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Medtronic earns FDA approval for expanded MRI labeling, making its best-in-class MRI capability even stronger

New MRI labeling extends active scan time for Medtronic DBS systems

Medtronic plc, a global leader in healthcare technology, has received U.S. Food and Drug Administration (FDA) approval of its expanded MRI (magnetic resonance imaging) labeling for Medtronic Percept™ PC and Percept™ RC, as well as Medtronic Activa™ PC, RC and SC.

The MRI labeling approval, exclusive to Medtronic Deep Brain Stimulation (DBS) systems, allows additional active scan time for scans below specified B1+rms limits, increasing the options available for diagnostic and functional assessments. Medtronic was the first medical device innovator in the U.S. to offer full-body MR Conditional DBS systems for patients to have safe scans anywhere on the body under specific conditions††.

"We know that nearly 70 percent of all DBS-eligible patients are estimated to require an MRI as part of their essential care[1]," said Ashwini Sharan, chief medical officer, Medtronic Neuromodulation, which is part of the Medtronic Neuroscience Portfolio. "Only Medtronic DBS systems can continue therapy ON in bipolar mode, under certain conditions, while a patient is having an MRI scan[2-4]. The updated labeling to remove the 30-minute active scan restriction, along with the Medtronic exclusive 3T MRI capability, provides patients with truly uncomplicated MRI access."

"Patients with movement disorders have debilitating tremors that often impact their ability to physically engage in everyday moments, as well as medical treatments that require stillness like an MRI," said Amaza Reitmeier, vice president and general manager of Medtronic Brain Modulation within the Neuromodulation business. "This updated labeling is another example of our unwavering commitment to enabling personalized patient care, with the goal of many more patient lives transformed with DBS therapy."

Since 1987, Medtronic has served more than 180 thousand patients with movement disorders and other indications in more than 70 countries with its life-changing DBS therapy[5]. Medtronic is dedicated to continuous advancement, also recently announcing U.S. FDA approval for Asleep DBS.

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 us 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 U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Medtronic DBS therapy is approved for five indications: Parkinson's disease, essential tremor, dystonia*, obsessive-compulsive disorder* (OCD), and epilepsy. Indications vary by product. Refer to product labeling for details.

***Humanitarian device**: The effectiveness of these devices for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

†† Under specific conditions. Refer to product labeling for full list of conditions: https://manuals.medtronic.com/manuals/mri/region.

References

1. Falowski S, Safriel Y, Ryan MP, Hargens L. The rate of magnetic resonance imaging in patients with deep brain stimulation. Stereotact Funct Neurosurg. 2016; 94(3):147-153
2. ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems – 92195369-01, accessed on 08/02/2024
3. MRI Procedure Information for Abbott Medical™* MR Conditional Deep Brain Stimulation Systems – ARTEN600090482 A. Accessed on 08/02/2024.
4. MRI guidelines for Medtronic deep brain stimulation systems 37601 37602 37603 37612 B35200 B35300 – M929535A_a_092 https://manuals.medtronic.com/manuals/mri/region
5. Medtronic data on file.

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