Medtronic News

Medtronic earns U.S. FDA approval for the world's first Adaptive deep brain stimulation system for people with Parkinson's

New closed-loop system self-adjusts DBS therapy to individual brain activity in real time; the largest commercial launch of brain-computer interface technology ever

GALWAY, Ireland, Feb. 24, 2025 /PRNewswire/ -- For the one million people diagnosed with Parkinson's disease in the United States[1], Medtronic plc (NYSE:MDT), a global leader in healthcare technology, proudly announces U.S. Food and Drug Administration (FDA) approval of BrainSense™ Adaptive deep brain stimulation (aDBS) and BrainSense™ Electrode Identifier (EI).

There is no cure for debilitating neurological conditions like Parkinson's, however, deep brain stimulation (DBS) has been transforming the lives of people with Parkinson's and other neurological disorders for more than 30 years. DBS is similar to a cardiac pacemaker, but for the brain. It uses a surgically implanted neurostimulator via a minimally invasive procedure to transmit electrical signals to specific parts of the brain affected by debilitating neurological disorders.

Now Medtronic has enhanced its Percept™ DBS neurostimulators with exclusive BrainSense™ Adaptive technology†, introducing aDBS for people living with Parkinson's. This feature personalizes therapy based on a patient's brain activity in real time – both in clinical settings and in daily life[2]. It provides enhanced therapy personalization for symptom control that automatically adjusts, minimizing the need for patients to manually adjust stimulation.

"Medtronic is the only company in the world to offer an adaptive DBS system that dynamically adjusts therapy in real time," said Brett Wall, executive vice president and president of the Medtronic Neuroscience Portfolio. "This new era in Parkinson's care represents more than a decade of intentional innovation—ushering in personalized neuromodulation at scale that responds to a patient's changing needs, equipping clinicians with unparalleled insights, and setting a new standard for DBS therapy."

For more than ten years, Medtronic has been developing a complete, sensing-enabled DBS system leveraging exclusive BrainSense™ technology to detect, capture, and classify different brain signals, putting Medtronic at the forefront of incorporating brain-computer interface (BCI) technology into DBS therapy. Medtronic considers BCI technology a crucial element for developing innovative products that treat some of the cardinal symptoms of Parkinson's with specific focus on rehabilitation and restoring health. BrainSense™ Adaptive DBS is available to Medtronic DBS patients with Parkinson's who have been implanted with a Percept™ neurostimulator, as well as future Medtronic DBS patients. With more than 40,000 DBS patients served worldwide[3] with Medtronic Percept™ devices, BrainSense™ Adaptive DBS presents the largest commercial launch (by several magnitudes) of BCI technology – ever.

"Adaptive deep brain stimulation will help revolutionize the approach to therapeutic treatment for patients with Parkinson's disease," said Helen Bronte-Stewart MD MSE, FAAN, FANA, John E. Cahill Family Professor in the department of Neurology and Neurological Sciences and Director of the Human Motor Control and Neuromodulation Lab at Stanford University School of Medicine. "The transformative personalized care we can achieve through automatic adjustment greatly benefits patients receiving therapy that adapts to their evolving needs."

The Medtronic Adaptive DBS Algorithm for Personalized Therapy in Parkinson's Disease (ADAPT-PD) trial highlights the potential of aDBS in clinical practice. Dr. Bronte-Stewart served as the global principal investigator for the trial, which was conducted as an international, multi-center, prospective, single-blind, randomized crossover study (between two modes of aDBS), and evaluated the safety and effectiveness of chronic dual- and single-threshold aDBS modes compared to continuous

DBS (cDBS) for eligible patients with Parkinson's disease receiving DBS therapy. This study represents the largest and longest assessment of aDBS conducted in both clinical and home settings and was developed in collaboration with more than a dozen world-renowned neurologists and neurosurgeons from leading academic institutions across the globe including Stanford University School of Medicine, University of California San Francisco, Massachusetts General Hospital and Amsterdam University Medical Center. The study methodology and sensing data from the study were published in *npj Parkinson's Disease*, a journal within the prestigious Nature Portfolio.

"For patients who struggle with motor symptom fluctuations, dyskinesias, and other side effects with cDBS, aDBS may offer improved symptom control," said Todd Herrington, MD, PhD, director of the Deep Brain Stimulation Program at Massachusetts General Hospital, assistant professor of neurology at Harvard Medical School, and investigator for the ADAPT-PD trial. "Approval of this therapy represents an important step forward for patients and I look forward to seeing the ADAPT-PD study results published soon."

"Our BrainSense technology provides unique and clinically important insights that no other DBS system can offer, using a person's own brain signals to provide a window into their condition, in real time, over time," said Paolo Di Vincenzo, president of the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "Our focus has always been on creating solutions that work for real lives, not just standalone symptoms. aDBS reflects that commitment, bringing a new expectation in Parkinson's treatment."

The U.S. FDA approval also includes the Medtronic BrainSense™ Electrode Identifier (EI), which helps reduce patient time spent in clinic to program their DBS settings. By using EI, clinicians can conduct an accurate and precise initial programming, 85% faster compared to traditional electrode selection [4].

"BrainSense™ Electrode Identifier offers less ambiguity and greater efficiency compared to the traditional method of electrode selection by providing a personalized, real-time snapshot of a patient's brain signals, which can help provide insights into the proximal sweet spot for programming. This new method reduces initial contact selection time, streamlining the process and ensuring more precise, tailored therapy for each patient," said Drew Kern, MD, MS, neurologist and associate professor of neurology at the University of Colorado School of Medicine.

"Our dedication to advancing DBS research and innovation has transformed therapeutic options for individuals with movement disorders and epilepsy," said Amaza Reitmeier, vice president and general manager, Neuromodulation portfolio at Medtronic. "With this FDA approval, which quickly followed our CE Mark, we are taking another significant step forward in delivering sensing-enabled personalized treatments to people with Parkinson's."

BrainSense™ aDBS and EI are also available in Europe. Patient programmings in the United States will begin at select healthcare systems over the coming weeks with availability nationwide in the coming months.

Since 1987, Medtronic has served more than 185,000 people with movement disorders and other indications in more than 70 countries with its life-changing cDBS therapy[3]. Patients considering DBS therapy should discuss treatment options with their healthcare provider. To learn more about Medtronic DBS with BrainSense™ technology, visit our website.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge,

insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE: MDT), visit www.Medtronic.com and follow Medtronic on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

†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.

References

1. Parkinson's Foundation. (2025). *Statistics: Get informed about Parkinson's disease with these key numbers*.Retrieved from https://www.parkinson.org.
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3. Medtronic data on file.
4. Thompson, J., Radcliffe, E., Ojemann, S.,et al. Monopolar sensing improves the efficiency of DBS programming in Parkinson's disease [abstract]. *Mov Disord*. 2024; 39 (suppl 1). https://www.mdsabstracts.org/abstract/monopolar-sensing-improves-the-efficiency-of-dbs-programming-in-parkinsons-disease/. Accessed 01/29/25

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