

Urgent Field Safety Notice

Medtronic Model 37751 Recharger included in Model 37754 and 97754 Charging System

Important Device Information related to Spinal Cord Stimulation

October 2016

Medtronic reference: FA735

Dear Healthcare Professional,

The purpose of this letter is to provide you with important information regarding the issue of unresponsive and beeping Model 37751 Rechargers. This letter provides recommendations on how to prevent occurrence of this issue and restore functionality of the Recharger if the issue occurs. Model 37751 Rechargers are sold in kit Models 37754 and 97754 Charging Systems for Spinal Cord Stimulation (SCS). This Recharger is used by SCS patients who are implanted with the following implantable neurostimulators:

- Restore™ (Model 37711)
- RestoreUltra™ (Model 37712)
- RestoreAdvanced™ (Model 37713)
- RestoreSensor™ (Model 37714)
- RestoreUltratm SureScan™ MRI (Model 97712)
- RestoreAdvanced™ SureScan™ MRI (Model 97713)
- RestoreSensor™ SureScan™ MRI (Model 97714)

Background:

Medtronic has identified an increased number of complaints from customers involving reports of Rechargers that are in an unresponsive error state, where the Recharger is non-functional with a blank display screen and is beeping every 5 seconds. Medtronic has determined all Rechargers manufactured starting in November 2014 (indicated by serial numbers beginning with "NKA4" or "NKU4") are more susceptible to this error state. This issue has been reported for approximately 2% of all Rechargers manufactured and sold since November 2014, and approximately 0,2% of Rechargers sold that were manufactured prior to November 2014.

When this error state occurs, the Recharger is unable to recharge the neurostimulator until the Recharger is reset. If the neurostimulator battery is allowed to become fully depleted, this can lead to loss of therapy and return of baseline pain levels and associated disease-specific symptoms. If the implanted neurostimulator battery is allowed to remain fully depleted, it may overdischarge, resulting in a permanent reduction in battery capacity and the need to recharge more frequently in the future.

Issue Mitigation:

1. In order to prevent this unresponsive error state, the Recharger should be plugged into the AC power supply (by aligning white triangles) prior to begin a recharging session of the neurostimulator and the Recharger should remain connected to the AC power supply until the recharging session is complete

(see Figure 1). Note: The AC power supply does not need to be plugged into a power outlet if the Recharger is charged.

2. If the Recharger is not connected to the AC power supply during a recharging session of the neurostimulator, the unresponsive error state may occur. In this situation, Medtronic requests that you assist patients with a reset of their Recharger by following the reset instructions enclosed. Note: This issue can recur after reset if the recharging instructions are not followed.



Figure 1

Recommendations:

- To ensure this issue does not occur, Medtronic recommends all affected patients follow the recharge practice explained above. Keeping the Recharger plugged into the AC power supply during recharging will prevent this error state from occurring.
- If you are contacted by a patient with a Recharger in an unresponsive error state, you can assist the patient with a reset of their Recharger by following the reset instructions enclosed.
- Medtronic is working on a permanent solution for this issue. Until this solution is in place, as appropriate please discuss this notification and the issue mitigation with your current and new patients implanted with a rechargeable neurostimulator to ensure they understand the mitigations to prevent this issue and the steps required to resolve the issue if it occurs. The enclosed patient notification can be used to facilitate this conversation as needed.

The Competent Authority of your country has been notified of this issue.

We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner. If you have any questions related to this notification please contact your Medtronic representative directly or via Tel. No: +353 1 5111 400.

Sincerely,

Keith Taverner Regulatory Affairs Manager UK & Ireland

Enclosures: (1) Recharger Reset Instructions

(2) Patient Notification