StrokeSENS Software Installation Guide

Version 1.4.1

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1. What is StrokeSENS?

StrokeSENS is a vendor-neutral software application for viewing and analyzing DICOM standard images to support the clinical management of acute stroke patients within the hospital environment and/or across a network of stroke hospitals.

2. What is the purpose of this document?

This document will give an overview of the application's main components and provide details for the deployment strategy including installation and configuration of services, and minimum hardware and software specifications of the application.

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 includes assessment of regions with suspected acute ischemic tissue. Analysis of contrast-enhanced CT images includes automated detection of suspected large vessel occlusion (LVO).

In the case of a suspected 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.

4. Warnings and Cautions

IMPORTANT: 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.

IMPORTANT: 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 the responsibility of the on-site/customer's IT and Security professionals.

5. Overview of StrokeSENS

The StrokeSENS application automatically analyzes images and provides image viewing and interactive reports through external devices securely connected via a web client service. It is designed to handle many concurrent users and studies to enable collaboration workflow among physicians during acute stroke treatments. It is comprised of the following main components:

Data storage server

- manages DICOM related resources
- manages other shared data resources

Worker services

- study-independent worklist daemon service
- study-based image retrieval service
- study-based workspace operational service
- study-based image analysis computational service

Web client service

- acts as a web server for providing HTML contents
- serves as the endpoint for most of the user interactions
- coordinates all worker services and other services

IAM service

- manages user identity and controls access

Consul service (3rd party)

- provides a service registry for worker services and others, and monitors services' health status

Pacemaker service

- bootstraps worker services
- manages worker services' lifecycles

Log service

- logs system events, user access histories, and operations on sensitive data

MongoDB service (3rd party)

- stores log data

RabbitMQ service (3rd party)

- manages message channels which are used for the communication between the web client service and worker services, as well as the log service

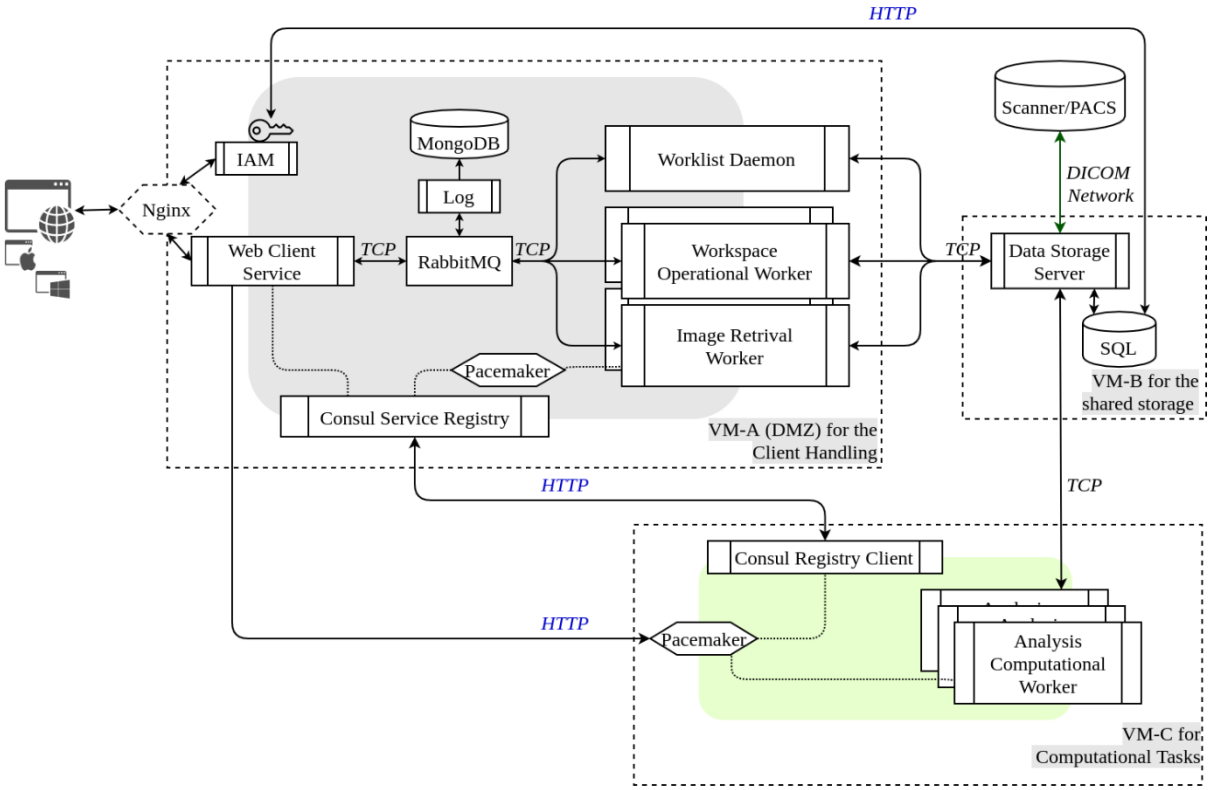
Nginx (3rd party)

- acts as a reverse proxy for directing client requests

Client UIs in browsers

- renders graphics, handles user interactions, and communicate to backend services

6. Deployed system diagram



Given the 3 components comprising StrokeSENS (see above architecture diagram), there is flexibility in how the solution can be deployed. Two potential deployment strategies are as follows:

a. Installing all services on the same host

Installing all services on the same host is recommended as the simplest deployment strategy. If this deployment strategy is selected, care should be taken to meet the software and hardware recommendations in Section 5 to ensure the solution's performance.

b. Installing on multiple hosts on the same LAN

The web client handling services, the data storage server, and the analysis computational services can be deployed on different hosts on the same subnet, switch, or VM virtual infrastructure. This configuration is the most complex to implement, but may address performance concerns, should they arise. Depending on the IS policies of sites, the client handling services could be installed on a system on a different network (e.g. a DMZ) to insulate the data storage server.

7. System hardware and software specifications

a. 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 6 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 6 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 or greater
Network	1 GB ethernet minimum, 10 GB preferred

b. Client web browser

Device	Web browser
Desktop	Chrome (after Jan 2019 / after version 72.0.3626) Safari (after Sept 2019 / version 13.0.4 and above) Microsoft Edge (after Jan 2020 / after version 79.0.309)
Mobile	Safari (after Sept 2019 / version 13 and above) Chrome (after Jan 2019 / after version 72.0.3626)

c. Client device specifications

Desktop	Recommendations
CPU	8th Gen Intel Core i5
RAM	8 GB DDR3
Storage	128 GB
OS	Windows 10, macOS Catalina
Android phone	Recommendations
CPU	4 core @ 2.7 GHz +
RAM	4GB+
Storage	64GB+
Screen resolution	1440 x 2960 (18.5:9 ratio)
OS	Android 8+
Tested devices	Samsung Note 9, Samsung S9
Apple phone	Recommendations
CPU	Apple A12+ (Max. Clock rate 2.49 GHz+)
RAM	3GB+
Storage	64GB+
Screen resolutions	1792 x 828p (326ppi)
OS	iOS 12+
Tested devices	iPhone XR, iPhone 11

Apple iPad	Recommendations
CPU	Apple A10+ (Max. Clock rate 2.32 GHz+)
RAM	2GB+
Storage	32GB+
Screen resolutions	2048 x 1536px (264ppi) with a 4:3 aspect ratio
OS	iOS 13.3+
Tested devices	iPad 6th Generation

The NVI system will require the following network ports to be reserved for system component communication which can be configured by the users if required:

1. 29001: IAM service that will accept requests and respond on this port for functions related to user authentication and management
2. 8500: Consul framework that is a DNS-based service discovery software which will monitor what services are running
3. 49680: Client service which will receive and handle requests from the browser related to study viewing and handling.
4. 49682: Pacemaker service which is used for load balancing
5. User-defined ports to allow Dicom image receival from Dicom nodes
6. 49696 and 49697: TCP communication between client and server services
7. 443: Enable SSL communication for HTTPS and WSS access
8. Other customer-specific ports will need to be opened to allow for DICOM study pushes

8. Clinical Module DICOM requirements for Algorithm Processing

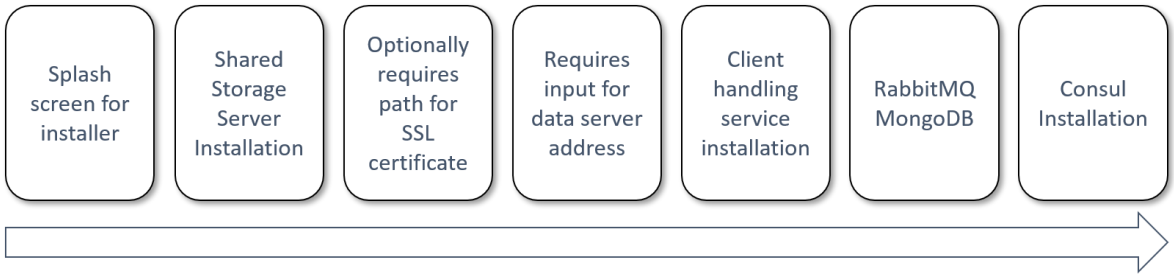
IMPORTANT: For accurate processing by the Artificial Intelligence (AI) algorithms, StrokeSENS requires DICOM standard CT images of the head that align with the following parameters

Non-contrast CT for ASPECTS Scoring
1. ImageType = Original/Primary
2. Volumes = 1
3. WindowWidth < 210
4. SliceThickness >= 2.5 mm & <= 5mm

CTA for LVO Detection
1. Volumes = 1
2. WindowWidth > 210 & <= 1000
3. SliceThickness <= 2.5 mm

9. Installer workflow

The StrokeSENS installer comes packaged with all software which will be needed to successfully complete the installation process. No additional software will need to be installed before or after running the installer. The installer follows the workflow in the diagram below:

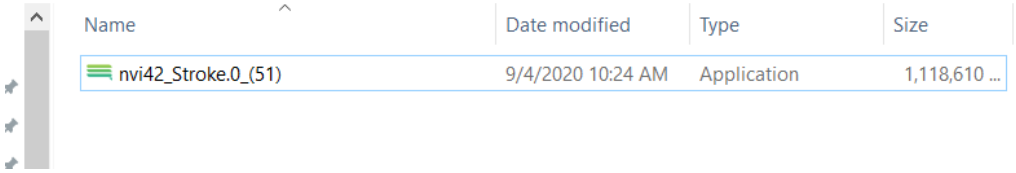


Upon the completion of the installer workflow the following services will be registered as windows service: data server, worklist daemon service, Consul service, RabbitMQ, MongoDB, log service, web client service, and Nginx. While the rest will be deployed as executable files and bootstrapped during the application's workflow.

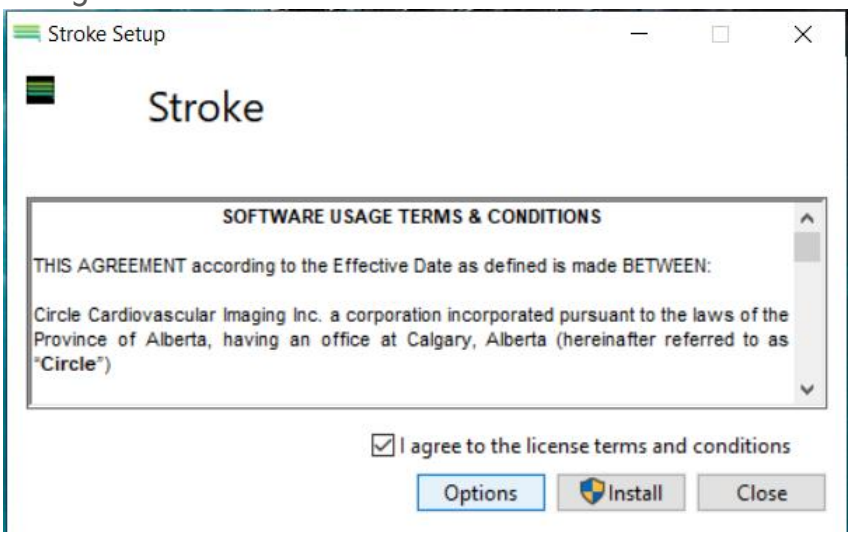
10. Installation Process

The installation .exe file should be saved to the server on which StrokeSENS will be installed. It can be run from any location. The resultant files will be installed to Program Data\cvi42. All additional config files can be found in this directory.

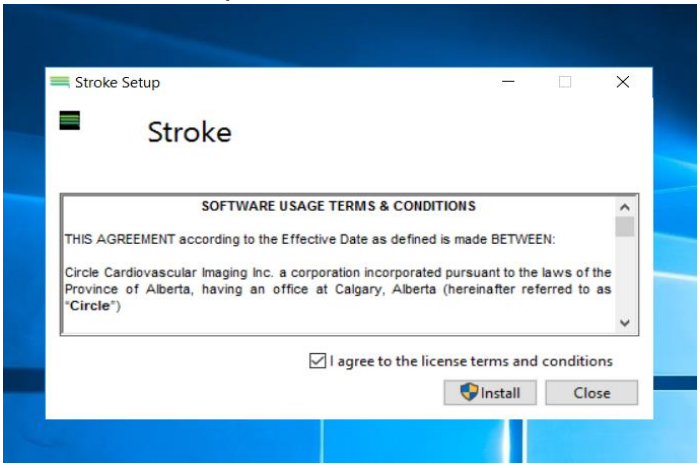
1. Run the installer – This will be the .exe file which was obtained from Circle NVI.



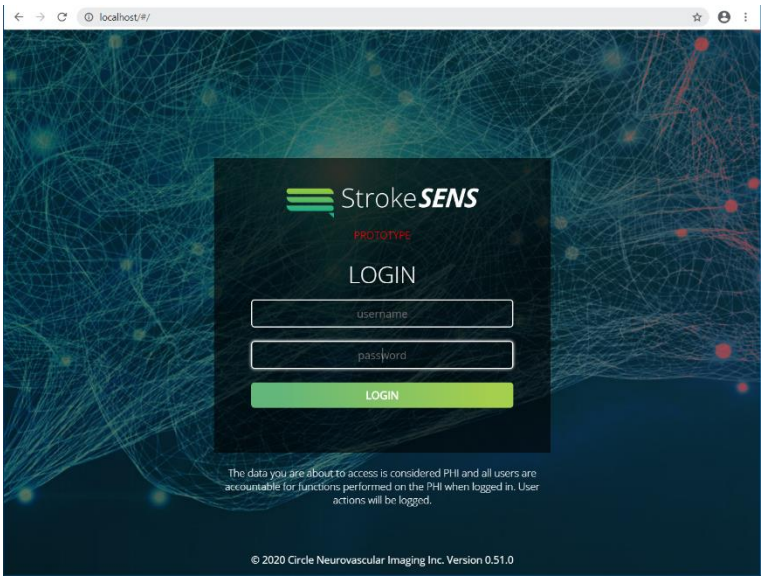
2. Select the install location for the software using the “Options” button. This will be the location for all program files as well as the initial image storage location.



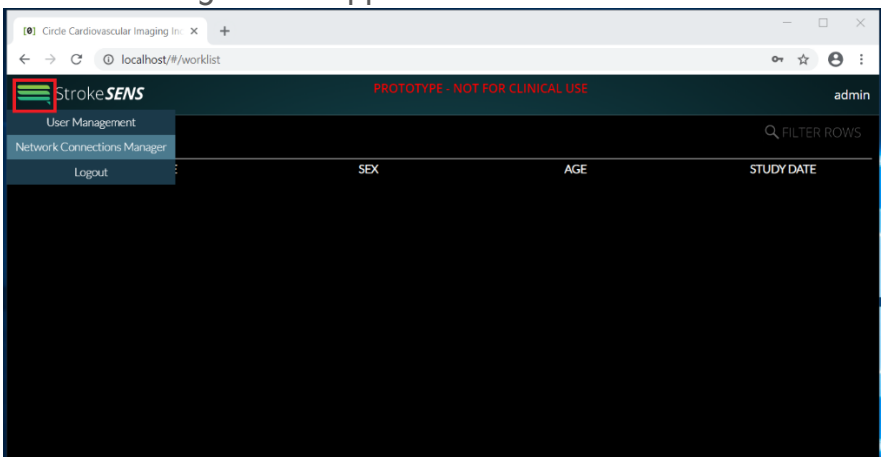
3. If you agree to the license terms and conditions, then check the box, and click “Install” to proceed with the installation.



4. After the installation finishes, you can access the admin interface through a web browser at http://<servername>. By default, the web service will be running on port 80. Initial login credentials will be provided by Circle NVI technical solutions.



5. After logging in, you can manage local users and DICOM connections through the options menu which is accessed by clicking on the StrokeSENS logo in the upper left corner of the site.



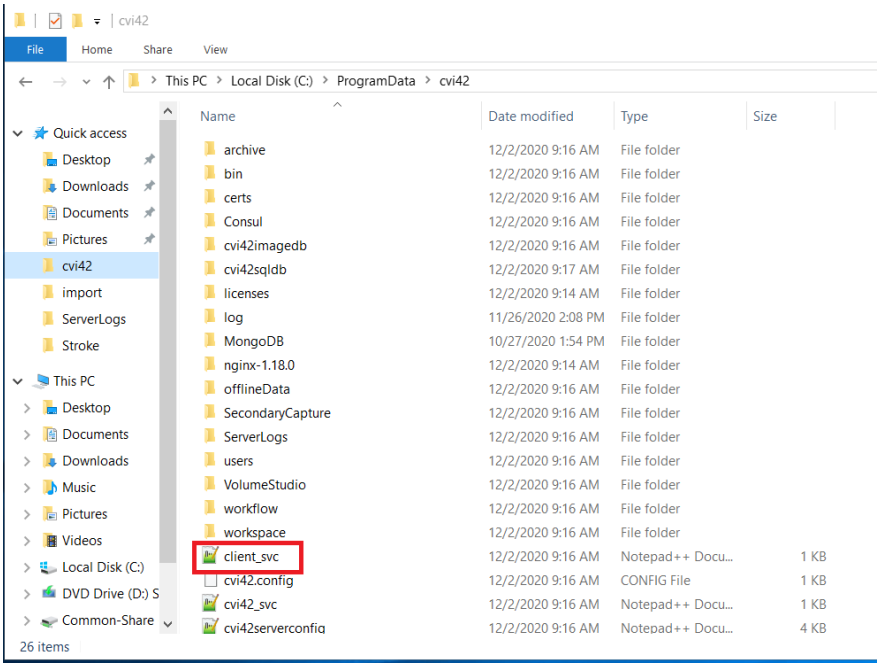
6. Local users can be added or removed through the User Management interface.

7. DICOM network connections and StrokeSENS DICOM listener settings can be modified from the Network Connections Manager interface.

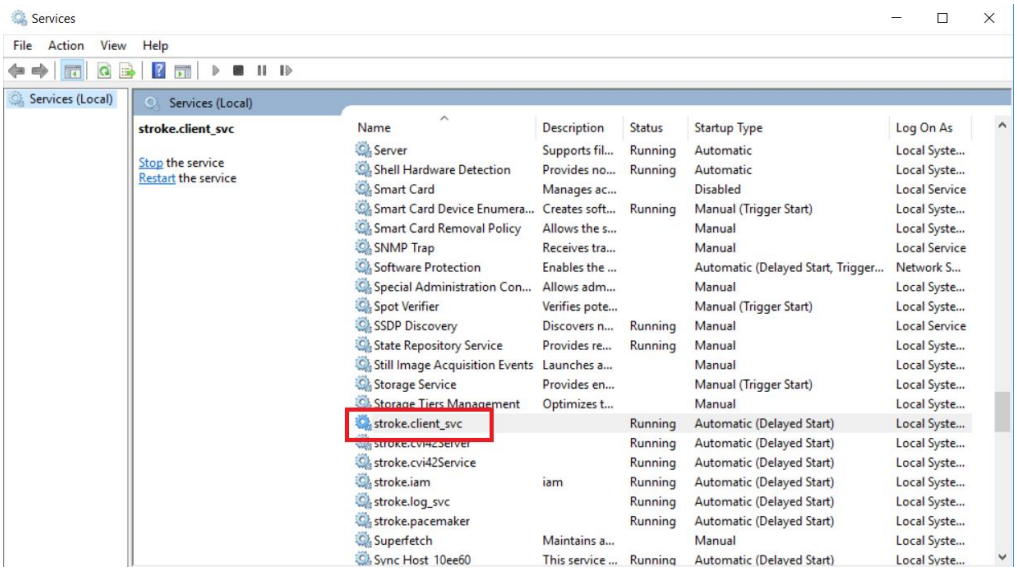
   Use “Edit Network Settings” to modify the StrokeSENS DICOM listener.

   Click on “+Add” to add new DICOM nodes which can push to StrokeSENS.

8. Additional configuration options, including those for setting up email notifications can be found in the client_svc.ini file in the Program Data\cvi42 folder.



9. After modifying any settings within the client_svc.ini file, the StrokeSENS client service will need to be restarted. You can find this in the windows services list as stroke.client_svc.



11. Post-installation user roles, DICOM network configurations, and email configuration

StrokeSENS v1.0 defines two roles that can be assigned to user accounts. (to do: attach screenshots, for add user, assign roles, deleting users, etc.)

Users with Admin permissions can set up the configuration for DICOM networking/PACS connections.

Email services can be setup with support from a Circle NVI Installation Support staff. The email list is configured and maintained by the on-site administrator.

12. General troubleshooting

Users can view audit level, error, and debug logs via Metabase, and the logs maintained in the cvi42 folder on the filesystem.

13. Additional Documentation

In addition to the StrokeSENS software installer, a package of accompanying documentation is also provided as a .zip archive. The documentation package includes the following documents:

- User Manual
- DICOM Conformance Statement
- Release Notes
- Installation Guide
- Software Usage Terms & Conditions