StrokeSENS

v.1.4.2 (325)

Release Notes

CIRCLE
NEUROVASCULAR IMAGING

<div align="center">

What's New in Version 1.4.2

</div>

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. Export to PACS
   - This functionality enables users to configure StrokeSENS to automatically export processed outputs/results to PACS by configuring export DICOM node(s).
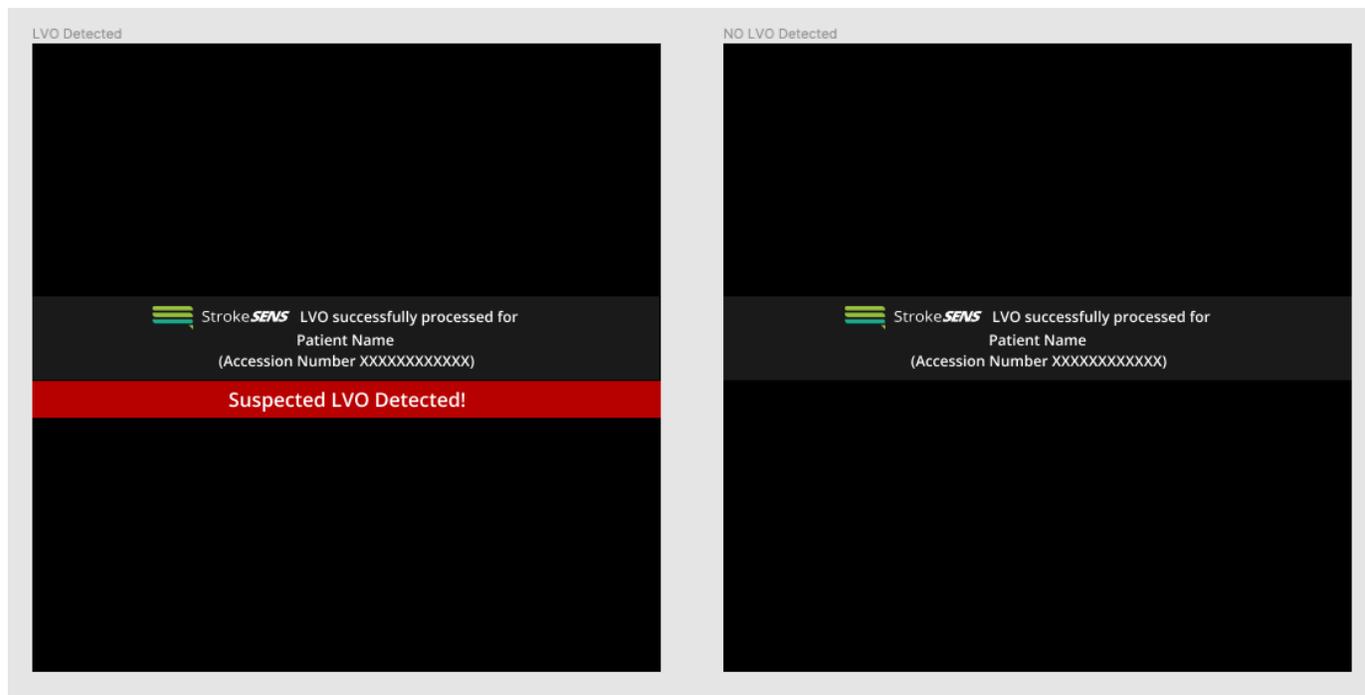

Figure 1.1: DICOM Secondary Captures prepared for export following LVO Detection. In the case that a suspected LVO was detected, it is clearly indicated by the addition of "Suspected LVO Detected!" to the output.
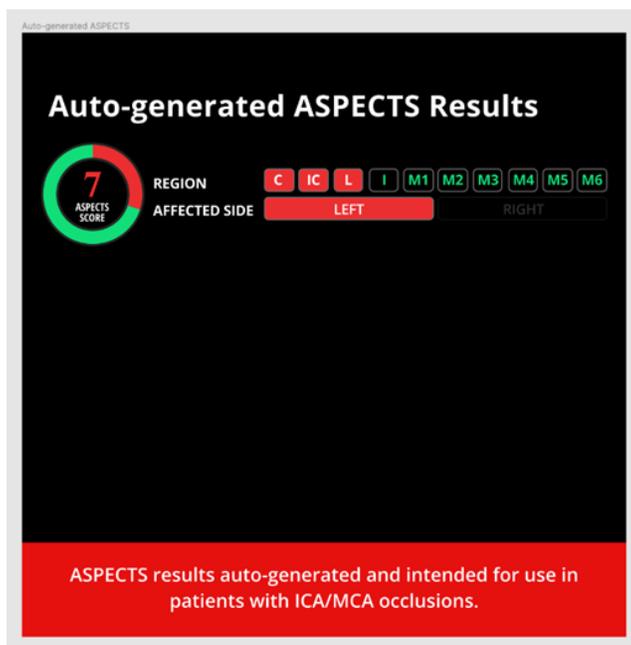

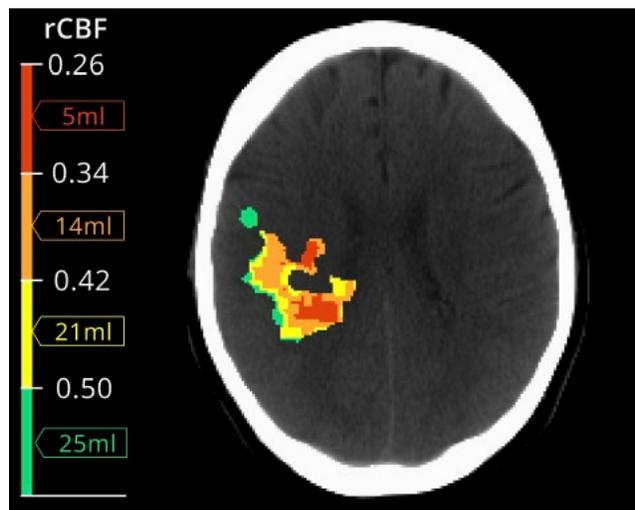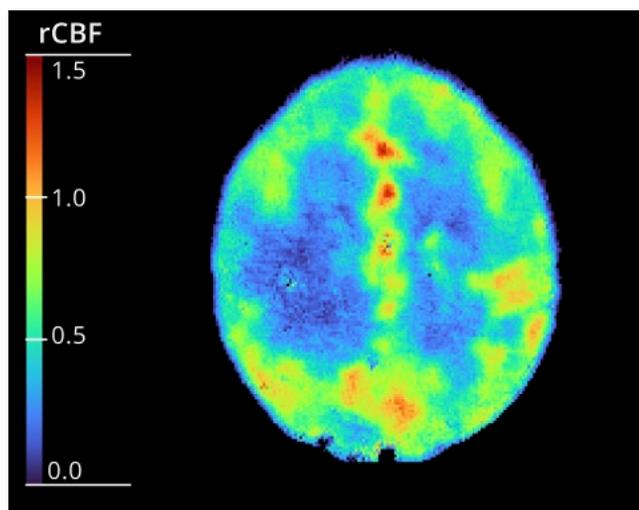*Figure 1.2: DICOM Secondary Captures prepared for export following ASPECTS results. DICOM export includes the original series CT with predicted ASPECTS masks written onto the CT DICOM image, as well as a report image as visualized above.*

2. Licensing
   - Licensing was updated to allow for licensing control of StrokeSENS installation at a institution/installation level as well as for each unique version

    o   Licenses will expire after a prescribed time
    o   Licenses can be renewed/replaced by Circle support following update or upgrade

3. LDAP Configuration for Active Directory group integration
   o Admin users can configure a connection to the hospital or health system's Lightweight Directory Access Protocol (LDAP) for Active Directory group integration
   o This enables configuration to allow for end-users to log in to StrokeSENS using the same credentials they would use throughout the hospital or health system
   o LDAP configuration is the responsibility of an ADMIN IT user upon installation

4. ASPECTS Module Updates
   o ASPECTS processing module was updated to enable processing of thin slice non-contrast CT's (0.6-5mm)
   o ASPECTS results no longer require confirmation of LVO

5. LVO Module Updates
   o The LVO detection algorithm was updated for increased performance
     ▪ Sensitivity of 90.3% (+0.9%) & Specificity of 95.1% (+7.7%) for detecting ICA and M1 occlusions
     ▪ Mean processing time ~2 minutes

6. Multi-phase CT Angiography Perfusion (mCTAp) Updates
   o This release includes updates to the mCTA Perfusion module for non-clinical use
   o The release includes updates to the algorithm to improve the performance and resolution of the perfusion maps.
   o The update includes calculation of relative cerebral blood flow (rCBF) and relative Delay (rDelay) maps
   o The update includes calculation and visualization of discrete thresholded maps with pre-defined thresholds and corresponding volumetric analysis
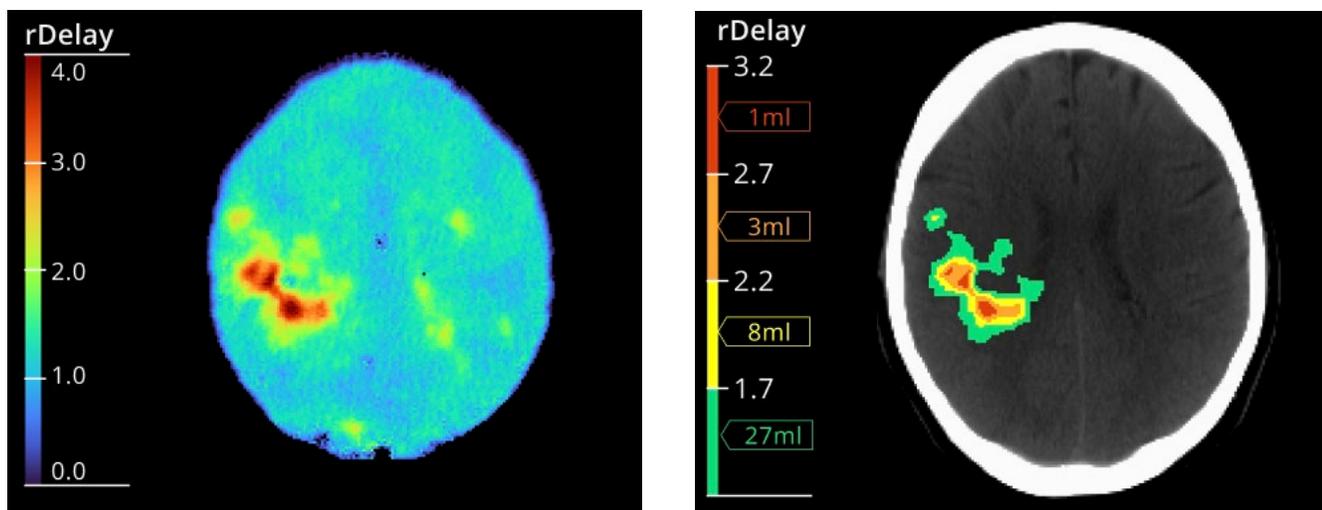   o mCTAp maps are labelled not for clinical use

Figure 6.1: Multi-phase CTA perfusion outputs. Please user manual for detailed descriptions.

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-1755	Heat map gradient showing up in non-brain region within pane
NV-1760	Some series found to separate Internal NCCT
NV-1773	Scaling on MPR incorrect with MIPS and switch to workstation
NV-1774	Switching between heatmaps and normal view 15 times blanks NCCT
NV-1775	mCTAp studies classify 2 times
NV-1779	Patient list doesn't update with new studies for users logged in
NV-1780	Processing Time Criteria for mCTAp not met
NV-1781	Important buttons and info cut off at min width
NV-1788	ML node occasionally crash when processing mCTAp algorithm on release and debug mode
NV-1791	Second row of viewers doesn't fit on screen in Safari
NV-1794	Institution Name tag not visible on study UI by default
NV-1795	Spoke user admin can't modify users to or from spoke admin
NV-1796	No hospital edit/delete confirmation dialog
NV-1797	No 'mCTA failed' messaging on front-end

Known Issues

Issue key	Summary
NV-999	Swipe does not respond as expected on mobile *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-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-1723	Quick findings icon always highlighted *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-1784	Workstation series tab previews don't resize correctly *Workaround: No workaround available.*
NV-1871	Default Zoom Opened Patient Study too far Zoomed In *Workaround: No workaround available.*
NV-2016	No way to access mCTAp when navbar buttons hide due to resize *Workaround: No workaround available.*
NV-2038	Not all series show up in viewer at all times *Workaround: No workaround available.*
NV-2069	Windows preset is not preserved between mCTA phases *Workaround: No workaround available.*
NV-2123	The 'OK' button to continue session does not always work on first click *Workaround: No workaround available.*
NV-2125	Sync Button not present on workstation viewer *Workaround: No workaround available.*
NV-2144	stroke.log_svc performance on Windows 10 *Workaround: No workaround available.*
NV-2185	Slice Scrolling Blocked by Series Tab in Workstation *Workaround: No workaround available.*
NV-2211	mCTAp Brain Windowing Option Blocked by the Gradient Scroller for Heatmaps *Workaround: No workaround available.*
NV-2243	Difference in Size between NCCT and Reconstructed NCCT in mCTAp Page *Workaround: No workaround available.*
NV-2251	Zoom level is not retained on switching between normal view and heatmaps *Workaround: No workaround available.*
NV-2252	Dicom Info Button Inaccessible on NCCTs in 2x2 and 3x2 Workstation *Workaround: No workaround available.*
NV-2253	MPR buttons style off while Mips is open on Edge browser

	Workaround: User can use a different browser.
NV-2256	Toggle Contours Button Still Accessible when using Mips/Mean *Workaround: No workaround available.*
NV-2257	Slicesync on mCTAp page doesn't disable for series when enabled on workflow *Workaround: No workaround available.*
NV-2279	Product name error in "Activation license not available" error message *Workaround: No workaround available.*
NV-2278	mCTAp heatmap gradient moves with arrow keys *Workaround: No workaround available.*
NV-2280	User manual switches pages too quickly while zoomed in *Workaround: No workaround available.*
NV-2287	Windowing Retained in Coronal and Sagittal Views when Switching from Heatmaps to Normal *Workaround: No workaround available.*
NV-2288	mctap link is disabled on reloading the browser while in patientlist page *Workaround: No workaround available.*
NV-2318	StrokeSENS performing ML on coronal image and not axial image for certain datasets. *Workaround: No workaround available.*
NV-2415	StrokeSENS Login / LDAP Solution on Mobile & Tablet is creating multiple (duplicate) users *Workaround: No workaround available.*
NV-2391	Series do not show in the Patient List according to their SeriesNumber *Workaround: No workaround available.*
NV-2488	ASPECTS has unhandled crash on 3mm NCCT study *Workaround: No workaround available.*
NV-2432	License server did not install after upgrade to version 1.4 *Workaround: No workaround available.*

External Libraries – Copyright and Licensing Requirements

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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