System Operating Manual

For List Number 16026-04 (One-Channel Infuser)

The SYMBIQ™ Infusion System is designed for use by health care professionals. The Hospira Customer Support hotline is available 24 hours a day (in the USA) to provide consultation and technical assistance regarding the SYMBIQ™ Infusion System.

Hospira Technical Support Operations
1-800-241-4002

To order additional copies of this manual
(P/N 430-10599-001), call 1-877-946-7747

Refer to the Device Development Document for complete specifications and restrictions.

Contents

What is in this book

Table 1 outlines the chapters and chapter contents of this manual.

Table 1: SYMBIQ™ Infusion System Operating Manual Contents

Chapter/Section	Chapter Contents
Chapter 1	Introduction, warnings, and cautions.
Chapter 2	Infuser layout, features, and touchscreen icons and symbols.
Chapter 3	Clinical modes including Power, Programming, Delivery, and Stop.
Chapter 4	Attaching infusers to an I.V. pole, administration sets, and fluid container compatibility.
Chapter 5	Basic infusion therapy.
Chapter 6	Advanced infusion therapies.
Chapter 7	Supplemental deliveries and program options.
Chapter 8	Piggyback
Chapter 9	Bolus
Chapter 10	Alarm messages, alarm urgency, and system messages.
Chapter 11	Data storage and instructions on accessing data.
Chapter 12	Cleaning and service guidelines.
Chapter 13	Product technical specifications, flow rate accuracy.
Appendix A	System messages, message criteria, and troubleshooting suggestions.
Appendix B	Alarm messages, alarm criteria, and troubleshooting suggestions.
Appendix C	Hospira accessories, administration sets, components, and list numbers.
Appendix D—Glossary	Acronyms, expressions, terms, and their definitions.
Appendix E	Default Drug Library (DDL) in tabular form.

NOTES:

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 system.

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

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. Therefore, figures and graphics may not exactly reflect the product.

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 microbore sets to reduce the amount of the fluid bolus that may be delivered when a distal line occlusion is released.
- To ensure low-flow continuity at rates less than 1 mL/hr, use SYMBIQ™ administration sets with microbore tubing.
- 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 (piggyback), 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.

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.
- 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 19 for more information).
- To prevent personal injury or product damage, make sure the pole clamp is tightened properly and the infuser is securely attached.

Epidural Administration

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

- 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) 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.
- The epidural space has 58 openings through which fluid can exit. Pressure buildup during administration is transient. However, if a large volume of fluid is administered over a short time period, the pressure will take longer to return to normal. If overdelivery 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 SYMBIQ™ administration sets with the SYMBIQ™ Infusion System. Use of unauthorized sets may result in injury to the patient or damage to the infuser.
- To prevent contamination, use aseptic techniques with all fluid-path connections. Remove protective coverings as administration set assembly progresses.
- When priming is complete or when finished loading a cassette, 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.
- To help prevent fluid flow, close ALL slide clamps before removing the cassette from the infuser.
- 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 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.
- The infuser screen displays the VTBI (volume to be infused) in whole numbers when a value is above 99.9. Any fraction of a milliliter delivered is not displayed; however, it is retained in memory.
- 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**.**
- USE ONLY SYMBIQ™ administration sets with the SYMBIQ™ Infusion System. Use of unauthorized sets may result in injury to the patient or damage to the infuser. Hospira Gemstar® administration sets are not compatible with the SYMBIQ™ Infusion System.
- 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, the channel must not be used until it is reset in Biomed mode.
- The Callback alarm activates if the amount of time between key presses are made exceeds the No Keypress time limit configured for the current CCA or DDL.
- If patient information is stored, the infuser uses this information for default weight, height, and BSA values when specifying dose rate parameters.

Battery Operation Cautions

- The battery may not be fully charged upon receipt. Connect the infuser to AC mains power for at least six 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, use only battery power.

Unintended Bolus Delivery

- To avoid delivering a bolus when a distal occlusion occurs, 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 151.
- 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.

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 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 circuit different from that to which 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.

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 separation of human body 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

NOTES:

Chapter 2: Infuser Overview

Chapter 2 describes the SYMBIQ™ Infusion System layout (front, rear, and bottom), infuser buttons and touchscreen buttons, touchscreen icons and symbols, and the features that control the infuser.

Many features of the SYMBIQ infuser system are configurable through the Hospira MedNet® software. For details on facility-defined configuration, contact the facility software administrator.

Infuser Layout—Front

Figure 1 depicts the front of a one-channel SYMBIQ™ Infusion System and the infuser touchscreen.

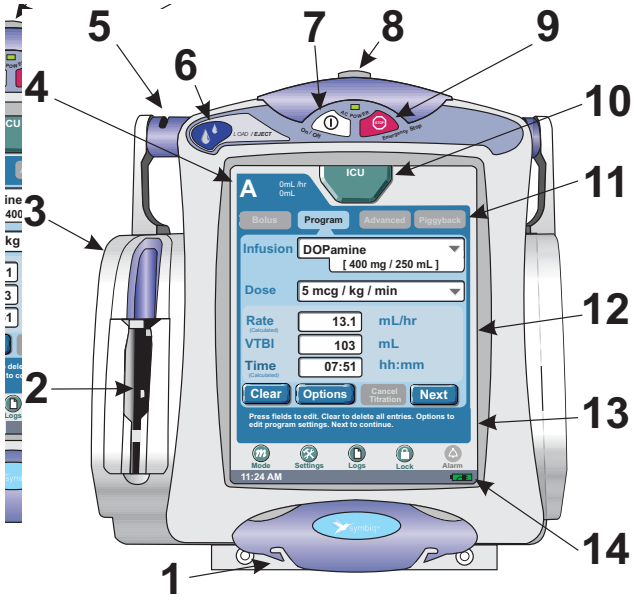


Figure 1: Front View and Touchscreen of the SYMBIQ™ Infusion System

Table 2 outlines the buttons and touchscreen elements that correspond to the numbers in Figure 1 above.

Table 2: Item Number and Corresponding Feature

Graphic #	Feature
1	Distal tubing guide
2	Cassette carriage
3	Cassette loader housing
4	Channel Identifier tab
5	Proximal tubing guide
6	Cassette LOAD/EJECT button
7	On/Off button

Graphic #	Feature
8	SILENCE button
9	Emergency Stop button
10	CCA/Patient Information button
11	Channel-level therapy buttons
12	Programming screen
13	Help/status text area
14	Battery indicator/AC power indicator

Infuser Buttons

Buttons on the infuser casing function in the following manner:

- **LOAD/EJECT**—opens and closes the cassette carriage
- **On/Off**—turns power on and off
- **SILENCE**—silences a silenceable alarm for a specified period of time, usually two minutes
- **Emergency Stop**—stops all channels, generates high urgency alarm
- **Cleaning Lock** (located on the rear of the infuser)—activates and deactivates the touchscreen

Touchscreen Buttons

The SYMBIQ™ Infusion System touchscreen allows you to access and use on-screen buttons and keypads. A membrane covers the LCD display so a single keypress does not cause significant infuser pole movement nor is it mistaken for a double keypress. When an active touchscreen button is pressed, the infuser sounds an audible valid key tone. The touchscreen also accommodates a keypress whether you are wearing wet gloves, dry gloves, or no gloves.

Note: *A triple-beep will sound when making entries that are touchscreen errors.*

Touchscreen Button Appearance

The appearance of touchscreen buttons varies depending on their status. A touchscreen button can be either active, depressed, selected, or unavailable. Table 3 depicts how touchscreen buttons appear based on their status.

Note: *Basic Program refers to functionality accessed by pressing the Program channel level button.*

Note: *Document copies should be printed in color to differentiate between button statuses.*

Table 3: Touchscreen Button Appearance

Touchscreen Button Status	Touchscreen Button Appearance
Active	
Depressed	
Selected	
Unavailable	

Touchscreen Icons and Symbols

Table 4 describes and illustrates the various touchscreen icons and symbols.

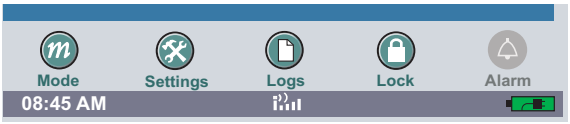
Table 4: Touchscreen Icons and Symbols

On-Screen Item Description	On-Screen Item Illustration
Horizontal navigation arrow buttons	
Vertical short scroll bar (up and down arrows scroll a list by one item)	
Vertical hot scroll bar (white interior arrows scroll a list by one item; each yellow arrow increases the scrolling increment by one item more than the previous arrow)	
Drop-down list field	
End-of-list indicator (for drop-down lists)	
CCA/Patient information button	

Table 4: Touchscreen Icons and Symbols

On-Screen Item Description	On-Screen Item Illustration
Infusion running drip icon	
Basic program icon	
Multistep therapy icon	
Intermittent therapy icon	
Piggyback icon	
Bolus icon	
Upper hard limit icon (displays on a channel tab when an upper hard limit is overridden, and the program confirmed on that channel)	
Lower hard limit icon (displays on a channel tab when a lower hard limit is overridden, and the program confirmed on that channel)	
Upper soft limit icon (displays on a channel tab when an upper soft limit is overridden, and the program confirmed on that channel)	

Table 4: Touchscreen Icons and Symbols

On-Screen Item Description	On-Screen Item Illustration
Lower soft limit icon (displays on a channel tab when a lower soft limit is overridden, and the program confirmed on that channel)	
No rule set icon (displays on a channel tab when a medication with no defined dose or dose rate limits is selected on a channel)	
Device Status Bar has two rows. The first row provides user adjustable device settings of Mode, Settings, Logs, Lock, and Alarm. The second row displays Time, WiFi Enabled Icon, and Battery Status.	

Infuser Layout—Rear

Figure 2 depicts the rear layout of the SYMBIQ™ Infusion System.

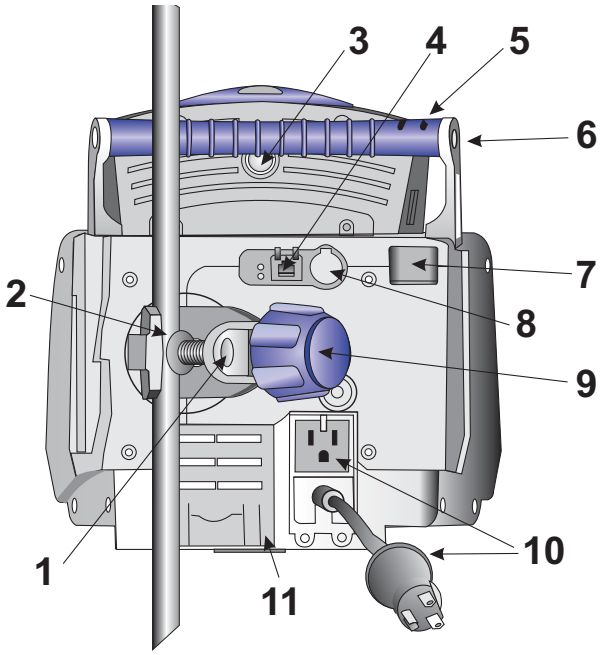


Figure 2: Rear View and Layout of the SYMBIQ™ Infusion System

Table 5 outlines features on the rear of the infuser that correspond to the numbers in Figure 2 above.

Table 5: Item Number and Corresponding Feature

Graphic #	Feature
1	Quick travel release clamp
2	Pole clamp
3	Cleaning Lock
4	Ethernet interface port
5	Proximal tubing guide
6	Carrying handle
7	Minipole insertion location
8	Nurse callback jack
9	Pole clamp knob
10	AC power cord and rear infuser AC power outlet (specifically for one additional SYMBIQ™ Infusion System only)
11	Battery compartment access door

Rear Infuser AC Power Outlet

The rear infuser AC power outlet on the back of the SYMBIQ™ Infusion System is specifically designed to accommodate one additional SYMBIQ™ Infuser. Never connect more than one additional infuser to the primary infuser connected to an AC power outlet; connecting any additional infusers may cause an electrical safety hazard. Before use, inspect the AC cord to check for defects.

Consider, for example, a primary infuser using AC (mains) power with a second infuser attached to it using the rear infuser AC power outlet. Do not attach an additional infuser to the rear infuser AC power outlet of the second infuser (Figure 3).

CAUTION: Never connect more than two infusers when using the rear infuser AC power outlet; connecting more than two infusers may cause an electrical safety hazard.

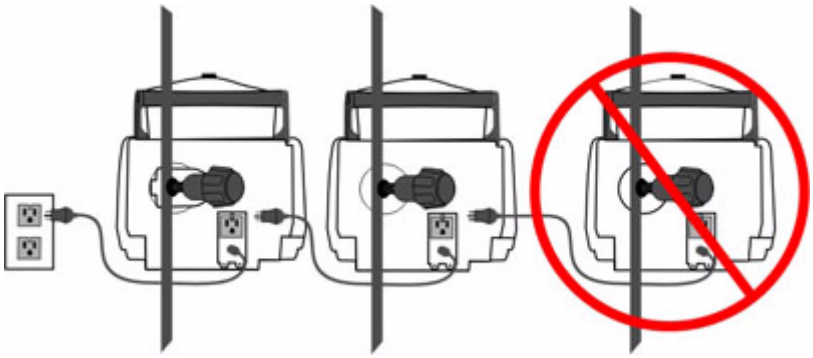


Figure 3: Incorrect Use of Rear Infuser AC Power Outlet

Instead, attach an additional infuser directly to an AC (mains) power source (Figure 4).

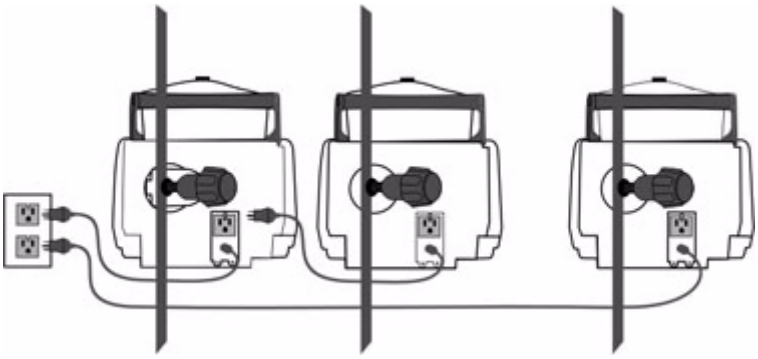


Figure 4: Correct Use of Rear Infuser AC Power Outlet

Wireless Communication

The *Wireless Connection Available* icon is displayed when the device is receiving a wireless signal. The infuser will connect to the network if a wireless network access point is recognized.

The SYMBIQ™ Infusion System supports wireless communication via an internal wireless communications module and antennae. Use the SYMBIQ™ Infusion System's wired or wireless connectivity options to communicate with server-based networks or hospital local area networks. Wireless communication to an infuser is direct rather than indirect through another infuser.

Infusers with the wireless module active display a wireless enabled icon on the touchscreen (Figure 5).

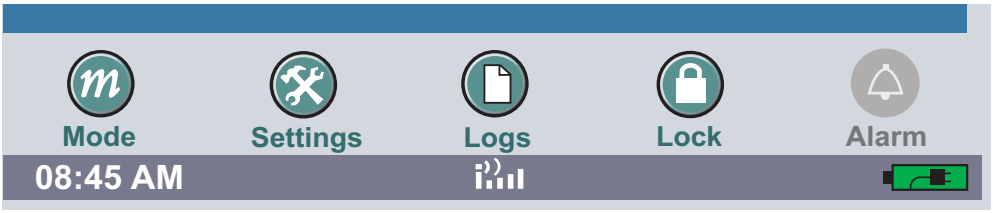


Figure 5: Wireless Enabled Icon on Infuser Touchscreen

Infuser Layout—Underside

Figure 6 depicts the underside layout of the SYMBIQ™ Infusion System.

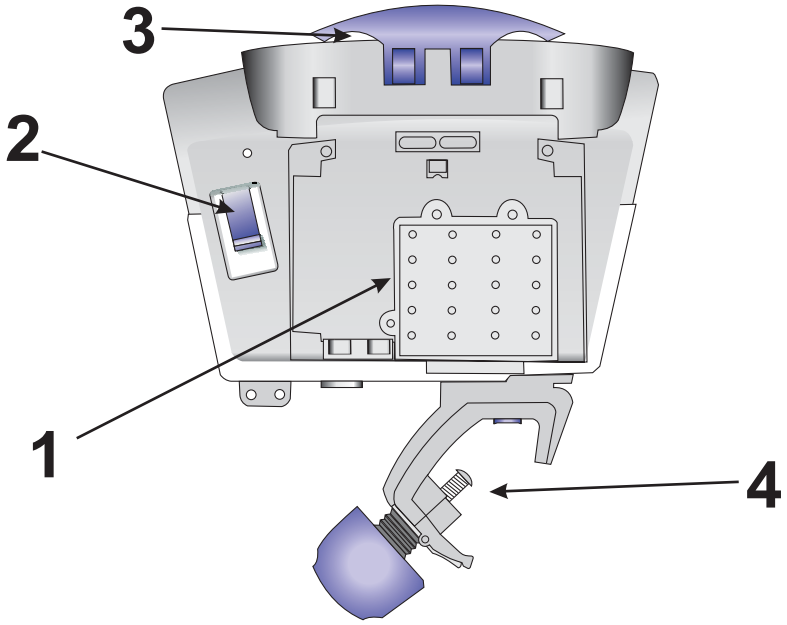


Figure 6: Bottom View and Layout of the SYMBIQ™ Infusion System

Table 6 outlines features on the bottom of the infuser that correspond to the numbers in Figure 6 above.

Table 6: Item Number and Corresponding Feature

Graphic #	Feature
1	Battery compartment access door
2	Cassette eject lever (EMERGENCY USE ONLY)
3	Distal tubing guide
4	Pole Clamp

Infuser Features

The SYMBIQ™ Infusion System has three levels of features:

- **Channel Level**—accessed by buttons on the infuser touchscreen. Used to select therapies and supplemental deliveries, these features include:
  - *Bolus*—displays the Bolus programming screen (if a Bolus therapy is partially or fully programmed) or the Bolus selection screen (if a Bolus therapy is not programmed)
  - *Program*—displays the Basic Programming screen
  - *Advanced*—displays the Advanced Therapies programming screen (if an Advanced therapy is partially or fully programmed) or the Advanced Therapies selection screen (if an Advanced therapy is not programmed)
  - *Piggyback*—displays the Piggyback programming screen
- **Program Level**—accessed by pressing Options button, these features include:
  - *Power Prime*—displays the Power Prime screen
  - *Delayed Start*—displays the Delayed Start Time entry keypad
  - *Standby*—displays the Standby drop-down list
  - *Alarm Options*—displays alarm options:
    - Distal Occlusion
    - Proximal Occlusion
    - Infusion Complete Callback
    - Air-in-Line
    - Nearing End of Infusion

  Note: *Alarm options set for a program apply only to that program.*

- **Device Level**—accessed by buttons at the bottom of the infuser touchscreen. These buttons control device level features including:
  - *Mode*—displays the Biomed Mode Passcode entry screen
  - *Settings*—displays the Settings Menu screen
  - *Logs*—displays the Clinical Logs Menu screen
  - *Lock*—displays the Program Lock/Unlock Passcode entry screen
  - *Alarm*—displays active alarms

Channel Level Features

Channel level features are accessed via buttons across the top of the touchscreen as depicted in Figure 7. The default channel level screen is the Basic Program screen.

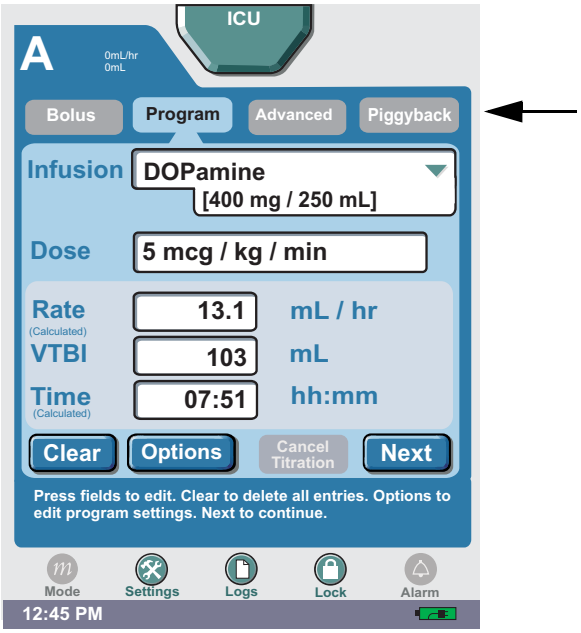


Figure 7: Channel Level Features

Use channel level buttons to access Bolus, Program, Advanced, and Piggyback programming screens when available.

Channel Feature Availability

Selecting a channel level feature affects the availability of other channel level features. For example, entering a single value on the Basic Program screen deactivates the Advanced button until the Basic program is cleared. Similarly, entering a single value on an Advanced program screen deactivates the Program button until the Advanced program is cleared

The Piggyback button is only available for a channel with a confirmed Basic program that has a VTBI greater than zero.

For more information on programming therapies, see “Chapter 5: Program (Basic) Therapy” on page 71, “Chapter 7: Advanced Therapies” on page 87, and “Chapter 8: Program Options” on page 105.

Program Level Features Options

Program level features are accessed on the programming screen shown in Figure 8.

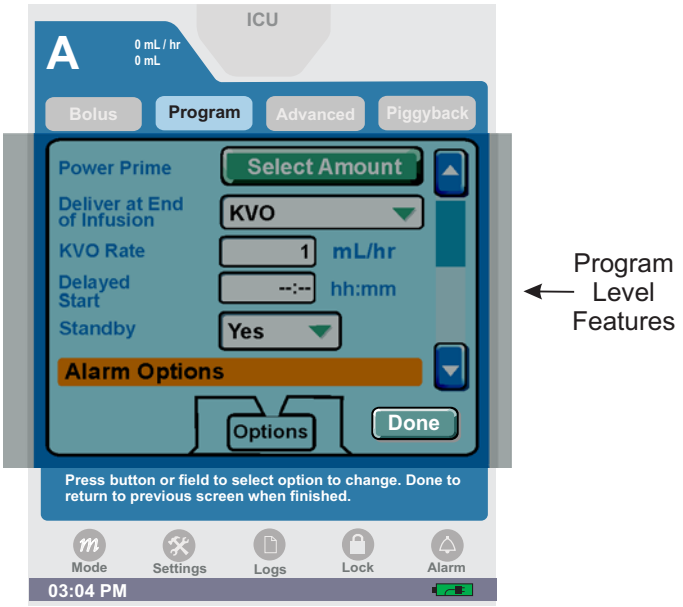


Figure 8: Program Level Features

While all options are visible on the Options screen, only options allowed for the selected therapy and enabled for the selected Clinical Care Area (CCA) are available. For example, if the selected therapy does not allow a delayed start or delayed start is not defined for the selected CCA, then the delayed start option will not be available. During an infusion, the air-in-line and distal and proximal occlusion settings are not accessible. For more information on CCAs, see “Clinical Care Areas” on page 138.

The following features are selectable on the Options screen:

- **Power Prime**—moves a selected amount of fluid through the administration set tubing
- **Deliver at End of Infusion**—displays Deliver at End of Infusion drop-down list
- **KVO Rate**—displays KVO Rate Numeric Entry keypad
- **Delayed Start**—delay an infusion for up to 12 hours
- **Standby**—place the infuser in Standby mode for up to 24 hours until **Start Program** is pressed
- **Alarm Options—**alarm options include:
  - Distal Occlusion
  - Proximal Occlusion
  - Infusion Complete Callback
  - Air-in-line
  - Nearing End of Infusion

Device Level Features

Device level features are accessed via buttons across the bottom of the infuser touchscreen (Figure 9).

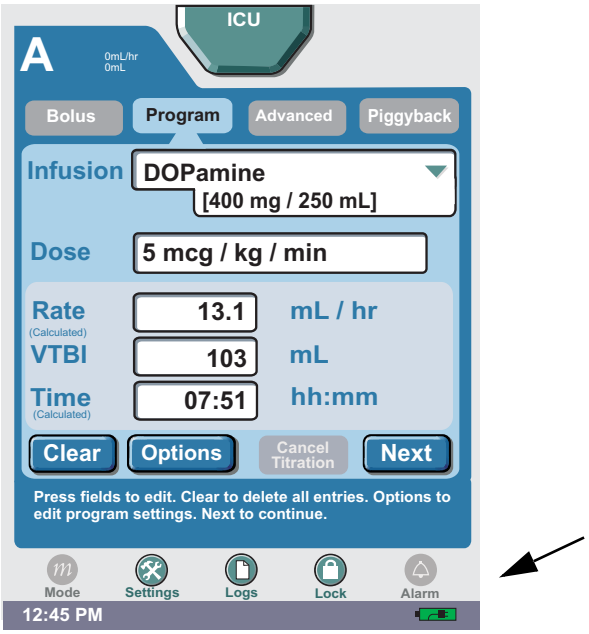


Figure 9: Device Level Features

Device level buttons are used to access the following features:

- **Mode**—displays the Biomed Mode Passcode Entry screen—if not in Delivery Mode and no other device-level button is currently selected
- **Settings**—adjusts key press and alarm volumes, screen brightness, and time mode settings
- **Logs**—displays clinical logs including:
  - Program Totals
  - Shift Totals
  - Event Log
  - Alarm Log
  - Rule Set Alert Override Log
  - Current Program

For more information on Logs, refer to “Chapter 11: Stored Data” on page 137.

- **Lock**—displays the Program Lock/Unlock Passcode Entry screen

Settings

Use the settings button to access and adjust the infuser settings:

- **Sound Volume**—keypress volume and alarm volume
- **Screen**—screen brightness

- **Time mode**—time mode settings

To access sound volume settings:

1. From any infuser screen, locate and press **Settings** to display the Settings screen.

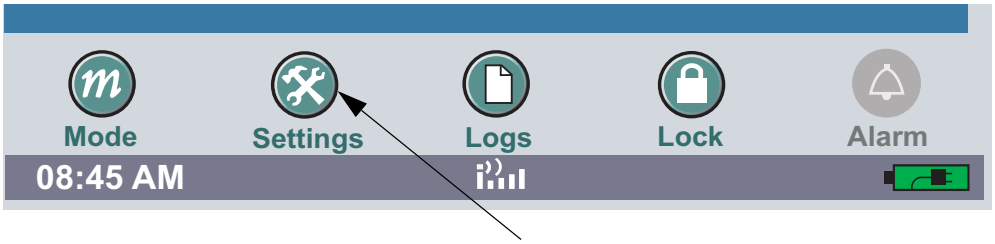


Figure 10: Settings button

2. On the **Settings** screen, press **Sound Volume** to display the Settings Sound Volume screen.

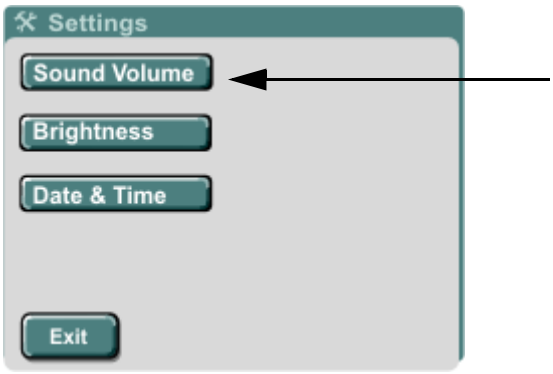


Figure 11: Settings Screen

3. On the **Settings Sound Volume** screen, press the **Key Press Volume** and **Alarm Volume** buttons to adjust volume levels. The infuser sounds an audible tone for the selected volume level.

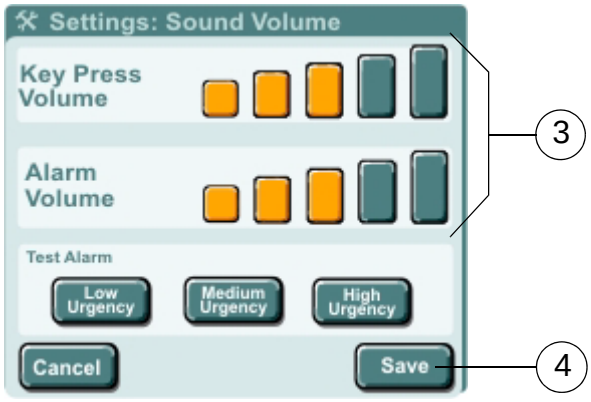


Figure 12: Settings Sound Volume Screen

Note: *Key Press Volume sets the volume for both valid and invalid key presses.*

4. When finished adjusting settings on the **Settings Sound Volume** screen, press **Save**.

Other Settings Sound Volume screen buttons do the following:
- Low Urgency—press button for audible Low Urgency alarm tone at the current level

- Medium Urgency—press button for audible Medium Urgency alarm tone at the current level
- High Urgency—press button for audible High Urgency alarm tone at the current level

5. **Cancel**—displays the Settings Menu screen without saving changes
6. On the **Settings** screen, press **Exit** to return to the screen from which the Settings screen was accessed.

Note: *If no keys are pressed for two consecutive minutes, the Settings Sound Volume screen reverts to the screen from which the Settings button was pressed.*

To access brightness adjustment settings:

1. From any infuser screen, locate and press **Settings** to display the Settings screen.
2. On the **Settings** screen, press **Screen** to display the Settings Brightness screen. See Figure 11: "Settings Screen" on page 27.
3. On the **Settings Brightness** screen, adjust the screen brightness by pressing **Brightness** buttons. The infuser increases or decreases screen brightness to the selected level.
4. When finished adjusting settings on the **Settings Brightness** screen, press **Save**. Press **Cancel** to return to the Settings Menu screen without saving changes.

Figure 13: Settings Brightness Screen

Note: *If no keys are pressed for two consecutive minutes, the Settings Brightness screen reverts to the previous screen.*

5. On the **Settings** screen, press **Exit** to return to the previous screen.

Date and Time Settings

Access the time mode settings to specify 12-hour or 24-hour clock formats.

To set the time mode:

1. From any infuser screen, locate and press **Settings** to display the Settings screen.
2. On the **Settings** screen, press **Date & Time** to display the Settings Date & Time screen. See Figure 11: "Settings Screen" on page 27.

3. Press the **Time Format** field to specify 12-hour or 24-hour clock formats. Select the desired time format button on the drop-down list.

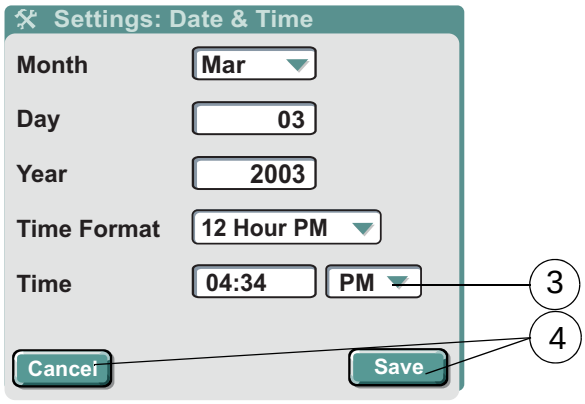


Figure 14: Settings Date & Time Screen

4. When finished adjusting settings on the **Settings Date & Time** screen, press **Save**. Press **Cancel** to return to the Settings Menu screen without saving changes.

5. On the **Settings** screen, press **Exit** to return to the screen from which the Settings screen was accessed.

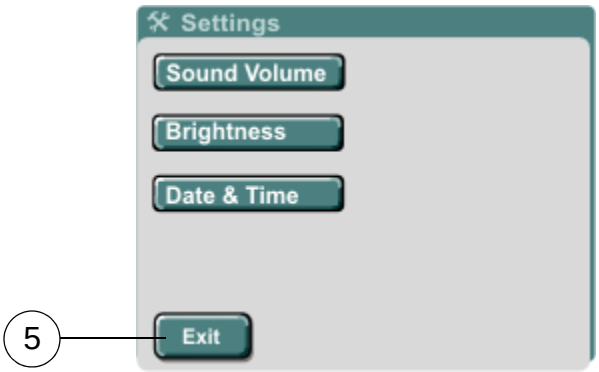


Figure 15: Settings Screen

Note: *If no keys are pressed for two consecutive minutes, the Settings Date & Time screen reverts to the previous screen.*

Program Lock

An active program lock prohibits changes to any touchscreen field or parameter related to a therapy program including:

- programming buttons
- date and time settings

The program lock is always available unless the Cleaning Lock is active, a system message is active, or the infuser is in an active alarm state.

You cannot start or stop a therapy while the program lock is active using on-screen buttons. However, pressing **Stop Program** on the touchscreen or pressing **Emergency Stop** does not deactivate the program lock.

With the program lock active, you can access the following infuser features:

- screen navigation
- brightness and volume control
- logs and program parameters
- touchscreen Stop Program button
- Emergency Stop button
- view shift/program totals

With the Program Lock active, program-related fields and features related are not available. To access program-related fields and features you must first de-activate the Program Lock.

To activate the program lock:

1. From any infuser screen, locate and press **Lock**. The Enter Code dialog box displays.

Figure 16: Accessing the Program Lock

2. On the **Enter Code** dialog box, use the touchscreen keypad to key in a valid passcode, and then press **Enter**. Press **Cancel** to return to the previous screen.

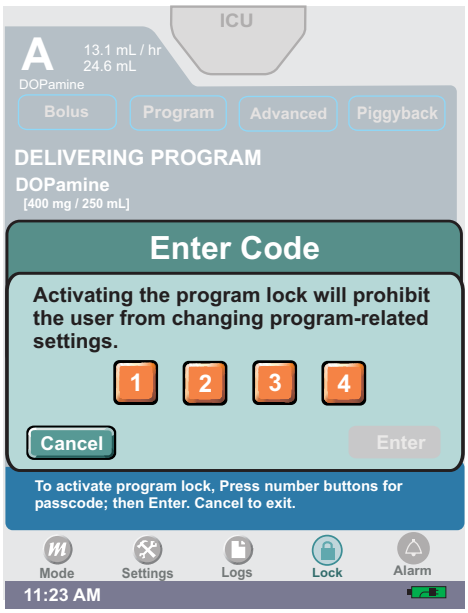


Figure 17: Enter Code Dialog Box (Activating)

Note: *See authorized facility personnel for password.*

3. The screen from which the program lock was accessed displays with the program lock activated.

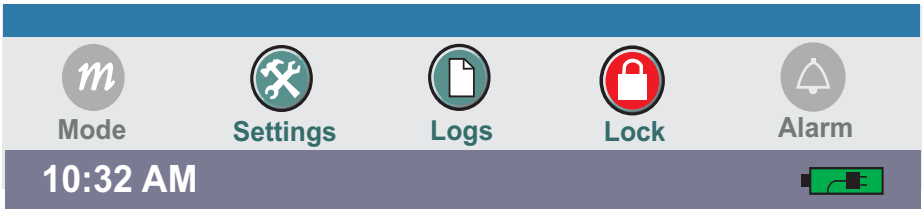


Figure 18: Program Lock Activated

Note: *Entering an invalid passcode three consecutive times activates the Invalid Passcode system message for each attempt. Entering an invalid passcode a fourth time closes the Enter Code dialog box and displays the screen from which the program lock was accessed without activating the program lock.*

To deactivate the program lock:

1. On the touchscreen, locate and press **Lock**. The Enter Code dialog box displays.

2. On the **Enter Code** dialog box, use the touchscreen keypad to key in a valid passcode, and then press **Enter**. Press **Cancel** to return to the previous screen.

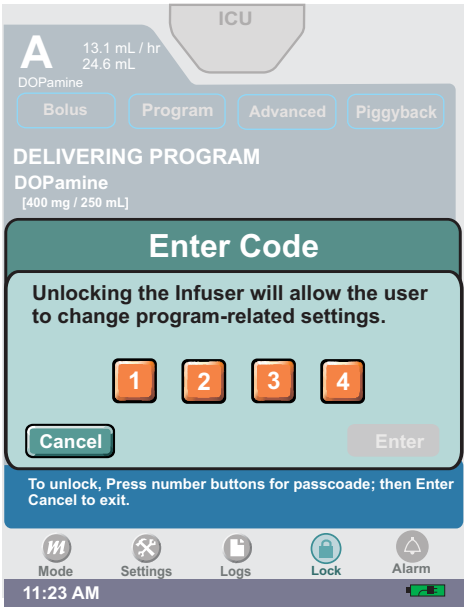


Figure 19: Enter Code Dialog Box (Deactivating)

3. The screen from which the program lock was accessed displays with the program lock deactivated.

Figure 20: Program Lock Deactivated

Note: *Entering an invalid passcode three consecutive times activates the Invalid Passcode system message for each attempt. Entering an invalid passcode a fourth time closes the Enter Code dialog box and displays the screen from which the program lock was accessed without deactivating the program lock.*

Chapter 3: Infuser Operations

Chapter 3 describes the Infuser Basic Operations of the SYMBIQ™ Infusion System. This includes a discussion of power on, power down, programming a therapy, and delivering a therapy.

Infuser Operations Overview

The infuser has four basic operations divided into four segments: power on, program, deliver and stop.

- **Power**—to power on and power off the infuser
- **Programming**—to program the following therapies:
  - Bolus (Bolus)
  - Program (Basic therapy)
  - Advanced (Multistep and Intermittent)
  - Piggyback
- **Delivery**—to observe and monitor the progress of an infusion
- **Stop**—to stop the infuser

Power Modes

The Power mode is used to power on and power off the infuser.

AC Power

When attached to an AC mains power source, the SYMBIQ™ Infusion System uses AC power regardless of the level of available battery power. Use AC power whenever possible; the battery is intended as a backup or emergency power source. However, if the quality of the earth grounding source is in doubt, use battery power.

Before initial use, connect the infuser to AC power for at least four hours to ensure the battery is fully charged. Whenever connected to an AC power source, the infuser charges the battery.

Procedure to power on the infuser:

1. Ensure sure the infuser is securely attached to an I.V. pole and is connected to an AC power source.

2. Press and hold the **On/Off** button for one second, and then release.

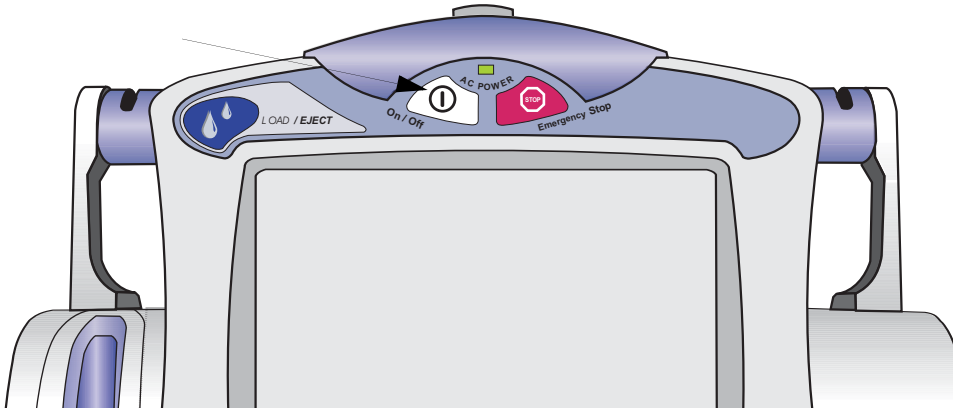


Figure 21: On/Off Button

3. At power on, the Startup screen displays during diagnostic self-tests.

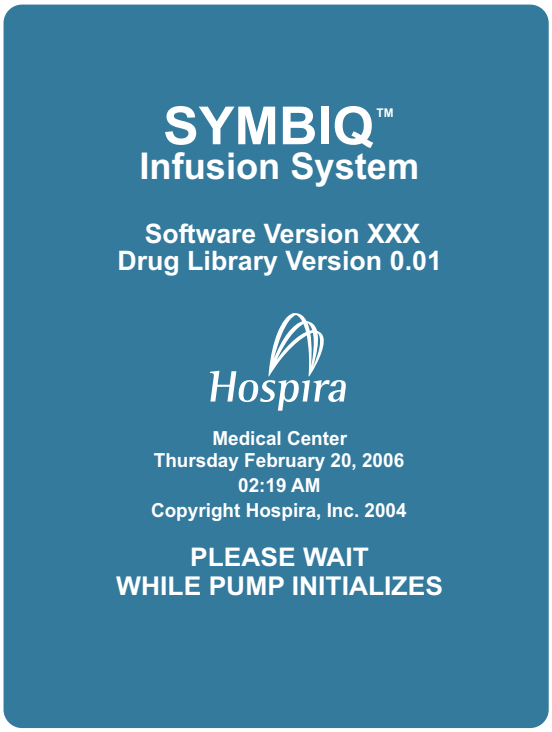


Figure 22: Infuser Startup Screen

The diagnostic self-tests take about ten seconds to complete. Once diagnostic self-tests complete, a startup screen displays indicating whether any program, patient, distal and proximal occlusion, or air-in-line sensitivity settings were saved.

CAUTION: DO NOT place the SYMBIQ™ Infuser in service if it fails any of the diagnostic self-tests.

If the infuser has been powered off for less than five hours, previous patient information, program information, and infuser settings are retained. The New Patient dialog box displays over the Startup screen (Figure 23).

Selecting **No** in the New Patient field and pressing **Continue** retains stored patient and program information and displays the Startup screen. The Startup screen shows infuser status and provides access to view both patient and program information. Selecting **Yes** in the New Patient field and pressing **Continue** clears stored patient and program information and displays a blank Patient Information screen.

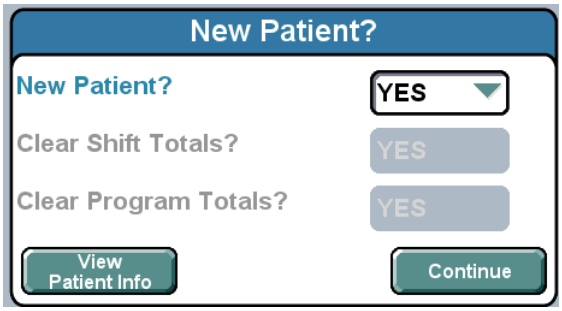


Figure 23: New Patient Dialog Box

When a Drug Library contains one or more Clinical Care Areas (CCAs), you must specify a CCA at power on. When prompted, either confirm the current CCA or select a new one.

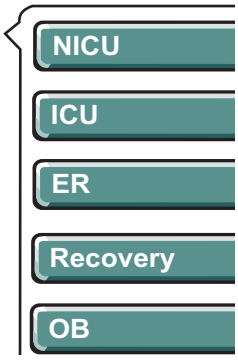


Figure 24: Specifying a CCA

Channel LEDs

During diagnostic self-tests, the channel LEDs located just above the cassette carriage (Figure 25) flash green once, yellow once, and red once.

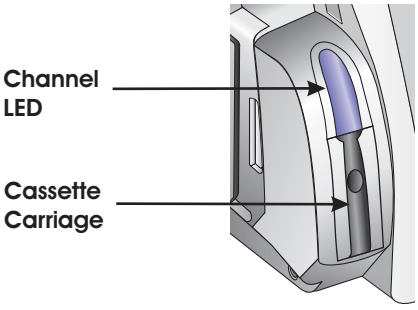


Figure 25: Channel LED Location

Table 7 outlines channel LED color and the conditions under which the channel LEDs illuminate. During an alarm state, the color and flashing characteristics of both the channel LED and channel alarm tab are the same.

Table 7: Channel LED Color and Conditions

Channel LED Color	Conditions
Solid Green	While in Delivery mode and delivery has not been interrupted.
Flashing Green	When the cassette carriage is either opening, closing, or open, and during power priming.
Solid Yellow	During a Low urgency condition.
Flashing Yellow	During a Medium urgency condition.
Flashing Red	During any High urgency condition.
Solid Red	During a latched High alarm condition. A latched High urgency condition notifies the user of a previous alarm condition—which no longer exists—until the alarm is cleared by the user.

Battery Power

The rechargeable battery provides up to four hours of power at 100 mL/hr.

The non-volatile battery life is sufficient to retain program parameters, delivery totals, patient information (ID, weight, and height), clinician information, and logs.

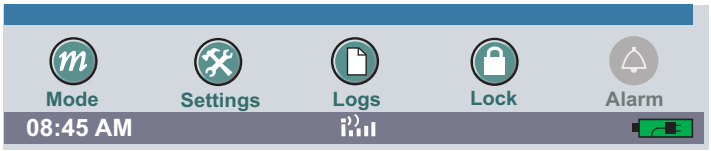
CAUTION: Before use, ensure the infuser has a functional battery installed. Use of a properly installed and functional battery helps ensure the infuser operates properly.

The battery indicator icon is located in the lower right corner of the touchscreen. Table 8 shows battery indictor icons and the associated battery life, power level, and alarm state for each indicator icon. When the infuser is attached to an AC power source, the battery indicator icon shows the current battery charge level.

Table 8: Battery Indicator Icons

Battery Indicator Icon	Power Level	Alarm State
Battery Indicators when Infuser is operating on battery power		
	Full (76%-100%):	None
	Three-quarters (51%-75%)	None

Table 8: Battery Indicator Icons (Continued)

Battery Indicator Icon	Power Level	Alarm State
	Half (50%) *Note: This indicator displays when the battery is at half capacity—until the activation of the 30-min. Low battery Alarm (see next indicator) when the Infuser is operating on battery power:*	
	30 minutes	Low
	15 minutes	Medium
	5 minutes	High
	Empty	
Charging Battery Indicators when Infuser is operating on AC Power		
	AC power (infuser using AC power only, battery fully charged)	None
	Charging, capacity at 75% or greater but less than 100% capacity	None
	Charging, capacity at 25% or greater but less than 75% capacity	None
	Charging, capacity less than 25%	None
	Displays when the Infuser is powered on and no battery above the Depleted Battery threshold is detected:	
Battery icon location:	 ***Note:*** *Icon is located in the lower right corner of the device level area.*	

If the Low Battery alarm activates, the battery has only enough charge remaining to continue the current delivery rate for approximately 30 minutes. Immediately connect the infuser to AC power.

Note: *As long as a low battery condition exists, the Low Battery alarm cannot be cleared, but it may be minimized by pressing the alarm tab.*

Do not use a SYMBIQ™ Infusion System without a properly functioning battery installed. If no battery is detected at power on, the No Battery system message activates (Figure 26). In this case, remove the infuser from service until a properly functioning battery can be installed.

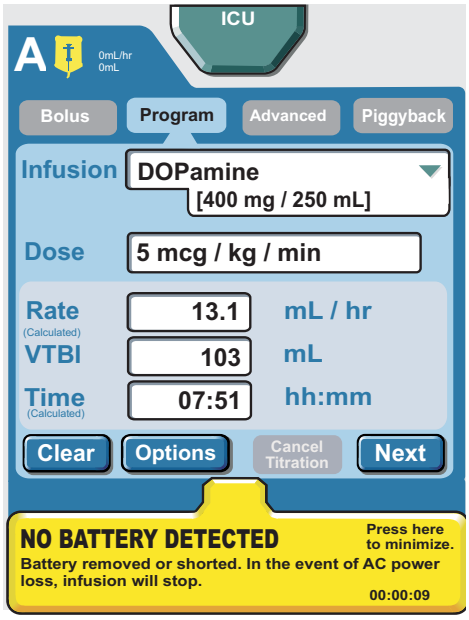


Figure 26: No Battery System Message

CAUTION: Before use, ensure the infuser has a functional battery installed. Use of a properly installed and functional battery helps ensure the infuser operates properly.

A/C Power LED

The A/C power LED (Figure 27) is located on the front of the infuser just above the **On/Off** and **Emergency Stop** buttons. When using AC power with a fully-charged battery, the A/C power LED is lit green. When using A/C power with the battery charging, the A/C power LED flashes. When using battery power only, the power LED is off.

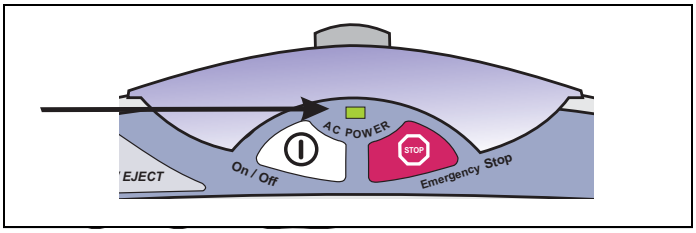


Figure 27: Location of A/C Power LED

Touchscreen Visibility

If no keystrokes or button presses are made for a CCA-defined period of time (the default is two minutes), the infuser enters Power Saving mode. Power Saving mode is marked by an 80% reduction in touchscreen brightness.

Turning touchscreen away from direct sunlight improves visibility. Any infuser alarm state or pressing the touchscreen restores brightness to normal levels.

Power Off

When power is removed from the infuser, it enters Power Down mode. During a normal power down, all critical data is saved to the appropriate logs, the current program and all user-configured settings are retained, and, if open, the cassette carriage closes. All alarm sensitivity settings are also retained at power down.

To power down the infuser:

1. Ensure all infusions are stopped and the infuser is not in Delivery mode.
2. Press and hold the **On/Off** button for one second, and then release. The infuser powers off. See Figure 21: "On/Off Button" on page 34.

   Note: *If the infuser is powered off before you complete or confirm a program, the partially entered program is cleared the next time the infuser is powered on.*

Programming Mode

Programming mode is used to program infusion therapies. Therapies and supplemental deliveries available in programming mode include:

- Bolus
- Program (Basic)
- Advanced
- Piggyback

Program (Basic)

From this screen, you can access these features:

- **Patient Information Button**—displays patient information
- **Channel Tab**—displays the channel screen.
- **Bolus**—displays the Bolus program screen (Bolus button unavailable until a primary infusion is programmed on the active channel)
- **Advanced**—displays the Advanced Therapy Selection screen
- **Piggyback**—displays the Piggyback program screen (Piggyback button unavailable until a primary infusion is programmed on the active channel)
- **Clear**—if not in Delivery mode, removes all values entered on a programming screen
- **Options**—displays the Options screen
- **Cancel Titration** (if accessing the Basic Program screen to titrate the therapy) cancels all changes made to the program
- **Next**—Displays the Confirm Program screen available only when all required program parameters have been entered,
- **Device Level Buttons**—displays device level features.

Delivery Mode

Two types of screens display during Delivery mode—Near Viewing and Far Viewing. A Near Viewing Delivery screen is shown in Figure 28.

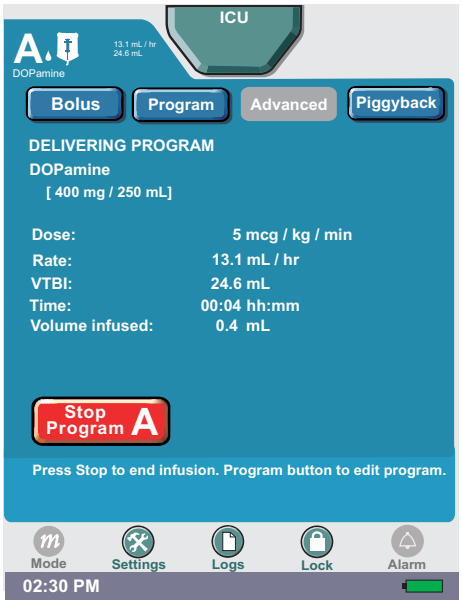


Figure 28: Near Viewing Delivery Screen

The Near Viewing Delivery screen displays medication name (if enabled in the selected CCA), concentration, dose rate (if applicable), time remaining, VTBI, volume infused, infusion status for advanced therapies, and alarm name for the highest priority alarm if in an alarm state. On the Near Viewing Delivery screen, both VTBI and Volume Infused values display with one decimal place for values up to 100.

Note: *The Near Viewing Delivery Screen shall only display the Dose label and value if a dose is programmed.*

The Far Viewing screen (Figure 29) is designed to have the rate and VTBI readable from a distance of 15 feet. In addition, the pump displays medication name (if enabled in the selected CCA), concentration, and, if in an alarm state, the alarm name for the highest priority alarm. On

the Far Viewing Delivery screen, VTBI values display with one decimal place for values less than 100. For values greater than or equal to 100, values display with no decimal.

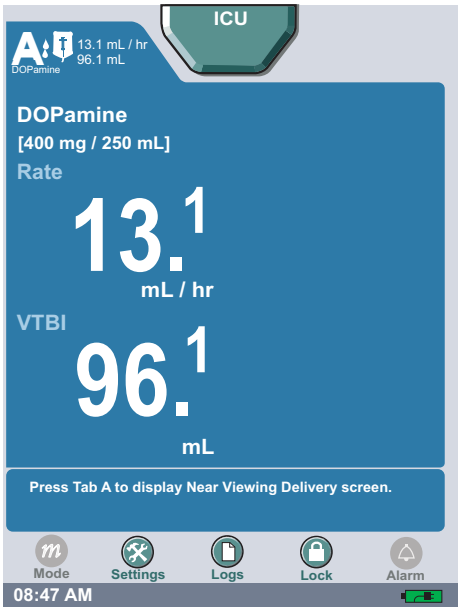


Figure 29: Far Viewing Delivery Screen

Pressing **LOAD/EJECT** while in delivery mode does not eject the cassette; to eject a cassette, the infuser must be in Stop mode.

Once the infuser completes a programmed therapy, the End of Infusion alarm activates. The infuser transitions to a KVO (Keep Vein Open) delivery rate. Pending on programming, the infuser continues to deliver at programmed rate or transitions to KVO.

Stop Mode

The SYMBIQ™ Infusion System stops in one of five ways:

1. Pressing **Stop Program** on the touchscreen.
2. Pressing **Emergency Stop** on the front of the infuser stops all channels.

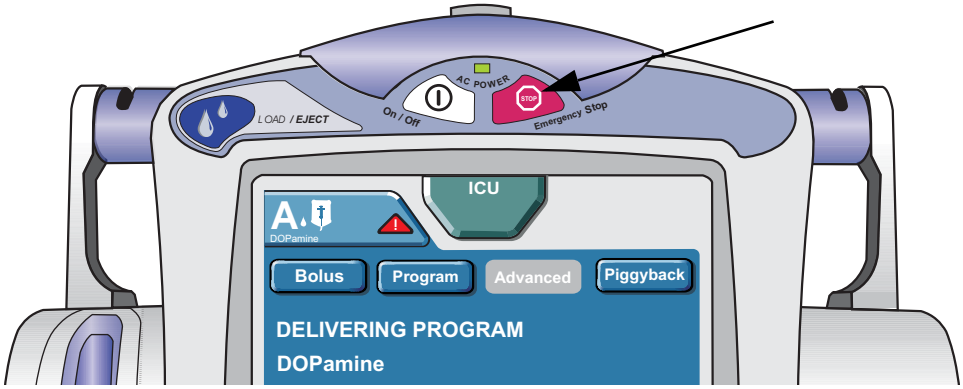


Figure 30: Emergency Stop Button

3. An active alarm state will stop the infusion.

4. When a programmed VTBI completes and there is no KVO.

5. A bolus is complete and Stop Infusion has been selected on the bolus setup screen.

When a delivery is manually stopped (by pressing **Stop Program**) and the VTBI has not completely delivered, the Stop mode screen shows **STOPPED** across the banner as in Figure 31.

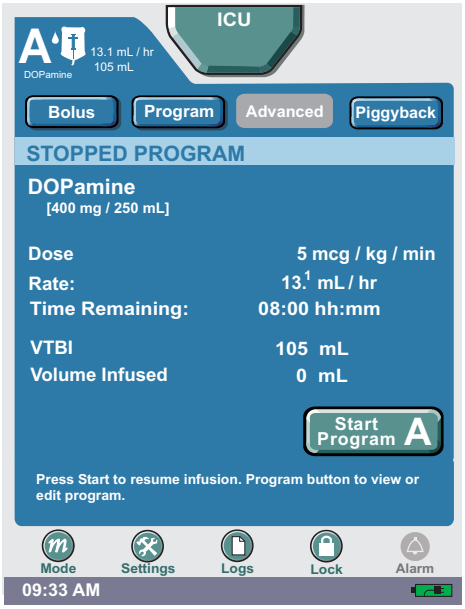


Figure 31: Stop Mode Screen—Manual Stop in a Basic Program

When a therapy is stopped due to an alarm state including Emergency Stop, the Stop mode screen shown in Figure 32 displays

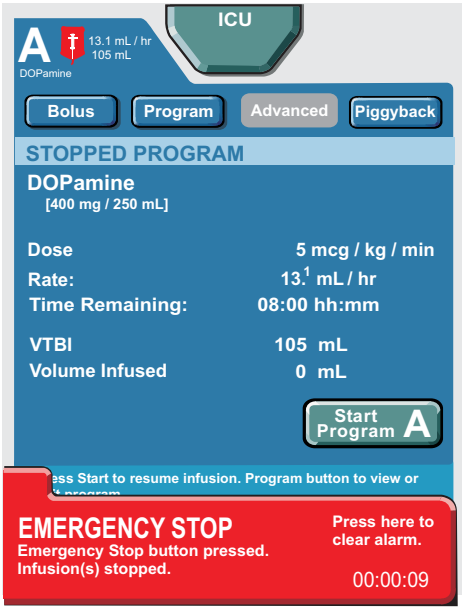


Figure 32: Stop Mode Screen—Alarm State

While in Stop mode, you can:

- access the current programmed therapy
- access the lock/unlock functionality
- access programming mode to start a new program or change a current program
- start a programmed therapy or continue the current therapy
- select a new CCA
- update patient information

Note: *The Stop Mode Screen shall only display the Dose label and value if a dose is programmed.*

To stop the infuser using the touchscreen Stop Program button:

1. If the Far Viewing screen is active, touch it to display the Near Viewing screen.
2. On the **Near Viewing** screen, locate and press **Stop Program**.

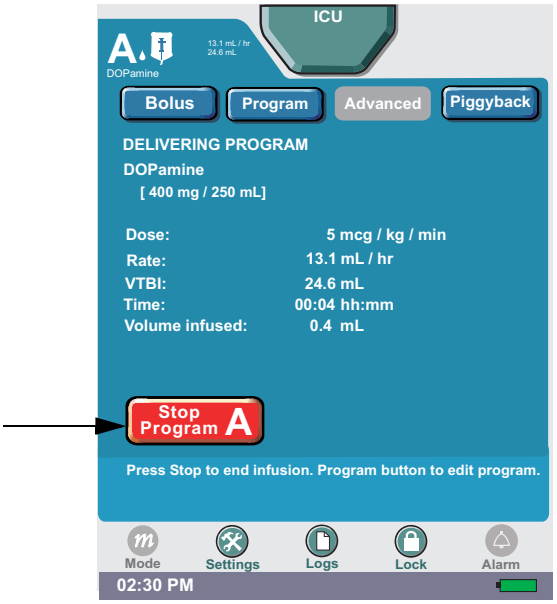


Figure 33: Stop Program Button

3. To resume infusing, press **Start Program**.

To stop the infuser using the Emergency Stop button:

Note: *In an Emergency, use **Emergency Stop** to stop all channels. Otherwise, use **Stop Program** on the touchscreen to stop individual channels.*

1. Locate the **Emergency Stop** button on the front of the infuser. See Figure 30: "Emergency Stop Button" on page 42.
2. Press and release **Emergency Stop**. All active programs stop infusing and a high urgency alarm sounds.

3. Press **Start Program** on the touchscreen to resume the therapy.

Figure 34: Touchscreen Start Program Button

General Programming Guidelines

If the infuser is powered off before you complete or confirm a program, the partially entered program is cleared the next time the infuser is powered on. If a change is made to a program during an infusion but is neither canceled nor confirmed, a Callback alarm activates.

Calculated Values

Calculated values for a given field display on the touchscreen as shown in Figure 35.

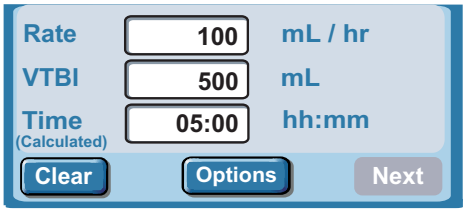


Figure 35: Calculated Field Value

A calculated value that either exceeds the current maximum medication delivery rate or the maximum volumetric rate for the selected CCA activates a warning message.

Invalid Value Handling

Entering a value in a field that exceeds a value limit defined for that field the following occurs:

- activates the Invalid Entry system message
- sounds the Invalid Key tone
- replaces the value with three dashes (“---”)

There are two types of value limits for a field; maximum field length and maximum field amount.

For fields with defined maximum lengths, entering a four-character value in a field with a three-character limit exceeds the length limit for that field and activates the Invalid Entry system message.

Entering an amount that exceeds the defined limit activates the Invalid Entry system message (Figure 36).

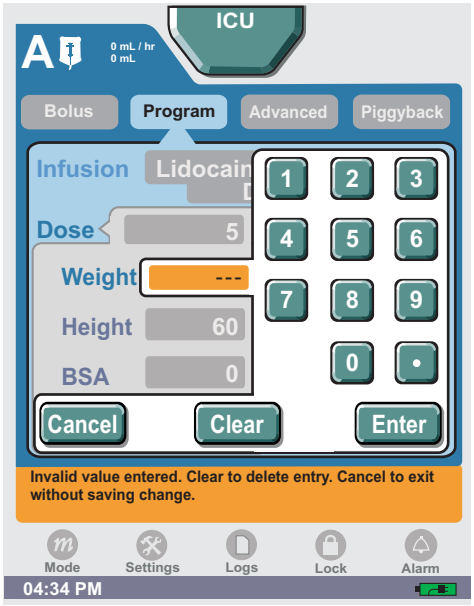


Figure 36: Invalid Entry System Message

A field must contain a valid value before exiting. To remove the Invalid Entry system message, press **Clear**. Pressing **Clear** also replaces the three dashes (“---”) in a field with field default values; either “0” for non-time fields or “--:--” for time fields.

Value Rounding

For calculated values, the infuser truncates the value one digit beyond what the screen can display, and then rounds off the value. If the therapy is based on either a calculated value or a rounded value, the infuser delivers the therapy at the stored value. For example, if the stored value is in hundredths but displays in tenths, the infusion rate has a granularity of hundredths. Stored information does not change. If a stored value contains more decimal places than can be displayed, the Infuser rounds the displayed value. The infuser uses the rounding rules based on one digit beyond what can be displayed.

Note: *Calculated interim values retain all decimal places supported by the infuser’s hardware.*

Biomed Mode

Biomed mode is used to perform calibrations and diagnostic tests on the SYMBIQ™ Infusion System. In Biomed mode, a trained and qualified biomedical technician can restore the infuser's default factory settings and default drug library, configure device settings, and clear all logs and viewable data.

CAUTION: Only qualified biomedical technicians should access the infuser's Biomed mode.

Note: *Biomed mode is password protected.*

NOTES: