

HeartMate II® with Pocket Controllers

1. **Can I do external CPR?**
Only if absolutely necessary
2. **If not, is there a "hand pump" or external device to use?**
No.
3. **If the device slows down (low flow state), what alarms will go off?**
A red heart alarm light indicator and steady audio alarm will sound if less than 2.5 lmp. Can give a bolus of normal saline and transport to an LVAD center.
4. **How can I speed up the rate of the device?**
No, it is a fixed speed.
5. **Do I need to heparinize the patient if it slows down?**
Usually no, but you will need to check with implanting center.
6. **Can the patient be defibrillated while connected to the device?**
Yes.
7. **If the patient can be defibrillated, is there anything I have to disconnect before defibrillating?**
No.
8. **Does the patient have a pulse with this device?**
May have weak pulse or lack of palpable pulse.
9. **What are acceptable vital sign parameters?**
MAP 70 - 90 mm Hg with a narrow pulse pressure
10. **Can this patient be externally paced?**
Yes.

FAQs

- May not be able to obtain cuff pressure (continuous flow pump).
- Pump connected to electric line exiting patient's abdominal area and is attached to computer which runs the pump.
- Pump does not affect EKG
- All ACLS drugs may be given.
- No hand pump is available.
- A set of black batteries last approximately 3 hours, gray batteries last 8-10 hours.
- Any emergency mode of transportation is ok. These patients are permitted to fly.
- Be sure to bring **ALL** of the patient's equipment with them.

Adapted from Sweet, L. and Wolfe, Jr., A. Mechanical Circulatory Devices in Transport in ASTNA: Patient Transport Principles and Practice, 4th ed., Mosby, 2010 in press.

Trouble Shooting HeartMate II® with Pocket Controllers

When the Pump Has Stopped

- Be sure to bring ALL of the patient's equipment with them.
- Fix any loose connection(s) to restart the pump.
- If the pump does not restart and the patient is connected to batteries replace the current batteries with a new, fully-charged pair. (see *changing batteries section on next page*)
- If pump does not restart, change controllers. (see *changing controllers section on next page*)

Alarms: Emergency Procedures



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on next page.



Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If patient is hypovolemic, give volume. If patient is in right heart failure-- treat per protocol. If the pump has stopped check connections, batteries and controllers as instructed in the section above.



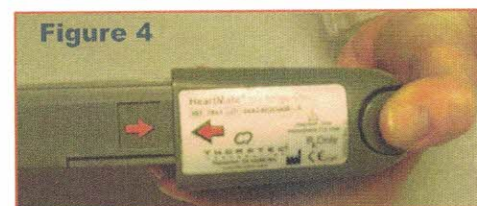
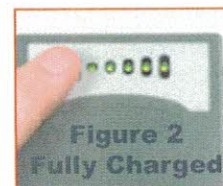
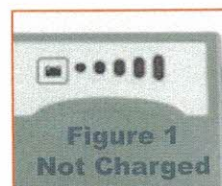
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Trouble Shooting HeartMate II® with Pocket Controllers

Changing Batteries

WARNING: At least one power lead must be connected to a power source **AT ALL TIMES**. Do not remove both batteries at the same time or the pump will stop.

- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each gray battery can be assessed by pressing the battery button on the battery. (Figures 1 and 2)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 3)
- Controller will start beeping, flash yellow signals and will read **power disconnect** on the front screen.
- Replace with new battery by lining up **RED** arrows on battery and clip. (Figure 4)
- Slide a new, fully-charged battery (Figure 2) into the empty battery clip by aligning the **RED** arrows. The battery will click into the clip. Gently tug at battery to ensure connection. If battery is properly secured, the beeping and yellow flashing will stop.
- Repeat previous steps with the second battery and battery clip.



Changing Controllers

- Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.
- Make sure patient is sitting or lying down since the pump will momentarily stop during this procedure.
- Attach the battery clips to the spare controller by lining up the half moons and gently pushing together and attach the batteries to the spare controller by aligning the **RED** arrows.



Release Button



- On the back of the replacement controller, rotate down the perc lock so the red tab is fully visible. Repeat this step on the original controller until the red tab is fully visible.
- Disconnect the drive line from the original controller by pressing down on the red tab and gently pulling on the metal end. The pump will stop and an alarm will sound. **Note:** The alarm will continue until the original controller is put to sleep. You can silence the alarm by holding down the silence button. **Getting the replacement controller connected and pump restarted is the first priority.**

- Connect the replacement Controller by aligning the **BLACK ARROWS** on the driveline and replacement Controller and gently pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:



Step 1. Firmly press the Silence Alarm or Test Select Button to restart the pump.

Step 2. Check the powersource to assure that power is going to the controller.

Step 3. Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.

- After the pump restarts, rotate up the perc lock on the new controller so the red tab is fully covered. If unable to engage perc lock to a fully locked position, gently push the driveline into the controller to assure proper connection. Retry to engage perc lock.
- Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.
- Hold down battery symbol for 5 full seconds for complete shutdown of old controller.

HeartMate II®

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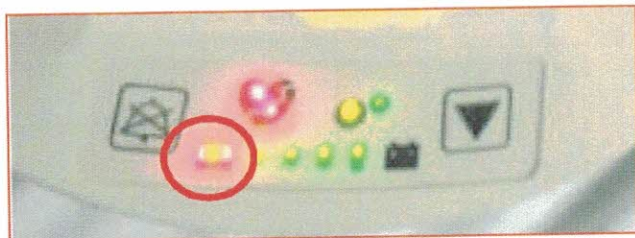
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Trouble Shooting HeartMate II®

When the Pump Has Stopped

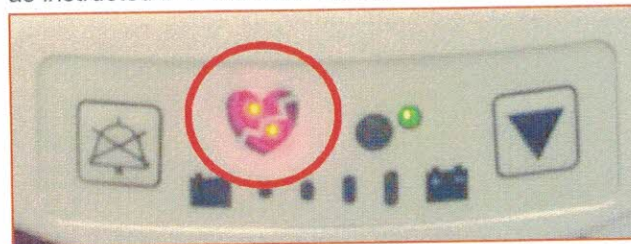
- Be sure to bring ALL of the patient's equipment with them.
- Fix any loose connection(s) to restart the pump.
- If the pump does not restart and the patient is connected to batteries replace the current batteries with a new, fully-charged pair. (see *changing batteries section on next page*)
- If pump does not restart, change controllers. (see *changing controllers section on next page*)

Alarms: Emergency Procedures



Yellow or Red Battery Alarm: Need to Change Batteries. See changing batteries section on next page.

Red Heart Flashing Alarm: This may indicate a Low Flow Hazard. Check patient--the flow may be too low. If patient is hypovolemic, give volume. If patient is in right heart failure-- treat per protocol. If the pump has stopped check connections, batteries and controllers as instructed in the section above.



Trouble Shooting HeartMate II®

Changing Batteries

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- Obtain two charged batteries from patient's accessory bag or battery charger. The charge level of each gray battery can be assessed by pressing the battery button on the battery. (Figures 3 and 4)
- Remove only **ONE** battery from the clip by pressing the button on the grey clip to unlock the battery. (Figure 1)
- Controller will start beeping and flashing green signals.
- Replace with new battery by lining up **RED** arrows on battery and clip. (Figure 2)
- Slide a new, fully-charged battery (Figure 4) into the empty battery clip by aligning the **RED** arrows. The battery will click into the clip. Gently tug at battery to ensure connection. If battery is properly secured, the beeping and green flashing will stop.
- Repeat previous steps with the second battery and battery clip.

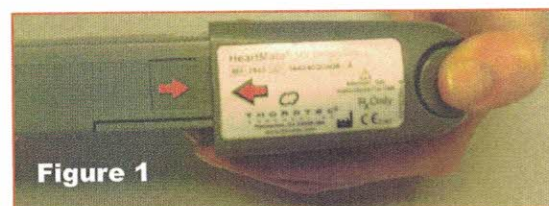


Figure 1



Figure 2

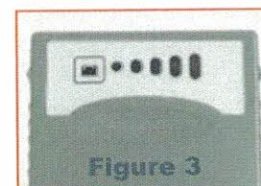


Figure 3

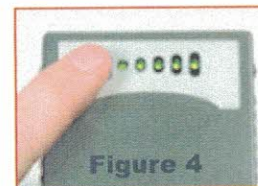


Figure 4

Changing Controllers

- Place the replacement Controller within easy reach, along with the batteries/battery clips. The spare Controller is usually found in the patient's travel case.
- Make sure patient is sitting or lying down since the pump will momentarily stop during this procedure.
- Attach the battery clips to the spare controller by lining up the half moons and gently pushing together and attach the batteries to the spare controller by aligning the **RED** arrows. **ALARMS WILL SOUND-THIS IS OK.**
- Depress the silence alarm button (upside-down bell with circle) until the alarm is silenced on the new, replacement Controller.
- Rotate the perc lock on the replacement controller in the direction of the "unlocked" icon until the perc lock clicks into the fully-unlocked position. Repeat this same step for the original Controller until the perc lock clicks into the unlocked position.
- Disconnect the perc lead/driveline from the original controller by pressing the metal release tab on the connector socket. The pump will stop and an alarm will sound.



Half-Moons



Perc Lock

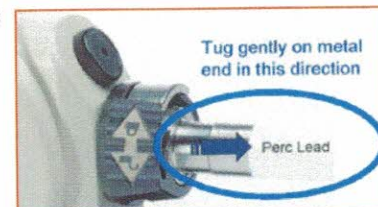
Note: The alarm will continue until power is removed from the original Controller. **Getting the replacement Controller connected and the pump restarted is the first priority.**

- Connect the replacement Controller by aligning the **BLACK LINES** on the driveline and replacement Controller and gently pushing the driveline into the replacement Controller. The pump should restart, if not complete the following steps:

Step 1. Firmly press the Silence Alarm or Test Select Button to restart the pump.

Step 2. Check the powersource to assure that power is going to the controller.

Step 3. Assure the perc lead is fully inserted into the socket by gently tugging on the metal end. **DO NOT** pull the lead.



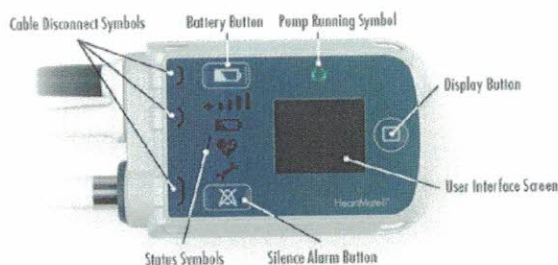
Tug gently on metal end in this direction

Perc Lead

- After the pump restarts, rotate the perc lock on the new controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position. If unable to engage perc lock to the locked position, gently push the driveline into the controller to assure a proper connection. Retry to engage perc lock.
- Disconnect power from the original Controller. The original Controller will stop alarming once power is removed.

HeartMate II® Controller Comparison Guide

POCKET CONTROLLER™



3 Modes: Run, Charge, Sleep

Run: Driveline + Power source connected.

Charge: Only power source connected.

Sleep: No driveline or power source connected; ready to use.

Backup Battery

An emergency backup battery is built into Pocket Controller, powering the pump for 15 minutes in the absence of an external power source. The backup battery is supplied NONSTERILE.

Event Logger

Pocket Controller includes date/time records in event history. Pocket Controller can store 240 events.

Green Pump Running Symbol



Green "pump running" symbol signifies that the pump is on and running.

Controller Buttons

Display Button: Enables viewing of pump parameters and backup battery charge status.

Silence Alarm Button: Silences hazard alarms for 2 minutes and advisory alarms for 4 hours.

Display Button + Silence Alarm Button Together: Displays previous six alarms.

Battery Button: Displays the battery power gauge when pressed. Activates a self test when held for 5 seconds then released. Enters sleep mode when driveline and external power are disconnected and button is held for 5 seconds then released.

Self Test



Press and hold the Battery Button for 5 seconds.

Low Power



Yellow Diamond Symbol: Displayed when only 15 minutes of external power is remaining.



Red Battery Symbol: Displayed when only 5 minutes of external power is remaining.

Backup Battery Mode: Entered after external power is depleted. Provides 15 minutes of internal emergency backup battery power.

Power Saver Mode: Entered when pump has run on backup battery for 15 minutes. Pump Speed is reduced to the set Low Speed Limit.

Starting the Pump

>8000 RPM: Pump starts automatically.

<8000 RPM with Backup Battery: Start pump by pressing any button on Pocket Controller.

<8000 RPM with no Backup Battery: Pump can only be started via System Monitor.

System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	PI Event
System Information:	10/04/13 01:30	4.8	6900	5.7	5.6	* System Information

Compatibility

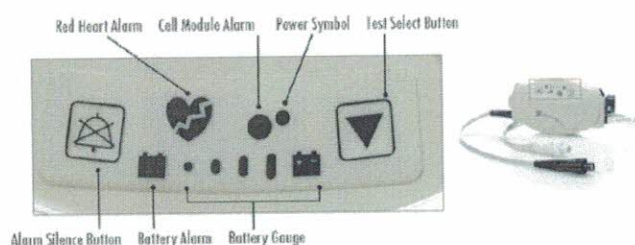
System Monitors I and II, Power Module, Power Module Patient Cable (14 Volt), 14 Volt Lithium-Ion Batteries and Battery Clips.



Alarms

For a review of alarms and their meanings, reference HeartMate II Alarms for Clinicians, Item 107526. Pocket Controller includes a yellow wrench icon to denote advisory alarms. Note that Pocket Controller includes drivelines fault detection.

EXTERNAL PERIPHERAL CONTROLLER (EPC)



2 Modes: On, Off

On: Driveline + Power source connected.

Off: No driveline or power source connected.

Cell Module Battery

No backup battery. The cell module battery powers an audible tone if EPC is removed from power while the driveline is connected. The cell module battery is supplied STERILE.

Event Logger

EPC does not include date/time records in event history. EPC can store 120 events.

Green Power Symbol



Green light only means that the controller is receiving power. Listen over the pump pocket for confirmation that the pump is running.

Controller Buttons

Alarm Silence Button: Displays the battery fuel gauge. Also silences hazard alarms for 2 minutes and advisory alarms for 4 hours.

Test Select Button: Activates a self test when held for 3 seconds.

Note: EPC does not include a display button or user interface screen. The Display Module is used to view pump parameters and alarm events.

Self Test



Press and hold the Test Select Button for 3 seconds.

Low Power



Yellow Battery Symbol: Displayed when only 15 minutes of external power is remaining.



Red Battery Symbol: Displayed when only 5 minutes of external power is remaining.

Power Saver Mode: Entered when the battery voltage falls to a critically low level. Pump Speed is reduced to 8000 RPM.

Starting the Pump

>8000 RPM: Pump starts automatically.

<8000 RPM: Start pump by pressing Alarm Silence Button or Test Select Button on EPC.

System Monitor Event History Screen

PI Event:	10/04/13 07:20	4.8	9590	5.6	5.4	PI Event
System Information:	10/04/13 01:30	4.8	6900	5.7	5.6	* System Information

Compatibility

System Monitors I and II, Power Module, Power Base Unit (PBU), Power Module Patient Cable (12 Volt and 14 Volt), 14 Volt Lithium-Ion Batteries and Battery Clips, 12 Volt SLA and NiMH Batteries and Clips.

Alarms

For a review of alarms and their meanings, reference HeartMate II Alarms for Clinicians, Item 103851. Note that EPC does not include driveline fault detection.

HeartMate II Controller Comparison Guide

DRIVELINE CONNECTION

Pocket Controller:

A safety tab is located on the back of the controller.



Unlocked



Locked

External Peripheral Controller (EPC):

A percutaneous lock is located on the side of the controller.



Unlocked

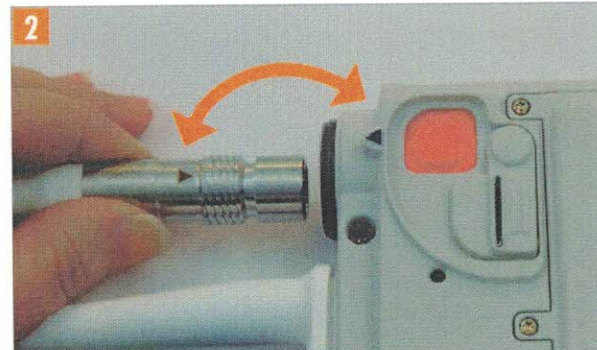


Locked

The Pocket Controller driveline connection and locking mechanism are different from the EPC. To insert and lock the driveline into Pocket Controller:



Slide the safety tab back to expose the red button.



Align the arrow on the driveline to the arrow on the Pocket Controller. Firmly insert the driveline until it snaps into place.



Tug gently on the metal portion of the driveline to ensure that it is fully engaged.



Slide the safety tab over the red button. Ensure the safety tab completely covers the red button.