

Nicolab Strengthens U.S. Presence with Multiple FDA-Cleared Algorithms, Transforming Stroke Care

Delaware, The United States of America – Nicolab, a global leader in artificial intelligence (AI)-powered stroke workflow technology, is proud to announce two major milestones in its mission to revolutionize acute stroke care in the United States. The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for both StrokeViewer LVO Triaging and the CT Perfusion algorithm, further validating Nicolab's cutting-edge AI technology designed to empower physicians and accelerate life-saving treatment decisions.

Accelerating Stroke Diagnosis and Treatment

Every minute counts during a stroke—two million brain cells die each minute until blood flow is restored. Nicolab's platform uses artificial intelligence, StrokeViewer, to detect and visualize critical imaging findings within minutes, helping physicians provide every stroke patient with the right treatment in time.

The LVO Triaging algorithm identifies image characteristics associated with a large vessel occlusion (LVO) and automatically alerts stroke teams. Embedded in the cloud-based Nicolab platform, it enables rapid notification and image review from any device—allowing physicians to assess CT scans and make timely treatment decisions, even remotely.

This FDA clearance was supported by a multicenter clinical study involving 384 patients across U.S. stroke centers. When compared with expert panel assessments, StrokeViewer's performance not only met but exceeded the target performance goals.

Enhancing Clinical Decision-Making with CT Perfusion

Building on this foundation, Nicolab's CT Perfusion algorithm has also received FDA clearance, expanding the company's comprehensive portfolio of AI-powered imaging tools. Integrated directly within StrokeViewer, the CT Perfusion module provides advanced perfusion maps that help clinicians evaluate brain tissue viability and make informed decisions about treatment eligibility.

"The integration of CT Perfusion into Nicolab's StrokeViewer allows physicians to assess crucial imaging data quickly and confidently," said Michael Macilquham, CEO of Nicolab. *"Together with LVO Triaging, these tools empower care teams to collaborate seamlessly and potentially reduce time to treatment, a key factor in improving outcomes for stroke patients."*

A Growing Commitment to U.S. Healthcare

Nicolab's technology is already transforming stroke workflows across Australia and Europe, where it has proven to reduce time from hospital arrival to treatment, resulting in 28% more Mechanical Thrombectomies performed in early window transfer patients*.

"Medical specialists are under enormous pressure to make rapid, complex decisions day and night," added Merel Boers, co-founder of Nicolab. "By combining human expertise with artificial intelligence, we're giving stroke teams the tools they need to act faster and more effectively. We are fully committed to unlocking the full healthcare potential for every patient."

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About Nicolab

Nicolab, established in 2015 following the world-leading MR CLEAN clinical trial, is an Australian-based public unlisted company. Comprised of a team of esteemed researchers, developers, and medical specialists, Nicolab is dedicated to developing innovative healthcare solutions that improve patient care. Operating globally, Nicolab's flagship product, StrokeViewer, enables clinicians to connect, communicate, and collaborate effectively within their stroke network, revolutionizing stroke workflow and treatment planning. Learn more www.nicolab.com

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*Source : 4 Innovation impulse study - Amsterdam UMC Hub and Spoke network; unpublished data.