GE HealthCare advances total body PET/CT innovation with Omni 128 cm, now 510(k) pending with the U.S. FDA

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- Omni 128 cm total body PET/CT is 510(k) pending with the U.S. Food and Drug Administration, marking continued progress in the aim to bring GE HealthCare's total body PET/CT platform to U.S. clinicians and researchers following its CE Mark
- Engineered to allow imaging from the highest point of the head to thigh in a single bed position – compared with conventional PET/CT systems that typically require five to six bed positions – helping simplify workflows while aiming to support short acquisition times, ultra-low-dose imaging, multi-organ dynamic imaging and advanced research applications
- Built for both clinical and research environments, the system is designed to support the investigation of new clinical pathways, novel PET tracers and emerging theranostic agents

CHICAGO--(BUSINESS WIRE)--Nov. 25, 2026-- GE HealthCare today announced that its Omni™ 128 cm total body positron emission tomography/computed tomography (PET/CT) system[i] is 510(k) pending with the U.S. Food and Drug Administration (FDA). Following the system's CE Mark in November 2025, this regulatory milestone represents another step toward bringing GE HealthCare's next-generation total body PET/CT technology to clinicians and researchers in the United States.

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GE HealthCare also included its Omni™ 64 cm PET/CT configuration for 510(k) review,[i] reflecting continued expansion of the Omni platform for a range of molecular imaging needs. Designed to deliver ultra-high sensitivity with a 64 cm axial field of view, the configuration aims to offer great flexibility for healthcare providers, with the potential to enable up to 73 percent shorter PET scan times or up to 77 percent lower PET doses.[ii] It is also designed to enable simultaneous multi-organ imaging within a single bed position, allowing investigation of the heart-brain axis and facilitating the research of interconnected disease pathways.

Molecular imaging is entering a new era. As precision medicine, targeted radiopharmaceuticals and theranostics continue to reshape cancer care, clinicians are seeking imaging technologies that can help guide more personalized treatment decisions. At the same time, researchers are advancing novel tracers, imaging biomarkers and quantitative approaches that introduce opportunities for new ways to characterize disease beyond conventional PET/CT imaging.

Against this backdrop, total body PET/CT represents a meaningful evolution in molecular imaging. By dramatically extending the scanner's axial field of view, these systems can image a much larger portion of the body simultaneously, enabling clinicians and researchers to observe simultaneous biological processes across multiple organ systems during a single acquisition. The expanded coverage is designed to enable greater sensitivity and support ultra-fast imaging workflows, ultra-low-dose protocols, dynamic imaging and research involving emerging tracers and therapies – capabilities that are becoming increasingly important as precision oncology continues to evolve.

"Long axial field-of-view PET/CT has the potential to fundamentally change how we study disease," said Dr. Erin Grady, Interim Division Chief of Nuclear Medicine and Molecular Imaging, Clinical Professor of Radiology, Stanford Medicine – a key collaborator on GE HealthCare's Omni 128 cm system. "Instead of looking for disease one organ at a time, we can begin to understand how biological processes interact across organ systems simultaneously. The ability to capture a large portion of the body in a single acquisition while supporting dynamic and low-activity imaging creates exciting opportunities to investigate new tracers, evaluate targeted therapies and advance translational research. This represents an important step toward more personalized care."

Omni 128 cm was designed with these evolving needs in mind. The system is engineered to allow imaging from the highest point of the head to thigh in a single bed position for a wide range of patients. By reducing the need for multiple acquisitions, the system is designed to help streamline imaging workflows while supporting ultra-low-dose scans, multi-organ dynamic imaging and imaging with slow-decaying and low-activity tracers. Furthermore, Omni 128 cm is designed with ultra-high sensitivity that can enable up to a 88% reduction in the PET dose or up to an 86% reduction in the PET scan time.[iii]

With its 128 cm axial field of view, the system is engineered for ultra-high sensitivity and spatial resolution across a broad range of PET/CT applications. Beyond today's clinical practice, the platform is also designed to support researchers investigating new clinical pathways, quantitative imaging approaches, novel PET tracers and emerging theranostic agents as molecular imaging continues to expand.

"The future of molecular imaging isn't simply about seeing more – it's about understanding more from every scan," said Erez Levy, Senior Executive Director, Molecular Imaging, GE HealthCare. "As precision medicine evolves, clinicians and researchers need imaging platforms capable of supporting new tracers, new therapies and entirely new ways of studying disease. Omni 128 cm was designed as a foundation for that future – bringing together broad anatomical coverage with ultra-high sensitivity, advanced imaging capabilities and a research-ready platform that can help healthcare systems keep pace with one of the fastest-moving areas of medicine. Reaching this 510(k)-pending milestone marks an important step as we work to bring this

next generation of total body PET/CT innovation to U.S. health systems."

The system leverages NVIDIA accelerated computing technology to help optimize image reconstruction and reduce the time required to generate images. When combined with GE HealthCare's MIM software solutions, Omni 128 cm is designed to support advanced quantitation tools and streamlined imaging workflows for molecular imaging research and clinical practice. This includes compatibility with MIM KineticID ™[iv] a modeling software engineered to enable dynamic PET workflows and kinetic modeling to deliver a clear, data-driven view of how radiotracers behave across the body over time to support clinical and research decision-making. Together, these capabilities aim to support advanced dynamic PET imaging and quantitative kinetic modeling workflows, helping clinicians and researchers gain deeper insights into tracer behavior and disease processes.

“When we installed the first Omni Legend 128 cm at Peter MacCallum Cancer Centre, we knew we were adopting a completely new platform and had high expectations for its performance,” said Michael Hofman, MBBS, FRACP, FAANMS, Professor and Head of PET/CT, Peter MacCallum Cancer Centre and the University of Melbourne. “Just 12 months later, the results have been outstanding. The scanner has provided expanding opportunities for advanced imaging research with capabilities not previously possible including ultra-delayed imaging and dynamic acquisition studies. Clinical results have demonstrated exceptional image quality, short scan times, high lesion detectability and rapid reconstruction. The system is helping us push the boundaries of molecular imaging. Our experience has been overwhelmingly positive.”

The 510(k)-pending milestone for both Omni 128 cm and Omni 64 cm configurations reflects continued efforts to advance the Omni PET/CT platform in the U.S. It also builds on Omni 128 cm’s CE Mark in November 2025 and GE HealthCare’s legacy of more than 25 years of PET/CT innovation.

From disease detection and characterization to therapy selection, treatment monitoring and translational research, GE HealthCare remains committed to developing technologies designed to help clinicians and researchers better understand disease biology, explore new clinical possibilities and support the future of precision care.

These technologies are the result of the company's investment in bold, purposeful innovation — leading to a wave of transformational products across GE HealthCare’s portfolio which are expected to drive 1-2% revenue growth.

For more information on GE HealthCare's molecular imaging portfolio, visit 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, Pharmaceutical Diagnostics and Patient Care Solutions 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] Omni is CE marked and 510(k) pending at the U.S. FDA. Not available for sale in the United States. CE marking applies to Omni 64 cm (upgrade from Omni Legend) and to Omni 128 cm system.

[ii] Compared to Omni Legend 32cm. As demonstrated in phantom testing based on NEMA NU 2024 with adaptation for 64cm FOV. The actual time/dose reduction depends on the clinical task, patient size, anatomical location and clinical practice. A radiologist should determine the appropriate scan time/dose for the particular clinical task.

[iii] Compared to Omni Legend 32cm. As demonstrated in phantom testing based on NEMA NU 2024 with adaptation for 128cm FOV. The actual time/dose reduction depends on the clinical task, patient size, anatomical location and clinical practice. A radiologist should determine the appropriate scan time/dose for the particular clinical task.

[iv] MIM KineticID is 510(k) cleared by the U.S. FDA. Not CE Marked. Not available for sale in the United States, Europe, Canada, or any other region.

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