

For use with list numbers 16026 and 16027

Technical Service Manual



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Section 1

INTRODUCTION

The SYMBIQ $^{\text{TM}}$ is a general purpose infusion system designed to deliver fluids, solutions, medications, agents, nutritionals, electrolytes, and blood and blood products for parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration.

A cassette-based, multi-function device, the SYMBIQ delivers basic therapy or advanced therapies such as multistep and intermittent, and is powered by either AC power or its rechargeable battery. The infusion system is available in one-channel and two-channel configurations.

The SYMBIQ is intended for use primarily in a hospital setting. Other care areas where the infusion system can be used include home care; nursing homes; mobile intensive care; ambulatory infusion centers; Hospice; subacute facilities; outpatient/surgical centers; long term care; urgent care; transport; and physician offices.

The SYMBIQ administration set is designed specifically for use with the SYMBIQ infusion system, assuring the correct administration set will be used with the correct device.

The device contains a Communication Engine (CE) module that provides wired Ethernet and wireless 802.11 a/b/g local area networking capabilities.

Hospira $MedNet^{TM}$ Software is designed to allow a facility to customize and download a drug library for use with the infusion system (see the Hospira MedNet Software User Guide).

1.1 **SCOPE**

This	manual	is	organized	into the	following	sections:

Section 1	Introduction
Section 2	Warranty
Section 3	System Operating Manual
Section 4	Theory of Operation
Section 5	Maintenance and Service Tests
Section 6	Troubleshooting
Section 7	Replaceable Parts and Repairs
Section 8	Specifications
Section 9	Drawings
Appendice	es
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 SYMBIQ System Operating Manual.

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

Figures are rendered as graphic representations to approximate actual product. Therefore, figures may not exactly reflect the product. Screen representations are examples only, and do not necessarily reflect the most current configuration

1.2 CONVENTIONS

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

Table 1-1. Conventions								
Convention	Application	Example						
Blue Italic	Reference to a section, figure, or table	(see Section 6.1)						
Red Bold	Warnings and Cautions	CAUTION: Use proper ESD grounding techniques when handling components.						
Bold	References to keys, buttons, icons, screens, and displayed messages	Press Start .						

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.

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

$\overline{1.3}$

ACRONYMS AND ABBREVIATIONS

Acronyms and abbreviations used in this manual are as follows:

- A Ampere
- AC Alternating current
- ADC Analog-to-digital converter
- CAN Controller area network
- CCA Clinical care area
 - **CE** Communication engine
- CPU Central processing unit
 - DC Direct current
- DDL Default drug library
- 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
 - **hr** Hour
 - Hz Hertz
 - **I/O** Input/output
 - IPB Illustrated parts breakdown
 - IrDA Infrared Data Association
 - IV Intravenous
 - KB Kilobyte
 - Kg Kilogram
 - KVO Keep vein open
 - LCD Liquid crystal display
 - **LED** Light emitting diode
 - LPA Linear pixel array
 - mA Milliampere
 - MB Megabyte
 - mcg Microgram
 - mg Milligram
 - mL Milliliter
 - mL/hr Milliliter per hour
 - ng Nanogram

NVRAM Non-volatile random access memory

PMC Pump mechanism controller

PSC Power supply controller

PVT Performance verification test

PWA Printed wiring assembly

RAM Random access memory

TFT Thin film transistor

UIC User interface controller

V Volt

VAC Volts AC

 V_{DC} Volts DC

VTBI Volume to be infused

1.4 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 infusion system and the administration of parenteral and enteral fluids and drugs, and whole blood or red blood cell components. Training should emphasize preventing related IV complications, including appropriate precautions to prevent accidental infusion of air. The epidural route can be used to provide anesthesia or analgesia.

1.5 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.

1.6

ELECTROMAGNETIC COMPATIBILITY

The equipment has been tested and found to comply with electromagnetic compatibility (EMC) limits in accordance with IEC/EN 60601-1-2 (2001). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

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

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

1.7

FCC INFORMATION

The device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference. The wireless LAN device in the CE has been evaluated and found to be compliant with the requirements of FCC radio frequency exposure standards.

1.8

INFUSION SYSTEM INSTALLATION

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

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e., IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-2. Any person who connects additional equipment to the signal input or output part is configuring a medical system, and is therefore responsible for assuring that the system complies with the requirements of IEC 60601-1-2. If in doubt, contact Hospira.

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 SYMBIQ 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 INSTALLATION



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 four hours.

See Figure 5-6, Figure 5-7, and Figure 5-8 for front, rear, and underside views of the infuser.

To install the infusion system, proceed as follows:

- 1. Plug the AC power cord into a grounded, hospital-grade 120 V_{AC} , 50-60 Hz receptacle, and confirm the AC power indicator is illuminated.
- 2. Press and hold the On/Off button for a minimum of two seconds to turn on the infuser. The infuser will perform a self test (see Figure 5-3).

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

3. Verify the date and time. To set the date and time, see Section 5.2.

If the infuser has a CE board installed and the Ethernet cable is not connected, the **CE Installed** icon will display in the device status information area.

To adjust brightness and volume, see the SYMBIQ System Operating Manual.

1.9 BIOMED MODE

In **Biomed Mode**, a trained and qualified Biomedical Technician can view device settings and logs, and configure and perform diagnostic tests.

Biomed Mode is password protected (see Section 5.3.3).

CAUTION: Only qualified Biomedical Technicians should access the Biomed Mode.

Note: Do not switch to Biomed Mode with the door open.

In Biomed Mode, the infuser allows the technician to perform the following:

- View the current Biomed settings
- View the serial number
- Configure the operation test
- Set the date and time

- Upload logs and data to a CE
- Reset a channel after a cassette was manually ejected
- Download new device software

In Biomed Mode, the infuser allows the technician to view the following logs:

- Event Log - Biomedical Log

- Alarm Log - Run Time log

- Keystroke Log - Malfunction Log

- Rule Set Alert/Override Log - Battery Charge Log

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Section 2

WARRANTY

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

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

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, "major repair or other service" means any repair or service other than the replacement of accessory items such as batteries and detachable AC power cords.

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

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Section 3

SYSTEM OPERATING MANUAL

A copy of the system operating manual is included with every SYMBIQ infusion system. If a copy of the system operating manual is not available, contact Hospira (see Section 6.1).



Section 4

THEORY OF OPERATION

This section describes the theory of operation for the SYMBIQ infusion system. The theory of operation details the system architecture, display subsystem, mechanical system, and cassette system.

4.1 SYSTEM ARCHITECTURE

The infuser is a multi-controller system comprised of the following components:

- User Interface Controller (UIC)
- Pump Mechanism Controller (PMC)
- Power Supply Controller (PSC)
- Communication Engine (CE)

All communications between the UIC, PMC, and PSC are accomplished by a **Control Area Network (CAN)** (see Figure 4-1). The UIC also interfaces with the CE and connects to user interface components.

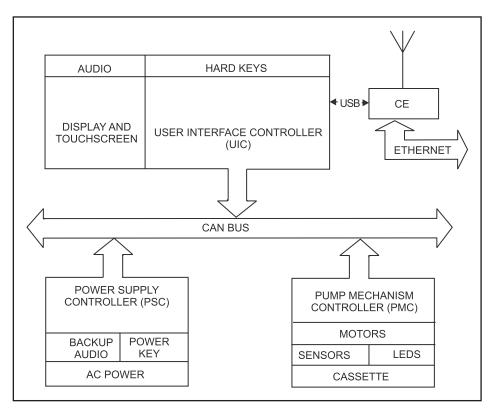


Figure 4-1. System Controllers

The following sections describe the functionality of system controllers and user interfaces.

4.1.1

USER INTERFACE CONTROLLER

The UIC contains a high-speed, 32-bit processor and a minimum of 32 MB Flash, 32 MB static RAM, and 256 KB of NVRAM. It provides the ability to interface to a liquid crystal display (LCD) and four-wire touchscreen.

The UIC manages all user interface related functions, including the following:

- System startup and shutdown
- Touchscreen and off screen key processing
- Text and graphics display
- LCD backlight control
- Keypress and audible alarm tones
- User interface navigation

- Nurse call support
- Drug library interface
- Software download interface
- System logs
- Protocol and configuration storage, retrieval, and maintenance

4.1.2

PUMP MECHANISM CONTROLLER

The PMC manages the pumping and sensing mechanisms as directed by the UIC, including the following:

- Cassette loader operation
- Fluid delivery
- Air-in-line sensing
- Distal and proximal pressure sensing
- Sensor monitoring for safe operation
- Motor movement monitoring to detect overdelivery or underdelivery
- Plunger position sensing
- Plunger pressure sensing

The PMC controls an LED indicating delivery status, cassette loader status, or alarm status, and has a watchdog to independently stop delivery if a major PMC or CAN failure is detected.

4.1.3

POWER SYSTEM CONTROLLER

The PSC manages power usage from external AC power or from the internal battery, controls an LED indicating the primary power source, and processes power on/off keypresses. The PSC also supports an audible alarm that sounds if the UIC's audible alarm has failed or a total loss of power occurs.

The PSC manages power-related functions, including the following:

- Power level sensing

- Battery temperature monitoring
- Switching between AC and battery power Cooling fan control

- Battery charging

The PSC also functions as a system watchdog. It monitors CAN activity and sounds an alarm before shutting down the system if communication with the UIC fails.

4.1.4

COMMUNICATION ENGINE

The CE is an internal assembly that provides wired Ethernet and wireless 802.11 a/b/g local area networking capabilities to the infusion system. This allows the Hospira MedNet Software to provide drug library downloads and system software upgrades, and to transfer history logs, nurse calls, alarms, and status data to the Hospira MedNet Software on the server.

The infuser provides an external Ethernet port to support wired communications, and a wireless interface for communication with external systems. The wireless interface is connected to an antenna integrated within the infuser housing. The Ethernet and wireless functionalities are mutually exclusive, with the CE providing the feature of auto-detecting an Ethernet link to allow switchovers between Ethernet and wireless ports.

Wireless communication design is compliant with IEEE 802.11 a/b/g wireless networking standards, operating in the 2.4 GHz frequency band.

4.1.5

CONTROL AREA NETWORK

All communications between the UIC, PMC, and PSC is accomplished by a CAN bus that is compliant with the CAN 2.0B standard. The CAN bus is based on a two-wire differential, bi-directional interface that provides robust hardware support to assure that messages are delivered.

$\overline{4.2}$

DISPLAY SUBSYSTEM

The infuser contains a color touchscreen for operator input and a display with program-defined content. Indication of pumping status and volumetric delivery rate is displayed on the screen and associated with each drug administration channel. Alarm output is both visual and auditory with a controlled sound level that provides an alarm for predefined conditions, delivery systems, and indication of internal self-test malfunctions detected by a combination of sensors, circuitry, and software.

4.2.1

LCD AND TOUCHSCREEN

The display employs a large thin film transistor (TFT) active matrix color liquid crystal display (LCD) with a touchscreen for readability and program entry by the clinician and easy viewing from a distance.

The touchscreen allows the operator to access and use on-screen buttons and keypads. When an active touchscreen button is pressed, the infuser sounds an audible valid key tone. A cleaning lock, located on the rear of the infuser, activates and deactivates the touchscreen (see Figure 5-7).

4.3

MECHANICAL SYSTEM

The following sections describe connectology, modularity, transport, communication, and the pole clamp assembly.

4.3.1 CONNECTOLOGY

The SYMBIQ's system of infuser connection is referred to as **Connectology**, a modular system that employs mechanical logic to explicitly allow all appropriate connection configurations, and prevent any unwanted configurations. Configuration guidelines are described in *Section 7* and the *SYMBIQ System Operating Manual*.

In addition to modularity, the connectology functions include pole clamp and minipole attachment, transport via the handle, and infuser alignment for Infrared Data Association (IrDA) communication (see Figure 4-2).

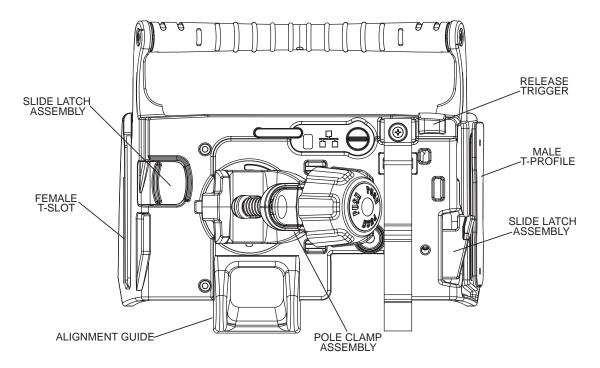


Figure 4-2. Connectology Features

4.3.1.1

MODULARITY

The connectology system employs male **T-Profile** and female **T-Slot** features on opposing side faces of the infuser units for the mechanical infuser-to-infuser interface (see Figure 4-3). The T-Slot features are tapered and have a small clearance to allow easier insertion. Also, the lower end of the T-Slot is closed on the female half to allow the male feature to bottom out on that surface and not wedge lock onto the tapered sides.

The connectology modules are designed such that additional infusers can be added horizontally from the left to the right. The male T-Profile part on the left side of the added two-channel part slides into the open female part on the right side of the one-channel infuser. The lack of a male feature on the left side of the one-channel infuser prohibits a one-channel device from being attached to another one-channel device.

The infusers may only be attached in the following combinations and configurations:

- A one-channel infuser may only be connected to a two-channel infuser.
- A two-channel infuser may be attached to a one-channel infuser or another two-channel infuser.

Features in the connectology and the pole clamp assure that only the allowable configurations are mechanically possible, preventing the user from improperly connecting two or more devices. All joined configurations are limited to only two devices. Features are incorporated to prevent unintended disconnect.

Attachments to an infuser mounted on a pole can only be done to the right of the infuser. This requirement is satisfied by employing a simple interaction with the pole clamp. By mounting an infuser to a pole, a feature in the pole clamp assembly (the sense pad) will sufficiently engage into a lockout slot feature into the latch of two-channel connectology to prevent the latch from completely moving out of the way, and preventing the addition of a device to the left side of a pole mounted, two-channel infuser.

See Section 4.3.2 for a description of the pole clamp assembly.

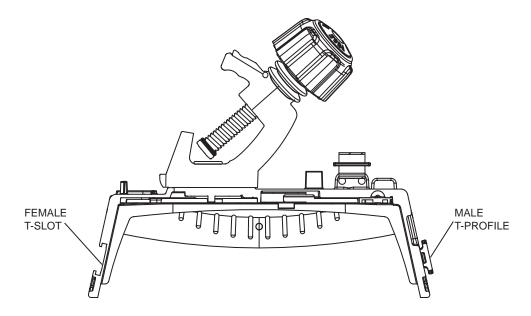


Figure 4-3. T-Slot and T-Profile Features

4.3.1.2

COMMUNICATION

The infuser is designed to accommodate data communication between two infusion devices. The communication requirement is met by using an IrDA protocol and situating the transceivers such that they face one another. Transceivers are placed facing outboard on the main PWA in the rear bezel. The lenses for these transceivers are visible on the exterior sides of the rear bezel assembly. Mechanical connection of the infusers provides sufficient line-of-sight alignment for communication between devices.



Note: At the time of printing, this data communication feature has not been activated.

4.3.1.3

TRANSPORT

The infuser can be transported via the handle. The handle is designed such that when two infusers are connected, the handles are aligned. This allows the user's hand to straddle the two handles and carry both infusers at once.

4.3.1.4

MINIPOLE ATTACHMENT

The connectology includes a feature for connecting a minipole. It consists of two holes on a rear boss into which the minipole is inserted.

4.3.2

POLE CLAMP ASSEMBLY

The SYMBIQ infusion system includes a specially designed pole clamp that allows the infuser to be mounted to an IV pole or bed rail. Similar to other conventional pole clamps, the system uses a threaded screw clamp to pinch the pole between a movable element and a fixed rest.

The pole clamp incorporates several features to increase its usability, including a locking feature, quick travel and quick release mechanisms, multiple mounting positions, and detachability (see Section 7.2.8).

In addition, the pole clamp sense pad helps prevent the user from incorrectly mounting two devices together. The pole clamp can accommodate the range of pole diameters and configurations typically seen in the hospital environment (see the SYMBIQ System Operating Manual).

4.3.3

CASSETTE LOADER

The purpose of the cassette loader is to allow for the automated insertion and ejection of the cassette into the infuser. This automation greatly reduces variability and human error that could be present with a manually loaded cassette, and assures that the cassette is properly loaded every time. However, an audible alarm will sound whenever the cassette is not properly loaded.

The cassette loader consists of the following components:

Cassette loader actuator
 Rear carriage assembly
 Release plate
 Emergency manual release
 Side plates
 Air sensor assembly
 Air sensor actuator
 Pumping mechanism
 Pump module control
 Sensor interface

Side platesSensor interfaceFront fasciaLinear pixel array

- Cassette carriage

The following sections describe the components that comprise the cassette loader.

4.3.3.1

CASSETTE LOADER ACTUATOR

The cassette loader actuator consists of a motor driven lead screw and nut, and is used to provide the opening and closing motions of the cassette loader. The stepper motor provides discrete and precise control of the loader. When it is driven at low speed it has maximum force available. When driven at high speed its force capabilities are diminished.

Once the loader has been positioned, external loads applied through the carriage will not cause the screw to rotate, thus not allowing the carriage to move.

4.3.3.2

REAR CARRIAGE ASSEMBLY

The rear carriage assembly provides the mechanical connection between the cassette loader actuator and the side plates. It is used to transmit force and movement from the actuator nut to the cassette and also contains the features necessary to provide emergency manual ejection capabilities.

4.3.3.3

RELEASE PLATE

The release plate is the part of the rear carriage assembly that connects the rear carriage to the nut on the cassette loader actuator. It slides up and down to allow the rear carriage to become uncoupled from the nut on the cassette loader actuator when the emergency manual release is pulled.

4.3.3.4

EMERGENCY MANUAL RELEASE

Pulling the emergency manual release allows the operator to manually eject the cassette in the event of a failure of the automatic loading system. The ramped surface on the emergency manual release pushes the release plate upward and uncouples it from the nut on the cassette loader actuator. The emergency manual release can be used to open the cassette loader no matter what position the loader is in at the time of release. The infuser will sense that the manual release has been used and the appropriate signal or alarm will be sent to the infuser display screen.

In the event the emergency manual ejection system is used, the infuser may be completely non-functional and will require troubleshooting and/or resetting.

4.3.3.5

SIDE PLATES

Left and right side plates connect the rear carriage assembly to the front fascia and cassette carriage. The direct connection between the side plates and the cassette carriage allows for precise loading of the cassette.

4.3.3.6

FRONT FASCIA

The left and right front fascia pieces are predominantly cosmetic pieces that contain the cassette carriage, and form the channel that helps guide the cassette as the operator inserts the cassette into the cassette carriage.

4.3.3.7

CASSETTE CARRIAGE

The cassette carriage forms the geometry that handles the cassette during the loading process. It floats loosely within the front fascia/side plate assembly, and allows the cassette enough movement to properly seat on the infuser chassis when it reaches the home (fully closed) position.

4.3.3.8

AIR SENSORS AND ACTUATOR

Left and right ultrasonic air sensor assemblies close around the tubing just below the cassette and detect air bubbles during infusing. The air sensor actuator is driven by a stepper motor and controls the position of the air sensors. The air sensors open and close as the air sensor actuator moves in and out.

4.3.3.9

PUMPING MECHANISM

The pumping mechanism assembly is located on the infuser chassis and moves the plunger in and out to allow the system to pump fluid. Its components include a DC motor, camshaft, clutch, plunger, and bearings.

4.3.3.10

NORMAL OPERATION

The basic operation of the cassette loader mechanism under normal conditions are summarized in the following steps:

- 1. Cassette loader closed with no cassette
- 2. Open cassette loader
- 3. Insert cassette
- 4. Close cassette loader with cassette
- 5. Fluid delivery
- 6. Open cassette loader
- 7. Remove cassette or insert new cassette
- 8. Close cassette loader

See the SYMBIQ System Operating Manual for preparing and loading the cassette.

4.3.4

FREE FLOW MITIGATION

In order to properly prime the cassette, the flowstop on the cassette must be opened, which allows fluid to flow freely through the cassette. However, if the cassette is inserted into the carriage with the flowstop open, the SYMBIQ infusion system includes several methods of mitigating potential free flow events.

The first major free flow mitigation feature is the automated cassette loading under microprocessor control. The operator inserts the cassette into the carriage and presses the **LOAD/EJECT** button. This assures that the cassette will be properly loaded every time. If for some reason it is not, the infuser senses this and sounds an alarm.

The second major free flow mitigation feature is the automatic closure of an open flowstop via the interaction of the distal pressure pin and the flowstop post with the flowstop switch. If the operator fails to close the flowstop switch prior to inserting the cassette, the distal pressure pin and the flowstop post will combine to automatically close the open flowstop when the cassette reaches its fully loaded position. This eliminates potential for free flow.

The third major free flow mitigation feature is the automatic closure of the cassette loader after it has been open for six seconds. If the operator fails to initiate the cassette loader loading sequence by pressing the **LOAD/EJECT** button within six seconds of the door opening, the door will automatically close. This assures that the flowstop will be closed via the distal pressure pin and flowstop post interaction even if the operator neglects to push the **LOAD/EJECT** button to close the cassette loader. Also, since the flowstop is automatically closed when the cassette is loaded, free flow to a patient cannot occur if the tubing is only connected to the patient after the cassette is fully loaded.

The infuser will display a message instructing the operator to close the door before powering down. The message also gives the operator the option to force a shutdown, which will leave the door open.

4.3.5

OFF-SCREEN KEYS

The infuser is equipped with several off-screen keys in addition to the touchscreen (see Figure 5-6, Figure 5-7, and Figure 5-8).

A membrane panel on the front bezel contains the following:

LOAD/EJECT buttonEmergency StopOn/Off buttonLED indicator

In addition, a Silence button and a touchscreen Cleaning Lock button are located on the central module of the infuser.

4.3.6

SENSOR INTERFACE

The sensor interface board contains connections to internal sensors on the infuser and connects to the PMC.

4.3.7

LINEAR PIXEL ARRAY

The linear pixel array (LPA) board contains a 256-pixel array that monitors the position of the cassette carriage. With an overall coverage area of .64 inches, the LPA coverage extends beyond the cassette's fully closed and fully open positions.

$\overline{4.4}$

CASSETTE SYSTEM

The cassette is a small, low cost, sterile pumping chamber with an infusion range from $0.1\,\text{mL/hr}$ to $1000\,\text{mL/hr}$. Air in the tubing is ultrasonically detected by the infuser as fluid exits from the cassette. When released, the cassette is automatically protected against fluid free flow. By opening the flowstop, the cassette may be gravity primed.

A pumping chamber forms the heart of the cassette. It interfaces to a plunger in the infuser. When the plunger is depressed, fluid in the chamber is exhausted through a one-way outlet valve to a small outlet chamber. When the plunger is retracted, the outlet valve closes and a one-way inlet valve opens to let fluid in from a small inlet chamber. The volume pumped for each pumping cycle is approximately 75.93 microliters for a nominal plunger stroke length of .060 inch.

The inlet and outlet chambers connect to strain gauges in the infuser to monitor proximal and distal tubing pressures. A latching flowstop contacts the outlet chamber. When it is latched open, the outlet valve is free to open and close. When it is latched closed, it causes the outlet valve to remain in the closed position, preventing fluid flow when the cassette is outside the infuser.

The cassette consists of a body and top, diaphragm, flowstop, and incompatibility collar.

4.4.1 BODY AND TOP

The body and top enclose the silicone diaphragm to form the inlet, pumping, and outlet chambers. The flexible diaphragm mates to the body to enclose the chambers and form the one-way valves. The infuser plunger presses on the diaphragm to empty the pumping chamber and when the plunger retracts, the spring force of the diaphragm refills the pumping chamber.

4.4.2 DIAPHRAGM

Fluid enters the cassette at the inlet port to fill the inlet chamber. The top of this chamber is part of the diaphragm. A pin from the infuser contacts the top of the chamber to detect any deflection. If pressure drops in the chamber, the top of the chamber will deflect, which the infuser can sense. The infuser analyzes this deflection to determine if there is a proximal occlusion.

When the pump plunger retracts, fluid is drawn from the inlet chamber to the pumping chamber through the one-way flapper valve. When the plunger completes the retracting stroke, it reverses direction, and the flapper valve to the inlet chamber closes. As the plunger advances, pressure builds in the pumping chamber and opens the outlet valve.

Like the inlet chamber, the outlet chamber top is part of the flexible diaphragm. The flowstop contacts the diaphragm and a pin from the infuser contacts the flowstop. If pressure builds up in the outlet chamber, the top of the chamber will deflect, which the infuser can sense. The infuser analyzes this deflection to determine if there is a distal occlusion.

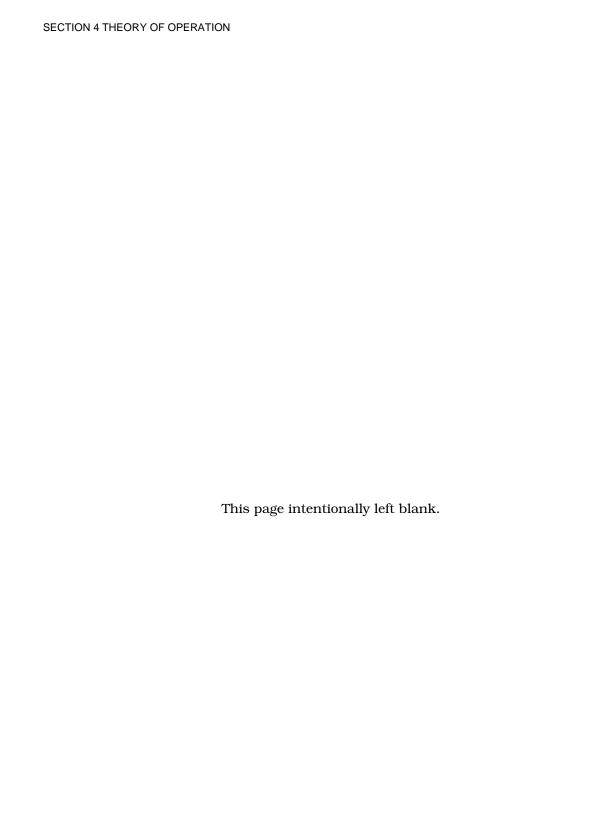
4.4.3 FLOWSTOP

The flowstop is a rocker switch that latches either open or closed. When closed, it will deflect the top of the outlet chamber to press the outlet valve closed. The flowstop pressure is sufficient to prevent free flow to approximately a seven-foot head height.

After priming, the flowstop should be closed prior to installing the cassette. However, when the cassette is installed into the infuser, the flowstop is switched to the closed position automatically. As the plunger engages the chamber, it relaxes the outlet valve and reduces the valve cracking pressure. When the cassette is removed from the infuser, the flowstop remains in the closed position and requires manual opening for priming.

4.4.4 INCOMPATIBILITY COLLAR

The incompatibility collar is a feature that prevents the SYMBIQ cassette from being used on any other Hospira infuser due to mechanical interference. It consists of a small annular piece of plastic that is bonded to the top of the cassette body.



Section 5

MAINTENANCE AND SERVICE **TESTS**

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

5.1 ROUTINE MAINTENANCE

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

5.1.1 CLEANING AND SANITIZING

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

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

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

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



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

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

CAUTION: Use only recommended cleaning solutions and follow manufacturers' recommendations. Using cleaning solutions not recommended by Hospira may result in product damage. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.

CAUTION: Never use sharp objects such as fingernails, paper clips, or needles, to clean any part of the infuser. Do not use abrasive scrub pads or brushes on the LCD touchscreen. Use only soft cloths or sponges. Do not sterilize by heat, steam, ethylene oxide (ETO), or radiation.

CAUTION: To avoid mechanical or electronic damage, do not immerse the infuser in fluids or cleaning solutions. Do not spray cleaning solutions toward any openings in the device, or directly on the device. Do not spray cleaning solutions directly into the rear infuser AC power outlets (see Figure 5-1).

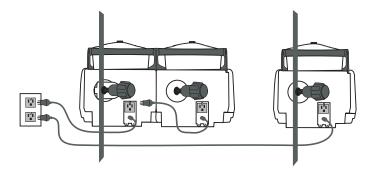


Figure 5-1. Rear Infuser AC Power Outlets

	Table 5-1. Cleaning Soluti	ons
Cleaning Solution	Manufacturer	Preparation
CaviCide [®]	Metrex Research	Per manufacturer's recommendation
CaviWipes TM /CaviWipes XL TM	Metrex Research	Per manufacturer's recommendation
Coverage [®] HB	Steris	Per manufacturer's recommendation
Dispatch [®] Hospital Cleaner Disinfectant with Bleach	Caltech Industries	Per manufacturer's recommendation
Formula C TM	JohnsonDiversey	Per manufacturer's recommendation
Manu-Klenz [®]	Steris	Per manufacturer's recommendation
Precise [®] Hospital Foam Cleaner Disinfectant	Caltech Industries	Per manufacturer's recommendation
Sani-Cloth [®] HB Wipe	Professional Disposables	Per manufacturer's recommendation
Sani-Cloth [®] Bleach Wipe	Professional Disposables	Per manufacturer's recommendation
Sporicidin [®]	Sporicidin	Per manufacturer's recommendation
Vesphene [®] II se	Steris	Per manufacturer's recommendation
Isopropyl Alcohol	Any	70% by volume
Household Bleach (Sodium Hypochlorite)	Any	Use per hospital procedures Do not exceed one part bleach to ten parts water

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

5.1.1.1

CLEANING LOCK

Easy wipedown can be performed during operation of the device by activating the Cleaning Lock located on the rear of the infuser (see Figure 5-7). The Cleaning Lock deactivates the infuser touchscreen and prevents inadvertent keypresses while off-screen keys remain enabled (see the System Operating Manual).

To activate the Cleaning Lock, press and hold the **Cleaning Lock** button for one second, then release it. The **Cleaning Lock Active** message displays.

To deactivate the cleaning lock, press the **Cleaning Lock** button then release it.

5.2

SETTING THE DATE AND TIME

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 date and time, proceed as follows:

- 1. Turn off the infuser, disconnect from AC power, and leave the infuser off for a minimum of six minutes.
- 2. Confirm shutdown has occurred. The screen will no longer display CE on-line.
- 3. Press and hold the **On/Off** key to turn on the infuser.
 - **Note:** The date and time must be set within 60 seconds of turning on the infuser.
- 4. If the New Patient? screen appears, press Continue.
- 5. Verify the **Select CCA** screen appears.
- 6. Press **Select CCA**, then select a CCA.
- 7. Confirm the selected CCA, then press **Done**.
- 8. Verify the **Program** screen appears.
- 9. To access the date and time screen, press the **Settings** icon.
- 10. Verify the **Settings** screen appears. Press **Date & Time**.
- 11. Verify the **Settings: Date & Time** screen appears (see Figure 5-2).
- 12. Set the date and time as described in step 13 through step 21.
- 13. To select the month, press the **Down** arrow in the **Month** field, then select the correct month.
- 14. To select the date, press the **Day** field. Using the on-screen keypad, input the correct date, then press **Enter**.
- 15. To select the year, press the **Year** field. Using the on-screen keypad, input the correct year, then press **Enter**.
- 16. To select the time format, press the **Down** arrow in the **Time Format** field, then select the desired time format.

- 17. To select the time, press the **Time** field. Using the on-screen keypad, select the hours field to change the hour setting, and select the minutes field to change the minute setting.
- 18. Press **Enter**, then select **AM** or **PM** from the **AM/PM** field. If the 24-hour time format was selected in step 16, the **AM/PM** field will not be a selectable option.
- 19. Press **Save** in the lower right of the touchscreen.
- 20. Press **Exit** to return to the **Program** screen.
- 21. Wait for the CE to fully reboot (within approximately two minutes), then power off the device.



Figure 5-2. Date & Time Screen

5.3

PERFORMANCE VERIFICATION TEST

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

The infuser automatically sets the delivery rate and air sensitivity when required during the PVT.

Note: Each section of the test should be run in sequence.

If any malfunction is detected as a result of the PVT, see Section 6. If any tests fail, contact Hospira.

5.3.1

EQUIPMENT REQUIRED

The PVT requires the following equipment, or equivalents:

- SYMBIQ macrobore administration set with microbore segment (List No.16090), 2 ea.
- Empty cassette, 2 ea.
- 18-gauge butterfly needle, latex-free, 2 ea.
- Sterile water or tap water in an IV bag/container
- Graduated cylinder, 25 mL, with 0.2 mL graduations (Class A), 2 ea.
- Container for expelled fluids
- Safety analyzer (Fluke[®] Biomedical 232D)
- Nurse call cable (optional)

5.3.2 INSPECTION

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

Inspect the following areas for missing or damaged parts:

- Labels - Pole clamp assembly

- AC power cord and retainer strap - Front bezel and rear enclosure

Rubber foot padsLCDExternal screwsLEDs

Note: On the two-channel device, inspect the release trigger and slide latch assembly to assure they move freely (see Figure 4-2).

5.3.3 TEST SETUP

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

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

- 1. Attach an administration set with a primed cassette to a sterile water container at a height of 18 to 24 inches above the infuser pumping chamber (see Figure 5-4).
- 2. Plug the AC power cord into a grounded, hospital-grade 120 $V_{AC},\,50\text{-}60\;\text{Hz}$ receptacle, and confirm the AC power indicator is illuminated.

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

3. Press and hold the **On/Off** button for a minimum of two seconds to turn on the infuser. The infuser will perform a self test (see Figure 5-3).

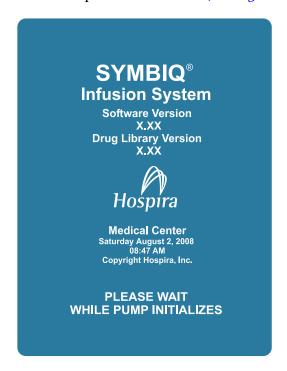


Figure 5-3. Self Test Screen

- 4. Verify the date and time. To set the date and time, see Section 5.2.
- 5. If the **New Patient?** screen appears, press **Continue**.
- 6. Verify the **Select CCA** screen appears.
- 7. Press **Select CCA**, then select a CCA.
- 8. Confirm the selected CCA, then press **Done**.
- 9. Verify the **Select Infusion** screen appears, then press **Mode**.
- 10. Verify the **Enter Passcode** screen appears. Using the on-screen keypad, enter **5513**, then press **Enter**.
- 11. The infuser restarts into the **Biomed Mode**.
- 12. Verify the **Biomed** screen appears, then press **Operation Test**.
- 13. Verify the Operation Test screen appears, then press Select Test.
- 14. The **Delete information?** question appears. Press **Yes**.
- 15. Verify the Operation Test screen appears, then press Run All.
- 16. Verify the **PSC Power Test** screen appears.

PSC POWER TEST

To perform the PSC power test, proceed as follows:

- 1. Press **Start**. The infuser runs the PSC power test.
- 2. Verify all PSC tests pass. See *Table 5-2* for acceptable power test values.

Table 5-2. PSC Power Test				
Test	Acceptable Power Test Value			
3.3 V	Pass if value is within 3.3 ±5% V			
5 V	Pass if value is within 5 ±5% V			
8 V	Pass if value is within 8 V \pm 5% V			
14.5 V (System voltage)	Pass if value is within 14.5 V $\pm 5\%$ V If the test fails, connect the device to AC power, then rerun the test			
Battery voltage	Pass if value is within 7 V _{DC} and 13 V _{DC}			
Battery current	Pass if value is within -4000 mA and +4000 mA			



Note: The infuser will not indicate Pass or Fail for the system current test and battery capacity test.

- 3. Press **Done** to exit the test, or **Rerun** to repeat the test.
- 4. Verify the **Temperature Test** screen appears.

5.3.5

TEMPERATURE TEST

To perform the temperature test, proceed as follows:

- 1. Press **Start**. The infuser runs the temperature test.
- 2. Verify the temperature test passes. See *Table 5-3* for acceptable temperature values.

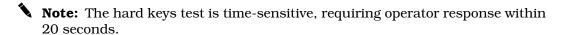
Table 5-3. Temperature Test				
Test	Acceptable Temperature Value			
Battery temperature	Pass if value is ≤65° C If battery is not present, results will show N/A			
UIC temperature	Pass if value is ≤70° C			
PSC temperature	Pass if value is ≤70° C			
PMC temperature (for both A and B channel)	Pass if value is ≤70° C			

- 3. Press **Done** to exit the test, or **Rerun** to repeat the test.
- 4. Verify the Hard Keys Test screen appears.

HARD KEYS TEST (ONE-CHANNEL)

The hard keys include the following buttons located on the one-channel infuser:

- Alarm SilencePower On/OffEmergency StopLoad/Eject
- Emergency Stop- Cleaning Lock



To perform the hard keys test, see *Figure 5-6*, then proceed as follows:

- 1. Confirm the five hard keys are highlighted on the display.
- 2. Press Alarm Silence and confirm the Pass result.
- 3. Press **Emergency Stop** and confirm the **Pass** result.
- 4. Press and hold Cleaning Lock and confirm the Pass result.
- 5. Press and hold Power On/Off and confirm the Pass result.
- 6. Press **Load/Eject** and confirm the **Pass** result.
- 7. Press **Done** to exit the test.
- 8. Verify the LCD Backlight Test screen appears.

5.3.7

HARD KEYS TEST (TWO-CHANNEL)

The hard keys include the following buttons located on the two-channel infuser:

- Alarm Silence
 Cleaning Lock
 Load/Eject A
 Emergency Stop
 Power On/Off
 Load/Eject B
 - **Note:** The hard keys test is time-sensitive, requiring operator response within 20 seconds.

To perform the hard keys test, see *Figure 5-6*, then proceed as follows:

- 1. Confirm the six hard keys are highlighted on the display.
- 2. Press Alarm Silence and confirm the Pass result.
- 3. Press **Emergency Stop** and confirm the **Pass** result.
- 4. Press and hold Cleaning Lock and confirm the Pass result.
- 5. Press and hold **Power On/Off** and confirm the **Pass** result.
- 6. Press Load/Eject A and confirm the Pass result.
- 7. Press Load/Eject B and confirm the Pass result.
- 8. Press **Done** to exit the test.
- 9. Verify the LCD Backlight Test screen appears.

LCD BACKLIGHT TEST

To perform the LCD backlight test, proceed as follows:

- 1. Press **Start**. The question **Did the backlight dim?** appears. Press **Yes**.
- 2. Press Start. The question Did the backlight brightness increase? appears. Press Yes.
- 3. Verify the LCD backlight test passes, then press **Done** to exit the test.
- 4. Verify the **LCD Test** screen appears.

5.3.9

LCD TEST

To perform the LCD test, proceed as follows:

- 1. Press **Start**, and verify the screen turns red.
- 2. The question Did the entire screen display red? appears. Press Yes.
- 3. Press **Start**, and verify the screen turns green.
- 4. The question Did the entire screen display green? appears. Press Yes.
- 5. Press **Start**, and verify the screen turns blue.
- 6. The question Did the entire screen display blue? appears. Press Yes.
- 7. Verify the LCD test passes, then press **Done** to exit the test.
- 8. Verify the **Touchscreen Test** screen appears.

5.3.10

TOUCHSCREEN TEST

To perform the touchscreen test, proceed as follows:

- 1. Press **Start**, and verify the on-screen touchpad appears.
 - Note: The numeral 1 key will be in 3-D mode.
- 2. Touch all the keys in sequence and verify their characteristics momentarily change to **3-D**.
- 3. If the test fails, press **Calibrate Touchscreen**, then press **Start** and follow the on-screen instructions.
- 4. If the test passes, press **Done** to exit the test.
- 5. Verify the **LED Test** screen appears.

LED TEST (ONE-CHANNEL)

The LED test includes the alarm LED test and the AC LED test.

To perform the LED test, proceed as follows:

- 1. Press **Start**. The question **Is the Channel A LED lit flashing green?** appears. Press **Yes**.
- 2. The question **Is the Channel A LED lit flashing yellow?** appears. Verify that two LED globes are flashing on Channel A and appear as a yellow-like color. If so, press **Yes**.
 - **Note:** The yellow-like color is created by the simultaneous lighting of the green and red LEDs.
- 3. The question is the Channel A LED lit flashing red? appears. Press Yes.
- 4. The question is the Channel A LED lit flashing white? appears. Press Yes.
- 5. The question **Is the AC LED flashing?** appears. Press **Yes**.
- 6. Verify the LED test passes, then press **Done** to exit the test.
- 7. Verify the Audible Tone/Microphone screen appears.

5.3.12

LED TEST (TWO-CHANNEL)

To perform the LED test, proceed as follows:

- 1. Press Start. The question Is the Channel A LED lit flashing green? appears. Press Yes.
- 2. The question **Is the Channel A LED lit flashing yellow?** appears. Verify that two LED globes are flashing on Channel A and appear as a yellow-like color. If so, press **Yes**.
 - **Note:** The yellow-like color is created by the simultaneous lighting of the green and red LEDs.
- 3. The question is the Channel A LED lit flashing red? appears. Press Yes.
- 4. The question Is the Channel A LED lit flashing white? appears. Press Yes.
- 5. The question is the Channel B LED lit flashing green? appears. Press Yes.
- 6. The question **Is the Channel B LED lit flashing yellow?** appears. Verify that two LED globes are flashing on Channel B and appear as a yellow-like color. If so, press **Yes**.
 - **Note:** The yellow-like color is created by the simultaneous lighting of the green and red LEDs.
- 7. The question is the Channel B LED lit flashing red? appears. Press Yes.
- 8. The question is the Channel B LED lit flashing white? appears. Press Yes.
- 9. The question Is the AC LED flashing? appears. Press Yes.
- 10. Verify the LED test passes, then press **Done** to exit the test.
- 11. Verify the Audible Tone/Microphone screen appears.

AUDIBLE TONE TEST

To perform the audible tone test, proceed as follows:

- 1. Press **Test Primary Speaker** and confirm the audible tone.
- 2. The question Did you hear the tone? appears. Press Yes.
- 3. Press **Test Secondary Speaker**, and confirm the audible tone.
- 4. The question Did you hear the secondary speaker tone? appears. Press Yes.
- 5. Verify the audible tone test passes.
- 6. Press **Done** to exit the test.
- 7. Verify the Nurse Call Relay Test screen appears.

5.3.14

NURSE CALL RELAY TEST



Note: The nurse call relay test may be bypassed if the function is not used. Press **SKIP** to bypass the nurse call relay test.

To perform the nurse call relay test, proceed as follows:

- 1. Plug the nurse call cable into the nurse call jack (see Figure 5-7).
- 2. Press **Start**, and follow the on-screen instructions.
- 3. The question Did the callback function correctly? appears. Press Yes.
- 4. Verify the nurse call relay test passes.
- 5. Press **Done** to exit the test, or **Rerun** to repeat the test.
- 6. Verify the Cassette Loading Mechanism Test screen appears.

CASSETTE LOADING MECHANISM TEST (ONE-CHANNEL)

Note: If the manual load eject lever is pulled during the PVT, the Biomed Mode menu will display.

To perform the cassette loading mechanism test, proceed as follows:

- 1. Press LOAD/EJECT, and insert the empty cassette upside down into the cassette carriage. The infuser will attempt to close the door but will alarm.
- 2. Press LOAD/EJECT, and remove the cassette.
- 3. Insert the cassette correctly, then press **LOAD/EJECT**.
- 4. Verify the cassette loading mechanism test passes, then press **Done** to exit the test.

5.3.16

CASSETTE LOADING MECHANISM TEST (TWO-CHANNEL)

Note: If the manual load eject lever is pulled during the PVT, the Biomed Mode menu will display.

To perform the cassette loading mechanism test, proceed as follows:

- 1. In the Cassette Loading Mechanism screen, select Channel A & B.
- 2. Insert an empty cassette upside down into channel A, and press LOAD/EJECT.
- 3. Remove the cassette.
- 4. Insert the cassette correctly into channel A, then press **LOAD/EJECT**.
- 5. Press **LOAD/EJECT** again, and remove the cassette.
- 6. Insert the empty cassette upside down into channel B, and press LOAD/EJECT.
- 7. Remove the cassette.
- 8. Insert the cassette correctly into channel B, then press LOAD/EJECT.
- 9. Press **LOAD/EJECT** again, and remove the cassette.
- 10. Verify the cassette loading mechanism test passes, then press **Done** to exit the test.

AIR SENSOR TEST (ONE-CHANNEL)

To perform the air sensor test, proceed as follows:

- 1. In the Air Sensor Test screen, press LOAD/EJECT.
- 2. Insert an empty, unclamped cassette, then press **Start**. The hourglass symbol appears.
- 3. Confirm the Air Detected message, and verify the air sensor test passes.
- 4. Press **Done** to exit the test.
- 5. Verify the **Pressure Sensor Test** screen appears.

5.3.18

AIR SENSOR TEST (TWO-CHANNEL)

To perform the air sensor test, proceed as follows:

- 1. In the Air Sensor Test screen, select Channel A & B.
- 2. Press the **LOAD/EJECT** keys.
- 3. Insert empty, unclamped cassettes into channel A and channel B, then press **Start**. The hourglass symbol appears.
- 4. Confirm the Air Detected message, and verify the air sensor test passes.
- 5. Press **Done** to exit the test.
- 6. Verify the Pressure Sensor Test screen appears.

PRESSURE SENSOR TEST (ONE-CHANNEL)

The pressure sensor test includes the distal occlusion test and the proximal occlusion test.

To perform the pressure sensor test, proceed as follows:

- 1. Press **LOAD/EJECT**, and remove the empty cassette.
- 2. Insert a primed cassette, and clamp the tubing approximately 10 to 12 inches below the cassette.
- 3. Press **Start**. The hourglass symbol appears.
- 4. Confirm the Distal Occlusion Detected message, and Pass/Fail result.
- 5. Unclamp the line, then press **Done**.
- 6. Clamp the tubing above the cassette, then press **Start**.
- 7. Confirm the Proximal Occlusion Detected message, and Pass/Fail result.
- 8. Unclamp the line, then press **Done** to exit the test.
- 9. Verify the **Volume Accuracy Test** screen appears.

5.3.20

PRESSURE SENSOR TEST (TWO-CHANNEL)

The pressure sensor test includes the distal occlusion test and the proximal occlusion test.

To perform the pressure sensor test, proceed as follows:

- 1. In the Pressure Sensor Test screen, select Channel A & B.
- 2. Press the **LOAD/EJECT** keys, and remove the empty cassettes.
- 3. Insert the primed cassettes into channel A and channel B, and clamp the tubing approximately 10 to 12 inches below the cassette.
- 4. Press **Start**. The hourglass symbol appears.
- 5. Confirm the Distal Occlusion Detected message, and Pass/Fail result.
- 6. Unclamp the lines, then press **Done**.
- 7. In the Pressure Sensor Test screen, select Channel A & B.
- 8. Clamp the tubing above the cassettes, then press **Start**.
- 9. Confirm the Proximal Occlusion Detected message, and Pass/Fail result.
- 10. Unclamp the lines, then press **Done** to exit the test.
- 11. Verify the **Volume Accuracy Test** screen appears.

VOLUME ACCURACY TEST (ONE-CHANNEL)

Note: Use a new macrobore set with microbore segment for the volume accuracy test.

To perform the volume accuracy test, proceed as follows:

- 1. Place the proximal end of the tubing in the IV bag/container.
- 2. Attach an 18-gauge needle to the distal end of the tubing.
- 3. Prime the cassette. Assure that no air bubbles remain in the line or cassette.
- 4. Verify the fluid container is 18 to 24 inches above the pumping chamber, and verify all lines are unclamped (see Figure 5-4).
- 5. Install the primed cassette into the infuser.
- 6. Place the distal end of the tubing into a clean and completely dry, commercially available, 25 mL graduated cylinder with 0.2 mL graduations.
- 7. Press **Start**. For software versions 3.11 and beyond, the infuser will deliver approximately 20 mL at a rate of 139 mL/hr. For software versions prior to 3.11, the infuser will deliver 20 mL at a rate of 400 mL/hr.
- 8. When delivery is complete (approximately nine minutes for software versions 3.11 and beyond, and approximately three minutes for software versions prior to 3.11), verify the fluid in the graduated cylinder measures between 19 and 21 mL.
 - **Note:** It is imperative to measure the fluid level at the bottom of the fluid meniscus (see Figure 5-5).
- 9. The question Was the amount infused for Channel A between 19 and 21 mL? appears.
- 10. Press **Yes**, then press **Done** to exit the test.
- 11. Verify the Operation Test: Results Summary screen appears.
- 12. Confirm all tests have been performed and passed, then press **Exit**.
- 13. Verify the Biomed: Operation Test screen appears, then press Exit.
- 14. Verify the **Biomed** screen appears, then turn off the device to exit the **Biomed Mode**.

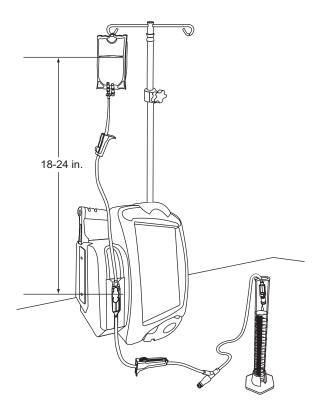


Figure 5-4. Volume Accuracy Test Setup (One-Channel)

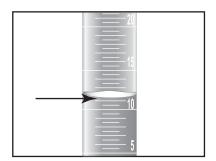


Figure 5-5. Reading the Meniscus

VOLUME ACCURACY TEST (TWO-CHANNEL)

Note: Use a new macrobore set with microbore segment for the volume accuracy test.

The volume accuracy test for the two-channel device requires two new administration sets and two 25 mL graduated cylinders.

To perform the volume accuracy test, proceed as follows:

- 1. In the Volume Accuracy Test screen, select Channel A & B.
- 2. Place the proximal ends of the tubing in the IV bags/containers.
- 3. Attach an 18-gauge needle to the distal end of the tubing.
- 4. Prime the cassettes. Assure that no air bubbles remain in lines or cassettes.
- 5. Verify the fluid containers are 18 to 24 inches above the respective pumping chambers, and verify all lines are unclamped (see Figure 5-4).
- 6. Install the primed cassettes into infuser channels A and B.
- 7. Place the distal ends of the tubing into separate clean and completely dry, commercial available, 25 mL graduated cylinders with 0.2 mL graduations.
- 8. Press Start. For software versions 3.11 and beyond, the infuser will deliver approximately 20 mL at a rate of 139 mL/hr. For software versions prior to 3.11, the infuser will deliver 20 mL at a rate of 400 mL/hr.
 - Note: Line A will deliver first. Line B will immediately start infusing at the completion of delivery of line A.
- 9. When delivery is complete (approximately 17 minutes for software versions 3.11 and beyond, and approximately six minutes for software versions prior to 3.11), verify the fluid in both graduated cylinders measures between 19 and 21 mL.
 - **Note:** It is imperative to measure the fluid level at the bottom of the fluid meniscus (see Figure 5-5).
- 10. The question Was the amount infused for Channel A between 19 and 21 mL? appears. Press Yes.
- 11. The question Was the amount infused for Channel B between 19 and 21 mL? appears. Press Yes.
- 12. Press **Done** to exit the test.
- 13. Verify the Operation Test: Results Summary screen appears.
- 14. Confirm all tests have been performed and passed, then press Exit.
- 15. Verify the **Biomed: Operation Test** screen appears, then press **Exit**.
- 16. Verify the **Biomed** screen appears, then turn off the device to exit the **Biomed Mode**.

ELECTRICAL SAFETY TEST

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

To perform the electrical safety test, see *Table 5-4*, and proceed as follows:

- 1. Connect the AC power cord to the safety analyzer.
- 2. Connect the safety analyzer ground lead to the device equipotential post.
- 3. Test the enclosure and earth leakage currents under normal and single fault conditions.
- 4. Measure the resistance of the AC connector ground lug and exposed metal parts.

Table 5-4. Electrical Safety Measurements	
Measurement	Not to Exceed
Enclosure leakage current normal condition (ground intact)	0.1 mA
Enclosure leakage current (open)	0.5 mA
Earth leakage current (ground intact)	0.5 mA
Earth leakage current (open ground)	1 mA
Chassis ground resistance	0.2 Ω

5.4

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.

<u>5.5</u>

BATTERY OVERVIEW

The battery is a $11.1~V_{DC}$, rechargeable, sealed, lithium ion battery with a 6.6 amp hour capacity. The battery is internal to the device and recharges whenever the infuser is connected to AC power. With the infuser powered off and connected to an AC power source, a depleted battery takes approximately four hours to recharge. Battery recharge takes longer if the infuser is powered on. In general, the more often the battery is partially discharged and recharged, the sooner it will need to be replaced.

The infusion system is designed to use battery power for emergency backup and temporary portable operation. An infuser with a fully charged battery delivers one channel or two channels for approximately four hours at 125 mL/hr with the LCD backlight set to Power Saving mode. An infuser with a fully charged battery delivers one channel for approximately six hours at 125 mL/hr with the LCD backlight set to Power Saving mode.

To maintain maximum battery charge and prolong battery life, connect the infuser to AC power whenever possible. The system will monitor battery lifetime and report as required.

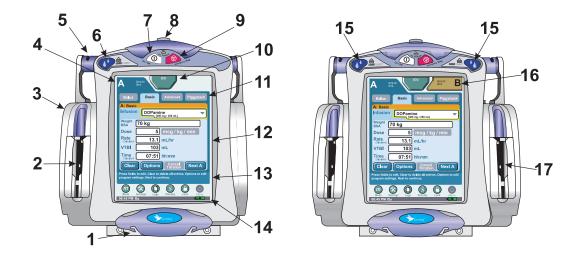


Figure 5-6. Front Views

#	Feature	#	Feature
1	Distal Tubing Guide	10	CCA/Patient Information Button
2	Cassette Carriage	11	Channel-Level Therapy Buttons
3	Cassette Loader Housing	12	Programming Screen
4	Channel Identifier Tab	13	Help/Status Text Area
5	Proximal Tubing Guide	14	Battery/AC Power Indicator
6	Cassette LOAD/EJECT Button	15	Cassette LOAD/EJECT Button
7	On/Off Button	16	Channel Identifier Tab
8	SILENCE Button	17	Cassette Carriage
9	Emergency Stop Button		

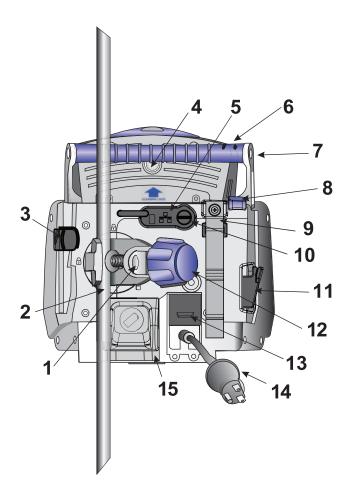


Figure 5-7. Rear View

#	Feature	#	Feature	#	Feature
1	Quick Release Button	6	Proximal Tubing Guide	11	Locking Mechanism
2	IV Pole	7	Carrying Handle		Pole Clamp Knob
3	Black Release Lever	8	Purple Release Lever	13	AC Power Outlet
4	Cleaning Lock	9	AC Power Cord Retainer Strap	14	AC Power Cord
5	Ethernet Port	10	Nurse Call Jack	15	Battery Compartment

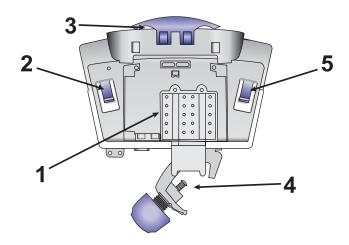


Figure 5-8. Underside View

#	Feature	#	Feature
1	Battery Compartment	4	Pole Clamp Assembly
2	Cassette Eject Lever (Emergency Use Only)	5	Cassette Eject Lever (Emergency Use Only)
3	Distal Tubing Guide		



Section 6

TROUBLESHOOTING

This section contains information on technical assistance, malfunction codes, and alarm messages for the SYMBIQ 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.

1-800-241-4002

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

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

6.2

MALFUNCTION CODES AND ALARM MESSAGES

Under most malfunction conditions the infuser ceases normal operation, generates an audible alarm, and displays an alarm message and malfunction code.



Note: After experiencing any alarm condition, perform the PVT before returning the device to service.

The SYMBIQ will display a 4-digit malfunction code (e.g., \$103) in the alarm tab, which will also contain a description of the error. The malfunction code will also be entered in the user history log.

In addition, the software will enter a 7-digit code in the Malfunction Log, which can be accessed only in the **Biomed Mode** (see Section 1.9). The code will contain the 4-digit code and three additional digits that provide more details on the error.

The 4-digit malfunction code is defined as follows:

<u>S</u>	<u>X</u>	XX
1-digit Product Code S for SYMBIQ	1-digit Processor/Channel Code 1 = UIC 2 = PSC 3 = PMC Left 4 = PMC Right	2-digit Subsystem Code

6.2.1

MALFUNCTION CODES

Table 6-1 lists malfunction codes, and includes processor/channel code, subsystem code, malfunction description, possible cause, and corrective action.

Note: After experiencing any malfunction condition, perform the PVT before returning the device to service.

To clear a malfunction, the infuser must be power cycled. If a malfunction continues to recur, contact Hospira (see Section 6.1).

	Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action	
3 or 4	01	ADC failure	CPU/voltage failure	Contact Hospira to return the device	
3 or 4	02	Air sensor failure	Dirty air sensor Air sensor damaged in PMC Defective air sensor	Clean air sensor Run the PVT	
1 or 2	03	Ambient temperature sensor failure	Temperature sensor failure Defective fan PSC failure Battery failure	Contact Hospira to return the device	
1 only	04	Primary audible alarm failure	Defective speaker Speaker open or shorted	Run the Audio Test in the PVT	
2 only	05	Backup battery failure	Backup battery discharged or unable to charge Problem with PSC	Charge the backup battery for 20 hours	
2 only	06	Battery temperature sensor failure	Battery temperature sensor failure Defective battery	Replace the battery	
1, 3, or 4	07	Calibration/ configuration data error	Software error BBRAM failure	Contact Hospira to return the device	

		Table 6-1. Malfun	ction Codes	
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action
1, 2, 3, or 4	08	CAN Bus failure with Generic Argument 1:778	PMC reports a CAN failure An outgoing CAN message took too long to transmit	If malfunction occurs within five seconds of power on with no other malfunctions, run the PVT If the infuser fails the PVT, contact Hospira to return the device
		Missing Heartbeat Op	UIC reporting it did not receive the operational status from another subsystem Note: This is most likely a duplicate message from another subsystem that can happen when the CAN retransmits a message.	If it is a one-time occurrence, run the PVT If the infuser fails the PVT, contact Hospira to return the device
		Node online timeout	Occurs on power up to indicate that the PMC did not get set online correctly for CAN Bus communication Single occurrence indicates a boot-to-Polo caused by the user pressing Emergency Stop during startup, or by an application image not loading properly	If it is a one-time occurrence, run the PVT If the infuser fails the PVT, contact Hospira to return the device
		Operational status missing with Generic Argument 1:861	CAN BUS heartbeat between the UIC and other devices on the Bus was lost for more than three seconds	If it is a one-time occurrence, run the PVT If the infuser fails the PVT, contact Hospira to return the device
		UIC CAN Bus error with Generic Argument 3:1017 and Generic Argument 4:1051	Acknowledgement timeout is happening to Stop Infusion/Abort Dose command	If it is a one-time occurrence, run the PVT If the infuser fails the PVT, contact Hospira to return the device
		UIC CAN Bus error with Generic Argument 3:1001	UIC detected a CAN message that was not within expected range UIC reports CAN Bus failure Incoming message was overwritten before the interrupt could copy the message was lost	If it is a one-time occurrence, run the PVT If the infuser fails the PVT, contact Hospira to return the device

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	Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action	
3 or 4	09	Cassette loader Generic Argument 1:3 Generic Argument 2:8	Cassette loader state jammed while ejecting in power up Note: On software versions prior to 3.0, three consecutive jams will cause an \$309 or \$409 malfunction.	Perform the Cassette Loading Mechanism Test	
		Cassette loader Generic Argument 1:11	PMC reports cassette loader status as unknown for more than 20 seconds after power up	Perform the Cassette Loading Mechanism Test	
		Cassette loader Generic Argument 1:12	Door has been stuck closed for three consecutive attempts to open or Door has been stuck open for five consecutive attempts to close Always follows a Check Cassette alarm	Perform the Cassette Loading Mechanism Test	
		Door open invalid cassette present with Generic Argument 1:658	Invalid status value reported by the LPA monitor module Invalid reading detected on proximal or distal sensors with the door open PMC checks the force sensor and pressure sensors to assure they are not reading contact with the cassette Note: This is a mechanism hardware failure, often accompanied by an S308 CAN Bus error.	Contact Hospira to return the device	
		LPA monitor bad door position with Generic Argument 1:708	Cassette loader requires recalibration Cassette door is detecting a bad position from the LPA sensor	In Service Mode, choose Calibration then Cassette Load Mechanism and follow instructions	

Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action
1, 2, 3, or 4	10	CPU/ALU failure	Software error Defective CPU	Contact Hospira to return the device
1, 3, or 4	11	Data integrity error	Software error RAM failure	Contact Hospira to return the device
3 or 4	12	Distal pressure sensor error	Distal pressure sensor error Defective cassette	Run the Pressure Test in the PVT
N/A	13	Not used	Not used	N/A
1 only	14	External comm failure	Unable to communicate with the MMU or CE	In Service Mode, reinitialize the CE Check CE configuration Check network connection
2 only	15	Fan failure	Defective fan Overcurrent PSC failure Battery failure	Replace the battery if malfunction occurs with a Service Battery alarm Replace the fan Replace the PSC
1, 2, 3, or 4	16	Flash/ROM failure	ROM or RAM checksum failure Software error	Contact Hospira to return the device
1, 2, 3, or 4	17	Invalid interrupt	Software error	Contact Hospira to return the device
3 or 4	18	Invalid message	Software error	Contact Hospira to return the device
1 only	19	LCD error	Defective LCD LCD open or short	Contact Hospira to return the device
N/A	20	Not used	Not used	N/A

6 - 5

	Table 6-1. Malfunction Codes					
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action		
3 or 4	21	Invalid Bolus dwell period	Time for an expected step during a low delivery rate (< 25 mL/hr) too long Caused by a high friction drive train	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device		
		Motor moves without permission	Secondary malfunction occurs immediately after another plunger position malfunction	Run the PVT If the infuser fails the PVT, contact Hospira to return the device		
		Pump Bolus overshoot	Excess overshoot on incremental Bolus	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device		
		Pump incremental Bolus undershoot	Step size during a low delivery rate (< 25 mL/hr) too large, indicating plunger is not keeping up with the expected delivery rate Caused by a high friction drive train	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device		
		Pump motor lack of movement	Motor failed to move when commanded	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device		
		Pump plunger homing timeout with Generic Argument 1:822	Plunger homing did not complete in the expected time following a forced shutdown caused by another malfunction or depleted battery	If following a forced shutdown or depleted battery shutdown, fully charge the battery and perform a power-up cycle If no malfunctions, return the device to service Otherwise, contact Hospira to return the device		

Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action
	21	Pump QEP count high	Encoder count for one full plunger stroke too high, indicating a defective encoder on the plunger motor	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device
		Pump QEP count low	Encoder count for one full plunger stroke too low, indicating a defective encoder on the plunger motor	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device
3 or 4	22	NVRAM/EEPROM error	RAM failure EEPROM failure Software download failure	Contact Hospira to return the device
1, 3, or 4	23	Oscillator timing/ RTC/BBRAM failure	Backup battery for EEPROM short or open in UIC board System timing error Software error	Contact Hospira to return the device
3 or 4	24	Plunger pressure sensor failure	Defective plunger sensor Defective sensor board Defective cassette	Contact Hospira to return the device
3 or 4	25	PMC software error	PMC software error	Contact Hospira to return the device
3 or 4	26	Proximal pressure sensor failure	Pressure sensor failure Defective cassette	Run the Pressure Test in the PVT
1 only	27	RAM error	Software error	Contact Hospira to return the device
1 only	28	Redundant delivery checks	Software error Delivery error	Contact Hospira to return the device
1, 3, or 4	29	Software deadlock	Software error	Contact Hospira to return the device
1, 3, or 4	30	Stack integrity failure	Software error	Contact Hospira to return the device
1 or 2	31	Stuck key	Hard key sensor too long Defective keypad	Run the Hard Keys Test in the PVT

Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action
1, 2, 3, or 4	32	8 V out of range	Power supply or PSC failure	Replace the power supply or PSC
		8 volts tolerance	Power supply or PSC failure	Replace the power supply or PSC
		PMC ADC ground volts out of range	Electrical noise or PMC problem	Replace the mechanism and run the PVT If the infuser fails the PVT, contact Hospira to return the device
		PMC distal volts out of range	PMC hardware failure	Contact Hospira to return the device
		PMC proximal volts out of range	PMC hardware failure	Contact Hospira to return the device
		PSC volts out of tolerance	Power supply or PSC failure	Replace the power supply or PSC
1, 2, 3, or 4	33	Overtemperature	Vents covered Room too warm Device overheating	Clear the vents Lower room temperature Turn power off, allow the infuser to cool down, then turn power on to reset the infuser
1 only	34	Touchscreen failure	Touchscreen out of calibration	Run the Touchscreen Test in the PVT
1 only	35	Uncontrolled node	Software error	Contact Hospira to return the device
1, 2, 3, or 4	36	Watchdog error	Software error	Contact Hospira to return the device
1 only	37	UIC software failure	Software error	Contact Hospira to return the device
2 only	38	PSC software failure	Software error	Contact Hospira to return the device
1, 3, or 4	39	Power off	Power down during sleep mode Software error Infuser turned off unexpectedly Battery discharged Battery removed while infuser running Defective battery	Recharge, replace, or reinstall the battery

Table 6-1. Malfunction Codes				
Processor/ Channel Code	Subsystem Code	Malfunction	Explanation	Corrective Action
3 or 4	41	SSC error	Serial communication software error	Contact Hospira to return the device
2 only	42	UIC transmitted malfunction	Software error	Contact Hospira to return the device
2, 3, or 4	43	Device in apploader mode	UIC detected PMC or PSC is in apploader mode Note: This is part of the software download process. These alarms do not trigger a state change or interfere with the software download. This is correct and expected behavior	If experienced during normal operation, contact Hospira to return the device

6.2.2

ALARM MESSAGES

Table 6-2 lists infuser alarm messages, possible causes, and corrective actions (see the System Operating Manual). Alarm messages are entered into the **Event Log** and the **Alarm Log**.

Table 6-2. Alarm Messages			
Alarm Message	Possible Cause	Corrective Action	
AIR-IN-LINE	An amount of air, greater than or equal to the current air sensitivity setting, is detected in the line distal to the cassette while the device is infusing or An amount of accumulated air over 15 minutes exceeds the 15 minute threshold	Remove air from the line and restart the infuser Clear the current program Press the alarm tab to reset the alarm	
CALLBACK	The infuser has been waiting for a user keypress for more than the time configured for the current CCA or DDL	Complete user input, and press the alarm tab to reset the alarm	
CHECK CASSETTE	The cassette is improperly loaded or missing while the infuser is in Delivery mode The cassette has been manually ejected	Properly install the cassette If the alarm persists, contact Hospira	
CHECK FLOWSTOP	The cassette is loaded with high distal pressure indicating that the flowstop may be open Often caused when loading a cassette with a clamp on the distal tubing close to the cassette Cassette flowstop may have been opened while removing the cassette Door is closed with high pressure indicating possible debris present	Close the clamp, open the door, and assure the flowstop is closed If the alarm persists, replace the administration set	
DEPLETED BATTERY	Battery has five minutes or less of delivery left at the current infusion rate	Connect the infuser to AC power to charge the battery Recondition the battery to determine battery capacity	
DISTAL OCCLUSION	Distal pressure is greater than the selected psi or mmHg level during infusion Delivery interrupted	Clear the occlusion and restart delivery If the alarm persists, check occlusion sensitivity setting	
EMERGENCY STOP	Emergency Stop button has been pressed	Press the alarm tab to reset the alarm	
END OF INFUSION	Infusion complete KVO is delivering as programmed	Clear or edit current program Press the alarm tab to reset the alarm	
FLOW RESTRICTION	Proximal occlusion has been reported Flow restriction above the infuser	Clear any flow restrictions, then restart delivery	

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Table 6-2. Alarm Messages		
Alarm Message	Possible Cause	Corrective Action
INFUSION COMPLETE	Stop Infusion or Callback requested by operator	Clear the associated program, and press the alarm tab to reset the alarm
INTERMITTENT CALLBACK	Selected callback time has been reached	Press the alarm tab to reset the alarm
LOW BATTERY	30 minutes or less of battery power remaining 15 minutes of battery power remaining	Connect the infuser to AC power Detection of AC power clears the alarm
NEARING END OF INFUSION	Total time remaining on an infusion is less than the user-defined Nearing End of Infusion setting	Press the alarm tab to reset the alarm
NEW DRUG LIBRARY	A library is available and ready to transfer to the infuser	Accept the transfer of the new library Accepting the library clears the alarm
POWER LOSS	The power level drops below the level required to operate the device when the infuser is powered by AC only	Restore AC power
PROXIMAL OCCLUSION	Proximal occlusion has been detected	Assure lines are unclamped Clear the occlusion and restart delivery Check proximal tubing and remove any tubing kinks
PUMP IDLE	Waiting for user input No programming entries have been made for two minutes	Start the infusion
RECONDITION BATTERY	Battery requires conditioning to recalibrate the gas gauge and assure that the battery state of charge is reported accurately Recondition does not affect battery chemistry or actual capacity Recondition Battery alarm may occur at initial power up after a long storage period because the gas gauge memory is erased when the battery is fully depleted	Access Biomed Mode and follow on-screen instructions to recondition the battery (see Section 6.2.2.3)
SERVICE BATTERY	Battery shorted, open, missing, or will not charge Battery undervoltage	Power cycle the infuser to clear the alarm If condition does not clear, replace the battery
SET TEST FAILURE	Administration set failure	Replace the administration set

6.2.2.1

CHECK CASSETTE ALARM

The Check Cassette alarm is activated when the following conditions occur:

- The carriage is jammed by incorrect insertion of the cassette
- The carriage is jammed by a foreign object or contamination
- The cassette is not seated properly

If the **Check Cassette** alarm activates, assure the cassette is inserted and seated correctly and there is no foreign object jamming the carriage. If the **Check Cassette** alarm continues to occur, the cassette eject lever may have been pulled.

In an emergency (i.e., complete power failure), the cassette can be manually ejected from the carriage (see the System Operating Manual).

CAUTION: If a cassette has been manually ejected, remove the infuser from service immediately.

CAUTION: The cassette should be manually ejected only in an emergency. Manually ejecting a cassette renders that channel incapable of infusing until it is reset in Biomed Mode.

6.2.2.2

INITIAL INFUSER TURN-ON

When an infuser is in storage with the battery installed, the battery is slowly depleted over a period of approximately 90 days. This does not harm the battery in any way, but may lead to a **Recondition Battery** alarm or other false battery alarms. Plugging the infuser into AC power to charge the battery before turning on the device will allow the infuser to wake up the battery and prevent a false **Recondition Battery** alarm or other battery alarms.

A minimum charging time of approximately five minutes with the infuser connected to AC power prior to turning on the infuser is sufficient to minimize alarms. The AC Power LED will be flashing to indicate battery charging has started. It is recommended that the battery be fully charged for at least four hours before use.

Charging the battery before use will not eliminate all Recondition Battery requests. If the battery has been sufficiently depleted, it will still have lost its gas gauge calibration and will require reconditioning (see Section 6.2.2.3).

If this initial infuser turn-on process is followed and there is still a **Recondition Battery** alarm, the reconditioning process will need to be completed in **Biomed Mode**.

The following popup system messages may occur that do not indicate the infuser or battery is defective.

- The **\$339** system message indicates that the previous power down was not normal. This may occur on a unit out of the box if the infuser is powered up without first connecting it to AC power. The result is a catastrophic power failure because the battery was depleted. In general, this popup can be ignored on the initial power up out of the box. If **\$339** occurs on a unit other than the first time out of the box, check its operation on battery power because that is a strong possibility for the catastrophic power failure.
- A **Recondition Battery** indicator or system message indicates that the battery needs reconditioning.
- A **Depleted Battery** popup message is an indication that the battery is not charged. This is not a failure.
- If the **Battery** icon indicates a depleted state, it is an indication that the battery is not charged. This is not a failure.

6.2.2.3

BATTERY RECONDITIONING

Prior to performing battery reconditioning, switch to **Biomed Mode** (see Section 5.3.3), then run the PSC Power test to verify battery operation (see Section 5.3.4). If the battery is charging, confirm the battery current is >300 mA, and verify the AC Power LED is flashing. If the battery is not charging, verify the battery capacity is nearly full (>90 %). If either of these conditions is met, the battery is good and reconditioning can proceed. Otherwise, replace the battery.

The following reconditioning process is performed automatically by the infuser:

- Fully charges the battery (may require small initial discharge for the battery to be depleted below 90 % to allow for full charging to be performed)
- Fully depletes the battery
- Fully charges the battery

Complete battery reconditioning will take approximately 14 hours if the battery is fully depleted. However, reconditioning should not be considered as failed until it has gone on for 18 hours.

If reconditioning fails, replace the battery and record the alarm to aid in investigation of the failure.

6.2.2.4

BOOT TO POLO - BLUE SCREEN

The blue screen and **Service Required** window is displayed (see Figure 6-1) when software fails to load an application, or the user presses keys during startup to enter the **Polo** diagnostic software application, as follows:

- Version 2.01 and earlier: Press **e-stop** multiple times during the splash (startup) screen
- Version 2.1 and later: Press **e-stop** and Channel A **LOAD/EJECT** during the splash (startup) screen

When in **Polo Mode**, the infuser will sound the backup buzzer after 30 seconds. After the buzzer sounds, the infuser can be powered down by pressing and holding the **On/Off** button. On the next power up, an **S308** system message will display. After this message is acknowledged, the infuser can be returned to service.

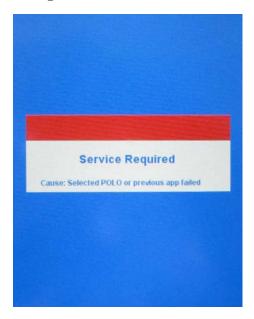


Figure 6-1. Blue Screen with Service Required Window

This event can also be identified when reviewing the logs by the following sequence of events:

- Power Off
- Power On
- Malfunction Alarm

'Device Id:PMC B' 'Channel:B' 'Error Group:Can Bus Error (S408)' 'Error Subgroup:5' 'Malfunction Code:Node Online Timeout' 'Urgency:High' 'Alarm Id:126' 'Generic Arg 1:863' 'Generic Arg 2:0' 'Generic Arg 3:0' 'Generic Arg 4:0'

Note: The **\$408** will only occur on dual channel devices.

- Malfunction Alarm

'Device Id:PMC A' 'Channel:A' 'Error Group:Can Bus Error (S308)' 'Error Subgroup:5' 'Malfunction Code:Node Online Timeout' 'Urgency:High' 'Alarm Id:103' 'Generic Arg 1:863' 'Generic Arg 2:0' 'Generic Arg 3:0' 'Generic Arg 4:0'

- [0205]2008/05/14 19:41:40 Malfunction Occurred Confirmed
- [0207]2008/05/14 19:41:41 Malfunction Occurred Confirmed

6.3

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 test failure exists, carefully inspect the infuser as described in Section 5.3.2.
- 2. If an infuser inspection does not disclose a problem, perform the PVT in Section 5.3. See *Table 6-3* for section reference, probable cause, and corrective action.

If the infuser persistently fails or problems continue to recur, contact Hospira.

Table 6-3. Troubleshooting with the PVT			
Test Failure	Probable Cause	Corrective Action	
PSC Power (Section 5.3.4)	System voltage failures (see Table 5-2) Infuser is not connected to AC power	Connect the infuser to AC power Replace the battery	
Temperature (Section 5.3.5)	Battery temperature or UIC, PSC, or PMC ambient temperature exceeds acceptable values (see Table 5-3) Sensor failures Vents covered	Turn off the infuser and wait until it cools down Replace the battery if battery temperature failure Replace the power supply Clear the vents	
Hard Keys (Section 5.3.6) (Section 5.3.7)	Alarm Silence, Emergency Stop, Cleaning Lock, Power On/Off, or Load/Eject hard key failure	Press each hard key within 20 seconds of being highlighted	
LCD Backlight (Section 5.3.8)	Backlight decrease or increase failure	Contact Hospira to return the device	
LCD (Section 5.3.9)	Displaying the screen in red, green, or blue for five seconds failed	Contact Hospira to return the device	
Touchscreen (Section 5.3.10)	Touchscreen grid test failure Touchscreen out of calibration	Repeat the test Calibrate the touchscreen	
LED (Section 5.3.11) (Section 5.3.12)	LED failure	Contact Hospira to return the device	
Audible Tone (Section 5.3.13)	Primary speaker open or shorted Secondary speaker failure	For primary speaker, contact Hospira to return the device For secondary speaker, connect the infuser to AC power for 20 hours	
Nurse Call Relay (Section 5.3.14)	Communication error	Verify test setup	
Cassette Loading Mechanism (Section 5.3.15) (Section 5.3.16)	Cassette did not load correctly	Repeat the test	

Table 6-3. Troubleshooting with the PVT			
Test Failure	Probable Cause	Corrective Action	
Air Sensor (Section 5.3.17) (Section 5.3.18)	Empty, unclamped cassette not installed in Channel A or Channel B	Reprime the cassette Insert an empty, unclamped cassette in Channel A or Channel B Replace the cassette	
Pressure Sensor (Section 5.3.19) (Section 5.3.20)	Empty cassette installed Defective cassette Line not properly clamped	Reprime the cassette Insert a primed cassette in Channel A or Channel B Clamp the line approximately 10 to 12 inches below the cassette	
Volume Accuracy (Section 5.3.21) (Section 5.3.22)	Amount infused for Channel A or Channel B is less than 19 mL or more than 21 mL	Reprime the cassette and/or the entire length of tubing Attach an 18 gauge needle to the distal end of the tubing Verify the fluid container is 18 to 24 inches above the pumping chamber Verify all lines are not occluded Replace the cassette	
Electrical Safety (Section 5.3.23)	Electrical Safety Test failure	Verify the AC power cord is connected to the safety analyzer Verify the safety analyzer ground lead is connected to the equipotential post Replace the power cord	

Section 7

REPLACEABLE PARTS AND REPAIRS

This section itemizes all parts and subassemblies of the SYMBIQ 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 identified in Figure 9-1. Table 9-2 identifies each part by an index number that correlates to Figure 9-1.

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

$\overline{7.2}$

REPLACEMENT PROCEDURES

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

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



Note: Unless otherwise indicated, replacement procedures, as they are described, are relevant to both the one-channel and two-channel infuser.

7.2.1

SAFETY AND EQUIPMENT PRECAUTIONS

Before beginning replacement procedures, take all necessary precautions for working on high-voltage equipment.

WARNING: **EXPLOSION HAZARD EXISTS IF THE INFUSER IS SERVICED**

IN THE PRESENCE OF FLAMMABLE SUBSTANCES.

UNLESS OTHERWISE INDICATED, DISCONNECT THE INFUSER WARNING:

FROM AC POWER BEFORE PERFORMING ADJUSTMENTS

OR REPLACEMENT PROCEDURES.

$\overline{7.2.2}$

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.

- Medium size Phillips screwdriver
- Medium and small size flat blade screwdrivers
- T-25 TORX® driver
- Set of nutdrivers
- Small crescent wrench

- Bearing Grease (Dow Corning Molykote® 1292)
- Mild solvent
- Lint-free cloth
- Compressed air

7.2.3

BATTERY ASSEMBLY REPLACEMENT

CAUTION: Use proper ESD grounding techniques when handling components. Wear an antistatic wrist strap and use an ESD-protected workstation.

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

Replacement parts for this procedure are:

Assembly, Integrated Battery Screw, 6-32 x 5/16, Pan Head, Phillips

To replace the battery assembly, see *Figure 7-1*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
 - **Note:** After disconnecting from AC power, wait at least five minutes for the CE to power down and the microprocessor to save data, then proceed to step 2.
- 2. Place the infuser on its side.
- 3. Using the Phillips screwdriver, remove the three screws that secure the battery assembly to the infuser. Press on the tab and carefully remove the battery assembly.
- 4. Align the battery assembly connection and screw holes, and replace the battery assembly using the screws that were removed in step 3.
 - **Note:** Confirm the battery assembly connects securely to the power supply board.
- 5. With the infuser disconnected from AC power, press the **On/Off** button and verify the infuser turns on. Confirm the battery indicator illuminates (see Figure 5-6).
 - **Note:** To maximize battery life, plug the infuser into AC power and charge for six hours.

Replacement of the battery assembly is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.3.

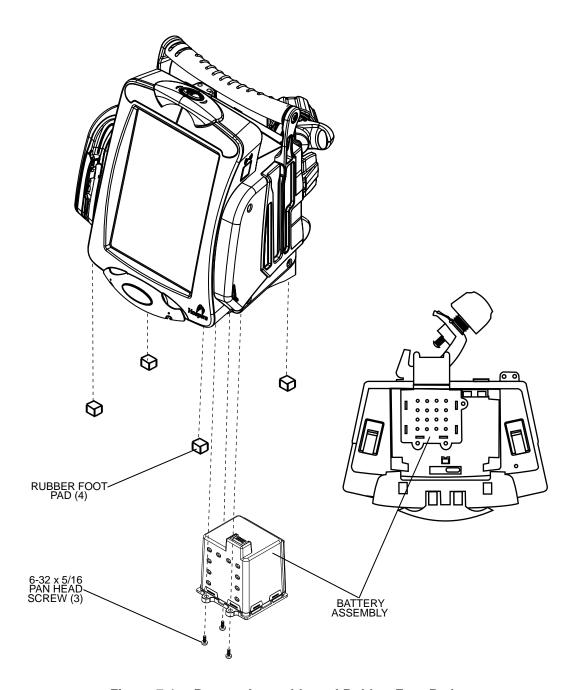


Figure 7-1. Battery Assembly and Rubber Foot Pads

7.2.4

RUBBER FOOT PAD REPLACEMENT

Recommended tools for this procedure are a small size flat blade screwdriver, 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 small flat blade screwdriver, remove the rubber foot pad from its recess.
 - **Note:** Each adhesive-backed 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 foot pad 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.
- 7. Connect the device to AC power, then press **On/Off** and verify the infuser turns on.

Replacement of a rubber foot pad is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.3.

7.2.5

AC POWER CORD, RETAINER, AND VELCRO STRAP REPLACEMENT

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

Replacement parts for this procedure are:

Cord, AC Power
Retainer, Power Cord
Gasket, Retainer
Boot, Retainer
Strap, Retaining, Velcro
Screw, 6-32 x 5/16, Pan Head, Phillips
Screw, 6-32 x 3/8, Pan Head, Phillips, with Washer

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

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Place the infuser face down on a smooth, flat surface.
- 3. Using the Phillips screwdriver, remove the two screws from the power cord retainer, and pull the retainer away from the infuser.

- 4. Remove the AC power cord from its receptacle by grasping the plug. Do not pull the cord.
- 5. Inspect the retainer boot and replace if required.

Note: Attach the boot to the retainer before installing the retainer.

- 6. Remove the retainer gasket, then remove the adhesive-backing from the replacement gasket and attach the gasket to the retainer.
- 7. Install the replacement AC power cord.
- 8. Install the replacement retainer, using the screws that were removed in step 3. Confirm the tab on the top of the retainer is aligned in its slot.
- 9. Using the Phillips screwdriver, remove the screw that secures the Velcro strap to the infuser, and remove the strap.
- 10. Inspect the Velcro strap and replace if required. Attach the replacement Velcro strap to the infuser using the screw that was removed in step 9.
- 11. Connect the device to AC power, then press **On/Off** and verify the infuser powers on. Confirm the AC power indicator is illuminated.

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 5.3*.

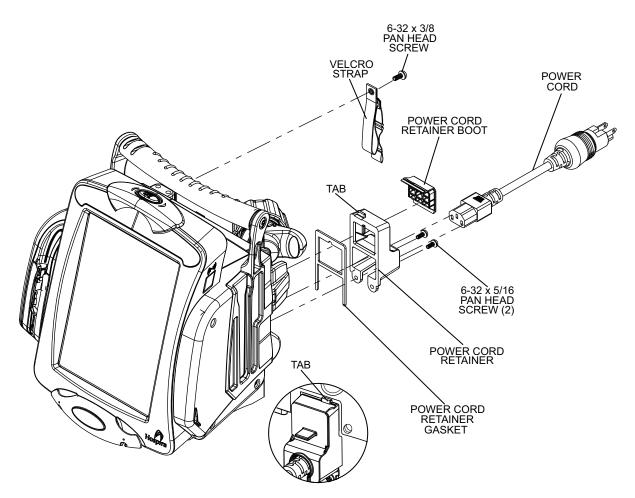


Figure 7-2. AC Power Cord, Retainer, and Velcro Strap

HANDLE REPLACEMENT

The recommended tool for this procedure is a T-25 TORX driver.

Replacement parts for this procedure are:

Handle, One-Channel Handle, Two-Channel Screw, TORX, 10-14 x 3/4

To replace the handle on the one-channel or two-channel infuser, see *Figure 7-3*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Using the TORX driver, remove the two screws that secure the handle, and carefully pull the handle away from the infuser.
- 3. Install the handle in the exact reverse order of removal, using the screws that were removed in step 2.

Replacement of a handle is routine maintenance and, with the exception of a visual inspection, no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.3.

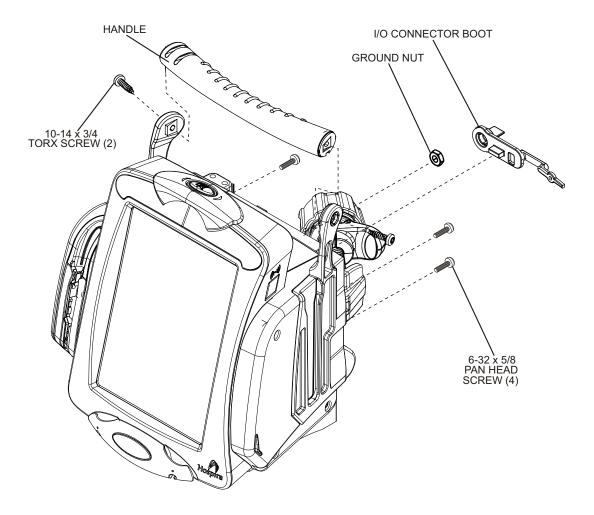


Figure 7-3. Handle Replacement (One-Channel)

$\overline{7.2.7}$

I/O CONNECTOR BOOT REPLACEMENT

Recommended tools for this procedure are a 3/8 nutdriver and medium size Phillips screwdriver.

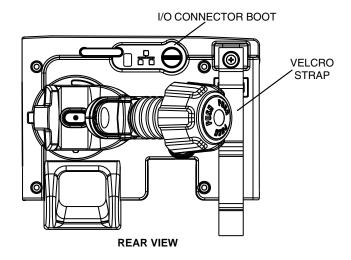
Replacement parts for this procedure are:

Boot, I/O Connector Nut, Ground Screw, 6-32 x 5/8, Pan Head, Phillips

To replace the I/O connector boot, see *Figure 7-3* and *Figure 7-4*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Place the infuser face down on a smooth, flat surface.
- 4. Remove the pole clamp assembly as described in Section 7.2.8.
- 5. Remove the connectology as described in Section 7.2.9.
- 6. To remove the I/O connector boot, remove the tail of the boot from its mounting post, then pull the tail through the pass-through hole in the connectology.
- 7. To install the replacement I/O connector boot, route the tail of the boot through the pass-through hole in the connectology, press the tail onto the post, and press the boot into place.
- 8. Reinstall the connectology.
- 9. Connect the device to AC power, then press **On/Off** and verify the infuser turns on.

Replacement of the I/O connector boot is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.3.



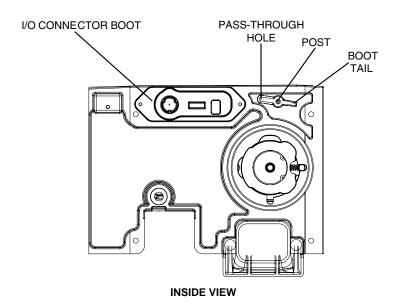


Figure 7-4. I/O Connector Boot

POLE CLAMP ASSEMBLY REPLACEMENT

Newer versions of the SYMBIQ infuser may include an arrow on the pole clamp and position and lock symbols on the connectology for easier pole clamp alignment and removal (see Figure 7-5 and Figure 7-7).

Newer assemblies may also include screws to prevent inadvertent pole clamp removal.

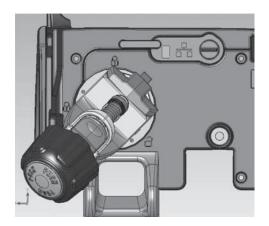
The recommended tool for this procedure is a medium size Phillips screwdriver.

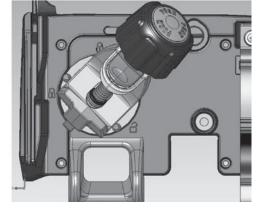
Replacement parts for this procedure are:

Assembly, Pole Clamp Screw, M3, 5 mm, Pan Head, Phillips Grease, Bearing, Long Life

To replace the pole clamp assembly, proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Using the Phillips screwdriver, remove the screws that secure the pole clamp assembly to the connectology if required.
- 3. Grasp the pole clamp body, press the pivot latch, and rotate the pole clamp until the flange releases from the connectology.





POLE CLAMP INSTALLATION/REMOVAL POSITION

SCREW INSTALLATION/REMOVAL POSITION

Figure 7-5. Removal and Installation Positions

4. Apply bearing grease to pole clamp and connectology interface surfaces (see Figure 7-6).

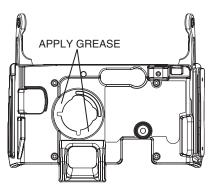


Figure 7-6. Applying Grease to Surfaces

- 5. To install the replacement pole clamp assembly, align the flange with the corresponding shape in the connectology, and rotate the pole clamp to the installation position (see Figure 7-5).
- 6. Secure the pole clamp to the connectology using the two screws that were removed in step 2.
 - **Note:** The screws serve as stops to prevent the pole clamp from rotating from its locked position.
- 7. Verify the pole clamp assembly locks at the 12 o'clock (horizontal) position, unlocks, and rotates freely to the 3 o'clock (vertical) position (see Figure 7-7).
- 8. Connect the device to AC power, then press **On/Off** and verify the infuser turns on.

Replacement of a pole clamp assembly is routine maintenance and no verification procedure is normally required. However, if the infuser may have been damaged during these procedures, perform the PVT in Section 5.3.

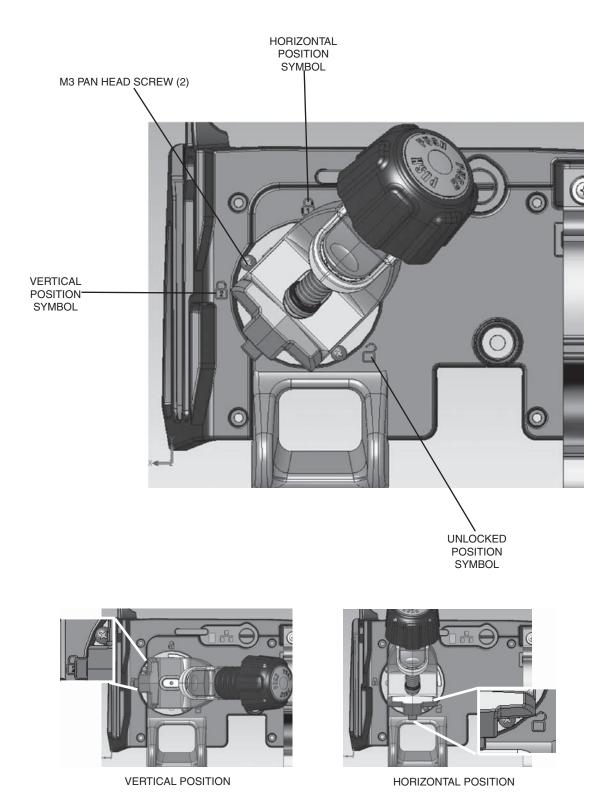


Figure 7-7. Pole Clamp Positions and Connectology

7.2.8.1

CLEANING THE POLE CLAMP

Recommended materials for this procedure are mild solvent, a lint-free cloth, and compressed air.

To clean the pole clamp, see *Figure 7-8*, then proceed as follows:

- 1. Pull back the bellows from the shaft, and inspect the threads. Clean the threads with the mild solvent and lint-free cloth, as required.
- 2. Using compressed air, clean the **Quick Release** button by blowing air under the button.

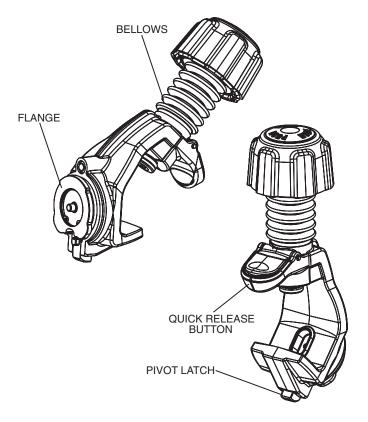


Figure 7-8. Pole Clamp Assembly

CONNECTOLOGY ASSEMBLY REPLACEMENT

Newer versions of the SYMBIQ infuser may include position and lock symbols on the connectology (see Figure 7-7).

Recommended tools for this procedure are a 3/8 nutdriver, small crescent wrench, and medium size Phillips screwdriver.

Replacement parts for this procedure are:

Assembly, Connectology, One-Channel Assembly, Connectology, Two-Channel Gasket, Connectology, One-Channel Gasket, Connectology, Two-Channel Nut, Ground Screw, 6-32 x 5/8, Pan Head, Phillips

To replace the connectology assembly, see Figure 7-9, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the pole clamp assembly as described in Section 7.2.8.
- 3. Using the nutdriver, remove the ground nut from the equipotential terminal.
- 4. Using the Phillips screwdriver, remove the four screws that secure the connectology assembly.
- 5. Inspect the connectology gasket and replace if required.
- 6. Inspect the I/O connector boot and replace if required (see Section 7.2.7).
- 7. Install the replacement connectology assembly, using the screws that were removed in step 6.
- 8. Reinstall the ground nut onto the equipotential terminal.
- 9. Reinstall the pole clamp, power cord, retainer, and battery in the exact reverse order of removal.
- 10. Connect the device to AC power, then press **On/Off** and verify the infuser turns on.

If the infuser may have had damage to cause the replacement of the connectology assembly, perform the PVT in Section 5.3.

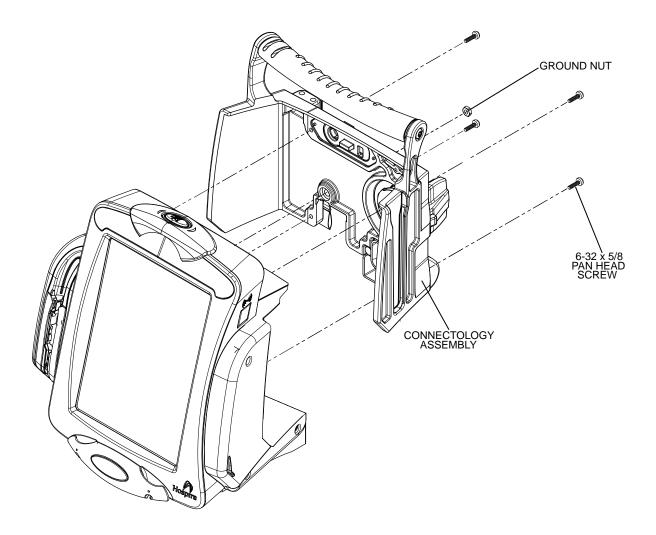


Figure 7-9. Connectology Assembly

FILLER PLATE REPLACEMENT

The recommended tool for this procedure is a small crescent wrench.

Replacement parts for this procedure are:

Plate, Filler, Board Cavity Cover, I/O, Elastomeric Nut, Hex, 10-32

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

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Remove the connectology as described in Section 7.2.9.
- 4. Using the crescent wrench, remove the nut that secures the nurse call jack to the filler plate.
- 5. Remove the hex nut from the post on the filler plate.
- 6. Carefully remove the elastomeric I/O cover. Inspect the cover and replace if required.
- 7. Carefully peel back the insulation tape that partially covers the filler plate, and remove the filler plate.
 - **Note:** Newer versions of the SYMBIQ infuser may not include insulation tape on the filler plate.
- 8. Install the replacement filler plate, then reinstall the nurse call jack nut. Assure the filler plate fits firmly against the board cavity.
- 9. Reinstall the connectology and the battery.
- 10. Connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the filler plate, perform the PVT in Section 5.3.

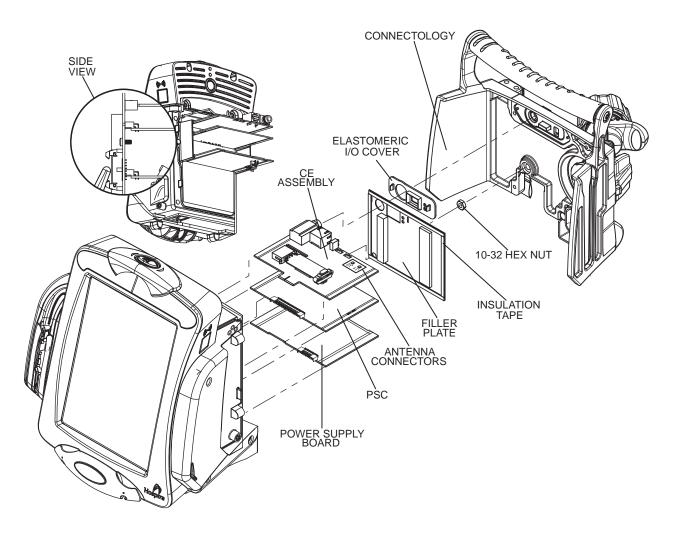


Figure 7-10. Filler Plate and Boards

CE ASSEMBLY REPLACEMENT

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

The replacement part for this procedure is:

Assembly, Communication Engine

To replace the CE assembly, see *Figure 7-10* and *Figure 7-11*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Remove the connectology as described in Section 7.2.9.
- 4. Remove the filler plate as described in Section 7.2.10.
- 5. Note the orientation of the antenna connectors, then remove the antenna assemblies.
 - **Note:** Newer versions of the SYMBIQ infuser are configured with only one antenna.
- 6. Note the location of the CE assembly in the board cavity, then carefully remove the CE assembly from its slot in the cavity.
- 7. Install the replacement CE assembly and reconnect the antenna assemblies in the exact reverse order of removal.
 - **Note:** Do not pinch the antenna cables.
- 8. Reinstall the filler plate and the connectology.
- 9. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the CE assembly, perform the PVT in Section 5.3.

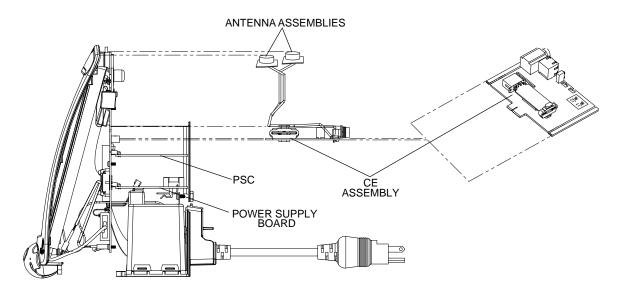


Figure 7-11. CE Assembly Replacement

PSC REPLACEMENT

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

The replacement part for this procedure is:

Power System Controller

To replace the PSC, see Figure 7-10 and 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 7.2.3.
- 3. Remove the connectology as described in Section 7.2.9.
- 4. Remove the filler plate as described in Section 7.2.10.
- 5. Note the location of the PSC in the board cavity, and carefully remove the PSC from its slot in the cavity.
- 6. Install the replacement PSC.
- 7. Reinstall the filler plate and the connectology.
- 8. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the PSC, perform the PVT in Section 5.3.

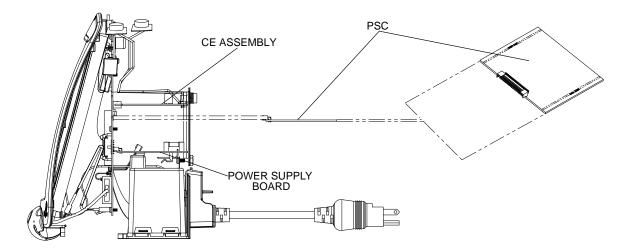


Figure 7-12. PSC Replacement

POWER SUPPLY BOARD REPLACEMENT

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

The replacement part for this procedure is:

Assembly, Power Supply Board

To replace the power supply board assembly, see *Figure 7-10* 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 7.2.3.
- 3. Remove the connectology as described in Section 7.2.9.
- 4. Remove the filler plate as described in Section 7.2.10.
- 5. Place the infuser face down. Note the location of the power supply board in the board cavity, then pull the power supply board out from its slot just enough to gain access to the power connector.
- 6. Using the flat blade screwdriver, remove the power connector from the underside of the power supply board.
- 7. Carefully remove the power supply board from its slot in the cavity.
- 8. If required, install fuses into the fuseholder on the replacement power supply board assembly (see Section 7.2.13.1).
- 9. Install the replacement power supply board assembly, and reconnect the power connector.
- 10. Reinstall the filler plate and the connectology.
- 11. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the power supply board assembly, perform the PVT in Section 5.3.

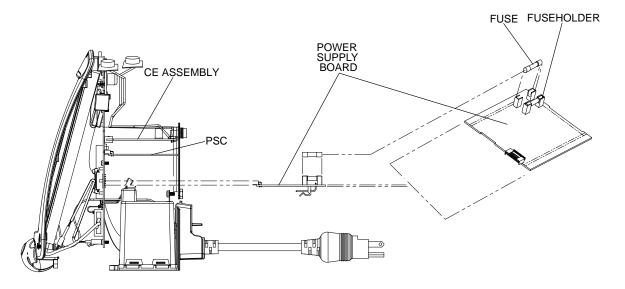


Figure 7-13. Power Supply Board Replacement

7.2.13.1

FUSE REPLACEMENT

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

The replacement part for this procedure is:

Fuse, T3.15A, 250 V

To replace the fuses, see *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 7.2.3.
- 3. Remove the power supply board as described in Section 7.2.13.
- 4. Using the flat blade screwdriver, carefully remove the fuses from the fuseholder, and install the replacement fuses.
- 5. Reinstall the power supply board, filler plate, and connectology.
- 6. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful fuse replacement, perform the PVT in Section 5.3.

7.2.14

INFUSER MECHANISM REPLACEMENT

Note: Do not interchange the left and right mechanism assemblies.

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

Replacement parts for this procedure are:

Assembly, Infuser Mechanism, Left Assembly, Infuser Mechanism, Right, Two-Channel Cover, Right, One-Channel Screw, 6-32 x 5/8, Pan Head, Phillips

To replace the left and/or right infuser mechanism, 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 7.2.3.
- 3. Remove the connectology as described in Section 7.2.9.
- 4. Place the infuser on its right side. Using the Phillips screwdriver, remove the four screws that secure the left infuser mechanism to the rear bezel and back assembly.
- 5. Carefully lift and rotate the left infuser mechanism approximately 90 degrees.
- 6. Release the cable from the mechanism and UIC, and remove the left mechanism.
- 7. Install the replacement left infuser mechanism in the exact reverse order of removal, using the screws that were removed in step 4.

8. Place the infuser on its left side. Using the Phillips screwdriver, remove the four screws that secure the right infuser mechanism or cover to the rear bezel and back assembly.

Note: The right mechanism will be present only on a two-channel infuser.

- 9. Carefully lift and rotate the right infuser mechanism or cover approximately 90 degrees.
- 10. Release the cable from the mechanism and UIC, and remove the right infuser mechanism or cover.
- 11. Install the replacement right infuser mechanism or cover in the exact reverse order of removal, using the screws that were removed in step 8.
- 12. Reinstall the connectology.
- 13. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the left and/or right infuser mechanism, perform the PVT in Section 5.3.

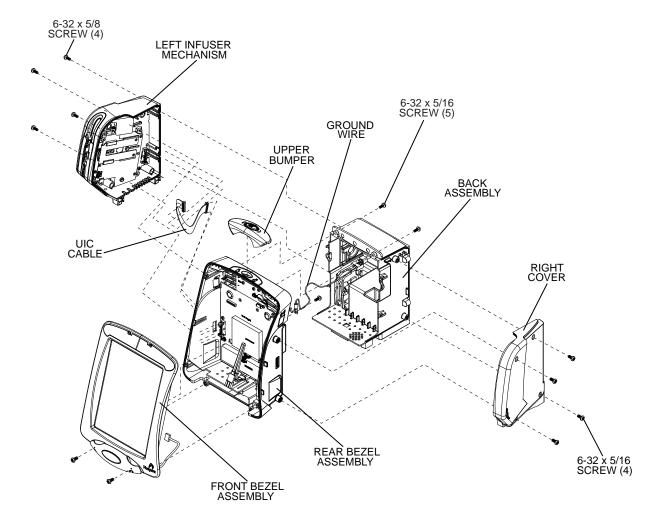


Figure 7-14. Infuser Mechanism Replacement

FRONT BEZEL REPLACEMENT

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

Replacement parts for this procedure are:

Assembly, Front Bezel, One-Channel Assembly, Front Bezel, Two-Channel Assembly, Cable, Touchscreen Extender Assembly, Ground Wire Screw, 6-32 x 5/16, Pan Head, Phillips

To replace the front bezel, see *Figure 7-15*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Place the infuser on its back. Using the Phillips screwdriver, remove the two bottom screws that secure the front bezel to the rear bezel.
- 4. Place the infuser on its face. Using the Phillips screwdriver, remove the two top screws that secure the front bezel to the rear bezel.
- 5. Return the infuser to its upright position, then carefully pull the front bezel out and down.
- 6. Release the touchscreen extender cable from the connector in the front bezel. Inspect the cable and replace if required.
- 7. Note the orientation of the left and right inverter cable connectors, then disconnect the cables from the inverter board on the UIC.
- 8. Note the position of the ground wire assembly. Using the Phillips screwdriver, remove the screw from the lower left of the front bezel and remove the ground wire assembly. Inspect the ground wire assembly and replace if required.
- 9. Remove the front bezel. Install the replacement bezel using the screws that were removed in step 3 and step 4.
- 10. Reattach the ground wire assembly, inverter cables, and touchscreen extender cable.
 - **Note:** Route the inverter cables outside of the standoffs on the back of the bezel assembly.
- 11. Reassemble the left and/or right infuser mechanism in the exact reverse order of disassembly.
- 12. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the front bezel, perform the PVT in Section 5.3.

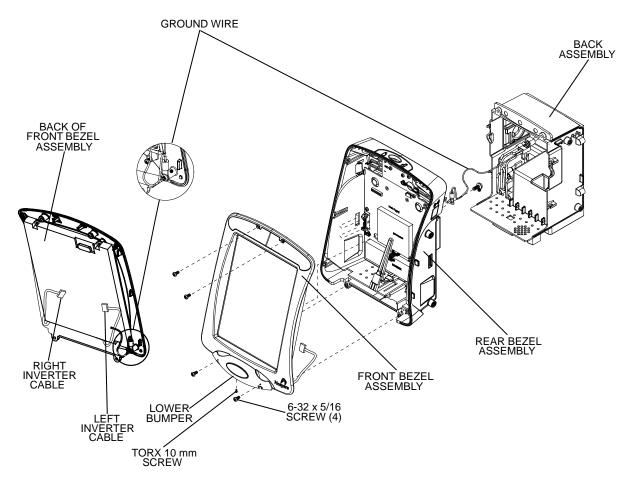


Figure 7-15. Front Bezel Replacement

7.2.15.1

LOWER BUMPER REPLACEMENT

The lower bumper assembly includes the logo badge.

The recommended tool for this procedure is a small TORX driver.

Replacement parts for this procedure are:

Assembly, Lower Bumper, with Logo Badge Screw, Textron, PT30, 10 mm

To replace the lower bumper, proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the front bezel as described in Section 7.2.15.
- 3. Using the TORX driver, remove the 10 mm screw that secures the lower bumper to the front bezel (see Figure 7-15).
- 4. Slide the replacement bumper into place at the bottom of the front bezel, and secure the bumper using the screw that was removed in step 3.
- 5. Reassemble the front bezel in the exact reverse order of removal.

To verify successful replacement of the lower bumper, perform the PVT in Section 5.3.

REAR BEZEL REPLACEMENT

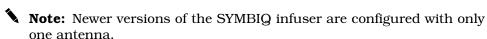
Recommended tools for this procedure are a medium size Phillips screwdriver and small flat blade screwdriver.

Replacement parts for this procedure are:

Assembly, Rear Bezel
Gasket, Upper, Rear Bezel
Gasket, Lower, Rear Bezel
Assembly, Antenna
Button, Touchscreen Lockout
Lens, IrDA
Screw, 6-32 x 5/16, Pan Head, Phillips

To replace the rear bezel, 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 7.2.3.
- 3. Remove the left and/or right infuser mechanism as described in Section 7.2.14.
- 4. Remove the front bezel as described in Section 7.2.15.
- 5. Remove the filler plate assembly as described in Section 7.2.10.
- 6. Remove the CE assembly, PSC, and power supply board, as described in Section 7.2.11, Section 7.2.12, and Section 7.2.13.
- 7. Using the Phillips screwdriver, remove the two screws that secure the back assembly to the rear bezel. Press the tab located on the bottom of the rear bezel to remove the bezel.
- 8. Disconnect the ground wire and the fan cable.
- 9. Inspect the upper and lower bezel gaskets and replace if required.
- 10. Note the orientation of the antenna connections, then remove the antenna assemblies from their respective slots in the rear bezel. Inspect and replace if required.



- 11. Remove and inspect the touchscreen lockout button and replace if required.
- 12. Release the cable from the mechanism and UIC. Inspect the cable and replace if required.
- 13. Remove the UIC as described in Section 7.2.18.
- 14. Remove and inspect the IrDA lens and replace if required. To install the lens, squeeze and snap it into the cutout on the rear bezel.
- 15. Install the replacement rear bezel using the screws that were removed in step 7.
- 16. Reassemble the front bezel and left and/or right infuser mechanism in the exact reverse order of disassembly.
- 17. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the rear bezel, perform the PVT in Section 5.3.

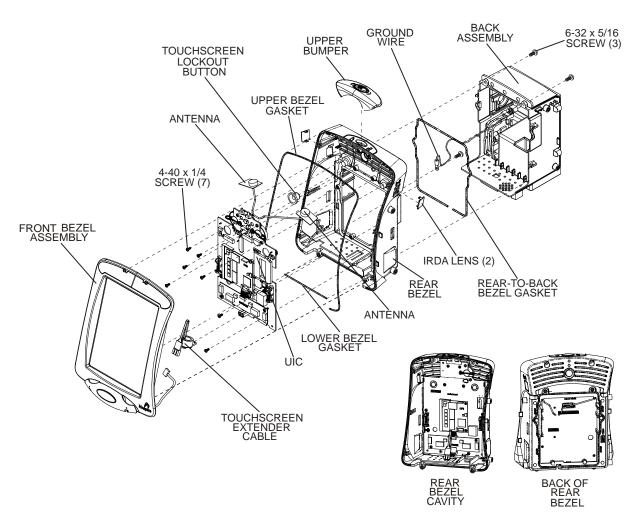


Figure 7-16. Rear Bezel Replacement

7.2.16.1

UPPER BUMPER REPLACEMENT

There are no required tools for this procedure. Replacement parts for this procedure are:

Assembly, Upper Bumper Gasket, Upper Bumper

Note: The upper bumper assembly includes the alarm silence key.

To replace the upper bumper assembly, proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the front bezel as described in Section 7.2.16.
- 3. Slide the upper bumper forward and lift to remove the bumper.
- 4. Inspect the bumper gasket and replace if required.
- 5. Slide the replacement bumper into place on the top of the rear bezel.
- 6. Reassemble the front bezel as described in Section 7.2.16.

To verify successful replacement of the upper bumper, perform the PVT in Section 5.3.

$\overline{7.2.17}$

BACK ASSEMBLY REPLACEMENT

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

Replacement parts for this procedure are:

Assembly, Back Screw, 6-32 x 5/16, Pan Head, Phillips

To replace the back assembly, see *Figure 7-16* and *Figure 7-17*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Remove the rear bezel as described in Section 7.2.16.
- 4. Using the Phillips screwdriver, remove the screws that attach the back assembly to the rear bezel.
- 5. Remove the AC input/output assembly and AC power connector as described in *Section 7.2.17.1*.
- 6. Remove the exhaust duct and fan assembly as described in Section 7.2.17.2.
- 7. Install the AC input/output assembly and AC power connector into the replacement back assembly.
- 8. Install the fan assembly into the replacement back assembly, and snap the exhaust duct into place (see Figure 7-17).
- 9. Install the replacement back assembly to the rear bezel, using the screws that were removed in step 4.
- 10. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the back assembly, perform the PVT in Section 5.3.

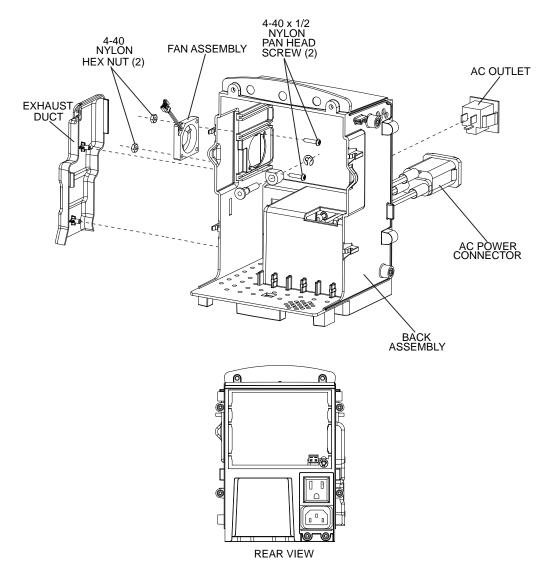


Figure 7-17. Back Assembly with Fan and AC Connectors

7.2.17.1

AC INPUT/OUTPUT ASSEMBLY AND AC POWER CONNECTOR REPLACEMENT

There are no required tools for this procedure. Replacement parts for this procedure are:

Assembly, AC Input/Output Connector, AC Power Cord

To replace the AC power outlet and AC power cord jack, see *Figure 7-17*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the back assembly as described in Section 7.2.17.
- 3. Squeeze the retaining clips that secure the AC input/output assembly to the back assembly and pull out the AC input/output assembly just enough to disconnect the wires from the rear terminals. Note the orientation of the wire connections.
- 4. Connect the wires to the rear terminals of the replacement assembly and snap it into place in the back assembly.
- 5. Squeeze the retaining clips that secure the AC power connector to the back assembly and pull out the connector just enough to disconnect the wires from the rear terminals. Note the orientation of the wire connections.
- 6. Connect the wires to the rear terminals of the replacement AC power connector and snap it into place in the back assembly.
- 7. Reattach the back assembly to the rear bezel as described in Section 7.2.17.

7.2.17.2

FAN ASSEMBLY REPLACEMENT

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

Replacement parts for this procedure are:

Assembly, Fan
Duct, Exhaust
Nut, Hex, 4-40, Nylon
Screw, 4-40 x 1/2, Pan Head, Phillips, Nylon

To replace the fan assembly, see *Figure 7-17*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the back assembly as described in Section 7.2.17.
- 3. Remove the exhaust duct by squeezing its sides and lifting it out and away from the mounting holes and tab slot.
- 4. Disconnect the fan cable from the back assembly.
- 5. Remove the nylon screws and nuts that secure the fan to the back assembly.
- 6. Align the replacement fan assembly into the cutout on the back assembly, then replace the nylon nuts and screws. Assure the nuts are finger-tight.
- 7. Reinstall the exhaust duct by inserting the mounting posts into the holes and the tab into its slot on the back assembly.
- 8. Reattach the back assembly to the rear bezel as described in Section 7.2.17.

UIC REPLACEMENT

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

Replacement parts for this procedure are:

User Interface Controller Assembly, Cable, UIC, Left/Right Screw, 4-40 x 1/4, Pan Head, Phillips

To replace the UIC, see Figure 7-16 and Figure 7-18, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the battery as described in Section 7.2.3.
- 3. Remove the front bezel as described in Section 7.2.15.
- 4. Using the Phillips screwdriver, remove the eight screws that secure the UIC to the rear bezel.
- 5. Note the orientation of the UIC cable connectors, then disconnect the UIC cables from the UIC (see Section 7.2.14).
- 6. Disconnect the touchscreen extender cable and fan extender cable from the UIC.
- 7. Remove the UIC by carefully pulling it up and out of the rear bezel.
- 8. Install the replacement UIC using the screws that were removed in step 4.
 - **Note:** Assure the button switches on the top of the UIC board insert properly into the cutouts on the rear bezel.
- 9. Reconnect the fan extender cable, touchscreen extender cable, and UIC cables.
- 10. Reinstall the front bezel.
- 11. Reinstall the battery, connect the device to AC power, then press **On/Off** and verify the infuser turns on.

To verify successful replacement of the UIC, perform the PVT in Section 5.3.

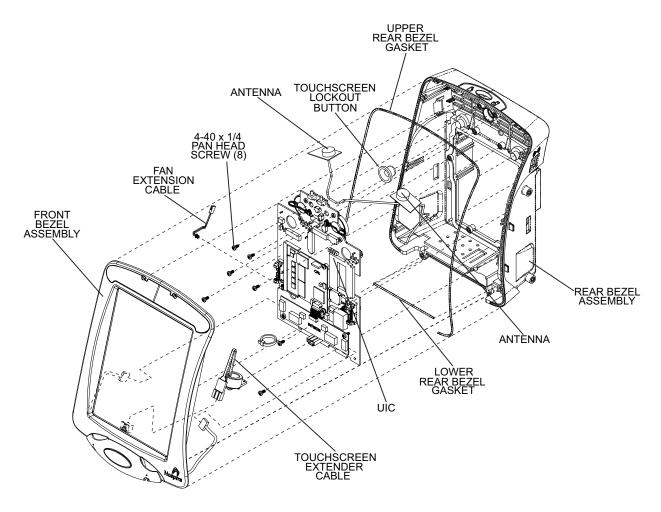


Figure 7-18. UIC Replacement

7.2.18.1

SPEAKER REPLACEMENT

Note: Older versions of the SYMBIQ are configured with only one speaker.

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

Replacement parts for this procedure are:

Assembly, Speaker Screw, 4-40 x 1/4, Pan Head, Phillips

To replace the speakers, see *Figure 7-19*, then proceed as follows:

- 1. Turn off the infuser and disconnect the device from AC power.
- 2. Remove the UIC as described in Section 7.2.18.
- 3. Using the Phillips screwdriver, remove the two screws from the speaker mount.
- 4. Disconnect the speaker cable connector from the UIC and remove the speaker.
- 5. Install the replacement speaker in the exact reverse order of removal.
- 6. Repeat step 4 through step 6 to replace the second speaker.
- 7. Reinstall the UIC as described in Section 7.2.18.

To verify successful speaker replacement, perform the PVT in Section 5.3.

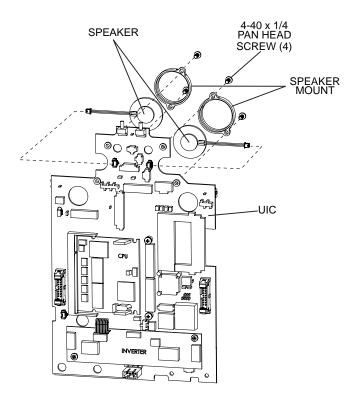


Figure 7-19. Speaker Replacement



Section 8

SPECIFICATIONS

The following specifications apply to the SYMBIQ infusion system.

PHYSICAL

Dimensions

(**One-Channel**): Approximately 10.2 H x 9.9 W x 8.6 D in.

(excluding pole clamp and power cord storage)

Dimensions

(**Two-Channel**): Approximately 10.2 H x 10.9 W x 8.6 D in.

(excluding pole clamp and power cord storage)

Weight

(**One-Channel**): Approximately 10.7 lbs. (with battery)

Weight

(Two-Channel): Approximately 12.1 lbs. (with battery)

Casing: High-impact plastic

ELECTRICAL

Power Frequency: 50-60 Hz

AC Power Rating: 100-240 V_{AC}; 100 VA max

Power Cord: Hospital-grade AC cord; approximately 10 ft.

Fuses: T3.15 A; 250 V

Battery: Rechargeable lithium ion; 11.1 V

Battery Operation: An infuser with a fully charged battery delivers one channel

or two channels for approximately four hours at 125 mL/hr

with the LCD backlight set to Power Saving mode.

An infuser with a fully charged battery delivers one channel for approximately six hours at 125 mL/hr with the LCD

backlight set to Power Saving mode.

Battery Recharge: With the infuser powered off and connected to an AC power

source, a depleted battery takes approximately four hours

to recharge.

The battery automatically recharges while the infuser

operates on AC power.

ENVIRONMENT

Operating Temperature: 5° to 40° C

Storage Temperature: -20° to 60° C

Relative Humidity: 10 % to 90 % non-condensing

Barometric Pressure: 0 - 10,000 ft.

DELIVERY RATE

Range: 0.1 to 99.9 mL/hr (in 0.1 mL/hr increments)

100 to 1000 mL/hr (in 1 mL/hr increments)

KVO: 0.1 to 20 mL/hr programmed in 0.1 mL increments

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

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

OCCLUSION SETTINGS

Distal: 1 to 15 psi in increments of 0.5

Proximal: Pressure sensor threshold set to -5 psi

AIR-IN-LINE

Single Bubble Air

Threshold Range: 50 to 500 microliters

WIRELESS CONNECTIVITY

Transceiver Band: 2.4 GHz

Communications

Standard: IEEE 802.11 a/b/g

Section 9

DRAWINGS

Figure 9-1 through Figure 9-4 show the illustrated parts breakdown (IPB) and assembly drawings for the SYMBIQ. Table 9-1 lists drawings by figure number and title. Table 9-2 identifies parts by index numbers which correlate to Figure 9-1.

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

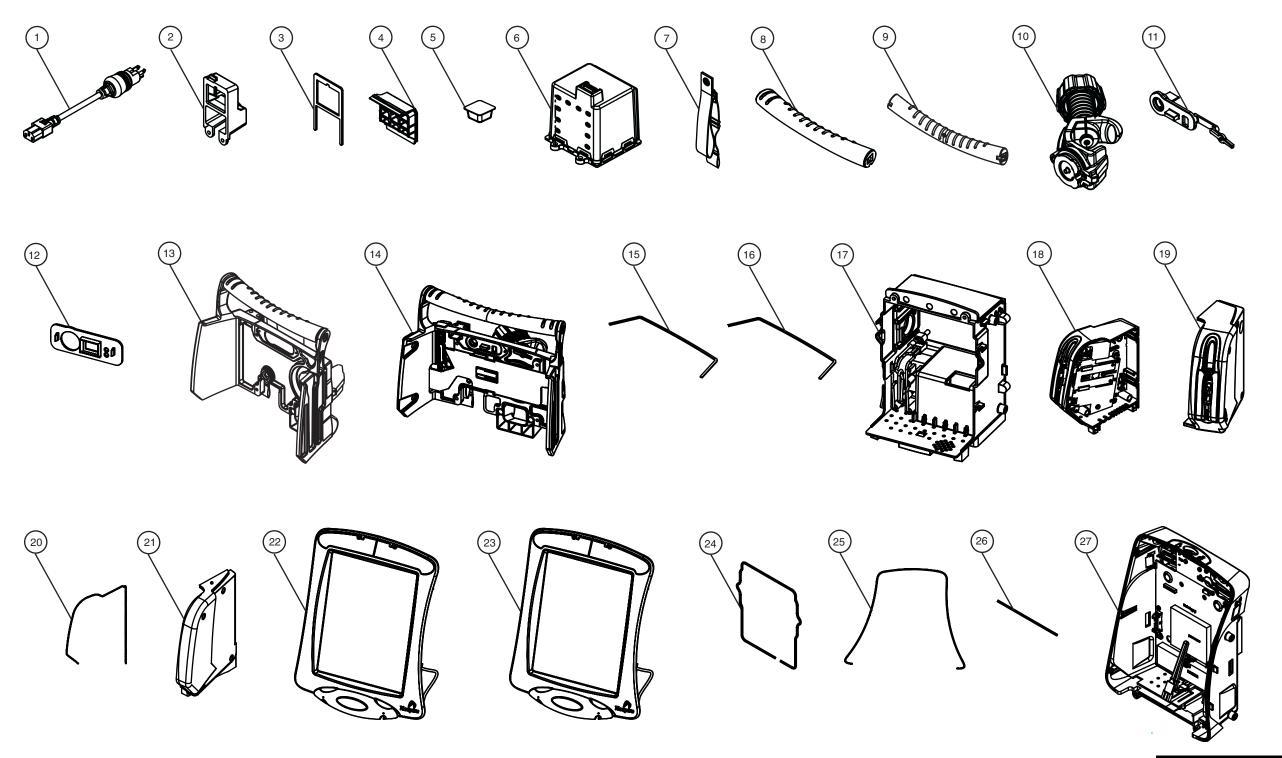
Table 9-1. Drawings		
Figure Number	Title	
9-1	Illustrated Parts Breakdown	
9-2	Infuser Assembly	
9-3	Front and Rear Bezels	
9-4	CE Assembly, PSC, and Power Supply	

Table 9-2. IPB for the Infuser				
Index Number	Nomenclature	Replacement Procedure		
1	Cord, AC Power	Section 7.2.5		
2	Retainer, AC Power Cord	Section 7.2.5		
3	Gasket, Retainer	Section 7.2.5		
4	Boot, Retainer	Section 7.2.5		
5	Pad, Rubber Foot	Section 7.2.4		
6	Assembly, Integrated Battery	Section 7.2.3		
7	Strap, Retaining, Velcro	Section 7.2.5		
8	Handle, One-Channel	Section 7.2.6		
9	Handle, Two-Channel	Section 7.2.6		
10	Assembly, Pole Clamp	Section 7.2.8		
11	Boot, I/O Connector	Section 7.2.7		
12	Cover, I/O, Elastomeric	Section 7.2.10		

	Table 9-2. IPB for the Infuser	
Index Number	Nomenclature	Replacement Procedure
13	Assembly, Connectology, One-Channel	Section 7.2.9
14	Assembly, Connectology, Two-Channel	Section 7.2.9
15	Gasket, Connectology, One-Channel	Section 7.2.9
16	Gasket, Connectology, Two-Channel	Section 7.2.9
17	Assembly, Back	Section 7.2.17
18	Assembly, Infuser Mechanism, Left	Section 7.2.14
19	Assembly, Infuser Mechanism, Right	Section 7.2.14
20	Gasket, Mechanism	Section 7.2.14
21	Cover, Right, One-Channel	Section 7.2.14
22	Assembly, Front Bezel, One-Channel	Section 7.2.15
23	Assembly, Front Bezel, Two-Channel	Section 7.2.15
24	Gasket, Bezel, Rear-to-Back	Section 7.2.15
25	Gasket, Bezel, Upper, Rear-to-Front	Section 7.2.16
26	Gasket, Bezel, Lower, Rear-to-Front	Section 7.2.16
27	Assembly, Rear Bezel	Section 7.2.16
28	Plate, Filler, Board Cavity	Section 7.2.10
29	Assembly, CE	Section 7.2.11
30	Power System Controller	Section 7.2.12
31	Board, Power Supply	Section 7.2.13
32	User Interface Controller	Section 7.2.18
33	Assembly, Upper Bumper	Section 7.2.16.1
34	Gasket, Upper Bumper	Section 7.2.16.1
35	Bumper, Lower, with Logo Badge	Section 7.2.15.1
36	Button, Touchscreen Lockout	Section 7.2.16
37	Lens, IrDA	Section 7.2.16
38	Antenna, Left/Right	Section 7.2.16
39	Assembly, Cable, Touchscreen Extender	Section 7.2.15
40	Assembly, Ground Wire	Section 7.2.15
41	Assembly, Cable, UIC, Left/Right	Section 7.2.18
42	Assembly, Fan	Section 7.2.17.2

	Table 9-2. IPB for the Infuser				
Index Number	Nomenclature	Replacement Procedure			
43	Duct, Exhaust	Section 7.2.17.2			
44	Assembly, AC Input/Output	Section 7.2.17.1			
45	Connector, AC Power	Section 7.2.17.1			
46	Assembly, Speaker	Section 7.2.18.1			
47	Fuse, T3.15A, 250 V	Section 7.2.13.1			
48	Nut, Hex, 10-32	Section 7.2.10			
49	Nut, Hex, 4-40, Nylon	Section 7.2.17.2			
50	Nut, Ground	Section 7.2.7			
51	Screw, Handle, TORX, 10-14 x 3/4, Self-Tapping	Section 7.2.6			
52	Screw, 6-32 x 5/16, Pan Head, Phillips	As Applicable			
53	Screw, 6-32 x 3/8, Pan Head, Phillips, with Washer	Section 7.2.5			
54	Screw, 6-32 x 5/8, Pan Head, Phillips	As Applicable			
55	Screw, 4-40 x 1/4, Pan Head, Phillips	As Applicable			
56	Screw, 4-40 x 1/2, Pan Head, Phillips, Nylon	Section 7.2.17.2			
57	Screw, Pole Clamp, M3, 5 mm, Pan Head, Phillips	Section 7.2.8			
58	Screw, Lower Bumper, TORX, PT30, 10 mm	Section 7.2.15.1			

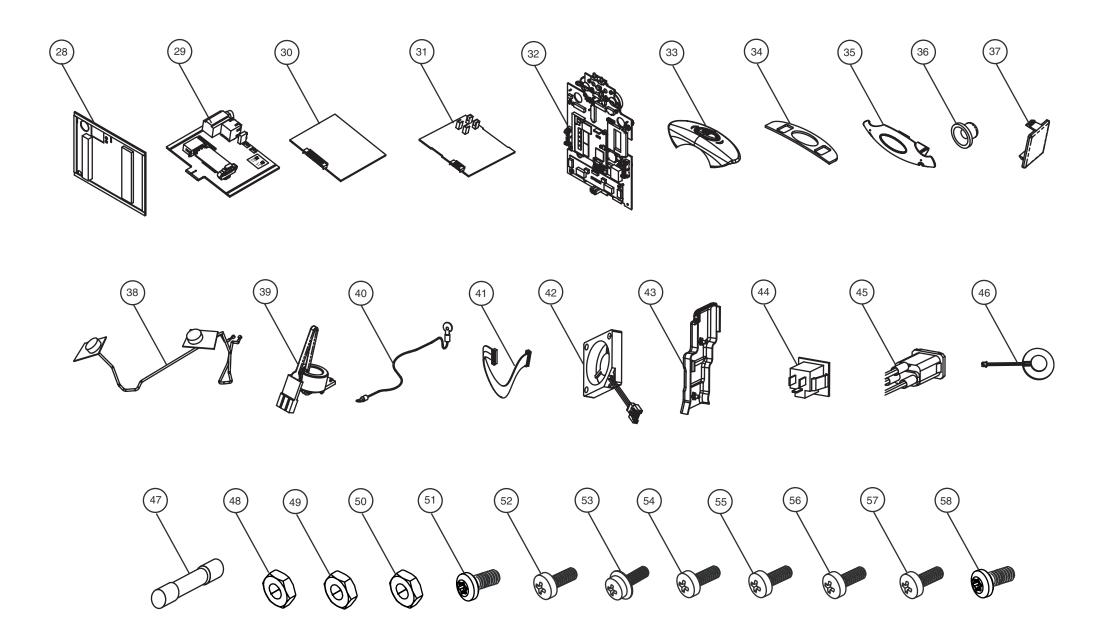
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		Sheet 1 of 2			

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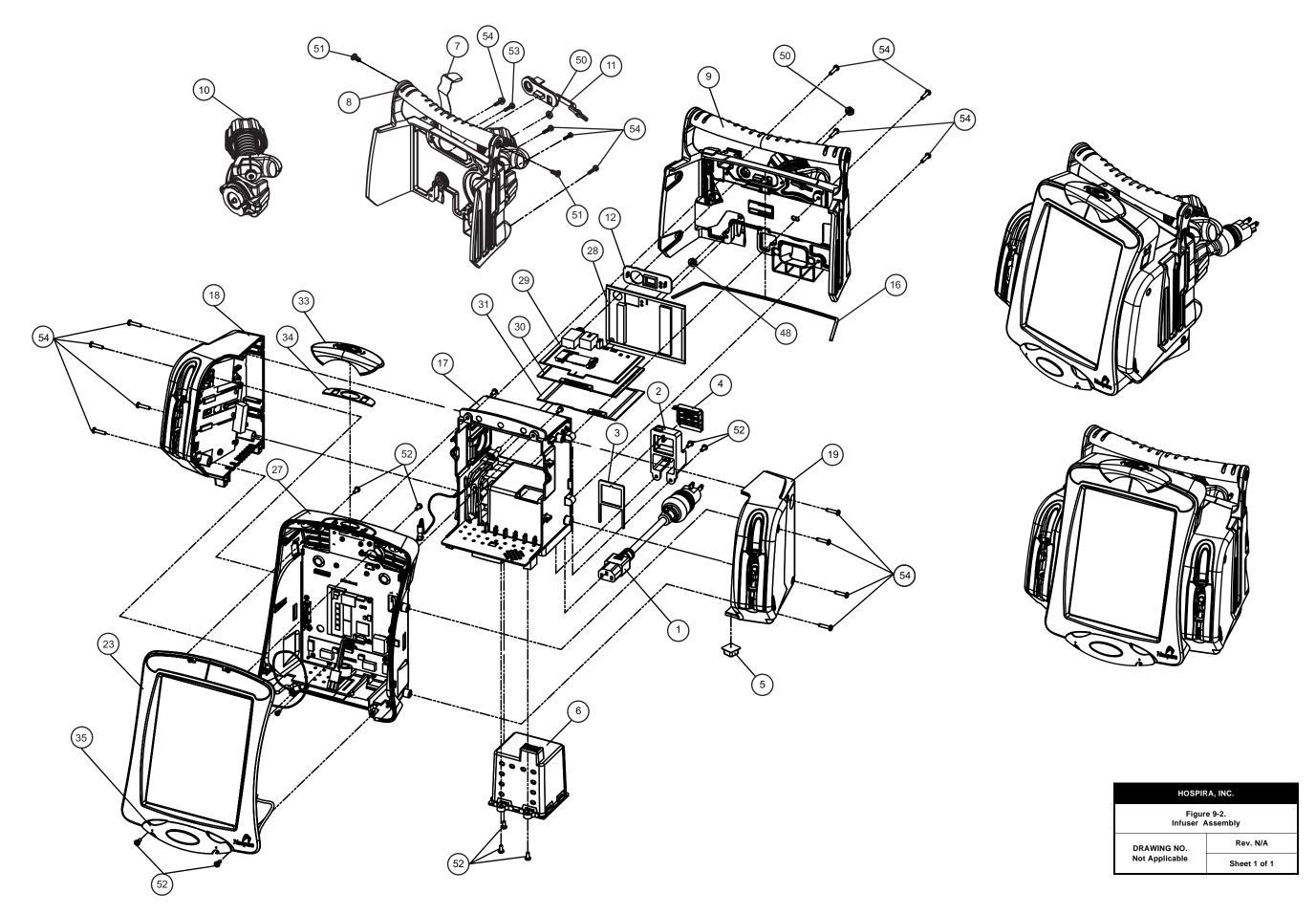
SYMBIQ Infusion System 9 - 6 Technical Service Manual



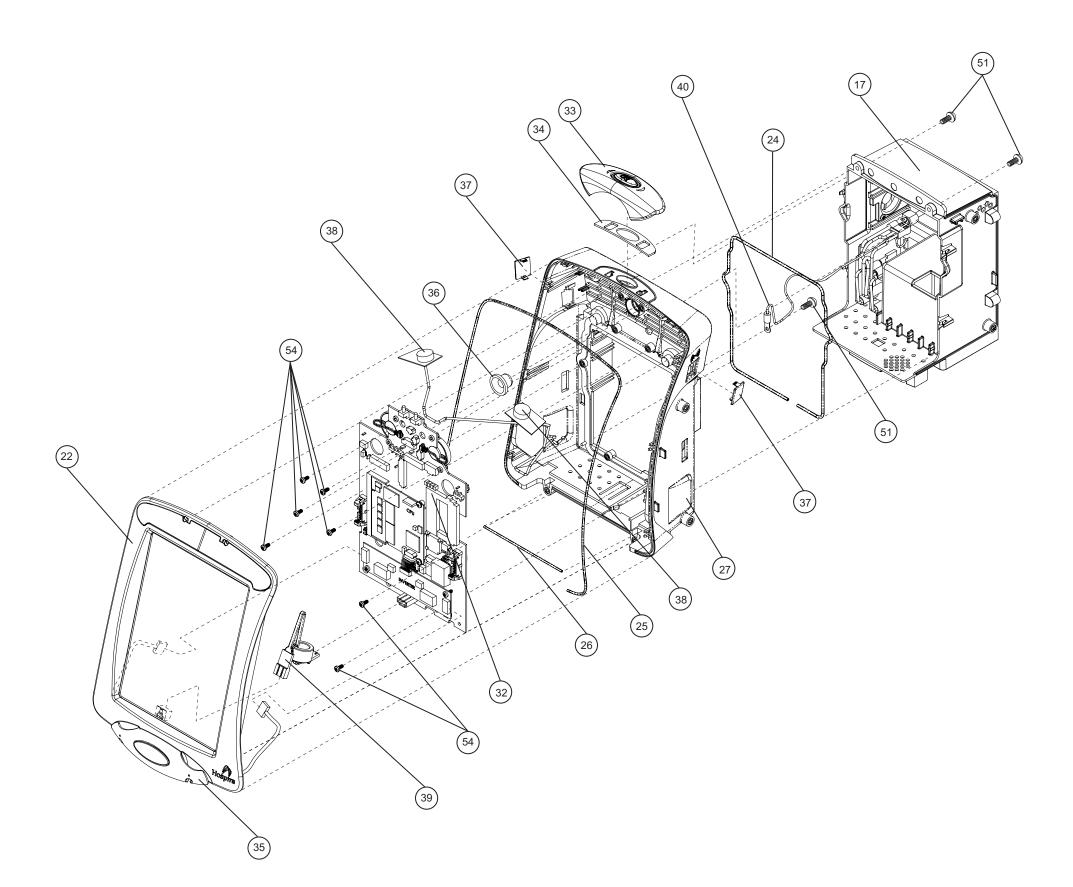
HOSPI	RA, INC.
Figure 9-1. Illustrated Parts Breakdown	
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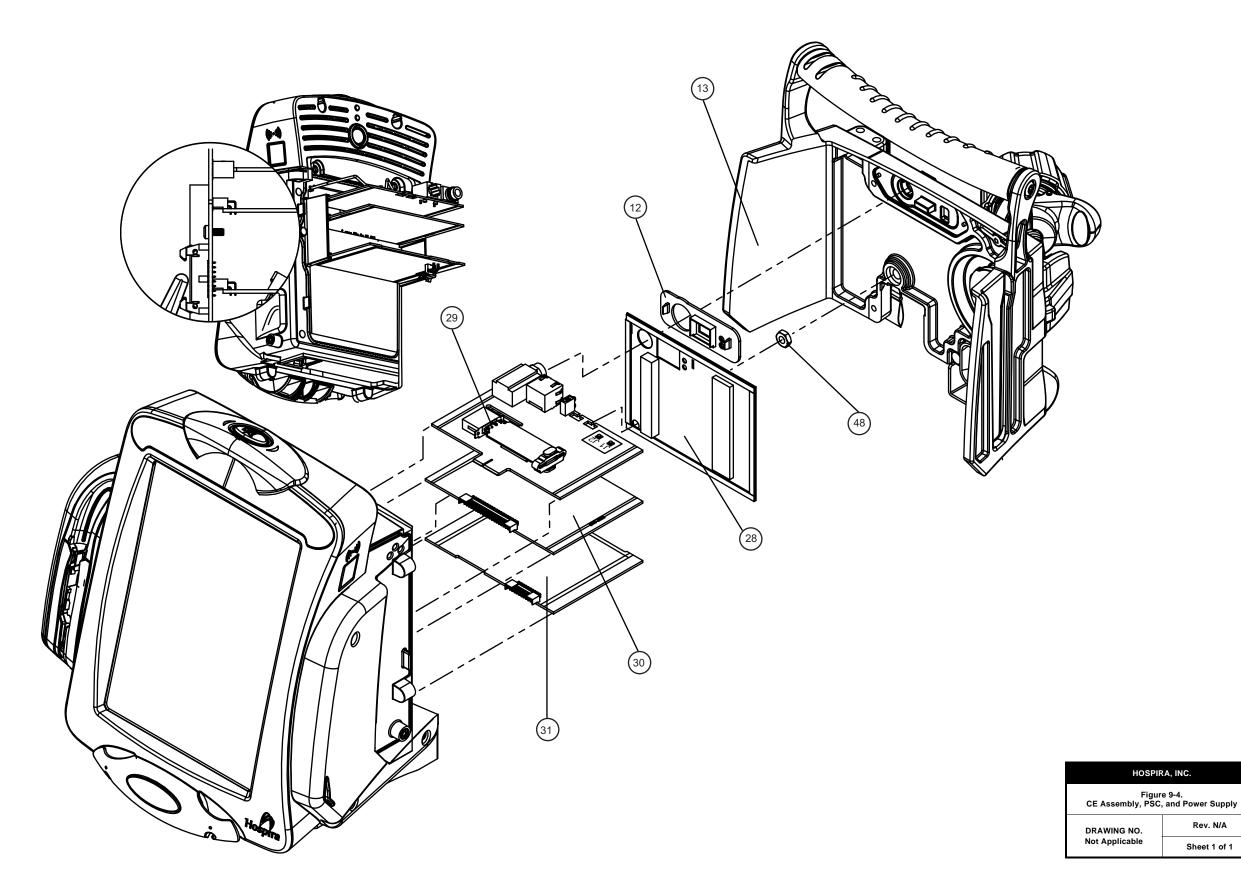


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Figure 9-3. Front and Rear Bezels	
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APPENDIX

USE OF THE INFUSION SYSTEM IN ELECTROMAGNETIC ENVIRONMENTS

The SYMBIQ infusion system (outside of the United States) is intended for use in the electromagnetic environment specified in *Table A-1*, *Table A-2*, *Table A-3*, and *Table A-4*. The user of the infusion system should assure that it is used only in the appropriate environment.

ELECTROMAGNETIC EMISSIONS

Table A-1 describes electromagnetic emissions compliance and guidance for the SYMBIQ.

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

ELECTROMAGNETIC IMMUNITY

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

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

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

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

ELECTROMAGNETIC IMMUNITY FOR LIFE-SUPPORTING EQUIPMENT AND SYSTEMS

Table A-3 provides guidance for use of the SYMBIQ near communications equipment.

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

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

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

- $^{\mathbf{a}}$ The industrial, scientific and medical (ISM) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.660 MHz to 40.700 MHz.
- 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.
- $^{f d}$ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V₁] V/m.

RECOMMENDED SEPARATION DISTANCES FOR COMMUNICATIONS EQUIPMENT

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

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

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

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

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

APPENDIX

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1-800-241-4002

For additional services and technical training courses, visit the website at www.hospira.com.

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

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

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

The SYMBIQ infusion system uses components and technologies protected by U.S. Patent Numbers USD500326; USD515205; US5989222; US519175; US5462256; US5586868; US5816779; US5681285. Other patents pending.



Complies with limits for Class B digital device established by FCC Rules, Part 15



The SYMBIQ infuser has been assessed and complies with IEC/EN 60601-1-2 (2001)



Attention, consult accompanying documents.



Provides adequate degree of protection against electrical shock and suitable for application to patient

IPX1

Protected against dripping water

Class 1

Mains supply equipment using protective earth



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

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