



HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM

DEVICE SETUP GUIDE IN THE OPERATING ROOM USING THE SYSTEM MONITOR



HeartMate 3™ Left Ventricular Assist System (LVAS)

DEVICE PREPARATION SETUP GUIDE

EQUIPMENT NEEDED FOR PUMP PREP

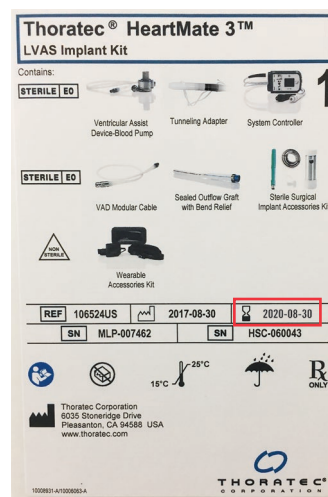
Power Module with patient cable and System Monitor with software version 7.32 or higher are set up and powered on.

Two fully charged 14-volt lithium-ion batteries and a pair of battery clips are readily available.

Primary and backup HeartMate 3™ LVAS implant kits are required. Verify the expiration dates are valid. If not, obtain another implant kit.

The following items will be needed from the implant kit:

- Pump and implant accessories
- System Controller
- Modular Cable with cap
- Outflow Graft with bend relief



SET UP THE TABLE FOR PUMP PREP

Perform pump preparation in a low traffic area of the operating room (OR) suite. Place the following items onto the sterile field:

- 1- to 1.5-liter graduated pitcher
- 2 basins — separate basin with antibiotic solution
- Bulb syringe
- 3 blue towels
- 3–4 lap sponges
- Powder-free finger cot
- Hemostat



SET UP THE SYSTEM CONTROLLER

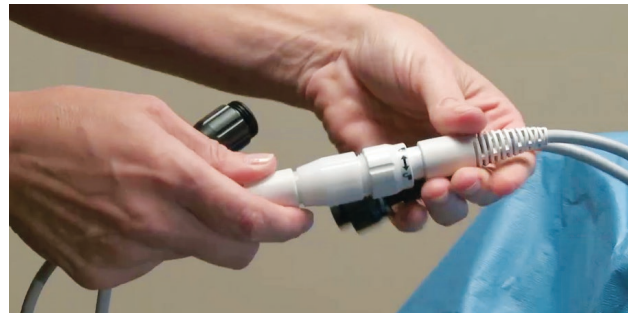
1. Open the HeartMate 3™ LVAS System Controller box, remove the emergency backup battery box (non-sterile) and set it aside. It will be inserted into the controller at the end of the case once the sterile field has been taken down.



2. Open the System Controller outer tray and pass the sterile inner tray off to a sterile person. Position the System Controller on the table with the white and black power cables draped slightly off the table. Secure them to the table drape with a hemostat to ensure most of the length of the power cables remains in the sterile field.

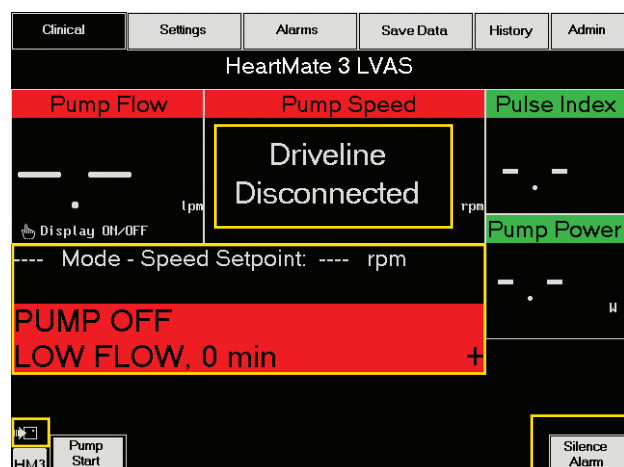


3. Next, a non-sterile individual should connect the System Controller power cables to the Power Module patient cable – white to white and black to black.



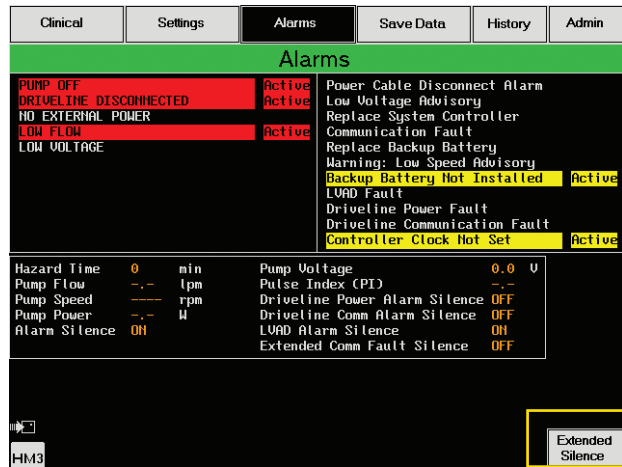
4. Silence the hazard alarms by pressing the Silence Alarm button on the System Monitor Clinical screen. **Do not silence the alarms using the System Controller.**

5. Verify that: - - - - Mode - Speed Setpoint: - - - - rpm, Driveline Disconnected, PUMP OFF and LOW FLOW are displayed on the Clinical screen. There should also be a flashing communication icon and HM3 in the lower-left corner.

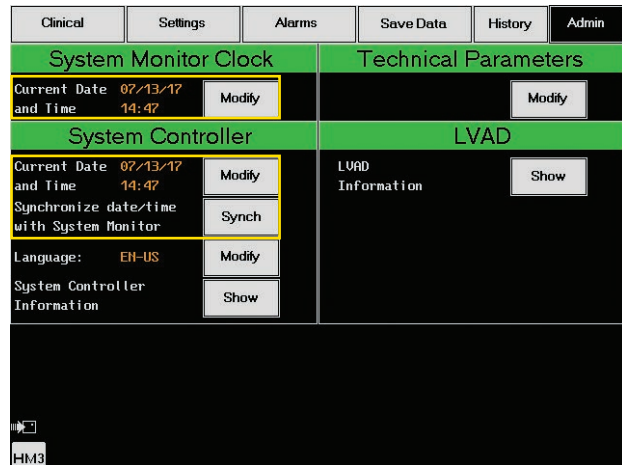


SET UP THE SYSTEM CONTROLLER (CONTINUED)

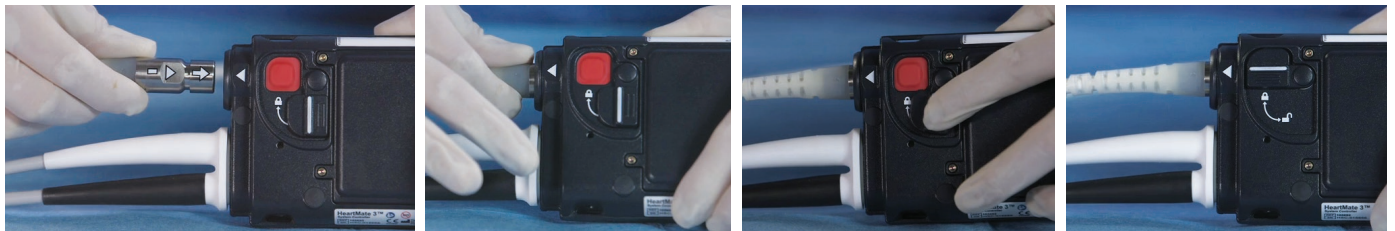
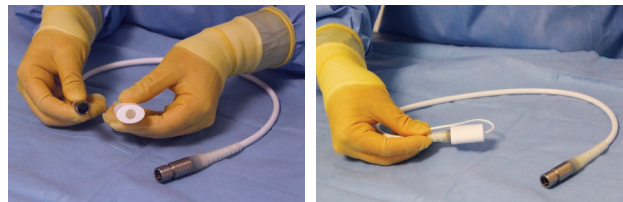
6. Access the Alarms screen and activate the Extended Silence to silence all alarms for four hours.
7. Confirm PUMP OFF, DRIVELINE DISCONNECTED, LOW FLOW, Backup Battery Not Installed and Controller Clock Not Set alarms are active.



8. Access the Admin screen to confirm the System Monitor date and time are correct. Then set the System Controller date and time.

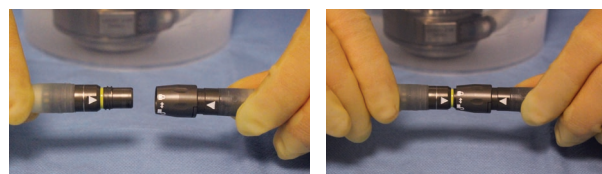
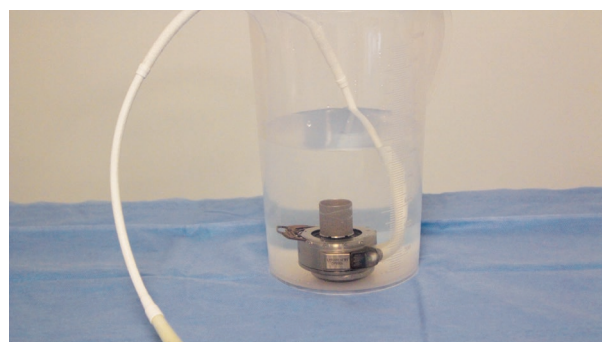
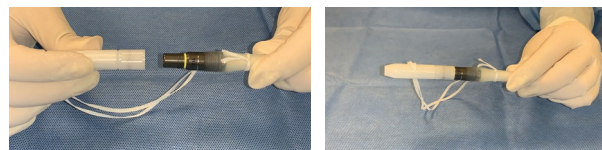
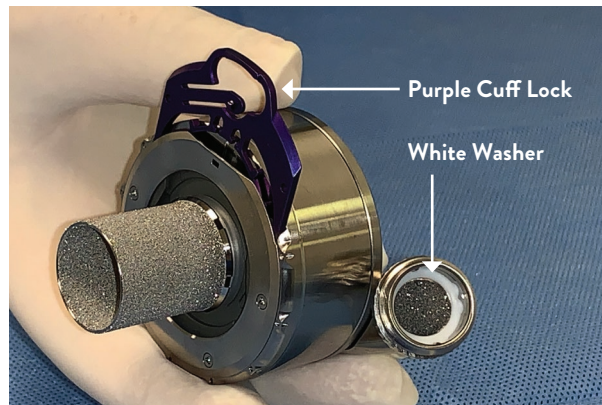
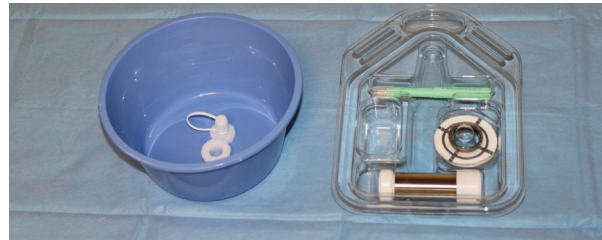
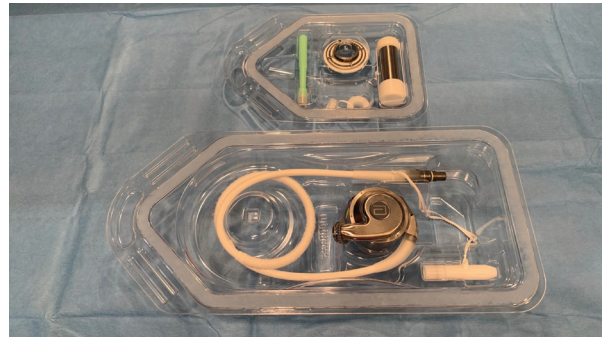


9. Pass the Modular Cable up to the sterile field.
10. Push the Modular Cable cap onto the end of the Modular Cable. Press firmly until the connector bottom is inside the cap. The cap protects the connector from fluids and debris.
11. Connect the Modular Cable to the System Controller by matching arrow to arrow. Gently tug on the end of the connector to ensure the cable is fully engaged. Then close the safety lock on the back of the System Controller.



PREPARING THE PUMP

1. Inspect the graduated pitcher for any debris. Add 1 liter of injectable sterile normal saline to the pitcher; verify no debris is present after adding the saline.
2. Open the HeartMate 3™ LVAS pump box and pass the pump and implant accessories onto the sterile field.
3. Remove the thread protector set and place it in a safe place on the table. Pass the remaining items up to the instrument table.
4. Remove the pump from the sterile package. Verify a white washer is present in the pump outlet and ensure the purple cuff lock is fully extended.
5. Screw the tunneling adapter onto the pump cable connector until the yellow line is covered.
6. Submerge the pump in the graduated pitcher of sterile normal saline, ensuring that the pump is fully submerged and free of air and debris. The inlet cannula should be pointing up. Gently shake the pump to remove any entrapped air. Dry your gloves.
7. Remove the tunneling adapter and Modular Cable cap. Connect the two cables by aligning the triangles, applying firm force to engage the cables and rotating the locking nut until the clicking sound stops and the yellow line is no longer visible. Keep the connection dry.

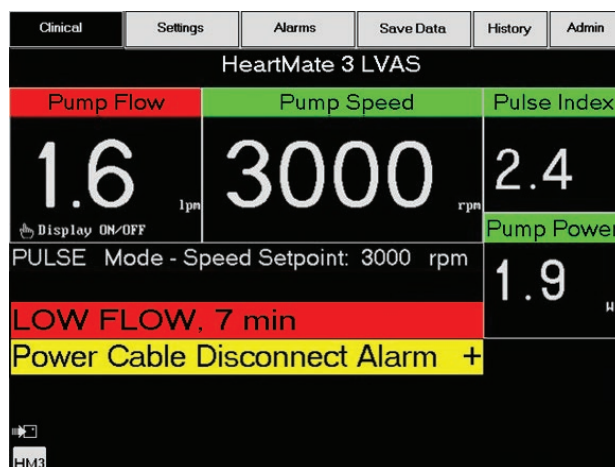
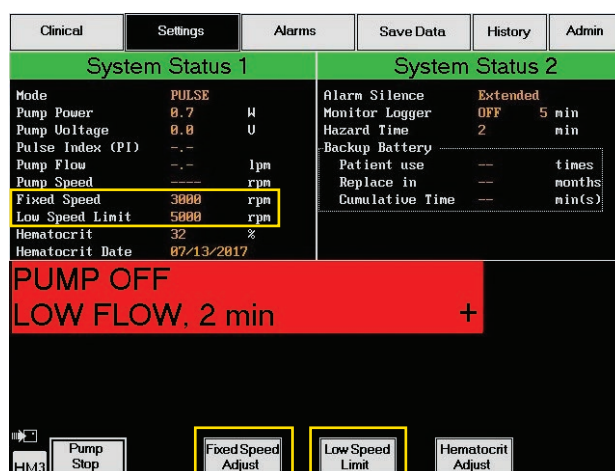
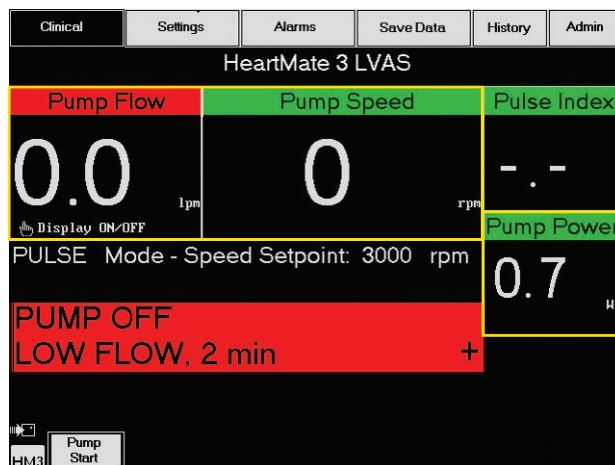


PREPARING THE PUMP (CONTINUED)

8. On the System Monitor, verify the Driveline Disconnected alarm has cleared, Pump Flow displays 0.0, Pump Speed displays zero and Pump Power displays 0.7–1 watt as the rotor levitates.

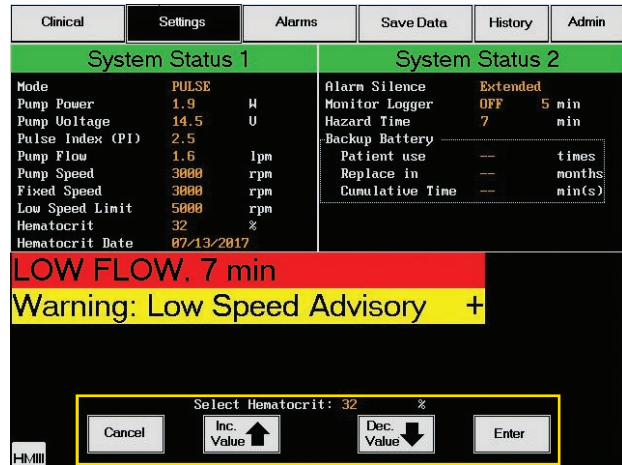
9. Access the Settings screen and verify the fixed speed is set at 3,000 rpm and low speed limit at 5,000 rpm. If not, press the appropriate speed adjust button, enter the correct speed value and confirm the change.

10. Start the pump by depressing the Pump Start button, and confirm that the pump is running. On average, it takes 3–4 seconds for the pump to start, but may take as long as 10 seconds. **Do NOT allow air or debris to enter the pump and NEVER run the pump dry. If the pump has been dropped or run dry, do not use it.** Obtain another pump.

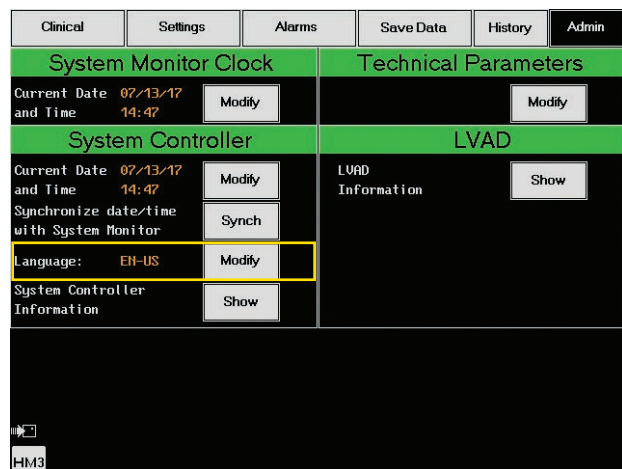


PREPARING THE PUMP (CONTINUED)

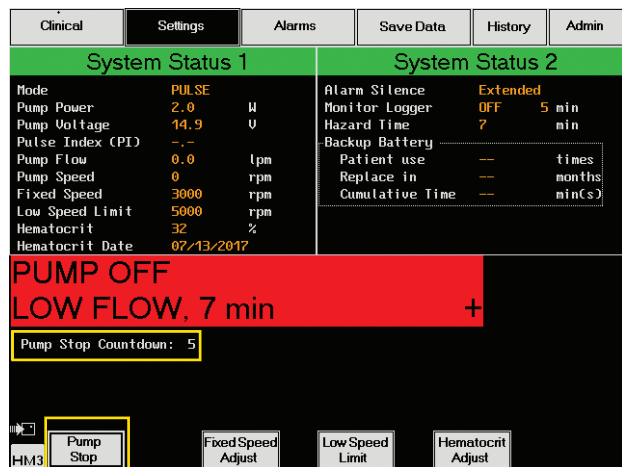
- Enter the patient's hematocrit value. It can only be entered when the pump is connected to the controller. It is used to increase the accuracy of the flow estimator. Default value is 32%.



- To change the language on the System Controller, go to the Admin screen, press the language modify button and select the desired language.



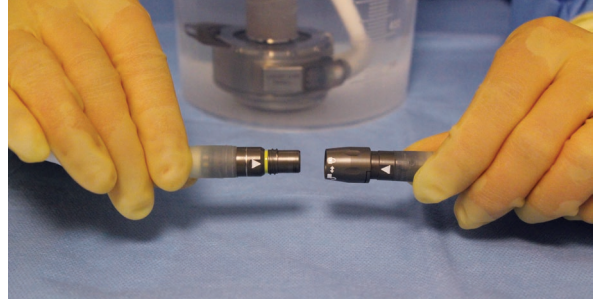
- On the Settings screen, depress and hold the Pump Stop button for 10 seconds until the countdown is complete. The button will change to Pump Start. Confirm the pump has stopped.



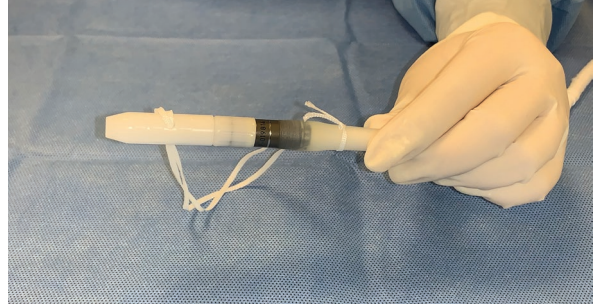
PREPARING THE PUMP (CONTINUED)

14. Perform the following steps to disconnect the pump from the controller.

a. Disconnect the pump cable from the Modular Cable.



b. Attach the tunneling adapter to the pump cable connector.



c. Place the Modular Connector Cap onto the Modular Cable.

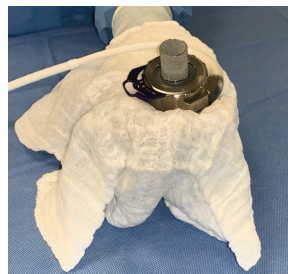
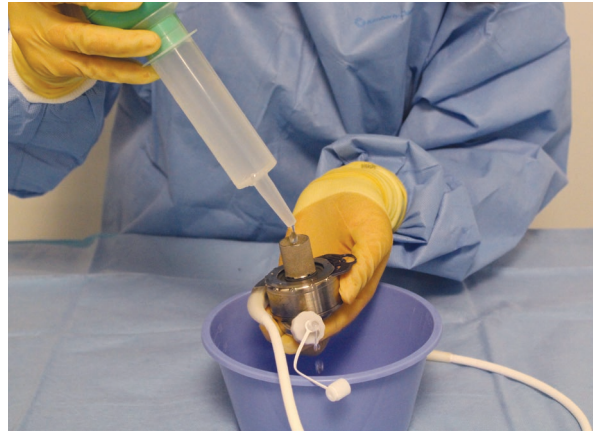


15. Secure the System Controller and attached Modular Cable so both maintain sterility — leave the controller connected to the Power Module patient cable.



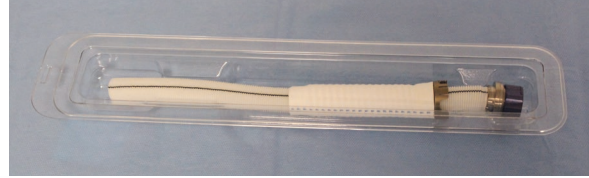
ASSEMBLING THE PUMP

1. Remove the pump from the graduated pitcher. Place the thread protector on the pump outlet and open the luer-lock cap.
2. Using a bulb syringe, fill the pump with sterile normal saline and vent air via the luer-lock cap.
3. Close the luer-lock cap once the air bubbles have cleared. Add additional saline to fill the inlet, then cover the pump inlet cannula with a powder-free sterile glove tip or finger cot.
4. Wrap the pump and velour portion of pump cable in antibiotic-soaked laps. Massage the solution into the velour part of the cable. Do not place the distal end of the pump cable in the solution. Place it in a sterile basin and cover with a sterile towel. Keep the pump cable end dry.



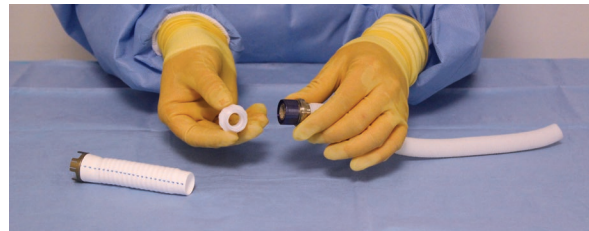
PREPARING THE OUTFLOW GRAFT

1. Open the sealed Outflow Graft foil pouch and outer tray. Pass the inner sterile tray onto the sterile field.

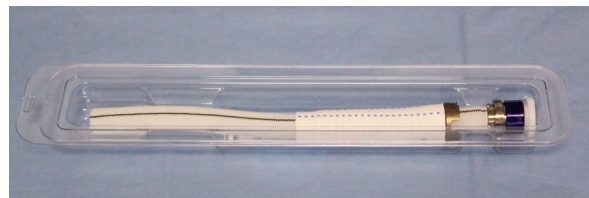


2. Remove the bend relief and inspect the exterior and interior of the graft. If debris is present on the interior of the graft, remove it. Then attach the open-ended thread protector onto the screw ring.

Note: The graft does not need to be rinsed prior to use. If it is, it must remain wet to prevent the sealant from drying out.



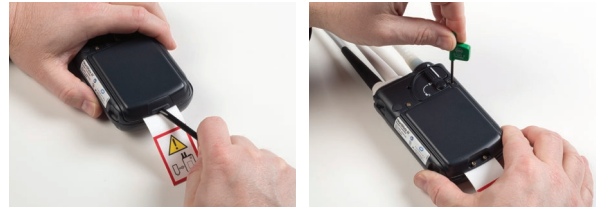
3. Slide the bend relief over the sealed Outflow Graft with the metal end toward the screw ring, keeping it disengaged to facilitate de-airing. Place the graft into its original container and pass it up to the main table.



PRIOR TO LEAVING THE OR

1. Once the sterile field has been taken down, with the patient still connected to the System Monitor, **INSTALL** the backup battery inside the System Controller.

a. Use the lever to remove the screw cover of the battery compartment and the screwdriver to loosen all four screws (they are threaded in and will not fall out).



b. Remove the battery from the box. **Do not remove the rubber protection** around the battery.



c. Align the arrow on the battery with the arrow on the ribbon cable and insert it into the battery socket. Confirm the ribbon is secure.



Note: A green, yellow or red light may appear on the battery.

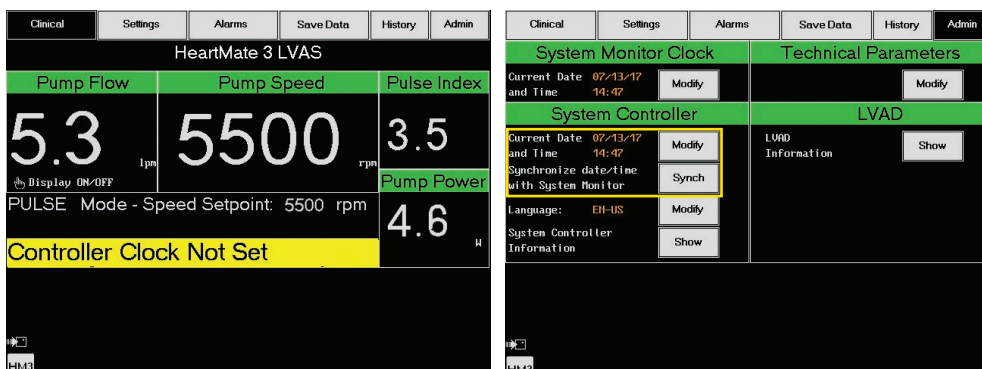
d. Lay the battery flat in the compartment and replace the battery cover and screw cover.



e. Confirm the Backup Battery Not Installed alarm clears from the controller.

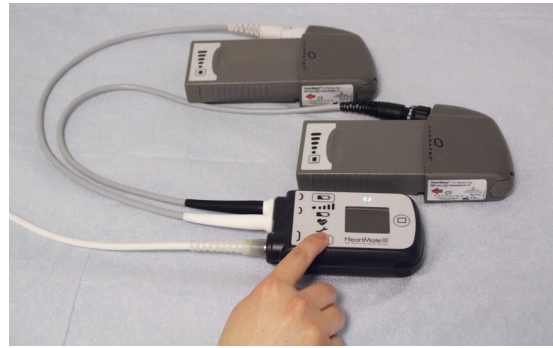


f. If the Controller Clock Not Set advisory alarm is active on the System Monitor after inserting the backup battery, access the Admin screen and sync or enter the System Controller date and time.

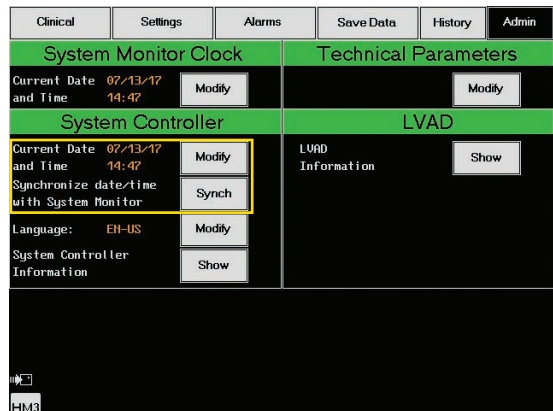


PRIOR TO LEAVING THE OR (CONTINUED)

2. Place the patient onto 14-volt lithium-ion batteries for transfer to the intensive care unit.
3. Inactivate the Extended Silence Alarm by pressing the Silence Alarm button on the System Controller.
4. Perform the following steps to set up the backup System Controller:
 - a. Insert the backup battery into the controller.



- b. Connect the controller to the Power Module and set the date and time in the controller using the System Monitor Admin screen. To change the language, press the modify button and select the desired language.



- c. Fully charge the backup battery using the Power Module or a pair of 14-volt lithium-ion batteries.



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Rx Only

Important Safety Information

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

HeartMate 3™ LVAS Indications: The HeartMate 3 Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g. as bridge to transplantation or myocardial recovery, or destination therapy) in patients with advanced refractory left ventricular heart failure.

HeartMate 3 LVAS Contraindications: The HeartMate 3 Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3 LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are listed here: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS) thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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