

HeartMate® XVE LVAS

Clinical Operation & Patient Management



Abbreviated and abstracted from the HeartMate® XVE Operating Manual



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Table of Contents

INTRODUCTION.....	1	Changing Batteries.....	22
Program Description.....	1	Performing System Controller Self-Test.....	22
Program Objective.....	1	Changing the System Controller Battery Module.....	23
Learning Objectives.....	1	Changing Vent Filters.....	24
SYSTEM OVERVIEW.....	2	Showering.....	25
Device Description.....	2	Sleeping.....	27
Indications for Use.....	3	HANDLING EMERGENCIES.....	28
Contraindication.....	3	Defibrillation/Cardioversion.....	28
Warnings & Precautions.....	3	Hand Pumping.....	29
Blood Pump & Percutaneous Tube.....	4	Changing System Controllers.....	29
How the LVAD Blood Pump Works.....	5	Using the Stroke Volume Limiter (SVL) with Pneumatic Drive Console.....	30
Pump Rates & Modes.....	5	Venting.....	30
Fixed Rate Mode.....	5	MANAGING POTENTIAL POST-IMPLANT COMPLICATIONS.....	32
Auto Rate Mode.....	6	Patient Assessment.....	32
Default Modes.....	6	Potential EARLY Post-Implant Complications.....	32
Basal Mode.....	6	Potential LATE Post-Implant Complications.....	32
Power Saver Mode.....	6	Post-Operative Patient Management.....	33
PERIPHERAL COMPONENTS.....	7	Exit Site Care.....	33
Power Base Unit (PBU).....	7	Infection Control.....	33
Power Base Unit (PBU) Alarms.....	8	Managing Physiologic Conditions that May Affect Pump Life.....	33
System Monitor.....	9	Anticoagulation.....	34
Clinical Screen.....	9	THORATEC RESOURCES.....	35
System Check Screen.....	10	Published Reference Material.....	35
Display Module.....	12	POST TEST.....	36
System Controller.....	13	COMPETENCY ASSESSMENT (for CEUs).....	38
System Controller Alarms.....	14	PROGRAM EVALUATION.....	39
Batteries & Battery Clips.....	16		
Battery Advisories & Alarms.....	18		
Emergency Power Pak (EPP).....	19		
Hand Pump.....	19		
ROUTINE OPERATING PROCEDURES & ACTIVITIES OF DAILY LIVING.....	20		
Switching from PBU to Battery- Powered (Untethered) Operation.....	20		
Switching from Batteries to PBU (Tethered) Operation.....	21		

Introduction

Program Description

This program reviews the theory of operation, function, components, diagnostic monitoring, and related nursing management for the HeartMate® EXtended Lead Vented Electric (XVE) Left Ventricular Assist System (LVAS).

Program Objective

The primary objective of this module is to supplement on-site educational programs presented by Thoratec Clinical Consultants. It is designed to help prepare clinicians for assuming care of patients implanted with the HeartMate XVE LVAS.

Learning Objectives

At the completion of this program, participants should be able to:

- 1** Identify major components of the XVE LVAS and their functions, and explain the theory of operation of the device.
- 2** Describe the path that blood follows from the right atrium to the aorta in patients with the XVE LVAS.
- 3** List 2 potential complications associated with the XVE LVAS.
- 4** Identify the purpose and function of each of the buttons on the XVE LVAS System Controller.
- 5** Describe the interventions appropriate in the event of an LVAS emergency.
- 6** Identify the purpose of the buttons on the pneumatic Drive Console, which is used to power the XVE LVAS when it cannot be powered in the standard fashion via Power Base Unit (PBU) or batteries.

System Overview

Device Description

The HeartMate XVE LVAS consists of an implanted blood pump, external System Controller, and external power supply components. The Left Ventricular Assist Device (LVAD), or “blood pump,” is a pusher-plate type device that is capable of producing a stroke volume of 83ml, generating approximately 10 liters of blood flow per minute, and a beat rate up to 120 beats per minute (bpm).

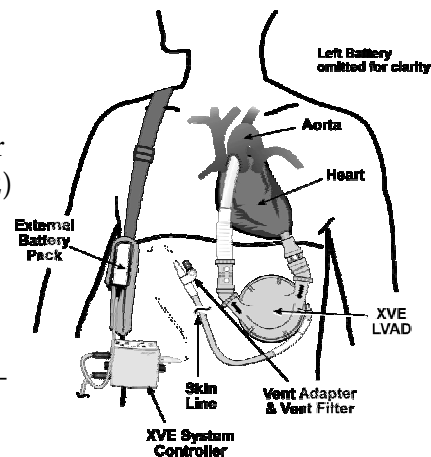
The pump consists of a rigid titanium housing divided in half by a flexible polyurethane diaphragm. One half functions as the blood chamber, while the opposite half serves as a chamber for the electric motor. This motor chamber is connected to the external control and power components via a percutaneous tube. Displacement of the diaphragm by rotation of the electric motor results in pumping of the blood.

The System Controller is a microprocessor-based unit that initiates motor actuation, monitors and reports on system function, and serves as the primary interface with the system. The Controller provides 2 modes of operation, either: 1) Fixed Rate Mode or 2) Auto Rate Mode (varying in response to physiologic demand).

A panel located on the top of the System Controller, or a separate System Monitor, allows for adjustment of LVAD function. The Controller's audio and visual alarms alert users of potentially dangerous conditions. Alarms are activated primarily if there are either low flow or low stroke volume conditions, or if battery charge levels are low.

The XVE LVAD is powered by 1 of 2 routine powers sources, either: 1) a pair of wearable, rechargeable batteries, or 2) via connection to a dedicated power supply through a device called a Power Base Unit (PBU). An optional, portable, back-up power source - the Emergency Power Pack (EPP) - can be used in periods of extended power outage. In the event that electric motor actuation is disrupted, the XVE LVAD also may be actuated by delivery of a pneumatic pulse through the percutaneous tube. Either the HeartMate hand pump or a standard HeartMate Implantable Pneumatic (IP) Drive Console can provide this pulse.

Figure 1 Implanted and worn components of XVE LVAS.



Indications for Use

The HeartMate XVE LVAS is intended for use as a bridge-to-transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate XVE LVAS is also indicated for use as Destination Therapy in patients with NYHA class IV end-stage left ventricular failure who have received optimal medical therapy for at least 60 of the last 90 days, who have life expectancy of less than 2 years, and who are not candidates for cardiac transplantation. The HeartMate XVE LVAS is intended for use both inside and outside the hospital.

Contraindication

The HeartMate XVE LVAS is contraindicated for patients whose body surface area is less than 1.5m².

Warnings and Precautions

- While most VE and XVE components are interchangeable (e.g., PBU, System Monitor, Display Module), the XVE System Controller and XVE vent adapter are NOT interchangeable with the VE system components. Therefore, the XVE LVAD should be used only with the XVE System Controller, System Controller battery module, and XVE vent adapter.
- Connect the PBU (and any peripheral devices) only to properly tested, grounded (3-pronged), and dedicated alternating current (AC) outlets. Do NOT use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or the risk of electrocution increases.
- Do NOT connect the PBU to an outlet controlled by a wall switch, or the PBU may be left inoperable.
- Do NOT subject patients implanted with the HeartMate XVE LVAS to MRI, as the LVAD contains ferro-magnetic components, and MRI exposure could cause device failure or patient injury.
- Post implant, patients should avoid strong static discharges (e.g., television or computer screens). Contact with strong static discharges can damage the electrical parts of the system and cause the pump to stop.
- In the event that the XVE LVAS stops operating, all attempts must be made to restore pump function immediately using electric or pneumatic activation. In the event that the XVE LVAS stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is risk of stroke or thromboembolism if, or when, the device is restarted.
- Loss of power will cause the XVE LVAS to stop and blood pumping to cease.

Power must be restored immediately. If power cannot be restored, use the hand pump to perform pneumatic pump activation.

- When the XVE System Controller is disconnected from the percutaneous tube, the pump will stop. The XVE System Controller and power must be reconnected as quickly as possible to resume pump function.
- Do NOT allow the percutaneous tube to become contaminated or its inner lumen to become wet, or the pump may stop.
- Diligent care throughout the course of LVAS support must be exercised to prevent infection and sepsis. System infections and localized infections of the percutaneous tube exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- Reports of a change in sounds and/or motion of the system by the patient should initiate evaluation for cause, including the possibility of device malfunction.
- Before connecting or disconnecting the XVE System Controller from the XVE LVAD, remove all power sources.
- A back-up XVE System Controller, spare batteries, and the hand pump must be with the patient at all times for use in an emergency.

Blood Pump and Percutaneous Tube

The LVAD, or blood pump, is a 2-chamber housing constructed of medical-grade titanium. It is implanted either preperitoneally or intra-abdominally in the left upper quadrant of the abdomen (depending on the preference of the implanting surgeon). An inflow valve conduit is attached to the apex of the left ventricle of the native heart, and a woven Dacron™ outflow graft is attached to the ascending aorta. The pump interior is separated in half by a flexible Cardioflex™ polyurethane diaphragm. One half comprises a motor chamber, while the other half comprises a blood chamber.

A flexible silicone percutaneous tube exits the patient's body in the right upper quadrant of the abdomen. The inside of the percutaneous tube contains: **1)** an electrical lead and **2)** an air line. The electrical lead supplies power to the pump and connects to the System Controller patient socket by aligning the black arrows. The air line allows air to flow in and out of the pump motor chamber with each beat of the LVAD.

The implanted portion of the percutaneous tube is covered in a polyester woven velour material designed to let skin cells grow into it. This helps the tube exit site to heal, which helps reduce the risk of infection. At the point where the velour percutaneous tube and air vent line terminates, there is a connector called the vent adapter which houses the vent filter. The vent adapter is locked into place on the percutaneous tube with a black spring-loaded button. The vent filter helps keep dust and

dirt out of the air line. The vent filter must be changed once a week, and as needed.

It is very important to NOT let any portion of the percutaneous tube become kinked or clogged. It is also very important to NOT get fluid into the tube or filter. Either of these conditions may cause the pump to stop.

A sterile dressing should be used at all times to cover the percutaneous tube exit site wound.

The percutaneous tube should be secured to the patient's body at all times with an abdominal binder or Stabilization Belt. This will reduce movement of the tube, which can cause trauma to the exit site and result in subsequent infection.

How the LVAD Blood Pump Works

The HeartMate XVE LVAS pump cycle works asynchronous to the electrical conduction of the native heart. The pump cycle is based on preload and filling pressures.

The pump fills (diastole) passively from the left ventricle (LV) via a unidirectional porcine valve. When pump pressure exceeds LV pressure, the inflow valve closes; then there is a short period of isovolumic pressurization within the pump. When pump pressure exceeds the pressure in the patient's ascending aorta, the outflow valve opens and the pump ejects (systole).

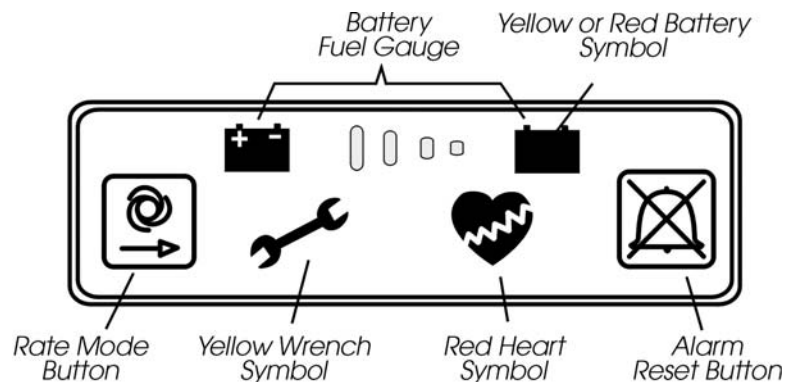
Pump Rates and Modes

The HeartMate XVE LVAD may be operated in either 1 of 2 modes:

- FIXED Rate Mode, or
- AUTO Rate Mode

The rate range for both modes is 50 - 120 bpm. Pump mode may be switched either on the System Controller keypad (**Figure 2**) or on the System Monitor touch screens (i.e., Clinical Screen or System Check Screen) (see "System Monitor" on page 9).

Figure 2 System Controller Keypad. Note Rate Mode Button.



The System Controller indicates the selected mode by sounding 1 or 2 beeps:

1 Beep = FIXED Rate Mode

2 Beeps = AUTO Rate Mode

Fixed Rate Mode

In Fixed Rate Mode, the pump ejects at a pre-set beat rate per minute that has been selected by the clinician and is independent of pump volume status. This mode is used in the operating room, and for some patients at night while they sleep.

Auto Rate Mode

In Auto Rate Mode, the XVE LVAD with Opti-Fill™ software in the Controller signals the pump to eject when approximately 97% capacity (approx. 80cc SV) is reached.

In Auto Rate Mode, the pump is responsive to physiologic demand; it speeds up or slows down based on pre-load to the LVAD.

Default Modes

Basal Mode

The Basal Mode occurs if fluid enters the air line or motor chamber, if there is a broken signal wire in the percutaneous tube, or if a malfunction occurs in the System Controller's microprocessor. In response to any of these conditions, the pump will default to a FIXED Rate Mode of 40 bpm accompanied by a YELLOW WRENCH Advisory and once-per-second BEEP. When the LVAD defaults to Basal Mode, the problem causing the beat/mode change should be promptly identified and resolved; otherwise, pneumatic actuation of the LVAD should be initiated.

Power Saver Mode

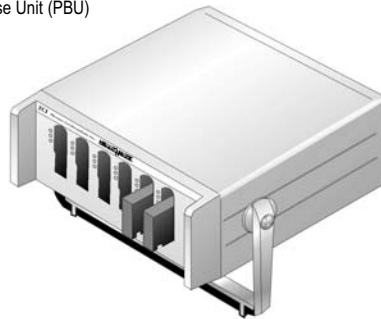
Power Saver Mode occurs with low battery or power voltage. In response to this low power/battery condition, the pump will default to a FIXED Rate Mode of 50 bpm accompanied by a RED BATTERY Alarm and CONTINUOUS AUDIO TONE. When the LVAD defaults to Power Saver Mode, it should prompt immediate replacement of batteries or connection to the PBU.

Peripheral Components

Power Base Unit (PBU)




The Power Base Unit (PBU) (Figure 3) provides AC power to the LVAD when the patient is connected to it via the 20-foot PBU cable; this is referred to as tethered operation. The PBU can charge up to 6 batteries in 8 hours or less, depending on the charge status of the batteries. Battery charging can occur simultaneously with tethered operation.

Figure 3 Power Base Unit (PBU)



The PBU has 6 battery charging stations; each station has 3 charge indicator lights that visually indicate battery condition (see charge indicator summary below). To charge or test a battery, slide the battery into the slot with the metal terminal facing UP. When the battery is in place, the yellow light will illuminate while an electrical check is performed on the battery. After testing, 1 of 3 lights will illuminate to indicate the status of that battery.

The patient should be connected to the PBU when sleeping or anticipating sleep. The PBU echoes (duplicates) alarms that are generated by the System Controller.

	Green	Indicates a fully-charged battery that is ready for use .
	Yellow	Indicates that a 10-second load test is being performed to check a battery's charge status. If a battery is fully charged, the light turns green after 10 seconds. Otherwise, the light remains yellow, indicating that the battery is still charging .
	Red	Indicates that the battery is: 1) improperly positioned in the slot, or 2) defective. If you get a red light, reinsert the battery into the same slot to perform a 2 nd 10-second load test. If the battery fails the 2 nd test, try another slot. If it the light is still red, the battery is defective; do not use . Note: If you get a red light in one slot and then a yellow or green light in another, the the PBU's daughter PCB may be suspect. Consult Thoratec's Field Service Department if this happens.

Power Base Unit (PBU) Alarms

AC FAIL

In the event of AC mains power failure, the PBU's AC FAIL Alarm will activate.

The AC FAIL ALARM is indicated by the illumination of a RED light on the front panel of the PBU and a CONTINUOUS AUDIO TONE.

If the AC FAIL Alarm activates, the PBU will automatically revert to its internal back-up battery to power the LVAD for approximately 45 minutes. In response to this condition, the patient should be promptly switched from tethered (PBU-powered) operation to battery-powered or EPP operation until AC mains power is restored.

Batteries in the PBU battery charging slots will not lose their charge during AC mains power failure; however, neither will they continue to charge during this time.

Note: Pressing the Alarm Reset Button below the red light will silence the AC FAIL Alarm.

Low Battery (LO Batt)

When the internal back-up battery in the PBU has been depleted to 10 minutes of remaining power, the PBU's low battery or "LO Batt" Alarm will activate. The LO Batt Alarm is represented by a RED light and a CONTINUOUS AUDIO TONE.

When the System Controller power leads are connected to the PBU cable and the LVAD is operating in tethered configuration this alarm cannot be silenced. It will continue until AC mains power has been restored to the PBU. In response to this condition, the patient should be changed immediately from tethered operation (PBU-powered) to battery-powered or EPP operation until AC mains power is restored.

System Monitor

The System Monitor (Figures 4a & 4b) communicates with the System Controller through the PBU. When the patient is in tethered configuration, certain LVAD function data may be obtained only from the System Monitor. The System Monitor has 2 screens: 1) the Clinical Screen and 2) the System Check Screen. The System Monitor is the only place in the system where the Fixed Rate Setpoint can be adjusted.

Figure 4a System Monitor
(Older Model)



Figure 4b System Monitor
(Newer Model)



Note: Both newer and older models of the System Monitor work with either the HeartMate XVE LVAS or the HeartMate II LVAS.

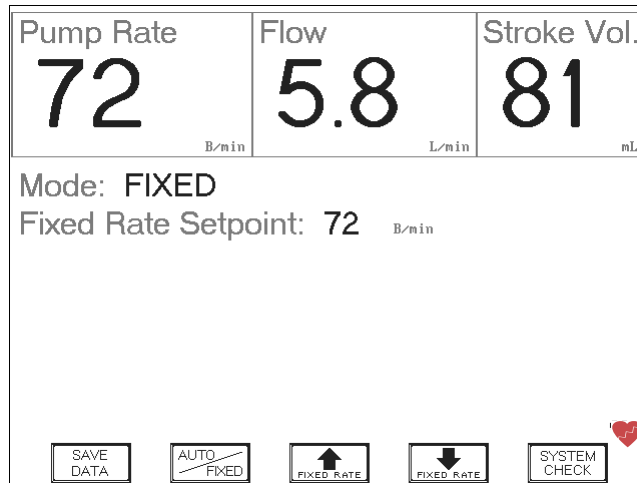
Clinical Screen

The Clinical Screen (Figure 5) displays pump rate, flow, and stroke volume as well as the selected operating mode (i.e., Fixed or Auto) followed by the fixed rate set point, a command line, and a flashing heart icon. The following table lists the Clinical Screen command buttons and describes their applications.

Command Button	Application
Save Data	Allows operator to save XVE LVAD motor waveforms on a memory card.
Auto/Fixed	Allows operator to change pump from Fixed Rate Mode to Auto Rate Mode and vice versa.
Fixed Rate ↑	Allows operator to increase pump's fixed rate. Fixed rate setpoint is stored in System Controller.
Fixed Rate ↓	Allows operator to decrease pump's fixed rate. Fixed rate setpoint is stored in System Controller.
System Check	Displays the System Check Screen that contains all primary operating parameters and alarm status information.

When an alarm occurs, the highest priority alarm message appears below the fixed rate setpoint. Hazard alarm messages appear in flashing capital letters and indicate how long (in minutes) the alarm has been active. Advisory alarm messages appear in lower case letters and do not flash.

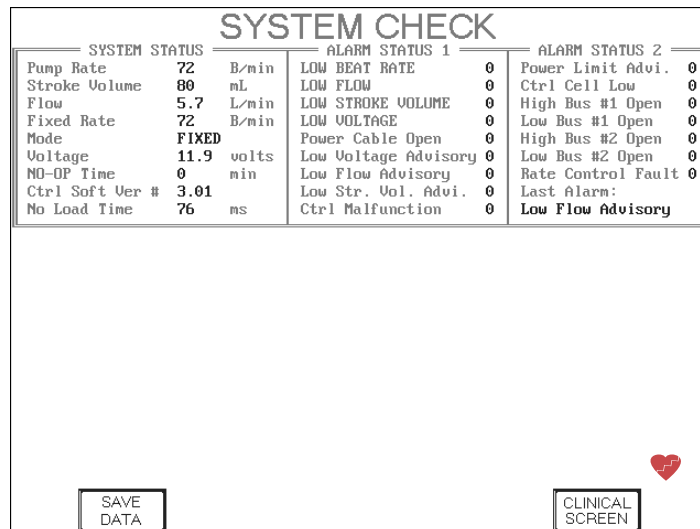
Figure 5 Clinical Screen



System Check Screen

The System Check Screen contains 3 information boxes, 2 command buttons and a flashing heart icon. The 3 information boxes at the top of the screen (**Figure 6**) provide various diagnostic information, including pump, system, and alarm status information.

Figure 6 System Check Screen



When an alarm is active, the alarm name is displayed in bold type. The number next to the alarm name indicates the alarm status. An inactive alarm is indicated by a “0” next to the name and an active alarm is represented by “1.” The System Check Screen will indicate all active alarms.

Display Module

When connected to the PBU, the Display Module (**Figure 7a**) provides an abbreviated, small-scale display of system performance. The Display Module reports data from the System Controller via the PBU. The Display Module displays pump rate, stroke volume, and flow data, as well as the current operating mode and operational status of the system.

Figure 7a Display Module

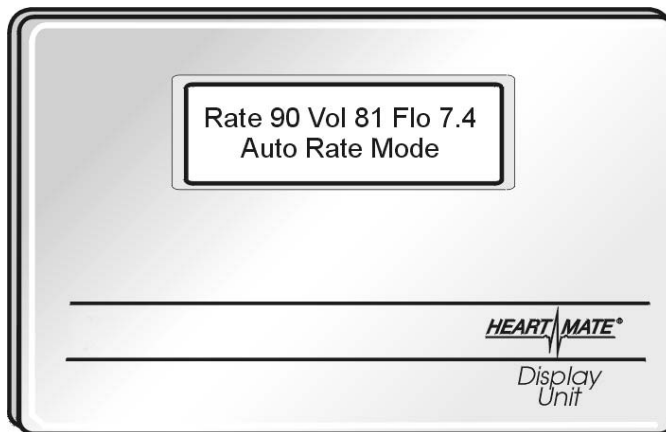
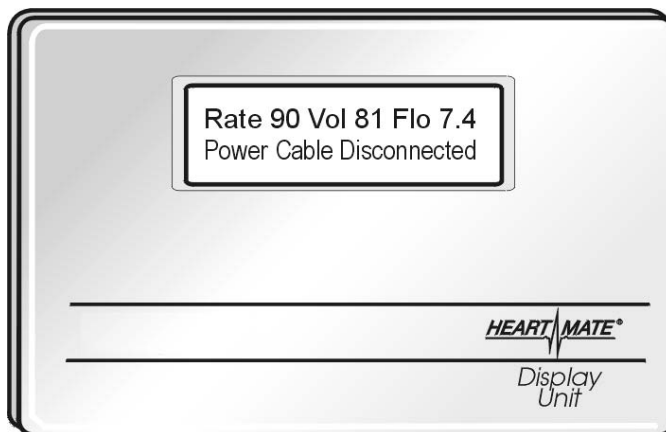


Figure 7b Display Module Showing Sample Advisory Alarm Message



When an alarm is active (**Figure 7b**), the highest priority alarm message replaces the pump mode and operating status information. Hazard alarms appear in upper case letters and Advisory Alarms appear in lower case.

System Controller

The XVE System Controller (**Figure 8**) is a microprocessor-based computer that connects to the electric lead of the XVE LVAD percutaneous tube. It is required for electrical operation of the LVAD. The System Controller monitors the performance of the implanted LVAD. The System Controller keypad (**Figure 9**) allows for rate mode changes (i.e., from Fixed Rate Mode to Auto Rate Mode, and vice versa), and displays battery charge levels. It can also be used to silence certain alarms by pressing the Alarm Reset Button.

Figure 8 XVE System Controller

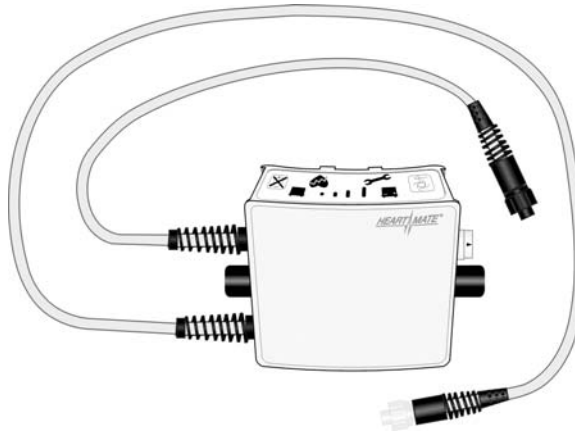
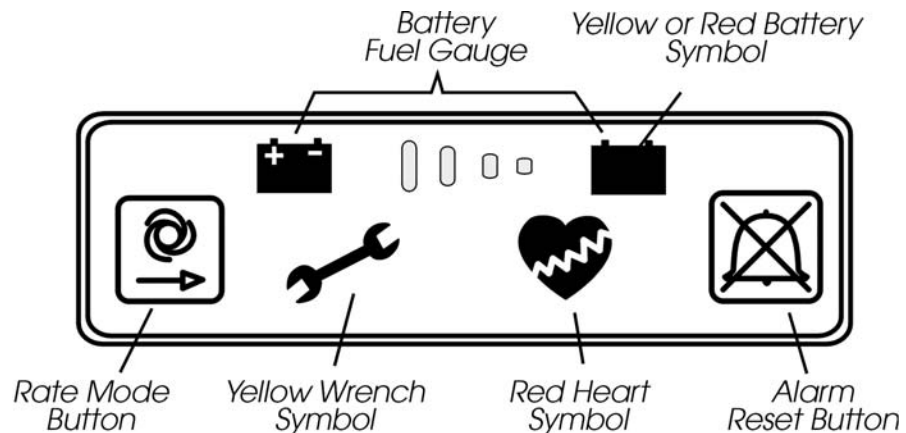


Figure 9 System Controller Keypad



The XVE System Controller weighs .57 lb. (260g) and is approximately the size of 2 pagers. It may be clipped to a patient's belt or waistband, or secured to the patient's abdominal binder or Stabilization Belt.

The XVE System Controller has 2 power leads (1 long white lead and 1 short black lead), both of which interface with either the Power Base Unit (PBU) cable or a pair of battery clips (depending on the power source used).

When connected to the PBU, the white System Controller power lead must be connected to the white PBU lead and the black System Controller power lead must be connected to the black PBU lead. Although both leads provide equal power, the white power lead contains a data link cable that allows the System Controller to display information on the System Monitor or Display Module. Either System Controller power lead can interface with either battery clip.

System Controller Alarms

The XVE System Controller diagnoses and generates Advisory and Hazard Alarms. If the patient is operating in tethered (PBU-powered) configuration, these alarms are displayed on either the System Monitor Clinical Screen or Display Module.

YELLOW WRENCH Advisories

YELLOW WRENCH Advisories indicate non-critical conditions. The YELLOW WRENCH icon on the System Controller keypad illuminates, accompanied by a once-per-second BEEP. If the patient is in tethered (PBU-powered) configuration, the advisory message appears on the System Monitor Clinical Screen or Display Module.

- **Controller Malfunction**
Potential causes of Controller Malfunction include power surges or static.
Action: Replace Controller.
- **Power/Current Limit Advisory**
Potential causes of Power/Current Limit Advisory include: hypertension, positional Inflow or Outflow occlusion, vent filter occlusion, or fluid in the air line.
Action: Replace vent filter. Ensure that vent port is not occluded or restricted by dressing or clothing. Treat hypertension.
- **Power Cable Disconnected**
Power lead or battery clip is loose or disconnected.
Action: Check lead or battery clip connections to ensure they are secure.
- **Rate Control Fault**
This advisory is generally transiently caused by increasing or decreasing the Fixed Rate Mode greater than 5 bpm at a time; however, it may also be indicative of more serious conditions relating to motor performance.
Action: Monitor the situation and treat as necessary.

Note: YELLOW WRENCH audio advisories can be silenced for 24 hours by pressing the Alarm Reset Button on the System Controller keypad.

RED HEART Alarms

RED HEART Alarms indicate critical conditions that warrant immediate response. If a RED HEART condition arises, the RED HEART icon on the System Controller keypad illuminates and a CONTINUOUS AUDIO TONE sounds. If the patient is in tethered configuration, the alarm condition will be displayed (in all capital letters) on the System Monitor Clinical Screen or Display Module, accompanied by a timer that indicates how long the condition has existed.

Note: If the pump is inoperable for more than a few minutes there is risk for thrombus formation, depending on the coagulation status of the patient.

· **No Operation (NO OP) or LO BEAT RATE (<35 bpm)**

Potential causes of a NO OP or LO BEAT RATE Alarm include: percutaneous tube disconnected from System Controller, loss of power to both power leads, disconnection from both battery clips, fluid in air line, or broken wires in percutaneous tube.

Actions: 1) Check connections between XVE System Controller and XVE LVAD percutaneous tube, and between XVE System Controller and batteries or PBU. 2) Remove vent filter and check for obstructions. 3) If condition persists, disconnect power and initiate hand pumping. 4) Seek professional medical help. 5) Consider systemic anticoagulation. 6) Have pneumatic Drive Console available as backup.

· **LOW STROKE VOLUME (<25cc) or LOW FLOW (<1.5 L/min.)**

Potential causes of Low Stroke Volume Alarm include: bleeding, hypovolemia, vasodilation, right heart failure, right heart ischemia, cardiac tamponade, pulmonary hypertension, arrhythmia, or positional Inflow or Outflow occlusion.

Action: Treat cause. Consider systemic anticoagulation.

· **FLASHING YELLOW BATTERY & RED HEART & YELLOW WRENCH**

Caused by the XVE System Controller being disconnected from the patient.

Actions: 1) Check XVE System Controller lead connection to the XVE LVAD percutaneous tube. 2) Ensure that both batteries are properly inserted into the battery clips and that the XVE System Controller power leads are properly connected to the PBU cable. 3) Ensure that PBU cable is connected to back of PBU. 4) If condition persists, disconnect power and initiate hand pumping. 5) Seek professional medical help.

Note: Prior to reconnecting percutaneous tube to System Controller, disconnect power for both power leads, reconnect percutaneous tube to System Controller, and then reconnect power.

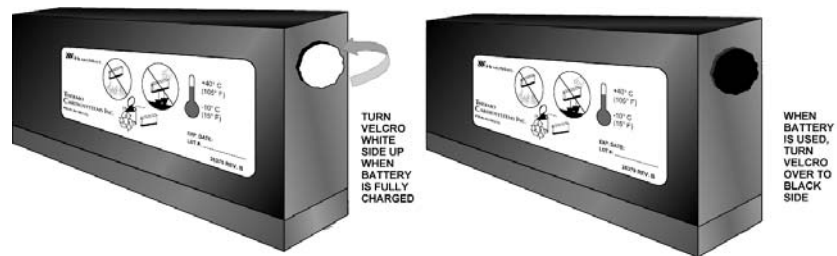
Batteries and Battery Clips

Batteries

The pump may be powered by a pair of wearable, rechargeable 12-volt sealed lead acid batteries. A pair of fully-charged HeartMate batteries provides approximately 4-6 hours of power, depending on the initial charge status of the batteries and on the hemodynamic condition of the patient. Before being connected to the System Controller, batteries must be inserted into 2 corresponding battery clips. Once fully-discharged, batteries may take up to 8 hours to recharge.

Velcro® indicator circles are supplied with each battery. Use them to designate a battery's charge status. When a battery is fully-charged, place the indicator on the battery with the white side facing up; when the battery is depleted, turn over the indicator and place it on the battery with the black side facing up (**Figure 10**).

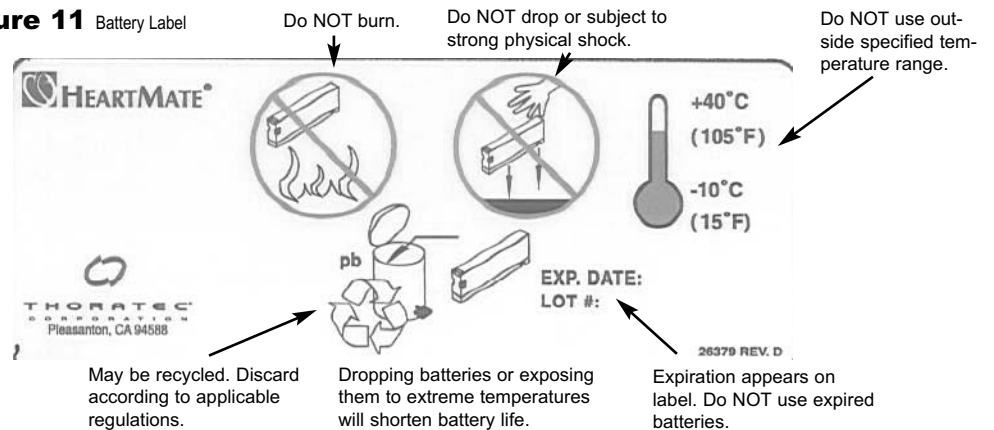
Figure 10 HeartMate Batteries



To prevent deterioration or damage to batteries, use according to label instructions (**Figure 11**):

- Do NOT drop or subject to strong physical shock.
- Do NOT leave or store in hot or cold areas (e.g., car trunks, etc.) or battery life will be shortened.
- Do NOT use in temperatures below 15°F (-10 °C) or above 105°F (40°C).
- Recharge within 12 hours of being depleted or battery life will be shortened.

Figure 11 Battery Label

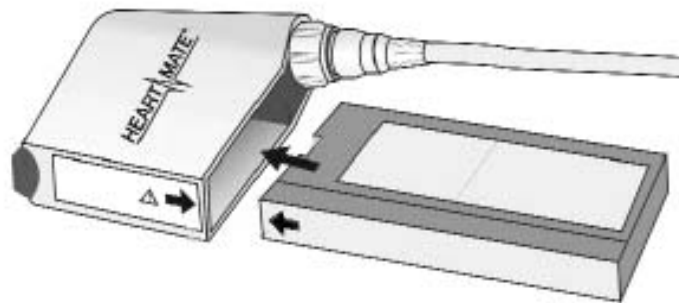


Battery Clips

Battery clips are used to hold the HeartMate batteries. They have an electrical connection for attaching the Controller power leads. One battery is inserted into each clip (match black arrow on battery with black arrow on clip) (**Figure 12**). Ensure that the battery clicks into place when inserted. Sliding the spring-loaded button releases a battery from its clip.

Note: NEVER disconnect both power leads from batteries at the same time, or the pump will stop.

Figure 12 Inserting Battery into Battery Clip



System Controller Battery Fuel Gauge

The HeartMate System Controller displays a set of indicator lights, collectively called the Battery Fuel Gauge. To activate the Battery Fuel Gauge, press and hold the Alarm Reset Button on the System Controller keypad.

The Battery Fuel Gauge provides an approximate measure of available battery power. See summary below.

Battery Fuel Gauge Signal	Meaning	Response
	Less than 25% of battery power remains (batteries less than a 1/4 charged).*	Replace used batteries with fully-charged batteries, or switch to PBU.
	Between 50% - 25% of battery power remains (batteries 1/2 charged).	No action necessary.
	Between 75% - 50% of battery power remains (batteries 3/4 charged).	No action necessary.
	Between 100% - 75% battery power available (batteries fully-charged).	No action necessary.

*When less than 25% of battery power remains, a battery alarm symbol will illuminate, first a YELLOW BATTERY, and then a RED BATTERY.

Battery Advisories and Alarms

Yellow Battery Advisory

When the YELLOW BATTERY icon on the System Controller keypad is illuminated and accompanied by a once-per-second BEEP there is less than 15 minutes of battery power remaining. **Action:** Replace depleted batteries *one at a time* with fully-charged batteries or switch to alternate power source (PBU or EPP).

Red Battery Alarm

When the RED BATTERY icon on the System Controller keypad is illuminated and accompanied by a CONTINUOUS AUDIO TONE, there is less than 5 minutes of battery power remaining. When this condition arises, the LVAD will default to Power Saver Mode, with a Fixed Rate of 50 bpm. **Action:** Immediately replace depleted batteries *one at a time* with fully-charged batteries, or switch to alternate power source (PBU or EPP), or prepare to hand pump.

Flashing Yellow Battery

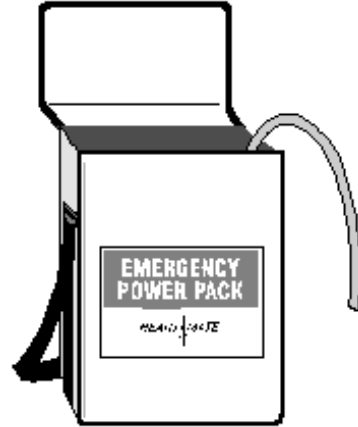
The YELLOW BATTERY icon on the System Controller keypad will flash without an audio tone when the System Controller battery module needs to be replaced.

Action: Replace the XVE System Controller battery module, then perform a XVE System Controller Self-Test to clear the alarm (see “Changing the System Controller Battery Module” on page 23 and “Performing a System Controller Self-Test” on page 22).

Emergency Power Pack (EPP)

The Emergency Power Pack (EPP) (**Figure 13**) is an optional, single-use power source enclosed in a plastic carrying case. It has a shoulder strap to make handling and carrying easier. The EPP should be used to power the LVAD only during an emergency or extended power outage. The EPP provides approximately 24 hours of power to the LVAD under "normal" conditions (flow 6 L/min., 115mmHg MAP).

Figure 13 Emergency Power Pack (EPP)



Note: The EPP is NOT rechargeable and must be replaced if used for 3 or more hours. See the instructions for use inside the top flap of the EPP for more information.

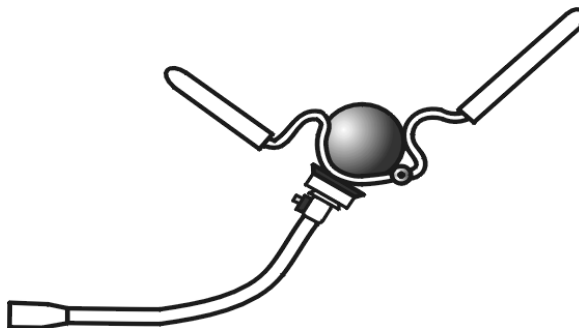
Hand Pump

The hand pump (**Figure 14**) is an emergency or back-up power source that may be used to power the LVAD in the event of a critical alarm state. The hand pump powers the LVAD by shuttling air behind the pump diaphragm.

NEVER use the hand pump while the patient is connected to a power source (i.e., batteries, PBU, or EPP). **Disconnect the patient from power source before hand pumping.** For complete hand pumping instructions, see "Hand Pumping" on page 29 or refer to the instructions on the hand pump label.

Note: Prior to hand pumping, the pump and LVAD must be primed. Refer to the hand pumping instructions in this manual or on the hand pump label.

Figure 14 HeartMate Hand Pump



Routine Operating Procedures & Activities of Daily Living

Switching from PBU to Battery-Powered (Untethered) Operation

The components required for operating the XVE LVAS with batteries are the implanted XVE LVAD, the System Controller, 2 battery clips, and a pair of 12-volt rechargeable HeartMate batteries.

To go from PBU (tethered) operation to battery (untethered) operation, perform the following procedure:

- 1 Explain procedure to patient.
- 2 Place 2 battery clips, 2 fully charged 12-volt batteries, and the white and black PBU cable connectors within easy reach.
- 3 Place 1 fully-charged battery into each battery clip by aligning the arrows on the battery and battery clip and pushing the battery into the battery clip until a gentle "click" is felt.
- 4 Unscrew the **white** System Controller / PBU connector. Connect the **white** connector on the System Controller to the 1st battery clip.
- 5 Unscrew the **black** System Controller / PBU connector. Connect the **black** connector on the System Controller to the 2nd battery clip.
- 6 Check the Battery Fuel Gauge by pressing and holding the Alarm Reset Button on the System Controller keypad.
- 7 Place the battery clips and batteries in the patient's holster or Pocket Pak™.
- 8 Place 2 additional fully-charged batteries in the patient's Travel Case for back-up use.

Note: NEVER remove power from both power leads at the same time, or the pump will stop.

Switching from Batteries to the PBU (Tethered Operation)

To go from battery (untethered) operation to PBU (tethered) operation, perform the following procedure:

- 1** Explain procedure to patient.
- 2** Insure that the PBU is plugged in and turned on, and the PBU cable is attached to the "Patient" socket on the back of the PBU.
- 3** Place the black and white PBU connectors within easy reach.
- 4** Remove batteries and battery clips from the patient's holster or Pocket Pak.
- 5** Unscrew the **white** connector from the battery clip. Put aside the battery and battery clip.
- 6** Connect the **white** PBU cable connector to the **white** System Controller connector. Align the pins, push together and hand tighten.
- 7** Unscrew the **black** connector from the battery clip. Put aside battery and battery clip.
- 8** Connect the **black** PBU cable connector to the **black** System Controller connector.
- 9** Press the battery release button on the 1st battery clip and remove the battery for recharging.
- 10** Turn over the Velcro indicator on the used battery to show that it needs to be recharged.
- 11** Repeat steps 9 - 10 for the 2nd battery / battery clip.
- 12** Place depleted batteries into PBU for recharging.

Note: NEVER remove power from both power leads at the same time, or the pump will stop.

Changing Batteries

To replace depleted batteries with fully-charged batteries, perform the following procedure:

- 1** Explain procedure to patient.
- 2** Remove batteries and attached battery clips from the patient's holsters or Pocket Pak.
- 3** Remove 2 fully-charged batteries from the PBU or patient's Travel Case.
- 4** Remove the 1st battery from its clip by pressing the battery release button on the battery clip, then pull the battery out of the clip and put it aside for later recharging.
- 5** Align the arrow on the new battery and the arrow on the battery clip. Slide the fully-charged battery into the battery clip until a gentle "click" is felt.
- 6** Repeat steps 4 - 5 with the 2nd battery / battery clip.
- 7** Check the Battery Fuel Gauge by pressing and holding the Alarm Reset Button on the System Controller keypad.
- 8** Place new batteries and clips into the patient's holster or Pocket Pak.
- 9** Turn over the Velcro indicator on the depleted batteries to show that the batteries need to be recharged.
- 10** Place depleted batteries into the PBU for recharging.

Note: NEVER remove power from both power leads at the same time, or the pump will stop.

Performing a System Controller Self-Test

At least once a day a System Controller Self-Test should be performed to ensure that the System Controller is working properly. To properly conduct a Controller Self-Test the patient should be connected to the PBU. To conduct the test perform the following procedure:

- 1** Explain procedure to patient.
 - 2** Have patient sit or lie down, as they may feel a change in beat rate.
 - 3** Press and hold the Rate Mode Button on the System Controller keypad for a count of 3. *The YELLOW WRENCH, RED HEART, RED BATTERY, and fuel gauge lights will come on and a CONTINUOUS AUDIO TONE will sound.*
 - 4** After 3 seconds, release the Rate Mode Button.
All warning lights will remain lit and the alarms will continue to sound for 3 seconds. Next, all the warning lights will turn off, except for the YELLOW WRENCH. Then, all the warning lights will turn back on (within 5 seconds or less) and will stay on for another 5 seconds. The alarm will continue to sound.
 - 5a** If all the warning lights and alarms operate as described above and then turn off after 5 seconds, the Controller has passed the self-test.
- OR*
- 5b** If the YELLOW BATTERY continues to flash, the System Controller battery module needs to be replaced.
 - 6** If there is a problem (if the Controller fails the self-test), the YELLOW WRENCH will remain illuminated and the once-per-second BEEP will sound. Repeat the self-test to confirm the problem.
 - 7** At the end of the self test, look at the System Monitor or Display Module screen to see if the patient is still in the desired mode, either Fixed or Auto. If necessary, press the Rate Mode Button on the System Controller to change the mode.

Changing the System Controller Battery Module

The XVE System Controller battery module should last approximately 1 year. However, if at any time you notice a flashing YELLOW BATTERY icon on the System Controller keypad, change the battery module by performing the following procedure:

- 1 Obtain a new System Controller battery module.
- 2 Examine the battery module. There should be an orange O-ring around the bottom of the module.
- 3 Unscrew (counterclockwise) the current battery module from the bottom of the System Controller and discard it.
- 4 Insert the new System Controller battery module into the System Controller. (Figure 15).
- 5 Tighten (clockwise) the new battery module until the orange O-ring is no longer visible. **Note:** Do NOT use tools; hand tighten only.
- 6 Perform a System Controller Self-Test as described above to reset the alarm.

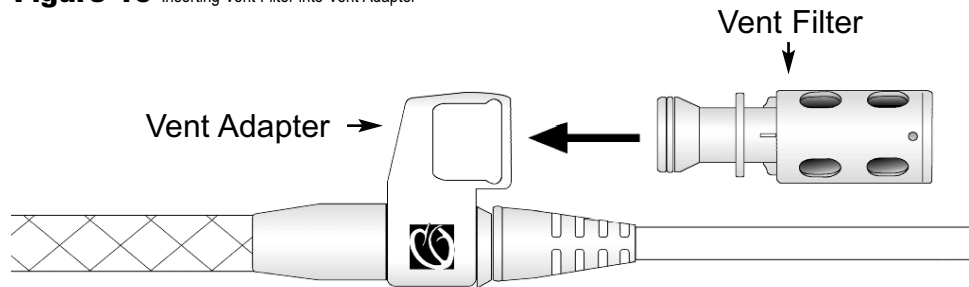
Figure 15 Inserting Battery Module into XVE System Controller



Changing Vent Filters

The vent filter snaps into place on the vent port of the vent adapter via a spring-loaded latch. (**Figure 16**) The vent filter insures that air being vented into the pump chamber is free of foreign material. The vent filter should be changed once a week, and as needed (e.g., when dirty or wet), to ensure optimum pump performance.

Figure 16 Inserting Vent Filter into Vent Adapter



Warning: Insure that water or fluid does NOT enter the percutaneous tube or vent filter. Water or fluid entering the percutaneous tube or vent filter may cause the pump to stop.

Showering

Although the externally worn components of the HeartMate XVE LVAS are moisture-resistant, they are not waterproof. Care must be taken to not expose the XVE LVAS components to water or a wet environment. When taking a shower, the patient must shield all external components from water by placing them in a waterproof pouch (HeartMate Shower Kit).

- Do NOT permit the patient to shower unless his or her physician has inspected the exit site wound and confirmed that sufficient healing has occurred.
- Never permit XVE LVAS patients to sit in a tub of water, or to take a bath or swim.
- Never allow water, or any fluid, to enter the vent port of the vent adapter. This could cause the XVE LVAD to stop.
- Keep the exit site as clean and dry as possible.
- Avoid excessive pulling on the percutaneous tube to minimize exit site trauma.
- Follow established HeartMate Shower Kit instructions for use.

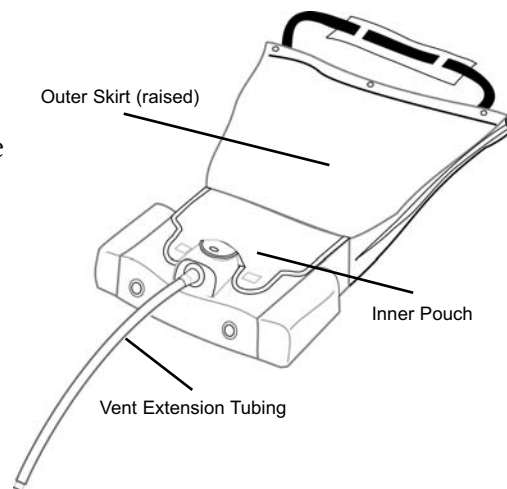
Preparing to Shower

- 1 Using the black nylon strap, hang the Shower Kit over one shoulder so the kit is at the patient's side. **Note:** Strap is adjustable.

OR

Figure 17 HeartMate Shower Kit

- 1 Put the strap around the patient's neck and hang the kit in front of the patient.
- 2 Raise the outer "skirt" to expose the inner pouch underneath (**Figure 17**).
- 3 Lift Velcro tabs on the inner pouch cover; open the cover.
- 4 Place the System Controller, cables, and connectors inside the pouch.
- 5 Reseal the pouch by pressing down the Velcro tabs.
- 6 If the patient is going to **use battery-power while showering**, follow step a - d below:
 - a Remove the 1st battery from its holster or from the Pocket Pak. **Note:** Leaving on the holsters or Pocket Pak until all of the equipment is transferred to the Shower Kit may reduce pulling on the exit site.
 - b Insert the 1st battery into one of the pockets located on either side of the



CLINICAL OPERATION AND PATIENT MANAGEMENT

inner pouch. **Note:** Insert the battery with the clip at the top and the cable facing away from the patient.

- c** Repeat steps a - b for the 2nd battery.
- d** Remove the holsters or Pocket Pak and place in dry location.

OR

- 6** If the patient is going to **use PBU power while showering**, follow steps a - e below:
 - a** Remove the vent filter from the vent adapter and throw it away.
Note: Make sure you have a replacement filter!
 - b** Insert the end of the vent extension from the shower kit into the vent port of the vent adapter (where the vent filter used to be).
 - c** Examine the percutaneous tube. Make sure the vent adapter covers the 2 blue O-rings on the tube.
 - d** Pull the shower kit skirt down over the inner pouch. **Note:** The kit's vent extension tubing should hang down between the snaps on the bottom of the skirt.
 - e** Press together the snaps at the bottom of the skirt.
- 7** Adjust the Shower Kit so it does not pull on the exit site while the patient is showering.

After Showering

- 1** Use a towel to dry the shower kit's strap and outer "skirt."
- 2** Undo the snaps at the bottom of the outer "skirt" and then lift the "skirt" to reveal the inner pouch underneath.
- 3** Lift the Velcro tabs on the inner pouch cover; open the pouch.
- 4** If the patient **used battery power while showering**, follow steps a - d below:
 - a** Hold the vent adapter in one hand and the end of the vent extension in the other.
 - b** Press the release tab on the vent adapter to release the vent extension from the vent port.
 - c** Insert a clean Vent Filter into the vent port of the vent adapter.
 - d** Remove the System Controller, cables, connectors and batteries from the inner pouch and return the equipment to the holsters or Pocket Pak.

OR

- 4** If the patient **used PBU power while showering**, follow steps a - c below:
 - a** Hold the vent adapter in one hand and the end of the vent extension in the other.
 - b** Press the release tab on the vent adapter to release the vent extension from the vent port.

- c** Insert a clean vent filter into the vent port of the vent adapter.
- 5** Remove Shower Kit and allow it to air dry. **Note:** Let it dry completely before storing or re-using it.

Caring for the Shower Kit

Keeping the Shower Kit clean helps it work properly. If it gets dirty, the Shower Kit can be washed by hand using mild soap and warm water. Before washing the kit, remove the vent assembly by undoing the snaps on the inner pouch and pulling out the entire assembly through the inner pouch.

Once the Shower Kit has been washed, hang it to drip dry. Always let it dry on its own. Never heat the Shower Kit to dry it. Make sure the Shower Kit is completely dry before using it for another shower.

Sleeping

The XVE LVAS patient must be attached to the PBU while sleeping. To reduce pulling on the exit site when the patient is sleeping, the System Controller should be secured to the patient's abdominal binder or HeartMate Stabilization Belt.

- Patients should plan to sleep only when they are connected to the PBU.
- Patients should not sleep on their stomach.
- Vent filters should be kept free from anything that restricts airflow.
- Keep both the hand pump and spare System Controller near a sleeping XVE LVAS patient for convenient access in the event of an emergency.
- Prior to sleeping, inspect and ensure that all electrical connections are secure.

Handling Emergencies

An LVAD emergency exists whenever the system cannot pump an adequate amount of blood. Emergency situations include, but are not limited to, the following:

- Loss of power to the pump
- Broken wires or a blocked percutaneous tube
- Damage to the pump motor
- Fluid in the vent filter or percutaneous tube

The System Controller will sound an alarm if the system is not working correctly. In the event of an LVAD emergency, assess pump function. If the pump is not working, immediately initiate hand pumping and seek professional medical help.

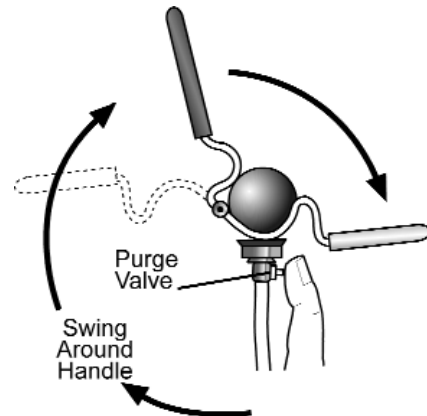
NEVER use the hand pump while patient is connected to power source. Disconnect power source before hand pumping. Do NOT hand pump if there is blood in the vent port. **Note:** Conditions that affect pump fillings, such as hypertension, hypovolemia or mechanical defects, may limit the restoration of normal pump flows until the conditions are resolved. Hand pumping may be ineffective under these conditions.

Defibrillation / Cardioversion

- 1 Explain procedure to patient.
- 2 Disconnect the System Controller from its power source (batteries, PBU, or EPP). **Note:** Always disconnect from power source before hand pumping.
- 3 Remove vent filter and connect the hand pump to the vent port of the vent adapter until a "click" is felt.
- 4 Prime the hand pump and LVAD per established protocol.
- 5 Initiate hand pumping at a rate of 60-90 bpm.
- 6 *Prior to* defibrillation or cardioversion, disconnect the System Controller from the percutaneous tube.
- 7 Defibrillate / cardiovert patient per hospital protocol.
- 8 Reconnect the System Controller to the percutaneous tube.
- 9 Disconnect hand pump.
- 10 Restore power to System Controller (i.e., batteries, PBU, or EPP).
- 11 Replace vent filter.
- 12 Assess patient.

Hand Pumping

- 1 Disconnect the System Controller from power source (i.e., batteries, PBU, or EPP). **Note:** ALWAYS disconnect from power source before hand pumping.
- 2 Connect hand pump to vent port of vent adapter. **Figure 18** Priming Hand Pump
- 3 Press and hold down white purge valve on hand pump (**Figure 18**).
- 4 Collapse bulb using your thumb.
- 5 Release white purge valve.
- 6 Release bulb.
- 7 Wait approximately 10 seconds, then press the white purge valve again and let the bulb inflate.
- 8 Separate and swing around handles.
- 9 Begin hand pumping by bringing together handles and releasing them at a rate of 60 - 90 pumps a minute. **Note:** Make sure the bulb inflates completely after each squeeze of the bulb. Do NOT exceed 90 bpm.



Changing System Controllers

In the event of a System Controller Malfunction Advisory (YELLOW WRENCH), it may be necessary to change the System Controller. To change an XVE System Controller, perform the following procedure:

- 1 Explain procedure to patient.
- 2 Have patient sit or lie down.
- 3 Obtain new XVE System Controller.
- 4 Have hand pump nearby.
- 5 Disconnect System Controller from power source (i.e., batteries, PBU, or EPP).
- 6 Disconnect the percutaneous tube from the System Controller by pushing down on the black release button and gently pulling the percutaneous tube connector out of the XVE System Controller socket.
- 7 Connect the percutaneous tube to the new XVE System Controller by lining up the small black arrows on the percutaneous tube connector and System Controller socket, and then gently pushing the connector into the socket until it snaps into place.
- 8 Connect the new System Controller to power source (i.e., batteries, PBU, or EPP).
- 9 Select desired operating mode.

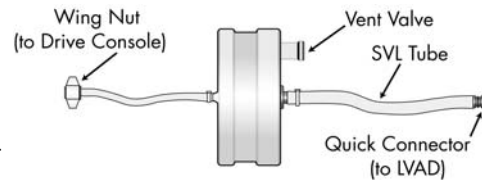
Note: A new XVE Controller will initiate in the Fixed Rate Mode at the previously selected set point (the factory setting is 50 bpm). It will be necessary to select a Rate and Mode that is appropriate for the patient. If the pump does not restart, disconnect System Controller from power source and call for professional medical help; then immediately begin hand pumping per established procedure.

- 10** Select desired Fixed Rate Setpoint on System Monitor Clinical Screen.
- 11** Assess patient.
- 12** Document that the System Controller was replaced and record the serial number for the new Controller on the Device Tracking Registry in the patient's chart.

Using the Stroke Volume Limiter (SVL) with the Pneumatic Drive Console

In the event of an emergency (e.g., in the event of electric motor failure or when the pump cannot be powered in the standard fashion via batteries or PBU), the pneumatic Drive Console may be used to actuate the XVE HeartMate with the Stroke Volume Limiter (SVL) (**Figure 19**).

Figure 19 Stroke Volume Limiter (SVL)



- 1** Explain procedure to patient.
- 2** Plug the Drive Console into a functioning, grounded (3-pronged) electric outlet.
- 3** Turn on the Drive Console by pressing the Power key.
- 4** Allow the Console to complete its system self-test.
- 5** Connect the **white** wing-nut end of the SVL to the brass fitting on the back of the Drive Console.
- 6** Disconnect hand pump from vent port of vent adapter.
- 7** Connect patient-end of SVL to vent port of vent adapter until a "click" is felt.
- 8** Simultaneously press and hold the vent valve on the SVL and the vent button on the Drive Console. Hold for 5 seconds, then release both.
The vent cycle will complete in approximately 10 seconds.
- 9** Press the FIXED key to begin pump operation (Fixed is the only mode that you can operate in).
- 10** Adjust the Fixed Rate by pressing the optional Adjustment key once and using up or down arrow keys.

- 11** Check movement of SVL Diaphragm regularly.
- 12** If diaphragm is not moving, contact Thoratec and seek professional medical help immediately. Do NOT vent or hand pump.

Venting

Venting is required once every 4 hours when using the SVL with the pneumatic Drive Console on an XVE LVAD patient. In addition, both ends of the SVL cable should be drained of condensation weekly, and as necessary.

To vent while using the SVL perform the following procedure:

- 1** Explain procedure to patient.
- 2** Ask patient to lie down.
- 3** Simultaneously press and hold the vent valve on the SVL and the vent button on the Drive Console. Hold for 5 seconds, then release both.
The vent cycle will complete and console will return to Fixed Mode.

Note: LVAD function will cease during VENT cycle.

Managing Potential Post-Implant Complications

Patient Assessment

HeartMate XVE LVAD patient assessment may include, but not be limited to, assessing the following:

- Pump function
- Vital signs
- Pump rate, stroke volume, flow, mode of operation
- Mental status, level of consciousness
- Percutaneous tube connection to System Controller
- Exit site status

Potential EARLY Post-Implant Complications

- Hypovolemia
- Right heart failure
- Pulmonary hypertension
- Cardiac tamponade
- Bleeding
- Arrhythmia
- Infection

Potential LATE Post-Implant Complications

- Hypovolemia
- Arrhythmia
- Infection
- Psycho-social issues

Post-Operative Patient Management

Exit Site Care

The percutaneous tube exit site dressing should be changed daily using strict aseptic technique (sterile gloves and mask minimally). The site should be gently cleansed with a mild disinfectant soap (preferably Chlorhexidine solution) and rinsed with sterile normal saline solution. The exit site should be covered with a dry, sterile dressing. Do NOT apply prophylactic topical agents to the exit site wound unless ordered by the patient's physician. **Note:** Do NOT cover the vent filter with the wound dressing.

Immobilize the percutaneous tube with abdominal wraps, binders, or the Stabilization Belt to reduce trauma to the exit site, especially when the patient is ambulatory. Trauma to the exit site will increase the risk of infection (see *Infection Control* below).

Infection Control

Infection among implantable LVAD patients is common, especially in patients with multi-system organ failure who require prolonged stays in the ICU. Infection rates can be minimized, however, by applying the following approaches to patient management:

- Strict adherence to aseptic technique during exit site dressings (as outlined above).
- Remove all intravascular lines as soon as practical to reduce the risk of systemic infection.
- Administer parenteral treatments with antibiotics for surgical drainage (as indicated) in patients with evidence of pump pocket infection.

Note: Refer to *Infection Control Guidelines* (document number 102512) for detailed information on approaches to successful infection control used by experienced LVAD implant centers with low rates of infection.

Managing Physiologic Conditions that May Affect Pump Life

Clinical experience indicates that high arterial pressure can put undue stress on the inflow valves, which can lead to valve incompetence that may diminished mean time to pump failure. Care must be taken, therefore, to manage physiologic conditions that may affect pump life. For example:

- Reduce arterial pressure by operating in Fixed Rate Mode whenever possible (e.g., during rest or sleep).
- Operate the LVAD at the lowest possible pump chamber pressure. **Note:** Pump

chamber pressure can be estimated by reviewing the current waveform produced by the LVAD.

Anticoagulation

Anticoagulation protocol for the HeartMate XVE LVAD is generally 80mg aspirin daily after post-operative bleeding has subsided, unless otherwise ordered by the patient's physician.

Thoratec Resources

HeartLine (24-Hour Clinical & Technical Support)

Clinicians may contact Thoratec's 24-hour HeartLine by dialing: 1-800-456-1477.

Note: The HeartLine is not intended for patient use. Patients should contact their health care providers.

Published Reference Materials

- *HeartMate XVE LVAS Instructions for Use*
- *HeartMate XVE LVAS Operating Manual*
- *HeartMate XVE LVAS Patient Handbook*
- *HeartMate XVE LVAS Surgical Checklist*
- *HeartMate XVE LVAS Pocket Guide to Hazard and Advisory Alarms*
- *HeartMate Community Living Manual*
- *Infection Control Guidelines*
- Videos and slides
- *Compendia of Selected Readings*

Published reference material and related supplies may be obtained through Thoratec's Clinical Consultants or Sales Representatives. Many of the published reference materials can be downloaded from Thoratec's web site @ www.thoratec.com

Post Test

1. **Which of the following is a contraindication for HeartMate XVE LVAS implantation?**
 - A. Increased PVR
 - B. BSA < 1.5m²
 - C. Mitral valve regurgitation

 2. **In a "LOW FLOW" (RED HEART Alarm) state which of the following is the least likely cause?**
 - A. Bleeding
 - B. Right Heart Failure
 - C. Cardiac Tamponade
 - D. Controller Malfunction

 3. **The exit site dressing should be:**
 - A. Changed daily
 - B. A sterile procedure
 - C. Changed TID and prn
 - D. Both A & B

 4. **What external system components are required for tethered operation?**
 - A. PBU, PBU cable, and System Monitor
 - B. PBU, PBU cable, and Display Module
 - C. PBU, and PBU cable only

 5. **When should the vent filter be changed?**
 - A. Weekly and prn
 - B. Monthly
 - C. Never

 6. **Before hand pumping, you should:**
 - A. Disconnect power to the System Controller
 - B. Remove the Controller battery module
 - C. Remove the vent filter
 - D. Both A & C
-

- 7. In what situation should you hand pump?**
- A. Controller Malfunction
 - B. Power Limit Advisory
 - C. LO BEAT RATE with Red Heart Alarm
- 8. The patient should be instructed to do the following in a LO BEAT RATE (Red Heart Alarm) state, after being discharged from the hospital?**
- A. Check connections & power, initiate hand pumping, and call 911
 - B. Call Thoratec's HeartLine
 - C. Change Controller
- 9. How often should the Controller self-test be performed?**
- A. Daily
 - B. Weekly
 - C. Never
 - D. When M.D. orders it
- 10. Blood flow in the HeartMate XVE LVAS patient:**
- A. Right atrium, right ventricle, lungs, left atrium, left ventricle, HeartMate XVE LVAD, aorta
 - B. Right atrium, right ventricle, HeartMate XVE LVAD, lungs, left atrium, left ventricle, aorta
 - C. Right atrium, right ventricle, lungs, left atrium, HeartMate XVE LVAD, left ventricle, aorta

Competency Assessment

HeartMate XVE LVAS Competency Assessment Documentation

Competency Criteria	Verification
1 Explain the differences between Fixed and Auto Modes.	
2 Name the major components of the HeartMate XVE LVAS.	
3 Interpret icons on the PBU battery charger.	
4 Verbalize typical battery times and estimate time remaining using the Battery Fuel Gauge.	
5 Identify differences between RED HEART hazard alarms and YELLOW WRENCH advisory alarms. Verbalize appropriate responses to alarm conditions.	
6 Demonstrate how to perform the System Controller Self-Test and explain reasons for performing this test.	
7 Verbalize frequency of changing vent filter.	
8 Demonstrate how to change modes.	
9 Explain significance of System Controller battery module.	
10 Identify alarm silence button and verbalize silence times for RED HEART and YELLOW WRENCH alarms.	
11 Demonstrate procedure for changing from PBU to battery power.	
12 Identify reasons for using the hand pump and then demonstrate procedure for priming the hand pump.	
13 Demonstrate procedure for exchanging System Controllers.	
14 Describe the reason why batteries or power leads should be disconnected/unplugged only one at a time.	

Signature _____ Date _____

Name (printed) _____

Program Evaluation

PROGRAM TITLE:

HeartMate XVE LVAS Clinical Operation & Patient Management

Program Date:

Presenter:

Location:

Program Evaluation	Excellent	Good	Fair	Poor	N/A
1 Program met stated objectives.					
2 Content covered topic adequately.					
3 Rate overall this program.					
4 Rate the program facilities.					

Speaker Evaluation	Excellent	Good	Fair	Poor	N/A
5 Rate overall quality of speakers.					
6 Speaker was organized & effective.					
7 Speaker was qualified.					
8 Speaker held interest.					

The most useful part of this presentation was:

The least useful part of this presentation was:

Additional suggestions:

