

UltraSight™ Receives FDA Clearance to Expand Its AI-Guided Cardiac Echo Stewardship Platform Across Ultrasound Systems

Expanded authorization enables AI-guided FoCUS across devices—supporting consistent diagnostic-quality imaging and cardiology oversight across care settings

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UltraSight™, a leader in AI-guided cardiac imaging workflows, today announced FDA clearance to expand its Echo Stewardship Platform to support compatibility with additional ultrasound system types, including handheld, laptop, and cart-based systems. This expanded authorization helps health systems scale AI-guided focused cardiac ultrasound (FoCUS) using compatible ultrasound equipment they already own, without hardware replacement.

 The logo for UltraSight, featuring the word "ULTRASIGHT" in a bold, sans-serif font. The "U" and "L" are in black, while "TRASIGHT" is in green.

This clearance allows health systems to deploy UltraSight™ technology across existing ultrasound fleets. With real-time AI-assisted image acquisition, including a quality meter and automatic guidance to the optimal view, UltraSight™ technology supports reliable, repeatable FoCUS across care settings and helps reduce variability at the point of care.

FoCUS examinations are increasingly used to expedite triage and accelerate clinical decision-making, but access often remains constrained by staffing limitations, device fragmentation, and workflow variability.

"What matters most is reliability at the point of care," said Harish Kinni, MD, Assistant Professor of Medicine and Emergency Medicine at Mayo Clinic School of Medicine. "Having a standardized approach to image acquisition across devices helps reduce variation, improves efficiency, and supports better stewardship of echo resources across the health system."

By enabling trained clinicians, including non-sonographer providers such as Advanced Practice Providers (APPs), to acquire diagnostic-quality FoCUS exams under physician oversight, the UltraSight™ Echo Stewardship Program helps expand the effective imaging workforce while preserving qualified physician oversight for final interpretation and reporting. The program is

designed to support efficient onboarding and activation within existing clinical workflows.

"Health systems want to increase their capacity for timely cardiac assessment without overhauling their hardware or relying on a single vendor," said Davidi Vortman, CEO of UltraSight™. "The FDA clearance supports a scalable workflow solution, enabling more clinicians to acquire high-quality FoCUS exams and helping hospitals reduce backlogs, manage variability, and expand access to cardiac care."

"Expanding access to diagnostic-quality FoCUS is essential as cardiac volume increases across care settings," said Itay Kezurer, Chief Technology Officer at UltraSight™. "By enabling deployment of UltraSight™ technology across a broader range of devices, this clearance strengthens the foundation for echo stewardship and helps teams deliver the right study at the right moment without compromising quality."

UltraSight™ will work with health systems and device partners throughout 2026 to bring expanded multi-device compatibility online and integrate the platform into cardiology, acute care, and outpatient workflows.

For more information or to request a demo, please contact info@ultrasight.com.

About UltraSight™

UltraSight™ is an AI-powered medical imaging company advancing access to high-quality cardiac ultrasound via its Echo Stewardship Platform. The platform combines structured training, real-time AI guidance, and advanced analytics to enable non-sonographer providers to safely and efficiently perform focused echocardiography (FoCUS) exams under qualified physician oversight. By improving image quality at the point of care while preserving physician-led interpretation and reporting, UltraSight™ helps expand access to cardiac assessment, reduce wait times, and improve workflow efficiency across care settings.

The company's software has FDA 510(k) clearance to assist medical professionals in performing cardiac ultrasound scans. For more information, visit www.ultrasight.com or follow the company on [LinkedIn](#) and [X](#).

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