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Medtronic has announced that systems within its Activa portfolio of Deep Brain Stimulation (DBS) neurostimulators have received FDA approval for full-body Magnetic Resonance Imaging (MRI) under specific conditions of use. Medtronic's MR Conditional DBS systems are the only approved for full-body MRI scans.

This approval expands access to MRIs, making it safe for patients receiving Medtronic DBS Therapy to also receive this important diagnostic standard of care. Additionally, this approval applies to individuals receiving new Medtronic DBS systems and to an estimated 43,000 people in the US already receiving Medtronic DBS Therapy as long as updated MRI guidelines are followed.

With full-body scanning capability, increased MRI RF power limits allow for improved image quality, faster scan times, or larger scan coverage for better diagnostic capabilities. Additionally, when programmed to appropriate stimulation settings and certain other conditions have been met, Medtronic DBS systems allow patients to continue receiving therapy during scans.

"The use of MRI as a diagnostic tool has grown significantly, and Medtronic is proud to offer the only DBS systems that allow patients access to full-body MRIs," said Dr Lothar Krinke, vice president and general manager of the Brain Modulation business, which is part of the Restorative Therapies Group at Medtronic. "Continuous innovation sets Medtronic apart, and we are allowing greater access to MRIs for those receiving DBS therapy as well as other implanted Medtronic systems such as pacemakers, ICDs and spinal cord stimulators."

To ensure devices are safe, Medtronic performed rigorous testing, including developing proprietary test and measurement systems, in conjunction with advanced electromagnetic modeling tools.

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Activa DBS systems were tested and evaluated across 10 million simulated patient scans spanning over 38,000 unique implant conditions to demonstrate patient safety. In all, Medtronic has 14 years of MRI research and testing experience.

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