

REF

7001101 Mini-Prime, Approx. 150 ml priming volume 7001102 Low Volume, Approx. 180 ml priming volume DESCRIPTION

- 1. Crystalloid Line
- 2. Mini-Prime Blood Line, 3/16 in. (4.8 mm) X 6 ft. (183cm)
- 3. Low Volume Blood Line, ¼ in. (6.35mm) X 6 ft. (183cm)
- 4. Blood:crystalloid pump cassette
- 5. Heat exchanger with integral bubble trap
- 6. Low Volume Extension line, (Sold Separately)
- 7. Vent line
- 8. Arrest Agent Cassette (50 ml)
- 9. Additive Cassette (50ml)
- Tubing Adapter: 3/16 in (4.76mm) to ¼ in. (6.35mm), with attached ¼ in (6.35mm) tubing segment (Mini-Prime only).

INDICATION FOR USE

The MPS Mini-Prime delivery set and the Low Volume delivery set are only for use with the Quest MPS and MPS2 consoles for delivery of cardioplegia solutions to the heart during cardiopulmonary bypass surgery.

CONTRAINDICATION

This device is designed and warranted for use with the Quest MPS and MPS2 myocardial protection systems only. Use with other systems is contraindicated. This device is not designed, sold or intended for use except as indicated.

WARNINGS and CAUTIONS

- Read and understand the information in these instructions prior to operating the MPS 2 console. See Operators Manual for a complete list of Warnings and Cautions. The attending clinician is solely responsible for the setup and use of the MPS 2 console / perfusion system.
- For use with Quest's MPS system only. All claims void if used separately.
- Examine ALL sterile packages carefully before opening to confirm the packages' integrity and verify that the expiration date has not passed. The devices are supplied in a sterile, single use package and are non-pyrogenic. DO NOT USE a damaged or opened package or if the expiration date has passed.
- Observe aseptic technique with all tubing connections. Do not over-tighten rigid connections. Use proper sterile technique when passing lines into the sterile field.
- Do not re-sterilize. These products are intended for single use only, do not reuse.
- Dispose of this device according to hospital procedure for contaminated material.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Observe all additional warnings and cautions contained in the following Instructions for use. The main door must be closed to operate the MPS console.
- Do not use force to open or close doors. Forcing a door closed may indicate an improperly installed or overfilled cassette.



INSTRUCTIONS FOR USE

INSTALLING THE HEAT EXCHANGER

1. Turn the MPS 2 console power switch off and then on to ensure the pump pistons are retracted. Open the red inner door to reveal the blood to crystalloid pumping chambers.



DO NOT LOAD cassettes if the pistons are in the forward position (convex). Cycle the power to reset the pistons. If the pistons do not retract, **STOP THE MPS 2 CONSOLE** and call for service. If the pump piston is not fully retracted, there may be an unintentional bolus delivery during the onset of flow.

- 2. Verify the heat exchanger latch is in the unlocked position (rotate counter-clockwise).
- 3. Using aseptic technique, open the packaging of the MPS delivery set and pass the extension line to the table.
- 4. With one hand, grasp the top of the heat exchanger bubble trap with delivery set tubing and remove the entire set except the arrest agent cassette from the tray.
- 5. To ensure proper installation when installing the heat exchanger, allow the blood : crystalloid cassette to lay inside the red inner door and verify that the blue locator ball is on the right side of the cassette. The locator ball ensures that the blood and crystalloid lines are positioned correctly. The red inner door will not close if the ball is on the left side.
- 6. While allowing the blood : crystalloid cassette to lay inside the red door, lift the heat exchanger vent line and position the heat exchanger on the mounting block.

- 7. Applying a constant pressure, seat the heat exchanger on the heat exchanger mounting block. Turn the latch clockwise to lock and seal the heat exchanger on the MPS 2 console and automatically engage and connect the water ports and the pressure, level and temperature sensors.
- Route the vent line through the vent valve on the back of the heat exchanger. To open the valve, press down and hold open while inserting line.

INSTALLING BLOOD :CRYSTALLOID CASSETTES

- 1. Secure the blood : crystalloid cassette by firmly seating cassette over the 13 mounting pins. Carefully close and latch the red inner door.
- Route the blood and crystalloid source lines through the mounting grooves on the left and right side of the console. Ensure that the blood and crystalloid lines do not twist and occlude the cassette inlet channels.



Avoid OPERATOR INJURY, make sure that all fingers are clear from the doors' edges before closing the inner and outer doors of the MPS 2 console.



Close the outer door before using the MPS 2 console. The outer door must be closed to operate the MPS 2 console. HOWEVER, do not use force to open or close the doors. Forcing a door closed may indicate an improperly installed or overfilled cassette.

CONNECTING MPS DELIVERY SET TO EXTRACORPOREAL CIRCUIT

Instructions for using the Mini Prime 3/16 in (4.8mm) Adapter (item 10) to connect the blood inlet line to a ¼ in (6.35mm) cardioplegia source::

- 1. Remove the separately packaged tubing adapter from the MPS tray. Use sterile technique to assemble.
- Uncoil the blood line. The length can be adjusted by cutting it to desired length. Priming volume is reduced by 5ml per foot of tubing removed.
- Push the blood line over the tubing adapter's barb. Sterile alcohol wipes may be used to assist the assembly.



During priming, ensure that the adapter connection is not leaking before patient use.

- 4. For either delivery sets, proceed as follows:
- Connect the delivery set / blood line to the cardioplegia outlet on the blood oxygenator.
- Uncoil the delivery set crystalloid line and clamp the line near the cassette.
- 7. Insert the I.V. spike into the crystalloid bag.



The crystalloid bag must be hanging at least 3 feet (1 meter) above the pumping chamber to ensure adequate pressure to fill the pump.

8. Route the cardioplegia delivery line through the air in line detector and antegrade delivery valve (A). To open the valve, press down and hold while inserting the line.



FULLY INSERT the tubing through the air in line detector for proper MPS 2 console operation.

- 9. Uncoil the vent line and attach the luer connector to the non-pressurized luer port of the cardiotomy reservoir.
- 10. Following catheterization, connect the extension line to the delivery catheter.

INSTALLING AND FILLING MPS ARREST AGENT CASSETTES

- DO NOT OVERFILL OR OVERPRESSURIZE arrest agent or additive cassettes. The normal maximum cassette capacity is 50 ml. Overfilling the arrest agent or additive cassettes before or after installation in the console can cause unintentional bolus delivery during the onset of flow and possible system malfunction. If the MPS 2 console senses that the cassette contains 50 ml or more of additive agent, the "ADDITIVE (or ARREST) IS OVERFULL Remove some fluid/CONTINUE" screen displays. Do not ignore this message and overfill the cassette.
- 1. Open the yellow arrest agent inner door on the right side of the console to expose the pump chamber.
- 2. Secure the arrest agent cassette over the mounting pins and route the infusion line up through the channel directly above the pump chamber.
- 3. Remove the arrest agent Luer cap from the heat exchanger and connect the normally closed checkvalve.
- 4. Carefully close the yellow inner door.
- 5. Fill a syringe with no more than 50 ml of arrest agent solution with a concentration of 2 mEq/ml.
- WARNING DO NOT USE an arrest agent (potassium chloride) concentration other than 2 mEqml. The MPS 2 console is designed to operate with an arrest agent concentration of 2 mEq/ml. Using an arrest agent concentration other than 2 mEq/ml will result in inaccurate delivery concentrations and may cause patient injury.
- 6. Connect the filled syringe to the yellow stopcock and turn the handle to the fill position.
- 7. Hold the syringe in an upright position and withdraw the plunger to ensure the cassette is free of air. Carefully fill the cassette by pressing the plunger.
- 8. Disconnect the syringe from the Luer port on the stopcock and turn the stopcock to the delivery position.



INSTALLING AND FILLING MPS ADDITIVE CASSETTES

- 1. Open the green additive inner door to expose the pump chamber. If the inner door cannot be opened, the piston is in the forward position. Cycle the power to reset the pistons. If the pistons do not retract, discontinue use of the console and call for service.
- 2. Secure the additive cassette over the mounting pins and route the infusion line up through the channel directly above the pump chamber (Figure 6-7).
- Remove the additive Luer port cover from the heat exchanger and connect the normally closed checkvalve.
- 4. Carefully close the green inner door.
- 5. Fill a syringe with no more than 45 ml of additive solution mixed to the proper concentration.
- 6. Connect the filled syringe to the green stopcock and turn the handle to the fill position
- Hold the syringe in an upright position and withdraw the plunger to ensure the cassette is free of air. Carefully fill the cassette by pressing the plunger.
- Disconnect the syringe from the Luer port on the stopcock and turn the stopcock to the delivery position.



During the Console setup procedure, set the desired additive delivery concentration between 0 and 50 ml/L of cardioplegia solution.

PRIMING THE SYSTEM

Case parameters must be set before the system can be primed. Refer to the MPS console Operations Manual for setup procedures.

Prior to delivering cardioplegia, the water circulation system is purged in parallel with the automated delivery set priming to remove all air from the system. The MPS 2 unit must successfully complete the purge and prime prior to cardioplegia delivery.

When the operator presses the **<START PRIME>** arrow key, the MPS 2 console performs two functions simultaneously: purging the water circulation system and priming the cardioplegia delivery set.

During the purge cycle, the internal warm water reservoir is filled. Water is circulated between the cold warm circuits.

During the automatic priming sequence, the MPS 2 console circulates just enough cardioplegia solution to clear the delivery line of air bubbles. At the completion of the auto priming sequence, the manual recirculation mode screen displays.

During the automated priming process the following operations are performed:

- 1. Crystalloid and blood line priming
- 2. Blood : crystalloid cassette priming
- 3. Heat exchanger priming
- 4. Level sensor function verification
- 5. Air in line sensor function verification
- 6. Blood-side heat exchanger leak test
- 7. Arrest agent pump volume check and diagnostics
- 8. Additive pump volume check and diagnostics
- 9. Water-side heat exchanger leak test



Prior to priming the system, an MPS 2 delivery set and hypothermic reservoir must be installed.

Prior to starting the Priming process, the arrest agent and additive cassettes must be filled. If a cassette is not filled, a message will be displayed giving the user the option to disable the specific pump or fill the cassette. If the user chooses to fill the cassette, the user is instructed to open and close the outer door to resume the priming process.



During the water purge process, visually examine the heat exchanger and water lines for leaks. A leak in the heat exchanger may cause biological contamination of the cardioplegia delivery fluid and blood hemolysis. If a leak is observed, DO NOT USE the delivery set. Promptly return the delivery set to Quest Medical, Inc



Confirm proper installation of delivery set and assessories. Observe tubing paths and check for kinks, twists and proper placement and routing. **Fill the arrest agent and additive cassette before** priming.

For further information, refer to the MPS Operators Manual.

The MPS Console and MPS sterile disposables are covered under one or more of the following U.S. patents: 5,385,540 5,573,502 5,588,816 5,638,737 5,645,531 5,899,873. Also covered by pending U.S. and International Patents and patent applications. MPS is a registered trademark of Quest Medical, Inc.

