

**URGENT FIELD SAFETY NOTICE**  
**Medtronic Wireless Recharger Model WR9200**  
**included in Model RS6200 Charging System**

Product Description	Product Number
RECHARGER KIT (ACTIVA RC)	RS6200

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) devices 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 device is used by the Activa™ RC (Model 37612) implantable neurostimulator.

**Issue Overview:**

Medtronic has identified through a complaint assessment, that the Medtronic WR9200 recharger, contained within the Recharger Kit RS6200, 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 Wireless Recharger becomes unresponsive, the Wireless Recharger will not respond to a button press, cannot pair with the recharger app, 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 Activa INS, if the INS battery continues to deplete and the over-discharge state is reached three times, the INS battery cannot be recharged and will require surgical intervention.

This issue only 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. From January 2020 to June 22, 2021, Medtronic has received 19 complaints associated to this issue, of which there have been no reports of serious patient injury attributed to this issue.

**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

# MEDTRONIC DBS THERAPY WIRELESS RECHARGER

## MODEL WR9200 FOR ACTIVA™ RC DEVICES

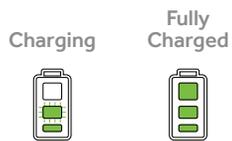
### Quick Guide



#### 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.  
**PLEASE NOTE:** If you are charging your recharger for the first time, it is 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.

#### PAIRING THE RECHARGER TO THE APP\*

\*recharger app is optional and not required to charge implant

- 1 Turn on and unlock your handset
- 2 Open the recharger app by tapping the app icon (📱)
- 3 Turn on your recharger.
- 4 In the recharger app, tap **Connect**.



- 5 Tap **Scan Code**.  
**Note:** Tap "Allow" on the pop-up requesting access to the camera, if it occurs.



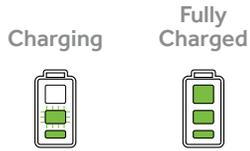
- 6 Aim the handset camera at the scannable code on the recharger, keeping the entire code visible on the handset screen, until you receive confirmation on the handset that pairing is complete.

See other side for additional instructions. >

For video tutorials, visit  
[Medtronic.com/myDBSRecharger](https://www.medtronic.com/myDBSRecharger)

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## CHARGING YOUR IMPLANT



- 1 Check the battery level of the recharger, and charge your recharger, if necessary. See "Charging your recharger" on the other side for instructions.



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

**Note:** Use the counterweight when using the drape to balance the recharger

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

## YOUR RECHARGER INDICATORS

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

## USING THE OPTIONAL RECHARGER APP



- 1 **Menu** button (☰) – Tap to access charging speed settings and app information. The recharger defaults to fastest speed.
- 2 **Neurostimulator Battery** icon – Your neurostimulator battery status. The number next to this image indicates how full the neurostimulator battery is.
- 3 **Connection** icon – Your connection status between your recharger and your neurostimulator.
- 4 **Recharger** button – Tap to view the recharger battery status and change the volume of your recharger.

## Medtronic

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