symbiq™ System Operating Manual

For use with the SYMBIQ™ One-Channel Infuser
List Number 16026-04
and SYMBIQ™ Two-Channel Infuser
List Number 16027-04

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430-11348-003 A(Rev. 07/07)

Hospira

Chapter 1: Introduction

The SYMBIQ™ Infusion System is a general purpose infuser designed to deliver fluids, solutions, medications, agents, nutritionals, electrolytes, blood and blood products for parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration.

The SYMBIQ™ Infusion System is available as a one-channel or a two-channel infuser. These infusers can be connected to configure a three or four channel pump. The connecting mechanism is designed to allow a maximum of 1 additional pump to be connected. The Symbiq Infusion System can be configured as a one-, two-, three-, or four-channel pump.

A cassette-based, multi-function device, the SYMBIQ™ Infusion System is powered by either AC power or can be powered by the enclosed rechargeable battery. The SYMBIQ™ Infusion System delivers Basic therapy or Advanced therapies such as Multistep, Intermittent, and Interchannel Sequencing.

The SYMBIQ™ Infusion System is intended for use primarily in a hospital setting. Other care areas where the infuser 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.

Intended Audience

The SYMBIQ™ Infusion System is intended for use at the direction of or under the supervision of licensed physicians or certified healthcare professionals who are trained in the use of infusers and the administration of parenteral, enteral, and epidural fluids and medications. Training should emphasize preventing I.V. related complications including appropriate precautions to prevent accidental infusion of air. Use the SYMBIQ™ Infusion System according to established hospital or institution guidelines, policies, and procedures.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of physicians or other licensed health practitioners.

Document Conventions

Throughout this manual, the following conventions are used to call attention to warnings, cautions, notes, and tips:

WARNING: A warning message contains special safety emphasis and must be observed at all times. Failure to observe a warning message is potentially life threatening.

CAUTION: A caution appears in front of a procedure or statement. It contains information that could prevent product damage or hardware failure. Failure to observe a caution could result in patient or user injury.

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

Tip: A Tip contains useful information, hints, and shortcuts that make the product easier to use.

Figures and graphics are rendered as representations to approximate the actual product, and may not exactly reflect the product.

Type Conventions

This manual uses the following style conventions to identify recurring objects.

Table 1.1 Type Conventions

Convention	Description	Example
Blue text	This indicates that it is a hypertext link.	*See* Table 1-1.1, "Type Conventions," on page 6.
Bold	Introduces important terms	The secondary container must be **higher** than the primary container.
Arial narrow	Names a button	Press On/Off key...
Small Capitals	Names of screens	The **STARTUP SCREEN** displays

Warnings and Cautions

The SYMBIQ™ Infusion System is designed and manufactured to be safe, reliable, and easy to use. This section describes possible hazards and explains how to prevent these hazards.

Warnings

- When infusing at low delivery rates (5.0 mL/hr or less), use thick-walled microbore sets to reduce the fluid bolus amount that may be delivered when a distal line occlusion is released.
- To obtain optimal low flow continuity at rates (between 0.1 and 1.0 mL/hr) manually prime the set.
- DO NOT use medications incompatible with silicone rubber or PVC plastic or medications not stable under infusion conditions.
- ALWAYS prime the administration set to remove air from the cassette, tubing, and injection sites prior to connecting to the patient. ALWAYS disconnect the administration set from the patient prior to priming or purging.
- Arrange tubing, cords, and cables to minimize the risk of patient strangulation or entanglement.
- Consult medication labeling to confirm medication compatibility, concentration, delivery rates, and volumes are all suitable for desired delivery mode.
- When using the infuser for secondary deliveries (piggybacking), ensure the fluids being infused are both chemically and physically compatible.

- When an administration set is loaded in the infuser, a small amount of fluid is expelled each time the cassette carriage is opened or closed. If potent medications are being used, disconnect the administration set from the patient to prevent over medicating the patient.
- Delayed respiratory depression following continuous epidural administration of preservative-free morphine sulfate has been reported.
- Administer only anesthetics and analgesics approved for epidural administration (as indicated by the medication's FDA approved labeling). Epidural administration of medications other than those indicated for epidural use could result in serious patient injury.
- Rate accuracy can be affected by variations of fluid viscosity, fluid temperature, head height, back pressure or any combination of these. Additional factors that may influence rate accuracy are administration set configuration and the duration of time the administration set is utilized.
- When delivering a secondary infusion, use a SYMBIQ™ primary administration set with a backcheck valve.
- For piggyback deliveries from a secondary container, ensure the secondary container is hung higher than the primary container.
- Use of additional non-SYMBIQ™ equipment or accessories on the same I.V. line to the patient may cause potential safety hazards.
- After pressing Emergency Stop, verify that the Emergency Stop Banner is displayed and delivery has stopped.

General Cautions

- Federal (USA) law restricts this device to sale by or on the order of physicians or other licensed health practitioners.
- DO NOT place the SYMBIQ™ Infusion System in service if it fails any of the diagnostic self-tests.
- Before use, inspect the AC cord to check for defects.
- Before use, ensure the infuser has a functional battery installed. Use of a properly installed and functional battery helps ensure the infuser operates properly.
- Only qualified biomedical technicians should access the infuser's Biomed mode.
- To prevent product damage, use proper care during unpacking and installation. DO NOT use a SYMBIQ™ Infusion System if it appears damaged in any way.
- DO NOT attach more than two connected infusers to an I.V. pole (see "Attaching and Detaching an Infuser to an I.V. Pole" on page 49.
- When a primary infuser is connected to an AC power main, never connect more than one additional infuser in a series to the rear infuser AC power outlet; connecting more than one additional infuser in a series may cause an electrical safety hazard (see "Rear Infuser AC Power Outlet" on page 20 for more information).
- Use ONLY Hospira MedNet® Server Suite with the SYMBIQ™ Infusion System.
- To prevent personal injury or product damage, make sure the pole clamp is tightened properly and the infuser is securely attached.

- Disconnect AC power line prior to opening unit or changing battery.
- Manually ejecting a cassette renders that channel incapable of infusing until it is reset by Biomed.
- NEVER use sharp objects such as fingernails, pens, pencils, paper clips, or needles as means to program the infuser. The **LCD SCREEN** may scratch.

Epidural Administration

Recommended use of the epidural route is to provide anesthesia or analgesia for periods up to 96 hrs.

- This device can be used to administer only those anesthetics/analgesics approved for epidural administration (as indicated or allowed by the medications' FDA approved labeling). Epidural administration of medications other than those indicated for epidural use could result in serious injury to the patient.
- For epidural administration, the use of Hospira catheters, SYMBIQ™ sets without Y-sites, and "epidural" stickers indicating ongoing epidural administration are recommended.

Administration of medications via the epidural route should be limited to personnel familiar with associated techniques and patient management problems. Proper epidural placement of the catheter is essential since catheter migration could result in intravascular or intrathecal administration. Facilities practicing epidural administration must be equipped with resuscitative equipment, oxygen, naloxone, and other resuscitative medications. Adequate monitoring equipment (e.g., Oximetry and/or Capnography) is recommended for continuous monitoring of the patient during epidural administration. Patients must be observed frequently for side effects in a fully-equipped and staffed environment for at least 24 hours following completion of medication administration by the epidural route. DELAYED RESPIRATORY DEPRESSION FOLLOWING CONTINUOUS EPIDURAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE HAS BEEN REPORTED. If over-delivery occurs during administration, observe the patient closely for signs of spinal cord compression (disorientation, headache, transient neuralgias) and medication overdose.

Administration Sets and Delivery Cautions

- USE ONLY Hospira SYMBIQ™ administration sets with the SYMBIQ™ Infusion System. Use of unauthorized sets may result in injury to the patient or damage to the infuser. GemStar® administration sets are not compatible with the SYMBIQ™ Infusion System.
- To prevent contamination, use aseptic techniques with all fluid-path connections. Remove protective coverings as administration set assembly progresses.
- When priming is complete and the cassette flow stop is closed, ensure no fluid flows at the distal end of the administration set. If fluid flow is observed, DO NOT use the administration set.
- Before using a CLAVE® connector, ensure administration set and fluid compatibility. DO NOT use needles to access the CLAVE® connector.
- Before removing the cassette from the infuser, close ALL slide clamps for added free flow protection.

- In vitro studies suggest packed red blood cells with unusually high hematocrit be diluted with blood-compatible fluids like 0.9% sodium chloride injection to decrease hemolysis and increase flow rate.
- Before disconnecting a syringe from the CLAVE®, pull the plunger up slightly to avoid spilling fluid. For rigid containers, close the upper slide clamp, open the cassette carriage, remove and invert the cassette (ports down).
- Air bubbles may form in the administration set as result of normal outgassing of dissolved air in the fluid. This may occur if using a chilled solution, if the infuser is mounted significantly above the patient, when an administration set is used for more than 24 hours, or when using certain fluids known to routinely outgas. In these cases, an air eliminating filter may be used.
- Repeatedly opening and closing the cassette carriage may defeat the proximal air-in-line alarm and may cause a distal alarm requiring repriming.
- SYMBIQ™ administration sets with integral non-blood filters are not for administration of blood, blood products, emulsions, suspensions, or any medications not totally soluble in the solution being administered. These medications may be administered through the lower Y-injection site below the filter or via SYMBIQ™ administration sets with blood filters.
- Administration sets should be changed per CDC guidelines or hospital policy. Ensure administration sets are properly discarded per CDC guidelines or hospital policy**.**
- DO NOT push the cassette carriage closed. Use the LOAD/EJECT button to open and close the cassette carriage.
- If a cassette is manually ejected from a channel, that channel must not be used until it is reset in Biomed mode.
- If patient information is stored, the infuser uses this information for default weight, height, and BSA values when specifying dose rate parameters.
- To protect the patient from equipment error resulting in over-infusion and—where applicable—in under-infusion refer to the Technical Service Manual and to “Chapter 10: Alarm and System Messages” on page 133 and “Appendix B: Alarm Messages and Troubleshooting” on page 187.
- The syringe container size must be between 1 mL and 60 mL. DO NOT use syringe containers larger than 60 mL with the syringe holder adaptor.
- DO NOT operate or store a SYMBIQ™ Infusion System with the cassette carriage opened. To avoid damaging the cassette carriage, keep it securely closed while the infuser is not in use.
- Accuracy of medication amounts recorded in the logs are dependent on the fill accuracy of IV container and amount discarded during priming.
- Programming a Piggyback VTBI less than the actual container volume results in the remaining volume being delivered at the primary rate after the completion of the Piggyback Program.

Battery Operation Cautions

- The battery may not be fully charged upon receipt. Connect the infuser to AC power for at least four hours prior to initial use. Failure to fully charge the battery may significantly reduce battery life.

- Before connecting a patient to the infuser, ensure the infuser has a fully charged battery installed for continuous infuser operation.
- If the low-battery alarm activates, connect the infuser to AC power immediately.
- Use AC power as the primary power source whenever possible. Before use, inspect the AC cord to check for defects. Connect to AC power during storage to ensure a fully charged battery for emergencies. If the quality of the earth grounding source is in doubt, DO NOT use the infuser on AC power, use only battery power.

Unintended Bolus Delivery

- To avoid delivering a bolus when a distal occlusion is cleared, disconnect tubing from the patient while eliminating a distal occlusion.

Cleaning Cautions

- To avoid mechanical or electronic damage, DO NOT immerse the SYMBIQ™ Infusion System in fluids or cleaning solutions. DO NOT spray cleaning solutions in or near infuser openings. DO NOT allow cleaning solutions to saturate the air-in-line detectors or enter the infuser when cleaning the air-in-line detectors.
- USE ONLY the recommended cleaning solutions and follow the manufacturer's recommendations. Using cleaning solutions not recommended by Hospira may result in product damage. The disinfecting properties of cleaning solutions vary; consult the manufacturer for specific information. See "Chapter 12: Cleaning, Maintenance, and Storage" on page 159.
- DO NOT use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.
- NEVER use sharp objects such as fingernails, paper clips, or needles to clean any part of the infuser.
- DO NOT sterilize by heat, steam, ethylene oxide (ETO), or radiation.
- DO NOT use abrasive scrub pads or brushes on the **LCD TOUCH SCREEN** as it may become scratched or damaged. Use only soft cloths or sponges.

US FCC (Federal Communications Commission) Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including that which may cause undesired operation of these devices.

FCC Interference Statement

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the distance between the equipment and the receiver.
  - Connect the equipment to an outlet on a different circuit from the circuit the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by Hospira could void the user's authority to operate the equipment.

WIRELESS DEVICE CAUTION

- The wireless 802.11 a/b/g device usage in the 5150-5250 MHz band is limited to indoor use to reduce potential for harmful interference to co-channel mobile satellite systems.
- In the 5250-5350 MHz and 5650-5850 MHz frequency bands, high power radars are allocated as primary users and these radars could cause interference and/or damage to LE-LAN devices.
- Operation is subject to the following two conditions: (1) the wireless device may not cause interference, and (2) the wireless device must accept any interference, including interference that may cause undesired operation of the wireless device.

Radio Frequency Exposure Statement

- The Wireless LAN radio device in the Connectivity Engine peripheral board with this infusion device has been evaluated and found compliant to the requirements of the following Radio Frequency exposure standards:
  - Federal Communications Commission, OET Bulletin 65 (Edition 97-01), Supplement C (Edition 01-01), Evaluating Compliance with FCC Guidelines for Human Exposure to Radio frequency Electromagnetic Fields, July 2001.

  - Industry Canada, Evaluation Procedure for Mobile and Portable Radio Transmitters with respect to Health Canada's Safety Code 6 for Exposure of Humans to Radio Frequency Fields, Radio Standards Specification RSS-102 Issue 1 (Provisional): September 1999.
- The radiated output power of this Wireless LAN device is far below the FCC radio frequency exposure limits. The Wireless LAN device has been evaluated with zero inches of human body separation from the antenna and found to be compliant with FCC RF exposure limits.

Electrical Artifacts in Clinical Settings

The SYMBIQ™ Infuser has been tested and found to comply with EMC/EMI limits in accordance with:

- The use of portable and mobile RF equipment may have an impact on this and other pieces of medical equipment
- Nonhazardous, low-level electrical potentials commonly occur 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. If the monitoring equipment is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated to the point of simulating actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infusion device instead of some other source in the environment, temporarily suspend fluid delivery (a therapy should only be suspended if doing so does not pose a clinical risk to the patient). Disappearance of the abnormality indicates it was probably caused by the electronic noise generated by the infusion device. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring equipment system documentation for setup and maintenance instructions.
- The SYMBIQ™ Infusion System is designed to operate around normally encountered electromagnetic interference (EMI) conditions. If extreme levels of interference like that produced by an electrosurgical generator are encountered, normal operation of a sensor or microcomputer might be disrupted.
- This equipment has been tested and found to comply with EMC/EMI 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. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device
  - Increase the separation between the equipment
  - Connect the equipment into an outlet on a circuit different from that to which the other device is connected
  - Consult the manufacturer or field service technician for help

- The use of portable and mobile RF equipment may have an impact on this and other pieces of medical equipment.
- Use of radio frequency emitting devices (other than the wireless communication module if installed in the SYMBIQ™ Infuser) such as cellular telephones and 2-way radios in close proximity of this device may affect its operation. Take the following measures to correct interference caused by these devices:
  - Relocate or re-orient other radio frequency emitting devices
  - Increase the distance between the infuser and other radio frequency emitting devices
  - DO NOT connect other radio frequency emitting devices to the same AC power source used by the infuser

Wireless LAN Module

Device Name:	Hospira MedNet 802.11 a/b/g Wireless (Upgrade) Module
Standards:	IEEE 802.11 a/b/g
Transmit Power:	802.11 b/g- 17 dBm 802.11 a- 16 dBm
Antenna:	Integrated surface mount antenna
Certifications:	Part 15.247, 15.407 IC RSS-210, RSS-102 FCC ID: STJ80411396001 IC: 5627A- 80411396 Model: CUSTOM DWL-AG132

Flow Continuity

At low flow rates (between 0.1 and 1.0 mL/hr) with microbore and macrobore tubing, the no-flow period does not exceed 20 seconds and the bolus volume released does not exceed 2 microliters.

Trumpet Curves

Trumpet curve graphs show representative maximum and minimum percent flow rate deviation from the programmed rate over observation intervals of 2, 5, 11, 19, and 31 minutes. The graphs plot the mean delivery rate error (average of 3 infusers) for the 2nd hour and the 72nd hour as a straight line. Flow rate graphics plot flow rates at 30 second intervals for the first 2 hours and for the 72nd hour of delivery. This information was developed in accordance with IEC 60601-2-24: 1998, Sub-Clause 50.102. Refer to this standard for detailed information.

Sample Trumpet Curve

On the trumpet curve graph sample shown in Figure 173, find the 5 minute interval (A) at the horizontal axis and read the corresponding points (B) and (C) on the vertical axis. The values are approximately +2.8% and -0.5%.

This means at the rate of 25 mL/hr, the average maximum flow rate fluctuation for any 5 minute time interval during the 2nd hour of operation was within the limits of +2.8% and -0.5% from the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

Hospira, SYMBIQ™ and Hospira MedNet® Server Suite are trademarks of Hospira.

The SYMBIQ™ Infusion System uses components and technologies protected by U. S. Patent Numbers USD500326, USD515205, US5989222, US5191795, US5462256, US5586868, US5816779, US5681285. Other patents pending.

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

The SYMBIQ™ Infusion System complies with the limits for a Class B digital device established by FCC Rules, Part 15.

Attention, consult accompanying documents.

The SYMBIQ™ Infusion System is Wide Fidelity (WiFi) enabled and complies with the IEEE 802.11 a/b/g communications standard.

Type CF

The SYMBIQ™ Infusion System provides an adequate degree of protection against electrical shock and is suitable for application to a patient.
Class 1, Internally Powered
Type CF Applied Part

Equipment not suitable for use in the presence of flammable mixtures.

MEDICAL EQUIPMENT

CLASSIFIED C UL US 35VR

WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1, IEC60601-1,
CAN/CSA C22.2 No. 601.1,
IEC60601-2-24

IPX1

Protected against dripping water.

The SYMBIQ™ Infusion System complies with UL60601-1 with respect to Protective Earthing (ground).