

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 Advanced Visualization Workspace configuration, this application may not be available.

Indications for Use

The CT Comprehensive Cardiac Analysis (CCA) application is intended to assist the user in viewing, processing and quantifying cardiac and coronary CTA datasets of patients with suspected or diagnosed cardiac disease including coronary artery disease, for the analysis of heart and coronary artery anatomy and cardiac function.

CT Cardiac Plaque Assessment, an option within the CT CCA application, helps physicians determine the presence, extent, and properties of coronary plaques.

Intended Users

Advanced Visualization Workspace CCA application is intended to be used by adequately trained and qualified medical professionals, including but not limited to physicians and medical technicians. The main clinicians or medical and para-medical professionals who use the Philips Advanced Visualization Workspace CCA application are listed below:

- Radiologists in the radiology department/clinic
- 3D technologists in the radiology department

Other clinicians/roles using the Philips Advanced Visualization Workspace are listed below:

- Cardiologists and cardiology technologists
- Surgeons
- Referring Physicians

Intended Patient Population

The application is intended for any patient needing a radiological diagnosis, management and follow-up for cardiac diseases with Computed Tomographic (CT) cardiac datasets.

Benefits

When used as specified in the Intended Use, under the circumstances and conditions as specified in the Indications for Use, the application assists the user with interpreting the clinical image data according to the clinical context and on par with the state of the art, thus providing diagnostic information from images and giving positive impact on patient management.

Specifically, with the resulting radiological conclusions obtained from quantitative and qualitative information of the heart and coronaries via the application and noninvasive medical imaging technique, the referring physician can:

- advise the patient on his current condition
- determine whether additional investigations are warranted
- present the patient with treatment options to prevent reoccurrence or worsening of the presenting symptoms
- If diagnosed, control the evolution of the cardiac disease by taking action in controlling risk factors with heart-healthy lifestyle changes and/or medication and/or interventional therapy.

Contraindications

None.

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.

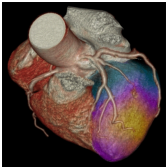
NOTICE

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 246.

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 143.
- **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 Extraction 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 180.
- **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 221.

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 Advanced Visualization Workspace 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.

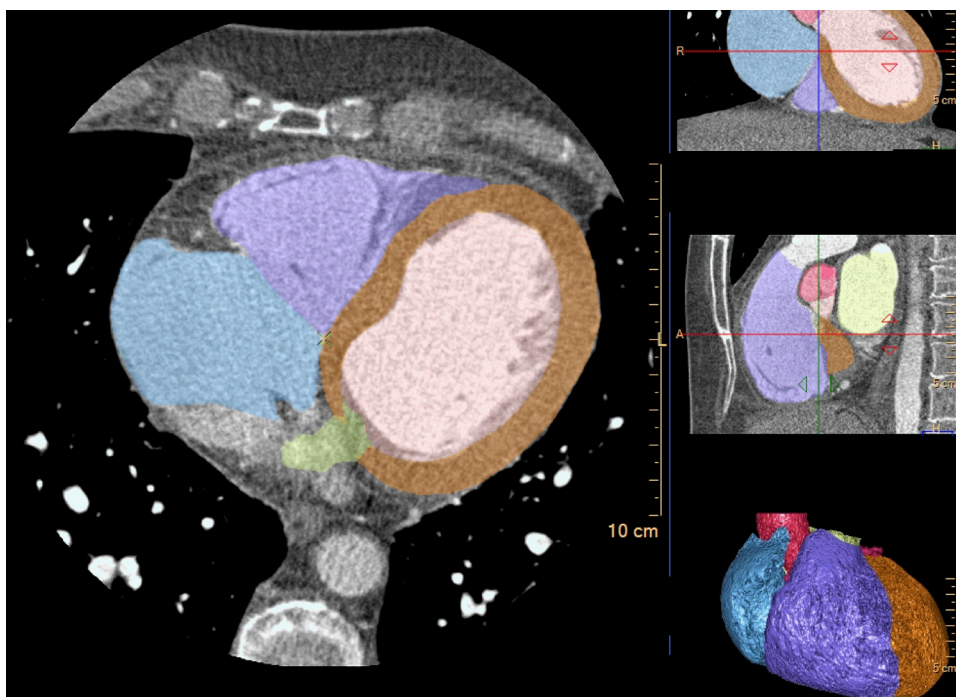


Image Types

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 147 .

Color Mapping

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

Layouts

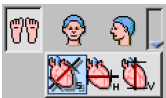
There are two layouts: 1x3 and 2x2. The layouts include:

- 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.

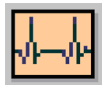
Rotation Center (checked by default)

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.

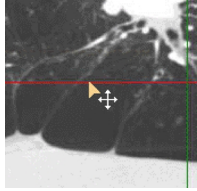
Magic Glass

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.

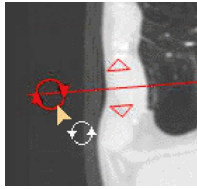
Using Crosshairs

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

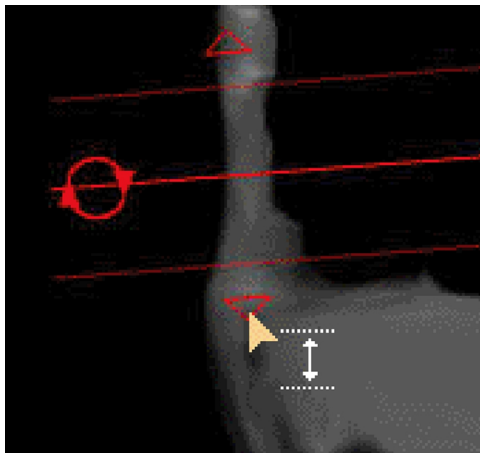
- Grab the crosshair and drag it to the correct position.



- 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.



WARNING

When using the Add Coronary tool, verify volume segmentation correctness. If necessary, correct tracing with correction tools.

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



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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. Your can return to this coronary definition after trying the re-segmentation option by closing and then reopening the application.

Configuration of Preferred Vessels Preference Setting

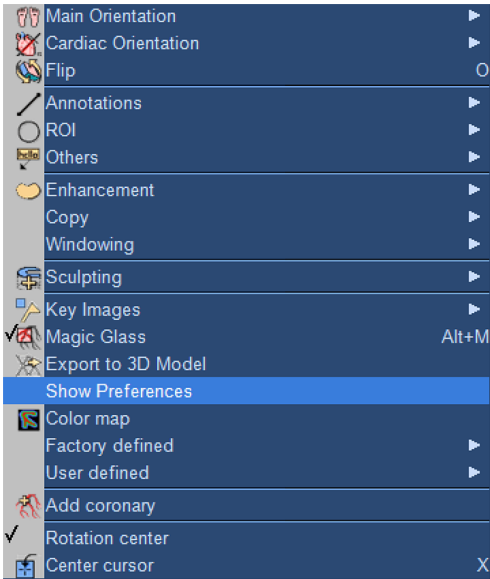
The **Configure Vessels** preference setting allows users to automatically configure extracted vessels from the vessel list.

This configuration is a one-time setting based on individual user preferences.

A list of coronary vessels is displayed. Users select the vessels to be displayed. Vessels that are not selected do not appear in the Vessel list displayed in the Coronary Extraction and Analysis stages.

To configure the display of user preferred vessels:

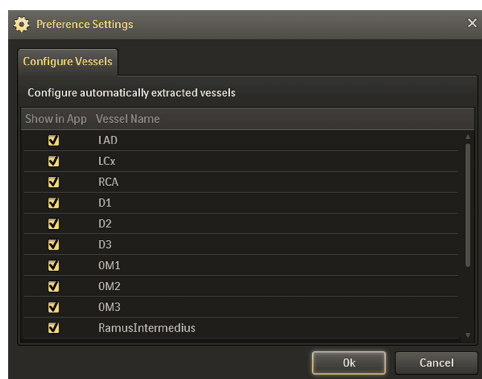
- 1. In the Coronary Segmentation stage, right click on any image viewport and select **Show Preferences** from the context menu.



The **Configure Vessels** Preference Settings window appears.

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2. Select the vessels to appear in the Vessel list by placing a checkmark next to the Vessel Name.
Deselect vessels that should not appear in the list.
3. Select **Ok**.
4. Exit the application and re-launch CCA to apply the selected changes.

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

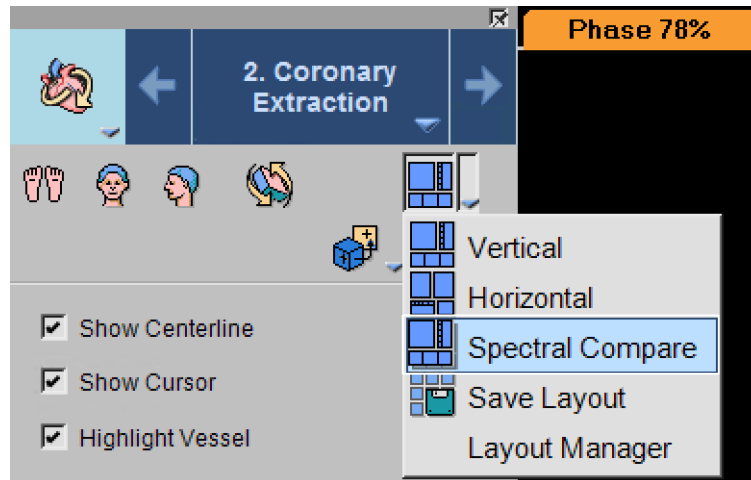
The Coronary Extraction stage has a horizontal or vertical layout that consists of:

- 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 Advanced Visualization Workspace 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 242.

**WARNING**

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

NOTICE

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

The following shortcuts are available in this application:

- Use the keyboard shortcut key : **<Shift> + <C>** to toggle centerline display on and off.
- Use the keyboard shortcut key : **<Shift> + <x>** to toggle cursor display on images on and off.

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.

Small Vessel Labeling

This option is available when using the default settings for the new centerline algorithm, **Use new coronaries algorithm** enabled in Preferences.

In addition to the main vessels RCA, LAD, PDA, LCX, the small branches of coronary arteries can be extracted and labeled optionally through the preference settings. Disable automatic labeling of small vessels using Preference settings when the small vessel labels are not required on images.

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 145.

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.

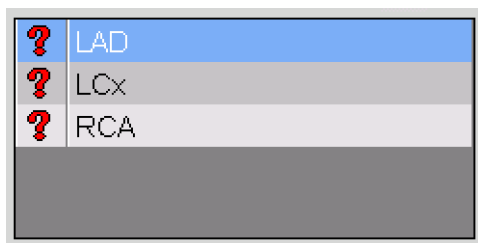
1. Find a vessel to work with by hovering the mouse over it. (Vessels show yellow centerlines.)
2. Click the desired vessel. Its centerline turns red and its name is displayed.
3. Right click on the red centerline. This opens the naming dialog again, allowing you to name or rename the vessel.

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.

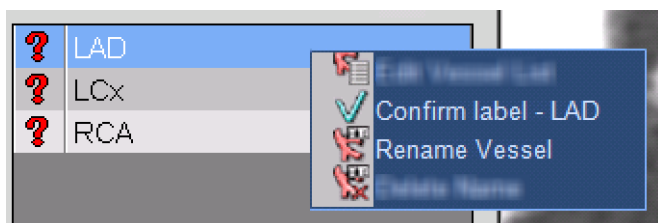
Automatic Labels

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.

- 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.

- 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.

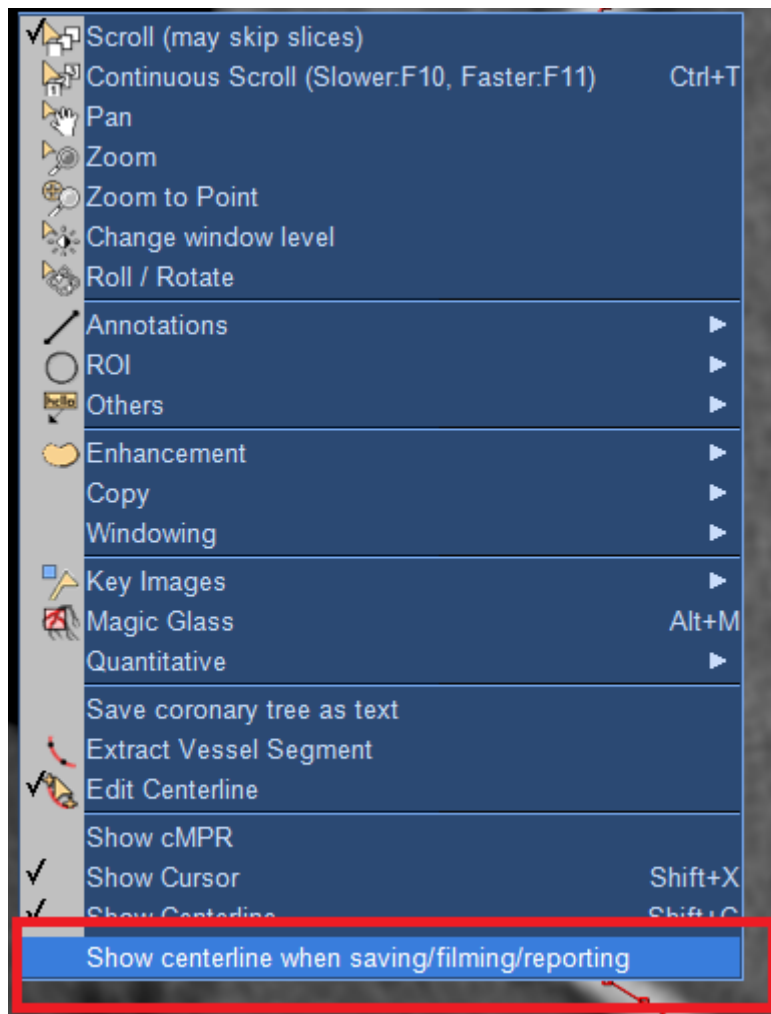
Vessel extraction and Vessel Editing tools are also provided as floating tools in different viewports in the Vessel Extraction stage.

Show Centerline When Saving/Filming/Reporting

- When users save/film/report an image with centerline displayed on the image in the application user interface, the saved image does NOT retain the centerline.
- When users uncheck the centerline in the application manually, the saved image does NOT display the centerline

The context menu includes an option, **Show centerline when saving/filming/reporting** which is disabled by default. Manually enable the check box to retain the centerlines on the exported images.

When manually enabled, the centerline is displayed on the exported images when saving, filming or reporting.



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.

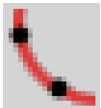
1. Click the **Connect Broken Segments** button. A network of yellow lines appears on the volumetric image showing all potential coronary segments that were identified during the auto segmentation process.

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 158.
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.

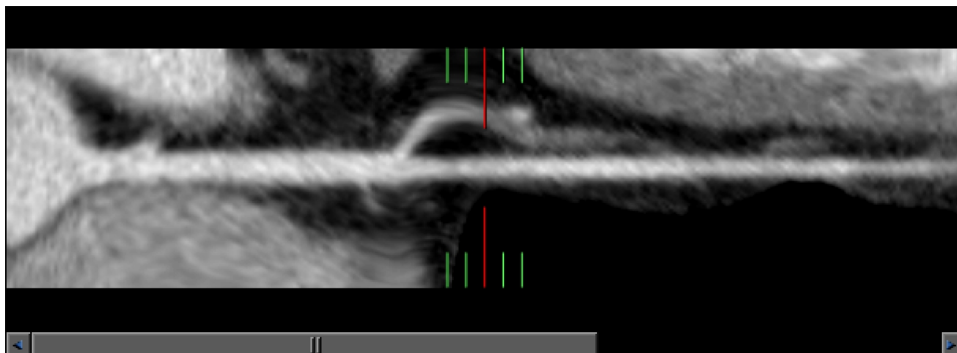
2. Click once at the start of the path to be redefined and click again at the end of the path. (Anatomically, the path direction is from the apex to the base of the heart.)
3. If the centerlines can be joined, a unified red centerline appears. The Curved planar reformed views of the centerline also appear.
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.

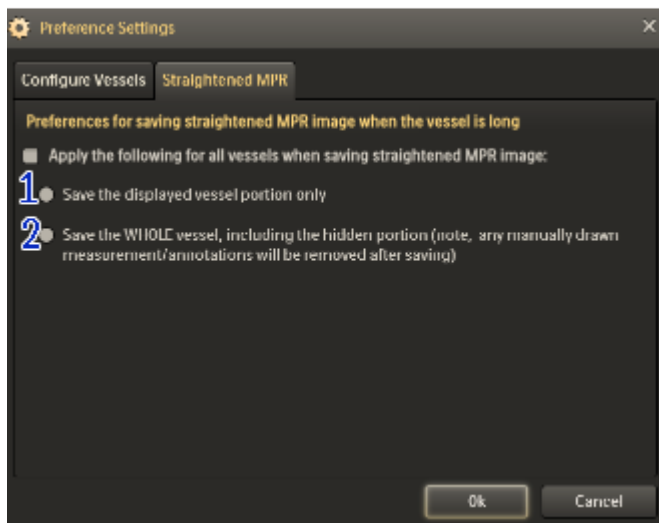
View Straightened Coronary Vessels

Use the horizontal slide bar to view all of the straightened vessel.



Preferences for Saving Straightened MPR Images When Saving SMPR Images

To save or export SMPR images, use the preference settings to export only the displayed portion of images in the viewport (1) or the whole SMPR image, including the hidden portion (2).



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

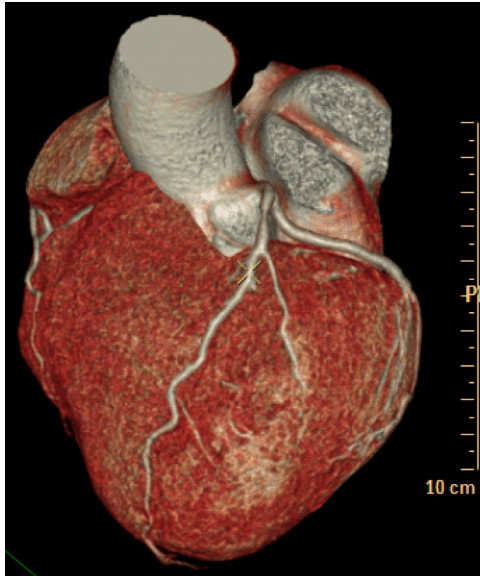
A viewport control in the volume viewport allows you to select specific cardiac viewing modes.

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.

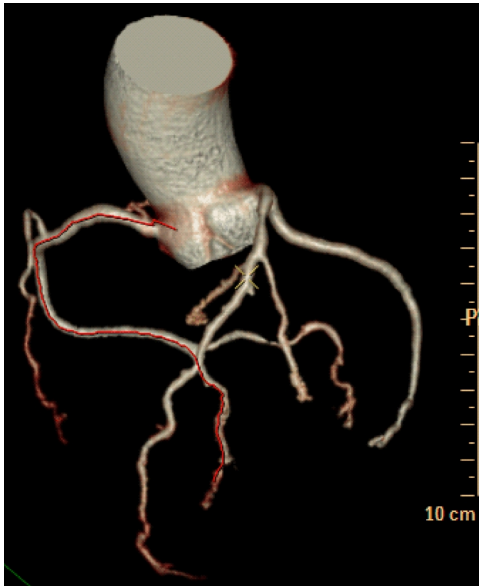
**Heart 2 Volume View**

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.



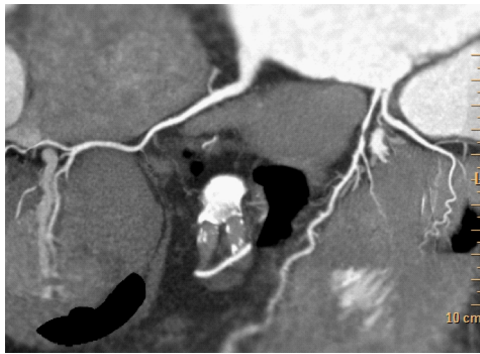
Outline Volume View

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.



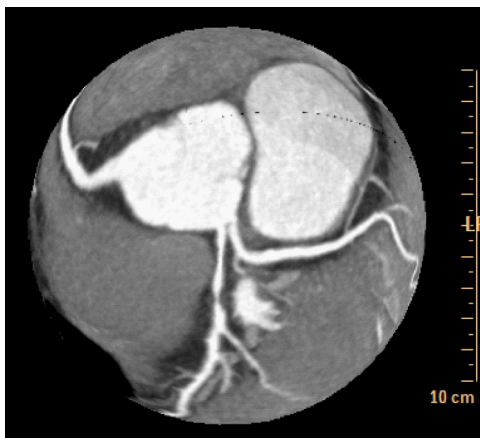
Globe 3D Map Volume View

This view shows the heart with blood in the cavities removed. Only viewable as MIP.



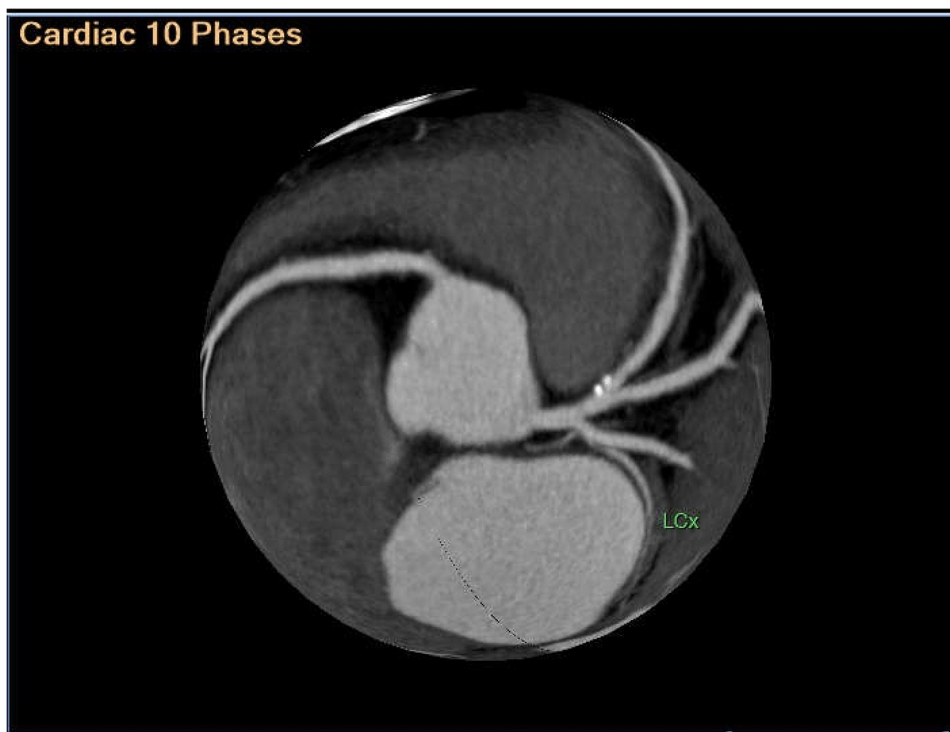
Globe Sphere Volume View

This view shows a 3D map mapped onto a sphere. It is only viewable as MIP.



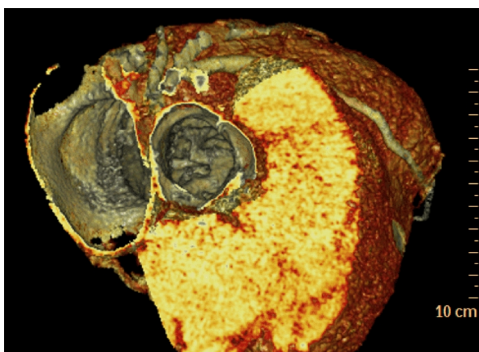
The Globe Sphere, 3D map views can be displayed in viewports aligned to axial image orientation for coronaries through a Preference settings option.

To make this change, go to the **Viewing** preference settings and activate the CCA option **Enable 3D, Globe View Display aligned to axial orientation**.



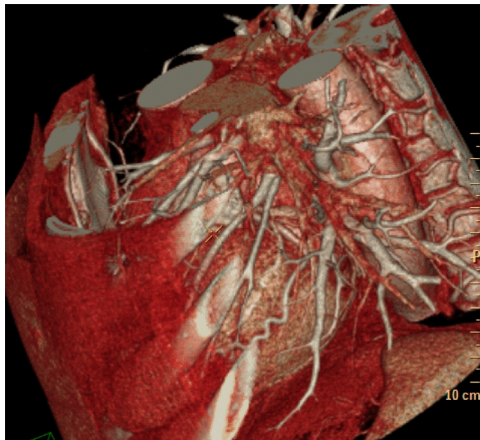
Aortic Volume View

This view of the aortic valve is adaptive to different phases.



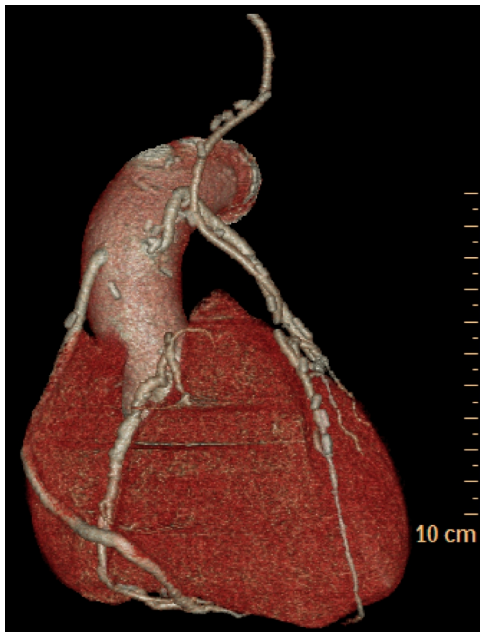
All Volume View

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.



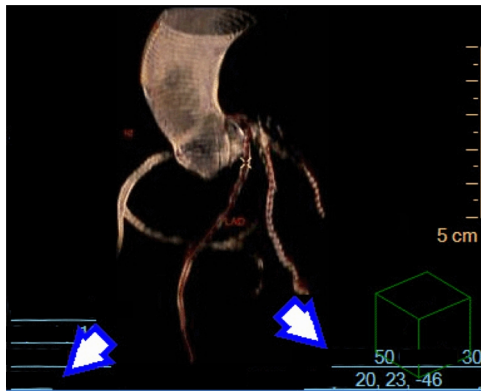
TAVI Volume View

Use the viewing mode to optimize the view angle for the TAVI procedure. 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.

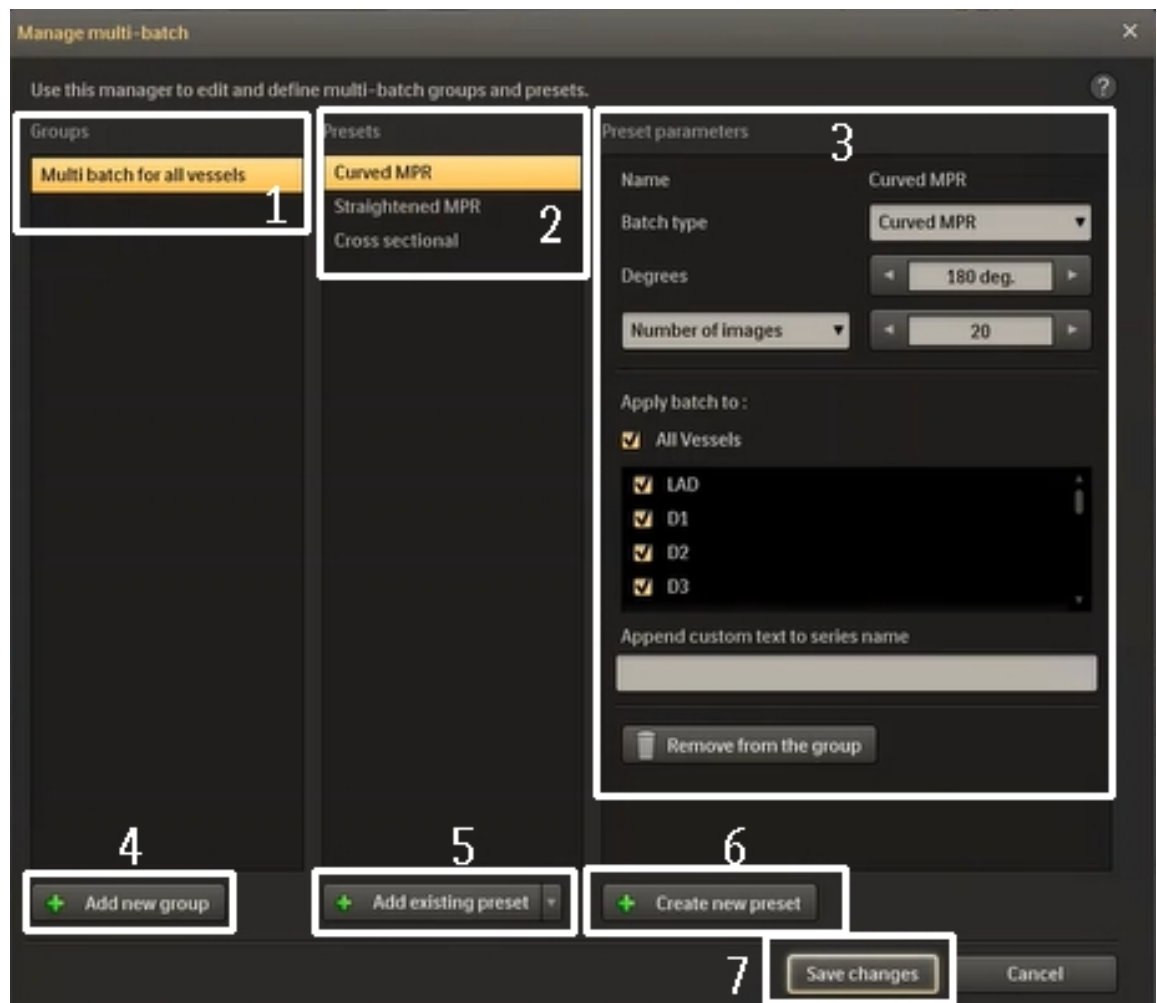


Multi-Batch Creation

Multi-Batch Creation accelerates batch creation of CT coronaries by creating batches in the background.

The creation of Multi--Batch is a one time setup per user. Once groups are created, batches are easily generated in the background..

Manage Multi-batch Description



In the Manage Multi-batch window, users create presets for batches.

By default, there is one Group preset available, **Multi batch for all vessels** (1). This group contains three Presets (2). Presets can be placed in different groups.

- Curved MPR
- Straightened MPR
- Cross sectional

Options are available to edit Groups, Presets and Preset Parameters

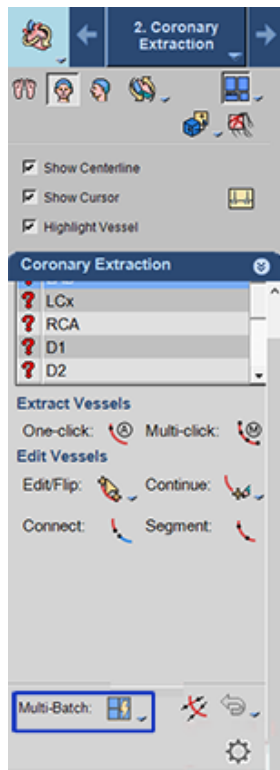
The following Preset parameters are available and can be modified (3).

- Preset Name
- Batch type (Curved MPR, Straightened MPR scroll, straighten MPR Rotation batches)
- Degrees (the rotational angle)
- Number of images
- Apply batch to: options are **All Vessels** or manually selected vessels.

- Append custom text to series name
- Remove from the group

Defining Batch Parameters, Batch Preset and Groups using Manage Multi-Batch Features

1. From the Coronary Extraction Stage, select the **Multi-Batch** option.



2. Select **Manage Groups**.
The Manage multi-batch window opens.
3. Select the **+Add new group button** (4).
4. Input a group name.
Once created, there are no Presets in the Presets list.
5. Select the **+Add existing preset** (5) button.
It is possible to select **+Create new preset** (6).
6. Choose an existing preset from the list.
7. Modify Preset Parameters (3) as required and select **Save changes** (7).
Once saved, the new group appears in the Multi-Batch Groups list.

Multi-Batch Generation

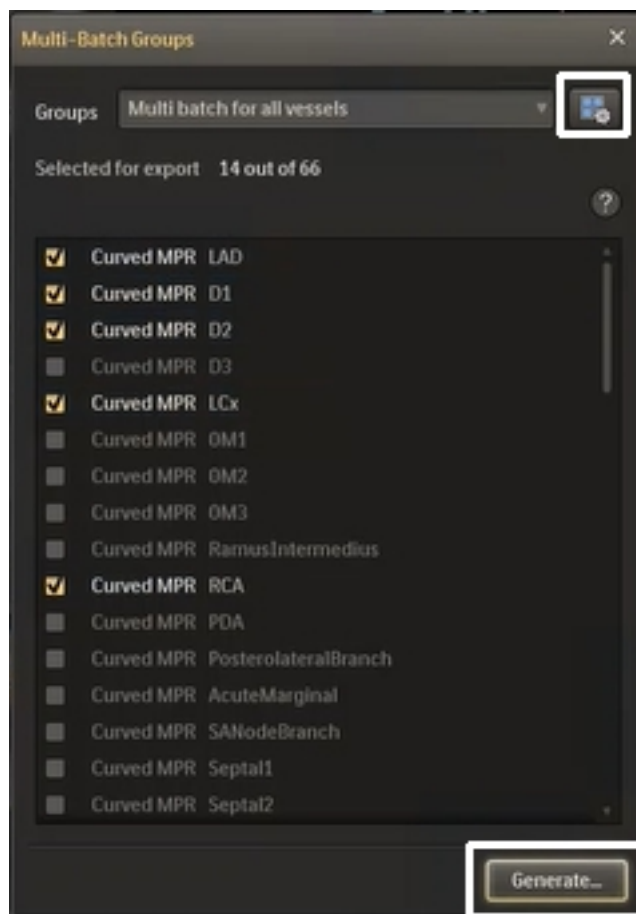
NOTICE

A batch cannot be created for vessels that have not been reviewed.
Only confirmed vessels can be selected for export.

NOTICE

In Preferences, if the option to automatically disable vessel confirmation workflow is used, the Multi-Batch option is not available.

1. Since batch creation is allowed for only those vessels that are confirmed by users, review vessels before starting batch creation.
2. From the Coronary Extraction Stage, select the **Multi-Batch** option.
The Multi Batch Groups window opens. This shows the vessel list for which a batch will be created. The batch that appears is based on the preset that was created.
The multi-batch batches selection criteria allows defining batches through individual, multiple or all coronary vessels from the coronary centerline list.
3. The Multi Batch Groups window opens.



This shows the vessel list for which a batch will be created. The batch that appears is based on the preset that was created.

4. To select a different Group, click on the **Groups** dropdown. To edit a group, use the icon to the right of the dropdown.
5. Select the **Generate** button.
6. Select a destination for the batches.
7. Select **OK**.

Automatic batches are created in the background. A message appears at the bottom, right corner. Once processing is completed, the batches appear in the destination location and can be viewed in the Patient Directory.

Configuration of Straightened MPR Preference Settings

The **Straightened MPR** preference setting allows users to automatically apply preferences for saving straightened MPR images when the vessel is long.

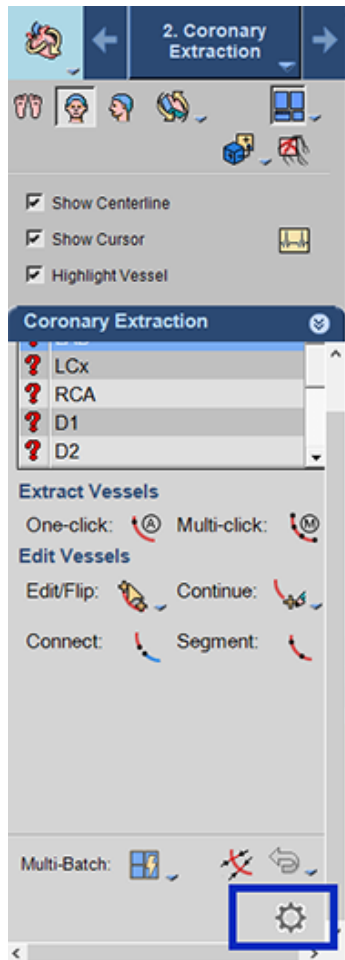
This configuration is a one-time setting based on individual user preferences.

The following option is available: **Apply the following for all vessels when saving straightened MPR images:**

- Save the displayed vessel portion only
- Save the WHOLE vessel, including the hidden portion (any manually drawn measurement/ annotations will be removed after saving).

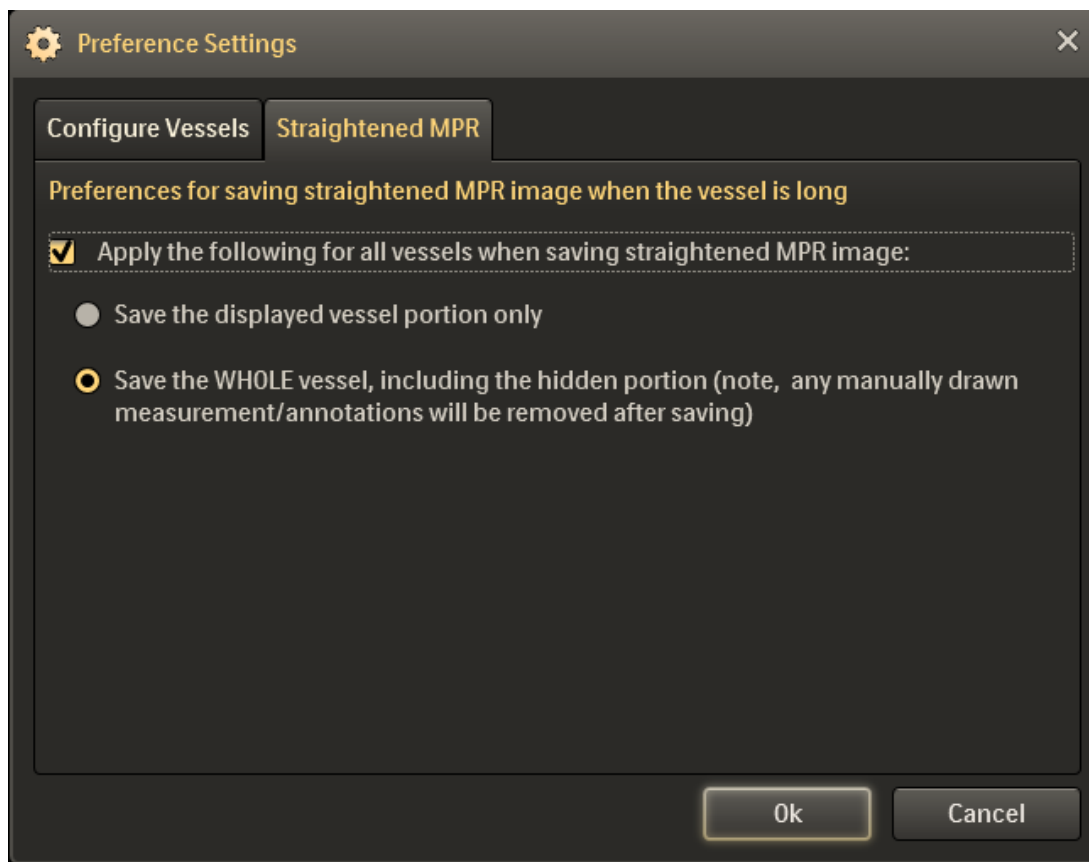
To configure preferences:

1. In the Coronary Extraction stage, click on the **Show Preferences** icon (or right click on any image viewport and select **Show Preferences** from the context menu).



The **Preference Settings** window appears.

2. Select the **Straightened MPR** tab.



3. Select the relevant settings.
4. Select **Ok**.
5. Exit the application and re-launch CCA to apply the selected changes.

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.

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 Advanced Visualization Workspace 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 145.

There are two available Layouts, Horizontal and Vertical. See section “Segmentation Opening Window” on page 144.

The Show Centerline and Show Cursor functions are the same as in the Coronary Extraction stage. See section “Coronary Extraction Viewing Tools” on page 156.

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 154.

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

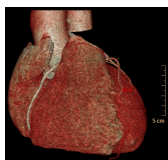


The Curved MPR image shows the selected artery with centerline. In the Contours mode, lumen lines are also displayed by default. (They can be turned off from the viewing tools.) In the Calipers mode, only the centerline is shown. The yellow X mark on the centerline corresponds to the red X mark in all 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.



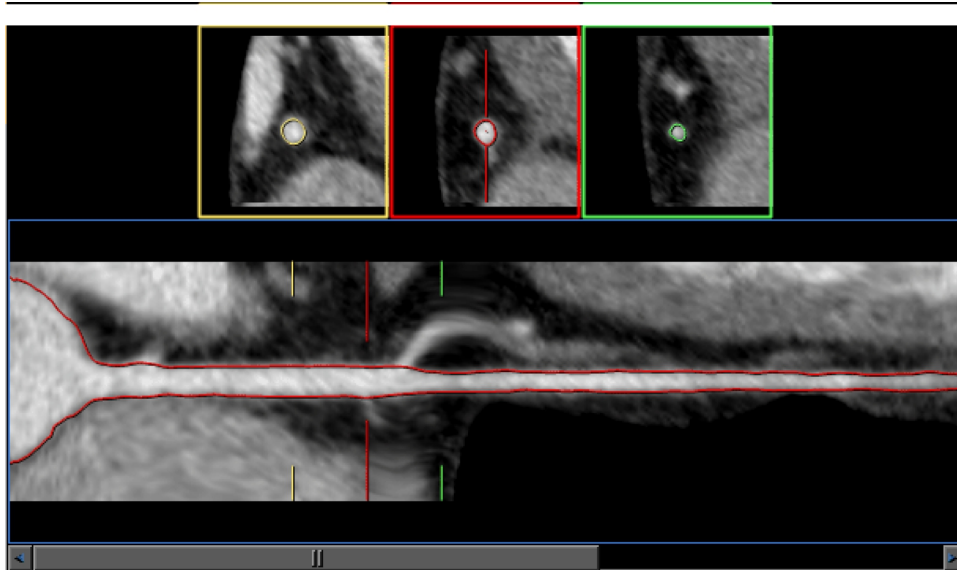
Straightened MPR Image with Cross-sections



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



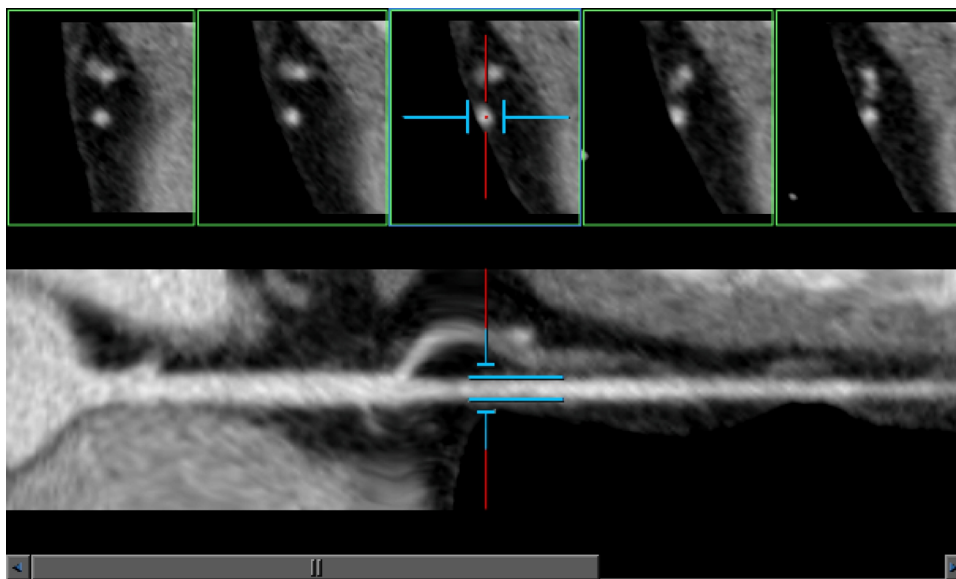
In the Contours mode, movable colored reference lines are provided in the sMPR image:

- 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.

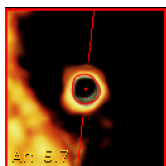
As you move the reference lines, the cross-section images are updated.

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



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

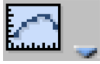
The IVUS display is based on a fixed HU color mapping protocol and may require adjustments per case.



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.

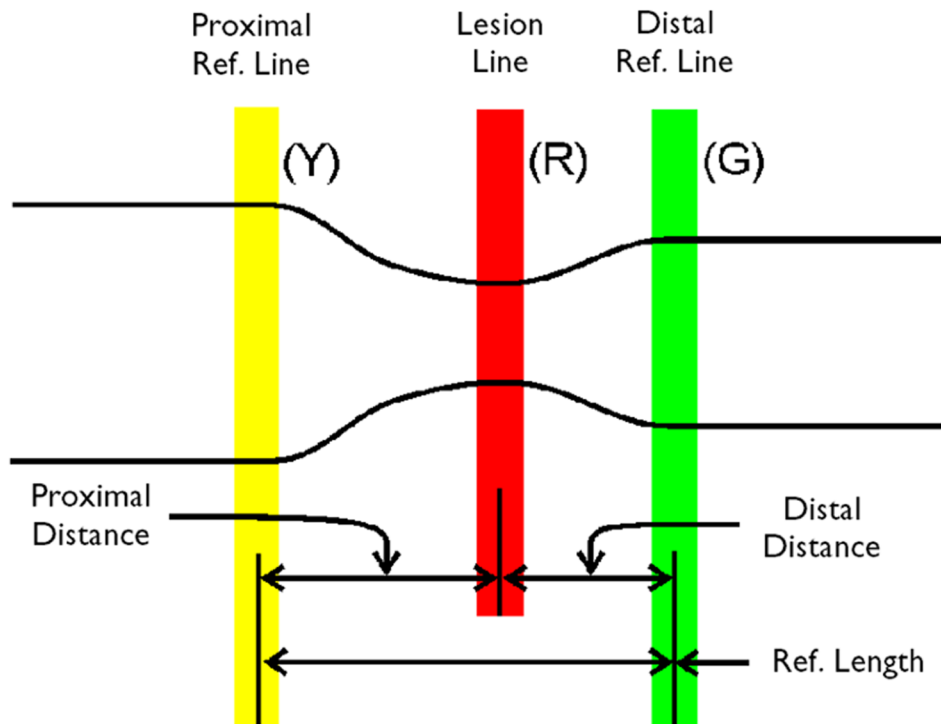
Use Contours Measurement Method

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.



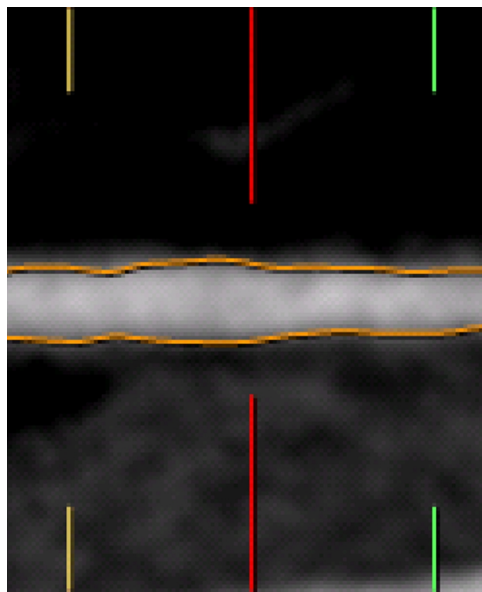
See section “Step 1: Set Reference Lines” on page 188.

Step 1: Set Reference Lines

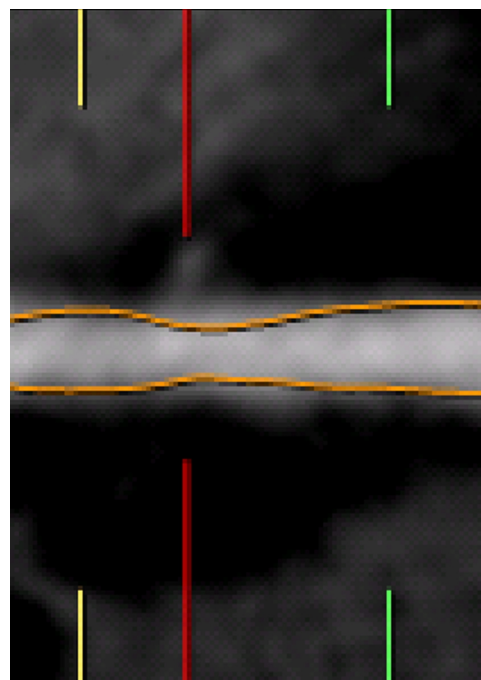
After the vessel’s lumen contours are verified and corrected if necessary, you will position the stenosis Reference lines:

- 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 190.

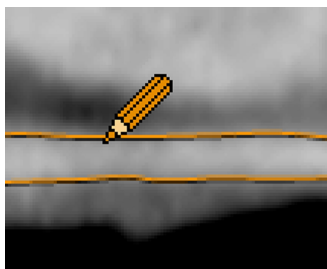
Step 2: Edit Lumen Contours on sMPR Image



WARNING

Verify the automatic extraction of the lumen contours. If necessary, correct the contours using the tools provided in this application.

Lumen Editing Cursor

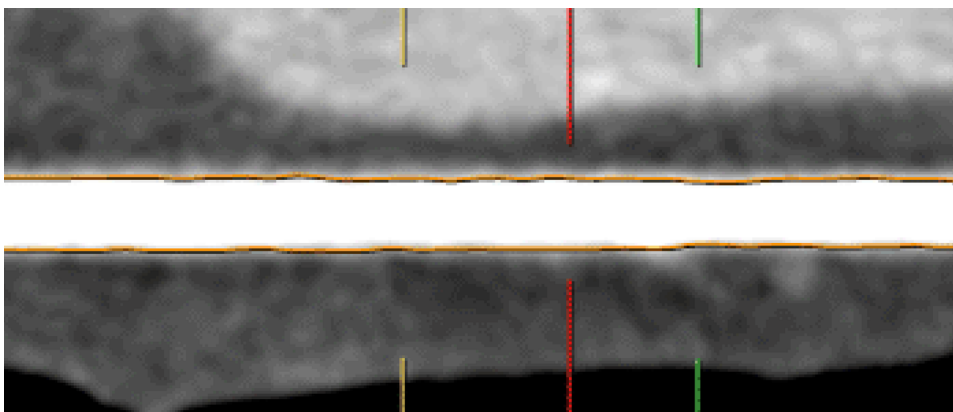


When the **Edit Contour** mode is activated, hovering over the lumen contour changes the cursor to an orange pencil.

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 190.

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**

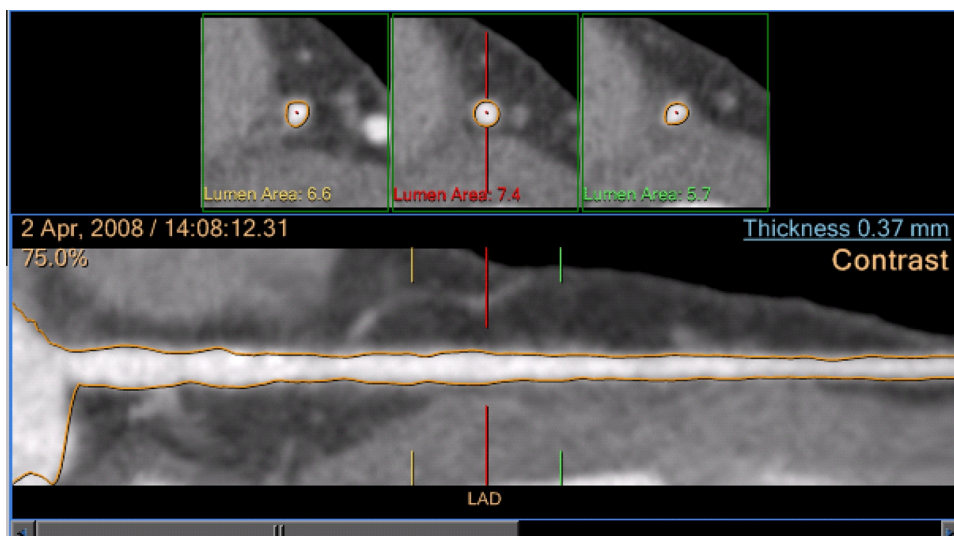
Verify the automatic extraction of the lumen contours and, if needed, correct them using the tools provided in this application.

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 | $2 \times \sqrt{\text{Area}/\pi}$. |
| Minimum Diameter | The % Stenosis of the minimum diameter, calculated in relation to the reference effective diameter at the lesion location. |
| 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.

NOTICE

The SCCT guidelines for the interpretation and reporting of coronary CT angiography recommend to report stenosis within broad stenosis ranges, as listed in the guidelines.

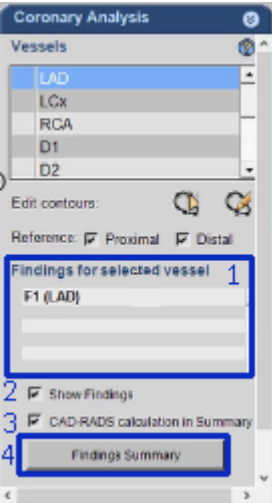
Leipsic J, Abbara S, Achenbach S, Cury R, Earls JP, Mancini GJ, et al. SCCT guidelines for the interpretation and reporting of coronary CT angiography: A report of the Society of Cardiovascular Computed Tomography Guidelines Committee. J Cardiovasc Comput Tomogr. 2014;8:342–58.

Create Profile Graph

The Line tool in Common Tools allows you to generate a Hounsfield unit profile graph across an artery diameter.

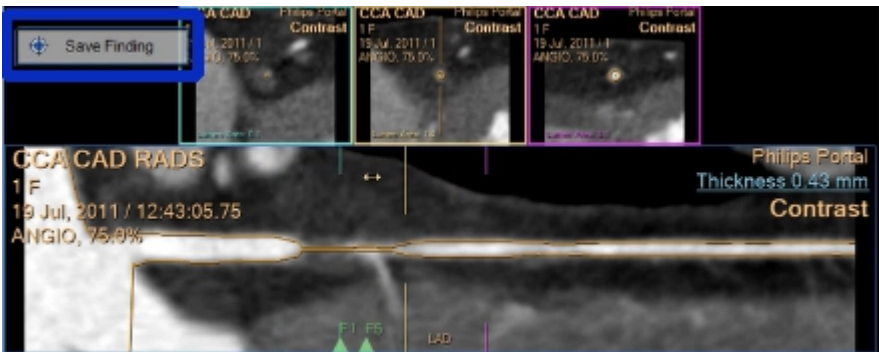
Stenosis Findings Management and CAD-RADS

The Coronary Analysis stage includes an option to capture Findings for stenosis assessment.

| Description | |
|---|---|
|  | <p>Findings for selected vessel list (1): Captured Findings are displayed in this list.</p> <p>Show Findings (2): Enable to on to display Findings.</p> <p>CAD RADS calculation in Summary (3): Remove the check mark to view the findings summary review without a CAD-RADS template.</p> <p>Findings Summary (4): Click on this button to open the findings summary dashboard, overview of all marked findings.</p> |

Workflow

- For each selected vessel, mark the stenosis on the in sMPR image using the **Save Finding** option.



- 2. Mark all findings in different vessels.

The color of the finding changes in the image and the finding is added to the **Findings for selected vessel** list.

When you mark a finding, the lesion and reference points are saved (Lesion, Proximal and distal images) and the findings are placed in the Findings list for the selected vessel.

Once a finding is added, the stenosis grading is added to the Measurements table under **Stenosis severity grading based on Min D for this measurement (1)**.

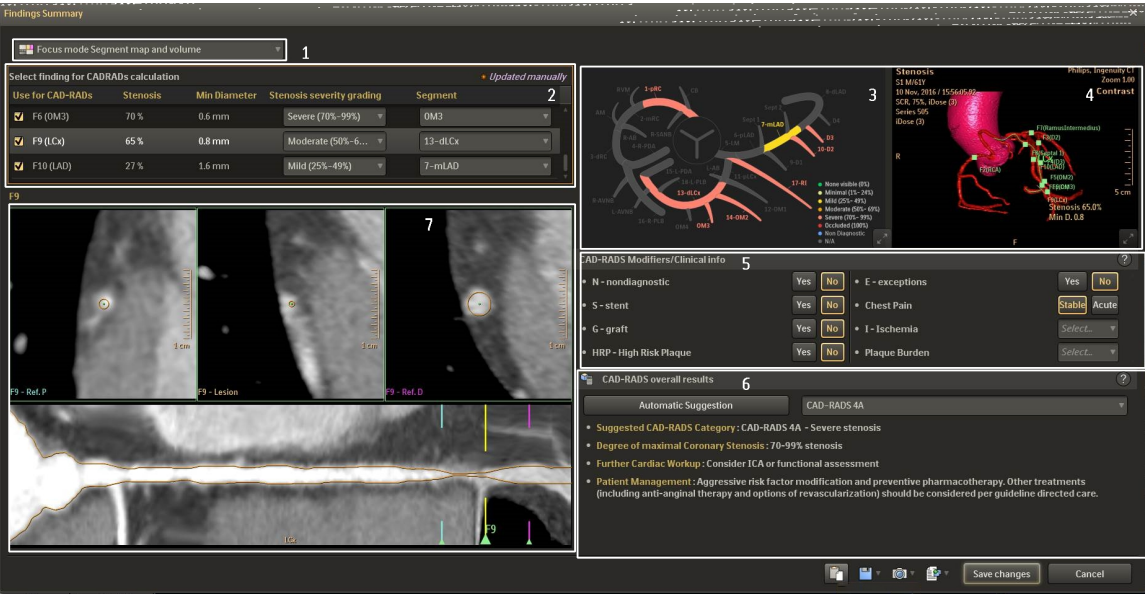
| | F1 (RCA) measurements | | |
|--------------------|--|----------|------------|
| | Reference | Lesion | Difference |
| Area | 10.2 mm² | 11.0 mm² | 108 % |
| Current Diam. | 3.6 mm | 3.8 mm | 106 % |
| Reference Diam. | 3.6 mm | 3.7 mm | 103 % |
| Minimum Diam. | | 3.8 mm | 106 % |
| Centricity | | 0.00 | |
| Reference Distance | 9.6 mm | | |
| Radius | N/A | 62.7 mm | N/A |
| | Stenosis severity grading based on Min D. for this measurement 1 | | |
| Stenosis grading | * Mild (25% - 49%) 2 | | |
| Updated manually | | | |

The quantitative stenosis measurement of lesion and % Stenosis, based on minimum diameter, is automatically calculated and displayed in the measurement table with stenosis grading.

- 3. To modify the stenosis grading to a user defined option, in the measurement table, double-click the actual **Stenosis grading** (2). Select an option from the dropdown list and select **OK**.
When the stenosis grading is updated, the text appears italicized, an asterisk appears and the color frame changes. Use the **Clear changes** option in the dropdown to revert to the original stenosis grading.
- 4. Click on the **Findings Summary** button in the Control Area to open the Findings Summary dashboard.

Findings Summary and CAD-RADS Calculation

The Findings Summary dashboard opens when the **Findings Summary** button is selected. This screen provides an overview of all findings marked in all of the coronary vessels.



| Item # | Description |
|--------|---|
| 1. | Layout selection |
| 2. | Findings table |
| 3. | Segment Map |
| 4. | Volume Image |
| 5. | CAD-RADS Modifiers |
| 6 | CAD results |
| 7 | sMPR Image with cross-sectional for Proximal, Stenosis and Distal |

The Findings Summary dashboard sections are detailed below based on the numbering in the above image.

Layout Selection (1)

Various layouts are provided for an overview of all the findings and a focused review of individual findings. These layouts allow the display of CMPR, SMPR ,Cross sectional, Segment Diagram and Coronary Volume tree views in Layouts.

There are six display layouts available. The screen is automatically updated each time a layout is selected. These layouts are selected from the dropdown.

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Overview mode

Three options that show all coronary vessels with all findings.

- Overview mode Segment map and volume
- Overview mode Segment map and cMPR
- Overview mode cMPR and volume

Focus mode

Three options that show a specific finding and the display of additional finding details.

- Focus mode Segment map and volume
- Focus mode Segment map and cMPR
- Focus mode cMPR and volume

Findings Table (2)

The measurement table in the Dashboard displays the following details:

| 1 Use for calculation | 2 Stenosis | 3 Min Diameter | 4 Stenosis severity grading | 5 Segment |
|--|---------------|-------------------|--------------------------------|--------------|
| <input checked="" type="checkbox"/> F1 (LAD) | 58% | 3.7 mm | Severe (70%-99%) ▼ | m-LAD 7 |
| <input checked="" type="checkbox"/> F2 (LAD) | 23% | 4.2 mm | Minimal (1%-24%) ▼ | d-LAD 8 |
| <input checked="" type="checkbox"/> F5 (RCA) | — | — | *Minimal (1%-24%) ▼ | p-RCA 2 |
| <input checked="" type="checkbox"/> F4 (RCA) | 36% | 2.1 mm | Mild (25%-49%) ▼ | d-RCA 3 |

| | Column | Description |
|---|---------------------|---|
| 1 | Use for calculation | Option to include/exclude a Finding from CAD-RADS calculation. To exclude a Finding from CAD-RADS calculation, uncheck the Use for CAD-RDS check box. Findings on vessels with a reference diameter less than 1.5 mm are automatically disabled. These findings can be manually enabled but message appears., |
| 2 | Stenosis | Percentage % Stenosis of the findings based on minimum Diameter. |
| 3 | Min Diameter | The Minimum Diameter of the stenosis findings. |

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| | Column | Description |
|---|---------------------------|---|
| 4 | Stenosis severity grading | <p>Automatically calculated Stenosis severity grading as per CAD-RADS.</p> <p>A dropdown menu in this column allows you to manually modify the Stenosis severity grading to update the CAD-RADS Score.</p> <ul style="list-style-type: none"> • None visible (0%) • Minimal (1% - 24%) • Mild (25% - 49%) • Moderate (50% - 69%) • Severe (70% - 99%) • Occluded (100%) • Non Diagnostic • N/A <p>Manually assigned severity grades are marked with asterisks and are shown in italics.</p> |
| 5 | Segment | <p>The coronary vessel Segment name for all the stenosis Findings.</p> <p>A dropdown menu in this column allows the user to modify the Stenosis Segment</p> |

Use the **Clear Changes** option in the dropdown menu to reset the grading to the automatic suggestions.

NOTICE

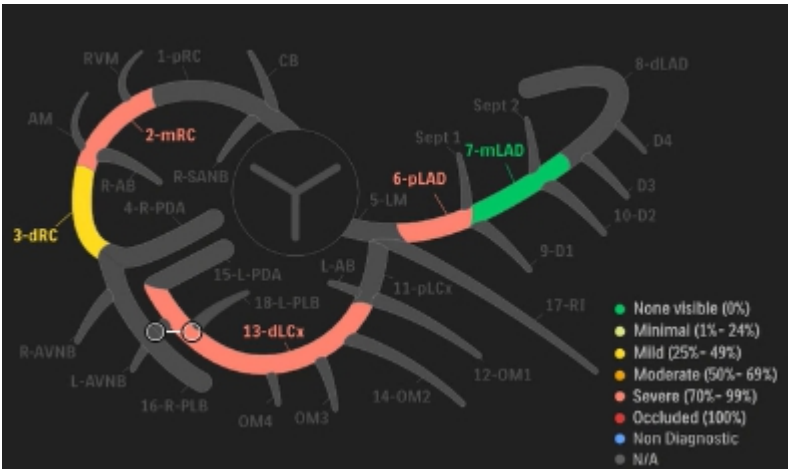
Findings on vessels with a reference diameter less than 1.5 mm are automatically excluded from CAD-RADS scoring as per CAD-RADS guidelines. (Use for CAD-RADS selection is disabled by default). When hovering over such findings in the summary table, the following tool tip message is displayed: **It is recommended not to include findings with reference diameter below 1.5mm.**

Segment Map (3)

The Schematic Segment diagram is integrated in the Results dashboard for the evaluation of different findings in Coronary Segments.

The coronary vessel segments are updated in relevant colors based on the severity of the stenosis Findings.

If you manually change the stenosis severity Grade or the Stenosis segment shown in the measurement table, the color of the relevant coronary segment in the Segment diagram is updated automatically.



None visible (0%)

1

Minimal (1%- 24%)

2

Mild (25%- 49%)

3

Moderate (50%- 69%)

4

Severe (70%- 99%)

5

Occluded (100%)

6

Non Diagnostic

7

N/A

8

1.

None visible (0%)
2.

Minimal (1% - 24%)
3.

Mild (25% - 49%)
4.

Moderate (50% - 69%)
5.

Severe (70% - 99%)
6.

Occluded (100%)
7.

Non Diagnostic
8.

N/A

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CAD-RADS Modifiers/Clinical Info (5)

Users can modify the information provided according to patient status.

CAD-RADS Modifiers/Clinical info

N - nondiagnostic

Yes

No

S - stent

Yes

No

G - graft

Yes

No

HRP - High Risk Plaque

Yes

No

E - exceptions

Yes

No

Chest Pain

Stable

Acute

I - Ischemia

I+

Plaque Burden

P3

CAD-RAD modifiers are:

- N–Non diagnostic
- S–Stent
- G–Graft
- HRP–High Risk Plaque
- E–Exceptions
- Chest Pain–Acute or Stable

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- I-Ischemia (I-, I+ or I+/-)
- Plaque Burden (P1, P2, P3, P4)

When finished reviewing and updating, select **Automatic Suggestion**. This opens the Automatic Suggestion window.

The CAD-RAD Overall Results (6)

Review the automatic suggestions of CAD-RADS.

The automatic suggestion Dialog displays:

Suggested CAD-RADS Category 1
CAD-RADS 4A /P3 /HRP /I+ - Severe stenosis

Degree of maximal Coronary Stenosis 2
70-99% stenosis

Further Cardiac Workup 3
Consider ICA or functional assessment

Patient Management 4
Aggressive risk factor modification and preventive pharmacotherapy. Other treatments (including anti-anginal therapy and options of revascularization) should be considered per guideline directed care.

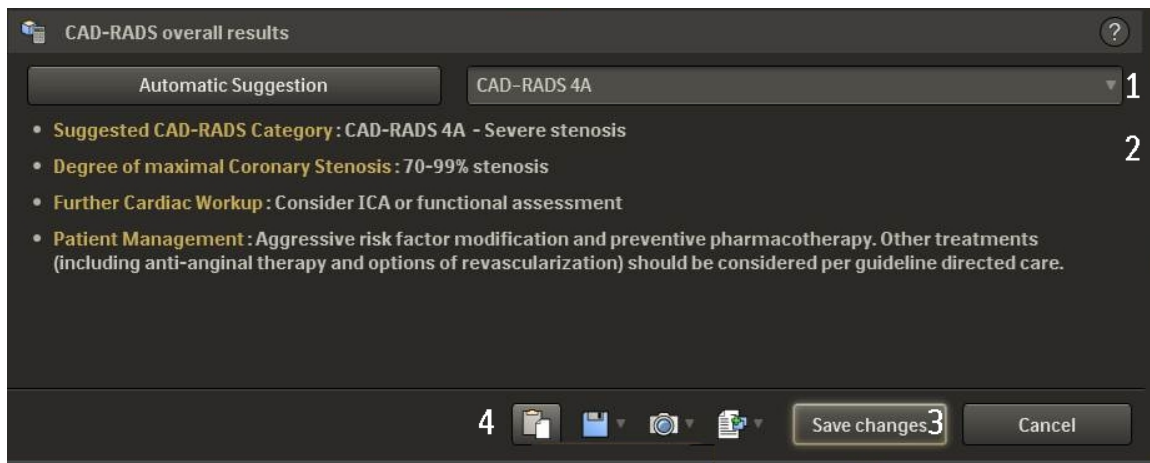
Rationale/Free text 5

The CAD-RADS management suggestion is based on approved Findings and clinical chest pain category selected(acute or stable). Make sure all the above inputs are correct before approving the suggestion.

6 Approve Cancel

1. **Suggested CAD-RADS Category**
2. **Degree of maximal Coronary Stenosis**
3. **Further Cardiac Workup**
4. **Patient Management suggestions**
5. **Rationale/Free text:** Add free text when required.
6. Select **Approve** when finished with review.

This opens the CAD-RADS Overall Results, displaying the approved results.



Modify the overall CAD-RADS automatic results by manually selecting the appropriate grade from the dropdown (1).

The CAD-RADS suggestions are automatically updated according to the selection performed (2).

Select **Save changes** (3) when finished reviewing. The dashboard closes.

Additional Options

Additional options are available via the displayed icons (4) and keyboard shortcuts.

- **Copy to clipboard:**
 - The Automatic Suggestion can be copied to the clipboard via **<Ctl> <c>** and pasted via **<Ctl> <v>**.
 - Copy individual images by clicking on the desired image, via **<Ctl> <c>** and pasted via **<Ctl> <v>**.
 - Copy all the images displayed together by clicking on the image boundary in viewport and use **<Ctl> <c>** and pasted via **<Ctl> <v>**
- **Additional information:** Information on CAD guidelines can be viewed by clicking ?.
- **Export options:**
 - **Save Results as Image Series:** Saves all images individually to the Patient Directory.
 - **Save Screen Snapshot as....:** Sends all snapshots to report as a series or snapshot.
 - **Send to report:** Send to report as series or snapshots.
 - **Send to Film:** Send to film as series or snapshots.

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.

| | | |
|--|------------|--|
| $\frac{\left(\frac{D_{prox}}{d1}\right) + \left(\frac{D_{dist}}{d2}\right)}{\left(\frac{1}{d1} + \frac{1}{d2}\right)} = \frac{(D_{dist} \times d1) + (D_{prox} \times d2)}{(d1 + d2)}$ | 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.

| | | |
|--|------------|--|
| $\frac{\left(\frac{A_{prox}}{d1}\right) + \left(\frac{A_{dist}}{d2}\right)}{\left(\frac{1}{d1} + \frac{1}{d2}\right)} = \frac{(A_{dist} \times d1) + (A_{prox} \times d2)}{(d1 + d2)}$ | 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):

| | | |
|---|------------|----------------------------|
| $\frac{D_{ref} - D_{diff}}{D_{ref}} \times 100 = \% \text{ Difference}$ | 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):

| | | |
|--|------------------------------------|--|
| $\frac{\text{Effective Diameter}_{ref} - \text{Minimum Diameter}_{lesion}}{\text{Effective Diameter}_{ref}}$ | 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:

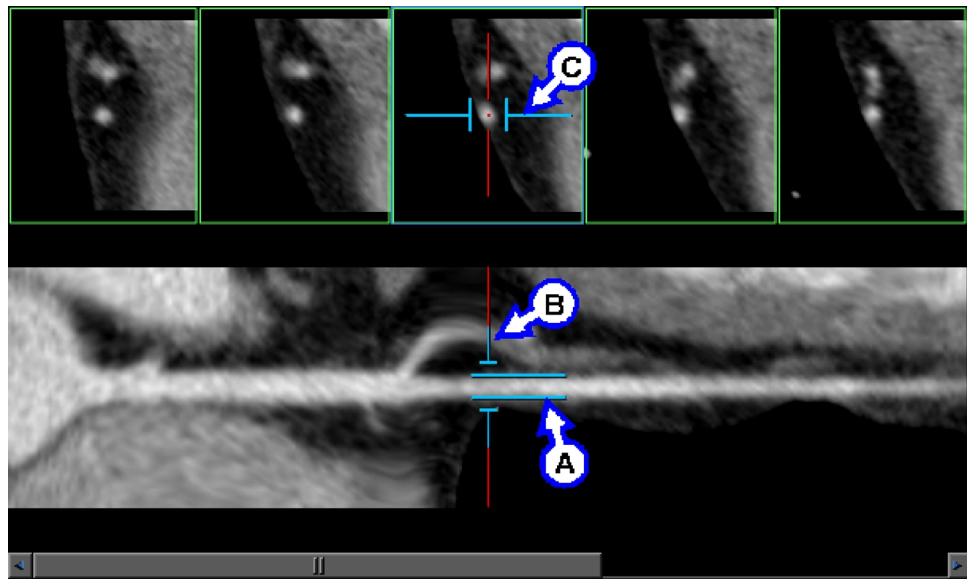
- the percent stenosis, which is derived from the Reference and Stenosis diameter measurements; and
- an estimation of the percent stenosis, which is a refined value of the stenosis, derived from the cross section dimension. (The percent stenosis is important when measuring an eccentric stenosis.)

See also section “Use Contours Measurement Method” on page 187.

Use Calipers Function

Begin this procedure after you have examined the study and identified a stenosis of interest.

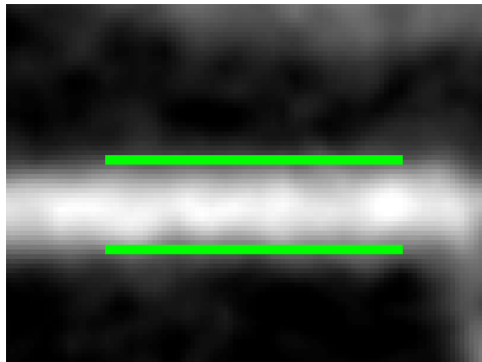
1. In the Coronary Analysis function tab, select Calipers from the drop down menu. The straightened MPR display becomes configured as shown below. The three caliper tools are positioned in their starting, default locations.



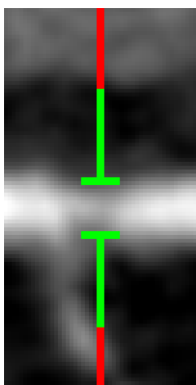
2. Point to the Reference caliper (A in the diagram). The caliper turns green to show it is selected.
3. Drag the Reference caliper to a part of the artery that has a “normal” external diameter.



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.



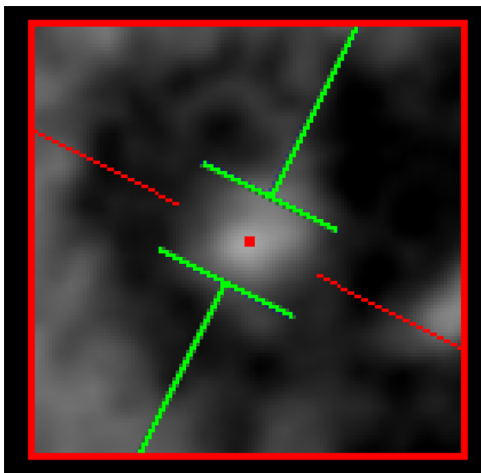
5. Next, point to the Stenosis caliper (B on the diagram). The caliper turns green to show it is selected.
6. Drag the Stenosis caliper to the region of stenosis, as shown below.



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.

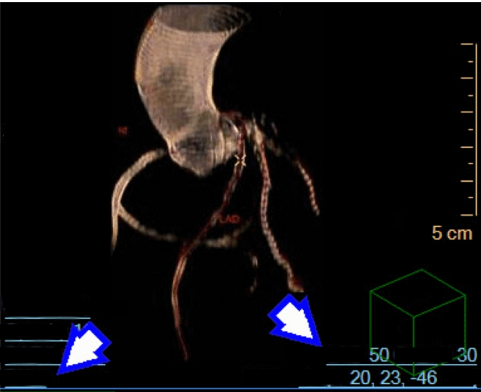
TAVI Volume View

Use the viewing mode to optimize the view angle for the TAVI procedure. The control sets the image angles at LAO 50, Cranial 30 (an angle which presents a plane almost perpendicular to the annulus plane).

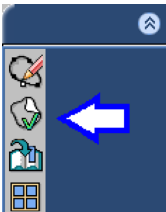
NOTICE

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.



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.

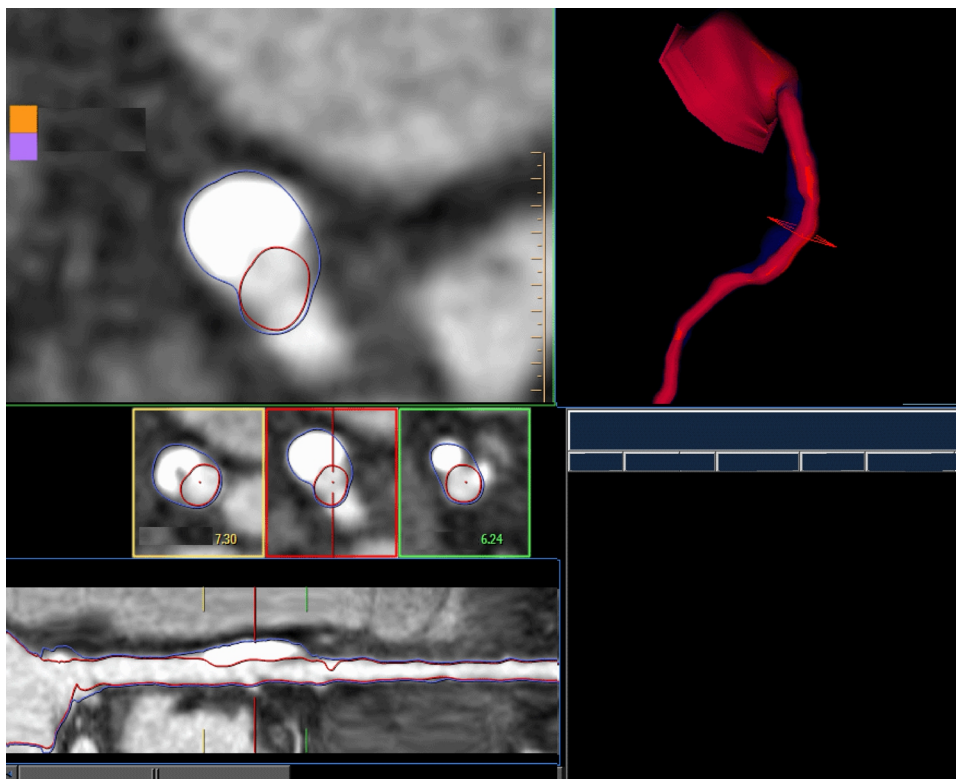
When the Coronary Analysis stage opens, the lumen and vessel contours are displayed on the cross-sectional and sMPR images. Some cross-sectional calculations are displayed on the cross-sectional images.

**WARNING**

Verify correctness of extracted lumen and vessel contour. Correct using editing tools, if required.

**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

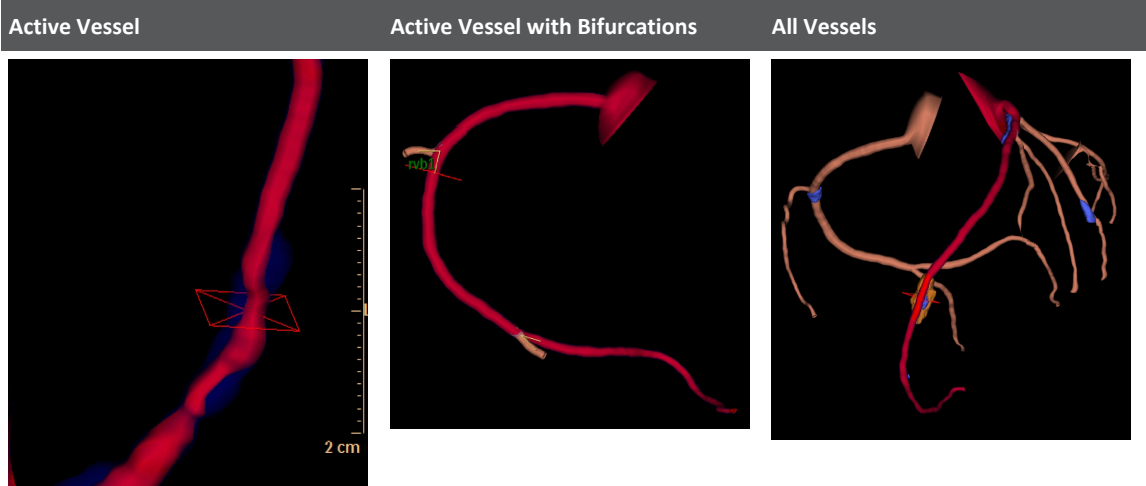
Three layouts are available: horizontal, horizontal "CS" and vertical. The layouts contain the following viewports:

- 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).

Indications for Use

The CCA Plaque Analysis option helps physicians determine the presence, extent, and properties of coronary plaques.

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.

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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.



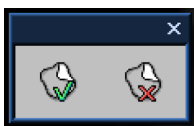
4. Click on the plaque location on the cross-sectional or sMPR images. To mark a finding you must click outside the lumen contour. It is recommended to click in the middle of the finding.



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.

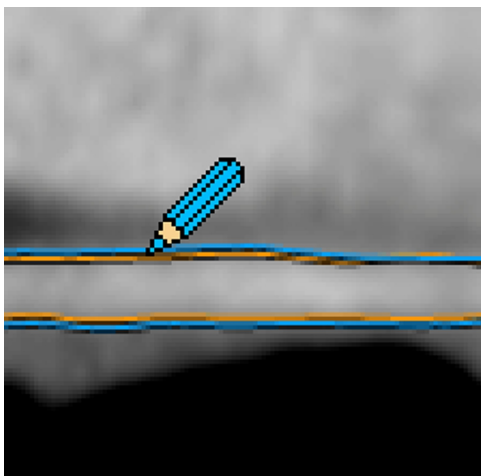
**WARNING**

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.

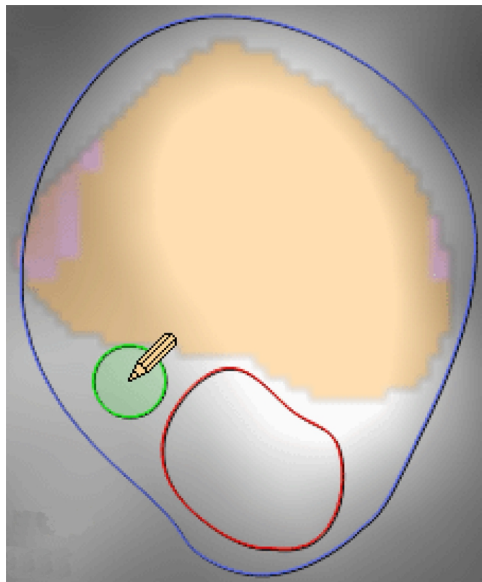


To add to the segmentation, use the brush tool on the cross-sectional image. The size of the brush (and the “eraser” tool, described below) can be changed from the “Size” box. (You can also decrease/increase the size of the brush and eraser with the “[” and “]” buttons on the keyboard)

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

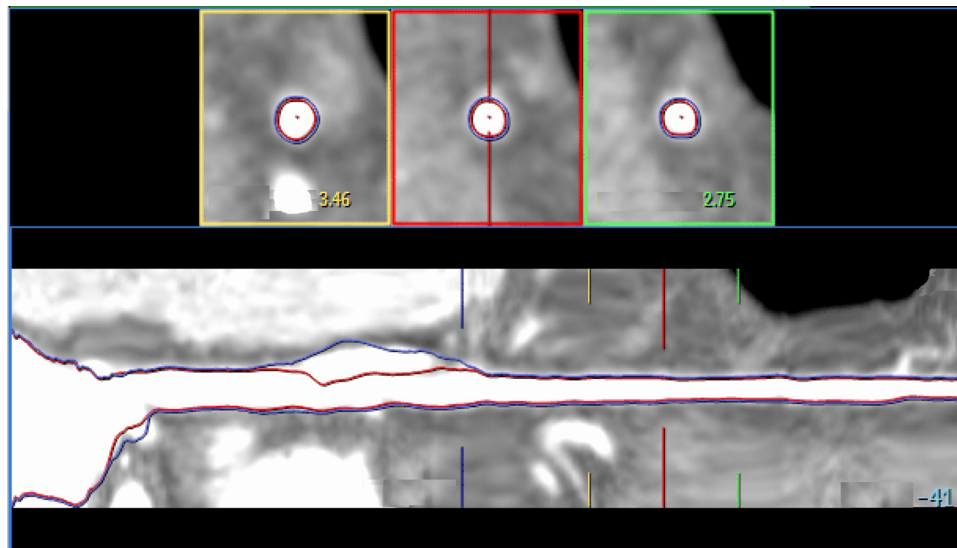
For vessels which do not appear in the standard vessels names list, the hierarchy is built by the naming order in the list. For example, if 2 vessels have a common part, the first vessel you name will be the parent and the second vessel will be the child.

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 180.

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

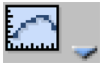
Show Lumen and Vessel Lines

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



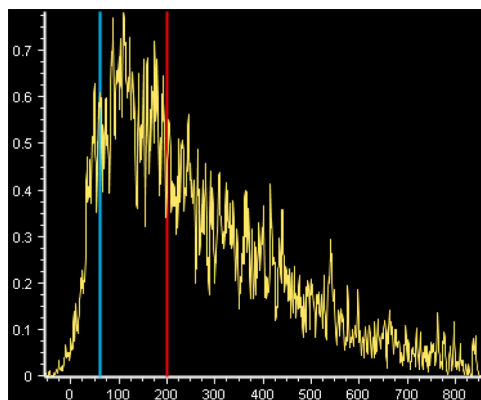
Activate this button to display one of five tables of vessel and plaque data (Vessel table, Finding table, Lesion cross-section table, Lesion versus reference table, and All vessels table). In the All Vessels table, if you mark the same finding on several vessels which have a common part, which means 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 in 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 in 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 |
| 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 |
|------------------------|---|

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| Measurement Definitions | |
|--------------------------------------|--|
| 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 | Wall Area / Vessel Area |
| Finding Burden | Finding Area / Vessel Area |
| 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 | — |

Measurement Definitions

| | |
|--------------------------|---|
| 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:

| | | |
|------------------------|------------------------|---|
| 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.

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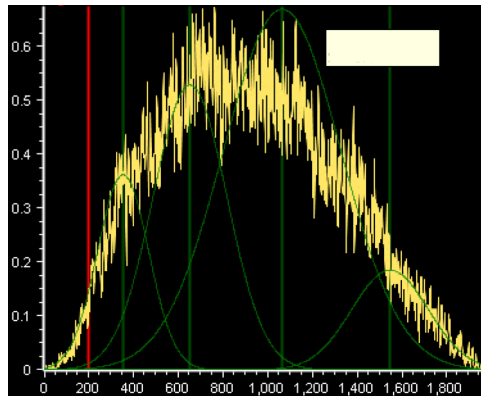
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In the Gaussian method there are voxels which have a certain probability to belong to each of the regions. The color of these voxels is a weighted linear combination of the colors between orange and purple. This causes the borders between the different 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).

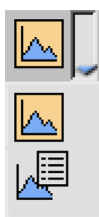
Set Content Calculation Parameters



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.

Finding Content Settings

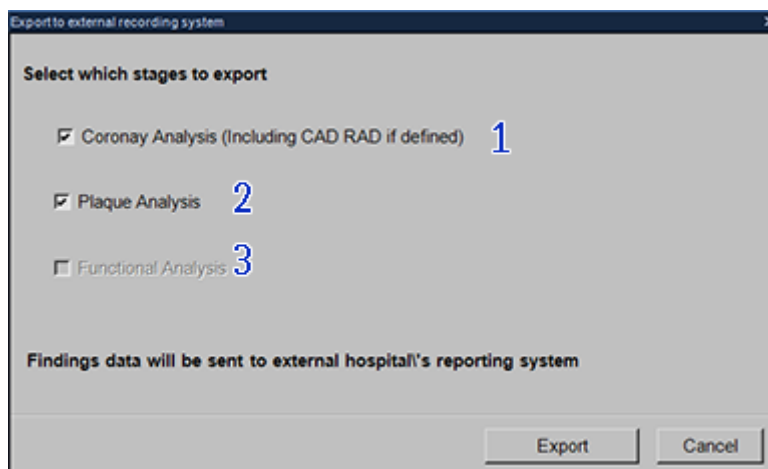
| Setting | Description |
|----------------------------|---|
| Gaussian method | This is the default method. |
| Threshold Method | — |
| High Attenuation Threshold | Default High threshold is 200 HU. You can use the combo-box or drag the red vertical line to set the High threshold from 1 HU to 1000 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). |

Exporting CCA Results in a Structured Discrete Format to External Systems

The CCA application allows exporting results in a structured format to external reporting systems.

The CCA report dropdown menu displays the option **Send to external Report** to send results to external reporting systems.

The **Export to external recording system** window allows the selection of stages for export.



- Coronary Analysis (including CAD-RAD if defined) (1)
- Plaque analysis (2)
- Functional Analysis (3)

The check boxes for the above options are enabled by default when reports are prepared by the user.

If a report is not created by the user for any of the stages, then that stage option is grayed out and reports will not be generated.

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 Advanced Visualization Workspace 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 180.

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

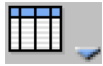
To obtain accurate Functional results, the heart must be correctly segmented.

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 226.
- Show Atrial Table (only available in Segmentation method).
- Show Atrial Table / BSA (only available in Segmentation method). See section “BSA Calculation” on page 226.

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

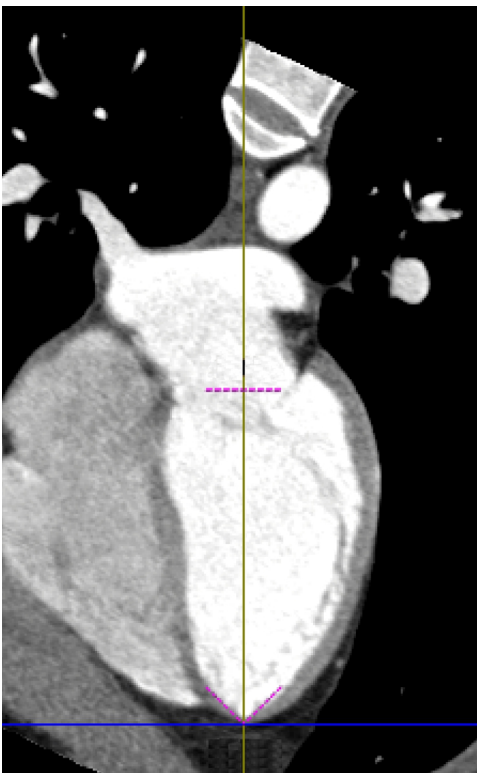
For all loaded phases, examine the position of the base and apex planes, and correct them if needed. (The long axis maintains the same position and orientation for all phases.)

**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.

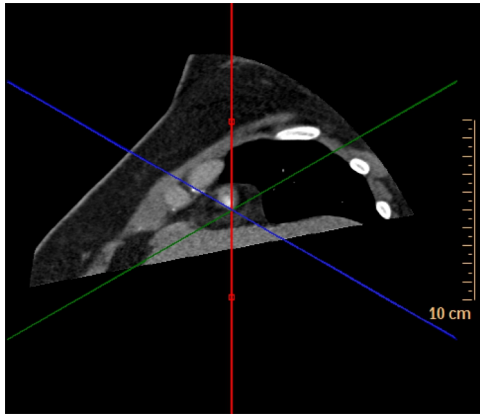


Correct the apex setting by dragging the Apex (V-shaped dashed line) to the correct position. If necessary, correct the Mitral valve plane by dragging Base (straight dashed line) to the correct position.

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

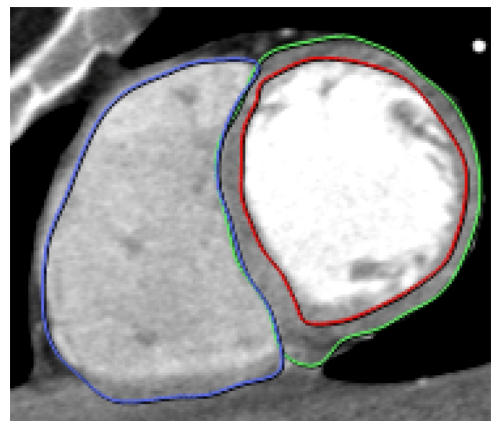
Correcting contours will only change results when using the Simpson method.

This function allows you to correct the chamber wall contours.

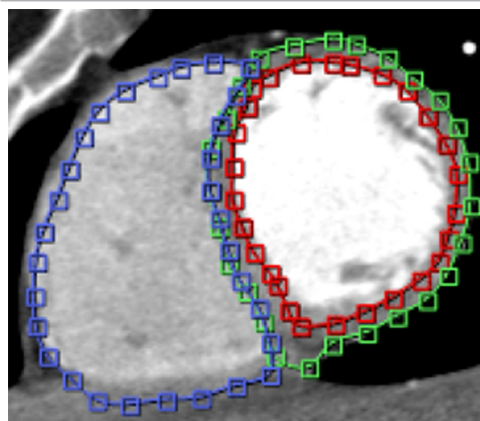
To begin, select **Correct Contours**. The view changes to 3x3 layout with inner and outer myocardial contours, and Right Ventricle contours.

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



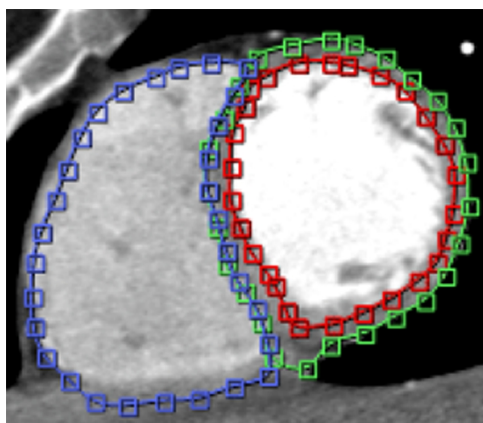
Double click any viewport to enlarge it to full screen.
Double click again to revert.



Edit Contour



Click the Edit Contours button to enable all contours for editing. With the mouse, drag the control points to the correct locations.



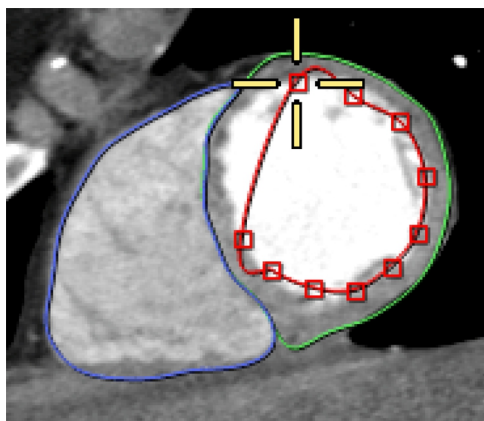
Delete and Draw Contour



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) |

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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 | $(LV \text{ StrokeVolume} - RV \text{ StrokeVolume}) / \max(LV \text{ StrokeVolume}, RV \text{ StrokeVolume})$ (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 | $(ES \text{ atrial volume}) - (ED \text{ atrial volume})$ |
| Passive emptying volume | $(ES \text{ atrial volume}) - (\text{diastasis atrial volume})$ |
| Active stroke volume | $(\text{diastasis atrial volume}) - (ED \text{ atrial volume})$ |
| Total emptying fraction | $[(ES \text{ atrial volume}) - (ED \text{ atrial volume})] / [(ED \text{ atrial volume}) * 100]$ |
| Active ejection fraction | $[(\text{diastasis atrial volume}) - (ED \text{ atrial volume})] / [(\text{diastasis atrial volume}) * 100]$ |
| Passive emptying fraction | $[(ES \text{ atrial volume}) - (\text{diastasis atrial volume})] / [(ES \text{ atrial volume}) * 100]$ |

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)

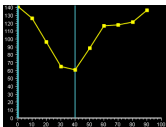
RA Volume (Segmentation only)

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

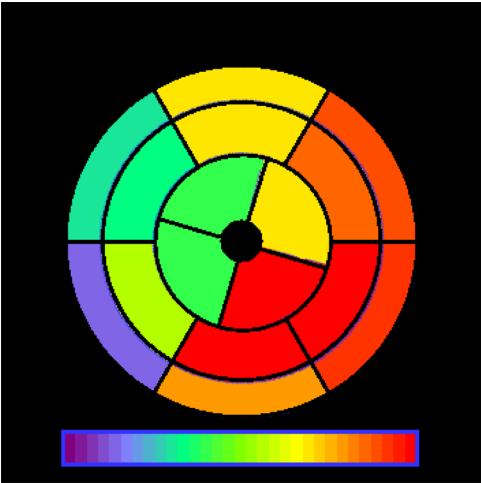
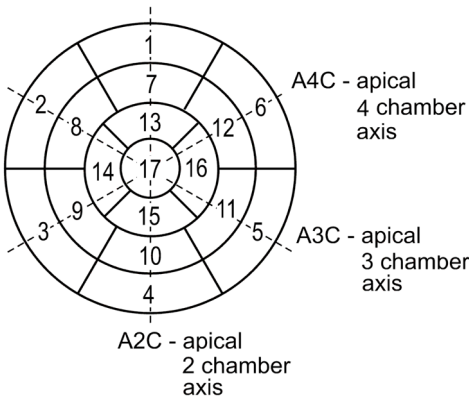
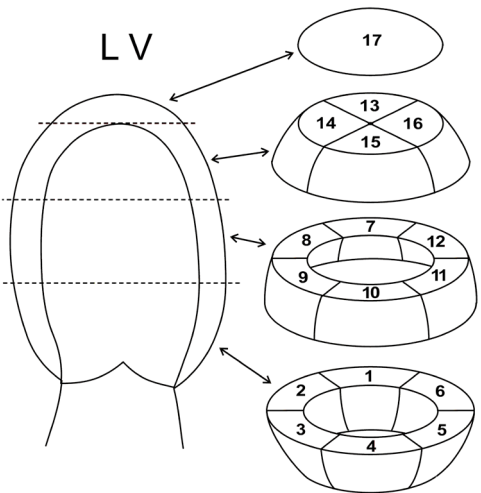


The blue vertical lines identify the ED and ES phases. The graph displays the change over time of the left ventricle (LV) volume (in ml). The horizontal scale uses the cardiac phase (%) as the reference time unit. As blood is ejected from the LV, the volume decreases to its minimum, which is the ES volume. 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.



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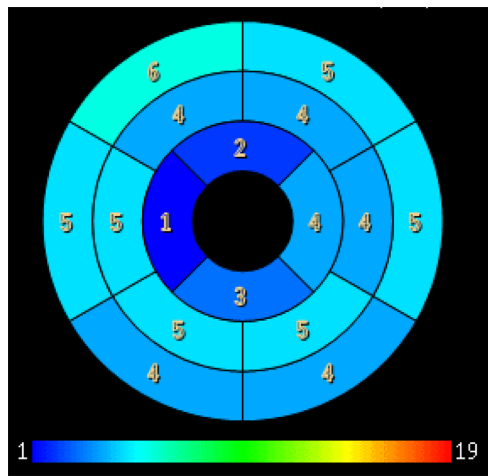
Polar Map Regional Type

The default regional map is divided into the standard 16 LV segmentation. Result values are given within each region.

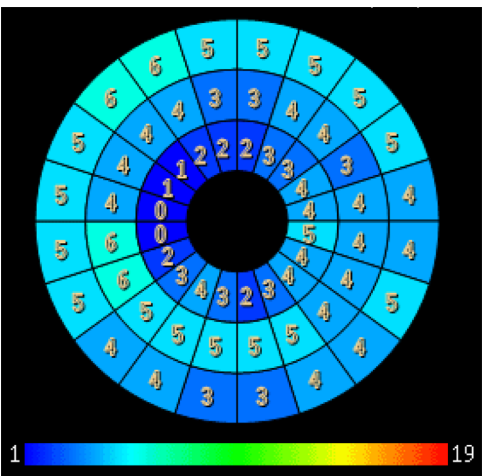
NOTICE

The default map is the regional map. The detailed map is available. Polar maps update when contours are corrected.

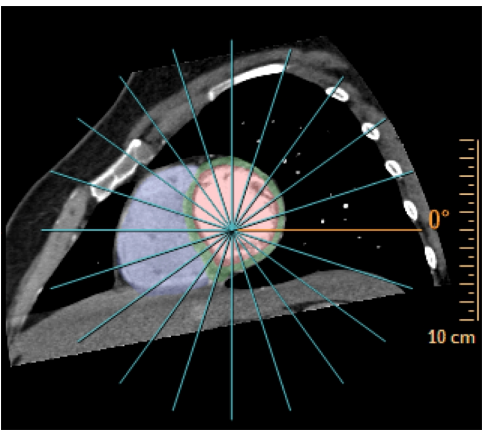
Regional - 6 Rays



Regional - 20 Rays



Short Axis - 20 Rays

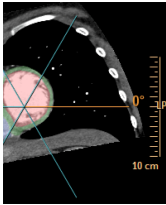


To divide the regional map into other layouts, use the Spoke Wheel tool and change the Number of Rays parameter in the Functional Analysis tab. Regional- 6 rays Regional - 20 rays Short Axis - 20 rays

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Configure Polar Map



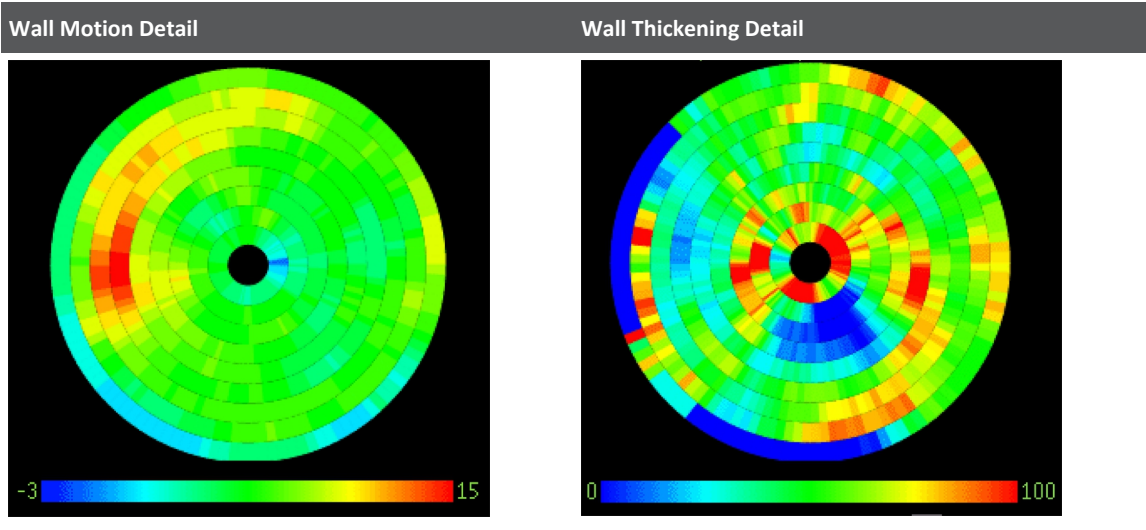
The Spoke Wheel is centered on the long-axis intersection point of each short-axis slice and divides the LV into a number of equal angle wedges, defining a specific division of the short axis slice into segments. An orange spoke (ray) marks the 0-degree (zero) point. Positive rotation is clockwise direction. 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.



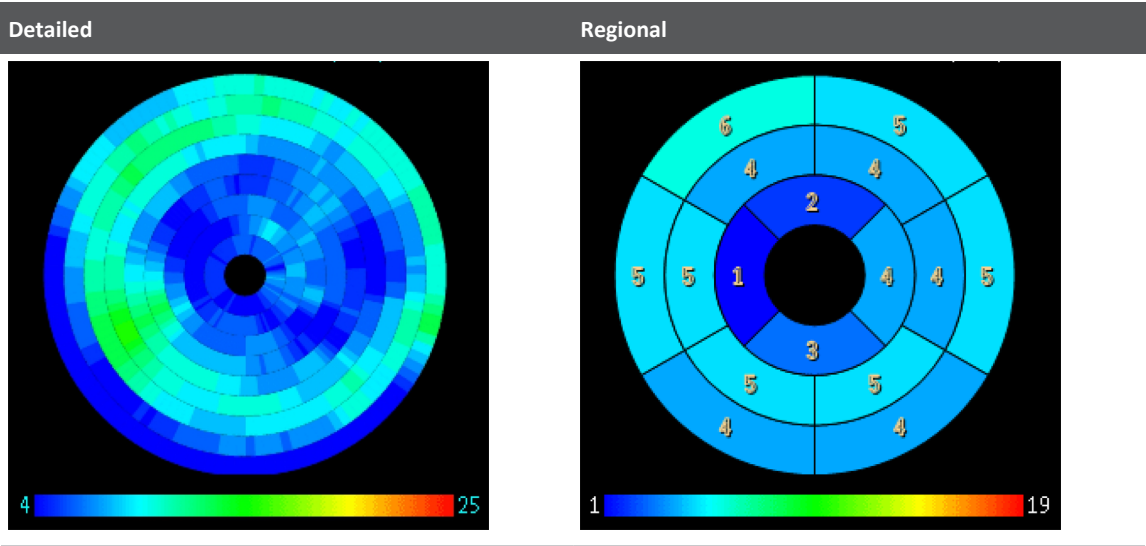
The colors within a circle represent attributes of the part of the left ventricle that corresponds to the same polar position of the matched short axis cut.

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.

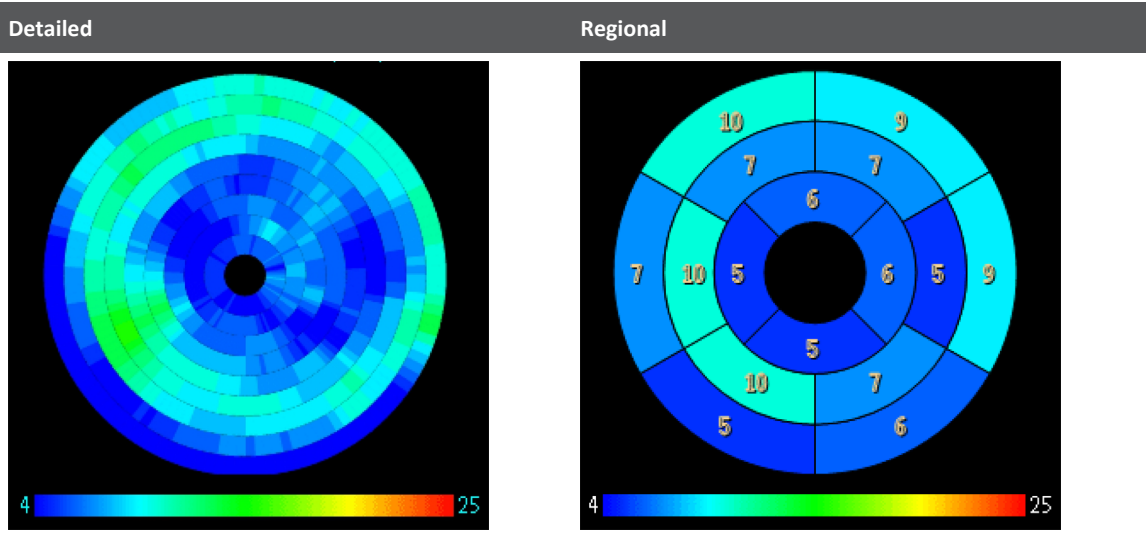
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ES Wall Thickness Maps

This map represents the left ventricular wall thickness of the loaded cardiac phase with the smallest ventricular volume and largest wall thickness.

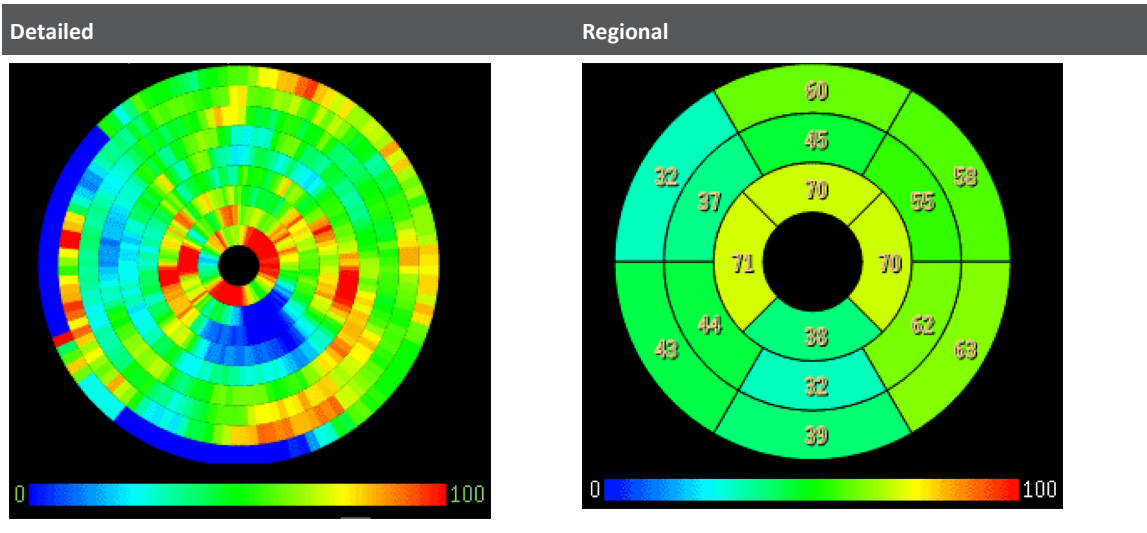


Wall Thickening Maps

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.

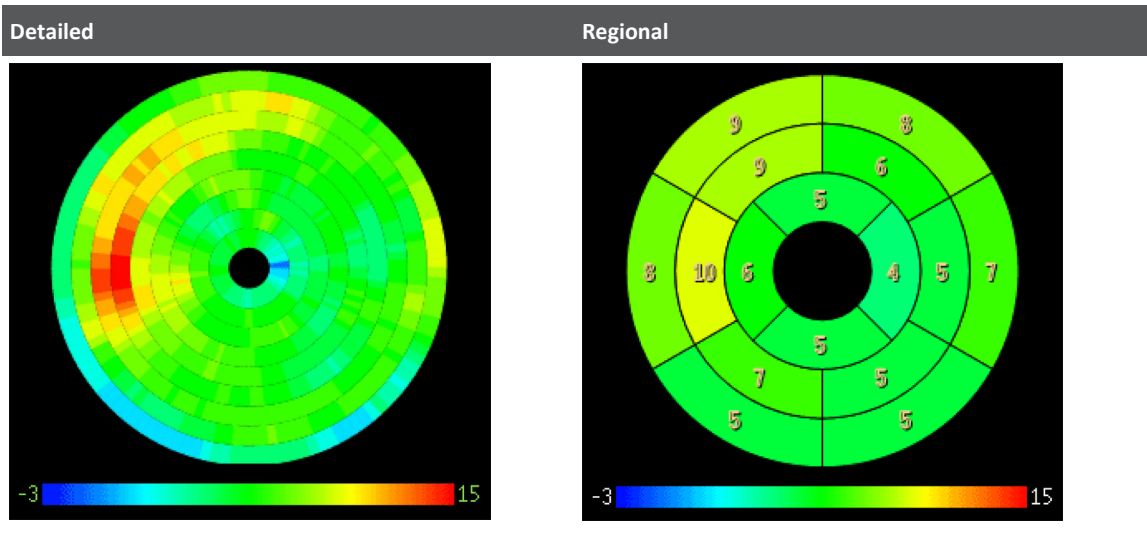
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Wall Motion Maps

The Motion map represents the change in the endocardial wall position between 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 the 3D radial distance between the center position of the endocardium at ED and its position at ES in the specified direction, and is measured in millimeters. The values will be positive if the wall motion is inwards and negative if it is outwards.



Aortic and Mitral Valve Display

You can view the 3D image cut along the plane through the aortic and mitral valves by choosing these options from the Heart drop-down list on the volume viewport.

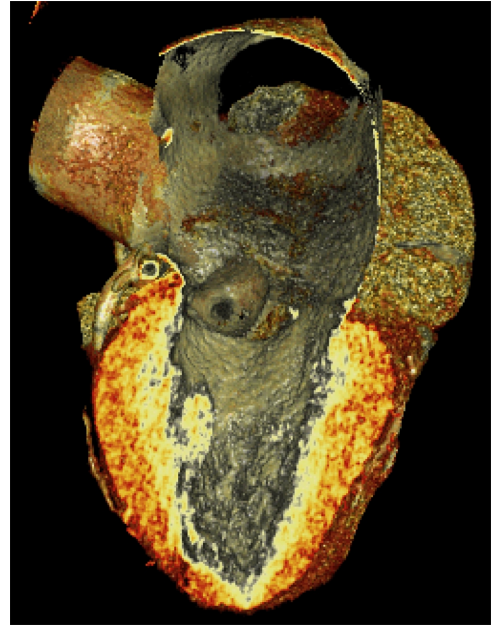
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Aortic valve - 3D



Mitral valve -3D

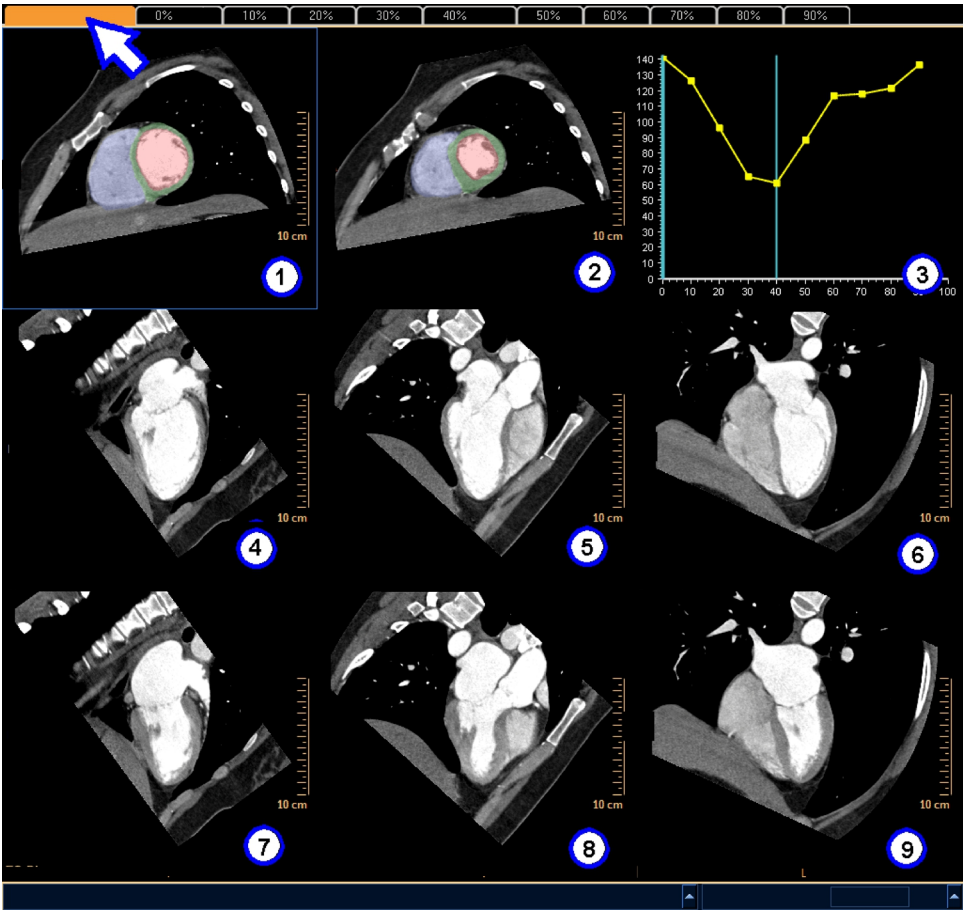


Compare Phases

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. The control sets the image angles at LAO 50, Cranial 30 (an angle which presents a plane almost perpendicular to the annulus plane).

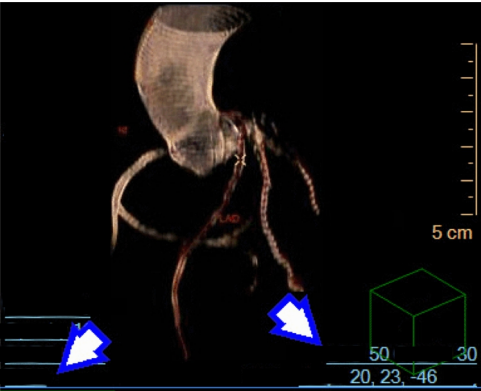
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NOTICE

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.



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.

NOTICE

The SCCT guidelines for the interpretation and reporting of coronary CT angiography recommend to report stenosis within broad stenosis ranges, as listed in the guidelines. Leipsic J, Abbara S, Achenbach S, Cury R, Earls JP, Mancini GJ, et al. SCCT guidelines for the interpretation and reporting of coronary CT angiography: A report of the Society of Cardiovascular Computed Tomography Guidelines Committee. J Cardiovasc Comput Tomogr. 2014;8:342–58.

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. |
| 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. |

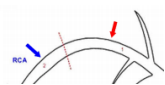
Add to Report (using SCCT guidelines)

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.

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:

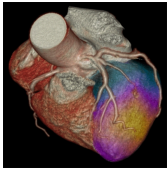
- If there are no existing CCA reports for the current patient, the procedure starts with the Risk Factors, Clinical History & Patient Parameters & Information window, shown on the next page.
- If one or more reports exist for the current patient, clicking Report Clinical Results brings up a selection 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 Advanced Visualization Workspace, refer to the "Cardiac Viewer" and "CT Viewer - Fusion mode" sections in the "Review" volume.

Indications for Use

The CCA NM Fusion option is designed to combine Cardiac CTA images with PET/SPECT data.

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.

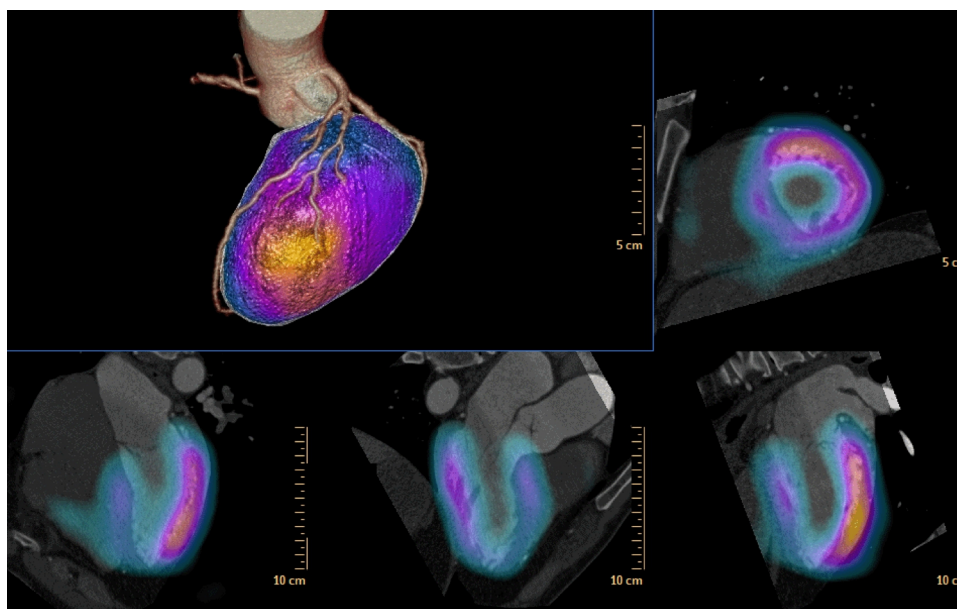
The CCA application is designed to combine Cardiac CTA images with PET/SPECT data.



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 227.

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.

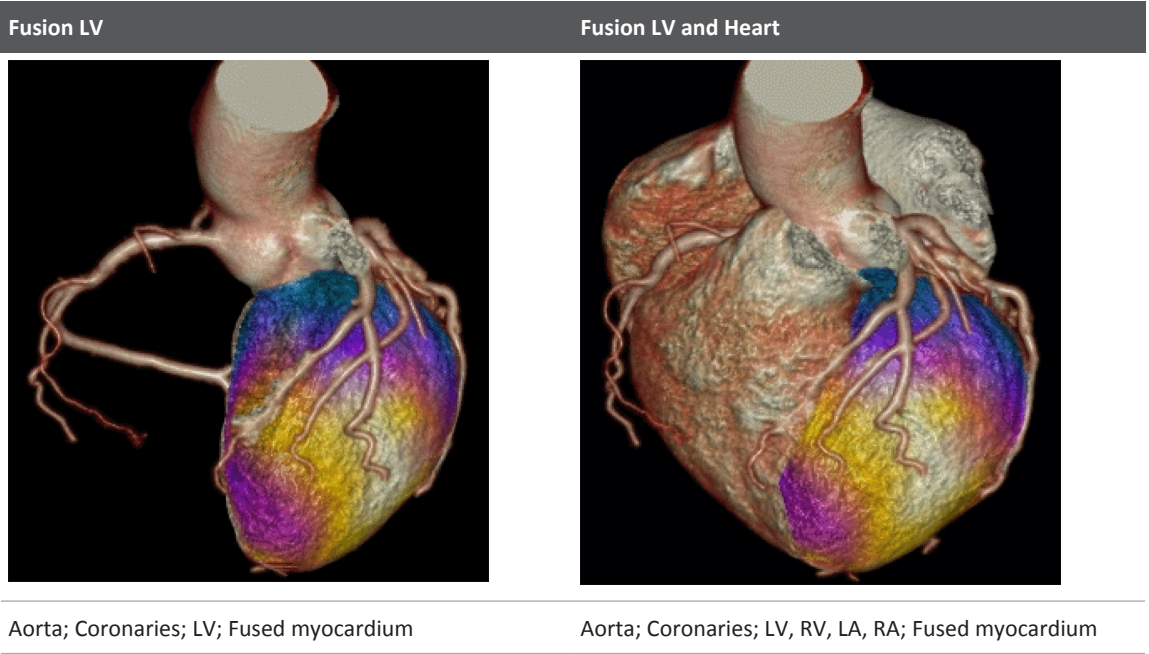
NOTICE

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 .

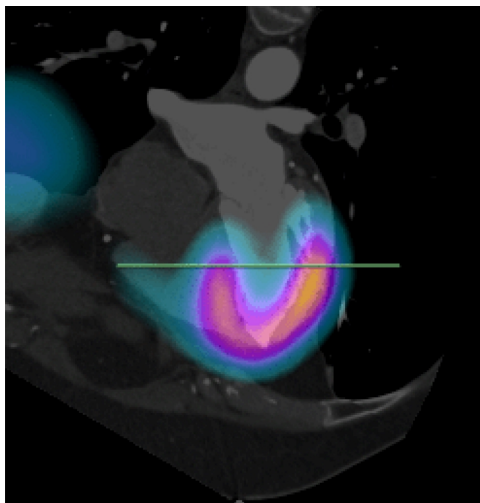
Fusion Relate



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

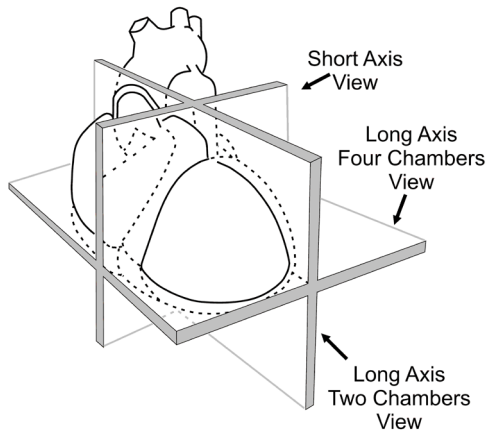
A green reference line is added to the long axis images indicating the location of the current short axis slice.



Licensing

The fusion capabilities in CCA and Cardiac Viewer are protected by a user license called CCA – NM Fusion.

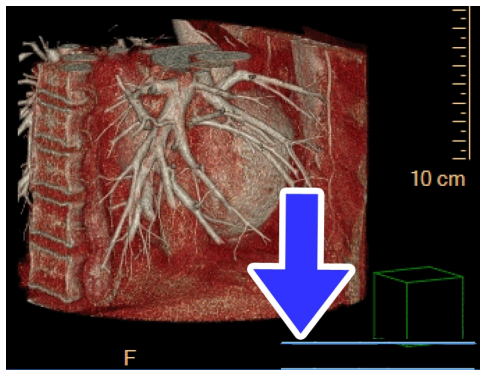
Cardiac Views



Adapted from M. Catherine M. Otto, Textbook of Clinical Echocardiography, 2nd Edition, W.B. Sanders 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 and the Comprehensive Cardiac Analysis 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.

Measurement Accuracy

- The mean (SD) position error of the coronary artery centerlines is 0.23 (0.8) mm.
- The accuracy of the volumes and ejection fractions obtained with MDCT are within 3% of the values obtained by the Gold standard 2D echocardiography (2DSE) method. More details can be found in the article by Amin et al: Amin MI, Hassan HA, Mousa MIA. Utility of 128-row multidetector CT in quantitative evaluation of global left ventricular function in patients with coronary artery disease.

The Egyptian Journal of Radiology and Nuclear Medicine 2018;49:12–22.

<https://www.sciencedirect.com/science/article/pii/S0378603X17301729?via%3Dihub>

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