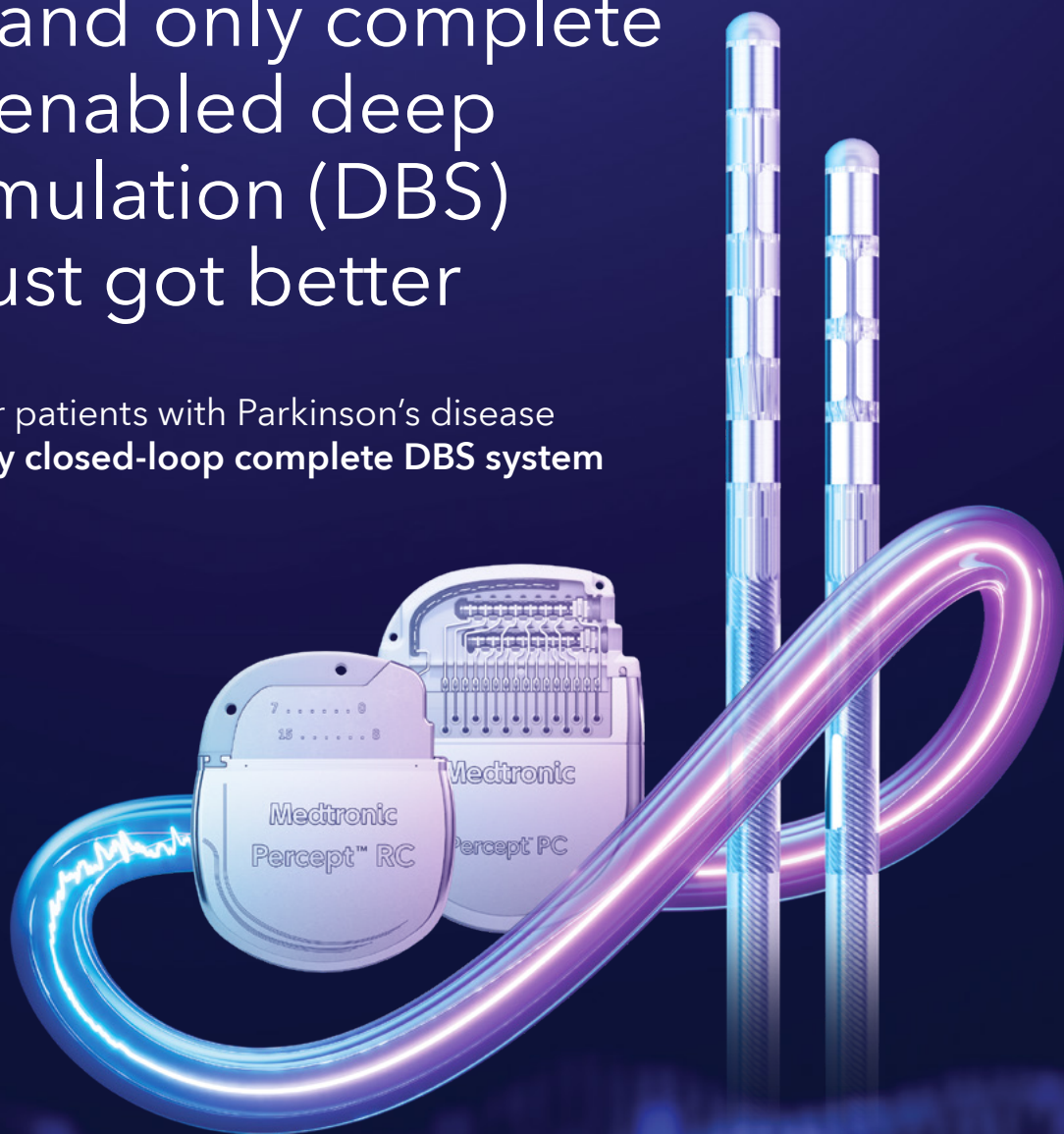




Percept™ family with adaptive BrainSense™ technology

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

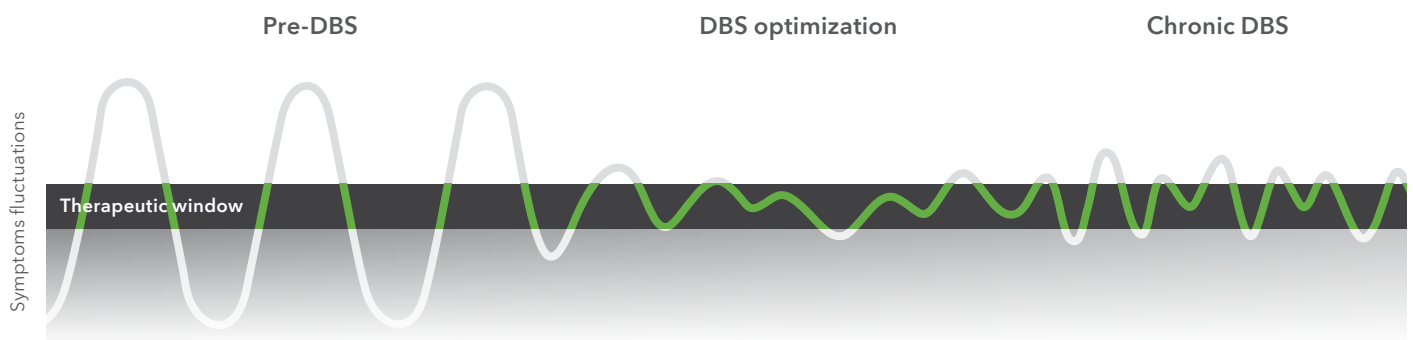
The **future** of care for patients with Parkinson's disease
with the **first and only closed-loop complete DBS system**



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 complete sensing-enabled DBS system offering insights into a patient's condition inside and outside of the clinic throughout the patient journey.

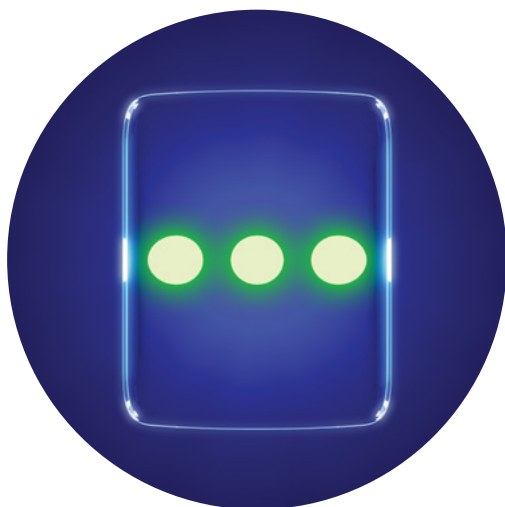
BrainSense™ suite of tools

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)

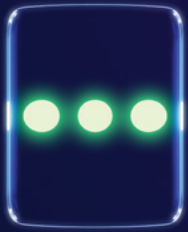
aDBS uses BrainSense™ technology to **automatically adjust** therapeutic stimulation to **maximize motor symptom control** throughout the day and night.‡



†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}



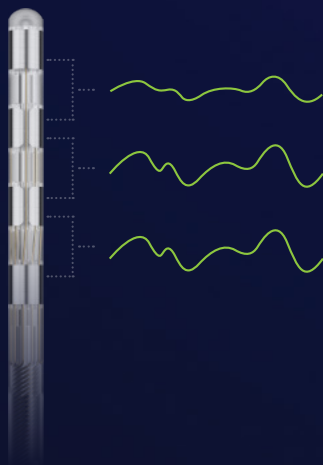
Electrode Identifier guides you to the “sweet spot” on the lead



Select an initial contact in **<2 minutes**^{†,3}

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

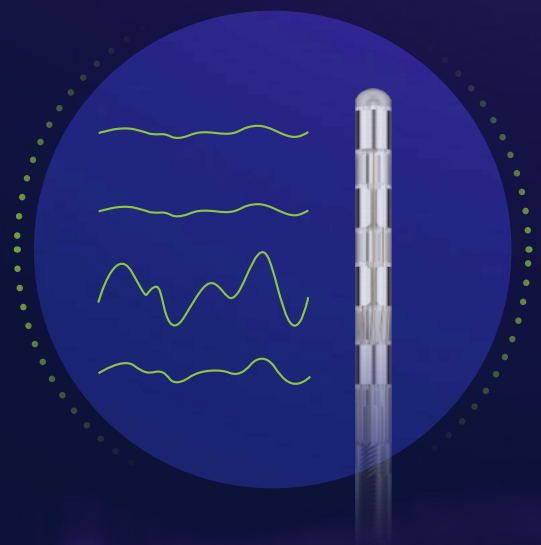
BrainSense™ Electrode Survey uses bipolar recordings, which are taken from 2 electrodes on the same lead.



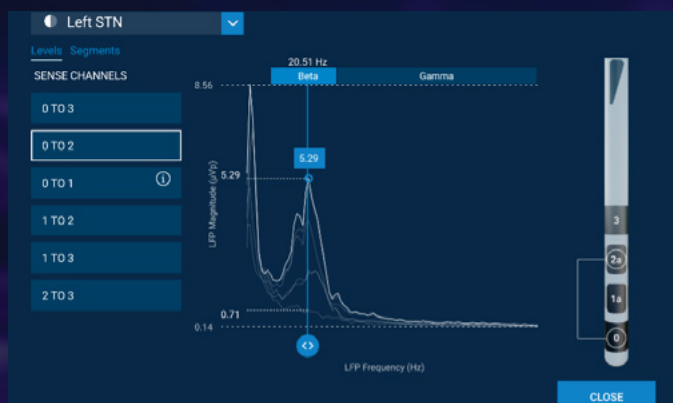
Advancing DBS technology with BrainSense™ Electrode Identifier (monopolar sensing)

BrainSense™ Electrode Identifier:

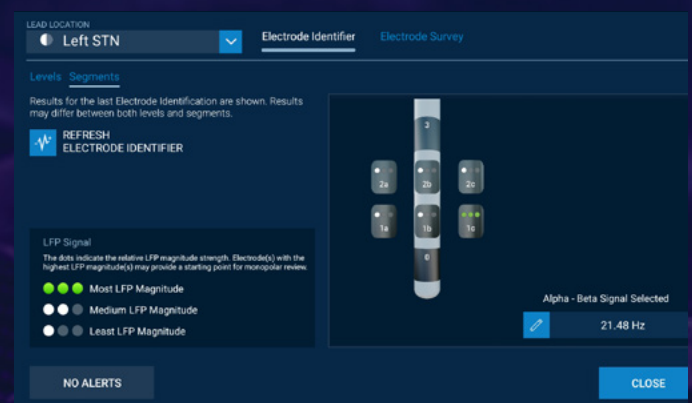
Monopolar recordings are taken from a **specific electrode on the lead** by using a distal reference (top electrode of the opposite lead).



Electrode Survey



BrainSense™ Electrode Identifier

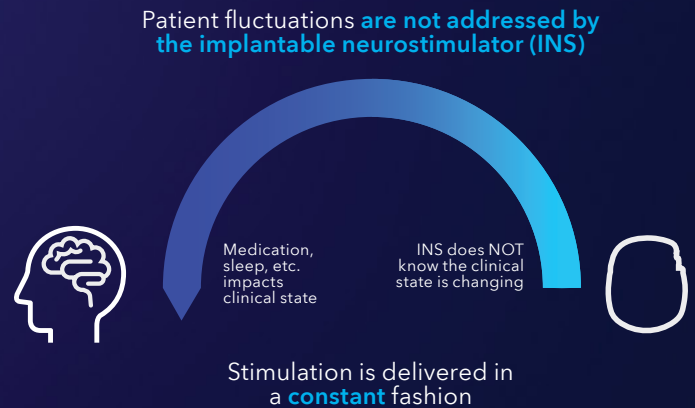


[†] At initial programming, compared to standard monopolar review for Parkinson's disease. Results based on bench testing, may not be indicative of clinical experience.

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.^{1,4-6}

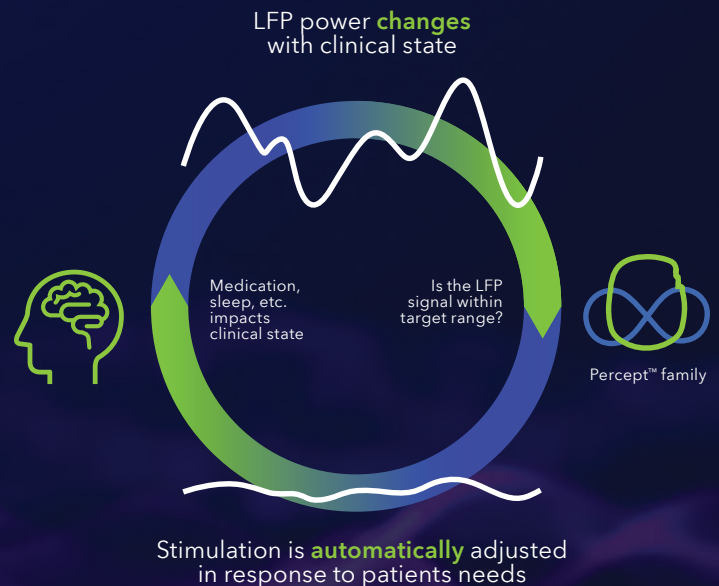


Percept™ family with BrainSense™ aDBS – the **only closed-loop DBS system available**

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.

Breaking new ground in Parkinson's disease research

ADAPT-PD clinical trial⁷

The ADAPT-PD clinical trial's intent was to determine safety and effectiveness of the adaptive feature within a clinical workflow and with the practicality and efficiency desired by clinicians managing Parkinson's disease.

Additionally, the trial helped to inform the overall user experience and workflow optimization to simplify BrainSense™ aDBS programming.

ADAPT-PD clinical trial is the **first** to study:

- **Chronic aDBS study** (>1 year)
- **aDBS in subthalamic nucleus (STN) & internal globus pallidus (GPi)**
- **Comparison of two aDBS modes** (single and dual thresholds)
- **aDBS with directional stimulation**

ADAPT-PD trial: comparable cDBS efficacy to two previous randomized control trials + **an increase, on average, in "On" time compared to cDBS**



aDBS Setup and adjustment phase

All but one stimulation-related adverse event resolved with reprogramming.

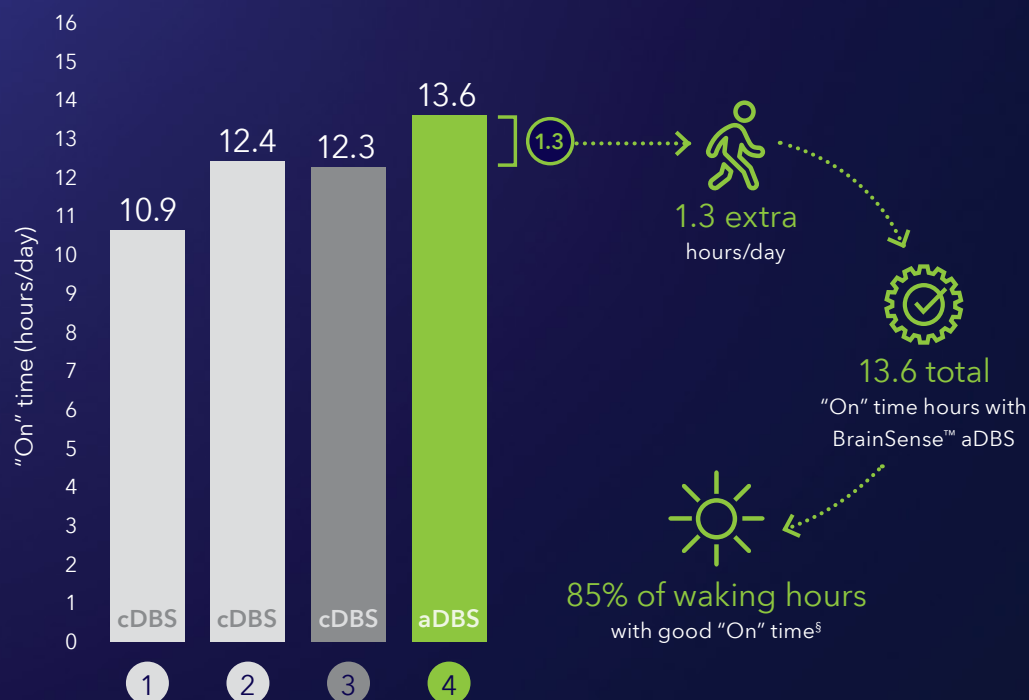


Enrollment through long-term follow-up

No serious adverse device events (N = 44).

Historical view of "On" time without troublesome dyskinesia^{†,‡,4,5}

- 1 Weaver et al., 2009 (N = 121) compared best medical therapy to cDBS at 6 mo follow-up postoperatively
- 2 Schuepbach et al., 2013 (N = 105) compared best medical therapy to cDBS at 24 mo[§]
- 3 Medtronic cDBS ADAPT-PD (n = 40) Prospective open-label, outcomes at 1 mo
- 4 Medtronic aDBS ADAPT-PD in Dual Threshold Mode (n = 40) Prospective open-label, outcomes at 1 mo



BrainSense™ aDBS means patients living with Parkinson's have more ways to manage their symptoms

98% preferred BrainSense™ Adaptive DBS over traditional DBS after using for 30 days^{†7}

[†] Study sizes, designs, and populations vary. Patients in the Medtronic ADAPT-PD study were previously implanted and on stable cDBS.

Patients in other studies were newly implanted. The figure legend provides additional study details.

[‡] Compared to continuous DBS (cDBS). Results presented for dual threshold aDBS. n = 40. Based on results from an open-label trial.

[§] 16 hours. Study data in 45 patients, 40 patients evaluated on Dual Threshold mode.

0.6 hours/day more "On" time without troublesome dyskinesias with single threshold (n = 35)

[¶] In Schuepbach et al. 2013, "On" time without troublesome dyskinesia when cDBS is active has been calculated by the addition of the baseline value of 10.3 ± 0.5 and the change from baseline to 24 months value of 2.1 ± 0.5 .

How does it work?

BrainSense™ aDBS automates a patient's stimulation therapy within clinician-defined parameters, including minimum and maximum stimulation amplitude limits, and local field potential (LFP) thresholds.

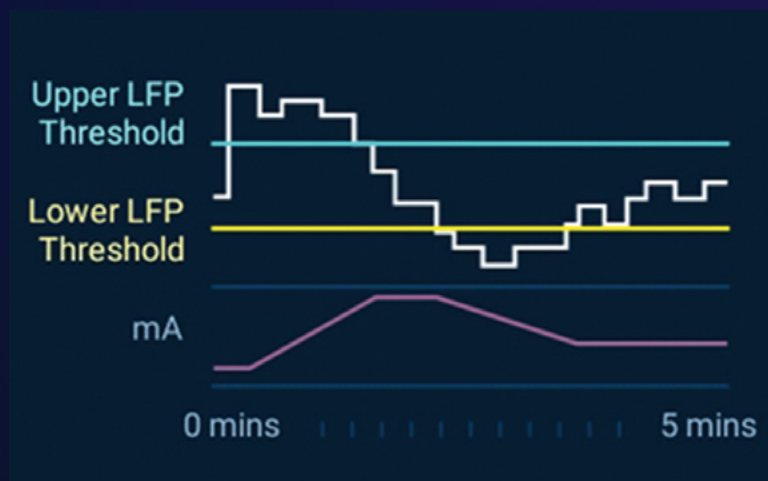
Choose between two threshold modes

To help further personalize your patient's DBS therapy, BrainSense™ aDBS uses an automated algorithm that can be powered by two threshold modes: single threshold mode or dual threshold mode.

The neurostimulator responds to patient needs with varied stimulation based on your selected mode of either single or dual threshold mode.

Dual threshold

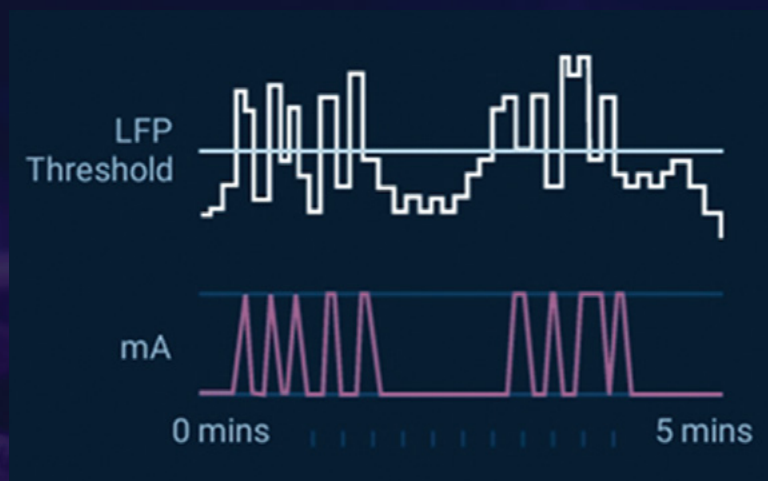
Slower (minutes)
adaptation of
therapy



Setting two
thresholds

Single threshold

Rapid (milliseconds)
adaptation of
therapy



Setting one
threshold

⋮ aDBS is feasible and tolerable



LFP signal present to set up aDBS in 84% (57/68) of patients at enrollment at On-medication



aDBS tolerable and successfully set up in 87% (45/52) of patients

⋮ aDBS is effective

Primary objective met: Effectiveness

Dual Threshold aDBS proportion of success was 91% (n = 40); and Single Threshold aDBS proportion of success was 79% (n = 35).

Primary endpoint success criteria:

No worse than -2 hour loss of "On" time without troublesome dyskinesia during aDBS relative to cDBS.

Dual Threshold

91%

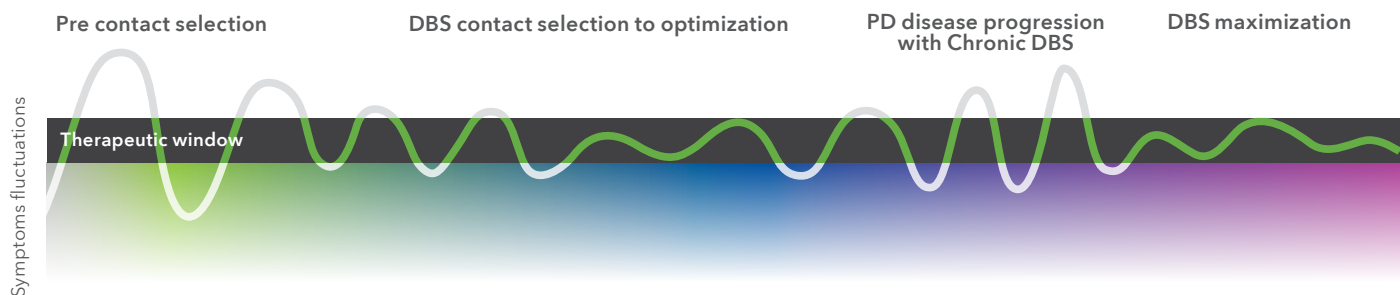
participants

Single Threshold

79%

participants

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 BrainSense™ aDBS -
only with Medtronic†

Select

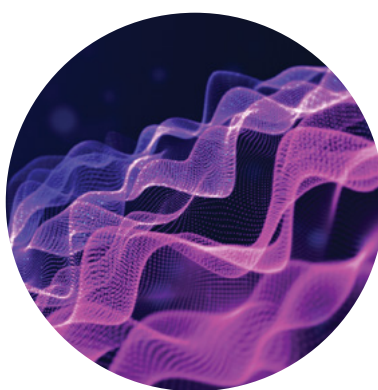
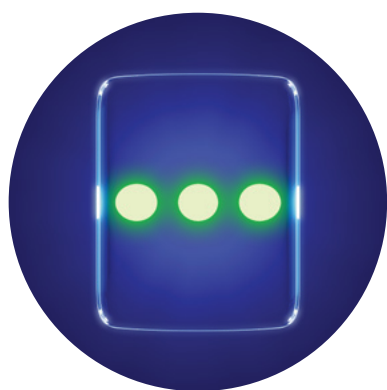
Optimize

Maximize

New
BrainSense™
Electrode Identifier

Enhanced
BrainSense™ Streaming,
Thresholds, Timeline,
and Events

New
BrainSense™ aDBS



† 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.

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

Engineered to adapt



Visit
Medtronic BrainSense



Visit
Medtronic Academy

[†] 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 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.

References

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Brief Statement:

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices. For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

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