

September 14, 2015

URGENT: MEDICAL DEVICE CORRECTION

Affected devices: All serial numbers of the HeartMate II® System Controller, Model No. 105109 (Pocket Controller™), provided within the following packaging configurations: Catalog Nos. 106016, 106017, 106762, 106015, 107801.

Description of problem:

Thoratec is issuing this Urgent Medical Device Correction Letter to remind all hospitals to carefully monitor the expiration date of the 11V Lithium-Ion Backup Battery (“backup battery”) in the HeartMate II LVAS System Controller. Failure to do so can result in preventable backup battery Advisory alarms and unwarranted System Controller exchanges by patients. Thoratec has received reports of two patient deaths and one serious injury associated with patients attempting to exchange System Controllers in response to these alarms. Thoratec’s investigations of the reports have not revealed any failure of the devices to meet specifications or deficiencies in quality control procedures that would have caused the backup battery Advisory alarms.

The System Controller is the external unit that controls the function of the implanted HeartMate II Left Ventricular Assist Device. The backup battery is installed inside the System Controller by hospital staff at the time of use and automatically provides at least 15 minutes of operating power if all other normal power sources (14V Lithium-Ion batteries or AC power) are inadvertently disconnected. The backup battery has a limited lifespan (36 months from manufacture date) and must be replaced prior to expiration. The Instructions for Use (IFU) recommends checking the backup battery expiration date monthly using the System Monitor and replacing the backup battery six (6) months before the mandatory replacement date. The backup battery does not cease to function after reaching its expiration date, but its ability to provide at least 15 minutes of power after that date has not been validated.

If the backup battery is not replaced before reaching its expiration date, a System Controller Advisory alarm is triggered at 12:00 am (midnight) on the first day of the month in which the battery reaches its expiration date. The Advisory alarm tone is a slow beep and the message displayed on the LCD user interface screen of the patient’s System Controller is either “Call Hospital Contact, Backup Battery Fault” + “Replace Controller, Backup Battery Fault” or “Call Hospital Contact, Backup Battery Fault”, depending on the System Controller software version.

The Backup Battery Fault alarm is an Advisory alarm that does not require any immediate action by the patient. This Urgent Medical Device Correction letter is intended to prevent the occurrence of Advisory alarms related to expired backup batteries that might prompt a patient to undertake an unwarranted System Controller exchange.

Immediate action to be taken:

1. Review the attached revision to the HeartMate II LVAS labeling (New Information for the Monthly Safety Checklist in the Instructions for Use) with all clinicians responsible for the care of HeartMate II LVAS patients during clinic visits.
2. Assess your hospital's processes and procedures for ensuring the replacement of backup batteries for patients' primary and backup System Controllers prior to the month of expiration.
3. If your hospital does not have an established process for ensuring the replacement of backup batteries prior to the month of expiration the following actions should be taken:
 - Contact all patients using the System Controller and evaluate the remaining months left on the backup battery of each System Controller and replace them if 6 months or fewer are remaining. Follow the steps in the IFU on Replacing a Backup Battery in the System Controller (Section 2-38).
 - Prioritize patient contacts, giving **highest priority** to those patients who have been on support for **two or more years** and have not had their backup batteries replaced previously.
 - Work with your Thoratec representative, who will help you to identify ongoing patients who were implanted at your hospital on or before September 1, 2013.

Preventive action:

1. Implement procedures to monitor and track backup battery expiration dates on patients' primary and backup System Controllers. Ensure that those backup batteries are replaced in advance of expiration so that patients never receive a Backup Battery Fault Advisory alarm due to an expired battery.
2. Provide patients with documentation of the expiration month and year of the backup batteries in each of their System Controllers. Advise them that the backup battery needs to be replaced six months before its expiration date and to schedule a clinic visit as soon as possible if they reach that point in time and have not had the backup battery replaced.
3. Regularly reinforce instructions to patients that if they receive any Advisory alarm, they should immediately contact the hospital, as prompted by the System Controller's user interface, before taking any action.

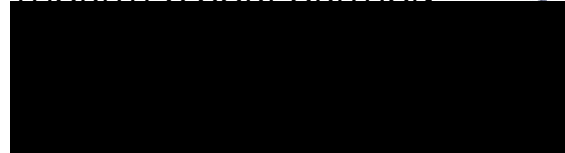
Acknowledgement:

The physician(s) most responsible for managing the care of HeartMate II LVAS patients should complete and sign the attached Acknowledgement Form and return it to Thoratec via fax (925-847-8571) or e-mail a scanned copy to customer.service@thoratec.com. Please forward this notice to any other appropriate parties (e.g. Risk Management) per your institution's procedures. If you feel that you should not be signing this form, please have the appropriate person sign it and forward it to Thoratec.

Thank you for your cooperation in this matter. Thoratec is committed to keeping you informed of product-related clinical information that could help to optimize patient outcomes.

Sincerely,

THORATEC CORPORATION



Donald A. Middlebrook
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Attachments:

- A – Acknowledgement Form
- B – Revised Instructions for Use (New Information for Monthly Safety Checklist)

ATTACHMENT A

ACKNOWLEDGEMENT FORM

Acknowledgement Form

HeartMate II LVAS System Controller (“Pocket Controller”)

**PLEASE COMPLETE ALL REQUESTED INFORMATION
AND RETURN IMMEDIATELY**

By signing below I acknowledge that:

- I have received Thoratec’s Urgent Medical Device Correction (dated September 14, 2015) concerning 11 Volt Lithium-Ion Backup Battery expiration Advisory alarms in the HeartMate II LVAS System Controller.
- I understand the information that Thoratec has provided in this notice and that the labeling for commercially distributed devices will be revised to reflect this new information from clinical experience.
- I have reviewed the attached revision to the HeartMate II LVAS labeling with all clinicians responsible for the care of HeartMate II LVAS patients care during clinic visits.
- I agree to develop a plan of action, prioritizing patients who have been on HeartMate II support for more than two years but have not had their backup batteries replaced previously.
- I have informed all appropriate personnel as required by my institution’s policies and procedures of this Urgent Medical Device Correction letter.

Name (print): _____

Title (print): _____

Signature: _____

Facility Name: _____

Date: _____

Phone Number: _____

E-mail: _____

**PLEASE RETURN THIS ACKNOWLEDGEMENT FORM
TO THORATEC CORPORATION
Fax: (925) 847-8571 or
e-mail: customer.service@thoratec.com**

ATTACHMENT B

NEW INFORMATION FOR THE MONTHLY SAFETY CHECKLIST



HeartMate II IFU
Addendum.2015.091

New Information for the Monthly Safety Checklist

- ☒ Check the expiration date of the 11 Volt Lithium-Ion backup battery by following the steps below:

1. Ensure that you advise all HeartMate II LVAS patients to bring their backup System Controller with them to all clinic visits.
2. Use the System Monitor to check the expiration date of the 11 Volt Lithium-Ion backup battery within the patient's primary and backup System Controllers.
3. The remaining months until the 11 Volt Lithium-Ion backup battery will expire is displayed on the backup battery Information screen on the System Monitor (review the *System Controller Backup Battery Information* on page 4-43).

Note: The number of months remaining until the backup battery will expire is displayed on the System Monitor as "Replace in XX month(s)". The number of months remaining until expiration is a number between 36 (maximum) and 0 (expired).

IMPORTANT! Once the number of months remaining reaches 6 months or less, the number will be highlighted to remind Hospital Staff to replace the backup battery. Depending upon a patient's clinic schedule, replacement of the 11 Volt Lithium-Ion backup battery should be considered when less than 6 months remain before the mandatory replacement date (see *Replacing a Backup Battery in the System Controller* on page 2-38).

WARNING !

Failure to replace the 11 Volt Lithium-Ion backup battery prior to its expiration date will result in an Advisory alarm (see *System Controller Backup Battery Fault Alarm* on page 7-17) at 12:00 am (midnight) on the first day of the month in which the actual expiration date is reached. It is critical that the clinician regularly check the backup battery expiration date and replace the backup battery as required (see *Replacing a Backup Battery in the System Controller* on page 2-38).
