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Technical Service Manual



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Section 1

INTRODUCTION

The Hospira Plum $A+^{\otimes}$ infusion system is an advanced medication management system designed to meet the fluid delivery requirements of today's evolving healthcare environments. With its primary line, secondary line, and piggyback fluid delivery capabilities, the Plum $A+^{\otimes}$ is suited for a wide range of medical, surgical, and critical care applications. Full compatibility with LifeCare® Plum® Series administration sets and accessories make the Plum $A+^{\otimes}$ a convenient and cost-effective infusion system.

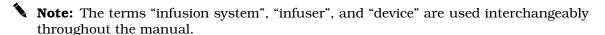
1.1 **SCOPE**

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 Repair
- ☐ Section 8 Specifications
- ☐ Section 9 Drawings
- Appendices
- □ Index
- ☐ 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+* $^{\otimes}$ *System Operating Manual*. Provision is made for the inclusion of the system operating manual in *Section 3* of this manual.



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

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

1.2 CONVENTIONS

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

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

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.

VEN-2 Indicates International Electrotechnical Commission (IEC) compliance.

1.3 COMPONENT DESIGNATORS

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

Battery	BT	Diode	D	Resistor	R
Capacitor	C	Fuse	F	Switch	sw
Crystal	Y	Integrated Circuit	U	Transistor	9

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

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

1.4

ACRONYMS AND ABBREVIATIONS

Acronyms and abbreviations used in this manual are as follows:

- A Ampere
- **AC** Alternating current
- A/D Analog-to-digital
- **ADC** Analog-to-digital converter
- APP Air, pressure, and pin
- **CCFT** Cold cathode fluorescent tube
 - cm Centimeter
- CMOS Complementary metal-oxide semiconductor
 - CPU Central processing unit
 - DAC Digital-to-analog converter
 - **DC** Direct current
 - **DIP** Dual in-line package
- **DMA** Direct memory access
- **DMM** Digital multimeter
- **DPM** Digital pressure meter
- ECG 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

lbs Pounds

LCD Liquid crystal display

LED Light emitting diode

L/S Line select

mA Milliampere

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

nF Nanofarad

ng Nanogram

Op-amp Operational amplifier

pF Picofarad

PROM Programmable read-only memory

PVT Performance verification test

PWA Printed wiring assembly

PWM Pulse width modulator

RAM Random access memory

rms Root-mean-square

RTC Real-time clock

SCC Serial communication controller

SCP Serial communication port

SLA Sealed lead acid

SMT Surface mount technology

SPI Serial peripheral interface

SRAM Static random access memory

TQFP Thin quad flat pack

V Volt

VAC Volts AC

V_{CC} Collector supply voltage

VCO Voltage controlled oscillator

V_{DC} Volts DC

VSC 5 V_{DC} supply circuitry

VSO Voltage sweep oscillator

VTBI Volume to be infused

WDI Watchdog input

μA Microampere

μL Microliter

μV Microvolt

μ**sec** Microsecond

1.5 USER QUALIFICATION

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

1.6 ARTIFACTS

Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infuser instead of some other source in the environment, set the device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by electronic noise generated by the infuser. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring system documentation for setup and maintenance instructions.

1.7 ELECTROMAGNETIC COMPATIBILITY

The Plum $A+^{\circ}$ infusion system has been tested and found to comply with electromagnetic compatibility (EMC) limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2:2001). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity (see the system operating manual).

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

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

The electromagnetic environment should be managed to permit the infusion system to perform as intended without disturbing other equipment. The infusion system should not be used adjacent to or stacked with other equipment. If the device must be used adjacent to or stacked with other equipment, monitor the equipment to assure there is no electromagnetic interference, and verify normal infuser operation.

1.8 INSTRUMENT INSTALLATION PROCEDURE

CAUTION: Infusion system damage may occur unless proper care is exercised during product unpacking and installation. The battery may not be fully charged upon receipt of the infuser. Do not place the infuser in service if it fails the self test.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment, and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input or output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of IEC 60601-1-1. If in doubt, contact Hospira Technical Support Operations (see Section 6.1).

The instrument installation procedure consists of unpacking, inspection, and self test.

1.8.1 UNPACKING

Inspect the shipping container as detailed in *Section 1.8.2*. 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 infuser to the factory. Verify the shipping container contains a copy of the system operating manual.

1.8.2 INSPECTION

Inspect the shipping container for damage. Should any damage be found, contact the delivering carrier immediately.

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 (see Section 6.1).

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

1.8.3 SELF TEST

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

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 (see Section 8).

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

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

- 1. Connect the AC power cord to a grounded AC outlet. Verify the charging/line indicator **CHARGE** illuminates and an alarm beep sounds.
- $2. \ \,$ Without a cassette installed, press the ON/OFF key to turn on the infuser.
- 3. The LCD screen briefly displays the **SELF TEST** screen (see Figure 1-1).
 - **Note:** If the **SELF TEST** screen does not appear, contact Hospira.
- 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 1.9.2.
- 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 the [YES] softkey.
- 8. Press the ON/OFF key to turn off the infuser.

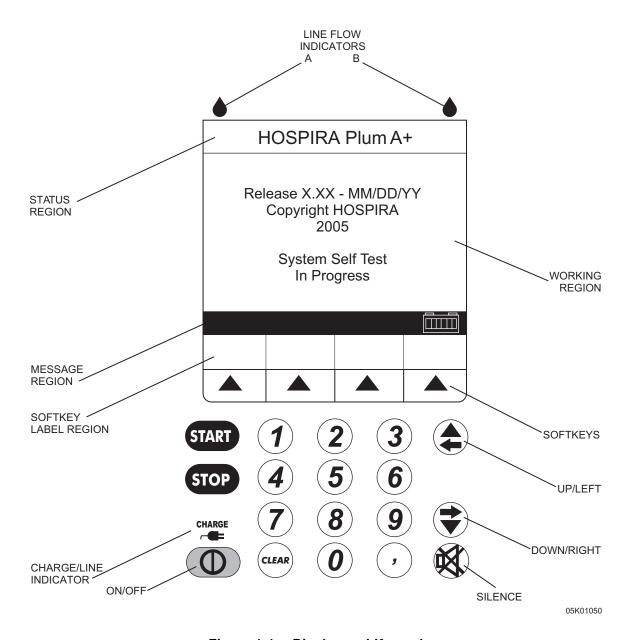


Figure 1-1. Display and Keypad

1.9

BIOMED SETTINGS

The biomed settings screens contain the following options that can be changed or reviewed by qualified personnel:

- Alarms log
- Set time and date

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

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

To access the biomed settings, proceed as follows:

- 1. Open the door and turn on the device. The infusion system will perform a self test.
- 2. After the self test is complete, the message "INSERT PLUM SET CLOSE LEVER" appears.
- 3. Press the comma [,] key, then [START], and verify the **BIOMED SETTINGS** screen is displayed (see Figure 1-2).
 - Note: The [CHANGE BATTERY] softkey appears on the biomed settings screen.

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					

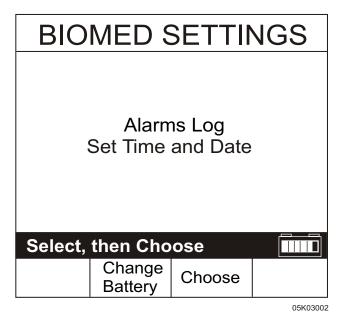


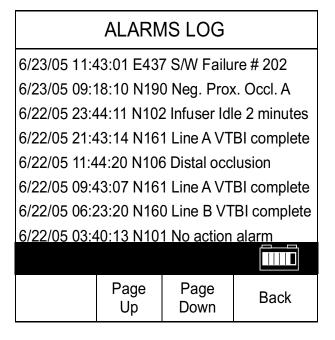
Figure 1-2. Biomed Settings

1.9.1 **ALARMS LOG**

Note: The alarms log will retain 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 1.9.
- 2. Select Alarms Log, and press [CHOOSE].
- 3. Use the [PAGE UP] and [PAGE DOWN] softkeys to view the alarms log.
- 4. Press [BACK] to exit the alarms log and return to the main biomed settings screen.



05K03008

Figure 1-3. Alarms Log

1.9.2 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 1.9.
- 2. Select **Set Time and Date**, and press [CHOOSE].
- 3. Select the parameter to be changed.
- 4. Enter the desired value.
- 5. Repeat step 3 and step 4 for each parameter to be changed.
- 6. Verify the time and date are correct, then press [ENTER] to return to the biomed settings screen.
- 7. If there are no other changes to the biomed settings, turn off the infuser.

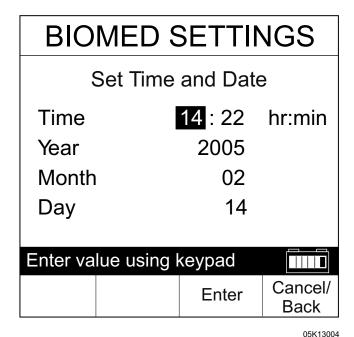


Figure 1-4. Setting the Time and Date

Section 2

WARRANTY

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

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

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial 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, flow detectors, detachable AC power cords, and patient pendants.

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

SECTION 2 WARRANTY

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Section 3

SYSTEM OPERATING MANUAL

A copy of the system operating manual is included with every Plum A+® infusion system. Insert a copy here for convenient reference. If a copy of the system operating manual is not available, contact Hospira Technical Support Operations (see Section 6.1).

SECTION 3 SYSTEM OPERATING MANUAL

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Section 4

THEORY OF OPERATION

This section describes the Plum A+® theory of operation. The theory of operation details the general description, electronic subsystem overview, printed wiring assemblies, remote mounted peripherals, and mechanical overview of the infuser. Related drawings are provided in *Section 9*.

$\overline{4.1}$

GENERAL DESCRIPTION

The infusion system includes the following features:

- Dose calculation
- Loading dose
- Multi-step programming
- Therapy selection
- Nurse call
- Delayed start setting
- Standby mode
- Drug label library
- Piggyback and 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
- Air removal/backpriming
- Battery gauge

- Air detection (proximal and distal)
- Serial communication
- 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 display
- Panel back illumination on mains power
- Lockout switch
- Standard fullfill, partfill, syringe, and vial use
- Enteral and parenteral fluid delivery
- Blood and blood product delivery
- Wide range of standard and specialty administration sets

Alarms include the following:

- Proximal occlusion

- Distal occlusion - Lockout violation

- Proximal air-in-line - Valve/cassette test failure

- Distal air-in-line - Nurse call

- Low battery - No action alarm

- Infuser idle for two minutes - Door open while pumping

4.2

ELECTRONIC SUBSYSTEM OVERVIEW

This section describes the function and electronic circuitry of three main subsystems in the infuser: CPU subsystem, power supply subsystem, and mechanism subsystem. Schematic diagrams of subsystem PWAs are in Section 9.

- VTBI complete

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

4.2.1CPU SUBSYSTEM

The CPU subsystem contains the main microcontroller, which is responsible for controlling the display/keypad 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
- Serial communication with host computer (DataPort)
- 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; MC68000 microprocessor core; a system integration block for peripherals; and an RISC communications processor. The MC68302 is packaged in a 144 pin thin quad flat pack (TQFP) package and operates from a $3.3~\rm V_{DC}$ power supply. The on-chip peripheral devices are isolated from the system through the dual port RAM. The 1152 byte dual port RAM has 576 bytes of system RAM and 576 bytes of parameter RAM, which contains various peripheral registers, parameters, and the buffer descriptors for each of the three serial communication controller (SCC) channels and the serial communication port (SCP) channels. The 24 bit address bus is capable of accessing up to 16 MB of data.

$\overline{4.2.1.2}$

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, which provide a total of 1024 KB. The PROM space is expandable up to 2 MB. The PROM memory devices operate off the 3.3 $\rm V_{DC}$ 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, which 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), which are high density, high speed, I/O intensive general purpose devices. They are used to implement all the digital control functions, including: memory-map address decoding; memory read-write enable; direct memory access (DMA) request; I/O status signals; chip-select control; motor control; sensor select; and power up/system reset control.

LCD CONTROLLER

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

The interface to the CPU is through the lower 8 bits of the data bus, which 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 K Ω The current counter value is stored in non-volatile memory after CSTUB* is returned high while the TUBINC* input is also high. The current counter value is not stored if CSTUB* is returned high and TUBINC* is low. The CCFT intensity is directly proportional to the CCFT current, where 0 mA $_{\rm rms}$ is minimum intensity and 5 mA $_{\rm rms}$ is maximum intensity. The CCFT current is inversely proportional to the counter value.

4.2.1.8

LCD CONTRAST CONTROL

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

REAL-TIME CLOCK

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

The external interface is a separate (non-multiplexed) 8 bit data bus and 6 bit address bus, with a contiguous address space of 64 bytes. When system power is turned off, a battery voltage input is available, which 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*), which involves address decoding circuitry.

4.2.1.10

VOLTAGE MONITOR WATCHDOG TIMER

It is important to protect the system during power transitions, and 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, which is used to disable access to the real-time clock's non-volatile SRAM during power transitions and power down mode.

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

ANALOG-TO-DIGITAL CONVERTER

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

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

Channel selection and conversion results are transferred through the SCP pins. A serial transfer synchronizing clock (SPCLK) must be fed into the I/O clock input pin when the CS* pin is driven low. The address to be converted is serially transmitted into the address pin, and the conversion results are serially shifted out the data-out pin. Typical access time is 21 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.

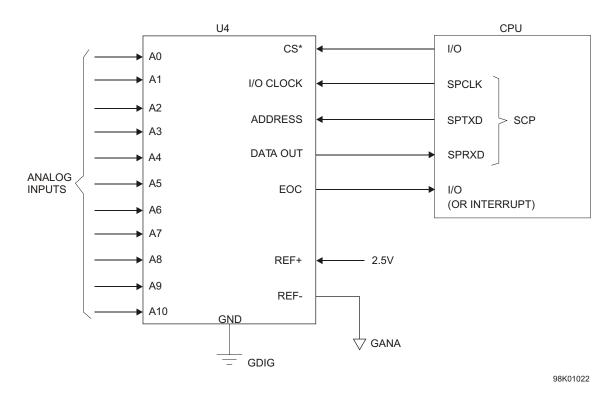


Figure 4-1. Serial Interface to ADC

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	А3	\$03	Distal air sensor				
IBATT	A4	\$04	Battery current				
VBATT	A5	\$05	Battery voltage				
BUZTST	A6	\$06	Buzzer test voltage				
LCDTST	A7	\$07	LCD contrast test voltage				
TUBTST	A8	\$08	CCFT intensity test voltage				
MI_STA	A9	\$09	Motor current A control				
MI_STB	A10	\$0A	Motor current B control				
		\$0B	(V _{ref(+)} - V _{ref(-)}) / 2				
		\$0C	V _{ref(-)}				
_		\$0D	V _{ref(+)}				

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, which 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 5×5 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	Up/Left			
Row 2	STOP	4	5	6				
Row 1	Charge/Line Indicator	7	8	9	Down/Right			
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 that the system is in the battery charge mode. A buffered AC on signal (BACON) drives the LED and is active only when AC power is present.

KEYPAD LOCKOUT INTERFACE

A lockout switch (SW1) on the peripheral PWA 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 peripheral PWA 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 peripheral board 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 for alerting 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 peripheral PWA, 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 front panel 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

DATAPORT INTERFACE

The CPU communicates with an external computer by way of a DataPort interface. The DataPort interface provides for remote monitoring of up to 15 infusers using a host computer with a modified RS-232-D serial interface. Infusers are either connected directly to the host or in a daisy chain configuration using junction boxes that provide a 5 bit hard ID via DIP switches on the junction box. The DIP switches are buffered (peripheral PWA U8) and read by the CPU via the memory-mapped input/output (MMIO) port.

The DataPort system conforms to the EIA-232-D standard, with the following exceptions:

- DataPort uses non-standard DB-15 and 6 pin modular connectors in addition to the standard DB-25 and DB-9 connectors
- With DataPort, more than one infuser is allowed on the line

- The minimum line impedance is 2 K Ω (EIA-232-D standard: 3 K Ω min.)
- The maximum line impedance is 30 K Ω (EIA-232-D standard: 7 K Ω max.)
- The maximum line capacitance is 13 nF (EIA-232-D standard: 2,500 pF)

The communications default is 1200 BAUD, no parity, 8 data bits and 1 stop bit. The BAUD rate is selectable (1200, 2400, 4800, and 9600). The data format on the serial port is a 10 bit frame with asynchronous start and stop. The CTS line is held high and the RTS line is disconnected. The DataPort is isolated from the main system by an optical data path on the peripheral PWA and an isolated power supply.

4.2.1.20

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

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

4.2.1.21

MECHANISM INTERFACE

The CPU subsystem provides the MMIO ports for interface to the mechanism subsystem, in addition to the analog interface mentioned 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	
SPCLK	D, O	SCP clock output	

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

POWER SUPPLY SUBSYSTEM

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

The power supply subsystem provides for the following functions:

- Main switching regulator
- AC power detection
- Main regulator fault detection
- System power (secondary regulators)
- Auxiliary supplies
- Power control
- Battery charging circuitry
- Battery terminal voltage measurement
- Battery charge/discharge current measurement\

MAIN SWITCHING REGULATOR

The main source of power for the infuser is the AC line. The main switching regulator is a pulse width modulated, AC-to-DC converter which 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 (T3, T4, C54-56). The bridge rectifier U14 and capacitors C52 and C53 provide the DC voltage required for the switching circuit. Voltage regulator U13 provides the pulse width modulator (PWM) device U12 startup supply voltage. After startup, supply voltage for U12 is supplied by half wave rectifier circuitry CR14, R76, and C51.

The PWM oscillation frequency is approximately 40 kHz, determined by external resistor R72 and capacitor C45. U12 controls the power delivered by varying the duty cycle of the power metal-oxide-semiconductor field-effect transistor (MOSFET) Q9, which drives T2. A half-wave rectifier rectifies the transformer's secondary voltage, which provides the raw DC voltage for the battery charger and system power. There are three feedback mechanisms that maintain control: a main loop for normal control, a secondary loop for overvoltage protection, and a current limit loop.

4.2.2.1.1

Main Loop

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

$\overline{4.2.2.1.2}$

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 $\rm V_{DC}$ threshold) of U12. The duty cycle of U12 is reduced until the excessive load is removed.

4.2.2.2

MAIN REGULATOR FAULT DETECTION

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

SYSTEM POWER

Along with the unregulated VMOT supply, a secondary switching regulator provides system power. The secondary switching regulator includes IC U4, transformer T1, and transistors Q4 and Q5. The regulator is a triple output, wide supply range, fly-back converter that provides regulated $3.3\,V_{DC}$, $5\,V_{DC}$, and $12\,V_{DC}$ outputs from the five winding transformer T1. The regulator operates over an input range of 4 to $10\,V_{DC}$ and provides output current limit as well as voltage overshoot limit. Primary feedback is metered through a bias arrangement on transistor Q3. A Schottky rectifier diode CR4 provides feedback in the event of V3_3 or V12_0 failure, and transistor Q10 provides feedback in the event of V5_0 failure. The positive terminal of the battery provides the raw DC voltage, VMOT, for the motors and backlight of the display.

4.2.2.4

AUXILIARY SUPPLIES

The power supply subsystem provides full time 5 V_{DC} and 2.7 V_{DC} supplies, which 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 (C3, R10, CR1, and Q1) that will temporarily turn the system power on. This three second one-shot period allows the CPU enough time to power up, initialize, and turn on the PWRHLD signal. The CPU monitors the STRTUP signal, via interrupt, to signal a user request for turning off the infuser.

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

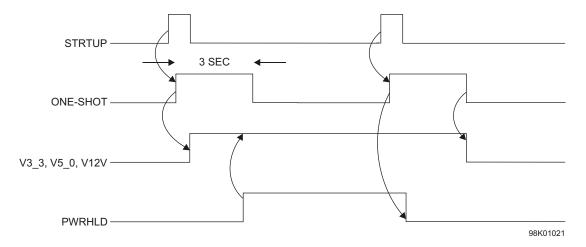


Figure 4-2. System Startup and Shutdown Timing, Battery Powered

BATTERY VOLTAGE MEASUREMENT

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

4.2.2.7

BATTERY CHARGE/DISCHARGE CURRENT MEASUREMENT

The battery management algorithms measure battery charge/discharge current for battery capacity estimation and charger control. The charge/discharge current is measured by integrating the voltage across current sense resistor R57. An operational amplifier (op-amp) integrator circuit, consisting of U2, C5, R12, R13, R19, and R20, provides a voltage proportional to the integration of battery current (IBATT) over a CPU controlled measurement period. The IBATT signal is fed to the CPU A/D converter, where it is sampled at the end of the measurement period. The battery management algorithm further accumulates the charge/discharge current for battery capacity estimation. The op-amp integrator is reset by the CPU system at the beginning of each measurement period by parallel analog switches U3, controlled by the CPU's ITGRST signal. The battery management algorithm periodically calibrates the op-amp integrator.

BATTERY CHARGER

The software battery management algorithm controls the battery charger. The charging scheme is a current limit/two stage voltage limit charger. The charge current is limited to 1.3 A and the voltage is limited to either 6.74 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 $2.5\,\rm V_{DC}$ 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, which overrides the feedback signal and disables the charger. Excessive voltage on the BATNEG terminal indicates that there is a shorted battery cell, and will disable the charger through the same comparator.

4.2.3

MECHANISM SUBSYSTEM

The mechanism subsystem includes the electronics and electromechanical components that interface 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 and type detection
- Serial electrically erasable PROM (EEPROM)

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

4.2.3.1

MOTORS/MOTOR DRIVE

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

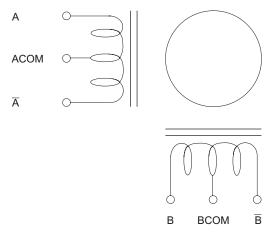
4.2.3.1.1 Stepper Motors

Each motor is named by its function, as follows:

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

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

The unipolar motor windings have a center tap connected on each of the two coils as shown in *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.



98K01020

Figure 4-3. Stepper Motor Coils

4.2.3.1.2

Chopper Motor Drive

The infuser stepper motor drive is a chopper drive, which 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, which are used to find the motor home positions and to verify proper motion. Flag positions are anticipated by software.

Optical switch flag sensors are used for tracking the following:

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

Each optical switch consists of an infrared LED, which 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 (U5, U9, and U10) 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, as follows:

- 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 which turns on the associated switch's infrared LEDs. The photo transistor states are sensed by Schmidt trigger inverters (U11 on driver PWA) which 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).

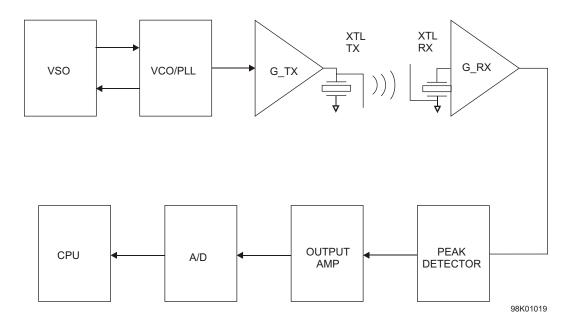


Figure 4-4. Air Sensor Block Diagram

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 $\rm V_{DC}$ and +3 $\rm V_{DC}$, and is used to sweep the VCO. The VCO sweeps through the sensor's peak coupling frequency, which is between 3 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 μ sec (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.

The following final signals are read by the CPU subsystem via the ADC:

- PXAIR proximal air sensor output
- DIAIR distal air sensor output

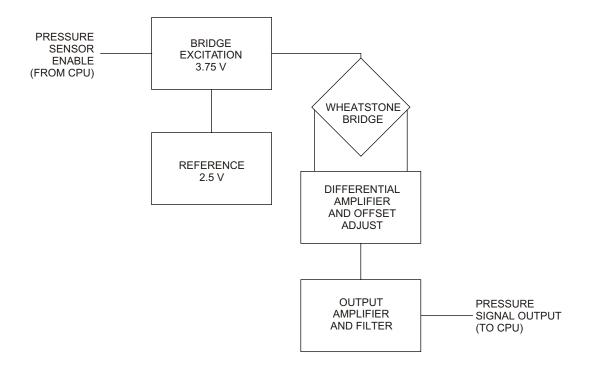
4.2.3.5

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*.

Note: Component references are made to the distal channel only.



05K01018

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.

The following 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 (U6B) with low gain. A trimming potentiometer (R48) 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, which is located on the CPU PWA.

The output signals to the A/D converter in the CPU PWA are, as follows:

- PXPRS proximal pressure signal
- DIPRS distal pressure signal

4.2.3.6

PRESSURE SENSOR CALIBRATION

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

4.2.3.7

CASSETTE TYPE/PRESENCE SELECTION

The mechanism subsystem includes one force sensing resistor (FSR) switch, which is coupled to the cassette and is used for cassette present detection. The FSR is a polymer thick film device, which 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 $120~\mathrm{K}\Omega$

4.2.3.8

SERIAL EEPROM

The driver PWA holds the 8 K x 8 bit, serial EEPROM, which 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, which 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.

$\overline{4.3}$

PRINTED WIRING ASSEMBLIES

Infusion system electronics are packaged into six printed wiring assemblies (PWA) and two remote mounted peripherals (see Section 4-4). The following sections provide a brief description of the functional interfaces of each PWA.

4.3.1

POWER SUPPLY PWA

The power supply PWA (see Figure 9-10) contains the following functions of the power supply subsystem:

Main switching regulatorAC power detectionPower control

- Main regulator fault detection - Battery management

- System power

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

See Section 4.2.2 for a functional description, and see *Table 4-5* for power supply PWA interface connections.

Table 4-5. Power Supply PWA Interface Connections			
Connector	nnector 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 (see Figure 9-11) contains part of the CPU subsystem circuitry, including system program and data memories (PROM and SRAM), external communication interface circuits, and rear instrument user controls. The peripheral PWA is designed to be field replaceable, to facilitate software upgrades or additional external interfaces.

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

See Section 4.2.1 for a functional description, and see Table 4-6 for peripheral PWA interface connections.

Table 4-6. Peripheral PWA Interface Connections			
Connector	Туре	Interface	
P1	96 pin receptacle	Board-to-board connection to CPU PWA	
J26	15 pin D-sub	DataPort	
J28	3 pin phone jack	Nurse call jack	

4.3.3 **CPU PWA**

The CPU PWA (see Figure 9-12) contains most of the CPU subsystem functions, with the exception of main memory and communications ports, which are located on the peripheral PWA. The CPU PWA also accommodates system interconnect.

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

See Section 4.2.1 for a functional description, and see Table 4-7 for CPU PWA interface connections.

Table 4-7. CPU PWA Interface Connections			
Connector	Туре	Interface	
J7	96 pin header	Connection to peripheral PWA (CPU bus; rear panel I/O; 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	Lock box connector	
J20	4 pin header	CCFT backlight connector	
J24	2 pin header	Main audible alarm connector	

4.3.4 DRIVER PWA

The driver PWA (see Figure 9-13) 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 Section 4.2.3 for a functional description, and see Table 4-8 for driver PWA interface connections.

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

4.3.5

SWITCH PWA

The switch PWA (see Figure 9-14) contains the plunger translation position sensor, which 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.

4.3.6

APP PWA

The APP (air, pressure, and pin) PWA (see Figure 9-15) is mounted in the mechanism sub-chassis. The APP PWA 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 Section 4.2.3 for a functional description, and see Table 4-9 for APP PWA interface connections.

Table 4-9. APP PWA Interface Connections			
Connector	Туре	Interface	
J15	20 pin SMT Flat flex cable to driver PWA		
J11	10 pin SMT	Pressure sensor connector	

$\overline{4.4}$

REMOTE MOUNTED PERIPHERALS

The following sections describe the major remote mounted peripherals.

4.4.1 LCD

The infuser uses a graphic LCD module with a CCFT. The CCFT provides a backlight source for the LCD. The LCD requires a nominal -16 $V_{\rm DC}$ supply for contrast control, which is controlled by the CPU. The infuser's graphic display data is shifted out to the LCD by the CPU LCD controller, which 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° .

4.4.2

SEALED LEAD ACID BATTERY

The infuser uses a nominal $6\,V_{DC}$ rechargeable sealed lead acid battery with a 4 amp-hour capacity.

$\overline{4.5}$

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 key 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 operates on a fluid displacement principle to volumetrically deliver fluid (see Figure 4-6 and Figure 4-7). See the system operating manual for a description of the major cassette functions.

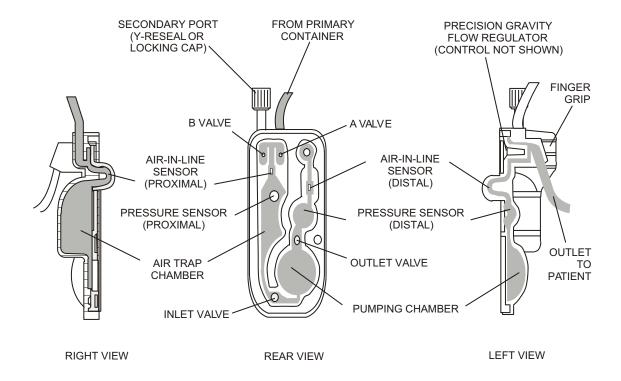
The pumping cycle begins when the outlet valve is opened and the inlet valve is closed. The plunger extends to deflect the cassette diaphragm and expel fluid. At the end of the pumping stroke, the outlet valve is closed, the inlet opens, the appropriate A or B valve opens, and the plunger retracts to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

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

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

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

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



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Figure 4-6. Major Elements of the Dual-Channel Cassette

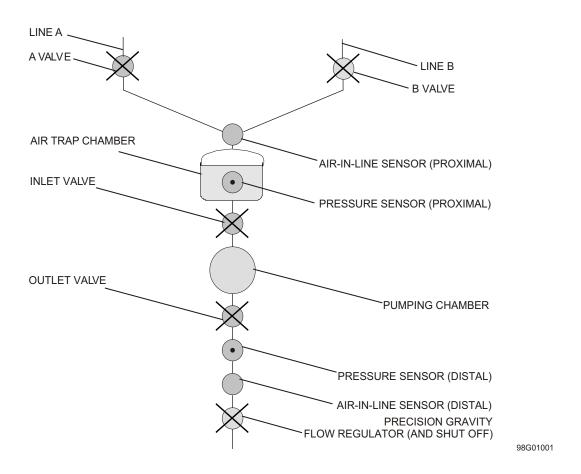


Figure 4-7. Fluid Path in the Cassette

4.5.2 MECHANISM ASSEMBLY

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

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

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 valve 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 (see Figure 4-8).

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.

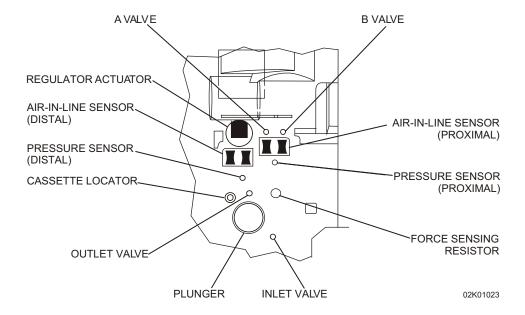


Figure 4-8. Mechanism Valve Pins and Sensor Locations

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 main components of the plunger drive subsystem are: plunger, lead screw and coupler, and stepper motor. When the infuser is turned on, the plunger moves from the retracted, PARK position to the HOME position. The cassette diaphragm is engaged. The stepper motor rotates approximately 1 2/3 revolutions per 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 4 THEORY OF OPERATION

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Section 5

MAINTENANCE AND SERVICE TESTS

A complete maintenance program promotes infusion system longevity and trouble-free operation. Such a program should include routine maintenance, periodic maintenance inspection, and following any repair procedure, performance verification testing.

5.1 **ROUTINE MAINTENANCE**

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

5.1.1 CLEANING

Accumulation of dust or spilled fluids on the cassette door and housing can affect proper operation. The following cleaning procedures are designed to sustain longevity and promote trouble-free operation.

Follow hospital protocol for establishing the infuser cleaning schedule.

WARNING: DISCONNECT THE INFUSER FROM AC POWER PRIOR TO CLEANING THE DEVICE. FAILURE TO COMPLY WITH THIS

WARNING COULD RESULT IN ELECTRICAL SHOCK.

CAUTION: Do not immerse the infuser in liquids. Immersion could damage the device. Do not allow liquids to enter the electronics compartment. Do not spray cleaning solutions toward any openings in the device.

CAUTION: Certain cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Hospira may result in product damage and, potentially, void the product warranty. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride. Do not use solvents that are harmful to plastic.

CAUTION: To avoid damage to the device, cleaning solutions should be used only as directed in *Table 5-1*. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information.

Table 5-1. Cleaning Solutions			
Cleaning Solution	Manufacturer	Preparation	
Coverage™ HB	Steris Corporation	Per manufacturer's recommendation	
Dispatch™	Caltech Industries	Per manufacturer's recommendation	
Manu-Klenz®	Steris Corporation	Per manufacturer's recommendation	
Precise [™]	Caltech Industries	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	

- 1. Clean the exposed surfaces of the infusion system with a soft, lint-free cloth dampened with one of the cleaning solutions listed in *Table 5-1*, or a mild solution of soapy water.
- 2. Remove soap residue with clear water.

5.1.2 SANITIZING

Sanitize the external surfaces of the infuser using a cleaning solution listed in *Table 5-1*.

Note: Not all cleaning solutions are sanitizers. Check product labeling.

CAUTION: Do not sterilize the infuser using heat, steam, ethylene oxide (ETO), or radiation. These methods may cause the device to malfunction.

5.2

PERFORMANCE VERIFICATION TEST

The performance verification test (PVT) consists of the tests described in the following sections. The PVT can be used for diagnostic purposes during the troubleshooting of a malfunctioning infuser. The PVT should be used for performance verification before an infuser is placed back in service after repair. If any malfunction is detected as a result of the PVT, see *Table 6-3*.

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

EQUIPMENT REQUIRED

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

- Graduated cylinder, 25 mL, with 0.2 mL graduations (Type A)
- Sterile water or tap water in an IV bag/container
- Digital pressure meter (DPM), 0 to 50 psi (Fluke® Biomedical DPM3)
- Three-way stopcock, latex-free (List No. 3233-01)
- IV Set (List No. 11419)
- 21-gauge butterfly needle, latex-free (List No. 4492-01), or 18-gauge blunt cannula
- Safety analyzer (Fluke® Biomedical 232D)
- Digital multimeter (DMM) (Fluke® 187) (optional)
- Nurse call test cable (P/N 561-88416-001) (optional)

5.2.2

INSPECTION

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

Inspect the following areas for missing or damaged parts:

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

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

5.2.3 TEST SETUP

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

To set up the infuser for the PVT, proceed as follows:

- 1. Confirm the infuser and appropriate accessories are assembled.
- 2. Hang two sterile water containers at a height of $46 \text{ cm} \pm 15.3 \text{ cm}$ above the pumping chamber of the infuser.
- 3. Connect the infuser to AC power, and press the ON/OFF key to turn on the device.
- 4. Verify the infuser is in the **unlocked** mode. Toggling the [LOCKOUT] switch alternates between **unlocked** [DOWN] and **locked** [UP] modes.
- 5. Turn off the infuser.

5.2.4 SELF TEST

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

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

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

To perform the self test, see *Figure 5-1*, 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 beep sounds.
- 2. Without a cassette installed, turn on the infuser.
- 3. The LCD screen briefly displays the **SELF TEST** screen (see Figure 5-1).
 - Note: If the SELF TEST screen does not appear, contact Hospira.
- 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 1.9.2.
- 6. Open the cassette door and insert a primed cassette. Close the cassette door. The cassette test is complete when the "CASSETTE TEST IN PROGRESS" message disappears.
 - **Note:** The message "MECHANISM INITIALIZATION IN PROGRESS" may briefly appear prior to the "CASSETTE TEST IN PROGRESS" message.
- 7. A "NEW PATIENT?" message may appear. Press [YES], then turn off the infuser.

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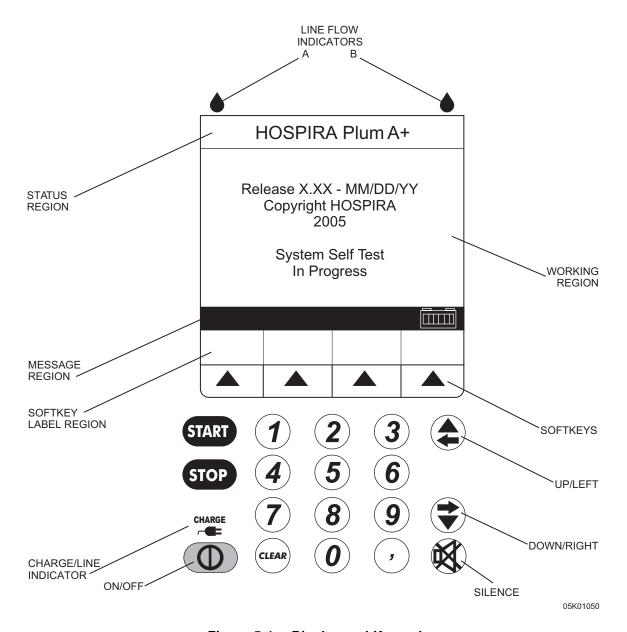


Figure 5-1. Display and Keypad

CASSETTE ALARM TEST

To perform the cassette alarm test, proceed as follows:

- 1. Verify the infuser is on. Insert an empty cassette and close the door.
- 2. Verify the "CASSETTE TEST FAIL" message is flashing on the display and the alarm sounds after the cassette test is complete.
- 3. Open the door and remove the cassette.
- 4. Turn off the infuser.

5.2.6

FREE FLOW TEST

To perform the free flow test, proceed as follows:

- 1. With a primed cassette installed, press the ON/OFF key to turn on the infuser.
- 2. A "NEW PATIENT?" message may appear. Press [YES].
- 3. Place the distal end of tubing into a collection container a minimum of 92 cm below the cassette.
- 4. With the cassette door closed, check the distal end of the tubing for fluid flow. Verify a minimal flow of fluid occurs (a few drops maximum).
- 5. Open the cassette door and check the distal end of the tubing for fluid flow. Verify a minimal flow of fluid occurs (a few drops maximum).
 - **Note:** A small amount of fluid may be expelled from the cassette when opening or closing the door.
- 6. Close the cassette door.

5.2.7

DISPLAY TEST

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

- 1. Verify the LCD backlight is illuminated and the display is clearly legible at eye level from approximately 46 cm.
- 2. With the infuser in the **DELIVERY** screen, press the [OPTIONS/VOL INF] softkey to select the **OPTIONS** screen.
- 3. Select **Lighting/Contrast**, and press [CHOOSE].
- 4. Press the [DECREASE SETTING] and [INCREASE SETTING] softkeys to change backlight intensity. Verify backlight intensity decreases and increases.
- 5. Select **Display Contrast**.
- 6. Press [DECREASE SETTING] and [INCREASE SETTING] to change display contrast. Verify the display contrast decreases and increases.
- 7. Press the [CANCEL] softkey to return to the **OPTIONS** screen.
- 8. Press the [BACK] softkey to return to the **DELIVERY** screen.

KEYPAD VERIFICATION/FUNCTIONAL TEST

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

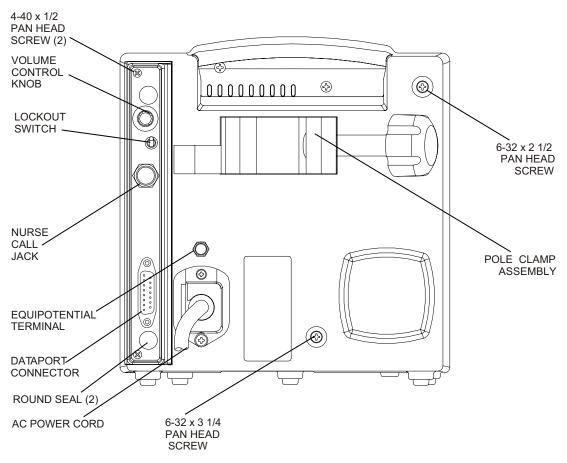
- 1. With the infuser in the **DELIVERY** screen, press the [A] softkey to select line A.
- 2. Verify the **PROGRAM** screen is displayed.
- 3. Enter a rate of 123 mL/hr and VTBI of 4567.
- 4. Press [START] and verify the "CONFIRM PROGRAM?" message is displayed. If rate and VTBI are correct, press [YES].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

5.2.9

ALARM LOUDNESS TEST

To perform the alarm loudness test, proceed as follows:

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



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Figure 5-2. Rear View

LOCKOUT SWITCH TEST

To perform the lockout switch test, proceed as follows:

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

5.2.11

PROXIMAL OCCLUSION TEST

To perform the proximal occlusion test, proceed as follows:

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

PROXIMAL AIR-IN-LINE TEST

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

1. Install the special cassette marked **proximal**, and close the cassette door.

Note: Confirm the special cassette proximal bubble sensor tips are removed.

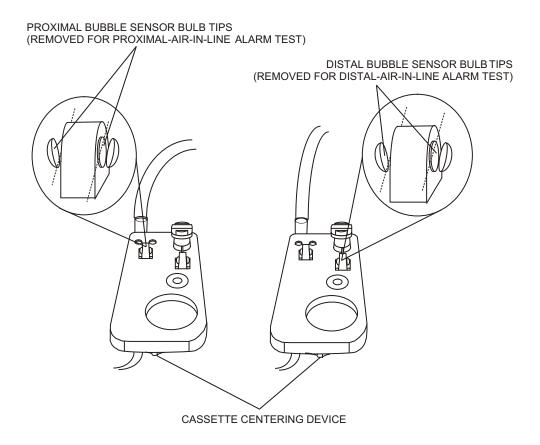
- 2. A "NEW PATIENT?" message may appear. Press [YES].
- 3. Press the [A] softkey to select line A.
- 4. Enter a rate of 400 mL/hr and VTBI of 50 mL.
- 5. Press [START] and verify the "CONFIRM PROGRAM?" message is displayed. If rate and VTBI are correct, press [YES].
- 6. Verify fluid is pumping, the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

5.2.13

DISTAL AIR-IN-LINE TEST

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

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



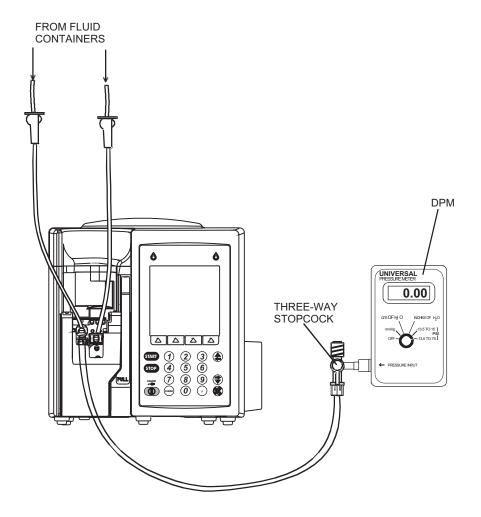
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Figure 5-3. Special Cassettes with Bubble Sensor Tips Removed

DISTAL OCCLUSION TEST

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

- 1. Install the cassette and connect the distal tubing to the DPM through a three-way stopcock as illustrated in *Figure 5-4*. Close the cassette door.
 - **Note:** A reflux valve may be attached between the stopcock and the DPM to keep moisture out of the DPM.
 - **Note:** The height of the DPM must be 0 ± 30.5 cm from the midline of the pumping chamber.
- 2. Turn on the infuser.
- 3. A "NEW PATIENT?" message may appear. Press [YES].
- 4. Press [OPTIONS/VOL INF] to select the **OPTIONS** screen.
- 5. Select **Pressure/Post Infusion Rate**, and press [CHOOSE].
- 6. Verify the distal pressure limit is set at 6 psi. If the pressure limit is not 6 psi, enter 6, and press [ENTER].
- 7. Press the [A] softkey to select line A.
- 8. Enter a rate of 40 mL/hr and VTBI of 50 mL.
- 9. Open the three-way stopcock to air.
- 10. Press [START] and verify the "CONFIRM PROGRAM?" message is displayed. If rate and VTBI are correct, press [YES].
- 11. Verify fluid is pumping, the message "PUMPING" is displayed in the line A status bar, and the line A LED flashes.
- 12. Set the three-way stopcock to measure pressure.
- 13. Verify the distal occlusion audible alarm occurs at 6 psi ± 3 psi. Verify the **DISTAL OCCLUSION** message is flashing on the screen.
- 14. Open the three-way stopcock to air.
- 15. Open and close the door. Press [NO] at the "NEW PATIENT?" prompt.
- 16. Press [OPTIONS/VOL INF] to select the **OPTIONS** screen.
- 17. Select Pressure/Post Infusion Rate and press [CHOOSE].
- 18. Select **Distal Pressure Limit**. Enter 10 psi, and press [ENTER].
- 19. Set the three-way stopcock to measure pressure, then press [START].
- 20. Verify the distal occlusion audible alarm occurs at 10 psi ± 3 psi. Verify the **DISTAL OCCLUSION** message is flashing on the screen.
- 21. Open the door and remove the cassette.



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Figure 5-4. Distal Occlusion Test Setup

DELIVERY ACCURACY TEST

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

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

To perform the delivery accuracy test, proceed as follows:

- 1. Open the cassette door and insert a primed cassette. Close the cassette door.
- 2. A "NEW PATIENT?" message may appear. Press [YES].
- 3. Install an 18-gauge blunt cannula or a 21-gauge needle to the distal end of the tubing. Verify the fluid container is 46 to 61 cm above the pumping chamber. Verify all lines are unclamped.
- 4. Place the distal output end of tubing into the graduated cylinder.
- 5. Press the [A] softkey to select line A.
- 6. Enter a rate of 200 mL/hr and VTBI of 10 mL.
- 7. Press [START] and verify the "CONFIRM PROGRAM?" message is displayed. If rate and VTBI are correct, press [YES].
- 8. Verify fluid is pumping, the message "PUMPING" is displayed in the line A status bar, and the line A LED flashes.
- 9. Press the [B] softkey to select line B.
- 10. Verify the infuser is in the PIGGYBACK delivery mode. If necessary, press [CHANGE MODE] to change the delivery mode.
- 11. Enter a rate of 200 mL/hr and VTBI of 10 mL.
- 12. Press [START] and verify the "CONFIRM PROGRAM?" message is displayed. If rate and VTBI are correct, press [YES].
- 13. Verify fluid is pumping, the message "PUMPING" is displayed in the line B status bar, and the line B LED flashes.
- 14. Verify the "KVO" message flashes on the display and an audible alarm sounds when total delivery is complete on line A.
- 15. Press [STOP] and verify the volume delivered is 20 mL \pm 1 mL.

5.2.16

NURSE CALL TEST



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

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

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

5.2.17

ELECTRICAL SAFETY TEST

To perform the electrical safety test, proceed as follows:

- 1. Connect the AC power cord to a safety analyzer.
- 2. Connect the safety analyzer ground lead to the ground test-point located on the rear of the infuser.
- 3. Check the leakage current with the safety analyzer. Leakage current (both open and closed ground) must not exceed 100 microamperes AC_{rms} .
- 4. Measure the resistance of the AC connector ground lug with the safety analyzer. Resistance should not exceed 0.1 Ω

5.2.18

END OF THE PVT

If all performance verification tests have been successful, proceed as follows:

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

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

5.3

PERIODIC MAINTENANCE INSPECTION

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

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

5.4 BATTERY OPERATION OVERVIEW

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

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

Factors that most commonly affect battery life are the depth and frequency of discharge and the length of the recharge period. As a general rule, the more often the battery is discharged and recharged, the sooner it will need replacement. The primary cause of damage is leaving the battery in a less than fully charged state for any period of time. Battery damage can occur in a matter of hours and cause a permanent loss of battery capacity. The amount of lost capacity depends on the degree of discharge, the storage temperature, and the length of time the battery was stored in a discharged state.

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

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

CAUTION: As soon as the low battery alarm occurs, connect the infuser to AC power.

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

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

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

Section 6

TROUBLESHOOTING

This section contains information on technical assistance, warning messages, alarm messages and error codes, and troubleshooting procedures for the Plum $A+^{\otimes}$ infusion system.

6.1

TECHNICAL ASSISTANCE

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

1-800-241-4002

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

Send all authorized, prepaid returns within the United States to the following address:

Hospira, Inc.
Technical Support Operations
755 Jarvis Drive
Morgan Hill, California 95037

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 16 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 remains	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		
Warning: Charger Service	A hardware problem with the battery charging circuit is detected Charging circuitry is not behaving as expected	Press the SILENCE key		

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 1.9.1).

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

1	Table 6-2. Operational Alarm Messages and Corrective Actions				
Alarm Code	Alarm	Description	Possible Cause	Corrective Action	
N181 or E181 (OD1)	Distal Occl	Negative distal occlusion, non-delivery	Distal occlusion detected during non-delivery	Backprime the cassette and restart the infuser	
N182 or E182 (OP2)	Prox. Occl B, Air or Prox. Occl B	Negative proximal occlusion B, non-delivery	Proximal occlusion detected on line B during non-delivery	Backprime the cassette and restart line B or Stop all lines, backprime the cassette, and restart all lines	
N183 or E183 (OP2)	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 (OP1)	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 (OP1)	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 (OD1)	Distal Occl	Peak distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser	
N187 or E187 (OD1)	Distal Occl	Negative distal occlusion, delivery	Distal occlusion detected during delivery	Fix occlusion, and restart the infuser	

Т	Table 6-2. Operational Alarm Messages and Corrective Actions			
Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N188 or E188 (OP2)	Prox. Occl B, Air	Negative proximal occlusion B, delivery	Proximal occlusion detected during delivery on line B	Fix occlusion, and restart line B or Stop all lines, fix occlusion and restart the infuser
N189 or E189 (OP2)	Prox. Occl B, Air	Peak proximal occlusion B, delivery	Proximal occlusion detected during delivery on line B	Fix occlusion, and restart line B or Stop all lines, fix occlusion, and restart the infuser
N190 or E190 (OP1)	Prox. Occl A, Air	Negative proximal occlusion A, delivery	Proximal occlusion detected during delivery on line A	Fix occlusion, and restart line A or Stop all lines, fix occlusion, and restart the infuser
N191 or E191 (OP1)	Prox. Occl A, Air	Peak proximal occlusion A, delivery	Proximal occlusion detected during delivery on line A	Fix occlusion, and restart line A or Stop all lines, fix occlusion, and restart the infuser
N230 or E230 (APT)	Prox. Air Total	Proximal air-in-line total	500 μL of air has entered the cassette	Backprime the cassette and restart the infuser or Remove and manually reprime the cassette and restart the infuser
N231 or E231 (APB)	Prox. Air on B, Backprime	Proximal air-in-line on line B	500 μL of air has entered the cassette on line B	Backprime the cassette and restart line B or Remove and manually reprime the cassette and restart the infuser

	Table 6-2. Operational Alarm Messages and Corrective Actions			
Alarm Code	Alarm	Description	Possible Cause	Corrective Action
N232 or E232 (APA)	Prox. Air on A, Backprime	Proximal air-in-line on line A	500 μL of air has entered the cassette on line A	Backprime the cassette and restart line A or Remove and manually reprime the cassette and restart the infuser
N233 or E233 (ADC)	Distal air Cumulative	Distal air cumulative	500 μL of air detected in the last 5.3 mL of fluid delivered	Remove and manually reprime the cassette and restart the infuser
N234 or E234 (ADB)	Distal air bolus	Distal air bolus	100 μL bolus of air detected at distal sensor	Remove and manually reprime the cassette and restart the infuser
N250 or E250 (DCO1)	Door opened while pumping	Door opened while pumping	Door opened while pumping	Turn off the infuser or Insert the cassette and close the door
N251 or E251 (CS1)	Valve/cass test fail	Valve/cassette test failure	Valve/cassette fails the leak test	Replace cassette and retest or Backprime and retest
N252 or E252 (BDP)	Depleted battery	Low battery	The battery terminal voltage is less than 5.45 V	Connect the infuser to AC power or Recharge or replace the battery
N253 or E253 (LOV)	Lockout violation	Hard lockout violation	The use of the [STOP] key or an attempt to open the door while the lockout switch is locked	Unlock the lockout switch
N254 or E254 (FPL)	Lockout enabled	Keypad locked	Any action not resulting in stopping of delivery while the lockout switch is locked	Unlock the lockout switch

Т	Table 6-2. Operational Alarm Messages and Corrective Actions				
Alarm Code	Alarm	Description	Possible Cause	Corrective Action	
N255 (SLV)	Lockout violation	Soft lockout violation	The use of the [STOP] key or an attempt to open the door while the lockout switch is locked	Unlock the software lockout switch	
N256 (SLV)	Lockout enabled	Soft lockout enabled	Any action not resulting in stopping of delivery while the lockout switch is locked	Unlock the software lockout switch	

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.

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 1.9.2)	
E301	Audio alarm failure	Piezo is off but sensed on or Piezo is on but sensed off	Turn power off, then on, to reset the infuser Replace piezo alarm (see Section 7.2.12.5) Replace CPU PWA (see Section 7.2.12.4) Reset time and date, if required (see Section 1.9.2)	
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 1.9.2)	

	Table 6-3.	rror Codes Requiring Technic	al Service
Error Code	Malfunction	Possible Cause	Corrective Action
E320	Battery charge current out of range	Battery charge current is out of range after 8 hours	Replace battery (see Section 7.2.4) Replace power supply PWA (see Section 7.2.12.1) Reset time and date, if required (see Section 1.9.2)
E321	Battery not charging	Battery charging timed out Complete battery discharge has occurred	Charge battery for additional 8 hours Replace battery
E322	Battery current calibration value out of range	Battery integrator calibration value is out of range	(see Section 7.2.4) Replace power supply PWA (see Section 7.2.12.1) Reset time and date,
E323	Battery trickle charge current out of range	Battery trickle charge current is out of range	if required (see Section 1.9.2)
E324	Supply overvoltage	An overvoltage condition is detected in the charging circuit	
E325	Battery overvoltage	An overvoltage condition is detected in the battery	
E326	Battery disconnected	Battery disconnected while the infuser is on	Check for loose battery connections Replace battery (see Section 7.2.4) Reset time and date, if required (see Section 1.9.2)
E327	Brownout condition	Brownout condition detected	Replace power supply PWA (see Section 7.2.12.1) Reset time and date, if required (see Section 1.9.2)
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 1.9.2)
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 1.9.2)

	Table 6-3. Error Codes Requiring Technical Service			
Error Code	Malfunction	Possible Cause	Corrective Action	
E342	Display failure	Defective display	Replace display assembly (see Section 7.2.12.3) Reset time and date, if required (see Section 1.9.2)	
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)	
E344	Distal air sensor failure 2	With the cassette inserted, the distal air sensor self test detects sensor out of range	Reset time and date, if required (see Section 1.9.2)	
E345	Distal pressure sensor failure 1	Distal pressure sensor failed while the infuser is off		
E346	Distal pressure sensor failure 2	Distal pressure sensor failed while the infuser is on		
E347	Hardware watchdog failure	Hardware watchdog failure	Replace CPU PWA (see Section 7.2.12.4) Reset time and date, if required (see Section 1.9.2)	
E378	I/O valve phase loss	Generic I/O valve failure	Turn power off, then on, to reset the infuser Replace mechanism assembly (see Section 7.2.12.6) Reset time and date, if required (see Section 1.9.2)	
E379	L/S valve phase loss	Generic L/S valve failure	Turn power off, then on, to reset the infuser	
E380	Plunger motor phase loss	Generic plunger motor failure	Replace mechanism assembly (see Section 7.2.12.6) Reset time and date, if required (see Section 1.9.2)	

	Table 6-3. Error Codes Requiring Technical Service			
Error Code	Malfunction	Possible Cause	Corrective Action	
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)	
E431	Proximal air sensor failure 2	Proximal air sensor self test detects liquid with cassette removed	Reset time and date, if required (see Section 1.9.2)	
E432	Proximal pressure sensor 1	Proximal pressure sensor failed while the infuser is off		
E433	Proximal pressure sensor 2	Proximal pressure sensor failed while the infuser is on		
E434	RAM failure	RAM failure	Turn power off, then on, to reset the infuser Replace peripheral assembly (see Section 7.2.6) Reset time and date, if required (see Section 1.9.2)	
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 1.9.2)	
E436	ROM failure	ROM checksum failure	Turn power off, then on, to reset the infuser Replace peripheral assembly (see Section 7.2.6) Reset time and date, if required (see Section 1.9.2)	
E437	Software failure	Generic software failure	Turn power off, then on, to reset the infuser	
E438	Stack out-of-range failure	Stack out-of-range failure	Replace CPU PWA (see Section 7.2.12.4) Reset time and date, if required (see Section 1.9.2)	

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)	
E440	Power hold stuck	Power hold signal stuck Power cannot be turned off	Reset time and date, if required (see Section 1.9.2)	
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 1.9.2)	
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 1.9.2)	
E445	RTC memory failure	Real-time clock memory is corrupt	Turn power off, then on, to reset the infuser Reset time and date, if required (see Section 1.9.2)	
E446	CPU timer failure	CPU timer 1 and timer 2 measured times disagree	Replace CPU PWA (see Section 7.2.12.4)	
E447	Battery ADC reading failure	16 consecutive readings have been either all zero or the max value	Reset time and date, if required (see Section 1.9.2)	
E448	SEEP write failure	SEEP data write failed	Replace mechanism assembly	
E449	SEEP calibration data corrupted	Calibration data block corrupted	(see Section 7.2.12.6) Replace CPU PWA (see Section 7.2.12.4) Replace CPU/driver cable (see Section 7.2.12.6) Reset time and date, if required (see Section 1.9.2)	
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 1.9.2)	

Table 6-3. Error Codes Requiring Technical Service				
Error Code	Malfunction	Possible Cause	Corrective Action	
E451	Inaccurate delivery	Over/under delivery detected	Turn power off, then on, to reset the infuser	
E452	Software failure	Miscellaneous software failures	Reset time and date, if required (see Section 1.9.2) If error codes recur, contact Hospira	
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 7.2.12.6) Reset time and date, if required (see Section 1.9.2)	
E455	Invalid device configuration	Incorrect flash memory on peripheral PWA	Turn power off, then on, to reset the infuser Replace peripheral assembly (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 peripheral assembly (see Section 7.2.6)	
E457	Drug library corrupted	CRC failure on drug library	Reload the library (see the system operating manual)	

Note: 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 Technical Support Operations (see Section 6.1).

TROUBLESHOOTING PROCEDURES

This section details recommended procedures for problems not associated with malfunction alarms. Before performing any troubleshooting procedure, turn the infuser off, then on.

Allow the self test to complete and proceed as follows:

- 1. If a malfunction exists, carefully inspect the infuser for damage as described in *Section 5.2.2*.
- 2. If an infuser inspection has not disclosed a malfunction, perform the PVT in *Section 5.2*. See *Table 6-4* for section reference, probable cause, and corrective actions.
- 3. If, after completing step 1 and step 2, a malfunction has not been located, or if the infuser persistently fails, contact Hospira (see Section 6.1).

Table 6-4. Troubleshooting with the PVT							
Test Failure	Probable Cause	Corrective Action					
Self test (Section 5.2.4)	Cassette not properly installed	Reseat cassette					
	Defective CPU PWA	Replace CPU PWA (see Section 7.2.12.4)					
Cassette alarm test (Section 5.2.5)	Cassette not properly seated	Reseat cassette					
	Defective cassette	Replace cassette					
Free flow test (Section 5.2.6)	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 5.2.7)	Defective display assembly	Replace display assembly (see Section 7.2.12.3)					
Keypad verification/ functional test (Section 5.2.8)	Defective keypad	Replace keypad (see Section 7.2.12.2)					
Alarm loudness test (Section 5.2.9)	Defective CPU	Replace CPU PWA (see Section 7.2.12.4)					
	Defective peripheral PWA	Replace peripheral assembly (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					
Lockout switch test (Section 5.2.10)	Defective peripheral PWA	Replace peripheral assembly (see Section 7.2.6)					
Proximal occlusion test	Closed proximal clamp	Open clamp					
(Section 5.2.11)	Cassette not properly primed	Re-prime cassette					
	Defective cassette	Replace cassette					
	Dirty sensor pin	Clean sensor pin					
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.12.6)					
Proximal air-in-line test	Defective special cassette	Replace special cassette					
(Section 5.2.12)	Dirty sensors	Clean sensors					
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.12.6)					
Distal air-in-line test	Defective special cassette	Replace special cassette					
(Section 5.2.13)	Dirty sensors	Clean sensors					
	Defective APP PWA	Replace mechanism assembly (see Section 7.2.12.6)					
Distal occlusion test (Section 5.2.14)	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	Set not properly primed	Re-prime cassette					
(Section 5.2.15)	Damaged or faulty cassette	Replace cassette					
	Defective mechanism assembly	Replace mechanism assembly (see Section 7.2.12.6)					
Electrical safety test (Section 5.2.17)	Defective AC power cord	Replace AC power cord (see Section 7.2.5)					

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 spare parts price list and are identified in *Figure 9-1*. *Table 9-2* identifies each part by an index number that correlates to *Figure 9-1*.

To request a copy of the current spare parts price list, contact Hospira Technical Support Operations (see Section 6.1), or to view the catalog online, visit the website at:

www.hospiraparts.com

For convenient reference, insert a copy of the spare parts price list here.

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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.

$\overline{7.2.1}$

SAFETY AND EQUIPMENT PRECAUTIONS

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

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

WARNING: UNLESS OTHERWISE INDICATED, DISCONNECT THE INFUSER

FROM AC POWER BEFORE PERFORMING ADJUSTMENTS

OR REPLACEMENT PROCEDURES.

CAUTION: Use proper ESD grounding techniques when handling components. Wear an antistatic wrist strap and use an ESD-protected workstation. Store PWAs in antistatic bags before placing them 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 - Wide-head pliers

- Set of Phillips® screwdrivers - Diagonal cutters

- Set of standard and metric nutdrivers - X-acto[®] knife

- Metric 10 mm wrench - Mild solvent

- Custom nutdriver (P/N 519-95056-001) - Lint-free cloth

- Long needle nose pliers

$\overline{7.2.3}$

RUBBER FOOT PAD REPLACEMENT

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

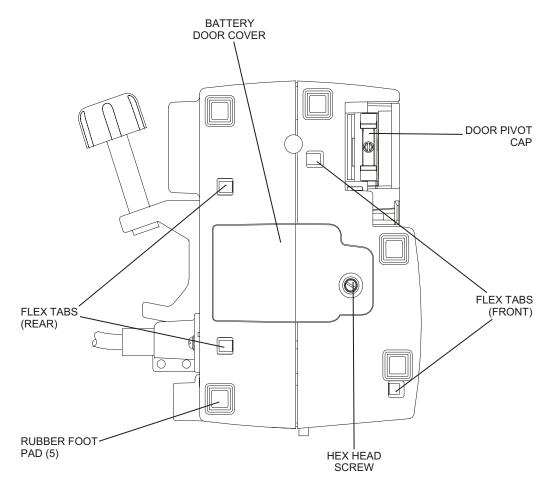
The replacement part for this procedure is:

Pad, Rubber Foot

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

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Place the infuser 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 rubber foot pad replacement, perform the PVT in Section 5.2.



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Figure 7-1. Bottom View

7.2.4

BATTERY, BATTERY DOOR, AND DOOR PAD REPLACEMENT

Recommended tools for this procedure are a medium size flat blade screwdriver, an X-acto knife, mild solvent, and a lint-free cloth.

The replacement parts for this procedure are:

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

To replace the battery, battery door, and door pad, see *Figure 7-2*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power. The AC LED indicator will turn off.
 - **Note:** Wait five minutes for the microprocessor to save data and complete the turn off sequence before unplugging the battery.
- 2. Place the infuser on its side.
- 3. Using the flat blade screwdriver, remove the screw that secures the battery door to the infuser, and remove the door.
- 4. Inspect the battery door and door pad for damage. Replace the door, if required.
- 5. If the battery door pad is defective, remove it and clean the door with mild solvent. Dry the battery door thoroughly, and install the replacement pad on the door.
- 6. Disconnect the battery harness from the charger circuit cable. Carefully pull the battery harness wires and connector outside the enclosure, and remove the battery.
- 7. Connect the replacement battery harness to the charger circuit cable, and insert the replacement battery into the enclosure.
 - **Note:** 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.
- 8. Replace the battery door using the screw that was removed in step 3.
- 9. Press the ON/OFF key with the infuser disconnected from AC power, and verify the front panel battery symbol illuminates.
- 10. Access the **BIOMED SETTINGS** screen and press [CHANGE BATTERY] (see Figure 1-2).

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

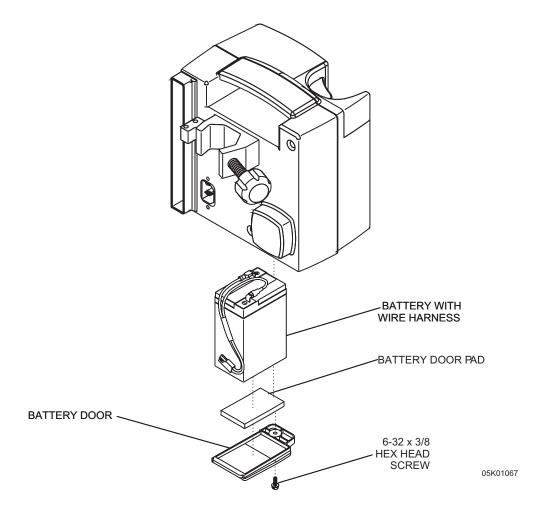


Figure 7-2. Battery, Battery Door, and Door Pad

$\overline{7.2.5}$

AC POWER CORD, RETAINER, AND VELCRO STRAP REPLACEMENT

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, #4 Washer, Lock, #4

To replace the AC power cord, retainer, and Velcro strap, see *Figure 7-3*, then 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.
 - **Note:** Remove the AC power cord from its receptacle by grasping the plug. Do not pull the cord.
- 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 device to AC power.
- 9. Press the ON/OFF key and verify the infuser powers on.

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

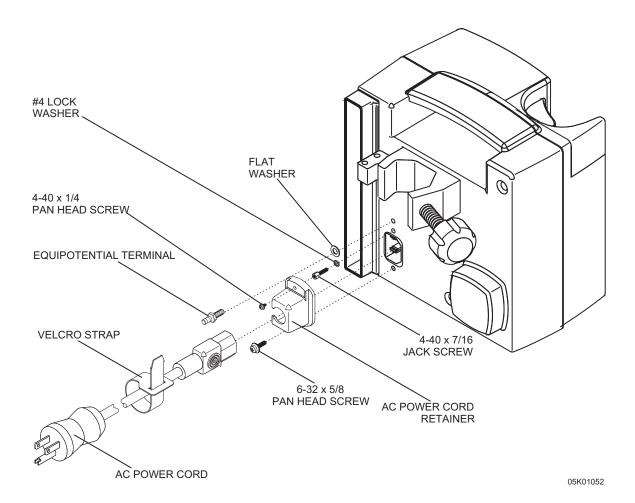


Figure 7-3. AC Power Cord, Retainer, and Velcro Strap

7.2.6

PERIPHERAL ASSEMBLY REPLACEMENT

CAUTION: Peripheral assembly replacement should only be performed after receiving approval from Hospira Technical Support Operations (see Section 6.1).

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

The replacement parts for this procedure are:

Assembly, Peripheral

Screw, 4-40 x 1/2, Pan Head, Square Cone, Phillips

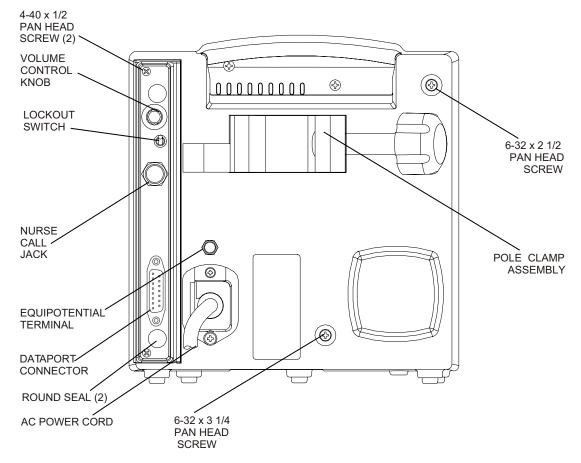
CAUTION: Use proper ESD grounding techniques when handling components. Wear an antistatic wrist strap and use an ESD-protected workstation. Store the PWA in an antistatic bag before placing it on any surface.

Note: Replacing the peripheral assembly does not change the existing biomed settings.

To replace the peripheral assembly, see *Figure 7-4* and *Figure 7-5*, then 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. Using the Phillips screwdriver, remove the two screws from the peripheral assembly.
- 5. Carefully pull the assembly away from the infuser.
 - **Note:** When removing the peripheral assembly, note the placement guides where the peripheral interface PWA rests.
- 6. Install the replacement peripheral assembly in the exact reverse order of removal.
 - Note: Verify the peripheral assembly is placed properly between the guides and fits correctly into the CPU PWA.
- 7. Reinstall the battery and connect the device to AC power.
- 8. Turn on the infuser, and verify completion of the self test (see Section 1.8.3).

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



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Figure 7-4. Rear View

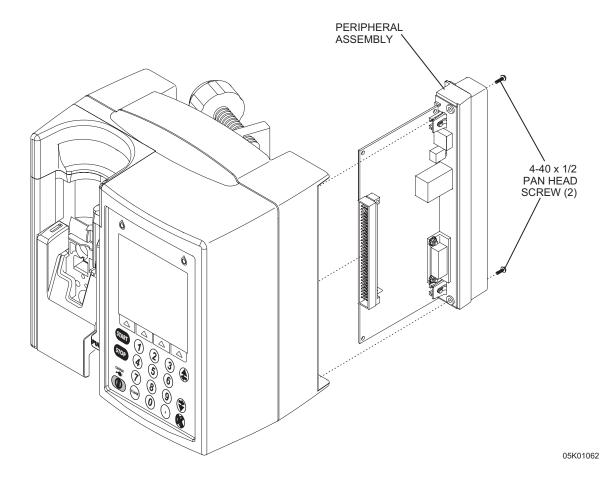


Figure 7-5. Peripheral Assembly Replacement

7.2.7 PERIPHERAL ASSEMBLY COMPONENT REPLACEMENT

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

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

To replace the peripheral assembly components, see *Figure 7-6*, then proceed as detailed in the following sections.

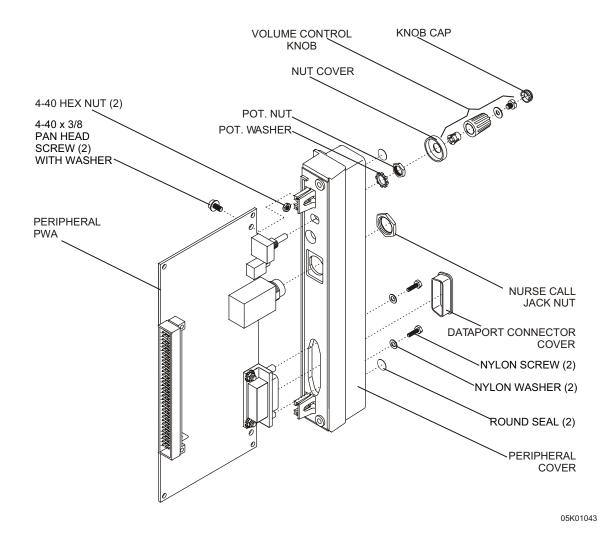


Figure 7-6. Peripheral Assembly Components

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 Cap, Knob Cover, Nut

To replace the volume control knob, see *Figure 7-4* and *Figure 7-6*, then 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 peripheral assembly as described in Section 7.2.6.
- 5. Using the X-acto knife, lift the volume control knob end cap away from the knob, exposing a flat head screw.
- 6. Using the flat blade screwdriver, remove the screw that secures the knob.
- 7. Using long needle nose pliers, remove the volume control knob.
- 8. Install the replacement volume control knob in the exact reverse order of removal.
- 9. Replace the peripheral assembly in the exact reverse order of removal.
- 10. Reinstall the battery and connect the device to AC power.

To verify successful volume control knob replacement, perform the PVT in Section 5.2.

7.2.7.2

PERIPHERAL COVER REPLACEMENT

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

The replacement parts for this procedure are:

Cover, Peripheral
Cover, DataPort Connector
Seal, Round
Screw, 4-40 x 3/8, Hex Head, Nylon
Screw, 4-40 x 3/8, Pan Head, Phillips, with Washer
Washer, Flat, .128 Dia., Nylon
Nut, Hex, Nurse Call Jack
Nut, Hex, 4-40

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

To replace the peripheral cover, see *Figure 7-6*, then 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 peripheral assembly as described in Section 7.2.6.
- 5. Remove the volume control knob as described in Section 7.2.7.1.
- 6. Using the 5/16 nutdriver, remove the nut that secures the potentiometer to the peripheral cover. Using the needle nose pliers, remove the lock washer.
- 7. Using the custom nutdriver, remove the hex nut that secures the nurse call jack to the peripheral cover.
- 8. Remove and inspect the DataPort connector cover and replace, if required.
- 9. Inspect the seals and replace, if required.
- 10. Using the Phillips screwdriver, remove the screws that secure the peripheral PWA to the cover.
- 11. Install the replacement peripheral cover in the exact reverse order of removal.
- 12. Install the volume control knob and nurse call jack nut in the exact reverse order of removal.
- 13. Install the peripheral assembly as described in Section 7.2.6.
- 14. Reinstall the battery and connect the device to AC power.
- 15. Turn on the infuser, and verify completion of the self test (see Section 1.8.3).

7.2.8

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

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

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 them on any surface.

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

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Using the Phillips screwdriver, remove the screws from the peripheral assembly and carefully pull the assembly away from the infuser (see Section 7.2.6).
- 3. Remove the battery as described in Section 7.2.4.
- 4. Remove the AC power cord and retainer, and the equipotential terminal as described in *Section 7.2.5*.
- 5. Using the 3/16 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, depress the two flex tabs that secure the rear enclosure while lifting up the rear enclosure. Remove the rear enclosure.

- 9. Using the Phillips screwdriver, remove the screws in the infuser handle, and remove the shoe from the front enclosure.
- 10. Carefully place the infuser face up.
- 11. Using the flat blade screwdriver, depress the flex tabs that secure the front enclosure while lifting up the front enclosure, and remove the front enclosure.

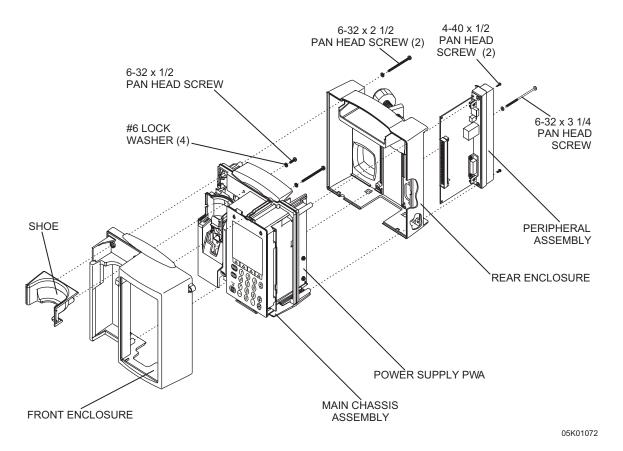


Figure 7-7. Separating the Front Enclosure, Main Chassis, and Rear Enclosure

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, and 3/16 nutdriver.

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 them on any surface.

The replacement parts for this procedure are:

Enclosure, Front
Enclosure, Rear
Chassis, Main
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, #6

To replace the front enclosure, rear enclosure, or main chassis assembly, see *Figure 7-7*, then 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 assembly 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 assembly, remove the specific components described in *Section 7.2.12*.
- 7. Reassemble the front enclosure, rear enclosure, or main chassis assembly components.
 - **Note:** Assure 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.
- 8. Join the front enclosure, main chassis assembly, and rear enclosure in the exact reverse order of separation.
- 9. Reinstall the battery and connect the device to AC power.

To verify successful front enclosure, rear enclosure, or main chassis replacement, perform the PVT in *Section 5.2*.

7.2.9.1

SHOE GASKET REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

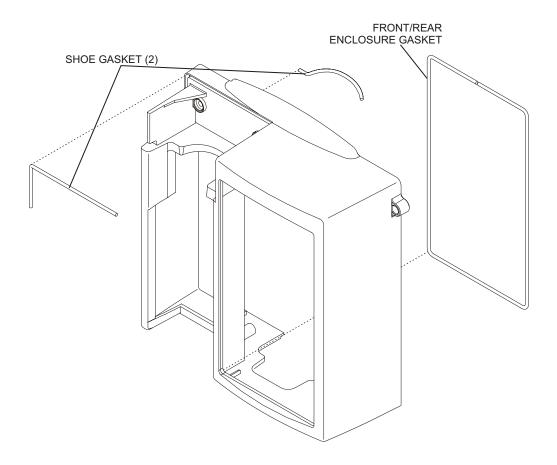
The replacement part for this procedure is:

Gasket, Shoe

To replace the shoe gaskets, see *Figure 7-8*, then 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 assembly 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 7-8*.
- 5. Install the replacement shoe gaskets in the exact reverse order of removal.
- 6. Join the front enclosure, main chassis assembly, and rear enclosure in the exact reverse order of separation.
- 7. Reinstall the battery and connect the device to AC power.

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



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Figure 7-8. Front Enclosure Gaskets

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 7-8*, then 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 assembly as described in *Section 7.2.8*.
- 4. 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, main chassis assembly, and rear enclosure in the exact reverse order of separation.
- 7. Reinstall the battery and connect the device to AC power.

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

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 7-9*, then proceed as detailed in the following sections.

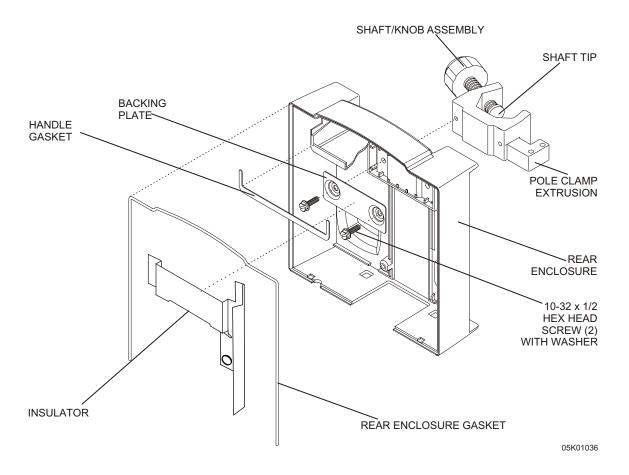


Figure 7-9. Rear Enclosure Components

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 7-9*, then 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 rear enclosure from the main chassis assembly 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 assembly.
- 5. Install the replacement backing plate and extrusion, using the screws that were removed in step 2.
- 6. Install the replacement insulator onto the backing plate.

CAUTION: Assure 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 rear enclosure and main chassis assembly in the exact reverse order of separation.
- 8. Reinstall the battery and connect the device to AC power.

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

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 7-9*, then 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 the pole clamp shaft tip and replace the tip, if necessary.
- 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 replacement procedure, perform the PVT in Section 5.2.

7.2.10.3

REAR ENCLOSURE AND HANDLE GASKETS REPLACEMENT

The recommended tool for this procedure is needle nose pliers.

The replacement parts for this procedure are:

Gasket, Rear Enclosure Gasket, Handle

To replace the rear enclosure and handle gaskets, see *Figure 7-9*, then 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 rear enclosure and main chassis assembly as described in Section 7.2.8.
- 4. Remove the rear enclosure and handle gaskets from the rear enclosure assembly.
- 5. Install the replacement gaskets in the exact reverse order of removal.
- 6. Join the rear enclosure and main chassis assembly in the exact reverse order of separation.
- 7. Reinstall the battery and connect the device to AC power.

To verify successful rear enclosure and handle gaskets replacement, perform the PVT in Section 5.2.

7.2.11

MINIPOLE ASSEMBLY REPLACEMENT

The minipole assembly attaches to the infuser through two holes in the heatsink and is held in place by a cotter ring. This cotter ring passes through a hole near the end of the longer of the two vertical rods on the bag hanger and prevents the removal of the minipole assembly from the holes in the pole clamp (see Figure 7-10).

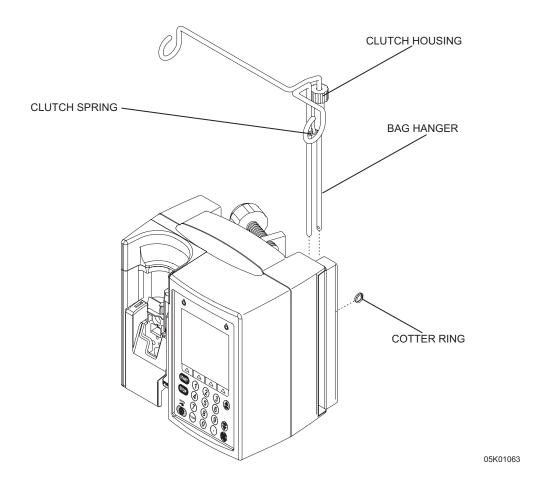


Figure 7-10. Minipole Assembly

7.2.11.1

COTTER RING REPLACEMENT

There are no recommended tools for this procedure.

The replacement part for this procedure is:

Ring, Cotter, Minipole

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

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Place the infuser face down on a soft surface.

- 3. Grasp the cotter ring with thumb and finger. Twist, rotate, and remove the cotter ring from the rod hole.
- 4. Replace the cotter ring in the exact reverse order of removal.

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

7.2.11.2

BAG HANGER REPLACEMENT

There are no recommended tools for this procedure.

The replacement part for this procedure is:

Hanger, Bag, Minipole

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

- 1. Remove the cotter ring as described in Section 7.2.11.1.
- 2. Remove the bag hanger from the pole clamp rod holes.
- 3. Insert the replacement bag hanger in the pole clamp rod holes.
- 4. Insert the cotter ring.

Replacement of the bag hanger is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during the replacement procedure, perform the PVT in Section 5.2.

7.2.11.3

CLUTCH HOUSING REPLACEMENT

There are no recommended tools for this procedure.

The replacement part for this procedure is:

Housing, Clutch, Minipole

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

- 1. Remove the bag hanger from the infuser as described in Section 7.2.11.2.
- 2. Turn the clutch housing knob counterclockwise to loosen the clutch spring, and slide the knob and spring downward to remove them.
- 3. Work the clutch spring free from the clutch housing hole and install it into the replacement clutch housing.
- 4. Install the replacement clutch housing by turning the clutch housing knob counterclockwise and sliding it up the short rod. Confirm the clutch spring slides up the long rod.
- 5. Install the cotter ring.

Replacement of the clutch housing is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during the replacement procedure, perform the PVT in Section 5.2.

7.2.11.4

CLUTCH SPRING REPLACEMENT

There are no recommended tools for this procedure.

The replacement part for this procedure is:

Spring, Clutch, Minipole

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

- 1. Remove the clutch housing as described in Section 7.2.11.3.
- 2. Work the clutch spring free from the clutch housing hole and install the replacement clutch spring.

Replacement of the clutch spring is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during the replacement procedure, perform the PVT in Section 5.2.

7.2.12

MAIN CHASSIS ASSEMBLY COMPONENT REPLACEMENT

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

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

To replace the main chassis assembly components, see *Figure 7-11*, then proceed as detailed in the following sections.

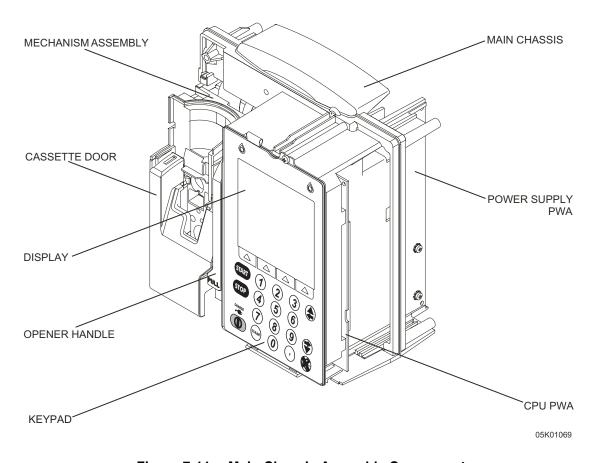


Figure 7-11. Main Chassis Assembly Components

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, Power Supply/Driver

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

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 rear enclosure from the main chassis as described in Section 7.2.8.
- 4. Disconnect the battery cable from the power supply PWA.
- 5. Disconnect the driver cable from the power supply PWA.
- 6. Remove the power supply PWA by sliding the board away from the CPU PWA.
- 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 rear enclosure and main chassis assembly in the exact reverse order of separation.
- 9. Reinstall the battery and connect the device to AC power.

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

7.2.12.2

KEYPAD REPLACEMENT

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:

Assembly, 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, see *Figure 7-12*, then 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 assembly as described in *Section 7.2.8*.

- 4. Disconnect the keypad cable from the CPU PWA.
- 5. Using the X-acto knife, lift the white insulation tape that secures the grounding tab to the lower main chassis.
- 6. Using the Phillips screwdriver, remove the screw that secures the keypad and display to the main chassis.
- 7. Carefully disconnect the flex ribbon cable from the display assembly by pushing the connector locking tabs down.
- 8. Using the flat blade screwdriver, separate the keypad and display by removing the screws and spacers that secure the keypad to the display assembly.
- 9. Inspect the keypad ground gasket and replace, if required.
- 10. Install the replacement keypad in the exact reverse order of removal.
- 11. Install the keypad and display assembly in the exact reverse order of removal.
- 12. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 13. Reinstall the battery and connect the device to AC power.

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

7.2.12.3

DISPLAY 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

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

To replace the display, see *Figure 7-12*, then 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 assembly as described in *Section 7.2.8*.
- 4. Remove the keypad as described in Section 7.2.12.2, then remove the display.
- 5. Install the replacement display assembly in the exact reverse order of removal.
- 6. Reassemble the keypad and display assembly.
- 7. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 8. Reinstall the battery and connect the device to AC power.

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

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

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

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

To replace the CPU PWA, see *Figure 7-12* and *Figure 7-13*, then 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 assembly as described in *Section 7.2.8*.
- 4. Remove the power supply PWA as described in Section 7.2.12.1.
- 5. Remove the display assembly as described in Section 7.2.12.3.
- 6. Using the flat blade screwdriver, remove the two screws that secure the CPU PWA to the main chassis.
- 7. Install the replacement CPU PWA 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 assembly in the exact reverse order of separation.
- 10. Reinstall the battery and connect the device to AC power.

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

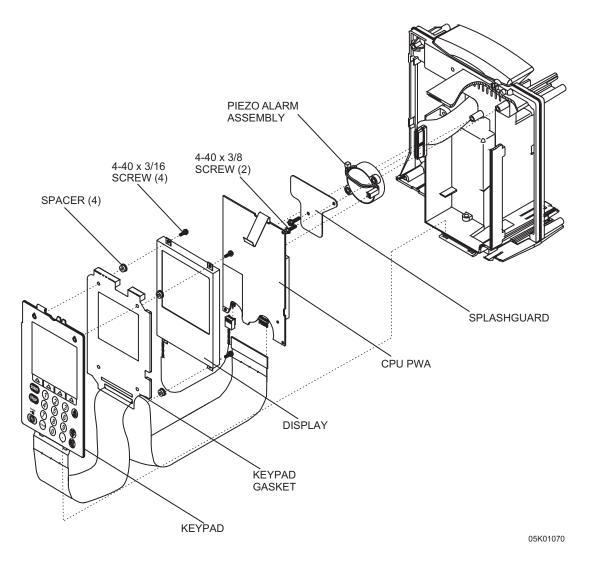


Figure 7-12. Keypad, Display, CPU PWA, and Piezo Alarm

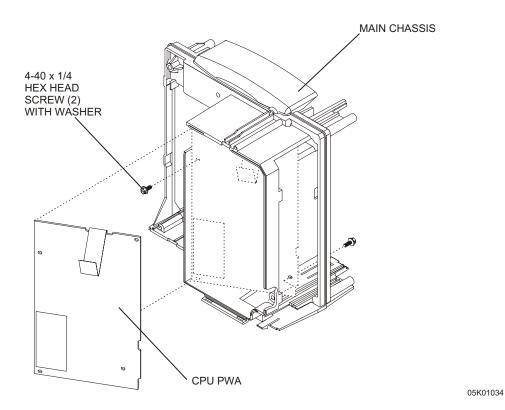


Figure 7-13. CPU PWA Replacement

7.2.12.5

PIEZO ALARM 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

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

To replace the piezo alarm, see *Figure 7-12*, then 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 assembly 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 assembly 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 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 assembly in the exact reverse order of separation.
- 10. Reinstall the battery and connect the device to AC power.

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

7.2.12.6

MECHANISM ASSEMBLY REPLACEMENT

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

The replacement parts for this procedure are:

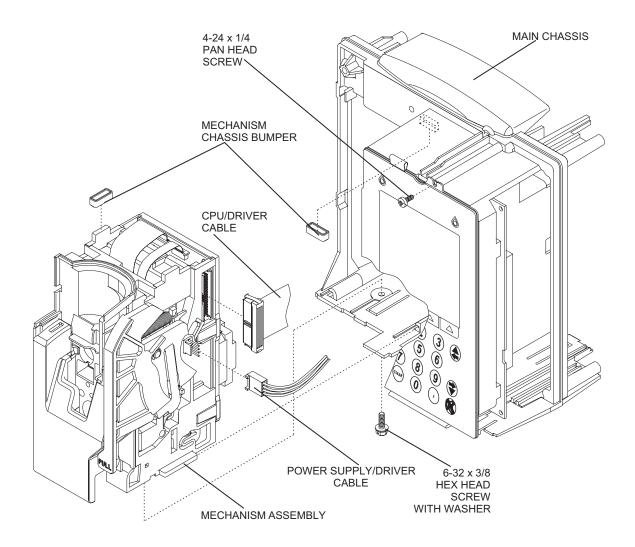
Assembly, Mechanism
Assembly, Cable, CPU/Driver
Bumper, Mechanism Chassis
Tie, Cable
Screw, 4-24 x 1/4, Pan Head, Phillips
Screw, 6-32 x 3/8, Hex Head, Slotted, with Washer

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

To replace the mechanism assembly, see *Figure 7-14*, then 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 assembly as described in *Section 7.2.8*.
- 4. Using diagonal cutters, cut the cable tie that secures the power supply/driver cable.
- 5. Using the flat blade screwdriver, remove the screw that secures the mechanism assembly to the main chassis assembly.
- 6. Inspect the mechanism chassis bumpers and replace, if required.
- 7. Slide the mechanism assembly away from the main chassis assembly.
- 8. Unlock and disconnect the CPU/driver cable 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 tie.
- 10. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 11. Reinstall the battery and connect the device to AC power.

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



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Figure 7-14. Mechanism Assembly Replacement

7.2.12.7

CASSETTE DOOR AND FLUID SHIELD REPLACEMENT

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

The replacement parts for this procedure are:

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

To replace the cassette door and fluid shield, see *Figure 7-15* and *Figure 7-16*, then 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 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. Disengage the cassette door from the opener handle assembly and remove the door.
- 6. Disengage the clips on the back side of the fluid shield that secure the upper portion of the shield to the mechanism assembly.
- 7. Lift the locking pins to release the fluid shield/driver flex connector, and disconnect the flex connector from the driver PWA.
- 8. 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: Prior to fluid shield replacement, align the mechanism assembly pins.

- 9. Install the replacement fluid shield in the exact reverse order of removal.
- 10. Install the replacement cassette door in the exact reverse order of removal.
- 11. Replace the mechanism assembly in the exact reverse order of removal.
- 12. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 13. Reinstall the battery and connect the device to AC power.

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

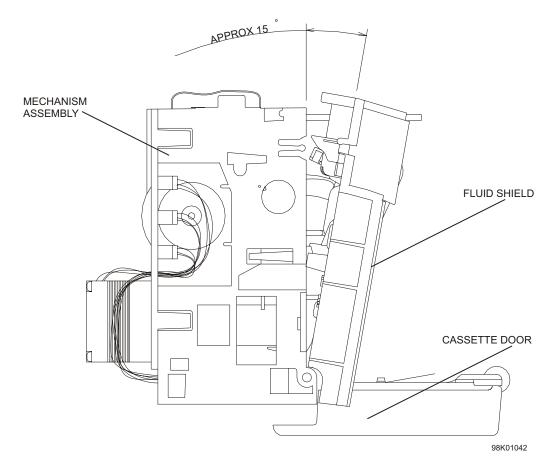


Figure 7-15. Fluid Shield Replacement

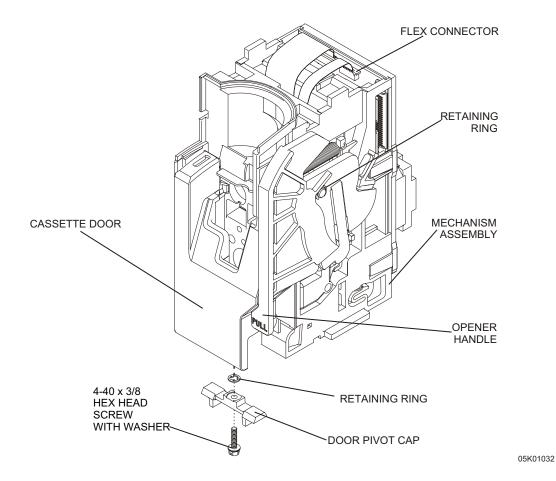


Figure 7-16. Cassette Door and Opener Handle Replacement

7.2.12.8

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 Ring, Retaining, Push-On, 3/32

To replace the opener handle assembly, see *Figure 7-16*, then 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 assembly 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. Close the opener handle assembly.
- 6. Remove the retaining ring and replace, if required.
- 7. Insert the flat blade screwdriver between the opener handle assembly and the mechanism assembly, and carefully pry the assemblies apart.
- 8. Install the replacement opener handle assembly in the exact reverse order of removal. Confirm the opener handle is aligned properly.
- 9. Replace the mechanism assembly in the exact reverse order of removal.
- 10. Join the front enclosure, rear enclosure, and main chassis assembly in the exact reverse order of separation.
- 11. Reinstall the battery and connect the device to AC power.

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

Section 8

SPECIFICATIONS

The following specifications apply to the Plum A+® infusion system.

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

ELECTRICAL

Power Requirements: 230 V_{AC}; 50-60 Hz; 35 VA

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

With transparent plug and retainer

Fuses: F1; F2; 250 V_{AC}; 0.5 A

Battery: Sealed lead acid; rechargeable; 6 V; internal

Battery Operation: A fully charged new battery provides approximately three

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

if > 126 mL/hr.

Operation time is measured from initial pumping to the

Depleted Battery alarm.

The infuser should be operated on battery power for three

continuous hours every six months for optimum

performance and battery life.

Recharge: The battery charges whenever the infuser is connected

to AC power.

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

recharge takes approximately 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: Circuitry Ratings: Voltage - 30 V_{DC} Max

Current - 0.25 A max Contact Rating - 3 W max

Default: Normally-open (NO)

Contact Hospira Technical Support Operations to make an internal adjustment to change the device from

normally-open to normally-closed (NC).

ENVIRONMENT

Operating: 5° to 40° C; 10 % to 90 % relative humidity

Transporting and

Storage: -20° to 60° C; 10 % to 90 % relative humidity

Atmospheric Pressure: 0 - 3000 meters or equivalent pressure

Relative Humidity: $10 - 90 \% (40^{\circ} \text{ C max})$

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 if the tubing proximal

to the cassette becomes occluded.

Distal Pressure Limit

(without alarm): 52 to 776 mmHg;

Maximum pressure is user-selectable; Factory default setting is 310 mmHg

Maximum Infusion

Pressure: 1034 mmHg

AIR-IN-LINE ALARM

PlumSet (**Distal**): Bolus: 0.5 mL of air or larger

Cumulative: 0.5 mL of air out of 5.3 mL of fluid

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

Section 9 **DRAWINGS**

Figure 9-1 through Figure 9-15 show the illustrated parts breakdown (IPB), assembly diagrams, and PWA schematic diagrams. Table 9-1 lists drawings by figure number, title, and part number. Table 9-2 identifies parts by index numbers which correlate to Figure 9-1.



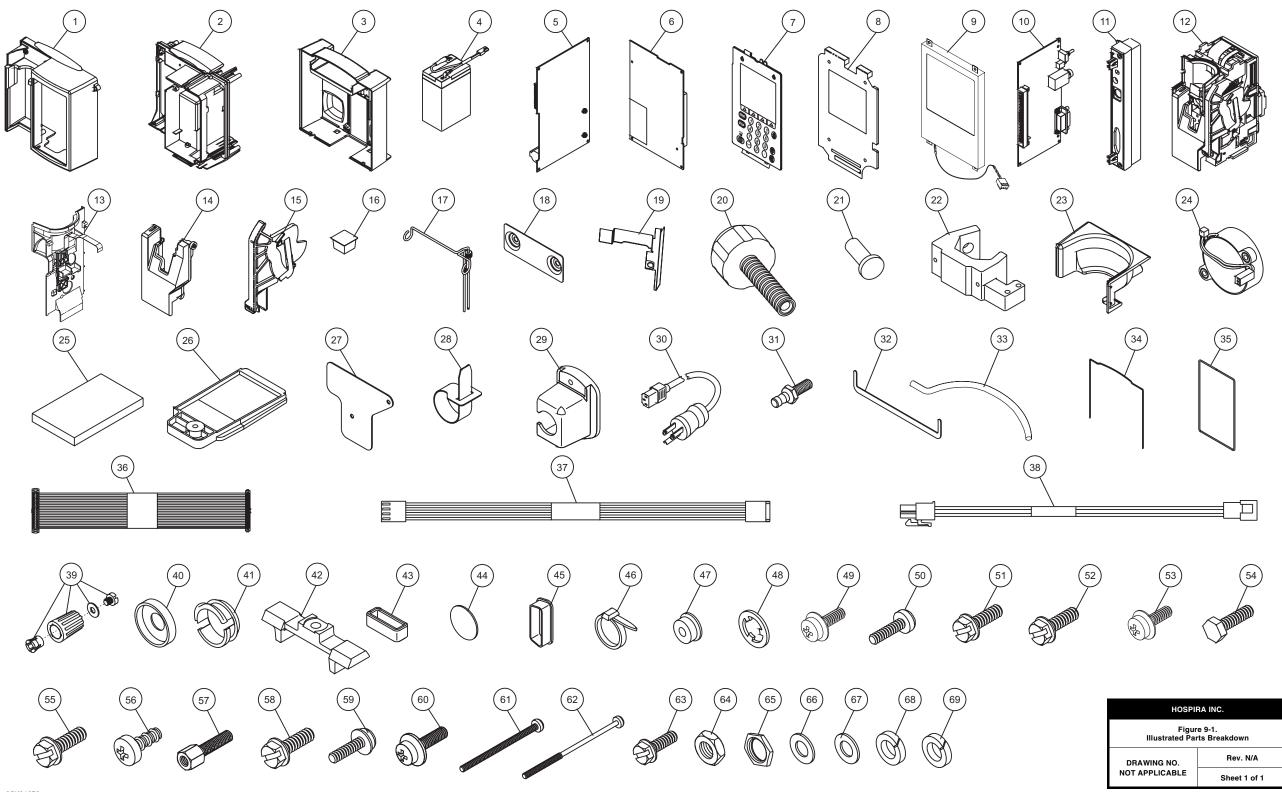
 \P **Note:** Drawings and schematics in Section 9 are provided as information only. Drawings and schematics may not exactly reflect current product configuration.

Table 9-1. Drawings				
Figure Number	Title	Drawing Number		
9-1	Illustrated Parts Breakdown	Not Applicable		
9-2	Front Enclosure, Rear Enclosure, and Main Chassis			
9-3	Front Enclosure Assembly			
9-4	Rear Enclosure Assembly			
9-5	Peripheral Assembly			
9-6	Main Chassis Assembly (3 sheets)			
9-7	AC Power Cord, Retainer, and Battery Assembly			
9-8	CPU PWA and Main Chassis			
9-9	Mechanism Assembly			
9-10	Power Supply PWA Schematic (5 Sheets)	249-95242		
9-11	Peripheral PWA Schematic (4 sheets)	249-95006		
9-12	CPU PWA Schematic (10 sheets)	249-95007		
9-13	Driver PWA Schematic (3 sheets)	249-95018		
9-14	Switch PWA Schematic	249-95022		
9-15	APP PWA Schematic (3 sheets)	249-95034		

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	Assembly, Battery, with Wire Harness	Section 7.2.4		
5	PWA, Power Supply	Section 7.2.12.1		
6	PWA, CPU	Section 7.2.12.4		
7	Keypad	Section 7.2.12.2		
8	Gasket, Ground	Section 7.2.12.2		
9	Assembly, Display	Section 7.2.12.3		
10	PWA, Peripheral	Section 7.2.6		
11	Cover, Peripheral	Section 7.2.7.2		
12	Assembly, Mechanism	Section 7.2.12.6		
13	Assembly, Fluid Shield	Section 7.2.12.7		
14	Assembly, Cassette Door	Section 7.2.12.7		
15	Assembly, Opener Handle	Section 7.2.12.8		
16	Foot, Rubber	Section 7.2.3		
17	Assembly, Minipole	Section 7.2.11		
18	Plate, Backing, Pole Clamp	Section 7.2.10.1		
19	Insulator, Backing Plate	Section 7.2.10.1		
20	Assembly, Shaft/Knob	Section 7.2.10.2		
21	Tip, Shaft, Pole Clamp	Section 7.2.10.2		
22	Extrusion, Pole Clamp	Section 7.2.10.1		
23	Shoe, Front Enclosure	Section 7.2.9		
24	Assembly, Piezo Alarm	Section 7.2.12.5		
25	Pad, Door	Section 7.2.4		
26	Door, Battery	Section 7.2.4		
27	Splashguard	Section 7.2.12.5		
28	Strap, Velcro	Section 7.2.5		
29	Retainer, AC Power Cord	Section 7.2.5		
30	Cordset, AC Power, Detachable	Section 7.2.5		
31	Terminal, Equipotential	Section 7.2.5		

	Table 9-2. IPB for the Infuser	
Index Number	Nomenclature	Replacement Procedure
32	Gasket, Handle	Section 7.2.10.3
33	Gasket, Shoe	Section 7.2.9.1
34	Gasket, Rear Enclosure	Section 7.2.10.3
35	Gasket, Front/Rear Enclosure	Section 7.2.9.2
36	Cable, CPU/Driver	Section 7.2.12.6
37	Cable, Power Supply/Driver	Section 7.2.12.1
38	Cable, Power Supply/Battery	Section 7.2.12.1
39	Assembly, Volume Control Knob	Section 7.2.7.1
40	Cover, Nut	Section 7.2.7.1
41	Cap, Knob	Section 7.2.7.1
42	Cap, Door Pivot	Section 7.2.12.7
43	Bumper, Mechanism	Section 7.2.12.6
44	Seal, Round	Section 7.2.7.2
45	Cover, DataPort Connector	Section 7.2.7.2
46	Tie, Cable	Section 7.2.12.6
47	Spacer	Section 7.2.12.2
48	Ring, Retaining	Section 7.2.12.8
49	Screw, 4-24 x 1/4, Pan Head, Phillips	As applicable
50	Screw, 4-40 x 1/4, Pan Head, Phillips	As applicable
51	Screw, 4-40 x 1/4, Hex Head, Slotted, with Washer	As applicable
52	Screw, 4-40 x 3/16, Hex Head, Slotted, with Washer	As applicable
53	Screw, 4-40 x 3/8, Pan Head, Phillips, with Washer	As applicable
54	Screw, 4-40 x 3/8, Hex Head, Nylon	As applicable
55	Screw, 4-40 x 3/8, Hex Head, Slotted, with Washer	As applicable
56	Screw, 4-40 x 1/2, Pan Head, Square Cone, Phillips	As applicable
57	Screw, Jack, 4-40 x 7/16	As applicable
58	Screw, 6-32 x 3/8, Hex Head, Slotted, with Washer	As applicable
59	Screw, 6-32 x 1/2, Pan Head, Phillips	As applicable
60	Screw, 6-32 x 5/8, Pan Head, Phillips, with Washer	As applicable
61	Screw, 6-32 x 2 1/2, Pan Head, Phillips	As applicable
62	Screw, 6-32 x 3 1/4, Pan Head, Phillips	As applicable

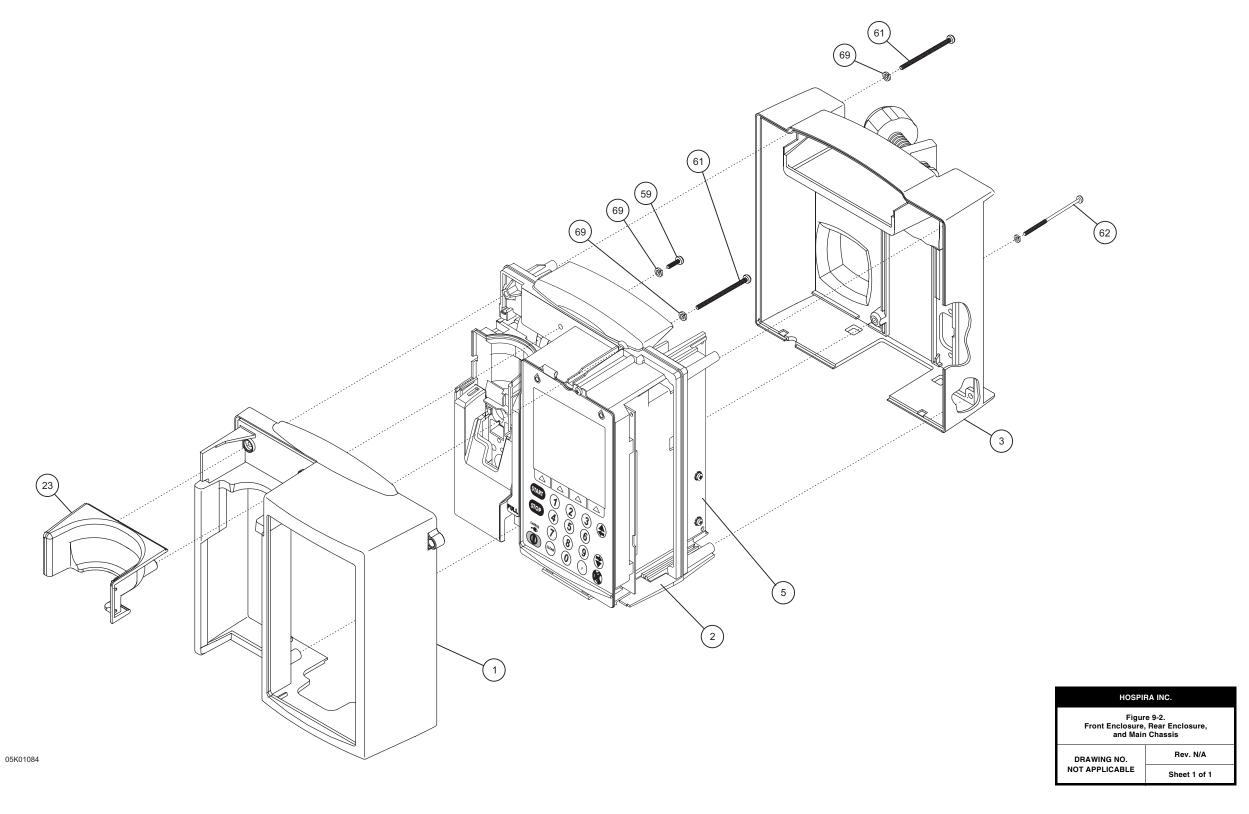
Table 9-2. IPB for the Infuser				
Index Number	Nomenclature	Replacement Procedure		
63	Screw, 10-32 x 1/2, Hex Head, Slotted, with Washer	As applicable		
64	Nut, Hex, 4-40	As applicable		
65	Nut, Hex, Nurse Call jack	Section 7.2.7.2		
66	Washer, Flat, #4	As applicable		
67	Washer, Flat, Nylon	As applicable		
68	Washer, Lock, Split, #4	As applicable		
69	Washer, Lock, Helical, #6	As applicable		



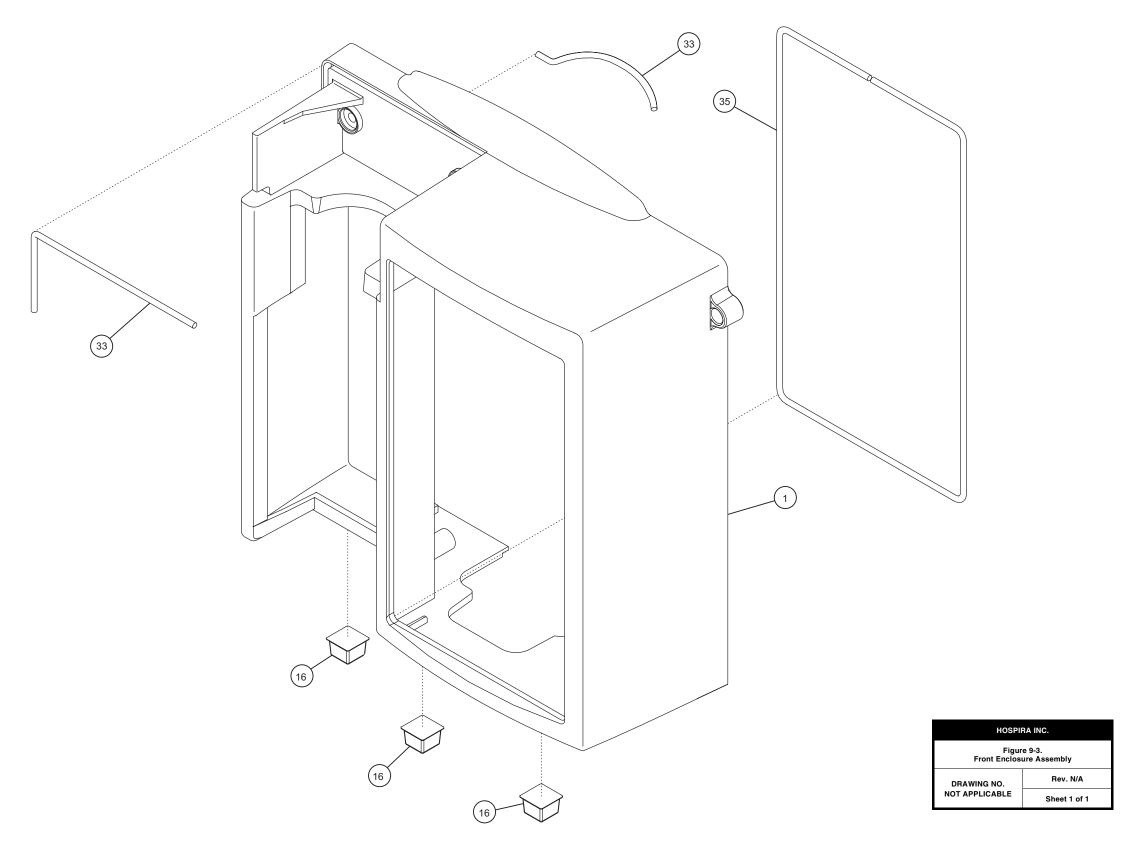
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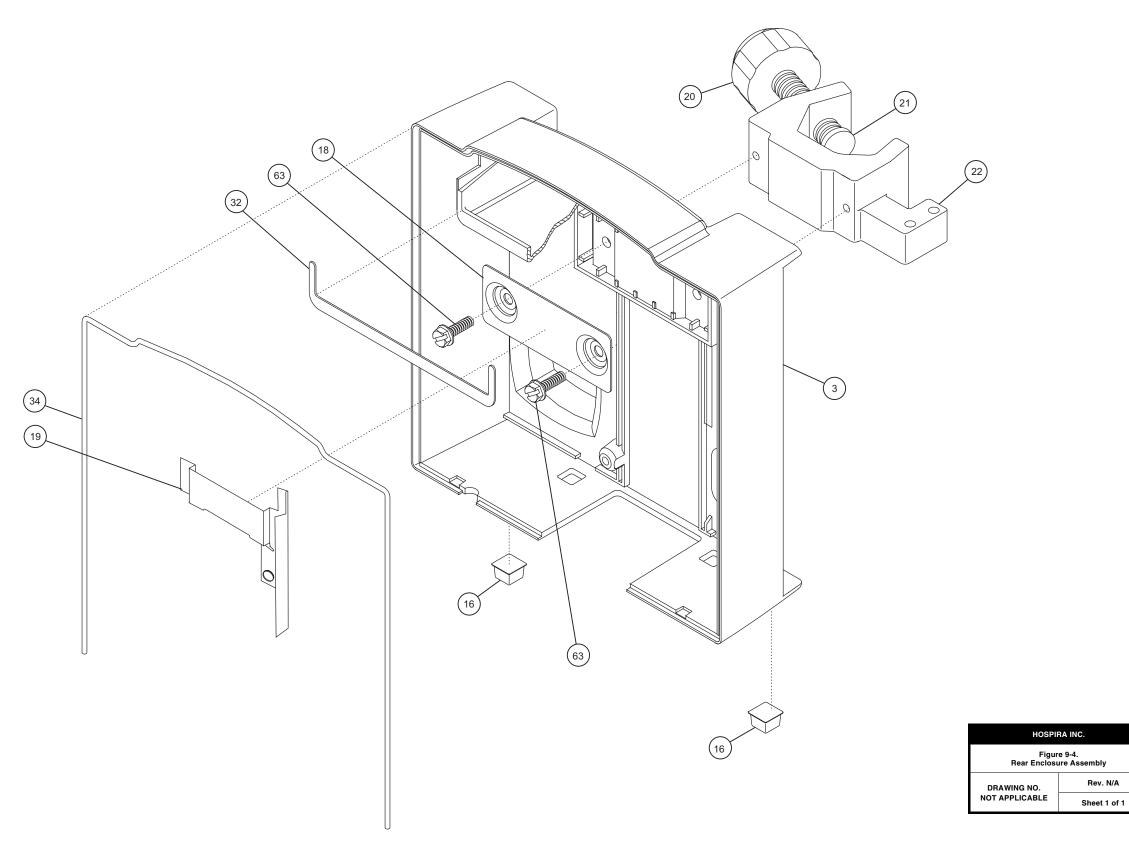
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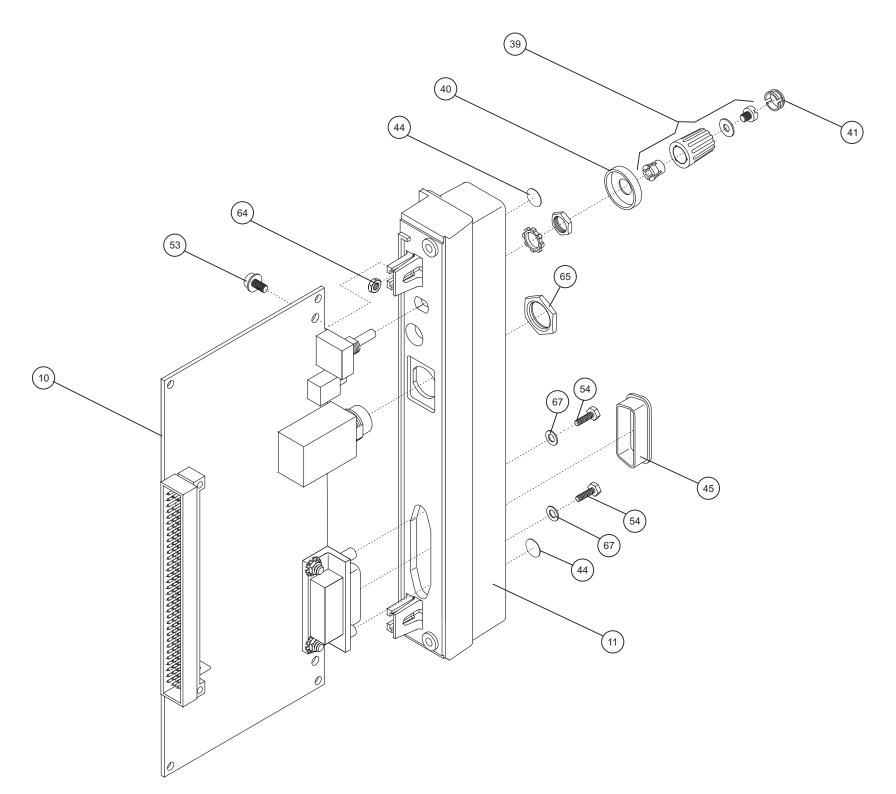
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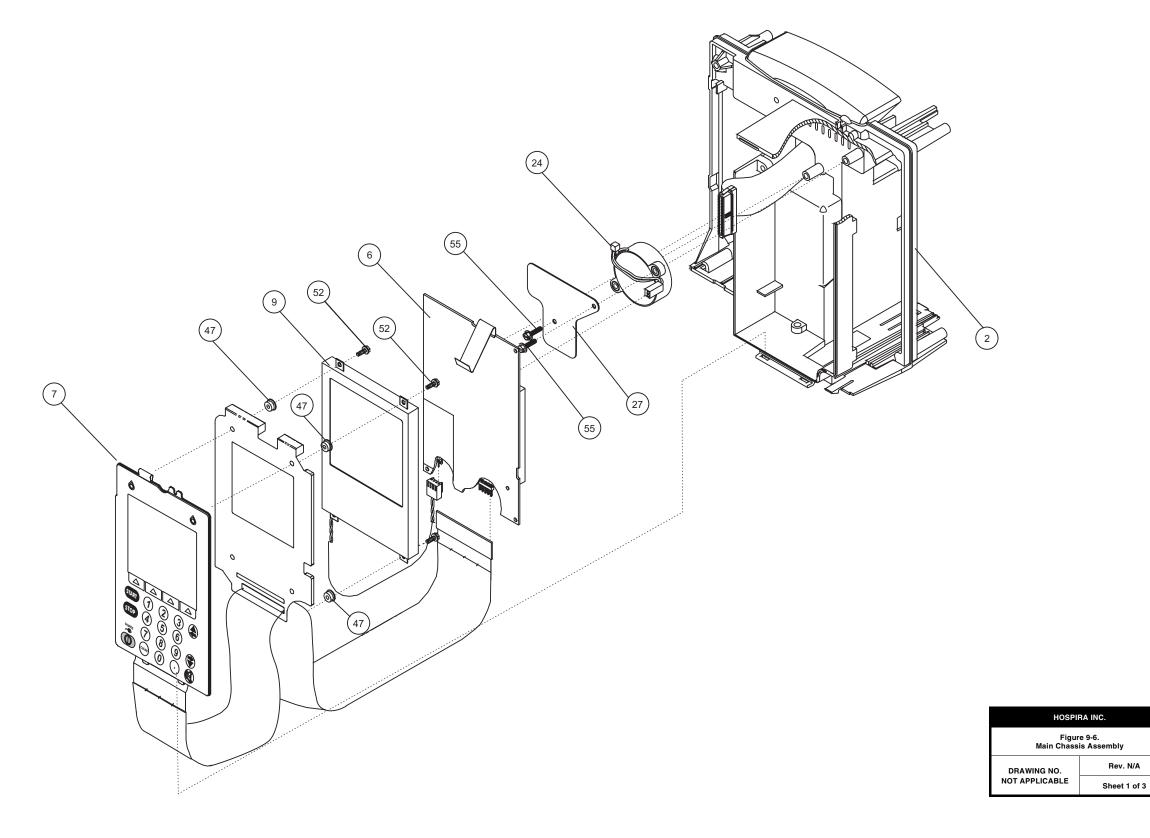
Figure 9-5.
Peripheral Assembly

DRAWING NO.
NOT APPLICABLE
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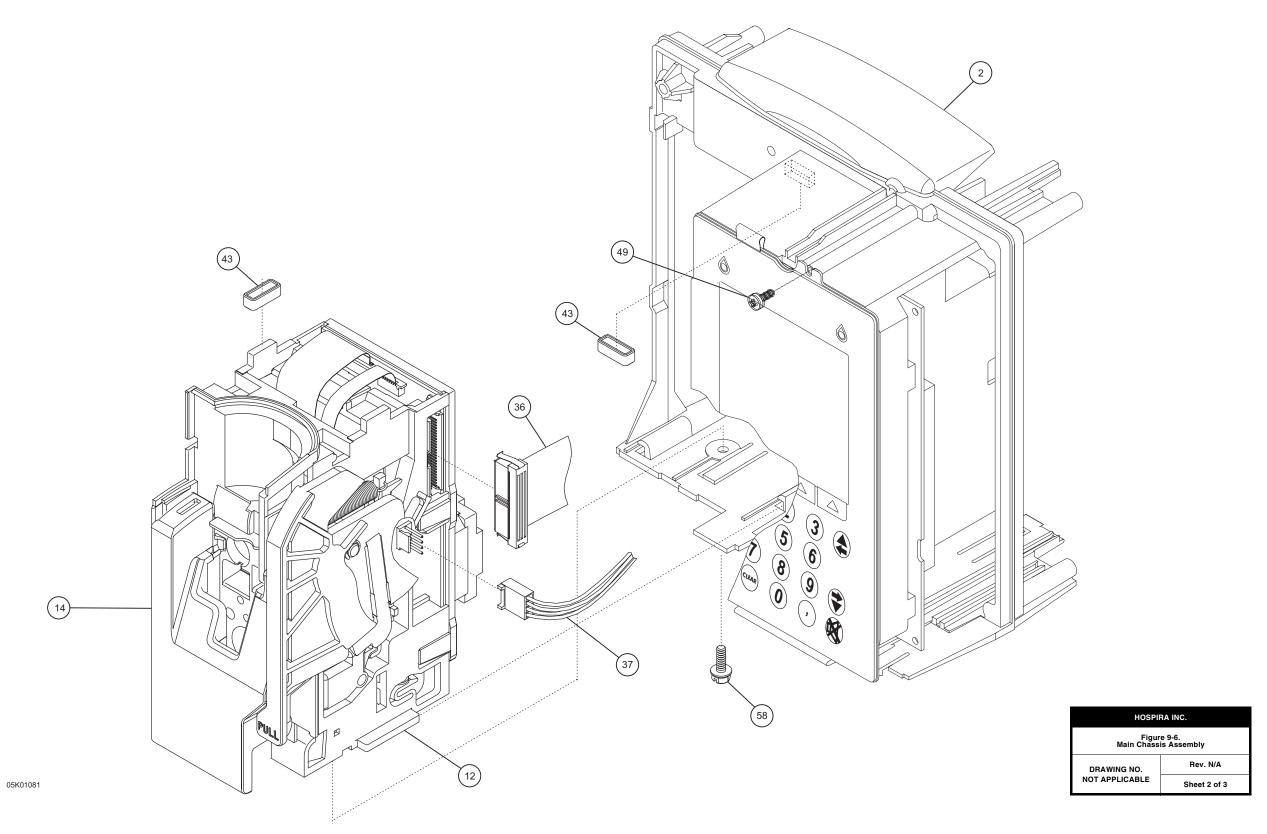
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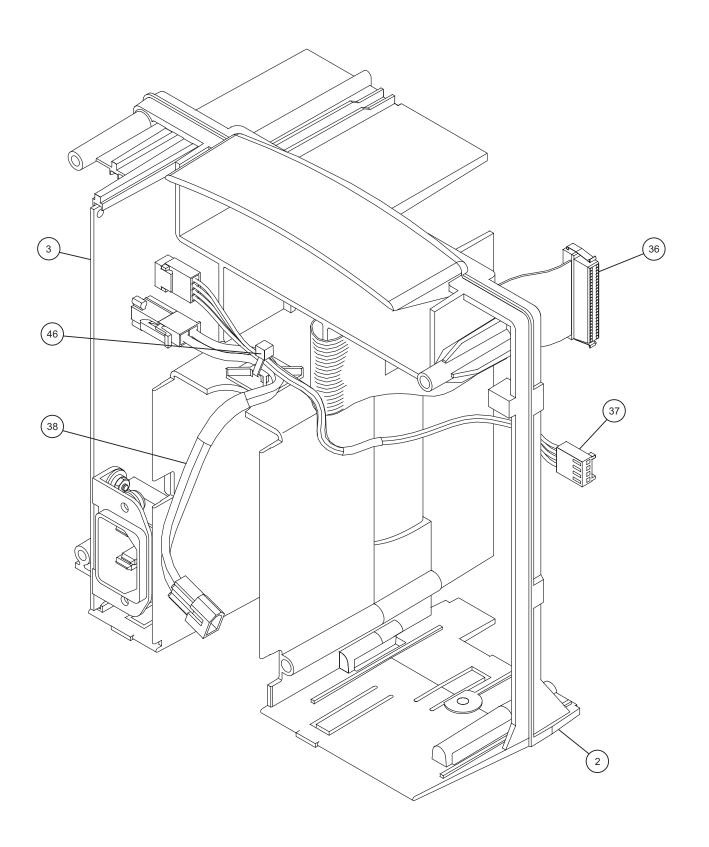
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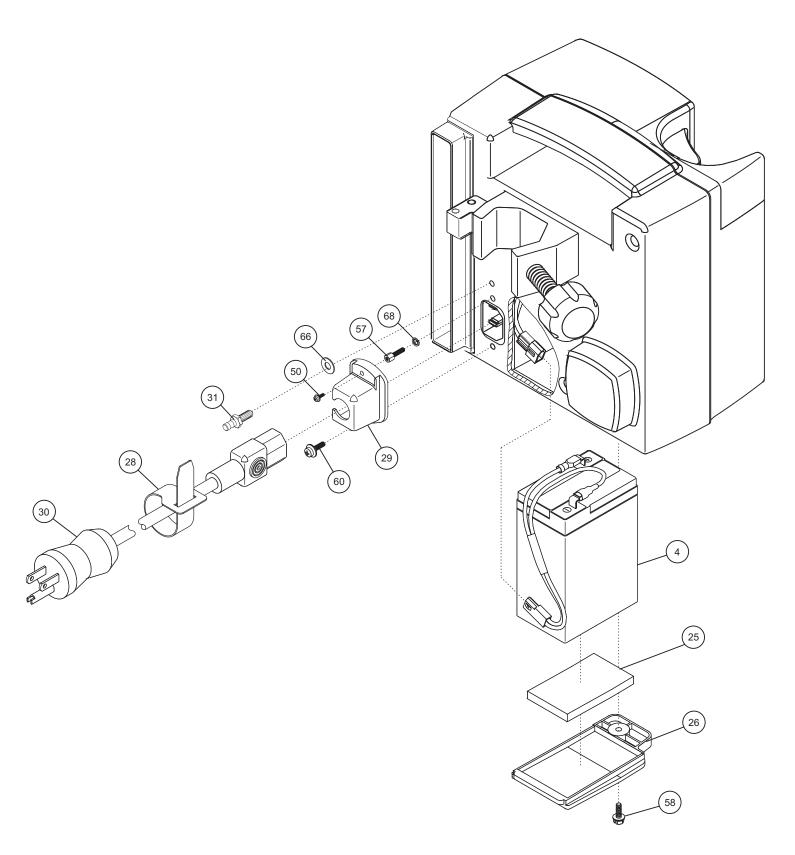
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HOSPIRA INC.	
Figure 9-6. Main Chassis Assembly	
DRAWING NO. NOT APPLICABLE	Rev. N/A
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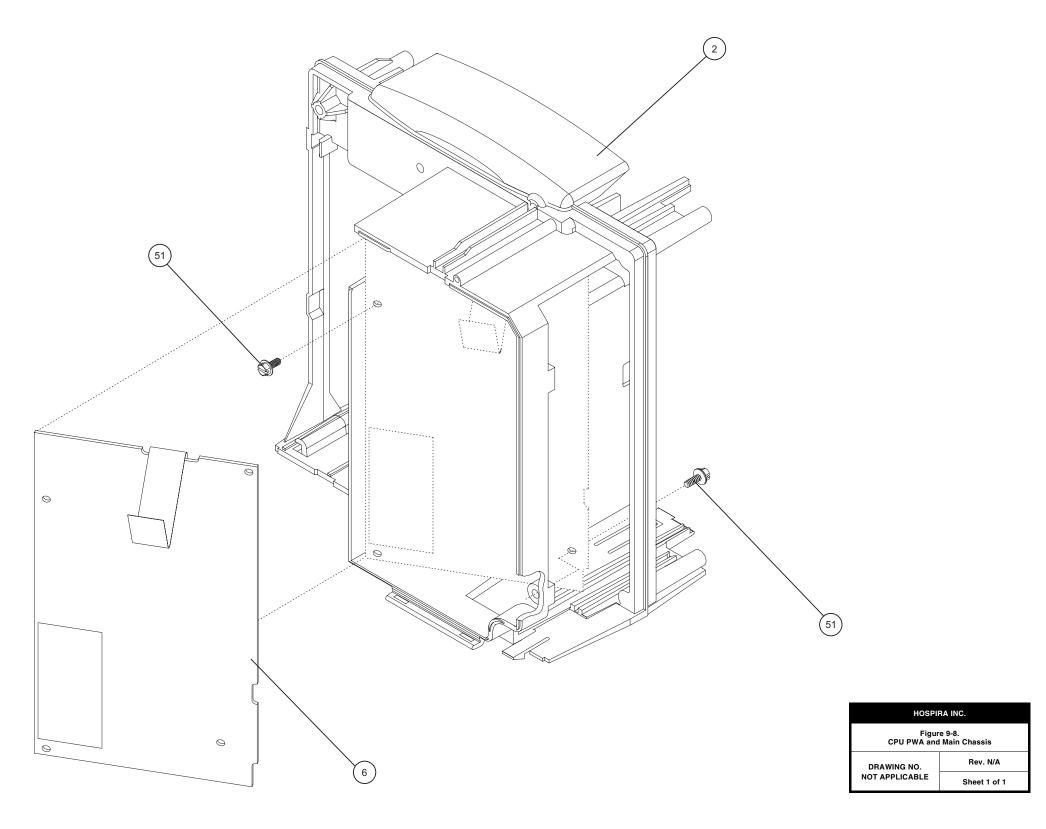
Figure 9-7.
AC Power Cord, Retainer, and Battery Assembly

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Sheet 1 of 1

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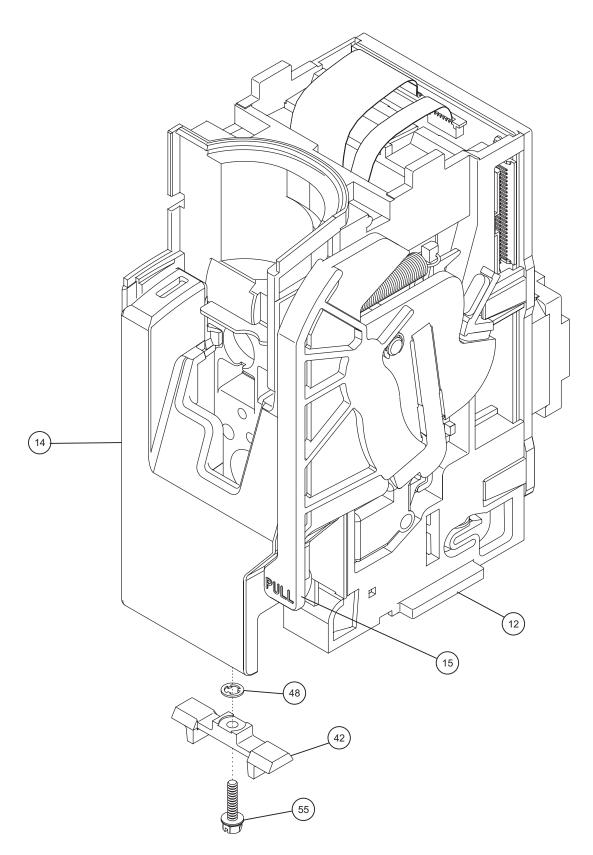
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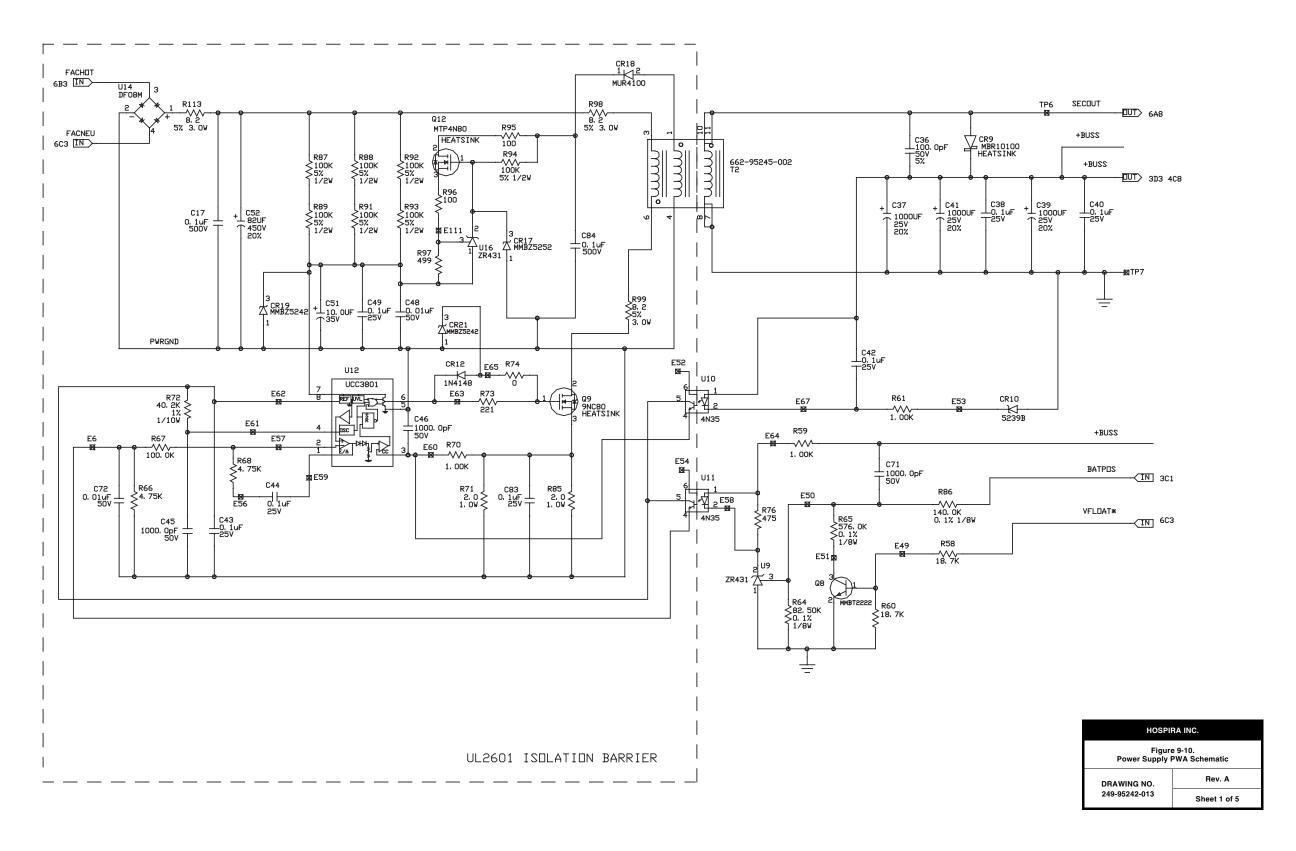


HOSPIRA INC.		
Figure 9-9. Mechanism Assembly		
DRAWING NO. NOT APPLICABLE	Rev. N/A	
	Sheet 1 of 1	

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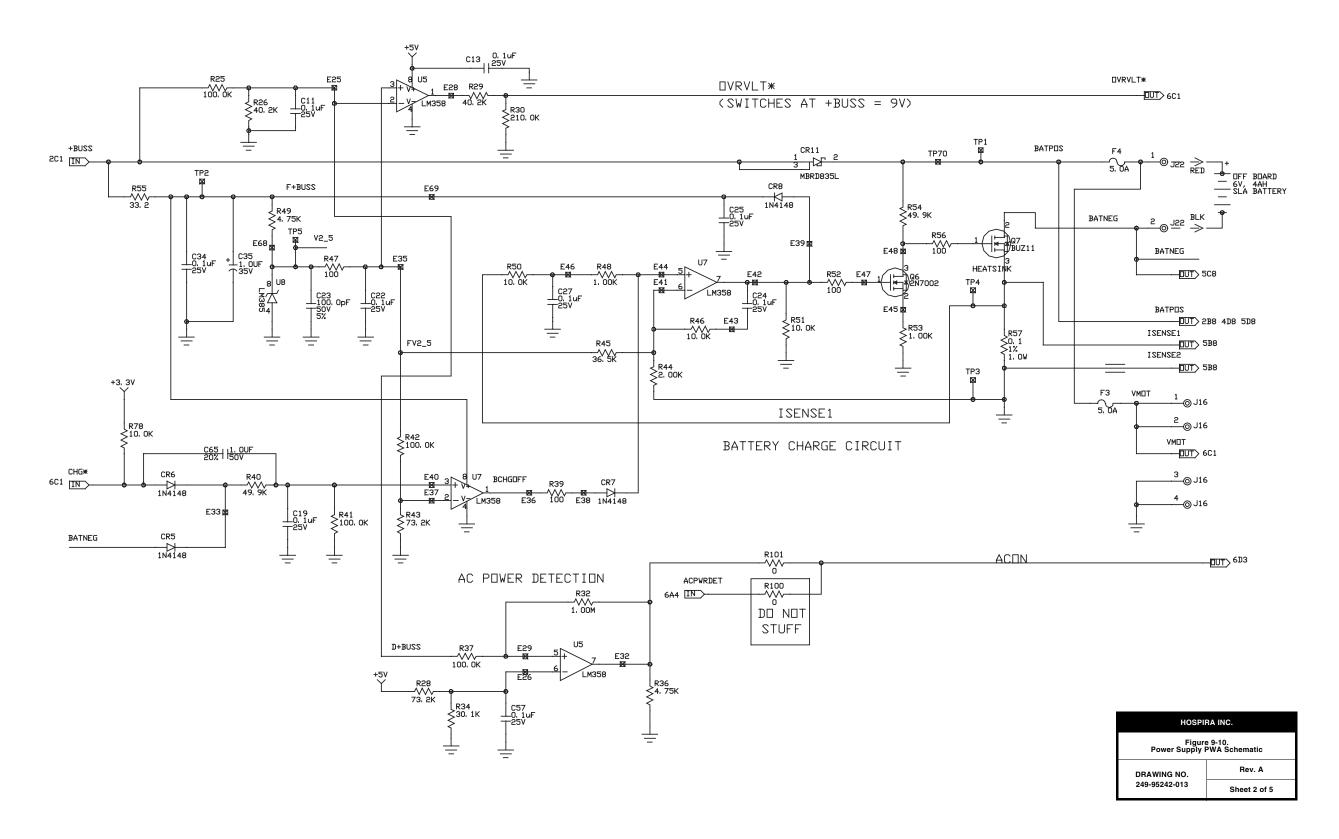
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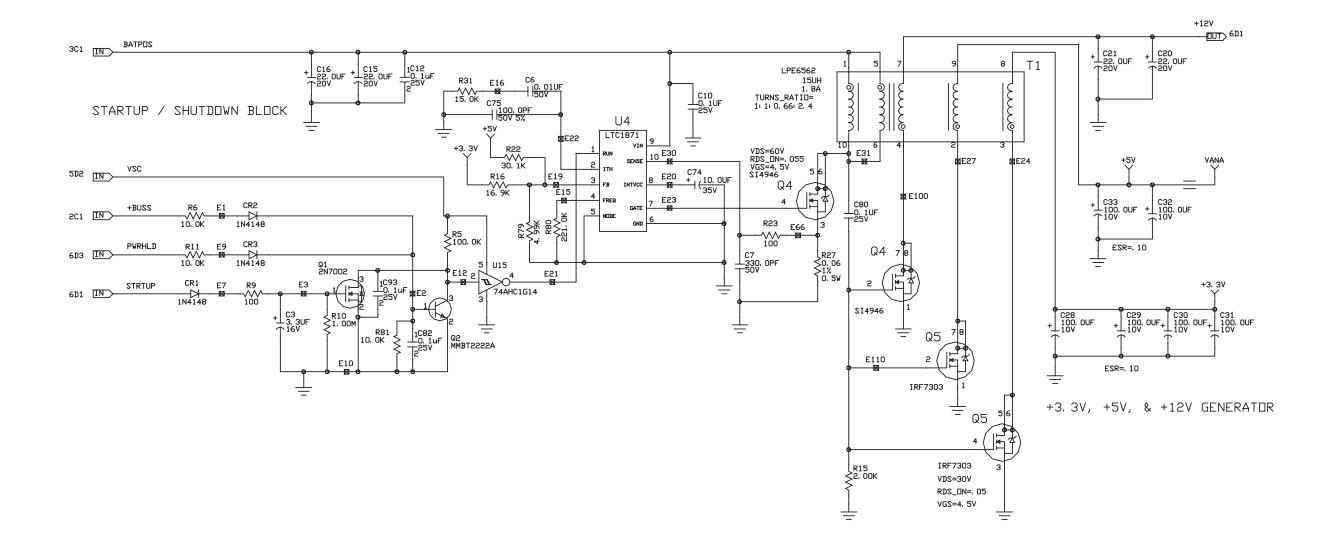
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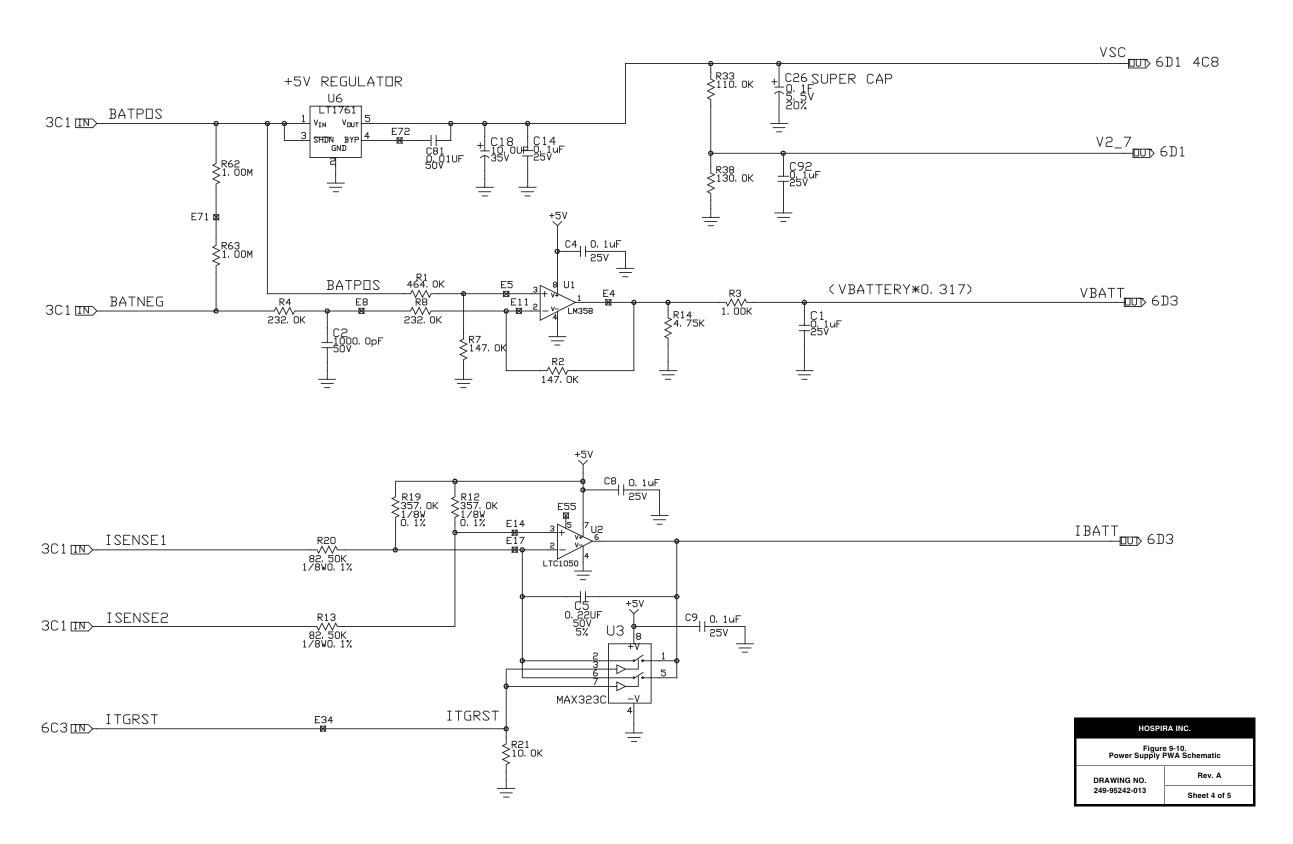
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HOSPIRA INC.	
Figure 9-10. Power Supply PWA Schematic	
DRAWING NO. 249-95242-013	Rev. A
	Sheet 3 of 5

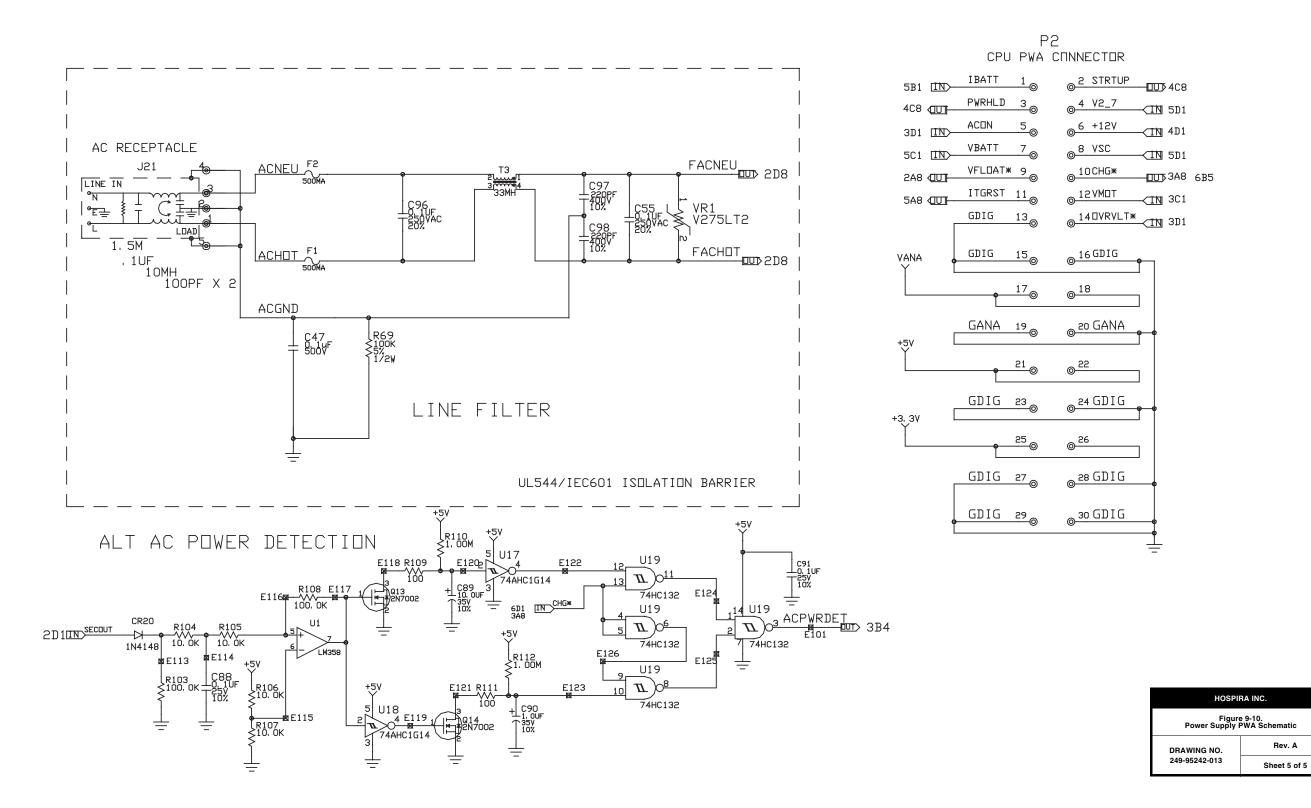
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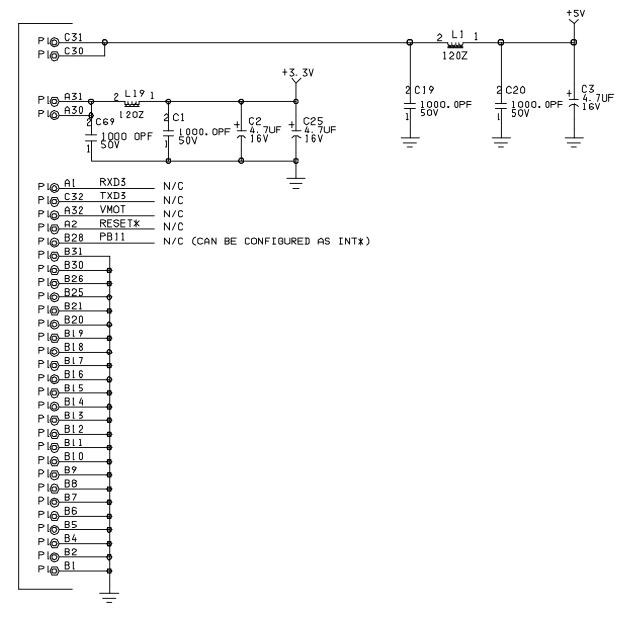
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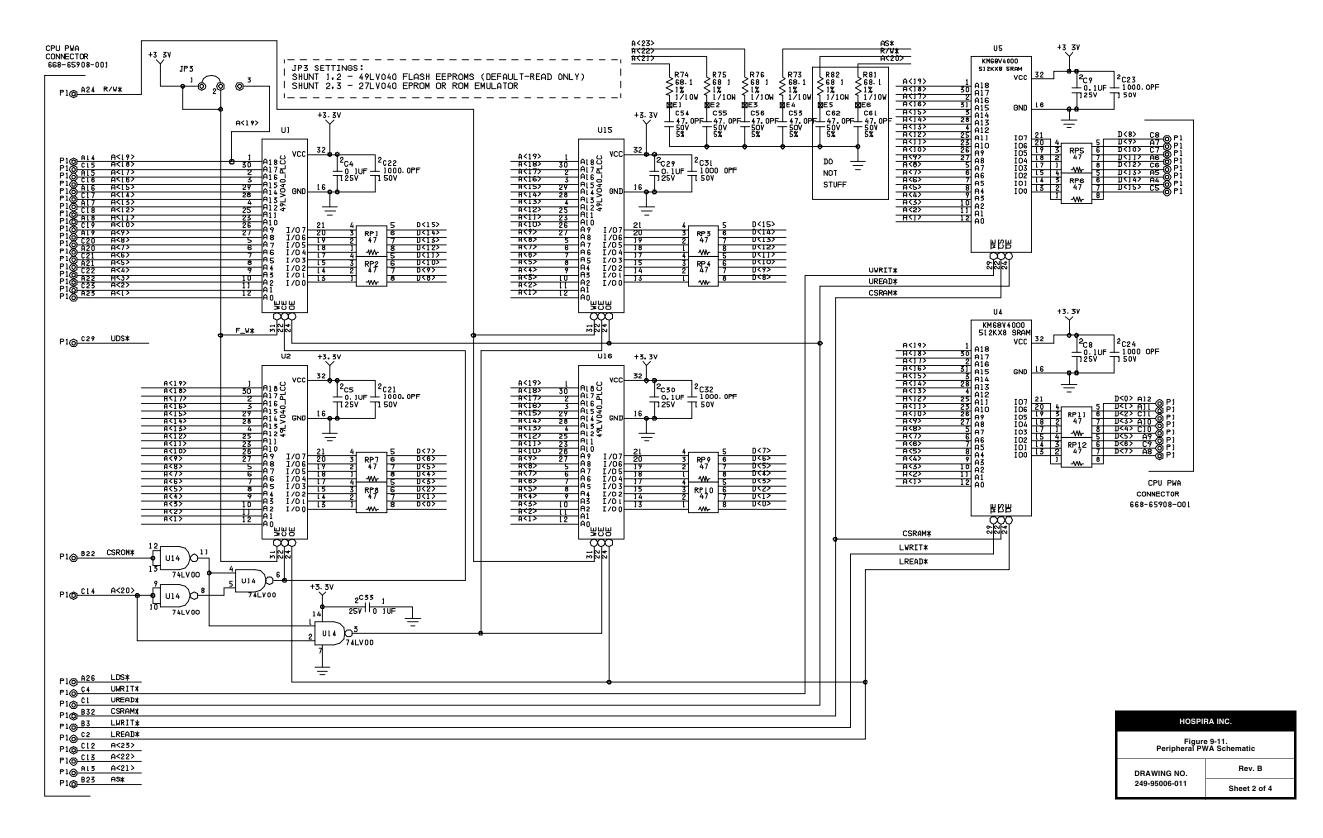
CPU BOARD CONNECTOR



HOSPIRA INC.		
Figure 9-11. Peripheral PWA Schematic		
DRAWING NO. 249-95006-011	Rev. B	
	Sheet 1 of 4	

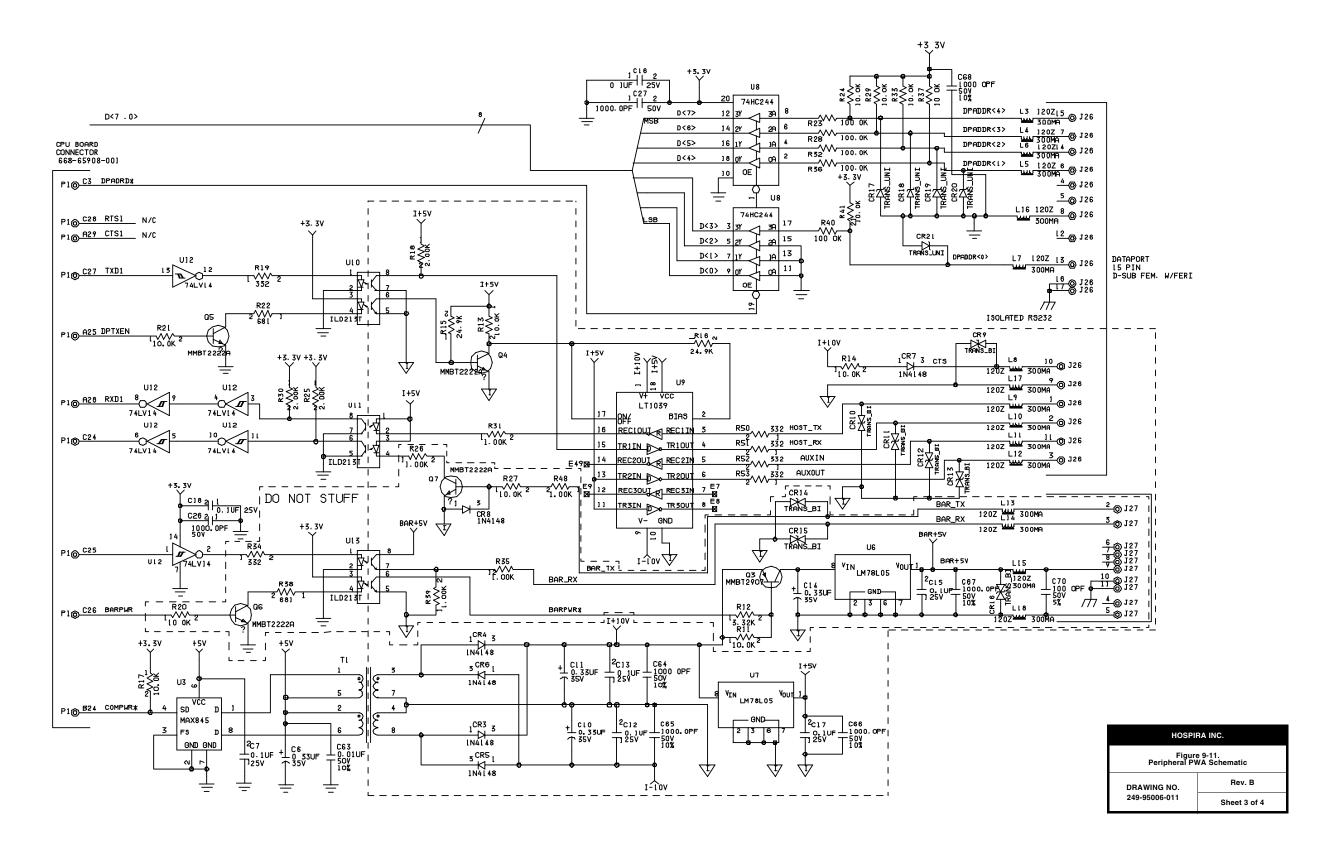
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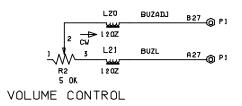
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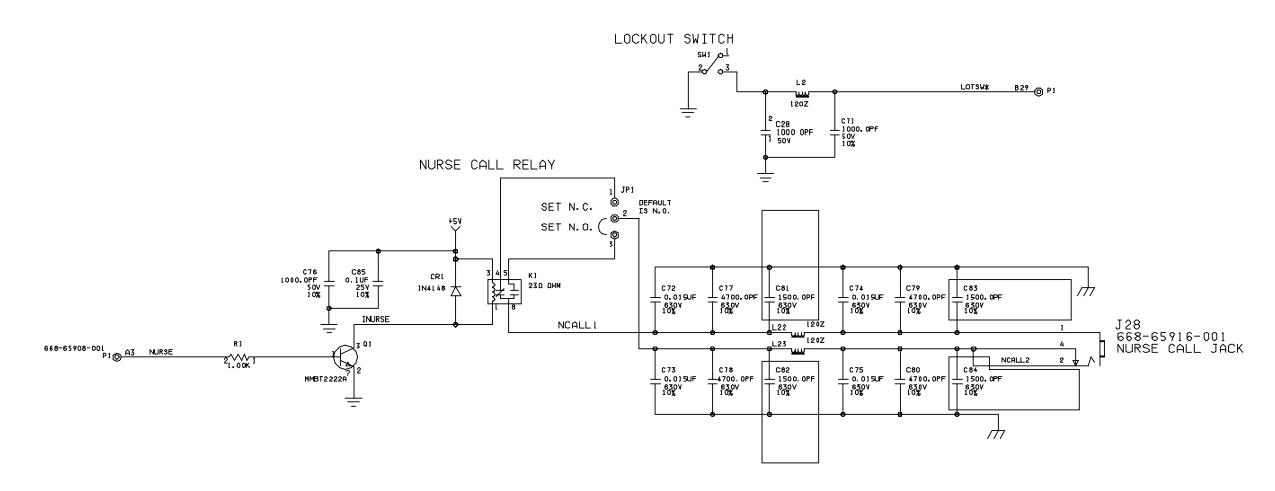
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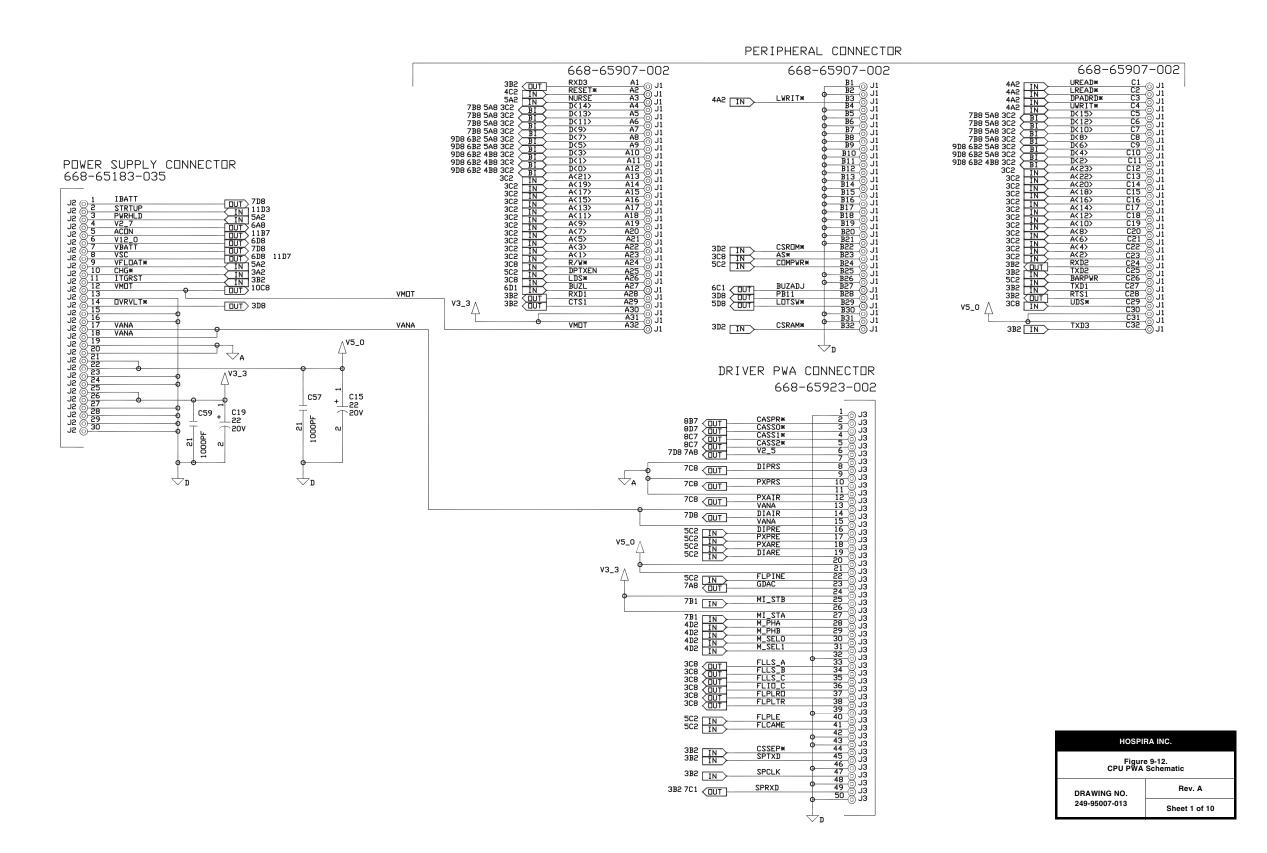




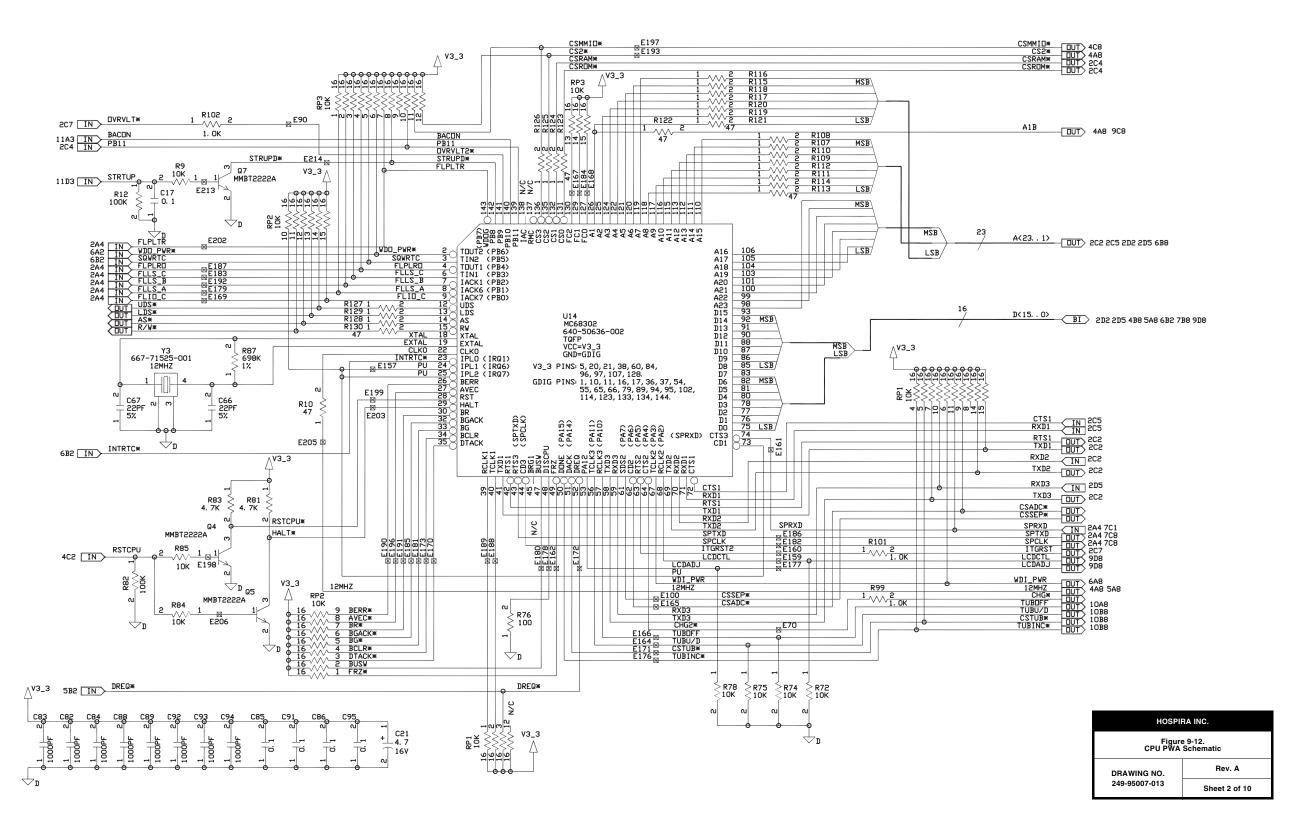
HOSPIRA INC.	
Figure 9-11. Peripheral PWA Schematic	
DRAWING NO. 249-95006-011	Rev. B
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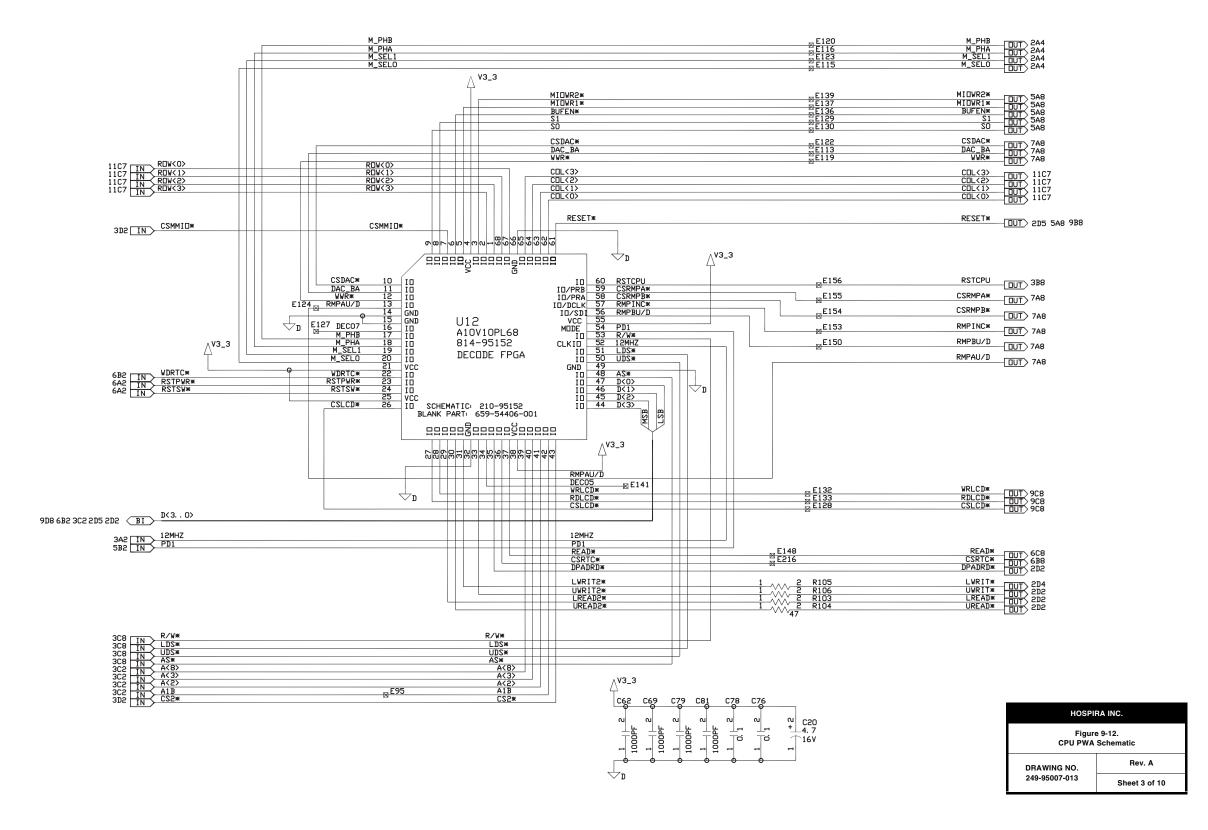


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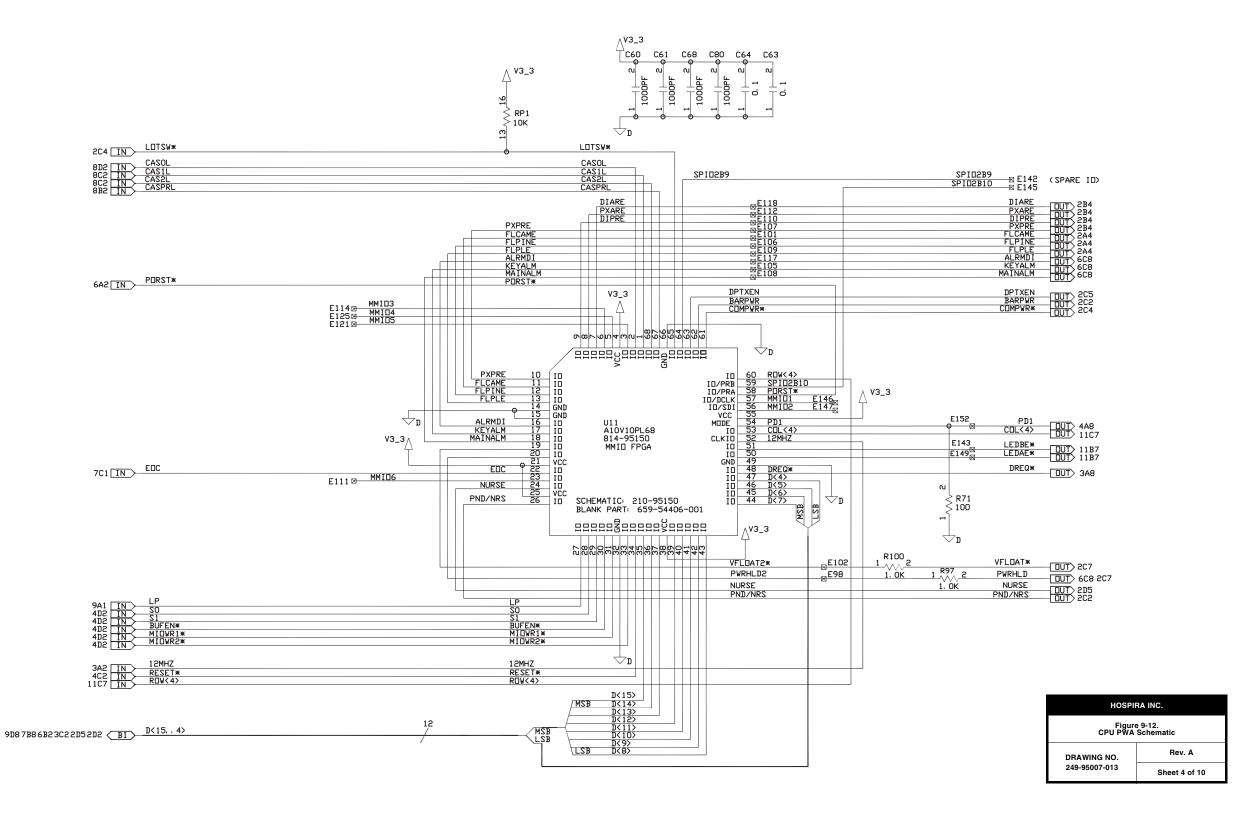
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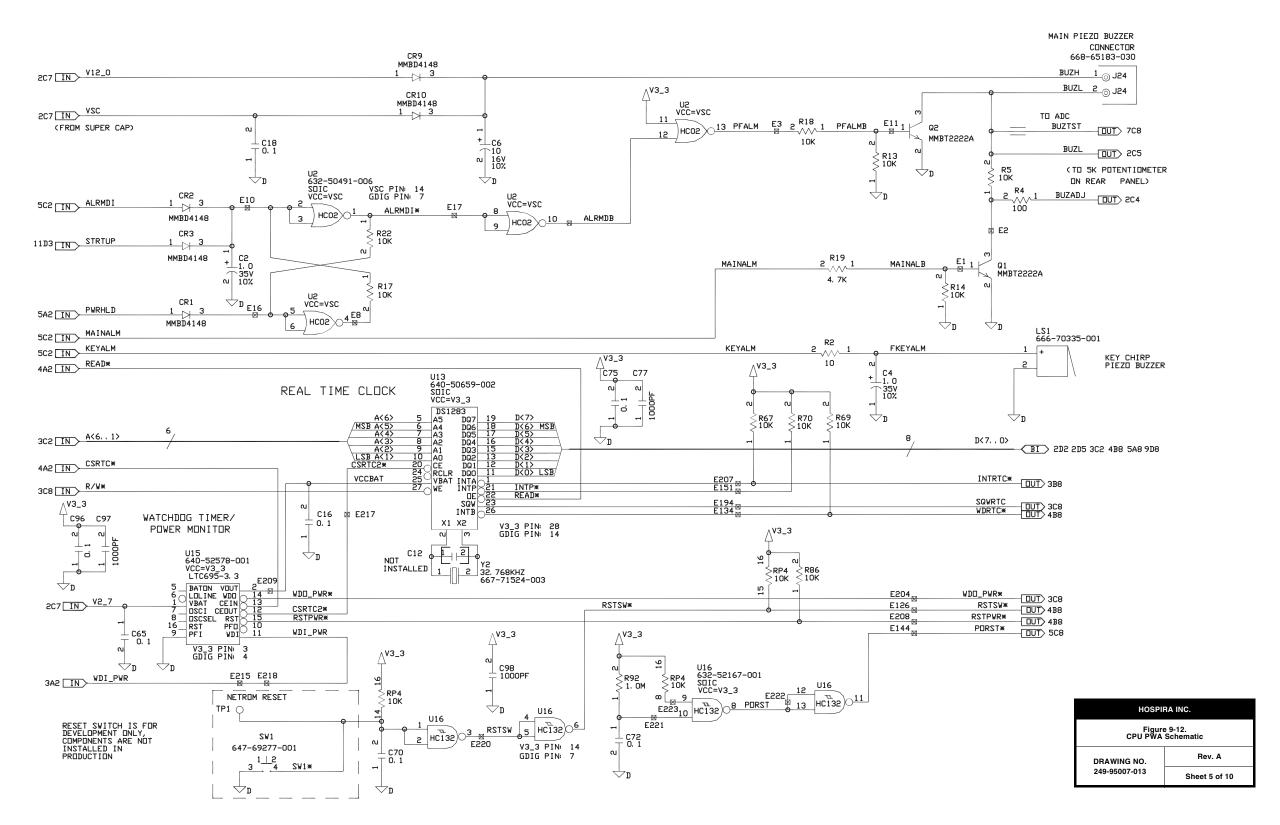
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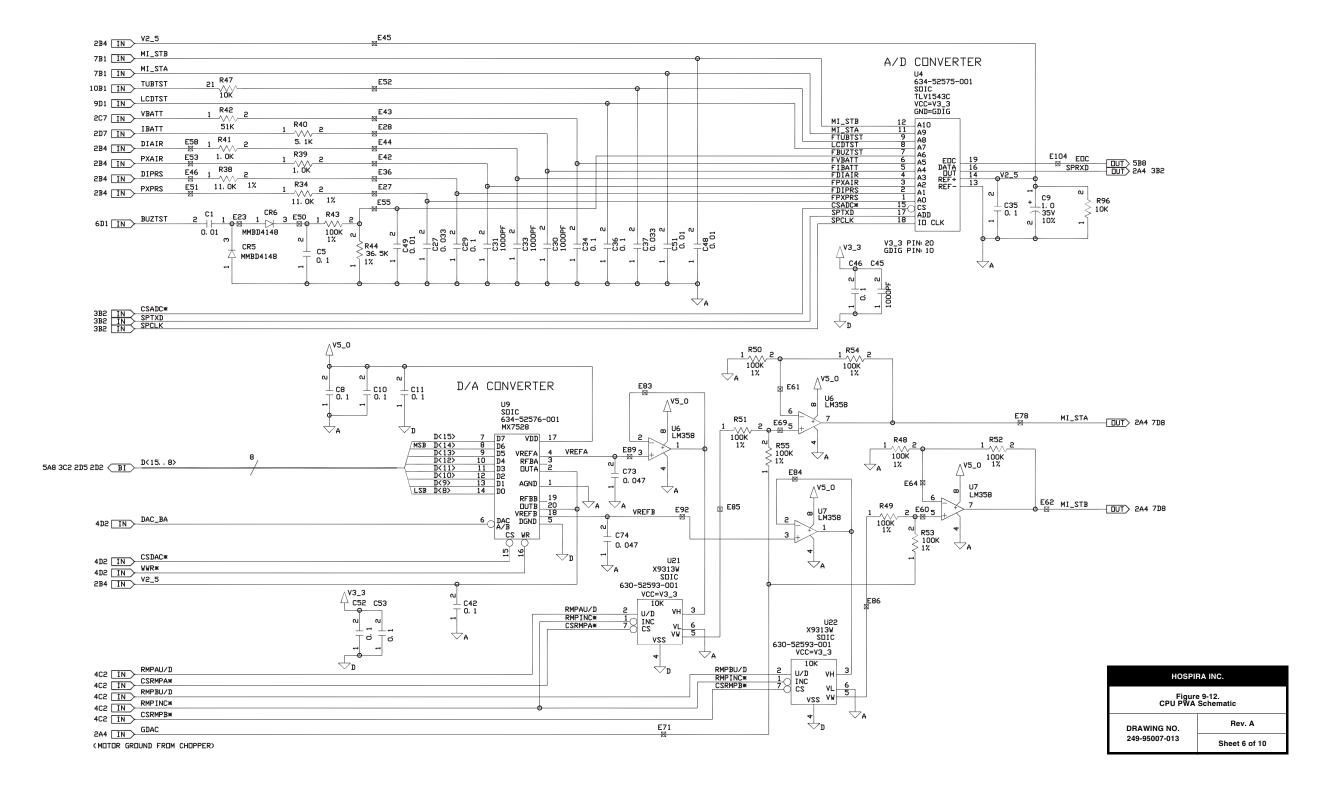


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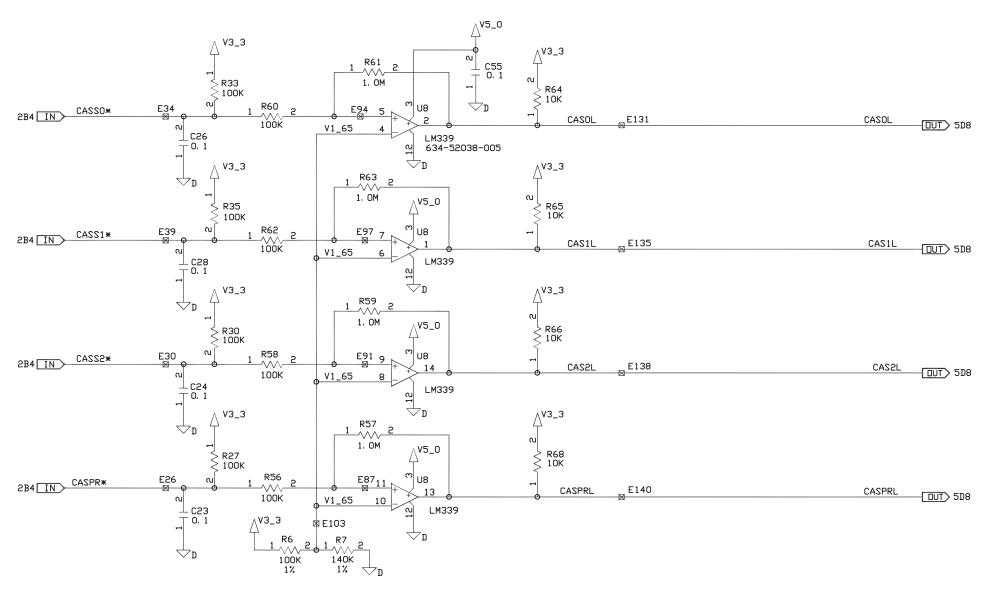
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Technical Service Manual 9 - 55 430-10996-001 (Rev. 12/05)

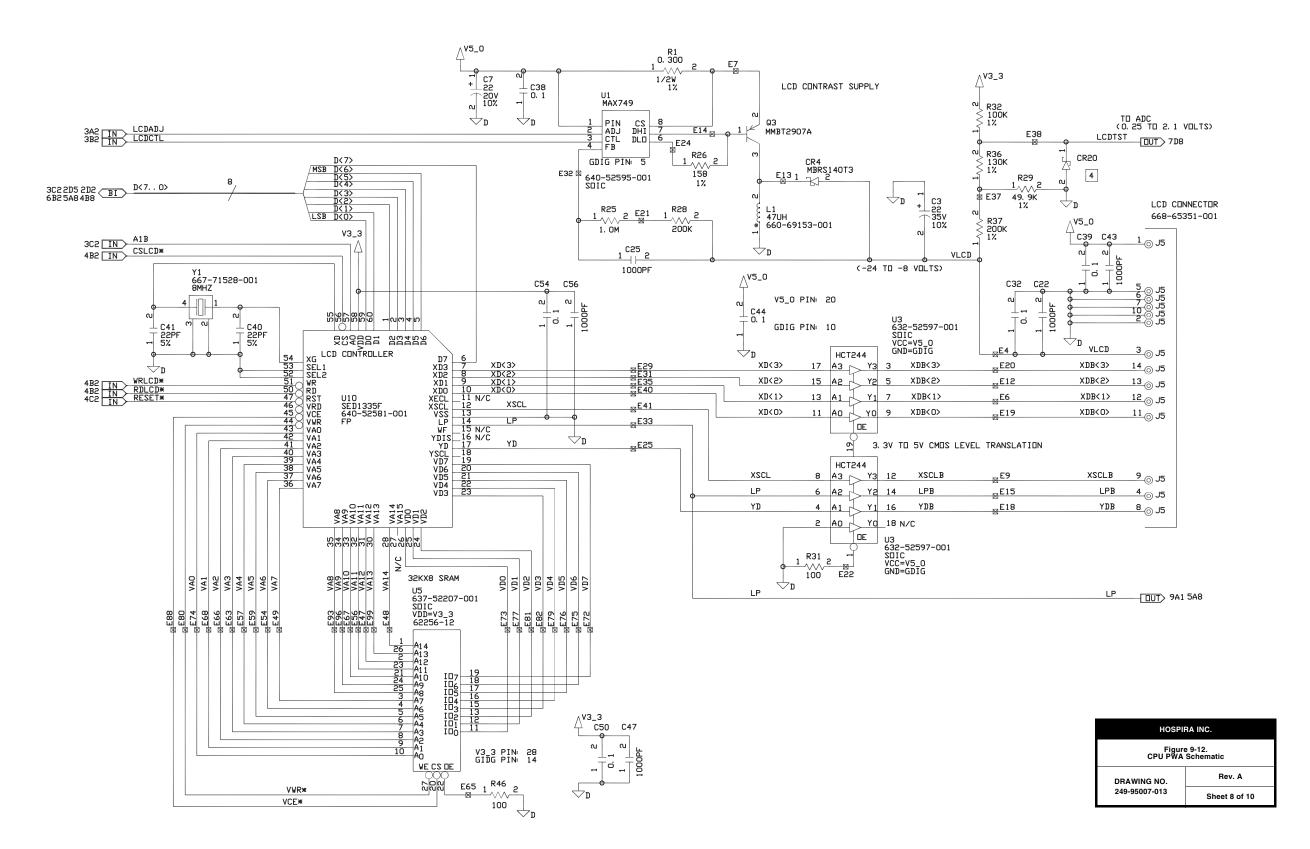
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CASSETTE ID FSR COMPARATORS

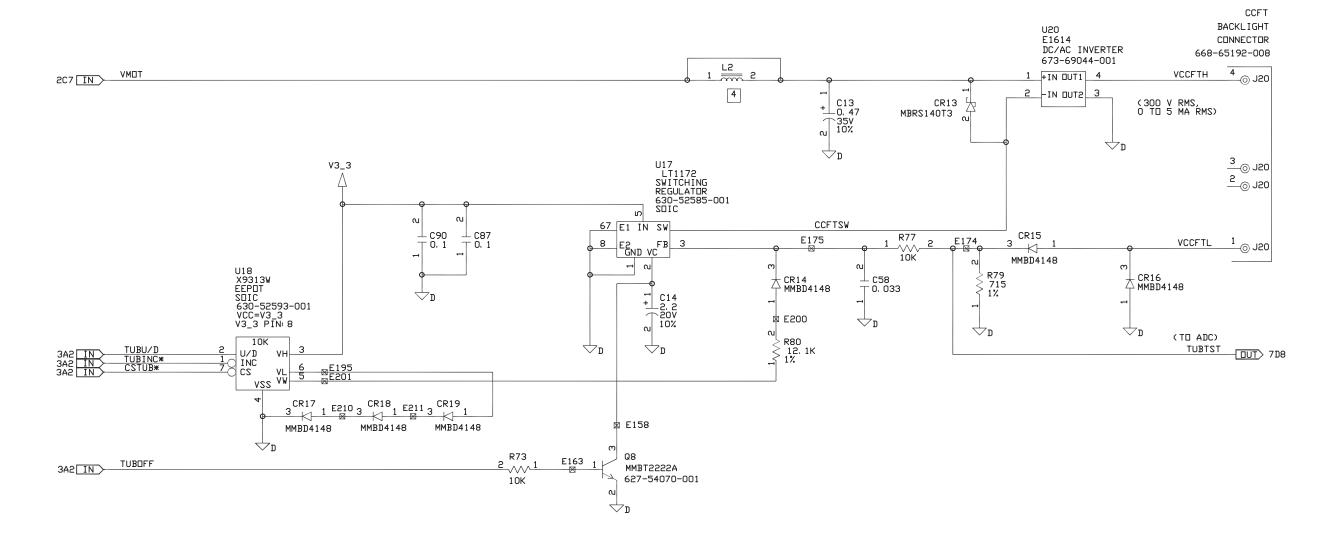


HOSPIRA INC.		
Figure 9-12. CPU PWA Schematic		
DRAWING NO.	Rev. A	
249-95007-013	Sheet 7 of 10	

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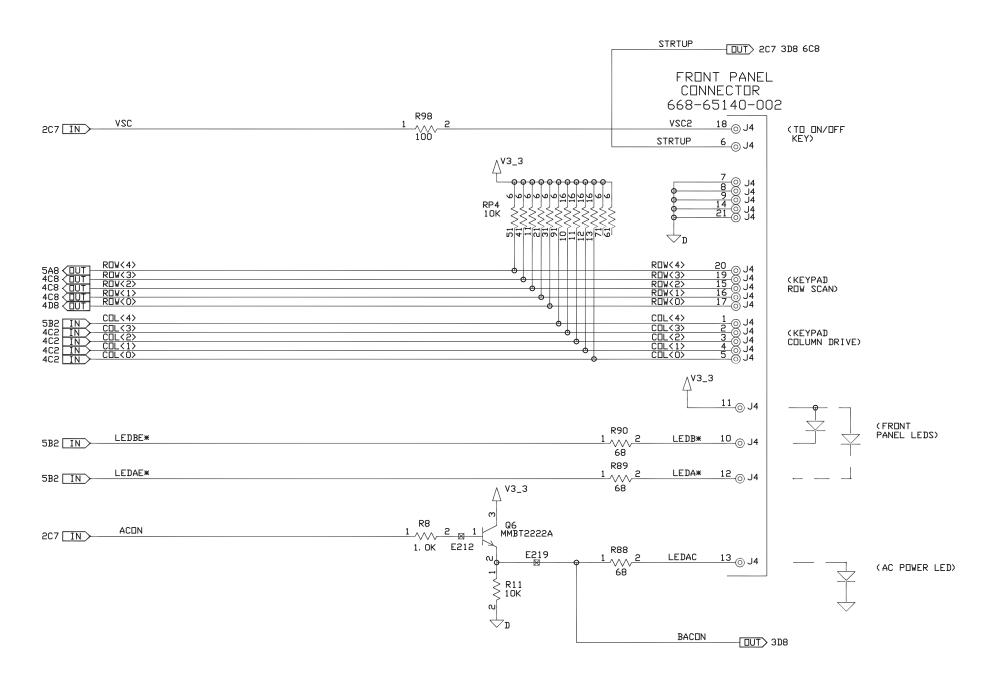
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HOSPIRA INC.		
Figur CPU PWA	Figure 9-12. CPU PWA Schematic	
DRAWING NO.	Rev. A	
249-95007-013	Sheet 9 of 10	

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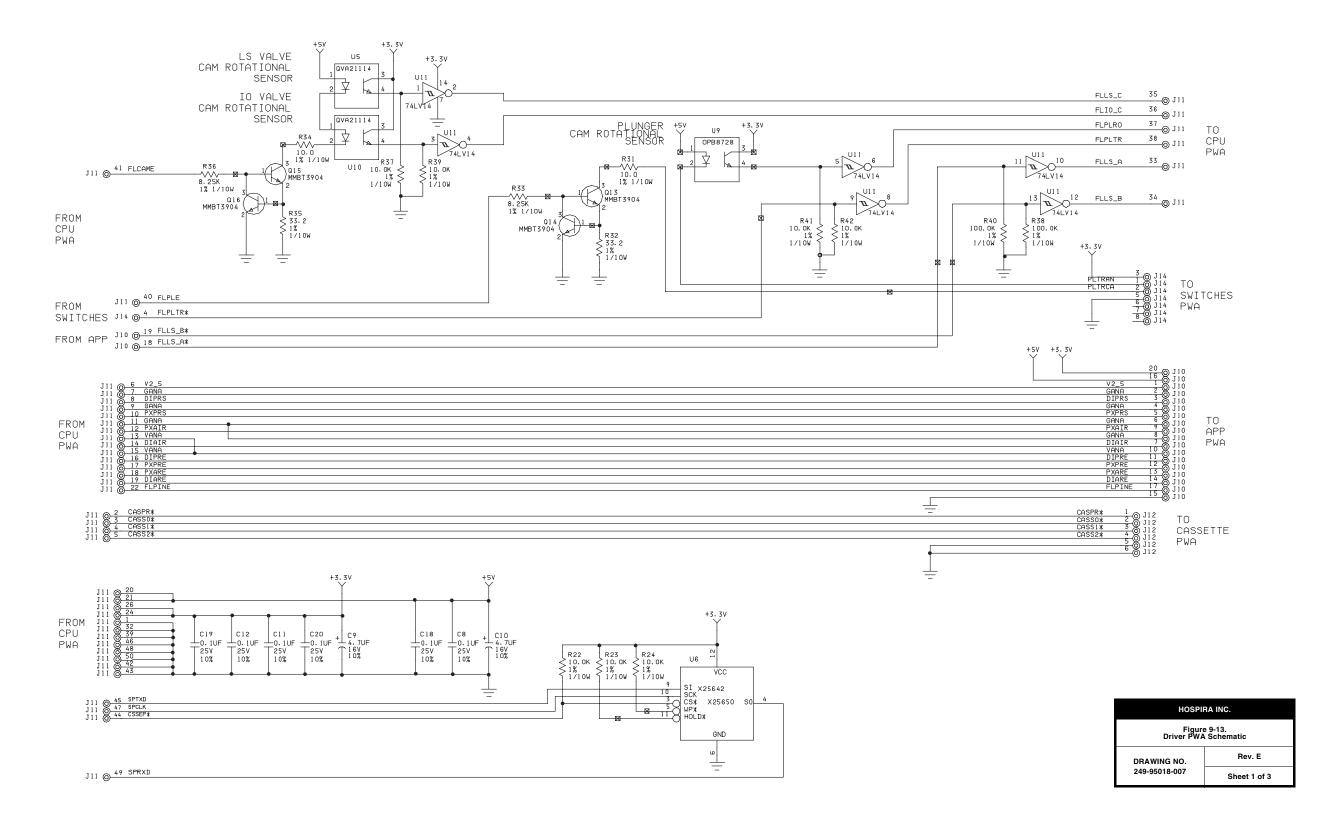
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HOSPIRA INC.	
Figure 9-12. CPU PWA Schematic	
DRAWING NO.	Rev. A
249-95007-013 Sheet 10 of 10	

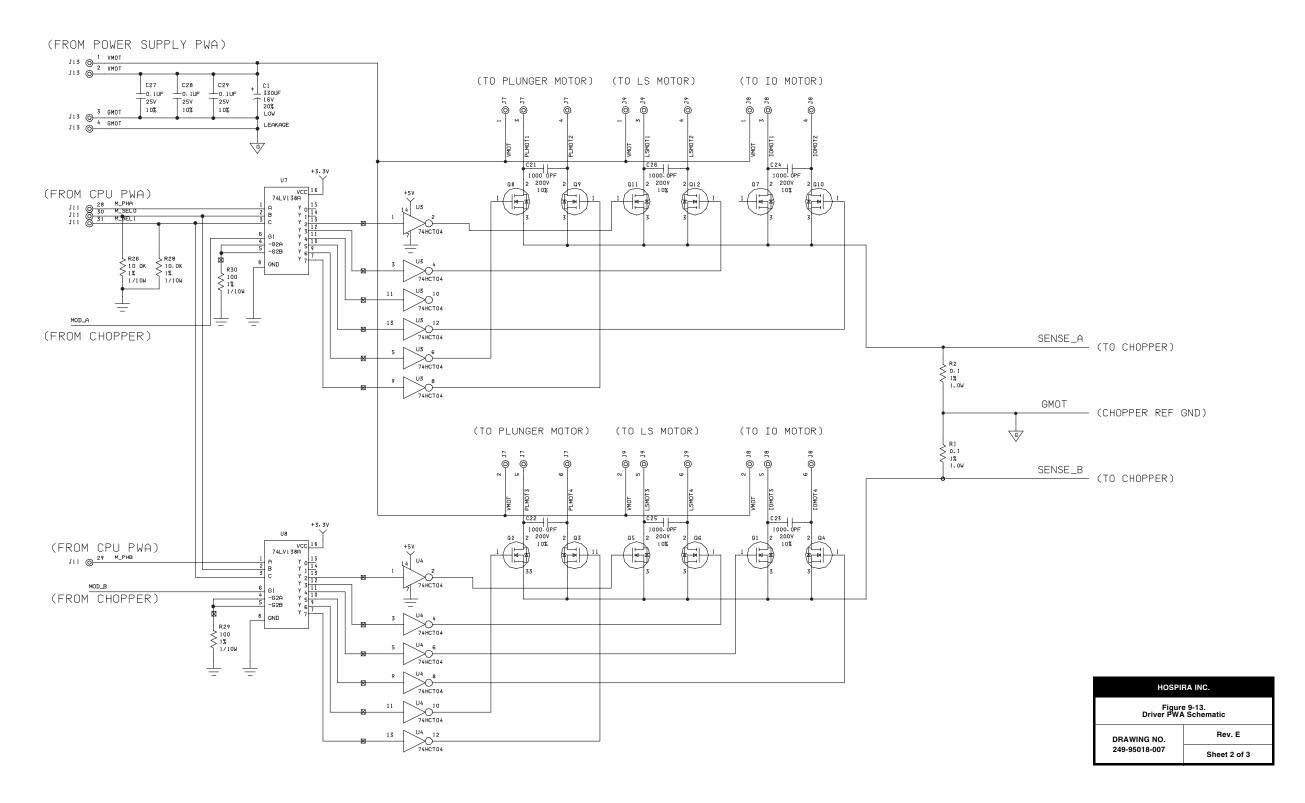
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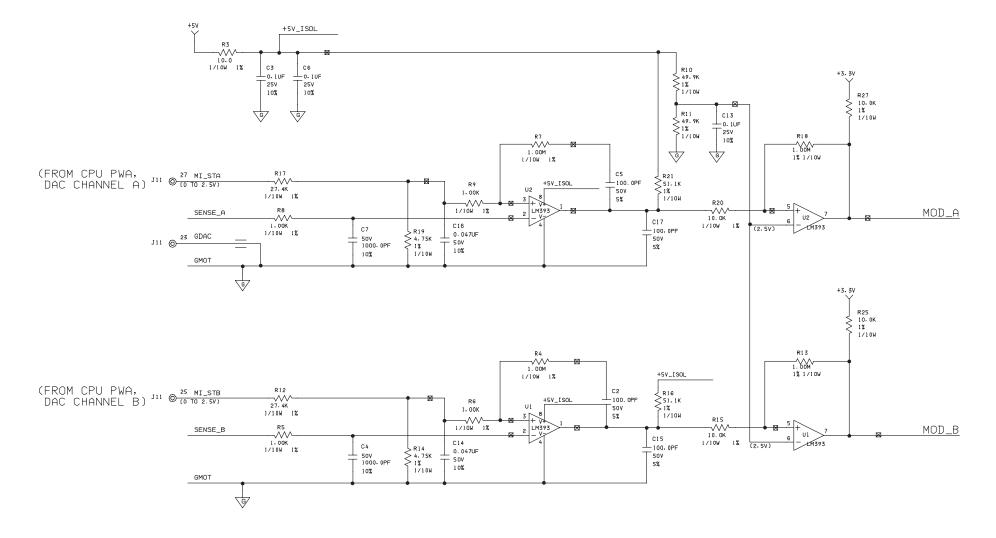
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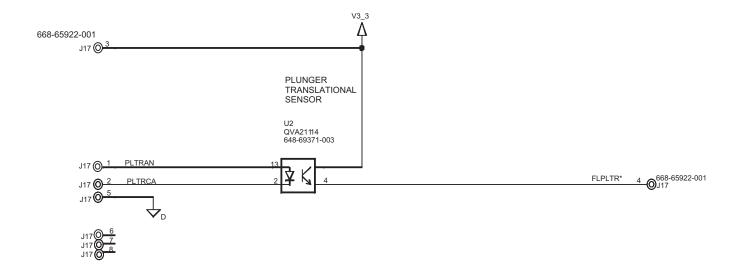
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HOSPIRA INC.		
Figure Driver PWA	Figure 9-13. Driver PWA Schematic	
DRAWING NO.	Rev. E	
249-95018-007	Sheet 3 of 3	

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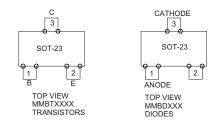
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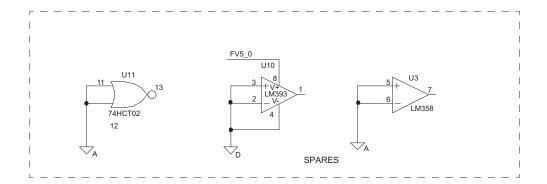


HOSPIRA INC.	
Figure 9-14. Switch PWA Schematic	
DRAWING NO.	Rev. C
249-95022-004	Sheet 1 of 1

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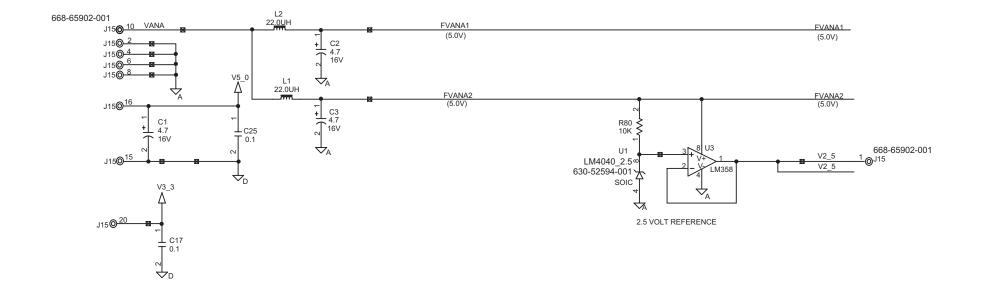




HOSPIRA INC.		
Figure 9-15. APP PWA Schematic		
DRAWING NO.	Rev. F	
249-95034-009	Sheet 1 of 4	

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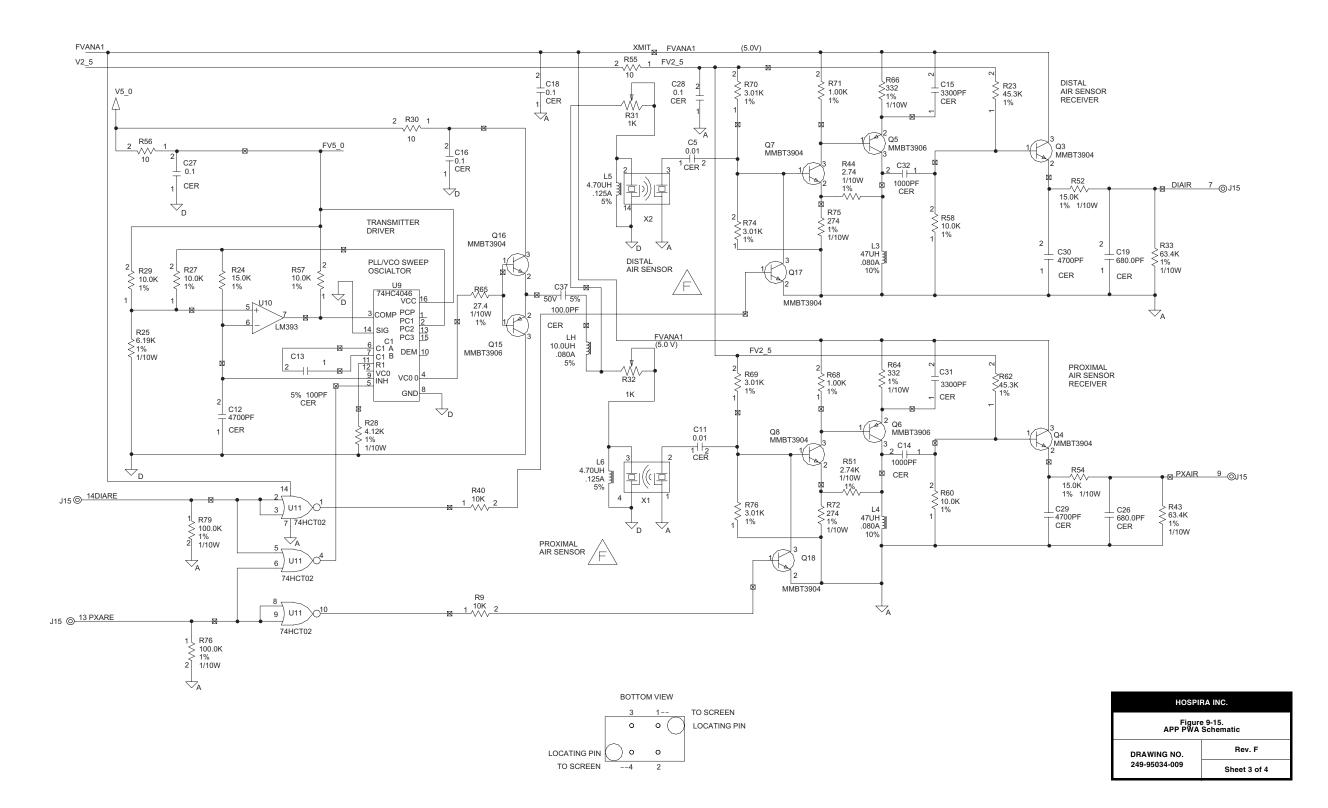
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HOSPIRA INC.	
Figure 9-15. APP PWA Schematic	
DRAWING NO.	
249-95034-009	Sheet 2 of 4

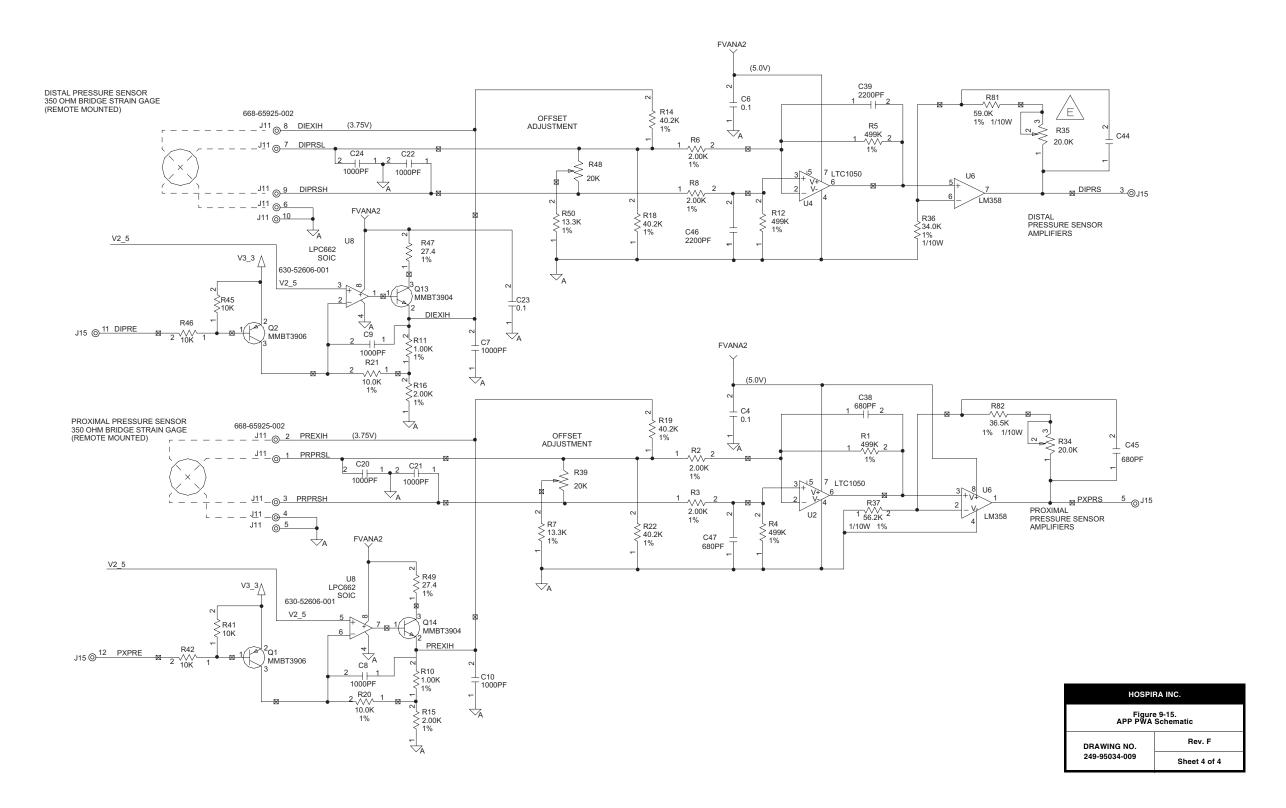
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APPENDIX

USE OF THE INFUSION SYSTEM IN ELECTROMAGNETIC ENVIRONMENTS

The Plum A+® infusion system (outside of the United States) is intended for use in the electromagnetic environment specified in *Electromagnetic Emissions*, *Electromagnetic Immunity*, and *Electromagnetic Immunity for Life-Supporting Equipment and Systems*. The user of the infusion system should assure that it is used only in the appropriate environment.

ELECTROMAGNETIC EMISSIONS

Table A-1 details electromagnetic emissions compliance and guidance for the Plum A+®.

Table A-1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions				
Emissions Test Compliance Electromagnetic Enforcement - Guidan				
RF Emissions CISPR 11	Class B	The infuser is suitable for use in all establishments, including domestic establishments and those		
Harmonic emissions IEC 61000-3-2	Class B	directly connected to the public low voltage power supply network that supplies buildings used for		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	domestic purposes.		

ELECTROMAGNETIC IMMUNITY

Table A-2 details guidance for the electromagnetic environment for the Plum A+®.

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 (See Note 2)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the 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	$<5\% \text{U}_{\text{r}}(>95\% \text{dip in U}_{\text{r}})$ for 0.5 cycle $40\% \text{U}_{\text{r}}(60\% \text{dip in U}_{\text{r}})$ for 5 cycles $70\% \text{U}_{\text{r}}(30\% \text{dip in U}_{\text{r}})$ for 25 cycles $5\% \text{U}_{\text{r}}(>95\% \text{dip in U}_{\text{r}})$ 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 (See Note 3)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note 1: U_r is the AC Mains voltage prior to application of the test level.

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

Note 3: Compliance levels tested to IEC 60601-2-24 requirements, which are more stringent than IEC 61000-4-8.

ELECTROMAGNETIC IMMUNITY FOR LIFE-SUPPORTING EQUIPMENT AND SYSTEMS

Table A-3 provides guidance for use of the Plum A+® near communications equipment.

Table A-3.				
Guidance and Manufacturer's Declaration - Electromagnetic Immunity for Life-Supporting Equipment and Systems				
Immunity Test	IEC 60601 Compliance Test Level 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: $d = \left[\frac{12}{E_1}\right]\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1}\right]\sqrt{P} 800 \text{ MHz to } 2.5 \text{ GHz}$ 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:	

- **Note:** At 80 MHz and 800 MHz, the higher frequency range applies.
- **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- ^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.
- $^{\mathbf{d}}$ 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 Plum A+® 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	150 kHz to 80 MHz in ISM bands	80 Mhz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3, 5}{V_1}\right] \sqrt{P}$	$d = \left[\frac{12}{V_2}\right] \sqrt{P}$	$d = \left[\frac{12}{E_1}\right] \sqrt{P}$	$d = \left[\frac{23}{E_1}\right] \sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

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

- **Note:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- Note: 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.
- Note: 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 80MHz 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.
- **Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.
- Note: $V_1=10 V_{rms}$, $V_2=10 V_{rms}$, and $E_1=10 V/meter$.

APPENDIX

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