# Instructions for Use StrokeViewer LVO Triaging

NIC-200058-04-F

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## Contents

## About

**Product:** StrokeViewer LVO Triaging

**Version:** 3

**Release year:** 2021

**GTIN, UDI-DI**: 8720299502338

SN svstandard21v3

## Manufacturer and contact

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Please consult the user manual for important cautionary information and instructions for use. The instructions for use can also be provided in paper form to customer site during user training. Additional copies can be delivered upon request by emailing to support@nicolab.com.

***Caution: In the United States, Federal law restricts this device to sale by, or on the order of a physician.***

# 1 Scope

This document includes or refers to all the information necessary for using and operating StrokeViewer LVO Triaging in accordance with its intended use. This document includes an explanation about the patient population for which StrokeViewer LVO Triaging was designed, and it is indicated for use. A summary of the performance of StrokeViewer LVO Triaging is also included in this document. In addition, this document presents all safety warnings related to the residual risks of StrokeViewer LVO Triaging. Finally, this document also includes an explanation regarding known issues and limitations related to the use of StrokeViewer LVO Triaging.

## 1.1 Device Description

StrokeViewer LVO Triaging is a notification only cloud-based image processing software application using artificial intelligence algorithms to analyze patient imaging data in parallel to the standard of care imaging interpretation. Its intended use is to identify suggestive imaging patterns of a pre-specified clinical condition and to directly notify an appropriate medical specialist.

After a CTA image is acquired, a copy is sent to StrokeViewer LVO Triaging and is processed automatically. StrokeViewer LVO Triaging performs analyses of the images and detects image characteristics associated with an LVO. StrokeViewer LVO Triaging also sends notifications to users via email, informing the user to review these images. Notifications provide links to access the analyzed data. Images processed by StrokeViewer LVO Triaging can be previewed remotely through the DICOM web viewer.

## 1.2 Indications for Use

StrokeViewer LVO Triaging is a notification only cloud-based image processing software application using artificial intelligence algorithms to analyze patient imaging data in parallel to the standard of care imaging interpretation. Its intended use is to identify suggestive imaging patterns of a pre-specified clinical condition and to directly notify an appropriate medical specialist.

StrokeViewer LVO Triaging's indication is to facilitate the evaluation of the brain vasculature on patients suspected of stroke by processing and analyzing CT angiograms of the brain acquired in an acute setting. After completion of the data analysis, StrokeViewer LVO Triaging sends a notification if a pattern suggestive for a suspected intracranial Large Vessel Occlusion (LVO) of the anterior circulation (ICA, M1 or M2) has been identified in an image.

The intended users of StrokeViewer LVO Triaging are defined as medical specialists or a team of specialists that are involved in the diagnosis and care of stroke patients at emergency departments or other departments where stroke patients are administered. They include, but are not limited to, physicians such as neurologists, radiologists, and/or other emergency department physicians.

StrokeViewer LVO Triaging's output should not be used for primary diagnosis or clinical decisions; the final diagnosis is always decided upon by the medical specialist. StrokeViewer LVO Triaging is indicated for CT scanners from GE Healthcare and Philips.

## 1.3 Patient Population

The target population includes (CTA brain scans of) patients of 18 years of age or older with neurological deficit due to (suspected) stroke who are admitted to an emergency department, dedicated stroke unit or any other (radiological) department in a medical center to undergo CTA imaging of the brain (neuroimaging) in a CT scanner for diagnostic purposes.

## 1.4 Image Quality Requirements

**Inclusion criteria**

- CTA images obtained from subjects with a suspicion of an acute ischemic stroke
- CTA images obtained from subjects who are 18 years of age or older
- Stroke CT protocol was performed
- Thin slice CTA image (<= 2 mm slice thickness)
- Entire head in field of view

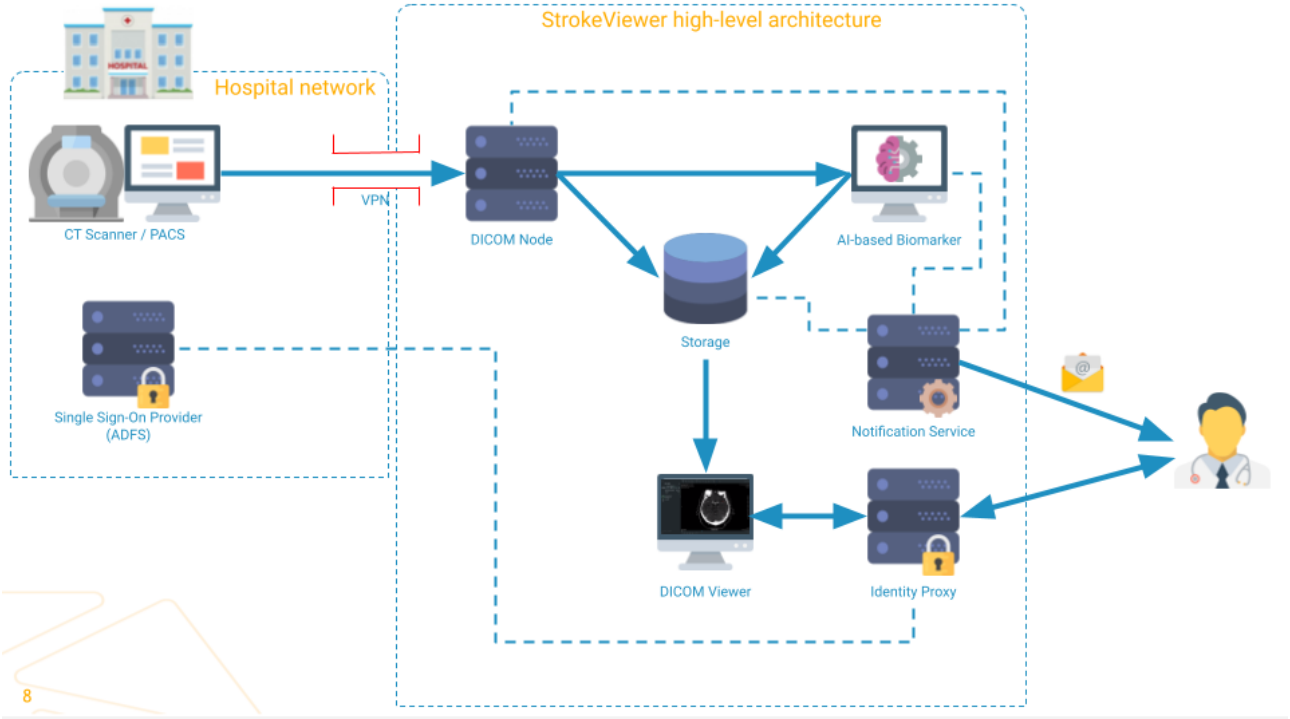
**Exclusion criteria**

- Technically inadequate CTA image (see subsection "Usage of Attributes from Received IODs" in ***NIC-200059-01-F DICOM Conformance Statement*** )
- Incomplete brain coverage (Whole skull is not completely in field of view, automatically detected)
- Motion and metal artefacts are not automatically detected. It is the users responsibility to verify if the results produced are based on acceptable image quality.

## 1.5 Operating Instructions

StrokeViewer LVO Triaging is a software-as-a-service product available over the internet and running on a cloud-based infrastructure. For using StrokeViewer LVO Triaging, no installation of software or hardware is required. The only requirement for using StrokeViewer LVO Triaging is the configuration of the existing infrastructure already in use by the hospital.

StrokeViewer LVO Triaging is designed to be seamlessly integrated with existing services and devices commonly used by hospitals. As can be seen in the figure below, the input data processed by StrokeViewer LVO Triaging can be directly sent from CT scanners or PACS systems. CT scanners and PACS are capable of initiating DICOM transfers to StrokeViewer LVO Triaging. These transfers are done via a VPN connection that connects the hospital network to a remote DICOM node which is part of StrokeViewer LVO Triaging's architecture. Once the DICOM files are successfully sent to StrokeViewer LVO Triaging, any DICOM series that fulfill the quality requirements are processed by the occlusion detection module. Once the occlusion detection result is available, an email notification is sent. Users can access StrokeViewer LVO Triaging by typing in their browser the StrokeViewer LVO Triaging's URL or by clicking on the link available in the email notification. When trying to access StrokeViewer LVO Triaging, the users are redirected to their institution authentication system. Once valid user credentials are provided, the user is able to access the result of the occlusion detection module in the web-based DICOM viewer. In this DICOM viewer, the users are also capable of visualizing the uploaded DICOM files and sharing these DICOM files with a pre-defined list of hospitals in the network. More details about how to operate and configure StrokeViewer LVO Triaging are available in the remaining sections of this document.




**Overview of how StrokeViewer LVO Triaging is integrated with existing services and devices available in the hospital network.**

**Related documents and Training**

Users will get on-site training on the usage of the device and interpretation of the results. Additionally, the following documents are available for the end-users to ensure correct usage of the device in the clinic:

- SVH201-UG56UNIENUS StrokeViewer® 2.0.1 User Guide
- NIC_200091_01_F Notification configuration on mobile devices

1.

### 1.5.1 Sending input data to StrokeViewer LVO Triaging

**Input data**

The input data processed by StrokeViewer LVO Triaging are computed tomography angiograph (CTA) brain scans from suspected ischemic stroke patients. These scans should be saved according to the DICOM standard and uploaded to StrokeViewer LVO Triaging via DICOM transfers. Details about the requirements related to the DICOM transfers the DICOM files and required DICOM tags are included in *<NIC-200059-01-F DICOM conformance statement>*. CT scanners, PACS, or other DICOM nodes that satisfy the requirements specified in StrokeViewer LVO Triaging's DICOM conformance statement are able to send image data to StrokeViewer LVO Triaging.

All DICOM files uploaded to StrokeViewer LVO Triaging can be visualized and shared in the web-based DICOM viewer. Only the DICOM series that meet the quality requirements will be processed by the occlusion detection module for triaging purposes. Determining if a DICOM series should be processed or not done automatically based on the requirements specified in *<NIC-200059-01-F DICOM conformance statement>*.

**Connecting hospital network to StrokeViewer LVO Triaging**

In order to initiate a DICOM transfer to StrokeViewer LVO Triaging, StrokeViewer LVO Triaging's DICOM node must be reachable by the CT scanner or PACS via the hospital network. For safe transfer of data between the hospital network and StrokeViewer LVO Triaging's DICOM node, the set-up of a VPN (virtual private network) connection is mandatory. The parameters for configuring this VPN connection are described in *<NIC-200056-01-F VPN configuration>* and will be shared with the hospital IT team.

**Firewall configuration**

To allow data transfer via the VPN connection, firewall configuration of certain traffic and ports for selected devices are required. This will be performed by the hospital IT team. The parameters for configuring the firewall are described in *<NIC-200056-01-F VPN configuration>*.

**Configuring the DICOM node that sends data to StrokeViewer LVO Triaging**

The correct configuration of the CT scanners or PACS is the responsibility of the hospital IT staff and is out of the scope of this manual. The necessary parameters for correctly adding StrokeViewer LVO Triaging's DICOM node as destination of DICOM transfers in the CT scanners or PACS can be found in *<NIC-200056-01-F VPN configuration>*. For more information on how to add a new DICOM node or DICOM service provider (DSP), please consult the documentation provided by the manufacturer of the CT scanner or PACS.

**Manual or automatic DICOM transfers to StrokeViewer LVO Triaging**

To ensure timely processing of the CTA scans and effective use of StrokeViewer LVO Triaging functionalities as intended, it is required to set up an auto-forward rule for the DICOM image transfer. The current notification times reported by StrokeViewer LVO Triaging are based on image transfer using automatic forward.

However, as a backup mechanism, users will always be able to trigger the upload process manually. This can be done by sending the CTA images to the StrokeViewer LVO Triaging DICOM destination as configured on the hospital CT or PACS. In terms of StrokeViewer LVO Triaging image processing and output there are no differences regarding the way the DICOM transfers are initiated (manually or automatically).

**DICOM transfer from CT scanner or PACS**

StrokeViewer LVO Triaging should operate as intended as long as the DICOM node initiating the DICOM transfer satisfies the requirements described in *<NIC-200059-01-F DICOM conformance statement>*. Therefore, the choice of uploading CTA scans to StrokeViewer LVO Triaging from a CT scanner or from a PACS is left to the hospital staff. Nevertheless, if two options are available, the selected option should be the one that allows the fastest data transfer.

### 1.5.2 Processing of the uploaded data

Whenever an upload is successfully made to StrokeViewer LVO Triaging, the occlusion detection algorithm searches the CTA scan for image features that indicate the presence of an intracranial LVO. The DICOM series that meet the quality requirements will be processed by the occlusion detection module for triaging purposes. All DICOM files uploaded to StrokeViewer LVO Triaging can be visualized and shared in the web-based DICOM viewer. After the completion of the occlusion detection algorithm, the user is notified via email. When a suspected LVO is detected, the subject of the email notification is "CTA Results ready".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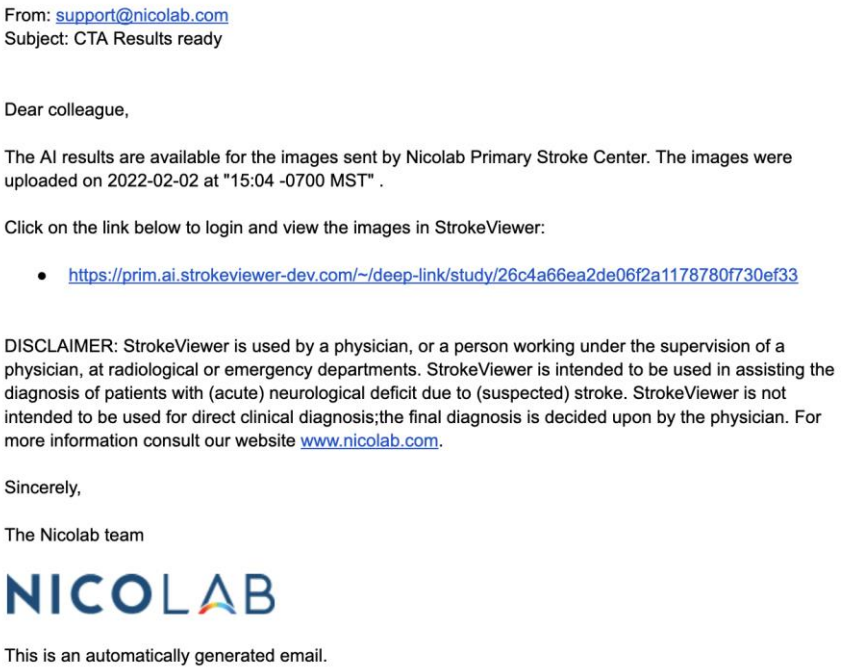
### 1.5.3 Accessing the output data generated by StrokeViewer LVO Triaging

To access StrokeViewer LVO Triaging results, users can login to the viewer by accessing the direct link in the email notification. The email notification includes information regarding the upload and analysis time of the images and enables the users to access and view the images and results directly on their mobile phone and/or Workstation.



From: support@nicolab.com
Subject: CTA Results ready

Dear colleague,

The AI results are available for the images sent by Nicolab Primary Stroke Center. The images were uploaded on 2022-02-02 at "15:04 -0700 MST" .

Click on the link below to login and view the images in StrokeViewer:

- https://prim.ai.strokeviewer-dev.com/~/deep-link/study/26c4a66ea2de06f2a1178780f730ef33

DISCLAIMER: StrokeViewer is used by a physician, or a person working under the supervision of a physician, at radiological or emergency departments. StrokeViewer is intended to be used in assisting the diagnosis of patients with (acute) neurological deficit due to (suspected) stroke. StrokeViewer is not intended to be used for direct clinical diagnosis;the final diagnosis is decided upon by the physician. For more information consult our website www.nicolab.com.

Sincerely,

The Nicolab team

NICOLAB

This is an automatically generated email.

**Notification when there is a suspected LVO detected.**

Alternatively, users can access the viewer by browsing to a URL provided to them (specific for their hospital) in their web-browser. Detailed information on how to interact with the output generated by StrokeViewer LVO Triaging is available in the user manual of the DICOM viewer **<SVH201-UG56UNIENUS StrokeViewer® 2.0.1 User Guide>**.

**Single sign-on configuration**

To access StrokeViewer LVO Triaging, authentication is required. StrokeViewer LVO Triaging interfaces with Active Directory Federation Services (ADFS). This enables users to have single sign-on access to StrokeViewer LVO Triaging via their existing hospital credentials. Details regarding how to configure the ADFS integration are included in ***<NIC-200055-01-F ADFS configuration>***.

**Notifications configuration**

All notifications are sent to the users via a mailing list which is managed by the hospital IT. This mailing list is defined by the hospital and responsible clinical lead. To be able to receive the notifications in a timely manner, users are required to set-up the hospital email account (specific for StrokeViewer LVO Triaging notifications) on their mobile devices and enable push notifications. Please see the instructions in **<NIC_200091_01_F Notification configuration on mobile devices>.**

## 1.6 Safety Warnings

**CT scanners**

StrokeViewer LVO Triaging is indicated for CT scanners from GE Medical Systems and Philips. During clinical validation the StrokeViewer LVO Triaging algorithm was primarily tested on CT scanners from GE and Philips and is NOT indicated for CT scanners of manufacturers other than GE and Philips. Please see section 1.9 for a list of CT scanner models.

**Device Limitations**

StrokeViewer LVO Triaging's output of suspected findings is for notification purposes only. Physicians are responsible for review of the images and engaging in appropriate patient evaluation before deciding the final diagnosis and further clinical work-up. StrokeViewer LVO Triaging is only limited to analysis of image data; the final diagnosis is always decided upon by the medical specialist. For a correct analysis, the entire head should be in the field of view. If the head is not scanned completely and the top of the skull is missing, the algorithm will not be able to process the images. CTA scans with poor image quality (motion, artefacts, absence of adequate vascular contrast) are not automatically detected. Analyses of these scans may fail or result in wrong output (false positive, false negative). It is the users' responsibility to verify if the results produced are based on acceptable image quality.

**False positive or false negative LVO detection**

The results generated by StrokeViewer LVO Triaging are not intended to be used for diagnostic purposes. The assessment of the patient is the full responsibility of the medical professionals. StrokeViewer LVO Triaging automatically detects CT angiography scans with more probable presence of a large vessel occlusion. These detections have no diagnostic value and shall not influence the decision of the medical professionals. Motion and metal artefacts will influence the algorithm results. It is the users' responsibility to verify if the results produced are based on acceptable image quality.

**Internet connection is not available**

StrokeViewer LVO Triaging requires a stable internet connection with an upload speed of at least 25MB/s for timely analysis of the uploaded scans and forwarding of those scans to intervention centers. In case of internet connectivity problems, the hospital should immediately proceed with the regular clinical workflow, and it should not delay the assessment of the suspected stroke patient.

**Delay in processing uploaded data**

Users should not allow that delays or malfunctions of StrokeViewer LVO Triaging lead to delays in the assessment of the patients. Users should immediately proceed with the regular stroke workflow, and they should not wait for notifications sent by StrokeViewer LVO Triaging to proceed with the regular clinical workflow.

**User authentication issues**

Users should pay attention in situations when logging in to StrokeViewer LVO Triaging is not possible. In these situations, the users are not capable of using StrokeViewer LVO Triaging for sharing images with the intervention center nor to inspect the results of the occlusion detection. In case users cannot log in, it is advised to continue the standard clinical workflow to avoid any delays.

## 1.7 Cybersecurity Requirements, Warnings, and Precautions

**VPN pre-shared keys**

The hospital is required to configure a VPN connection linking the local hospital network and the dedicated network provided by StrokeViewer LVO Triaging specifically for that hospital. This VPN network should enable the CT scanner, PACS, or other DICOM node in the hospital network to start DICOM transfers to the DICOM service provider made available by StrokeViewer LVO Triaging.

The hospital is required to provide a strong (random) 32-character long pre-shared secret key for configuring the VPN connection. The hospital is responsible for making sure that this key is safely stored and it is not accessible to unauthorized people and/or services. If this pre-shared key is compromised, the hospital network is vulnerable to unauthorized access. Furthermore, an attacker with access to this pre-shared key might be able to have unauthorized access to the DICOM files uploaded to StrokeViewer LVO Triaging. More details about the security requirements for the VPN configuration are available in *<NIC-200056-01-F VPN configuration>.*

**ADFS server protection**

Hospitals are required to have an ADFS server which is used to authenticate the users of StrokeViewer LVO Triaging. The ADFS server should be configured to have a user group with access rights to StrokeViewer LVO Triaging. The hospital is responsible for protecting its ADFS server from malicious software and/or attacks. If the ADFS server is compromised, users might not be able to access StrokeViewer LVO Triaging.

**ADFS certificates**

Hospitals should provide a URL to the Federation Metadata XML file of the ADFS. This file contains information which is necessary to create trusts and identify token-signing certificates. StrokeViewer LVO Triaging automatically renews these certificates once a new certificate is available.

**Firewall configuration**

Hospitals are responsible for the correct configuration of the firewall between the source of the DICOM transfer and StrokeViewer LVO Triaging. Details regarding the firewall configuration are available in *<NIC-200056-01-F VPN configuration>.*

**Authentication policy**

Authentication/user credential policies are full responsibility of the hospital and they are configured and managed via the ADFS server. These policies include requirements for multi-factor authentication and for password length, complexity, and expiration time. The hospital is responsible for implementing and using policies in line with the best security practices available. Furthermore, the hospital should ensure that the users do not share their user credentials with 3rd parties.

**Security updates**

Since StrokeViewer LVO Triaging is a software-as-a-service product, security updates are automatically delivered to the users without requiring any further action from the user side. If a major update requires a configuration change by the user, the user is contacted prior to the update and informed accordingly. Continuous support is available for the end users throughout the validity of the hospital's contract.

**Malware protection**

All modules that compose StrokeViewer LVO Triaging's architecture are monitored for the presence of any malicious software. No action from the user side is required since no component of StrokeViewer LVO Triaging's architecture is deployed on the hospital premises.

**Mailing list for notifications**

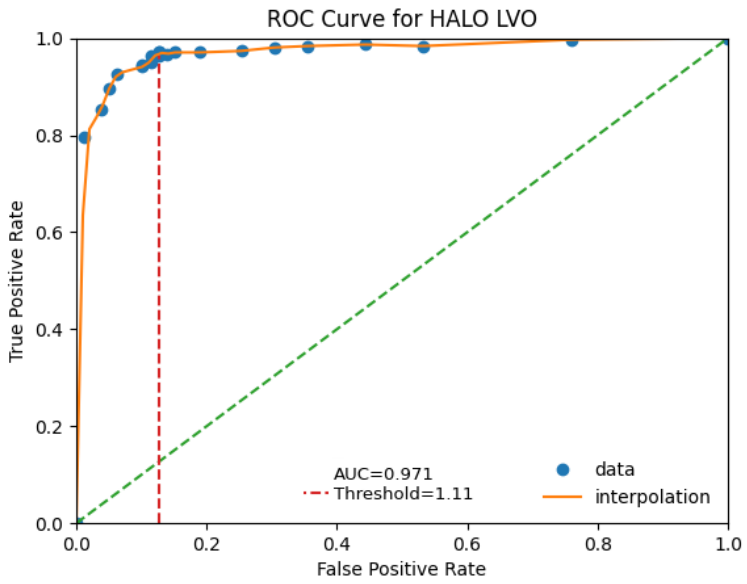
Hospitals are required to provide a dedicated electronic mailing list address. Hospitals should subscribe all StrokeViewer LVO Triaging users to that mailing list to enable these users to receive StrokeViewer LVO Triaging's email notifications. Thus, it is important that only the users with access rights to StrokeViewer LVO Triaging are included in this list. In case the email from an unauthorized person and/or service is included in this list, that person and/or service will be able to read the content of the notifications sent by StrokeViewer LVO Triaging.

## 1.8 Performance Test Summary

In a multi-reader clinical study, the performance of the StrokeViewer LVO Triaging clinical decision support algorithm for LVO detection was retrospectively evaluated in a consecutive patient cohort admitted to US stroke centers.

Four hundred and thirty-four CTA scans of the brain were collected. After exclusion, 427 patients were included for further analyses. Ground truth was established by an expert panel who identified patients with an LVO. The expert panel identified 207 positive LVO cases and 220 cases were tagged as non-LVOs. The distribution of the reported LVO locations was as follows: ICA n=54 (26.1%), M1 n=109 (52.7%) and M2 n=44 (21.3%).

The performance testing of the StrokeViewer LVO Triaging algorithm showed a sensitivity and specificity for LVO detection of respectively 91.3% (95%-CI, 86.6%-94.8%) and 85.9% (95% CI, 80.6%-90.2%).The area under the curve (AUC) is 0.97. The threshold is marked with the dashed vertical red line (see figure below). The median notification time for the detected LVO cases was 4 minutes 29 seconds, with a minimum of 3:47 and maximal 7:12min.



The device was primarily tested on images from GE and Philips scanners with a limited number of scans from Siemens and Toshiba Data scanners:

| | |
|---|---|
| GE MEDICAL SYSTEMS (74%) | Revolution CT<br>Revolution EVO<br>Optima CT660<br>LightSpeed VCT<br>Discovery 750HD |
| TOSHIBA/CANON (3%) | Aquilion PRIME<br>Aquilion |
| SIEMENS (8%) | SOMATOM Definition AS+<br>SOMATOM Definition<br>SOMATOM Definition Flash<br>Perspective |
| Philips (15%) | Brilliance 64<br>IQon Spectral CT<br>iCT 256<br>Ingenuity CT |