GE HealthCare receives FDA 510(k) clearance for MIM Contour ProtégéAI+ 2.0, advancing AI-enabled radiation therapy planning with expanded clinical capabilities

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- Marking the evolution of MIM AI-enabled auto-contouring software, MIM Contour ProtégéAI+ 2.0 introduces new models, including a Magnetic Resonance (MR) Brain model, as well as an updated Computed Tomography (CT) Male Pelvis model, expanding clinical capabilities across key anatomical regions.
- GE HealthCare will showcase MIM Contour ProtégéAI+ 2.0 at booth #202 during the American Association of Medical Dosimetrists 51st Annual Meeting taking place June 7-10, 2026 in Orlando, Florida.

CHICAGO--(BUSINESS WIRE)--Jun. 4, 2026-- GE HealthCare (Nasdaq: GEHC) today announced it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for MIM Contour ProtégéAI+™ 2.0, an AI-enabled auto-contouring software to assist radiation oncology care teams with treatment planning. This can help clinicians reduce treatment planning time, enabling them to focus on delivering more timely and personalized care for patients.

The FDA clearance includes a Predetermined Change Control Plan (PCCP), which establishes a framework for introducing future model updates and enhancements. This will help enable the expansion of models across additional anatomical regions and imaging modalities.

According to the World Health Organization, cancer continues to be a leading cause of death worldwide, accounting for nearly ten million deaths per year.[i] Earlier detection and treatment could help reduce a meaningful portion of this burden. Radiation therapy plays a central role in cancer care, used in nearly 60% of cases and for over 2 million U.S. patients annually.[ii,iii] The radiation therapy field continues to evolve to meet increasingly complex patient needs, with emerging technologies helping clinicians deliver more precise, efficient care.

“As radiation therapy continues to expand, there is a growing need to accelerate innovation to support the practice,” said Dr. Ben Newton, Global Head of Oncology at GE HealthCare. “The introduction of MIM Contour ProtégéAI+ 2.0 represents an important step forward in advancing AI-enabled radiation therapy planning. The FDA clearance of a Predetermined Change Control Plan allows us to iterate more quickly, bringing new models and enhancements to our customers to help enhance the treatment planning experience.”

Manual contouring is one of the most time-intensive steps in radiation therapy planning. AI-based approaches can help make contouring more efficient while maintaining accuracy. The underlying AI models for MIM Contour ProtégéAI+ were developed and validated using multi-institution datasets and have demonstrated contour quality comparable to, or exceeding, traditional approaches, supporting consistent and reliable performance across clinical use cases.[iv]

Unlike traditional auto-contouring tools, MIM Contour ProtégéAI+ is designed to operate with minimal user interaction, initiating contouring automatically and helping enable automated processing of CT and MR images. Results can be exported directly into treatment planning systems or MIM Workflows™, helping reduce manual contouring effort and providing care teams more time to focus on creating treatment plans for their patients.

“Our technology is designed with the realities of our customers in mind,” said J. Anders, General Manager, MIM, GE HealthCare. “By automating one of the most time-intensive steps in radiation therapy planning, MIM Contour ProtégéAI+ 2.0 can help reduce treatment planning time and enable care teams to focus on refining treatment plans tailored to each patient’s needs.”

The software is part of the MIM portfolio within GE HealthCare’s radiation oncology ecosystem and is designed to integrate seamlessly into existing clinical workflows. Learn more about MIM Contour ProtégéAI+ 2.0 and other MIM software solutions at the booth (#202) at the American Association of Medical Dosimetrists 51st Annual Meeting or visit online at gehealthcare.com.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global healthcare solutions provider of advanced medical technology, pharmaceutical diagnostics, and AI, cloud and software solutions that help clinicians tackle the world’s most complex diseases. Serving patients and providers for 130 years, GE HealthCare is delivering bold innovations designed for the next era of medicine across its Advanced Imaging Solutions, Patient Care Solutions, and Pharmaceutical Diagnostics segments to help clinicians deliver more personalized, precise patient care. We are a $20.6 billion business with approximately 54,000 colleagues working to create a world where healthcare has no limits.

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[i] World Health Organization, *Cancer*, 2025, https://www.who.int/news-room/fact-sheets/detail/cancer.

[ii] American Society for Radiation Oncology. *Radiation Oncology Case Rate (ROCR) Report.* June 26, 2023. https://www.astro.org/ASTRO/media/ASTRO/Advocacy/PDFs/ROCRReport.pdf

[iii] American Society for Radiation Oncology (ASTRO). “Geographic Access to Radiation Therapy in the United States.” ASTRO Press Kit, 2020.

[iv] Wan, Hanlin, and Soroush Heidari Pahlavian. *Automated Contouring Using Neural Networks*. White paper, MIM Software Inc., September 24, 2025.

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