StrokeSENS

v.1.3 (140)

Release Notes

CIRCLE
NEUROVASCULAR IMAGING

What's New in Version 1.3

Intended 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 is provided by the StrokeSENS ASPECTS module, which includes assessment of regions with suspected acute ischemic tissue (ie. 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).

StrokeSENS ASPECTS is a computer-aided diagnosis software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of lnterest (ROIs). StrokeSENS ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT (Alberta Stroke Program Early CT) Score. StrokeSENS ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with anterior circulation Large Vessel Occlusion (LVO), for evaluation of extent of disease. Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. This device provides information that may be useful in the characterization of early ischemic brain tissue injury during image interpretation (within 6 hours). StrokeSENS ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring.

StrokeSENS LVO is a radiological computer-aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) 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.

Device Description

StrokeSENS is a software package that provides for the visualization and study of changes in brain tissue using digital images captured by Computed Tomography (CT) diagnostic imaging systems. StrokeSENS is compliant with the DICOM standard and can be installed to run on an off-the-shelf physical or virtual server.

It provides viewing, quantification, analysis, and reporting capabilities which, when interpreted by a trained physician, may yield information useful in clinical decision making.

StrokeSENS works with the following types of (DICOM-compliant) medical image data:

- CT (Computed Tomography)

StrokeSENS acquires (DICOM-compliant) medical image data from the following sources:

- DICOM file
- Network using DICOM protocol

StrokeSENS provides tools for performing the following types of analysis:

- ASPECTS - Ischemic Tissue Changes (ASPECTS)
- LVO - Large Vessel Occlusion detection

StrokeSENS provides tools for performing the following types of analysis under evaluation (Not for clinical use):
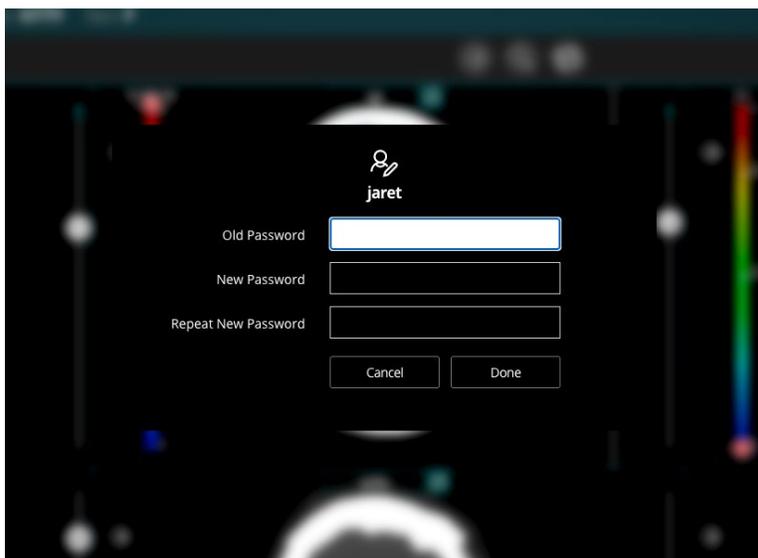
- mCTAp - Maps related to cerebral blood flow

What's New

1. Hospital Management (Admin only)
   o This functionality is intended to support access to spoke physicians in those hub-and-spoke stroke care networks in which the imaging data is centralized at the hub hospital.
   o Hub clinicians should have access to **all** studies in the StrokeSENS database, while Spoke clinicians should have access to only those studies that were acquired at their hospital
   o In the Hospital Management interface, the Admin will provide for each site: a human-readable name, an email address for the sending of notifications for that site, and an Institution Name (to identify studies acquired there). It is important to note that the Institution Name DICOM tag should be populated for all studies originating from a site.
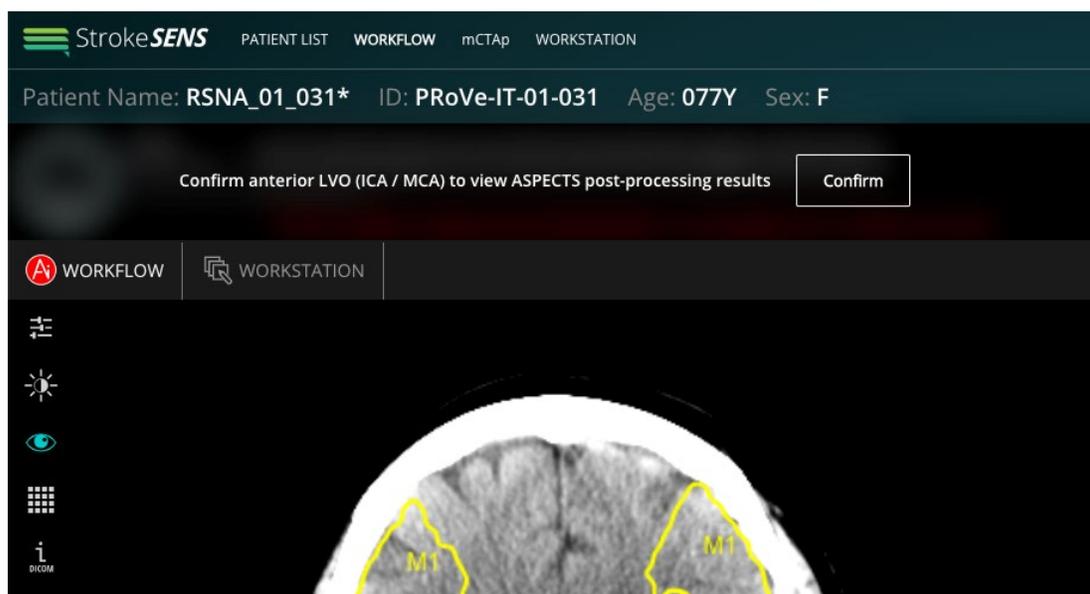

2. Change Password (all users)
   o Users have the ability to change their password from the application menu.
   o In order to change their password, the user must:
     ▪ Have an active session (ie. have logged in and not yet been logged out)
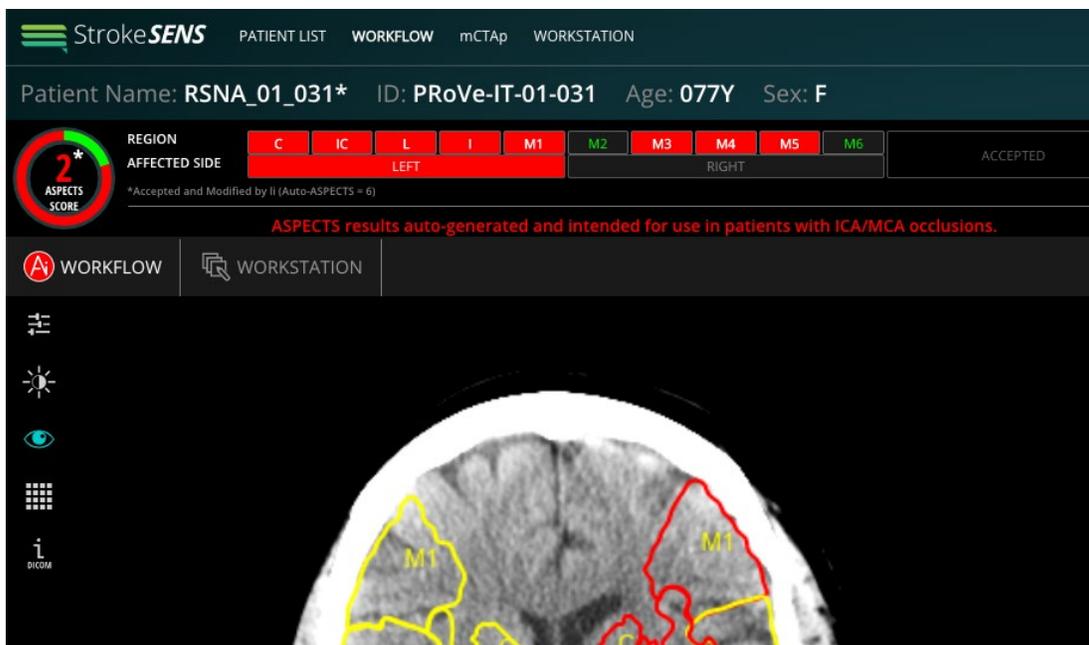   ▪ Provide their current password

3. LVO Confirmation (Clinician users)
   o When a suitable non-contrast CT (NCCT) scan is processed to generate ASPECTS results, the clinician will be required to confirm an LVO occlusion before they are given access to the ASPECTS results. The ASPECTS results panel content will be hidden, with the following message posted for the user:
      ▪ "Confirm anterior LVO (ICA/MCA) to view ASPECTS post-processing results"
   o A button labelled "Confirm" will be presented. Clicking this button will remove the message and provide the user with access to the ASPECTS results.
   o Before the message is dismissed, the NCCT images will be available for review (including all standard viewing functionality) by the user, but all of the ASPECTS regions will be presented with the same colour.
   o The occlusion does *not* require confirmation in StrokeSENS. (ie. the user could review the CTA in another viewing solution)
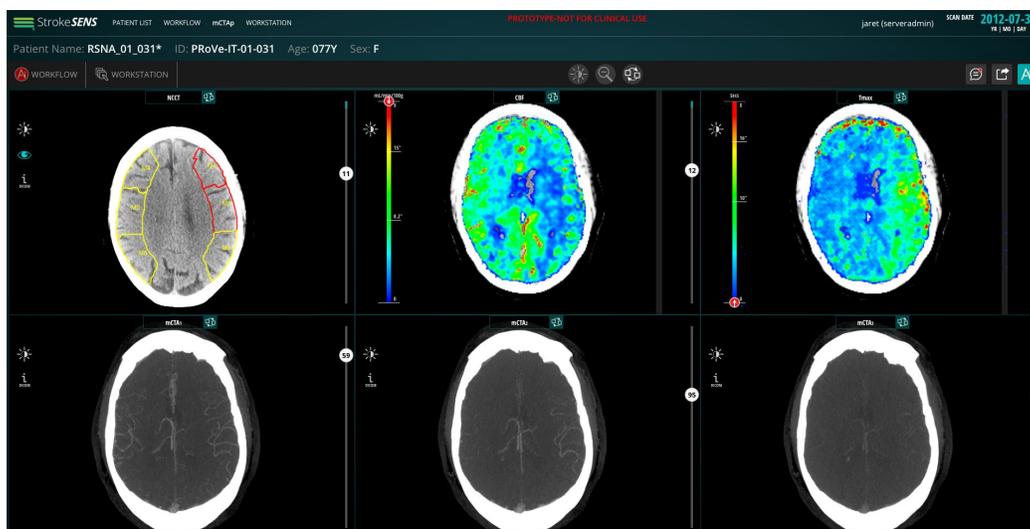

4. ASPECTS Review & Acceptance (Clinician users)
   o Both the Affected Side and the Regions will be editable by the user. An "Accept" button will be provided to allow a clinician to indicate when the score is correct (whether the original or modified score).
   o When a clinician clicks the "Accept" button, it 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 (ie. accepted without changing the algorithm output) it will read "Accepted by <user>". 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>)".
   o ASPECTS will only be accepted once. After that, all users loading the series will just see the accepted score, regions and side, with the indication of which user updated/accepted the result.

5. Multi-phase CT Angiography Perfusion (mCTAp) View (Clinician user)
   o On navigating to the mCTA view, the clinician will be presented with 6 image windows (2 rows x 3 columns) by default:
      ▪ Row 1: NCCT/ASPECTS, CBF, Tmax
      ▪ Row 2: mCTA Phase 1, mCTA Phase 2, mCTA Phase 3
   o All windows will display anatomy corresponding to the NCCT window and scroll synching will be turned on (ie. slice scrolling in any window should update all views). The user will be able to turn off scroll synching to scroll windows independently.
   o As long as NCCT and mCTA (3-phases) series identified, users will be able to access this page. Otherwise, the option for mCTAp will be disabled.

Resolved Issues

The following list contains resolved usability related issues, in addition to all other internal issues resolved during the product development process.

Issue key	Summary
NV-1462	mips/mean stack doesn't collect backwards
NV-1426	Failed Mips/Mean Content Test
NV-1233	ESCAPENA1 14-012 Study not accepted by ML. ITK Library error.
NV-1391	MIPS/Mean Slicer Sensitivity Issue
NV-1459	SliceSync doesn't sync when heatmaps are scrolled
NV-1418	Spline tool offset issue with heatmaps

Known Issues

Issue key	Summary
NV-999	Swipe does not respond as expected on mobile *Workaround: No workaround available.*
NV-1390	Failed mCTA heatmap on select cases. *Workaround: No workaround available.*
NV-1267	Manufacturer is not listed on the worklist. *Workaround: No workaround available.*
NV-1299	Patient Protocol images not carried over using combine studies feature *Workaround: No workaround available.*
NV-1297	Inconsistent series slice thickness info after combining studies *Workaround: No workaround available.*
NV-1289	Password field from the LDAP Config view need to be encrypted. *Workaround: No workaround available.*
NV-1257	Patient List Name Sorting isn't Truly Alphabetical *Workaround: No workaround available.*
NV-1256	Patient Names Overlap Date in Worklist on Mobile devices. *Workaround: No workaround available.*
NV-1161	Presence of CTP ML loading icon in newly uploaded studies *Workaround: No workaround available.*
NV-1619	Older versions of Safari browser might show case high usage of system memory. *Workaround: Use updated browser version or other supported browsers.*

NV-1620	Switching to heatmaps on workflow page loads extra tiny image first. *Workaround: No workaround available.*
NV-1623	Loading MPR on 2 viewers sometimes causes the images to be stuck and sometime blank in the viewers. *Workaround: No workaround available.*
NV-1625	Login is required when opening second notification link. *Workaround: No workaround available.*
NV-1631	Layout frames column and rows have conflicting dimensions *Workaround: No workaround available.*
NV-1657	Header disclaimer "ASPECTS results auto-generated..." gets cut off when the browser is shrunk. *Workaround: No workaround available.*
NV-1665	Inconsistent Modal pop-ups between Hospital management and User Management/Network Management *Workaround: No workaround available.*
NV-1666	Inconsistent resets when editing hospitals with invalid info *Workaround: No workaround available.*
NV-1691	Improvements to password error messaging *Workaround: No workaround available.*
NV-1724	No ASPECTS Score Generated / mCTA Perfusion Maps Created for loaded studies *Workaround: No workaround available.*
NV-1755	Heat map gradient showing up in non-brain region within pane *Workaround: No workaround available.*
NV-1760	Some series found to separate Internal NCCT *Workaround: No workaround available.*
NV-1773	Scaling on MPR incorrect with MIPS and switch to workstation *Workaround: No workaround available.*
NV-1774	Switching between heatmaps and normal view 15 times blanks NCCT *Workaround: No workaround available.*
NV-1775	mCTAp studies classify 2 times *Workaround: No workaround available.*
NV-1779	Patient list doesn't update with new studies for users logged in *Workaround: Refresh/Reload the page.*
NV-1780	Processing Time Criteria for mCTAp not met *Workaround: No workaround available.*
NV-1781	Important buttons and info cut off at min width

	Workaround: No workaround available.
NV-1782	In mobile width, using the windowing tool horizontally can swipe series *Workaround: No workaround available.*
NV-1785	Multiview doesn't resize correctly *Workaround: No workaround available.*
NV-1788	ML node occasionally crash when processing mCTAp algorithm on release and debug mode *Workaround: No workaround available.*
NV-1791	Second row of viewers doesn't fit on screen in Safari *Workaround: Use updated browser version or other supported browsers.*
NV-1794	Institution Name tag not visible on study UI by default *Workaround: No workaround available.*
NV-1795	Spoke user admin can't modify users to or from spoke admin *Workaround: No workaround available.*
NV-1796	No hospital edit/delete confirmation dialog *Workaround: No workaround available.*
NV-1797	No 'mCTA failed' messaging on front-end *Workaround: No workaround available.*

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This is a list of free and open source software used in our products, including any modifications made by Circle Neurovascular Imaging Inc., throughout the course of our development.

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Modifications	Disable MD2 if not available in OpenSSL (patch)
	Fix Lookup in Templates (patch)
	Fix Outdated Link to Qt Documentation (patch)

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Support

For further information on installing/exchanging the dynamic libraries please contact Circle Neurovascular Imaging support.

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