HEARTMATE 3™
LEFT VENTRICULAR ASSIST DEVICE (LVAD)
PATIENT GUIDE

VIVIAN
HeartMate 3™ LVAD Recipient
QUICK START GUIDE

This patient guide is for using the HeartMate 3™ Left Ventricular Assist Device (LVAD) that both the patient and caregiver will need to be familiar with upon hospital discharge. Although most of the procedures can be performed by the patient, a caregiver’s assistance will be needed in some cases. For more detailed information about monitoring and maintaining the equipment, consult the complete HeartMate 3™ Left Ventricular Assist System Patient Handbook.

WARNINGS AND CAUTIONS

Review all the warnings and cautions in the HeartMate 3 Left Ventricular Assist System Patient Handbook.

**WARNINGS** refer to actions or hazardous conditions that could cause serious injury or death.

**CAUTIONS** refer to actions or potentially unsafe conditions that are usually not life-threatening risks but may cause injury, damage the equipment or affect how the system works.
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THE HEARTMATE 3™ LVAD SYSTEM

1. **HEART PUMP**
   Connects to the left side of your heart and moves blood from your heart to the rest of your body.

2. **DRIVELINE**: PAGE 23
   Transfers power and information between the controller and the heart pump.

3. **SYSTEM CONTROLLER**: PAGE 9
   Powers and checks the pump and driveline. The controller uses alerts to tell you how the system is working and includes 15 minutes of emergency backup power.

4. **BATTERIES AND BATTERY CLIPS**: PAGE 27
   Powers the system when you are active or outdoors. You always need to use two batteries at a time.

5. **BATTERY CHARGER**: PAGE 28
   Charges up to four 14 V lithium-ion batteries at a time and measures battery charge status.

6. **MOBILE POWER UNIT (MPU)**: PAGE 30
   Provides power to the System Controller and pump. Echoes System Controller alarms.
THE HEARTMATE 3™ LVAD SYSTEM:
WHAT SHOULD I KNOW PRIOR TO HOSPITAL DISCHARGE?

• How to switch the power sources, from MPU to battery to MPU
• How to change the batteries
• How to recharge the batteries
• How to calibrate the batteries
• How to care for the driveline exit site
• How to change the internal MPU battery
• How to change to the backup System Controller (in case of an emergency)

IMPORTANT:
Be sure to keep a backup System Controller and charged batteries with you at all times for use in case of an emergency.
The **System Controller** is a small computer that controls and checks system information. It is connected to the pump via the driveline. It is used to control and respond to system operation. It identifies and warns of any problems in the system operation.

The System Controller consists of control buttons, lighted symbols and a user interface screen.

1. **POWER SOURCE CONNECTIONS**

2. **DRIVELINE CONNECTION**

3. **CONTROL BUTTONS**
   a. Battery button
   b. Display button
   c. Silence alarm button

4. **LIGHTED SYMBOLS**
   a. Cable disconnect symbols
   b. Status symbols
   c. Pump running symbol

5. **USER INTERFACE SCREEN**
SYSTEM CONTROLLER: BUTTONS AND USER INTERFACE SCREEN

1. BATTERY BUTTON
   - Displays the battery power (press and release).
   - Tests the controller (press and hold for 5 seconds).
   - Puts the controller into sleep mode (press and hold for 5 seconds when nothing is connected to the controller).

2. DISPLAY BUTTON
   Activates the user interface screen (press and release) to display information about system operation.

3. SILENCE ALARM BUTTON
   - Silences an active alarm (press and release).
   - Displays previous alarms (press and release the silence alarm and display buttons simultaneously).

4. USER INTERFACE SCREEN
   Displays information including pump speed, pump flow, pulsatility index, power and charge status of the backup battery.
# SYSTEM CONTROLLER: USER INTERFACE SCREEN DISPLAY

<table>
<thead>
<tr>
<th>DISPLAY BUTTON ACTIONS</th>
<th>SCREEN DISPLAYED (EXAMPLE)</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press ONCE</td>
<td>Pump Speed ▲ 5500 RPM</td>
<td>Pump speed in revolutions per minute</td>
</tr>
<tr>
<td>Press SECOND time</td>
<td>Flow 5.2 LPM</td>
<td>Pump flow in liters per minute</td>
</tr>
<tr>
<td>Press THIRD time</td>
<td>PI 3.2</td>
<td>Pulsatility index</td>
</tr>
<tr>
<td>Press FOURTH time</td>
<td>Power 5.2 W</td>
<td>Power in watts</td>
</tr>
<tr>
<td>Press FIFTH time</td>
<td>Backup Battery Charged</td>
<td>The System Controller’s backup battery (located inside the System Controller and used to temporarily run the pump during an emergency) has three charge status states: 1. Charged (ready for use) 2. Charging (actively charging)</td>
</tr>
<tr>
<td>Press SIXTH time</td>
<td>Blank user interface screen</td>
<td>Blank user interface screen indicates the screen is off, which is normal</td>
</tr>
</tbody>
</table>
SYSTEM CONTROLLER: LIGHTED SYMBOLS

The System Controller provides information about the system’s functioning using lighted symbols on the device. The symbols indicate when the pump is running or when there's a problem with the pump's functioning that needs immediate attention. Other symbols indicate remaining battery power, problems with the connections to the power cable or driveline, or other issues with the system.

YELLOW LIGHT
Near the white or black power cables comes on when a power cable is not well connected with or is disconnected from the System Controller.

RED LIGHT
Near the driveline connector comes on when the driveline is not well connected with or is disconnected from the System Controller.
**PUMP RUNNING LIGHT**
Stays lit green as long as the LVAD is running.

**BATTERY CAPACITY LIGHT**
4 green lights = Approximately 75%–100% of power remains
3 green lights = Approximately 50%–75% of power remains
2 green lights = Approximately 25%–50% of power remains
1 green light = Less than 25% of power remains
Yellow diamond only = Less than 15 minutes of power remains

**LOW BATTERY ALERT**
Less than 5 minutes of battery power remain. Immediately replace used batteries with fully charged batteries or switch to the MPU.

**HAZARD ALARM**
When the red heart symbol comes on, follow the on-screen instructions. Do this immediately.

**YELLOW WRENCH**
Lights up yellow when the System Controller detects a mechanical, electrical or software issue with the system.
SYSTEM CONTROLLER: ALARMS

System Controller advisory and hazard alarms are messages that appear on the user interface screen when some problem with the system needs immediate attention. Some of the alarms indicate problems you can address yourself (for example, a disconnected power cable that you should reconnect). But most instruct you to call your hospital contact for instructions.

### ADVISORY

<table>
<thead>
<tr>
<th>SYSTEM CONTROLLER SCREEN</th>
<th>ACTIVE SYMBOLS</th>
<th>ALARM MEANS</th>
<th>TO RESOLVE ALARM</th>
</tr>
</thead>
</table>
| Connect Power             | ![Disconnect symbol] | One of two power cables is disconnected | 1. Promptly connect the disconnected power cable to the power source (functioning MPU or two fully charged HeartMate 3™ LVAD 14 V lithium-ion batteries).  
2. If alarm persists, call your hospital contact. |
| Replace Power             | ![Batteries symbol] | Low battery, power input is low, with less than 15 minutes remaining | 1. Promptly connect to a working or different power source (MPU or two fully charged HeartMate 3 LVAD 14 V lithium-ion batteries).  
2. If alarm persists, call your hospital contact. |
| Low Battery               | ![Batteries symbol] | System Controller hardware fault | Call your hospital contact as soon as possible for diagnosis and instructions. |

ADVISORY OR SYSTEM CONTROLLER: ALARMS

System Controller advisory and hazard alarms are messages that appear on the user interface screen when some problem with the system needs immediate attention. Some of the alarms indicate problems you can address yourself (for example, a disconnected power cable that you should reconnect). But most instruct you to call your hospital contact for instructions.
### SYSTEM CONTROLLER: ALARMS

#### ADVISORY

<table>
<thead>
<tr>
<th>SYSTEM CONTROLLER SCREEN</th>
<th>ACTIVE SYMBOLS</th>
<th>ALARM MEANS</th>
<th>TO RESOLVE ALARM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call Hospital Contact</td>
<td>![Symbol]</td>
<td>System Controller backup battery fault</td>
<td>Call your hospital contact as soon as possible for diagnosis and instructions.</td>
</tr>
<tr>
<td>Backup Battery Fault</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call Hospital Contact</td>
<td>![Symbol]</td>
<td>System Controller backup battery not installed</td>
<td>Call your hospital contact as soon as possible for diagnosis and instructions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**IMPORTANT:** The pump running symbol 🎉 is always lit green when the pump is running.
# System Controller: Alarms

<table>
<thead>
<tr>
<th>System Controller Screen</th>
<th>Active Symbols</th>
<th>Alarm Means</th>
<th>To Resolve Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Flow</td>
<td>⚠️ :03</td>
<td>Heart</td>
<td>1. Immediately connect to a working power source (MPU or two fully charged HeartMate 3™ LVAD 14 V lithium-ion batteries).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Running</td>
<td>2. If connecting to a power source does not resolve the problem, press any button on the System Controller to attempt a pump start and call your hospital contact immediately.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symbol ☢</td>
<td></td>
</tr>
<tr>
<td>Call Hospital Contact</td>
<td>⚠️ :07</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connect Power Immediately</td>
<td>⚠️ :03</td>
<td>Battery</td>
<td>1. Immediately connect to HeartMate 3 LVAD 14 V lithium-ion batteries.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Running</td>
<td>2. If restoring power does not resolve, press any button on the System Controller to attempt pump start.</td>
</tr>
<tr>
<td>Backup Battery</td>
<td>⚠️ :07</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Connect Driveline</td>
<td>⚠️ :02</td>
<td>Driveline</td>
<td>1. Immediately reconnect the driveline to the System Controller and move the driveline safety tab on the System Controller to the locked position.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Running</td>
<td>2. If alarm persists after reconnecting the driveline, press any button on the System Controller to potentially resolve.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symbol ☢</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3. If driveline is connected and alarm persists, replace System Controller with a programmed backup System Controller.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4. If alarm persists, call your hospital contact immediately.</td>
</tr>
<tr>
<td>SYSTEM CONTROLLER SCREEN</td>
<td>ACTIVE SYMBOLS</td>
<td>ALARM MEANS</td>
<td>TO RESOLVE ALARM</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------</td>
<td>-------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Backup Battery</td>
<td></td>
<td>Both power cables are disconnected.</td>
<td>1. Immediately connect to a working power source (MPU or two fully charged HeartMate 3™ LVAD 14 V lithium-ion batteries). 2. If alarm persists, call your hospital contact immediately.</td>
</tr>
<tr>
<td>Connect Power Immediately</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call Hospital Contact</td>
<td></td>
<td>Low flow: Flow is less than 2.5 liters per minute.</td>
<td>Call your hospital contact immediately for diagnosis and instructions.</td>
</tr>
<tr>
<td>Replace Power Immediately</td>
<td></td>
<td>Low voltage: Power input is extremely low, with less than 5 minutes remaining.</td>
<td>1. Immediately connect to a working power source (MPU or two fully charged HeartMate 3 LVAD 14 V lithium-ion batteries). 2. If alarm persists, call your hospital contact immediately.</td>
</tr>
<tr>
<td>Low Battery</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
SYSTEM CONTROLLER: CHANGES TO BACKUP SYSTEM CONTROLLER — MULTIPLE SOURCES

Replace the running System Controller with the backup controller and multiple available power sources.

1. SET UP

This procedure will require assistance from a caregiver.

1. Place the backup System Controller within reach.

2. Ensure the patient is sitting or lying down, as he or she may get dizzy if the pump stops briefly.

3. Unlock the driveline safety tab for both controllers (see the image below).

CAUTION:

Do NOT attempt to change your System Controller without having a trained, competent caregiver at your side to assist. Follow all alarm instructions, including calling the hospital. Always contact your LVAD center before changing System Controllers.
SYSTEM CONTROLLER: CHANGES TO BACKUP SYSTEM CONTROLLER — MULTIPLE SOURCES

Replace the running System Controller with the backup controller and *multiple available* power sources.

2. REPLACE SYSTEM CONTROLLER

**Important:** Keep the running System Controller connected to power.

1. Connect the white and black connectors on the backup System Controller to power.

2. Promptly move the driveline from the running controller to the backup controller (see steps A–C below).

3. Make sure that the green pump running symbol (○) on the backup System Controller is illuminated.

A. Align the driveline arrow/alignment mark with the arrow on the controller.

B. Push the red button and firmly insert the driveline until it snaps into place.

C. Slide the safety tab over the red button.

**Important:** If the safety tab does not slide fully over the red button, the driveline is not connected. Disconnect the driveline and reconnect it.

3. FINISH

1. Put the old, replaced System Controller into sleep mode by disconnecting from the power, and then pressing and holding the battery button for 5 seconds.

2. Do not use the old System Controller ever again. To request a new backup System Controller and for instructions on returning the old one, contact the hospital.
SYSTEM CONTROLLER: **CHANGES TO BACKUP SYSTEM CONTROLLER — SINGLE SOURCE**

Replace the running System Controller with the backup controller and a *single available* power source (exchange while on MPU or batteries only).

**1. SET UP**

This procedure will require assistance from a caregiver.

1. Place the backup System Controller within reach.

2. Ensure the patient is sitting or lying down, as he or she may get dizzy if the pump stops briefly.

3. Unlock the driveline safety tab for both controllers (see the image below).

---

**CAUTION:**

Do NOT attempt to change your System Controller without having a trained, competent caregiver at your side to assist. Follow all alarm instructions, including calling the hospital. Always contact your LVAD center before changing System Controllers.
SYSTEM CONTROLLER: CHANGES TO BACKUP SYSTEM CONTROLLER — SINGLE SOURCE

Replace the running System Controller with the backup controller and a single available power source.

2. REPLACE SYSTEM CONTROLLER

1. Move the white connector’s power source from the running controller to the backup System Controller.

2. Promptly move the driveline from the running controller to the backup controller (see steps A–C below).

   A. Align the driveline arrow/alignment mark with the arrow on the controller.

   B. Push the red button and firmly insert the driveline until it snaps into place.

   C. Slide the safety tab over the red button.

   Important: If the safety tab does not slide fully over the red button, the driveline is not connected. Disconnect the driveline and reconnect it.

3. Make sure that the green pump running symbol (直辖市) on the backup controller is illuminated.

4. Move the black connector’s power source from the running System Controller to the backup controller.

3. FINISH

1. Put the old, replaced System Controller into sleep mode by disconnecting from the power, and then pressing and holding the battery button for 5 seconds.

2. Do not use the old System Controller ever again. To request a new backup System Controller and for instructions on returning the old one, contact the hospital.
SYSTEM CONTROLLER: PERFORM A CONTROLLER SELF TEST

Perform a System Controller self test every day to check the audible and visual alarm indicators on the user interface. The System Controller self test is a loud, bright function. All the audible and visual indicators should come on and “Self Test” should appear on the screen.

To perform a System Controller self test:

1. Press and hold the battery button for 5 seconds.
2. Check that:
   - “Self Test” appears on the screen.
   - All symbols and indicators on the user interface illuminate at the same time.
   - System Controller is making a loud, steady, audible alarm tone.
3. Release the battery button. All the audible indicators/lights should remain on for 15 seconds, after which the audible indicators/lights stop, the screen goes black and the self test is complete.

IMPORTANT:
If an alarm occurs during a self test, the self test terminates and the alarm’s on-screen indicator remains active. A System Controller self test cannot be initiated during the following alarms: any hazard alarm, power cable disconnected advisory alarm or low battery power advisory alarm.
It is very important to keep the driveline exit site (where the driveline goes through the skin) clean and dry at all times. Keeping the exit site clean and dry lowers your risk for infection. After leaving the hospital, you are responsible for caring for the exit site. Be sure to always follow the steps provided by your nurse or hospital contact. A driveline management system, supplied by the implanting center, should be used at all times. The driveline management system should consist of a dressing and stabilizer.

If you notice any signs of infection, call your hospital contact right away. Do not wait! Early treatment makes a difference.
An 11 V lithium-ion backup battery inside the System Controller provides at least 15 minutes of backup power to the LVAD if the in-use power source is disconnected or fails.

The System Controller’s backup battery will be charged once external power is connected to the System Controller (batteries or MPU).

**WARNING:**
The 11 V lithium-ion backup battery should be used only for temporary support during a power-loss emergency. Inappropriate use of this backup battery may result in diminished run time during a power-loss emergency.
CHEST ECG OR SLIPPER ECG

System Controller: Charging the Backup Battery

Charge the backup battery inside the backup System Controller.

1. Connect the backup System Controller to a power source (MPU or two HeartMate 3™ LVAD 14 V lithium-ion batteries).

2. When the System Controller is connected to power, the user interface screen displays “Charging” or “Charging Complete.”

3. When charging is complete, perform a self test on the backup System Controller (press and hold the battery button for 5 seconds).

4. Disconnect power from the backup System Controller. Place the backup System Controller back in the protective case. No further action is needed for 6 months.

**CAUTION:**
The 11 V lithium-ion backup battery inside the backup System Controller must be charged once every 6 months.

**IMPORTANT:**
Do not remove power until “Charging Complete” is displayed. It can take up to 3 hours to charge the System Controller’s backup battery.
POWERING THE SYSTEM
POWERING THE SYSTEM: 14 V LITHIUM-ION BATTERIES

The HeartMate 3™ LVAD uses 14 V lithium-ion batteries that provide up to 17 hours of support. They require 4 hours to charge. Five lights on each battery indicate the amount of power remaining in the battery.

SUPPORT TIME
10–17 hours

CHARGING TIME
4 hours

<table>
<thead>
<tr>
<th>NUMBER OF LIGHTS ILLUMINATED</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚫⚫⚫⚫⚫ 5 lights</td>
<td>Approximately 80%–100% of power remains</td>
</tr>
<tr>
<td>⚫⚫⚫⚫ 4 lights</td>
<td>Approximately 60%–80% of power remains</td>
</tr>
<tr>
<td>⚫⚫⚫ 3 lights</td>
<td>Approximately 40%–60% of power remains</td>
</tr>
<tr>
<td>⚫⚫ 2 lights</td>
<td>Approximately 20%–40% of power remains</td>
</tr>
<tr>
<td>⚫ 1 light steady</td>
<td>Approximately 10%–20% of power remains</td>
</tr>
<tr>
<td>⚫ 1 light blinking</td>
<td>Approximately 10% or less of power remains. <strong>Do not</strong> use if battery has one blinking light. The HeartMate 3 LVAD System Controller will indicate a power advisory</td>
</tr>
</tbody>
</table>
POWERING THE SYSTEM: UNIVERSAL BATTERY CHARGER

<table>
<thead>
<tr>
<th>LED INDICATORS</th>
<th>LED LIGHT COLOR</th>
<th>STATUS/MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Green</td>
<td>Battery is charged and ready for use.</td>
</tr>
<tr>
<td></td>
<td>Yellow</td>
<td>Battery is undergoing test, charging or calibration.</td>
</tr>
<tr>
<td></td>
<td>Yellow blinking</td>
<td>Battery requires calibration cycle (see the example on the next page).</td>
</tr>
<tr>
<td></td>
<td>Red</td>
<td>Battery or charging system is defective. <strong>DO NOT USE BATTERY.</strong></td>
</tr>
</tbody>
</table>
POWERING THE SYSTEM:
BATTERY CHARGER DISPLAY MESSAGES

MESSAGES GENERATED BY PRESSING THE SLOT NUMBER

Available power

Cycle count and charger capacity

AUTOMATIC MESSAGES

Call hospital for service

For example, slot 4 needs calibration

Press 4

Calibration is in progress for 12 hours
POWERING THE SYSTEM: MOBILE POWER UNIT (MPU) OVERVIEW

The MPU plugs into an AC outlet to provide power to the HeartMate 3™ LVAD System and is used while indoors, stationary or sleeping. The MPU transfers power to the System Controller through the patient cable.

1. SPEAKERS
   Sound alarm in case of system problems that need attention.

2. AC POWER RECEPTACLE
   For plugging unit into AC power outlet.

3. STATUS SYMBOLS
   Provide information about the system status.

4. PATIENT CABLE
   Connects to the System Controller to transfer power.
POWERING THE SYSTEM: SWITCHING POWER SOURCES

FROM MPU TO BATTERIES

CONNECT
Black to black
White to white

FROM BATTERIES TO MPU
POWERING THE SYSTEM:
MPU ALARMS AND TROUBLESHOOTING

ADVISORY

<table>
<thead>
<tr>
<th>STATUS SYMBOLS</th>
<th>ALARM MEANS</th>
<th>TO RESOLVE ALARM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Internal fault</td>
<td>1. Promptly connect to two fully charged HeartMate 3™ LVAD 14 V lithium-ion batteries.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Call your hospital contact as soon as possible for diagnosis and instructions.</td>
</tr>
</tbody>
</table>

Replace MPU batteries

| Replace MPU batteries | Replace the AA batteries in the MPU. |

CHANGING THE ALKALINE AA BATTERIES

1. Loosen the screw from the rear panel.

2. Open the battery compartment and pull the red ribbon to remove the batteries.

3. Place the alkaline AA batteries in the compartment.

4. Close the compartment and tighten the screw.
ACCESSORIES
Shower Bag
Keeps the controller and the batteries dry when you shower.

Consolidated Bag
Holds both the controller and the batteries in one bag.

Battery Holster
Allows the batteries to be carried in shoulder straps.

Belt Attachment
An alternative way of wearing the controller.

Holster Vest
A mesh vest that carries the batteries and spreads their weight across the torso.
Important Safety Information

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

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

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

Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: 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) or device thrombosis.