Medtronic
Medtronic International, Ltd. (Singapore Branch)
(Co. Reg. No. S98FC5604C)
50 Pasir Panjang Road
#04-51
Mapletree Business City
Singapore 117384
www.medtronic.com

tel 65.6870.5300
fax 65.6482.0300

Urgent: Medical Device Correction

Update to September 2016 Field Action:
Important information regarding the Medtronic Model 37751 Recharger

(Included in Kit Models 37754, 97754, and 37651)

28 February 2019

Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional,

Medtronic has implemented a design change to correct the issue that resulted in some Model 37751 Rechargers becoming unresponsive and beeping as discussed in the September 2016 Medical Device Correction Communication. Devices with the design change are now included in recharging systems for Spinal cord Stimulation (SCS – Kit Models 37754 and 97754) and in recharging systems for Deep Brain Stimulation (DBS – kit Model 37651).

This letter provides you information on the design change, including how to differentiate Rechargers manufactured prior to the design change from those manufactured after the change. Medtronic's recommendation for the two device populations, explained in the "Recommendations" portion of this letter, differ.

Requested Actions

- Read the information contained in this letter.
- Confirm your receipt of this letter by filling out and returning the attached Physician Reply form to your local Medtronic Representative.

Background:

In 2016, Medtronic 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 determined that Rechargers manufactured

starting in November 2014 (indicated by serial numbers beginning with [redacted]) are more susceptible to this error state. At the time of the initial communication, this issue had 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 and/or replace the implanted device.

Medtronic Implemented a Field Corrective Action in September 2016 at which time a**ll DBS and SCS implanting and managing physicians of patients associated with active rechargeable neurostimulator devices received an HCP letter describing the issue. The communication provided preventative recommendations to reduce the occurrence of the issue as well as instructions on how to restore Recharger functionality if the issue did occur. Based on device registration records, impacted** Health Care Professionals associated with DBS and SCS therapy since the 2016 communication have also received the notification on an ongoing basis.

Due to possible life-threatening severity of patient harms associated with loss of DBS therapy and to assist health Care Providers in informing patients, DBS patients with a rechargeable neurostimulator registered with Medtronic were sent a copy of a patient notification. As there are no possible life-threatening patient harms associated with loss of SCS therapy, SCS patients did not receive a patient notification.

Design Change:

The implementation of the design change to address the beeping/non-responsive issue for newly-manufactured Model 37751 Rechargers began in October 2018. The rechargers manufactured with the design change will be identifiable from devices manufactured prior to the design change by their serial numbers. Devices manufactured with the design change will contain serial numbers beginning with a "[redacted]"
[redacted]

Recommendations

For product manufactured prior to the design change [redacted]

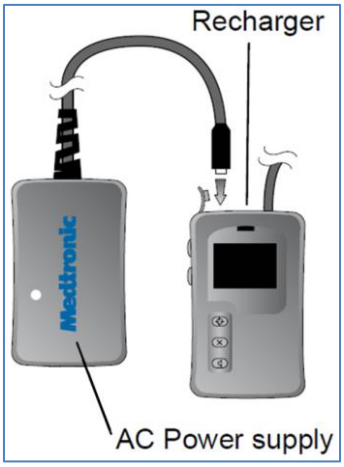

Figure 1

•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.

•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. Note: This issue can recur after reset if the recharging instructions are not completely followed.

- For product manufactured after the design change [redacted]

  Follow the instructions included with the Charging System user manual shipped with the device. Instructions in the user manual do not require the Recharger to be plugged into the AC power supply for a recharging session to occur.

If at any point 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.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced any other quality problems or adverse events.

If you have any questions or concerns regarding this Field Action, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,
Diana Teo
Quality Management System Manager

South East Asia
Medtronic

Enclosure: Customer Confirmation Form

Medtronic

Medtronic International, Ltd. (Singapore Branch)
(Co. Reg. No. S98FC5604C)
50 Pasir Panjang Road
#04-51
Mapletree Business City
Singapore 117384
www.medtronic.com

tel 65.6870.5300
fax 65.6482.0300

Customer Confirmation Form

Update to September 2016 Field Action:
Important information regarding the Medtronic Model 37751 Recharger
(Included in Kit Models 37754, 97754, and 37651)

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
	Name:
Physician / HCP :	**Contact:**
Address:	**Email:**
Phone no:	
E-mail:	

Dear Physician / Healthcare Professional,

According to our records, you are currently an implanting and/or managing physician for patients implanted with a Medtronic rechargeable neurostimulator system for Deep Brain Stimulation (DBS) and/or Spinal Cord Stimulation (SCS) therapies.

Indicate in the columns below all serial numbers you have in your facility.

37751 Recharger Serial Number	QTY

By signing this form, I confirm that I have received and understand attached information: **Update to September 2016 Field Action: Important information regarding the Medtronic Model 37751 Recharger (Included in Kit Models 37754, 97754, and 37651),** dated on 28 Feb 2019.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____