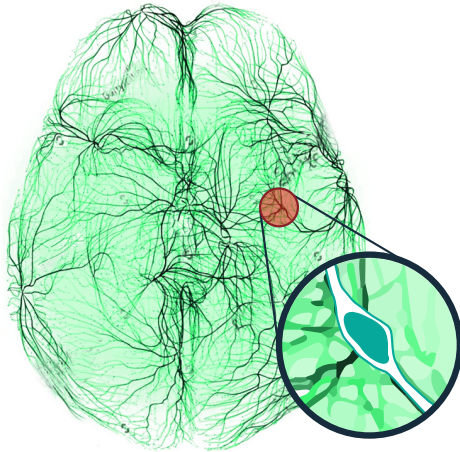




Stroke**SENS**LVO



What is LVO



Large Vessel occlusion (LVO) strokes are a type of ischemic stroke that occurs when a major artery in the brain is blocked. LVO strokes are considered one of the more common and severe kind of strokes which, if left untreated, can result in significant morbidity and mortality. Fortunately, patients with acute ischemic stroke due to large vessel occlusions (LVO) are eligible to receive lifesaving¹ endovascular treatment, which is only available at Comprehensive Stroke Centers (Tertiary hospitals). Effective treatment relies on timely and reliable detection of LVO on CTA. Quick and accurate image interpretation is however challenging in many primary stroke care centers where specialist physicians are not always available². Delays in the identification and triage of patients with LVO occur and can significantly affect patient outcomes.



Performance Summary of StrokeSENS LVO:

StrokeSENS LVO performance was tested on a dataset of N=400 (217 LVO, 183 non-LVO) baseline CTA images randomly sampled from multiple large international multi-center clinical trials. ICA and M1 occlusions were considered LVO; all other cases were considered non-LVO including challenging cases such as distal or no occlusions and intracranial hemorrhage. StrokeSENS LVO module had a Sensitivity of 89.4%, Specificity of 87.4%, with a time-to-notification of 0.75 ± 0.17 mins (Min: 0.46 mins, Max: 1.23 mins)³.



Intended Use

StrokeSENS LVO is a radiological computer-aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) on head CTA images, using artificial intelligence (AI). In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of a suspected LVO that requires review.

StrokeSENS LVO is cleared and available for clinical use in USA, Canada, Australia, EU and UK.

1. Goyal M, Menon BK, van Zwam WH, et al; HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. Lancet 2016;387:1723-31

2. Almekhlafi MA, Kunz WG, Menon BK, et al. Imaging of Patients with Suspected Large-Vessel Occlusion at Primary Stroke Centers: Available Modalities and a Suggested Approach. AJNR. American Journal of Neuroradiology. 2019 Mar;40(3):396-400

3. FDA 510K summary of StrokeSENS LVO, Oct 21, 2021
https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212261.pdf