

Medtronic achieves CE Mark approval for BrainSense™ Adaptive deep brain stimulation and Electrode Identifier, a groundbreaking advance in personalized, sensing-enabled care for people with Parkinson's through innovative brain-computer interface technology

European approval introduces the world's only closed-loop DBS system with real-time, self-adjusting brain stimulation for people with Parkinson's disease

GALWAY, Ireland, Jan. 13, 2025 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, announced today CE (Conformité Européenne) Mark approval in the European Union (EU) and the United Kingdom (UK) for BrainSense™ Adaptive deep brain stimulation (aDBS) and BrainSense™ Electrode Identifier (EI), having achieved the standards required by the EU Medical Device Regulation (MDR). In addition, the first programming was completed today, performed by Martijn Beudel, MD, PhD, neurologist and associate professor, Department of Neurology, Amsterdam University Medical Center. This landmark approval and first-in-Europe patient programming demonstrate significant advancements in personalized DBS therapy for people with Parkinson's in Europe, including the UK.

For 30 years, people with Parkinson's disease have benefitted from deep brain stimulation (DBS), a technology that transmits electric signals to the brain to disrupt certain unwanted movement. With BrainSense™ aDBS, people with Parkinson's disease can now benefit from real-time, adaptive therapy that dynamically adjusts stimulation based on each person's unique brain activity, both in clinical settings and daily life¹. BrainSense™ Electrode Identifier can improve DBS programming by ensuring optimal initial contact selection in less time².

Caregivers and healthcare providers alike intimately understand how disruptive Parkinson's can be on one's daily life. Affecting over 1.2 million patients in Europe alone and more than 10 million people worldwide, Parkinson's is known to impact an individual's mobility, speech, focus, sleep, independence, and overall ability to participate fully in work, family, and social life. From sipping a cup of coffee to holding hands with a loved one, the disease can be debilitating and demoralizing, stripping away what many of us take for granted. For spouses and caregivers, this can be immensely demanding and distressing^{3,4}.

"BrainSense™ technology[†] is at the center of personalizing DBS therapy, and we are advancing this capability through innovation that builds on our sensing-enabled DBS platform," said Paolo Di Vincenzo, president of the Neuromodulation business, which is part of the Neuroscience Portfolio at Medtronic. "From improved precision for contact selection to automatically adjusting DBS therapy, these milestones mark significant advancements in our ability to customize care for people with Parkinson's, and we're just getting started. The mission is to impact and improve many more lives with Medtronic DBS therapy."

The Medtronic Percept™ DBS system with BrainSense™ technology is designed to record and analyze brain signals, enabling therapies tailored to each patient's unique neurological patterns¹. Medtronic has been at the forefront of incorporating brain-computer interface (BCI) technology into DBS therapy with the specific purpose of making advances in prevention, detection, diagnosis, rehabilitation, and restoration for patients with complex neurological conditions. As the world leader in DBS therapy, the Medtronic Percept™ neurostimulators with BrainSense™ technology serves as a benchmark for DBS sensing innovation.

"Adaptive deep brain stimulation represents an exciting evolution in how we manage Parkinson's," said Martijn Beudel, MD, PhD, neurologist and associate professor, Department of Neurology, Amsterdam University Medical Center. "By using real-time brain activity to automatically adjust stimulation, this technology enhances the ability to deliver patient-specific stimulation that can be adapted to an individual's unique needs."

Medtronic is the originator of continuous deep brain stimulation (cDBS), which has been available for decades as a proven therapy for managing certain Parkinson's disease symptoms. BrainSense™ Adaptive DBS (aDBS) takes treatment to the next level, dynamically calibrating stimulation based upon a patient's own brain signals¹.

"Medtronic remains the first and only company in the world to offer a complete sensing-enabled DBS system, and now we have enhanced this innovation to allow patients with Parkinson's to spend less time thinking about their disease," said Amaza Reitmeier, vice president and general manager, Neuromodulation marketing and strategy at Medtronic. "Patients and clinicians have been eagerly awaiting these BrainSense™ technology enhancements, which represent another transformative step forward in our ability to personalize therapy for people living with Parkinson's."

The Adaptive DBS Algorithm for Personalized Therapy in Parkinson's Disease (ADAPT-PD) trial further highlights the potential of aDBS in clinical practice. Conducted as a global, multi-center, prospective, single-blind randomized crossover study (between two modes of aDBS), the trial evaluates the safety and effectiveness of chronic dual- and single-threshold aDBS modes compared to cDBS for eligible Parkinson's patients receiving DBS therapy. Developed in collaboration with more than a dozen world-renowned neurologists and neurosurgeons from leading academic institutions across the globe, this study represents the largest and longest assessment of aDBS conducted in both clinical and home settings¹. The study methodology and sensing data from the Medtronic study were published in [npj Parkinson's Disease](#), a journal within the prestigious Nature Portfolio.

"The CE Mark approval of BrainSense™ Adaptive DBS is a critical advancement in how we treat Parkinson's disease," said Alan Whone, PhD, professor of movement disorders neurology, University of Bristol and North Bristol NHS Trust. "Its potential to address certain challenging motor symptoms and improve day-to-day disease management offers new hope for patients and their families, broadening the transformative impact of deep brain stimulation."

BrainSense™ Electrode Identifier (EI) elevates precision and efficiency to unprecedented levels by providing a detailed view of each Parkinson's patient's unique brain signals and guiding clinicians to the exact location of the strongest signal in a fraction of the time needed for standard monopolar reviews². This exclusive technology pinpoints the optimal contact location by leveraging local field potentials (LFP) and alpha-beta activity to guide optimized and effective programming compared to the standard of care, the monopolar review².

"BrainSense™ Electrode Identifier allows clinicians to now conduct an accurate and precise initial programming, offering a level of personalization unmatched in the field," said Domenico De Paolis, vice president of Neuromodulation International at Medtronic. "Clinicians will appreciate less ambiguity and greater efficiency compared to the traditional method of electrode selection. CE Mark approval is just the first step in our effort to bring this new technology to customers around the world."

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 DBS therapy⁵.

BrainSense™ aDBS and BrainSense™ Electrode identifier will be available in Europe in early 2025. Patients considering DBS therapy should discuss treatment options with their provider. Medtronic has filed for U.S. FDA approval of aDBS; it is not yet approved for sale or distribution in the United States.

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, 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

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