

CT Analysis

English

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Instructions for Use

IntelliSpace Portal

PHILIPS

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1 About the CT Applications Guide

This guide includes information about using the CT applications. For Intended Use, Safety and Security, and other important information, please refer to the "Instructions for Use" included with your IntelliSpace Portal system before using the CT applications.

Analysis applications allow you to access powerful Portal software for analyzing patient studies.

After selecting the desired study and/or series from the Directory, you may launch the appropriate Analysis application (only one at a time) and begin image processing and analysis functions.

Click the Analysis down-arrow to display a selection of application icons.

Click the icon of the desired application to load your selected study into the application.

NOTICE

Some application icons may be grayed out if the application is not suitable for the study or studies you have selected. Example: Loading multiple studies to an application that only supports loading one study. In addition, your Portal configuration may not support every analysis application.

NOTICE

When loading data into an application, ensure the orientation shown on the images is consistent with the images' appearance. This precaution is required for data that contains wrong orientation information because the data will be incorrectly presented within the application.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

2 Bone Mineral Analysis



The Bone Mineral Analysis (BMA) application is designed to measure a patient's bone density, helping the physician assess the patient's risk of osteoporosis. Osteoporosis is characterized by low bone mass and structural deterioration of bone tissue. The BMA application uses the patient's own muscle and fat tissues as internal references, instead of using an external phantom. This helps reduce reproducibility errors when later studies are used to track the patient's bone density changes over time.

NOTICE

Before continuing, refer to the "Instructions for Use" that came with your scanner.

NOTICE

BMA results should not be used as the sole basis for clinical diagnosis.



CAUTION

The use of contrast CT images may bias the results.

The BMA application can process subsequent studies of the patient to determine the trending of the patient's bone density. However, the same scan parameters must be used on subsequent exams to maintain accuracy.

NOTICE

There are two situations under which the bone analysis application might be applied to analyzing a patient's spine CT image: either the imaging was performed as (1) a dedicated bone mineral density (BMD) study or (2) as an adjunct to a lumbar spine procedure. The images used in the BMD calculations should be targeted so that the lumbar spine is centered and the retrosplinal muscle and fat are included in the images.

Please refer to the user documentation that came with the scanner (from which the images derived) for more information about scanning protocols, etc., before beginning the Bone Mineral Density (BMD) analysis.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Portal configuration, this application may not be available.

Guidelines for Defining Osteoporosis

The Bone Mineral Density Results table displays the list of measured vertebrae, the vertebral average BMD score and indicates the QCT Trabecular Spine BMD range with its equivalent WHO diagnostic category.

Bone Mineral Density Results				
Date	Measured Vertebrae	Average BMD (mg/cm ³)	QCT Trabecular Spine BMD	Equivalent WHO diagnostic cate
12 Nov 2007	T12, L1	151.7(mg/cm ³)	BMD>120mg/cm ³	Normal

According to the average Spine BMD range of the measured vertebrae, the equivalent WHO diagnostic category is automatically displayed.

BMD Range	Equivalent WHO diagnostic Category
BMD >120 mg/cm ³	Normal
80 mg/cm ³ ≤ BMD ≤120 mg/cm ³	Osteopenia
BMD <80 mg/cm ³	Osteoporosis

Tab. 1: Guidelines for Bone Mineral Density Results Analysis

If further analysis pertaining to bone density measurements and the average BMD color graph is required, the Bone Mineral Density Detailed Results table is accessible both from the Control Panel or through the BMD results table.

Bone Mineral Density Results				
Date	Measured Vertebrae	Average BMD (mg/cm ³)	QCT Trabecular Spine BMD	Equivalent WHO diagnostic cate
14 Jan 2013	L2	135.5(mg/cm ³)	BMD>120mg/cm ³	Normal

The detailed Results obtained from a BMD study include a Bone Mineral Density (BMD) score and a T-score and a Z-score for each body vertebra measured.

Bone Mineral Density Detailed Results				
Date	Vertebra	BMD (mg/cm ³)	T-Score	Z-Score
14 Jan 2013	L2	135.5	-1.6	0.9

Process Follow-up Studies

To ensure accurate reproducibility for BMD trend analysis evaluations, use the same scan parameters on all subsequent exams.

1. From the Directory, select the patient’s original study, and all follow-up studies, along with the results file saved from the original study.
2. Load the studies into the Bone Mineral Density analysis application.
3. Starting with the Define stage, follow the same procedure for follow-up studies as described for original studies.
 - The new Results stage displays the information from all the studies. The trend lines and rate of change calculations are expressed as the rate of bone change in mg/cm³/year.

$$\text{Rate Of Change} = \frac{[(\text{BMD value for first date} - \text{BMD value for last date})]}{(\text{number of days between first date and last date})} * 365$$
 - The results will be saved into the newer study.

BMAP Trend Graph

This graph displays if you are doing a comparison when subsequent studies are loaded for trend analysis calculations. It shows the change in BMD value and the rate of change. Results are presented in both graph and table form, and indicate the rate of bone change in mg/cm³/year.

Define Work Stage

The default display in the Define work stage opens with a main axial image and coronal and sagittal reference images. The BMD histogram graphs are blank until ROIs are placed.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Mark Locations

Draw locations/ROIs (regions of interest) in specific bone, muscle, and fat locations on patient images. The BMD application will generate histograms of each ROI’s Hounsfield values, then (in the section “Results Work Stage”), determine the patient’s bone density from the data.

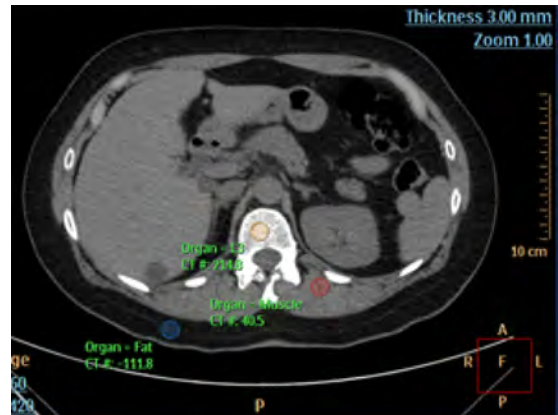
Draw ROIs in at Least 3 Different Vertebral Bodies

To ensure accurate results, you must draw the ROIs on at least 3 different vertebral bodies. The recommended vertebral bodies are L1 through L4. You can use T12 or L5 if pathology exists in other vertebral bodies.

Draw ROIs in Sets of Three

The ROIs must be drawn on at least three images of vertebral bodies, in sets of three (3):

- **Vertebral ROI.** Placed in the central portion of the trabecular bone.
- **A Muscle ROI.** Placed in retrosplinal muscle.
- **A Tissue ROI.** Placed in fat tissue.



Place ROIs

On each of at least three vertebral bodies, you will draw an ROI on a vertebral body and label it. After you label the ROI, the application automatically draws two more ROIs for muscle and fat. They are placed in unspecific locations. You must move and re-shape them to accurately include only the desired tissue.

1. Scroll through the images.
2. Find the mid-portion of the first desired vertebral body (L1 for example). You can angle the image to the vertebral body if necessary.
3. Activate the desired ROI shape (circle, ellipse, or spline) using the “Mark bone & locate muscle/fat” function.
4. Click near the anterior portion of the vertebral body and drag the ROI to include only the Trabecular Bone.

NOTICE

When drawing an ROI, avoid any pathology, nerves, or blood vessels that are in the body of the vertebra. If there is no optimal location to place the ROI, go to the next vertebral body.

5. Select the appropriate label from the “Select location” menu.
 - Fat and muscle ROIs automatically are drawn on the image. They are labeled and CT# values are displayed.
 - Histograms of the three ROIs are displayed at the display’s bottom.

- The “mark bone & muscle fat” function becomes populated with a list of tissues when ROIs are drawn and labeled.
6. Move (by dragging) the fat and muscle ROIs to appropriate locations. If the ROI does not contain enough of the needed tissue, resulting in an invalid Hounsfield value, a caution sign appears in the list next to the label.
 - Vertebra ROI CT# should be above 15.
 - Muscle ROI CT# should be in the range of 40 – 120.
 - Fat ROI CT# should be in the range of -150 – 0.
 7. If correction of the muscle or fat ROIs are needed, use the Editing ROIs procedure to adjust the ROIs to include only the desired tissue.
 8. Repeat the above steps for each vertebral ROI that you place. You can scroll between images with Page Up and Page Down, or with Up Arrow and Down Arrow.

Optimize Histograms

Once the ROIs are placed the histogram is created. Make sure that the histogram displays an appropriate bell curve; this indicates good ROI placement. Once bone, muscle, and fat Histograms are defined, proceed to the Results stage using the navigation button next to the “Define” stage indicator.

1. Examine the histograms.
2. Make sure that the histogram displays an appropriate bell curve, which indicates good ROI placement.
3. If necessary, you can modify an ROI (and thus improve its corresponding Histogram), using the following techniques:
 - To move an ROI: Point the mouse into the ROI to activate it and drag the ROI to the desired location.
 - To resize an ROI: Point the mouse onto the ROI to activate it and drag a control point to resize or reshape the ROI.
 - To delete a Bone ROI: Point the mouse into a bone ROI to activate it. Right mouse click on the ROI, and select Delete. The Bone ROI and its corresponding fat and muscle ROIs are deleted. You cannot delete a fat or muscle ROI only.
4. If desired, you can move the ROI’s on-screen label. Place the mouse over the label to make it active. Drag the label to the desired location.

Results Work Stage

In this work stage, review the patient’s results and compare them to those of a normal (reference) population. You also can save the results for future use in trend analysis and send the results to a report.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Results with Multiple Studies

When loading results with multiple studies, the Bone Results Table gives results for each vertebra which was marked on a study (only BMD results) per date.

NOTICE

Vertebra that were not marked on a specific date have the value of zero. Only vertebra marked on more than one study are marked.

The BMAP Trend Graph displays if you are doing a comparison when subsequent studies are loaded for trend analysis calculations. It shows the change in BMD value and the rate of change. Results are presented in both graph and table form, and indicate the rate of bone change in mg/cm^3 year.

Select Population Reference

You can compare the patient's bone mineral density to three reference populations. Two of the databases can be applied to male patients and all three to female patients.

- European - male or female
- Icelandic - female only
- University of California at San Francisco (UCSF) - male or female



WARNING

If the reference population is changed, all results are re-calculated. Verify the new values before continuing.

NOTICE

The European database is recommended because it fits a more general population model. It can be applied to both male and female patients, and to an age range from 20 to 80.

Bone Density Results Table and Graph

Results are presented in both graph and table forms. In the table form, each vertebral body measured includes a BMD, T-score, and Z-score value, as well as the date the BMD scan was acquired. Also included is an average BMD, T-score, and Z-Score.

The graph includes colored reference curves. These colored curves relate to the reference population database. The reference curves demonstrate the distribution of the mean population for the appropriate age and gender. The average BMD result (blue ball on graph) displays on top of the colored reference population curves. Standard deviation values are related to the following color codes:

T-score. Compares a given patient's BMD to the mean BMD of a young, healthy individual.

Z-score. Compares a patient's BMD to the average BMD value of other patients their own age and gender, displayed in units of standard deviation (SD).

Graph Colors

Green	1 to 2 SD above the average
Yellow	within ± 1 SD
Red	1 to 2 SD below the average

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Rate Calculation

NewM = BMD value from the most recent scan

PrevM = BMD value from the first scan

Diff = Time between scans (years)

The rate is calculated as follows:

$$Rate = \frac{NewM - PrevM}{Diff} \left[\frac{\frac{mg}{cc}}{Year} \right]$$

3 Brain Perfusion

Introduction



The Philips Medical Systems' Brain Perfusion (BP) application is a post processing software to be used as an advanced visualization application of CT brain perfusion images. The BP application is used to support the analysis of dynamic and/or serial CT brain images after injection of contrast. The BP application is intended to assist with the evaluation of an area of interest, and to generate qualitative and quantitative information about changes in image intensity over time. The BP application presents the results as a composite (single image that is calculated from a set of time course images at a single location) images and provides perfusion parameters maps. The following parameters related to brain perfusion are calculated: Cerebral Blood Flow (CBF), Cerebral Blood Volume (CBV), local bolus timing (Time to Peak (TTP)/Time to Maximum (Tmax)) and Mean Transit Time (MTT) and supports processing and visualization of Permeability maps.

The physician retains the ultimate responsibility for making the final diagnosis.

The BP application is launched from Philips Medical Systems' IntelliSpace Portal (ISP) environment.

Key Features

The Brain Perfusion (BP) application has the following key features:

- Supports visualization and processing of dynamic and/or serial brain CT scans with contrast agent injection.
- Displays results as composite (single image calculated from a dynamic set of images at a single location) images (tMIP images).
- Displays time-density curves reflecting the HU contrast enhancement tracked for an ROI over time.
- Supports detection of reference artery, reference vein, mirror line placement and brain mask.
- Supported option for 3D motion correction with anatomical alignment.
- Provides Perfusion maps of Cerebral Blood Volume (CBV), Mean Transit Time (MTT), Cerebral Blood Flow (CBF) and Time to Peak (TTP), using the time arrival *sensitive* method.
- Provides Perfusion maps of Cerebral Blood Volume (CBV), Mean Transit Time (MTT), Cerebral Blood Flow (CBF) and Time to maximum (Tmax), using the time arrival *insensitive* method.
- Provides summary maps according to default thresholds. The user may manually adjust the summary map thresholds and/or different parameters according to the physician's preference.
- Provides colored warning strips (Traffic Lights), indicating the quality of the Brain Perfusion data (acquisition).
- Supports processing and visualization of permeability maps.

- Displays pre-defined ROI templates for localized quantitative evaluation of perfusion information.
- Supports automatic workflow – Brain Perfusion application can generate and send automatic results to defined external destination.

NOTICE

The Brain Perfusion Application's Arrival-Time Insensitive method is not available for sale in the United States.

Indications for Use

The Philips Medical Systems' Brain Perfusion (BP) application is a post processing software application intended to assist with the evaluation of an area of interest, to generate qualitative and quantitative information about changes in image intensity over time. It supports the analysis of dynamic/serial CT after injection of contrast agent, by calculating the parameters related to brain perfusion and displays the results as a composite (single image that is calculated from a set of time course images at a single location) images.

Intended User Population

The expected users of the application are trained professionals, including but not limited to physicians and medical technicians.

Limitation for Use

Rx Only**CAUTION**

In the United States, Federal law restricts this device to sale, distribution and use by or on the order of a physician.

NOTICE

Depending on your Portal configuration, this application may not be available.

**WARNING**

When loading data into any application, verify that the image orientation shown is consistent with the image appearance. This precaution is required for data that contains incorrect orientation information and therefore, will be incorrectly presented within the application. For example: Legacy nuclear medicine volume data (SPECT or PET), reconstructed using cardiac orientations, may not encode the orientation information correctly.

**WARNING**

When loading CT images into Brain Perfusion, all images which contain 16 bit data are converted to 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

Brain Perfusion Preprocessing

To run preprocessing, right-click on a **Series** in the **Directory** and select **Run Processing > Brain Perfusion** from the menu.

Once preprocessing is complete, a **TI-CTA** series is created (the original **Series** is retained by default). The **TI-CTA** series can be loaded into other viewing applications.

When preprocessing is selected for thin slices (typically less than 5 mm), it combines all time-points (volumes) to an approximate thickness of 5 mm and generates a new Brain Perfusion preprocessed result series. The combining process begins with the first axial slice (lowest slice position) and performs 3D registration based on the original thin- slice data. The Brain Perfusion processed result series can be launched into the brain perfusion application.

When Automatic Results Creation is configured in the Brain Perfusion application (from the Brain Perfusion batch Tab options), the Auto batch series is created based on the default settings defined by the Administrator. For detailed Automatic results creation workflow, please refer to section “Automatic Results Creation Workflow” on page 88.

NOTICE

Preprocessing – slice thickening: Since some scans have thickness that is not a natural denominator of the predefined thickness, approximations are made. For example, for a 1.2-mm slice thickness, the system combines every 4 images to achieve a slice thickness of 4.8 mm, which is the closest slice-thickness for 5 mm (the default value).

In some cases, the application removes some slices in the time points. For example, if a 1-mm dataset contains 43 images per time point, the application starts thickening at the first image and combines every 5 images in each time point, so images [41-43] are discarded.

If more than one **Series** is selected, all **Series** will be combined into one resulting **Series**.

NOTICE

Some slices may be removed during the preprocessing procedure.

Configure Thin-slice Processing Preferences

1. Go to the **Directory**, select **Preferences**, and then select **Processing**.
2. In order to set the processing parameters for the Brain Perfusion application, select the relevant **Protocol**, **Body Part** and other settings for which preprocessing must be run.

About the Brain-Perfusion Time-invariant CTA Series

The CT **Brain Perfusion** application includes a preprocessing option that creates the **TI-CTA** (time invariant CTA) series that may be loaded into viewing applications. The **TI-CTA** series includes tMIP images with information about the arterial, venous and collateral systems.

To create the **Series**, right-click on the desired study and select the **Brain Perfusion** preprocessing option from the menu.

Once preprocessing is complete, select the **TI-CTA** series and load it into a viewing application.

Perfusion Images

- **The original images.** These can be viewed in tMIP or Average modes.
- **CBF.** Cerebral Blood Flow.
- **TTP.** Time To Peak (Available only when using Time Arrival sensitive method).
- **CBV.** Cerebral Blood Volume.
- **MTT.** Mean Transit Time.
- Permeability (special scan protocol required).
- **Tmax.** Time to peak of deconvolution residual function (available only when using Time Arrival Insensitive method).

Summary Maps

The Brain Perfusion (BP) application provides color-coded summary maps. The default summary maps are based on the Arrival Time Sensitive method and show areas of increased MTT relative to the contra-lateral hemisphere and reduced or non-reduced absolute CBV.

The user can manually adjust the summary maps thresholds and/or different parameters according to the physician's preference.

Data Tables and Graphs

NOTICE

Before continuing, refer to the **Instructions for Use** that came with your scanner. Ensure you use the applicable protocols for the Perfusion Map functions as well as the Permeability measurements and Permeability maps.

- Reference Vessel Statistics
- ROI Statistics
- 2D Measurements-Summary Map (Areas Statistics Table)
- 3D Measurements-Summary Map (Volume Statistics Table)
- Time and Vessel curves

NOTICE

Images from ongoing longitudinal studies that were initially processed using earlier versions of Philips Brain Perfusion application should be reprocessed in their entirety using the latest software version.

NOTICE

Before continuing, refer to the **Instructions for Use** that came with your scanner. Ensure you use the applicable protocols for the Perfusion Map functions as well as the Permeability measurements and Permeability maps.

With studies of sufficient scan duration, Permeability Analysis can be used to measure the contrast agent permeation of the blood-brain barrier.

To properly launch the **Brain Perfusion** application, you must load a **Series** with **at least 8 consecutive time points**, with a maximum of 2,080 total images.

Brain Perfusion Scanning Protocols

NOTICE

The protocols in the following section are applicable to the Perfusion Map functions.

For the most updated scan parameters, please refer to the factory protocols for scanning. It is also recommended to consult with your local Philips application specialist.

For details about Permeability measurements and Permeability maps, see: section “Reference Permeability Scan Protocols” on page 30.

Suggested Brain Perfusion Protocols (Brilliance scanners only)

	Brilliance Big Bore		Brilliance 16 slice	
	Non-Jog Mode	Perfusion Jog Mode*	Non-Jog Mode	Perfusion Jog Mode*
Thickness	6.0	6.0	Thickness	6.0
Increment	0.0	0.0	Increment	0.0
KV	90	9.0	KV	90
mAs	200	200	mAs	125
Cycle Time	2.3	–	Cycle Time	2.0
Cycles	30	–	Cycles	30
# of Jog Cycles	--	15	# of Jog Cycles	–
Resolution	Standard	Standard	Resolution	Standard
Collimation	16x1.5	16x1.5	Collimation	16x1.5
RT	0.5	0.5	RT	0.5
FOV	250	250	FOV	250
Filter	UB	UB	Filter	UB
WC/WW	80/40	80/40	WC/WW	80/40
Matrix	512	512	Matrix	512

* Perfusion Jog Mode is an available option for Philips Brilliance scanner.

Suggested Brain Perfusion Protocols (Brilliance scanners only)

Brilliance 40 slice			Brilliance 64 slice		
	Non-Jog Mode	Perfusion Jog Mode*		Non-Jog Mode	Perfusion Jog Mode*
Thickness	5.0	5.0	Thickness	5.0	5.0
Increment	0.0	0.0	Increment	0.0	0.0
KV	80	80	KV	80	80
mAs	125	125	mAs	125	125
Cycle Time	2.0	–	Cycle Time	2.0	–
Cycles	30	–	Cycles	30	–
# of Jog Cycles	--	15	# of Jog Cycles	–	15
Resolution	Standard	Standard	Resolution	Standard	Standard
Collimation	32x1.25	32x1.25	Collimation	32x1.25	32x1.25
RT	0.4	0.4	RT	0.5	0.5
FOV	250	250	FOV	250	250
Filter	UB	UB	Filter	UB	UB
WC/WW	80/40	80/40	WC/WW	80/40	80/40
Matrix	512	512	Matrix	512	512

* Perfusion Jog Mode is an available option for Philips Brilliance scanner.

Suggested Brain Perfusion Protocols (Brilliance scanners only)

Brilliance iCT SP			Brilliance iCT		
	Non-Jog Mode	Perfusion Jog Mode*		Non-Jog Mode	Perfusion Jog Mode*
Thickness	5.0	5.0	Thickness	5.0	5.0
Increment	0.0	0.0	Increment	0.0	0.0
KV	80	80	KV	80	80
mAs	125	125	mAs	125	125
Cycle Time	1.5	–	Cycle Time	1.5	–
Cycles	40	–	Cycles	40	–
# of Jog Cycles	–	15	# of Jog Cycles	–	15
Resolution	Standard	Standard	Resolution	Standard	Standard

Suggested Brain Perfusion Protocols (Brilliance scanners only)

Brilliance iCT SP			Brilliance iCT		
Collimation	32x1.25	64x0.625	Collimation	64x1.25	64x1.25
RT	0.4	0.4	RT	0.4	0.4
FOV	220	220	FOV	220	220
Filter	UB	UB	Filter	UB	UB
WC/WW	80/40	80/40	WC/WW	80/40	80/40
Matrix	512	512	Matrix	512	512

* Perfusion Jog Mode is an available option for Philips Brilliance scanner.

NOTICE

When applying the **Summary Maps** functionality, note that there are no standard recommended threshold values for the reduced CBV and increased MTT when using scans acquired with Perfusion Jog Mode standard scan protocol in iCT/iCT SP scanners.

Reference Permeability Scan Protocols**WARNING**

As with all time series, motion artifacts may affect the accuracy of permeability maps.

Patient motion should be restricted during the longer duration acquisition recommended for permeability analysis.

NOTICE

Padded hook-and-loop straps can be used for better patient fixation.

Reference Protocols - Perfusion / Permeability Scan		
Perfusion part of scan		Permeability part of scan
Frames - 40		Frames - 5 or 6
Cycle time - 1.5 s		Cycle time - 30 s
60 s total acquisition		150 - 180 s
Follow the instructions for Brain Perfusion scanning in the next section, and in the Brilliance scanner Instructions for Use.	Allow less than <- 30 seconds -> between scans	Switch the scanner to a 30 second cycle time and start acquiring as soon as possible.
For reference: the perfusion scan duration should be approximately 60 s (using the reference protocols), and should not be less than 45 s.		Note: To identify extravasated contrast agent that has permeated the blood-brain barrier, the scan duration must be extended to include delayed phases of the passage and recirculation of contrast agent in the brain. As a reference, the total scan duration (perfusion + permeability) should be at least 210 s.
Total scan duration not less than 210 seconds.		
Be sure to minimize patient motion.		

Minimizing Patient Motion

Patient motion is the main cause of unreliable perfusion and permeability maps. Permeability maps are especially sensitive to motion because the measurement is based on smaller contrast changes. Disruptive motion events (for example coughing and body motion) are more likely in a longer acquisition. Out-of-slice motion that cannot be corrected by the application may result in errors in the permeability maps.

- Motion restriction is important in perfusion and permeability analysis, particularly when low patient compliance is observed.
- Consider using fixation equipment or methods (for example, use a head holder).
- Consider using padded hook-and-loop straps to further suppress motion.
- To evaluate the presence of motion artifacts, change the rendering of tMIP images to **Average** using a viewpoint control at the bottom left corner and scroll along the time dimension to detect any residual motion.



Use the Cine tool to scroll through the images. When activated, the Cine tool uses the Average rendering mode. The main image viewport must be active to use the Cine tool.

While scrolling along the time dimension manually, focus on easily recognizable objects to track the motion. For example: you can follow the location of the artery cursor and search for time points where the cursor has shifted away from the artery.

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Review of Brain Perfusion Scanning

This section explains one possible way to perform a Brain Perfusion scan based on the Philips Brilliance scanner. For information applicable to different scanners, please refer to the Instructions for Use of the specific scanner.

NOTICE

A special scan protocol must be used to acquire a study for viewing Permeability maps and measurements.

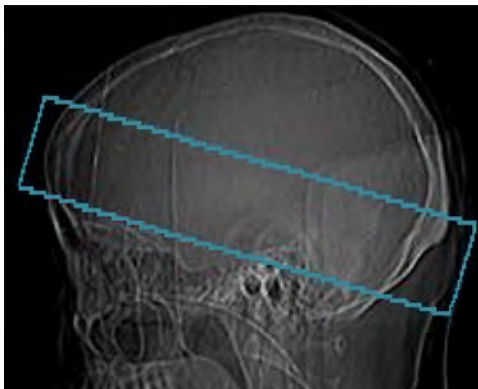
NOTICE

Contrast flow and volume parameters may vary by institution protocols. Consult your Radiologist prior to setting up or changing any injection protocols in your department.

1. Place patient on the table.
2. Start an IV using an appropriate size IV catheter (18/20 gauge).
3. Center patient for head scan by placing the lateral laser on the EAM.
4. Perform a non-contrast study of the brain using your department's routine brain protocol.
5. Click **Plan Scan**.
6. Click **Insert Scan**.
7. From the Exam Protocol Exam Group, select **Head**.
8. From Exam Protocols, select **Brain Perfusion**.
9. Plan the desired Perfusion location.

Refer to the illustration below of Representative Surview Plans. (Please consult with the Radiologist for exact location).

Representative Surview plan - 64-Slice:



10. Arm the injector with Contrast. Refer to suggested Reference Contrast Protocols:

- **For Non-Jog scans:** 40-50mL contrast, followed by 20-40mL saline.
- **For Jog Mode scans:** 70mL contrast, followed by 45mL saline.
- **For All scans:** injection rate of 4-6mL per second; 18-20 gauge IV placed in right antecubital vein.

NOTICE

Consult your Radiologist prior to setting up or changing any injection protocols in your department.

11. Start the Scanner and Injector at the same time.
12. End the Exam.

NOTICE

The scan will take around 45 - 60 seconds for a perfusion scan and a minimum of 210 seconds for permeability scans.

NOTICE

A proper scanning procedure is essential for obtaining meaningful perfusion images. Special care must be taken to ensure that:

- The scan duration is sufficient to cover a pre-contrast period as well as the entire first pass of the injected contrast bolus. The pre-contrast period consists of a base line which should include at least 3 cycles. (Recommended scan minimum: 45 second scan duration; for Permeability Analysis: 210 seconds.)
- For Quantitative results, please ensure that the temporal resolution does not exceed 4.0 seconds.
- Quantitative results include the Summary maps display.
- The contrast injection is sufficiently rapid to provide reasonable enhancement in white matter while preserving a narrow bolus. See the **Reference Contrast Protocols**.
- Please verify no residual motion is present after the registration is complete by switching the rendering mode to **Average** and scrolling horizontally. Use the Cine tool to support verifying the residual motion.
- When verifying the artery and vein detection, ensure the Artery time attenuation curve (TAC) peaks before the vein TAC.
- When verifying the artery and vein detection, ensure the Artery bolus arrival time (BAT) is earlier than vein BAT.

Failure to meet the above requirements may result in the creation of unreliable perfusion images.

**WARNING**

If the temporal resolution of the scans is greater than 4.0 seconds, quantitative perfusion measurements are not provided. The color maps and numeric values represent relative values only. Specifically, when applying the Summary Maps functionality note that for cases with such poor time resolution there are no recommended threshold values for Philips Brain Perfusion application for the reduced CBV and increased MTT.

- To improve the quality of results based on Jog-mode scans, please follow the modified injection parameters procedure.
- When loading images into Brain Perfusion, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

NOTICE

Quantitative results include the Summary maps display as well.

**WARNING**

The application results should not be used as a **SOLE** basis for diagnosis.

**WARNING**

There are no recommended threshold values for Philips Brain Perfusion application for the Summary Maps calculation in conjunction with the Arrival Time Insensitive method. The default threshold values are only applicable for Brain Perfusion Application Arrival Time Sensitive method and are not transferable to other methods or to other vendors. When using the system default thresholds for the Summary Maps, after applying the Arrival Time Insensitive method, the Summary Maps results may not be optimal.

NOTICE

The Brain Perfusion Application's Arrival-Time Insensitive method is not available for sale in the United States.

Review Adequacy of Input Data

If input data to the Brain Perfusion application is incomplete or incorrect, the resulting perfusion maps may provide inaccurate results.

Perfusion analysis requires that the scan includes the entire transit of contrast agent through tissue, from its earliest arrival to a point when the majority of the contrast agent has washed out on the venous side. Shown below is an example of a typical bolus' time attenuation curve (TAC).

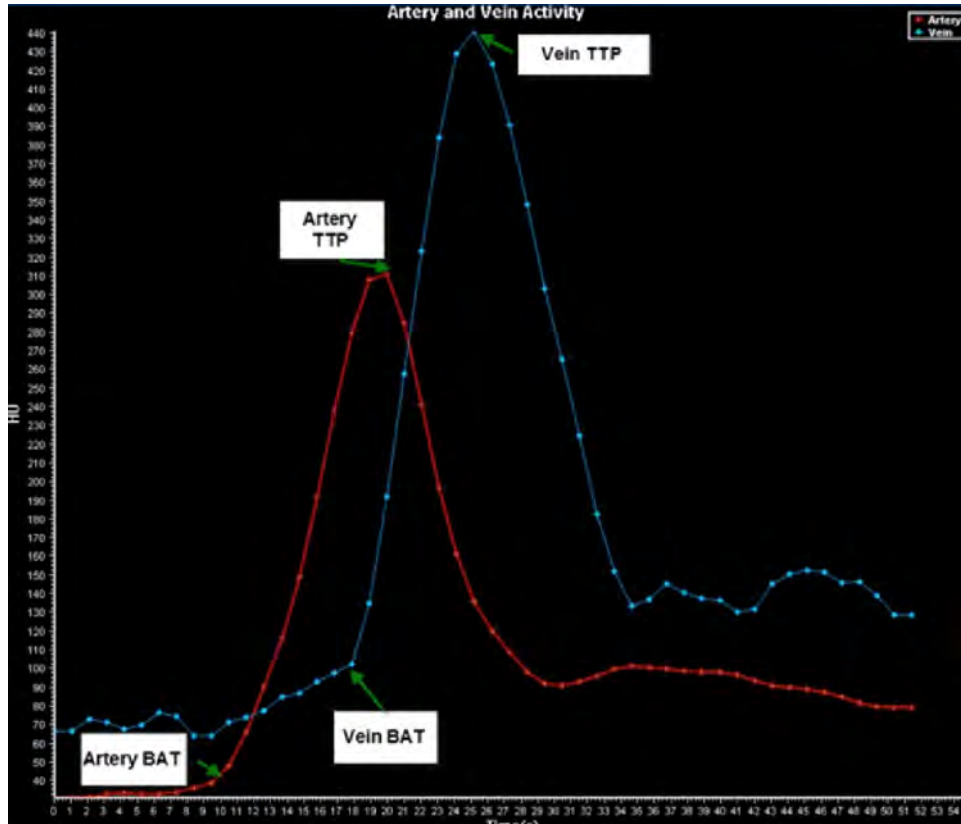


Fig. 1: Artery and Vein Activity

Therefore, one should verify that the total number of scan cycles and duration of the scan is adequate to cover the full inflow and outflow phases.

In addition, it is important to make sure that no significant patient motion occurred during the scanning. The verification should be performed after changing the rendering mode from **tMIP** to **Average** and scrolling the images (by moving the mouse in a horizontal direction from left to right) along the time domain.

- **Presence of Motion** – Cine view assists the user’s review presence of motion. When activated, Cine scrolls through Average mode images from the same z location.



- **Motion Correction** – In cases where unacceptable motion has occurred, the user may remove displayed time-points to exclude specific images (up to 8 points per scan and no more than 2 consecutive time point). Additional feature “3D motion correction” can be applied by the user to perform 3D registration and anatomical alignment. After the operation of anatomical alignment, the image is adjusted in order to have the cerebral mirror as a vertical line at the center of the image.

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NOTICE

In case of patient motion, the resulting perfusion may provide inaccurate results.

Brain Perfusion Input Requirements

The following are requirements for input data to the Brain Perfusion application.

Contrast Agent Injection and Timing

The duration of the scan must cover the whole uptake and outflow phase for the arterial and vein curve.

If the curves are not entirely included in the scan (i.e., if some data is missing, see below), the calculation of perfusion parameters cannot be used for diagnosis.

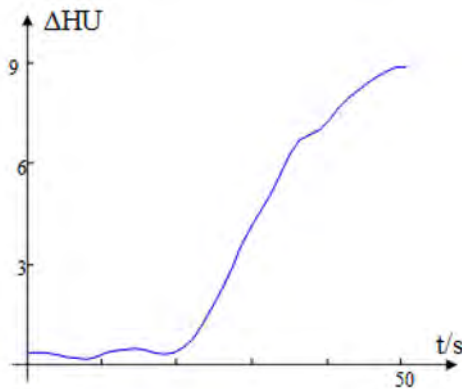


Fig. 2: Time attenuation curve with incomplete bolus (wash-out period is missing).

The perfusion analysis is also susceptible to problems during the contrast injection:

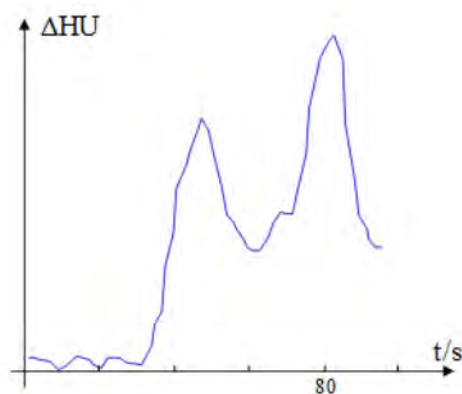


Fig. 3: Shape of the time attenuation curve due to problems during the injection.

In addition, the bolus arrival time should not be too delayed (i.e., more than 15 seconds). A delayed bolus arrival time and a normal bolus arrival time are shown in the figures below:

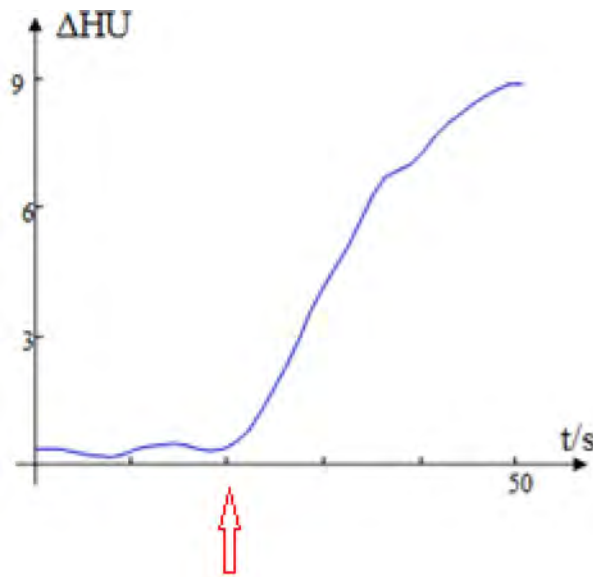


Fig. 4: The delayed bolus arrival time is identified by the red arrow.

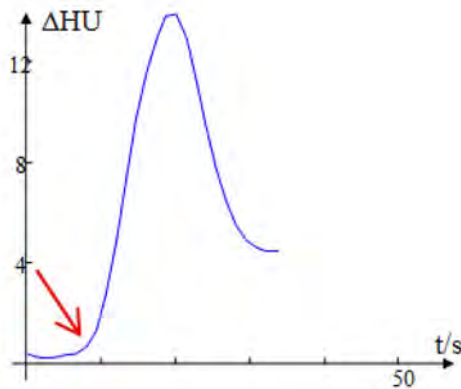


Fig. 5: The normal bolus arrival time is identified by the red arrow.

Analysis of Data

Brain Mask

Check the brain mask and verify all brain tissue is included in the mask. Adjustments of the mask can be done manually or by tuning the threshold value. See section “Vessel Definition Work Stage” on page 41 and section “Perfusion Map Work Stage” on page 56.

Vessel Selection

The perfusion maps and values are affected by the vessels selected by the user for the calculation.

- **Arterial curve.** The artery that peaks first (lowest TTP) should be selected (automatic or manual selection). Most commonly the anterior cerebral artery, or ACA, or middle cerebral artery (MCA) is selected as the reference vessel. If possible, the artery on the contralateral (non affected side) should be used.

- **Vein curve.** Verify that the vein with the highest enhancement is selected. The curve should peak later than the arterial curve and its amplitude should be higher in most cases. The vein commonly selected is the Superior Sagittal Sinus (SSS).

Remove Vessels

When using the remove vessels functionality, make sure that only vessels are removed from the cerebral mask. This can be done by comparing the resulting perfusion maps with the corresponding tMIP image. Adjustment of the threshold for vessel removal might be needed. See section “Vessel Definition Work Stage” on page 41 and section “Perfusion Map Work Stage” on page 56.

The figure below illustrates tuning the threshold of the removed vessels:

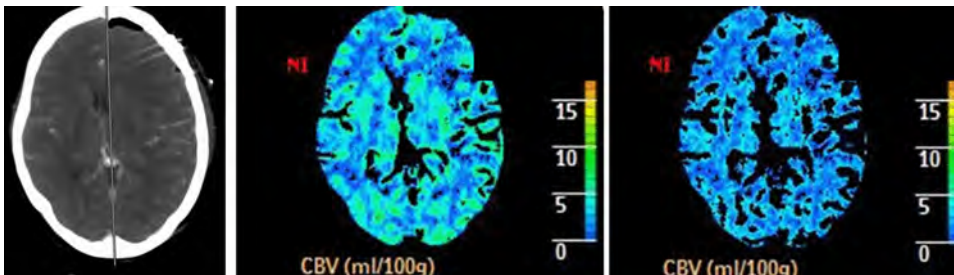


Fig. 6: (a.) original tMIP image; (b.) CBV map after removing vessels with the default value (9 ml/100 g); and (c.) CBV map after removing vessels with an incompatible threshold (too low in this case) and consequently a big portion of the cerebral mask not representing vessels was also removed.

Merge Two Series from Same Study

The Merge function is a procedure that allows you to merge (in the time domain) two perfusion scan series from the same patient into one series.

The Merge function is initiated within the Patient Directory just before the Brain Perfusion application is launched.

Permeability Analysis

The Merge procedure is required when you want to do a Permeability Analysis calculation using two series of the same patient, which were scanned one after the other, but were acquired using different time intervals.

Note the following series characteristics that must be observed:

- the two series belong to the same study (same Study ID and FOV);
- all reconstruction parameters are the same between the two series: FOV, center x/y, filter, matrix, thickness, increment, orientation;
- the series to be merged have the same z-axis coverage; and
- the time gap between the end of the first scan and the beginning of the next is brief (ideally, less than 30 seconds).

Merge Procedure

1. In the Patient Directory find the desired Brain Perfusion study.
2. Select 2 or more brain perfusion or permeability series (from the Series List).
The following message displays: Loading more than 1 series is not supported. Would you like to merge the series into one?" The available responses are Merge and Close the application.
3. Click **Merge**.

Merge Outcomes

If all requirements for a successful merge are satisfied, the merge is performed.

If the time gap between the end of the first scan and the beginning of the next is more than 30 seconds, this message displays: "The time delay between the scans is higher than 30s. This may impact the analysis. Do you want to continue?" (yes, no).

Merge Output

A DICOM series is created that includes the data (pixel data) from both original series.

The resulting series is a new series which is added to the Series List, named Merged: [the series description of series 1]/[the series description of series 2].

The new series is a temporary series inside the Brain Perfusion application.

Launch Brain Perfusion

The Brain Perfusion application performs several automatic functions as it launches the study:

- Registration;
- Filtering;
- Brain mask detection;
- Reference artery detection;
- Reference vein detection;
- Mirror line placement; and
- Traffic Light check.

To properly launch the **Brain Perfusion** application, you must load a **Series** with **at least 8 consecutive time points**, with a maximum of 2,080 total images.

NOTICE

You can configure pre-processing to reduce loading time. If thin-slice data is present, the application will combine slices to an approximate thickness of 5 mm as part of preprocessing (see section “Brain Perfusion Preprocessing” on page 25 and section “Automatic Results Creation Workflow” on page 88).

1. From the **Directory** find and select the desired study and series.
2. Select the Brain Perfusion icon from the application icon chart.



The application processes the patient study opens in the Vessel Definition Work Stage.

NOTICE

Please verify vessels were detected correctly. See section “Brain Perfusion Reference Vessel Selection Guide” on page 77.

If Artery and Vein detection is not successful, you must manually mark the Artery and Vein.

NOTICE

If Traffic Lights found an issue with the acquisition data, before continuing see section “Using Brain Perfusion Traffic Lights” on page 83.

Minimum Scan Duration

The minimum scan duration for calculating Permeability results using the Brain Perfusion application (a Patlak analysis) is 210 seconds.

If the patient study you are launching has a shorter scan duration, the following warning message is displayed:

Scan duration is shorter than the Permeability scan duration value in the Calculation Parameters, therefore, permeability measurements are not available.

To properly launch the **Brain Perfusion** application, you must load a **Series** with **at least 8 consecutive time points**, with a maximum of 2,080 total images.

Vessel Definition Work Stage

The Brain Perfusion application attempts to perform Vessel Definition (and mirror line generation) automatically. You must verify the correctness of the automated processes. If required, manually define vessels and adjust the mirror line.

You can always access this stage and make changes manually, if desired.

NOTICE

If Traffic Lights found an issue with the acquisition data, either the Non-Severe Warning or Severe Warning message will appear throughout the application. For example, original tMIP/ average axial view, Summary Maps and Perfusion Maps, display a red or yellow warning light (depending on the warning type). Before continuing, see section “Using Brain Perfusion Traffic Lights” on page 83.

Main Viewport

Contains a grayscale tMIP slab image. You can scroll through the slab images with the Scroll function in the **Common Tools**. It is also possible to switch to Average mode which allows scrolling along the time dimension at the same z-location.

Reference Viewports

These artery and vein Reference tables and the Activity chart (time attenuation curves) are empty until you define the blood vessels.

Image Type

A **tMIP** (temporal Maximum Intensity Projection) image is a maximum intensity projection (across the time domain) for each z-axis location. One tMIP image is created for each z-axis slice location, and user may scroll in z direction to visualize entire volume.

Average images- The user may scroll the dynamic scan images in z direction or over time and visualize the entire volume over time.

NOTICE

Switch between the two image types with the active blue title shown in the bottom left corner of the viewport. When image type tMIP is selected, cine and scrolling along the time dimension is disabled.

Average Image tMIP Image

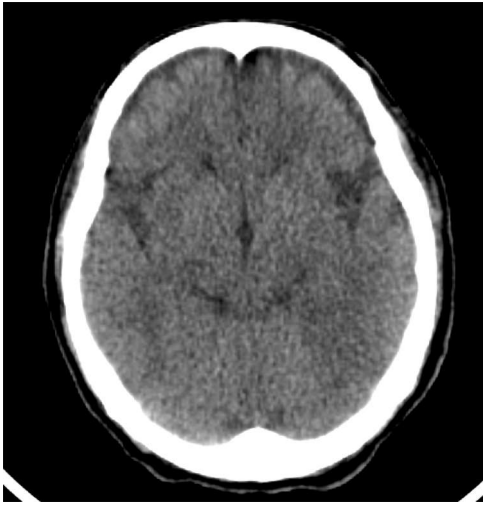


Fig. 7: Average Image

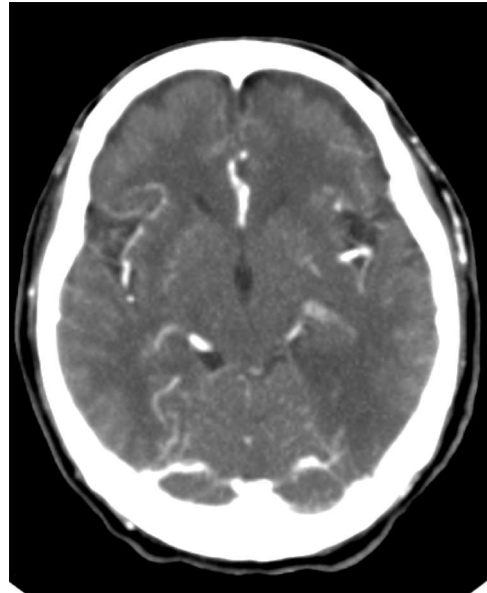


Fig. 8: tMIP Image

Artery and Vein Activity

This color-coded chart beneath the vessel definition image shows three contrast wash-in curves (arteries) and three wash-out curves (veins), with points marking each acquisition along the time axis. Arteries should enhance before the vein; this can be verified by observing that the arteries have smaller TTP than the vein.

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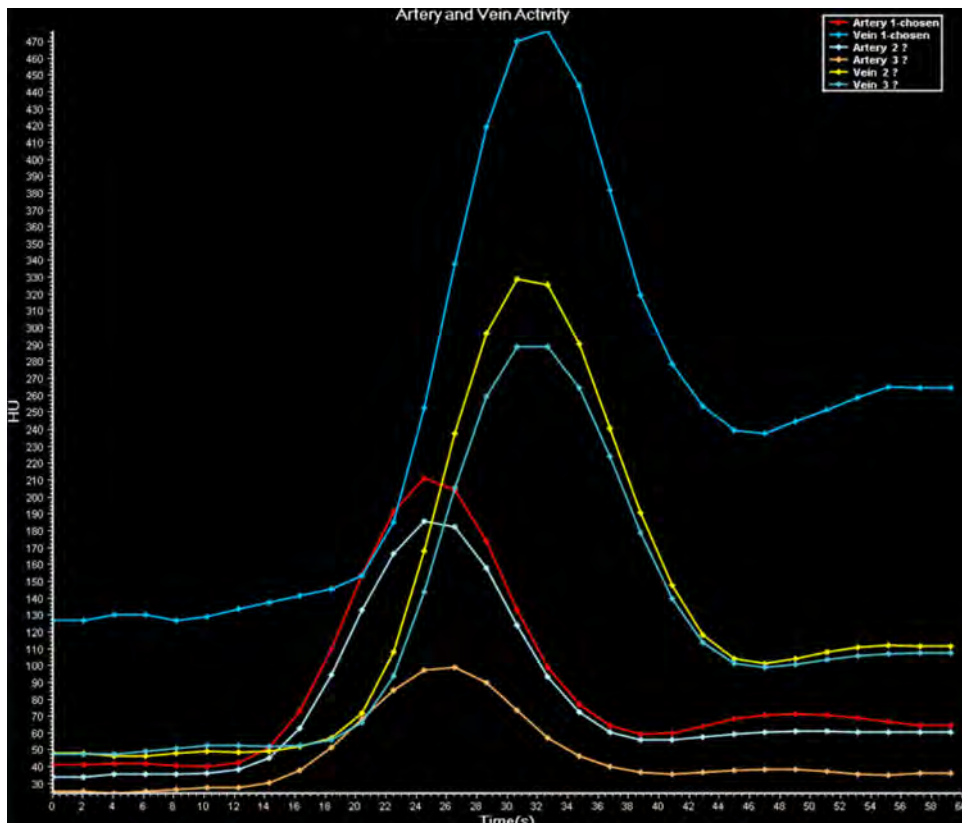


Fig. 9: Artery and Vein Activity

NOTICE

If one or more of the wash-in and wash-out curves are partial (that is, they do not show an up-slope and a down-slope), the scan is incomplete, and the data may be unreliable.

Vessel Statistics

The data table shows enhancement values and the TTP (time-to-peak) statistics for the defined arteries and vein.

NOTICE

If Traffic Lights found an issue with the acquisition data, either the Non-Severe Warning or Severe Warning message will appear throughout the application. For example, original tMIP/ average axial view, Summary Maps and Perfusion Maps, display a red or yellow warning light (depending on the warning type). Before continuing, see section “Using Brain Perfusion Traffic Lights” on page 83.

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The numeric values in the vessel statistics table are calculated based on curve-fitting, and vary slightly from the raw data seen in the vessel graph.

The Enhancement is calculated as: peak enhancement value minus base line enhancement value.

The vessels are identified by ROI number and Slice number. Click on any of the vessels and the main viewport image is updated to show the slice it appears on. The vessels are color-coded so they can be correlated with the curves in the Artery and Vein Activity chart.

Time Batch

Time Batch allows creating a batch of images at the same slice position across the different time points. The Time Batch option is available only when Average rendering mode is selected.

1. Select the **Average** display mode.
2. Select Time in the Batch function tab.
3. To define the batch, click the **Start** button.
4. In the axial viewport scroll horizontally across the different times.
5. Click the **End** button when finished.

You can skip steps 3, 4, and 5 and define all time points using the **All** button. You can limit the number of time points with the Sub-select Every option.

6. If desired, preview the batch with the **Preview** button.
7. Save the batch either from the Preview window or by using the **Save Batch As...** function in the Common Tools.
8. To create a new batch, first use the **Clear batch** button.

Vessel Definition Tools

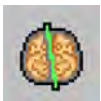
Use the following tools located in the upper toolbox:

Show Mirror Line

The mirror line should divide the left and right brain hemispheres. You should inspect the line and correct it, if needed.

Detect Mirror Line

You can have Brain Perfusion try to automatically detect the mirror line by clicking the **Detect Mirror Line** button.



Edit Mirror Line Slice by Slice

Check the box to edit the mirror line slice by slice. Scroll through the images and adjust the mirror line on each slice.

Show All Vessel Curves

Check the box to display the arteries and veins in reference graph. You can define up to 10 arteries in the Vessel Definition stage. After evaluating the artery statistics, select just one to make it “active.”

Restrict Vessel to the Cerebral Mask

When checked, the manual vessel detection range (performed by the draw functionality in artery/vein selection steps) is restricted to the cerebral mask. When checked, no vessel can be defined manually outside of cerebral mask.

Verify Mirror Line, Motion, Mask and Vessels

Typically, the following steps should be performed in the order presented.

Verify No Residual Motion Present



Use the Cine tool to scroll through the images. When activated, the **Cine** tool uses the Average rendering mode. The main image viewport must be active to use the **Cine** tool.

Correct Motion

After using the **Cine** tool, use the **Motion Correction** tools to remove time points where unacceptable motion occurred.

NOTICE

Remove undesirable motion before correcting the cerebral mask and selecting the artery and vein.

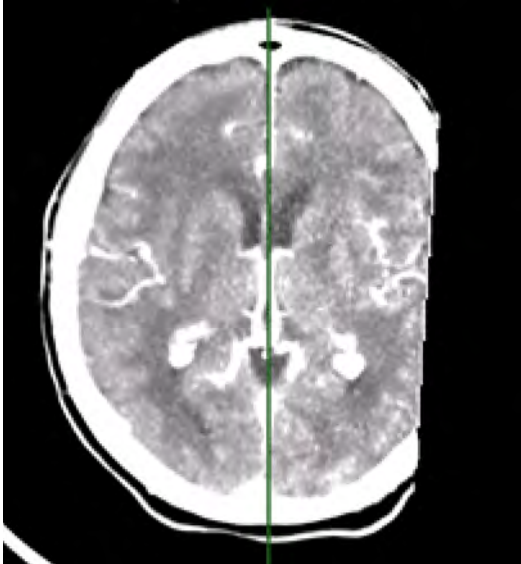
3D Motion Correction



Use the **3D Motion Correction** button to perform 3D registration and anatomical alignment (this will reinitiate the registration and all subsequent checks: vessel detection, cerebral mask, and traffic lights).

NOTICE

The 3D registration process may modify images: the first and last slices (in terminal locations) may have black regions due to insufficient data.



Black Regions Due to Insufficient Data

Verify correctness of cerebral and perfusion maps in the central scan region. If needed, refer to original images.

In the **Perfusion Map Work Stage**, the slices with black regions in the tMIP images do not display summary maps in the contra-lateral regions to black regions, as side-by-side comparison is not available.

Before applying **Summary Maps** for a **Study**, one side of the tMIP images and **Perfusion Maps** have black regions as a result of 3D registration:

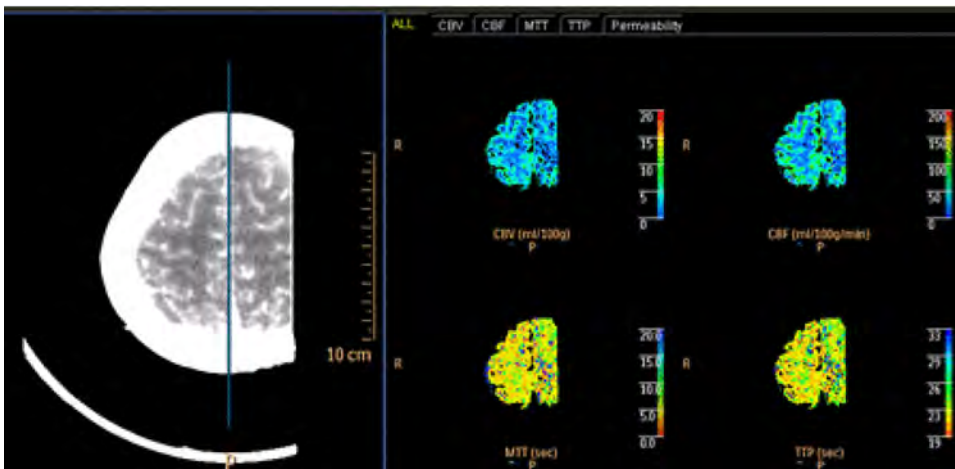
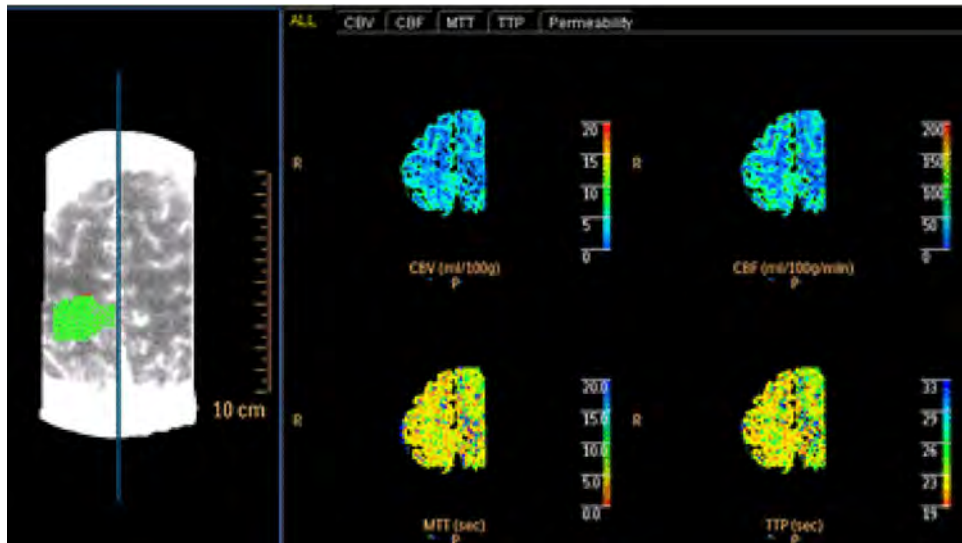


Fig. 10: tMIP Images and Perfusion Maps with Black Regions

Study After applying **Summary Maps**, the tMIP contra-lateral hemisphere includes added black regions. The **Perfusion Maps** remain intact:



The anatomical alignment is performed on a tilted scan as part of the 3D motion correction process. The cerebral midline should be a vertical line at the center of the image after successful operation of anatomical alignment. Below, the left images shows the original, tilted scan; the image on the right shows the scan after alignment, with the vertical cerebral midline.

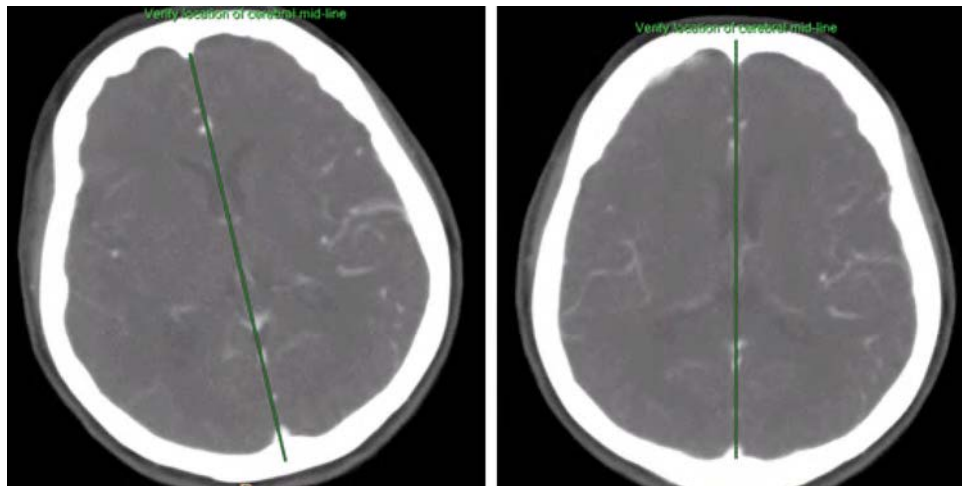


Fig. 11: A. Original Tilted Scan. B. Image After Anatomical Alignment

NOTICE

In some cases, 3D registration is successful but anatomical alignment fails. In such cases, a message appears in the status bar: **Anatomical alignment failed. Please verify patient location is correct and verify the cerebral symmetry.**

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Remove Time Points

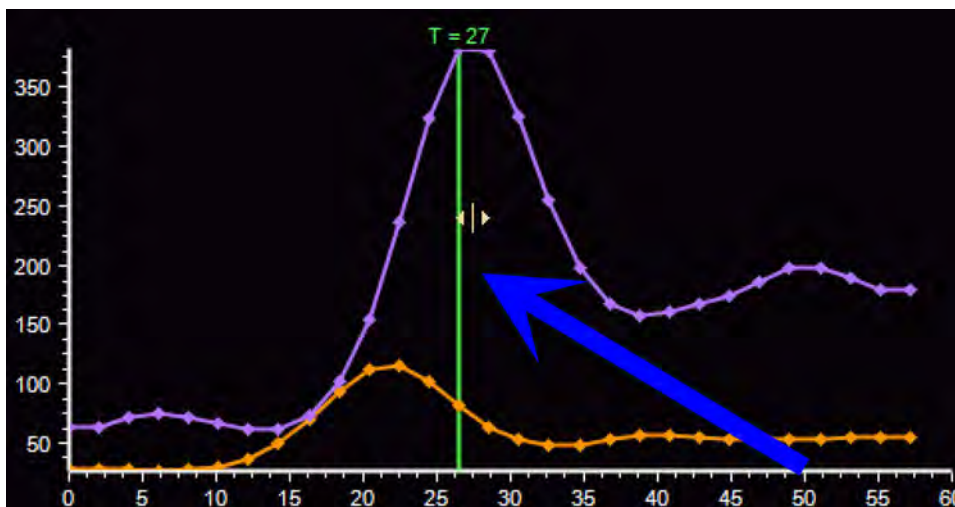
General guidelines for removing time points:

- Remove up to 8 time points from the scan.
- No more than 2 consecutive time points may be removed.
- The maximum difference between two consecutive scans must be less than 12 seconds when removing time points.



1. Click the **Remove Displayed Point** button while in tMIP rendering mode.
2. Review the time points in the **Artery and Vein Activity** graph.
3. Scroll through the various Perfusion time points using the **Cine** tool or other methods. Pause the **Cine** tool on the time point to be removed.

Alternately, click on a time point in the graph or grab the **Examine Line** (time-indication line) and drag it to the time point to be removed.



4. Click the **Remove Displayed Point** button. Alternately, right click on the time point and select **Remove Displayed Point** from the menu.



5. Remove additional time points as necessary.
6. Use the **Bring Back Deleted Points** undo button (or select it from the right-click menu) to revert all changes.

The removed time points are marked in the artery/vein time attenuation curve with an orange dashed line.

NOTICE

After removing a time point, the title of the **Artery and Vein Activity** graph is appended with the statement: **Time points were removed.**

Verify and Edit Mirror Line

The mirror line - cerebral mid line between the hemispheres is suggested by the application. You may need to adjust the mirror line for all slices or for individual slices.

Incorrect Mirror Line **Corrected Mirror Line**

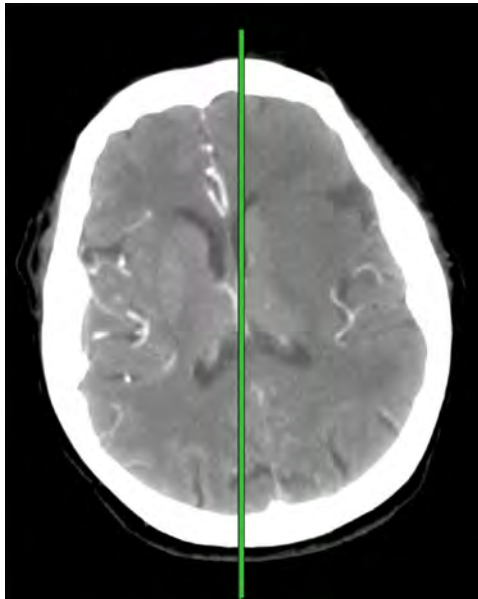


Fig. 12: Incorrect Mirror Line

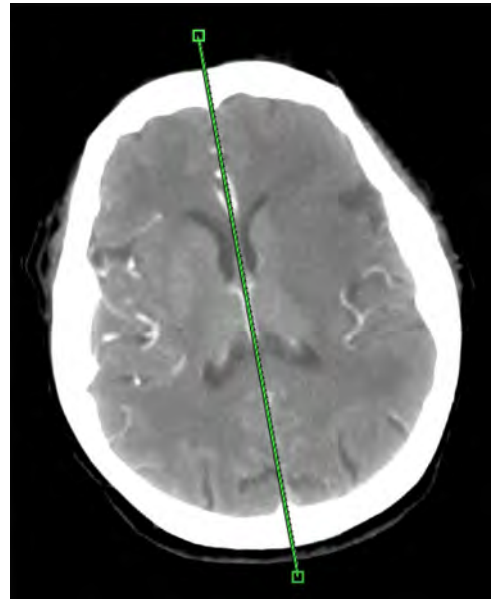
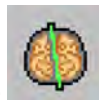


Fig. 13: Corrected Mirror Line

NOTICE



If you use the **Detect Mirror Line** feature after manually correcting the centerline, your changes will be lost and the centerline will be reverted to the auto-detected state.

Edit Mirror Line for All Slices

Editing the mirror line is applicable for all slices. Verify the correctness of the mirror line on all slices, after editing has taken place.

1. Ensure the **Mirror Line** box is checked.
2. To move the centerline, click it and drag to the correct location.
3. To rotate, extend, or shorten the mirror line, hover over the line and click on the appropriate control point. Drag the line to the correct location.

Edit Mirror Line Slice by Slice

Editing the mirror line is applicable only for the active slice. Verify the correctness of the mirror line on all slices, after editing has taken place.

1. Ensure the **Mirror Line** box is checked.
2. Select the **Edit Mirror Line Slice by Slice** option.
3. To move the centerline for the displayed slice, click it and drag to the correct location.
4. To rotate, extend, or shorten the mirror line for the displayed slice, hover over the line and click on the appropriate control point. Drag the line to the correct location.
5. Scroll through the images and review and adjust as needed.

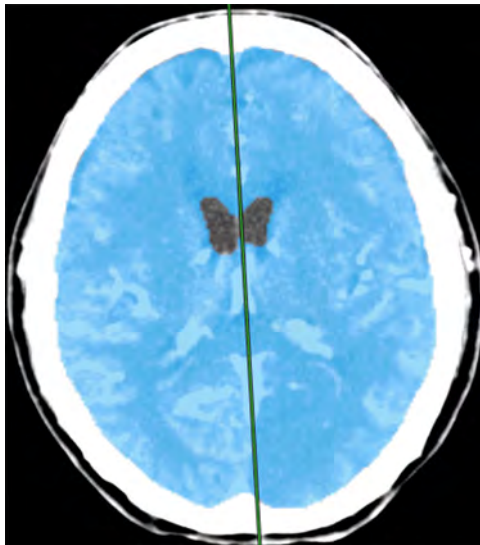
Verify and Edit Cerebral Mask

NOTICE

Verify the correctness of the Cerebral Mask. If needed, correct it manually using the Cerebral Mask tools.



Click the **Show Mask** button to display the mask. The Cerebral Mask is an overlay that shows the volume identified as the brain by the Brain Perfusion application.



Scroll through the tMIP for the entire scan coverage to verify that the mask includes all brain tissue and excludes ventricles and the skull.

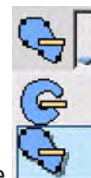
If necessary, correct the Cerebral Mask (follow the **Correct...** link to go to the **Edit Cerebral Mask** tab).

Click the **Show Mask** button in the Edit Cerebral Mask work step and scroll through the slices.

- If small corrections need to be made to the mask, these may be done by adjusting the Threshold values that define the mask.
- If old infarcts exist in the brain, they may not be included in the mask, due to low HU value. If required, lower the Threshold until the relevant area is included in the mask.



To add regions from the mask per slice, use the **Add to mask:** feature in the **Edit Cerebral Mask** panel.



To remove regions from the mask per slice, use the **Remove from mask:** feature in the **Edit Cerebral Mask** panel.

Each option provides two editing choices: Freehand ROI or Spline ROI, whichever is your preference.

- In the freehand mode, hold down the left mouse button and trace the shape you want to add/remove from the mask by dragging the pencil pointer around the brain image until the end of the line meets the beginning.

- In the spline mode, move the pencil pointer around the perimeter of the brain, clicking wherever you want to place a line segment. Double click to end the spline drawing.

Use Thresholds to Correct Cerebral Mask

1. Raise or lower the Threshold settings until the mask correctly defines the brain volume.
2. Examine all slices to verify correct brain volume definition.
3. Click **All slices** to apply the threshold changes to all slices.

Draw New Cerebral Mask



There are two drawing choices: Freehand ROI or spline ROI, whichever is your preference. In the freehand mode, hold down the left mouse button and trace the shape of the new mask by dragging the pencil pointer around the brain image until the end of the line meets the beginning. In the spline mode, move the pencil pointer around the perimeter of the brain, clicking wherever you want to place a line segment. Double click to end the spline drawing.

1. Pick one or the other drawing mode, available from the drop-down.
2. Draw the new mask. Once the mask is drawn, it is based on threshold values that warrant what appears in the mask.
3. When done, use the left mouse click to scroll through all images; examine the green mask and verify correct definition of the brain volume.

Editing a Cerebral Mask



There are two cerebral mask editing choices: Freehand ROI or spline ROI, whichever is your preference. In the freehand mode, hold down the left mouse button and trace the shape of the new mask by dragging the pencil pointer around the brain image until the end of the line meets the beginning. In the spline mode, move the pencil pointer around the perimeter of the brain, clicking wherever you want to place a line segment. Double click to end the spline drawing.

Verify Suggested Reference Vessels

Brain Perfusion suggests reference vessels upon loading of the application. If these vessels were altered, reference vessels can be detected again by clicking the automatic function buttons.



NOTICE

Verify the correctness of the vein and artery detection and correct it manually, if required.

You can also manually define vessels. See section “Manually Define Vessels” on page 53.

Manually Define Vessels

You can manually define arteries and the vein in two ways:

- with the Draw ROI method, using the circular tool; or
- with the Draw Point method, using the cross hair tool.

To change tools, click the drop-down arrow and select the desired tool.

**Verify and Edit Artery Selection**

Brain Perfusion suggests reference artery upon loading of the application. If the vessel was altered, the artery can be detected again by clicking the automatic function button.

NOTICE

Verify the correctness of artery detection and correct it manually, if required.

If needed, you can manually define an artery.



After reviewing the study by scrolling through the slices, select the Draw method you want and by clicking its icon. The mouse pointer changes to a pencil.

Draw Artery ROI



To use this tool, encircle the area containing the artery you want to define. To obtain correct perfusion values (perfusion maps) vessel selection is very important:

- **Arterial curve** - The artery that peaks first should be selected (automatic or manual selection). Most commonly the anterior cerebral artery (ACA), or middle cerebral artery (MCA) is selected as the reference vessel. If possible, the artery on the contra-lateral (non affected side) should be used.

The application searches for the single pixel within the ROI having the maximum enhancement, and marks it as the reference vessel with a colored cross-hair and labels it “Artery.”

Draw Artery Point



To use this tool, click the pencil pointer on a single pixel in an artery of interest. The application marks the pixel as the reference vessel with a cross-hair, assigns it a color code, and labels it “Artery.”

You can draw up to 10 arteries to find the highest HU. You can draw arteries on any and all of the slices in the study.

Each artery you define appears in the table called “Reference Artery Statistics” and is color coded. (You can double click on the table to expand it to full viewport size; double click again to reduce it.)

The artery’s enhancement curve appears in the “Artery and Vein Activity” chart, and is coded the same color as in the table.

NOTICE

After you draw an artery, the mouse cursor changes to the scroll pointer. If you want to draw another artery ROI, you must click the Draw icon again.



When the cursor is a scroll pointer, you can scroll the slices to search for another artery you want to define, and then click the Draw icon again.

There is no Undo option available, so if the marked artery is not the one you wanted, you must delete the artery (delete is a selection from the right mouse menu) and redraw the ROI.

Verify and Edit Vein Selection

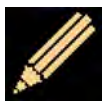


Brain Perfusion suggests a reference vein upon loading of the application. If the vessel was altered, the vein can be detected again by clicking the automatic function button.

NOTICE

Verify the correctness of vein detection and correct it manually, if required.

If needed, you can manually define a vein.



To activate the Draw ROI tool, click its icon. The mouse pointer changes to a pencil.

Draw Vein ROI

To use this tool, encircle the area containing the vein you want to define.

Verify that the vein with the highest enhancement is selected. The curve should peak later than the arterial curve and its amplitude should be higher in most cases. The vein commonly selected is the Superior Sagittal Sinus (SSS).

The application searches for the single pixel within the ROI having the maximum enhancement, and marks it as the reference vessel with a blue cross-hair and labels it "Vein."

Draw Vein Point

To use this tool, point the mouse cursor to select a single point in a vein of interest. The application marks the point as the reference vessel with a Draw Vein Point cross-hair and labels it "Vein."

You can draw up to ten veins to find the highest HU. You can draw veins on any and all of the slices in the study.

The vein you define appears in the table called "Reference Vein Statistics" and is color coded. The veins's blue enhancement curve appears in the "Artery and Vein Activity" chart.

NOTICE

A vein and an artery must be defined before a perfusion image can be generated.

Set Artery and Vein to Use for Calculations

All calculations performed in the Perfusion work stage are based on the artery and vein you set in the procedure below. All automatically or manually detected vessels are initially marked as **Artery?** and **Vein?** until you actively select them for calculation.

1. Hovering over a detected vessel in main viewport to show the **Use for Calculation** dialog. Or, using the right mouse button, click on the vessel (either in the table or on the image) you want to be active in the statistics table. Select **Use for Calculation**.
2. Click on the message. The color of the vessel data is changed to red, and the background is highlighted on the reference table. The selected vessel is appended with the word chosen, and the ? (question mark) is removed from the vessel name.

3. Repeat the previous steps until both an artery and vein are selected.

When you proceed to the Perfusion Work Stage, only the active vessel is shown on the main image. See section “Perfusion Map Work Stage” on page 56.

Perfusion Map Work Stage

NOTICE

If Traffic Lights found an issue with the acquisition data, either the Non-Severe Warning or Severe Warning message will appear throughout the application. For example, original tMIP/ average axial view, Summary Maps and Perfusion Maps, display a red or yellow warning light (depending on the warning type). Before continuing, see section “Using Brain Perfusion Traffic Lights” on page 83.

NOTICE

Verify the correctness of the vein and artery detection and correct it manually, if required.

NOTICE

If a high percentage of voxels within the cerebral mask could not be analyzed due to incompatibility to the analysis algorithms, the resulting perfusion calculations may be inaccurate.

If the system recognized a large area that cannot be analyzed, a message is displayed in the application.

A lack of suitability can stem from:

- Missing outflow phase within the tissue time attenuation curve.
- Missing inflow phase within the tissue time attenuation curve.
- High noise presence in the input images.

NOTICE

If **3D Motion Correction** was performed, the slices with black regions in the tMIP images do not display summary maps in the contra-lateral regions to black regions, as side-by-side comparison is not available. See section “Verify No Residual Motion Present” on page 45.

Create Batch in Brain Perfusion

To create a batch in Brain perfusion, you can choose either of the following two options:

- **Whole screen for all locations:** Sends entire screen as an image, including all viewports and tables, for the entire z-coverage of the study.
- **Create a batch of a sub-set of images.** For that, please perform the following operations:

NOTICE

The **Perfusion Map** uses **TTP** for the time-arrival sensitive method and **Tmax** for the time-arrival insensitive method.

Creating a Batch

1. Choose batch content. You can select any combination (or all) of the following content types:
 - Perfusion maps (CBV, CBF, MTT, TTP, Tmax, Permeability);
 - Original image (tMIP series only);
 - ROIs on map + graph;
 - ROIs;
 - tMIP +Summary maps;
 - 2D summary map measurements;
 - 3D summary map measurements;
2. Sort batch content by:
 - **Whole screen for all locations** – Sends entire screen as an image, including all viewports and tables, for the entire z-coverage of the study.
 - **Sorted by Z-position (sort by slice)**– When the batch is created, all the content you selected is grouped together: for the first slice, then for the next slice, and so on.
 - **Sorted by map type** – When the batch is created, all selected content is grouped together by type. For example, all CBV images are shown together, then all CBF, and so on.
 - **Sorted by map type: multi series** – Same as “Sorted by map type” batch format, but each type/table/graph is saved in a separate series.
 - **Current** – The batch will only contain the selected content for the currently active slice.
 - **Comparison Overview** – When the batch is created, the defined content is displayed side by side to allow comparison between the different results types. If summary maps are defined they are displayed aside the Perfusion maps.
3. When done with your selections, click **Save batch as...** (or click on **Save Batch as...** in the Common Tools). A dialog window opens, where you can type in the batch name, the desired format (Secondary Capture, TIFF) and the destination device.

4. Click **OK** when done. The batch is saved to the destination device. As the batch is saved, a message displays the number of images and the device.

For additional information, see section “Automatic Results Creation Workflow” on page 88.

Layout of Perfusion Maps Display

The Perfusion Map Display has a number of viewports available, each providing different information.

NOTICE

The **Perfusion Map** uses **TTP** for the time-arrival sensitive method and **Tmax** for the time-arrival insensitive method.

Perfusion Maps

This viewport may display the following perfusion maps:

- Cerebral blood volume (CBV).
- Mean Transit Time (MTT).
- Cerebral Blood Flow (CBF).
- Time to Peak (TTP) - only available for Time Arrival Sensitive method.
- Tmax (only available for Time Arrival Insensitive method).

Several Color schemes that can be applied to the maps: Rainbow, Black and White, Thallium, and a-LUT.

Statistics Tables

Three statistics tables are available:

- ROI Statistics (for each slice).
- 2D measurements –Summary Map Statistics (area statistics table)
- 3D Measurements –Summary Map Statistics (volume statistics table)

NOTICE

If Traffic Lights found an issue with the acquisition data, either the Non-Severe Warning or Severe Warning message will appear throughout the application. For example, original tMIP/ average axial view, Summary Maps and Perfusion Maps, display a red or yellow warning light (depending on the warning type). Before continuing, see section “Using Brain Perfusion Traffic Lights” on page 83 section “Using Brain Perfusion Traffic Lights” on page 83.

The Vessel and Tissue Curves Viewport

This viewport shows time-density curves of the selected Artery and the Vein (which you defined in the Vessel Definition stage), and the time-density curves of any Tissue ROIs (up to 10) that you draw. See section “Vessel Definition Work Stage” on page 41.

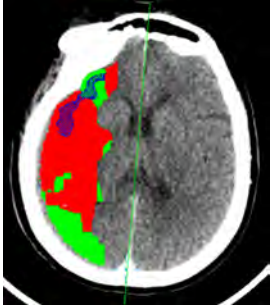
Summary Map

The Summary Map summarizes information from Perfusion Map images into a single depiction. It shows the areas with increased MTT and, within those areas, it highlights the reduced CBV versus non-reduced CBV areas. The summary maps are presented only when user manually activates them. When the user clicks on **Apply stroke Summary Map** options, it is displayed on the original tMIP or Average axial images.

View Summary Map

The Summary Map image shows (with color maps) areas of increased MTT relative to the contralateral hemisphere and reduced or non-reduced absolute CBV when factory default settings are used. (It is called the Summary Map because it summarizes information from all Perfusion Map images into a single viewport.)

COLOR CODING of the SUMMARY MAP	
GREEN and RED	Total area of increased MTT relative to the contralateral hemisphere.
GREEN	Area having increased relative MTT with non-reduced absolute cerebral blood volume.
RED	Area having increased relative MTT with reduced absolute cerebral blood volume.



View Statistics Tables

Tables contain data only if the right or left Summary Map is enabled. You can control which statistics tables are displayed from the right click menu.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

2D & 3D Measurements-Summary Maps (Volume and Area Statistics Tables)

The 3D Measurements –Summary Map table displays the total volume.

The 2D Measurements –Summary Map/ Area Statistics table displays the calculated areas (in each slice) of the green and red overlays shown in the Summary Map.

The Refer area/volume statistics table below provides explanations about the measurements at the bottom of each column.

3D Measurements - Summary Map (Arrival Time Sensitive)					
Warning: Measurements may include anatomy outside the cerebral hemispheres (e.g. eyeballs)					
Relative MTT<150% & CBV>2ml/100g		Relative MTT>150% & CBV<2ml/100g		Index	Permeability>5ml/min/100g
ml	(%)	ml	(%)	Index	ml
120.0	13.5	72.2	9.2	0.62	189.7
The volume within the total summary map region suspected for reduced perfusion (green) (for all slices)		The volume within the summary map region that is suspected for severely reduced perfusion (red) for all slices		The Green Volume / (Green + Red volumes) for all slices	
The % of suspected reduced perfusion volume (green) within the total cerebral volume (for all slices)		The % of suspected severely reduced perfusion volume (red) within the total cerebral volume (all slices)		The high permeability volume with the entire summary map region (for all slices)	

Fig. 14: Table-3D Measurements-Summary Map (Arrival Time Sensitive)

Note: The measurements on the statistics columns (and explanations at the bottom of the column) are for illustration purpose only.

2D Measurements - Summary Map (Arrival Time Sensitive)								
Warning: Measurements may include anatomy outside the cerebral hemispheres (e.g. eyeballs)								
Slice Number	Relative MTT<150% & CBV>2ml/100g & Relative CBF<65%		Relative MTT>150% & CBV<2ml/100g		Relative MTT<150% & CBV>2ml/100g & Relative CBF>65%		Index	Permeability>5ml/min/100g
	mm²	(%)	mm²	(%)	mm²	(%)	Index	mm²
Slice 1	45.8	0.6	186.2	2.0	529.5	6.4	0.06	721.5
Slice 2	599.7	5.4	519.2	4.6	398.8	3.6	0.40	1502.9
Slice 3	975.4	7.3	569.3	7.2	165.4	1.2	0.46	1948.7
Slice 4	843.4	6.2	2127.7	15.6	254.3	1.9	0.26	3030.9
Slice 5	1888.2	13.1	1820.4	11.3	31.8	0.2	0.53	3297.5
Slice 6	2095.9	14.9	1525.8	10.8	80.5	0.6	0.57	3242.1
Slice 7	2121.7	14.4	411.4	3.2	144.8	1.1	0.85	3026.2
Slice 8	2003.6	13.2	0.0	0.0	223.8	2.1	0.90	2127.7
Measurements displayed per slice	The area within the summary map region that is suspected for reduced perfusion (per slice)	The % of suspected reduced perfusion (green areas) within both hemisphere areas (per slice)	The area within the summary map region that is suspected for severely reduced perfusion (per slice)	The % of suspected severely reduced perfusion (red) within both hemisphere areas (per slice)	(Optional) The area within the summary map region that is suspected for slightly reduced perfusion (per slice)	(Optional) The % of suspected "slightly reduced" (yellow) area within both hemisphere areas (per slice)	The Green area / (Green + Red + Optional Yellow) per slice	The high permeability area with the entire summary map region (per slice)

Fig. 15: Table-2D Measurements-Summary Map (Arrival Time Sensitive)

Note: The measurements on the statistics columns (and explanations at the bottom of the column) are for illustration purpose only.

ROI Statistics Table

As you draw ROIs, each is automatically assigned a unique color and number. The color is correlated to the ROI statistics in the table, and to the ROI curve graphs.

NOTICE

If you drew Tissue ROIs on more than one slice, scroll to other slices in the map images to see the ROI statistics for those slices in the table. The heading of the table identifies the slice number. The number indicates the average value within the ROI.

ROI#

the ROI number

CBV(ml/100g)

The integral of the tissue time-attenuation curve normalized by the integral of the selected vein time-attenuation curve and the hematocrit.

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CBF(ml/100g/min)	The CBV divided by the MTT, per the Central volume Principle.
MTT(s)	The mean-transit-time of blood through a given brain region, measured in seconds.
TTP(s)	Time to peak enhancement at each x, y location, measured in seconds.
Tmax (s)	Time to peak enhancement of the residual function of the Singular Value Decomposition (SVD) based deconvolution, measured in seconds. (Time Arrival Insensitive method).
Permeability *	The permeability is calculated using a Patlak analysis. *

* For the Permeability analysis, the acquisition must be extended to include delayed phases of the passing and re-circulation of contrast agent in the brain to identify extravasated contrast agent that has permeated the BBB. For Patlak analysis, the time attenuation curve describing the observed amount of contrast agent in a per-fused voxel is modeled as the sum of intravascular and interstitial, extravasated contrast agent. The amount of contrast agent that has permeated through the BBB is modeled as a fraction of all contrast that has passed through the voxel since the start of the acquisition, and this fraction is interpreted as blood-to-brain transfer constant -- which is the definition of Permeability.

Perfusion Maps Tools

Use the following tools located in the upper toolbox:

Show High Permeability Areas

This check box allows you to turn off and on the areas of high permeability. Permeability measures the contrast agent permeation of the BBB (blood-brain barrier).

Show Mirror Line

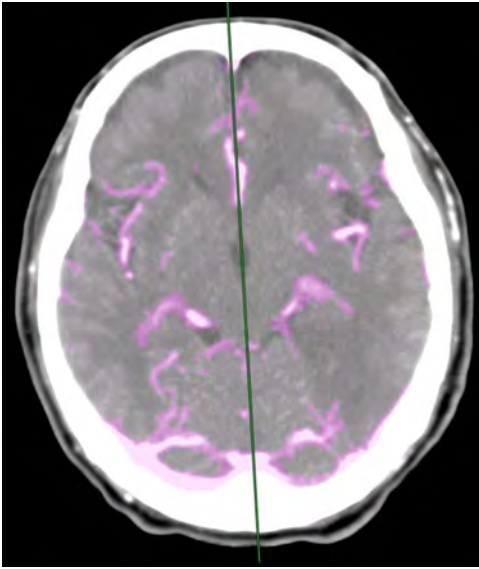
This check box allows you to turn off and on the mirror line that was created in the Vessel Definition stage. (If you want to edit the mirror line's position, see section "Vessel Definition Work Stage" on page 41.)

Show Tissue ROIs

This check box allows you to turn off and on the Tissue ROIs that you draw.

Show Vessels Segmentation

Check the box to display or hide the vessels segmentation. The purple overlay depicts areas automatically detected as **vessels**, that are removed from calculations when the **Remove Above** checkbox is checked. See section "Verify and Edit Vessel Removal" on page 70.



NOTICE

By default, the vessel segmentation overlay is disabled, if the Display Summary Maps tool is used. Check the box again to display again.

Show Invalid Voxels

Use the checkbox to display or hide the voxels that cannot be analyzed.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Use Summary Map

NOTICE

There are no recommended threshold values for Philips Brain Perfusion application for the **Summary Maps** calculation in conjunction with poor temporal resolution cases (cycle time longer than 4 seconds). When using such data, the default thresholds that apply on densely sampled cases may not be optimal. If you wish to use the **Summary Maps** functionality in conjunction with poorly sampled data, you may adjust the thresholds manually.

NOTICE

See also section “Apply Summary Map” on page 72.

NOTICE

The **Perfusion Map** uses **TTP** for the time-arrival sensitive method and **Tmax** for the time-arrival insensitive method.

For Arrival-time-sensitive Method Only

- The value of Increased MTT (mean transit time) affects the areas depicted as Green or Red on the Summary Map. The default factory parameter threshold for this is Increased Relative MTT at greater than 150% of contra lateral hemisphere, meaning all areas exhibiting mean transit time that increased by 50% (or more) when compared to the contra-lateral hemisphere will be shown as either Green or Red, depending on the CBV value.
- The value of Reduced CBV (cerebral blood volume) determines whether tissue identified as having a prolonged MTT will be depicted in Red or Green in the Summary Map. All tissue with a prolonged MTT and a CBV below the Reduced CBV threshold will be colored red. All tissue with a prolonged MTT and a CBV above the Reduced CBV threshold will be colored green.

NOTICE

The CBV threshold affects only tissue that has met the MTT threshold. That is, for the example given:

- Green: Relative MTT increase by 50%, CBV above 2.0 ml/100g
- Red: Relative MTT increase by 50%, CBV below 2.0 ml/100g

NOTICE

The default thresholds for the **Summary Maps**, proposed by the application, increased relative MTT at greater than 150% of the contra lateral hemisphere, and within those areas absolute non-reduced or reduced CBV of 2 ml/100g. They were calculated based on the **Arrival Time Sensitive** method. For more information on this topic please refer to the following publication: *Wintermark M, Flanders AE, Velthuis BV et al. Perfusion-CT Assessment of Infarct Core and Penumbra: Receiver Operating Characteristic Curve Analysis in 130 Patients Suspected of Acute Hemispheric Stroke. Stroke 2006; 37: 979-985.*

NOTICE

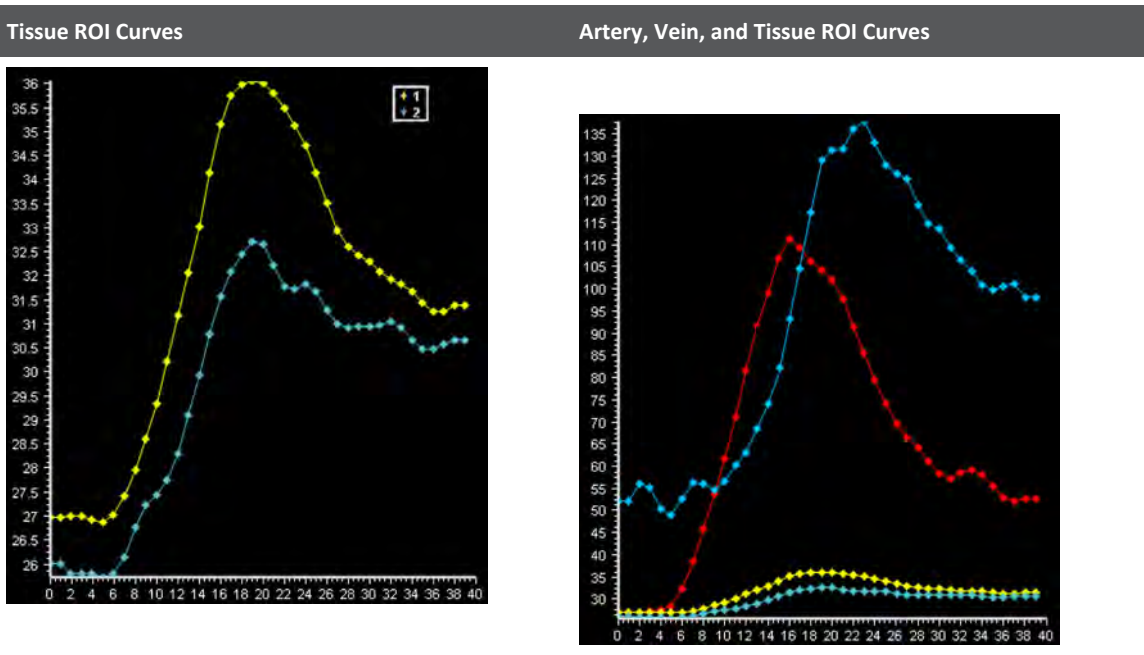
There are no recommended threshold values for Philips Brain Perfusion application for the **Summary Maps** calculation in conjunction with the **Arrival Time Insensitive** method. When using the above mentioned system default thresholds for the **Summary Maps**, after applying the **Arrival Time Insensitive** method, the **Summary Maps** results may not be optimal.

If you wish to use the **Summary Maps** functionality in conjunction with the **Arrival Time Insensitive** method, please adjust the thresholds manually. For more information on the **Arrival Time Insensitive** method refer to: *Cenic A, Nabavi DG, Craen RA, et al. Dynamic CT measurement of cerebral blood flow: a validation study. AJNR Am J Neuroradiol 1999;20:63–73.*

Show Tissue Curves

The Show Tissue ROIs function controls the display of curves in the graph viewport.

- The default curve display shows the statistics for the two user-drawn ROI curves. The two Tissue ROI curves are colored yellow and blue. (The colors were automatically assigned when the ROIs were created. You can click on a data point to see its statistics.)
- To show/hide the Artery and Vein curves, right click in the graph viewport and select **Show Artery-Vein Curve**. The red and blue Artery and Vein curves are now included in the graph viewport. The graph has been re-scaled, and the original Tissue ROI curves are smaller. (The peak of the tallest ROI may be cut off.)



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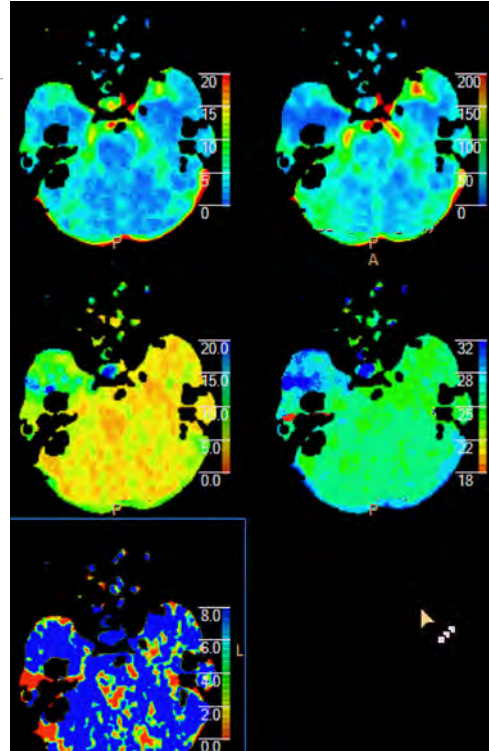
Perfusion Map Images

The viewport in the upper-right corner in the layout displays color-mapped Perfusion and Permeability images.

A Tab strip at the top of the maps viewport enables you to display all images at once or each one individually.

Cerebral Blood Volume (CBV)

CBV is defined as the total volume of flowing blood in a given volume in the brain, with units of milliliters of blood per 100 g of brain tissue. Cerebral blood volume is calculated by the ratio of two areas: area under the TAC of the tissue and the area under the TAC of the reference vein normalized by the hematocrit value. The CBV calculation is based on the partial volume effect. The color bar is scaled in milliliters/100 grams.



Mean Transit Time (MTT)

MTT is defined as the average transit time of blood through a given brain region, measured in seconds. The color bar is scaled in seconds.

MMT is computed differently for sensitive vs. insensitive.

Sensitive: MTT is extracted from the TAC of the tissue after Gaussian curve fitting. MTT is computed by summing the standard deviation of the fitted curve and the TTP and subtracting the MTT of the reference artery.

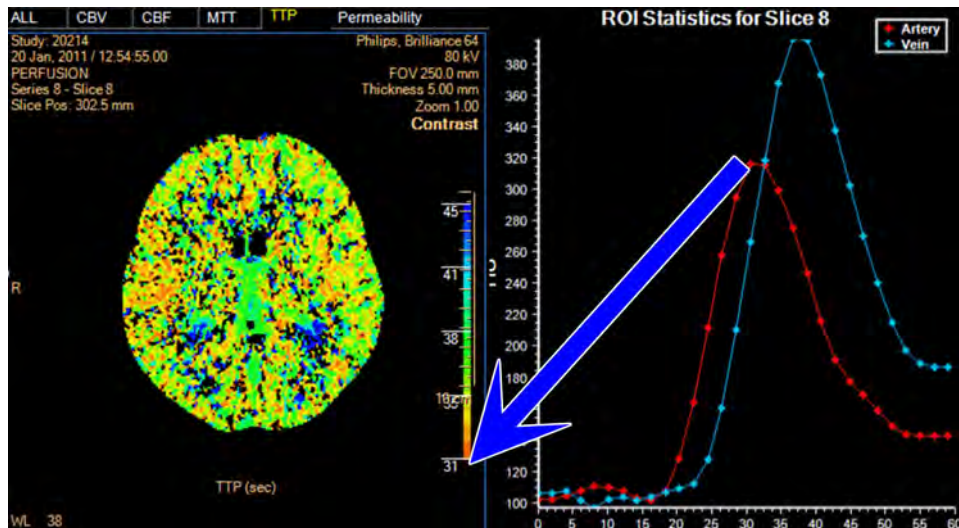
Insensitive: MTT is the first moment of the retention function.

Cerebral Blood Flow (CBF)

CBF is defined as the volume of blood moving through a given volume of brain per unit of time, with units of milliliters of blood per 100 g of brain tissue per minute. CBF is calculated by dividing the CBV by the MTT, per the Central Volume Principle. The color bar is scaled in milliliters/100 grams/minute.

Time To Peak (TTP)

TTP displays the time it takes for the peak enhancement to be reached at each x, y location. The color bar is scaled in seconds. The lower threshold of the scale bar is set to the arterial input TTP (to accommodate for late contrast injection by default). This parameter is applicable for the Time Arrival Sensitive method.



Tmax

Tmax displays the time it takes for the peak enhancement of the residual function of the SVD-based deconvolution. The color bar is scaled in seconds.

Permeability

Areas of High Permeability are shown with a pleated blue overlay on the axial image. The Permeability perfusion map represents the ability of extravasation of a contrast agent from the intravascular space to the extravascular space [the contrast agent permeation of the BBB (blood-brain barrier)]. The default color scale displays high permeability in blue and low permeability in red yellow in the middle. The range of the scale is: [0, 8] ml/100g/min.

The amount of contrast agent that has permeated through the BBB is modeled as a fraction of all contrast that has passed through the voxel since the start of the acquisition. This fraction is interpreted as blood-to-brain transfer constant - which is defined as Permeability.

NOTICE

The **Perfusion Map** uses **TTP** for the time-arrival sensitive method and **Tmax** for the time-arrival insensitive method.

NOTICE

The Permeability analysis is only available if the scan duration is long enough.

NOTICE

The Brain Perfusion Application's Arrival-Time Insensitive method is not available for sale in the United States.

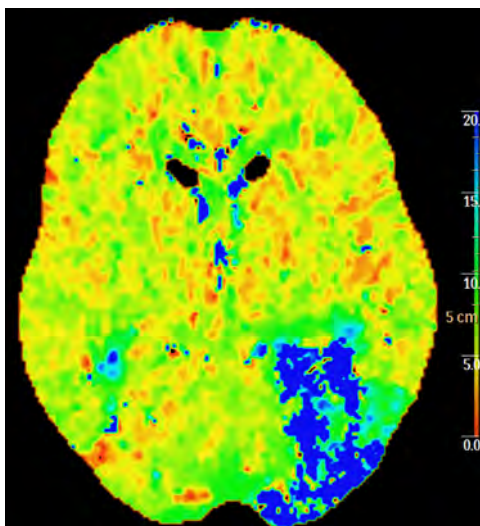
Perfusion Map Color Schemes

Various color schemes for the Perfusion Maps are available for use as needed. The choice of color map is a user preference that affects only the types and ranges of colors used to display the perfusion parameters (e.g., CBF, CBV, MTT, TTP). The values of the perfusion parameters are not changed when selecting different color maps.

- Right mouse click on a Perfusion Map image to activate a drop-down menu.
- Select "Color Schemes." The list of available color schemes appears:
 - Rainbow black edges
 - Rainbow red/blue edges
 - Rainbow 3
 - Black and white
 - Thallium
 - a-LUT
 - Red Over Blue
 - Back to default (to set display back to default "Rainbow black edges")

Rainbow Black Edges Color Scheme

In this (the default) color scheme, perfusion data is represented as a range of colors having the same sequence as a rainbow spectrum.



Rainbow Red/Blue Edges Color Scheme

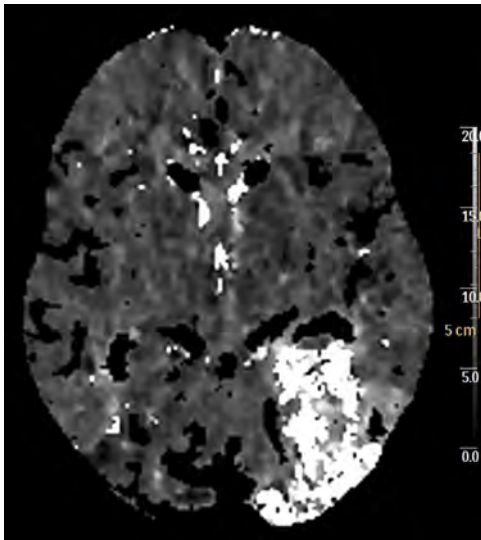
This color scheme is similar to Rainbow Black Edges Color Scheme, with this exception: Those values on the Perfusion maps that are lower than the lowest value of the scale are colored with the same color as the lowest color of the scale. (In the Rainbow color scheme, those values are colored black.)

Rainbow 3 Color Scheme

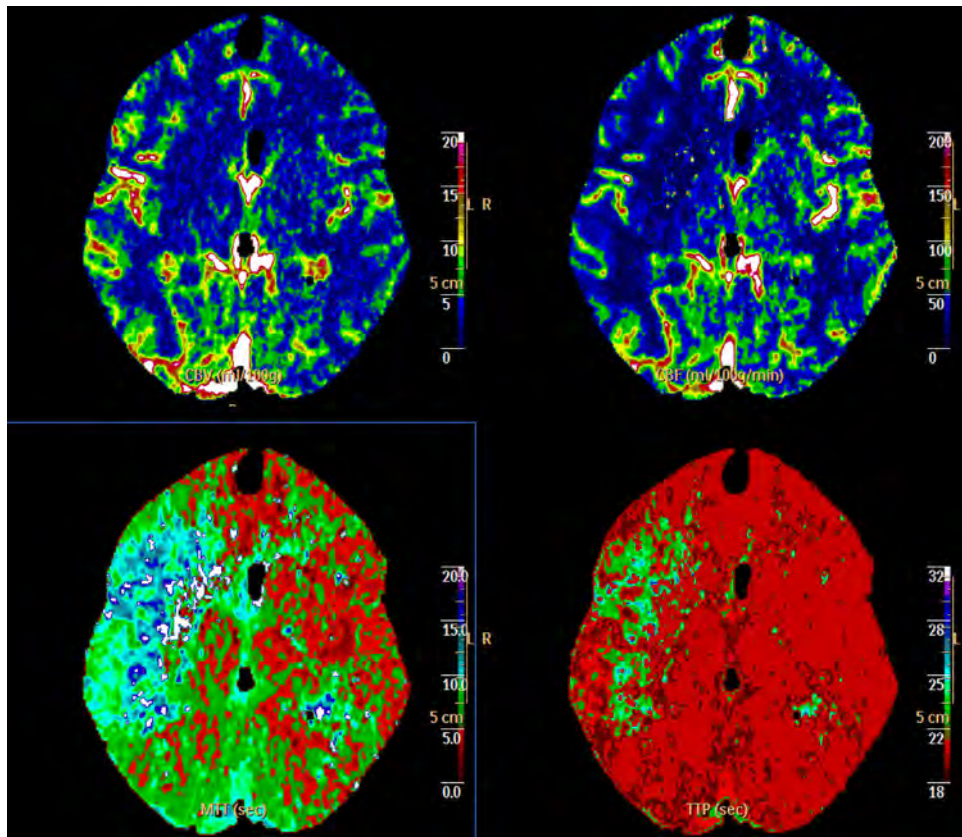
Rainbow 3 Color Scheme is similar to Rainbow Black Edges Color Scheme, with red at the bottom of the scale and blue at the top of the scale.

Black and White Color Scheme

Perfusion data is represented as a range of grayscale intensities. These maps are suitable for storage and display systems (e.g., PACS) that are incompatible with color maps.

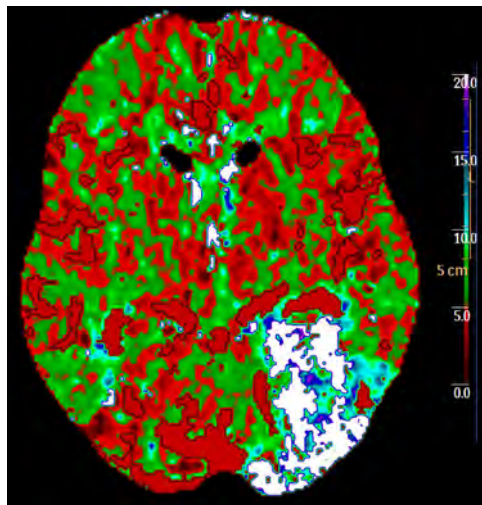
**Thallium**

Perfusion data is represented by a range of colors similar to those used in conjunction with nuclear medicine perfusion scans (e.g., Thallium-201 SPECT).



a-LUT

Perfusion parameter color maps that use the Acute Stroke Imaging Standardization Group (Japan) recommended lookup table (a-LUT).

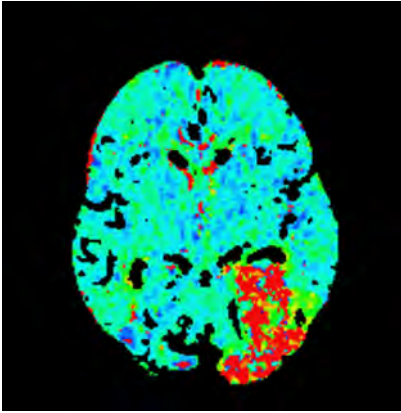


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Red Over Blue

In this color scheme, perfusion data is represented as a range of colors with a “Red over Blue Color Scheme”. It is similar to Rainbow 3 color scheme with MTT and TTP (Tmax) color scale reversed red over blue with color scheme applied on perfusion maps.



Review Perfusion Results

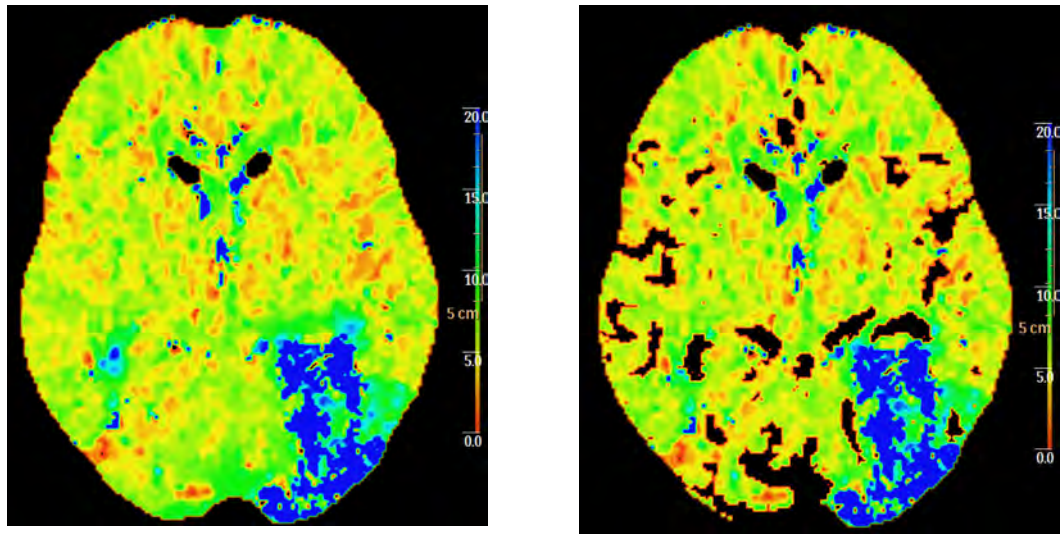
To calculate the average value of the Perfusion Maps within a region, and draw an ROI on the axial image or one of the maps.

Verify and Edit Vessel Removal

You should remove vessels after creating the perfusion maps if you plan to make quantitative ROI measurements. This removes vessel pixels from the perfusion calculation and from the CBF, MTT, TTP/Tmax, and Permeability perfusion images.

Check the **Exclude vessels from maps/ROIs** box to eliminate pixels from the calculation and from the color perfusion images. Removed pixels are colored black (zero value).

Shown below is an MTT image before (left) and after (right) the vessel removal function was activated.



Edit Vessel Threshold

The user may use the Vessel Threshold function to exclude the blood flow in larger vessels from the statistical calculation. The Vessel threshold is expressed as a pixel value in the CBV image. The default threshold value is 9. This means that any pixel in the CBV image with the value 9ml/100g and greater is not displayed on the perfusion maps or included in the ROI measurements. In cases where the temporal resolution is greater than 4.0 second, the threshold is relative.

NOTICE

Depending on the case, you may need to adjust the default value if the results are not as expected. This may be caused by too many vessels removed or too many vessels remaining after Vessel Removal.

Measure Tissue ROIs

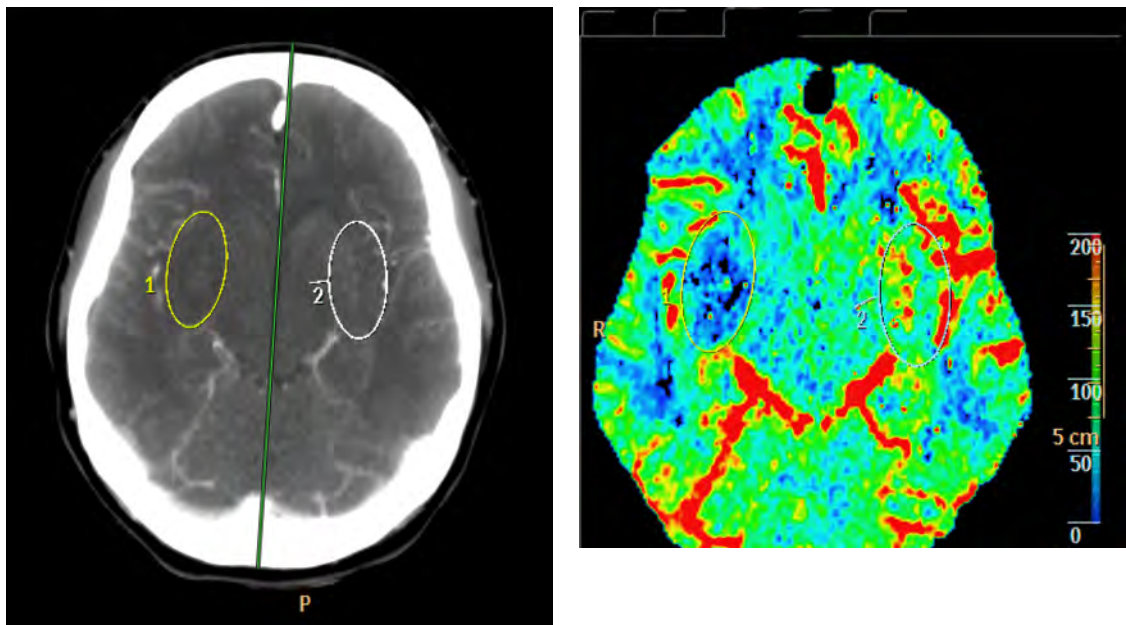


Tissue ROIs are used for blood-flow analysis. The results are shown in the ROI Statistics Curve display and ROI Statistics table. You can draw up to 10 ROIs on both the Summary Map image and the Perfusion Map images. You can draw on all slices. Each ROI is automatically assigned a unique color and number.

Three types of ROI drawing tools are available: Ellipse, Spline, and Freehand.

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Create Contra-lateral ROI Automatically

With this feature active, any Tissue ROI drawn on one side of the mirror line automatically is mirrored the other side. Uncheck this box if you do not want mirror-image ROIs to be drawn.

Edit Tissue ROI

A Tissue ROI can be modified and deleted like any other ROI graphic. Refer to the **Common Tools** section for instructions about editing ROIs.

Place Template ROIs



When this feature is activated, Template ROIs appear in the brain periphery.

Apply Summary Map

Patient Right Hemisphere



Click the button to display the summary map on the right side (relative to the image) of the mirror line. To hide, click the button again.

Patient Left Hemisphere



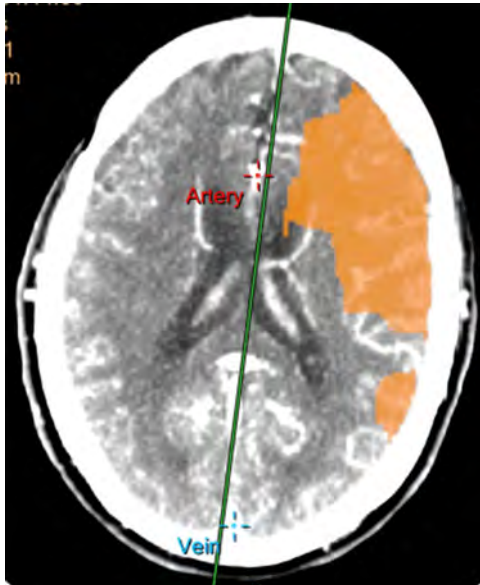
Click the button to display the summary map on the left side (relative to the image) of the mirror line. To hide, click the button again.

NOTICE

See also section “Use Summary Map” on page 62.

High Inter-scan Delay and the Time Sensitive Method

If the application identifies that the inter-scan delay is greater than 4.1 seconds but less than 4.5 seconds, the temporal resolution is not sufficient to highlight reduced CBV and non-reduced CBV within the increased MTT area. Therefore, the default Summary Maps cannot present two distinct areas. For example, there are no red/green areas when applying the summary maps. Instead, an orange overlay depicting the entire area of increased MTT is displayed, with no differentiation between reduced/non-reduced CBV. This overlay describes the full extent of area where there is a flow deficit, enabling you to determine whether there is decreased blood volume using the appropriate perfusion map. The user can manually add values/relative thresholds to be represented in the different colors of the summary maps.

**NOTICE**

When applying the summary maps, it is NOT possible to separate into different areas due to the low sampling rate.

High Inter-scan Delay Statistics Tables

The default Increased **Area Statistics** and **Volume Statistics** tables do not separate to different summary map (no green and red regions) regions based on CBV values, but instead show entire region of increased MTT.

Very High Inter-scan Delay and the Time Sensitive Method

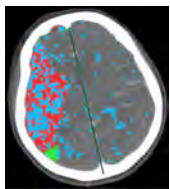
If the application identifies that the inter-scan delay is greater than 4.5 seconds, the summary map thresholds are not available by default because the delay is too long. You can only use the Perfusion Maps. You can manually insert threshold values in the **Set Calculation Settings** dialog, each time the application is used to obtain summary maps.

Invalid Voxels and the Time Sensitive Method

Under certain conditions, a high number of voxels within the left\right (screen relative) side of mirror line may not be analyzed due to incompatibility to the analysis algorithms. Such lack of suitability can stem from:

- Missing outflow phase within the tissue time attenuation curve.
- Missing inflow phase within the tissue time attenuation curve.
- High noise presence in the input images.

In such cases, a severe traffic lights warning is registered when proceeding to second stage.



In addition to the red/green summary maps, an additional blue overlay is shown, depicting all voxels which cannot be analyzed. This overlay, unlike the summary maps, is displayed on both hemispheres simultaneously.

The Invalid Voxels overlay can be removed by unchecking **Show Invalid Voxels** in the upper tool box.

Modifying Calculation Settings

To change the **Calculation Settings** parameters, click the **Edit...** link. The **Set Perfusion Parameters** window opens.

In the **Set Perfusion Maps Parameters** window, choose from a number of parameters:

- **Set Method**— Sets the calculation method. The following options are available:
 - Arrival Time Sensitive
 - Arrival Time Insensitive
- **Set Summary Maps Parameters** — Used to highlight areas with reduced perfusion. Please refer to section “Set Summary Maps Parameters” on page 74 for detailed information on parameters and applicable values.

Set Summary Maps Parameters



WARNING

Changing the default factory settings may change application-generated results. Please pay attention to the implications of all modifications.

This section sets the threshold and parameters for summary maps.

Areas Suspected for Reduced Perfusion (all highlighted areas)

- This parameter defines the threshold for all of the colored regions (green, red and potentially yellow).
- Define any perfusion parameter as the basis for this area (which includes all affected regions).
- Options include: Absolute/Relative values of MTT, CBF, CBV, TTP/Tmax.
- The default factory parameter for this region is **Increased Relative MTT** at greater than 150% of contra lateral hemisphere when using the time sensitive method.

NOTICE

In most cases, it is necessary to select both *Areas suspected for reduced perfusion* and *Areas suspected for severely reduced perfusion* to visualize summary maps.

Areas Suspected for Severely Reduced Perfusion (red areas)

- This parameter defines the threshold parameters for the red regions in the map.
- Options include: Absolute/Relative values of MTT, CBF, CBV, TTP/Tmax.
- The default factory parameter for this region is **Reduced CBV** at less than 2 ml/100gr when using the arrival time sensitive method.

Areas Suspected for Slightly Reduced Perfusion (yellow areas) - Optional

- This parameter defines the threshold parameters for yellow regions in the map. This is an optional setting.
- Options include Absolute/relative values of MTT, CBF, CBV, TTP/Tmax.
- If the slightly reduced perfusion threshold is populated, the yellow regions are defined as regions that meet the slightly reduced perfusion threshold and reduced perfusion threshold, but do not meet the severely reduced perfusion threshold.
- By default, this option is not enabled and must be manually enabled by placing a checkmark in the checkbox. There is no default factory parameter set for this region.

Limitations on Input of Perfusion Parameters

- For CBV and CBF thresholds:
 - Severely reduced perfusion < reduced perfusion < slightly reduced perfusion
- For MTT, TTP and Tmax thresholds:
 - Severely reduced perfusion > reduced perfusion > slightly reduced perfusion

Resulting Summary Maps Table

A table of the various regions and the parameters that make up the region is displayed.

Saving Perfusion Parameters

To save the parameters as system default parameters, place a checkmark in the **Set above parameters as default** checkbox and select **OK**. Changes will be applicable for all future uses.

If the **Set above parameters as default** is not selected, changes will be applicable for the current session only.

Special Modes of Summary Maps

- In cases with a low sample rate (interscan delay between 4.1 sec and 4.5 sec,), default values cannot include absolute perfusion parameter thresholds. Users can insert manually per case and/or change the default values to any relative parameter and save as default. Example: reduced perfusion set at relative MTT > 150%, severely reduced perfusion as relative CBF lower than 30%
- In cases with a very low sample rate (interscan delay is higher than 4.5 sec.), it is not possible to use default values and the user would have to manually insert values each time the application is used.
- In cases with a low CBV (average CBV values are lower than 2.5 ml/100gr on entire brain tissue) absolute CBV values will not be shown by default for summary map threshold in case that is the user setting.

Show More Parameters

This section includes additional parameters including Permeability threshold, Minimal scan duration for permeability and Hematocrit factor.

High Permeability

Use the parameter to separate between the high and normal permeability regions within suspected reduced Perfusion areas.

Permeability Scan Duration

Set the minimum scan duration for permeability analysis. Permeability maps and measurements will not be shown by default for scans with a lower duration.

Hematocrit Factor

The hematocrit factor is the ratio of red blood cells to the total volume of blood. The factor is used to convert contrast enhancement (in HU) to CBV (in ml/100g of tissue). The default Hematocrit factor is 0.45. Do not change the default value unless you have measured the patient's factor and it is different from the default value.

Recommended: Extended Scanning Duration for Permeability Analysis

When Patlak analysis is applied to the delayed phase of an extended acquisition, it provides quantitative permeability information. However, for shorter acquisitions the analysis is strongly biased by local blood flow.

It is difficult to separate late intravascular contrast enhancement from truly extra-vascular contrast enhancement during or shortly after the first pass of predominantly intravascular contrast agent. This is because contrast agent flows in and out (especially out) much later in ischemic areas than in normally perfused regions. In such cases, residual intravascular contrast enhancement can obscure all extra-vascular contrast enhancement.

Recommended Scan Duration

The recommended duration for the delayed PCT acquisition is at least 210 seconds because acquisitions shorter than 210 seconds lead to significantly overestimated BBBP (blood-brain barrier permeability) values [Hom et. al 2009]. See also section “Brain Perfusion References” on page 92.

Brain Perfusion Reference Vessel Selection Guide

This guide includes 5 steps to be performed in both the Vessel Definition stage and the Perfusion Maps stage:

- Steps 1 through 3 are associated with the **Stage 1**.
- Steps 4 and 5 are associated with the **Stage 2**.

Stage 1: Vessel Definition

In this stage, it is crucial to verify the quality acquisition and the quality of artery and vein automatically detected by the application or manually defined by the user.

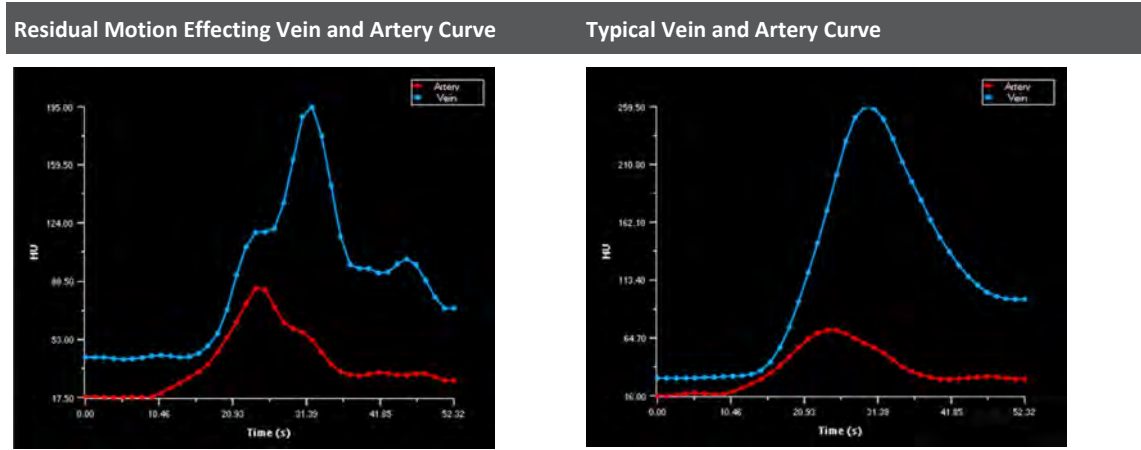
Step 1: Check Automatic Motion Correction

Verify no motion remained once registration completes. Typically, the motion correction implemented with the registration should be able to minimize the motion that was detected during the scan. However, in some cases some residual motion remains.

To detect any residual motion:

1. Switch to the **Average** rendering mode (instead of **tMIP**) using the control on the bottom left of main viewport.
2. Turn on **Cine mode**. See the **CT Common Tools** section for more information.
3. Press play and verify no motion is observed throughout scan duration.

Another way to recognize residual motion in this stage is by looking at the “artery and vein activity” graph at the bottom right viewport corner. If parts of the ascent/descent phases of either of the vessels seem highly inconsistent, it could imply that motion is still evident after the registration.



Step 2: Verify Perfused Areas

Verify that the cerebral mask includes all the relevant perfused areas. The cerebral mask defines the area within the image that is considered as “brain” and only for this area are perfusion maps calculated. In addition, the BP application suggests potential reference vessels only from within the defined cerebral mask area. Thus, if the cerebral mask was defined incorrectly, the suitability of the suggested reference vessels may be affected.

Optimally, the cerebral mask does not include skull, brain ventricles, and eye lenses when these are present in the scan.

The recommended cerebral mask settings are as follows: lower threshold as 15 HU and upper threshold at 400 HU.

These settings can be changed by switching to **Cerebral Mask/Edit Cerebral Mask** tab and turning on the mask display. When changing the cerebral mask threshold, please note that changes can either affect all slices or only the currently active slice.

NOTICE

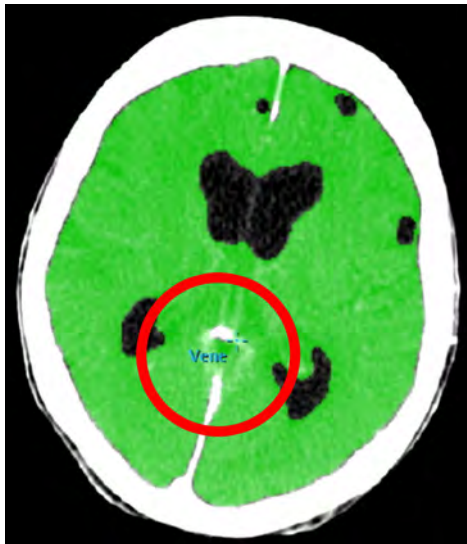
Verify the correctness of the cerebral mask and fix it before selecting reference vessels.

Mask Upper Threshold 100 HU and Optimal Vein Is Excluded from Cerebral Mask

Same Case (as left image) with Upper Threshold Set to 400 HU, Including Optimal Vein



It is advised to pay special attention in cases where a CTA scan was done prior to perfusion scan. The left image below shows the optimal vein not included in the cerebral mask due to CTA exam prior to perfusion exam. The image on the right shows the same case after manual editing: the cerebral mask optimal vein is included in the search range of reference vessels.



NOTICE

The green color will appear as blue in the application.

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Step 3: Vessel Detection

The BP application vessel detection capability suggests potential reference artery and reference vein to the user. The user may also choose to define reference vessels manually by drawing an artery or vein point, or by drawing an ROI in which the pixel with the highest enhancement value will be selected by the application to represent the vessel. It is possible to add up to ten artery and ten vein points (displayed in the time attenuation curve and reference vein statistics table), from which the user can choose the optimal reference artery and reference vein.

Whether defined manually, or suggested by the Brain Perfusion application, in order to continue to the second stage, the user must apply the "use for calculation" confirmation to the reference artery and reference vein location to be used for calculation.

NOTICE

When defining the artery for calculation, the optimal artery would be the artery which peaks first (lowest TTP).

The reference-artery detection search of the application is usually restricted to the upper part of the brain and includes ACA and MCA regions.

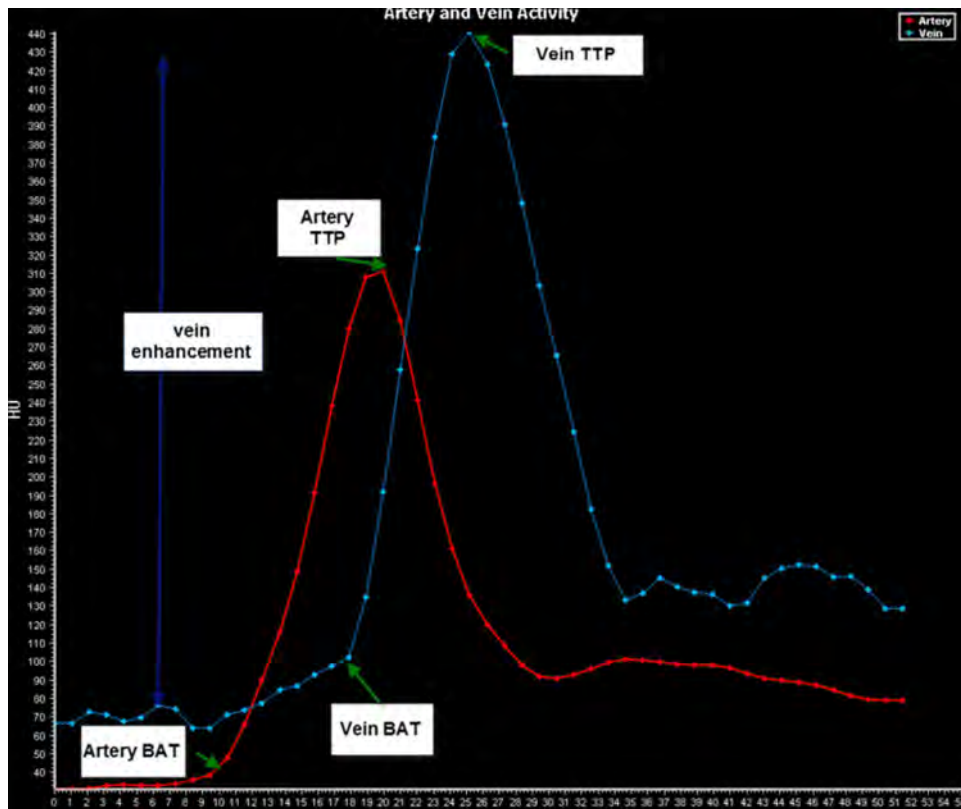
Incorrect artery selection could impair the analysis and affect perfusion results, especially if the chosen artery has a TTP (time to peak) and FWHM (Full Width Half Max) which are significantly different than those of the reference artery.

This information should be obtained from both the reference vessel statistics table and the vessel activity graph.

When defining the vein for calculation, the optimal vein would be the vein with the highest enhancement.

NOTICE

The enhancement is calculated as Max enhancement – baseline enhancement.



Stage 2: Perfusion Maps

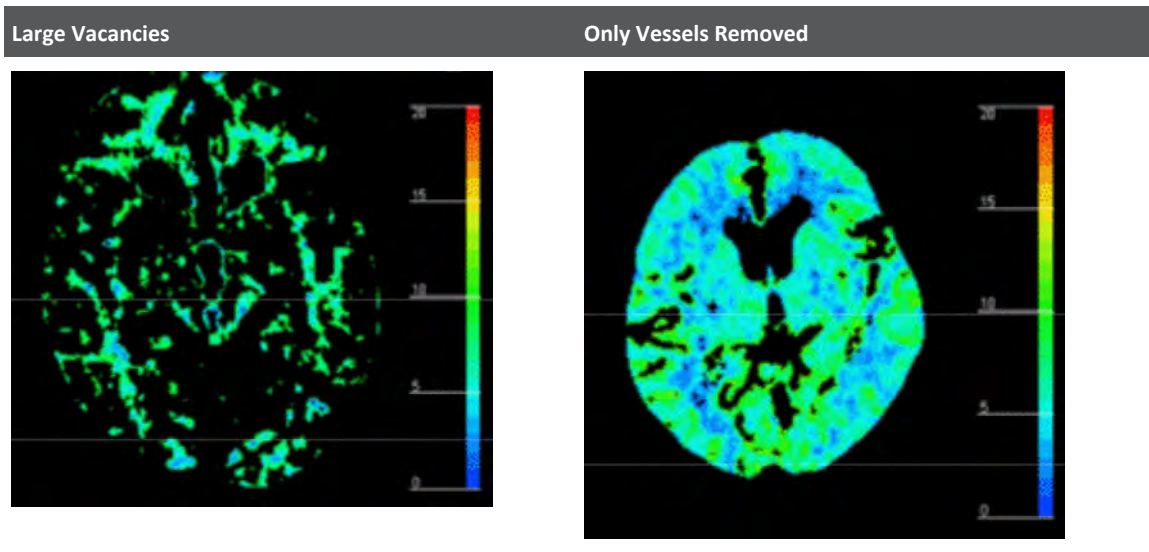
In this stage, use the remove-vessels functionality to check the resulting values and then quantify and correct errors.

Step 4: Check the Plausibility of Resulting CBV (and CBF) Values

The Remove vessels functionality can be used to check the plausibility of the resulting CBV (and CBF) values. Systematic errors in CBV assessment, resulting from the use of non-optimal reference veins, become apparent if the elimination of the vessels with the default setting (9 ml/100 g) removes more than the opacified vessels. This leads to vacancies that are larger than expected from the corresponding tMIP image. Other indications for non-optimal veins and systematic errors in CBV assessment are:

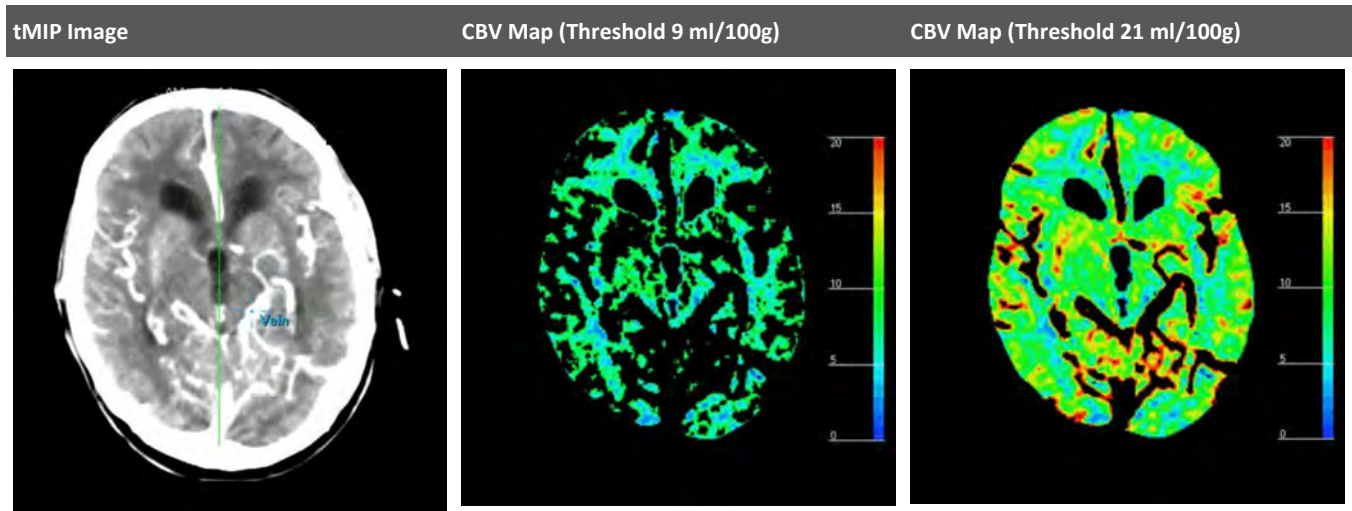
- The venous time-density curve (TDC) is only somewhat higher or even lower than the arterial curve. Normally, the venous TDC is by a factor 2 to 3 higher.
- The prevailing colors in the CBV map are green, and the vessels (red) are much broader than expected. Normal CBV values are 5-6 ml/100 g for gray matter and 2-3 ml/100 g for white matter, resulting in light-blue to light-green colors.

The corresponding images and reference vessel window for regular cases without systematic errors in CBV assessment are shown below. If at least one of these indications is found, the mask should be adjusted as described in the following section:



Step 5: Quantify and Correct Systematic Errors

If any indications for systematic errors in CBV should remain, the errors need to be quantified and corrected. This can be achieved by increasing the remove-vessels threshold until the eliminated portions in the CBV map match the vessels shown in the corresponding tMIP image.



The ratio of the adjusted threshold to the default setting can be used as an estimate of the systematic error. For the example above, this amounts to $21/9 = 2.33$. The inverse of this factor (here: $9/21 = 0.43$) provides a correction factor that can be applied to the erroneous CBV and CBF values.

Using Brain Perfusion Traffic Lights



The **Traffic Lights** feature indicate the presence of many common Perfusion-Map quality issues. When you load a **Study** into the **Brain Perfusion** application, the **Traffic Lights** feature automatically checks the:

- Symmetry (brain hemispheres identified are not symmetrical)
- Contrast injection quality (amount, shape and timing, invalid voxels). These tests are based on average voxel within the cerebral mask Time Attenuation Curve and are not tested for the selected reference vessels.
- Scan sampling rate
- Residual motion after registration

If **Traffic Lights** finds any quality issues with the **Study** (acquisition) data, you will see either a **Non-severe Warning** or a **Severe Warning**. The warning will appear across the top of the viewports. Traffic light warning messages are saved along with the automatic result series. When Traffic lights are present on a perfusion study that is used for automatic result creation, the default rules discretely control the outcome of the result creation process. Automatic results are not available in the defined destinations in relevant cases; you will see an information series in such cases.

NOTICE

When Traffic Lights detects a **Non-severe Warning** and a **Severe Warning**, all warning messages will appear as part of the **Severe Warning** dialog.

Click **Learn more ...** in the header to help you:

- understand the cause of the issue;
- gather information to improve data quality; and
- propose changes to the acquisition protocol for future **Studies**.

When you have reviewed the implications of each warning, you can choose to:

- Save warnings as a table to a local or remote location. Once saved, either continue or quit the application.
- Proceed anyway. (For some cases, edits within the application can assist with some of the identified issues.)
- Close **Brain Perfusion**.

NOTICE

The **Traffic Lights** warning is included when saving, reporting, or filming images.

About Non-severe Warnings



Non-severe Warnings are classified as acquisitions with **mildly insufficient quality**, represented

by a yellow light .

NOTICE

If you see even one **Non-severe Warning** message (yellow light), **the resulting perfusion calculations may be inaccurate.**

If the loaded **Study** produces one or more of the following warnings, consider the implications before continuing:

Non-severe Warning	Implications
<p>Asymmetry: The brain hemispheres in the image are not symmetric.</p>	<p>Visual and quantitative comparisons between hemispheres, as well as summary map calculations, have some probability of yielding incorrect results.</p> <p>Recommendations: In case of incorrect cerebral midline positioning, edit the midline within the Brain Perfusion application. In cases of head tilt, use 3D motion correction within the Brain Perfusion application. To improve future scans, position the patient's head symmetrically, without head tilt on the "couch".</p>
<p>The average contrast enhancement in the brain is lower than expected.</p>	<p>Perfusion results have some probability of yielding incorrect results. This may be due to:</p> <ul style="list-style-type: none"> • Low amount of injected contrast • Low cardiac output of the patient <p>Recommendations:</p> <ul style="list-style-type: none"> • Adjust the perfusion maps color scale to display relevant ranges within the Brain Perfusion application. • Consider reducing the vessel's threshold in the 'Perfusion Maps' step within the Brain Perfusion application to ensure correct vessel removal. • To improve future scans, see instructions for use for recommendations of injection parameters.

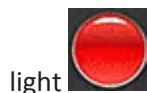
Non-severe Warning	Implications
<p>The contrast injection outflow phase (washout) for the left/right hemisphere is incomplete.</p>	<p>The contrast injection outflow phase (washout) for the left/right hemisphere is incomplete. The downslope of the Time attenuation curve is incomplete.</p> <p>Warning: Perfusion results have some probability of yielding wrong results. This may be due to:</p> <ul style="list-style-type: none"> • Incorrect contrast timing (e.g. the scan started too late and/or ended too early) • Patient-specific issues (e.g. low cardiac output). <p>Recommendations:</p> <ul style="list-style-type: none"> • Adjust the perfusion maps color scale to display relevant ranges within the Brain Perfusion application • To improve future scans, see instructions for use for recommendations of scan and injection protocols
<p>The system has detected some residual motion after image registration.</p>	<p>Perfusion results have some probability of yielding incorrect results.</p> <p>It is recommended to use the following Motion Correction tools within the Brain Perfusion application:</p> <ul style="list-style-type: none"> • Use the "3D motion correction" tool to reduce residual motion. • Use the "Remove displayed point" tool to remove time-points with high motion. • To improve future scans, make sure the patient's head is properly fixated during the scan.

Non-severe Warning	Implications
<p>Long interscan delay: The inter-scan delay between perfusion sampling points is higher than 4.1 seconds</p>	<p>The inter-scan delay between perfusion sampling points is higher than 4.1 seconds and lower than 4.5 seconds.</p> <p>It is not recommended to use absolute perfusion values (e.g. absolute thresholds for summary maps calculations, ROI measurements etc.).</p> <p>Warning: Perfusion results have some probability of yielding wrong results. This may be due to:</p> <ul style="list-style-type: none"> • Incorrect contrast timing (e.g. the scan started too late) • Patient-specific issues (e.g. motion). <p>Recommendations:</p> <ul style="list-style-type: none"> • To improve future scans, see Instructions for Use for recommended scan and injection parameters.
<p>Contrast Injection: Baseline: Shifts in the pre-bolus phase for an average pixel.</p>	<p>The pre-contrast arrival period (baseline) of the time attenuation curve was not detected or is too short.</p> <p>Warning: Perfusion results have some probability of yielding wrong results. This may be due to:</p> <ul style="list-style-type: none"> • Incorrect contrast timing (e.g. the scan started too late) • Patient related issues (e.g. motion) <p>Recommendations:</p> <p>To improve future scans, see Instructions for Use for recommended scan and contrast injection settings,</p>

About Severe Warnings



Severe Warnings are classified as acquisitions with **inadequate quality**, represented by a red



NOTICE

If you see at least one **Severe Warning** (red light), **it is not recommended to use the perfusion analysis with the loaded data.**

If the loaded **Study** produces one or more of the following warnings, it is not recommended to continue:

Severe Warning	Implications
<p>The average contrast enhancement in the brain is significantly lower than expected.</p>	<p>Perfusion results have high probability of yielding wrong results . This may be due to:</p> <ul style="list-style-type: none"> • Low amount of injected Contrast. • Low cardiac output of the Patient. <p>Recommendation: To improve future scans-see Instructions for Use for recommendations of injection parameters.</p>
<p>The system has detected severe residual motion after image registration.</p>	<p>The presence of motion is due to patient movement during the scan. When performing subsequent scans, ensure the patient's head does not move during the scan.</p> <p>Recommendations:</p> <p>Use the following Motion correction tools within the Brain Perfusion application.</p> <ul style="list-style-type: none"> • Use the "3D motion correction" tool to reduce residual motion. • Use the "Remove displayed point" tool to remove time-points with high motion.
<p>Long Inter scan Delay: The inter-scan delay between perfusion sampling points is higher than 4.5 seconds.</p>	<p>The perfusion maps values and the summary maps have high probability of yielding wrong results.</p> <p>Use the recommended scan and contrast injection parameters.</p> <p>Recommendation: Do not use absolute values and summary maps.</p>

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Severe Warning	Implications
<p>Invalid voxel data : A high number of voxels within the brain could not be analyzed due to incompatibility with the perfusion algorithms.</p>	<p>Perfusion results have high probability of yielding wrong results. This may be due to :</p> <p>Missing inflow and/or outflow phase within the tissue time attenuation curve</p> <p>High noise in the images (can be due to low slice thickness, motion etc)</p> <p>This may be due to:</p> <ul style="list-style-type: none"> • Missing outflow phase within the tissue time attenuation curve. • Missing inflow phase within the tissue time attenuation curve • High noise presence in the input images. <p>Recommendations: To improve future scans, please refer to the Instructions for Use for recommended scan and contrast injection settings.</p>
<p>Cerebral Blood Volume (CBV) values in both hemispheres are very low. Please verify artery and vein were defined correctly.</p>	<ul style="list-style-type: none"> • If absolute CBV/CBF thresholds are used for the Summary maps, they require proper adjustment. Perfusion results have high probability of yielding wrong results. • The average CBV values within both hemispheres are lower than 2.5 ml/100gr. • It is recommended to verify vessel detection in the “vessel detection stage”. Verify that the detected vein/artery is not located within ischemic tissue. • In addition, this could imply a very low contrast injection or multi-regional perfusion deficits. • For more information on selecting appropriate vessels, please refer to section “Brain Perfusion Reference Vessel Selection Guide” on page 77. <p>Recommendations: To improve future scans, please refer to the Instructions for Use for recommended scan and contrast injection settings.</p>

Automatic Results Creation Workflow

When Brain Perfusion data arrives to IntelliSpace Portal, the system can generate automatic Brain Perfusion results for reading on targeted devices by a user.

Automatic Results – Results Series

When automatic results are configured (by an Administrator), the following series are available on remote devices (for example PACS):

- Auto – Automatic results series will contain the map/table/graph as configured in the application by the Administrator user, displayed in the defined Batch format (detailed in “Batch format” section below). Series description will begin with “Auto”. If Summary Maps are part of automatic results, the summary maps and measurements for both right and left hemisphere are included in the results.

- If the administrator configured automatic results, three types of series will be available in the IntelliSpace Portal local folder (under the same study as the original series):
 - **Auto** – Automatic results series – Same as described above.
 - **TI CTA series** – Can be loaded into other viewing applications. Series description will begin with TI CTA.
 - **BP Batch** – Series will only be generated if BP preprocessing was initiated on thin slices series. The series can be launched in the Brain Perfusion application. Series description will begin with BP Batch.
 - **Batch Formats** – Automatic results may be generated in the following batch formats:
 - ◊ **Whole screen for all locations** – Sends entire screen as an image, including all viewports and tables, for the entire z-coverage of the study.
 - ◊ **Sorted by Z-position (sort by slice)** – When the batch is created, all selected content is grouped together: for each slice, consecutive images per map type/table/graph, first for the first slice, then for the next slice, and so on.
 - ◊ **Sorted by map type** – When the batch is created, all selected content is grouped together by type. For example, all CBV images are shown together, then all CBF, and so on.
 - ◊ **Sorted by map type : multi series** – Same as “Sorted by map type” batch format, but each type/table/graph is saved in a separate series.
 - ◊ **Current** – The batch will only contain the selected content for the currently active slice.
 - ◊ **Comparison Overview** – When the batch is created, the defined content is displayed side by side to allow comparison between the different results types. If summary maps are defined they are displayed aside the Perfusion maps.

Typical Automatic Results Creation Workflow (Configurable by Administrator)

Step One - Patient Directory Preferences

1. From the Patient Directory, click Preferences.
2. Go to the Processing page.
3. Verify that the Enable Processing checkbox is checked; otherwise place a check mark.
4. Verify that the Run Processing according to the following checkbox is checked; otherwise place a check mark.
5. Click on Add. A new line appears in the table.
6. In the Algorithm column, select Brain Perfusion from the drop down menu.
7. Add the relevant DICOM tags.
8. Click on OK to save and close the window.

Step Two - Perfusion Maps Batch Tab Configuration

Identification of Brain Perfusion automatic results format and targeted send destination is based on the settings within the Brain Perfusion application.

To configure Automatic Results:

1. Navigate to the Batch tab of the 2. Perfusion Maps stage.
2. Select the batch content to be configured for automatic results.
3. Click the Configure automatic results icon.
The Automatic results creation window opens.
4. Place a check mark in the Enable automatic results creation for all future studies check box to enable automatic results creation.
5. Review the dialog defined batch content and settings.

NOTICE

When Enable automatic results creation for all future studies is enabled, if the configured parameters are different from the factory default settings a warning is displayed. To revert to factory settings, select the Restore factory settings option.

6. (Optional) If Automatic results creation is already activated/the user wants to modify the defined calculation setting for the automatic results, the user can change the calculation settings within the application, and then from the dialog box click on the Copy application calculation settings button.
7. Select the following settings: the 3D motion correction and set the destination for yellow Traffic light results if needed.
8. Select the Select devices button within the Target Devices section.
9. Click Activate automatic results to proceed. A confirmation dialog opens.
10. Enter your name in the confirmation dialog and click Activate automatic results to complete automatic results configuration.

NOTICE

This change affects ALL users reviewing Brain Perfusion images.

11. Close the IntelliSpace Portal client and reopen it to update changes. From now on, the system will identify Brain Perfusion studies arriving to IntelliSpace Portal based on this DICOM information and will apply Automatic results creation.

Automatic Results Label

An Automatic Results label is added at the middle upper location of all the images in the automatic results series, as a notification to the user that the series was created automatically.

Traffic Light Indication in Automatic Results

If data quality issues are detected by the system, a traffic light summary page is added to the results. In addition, an indication with the detected issue header is added to the top of all images in the automatic results series.

Traffic lights indicators: If severe quality issues (i.e. Red Traffic Lights) are identified in the data, automatic results series are not created. A Traffic Light summary page will be available in the remote location, containing details of the quality issues identified.

If non-severe quality issues (i.e. Yellow Traffic Lights) are identified in the data, automatic results are sent to remote location (along with the Traffic Lights information), according to the predefined settings by the administrator user. If automatic results are not generated, a Traffic Light summary page will be available in the remote location, containing details of the quality issues identified. For relevant cases, the user may review and edit the information from within the Brain Perfusion application.

Quality Assurance Images

User's Review images are added to the Automatic results series, allowing the user to review before proceeding to the next images.

There are three types of User's Review images:

- **Reference Artery and Vein** - An image with the location of the automatically detected Artery and Vein is saved. The image contains tMIP images with the location of the detected Artery and Vein, an enlarged image of that location and the corresponding activity graph.
- **Cerebral Mask** - An image with the location of the automatically detected cerebral mask is saved in case Summary maps or ROIs are included in the batch. All tMIP slices are displayed with the with the automatically detected cerebral mask blue overlay.
- **Mirror line** - An image with the location of the automatically detected midline is saved in case Summary maps or ROIs are included in the batch. All tMIP slices are displayed with the green midline overlay.

NOTICE

Carefully review the User's Review images prior to continuing with the review of the automatically generated results. If required, do further analysis in the BP application

Cases Excluded from Automatic Results

- If severe quality issues (i.e. Red Traffic Lights) are identified in the data, automatic results series is not created. A Traffic Light summary page will be available, containing details of the quality issues identified.(see details in the Traffic Light Indication in Automatic Results section)
- If the BP application failed to detect automatic Artery and/or Vein, automatic results are not created. A notification will be available.
- If the data is identified as invalid data for the Brain Perfusion application.

Brain Perfusion References

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Minimizing Patient Motion

Patient motion is the main cause of unreliable perfusion and permeability maps. Permeability maps are especially sensitive to motion because the measurement is based on smaller contrast changes. Disruptive motion events (for example coughing and body motion) are more likely in a longer acquisition. Out-of-slice motion that cannot be corrected by the application may result in errors in the permeability maps.

- Motion restriction is important in perfusion and permeability analysis, particularly when low patient compliance is observed.
- Consider using fixation equipment or methods (for example, use a head holder).
- Consider using padded hook-and-loop straps to further suppress motion.
- To evaluate the presence of motion artifacts, change the rendering of tMIP images to **Average** using a viewpoint control at the bottom left corner and scroll along the time dimension to detect any residual motion.



Use the Cine tool to scroll through the images. When activated, the Cine tool uses the Average rendering mode. The main image viewport must be active to use the Cine tool.

While scrolling along the time dimension manually, focus on easily recognizable objects to track the motion. For example: you can follow the location of the artery cursor and search for time points where the cursor has shifted away from the artery.

4 Chronic Obstructive Pulmonary Disease Analysis



The **Chronic Obstructive Pulmonary Disease (COPD) Analysis** application provides semiautomatic and manual tools to help visualize and measure COPD disease in adults.

COPD supports loading up to 4 **Studies** of the same patient for comparison, as well as loading **Results** saved from the **Lung Nodule Assessment (LNA)** and **Multimodality Tumor Tracking (MMTT)** applications.

The COPD application enables the calculation of total lung volume, right lung volume, left lung volume, individual lobes in the lungs, volume of low attenuation area in lung in each lobe (LA Volume), each lung and total Low attenuation volume. The application can also be used to calculate the measurement of the airway and lumen along the centerline of the segmented airway tree.

COPD Analysis consists of 4 workflow stages:

- **Segmentation.** Review, edit and verify the results of semiautomatic airway segmentation, lung segmentation and lung lobe segmentation.
- **Lung Density.** Calculate the low attenuation volume for each lung and lung lobe on the **Emphysema Analysis** tab. On the Air Trapping Analysis tab, measure the air trapped in each lung based on the identified end inspiration and end expiration scans (requires at least 2 **Series**).
- **Airway Extraction.** Review and edit the airway tree and centerline during this stage. If only non-contiguous contrast or non-contrast axial datasets are loaded into the application, this stage is unavailable.
- **Airway Measurement.** Measure the airway lumen and wall cross sectional for different locations on the airway tree.

Supported Scan Types

The application supports contrast-enhanced and non-contrast prospectively ECG-gated axial or retrospectively-gated helical CT images, as well as contrast and non-contrast volumetric helical scans of the lungs, 1-mm thin images every 10 to 15 mm in either standard or high resolution. Data reconstructed with 512, 768, and 1024 matrix is also supported.

COPD only supports Supine scans.

Exclusion Criteria for COPD Analysis

The COPD application might have sub-optimal segmentation and measurement results for studies in which the patient has one of the following:

- Partial lung (for example, post lobectomy or congenital disorder)
- Severe lung disease (for example, pleural effusion or pulmonary edema)
- Post treatment hardware (for example, metal grafts, endo bronchial tubes, pacemakers)

Recommended Protocol for COPD Analysis

For optimal results, the use of thin slices (up to 3 mm, with overlap) and a sharp reconstruction filter (C, L or YA, YB, YC on Philips scanners) is recommended. However, excessive noise may result in sub-optimal airway, lung and lobes segmentation and measurements. To mitigate high noise studies, apply the soft tissue reconstruction filter and/or make use of the appropriate iterative reconstruction (IR) techniques such as Philips iDose4 or IMR.

Pre-processing

When pre-processing is configured in the **Preferences**, segmentation is performed on the **Study** prior to loading it into the application (reducing loading time). For example, pre-processing may be configured for the following CT helical **Exams: Chest, Large Chest, and HRCT Spiral** scan types in the **Chest** protocol group on Philips scanners (pre-processing is also supported for non-Philips scanners). The following algorithms should be selected:

- Automatic Airway Segmentation
- Automatic Lung Segmentation
- Automatic Lung Lobe Segmentation
- Automatic Airway Centerline Calculation

Threshold Settings for Calculating Low Attenuation Area/Volume (LAA/LAV)

It is possible to set the default threshold values for the emphysema calculation (available in the Lung Density stage). This is set within **Preferences (Viewing Applications** page). The two threshold values that can be set are:

- **Threshold for Threshold method**
- **Threshold for Percentile method**

Additionally, for clinical administrators only, there is an option available to share these settings with all users. Placing a check mark in the **Share with all users** check box will share the default threshold values with all users.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

Indications for Use

The CT Chronic Obstructive Pulmonary Disease (COPD) application supports users with the viewing and analysis of Chest CT scans. The application enables localization of affected areas and calculates diseased lung volume and percentage of affected lungs based on low attenuation areas/volumes via a guided workflow for airway analysis, reviewing and measuring airway lumen, and assessing air trapped.

Launch COPD Analysis

Select the desired **Study** in the **Directory** and select **COPD** from **Analysis** applications menu.

NOTICE

When launching the COPD application, Portal also loads the **Study** into the **CT Viewer**. See the **CT Review** section for more information on using the viewer.

1. From the **Patient Directory** find and select the desired **Study** and **Series**.
2. Select the **COPD** icon from the application icon chart.



3. The application opens in the **Verify Segmentation** stage.

NOTICE

If non-contiguous, 2D datasets are loaded, the application opens in the **Lung Density** stage. Automatic segmentation is not performed with non-contiguous axial (contrast or non-contrast) datasets.

Loading Multiple Series

If multiple **Series** of an acquisition are loaded, automatic segmentation is performed on all **Series**. When segmentation is complete, select the desired **Series**. For example, the end-inspiration or end-expiration **Series** may be viewed using the **Series** tab or **Next Series** button.

NOTICE

Once all **Series** are loaded, review, verify, and edit every **Series** before continuing.

Loading Follow-up Data Sets

When loading data sets from different time points of an acquisition, segmentation is performed on the most recent set. In cases where previously saved **COPD** results are loaded, segmentation begins on the most recent data set without results. Once loaded, the **Compare** feature can be used.

NOTICE

Saved results from the **COPD Analysis** application are available on the **Findings** tab.

Loading Results from Other CT Applications

Saved results from the **LNA** and **MMTT** applications may be loaded to the application. Once loaded, the results are available on the **Findings** tab.

COPD Options, Tools and Functions

Use the common tools and processes to perform many basic tasks, including: saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing during all stages of **COPD Analysis**.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Viewing Tools and Options**Orientation**

Use these buttons to select the viewing orientation of the main viewport: axial, coronal, or sagittal.

**Flip**


Use this button to flip the image in the main viewport right to left.

**Layout**


Click the down arrow to select an alternate layout. The currently active layout is displayed as the icon. Use the tool to launch the **Layout Manager** to create a custom layout (see the **CT Common Processes** section for more).

Compare

Select the **Compare** button to compare up to 4 **Studies** from different time points for the same patient.

When using the **Compare** function, the **Link** icon , which is active by default, allows you to lock **Series** together. Enabling you to perform the same tasks on all linked images: for example, filming or saving.

It is not possible to compare a 2D axial data set with a volumetric dataset.

When the **Compare** mode is active, you can click the **Spread** icon  to spread the images you are comparing across both of the system's monitors (only available with Dual Monitor option).

Viewing Tools and Options

Relate



Relate allows you to relate a location on one image of the patient to that location as viewed on other image(s) of the patient. Use the drop-down to access scene and view port options.

Next Series



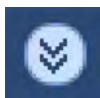
Use this button to move to the next series. The button is only enabled when more than one series has been loaded to the current application.

Saving and Reporting Results

All saved segmentation and table measurements can be reloaded into the **COPD Analysis** application. The saved segmentation tissues can be loaded into the **CT Viewer**. The results table may also be saved in .csv or .txt format. You may also use the standard CT saving options.

Use the **Send Findings to Report** option to automatically send the volume rendered image/SSD image and the result table to the **Report** application. Or, use the standard CT reporting options.

Common Functions



To access additional functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

- **Bookmarks.** This function allows you to access any saved **Bookmarks**.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.
- The **Series** function displays a list of the studies and series that are loaded into the application, and also any other elements (like batches) that have been created.
- **Findings.** Review all the previously saved results on all viewports when selecting a finding from the list.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Verify Segmentation Stage

Review, edit and verify the lung anatomy structures resulting from automatic airway segmentation, lung segmentation and lung lobe segmentation.

The three segmentation processes run serially (**Airways** followed by **Lungs** and **Lung Lobes**) upon launching the application and cannot not be interrupted. Each segmentation process depends on the previous process.

Once the segmentation processes are done, editing is available for each segmented lung structure (via the **Edit Lung Structures** section). If a step in the segmentation process is missing, use the Re-segment options in the **Edit Lung Structures** options, to initiate the required segmentation process.

Studies that contain multiple **Series** require review and verification of each **Series** before completing the stage.

NOTICE

If non-contiguous, 2D data sets are loaded or slices are too thick (above 3 mm), the application opens in the **Lung Density** stage. Automatic segmentation is not performed with non-contiguous axial (contrast or non-contrast) data sets. The 2D low attenuation area calculation and 3D ROI tools are available.



WARNING

In cases where the orientation annotations are not displayed on the image, do not assume any specific orientation. For correct orientation information, use only the images that display such information.

COPD Segmentation Options, Tools and Functions


In addition to the basic **COPD Analysis** tasks (see section “COPD Options, Tools and Functions” on page 98), the **Segmentation** stage has additional selections to control views and perform analysis.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Tools and Options

Show Table



Click **Show Table** to view or hide the results table. This option displays the **Volume** and **Mean Density** of the **Lung Structures**. Use the **Copy Table to Clipboard** button , located in the table header, to add the selected table measurements to the clipboard. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Lung Structures List



Lung tissues resulting from automatic segmentation are displayed on the **Lung Structure** tissue list.

Check the box next to the tissue name to show or hide the tissue in linked viewports. The **Right Lobes** and **Left Lobes** checkbox toggles the view for all the left and right lobes.

To change the color of a tissue, click on the color button in the list (item 1 in the image). The left/right lung lobes groups are not assigned a color; however, the individual lobes are colored. Once a color is changed, it is saved for the next loading of this segmentation.

Use the expand/collapse button to display the contents of the tissue groups (item 2).

Display of tissues may also be controlled using the **Show this Structure** and **Show All** right-click options.

The default structures are:

- Airways
- Both Lungs
- Right Lobes
 - RUL
 - RML
 - RLL
- Left Lung
- Left Lobes
 - LUL
 - LLL

Adjust Opacity of Active Tissue

To adjust the opacity of the active tissue (highlighted in blue), grab the slider bar and move it left to reduce opacity or right to increase opacity.

Review and Edit Airways



Click the **Edit Airways** button to review and edit airways as necessary. When active, only the segmented airways are shown and editable.

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NOTICE

During editing, all the **CT Common Tools** are available. The editing tools are also available using the right-click menu.

Add Airway Segment

Select the **Click to Extend** button to add a new airway segment. When active, the **Place Seed** tool becomes available on all MPR images.

Once this button is selected, there are two options available to extend airways:



Fine extend - Allows multiple clicks. The result will be a very fine extension of the airway tree, up to the point where the user clicked.

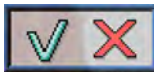


Coarse extend - Allows a single click. The result is a rough segmentation of the area that was clicked.

NOTICE

For optimal functionality of the **Add Airway Segment** tool, always use this tool before proceeding to the **Verify Airway Extraction Stage** (section “Verify Airway Extraction Stage” on page 114).

1. Scroll through the MPR images (Ctrl + left mouse button) to find the airway to add to the segmentation.
2. Place the seed in the desired location. If necessary, grab the point (it turns yellow) to adjust its location.
3. Once the seed is placed, use the **Accept/Reject** pop-up to add the airway or to reject it.



You can move the pop-up if it obstructs the airway of interest. When the pop-up is active and you click anywhere else on the image, the dialog will disappear along with the seed you placed.

Upon acceptance, the segmentation is extended into the airway, connected to the nearest airway tree, and the centerline calculated. All images are automatically updated.

4. If necessary, use the **Swivel** tool to review the volume image. The new airway is shown with a colored overlay.



5. Use the **Undo/Redo** button to remove the new segment as necessary.

- Click **Update and Close** to complete editing and update the airway segmentation. Or, click **Cancel** to exit the editing tools without applying changes.

Remove Airway Segment



Select the **Click to Remove** button to remove an airway that was included as part of the automatic segmentation. When active, the **Place Seed** tool becomes available on all MPR images.

- Scroll through the MPR images (Ctrl + left mouse button) to find the segmentation to be removed.
- Place the seed in the desired location. If necessary, grab the point (it turns yellow) to adjust its location. Segment to be removed has a red overlay.
- Once the seed is placed, use the **Accept/Reject** pop-up to remove the airway.




You can move the pop-up if it obstructs the airway of interest. When the pop-up is active and you click anywhere else on the image, the dialog will disappear along with the seed you placed.

Upon acceptance, the segmentation is removed, along with any leakage into the associated parenchyma, and the airway centerline is deleted. All images are automatically updated.

- If necessary, use the **Swivel** tool to review the volume image.



- Use the **Undo/Redo** button  to revert changes as necessary.
- Click **Update and Close** to complete editing and update the airway segmentation. Or, click **Discard changes and close** to exit the editing tools without applying changes.

Review and Edit Lungs and Update Lobes



Click the **Edit Lungs** button to review and edit the left and right lungs as necessary. When active, only the segmented lung tissues are editable.

NOTICE

During editing, all the **CT Common Tools** are available. The editing tools are also available using the right-click menu.

Edit Lung Segmentation with Smart Segmentation Tools (3D)



Select the **Smart Segmentation Tools (3D)** button to edit the lung segments if segmentation missed a portion of the lung or if another organ was identified as part of the lung. Select the eraser tool if another organ was identified as part of the lung.

1. Scroll through the MPR images (Ctrl + left mouse button) to find the segmentation to be added or removed.
2. Use the **Smart Segmentation Tools (3D)**. For information on using the **Smart Segmentation Tools (3D)**, see **CT Common Processes** in the **CT Review** section.
3. If necessary, use the **Swivel** tool to review the volume image.



4. Use the **Undo/Redo** button to remove the new segment as necessary.
5. Click **Update lobes and close** to complete editing and update segmentation. Or, click **Discard changes and close** to exit the editing tools without applying changes.



Use the Eraser tool to remove organs that are not part of the lungs. To change the size of the eraser tool, click on the arrow to choose between a small, medium, or large spherical eraser.


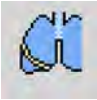

Review and Edit Lung Lobes

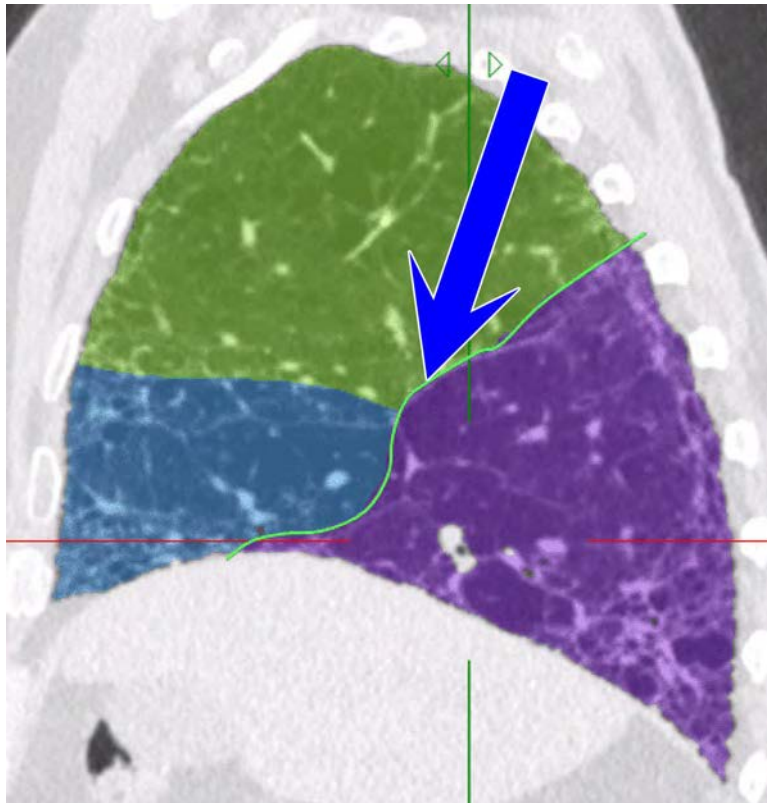


Click the **Edit Lobes** tools button to review and edit the lung lobes as necessary. The result effects the segmentation of the lobes.

Edit Fissures

If minor edits are required for the lung fissures, use the **Edit Fissures** tools.

1. Select the appropriate fissure under **Edit Fissures** to edit the Left oblique  , Right oblique  or Right horizontal  . The selected fissure is highlighted in green.



2. Use the left mouse button to edit the line. When finished editing, click the Accept/Reject






button. A preview of the updated lobes is displayed.

3. Repeat the previous steps until all fissures are segmented correctly.



4. Use the **Undo/Redo** button to revert changes as necessary.
5. After editing all the required fissures, click **Update lobes and Close**. Or, click **Discard changes and close** to exit the editing tools without applying changes..

Re-draw Fissures

In cases where automatic segmentation fails or requires extensive manual editing, click one of the **Re-draw Fissure** tools to draw a left oblique , Right oblique , or Right horizontal fissure .

1. Select one of the **Re-draw Fissure** tools.
2. Scroll through the MPR images (Ctrl + left mouse button) to find an appropriate image on which to redraw the selected fissure.
3. Draw a new fissure using the active editing tool.
4. Verify that the interpolation is correct and edit as necessary.

- Repeat the previous steps until all fissures are segmented correctly.



- Use the **Undo/Redo** button to revert changes as necessary.
- Click **Update lobes and Close** to complete editing and update the fissures. Or, click **Discard changes and close** to exit the editing tools without applying changes.

Re-segment Lung Structures

In cases where automatic airway segmentation fails or requires extensive manual editing, use the **Mark Trachea** tool to initiate a complete re-segmentation of lung structures.

Review, edit and verify the lung anatomy structures resulting from automatic airway segmentation, lung segmentation and lung lobe segmentation. Once the segmentation processes are done, editing is available for every segmented lung structure (via the Edit Lung Structures section). If a step of the segmentation process is missing, use Re-segment options (either Re-segment Structures or Re-segment Lungs and Lobes) in the Edit Lung Structures options, to initiate the required segmentation process.



- Click the **Edit Airways** button and select the **Mark Trachea** tool. Scroll through the MPR images (Ctrl + left mouse button) to find the trachea.
- Place the seed in the desired location. Once the seed is placed, the system automatically resegments airways and proceeds to Lung and Lobe segmentation.
- Review and, if necessary, edit the re-segmentation.

Lung Density Stage

NOTICE

If non-contiguous, 2D datasets are loaded, the application opens in the **Lung Density** stage. Automatic segmentation is not performed with non-contiguous axial (contrast or non-contrast) datasets. Only the 2D emphysema calculation tools are available.

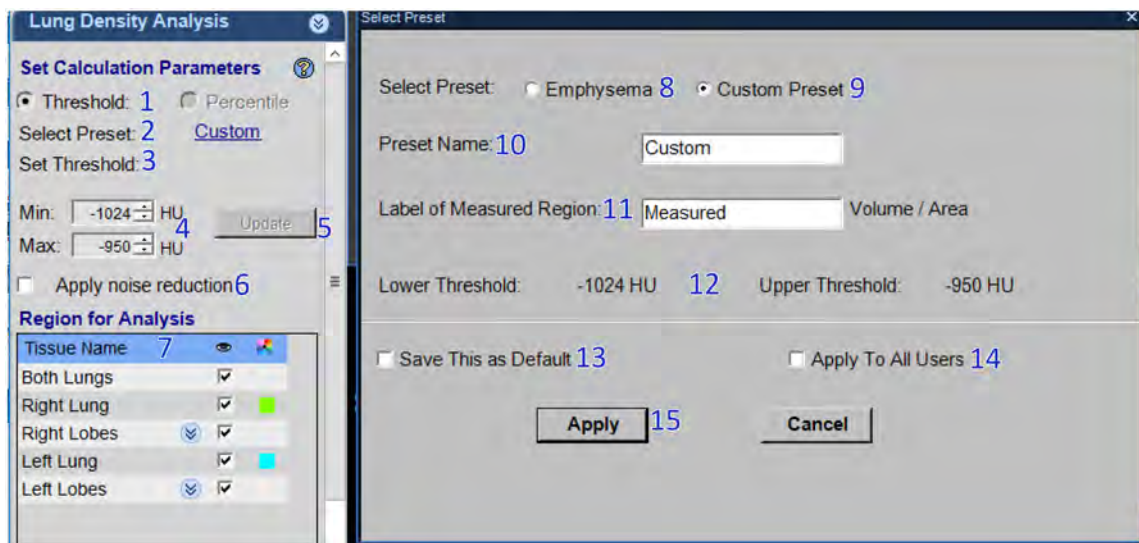
During the Lung Density stage, calculate the Low attenuation Area/Volume for each lung and lung lobe on the Lung Density Analysis tab using the default **Emphysema** Preset option. The **Custom** preset allows selecting a Custom HU Threshold range for defining lung structures. On the Air Trapping Analysis tab, measure the air trapped in each lung based on the identified end inspiration and end expiration scans (both Series must be loaded to perform Air Trapping Analysis).

The Lung Density Analysis stage enables setting the Calculation Parameters and Region for Analysis. The Region for Analysis (#7) settings are described in section “COPD Lung Density Options, Tools and Functions” on page 109.

Setting Calculation Parameters

There are two Preset measurement options available in the Lung Density stage: **Emphysema Preset** and **Custom Preset**.

Note: Refer to the below image for the labeling in this section.



Threshold/Percentile values (#1) Sets Threshold value type for emphysema calculation.

Select Preset: for Measurements #2) Use this option to select one of the presets for measurement:

- **Emphysema Preset (#8):** Used to calculate the Low attenuation Area/Volume for each lung and lung lobe. This is the default option for measuring Low attenuation volumes.
- **Custom Preset (#9):** Allows the selection of a Custom HU Threshold range for defining lung structures. This method allows editing values for the lower and upper HU Thresholds (Min and Max HU thresholds).

Set Threshold: (#3) When the Custom Preset is selected, Min and Max (#4) values can be edited. After editing the desired threshold values, click **Update** (#5) to apply the changes.

Apply noise reduction (#6) The noise reduction filter removes noise from sharp filters, low dose acquisitions, or other sources when 3D volumetric images are loaded. Apply noise reduction by enabling the **Apply noise reduction** check box.

Setting Custom Preset Parameters

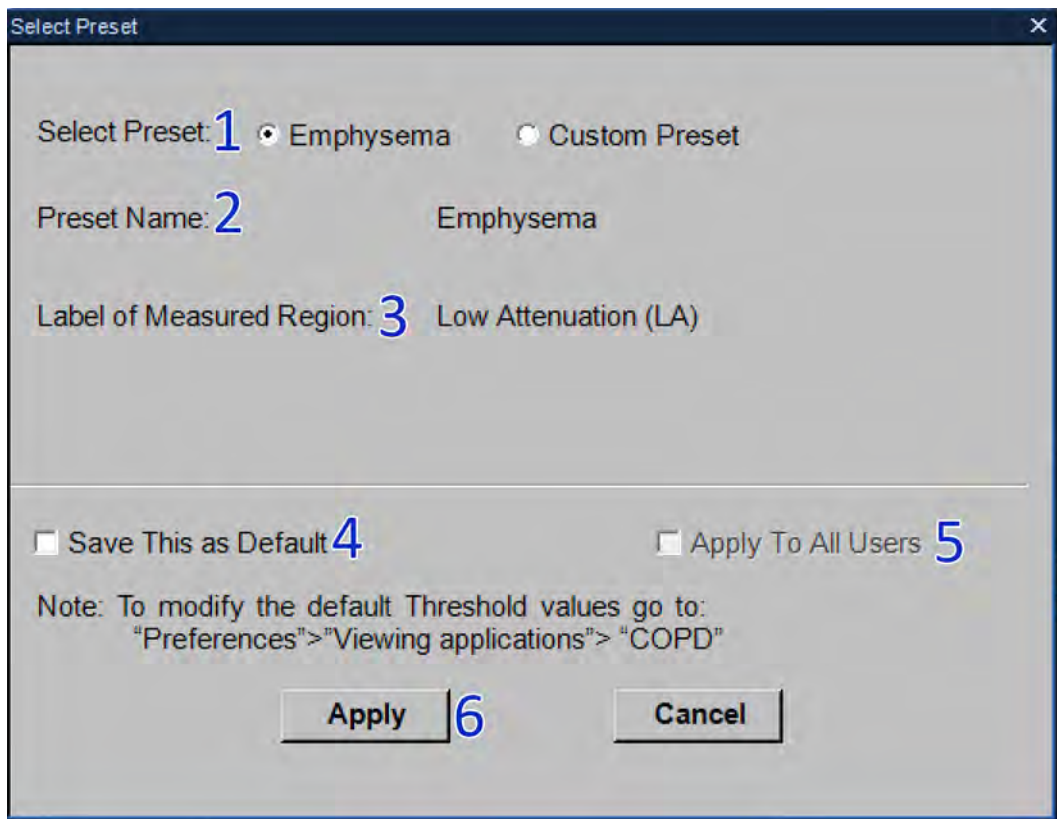
1. Select the **Custom** (#9) option.

Preset Dialog includes an option to input a Custom **Preset Name** (#10) and also Custom **Label of Measured Region** (#11).

2. Enter a **Custom Preset Name** and select **Apply** (#15) to automatically display the labels in the measurement tables headers and exported results.
The Custom presets use the Threshold (#1) method. The Percentile method is disabled for Custom presets.
3. Edit the **Min:** and **Max:** values (#4).
4. Review the lung structures segmented with the updated custom threshold range. The measurement tables and histogram are also updated accordingly.
5. To make this the default setting, enable **Save this as Default** (#13) and select **Apply** (#15).
Administrative users can apply this setting to all users by enabling **Apply To All Users** (#14).

Setting Emphysema Preset Parameters

Note: Refer to the below image for the labeling in this section.



Emphysema is the default option for measuring Low attenuation volumes.

In the **Emphysema** preset for Threshold based Low attenuation volume calculations, the table displays the LA Volume, the Total Volume and the LA Volume Ratio (LA Volume/Total Volume) lung structures.

For Percentile based calculation, the table displays the LA Volume, the Total Volume and the LA Volume Threshold.

Users can select a desired setting for the Upper threshold value in the control panel and use the **Save This as Default** (#4) save option shown below to make it as default.

Administrative users can apply this setting to all users by enabling **Apply To All Users (#5)**. Select **Apply (#6)** to save all changes.

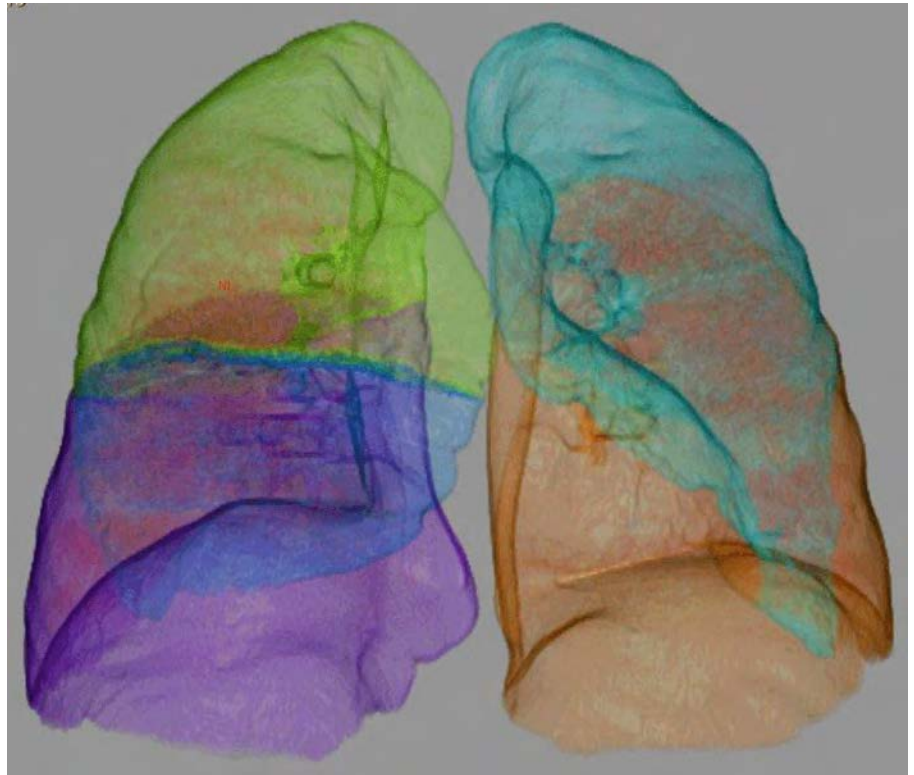
COPD Lung Density Options, Tools and Functions

In addition to the basic **COPD Analysis** tasks (see section “COPD Options, Tools and Functions” on page 98), the **Lung Density** stage has additional selections to control views and perform analysis.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Tools and Options

Show low attenuation Volume Check the box to show or hide the segmented Low attenuation volume on the viewports during **LA Volume Analysis**. Detected low attenuation area is represented by a red overlay.



Show Airway Check the box to show or hide the segmented airways in all the view ports.

Show Color Overlay Check the box to show the color overlay.

Show Air Trapping Check the box to show or hide the trapped air during **Air Trapping Analysis**. The display is automatically updated when the threshold values are changed using the **Recalculate Air Trapping** tool.

Tools and Options

Show Table

Click **Show Table** to view or hide the results table as well as the graph.



**Low attenuation
Volume Histogram
Display**

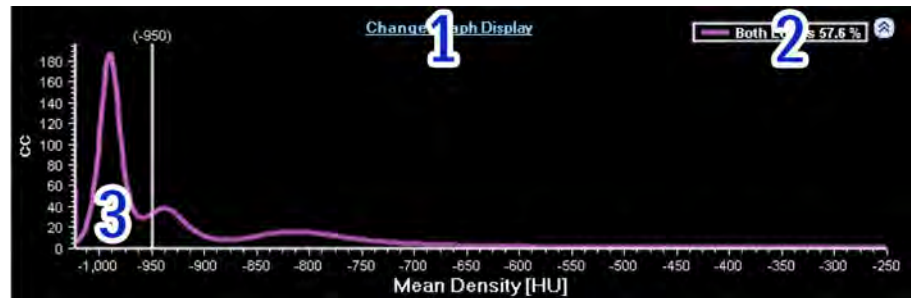
The table viewport includes a histogram during **Lung Density Analysis**. The histogram displays the threshold or percentile, depending on which method is being used.

To change the histogram, click on **Change Graph Display** (item #1 in the image) and select the segments you want displayed. Select the curves to display from the pop-up menu.

The legend (item #2) corresponds to the selected curves that are displayed, with each curve a different color.

Any overlapping curves are represented by a dashed line.

By default, the curve of both lungs is displayed (item #3).



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Tools and Options

Region for Analysis



Check the box next to the tissue name to show or hide the tissue in linked viewports and the corresponding measurements in the table. The **Right Lobes** and **Left Lobes** checkbox toggles the view for all the left and right lobes.

To change the color of a tissue, click on the color button in the list (item 1 in the image). The left/right lung lobes groups are not assigned a color; however, the individual lobes are colored.

Use the expand/collapse button to display the contents of the tissue groups (item 2).

Display of tissues may also be controlled using the **Show this Structure** and **Show All** right-click options.

The default structures for emphysema analysis are:

- Both Lungs
- Right Lung
 - Right Lobes
 - RUL
 - RML
 - RLL
- Left Lung
 - Left Lobes
 - LUL
 - LLL

Adjust Opacity of Active Tissue

To adjust the opacity of the active tissue (highlighted in blue), grab the slider bar and move it left to reduce opacity or right to increase opacity.

Perform Lung Density Analysis

In the Emphysema option, review emphysema calculations, modify the parameters, draw regions of interest, and recalculate emphysema as necessary.

NOTICE

When non-contiguous non-contrast- or contrast-enhanced axial images are loaded into the application, only the 2D emphysema calculation tools are available.

Set Calculation Parameters



By default in the Emphysema Preset, the **Threshold** (-950 HU) parameter is used to calculate Low Attenuation Volume. Use the up and down arrows or type a new value in the box to change the threshold as required. Click the **Update** button.

Select the **Percentile** radio button and use the up and down arrows or type a new value in the box to view the calculations based on percentage. Click the **Update** button.

Apply Noise Reduction

The noise reduction filter removes noise from sharp filters, low dose acquisitions, or other sources when 3D volumetric images are loaded. Apply noise reduction by enabling the **Apply noise reduction** check box.

Measure Low Attenuation Volume Based on Selected Region(s)

Use the **Draw ROI**  or **Draw VOI**  tools to calculate Low Attenuation Volume within the ROI or VOI based on threshold or percentile methods.

NOTICE

For more information on using the ROI and VOI tools, see **Smart Segmentation Tools (3D)** and **Spline ROI** in the **CT Review** section.

Measurements Table

In the Emphysema Preset, for threshold based Low Attenuation Volume calculation, the table displays the Low Attenuation Volume, the Total Volume and the Low Attenuation Volume Ratio (Low Attenuation Volume/Total Volume) of structures checked in the **Tissue Name** list. For Percentile based calculation, the table displays the Low Attenuation Volume, the Total Volume and the Low Attenuation Threshold.

Perform Air-trapping Analysis

Measure the amount of air trapped in the lungs: manually select the end inspiration and end expiration scans, set parameters, and identify areas of interest.

NOTICE

Air-trapping requires at least 2 **Series**: inspiration and expiration scans.

The air trapping measurements are calculated by subtracting relative lung volume of end inspiration from end expiration.

Air Trapping	
$RLV_{exp} - RLV_{ins}$	RLV_{exp} : Relative Lung Volume from end expiration
	RLV_{ins} : Relative Lung Volume from end inspiration

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The relative lung volume is calculated for each **Series** by measuring the volume of voxels between upper and lower thresholds (by default, -860 HU to -950 HU) and dividing it by volume of voxels with attenuation greater than -950 HU.

$$\frac{Vol_{-950x < -860}}{Vol_{x > -950}}$$

Change End Expiration/Inspiration

By default, the application selects the end expiration and end inspiration **Series**. After review, either accept the automatic detected **Series** or select a different **Series** from the drop-down.

Click the button to review and, if necessary, edit the selected **Series**. Once selected, ensure that the correct series is marked as either **End Inspiration** (often the largest volume) and **End Expiration** (often the smallest volume) on the view ports.

Change Upper and Lower Thresholds

Use the up and down arrows or type in new HU values to change the parameters as desired. When done, click the **Recalculate Air Trapping** button.

Region of Analysis

Select the appropriate tissues from the list. By default, both lungs are selected. Use the Opacity slider to control the segmentation overlay.

Measure Air Trapping Based on Selected Region(s)



Use the **Draw ROI** tool to calculate air trapping for the region. At least one ROI must be drawn on both the inspiration and expiration **Series**. Once drawn, the table updates with the new calculations. Click on the ROI in the table to show the corresponding image.

NOTICE

For more information on using the ROI tool, see **Spline ROI** in the **CT Review** section.

Measurements Table

The table displays the Total Volume End-Inspiration, Total Volume End-Expiration, Relative Volume Ratio End-Inspiration, Relative Volume Ratio End-Expiration, Relative Volume Change, and Mean Lung Density E/I Ratio of structures checked in the **Tissue Name** list.

Verify Airway Extraction Stage

Review, identify, and edit the segmented airway tree and centerline during this stage. Ensure that:

- the centerlines are complete, properly located and positioned in the airway centers; and
- the airways are correctly named.

At least one airway must be identified before continuing to the next stage.



WARNING

Verify the accuracy of the airways and their labels. If needed, use the manual tools provided in this stage to correct airway extractions and labels.

NOTICE

If only non-contiguous contrast or non-contrast axial datasets are loaded into the application, this stage is unavailable.

COPD Airway Extraction Options, Tools and Functions

In addition to the basic **COPD Analysis** tasks (see section “COPD Options, Tools and Functions” on page 98), the **Airway Extraction** stage has additional selections to control views and perform analysis.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Tools and Options

Show Centerline	Check the box to view/hide the centerline.
Show Cursor	Check the box to view/hide the cursor.
Highlight Airway Tree	Check the box to view/hide the airway tree.
Show Color Coded Mesh	Check the box to display the tubular representation of the automatically detected airway segments.

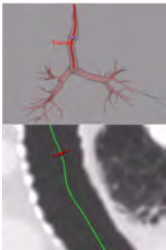
Verify and Edit Centerlines

On the volume image, right-click on the segment of interest to rename it. Select one of items from the menu or type the airway name in the space provided. The **Label Airways Path to Carina** dialog automatically detects the right and left lung. Verify the side of the lung. Once done, the airway is added to the airways list. Review and edit the centerlines as needed.


NOTICE

To rename or remove an airway, right-click on it in the tissue list and select **Remove from list** or **Rename**.

On the volume image, hover over the airways to select the segment of interest. Right-click on the segment of interest and label it. Once selected, a path to the carina is created

Adjust Centerlines

The automatically defined centerline will, in most cases, pass through the center of the airway. If this is not the case, use the **Edit Centerline** tool.

1. Select an Airway from the **Select Airway** list.
2. Select the **Edit Centerline**  button under **Edit Select Airway** to edit the selected airway.
3. Edit the centerline as needed from the volume, cMPR or cross-sectional views.

Airway Measurement Stage

Measure the airway lumen and wall cross section for different locations on the airway tree. There are two modes for contour inspection:

- **Along Centerline.** Review the inner and outer contours for the airways identified in the previous stage. If 2D axial data sets are loaded, this mode is not available.
- **Local 2D inspection.** Manually mark airways of interest and review measurements for axial datasets.

Once the airways are identified, it is possible to review the airways using the **Endo Luminal View**.

NOTICE

Airway measurements can be impacted by the phase of respiration. For optimal results, please use inspiration datasets.

NOTICE




Contour measurements might be incorrect in the area of branching.

COPD Airway Measurement Common Tools and Functions

In addition to the basic **COPD Analysis** tasks (see section “COPD Options, Tools and Functions” on page 98), the **Air Extraction** stage has additional selections to control views and perform analysis.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Tools and Options

Show Centerline	Check the box to view/hide the centerline.
Show Cursor	Check the box to view/hide the cursor.
Show Airway Tree	Check the box to view/hide the airway tree.
Show Graph	Use the checkbox to show or hide the Lumen Maximum Diameter graph. The vertical line is linked to the images. Drag the line to navigate through the images.
	Display Lumen Contours
	Display Airway Contours
	Show Summary Table

Measurement Display

By default the lumen maximum diameter and wall thickness are displayed on the cross-section image. To modify the displayed measurements:

1. On the axial image, hover over the measurements until it turns yellow.
2. Right click and select **Properties** from the menu.
3. Click on the desired measurement to either show or hide it.

Table

When using the centerline mode, the table displays the measurements from the cross-sectional image for centerline mode and displays the measurements from the active axial image for 2D mode.

There are two tables that are displayed when using centerline mode, local measurements and average measurements. Average measurements take into account the values between the two yellow lines (the start and end positions).

Table columns can be configured by clicking on **Edit Column**.

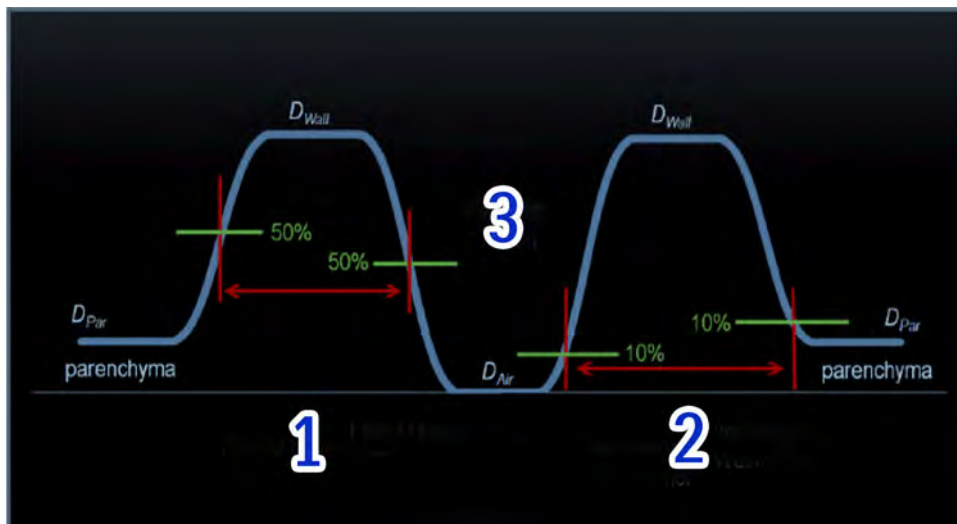
Integral Airway Measurements

Airway measurement is performed using the Integral (Weinheimer) method.

The principal underlying idea of the estimation method presented by Weinheimer et al [P. A. de Jong, N. L. Müller, P. D. Paré, and H. O. Coxson, “Computed tomographic imaging of the airways: relationship to structure and function,” *European Respiratory Journal*, vol. 26, no. 1, pp. 140–152, Jul. 2005] is that the airway wall has a certain characteristic density independent of its thickness and that the blur, as well as the rebinning, is essentially only spreading out the mass of the wall while conserving its total amount. Consequently, an integration over the spread-out wall can recover the total mass completely and division by the true density will then yield the true thickness. Although the assumption of a constant characteristic true wall density (D_W) may be oversimplifying, the approach is straightforward, computationally efficient, numerically robust, and has been confirmed with physical tube phantoms.

The image below displays the difference between the Integral method and the conventional FWHM (Full Width Half Maximum) measurement method used in CT. FWHM was found inaccurate on small airways due to the blurring effect.

- #1 - FWHM boundaries
- #2 - Wall integral boundaries Weinheimer
- #3 - Airway lumen



NOTICE

The contour measurements close to the bifurcation area may be incorrect. Before capturing a measurement, please verify the correctness of the contours as displayed on the cross-sectional image. When placing the start and end regions to obtain the average measurements, do *not* include bifurcation area.

Review Along Centerline

In the image below, the airway contour is orange (item 1) and the lumen contour is colored pink (item 3). The centerline is a green crosshair (item 2) on cross-sectional images.

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**NOTICE**

If only 2D axial datasets are available, you must use the **Local 2D Inspection** mode.

To view additional contours along the vessel:

- scroll the image in the viewport (above); or
- drag the reference marker along the centerline in a cMPR viewport.



NOTICE

It is possible to compare the centerlines of up to four studies for one patient. However, one-click compare only shows the centerlines that are repeated in all studies.

Perform Local 2D Inspection

In cases where only 2D datasets are available, manually mark the airways of interest.



1. Ensure the **Local 2D Inspection**  and **Mark Airway for Inspection**  buttons are selected.
2. Scroll through the axial image and click on the airway of interest.
3. The other viewport displays the airway lumen and wall contours.
Continue scrolling through the images until all airways of interest are marked.
4. To review airways, select the airway from the table. The reference images will snap to the location.
5. To review the captured measurements, select the relevant row from the table. The reference images will snap to the location.

Endo View

Navigate through the active centerline navigation in the endo view.

1. Select the **Endo Luminal View** function tab from the drop-down menu.
2. From the tissue list, click on the airway of interest.
3. Use the **Forward** and **Back** buttons to move forward and backward through the airway. If necessary, change the speed.
4. To manually move through the view, hover over the Endo view and use the paddle wheel to scroll forward and back.

5 Comprehensive Cardiac Analysis

Comprehensive Cardiac Analysis (CCA) application is used to assess the state of the coronary arteries and to analyze functional heart data.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

NOTICE

This application was verified using only cases from Philips scanners. If you load cases from another manufacturer there may be differences in application behavior.

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Loading multiple studies in CCA does not support CT+CT from different dates but only CT+PET/SPECT from different dates.

NOTICE

When loading data into an application, ensure the orientation shown on the images is consistent with the images' appearance. This precaution is required for data that contains wrong orientation information because the data will be incorrectly presented within the application. For example: Legacy nuclear medicine volume data (SPECT or PET) reconstructed using cardiac orientation may not encode the orientation information correctly.

NOTICE

Depending on your Portal configuration, this application may not be available.

Automatic Segmentation

When you first load a heart study, the application performs a full segmentation procedure. The entire organ is segmented at one time based on a pre-defined model. The segmentation model consists of ventricles, atria, muscle, aorta, and coronary arteries.

NOTICE

Each time a study is loaded, the system performs a new auto segmentation. Auto segmentation data is not automatically saved when the study is closed. You must save the segmentation using Save Results as ... in the Common Tools.

The different tissues are then color-coded. You may highlight the various segments as desired and examine the correctness of the segmentation.



WARNING

Verify the accuracy of the automatic segmentation. If necessary, manually correct the segmentation using the Heart Segmentation correction tools provided in this stage.

The aortic root and the coronary arteries are detected automatically by the application and artery centerlines are generated and named. You can also name any arteries that were not automatically named.

Curved planar reformations and a series of cross-sectional images allow you to inspect an entire artery and estimate the size of stenosis along the artery.

**WARNING**

Cross sectional images might rotate around the centerline. Please note orientation annotations on images.

In cases where the orientation annotations are not displayed on the image - you must not assume any specific orientation. For correct orientation information - use only the images which display such information.

One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.

Objects in thick curved MPR images may appear distorted. Use caution when making measurements on MPR images.

Use Cardiac Viewer to Review Study

When you launch a patient study into the CCA application, the system will open the Cardiac Viewer application on the left monitor, under the Review workflow function. This allows you to review the original axial images for each of the loaded phases while waiting for the automatic segmentation to complete.

NOTICE

Refer to the Cardiac Viewer section in the Review volume for instructions for use.

If the ECG strip was loaded, the ECG signal can be displayed. The ECG strip displays a white arrow which correlates with the current rotation center location.

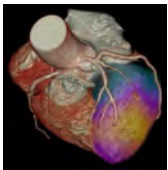
NOTICE

Change the standard cardiac angles on the volume image to modify the view, as described in the Cardiac Viewer section. Select either from a preset option or enter exact angles manually.

Reporting Features

If the ECG strip was loaded, the ECG signal can be displayed. The ECG strip displays a white arrow which correlates with the current rotation center location.

PET/SPECT Cardiac Support



The CCA application supports Nuclear Medicine (NM) image data. Support for PET/SPECT includes viewing tools, the Fusion mode, dedicated layouts, PET/SPECT/Fused colormaps, image manipulations, and other functions. See also section “PET/SPECT Support in CCA” on page 230.

Application Stages

The CCA application consists of the following workflow stages:

- **Segmentation** is the first workflow stage. You can view details of the segmentation, make manual corrections, save the segmentation, and re-segment using anatomical landmarks. See section “Segmentation Stage” on page 126.
- **Coronary Extraction** allows you to view the heart anatomy—the aorta, the aortic valves, and the arteries—in high detail. Arteries can be reformed into straightened views, and the heart can be viewed in the full volume-rendered mode, including rotations, curved planes and cine. See section “Coronary Analysis Stage” on page 154.
- **Coronary Analysis** allows you to perform quantitative measurements concerning the coronary arteries. There are 2 options for analysis:
 - Coronary Analysis. Calculate percent stenosis and cross-sectional area, based on either automatic lumen contouring or manual methods.
 - Plaque Analysis (an available option. Evaluate the condition of coronary arteries, including plaque characterization and volumes.

See section “Coronary Analysis Stage” on page 154.

- **Functional Analysis** allows you to analyze a variety of heart functions: including left and right ventricle volumes, left and right atria volumes, ejection fraction, stroke volume, and cardiac output. You can also use this function to visualize the mitral and aortic valve planes. Color maps display the values of regional functional parameters for each part of the left ventricle, such as wall thickness, wall motion, and thickening. see section “Functional Stage” on page 192.

An available option is Myocardial Defects Assessment, which provides visual and quantitative assessment of hypo-enhanced areas within the myocardium. See section “Myocardial Defects Assessment” on page 212.

NOTICE

Clicking on the left or right arrow of the workflow menu will return you to the previous stage or advance you to the next stage. Clicking on the down-arrow allows you to select from the list of workflow steps. (A grayed out right arrow or next stage selection means that you have not finished the current stage.)

While following the workflow, you can go back to a previous stage without losing any work performed in the current stage. However, returning to a previous stage and making changes (for example, returning to Segmentation from the Coronary Analysis stage and making changes to vessel segmentation) affects your previous work.

Load Study**WARNING**

When loading images into Comprehensive Cardiac Analysis, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

When selecting and loading a study keep the following in mind:

- The maximum of 5500 images may be loaded.
- If you intend to use the Functional stage, be sure to load at least two phases, the End Systolic and End Diastolic phases.

**WARNING**

When loading several phases with different scan and/or reconstruction parameters (for example: different zoom, pan, image number, FOV, matrix) the application performs automatic alignment between the phases. Image quality may be reduced due the alignment.

Automatic Segmentation Sequence

When the study is opened, the CCA application automatically performs segmentation. The segmentation process is repeated for every phase that is being loaded.

NOTICE

The order of the segmentation is as following:

- first the segmentation is calculated for phase 75%;
- then all phases between 75% and 80% in ascending order;
- then all phases between 70% and 75% in ascending order;
- then phase 40%; and
- then the rest of the loaded phases are calculated in ascending order.

Once segmentation is finished for at least one phase you can proceed to Coronary Extraction scene. The status of segmentation is displayed by naming the phase that is being segmented in the status bar location at the lower right corner of the display.

NOTICE

You can stop the segmentation by clicking the X button in the status line. You cannot continue segmentation after it has been stopped. You must repeat the procedure. To restart the segmentation, hit the Reset All button or reload the images into the application.

**WARNING**

Verify the correctness of extracted vessels. If necessary, manually correct the extracted vessels using the tools provided by the application.

Segmentation Stage

The Segmentation stage allows you to view the tissue definitions created by the automatic segmentation function of the CCA application.

Segmentation enables rapid analysis of the coronary arteries and cardiac function (after the images have been loaded into CCA). You can determine if manual corrections are needed, and make the needed corrections before moving to the next stage.

Please refer to the following sections of the IntelliSpace Portal Spectral Applications IFU for information on spectral results and processes:

- Understanding Spectral Results
- Common Spectral Processes

Review and Correct Automatic Segmentation

The automatic segmentation that is initially performed by the CCA Segmentation function requires your review. The various tissue definitions may be incomplete, or may exceed or fall short of the actual tissue boundaries.

Look for good coronary segmentation, which produces the accurate artery centerlines necessary for the Coronaries Extraction stage.

After reviewing the results of the automatic segmentation, if necessary perform the following:

1. Add additional parts of the relevant tissue portions that were not segmented.
2. Remove incorrectly segmented tissue from the coronary tissue.
3. If the segmentation is completely off for all the tissues, use the Re-Segment tool to recalculate the segmentation.

Segmentation Opening Window

The initial Segmentation window consists of an axial image in the main viewport and two orthogonal images and one volume image in the reference viewports. The crosshair colors on the reference images correspond to different orientations.

- When General Axes orientations are chosen the colors are: red-axial, green-coronal, blue-sagittal.
- When Cardiac Axes orientations are chosen the colors are: red-short, green-horizontal long, blue-vertical long. Green corresponds to the coronal view and blue corresponds to the sagittal view.

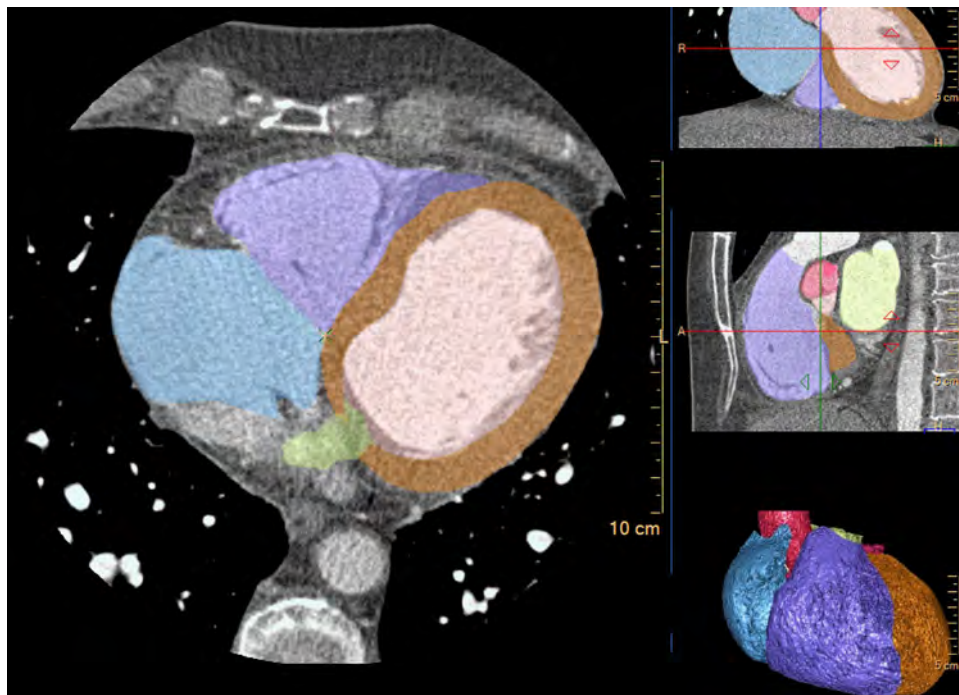


Image Types

In any viewport, you can choose to view Conventional or MonoE images. Pause the pointer on the name of the data type to see the options and click to make your selection. In addition, you can adjust the MonoE keV level using the accompanying arrows. These actions adjust the associated viewports accordingly.

You can choose to re-run segmentation at a different keV level. See section “Segmentation Functions” on page 130 .

Color Mapping

- Red: Aorta
- Pink: Coronaries
- Cyan (blue): Right Atrium
- Purple: Right Ventricle
- Brown: Myocardium
- Pale pink: Left Ventricle
- Green: Left Atrium

Layouts

There are two layouts: 1x3 and 2x2. The layouts include:

- Main slab image with the colored tissue overlays. This image is displayed as default in Axial orientation.
- Reference slab image with the colored tissue overlays. This image is displayed as default in Coronal orientation.
- Reference slab image with the colored tissue overlays. This image is displayed as default in Sagittal orientation.
- Volume color coded image displaying all the segmented tissues with it's specific color.

Segmentation Viewing Tools

Use the tools to change the view during the segmentation stage.

Orientation



You can change the image orientation between the General Axes and the Cardiac Axes modes. Click the down arrow to switch between the two orientation modes:

- **General axes.** The general axes are the standard anatomical orientations: axial; coronal; and sagittal.
- **Cardiac axes.** The cardiac axes orient the views of the heart as follows: short axis; horizontal long axis (4 chamber view); and vertical long axis (2 chamber view).

Use the Flip button to flip the active volume viewport 180 degrees.

Rotation Center (checked by default)

Click to show the center point (indicated by a green X) around which the volume can be rotated.

Center Cursor

This function centers the image around the rotation center. Change the rotation center as follows:

1. Move the mouse over the current rotation center (the green X) in the slab view. The mouse pointer turns into an arrow cross symbol.
2. Drag the rotation center to the desired region of interest.
3. Click **Center Cursor** and the slab view centers around the new rotation center location. Swiveling and rotating of the image will be performed around this new rotation center.

ECG

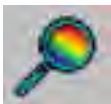
Click the Show ECG button to display the ECG strip (if it was loaded) along the bottom of the screen. See the "Cardiac Viewer" section in the "Review" volume.

Calculate Volume

Click this button to calculate the volume of the currently displayed tissue(s). A purple overlay in the reference images covers the tissue(s) included in the volume calculation. The calculated volume consists of all pixels in the purple overlay.

Relate

Relate is a Common Tool that allows you to relate a location on one image of the patient to that location as viewed on other image(s) of the patient.

Spectral Magic Glass

Use the Spectral Magic Glass tool to open an ROI window on the main image. The region displayed within this window is then also displayed within a moveable dialog box containing multiple viewports of default spectral images. Each viewport can display a different image type, each with its own window and level capability. In addition, the viewport display adjusts as you change the size of the magic glass window.

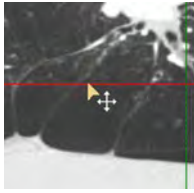
Magic Glass

The Magic Glass function displays a moveable, mini-window (3 cm default) which can be set with its own windowing, image enhancement and rendering parameters. With the Magic Glass function you can enhance visualization and assessment of certain elements of the image, such as calcium and stents, while maintaining optimal viewing parameters for the main viewport.

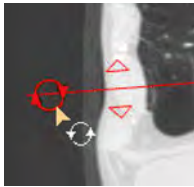
Using Crosshairs

For viewports with crosshairs, perform one or more of the following to adjust:

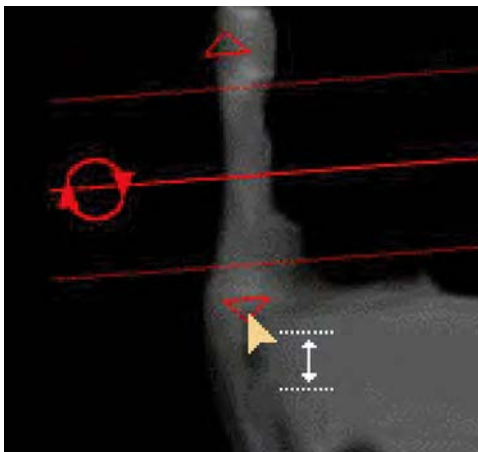
- Grab the crosshair and drag it to the correct position.



- To rotate, grab near the end of the crosshair and drag in the appropriate direction.



- To change thickness of the images represented by the crosshair, grab the triangle and drag it.



See **Report**, **Film**, **CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Segmentation Functions

To switch between functions, hover over the tab title and select from the menu.

Heart Segmentation

This is the default function tab when the Segmentation stage opens. At the top of the tab is the list of segmented tissues, displayed as color overlays:

- Coronaries
- Aorta
- Left Ventricle

- Left Atrium
- LV Myocardium
- Right Ventricle
- Right Atrium

Check boxes indicate whether the tissue is displayed or hidden. (Default is all boxes checked, showing all tissues.) Use the check boxes and these three buttons to show segmentations in any combination:

- **All.** Displays all the color overlays.
- **None.** Clears all check boxes to hide all the color overlays.
- **Check box.** Check to show, uncheck to hide, individual segmentations.
- **Coronaries.** Hides all the color overlays except the Coronaries and the Aorta.

Re-segment

This function is used if the automatic segmentation fails completely.

Bookmarks

This function allows you to access Bookmarks, if any are saved.

Batch

The Batch function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Choose Tissue Colors

The colors of the segmentation overlays are set to factory defaults. You can change them as desired.

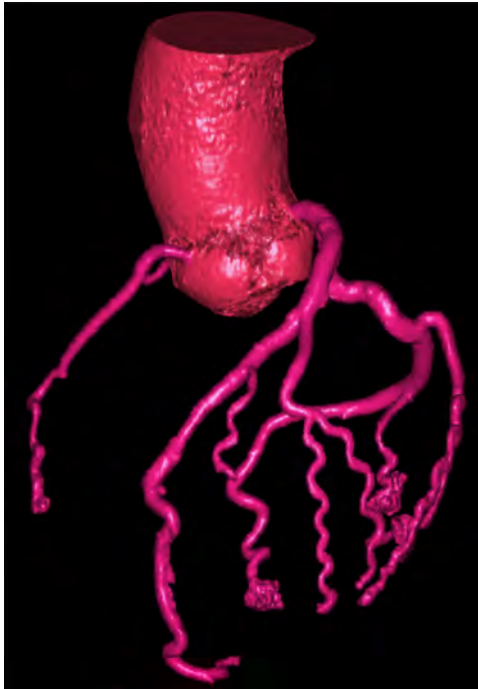
1. Click on the colored square that appears next to the name of the tissue in the **Heart Tissues List**.
2. The **Choose Tissue Color** dialog opens, showing a color selection interface. There are different ways to set a new color for a tissue:
 - Type in the V, H, and S values of the desired color
 - Click on the desired color in the color palette and choose the value by moving the value controller

You can set the new color as the default. You can also return a changed color to the System (factory) default.

3. Click **OK** when you are finished. The tissue is displayed in the new overlay color.

Correct Coronaries

1. Examine the Coronary tree.



2. Scroll through the images. Examine the segmentation of the coronary arteries.
3. If corrections are necessary to the Coronary tree, click the **Add Coronary** button and click on the relevant artery in the image. The application will attempt to segment the artery.



4. Click on a coronary vessel which was not segmented. The algorithm will attempt to detect the whole vessel.
5. Continue scrolling with the mouse wheel and adding coronaries until all corrections are made.
6. To undo your last correction(s), click Undo. Each Undo click reverses the previous change.



7. If the Add coronary tool is not working you can use the Inject dye tool described in the next section. (The Redo function - accessed from the drop-down - becomes active after you make a coronary correction. This allows you to reverse your last Undo function.)

NOTICE



During coronaries segmentation editing you can use the <Ctrl>+ Left mouse drag for fast scrolling.

Manual Segmentation Tools

The manual segmentation tools allow you to correct the segmentation of tissues, one tissue at a time. Manual segmentation tools include:

Smart Segmentation Tools (3D)

Use the Smart Segmentation Tools (3D) to improve 3-dimensional segmentation. Click the

button to access the **Add smart ROI to tissue (3D)**  and **Subtract smart ROI from tissue (3D)**  options.

Inject Dye (3D)

Colors additional unsegmented areas and adds them to the active tissue. The rate and type (viscosity) of the injection can be controlled by the relevant boxes.

**WARNING**

When using the Dye Injection tool verify the correctness of volume segmentation. If necessary, correct the dye tracing using correction tools supplied by this application.

Eraser (3D)

Removes volume from the active tissue.

Fill Holes (3D)

When there is a check mark in the check box, all of the “holes” are filled in the color overlay of the active tissue.

Expand Tissue (3D)

Allows you to increase the edges of the active contrasted tissue. Each click expands the edge by a one-voxel increment.

Erode Tissue (3D)

Allows you to decrease the edges of the active contrasted tissue. Each click reduces the edge by a one-voxel increment.

Brush (3D)

Allows you to add to unsegmented areas of active tissue, by “painting” with 3 sizes of brushes.

Re-run Segmentation

Use this function to re-run segmentation on the current series. For example, you can change the MonoE energy level to 65 keV, and then use this function. The new segmentation replaces the old/current one.

Manual Editing Procedure

1. Select the tissue you want to edit by clicking on it in the tissues list. The active tissue is denoted by the blue color in the list.
2. Make sure the tissue is displayed (the check box next to it is checked).
3. If you want to add unsegmented parts to the active tissue without changing the other tissues, make sure that the other tissues are also checked (displayed). As long as a non-active tissue is displayed (checked and not highlighted in blue), the editing tools do not influence it.
4. If you want to add unsegmented parts to the active tissue and you do not mind changing other tissues, you can un-check the other tissues.
5. Once the tissue is active and displayed, use one of the manual editing tools to edit it.

NOTICE

If you choose another tissue from the segmentation list, the Undo function will no longer be effective for the previous tissue.

During segmentation editing you can use the <Ctrl>+ Left mouse drag for fast scrolling.

Change Tissue Color



The colors of the segmentation overlays are set to factory defaults. You can change them as desired.

1. Click on the desired tissue in the Segmentation list. The tissue name is highlighted.
2. Click the **Change Tissue Color** button. The Choose Tissue Color dialog opens, showing a color selection interface. There are several ways to set a new color for a tissue:
 - Type in the HSV values of the desired color
 - Click on the desired color in the color palette and choose the value by moving the value controller

You can set the new color as the default. You can also return a changed color to the System (factory) default.

3. Click **OK** when you are finished. The tissue is colored in the new overlay color.

Re-segment Function

If the automatic segmentation failed, or if the coronaries were not segmented at all, you can redo the segmentation process using Re-Segment function, which uses manually placed landmarks to perform the segmentation.

You can choose to Re-Segment either one phase (the current phase) or All phases.

The Re-Segment process is initialized by manually placing Seeds on the following anatomical locations:

Pulmonary valve	Mitral valve	Apex
-----------------	--------------	------

1. Activate (or deactivate, as desired) the All phases option.
2. Click the **Seed** button. The location names become active.
3. Using the mouse wheel, scroll the axial image to locate one of the 3 required anatomical locations.
4. Click the button corresponding to the location you have seeded.
5. Point with the mouse cursor (a pencil) to the location and click. The designated name is displayed.
6. Click on the button corresponding to the next location and use <Ctrl>+Left mouse drag to scroll to the relevant location.
7. Repeat the steps above to locate, identify, and seed the third anatomical location.
8. Click **Redo Segmentation**.



NOTICE

You cannot reverse the Re-segment process with the Undo function.

To redo the segmentation using the interspace automatic CCA algorithm, click Reset All. This will reload the study images.

If a coronary file was loaded with the series, Reset All will not reload the coronary file. You can return to this coronary definition after trying the re-segmentation option by closing and then reopening the application.

Coronary Extraction Stage

After you have completed the Segmentation stage, click in the Workflow menu to access the Coronary Extraction stage. The Coronary Extraction stage allows you to view the heart anatomy - the aorta, the aortic valves, and the arteries - in high detail. Arteries can be reformed into straightened views, and the heart can be viewed in the full volume rendered mode, including rotations, curved planes and cine display.

**WARNING**

Verify the accuracy of the coronary arteries and their labels. If needed, use the manual tools provided in the Coronary Extraction stage to correct coronary artery extractions and labels.

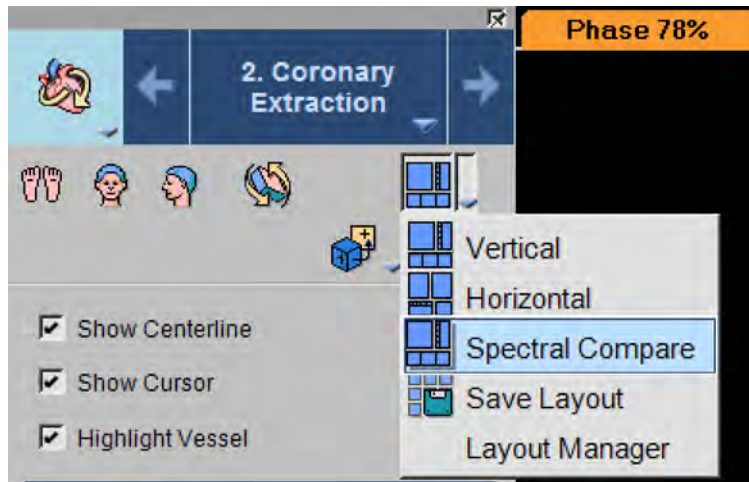
Layouts

The Coronary Extraction stage has a horizontal or vertical layout that consists of:

- a cMPR image (along the selected artery centerline);
- a second cMPR image, orthogonal to the image in A
- the volume image is ideal for locating vessels and selecting them to make them active. The volume image can be rotated freely in all axes;
- straightened MPR image of the selected artery;
- five cross-sectional images of the selected vessel:
 - center image corresponds to red line in straightened image,
 - left two images correspond to two green lines on left,
 - right two images correspond to two green lines on right; and
- axial image.

To enlarge any image for better viewing, double-click in its viewport. (The straightened MPR image is enlarged only inside viewports D and E.) Double-click again to return to original display.

Spectral Compare mode enables viewing two cMPR images from the same phase side by side, comparing two spectral image types. Select the **Spectral Compare** layout provided in the **Coronary Extraction** stage to automatically switch to Spectral Compare mode.



Please refer to the following sections of the IntelliSpace Portal Spectral Applications IFU for information on spectral results and processes:

- Understanding Spectral Results
- Common Spectral Processes

Image Types

In the main viewport, you can choose to view from among all spectral results. Pause the pointer on the name of the data type to see the options; and click to make your selection. In addition, you can adjust the MonoE keV level using the accompanying arrows. These actions adjust the associated viewports accordingly.

Coronary Extraction Procedure

1. Verify the completeness of coronary segmentation.
2. Verify vessel centerlines and their labels.
3. Correct any problems that exist in the segmented coronaries and centerlines.
4. Manually define any unsegmented coronaries.
5. Analyze coronaries.
6. Generate a report. See section “Report Clinical Results” on page 227.

NOTICE

You may perform steps 2 and 3 in any order, depending on the study.

Automatic Vessel Labeling

Coronary Extraction automatically extracts and labels the following coronary arteries:

- LAD
- RCA
- LCx
- PDA

The automatic labels are considered "unconfirmed" and should be confirmed by the user.

Users can also set the vessel label into an automatically confirmed state through the Preference settings. When vessel Label confirmation workflow is disabled through Preference settings, review the automatic vessel labels thoroughly and ensure labeling accuracy manually. Use the **Rename** option displayed on images and vessel list for optimizing the vessel labels.

Coronary Extraction Viewing Tools

Some viewing tools are carried over from the Segmentation stage, including the General Axes Orientation tools (but not the Cardiac Axes orientations), the ECG function, and the Magic Glass tool. See section "Segmentation Viewing Tools" on page 128.

Note the following:

- The Flip tool only affects the volume and cMPR images.
- The Relate function can be used on the axial and volume images, but cannot be used on the sMPR or cMPR images.)

There are two available Layouts, Horizontal and Vertical, described previously.

Show Centerline

When this function is checked, the selected vessel's centerline is shown. When un-checked, the centerline is not shown, and the Edit Centerline function is disabled.

Show Cursor

When this function is checked, the cursor is visible on the curved MPR image, and the volume and axial images.

The yellow X mark on a vessel centerline corresponds to the red X mark in all the other viewports, including the cross-sections and the straightened MPR.

You can move the X mark (red lesion line) by dragging the mouse pointer up and down anywhere in the viewport. Moving the X mark simultaneously updates the images in the other viewports.

Highlight Vessel

When this function is checked, the system displays a highlight on the selected vessel in the axial view.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Coronary Extraction Functions

To switch between functions, hover over the tab title and select from the menu.

Coronary Extraction

This is the default function when the Coronary Extraction stage opens.

Bookmarks

This function allows you to access Bookmarks, if any are saved.

Clip

The Clip function is used to remove unwanted anatomy from the volume images.

Batch

The Batch function allows you to create a series of sequential images (including cross-section images) for viewing, saving, reporting and filming purposes.

For detailed information about creating Time Mode batches, see **Batch Creation - Multi-viewports** time mode in the **Cardiac Viewer** section of the **Review** volume.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Coronary Extraction Tools

The Coronary Extraction tools allow you to:

- Specify a name (label) for an automatically extracted, unnamed vessel.
- Configure (“customize”) the vessels names list on the labeling dialog.
- Extract a new vessel (one that was not automatically extracted).
- Rename a vessel or delete a vessel name.
- Edit a labeled vessel’s centerline.
- Continue a vessel’s centerline (if it was not fully extracted).
- Connect between two centerlines and create a new vessel.
- Create a new vessel by choosing a certain segment from an existing centerline using the Define vessel path tool.

NOTICE

The size and shape of anatomies can change when tweaking a protocol. When you examine the volume image, note that to prevent wrong interpretation, follow the recommended volume rendering protocol modification procedure in the Common Processes chapter of the Review volume.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Label Vessel

You can drag this list to a different location using the bar at the upper part of the dialog.

1. Move the cursor over the volumetric image. As the cursor moves over a segmented vessel the vessel centerline becomes yellow.
2. Click on a centerline to select it. The centerline turns red. (If this is the first centerline selected, the straightened view and curved MPR views are generated.) The Vessel name selection list displays.
3. Select the desired name from the list. (You cannot select the same name twice.)

Or:

Type an appropriate name in the text box at the bottom of the list.

The vessel name appears in the Coronary Extraction list and is also added to the Vessel name selection list.

4. Continue naming vessels.

As you name vessels, the names appear in the list in the Coronary Extraction function tab (at the left of the display). The selected vessel is highlighted in the list.

In the volume viewport, only the selected vessel centerline is displayed (colored red) and named.

In the Axial viewport the selected vessel centerline is identified by an X symbol and is highlighted in color. This vessel is also displayed in the straightened MPR, curved MPR, and cross-sectional images.

Label Vessel Using the Axial Image

You can use the Axial image to select a vessel to label.

1. Hover with the mouse cursor over a coronary vessel on the axial image. If a centerline was detected for the vessel, the mouse cursor turns into a "Select vessel" cursor.
2. Click on the vessel to select it. The vessel is highlighted in color on all the images.
3. Right click and select the **Name vessel** option.
4. The Vessel name selection dialog is displayed.

Work with Vessel Names

You can rename a selected vessel or delete its name using a right mouse click on the vessel's name in the list or on the vessel's centerline on the volume image.

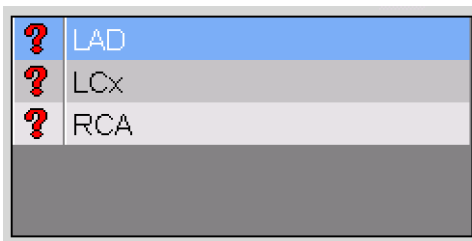
1. Find a vessel to work with by hovering the mouse over it. (Vessels show yellow centerlines.)
2. Click the desired vessel. Its centerline turns red and its name is displayed.
3. Right click on the red centerline. This opens the naming dialog again, allowing you to name or rename the vessel.

NOTICE

To prevent the naming dialog from popping up when clicking on an unnamed centerline, hold the <Ctrl> key when clicking on the centerline. The centerline becomes active but no naming dialog pops up.

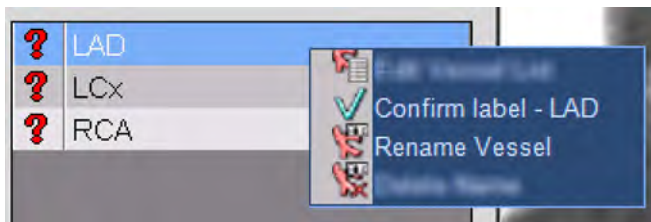
Automatic Labels

Vessels that were automatically labeled are marked with a question mark ("?") in the vessels list.



The label can be confirmed or renamed from the selected vessel's context menu or from the viewports.

To *confirm* a label, use either the **Confirm label** option in the vessel's context menu or click on the **Confirm Label** link, which is located on the viewport next to the vessel.



To *change* a label, use the **Rename Vessel** option in the vessel's context menu or click on the **Rename...** link, which is located on the viewport next to the vessel.

To automatically confirm unconfirmed labels when saving, filming or reporting images of vessels with unconfirmed labels:

1. Open **Preferences**.

2. Select the **Viewing Applications** option.
3. In the **Comprehensive Cardiac Analysis** section, place a check mark in the **Automatically confirm vessels' labels when saving, filming or reporting images** checkbox.

Edit Vessel List

This dialog allows you to create new vessel names in the labeling dialog, to change how many vessel names are shown in the vessel name list, and to change the order that the names in the list are displayed.

Two lists are shown in the Configure vessels list, the Standard Vessels list and the Custom Vessels list.

The Standard Vessels list shows the pre-defined standard coronary vessel names.

NOTICE

The Standard list is the factory list, and is only shown in this box.

The Custom list is the list configured by the user.

At first, these lists are identical (from the factory). Depending on your needs, you can remove vessels from the Custom list by selecting them and clicking the << button.

Add New Vessels

To add a vessel name to the Custom list, scroll to the bottom of the list to the <New Vessel> field and click on it. Type in a name and hit <Enter>.

Arrange Vessel Order

You can move any vessel higher or lower in the list by selecting it and clicking the Up or Down buttons.

Edit Centerline Path

The centerline of each segmented coronary is viewed in the volumetric view and a Curved planar reformed view. The automatically defined path will, in most cases, pass through the center of the lumen, but if not, you may use the Edit Centerline tools to make adjustments to the path.



WARNING

After applying the connect centerlines tool - verify correctness of extracted vessel. Use centerline editing tools to edit , if required.

In the Edit Centerline mode, control points appear along the centerline path on both the Curved planar reformed and the volumetric views. You can change the position of each point by dragging it to the correct position.

NOTICE

You can also adjust the centerline location by moving the cursor displayed on the cross-sectional image. This editing method is especially recommended for fine-tuned editing, as it allows you to make sure the centerline passes through the center of the lumen.

NOTICE

Editing the centerline affects contours in the Coronary Analysis Stage and therefore, the contours should be reviewed after each instance of centerline editing.

Use this procedure to re-define the path of a segmented vessel:

1. Pass the cursor over the desired vessel in the volumetric view. The line turns yellow.
2. Click on the centerline to select it. It turns red.
3. Click the **Edit centerline** tool.



Control points appear along the centerline in the Curved planar reformed and volume views. A cross-section cut also displays the centerline location at the selected control point. You can edit any point by dragging it to the correct location, including the cross-sectional cut.

- To undo the last change made to the centerline click Undo. Each Undo removes the previous change.



- To add a control point, click the desired location on the centerline.
 - To remove a segment from the centerline, drag a control point to overlap another control point farther along the centerline. The looped segment disappears.
4. To close the Edit mode, click the **Edit centerline** tool again.

Flip Centerline



You can access the Flip centerline option from the Edit centerline drop-down. This option flips the curved MPR and straightened MPR images, swapping the proximal and distal ends of the vessel.

Continue Centerline



This function allows you to add vertices beyond the distal and proximal ends of the extracted vessel centerline. You can select which end will be continued from the drop-down.

1. Select the vessel to be continued.
2. Decide which end you want to continue, distal or proximal, and click the appropriate button. The cMPR, volume, and axial images update. An X appears on the cMPR and volume images marking the end you selected. The axial image identifies the segmented vessel with a pink overlay.
3. Locate the continuing vessel using the volume and/or axial images.
To rotate the volume image while remaining in Continue Centerline mode, hold <Ctrl +Shift> and drag or scroll the axial image.
Scroll with the mouse wheel through the axial images.
4. Using the mouse crosshair pointer, click on the axial or the volume images to locate the next point of the centerline. The red centerline extends and the Curved planar reformed image updates to display the extended vessel.
5. Continue extending the centerline by placing more points. To undo the last change made to the centerline click Undo. Each Undo removes the previous change.
6. When the vessel extension is complete, click the Continue Centerline button again to end the procedure, or double-click to end the procedure.

One-click Vessel Extraction



This function automatically segments a new vessel with a single click on the volumetric or axial image.



WARNING

After applying the one-click centerline extraction tool, verify correctness of extracted vessel. Use centerline editing tools to edit , if required.

1. Click **Auto Track Vessel**.

2. Using the axial or volume images, click on the location of the vessel that you wish to define.
3. The system calculates and displays a new centerline and displays the Vessel Name Selection list. If the system is unable to define a vessel, a centerline does not appear and the message “Vessel not found” is shown.
4. Name the vessel using the procedure described earlier.
5. Edit the centerline if necessary.

Manual Centerline Extraction (Multi-click)



This function allows you to define a new vessel centerline by marking control points along the path. You may perform this procedure on the volume or axial image.

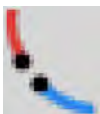
1. Click the **Manual Centerline Extraction (Multi-click)** button. The crosshair mouse pointer appears as you point to the image.
2. Click on the vessel where you want to start a new path.
3. Continue adding path points. Add enough points to follow the vessel’s curvature. You can add new points on both the axial and volumetric images. The points should be located in a consecutive manner.

The Curved planar reformed image of the defined path appears as you add points. As the path gets longer the Curved planar reformed image zooms out to include the entire defined path.

To rotate the volume image while remaining in Centerline Extraction mode, hold <Ctrl +Shift> and drag or scroll the axial image.

4. To end the path, click the **Manual Centerline Extraction (Multi-click)** button again, or double-click to end the procedure.
5. The Vessel Name Selection list appears.
6. Name the vessel using the procedure described earlier.
7. Edit the centerline if necessary.

Connect Broken Segment



The Connect Broken Segments function allows you to join two disjointed segments.



WARNING

After applying the connect broken segments tool, verify correctness of extracted vessel. Use the centerline editing tools to edit, if required.

With this function you can:

- create a new path;
 - continue a current path; and
 - or join disconnected segments by adding points on either the volumetric image or the axial image.
1. Click the **Connect Broken Segments** button. A network of yellow lines appears on the volumetric image showing all potential coronary segments that were identified during the auto segmentation process.
A red X marks the location of a new point on both the axial and volumetric images.
 2. To continue adding path points, click along the vessel path. The Curved planar reformed image of the defined path appears as you add points. As the path gets longer the Curved planar reformed image zooms out to include the entire defined path.
 3. To connect broken segments, rotate the 3D image.
 - Click at the end of the proximal segment.
 - Continue adding points until you can mark the start of the distal segment.
In the axial image use the mouse wheel to scroll. Points are added to the path’s end—be sure to track the vessel path forward. (This is best determined using the volumetric image.)
 4. To end the path, click the **Connect Broken Segments** button. The Vessel Name Selection list appears.
 5. Name the vessel using the procedure described earlier. See section “Label Vessel” on page 140.
 6. Edit the centerline if necessary.

Extract Vessel Segment



The Extract Vessel Segment function allows you to create a new vessel from a section of an existing centerline.



WARNING

After applying the extract vessel segment tool - verify correctness of extracted vessel. Use centerline editing tools to edit , if required.

NOTICE

This tool works only on continuous centerlines. Make sure there is a path defined between the start and end point you place. If there is a “hole” this function tool will not work.

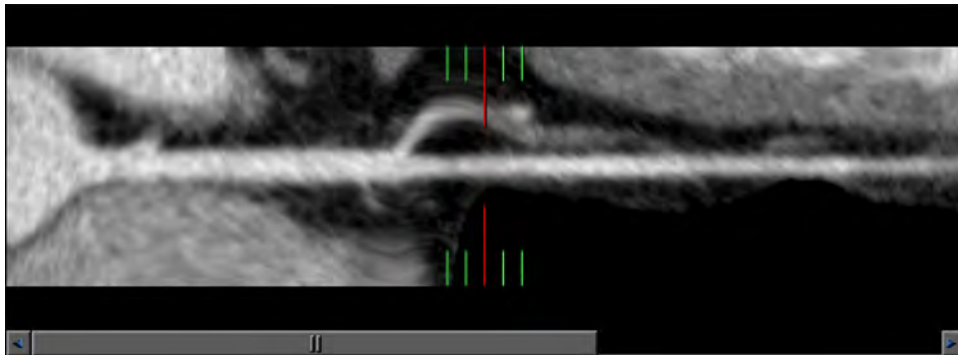
1. Click on the **Extract Vessel Segment** button. All existing centerlines become visible and colored yellow.
2. Click once at the start of the path to be redefined and click again at the end of the path. (Anatomically, the path direction is from the apex to the base of the heart.)
3. If the centerlines can be joined, a unified red centerline appears. The Curved planar reformed views of the centerline also appear.
4. Name the vessel. You must name the vessel in order to save the new vessel.

Use Mouse Functions

- Curved planar reformat image: <Shift>+Left mouse drag to adjust thickness; left mouse drag scrolls cross-sectional and axial images and moves the lines on the straightened images; and the cursor (X) moves.
- Straightened image: left mouse drag up and down rotates vessel on its axis.
- Axial and cross-sectional image: mouse wheel scrolls through images.
- Straightened, cross-sectional, curved MPR, and axial images: press and drag mouse wheel up and down to adjust window/center; press and drag mouse wheel left and right to adjust window/level.

View Straightened Coronary Vessels

Use the horizontal slide bar to view all of the straightened vessel.



Use IVUS View

The Virtual IVUS (Interventional Vascular UltraSound) is a volumetric image of the vessel lumen, wall, and plaque. Use this procedure to display the IVUS image in the middle cross section.

- Right click in any cross section image or the straightened MPR image.
- Select **Show IVUS** from the context menu.

**WARNING**

The IVUS display is based on a fixed HU color mapping protocol and may require adjustments per case.

The virtual IVUS image is color coded as follows:

- blood appears black;
- normal artery wall is yellow; and
- calcium is white.

You can change the protocol of the IVUS with the middle mouse wheel.

**CAUTION**

The IVUS view should not be used as the **SOLE** basis for clinical diagnosis.

Volume Viewing Modes

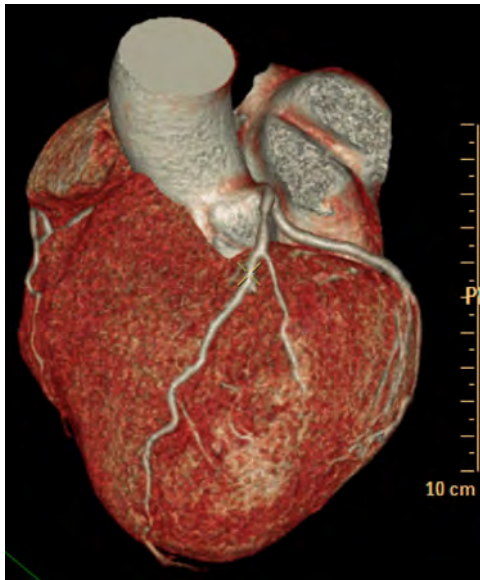
A viewport control in the volume viewport allows you to select specific cardiac viewing modes.

NOTICE

2D map, Globe - 3D map, and Globe - sphere are grayed out until at least three arteries are labeled.

Heart 1 Volume View

This heart view shows a volumetric view of the heart.



Heart 2 Volume View

You can also get a MIP view of the whole heart.



Coronary Tree Volume View

This view shows all arteries connected to the aorta. It may be viewed in volume rendered or MIP mode.

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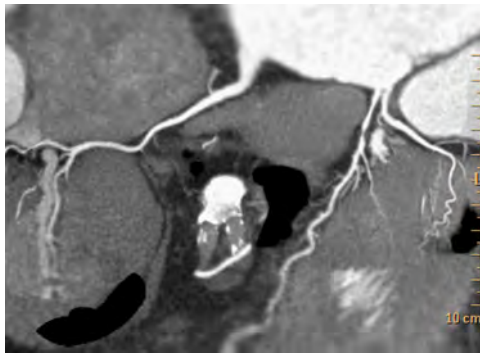
Outline Volume View

This view shows the heart with blood in the cavities removed. Only viewable as MIP.



2D Map Volume View

This view shows the heart with blood in the cavities removed. Only viewable as MIP.



Globe 3D Map Volume View

This view shows the heart with blood in the cavities removed. Only viewable as MIP.



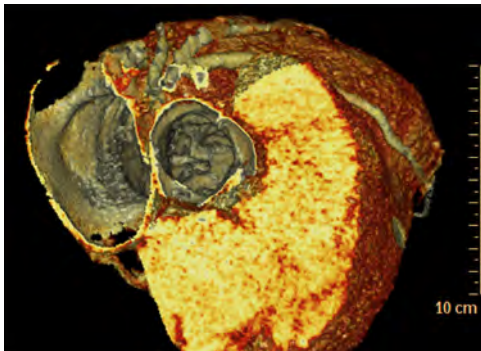
Globe Sphere Volume View

This view shows a 3D map mapped onto a sphere. It is only viewable as MIP.



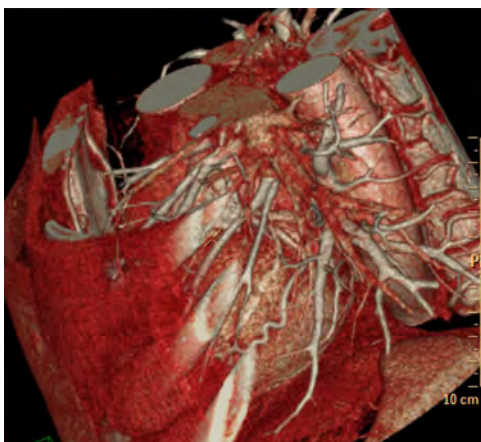
Aortic Volume View

This view of the aortic valve is adaptive to different phases.



All Volume View

This view shows all data included from the scan, and can be visualized in volume rendering or MIP mode.



Bypass Volume View

This view shows additional structures around the heart. It helps create centerlines of bypasses in case they were not detected automatically.



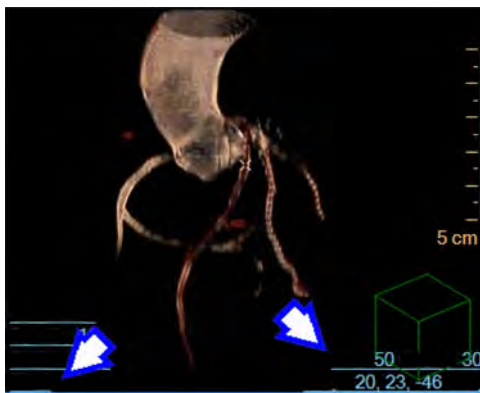
TAVI Volume View

Use the viewing mode to optimize the view angle for the TAVI procedure in Cath Lab. The control sets the image angles at LAO 50, Cranial 30 (an angle which presents a plane almost perpendicular to the annulus plane).

NOTICE

This plane is not detected automatically. Adjust as necessary to find the perpendicular to the annulus plane.

The TAVI mode includes the Aorta and coronaries in a semi-transparent view.



Coronary Analysis Stage

NOTICE

If your system is equipped with the available Plaque Analysis option, you may use Preferences to make Plaque Analysis the default application for the Coronary Analysis stage. Refer to the Preferences chapter in the "Instructions for Use" volume.

The Coronary Analysis provides viewing and measuring tools that allow you to perform dimensional and quantitative measurements of the coronary arteries to help you identify and examine the patient study for stenoses.

The opening window presents images and measurements processed and calculated from a single artery: the active artery in the Coronary Extraction stage prior to the activation of the Coronary Analysis stage.

Image Types

Work in the Coronary Analysis stage can be performed on Conventional or MonoE images, however, you cannot switch image types. When using MonoE images, the energy level cannot be adjusted.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

The layout consists of the following:

- A cMPR image (along the selected artery centerline). Lumen lines can also be displayed.
- A second cMPR image, orthogonal to the curved image.
- Volume rendered image of the heart.
- Straightened MPR image of artery. (Plots of arterial data are optionally available.)
- Cross section images of artery (3 sections).
- Table of measurements.

Please refer to the following sections of the IntelliSpace Portal Spectral Applications IFU for information on spectral results and processes:

- Understanding Spectral Results
- Common Spectral Processes

Before You Begin

1. Review the automatic Segmentation of the coronary arteries to verify correctness.
2. Accuracy of measurement in Coronary Analysis depends on accurate centerline extraction. Examine the centerlines in the Coronary Extraction stage and correct them if needed.
3. Coronary Analysis is only available for the vessels that were identified in the Coronary Extraction stage.
4. You can only access Coronary Analysis if a named vessel is active in Coronary Extraction.
5. The active vessel from the Coronary Extraction stage will be the active vessel in Coronary Analysis.

What You Can Measure

- Diameter and area of stenosis and reference locations.
- Length of stenosis.
- Percent of stenosis.
- Cross-sectional vessel eccentricity.
- Plot of the area, diameter, effective diameter and minimum diameter along the vessel.

Coronary Analysis Images

- Volume rendered image
- Curved MPR image (cMPR)
- Straightened MPR image
- Cross section images of vessel

Coronary Analysis Viewing Tools

The General Axes Orientation tools, the Flip tool, the Relate function, the Magic Glass tool, and the ECG function are carried over from the Segmentation and the Coronary Extraction stages. See section “Segmentation Viewing Tools” on page 128.

There are two available Layouts, Horizontal and Vertical. See section “Segmentation Opening Window” on page 127.

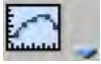
The Show Centerline and Show Cursor functions are the same as in the Coronary Extraction stage. See section “Coronary Extraction Viewing Tools” on page 138.

Stenosis Table

When active, the Measurements table replaces an axial image in the lower right viewport.



Graph



When active, a graph is displayed showing different parameters along the straightened vessel. Available graphs are:

Lumen Area	Lumen Minimum Diameter
Lumen Diameter	Lumen Effective Diameter

Show Lumen Lines



This function shows / hides lumen lines in the cross-section and cMPR viewports.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Coronary Analysis Tab

This is the default function tab when you open Coronary Analysis.

The Choose Vessel list is carried over from the Coronary Extraction stage. See section “Coronary Extraction Stage” on page 136.

Choose Method

You can choose between the Contours and Calipers measuring modes from the drop down box.

Choose Reference Lines

(This function is only available in the Contours Measuring Method.) The check boxes activate and deactivate the Proximal and Distal Reference Lines in the cross-section and sMPR viewports.

- If both boxes are checked, the Measurements table displays the Reference Distance value as the distance between the Proximal and Distal locations.

In this case, the reference values in the table are calculated from an weighted average of the two reference locations.

- If only one reference line is checked (at least one must be checked) the table displays the distance of each of the lines (reference and lesion) from the aortic root and the distance between them.

In this case the reference values in the table are calculated based on one reference location.

Edit/Draw Contours

(These functions are only available in the Contours Measuring Method.) Activating one or the other of these tools allows you to edit or create new lumen contours in the cross-section and sMPR viewports.

Measure Line



(This function is available in the cMPR and sMPR viewports.) Click this button to activate the function. You can draw a line by dragging it along the centerline. Release the mouse button, and the length is displayed as an annotation. On the cMPR image, the cross-section diameters at each end are also displayed.

Undo/Redo



To undo your last contour correction(s), click **Undo**. Each Undo click reverses the previous change. (The Redo function - accessed from the drop-down - becomes active after you make a correction. You can Redo (reverse) your last Undo function.)

Contours Method

The Coronary Analysis stage automatically contours the coronary arteries that were segmented and named in the Coronary Extraction stage of the CCA application. These contours overlay the active artery in both curved and straightened MPR views. First you have to verify the correctness of the automatic contours and edit if needed. Then, after you visually identify a stenosis, you will place stenosis and reference line markers on key vessel locations to define the extent of the stenosis.

Calipers Method

This is the manual method of marking the stenotic area of an artery. Three pairs of caliper-like parallel lines are shown on images of the straightened MPR and cross-sectional arterial images. With the mouse, you position the calipers on key vessel locations and, with the mouse wheel, adjust the calipers to gauge the extent of the stenosis.

Functions

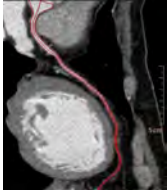
- **Coronary Analysis.** This is the default function when the Coronary Analysis stage opens, and is described on these pages.
- **Plaque Analysis (an available option).** Evaluate the condition of coronary arteries, including plaque characterization and volumes. The application is described later in this chapter.
- **Bookmarks.** This function allows you to access Bookmarks, if any are saved.
- **Batch.** The Batch function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.
- **Clip.** The Clip function is used to remove unwanted anatomy from the volume images.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Coronary Analysis Viewports

A number of different viewports are available to the Coronary Analysis Stage, as outlined below.

cMPR Image

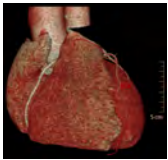


The Curved MPR image shows the selected artery with centerline. In the Contours mode, lumen lines are also displayed by default. (They can be turned off from the viewing tools.) In the Calipers mode, only the centerline is shown. The yellow X mark on the centerline corresponds to the red X mark in all the other viewports, including the cross-sections and the straightened MPR. You can move the X mark (red lesion line) by dragging the mouse pointer up and down anywhere in the viewport.

Moving the X mark simultaneously updates the images in the other viewports.



Volume Rendering Image



The volume image in the upper right viewport is ideal for locating vessels and selecting them to make them active. The volume image can be rotated freely in all axes.



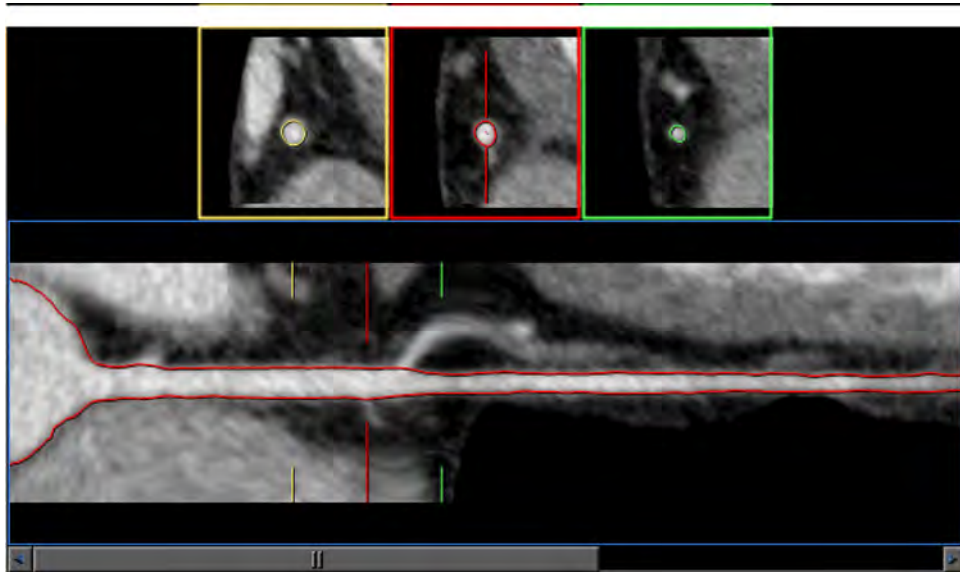
Straightened MPR Image with Cross-sections



The sMPR image shows the selected vessel as a linear vessel along its centerline. (A slide bar allows viewing longer images.) The sMPR image can be rotated around its centerline to help visualize the artery.

Directly above the sMPR image are cross-sectional images of the selected vessel. These images correspond to locations marked in the sMPR image. The viewport displays depend on which measurement Method is in effect:

Contours Measurement Method



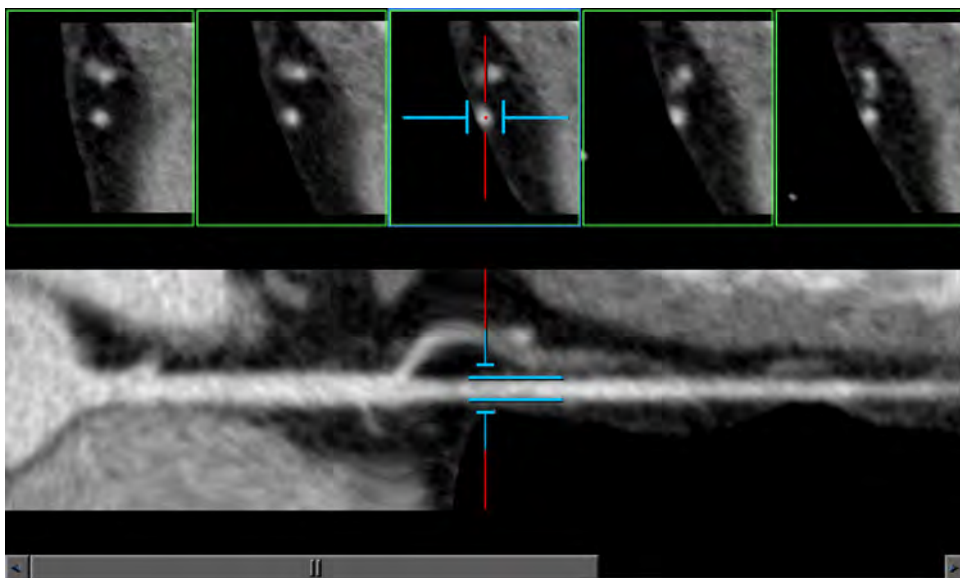
In the Contours mode, movable colored reference lines are provided in the sMPR image:

- the Red line is used to mark the stenosis location;
- the Yellow line is used to mark the proximal reference location; and
- the Green line is used to mark the distal reference location.

As you move the reference lines, the cross-section images are updated.

Calipers Measurement Method

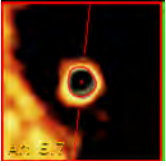
In this mode, caliper tools are provided in the sMPR image and in one cross-section image. Calipers are movable and adjustable, and are used to produce measurements by gauging the diameter of the artery at any location



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IVUS View



The Virtual IVUS (Interventional Vascular UltraSound) is a volumetric image of the vessel lumen, wall, and plaque. Use this procedure to display the IVUS image in the middle cross section. To access the view: Right click in any cross section image or the straightened MPR image. Then select **Show IVUS** from the context menu.

The virtual IVUS image is color coded as follows:

- blood appears black;
- normal artery wall is yellow; and
- calcium is white.

You can change the protocol of the IVUS with the middle mouse wheel.



WARNING

The IVUS display is based on a fixed HU color mapping protocol and may require adjustments per case.



WARNING

The IVUS view should not be used as the **SOLE** basis for clinical diagnosis.

Graph



In the Contours mode only, you can view a continuous graph of the artery's diameter and area at each point along the centerline. This is helpful when you wish to closely determine the extent of a stenosis. Move the mouse cursor to left and right to view the value of the graph.

The following graphs can be displayed (select from the graph button drop-down in the tool panel or from a right mouse menu in straightened MPR image):

- lumen area;
- lumen diameter;
- lumen effective diameter; and
- lumen minimum diameter.

Measurements Table

The Table of Measurements is displayed by default when you open the Coronary Analysis stage. (You may choose to display an axial image of the heart in this viewport, as described later.)

NOTICE

The Position is measured from the beginning of the vessel centerline.

As you move reference lines in the Contours mode or adjust calipers in Calipers mode, the table continuously displays the calculations of diameter, area and percent stenosis.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

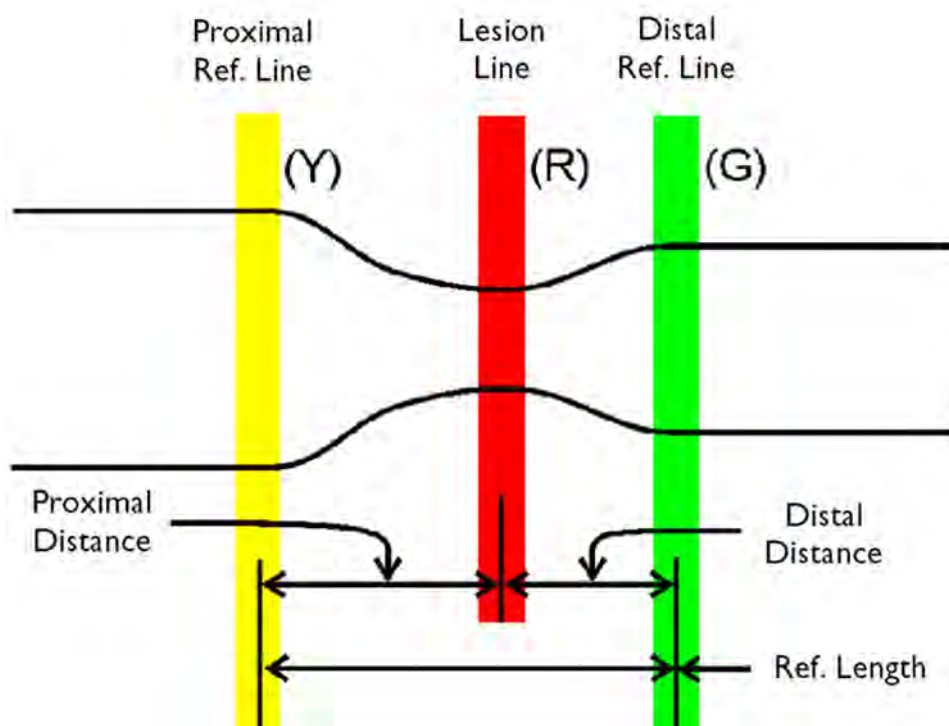
Use Contours Measurement Method

After you have examined the study for stenosis using the various image viewports and tools, and have found a stenosis you wish to measure, you may choose the Contours Method to acquire measurements.

The Contours Method of dimensioning the stenosis employs the positioning of three reference lines in specific locations on the sMPR viewport.

When you are finished, the calculations are made automatically and the Measurements table is updated automatically.

Below is a diagram of the parameters that define the stenosis.



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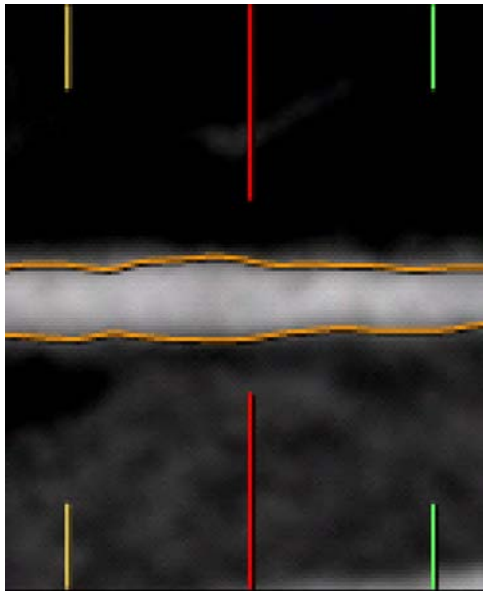
See section “Step 1: Set Reference Lines” on page 162.

Step 1: Set Reference Lines

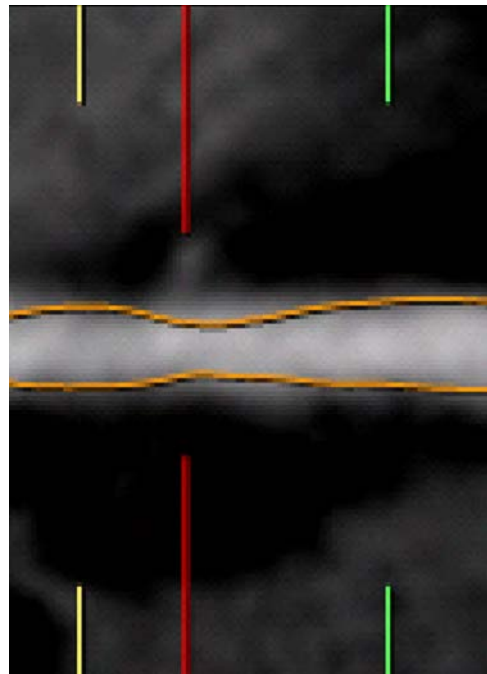
After the vessel’s lumen contours are verified and corrected if necessary, you will position the stenosis Reference lines:

- the Red line is used to mark the stenosis location;
- the Yellow line is used to mark the proximal reference location; and
- the Green line is used to mark the distal reference location.

In this sMPR image, the red, yellow and green reference lines are shown on an example vessel at their default positions.



In this sMPR image, the red, yellow and green reference lines are positioned to define the extent of the stenosis.



1. Be sure to rotate the straightened MPR view to assure that you have correctly identified the area of stenosis.
2. Click and drag the left mouse button upwards and/or downwards in the straightened MPR view to rotate the artery. (Be aware that the vessel segment just before an artery branch can look like a stenosis.)



3. Drag the red lesion line to the location where the vessel is most stenotic.
When you move the red lesion line, both the yellow and green reference lines move also.
4. Drag the yellow reference line to the proximal location closest to the lesion where the artery is of normal size.

When you move the yellow and the green reference lines, they move independently of each other.

5. Drag the green reference line to the distal location closest to the lesion where the artery is of normal size.
6. Notice that the data in the Measurements table will update each time you change the position of the lesion line and the two reference lines.
7. See section “Step 2: Edit Lumen Contours on sMPR Image” on page 163.

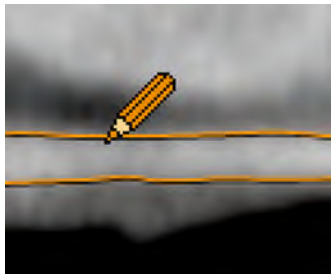
Step 2: Edit Lumen Contours on sMPR Image



WARNING

Verify the automatic extraction of the lumen contours. If necessary, correct the contours using the tools provided in this application.

Lumen Editing Cursor

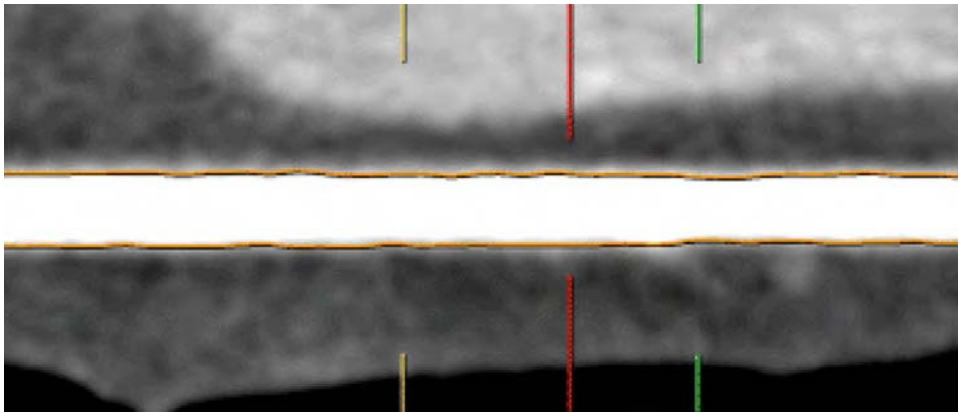


When the **Edit Contour** mode is activated, hovering over the lumen contour changes the cursor to an orange pencil.

1. Examine the lumen contours in the sMPR image.
2. If changes are needed, click the **Edit** button.



3. On the sMPR image, place the drawing tool in the appropriate position. Hold down the left mouse button and drag along the lumen position to be corrected. Use <middle+left> mouse buttons to zoom the sMPR image while editing.



4. When finished, click the **Edit** button to exit the Edit mode.
5. See section “Step 3: Edit Lumen Contours on Cross-section Images” on page 164.

Step 3: Edit Lumen Contours on Cross-section Images

Once you have the Reference Lines positioned correctly, you should edit the vessel contours in the cross-section images.



WARNING

Verify the automatic extraction of the lumen contours and, if needed, correct them using the tools provided in this application.

To help visualize the vessel for editing and achieve more precise stenosis data, zoom the cross-section images, or enlarge them by double-clicking on them. (Double-click again to return to normal size.) Zooming is also possible using <left+middle> mouse buttons.

1. Examine the lumen contours in the cross-section images.
2. Click the **Edit** button.



3. The cross-section image shows the lumen contours and drawing control points, as shown below.



4. Drag the control boxes of the lumen lines as needed to accurately position the contours on the lumen walls.
5. Perform the contour editing procedure for all 3 cross-sections.
6. When finished, click the **Edit** button to exit the Edit mode.

Alternate Method: Draw New Lumen Contour



If desired, you may draw a new lumen contour instead of editing the existing one.

1. Click the **Draw** button.
2. Point into the cross-section image and click where you want to begin the contour. The existing contour disappears and a new one begins.
3. Keep clicking around the lumen wall until the new contour is complete.
4. To quit drawing, double click, or click the **Draw** button again. You can use the Edit function to make corrections, if needed.

Observer Results in Measurements Table

When finished with the Contours Method of measurements, you can assess the results on the Measurements table.

Measurement Definitions	
Area	The area of the cross-section within the lumen contours.
Current Diameter	The diameter of the current sMPR view at the lesion location.
Effective Diameter	$2 * \sqrt{\text{Area} / \pi}$.
Minimum Diameter	The % Stenosis of the minimum diameter, calculated in relation to the reference effective diameter at the lesion location.

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Measurement Definitions

Eccentricity	$(\text{Max. diameter} - \text{Min. diameter}) / \text{Max. diameter}$.
Reference Distance	The distance between the proximal and distal reference lines (if both reference lines are displayed).
Position	The distance along the centerline from the beginning of the centerline to the lesion and the reference lines. (The position of the reference is shown if only one of the reference lines is displayed.)

The above definitions are relevant for Effective Diameter, Minimum Diameter and Maximal Diameter calculations for the reference location.

NOTICE

The Position is measured from the beginning of the vessel centerline. (This point does not necessarily correspond to the real ostia of the vessel.)

Save Measurements

You can save the table in different formats using the Save image(s) as... tool from the Common Tools and choosing the desired format from the Format dialog. Available formats:

- Secondary capture DICOM image;
- JPEG;
- BMP; and
- TIFF.

When saving the table in a non DICOM format, the file is saved under "Files" tab of the Directory. From there you can right click on the file and export to any location in your PC.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Create Profile Graph

The Line tool in Common Tools allows you to generate a Hounsfield unit profile graph across an artery diameter.

Difference Calculations

Reference Diameter Calculation (Contours Mode)

If only one of the reference lines (proximal or distal) is active, the reference diameter is the diameter at the location of the reference line. If both the proximal and distal reference lines are active, the reference diameter is the weighted average of the two diameters, as shown below.

$$\frac{\left(\frac{D_{\text{prox}}}{d1}\right) + \left(\frac{D_{\text{dist}}}{d2}\right)}{\left(\frac{1}{d1} + \frac{1}{d2}\right)} = \frac{(D_{\text{dist}} \times d1) + (D_{\text{prox}} \times d2)}{(d1 + d2)}$$

D_{dist}	diameter, distal reference
D_{prox}	diameter, proximal reference
d1	distance between location of stenosis and location of proximal reference
d2	distance between location of stenosis and location of distal reference

The above explanation is relevant for Effective Diameter and Maximum Diameter calculations for the reference location.

Reference Area Calculation (Contours Mode)

If only one of the reference lines (proximal or distal) is active, the reference area is the area at the location of the reference line. If both the proximal and distal reference lines are active, the reference area is the weighted average of the two areas, as shown below.

$$\frac{\left(\frac{A_{\text{prox}}}{d1}\right) + \left(\frac{A_{\text{dist}}}{d2}\right)}{\left(\frac{1}{d1} + \frac{1}{d2}\right)} = \frac{(A_{\text{dist}} \times d1) + (A_{\text{prox}} \times d2)}{(d1 + d2)}$$

A_{dist}	area, distal reference
A_{prox}	area, proximal reference
d1	distance between location of lesion and location of proximal reference
d2	distance between location of lesion and location of distal reference

% Difference Calculation

If the value is negative, the result is shown as: %Difference = 100-(the equation):

$$\frac{D_{\text{ref}} - D_{\text{diff}}}{D_{\text{ref}}} \times 100 = \% \text{ Difference}$$

D_{ref}	Reference diameter or area
D_{diff}	Lesion diameter or area

The above equation is relevant for the difference calculation in Effective Diameter, Current Diameter and Area.

% Difference in Minimum Diameter Calculation

If the value is negative, the result is shown as: %Difference = 100-(the equation):

$\frac{\text{Effective Diameter}_{\text{ref}} - \text{Minimum Diameter}_{\text{lesion}}}{\text{Effective Diameter}_{\text{ref}}}$	Effective Diameter _{ref}	Effective diameter calculated at the Reference location (see Reference Diameter Calculation above)
	Minimum Diameter _{lesion}	Minimum diameter calculated at the Lesion location

Difference in Position

The Difference in Position is only calculated when only reference location (distal or proximal) is displayed.

abs(Position _{reference} -Position _{lesion})	Position _{reference}	Distance of the reference location from the beginning of the center line, along the center line.
	Position _{lesion}	Distance of the lesion location from the beginning of the center line, along the center line.

Reference Distance

The Reference Distance is only calculated if both distal and proximal references are shown.

abs(Position _{distal reference} – Position _{proximal reference})	Position _{reference}	Distance of the reference location from the beginning of the center line, along the center line.
	Position _{lesion}	Distance of the lesion location from the beginning of the center line, along the center line.

Use Calipers Measurement Method

The Caliper method of stenosis measurement provides caliper-like tools for measuring the following arterial diameters:

- the Reference diameter of the blood vessel;
- the Stenosis diameter; and
- the Cross section diameter of the stenosis.

From these three measurements, the system will perform the same calculations as the Contours mode and display them in a table of Measurements, including the following:

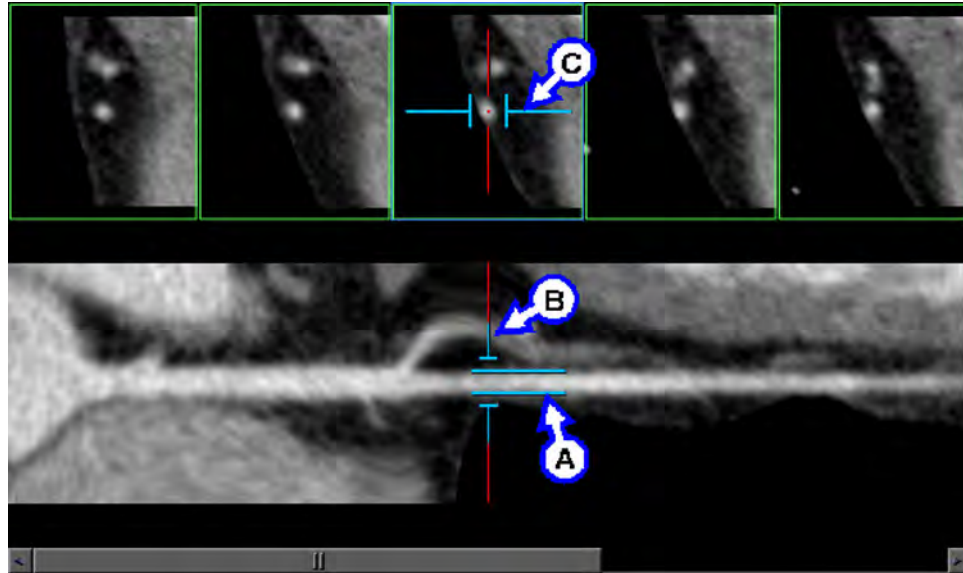
- the percent stenosis, which is derived from the Reference and Stenosis diameter measurements; and
- an estimation of the percent stenosis, which is a refined value of the stenosis, derived from the cross section dimension. (The percent stenosis is important when measuring an eccentric stenosis.)

See also section “Use Contours Measurement Method” on page 161.

Use Calipers Function

Begin this procedure after you have examined the study and identified a stenosis of interest.

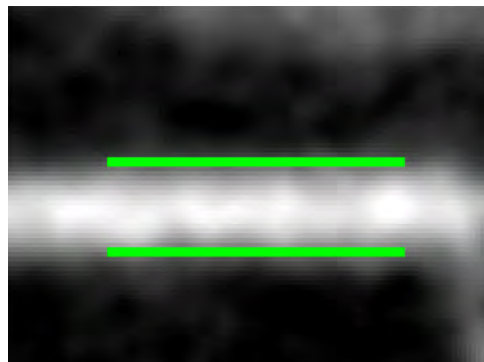
1. In the Coronary Analysis function tab, select Calipers from the drop down menu. The straightened MPR display becomes configured as shown below. The three caliper tools are positioned in their starting, default locations.



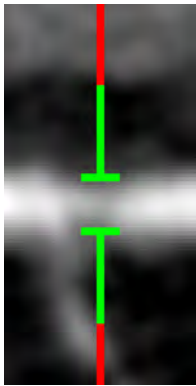
2. Point to the Reference caliper (A in the diagram). The caliper turns green to show it is selected.
3. Drag the Reference caliper to a part of the artery that has a “normal” external diameter.



4. Using the mouse wheel, adjust the spacing of the Reference caliper so that the two caliper lines fit the greatest diameter of the artery, as shown at left.



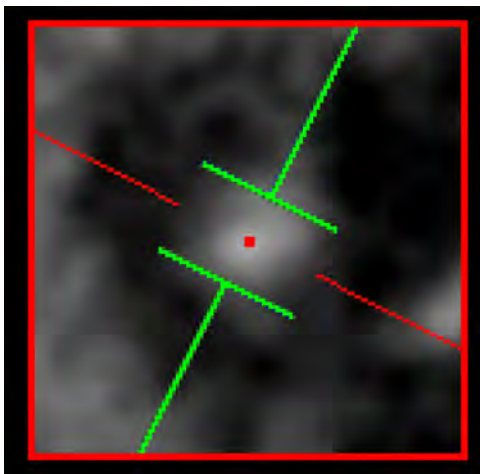
5. Next, point to the Stenosis caliper (B on the diagram). The caliper turns green to show it is selected.
6. Drag the Stenosis caliper to the region of stenosis, as shown below.



7. Using the mouse wheel, adjust the spacing of the Stenosis caliper so that the two caliper lines fit the smallest diameter of the stenosis.
8. To help visualize the vessel in the cross-section image, zoom the cross-section images by double-clicking on them. (Double-click again later to return to normal size.)
9. Point to the Cross section caliper on the middle cross sectional image (C on the diagram). The caliper turns green to show it is activated.
10. If needed, you can rotate the Cross section calipers around the vessel centerline. Do this by pointing at the centerline of the vessel (the red point in the image) and dragging the mouse up and/or down.



11. Drag the green Cross section calipers so that you can accurately measure the stenosis cross section.



12. Using the mouse wheel, adjust the Cross section caliper so that the two caliper lines fit the diameter of the stenosis.

The measurements of the stenosis as derived from the Caliper method of measurement appear on the Measurements table.

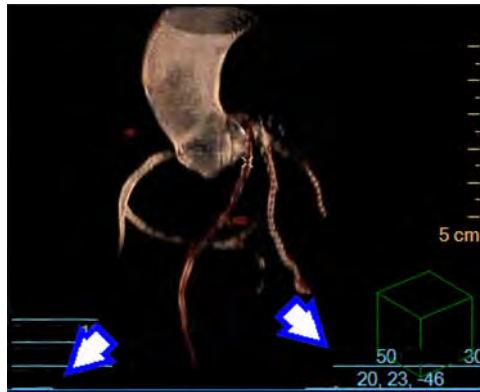
TAVI Volume View

Use the viewing mode to optimize the view angle for the TAVI procedure in Cath Lab. The control sets the image angles at LAO 50, Cranial 30 (an angle which presents a plane almost perpendicular to the annulus plane).

NOTICE

This plane is not detected automatically. Adjust as necessary to find the perpendicular to the annulus plane.

The TAVI mode includes the Aorta and coronaries in a semi-transparent view.



True View Cath-lab Planning Tools

CathLab planning tools assist with PCI planning. CCA provides a 3D model of the coronary artery tree, thus providing a quick quantitative assessment of coronary lesions. Practical, direct quantification and determination of the C-arm orientation can be derived through PCI Planning. This feature is compatible with the applications used by the Philips Cardiovascular.



WARNING

The output of True View can be used only for Cathlab with the following Philips products:

- C-arm model FD 10 & FD 10/10 PBL 51;
- C-arm model FD 20 & FD20/10 & FD 20/20 PBL 6; and
- ExtraVision system version 7 and above.



WARNING

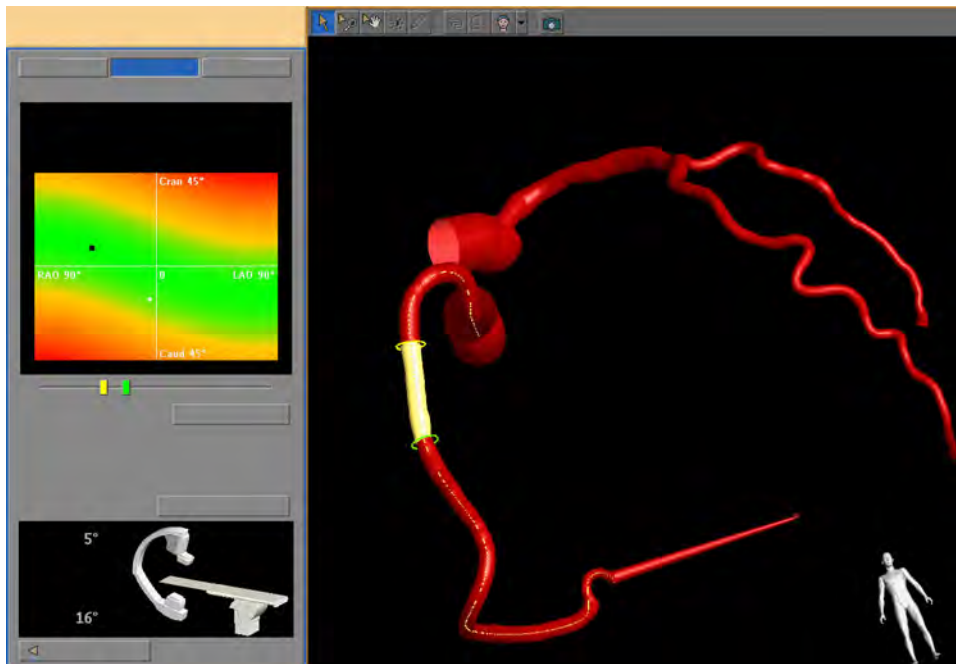
This application displays angles and calculations based on Philips Accelera angiography systems. Most flat panel systems are also compatible. If other angiography systems are used results may not be compatible.

You can use this application to complete these tasks:

- Provide quantitative information of the stenotic region.
- Calculate an interactive color-coded map (called the optimal view map), which provides the optimal working position of the C-arm for intervention with minimal foreshortening.
- Store lesion states and associated Coronary Analysis and selected optimal view C-arm coordinate for each state.
- Allow these lesion states and data to be exported for use in the interventional suite.



To access the CathLab Planning tools, from the Coronary Analysis window under the True View tab, click the **Run True View** button. The application opens in True View mode using the current view angles from the most recent Coronary Analysis view.



In the tool panel, there are three viewing options: True Length (default); True View; and Views. To activate the CathLab tools, you must first wait for all the lumen lines to be calculated for all the named vessels. To calculate the lines, select each one of the extracted vessels and wait until the red lumen lines appear on the straightened MPR. A model of the C-arm is visible at the bottom of the tab area.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View Common Tools

The Common tools available across the top of the CathLab planning window allow you to swivel, zoom, pan, set orientation and take snapshots. The Settings button, located in the tool panel, allows you to alter the parameters displayed on the screen.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View Snapshot



Use the snapshot feature to export the main viewport (including the coronaries model, the optimal view map and the graphs) from the CathLab Planning tool back to the CCA. The export of the includes the rotation/angulation coordinates and the reference lines location. Upon returning to CCA, a message displays indicating the number of snapshots stored.

Use the Snapshot tools in the CCA window to save snapshots:

- **Save as** saves snapshots in DICOM format.
- **Film** sends snapshots to the filming application.
- **Send to report** sends snapshots to report.
- **Export 3D model** exports a 3D coronary model to Xtravision workstation.
- **Delete** snapshots by clicking the Delete snapshots button.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

Exporting the Heart 3D Model to Xtravision

It is possible to export the 3D segmentation of the heart and display it within the Xtravision workstation. The required steps are:

1. Ensure the Xtravision workstation is one of the remote devices available in the **Patient Directory**.
2. After the heart and coronaries segmentation is completed and verified, select the **Save results as...** option in the drop down of the **Save images as...** option.
3. Save the results file to the Xtravision workstation.

4. Copy the original CT data to the Xtravision workstation.
5. Use original CT data and the results series into the Xtravision workstation to view the heart 3D model.

NOTICE

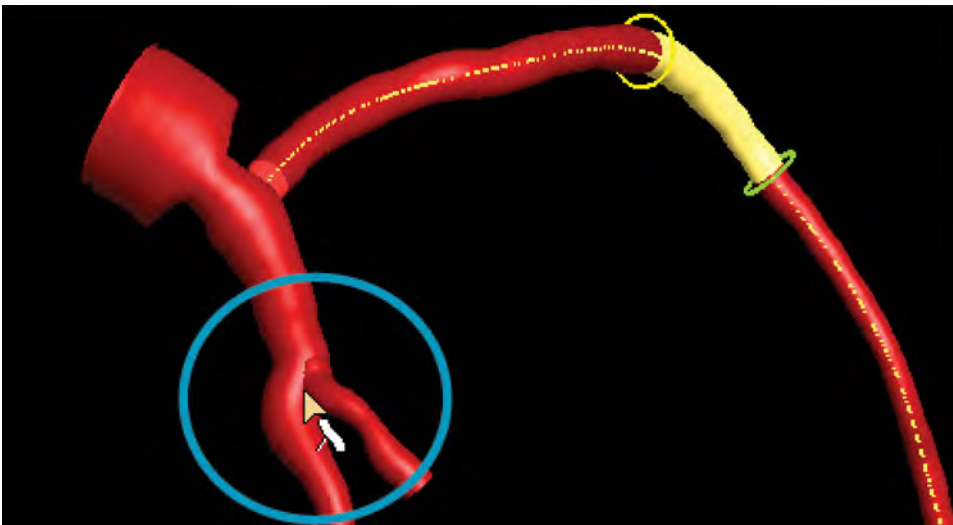
To use this feature, IT personnel must ensure the LAN Config is setup correctly.

NOTICE

Exporting the results file cannot be done via copying to DVD/CD/USB.

True View Bifurcation

When you move the cursor over a bifurcation, a bifurcation icon displays. If a bifurcation has a fixed length, click once to highlight the entire bifurcation region.



True Length, TrueView and Views are active only if one segment is defined. Once a bifurcation is defined, True Length is disabled.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View Option

The True View option includes a color-coded map providing the amount of foreshortening within the pre-defined range of rotation and angulation values of the C-arm. The current orientation is displayed numerically and visualized as a cursor in the color map:

- Green area is an ideal planning location.
- Yellow area is a possible location.
- Red is not useful for PCI planning procedures.

The map and the 3D tree are related. A change to the map or the 3D view results in a corresponding change in the other view:

- Drag the cursor in the color-coded map to the ideal location (black rectangle). The system automatically changes the orientation of the 3D- tree and the C-arm, displaying the numerical rotation/angulation values by the C-arm.
- The foreshortening for the current orientation and the minimum foreshortening are displayed as numerical values. To locate the orientation of the region of interest that is least foreshortened, drag the cursor to the optimal point.
- Use the slider bar to re-position the start and end rings to define the sub-segment of interest.

Click **Swap** to change the positions of the map and 3D viewports.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View Regression Line

A straight brown line between the first and the last value on the effective diameter graph of the active segment. The stenosis diameter is the minimum value on the minimum diameter graph between the two vertical reference lines (yellow and green). The reference diameter is the value on the regression line at the stenosis location.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View TrueLength

Click the **TrueLength** icon to access the window. TrueLength contains two plot areas:

- The upper plot area contains the complete length of the active artery. It plots the effective and the minimum diameters along the centerline. The vertical dotted lines represent the position of the probes in the 3D view of the tree. You can adjust the position of the probes by moving the knobs on the slider bar. The vertical lines move and, the distance between the lines (expressed in mm) is automatically updated.
- The lower plot area shows the view of the graph corresponding to the sub-segment of interest.

Click **Swap** to change the positions of the map and 3D viewports.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

True View Stored Views

The view window provides a graphical representation of views stored.

The **Store** button, when pressed, stores the current view from the main view port and adds it to the list.

The **Recall** button has the same effect as double-clicking on a view in the list.

The **Delete** button removes the highlighted view. The other views remain in their respective positions.

Store Images

To highlight a view, click on it one time. Double-click the view to display it in the main view port. Use this procedure to define a segment:

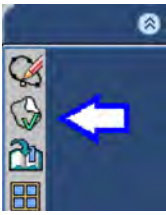
- Move the cursor over the coronary to display the centerline. You are automatically in the Define Segment mode.
- Click the artery:
 - If it is a new artery (an artery for which no sub-segments have been defined), the entire artery displays as a segment, with a colored ring at each end. Define the sub-segment by moving the rings either in the main view port or on the slide bar on the left.
 - If it is an artery with a pre-defined sub-segment, the system will remember this and show the last defined sub-segment (in yellow), with the rest of the artery in red and with the rings at either end.

If desired, select another artery and repeat the above steps.

NOTICE

True View is only available for the IntelliSpace Portal Workstation during the Coronary Analysis stage.

Plaque Analysis



Use Plaque analysis to: identify possible lesions along the vessel wall for clinical evaluation by the physician. Provide plaque characterization using a one-click algorithm (calcified and non-calcified). Provide color coded visualization of user-approved findings of plaque content areas on vessel cross-sectional images. Automatically calculate and display lumen and vessel contours. Measure cross-sectional measurements along the arteries. And calculate regional and global quantities of plaque volume.

NOTICE

If your system is equipped with the available Plaque Analysis option, you may use Preferences to make Plaque Analysis the default application for the Coronary Analysis stage. Refer to the "Preferences" section in the "Instructions for Use" volume. If your system is equipped with Plaque Analysis and is not the default option, select it from the Coronary Analysis function tab.

When the Coronary Analysis stage opens, the lumen and vessel contours are displayed on the cross-sectional and sMPR images. Some cross-sectional calculations are displayed on the cross-sectional images.



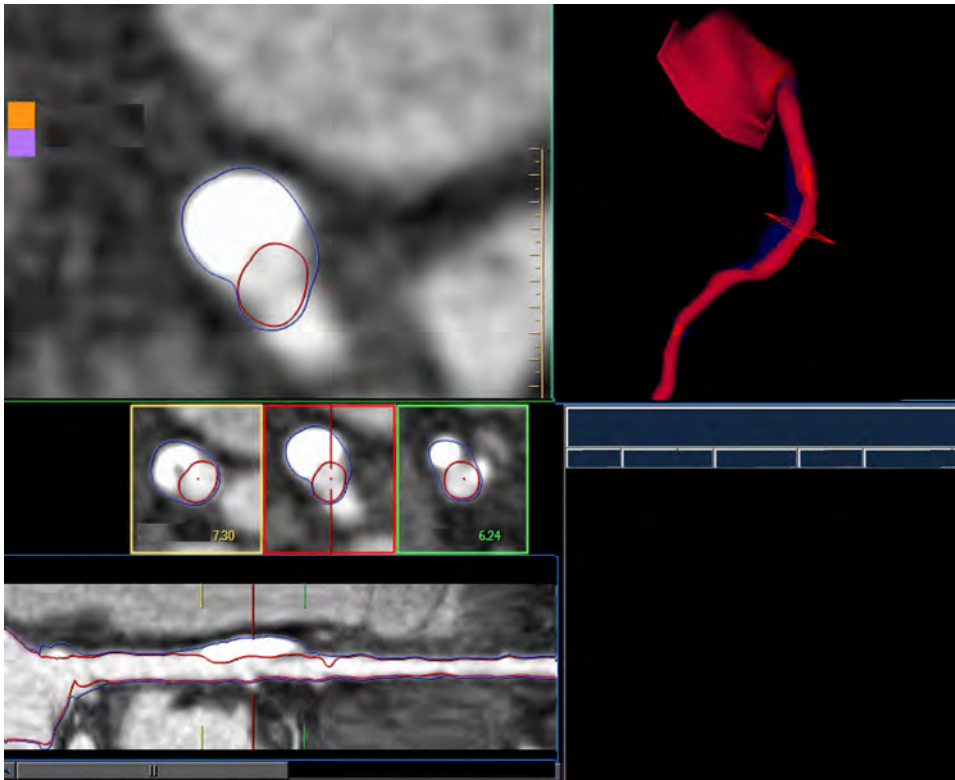
WARNING

Verify correctness of extracted lumen and vessel contour.



WARNING

When editing, continuing or flipping the centerline in Coronary Extraction stage – the lumen contours and vessel contours are re-calculated again and require additional verification.



The vessel wall (which is the volume enclosed by the vessel and lumen contours) is presented as a blue semi-transparent tissue on the Surface Shading image (the upper-right viewport, shown above).



WARNING

Cross sectional images might rotate around the centerline. Please note orientation annotations on images.

In cases where the orientation annotations are not displayed on the image - you must not assume any specific orientation. For correct orientation information - use only the images which display such information.

One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.

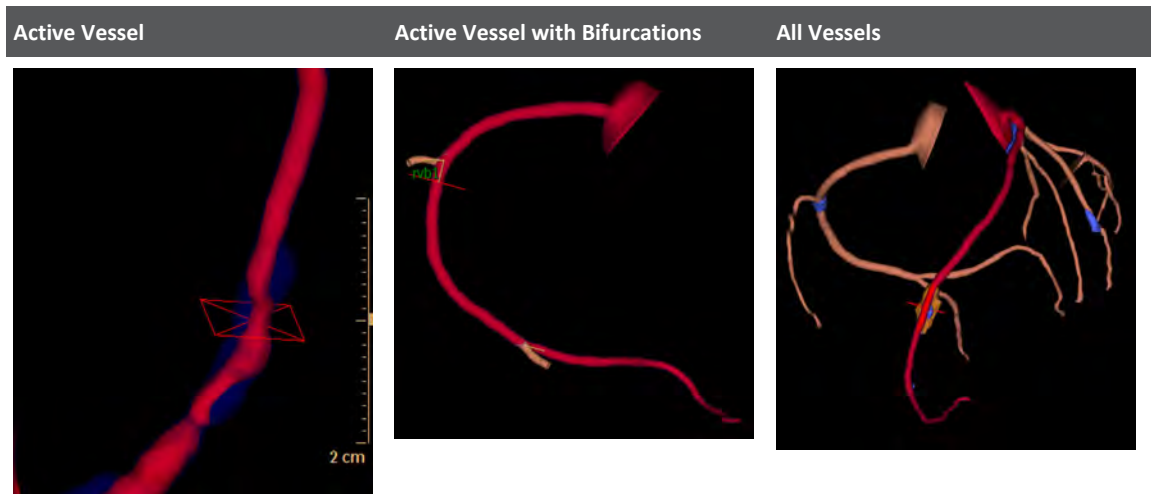
Objects in thick curved MPR images may appear distorted. Use caution when making measurements on MPR images.

Layouts

Three layouts are available: horizontal, horizontal "CS" and vertical. The layouts contain the following viewports:

- A cross-sectional image of the artery showing lumen and vessel contours. The cross-section can be moved along the vessel's centerline by scrolling in the viewport or by dragging the red line in the sMPR image.
- A cross-sectional image without the show finding overlays, allowing you to view the same image with and without highlighting. To activate the viewport in the Horizontal layout, click the "Show CS" function in the right mouse menu on the surface shading viewport.
- A Shaded Surface Display (volume) image of the lumen. (You can select "Show cMPR" and display the curved MPR image instead.) An X-shaped frame identifies the location of the cross-sectional image.
- A straightened MPR (sMPR) image of the selected artery. When you activate the Plot display, this viewport shows two objects, the sMPR image and a Plot graph of vessel and lumen diameters and areas.
- Three cross-sectional images of the selected vessel: the center image corresponds to red line in the sMPR image; and two other cross-sectional images that correspond to the yellow and green lines in the sMPR image.
- A measurements table (if table is turned off, an axial image is shown).

Shaded Surface Display



The SSD viewport control allows you to pick from 3 viewing modes from a drop-down menu on the bottom right corner of the SSD image.

- **Active vessel.** Only the active vessel is shown.

- **Active vessel with bifurcations.** The active vessel and a small portion (about 1 cm long) of all vessels that overlap the active vessel (the “branches”) are displayed. The branches must be named and have their contours already extracted. To see all the branches of the active vessel make sure all branches are named and the lumen and vessel contours of these vessels are calculated.
- **All vessels.** In this view all the named vessels are displayed with all the defined plaques. To see all the vessels in the “All vessels” view make sure all vessels are named and the lumen and vessel contours of these vessels are calculated.

SSD Annotations

By default, the vessel names and angles appear on the view. From the right click menu on the SSD image you can hide or show the angles and vessel names.

Also displayed on the SSD viewport in the “All Vessels” view are these measurements: Total findings volume and Total findings content.

Plaque Analysis Findings

At the top of the tab is the vessel name. You can select other extracted and named vessels from the drop-down.

Below the name is the list of accepted findings for the active vessel. The active finding is highlighted blue in the list and highlighted in orange on the surface shading image. (Only one finding can be active.) The active finding may be edited or deleted. The measurements displayed on-screen apply to the active finding.

Edit Contours and Mark Findings

1. Scroll along the vessel to view and select a potential finding.
2. With the Edit Lumen Contours tool, edit the lumen of the finding on the sMPR and cross-sectional images. It is recommended to edit first on the sMPR image (on several views) and then perform the final editing on the cross-sectional images.



The lumen contour is not updated during segmentation of a finding. The lumen contour should be edited before you mark the finding. Use <middle+left> mouse buttons to zoom the sMPR image while in the lumen contour editing mode.



WARNING

Editing the lumen contours using the straightened MPR image affects other views as well. Rotate the straightened MPR image and verify the correctness of the extracted contours in all views.

3. Select the Mark Plaque Finding tool.



4. Click on the plaque location on the cross-sectional or sMPR images. To mark a finding you must click outside the lumen contour. It is recommended to click in the middle of the finding.



WARNING

Verify the correctness of finding segmentation. If necessary, correct the segmentation with correction tools provided in this application.

5. The Plaque Analysis application processes the finding by segmenting it and adjusting the vessel contours automatically. A small dialog pops-up for the physician to accept or reject the finding.



- If the finding is rejected, the segmentation disappears and the vessel contours shrink to fit the lumen contours.
- If the finding is accepted, it is added to the findings list and the measurements become available.
- If the finding was not segmented correctly, select the Mark Finding tool again and click at a different location.



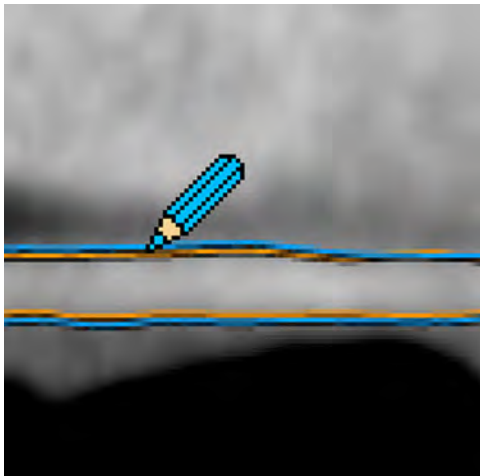
WARNING

The Plaque Analysis findings should not be used as a **SOLE** basis for clinical diagnosis.



6. Use **Edit Vessel Contours** to edit vessel contours on sMPR and cross-sectional images.

When the **Edit Contour** mode is activated, hovering over the vessel contour changes the cursor to a blue pencil.



If you reduce vessel contours, the finding segmentation is updated automatically. The vessel contour should be edited before you use the “brush” tool.



WARNING

Editing the lumen contours using the straightened MPR image affects other views as well. Rotate the straightened MPR image and verify the correctness of the extracted contours in all views.

7. Use the **Edit Finding** Spherical brush (3D) tool if you want to add segmentation to the active finding.

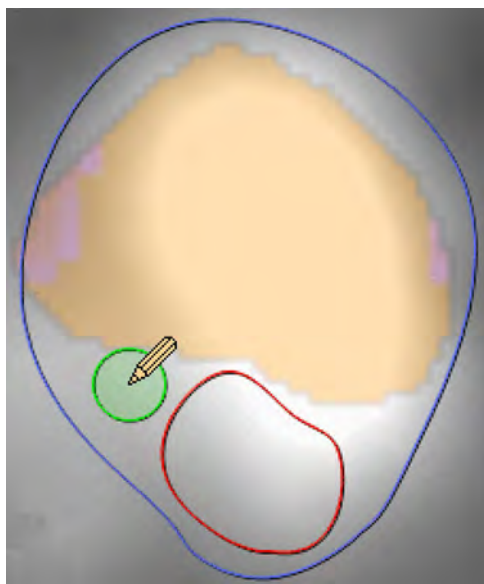


To add to the segmentation, use the brush tool on the cross-sectional image. The size of the brush (and the “eraser” tool, described below) can be changed from the “Size” box. (You can also decrease/increase the size of the brush and eraser with the “[” and “]” buttons on the keyboard)

Since you can use the brush tool only inside the contour of the lumen and vessel, be sure to first edit the contours.

To add segmentation to a non-active finding (one with blue highlight on the cross-sectional images and surface shading image), first click the finding to make it active, then use the brush.

It is possible to add segmentation on a slice without a finding on it, but only on the single slices before and after where a finding exists.



Automatic merging. When you are using the brush tool on a cross-sectional image which has several findings - one active (color highlighted) and the rest non-active (blue) - and the brush touches several findings, these findings are automatically merged into one.

8. Use the Spherical eraser (3D) tool if you want to remove segmentation from the active finding.

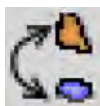


Rename or Delete Finding

To rename a finding double click its name in the list, type in the new name and click **Enter**.

To delete a finding right click its name in the list and choose **Delete**. You can also right click on the finding itself on the cross-sectional or surface shading image and choose **Delete**.

Merge Findings



Use the Merge with Finding tool to merge two findings into one.

1. Choose an active finding.
2. Right click on the finding.
3. Click **Merge with Finding** button.
4. Click on the second finding. The findings are merged.

You can merge findings on the surface shading image and on the cross-sectional image.

Use Parent/Child Logic

The Parent/Child logic is applied on vessels that have branches. The logic is designed to prevent you from marking the same finding more than once on different vessels.

If several vessels share a common part, the Parent/Child logic is defined according to the standard vessels list (from parent to child in descending order) as follows:

LCA*	M3	Rv2
RCA*	b1	Rv3
LAD*	b2	Rv4
LCx*	b3	Rv5
CRx*	b4	Dd1
PDA	b5	Dd2
Am	D1, Diagonal 1	Dd3
Ramus	D2, Diagonal 2	Dd4
M1	D3, Diagonal 3, Septal 1, Septal 2	Dd5
M2	Rv1	–

* LAD, RCA, LCx/CRx are always be parents, if they exist. For example, if you have LAD, D1 and D2 named, the LAD will be the “Parent” (the main vessel), and D1 and D2 will be the “children.”

Naming Non-standard Vessels

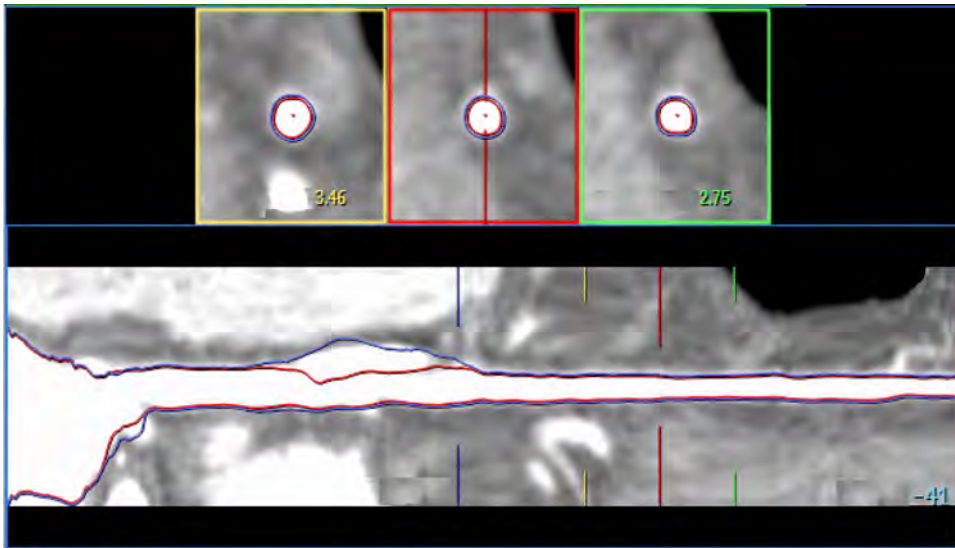
For vessels which do not appear in the standard vessels names list, the hierarchy is built by the naming order in the list. For example, if 2 vessels have a common part, the first vessel you name will be the parent and the second vessel will be the child.

Apply Parent/Child Logic

If you then switch to a child vessel which shares the common part with the Parent vessel and try to mark a finding on the common part, the following message pops up: “You cannot mark a finding on a vessel segment which belongs to [the parent name vessel]. Do you want to select [the parent name vessel]? (“Yes,\” “No”).

If you choose “Yes” the application opens the parent vessel. If you choose “No” nothing happens.

A blue line appears on the sMPR image showing the border of the common part. Also the name of the Parent vessel appears above the common part in blue: Main:[the name of the parent vessel].



Plaque Analysis without Lumen Calculation

If you switch to Plaque Analysis and one or more vessels are without lumen calculation the following message displays: “Calculate lumen for all vessels? (Yes, No).”

- Clicking “Yes” causes the software to calculate all lumen lines for all the named vessels.
- Clicking “No” displays this message: “Some functions are not available before all lumen lines are calculated.”

NOTICE

It is recommended to calculate all the lumen lines for all the vessels before entering Plaque Analysis.

Before all lumen lines are calculated the “All vessels” and “Active vessel with bifurcations” views are not fully available. Also, the Parent/Child logic is not fully applied.

Make sure not to mark the same finding on different vessels to avoid wrong calculations.

Save Results

From the right click menu select this option to save detailed measurement results for each cross-section along the vessel as .txt or .csv files (saved in the “Files” folder in the Patient Directory).

You can also save the Histogram in .txt or .csv formats and extract all the data of the detected Gaussians.

Plaque Analysis Tools

The Coronary Analysis tool panel consists of two parts. The upper part has tools that control viewing operations and the bottom part consists of function tabs.

Some of the tools in the upper part are the same as described in the Coronary Analysis. See section “Coronary Analysis Stage” on page 154.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Show Lumen and Vessel Lines



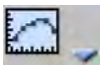
Use these tools to display and hide the lumen (red) and vessel (blue) lines on the cross-sectional and sMPR viewports.

Show Findings Tissue



Activate this button to show the findings segmentation of the active vessel on the cross-section images. (If this button is off, findings overlay on the cross-sectional images is hidden.)

Show Plot Graph



Activate this button to show the findings segmentation of the active vessel on the cross-section images. (If this button is off, findings overlay on the cross-sectional images is hidden.)

Display Measurements Table



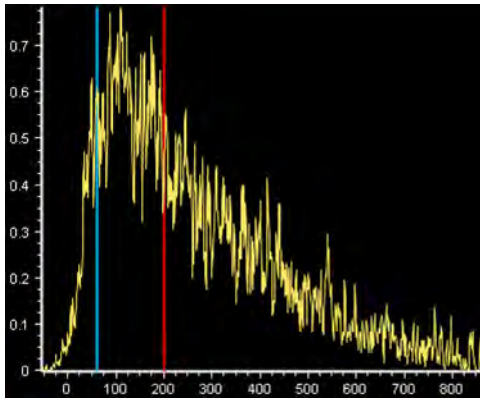
Activate this button to display one of five tables of vessel and plaque data (Vessel table, Finding table, Lesion cross-section table, Lesion versus reference table, and All vessels table). In the All Vessels table, if you mark the same finding on several vessels which have a common part, which means there will be an overlap, data will be calculated for each vessel separately.

Plaque Histogram Graph



Activate this button to display the HU distribution histogram of the active finding. A movable threshold line allows you to set (define) the threshold between calcified and non-calcified findings.

After adding “Low attenuation threshold” it also allow you to set the threshold between medium attenuation and low attenuation findings.



Set Plaque Definition Method



Setting the Method of defining Plaque - Plaque is categorized as calcified and non-calcified, based on the HU values in the finding. Two methods are available, the Threshold and Gaussian methods. You can specify the method by clicking the drop-down, then clicking the Finding Contents Settings button. (You can also switch between methods from a right click menu n the histogram.)

Show Measurements



Plaque is categorized as calcified and non-calcified, based on the HU values in the finding. Two methods are available, the Threshold and Gaussian methods. You can specify the method by clicking the drop-down, then clicking the Finding Contents Settings button. (You can also switch between methods from a right click menu n the histogram.)

Display Measurements and Annotations (“Show Measurements” function)

Changes made in this dialog are remembered next time application is launched.

Annotations

Lumen Diameter	Minimum	Maximum
Wall thickness	Minimum	Maximum

Measurements

Cross-sectional Image. If no finding is active, only the measurements in the left column below are displayed; if there is an active finding, all measurements below are displayed.		Volume Image. If no finding is active, none are displayed.
Lumen Area	Finding Area	Finding Volume
Wall Area	Finding Burden	Finding Content
Remodeling Index	Finding Mean HU	Finding Non-calcified Content
Min Lumen Diameter	Finding Content - In Threshold method only. Shows % Calcified and % Non-calcified at the finding area, at the active cross-section.	Finding Mean HU

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Philips

Display Measurements and Annotations (“Show Measurements” function)
Changes made in this dialog are remembered next time application is launched.

Max Wall Thickness	Non-calcified Content - In Threshold method only, and only if “Low Attenuation threshold” is checked in the “Set threshold” dialog	Finding Position - At minimum lumen area along the finding.
Position	–	Total Findings volume
–	–	Position (find. start) - length of the centerline from its proximal origin till the first cross-section
–	–	Finding length - relates to the active finding

Measurement Notes

If the Wall thickness (max/min) measurement is less than 0.55 mm the measurement will be displayed as “N/A.” If Wall thickness (maximum) at a specific slice is less than 0.55 mm the following additional measurements also will be displayed as “N/A.”

- Wall
- Wall burden
- Remodeling Index
- Eccentricity
- Wall HU

Measurement Definitions

2D Measurements (cross-sectional)

Minimum Lumen Diameter	The shortest diameter through the center point of the lumen
Maximum Lumen Diameter	The longest diameter through the center point of the lumen
Lumen Eccentricity	$(1 - \text{Min. Lumen diameter} / \text{Max. Lumen diameter})$
Effective Lumen Diameter	calculated from the equation $\text{Area} = \pi * \text{Radius}^2$, thus $\text{Effective_diameter} = 2 * \sqrt{\text{Area} / \pi}$
Vessel Area	The area bounded by the vessel (outer blue) border
Lumen Area	The area bounded by the luminal (inner red) border.
Finding Area	The area segmented as finding between the inner and the outer lumen
Maximum Wall Thickness	The largest distance from the lumen border to the wall border passing through the lumen center
Minimum Wall Thickness	The smallest distance from the lumen border to the wall border passing through the lumen center
Wall Eccentricity	$(1 - \text{Min. Wall Thickness} / \text{Max. Wall thickness})$
Wall Burden	$\text{Wall Area} / \text{Vessel Area}$
Finding Burden	$\text{Finding Area} / \text{Vessel Area}$

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Measurement Definitions	
Wall Area	The area bounded between the lumen and vessel borders
Remodeling Index	Vessel Area at lesion / Vessel Area at reference. (If >1.05, then positive remodeling. If <0.95, then negative remodeling)
Mean HU	At lumen and finding
Finding Content	% Calcified, % Non-calcified on a specific cross-sectional image. The finding content is determined according to the threshold set in the histogram. (This option is available only in Threshold method.)
Finding Non-calcified Content	% Medium Attenuation, % Low Attenuation. The finding content is determined according to the threshold set in the histogram and according to the method. Only available if the "Low attenuation" option is checked in the "Set threshold" dialog.
Standard Deviation HU	At lumen and finding
Position on cross-sectional image	The distance of the lesion/reference lines from the beginning of the centerline
Finding coordinates	The coordinates of the minimum lumen location along the finding.
3D Measurements (per finding)	
Finding Volume	for the active finding
(Finding) Content	% Calcified, % Non-calcified. The finding content is determined according to the threshold set in the on the histogram and according to the method.
Finding Non-calcified Content	% Medium Attenuation, % Low Attenuation. The finding content is determined according to the threshold set in the histogram and according to the method. Only available if the "Low attenuation" option is checked in the "Set threshold" dialog.
Mean HU	–
Standard Deviation HU	–
Position on Volume image	The distance of the location along the finding with the minimum lumen area from the beginning of the centerline

Calculate Plaque Content

Once the physician marks and accepts the findings, Plaque Analysis will calculate the content of the findings (based on detected finding segmentation) and display the total content as the percent (%) of calcified plaque plus the percent of non-calcified plaque. The findings are presented on the cross-sectional image in these highlight colors:

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Orange	Calcified voxels	
Purple	Non-calcified voxels	
Low attenuation voxels	Low attenuation voxels	

The active plaque is highlighted in orange on the volume image and is colored according to the content on the cross sectional images. The non-active plaques are highlighted as blue on both cross sectional and volume images.

NOTICE

You can use the “Opacity” viewport control to increase the color intensity of the highlights.

Threshold Calculation Method

Calcified plaque is defined as all the voxels above a threshold HU value and non-calcified plaque is all the voxels below the threshold.

In the Threshold method the borders between the highlighted (orange and purple) regions are well determined, since each voxel belongs to a certain region.

Gaussian Calculation Method

The Gaussian method uses the mixture Gaussian model of calculating plaque distribution.

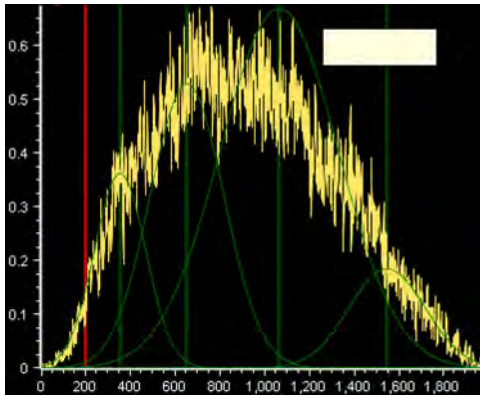
When using this method the content is not calculated according to the absolute number of voxels below and above a threshold HU value. Instead, the distribution of a finding is remodeled into a linear combination of Gaussians, and the mean of each Gaussian is calculated. If the high threshold is set lower than the mean of specific Gaussians, all the voxels covered by the Gaussian curve are regarded as calcified plaque and the rest of the voxels are non-calcified plaque.

In the Gaussian method there are voxels which have a certain probability to belong to each of the regions. The color of these voxels is a weighted linear combination of the colors between orange and purple. This causes the borders between the different regions to seem blurry.

View Gaussians

When the Gaussian histogram is active, right mouse click in the histogram viewport.

Click **Show Gaussians**. The detected Gaussians are displayed on the histogram. A green vertical line locates the mean location of each Gaussian. To view the Mean and Standard Deviation (SD) HU parameters of any Gaussian, hover the mouse cursor over a vertical line. A tooltip appears showing the HU parameters.



Switch Methods

When the Gaussian histogram is active, right click in the histogram and point to the Method selection.

Click **Threshold** to change the histogram to the Threshold method. Switching between the methods is also possible using Finding Content Setting dialog (described in the next section).

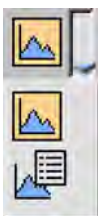
Set Content Calculation Parameters



This button displays the Plaque Histogram Graph, which displays the HU distribution of the active finding. The default High Threshold value is 200 HU. The threshold value can be changed by dragging the vertical line on the histogram display or typing a new setting in the Finding Content Settings dialog.

NOTICE

Changing the threshold changes it only for the currently active finding (the threshold can be set differently from finding to finding). If you want to apply the same threshold to all findings, use the Set as Default setting in the Findings Content Settings dialog.



To change Threshold settings, drop-down the Histogram button and select the Finding Content Settings button. The Finding Content Settings dialog is automatically opened the first time you click on the histogram button.

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Finding Content Settings

Setting	Description
Gaussian method	This is the default method.
Threshold Method	–
High Attenuation Threshold	Default High threshold is 200 HU. You can use the combo-box or drag the red vertical line to set the High threshold from 1 HU to 1000 HU. The threshold applies to all currently accepted findings.
Low Attenuation Threshold	<p>To distinguish between low attenuation and the medium attenuation findings, add the Low Attenuation Threshold to the histogram by clicking the checkbox.</p> <ul style="list-style-type: none"> • Non-calcified plaque is divided into two subgroups: medium attenuation and low attenuation. • The histogram displays the additional, low threshold line (colored blue). • The active finding on the cross-sectional image is colored appropriately (the low attenuation voxels are colored in green). • Non-calcified content measurements are displayed on the cross-sectional and surface shading images. • All the tables have additional measurements of non-calcified content. <p>Default Low threshold is 60 HU. It can be set from 0 HU to 199 HU.</p>
Set as Default	Sets the current calculation method and current threshold value as the defaults when entering the application the next time. These parameters also are applied on all the currently defined findings and vessels.
Factory Default	Sets the calculation method to Gaussian and the Threshold to 200 HU (60 HU Low Attenuation).

Functional Stage

The Functional stage of Comprehensive Cardiac Analysis allows you to analyze a variety of heart functions, including:

- ventricular and atrial volumes;
- ejection fraction;
- stroke volume;
- cardiac output;
- left ventricle wall mass, motion, and thickening;
- using Simpson or Segmentation methods of calculation; and
- normalize functional results by Body Surface Area.

Layout

The stage opens by default with a split viewport: Volume rendered image of the heart and Results table. You can turn the table off, and the viewport shows only a large volume image. The layout also contains:

- a graph viewport / polar map;
- the short axis image with colored tissue overlays (which can be turned off); and
- three reference viewports show cardiac axes images through the LV axes, typical of echo cardiographic planes. From left to right they are 4 chamber, 3 chamber, and 2 chamber images.

Stage Tabs

- **Functional Analysis.** This is the default function when the Functional stage opens, and is described on these pages.
- **LV / RV Corrections.** This function allows you to re-orient (correct) the long axis, and is described on these pages.
- **Defects Assessment.** Myocardial Defect Assessment (a purchasable option) provides visual and quantitative assessment of segmented, low-attenuation areas within the myocardium.
- **Bookmarks, Batch, and Clip.** The Batch function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.
- **Fusion.** The Fusion option in CCA allows combining the volumetric image of the heart, extracted from the segmentation of the CT images, together with the colored functional data extracted from the PET/SPECT images. In addition, the Fusion Viewer employs standard CT Viewer functions, allowing you to view PET and SPECT images, and to fuse NM images with CT images.
- **PET/SPECT Support.** in CCA The CCA application supports Nuclear Medicine (NM) image data within the Functional stage only. Support for PET/SPECT includes viewing tools, the Fusion mode, dedicated layouts, PET/SPECT/Fused colormaps, and image manipulations.

NOTICE

The functional stage supports conventional and MonoE data.

Please refer to the following sections of the IntelliSpace Portal Spectral Applications IFU for information on spectral results and processes:

- Understanding Spectral Results
- Common Spectral Processes

NOTICE

Loading NM images by themselves into CCA is prevented.

**WARNING**

The functional measurements accuracy depends on the accuracy of the tissues segmentation. Please verify the tissues segmentation correction and edit if required using the Segmentation tools.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Ensure Accurate Results

Obtaining accurate results from Functional depends on correct segmentation of the heart and correct alignment of the heart axes.

You should carefully review the results of the Segmentation stage before accessing Functional. If necessary, you may correct the segmentation of the chambers and coronaries of the different phases.

After verifying segmentation, you may skip the Coronary Extraction and the Coronary Analysis stages and directly enter the Functional stage.

NOTICE

Verify that the appropriate phases are loaded.

Verify the correctness of cardiac segmentation.

When using the Simpson method, verify the correctness of the LV, long axis and short axis contours.

Set ED, ES and Diastasis Phases

If appropriate phases are launched into the Functional stage, the ES and ED phases are set automatically. Appropriate phases are:

- At least one phase between 90%-10%.
- At least one phase between 30%-50%.

If the appropriate phases are launched, a dialog opens. Confirm the correctness of the phases settings.

If the dialog is not opened automatically, you can open it with the Set ED/ES button. (You may need to set the phases if the appropriate phases were not loaded.)

The Functional stage examines the loaded cardiac phases and recommends the best ED, ES, and Diastasis phases. You can accept the recommendations or change them.

- End-Systole is the end of the pumping (ejecting) phase of the left ventricle (LV). The software recommends the phase which has the minimum LV volume between 30-50%. If no phase is available in this range it recommends the minimum LV volume phase from the available phases.
- End-Diastole is the end of the filling phase of the left ventricle (LV). The software recommends the phase which has the maximum LV volume between 90-10%. If no phase is available in this range it recommends the maximum LV volume phase from the available phases.
- Diastasis is the phase preceding the atrial contraction phase. (This phase is used in Atrial volume calculations.) The software automatically recommends the first phase available between 75-80%. If no phase is available in this range it displays “None” and you can choose any other phase from the loaded phases.

Functional Analysis Viewing Tools

Some viewing tools are carried over from the Coronary Analysis stage, including the General Axes Orientation tools (but not the Cardiac Axes orientations), the ECG function, and the Magic Glass tool. See section “Coronary Analysis Stage” on page 154.

Note the following:

- The Flip tool only affects the volume and cMPR images.
- The Relate function can be used on the axial and volume images, but cannot be used on the sMPR or cMPR images.)

There is one Layout, described on the previous page.

Show/Hide Overlays



Use this function to display or hide the colored segmentation overlays on the Short Axis image.

Short Axis Image Creation



Click this button to open the Short Axis Image Creation dialog, which displays the current settings for thickness (width) and number of the short axis images. These parameters are used in the calculations for the Polar Maps and other functional parameters. The default parameters (shown) are selected for good analytical results, and may be modified if needed.

Set ED/ES

Click this button to open the Short Axis Image Creation dialog, which displays the current settings for thickness (width) and number of the short axis images. These parameters are used in the calculations for the Polar Maps and other functional parameters. The default parameters are selected for good analytical results, and may be modified if needed.

Functional Analysis Tools

The Functional Analysis tools are the default tools when the Functional stage opens.

Method

You can choose from two methods of functional analysis of the heart chambers.

Once all manual corrections and settings have been made, you can freely switch between the Simpson and Segmentation methods.

Simpson

This method uses dimensions derived from heart contours to calculate Functional results. Simpson's Rule is a fundamental mathematical principle. It is based on the idea that the volume of an object can be determined by "cutting" the object into thin "slices." measuring the volume of each slice and summing the volumes of all slices.



WARNING

Every time a heart tissue is being modified, the axes and the relevant contours are being recalculated and require verification. Verify the correctness of the cardiac axes and contours every time you modify one of the following tissues: left ventricle, myocardium, right ventricle.

Segmentation

This method calculates the LV, RV, RA, and LA volumes from the absolute tissue volume segmented.



WARNING

To obtain accurate Functional results, the heart must be correctly segmented.

Verify the correctness of the heart segmentation and, when required, correct it manually using the tools in the Segmentation stage.

NOTICE

Functional results may differ between the Segmentation and Simpson methods.

Show Table

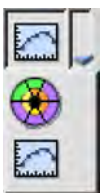


The following measurement tables can be displayed:

- Show Ventricular Table.
- Show Ventricular Table / BSA. See section “BSA Calculation” on page 197.
- Show Atrial Table (only available in Segmentation method).
- Show Atrial Table / BSA (only available in Segmentation method). See section “BSA Calculation” on page 197.

When a table is being displayed, the Show Table button appears depressed. To select a different table, click the down arrow to see the list of available tables and click the desired one. To turn off the table display click the button so it does not appear depressed.

Graph/Polar Map Selector



You can display either a graph or a polar map in the upper right viewport. (Polar maps are available only in the Simpson method). More information about graphs and polar maps are provided later.

Parameter

Click the down arrow to select from a list of available graphs or polar maps.

Spoke Wheel On/Off



Use this button to control the display of the Spoke Wheel on the Short Axes image.

Number of Rays

When the Spoke Wheel is active, change the numbers of Rays displayed on the active image.

BSA Calculation

If you enter the patient’s weight and height, you can have the Functional results normalized by Body Surface Area. Body surface area is the total surface area of the patient’s body.

BSA is often used to produce the cardiac index, which is a measure of cardiac output divided by the BSA, giving a better approximation of the required cardiac output.

Set the BSA calculations:

1. Click the Show Table drop-down and select a table that employs BSA. If the patient weight and height have not been previously entered, the BSA Calculation dialog will open.
Or:
Right click in any image viewport and select BSA Calculation. The dialog will open. Use this method also if you later want to change the weight or height values.
2. Type in the patient's weight and height. Note If weight and height values were typed in before the scan, CCA reads these values from the DICOM information.
3. Click **OK**.
4. To see the calculation result, right click in any image viewport and select BSA Calculation.

NOTICE

BSA is defined as "The square root of product of the weight (in kg) times the height in cm divided by 3600." Reference: Mosteller RD. Simplified calculation of body-surface area. N Engl J Med 1987;317:1098.

LV/RV Correction Function

If using Simpson's method, you can adjust the heart axes and the contours in the LV / RV Corrections function.

Examine all phases for correct Axes and perform the Correct Axis procedure, if necessary (Simpson method).

Perform the Correct Contours procedure (Simpson method).

Correct Axis Mode

The mode provides tools to correct the axis. The layout contains the following:

- **Viewport 1: short-axis view.** Three colored lines 60 degrees apart mark the planes of the 2-chamber, 3-chamber, and 4 chamber echo views (red, green, and blue, respectively). You can move intersection and rotate the lines.
- **Viewports 2, 3, and 4: the 2-chamber, 3-chamber, and 4-chamber (respectively) echo views.** The vertical green reference line in each viewport is the calculated long axis. In each view the Base (valve plane) and Apex of the heart are marked with dashed lines, which are moveable to correct them.

Correct Valve and Apex Planes

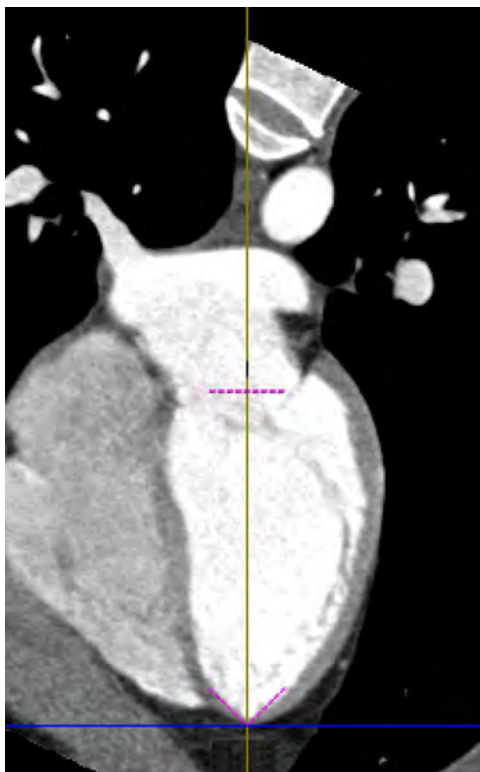
For all loaded phases, examine the position of the base and apex planes, and correct them if needed. (The long axis maintains the same position and orientation for all phases.)

**WARNING**

When modifying the cardiac axes or apex/base definition, the contours are being recalculated. Please verify the contour correctness after modifying the cardiac axes or apex/base definition.

NOTICE

Make sure to define the valve plane separately for ED and ES, as this plane moves caudally during systole. Failure to do so may result in an underestimation of Ejection Fraction.

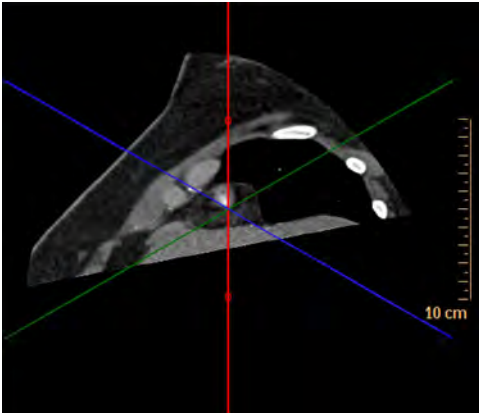


Correct the apex setting by dragging the Apex (V-shaped dashed line) to the correct position. If necessary, correct the Mitral valve plane by dragging Base (straight dashed line) to the correct position.

Re-orient Long Axis

1. Click the ED phase tab. (The Long axis can only be corrected in the ED phase.)
2. Examine the Short Axis image. If corrections are necessary, first correct the apex location on the short axis image.
3. Move the pointer cursor to a green line (the long axis). The pointer will change to either a Rotate cursor at the edges of the line, or to a Move cursor, when it is closer to the center of the line.

4. Dragging the left mouse cursor causes the image to either rotate or pan relative to the fixed green line.



Re-establish ED and ES Phases

Perform this procedure after correcting the apex plane and the Mitral valve plane.

Slightly rotate the long axis in the ED phase, offsetting it from its current position.

During the correction, an intended function will also automatically occur: the apex and valve positions on all other phases will interpolate to locate between ED and ES.

Correct Contours

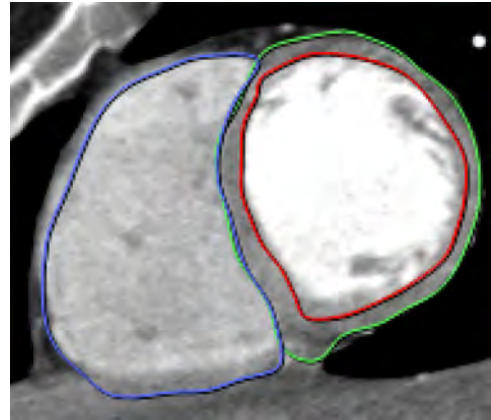
Correcting contours will only change results when using the Simpson method.

This function allows you to correct the chamber wall contours.

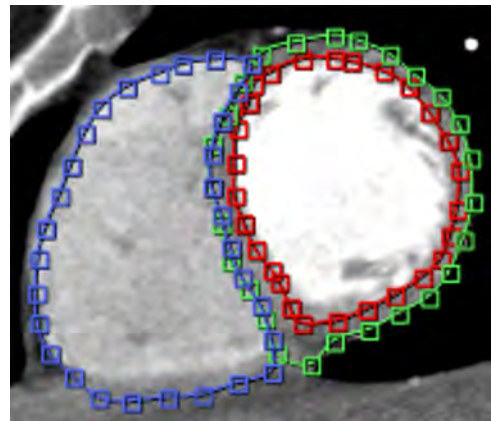
To begin, select **Correct Contours**. The view changes to 3x3 layout with inner and outer myocardial contours, and Right Ventricle contours.

In the Correct Contours mode, 3 contours are shown at the same time on all 9 viewport images.

- Red = Endocardium contour
- Green = Epicardium contour
- Blue = Right Ventricle contour



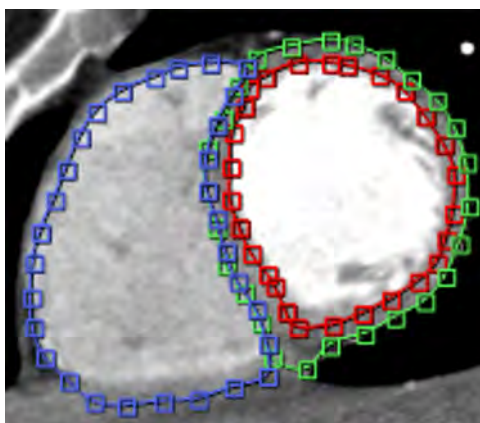
Double click any viewport to enlarge it to full screen.
Double click again to revert.



Edit Contour



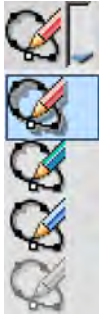
Click the Edit Contours button to enable all contours for editing. With the mouse, drag the control points to the correct locations.



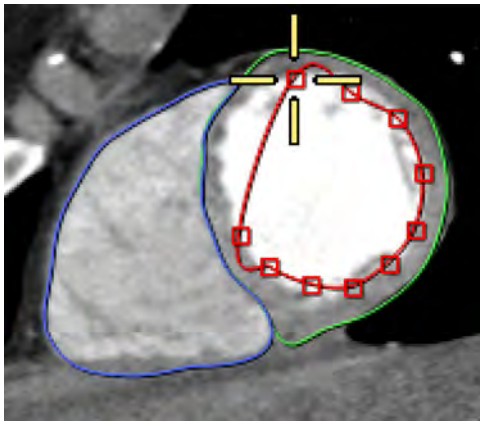
Delete and Draw Contour



1. Select a viewport to delete a contour from.
2. Click the **Delete contour** button.
3. Click the contour(s) you want to delete.
4. From the Draw Contours drop-down, select the contour type to draw.



5. Click repeatedly in the viewport, following the anatomy, as shown below, to draw a new contour.



6. Double click to end drawing.
7. If needed, use the Edit Contours function to refine the contour.

Show Papillary Muscles

The Papillary function allows you to exclude the volume of the Papillary muscles when calculating the LV volume.

The Show Papillary Muscles function is active only when the Simpson method is selected.

1. To activate the Papillary function, check the Papillary checkbox. A message appears: "Papillary muscles shall be excluded from the LV cavity. Continue?"
2. Click **Yes**.
3. You will be instructed to "Verify correctness of papillary contours."
4. Use this application's contour editing tools to correct as needed.

Results

- The Papillary contours are added to the short axis images.
- The Ventricular table displays LV volume measurements that exclude the volume of the papillary muscles.
- The Papillary contours drawing option appears in the Draw contour drop down list.
- The highlight of the papillary muscles is displayed on the short axis images in “Review results” mode.

Undo the Papillary Function

If you un-check the Show Papillary Muscles option, a message appears: “Papillary muscles shall be included in the LV cavity. Continue?” If you answer YES, the results described in the procedure above are reversed.

Checking the Show Papillary Muscles option does not influence the Polar Maps or the Wall Thickness / Thickening / Motion graphs.

Functional Stage Results

The Functional stage provides a number of tools to view results.

Results Table



The Results table shows the calculations made by the Functional stage. Four table variations can be viewed, as selected from the Show Table drop-down:

- Show Ventricular Table;
- Show Ventricular Table / BSA;
- Show Atrial Table (Segmentation method only); and
- Show Atrial Table / BSA (Segmentation method only).

Ventricular Table

ES Ventricular Volume (Phase xx%)	The ventricle volume at end-systole
ED Ventricular Volume (Phase xx%)	The ventricle volume at end-diastole
Ventricular Stroke Volume	(ED volume) - (ES volume)
Ventricular Ejection fraction	$[(ED\ volume) - (ES\ volume)] / [(ED\ volume * 100)]$
Ventricular Cardiac Output	(ventricular stroke volume) * (heart rate)
LV wall mass	(volume at ED) * 1.05 --- measured from Simpson
HR	If ECG strip is loaded to CCA the HR value is the mean HR during scan. If the ECG is not loaded, the HR is taken from the DICOM information and is the initial HR before the scan.
Early (passive) filling volume	Diastasis LV volume - ES LV volume (units=ml) Diastasis RV volume - ES RV volume (units=ml)

Ventricular Table	
Late (active) filling volume	ED LV volume - Diastasis LV volume (units=ml) ED RV volume - Diastasis RV volume (units=ml)
Early/late filling	early filling LV volume /late filling LV volume (unitless) early filling RV volume/ late filling RV volume (unitless)
Regurgitation volume	LV StrokeVolume - RV StrokeVolume (units=ml)
Regurgitation fraction index	$(LV\ StrokeVolume - RV\ StrokeVolume) / \max(LV\ StrokeVolume, RV\ StrokeVolume)$ (unitless)

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Atrial Table (Heart Segmentation only)	
Maximum Atrial Volume (Phase xx%)	Atrial volume at ES
Minimum Atrial Volume (Phase xx%)	Atrial volume at ED
Mid diastolic atrial volume	Diastasis volume
Total emptying volume	$(ES\ atrial\ volume) - (ED\ atrial\ volume)$
Passive emptying volume	$(ES\ atrial\ volume) - (diastasis\ atrial\ volume)$
Active stroke volume	$(diastasis\ atrial\ volume) - (ED\ atrial\ volume)$
Total emptying fraction	$[(ES\ atrial\ volume) - (ED\ atrial\ volume)] / [(ED\ atrial\ volume) * 100]$
Active ejection fraction	$[(diastasis\ atrial\ volume) - (ED\ atrial\ volume)] / [(diastasis\ atrial\ volume) * 100]$
Passive emptying fraction	$[(ES\ atrial\ volume) - (diastasis\ atrial\ volume)] / [(ES\ atrial\ volume) * 100]$

Graph Display

The graph display in the upper right viewport is labeled to identify the data that is being shown and, if applicable, which Functional method was used to derive the data, Simpson or Segmentation.

To select different data to view in the graph, right click in the graph viewport:

Wall Thickening (Simpson only)	RV Volume
Wall Thickness (Simpson only)	LV Volume

RV Area Change (Simpson only)

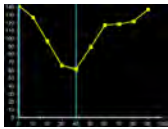
RA Volume (Segmentation only)

Wall Motion (Simpson only)

LA volume (Segmentation only)

The Thickening, Thickness, and Motion Wall graphs display results of a single short-axis slice. The results are presented in clockwise rotation from zero on the spoke wheel.

LV Volume Graph

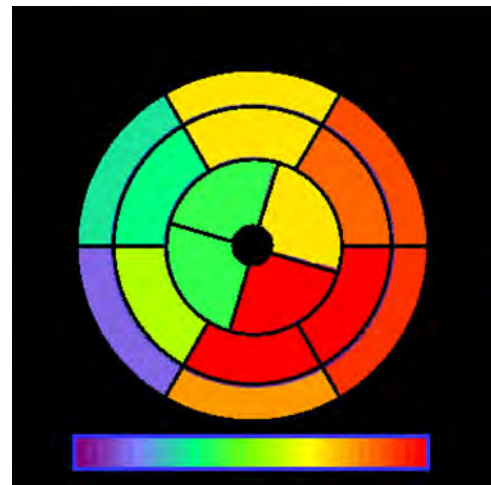
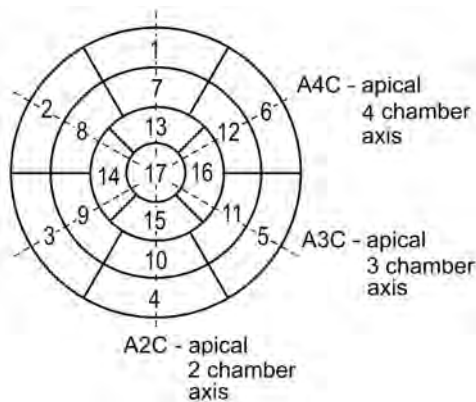
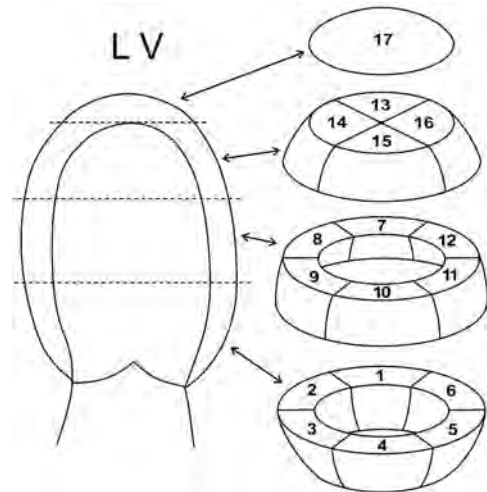


The blue vertical lines identify the ED and ES phases. The graph displays the change over time of the left ventricle (LV) volume (in ml). The horizontal scale uses the cardiac phase (%) as the reference time unit. As blood is ejected from the LV, the volume decreases to its minimum, which is the ES volume. As the blood fills the LV, the volume increases to its maximum (0% phase at right), which is the ED volume.

Polar Maps

Color-scaled Polar Maps to show the functional parameters for each segment of the left ventricle.

The default Polar map is based on the American Heart Association's standardized 16 myocardial segment recommendation for the orientation of the heart, angle selection and names for the cardiac planes.



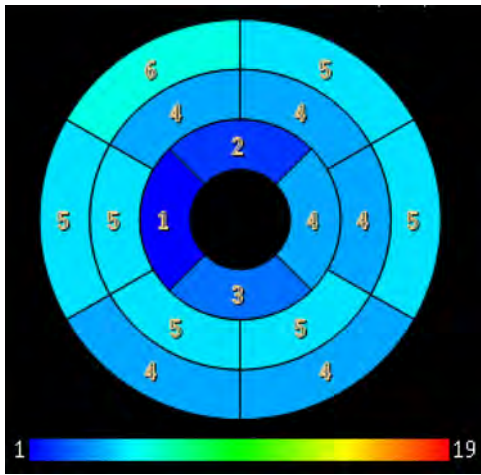
Polar Map Regional Type

The default regional map is divided into the standard 16 LV segmentation. Result values are given within each region.

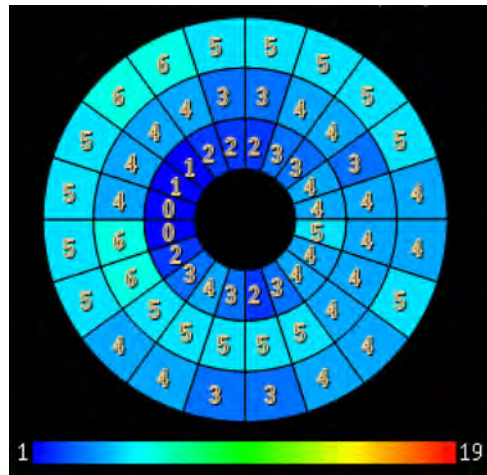
NOTICE

The default map is the regional map. The detailed map is available. Polar maps update when contours are corrected.

Regional - 6 Rays

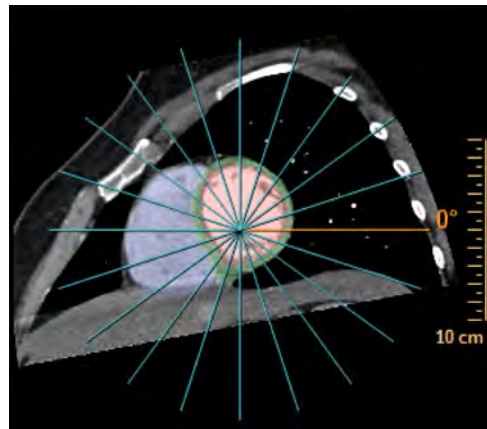


Regional - 20 Rays



To divide the regional map into other layouts, use the Spoke Wheel tool and change the Number of Rays parameter in the Functional Analysis tab. Regional- 6 rays Regional - 20 rays Short Axis - 20 rays

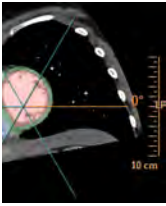
Short Axis - 20 Rays



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Configure Polar Map



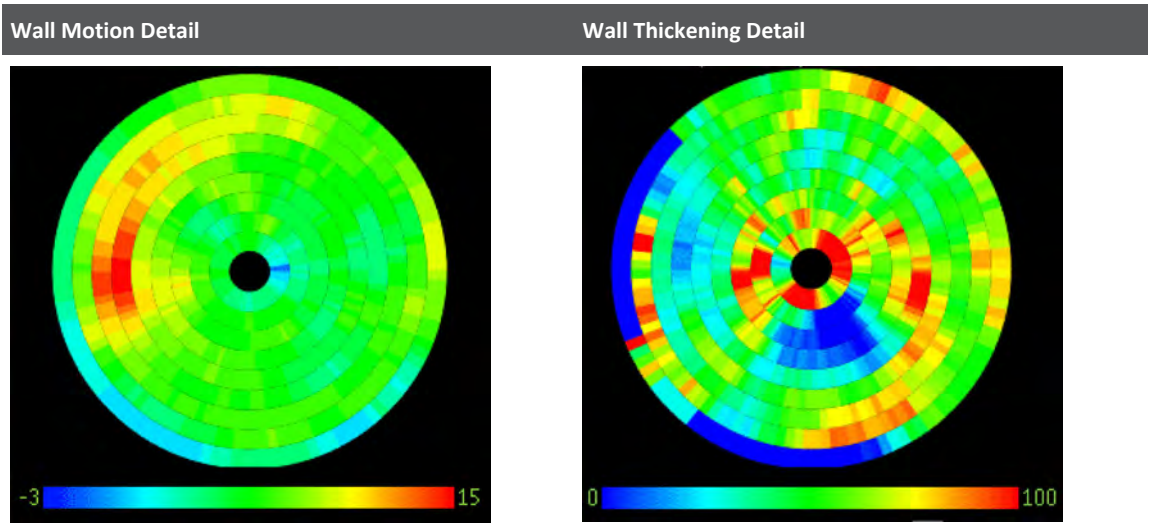
The Spoke Wheel is centered on the long-axis intersection point of each short-axis slice and divides the LV into a number of equal angle wedges, defining a specific division of the short axis slice into segments. An orange spoke (ray) marks the 0-degree (zero) point. Positive rotation is clockwise direction. The zero location in the Spoke Wheel corresponds to the zero location on the regional Polar Maps (such as thickness, thickening, and wall motion). By default the regional Polar Maps are divided into the conventional 16 segments.

You can change the number of segments for LV with the Spoke Wheel function, as follows:

1. Click the **On/Off Spoke Wheel** button to activate the wheel display.
2. Change the number of spokes with the No. Rays combo box by clicking the up or down arrows or by typing in the desired number.
3. You can change the 0-degree location by dragging any spoke.

Polar Map Detailed Type

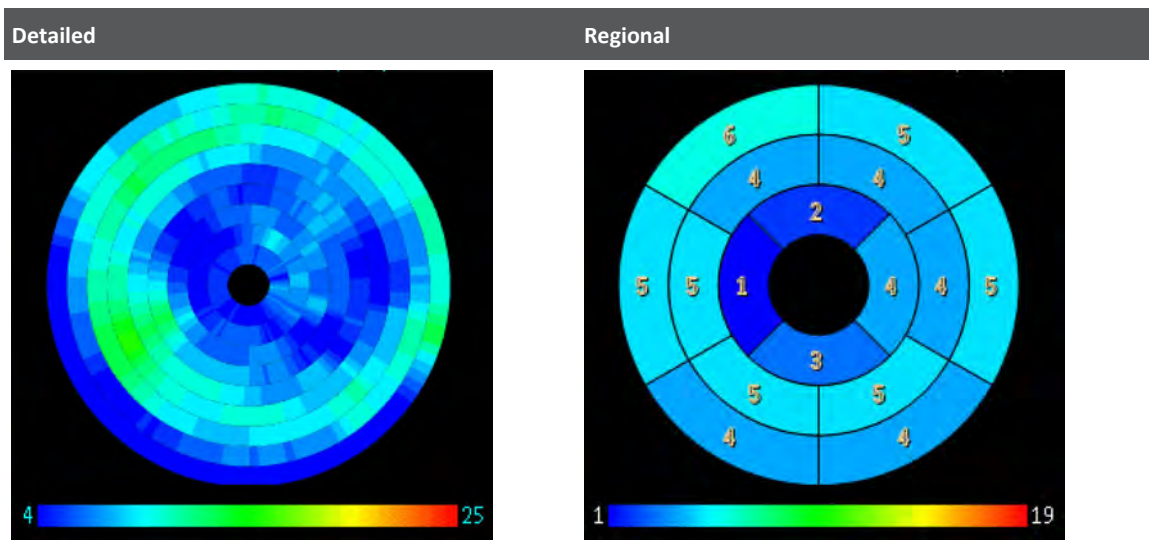
The default map is the detailed Polar Map. Each circle on the map corresponds to a specific short axis slice, where the inner circle near the center of the polar map image represents the Left Ventricular apex, and the outer circle represents Left Ventricular base.



The colors within a circle represent attributes of the part of the left ventricle that corresponds to the same polar position of the matched short axis cut.

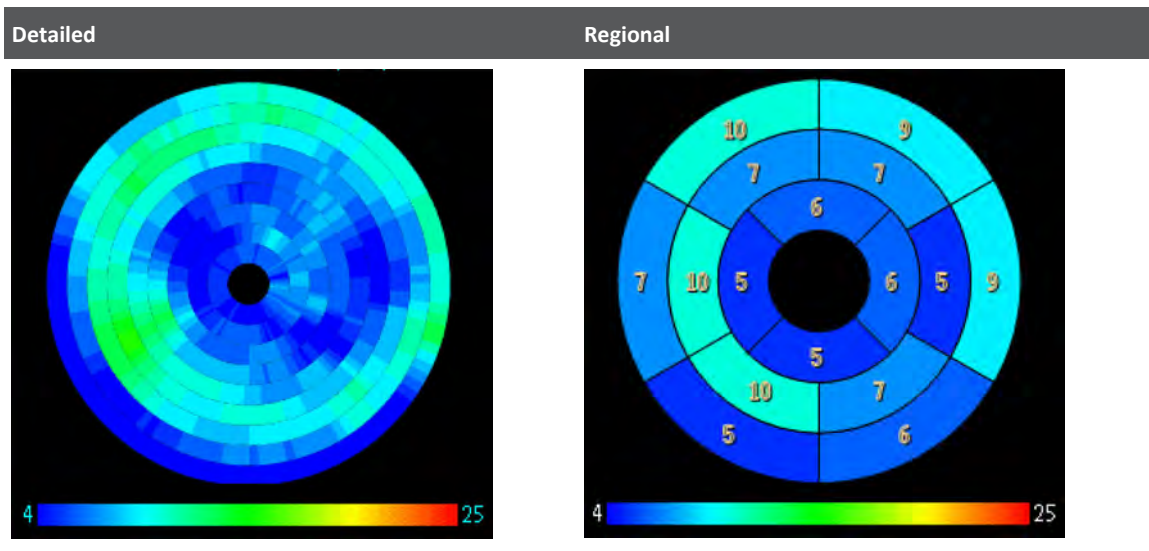
ED Wall Thickness Maps

This map represents the left ventricular wall thickness of the loaded cardiac phase with the largest ventricular volume and smallest wall thickness.



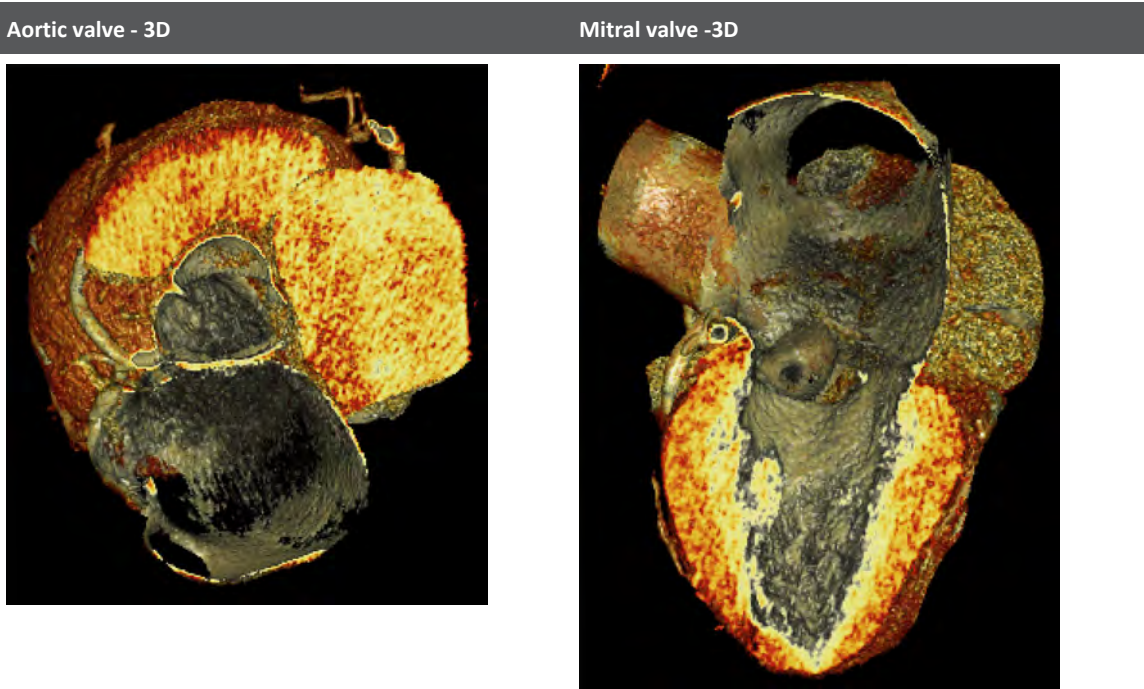
ES Wall Thickness Maps

This map represents the left ventricular wall thickness of the loaded cardiac phase with the smallest ventricular volume and largest wall thickness.



Wall Thickening Maps

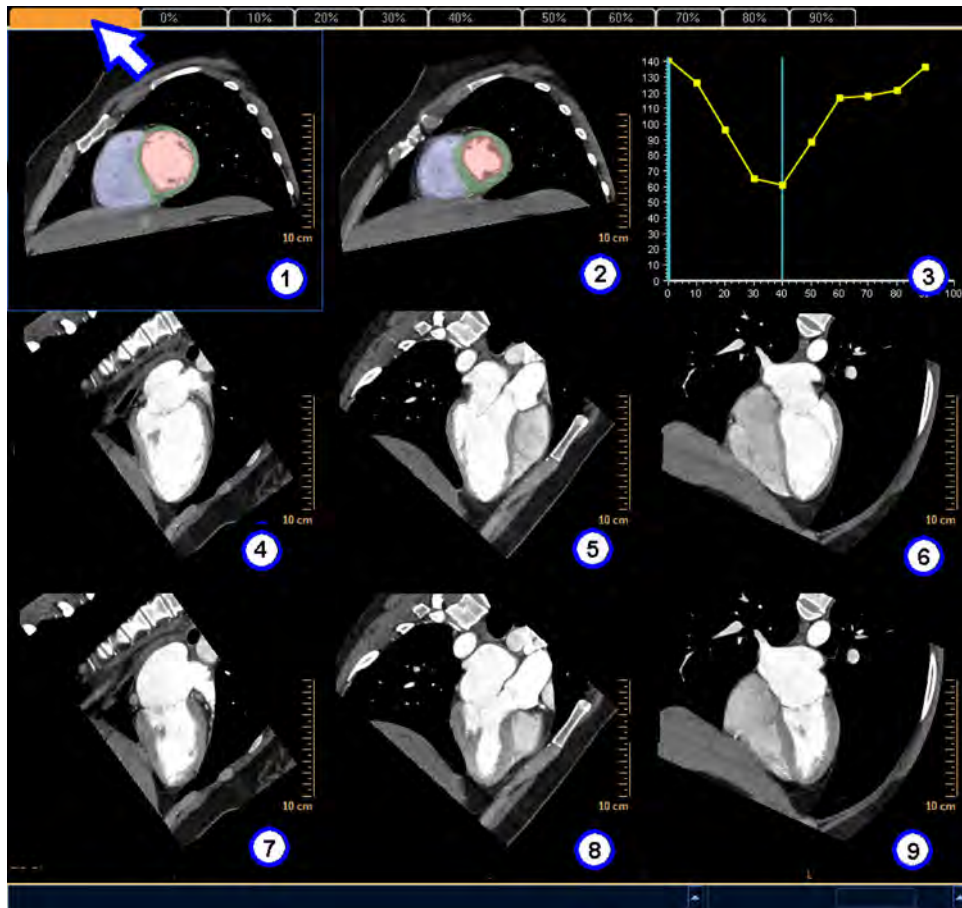
The Wall Thickening map represents the percent change in wall thickness between the two extreme phases in the cardiac cycle, ES and ED, or between a phase where the muscle is most contracted and a phase where it is most relaxed. The change is measured in percent relative to the ED wall thickness.



Compare Phases

Click the **ED/ES phase** tab in the upper left corner of the display (see the arrow in the graphic below) to compare ES\ED phases. The screen has 9 regions:

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Viewports 1 and 2*

These are the ED and ES short axis views. You can scroll to any height along the LV long axis, from the apex to the base.

Viewport 3*

This is the LV volume graph. You can also display the Polar Maps using the right click menu in this viewport.

Viewports 4, 5, and 6*

These viewports show images of the ED phase, with (from left to right) the 2-chamber view, the 3-chamber view, and the 4-chamber view.

Viewports 7, 8, and 9*

These viewports show images of the ES phase, with (from left to right) the 2-chamber view, the 3-chamber view, and the 4-chamber view.

*Only time-mode Cine is available in the above viewports.

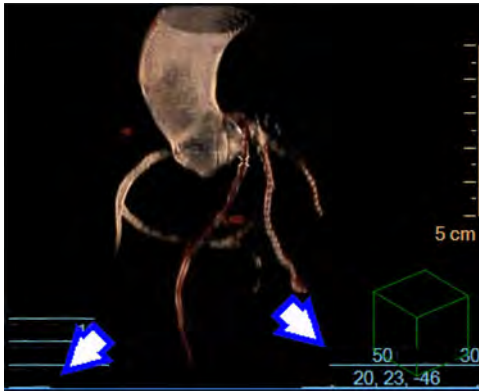
TAVI Volume View

Use the viewing mode to optimize the view angle for the TAVI procedure in Cath Lab. The control sets the image angles at LAO 50, Cranial 30 (an angle which presents a plane almost perpendicular to the annulus plane).

NOTICE

This plane is not detected automatically. Adjust as necessary to find the perpendicular to the annulus plane.

The TAVI mode includes the Aorta and coronaries in a semi-transparent view.



Myocardial Defects Assessment

Note: The Myocardial Defects Assessment application is not available for sale in the EU market.

Myocardial Defect Assessment (a purchasable option) provides visual and quantitative assessment of segmented, low-attenuation defect areas within the myocardium from a single, gated cardiac CTA scan (retrospectively-gated spiral or Step & Shoot Cardiac).

The Defects Assessment is based on the segmentation extracted within the Segmentation stage. See section “Segmentation Stage” on page 126.

**WARNING**

The Defects Assessment analysis is based on the segmentation of the myocardium. Please verify the myocardial segmentation correctness, and correct if required.

Defect Assessment provides visual assessment of low-attenuation deficits within the left-ventricular myocardium via the following:

- Color maps shown in short axis views.
- Segmentation maps shown on short-axis and polar plots, displayed along with long-axis reference images
- A volumetric visualization of coronary arteries along with a segmentation maps displayed as an overlay on top of a 3D myocardial surface.

- Quantitative information provided includes (1) the volume of low attenuation areas within the myocardium based on the various maps and (2) the percentage of the defects volume out of the total myocardial volume.

Scan Requirements

You can use standard Cardiac gated CT scans with contrast. No changes are required to the acquisition protocol.

Cautions and Warnings



CAUTION

You should use diastolic cardiac phases for assessment. The algorithm is optimized for diastolic phases (around 75%). While the application can be used with any phase, non-diastolic phases may find more false positive values.



WARNING

The results of Defects Assessment should not be used as a **SOLE** basis for diagnosis.

Verify the correctness of the myocardial segmentation and, when required, correct it manually using the tools in the Segmentation stage.

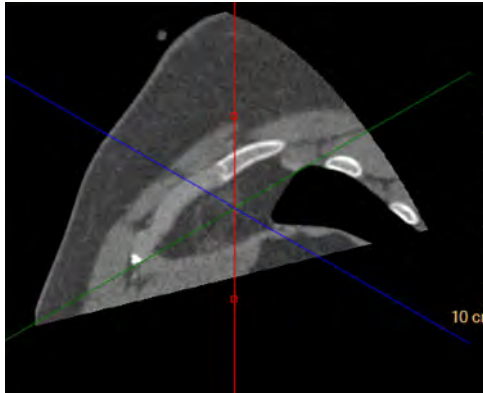
In areas with artifacts, such as beam hardening artifact, false positive results may be present. Several locations in the myocardium are more prone to such artifacts, especially the basal infero-lateral wall. Therefore, all potential defects require visual confirmation by the user. Below is a list of typical characteristics of true defects:

- A crescent shaped appearance.
- Sub-endocardial location, appearing on more than 1 phase.
- Occurring in the distribution of a coronary artery territory (though there is yet no evident correlation between severe stenosis and myocardial defects).

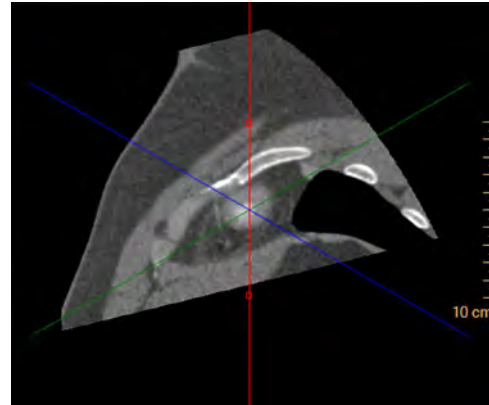
Set Apex and Base Locations

The assessment algorithm works on short axis slices with closed myocardium. Therefore, it is recommended to locate the apex and base at the proper locations, using LV/RV Corrections. See section “LV/RV Correction Function” on page 198.

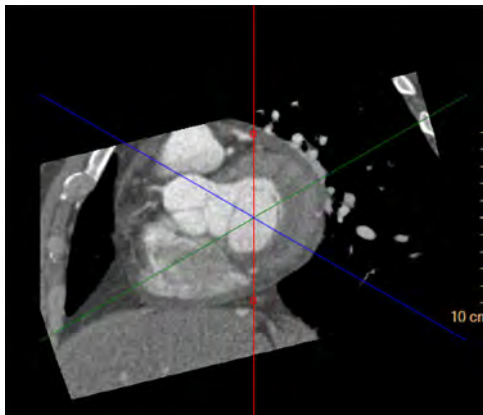
Apex - Wrong Location



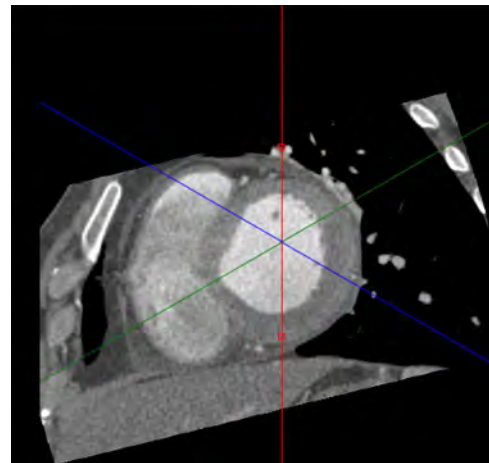
Apex - Recommended Location



Base - Wrong Location



Base - Recommended Location



Myocardial Defects Assessment Workflow

1. Load several cardiac phases of a patient study to CCA. (If you load only one, the diastolic phase is preferred.)
2. Make sure the myocardium is segmented correctly. If not, correct it using the correction tools in the Segmentation stage. See section “Segmentation Stage” on page 126.
3. Access the Functional stage.
4. Access the LV/RV Corrections tab and place the base and apex indicators at locations where the myocardium has a form of closed ring. Also make sure the vertical axis line is located in the center of the left ventricle.
5. Access the Defects Assessment tab. The Myocardial Defects Assessment function is processed and the results are presented.
 - The viewing parameters are optimized for display of myocardial defects. (The thickness changes to 6 mm, the windowing is automatically adjusted based on the myocardial HU values, and the rendering is changed to “Average”.)

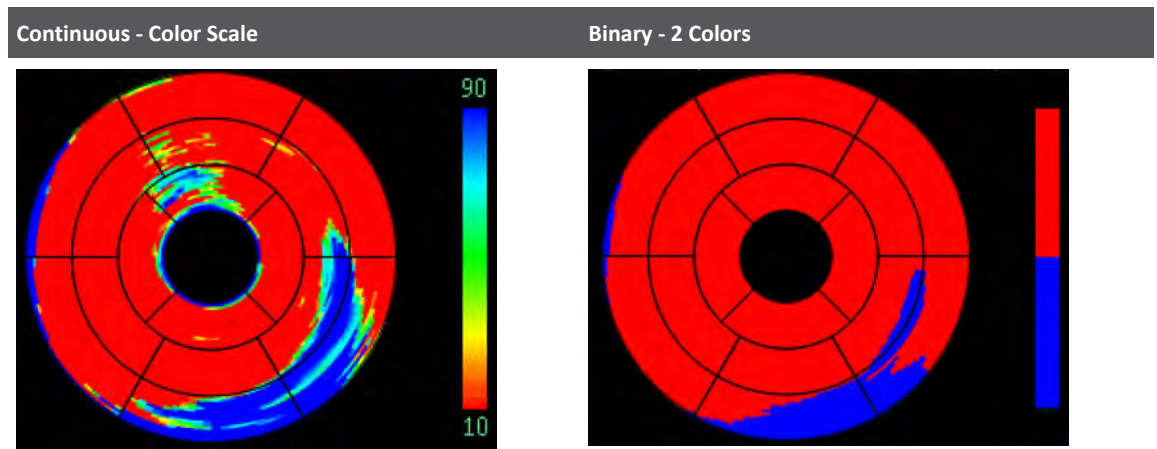
- The Polar map displays the “Defect Probability” perfusion map.
- The short axis images are displayed with a “Defect Probability” overlay.
- The volume image displays the “Perfusion” surface rendering image with the coronary arteries on top. The surface colors are based on the Perfusion map.

Defect Assessment

On the Defect Assessment Tab, the method option selects between:

- Defect Probability map;
- HU map; and
- Endo-Epi map.

The Mode option allows switching the Perfusion map display as shown below:



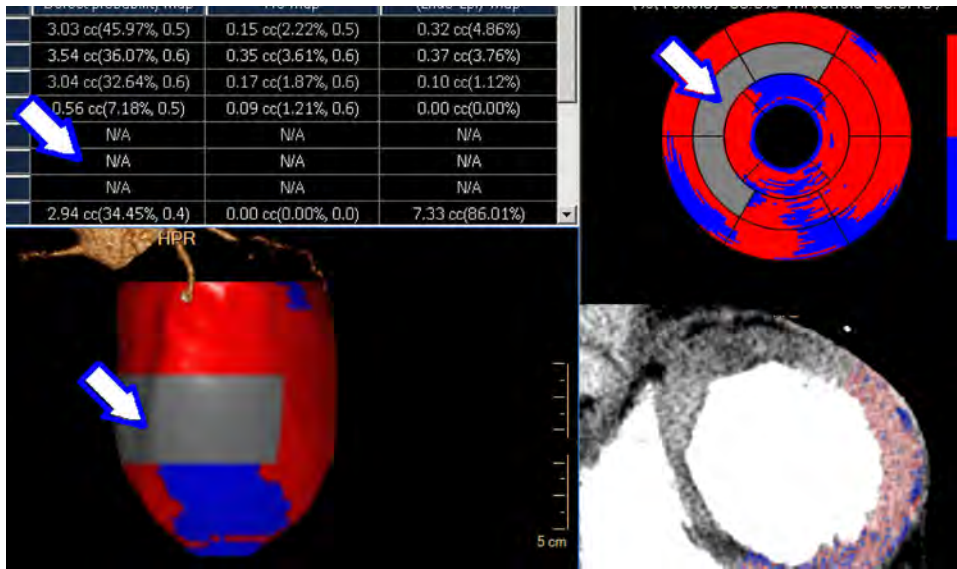
Remove Segments

Use this function to remove myocardial segments from the analysis. This is useful if a segment was marked as defect but is actually an artifact.

- Click **Remove segments**.
- Or:
- Click the segment in the Measurements table.
- The segment is removed from the calculations.

Excluding segments is also possible from a right click menu in all the images in Perfusion mode. Default - all segments checked.

The removed segment(s) are displayed in grey on the surface rendering image and on the Polar Maps to indicate that they do not participate in the statistical measurements.



The segment removal operation is equivalent to marking the “abnormal” voxels as “normal.” The removed segment(s) are not taken into consideration in Myocardial Defect measurements, as follows:

- In the "Total volumetric summary table" the voxels of the findings coming from the removed segment are ignored.
- In the "Segments volumetric summary table" the removed segment row is marked “N/A.”
- In the "Segments table - Perfusion map values" the removed segments appear in parentheses.

Add Segments



To return the segments into the analysis:

Click **Include** segments.

Click on the relevant segment in the table.

Or:

Select the include function from the right click menu.

Perfusion Maps Right-click Menu

You can switch between the 3 available Perfusion maps.

Reset Color Scale

When choosing this option - the color scale of the active map is back to the default color map scale values.

Segments Numbers

Displays the myocardial segments numbers of each of the segments.

Show Number

Displays the current perfusion map average numbers within each segment

Display Results Table

Three tables of results are available. (The table is not displayed by default. Click the **Tables** button to display it.)

Defect Assessment Layouts

There are various ways to switch between available layouts:

- use the Layout function
- use the right click menu; on the Polar map;
- use the viewport control on the short axis images; and
- use the tabs in the Perfusion map viewport.

Switching between layouts may change the way Polar map, the short axis overlay, and the volume image color-map are displayed. (You can change the way the maps and overlays appear, as described in “Selecting Presentation Methods,” in the next section.)

Layout with Two Short-axis Viewports

This displays two short axis images – one with the overlay and one without the overlay, to allow better verification of the overlay correctness.

Layout with 6 Short-axis Images

The images are evenly distributed along the left ventricle – from base to apex. The long axis view displays vertical lines indicating the displayed short axis images locations. Upon activating a short axis image - the orange line indicates the active short axis image. You can move the upper and lower lines and change the coverage of the short axis images displayed.

All Perfusion Maps

This layout displays all the perfusion maps, one next to the other.

Results Presentation Methods

There are several ways to switch between the Results methods:

- Use a drop down list on the toolbox: Perfusion maps.
- Use a right click menu on the Polar map.
- Use a viewport control on the short axis images.
- Use the tabs in the Perfusion map viewport.

Switching between the methods changes the Polar map display, the short axis overlay and the volume image color-map to the chosen method.

- Defect Probability map;

- HU map; and
- Endo-Epi map.

Mode

You can choose the mode of the maps and overlays between Continuous and Binary, or the right click menu on the Polar maps.

Defect Assessment Results

The calculation method of the Endo-Epi and Defect Probability maps first checks all the myocardial radial rays from the Endo and from the Epi directions and removes all the voxels which are not in the range of [-10 150] HU. This is done to exclude the LV contrast and the pericardial fat from the analysis. This may cause holes in the short axis overlay.

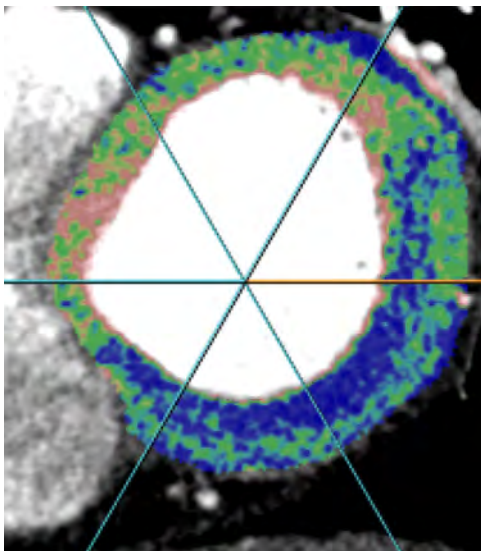
Polar Maps and Short-axis Images

Clicking on a Polar map displays the relevant short axis image.

Spoke Wheel



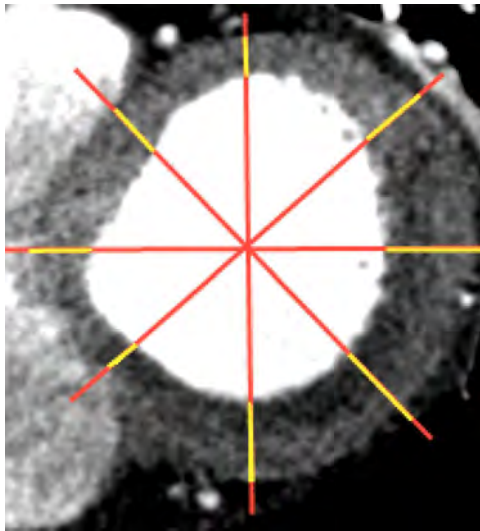
The “Spoke wheel” display can be activated on the short axis images. The spoke wheel provides addition relation between the Polar map and the short axis images:



You can rotate the spoke wheel to edit the separation of the Polar map into the different anatomical segments.

Schematic Rays

The analysis is performed along radial rays, originating at the center of the LV. The yellow parts of the rays (the ones within the myocardium) are used for the analysis.



Defect Probability Polar Map Continuous

Each voxel of the myocardium is classified as a defect or as a normal tissue. The classification is calculated using an algorithm which detects Gaussians within the myocardial voxels distribution using statistical analysis methods. The pixels with probability of being a defect higher than 0.5 are classified as defect. Each ring of the Polar map represents the % of pixels calculated along radial rays in the endo region at a certain short axis view which are classified as defect.

Prior to Performing Statistical Analysis

The HU values within the myocardium are normalized, to remove a radial linear gradient which normally exists within the myocardium making the endo HU values higher than the epi HU values.

Parameters

Normalized HU Threshold: The default normalized HU threshold value, used for the classification, is calculated as part of the Perfusion algorithm

User Input

It is possible to change the classification into defect/normal using a 'Normalized HU Threshold' viewport control located on the short axis image. The HU value is marked with an * to indicate that this is not a simple but a normalized HU threshold. The change influences both Polar map and the overlay on the short axis image.

Scale

Colors: High percentage is blue, low percentage is red and everything in between is continuously changed from red to blue through yellow and green.

Defect Probability Polar Map Binary

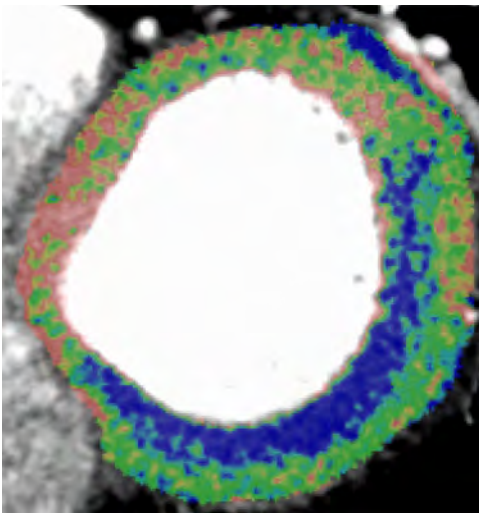
All the values above a certain threshold of % are colored in blue and all the values below this threshold are colored in red.

Parameters

%Threshold: The default threshold of % is 50%.

Defect Probability Overlay Continuous

The overlay colors each voxel of the myocardium in the short axis image according to its probability to be a defect.



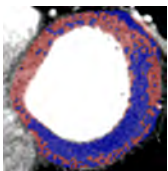
Parameters

The normalized HU Threshold viewport control allows changing the threshold of the HU used for calculating the overlay. To change the threshold type in a value or use the up/down arrows. The threshold is shared between the Polar map and the short axis overlay. The default threshold is provided by the algorithm.

Colors

The colors of the pixels represent the probability of the pixels to belong to a defect. The highest probability is colored in blue and the lowest probability is colored in red.

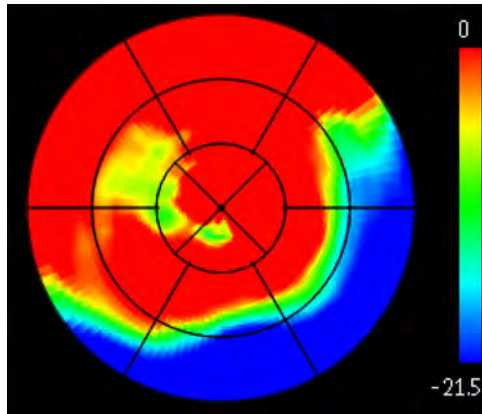
Defect Probability Overlay Binary



All the voxels classified as defect are colored in blue and all the voxels classified as normal are colored in red. The pixels with probability of being a defect higher than 0.5 will be classified as defect.

Endo-Epi Polar Map Continuous

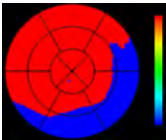
The myocardial wall is divided into epi and endo areas. The mean HU value of the epi and endo pixels along each ray is calculated. Then the values are subtracted: mean (endo)-mean (epi) and a value is calculated for each ray.



Scale: Colors

Low Endo-Epi values (negative) are blue, high Endo-Epi values (close to zero) are red and everything in between is continuously changing from red to blue through yellow and green. It is possible to change the scale lower bound using the scale parameter on the short axis viewport.

Endo-Epi Polar Map Binary



All the values above a certain HU threshold are colored in red and all the values below this threshold are colored in blue. It is possible to change the binary threshold using a viewport control.

Endo-Epi Overlay Binary

All the radial rays within 3 degrees below a certain threshold are colored in blue and all the rays above this threshold are colored in red, as in the relevant Perfusion map.

Parameters

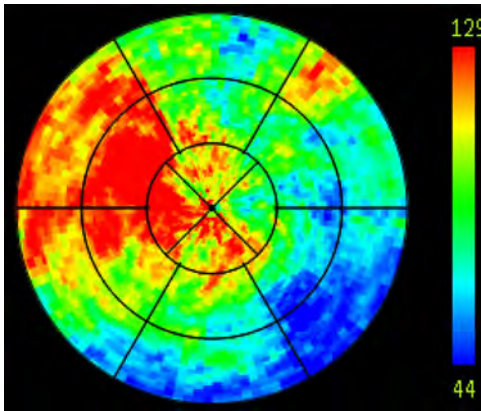
Same as the binary Polar map. See section “Endo-Epi Polar Map Binary” on page 221.

Scale

Same as the binary Polar map. See section “Endo-Epi Polar Map Binary” on page 221.

HU Polar Map Continuous

Each ring of the Polar map represents a mean HU value calculated along the radial rays at a certain short axis view.



Colors

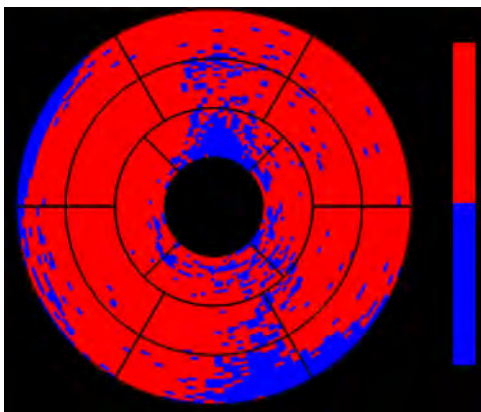
Blue represents the lowest HU values, red represents the highest. The colors gradually change from blue to red through green and yellow.

Scale Range

The default middle of the scale is the peak of the HU histogram of all the voxels of the myocardium. The width is $\pm 75SD$. It is possible to change the scale of the colors using the "Scale" viewport control (slider) on the short axis image. The number in this viewport control indicates the middle of the scale.

HU Polar Map Binary

All the values above a certain threshold are colored in red and all the values below this threshold are colored in blue.



Parameters

HU Threshold: The default threshold is: (The peak of the HU histogram of all the voxels of the myocardium-0.5 SD) It is possible to change the threshold using a 'Threshold' viewport control located on the short axis image.

Defect Assessment Measurement Tables



Three measurements tables are available. Switching between the tables is done using the Show Table drop-down on the toolbox:

- Total volumetric summary table;
- Segments volumetric summary table; and
- Segments - Perfusion map values.

After you activate a table, the Polar maps change to Binary mode.



WARNING

Artifacts may be included in the calculations displayed in the table. Please verify the defects segmentation correctness using the binary maps and the overlay on the short-axis images.

Volumetric Summary Table

	HU	Finding probability Percentage map	Endo-Epi map
Volume of Myocardial finding	The volume of all voxels in the rays identified as findings. Rays are classified as “findings” when the average HU value of the ray is below the calculated HU threshold.	The volume of all the voxels within the rays identified as findings. Rays are classified as “findings” when the % of the high probability voxels is higher than the binary map % threshold (default=50%).	The volume of all the rays whose Endo-Epi ratio is below a certain threshold.
%Volume of Myocardial finding	The % of the finding volume, out of the total myocardial volume being analyzed in Defects Assessments mode.	The % of the finding volume as calculated from the Defects probability map out of the total myocardial volume.	The % of the finding volume as calculated from the Defects probability map out of the total myocardial volume.

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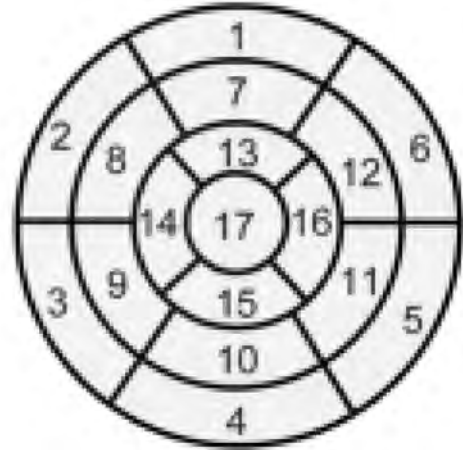
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	HU	Finding probability Percentage map	Endo-Epi map
Transmurality ratio	Defined as: (the number of voxels below the threshold within the rays identified as findings) - (divided by) - (the number of all the voxels within the rays identified as findings) This is an indication of whether the finding is transmural or not - ratio close to 1 means it is a transmural finding, or an artifact.	Transmurality ratio is calculated – the same as in HU map.	
Thresholds	The relevant HU threshold used to calculate the volume. The threshold is the same HU threshold as the one used for the binary HU map. When changing the threshold of the binary HU map the table is updated accordingly.	The relevant normalized HU threshold (marked by *), and %threshold used to calculate the volume. When changing the threshold value using the viewport control on the short axis image, or the settings dialog, the table updates accordingly.	The relevant HU threshold is used to calculate the volume. This is the same HU threshold that is used by the binary Endo-Epi map. When changing the Threshold - the table updates accordingly.

Segments - Volumetric Summary Table

1. Basal Anterior
2. Basal Antero-septal
3. Basal Antero-septal
4. basal Inferior
5. Basal Infero-lateral
6. Basal Antero-lateral
7. Mid Anterior
8. Mid Antero-septal
9. Mid Infero-septal
10. Mid Inferior
11. Mid-Infero-lateral
12. Mid Antero-lateral
13. Apical Anterior
14. Apical Septal
15. Apical Inferior
16. Apical Lateral
17. Apex

The segments table summarizes the measurements for each myocardial segment.



The volume, %volume and transmural ratio is calculated using the same method as in the volumetric summary table, except they are calculated separately for each myocardial segment.

Segments - Perfusion Map Values Table

This tables display the values of the Polar maps at each segment.

1. Basal Anterior
2. Basal Antero-septal
3. Basal Antero-septal
4. basal Inferior
5. Basal Infero-lateral
6. Basal Antero-lateral
7. Mid Anterior
8. Mid Antero-septal
9. Mid Infero-septal
10. Mid Inferior
11. Mid-Infero-lateral
12. Mid Antero-lateral
13. Apical Anterior
14. Apical Septal
15. Apical Inferior

16. Apical Lateral

17. Apex

Settings Dialog

The Settings dialog allows changing some of the default settings of the Myocardial Defects Assessments application.

- **Viewing Settings.** You can configure the default thickness and default window width upon opening Defects Assessment.
- **Perfusion Map Settings.** You can configure the algorithm parameters. Define the default threshold for the % of the “finding” voxels within each ray. This threshold is used to define which ray should be counted as part of the finding in Defect Probability method.

Glossary

BSA	Body Surface Area
LV	Left Ventricle
RV	Right Ventricle
LA	Left Atrium
RA	Right Atrium
Phase	A portion of the heart cycle, expressed as a percent (%), where 0% is the End-Diastole phase.
ES	End-Systole - the end of the pumping (ejecting) phase of the left ventricle; occurs at the end of the T-wave on an ECG. Usually occurs at about 40%.
ED	End-Diastole - the end of the filling phase of the left ventricle; this occurs just before a contraction. Usually occurs at about 0%.
Diastasis	The phase which precedes the atrial contraction (mid-diastole)
SV	Stroke Volume - the difference between end-diastolic and end-systolic volumes of blood ejected with each beat.
EF	Ejection Fraction - the fraction of blood pumped out of the ventricle with each heart beat. The EF = the stroke volume divided by the end-diastolic volume, expressed as a percent (%).
CO	Cardiac Output - The amount of blood that is pumped by the heart per unit time, measured in milliliters per minute (ml/min).
ED volume	The volume at ED phase - the biggest volume of the ventricle during the heart cycle.
ES volume	The volume at ES phase of the heart - the smallest volume of the heart during the heart cycle.
Echocardiogram	An echocardiogram (often called "echo") is a graphic outline of the heart's movement. During this test ultrasound waves provide pictures of the heart's valves and chambers. See previous section.
Apex	The conical tip of the heart which is usually its most caudal point.

Base	That part of the heart that lies opposite the apex, formed mainly by the left atrium but to a small extent by the posterior part of the right atrium; it is directed backward and to the right and is separated from the vertebral column by the esophagus and aorta.
Mitral valve	The valve between the left atrium and the left ventricle of the heart.
Aortic valve	The valve separating the aorta from the left ventricle of the heart.
Valve plane	Valve plane in the context of Cardiac Axes is the Mitral valve plane.
Long axis	A cut along the long axis of the heart. The long axis is defined as the axis passing through the middle of the left ventricle - through the apex and the mitral valve.
Short axis	A cut along the short plane of the heart, orthogonal to the long axis. Allows you to see a cut of the left and right ventricles.
Wall mass	Myocardial mass.
Wall thickness	Myocardial wall thickness in the radial direction (in short axis plane).
Wall thickening	The change in wall thickness between ED and ES phases.
Wall motion	A measure of regional myocardial function.

Report Clinical Results

The Report Clinical Results option in CCA provides a way to send patient findings to the Report application according to SCCT guidelines.

Background

The Society of Cardiovascular Computed Tomography (SCCT) published “SCCT Guidelines for the interpretation and reporting of coronary computed tomographic angiography” in the March 2009 edition of the Journal of Cardiovascular Computed Tomography (Raff, March 2009, JCCT).

The article was published after a multi-disciplinary 10 member group comprising Cardiologists, Radiologists and Researchers spent in excess of 12 months developing Interpretation and Reporting Guidelines.

The objective was to standardize how to appropriately read, interpret and diagnose coronary computed tomography angiography (CCTA) studies and thereby develop systematic standards of practice for CCTA Interpretation and Reporting.

The standards of practice in turn is anticipated to lead to diagnostic information provided to the treating Physician that has as much clarity and accuracy as possible.

Structured reporting therefore assures quality and consistency from site to site and Physician to Physician.

The reporting workflow in the CCA application includes all the required and recommended reporting data, and also some of the optional items described in the guidelines.

Using Report Clinical Results

You can use Report Clinical Results in all CCA work stages.

You can use Report Clinical Results in addition to the usual Reporting functions in all applications.

When using Report Clinical Results in the Functional Analysis stage, all relevant measurements available in that stage are added to the report. The reported measurements change depending on the method selected (Segmentation or Simpson).

Information Forms

Various forms are provided for you to enter CCTA data (results, patient history, comments, and other information).

Not all forms are available in all stages.

Form - Risk Factors, Clinical History and Patient Parameters and Information

Enter relevant patient information in the Risk Factors form and click OK when finished. The information is added to the report.

List: Factors, History, Parameters and Information

Risk Factors	Diabetes Mellitus; Hypertension; Hypercholesterolemia; Pulmonary Disorders; Family History; Obesity; Smoker, Present or Former; Alcohol; Sedentary Lifestyle
Clinical History	Asymptomatic; Unstable Angina; Stable Angina; Atypical Angina; Atypical Chest Pain; Dyspnea; Previous Myocardial Infarction; Other (type in); Previous Coronary Revascularization; Bypass Surgery; Balloon Angioplasty; Coronary Stenting
Patient Parameters	Arrhythmia - was there an arrhythmia during the scan?; Complications - were there any complications during the scan?; Height - taken from the DICOM or user input; Weight - taken from the DICOM or user input

Form: Additional Information

If desired, you can add more information using the “Additional Information” dialog. Then click **OK** - the information is added to the patient report.

List: Additional Information

Scan Quality and Artifacts	Overall Quality, presence and type of artifact and effect on interpretation.
Cardiac Chambers Abnormalities, Abnormal Chamber Dilation	Masses, thrombus, shunts, LV Size and Volume, other structural disease. LV size can be manually measured on the image and then sent to the Report. For LV Volume calculation - use ‘calculate volume’ tool in the Segmentation Stage according to selected phase, etc.

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Non Coronary Cardiac Abnormalities	(available only in Functional stage) Myocardium - LV Wall motion, LV Ejection Fraction, ED LV Wall thickness, Pericardium - Abnormal thickness, calcification, effusion, etc.
Non Coronary Vessels abnormalities	Abnormalities in Lungs, mediastinum, esophagus, bony structures, chest wall, etc.

Add to Report (using SCCT guidelines)

The "Add to Report - according to SCCT guidelines" window allows you to report findings using the standardized Axial Coronary Anatomy schematic image.

Coronary Extraction and Coronary Analysis Stages

The "Add to report..." dialog opens when you select Report Clinical Results in the Coronary extraction and Coronary Analysis stages. This dialog allows choosing the vessel name and selecting the relevant findings for that vessel. You can keep the "Add to report . . ." dialog open and examine the vessel and manipulate the images in the CCA application. The vessel you select in the report activates the corresponding vessel in CCA application.

Reported Segments



The schematic Axial Coronary image displays a schematic drawing of the various segments and adds arrows pointing at the reported segments: Blue arrow means normal stenosis grading; red arrow means stenosis grading different than normal.

Segment

The dialog allows reporting the condition of various vessels segments The Segments drop down allows to select one of the segments belonging to the currently active vessel. The example at left shows RCA segments. The segment names and number are according to SCCT guidelines.

Stenosis Grading

The dialog allows reporting the condition of various vessels segments The Segments drop down allows to select one of the segments belonging to the currently active vessel. The example at left shows RCA segments. The segment names and number are according to SCCT guidelines.

Stenosis Grading Types

There are 3 types of grading.

Quantitative

Only the Quantitative checkbox is checked.

Qualitative

Only the Qualitative checkbox is checked.

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Combined

Both check boxes are checked.

Add Findings to Existing Report

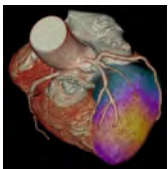
You can keep adding new CCTA data during multiple CCA sessions. When you select the Report Clinical Results option:

- If there are no existing CCA reports for the current patient, the procedure starts with the Risk Factors, Clinical History & Patient Parameters & Information window, shown on the next page.
- If one or more reports exist for the current patient, clicking Report Clinical Results brings up a selection window (shown below). From this window, you can continue editing an existing report, or you can Create a new report.

After you select either option, the procedure advances to the Risk Factors, Clinical History & Patient Parameters & Information window, shown on the next page.

NOTICE

When adding findings to an already existing report, the information already contained in the report will not be removed. New information generated by the Report Clinical Results function will be added to the existing report.

PET/SPECT Support in CCA

The CCA application supports Nuclear Medicine (NM) image data within the Functional stage only. Support for PET/SPECT includes viewing tools, the Fusion mode, dedicated layouts, PET/SPECT/Fused colormaps, and image manipulations.

Loading NM images by themselves into CCA is prevented.

When you load PET/SPECT data along with CT data, the Functional stage displays CT, PET/SPECT, and Fusion tabs across the top of the image viewport window. If the loaded series were not auto-fused, you can fuse between the CT and SPECT/PET series using the phase tabs (similar to the way Cardiac Viewer works).

NOTICE

For additional information about PET/SPECT support in IntelliSpace Portal, refer to the "Cardiac Viewer" and "CT Viewer - Fusion mode" sections in the "Review" volume.

NM Data for Viewing

The CCA application is optimized to use data that was reconstructed using transverse orientation.

Using short axis reconstructed data is not recommended.

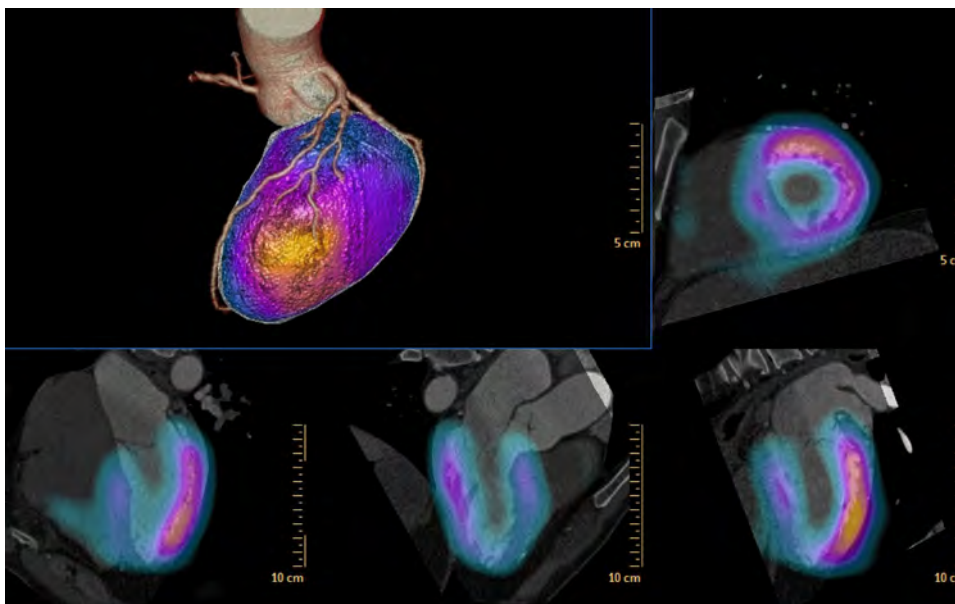
The CCA application is designed to combine Cardiac CTA images with PET/SPECT data.



WARNING

When loading data into an application, ensure the orientation shown on the images is consistent with the images' appearance. This precaution is required for data that contains wrong orientation information because the data will be incorrectly presented within the application. For example: Legacy nuclear medicine volume data (SPECT or PET) reconstructed using cardiac orientation may not encode the orientation information correctly.

When you select the fused series, the display appears as shown below:



Use the "LV/RV Corrections" tab to correct the short and long axes orientation, if required. See section "LV/RV Correction Function" on page 198.

Phase Tabs

Each series loaded to CCA is represented by a phase tab along the top of the main display window. The CT, PET/SPECT, and Fused series are color coded to identify the modality and status of each series.

Fuse Series

1. Click on the first series phase tab (CT or PET/SPECT).
2. Hold the <Ctrl> key and click on the second series phase tab (PET/SPECT or CT).

3. Right click and select the Fuse option from the context menu. The two series are fused and an additional tab starting with "Fused" is added on the top of the screen.

Fuse Multiple Series

You can create more than one fused series and switch between the fused series using the phase tabs.

Fused Image Viewports

All parameters in the table and graph are calculated based on the CT data.

In the fused image, it is possible to change the opacity of the myocardium using the "Myocardium opacity" viewport control.

In the 3D (volume) image of the full heart, you can switch to the Fusion LV+Heart image.

You can scroll the fused short axis images using the <left+middle> mouse in the viewport. Alternately, you can grab and move the green line on the long axis images.

The main viewport opens by default with a split viewport: Results table on top, Volume rendered fused image on bottom. Turn the table off to view the large volume image only. Also included are:

- Graph viewport / Polar map.
- The short axis image with colored tissue overlays (which can be turned off).
- Reference viewports show cardiac axes images through the LV axes, typical of echo cardiographic planes. From left to right they are 4 chamber, 3 chamber, and 2 chamber images.

Viewing Large Fusion Image

If you turn off the table in the Functional stage, the volume fused image is enlarged.

Fusion and PET/CT Color Maps

You can select color maps for fused images using:

- the Fusion tab in the Functional work stage; and
- using a right-click menu in any viewport.

See the "CT Viewer - Fusion mode" section in the "Review" volume for more information about color maps.

Change Fusion Color Maps



The Fusion tab contains tools for working with fused series.

Click the left and right arrows to change the color map of the PET/SPECT series (not the fused series). Repeated clicking scrolls through the available color maps.

Click the left and right arrows to change the color map of the PET/SPECT data on the fused series.

The blending slider controls the proportion of the two image types (CT and PET/SPECT) in the display.

While observing the fused display, move the blending slider to create the desired image. In the slider's farthest left position, the CT image is most prominent. In the slider's farthest right position, the PET/SPECT image is most prominent.

Right-click Option

You can select color maps from the right-click menu in any viewport.

PET/CT Image Registration

The PET/SPECT image can be offset and/or rotated to any direction or orientation relative to the CT image using two methods: 1) interactively, using the Pan and Rotate buttons in the Fusion tab and 2) using the type-in Offset and Angle function.

NOTICE

It is recommended to pre-register the data using software with more automatic registration tools, such as Auto Registration on the Extended Brilliance Workspace NM. The registration is done using the "Fusion" tab. The registration corrections are propagated to other fused series.

Cardiac Axes Definition

The CCA application uses CT data to determine the orientation of the Short axis, Horizontal long axis (4 Chamber View), and Vertical long axis (2 Chamber View). The cardiac axes orientations determined from the CT data are then applied to the PET/SPECT dataset.

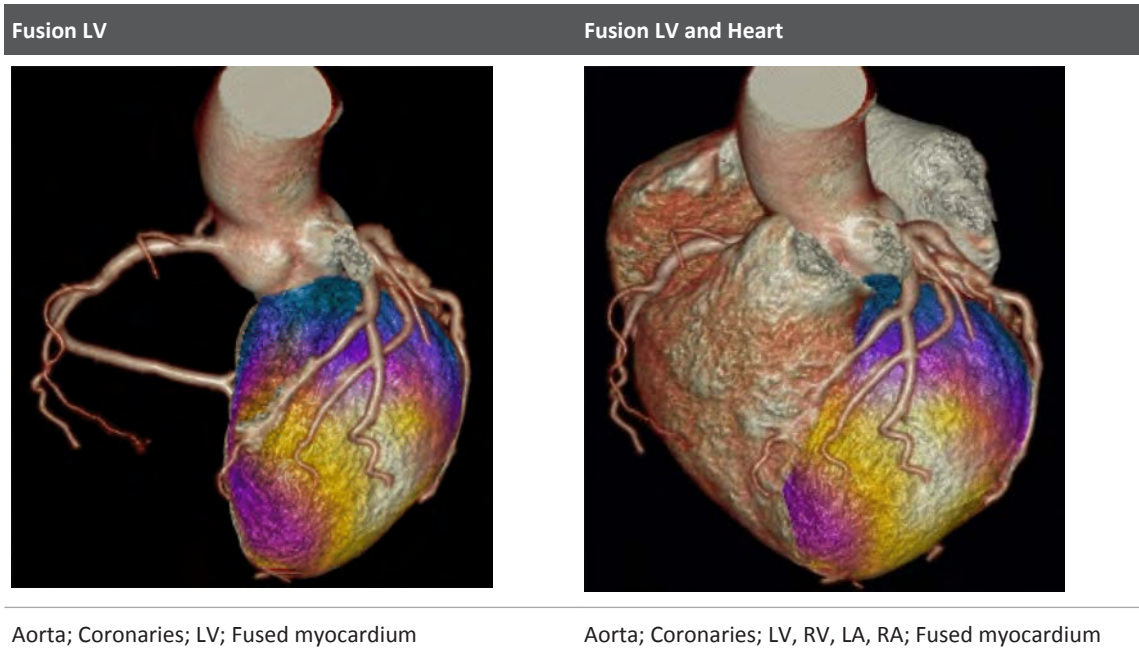
NOTICE

To edit the Cardiac Axes orientations use the Functional Analysis tab, Correct Axes mode.

Fusion Viewing Mode

When you activate a fusion series, the surface of the CT volume image displays the Fusion viewing mode.

- This mode combines the information from the CT and the SPECT/PET series.
- The myocardial 3D tissue, which is extracted from the CT heart segmentation, is shown with the colors derived from the NM SPECT/PET series.
- The rest of the heart tissues are displayed using the CT volume rendering display:



The NM texture is calculated using the average value along the radial rays of the myocardium, within the myocardial segmentation.



WARNING

In case of myocardial perfusion deficits presence in the bottom part of the apex, those defects may not be clearly shown on the fused CT+NM volume display. Please use the MPR images to examine the apical area.



WARNING

The correctness of the fused view depends on the correctness of the registration. Verify the registration of the CT and PET/SPECT images using the short/long axis images. Use the registration tools in the Fusion tab to correct the registration, if required.



WARNING

Any shift between the CT and NM data may change the color-coded fused volume display and may potentially affect the appearance of the perfusion deficits.



CAUTION

When changing the color-map display on the fused images using the middle mouse button, the visual appearance of the myocardial fused volume display is affected. It may potentially modify the appearance of the perfusion deficits within the myocardium.



CAUTION

In order to get an accurate myocardial representation on the fused volume image, the segmentation of the myocardial tissue must be accurate. Please verify the correctness of the myocardial segmentation prior to using the Fusion tools.

Change Fusion Views

Use the Fusion LV viewport control to switch between three fusion views:

- All
- Fusion LV
- Fusion LV + Heart

Use the Myocardium Opacity viewport control to change the opacity of the fused Myocardium view separately from the rest of the tissues.

To change the volume rendering of all the tissues except the fused myocardium:

- point the mouse cursor into the viewport and use the middle mouse button;
- or:
- use the Volume Rendering protocols editor .

Fusion Relate



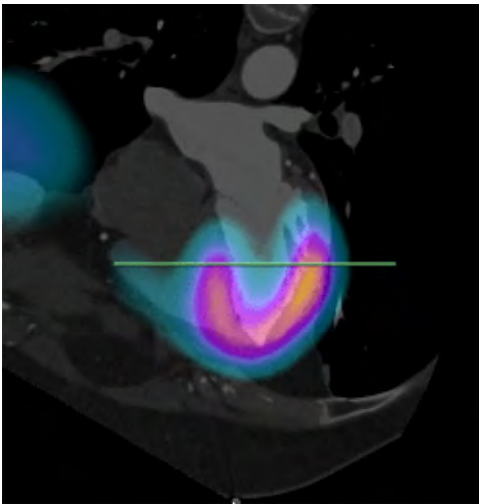
It is possible to apply the “Relate” functionality between the volume and the short axis images by placing a “Relate” seed on the volume image. A relate cursor then appears on the volume image and also in the corresponding location on the short axis images.

Indicate Short Axis Slice

A green reference line is added to the long axis images indicating the location of the current short axis slice.

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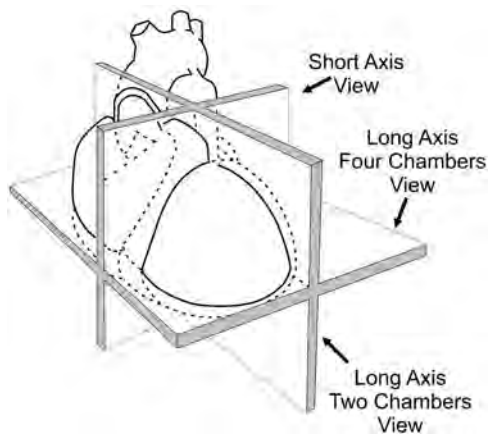
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Licensing

The fusion capabilities in CCA and Cardiac Viewer are protected by a user license called CCA – NM Fusion.

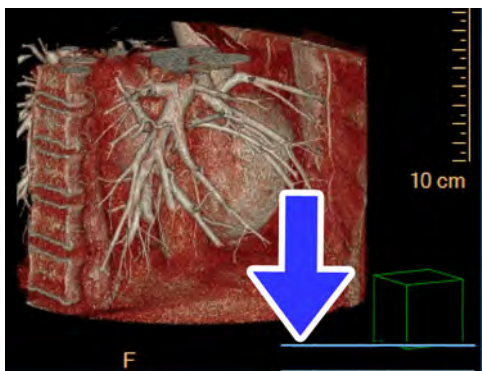
Cardiac Views



Adapted from M. Catherine M. Otto, Textbook of Clinical Echocardiography, 2nd Edition, W.B. Saunders Company, Philadelphia, PA, 2000, ISBN-7216-7669-3.

Modify Standard Cardiac Angles

Change the standard cardiac angles on the volume image to modify the orientation of the volume image. Select either from a preset option or enter exact angles manually. The angles are located in the lower right-hand corner of the volume image.



NOTICE

The standard cardiac angles may be modified on Volume images within the Cardiac Viewer, the Comprehensive Cardiac Analysis application, and the EP Planning application.

Use Preset Options

Use the preset options to adjust the common viewing angles. In the bottom right-hand corner of the image, click on the drop-down menu to select the viewing angle:

- RAO 30
- AP
- LAO 60
- LAO 60 Cranial 20
- Left Lateral
- LAO 45 Caudal 15
- RAO 45
- RAO 120 Cranial 10

NOTICE

In addition to setting the angles, use the Roll/Rotate tool to grab and rotate the image. The cardiac angles are updated in real time.

Manually Enter Angles

For a precise view, use the drop-downs and insert fields to enter the angles.

1. Select either **RAO** or **LAO** from the second drop-down menu.
2. Click in the field next to the RAO/LAO selection and enter the appropriate angle.
3. Select either **Caudal** or **Cranial** from the drop-down menu.

4. Click in the field next to the Caudal/Cranial selection and enter the appropriate angle.

6 CT Pulmo Auto Results

Introduction

CT Pulmo Auto Results is a fully automatic image analysis application that identifies several radiological findings (e.g. consolidation and ground-glass opacity) to support the management of adult patients with suspected or diagnosed COVID-19 pneumonia.

The CT Pulmonary Auto Results application segments and quantifies lung volume, as well as regions suggestive of pneumonia in adults.

Regions suggestive of pneumonia are classified as ground glass opacities (GGO) and consolidation areas. A quantitative assessment of the disease burden is performed and results are calculated and included in the generated images in a tabular format, automatically available for review on PACS.

CT Pulmo Auto Results is an automatic processing application, without a user interface. The application is applied automatically (based on user defined rules) on the input series, and generates a set of images which are then saved back to the defined location (which can be the PACS).

Key Features

The CT Pulmo Auto Results imaging application includes the following key features:

- Automatic lung segmentation (left and right lungs)
- Automatic segmentation of regions suggestive of pneumonia
- Automatic color-coded classification of findings
- Quantitative results in a table format
- Rotating batch of a volumetric rendered lungs (optional)
- Result series of segmentation in IntelliSpace Portal proprietary format (optional)
- Images are automatically sent to PACS, as additional series in the original study.
- Segmentation results are saved in proprietary format that can be further processed in IntelliSpace Portal.

Limitations for Use

NOTICE

- The physician retains the ultimate responsibility for making the final diagnosis based on image visualization, as well as any segmentation and measurement results obtained from the application. CT Pulmo Auto Results should not be used as the sole basis for clinical diagnosis.
- Depending on your IntelliSpace Portal configuration, this application may not be available.
- Only the original chest CT series should be used for diagnostic interpretation by physicians. CT Pulmo Auto Results output, including lung volume segmentation, findings volume segmentation, findings classification and quantitative results, should be verified and only used as an aid to interpretation.
- Incorrect DICOM headers or other factors can cause CT Pulmo Auto Results to reject an input CT series for processing, in which case no result is returned for viewing and there is a page with a failure notification. Physicians reading the original CT series should not be delayed based on the availability of the automated results.
- The CT Pulmo Auto Results application uses the DICOM header tags referring to Patient Position and Patient Orientation information. If the header tags are incorrect, the CT Pulmo Auto Results application might fail to process the series or might create results that are not optimal. If a failure occurs, additional information is provided as part of the automatic results.
- Users of the CT Pulmo Auto Results application should review all findings, even if not identified or segmented by the CT Pulmo Auto Results application.
- In the United States of America, the CT Pulmo Auto Results can only be used under the National Emergency Concerning the Novel Coronavirus Disease (COVID-19), and is not cleared by the FDA.
- CT Pulmo Auto Results is not yet approved in all markets. Please consult your Philips representative for more details.



CAUTION

- **The CT Pulmo Auto Results application is not intended to be used for COVID-19 screening or as a sole basis for COVID-19 diagnosis.**
- **Chest CT scans cannot be used as the sole basis for COVID-19 diagnosis due to the non-specific nature of the targeted radiological findings.**
- **Please consider the latest COVID-19 patient management and diagnosis guidelines when using this software.**

Main User Workflow

Valid Studies for CT Pulmo Auto Results

For optimal results in the CT Pulmo Auto Results application, the following acquisition parameters are recommended:

- Slice thickness \leq 3 mm
- Standard dose
- Supine patient orientation (FFS and HFS)
- Both lungs should be included in the scanned FOV



CAUTION

The CT Pulmo Auto Results AI algorithms were trained with the data as specified in the intended data type. Using other acquisition parameters may lead to failed processing or inaccurate results and should be avoided.

Creation of CT Pulmo Auto Results

Automatic Results Creation

It is possible to enable automatic results creation on the arrival of relevant data to IntelliSpace Portal.

Once relevant data (as configured in Preferences) arrives to IntelliSpace Portal, ISP recognizes the data as suitable for CT Pulmo Auto Results creation. The CT Pulmo Auto Results are generated in the background and are auto-sent to the DICOM devices configured by the user. For configuration information, see section “Configuration of CT Pulmo Auto Results” on page 242.

Manual Results Creation

It is also possible to activate the CT Pulmo Auto Results creation manually, from the Patient Directory of IntelliSpace Portal.

Right click on the relevant series within the study and select: **Run Processing > Automatic Pulmonary Assessment.**

The results series is created and is stored locally on IntelliSpace Portal and can be viewed/copied/deleted.

Configuration of CT Pulmo Auto Results

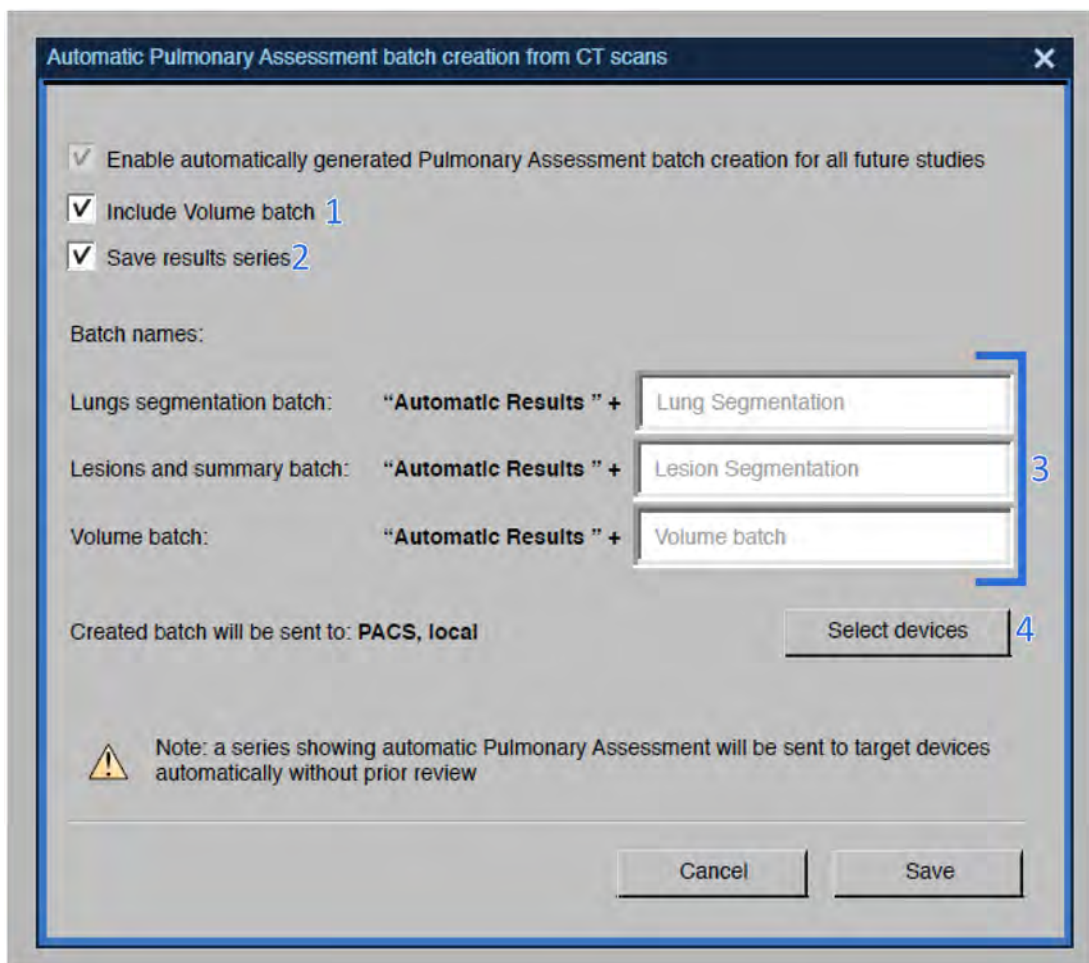
To configure CT Pulmo Auto Results:

1. Go to **Preferences** and select the **Processing** page.
2. Verify that **Enable Processing** is selected.
3. Verify that **Run processing according to the following** is selected.
4. Select the **Add** button.

A new processing rule is added to the table.

5. In the **Algorithm** column (first column), select **Automatic Pulmonary Assessment>>**

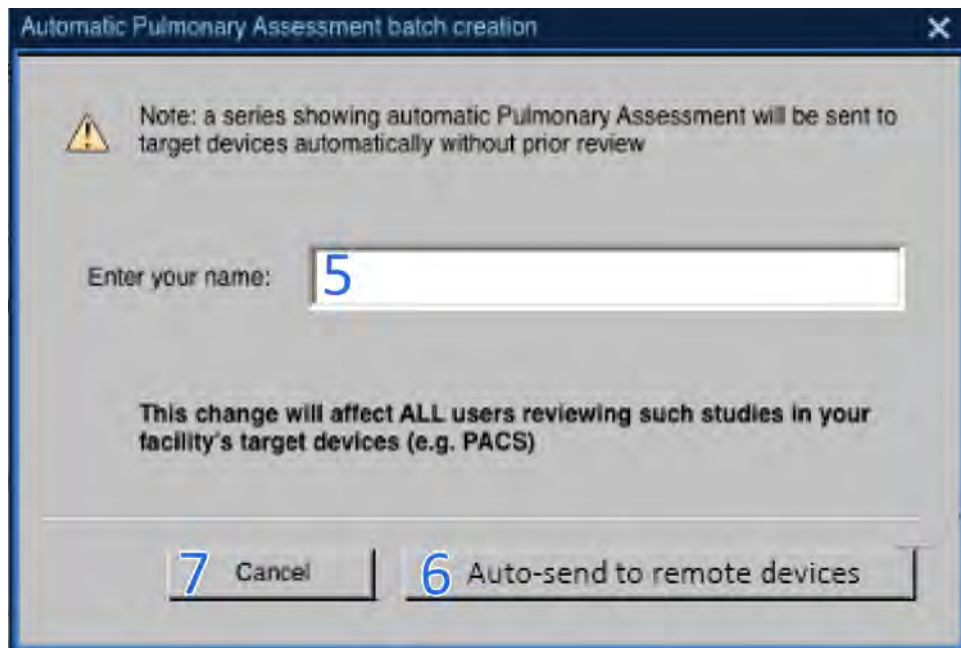
A configuration dialog is displayed.



6. Configure the following settings:
 - Select whether to include volume batch creation (#1). Volume batch provides a 360 degree volume rendering rotation showing the lungs/lesions segmentation within the whole body volume rendering.

- Select whether to create a results series (#2) (a non-image series, containing the lungs and lesion tissues). This series can further be used to edit the tissues in IntelliSpace Portal.
- Configure the series description of each of the auto-created series (#3). The description should have the fixed prefix: **Automatic Results**.
- Select the target devices (#4) to automatically send these series to (e.g. PACS).
- Fill in the relevant DICOM attributes for identification of the suitable series - Protocol, Body Part, series description, procedure description (this is a standard setting for all preprocessing algorithms).

If a remote device was selected for saving, when **Save** is selected, another window appears asking the user to confirm sending results to PACS.



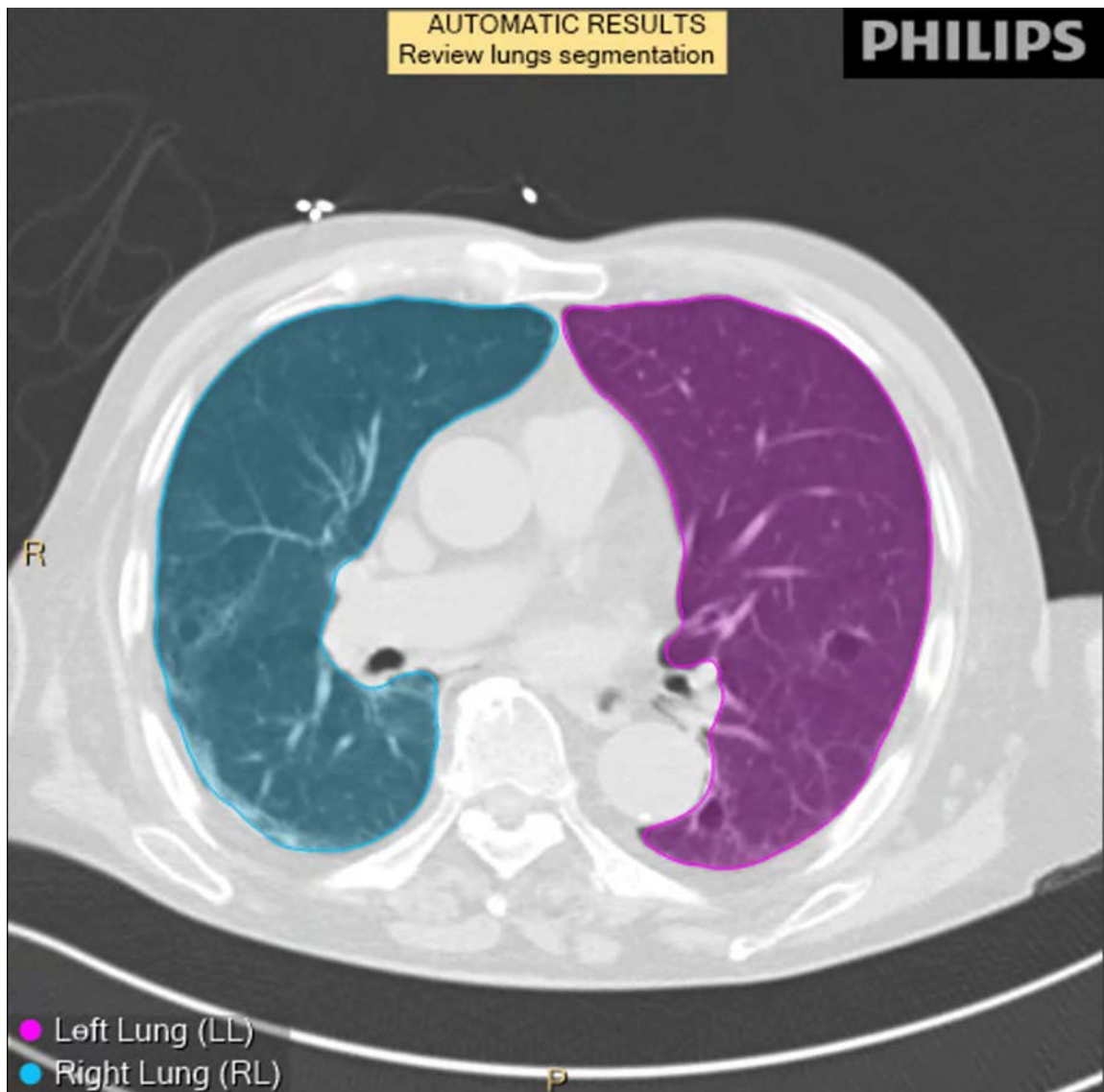
7. Type in your name (#5) and click **Auto-send to remote devices** (#6) to save the configuration.

If the user clicks **Cancel** (#7), the remote device is removed and the window closes.

These settings can be updated by returning to the **Processing** page in **Preferences** and selecting a rule from the table. Click the **Settings** button at the bottom of the page (below the rules table).

Segmentation

The application outputs a series of batch images to the PACS for users to inspect the quality of the automatic results: lung segmentation (Fig. 1) and segmentation of regions suggestive of pneumonia.



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Fig. 16: Batch with segmented lungs identified as image overlays.

Regions suggestive of pneumonia are segmented and classified in two groups: ground-glass opacities (GGO) with a green contour and consolidation with a yellow contour (Fig. 2). The lungs are also marked on the images.

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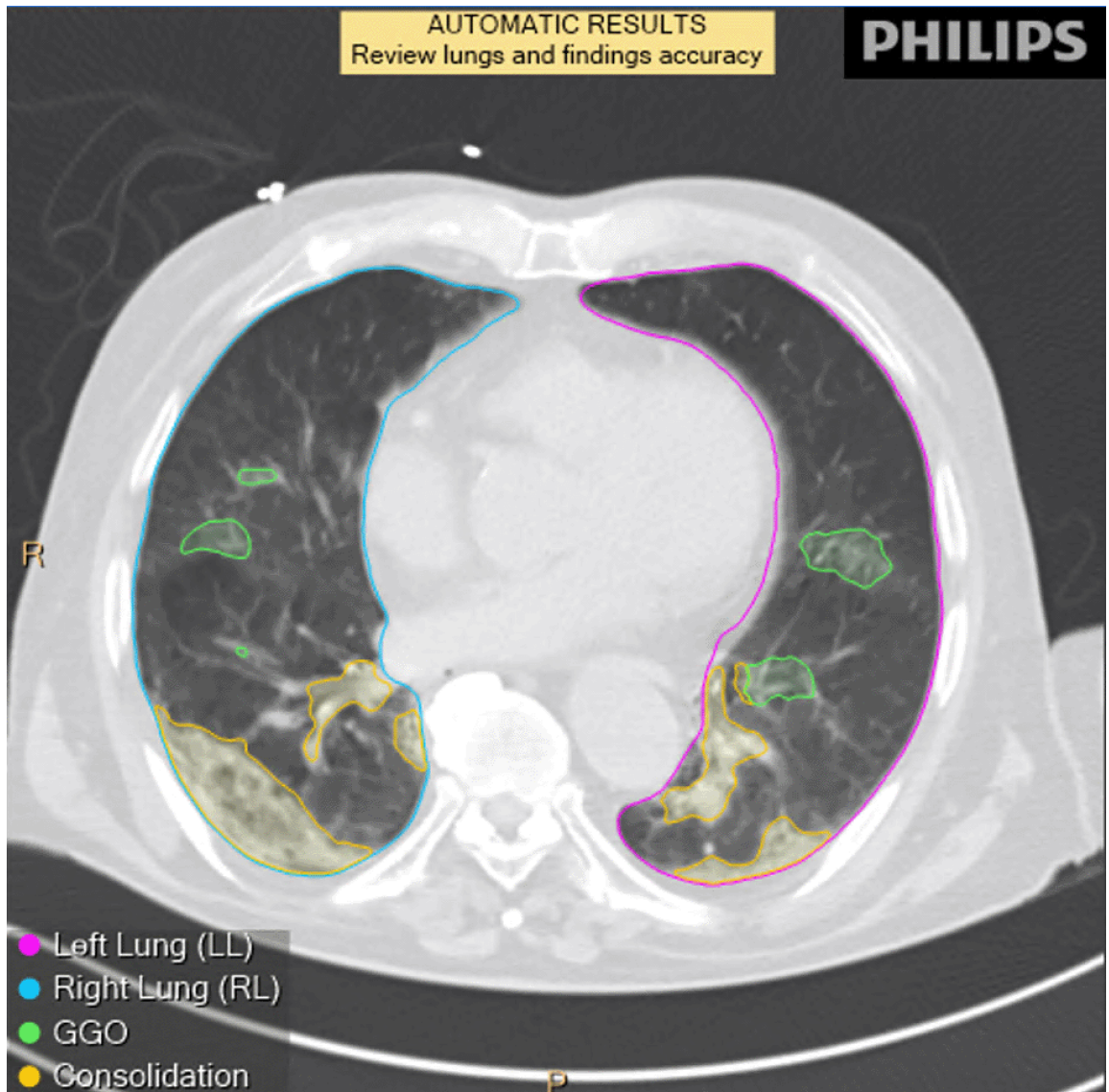


Fig. 17: Batch with areas suggestive of ground-glass opacity (GGO) and consolidation.

Segmentation results are saved in a proprietary format that can further processed in IntelliSpace Portal.

Viewing Segmentation Results in IntelliSpace Portal

The CT Pulmo Auto Results application does not provide a dedicated user interface or editing tools.

Resulting segmentation tissues are saved in an ISP proprietary format and can be launched with CT Viewer or 3D Modeling for visualization.

Results



CAUTION

Before accepting the summary results and associated Measurements summary, verify the correctness of the lungs and lesion volume segmentation as well as the findings classification.

The CT Pulmo Auto Results application provides quantitative results (for lung volume measurements and lesion volumes per radiological classification).

Volume in ml of the following structures are provided each for: both lungs, left lung and right lung:

1. Total volume of the lungs (including lesions)
2. Lung volume after excluding lesion
3. Total lesions
4. GGO lesions
5. Consolidation lesions

The distribution between of lesion types (calculated in percentage) is per both lungs, left lung and right lung, as shown in the example below: (Fig. 3).

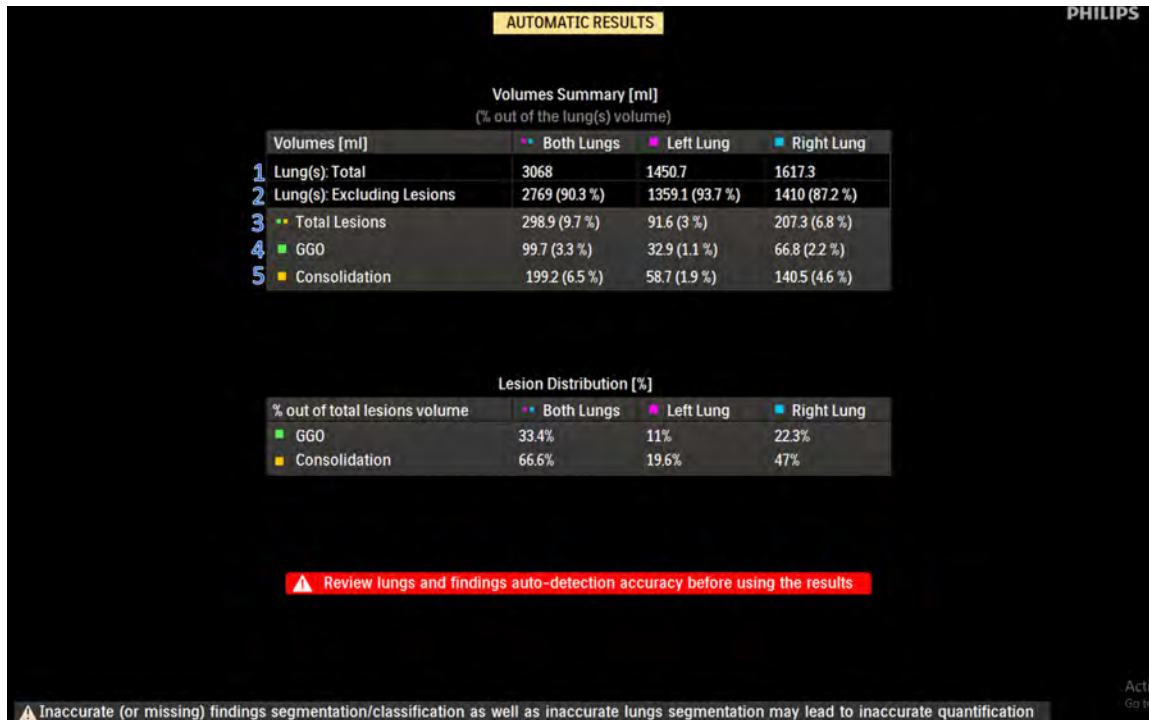


Fig. 18: Summary Results

The CT Pulmo Auto Results application also provides the results summary as a PDF.

Measurement Accuracy

The estimated volume errors (tolerance) of lung volume, total lesion (GGO and consolidation), GGO and consolidation are 19.652 (9.060–31.989) ml, 22.281 (6.622–41.593) ml, 21.856 (12.575–118.276) ml, and 13.323 (4.341–28.693) ml, respectively.

The estimated volume ratio errors (tolerance) of the total lesion, GGO and consolidation to the lung(s) are 0.638 (0.163–1.601)%, 0.592 (0.320–2.961)%, and 0.441 (0.115–1.092)%, respectively.

7 Dental Planning



The Dental Planning application is used to create true-size (life-size) film images of the Mandible and the Maxilla. The resulting cross-sectional images assist oral surgeons in planning the implantation of prostheses. The patient is scanned on a CT scanner using a Dental Planning procedure (outside of IntelliSpace Portal) and then the scanned images are used in the Dental Planning analysis application.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Dental Planning consists of the following steps:

- Defining panoramic views.
- Defining cross-sectional planes.
- Filming the reference, panoramic and cross sectional images in true size.



WARNING

Filming to true-size can be performed only when printing directly from the Dental Planning application to an installed and configured film printer. The required film printer must be calibrated by qualified service personnel.



WARNING

When loading images into Dental Planning, all images which contain 16-bit data are converted into 12-bit images. This means that for rescale intercept equal to negative 1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to negative 1024, HU values above 3071 are displayed as 3071.

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Portal configuration, this application may not be available.

Calibrate Image Size for True-size Filming

Before calibrating, make sure a printer is properly installed and appears in the filmview list.



WARNING

Calibration of True-size filming should be performed only by qualified service personnel. Calibration must be completed the first time Dental Planning is performed, and each time the film format, film image or the Dental Planning scan protocol on the scanner are changed. Any time you change the page layout, header, or footer of the film, you must re-calibrate the dental application to get true size measurements. The calibration factor (DFOV) sets the size on film. After changing the factor, use a scale to measure the horizontal and vertical scales on the film to ensure true-size.

On systems filming through AMC-4 interface, set the film image to the Dental Planning film size and format.

NOTICE

Changing the calibration of the True Size filming is only available for users with administrative rights.

1. Open a Dental Planning study.
2. Open the True Size tab in the Panoramics work stage.
3. Click **Use True Size Filming**.
4. Click the **Select Printer** arrow to view your printer choices. Select a printer.
5. Open the **Define Panoramics** tab. Draw a Panoramic curve center line.
6. In the Sections work stage, set up one of the cross section images to have both vertical and horizontal scales (from the right-click menu, click Show Horizontal Scale.)
7. Send the image to Film.



8. Open the Film application and print the image to the printer. The required film size for True Size filming is 14 x 17 inch film, using the 2 x 3 format.
9. Return to Dental Analysis > Panoramics. From the True Size tab, record the scale lengths from the Image Scale column (for example, vertical = 5 cm, horizontal = 2 cm).
10. On the printed film, using a calibrated ruler, measure the actual scale lengths (for example, vertical = 4.9 cm, horizontal = 2.1 cm).
11. Write the measured values in the table under the Ruler column.



12. Click **Calibrate** and see that the value of DFOV has changed to a new value (DFOV is the calibration factor that sets the size on film).

Verify Calibration

Repeat basic calibration as above, starting by drawing a new Panoramic curve. After printing on film, the scales on the printed page should match your calibrated ruler. If not, repeat the rest of the calibration procedure until the measurements match. Repeat entire procedure for all printers.

Configure Printers that Support Dental Planning

1. Select **Define Printers** from the Select Printer options.
2. Choose a printer by clicking the **Selected** checkbox. Only select printers that support true-size.
3. After changing the size of the header/footer in filmview, you will be asked to re-calibrate the next time you open Dental Planning.
4. Type the value in the DFOV field and click **Calibrate**.

Displayed Field of View (DFOV)

Displayed Field of View (DFOV) is the length of the image shown in the axial viewport in mm.

DFOV is calculated as follows:

$$DFOV (after\ calibration) = DFOV (before\ calibration) \times CorrectionFactor$$

The Correction Factor is calculated as follows:

- The user should print an image from the application and measure a vertical scale and a horizontal scale with a ruler, and type in the values into two text boxes.
- **Parameters:**
 - L_H= the real length of the horizontal scale (the one written on the image).
 - L_V= the real length of the vertical scale (the one written on the image).
 - ML_H= the measured length of the horizontal scale (the one measured with the ruler).
 - ML_V= the measured length of the vertical scale (the one measured with the ruler).
- **Correction Factor Calculation:**

$$F_H = \frac{ML_H}{L_H}$$

$$F_V = \frac{ML_V}{L_V}$$

$$\text{Correction Factor} = \frac{F_H + F_V}{2}$$

Dental Planning Workflow

The Dental Planning application opens in the Panoramics stage, in the default layout (Layout A).

- **Top left viewport.** Shows axial images of the study. Draw a curved line on this image to define the desired panoramic images. You can scroll through the images to find the optimum view.
- **Bottom left viewport.** Shows a volumetric image of the study. Use the Volume and Clipping Tools for editing this image.
- **Right viewport.** Shows the panoramic images produced from your curved line on the axial image.



Click **Layout** to change.



WARNING

One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly. The volume image displays the anatomy according to the defined protocol. Do not use the volume image as the sole basis for a diagnosis.

Functions Tab

- **Define Panoramics.** Use this function to define the panoramic curve.
- **True Size.** Use this function to calibrate the image size for true-size.
- **Nerve Canal.** Use this function to highlight the nerve canals.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Panoramics Work Stage

The Dental Planning application opens in the Panoramics stage.



WARNING

Measurements on Panoramic images are calculated along the curved plane, and should not be used as the sole basis for diagnosis. Objects in thick curved MPR images may appear distorted. Use caution when making measurements on MPR images. Cross sectional images might rotate around the centerline. Please note orientation annotations on images.

Set Plane



Scroll through the images in the axial slab viewport to find the best cross-section for dental planning. If the original (orthogonal) viewing plane does not form an ideal cross-section through the Maxilla or Mandible, adjust the plane as described:

1. Click **Rotate Plane**. Ensure the Define Panoramics tab is open and the sagittal and coronal images, in addition to the original axial image, are visible.
2. Click and drag to reposition the plane lines in the sagittal and/or coronal viewports. The slab viewport is updated as you move the line(s).
3. When done, click the **Accept** checkmark.

Define Panoramics



Draw one curve on the axial viewport, approximately following the tooth centers. When you finish, the application displays your curve, and also creates and displays additional curves (in parallel to your original curve). Up to six curves can be seen at one time in the right-side viewport. The Number and Spacing options of the curves can be changed at any time.

Draw a Panoramic Curve

1. Click **Draw Curve**.
2. Point the cursor in the axial image viewport and click where you want to start the curve.
3. Click as you move along the proposed curve (creating control points). A green line forms showing your progress.
4. Double-click on the end point of the curve to complete it.
 - Purple parallel lines appear on each side of the green line. These lines are numbered, and corresponding numbers are shown in the right-side panoramic images.

5. Verify that the panoramic images are in the desired plane.

Modify the Curve Shape

1. Select **Edit Control Points**.
2. To move a control point, drag it to the desired location.
3. To add a control point, click on the green curve where you want a new point.

Move the Curve

Select **Move Curve**. Point anywhere on the center curve, then click and drag the entire line to the desired location.

Delete the Curve

Click **Draw Curve**. Point the cursor in the axial image viewport and click where you want to start a new curve. The old curve disappears.

Define Nerve Canal

After you define the panoramics, you can choose to mark the nerve canals.

NOTICE

There are separate Right and Left tools for marking the nerve canals. Be sure to match the tools with the corresponding nerve canals. The orientation labels are marked in the panoramic image.

1. Select the panoramic image that shows the nerve canals.
2. Click **Mark Canal (Right or Left)**.
3. In the panoramic image, click as you move along the proposed canal (creating control points). A line forms showing your progress.
4. Move the cursor away from the line when complete.
5. Select the other **Mark Canal** tool and draw the line along the remaining canal.
6. To visually emphasize the marked canal, select it and change its thickness using **Highlight Canal**.

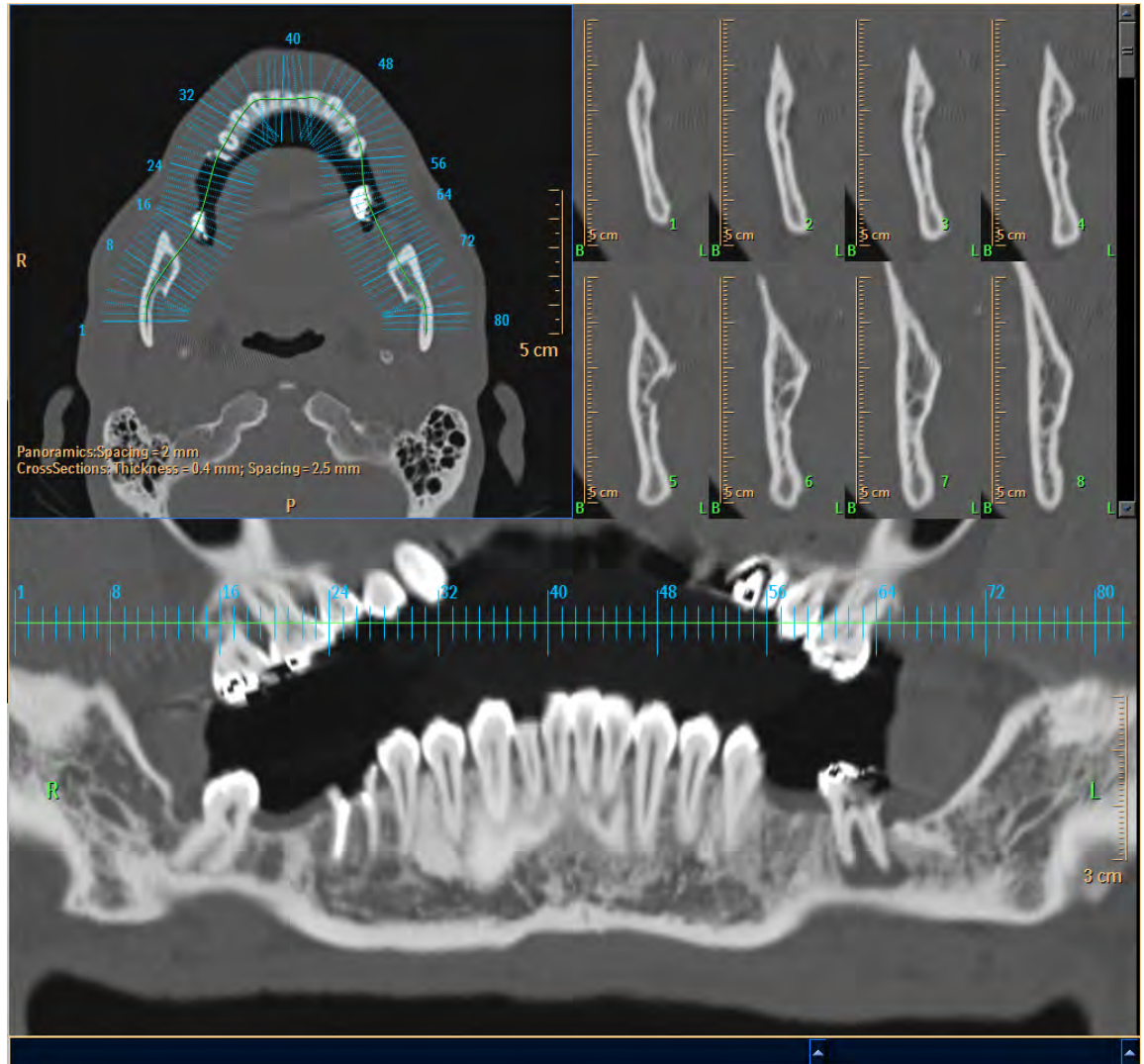
When you are satisfied with the Panoramics and Nerve Canal curves, you can begin the Sections work stage. Select the **Continue** arrow next to the Panoramics stage indicator.

NOTICE

You cannot access the Section work stage unless a curve has been defined. Curves cannot be added, deleted or changed in the Sections work stage.

Sections Work Stage

The Sections work stage displays cross-section dental images of the patient. The images are regularly spaced along the panoramic curve of the Mandible or the Maxilla.



- **Top left viewport.** Shows an axial image, overlaid with a diagram of cross-sectional cuts along the panoramic curve.
- **Top right viewport.** Shows the section images. The slice number displays on the right edge of each image, and can be turned off and on with Show slices on section. The cross section images are labeled B and L, identifying the Buccal and Lingual sides of the teeth. Measurement scales on the images are for true-size measuring of dental features.
- **Bottom viewport.** Shows a coronal image, displayed as a flattened view along the green panoramic curve line that you created in the Define stage.

Click Layout to select a different layout than the one shown.

Viewport Options

You can change the following display characteristics:

Long Sections. The length of the sections displayed in the top right viewport (on = 5 cm, off = 3 cm)

Show Section Lines. Turns section lines on and off in the top left and bottom viewports

Edit Sections



Use the Add Sections function to add additional cross-sectional images to the defined curve. If there is enough space on the curve, a new set of section lines is created to the right of the last set, with the same number of cuts and the same spacing between lines. If there is not enough space for a new set, a notice displays.

1. Click **Add Sections**.
2. Click on the image.
3. You can change the parameters of cross section image sets using functions in the Cross Sections tab:
 - **Set Number.** The number of sets to display.
 - **Spacing.** The distance between section lines (mm).
 - **No. Sections.** The number of sections displayed on the panoramic curve.
4. Select **Change Angles**.
5. Drag the round handle(s) in either the upper left (axial) or lower (panoramic) viewports and swivel to the optimum position. The cross-sections display in the upper right viewport.
 - Restore the original perpendicular angles by selecting **Reset Angles**.

Sections Results

After you complete any cross section operations, you can view the cross-section images in the top right viewport. Use the slider bar along the right edge of the viewport to scroll through the images.

Viewing Cross Section Results in Pair Mode and Moving CS (Cross Section) Continuously



Clicking **Enter Pair Mode** causes the viewing capabilities to be changed. Instead of viewing all cross sections, the viewable cross sections are reduced to eight.



Clicking **Move CS Continuously** (while in the Enter Pair mode), moves the eight-section set to the right, adjacent to its existing location on the curve. Each click moves the set to the next adjacent location.

Presets: Setting up Results for Film or Print

A Preset is a saved specification of how images are arranged for filming or printing (the film layout and the image list, respectively). Presets are not active in the Enter Pairs Mode. You can use a Preset or you can create your own. The following images are available for arranging into user's Presets:

- some or all cross-section images (you select);
- the axial image with cross-section lines;
- the axial image with the panoramic curves;
- the panoramic images; or
- the volume image.

1. Click **Define Presets** to open the Presets definition dialog box.



2. Select the **Preset** name/number to edit, or **New** to add a preset (if New, then type a name or number).
3. Select the **View (Film Layout or Image List)**.
You can **Save**, **Delete**, or **Reset** at any time. Reset deletes the entire preset content.
4. Right click to access basic editing functions.

Default Presets

You can replace the default preset in a selected preset window (shown with a yellow frame) by clicking in the preset window you want to change, then clicking the appropriate preset button (for example, Volume Image). When you have finished editing or adding presets, click the Save and Close button to save your edits and close the Define Preset dialog box, or click Cancel to close the dialog box without saving any changes.

Save, Report, and Film Dental Results

There are two modes for printing the results:

- **True-size filming.** Images are output to a film printer (zoom is not available)
- **Regular printing.** Images are output to a paper printer



WARNING

Calibrate the film printer for true size filming before producing films. For true size images, use only the special Dental Planning film format (2 x 3 with a film size of 14 x 17 inches). Any time you change the page layout, header, or footer of the film, you must re-calibrate the dental application to get true size measurements. The calibration factor (DFOV) sets the size on film. After changing the factor, use a scale to measure the horizontal and vertical scales on the film to ensure true-size.

Save Pairs

1. From the Common Tools area, click **Save Pair** as. The Save Pair As dialog box opens. Ensure that the Pair mode button is selected in the **Cross Section** tab.
2. Type a name for the pair, or accept the suggested name.
3. Select a format for the saved pair.
4. Select a location to save the Pairs from the Local Devices.
5. Click **OK** to save the Pairs file.

Send Pair to Report

1. From the Common Tools area, click **Send pair to report**. The report is loaded and the Select Existing Report dialog box opens. Ensure that the Pair mode button is selected in the Cross Section tab.
2. From the Select Existing Report dialog box, you can select an existing report or create a new one:
 - Select a report from the list, then click **OK**. The Pair images are sent to the existing report.
 - You can click **Create new report**. A message displays while the new report is created.
3. To view the (existing or new) Report, click the **Report** button on the workflow bar.

Send Pair to Film

1. From the Common Tools area, click **Film** images.
2. Go to the Film application.
3. Follow the instructions for printing given in the **Calibration** section.

8 Dual Energy

Dual Energy is an application for review and analysis of CT dual-energy scans.

NOTICE

Before loading scans into the Dual Energy application, ensure a suitable dual-energy scan protocol (Exam Card) was used. Refer to the documentation that came with your scanner for more information.

Dual Energy consists of 3 stages:

1. **Registration.** Use this stage to align the two scans that were performed at two energy levels (for example: 80kV and 140 kV).
2. **Analysis.** Use this stage to conduct an analysis of the different energy series. Three analysis methods can be performed: binary separation; vectors separation (non-binary range); probability classification.
3. **Segmentation.** In this stage you will use the spectral tissues obtained from the Analysis stage and manually segment the region of interest. The results of the segmentation may be reviewed against the original series (with and without registration results) as well as with the combined series.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

NOTICE

Depending on your Portal configuration, this application may not be available.

Registration Stage

The Registration stage provides tools for rigid registration of two scans of the same patient acquired at different energies.

Registration Workflow

1. Select the Base and Aligned series and start Registration.
2. Position the Aligned series to directly overlay the Base series.

3. Accept the registration. The Spectral combined series is created.
4. Before moving to the next stage, make sure that the active series is the spectral combined series with which you want to perform energy separation.
5. Use the Weighted Energy slider to select the weighted energy to create different, multiple series with different KV values using the same base and aligned series.
6. When verified, move to stage 2, Analysis. See section “Analysis Stage” on page 263.

Registration Tools

Use these tools to accurately align the Aligned series over the Base series.

Show Crosshair (default)

Shows the crosshairs on reference images.

Rotation Center

Show the center point around which the volume can be rotated.

Center Cursor

This function moves the middle of the image to the rotation center.

Select the Base and Aligned Series

Each series is displayed with its kV value to help with selection. The Base series does not move. The Aligned series appears as a translucent layer for you to move over the Base series. If desired, you can switch the series.

Swap Series



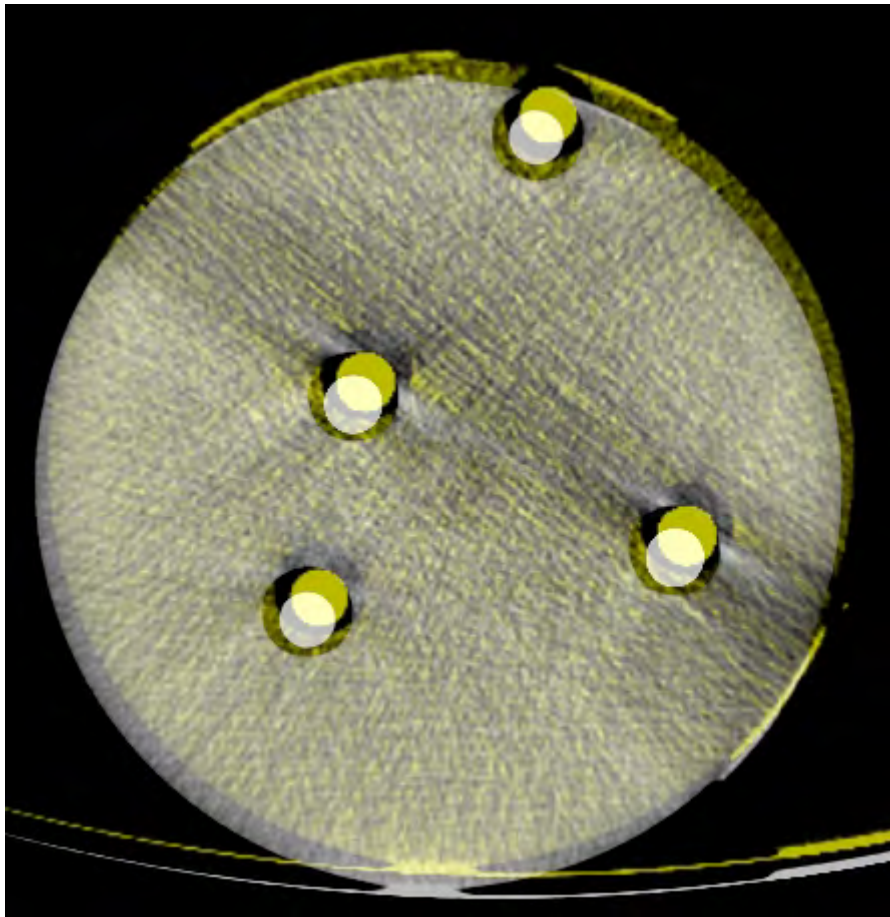
Click this button to switch the two series between Base and Aligned.

Apply Registration



Click this button after selecting Base and Aligned series. This will place the aligned data on top of the base data with a yellow, semi-transparent overlay.

In addition, when the Apply Registration button is selected, the Translate and Rotate buttons, as well as the “create registered series” checkbox are activated.



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Windowing



This tool controls display of the overlay data (of the Aligned volume).

Subtract Series

This tool helps you perform the registration of the two series images. Checking this tool changes the display to a subtraction image of the base and aligned series. The best registration is achieved when the subtraction image is completely black.

Translate



Use the Translate button to pan the aligned data according to the base data. Using the mouse scroll wheel for windowing in rotate or translate modes, the windowing is overlaid. You may also use the Ctrl+Shift+scroll wheel shortcut.

Rotate

Use the Rotate button to move the aligned data according to the base data.

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Create Series/Create Weighted Series



Click on the check mark to create a new Spectral Combined series using the current setting in the slider.

Weighted Energy

The Weighted Energy slider controls how the High energy series and Low energy series are combined. Moving the slider to the right results in a combined series with more high-energy data. Moving the slider to the left results in a combined series with more low-energy data.

Apply Colormap

Use the Colormap function as a visual aid during image alignment of the Base and Aligned series. The Colormap function lets you choose a predefined colormap overlay for the Base series.

Click the **Apply Colormap** checkbox to activate the function. The Edit Colormap dialog opens.

Select the desired colormap from the Colormap Preset. The buttons in this dialog provide these functions (from left to right):



Save the edited colormap preset.



Delete the current colormap preset.



Edit the colormap preset using the preset editor tool. (The editing procedure is the same as in the CT Viewer application.)



Rename the current colormap.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Combined Volume



WARNING

The Spectral Viewer volume image is created by combining high- and low-energy data. Combined images should not be used as the **SOLE** basis for clinical diagnosis.

The combined spectral volume is created as a temporary series. It is not saved to the database by default. To save it:

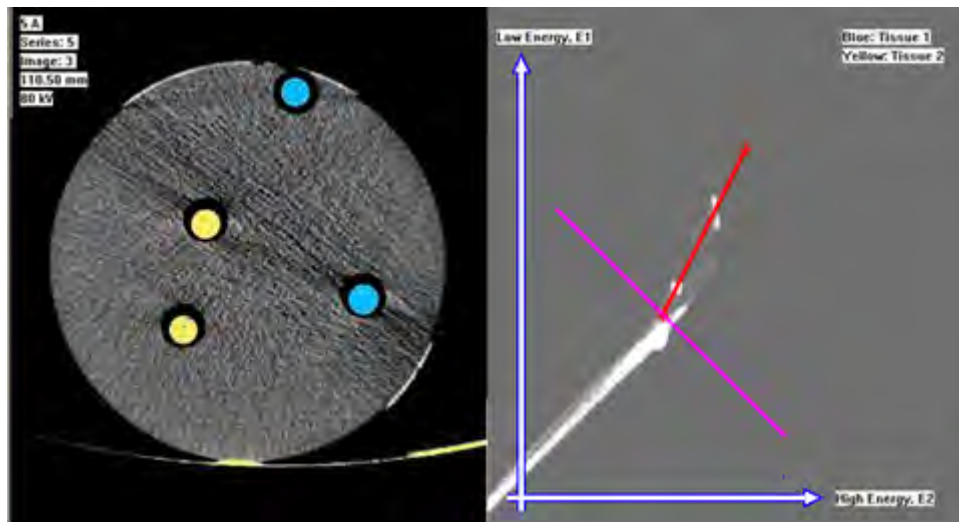
- Right click on it in the series list.
- Select **Save**.

Analysis Stage

The Analysis stage is used to perform a separation between different tissue materials, based on their energy values.

Each tissue pixel in the scanned volume has two CT values, one for high energy and one for low energy.

When you open the Analysis stage, each pixel in the CT image is characterized by the ratio of low and high energy values, and displayed on an Energy Map, shown in the viewport at right below.



An Energy Map displays, plotting values on a 2-dimensional diagram, where the vertical axis (E1) is its low-energy value and the horizontal axis (E2) is its high-energy value. (The corresponding CT image, in the left viewport above, is also displayed. The CT image will be used for review and analysis in the third stage, Segmentation.)

Analysis Tools

This section provides instruction for using tools and processes specific to the application or viewer.

Smooth

A filtering operator that is applied to the images before they undergo a separation procedure. The Smooth level may be adjusted from 1 (low smoothing) to 300 (high smoothing).

Binary

When active, this function changes the presentation:

- quantitative assessment = hue of pixels of the tissue;
- non-quantitative assessment = solid-color; and
- (also effects the Tissue 1 and Tissue 2 visualization).

Show Tissue 1 Map, Show Tissue 2 Map

These functions each add a new viewport to the display, and calculate new spectral tissue 1 or tissue 2 series, respectively, according to the chosen separation mode. (An example display is shown on the next page.)

- **Show Tissue 1** enhances tissue 1 pixels and suppresses Tissue 2 pixels.
- **Show Tissue 2** enhances tissue 2 pixels and suppresses Tissue 1 pixels.
- Pixels below the defined Threshold are clipped to 0.

To save the new calculated series, right-click on the image for the save menu. (You can import the saved series from D/pms/data/DualEnergySeries.)

Separation Modes

You can choose from three methods of Analysis:

- Separation by Graph line (binary separation).
- Separation by Vectors (non-binary range).
- Separation by Probabilistic classification.

Threshold

Setting this (to any value other than -1024) allows you to define the lower limit for the CT values that should be separated and displayed on the Tissue Maps.

Save state - Use this to save:

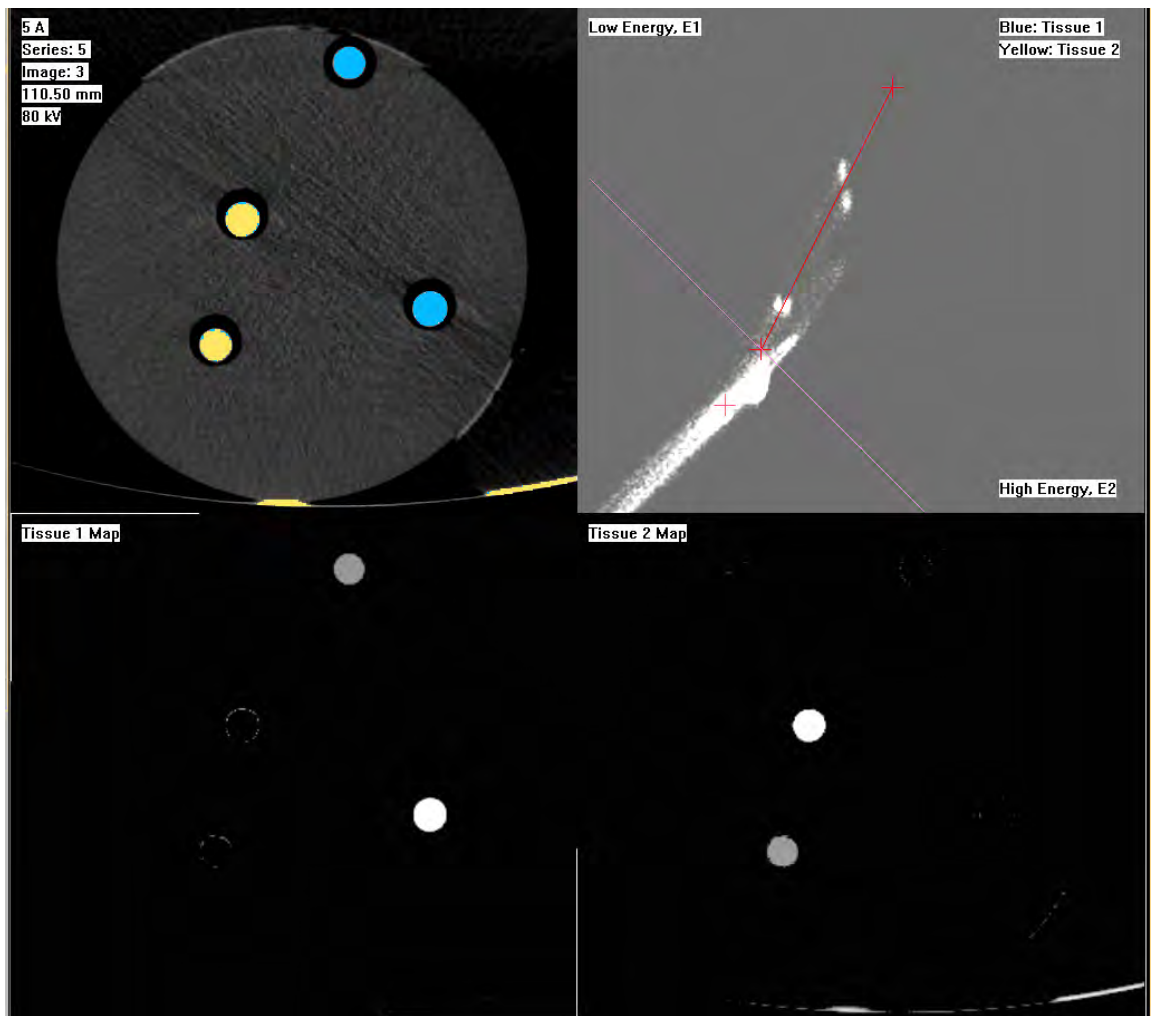
- the graph;
- the graph position;
- the parameters of each method (smooth, binary, and threshold); and
- the meeting point (for Vectors and Probability modes only).

Load State

Use this to load a saved state (as described above) from each separation method.

Prepare Tissues

Calculates the tissues for the segmentation scene (2 or 3 tissues).



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Right-click Context Menu

Right click in the CT image viewport to access additional options.

Define ROI

Use this function to drawing a circular ROI on the CT image. As a result, only the pixels within the ROI will be displayed on the energy map.

- You may define several ROIs.
- To move the ROI, left click in the middle of the ROI and drag with the mouse.
- To change the ROI shape, grab the ROI in either of the 4 (invisible) areas (12, 3, 6, and 9 o'clock) and drag to a new shape.

More options are available from a right click menu inside the ROI:

- delete;
- copy to Tissue maps;
- set color;

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- rename; and
- text.

Select Image (Ctrl+G)

Use this function to select a specific image. A Go To box opens where you can enter an image number.

Next series (Ctrl+N)

Use this function to move between different loaded series (low energy, high energy, weighted).

Local Focus

Use this function to optimize automatic window parameters for better visualization of features at the location you point to with the mouse.

Toggle Colors (Ctrl+C)

Use this function to alternate between displaying an overlay tissue color, or no color on the CT image.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Separate by Graph Line

There are three ways to separate tissue materials using the graph line:

- Separate into two materials.
- Separate into three materials.
- Characterize several materials by defining a set (or sets) of reference lines.

Graph Separation into Two Materials

When you choose Graph separation, a red separation line is displayed on the energy map, with X-marks at each end. Attached to the lower point of the red line is a purple line which represents the Threshold value.

- All pixels on the energy map below the Threshold line are not included in the Spectral Analysis.
- All pixels above the threshold line and above the red line are classified as one substance (colored in light blue in the CT image)
- All pixels above the threshold line and below the red line are classified as another substance, (colored in yellow in the CT image).

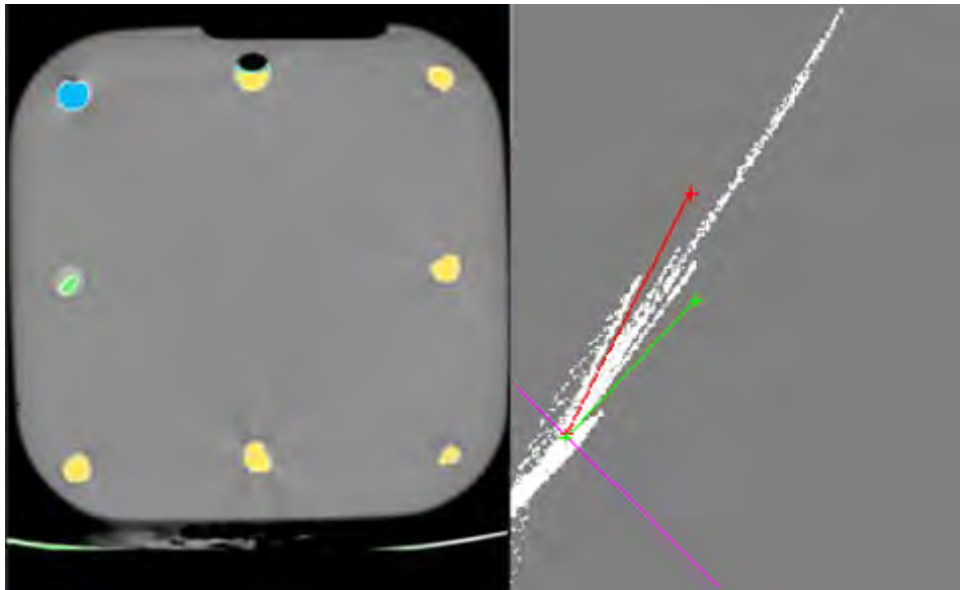
To move the separation and threshold lines, the red line can be edited by moving the X-mark at either end in any direction. The lower X-mark also moves the Threshold line. (You can also change the position of the Threshold line by changing the Threshold parameter in the tool-box.)

Graph Separation into Three Materials

By adding a second separation line you can define a third material.

- Right-mouse click in the map and select “Add Second Graph.” A green line is added to the graph viewport below the red line.
- You can change the location of the second line by dragging the line by its edge. (You can remove the second line by selecting “Remove Second Graph” from the right-mouse menu in the Energy Map.)

With two separation lines on the Energy Map, all pixels above the threshold line and below the second separation line are classified as a third substance (colored in green in the CT image).



User-defined Characterization for Several Materials

In this method you can create, name and save a set of your own reference lines. You can designate any set as the default set.

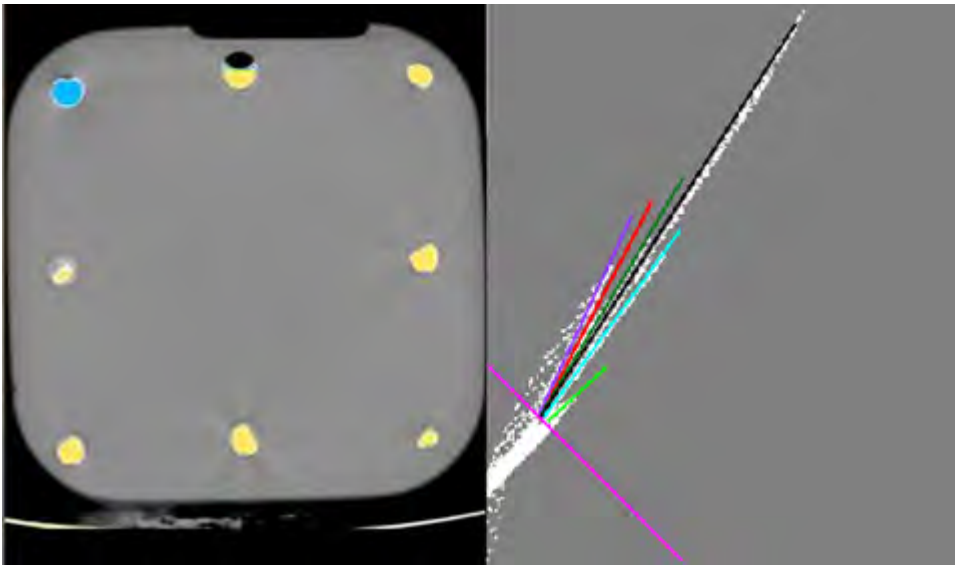
The Edit-Create Function

Right-click on the desired line in the Energy Map. A context menu opens. From the menu select the desired function: add a new line (above or below the line you clicked), rename the line, change the color, or delete it.

The Save-Load Function

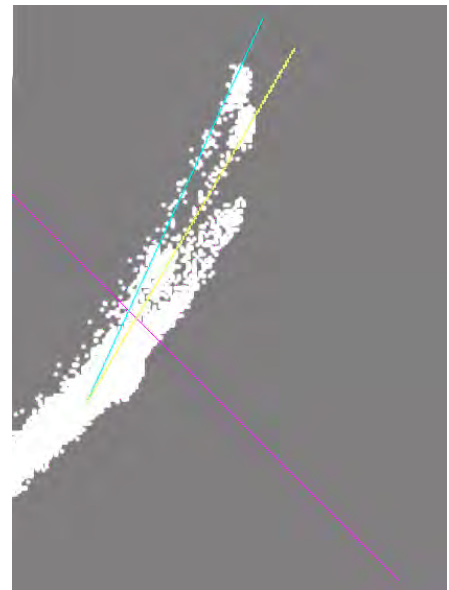
To access this function, right-click on an open area in the Energy Map. A different context menu opens, with these selections:

- **Load reference lines.** Load a set of saved reference lines.
- **Save reference lines.** Save a new set of lines.
- **Load default lines.** If you saved lines as “default” this option displays the default set of lines.

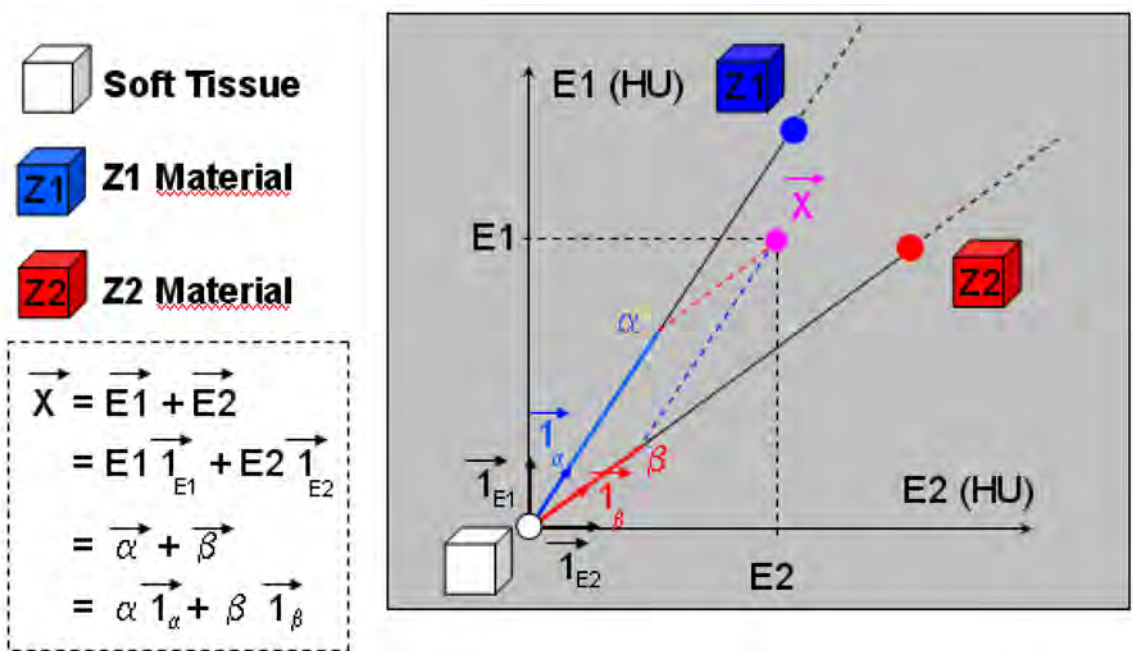


Separate Materials by Vectors

This method of separating materials assumes that the CT value of each voxel may be analyzed as a composition of two materials. When you select this method, two vector lines, blue and yellow, are displayed on the Energy Map. You should position these two vector lines on the corresponding material axis which represents the “pure” behavior of the two chosen materials.



The CT value of each voxel is seen as a vector summation of two vectors along those basic directions, as shown in the “Material Specific Base Projection Method” diagram below, which shows parallel projections in (E1,E2) plane.

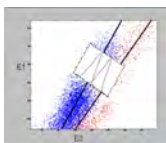


The coordinates α , β of the two vectors along the basic directions represent the concentration of each material in the corresponding voxel. To view material-specific images that correspond to the coordinates α and β , click **Show Tissue 1 Map** and **Show Tissue 2 Map**, respectively.

Changing Vector Parameters

- **Meeting point.** The blue and yellow vector lines are tied together and define the meeting point of the Energy Map. You can change meeting point location by selecting one of the following parameters:
 - **Water.** The vector lines are tied in water reading (0,0).
 - **Air.** The vector lines are tied in air reading (-1000,-1000).
 - **User Defined.** You can change the meeting point to any desired coordinate value.
- **Threshold** in the Vector method works the same as it does in the Graph method. But, unlike in the Graph method, the purple line is not tied to the meeting point.

Probabilistic Separation



The Probabilistic Separation method uses a statistical model to separate between two materials. An advantage to the Probabilistic method is that it gives not only a binary separation, but also quantitative assessment of its statistical significance. When using this model, the separation is adaptive to the local structure of the volume, which enables advanced non-linear classifications. The output of this method is an estimate of the probability that each voxel is either material 1 or material 2. When you select this method, two vector lines, blue and yellow, are displayed on the Energy Map (the same as in the Vectors method). Each line represents the “pure” behavior of the two materials. You can change the location of the two lines. Note the illustration of the Probability estimate method, showing the fitting of mixture Gaussian model to the measurements.

Probabilistic Parameters

Meeting point	The Probabilistic meeting point operates the same as it does in the Vector separation method.
Noise level	This HU value defines the mean noise standard deviation of the study (according to the average between the standard deviation of the low and the high energy images). Sigma may be adjusted from 0.1-80
Threshold	Threshold in the Probabilistic method works the same as it does in the Graph and Vector methods. Unlike in the Graph method, the purple line is not tied to the meeting point.

Segmentation Stage

The Segmentation scene allows the viewing and analysis of the spectral tissues which were created in stage two. The tissues are available from within the tissue management tab. Also in the tissue management tab are tools for manual editing of the tissues.

Function Tabs in Segmentation

The Segmentation stage is based on the CT Viewer - Volume mode application.

Tissue Management Functions

Tissue management tab displays the list of tissues of the active series. Use it to control display of tissues. Spectral tissues which were created in the second stage appear as Tissue 1, Tissue 2, etc. in the tissue list. Couch "tissue" is automatically created and the couch is removed from the image.

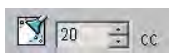
Functions Useful in Analysis Segmentation



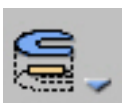
Change color of active tissue.



Change the volume rendering protocol of active tissue.



Remove residuals (as in CT Viewer). Useful to clean the tissues and remove unwanted remnants.



Perform clipping of the active tissue.



Expand / erode the active tissue.



Reset the active tissue to the same settings it had when it was created in stage 2.



Saving the tissues is done from the Save results button.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

9 Dynamic Myocardial Perfusion



The **Dynamic Myocardial Perfusion (DMP)** application provides automatic and manual tools to help visualize and assess cardiac images, focusing on the left ventricular myocardium: specifically providing quantitative myocardial blood flow measurements for CT images. The application also calculates measurements of Perfusion, Peak Enhancement, Time To Peak, and Blood Volume.

The application supports ECG-gated dynamic (repeated) axial scans focusing on the left ventricular region of the heart.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

Suggested Scan Protocol

Parameter	Suggestion
ECG	Gated Step & Shoot Cardiac with zero increment, centered around the LV
Detector Configuration	64x1.25mm
Targeted Cardiac Phase	Typically 40 or 45
kVp	80 – 100
mAs	40 – 60 (with 100 kVp); 60 – 80 (with 80 kVp). To be optimized accordingly.
#shots	~30
Cycle time	0.5 sec or 1.1 sec. 0.5 sec will scan every cardiac cycle, whereas 1.1 sec will scan every alternate cardiac cycle for the heart rates encountered.
Reconstructed Slice Thickness	2 mm
Reconstruction Kernel	CB/XCB (or CA in case of heavy patients)
iDose ⁴ Level	If iDose is available.

Parameter	Suggestion
FOV	<ul style="list-style-type: none"> Plan from the calcium scoring scan (if performed) or from the locator scan. Typically 150 – 200 In iCT V3.2, the smaller the FOV, the greater the reconstructable length. For example, FOV of 150 provides a reconstructable length of 6.8 cm, decreasing to 6.4 cm at FOV of 200. This is because x-rays are ON only for about 240-degrees, causing incomplete data at the edges; all reconstructions are therefore partial angle-based (240-degrees). In iCT 4.1, the FOV is enabled to reach a reconstructable length of 8 cm for all FOVs.
Jog Mode	No jog mode scans are allowed for DMP.

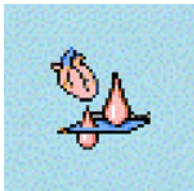
Application Stages

There are two stages in the application:

- **Review and Verify.**
- **Perfusion Maps.**

Launch DMP

1. From the **Directory** find and select the desired **Study** and **Series**.
2. Select the **CT DMP** icon from the menu.



3. The application opens in the **Review & Verify** stage.

Review & Verify Stage

Upon loading, the application creates a registered series from the original dataset and attempts to find an **arterial input** pixel to be used as the reference Time Attenuation Curve.

NOTICE

All steps performed in this stage should be performed on the registered series.

DMP Review & Verify Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Orientation



You can change the image orientation between the General Axes and the Cardiac Axes modes. Click the down arrow to switch between the two orientation modes:

- **General axes.** The general axes are the standard anatomical orientations: axial; coronal; and sagittal.
- **Cardiac axes.** The cardiac axes orient the views of the heart as follows: short axis; horizontal long axis (4 chamber view); and vertical long axis (2 chamber view).

Use the Flip button to flip the active volume viewport 180 degrees.

Flip



Use this button to flip the image in the main viewport right to left.

Relate



The **Relate view ports** and **Relate scenes** tools can help orient yourself.

To use, select either **Relate view ports** or **Relate scenes** and click on any pixel in any viewport. The location of that pixel is automatically marked on all the other view ports.

On/off ECG



If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Cine Tool



The cine tool allows reviewing all images of the perfusion data set. Each axial slice can be scrolled through all time points. It is recommended to use this tool after registration which minimizes the presence to anatomical motion, if any. Select the number of images (this also affects the number of images displayed) and the speed.

Cardiac Overview Viewing Modes

Verify short axis images, either by displaying all short axis images or by selecting a region of short axis. When examining a region of the short axis, scroll the displayed images by scrolling the short axis cMPR image on the bottom right viewport.



Use the **Show Short Axis Indication** button to show or hide the reference image on the bottom viewport shows the examined region.



Use the **Examine Myocardium** button to display several short axis images covering part of the myocardium. Scroll through the images to examine the entire myocardium.

The images that are displayed cover the upper part of the series as calculated as:

$y = \frac{\textit{Thickness of Each Short Axis Image}}{\textit{Minimum Increment * Number of Short Axis Slices}}$	y	Entire area along long axis covered in Examine Myocardium mode
--	---	---

NOTICE

Toggling between **Examine Myocardium** and **Myocardial Overview** can also be done using the right-click menu.



Use the **Myocardial Overview** button to display several short axis images covering the entire myocardium.

Single Viewing Mode



Use the **Single Slice** button to display a large single-slice viewport. Scroll through the images to examine the entire Series (including the axial image both in time and z-location). This should be done both in average rendering mode (time + z-location) and in tMIP rendering mode (only z-location).

On/off ECG

If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Cardiac Orientation (Right-click Option)



To change the default layout (axial image with reference coronal and sagittal images) to the **Cardiac** orientation, which include short/long axis views, right click on the image and select the appropriate option from the **Cardiac Orientation** menu.

When changing to cardiac orientation, it is possible to use each of the orientations as the main orientation.

NOTICE

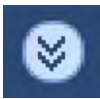
The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

DMP Review & Verify Common Tools and Functions

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions

To access additional functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

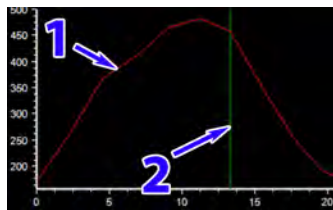
- **Bookmarks.** This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Mark DMP Arterial Input

Upon loading, the application attempts to detect an arterial input automatically.

Arterial Input - Time Attenuation Curve

The red line (item 1 in the image) represents the arterial input. The green line on the arterial input graph (item 2) represents the current time point shown in the main viewport. The line is adjustable and when it is scrolled to a certain time point, the image in the main viewport shall be updated accordingly.

NOTICE

The arterial input should be within the left ventricle and should have a distinct Time Attenuation Curve (TAC).

Automatic Detection

Use this button to perform automatic arterial detection.

Manual Detection

Manual detection of the arterial input is possible using either an **Ellipse** (average TAC for a region) or a **Cursor** (highest enhancement pixel TAC within a region).

Manual detection calculation:

Average Max Value - Min Value

Select either **Cursor** or **Ellipse** and mark the artery. The recommended location for marking the artery is within the left ventricle.

**WARNING**

Verify the correctness of the segmentation and labels, (manual visualization) and correct it manually if required.

Verify and Correct DMP Cardiac Axes

Upon loading, the application attempts to detect the axes defining the left ventricle. These are defined based upon four reference images: 3 planes of the long axis and one cross sectional image of the short axis. The base and apex of the left ventricle can be reviewed and corrected on each of the long axis reference images, and the planes of the long axis can be rotated using the **spoke wheel** on the short axis cross sectional image. Once the axes are reviewed and corrected, select **Accept Axes**.

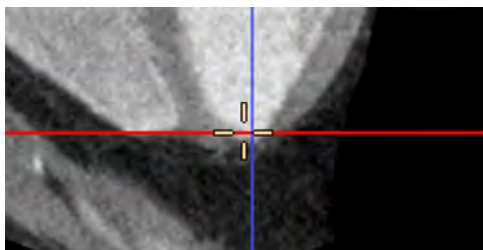
NOTICE

You must verify and correct, if necessary, the axes before continuing.

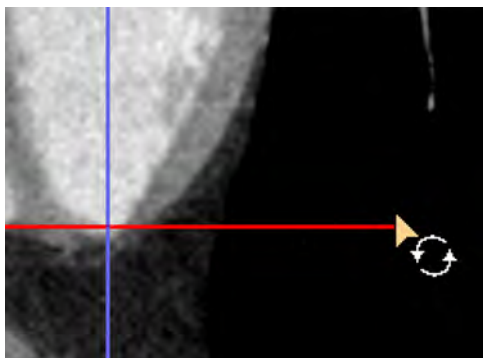
The Cardiac Axes are generated so that the cross-hairs of the long axes views cross the left ventricle through the apex and the mitral valve. After you examine the Cardiac Axes, if you want to adjust the crosshairs, use the Correct Axis function.

You can zoom and pan the viewport to better observe the crosshairs. You can also expand any viewport to full size by double-clicking in it. Double click again to return to the original layout.

1. With the Correct Axis function active (the button appears depressed), move the mouse pointer toward the crosshairs you want to adjust.
2. The pointer changes to a crosshair pointer.



3. Holding down the left mouse button, drag the crosshairs to the desired position.
4. Repeat the Correct Axis procedure in other viewports, as needed.
5. If correcting the cross-hairs requires rotating them, move the mouse pointer to the edges of the cross-hairs. The cursor changes to a rotation cursor, making it possible to rotate the cross-hair.

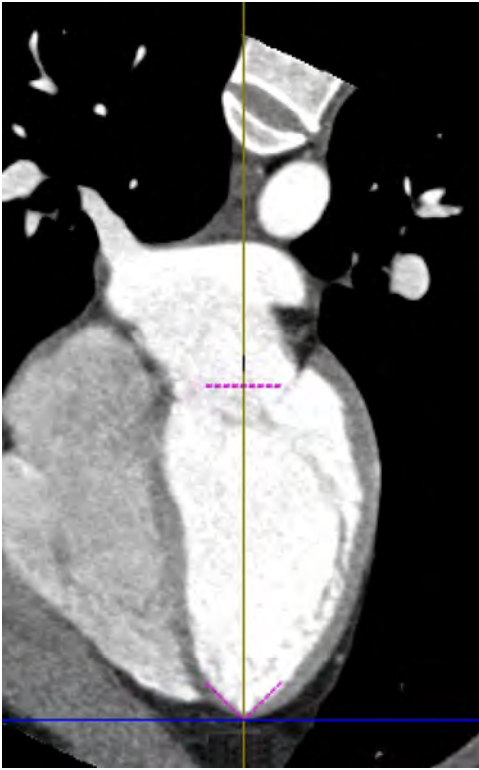


Correct DMP Valve and Apex Planes

Examine the position of the base and apex planes, and correct them if needed.

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Correct the apex setting by dragging the Apex (V-shaped dashed line) to the correct position. If necessary, correct the Mitral valve plane by dragging Base (straight dashed line) to the correct position.

Configure DMP Filter Settings

If you feel that the data is noisy and needs filtering (by visual inspection), use the **Filter Settings** tab. There are three available filter types:

Spatial Filter



The spatial filter is designed to reduce image noise in the spatial domain, while at the same time maintaining the edges of the relevant structures. Click on the button to turn the filter on. The spatial filter has a slider controlling the aggressiveness of the filtering (higher number -> the filtering is more aggressive). Default setting is 0.65.

Temporal Filter



The temporal filter is designed to reduce noise in the image data over the adjacent temporal positions. Click on the button to turn the filter on.

Spatio-Temporal Filter



This filter is a combination of the Spatial & Temporal Filters. Click on the button to turn the filter on.

Loading Settings



Use this tool to choose specific loading settings for the data, including the workflow for registration and filtering (default does not include filtering). Define the modified **Loading Settings** as default if to have the application load the new settings upon relaunch.

DMP Perfusion Maps Stage

In the **Perfusion Maps** stage, assess the perfusion of the various regions of the left ventricle myocardium. The perfusion analysis is done based upon the perfusion analysis used in the **Functional CT** application's **max slope** method. It provides a long and short view, in addition to four distinct perfusion maps:

- Perfusion
- Peak Enhancement
- Time To Peak
- Blood Volume

The maps can either be viewed altogether or toggled using the upper toolbox controls. The perfusion maps have several different color schemes, which can be toggled using the RMB context menu. **Cardiac** is the default color scheme, and **Thalium** color scheme is also used.

On the bottom of the default layout there are two viewports:

- Arterial TAC.
- ROI statistics table for short axis slices.

DMP Perfusion Maps Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Layout



The currently active layout is displayed as the icon. Click the down arrow to select one of the alternate layouts:

- All Perfusion Maps
- One Perfusion Map + 2 Vertical axes
- Short Axis large + 4 Perfusion Maps
- Long Table

The **Layout Manager** allows you to perform various layout (display) management functions.

On/off ECG



If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

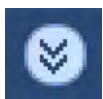
DMP Perfusion Maps Common Tools and Functions

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions



To access additional functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

- **Bookmarks.** This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Draw DMP Myocardial ROIs

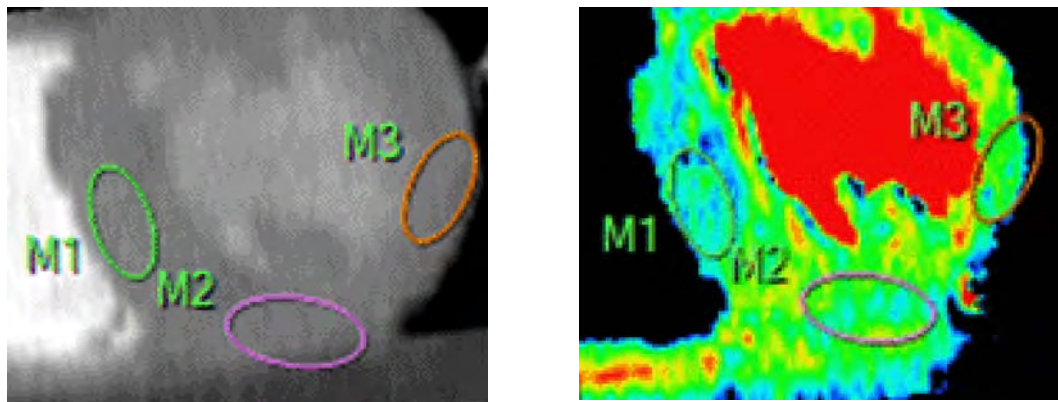
The Myocardial ROI allows drawing ROI in various shapes and observe the perfusion results for them.

Draw several ROIs on a certain short-axis slice to cover most of the range of Myocardium in that slice with an emphasis.

Repeat the process with any short slice axis that seem to have any deficits in perfusion.

When a ROI is drawn at a certain location on a specific time point, it is automatically drawn on all other time points at that location. The perfusion calculations are based on location of ROI in all time points. When moving the ROI in one time point, the application automatically moves the ROI on all time points.

The application also draws the ROI on all perfusion maps, and updates the maps if an ROI is moved.



Make Special

If additional registration corrections are needed, right click on an ROI and select **Make Special** from the menu: An additional ROI is drawn only on active time point. This ROI replaces the original ROI for the activate time point, which remains visible, and moving this ROI shall only affect active time point. To remove a special ROI, right click and select **Remove Special**.

NOTICE

As perfusion maps are for entire scan duration, and not for specific time point, the **Special** ROI created on the short axis image does not appear on perfusion maps.

Disable

To exclude a certain time point from ROI statistics table, without changing the ROI for other time points, right-click on the ROI and select **Disable**. The ROI remains visible on all time points, but the ROI graph will exclude the time point.

ROI Calculation Results

For each ROI, the perfusion parameters are calculated by the algorithm based upon the **max slope** analysis method. The results are displayed both in a table and in a graph.

Configure DMP Perfusion Options

This tab allows controlling the parameters according to which the application defines the range of pixel data it uses for calculation. Changing these parameters will result in a change of the perfusion pixels shown within the perfusion maps.

By default, the application removes air and bone which have an average HU number above/below certain threshold.

It is possible to choose to remove vessels, which are defined (by default) as pixels which have an enhancement of more than 20% of reference artery.

When changes are made, the ROI statistics table updates to exclude/include the relevant tissues.

**WARNING**

Verify the correctness of vessel removal.

DMP Perfusion Calculation

Arterial perfusion: perfusion during arterial phase:

$$\text{Perfusion} = \frac{\text{Flow}}{\text{Volume}} = \frac{\frac{d}{dt}[c(t)]_{\max}}{a(t)_{\max}}$$

Peak Enhancement

$$\text{Peak Enhancement} = \text{MaxVal} - \text{MinVal}$$

Time to Peak

$$\text{Time to Peak} = \text{Time of Local Peak} - \text{Time of Start of Bolus Arrival in LV}$$

Blood Volume

$$\textit{Blood Volume} = \textit{Computed Blood Volume} * \frac{\textit{Hematocrit Scale (85)}}{\textit{CbvFactor}}$$

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10 ElectroPhysiology Planning

Before treating heart rate arrhythmia with an interventional RF ablation procedure, it is useful to have an anatomic view of the left atrium (LA) and the pulmonary veins (PV). You can obtain these views using the ElectroPhysiology Planning (EP Planning) application.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

NOTICE

This application was verified using only cases from Philips scanners. If you load cases from another manufacturer, there may be differences in application behavior.

These anatomic images can be exported to other modalities to provide three-dimensional visualization of the anatomy during the ablation. The application has 2 stages, with specific goals and clinical uses:

- **Segmentation.** Verify auto-segmentation of the heart; edit tissues; and identify landmarks.
- **EP Planning.** Analyze the left atrium and pulmonary veins using various viewing modes.

The EP Planning application is also useful during patient follow-up to help assure that pulmonary vein stenosis did not develop following the ablation.



WARNING

Cross sectional images might rotate around the centerline. Please note orientation annotations on images. One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly. Objects in thick curved MPR images may appear distorted. Use caution when making measurements on MPR images.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

NOTICE

Depending on your Portal configuration, this application may not be available.

EP Planning Options and Tools

Use the EP Planning options and tools to modify the view and perform analysis. Note that some tools and options are stage dependent.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Brush



Add to unsegmented areas of active tissue by “painting” with 3 sizes of brushes: 3 cm; 1 cm; and 0.5 cm).

1. Activate the appropriate tissue segmentation.
2. Select the brush size from the drop down.
3. Drag the mouse across the unsegmented tissue while holding down the mouse button. The brush will “paint” new segmentation in the same color as the selected tissue.

Create New Vessel



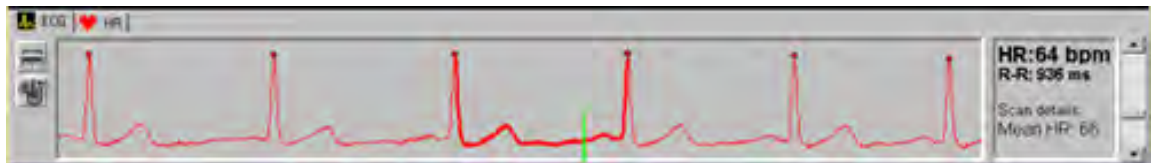
The application detects the maximum LA diameter automatically. If necessary, use the Draw LA Diameter tool to redraw the LA Diameter.

1. Select the **Draw LA** diameter button.
2. Redraw the line on the axial image.
3. Click the **Draw LA** diameter button again to finish.

ECG Display



Click the **Show/Hide ECG** button to display the ECG strip if one was loaded as part of the study.



The display appears at the bottom of the window and shows the ECG signal in graphic form.

NOTICE

The ECG display is available only in the Heart Review mode. Close it with the Show/Hide button before you leave the Heart Review mode.

The display's starting point is 5 seconds before the scan started. The ending point is 5 seconds after the scan ended.

The ECG signal is colored red for the duration of the scan (that is, the period that radiation is applied). It is synchronized with the other viewports, and as you scroll through the images, a green line correlates the displayed viewport images to the ECG signal. A green line marks the position of the currently viewed slab image.

On the right of the ECG viewport, the instantaneous heart rate and R-R interval are shown, as well as the mean heart rate over the scan and the number of heart beats.

Various other measurement and viewing functions are available. Refer to the CCA chapter in this volume for more details about the ECG display.

Edit Centerline

Edit a centerline on the cMPR view.

1. Select a vessel from the Vessel List. To select a vessel from the Result Table, click on the appropriate small, cross-sectional image.
2. Click the **Edit centerline** button. The system will automatically create centerline points in one of the viewports.
3. Grab the centerline and drag it to the desired location. You may also drag the centerline markers as well.
4. To add an addition centerline marker, click on the line.
5. Click the **Edit centerline** button again to update the centerline.

Edit Contour

Select to create new lumen contours in the cross-section and sMPR viewports. Change the contour using any of the active cross-sectional images. Modifying the contour works similar to what is described in the Edit Centerline section.

Place Landmark



Use the Place Landmark tool to name, delete or define a landmark. Once created, a landmark's name can be changed by right clicking over the landmark.

1. Determine the location of the landmark on one of the MPR images.
2. Activate the **Place Landmark** button.
3. When the center of the crosshairs pointer is over the desired area, click the mouse to place the landmark. To place multiple landmarks, click another region: your landmarks will be saved.
4. Change the name of the landmark by double clicking it in the Select Landmark to Display list and typing the new name.
5. To delete a landmark, select it from the list and use the Delete button.



WARNING

It is possible to delete auto-generated landmarks as well as landmarks you create.

Rendering Tools

Use the rendering tools options for viewing the 3D image.

Left Atrium

In this window the Left Atrium (LA) is displayed, together with the Pulmonary Veins (PV), which may be individually viewed and measured.

2D Rendering Map

The 2D map is a slab MIP through the LA, showing a quick view of the PV's anatomy.

On the volume image, selecting the “Left Atrium” annotation gives you the option to view the entire heart.

Result Table with Cross-sectional Cuts

Once a PV is named, its cross-section at the level of its ostium appears, outlined in red. The vein's maximum and minimum diameters are indicated by crosshairs. Various measurements and data are listed below the image.

Area	The Area of the cross section.
Max Diam	The maximum diameter of the cross section.
Min Diam	The minimum diameter of the cross section.
Effective Diam	The mean diameter of the cross section.

Eccentricity	<p>Is defined as:</p> $\text{sqrt}(1 - (\text{min diameter}^2 / \text{max diameter}^2))$ <p>Eccentricity index varies from 0 (minimum, perfectly circular) to 1 (maximum, highly elliptical).</p>
LA volume	<p>When you first enter the scene, the volume includes the pulmonary veins. When a vessel is named, its volume is excluded from the volume calculation. Note that when you move the ostia location, the volume is updated.</p>
LA diameter	<p>The max AP diameter of the LA. You can draw LA diameter in a different location using 'Line' tool from the common graphic toolbox and the table will be updated accordingly.</p>

Show Contours

Check the box to show the contours of the selected vessel on the viewports during the EP Planning stage.

Show Diameters

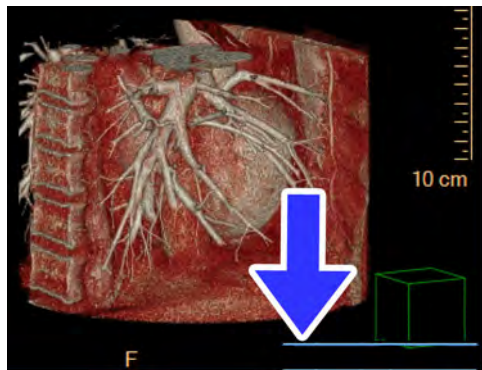
Check the box to show the diameter of the selected vessel on the viewports during the EP Planning stage.

Show Centerline

Check the box to show the centerline of the selected vessel on the viewports during the EP Planning stage.

Modify Standard Cardiac Angles

Change the standard cardiac angles on the volume image to modify the orientation of the volume image. Select either from a preset option or enter exact angles manually. The angles are located in the lower right-hand corner of the volume image.



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NOTICE

The standard cardiac angles may be modified on Volume images within the Cardiac Viewer, the Comprehensive Cardiac Analysis application, and the EP Planning application.

Use Preset Options

Use the preset options to adjust the common viewing angles. In the bottom right-hand corner of the image, click on the drop-down menu to select the viewing angle:

- RAO 30
- AP
- LAO 60
- LAO 60 Cranial 20
- Left Lateral
- LAO 45 Caudal 15
- RAO 45
- RAO 120 Cranial 10

NOTICE

In addition to setting the angles, use the Roll/Rotate tool to grab and rotate the image. The cardiac angles are updated in real time.

Manually Enter Angles

For a precise view, use the drop-downs and insert fields to enter the angles.

1. Select either **RAO** or **LAO** from the second drop-down menu.
2. Click in the field next to the RAO/LAO selection and enter the appropriate angle.
3. Select either **Caudal** or **Cranial** from the drop-down menu.
4. Click in the field next to the Caudal/Cranial selection and enter the appropriate angle.

Segmentation Stage

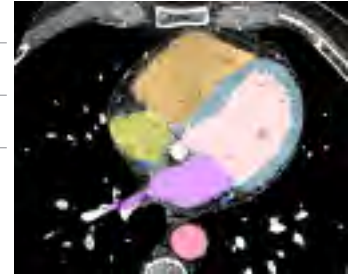
The Segmentation stage opens with 4 image viewports showing axial, coronal, sagittal and volume images. In addition, the application launches the Cardiac Viewer.

NOTICE

Change the standard cardiac angles on the volume image to modify the view. Select either from a preset option or enter exact angles manually. See the Cardiac Viewer section of the Operator Notes for more information on changing the standard cardiac angles.

The automatically segmented heart tissues (shown in the Heart Tissue List) include the following:

Left Atrium + Pulmonary Veins	Aorta
Left Ventricle	LV Myocardium
Right Atrium	Coronary Sinus+SVC +IVC
Right Ventricle	–

**WARNING**

Verify segmentation correctness. If necessary, correct the segmentation using the correction tools provided in this work stage.

The automatic segmentation that is initially performed by the EP Planning application requires your review and possible modification. The various tissue definitions may be incomplete, or may exceed or fall short of the actual tissue boundaries.

Segmentation Workflow

1. Load a Study into the EP Planning application. Select the Heart Segmentation tab if the viewer did not open it by default.
Auto-segmentation may take several minutes. During this time, the Heart Review stage is functional and you may examine the heart images using the review tools. Until the opening process is finished you cannot move to any subsequent work stages.
2. Review the segmentation using the Heart Tissue List and use the Edit Active Tissue tools to correct the segmentation if required. See section “EP Planning Options and Tools” on page 288.
3. Identify landmarks using the presets using the Landmarks tab. Optionally, create additional landmarks to use. See section “EP Planning Options and Tools” on page 288.

Heart Segmentation

Use the Heart Tissue List to display or hide segmented tissue when verifying and modifying the automatic segmentation. Click the **Left Atrium** button for a quick view.

**CAUTION**

The cubic volume displayed in the viewport is only as reliable as the correctness of the segmentation.

Before you save any EP Planning images and data or move to the next stage, verify the accuracy of the segmentation. If necessary, use the Edit Active Tissue tools to add or remove tissue from the segmentation.

1. Go to the Heart Segmentation tab (if not already open) and select a tissue from the Heart Tissue List.
2. Use the **Inject dye (3D)** tool to add unsegmented areas to the active tissue. The rate and type (viscosity) of the injection can be controlled by the relevant boxes.

**WARNING**

When using the dye-injection tool verify the correctness of volume segmentation. If necessary, correct the dye tracing using correction tools supplied by this application.

3. To remove either manually or automatically segmented tissue, use one of the erasers.

NOTICE

Since the eraser is cylindrical, it erases from the volume, not just the slice you use it on. Be sure to verify the results of the eraser by scrolling the reference images.

4. Use the **Fill**, **Expand**, **Erode**, and **Brush** tools to fill all the “holes” in the color overlay of the active tissue; increase or decrease the edges of the active contrasted tissue; and add to the active tissue. See section “EP Planning Options and Tools” on page 288.
5. To remove volume from the tissue segment, use the **Sculpting Tools**. See section “EP Planning Options and Tools” on page 288.

**CAUTION**

Remove All replaces the active tissue permanently. Therefore, if you want to restore the original segmentation before you proceed to another overlay in the overlays list, you should choose 'Undo'.

6. Repeat the previous steps for all automatically segmented tissues. When done, switch to the **Landmarks** tab.

Landmarks

Landmarks are segmented automatically, and their locations can be seen by selecting each landmark from the list. (The exception is the Fossa Ovalis, which must be manually located and segmented.) The automatically segmented landmarks (shown in the Select Landmark to Display list) include the following:

Aortic Valve	RV Center	IVC Os
Mitral Valve	LIPV Os	SVC Os
Tricuspid Valve	LSPV Os	Apex
LA Center	RIPV Os	LCA Os
LV Center	RSPV Os	RCA Os
RA Center	Coronary Sinus Os	Pulmonary Valve

Select landmarks for viewing from the Landmark list and you may define new landmarks if desired.

NOTICE

The Landmarks tab displays only the tissue segments you selected on the previous tab.

Clicking on a landmark will cause the axial, sagittal and coronal views to jump to the location of the landmark.



WARNING

Segmentation and landmarks must be verified.



To manually define a landmark use the Define tool. A landmark's name can also be changed by right clicking over the landmark. See section “EP Planning Options and Tools” on page 288.

NOTICE

It is possible to delete auto-generated landmarks as well as landmarks you create.

Planning Stage

When finished with the Heart Segmentation stage, access the EP Planning stage from the navigation tool bar. Use the EP Planning stage to perform qualitative and quantitative analysis of the left atrium and pulmonary veins (using various viewing modes).

NOTICE

Change the standard cardiac angles on the volume image to modify the view. Select either from a preset option or enter exact angles manually. See "Cardiac Viewer" in the CT Review section for more information on changing the standard cardiac angles.

When a new study is loaded into the EP Planning window for the first time, two of the viewports will be blank: the curved MPR view, and the measurements table. As you move through the EP Planning stage, the viewports are populated with relevant images.

EP Planning Workflow

- On the Extract & Define PV tab, use the automatic extraction to choose vessel. You may need to also extract a new vessel or edit the vessel centerline, contour, and LA diameter of the selected vessels.
- Use the Clip tab to remove unwanted anatomy from the volume images using common tools and processes.

Extract and Define PV



WARNING

Verify the correctness of the extracted centerlines and contours and correct if required.

1. Click on the location of the vessel you wish to define.
2. Choose a vessel name from the list. To mark a vessel not on the list, type the name of the new vessel in the text box on the Choose Vessel Name dialogue box.
3. If necessary, extract a new vessel using the multi-seed tool. Repeat the steps until all vessels of interest are defined.
4. Verify the vessel extraction and definition. If necessary, use the Edit centerline, Edit contour, and Draw LA diameter tools to modify the vessels. See section "EP Planning Options and Tools" on page 288.
5. When vessel extraction is verified, switch to the Clip tab.

Clip

The Clip tools are used to remove unwanted anatomy from the volume images using common tools and processes.

11 Body Perfusion (Functional CT)



Functional CT (FCT) perfusion is a blood flow imaging application that analyzes the uptake of injected contrast bolus, in order to determine functional blood flow information about a region of interest (ROI). The region of interest is scanned in the same position and at the same time intervals, as per the expected rate of change.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Intravenous contrast bolus is injected into the patient, and a region of interest is scanned repeatedly for a period of time. The Hounsfield unit enhancement is tracked for each voxel over time to produce tissue specific time-density curves. Measurements made from these time-density curves and user-selected regions of interest (ROIs) are used to create various parametric functional images.

In addition to displaying color-mapped parametric functional images, statistical measurements (such as mean, and standard deviation) can be recorded for any user-selected region.

The CT perfusion application consists of the following steps:

- Load the image set;
- Select Input ROI(s);
- Calculate Perfusion; and
- Create quantitative report.

This application is intended for Oncology, for the detection and follow-up of tumor growth by examining the relationship between arterial tissue and venous enhancement after the contrast bolus injection.

Perfusion series must include at least one non-contrasted image to be used as baseline. The baseline image is subtracted from the enhanced images set to obtain time enhanced data. An ROI on this data allows the generation of the Time Enhancement Curve (TEC).

NOTICE

Depending on your Portal configuration, this application may not be available.

Open Study in Functional CT

1. Click **Directory**.

2. Select the series to open. In order to run the applications properly you must load original images. Loading derived images may cause the system to close the application and return you to the Directory, where you must select original images and launch the application again.
3. Select **Functional CT** from the Directory Applications drop-down.

Functional CT opens in the Vessel Definition stage with a tMIP image in the main viewport.



WARNING

When loading images into Functional CT, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

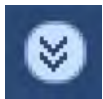
Vessel Definition Stage

Functional CT opens in the Vessel Definition stage. In this stage you select a perfusion type and define vessels for analysis.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Function Tabs



To access additional application functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Batch Function

The Batch function in Vessel Definition has a Time function. It is active only when the axial image is in “average” mode - it should be grayed out in tMIP. It locks the scroll in position so that batch includes images in the same position at different times.

Mark Perfusion ROIs

The Functional CT application opens with the ROIs tab displayed. The ROIs tab contains the drawing tools for placing regions of interest on images.

Perfusion types --You must select the type of perfusion study you are working with: Liver, General, or TimeLapse.

Liver Study ROIs

Liver perfusion maps include the following items:

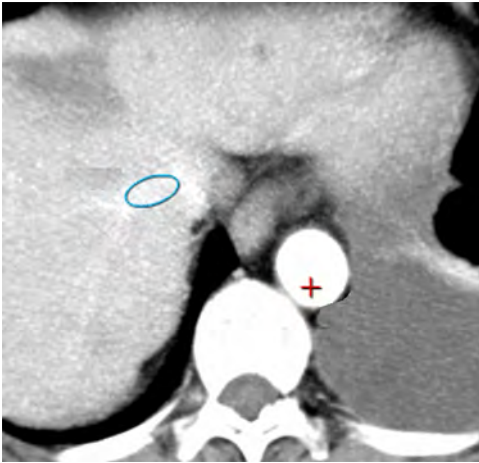
- Arterial perfusion;
- Portal venous perfusion;
- Total perfusion;
- Hepatic perfusion index; and
- All - scroll between all four of them (above).

Liver perfusion allows you to draw ROIs for the artery (Aorta), vein (Portal Vein), and spleen (draw on the spleen, ROI should be large).

Draw Artery



Use arterial ROI to set the reference ROI on the artery (Aorta), on the original (Reference) or tMIP image. Additional arterial ROIs may be drawn for viewing and comparing the contrast curves; only the ROI with the highest contrast enhancement (highest contrast peak relative to its background level before contrast enhancement) is used as reference in the functional calculations.



Select the cursor or ellipse ROI drawing tool, and drag the pencil shaped pointer across the artery (Aorta).

Draw Vein



Use venous ROI to set the reference venous ROIs on the portal vein, on the original (Reference) or tMIP image. Additional venous ROIs may be drawn for viewing and comparing the contrast curves; only the ROI with the highest contrast enhancement (highest contrast peak relative to its background level before contrast enhancement) is used as reference in the functional calculations.

Select the cursor or ellipse drawing tool, and drag the pencil shaped pointer across the vein (Portal Vein).

Draw Spleen



Use splenic ROI to set the reference ROI on the spleen, on the original (Reference) or tMIP image. Additional splenic ROIs may be drawn for viewing and comparing the contrast curves; only the ROI with the highest contrast enhancement (highest contrast peak relative to its background level before contrast enhancement) is used as reference in the functional calculations.

Mark the spleen. Draw on the spleen; the ROI should be large.

When an ROI is placed, the TLCT Graph plots the HU values over time. The TLCT Results table identifies the ROIs by vessel name and color, displaying the results for Vessel, Slice#, Enhancement, and TIP.



WARNING

Verify the correctness of the segmentation and labels, (manual visualization) and correct it manually if required.

General Perfusion

General perfusion maps include the following items:

- Perfusion;
- Peak Enhanced - the highest value at each point, minus the baseline;
- TTP;
- Blood volume; and
- All - scroll between all five of them (above).

This perfusion type allows you to draw only one artery. No other vessels are used in the General perfusion type.

Draw Artery



Select the cursor or ellipse drawing tool, and drag the pencil shaped pointer across the artery. When an ROI is placed, the TLCT Graph plots the HU values over time, and the TLCT Results table identifies the ROIs by vessel name and color, displaying the respective results for Vessel, Slice#, Enhancement, and TIP.

When an ROI is placed, the TLCT Graph plots the HU values over time, and the TLCT Results table identifies the ROIs by vessel name and color, displaying the respective results for Vessel, Slice#, Enhancement, and TIP.

Time-lapse Perfusion



All non-relevant buttons are grayed out. Drawing tissue ROIs activates the Time Lapse CT (TLCT) graph. You can draw multiple ROIs. Select the ellipse, spline, or circle drawing tool, and drag the pencil shaped pointer across the region of interest: Ellipse; Spline; or Circle.

General Perfusion Calculation

The IntelliSpace Portal mathematical modeling technique is based on a single compartment model.

This compartmental model is used to estimate the tissue perfusion, and as the name suggests, it considers the intravascular and extra-vascular spaces as a single compartment.

This model is based on the application of the Fick's principle of conservation of mass to a given region of interest within the target organ. The accumulated mass of contrast, $Q(T)$, in a voxel of tissue during a time period corresponding to the complete wash in and wash out of contrast during a bolus injection is equal to the product of the volume of blood moving through a given volume of interest per unit time, (with units of milliliters of blood per 100 g of tissue per minute) and the time integral of the arteriovenous difference in contrast concentration.

The implemented calculation is also known as the Mullani-Gould formulation or single-compartment formulation.

Additional information can be obtained from <http://www.ajnr.org/content/30/4/662>¹.

$$C(t) = a(t) \otimes \frac{F}{V} \cdot R(t)$$

¹ Konstas AA, Goldmakher GV, Lee TY, Lev MH. Theoretic Basis and Technical implementations of CT Perfusion in Acute Ischemic Stroke, Part 1: Theoretic Basis. AJNR Am J Neuroradiol. 2009 Apr;30(4):662-8. DOI: <https://doi.org/10.3174/ajnr.A148>.

Perfusion Maps Stage

After you have finished defining ROIs in the Vessel Definition stage, access the Perfusion Maps stage. (Once you move to the Perfusion Maps stage, you cannot change the Perfusion type.) See section “Vessel Definition Stage” on page 300.

Perfusion Map Color Schemes

Various color schemes for the Perfusion Maps are available for use as needed. The choice of color map is a user preference that affects only the types and ranges of colors used to display the perfusion parameters. The values of the perfusion parameters are not changed when selecting different color maps.

- Right mouse click on a Perfusion Map image to activate a drop-down menu.
- Select **Color Schemes**. The list of available color schemes appears.

Rainbow

In this (the default) color scheme, perfusion data is represented as a range of colors having the same sequence as a rainbow spectrum.

Black and White

Perfusion data is represented as a range of grayscale intensities. These maps are suitable for storage and display systems (e.g., PACS) that are incompatible with color maps.

Thallium

Perfusion data is represented by a range of colors similar to those used in conjunction with nuclear medicine perfusion scans (e.g., Thallium-201 SPECT).

a-LUT

Perfusion parameter color maps that use the Acute Stroke Imaging Standardization Group (Japan) recommended lookup table (a-LUT).

Perfusion Maps Stage Functions



Click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays. There are two additional application functions available only in stage 2, Perfusion Maps; they are Perfusion Options and Perfusion Mask.

Also, Batch is different in the Map stage than the Vessel Definition stage.

Key Images

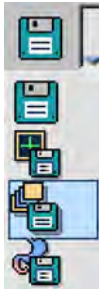
Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Create Batch in Functional CT

To create a batch in Functional CT:

1. Choose batch content. You can select any combination (or all) of the following content types:
 - Summary maps (Arterial, Portal, Total, HPI).
 - Original image (tMIP only).
 - Graph (TLCT).
 - Liver Perfusion Results table.
2. Sort batch content.
 - **By z-position (sort by slice)**. When the batch is created, all the content you selected is grouped together: for the first slice, then for the next slice, etc.)
 - **By type**. When the batch is created, all the content you selected is grouped together by type. (The “Split batch” option is active in this mode.)
 - **Current**. The batch will only contain the selected content for the currently active slice.
3. Split batch to series. Choose **Yes** if you want each content type to be grouped together and saved as separate series.



4. When done with your selections, click **Save batch as...** in the Common tools. A dialog window opens, where you can type in the batch name, the desired format (Secondary Capture, TIFF, etc.) and the destination device.
5. Click **OK** when done. The batch is saved to the destination device. As the batch is saved, a message displays the number of images and the device.

Perfusion Options

The perfusion options include:

Portal Perfusion Type (Only for Liver)

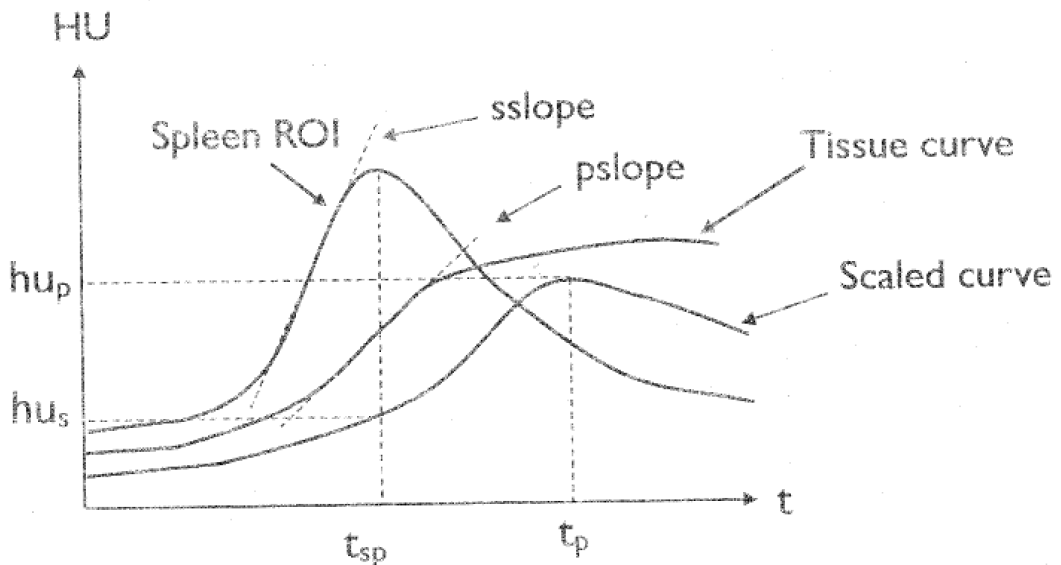
There are two perfusion methods, based on different research: the selected method affects the perfusion map. Your choices are:

- **Blomley Method (Method 1)**

t_p -scaled tissue enhancement peak time

hu_p -scaled tissue enhancement peak

Scaled curve = Tissue curve pslope / sslope * Spleen curve



$$\text{Portal Perfusion} = (hu_p - hu_s) * 6000 / ((t_p - t_{sp}) * \text{venous enhancement})$$

• **Mile's Method (Method 2 - default)**

t_s —bolus start time

t_{ap} —arterial enhancement peak time

t_{vp} —venous enhancement peak time

t_{sp} —spleen enhancement peak time

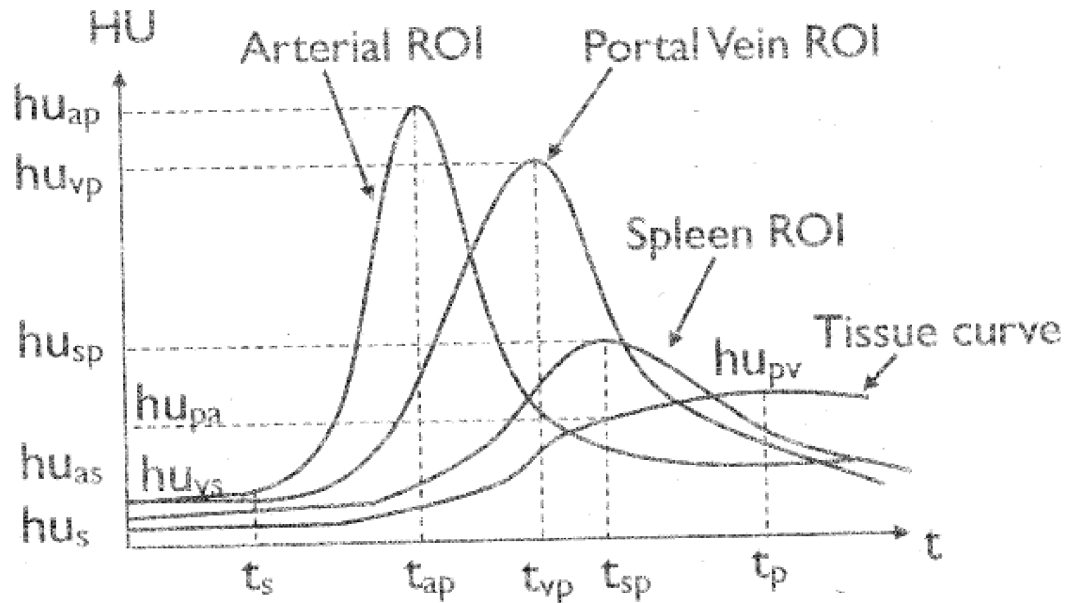
t_p —tissue enhancement peak time

hu_{ap} — hu_{as} - arterial enhancement

hu_{vp} — hu_{vs} - veneous enhancement

hu_{pa} - tissue enhancement peak on arterial stage

hu_{pv} - tissue enhancement peak on portal stage



$$\text{Arterial Perfusion} = (hu_{pa} - hu_s) * 6000 / ((t_{sp} - t_s) * \text{arterial enhancement})$$

$$\text{Portal Perfusion (by Miles method)} = (hu_{pv} - hu_{pa}) * 6000 / ((t_p - t_{sp}) * \text{veneous enhancement})$$

$$\text{Total Perfusion} = \text{Arterial Perfusion} + \text{Portal Perfusion}$$

$$\text{HPI (hepatic perfusion index)} = \text{Arterial Perfusion} / \text{Total Perfusion} * 100\%$$

Set as Default

Brings back the factory defaults settings.

Smooth Maps

Smoothing size: x4 = 256 x 256.

Thresholds to Exclude

Checkbox to turn on/off.

- Bone - above the HU threshold, area is in white in the perfusion maps
- Air - below the HU threshold, area is in black in the perfusion maps
- Vessels - to remove vessels from the maps. If Y=20% and the maximum of the artery enhancement is 100 HU, it colors in black all the areas that are above 20% out of 100 (meaning above 20 HU). In 100%, you see perfusion on all vessels. If Y is reduced, you see more black holes.

Values are saved on exit and reload.

Perfusion Mask



This tab is grayed out by default when a new perfusion study is opened. To Draw a New Mask: Click the Show Perfusion Mask checkbox. Then select one of the mask drawing tools from the drop-down arrow: FreeHand or Spline.

Liver Perfusion Maps

You can display Liver Perfusion Maps viewport in 5 forms. Click on a tab at the top of the viewport to select:

- ALL - (default) click to display all 4 perfusion maps in the viewport.
- TOTAL PERFUSION - display the Arterial + Venous Perfusion map.
- ARTERIAL PERFUSION - display the Arterial Perfusion map.
- PORTAL VENOUS PERFUSION - display the Portal Venous Perfusion map.
- HEPATIC PERFUSION INDEX - display the Hepatic Perfusion Index map.

General Perfusion Maps

You can display General Perfusion Maps viewport in 4 forms. Click on a tab at the top of the viewport to select:

- ALL - (default) display all 4 perfusion maps.
- PEAK ENHANCED - display the Peak Enhanced perfusion map, which shows peak enhancement from injected contrast.
- TTP (time-to-peak) - display the TTP perfusion map, which shows the time it takes for peak enhancement to be reached at each x, y location. The color bar is scaled in seconds.
- BLOOD VOLUME - display the Blood Volume perfusion map, which shows the total volume of blood.

Perfusion Results Table

The following information is included in the table:

- ROI name;
- Slice number; and
- All measurements of the selected type (General and Liver), as shown in the maps in the upper right viewport.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Recommended Scan Protocol

Before continuing, see the "Instructions for Use" that came with your scanner.

1. Position the slice location to include the liver, spleen, portal vein, and aorta.
2. Inject Contrast. (Recommended injection parameters: 40-50 ml total, >300 mgI/ml, 5-7 ml/second.)
3. Obtain axial, contrast-enhanced scans at the same location during patient's breath-hold for the duration, from the injection to the end of the portal phase. (Recommended scan parameters: 5 mm slice thickness, 1 second scan duration, 3 second cycle time, 360 degree rotation, 120kV, 150-200 mAs, breath hold.)
4. For a Liver study the Scan Range should include: Liver, Spleen, Portal vein, Aorta.



WARNING

A proper scanning procedure is essential for obtaining meaningful perfusion images. Special care must be taken to ensure that:

- **The scan duration is sufficient to cover a pre-contrast period as well as the entire first pass of the injected contrast bolus. (Recommended: minimum 60 second scan duration.)**
- **The scans are spaced no more than 5 seconds apart. (Recommended: 3.0 second temporal spacing.)**
- **The contrast injection is sufficiently rapid to preserve a narrow bolus. (Recommended: injection of 5-6 cc per second contrast for 8-10 seconds.)**
- **The Patient is able to breath-hold for the duration of the scanning. (Recommended: breath-hold test and patient hyperventilation preceding scanning.)**

Failure to meet these requirements will result in the creation of unreliable functional images.

12 Calcium Scoring



The (Cardiac) Calcium Scoring (CS) option is used to estimate the amount of calcium in the coronary arteries or other organs. This is achieved by performing automatic calculations on CT numbers inside Regions of Interest (ROIs), which the operator places around selected areas within a sequence of images.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

The (Cardiac) Calcium Scoring application accepts gated and non-gated images in DICOM format from any vendor, however, only Philips images access the Score database.



WARNING

When loading images into Cardiac Calcium Scoring, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Portal configuration, this application may not be available.

Cardiac Calcium Scoring Algorithm

The Cardiac Score of each ROI in each image depends on the Area of CT values greater than the threshold and on the density of CT values in that region. A total score is calculated for the selected sequence of images by selecting a preset, or user-defined, scoring method.

Mass Score

Mass score is possibly the most definitive method for quantifying calcium within a lesion. The method is based on calculating the mean CT number of a calcification and multiplying the result by the volume of the calcification and a calibration factor to obtain the calcification mass. This is expressed this way:

$$m_i = c \text{ CT}_i v_i$$

- The calcification mass is represented by m_i .
- The calcification volume, v_i , is obtained by multiplying the lesion area (in mm^2) that is above the defined threshold by the distance between the reconstructed slices (in mm).
- The calibration factor, c , is included in the software.

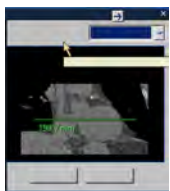
Calculate Lateral Thickness for Mass Score



When you use the Mass Score method for the first time, the Edit Lateral Thickness dialog automatically opens for you to specify the lateral thickness value. Access the drop-down menu and select the desired thickness.

- Small: < 32.0 cm lateral thickness;
- Medium: 32.0 - 38.0 cm lateral thickness;
- Large: > 38.0 cm lateral thickness; and
- From Surview. See section “Calculate Lateral Thickness from Surview” on page 312.

Calculate Lateral Thickness from Surview



You can also calculate the lateral thickness using the surview image. When you click **From Surview...** in the Edit Lateral Thickness dialog box, the surview image appears. If a surview was not loaded with the study, the application creates a coronal MPR in MIP mode in the middle of the volume.

1. A green line is displayed on the image.
2. Adjust the line as described in the tool tip: “Lateral thickness should be measured from skin-to-skin, at the level of the proximal ascending aorta, from an A/P surview image.”
3. Point the mouse on the line. The line turns yellow.
4. Move the line with the mouse as desired.
5. Adjust the ends of the line as desired with control points.

Area/step Method (Agatston)

The Area/Step method - the most commonly used scoring method - is based on Agatston score, which takes into account the Area of the calcified lesion and the average CT value within the lesion. This is the original Agatston method).

Step/Weight Factor	Value When CT Number Is Equal to or Greater Than	Value When CT Number Is Less Than Value
1	Threshold	200 HU
2	200	300 HU
3	300	400 HU
4	400	–

Score for the ROI = (step/weight factor) x (the Area of the lesion)

The calculated score is normalized to slice thickness of 3 mm.

The following scan parameters are required for Agatston Score protocol:

- Axial CT data
- Gated scan
- Non Contrast scan
- Thickness: 2.5 - 3 mm
- 120 kV
- mAs according to patient body habitus

For detailed information, please see Agatston Score Publication and 2016 SCCT/STR Guidelines:

[1] Arthur S. Agatston, Warren R. Janowitz, Frank J. Hildner, Noel R. Zusmer, Manuel Viamonte Jr. and Robert Detrano, "Quantification of coronary artery calcium using ultrafast computed tomography", JACC Vol. 15 No. 4 March 15. 1990:827-32. [2] Harvey S. Hecht a, Paul Cronin b, Michael J. Blaha c, Matthew J. Budoff d, Ella A. Kazerooni b, Jagat Narula e, David Yankelevitz f, Suhny Abbara, "2016 SCCT/STR guidelines for coronary artery calcium scoring of noncontrast noncardiac chest CT scans: A report of the Society of Cardiovascular Computed Tomography and Society of Thoracic Radiology", Journal of Cardiovascular Computed Tomography xxx (2016) 1-11.

Continuous Weight-factor Method (Lesion Volume)

In this scoring method, which is based on spiral CT data acquisition, the volume and the weighting factor are continuous.

The lesion volume is obtained by multiplying the area (in mm²) that is above the threshold, by the distance between reconstructed slices (in mm). This provides a score on a volumetric basis (in mm³). The continuous weight factor (WC), for calcified lesions above the threshold, is calculated by the formula:

$$W_c = (CT-50) / 100$$

The Volumetric score is calculated as follows:

$$\text{Score} = (W_c) \times (\text{the lesion volume})$$

NOTICE

Add the Score of all ROIs attained for all images. The sum is the Total Score of the study.

NOTICE

Volume and Area are calculated differently per protocol, as they are based on the threshold defined for the protocol. If the thresholds differ, the volume/area calculation may vary.

Accuracy and Reproducibility

Using the recommended protocols for the total score measurements and calculations:

- Error: 25% typical
- Reproducibility: 25% typical

**CAUTION**

The estimated accuracy of Calcium Mass scores of 10 mg or higher is 20%. Lower scores may exhibit larger variability.

Scan Protocols

On the scanner, one of the Cardiac Calcium Scoring-specific scan protocols should be selected for getting the best results from the Cardiac Calcium Scoring application.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

**CAUTION**

For follow-up studies, always use the same scan protocol and scoring protocol as in the baseline measurements.

Cardiac Calcium Scoring Window

The Cardiac calcium scoring window shows the selected images.

Areas of pixel values above the threshold are marked in pink (in Agatston Score) when the Highlight feature is on (default state). Turn off the Highlight to display the original colors of the image, without highlighting.

To increase the accuracy of the procedure, enlarge the selected scoring images by choosing a screen format of one or four. You can also use the zoom function to display only the area of interest in the screen frames.

Cardiac Calcium Scoring Viewing Tools

Use the tools to change the Cardiac Calcium Scoring views.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Layout

The Layout function controls how the images display in the viewport. Click the Layout down-arrow to select from four image layout arrangements, 1x1, 2x2, 3x3, 4x4, and Custom, which allows you to set the number of images.

Selection

Selecting images allows you to perform the same manipulation on the selected image(s) of your choice, such as scrolling, panning, zooming, filming, or saving. The Selection buttons, from left to right, are:

- One image (at a time).
- A series of images.
- The screen (the whole window).
- All images loaded in the viewer.

When switching between selection modes, the active image in the new mode is the same image that was active beforehand.

Display

When switching between selection modes, the active image in the new mode is the same image that was active beforehand.

Protocols

Protocols allows you to select the scoring method used for the study. The default method is based on the original method used for the scan.

The Edit Protocol drop-down provides options for adding, editing and deleting protocols.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Highlight

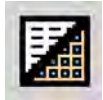
Cardiac Calcium Scoring uses Highlight to mark in color the image regions that have pixel values within a user defined range.

Changing the highlight window affects only the display on the screen. It does not affect the threshold values used for score calculation.

Cardiac Calcium Scoring Functions

To access additional HeartBeat-CS functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

Series



The Series tree displays a list of the studies and series that are loaded into the viewer, and also other elements (like batches) that have been created. Show Pictorials changes list to thumbnails.

Bookmarks

While using a viewer or an application, you can use a bookmark at any time to “save the current status” of your work.

Batch

The Batch function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Vessel List (Seed Tab)

Seed allows you to control seed placement in the vessels. You have the option to add, edit or delete items in the vessel list:

- To Add vessel to the list, type a name in the top field of the Seed tab.

You can change the names of the vessels you create at any time. Right click on a user-created vessel name to display these options:

- Rename allows you to rename an existing vessel.
- Delete allows you to delete vessel from the list.
- Reset allows you to delete all created vessels from the list.

These options are not available for factory default settings.

Scoring Procedure

The scoring procedure consists of user and software steps.

User Steps

Opening the Cardiac Calcium Scoring application and selecting images for processing.

Selecting a scoring protocol from the menu.

Identifying a calcified region and relating it to a specific organ (artery or valve) by selection from a menu.

Marking the areas to be processed (ROI) on each image.

Software Step

Calculating the score (once the user steps are complete, results are calculated from the seeded areas).

Open Cardiac Calcium Scoring Application

Images selected for scoring must be from the same series, with equal spacing between them, and whose slice thickness is equal to or greater than the spacing.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

1. From the Directory, select the storage device from which to read image files.
2. Select a patient’s name from the patient list.
3. Select the appropriate series from the series list:
 - Must be a gated axial or helical scan.
 - Must be a single volume.
4. From the Analysis options, select (Cardiac) Calcium Scoring (Heartbeat CS).



The system launches the application with the selected images.

NOTICE

Since the scoring process provides quantitative results, all images from the region being scored must be selected, not just those images with visible calcifications.

Mark ROIs for Processing

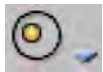
You can mark areas for processing using a manual or automatic method. Once an area is defined, the ROI displays with the vessel color and name.

Use the Seed tools to define the ROI.



CAUTION

Do not use the ROI tools in the Common tool box.



The Manual seed tools provide a variety of shapes to manually draw the ROI (Circle, Polygon, Ellipse, Free ROI).



The One-click seed tool allows you to create the ROI using a single click.

Use this procedure to mark the areas of calcification. Scoring is performed only on the marked areas.

1. Select an organ to mark from the list of vessels. The organ in the list becomes highlighted. Note that each vessel name has a different color.
2. Click the desired tool for marking the area:

- **Manually Draw ROI**

Click and drag around the area you want to identify with the ROI. After you finish drawing an ROI, the ROI shrinks to include only the area that is calcified.

If your manual ROI did not capture the entire calcified area, draw another ROI to capture more area. As shown below, you can overlap the first ROI with the second ROI, which then shrinks so there is no duplication of area. (Note that if your new ROI completely overlaps the old ROI, the new ROI is invalid.)

Start Overlap



Finish Overlap



– Use Automatic ROI

If calcification extends across more than one vessel (e.g., it starts in the Left Main and continues into the LAD), **do not use the automatic ROI tool**. Perform slice-by-slice manual seeding until the entire lesion is identified. Otherwise, the lesion may be included in multiple vessel scores.

With the automatic tool, click on a pink highlighted calcified area within the selected area. The system automatically identifies the calcified volume (the automatic tool detects calcium on several slices if the calcification is contiguous), changes the color of the area, and adds it to the score calculation.

Click the Show table or Show graph icon to display score.



WARNING

To ensure the accuracy of the score, verify the placement of the ROI and correct manually if necessary.

NOTICE

Do not use the ROI tools in the Graphic tools. ROIs created with these tools are not included in the scoring calculations.

3. You can define ROIs in each image you want to analyze. For each vessel, an unlimited number of ROIs per image are allowed. Use the center wheel on the mouse to scroll to another image within the selected viewport.
4. To mark additional vessels, select another vessel from the Artery list and repeat.

NOTICE

A non-valid ROI (overlapped with nearby ROI or covering too small a calcification area, as defined in the scoring protocol) will not be taken into account in the calculation. It will display in gray. Only a valid ROI appears in the organ color.

NOTICE

Manually verify the accuracy of all automatic and semiautomatic functions to avoid misdiagnosis.

Delete ROI



To delete an ROI created with the auto seed function, two options are available.

Delete segmented ROI(s). Click this button, then click on the ROI you want to delete. The ROI is deleted from all the slices which belong to this calcified volume that was marked with auto seed.

Delete Current ROI. Click this button, then click on the ROI you want to delete. (If more than one ROI belonging to same auto-seeded ROI exists on the current slice, only the ROI which was right clicked is deleted.)

NOTICE

You can also delete an ROI by right clicking on it, then selecting Delete.

Re-assign Vessel to ROI

To re-assign segmented calcium lesion ROI's, use the context menu (right-click). Select **Reassign to...** and select the labeled organ name in the sub-menu to reassign.

- Re-assignment for automatic ROIs is realized by deleting the ROI to be re-assigned and recreating the ROI for the new selected organ using the same seeding point. Thus, any conflicts due to intersections (in any slices of the ROI) with other ROIs are mitigated using the rules of the ROI creation process.
- Re-assignment for manual ROIs is possible only if the ROI to be reassigned does not intersect with other ROIs.
- Reassignment of the manual ROI is done by recreating the ROI for the new organ with the same characteristics of the old ROI (i.e. contour, statistics).

Display Selected ROI Values

After marking the ROI in one image, you can set the system to calculate the area, the volume, the average, the maximal CT number, and other parameters of the calcified lesion.

1. Click the **Plaque info** icon.
2. Click the parameters you want displayed.
3. Click **Ok**. The values you selected display near the marked ROI.

Save ROIs

You have the option of saving the ROIs in a separate entry in the Series List. When you reload the original images, the saved ROIs display on the images.

1. Click **Save ROIs as...** (from Common Tools, the Save as... function). The Saving results... dialog opens.
2. Accept the suggested Description, or enter a new name.
3. Select the Device, as desired.
4. Click **OK**.

Scoring Protocols

Selecting an appropriate protocol is important for viewing images in the Cardiac Calcium Scoring application.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Parameters Definition

Various preset scoring protocols are available. The preset protocols include these options:

- The original Agatston score, based on threshold value of 130 HU.
- Mass score protocol (calculates the score by taking into account each individual lesion volume, the CT value of each pixel in the lesion volume, and a calibration factor to obtain the calcification mass in mgHA, based on a threshold of 100 mgHA).

**CAUTION**

The estimated accuracy of Calcium Mass scores of 10 mg or higher is 20%. Lower scores may exhibit larger variability.

The scoring protocol displays in the Scoring tools panel. The default protocol is the Agatston score. Use this procedure to select a different protocol:

- Click the box showing the default protocol.
- Select a scoring protocol from the list of preset protocols.

Protocol Options

You have the option to add, edit, or delete any protocol in the list. Use this procedure to access the protocol options.

1. Click the protocol icon to display the protocol options menu.
2. Select an option:
 - **Add.** New protocol box displays.
 - **Edit.** Edit protocol box displays.
 - **Delete.** Protocol is automatically removed from the list.

The Edit protocol box includes the protocol name in the Name field.

3. Fill in the fields.
4. Click the desired option:
 - **Ok** to store the protocol and close the dialog box.
 - **Cancel** to close the dialog box without saving.

Display Scores

You can view the calcium score in either table or graph form.

Show Table



Click Show Table to toggle on or off the scoring results table. The system calculates the scoring along with the changes in the ROIs set for all the marked organs.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Right-click Options

Right click on the table (or click the small arrow in the upper right part of the table) to access these options:

- Score;
- #ROIs; and
- Area Sq. (sq. mm).

NOTICE

These options are only relevant when more than one series is being seeded in compare mode.

Use the Save As option to export the table information as text.

Use the Film option to export the table information to film.

Use the Report options to export the table information to the report.

Show Graph



When you have two or more series loaded, you can also view the results in graphical form. Click **Show Graph** to toggle on or off the scoring results graph. The system calculates the scoring along with the changes in the ROIs set for all the marked organs.

You cannot view the graph and the table simultaneously.

These cases are not included in the score or counted in the score table:

- an ROI covering calcifications with area smaller than the minimal area specified in the scoring protocol;
- an ROI overlapping another ROI; and

- an ROI not created by the Seed tools.



CAUTION

The estimated accuracy of Calcium Mass scores of 10 mg or higher is 20%. Lower scores may exhibit larger variability.

Relate Score to Database

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Within this procedure, there is an option to relate the individual patient score to an asymptomatic population score database. The **MESA** database is supported, as described below.

MESA database - **M**ulti-**E**thnic **S**tudy of **A**therosclerosis for Risk stratification. The MESA Database calculator is based on the following references:

- Reference: Robyn L. McClelland, Hyoju Chung, Robert Detrano, Wendy Post and Richard A. Kronmal "Distribution of Coronary Artery Calcium by Race, Gender, and Age: Results from the Multi-Ethnic Study of Atherosclerosis (MESA)", Circulation 2006

This article provides information that can be used to examine whether a patient has a high CAC score relative to others with the same age, gender, and race/ethnicity who do not have clinical cardiovascular disease or treated diabetes. These results come from MESA, a prospective cohort study of the prevalence, risk factors, and progression of subclinical cardiovascular disease, which was done on a United States population.

When the Calcium score result, according to Agatston Protocol is obtained, a percentile value is presented at the bottom of the scoring table or in the last column of the table if several series are displayed.

The indication for the **MESA** database is only visible if the Agatston score protocol is selected.

Score Database

See the "Instructions for Use" that came with your scanner for the parameters of “Calcium Scoring” or “Body” scan protocols included in the database.



CAUTION

If using the Calcium Scoring application on scanners prior to Brilliance 4, you must use the 0.5 Rotation time.

Scan Parameters

Philips Scan Parameters for Heartbeat Calcium Scoring Protocol

Axial/Helix	Tagging	KV	mAs	COLLIMATION	RESOLUTION	FILTER ¹
Axial	ECG	120	55-165	6x3	STANDARD	B
Axial	ECG	120	55-165	6x3	UFDETAIL ²	B
Axial	ECG	120	55-165	6x3	ULTRAFAST	B
Axial	ECG	120	55-165	8x3	STANDARD	B
Axial	ECG	120	55-165	8x3	UFDETAIL ²	B
Axial	ECG	120	55-165	8x3	ULTRAFAST	B
Axial	ECG	120	55-165	16x2.5	STANDARD	B
Axial	ECG	120	55-165	16x2.5	STANDARD	CB
Axial	ECG	120	55-165	16x2.5	DETAILED	B
Axial	ECG	120	55-165	16x2.5	DETAILED	CB
Axial	ECG	120	55-165	32x0.625	STANDARD	B
Axial	ECG	120	55-165	32x0.625	DETAILED	B
Axial	ECG	120	55-165	32x0.625	STANDARD	CB
Axial	ECG	120	55-165	32x0.625	DETAILED	CB
Axial	ECG	120	55-165	40x0.625	STANDARD	B
Axial	ECG	120	55-165	40x0.625	STANDARD	CB
Axial	ECG	120	55-165	40x0.625	DETAILED	B
Axial	ECG	120	55-165	40x0.625	DETAILED	CB
Axial	ECG	120	55-165	64x0.625	STANDARD	B
Axial	ECG	120	55-165	64x0.625	DETAILED	B
Axial	ECG	120	55-165	64x0.625	STANDARD	CB
Axial	ECG	120	55-165	64x0.625	DETAILED	CB
Axial	ECG	120	55-165	128x0.625	STANDARD	B
Axial	ECG	120	55-165	128x0.625	DETAILED	B
Axial	ECG	120	55-165	128x0.625	STANDARD	CB
Axial	ECG	120	55-165	128x0.625	DETAILED	CB
Axial	ECG	120	55-165	112x0.625	STANDARD	B
Axial	ECG	120	55-165	112x0.625	DETAILED	B

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Philips

Axial/Helix	Tagging	KV	mAs	COLLIMATION	RESOLUTION	FILTER ¹
Axial	ECG	120	55-165	112x0.625	STANDARD	CB
Axial	ECG	120	55-165	112x0.625	DETAILED	CB
Axial	ECG	120	55-165	96x0.625	STANDARD	B
Axial	ECG	120	55-165	96x0.625	DETAILED	B
Axial	ECG	120	55-165	96x0.625	STANDARD	CB
Axial	ECG	120	55-165	96x0.625	DETAILED	CB

- ¹B filter: Standard resolution, recommended for CTA, routine abdomen, pelvis and spine. High resolution: Offers moderate sharpness and noise. Ultra-High Resolution: Moderate noise for soft tissue.
- ¹CB filter: Smooth, cardiac scan only
- ²UFDETAIL = Ultra-Fast Detailed

For more details, please refer to the Instructions for Use that came with your scanner.

Missing Parameters

When loading series with missing parameters, such as age, gender, ethnicity (if relevant), an indication is displayed that asks from the user to enter the missing, relevant parameters via the **Patient Information** dialog.

If some of the parameters are not compatible to the database parameters, then another indication is displayed that notifies the user about it.

The percentile is calculated only if the parameters match the database parameters.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

If all the parameters are missing from DICOM, a dialog box pops up. Only missing parameters are displayed in the popup.

Only missing DICOM parameters can be edited by the user.

- Gating menu options are: ECG and Other.
- Phase options are: 75%, 85%, and Other.

NOTICE

You may see a database even if entered parameters do not match the scan.

If some of the parameters are not compatible with the database parameters, an additional message notifies the user.

Cardiac Calcium Scoring References

The following articles contain information relevant to the use of the Scoring algorithms to quantify calcium in the coronary arteries.

Agatston A., Janowitz W., Hindler F., et al., Quantification of Coronary Artery Calcification using UltraFast Computed Tomography: J Am College Cardiol 1990; 15; 827-832.

Broderick L.S., Shemesh J., Wilensky R.L., et al., Measurement of Coronary Artery Calcium with Dual-Slice Helical CT Compared with Coronary Angiography: Evaluation of CT Scoring Methods, Interobserver Variations, and Reproducibility: AJR 1996; 167; 439-444.

McClelland, R.L., Chung, H., Detrano, R., Post, W. and Kronmal, R.A., "Distribution of Coronary Artery Calcium by Race, Gender, and Age: Results from the Multi-Ethnic Study of Atherosclerosis (MESA)", Circulation 2006.

Schmermund A, Silber S, et al., "Age and Gender Distribution of Coronary Artery Calcium Measured by Four-Slice Computed Tomography in 2,030 Persons With no Symptoms of Coronary Artery Disease", AJC 2002;90:168-173.

Shemesh J., Apter S., Rosenman J., et al., Calcification of Coronary Arteries: Detection and Quantification with Double Helix CT: Radiology 1995; 197; 779-783.

Wexler L., Brundage B., Crouse J., et al., Coronary Artery Calcification: Pathophysiology, Epidemiology, Imaging Methods, and Clinical Implications: A Statement for Health Professionals from the American Heart Association. Circulation 1996; 94; 1175-1192.

MESA Database Calculator

The MESA Database calculator is based on the following references – [Robyn L. McClelland, Hyoju Chung, Robert Detrano, Wendy Post and Richard A. Kronmal "Distribution of Coronary Artery Calcium by Race, Gender, and Age: Results from the Multi-Ethnic Study of Atherosclerosis (MESA)", Circulation 2006]

Image Quality Assurance

Quality assurance procedures for the Cardiac Calcium Scoring application must be followed. See the Image Quality Assurance section in the Philips CT user manual regarding QA procedures for the scanner.



CAUTION

Because the cardiac calcium scoring function supplies quantitative results, following the QA procedure is mandatory.

13 Liver Analysis



The Liver Analysis application provides segmentation tools to facilitate for assessing the liver, hepatic vasculature of individual vascular segments, and physician-identified lesions. The application has 3 stages, with specific goals and clinical uses:

1. **Segmentation.** Perform segmentation of the liver tissue, vessels, and lesions.
2. **Liver Segments.** Define liver segments as well as the number of segments.
3. **Surgery Planning.** Plan liver resection.

NOTICE

Liver volume can be auto segmented on any series. However the auto segmentation of the vessels is done only for the hepatic and portal veins.

A Portal-Hepatic scan of the liver is recommended for the Liver Analysis application.

NOTICE

Each time a study is loaded, the system performs a new auto segmentation. Auto segmentation data is not automatically saved when the study is closed. You must save the segmentation using Save Results in the Common Tools.

When you load a study, automatic segmentation segments the liver tissue and portal and hepatic vessel trees, and classifies the liver vascular segments. This process may take several minutes.



WARNING

Verify the accuracy of the automatic segmentation. If necessary, manually correct the segmentation using the correction tools provided in this stage.

In cases where the orientation annotations are not displayed on the image, you must not assume any specific orientation. For correct orientation information, use only the images which display such information.

- **Volume or slab images may appear in this application. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.**
- **Objects in thick-slab images may appear distorted. Use caution when making measurements.**

NOTICE

Cross sectional images cannot be rotated. Please note orientation annotations on images.

**WARNING**

Loading cases with thicknesses greater than 2 mm may result in inaccuracies when the Add/Remove Smart Brush and Add/Remove Smart ROI editing tools are used.

**WARNING**

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

About Anatomical Landmarks

The method of using anatomical landmarks for liver-segments definition was developed in a close collaboration with Professor Pierre-Jean Valette (Hospices Civils de Lyon, France).

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Portal configuration, this application may not be available.

Loading Results from the Multimodality Tumor Tracking Applications

The application supports the loading of Tumor Tracking results. Findings that were marked in the Tumor Tracking application appear in the Liver Analysis Findings List and on the image (with the name that was assigned in the Tumor Tracking application). Results from the Liver Analysis application can also be loaded to the Tumor Tracking application.

Liver Analysis Options and Tools

Use the following options and tools (in the upper tool box) during each stage, except where noted, to modify the view and perform analysis.

Incremental Segments Creation (Stage 2)

By default, the **Incremental Segments Creation** feature is active. This enables you to view and edit the segmentation results during landmark placement. If real-time segment creation is excessively slow, uncheck the box to disable the feature.

Show Liver (All Stages)

Check the box to show the liver tissue and segments in the 3D and 2D rendering viewports on and off. This only works after liver segmentation is complete.

Show Vessels (All Stages)

Check the box to show blood vessels.

Show Findings (All Stages)

Check the box to show findings (if any). This option shows the Findings you add on the Findings tab during the Segmentation stage.

Show Crosshair (Stages 1 and 2)

Check the box to show the crosshair in the axial, coronal, and sagittal viewports.

Show Transparent (All Stages)

Use to show or hide the liver segments. Only active after segmentation has been completed **and** the volume image is in Volume Rendering mode.

Show Contour (Stage 1)

Click to show or hide tissue contour on slab image. When selected, the active tissue contour is highlighted in green.

Show Summary Table (All Stages)

Click to show or hide a summary of the view (the table is shown by default). The table provides stage-specific information and functionality. During Segmentation stage use the table to view the HU, Volume, and Percentage of segmented liver, vessels, and your findings. During the Liver Segment stage, the table includes additional information about the segments you create. For the Surgery Planning stage, the table provides a summary of placed electrodes and resections (the table during this stage is not interactive). Within the table, change the liver or vessel color and opacity.

Click on the color icon in the Edit color and opacity column and select the Color dialogue box.

To change liver or vessel opacity, hover over the Edit color and opacity column and drag the opacity indicator right or left.



NOTE: Editing the color and opacity is only available for the first and second stages.

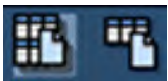
When viewing the table in the Liver Segments stage, adjust the opacity and color as outlined for the Segmentation stage. Any changes made are specific to the stage and will not change the view settings of the Segmentation stage.

NOTICE

In the Segments stage (second stage), the table gives the results (in cc and %) of the segments based on the total liver or on the functional liver (click on the table header to switch between results): functional liver = Total liver – (total vessels + total findings).

For the Surgery Planning stage, click to view the resection summary table and any findings.

Copy Table to Clipboard (Stages 1 and 2)



In the **Segmentation** and **Liver Segments** stages, use the **Copy Table to Clipboard** button to add the selected table to the clipboard. The button is located in the table header. The first table has an additional option to copy all the tables to the clipboard (as shown in the image).

Once on the clipboard, the contents may be pasted into a different application, such as a reporting system or Microsoft Word document.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Segmentation Stage

When the Segmentation stage opens, the liver tissue is segmented automatically, followed by the vessels segmentation. When segmentation completes, all tissues are displayed in the appropriate viewport.

**WARNING**

Please verify correctness of the segmentation on all the segmented slices and edit if required.

NOTICE

SSD - Surface Shading Display is a rendering mode that provides superior transparency for tissues. This is the ideal rendering mode for displaying tissues which reside inside another tissue. SSD is the default rendering mode for the Liver Analysis application.

Edit Tissues

Review the liver segmentation and volume, and correct the segmentation if required. You can manually activate liver segmentation if needed for another series (different contrast phase). If correction is required, it can be done in a subsequent stage using the editing tools on the Liver/Vessel Segmentation tab. Review classification into vascular segments, and correct if required.

NOTICE

If initial vessel segmentation is incomplete, the re-segment vessels function might result in an improved segmentation of the vessels. If not, use the manual tools to edit.

**WARNING**

Please verify correctness of the segmentation on all the segmented slices and edit if required.

**WARNING**

Verify correctness of vessels segmentation. If required use the editing tissues or the reclassify tools.

1. Go to the **Liver/Vessels Segmentation** tab.
2. In the Select Tissue table, click a tissue segment to highlight it (for example, Liver, Hepatic, Portal, Unclassified).
 - Check the box to show or hide the tissue segment in the viewer.
 - To change the color of a segment, click on the color icon to open the Color dialogue box. See section “Liver Analysis Options and Tools” on page 330.

3. To edit active tissue, modify the view and the segmentation of the selected tissue. Set the opacity. Add tissue using one of the draw tools. See section “Liver Analysis Options and Tools” on page 330.
4. Where necessary, change the classification and segmentation of selected vessels.
5. When done, Go to the **Findings** tab.

Re-classify Vessels



Use to turn a portal vessel into a hepatic vessel, hepatic into portal, or unclassified into hepatic or portal. First activate the tool, then select a vessel from the pop up dialog, you want to assign a seed to.



WARNING

Verify correctness of vessels classification. If required use the editing tissues or the reclassify tools.

1. Activate the reclassify tool. This will open a menu to the active viewport. In addition, activating the tool will show the seed points used for the auto segmentation of the vessels. These seed points can be moved by dragging them.
2. Position seeds by dragging the +H (hepatic) or +P (portal) seeds onto the vessel to be re-classified. Or, use the Edit menu and select:

Place seeds on Hepatic



then

Place seeds on Portal



if multiple seeds must be placed. This may be done on either the volume or MPR images.

3. When done click the **Accept** seed button.

Re-segment Liver

Use **Re-segment Liver** if the zero-click, automatic liver-segmentation failed.



WARNING

Verify correctness of the segmentation on all segmented slices and edit if required.

1. Active the **Re-segment liver** button.



2. Place a seed point in the center of the liver.

The auto segmentation will start looking for the liver based on the seed point.

Re-segment Vessels



Use to toggle between standard and high resolution rendering when re-segmentation is used. While high quality segmentation increases the process time, using this re-segment option may improve upon the standard segmentation performed during automatic segmentation.



WARNING

Verify correctness of vessels segmentation. If required use the editing tissues or the reclassify tools.

NOTICE

Using Re-segment will remove any re-classification changes you have made.

Findings

Use the Findings tools to segment lesions (and other areas of interest) inside the liver. The tools used to mark and edit findings function similar to those described in the Liver/Vessels Segmentation section.



WARNING

Please verify correctness of the segmentation on all the segmented slices and edit if required.

Mark your findings on the MPR images (not the Volume image).

NOTICE

This is a volumetric tool and its effect extends beyond the current visible slice. After using this tool, review its effects by scrolling through the slices on which the lesion is displayed.

1. Go to **Segmentation** stage > **Findings** tab.
2. Use either the:
 - **Draw Smart ROI (3D)**



OR

- **Draw smart brush (3D)**



tool to mark lesions and other areas of interest.

3. To edit finding, click on a finding in the Findings table and use the **Add**, **Subtract**, and **Edit contour** functions to modify the selected Finding. The editing tools are automatically activated when you draw a finding.
4. Repeats the previous steps for each finding. When done, Go to the **Liver Segments** stage by using the stage navigation pane.



WARNING

Loading cases with thicknesses greater than 2 mm may result in inaccuracies when the **Add/Remove Smart Brush** and **Add/Remove Smart ROI** editing tools are used.

Liver Segments Stage

In the Liver Segments stage, a complete segmentation of the liver vessels and lobes, using seed points you provide, is performed. Using the segmentation tools, place seed points on one of the images.



WARNING

Verify correctness of the division of the segments. If required edit or add the appropriate seed points.

Determine Number of Segments



During the Liver Segments stage, use when defining the liver segments. Once defined, use the drop-down to switch among the different liver segment views. Select from the following options:



1. **Two (2) segments L-R Liver.** Landmarks include: Inferior vena cava; middle hepatic vein.
2. **Two (2) segments L-R Lobe.** Landmarks include: Inferior vena cava; Umbilical fissure; Left portal bifurcation; Superficial ligamentum venosum; Deep ligamentum venosum; Superior deep ligamentum venosum.
3. **Four (4) segments L-R medial and lateral.** Landmarks include: Inferior vena cava; Right hepatic vein; Mid hepatic vein; Umbilical fissure; Left portal bifurcation; Superficial ligamentum venosum; Deep ligamentum venosum; Superior deep ligamentum venosum.
4. **Seven (7) segments.** Landmarks include: Inferior vena cava; Right portal bifurcation; Right hepatic vein; Mid hepatic vein; Umbilical fissure; Left portal bifurcation; Superficial ligamentum venosum; Deep ligamentum venosum; Superior deep ligamentum venosum.
5. **Eight (8) segments Couinaud.** Landmarks include: Inferior vena cava; Right portal bifurcation; Right hepatic vein; Mid hepatic vein; Umbilical fissure; Left portal bifurcation; Tip left liver; Superficial ligamentum venosum; Deep ligamentum venosum; Superior deep ligamentum venosum.
6. **Nine (9) segments Bismuth.** Landmarks include: Inferior vena cava; Right portal bifurcation; Right hepatic vein; Mid hepatic vein; Umbilical fissure; Left portal bifurcation; Tip left liver; Superficial ligamentum venosum; Deep ligamentum venosum; Superior deep ligamentum venosum.

Define Segments

Use the Add Landmark tool to identify the liver segments. The number of landmarks placed depends on the number of liver segments selected using the Segment Liver tool. Landmark placement determines the 3-dimensional segmentation of the liver.



WARNING

Verify correctness of the division of the segments. If required edit or add the appropriate seed points.

To assist in placement, click the **Show segmentation guidance** tool.

Add Landmark

NOTICE

By default, the **Incremental Segments Creation** feature is active. This enables you to view and edit the segmentation results during landmark placement. If real-time segment creation is excessively slow, uncheck the box to disable the feature (you will need to click the **Start Segmentation** button to complete segmentation).



Click the Add landmark button and place landmark seeds on either the slab or volume images for every segment in the list.

Inferior vena cava	Position landmark in center of the Vena Cava. It serves as a central point connecting with other landmarks.
Right portal bifurcation	Position landmark at bifurcation of the Right Portal Vein to horizontally divide the right liver lobe.
Right hepatic vein	Position landmark in the direction of the Right Hepatic Vein to define the borders of right lateral segments .
Mid hepatic vein	Position landmark in the direction of the Middle Hepatic Vein or gall bladder fossa direction to define the borders of the right medial segments .
Umbilical fissure	Position landmark at umbilical fissure to define the separation between left and right liver lobe.
Left portal bifurcation	Position landmark at bifurcation of Left Portal Vein to horizontally divide the left liver lobe.
Tip left liver	Position landmark at tip of the left liver lobe. Optimal location is the most left position of the liver at the same slice where the Left Portal Bifurcation landmark is positioned.
Superficial ligamentum venosum	Position landmark superficial and posterior of the liver where the separation between segment 1 and 2 is clearly visible.
Deep ligamentum venosum	Positioned landmark on the same slice as the Superficial ligamentum venosum.
Superior deep ligamentum venosum	Position landmark in the cranial direction, where segment 1 is ending.

NOTICE

Scroll through the slices while dragging the mouse.

When placing landmarks, use the Show Segmentation Guidance tool (see below) for assistance or perform the following:

1. Click the **Add Landmark** button. When the button is active, the first landmark is highlighted in the table by default. To place a different landmark first, select it from the table.
2. Place the necessary landmarks on either the volume or slab images to identify the tissue segments. If using the default settings, the next landmark is automatically selected and real-time segmentation begins.
3. When all landmarks are placed, the system completes segmentation.
Use multiple landmarks, except for the left and right portal end, to increase the accuracy of a segment. Highlight the landmark in the table or on the guided image and mark the extra landmark onto one of the images in the available viewports. The system will add an addition landmark in the table and on the image.
4. Verify the segmentation and make changes as necessary.

- Click a landmark to view the landmark’s associated seed point.
- Drag and drop the landmarks in the new location.
- Select a landmark from the table and place additional landmarks to improve segmentation.
- Right-click a landmark to delete it.
- Click the **Start Segmentation** button to complete segmentation if you disabled the **Incremental Segments Creation** feature.



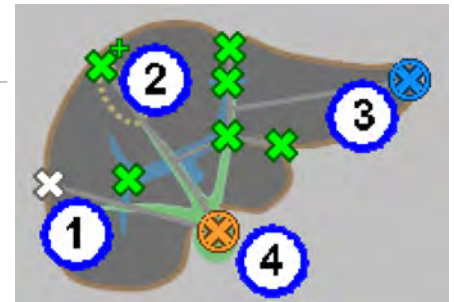
5. If segmentation failed, move or replace the landmarks and perform segmentation again. Use the Show Segmentation Guidance tool (see below) for assistance when placing landmarks.

Show Segmentation Guidance



Use the interactive Segmentation guidance dialogue when seeding landmark points using the Add Landmarks tool.

1. White cross indicates landmark inactive and no seed points have been assigned.
2. Green cross indicates landmark not active but seed points have been assigned. The small green cross represents a secondary seed has been placed for the landmark.



3. Blue cross indicates landmarks is active and has a seed point already assigned.
4. Orange cross indicates landmark is active but no seed points are defined.

The guidance image and the landmark list are related. Once a landmark is assigned with the guidance image, the list is updated to help with assigned landmarks.

To use the guidance image when placing landmarks perform the following:

1. Click the **Show segmentation guidance** button.
2. Click the **Add landmark** button.
3. Place the landmark seed on the volume or slab image in the appropriate location, as indicated by the orange cross in the guidance dialogue box.

After placing a seed, the system will automatically move to the next landmark. Follow the same process when placing multiple seeds.

4. Perform and verify segmentation. Click a seed on the guidance image to highlight it on the volume and slab images. Click the **Start Segmentation** button to complete segmentation if you disabled the **Incremental Segments Creation** feature.



Surgery Planning Stage

Use this stage for planning resection or transplant surgery procedures. Define what parts of the liver will be removed.

NOTICE

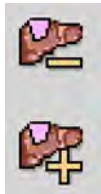
When safety margins are applied they are added to the volume of the findings.

Use for resection/transplant planning. Determine the atypical or anatomical resection.

NOTICE

Icons with “-” sign are used to define a region for resection and icons with “+” sign are used to define a region that should not be resected.

Anatomical Resection



To perform an anatomical resection, click the **Remove segment** button to define the lobe/segment that is planned for resection. Resection can be done by clicking the **Add segment** button. Use the Clipping Tools as outlined in the Common Tools and Common Processes sections.

Atypical Resection



To perform an atypical resection, click the **Remove tissue** button to define the lobe/segment that is planned for resection. Resection can be done by clicking the **Add tissue** button.

14 Lung Nodule Assessment

Introduction



The Lung Nodule Assessment and Comparison Option is intended for use as a diagnostic patient-imaging tool. It is intended for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. The system automatically performs the measurements, allowing lung nodules and measurements to be displayed.

The user interface and automated tools help to determine growth patterns and compose comparative reviews. The Lung Nodule Assessment and Comparison Option requires the user to identify a nodule and to determine the type of nodule in order to use the appropriate characterization tool. Lung Nodule Assessment and Comparison Option may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening.*



CAUTION

***Screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.**

Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Results of this application include nodule measurements, clinical decision-support tools and category calculations based Lung-RADS™ guidelines.

The LNA application features include nodule identification using single click segmentation, nodule volume calculation and an optional Lung Nodule Computer Aided Detection (CAD) feature.

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

Limitations for Use



WARNING

When loading images into Lung Nodule Assessment, all images which contain 16 bit data are converted into 12 bit images. This means that for rescale intercept equal to -1000, HU values above 3095 are displayed as 3095. For rescale intercept equal to -1024, HU values above 3071 are displayed as 3071.

Supported Scan Types

The application supports chest volumetric CT data with Axial orientation. The application supports loading of up to eight time-points, with a single series in each time-point.

LNA only supports Supine scans.

Device Description

Philips Medical Systems enhanced Lung Nodule Assessment (LNA) and Comparison Option application is intended for use as a diagnostic patient-imaging tool for reviewing and analyzing thoracic CT images for Lung Nodule assessment and characteristics.

The Philips Medical Systems enhanced Lung Nodule Assessment (LNA) and Comparison Option application is a software package used with Phillips IntelliSpace Portal.

Using the LNA application, the user can identify nodules and measure their volumes in a single study and, using the follow-up mode with subsequent studies, compare matching nodules in two studies. The Lung Nodule CAD Option may be used to assist in nodule detection. The growth of nodules can be tracked over time.

The application features volumetric quantitative measurement tools and a set of advanced editing tools.

In addition, the application consists of a Risk Calculator tool that uses image-based features and clinical information and a Lung RAD™ calculator, according to ACR guidance, which can assist the physician when making decisions regarding the next treatment steps.

The LNA application may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening*.

*The screening must be performed within the established inclusion criteria of programs/protocols that have been approved and published by either a governmental body or professional medical society.

Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Key Features

- Automatic Lung and Lobe segmentation
- Single-click lung nodule segmentation
- Manual nodule segmentation editing tools
- Loads up to 8 concurrent studies for temporal measurements
- Restores previously segmented nodules from prior studies for comparison
- Enhanced comparison feature that allows matching and correspondence between pre-identified nodules in two studies
- Synchronization between studies from different time-points
- 3D or MIP visualization of segmented nodules
- Reporting based on Lung-RADS™ guidelines. An option enables exporting to Clipboard
- Risk Calculator tool based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919.*
- Reporting based on Fleischner Society Guidelines. An option enables exporting to Clipboard
- Automatic software calculation of the following measurements for each segmented nodule:
 - Quantification of nodule parameters
 - Long Axis- Longest diameter on an axial/coronal/sagittal slice (mm)
 - Short axis- Longest diameter perpendicular to the long axis on the same slice (mm)
 - Average \ Max 3D \ Effective diameter (mm)
 - Volume (mm³)
 - Mean densities (HU)
 - Nodule Mass (mg)
 - Manual editing of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing
 - **Specification of the following characteristics for each nodule in configurable presets**
 - Nodule type (solid, part-solid, ground glass, calcified)
 - Lobe location
 - Nodule shape (Circular/Oval/Triangular)
 - Nodule Spiculation
 - Comparison and matching feature automatic calculation of the following measurements between each follow-up scan and the previous scan:
 - Doubling time in days

- Percent (%) and absolute change of all numerical parameters (growth in nodule long axis, short axis, average diameter, max 3D diameter, effective diameter, volume and mean HU).

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

Functionality Workflow

The Lung Nodule Assessment (LNA) and Comparison Option application may be utilized in both diagnostic and screening evaluations supporting Low Dose CT Lung Cancer Screening.*

***The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.**

Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Main LNA application Workflow And Stages

The Lung Nodule Assessment (LNA) and Comparison Option application includes three main scenes:

1. Scene 1: Detect & Segment

This is the initial stage, which allows the user to perform the following:

- Explore a single study in order to find nodules
- **Segmentations of nodules** - Single-click lung nodule segmentation - segmentation of the physician indicated lung nodules is initiated manually by clicking on the nodule, and the nodules are detected and marked by the user. Segmentation of nodules is performed by the designated 3D tools.

2D segmentation of the physician indicated lung nodules is also available and is being performed with dedicated 2D segmentation tools. 2D segmentation is performed manually.

Edit the segmentation by enhanced editing tools. Manual edit of the nodule segmentation contour lines with automatic recalculation of geometric measurements post-editing is available.

- **Characterization of nodule** – Including automatic measurements as well as suggesting nodule characteristics in configurable presets. User needs to confirm the suggestion or to manually select another value.

2. Scene 2: Compare & Match

This workflow stage is available when performing a follow-up Lung Nodule Assessment (LNA) and Comparison Option procedure. This scene purpose is to compare between studies (initial and follow-up) in order to assess nodule characterization changes over the course of time of several thoracic studies. This scene includes all the available options of scene #1, presented above, with the addition of the following features:

- Loading the follow up studies.
- Synchronization between studies from different time-points. User can disable and/or override using the “Link” tool.
- **Matching** - An automatic matching suggestion of lung nodules between studies. The user needs to decide whether to accept the suggested match of the two nodules or to create a new un-matched nodule.
- **Propagation** - Propagation functionality could be automatic and manually done by the user. Automatic suggestion and presentation of a potentially matching nodule, based on an already segmented nodule from another time-point.

The user reviews suggested matches and nodule propagation and either accepts or rejects them.

3. Scene 3: Results

The Results work stage consists of the following:

- **Population of patient related information** – Patient and family history of lung cancer. User fills in the patient related information manually.
- **Nodule result table** – This table includes all the confirmed by the user lung nodules that were identified in the first two scenes, scenes #1 and #2. Each nodule with the characteristics that are available per each specific nodule, such as identified nodules number, characteristics and measurement, as well, changes over time (for follow-up studies). If a characteristic was left empty or unconfirmed- it will be displayed as “undefined” in the table.
- **Additional finding** – Allows the user to add manually further patient related information when a patient has an additional finding, related or unrelated to lung cancer.
- **Lung-RADS™** – The Lung-RADS reporting criteria provide automatic Lung-RADS calculation according to the American College of Radiology (ACR) guidelines, including: category, suggested management and a rationale. The user has to confirm or reject the suggestion and can override it by manual selection of Lung-RADS category.
- **Risk Calculator tool** based on patient and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, based on *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919.* The subject Lung Nodule Assessment and Comparison Option provides this additional feature to assist and support user decision.
- **Fleischner Society Guidelines Calculation** provides management suggestion based on rev. 2017 of the Fleischner Society guidelines.

- Different results management options are available to the user:
 - Copy results to Clipboard
 - Save results as image series
 - Export results to PDF
 - Send results to report
 - Save option – the tables could be saved as HTML or Text file

Single Study (Single time point) work flow

The following flow presents the main stages in Single study (single time point) operation work flow:

Data Loading → Chest Inspection → Nodule Segmentation and Editing → Nodule Characteristics → Review Results → Export Results

Follow-up (multiple time-points) workflow

The following flow shows the main stages in Follow-up (multiple time-points) operation workflow:

Data Loading → Chest Inspection → Nodule Segmentation and Editing → Nodule Characteristics → Propagate and Match Nodules → Review Results → Export Results

NOTICE

Depending on your Portal configuration, this application may not be available.

Validation Activities

For the Lung Nodule Assessment and Comparison Option (LNA), validation activities were conducted to provide objective evidence that the design meets user needs and intended use.

These validation activities assure that the lung and lobe segmentation, the comparison, as well as the nodule matching and propagation functionality, and the Prefill functionality for the Lung-RADS score and the risk prediction are adequate from an overall product perspective.

Recommended Scan Parameters

When using the Lung Nodule Assessment clinical application, there are recommended parameters that should be used to insure accurate and reproducible results.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

If the radiologist prefers different parameters based on preference or clinical indication, certain guidelines should be followed if the case is intended to be processed with the LNA application. In these instances, if guidelines cannot be met, it is suggested to perform a second reconstruction from raw data with the recommended parameters for use in the Lung Nodule Assessment package.

Scanning Parameter	Follow These Guidelines When Creating a Protocol for Lung Nodule
Resolution	Standard resolution
Filter	Filter C <ul style="list-style-type: none"> • The B filter can be used • Never use the D, L, or Y filters • Do not add any additional enhancements
Slice thickness	Slice thickness 3mm or less with a 50% overlap <ul style="list-style-type: none"> • The slice thickness is related to the size of the nodule. If the nodule is small, then the thinnest slice thickness available should be used to make volumetric measurements • There are several factors that can affect the segmentation of the nodule: <ul style="list-style-type: none"> – Scan parameters (slice thickness, filters) – Nature of the nodule (shape, homogeneity)



CAUTION

If the recommended parameters are not used the accuracy of the results cannot be assured.

When performing follow-up studies it is important to use the same parameters as the original case to get a consistent volumetric comparison between current and previous studies.

Loading Studies

Load Multiple Studies in Application

To load multiple studies in the application:

1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

From the IntelliSpace Portal Patient Directory, locate the LNA study you want to work with.

NOTICE

If performing a follow-up procedure, load at least two studies (up to eight studies can be loaded) at this time. The follow-up procedure is described in the section “Compare & Match Work Stage” on page 367. Although you can load multiple studies, only two studies are displayed at a time. The remaining studies are loaded and can be used within the application.



Select Lung Nodule Assessment from the Analysis tab. The LNA study loads.

- LNA supports the loading of up to eight time-points, with a single series in each time-point.
- By default, images are loaded with Lung windowing, original slice thickness and MIP rendering mode.
- When loading a single time-point to the application, the **Detect & Segment** stage is active by default and the **Compare & Match** scene is unavailable.
- When loading multiple time-points to LNA, the **Compare & Match** stage is active by default. It is possible to navigate back to the **Detect & Segment** stage if needed.
- When attempting to load more than one axial series within a time-point, a **Series Selection** window appears. The user must select a single representative series for each timepoint.

NOTICE

One or more of the following image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.

Workflow

1. Detect & Segment Work Stage



The initial workflow stage, **Detect & Segment**, allows you to perform the following:

- Lung and lobe segmentation on the CT image (pre-processing performed automatically).
- Use the Lung Nodule CAD option as an adjunct detection process (if available).
- Explore a single study in order to find nodules.
- Select and segment nodules using 3D or 2D segmentation tools.
- Edit the segmentation using the enhanced editing tool.
- Calculate nodule measurements and fill in nodule characteristics via by automatic pre-fill option or manually.

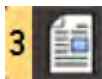
2. Compare & Match Work Stage



Use the additional workflow stage, Compare & Match, when performing a follow-up LNA procedure.

Use the Compare & Match stage to compare the two studies (initial and follow-up) and assess changes over time. After you have matched nodules between the studies, you can generate a report that includes calculations of nodule measurement changes and projected doubling time.

3. Results

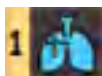


A Summary table is created, showing all identified nodules, with characteristics and measurements that include Maximum 3D diameter, volume, effective diameter, Long & Short Axes and mean Hounsfield units, as well as calculations of percentage of growth and doubling days.

In addition, the LNA application provides Lung RAD calculation according to ACR guidelines and a risk calculator result of the calculation of the probability of malignancy based on Risk Calculator tool based on patient information and nodule characteristics for estimation of the probability that lung nodules detected on baseline screening low-dose CT scans are malignant, McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. *New England Journal of Medicine*, 369(10), pp.910-919.

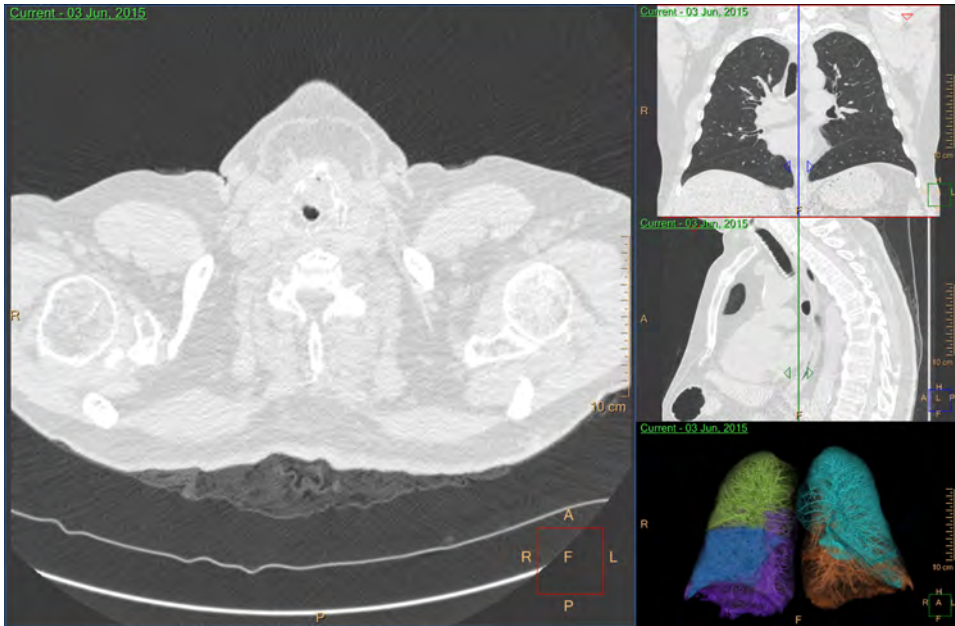
Images can be sent to film or report at any time during the analysis. After segmentation has been done, the identified nodules and results can be saved, filmed, and sent to report.

Detect & Segment Work Stage



When loading a single study into the Lung Nodule Assessment application, it defaults to the **Detect & Segment** workflow stage.

The main viewport displays the axial slab image (using the original thickness it was reconstructed with). Use this image to look for nodules. It can be manipulated like any slab image.

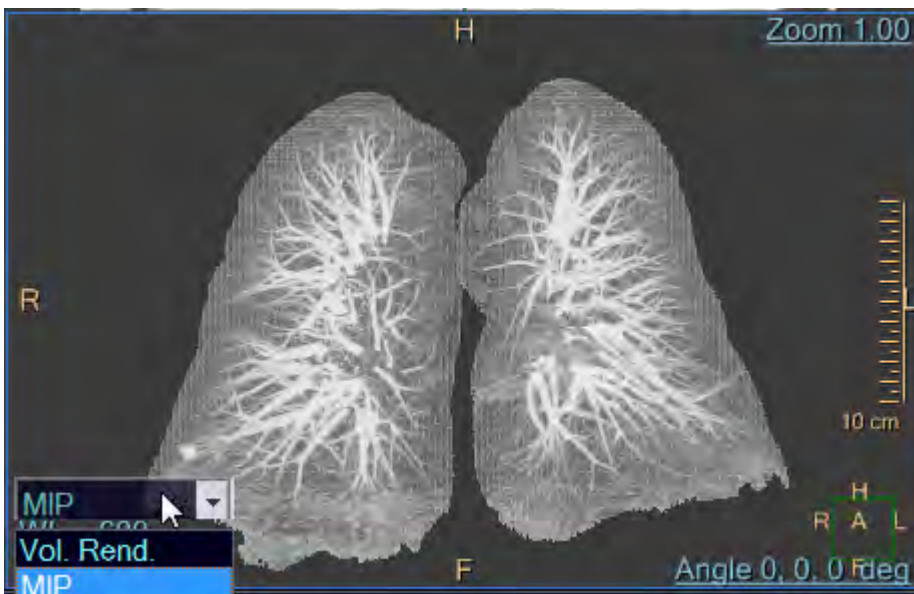


Reference Images, Coronal and Sagittal

Reference images are displayed in the minimum slice thickness. After nodules are marked and accepted, these images visually indicate the locations of the nodules by surrounding each of them with a blue circle and a Finding number.

Mode

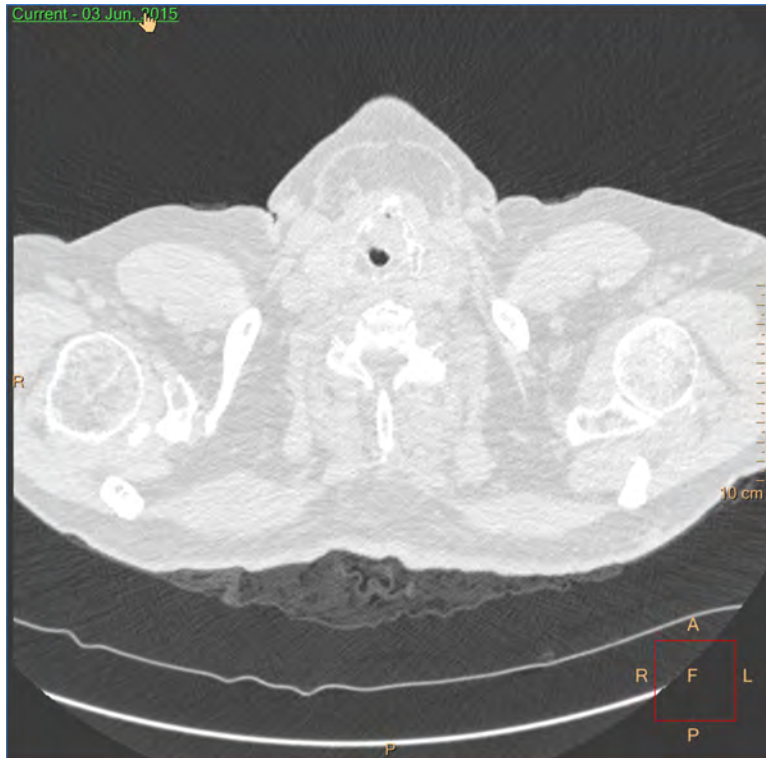
To change a VR image to MIP Rendering mode, use the viewport control.



Switching Between Time Points

When loading multiple timepoints and navigating to the Detect & Segment work stage, it is possible to switch between the time points using either:

- The series selection viewport control.



- The Next and Previous series button in the upper toolbox.

CT Common Tools

These are the tools that are common to other IntelliSpace Portal applications.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Image Review Tools

Various viewing techniques and tools are provided to assist in your image viewing, nodule detection, and matching process.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Orientation

You can select from three viewing orientations: Axial, Coronal, Sagittal, and Flip. The Flip button becomes available when you select the Volume image or MIP Overview image. You can use the orientation buttons, the keyboard shortcuts (A, C, S, or O for Flip), or select from the right mouse menu (right click in any viewport and select from the menu's Orientation list).

Layouts

There are three layout selections available from the factory:

- 1 +2
- 1 +3 (default)
- 2 x 2

You can also create and save your own layouts with **Layout Manager**, a common process function.

Rotation Center



If a marked nodule is selected, when selecting the Rotation center box, the rotation center appears on that nodule.

If no nodule is marked when checking the Rotation center box, the rotation center defaults to the middle of the image. You can move the center of rotation to any location in the image (left click on the center and drag it to the desired location).

The Rotation Center icon is a dropdown, sharing the same location as the **Show Crosshair**



and **Center Cursor**




icons.

Center Cursor



Click on this icon to move the rotation center cursor to the center of the viewport.


The Center Cursor icon is a dropdown, sharing the same location as the  **Show Crosshair**

and  **Center Cursor** icons.

Show Crosshair



Click on this icon to show crosshairs on reference images.

The Show Crosshair icon is a dropdown, sharing the same location as the  **Center Cursor**

and  **Rotation Center** icons.

Inspect Chest

Windowing

There are three windowing preset buttons which allow toggling between the following presets:

- Lung
- Mediast. (Mediastinum)
- Bone

These buttons affect all slab images (including focus viewports, when they are displayed).

Slab Thickness

- The two **Slab Thickness** buttons allow toggling between the original slice thickness of the images and the value displayed on the left button.
- Use the drop down menu on the left button to select a different Slab Thickness value.
- Select the **Other...** option in the drop down menu to type-in thickness values.
- Select **Original** to return to the original slice thickness.
- The default thickness for the slab image is the original slice thickness of the images and the reference images are defaulted to the minimum slice thickness available. The slice thickness, a common process function, can be controlled for the slab image and reference images.
- The minimum slice thickness depends on the scan parameters and the maximum slice thickness is 200 mm.
- The Slab Thickness buttons affect the main slab viewport only.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Key Images can be used to save images of findings that are not lung nodules.

Show Findings



This function controls the display of the blue circle (or orange for unconfirmed findings) around a marked finding, and is ON by default.

To display findings on the different viewports, including the focus viewports, place a check mark in the **Show Findings** checkbox.

If there is no check mark in the checkbox, all finding indications, including the contours from the focus viewports, are hidden.

Mark Nodules

When a nodule is observed, it can be marked using one of the following tools:

- Mark Nodule 3D 
- Mark Nodule 2D 

When a nodule is segmented using the Mark Nodule 3D or Mark Nodule 2D tools, it is treated as a confirmed nodule.

Once a nodule is segmented, it appears in the Findings list and on the different viewports, including the focus viewports.

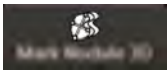
Mark Nodule 3D



WARNING

Verify the correctness of the segmentation and labels (manual visualization). If needed, correct them manually using the correction tools provided by the application.

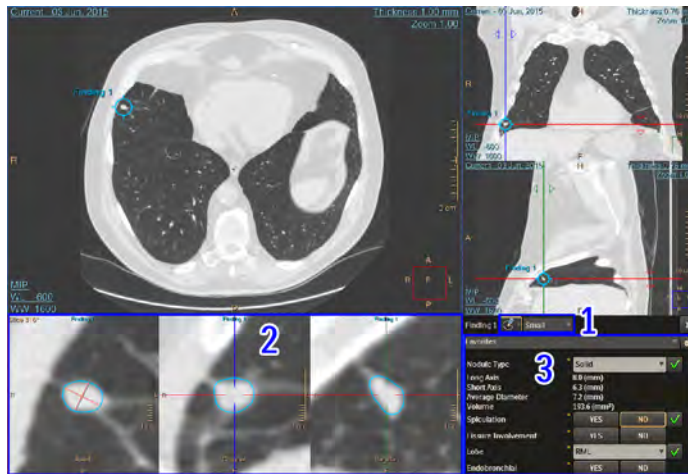
Mark Nodule 3D Tool



The Mark Nodule 3D tool provides one-click volumetric segmentation.

To segment a nodule using the Mark Nodule 3D tool:

1. Select the **Mark Nodule 3D** button.
2. Click on a nodule in any of the Slab viewports (axial, coronal or sagittal).
Once segmentation is performed, focus viewports are added based on the current layout.
3. Review all slices of the nodule to verify the correctness of the segmentation. Use the editing tools (#3 in below image) to correct the segmentation if needed. For additional information, see section “3D Segmentation Correction or Editing ” on page 355.

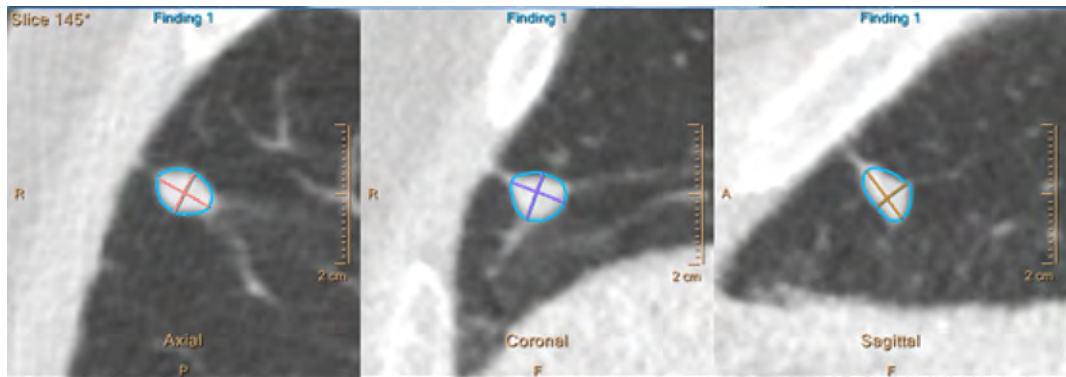


The segmentation's contour is displayed on each of the focus viewpoints.

Each finding is added to the Findings List. If the **Show Findings** checkbox is enabled, findings appear in the viewpoints (#2 in above image).

The nodule's characteristics are displayed next to the nodule's focus viewpoints (#3 in above image). For additional information, see section "Characteristics Table" on page 363.

The Long Axis and Short Axis are automatically extracted from the segmentation and are displayed on the Axial, Coronal and Sagittal focus viewpoints.



Nodule Volumetric Display





To change the focus axial display of a selected nodule (confirmed or unconfirmed) to a volume rendering image (and back), use the **Show 3D Cube** button (located in the upper toolbox).

To change the display using the context menu, right click in the axial focus viewport and select **Show 3D Cube**.

3D Segmentation Correction or Editing

The editing tools are only displayed for accepted nodules.

There are two types of Editing Tools for 3D segmentation:

- **Drag to Edit** 
- **Click to Edit** 

When a nodule is segmented using the **Mark Nodule 3D** tool, the **Drag to Edit** tool is activated by default.

Drag to Edit Tool



To use the **Drag to Edit** tool:

1. Hover over the contour in any of the focus viewports and correct the contour by dragging it.
2. Review all slices to verify the correctness of the segmentation after editing.

Click to Edit Tool



The **Click to Edit** tool can be selected from the Editing Tools dropdown menu (located next to the name of the finding in the Characteristics table).

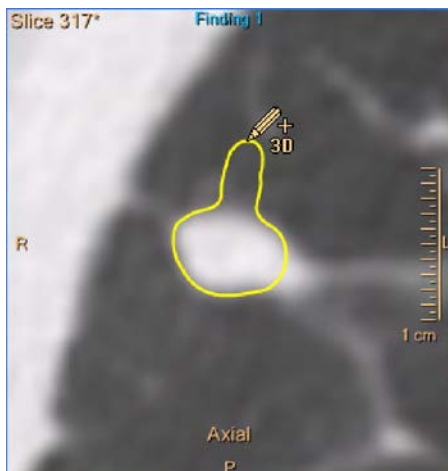
To use the **Click to Edit** tool:

1. Select the **Click to Edit** tool from the Editing Tools dropdown list.
2. Click the desired location.
The contour is relocated to this location. This can be done on any of the focus viewports.
3. Review all slices to verify the correctness of the segmentation after editing.

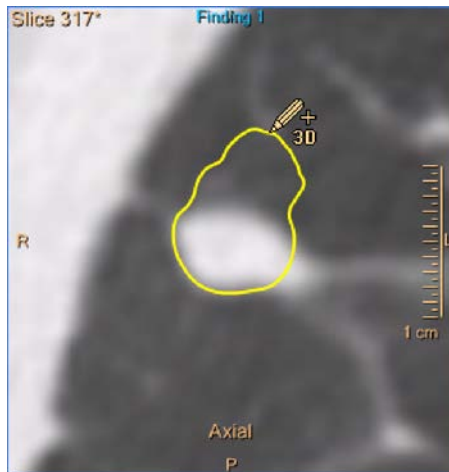
Editing Radius Size

The area of the contour to be affected by the editing tool can be adjusted using the size dropdown menu. The available options are:

- Small



- Medium
- Large



Mark Nodule 2D



This tool allows you to manually draw the Long and Short Axis on the focus viewports.

To segment a nodule using the Mark Nodule 2D tool:

1. Select the Mark Nodule 2D tool.
2. Click on a nodule in any of the Slab viewports (axial, coronal or sagittal).
Three focus viewports are added, displaying the clicked location: axial, coronal and sagittal.
3. Manually draw the Long and Short Axes on any of the focus viewports, as required.

2D Segmentation Editing Tools

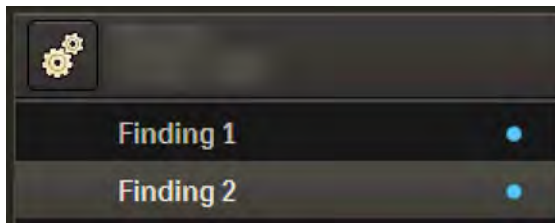
It is possible to edit diameters by hovering over a line's edges and dragging. Dragging:

- in the line's direction changes its length
- in any other direction rotates the diameters, while keeping them perpendicular

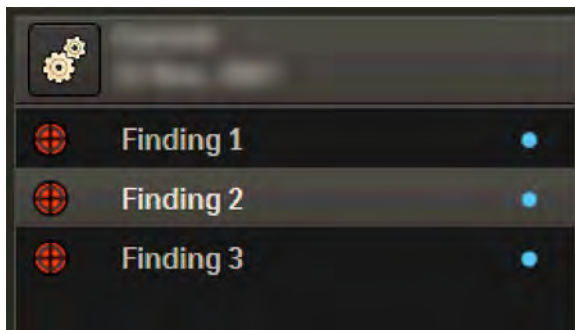
It is possible to redraw the diameters by selecting the **Redraw diameter** tool (located in the Characteristics table) and drawing new/additional diameters on any of the focus viewports. If diameters already existed on a specific focus viewport, the new diameters are updated, replacing the old ones.

Findings List

Each finding, confirmed or unconfirmed, is added to the Findings List.




- Manually segmented nodules or confirmed nodules are displayed with a blue dot to the right of the name of the finding.
- If the CAD licensed option is available and **Show CAD Suggestions** is enabled, a red icon is displayed for nodules that were segmented manually, but were also detected by the CAD algorithm. For additional information on this option, see section “Lung Nodule CAD Option” on page 359,



Navigating Between Findings

To navigate between Findings:

1. Select a finding from the Findings list or click on the finding’s indication  on any of the slab viewports or volume images.

Once a finding is activated, all viewports display this finding. The finding’s focus viewports and characteristics table are displayed.

2. To select more than one finding from the Findings list, hold the **Ctrl** button on your keyboard while selecting findings.

Deleting a Finding

To delete a confirmed nodule in the Findings list:

1. Select the finding and right click on the nodule in the Findings list.
2. Select **Delete**.

It is also possible to right click on the nodule in the slab/volume viewport and select **Delete**.

Lung Nodule CAD Option

NOTICE

The Lung Nodule CAD Option requires an additional license key.

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

Philips Lung Nodule CAD Software Option is a Computer Aided Detection (CAD) software option designed to assist radiologists in the detection of solid pulmonary nodules during review of multi-detector CT (MDCT) scans of the chest. It is intended to be used as an adjunct by the radiologist to identify regions of interest following the initial reading of the study. Upon further assessment of each CAD-suggested region, the radiologist may either accept the CAD result as a nodule, or reject it.

The device is intended for use as an aid for image evaluation, only after the radiologist has performed an initial interpretation of the diagnostic images and it improves the radiologist's ability to detect lung nodules. It assists the radiologist in minimizing observational oversights.

Lung CAD Option Warnings



WARNING

Before using the CAD option, review the entire study and use your own radiological interpretation to identify and mark your findings. The CAD option does not detect all pulmonary nodules. You may miss nodules if you do not review the entire study before using the CAD option.

Do not change your initial interpretation based on the results of the CAD option. Since the CAD option does not detect all pulmonary nodules, changing your initial interpretation may result in misdiagnosis.

Use the CAD option only as an adjunct for detecting lung nodules. Use your own independent interpretation to distinguish between true nodules and false positives.

The CAD option also detects structures that are not true nodules (false positives). Use your radiological interpretation to reject false positives that may lead to misdiagnosis.

Do not use the CAD option to detect the following: ground-glass opacities, semi-solid nodules, and pulmonary parenchymal abnormalities that do not represent solid nodules. The CAD option does not reliably detect these abnormalities, which may cause misdiagnosis.

Do not use the CAD option for patients with diffuse interstitial lung disease or extensive granulomatous disease. Using the CAD option for these patients may reduce detection performance.

Do not use the CAD option for patients with prior thoracotomy or radiation therapy involving lung parenchyma. Using the CAD option for these patients may reduce detection performance.

Use the CAD option only on CT images that were acquired with the recommended scan protocol parameters presented later in this section.

Using the CAD option on images that were acquired with non-recommended parameters may reduce detection performance, which may cause misdiagnosis.

Do not use the CAD option on CT images that exhibit patient motion, such as exams not performed during a single breath-hold period. Patient motion may contribute to false positive readings, which may cause misdiagnosis.

The Lung Nodule CAD option should not be used as the SOLE incontrovertible basis for clinical diagnosis

CAD Scan Parameters and Specifications

NOTICE

The Philips Lung Nodule CAD option is not FDA cleared and is not commercially available in the United States.

The following parameters need to be met for optimal image reconstruction. Additionally, good imaging practices for lung/chest studies need to be followed, as outlined in the scanner instructions for use.

Scanners	Philips or other vendor multislice CT scanners
Detector rows	4 or more
Scan area	The entire thorax should be in scan area but it is not required
Exposure	up to 365 mAs
Voltage	120 kV
Slice width	0.9 (submillimeter) to 3 mm
Slice overlap	0 - 50% overlap
Number of images	Up to 1,200
Contrast	Intravenous contrast is optional

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

CAD Results

When the CAD algorithm’s results are available, the **Show CAD Suggestions** checkbox is enabled and can be checked.


To view the CAD results, place a check mark in the **Show CAD Suggestions** check box. The below warning appears.

**WARNING**

CAD results should not be used as a SOLE basis for clinical diagnosis.

After clicking **OK** on the warning message, the nodules suggested by CAD are surrounded by orange circles in the Slab image, reference images and Volume Rendering image. The CAD suggested findings are added to the Findings list and are labeled CAD 1, CAD 2, and etc.


It is possible to configure the order of the CAD suggestions in the list according to location or

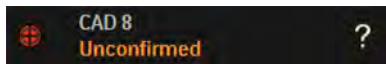
size, by clicking on the  **CAD Suggestions Settings** button and selecting an option from the dialog:

- Location (cranial to caudal)
- Size (large to small)

The selected order is used the next time the CAD algorithm is run.

CAD Findings List

Unconfirmed nodules are displayed with a  icon and there is an **Unconfirmed** label.



A finding that was detected by CAD is marked with the CAD icon.


The icon is also displayed for nodules that were segmented manually, but were detected by the CAD algorithm as well.

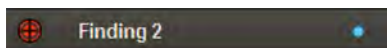
Accepting CAD Suggestions

To accept a CAD suggestion: either:

- Right click on the CAD indication (orange circle) on the slab viewports and choose **Accept CAD x as a nodule** (where x is the number assigned to the CAD suggestion).
- Click the **Accept as nodule** button in the nodule's Characteristics table.

Once a CAD suggestion is accepted:

- The nodule becomes a confirmed finding. The  icon and the **Unconfirmed** label are replaced with a "confirmed" icon.



- The contour editing tools become visible and it is possible to edit the contours.
- It is possible to edit the nodule characteristics.



WARNING

Verify the correctness of the segmentation and labels (manual visualization). If needed, correct them manually using the correction tools provided by the application.

Rejecting CAD Suggestions

To reject a CAD suggestion:

- Right click on the CAD indication (orange circle) on the slab viewports and choose **Reject**.
- Click on the **Reject** button in the nodule’s characteristics table.

When a CAD suggestion is rejected, the suggestion is deleted from the viewports and Findings list.

Re-running the CAD Algorithm

To re-run the CAD algorithm for a selected series, use the context menu from the viewport to select the **Run CAD algorithm for active series** option.

Characteristics Table

- Each nodule has a characteristics table (located next to the focus viewports), with all the parameters related to this nodule.




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- The characteristics table allows filling in the different characteristics of accepted nodules.
- Part of the characteristics are automatically extracted from the segmentation:
 - For 2D segmentation: Long Axis, Short Axis and Average Diameter
 - For 3D segmentation: Long Axis, Short Axis, Average Diameter, Volume, Max 3D Diameter, Effective Diameter and Mean HU.
- Empty characteristics are marked with a yellow asterisk.
- The characteristics are grouped into four presets that can be selected from the dropdown menu:
 - **Lungs-RADS™** - Includes all the characteristics that are mandatory for the Lung-RADS category calculation.
 - **Risk Calculator** - Used to calculate the probability of lung nodule malignancy.
 - **Fleischner Society** - Used to suggest an appropriate management for follow-up based on the 2017 revision of the Fleischner Society guidelines for management of incidental pulmonary nodules.
 - **Favorites** - Allows user-defined configuration of the displayed characteristics.
- If the Pre-fill option is available, some of the parameters are automatically filled in by the application. For additional information, see section “Characteristics Prefill (Licensed Option)” on page 365.
- Once all values are selected, check for missing parameters. For additional information, see section “Checking For Missing Parameters” on page 366.

Configuring Favorites

To configure the **Favorites** preset:

1. Select **Favorites** from the drop down list.
2. Click on the  Favorites Preset Settings button, which opens the configuration dialog. The **Select Measurements, Characteristics and Information for display** window opens. The four buttons at the top of the dialog function as shortcuts for characteristic selection:
 - **All** - Selects all parameters.
 - **None** - Deselects all parameters.
 - **Lung-RADS™** - Selects all characteristics that are mandatory for the Lung-RADS™ calculation, in addition to the characteristics that are already selected.
 - **Risk Calculator** - Selects all characteristics that are mandatory for the probability of lung nodule malignancy, in addition to the characteristics that are already selected.
 - **Fleischner** - Selects all characteristics that are mandatory for the Fleischner calculation, in addition to the characteristics that are already selected.
3. Select the appropriate options as described below:
 - To exclusively select only **Lung-RADS™** or **Risk Calculator** or **Fleischner**, select **None** first and then select one of the shortcuts.

- To select more than one of the shortcuts (**Lung-RADS™**, **Risk Calculator** a or **Fleischner**), select **None** first and then select the relevant shortcuts.
- Place a check mark on additional characteristics as desired.
- Select **Save** to save the **Favorite**.

NOTICE

The **Doubling Days** option at the bottom of the dialog controls whether the Doubling Days value is displayed in the Results work stage for follow-up cases.


Characteristics Prefill (Licensed Option)

NOTICE

Characteristics Prefill requires an additional license key.

When the Pre-fill license key is available, the following parameters are automatically filled-in by the application:

- Nodule Type
- Spiculation
- Lobe (once the lobe segmentation is available)
- Shape
- Endobronchial
- Perfissural\Subpleural

Values that are automatically filled-in by the application must be confirmed. Click on  for each parameter or select **Confirm all suggestions*** to confirm all of the pre-fill parameters. If the pre-fill is not correct, replace it with a different selection.

*The **Confirm all suggestions** button is only enabled if:

- All pre-fill values are set (i.e. Lung & Lobe segmentation finished running).
- There are at least two unconfirmed pre-fill values in the displayed preset.

Characteristic	Value	Confirmation
Short Axis	6.4 (mm)	
Average Diameter	7.3 (mm)	
Volume	195.7 (mm ³)	
Spiculation	NO	✓
Shape	Oval	✓
Endobronchial	YES	
Perifissural/Subpleural	YES	
Lobe	RML	✓

Confirm all suggestions

A value that is automatically filled-in by the application and that is not confirmed is considered an empty/undefined field.

Once all values are confirmed (or manually replaced by another value), check for missing parameters. For additional information, see section “Checking For Missing Parameters” on page 366.

Checking For Missing Parameters

- Once all nodules are segmented and matched, and before proceeding to the Results Scene, verify that all characteristics are filled in and confirmed.
- Leaving empty/unconfirmed characteristics may result in partial data displayed in the Results stage, or an inability to use the decision support tools.



- To check which characteristics are missing, click on the **Check if there are missing parameters in any of the findings** button located below the Findings list. The **Missing Parameters** dialog opens.
- The **Missing Parameters** dialog details all of the missing parameters for all accepted nodules, according to the currently selected preset.
- It is possible to check the missing parameters for another preset, by selecting the required preset from the dropdown menu.
- It is possible to fill-in the characteristics for the different nodules while keeping the dialog open. To refresh the list, click on the **Refresh** button.
- To close the dialog, click on the **OK** button.

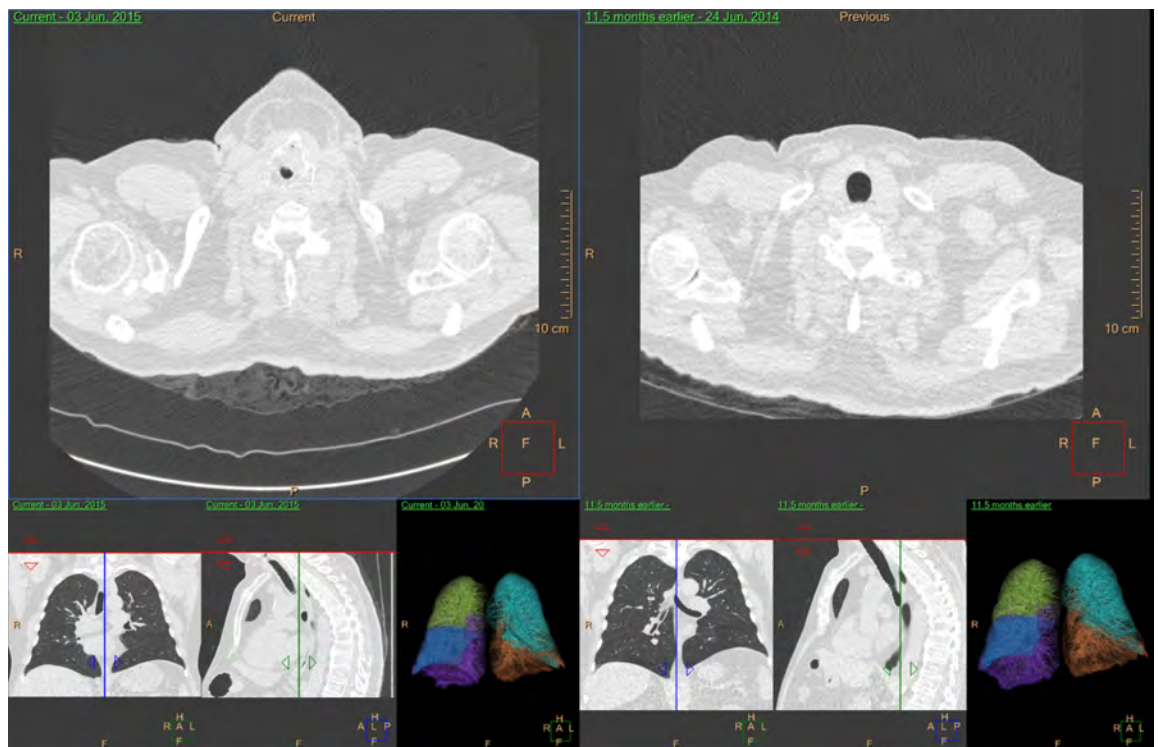
Compare & Match Work Stage

The **Compare & Match** workflow stage allows matching nodules for follow-up.

- This stage provides quick tools for chest inspection, nodule detection, comparison and matching.
- This stage displays two timepoints side by side. The most recent timepoint is displayed on the left side, with a **Current** label. The previous timepoint is displayed on the right side with a **Previous** label.



- To switch between the previous time-points, use the **Previous/Next Series** buttons from the upper toolbox (or select another timepoint from the timepoints viewport control).
- The current time-point is always displayed and cannot be replaced.
- The default layout of the **Compare & Match** work stage is shown below.



Load Follow-up Studies

1. From the Patient Directory of IntelliSpace Portal, locate the original and follow-up studies you want to work with.
2. Hold down the **<Ctrl>** key on the keyboard and click both studies to select them.
3. In the Series folder, make sure that only the Original series and the results series, along with the follow-up series are selected.
4. From the Directory, under the Analysis tab, select Lung Nodule Assessment.

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A message displays, requiring you to verify the two studies.

- Click **OK** if you have selected the correct studies. Both studies load.

Apply Registration

The automatic registration algorithm runs between the different series on start up.

Once registration is available, it is applied automatically and the **Apply Registration** button is "selected".

If registration is unsatisfactory, de-select the **Apply Registration** button.



Scroll through the series to the desired slices and press the **Link** button, to scroll side by side according to the link.

Matching Findings

Matching is only possible between two single accepted nodules that are segmented on two different timepoints.

Automatic Matching

- Once a nodule is manually segmented or when a CAD suggestion is accepted (see section "Lung Nodule CAD Option" on page 359), the application looks for a potential match for this nodule in the second timepoint.
- When a potential match is found, a message is displayed, allowing either:
 - Matching between the two nodules.
 - Creating a new un-matched nodule.


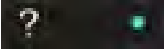

Matching Nodules

To manually match two nodules:

- Select the two nodules from the list, while holding the keyboard **Ctrl** key.
- Click the **Match** button, located below the Findings list.

The nodules are matched and appear in the same line of the list.

The table below provides an example for a Confirmed Match, Unconfirmed Match and an Un-matched nodule.

	Confirmed Match
	Unconfirmed Match
	Un-matched

Unmatching Nodules

To un-match a nodule:

1. Select the matched nodule in the Findings list.
2. Select the **Un-Match** button, located below the Findings list.

The nodules are un-matched and appear in separate lines with separate names.

Manual Propagation

To manually propagate a single (un-matched) nodule from one timepoint to another, select the **Propagate** option from the nodule's context menu.

If the propagation succeeds, a new unconfirmed match is created.

The match can be accepted or rejected using the **Yes, Finding X is a match** and **No, this is not a match** buttons, in the dialog that is displayed while the nodule is selected.



WARNING

When propagation is applied, verify the accuracy of segmentation of the propagated finding.

Automatic Propagation From Saved Results

When loading multiple time-points and when the previous time-point has saved results, the application automatically propagates the previously segmented nodules from the results to the most recent time-point.

To view these suggestions, check the **Show suggestions from previous** checkbox (checked by default when propagation from results is available).

When the checkbox is checked, the suggestions are displayed on the current time-point's viewports and in the Findings list, as unconfirmed matches of the nodules they originated from.



WARNING

When propagation is applied, verify the accuracy of segmentation of the propagated finding.

To accept the match, click on the **Yes, Finding X is a match** button. Accepting the match automatically accepts the propagated nodule as well.

To reject the match, click on the **No, this is not a match** button. This deletes the propagated nodule.

Characteristics Table

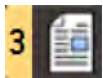
- For the current timepoint, an additional parameter **New Nodule** is available.

- If the nodule has a match in a previous timepoint, then the **New Nodule** is assigned the value **No** and this value cannot be changed.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Results Work Stage



The Results work stage consists of the following:

- **History of Lung Cancer Inquiries** - The top of the screen includes two inquiries regarding:
 - **Patient information**
Options include: **Positive**, **Negative** or **Undefined**.
 - **Family history of lung cancer**
Options include: **Positive**, **Negative** or **Undefined**.
 - Patient Risk
Options include: **High**, **Low** or **Undefined**.
- **Nodules Table** - See section “Nodules Table” on page 370.
- **Additional Findings** - See section “Additional Findings” on page 371.
- **Lung-RADS™ Assessment** -See section “Lung-RADS™ Category Calculation” on page 371.
- **Risk Calculator** - See section “Risk Calculator” on page 372.
- **Fleischner Society** - See section “Fleischner Society Guidelines Calculation” on page 375.

Nodules Table

- If there are unconfirmed suggestions that were not accepted or rejected, they are excluded from the Nodules Table. In addition, a message appears above the Nodules Table.
- All accepted nodules are displayed in the nodules table, with their characteristics, as filled-in during previous stages.
- The characteristics that are displayed in the nodules table are based on the last set of characteristics used in the previous stages (i.e. last selected preset).
- Each nodule has a thumbnail of the slice with the long and short axes from the most recent timepoint.
- When multiple timepoints are loaded:
 - The **Current** and **Previous** timepoint columns display side-by-side parameters.
 - The change is displayed in the **Change** column, for each parameter.

- To change the **Previous** timepoint when more than two timepoints are loaded for comparison, select the desired timepoint from the dropdown menu below the **Previous** column heading.

Nodule Selection

By default, all nodules are selected for calculation.

To choose which nodules will be used for the calculation of the different decision support tools:

- Remove/Place a checkmark in the **Use for calculations** checkbox.
- Select the **None** button to deselect all nodules.
- Select the **All** button to reselect all nodules.

When calculating one of the decision support guidelines, only the selected nodules are considered in the calculation. If any of the unselected nodules are missing mandatory parameters for calculation, this is disregarded, as the calculation is performed based only on the selected nodules.

Additional Findings

This section allows the addition of further information when a patient has additional findings, related or unrelated to Lung Cancer. When **Yes** is selected, a textbox appears, allowing text input. **Additional Findings** parameters include:

- **Other cancer related findings that increase the suspicion of Lung Cancer (Lung-RADS™ Category 4X)**
- **Emphysema** - A suggestion is provided (Yes/No). Confirm or change the suggestion.
If the suggestion is **Yes**, a **Preview** button is displayed. Selecting **Preview** opens a thumbnail of a slice on which Emphysema is suspected, according to the pre-fill algorithm.
- **Non Lung Cancer Related Incidentals (Lung-RADS™ Category S)**
- **Other Incidentals**

Lung-RADS™ Category Calculation

The Lung-RADS™ Assessment tab provides an automatic Lung-RADS™ calculation according to the ACR guidelines. In addition, it provides a manual selection option.

Automatic Lung-RADS™ Calculation

NOTICE

The Automatic Lung-RADS™ Calculation requires an additional license key.

Use the Manual Lung-RADS™ Calculation (see below), if a license key is not available.

1. Click **Calculate** to use the automatic calculation option.

2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

If parameters are missing:

- Return to one of the previous stages.
- Fill in the missing parameters.
- Return to Results stage.
- Click **Calculate** again.

3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with the automatic calculation suggestion.
4. Select **Approve** to accept the automatic calculation. Select **Reject** to reject the automatic calculation.

Once the suggestion is approved, the **Lung-RADS™ Assessment** tab is populated with the approved information.

- The calculation is based on the approved nodule's characteristics, general information and additional information that was input per nodule.
- The suggestion is based on the nodule(s) with the highest category from the automatic calculation.

Manual Lung-RADS™ Calculation

To manually select the Lung-RADS™ category:

1. Click the **Select Manually** button.
The **Lung-RADS™ Category and Management Manual Selection** window opens.
2. Select a category from the drop down list.
3. Place a check mark in the **Suspicious** or **Significant** check boxes if required.
4. Input a **Rationale**.
5. Select **Approve**.

Risk Calculator

NOTICE

The Risk Calculator requires an additional license key.

The Risk Calculator suggestion provides a calculation of the probability of malignancy based on the McWilliams Lung Cancer Risk Calculator for probability of malignancy.

NOTICE

Indication: The Risk Calculator feature of the IntelliSpace Portal LNA application is intended to be used on baseline screening low-dose CT scans.

Contra-indication: The Risk Calculator feature of the IntelliSpace Portal LNA application is not to be used with regular dose CT or follow-up CT scans.

NOTICE

The radiologist must explicitly verify and correct if necessary, all proposed measurements (suggested by the LNA algorithms or prepared by a technician) before they can be used as inputs to the Risk Calculator and the LUNG RADS report.

The Risk Calculator is available from the dropdown menu (the same drop down menu as Lung-RADS™ Assessment).

The Risk Calculator can only be used for the first (baseline) screening low-dose CT.

To use the automatic calculation:

1. Select the **Calculate** button.
2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

If parameters are missing:

- Return to one of the previous stages.
- Fill in the missing parameters.
- Return to Results stage.
- Click **Calculate** again.

3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with general parameters that are mandatory for the calculation.
4. Verify that all of the parameters in the **Risk Calculator Assessment - Verify Parameters** window are correct. Update values if necessary. These parameters are essential for accurate calculation.

The **Total number of nodules** value must be equal to the total number of nodules found, excluding the ones that are marked as:




- Nodule Type = Calcification
- Nodule Type = Fat Containing
- Perifissural/Subpleural = Yes

5. Click **Calculate**.

The calculation is performed and the probability of malignancy of the nodule with the highest probability is displayed. In addition, the probability of malignancy is added to each of the nodules in the nodules results table.

If the **Family history of lung cancer** is unknown (marked as **Undefined**), it is still possible to calculate the probability of malignancy. In this case, the probability is displayed as a range, with the low value assuming a negative family history and the high value assuming a positive family history.

A traffic light is displayed next to the nodule with the highest probability of malignancy, according to the following:

0-5%	Green	
5-10%	Yellow	
Above 10%	Red	

Manual Selection

To manually select another nodule to be displayed, along with its probability of malignancy and traffic light visualization:

1. Click the **Select Manually** option.
A window with all nodules and their probability of malignancy appears, allowing the selection of a representative nodule.
2. Select a nodule.
3. Input text if relevant.
4. Click **Approve**.

Additional Information for Risk Calculator

The Risk Calculator feature in LNA is based on the full model with spiculation developed by Brock University as described in *McWilliams, et al (2013)*. This model allows to estimate the probability that lung nodules detected on baseline screening low-dose CT scans are malignant. The model's performance was validated using two large population-based prospective studies: the Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and the chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute.

Below is the Abstract of the *McWilliams, et al (2013)* article:

BACKGROUND—Major issues in the implementation of screening for lung cancer by means of low-dose computed tomography (CT) are the definition of a positive result and the management of lung nodules detected on the scans. We conducted a population-based prospective study to determine factors predicting the probability that lung nodules detected on the first screening low-dose CT scans are malignant or will be found to be malignant on follow-up.

METHODS—We analyzed data from two cohorts of participants undergoing low-dose CT screening. The development data set included participants in the Pan-Canadian Early Detection of Lung Cancer Study (PanCan). The validation data set included participants involved in

chemoprevention trials at the British Columbia Cancer Agency (BCCA), sponsored by the U.S. National Cancer Institute. The final outcomes of all nodules of any size that were detected on baseline low-dose CT scans were tracked. Parsimonious and fuller multivariable logistic regression models were prepared to estimate the probability of lung cancer.

RESULTS—In the PanCan data set, 1871 persons had 7008 nodules, of which 102 were malignant, and in the BCCA data set, 1090 persons had 5021 nodules, of which 42 were malignant. Among persons with nodules, the rates of cancer in the two data sets were 5.5% and 3.7%, respectively. Predictors of cancer in the model included older age, female sex, family history of lung cancer, emphysema, larger nodule size, location of the nodule in the upper lobe, part-solid nodule type, lower nodule count, and spiculation. Our final parsimonious and full models showed excellent discrimination and calibration, with areas under the receiver-operating-characteristic curve of more than 0.90, even for nodules that were 10 mm or smaller in the validation set.

CONCLUSIONS—Predictive tools based on patient and nodule characteristics can be used to accurately estimate the probability that lung nodules detected on baseline screening low-dose CT scans are malignant. (Funded by the Terry Fox Research Institute and others; ClinicalTrials.gov number, NCT00751660.)

Further details can be found in *McWilliams, A., Tammemagi, M.C., Mayo, J.R., Roberts, H., Liu, G., Soghrati, K., Yasufuku, K., Martel, S., Laberge, F., Gingras, M. and Atkar-Khattra, S., (2013). Probability of cancer in pulmonary nodules detected on first screening CT. New England Journal of Medicine, 369(10), pp.910-919.*

Fleischner Society Guidelines Calculation

NOTICE

The Fleischner Society Guidelines Calculation requires an additional license key.

The Fleischner Society tab provides automatic calculation based on the 2017 revision of the Fleischner Society guidelines for management of incidental pulmonary nodules. These recommendations do not apply to lung cancer screening, patients with immunosuppression or patients with known primary cancer. A **Select Manually** option is also available in the Fleischner Society tab.

- Automatic calculation can only be performed when a single time-point is loaded to the application.
- When multiple time-points are loaded to the application, use the **Select Manually** option.
- Automatic calculation can be performed based on the nodules' average diameter or volume.
 - The calculation method can be selected using the **Based on average diameter** or **Based on volume** options at the top of the Fleischner Society tab.

- When the **Based on average diameter** calculation option is selected, the average diameter used per nodule is the greatest average diameter that is available for this nodule on the three planes: Axial, Coronal or Sagittal.
- The **Based on volume** calculation option is available only when all selected nodules are marked using 3D segmentation, since for nodules that are marked using the 2D tool, volume measurement is not available.

Calculation Information

- The calculation is based on the approved nodule's characteristics, general information and additional information that was input per nodule.
- The suggestion is based on the nodule(s) with the highest category from the automatic calculation.
- The calculation is performed according to patient risk, nodule characteristics that are extracted from the segmentation and that are manually filled-in for each nodule, and the selected method (average diameter or volume).
- Separate suggestions are provided for solid nodules and subsolid nodules.

Automatic Fleischner Society Calculation

1. Click **Calculate** to use the automatic calculation option.
2. If any of the mandatory characteristics for the calculation are missing, a message appears, detailing the names of the nodules and the parameters that are missing.

If parameters are missing:

- Return to one of the previous stages.
 - Fill in the missing parameters.
 - Return to Results stage.
 - Click **Calculate** again.
3. Once all mandatory parameters are available and **Calculate** is selected, a window appears with the automatic calculation suggestion.
 4. Select **Approve** to accept the automatic calculation. Select **Reject** to reject the automatic calculation.

Once the suggestion is approved, the **Fleischner Society** tab is populated with the approved information.

Manual Fleischner Society Calculation

To manually select the Fleischner Society Guidelines:

1. Click the **Select Manually** button.
The **Fleischner Society Guidelines Manual Selection** window opens.
2. Place check marks in the relevant check boxes.
3. Input a **Rationale**.
4. Select **Approve**.

Results Management

The following Results Management options are available:

- Copy Results to Clipboard
- **Save results as image series**
- **Export Results to PDF**
- **Send Results to Report**
- **Save all tables as...**

Copy Results to Clipboard

To copy the content of the following sections to the clipboard, use either the context menu (from the selected section) or click on a section and use the **<Ctrl+C>** keyboard shortcut.

- Nodules Table
- Lung-RADS™ Assessment tab
- Risk Calculator tab
- Fleischner Society

Once copied, paste the content into another document, including Word, Excel, NotePad, etc.

Save results as image series

To save the results as an Image Series, select the option from the **Manage Results** toolbox (or from the common tools area).

The series of images contains the following items:

- General information section (patient information related to lung cancer)
- Nodule parameters table, including a thumbnail for each nodule as a separate image
- Additional findings tab
- Lung-RADS™ Assessment tab
- Risk Calculator tab
- Fleischner Society

15 Pulmonary Artery Analysis



The **Pulmonary Artery Analysis** (PAA) application provides semiautomatic and manual tools to help visualize and measure Pulmonary Embolism (PE) in adults.

PAA supports loading airway tree **Results** saved from the **COPD Analysis** application.

PAA consists of 2 workflow stages:

- **Find Filling Defects.** Use the semiautomatic and manual tools to visualize the lungs, review CAD results (if enabled), as well as mark and report any PE findings.
- **Cardiac Analysis.** Extract, save, and report the relevant cardiac measurements for PE identification, such as RV/LV ventricular ratio and chambers volumes, using manual and semiautomatic tools.

Supported Scan Types

The application supports chest volumetric CT data, including axial, contrast-enhanced, ECG-gated or non-gated chest scans.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

Launch Pulmonary Artery Analysis

Select the desired **Study** in the **Directory** and select **Pulmonary Artery Analysis** from **Analysis** applications menu.

1. From the **Patient Directory** find and select the desired **Study** and **Series**.



2. Select the **PAA** icon from the application icon chart.
3. The application opens in the **Find Filling Defects** stage.

Loading Multiple Series

When more than one **Series** is loaded to the application, **PAA** runs the CAD (if enabled), segmentation, and extraction algorithms based on the order of **Series** being loaded. During processing, the common visualization and editing tools are available.

You can switch between **Series** by clicking on the **Series** tabs across the top of the display.

Loading a Series with Previously Saved Results

Saved airway tree **Results** from the **COPD Analysis** application may be loaded to the application, as well as any previously saved **PAA** results.

Pulmonary Artery Analysis Options, Tools and Functions

Use the common tools and processes to perform many basic tasks, including: saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing during all stages of **Pulmonary Artery Analysis**.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Viewing Tools and Options

Orientation

Use these buttons to select the viewing orientation of the main viewport: axial, coronal, or sagittal.



Layouts

Click the down arrow to select an alternate layout. The currently active layout is displayed as the icon. Use the tool to launch the **Layout Manager** to create a custom layout (see the **CT Common Processes** section for more).



Relate

Relate is allows you to relate a location on one image of the patient to that location as viewed on other image(s) of the patient. Use the drop-down to access scene and view port options.



Show ECG Viewer

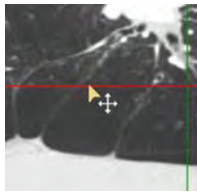
Click the **Show ECG** button to display the ECG strip (if it was loaded) along the bottom of the screen. See the **Cardiac Viewer** section in the **CT Review** section for information on using the ECG viewer.



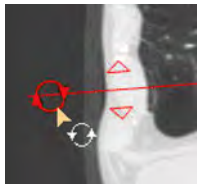
Crosshairs

For viewports with crosshairs, perform one or more of the following to adjust:

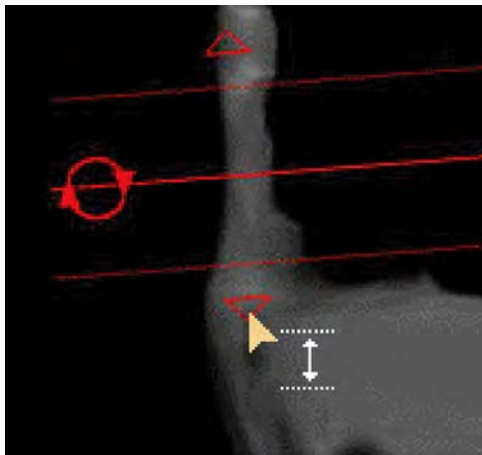
- Grab the crosshair and drag it to the correct position.



- To rotate, grab near the end of the crosshair and drag in the appropriate direction.



- To change thickness of the images represented by the crosshair, grab the triangle and drag it.

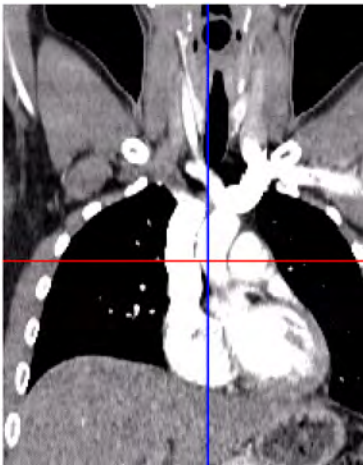


Some applications display a hole in the center of a crosshair by default. A hole in the crosshair prevents hiding important anatomical structures.

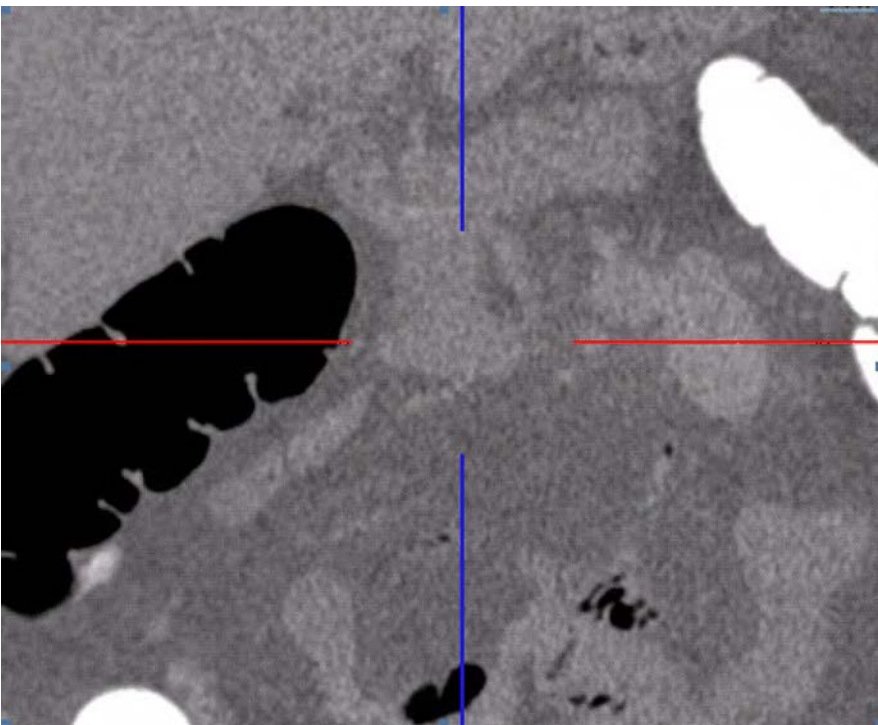
The right click menu on the crosshair allows switching between modes where the hole in the crosshair is displayed/not displayed.

Once crosshair settings are selected, (Show short crosshair, Hide crosshairs center, Show short/long crosshairs), these settings are remembered the next time the application is opened by the same user.

The **Show Crosshair Center** option shows a continuous crosshair without a hole.



The **Hide Crosshair Center** option shows a crosshair with a hole



Shortened Crosshairs

In order to minimize the possibility of crosshairs hiding anatomical structures, it is possible to display shortened crosshairs and to only show the crosshairs where relevant.

- To switch to a shortened crosshair mode, right click on the crosshair and select **Show short crosshairs**.
- To switch to the default (long) crosshair, right click on the crosshair and select **Show long crosshairs**.

Common Functions

- **Bookmarks.** This function allows you to access **Bookmarks**, if any are saved.
- The **Create movie or series** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Findings Navigator

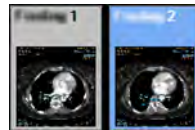
There are two types of findings that can be added to the Findings Navigator:

- **Images.** Any image from the viewport can be added as an image. These images are marked



with a black color.

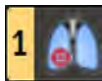
- **PE findings.** These findings are specific to the PAA application and are marked with a gray



color if not active or with a blue color if active.

All **Findings** may be saved and sent to film or report using the **Findings Navigator**. See **CT Common Tools** in the **CT Review** section for more information.

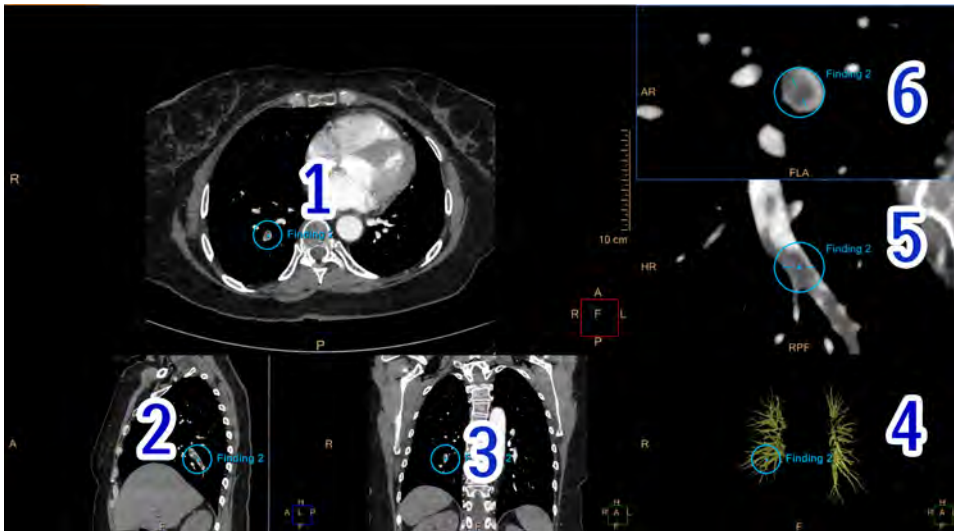
Find Filling Defects Stage



Use the semiautomatic and manual tools to visualize the lungs, review CAD results (if enabled), as well as mark and report any PE findings.

Find Filling Defects Default Layout

The viewports are linked: for example, when using **Roll/Rotate** or when scrolling through slices, linked viewports automatically update.



Upper-left viewport: main axial image (item 1).

Lower-left viewport: sagittal reference image (item 2).

Lower-middle viewport: coronal reference image (item 3).

Lower-right viewport: volume image (item 4). Use the viewport controls to change views:

- **Pulmonary Arteries (PA) tree**, default view. When segmentation is complete, CAD findings, if enabled, are displayed on this viewport.
- **All**. Displays the entire volume of the scan.
- **Bronchial Tree**. If saved in the **COPD Analysis** application, shows the bronchial-tree tissue.







Right-middle viewport: longitudinal image (item 5). Only active when a **Finding** is selected in the **Findings Navigator**, or when a CAD suggestion is selected from the CAD list.

Right-top viewport: cross-sectional image (item 6). Only active when a **Finding** is selected in the **Findings Navigator**, or when a CAD suggestion is selected from the CAD list.

Find Filling Defects Options, Tools and Functions

In addition to the basic **PAA** tasks (see section “Pulmonary Artery Analysis Options, Tools and Functions” on page 380), the **Find Filling Defects** stage has additional selections to control views and perform analysis.

See **Report**, **Film**, **CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Tools and Options	
<p>Crosshair</p> 	<p>Click the button to display the crosshair on the reference viewports. If a Finding is active, it is initially placed in the center of the crosshairs on the reference viewports. To adjust crosshairs, see section “Pulmonary Artery Analysis Options, Tools and Functions” on page 380.</p>
<p>Rotation Center</p> 	<p>Click to show the center point around which the volume can be rotated.</p>
<p>Center Cursor</p> 	<p>This function centers the image around the rotation center. Change the rotation center as follows:</p> <ol style="list-style-type: none"> 1. Click on the Rotation Center button and move the mouse over the current rotation center (the green X) in the slab view. The mouse pointer turns into an arrow cross symbol. 2. Drag the rotation center to the desired region of interest. 3. Click Center Cursor and the slab view centers around the new rotation center location. <p>Swiveling and rotating of the image will be performed around this new rotation center.</p>
<p>Quick Windowing</p> 	<p>Use the button to switch between the default (vessels) view and the lungs view, which may provide an optimized view for reviewing images of the lung.</p> <p>You can also use the keyboard shortcut Q to switch between views.</p>
<p>Show Non-active Findings</p> 	<p>Place a check mark in the checkbox. For example, if multiple findings have been marked on a single slice, only the active finding in the Findings Navigator is shown by default. To show all findings for the slice, place a check mark in the Show non-active findings check box to show all findings on the axial, coronal and sagittal viewports. When the option is checked, all findings are shown in the volume (PA Tree) viewport in the bottom right. Remove the check mark from the check box to only show the active finding.</p>
<p>Show Colormap</p> 	<p>Select the button to display a HU-based colormap on the main and reference images.</p>



WARNING





The colormap should not be used as a **SOLE** basis for diagnosis. Use the middle mouse to adjust the colormap to the loaded data."

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Review Lung Images and Mark Findings

Focus on the lungs, mark **Findings** using the **PE Detection** tools, and verify **Peripheral CAD Suggestions** (if available).

1. Select either the **Focus on Left Lung**  or **Focus on Right Lung**  button.
2. Scroll through the images and review the lung.
3. Activate the **Mark New Finding** button  and click on either the main or a reference viewport to add a new **Finding**. Use the **Findings Navigator** tools to rename, classify, annotate, film, report, and save the **Finding** (see **CT Review > CT Common Tools** for more information).
4. When done, focus on the other lung and repeat the review and mark-findings process.
5. Select the **Focus on Both Lungs** button  and repeat the review and mark-findings process.
6. To delete a **Finding**, right-click on it in the **Findings Navigator** or right-click the **Finding** on the image.

Review and Mark Findings in Paddle Wheel Mode

The **Paddle Wheel** mode allows you to scroll and view images radially around the X-Axis or Y-Axis. The location of the line in the volume is determined by the crosshair on the reference images.

1. Click the **Paddle Wheel** button .
2. Select X-Axis or Y-Axis from the viewport controls (the horizontal axis is active by default).
3. Use the left mouse button on the main viewport to navigate through the generated paddle wheel MPRs. The image rotates around the axis that is set by the crosshair in the reference images. The reference images remain constant.
4. Activate the **Mark New Finding** button  and click on either the main or a reference viewport to add a new **Finding**. Use the **Findings Navigator** tools to rename, classify, annotate, film, report, and save the **Finding** (see **CT Review > CT Common Tools** for more information).
5. To delete a **Finding**, right-click on it in the **Findings Navigator** or right-click the **Finding** on the image.

Accepting and Rejecting Peripheral CAD Suggestions

The Computer Assisted Detection (CAD) option detects only peripheral filling defects after automatic segmentation of the lungs and PA tree were performed. When complete, the **Peripheral CAD Suggestions** are displayed as **CAD Findings** on the relevant slice(s) and in the **PA Tree** viewport.

NOTICE

The CAD suggestions are displayed as annotations on single slices (not necessarily in the middle of the finding nor in the most blocked region of the vessel). Scroll to the neighboring slices to review the entire CAD finding.

NOTICE


Depending on your system, the CAD option may not be available.

Peripheral CAD Suggestions must be reviewed before they are added as findings to the Findings Navigator.



WARNING

The Pulmonary Artery Analysis CAD option should not be used as the **SOLE** basis for clinical diagnosis.

1. If the CAD option is available, click on the **Show Peripheral CADs** button  to display them in the **Pulmonary Arteries (PA) tree** viewport (bottom right).
2. Select a **Peripheral CAD Suggestion** from the table or click on it in the viewport.
3. When the Peripheral CAD Suggestion is displayed in all viewports, accept or reject the suggestion by right-clicking on it on one of the viewports.
4. Accepted **Peripheral CAD Suggestions** are added as Findings to the **Findings Navigator** where they can be reviewed and modified similarly to any manual **Findings** you have added.
5. Rejected Peripheral CAD Suggestions are removed from all viewports and from the **Peripheral CAD Suggestions** list. Once a Peripheral CAD Suggestion is rejected, the next Peripheral CAD Suggestion on the list is displayed.
6. You can use the keyboard shortcut **>** to move to the next Peripheral CAD Suggestion on the list.

NOTICE

Automatic segmentation of the lungs may fail in cases where the scan FOV does not include the entire lung volume. In such cases, the **Focus** and **Show Peripheral CADs** buttons are not enabled. In this case, use manual tools such as Pan, Zoom and Mark New Finding.

Annotate PE Findings

To annotate a **PE Finding**, activate it in the findings tray, and then hover or click on it again. You

can also use the **Preview**  button on the findings tray.

Use the drop-down menu to select from the pre-populated drop-down menu for name, lung, lobe, segment, and other properties.

To manually enter properties or comments, type in the appropriate box.

NOTICE

The application supports both **PE Findings** (marked as **Findings**) and standard **Findings** (marked as **Images** by default).

Although both types of findings are added to the findings navigator, the functionality is slightly different. **PE Findings** include application-specific options and functionality that the standard **Findings** do not. For example, clicking on a PE finding on the tray (marked as **Findings**), will activate the finding and display it in all of the viewports, unlike standard findings (marked as **Images**).

All **Findings** may be saved and sent to film or report using the **Findings Navigator**. See **CT Common Tools** in the **CT Review** section for more information.

Verify and Edit PE Finding

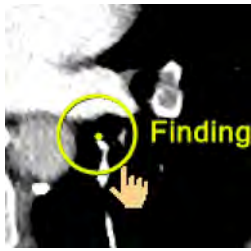
Once a **Finding** has been marked (see section “Review Lung Images and Mark Findings” on page 386), verify the cross-section and longitudinal images. When done save selected images to the active **Finding**.

NOTICE

Double click on an image to open it in full screen mode.

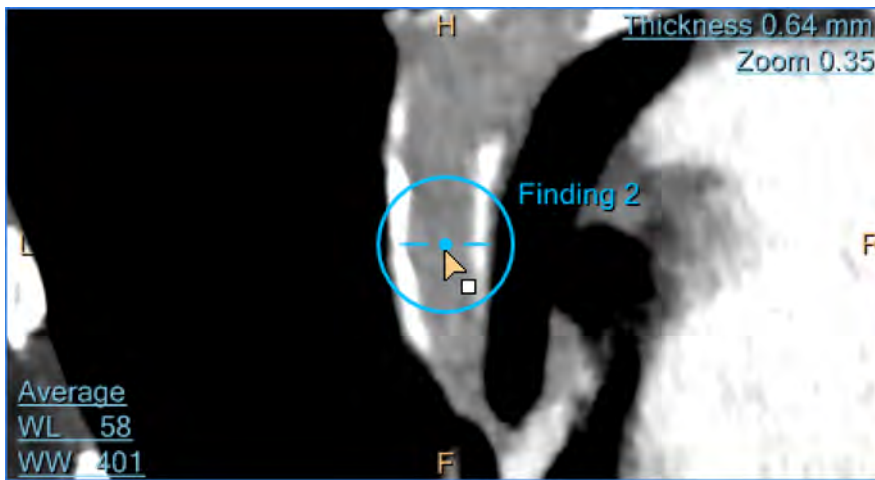
Verify and Edit Findings

To reposition the finding annotation on the axial/coronal/sagittal images, hover over the finding annotation and drag it to the desired position. All images and the finding thumbnail on the tray will be updated to the new finding location.



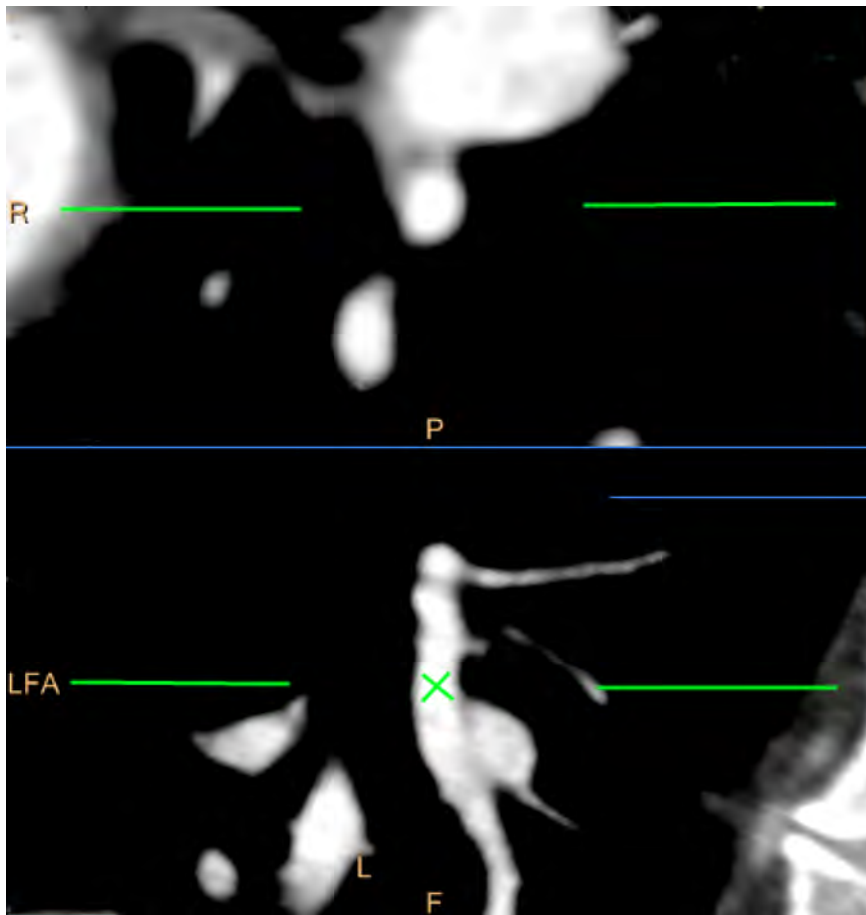
Examine Additional Locations on the Longitudinal Image

Grab the center point on the longitudinal image to drag it to a new position (upper image). The annotations on the longitudinal and cross-sectional images change their display to a green x and will be correlated to the rotation center position (middle and bottom images).



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Adding Additional Images to a Finding

1. Click on a finding in the findings tray to activate it.
2. Right-click on the image to be added and select **Findings**.
3. Add the active image to this finding from the menu.

Alternatively, drag the image to the relevant finding using the right mouse button.

Adding Images of Interest to the Findings Navigator

1. Right-click on the image to be added and select **Findings**.
2. Add the selected image to Findings Navigator using the menu. Alternatively click on the



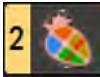
Add selected image to findings navigator button on the tray or press the space button.

Adding the Display to the Findings Navigator



Click on the **Add display to findings navigator** button on the tray or press the <Shift> +<space bar> keys.

Cardiac Analysis Stage



Extract, save, and report the relevant cardiac measurements associated with PE severity, such as RV/LV ventricular ratio and chambers volume, using manual and semiautomatic tools.

There are two methods for calculating the RV/LV ratio:

- **2D RV - LV Ratio Method** - Manually set the RV and LV planes starting from axial view, and draw the maximal diameters. Manually set the RV and LV planes starting from 4-Chambers view, and draw the maximal diameters.
- **3D Ratio Method** - Extract the RV/LV volumetric ratio based on volumetric segmentation, edited, and accepted.

2D RV - LV Ratio Method

Manually set the RV and LV planes and draw the maximal diameters.

By default, the **PAA Cardiac Analysis** stage opens to the **2D RV - LV Ratio method** tab.

2D RV - LV Ratio Method Default Layout (Planar Mode)

The RV viewports (items 1, 2, and 3) and LV viewports (items 4, 5, and 6) are not linked by default: you can scroll or swivel through them independently (use **Align and Link RV&LV Planes** to connect all viewports).

NOTICE

If the **Align and Link RV&LV Planes** feature is used after one diameter is marked, both axial images will align to the image that is marked (not necessarily the active image).

If the **Align and Link RV&LV Planes** feature is used after both diameters are marked, you will need to delete one of the diameters and then redraw it.

NOTICE

To adjust the crosshairs, see section “Pulmonary Artery Analysis Options, Tools and Functions” on page 380.



Upper-left viewport (item 1): RV plane used to draw the maximal RV diameter.

Lower-left viewport (item 2): RV plane coronal reference image.

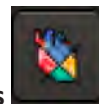
Lower-left-center viewport (item 3): RV plane sagittal reference image.


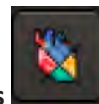
Upper-right viewport (item 4): LV plane used to draw the maximal LV diameter.

Lower-right-center viewport (item 5): LV plane coronal reference image.

Lower-right viewport (item 6): LV plane sagittal reference image.

Set Planes and Draw Diameters



1. Choose either the **Axial**  or **4-Chambers**  view to be used for setting the desired plane.
2. Click on either the RV or LV viewport. Scroll through the images to find the appropriate image on which to draw the diameter.
3. If necessary, select **Align and Link RV&LV Plane** to align the non-active plane by orientation, zoom and pan to that of the active plane.
4. Select either the **Draw RV Diameter** or **Draw LV Diameter** button on the top of the viewport. Click where the diameter should begin. Locate the ending of the diameter and click to add the diameter.
 - To move the diameter line, grab it and drag to a new position.
 - To adjust the diameter length, grab a control point and drag in any direction.

**WARNING**

When trying to draw the LV maximal diameter on the RV plane, a message is shown: You cannot draw the LV Max diameter on the RV plane. Please use the image on the upper right to draw the LV Max diameter.

When trying to draw the RV maximal diameter on the LV plane, a message is shown: You cannot draw the RV Max diameter on the LV plane. Please use the image on the upper left to draw the RV Max diameter.

When trying to draw the RV diameter on the wrong tissue, a message is shown: Note, The RV max diameter seems not to be drawn on the right ventricle. Please re-draw the diameter on the correct ventricle.

When trying to draw the LV diameter on the wrong tissue, a message is shown: Note, The LV max diameter seems not to be drawn on the left ventricle. Please re-draw the diameter on the correct ventricle.

5. Select the other image and repeat the previous step.
6. Add your findings to the **Findings Repository** to save or send them to **Report** and **Film** applications. See **CT Common Tools** in the **CT Review** section for more information.

Review Results

The diameters values and ratio appear on the 2D Ratio calculation measurements table. Click on the table to display the images with the drawn diameters.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

3D Ratio Method

Extract the RV/LV volumetric ratio based on volumetric segmentation.

**WARNING**

Verify the accuracy of the automatic segmentation. If necessary, manually correct the segmentation using the segmentation-correction tools provided in this stage.

Verify and Edit RV/LV Volumetric Segmentation

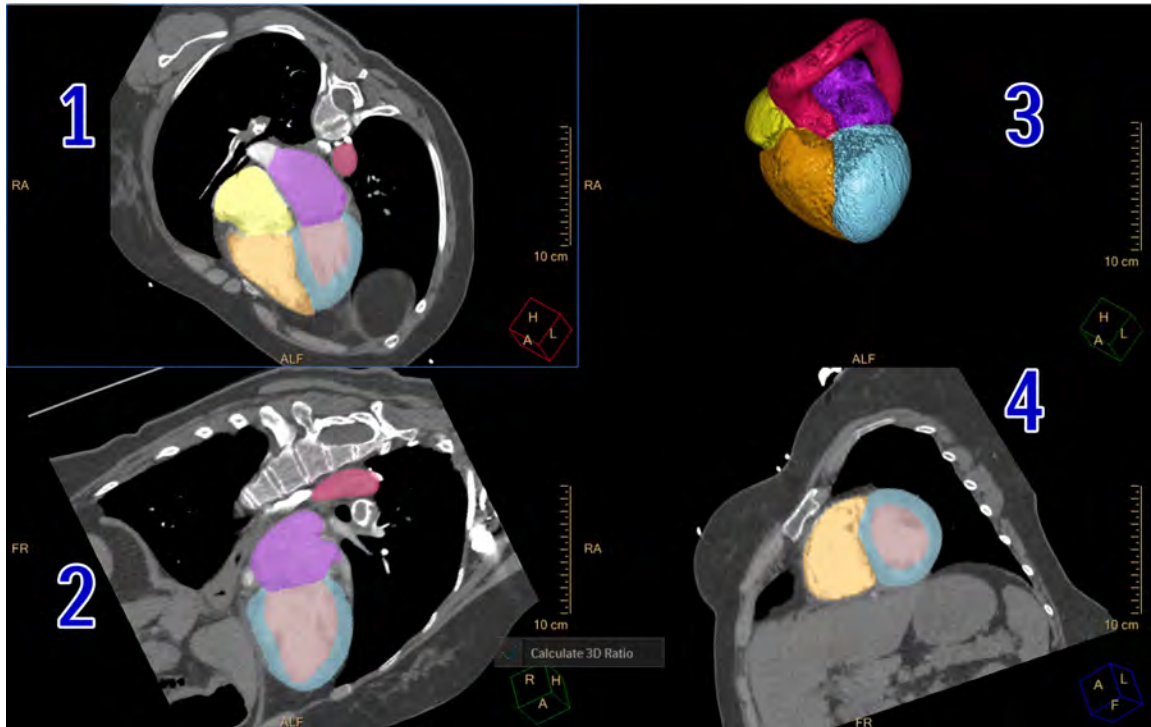
Verify and, if necessary, edit the extracted cardiac tissues: left ventricle; right ventricle; left atrium; right atrium; LV myocardium; and aorta.

Upper-left viewport: 4-chambers cardiac orientation image (item 1).

Lower-left viewport: 2-chambers cardiac orientation image (item 2).

Upper-right viewport: volume image (item 3).

Lower-right viewport: short axis cardiac orientation image (item 4).



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NOTICE

See **CT Common Tools** in the **CT Review** section for information on using the **Edit Tissues Tools**.

1. Select a tissue from the tissue list and review the segmentation.
2. Use the **Edit Tissues Tools** to edit the segmentation as needed.
3. Select, review, and edit the remainder of the tissues in the tissue list.
4. When done, click the **Calculate 3D Ratio** button.

Review Results

The RV&LV, RA&LA volume measurements and ratio are displayed on the 3D Ratio Calculation (Volume) table.

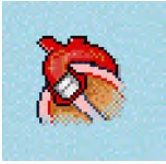
NOTICE

After clicking the **Calculate 3D Ratio** button for the first time and then editing segmented tissues, the table measurements are updated accordingly.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

16 Transcatheter Aortic Valve Implantation Planning



The **Transcatheter Aortic Valve Implantation (TAVI) Planning** application provides semiautomatic and manual tools to help determine the size and shape of the aortic root anatomy, ascending aorta and left ventricular outflow tract.

The application supports contrast-enhanced, prospectively ECG-gated axial or retrospectively-gated helical CT images.



WARNING

When loading images into the application, all images which contain 16 bit data are converted into 12 bit images. (Therefore, when the rescale intercept equals -1000, Hounsfield Unit values above 3095 are displayed as 3095, and when the rescale intercept equals -1024, Hounsfield Unit values above 3071 are displayed as 3071.)

Application Stages

There are three stages in the application:

- When the application opens in the **Verify Segmentation and Landmarks** stage, review and edit (if necessary) the automatic landmarks locations and segmentation.
- After reviewing and editing (if necessary) the planes and measurements in the **Device Sizing** stage, review the results.
- **Access Route Assessment** provides tools (including inspection of minimal diameter, calcification and tortuosity of the vessel) to analyze the peripheral vessels when performing **Device Sizing**.

TAVI-related Measurements

Measurements related to access root assessment for calcium scoring should be performed within the Calcium Scoring application.

Common TAVI Planning Scan Protocols (Exams)

The following Protocols (Exams) are intended as examples for Philips scanners only (for 64-256 slice scanners). Before performing a scan, consult the **Instructions for Use** that came with your scanner.

Recommended Protocol 1: Gated Helical CTA

1. Optional: Start with a non-contrast enhanced Calcium Scoring scan which can be used for quantification of the calcium load on the aortic valve leaflets.
2. **TAVI Planning** related scan/reconstruction:

Gated Aorta protocol, starting from the level of the subclavian artery and ending such that it includes the proximal femoral arteries.

Reconstruct 8 to 10 cardiac phases (0-100% RR interval) of the heart section only with small (optimal for cardiac) FOV.

In addition, reconstruct one untagged recon of the entire section with large FOV. The untagged recon is used to measure the diameter of the subclavian and/or iliac/femoral arteries. This scan is for access route assessment and would be analyzed with the **AVA** application.

Usually the mid-to End-Systolic cardiac phase (30-40% RR interval) is used to measure the Annulus dimensions. This scan would be analyzed with **TAVI Planning**.

3. Un-gated reconstruction for the whole range.
4. Optional: Coronaries reconstruction.
5. Optional: Chest unTagRec with filter YB for extra cardiac findings.

Parameter*	Recommended Value
mAs	400-500 with iDose ⁴
KV	100
Dose Modulation	No
Scan Length	Depending on the patient. About 650mm.
Cardiac phases	0, 20, 25, 30, 35, 40, 45%, 75%. From these select the mid-end systolic phase with the least amount of motion and perform the annulus measurements.

* Parameters are for average-size patient.

Recommended Protocol 2: Split-scan Technique

1. Optional: Start with a non-contrast enhanced Calcium Scoring scan which can be used for quantification of the calcium load on the aortic valve leaflets.
2. An ECG gated CTA of the heart including the aortic root*. Acquisition can be:
 - **Retrospective:** Reconstruct 10 phases (0-100% RR interval) of the heart section only with smaller FOV. Usually the mid-to End-Systolic cardiac phase (30-40% RR interval) is used to measure the Annulus dimensions. This scan would be analyzed with **TAVI Planning**.
 - Or:
 - **Prospective:** Targeted at either 35% or 75% of the RR interval.

Alternatively, the scan can be extended to the entire Thoracic Aorta.

3. A non-gated CTA of the entire aorta, starting from the subclavian artery and including proximal femoral arteries. This scan is for access route assessment and would be analyzed with **AVA**.

Alternatively, the scan can be limited to abdominal/iliofemoral section only if step 2 already covered the thoracic aorta (see above) **Aorta CTA protocol**.

NOTICE

There should be a minimal delay between step 2 and 3.

Parameter*	Recommended Value
mAs	100 with iDose ⁴
KV	100
Step & Shoot	at 35% or 75% with tolerance
Scan Length	Depending on the patient. About 650mm.

* Parameters are for average-size patient.

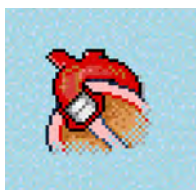
Launch TAVI Planning

1. From the **Directory** find and select the desired **Study** and **Series**.

NOTICE

The application supports contrast-enhanced, prospectively ECG-gated axial or retrospectively-gated helical CT images.

2. Select the **TAVI Planning** icon from the application icon chart.



3. The application opens in the **Verify Segmentation** stage.

NOTICE

When launching the TAVI Planning application, Portal will also load the CT **Cardiac Viewer**. See the **CT Review** section for more information on using the **Cardiac Viewer**.

Verify Segmentation and Landmarks Stage

When the series are loaded, automatic segmentation is run for each loaded phase. Once the segmentation is completed, a plane is shown that displays the three (3) aortic sinuses landmarks (also known as **hinge points**).

If several cardiac phases were loaded, the order of the automatic segmentation is applied as follows: first 40 %; next, all the phases between 40 % and 30 % in descending order; followed by 30% and then 75%; then all the phases between 70% and 80% in ascending order; ending with the remaining phases segmented in ascending order.

NOTICE

The MPR images on the first stage of the application are displayed in Planar mode, meaning that they are always 90 degrees to each other. When swiveling one of the images, the other images update accordingly.



WARNING

During this stage, first verify and correct (if necessary) the automatic landmark placement for the RCA/LMCA ostia and the aortic sinuses. Second, verify and edit the segmentation using the Edit Tissues tools.

TAVI Aortic Root Calcium Segmentation and Visualization of Calcium

The TAVI application uses an automatic calcium segmentation algorithm to detect and segment the calcium present in the aortic root and provides visualization of calcification in the aortic root: Aortic sinuses and cusps.

In the **Verify Landmarks & Segmentation** stage, in the **Edit Tissue(s)** list, the application displays an additional option named as “Aortic root calcium”

Similar to rest of the tissues in Tissue(s) list, use the “Edit Tissue” tools to edit the colored display of the automatically segmented tissue of calcification in Volume Rendered (VR) and MPR images to verify its correctness. Use various tissue editing tools presented by default settings for editing and optimization of the segmented calcium, if required.

TAVI Verify Segmentation Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Orientation



You can change the image orientation between the General Axes and the Cardiac Axes modes. Click the down arrow to switch between the two orientation modes:

- **General axes.** The general axes are the standard anatomical orientations: axial; coronal; and sagittal.
- **Cardiac axes.** The cardiac axes orient the views of the heart as follows: short axis; horizontal long axis (4 chamber view); and vertical long axis (2 chamber view).

Use the Flip button to flip the active volume viewport 180 degrees.

Flip



Use this button to flip the image in the main viewport right to left.

Layout



Two default layouts are available, 1+3 and 2x2. The currently active layout is displayed as the icon. Click the down arrow to select the alternate layout.

In the 1+3 layout, the images consist of the volume image in the main viewport and the axial, coronal, and sagittal images from top to bottom in the reference viewports.

The 2x2 layout has the same views as 1+3, but is arranged differently.

The **Layout Manager** allows you to perform various layout (display) management functions.

Relate



The **Relate view ports** and **Relate scenes** tools can help orient yourself.

To use, select either **Relate view ports** or **Relate scenes** and click on any pixel in any viewport. The location of that pixel is automatically marked on all the other view ports.

Magic Glass



The **Magic Glass** function displays a moveable, mini-window (3 cm default) which can be set with its own windowing, image enhancement and rendering parameters. With the **Magic Glass** function you can enhance visualization and assessment of certain elements of the image, such as calcium and stents, while maintaining optimal viewing parameters for the main viewport.

Rotation Center



When the box is checked, click to show the center point (indicated by a green X) around which the volume can be rotated.

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Center Cursor



This function centers the image around the rotation center. Change the rotation center as follows:

1. Move the mouse over the current rotation center (the green X) in the slab view. The mouse pointer turns into an arrow cross symbol.
2. Drag the rotation center to the desired region of interest.
3. Click **Center Cursor** and the slab view centers around the new rotation center location. Swiveling and rotating of the image will be performed around this new rotation center.

Show Landmarks

Check the box to show landmarks on displayed images. Uncheck the box to hide landmarks.

On/off ECG



If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Show Tissues

Check the box to display the active tissues in the **Select Tissue** table.

Calculate Volume



Click the button to calculate the volume of the currently active tissue or tissues (to select an active tissue, see section "Verify Segmentation and Landmarks Stage" on page 399). Clicking the button displays the volume of the displayed tissues on the volume image. A highlight appears on the reference images. The calculated volume is that of the colored pixels on the reference images.



WARNING

Exclude the Aortic Root Calcium tissue from volume calculation by removing the check mark for Aortic Root Calcium in the Edit Tissue(s) selection check box, as calcium quantification may not be accurate on data with contrast enhancements.

The following message appears when clicking the Calculate Volume button with "Aortic Root Calcium" tissue selection box checked:

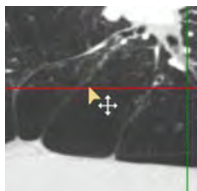
Volume calculation may not be accurate as long as the "Aortic Root Calcium" tissue is checked in the tissues list, since calcium quantification is not accurate on data with contrast enhancement. Uncheck the tissue and calculate the volume again.

Select OK and close the Calculate Volume Button. Remove the check mark from the "Aortic Root Calcium" tissue and select other desired tissue(s) from the Tissues list. Re-initiate the Volume Calculation by clicking on the Volume Calculation tab.

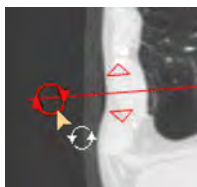
Using Crosshairs

For viewports with crosshairs, perform one or more of the following to adjust:

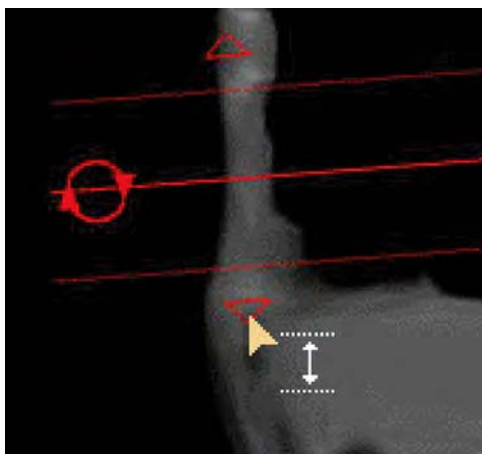
- Grab the crosshair and drag it to the correct position.



- To rotate, grab near the end of the crosshair and drag in the appropriate direction.



- To change thickness of the images represented by the crosshair, grab the triangle and drag it.



TAVI Segmentation Common Tools and Functions

See **Report**, **Film**, **CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions



To access additional functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

- **Bookmarks.** This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Verify and Edit Sinuses and Coronary Ostia Landmarks

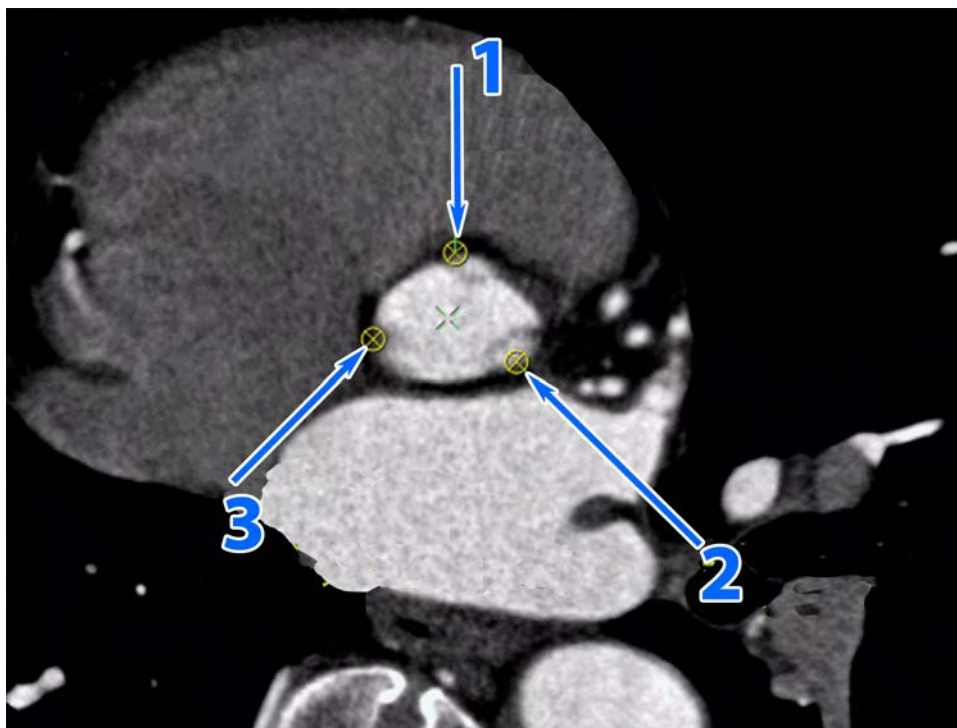
1. Ensure the **Edit Automatic Results** tab is open. This is the default tab (in the middle of the toolbox).
2. If the aortic sinus landmarks are not visible, click the **Go to aortic sinuses landmarks**



button.

The 3 aortic sinuses landmarks (which corresponds to the proposed annulus plane) are displayed.

3. To adjust the automatic landmark placement for the right sinus (item 1 in the image), left sinus (item 2), or non-coronary sinus (item 3): Grab the crosshair, move it to the correct location, and confirm the move.



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If necessary, use the **Undo/Redo** button to revert the change. The last 10 changes can be undone. Alternately, right-click on a landmark and select **Reset Landmark Location** to revert the change to the initial location.

- To move the landmark to a different slice, scroll to the correct slice, click the **Relocate**

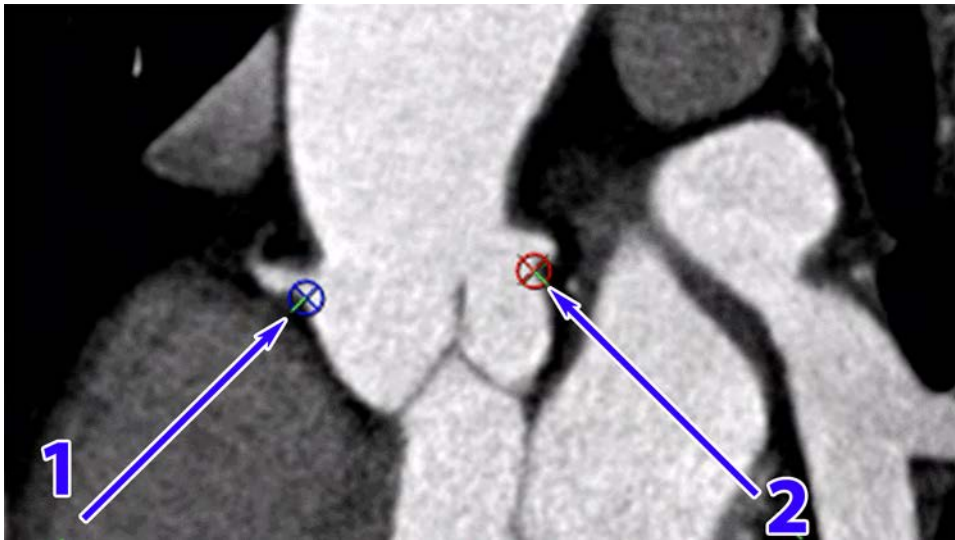


landmark button, click on the new location, and then select the landmark name from the dialog. All landmarks can be relocated at the same time. Click the **Relocate landmark** button again to exit and return to image scrolling.



- Click the **Show ostia landmarks** button.
- To adjust the automatic landmark placement for the RCA ostium (item 1 in the image) and LMCA ostium (item 2): Grab the crosshair, move it to the correct location, and confirm the move.

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If necessary, use the **Undo/Redo** button to revert the change. The last 10 changes can be undone. Alternately, right-click on a landmark and select **Reset Landmark Location** to revert the change to the initial location.

- To move the landmark to a different slice, scroll to the correct slice, click the **Relocate**



landmark button, click on the new location, and then select the landmark name from the dialog. All landmarks can be relocated at the same time. Click the **Relocate landmark** button again to exit and return to image scrolling.

- When all landmarks locations are properly located, click the **Accept all landmarks**



NOTICE

To reset a landmark location to the automatic one, right-click on the landmark and select **Reset landmark to the automatic location**.

Verify and Edit Segmentation

NOTICE

Perform the verify and edit segmentation procedure below for all of the automatically detected tissues:

- Aorta
- Aortic root
- Left ventricle
- RCA ostium
- LMCA ostium

1. In the **Select Tissue** list, ensure the checkbox is checked and the tissue to be verified is selected (highlighted in blue).
2. If you need to change the color of the selected tissue, click on the color icon in the list and select a new color.
3. To expand or erode the selected tissue, right-click on the tissue name in the list and select the appropriate option from the menu.
4. Use the **Edit Tissue(s) (3D Tools)** to edit the segment.



WARNING

When using the following tools, segmentation is performed in 3D (not 2D): Eraser; Brush; Exclude/Include; Expand; Erode; Inject Dye; Add smart brush; Add smart ROI; Remove smart brush; Remove smart ROI.

Erode/Expand Tissue (3D)

Right-click on a tissue in the **Tissue List** and select **Erode** or **Expand** from the menu.

Erode Tissue



The Erode Tissue function allows you to decrease the edges of the segmented tissue. Each click reduces the edge by a one-voxel increment.

Expand Tissue



The Expand Tissue function allows you to increase the edges of the segmented tissue. Each click expands the edge by a one-voxel increment.

Smart Segmentation (3D)



Use the **Smart Segmentation Tools (3D)** to improve the 3-dimensional segmentation. Click the button to open the floating dialog box that contains the segmentation tool. The dialog box will snap to the active viewport every time it is re-opened (if the box is in the way, drag it to a different location on the screen).



WARNING

Verify correctness of the segmentation on all the segmented slices and edit if required.

See **CT Review > CT Common Processes** for instruction on using the **Smart Segmentation Tools (3D)**.

Inject Dye (3D)



The Inject dye function is used on the reference images to create a tissue of the volume of interest.

See **CT Review > CT Common Processes** for instruction on using the **Inject Dye (3D)** tool.



WARNING

When using the Dye Injection tool verify the correctness of volume segmentation. If necessary, correct the dye tracing using correction tools supplied by this application.

Eraser (3D)



The Eraser function allows you to remove the contrast from reference images by hovering over the contrast and clicking the left mouse button (you can also hold down the button and drag). The Eraser is a sphere whose radius you can set. The Small eraser is 5 pixels; Medium is 10 pixels; Large is 30 pixels.

NOTICE

Because the eraser is the shape of a sphere, it erases from the volume, not only the slice you use it on. Be sure to verify the results of the eraser by scrolling the reference images.

Brush (3D)



Add to unsegmented areas of active tissue by “painting” with the brush.

1. Activate the appropriate tissue segmentation.
2. Select the brush size from the drop down.
3. Drag the mouse across the unsegmented tissue while holding down the mouse button. The brush will “paint” new segmentation in the same color as the selected tissue.

Fill Holes

Check the box to add to the injected soft tissue, filling in any holes within the volume. The holes are filled as long as the box is checked.

Volume Sculpting (3D)



Manual sculpting tools are available for volume removal. Three Region of Interest (ROI) sculpting tools are available: Freehand, Rectangle, and Circle. The Exclude function removes everything enclosed within the ROI. The Include function removes everything outside the ROI.

See **CT Review > CT Common Processes** for instruction on using the **Volume Sculpting (3D)** tools.

Undo/Redo



The Undo/Redo function allows you to reverse your most recent action. If, for example, you over-inject, you can correct the result with the Undo function. Each click of Undo erases the last voxels that were added to the tissue during Inject, Fill, Expand, or Erode during landmark editing. Redo allows you to reverse the Undo.

Manually Re-segment Heart

If the automatic segmentation is inaccurate or failed, place three anatomical landmarks and re-segment the heart anatomy.

1. Go to the **Re-segment** tab (for example, hover over **Edit Segmentation** in the middle of the toolbar and select **Re-segment** from the menu).



2. Click on the **Activate Seed** button.
3. Select Aortic Valve, Mitral Valve, or Apex radio button from the list.

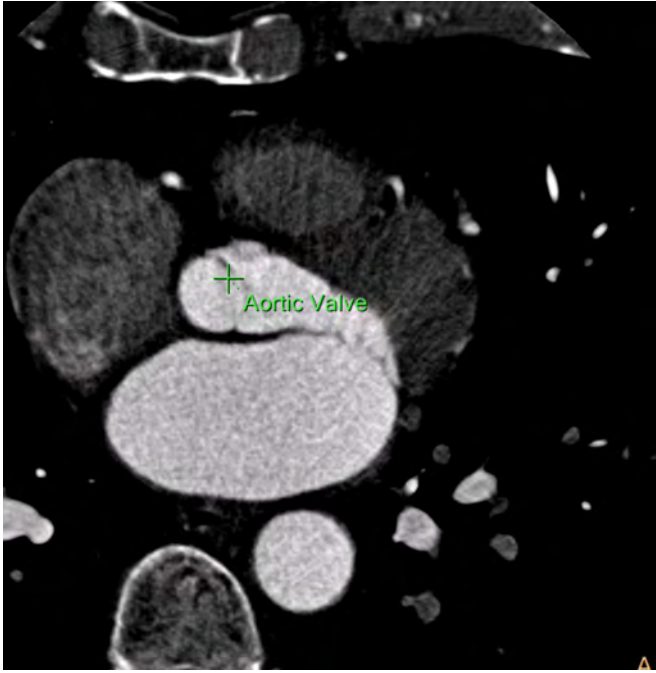
4. Scroll through the images and place the seed by clicking on the correct location (for fast scroll, hold down **Ctrl + left mouse** button and drag the cursor across the active image. Only one seed per landmark is necessary. See images below.
5. To adjust the seed, grab the crosshair and drag it to the desired location.
6. Place seeds for the other 2 landmarks in the same manner. See images below.
7. Select either the **All** or **Current** radio button to determine which phases to re-segmented:
 - **All** re-segments every phase loaded with the **Study**.
 - **Current** only re-segments the active phase.



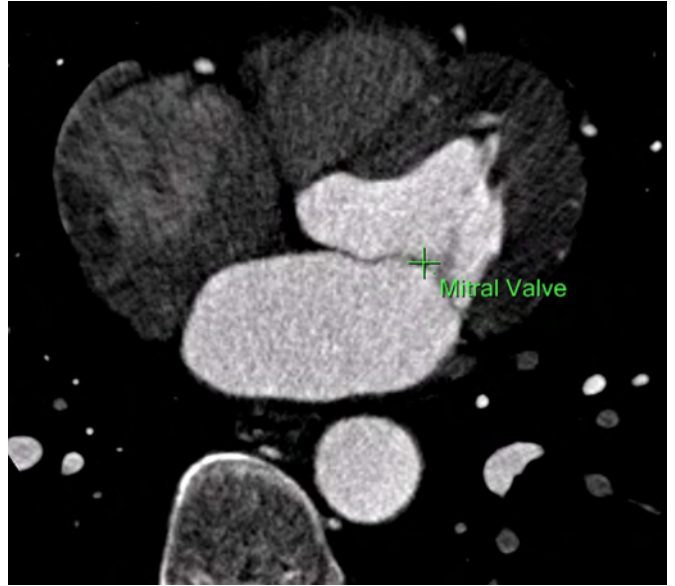
8. Click the **Re-segment** button.
9. See section “Verify and Edit Sinuses and Coronary Ostia Landmarks” on page 404 and section “Verify and Edit Segmentation” on page 407.

Example Aortic Valve, Mitral Valve, and Apex Landmark Placement

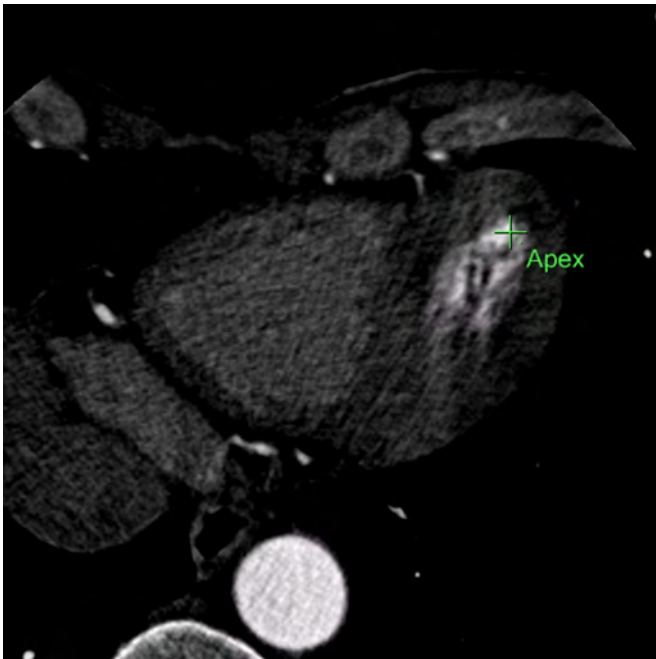
Aortic Valve



Mitral Valve



Apex



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Device Sizing Stage

Use the Device Sizing Stage to:

- Edit if necessary the automatically detected planes and then accept the planes along the aortic root and the ascending aorta.
- Accept the contours and distances after verifying the automatic detection and correcting them as needed.
- Review the measurements table for device sizing, based on the accepted planes.
- Review the various recommended CathLab angles. All the angles provide a view perpendicular to the annulus plane.
- Save or send the results to **Report**.



WARNING

Accuracy of measurements is based on the landmarks placed in the previous stage.

TAVI Device Sizing Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Orientation



You can change the image orientation between the General Axes and the Cardiac Axes modes. Click the down arrow to switch between the two orientation modes:

- **General axes.** The general axes are the standard anatomical orientations: axial; coronal; and sagittal.
- **Cardiac axes.** The cardiac axes orient the views of the heart as follows: short axis; horizontal long axis (4 chamber view); and vertical long axis (2 chamber view).

Use the Flip button to flip the active volume viewport 180 degrees.

Flip



Use this button to flip the image in the main viewport right to left.

Layout



Two default layouts are available. The currently active layout is displayed as the icon. Click the down arrow to select the alternate layout.

The **Layout Manager** allows you to perform various layout (display) management functions.

Relate



The **Relate view ports** and **Relate scenes** tools can help orient yourself.

To use, select either **Relate view ports** or **Relate scenes** and click on any pixel in any viewport. The location of that pixel is automatically marked on all the other view ports.

Magic Glass



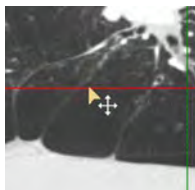
The **Magic Glass** function displays a moveable, mini-window (3 cm default) which can be set with its own windowing, image enhancement and rendering parameters. With the **Magic Glass** function you can enhance visualization and assessment of certain elements of the image, such as calcium and stents, while maintaining optimal viewing parameters for the main viewport.

Show Crosshair

Check the box to show the crosshair in the viewports.

For viewports with crosshairs, perform one or more of the following to adjust:

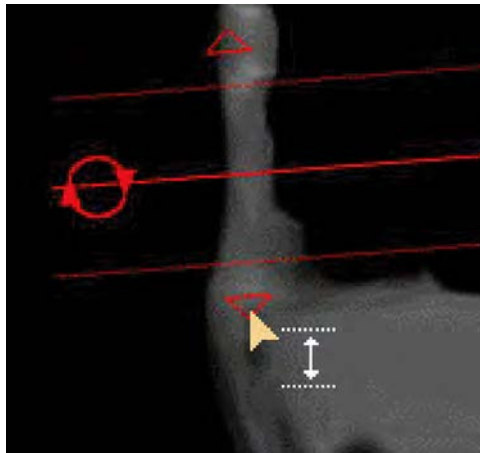
- Grab the crosshair and drag it to the correct position.



- To rotate, grab near the end of the crosshair and drag in the appropriate direction.



- To change thickness of the images represented by the crosshair, grab the triangle and drag it.



Show Contours

Check the box to show the contours on the cross-sectional planes MPR images. Used with **Edit Measurements** and **Review Results** modes.

On/off ECG



If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Selected Plane/Non-selected Plane

Use the drop-down to toggle the volume image between the selected plane and the non-selected plane views.



Non-selected (non-active) planes indication colored in green on the VR image.



Active plane indication colored in orange on the VR image.

Configure Measurements

Use the Results Settings button to configure the list of measurements to show per plane in the table and on the MPR images. See section “Configure Review Measurements” on page 427.

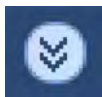
TAVI Device Sizing Common Tools and Functions

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions



To access additional functions, click the down arrow in the tab window, or hover the mouse over the tab window. The list of available functions displays.

- **Bookmarks.** This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Verify and Edit Automatic Planes

The Planes and Measurements tab contains 3 working modes that need to be followed to get accurate results:

- Edit Planes
- Edit Measurements (contours)
- Review Results

The currently active mode is highlighted in orange color. It is possible to activate a mode by pressing the header text or the icon to the left of the text.

Choose the planes you need for the TAVI Planning procedure. Edit as necessary the automatically detected planes and then accept the following planes along the left ventricle aortic root and the ascending aorta:

- Annulus. When accepted, the Annulus Angulation, Distance to LMCA Ostial plane and Distance to RCA Ostial plane are automatically calculated.
- Sinus of Valsalva
- Sinotubular junction. When accepted, the Left Coronary Sinus Height, Right Coronary Sinus Height, and Non-coronary Sinus Height are automatically calculated
- LVOT (Left ventricular outflow tract)
- Ascending aorta

You can continue to next steps after reviewing and accepting at least one of the planes.

NOTICE

By default, all the automatically detected planes are not accepted. If you need measurements for a certain plane, the plane must be reviewed and edited (if required). Unaccepted planes are shown with a question mark in the planes table and on the images.

1. If not already open, go to the **Planes & Measurements** tab.



Ensure that the **Edit Planes** button is active (the header is orange and the icon to the left of the header is pressed).

2. Click on a plane in the plane table and edit using one or more of the following:
 - Scroll the upper left plane image to the right location.
 - Swivel the upper left plane image.
 - Grab and move/rotate the long red horizontal crosshair on the reference MPR images.
3. If you changed the plane and want to keep the new plane as the true plane, click the



Accept button in the **Relocate the [name of the selected plane] to this plane** dialog.

4. If no edits to the automatically detected plane is necessary, ensure you are on the correct plane and then click the **Accept Plane** button.
5. Follow the procedure until all planes you want to examine are correct and accepted.

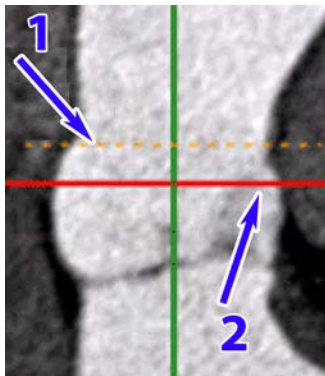
NOTICE

Every time you accept a plane, the system automatically moves to the next unaccepted plane in the list. You can go back to any of the accepted planes by selecting those in the list again.

Device Sizing Viewports

The left upper viewport shows the current active plane.

The lower left and right viewports show 2 double oblique reference MPR images, perpendicular to the active plane.



1. The active plane is indicated by a dashed line on the MPR images (a plane is active when it is selected in the plane list).
2. The red line corresponds to the plane currently displayed in the upper left viewport. By default, this plane coincides with the active plane location (selected in the planes list). However, after scrolling or rotating the plane (for review or editing of the plane), those two lines no longer coincide. Click on the dashed line or the plane name in the toolbox to make the displayed plane coincide with the active plane.

After editing the displayed plane (for example, annulus plane), it is possible to make the plane the active plane by selecting the option:
Relocate the [name of the currently active plane] to this plane.

The upper right viewport shows the volume image with all the automatically detected planes indications.



For volume images, a ring indicates the location of the displayed plane. The orange line indicates the active plane (selected in the list and corresponding to the dashed line on the reference images). The green line indicates the rest of the planes.

TAVI Volume Images

Aorta+Aortic Root+LV



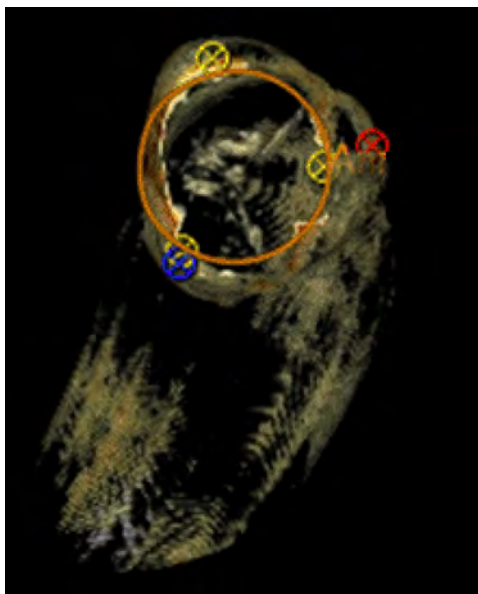
Aorta+Aortic Root



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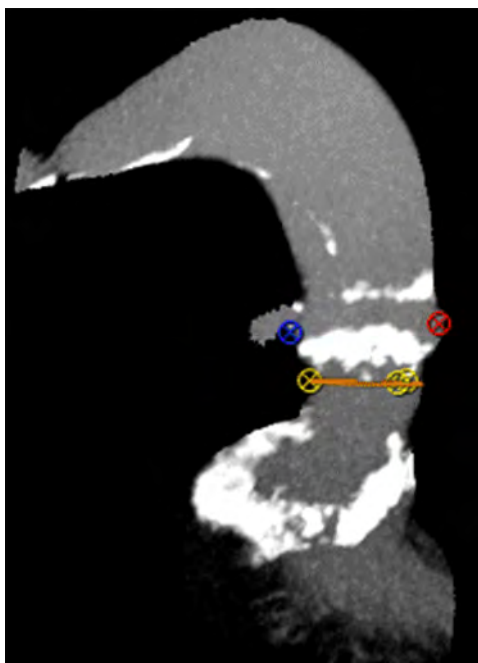
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Aorta+Aortic Root



Aorta+Aortic Root+LV with MIP rendering selected

May be used to examine calcium.



Verify and Edit Automatic Measurements

Before verifying or editing the contours, you must first accept at least one plane. See section “Verify and Edit Automatic Planes” on page 415.

After accepting necessary planes, the **Edit Measurements** mode is activated by default. You can

also activate it manually by pressing the **Edit Measurements**  icon.

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1. Examine the displayed contour types. See section “Select Displayed Contour Types” on page 420.
2. When required, manually draw diameters for the sinus of valsalva. See section “Draw Sinus of Valsalva Diameters” on page 421.
3. If necessary, edit contour. See section “Edit TAVI Contour” on page 422.
4. If a contour is incorrect, re-draw contour. See section “Re-draw TAVI Contour” on page 422.
5. Define additional measurements. Some measurements are not automatically extracted. You can draw those measurements manually (to show them in the **Review Results** table) using the **Draw measurement** tool. See section “Define Additional TAVI Measurements” on page 422.
6. When done editing and verifying all contours and measurements, click the **Accept all**



button.



When done, the **Review Results** mode is activated (the **Review Results** button becomes active).

NOTICE

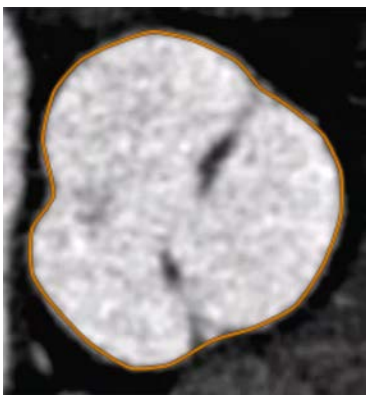
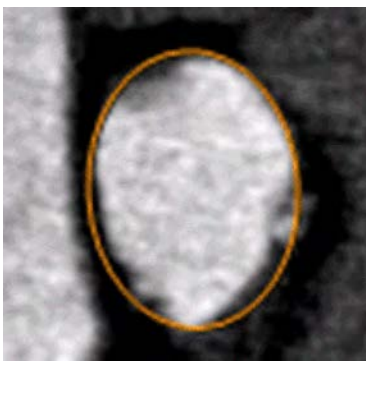
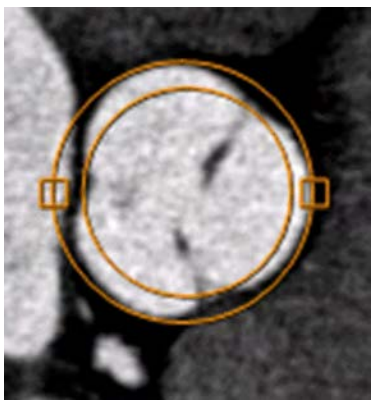
The distance to RCA/LMCA ostium is calculated as the distance between the RCA/LMCA landmark and the annulus plane. If the distance is incorrect, (due to wrong landmark or wrong annulus plane), edit the relevant landmark in the **Verify Segmentation and Landmarks** stage or edit the planes. See section “Verify Segmentation and Landmarks Stage” on page 399.

NOTICE

The left, right and non-coronary Sinus heights are calculated as the distances between the left, right and non coronary Sinus landmarks and the Sinotubular junction plane respectively. If any of the height lines is incorrect, (due to wrong landmark or wrong Sinotubular junction plane), edit the relevant landmark in the Verify Segmentation & Landmarks stage or edit the Sinotubular junction plane. See section “Verify Segmentation and Landmarks Stage” on page 399.

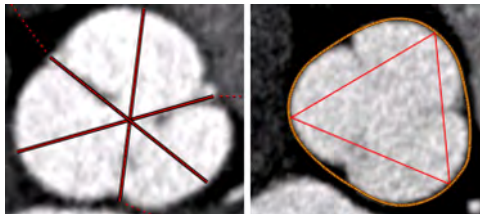
Select Displayed Contour Types

In the bottom left corner of the active plane, click on the contour type name (either **Contour**, **Elliptical**, or **Circular**) and select one of the options to change the displayed contour type.

Contour	Elliptical	Circular
		
<p>Approximates the contour of the plane.</p>	<p>Approximates the contour to an ellipse. Suitable for planes that have an ellipse-like shape (for example, annulus).</p>	<p>Approximates the contour to 2 circles: inner and outer. Suitable for planes that have a circle-like shape (for example, mid-sinusal plane or ascending aorta).</p>

Draw Sinus of Valsalva Diameters

Manually draw the 3 representative diameters at the sinus of Valsalva plane: NC Cusp, RC Cusp, and LC Cusp. Below are two examples of possible ways to measure the 3 diameters:



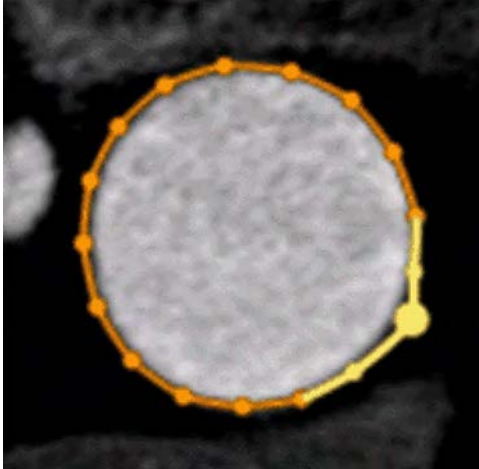
1. Select the **Draw** button for the Sinus of Valsalva image.
2. On the image, click where the first diameter should begin. Find where the diameter should end and click again.
3. From the pop-up menu, select the appropriate diameter name.
4. If necessary, edit the diameter by hovering over it until it turns yellow and then:
 - grab the line and drag it to the correct location; or
 - grab the end control points to lengthen, shorten, or swivel the line.
5. Draw and adjust the other two diameters accordingly.

NOTICE

To replace a diameter, add new line and select the diameter name from the list.

Edit TAVI Contour

1. Select the contour type to be edited.
2. Hover over a contour then grab and move a control point.



3. When needed, hover over the contour and click on the line. This will add a new point.

Re-draw TAVI Contour



If necessary, use the **Re-draw contour** button to replace the existing contour. This procedure is used for rare cases when the contour is completely off.

1. Select the contour type to be re-drawn.
2. Click the **Re-draw contour** button.
3. On the active image, click the location where the first contour point is to be inserted.
4. Click the image to add contour points.
5. Double-click when the last point is added.
6. Edit the contour as needed.

Define Additional TAVI Measurements

Some measurements are not automatically extracted. For example, the 3 maximum diameters at the level of the sinus of Valsalva. You can draw those measurements manually (to show them in the **Review Results** table) using the **Draw measurement** tool.

NOTICE

For information on using the **Draw measurements** tools, see **CT Review > CT Common Tools**.

1. Select one of the options from the **Draw measurements** menu.
 - Line

- Circle
 - Ellipse
 - Spline contour
 - Freehand contour
2. Draw the measurement.
 3. Enter the measurement name or select a name from the menu.
 4. To edit the measurement name, right-click on it.

TAVI-related Measurements

Measurements related to access-rout assessment should be performed within the AVA application.

Measurements related to access-rout assessment for calcium scoring should be performed within the Calcium Scoring application.

Review TAVI Planning Results



WARNING

Before reviewing results, you must review, edit (if required), and accept all measurements. See section “Verify and Edit Automatic Measurements” on page 419.



The review enables you to:

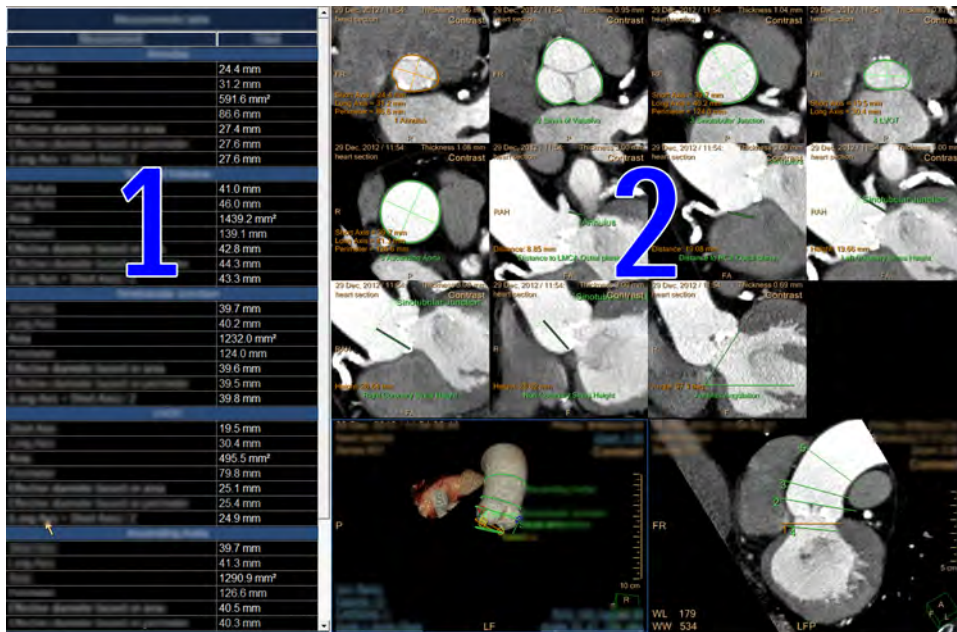
- Display the cross sectional measurements required for device sizing.
- Display the distances to ostia measurements.
- Display a set of optimal CathLab angles.

NOTICE

The active table may be added to the clipboard using **Ctrl + C** or by right-clicking on the table and selecting copy. The measurements may then be pasted into common document types, including plain text, Microsoft Word, and Microsoft Excel documents.

Results Summary View

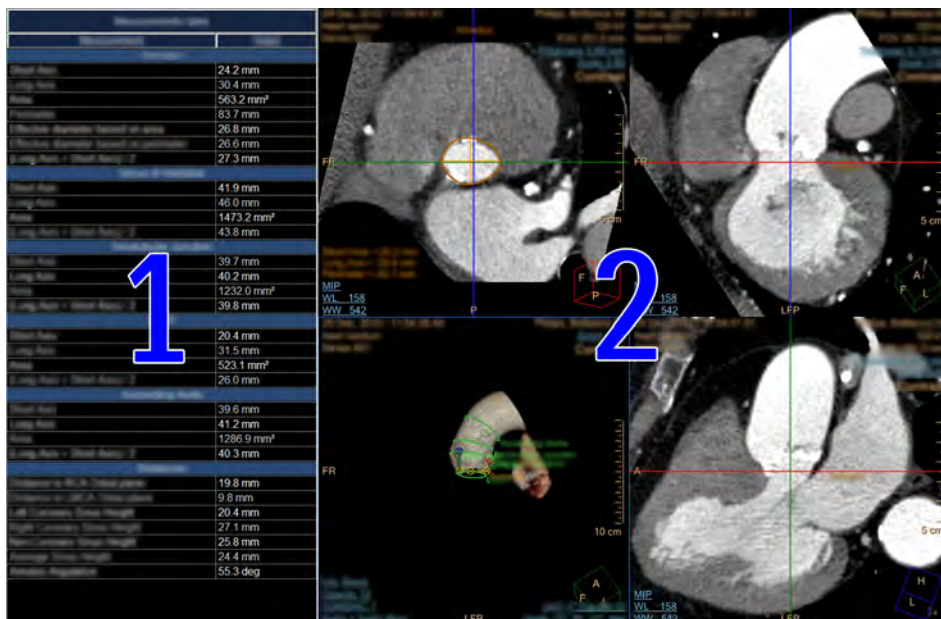
Use the **Summary Measurements Table** to view all configured measurements in the accepted planes. Select a plane from the **Tissues List** focus on it.



1. Measurements Table
2. Accepted Planes

Results Single-plane View

To examine the active plane in more detail, click the **Single Plane** radio button and select the plane from the **Tissues List**.



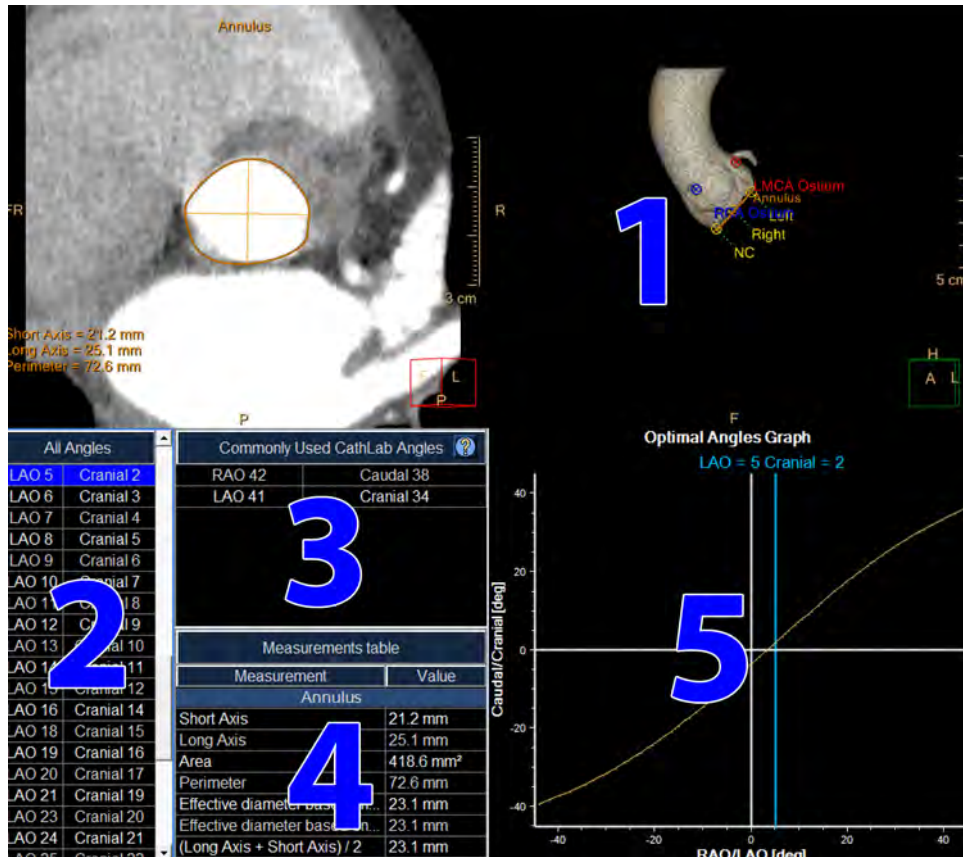
1. Measurements Table for the active plane.
2. Active plane views.

Results Optimal CathLab Angle View

NOTICE

The optimal CathLab angle correctness depends on the correctness of the annulus plane. If the annulus plane was not accepted, the Optimal CathLab angle mode is disabled.

To view CathLab orientations, select the **Optimal CathLab Angle** view.



- **Volume image (item 1 in the image).** The volume image, including landmark locations, is displayed with the VR image perpendicular to the annulus plane.
- **All Angles (item 2).** The graph shows 180 degrees of optimal angles, with the plane always perpendicular to the annulus plane. The active VR view is highlighted in blue. To view a different angle, select it from the table.
- **Commonly Used CathLab Angles (item 3).** In the table header, select the **Add Angles** button and select the angles from the menu. Configure up to 6 commonly used angles.
- **Measurements Table (item 4).** Shows the relevant measurements for the annulus plane.
- **Optimal Angles Graph (item 5).** The yellow line shows 180 degrees of optimal angles, with the plane always perpendicular to the annulus plane. The active VR view is represented by a blue vertical line. To view a different angle, grab the blue line and move it.

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Cross-sectional Measurements

Measurements for Contours and Ellipse Methods

Long Axis value is calculated as the longest diameter between 2 points on the contour crossing via the centroid.

Short Axis value is calculated as the diameter perpendicular to the long axis crossing via the centroid.

Area value is calculated as the anatomical area within the contour.

Perimeter value is calculated as circumference of the contour.

Effective Diameter based on area is calculated from the following equation: $\text{Effective diameter} = 2 \cdot \sqrt{\text{Area}/\pi}$.

Effective Diameter based on perimeter is calculated from the following equation: $\text{Effective diameter} = \text{Perimeter}/\pi$.

Average diameter: $(\text{Long Axis} + \text{Short Axis})/2$.

Measurements for Circle Method

Long Axis value is calculated as the diameter of the bigger circle.

Short Axis value is calculated as the diameter of the smaller circle.

Maximum Area value is calculated as the anatomical area within the bigger contour.

Minimum Area value is calculated as the anatomical area within the smaller contour.

Maximum Perimeter value is calculated as perimeter of the bigger contour.

Minimum Perimeter value is calculated as perimeter of the smaller contour.

Average diameter: $(\text{Long Axis} + \text{Short Axis})/2$.

Other Measurements

Distances

Distance to RCA Ostium - the shortest distance between the annulus plane and the RCA Ostium

Distance to LMCA Ostium - the shortest distance between the annulus plane and the LMCA Ostium

Left Coronary Sinus Height - the shortest distance between the Left Sinus Landmark and the Sinotubular junction plane

Right Coronary Sinus Height - the shortest distance between the Right Sinus Landmark and the Sinotubular junction plane

Non- Coronary Sinus Height - the shortest distance between the non-Coronary Sinus Landmark and the Sinotubular junction plane

Average Sinus height - the average between the left, right and non-coronary sinus heights

Annulus Angulation - the angle between the annulus plane and the axial plane

Configure Review Measurements



Click the button to configure the list of measurements to show per plane in the table and on the MPR images.

- Select a plane and define which measurements should be displayed in the table and on the MPR image.
- Define the default type of contour for each plane by selecting it from the drop-down.
- Use the **Show diameters graphics** checkbox to either show or hide the diameter lines on the planes.
- Set the default distance between the annulus plane and the ascending aorta plane (default is 4.5 cm).

NOTICE

The Ascending Aorta plane is NOT updated automatically after editing the Annulus plane.

NOTICE

Any changes will be applied the next time the application is loaded.

Report TAVI Results

1. To send the results to a report, use the **Report clinical results** button from the drop-down menu.



2. Configure the **Risk Factors**, **Clinical History**, and **Patient Parameters and Information** as required.
3. Provide any additional information such as the aortic valve type and the amount of calcification in the aortic root.

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Access Route Assessment Stage

The Access Route Assessment Stage includes the following:

- Extract Vessels - Options available include:
 - Creating a New Vessel
 - Edit/Extend centerline

- Measure Vessel Diameters - Options available include:
 - Manually measure diameters
 - Automatic extraction of diameters

Extracting Vessels

Centerline Creation Methods

The following methods for creating a centerline are available:

- Semi-automatic aorta-iliac tree creation mode.
- Semi-automatic creation mode.
- Manual creation mode.

Auto track sequence mode is recommended; this mode automatically locates the center of the vessel as you place seed points.

Manual centerline creation mode can be used if auto track sequence mode is not successful (for example, when using low quality data sets, or data sets with difficult anatomies such as vessels close to bone).

Creating a Centerline for the Aorta-Iliac Tree

You can use the aorta-iliac tree creation mode to extract the aorta and both iliacs.

NOTICE

This function only works with the Aorta & Iliacs vessels.



1. In the task guidance panel, click **Aorta-Iliac Tree**.
2. In the volume view, click to place a point in each of the three vessels.



3. When the tree is correctly defined, click **Accept** in the task guidance panel.
 - ⇒ The aorta-iliac tree is connected with a bifurcation point and it is automatically named and displayed in the vessel list.
4. If desired, drag the bifurcation point to correct its position.
 - ⇒ You can also double-click the last centerline point to finish tree creation.

Extracting Any Vessel

1. In the task guidance panel, select a centerline creation tool:

-  **Semi-Automatic Centerline**

-  **Manual Centerline**

⇒ The procedure for creating a centerline is the similar for both tools, with the following difference:

- In **Semi-Automatic Centerline** mode seed points are centered in the vessel and the centerline is tracked along the vessel after all seed points have been placed.
- In **Manual Centerline** mode seed points are also centered in the vessel (in the depth direction only), and a new centerline segment is created using a smooth curve. This mode is more effective for vessels that are highly curved or that are close to bone.

2. Place a seed point by clicking in the volume image or in one of the MPR images.

⇒ All images display the last entered seed point location.

3. Continue following the centerline by placing seed points on any of the available images.



4. If desired, you can undo the most recently placed point by clicking **Undo** in the task guidance panel.



5. When the centerline is defined, click **Accept** in the task guidance panel.

⇒ You can also double-click the last centerline point to finish centerline creation.

6. Enter a name for the vessel in the vessel naming dialog box.

⇒ The vessel list is updated with the new vessel.

Editing Centerlines



WARNING

Verify the accuracy of the vessels and their labels. If needed, use the manual tools provided in this step to correct vessel extractions and labels.

You can correct centerlines if they are not positioned in the center of the vessel lumen or if they do not extend far enough along the vessel. For CT studies, you can also connect centerlines.

The following editing tools are available:

- Edit
- Extend

Editing Vessels in the Vessel List

At the top of the task guidance panel is the vessel list. Right-click on a vessel in the vessel list to access the following functions:

- **Delete vessel**
Select this function to delete the selected vessel.
- **Rename vessel**

This selection opens the vessel labeling dialog box. Select a vessel name from the active group or enter a vessel name in the text box. If the wrong vessel list is displayed in the vessel labeling box, you can switch to the desired list by clicking **Switch to Body (or Head) vessels list** in the vessel labeling box.

Editing a Centerline



You can edit a centerline if it does not pass through the center of the vessel lumen.



1. Select the centerline that you want to edit.
2. In the task guidance panel, click **Edit**.
 - ⇒ Seed points are displayed on the selected centerline.
 - ⇒ The **Edit** tool allows you to edit the centerline by relocating the seed points.
3. Select a seed point.
 - ⇒ The selected point is highlighted in the curved/MPR image, and the cross section image is updated to the seed point position. In the cross section image, the seed point is indicated with an "x".
4. Drag the seed point to the correct position.
 - ⇒ You can drag the seed point in any of the available images.
5. To create a new seed point, click at the desired position on the centerline.
6. To delete a seed point, drag it over another seed point on the centerline.
7. To complete the centerline edit, click **Accept** in the task guidance panel.



Extending a Centerline

1. Select the centerline that you want to extend.
 - ⇒ You can extend the centerline from either end of the existing centerline.
2. Select one of the following tools in the task guidance panel:
 - 
 - Click **Extend Superior** to extend the centerline from the superior end. Selecting this tool automatically places the inspection ring at the superior end and reference images are updated accordingly.
 - 
 - Click **Extend Inferior** to extend the centerline from the inferior end. Selecting this tool automatically places the inspection ring at the inferior end and reference images are updated accordingly.
- ⇒ For CT studies, regular MPR images are displayed.

NOTICE

You can extend the vessel at either end using each of these tools; whenever you place a point it is automatically connected to the closest existing point. However, selecting the tool for the direction in which you want to extend the vessel displays appropriate reference images before placing the first point. If you continue extending the centerline at the other end of the vessel, reference images are flipped after placing the next point.

3. Place a point to extend the centerline.
 - ⇒ The point is automatically adjusted to the center of the vessel lumen and the reference images are updated.
4. Continue placing points to extend the centerline as desired.
5. When the centerline is defined, click **Accept** in the task guidance panel.
 - ⇒ The edited centerline is calculated.
 - ⇒ After extending a centerline, you do not need to update measurements performed on the original centerline.



Measuring Vessel Diameter

Manual Measurement

1. Identify the cross section for measuring the min/max diameter.



2. Select the **Measure diameters** option.

It is also possible to select the icon from the cross-sectional image viewport.

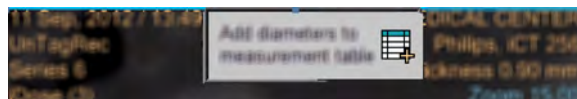
3. Draw two lines on the cross section image.

Measuring Using Automatic Lumen

Another way to extract the minimum and maximum diameter of a cross sectional image, is by using the auto Lumen contours. Once activated the automatically calculated contours appear on the CS and sMPR image, the min and max will be calculated from the contour and displayed.



1. Select the **Show/Edit auto-lumen contours** icon (and auto diameters) to enable/disable the Contours.
2. Identify the cross section for measuring the min/max diameter.
3. Once the relevant cross-sectional image is identified, select the icon from the cross-sectional image viewport **Add Diameters to Measurement Table**.



Measurement Table

Once measurements are completed, select the **Measurement table** option to view the measurement table and the relevant CS image, together with the VR image.

17 Virtual Colonoscopy

The Virtual Colonoscopy application enables fast and easy visualization of colon scans, using acquired CT images.

Two workflow stages are provided in Virtual Colonoscopy:

- **Define stage.** When a study is loaded, the application automatically segments the air-filled colon and displays a calculated center line.
- **Navigation stage.** In this stage you can examine the virtual colon to search for suspected colon polyps. Various imaging methods are available for viewing, as well as various display arrangements (layouts), including cine mode. When examining the colon, both manually and automatically, you can mark your “Findings” in a list and send the results as images and text to the Reporting function.

NOTICE

Before continuing, refer to the “Instructions for Use” that came with your scanner.

Other Features

- **Single Image Navigation.** The 3D Single Image Navigation feature improves the perception of navigation performance when operating the Portal in the “lossless” mode. (More information is provided in the section “Navigation Workflow” on page 461 section, later in this chapter).
- **Electronic Cleansing.** The (optional) Cleansing function (fecal tagging) removes oral contrast, if any is present in the bowel. The Cleansing function detects the presence of the contrast in the colon and removes it from images. This reduces artifacts and presents an image with a true anatomic display of all structures, with a smooth, accurate transition at the air-fluid interface. Cleansing can potentially improve polyp detection where lesions are under fluid, or rule out lesions where residual stool could mimic a polyp.
- **Computer Assisted Detection.** The (optional) Computer Assisted Detection function (CAD) can assist your search for polyps.

There are two CAD algorithms in use. The user interface for the two algorithms is identical. The algorithm used is dependent on geographic location:

- The CAD algorithm is not available in the United State. See section “Computer Assisted Detection” on page 455.
- The VeraLook iCAD algorithm is only available in the USA. See section “VeraLook iCAD Algorithm” on page 457.

NOTICE

The CAD Option in both configurations requires an additional license key.

NOTICE

The Electronic Cleansing function is not available in the United States.
The Electronic Cleansing function requires an additional license key.

Load Multiple Studies in Application

To load multiple studies in the application:

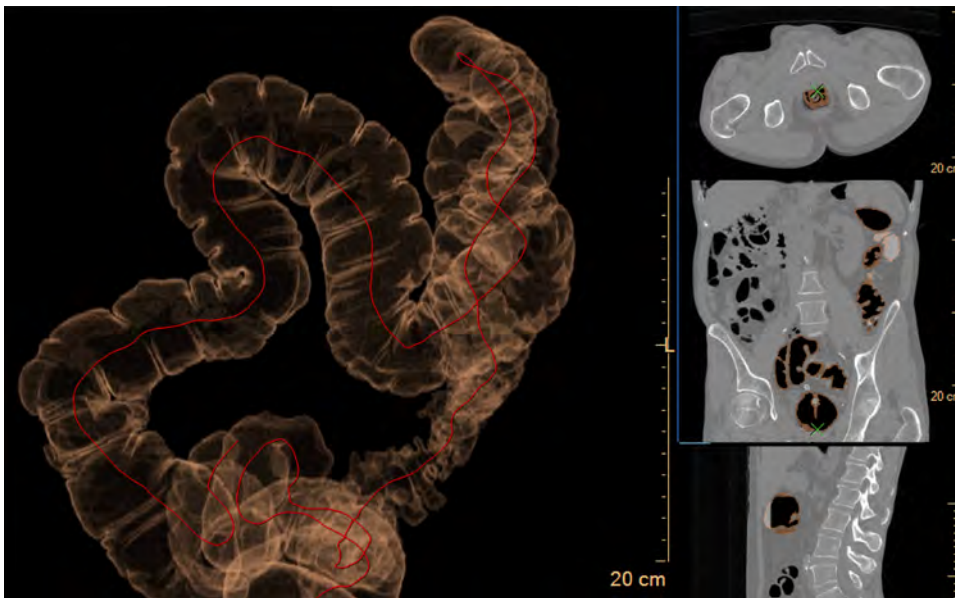
1. Use the **Ctrl** key when selecting studies from the Directory list.
2. Select the application from the Applications menu.
3. Confirm the studies are from the same patient.

NOTICE

Depending on your Portal configuration, this application may not be available.

Define Work Stage

Click on the Virtual Colonoscopy application icon once you have selected the appropriate colonoscopy studies from the Directory.



There is a delay before you see the opening display (shown above). During colon segmentation, the application is looking for air-filled structures, according to specific Hounsfield Unit values.

Status messages are shown at the bottom of the screen, including “Computing colon segments,” “Contrast was removed,” and “Verify centerline extraction. If necessary manually correct segmentation . . .”

The application automatically segments the air-filled colon. calculating and displaying a center line, with start and end points labeled.

Structures identified as the colon are colored; other air-filled structures are colored translucent white.

Define Work Stage Warnings



WARNING

One or more of these image types may appear in this application: curved MPR, straightened MPR, volume images, and thick slab images. Measurements you make on such processed images can sometimes be misleading. When saving such images, make sure they are labeled properly.

Cross sectional images might rotate around the centerline. Please note orientation annotations on images.

In cases where the orientation annotations are not displayed on the image - you must not assume any specific orientation. For correct orientation information - use only the images which display such information. The distance from start of navigation (marked as S) measurement is based on the extracted centerline.

The distance should not be used as a SOLE basis for locating findings in any clinical procedure.

Define Work Stage Tools

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Orientation



The three Orientation buttons allow you to select the viewing orientation, Axial, Coronal, and Sagittal, of the active viewport (the viewport with the blue frame).

Flip



Use the Flip button to flip the active volume viewport 180 degrees.

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Layout

Use the Layout button to select a different layout or create a custom layout.

Compare

The Compare function allows you to perform a side-by-side review of images from two studies of the same patient, supine and prone.

Relate



The Relate functions allow you to relate a location on one image of the patient to that location as viewed on other image(s) of the patient.

Next or Previous Series



Use this function to move to the next or previous series in the patient study. The button is enabled when more than one series has been loaded to the current application.

Show Transparent



Click Show Transparent to view, in a semi-transparent mode, all bone that was removed during launch.

High Quality



This function adjusts the rendering parameters to display a sharper image to enhance details.

NOTICE

Activating High Quality can slow processing. It is best to complete all image processing before activating it.

Define Work Stage Functions

See **Report, Film, CT Common Processes** and **CT Common Tools** for information on using common options, tools, functions, and processes.

Key Images

Save groups of images that can be reviewed in any system supporting the defined standard. See **Instructions for Use > Directory > Key Image Notes** for more information.

Electronic Cleansing

NOTICE

The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

The Electronic cleansing option requires an additional license key.

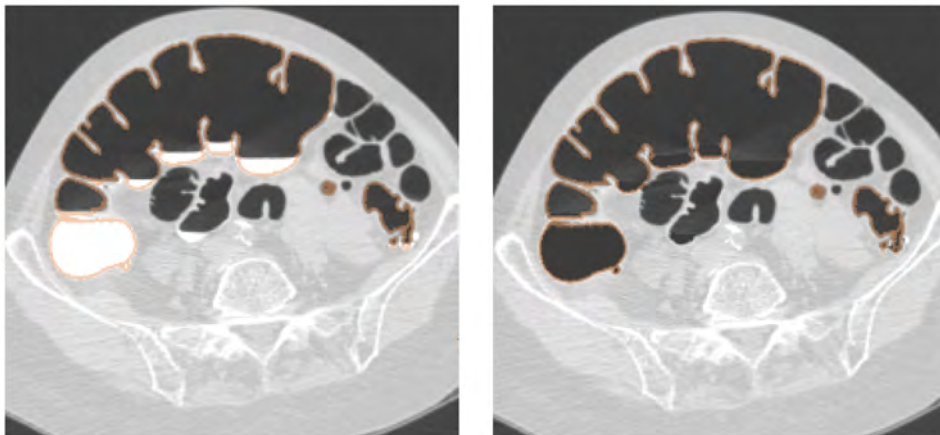
If your Portal system is equipped with electronic Cleansing, the Virtual Colonoscopy application attempts to detect contrast in the bowel during the launch. During launch, the application assesses the amount of contrast and its HU threshold and automatically applies it if cleansing is needed.

NOTICE

You can turn off Cleansing by un-checking the check box.

The Cleansing function is never applied to the Volume viewport.

If no contrast is detected by the application the cleansing function remains inactive as indicated by the grayed-out Apply Cleansing check box.



**WARNING**

Verify accuracy of the cleansing operation to avoid misdiagnosis.

Electronic Cleansing Method

NOTICE

To specify the default method of Cleansing, select a setting in the VC Properties function tab in the Define and Navigation work stage. See section “Navigation Workflow” on page 461.

The IntelliSpace Portal makes available two fecal tagging (electronic cleansing) algorithms:

High-density Contrast

This algorithm is new to the Portal, and is adapted from the Philips ViewForum workstation, where it was clinically validated. It can yield better image quality, especially on high contrasts (>250 HU) in the bowel.

NOTICE

On the first use of the Virtual Colonoscopy application, the High Contrast type is enabled.

In bowels that have low density contrast, it is possible that the High Contrast method may not cleanse all fecal matter.

When comparing images of the same study using the two cleansing methods, you may notice that the cleansing results differ, and the resulting surface rendered images may be different.

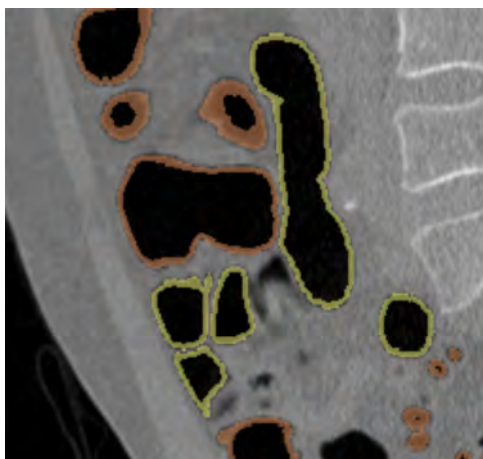
NOTICE

When a study has low density contrast (less than 250 HU), the High Contrast method will not be applied. A warning message appears in the message bar to alert the user.

Show Highlights



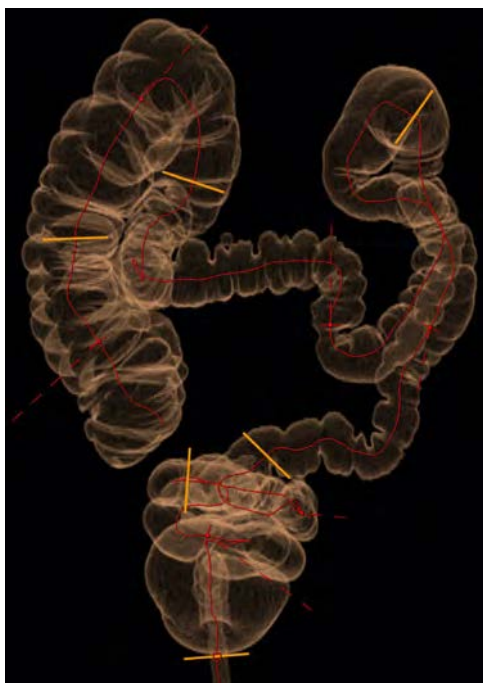
Click Show Highlights to display highlights identifying the colon and small intestine. Highlights are shown in the reference viewports.



Show Anatomical Segments



Anatomical segments are the boundaries (or interfaces) between the six colon segments, starting with the beginning of the rectum; the second is the beginning of the sigmoid, and so on. Click the Show Anatomical Labels icon to turn the labels on and off.



One or more of the Anatomical Segments boundaries may need manual adjustment. To adjust a boundary (or interface) line, drag it along the centerline to its correct position.

Opaque Colon

In the volume image viewport you can change the default Transparent mode to the Opaque mode. This changes the colon image from transparent (left) to an opaque (right), which may help orient you to the partial views presented in other viewports.



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Centerline Editing

In some cases the colon is segmented as a single complete structure. In other cases, the colon is segmented in several parts, depending on the contiguity of the air-filled structures. If the centerline is not correctly placed, use one of the editing tools described below.



WARNING

Verify center line extraction. If necessary manually correct segmentation with the tools provided in this application.

Scroll Along Centerline

The **Scroll Along Centerline** feature helps to check for the correctness of the centerline.

By default, this feature is enabled in the Define stage. When scrolling the MPR image, the green cross represents the centerline location.

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To disable the **Scroll Along Centerline** function, use the Context menu (right mouse button). Unchecking this feature allows scrolling along the Z-position.

NOTICE

This feature is also available in the Navigation stage.

Editing Per Segment



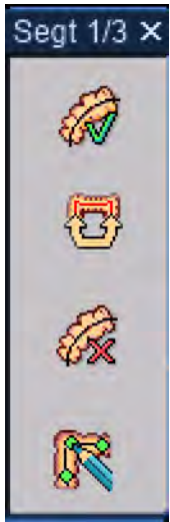
If the colon is produced with more than one segment, click the **Enable editing** button to activate the editing tools, in order to manually identify the missing parts and connect them.

Enable editing is selected by default. To check the centerline, start by selecting the first segment (i.e. rectum).

The colon turns blue. When you approach the centerline it turns yellow. The segment Edit tools appear as a floating dialog on the 3D volume view.



Editing Tools



A floating dialog appears when a segment is selected. The dialog includes four options, which are described below.



Recalculate & Add Centerline - This button is active when a segment is rejected or it is necessary to recalculate the centerline. Click to add the active segment. The centerline of this segment is now added to the existing centerline.



Flip Start & End Position - Exchanges the start and end points of the centerline per segment. The centerline starts in the rectum and ends in the cecum, by default. The connection of each segment is established in this order.



Remove Centerline & Hide Segment - When selected, simultaneously rejects the segment (centerline) and hides the segment. When clicked, the active segment disappears from the image.



Position Seed Points - Allows the addition of seed points to the centerline. The pencil cursor numbers the seed points as they are placed on the centerline.

Reject All Segments



Clicking this button removes the calculated centerline and allows the user to build the centerline starting at the rectum.

Hide Rejected (white) Segments

Selecting the **Hide rejected (white) Segments** check box hides the white segments without the presence of a centerline on the 3D volume image. Deselect the check box to regain access to the hidden segments.

Editing Entire Centerline

Drawing a New Centerline



When the algorithm fails or the calculated centerline cannot be fixed using the segmentation editing tools, manually draw a new centerline.

1. Select the **Draw new Centerline** icon to remove the current centerline and start drawing the centerline from scratch.
 - The mouse pointer turns into a pencil, as an indication for positioning seed points.
2. Place seed points.
3. Once the centerline is completed, either double-click on the last point or press the **Draw new Centerline** icon again.
 - A seed point can be placed in any viewport, including outside of the calculated segments.
 - Users can switch between viewports.
 - While drawing, it is possible to reposition the centerline by pointing at the line and moving the point.
 - When drawing a new centerline, it is possible to select a layout that includes a cMPR.
 - If rotation is required, either press the left and right mouse buttons simultaneously or use the **Roll/Rotate** option (from the Context Menu or Common Tools).
 - If necessary, use the Context Menu to delete a selected point. All seed point numbers are re-ordered by the system.
 - All points are connected consecutively, using a simple spline.
 - When the colon is very curvy, ensure to set enough points.
 - There is no automatic centering. If the manual created centerline is set closely to the colon wall, this might limit the endo view.

Editing an Entire Centerline



Edit Entire Centerline allows manual corrections to complete the centerline. It can be used to make corrections after drawing a new centerline. In addition, it can be used to make corrections of the entire centerline that was calculated per Segment.

NOTICE

When selected, the Per Segment Tools are disabled.

Navigation Work Stage

In this stage you can examine the virtual colon and search for and view suspected colon polyps. Various image types are available for viewing, as well as various display arrangements (layouts), including cine mode.

The (optional) automatic detecting function (CAD) can assist your search for polyps.

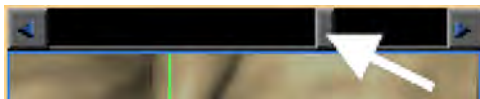
NOTICE

The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

When examining the colon, both manually and automatically, you can mark your “Findings” in a list and send the results as images and text to the Reporting function.

The navigate stage provides a variety of viewing utilities, image types, and display arrangements (layouts). These utilities allow you to search the virtual colon, and identify and examine suspected polyps:

- The scroll bar at the top of the Navigate display lets you quickly view the entire colon along the center line.



- The center line navigation utility lets you to “fly” through the colon in cine fashion, continuously or step-by-step.
- Interactive navigation lets you “fly” through the colon by steering the view, using your mouse on the image.
- The (optional) colon polyp computer aided detection (CAD) helps you detect and analyze intracolonic polyps. Polyp-like tissues are highlighted and displayed as you scroll through the images.
- Compare - for quick correlation, lets you look at two views of the patient at the same time, such as supine, prone and decubitus views.

To use the Compare function, both cases must be loaded at the same time, when the application is started.

Cursor Display

In this stage, it is possible to switch between three different crosshair states. Select **Show lesions cross-hair** from the **Context** menu (right-click). The following cursor display options are available:

- **Show as "Plus" shaped** - This option is the system default.
- **Show as "dot" shaped** - A cursor in the shape of a red dot appears.
- **Do not show** - There is no cursor displayed.

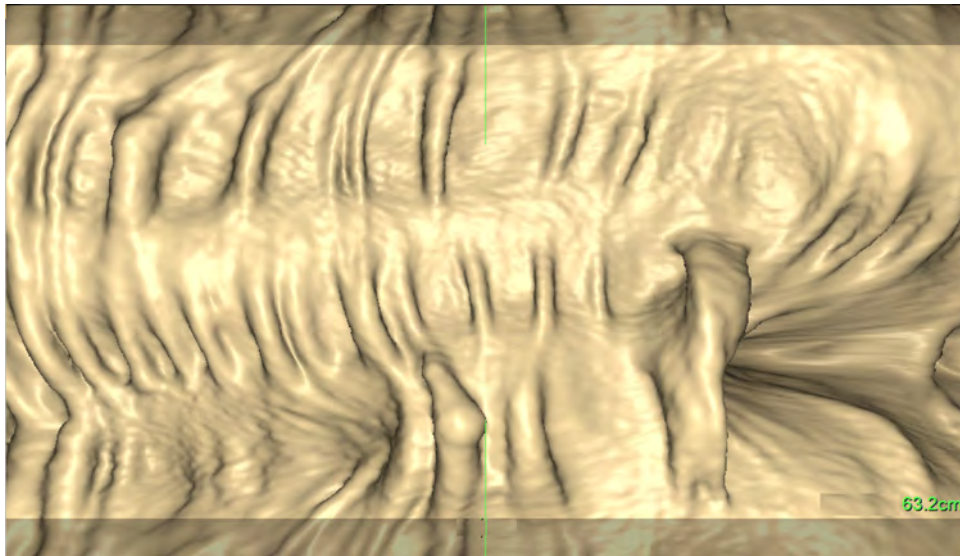
The cursor display setting affects all images at once (including endo, fillet, volume, MPR, CS 4). The cursor setting is not saved with Bookmarks. The system remembers the last setting (per user), which will be either a plus shape or dot. The **Do not show** option is not permitted as a possible default option.

Colonoscopy Images

You can also use any of the view modes, in addition to the orthogonal views, for the colon study.

Filet

A view that cuts a tubular section of the colon longitudinally and stretches it onto a 420-degree image. This view displays the 30-degree overlap on top and bottom of the image. The overlap area is shaded for identification, and allows full viewing coverage. The filet image provides a fast visual examination of the colon, and gives you a broader range of view than either Endo or Split.

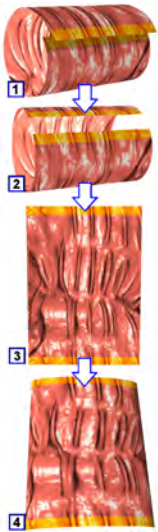


WARNING

The Filet viewing mode should **NOT** be used as the **SOLE** basis for clinical diagnosis.

Orientation of view is with the end of the colon toward the right, toward the cecum. The green vertical lines at the center of the viewport correspond to the center of the yellow highlight in the 3D Colon Map (the location is marked with a blue arrow).

Filet View Measurement



Mixed Layout measures approximately 6 centimeters.

Filet Layout measures approximately 10 centimeters.

420 degree view with a 30 degree overlap.

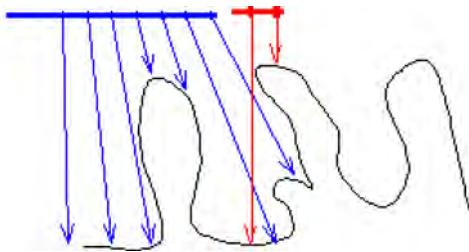
The Filet image gives a virtual dissection projection that is, in effect, like cutting a section of the colon open longitudinally and spreading it from top to bottom in the viewport, so the entire wall circumference of the colon section can be seen in one view.

The Filet view is formed with an overlap of 30-degrees at the top and bottom, yielding a 420-degree image. (The overlap guarantees full viewing coverage.)

The overlap is marked by shaded portions at the top and bottom of the viewport.

The Filet image is created using a novel visualization technique called the perspective-filet view. This is designed to show as much of the entire colon wall as possible from any point along the centerline. It overcomes the “blind spots” sometimes created when all of the projection rays are perpendicular to the centerline.

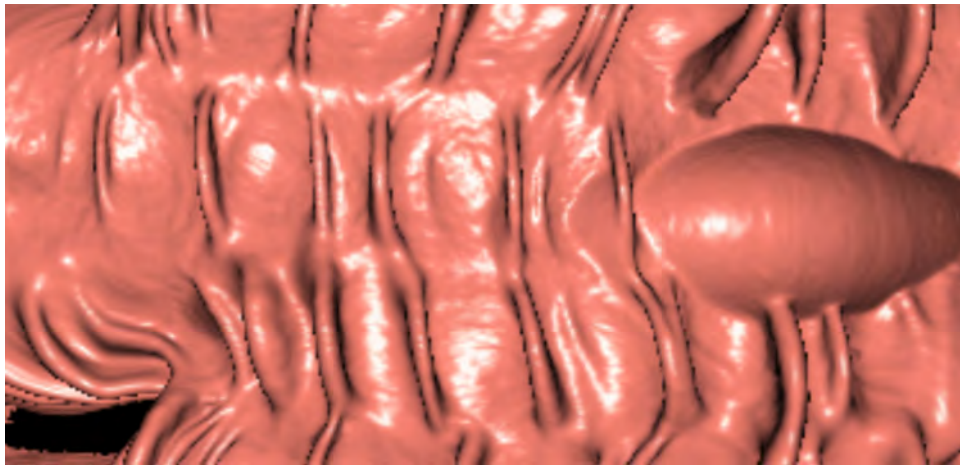
The illustration below is a simple diagram of the perspective technique.



By tilting the projection rays as a function of the distance from the central location, the view adds perspective to the previously flat view. You can now see the antegrade and retrograde sides of the folds without having to manipulate the view at all.

This technique produces some display distortions, both horizontal and vertical. Horizontal distortion is pronounced at the left and right regions of the image, where parts of the colon wall that are not “visible” with the perspective technique are black. (Scrolling and/or navigating reveals these hidden areas at left and right.)

Below is another image that demonstrates distortion in the filet image. What appears to be a domed structure is actually a flat pool of oral contrast (which may be removed with the Cleansing function).

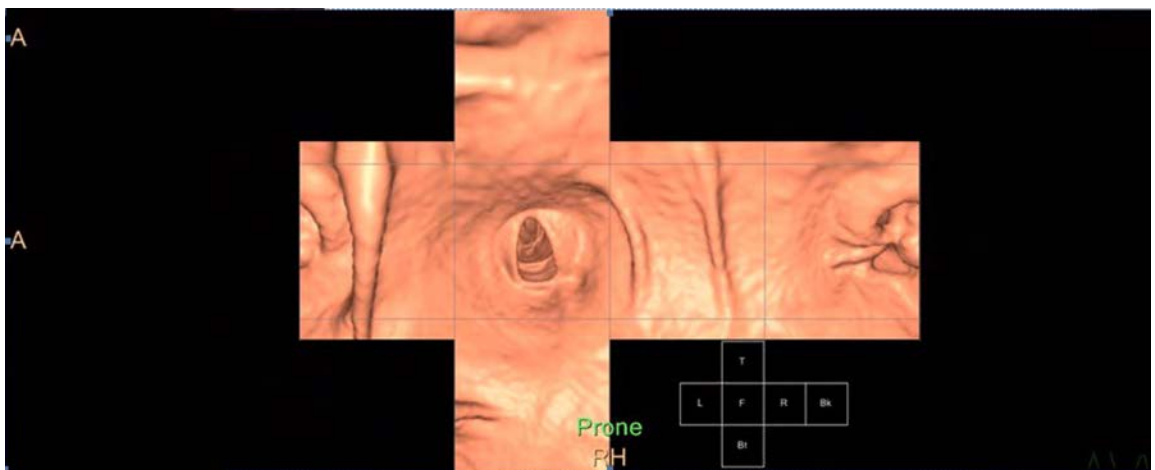


NOTICE

The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

Unfolded

The navigation covers the whole colon in one fly-through (as with filet) by presenting a "flat" image of an unfolded cube, having 6 square surfaces.



	Top			
Left	Forward	Right	Backward	
	Bottom			

The surfaces are displayed based as from the center of a cube, viewing along the centerline. The unfolded surfaces are the walls forward, back, left, right, and top and bottom respectively, as shown in the legend which accompanies the layout. (The legend can be shown or hidden: use the Show/hide legend function in the right-click menu of the main viewport.)

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On the Unfolded view, there exist “overlapping areas” that correspond to the squares that “touch” each other when the cube is reassembled.

The Unfolded viewport includes the unfolded image and three reference images: 3D colon with centerline path and eye-direction, axial, and cross-section. (In the Compare mode, only two reference images are shown: 3D and axial.)

The functionality and navigation for Unfolded are similar to Endo mode, with the exception of the following:

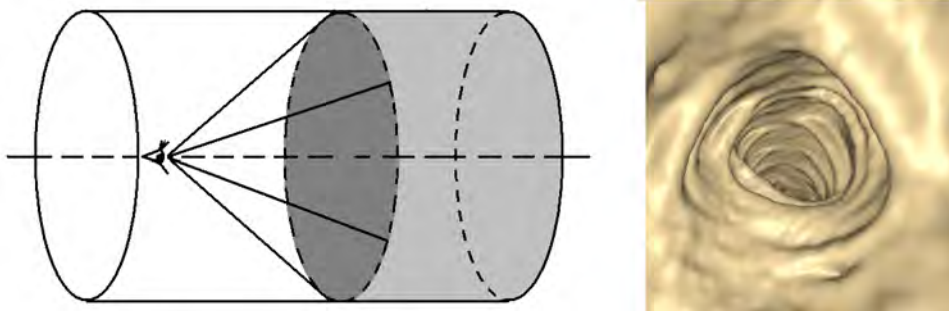
- Zoom, Pan and Swivel cannot be applied to the unfolded view.
- 3D measurements are restricted within one square at the time.
- Findings are displayed directly on the surfaces. The same finding/lesion can be displayed simultaneously in several squares due to the overlapping nature of the view.
- No diameter is displayed for the unfolded view.
- A lesion from the CAD results is displayed on the unfolded view.

NOTICE

The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

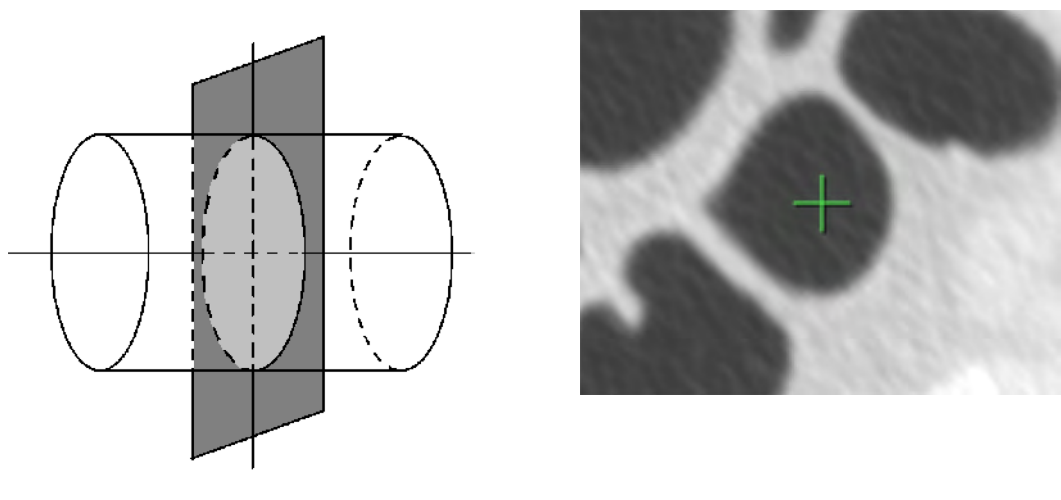
Endo

This is an endoscopic view of the colon. The view direction is toward the end of the colon, the cecum (default). The 3-D endo-luminal view of the colon is displayed when the (virtual) camera is oriented parallel to the centerline passing through the colon.



Cross-section

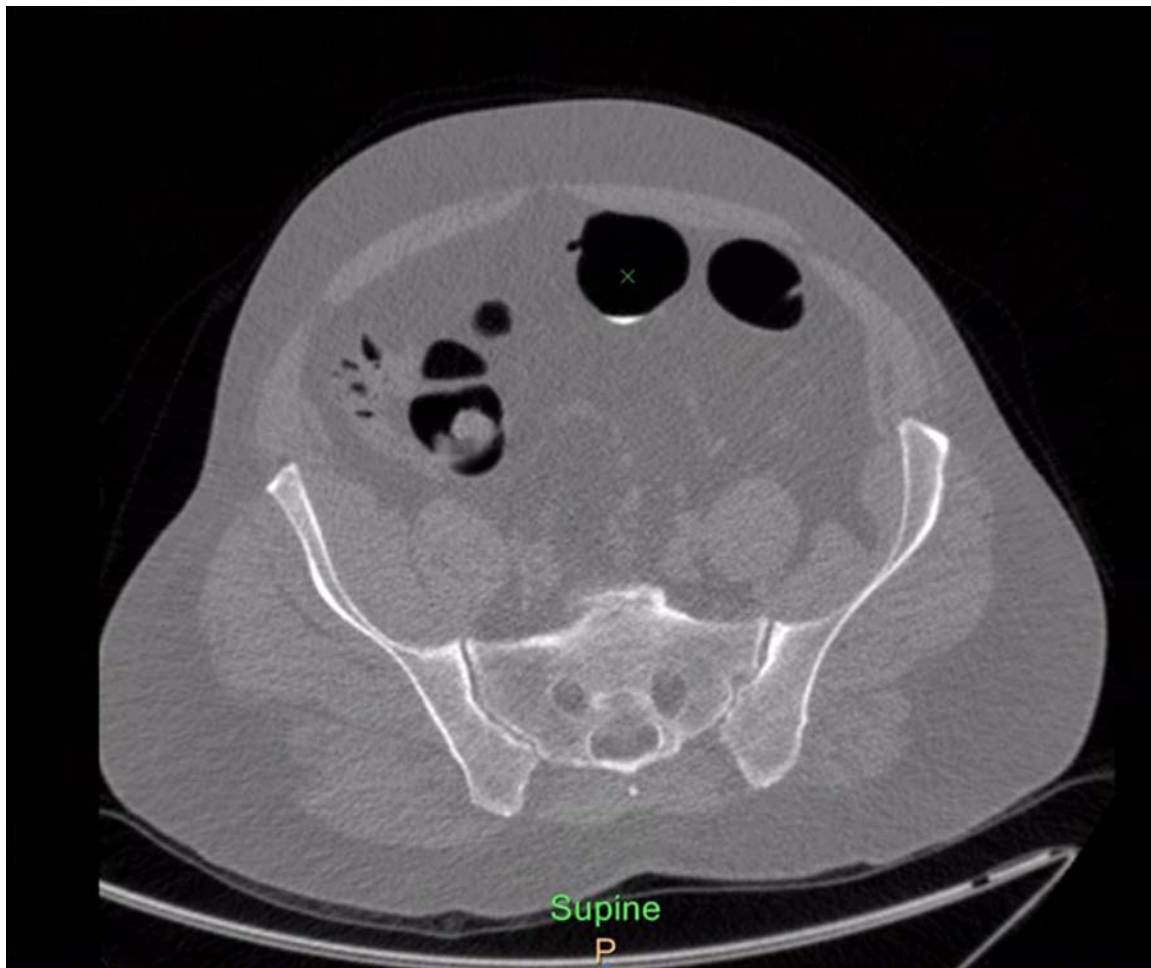
The cross-sectional view is perpendicular to the centerline. The centerline is identified by the green crosshair. The cross-sectional view of the colon is formed by a plane cutting through it at right angle to the centerline.



Axial

Reference Images

The axial image is one of the MPR images that can be used as reference.



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There are two ways to scroll through the axial images:

- **Scroll along centerline** - When scrolling the images, the centerline is followed. This may result in jumping from one Z-position to the other. The green cross shows an arrow next to it, showing the direction of the centerline in depth.
- **Scroll in consecutive order of Z-position** - Using the right mouse button, the scroll along centerline function can be disabled to allow to scrolling in consecutive order.

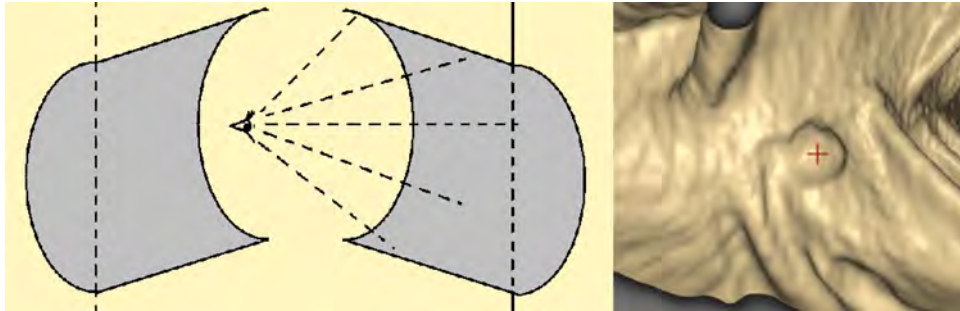
Split Image

NOTICE

This view is only available in the Endo view after a finding is marked with **Mark new finding** feature.

Philips

The Split image allows you to view the colon (perpendicular to the center line), splitting the colon in half to show the far wall. It is the 180° view of the colon, displayed when the eye point is at the centerline, oriented towards the colon mucosa.



Layouts

The opening display defaults to the last layout used (user dependant, no default factory or according to the **Save User Settings** feature [see section “Navigation Workflow” on page 461]).

You can Enlarge any of the images in any of the layouts by double clicking in the desired viewport.

Layout selections allow you to choose various viewport arrangements, combining 3D Colon Map, Endo or Split, Filet, and several conventional image formats.

NOTICE

You can adjust display parameters of the Filet, Endo, and Split images with tools in the Image Properties function tab.

Save Layouts



Allows you to keep your layouts: Click the **Save Layout** icon. Type a name for the layout. Click **OK** to save the layout, or **Cancel** to close the dialog box without saving the layout.

Layout Manager

Allows you to manage layouts (viewport display arrangements). It operates the same as described in Common Processes, except that it is more oriented toward the colon. So, you can customize and save your layouts to include Filet, Endo, and Inspect view. (The Inspect image type is accessed from the Image Properties function tab.)

Filet Layout



In the upper half of the image area is the Long Filet view. In the lower half are the 3D Colon Map, the cross section, and Endo images.



WARNING

The Filet viewing mode should **NOT** be used as the **SOLE** basis for clinical diagnosis.

Standard Layout



This is the default layout. In the upper half of the image area are the Endo and 3D Colon Map views. In the lower half are the axial, coronal, and sagittal images. There is no filet view.

Filet Endo Layout



The upper half of the image area consists of the Filet and Endo views. In the lower half are the Axial and 3D Colon Map images.

Basic Layout



In the left half of the image area is the Axial view. On the right are the Endo and 3D Colon Map images.

Reference Image

If a layout does not display the desired images, open the Context Menu (right mouse button) .

Select the first option, **Reference Image** and then make a selection from the submenu to replace the active image.

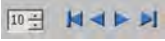
Navigation Tools

Anatomical Segments



Enable to view the different colon segments onto the 3D volume image. See section “Navigation Work Stage” on page 444.

Centerline Navigation



The cine controls allow you to automatically navigate the centerline forward (to C, cecum) or backward (to R, rectum). Set the navigation speed as desired.

There is an “anti-data-skip” function may be automatically applied in the case of network slowness. This function slows down the navigation “play” speed if the slowness might cause the display of some 3D colon data to be dropped.

When using Compare in the Navigation Stage, the speed of the shorter segment decreases to ensure that navigation reaches the next segment at the same time. This is done using the registration process with the user-located anatomical sections.

Flip Endo View



Use the Flip Endo View button to flip the active image during the Navigation stage. The tool will flip volume, Eye direction in 180 deg. (via Endo), and cross-section images prone to supine and vice versa.

NOTICE

The Flip Endo View function is only active when the Endo View image is active. Click the button or activate the desired image and use the **O** key on the keyboard.

Alternate Window



Use the **Alternate window** button to switch between Colon and Abdomen window settings that are preset in **Preferences**. The window settings can also be changed by using the numbers on the keyboard.

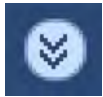
Set Exterior Cannula Length

Use the Set Exterior Cannula Length feature to compensate for the length of the inflation cannula length out of the rectum when the centerline is passing through it. To set the length, prone and supine are set independently:

- Using the reference views, navigate along the centerline in the cannula until the start of the rectum.
- Copy the distance into the Exterior Cannula Length setting. This creates a new reference origin for the findings during navigation.

NOTICE

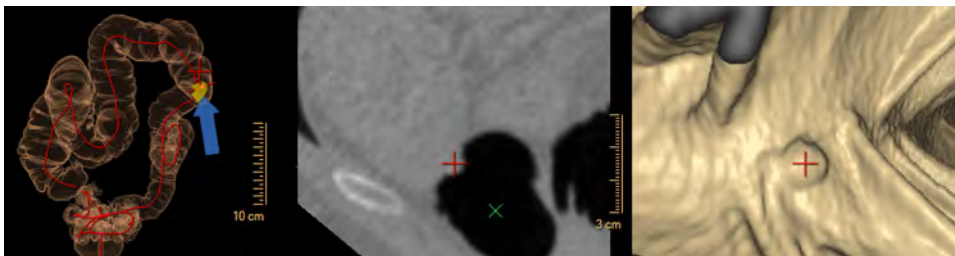
The distance before the new reference origin is annotated as **** cm on the viewports during navigation.

Findings Tab

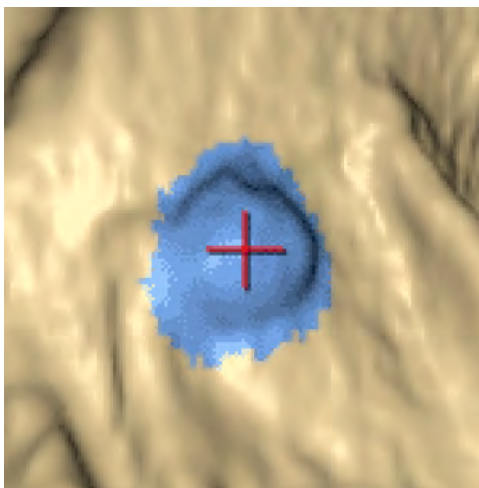
The Findings functions allow you to search for, display, and mark polyps that may exist in the virtual colon images. Select the Findings tab from the Navigate stage drop-down.

Mark Findings

Click **Mark Findings**. Place the pencil cursor over the area of interest. Left mouse click to mark the area. This area is automatically centered on all images of the same series..



Split appears on the endoscopic view with measures that are adjustable.

**NOTICE**

Findings may also be marked by using **Alt + F** on the keyboard and then clicking on the appropriate location on an image.

Click **Accept finding**, the finding is displayed with a blue overlay; or click **Reject finding** to continue without listing the finding.



NOTICE

These findings also appear on the 3D Translucent Colon Map.

Working With the Findings List

Accepting/Rejecting Findings



Click the Accept Findings icon to

Rename Finding

Edit your marked findings with the following procedure:

1. Right mouse click on the finding you want to edit.
2. Select **Rename**.
3. Type in a name for the finding.
4. Click **OK** to accept the name. The new name appears in the findings tab.

Editing Measurements

You can edit a Finding's Name, measurements (Length and Width), Shape and Segment on the finding's Measurement Sheet.

1. Right mouse click on the finding name in the Findings tab.
2. Select **Measurement Sheet**. The **Finding's Measurement Sheet** opens.
3. Change the Finding's Name, measurements, Shape or Segment as needed.
4. Click **OK** to accept changes, or **Cancel** to return without saving any measurement changes.

Computer Assisted Detection

CAD can assist you in polyp detection. CAD is set to detect, optimally, polyps of 6 mm or larger. You may choose whether or not to display the CAD results during the Findings procedure.

**WARNING**

CAD must be used only as an adjunct procedure to your primary reading of a study. Final diagnosis and identification of lesions is the responsibility of the radiologist.

**WARNING**


The Virtual Colonoscopy CAD option should not be used as the SOLE basis for clinical diagnosis.

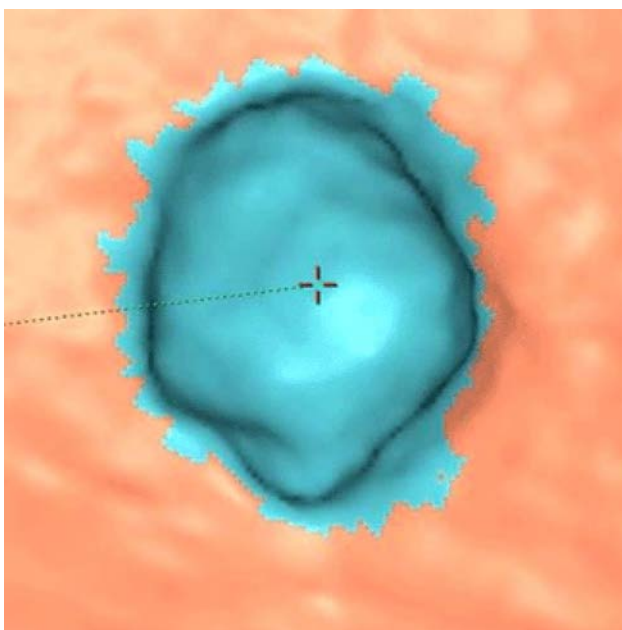
When Show CAD Results is active (checked), all findings found (suggested) by CAD are marked with a cyan blue overlay. The overlay turns purple when you accept the finding.

NOTICE



The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

CAD Procedure

1. Click the **Show CAD Results** check box, which displays CAD Results in the Findings list.
2. CAD displays the number of potential polyps found in the study in the Findings list. The CAD findings are identified with a red dot  CAD1.
3. The 3D images shows the CAD findings in light blue.



- Click on each CAD finding in the Findings list to view the selected finding on all images.

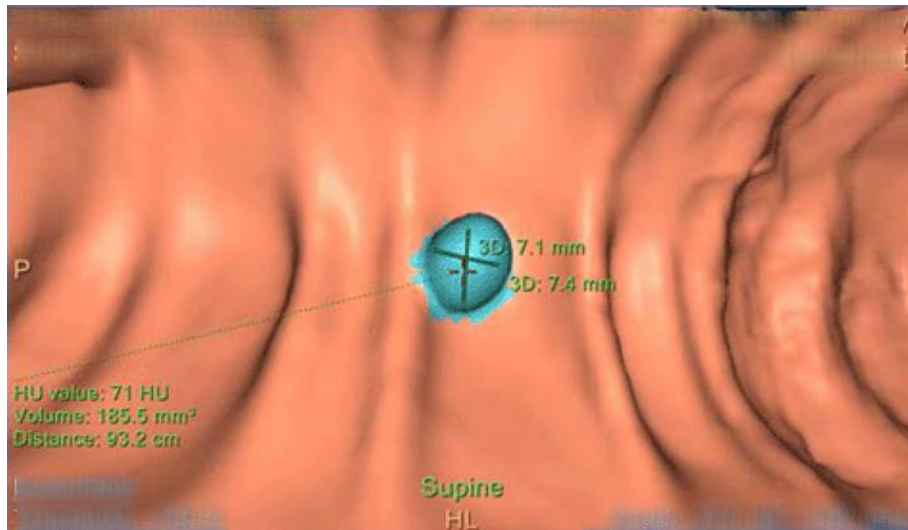
- Click the  Accept or  Reject icon to accept/reject findings.
- Once a finding is accepted, the light blue color changes to a dark blue color.
- To edit an accepted finding, see section “Editing Measurements” on page 455.

NOTICE

Only Accepted CAD Findings can be edited.

Show 3D Diameters

When you activate **Show 3D Diameters**, the system displays the measured diameters of the finding onto the 3D endo image in millimeters (mm).



NOTICE

Applicable for VeraLook iCAD Users (available in the USA only): Please note that only one diameter of the finding is displayed (the length diameter of the finding)

VeraLook iCAD Algorithm

The VeraLook, iCAD third party CAD algorithm is integrated into the Virtual Colonoscopy application. This algorithm is available only in the USA and requires an additional license key.

Some information on the company and algorithm:

- VeraLook™ CTC CAD Software is intended to automatically detect potential polyps in CT Colonography exams.

- The VeraLook CAD license is only available for customers in the USA.
- VeraLook is recommended to be used with a slice thickness of ≤ 3 mm and a reconstruction interval of ≤ 2 mm.

VeraLook™ Company Information:

VeraLook© CTC CAD

Software version number – V1.0.11

Software for Computed Tomographic Colonography Computer-Aided Detection

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iCAD, Inc. 98 Spit Brook Road, Suite 100 NASHUA, NH 03062 USA

Create Movie

Only the **All Curve Batch** function is described in this section. Instructions for using other Batch functions are provided in the Common Processes section.

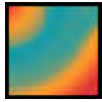


1. After selecting the Batch function tab, click **All Curve**.
2. Set the Batch Parameters (Increments, Number of Images, and Whole Screen) and **Add** features, as desired.
3. Click **Preview**. The Batch Preview window opens and the batch is prepared.
4. If the batch for movie is satisfactory, click the **Save Batch As...** button at the bottom of the Batch Preview window.

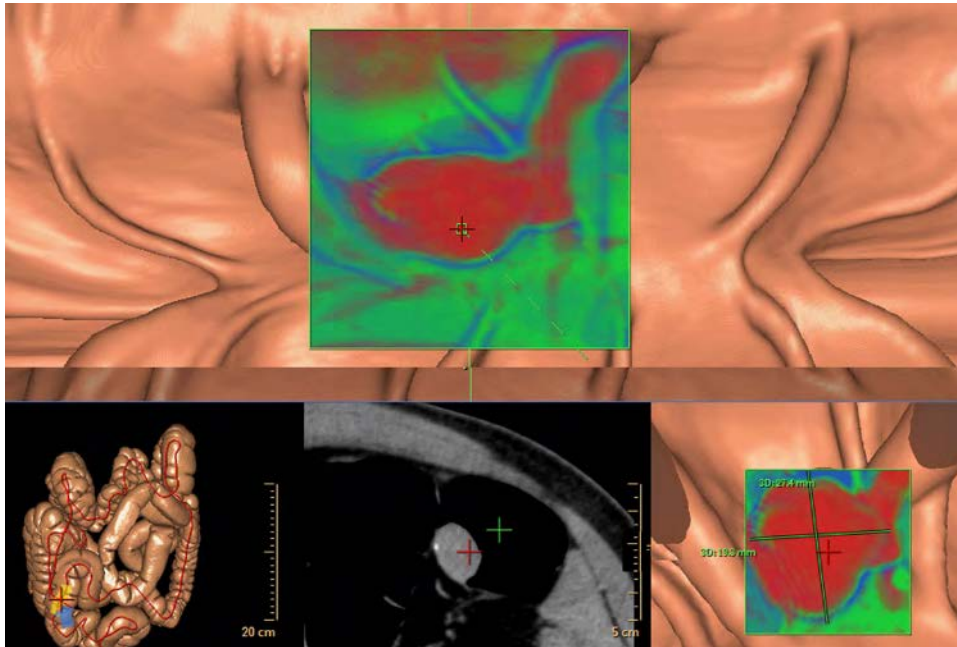


5. Name the batch Description as desired.
6. Select the **Movie** format and set the Quality. The movie is saved as a Windows Media Video (wmv) file. The file size is proportional to the selected quality (higher quality = larger file size).
7. Select the Devices destination.
8. Click **OK**. The Preparing movie window opens, showing the progress of the movie preparation.
9. Locate the newly created movie under the File tab in the Patient Directory.
10. Right-click on the movie file to Copy to CDR, View, Send to Multimedia Viewer, Export, or Delete.

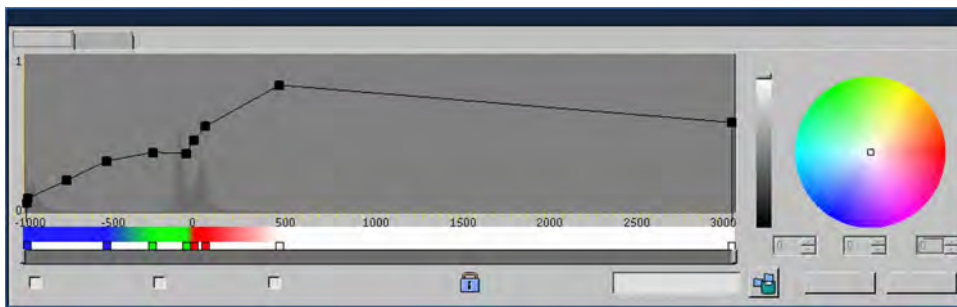
Color Map



This window is an example of a translucent color map view, which can help distinguish between polyps and stool.



In this view, an attenuation dependent color map is superimposed on the image. The color scale is determined by an opacity curve with colors (shown below).



A detailed description of Volume Rendering, including translucent color mapping and opacity can be found in the Common Processes section.

VC Properties

The VC Properties function tab allows you to set the parameters that control the way various images are shown in the viewports. You can set parameters for the Filet, Endo, Inspect, and Unfolded image types.

In the Inspect image view (which shows a longitudinal cut of the colon), the 2D cutting plane is displayed in grey-white (as an MPR plane) and can be windowed via the reference images (for example, the axial and cross-section views).

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Philips

Image Type

Use this option to select Image Type. Options include:

- Filet
- Endo
- Inspect
- Unfolded

Projection Radius

Allows the selection of Projection Radius for Filet image type.

Shape

Allows the selection of a shape for Filet image type. Options include:

- Rectangular
- Scaling

Custom Colors



Click the **Custom Colors** icon to open a window that allows the selection of colors to change the color of the 3D Volume rendered images.

Cleansing Method

NOTICE

The computer assisted detection (CAD) for polyps and the Electronic Cleansing functions are not available in the United States.

When the IntelliSpace Portal has the (optional) Apply Cleansing function, it is accessible in both the Define work stage and the Navigation work stage. See section “Electronic Cleansing” on page 437.

In the VC Properties function tab, you can specify the type of cleansing method you want to apply, **Low Density Contrast**, or (the default) **High Density Contrast**.

The most recent setting selected is remembered for the next time the Virtual Cleansing application is opened.

Setting the cleansing method is only available on the Navigation work stage.

When comparing images of the same study using the two cleansing methods, you may notice that the cleansing results differ, and the resulting surface rendered images may be different.

High Density Contrast is used to filter out high density contrast material.

If the patient preparation consists of less dense contrast, the cleansing may be optimized by using the **Low Density Contrast** cleansing method.

Switching methods updates the cleansing in the current image. However, to update the CAD results based on the new selection, the application must be relaunched.



CAUTION

Be aware that the High Density method will not be applied to studies having low density (<250 HU). A warning message appears on the bottom tool-bar to alert the user.

Navigation Workflow

Set Current Settings as Default

If the user clicks on **Set current settings as default**, the application “remembers” the following items when relaunching the application. • • • •

- Compare status
- Link Status and selected mode
- The selected layout with or without the spread mode
- The “Scroll along centerline” mode for the Navigation stage

NOTICE

If an existing layout was modified, be sure to save this layout first!

Single Image Navigation

Single Image Navigation improves the perception of navigation performance when operating the Portal in the “lossless” mode.

When Single Image Navigation is activated, while you scroll or navigate in an active viewport, non-active viewports are “frozen” (not updated). After you stop or pause the scrolling/navigation activity, all reference viewports are updated to the new position.

VC Compare

If the patient study you loaded includes two series of the patient in different orientations (Supine and Prone, for example), Compare allows you to view the two series in adjacent viewports.

In the display below, the patient’s Supine and Decubitus Left series are shown, one above the other.

In general, all the functions available for assessing one Patient Series in Virtual Colonoscopy are available in the Compare mode.

Compare Tools

To perform the Compare function, both studies for the comparison must be loaded at the same time (when the application is launched).

The Compare mode in Virtual Colonoscopy is adapted from the Compare mode available in various other Portal applications. But, instead of comparing images from the same patient series, here you compare images from separately scanned series (of a single patient).

Spread Mode



The Spread mode allows you to display the two compared series on separate display monitors (if your system is so equipped).

Link



The Link function allows you to navigate the colon centerlines simultaneously (in “parallel” views) after linking them at a common location.

Match Findings



The Match Findings function allows you to mark as “matched” the same polyps found in the two patient orientations. (You can also “unmatch”.)

Automatic Path Registration

The Automatic Path Registration function ties together the prone/supine centerlines for simultaneous navigation.

NOTICE

Automatic Path Registration is applied by default, but only after clinical validation, and after the Compare and Link buttons are pressed.



The Automatic Path Registration button appears depressed when the function is activated.

Anatomical Registration allows for manual matching via the P/S link (prone/supine) button.



Click the **Anatomical Registration** button to cancel automatic registration and link the prone and supine centerlines manually.

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