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Medtronic

Urgent Field Safety Notice

Medtronic Model 37751 Recharger included in Model 37651 Charging System

Important Device Information related to Deep Brain 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 how to restore functionality of the Recharger if the issue occurs. Model 37751 Rechargers are sold in kit Model 37651 Charging System for Deep Brain Stimulation (DBS). This Recharger is used by DBS patients who are implanted with a Medtronic Activa™ RC (Model 37612) implantable neurostimulator.

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 that were 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 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.

For a subset of patients receiving DBS therapy, in rare instances, a loss of DBS therapy may result in a life threatening injury or death. For example, patients being treated for Parkinson's disease may experience akinetic crisis, and patients treated for epilepsy may experience status epilepticus. Medtronic has not received any reports of life threatening injury or death associated with this issue.

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.

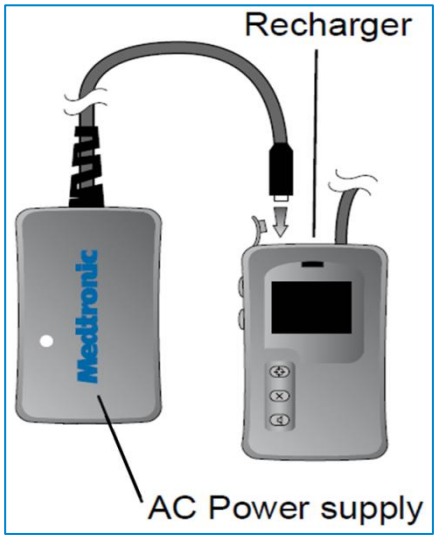

Figure 1

Patient notification:
Medtronic recommends that you inform your DBS patients registered with a Medtronic Activa™ RC (Model 37612) neurostimulator of this issue and mitigations provided in this letter, as soon as possible. A copy of a patient letter is enclosed along with the list of Model 37651 Recharger Systems shipped to your facility per Medtronic's records. Please use this information to manage conversations with your patients and ensure that they understand the recommendations to prevent lock-up and the steps required to resolve lock-up if it does occur.

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 a permanent solution is in place, Medtronic recommends you discuss this issue and the issue mitigation with any new patient implanted with a rechargeable neurostimulator and provide them with a copy of the patient notification.

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
(3) List of Model 37651 Recharger systems shipped to your facility