September 2016

Urgent: Medical Device Correction

Important information regarding the Medtronic Model 37751 Recharger,
which is included in Model 37651 Charging System,
Deep Brain Stimulation

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 information 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 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 after 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[1] may experience status epilepticus. Medtronic has not received any reports of life threatening injury or death associated with this issue.

Issue Mitigation:

1. To prevent this unresponsive error state, the Recharger should be plugged into the AC power supply (by aligning white triangles) prior to starting a recharging session of the neurostimulator and remain connected to the AC power supply until the recharging session has finished (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. Patients can contact Medtronic Neuromodulation Patient Services at 1-800-510-6735, where they will receive instructions to reset their unresponsive Recharger. Patients will be instructed to contact their physician if they experience a return of symptoms. Note: This issue can recur after reset if the recharging instructions are not completely followed.

Figure 1

[1] Epilepsy is not an approved indication in the US

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Patient notification:
Beginning the week of October 31, 2016, Medtronic will notify affected DBS patients of this potential issue and the mitigation steps to prevent this issue from occurring. Affected DBS patients are those implanted with a Medtronic Activa® RC (Model 37612) neurostimulator. A copy of the patient notification is enclosed along with a list of your affected patients (based on Medtronic's current registration records). Medtronic is providing this information to you so you can manage conversations with your patients as you deem appropriate.

Recommendations:

- To ensure this issue does not occur, Medtronic recommends all affected patients follow the issue mitigation recharge practice identified 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.

Additional information:
Medtronic is communicating this information to the appropriate regulatory agencies globally, including the US Food and Drug Administration.

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, as a healthcare provider, have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am – 6pm CT. Please report any malfunction or adverse event to Medtronic Neuromodulation Technical Services and to FDA's MedWatch Program (www.fda.gov/medwatch).

Sincerely,

Michael Ronningen
Vice President of Quality

Enclosures: (1) Recharger Reset Instructions
(2) Patient Notification
(3) List of your registered Rechargeable Neurostimulator patients
(4) Physician / HCP Reply Form

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