



Instructions for Use – *syngo*.CT Dynamic Angio VB60



Legend

-	Indicates a hint
	Is used to provide information on how to avoid operating errors or informa- tion emphasizing important details
	Indicates the solution of a problem
	Is used to provide troubleshooting information or answers to frequently asked questions
	Indicates a list item
✓	Indicates a prerequisite
	Is used for a condition that has to be fulfilled before starting a particular oper- ation
•	Indicates a one-step operation
1 2 3	Indicates steps within operating sequences
Italic	Is used for references and for table or figure titles
→	Is used to identify a link to related information as well as previous or next steps
Bold	Is used to identify window titles, menu items, function names, buttons, and keys, for example, the Save button
	Is used for on-screen output of the system including code-related elements or commands
Orange	Is used to emphasize particularly important sections of the text
Courier	Is used to identify inputs you need to provide
Menu > Menu Item	Is used for the navigation to a certain submenu entry
<variable></variable>	Is used to identify variables or parameters, for example, within a string

	CAUTION
_	Used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage.
	CAUTION consists of the following elements:
	Information about the nature of a hazardous situation
	Consequences of not avoiding a hazardous situation
	Methods of avoiding a hazardous situation
	WARNING
	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	WARNING consists of the following elements:
	Information about the nature of a hazardous situation
	Consequences of not avoiding a hazardous situation

• Methods of avoiding a hazardous situation

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1 *syngo*.CT Dynamic Angio

In the following sections, you find procedural information and background information on *syngo*.CT Dynamic Angio.

1.1 Legal notes

The functions described in this document are not commercially available in all countries. Some functions may be protected by a software license that is currently restricted for regulatory reasons. Some functions may be available with an optional software license. Please contact your local Siemens Healthineers Representative for further details.

1.1.1 Intended purpose

Image analysis software for evaluating computed tomography data sets.

1.1.2 Intended use

The syngo.CT Dynamic Angio software package has been designed to evaluate CT data which has been continuously acquired with computed tomography (CT) imaging systems. Contrast enhanced CT images are used to visualize the flow of contrast from the arteries to the veins.

syngo.CT Dynamic Angio can be used to assist the physician in the diagnosis of blood vessels and it supports in the evaluation of regions of interest, the visual inspection of time attenuation curves, and the creation of specific CT volumes, for example, arterial or venous phase. It will aid in the inspection of diseases which affect the vessel system, for example, vessel stenosis, collateral or late filling of vessels, vascular malformations, control of stent graft extravasation, or in the evaluation of tumor vascularization.

1.1.3 Indications for use

The *syngo*.CT Dynamic Angio software package has been designed to evaluate CT data which has been continuously acquired with computed tomography (CT) imaging systems. Contrast enhanced CT images are used to visualize the flow of contrast from the arteries to the veins.

syngo.CT Dynamic Angio can be used to assist the physician in the diagnosis of blood vessels and it supports in the evaluation of regions of interest, the visual inspection of time attenuation curves, and the creation of specific CT volumes, for example, arterial or venous phase. It will aid in the inspection of diseases which affect the vessel system, for example, vessel stenosis, collateral or late filling of vessels, vascular malformations, control of stent graft extravasation, or in the evaluation of tumor vascularization.

1.1.4 Contraindications

There are no known specific situations that contraindicate the use of this device.

1.1.5 Clinical benefit

The use of the *syngo*.CT Dynamic Angio software allows to analyze the dynamic filling and vessel enhancement based on Computed Tomography data sets.

1.1.6 Side-effects

There are no known side-effects.

1.1.7 Residual risk

The overall residual risk is acceptable according to the defined risk acceptance criteria. User-relevant safety information is provided in the Instructions for Use documents of the medical device.

1.1.8 Incident reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

1.1.9 Storage and handling conditions

There are no known specific storage and handling conditions for this medical device.

1.1.10 Intended patient population

The intended patient population is not subject to any restrictions. However, automation support provided works best with adult patients.

1.2 User profiles

Please note that the following profiles may vary in practice depending on (hospital) organization, qualification, and personal responsibilities and can only be considered as a general guide. Customer Service Engineer and IT Administrator are not in focus of this specification that focuses on clinical applications. Therefore, these roles are not described.

The following user roles and profiles have been identified for the *syngo*.CT applications:

Technologist (Radiographer)

• Role

Quality assurance of the images; preparation of images for reading, such as manipulation of size, position, or windowing values; creation of preliminary markers or measurements; generation of additional result series, for example, parallel ranges; (sending data for archiving).

• Knowledge and experience

Radiation technologist training, work experience, product training certificate or comparable product experience.

Radiologist

• Role 1

Performing the imaging examination, reporting of patient images, completing but not verifying reports, intervention, responsible for the safety of patients and employees, (sending data for archiving).

• Role 2

All of the above, plus justifying indication (medical check) and verifying reports.

Knowledge and experience

Physician, consultant for radiology, work experience, product training certificate or comparable product experience.

Clinical Administrator

• Role 1

Configuration of application-related settings, user management, patient data administration, first support contact for radiologists and other users (e.g. technologists).

• Role 2

Responsible for managing Dual Energy application classes and corresponding algorithm parameters.

• Knowledge and experience

Application specialist who typically works in the radiology department, radiologist, or radiographer, with work experience, product training certificate or comparable product experience, and knowledge of the RIS/ PACS workflow, configuration of DICOM nodes, archiving, management of Short Term Storage (STS), and license handling.

In addition to the configuration information provided, the clinical administrator needs to follow the information in the *syngo*.via Administration Online Help.

For role 2 the radiologist needs expert knowledge on Dual Energy technology.

1.3 Functionality of syngo.via

syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options. The functionality of the syngo.via software that is used in combination with a syngo.CT medical device is described in the syngo.via Basic Operator Manual. The syngo.via Basic Operator Manual and the syngo.via Administrator Manual are the Instructions for Use of syngo.via.

Not observing the Instructions for Use and the safety information of the medical device!

Injury to the patient.

- Always observe the Instructions for Use and follow the safety instructions of the medical device.
- Always use this Instructions for Use document in conjunction with all Instructions for Use documents provided.

1.4 Image requirements and data loading of *syngo*.CT Dynamic Angio

1.4.1 Image requirements

The following image requirements have to be met, otherwise the image segments remain empty:

- Multi-slice reconstruction images (two slices at least)
- Axial images
- Images of dynamic CT data sets, such as adaptive 4D spiral scan, Heart perfusion scanning mode, Dynamic Sequence, and Dynamic Multiscan
- Uncompressed or loss-less compressed images
- 512 x 512 matrices

1.4.2 Data loading

CT Dynamic Angio loads and processes dynamic data sets of 5.000 images at a reasonable speed, if the necessary system resources are available. More than 5.000 images are possible, but the performance of **CT Dynamic Angio** depends on the system load.

CT Dynamic Angio loads at least three time point volumes, each of which containing two or more slices.

CT Dynamic Angio checks the validity of individual CT images and ensures that the different time point volumes correctly correspond to each other.

1.4.3 Volume types

CT Dynamic Angio supports the following volume types:

- Time point volumes: Original CT volumes where each volume consists of several CT images, and each volume represents one time point of a dynamic CT scan.
- Baseline volume: A combined volume consisting of early time points without contrast medium.

Baseline volumes can only be loaded from the Result Gallery. They are calculated from the dynamic CT scan.

• Phase volumes: Newly generated volumes, for example, of the arterial or venous phase, created from a subset of user-defined neighboring time point volumes.

Phase volumes can only be loaded from the Result Gallery. They are calculated from the dynamic CT scan.

 Temporal Maximum Intensity Projection (tMIP): An automatically generated volume created from all loaded time point volumes. Each voxel in the new volume displays the maximum HU value of all time point voxels at the same image position.

tMIP volumes can only be loaded from the Result Gallery. They are calculated from the dynamic CT scan.

• Temporal Average (tAVG): An automatically generated volume created from all loaded time point volumes. Each voxel in the new volume displays the average HU value of all time point voxels at the same image position.

tAVG volumes can only be loaded from the Result Gallery. They are calculated from the dynamic CT scan.

Averaging in time may lead to a smoothing of anatomical structures. In the averaged images, regions with significant amounts of patient motion can appear blurred. In this case, it is recommended to review the original images.

1.4.4 Image loading

As soon as the dynamic data has been automatically selected and loaded, **CT Dynamic Angio** calculates the Baseline, Temporal Maximum Intensity Projection (tMIP), and Temporal Average (tAVG) volumes for enhanced vessel and soft tissue visualization. All time point volumes are attributed to the corresponding segments. The loading and calculation process is indicated in the progress bar.



Automatic data mapping can be manually overwritten at the scanner.

1.4.5 Preprocessing

CT Dynamic Angio does not perform preprocessing after the assignment. Calculations, for example, for bone removal, have to be started manually.

1.5 Layouts

The **CT Dynamic Angio** workflow step provides access to the layout gallery. **CT Dynamic Angio** provides layouts that are predefined and cannot be changed manually. The provided layouts depend on your current monitor configuration. There are dedicated layouts for single-monitor and dual-monitor configurations, as well as for different aspect ratios (4:3, 16:10, and portrait orientation). The following schematic examples show layouts for wide screen monitors.

1.5.1 Default layouts

• Single-monitor configuration (default):



- (1) Time point volumes MPR left-right
- (2) Time point volumes MPR feet-head
- (3) Time point volumes MPR anterior-posterior
- (4) Result Gallery
- (5) Temporal MIP MIP Thin (10 mm) feet-head
- (6) Temporal Average MPR Thick feet-head (MPR filter is selected by default)
- Dual-monitor configuration (default):



- (1) Time point volumes MPR left-right
- (2) Time point volumes MPR feet-head
- (3) Time point volumes MPR anterior-posterior
- (4) Result Gallery
- (5) Time point volumes MPR feet-head
- (6) Temporal MIP MIP Thin (10 mm) feet-head
- (7) Temporal Average MPR Thick feet-head (MPR filter is selected by default)

1.6 Result Gallery

In **CT Dynamic Angio**, a Result Gallery provides an overview of all available volumes. The Result Gallery always contains 10 segments.

The following volumes are generated automatically:

- Time point volume
- Temporal Maximum Intensity Projection (tMIP) volume

- Temporal Average (tAVG) volume
- Baseline volume

You can create 6 additional volumes. When you try to create more than 6 volumes, you are asked to delete volumes from the Result Gallery.

When phase volumes are generated, these are made available in the Result Gallery. After the work item is completed, the phase volumes are stored in the database and displayed in the **Series** panel.

The position of the Result Gallery depends on your monitor configuration as follows:

- In a 4:3 landscape configuration, and in all portrait monitor configurations, it is positioned horizontally at the bottom.
- In a 16:10 landscape monitor configuration, it is positioned vertically on the right.

1.7 Modifying preselected volumes

In **CT Dynamic Angio**, you can replace preselected volumes with user-defined ones. Different volumes can be loaded from the following tools:

- Series panel
- Result Gallery

1.7.1 Loading volumes from the Series panel

You can modify the current data.

• From the **Series** panel, drag one or more series into the Image area.

All currently available results are removed. The new data is loaded and can be processed.

1.7.2 Loading volumes from the Result Gallery

From the Result Gallery, you can drop the time point series or any of the volumes into the bigger segments, but not vice versa.

You can also load the same volumes into several segments at the same time.

• From the Result Gallery, drag a volume to a segment.

Loading a volume into an arbitrary segment of the upper three segments replaces the views in all three segments.

1.8 Time Slider

The Time Slider allows you to to scroll though the time point series of the data set by using the left arrow and the right arrow.

The small white triangle represents the motion correction base:



The bright bar represents the segmentation baseline:



The position marker indicates the currently displayed time point series, which is displayed in the orthogonal MPRs and indicates the time in seconds within the acquisition.

1.9 Navigating through time points and inside volumes

You can inspect each time point series in the upper three MPR segments, which are orthogonally synchronized. Each time point series represents one particular point in time of a CT examination. You can navigate from one time point series to another or you can scroll through the images of a single time point series.

• Time Navigation

Use one of the following methods to navigate through time point series, for example to review the contrast enhancement in particular regions:

- Press and hold the Alt key and scroll with the mouse wheel.
- Right-click and drag the mouse pointer to the right or to the left.
- Press the left and right arrow keys.
- Use the Time Slider.
- Volume Navigation

Use one of the following methods to navigate inside a time point series:

- Scroll with the mouse wheel.
- Right-click and drag the mouse pointer up and down.
- Use the reference lines.

1.10 Measurement accuracy

The measurement tools provided by *syngo*.via are developed using established mathematical and scientific methods. However, the accuracy of a measurement is primarily determined by the image data to which the measurement tools are applied.

The following factors influence measurement accuracy:

- Accuracy and calibration of the CT scanner used to acquire the images
- Image reconstruction settings, such as reconstruction kernel, slice thickness, spacing, resolution, and Field of View (FoV)
- · If applicable, quantity of contrast media and injection protocol used
- Scan protocol used
- Patient compliance during image acquisition, for example, breathhold and motion
- Patient anatomy
- Patient orientation and position during image acquisition

- Zoom factor and image orientation when the measurements are performed
- Placement of the end points of the measurement; placement is more accurate when the image is zoomed in
- User skills

1.10.1 Measurement accuracy in syngo.CT Dynamic Angio

This application only uses the general measurement tools that are provided by the *syngo*.via basic software. No specific measurement tools for *syngo*.CT Dynamic Angio are available.

2 Safety information

Follow the safety information in this document.

To ensure the safe use of your product and the safety of people, you must adhere to the safety information provided in the Instructions for use documents. In addition, also observe your country-specific regulations and guidelines.

Safety information is located in the safety section and repeated within context where a hazardous situation may occur. To make sure safety information is understood, always read it in context of the situation.

WARNING and CAUTION are highlighted in the text:

WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

WARNING and CAUTION have the same structure. The following example CAUTION instructs you how to read a WARNING or a CAUTION:

This text describes the hazardous situation: Images with lossy compression are used for diagnosis!

This text describes the hazard: Wrong diagnosis.

- This text describes how to avoid the hazardous situation: Always verify your evaluation results with the original DICOM images (first reader duty).
- Never use lossy ...

2.1 General safety information

For the secure operation of your medical device, it is the responsibility of the system owner to ensure that each person who operates the system reads and understands the provided Instructions for Use.

Not observing the Instructions for Use and the safety information of the medical device!

Injury to the patient.

- Always observe the Instructions for Use and follow the safety instructions of the medical device.
- Always use this Instructions for Use document in conjunction with all Instructions for Use documents provided.

2.2 Safety information on training

Operation of the medical device by non-trained users!

Injury to the patient.

 Only trained and qualified users, certified in accordance with countryspecific regulations, are authorized to operate the system. For example, physicians, radiologists, or technologists.

For appropriate training, contact your Representative at Siemens Healthineers.

2.3 Safety information on patient data

Displayed information about changed patient data is not observed!

Wrong diagnosis due to patient data that has not been updated.

 Always read and observe the displayed information about changed patient data.

Follow the instructions provided with the displayed information.

Check all results and delete results that include patient data that has not been updated.

Patient data is changed using the correct and rearrange function while a time-critical workflow for this patient is in progress!

Delayed diagnosis due to restart of workflow.

• Do not perform correct and rearrange actions while time-critical cases are in progress. Always check the **Workflows** section in the **Job View** for time-critical workflows.

Loading image data sets of different patients!

Mix-up of patients and incorrect diagnosis.

• When loading two or more reference series or model series, make sure that you select the data of the same patient.

2.4 Safety information on algorithms

Incorrect input data set used with algorithms leads to incorrect results!

Wrong basis for diagnosis.

- Make sure that you use the specified input data.
- Verify algorithm results with the original data set.

Algorithms may return inaccurate results or incomplete anatomy information!

Wrong basis for diagnosis or treatment.

• Before diagnosis or further processing, check and correct algorithm results. For example, results from segmentation or masking.

Incomplete data is used for diagnosis!

Wrong basis for diagnosis.

- Verify that the input data is sufficient for the creation of automatically generated results.
- Verify the correctness of automatically generated results.

2.5 Safety information on motion correction

Wrong motion correction of input data sets!

Wrong basis for diagnosis.

• Ensure that the motion correction results are adequate. The user should navigate through all volumes of the time series. If motion correction is not correct, reset to original data.

2.6 Safety information on segmentation and masking

CAUTION

Removal of relevant body parts due to automatic segmentation!

Wrong basis for diagnosis.

 Make sure that the segmentation results are adequate. If segmentation is not proper, correct manually or reset to original data.

2.7 Safety information on Rapid Results Technology

Automatically generated or saved results may be results are not reviewed and sent to another DICOM node!

Wrong diagnosis due to wrong information.

• Always review automatically generated results before sending them to other DICOM nodes.

3 The CT Dynamic Angio workflow

The **CT Dynamic Angio** workflow allows for the visualization and evaluation of dynamic CT data sets. You can generate time-resolved dynamic angiographies, inspect and evaluate time attenuation curves, and create CT phase volumes, for example, of the arterial and venous phases.

The workflow consists of the following steps:

- Before you can start evaluating images, you have to prepare the study for reading by loading patient data into the Viewer and modifying preselected volumes. (→ Page 15 *Modifying preselected volumes*)
- Navigate through the time points and check the quality of the CT examination, for example, with respect to patient or organ motion.
 (→ Page 16 Navigating through time points and inside volumes)
- If no motion or only small motion is observed, it is not necessary to perform motion correction, as this will not improve the results.
- If the time points show motion, remove or reduce these effects by using the appropriate tools for the head, body, or myocardium.
 (→ Page 27 Correcting motion)
- If the time points still show strong motion or motion artifacts, you can remove the affected time points. (→ Page 29 Excluding a time point from evaluation) (→ Page 29 Excluding a range of time points from evaluation)
- If the time point defined as the Motion Correction Base shows strong motion or motion artifacts, set a new Motion Correction Base.
 (→ Page 28 Setting the motion correction base)
- If the time point images are very noisy because of low kV, low dose, or thin slice reconstruction, you can reduce the image noise. For 4D Noise Reduction, proceed to Step 2: Segmentation. (→ Page 30 Reducing image noise)
- Remove the patient table using the automatic Table Removal function.
 (→ Page 31 Removing the patient table)
- Remove bone structures by using the automatic Bone Removal function to display vessels more clearly. (→ Page 31 *Removing bones*)

- Check the time points for remaining bone structures.
- If bone structures still exist, you can remove these using an additional HU-based segmentation that operates on the segmentation baseline, that is, on all time points from the start of the examination to the earliest rise of the contrast media. (→ Page 32 Segmenting based on HU values)
- If the segmentation baseline is not ideal, change it in Step 1: Motion Correction and perform the HU segmentation again. (→ Page 33 Defining the Baseline volume)
- You can start a time-resolved dynamic angio movie, at any time.
 (→ Page 41 *Playing the movie*)
- You can define and store phase volumes, for example, of the arterial or the venous phase. (→ Page 39 *Creating new phase volumes*)
- You can draw and evaluate regions of interest. (→ Page 35 Drawing a circular TAC ROI) (→ Page 35 Drawing a freehand TAC ROI)
 - At this stage, you can observe the time attenuation curves and their curve parameters. (→ Page 34 Displaying time attenuation curves)
 - You can also observe the statistical ROI parameters.
 (→ Page 37 Analyzing the ROI statistics)

3.1 Case preparation

CT Dynamic Angio offers several tools and features that need to be used according to the corresponding use case. The following use cases are described in this chapter:

- (→ Page 14 Result Gallery)
- (→ Page 16 Navigating through time points and inside volumes)
- (→ Page 26 Motion correction)
- (→ Page 27 Correcting motion)
- (→ Page 28 Setting the motion correction base)
- (→ Page 29 Excluding a time point from evaluation)
- (→ Page 29 Excluding a range of time points from evaluation)

- (→ Page 29 Segmentation and 4D Noise Reduction)
- (→ Page 30 Reducing image noise)
- (→ Page 31 Removing the patient table)
- (→ Page 31 Removing bones)
- (→ Page 32 Segmenting based on HU values)
- (→ Page 33 Defining the Baseline volume)

3.1.1 Motion correction

CT Dynamic Angio provides body-region dependent motion correction, since patient or organ motion affects the quality of the results.

The following motion correction methods are provided:

correction methods

Motion

- Neuro Motion Correction: Rigid motion correction that can be used for brain data sets.
- **Body Motion Correction**: Elastic motion correction that is suited to reduce motion based on patient or organ movement in body data sets.
- **Myocardium Motion Correction**: Specific Myocardium motion correction that can be used for Siemens Heart Perfusion data sets.

CT Dynamic Angio does not automatically apply any motion correction algorithm. You are required to initiate the motion correction manually.

When motion correction is completed, all CT volumes, except for usergenerated phase volumes, are replaced by the motion corrected data.

If time points show strong patient or organ movement that cannot be corrected by the motion correction methods, the affected time point volumes can be removed from the current evaluation. You can either remove a single time point or a range of time points. See (\rightarrow Page 29 *Excluding a time point from evaluation*) or (\rightarrow Page 29 *Excluding a range of time points from evaluation*). Motion correction base A motion correction algorithm uses a motion correction base volume that should be representative of all other time point volumes and not contain motion itself. The motion correction base is set to a predefined time point from the whole study by default. This default can be changed manually in the configuration. See (→ Page 49 Defining the motion correction base). The current and patient individual motion correction base can be adapted during the case preparation.

On the Time Slider, a small white triangle represents the motion correction base. If the time point volume that is defined as the motion correction base shows strong motion artifacts, set a new motion correction base. See (\Rightarrow Page 16 *Time Slider*) and (\Rightarrow Page 28 *Setting the motion correction base*).

3.1.2 Correcting motion

Wrong motion correction of input data sets!

Wrong basis for diagnosis.

• Ensure that the motion correction results are adequate. The user should navigate through all volumes of the time series. If motion correction is not correct, reset to original data.

Perform motion correction only if significant patient movement is observed. Depending on the scope of the study, the number of images, and on the algorithm, the motion correction can take a few minutes.

Correcting a head motion



• Click the Align Neuro icon.

After motion correction has been performed, the system displays the aligned volumes, as well as the improved Temporal Maximum Intensity Projection (tMIP), Temporal Average (tAVG), and Baseline volumes.

Correcting an organ motion



• Click the Align Body icon.

After motion correction has been performed, the system displays the aligned volumes, as well as the improved tMIP, tAVG, and Baseline volumes.

Correcting a heart motion



• Click the Align Myocard icon.

After motion correction has been performed, the system displays the aligned volumes, as well as the improved tMIP, tAVG, and Baseline volumes.

3.1.3 Setting the motion correction base

If the time point volume that is defined as the motion correction base is not representative or shows strong motion, set a new motion correction base.

1 Navigate to the time point that should be defined as the motion correction base.





2 Click the Align Base icon.

On the Time Slider, the triangle jumps to the position of the current time point, which is now the motion correction base.



3.1.4 Excluding a time point from evaluation

You can exclude a single time point from evaluation, if the images show strong movements. At least four time points of the series have to be kept for evaluation. You can repeat this process several times.

- ✓ The Motion Correction step is active.
- 1 On the Time Slider, navigate to the time point that you want to exclude.



3.1.5 Excluding a range of time points from evaluation

You can exclude all time points from the currently displayed to the last available time point, if the last time points in the series are not required for evaluation. At least four time points of the series have to be kept for evaluation. You can repeat this process several times.

- ✓ The Motion Correction step is active.
- 1 On the Time Slider, navigate to the time point from which on you want to exclude data.
- 2 In the Motion Correction step, click the Exclude Range icon.

The selected time range is excluded.

3.1.6 Segmentation and 4D Noise Reduction

CT Dynamic Angio provides a specific noise reduction algorithm that preserves time-density information, improving the image quality of noisy input images and allowing for a solid evaluation of images. Once noise reduction has completed, all CT volumes, except for user-generated phase volumes, are replaced by the data with reduced noise.

CT Dynamic Angio allows for any combination of segmentations, such as table removal, bone removal for different body regions, or simple HU segmentation, to visualize the blood vessels without interfering structures. The HU-based segmentation operates exclusively in the baseline volume, that is, on all time points that do not show contrast. After any of the segmentation operations have completed, all CT volumes, except for user-generated phase volumes, are replaced by the new data.

Baseline volume

The baseline volume is the time range from the start of the examination to the earliest rise of the contrast media. All time points in this time range are averaged, representing the baseline volume. This baseline volume is required for the calculation of HU segmentations. In the Time Slider, a brightly colored bar represents the baseline volume.



In Neuro cases, the system suggests a baseline; in all other cases, the first time point is used as a baseline instead.

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When removing a time point within the segmentation baseline, a new baseline volume is recalculated.

Segmentation tools

In CT Dynamic Angio, the following tools are available for segmenting areas:

- Table Removal: Automatically removes the table and head holder.
- Bone Removal: Automatically removes bone.
- **HU Segmentation**: Removes all pixels that lie outside the Min HU and Max HU thresholds. The HU-based segmentation operates exclusively in the baseline volume.

3.1.7 Reducing image noise

You can reduce image noise that results from low kV or low dose to preserve time-density information and smooth the display of images.

✓ The **Segmentation** step is active.



• In the Segmentation step, click the Reduce Noise icon.

The Temporal Maximum Intensity Projection (tMIP), the Temporal Average (tAVG), the time points, and the baseline volume are recalculated.

3.1.8 Removing the patient table



Before removing the patient table, make sure that the image quality is high and that no image noise reduction is necessary. Otherwise, reduce the image noise first. See (\rightarrow Page 30 *Reducing image noise*).

✓ The **Segmentation** step is active.



• In the Segmentation step, click the Delete icon.

The table removal is applied to all available volumes except for the already defined phase volumes.

3.1.9 Removing bones

Removal of relevant body parts due to automatic segmentation!

Wrong basis for diagnosis.

 Make sure that the segmentation results are adequate. If segmentation is not proper, correct manually or reset to original data.

Before removing bone structures, make sure that the image quality is high and that no motion correction or image noise reduction is necessary. Otherwise, reduce the motion and the image noise first. See (→ Page 27 *Correcting motion*) and (→ Page 30 *Reducing image noise*).

✓ The **Segmentation** step is active.



• In the Segmentation step, click the Delete icon.

Bone removal is applied to all available volumes.

When Bone Removal is active, all pixels inside the bone removal mask are set to -1024 HU. Keep this in mind when using evaluation tools such as ROI or the Pixel Lens.

3.1.10 Segmenting based on HU values

Removal of relevant body parts due to automatic segmentation!

Wrong basis for diagnosis.

- Make sure that the segmentation results are adequate. If segmentation is not proper, correct manually or reset to original data.
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Before removing bone structures, make sure that the image quality is high and that no motion correction or image noise reduction is necessary. Otherwise, reduce the motion and the image noise first. See (→ Page 27 *Correcting motion*) and (→ Page 30 *Reducing image noise*).

✓ The **Segmentation** step is active.

Activating the HU Segmentation results in a first segmentation according to the predefined HU threshold values.



1 In the **Segmentation** step, click the **Segment** icon.

HU segmentation is applied to all available volumes, except for the already defined phase volumes. The text fields for both the min. and max. HU thresholds are activated.

- 2 Check whether the required regions are excluded.
- **3** If, for example, bone structures still exist, enter a new max. HU threshold value and press **Return**. Repeat this step until the required result has been achieved.



After HU Segmentation has been deactivated, all structures that were excluded by the HU segmentation are visible.

3.1.11 Defining the Baseline volume

The Baseline volume is used as a basis for the HU segmentation calculation. For the head, the Baseline volume is detected automatically. For each other body part, you have to define the Baseline volume or use the first time point volume that is set as the default baseline.





2 In the Motion Correction step, click the Baseline icon.

A Baseline volume is calculated and is updated in the Result Gallery. The brightly colored bar of the Time Slider is updated.



When removing a time point from the Baseline volume, a new Baseline volume is recalculated and updated in the Result Gallery.

3.2 Reading

CT Dynamic Angio supports workflows for 2D/3D evaluation. Perform the following steps.

- (→ Page 34 Time attenuation curves)
- (→ Page 34 Displaying time attenuation curves)
- (→ Page 35 Drawing a circular TAC ROI)
 - (→ Page 35 Drawing a freehand TAC ROI)
- (→ Page 37 Analyzing the ROI statistics)
- (→ Page 39 Phase volume definition)
- (→ Page 39 Creating new phase volumes)
- (→ Page 40 Changing the orientation of the result volumes)

- (→ Page 40 *Movie*)
- (→ Page 41 Playing the movie)
- (→ Page 42 Modifying the movie)

3.2.1 Time attenuation curves

Local vessel or tissue enhancement can be visualized in **CT Dynamic Angio** using ROI-specific Time Attenuation Curves (TAC).

Additionally, curve parameters, such as time-to-peak or peak-value, as well as statistical ROI parameters, such as **Mean Value**, **Standard Deviation**, and **Area** are calculated. These are displayed in tabular form.

The TAC is always calculated on the basis of original data and does not take into account slice thickness modifications or different display types, for example, MIP Thin.

CT Dynamic Angio supports any number of TACs. The y-axis ranges are adapted to the currently displayed TACs. Therefore, the deleting or deactivation of an ROI can result in the rescaling of the y-axis and the displayed curves.

The TAC display can also be used in combination with the phase volume definition. In this case, two vertical reference lines in the TAC section indicate the earliest and the latest time point that is currently being used by the phase volume definition slider.

TACs are shown in color and can be displayed with absolute or relative scaling.

You can set the default display of the TAC to absolute or to relative in the configuration. You can switch the display of TACs on or off. See (\Rightarrow Page 34 *Displaying time attenuation curves*).

By default, the time attenuation curves are displayed relative to each other.

Displaying time attenuation curves

After evaluating a circular or an ellipsoidal area, for example, by drawing a TAC ROI Ellipse, the respective Time Attenuation Curve (TAC) and the related parameters are displayed in the TAC tool.



• In the Case Navigator, click the TAC icon.

The TAC tool is displayed or hidden.

In the TAC tool, the TACs and Curves tabs are displayed by default.

Drawing a circular TAC ROI

To evaluate tissue regions, you can draw circular ROIs.



1 From the upper right corner menu, choose **TAC ROI Circle**.

The TAC ROI mode starts and the mouse pointer changes its shape.

2 To draw a circle, click and drag the mouse until the circle is of the required size.

– or –

To draw an ellipse, press and hold the Shift key while drawing.

The evaluation results are displayed in the segment, preceded by the graphic identification tag. The time attenuation curve of this ROI and its curve and statistical values are displayed in the TAC tool.

Drawing a freehand To ev TAC ROI

To evaluate tissue regions, you can draw freehand Regions of Interest (ROIs).



1 From the upper right corner menu, choose TAC ROI Freehand.

The TAC ROI mode starts and the mouse pointer changes its shape.

2 To draw a freehand ROI, click and drag the mouse while drawing the required shape.

The evaluation results are displayed, preceded by the graphic identification tag. The time attenuation curve of this ROI and its curve and statistical values are displayed in the TAC tool.



To change the size of a freehand ROI, select it and move the handles to resize the geometric figure.

- Correcting a freehand ROI using the correction pen
- To edit a part of a freehand ROI, right-click the ROI, choose **Correction Pen** from the context menu and redraw the part of the figure you want to correct. The smaller part of the original line will be removed.



- Correcting a freehand ROI using the nudge tool
- 1 To fit a freehand ROI to a certain section of the image, right-click the ROI and choose **Nudge Tool** from the context menu.



- 2 Click the required point in the segment. The size of the **Nudge Tool** is determined by the distance between the point you have clicked and the nearest point of the line.
- 3 Click and drag the mouse to move the borders of the ROI.

3.2.2 Defining the values to be calculated for ROIs



- 1 From the upper right corner menu, move the mouse pointer over TAC ROI Circle or TAC ROI Freehand and click the Configuration icon.
- 2 From the **ROI Properties** dialog box, select the check boxes that correspond to the evaluation result that should be displayed.

Min/Max: The minimum and maximum grayscale value in the ROI

Mean/SD: The mean value and the standard deviation of the grayscale values in the ROI

Area (cm2): The area of the ROI in cm²

Sum: The sum of all pixel values inside the ROI

Number of Pixels: The total number of pixels inside the ROI

3 Click OK to confirm.

The settings are applied to subsequently drawn ROIs.

3.2.3 Analyzing the ROI statistics

To analyze the ROI statistics, perform the following steps:

✓ Time attenuation curves are displayed.



1 On the TAC tool, click the **Statistics** tab to display the ROI statistics.

You can choose between the following parameters:

- Mean Value (HU)
- Standard Deviation (HU)
- Area (cm²)
- 2 Change the display of ROI parameters according to your needs.

The **MIP**, **AVG**, and **BASE** values are adapted according to your selection. You can also export the ROI statistics for further analysis. See (\rightarrow Page 43 *Exporting ROI statistics*).

3.2.4 Phase volume definition

CT Dynamic Angio allows for the creation of user-defined phase volumes, for example, for the calculation of the arterial phase. A slider allows for the calculation of new CT phase volumes to be restricted to any user-defined time range within the dynamic scan.

The central and the earliest and latest time points of the dynamic data set may be defined by means of a phase volume definition slider within the segment.

The new phase volume may be of type Temporal Maximum Intensity Projection (tMIP) or Temporal Average (tAVG), and is stored and displayed in the first free segment of the Result Gallery. The maximum number of user-defined phases is limited to six.

The name of a phase volume is defined automatically as follows:

- For phase volumes of type tMIP, the name consists of **PMIP** followed by a consecutive number.
- For phase volumes of type tAVG, the name consists of **PAVG** followed by a consecutive number.

Creating new phase volumes You can precisely identify phases by reading the earliest and latest included time points of the Time Attenuation Curves. Two or more suitable ROIs are recommended to separate the phases from each other.

Creating a phase volume



- 1 Click the Create icon.
- 2 In the mini toolbar of the lower left segment, select the volume type option tAverage or tMIP.
- 3 Move the phase definition slider to search for the required phase.
- 4 Expand or reduce the included time points with the help of the slider. Depending on the slider range, more or less time point volumes are used for the calculation of the phase volume.
- 5 Click the Create button.

The phase volume is created and displayed in the Result Gallery.



Note that the Time Slider in the Case Navigator is inactive during volume creation.

Renaming a phase volume		In the Result Gallery, right-click the segment of the phase volume to be renamed and choose Rename from the context menu.
	2	Enter the new name of the phase volume and press Return.
	Th	e phase volume is renamed.
Deleting a phase volume	•	In the Result Gallery, right-click the segment of the phase volume to be deleted and choose Delete from the context menu.
	Th	e phase volume is deleted.
Changing the orientation	~	Result volumes are available.
of the result volumes	1	In one of the upper three segments, change the orientation, for example by using the reference lines.



2 In one of the upper three segments, right-click and choose Apply Orientation to Lower Segments from the context menu.

The orientation of all displayed result volumes changes accordingly.

3.2.5 Movie

CT Dynamic Angio allows you to run a movie over all time points and proceed it using the usual 3D Tools, such as Clip box and Clip plane, if necessary. By default, the movie is displayed using the VRT display type. All display types, except MinIP, are supported and can be configured. See (→ Page 41 *Playing the movie*).



It is possible to set the movie speed, the VRT display type, and other filter settings, as well as the movie orientation. See 'Controlling the movie' in the *syngo*.via Basic Applications Online Help. The main orientation of a VRT and the VRT preset are retained when you start the movie tool the next time.

You can store a series of snapshots from all time points, representing the current state of the movie, to review these later in the PACS. See (\rightarrow Page 44 *Saving series of snapshots*).

3.2.6 Playing the movie

The movie mode scrolls through a time series or a 3D volume. The images are displayed one after another, as in a flipbook.

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• In the Case Navigator, click the Watch icon.

The display type of the Movie changes to VRT and the animation starts.

You can hide or show the image text while playing a movie. Use the **Hide Image Text** icon in the Common Tools area.

If the Movie Panel is hidden, move the mouse over the icon at the bottom of the Movie.

3.2.7 Modifying the movie

You can modify the movie using the usual 3D tools, such as Clip box or Clip plane.

• See '3D postprocessing' in the *syngo*.via Application Basics Online Help.

– or –

See 'Controlling the movie' in the syngo.via Application Basics Online Help.

3.2.8 Resetting the workflow

You can reset the workflow to its initial state at any time. All unsaved results will be lost.



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In the Case Navigator, click the Reset icon.

3.3 Documenting results

All findings are listed in the **Findings Navigator**. You can review the markers and other findings in the **Findings details** window.

- · Setting markers
- Reviewing findings
- (→ Page 43 Exporting ROI statistics)
- (→ Page 44 Saving series of snapshots)

- (→ Page 44 Editing the findings details)
- · Generating the report
- · Completing the workflow

3.3.1 Exporting ROI statistics

To export the TACs and ROI statistics, perform the following steps:

- ✓ At least one TAC ROI is drawn and the TAC tool is displayed.
- 1 In the TAC tool, right-click and choose **Export Statistics and Curves** from the context menu.

The Browse For Folder dialog box opens.

2 Navigate to the target folder of the export and click OK.

The TAC and ROI statistics are exported to a file which is saved in the selected folder.

3.3.2 Exporting result volumes

You can send your calculated result volumes to the RIS or PACS when you complete the workflow.

You can configure to automatically store the result volumes that you frequently use for further evaluation in the RIS or PACS. See (\rightarrow Page 52 Selecting result volumes for archiving).



 In the Result Gallery, click the Result Storage icon of the required result volume.



An icon with a checkmark is displayed for selected result volumes.

3.3.3 Saving series of snapshots

You can create a series of snapshots that correspond to a sequence of images in all time points of the series. The series is created with the currently applied visualization settings, such as windowing and orientation. This is particularly useful for documenting the contrast medium flow in the vessels.



 Click a segment that contains original time points, and from the Case Navigator, click the Save icon. Alternatively, press the Alt + S keys.

– or –

Right-click a segment that contains original time points and choose **Save Series of Snapshots** from the context menu.

A new image series for the patient is created but is not visible in the **Series** panel. Depending on the archiving configuration of *syngo*.via, the series is automatically sent to a Picture Archiving and Communication System (PACS) workstation after the work item has been completed. On the PACS, you can redisplay the series as a movie, for example.

3.3.4 Editing the findings details

In the **Findings details** window, you can edit the details of measurements and markers. The different types of findings are listed on the following tabs:

- Markers
- Other: General measurements

Opening the Findings details window



• In the Findings Navigator, click the Finding Details icon.

The Findings details window opens.

Defining the location of a marker

- You can define the position of findings.
- 1 Click the Markers tab.
- 2 From the list of markers, select an entry.

	3	On the left-hand side of the window, select the body region and click the corresponding vessel in the pictogram.	
		– or –	
		From the Location list, select one of the proposed locations.	
		– or –	
		Click an existing position marker in the pictogram and drag it to a new position.	
	Th	e location label of the marker is updated accordingly.	
Adding comments	Yo	u can add an arbitrary text to the comment attribute of a finding.	
to findings	1	From the lists, select an entry.	
	2	Click the Comment field and enter your comment.	
	Th ca	e comment attribute of the finding is updated accordingly. Alternatively, you n edit the comment attribute in the Viewer.	
Preparing the report		In the Findings details windows, you can define which data shall be added to the report.	
	1	Click the Markers tab or the Other tab.	
	2	In the first column of the list of findings, clear the check boxes of the findings that you do not want to add to the report.	
	3	Check the attributes of the remaining findings.	
	4	In the Summary field, enter a summary of your findings.	
	5	From the list of findings, select an entry.	
	6	Clear the Add to report check boxes of the snapshots that you do not want to add to the report.	
	7	Check the snapshots of the remaining findings.	
	Th	e report data is prepared. You can now continue to generate the report.	
Exporting finding data	1	In the Findings details window, select one or multiple findings.	

2 Press the Ctrl + C keys.

– or –

Right-click the list of findings and choose Copy from the context menu.

- **3** Switch to the application with which you would like to use the selected data, for example, MS Word.
- 4 Paste the information to the application, for example, with the Ctrl + V keys.

4 Configuring CT Dynamic Angio

Configuration of **CT Dynamic Angio** allows you to customize the calculation and the visualization in the workflow.

No special user rights are necessary to change settings in the **CT Dynamic Angio Configuration** dialog box. Note that your settings apply only for the currently active workflow. Applying changed settings while you read data may require a reset and the recalculation of results in the currently active workflow. This reset can affect the calculation and visualization, even of resumed data sets. As a Clinical Administrator, you can change the settings permanently for all users.

- (\rightarrow Page 47 Opening the configuration dialog box)
- (→ Page 49 Defining the motion correction base)
- (→ Page 50 Defining the thresholds for segmentation)
- (→ Page 51 Changing the initial display of specific volumes)
- (→ Page 52 Setting the display properties for curves and tables)
- (→ Page 52 Selecting result volumes for archiving)
- (→ Page 53 Restoring Siemens default settings)

4.1 Opening the configuration dialog box



1 In the Case Navigator, click the settings icon.

The CT Dynamic Angio Configuration dialog box opens.

2 Click a tab to open it.

No special user rights are necessary to change settings in the **CT Dynamic Angio Configuration** dialog box. Note that your settings apply only for the currently active workflow. Applying changed settings while you read data may require a reset and the recalculation of results in the currently active workflow. This reset can affect the calculation and visualization, even of resumed data sets. As a Clinical Administrator, you can change the settings permanently for all users.

4.2 The configuration dialog box

The **Configuration** dialog box of **CT Dynamic Angio** consists of the following tabs:

Calculation

On the **Calculation** tab, you can adjust the values of the **Default Motion Correction Base** and the **Default Segmentation Thresholds**.

See (→ Page 49 Defining the motion correction base) and (→ Page 50 Defining the thresholds for segmentation).

Visualization

On the **Visualization** tab, you can adjust the default settings for **Volumes**, **Time Attenuation Curves**, and **Tables**.

See (\rightarrow Page 51 Changing the initial display of specific volumes) and (\rightarrow Page 52 Setting the display properties for curves and tables).

Results

On the **Results** tab, you can select the volumes that are archived when you complete the workflow.

See (→ Page 52 Selecting result volumes for archiving).

4.3 Calculation settings

The **CT Dynamic Angio Configuration** dialog box opens with the **Calculation** tab displayed by default.

CT Dynamic Angio identifies the body part of a study by the content of the Body Part Examined DICOM tag. In the **Default Motion Correction Base** section, you can define the time point of the series that is used as the motion correction base for each body part. See (→ Page 49 *Defining the motion correction base*).

In the **Default Segmentation Thresholds** section, you can define the threshold values that are used by the HU-based segmentation algorithm by default. These threshold values are displayed in the text fields of the HU-based segmentation function in the Case Navigator.

Name	Description	Default (HU)	Range (HU)
Brain	All voxels having HU values within the specified range (Min. to Max.) are kept for display and calculation, while all other voxels are excluded.	Min.: 20 Max.: 100	-1024 to 3071
Body	All voxels having HU values within the specified range (Min. to Max.) are kept for display and calculation, while all other voxels are excluded.	Min.: -50 Max.: 150	-1024 to 3071
Myocardium	All voxels having HU values within the specified range (Min. to Max.) are kept for display and calculation, while all other voxels are excluded.	Min.: -50 Max.: 150	-1024 to 3071

You can change these settings. See (\rightarrow Page 50 Defining the thresholds for segmentation).

4.3.1 Defining the motion correction base

For each body part, you can select the time point position within the series that is used as the motion correction base by default. The motion correction base is used to align images that show strong patient or organ movements.

✓ The CT Dynamic Angio Configuration dialog box is open.

For the motion correction base you can select one of the following options:

- First: to use the first time point of the series
- Second: to use the second time point of the series

- · Middle: to use the middle of all time points in the series
- Custom: to specify a time point of your choice
- 1 On the **Calculation** tab, select the **First**, **Second**, or **Middle** option for the respective body part.

– or –

Select the **Custom** option and enter a number to specify a time point of your choice. The number reflects the position of the time point within the loaded series

2 Click OK to save your changes.

The **Reset** dialog box opens. If you agree, a reset of all the data in the workflow is performed.

4.3.2 Defining the thresholds for segmentation

You can change the threshold values according to your clinical preferences. All voxels with HU values within the range you specify are kept for display and calculation, while all other voxels are excluded. Consider the minimum and maximum threshold values. See (\rightarrow Page 48 *Calculation settings*).

- ✓ The CT Dynamic Angio Configuration dialog box is open.
- 1 In the **Default Segmentation Thresholds** section of the **Calculation** tab, check whether the currently set segmentation threshold values correspond to your clinical preferences.
- **2** To change the threshold values for a body region, enter new minimum and maximum HU values in the corresponding fields.
- 3 Click OK to save your changes.

The **Reset** dialog box opens. If you agree, a reset of all the data in the workflow is performed.

4.4 Visualization settings

On the **Visualization** tab, you can change the settings for **Volumes**, **Time Attenuation Curves**, and **Tables**.

- In the Volumes section, you can change the predefined display type, slice thickness, and window values for each volume type. See (→ Page 51 Changing the initial display of specific volumes).
- Time Attenuation Curves (TACs) can be displayed in two ways:
 - With absolute scaling (curves start at their own values)
 - With relative scaling (curves are aligned, so that they all start near 0 HU)

You can set the initial display of the TACs to **Absolute** or to **Relative**.

- There are two Tables that display the following:
 - Values related to Time Attenuation Curves
 - Statistical ROI values

You can choose one of the two tables that should be in the foreground of the TAC tool.

See (→ Page 52 Setting the display properties for curves and tables).

4.4.1 Changing the initial display of specific volumes

- ✓ The CT Dynamic Angio Configuration dialog box is open.
- 1 On the **Visualization** tab, select a **Display Type** from the list of the **Volume** you want to change.
 - If you have selected the MPR Thick, VRT Thin, or MIP Thin display type, the Slice Thickness fields are available.
 - For the MPR, MPR Thick, MIP, and MIP Thin display types, you can adjust the Window Values fields.
 - For the MPR display type selected in the Original Data and the Baseline fields, the Window Values from the DICOM image header are used.
- 2 Enter a value for the Slice Thickness in mm.

- **3** Enter a value for the **Width** (contrast) and the **Center** (brightness) to specify the window in HU.
- 4 Click OK to save your changes.

The **Reset** dialog box opens. If you agree, a reset of all the data in the workflow is performed.

4.4.2 Setting the display properties for curves and tables

You can specify the initial display of curves and tables in the TAC tool.

- ✓ The CT Dynamic Angio Configuration dialog box is open.
- 1 In the **Time Attenuation Curves** section of the **Visualization** tab, select the **Absolute** option to display the curves with absolute scaling.

– or –

Select the **Relative** option to display relative curves (all curves start near 0 HU).

2 For the **Result Table**, select the **Curve** option to display the ROI data represented by curves in the foreground.

– or –

Select the **Statistics** option to display the ROI data represented by a table in the foreground.

3 Click OK to save your changes.

The **Reset** dialog box opens. If you agree, a reset of all the data in the workflow is performed.

4.5 Selecting result volumes for archiving

You can send your result volumes to the RIS or PACS when you complete the workflow. You can configure which result volumes should be sent by default.

- ✓ The CT Dynamic Angio Configuration dialog box is open.
- 1 On the **Results** tab, select the check boxes of the required result volumes in the **Archive** section.

2 Click OK to save your changes.

The **Reset** dialog box opens. If you agree, a reset of all the data in the workflow is performed.

4.6 Restoring Siemens default settings

You can restore the Siemens default settings, at any time.

- ✓ The CT Dynamic Angio Configuration dialog box is open.
- 1 Click the tab on which you want to restore the settings.
- 2 Click the Restore Default Settings button.
- **3** Click **OK** to save the changes.

5 Glossary

4D noise reduction	A noise reduction algorithm that preserves time-density information and improves the image quality of the noisy input images for a solid evaluation of the images.
Baseline volume	A combined volume consisting of early time points without the contrast medium.
Body Motion Correction	An elastic motion correction method that reduces motion, based on patient or organ movement in body data sets.
image noise	A random variation of brightness in computed tomography (CT) images due to low kV or low dose.
motion correction base	An algorithm to select the time point position within the series for each body part. It aligns images that show strong patient or organ movements.
movie	An animation mode that scrolls through a time series or a 3D volume. It displays the images one after another, as in a flipbook.
Myocardium Motion Correction	A specific myocardium motion method that reduces motion for Siemens Heart Perfusion data sets.
Neuro Motion Correction	A rigid motion correction method that reduces motion in brain data sets.
temporal average (tAVG) volume	An automatically generated volume created from all the loaded time point volumes. At the same image position, each voxel in the new volume displays the average Hounsefield units (HU) of all the time point voxels.
temporal maximum intensity projection (tMIP) volume	A segment type to display a calculated volume created from all the loaded time points of the series. At the same image position, each voxel in the new volume displays the maximum Hounsefield units (HU) of all the time point voxels.

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Manufacturer's note:

The CE marking applies only to Medical Devices which have been put on the market according to the EC Regulation. Unauthorized changes to this product are not covered by the CE mark and the related Declaration of Conformity.

Caution: Federal law restricts this device to sale by or on the order of a physician, dentist, or veterinarian (21 CFR 801.109(b)(1)).

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