

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.



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 your Medtronic representative.

Sincerely,

Enclosures: (1) Recharger Reset Instructions

(2) Patient Notification

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

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)
- RestoreAdvanved™ 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 your Medtronic representative.

Sincerely,

*Enclosures: (1) Recharger Reset Instructions
(2) Patient Notification*

Important information about your Medtronic Model 37751 Recharger

Dear patient:

The purpose of this letter is to provide you with important information regarding your Model 37751 Recharger. Medtronic recently notified our office of the potential for your Recharger to become unresponsive (stop working) and beep every 5 seconds. This Recharger is the device you use to recharge your implanted rechargeable neurostimulator (implant). This letter provides information on how to prevent the occurrence of this issue and how to restore Recharger functionality if this issue occurs.

How to know if this issue happens:

You will notice when this issue happens because your Recharger will beep every 5 seconds, the display screen will be blank, and the buttons will not be responsive. If this happens, your Recharger will not be able to recharge your implant.

Why understanding this issue is important:

If this error state occurs, the Recharger cannot charge the implant. If the implant battery becomes fully depleted, this can lead to loss of your therapy and return of symptoms.

How to prevent this issue from happening:

To prevent this issue, take the following steps every time you recharge your implant:

1. Plug the AC power supply into your Recharger, lining up the white triangles, prior to begin a recharging session of the implant (see Figure 1).
Note: The AC power supply does not need to be plugged into a power outlet, if the Recharger is charged.
2. Keep the AC power supply connected to the Recharger until the recharging session is complete.
Note: Make sure that you handle the Recharger, antenna, and AC power supply with care, and stabilize and secure the connections.



Figure 1

How to restore Recharger functionality if this issue occurs:

If you do not plug the AC power supply into the Recharger when recharging your implant and this issue occurs, please contact our office at [<Insert clinic contact information>](#) to speak with our staff. We can help you with instructions to reset your Recharger so it will start working again.

This issue can still happen after reset if the charging instructions above are not completely followed. Remember, keeping the Recharger plugged into the AC power supply during recharging will prevent this issue from occurring.

Contact our office immediately if you experience a return of underlying symptoms so that your symptoms can be prevented from becoming worse.

We are sorry for the inconvenience that this issue may cause, and we appreciate your time and attention to this important notification.

Sincerely,

[<Insert Physician Practice Information>](#)

MODEL 37751 RECHARGER RESET INSTRUCTIONS

Medtronic

1 WHAT YOU NEED

- small Flathead screwdriver
- standard paper clip



WARNING: Recharger must be unplugged. Do not reset the recharger while it is plugged into the AC power supply.

2 REMOVE ACCESS COVER



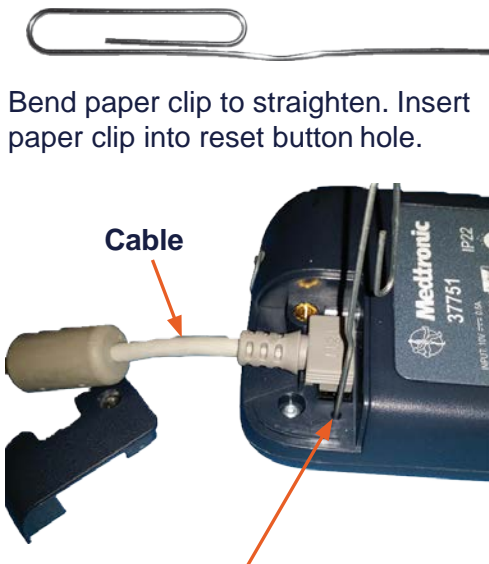
Use small Flathead screwdriver to unscrew and remove access cover.

3 LOCATE RESET HOLE



Locate reset button hole.

4 PERFORM RESET



Bend paper clip to straighten. Insert paper clip into reset button hole.

Press and hold reset button for 2 seconds. Replace access cover and tighten the screw.

Note: Ensure that the cable is still securely plugged in before you replace the access cover.

5 CLEAR SCREEN



The recharger displays the AC Recharge screen. Press the green button to clear the screen.

6 CONFIRM RESET COMPLETE



Press the green button again to start a charging session. If the recharger does not function, contact your Medtronic Representative.