



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

Heart Failure Division
Abbott Medical
6035 Stoneridge Dr.
Pleasanton, CA 94588

June 2025

Dear Physician or Healthcare Professional,

The purpose of this letter is to advise you that Abbott is initiating a voluntary recall of the AC Power Cord (model 107760) for the HeartMate™ Mobile Power Unit (MPU; model 107754). Abbott has received one customer complaint in which some MPU AC power cords did not fully lock into place when inserted into the MPU and could be pulled from the MPU without pressing the yellow button on the plug. This issue has been linked to nonconforming power cords packaged with certain MPUs distributed in May 2025 and June 2025. Abbott is recommending removal of impacted cords, but not recommending removal of the MPU from the field at this time because the issue is related solely to the cord and not the MPU itself.

Impact and Associated Risk

As of June 16, 2025, the reported impact on patients by this issue included anxiety and inconvenience. Although not having been reported, this issue could also potentially lead to serious adverse health consequences such as hemodynamic compromise, thromboembolism, or death when power to the HeartMate left ventricular device is interrupted.

Per the Instructions For Use (IFU), when the power cord is inserted into the MPU, the user should pull on the cord to confirm that the yellow lock has engaged, see Figure 1.



Figure 1: MPU Power Cord IFU Instructions (pg. 3-42 HeartMate 3™ (HM3) IFU)

If the power cord is disconnected from the MPU, a red battery alarm and a “No External Power” alarm will display on the System Controller, see Figure 2. Additionally, the green light will not remain illuminated on the MPU, see Figure 3.

System Controller Screen	Active Symbols	Silence Period	Alarm Means	To Resolve Alarm
	 	2 minutes	Both power cables are disconnected.	Immediately connect to a working power source (Power Module, Mobile Power Unit, or two HeartMate 14 Volt Lithium-Ion batteries). See page 7-14.

Figure 2: System Controller No External Power Alarm (pg. 7-7 HM3 IFU)

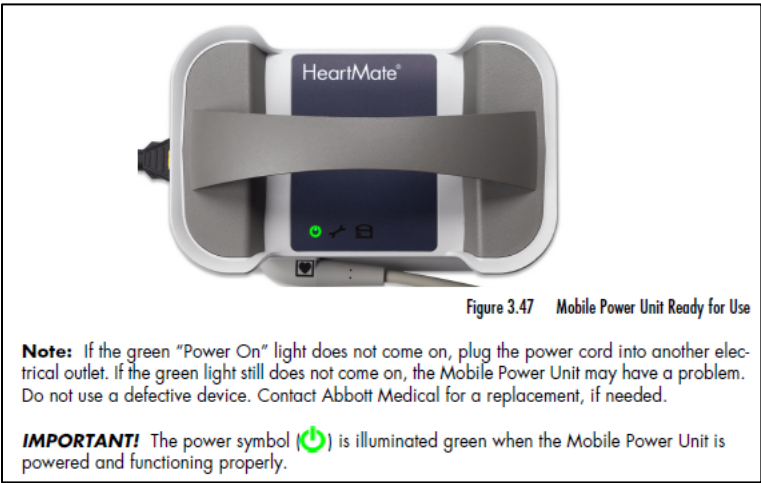


Figure 3: Expected MPU Power Symbol with Power (pg. 3-43 HM3 IFU)

Abbott Action

Abbott investigation has confirmed that the specific subset of AC power cords mentioned above may not meet Abbott quality standards and specifications. The issue is isolated to just the power cord for the MPU. The MPU itself is still functioning as intended.

Each MPU is shipped with a power cord included. Standalone power cords are also distributed. A list of the AC power cord lots and associated MPUs identified with the affected power cord component is provided in Appendix A.

Abbott is taking the following actions:

- Abbott is notifying clinics that received impacted power cords (Appendix A).
- Abbott Representatives will visit impacted clinics and evaluate the MPU power cord inventory. Any power cords that are identified with this issue will be replaced through Abbott Technical Services.

User Action Requested

Review the enclosed Appendix A to identify the potentially impacted MPU power cords that are either on your shelves, used in your clinic, or already assigned to patients. If the power cords and MPUs are not listed on Appendix A, it is safe to continue using them.

For units that are on your shelves or used in your clinic, Abbott Representatives will visit your clinics and evaluate them. However, if you choose to evaluate any additional inventory to ensure a secure connection between the MPU and its power cord, please use the instructions provided in the IFU, as shown above in Figure 1. For any defective power cords

identified, please contact Abbott Technical Support at 1-800-456-1477 (Business hours: 8 AM EST to 7 PM EST) to return them and receive replacements.

For units already assigned to patients, as reflected in Appendix A, the following actions should be taken:

1. Provide the impacted patient the attached patient letter (Appendix B).
2. Remind the patients to follow the instructions provided in the IFU, as shown above in Figure 1. If the power cord does not lock into the MPU per the IFU, please contact Abbott Technical Support at 1-800-456-1477 for a replacement power cord.
 - Remind the patients to use the 14V batteries while they wait for the replacement power cord. Remind the patients that the Backup Battery in the System Controller will temporarily power the pump for 15 minutes while transferring to the battery power. The patients must not rely only on the System Controller's Backup Battery as a power source during power failure, as it will only power the pump for the 15-minute time period.
 - As a precaution, educate the patient to ensure the 14V batteries are ready and available for use at any time.
 - Once the new power cord is received, the patient should continue to use the MPU with the new power cord and return the defective power cord to Abbott if possible.

Please distribute this notice to those who need to be aware within your institution and to any organization to which these devices may have been transferred. Additionally, please complete the attached acknowledgment form included with this letter and return it to Abbott.

Abbott has notified the United States Food & Drug Administration (FDA) about the issue. Should you have any questions about this notice, please contact your Abbott representative or Abbott Technical Support at 1-800-456-1477.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete the voluntary Form FDA 3500 online at <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>.
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return it to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178.

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process.

Sincerely,



Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

Enclosed:

- Appendix A – Reference Pictures and Listing of Potentially Impacted MPUs and Patients
- Appendix B – Patient Letter
- Acknowledgment Form

Reference Images of Power Cord Model and Lot Number



Appendix A – Affected AC Power Cord Lot Numbers (Model Number: 107760)

10763925
10770095
10794158
10794159
10794161
10794162
10794164
10794166
10794167
10794170
10794172
10814683
10814684
10814685
10831828

Appendix A – MPU Serial Numbers with Affected Power Cords (Model Number: 107754)

20539017	20541384	20541459	20541505	20541550	20541595
20539018	20541385	20541460	20541506	20541551	20541596
20539019	20541386	20541461	20541507	20541552	20541597
20539020	20541387	20541462	20541508	20541553	20541598
20539021	20541388	20541463	20541509	20541554	20541599
20539022	20541419	20541464	20541510	20541555	20541600
20539023	20541420	20541465	20541511	20541556	20541601
20539024	20541421	20541466	20541512	20541557	20541602
20539025	20541422	20541467	20541513	20541558	20541603
20539026	20541423	20541468	20541514	20541559	20541604
20539037	20541424	20541469	20541515	20541560	20541605
20539038	20541425	20541470	20541516	20541561	20541606
20539039	20541426	20541471	20541517	20541562	20541607
20539040	20541427	20541472	20541518	20541563	20541608
20539041	20541428	20541473	20541519	20541564	20541609
20539042	20541429	20541474	20541520	20541565	20541610
20539043	20541430	20541476	20541521	20541566	20541611
20539044	20541431	20541477	20541522	20541567	20541612
20539045	20541432	20541478	20541523	20541568	20541613
20539046	20541433	20541479	20541524	20541569	20541614
20539057	20541434	20541480	20541525	20541570	20541615
20539058	20541435	20541481	20541526	20541571	20541616
20539059	20541436	20541482	20541527	20541572	20541617
20539060	20541437	20541483	20541528	20541573	20541618
20539061	20541438	20541484	20541529	20541574	20560235
20539062	20541439	20541485	20541530	20541575	20560236
20539063	20541440	20541486	20541531	20541576	20560237
20539064	20541441	20541487	20541532	20541577	20560238
20539065	20541442	20541488	20541533	20541578	20560239
20539066	20541443	20541489	20541534	20541579	20560240
20539077	20541444	20541490	20541535	20541580	20560241
20539078	20541445	20541491	20541536	20541581	20560242
20539079	20541446	20541492	20541537	20541582	20560243
20539080	20541447	20541493	20541538	20541583	20560245
20539081	20541448	20541494	20541539	20541584	20560246
20539082	20541449	20541495	20541540	20541585	20560247
20539083	20541450	20541496	20541541	20541586	20560248
20539084	20541451	20541497	20541542	20541587	20560249
20539085	20541452	20541498	20541543	20541588	20560250
20539086	20541453	20541499	20541544	20541589	20560251
20541379	20541454	20541500	20541545	20541590	20560252
20541380	20541455	20541501	20541546	20541591	20560253
20541381	20541456	20541502	20541547	20541592	20560254
20541382	20541457	20541503	20541548	20541593	20560255
20541383	20541458	20541504	20541549	20541594	20560256

Appendix A – MPU Serial Numbers with Affected Power Cords (Model Number: 107754)

20560257	20560303	20560349	20561563	20561630	20561700
20560258	20560304	20560350	20561564	20561631	20561701
20560259	20560305	20560351	20561565	20561632	20561702
20560260	20560306	20560352	20561566	20561633	20561703
20560261	20560307	20560353	20561567	20561634	20561704
20560262	20560308	20560354	20561568	20561635	20561705
20560263	20560309	20560365	20561569	20561636	20561706
20560264	20560310	20560366	20561570	20561637	20561707
20560265	20560311	20560367	20561571	20561638	20561708
20560266	20560312	20560368	20561572	20561639	20561709
20560267	20560313	20560369	20561581	20561640	20561710
20560268	20560314	20560370	20561583	20561641	20561711
20560269	20560315	20560371	20561584	20561642	20561712
20560270	20560316	20560372	20561585	20561643	20561713
20560271	20560317	20560373	20561586	20561644	20561714
20560272	20560318	20560374	20561587	20561645	20561715
20560273	20560319	20561513	20561588	20561646	20561716
20560274	20560320	20561514	20561589	20561647	20561717
20560275	20560321	20561516	20561590	20561648	20561728
20560276	20560322	20561517	20561591	20561649	20561729
20560277	20560323	20561518	20561592	20561650	20561730
20560278	20560324	20561519	20561593	20561651	20561731
20560279	20560325	20561520	20561594	20561652	20561732
20560280	20560326	20561521	20561595	20561678	20561733
20560281	20560327	20561522	20561596	20561679	20561734
20560283	20560329	20561523	20561597	20561680	20561736
20560284	20560330	20561524	20561598	20561681	20561737
20560285	20560331	20561525	20561599	20561682	20561738
20560286	20560332	20561526	20561600	20561683	20561739
20560287	20560333	20561527	20561601	20561684	20561740
20560288	20560334	20561528	20561602	20561685	20561741
20560289	20560335	20561529	20561603	20561686	20561742
20560290	20560336	20561530	20561604	20561687	20561743
20560291	20560337	20561531	20561605	20561688	20561744
20560292	20560338	20561532	20561606	20561689	20561745
20560293	20560339	20561533	20561607	20561690	20561746
20560294	20560340	20561534	20561608	20561691	20561747
20560295	20560341	20561535	20561609	20561692	20561748
20560296	20560342	20561536	20561610	20561693	20561749
20560297	20560343	20561537	20561611	20561694	20561750
20560298	20560344	20561538	20561612	20561695	20561751
20560299	20560345	20561539	20561626	20561696	20561752
20560300	20560346	20561540	20561627	20561697	20561753
20560301	20560347	20561541	20561628	20561698	20561754
20560302	20560348	20561542	20561629	20561699	20561755

Appendix A – MPU Serial Numbers with Affected Power Cords (Model Number: 107754)

20561756	20561805
20561757	20561825
20561768	20576653
20561769	20576654
20561770	20576655
20561771	20576656
20561772	20576657
20561773	20576658
20561774	20576659
20561775	20576660
20561776	20576661
20561777	20576662
20561778	20576663
20561779	20576664
20561780	20576665
20561781	20576666
20561782	20576667
20561783	20576668
20561784	20576669
20561785	20576670
20561786	20576671
20561787	20576672
20561788	20576673
20561789	20576674
20561790	20576675
20561791	20576676
20561792	20576677
20561793	20576678
20561794	20576679
20561795	20576680
20561796	20576681
20561797	20576682