

Medtronic announces regulatory milestones for newest cardiac mapping and ablation software

FDA clearance and CE Mark for latest Affera™ Prism-2 Mapping Software expand cardiac mapping capabilities

CE Mark for PulseSelect ProxBox™ Adapter with Proximity Indicator software adds real-time tissue proximity feedback

GALWAY, Ireland, Sept. 30, 2026 /[PRNewswire](#)/ -- Medtronic (NYSE: MDT), a global leader in healthcare technology, today announced regulatory milestones for software used with two cardiac ablation platforms. This includes U.S. Food and Drug Administration (FDA) clearance and CE Mark for the latest Affera™ Prism-2 Mapping Software. The company also obtained CE Mark for the PulseSelect ProxBox™ Adapter with Proximity Indicator software. These milestones expand integrated mapping and tissue-proximity capabilities across the Medtronic cardiac ablation portfolio.

"Innovation in mapping software is essential to realizing the full potential of cardiac ablation technologies and supporting the precision physicians seek during procedures," said Khaldoun Tarakji, MD, MPH, vice president and chief medical officer, Cardiac Ablation Solutions at Medtronic. "We are integrating catheters, hardware and software to give physicians a more connected experience and help improve care for patients with heart rhythm disorders."

Affera Mapping and Ablation System with Prism-2 Software

The Affera Prism-2 Mapping Software helps physicians create detailed three-dimensional maps of the heart's electrical activity during cardiac ablation procedures for arrhythmias, or abnormal heart rhythms.

The software uses magnetic and impedance-based tracking to display the location of specialized and conventional diagnostic catheters, including coronary sinus catheters, on a three-dimensional map. This capability can support procedures that use little or no fluoroscopy, reducing reliance on X-ray imaging during cardiac ablation.

Recent software enhancements add advanced cardiac mapping tools to the Affera system, including:

- Beat Matching, which helps physicians compare heartbeats and identify those that have abnormal signals.
- Pace Tagging, which compares heartbeats and marks locations when pacing is performed during a procedure.
- Improvements to the system's internal pacing stimulator, which assists with cardiac mapping and procedural workflow.

Together, these tools can help physicians visualize, analyze and compare the heart's electrical activity, supporting efficient mapping and informed decision-making during cardiac ablation procedures.

The Affera Mapping and Ablation System is the platform used with the Sphere-9™ Catheter, an all-in-one catheter that combines high-definition mapping with dual-energy pulsed field and radiofrequency ablation.

PulseSelect PFA System with Proximity Indicator

The PulseSelect ProxBox™ Adapter with Proximity Indicator software adds real-time, impedance-based feedback to the PulseSelect™ pulsed field ablation (PFA) System. The feedback helps physicians assess whether the catheter is near the targeted heart tissue before energy is delivered.

The PulseSelect PFA System was the first PFA catheter approved by the FDA and is used in more than 60 countries.

"Software excellence is a priority across our electrophysiology business and is central to the integrated experience physicians expect," said Rebecca Seidel, senior vice president and president, Electrophysiology Therapies at Medtronic. "These regulatory milestones advance our software capabilities alongside the continued expansion of our cardiac ablation portfolio."

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 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 [Medtronic.com](https://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.

Contacts:

Leslie Williamson
Public Relations
+1-612-227-5099

Ingrid Goldberg
Investor Relations
+1-763-505-2696

<https://news.medtronic.com/2026-09-30-Medtronic-announces-regulatory-milestones-for-newest-cardiac-mapping-and-ablation-software>