

## Medtronic initiates global pivotal study of cardiac pacing in a new patient population

Study to evaluate whether a new approach to pacing the heart can improve the lives of patients with heart failure with preserved ejection fraction (HFpEF) who have limited treatment options today

GALWAY, Ireland, Sept. 15, 2025 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced the initiation of a pivotal study evaluating the use of elevated and personalized cardiac pacing rates for the treatment of patients with Heart Failure with preserved Ejection Fraction (ELEVATE-HFpEF, [NCT06678841](#)). Physicians routinely use pacing therapy to treat patients whose hearts beat too slowly (bradycardia). This study, however, will investigate a potential novel treatment for patients with HFpEF by using conduction system pacing to improve patient outcomes and heart failure symptoms. Medtronic intends to use the study results to pursue a new pacing indication for patients with HFpEF who currently have limited clinically proven treatments.

HFpEF is a condition when the cardiac muscles stiffen and do not relax properly, causing diminished blood flow and an inability to meet the body's needs. Patients with HFpEF experience shortness of breath (especially during exercise or exertion, or when lying down), fast or irregular heartbeats, chest pain, weakness, and swelling in their lower legs. Researchers estimate that this condition affects around 32 million people worldwide and 3 million in the United States.<sup>1</sup> It represents approximately 50% of the overall heart failure population, and its prevalence is expected to rise with the aging population.<sup>2</sup>

Earlier clinical studies have suggested that personalized elevated pacing rates could positively impact patient outcomes for those with HFpEF and bradycardia.<sup>3</sup> The ELEVATE-HFpEF trial seeks to validate this in a broader group, using personalized pacing settings and conduction system pacing in patients who do not have a current indication for pacing.

"Millions of people around the world have HFpEF and experience reduced quality of life and increased risk of hospitalization and death. For some patients with HFpEF, current medical management alone may not be enough to alleviate their symptoms, and new treatment strategies are needed to improve these outcomes," said Brett Atwater, M.D., cardiac electrophysiologist at Inova Schar Heart and Vascular, Fairfax, Va., and global co-principal investigator on the ELEVATE-HFpEF trial. "This pivotal study will provide important insights into the potential of personalized pacing as an innovative approach for improving quality of life and cardiac outcomes for patients living with this serious and often deadly condition."

ELEVATE-HFpEF is a randomized, controlled, double-blinded, multi-center, global study that will enroll up to 700 participants across the North America, Europe, Middle East, Africa, Australia, and Asia Pacific regions. Study participants will receive conduction system pacing with a commercially available Medtronic pacemaker and SelectSecure™ MRI SureScan™ Model 3830 pacing leads. Conduction system pacing is a type of pacing therapy that taps into the heart's natural electrical pathways to stimulate a coordinated heartbeat, closely mimicking the heart's physiologic contractions. Physicians will program study patients' pacemakers to either a personalized cardiac pacing rate using an allometric scale, which is based on each individual's body size, and baseline left ventricular ejection fraction (a measure of how well the heart pumps blood); or to provide backup pacing if needed (control group). Health care providers participating in the study will follow patients for one year as researchers assess the efficacy and safety of this investigative treatment.

The first study implant procedures were performed at The Alfred Hospital in Melbourne, Australia and at The Ohio State University Wexner Medical Center in Columbus, Ohio. The global co-principal investigators for the study are Dr. Atwater and Harriette Van Spall, M.D., Associate Professor of Medicine at McMaster University, Canada, and Director of Implementation Science at Baim Institute for Clinical Research, Hamilton, Ontario, Canada.

"Since Medtronic invented the first battery-powered pacemaker nearly 70 years ago, we have continually worked with physician and patient communities to both innovate new pacing technology and deliver landmark clinical evidence to broaden the types of patients that may benefit from pacing," said Robert C. Kowal, M.D., Ph.D., general manager for Cardiac Pacing Therapies in the Cardiac Rhythm Management business, which is part of the Medtronic Cardiovascular Portfolio. "With the initiation of this study, we are opening the door to our next era – pacing therapy as a potentially safe and effective intervention to improve the lives of patients with HFpEF, a cardiac condition that pacemakers do not currently treat."

### **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](http://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.**

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<sup>1</sup> Redfield MM, Borlaug BA. Heart Failure With Preserved Ejection Fraction: A Review. JAMA. 2023 Mar 14;329(10):827-838. doi: 10.1001/jama.2023.2020. PMID: 36917048.

<sup>2</sup> Hamo, C. E., et al. (2024). "Heart failure with preserved ejection fraction." Nat Rev Dis Primers 10(1): 55.

<sup>3</sup> Infeld, M., et al. (2023). "Effect of Personalized Accelerated Pacing on Quality of Life, Physical Activity, and Atrial Fibrillation in Patients With Preclinical and Overt Heart Failure With Preserved Ejection Fraction: The myPACE Randomized Clinical Trial." JAMA Cardiol 8(3): 213–221.

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