NICOLAB

Instructions for Use

StrokeViewer Perfusion

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1. Introduction

Welcome to the StrokeViewer Instructions for Use. Before using StrokeViewer, read the Instructions for Use, especially the Section "2. Safety".

1.1. About these Instructions for Use

These Instructions for Use are intended to assist you in the safe and effective use of StrokeViewer.

The product can be identified via the information provided in the DICOM summary report or the command line interface (CLI; in case of manual deployment). This information can be used to identify for which software tools the Instructions for Use are intended (please consult the installation and configuration manual for more information).
The full labeling information of the device is presented in Section "1.2. Label of StrokeViewer". The DICOM summary report will contain the following information:

- Name of the device
- Manufacturer name
- Contact information
- Unique Device Identifier (UDI)
- URL to the webpage where the Instructions For Use can be accessed.

Before using the product, you must read these Instructions for Use, noting and strictly observing all **WARNING** and **CAUTION** notices. Important safety information is provided in the following manners:

	**WARNING**
	A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the patient.

	**CAUTION**
	A caution alerts you when special care is necessary for the safe and effective use of the device. Failure to observe a caution may result in moderate injury to the operator or patient, or damage to the equipment, and presents remote risk of more serious injury or environmental pollution.

NOTE	*A note highlights unusual points to assist you when using the device.*

1.2. Label of StrokeViewer

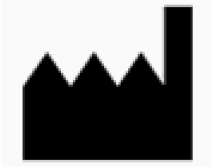
The information provided in this Section gives an overview of the information needed to identify and correctly use the device. Please make sure you read and fully understand this Section. For explanation on the symbols used, please consult Section 8, Symbols Glossary.

Product	StrokeViewer Perfusion
Major system version	4
	Product or trade name: StrokeViewer Model/Versions: StrokeViewer Perfusion, Version 4 Product Classification: 10005844 GTIN: 8720299502352 
	Initial release: 2024
Intended Purpose	StrokeViewer is an image processing software application that analyzes CT scans of the brain to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients. StrokeViewer provides this information to the user to include it as additional data to interpret and analyze CTP scans of suspected stroke patients for the adult population. There is no change to the standard of care assessment of suspected stroke patients where the healthcare professional assesses the medical images. StrokeViewer only provides additional imaging data and numerical data that may be taken into consideration by a healthcare professional. StrokeViewer is not intended to be used as a standalone diagnostic tool, and StrokeViewer output should always be interpreted in the context of clinical information about the patient rather than in isolation.
	Please consult the Instructions For Use for important cautionary information and instructions for use.

MD

⚠	**CAUTION**
	Federal law restricts this device to sale by or on the order of a physician (21 CFR 801.109(b)(1)).

Manufacturer and Contact



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To request support, please call +31 20 244 0852 or e-mail to support@nicolab.com. To request paper copies of the instructions for use, please e-mail to support@nicolab.com.

No special handling and/or storage conditions apply.

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6/505 Little Collins Street, Melbourne, Victoria, 3000 Australia (AU)

Sponsor New Zealand

NICOLAB NZ Limited
NZBN: 942905651443
1/50 Customhouse Quay, Wellington, 6143, New Zealand (NZ)

1.3. Electronic Instructions for Use

These Instructions for Use are available to view in PDF file format. The Instructions for Use can be opened by copying the URL from the DICOM report (or CLI; in case of manual deployment) into the address bar of your browser. After that, an internet page appears that provides you information on minimum requirements to be able to access the Instructions for Use. On this page you will have access to the current version of the Instructions for Use.

NOTE	*Downloaded versions of the Instructions for Use may be outdated, please use the URL provided in the label to have access to the latest version of the Instructions for Use.*

NOTE	*Translations of the Instructions for Use are available via the same URL. Printed versions of this Instructions for Use can be made available on request. Please contact the manufacturer to request printed Instructions for Use.*

NOTE	*Please ensure that you are using a compatible web browser, such as Google Chrome, Microsoft Edge, Mozilla Firefox, Apple Safari or any other browser that supports reading PDF documents, in order to access and view the electronic Instructions for Use.*

1.4. User Training

Users of StrokeViewer must have received adequate training on its safe and effective use before using StrokeViewer as described in this Instructions for Use. Users should ensure that they receive adequate training in accordance with local laws and/or regulations. As a minimum level of training, users should read and understand these Instructions for Use.

NOTE	*Do not use the product in clinical practice until you have met the following conditions:* • *You have read, understood and know all the safety information contained in Section 2, Safety.* • *You have received adequate training in the safe and effective use of Strokeviewer's output. If you are unsure of your ability to use the output in a safe and effective manner, do not use it.* • *You have received adequate training on retrieving information from StrokeViewer (e.g., event logs, termination of analysis, Unique Device Identifier Production Identifier (UDI-PI) retrieval).*

For more information about the application training, please contact Nicolab (see Section "1.5. Contacting the Manufacturer").

1.5. Contacting the Manufacturer

You can get in touch with the manufacturer via different contacting channels, e.g., e-mail, telephone, or post:

NICo-Lab B.V.
Address: Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands (NL)
E-mail: support@nicolab.com
Telephone: +31 20 244 0852

2. Safety

All Nicolab products are designed to meet stringent safety standards. In order to protect patient safety, all medical device software should be installed, used and maintained properly. In order to use the product safe and effectively, it is necessary to understand and follow all the **WARNINGS** and **CAUTIONS** provided in these Instructions for Use. Only authorized and qualified personnel may use this device. In addition to the generic safety warnings / cautions presented in this Section, algorithm specific warnings/cautions are explained in the algorithm specific sections of this Instructions for Use.

	**WARNING**
	The results obtained should only be used to support clinical decision-making made by a physician.

	**WARNING**
	Strong motion or metal artifacts might lead to incorrect results.

	**CAUTION**
	Because StrokeViewer is a medical device, it is imperative that you fully understand the information provided in these instructions for use before you start using the product.

	**CAUTION**
	In case of StrokeViewer malfunctions or processing is delayed, it is imperative that you continue the usual clinical workflow. StrokeViewer is intended to be used in parallel to the usual clinical workflow and should not delay clinical decision-making.

	**CAUTION**
	Please make sure you have access to processing information when using StrokeViewer. The processing information will provide you with the notification of whether the processing is done, failed or prematurely terminated.

	**CAUTION**
	Make sure that image requirements as defined in the Annex (see Section "10. Annex") are met when providing imaging to StrokeViewer. When these requirements are not met a message might be presented to the user.

	**CAUTION**
	Please refrain from running StrokeViewer while an update is in progress. Running StrokeViewer during an update can interrupt the analysis and potentially cause the update process to become corrupted.

NOTE	*Features will be available for use when enabled for your hospital. This implies that not all algorithm results might be available for you as only a subset of the algorithms might be enabled for your hospital. Please contact your system administrator for more information on which algorithms are enabled.*

NOTE	*Paper printouts with StrokeViewer output should not be used for diagnosis unless the used Postscript printer has specifically received clearance for this purpose.*

2.1. Information Security

Access to the StrokeViewer application is arranged via your system administrator. Please contact your system administrator for access to the StrokeViewer application. The application can be accessed via your regular authentication workflow and you will then have access to the application as an authenticated user. Additional Information Security documentation can be provided upon request, please contact the Manufacturer (see Section "1.5. Contacting the Manufacturer").

	**CAUTION**
	Unauthorized access to the system may lead to the system becoming non-operational and the loss of patient data. Please contact the manufacturer for information about minimum system requirements .

2.2. Reporting of a serious incident

In the case a serious incident occurs in relation to StrokeViewer, it should be reported to the manufacturer and the competent authority of the country where you are located.

A serious incident can be defined as any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person,
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- a serious public health threat.

If a serious incident happens, please contact the Nicolab office (see Section "1.5. Contacting the Manufacturer") without undue delay. Nicolab might contact you for additional information.

3. Intended Purpose

StrokeViewer is an image processing software application that analyzes CT scans of the brain to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients.

StrokeViewer provides this information to the user to include it as additional data to interpret and analyze CTP scans of suspected stroke patients for the adult population. There is no change to the standard of care assessment of suspected stroke patients where the healthcare professional assesses the medical images. StrokeViewer only provides additional imaging data and numerical data that may be taken into consideration by a healthcare professional. StrokeViewer is not intended to be used as a standalone diagnostic tool, and StrokeViewer output should always be interpreted in the context of clinical information about the patient rather than in isolation.

3.1. Indications for Use

StrokeViewer Perfusion is an image processing software package intended to provide quantitative perfusion information in brain tissue for suspected ischemic stroke patients. It is to be used by medical imaging professionals who analyze dynamic perfusion studies, including but not limited to physicians such as neurologists, and radiologists.

The software is packed as a Docker container allowing installation on a standard "off-the-shelf" computer or a virtual platform. The software can be used to perform image viewing, processing, and analysis of brain CT perfusion (CTP) images. Data and images are acquired through DICOM compliant imaging devices.

StrokeViewer Perfusion is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time, which are visualized as colored perfusion maps including flow-related parameters and tissue blood volume quantification.

3.2. Contraindications

- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate
- Presence of hemorrhage

3.3. Intended User

The intended users of StrokeViewer are defined as healthcare professionals involved in the diagnosis and care of stroke patients. They include, but are not limited to, physicians such as neurologists, and radiologists.

3.4. Patient Target Population

The device is intended to be used in adult patients suspected of stroke. This is not intended for use with a pediatric population.

4. Device description

StrokeViewer Perfusion is an image processing application that runs on a standard "off-the-shelf" computer or a virtual platform, and can be used to perform image processing and analysis of CT perfusion images of the brain.
StrokeViewer Perfusion has a general purpose command line interface (CLI) that can be used to connect to other DICOM compliant devices such as picture archiving and communication systems (PACS) or CT scanners. For automatic processing of images, the device requires a one-time configuration by a system administrator using the CLI.
The software can receive, identify and extract DICOM information embedded in the imaging data. The output includes parametric maps related to tissue blood flow (perfusion) and tissue blood volume. Results of the analysis are exported as DICOM series and DICOM reports and can be sent to a preconfigured destination and can be reviewed on a compatible DICOM viewer.

StrokeViewer Perfusion image analysis includes calculation of the following perfusion related parameters:

- Cerebral Blood Flow (CBF)
- Cerebral Blood Volume (CBV)
- Mean Transit Time (MTT)
- Residue function time-to-peak (Tmax)
- Arterial Input Function (AIF)
- Volume calculations of affected tissue based on Tmax and CBF abnormalities

4.1. Minimum Requirements and Compatibility

In order to execute and use StrokeViewer in a safe and effective manner, minimum requirements are set. The input imaging data should adhere to the DICOM standard. StrokeViewer's output is provided in a DICOM format (DICOM series and annotation overlays) and to be able to view these results a compatible DICOM viewer is required (see **NOTE** for the requirements). In order to have a timely analysis provided by StrokeViewer a stable and fast internet connection is required (see **NOTE** for the requirements). To be able to use the command line interface, please consult the installation and configuration manual (as provided by the Manufacturer) for the minimum requirements.
StrokeViewer is not supplied with any accessories.

NOTE	*A DICOM viewer is required to meet the following requirements to be compatible with StrokeViewer:* • *DICOM viewer conforms to DICOM standard;* • *DICOM viewer supports CSPS file format;* • *DICOM viewer supports secondary capture file format.*

NOTE	*To be able to have timely analysis, StrokeViewer requires a stable internet connection with a minimum upload speed of at least 20 MB/s. This only applies in case the StrokeViewer is deployed in a remote/cloud environment.*

4.2. Getting started

1. **System requirements**
   The requirements to run StrokeViewer are provided with the onboarding of the hospital. Please contact the manufacturer for more information (see Section "1.5. Contacting the Manufacturer").
2. **Installation**
   StrokeViewer requires installation prior to use. In case of manual deployment, please consult the installation and configuration manual , as provided during the installation, regarding instructions on how to install and configure the medical device. This manual also includes instructions on maintenance, and detailed description of operating of the device.
3. **Configuring the software**
   StrokeViewer can be deployed to automatically or manually trigger the analysis. For both automatic and manual deployment, the device requires a one-time configuration by a system administrator. Instructions for setup and configuration for the IT team are provided with the onboarding of the hospital. The set-up of the thresholds for Tmax and CBF to calculate mismatch volume and mismatch ratio can be configured on hospital level during onboarding. Please contact the manufacturer for more information.
4. **User access level**
   StrokeViewer is protected against unauthorized access. IT networks characteristics and IT security measures to protect against unauthorized access are provided in system requirements (please consult your system administrator for more information).
5. **User interface**
   In case of manual deployment, the user will be provided with a command line interface (CLI). In case of automatic deployment, the user will be provided with an interface to trigger StrokeViewer analysis. The results computed by StrokeViewer can be viewed by a compatible DICOM viewer. To view requirements on compatible DICOM viewers, please consult the Section "4.3 Minimum Requirements and Compatibility" and section '5.5 and 5.6 Accessing results via the mobile app and web-viewer".

5. Operating the application

5.1. Installation and configuration

StrokeViewer can be deployed to run manually via a command line interface (CLI) or can be configured to run automatically. For more information about the CLI and how to deploy the application, please consult the installation and configuration manual.

5.2. Input Data

Input data for StrokeViewer are head CT perfusion scans from suspected stroke patients. Supported and recommended parameters are presented in Annex (see Section "10. Annex"). For more information regarding the required properties of the DICOM files please consult the DICOM Conformance Statement.

5.3. Starting the Analyses

In case of an automatic StrokeViewer deployment, the images are automatically sent to StrokeViewer. The application is able to receive and identify DICOM compliant images and run the image analysis pipeline. StrokeViewer output is automatically generated and exported to a pre-specified destination. In case of a manual deployment, analyses are triggered by the CLI. This includes specification of the input, output, and algorithm. Please consult the installation and configuration manual for the commands that need to be executed as provided during installation.

5.4. Output Data

Results of the analysis are generated as DICOM compliant series and stored to a pre-specified location. The output can be accessed and reviewed on a DICOM compliant viewer through hospital PACS or through a separate mobile app and/or DICOM web-viewer provided by the manufacturer (see section 5.6).

DICOM secondary capture series are defined as the color overlays embedded into the series, creating a new DICOM series with both the original DICOM images and the embedded overlay. This secondary capture is not togglable. In case the analysis does not provide any results, a secondary capture series is created.

DICOM summary reports are created as highlights from the result series with additional clinical/relevant information (patient, image, and StrokeViewer output). DICOM summary reports are always created when StrokeViewer is executed.

5.5. Accessing the Application

Access to the StrokeViewer application, both to the CLI interface as well as the hospital PACS viewer or the separate mobile app and DICOM viewer is arranged via the hospital system administrator. Please contact your system administrator for access to the StrokeViewer application. StrokeViewer can then be accessed via your regular authentication workflow and you will have access to the application as an authenticated user. (SSO manual is provided to hospital administrator/IT)

5.6. Mobile app and web-viewer (optional)

Optionally, StrokeViewer output can be reviewed on a separate mobile application and DICOM web viewer in addition to the PACS or other DICOM viewers available in the hospital. Instructions for the mobile app and the webviewer are available in Mobile app instructions for use document and StrokeViewer Image Viewer instructions for use.

5.7. Error Messages

Error messages may be presented to the user for different reasons, as explained in the notes and cautions throughout these instructions for use. In rare cases (for example when the DICOM series is not an axial series, StrokeViewer will not process these images), there will be no output from StrokeViewer, nor will there be any error message. For manual deployment, you should access the StrokeViewer event logs for detailed information on the error (please consult the installation and configuration manual).

NOTE	*In case of manual deployment, you need access to the StrokeViewer event logs to retrieve information on termination of the analysis of StrokeViewer due to completion or failure of the analysis.*

5.8. Maintenance and Device Disposal

The device is subjected to updates/releases, which will be coordinated and communicated by the manufacturer. In case of manual deployment, the installation and configuration manual contains information on how these updates can be deployed. The user is advised to update StrokeViewer as soon as the new version is made available. Servicing of StrokeViewer will be performed when needed. For information on deinstallation of the software, please refer to the installation and configuration manual . In case of automatic deployment, updates/releases will be performed by the Nicolab team. Please contact Nicolab when you experience any problems (see Section “1.5. Contact the Manufacturer”). Since StrokeViewer is software, physical device installation and calibration are not applicable.

6. Features

6.1. Safety and Performance

	**WARNING**
	If the number of imaging slices is not considered sufficient to cover the full MCA territory, the calculated volumes might be underestimated, and a message will be presented to the user for cautious interpretation.

	**CAUTION**
	StrokeViewer Perfusion is a tool to support patient management in acute ischemic stroke. Decisions must never be made based on the Perfusion results alone. The product should only be used by trained users familiar with the current guidelines and the perfusion measurement technique. It is the user's responsibility to carefully take into account all available patient information.

6.2. Analysis Output

The output of the Perfusion analysis is shown to the user in different DICOM outputs described below. All the outputs are automatically generated and presented in separate secondary capture DICOM series.

SV Perfusion Lesion Map

The "**SV Perfusion Lesion Map"** output series includes:

- Segmented reduced CBF (red) and mismatch volume (yellow) overlaid on the reference images;
- Perfusion maps in color for:
  - Tmax (0- 10s);
  - MTT (0-15s);
  - CBF (0-150%);
  - CBV (0-150%);
- Automatically computed volumes:
  - Extended Tmax volume in mL, defined as the volume with Tmax > 6s*;

- Reduced flow volume in mL, defined as the volume with CBF < 30%* compared to the contralateral hemisphere;
- Mismatch volume in mL, defined as the extended Tmax volume (Tmax > 6s) minus reduced flow volume (CBF < 30%);
- Mismatch ratio, defined as extended Tmax volume (Tmax > 6s) divided by the reduced flow volume (CBF < 30%);

- A horizontal graphical bar presenting the relative proportions of reduced flow (red) and mismatch volume (yellow).

Images and maps are arranged in a stack of slices, such that the user can scroll through the full brain volume (see Figure 1).

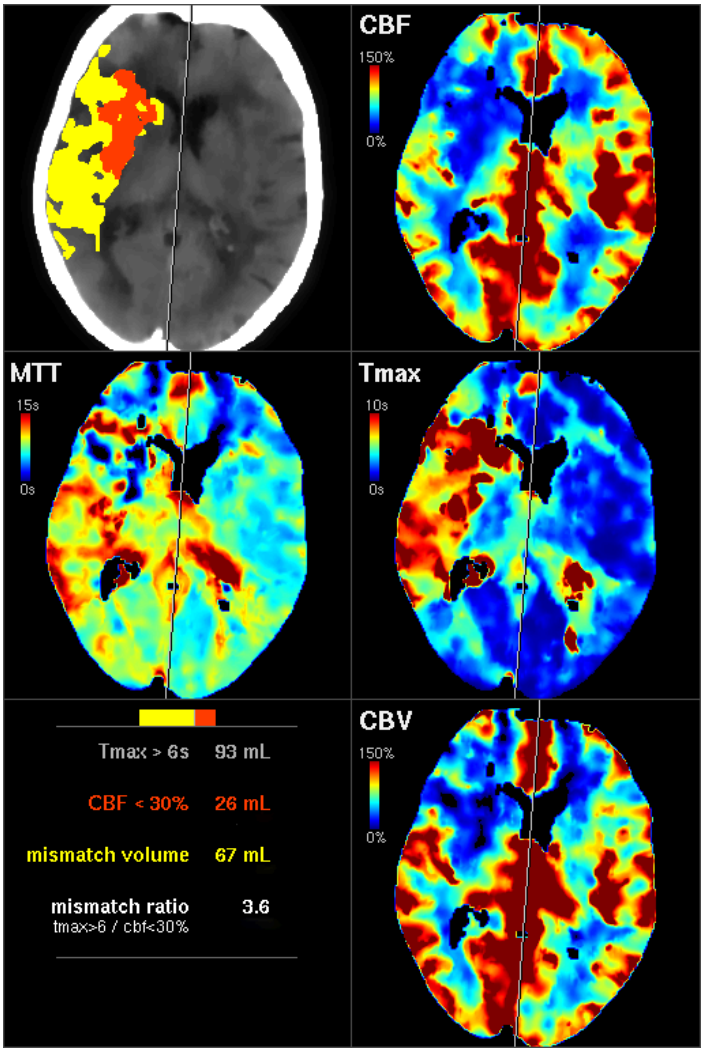

Figure 1. Example of the output of StrokeViewer Perfusion, including different perfusion maps and segmented volumes based on pre-configured thresholds. Areas with reduced flow (CBF <30%, red) and mismatch volume (yellow).*

** Thresholds for Tmax and CBF or configurable for advanced use on hospital level. Default values are set as CBF<30% and Tmax>6s.*

SV Perfusion multiple thresholds

The **"SV Perfusion multiple thresholds"** series provides segmentations and volume calculations for different thresholds of CBF and Tmax:

- The following CBF thresholds: CBF < 20%, CBF < 30%, CBF < 34%, CBF < 38%, including calculated volumes corresponding to these thresholds (Figure 2; left);
- The following Tmax thresholds: Tmax > 10s, Tmax > 8s, Tmax > 6s, Tmax > 4s, including calculated volumes corresponding to these thresholds (Figure 2, right).

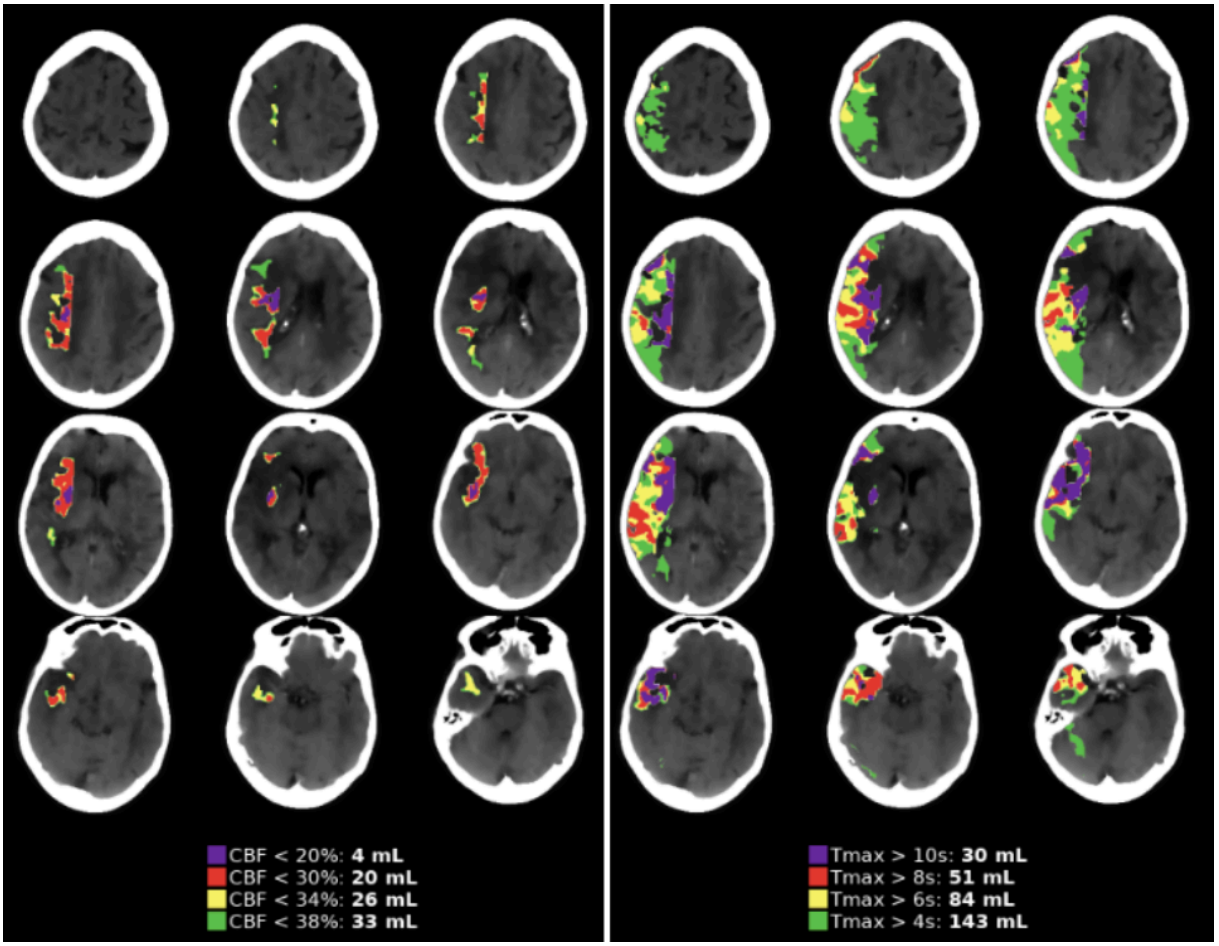

Figure 2. Example of the output of StrokeViewer Perfusion with visualization and volume calculations based on different CBF and Tmax thresholds.

SV Perfusion Quality Control Motion and SV Perfusion Quality Control Bolus

To ensure correct interpretation of the output, two series are created providing information about quality control of the acquisition images.

StrokeViewer Perfusion automatically corrects for patient motion on the input images. The "**SV Perfusion Quality Control Motion"** series output (see Figure 3 (Left)) includes the original and motion-corrected temporal series of images, which can be scrolled/browsed using a DICOM image viewer so that the user can assess the effectiveness of the motion correction. Correlation of each image volume with the first image volume over time is plotted for uncorrected (red line), and motion-corrected (blue line) images to give a quantitative measure for motion. The vertical white line indicates the current time point in the stack of images.

The "**SV Perfusion Quality Control Bolus"** series output (see Figure 3 (Right)) includes the following information:

- Contrast agent bolus details (including a message whether each value is within pre-configured optimal limits):
  - Temporal sampling of the perfusion time series;
  - Relative peak position of the bolus on the time axis of the AIF;
  - Average peak height of the bolus (Hounsfield units for CT, relative units for MR);
  - Lowest correlation in time series, serving as an index for maximal patient motion;
- Normalized curves showing contrast intensity over time clustered into "all vessels" (white curve), "veins" (blue curve) and "arteries" (red curve). The Arterial Input function (AIF, yellow curve) is chosen from the arterial pool by the features early arrival time, narrow shape and low signal-to-noise ratio.
- The same patient motion correlation information as indicated in the paragraph above.

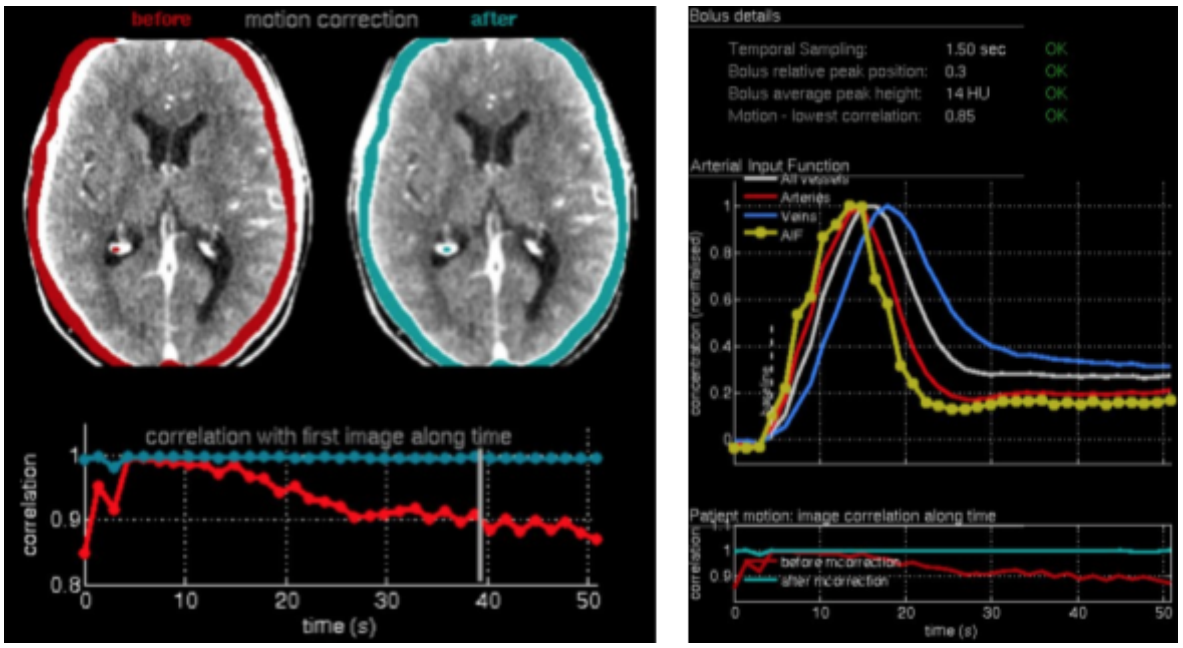

Figure 3. Example of the output of StrokeViewer Perfusion quality control information about patient motion during acquisition (Left) and bolus details (Right).

Summary report

The summary report is a DICOM object that includes, on top of patient and image information, the following summary of the analyses:

- Reduced CBF (CBF < 30%) volume in mL;
- Mismatch volume in mL;
- Mismatch ratio

This output is automatically generated and presented as part of the DICOM series named **"StrokeViewer Reports".**

6.3. Performance specifications

During testing, StrokeViewer Perfusion has been compared to a ground truth. StrokeViewer Perfusion showed a good correlation with the ground truth. Details are provided in Table 1 for flow-related parameters and Table 2 for volumes.

	Pearson correlation (r)	**Mean error**	**Standard deviation**
CBF	0.91	3.1%	10.9%
CBV	0.99	7.7%	5.8%
MTT	0.94	-3.3s	2.4s
Tmax	0.98	0.04s	0.7s

Table 1. Pearson correlation, mean error and standard deviation for CBF, CBV, MTT, and Tmax. Please note that the Pearson correlation is a measure for assessing correlation. A Pearson correlation of >0.9 is considered a good correlation.

	median DICE (min-max)	**median Ground Truth Vol in ml (min-max)**	**median Estimated Vol in ml (min-max)**
CBF < 30%	0.85 (0.80 - 0.91)	30.0 (0.0-127.2)	27.6 (0.0-134.4)
Tmax > 6s	0.87 (0.80 - 0.93)	139.6 (59.8-359.0)	120.0(46.6-348.4)

Table 2. DICE similarity coefficient and volumes. DICE can be explained as the spatial overlap of the segmentation provided by StrokeViewer Perfusion and the ground truth. A DICE of >0.7 is considered a good overlap.

6.4. Suggested workflow

We suggest the following workflow when interpreting the results:

1. Open the main result image "**SV Perfusion Lesion Map";**
2. When there are warning signs about bolus quality or patient motion, check "**SV Perfusion Quality Control Motion"** and/or "**SV Perfusion Quality Control Bolus;**
3. Check the perfusion maps **"Tmax", "CBF"** and **"CBV"**. Assess extended Tmax, reduced CBF lesion, image quality and whether the full MCA territory is covered.
4. Check automated segmentations of reduced CBF and extended Tmax in "**SV Perfusion Lesion Map"** and review the segmentations with different thresholds in **"SV Perfusion multiple thresholds**", to assess volume calculations based on the information from the Perfusion maps.
5. Check the original non-contrast CT and assess possible underestimations in reduced CBF segmentation.

6. Assess the accuracy of the automated computed volumes for reduced CBF and mismatch volume in relation to the interpretations in previous steps.

NOTE	*The contrast medium used are approved by their respective manufacturers for use with the parameters you select.*

7. Acronyms, Abbreviations and Definitions

The following acronyms, abbreviations and definitions are used throughout this Instructions for Use.

AIF	Arterial Input Function
Caution	A caution alerts you when special care is necessary for the safe and effective use of the device. Failure to observe a caution may result in moderate injury to the operator or patient, or damage to the equipment, and presents remote risk of more serious injury or environmental pollution
CBF	Cerebral Blood Flow
CBV	Cerebral Blood Volume
CT	Computed Tomography
CTP	CT Perfusion
DICOM	Digital Imaging and Communications in Medicine
HU	Hounsfield Unit
ICA	Internal Carotid Artery
IFU	Instructions for Use
Incident	Any malfunction or deterioration in the characteristics or performance of the device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect
MCA	Middle Cerebral Artery
Note	A note highlights unusual points to assist you when using the device
Serious incident	Any incident that directly or indirectly led, might have led or might lead to any of the following: (A) the death of a patient, user or other person (B) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (C) a serious public health threat
Tmax	Time to maximum contrast

UDI-PI	Unique Device Identifier, Production Identifier
Warning	A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient

8. Symbols Glossary

Information of the left column (symbols) of the table below (Table 3) can be used for understanding the symbols used throughout these Instructions for Use.

Symbol	Reference	Explanation
	n/a	Indicates a warning and alerts the user to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient
	EN ISO 15223-1 5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	EN ISO 15223-1 5.4.3	Indicates the need for the user to consult the instructions for use
	• Medical Device Regulation (EU) 2017/745 Annex I Chapter III 23.2 (c) • EN ISO 15223-1 5.1.1 • EN ISO 20417:2021 6.1.2	Indicates the medical device manufacturer (name & address) NICo-Lab B.V. Paasheuvelweg 25 1105 BP Amsterdam The Netherlands (NL)
	EN ISO 15223-1 5.1.3	Indicates the date when the medical device was manufactured Date of initial software release
	EN ISO 15223-1 5.7.7	Indicates the product is a medical device

UDI	• Medical Device Regulation (EU) 2017/745 Article 27 • EN ISO 15223-1 5.7.10 • Food and Drug Administration HHS, UDI Final Rule; 9/24/2013	Indicates a carrier that contains unique device identifier information UDI-PI can be found on the label on the device (CLI and DICOM summary report). UDI-DI will be part of the label within the IFU
	EN ISO 15223-1 5.7.8	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information This symbol will be accompanied with the address of the entity responsible for the translation

Table 3. Symbols glossary

9. Revision history

Instructions for Use are identified by a, for Nicolab, unique document number (as shown in the footer of this Instructions for Use). The revision number can be identified behind the document number; -rr-F (e.g., 01-F identifies the first approved version of the document).

Version	Date	Change description
01-F	16-May-2023	Creation of Instructions for USe of StrokeViewer Perfusion for the U.S. 510(k) Submission.
02-F	30-May-2023	Administrative updates
03-F	06-Jun-2023	Incorporating feedback from FDA
04-F	12-Jul-2023	Administrative updates
05-F	13-Sep-2023	Incorporating feedback from FDA and administrative updates
06-F	17-Nov-2023	Incorporating feedback from FDA
07-F	11-Dec-2023	Incorporating feedback from FDA
08-F	29-Apr-2024	Incorporating the initial release year

10. Annex

The information provided in Table 4 presents the supported and recommended imaging parameters.

Parameter	Supported range	Recommended setting
Orientation	AXIAL	AXIAL
Slice spacing	spacing should be equal or less than slice thickness	spacing should be equal or less than slice thickness
Number of timepoints:	16 - 100	25
Temporal sampling	0.5 to 3 sec	<2 sec
Matrix size	512 x 512	512 x 512
Slice thickness	0.5 - 5 mm	5 mm
Number of slices per timepoint	any	>10
Kernels	Soft tissue	Soft tissue

Table 4. An overview of the supported and recommended image acquisition parameters that are recommended for StrokeViewer Perfusion.