

USER MANUAL

StrokeSENS LVO
Version 1.4.3



StrokeSENS LVO

User Manual

March 2023

Regulatory Information



Manufactured by:



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Health Canada device license number: **107386**

United States of America

The following 510K clearance(s) applicable for this product:

K212261



UDI: ***+B926SSSX10***

European Union



StrokeSENS is qualified as a class IIa medical device.



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IMPORTANT: US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

R_x Only

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1 Regulatory

1.1 Regulatory Information

| Agency | Authorized Representative | Approval / Clearance Reference |
|-----------------------------------|---|--|
| Australia TGA ARTG | Australian Sponsor: Siemens Healthcare Pty Ltd Level 3, 141 Camberwell Road Hawthorn East, VIC 3123, Australia Ph: 1 (800) 310-300 | ARTG number: 399398 |
| CE Mark (MDD) | Circle Cardiovascular Imaging BV SingelStaete Singel 250 1016 AB Amsterdam The Netherlands | CE Mark Certificate US21/819944332 issued by SGS for StrokeSENS. |
| Health Canada | N/A | Health Canada device license number: 107386 |
| US FDA | N/A | StrokeSENS LVO – K212261 |
| UK | Circle Cardiovascular Imaging UK LTD. Ty Mentor, Navigation Park, Abercynon Mountain Ash, Mid Glamorgan, Wales, UK, CF45 4SN | MHRA registration: 22027 |

2 Introduction

This User Guide is also available:

- On the Internet at: www.circlenvi.com/documentation/

A paper copy of this User Guide can be ordered at no additional cost. Please, send a request to your Sales or Service representative. They will transfer your request to info@circlecvi.com. In application of the EU Commission Regulation on electronic instructions for use of medical devices, in European Union, your request should be treated within 7 days.

2.1 Product Description

StrokeSENS is a decision-aid software package to be used by clinicians to perform image processing, analysis, viewing and communication of computed tomography (CT) scans of the brain in patients with suspected acute stroke. Analysis of contrast-enhanced CT images is provided by the StrokeSENS LVO module, which includes automated detection of suspected large vessel occlusion (LVO).

2.2 Symbols used in documentation

| Symbol | Description |
|---|--|
|  | Consult Instructions for Use: Indicates that the user shall read Instructions for Use. |
|  | Manufacturer: Indicates the medical device manufacturer's name and address. |
|  | Importer: Indicates the entity Importing the medical device into the locale |
|  | Unique device identifier (UDI): Indicates a carrier that contains Unique Device Identifier information |
|  | General caution: Used to highlight the fact that there are specific warnings or precautions associated with the application, which are not otherwise found on the label. |
|  | Medical Device: Indicates this product is a medical device. |
|  | Authorized representative in the European Community: Indicates the authorized representative in the European Community. |

2.3 Terms and Definitions

| Term | Definition |
|---|---|
| StrokeSENS LVO | The StrokeSENS LVO software device is a computer-aided triage and notification software intended to flag and communicate findings of suspected LVO in head CTA images. It consists of algorithms and processing methods intended to be used as part of an integrated compatible radiological software platform such as StrokeSENS platform, or other compatible radiological software platform solutions. |
| Compatible Radiological Software Platform | A compatible radiological software platform solution is responsible for providing the electronic medium for communication, storage, and transfer of medical images as well as may be responsible for the coordination of email/notification results, as specified by the requirements of the StrokeSENS LVO devices. The compatible radiological software solution may also provide other radiological functionalities outside the scope of the StrokeSENS LVO devices functionality including image review functionality and image processing/analysis workflow. |
| CTA | CTA or Computed Tomography Angiography is a type of medical imaging in which contrast-enhanced images are acquired by computed tomography devices. CTA of the head (and neck) are commonly acquired in suspected acute stroke patients. |
| DICOM | Digital Imaging and Communications in Medicine (DICOM) is the standard for the communication and management of medical imaging information and related data. DICOM is most commonly used for storing and transmitting medical images enabling the integration of medical imaging devices such as scanners, servers, workstations, printers, network hardware, and picture archiving and communication systems (PACS) from multiple manufacturers. |
| Large vessel occlusion (LVO) | Common pathology of acute ischemic stroke, wherein a large arterial vessel in the brain is occluded by a clot. StrokeSENS LVO is indicated for large vessel occlusions in the anterior circulation only (ie. ICA – MCA vessels). |

3 Basic Components and Indication for Use

3.1 Indication for Use

StrokeSENS LVO is a radiological computer-aided triage and notification (CADt) 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) in head CTA images.

StrokeSENS LVO uses a software algorithm to identify suspected LVO findings. In the case of a suspected LVO, the system will send a notification to a pre-configured destination(s), notifying the clinicians of the existence of a suspected LVO that requires review. The notification system is intended to be used in parallel to the standard of care workflow to notify clinicians of the existence of the case earlier that they may have been notified as part of the standard of care workflow.

Notifications may include a compressed preview of images. Notifications are meant for informational purposes only and are not intended for diagnostic use beyond notification. The StrokeSENS LVO device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of StrokeSENS LVO are intended to be used in conjunction with other patient information and based on professional judgement, to assist with triage / prioritization of medical images. Notified clinicians are responsible for viewing full images per standard of care.

3.2 Patient population

StrokeSENS is intended to be used on adults (22 years and older) with suspected acute stroke.

The StrokeSENS LVO module is intended to be used on adults to detect anterior circulation Large Vessel Occlusion (LVO).

3.3 Intended user population

The intended users of StrokeSENS shall be clinicians and hospital networks involved in the management of acute stroke patients. Specifically, the intended users of StrokeSENS shall be clinicians including radiologists, neurologists, neuro-interventionalists, emergency physicians, and neurocritical care specialists.

3.4 Training required for use of this device

Training for the StrokeSENS device is satisfied through this User Manual in the form of the Indications For Use / Intended Use, the system and image requirements, workflow / user management / configuration instructions (with screenshots), and Device Operating Instructions. Detailed installation instructions and on- or off-site support are provided to the IT Administrators upon installation. The intended users of the software are specialists trained in the diagnosis and management of acute stroke and are familiar with the use of radiological software environments. No additional formal training is necessary to effectively use the software.

4 Warnings and Cautions

Safety notice legends



WARNING:

This indicates a potentially hazardous situation, which, if not avoided, could result in serious injury.



CAUTION:

This indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.



NOTICE:

This indicates a non-hazardous situation, which, if not avoided, could result in equipment damage, lost time, or reduced image quality.



WARNING: Patient Data

The displayed study/patient data as well as information used for processing images are initially derived from the DICOM information where available. Note that editing these values in the original DICOM may affect the calculations in the software. It is the responsibility of the user to verify the results before being used for making diagnostic or treatment decisions.



WARNING: Artificial Intelligence (AI) algorithms are used to produce visualizations, predict scores, and identify suspicious findings in CT images for the purpose of aiding the clinician in the assessment of patients with suspected acute stroke. Inaccurate results may be produced. Results are not to be considered a primary diagnosis. Users are intended to review all available information, including the original CT images, before making patient management decisions.



WARNING: StrokeSENS is a parallel workflow tool intended to be used in conjunction with standard of care procedures. StrokeSENS should not replace the standard of care procedure.



WARNING: Misleading information due to user error, inadequate source images, and/or inaccurate Artificial Intelligence predictions may lead to misdiagnosis.



CAUTION: StrokeSENS relies on the quality and correctness of the image source data, for the software to satisfy its intended use. Clinicians are intended to confirm findings on original images prior to making diagnostic or treatment decisions. Information provided by StrokeSENS is intended to be used as an adjunct to standard of care procedures and should not be considered as primary diagnosis.



CAUTION: StrokeSENS undergoes rigorous Cybersecurity and Systems testing prior to release. Once deployed on-site, the security and connectivity of the StrokeSENS system within the hospital IT infrastructure is managed by the on-site/customer's IT and Security professionals. It is therefore the responsibility of the customer to ensure appropriate security measures are in place to promote safe and effective use of the product within their local and jurisdictional regulations.



CAUTION: No known susceptibilities to other software applications have been identified, however, it is the end-user's responsibility to ensure the environment in which the StrokeSENS application is installed is maintained and free of other applications that may jeopardize the safe and effective use of the software.



CAUTION: This user manual is considered adequate training for the safe and effective use of the product. Training will be made available to the customer at time of installation and for major product upgrades, however training is not mandatory or required. Ongoing technical support and customer service is available. See Technical Support section below.



CAUTION: StrokeSENS is not for use in patients younger than 22 years of age. Use of this device in a population outside of the intended use, could result in incorrect outputs from the device, potentially leading to minor Harm of the patient or minor functionality failure.



Notice: Note on IEC 60601-1: As a software-only solution, StrokeSENS does not fall under the safety and compliance considerations of the IEC 60601-1 standard. Complying with these standards for medical electrical equipment used in conjunction with StrokeSENS is the responsibility of the relevant clinicians and institutions.



Notice: Software may slow down when other applications are being run on the same machine.

5 Clinical Benefits

StrokeSENS LVO allows clinicians and hospital networks to be notified of time-sensitive and potentially dangerous cases earlier than they may have been in the standard of care pathway.

6 Contraindications

None

7 Undesirable Side Effects

None

8 System Hardware and Software Specifications

8.1 Compatible Imaging Systems

StrokeSENS is a CT vendor-agnostic post-processing software that leverages artificial intelligence (AI) to process CT medical images of the head for suspected acute stroke, for the purpose of early identification and notification of potentially time-sensitive cases. StrokeSENS has been tested on CT images from a variety of different scanner systems in the market, including:

- Siemens (Somatom Definition series, Sensation series, Somatom Force)
- General Electric (Discovery series, Lightspeed series, Revolution series, Optima series)
- Philips (Brilliance series, iCT series, Ingenuity series, MX8000 series)
- Toshiba (Aquilion series)

The StrokeSENS LVO notification system is intended to be used as part of an integrated medical imaging system. Integration into a compatible imaging system is necessary to provide infrastructure and services such as DICOM handling, login and user management, and basic image viewing. Comprehensive testing of the StrokeSENS LVO software in the StrokeSENS Platform has been conducted, verifying the performance of the StrokeSENS LVO software in the compatible system. This document provides user instructions and labelling for the StrokeSENS LVO software as integrated into the compatible StrokeSENS Platform.

8.2 DICOM requirements for Algorithm Processing



NOTICE: StrokeSENS was developed and tested with datasets acquired with the following parameters listed below. For accurate processing by the Artificial Intelligence (AI) algorithms, StrokeSENS requires DICOM standard CT images of the head that align with the following parameters

| CTA for LVO Detection |
|---|
| 1. ImageType = Original/Primary |
| 2. Modality = "CT" |
| 3. Volumes = 1 *A multi-volume CTA (i.e., multi-phase CTA) is acceptable. Only the first phase will be used for processing. |
| 4. Scan range = CT head volume covering the whole head (vertex to base) is recommended |
| 5. Image characteristics: <ul style="list-style-type: none">• Window Width: 210 – 1170• Slice Thickness: 0.5 - 2.5 mm• Matrix Size: 512 x 512• DFOV along the X/Y axis: 180 – 412 mm |

In addition to the acceptable DICOM requirements listed above, accurate processing of CT images relies on technically adequate input images. Technically inadequate CT input images may result in reduced performance (potential increase in false positive and/or false negative findings). Reasons a CT input image may be technically inadequate include severe motion, poor contrast timing, and inaccurate anatomical coverage of the head. To ensure accurate processing, CT images should encompass the entire head with no severe artifacts.

9 Device Operating Instructions

9.1 LVO Detection

CTA Head scans appropriate for LVO detection (see 8.2 above) will be identified by syngo.via and shared with the StrokeSENS LVO algorithm for processing. Once LVO Detection post-processing is complete, the results will be saved as a single-image Series in the same Study to which the CTA source images belong. Both the original CTA and the LVO Detection results will be available to the user via the Patient Browser (see below).

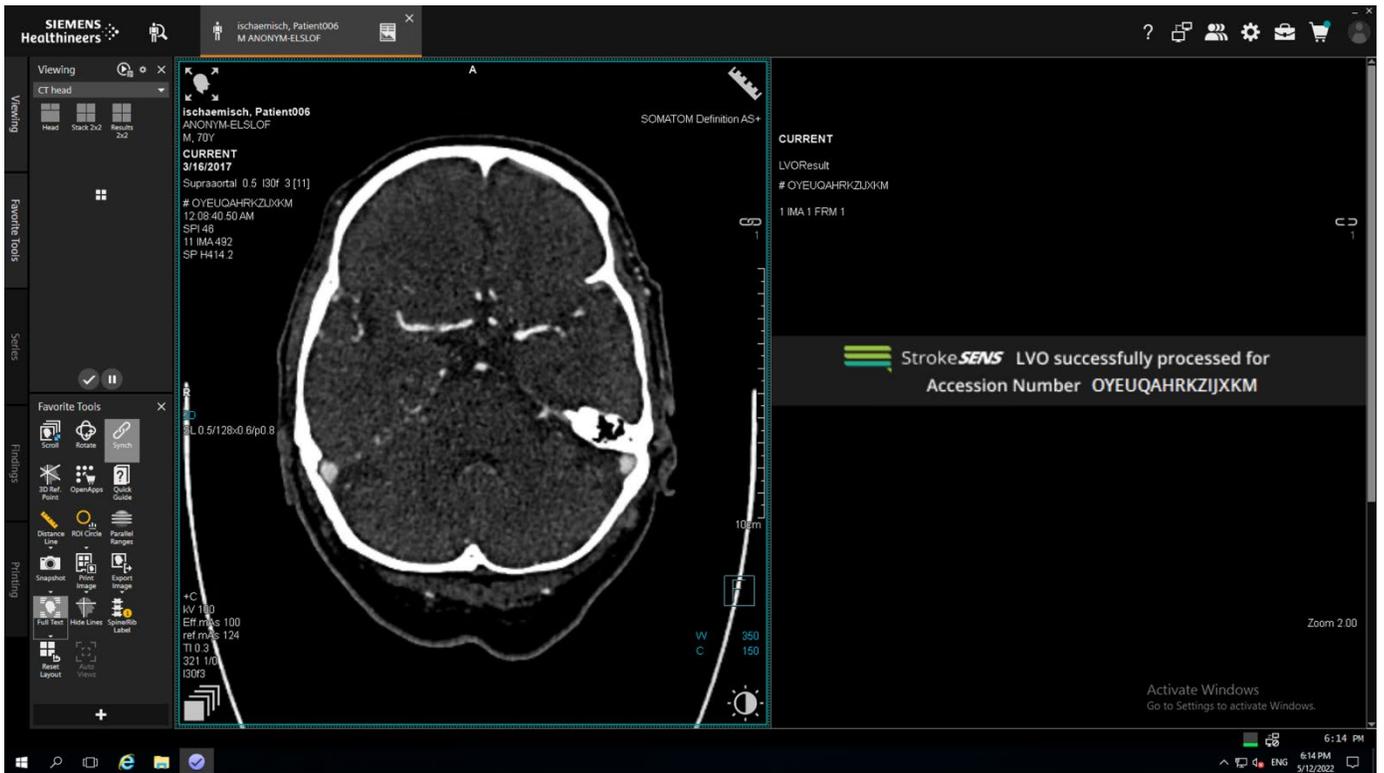
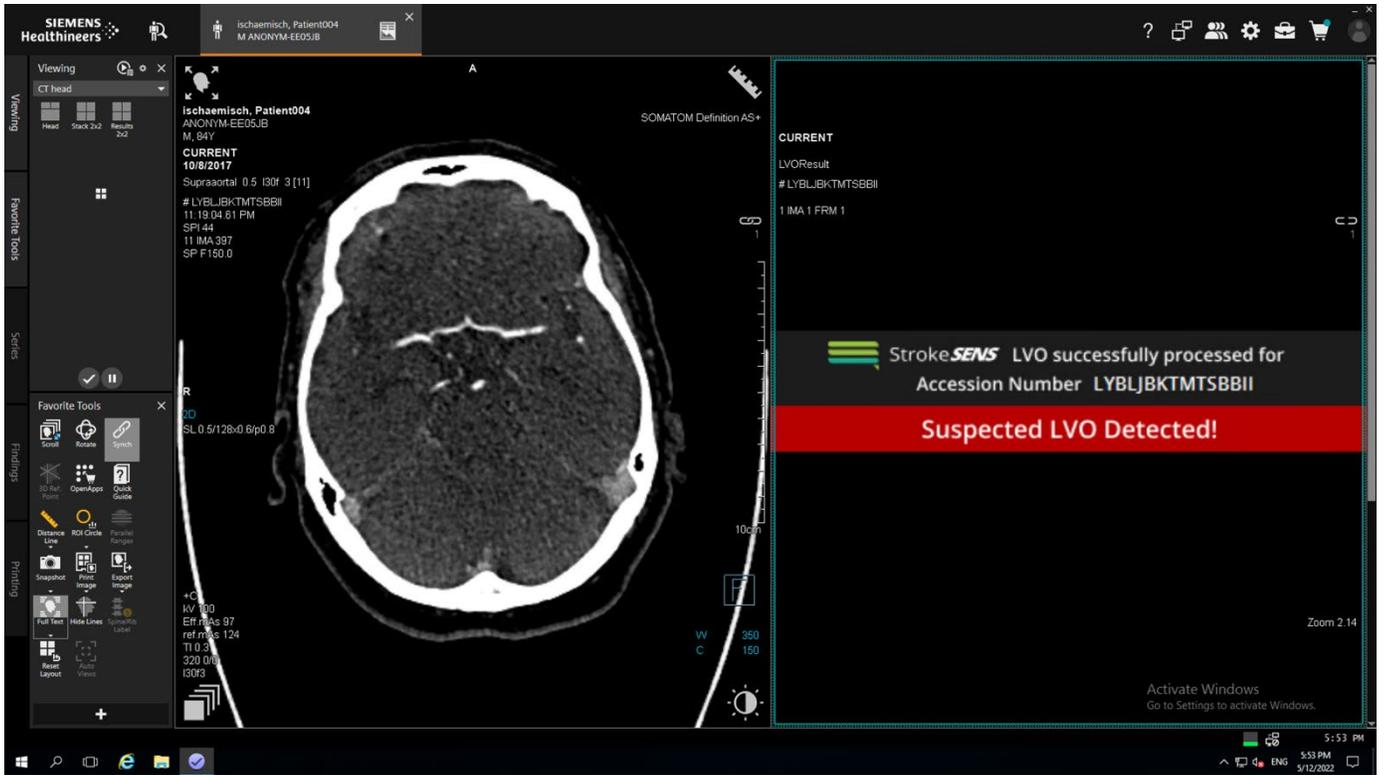
The screenshot displays the Siemens Healthineers Patient Browser interface. The main window is titled "Patient0" and shows a list of results under the heading "Results (10 results, 5:51:55 PM)". The results are organized in a table with columns for Workflow Status, Workflow Desc..., Patient Name, Date of Birth, Patient ID, Modality, Study Date and Time, and Study Description. The table lists 10 entries, all with a status of "Ready".

| Workflow Status | Workflow Desc... | Patient Name | Date of Birth | Patient ID | Modality | Study Date and Time | Study Description |
|-----------------|------------------|-------------------------|---------------|---------------|----------|------------------------|----------------------|
| Ready | MM Reading | ischaemisch, Patient001 | | ANONYM-NQ... | CT | 11/26/2016 1:52:02 AM | CT Schädel |
| Ready | MM Reading | ischaemisch, Patient002 | | ANONYM-VD... | CT | 11/18/2017 12:45:45 PM | CT Schädel + Perf... |
| Ready | MM Reading | ischaemisch, Patient003 | | ANONYM-JD... | CT | 9/7/2016 4:04:05 PM | CT Schädel + Perf... |
| Ready | MM Reading | ischaemisch, Patient004 | | ANONYM-EE0... | CT_SEG | 10/9/2017 11:01:53 PM | CT Schädel |
| | | ischaemisch, Patient005 | | ANONYM-1N... | CT | 11/19/2016 11:40:28 AM | CT Schädel |
| | | ischaemisch, Patient006 | | ANONYM-ELS... | CT | 3/16/2017 12:02:37 AM | CT Schädel |
| Ready | MM Reading | ischaemisch, Patient007 | | ANONYM-WS... | CT | 9/27/2017 1:19:04 PM | CT Schädel |
| | | ischaemisch, Patient008 | | ANONYM-D7... | CT | 12/18/2017 11:33:34 AM | CT Schädel |
| | | ischaemisch, Patient009 | | ANONYM-V42... | CT | 12/14/2017 10:12:56 AM | CT Schädel |
| | | ischaemisch, Patient010 | | ANONYM-ED... | CT | 10/8/2017 10:11:03 PM | CT Schädel |

On the right side of the interface, there are two panels: "Series" and "Instances". The "Series" panel shows three thumbnails: "LVOResult", "Syringasim 0.5 (DOP)", and "Table Segmentations". The "Instances" panel shows a preview of a CT scan slice with a vertical scale on the right indicating a value of 316. The interface also includes a search bar at the top, a "More Filters" dropdown, and various utility icons like "Open", "Print", "Open with", "DICOM QR", "Send to Archive", "Import", "Export", and "Delete".

Head CT Angiogram (CTA) and LVO Detection results Series made available for viewing from the Patient Browser

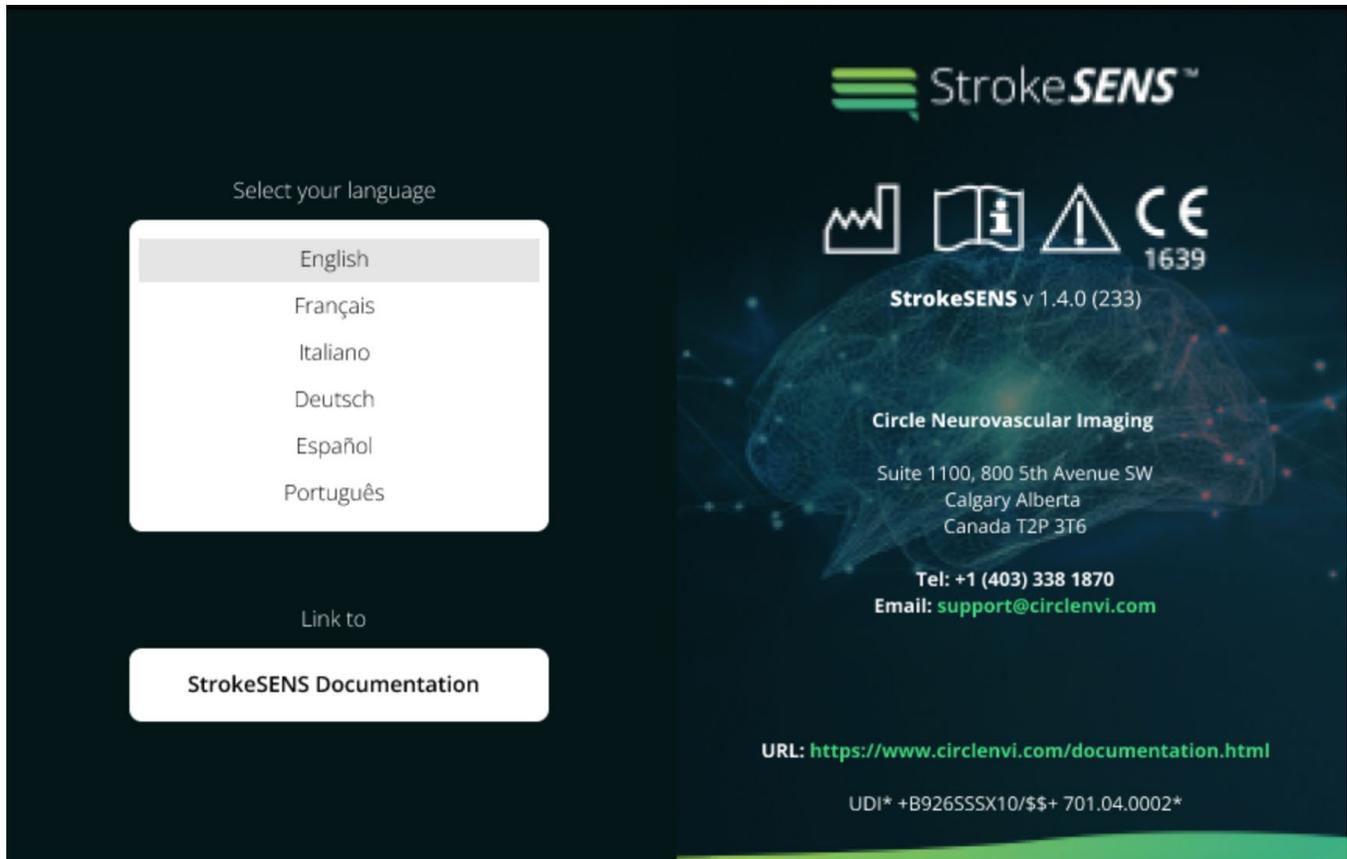
The LVO Detection results indicate that processing was successfully completed, provide an Accession Number for the user's reference, and in the case a suspected LVO is detected, that is indicated. (see below for cases where an LVO was and was not detected, respectively).



9.2 Language Selection and About Box

End users have the option to select their preferred language by launching a StrokeSENS language configuration panel within the Syngo.via environment. User will be able to toggle the languages provided in the configuration panel and save their preferred language. LVO Detection results and outputs will be translated to the selected language. By default, the language is set to English.

The configuration panel also contains the StrokeSENS About Box and a link to launch to StrokeSENS Documentation hosted online.



StrokeSENS Configuration Panel displayed in the Syngo.via workstation.

10 Summary of data and device performance

10.1 StrokeSENS LVO

Description of Data used for Development and Testing

The LVO detection module was developed using a pooled dataset composed of retrospective patient imaging data from five clinical study/trial databases, namely the Prove-IT clinical study (N=76, ClinicalTrials.gov Identifier: NCT02184936), ESCAPE randomized controlled trial (N=25, ClinicalTrials.gov Identifier: NCT01778335), ESCAPE-NA1 randomized controlled trial (N=451, ClinicalTrials.gov Identifier: NCT02930018), ALIAS randomized clinical trial (N=24, ClinicalTrials.gov Identifier: NCT00235495), and PREDICT study (N=95, PMID: 22405630). The development dataset was composed of 476 positive cases with an anterior large vessel occlusion (i.e., intracranial ICA and M1-MCA) and 195 negative no-occlusion cases.

The imaging data was acquired from multiple CT scanner models, manufactured by four different CT scanner vendors (GE, Siemens, Philips, Toshiba) from multiple sites across North America (Canada and USA), EU and Asia. The following table summarizes the properties of both the development and test sets:

| | Development Set | Test Set |
|-----------------------------|-----------------|----------|
| Total | 671 | 400 |
| Manufacturer | | |
| GE Medical Systems | 410 | 146 |
| Siemens | 240 | 143 |
| Philips | 15 | 47 |
| Toshiba | 6 | 64 |
| Slice Thickness (mm) | | |
| [0.5, 1.5] | 652 | 378 |
| (1.5, 2.5] | 14 | 22 |
| >2.5 | 5 | 0 |
| kVp | | |
| [80, 100] | 151 | 80 |
| (100, 120] | 482 | 281 |
| (120, 140] | 38 | 39 |
| Age | | |
| <=50 | 77 | 40 |
| 51-60 | 117 | 67 |
| 61-70 | 167 | 107 |
| 71-80 | 157 | 113 |
| 81-90 | 131 | 60 |
| 91-100 | 16 | 13 |
| Data not available | 6 | 0 |
| Sex | | |
| Male | 351 | 217 |
| Female | 308 | 183 |
| Data not available | 6 | 0 |
| Geography | | |
| Canada | 326 | 179 |
| US | 236 | 153 |
| Europe | 81 | 43 |
| Asia | 3 | 1 |
| Australia | 22 | 24 |
| Data not available | | |
| Site of Occlusion | | |

| | | |
|--------|-----|-----|
| ICA | 106 | 77 |
| M1-MCA | 370 | 140 |

Summary of Performance

To demonstrate the standalone performance of StrokeSENS LVO software, a retrospective case study was conducted to assess the sensitivity and specificity of StrokeSENS LVO for detecting anterior Large Vessel Occlusion (LVO). Performance was reported on a heterogenous dataset of 400 independent studies (217 LVO cases and 183 non-LVO cases). Patient cases consisted of baseline CT Angiography images acquired for suspected vessel occlusion or intracranial hemorrhage. This data was retrospectively collected from four clinical study/trial databases, namely the ESCAPE NA1 randomized controlled trial (N=219, ClinicalTrials.gov Identifier: NCT02930018), Predict study (N=110, PMID: 22405630), Tempo1 open label clinical trial (N=17, ClinicalTrials.gov Identifier: NCT01654445) and Alias randomized clinical trial (N=54, ClinicalTrials.gov Identifier: NCT00235495).

The positive LVO subgroup (N=217) included cases with occlusions in the intracranial ICA and M1-MCA arteries. The negative non-LVO subgroup (N=183) included challenging cases typically seen in the intended clinical population. These include non-LVO anterior circulation occlusion cases (i.e., more distal anterior occlusions), posterior circulation occlusions (i.e., basilar, vertebral and more distal posterior occlusions), and no occlusion cases (i.e., with or without hemorrhage).

A 2+1 expert consensus was used for truthing to establish the reference dataset labels for each dataset. The expert truthers were US board-certified neuroradiologists experienced in clinical identification of the presence and location of vessel occlusion. Truthers were instructed to independently review all patient cases in the above test set (N=400). For each case, readers were asked to specify the presence or absence of a large vessel occlusion (LVO), presence or absence of hemorrhage, and site of occlusion (if occlusion present). Readers made their interpretations based on the provided single-phase CTA scan only. Readers were also asked to comment on the existence of other significant radiological findings and/or whether the scan was interpretable or not.

The device achieved a mean sensitivity of 90.3% CI = [86.4%, 94.3%], and mean specificity of 95.1% CI = [91.9%, 98.2%] for the binary LVO detection task on the test set (N=400, LVO=217, Non-LVO=183). In addition, an analysis of time to notify of suspicious cases was conducted by evaluating the average time for the StrokeSENS LVO device to process the CTA image and generate a notification (for LVO positive cases). The device achieved a mean value of 1.94 minutes (S.D: ±0.06 mins, Min: 1.79 mins, Max: 2.14 mins).

| Test | Test Results |
|-----------------|--|
| Sensitivity | 0.903, 95% CI = [0.864, 0.943] |
| Specificity | 0.951, 95% CI = [0.919, 0.982] |
| Processing Time | Mean: 1.94 mins S.D: ±0.06 mins Min: 1.79 mins Max: 2.14 mins |

The results of the secondary analysis as well as a breakdown of the subgroups of interest are summarized below:

| Sub-Group | # of LVO | # of Non-LVO | Total | Sensitivity [95% CI] | Specificity [95% CI] |
|--------------------------|----------|--------------|-------|----------------------|----------------------|
| Full cohort | 217 | 183 | 400 | 0.903 [0.864, 0.943] | 0.951 [0.919, 0.982] |
| Site of Occlusion | | | | | |
| ICA Set | 59 | 183 | 242 | 0.872 [0.798, 0.946] | - |
| M1-MCA Set | 158 | 183 | 341 | 0.921 [0.876, 0.966] | - |
| Hemorrhage Set | 217 | 109 | 326 | - | 0.973 [0.923, 0.991] |

| | | | | | |
|-----------------------------|-----|----|-----|----------------------|----------------------|
| Non-LVO-Non-Hemorrhage Set | 217 | 74 | 291 | - | 0.918 [0.855, 0.981] |
| Age | | | | | |
| >= 70 years old | 109 | 88 | 197 | 0.881 [0.82, 0.942] | 0.943 [0.874, 0.975] |
| < 70 years old | 108 | 95 | 203 | 0.926 [0.877, 0.975] | 0.958 [0.897, 0.984] |
| Sex | | | | | |
| Male | 120 | 97 | 217 | 0.900 [0.846, 0.954] | 0.959 [0.899, 0.984] |
| Female | 97 | 86 | 183 | 0.907 [0.849, 0.965] | 0.942 [0.871, 0.975] |
| Slice Thickness (mm) | | | | | |
| 0.5mm - 0.8mm | 108 | 95 | 203 | 0.880 [0.818, 0.941] | 0.958 [0.897, 0.984] |
| 0.9mm - 2mm | 109 | 88 | 197 | 0.927 [0.878, 0.976] | 0.943 [0.874, 0.975] |
| Manufacturer | | | | | |
| GE Medical | 62 | 84 | 146 | 0.919 [0.825, 0.965] | 0.952 [0.884, 0.981] |
| Siemens | 63 | 80 | 143 | 0.889 [0.811, 0.966] | 0.950 [0.878, 0.987] |
| Other | 92 | 19 | 111 | 0.902 [0.841, 0.963] | 0.947 [0.754, 0.991] |

Also, the Positive Predictive Value (PPV) of the device at multiple prevalence values of LVO are as follows:

| Prevalence of LVO (%) | Positive Predictive Value | Sample Size (Bootstrapping) |
|-----------------------|---------------------------|-----------------------------|
| 54.25% | 0.956 | 205 |
| 40% | 0.925 | 119.9 |
| 20% | 0.82 | 50.1 |
| 10% | 0.674 | 27.7 |
| 5% | 0.482 | 17.4 |

10.2 Potential Limitations of the Device Performance Assessment

- The StrokeSENS LVO detection performance assessment had low representation of non-LVO cases from non-GE and non-Siemens scanners.
- The StrokeSENS LVO detection performance assessment was conducted on retrospective imaging data; no prospective clinical studies were conducted.
- Ethnicity was not available in the patient-level data and therefore was not included in the subgroup analysis for StrokeSENS LVO.
- Young adults (<50) were underrepresented in the data used for training and testing LVO detection algorithms.

10.3 Hardware Specifications for testing environment

Analysis was conducted on a machine with the specified requirements below:

| | Hardware Specification |
|----------------|--|
| CPU | Intel(R) Xeon(R) CPU E5-2680 v3 @ 2.50GHz, 2500 Mhz, 4 Core(s), 4 Logical Processor(s) |
| RAM | 16 GB |
| Storage | 1 TB SSD |
| OS | Microsoft Windows Server 2019 Standard. Ver: 10.0.17763 Build 17763 |
| Network | 1 GB ethernet |

11 Technical Support

For technical questions please contact our team by phone or e-mail:

Global support

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