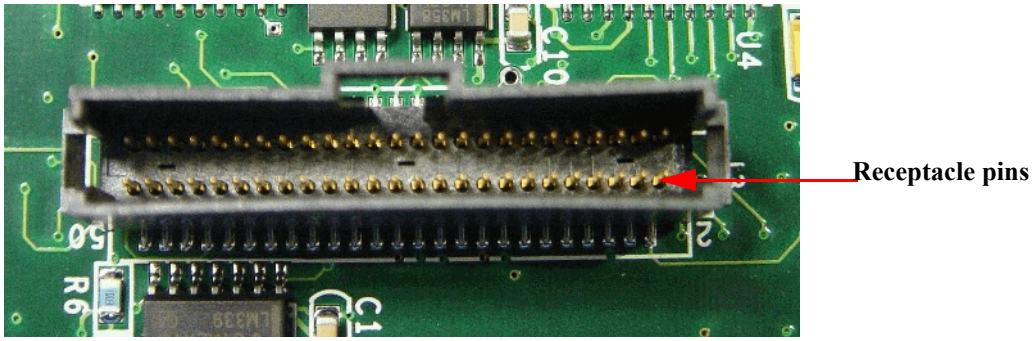

Figure 7-19. Male Receptacle Header Socket on the CPU PWA Board

Note: Verify that the pins inside the male receptacle socket housing on the CPU PWA are not damaged or bent.

12. After the female connector on the CPU/Driver cable is plugged into the male connector on the CPU PWA, verify that the connector is properly seated and the female connector is completely locked to the male receptacle socket housing (***see Figure 7-20*** and ***Figure 7-21***).

Note: There can be no gap between the male and female connectors.

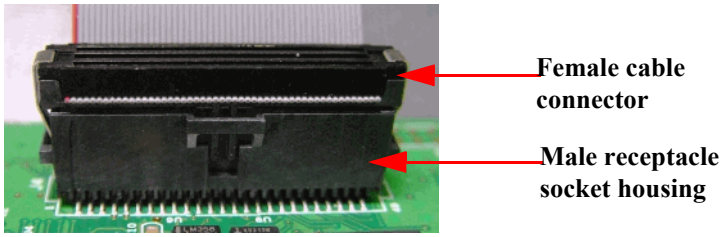

Figure 7-20.
Female Cable Connector on the CPU/Driver Cable Connected to the Male Receptacle Header Socket on the CPU PWA

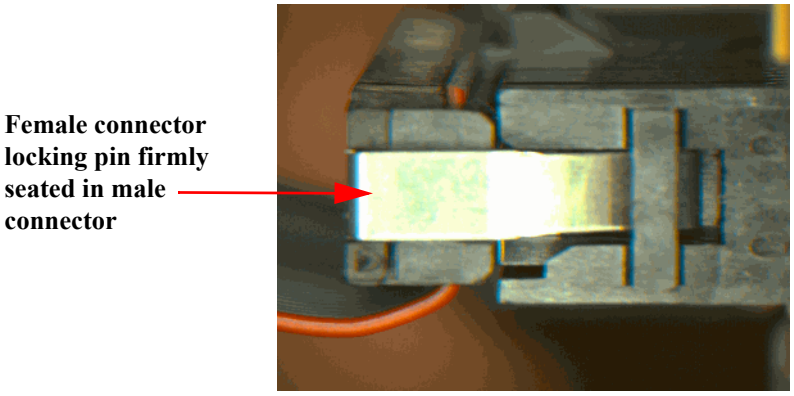

Figure 7-21.
Side View of the CPU/Driver Cable Female Connector Firmly Seated and Locked to the CPU PWA Male Connector

13. Install the replacement CPU board.
14. Reinstall the display assembly.
15. With the infusion mechanism in front of the chassis ***(see Figure 7-22)***, connect the other end of the CPU/Driver cable to the J11 cable connector on the infusion mechanism PWA (***see Figure 7-23*** and ***Figure 7-24***).

Figure 7-22. Infusion Mechanism in Front of Chassis

Note: Verify the male receptacle is not damaged and the pins are not bent.

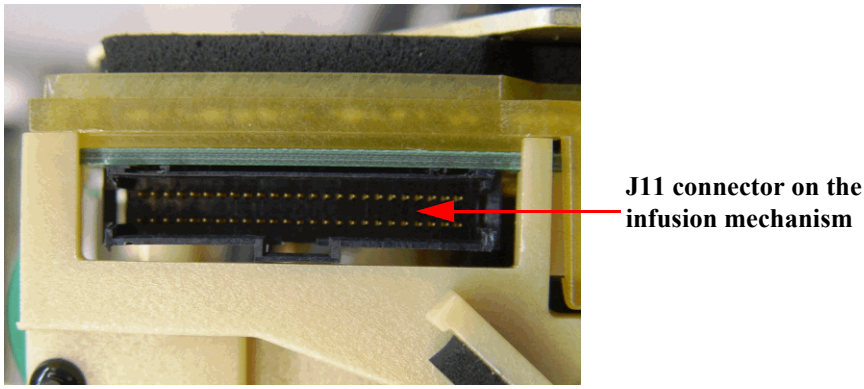

Figure 7-23. J11 Connector on the Infusion Mechanism Driver PWA

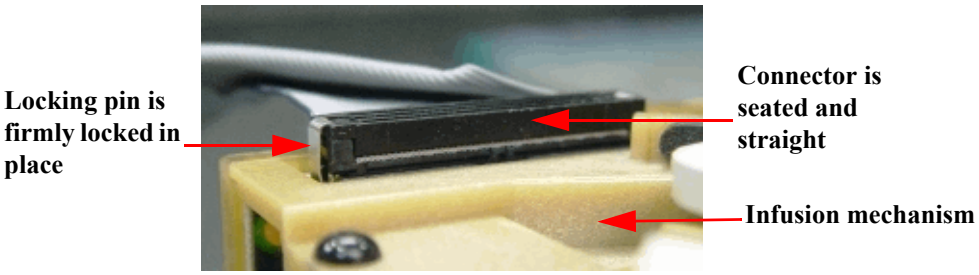

Figure 7-24. CPU/Driver Cable Connected to the Infusion Mechanism Driver PWA

16. Slide the infusion mechanism onto the main chassis rails and into the main chassis (*see Figure 7-22*).

17. Route the battery power cable in the cutout of the battery box *(see Figure 7-25)*.

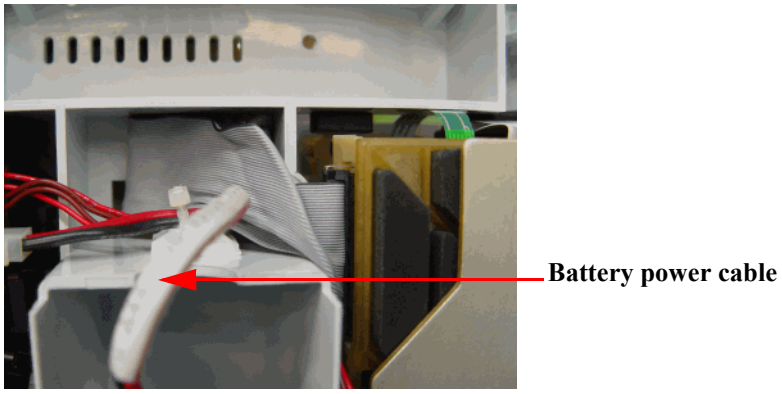

Figure 7-25. Battery Power Cable Routed Toward Infusion Mechanism

18. Route the CPU/Driver cable and motor power cable over the top of the battery box and stow the excess ribbon cable in the recess above the battery box *(see Figure 7-26)*.

> **Note:** Keep the cables away from the back end of the battery box.

19. Tuck the motor power cable underneath the CPU/Driver cable. Position the spiral wrap so that the top partially covers the bottom of the label on the motor power cable.

20. Replace the tie wrap around the power cable and battery cable.

21. Route the motor power cable with spiral wrap down the side of the infusion mechanism.

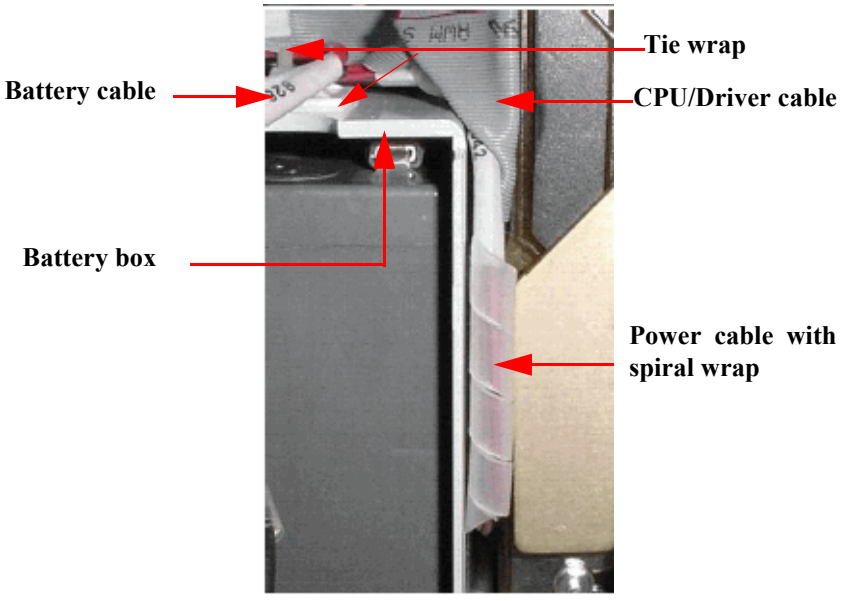

Figure 7-26. Power Cable, Battery Cable, and Spiral Wrap

22. Connect the Piezo alarm cable.
23. Reinstall the power supply and display in the exact reverse order.
24. Install the front and rear enclosures.
25. Install the peripheral board.
26. Reinstall the battery and connect the infuser to AC power.
27. Perform the PVT in ***Section 5.3*** to verify successful CPU PWA replacement.

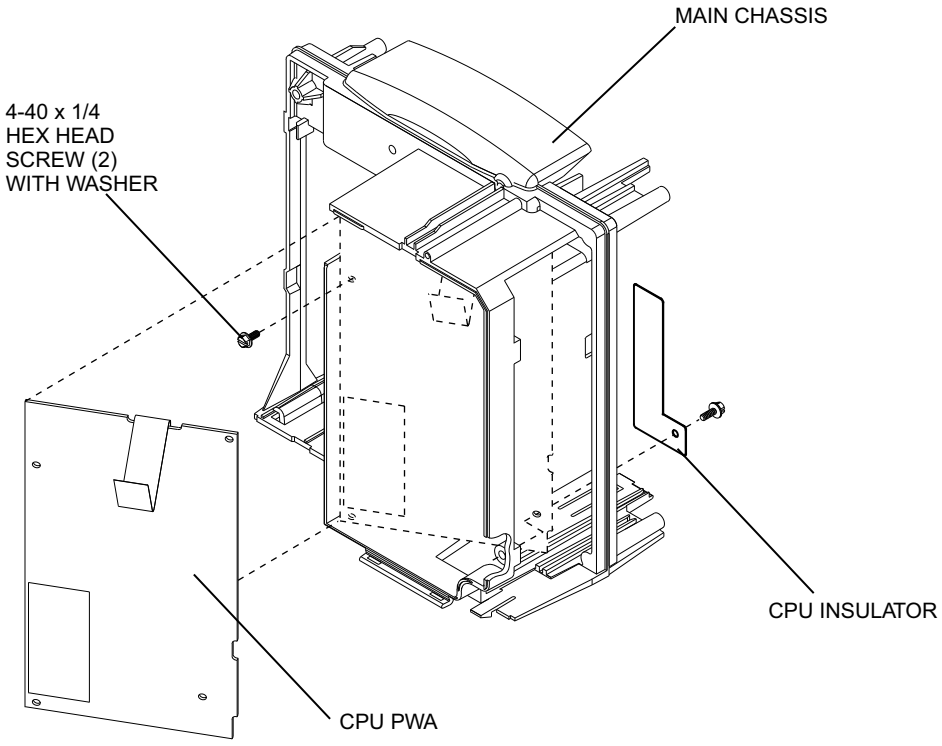

Figure 7-27. CPU PWA Replacement

7.2.12.5

PIEZO ALARM ASSEMBLY REPLACEMENT

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

The replacement parts for this procedure are:

Assembly, Piezo Alarm
Splashguard
Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer

To replace the piezo alarm assembly, see ***Figure 7-15***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the power supply PWA as described in ***Section 7.2.12.1***.
5. Remove the CPU PWA as described in ***Section 7.2.12.4***.
6. Using the flat blade screwdriver, remove the screws that secure the splashguard and piezo alarm to the main chassis.

   Note: Note the alignment of the piezo alarm assembly connecting wires, and verify the replacement assembly is aligned the same way.
7. Install the replacement piezo alarm assembly in the exact reverse order of removal.
8. Reassemble the keypad, display assembly, CPU PWA, and power supply PWA.
9. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
10. Reinstall the battery and connect the infuser to AC power.

To verify successful piezo alarm assembly replacement, perform the PVT in ***Section 5.3***.

7.2.12.6
MECHANISM ASSEMBLY REPLACEMENT

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

The recommended tools for this procedure are a medium size flat blade screwdriver, No. 2 Phillips screwdriver, and diagonal cutters.

The replacement parts for this procedure are:

Assembly, Mechanism
Bumper, Mechanism Chassis
Tie, Cable
Screw, 4-24 x 1/4, Pan Head, Phillips
Screw, 6-32 x 3/8, Hex Head, Slotted, with Washer

To replace the mechanism assembly, see ***Figure 7-28***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Using diagonal cutters, cut the cable ties that secure the cables.
5. Using the flat blade screwdriver, remove the screw that secures the mechanism assembly to the main chassis.
6. Remove and inspect the mechanism chassis bumpers and replace, if required.
7. Slide the mechanism assembly away from the main chassis.
8. Unlock and disconnect the cables from the mechanism assembly, and remove the mechanism assembly.
9. Install the replacement mechanism assembly in the exact reverse order of removal, and replace the cable ties.
10. Join the front enclosure, rear enclosure, and main chassis in the exact reverse order of separation.
11. Reinstall the battery and connect the infuser to AC power.

7.2.12.6.1
Enter the Serial Number

After the mechanism assembly has been replaced, the device serial number must be entered.

To enter the serial number:

1. Press the ON/OFF key to turn on the device and view the setup screen and prompt for the device serial number.
2. In the SETUP screen, enter the serial number of the infuser. The serial number is found on the Product Identification Label (***see Figure 5-1***).

   Press [ENTER].

3. Turn off the device. After the device is completely turned off, turn it back on.
4. Go to the BIOMED SETTINGS screen and verify that the correct serial number has been entered.

To verify successful mechanism assembly replacement, perform the PVT in ***Section 5.3***.

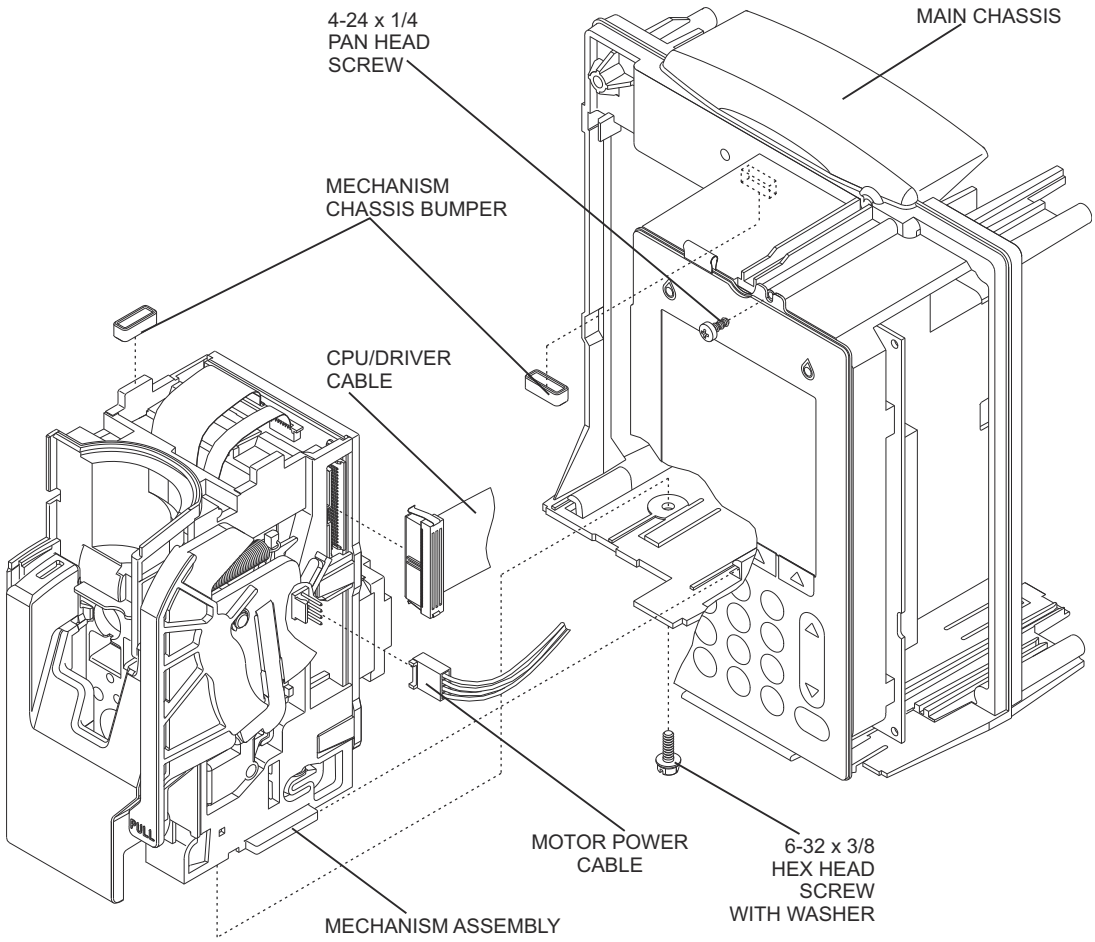

Figure 7-28. Mechanism Assembly Replacement

7.2.12.7
MECHANISM CHASSIS GASKET TAPE INSTALLATION

Note: Installation of gasket tape to cover the opening on the mechanism chassis helps protect the Switch PWA from being exposed to fluid ingress.

The required tool for this procedure is the Hospira alignment fixture (P/N 519-97225-001).

The replacement part for this procedure is:

Tape, Gasket

To install the gasket tape on the mechanism chassis, see ***Figure 7-29***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Remove the mechanism assembly as described in ***Section 7.2.12.6***.
4. Clean and dry the location on the mechanism chassis surface where the gasket tape will be installed.
5. Place the alignment fixture on the mechanism chassis.
6. Remove the small liner from the gasket tape.
7. Hold the alignment fixture in place and align the two edges of the gasket tape against the fixture, then partially attach the gasket tape to the chassis.
8. Remove the fixture from the chassis, remove the large liner from the gasket tape, and attach the gasket tape. Ensure the gasket tape is secure and that it does not protrude beyond the chassis.
9. Reinstall the mechanism.

To verify successful mechanism chassis gasket tape installation, perform the PVT in ***Section 5.3***.

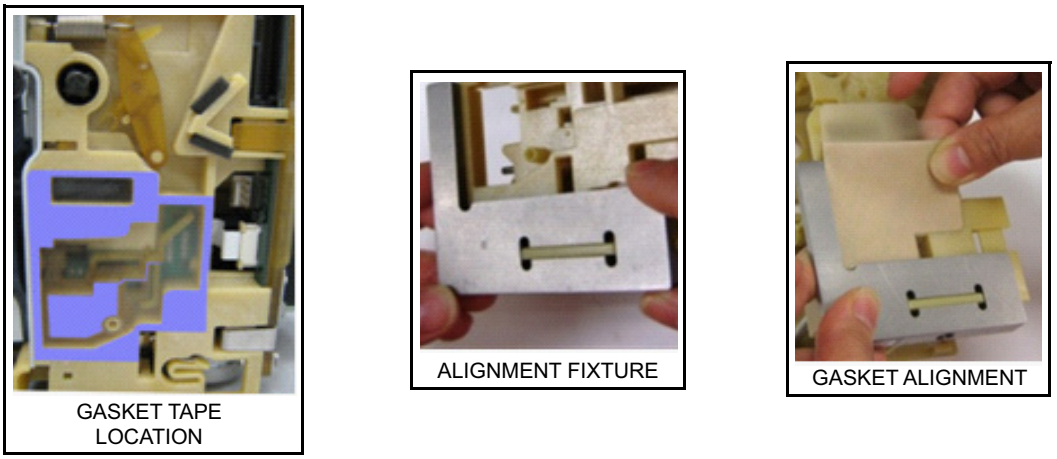

Figure 7-29. Installing the Mechanism Chassis Gasket Tape

7.2.12.8

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 tools for this procedure are a medium size flat-blade screwdriver and long needle nose pliers.

Replacement parts for this procedure are:

Assembly, Cassette Door
Assembly, Fluid Shield
Cap, Door Pivot
Gasket, .72 in.
Gasket, 1.09 in.
Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer

To replace a cassette door (if required) and fluid shield, see ***Figure 7-33*** and ***Figure 7-34***, and 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 7.2.8***.
4. Remove the mechanism assembly as described in ***Section 7.2.12.6***.
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 7-33)***.
10. Inspect and replace the fluid shield gaskets, if required.

    Note: If gasket tape is not present, it must be installed before replacing the fluid shield ***(see Figure 7-29)***.

    Note: Fluid shield gaskets may not be present in older versions of the Plum A+.

11. If the feeler gauge test fails during the preventive maintenance inspection ***(see Section 5.2.5)***, clean and reinstall the fluid shield, and retest with the feeler gauge. Replace the fluid shield if the retest fails.

12. 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***.

13. Inspect the fluid shield tab and ensure that it is not bent or damaged ***(see Figure 7-30)***. If the fluid shield tab is bent or damaged, 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.

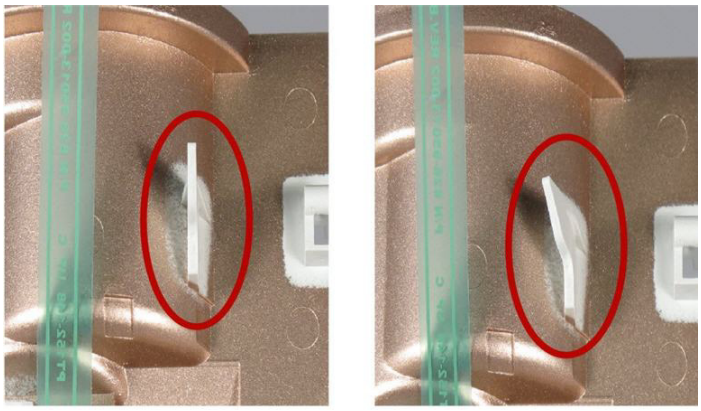

Figure 7-30. Fluid Shield Tab

14. 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 installing or replacing the fluid shield. Ensure that the fluid shield is properly aligned with the mechanism assembly pins.

15. Ensure that the fluid shield tab is aligned during installation of the fluid shield assembly. ***Figure 7-31*** 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 7-31. Normal Fluid Shield Tab Before and After Assembly is Seated

16. Once the fluid shield assembly is installed, the aligned fluid shield tab is visible from the open corner of the mechanism assembly ***(see Figure 7-32)***. Continue replacement of the cassette door.

17. 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 7-32)***, then the fluid shield tab may be bent or damaged and the regulator closer may be unseated.

    CAUTION: This inspection of the fluid shield tab is an indirect method to verify that the regulator closer has not become unseated during installation of the fluid shield assembly. The only way to fully verify that the regulator closer is seated correctly is by direct visual inspection of the regulator closer (*see Section 6.4.1*).

    Remove the fluid shield assembly and inspect the fluid shield tab. Inspect the regulator closer (***see Section 6.4.1***) to ensure that it is seated properly. 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***.

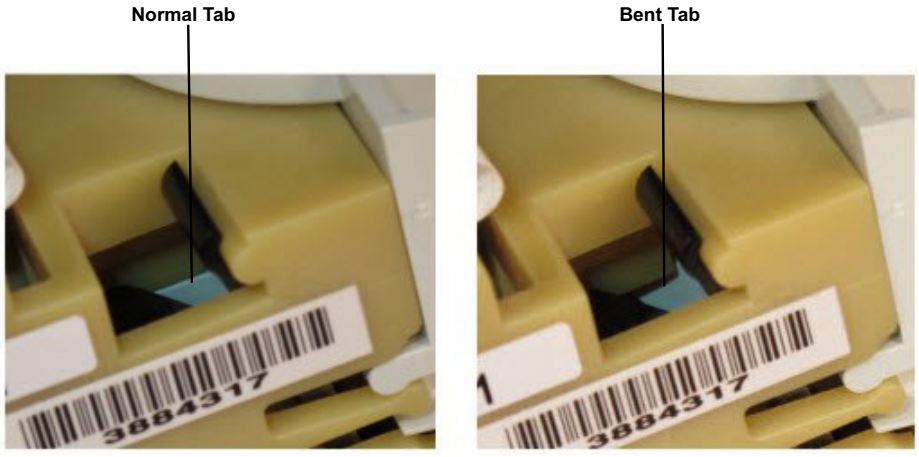

Figure 7-32. Close-up Views of Normal (left) and Bent (right) Fluid Shield Tab

18. Install the replacement cassette door in the exact reverse order of removal.

19. Replace the mechanism assembly in the exact reverse order of removal.

20. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
21. Reinstall the batteries and connect the infuser to AC power.

To verify correct cassette door and fluid shield replacement, perform the PVT in ***Section 5.3***

CAUTION: The Unrestricted Flow Test in *Section 5.3.5* of the PVT is not a direct method to verify correct seating of the regulator closer. A pump with an unseated regulator closer may pass the Unrestricted Flow Test.

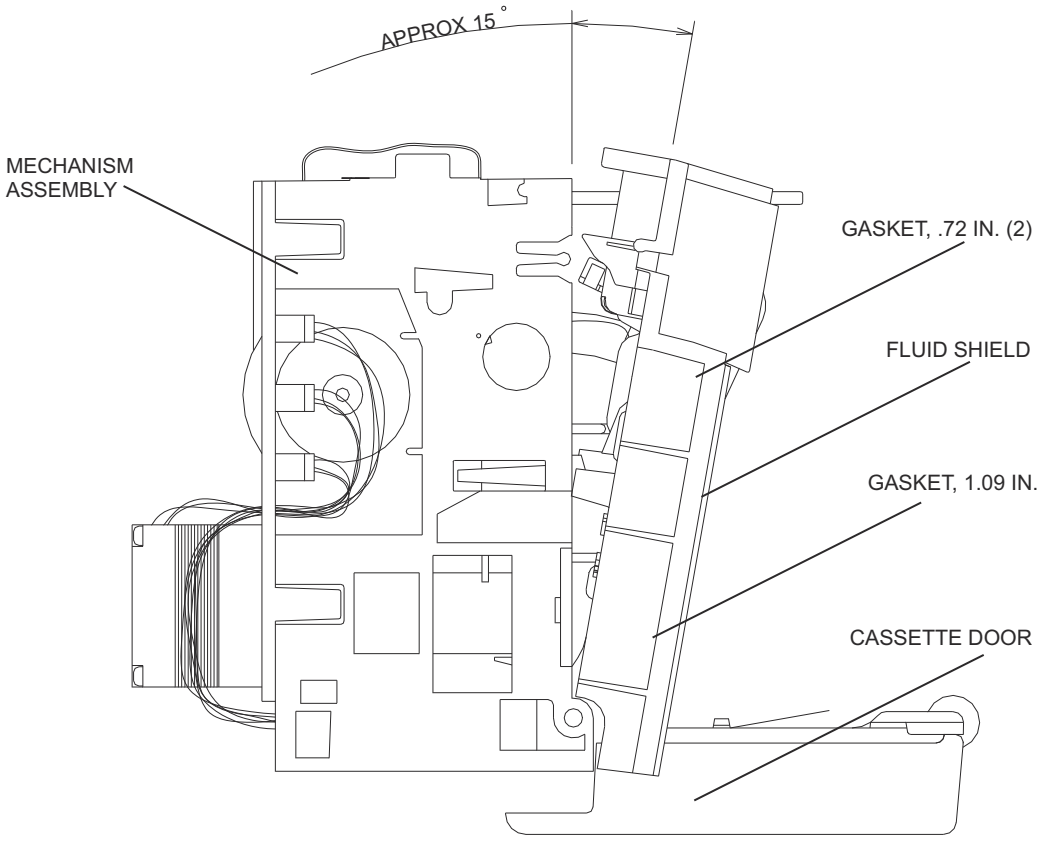

Figure 7-33. Fluid Shield Replacement

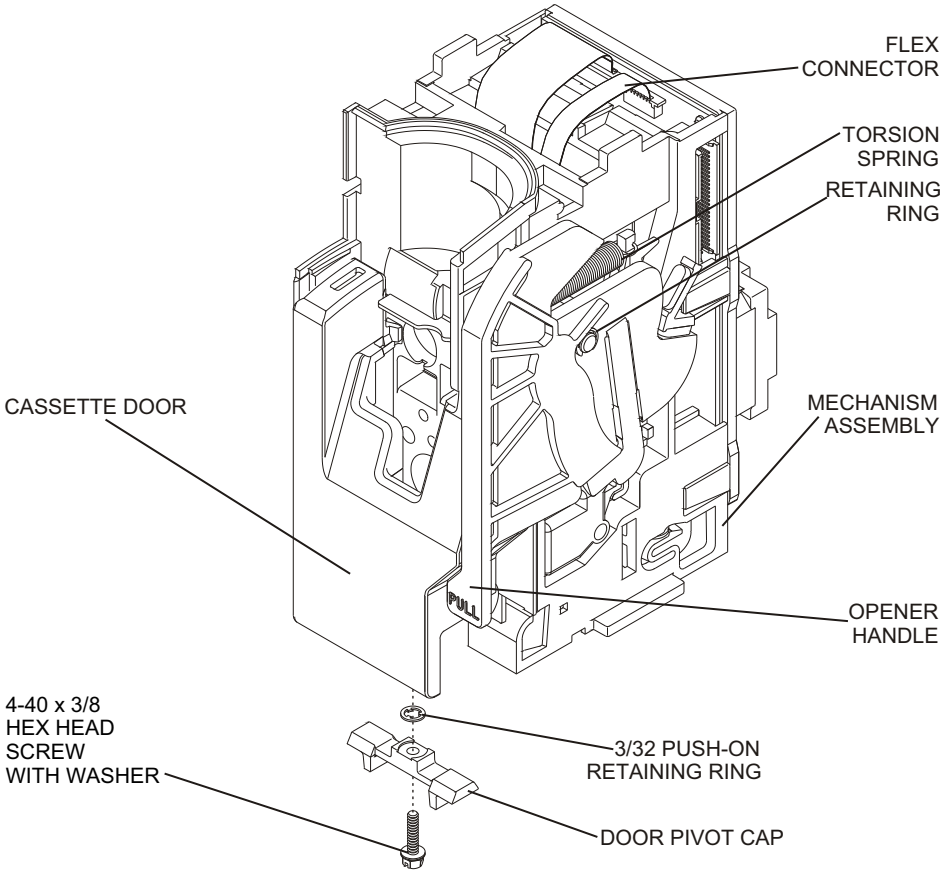

Figure 7-34. Cassette Door and Opener Handle Replacement

7.2.12.9

OPENER HANDLE ASSEMBLY REPLACEMENT

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

The replacement parts for this procedure are:

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

To replace the opener handle assembly, see ***Figure 7-34***, and proceed as follows:

1. Turn off the infuser and disconnect the device from AC power.
2. Remove the battery as described in ***Section 7.2.4***.
3. Separate the front enclosure, rear enclosure, and main chassis as described in ***Section 7.2.8***.
4. Remove the mechanism assembly as described in ***Section 7.2.12.6***.
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, and 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 in the exact reverse order of separation.
13. Reinstall the battery and connect the infuser to AC power.

To verify successful opener handle assembly replacement, perform the PVT in ***Section 5.3***.

Section 8

SPECIFICATIONS

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

PHYSICAL	
Dimensions:	Approximately 8 H x 8 W x 6 D inches (excluding pole clamp and power cord storage)
Weight:	Approximately 9.5 lbs (with battery)
Casing:	High-impact plastic
Expected Service Life*:	10 years
ELECTRICAL	
Power Requirements:	120 V_{AC}; 50-60 Hz; 35 W
Power Cord:	Hospital-grade AC cord; 10 feet; with transparent plug and retainer plate
Fuses:	0.5 A, 250 V_{AC}
Battery:	Sealed lead acid; 6 V; internal; rechargeable
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
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)

* *For only Plum A+ infusion systems manufactured after August 1, 2013*

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 three 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 9-10*** show the Illustrated Parts Breakdown (IPB) and assembly drawings. ***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.

Note: PWA schematic drawings are available from Hospira upon request.

Table 9-1. Drawings

Figure Number	Title
9-1	Illustrated Parts Breakdown (2 Sheets)
9-2	Front Enclosure, Rear Enclosure, Main Chassis, and CE Module
9-3	Front Enclosure Assembly
9-4	Rear Enclosure Assembly
9-5	CE Module
9-6	Main Chassis Assembly (2 Sheets)
9-7	AC Power Cord Assembly and Battery Assembly
9-8	Antenna PWA and Ethernet Quick Release Latch
9-9	CPU PWA and Main Chassis
9-10	Mechanism Assembly

Table 9-2. IPB for the Infuser		
Index Number	**Nomenclature**	**Replacement Procedure**
1	Enclosure, Front	***Section 7.2.9***
2	Chassis, Main	***Section 7.2.9***
3	Enclosure, Rear	***Section 7.2.9***
4	Battery	***Section 7.2.4***
5	Assembly, Wire Harness, Battery	***Section 7.2.4***
6	PWA, Power Supply	***Section 7.2.12.1***
7	PWA, CPU	***Section 7.2.12.4***
8	Keypad	***Section 7.2.12.2***
9	Gasket, Keypad Ground	***Section 7.2.12.2***
10	Assembly, Display	***Section 7.2.12.3***
11	Module, CE	***Section 7.2.6***
12	Adaptor, USB	***Section 7.2.6.1***
13	Cover, CE Module	***Section 7.2.7.4***
14	Assembly, Mechanism	***Section 7.2.12.6***
15	Assembly, Fluid Shield	***Section 7.2.12.8***
16	Assembly, Cassette Door	***Section 7.2.12.8***
17	Assembly, Opener Handle	***Section 7.2.12.9***
18	Foot, Rubber	***Section 7.2.3***
19	Plate, Backing, Pole Clamp	***Section 7.2.10.1***
20	Insulator, Backing Plate	***Section 7.2.10.1***
21	Assembly, Shaft/Knob, Pole Clamp	***Section 7.2.10.2***
22	Tip, Shaft, Pole Clamp	***Section 7.2.10.2***
23	Extrusion, Pole Clamp	***Section 7.2.10.1***
24	Shoe, Front Enclosure (only available in older versions)	***Section 7.2.9***
25	Assembly, Piezo Alarm	***Section 7.2.12.5***
26	Gasket, Cover, CE Module	***Section 7.2.7.4***
27	Shield, Spring, EMI	***Section 7.2.7.4***
28	Gasket, Antenna Cover	***Section 7.2.7.3***

Table 9-2. IPB for the Infuser		
Index Number	**Nomenclature**	**Replacement Procedure**
29	Assembly, Minipole A: Hanger, Bag B: Housing, Clutch C: Clip, Hairpin D: Spring, Clutch	***Section 7.2.11***
30	Pad, Battery Door	***Section 7.2.4***
31	Door, Battery	***Section 7.2.4***
32	Gasket, Battery	***Section 7.2.4***
33	Splashguard	***Section 7.2.12.5***
34	Strap, Velcro, AC Power Cord	***Section 7.2.5***
35	Retainer, AC Power Cord	***Section 7.2.5***
36	Cordset, AC Power, Detachable	***Section 7.2.5***
37	Terminal, Equipotential	***Section 7.2.5***
38	PWA, Antenna	***Section 7.2.7.3***
39	Gasket, Handle	***Section 7.2.10.3***
40	Gasket, Shoe	***Section 7.2.9.1***
41	Gasket, Conductive, .129 x .188 x 1.04 L	***Section 7.2.9***
42	Gasket, Conductive, 1.04 L	***Section 7.2.9***
43	Gasket, Conductive, .129 x .188 x 2.7 L	***Section 7.2.9***
44	Gasket, Conductive, .129 x .188 x 1.6 L	***Section 7.2.9***
45	Gasket, Front/Rear Enclosure	***Section 7.2.10.3***
46	Gasket, Rear Enclosure	***Section 7.2.9.2***
47	Gasket, Conductive, .060 x .150 x 6.5 L	***Section 7.2.9***
48	Gasket, Conductive, 6.5 L	***Section 7.2.9***
49	Assembly, Cable, CPU/Driver	***Section 7.2.12.2***
50	Assembly, Cable, Motor Power	***Section 7.2.12.1***
51	Assembly, Cable, Power Supply/Battery	***Section 7.2.12.1***
52	Assembly, Cable, Wireless	***Section 7.2.7.3***
53	Assembly, Volume Control Knob	***Section 7.2.7.1***
54	Cover, Knob	***Section 7.2.7.1***
55	Cap, Knob	***Section 7.2.7.1***
56	Cap, Door Pivot	***Section 7.2.12.8***

Table 9-2. IPB for the Infuser		
Index Number	**Nomenclature**	**Replacement Procedure**
57	Bumper, Mechanism	***Section 7.2.12.6***
58	Seal, Round	***Section 7.2.7.4***
59	Cover, Antenna	***Section 7.2.7.3***
60	Gasket, Fluid Shield, .72 in.	***Section 7.2.12.8***
61	Gasket, Fluid Shield, 1.09 in.	***Section 7.2.12.8***
62	Spring, Extension, Door	***Section 7.2.12.9***
63	Insulator, CPU	***Section 7.2.12.4***
64	Wrap, Spiral	***Section 7.2.12.1***
65	Latch, Quick Release, Ethernet	***Section 7.2.7.2***
66	Tie, Cable	***Section 7.2.12.6***
67	Spacer	***Section 7.2.12.2***
68	Ring, Retaining	***Section 7.2.12.9***
69	Link, Door	***Section 7.2.12.9***
70	Screw, 4-24 x 1/4, Pan Head, Phillips	As applicable
71	Screw, 4-40 x 1/4, Pan Head, Phillips	As applicable
72	Screw, 4-40 x 1/4, Hex Head, Slotted, with Washer	As applicable
73	Screw, 4-40 x 3/8, Pan Head, Phillips, with Washer	As applicable
74	Screw, 4-40 x 3/8, Hex Head, Nylon	As applicable
75	Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer	As applicable
76	Screw, 4-40 x 3/8, Button Head, Socket	***Section 7.2.7.4***
77	Screw, 4-40 x 3/16, Hex Head, Slotted, with Washer	As applicable
78	Screw, 4-40 x 1/2, Pan Head, Square Cone, Phillips	As applicable
79	Screw, 4-40 x 5/8, Pan Head, Phillips	***Section 7.2.6***
80	Screw, Jack, 4-40 x 7/16	***Section 7.2.5***
81	Screw, 6-32 x 1/4, Hex Head, Slotted, with Washer	As applicable
82	Screw, 6-32 x 3/8, Hex Head, Slotted, with Washer	As applicable
83	Screw, 6-32 x 1/2, Pan Head, Phillips	As applicable
84	Screw, 6-32 x 5/8, Pan Head, Phillips, with Washer	As applicable
85	Screw, 6-32 x 2 1/2, Pan Head, Phillips	As applicable
86	Screw, 6-32 x 3 1/4, Pan Head, Phillips	As applicable

Table 9-2. IPB for the Infuser		
Index Number	**Nomenclature**	**Replacement Procedure**
87	Screw, 10-32 x 1/2, Hex Head, Slotted, with Washer	As applicable
88	Nut, Hex, Nurse Call Jack	***Section 7.2.7.4***
89	Nut, KEP, 4-40	As applicable
90	Nut, 4-40, Hex, Cad/Zinc Plate	***Section 7.2.7.4***
91	Washer, Flat, .566 x .255 x .03 Thk.	***Section 7.2.5***
92	Washer, Flat, #4	As applicable
93	Washer, Flat, .128 Dia., Nylon	As applicable
94	Washer, Flat, Mica	As applicable
95	Washer, Lock, Split, #4	As applicable
96	Washer, Lock, Helical, #6	As applicable
97	Washer, Lock, External Tooth	As applicable
98	Tape, Gasket	***Section 7.2.12.7***

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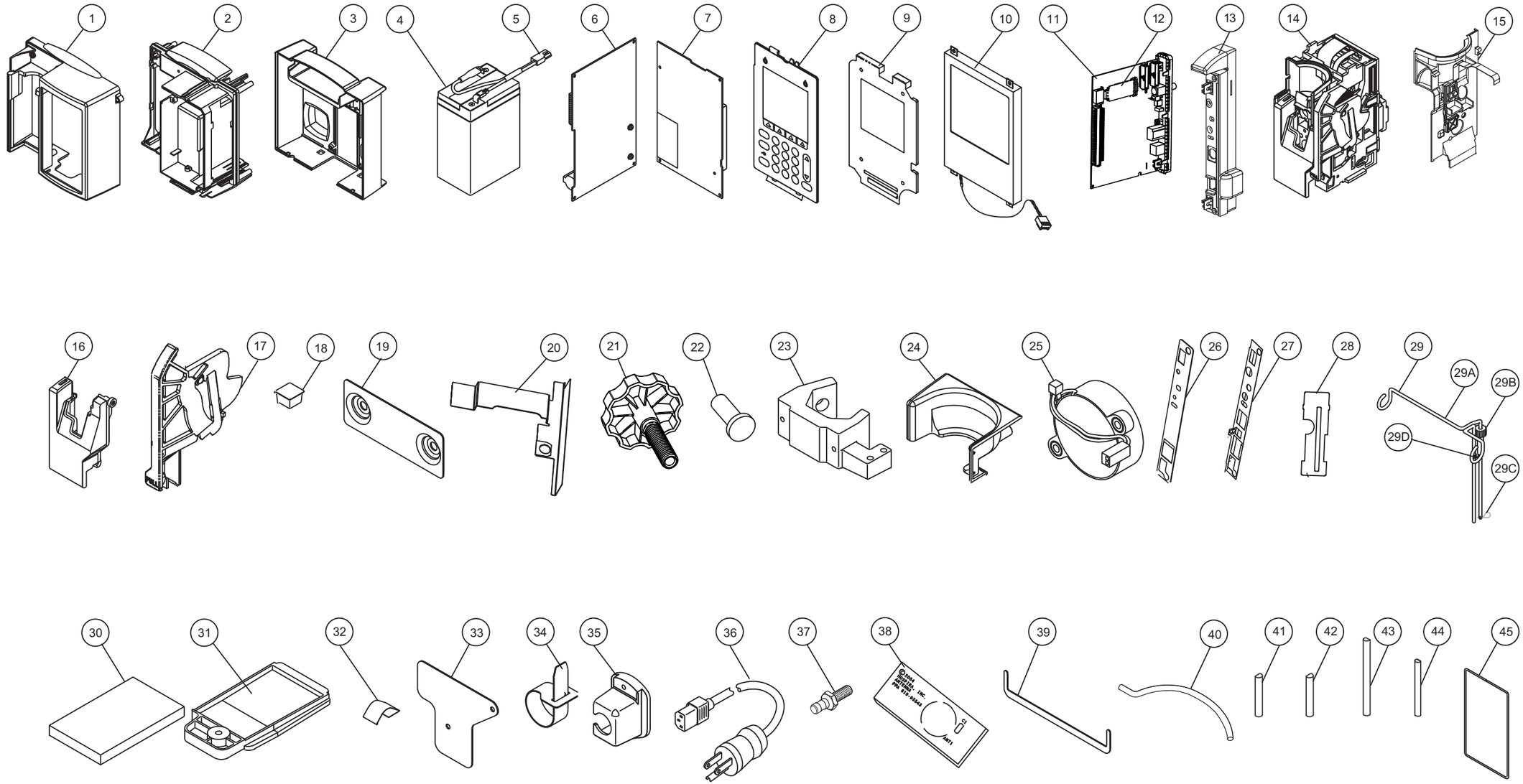

HOSPIRA, INC.	
Figure 9-1. Illustrated Parts Breakdown	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 2

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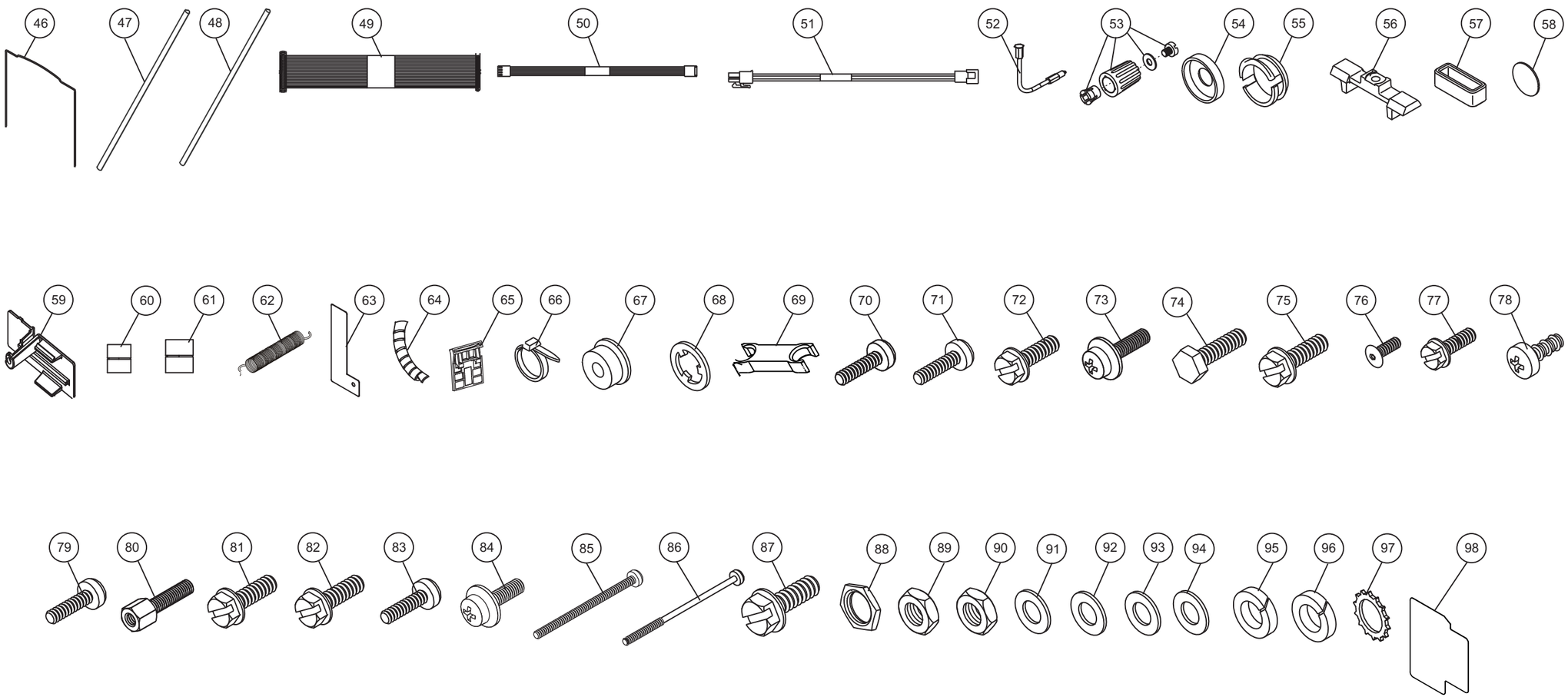

HOSPIRA, INC.	
Figure 9-1. Illustrated Parts Breakdown	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 2 of 2

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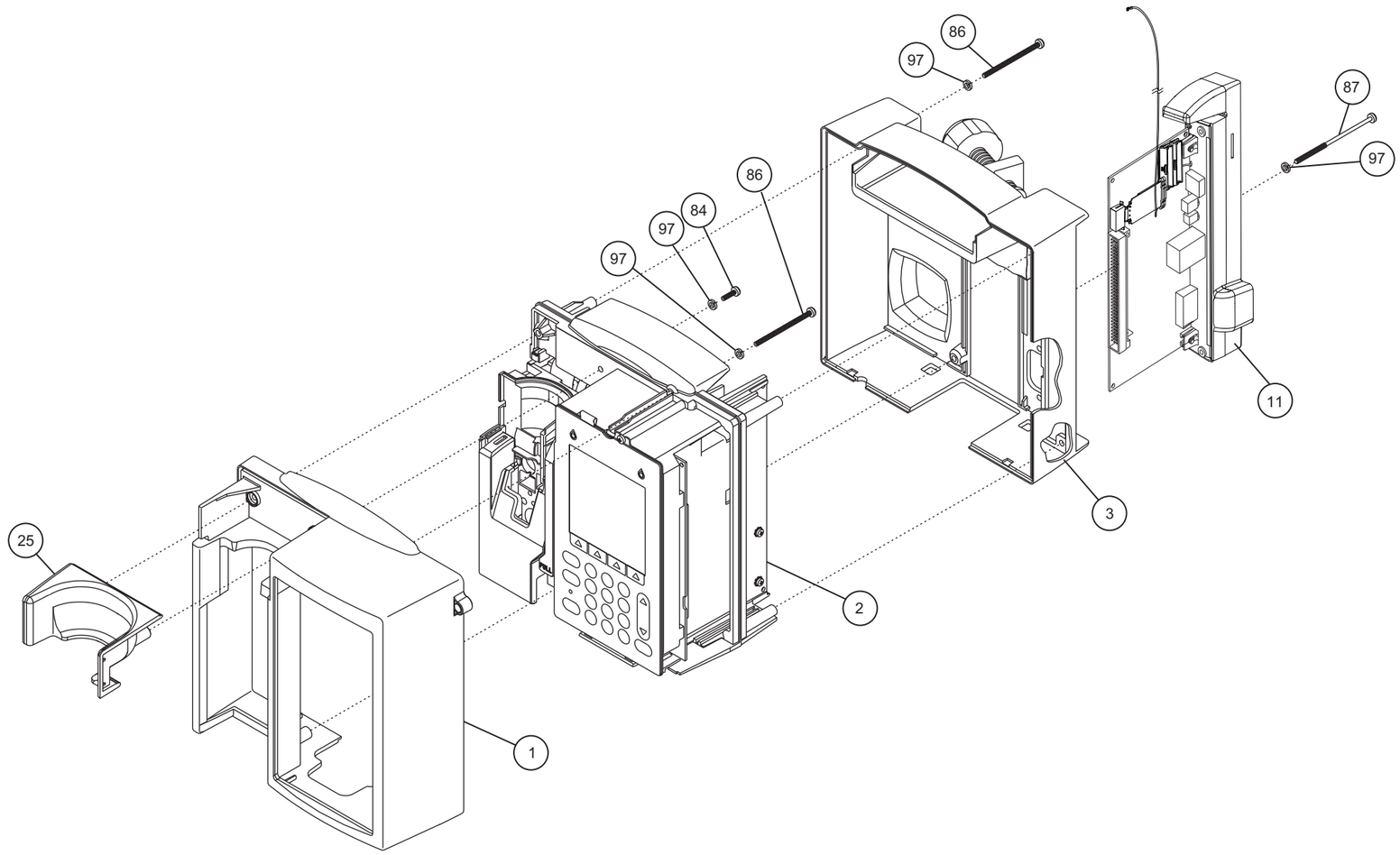

HOSPIRA, INC.	
Figure 9-2. Front Enclosure, Rear Enclosure, Main Chassis, and CE Module	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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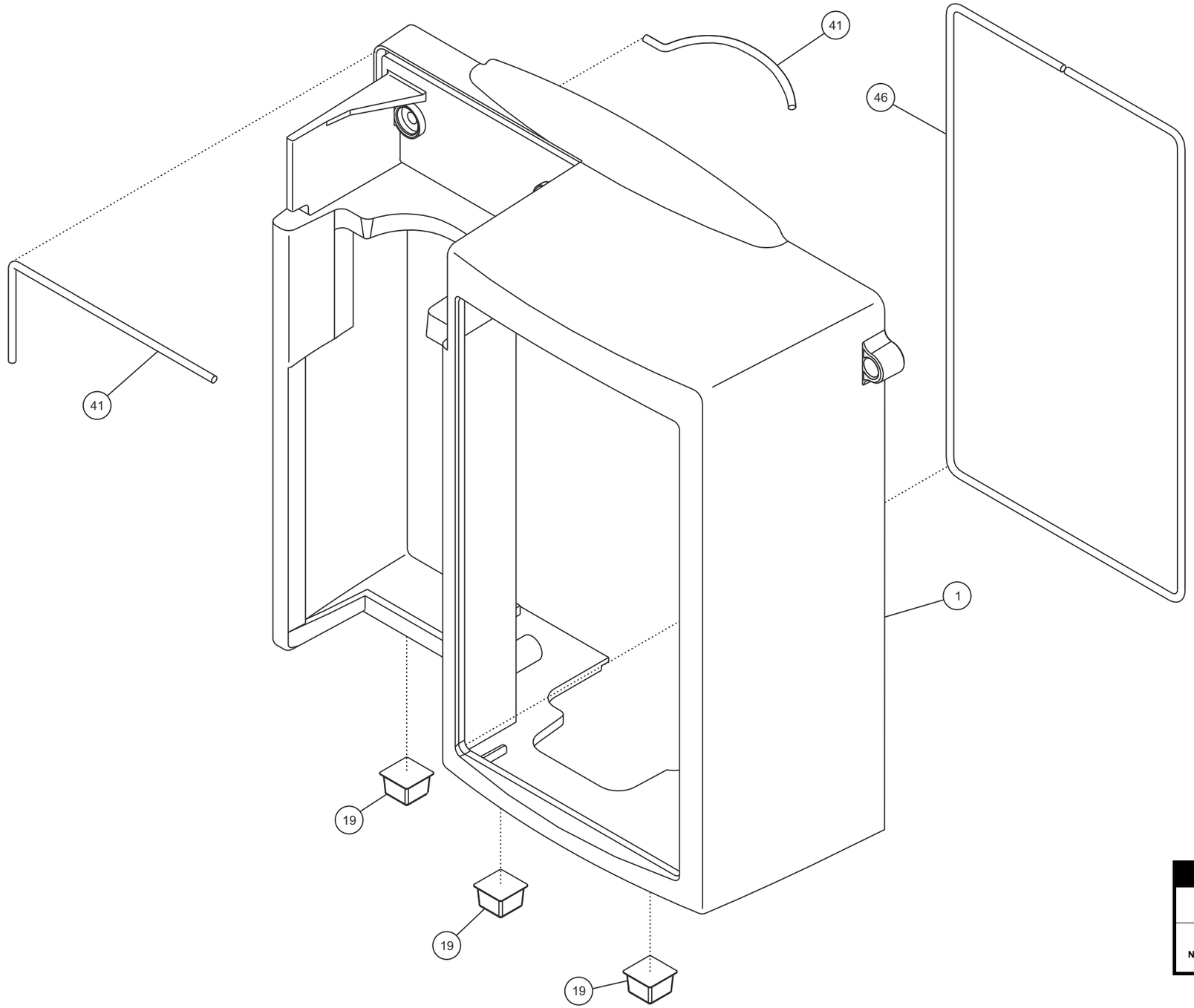

HOSPIRA, INC.	
Figure 9-3. Front Enclosure Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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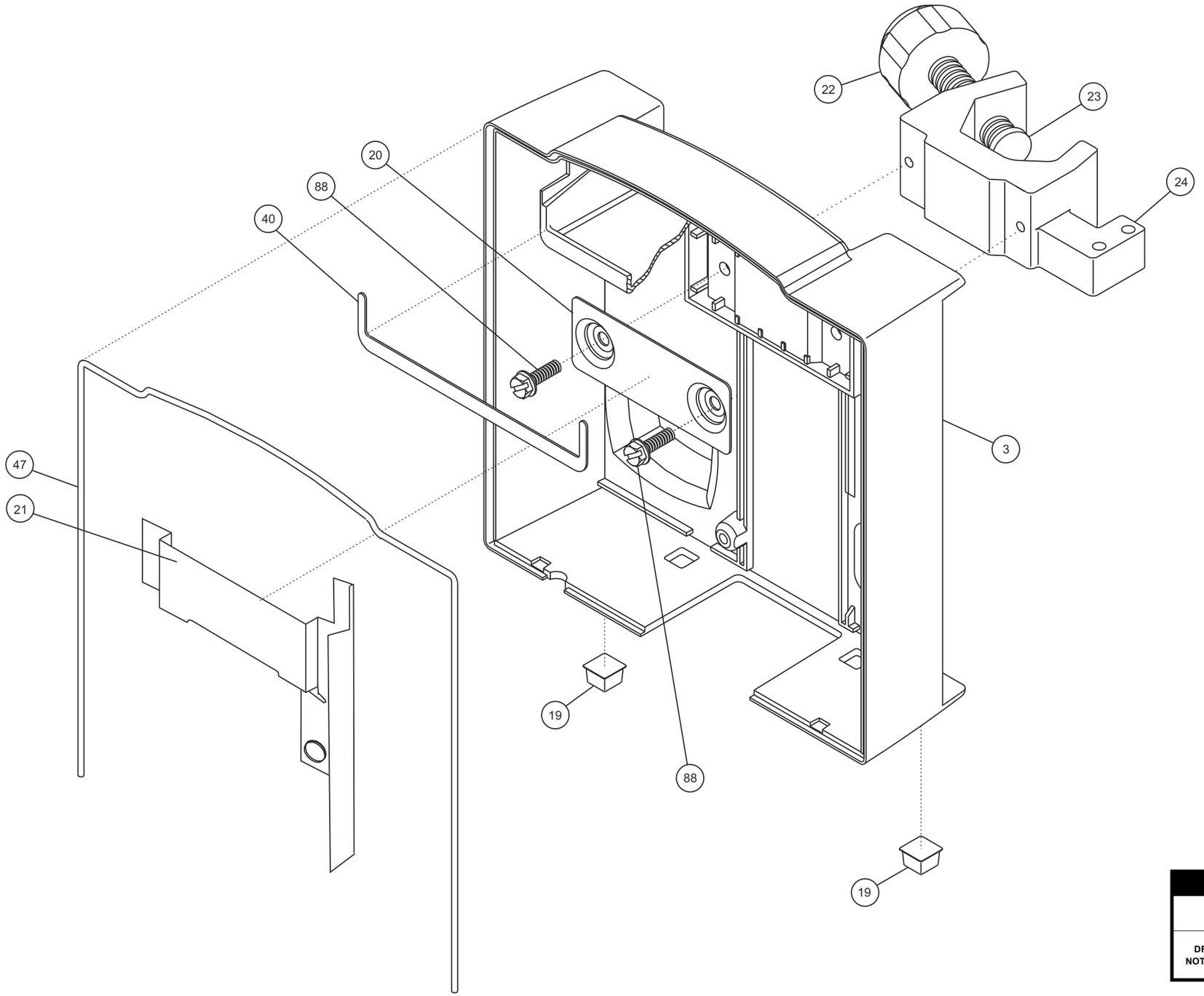

HOSPIRA, INC.	
Figure 9-4. Rear Enclosure Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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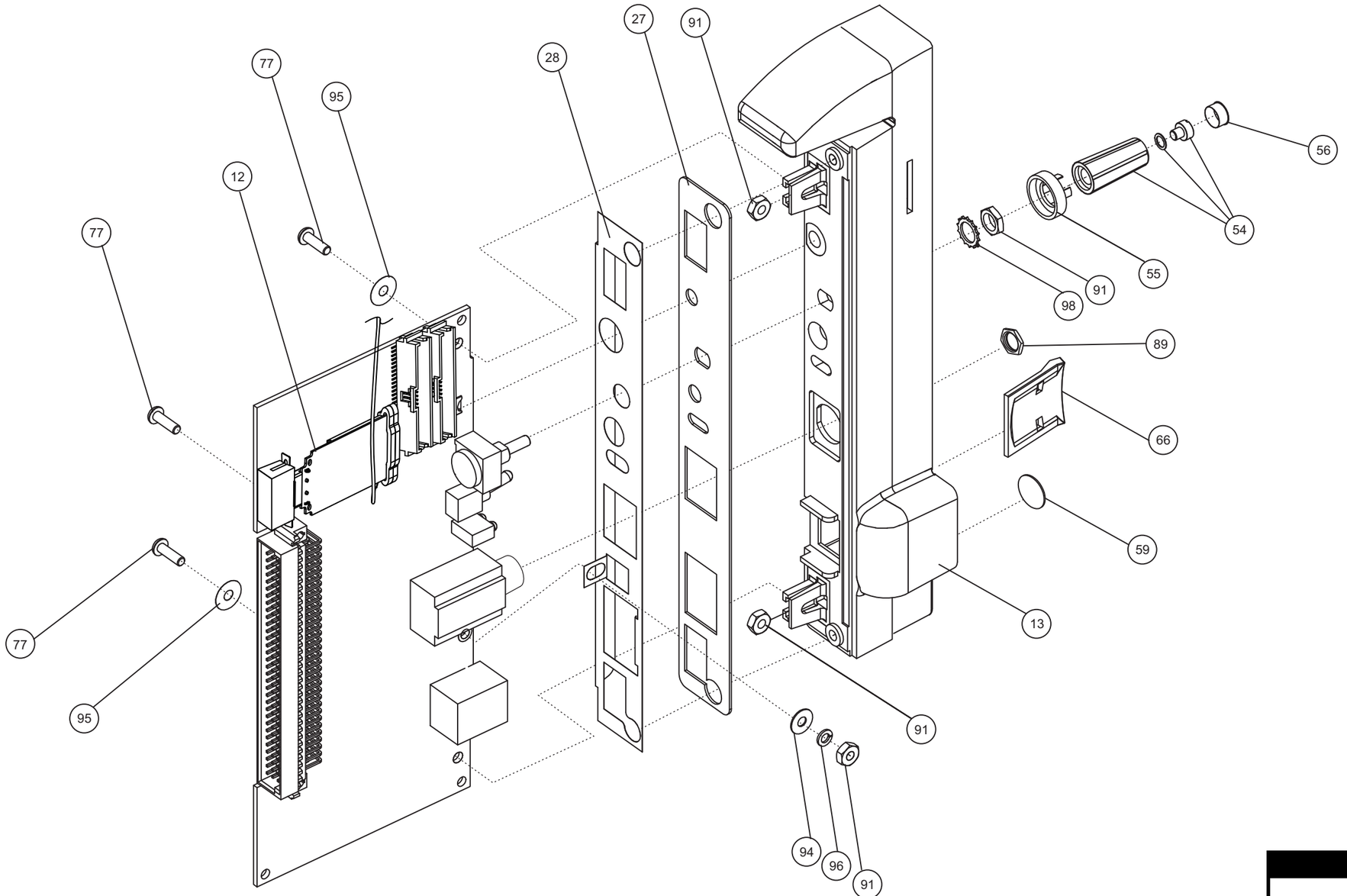

HOSPIRA, INC.	
Figure 9-5. CE Module	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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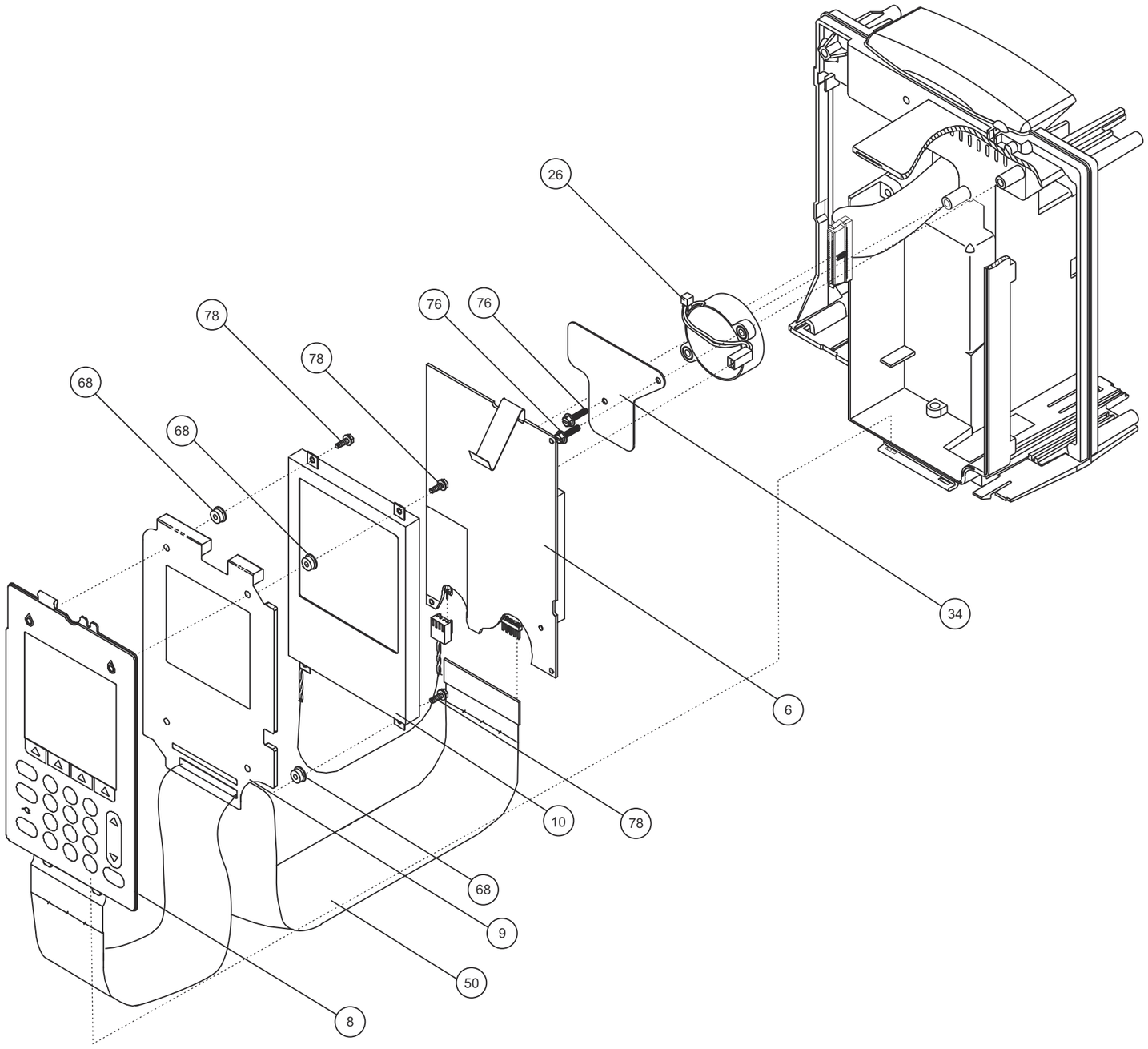

HOSPIRA, INC.	
Figure 9-6. Main Chassis Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 2

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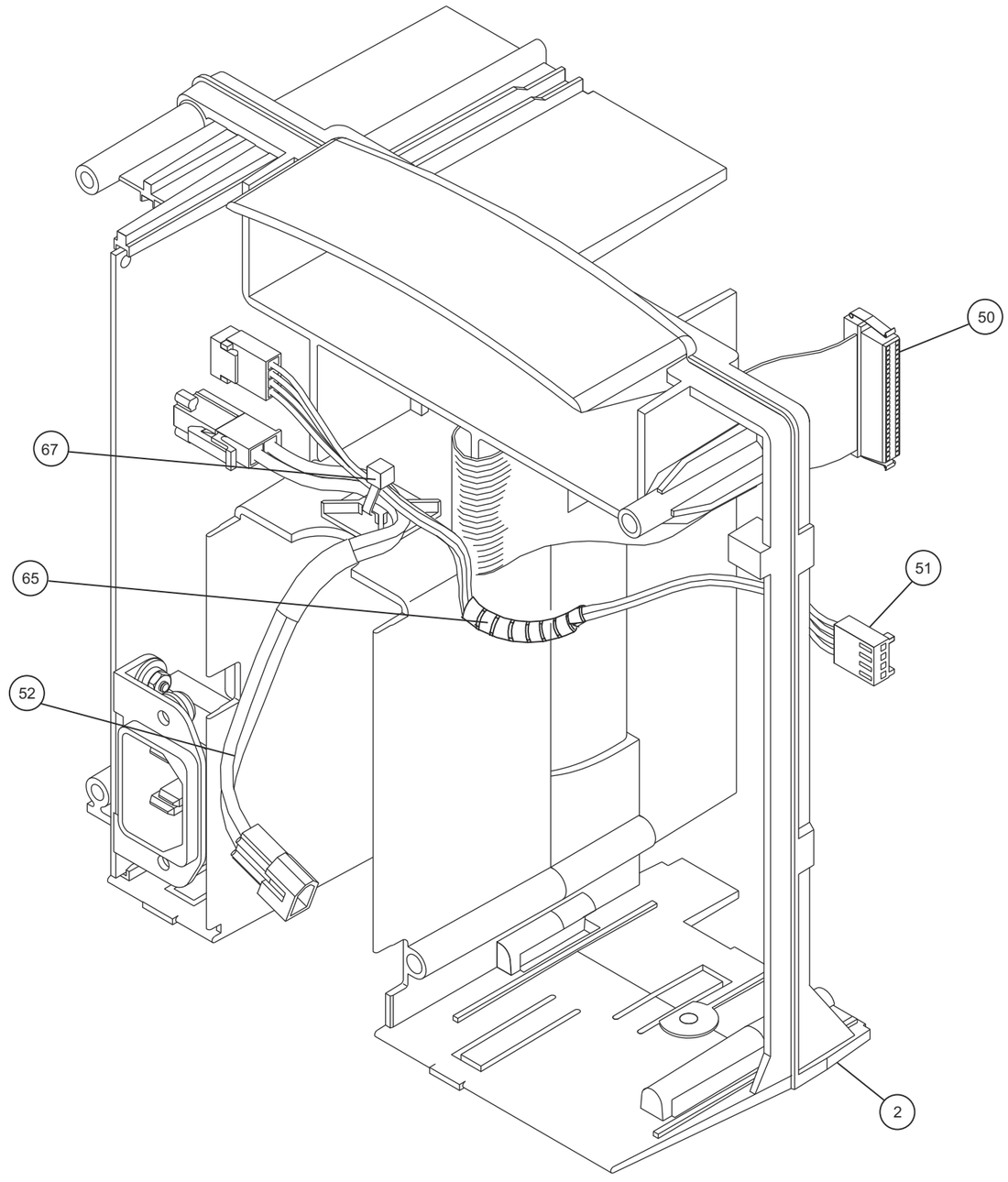

HOSPIRA, INC.	
Figure 9-6. Main Chassis Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 2 of 2

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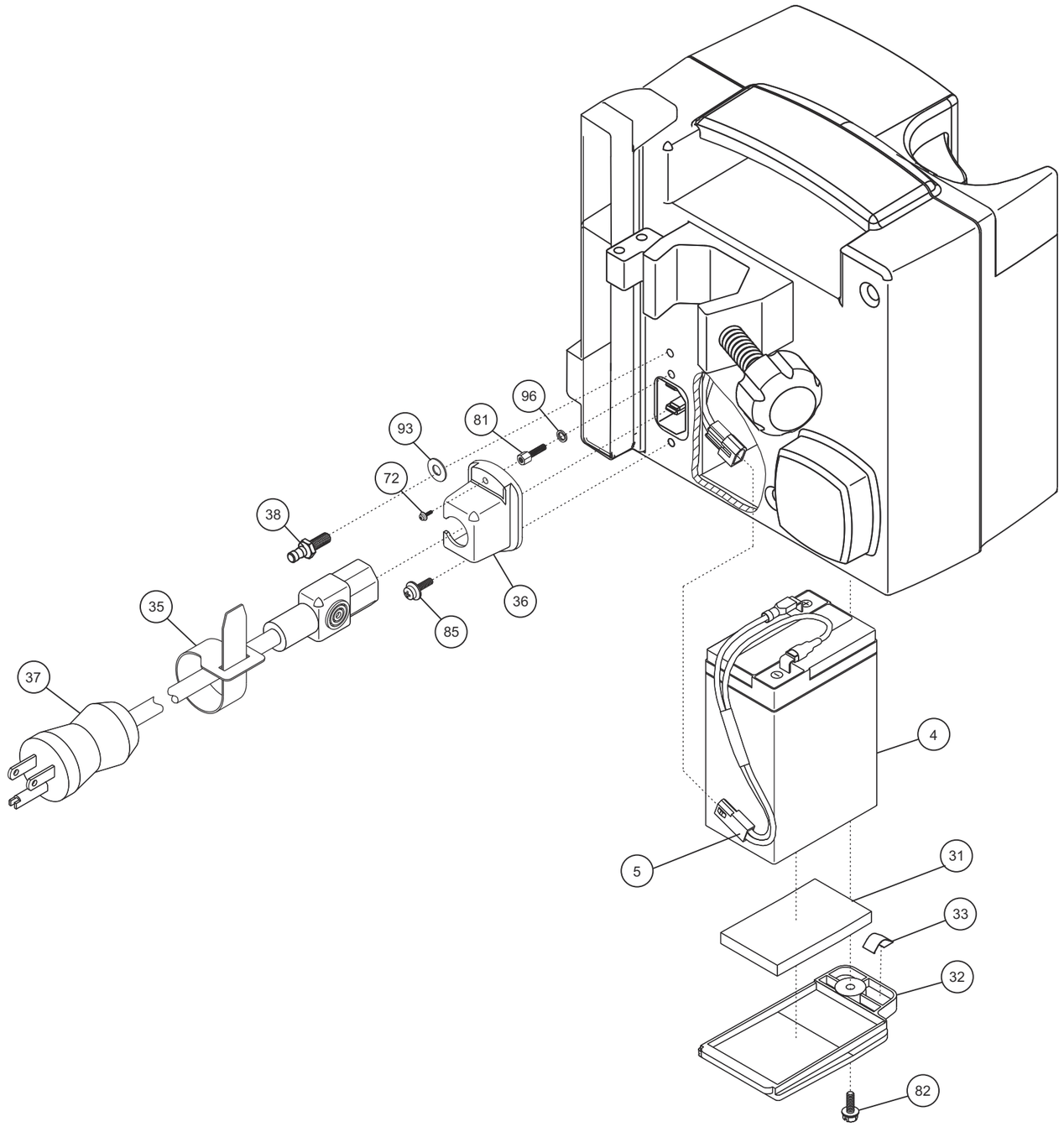

HOSPIRA, INC.	
Figure 9-7. AC Power Cord Assembly and Battery Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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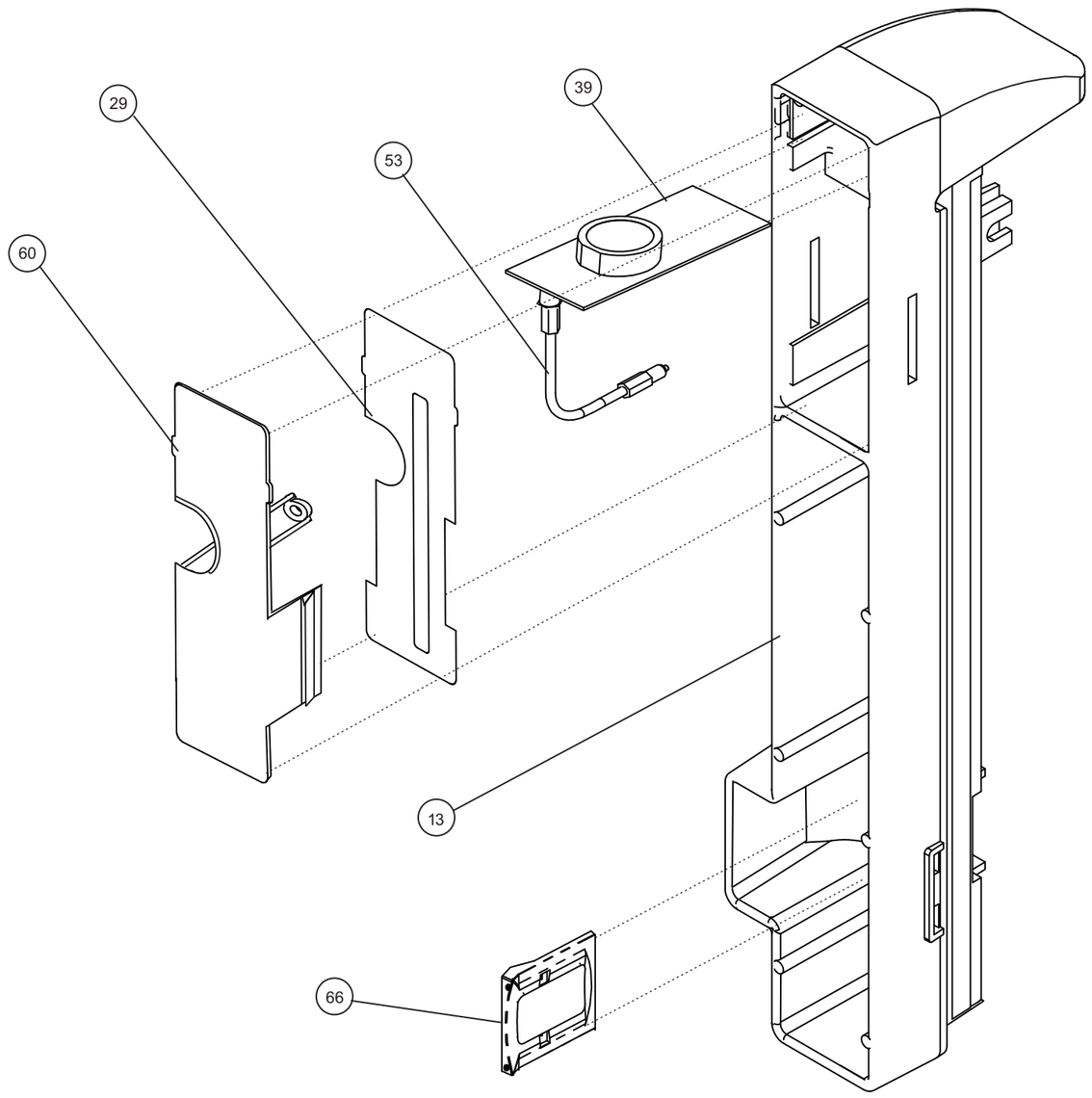

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Figure 9-8. Antenna PWA and Ethernet Quick Release Latch	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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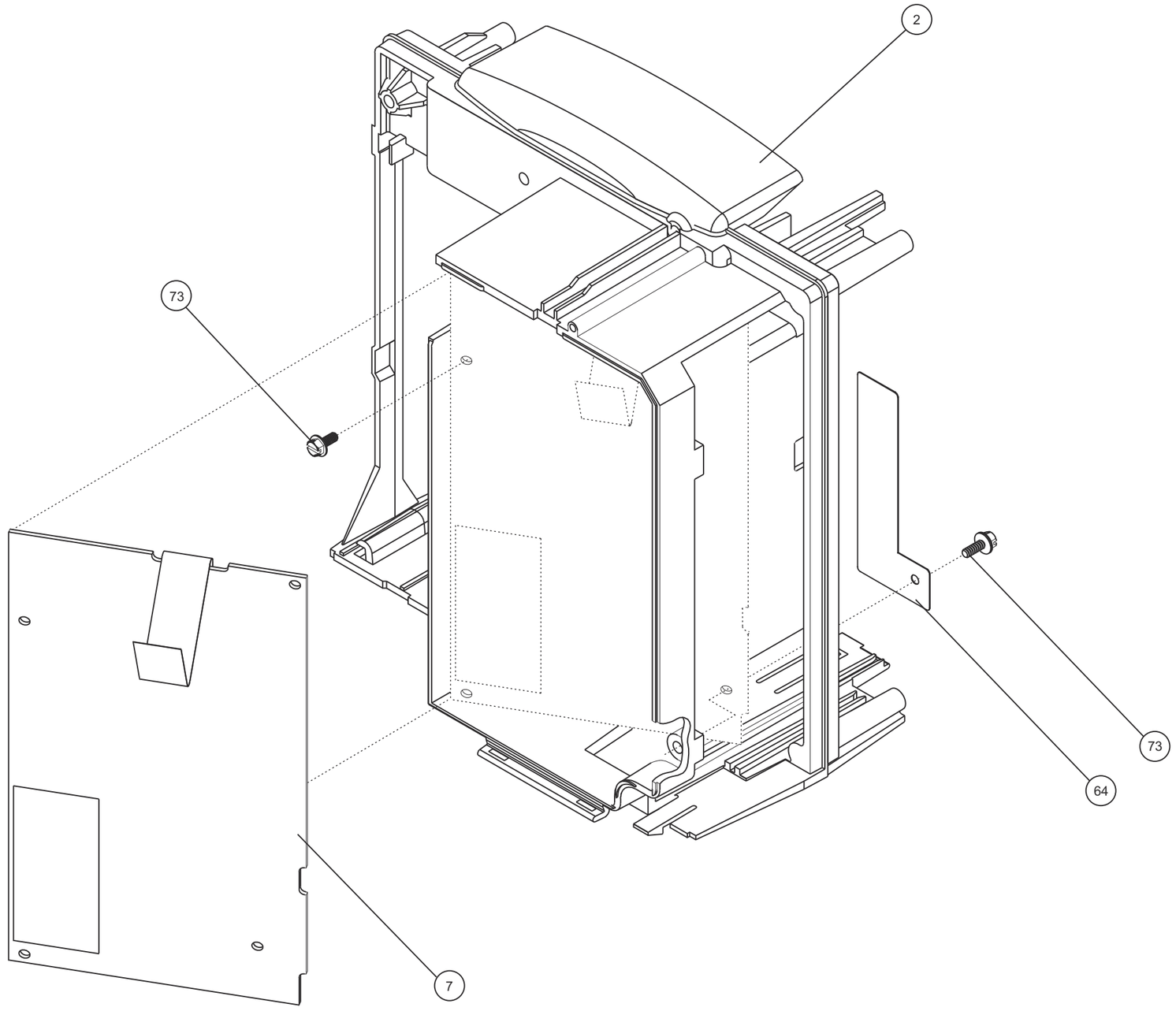

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Figure 9-9. CPU PWA and Main Chassis	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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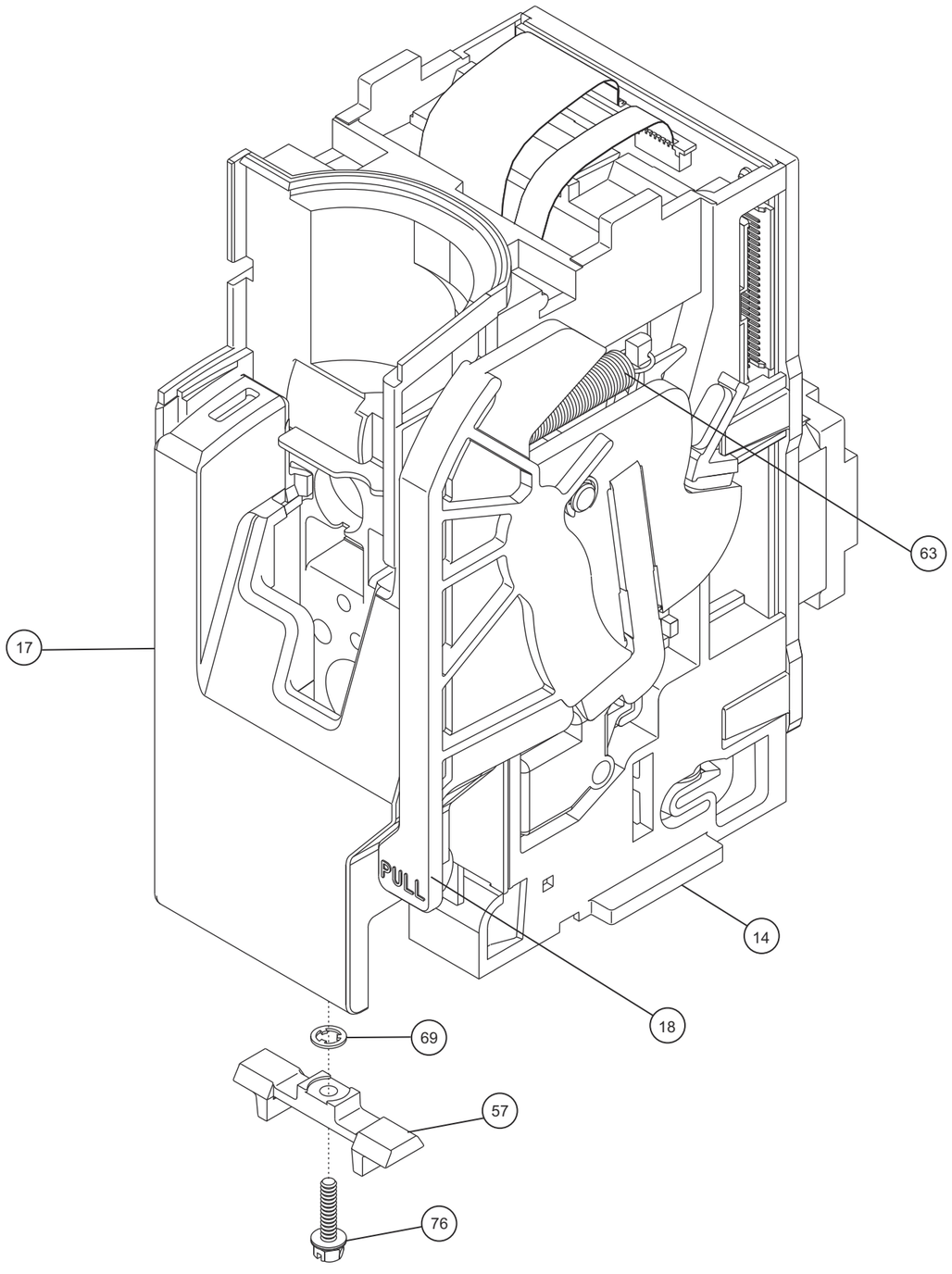

HOSPIRA, INC.	
Figure 9-10. Mechanism Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
	Sheet 1 of 1

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APPENDIX

USE OF THE INFUSION SYSTEM IN ELECTROMAGNETIC ENVIRONMENTS

✓EN-2 The Plum A+ 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 ensure 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 that supplies buildings used for domestic purposes
Harmonic Emissions IEC 61000-3-2	Class B	
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	
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U_r (>95% dip in U_r) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles 5% U_r (>95% dip in U_r) for 5 seconds	<5% U_r (>95% dip in U_r) for 0.5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles 5% U_r (>95% dip in U_r) 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

U_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 IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz outside ISM bands[a]	[V_1] V	Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
	10 V_{rms} 150 kHz to 80 MHz in ISM bands[a]	[V_2] V	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHZ to 2.5 GHz	[E_1] V/m	Recommended separation distance: $d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m)[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range[d] Interference may occur in the vicinity of equipment marked with the following symbol 

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.

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.

b 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.

c 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.

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 outside ISM bands $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	80 Mhz to 800 MHz $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
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.

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

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

www.hospira.com

For technical assistance and services outside the United States, contact the local Hospira sales office.

WARNING: EXPLOSION HAZARD EXISTS IF THE INFUSION SYSTEM IS USED IN THE PRESENCE OF FLAMMABLE SUBSTANCES.

CAUTION: Federal (USA) law restricts this infuser to sale by or on the order of a physician or other licensed practitioner.

	Caution or Attention: consult accompanying documents.		Keep dry
Class 1	Mains supply equipment using protective earth	IPX1	Protection against vertically falling water drops
	Fragile, Handle with Care		Temperature limitation
	This Way Up	✓EN-2	Compliant to IEC/EN 60601-1-2 (2001)
	Complies with limits for Class B digital device established by FCC Rules, Part 15		WiFi enabled and complies with IEEE 802.11 a/b/g

Type CF

Per IEC 60601-1 F-Type Applied Part complying with the highest degree of protection against electronic shock. Type CF Applied Parts are those parts suitable for direct cardiac application.

The ‘C’ and ‘US’ indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the U.S., respectively. This ‘US’ indicator includes products eligible to bear the ‘NRTL’ indicator. NRTL (National Recognized Testing Laboratory), is a designation granted by the U.S. Occupational Safety and Health Administration (OSHA) to laboratories which have been recognized to perform certification to U.S. Standards.