

Automated Stroke Imaging Software Package (Ischemaview RAPID) Implementation Frequently Asked Questions and Lessons Learned July 2020

Introduction

This resource is made available by CorHealth Ontario on behalf of the Regional Stroke Networks that have experience with implementing this Automated Stroke Imaging software. The purpose of the resource is for sharing learnings and support others who may be interested in using similar software, not to provide evidence based best practice recommendations. This resource was developed by a collaboration of the Central South, Southwest and Southeast Stroke Networks. This resource represents Ischemaview RAPID implementation experience only and that other software manufactured by different vendors may be available or considered.

Background:

Two recent endovascular thrombectomy (EVT) research studies, DAWN² and DEFUSE3³, evaluated the effect of EVT in patients presenting between 6 and 24 hours of stroke symptom onset. These trials identified patients eligible for EVT based on CT or MR perfusion (CTP/MRP) with software to identify the mismatch between infarct core and ischemic penumbra volumes. Patients with no or minimum infarct and large area of ischemic penumbra would be potential EVT candidates. Both trials found that a significantly higher proportion of patients identified by this imaging method achieved increased functional independence at 90 days compared to the control group (49% versus 13% and 44.6% versus 16.7%) with no significant increase in symptomatic hemorrhage at 24 hours.^{2,3}

Based on these trials, the Canadian Stroke Best Practice Recommendations for Acute Stroke Management were updated in 2018¹ to indicate that **highly selected** patients with disabling stroke symptoms may benefit from EVT **up to 24 hours from the time they were last known well** (Evidence Level A). Sites should select potential patients using CTP or MRP with automated imaging software package that provides reproducible objective quantifiable measurements of infarct core and ischemic penumbra.

Frequently Asked Questions (FAQ's):

What is an Automated Imaging Software Package for Stroke?

- It is a fully automated image processing software application package that allows for quick visualization and analysis of brain physiology that runs from a standard computer.

What are the Benefits of an Automated Imaging Software Package?

- Provide clear, easy to interpret perfusion maps which accurately quantifies reduced cerebral blood flow, volume and transit time that can be viewed by computer or mobile device.
- Support timely, standardized interpretation of the perfusion imaging to assist with rapid clinical decision making and patient triage.
- Support communication and collaboration between referring sites and EVT centres.
- Facilitate appropriate patient transfer to EVT treating centres and eliminate unnecessary transfers.

How can the Automated Imaging Software Package be implemented?

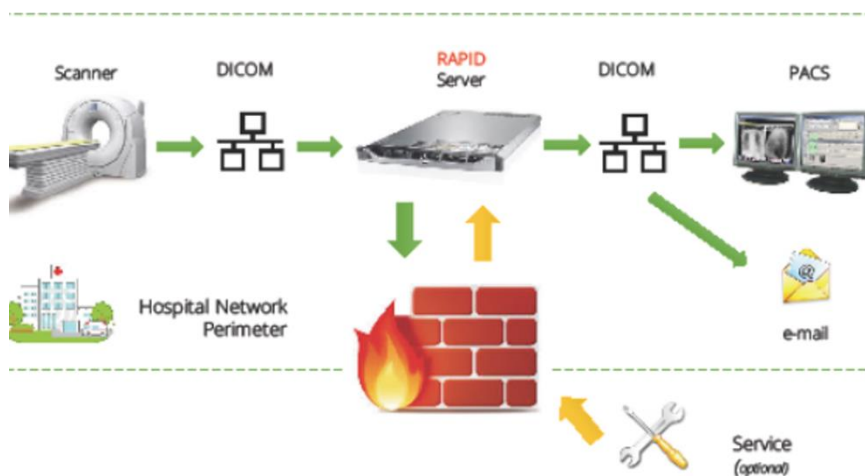
- Single Site (Hub) Model.
- Hub and Spoke Model.

How does the Automated Imaging Software Package work at a Single Site (Hub) model?

- Automated Software Package application is loaded onto a local server that is housed behind the organization firewall.
- CT/MR scanner and PACS modalities are connected to the server.

- CT/MR images are sent to the automated software server through DICOM connections from the scanners.
- Size of data source coming into the server ranges from 300 MB to 3GB depending on make and model of scanners.
- Automated server takes raw CT, CTP, CTA images and created a quantifiable output within 30 seconds to 2 minutes
- Automated server pushes processing results to PACS and ENITS for viewing and storage by a computer or mobile device.
- Size of results pushed to PACS are 3 MB to 7MB depending on make and model of the scanner.
- De-identified emails can be sent to local Stroke Neurologists/Physician, Radiologists and NeuroInterventional Physicians/Interventional Radiologists at Hub Site.
- All data is purged from server after processing at a pre-established timeframe.

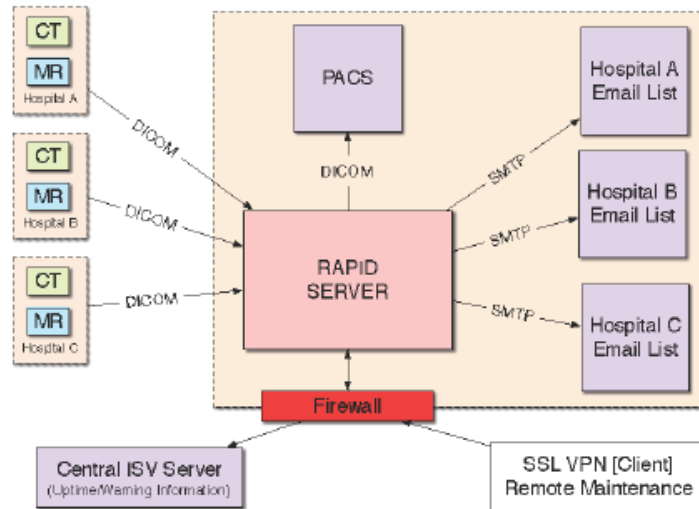
Automated Imaging Software Single Site (Hub) Work Flow⁴



Automated Imaging Software Hub and Spoke Model Work Flow

- Single server installed behind the firewall of one organization which is shared by all sites.
- CT scanners at each spoke sites are configured to push images through a DICOM connection through a dedicated E-Health Tunnel that is unique to each site to the centralized server.
- Size of data source coming into the server ranges from 300 MB to 3GB depending on make and model of scanners.
- Automated server takes raw CT, CTP, CTA images and created a quantifiable output within 30 seconds to 2 minutes.
- Server pushes processed results back through dedicated E-Health Tunnel through a DICOM connection to the appropriate local spoke PAC system for viewing and storage.
- Server routes the results to ENITS for viewing by Telestroke Physician or Local Stroke Neurologists and NeuroInterventional Physicians/Interventional Radiologists.
- Size of results pushed to PACS are 3 MB to 7MB depending on make and model of the scanner
- De-identified emails can be sent to local spoke stroke team and to the consulting Stroke Neurologists and NeuroInterventional Physicians/Interventional Radiologists at Hub Site.
- All data is purged from server after processing at a pre-established timeframe.

Automated Imaging Software Hub and Spoke Work Flow⁴



What are the Differences between a Single Site (Hub) Model and a Hub and Spoke Model?

Parameter	Single Site (Hub) Model	Hub and Spoke Model
Cost	<ul style="list-style-type: none"> - Server Installation Cost. - Annual Hub Licensing Fee. - One Time Set up and Training Fee. - Unlimited scans on primary scanner. - Limited number of scans on back up scanner. 	<ul style="list-style-type: none"> - Shared Server Installation Cost. - Shared One Time set up fee and training. - Annual Hub Licensing Fee. - Reduced Annual Licensing Fee for Spoke sites (e.g. potential reduction in cost of 40% per license). - Hub and Spoke sites have unlimited scans on primary scanner and limited scans on back up scanners.
Required Connection	<ul style="list-style-type: none"> - None. 	<ul style="list-style-type: none"> - Recommended Bandwidth is 1 GB/second. - Minimum connection required is 100 MB.
IT Security Requirements	<ul style="list-style-type: none"> - Review and approval of software architecture by ICT Security Team. 	<ul style="list-style-type: none"> - Review of software architecture by ICT Security Team. - External Threat Risk Assessment by external provider required.
Privacy Requirements	<ul style="list-style-type: none"> - Privacy Impact Assessment to be completed. 	<ul style="list-style-type: none"> - Privacy Impact Assessment to be completed.
Procurement Requirements	<ul style="list-style-type: none"> - Advanced Contract Award Notice (ACAN) posted for 25 business days prior to purchase. 	<ul style="list-style-type: none"> - Advanced Contract Award Notice (ACAN) posted for 25 business days. - The Ministry of Health requires procurement contracts over \$100,000 to be submitted for approval prior to entering into the

		contract. This Ministry of Health approval process can take up to 90 days.
Data Sharing Agreement	- Not required.	- Required between Hub and Spoke Sites.

What are the Essential Elements for Implementation of the Automated Imaging Software Package?

Stakeholder Engagement

In order to implement access to Automated Imaging Software Package across multiple sites with a centralized server at a hub-site, numerous departments and programs are required to be engaged in the process to ensure appropriateness and safety of the implementation.

The timelines for each of the Stakeholder Agreement can vary depending on the model. For a Single Site (Hub) Model the timelines from initial identification of the project to implementation can range from 3 to 6 months while for a Hub and Spoke Model this timeline can range from 6 to 9 months.

The table below outlines the possible programs/departments and possible roles each may play in the project. The lead roles may vary depending on the organizations involved and the type of Automated Imaging Software Package Model implemented.

Department/Program	Possible Role
Senior Leadership at Hub Site	Approve/Sponsor the Project.
Physicians	Endorse/Advocate for Project. Facilitate Education of partner sites.
Regional Stroke Team	Coordinate/support the team(s) involved in the implementation of the automated software package. Engage local stakeholders at EVT/Hub site. Engage regional stakeholders at Referral/Spoke sites.
Procurement	Take required steps to appropriately acquire automated software package.
Finance	Work with various departments and programs to secure appropriate funding for project.
Information Technology (IT) Security	Take required steps to ensure security of software and software architecture are appropriate.
Information Technology (IT)	Establish and test connections between sites for Hub and Spoke Model. Project manage installation from technical standpoint.
External Information Technology (IT) Security Company	To complete an independent Threat Risk Assessment of the Automated Imaging Software Package.
Privacy	Ensure the automated software package meets PHIPA privacy standards. Facilitate completion of Privacy Impact Assessment. Connect with privacy departments at partner sites for alignment for Hub and spoke Models.
Legal/Risk Management	Review and provide feedback on contract language. Create Data Sharing Agreement for partner sites for Hub and Spoke Models.
Diagnostic Imaging	Support/lead the local implementation of the automated software package with assistance with the Vendor Project Manager.

	Ensure compatibility of software with hospital equipment Implementation and testing of new imaging protocols. Education and Training of Technologists on Brain CT Perfusion imaging if site not previously doing Brain CT Perfusion imaging.
PACS Coordinator	Sets up the connection for the images to be sent to PACS for viewing and storage. Assist with project implementation.
Partner Referral tPA Centres for Hub and Spoke Models	Engage their local teams (Senior Leadership, Physicians, IT Security Team, IT Department, Privacy, Legal, Finance Diagnostic Imaging, and PACS Coordinator). Facilitate implementation of new protocols.
ENITS	Ensure connections to ENITS is established so Telestroke Physicians and EVT Centre Stroke Neurologists and NeuroInterventional Physicians/Interventional Radiologists are able to access appropriate imaging for clinical decision making in a timely fashion.
Vendor	Will assign a Project Manager to support the Automated Software Program implementation.

Automated Imaging Software Program Implementation (4 to 6 weeks/site)⁵

Establish a project implementation task group comprised of Diagnostic Imaging, Information Technology, Stroke Neurologists, Radiologists, NeuroInterventional Physicians/Interventional Radiologists, Regional/District Stroke Team, the vendor and other stakeholders as required.

If implementing a Hub and Spoke Model, it is recommended to do a staggered implementation at the Hub site and then rolling out to Spoke Sites.

Initial Project Implementation Meeting:

- Organize an initial meeting with all key stakeholders to outline the Project Plan.
- For Hub and Spoke Models, there needs to be a Kick Off meeting at each spoke site.
- Complete Questionnaire to provide key stakeholder contact information and scanner, IT/Network, PACS information.
- Ensure clinical protocols are in place.

Server Installation:

- Install and configure Server at Hub site.

Scanner, PACS, ENITS and Email Setup:

- Add DICOM connection to required Scanners by external vendors to send images to Server.
- Set up and Configure PACS to receive outputs from Server.
- Set up and configure DICOM connection from RAPID Server to ENITS to send non-contrast CT Head, RAPID CT Perfusion Images including RAPID CT Perfusion Summary, tsMIP series, rCBV series, AIF/VOF series, and CTA.
- Determine if Email option will be utilized and set up email distribution list.
- Determine if application will be placed on mobile devices.

Imaging Protocol and Optimization:

- Expanded Window protocol includes the completion of CT, CT Perfusion, CTA.
- Set up CTP Protocols on scanners.

- Send Test scans to Server for test scanning and that results are displayed in PACS.
- Server Technical Team to review and make recommendations to optimize protocols on local scanners.

Training:

The training for implementation of the automated software package may involve a combination of online webinars and/or in person Vendor Hosted session.

- Stroke Neurologists/NeuroInterventional Physicians/Interventional Radiologists and Radiologists:
 - o Clinical Training regarding the automated software outputs, basic and advanced CTP image interpretation and recognizing artifacts or trouble shooting.
 - o Reviewing local clinical protocols.
 - o Follow-up meeting after implementation to review individual cases and discuss complex clinical scenarios.
- Technical Training for CT/MR Technologists :
 - o Vendor Training on CT Perfusion if not previously doing CT Perfusion Brain Scans.
 - o Clinical training regarding automated software outputs, Stroke CTP Protocol, IV placement and recognizing artifact and trouble shooting.
 - o Reviewing local clinical protocols.
- Emergency Department Physicians and Nursing Staff
 - o Reviewing local clinical protocols

Lessons Learned during Training:

- Have an end-user(s) of the system be involved in training and education.
- Test the system including ENITs link before going live.

Down Time Protocol:

- As the automated software is not a redundant system, if the system/software is down for any reason, it is essential for a downtime protocol to be in place.
- Imaging Protocol at referring sites (Hub and Spoke Model) would revert back to Provincial Stroke CT/multiphase CTA Protocol.
- The Telestroke Physician and/or Local Stroke Team would make case by case decisions regarding the patient's eligibility for EVT in the expanded window.
- Establish a downtime notification system between the Hub and Spoke Sites so that all sites are aware the server is down and to implement Provincial Stroke CT/mCTA Protocol.

Troubleshooting Issues in Real Time

- The automated software package vendor provides a 24/7 Technical Support Phone and Email Address that quickly responds to troubleshoot any in-the-moment issues with the image quality or difficulty understanding software output.
- It is important that the physicians, radiologists and CT Technologists are aware of this line so that any issues can be responded to quickly.

Quality Improvement and Monitoring

- It is important to link this implementation particularly at the outset of the new model/process to an established Hyperacute Stroke/Endovascular Therapy Committee that meets regularly. This would allow any quality issues to be brought forward in a timely manner and troubleshooting to be completed quickly.
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References

1. Boulanger, J.M., et al. (2018) Canadian Stroke Best Practice Recommendations for Acute Stroke Management: Prehospital, Emergency Department and Acute Stroke Inpatient Stroke Care, 6th Edition, Update 2018. *International Journal of Stroke*. July 18, 2018: 0 – 36. DOI: <https://doi.org/10.1177/1747493018786616>.
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3. Albers, G.W. et al for the DEFUSE 3 Investigators (2018) Thrombectomy for stroke 6 to 16 hours with Selection by Perfusion Imaging. *The New England Journal of Medicine*. February 12, 2018. DOI: 10.1056/NEJMoa13973.
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