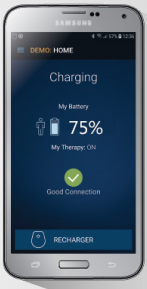
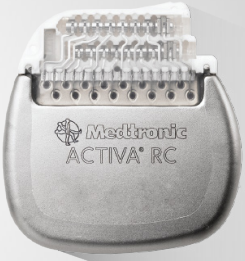
NOW YOU'RE IN CHARGE

with a 15-year* rechargeable DBS System that's designed to fit around your life.



TH90D01 Activa™ Patient Programmer

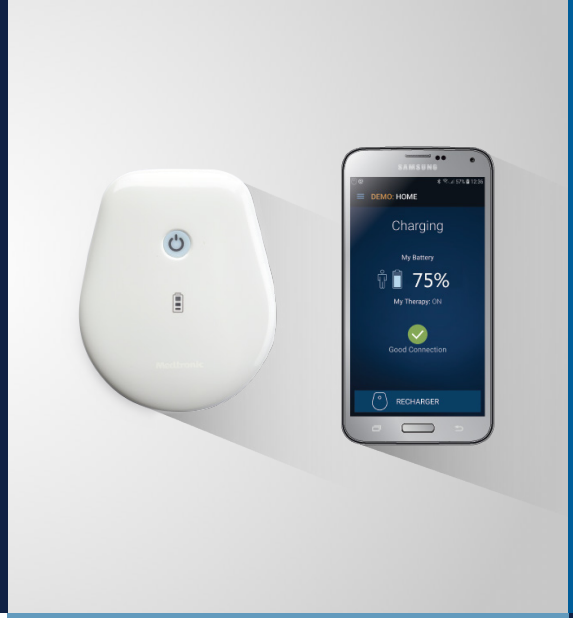
WR9200 Recharger



Activa™ RC Neurostimulator

Medtronic
Further, Together

It's time for a therapy that works for you, not the other way around. So we've designed a system that offers flexibility, ease, and a 15-YEAR SERVICE LIFE—in a smart, updated package that gives you what you need without holding you back.



THE EASE YOU DESIRE.

Staying powered up has never been easier. And with the intuitive design of the system, you can be confident you're getting an optimal charge, every time.

- Streamlined components
- Simple charging process, initiated with a single press of a button
- Large coupling area for a consistent connection
- Simple LED indicators

PROVEN 15 YEAR PERFORMANCE.

Your Activa™ RC Neurostimulator is warrantied and approved to provide service for 15 years between replacement surgeries, leaving you more time to engage in your life.

KEEPING ACCESS TO MRI.

Approximately 7 out of 10 DBS-eligible patients with movement disorders may need an MRI within 10 years of receiving their device[1]. So why limit your imaging options down the road? Your Medtronic Activa™ RC DBS system is approved for use with MRI, under certain conditions.**

AN UPDATED RECHARGING EXPERIENCE.

Keeping your therapy on with an altogether smarter experience.

- Wireless mobility while charging
- Proprietary recharge algorithm to maintain safe temperatures
- Exclusive companion recharge application
- The majority of Parkinson's Disease and Essential Tremor patients find the Activa™ RC recharge system to be easy to use***

A HELPFUL COMPANION

The Medtronic Recharger Companion App offers you an easy way to access information and controls during your charge including:

- Progress toward completion
- Volume Control
- Speed and temperature controls

"Knowing that I can postpone surgery for so long is better for me and my family."

—Amybel,
Receiving DBS Therapy with Activa™ RC device on 15 year rechargeable battery.

A SMARTER DBS EXPERIENCE IS IN YOUR HANDS.

We're here to help you get more of your life back, with an experience that's more tailored for you—because you're in charge.

Brief Statement: Medtronic DBS Therapy for Parkinson's Disease and Tremor

Medtronic DBS Therapy for Parkinson's Disease and Tremor: Patients should always discuss the potential risks and benefits with a physician.

INDICATIONS:
Medtronic DBS Therapy for Parkinson's Disease: Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

Medtronic DBS Therapy for Tremor: Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

CONTRAINDICATIONS: Medtronic DBS Therapy is contraindicated (not allowed) for patients who are unable to properly operate the neurostimulator and patients for whom test stimulation is unsuccessful. The following procedures are contraindicated for patients with DBS systems: diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy), which can cause neurostimulation system or tissue damage and can result in severe injury or death; Transcranial Magnetic Stimulation (TMS); and certain MRI procedures using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area if the patient has an implanted Soletra™ Model 7426 Neurostimulator, Kinetra™ Model 7428 Neurostimulator, Activa™ SC Model 37602 Neurostimulator, or Model 64001 or 64002 pocket adaptor.

WARNINGS: There is a potential risk of brain tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths and a potential risk to drive tremor (cause tremor to occur at the same frequency as the programmed frequency) using low frequency settings. Extreme care should be used with lead implantation in patients with an increased risk of intracranial hemorrhage. Sources of electromagnetic interference (EMI) may cause device damage or patient injury. Theft detectors and security screening devices may cause stimulation to switch ON or OFF and may cause some patients to experience a momentary increase in perceived stimulation. The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/ defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. MRI conditions that may cause excessive heating at the lead electrodes which can result in serious and permanent injury including coma, paralysis, or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). The safety of electroconvulsive therapy (ECT) in patients receiving DBS Therapy has not been established. Abrupt cessation of stimulation should be avoided as it may cause a return of disease symptoms, in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). New onset or worsening depression, suicidal ideations, suicide attempts, and suicide have been reported.

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement that may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Patients should avoid manipulating the implanted system components or burr hole site as this can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA) as this could damage the neurostimulation system, before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician. Patients using a rechargeable neurostimulator must not place the recharger over a medical device with which it is not compatible (eg, other neurostimulators, pacemaker, defibrillator, insulin pump). The recharger could accidentally change the operation of the medical device, which could result in a medical emergency. Patients should not use the recharger on an unhealed wound as the recharger system is not sterile and contact with the wound may cause an infection.

PRECAUTIONS: Loss of coordination in activities such as swimming may occur. Patients using a rechargeable neurostimulator for Parkinson's disease or essential tremor should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

ADVERSE EVENTS: Adverse events related to the therapy, device, or procedure can include intracranial hemorrhage, cerebral infarction, CSF leak, pneumocephalus, seizures, surgical site complications (including pain, infection, dehiscence, erosion, seroma, and hematoma), meningitis, encephalitis, brain abscess, cerebral edema, aseptic cyst formation, device complications (including lead fracture and device migration) that may require revision or explant, extension fibrosis (tightening or bowstringing), new or exacerbation of neurological symptoms (including vision disorders, speech and swallowing disorders, motor coordination and balance disorders, sensory disturbances, cognitive impairment, and sleep disorders), psychiatric and behavioral disorders (including psychosis and abnormal thinking), cough, shocking or jolting sensation, ineffective therapy and weight gain or loss.

Safety and effectiveness has not been established for patients with neurological disease other than idiopathic Parkinson's disease or Essential Tremor, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years. Safety and effectiveness of Medtronic DBS Therapy for Tremor has not been established for bilateral stimulation or for patients over 80 years of age.

USA Rx only Rev 03/20

[1] Falowski S, Safriel Y, Ryan MP, Hargens L. The rate of magnetic resonance imaging in patients with deep brain stimulation. Stereotactic Funct Neurosurg. 2016; 94(3):147-153.
*Activa™ RC devices eligible for the 15 year service life extension are those that have successfully been interrogated with the A610 application on the Medtronic Activa Clinician Programmer prior to reaching End of Service (EOS). Proper maintenance is required.
**Medtronic DBS systems are MR Conditional which means they are safe for MRI scans only under certain conditions. If the conditions are not met, the MRI could cause tissue heating especially at the implanted lead(s) in the brain which may result in serious and permanent injury or death. Before having an MRI, always talk with the doctor who manages your DBS Therapy to determine your eligibility and discuss potential benefits and risks of MRI. For further information, please call Medtronic at 1-800-328-0810.
***Medtronic Data on File

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
Toll-free: 1 (800) 328-2518
24-hour technical support for
physicians and medical professionals

medtronic.com