USER MANUAL

StrokeSENS
Version 1.4.2

StrokeSENS

User Manual

February 2023

Regulatory Information

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UDI-DI: *+B926SSSX10*

Manufactured by:

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doing business as
Circle Neurovascular Imaging.

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1016 AB Amsterdam
The Netherlands

European Union

CE
1639

StrokeSENS is qualified as a class IIa medical device.

EC REP

EU Authorized Representative

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1016 AB Amsterdam
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CH REP

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

℞ Only

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1 Regulatory

1.1 Regulatory Information

Agency	Authorized Representative	Approval / Clearance Reference
Australia TGA ARTG	Australian Sponsor: **KD&A Pty Ltd** 286 Flinders Street Adelaide SA 5000	ARTG number: 380409
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
FDA	N/A	StrokeSENS LVO – 510k (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 Manual is also available:
• On the Internet at: www.circlenvi.com/documentation/

A paper copy of this User Manual 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 non-contrast CT images is provided by the StrokeSENS ASPECTS module, which includes assessment of regions with suspected acute ischemic tissue (i.e., ASPECTS scoring). Analysis of contrast-enhanced CT images is provided by the StrokeSENS LVO module, which includes automated detection of suspected large vessel occlusion (LVO). The StrokeSENS mCTA Perfusion (mCTAp) module produces dynamic image data from CT images to generate information regarding changes in image intensity over time.

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.
	**Distributor:** Indicates the entity distributing the medical device into the locale
	**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.

EC REP	**Authorized representative in the European Community:** Indicates the authorized representative in the European Community.
CH REP	**Authorized representative in Switzerland:** Indicates the authorized representative, physical or legal, with registered office in Switzerland acting on behalf of Medical Devices Manufacturers based outside the Swiss territory.

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.
StrokeSENS ASPECTS	The StrokeSENS ASPECTS software device is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities by predicting the ASPECT (Alberta Stroke Program Early CT) score based on CT image data. 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.
StrokeSENS mCTAp	StrokeSENS mCTA Perfusion (mCTAp) is an image processing software package that allows the user to produce dynamic image data derived from DICOM compliant CT imaging device, and to generate information regarding changes in image intensity over time. StrokeSENS mCTA Perfusion provides viewing and analysis of dynamic contrast-enhanced CT data (multi-phase CT Angiogram images of the head), showing properties of changes in contrast over time, including calculation of parametric maps related to tissue flow (perfusion). The perfusion information is intended to aid the clinician in the visualization and assessment of the extent and type of perfusion which may be related to ischemic stroke.
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, ASPECTS and mCTAp devices. The compatible radiological software solution may also provide other radiological functionalities outside the scope of the StrokeSENS LVO, ASPECTS and mCTAp 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).
Alberta Stroke Program Early CT Score (ASPECTS)	A 10-point quantitative score used to assess early ischemic changes on non-contrast CT head scan.

3 Basic Components and Indication for Use

3.1 Indication for Use

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. Data and images are acquired through DICOM-compliant imaging devices prior to processing and analysis in StrokeSENS.

The StrokeSENS software provides analysis capabilities for imaging datasets acquired with standard CT imaging and contrast enhanced CT Angiography (CTA) modalities. Analysis of non-contrast CT images includes assessment of regions with suspected acute ischemic tissue. Analysis of contrast-enhanced CT images includes automated detection of anterior circulation Large Vessel Occlusion (LVO).

In the case of a suspected anterior circulation LVO, the system will send a notification to a pre-configured destination(s) (members of the acute stroke team), notifying them 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 than they may have been notified as part of the standard of care workflow. Images are available for viewing on a mobile device and on a standard radiology workstation. Images that are previewed on a mobile device are for informational purposes only and are not intended for diagnostic use beyond notification.

3.2 Patient population

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

The StrokeSENS ASPECTS module is intended to be used on adults with confirmed anterior circulation Large Vessel Occlusion (LVO) within 6 hours of symptom onset.

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 ASPECTS provides automated ASPECTS scoring to aid clinicians in their assessment of early ischemic changes (ASPECTS) on non-contrast CT. This standardizes ASPECT scoring across clinicians from different sub-specialties. The clinical study referenced in section 18.2 in this user manual provides evidence that the use of StrokeSENS ASPECTS enables less-experienced readers to improve their ability to read ASPECTS, approaching the performance of expert readers.

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. StrokeSENS has been tested on CT images from a variety of different scanner systems in the market, including:

- General Electric (Discovery series, Lightspeed series, Revolution series, Optima series)
- Siemens (Somatom Definition series, Sensation series, Somatom Force)
- 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. This release of the StrokeSENS LVO software is integrated into the StrokeSENS Platform system only. Comprehensive testing of the StrokeSENS LVO software in the StrokeSENS Platform has been conducted, verifying the performance of the StrokeSENS LVO and StrokeSENS ASPECTS software in the compatible system. This document provides user instructions and labelling for the StrokeSENS LVO and StrokeSENS ASPECTS software as integrated into the compatible StrokeSENS Platform.

8.2 Software architecture

The StrokeSENS software runs in a client/server architecture. StrokeSENS and all its associated services are installed on a server running the Windows Server OS, and users access the software from a client device via a web browser. The web browser on the client device connects to the web services running on the StrokeSENS server to provide users access to the software. All web services, computation, user management, and storage is handled by StrokeSENS on the server it is installed on. The server, client device, and web browser requirements are outlined below.

8.3 Virtual Machine for Backend Services

The following specification can be applied to provision one virtual machine which is capable of supporting 2 concurrent studies and up to 2 concurrent users per study.

Requirement	Recommendations
CPU	Quad core 8th Gen Intel Core i7 or Xeon to support up to 2 concurrent study analysis. (Analysis of a single study requires 2 cores to support up to 2 concurrent users, and an additional 2 cores to perform machine learning computation tasks)
RAM	16 GB DDR3 to support to 2 concurrent study analysis (A single study analysis requires 8 GB RAM to support study loading, data caching, and other tasks)
Storage	1 TB SSD (for data storage server) (Depending on the number and the sizes of studies stored, this number may be varied.)
OS	Windows Server 2016/2019/2022
Network	1 GB ethernet minimum, 10 GB preferred

8.4 Recommended Client Web Browser

Recommendations
Chrome (version 96.0.4664+) Safari (version 14.1.2+) Microsoft Edge (version 96.0.1054.43+)

8.5 Recommended Client Device Specifications

Desktop	Recommendations
RAM	8 GB DDR3
Resolution	1920x1080 (or higher)
OS	Windows 10 (build 19041+)/11 (latest), macOS (11+)

Android phone	Recommendations
OS	Android (11+)

Apple phone	Recommendations
OS	iOS (14+)

8.6 DICOM requirements for Algorithm Processing

To support the full suite of algorithms supported by StrokeSENS (auto-ASPECTS, LVO Detection, mCTAp colour maps), the following acquisitions are recommended:

- Non-contrast CT (NCCT) of the head
- Multi-phase CTA (mCTA) of the head

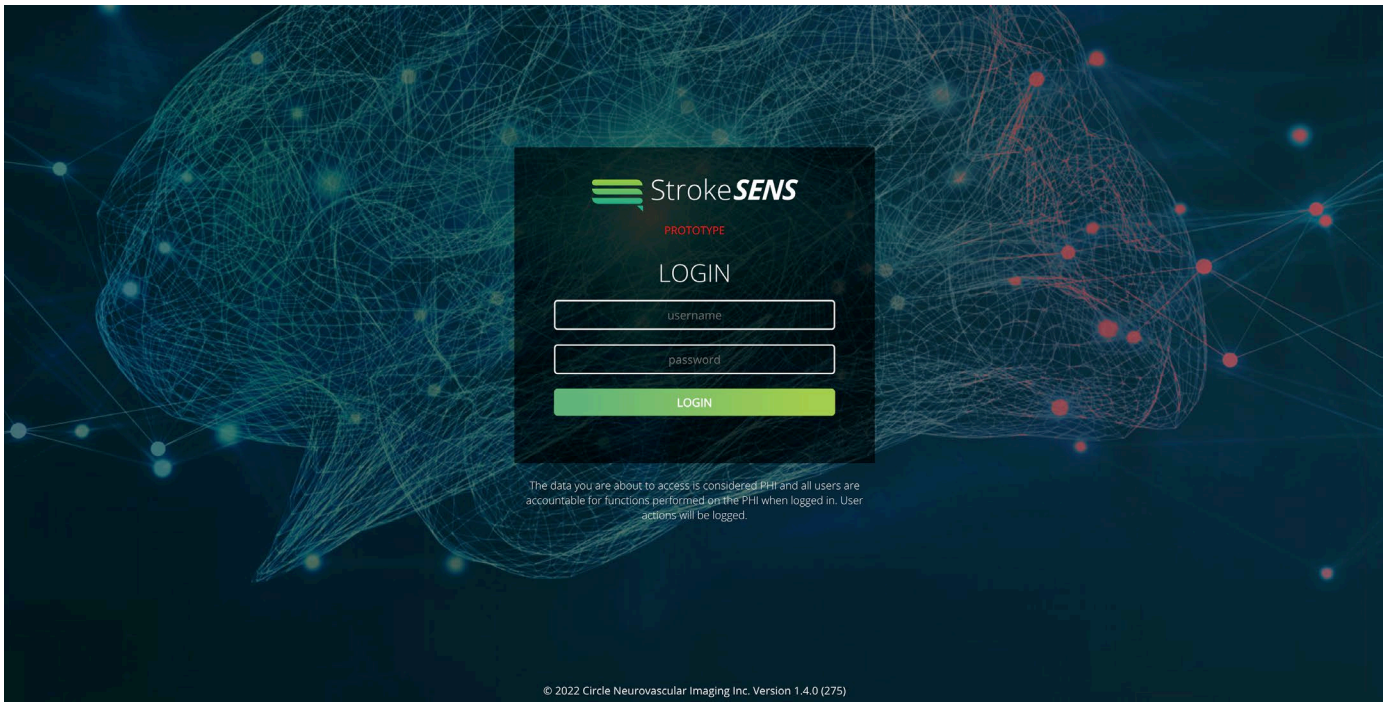
Recommended NCCT Head parameters
1. ImageType = Original/Primary
2. Modality = CT
3. Scan range = CT head volume covering the whole head (vertex to base)
4. Image characteristics: o Window Width: < 210 o Slice Thickness: 2.5 - 5 mm o Matrix Size: 512 x 512 o DFOV along the X/Y axis: 201 – 251 mm

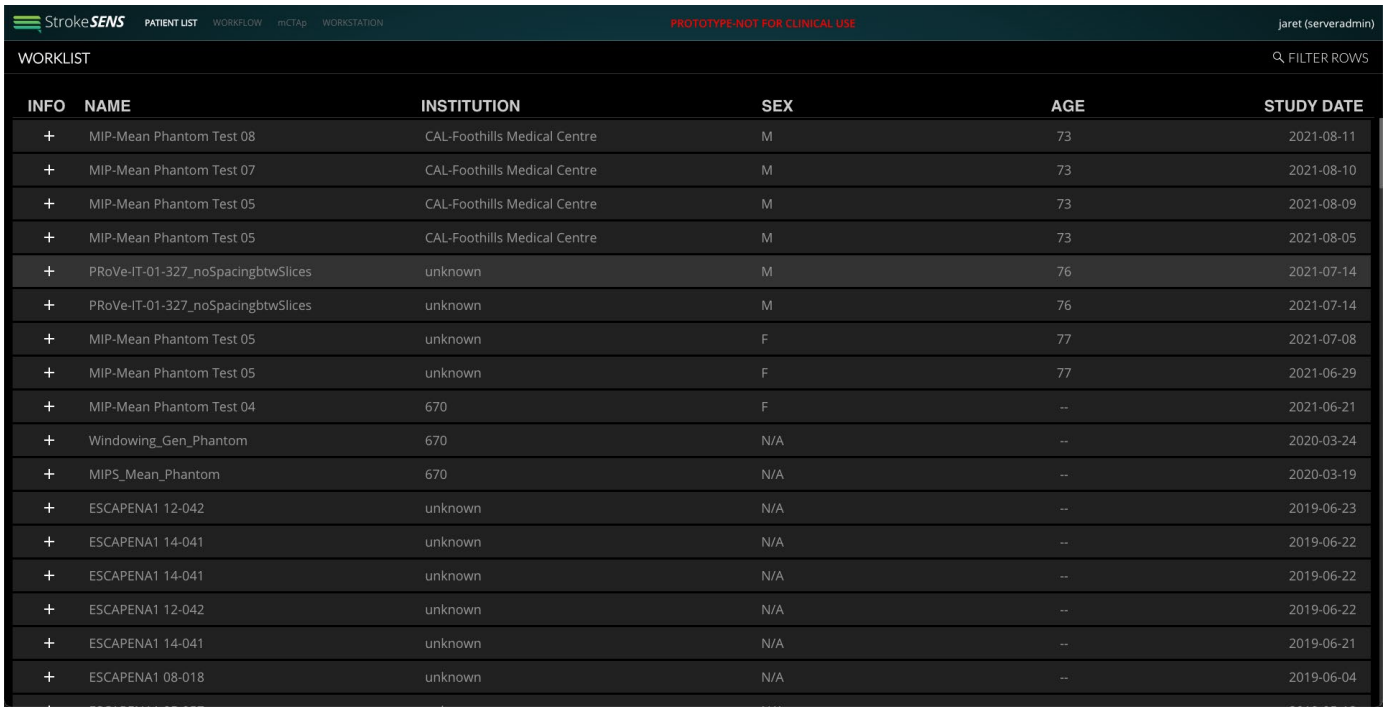
Recommended mCTA Head parameters
1. ImageType = Original/Primary
2. Modality = CT
3. Volumes = 3 CTA volumes (only the first volume is required for LVO detection) * If the 3 CTA volumes are provided as separate series, the Acquisition Date and Acquisition Time (or Acquisition DateTime) DICOM tags must be specified.
4. Scan range = CT head volume covering the whole head (vertex to base)
5. Image characteristics: o Window Width: 210 - 1170 o Slice Thickness: 0.6 – 1.25 mm o Matrix Size: 512 x 512 o DFOV along the X/Y axis: 213 – 300 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. For more information, please refer to section 18.5 below for detailed information.

9 Worklist (Clinical user)

Upon launching StrokeSENS, the user will be prompted to enter their login details in the form of a username and password. Following a temporary “loading worklist” message, the Patient List interface will open. (see Login and Patient List interfaces below)

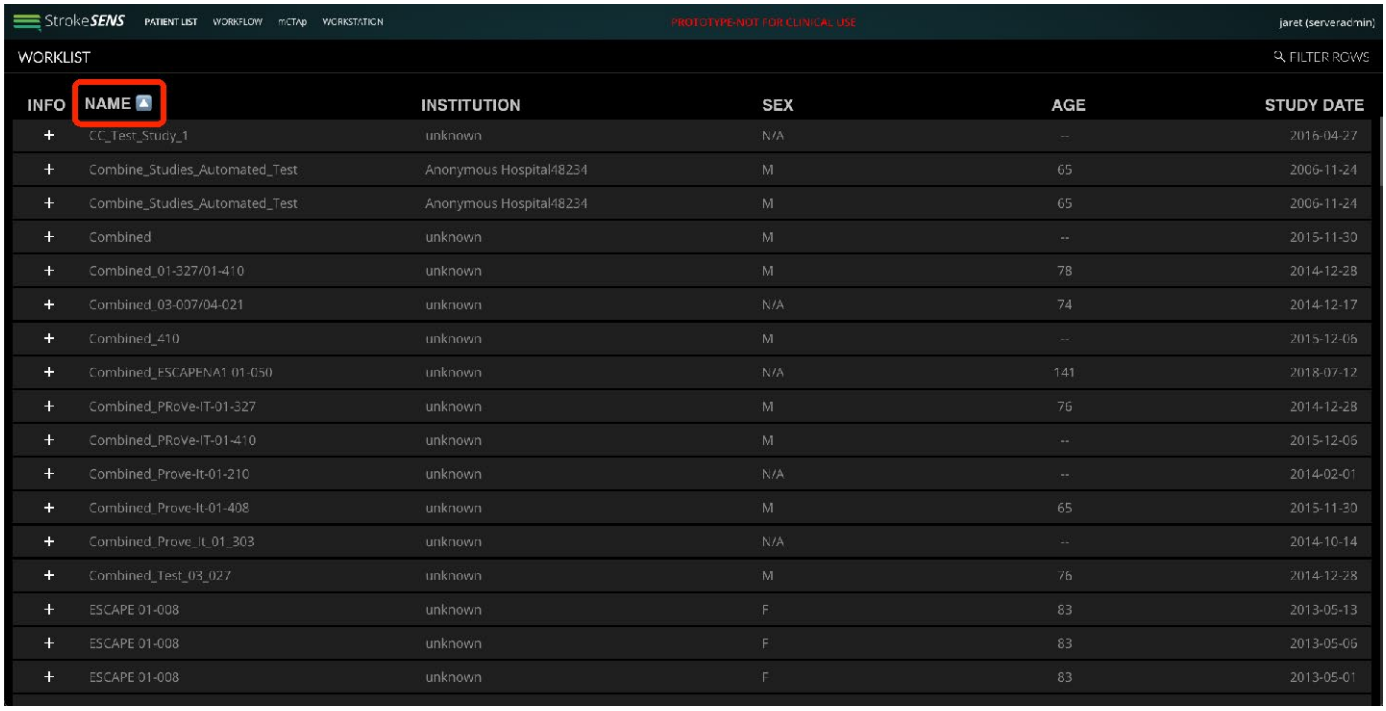




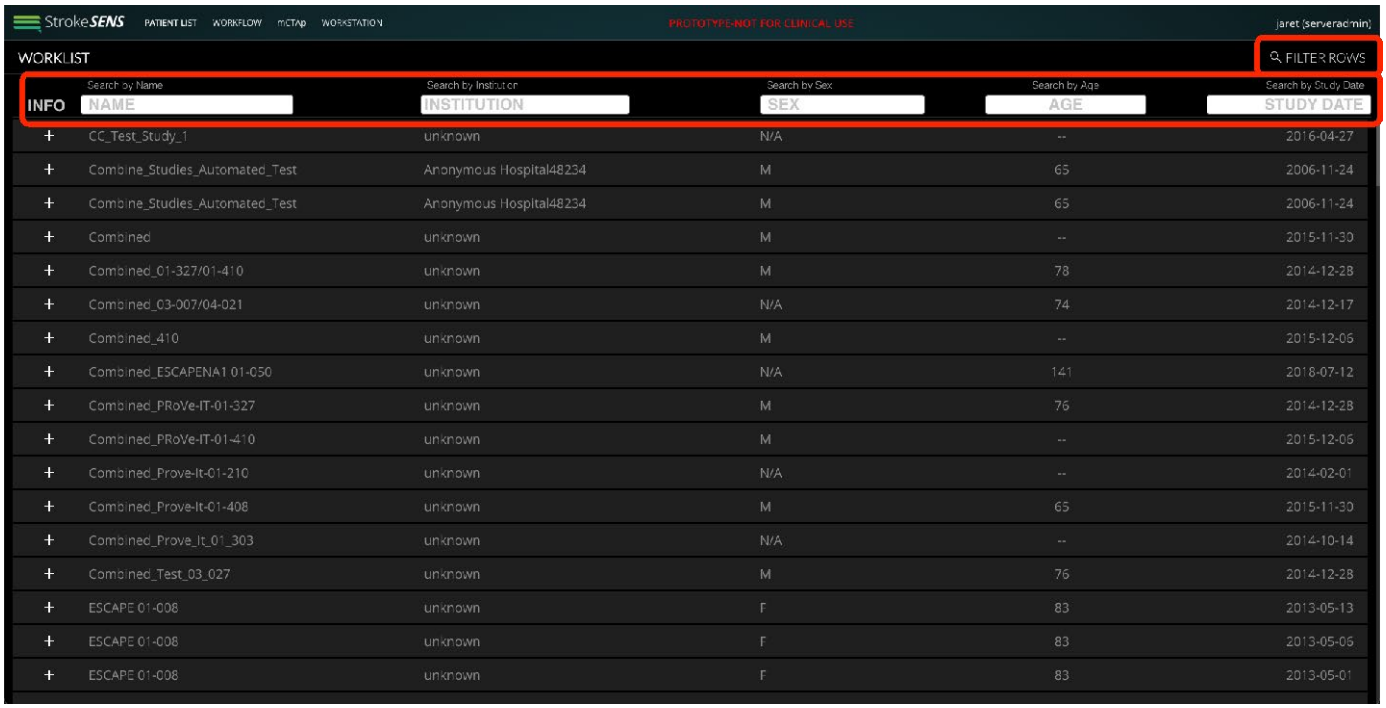
INFO	NAME	INSTITUTION	SEX	AGE	STUDY DATE
+	MIP-Mean Phantom Test 08	CAL-Foothills Medical Centre	M	73	2021-08-11
+	MIP-Mean Phantom Test 07	CAL-Foothills Medical Centre	M	73	2021-08-10
+	MIP-Mean Phantom Test 05	CAL-Foothills Medical Centre	M	73	2021-08-09
+	MIP-Mean Phantom Test 05	CAL-Foothills Medical Centre	M	73	2021-08-05
+	PRoVe-IT-01-327_noSpacingbtwSlices	unknown	M	76	2021-07-14
+	PRoVe-IT-01-327_noSpacingbtwSlices	unknown	M	76	2021-07-14
+	MIP-Mean Phantom Test 05	unknown	F	77	2021-07-08
+	MIP-Mean Phantom Test 05	unknown	F	77	2021-06-29
+	MIP-Mean Phantom Test 04	670	F	--	2021-06-21
+	Windowing_Gen_Phantom	670	N/A	--	2020-03-24
+	MIPS_Mean_Phantom	670	N/A	--	2020-03-19
+	ESCAPENA1 12-042	unknown	N/A	--	2019-06-23
+	ESCAPENA1 14-041	unknown	N/A	--	2019-06-22
+	ESCAPENA1 14-041	unknown	N/A	--	2019-06-22
+	ESCAPENA1 12-042	unknown	N/A	--	2019-06-22
+	ESCAPENA1 14-041	unknown	N/A	--	2019-06-21
+	ESCAPENA1 08-018	unknown	N/A	--	2019-06-04

By default, the studies most recently pushed to StrokeSENS will be displayed at the top of the list. To locate other studies the user can:

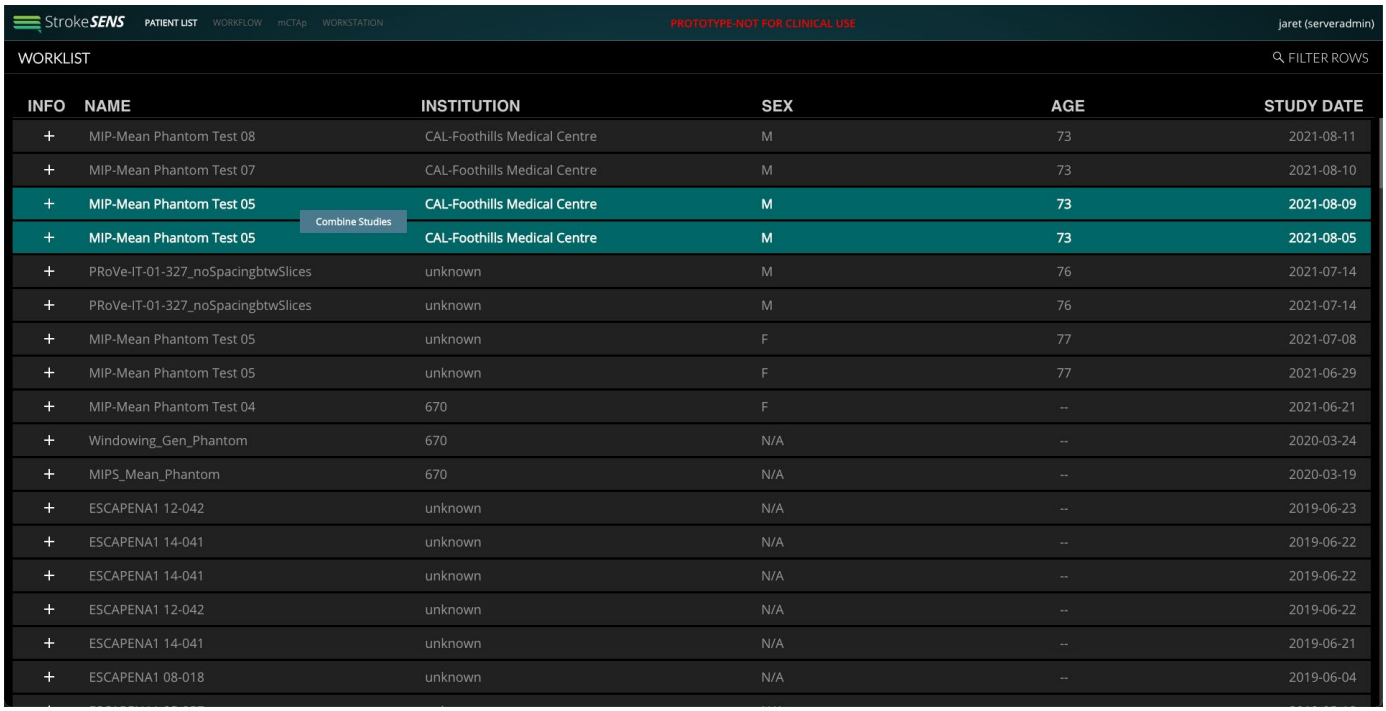
- Sort the list by any of the columns by clicking the column header (alternates between ascending and descending order)



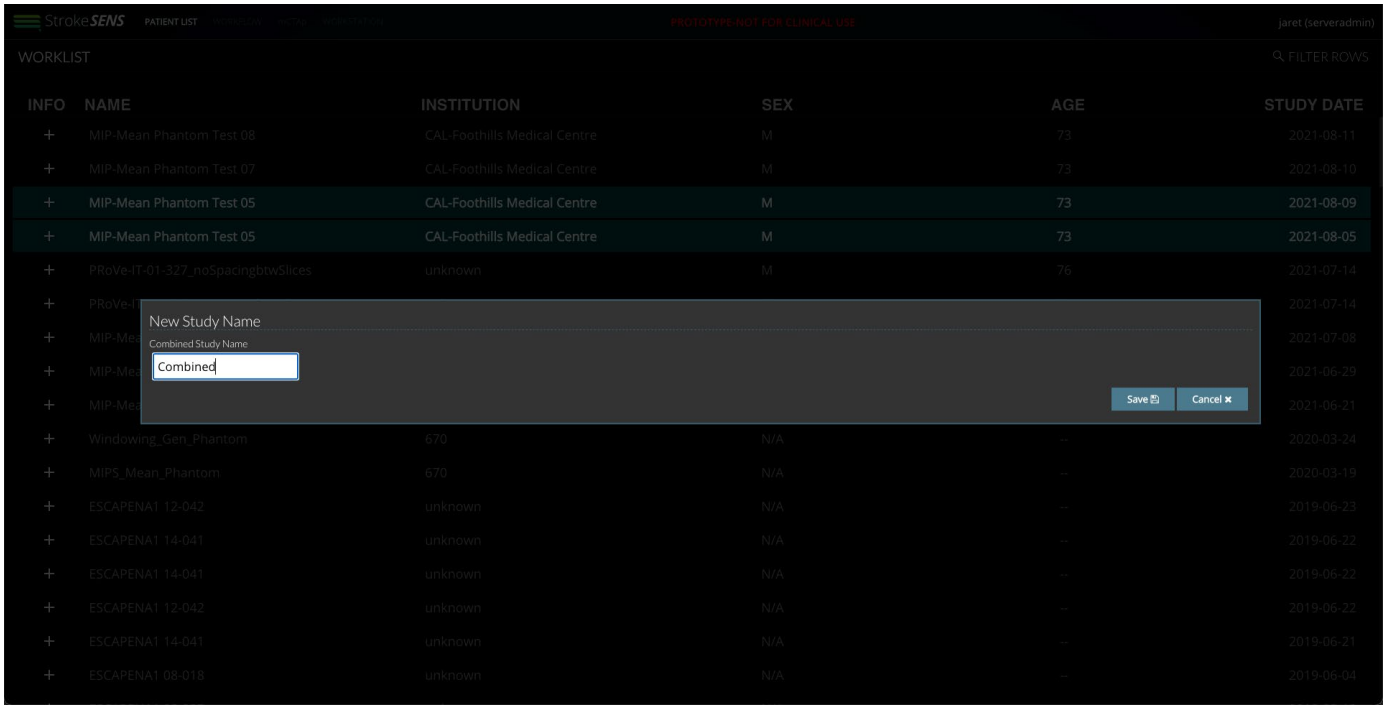
- Use the *'Filter Rows'* functionality to narrow Patient List entries to those matching provided search criteria for a given column



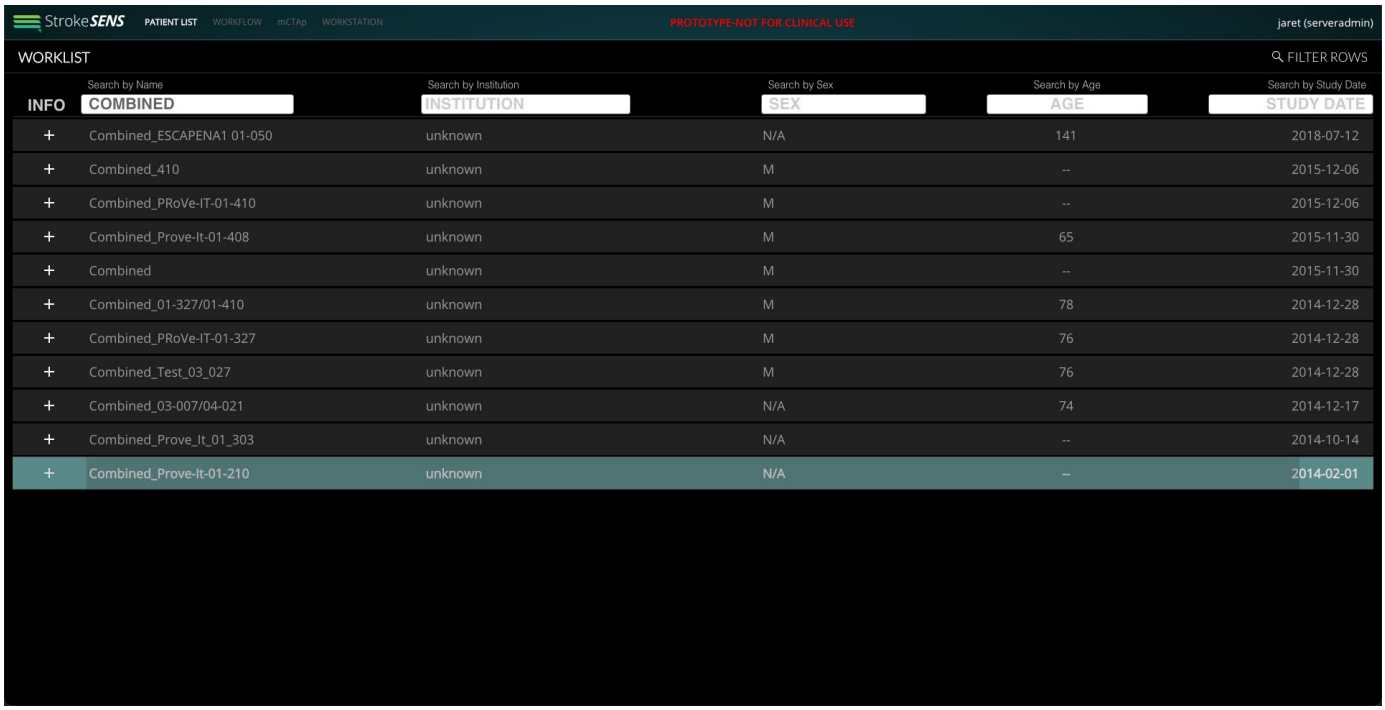
Studies in the worklist can be combined by multi-selecting studies from the Patient List (Windows: Ctrl-left click; Mac: Cmd-left click), then right clicking to reveal the *'Combine Studies'* option.



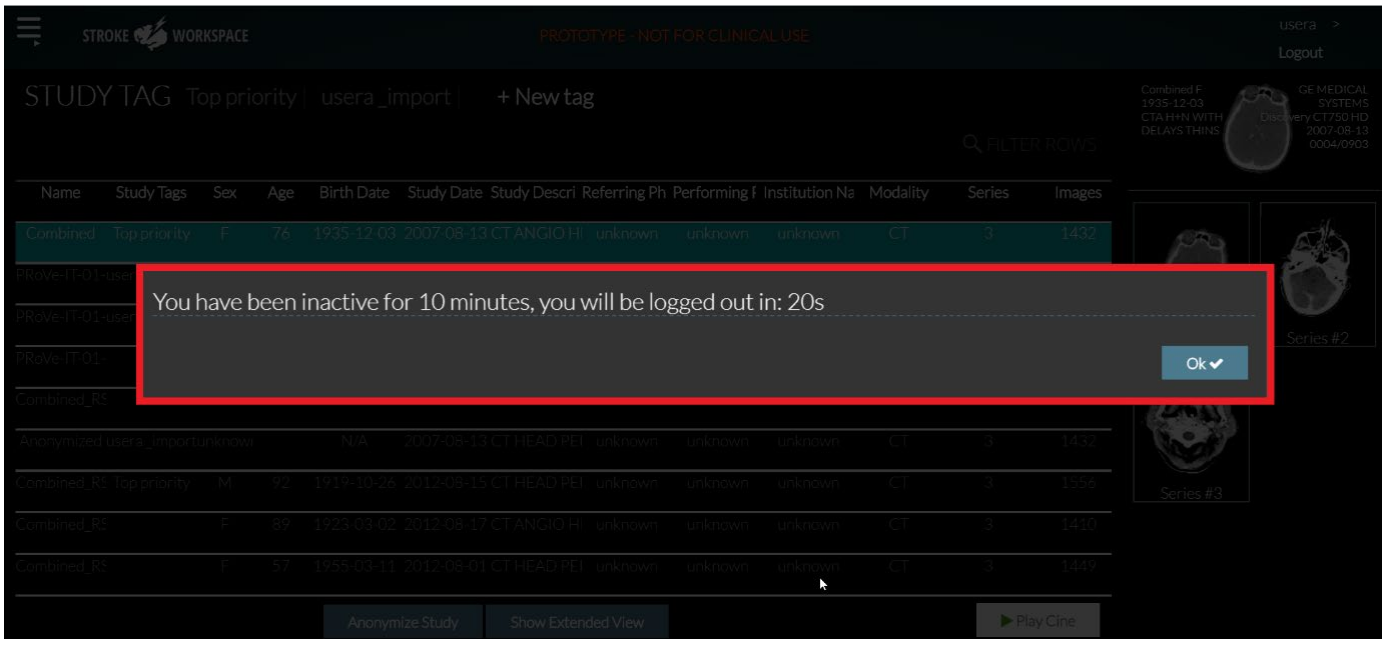
Once *'Combine Studies'* is selected, the user will have the option to name the combined study.



To load a study for viewing, the user can double-click that entry in the Patient List. The entry will briefly animate during loading, then display the study in the Workflow view. (see the Workflow section for additional details)



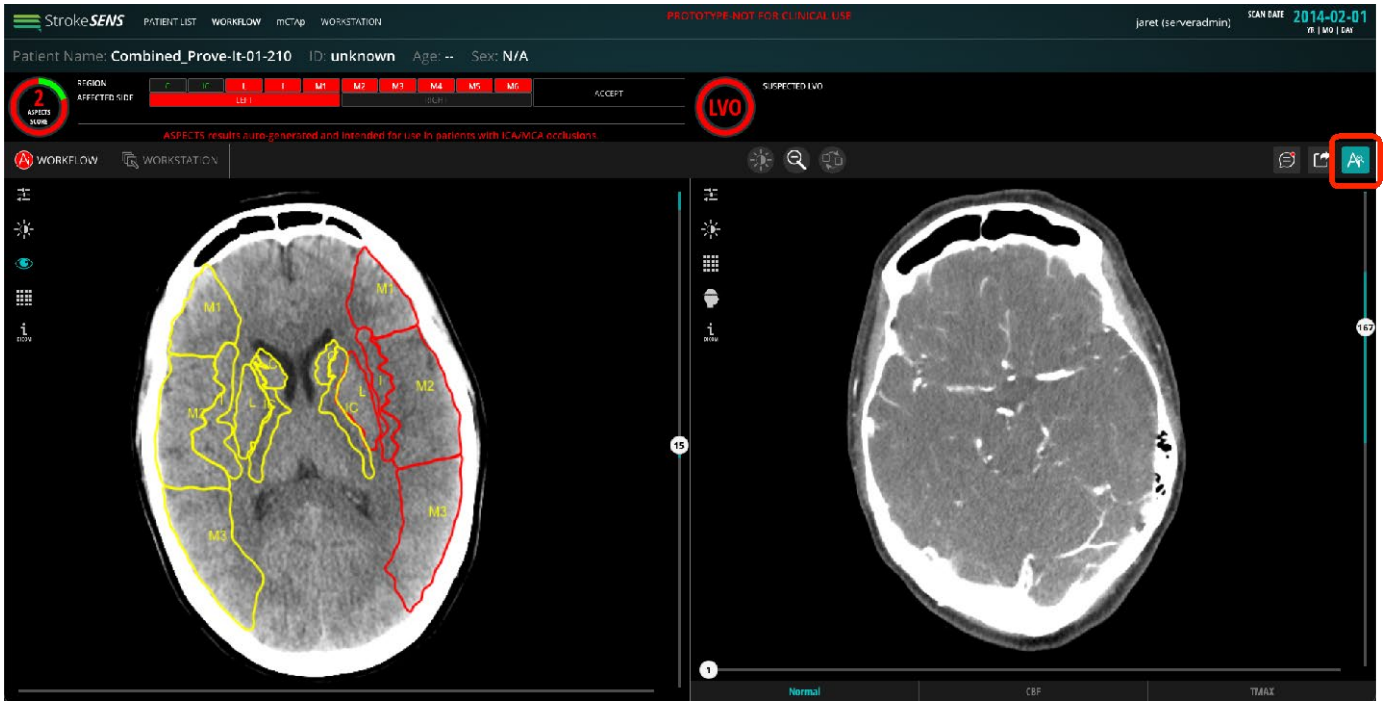
NOTICE: If a user is not active on any page for more than 10 minutes, the user will automatically be logged out with a 30 second countdown notification that the user can interrupt by clicking the 'OK' button.



10 Workflow (Clinical user)

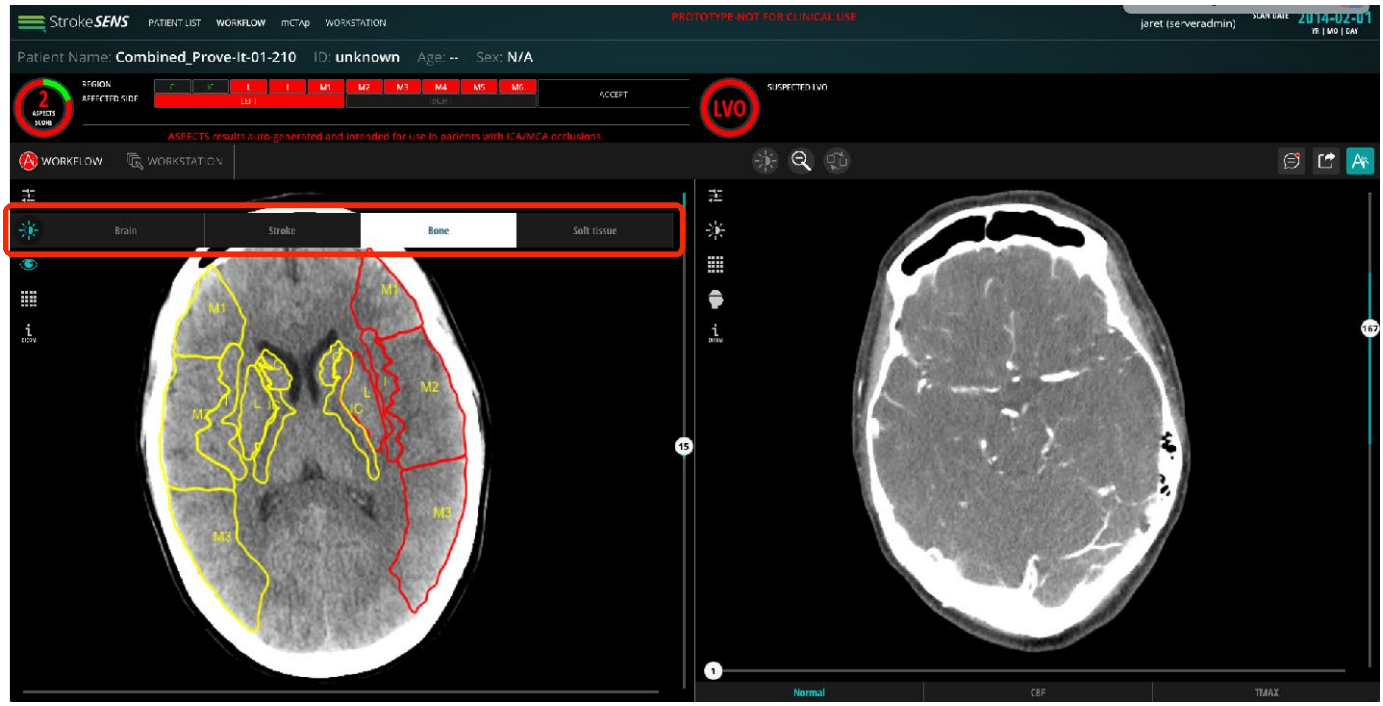
10.1 Quick Findings

Upon loading a study, the workflow page will display the first scanned NCCT (left) and CTA (right) images. The output of the ML algorithm can be viewed/hidden by clicking the *'Quick Findings'* button (see following diagram). The NCCT ASPECTS regions can also be seen on the NCCT image as well as whether a suspected LVO has been identified on the CTA image.



10.2 Windowing

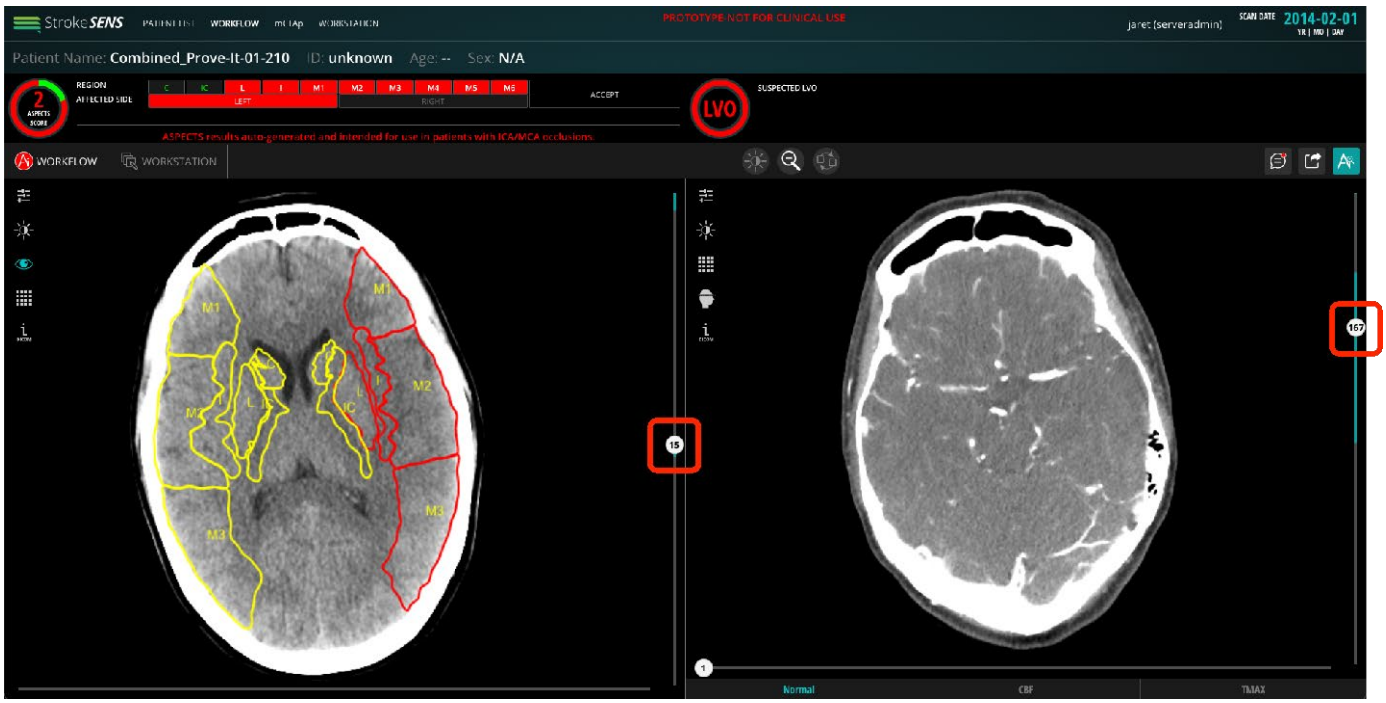
In any of the viewers, a windowing pre-set can be selected by clicking on the windowing icon within the view, as shown below.



To further adjust window to satisfaction, the manual windowing button can be selected from above the views, and the windowing adjusted by clicking and dragging in the view of interest.

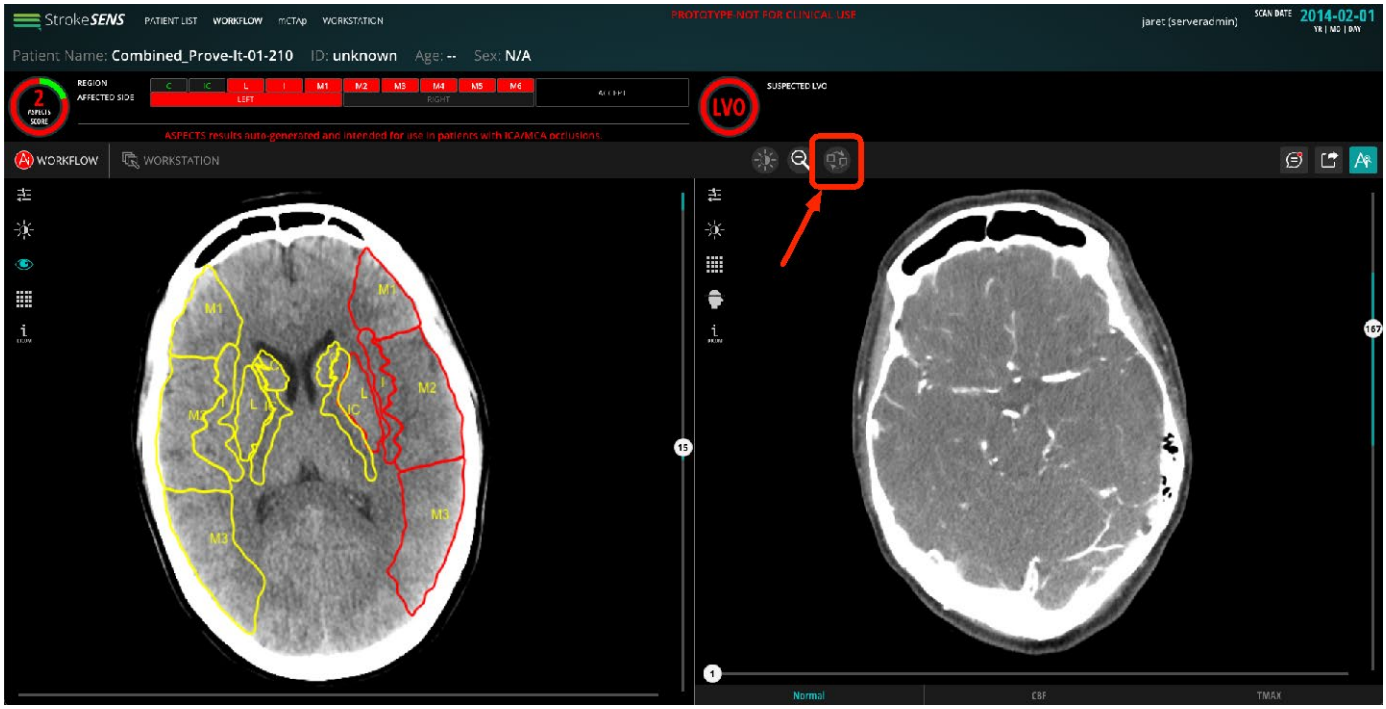
10.3 Slice Scrolling

Users can navigate through the slices of any of the image series by either clicking and dragging within a view or using the slice scroller on the right-side of the view, as shown below.



10.4 Synchronized Slice Scrolling

The user can scroll through images in each view simultaneously by clicking on the synch button and scrolling with the mouse scroller button or scrolling through any of the image slice scrollers. The images will scroll in synch when they are in similar slice locations as seen from the info icon output.

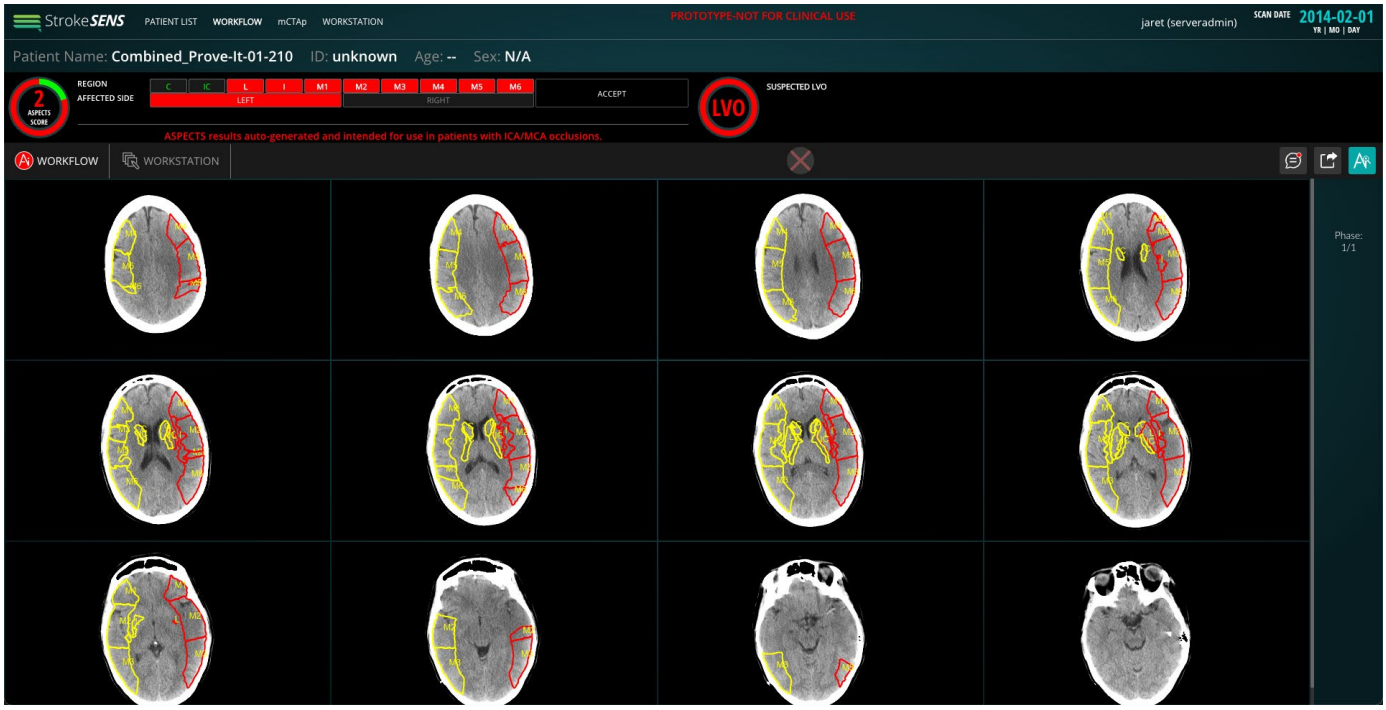


10.5 ASPECTS Regions

The ASPECTS region contours can be toggled on and off with the toggle button as seen below.

10.6 Multiview Mode

Any image can be viewed in Multiview mode by clicking the Multiview button. Multiview mode will then appear with the current slice from which Multiview was selected in the second row and third column.

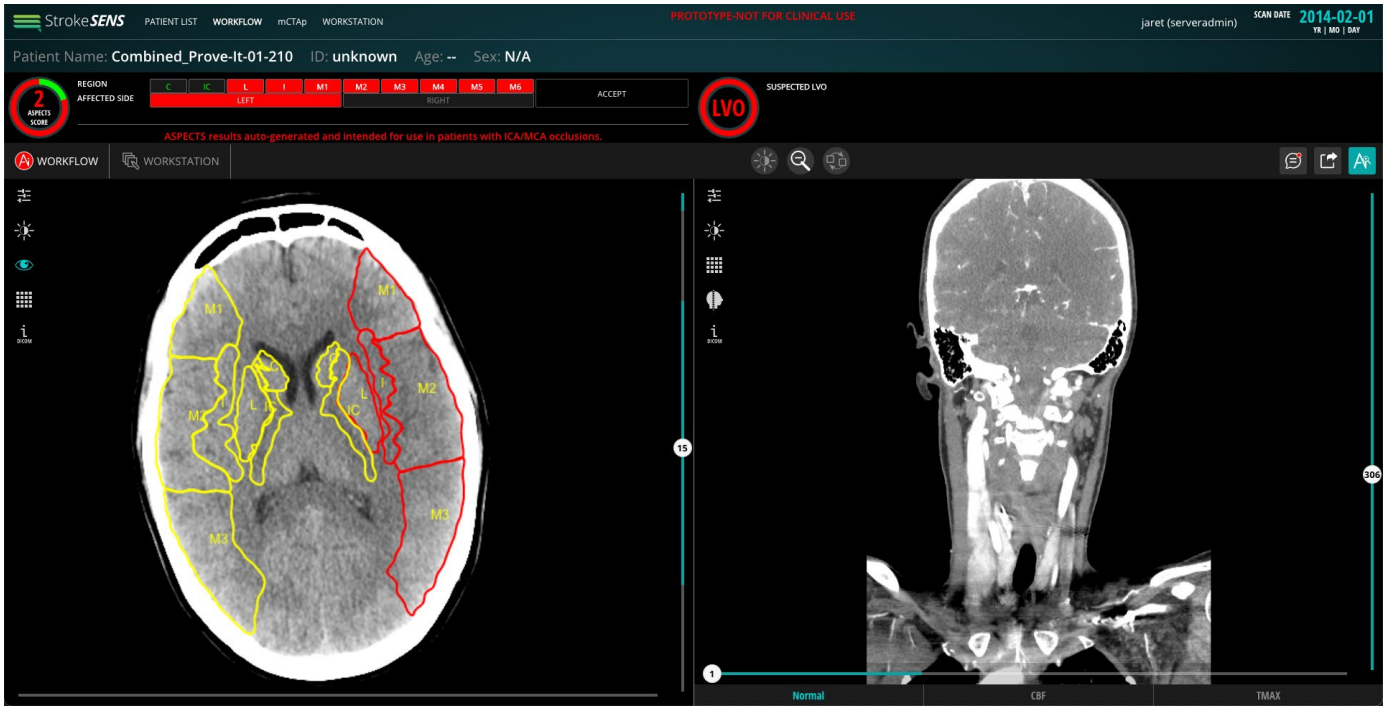


10.7 Study Metadata

Image metadata for the study can be toggled on and off by clicking on the info button in any of the viewers.

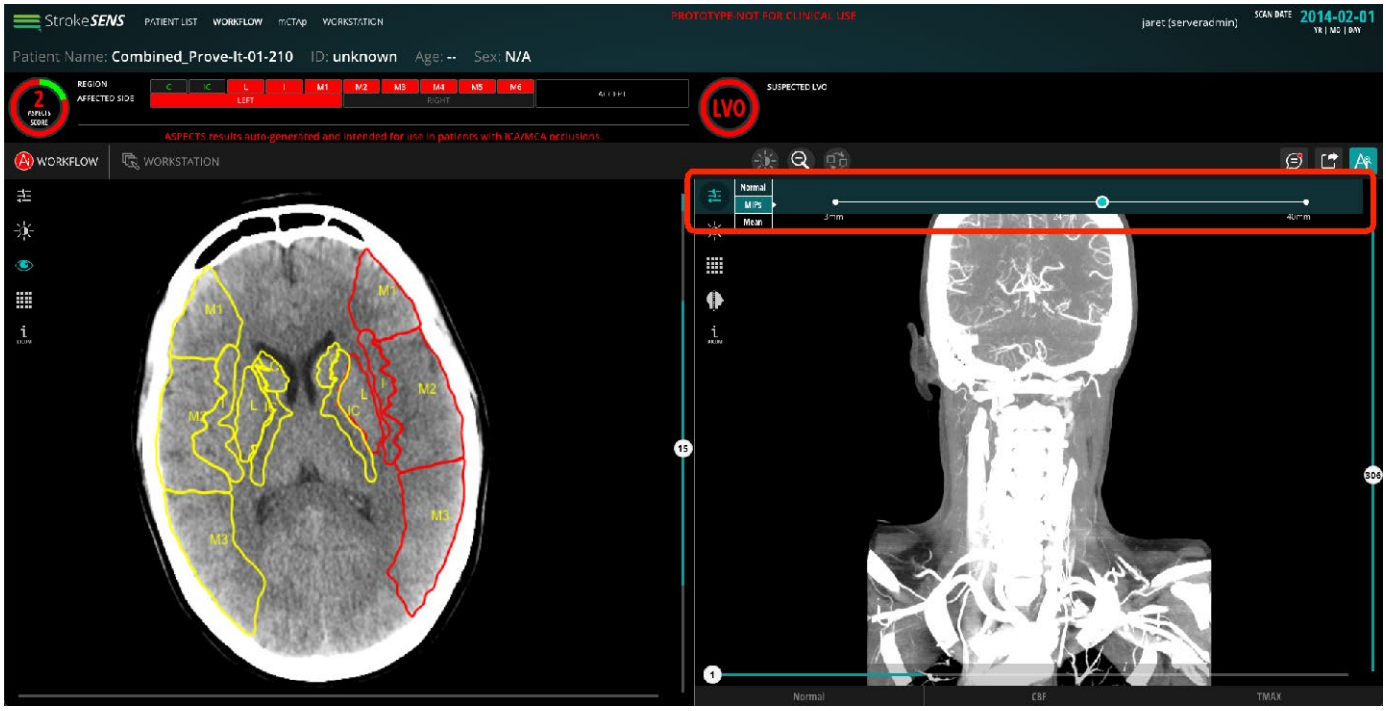
10.8 Multiplanar Reconstruction (MPR) Viewing

MPR mode for any of the desired three planes (axial, sagittal and coronal) can be selected by clicking on the MPR button as shown in the image below. The MPR mode will first show a 'fetching MPR images…' loading page and then display the reformatted images.



10.9 Maximum/Mean Intensity Projection (“MIPs”/”Mean”) Viewing

In any of the MPR orientations, the MIPS/Mean buttons can be selected to view the images as Maximum/Mean Intensity Projections. A slider is provided to adjust the slab thickness for each of these modes.

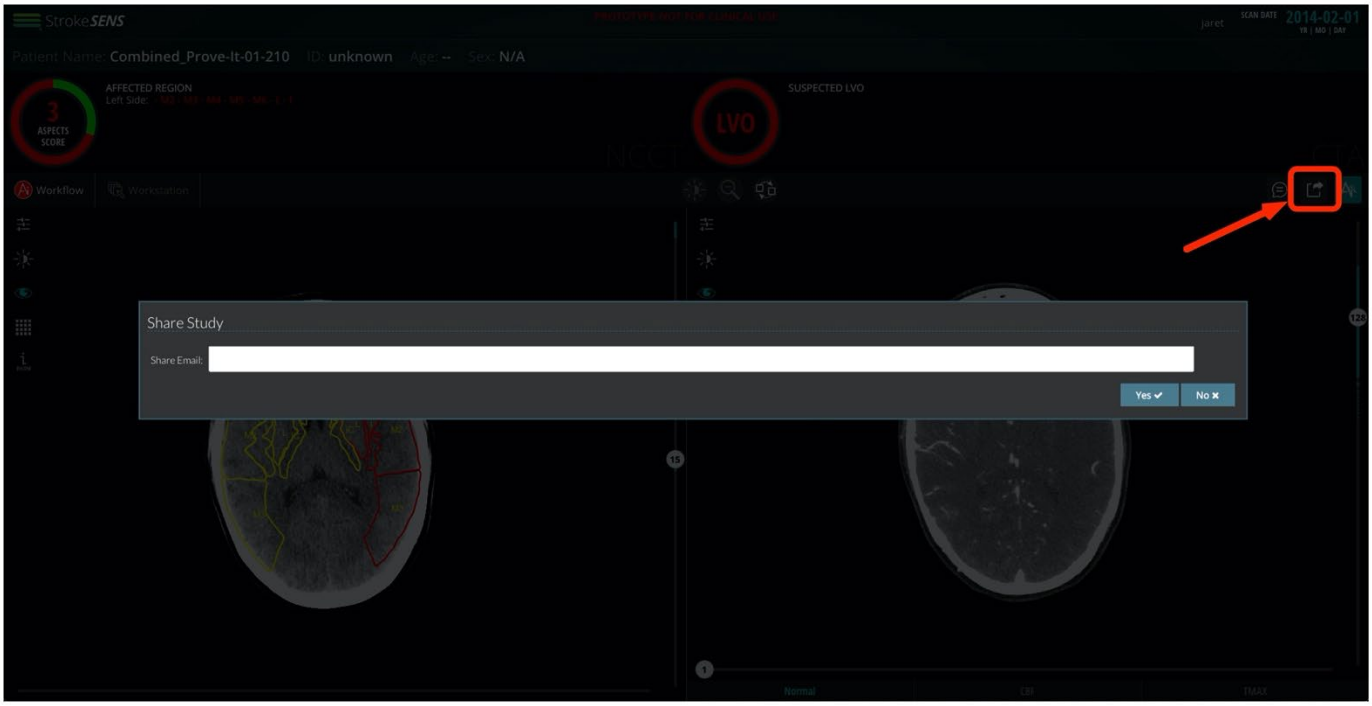


10.10 Multi-phase Viewing

In an image with more than one phase, the user can navigate through the phase with the scrollbar at the bottom of the view by clicking and dragging across the bar. Multi-phase image sets will also indicate the phase being viewed and the total number of phases in the top-right corner when meta-data is displayed.

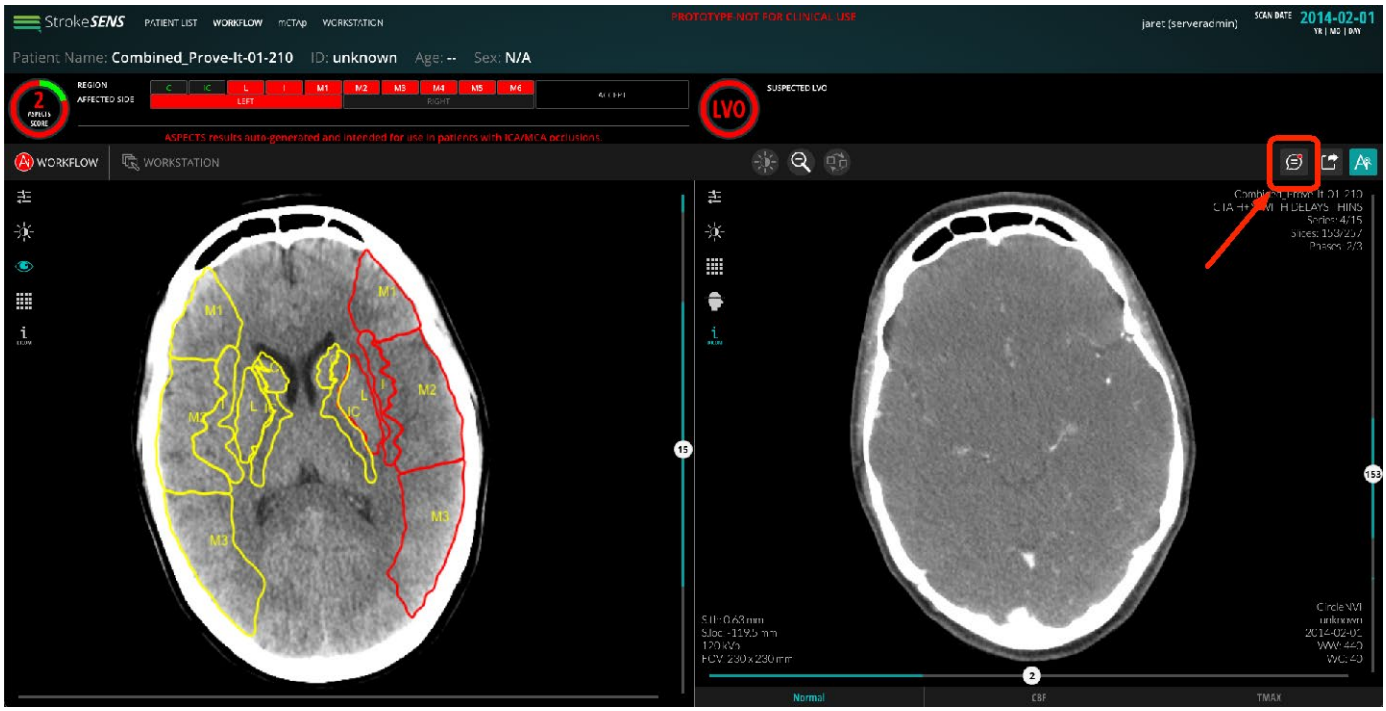
10.11 Study Sharing

A user can share a unique link with another user to view the current study by clicking on the 'Invite' button in the upper-right and entering the receiver's email address in the field provided. With this link, the shared study will be automatically displayed after the second user logs in.



10.12 Text Chat

When users are viewing the same study, they can communicate via the text chat functionality. When a message is received, a small notification dot is seen by the chat icon. When the chat icon is clicked, the chat bar is open with a message field and a send button. Messages can be typed and sent by either the keyboard 'Enter' key or the send button. The chat bar can either be closed by clicking the 'x' button or clicking the chat icon again.



11 Device Operating Instructions - LVO (Clinical user)

11.1 LVO Detection and Notification

After a CT Angiography (CTA) head scan is performed, the images are automatically routed to StrokeSENS LVO where they are processed and analyzed for characteristics suggestive of LVO. The notification system is comprised of an outbound notification to a neurovascular specialist as well as an on-screen indication of a suspected LVO to the user. Specifically, in the case of a positive finding, the system will automatically generate a notification which is pre-configured to be sent to a list of subscribers (clinician specialists involved in acute stroke patient management) maintained by the hospital site/network, and the user interface will update to indicate a suspected LVO is present for that patient case (see figures below).

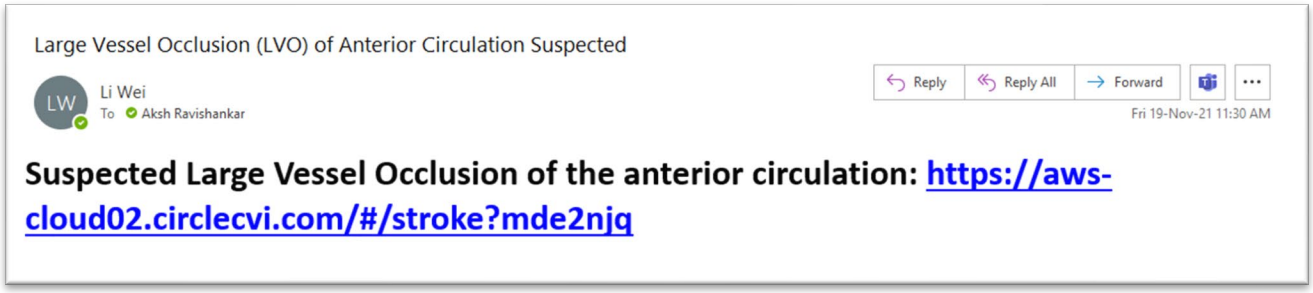


Figure 12.1 Example of Email Notification. Notifications provide clinicians immediate access to review images of patients with suspected Large Vessel Occlusion, in parallel to the standard of care workflow. Clinicians are required to authenticate using hospital IT managed credentials prior to reviewing the case linked in the StrokeSENS Platform.

Figure 12.2: Example screenshot of the StrokeSENS Platform User Interface in the case of a suspected LVO. The original DICOM images are available for review in the StrokeSENS Platform. No additional diagnostic mark-up or information is provided beyond the notification.

The notification states that a suspected LVO is present. In the case of a negative finding, no notification is sent, and the standard of care workflow remains in place.

No images are marked up. The outputs of the algorithm are binary (YES or NO) and no information on the specific location of the LVO is conveyed. In the StrokeSENS Platform user interface (or other Compatible Radiological Viewers), the entire unmarked original CT DICOM image is available for viewing and the presence of the LVO notification does not correspond to or indicate a particular slice or location in the image. Images that are previewed through the StrokeSENS Platform mobile device are for informational purposes only and are not intended for diagnostic use.

11.2 LVO Results Export

StrokeSENS can be configured to export LVO results in the form of DICOM Secondary Captures. If enabled, LVO detection results will be automatically routed to specified image repositories, in a Series containing a single image. The image will indicate that the LVO detection algorithm has successfully run and provide the patient's name and the Accession Number. (see figure below, on right)

In the case that a suspected LVO was detected, the image will also contain "Suspected LVO Detected!" in white lettering on a red background. (see figure below, on left)

Please contact your system administrator or IT department to have LVO results export enabled.

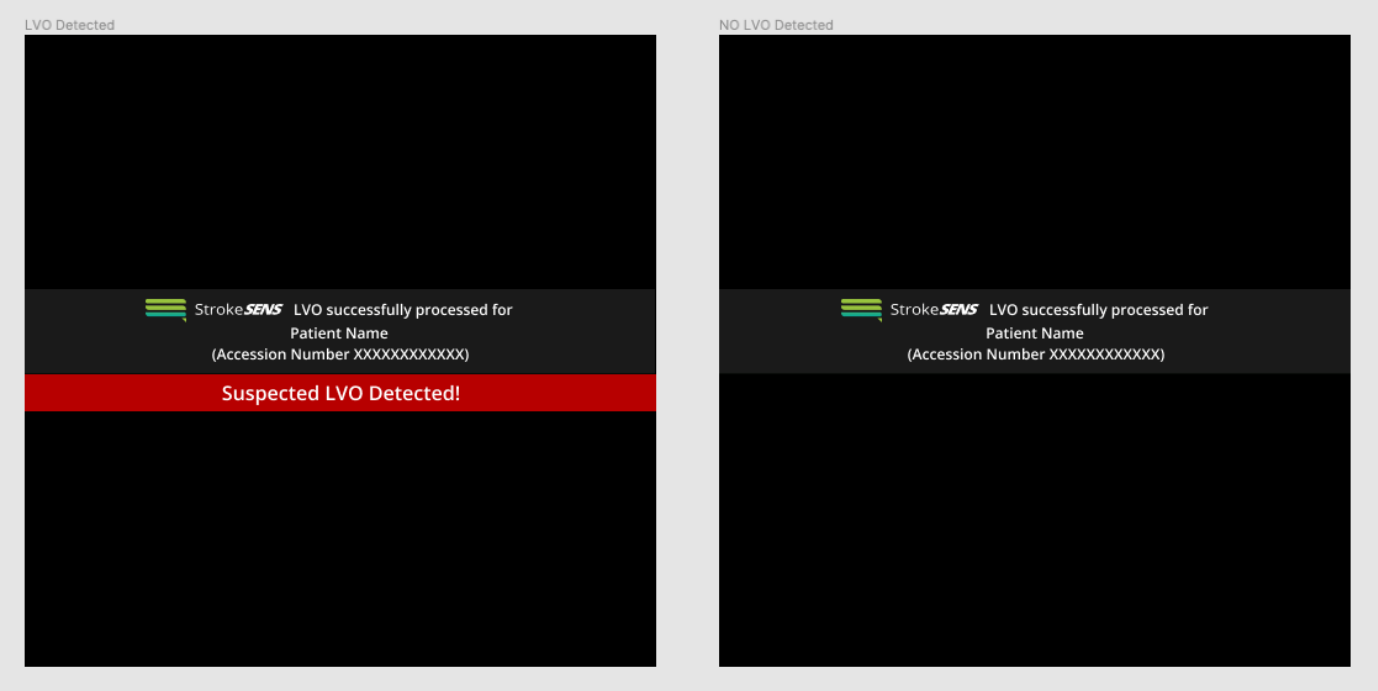


Figure 13.1: DICOM Secondary Captures prepared for export following LVO Detection. In the case that a suspected LVO was detected, it is clearly indicated by the addition of "Suspected LVO Detected!" to the output.

12 Device Operating Instructions - ASPECTS (Clinical user)

NOTICE: If the user is viewing a patient case while the image is being processed a progress indicator will appear in the results tab. The user can still interact with the original images while the AI is running in the background.

When multiple series of the same image type are available, the first (earliest acquisition time) is selected for automated AI analysis.

Automated processing occurs in the following priority:
1. Large Vessel Occlusion (LVO) Detection
2. ASPECTS Scoring

12.1 ASPECTS Acceptance

When a suitable non-contrast CT (NCCT) scan is processed to generate ASPECTS results, the clinician will be given the opportunity to review and accept the auto-generated score. They will be able to accept the score as generated or update the affected regions to match their clinical assessment. Changing any of the affected regions will automatically update the indicated ASPECTS score and the regions indicated by red outlines in the image view. When they are satisfied that the correct results are displayed, they can lock in the score by clicking the “ACCEPT” button.

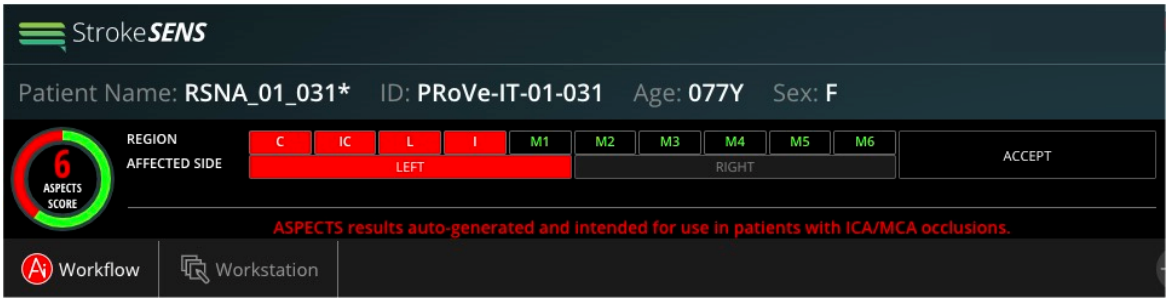


Figure 12.1 Auto-generated ASPECT score for clinician review and acceptance

When a clinician clicks the “ACCEPT” button, the label will change to read “ACCEPTED” and a note will appear below the Affected Side label. In the case that they verified the original side/score it will read "Accepted by <user>", where “user” is the ID of the accepting clinician. If they changed and then accepted the side/score, it will read "Modified and accepted by: <user>" and list the original score in the format "(Auto-ASPECTS = <original score>)". After a clinician has accepted an ASPECT score, the “ACCEPT” button will be disabled and relabelled “ACCEPTED”.

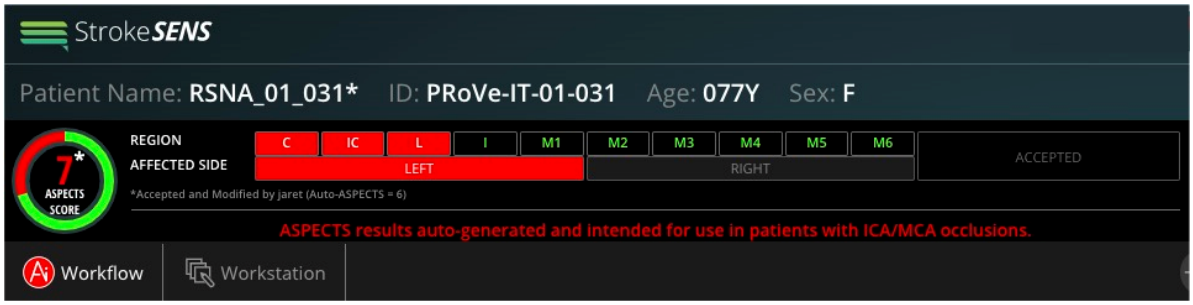


Figure 12.2 ASPECT score after clinician review and acceptance

12.2 ASPECTS Results Export

StrokeSENS can be configured to export ASPECTS results in the form of DICOM Secondary Captures. If enabled, auto-generated ASPECT results will be automatically routed to specified image repositories, in a Series containing each of the original non-contrast CT images overlaid with ASPECTS regions and the scoring results, including the ASPECT score and the affected side and regions, as presented in the below (see Figure 12.3). In the case that a clinician reviews and accepts the ASPECT score, the export will be updated to include an image with both the auto-generated score and the reviewed accepted score, as presented below (see Figure 12.4).

Please contact your system administrator or IT department to have ASPECTS results export enabled.

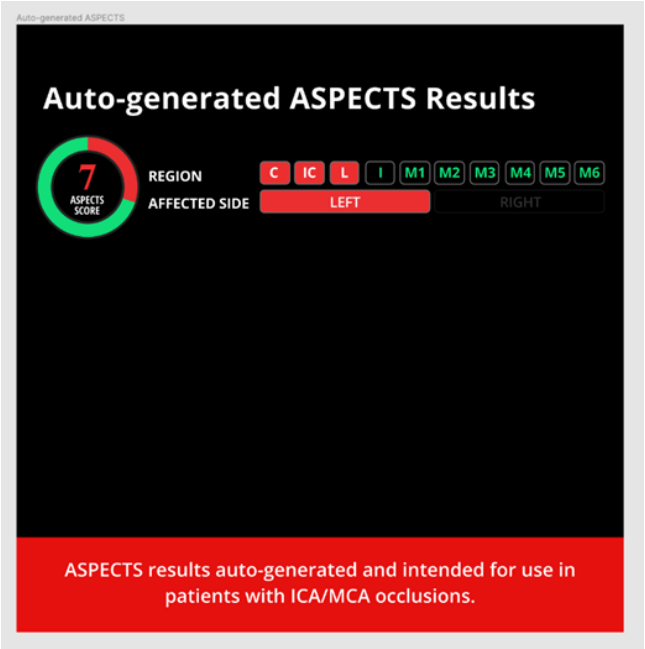


Figure 12.3

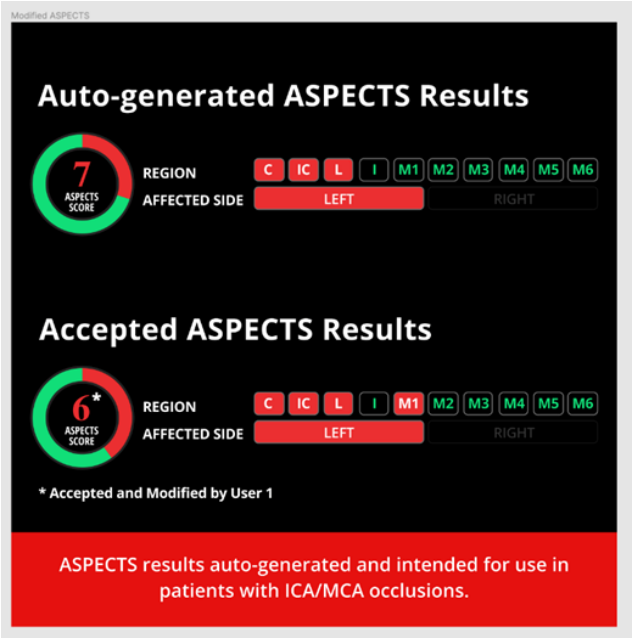


Figure 12.4

13 Device Operating Instructions - mCTA (Clinical user)

13.1 Usage Disclaimer

StrokeSENS mCTAp is not for clinical use. The device has not been cleared for clinical use in any geographical location or by any regulatory body.

13.2 Intended use

StrokeSENS mCTA Perfusion (mCTAp) is an image processing software package that allows the user to produce dynamic image data derived from DICOM compliant CT imaging device, and to generate information in regard to changes in image intensity over time. StrokeSENS mCTA Perfusion provides viewing and analysis of dynamic contrast-enhanced CT data (multi-phase CT Angiogram images of the head), showing properties of changes in contrast over time, including calculation of parametric maps related to tissue flow (perfusion). The perfusion information is intended to aid the clinician in the visualization and assessment of the extent and type of perfusion which may be related to ischemic stroke.

13.3 Procedures for use

After a multiphase CT Angiography (mCTA) head scan is performed, the images, in addition to the NCCT acquisition, are routed to the StrokeSENS mCTAp device where they are processed and analyzed for perfusion characteristics. Outputs will include four DICOM series: the Relative Delay (rDelay) and Relative Cerebral Blood Flow (rCBF) perfusion maps in both continuous and discrete form (see Figure(s) 13.1 below). The definition of these output maps is provided in the below table for clarity.

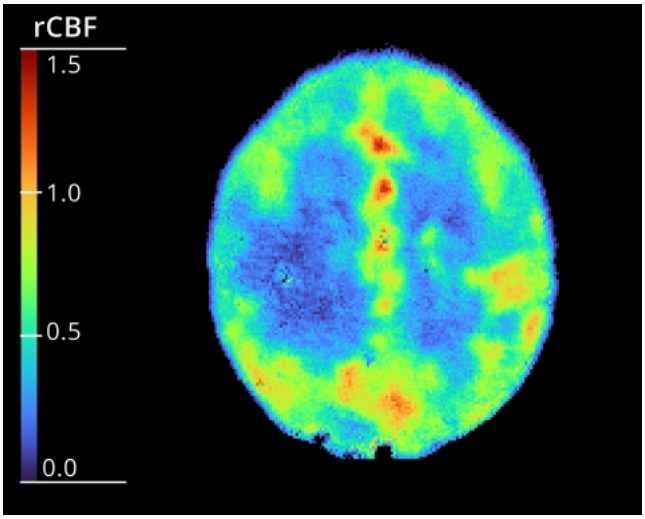


Figure 13.1(a)

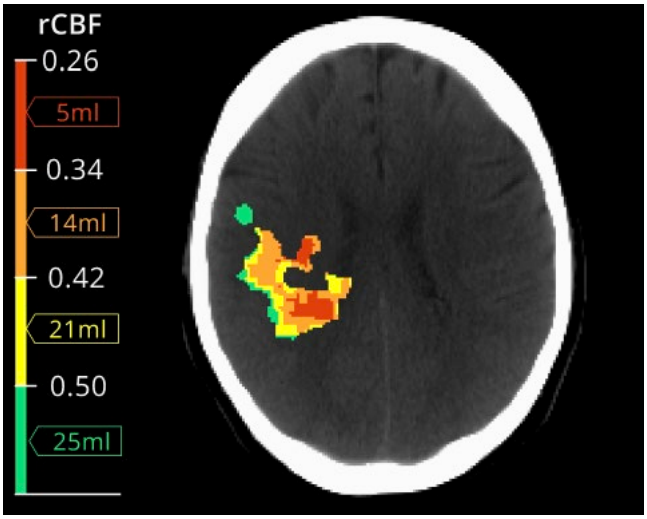


Figure 13.1(b)

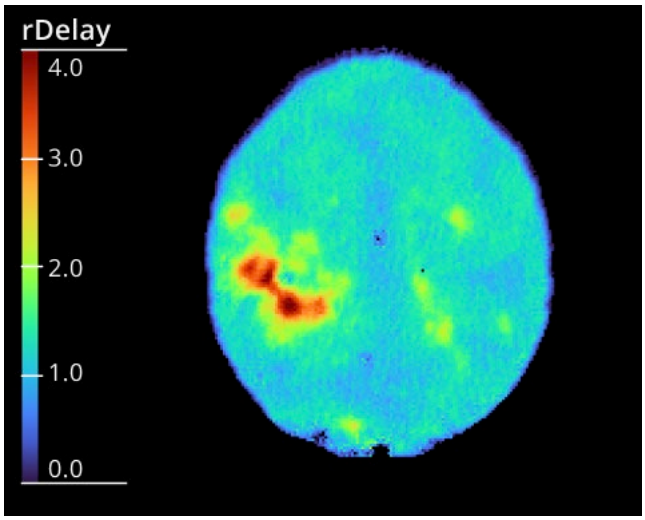


Figure 13.1(c)

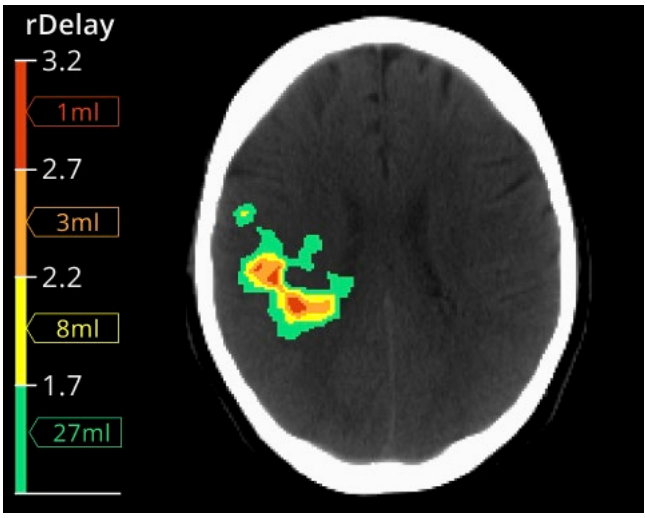


Figure 13.1(d)

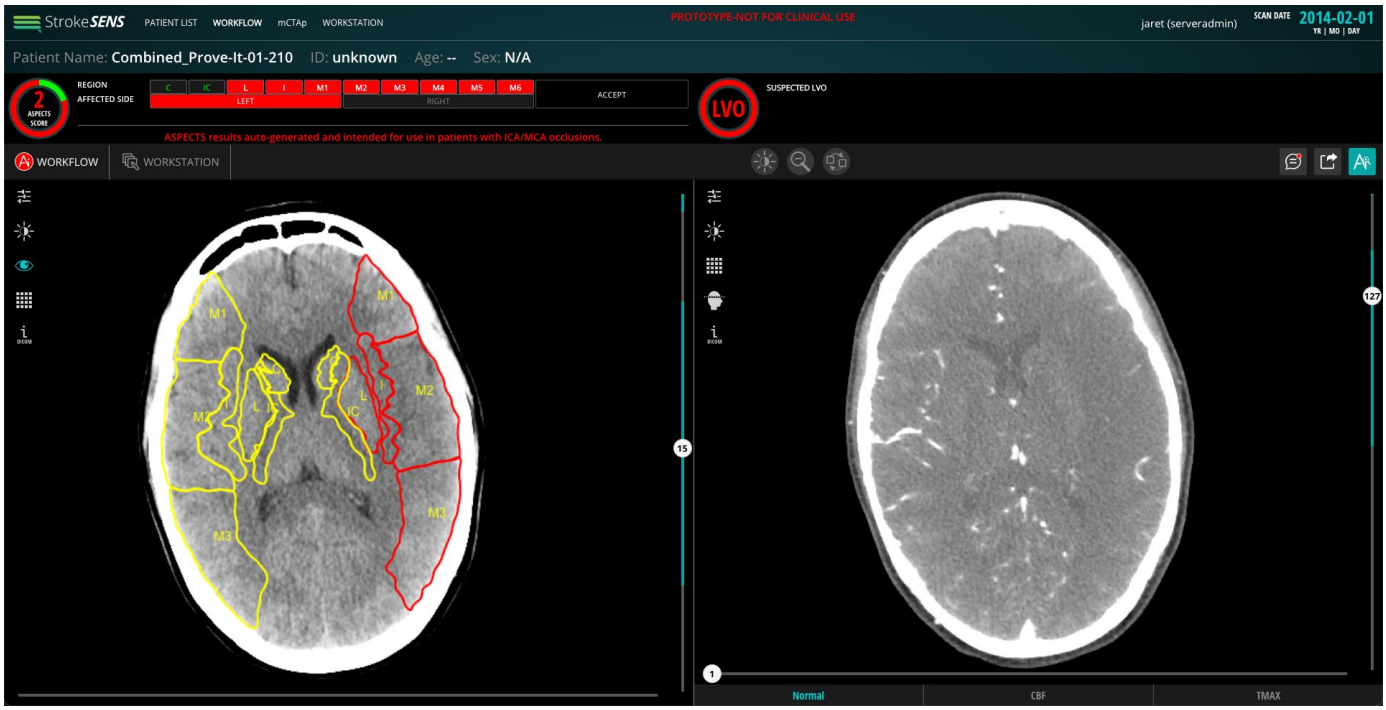
Figure 13.1(a-d): Multi-phase CTA perfusion outputs. Please see table below for descriptions.

Table 13.1(a-d): Description of the outputs of StrokeSENS mCTAp

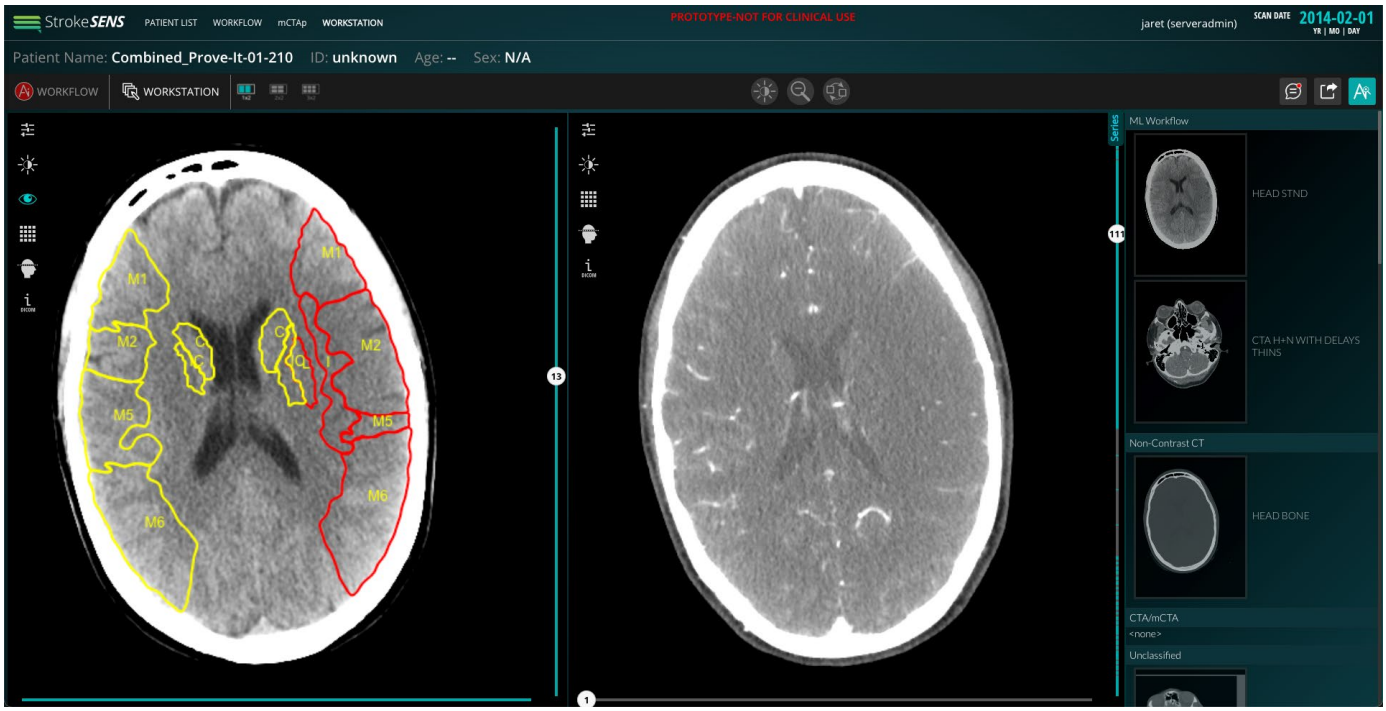
Outputs	Description
rCBF (continuous) 1a) above	The Relative Cerebral Blood flow map describes normalized cerebral blood flow with respect to healthy tissue of the unaffected hemisphere. The Turbo color scheme is used to produce this color map.
rCBF (discrete) 1b) above	A discretized version of the continuous rCBF map which uses four pre-defined and equally spaced threshold values to define the four labels (ischemia severities) that are overlaid on top of the input NCCT.
rDelay (continuous) 1c) above	The Relative Delay map describes the normalized delay of contrast with respect to the healthy tissue of the unaffected hemisphere. The Turbo color scheme is used to produce this color map.
rDelay (discrete) 1d) above	A discretized version of the continuous rDelay map which uses four pre-defined and equally spaced threshold values to define the four labels (ischemia severities) that are overlaid on top on the input NCCT.

14 Workstation (Clinical user)

The user can navigate to the Workstation module by clicking on the Workstation tab from the Workflow module (in the upper-left).



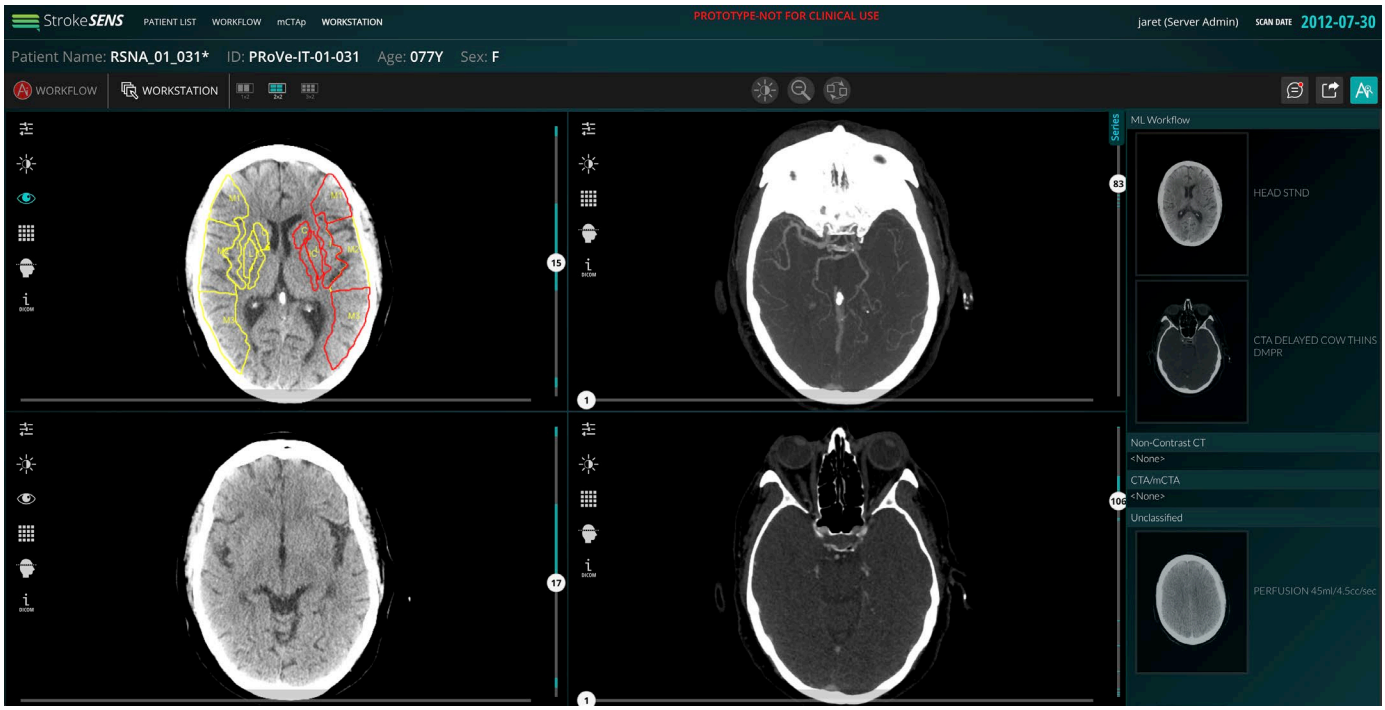
In the workstation tab, the default viewer is '1x2' and any image within that study can be loaded by dragging them into any of the viewing panes from the 'Series' tab.



Users can also display more images simultaneously by selecting other layouts – ‘2x2’ or ‘3x2’- and loading additional images for viewing.

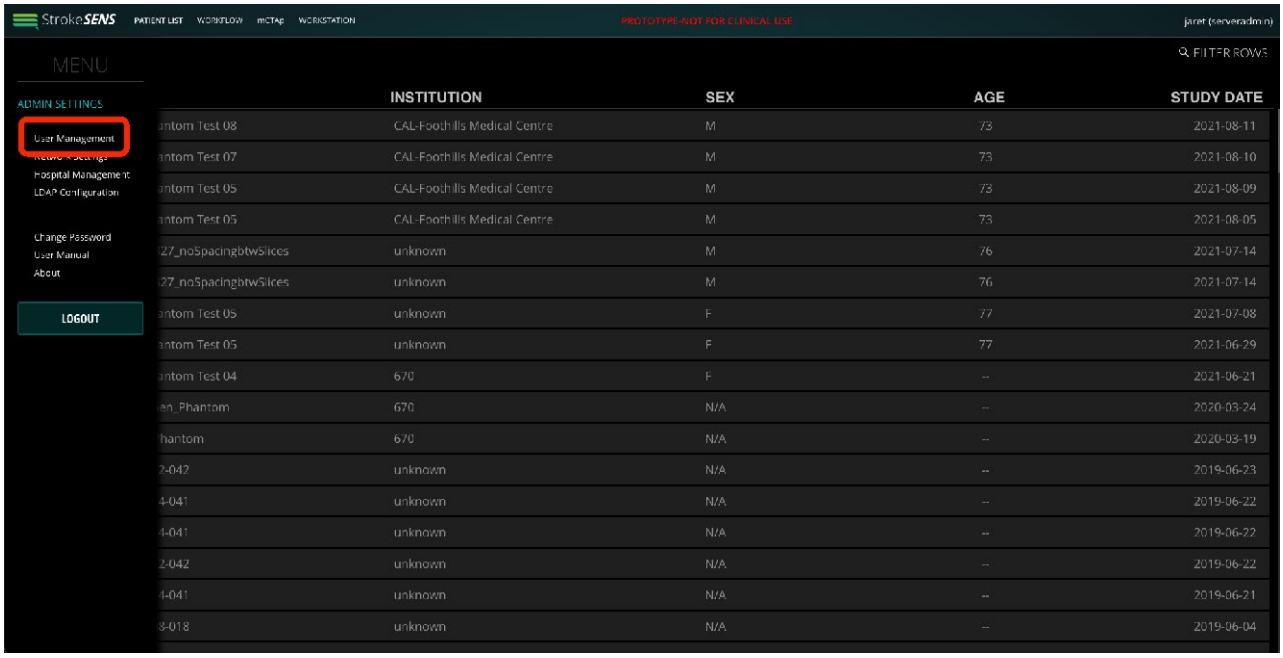
In any of the viewers in the Workstation module, the same local functionalities (MIPS/Mean, window pre-set, toggle contour, Multiview, MPR, info) as described for the workflow module can be carried out on every image.

The global functionalities (manual windowing, zoom, synch, invite, chat, quick findings) also work the same as they do in the workflow module, for all the images within the viewers in this module (Workstation).



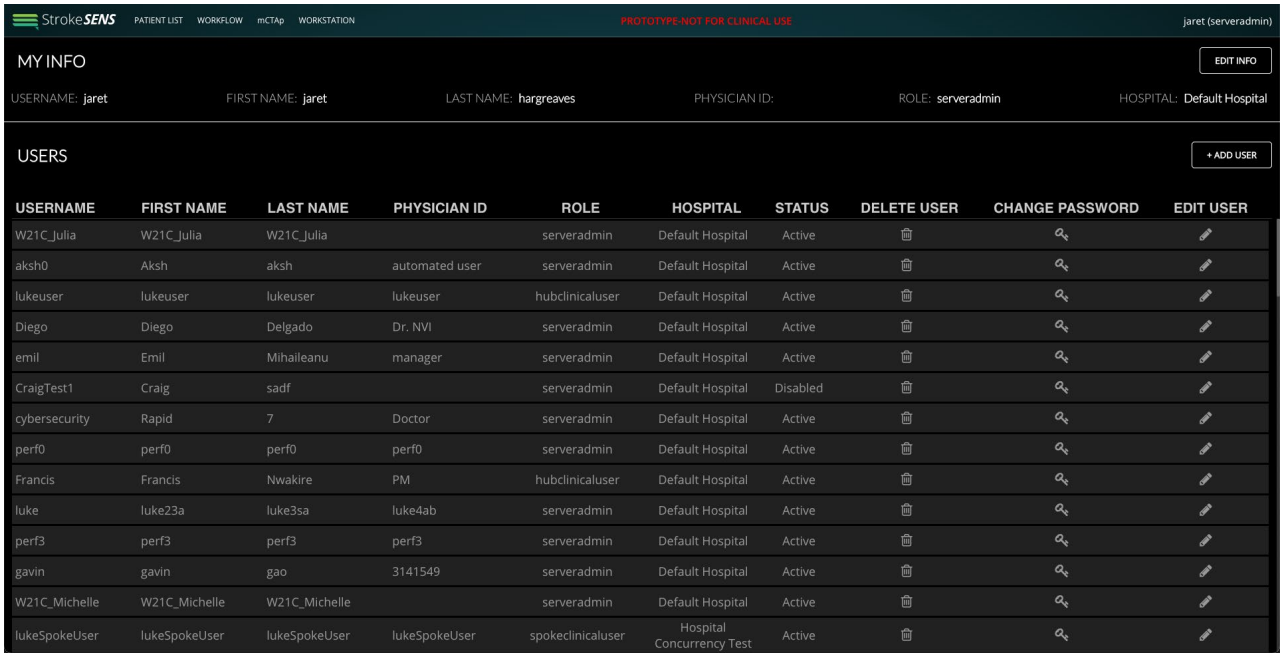
15 User Management (Admin user)

From the Patient List, Network Settings or LDAP Configuration pages, if user has admin rights, a *'User Management'* option will be present in the workspace menu, as seen below.



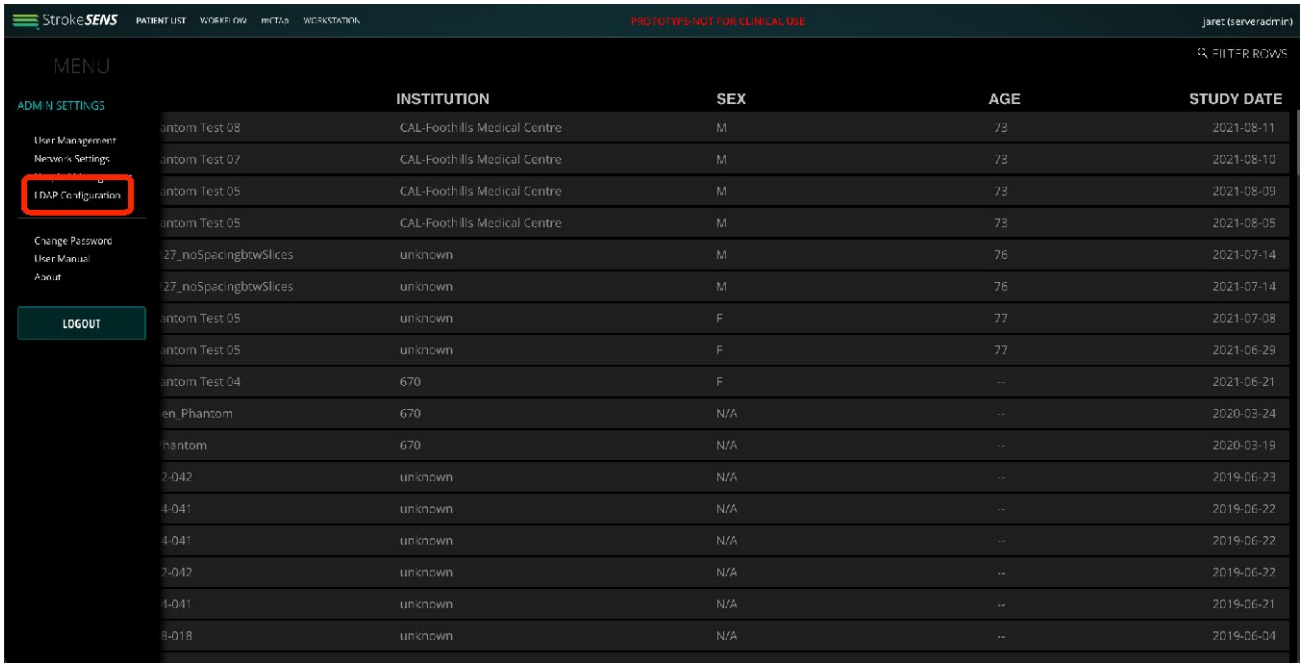
When *'User Management'* is clicked, a list of all users within the network will be displayed, as seen in the image below. From this page, user can:

- Add a new user
- Edit user details, including user privileges (Admin or User account)
- Change a user password
- Delete a user
- An Admin user cannot change an Admin user's status to a standard User if they are the only Admin user on the network.



16 LDAP Configuration (Admin user)

From the Patient List, User Management or Network Settings pages, if user has admin rights, an *'LDAP Config'* option will be present in the workspace menu, as seen below.

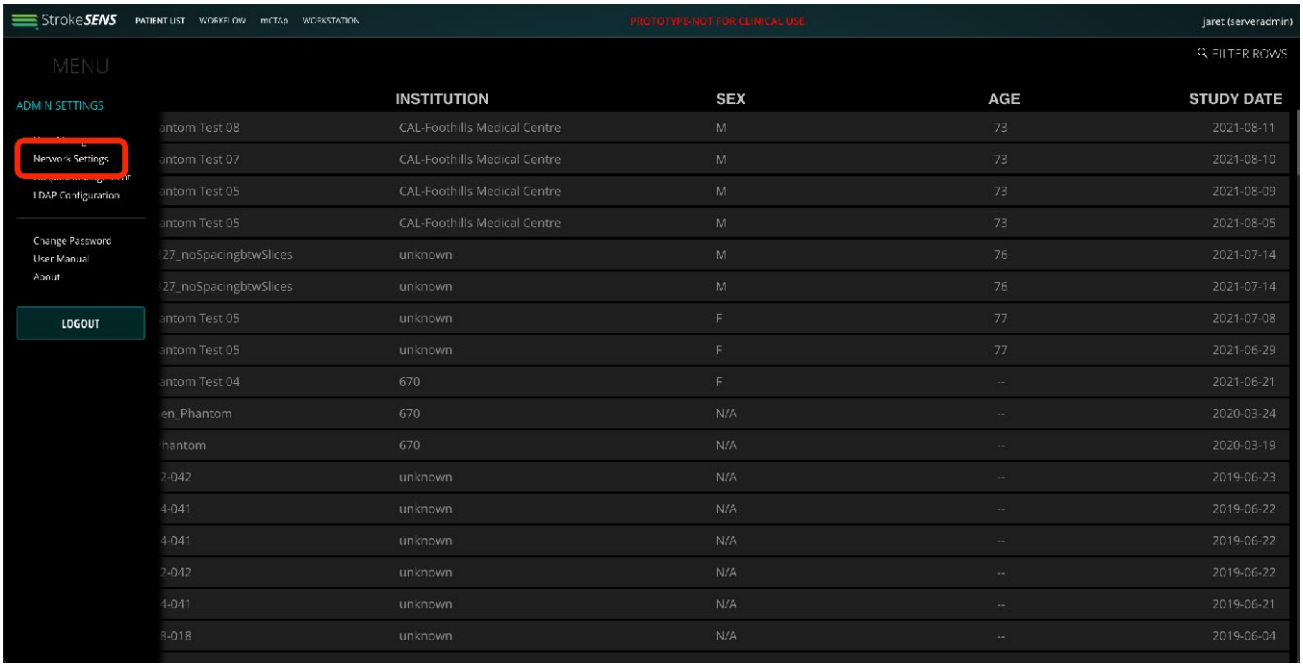


When *'LDAP Config'* is clicked, options to configure user authentication via Active Directory/Lightweight Directory Access Protocol (AD/LDAP) will be displayed, as seen in the image below. If configured, these protocols will allow users to log in to StrokeSENS with the same credentials configured for them by hospital IT.

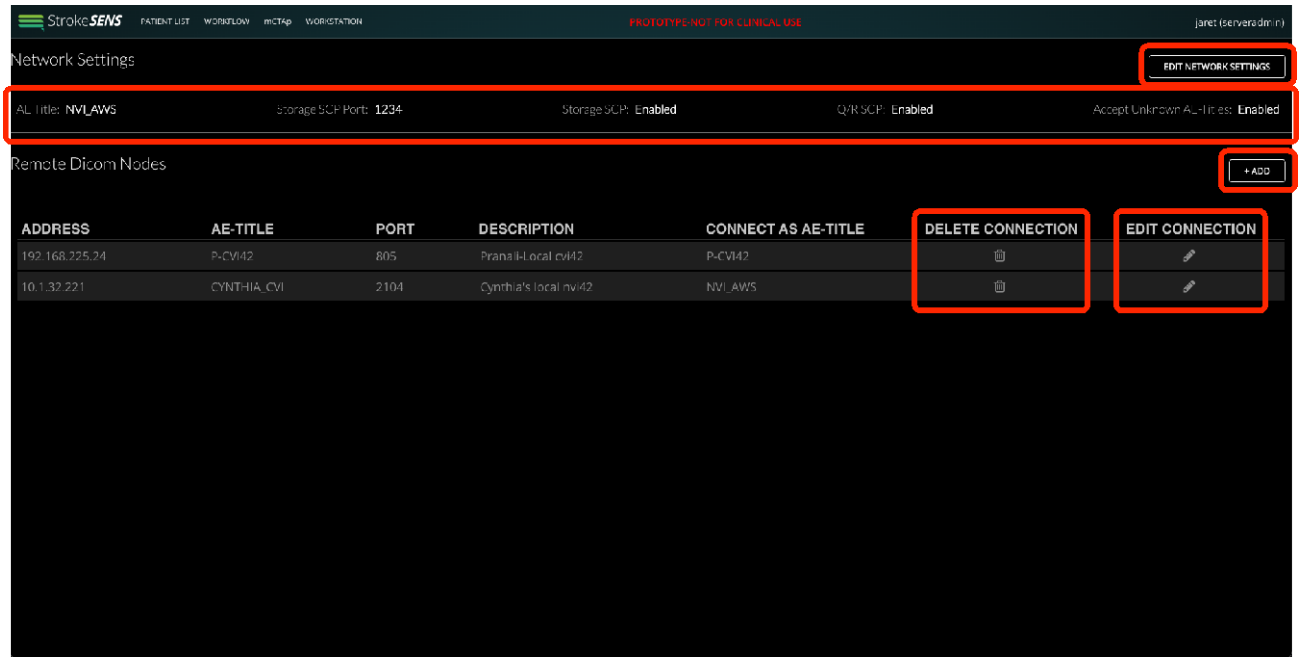
Utilizing LDAP configuration is optional (see interface below). If it is not used, Admins still have the ability to add users accounts as described in the User Management section above.

17 Network Settings (Admin user)

From the User Management or LDAP Configuration pages, an Admin can go to the Network Settings page. Both Admins and Users also have access to this page from the Patient List page.



In the Network Settings page, the user has the option of adding new DICOM nodes from which images can be pushed into the current network. Clicking the 'Edit Network Settings' button, the current network details can be changed. Using the '+ADD' button, the details for new DICOM nodes can be added to the list. Existing nodes on the list can also be deleted and edited by clicking the icon in the relevant column for that node. The details of the current network are also present on this page.



18 Summary of data and device performance

18.1 Validation of StrokeSENS LVO Performance

Description of Data Used for Development

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	3	0
Site of Occlusion		
ICA	106	77
M1-MCA	370	140
Non-LVO	195	183

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, 0.98] 878, 0.98]
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

18.2 Validation of StrokeSENS ASPECTS Performance

Description of Data Used for Development

Data were selected for development from a database composed of pooled imaging data from a multi- center clinical study, namely Prove-IT (ClinicalTrials.gov Identifier: NCT02184936), with subjects 22 years or older who underwent baseline non-contrast CT (NCCT) imaging for suspected acute ischemic stroke. The development dataset was composed of 57% anterior large vessel occlusion (ICA, M1, proximal M2), while the remaining cases included a variety of other cases (no occlusion, distal occlusions, and non- anterior circulation occlusions i.e., Basilar, posterior, vertebral) typically seen in the intended clinical population. The imaging data was acquired from multiple CT scanner models, manufactured by two different CT scanner vendors (GE & Siemens) from multiple sites across North America and EU.

The following table summarizes the properties of both the development and test sets:

	Development Set	**Test Set (MRMC)**
Total	438	200
Manufacturer		
GE Medical Systems	404	93
Siemens	34	44
Philips	0	34
Toshiba	0	29
Slice Thickness		
[2.5, 3.75]	49	69
(3.75, 5]	389	131
KVP		
[100, 120]	273	164
(120, 140]	165	36
ASPECTS		
0	0	3
1	0	5
2	1	8
3	3	11
4	4	7
5	3	19
6	19	16
7	30	21
8	36	36

9	70	27
10	272	47
Age		
<=30	1	1
(30, 40]	9	7
(40, 50]	31	22
(50, 60]	56	26
(60, 70]	94	43
(70, 80]	137	64
(80, 90]	92	34
(90, 100]	12	3
NA	6	0
Sex		
Male	224	89
Female	208	111
NA	6	0
Geography		
Canada	365	77
US	0	59
Europe	73	51
Asia	0	11
Australia	0	2
Onset to CT Time (minutes)		
<=60	55	28
(60, 120]	154	77
(120, 180]	60	33
(180, 240]	50	29
(240, 300]	30	26
(300, 360]	20	7
(360, 420]	10	0
(420, 480]	9	0
(480, 540]	10	0
(540, 600]	10	0
(600, 660]	5	0
(660, 720]	7	0
>=720	18	0
NIHSS Score		
[0, 4]	78	6
(4, 8]	87	21
(8, 12]	63	19
(12, 16]	59	47
(16, 20]	68	61
(20, 24]	52	24
(24, 28]	21	18
(28, 32]	2	4
(32, 36]	1	0
NA	7	0

Summary of Standalone Performance Assessment

To demonstrate the standalone performance of the StrokeSENS ASPECTS software a retrospective case study was conducted. The test dataset is composed of 200 retrospective patient imaging data cases from two clinical trials and two randomized control trials, namely the Prove-IT clinical study (N=40, ClinicalTrials.gov Identifier: NCT02184936), the INTERRSeCT clinical study (N=59, JamaNetwork.com Identifier: 2702146), ESCAPE randomized controlled trial (N=16, ClinicalTrials.gov Identifier: NCT01778335), ESCAPE-NA1 randomized controlled trial (N=85, ClinicalTrials.gov Identifier: NCT02930018). Composition of the test data included different geographical regions (Canada, US, EU, Asia), multiple CT scanner models manufactured by different CT scanner vendors (GE, Siemens, Toshiba, Philips), slice thickness of 2.5-5mm, and kVp value range of 100-140. The test data were representative of a wide range of clinical severities (ASPECTS score range of 0-10, median ASPECTS = 8; NIHSS score range 0-30, median NIHSS score = 17) with an onset to CT time range <360 minutes.

The truthing process involved a panel of three experts reporting the presence or absence of early ischemic changes on NCCT in each of the 10 regions of a standard ASPECTS template. The three experts (one neuroradiologist and two stroke neurologists; Canadian Board Certified) each have >15 years clinical experience scoring ASPECTS on head NCCT images of patients with acute ischemic stroke. Consensus was achieved by a process of majority rule. Specifically, all three expert truthers read all scans independent of each other. In cases of disagreement in assessing early ischemic changes at any region of the ASPECTS template, a final determination of whether that specific region is affected or not was determined by the majority rule (2/3) involvement for that specific region.

The standalone performance assessment was used to demonstrate the accuracy of the automated ASPECTS software with reference to the expert-annotated reference standard. The StrokeSENS ASPECTS software predicts the presence of early ischemic changes (EIC) in each of the 10 anatomical regions-of- interest (ROI) per hemisphere of the brain. Receiver Operating Characteristics (ROC) analysis was used to assess the region-level accuracy of the StrokeSENS automated ASPECT score prediction vs the expert annotation, achieving a per-region clustered AUC of 83.5%. Further analysis shows the StrokeSENS ASPECTS module performed with a side classification accuracy of 97.3% and an ICC of 74.6%.

ASPECT Score Performance	
Clustered AUC	0.835 [0.802 0.869]
Intraclass correlation coefficient (ICC)	0.746 [0.680 0.800]

Side Prediction Summary	
Accuracy	0.973 [0.932 0.989]
Sensitivity	0.989 [0.956 0.997]
Specificity	0.942 [0.904 0.980]

The predetermined operational points (OPs) were selected on a subset of the development dataset based on (1) manual EIC segmentations performed by an expert neuroradiologist, (2) automatic ASPECTS region segmentation generated by the algorithm, and (3) the reference ASPECTS read. For each of the ten ASPECTS regions, the receiver operating characteristics (ROC) curve is calculated, and the point that was closest to the point of the perfect classifier (i.e., the top left corner of the ROC) was selected as the operational point for that region. The following table specifies the OP for each of the 10 ASPECTS regions, and the corresponding performance of the device on the test dataset (N=200).

Affected Region Performance				
Region	AUC	Selected OP	Sensitivity	Specificity
M1	0.837	0.026797961	0.773 [0.715 0.831]	0.843 [0.793
M2	0.821	0.048311334	0.850 [0.801 0.899]	0.608 [0.541
M3	0.892	0.067800194	0.852 [0.803 0.901]	0.757 [0.698
M4	0.85	0.004963366	0.867 [0.820 0.914]	0.761 [0.702
M5	0.865	0.017413441	0.907 [0.867 0.948]	0.699 [0.635
M6	0.801	0.051263440	0.857 [0.809 0.906]	0.743 [0.682
Caudate	0.761	0.015985325	0.609 [0.541 0.676]	0.877 [0.831
Lentiform	0.786	0.058007717	0.808 [0.753 0.862]	0.615 [0.547
Insula	0.872	0.016447369	0.883 [0.838 0.927]	0.611 [0.544
Internal Capsule	0.799	0.255516827	0.375 [0.308 0.442]	0.917 [0.878

Summary of Clinical Performance Assessment

To demonstrate the clinical performance of the StrokeSENS ASPECTS software, a concurrent read, fully- crossed multi-reader multi-case (MRMC) reader study was conducted on retrospective imaging data pooled from above mentioned PROVE-IT, INTERRSeCT, ESCAPE, ESCAPE NA1 trials. A sample of 100 non- contrast CT Head scans (2.5 - 5mm slice thickness) from subjects with a vessel occlusion of the anterior circulation with varying degrees of ischemic severity was randomly selected. There were a total 8 readers (4 female) with a range of clinical training as neurologists, radiologists and neuroradiologists of0-10 years' experience. Each reader read all 100 cases (in randomized order) twice (once unaided and once aided by device) in two reading sessions separated by 2-4 weeks interval, in similar reading condition. The truthing process was identical to the one used in standalone performance assessment.

Descriptive analysis showed that the average improvement in the proportion of correctly rated regions when aided versus when unaided was 1.86%. Also, using a mixed effect model considering reader sequence, scan, and regions as a fixed effect, and readers as a random effect, the calculated area under the receiver operating characteristic curve (AUC) yielded 87.4% for aided with StrokeSENS, compared with an AUC of 86.3% when unaided. The overall sensitivity and specificity from the mixed model using Youden index showed 85.0% and 74.9% when aided with StrokeSENS vs 83.4% and 75% when unaided. The difference in AUC of 1.1% in favor of StrokeSENS was statistically significant (two-sided p-value <0.01) using bootstrap modeling. Further analysis showed that the overall intraclass correlation for reader level across reads was improved when aided by StrokeSENS (.65) vs when unaided (.48) meaning that StrokeSENS helps to introduce better consistency across reads for readers. The predictive accuracy of the readers' ratings for dichotomized total ASPECTS (for total ASPECTs score <= 5) also improved when aided with StrokeSENS (AUC=84.2%) vs unaided (AUC=78.1%) in reference to the truther consensus aspects.

18.3 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-Siemen's 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 either the ASPECTS or LVO modules.

Young adults (<50) were underrepresented in the data used for developing and testing the ASPECTS and LVO detection algorithms.

Interobserver variability in expert ASPECT scoring may limit the reliability of the reference standard; Inter- and intra-rater agreement is not available for the expert consensus reference standard.

18.4 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

18.5 DICOM Parameters validated for algorithm performance

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

Non-contrast CT for ASPECTS Scoring
1. ImageType = Original/Primary
2. Modality = CT
3. Volumes = 1
4. WindowWidth < 210 *Criterion used in the automatic detection of non-contrast-enhanced images.
5. 0.625 mm <= SliceThickness <= 5 mm
6. Scan range = CT head volume covering the whole head (vertex to base) is recommended
7. Matrix size = 512 x 512
8. DFOV along the X/Y axis = 180 – 324 mm

Summary of Parameters used 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. 210 < WindowWidth <= 1170 *Criterion used in the automatic detection of contrast-enhanced images.
5. 0.5 <= SliceThickness <= 2.5 mm
6. Scan range = CT head volume covering the whole head (vertex to base) is recommended
7. Matrix size = 512 x 512
8. DFOV along the X/Y axis = 180 – 412 mm

Summary of Parameters used for mCTAp map generation
1. ImageType = Original/Primary
2. Modality = CT
3. Volumes = 3 CTA volumes (i.e., the mCTA volumes) and 1 NCCT volume
4. WindowWidth: NCCT: WindowWidth < 210 mCTA: 210 < WindowWidth <= 1170 *Criterion used in the automatic detection of contrast/non-contrast images
5. SliceThickess: NCCT: 2.5 mm <= SliceThickness <= 5 mm mCTA: 0.6 <= SliceThickness <= 1.25 mm
6. Scan range = CT head volume covering the whole head (vertex to base) is recommended
7. Matrix size = 512 x 512
8. DFOV along the X/Y axis: NCCT: 201 – 251 mm mCTA: 213 – 300 mm

19 Technical Support

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

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