



URGENT MEDICAL DEVICE RECALL
AC Power Cord (Model Number: 107760) for HeartMate™ Mobile Power Unit (Model Number: 107754)

Abbott Medical
6035 Stoneridge Drive
Pleasanton, CA 94588
USA

June 2025

Dear Patient,

We want to share some important information related to the AC power cord for your HeartMate Mobile Power Unit (MPU). As you know, the MPU device connects to the wall outlet in your home and powers your HeartMate 3 LVAD. Abbott is currently conducting a recall of this AC power cord. This is due to the potential risk of the AC power cord not locking into place to the MPU and becoming separated from the MPU.

Please read this letter carefully. If you have any questions, please contact your clinical team. We have also shared this information with your doctor and the hospital where you received your heart pump.

WHAT YOU NEED TO KNOW:

This recall covers some AC power cords distributed in May and June 2025.

We are not currently aware of any patient injury associated with this potential issue. However, impacted AC power cords could become disconnected from the MPU. This could cause loss of power to the MPU. If this happens, a red alarm on the System Controller will display (see Figure1). Additionally, the green light will not remain lit on the MPU (see Figure 2).

System Controller Screen	Active Symbols	Alarm Means	To Resolve Alarm
		Both power cables are disconnected.	1. Immediately connect to a working power source (Mobile Power Unit or two HeartMate 1.4 Volt Lithium-Ion batteries). 2. If alarm persists, call your hospital contact immediately. For more information, see page 222.

Figure 1: Low Battery Alarm (pg. 226 in HM3 Patient Handbook)

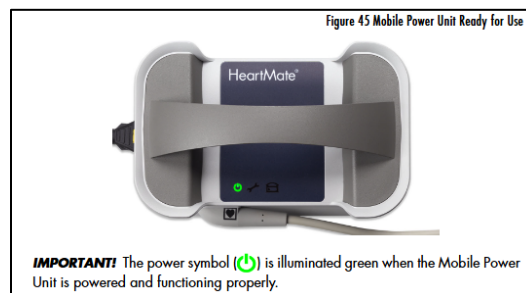


Figure 2: Expected MPU Power Symbol with Power (pg. 87 in HM3 Patient Handbook)

WHAT YOU NEED TO DO:

Please follow the HeartMate 3 Patient Handbook. Each time before you use the MPU, test the MPU power cord by pulling on it after it is fully inserted into the MPU (see Figure 3). The yellow button should click into place when the power cord is fully inserted. This will prevent the removal of the power cord unless the yellow button is pressed. If the yellow button does

not click into place and/or the power cord can easily be removed, do not use the MPU and contact your clinic or Abbott Technical Support at 1-800-456-1477 (Business hours: 8 AM EST to 7 PM EST) for a new power cord. Please throw away the defective power cord or return it to your clinic or Abbott.

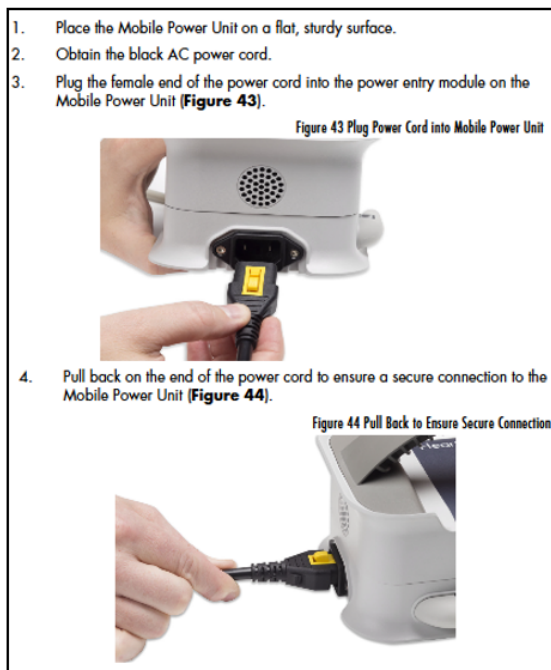


Figure 3: MPU Power Cord Instructions for Use (page 85-86 in HeartMate 3 Patient Handbook)

If your MPU loses power during use, please confirm that the power cord is fully inserted. If the power cord does not remain fully inserted, switch to your fully charged 14V batteries within 15 minutes and then contact your clinic.

As a reminder, the backup battery in your system controller can power your heart pump for up to 15 minutes. This safeguard allows you to switch from your MPU to your fully charged 14V batteries within those 15 minutes. Please also consider the following:

- Every time you use the MPU for power, make sure your 14V rechargeable batteries are ready and available for use.
- If the yellow battery sign on the MPU is on, replace the AA batteries inside the MPU immediately. These batteries make the MPU alarms work.

Your clinic will replace the AC power cords affected by this recall. If you work with Acelis Connected Health (ACH) for your durable medical equipment, please contact Acelis for your replacement. As long as your power cord can be fully inserted, your MPU is safe to use while you wait for a new power cord.

If you need a new copy of the HeartMate 3 Patient Handbook, contact your clinical team at the hospital. You can also download it from the Abbott website: <https://manuals.eifu.abbott/en/index.html>.

A device lookup tool with the impacted MPU devices will be available on the Abbott Product Advisories website by July 1, 2025, at this link: <https://www.cardiovascular.abbott/us/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/indications-safety-warnings/advisories.html>

Your safety and satisfaction are important to us. We apologize for any inconvenience. Thank you for your understanding.

Sincerely, .

Carolyn Tabion
Divisional Vice President, Quality - Abbott Heart Failure