Medtronic

Percept™ family with adaptive BrainSense™ technology

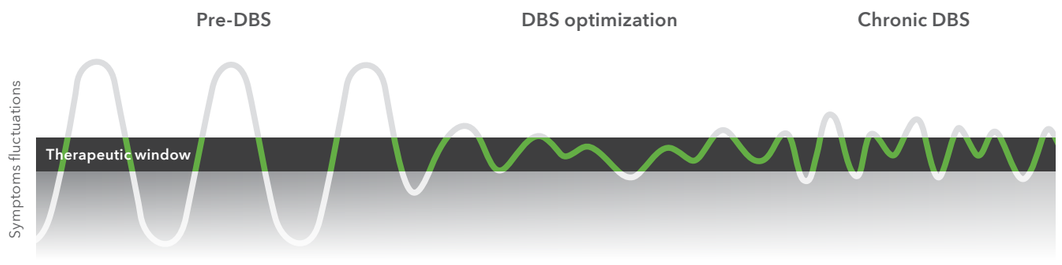
The first and only sensing-enabled deep brain stimulation (DBS) system just got better

The **future** of care for patients with Parkinson's disease with the **first and only closed-loop DBS system**

Every patient's journey with Parkinson's disease is different.

Managing each patient's disease can be complicated and time consuming.[1,2]

Motor symptom fluctuations over time



Initial challenges

DBS programming can take time. It's not always easy to locate the sensing "sweet spot" on the lead.

Ongoing challenges

Once DBS therapy begins, a patient's motor symptoms can fluctuate throughout the day due to various factors, including the effects of medications. Additionally, physicians typically spend only a few hours each year with each patient during clinic visits, making it challenging to capture a comprehensive view of their condition.

Why BrainSense™ technology†?

The Percept™ family with BrainSense™ technology is the only sensing-enabled DBS system offering insights into a patient's condition inside and outside of the clinic throughout the patient journey.

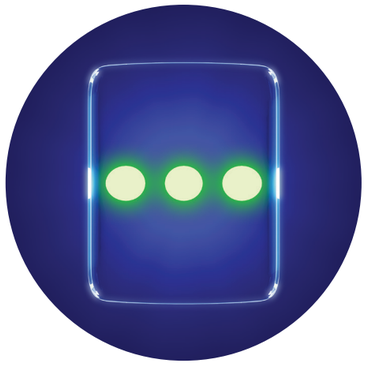
BrainSense™ suite of tools

The BrainSense™ suite of tools offers decision-making support to select and optimize programming configurations and to maximize therapeutic results.

Experience the cutting-edge advancements exclusive to the Medtronic Percept™ family of devices:

BrainSense™ Electrode Identifier

The BrainSense™ Electrode Identifier feature **guides you to the sensing "sweet spot"** on the lead, providing a starting point for DBS programming and identification of initial contacts for stimulation delivery.

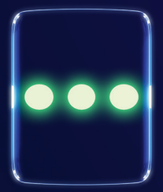


BrainSense™ Adaptive DBS (aDBS)

aDBS uses BrainSense™ technology to **automatically adjust** therapeutic stimulation to **maximize motor symptom control** throughout the day and night.‡

†The sensing feature of the Percept™ PC and Percept™ RC system is intended for use in patients receiving DBS where chronically recorded bioelectric data may provide useful, objective information regarding patient clinical status.
‡Improved motor symptom control results were based on post hoc analysis averaging overall patient aDBS on time results compared to cDBS. Results presented for dual threshold aDBS. N=40. Based on results from an open-label comparison.

Conduct an initial programming – **faster**, compared to monopolar review†,[3]



Electrode Identifier guides you to the "sweet spot" on the lead

Select an initial contact in **<2 minutes**†,[3]

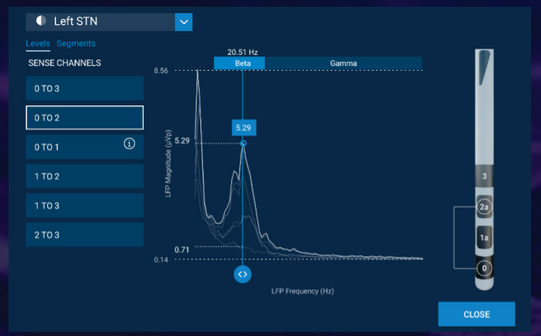
Bipolar sensing with BrainSense™ Survey (now called Electrode Survey)

BrainSense™ Electrode Survey uses bipolar recordings, which are taken from 2 electrodes on the same lead.

Advancing DBS technology with BrainSense™ Electrode Identifier (monopolar sensing)

BrainSense™ Electrode Identifier: Monopolar recordings are taken from a **specific electrode on the lead** by using a distal reference *(sufficiently far away)*.

Electrode Survey



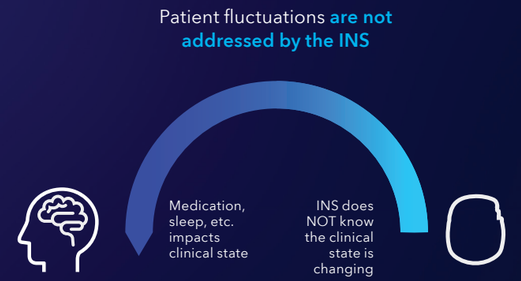
BrainSense™ Electrode Identifier

† At initial programming, compared to standard monopolar review for Parkinson's disease. Results based on bench testing, may not be indicative of clinical experience.

Improved motor symptom control, on average, with **BrainSense™ aDBS** compared to cDBS†

Open-loop cDBS therapy

While open-loop DBS therapy – also called continuous DBS (cDBS) – is a proven therapy for treating symptoms of Parkinson's disease (tremor, bradykinesia, rigidity), patients may continue to exhibit fluctuations in their motor symptoms.[1,4,5]

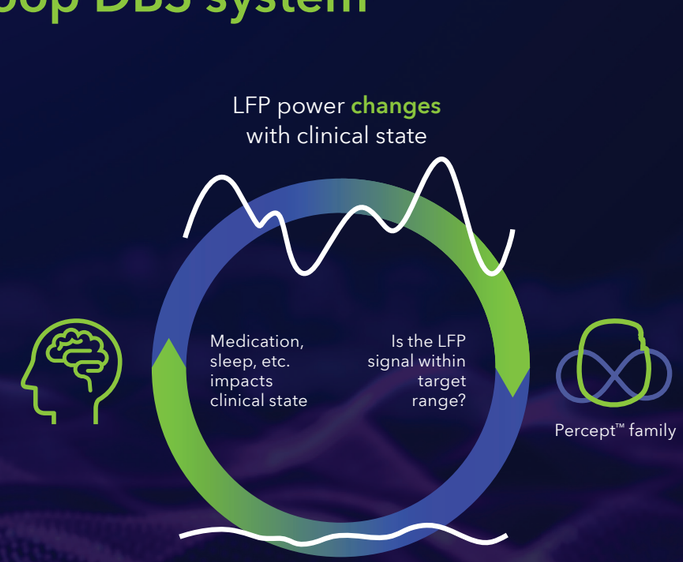


Percept™ family with BrainSense™ aDBS – the **only closed-loop DBS system**

BrainSense™ aDBS closed-loop therapy

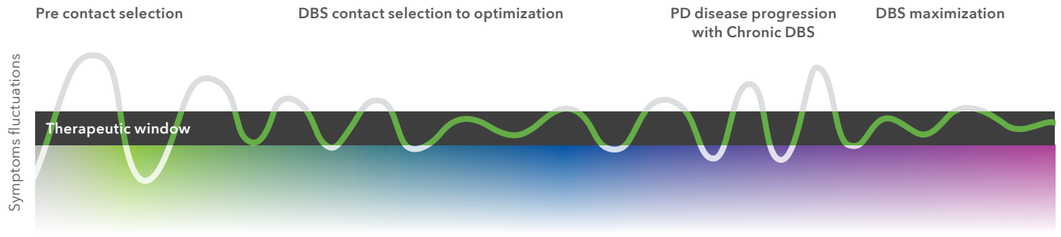
Addressing motor symptom fluctuations of Parkinson's disease

BrainSense™ aDBS continuously adapts to a patient's unique neurophysiological signals, allowing for a more consistent and personalized therapy throughout the day.



† Improved motor symptom control results were based on post hoc analysis averaging overall patient aDBS on time results compared to cDBS. Results presented for dual threshold aDBS. N=40. Based on results from an open-label comparison.

Adapting to patients' dynamic needs over time

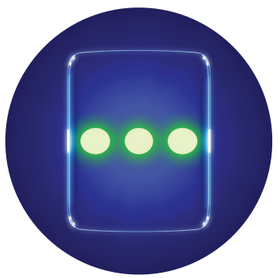


Select and **Optimize** DBS with Electrode Identifier and Enhanced BrainSense™ tools – **only with Medtronic**

Maximize DBS therapy with aDBS – **only with Medtronic†**

Select Optimize Maximize

New
BrainSense™ Electrode Identifier



Enhanced
BrainSense™ Streaming, Thresholds, Timeline, and Events

New
BrainSense™ aDBS

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Percept™ family with BrainSense™ technology

The Percept™ family with BrainSense™ technology is the first and only sensing-enabled, fully closed-loop DBS system. It empowers you to tailor DBS therapy to meet your patients' evolving needs over time.

Designed to address both current and future clinical challenges, the Percept™ family with exclusive BrainSense™ technology offers:

Personalized decision-making support

Increased in-clinic efficiency†,3

Improved motor symptom control, on average‡

Designed for software upgradeability – no need for device exchanges

Patient Safety

The safety profile observed for aDBS is consistent with the safety profile for cDBS. Stimulation-related side effects are expected during initial aDBS setup, such as worsening of Parkinson's disease symptoms and dyskinesias, and are expected to resolve with reprogramming. It's important to ensure patients have regular follow up visits to monitor response to therapy, optimize programming, and manage any stimulation-related side effects promptly, especially within aDBS adjustment and set up periods (at least within the first few months of aDBS programming). aDBS is an optional programming feature and may not work for everyone.

Engineered to adapt

Visit
Medtronic.com/BrainSense

Visit
Medtronic Academy

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References

1. Fox SH, Katzenschlager R, Lim S-Y, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease. *Mov Disord* 2018;33(8):1248–66. https://pubmed.ncbi.nlm.nih.gov/29570866.10.1002/mds.27372.
2. Pedrosa DJ, Timmermann L. Review: management of Parkinson's disease. *Neuropsychiatr Dis Treat*. 2013;9:321-340 https://doi.org/10.2147/NDT.S32302.
3. Data on file, Medtronic.
4. Schuepbach WMM, Rau J, Knudsen K, et al: Neurostimulation for Parkinson's disease with early motor complications. *N Engl J Med*. February 14, 2013;368:610-22 7.
5. Weaver FM, Follett K, Stern M, et al. Bilateral deep brain stimulation vs best medical therapy for patients with advanced Parkinson disease: a randomized controlled trial. *JAMA*. 2009;301(1):63–73. https://pubmed.ncbi.nlm.nih.gov/19126811.10.1001/jama.2008.929.

Brief Statement: Medtronic DBS Therapy for Parkinson's Disease

Product labeling must be reviewed prior to use for detailed disclosure of risks.

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.

CONTRAINDICATIONS: Medtronic DBS Therapy is contraindicated for patients who are unable to properly operate the neurostimulator. 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 implanted cardiac devices (e.g., pacemaker, defibrillator), external defibrillation/cardioversion, 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 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, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression, patients who are pregnant, or patients under 18 years.

USA Rx only Rev 10/24

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