

URGENT FIELD SAFETY NOTICE

Medtronic Wireless Recharger Model WR9200 included in RS7200 Charging System

Product Description	Product Number
RECHARGER KIT (RestoreUltra® & RestoreSensor®)	RS7200

November 2021

Medtronic Reference: FA1183

Dear Health Care Professional,

The purpose of this letter is to inform you of the potential for the Medtronic Wireless Recharger (WR) device WR9200 to become unresponsive if the charging steps indicated in the Recharger Patient User Guide are not followed. This issue can be prevented by adhering to the charging instructions for use. Below we provide more information on the issue and how to prevent it from occurring.

The Wireless Recharger devices are used by Spinal Cord Stimulation (SCS) patients who are implanted with the following implantable neurostimulators:

- SCS: RestoreUltra® (Model 37712)
- SCS: RestoreSensor™ (Model 37714)
- SCS: RestoreUltra® SureScan® MRI (Model 97712)
- SCS: RestoreSensor® SureScan® MRI (Model 97714)

Issue Overview:

Medtronic has identified through a complaint assessment, that the Medtronic WR9200 recharger, contained within the Recharger Kit RS7200, have had occurrences where the WR device becomes unresponsive. This issue may occur when the WR is fully depleted and the WR is placed on the dock and quickly removed within 20 seconds, interrupting the initialization routine. The Recharger Patient User Guide instructs the user to place the WR on the dock and charge to full before first use. When the WR becomes unresponsive, the WR will not respond to a button press and will cause the recharger battery indicator to continuously flash when placed on the battery dock.

In the event of an unresponsive wireless recharger, the user will not be able to charge their implanted neurostimulator, until a replacement WR device is received. The unresponsive state of the wireless recharger may lead to unanticipated implanted neurostimulator (INS) battery depletion. For the Restore INS, if this unanticipated INS battery depletion (over-discharge state) occurs three times, the battery cannot be recharged and will require surgical intervention.

This issue potentially occurs if the specific sequence described above is followed. This issue can be prevented by adhering to the instructions outlined in the Recharger Patient User Guide. Since January 2020, Medtronic has received no complaints associated to this issue for Restore INS patients.

Requested Actions:

- Enclosed is a Patient Quick User Guide, which provides guidelines to ensure proper care and maintenance of the Wireless Recharger. Please reinforce these instructions with your patients. Additional copies of the Patient Quick User Guide are available through your Medtronic Representative.
- If the WR device appears unresponsive, first attempt to reset the WR by holding the power button down (located at the top of your recharger device) until the battery lights begin to flash. This could take up to 45 seconds. If the problem is not resolved, contact your Medtronic Representative.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.



We regret any inconvenience that this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Local / BU Manager

Enclosure:

Patient Quick User Guide

SCS THERAPY WIRELESS RECHARGER

Model WR9200 for RestoreSensor™ and RestoreUltra™

Quick Guide



RECHARGER KIT ITEMS



Recharger



Dock



Belt



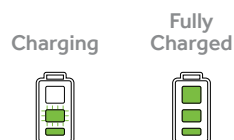
USB Cable

CHARGE YOUR RECHARGER



- 1 Connect the USB cable to the dock.
- 2 Plug the USB cable into the power adapter, and plug the adapter into a wall outlet. The dock must rest on a flat surface while plugged in.
- 3 Place the recharger, button-side up, into the dock. Leave your recharger on the dock between recharging sessions to maintain full charge.

Note: If you're charging your recharger for the first time, it's important to complete the charge without removing the charger from the dock to properly take it out of shipping mode.



- 4 When your recharger is fully charged, the battery icon will display as shown in the figure.

CHARGE YOUR IMPLANT

Charging



Fully Charged



- 1 Check the battery level of the recharger, and charge your recharger, if necessary.













See "Charge your recharger" on the other side for instructions.



- 2 Place the recharger into your belt, and position the two concentric circles on the belt and recharger over your neurostimulator site.

- 3 Turn on the recharger. The recharger will beep until it connects to your neurostimulator.

YOUR RECHARGER INDICATORS

Tone	Light	Meaning
 Repeating beeping tone	 Spinning	Recharger is searching for the neurostimulator.
 2 tones, rising in pitch	 Solid	Neurostimulator has been found. Note: If you hear 3 additional tones, see Elective Replacement Indicator in the following row.
 3 tones at the same pitch	 Solid	Elective Replacement Indicator See your recharger manual for more information.
None	 Slow Pulsing	Recharging neurostimulator.
 A series of tones, rising in pitch	 Solid	Recharging session is complete.
 2 tones, falling in pitch and repeating	 Flashing	Neurostimulator not found or Other alert/error See your recharger manual for more information.
2 tones, falling in pitch and repeating	 Flashing	Recharger battery is low.

Medtronic

710 Medtronic Parkway
 Minneapolis, MN 55432-5604
 USA
 Tel: (763) 514-4000

medtronic.com

© 2021 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. UC202120698aEN