StrokeSENS Software Installation Guide

Version 1.3

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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

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.

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.

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

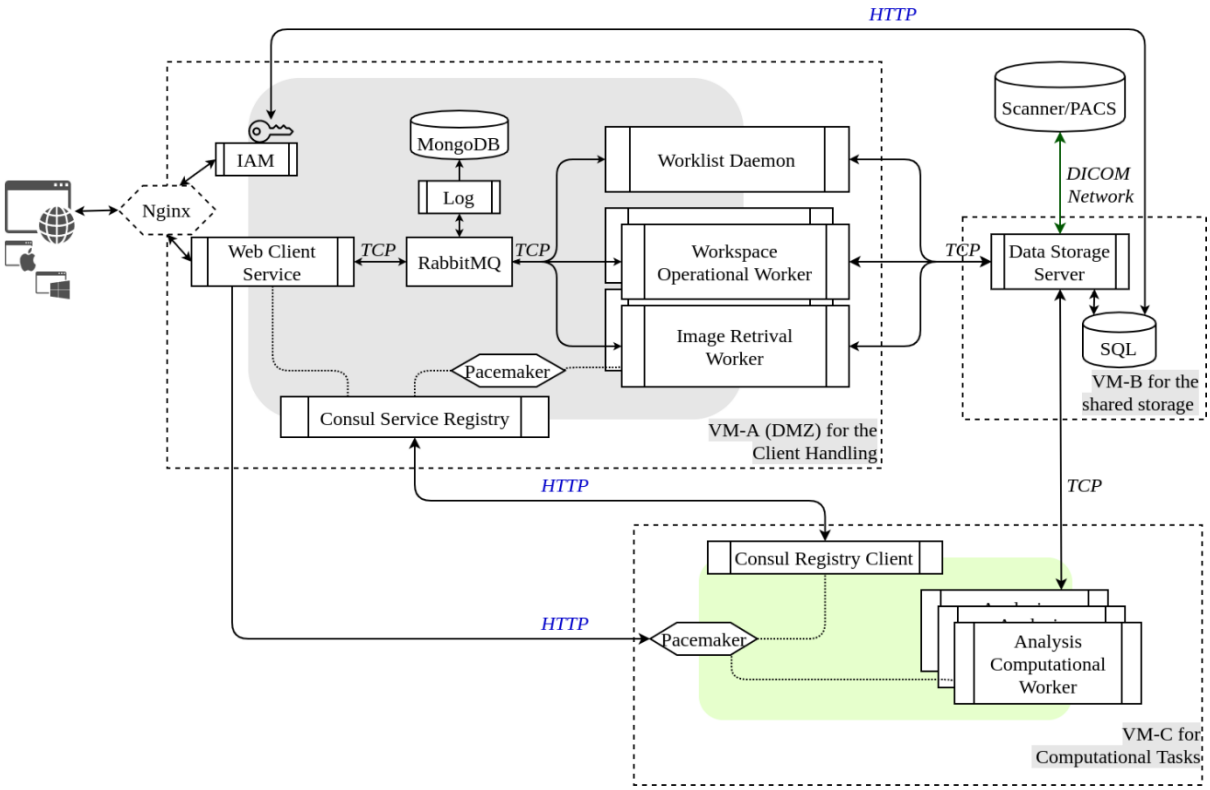
MongoDB service (3rd party)
- stores log data

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



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 (or greater) 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 (or better) 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

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

c. 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+)

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

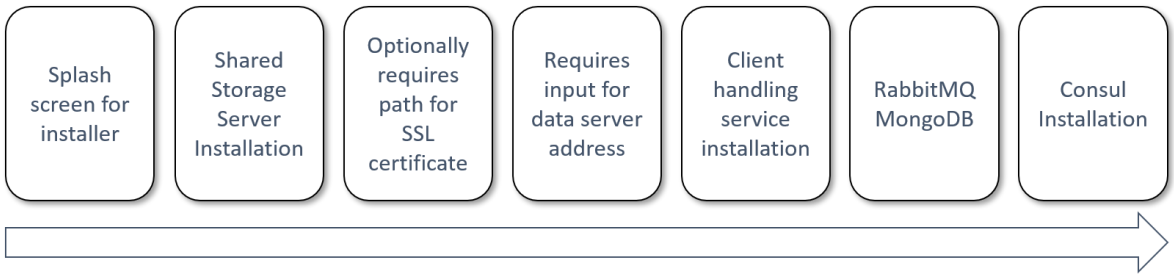
NOTICE: StrokeSENS was trained and tested with datasets acquired with the following parameters listed below. For accurate processing by the Artificial Intelligence (AI) algorithms, StrokeSENS requires DICOM standard CT images of the head that align with the following parameters

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

CTA for LVO Detection
1. ImageType = Original/Primary
2. Modality=”CT”
3. Volumes = 1 *a multi-volume CTA (i.e. multi-phase CTA) is acceptable. Only the first phase is used for processing.
4. WindowWidth > 210 & <= 1170 *Criteria used in the automatic detection of contrast-enhanced images.
5. SliceThickness <= 3.0 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:

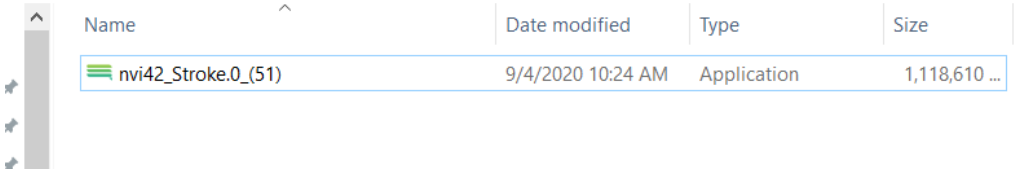


Upon the completion of the installer workflow the following services will be registered as windows service: data server, worklist daemon service, Consul service, RabbitMQ, MongoDB, log service, web client service, and Nginx. While the rest will be deployed as executable files and bootstrapped during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

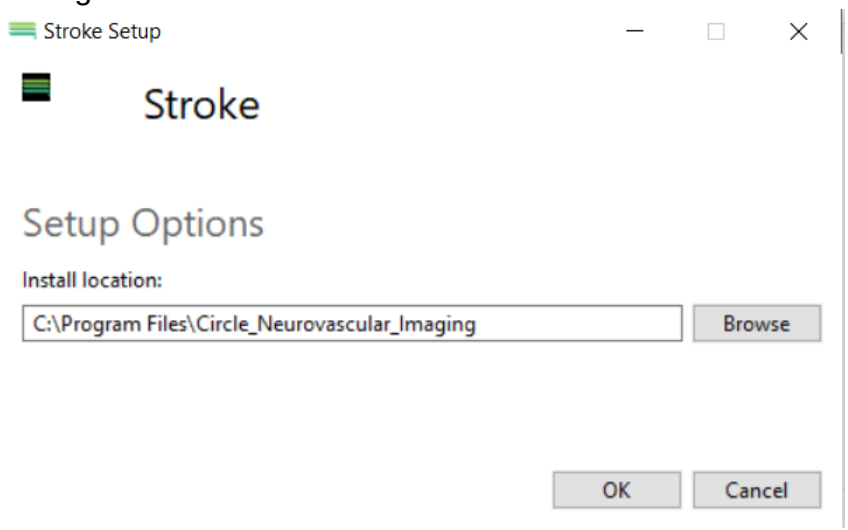
10. Installation Process

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.

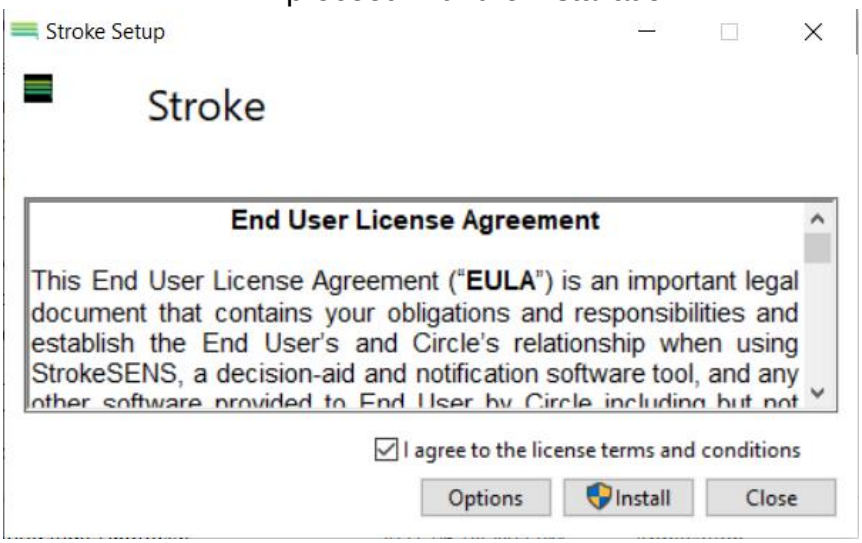
1. Run the installer – This will be the .exe file which was obtained from Circle NVI.



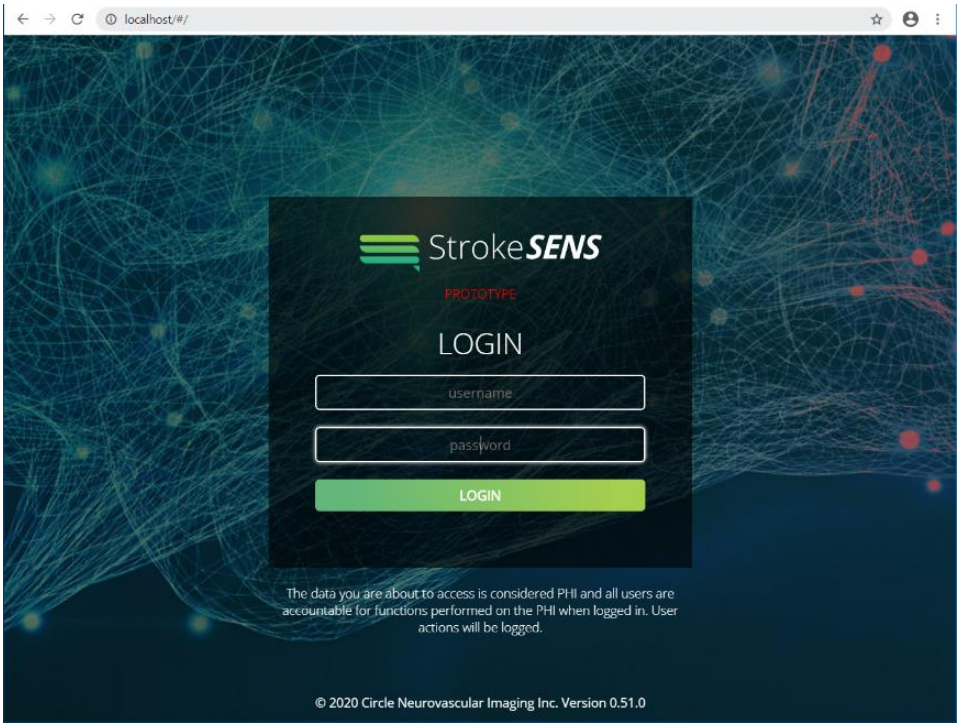
2. Select the install location for the software using the “Options” button. This will be the location for all program files as well as the initial image storage location.



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



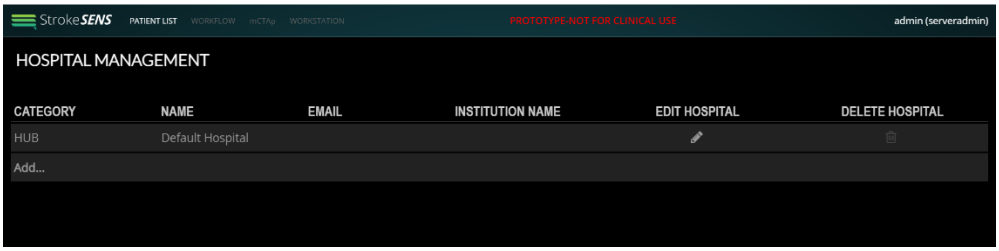
4. After the installation finishes, you can access the admin interface through a web browser at http://<servername>. By default, the web service will be running on port 80. Initial login credentials will be provided by Circle NVI technical solutions.



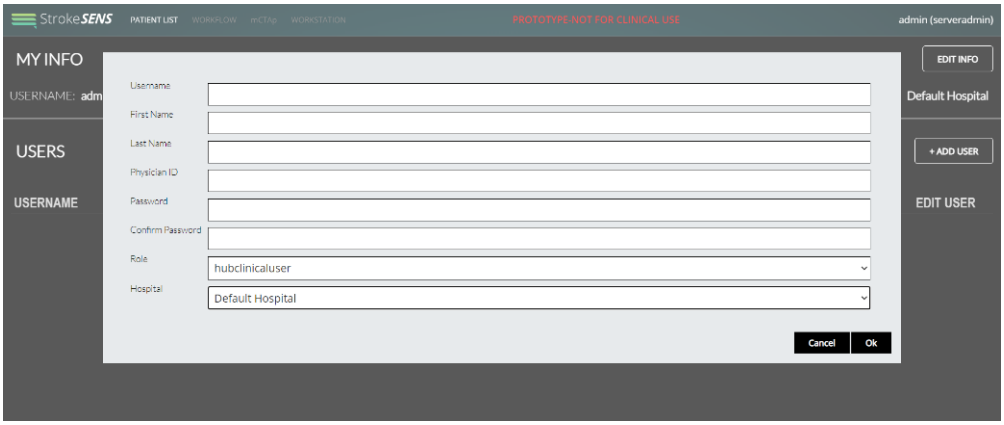
5. After logging in, you can manage local users, hospitals, and DICOM connections through the options menu which is accessed by clicking on the StrokeSENS logo in the upper left corner of the site.

6. For installations which will be accessible to a multi-hospital network, additional sites can be managed from the Hospital Management interface.

   Additional hospitals will need to be added through this interface before local users for those sites are created in the User Management interface.



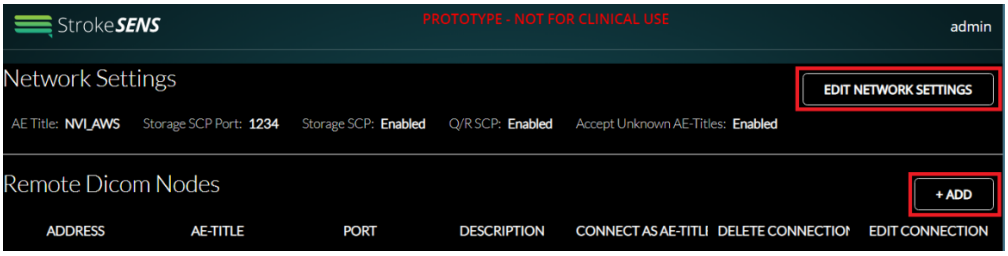
7. Local users can be added or removed through the User Management interface.



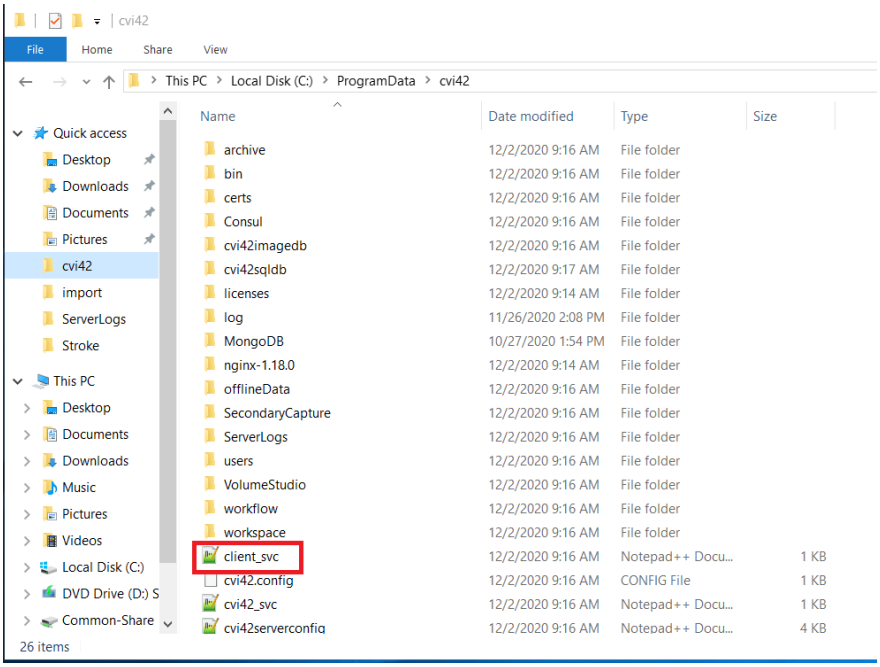
8. DICOM network connections and StrokeSENS DICOM listener settings can be modified from the Network Connections Manager interface.

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

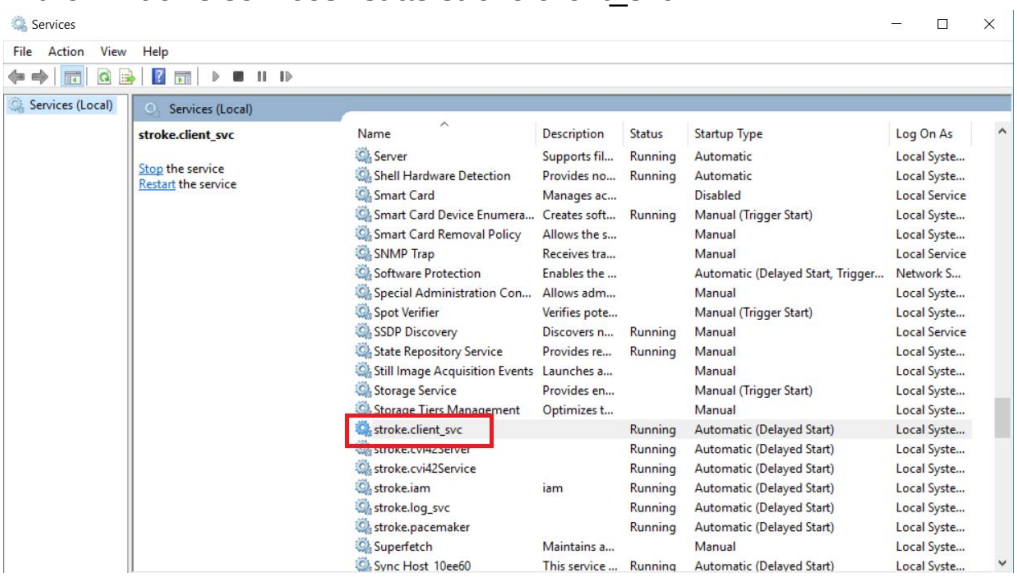
   Click on “+Add” to add new DICOM nodes which can push to StrokeSENS.



9. 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.



10. 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. General troubleshooting

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

12. 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