6.0 IMPLANT PROCEDURE

The patient is transported to a cardiovascular operating room (OR), prepped and anesthetized according to standard procedures. A sternotomy with extended midline abdominal incision should be made and cardiopulmonary bypass instituted.

CAUTION: The HeartMate II LVAS rechargeable batteries should be fully charged prior to beginning the implantation procedure to allow patient transfer following the procedure. The PBU will charge and test up to 6 Batteries in 8 hours or less depending on the initial state of discharge.

6.1 Setting Up and Initializing the System

During implant, the HeartMate II LVAS must be operated with the Power Base Unit (PBU) as shown in Figure 1.

1 Plug the large circular connector end of the PBU Cable into the rear of the PBU.

2 Plug the PBU into the AC mains and turn it on.

3 Connect the System Monitor to the back panel "Display" connector, and turn it on. When System Monitor initialization is complete, the flashing "NOT RECEIVING DATA" message will appear at the bottom of the screen, indicating that the System Monitor is not yet linked to the System Controller (Figure 3).

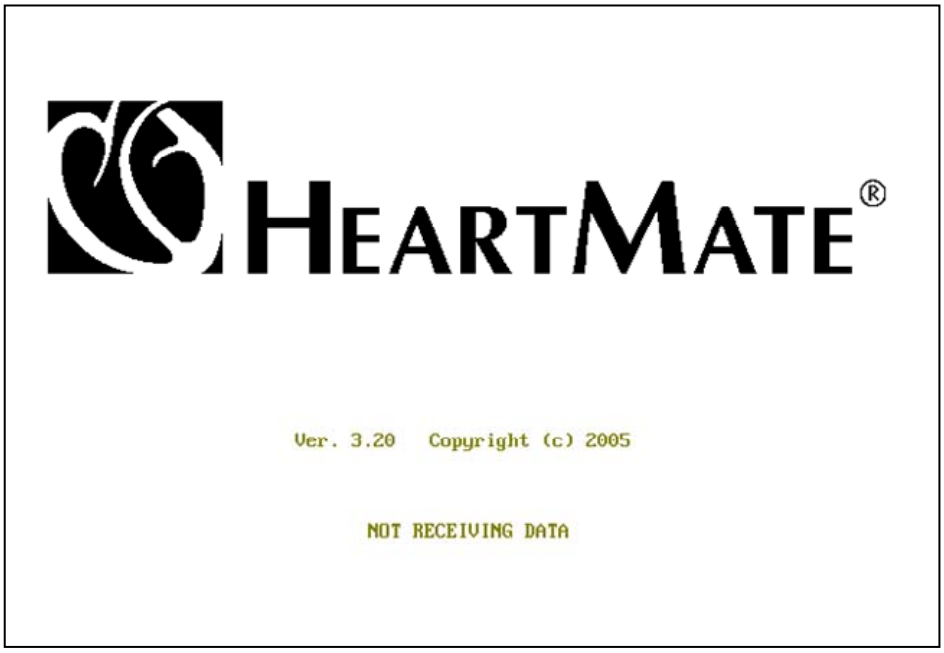

Figure 3: HeartMate II System Monitor not receiving data

4 Insert a minimum of 4 Batteries into the PBU charging slots. Ensure that at least 2 batteries are fully charged (green indicator light next to the battery slot is illuminated) so that they will be available for patient transport from the OR.

CAUTION:

- **Only use the THORATEC CORPORATION Power Base Unit (PBU) to charge batteries. Other battery chargers may damage the batteries.**
- **The power entry module on the rear panel of the PBU has been equipped with the proper fuse and set to the appropriate AC mains voltage for your location. Replacement of the fuse should be performed only by qualified service personnel.**

6.2 Initializing the System Controller & Preparing the Pump

1 Remove the System Controller from its sterile package. A battery module, to be installed in the System Controller at a later time, is included in the sterile package. See that this battery module is set aside in a safe place.

2 Pass the 2 System Controller cable ends out of the sterile field and connect them to the bifurcated ends of the PBU Cable, white-to-white, and black-to-black. Both the PBU and the System Controller will indicate a Hazard Alarm condition (signifying that the System Controller is powered but not connected to the HeartMate II LVAD). Reset these alarms with the Alarm Reset Switch (Figure 4) on the System Controller's user interface panel. This will silence the alarms for 2 minutes.

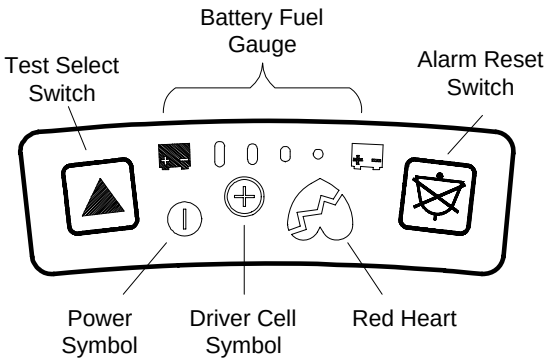

Figure 4: HeartMate II System Controller User Interface Panel

3 Verify that a flashing "HMII" icon is shown in the lower right hand corner of the System Monitor screen. This icon establishes that System Monitor is properly connected to the System Controller and the correct monitoring software is running. The System Monitor display will indicate FIXED mode and also display the "PUMP OFF" and "Pump Disconnected" messages in the clinical and system check screens (Figures 5 & 6).

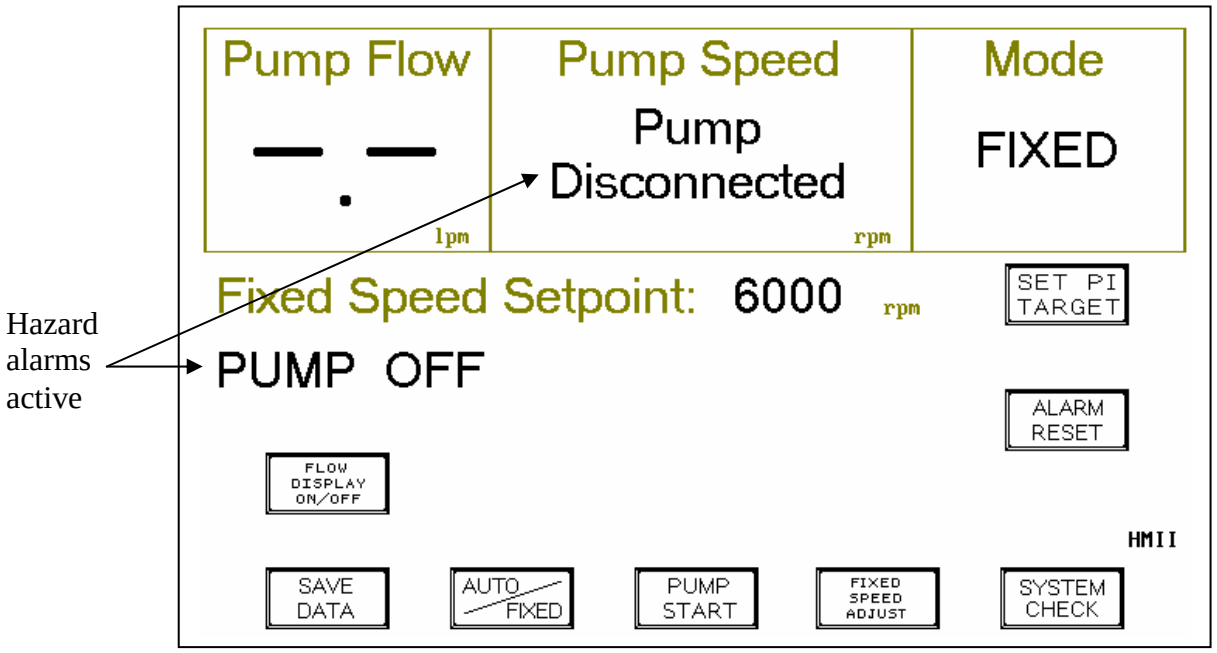

Figure 5: System Monitor Clinical Screen - detecting a hazard alarm condition

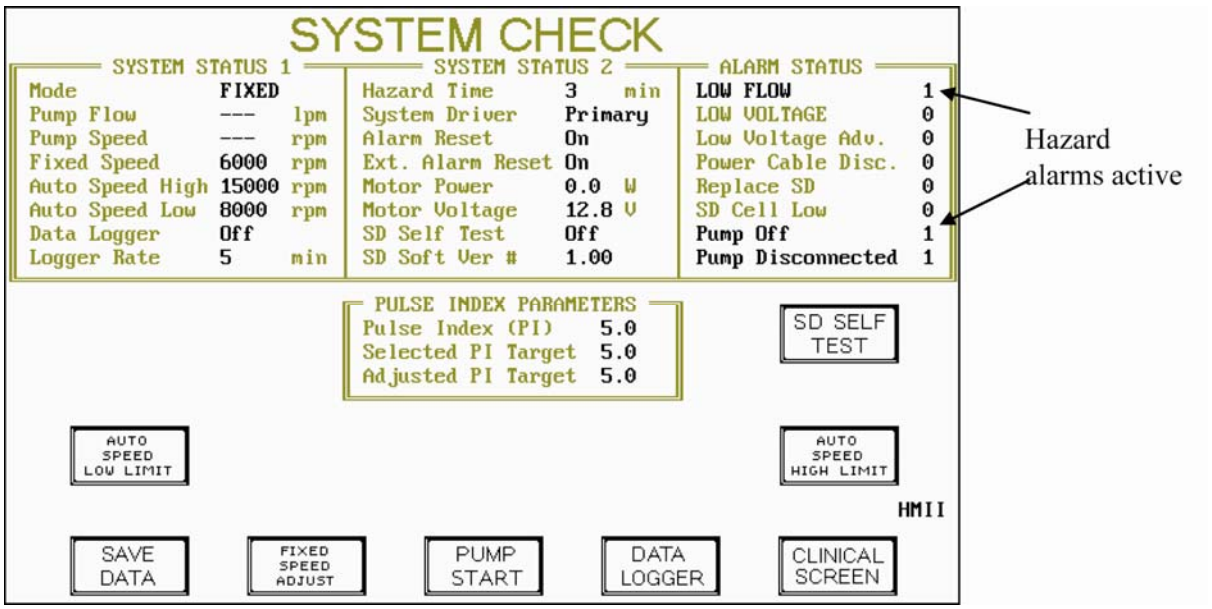

Figure 6: System Monitor System Check Screen - detecting a hazard alarm condition

4 Depress the “System Check” button in the System Monitor’s Clinical screen to activate the System Check screen.

5 **Turning off Alarms**: Depress the “Extended Alarm Reset” button in the System Check screen (Figure 6) to ensure that the alarms will not be sounded in the OR. The extended 4 hour alarm reset can be canceled by depressing the “Alarm Reset” button on the System Controller’s user interface panel (Figure 4). Switch back to the Clinical screen by depressing the “Clinical Screen” button in the System Check screen.

6 **Setting Fixed Mode**: The System Controller is shipped with FIXED mode active and with Fixed Speed Setpoint at 6,000 rpm. Verify these settings.

7 Review the System Check screen and verify that all commands are in place as shown on Figure 7. Ensure that the operating mode is set at "Fixed" (see System Status 1 window).

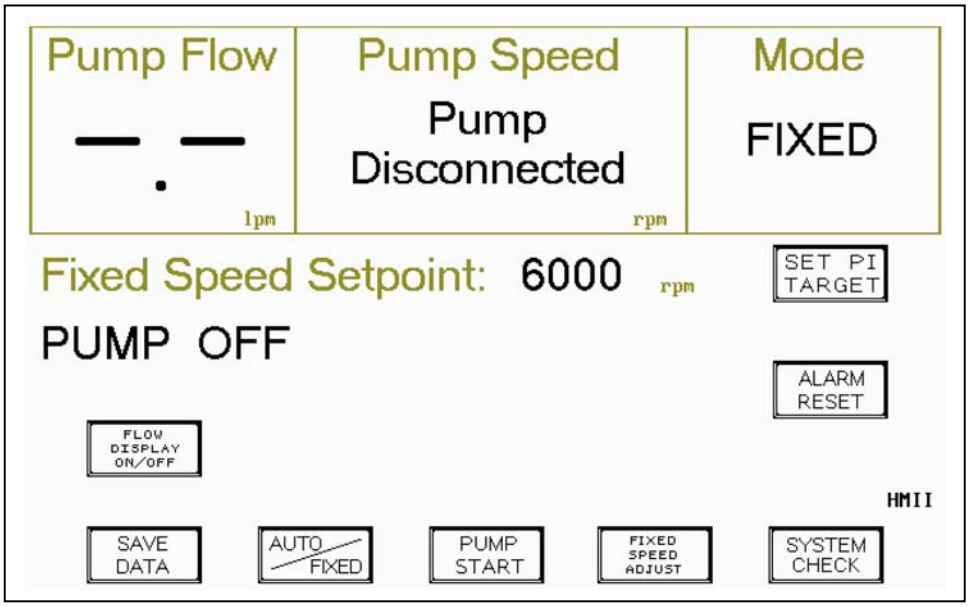

Figure 7: System in FIXED mode & Fixed Speed set at 6,000 RPM

8 If the mode is still set at "Auto," depress the Auto/Fixed button, then the "ENTER" button in the "Clinical Screen" (Auto/Fixed button is only available in the Clinical Screen).

9 Ensure that the "LOW FLOW", "PUMP OFF' and "PUMP DISCONNECTED" flags in the Alarm Status window are set to "1". If not, depress and hold the "PUMP STOP" button for minimum 10 seconds or until the "Pump Off" status is set to "1", and make sure the HeartMate II LVAD is disconnected from the System Controller.

10 Ensure that the time and date have been properly entered in the System Monitor as described in the HeartMate II Operating Manual.

11 System Controller initialization is now complete. The "PUMP DISCONNECTED" alarm message will remain until the System Controller is connected to the LVAD and the "PUMP OFF" alarm message will remain until the LVAD is turned on via the System Monitor "PUMP START" command.

CAUTION: When the pump is on, do not run the pump dry or allow air to enter, as this may damage the bearings.

12 To prepare the pump for implantation, remove the red caps and fully submerge the pump in a sterile basin with sterile saline for injection for a minimum of 5 minutes at 6,000 rpm in FIXED Mode.

13 To initiate HeartMate II pump operation, remove the tunneling bullet and attach the LVAD's percutaneous cable to the System Controller (Figure 13) by first aligning the marker on the cable's connector with the marker on the System Controller quick-disconnect receptacle. Then firmly advance the cable connector into the System Controller's quick-disconnect receptacle until you hear the quick-disconnect latch clamp onto the cable's connector. Test the connection by gently pulling back on the cable's connector. The "PUMP DISCONNECTED" message should disappear.

14 Initiate pump flow at 6,000 rpm by depressing the "PUMP START" button from the Clinical or System Check screens. The "PUMP OFF" message should disappear.

15 After 5 minutes has elapsed, STOP the pump by depressing and holding the "PUMP STOP" button on the System Monitor for a minimum of 10 seconds. The "PUMP OFF" message should appear. Disconnect the percutaneous connector and leave the pump in the sterile basin of sterile saline for injection.

16 Attach the bullet to the percutaneous connector. Ensure that the bullet is completely screwed down tight on to the connector end of this cable.

7.2 Pre-Clotting

The flexible inflow section of the Inflow Cannula and the Outflow Graft must be pre-clotted prior to use in order to facilitate hemostasis. The next section of these directions describes the pre-clotting steps. Care must be taken to ensure that pre-clotting occurs as indicated.

6.3.1 Outflow Graft

Coat the external surface of the outflow graft with whole blood or other standard approved pre-clotting agent(s) as follows:

1 Remove the Outflow Graft and Bend Relief from the tray.

2 Attach the open thread protector to the screw ring connector.

3 Using strict aseptic technique, remove the Bend Relief from the graft and reserve for use after pre-clotting procedure.

4 Coat the graft evenly with whole blood or other approved pre-clotting agent(s) in an emesis basin, drain, and place in a dry basin.

5 Heat the graft in an autoclave if necessary to coagulate the pre-clotting agent(s). Allow graft to cool after heating.

6 Inspect the interior of the graft and remove any debris or clots.

Figure 18: Insert Battery Module into System Controller Receptacle

7.7 Securing the Pump and Connections

Once the flow through the blood pump is satisfactory, assure that all inflow and outflow connections are dry and secure. Obtain hemostasis and close all wounds in the standard fashion.

7.8 Transferring Patient Out of the Operating Room

When it is time to transfer the patient out of the Operating Room, the HeartMate II LVAS system must be transferred from PBU power to battery power. To enable the transfer, insert a battery into each of the 2 battery clips. Unplug either of the System Controller Power Leads from the PBU cable and connect it to the Battery Clip. When the first connection is complete, disconnect the second PBU cable from the System Controller Power Cable and connect it to the other battery clip. Tuck the batteries safely beside the patient so that the System Controller leads are not under strain. Cancel the extended 4 hour alarm reset by depressing the "Alarm Reset" button on the System Controller's user interface panel.

Note: It is not possible to monitor speed during transport. A portable blood pressure monitor is recommended for use during transport to gauge the effectiveness of support during periods of fluctuating pre-and afterload. A cart containing the PBU and System Monitor can closely follow the patient and should be reattached when the patient arrives at his or her destination.

NOTE: For System Controllers with Version 3.10 software (and higher), at pump speeds of 8,000 RPM or higher, if complete power to the pump is interrupted and/or percutaneous lead is disconnected causing the pump to stop, then the pump will automatically restart at the previously set mode and speed when power is restored.

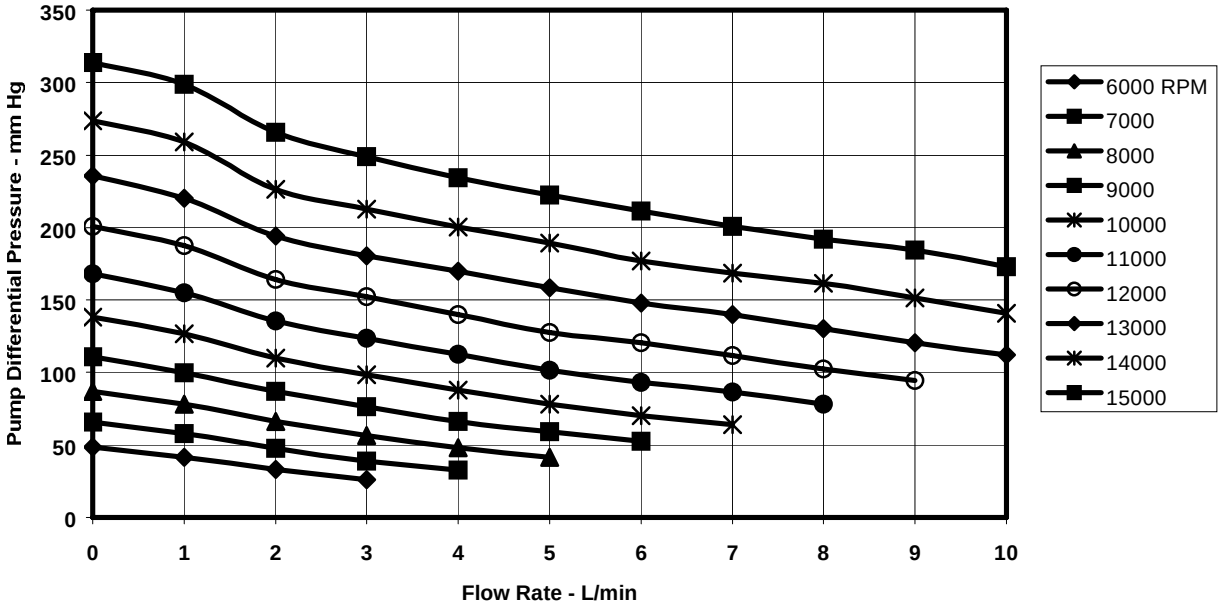

Figure 16: Typical HeartMate II Flow Characteristics

18 When convenient, insert the System Controller battery module into the System Controller body and screw it down until it is finger tight (Figure 17). This battery module enables the System Controller alarm to sound if the System Controller loses power while connected to a patient. Do not touch the metal contact point on the battery module while handling it.

CAUTION: Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning of cardiopulmonary bypass should provide a minimum of two liters per minute of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.

WARNING: All entrapped air must be removed from the LVAD blood pumping chamber and cannulae prior to fully releasing the outflow graft cross-clamp.

12 Remove the vent needle from the outflow graft only when air can no longer be observed exiting through the needle and repair site. If air persists in the pump outflow graft for a prolonged period (> 5-10 minutes), rule out leaks at the inflow cannula/pump connection.

13 Slide the Bend Relief over the metal fitting toward the locking screw ring until it "snaps" in place. This is confirmed by the inability of the Bend Relief to slide back toward the anastomosis.

14 When all air has been removed from the blood pump, it is safe to increase the pump speed (rpm). Adjust the Fixed Speed Setpoint by depressing the "FIXED SPEED ADJUST" button in the Clinical or System Check screens (Figures 14 & 15). followed by the "DEC. VALUE" or "INC. VALUE" key to select the desired pump speed setting Once the desired speed (rpm) is selected, press the "Enter" button to send the command to the System Controller.

15 Cardiopulmonary bypass should now be terminated to provide ample blood flow to the LVAD. The goal at this time is to achieve and maintain appropriate flow levels by adjusting the fixed speed of the LVAD.

16 Recognizing that arterial pressure (pump outlet pressure) is closely regulated by the intrinsic cardiovascular regulatory mechanisms of the body, the principle factor influencing pump flow is the inlet pressure (left ventricular pressure). Figure 16 illustrates that running the pump at 6,000 rpm will result in a maximum flow of 4 lpm, provided left ventricular pressure equals arterial pressure. A pressure difference of 20 mmHg would be required to obtain 2.5 lpm flow at 6,000 rpm, which would result in a left ventricular pressure of 100-20=80 mmHg at an arterial pressure of 100 mmHg. By increasing the pump speed to 10,000 rpm, a 100 mmHg pressure difference would be needed to maintain a 2.5 lpm flow rate. This relationship demonstrates that the flow generated by the pump is directly proportional to left ventricular pressure.

17 Adjustment in pump speed and therefore flow can be made by depressing the "Fixed Speed Adjust" button in the Clinical or System Check screens and increasing the speed by depressing the "INC. VALUE" button. Speed will only change after depressing the "Send" button. And increase of 200 rpm will represent approximately 1/3 of lpm of blood flow. The actual increase is dependent on many factors and could vary significantly.

9 Initiate pump flow at 6,000 rpm by depressing the “PUMP START” button from the Clinical or System Check screens and observe for air being expelled through the venting needle. The “PUMP OFF” message should disappear.

10 Figures 14 and 15 demonstrate the typical screens that will be displayed by the System Monitor upon system startup.

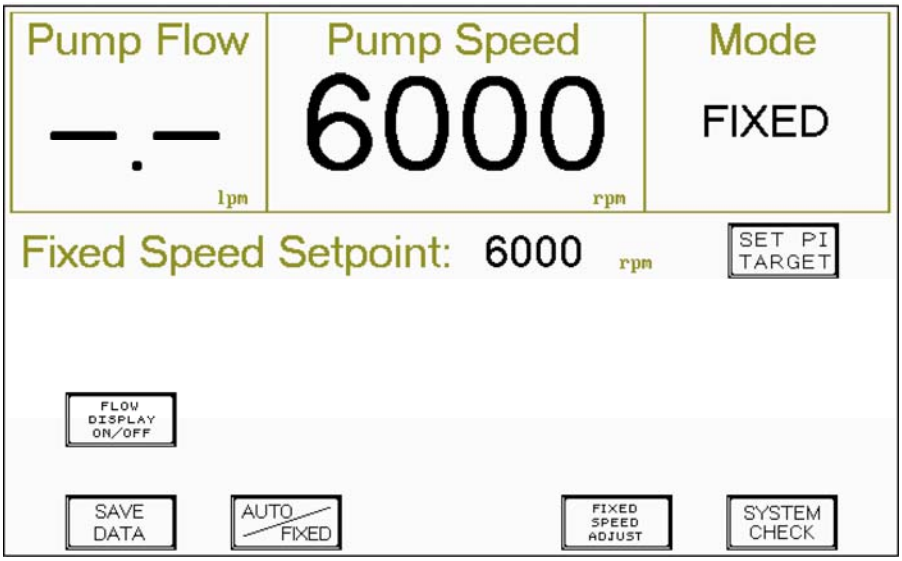

Figure 14: Clinical screen - LVAD in Fixed Mode & operating at 6,000 RPM

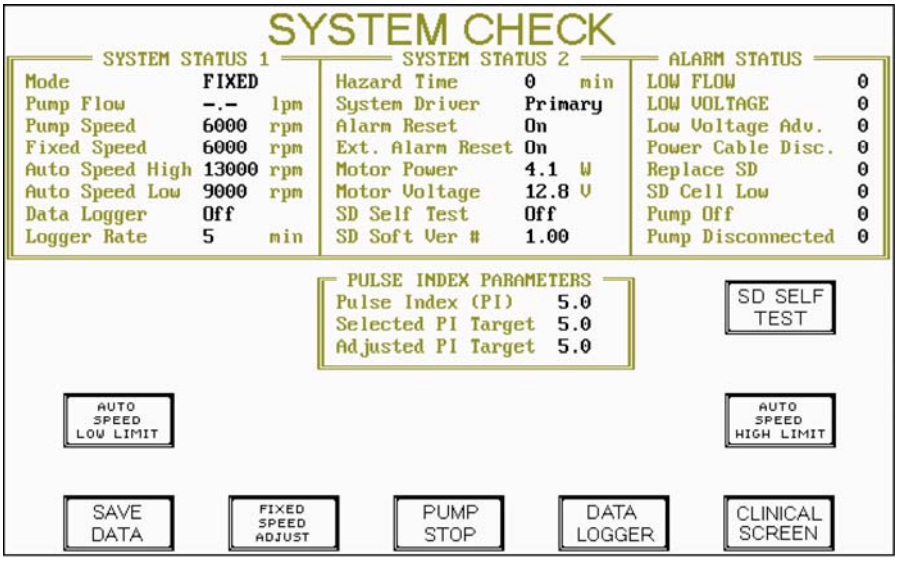

Figure 15: System Check screen - LVAD in Fixed Mode & operating AT 6,000 RPM

11 When de-airing is completed, partially remove the outflow graft cross-clamp while continuing to operate the LVAD. Blood volume should be shifted from cardiopulmonary bypass to the patient to allow for adequate pump flow.

8 To initiate HeartMate II pump operation, remove the bullet and attach the LVAD's percutaneous cable to the System Controller (Figure 13) by first aligning the marker on the cable's connector with the marker on the System Controller quick-disconnect receptacle. Then firmly advance the cable connector into the System Controller's quick-disconnect receptacle until you hear the quick-disconnect latch clamp onto the cable's connector. Test the connection by gently pulling back on the cable's connector. The "PUMP DISCONNECTED" message should disappear.

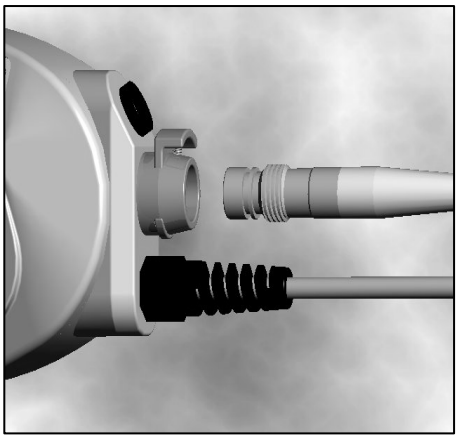

Figure 13: Attach Percutaneous Cable to the System Controller

7.6 De-airing the LVAD

Once the LVAD is in place and the inflow and outflow anastomoses are completed, residual air must be completely evacuated from the LVAD blood chamber prior to initiating LVAD activation. Transesophageal echocardiography may be utilized to monitor for air emboli. It is advisable to monitor the left atrial pressure, which should be maintained at greater than 10 mmHg.

WARNING: HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure (LAP) at greater than 10 mm Hg at all times to prevent air entrainment.

WARNING: All entrapped air must be removed from the LVAD blood pumping chamber and cannulae in order to reduce the risk of air embolus.

1 Cross-clamp the outflow graft at the distal end and move the Bend Relief toward the aortic anastomosis.

2 Position the outflow graft in a vertical position, such that an arch forms the highest point

3 Insert a vent needle at the highest point in the graft between the clamp and the outflow cannula connection.

Note: The needle vent should be placed in the outflow graft in the highest point in the lumen (anterior side to optimize air removal).

4 Reduce cardiopulmonary bypass flow to allow filling of the left ventricle and LVAD by diverting at least 2 liters per minute of blood to the ventricle

Note: The surgical field may be optionally flooded with sterile saline to further minimize the risk of air entry and possible embolization.

CAUTION: Remove all vents on the inflow side of the LVAD, including needles in the pulmonary vein, left atrium, and the left ventricle prior to initiation of pumping. MOVE TO SIDEBAR

5 Place the patient in the Trendelenburg position.

6 Review the System Monitor's System Check screen and verify that all commands are in place as shown on Figure 7.

7 Ensure that "PUMP OFF" and "PUMP DISCONNECTED" status are set to "1" in the System Check's "Alarm Status" window. If not, depress and hold the "Pump Stop" button for minimum of 10 seconds or until the "Pump Off" status is set to "1".

Table 5.2 summarizes the appropriate user corrective action during alarm conditions.

ALARM SYMBOL	AUDIO ALARM	ALARM CONDITION MESSAGES	CORRECTIVE ACTION
RED HEART	STEADY TONE	LOW FLOW HAZARD (<2.5 lpm)	1. Check the connection between the System Controller and the LVAD. 2. Check the connection between the System Controller and the Batteries or PBU. 3. Seek additional help.
None	STEADY TONE	None	Connect power to System Controller (no power present other than alarm battery module)
RED BATTERY	STEADY TONE	LOW VOLTAGE	<5 minutes of Battery power remains. Immediately replace Batteries or change to alternate power source. LVAD will automatically go into Power Saver Mode (8,000 rpm).
YELLOW BATTERY	ONE BEEP EVERY 4 SECONDS	Low Voltage Advisory	<15 minutes of battery power remains. Replace batteries or change to alternate power source.
FLASHING POWER SYMBOL	ONE BEEP EVERY 4 SECONDS	Power Cable Disconnected	Connect power cable
SYSTEM CONTROLLER BATTERY MODULE	ONE BEEP EVERY 4 SECONDS	System Controller Alarm Battery Module Low	Change alarm battery module.
None	ONE BEEP EVERY 4 SECONDS	Low Speed Operation	Increase Fixed Speed, switch to Auto or connect to the System Monitor.
None	BROKEN TONE	Replace System Controller	Replace System Controller with a new System Controller

Table 5.2: User Action During Alarm Conditions

Low Speed Operation

Whenever the System Controller is connected to the System Monitor and operating at a fixed speed less than the value set for the Auto Speed Low Limit, an advisory will be posted on the System Monitor indicating "WARNING: Low Speed Operation".

If the System Controller is disconnected from the System Monitor during a period of low speed operation, an audio beep will be generated once every four seconds. There is no accompanying symbol on the System Controller. This alarm stops whenever the System Controller is reconnected to the System Monitor.

Replace System Controller

If the System Controller reverts to the backup mode, the System Controller initiates an advisory alarm indicated by a broken audio tone at the rate of two beeps per second. There is no accompanying symbol on the System Controller but a warning is posted on the System Monitor or Display Module if either is connected.

System Controller Self Test

The System Controller should be checked ***daily*** for proper operation. **The System Controller Self-Test,** accomplished with a single button push by the clinician or the patient, is a functional check that completes in less than a minute. Pump operation will continue while the test is running.

The test sequence activates all of the lamps and audio alarms. The clinician or patient must determine whether the symbol lamps actually light and the audio alarms actually sound. Thus, audio-visual observation is the only verification method available to the operator.

To perform the System Controller Self-test:

- Press and hold the Test Select Switch on the System Controller.
- Look closely at the display and make sure that all of the lights are on and the alarm is making a continuous tone. If there is a problem with the alarm, it will sound for one second every other second.
- Release the Test Select Switch. All the lights remain lit and the alarms sound for an additional 5 seconds.
- If there is a problem that requires you to replace the System Controller, the lamps will not illuminate and you will hear a broken audio tone at the rate of two beeps per whenever the Test Select Switch is pressed. Follows the steps in the "Changing System Controllers" section to correct this problem.
- If there is no rapid beep, all the warning lights and alarms operate as described above and turn off 5 seconds after you release the switch, the System Controller has passed the Self Test.
- Upon finishing the self-test, the pump will be operating in the same mode (**AUTO** or **FIXED**) as it was, prior to starting the test. If the lamps or audio alarms fail, replace the System Controller.

NOTE: The System Controller Self-test cannot be initiated during a Hazard Alarm condition.

5.2.10 Changing System Controllers

Figure 5.10 illustrates connection of the percutaneous cable to the System Controller. This connection remains intact throughout support on the LVAS. However, should it become necessary to replace the System Controller, the steps below are to be followed.

To change the System Controller, follow these steps:

1. Place new System Controller within easy reach.

2. Have the patient sit or lie down.

3. Remove the Latch Guard from the System Controller connector.

4. Disconnect the System Controller from the power source. The System Controller alarm sounds and the pump stops.

5. Disconnect the System Controller by depressing the tab on the connector socket.

6. Connect the new System Controller by aligning and mating the percutaneous connector (connector on the cable coming through the patient's skin) with the System Controller socket and fully inserting the connector into the socket. Connect the new System Controller to the Batteries or PBU.

7. **Push the Test Select Switch ▲ or the Alarm Reset Switch ☒**. The pump restarts.

   NOTE: For System Controllers with Version 3.10 software (and higher), at pump speeds of 8,000 RPM or higher, if complete power to the pump is interrupted and/or percutaneous lead is disconnected causing the pump to stop, then the pump will automatically restart at the previously set mode and speed when power is restored.

8. If pump does not restart a Red Heart alarm sounds, check all power sources.

9. Insure the percutaneous connector is fully engaged in the System Controller socket and check the connection by gently tugging on the metal end of the percutaneous lead.

10. Inspect the Latch Guard for cracks or other defects before applying it onto the System Controller. If any defects are found, discard the Latch Guard and attach a new one. Patients will be discharaged from the hospital with a minimum of 4 Latch Guards. Should the Latch Guards become lost or damaged, they must be replaced.

11. Advise the patient to periodically examine his or her Latch Guard for defects (without removing it). If any defects are found, the patient should immediately remove the defective Latch Guard and attach a new one.

12. Recheck the connection to the System Controller by gently tugging on the metal end of the percutanous lead.

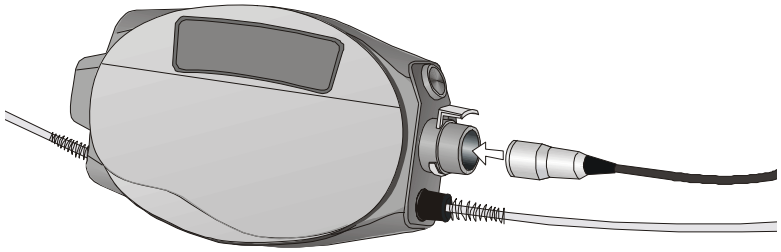

Figure 5.10: System Controller to LVAD Percutaneous Cable

WARNING:

- When the System Controller is disconnected from the percutaneous cable, pump function will stop. The System Controller and power must be reconnected as quickly as possible to resume pump function.

PRECAUTION:

- When connecting cables, do not force connectors together without proper alignment. Forcing connectors together may cause damage to the connectors.

PRECAUTION:

- **Ensure all backup System Controllers are programmed with identical settings as the primary controller. Backup controllers with settings that differ from the primary controller may result in diminished support or patient harm.**