HeartMate II® Left Ventricular Assist Device

JMT 2017 System Overview

[Logos of Miami Transplant Institute and Jackson Memorial Hospital]
HeartMate II System

HeartMate II (HM II)

Thin, flexible driveline cable exits skin

Small pump

A small controller & batteries run the pump

Doc # 104249C
HM II- System-External View

**HM II Pump External View**

- Sealed Outflow Graft (14 mm)
- Bend Relief
- Inflow Conduit (20 mm)
  - Flex Section
    - Knitted polyester sealed graft
    - Silastic sleeve
- Percutaneous lead (8 mm)
- Blood Pump
**HM II- LVAD Pump**

- Flexible inflow conduit
- Textured surfaces
- Outflow graft with bend relief
- Anastomosed to LV apex and ascending aorta
- Pump output varies over cardiac cycle
  - Follows native pulse
  - Afterload sensitive
HM II- Device Parameters

❤ Device parameters
  - Speed
  - Power
  - Flow
  - PI

❤ Monitoring
  - Normal:
    - Fixed set speed ±150 rpm
    - Decrease in RPM to low speed limit (PI Event)
  - Failure to maintain fixed speed in absence of PI event indicates issue with:
    - Pump
    - Percutaneous lead
    - Controller
HM II- Pump Power

❤ Measured in watts
❤ Related to pump speed and flow
❤ Under normal patient conditions, power should remain within a certain range for a specified speed
  ↑ Speed → ↑ Power
  ↓ Speed → ↓ Power

❤ Flow
  ↑ Flow → ↑ Power (takes more work to move more blood)
  ↓ Flow → ↓ Power (does not compensate for ↑ afterload
HM II-Pump Power

❤ Monitoring
- Normal
  - Increases or decreases with pump flow and speed without abrupt changes
  - Power fluctuations of 1-2 watts do not necessarily indicate a problem but should be closely monitored
  - Power values > 10–12 Watts requires further investigation
    - Monitor trends for both ↑ and ↓ in Watts
    - Is patient symptomatic?
    - If yes, assess for elevated LDH and hemolysis!
Pump flow is a function of:

- The speed of the rotor
  - ↑ Speed → ↑ Flow
  - ↓ Speed → ↓ Flow

- At any given speed, increased B/P will decrease flow.
The Pulsatility Index (PI) is a measurement of the flow pulse through the pump:

- It is determined by pump speed and the degree of native LV contractility
- Pump speed determines the amount of LV unloading
  - ↑ Speed → ↓ PI
  - ↓ Speed → ↑ PI

- Size of flow pulse reflects degree of LV contractility
  - ↑ LV Preload → Frank-Starling curve is impacted → ↑ PI
  - ↓ LV Preload → pulsatility of the LV decreases → ↓ PI
HM II- Pulsatility Index Cont’d

- PI will naturally vary by patient.
- Changes in patient status is indicative of alternation in:
  - Volume status due to altered preload
  - Natural heart's contractility
**HM II- System Monitor Function**

- Monitor and adjust system parameters:
  - Displays current LVAD performance information
  - Displays alarms and operating status
  - Modification of fixed speed set point and low speed limit
  - Stop or start pump
- View and save performance data
HM II-System Monitor Software

- Touch screen menu tabs across top of the screen
HM II-Clinical Screen

❤ Displays:
  - Primary operating parameters
  - 2 highest priority alarm message banners
❤ Information updated every second
❤ Default screen
HM II-Clinical Screen
Pump Flow Display

- Flow display on
- Flow display off, no alarms
- Pump speed below 8,000 rpm
- Flow estimation above green zone
- Flow estimation below green zone
HM II-Clinical Screen
Pump Flow display

♥ Pump stopped or percutaneous lead disconnected!

♥ Low Flow hazard!

♥ Low flow alarm!
  - Pump stopped or driveline disconnected!
HM II- Clinical Screen

Pump Speed Display

🖤 Pump on

🖤 Pump stopped!

🖤 Driveline disconnect from controller!
HeartMate II Pocket System Controller
HeartMate II Pocket System Controller

User Interface displays the following and is available in 37 languages:

- Pump parameters (Flow, Speed, Power, PI) and status of Backup Battery charge
- Visual alarms with clear, actionable instructions
- Accessible alarm history of last six alarms
- Delivers power to the pump
- Controls and monitors system operation
- Identifies alarm conditions and initiates Hazard and Advisory Alarms
- Contains a backup battery that provides emergency power to the pump
- Provides driveline diagnostic capability
- Records and stores alarm data and device performance (240 events)
- Display Module no longer required
Pocket System Controller-User Interface

User Interface
HeartMate II Pocket System Controller

Alarm Indicators

- Black Power Lead Symbol
- White Power Lead Symbol
- Driveline Symbol
- Battery Advisory symbol
- Battery Hazard symbol
- Red Heart Hazard symbol
- Yellow wrench advisory symbol
HeartMate II Pocket System Controller Battery Gauge

On 14 Volt Lithium-Ion battery power:

- 4 green bars = 75–100% of battery power remains.
- 3 green bars = 50–75% of battery power remains.
- 2 green bars = 25–50% of battery power remains.
- 1 green bar = less than 25% of battery power remains.
HeartMate II Pocket System Controller
Self Test

Perform a Pocket System Controller Self Test daily:

- Press and hold Battery Button
- Release button after alarm sounds and indicators light up
- Screen will briefly turn white then black, and then display “Self Test”
- All audible/visible indicators remain on for 15 seconds, then turn off & screen goes black to indicate self test is complete
- Pump running light will stay off briefly then illuminate green
HeartMate II Pocket System Controller - Self Test Cont’d

- Self test terminates if an alarm occurs; the alarm’s indicator remains active.
- A Self test cannot be initiated when an alarm is active.
HeartMate II Pocket System Controller - Advisory & Hazard Alarms

♥ Advisory Alarms
- Power Cable Disconnected
- Low Voltage
- Controller Fault
- Backup Battery Fault
- Low Speed
- Driveline Fault
- Backup Battery Not Installed
- Controller Clock Not Set

♥ Hazard Alarms
- Pump Off
- Driveline Disconnected
- No External Power
- Low Flow
- Low Voltage
HeartMate II Pocket System Controller- Alarms Cont’d

♥ Only highest priority alarm displayed on Pocket System Controller user interface screen.

♥ Active alarms indicated by:
   – Message
   – Visual symbol
   – Audible tone

♥ Alarm History can be viewed during active alarms
HeartMate II Pocket System Controller- Silencing Alarms

❤ Advisory Alarms
- Yellow Wrench alarms 4 hours
- Low Battery advisory alarm 5 minutes
- Alarm resets when:
  - Alarm condition is resolved
  - Silence period expires
  - Hazard or new advisory alarm occurs

❤ Hazard Alarms and Power Cable Disconnected Advisory Alarm 2 minutes
- Alarm resets when:
  - Alarm condition is resolved or 2 minute silence period expires
  - New hazard alarm occurs
  - Audible advisory alarms will not occur until the hazard or power cable disconnected alarm has resolved
HeartMate II Pocket System Controller - Viewing Alarm History

❤️ Last 6 alarms can be viewed on controller display
  • Simultaneously press silence alarm & display buttons
  • To view the next alarm, press display button
HeartMate II Pocket System Controller-Viewing Alarm History Cont’d

- Alarms NOT displayed on controller alarm history
  - Non transient alarms that require specific action to resolve
    - Driveline Fault
    - Backup Battery Fault
    - Controller Fault
  - Routine events
    - PI Events
    - Power Cable Disconnected (< 30 seconds)
HeartMate II Pocket System Controller: Controller Alarms

To hear alarm:
Click on picture and then click on play button

Power Cable Disconnected advisory alarm can be silenced for 2 minutes

Actions:
- Ensure power leads are connected to a power source
- Check PM patient cable and pocket system controller power leads for damage, replace if necessary
HeartMate II Pocket System Controller - Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

- Backup Battery Fault advisory alarm can be silenced for 4 hours
  - If this alarm appears, contact VAD team so they can replace pocket system controller’s 11 volt Li-ion backup battery
HeartMate II Pocket System Controller-Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

Backup Battery Not Installed advisory alarm can be silenced for 4 hours
– If this alarm should appear contact VAD team so they can install pocket system controller’s 11 volt Li-Ion backup battery
HeartMate II Pocket System Controller-Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

Controller Clock Not Set advisory alarm can be silenced for 4 hours
– If this alarm appears, contact VAD team so they can set the controller clock via the Admin screen
HeartMate II Pocket System Controller - Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

♥ Driveline Fault advisory alarm can be silenced for 4 hours or until any new alarm occurs.
  – Can permanently silence from System Monitor Alarms screen.

♥ If this alarm appears, contact VAD team
HeartMate II Pocket System Controller - Controller Alarms Cont’d

- Low Speed advisory alarm can be silenced for 4 hours or until any new alarm occurs
  - If this alarm occurs contact VAD team
Controller Fault Alarm advisory alarm, operating on primary system, can be silenced for 4 hours or until any new alarm occurs.

Action:
- Replace pocket system controller
- Provide another backup pocket system controller
NOTE:
- If LED display affected, only “Replace Controller, Controller Fault” will be displayed. Visual indicators and audio tones for other alarms will occur as normal. Pump parameters and alarm history cannot be viewed.
- If this alarm should appear contact VAD team
Controller Fault advisory alarm, operating on backup system, can be silenced for 1 hour or until a hazard alarm occurs.

Action
- Replace pocket system controller
- Provide another backup pocket system controller

Note: Pocket system controller will not communicate with System Monitor — initialization screen and “Not receiving data” will be displayed. If this alarm should appear contact VAD team.
HeartMate II Pocket System Controller-Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

♥ Low Battery advisory alarm can be silenced for 5 minutes or until any new alarm occurs
♥ Action: Immediately replace batteries or switch to the Power Module
HeartMate II Pocket System Controller- Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

♥ Low Battery hazard alarm can be silenced for 2 minutes
♥ Action: Immediately replace batteries or switch to the Power Module
HeartMate II Pocket System Controller-Controller Alarms Cont’d

To hear alarm:
Click on picture
and then click on play button

♥ Low Flow hazard alarm can be silenced for 2 minutes
♥ Action: Evaluate patient for signs/symptoms of distress
HeartMate II Pocket System Controller - Red Heart Hazard Alarms: Low Flow

♥ Causes:
- Decreased preload (right heart failure, tamponade, hypovolemia, bleeding, etc)
- Obstruction of pump inflow or outflow
- Systemic hypertension
- Pump off or driveline disconnected

♥ Actions:
- Assess patient
- Obtain ECHO to assess RV, LV function, and inlet cannula obstruction
- Treat underlying cause
HeartMate II Pocket System Controller
Alarms

To hear alarm:
Click on picture
and then click on play button

♥ Driveline Disconnected hazard alarm can be silenced for 2 minutes
♥ Action:
  — Immediately reconnect driveline and lock safety tab. If pump does not automatically start, press any button on the controller.
  — If alarm persists, replace pocket system controller with programmed backup controller.
  — If this alarm appears contact VAD team

Warning: If pump stops, retrograde flow may occur; and, if blood is stagnant in the pump for more than a few minutes, there is a risk for stroke or thromboembolism should the device be restarted!
HeartMate II Pocket System Controller - Driveline Disconnected

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<th>Alarms</th>
<th>Save Data</th>
<th>History</th>
<th>Admin</th>
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</thead>
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<tr>
<td><strong>Pump Flow</strong></td>
<td><strong>Pump Speed</strong></td>
<td><strong>Pulse Index</strong></td>
<td><strong>Driveline Disconnected</strong></td>
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<tr>
<td><strong>Fixed Mode - Speed Setpoint: 9000 rpm</strong></td>
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<tr>
<td><strong>PUMP OFF</strong></td>
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<tr>
<td><strong>LOW FLOW, 0 min</strong></td>
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</tbody>
</table>
HeartMate II Pocket System Controller - Alarms

- Pump Off hazard alarm can be silenced for 2 minutes

- Action:
  - Check if fixed speed < 8,000 rpm
    - Backup battery installed – press any button on controller
    - Backup battery NOT installed – press pump start button on System Monitor
  - If alarm persists, replace controller with programmed backup controller
  - Clinically evaluate patient
  - If this alarm should appear contact VAD team
HeartMate II Pocket System Controller - Alarms

♥ No External Power hazard alarm can be silenced for 2 minutes

♥ Action:
  – Check controller connections to power
  – Check PM patient cable connected to PM
  – Change power source

♥ Note: Backup battery will provide full support for at least 15 minutes. Then enters power saver mode and pump speed drops to low speed limit to conserve power. Once external power connected, pump speed returns to fixed speed setting.
HeartMate II EPC System Controller
HeartMate II System Controller

Microprocessor:
- Delivers power to the pump
- Controls pump speed and power
- Monitors, interprets & responds to system performance
- Performs diagnostic monitoring
- Indicates hazard and advisory alarms
- Provides complete backup system
- Event recording capability
System Controller User Interface
System Controller User Interface

- Test Select Button
- Battery Fuel Gauge
- Battery Symbol (Yellow & Red)
- Silence Alarm Button
- Power Symbol
- Cell Module Symbol
- Red Heart Symbol
System Controller Perc Lock

Design implemented to prevent accidental driveline disconnects from the system controller.
After inserting the driveline into the controller, check the connection by gently tugging on the metal end of the driveline to ensure proper attachment.
System Controller Event Recorder

- Allows performance data to be collected and stored in the system controller’s memory in 2 ways:
  - As events occur
    - Automatically records data during alarm conditions or change in fixed speed setting
    - Factory setting: On (cannot be turned off)
  - At specified record intervals
    - Captures and stores data in system controller at set time intervals from 30 minutes up to 24 hours in hourly increments
    - Factory setting: Off
- Maximum of 120 events can be stored
  - Once full, oldest events are deleted and new ones are saved

NOTE: Events can be viewed on the System Monitor History Screen
System Controller Self Test

❤ Perform daily
   - Pump operation is not affected
   - Checks lamps and audio tones only

❤ To Perform:
   - Press and hold Test Select button
   - After 3 seconds, verify all lamps illuminate and unbroken audio tone
   - Release the button. Tone and lamps will remain for at least 5 seconds
Advisory & Hazard Alarms

❤️ Advisory Alarms
- Power Cable Disconnected
- SC Battery Module Low
- Replace System Controller
- Low Speed Operation
- Low Voltage

❤️ Hazard Alarms
- Low Voltage
- Percutaneous Lead Disconnected
- Low Flow
- Loss of Power
Silencing Alarms

♥ Advisory Alarms 4 hours
  – Alarm resets when:
    • Alarm condition is resolved
    • 4 hour silence period expires
    • A hazard or new advisory alarm

♥ Hazard Alarms and Power Cable Disconnected Advisory Alarm 2 minutes
  – Alarm resets when:
    • Alarm condition is resolved or 2 minute silence period expire
    • New hazard alarm occurs
  – Audible advisory alarms will not occur until the hazard or power cable disconnected alarm has resolved
Advisory Alarms Power Cable Disconnected

♥ Visual: Flashing 4 green battery fuel gauge lights and rapidly flashing green power symbol
♥ Audio: One beep every second
♥ Silence: 2 minutes
♥ Action:
  – Check power lead connections to power source
  – Check PM or PBU patient cable and system controller power leads for damage, replace if necessary
Advisory Alarms-SC Battery Module Low

- Visual: Yellow cell symbol
- Audio: One beep every 4 seconds
- Silence: 4 hours
- Action – replace cell battery
Pump speed is below the low speed limit setting
- Visual: None
- System Monitor
  - Message, no audible alarm
- Display Module
  - Message with one beep every 4 seconds
- Battery operation
  - One beep every 4 seconds
- Silence: 4 hours
- Action
  - Confirm that low speed is not intentional
  - Increase fixed speed setting or decrease low speed limit
Advisory Alarms—Replace System Controller

- System Controller operating on back-up system
  - Visual: None
  - Audio: Repeating cycle of 1 beep per second for 2 seconds followed by 2 seconds of silence
  - Silence: 4 hours
  - Will not perform self test

- Action — replace System Controller

- Contact VAD team immediately
Advisory Alarms
Replace System Controller
Advisory Alarm - Low Voltage

Less than 15 minutes of power
- Visual: Yellow Battery
- Audio: One beep every 4 seconds
- Silence: Until hazard alarm occurs
- Action – immediately replace batteries or switch to alternate power source
Hazard Alarm- Low Voltage

- < 5 minutes of power remains
- Visual: Red Battery
- Audio: Continuous tone
- Silence: 2 minutes
- Defaults to Power Saver Mode
  - Pump speed gradually ramps down to 8000 rpm, or remains at current speed if set below 8,000 rpm
  - System will return to set speed once adequate power is restored
- Action – immediately replace batteries or switch to alternate power source
Red Heart Hazard Alarms

- Low Flow < 2.5 L/min
- Percutaneous lead disconnected
- Pump off
  - Visual: Red heart
  - Audio: Steady tone
  - Silence: 2 minutes
Red Heart Hazard Alarms: Low Flow

❤ Causes:
  - Decreased preload (right heart failure, tamponade, hypovolemia, bleeding, etc.)
  - Obstruction of pump inflow or outflow
  - Systemic hypertension
  - Pump off or percutaneous lead disconnected.

❤ Action
  - Assess patient
  - ECHO to assess RV, LV function, inlet cannula obstruction
  - Treat underlying cause
Red Heart Hazard Alarms: Percutaneous Lead Disconnected

- Percutaneous lead disconnected from system controller
- Visual: Red heart
- Audio: Steady tone
- Silence: 2 minutes
- System Monitor
  - PUMP OFF & LOW FLOW messages
  - PUMP DISCONNECTED in pump speed display
- Display Module
  - LOW FLOW message

**Warning:** If the pump stops, retrograde flow may occur; and, if blood is stagnant in the pump for more than a few minutes, there is a risk for stroke or thromboembolism should the device be restarted.
Hazard Alarm: Loss of Power

♥ System Controller disconnected from power
  – Visual: Absence of green power symbol
  – Audio: Continuous tone
  – Silence: None

♥ Action:
  – Check system controller connections to power
  – Check PBU/PM patient cable connected to PBU/PM
  – Change power source
  – Once power is re-established:
    • Set speed is $\geq 8,000$ rpm, pump automatically restarts
    • Set speed $< 8,000$ rpm, firmly press silence alarm or test select button to restart pump

⚠ Warning: If all power is removed, the pump will stop! This could result in serious injury or death!
Power Sources

Power Module

14 Volt Lithium Ion Batteries and Clips
Power Module (PM): Functions

❤ Supplies power to the LVAD when plugged into:
  – Electrical outlet
  – Automobile power outlet

❤ Visual and audio alarm indicators provide feedback on PM system operation
  – Perform self-test daily

❤ Serves as electrical interface between System Controller and System Monitor via 20 foot patient cable
  – Data is transmitted through the data link cable in the white power lead

❤ Repeats alarms generated by the System Controller
  – PM Silence button will only silence the PM alarm for 5 minutes
Power Module: Front Panel

- Silence Alarm Button
- Power On Indicator (Green or Yellow)
- Yellow Wrench Advisory & Hazard Alarm
- Internal Battery Charge Indicator (Green or Yellow)
- Internal Battery Alarm (Yellow or Red)
# Power Module: Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power ON Green</td>
<td>PM is receiving power.</td>
</tr>
<tr>
<td>Internal Battery Green</td>
<td>Internal backup battery is charged and ready for use if needed.</td>
</tr>
<tr>
<td>Internal Battery Yellow</td>
<td>Internal backup battery is being charged.</td>
</tr>
</tbody>
</table>
# Power Module: Alarm Indicators

<table>
<thead>
<tr>
<th>INDICATOR</th>
<th>MEANING</th>
<th>ACTION</th>
</tr>
</thead>
</table>
| Power ON Yellow                                | AC FAIL - power off or disconnected | Silence: 8 hours or another alarm occurs  
Switch to another power source                  |
| Internal Battery Advisory                      | ▪ < 15 minutes of backup battery power  
▪ Once per second beep                        | Silence: 8 hours or another alarm occurs  
Switch to another power source                  |
| Internal Battery Hazard                        | ▪ < 5 minutes of backup power  
▪ Continuous audio tone                      | IMMEDIATELY switch to another power source. Without power pump will stop. |
| Yellow Wrench                                  | ▪ Internal malfunction within PM  
▪ Advisory Fault – once per second beep  
▪ Hazard Fault – continuous audio tone       | Silence Advisory 8 hours; Hazard cannot silence  
Switch to another PM or power source          |
| Yellow Wrench + Red Battery                    | Internal battery is malfunctioning or is not connected | Silence: 2 minutes  
Switch to another PM or power source          |
14 Volt Lithium Ion Batteries

- Pair of batteries average support time 10 hours
  - Drains power from both batteries simultaneously
  - On battery fuel gauge indicates charge level
- Universal Battery Charger to charge & calibrate
  - 4 hours to recharge fully depleted battery
  - Calibration of fuel gauge required periodically
- Battery life
  - 360 cycles
  - 36 years from the date of manufacturer
- Dispose of expired batteries according to local, state, and federal regulations
Universal Battery Charger

- Charges 4 Lithium Ion batteries in 4 hours or less
- Pocket lights indicate battery charge status
  - Green = 100% charged
  - Yellow = Charging
  - Red = Battery defective, improperly inserted or contacts dirty
- Performs diagnostic testing
  - Most accurate percent of battery charge level
  - Monitors use cycles of each battery
  - Monitors need for calibration and calibrates individual HeartMate batteries
    - Yellow blinking pocket light
- Weighs eight pounds
Accessories

- Holster Vest
- Shower Bag
- Modular Belt
- Consolidated Bag
Ongoing Nursing Checks

• VAD parameters – Flow (L/min), Speed (RPM), Power (Watts), PI
• Blood pressure – MAP 65-85 mmHg
• Overview of daily labs
• INR level
• LDH level
• Driveline exit site - Driveline dressing change every 48 hours unless instructed otherwise
• Neurological checks
Device Assessment

- Pump function
  - Pump Parameters
    - Speed
    - Power
    - Flow estimation
    - Pulsatility index (PI)
  - System controller settings, alarm status
  - Review system controller event recorder log file
- Auscultate over pump pocket
- Driveline connection to system controller and locked in place
- Exit site status, immobilization of driveline
- Backup system controller available & programmed
Long Term Management – Anticoagulation/Antiplatelet

- Combination of Warfarin and aspirin
- Warfarin should be started and titrated to maintain INR of 2.0-3.0
VAD No’s

♥ NO swimming or bathing

♥ NO contact sports

♥ NO MRI Scans

♥ NO sharp objects near the driveline

♥ DO NOT disconnect both power sources at the same time

♥ No pregnancy

♥ Avoid strong static discharge (i.e. TV, computer screens, vacuuming carpets)
Arrhythmias/Emergency Procedures

- Arrhythmias may occur in the post operative period
- OK to defibrillate/cardiovert
- Initiate appropriate BLS/ACLS protocols
- ONLY perform chest compressions:
  - Under direction of physician and as a last resort!