16 Transcatheter Aortic Valve Implantation Planning

The **Transcatheter Aortic Valve Implantation (TAVI) Planning** application provides semiautomatic and manual tools to help determine the size and shape of the aortic root anatomy, ascending aorta and left ventricular outflow tract.

The application supports contrast-enhanced, prospectively ECG-gated axial or retrospectively-gated helical CT images.

WARNING

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

Application Stages

There are three stages in the application:

- When the application opens in the **Verify Segmentation and Landmarks** stage, review and edit (if necessary) the automatic landmarks locations and segmentation.
- After reviewing and editing (if necessary) the planes and measurements in the **Device Sizing** stage, review the results.
- **Access Route Assessment** provides tools (including inspection of minimal diameter, calcification and tortuosity of the vessel) to analyze the peripheral vessels when performing **Device Sizing**.

TAVI-related Measurements

Measurements related to access root assessment for calcium scoring should be performed within the Calcium Scoring application.

Indications for Use

The CT TAVI Planning application is intended to be used for patients with aortic valvular disease, severe symptomatic aortic stenosis or tricuspid aortic valve. The intended part of the body for this application is the human heart specifically the ascending aorta, aortic root, coronary ostia and left ventricle in order to assess the aortic valve in pre-operational planning of transcatheter aortic valve replacement procedures.

CT TAVI Planning is a non-invasive post-processing application providing 3D model-based segmentation of the aortic valve and aortic arch. The CT TAVI Planning application provides assessment and measurements of relevant heart structures for TAVI-device sizing, and allows

881 * 2021-06-30

Philips

the user to select a starting angle for C-arm position from the possible optimal positions from the CT TAVI and select a C-arm angle the user feels is appropriate to use in the catheterization laboratory by the Interventional team performing the procedure (to be used during the procedure itself).

The physician retains the ultimate responsibility for making the determination of patient eligibility or which device is implanted based on their standard practices and additional imaging modalities such as echocardiography.

Common TAVI Planning Scan Protocols (Exams)

The following Protocols (Exams) are intended as examples for Philips scanners only (for 64-256 slice scanners). Before performing a scan, consult the **Instructions for Use** that came with your scanner.

Recommended Protocol 1: Gated Helical CTA

1. Optional: Start with a non-contrast enhanced Calcium Scoring scan which can be used for quantification of the calcium load on the aortic valve leaflets.
2. **TAVI Planning** related scan/reconstruction:

   Gated Aorta protocol, starting from the level of the subclavian artery and ending such that it includes the proximal femoral arteries.

   Reconstruct 8 to 10 cardiac phases (0-100% RR interval) of the heart section only with small (optimal for cardiac) FOV.

   In addition, reconstruct one untagged recon of the entire section with large FOV. The untagged recon is used to measure the diameter of the subclavian and/or iliac/femoral arteries. This scan is for access route assessment and would be analyzed in the third stage of the TAVI application: **Access Route Assessment**.

   Usually the mid-to End-Systolic cardiac phase (30-40% RR interval) is used to measure the Annulus dimensions. This scan would be analyzed with **TAVI Planning**.
3. Un-gated reconstruction for the whole range.
4. Optional: Coronaries reconstruction.
5. Optional: Chest unTagRec with filter YB for extra cardiac findings.

Parameter*	Recommended Value
mAs	400-500 with iDose[4]
KV	100
Dose Modulation	No
Scan Length	Depending on the patient. About 650mm.
Cardiac phases	0, 20, 25, 30, 35, 40, 45%, 75%. From these select the mid-end systolic phase with the least amount of motion and perform the annulus measurements.

* Parameters are for average-size patient.

/881 * 2021-06-30

Philips

Recommended Protocol 2: Split-scan Technique

1. Optional: Start with a non-contrast enhanced Calcium Scoring scan which can be used for quantification of the calcium load on the aortic valve leaflets.
2. An ECG gated CTA of the heart including the aortic root*. Acquisition can be:
   - **Retrospective:** Reconstruct 10 phases (0-100% RR interval) of the heart section only with smaller FOV. Usually the mid-to End-Systolic cardiac phase (30-40% RR interval) is used to measure the Annulus dimensions. This scan would be analyzed with **TAVI Planning**.
   - Or:
   - **Prospective:** Targeted at either 35% or 75% of the RR interval.

   Alternatively, the scan can be extended to the entire Thoracic Aorta.
3. A non-gated CTA of the entire aorta, starting from the subclavian artery and including proximal femoral arteries. This scan is for access route assessment and would be analyzed in the third stage of the TAVI application: **Access Route Assessment**.

   Alternatively, the scan can be limited to abdominal/iliofemoral section only if step 2 already covered the thoracic aorta (see above) **Aorta CTA protocol**.

NOTICE

There should be a minimal delay between step 2 and 3.

Parameter*	Recommended Value
mAs	100 with iDose[4]
KV	100
Step & Shoot	at 35% or 75% with tolerance
Scan Length	Depending on the patient. About 650mm.

* Parameters are for average-size patient.

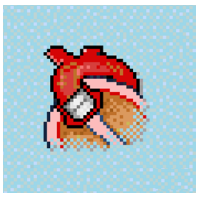
Launch TAVI Planning

1. From the **Directory** find and select the desired **Study** and **Series.**

NOTICE

The application supports contrast-enhanced, prospectively ECG-gated axial or retrospectively-gated helical CT images.

2. Select the **TAVI Planning** icon from the application icon chart.



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

NOTICE

When launching the TAVI Planning application, Portal will also load the CT **Cardiac Viewer**. See the **CT Review** section for more information on using the **Cardiac Viewer**.

Verify Segmentation and Landmarks Stage

When the series are loaded, automatic segmentation is run for each loaded phase. Once the segmentation is completed, a plane is shown that displays the three (3) aortic sinuses landmarks (also knows as **hinge points**).

If several cardiac phases were loaded, the order of the automatic segmentation is applied as follows: first 40 %; next, all the phases between 40 % and 30 % in descending order; followed by 30% and then 75%; then all the phases between 70% and 80% in ascending order; ending with the remaining phases segmented in ascending order.

NOTICE

The MPR images on the first stage of the application are displayed in Planar mode, meaning that they are always 90 degrees to each other. When swiveling one of the images, the other images update accordingly.

WARNING

During this stage, first verify and correct (if necessary) the automatic landmark placement for the RCA/LMCA ostia and the aortic sinuses. Second, verify and edit the segmentation using the Edit Tissues tools.

TAVI Aortic Root Calcium Segmentation and Visualization of Calcium

The TAVI application uses an automatic calcium segmentation algorithm to detect and segment the calcium present in the aortic root and provides visualization of calcification in the aortic root: Aortic sinuses and cusps.

/881 * 2021-06-30

Philips

In the **Verify Landmarks & Segmentation** stage, in the **Edit Tissue(s)** list, the application displays an additional option named as “Aortic root calcium”

Similar to rest of the tissues in Tissue(s) list, use the “Edit Tissue” tools to edit the colored display of the automatically segmented tissue of calcification in Volume Rendered (VR) and MPR images to verify its correctness. Use various tissue editing tools presented by default settings for editing and optimization of the segmented calcium, if required.

TAVI Verify Segmentation Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Orientation

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

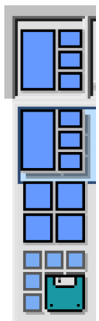
- **General axes.** The general axes are the standard anatomical orientations: axial; coronal; and sagittal.
- **Cardiac axes.** The cardiac axes orient the views of the heart as follows: short axis; horizontal long axis (4 chamber view); and vertical long axis (2 chamber view).

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

Flip

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

Layout



Two default layouts are available, 1+3 and 2x2. The currently active layout is displayed as the icon. Click the down arrow to select the alternate layout.

In the 1+3 layout, the images consist of the volume image in the main viewport and the axial, coronal, and sagittal images from top to bottom in the reference viewports.

The 2x2 layout has the same views as 1+3, but is arranged differently.

The **Layout Manager** allows you to perform various layout (display) management functions.

Relate

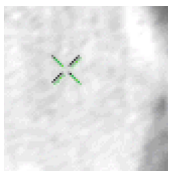
The **Relate view ports** and **Relate scenes** tools can help orient yourself.

To use, select either **Relate view ports** or **Relate scenes** and click on any pixel in any viewport. The location of that pixel is automatically marked on all the other view ports.

Magic Glass

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

Rotation Center



When the box is checked, click to show the center point (indicated by a green X) around which the volume can be rotated.

Center Cursor

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

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

Swiveling and rotating of the image will be performed around this new rotation center.

Show Landmarks

Check the box to show landmarks on displayed images. Uncheck the box to hide landmarks.

On/off ECG

If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Show Tissues

Check the box to display the active tissues in the **Select Tissue** table.

/881 * 2021-06-30

Philips

Calculate Volume

Click the button to calculate the volume of the currently active tissue or tissues (to select an active tissue, see section “Verify Segmentation and Landmarks Stage” on page 402). Clicking the button displays the volume of the displayed tissues on the volume image. A highlight appears on the reference images. The calculated volume is that of the colored pixels on the reference images.

WARNING

Exclude the Aortic Root Calcium tissue from volume calculation by removing the check mark for Aortic Root Calcium in the Edit Tissue(s) selection check box, as calcium quantification may not be accurate on data with contrast enhancements.

The following message appears when clicking the Calculate Volume button with “Aortic Root Calcium” tissue selection box checked:

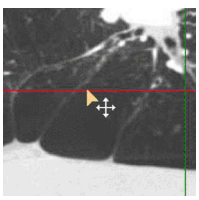
Volume calculation may not be accurate as long as the "Aortic Root Calcium" tissue is checked in the tissues list, since calcium quantification is not accurate on data with contrast enhancement. Uncheck the tissue and calculate the volume again.

Select OK and close the Calculate Volume Button. Remove the check mark from the "Aortic Root Calcium" tissue and select other desired tissue(s) from the Tissues list. Re-initiate the Volume Calculation by clicking on the Volume Calculation tab.

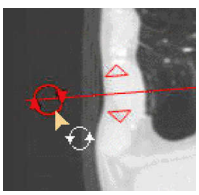
Using Crosshairs

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

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



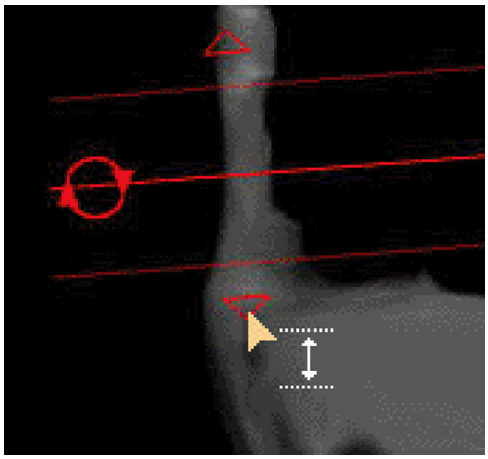
- To rotate, grab near the end of the crosshair and drag in the appropriate direction.



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

881 * 2021-06-30

Philips



TAVI Segmentation Common Tools and Functions

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

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions

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

- **Bookmarks**. This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

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

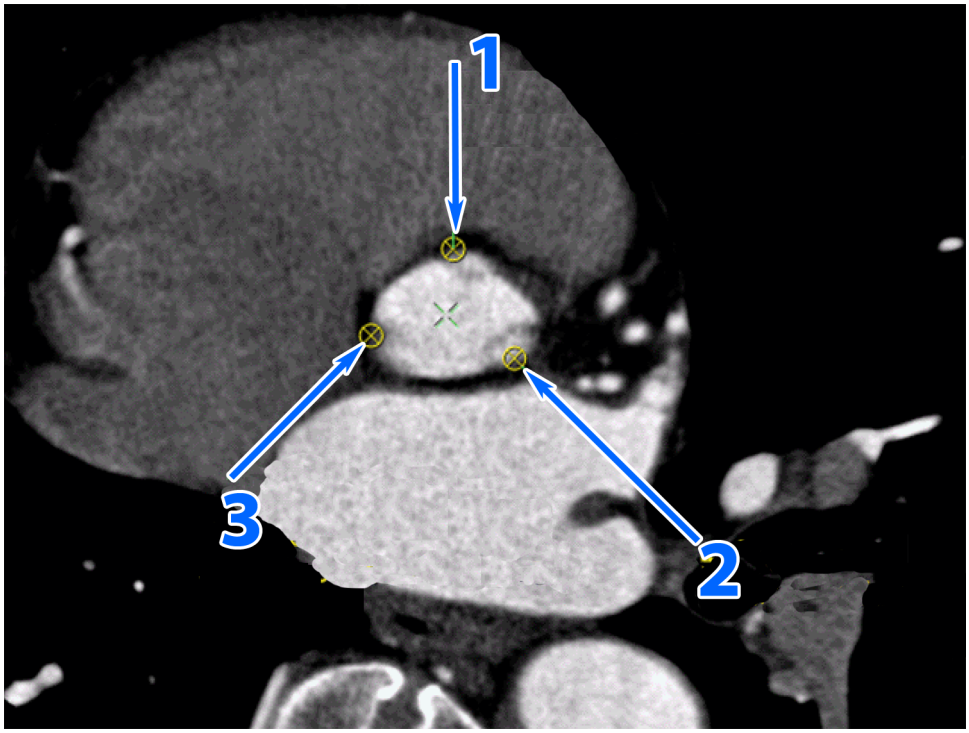
Verify and Edit Sinuses and Coronary Ostia Landmarks

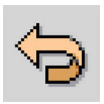
1. Ensure the **Edit Automatic Results** tab is open. This is the default tab (in the middle of the toolbox).
2. If the aortic sinus landmarks are not visible, click the **Go to aortic sinuses landmarks**  button.

/881 * 2021-06-30

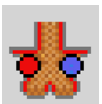
The 3 aortic sinuses landmarks (which corresponds to the proposed annulus plane) are displayed.

3. To adjust the automatic landmark placement for the right sinus (item 1 in the image), left sinus (item 2), or non-coronary sinus (item 3): Grab the crosshair, move it to the correct location, and confirm the move.

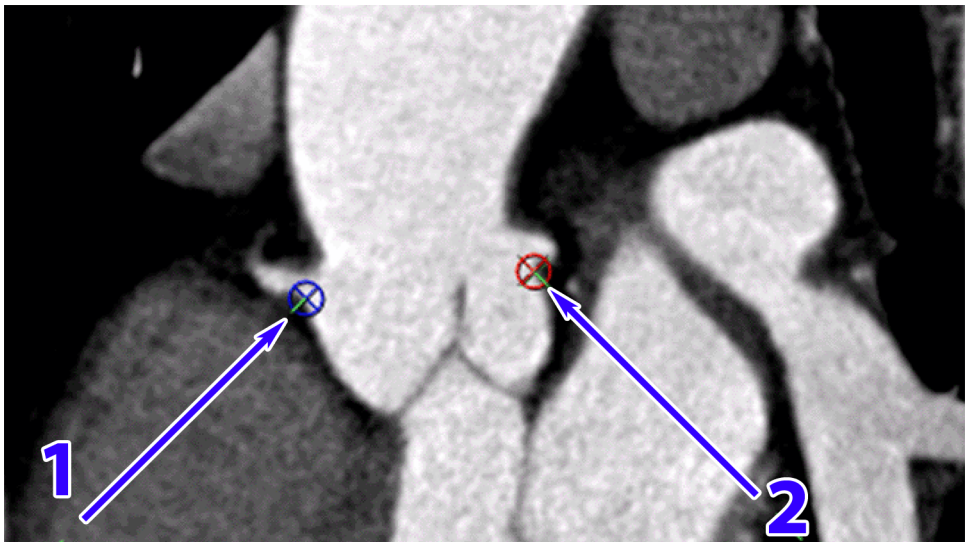


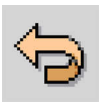
If necessary, use the **Undo/Redo**  button to revert the change. The last 10 changes can be undone. Alternately, right-click on a landmark and select **Reset Landmark Location** to revert the change to the initial location.

4. To move the landmark to a different slice, scroll to the correct slice, click the **Relocate landmark**  button, click on the new location, and then select the landmark name from the dialog. All landmarks can be relocated at the same time. Click the **Relocate landmark** button again to exit and return to image scrolling.

5. Click the **Show ostia landmarks**  button.

6. To adjust the automatic landmark placement for the RCA ostium (item 1 in the image) and LMCA ostium (item 2): Grab the crosshair, move it to the correct location, and confirm the move.



If necessary, use the **Undo/Redo**  button to revert the change. The last 10 changes can be undone. Alternately, right-click on a landmark and select **Reset Landmark Location** to revert the change to the initial location.

7. To move the landmark to a different slice, scroll to the correct slice, click the **Relocate landmark**  button, click on the new location, and then select the landmark name from the dialog. All landmarks can be relocated at the same time. Click the **Relocate landmark** button again to exit and return to image scrolling.

8. When all landmarks locations are properly located, click the **Accept all landmarks**  button.

NOTICE

To reset a landmark location to the automatic one, right-click on the landmark and select **Reset landmark to the automatic location**.

Verify and Edit Segmentation

NOTICE

Perform the verify and edit segmentation procedure below for all of the automatically detected tissues:

- Aorta
- Aortic root
- Left ventricle
- RCA ostium
- LMCA ostium

1. In the **Select Tissue** list, ensure the checkbox is checked and the tissue to be verified is selected (highlighted in blue).
2. If you need to change the color of the selected tissue, click on the color icon in the list and select a new color.
3. To expand or erode the selected tissue, right-click on the tissue name in the list and select the appropriate option from the menu.
4. Use the **Edit Tissue(s) (3D Tools)** to edit the segment.

WARNING

When using the following tools, segmentation is performed in 3D (not 2D): Eraser; Brush; Exclude/Include; Expand; Erode; Inject Dye; Add smart brush; Add smart ROI; Remove smart brush; Remove smart ROI.

Erode/Expand Tissue (3D)

Right-click on a tissue in the **Tissue List** and select **Erode** or **Expand** from the menu.

Erode Tissue

The Erode Tissue function allows you to decrease the edges of the segmented tissue. Each click reduces the edge by a one-voxel increment.

Expand Tissue

The Expand Tissue function allows you to increase the edges of the segmented tissue. Each click expands the edge by a one-voxel increment.

Smart Segmentation (3D)

Use the **Smart Segmentation Tools (3D)** to improve the 3-dimensional segmentation. Click the button to open the floating dialog box that contains the segmentation tool. The dialog box will snap to the active viewport every time it is re-opened (if the box is in the way, drag it to a different location on the screen).

WARNING

Verify correctness of the segmentation on all the segmented slices and edit if required.

See **CT Review > CT Common Processes** for instruction on using the **Smart Segmentation Tools (3D)**.

Inject Dye (3D)

The Inject dye function is used on the reference images to create a tissue of the volume of interest.

See **CT Review > CT Common Processes** for instruction on using the **Inject Dye (3D)** tool.

WARNING

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

Eraser (3D)

The Eraser function allows you to remove the contrast from reference images by hovering over the contrast and clicking the left mouse button (you can also hold down the button and drag). The Eraser is a sphere whose radius you can set. The Small eraser is 5 pixels; Medium is 10 pixels; Large is 30 pixels.

NOTICE

Because the eraser is the shape of a sphere, it erases from the volume, not only the slice you use it on. Be sure to verify the results of the eraser by scrolling the reference images.

/881 * 2021-06-30

Philips

Brush (3D)

Add to unsegmented areas of active tissue by “painting” with the brush.

1. Activate the appropriate tissue segmentation.
2. Select the brush size from the drop down.
3. Drag the mouse across the unsegmented tissue while holding down the mouse button. The brush will “paint” new segmentation in the same color as the selected tissue.

Fill Holes

Check the box to add to the injected soft tissue, filling in any holes within the volume. The holes are filled as long as the box is checked.

Volume Sculpting (3D)

Manual sculpting tools are available for volume removal. Three Region of Interest (ROI) sculpting tools are available: Freehand, Rectangle, and Circle. The Exclude function removes everything enclosed within the ROI. The Include function removes everything outside the ROI.

See **CT Review > CT Common Processes** for instruction on using the **Volume Sculpting (3D)** tools.

Undo/Redo

The Undo/Redo function allows you to reverse your most recent action. If, for example, you over-inject, you can correct the result with the Undo function. Each click of Undo erases the last voxels that were added to the tissue during Inject, Fill, Expand, or Erode during landmark editing. Redo allows you to reverse the Undo.

Manually Re-segment Heart

If the automatic segmentation is inaccurate or failed, place three anatomical landmarks and re-segment the heart anatomy.

1. Go to the **Re-segment** tab (for example, hover over **Edit Segmentation** in the middle of the toolbar and select **Re-segment** from the menu).
2. Click on the **Activate Seed**  button.
3. Select Aortic Valve, Mitral Valve, or Apex radio button from the list.

881 * 2021-06-30

Philips

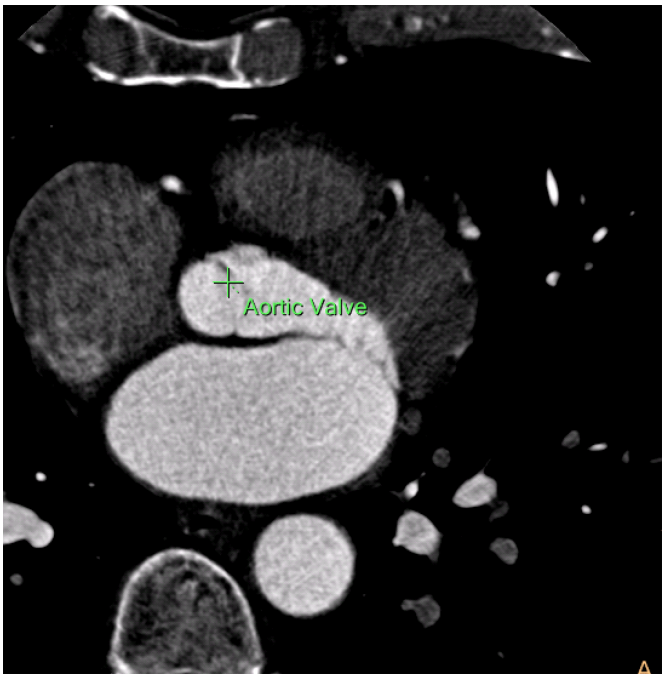
4. Scroll through the images and place the seed by clicking on the correct location (for fast scroll, hold down **Ctrl + left mouse** button and drag the cursor across the active image. Only one seed per landmark is necessary. See images below.
5. To adjust the seed, grab the crosshair and drag it to the desired location.
6. Place seeds for the other 2 landmarks in the same manner. See images below.
7. Select either the **All** or **Current** radio button to determine which phases to re-segmented:
   - **All** re-segments every phase loaded with the **Study**.
   - **Current** only re-segments the active phase.
8. Click the **Re-segment**  button.
9. See section “Verify and Edit Sinuses and Coronary Ostia Landmarks” on page 406 and section “Verify and Edit Segmentation” on page 409.

/881 * 2021-06-30

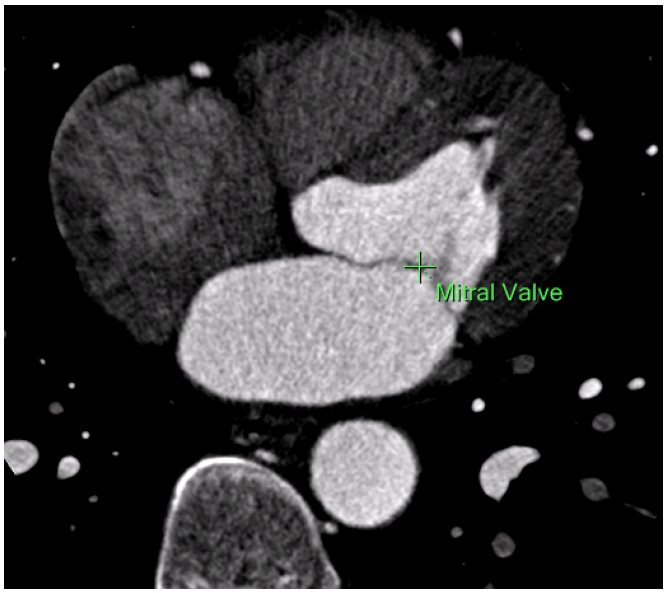
Philips

Example Aortic Valve, Mitral Valve, and Apex Landmark Placement

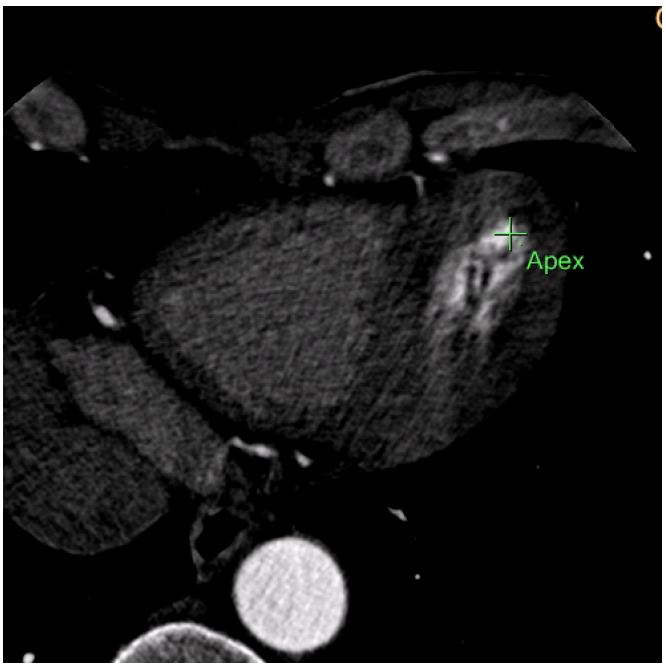
Aortic Valve



Mitral Valve



Apex



Device Sizing Stage

Use the Device Sizing Stage to:

- Edit if necessary the automatically detected planes and then accept the planes along the aortic root and the ascending aorta.
- Accept the contours and distances after verifying the automatic detection and correcting them as needed.
- Review the measurements table for device sizing, based on the accepted planes.
- Review the various recommended CathLab angles. All the angles provide a view perpendicular to the annulus plane.
- Save or send the results to **Report**.

WARNING

Accuracy of measurements is based on the landmarks placed in the previous stage.

TAVI Device Sizing Options and Tools

Use the following options and tools (in the upper tool box) to modify the view and perform analysis.

Orientation

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

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

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

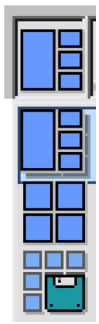
Flip

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

/881 * 2021-06-30

Philips

Layout



Two default layouts are available. The currently active layout is displayed as the icon. Click the down arrow to select the alternate layout.

The **Layout Manager** allows you to perform various layout (display) management functions.

Relate

The **Relate view ports** and **Relate scenes** tools can help orient yourself.

To use, select either **Relate view ports** or **Relate scenes** and click on any pixel in any viewport. The location of that pixel is automatically marked on all the other view ports.

Magic Glass

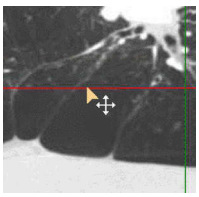
The **Magic Glass** function displays a moveable, mini-window (3 cm default) which can be set with its own windowing, image enhancement and rendering parameters. With the **Magic Glass** function you can enhance visualization and assessment of certain elements of the image, such as calcium and stents,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

Show Crosshair

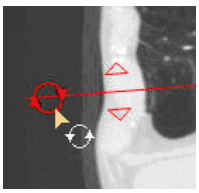
Check the box to show the crosshair in the viewports.

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

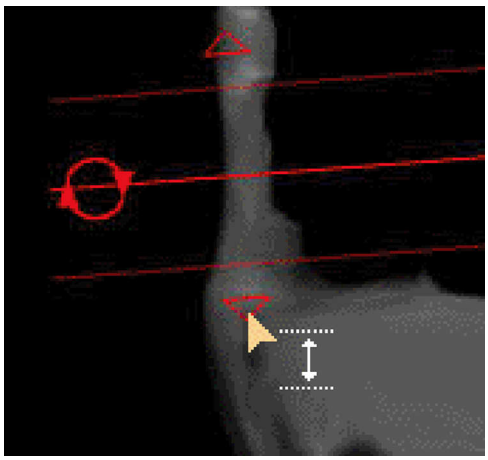
- Grab the crosshair and drag it to the correct position.



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



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



Show Contours

Check the box to show the contours on the cross-sectional planes MPR images. Used with **Edit Measurements** and **Review Results** modes.

On/off ECG

If an appropriate ECG is included in the study, click the button to display the ECG viewer. For information on using the ECG viewer, see the **Cardiac Viewer** section.

Selected Plane/Non-selected Plane

Use the drop-down to toggle the volume image between the selected plane and the non-selected plane views.

Non-selected (non-active) planes indication colored in green on the VR image.

Active plane indication colored in orange on the VR image.

Configure Measurements

Use the Results Settings button to configure the list of measurements to show per plane in the table and on the MPR images. See section “Configure Review Measurements” on page 430.

TAVI Device Sizing Common Tools and Functions

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

/881 * 2021-06-30

Philips

Common Tools

Common tools provide many basic functions, including saving, filming, reporting, scrolling, measurements/annotations, panning, zooming, rotating, and windowing.

Common Functions

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

- **Bookmarks**. This function allows you to access Bookmarks, if any are saved.
- The **Batch** function allows you to create a series of sequential images for viewing, saving, reporting and filming purposes.

Key Images

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

Verify and Edit Automatic Planes

The Planes and Measurements tab contains 3 working modes that need to be followed to get accurate results:

- Edit Planes
- Edit Measurements (contours)
- Review Results

The currently active mode is highlighted in orange color. It is possible to activate a mode by pressing the header text or the icon to the left of the text.

Choose the planes you need for the TAVI Planning procedure. Edit as necessary the automatically detected planes and then accept the following planes along the left ventricle aortic root and the ascending aorta:

- Annulus. When accepted, the Annulus Angulation, Distance to LMCA Ostial plane and Distance to RCA Ostial plane are automatically calculated.
- Sinus of Valsalva
- Sinotubular junction. When accepted, the Left Coronary Sinus Height, Right Coronary Sinus Height, and Non-coronary Sinus Height are automatically calculated
- LVOT (Left ventricular outflow tract)
- Ascending aorta

You can continue to next steps after reviewing and accepting at least one of the planes.

NOTICE

By default, all the automatically detected planes are not accepted. If you need measurements for a certain plane, the plane must be reviewed and edited (if required). Unaccepted planes are shown with a question mark in the planes table and on the images.

1. If not already open, go to the **Planes & Measurements** tab.

   Ensure that the **Edit Planes**  button is active (the header is orange and the icon to the left of the header is pressed).
2. Click on a plane in the plane table and edit using one or more of the following:
   - Scroll the upper left plane image to the right location.
   - Swivel the upper left plane image.
   - Grab and move/rotate the long red horizontal crosshair on the reference MPR images.
3. If you changed the plane and want to keep the new plane as the true plane, click the **Accept**  button in the **Relocate the [name of the selected plane] to this plane** dialog.
4. If no edits to the automatically detected plane is necessary, ensure you are on the correct plane and then click the **Accept Plane**  button.
5. Follow the procedure until all planes you want to examine are correct and accepted.

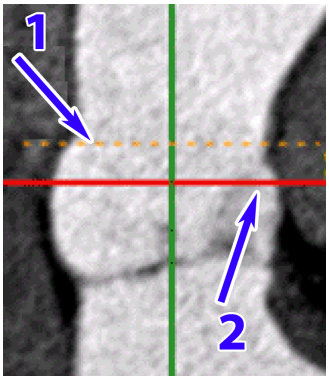
NOTICE

Every time you accept a plane, the system automatically moves to the next unaccepted plane in the list. You can go back to any of the accepted planes by selecting those in the list again.

Device Sizing Viewports

The left upper viewport shows the current active plane.

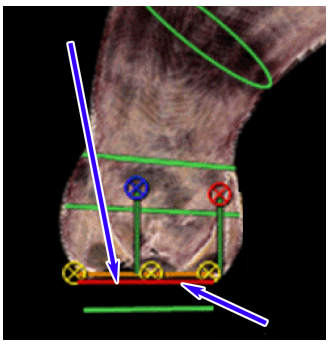
The lower left and right viewports show 2 double oblique reference MPR images, perpendicular to the active plane.



1. The active plane is indicated by a dashed line on the MPR images (a plane is active when it is selected in the plane list).
2. The red line corresponds to the plane currently displayed in the upper left viewport. By default, this plane coincides with the active plane location (selected in the planes list). However, after scrolling or rotating the plane (for review or editing of the plane), those two lines no longer coincide. Click on the dashed line or the plane name in the toolbox to make the displayed plane coincide with the active plane.

   After editing the displayed plane (for example, annulus plane), it is possible to make the plane the active plane by selecting the option: **Relocate the [name of the currently active plane] to this plane**.

The upper right viewport shows the volume image with all the automatically detected planes indications.



For volume images, a ring indicates the location of the displayed plane.

The orange line indicates the active plane (selected in the list and corresponding to the dashed line on the reference images). The green line indicates the rest of the planes.

881 * 2021-06-30

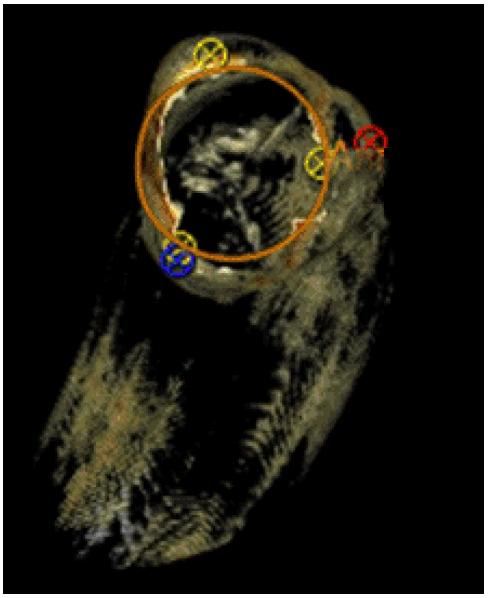
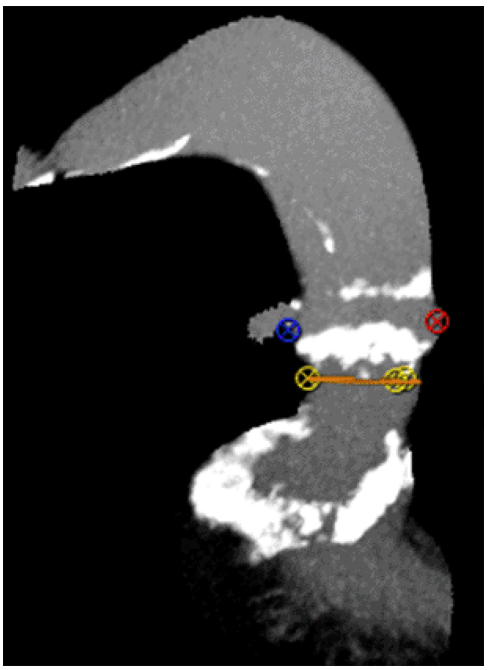
Philips

TAVI Volume Images

Aorta+Aortic Root+LV

Aorta+Aortic Root

/881 * 2021-06-30

Aorta+Aortic Root	
Aorta+Aortic Root+LV with MIP rendering selected May be used to examine calcium.	

Verify and Edit Automatic Measurements

Before verifying or editing the contours, you must first accept at least one plane. See section “Verify and Edit Automatic Planes” on page 417.

After accepting necessary planes, the **Edit Measurements** mode is activated by default. You can also activate it manually by pressing the **Edit Measurements**  icon.

1. Examine the displayed contour types. See section “Select Displayed Contour Types” on page 422.
2. When required, manually draw diameters for the sinus of valsalva. See section “Draw Sinus of Valsalva Diameters” on page 423.
3. If necessary, edit contour. See section “Edit TAVI Contour” on page 424.
4. If a contour is incorrect, re-draw contour. See section “Re-draw TAVI Contour” on page 424.
5. Define additional measurements. Some measurements are not automatically extracted. You can draw those measurements manually (to show them in the **Review Results** table) using the **Draw measurement** tool. See section “Define Additional TAVI Measurements” on page 425.
6. When done editing and verifying all contours and measurements, click the **Accept all**  button.

When done, the **Review Results** mode is activated (the **Review Results** button  becomes active).

NOTICE

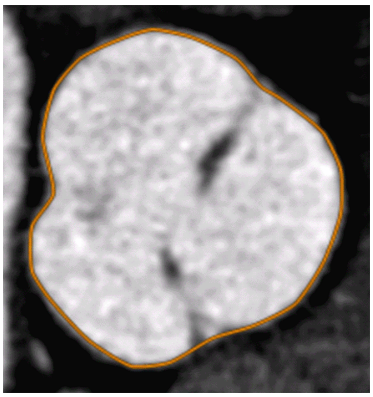
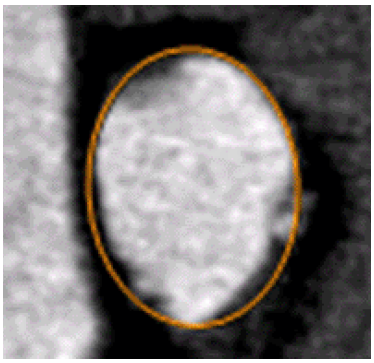
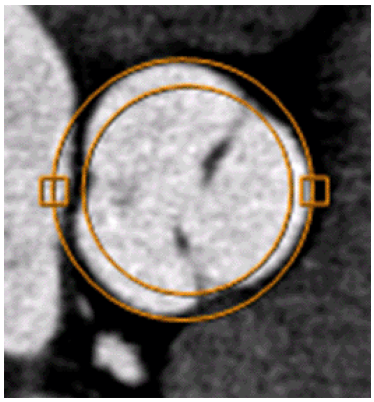
The distance to RCA/LMCA ostium is calculated as the distance between the RCA/LMCA landmark and the annulus plane. If the distance is incorrect, (due to wrong landmark or wrong annulus plane), edit the relevant landmark in the **Verify Segmentation and Landmarks** stage or edit the planes. See section “Verify Segmentation and Landmarks Stage” on page 402.

NOTICE

The left, right and non-coronary Sinus heights are calculated as the distances between the left, right and non coronary Sinus landmarks and the Sinotubular junction plane respectively. If any of the height lines is incorrect, (due to wrong landmark or wrong Sinotubular junction plane), edit the relevant landmark in the Verify Segmentation & Landmarks stage or edit the Sinotubular junction plane. See section “Verify Segmentation and Landmarks Stage” on page 402.

Select Displayed Contour Types

In the bottom left corner of the active plane, click on the contour type name (either **Contour**, **Elliptical**, or **Circular**) and select one of the options to change the displayed contour type.

Contour	Elliptical	Circular
		
Approximates the contour of the plane.	Approximates the contour to an ellipse. Suitable for planes that have an ellipse-like shape (for example, annulus).	Approximates the contour to 2 circles: inner and outer. Suitable for planes that have an circle-like shape (for example, mid-sinusal plane or ascending aorta).

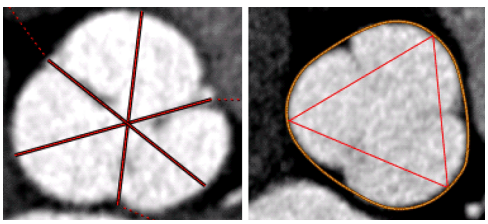
Configure Default Distance for Ascending Aorta Measurements

The **Configure measurements** dialog allows users to enter a preferred value for the default distance measurement from the annulus plane to the ascending aorta plane.

This setting can also be modified through the TAVI Application Preference settings. Administrative Users can share the default value entered to all users of the site. When an administrative user enables the option to share to all Users, individual user's preference values are overwritten by the Site preference value entered.

Draw Sinus of Valsalva Diameters

Manually draw the 3 representative diameters at the sinus of Valsalva plane: NC Cusp, RC Cusp, and LC Cusp. Below are two examples of possible ways to measure the 3 diameters:



1. Select the **Draw**  button for the Sinus of Valsalva image.
2. On the image, click where the first diameter should begin. Find where the diameter should end and click again.
3. From the pop-up menu, select the appropriate diameter name.

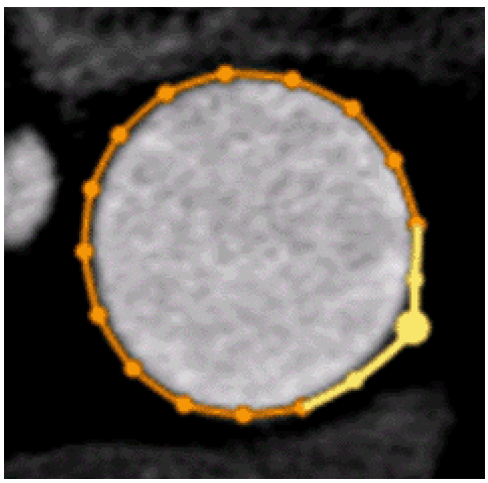
4. If necessary, edit the diameter by hovering over it until it turns yellow and then:
   – grab the line and drag it to the correct location; or
   – grab the end control points to lengthen, shorten, or swivel the line.
5. Draw and adjust the other two diameters accordingly.

NOTICE

To replace a diameter, add new line and select the diameter name from the list.

Edit TAVI Contour

1. Select the contour type to be edited.
2. Hover over a contour then grab and move a control point.



3. When needed, hover over the contour and click on the line. This will add a new point.

Re-draw TAVI Contour

If necessary, use the **Re-draw contour** button to replace the existing contour. This procedure is used for rare cases when the contour is completely off.

1. Select the contour type to be re-drawn.
2. Click the **Re-draw contour** button.
3. On the active image, click the location where the first contour point is to be inserted.
4. Click the image to add contour points.
5. Double-click when the last point is added.
6. Edit the contour as needed.

Define Additional TAVI Measurements

Some measurements are not automatically extracted. For example, the 3 maximum diameters at the level of the sinus of Valsalva. You can draw those measurements manually (to show them in the **Review Results** table) using the **Draw measurement** tool.

NOTICE

For information on using the **Draw measurements** tools, see **CT Review > CT Common Tools**.

1. Select one of the options from the **Draw measurements** menu.
   - Line
   - Circle
   - Ellipse
   - Spline contour
   - Freehand contour
2. Draw the measurement.
3. Enter the measurement name or select a name from the menu.
4. To edit the measurement name, right-click on it.

TAVI-related Measurements

Measurements related to access-rout assessment should be performed within the AVA application.

Measurements related to access-rout assessment for calcium scoring should be performed within the Calcium Scoring application.

Review TAVI Planning Results

WARNING

Before reviewing results, you must review, edit (if required), and accept all measurements. See section “Verify and Edit Automatic Measurements” on page 421.

The review enables you to:

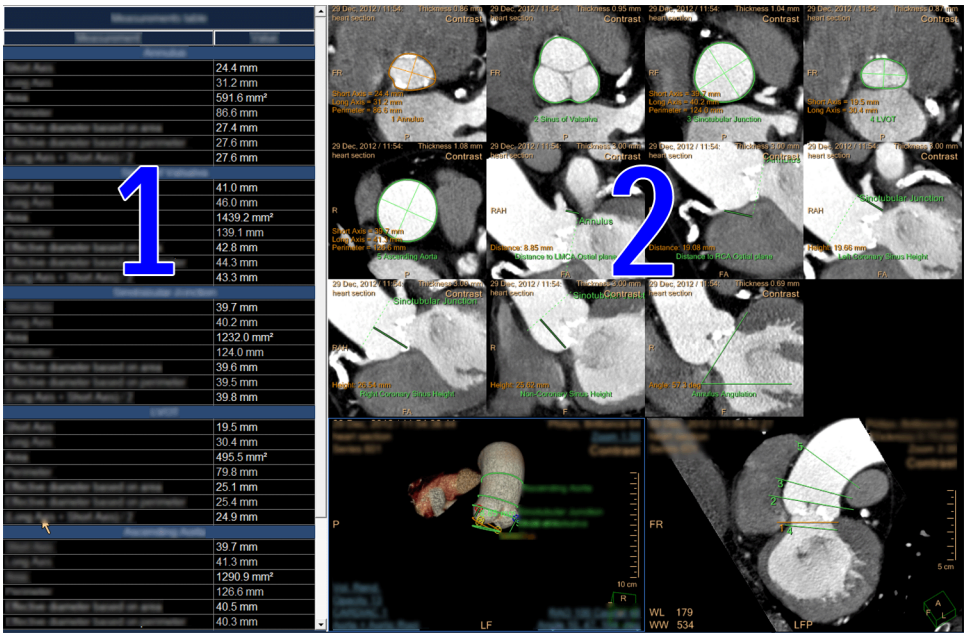
- Display the cross sectional measurements required for device sizing.
- Display the distances to ostia measurements.
- Display a set of optimal CathLab angles.

NOTICE

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

Results Summary View

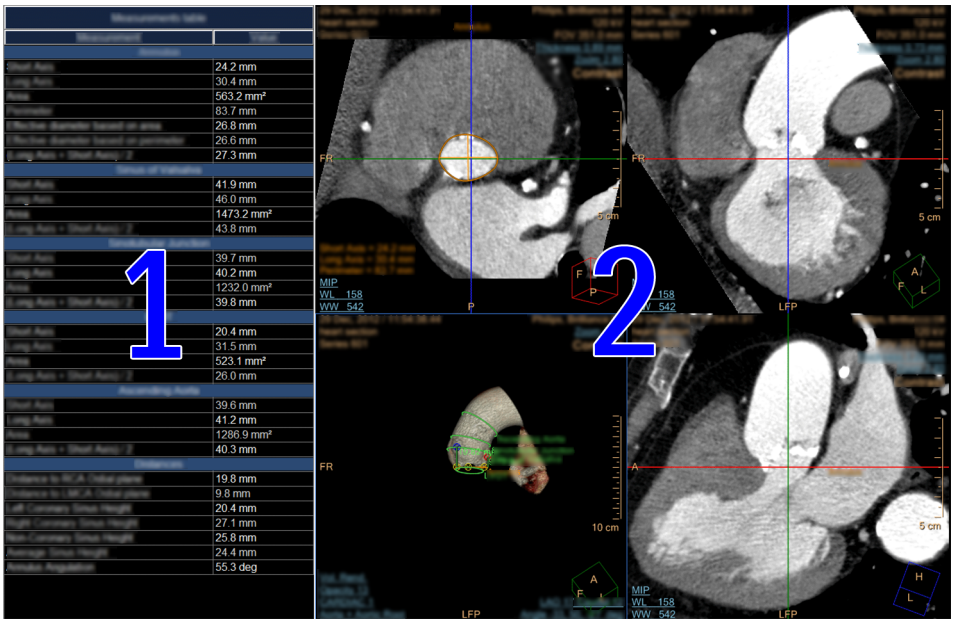
Use the **Summary Measurements Table** to view all configured measurements in the accepted planes. Select a plane from the **Tissues List** focus on it.



1. Measurements Table
2. Accepted Planes

Results Single-plane View

To examine the active plane in more detail, click the **Single Plane** radio button and select the plane from the **Tissues List**.



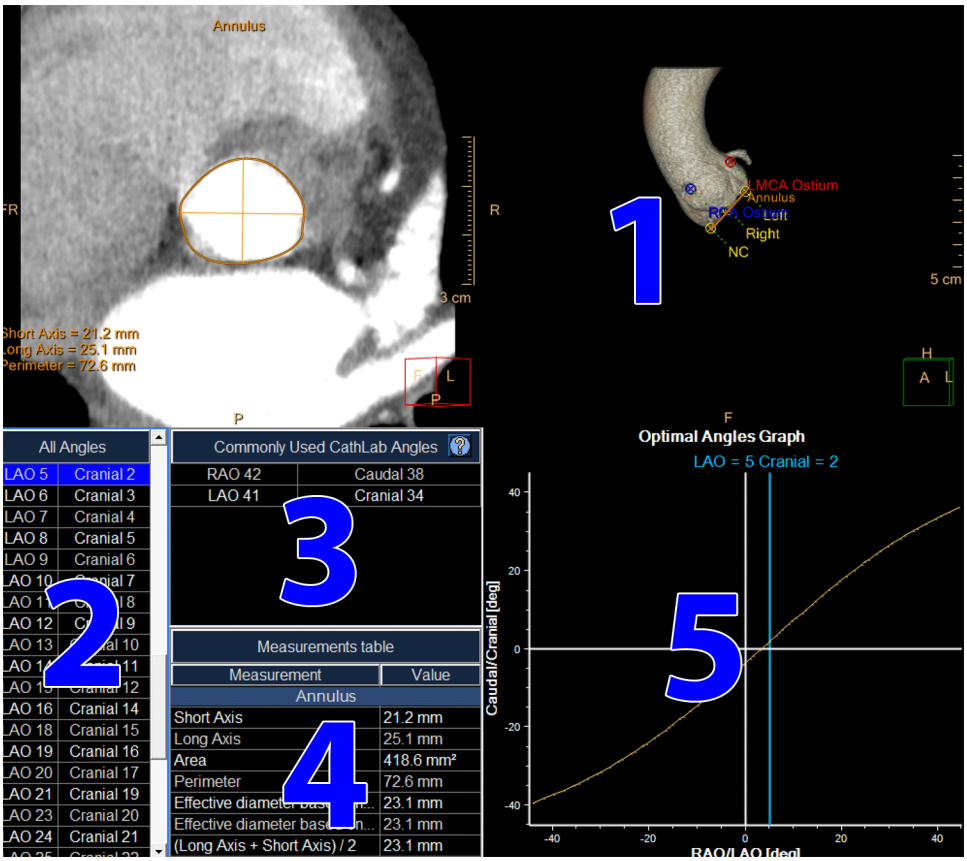
1. Measurements Table for the active plane.
2. Active plane views.

Results Optimal CathLab Angle View

NOTICE

The optimal CathLab angle correctness depends on the correctness of the annulus plane. If the annulus plane was not accepted, the Optimal CathLab angle mode is disabled.

To view CathLab orientations, select the **Optimal CathLab Angle** view.



- **Volume image (item 1 in the image).** The volume image, including landmark locations, is displayed with the VR image perpendicular to the annulus plane.
- **All Angles (item 2).** The graph shows 180 degrees of optimal angles, with the plane always perpendicular to the annulus plane. The active VR view is highlighted in blue. To view a different angle, select it from the table.
- **Commonly Used CathLab Angles (item 3).** In the table header, select the **Add Angles** button and select the angles from the menu. Configure up to 6 commonly used angles.
- **Measurements Table (item 4).** Shows the relevant measurements for the annulus plane.
- **Optimal Angles Graph (item 5).** The yellow line shows 180 degrees of optimal angles, with the plane always perpendicular to the annulus plane. The active VR view is represented by a blue vertical line. To view a different angle, grab the blue line and move it.

Cross-sectional Measurements

Measurements for Contours and Ellipse Methods
Long Axis value is calculated as the longest diameter between 2 points on the contour crossing via the centroid.
Short Axis value is calculated as the diameter perpendicular to the long axis crossing via the centroid.
Area value is calculated as the anatomical area within the contour.
Perimeter value is calculated as circumference of the contour.

Measurements for Contours and Ellipse Methods
Effective Diameter based on area is calculated from the following equation: Effective diameter=2*sqrt(Area/pi).
Effective Diameter based on perimeter is calculated from the following equation: Effective diameter= Perimeter/pi.
Average diameter: (Long Axis + Short Axis)/2.

Measurements for Circle Method
Long Axis value is calculated as the diameter of the bigger circle.
Short Axis value is calculated as the diameter of the smaller circle.
Maximum Area value is calculated as the anatomical area within the bigger contour.
Minimum Area value is calculated as the anatomical area within the smaller contour.
Maximum Perimeter value is calculated as perimeter of the bigger contour.
Minimum Perimeter value is calculated as perimeter of the smaller contour.
Average diameter: (Long Axis + Short Axis)/2.

Other Measurements

Distances
Distance to RCA Ostium- the shortest distance between the annulus plane and the RCA Ostium
Distance to LMCA Ostium - the shortest distance between the annulus plane and the LMCA Ostium
Left Coronary Sinus Height - the shortest distance between the Left Sinus Landmark and the Sinotubular junction plane
Right Coronary Sinus Height - the shortest distance between the Right Sinus Landmark and the Sinotubular junction plane
Non- Coronary Sinus Height - the shortest distance between the non-Coronary Sinus Landmark and the Sinotubular junction plane
Average Sinus height - the average between the left, right and non-coronary sinus heights
Annulus Angulation - the angle between the annulus plane and the axial plane

881 * 2021-06-30

Philips

Configure Review Measurements

Click the button to configure the list of measurements to show per plane in the table and on the MPR images.

- Select a plane and define which measurements should be displayed in the table and on the MPR image.
- Define the default type of contour for each plane by selecting it from the drop-down.
- Use the **Show diameters graphics** checkbox to either show or hide the diameter lines on the planes.
- Set the default distance between the annulus plane and the ascending aorta plane (default is 4.5 cm).

NOTICE

The Ascending Aorta plane is NOT updated automatically after editing the Annulus plane.

NOTICE

Any changes will be applied the next time the application is loaded.

Report TAVI Results

1. To send the results to a report, use the **Report clinical results** button from the drop-down menu.

2. Configure the **Risk Factors**, **Clinical History**, and **Patient Parameters and Information** as required.
3. Provide any additional information such as the aortic valve type and the amount if calcification in the aortic root.

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

Access Route Assessment Stage

The Access Route Assessment Stage includes the following:

- Extract Vessels - Options available include:
  - Creating a New Vessel
  - Edit/Extend centerline

- Measure Vessel Diameters - Options available include:
  - Manually measure diameters
  - Automatic extraction of diameters

Extracting Vessels

Centerline Creation Methods

The following methods for creating a centerline are available:

- Semi-automatic aorta-illiac tree creation mode.
- Semi-automatic creation mode.
- Manual creation mode.

Auto track sequence mode is recommended; this mode automatically locates the center of the vessel as you place seed points.

Manual centerline creation mode can be used if auto track sequence mode is not successful (for example, when using low quality data sets, or data sets with difficult anatomies such as vessels close to bone).

Creating a Centerline for the Aorta-Iliac Tree

You can use the aorta-iliac tree creation mode to extract the aorta and both iliacs.

NOTICE

This function only works with the Aorta & Iliacs vessels.

1. In the task guidance panel, click **Aorta-Iliac Tree**.
2. In the volume view, click to place a point in each of the three vessels.

3. When the tree is correctly defined, click **Accept** in the task guidance panel.

⇨ The aorta-iliac tree is connected with a bifurcation point and it is automatically named and displayed in the vessel list.

4. If desired, drag the bifurcation point to correct its position.

⇨ You can also double-click the last centerline point to finish tree creation.

Extracting Any Vessel

1. In the task guidance panel, select a centerline creation tool:
   -  **Semi-Automatic Centerline**

-  **Manual Centerline**

⇨ The procedure for creating a centerline is the similar for both tools, with the following difference:

- In **Semi-Automatic Centerline** mode seed points are centered in the vessel and the centerline is tracked along the vessel after all seed points have been placed.
- In **Manual Centerline** mode seed points are also centered in the vessel (in the depth direction only), and a new centerline segment is created using a smooth curve. This mode is more effective for vessels that are highly curved or that are close to bone.

2. Place a seed point by clicking in the volume image or in one of the MPR images.

⇨ All images display the last entered seed point location.

3. Continue following the centerline by placing seed points on any of the available images.

4. If desired, you can undo the most recently placed point by clicking **Undo** in the task guidance panel.

5. When the centerline is defined, click **Accept** in the task guidance panel.

⇨ You can also double-click the last centerline point to finish centerline creation.

6. Enter a name for the vessel in the vessel naming dialog box.

⇨ The vessel list is updated with the new vessel.

Editing Centerlines

WARNING

Verify the accuracy of the vessels and their labels. If needed, use the manual tools provided in this step to correct vessel extractions and labels.

You can correct centerlines if they are not positioned in the center of the vessel lumen or if they do not extend far enough along the vessel. For CT studies, you can also connect centerlines.

The following editing tools are available:

- Edit
- Extend

Editing Vessels in the Vessel List

At the top of the task guidance panel is the vessel list. Right-click on a vessel in the vessel list to access the following functions:

- **Delete vessel**

  Select this function to delete the selected vessel.

- **Rename vessel**

This selection opens the vessel labeling dialog box. Select a vessel name from the active group or enter a vessel name in the text box. If the wrong vessel list is displayed in the vessel labeling box, you can switch to the desired list by clicking **Switch to Body (or Head) vessels list** in the vessel labeling box.

Editing a Centerline

You can edit a centerline if it does not pass through the center of the vessel lumen.

1. Select the centerline that you want to edit.

2. In the task guidance panel, click **Edit**.

⇨ Seed points are displayed on the selected centerline.

⇨ The **Edit** tool allows you to edit the centerline be relocating the seed points.

3. Select a seed point.

⇨ The selected point is highlighted in the curved/MPR image, and the cross section image is updated to the seed point position. In the cross section image, the seed point is indicated with an "x".

4. Drag the seed point to the correct position.

⇨ You can drag the seed point in any of the available images.

5. To create a new seed point, click at the desired position on the centerline.
6. To delete a seed point, drag it over another seed point on the centerline.

7. To complete the centerline edit, click **Accept** in the task guidance panel.

Extending a Centerline

1. Select the centerline that you want to extend.

⇨ You can extend the centerline from either end of the existing centerline.

2. Select one of the following tools in the task guidance panel:

-  Click **Extend Superior** to extend the centerline from the superior end. Selecting this tool automatically places the inspection ring at the superior end and reference images are updated accordingly.
-  Click **Extend Inferior** to extend the centerline from the inferior end. Selecting this tool automatically places the inspection ring at the inferior end and reference images are updated accordingly.

⇨ For CT studies, regular MPR images are displayed.

NOTICE

You can extend the vessel at either end using each of these tools; whenever you place a point it is automatically connected to the closest existing point. However, selecting the tool for the direction in which you want to extend the vessel displays appropriate reference images before placing the first point. If you continue extending the centerline at the other end of the vessel, reference images are flipped after placing the next point.

3. Place a point to extend the centerline.

⇨ The point is automatically adjusted to the center of the vessel lumen and the reference images are updated.

4. Continue placing points to extend the centerline as desired.

5. When the centerline is defined, click **Accept** in the task guidance panel.

⇨ The edited centerline is calculated.

⇨ After extending a centerline, you do not need to update measurements performed on the original centerline.

Measuring Vessel Diameter

Manual Measurement

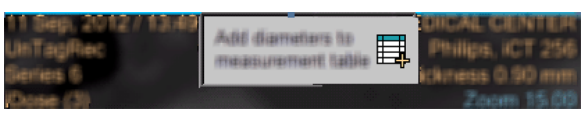
1. Identify the cross section for measuring the min/max diameter.
2. Select the  **Measure diameters** option.

   It is also possible to select the icon from the cross-sectional image viewport.
3. Draw two lines on the cross section image.

Measuring Using Automatic Lumen

Another way to extract the minimum and maximum diameter of a cross sectional image, is by using the auto Lumen contours. Once activated the automatically calculated contours appear on the CS and sMPR image, the min and max will be calculated from the contour and displayed.

1. Select the  **Show/Edit auto-lumen contours** icon (and auto diameters) to enable/ disable the Contours.
2. Identify the cross section for measuring the min/max diameter.
3. Once the relevant cross-sectional image is identified, select the icon from the cross-sectional image viewport **Add Diameters to Measurement Table**.



Measurement Table

Once measurements are completed, select the **Measurement table** option to view the measurement table and the relevant CS image, together with the VR image.

881 * 2021-06-30

Philips