

QTavi 1.0

User Manual



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Regulatory Information

Intended Use

QTavi is software intended to be used for the visualization and analysis of CT images of the heart and blood vessels, to support the planning and evaluation of trans-catheter aortic valve implantation / replacement (TAVI or TAVR) procedures.

QTavi is intended to support the following visualization functionalities:

- double oblique review of CT Angiographic images
- performing caliper measurements

QTavi is also intended to support the following analyses:

- quantification of the anatomy both in and around the aortic root, providing aortic annulus / annular plane dimensions, and distances between aortic vessel landmarks

These analyses are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing. The results obtained are displayed on top of the images and provided in reports.

The analysis results obtained with QTavi are intended for use by cardiologists and radiologists to support clinical decisions concerning the planning and evaluation of TAVI or TAVR procedures.

Indications for Use


QTavi is indicated for use in clinical settings where more reproducible than manually derived quantified results are needed to support the visualization and analysis of CT images of the heart and blood vessels for use on individual patients with cardiovascular disease.


When the quantified results provided by QTavi are used in a clinical setting on CT images of an individual patient, they can be used to support the clinical decision making for the diagnosis of the patient. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

Limitations


Currently no limitations have been specified for QTavi 1.0.

WARNINGS


 QTavi must be used by cardiologists, radiologists, or trained technicians who are qualified to perform TAVI/TAVR pre or post processing analysis. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. In clinical practice QTavi should not be used for purposes other than those indicated in the section Intended Use.

 Users must have sufficient proficiency in the English language, read this manual, become familiar with the software, and must be certified by Medis before using QTavi in a clinical environment in order to obtain reliable analysis results.

Note on Monitor Aspect Ratio and Resolution

 The shapes of objects and calipers displayed may be slightly distorted when the resolution is set to an aspect ratio different than the monitor's physical aspect ratio. This distortion does **NOT** affect the accuracy of measurements or analyses. To avoid distortion, set the resolution of the monitor to an aspect ratio equal to the physical aspect ratio. LCD monitors typically operate best at their native resolution. Microsoft Windows recommends a resolution when it has sufficient information to do so.

European Regulations

 <p>1639</p>	<p>QTavi is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.</p>
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North American Regulations

QTavi has not yet been cleared for market in the United States by the FDA (Food and Drug Administration) under the provisions of Section 510(k) of the Food, Drug, and Cosmetic Act. Clearance is pending.

QTavi complies with the requirements of the Canadian Medical Devices Regulations and has been licensed as a Class II medical device.

Conventions Used

The following conventions and acronyms are used throughout this manual to indicate mouse and keyboard actions and to refer to elements in the user interface.

TAVI Refers to both TAVI (Transcatheter Aortic Valve Implementation) and TAVR (Transcatheter Aortic Valve Replacement).

Mouse

Click Press and release the primary mouse button. If you are left-handed, you may have set the right mouse button as your primary mouse button.

Click and drag Press and hold the primary mouse button. Drag the mouse to perform a function. Release the primary mouse button. If you are left-handed, you may have set the right mouse button as your primary mouse button.

Right-click Press and release the secondary mouse button. If you are left-handed, you may have set the left mouse button as your secondary mouse button.

Middle-click Press and release the wheel button or the middle mouse button. If you have a two-button mouse, press and release the left and the right mouse button simultaneously.

Double-click Press and release the primary mouse button twice.

Wheel Rotate the mouse scroll wheel.

Keyboard

SHIFT/CTRL+click Press and hold down the SHIFT/CTRL key on your keyboard while you click a button or object.

CTRL+K Press and hold down the CTRL key on your keyboard while you press K, then release both keys.

Typographical Conventions

On the Annotations node of the Results pane... Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold.

Procedures > Text Annotation A sequence of menu options that you select to perform a specific task is indicated by angular brackets.

View > Movie

A sequence of menu options that you select to perform a specific task, is indicated by angular brackets.

Label: `Aortic root`

Text that you type or that appears on the screen, such as annotation labels, is displayed in `Courier New`.

On the **Display** tab, select the **Hide all drawings** option.

Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold.

Symbols Used



Reference: Points to related documentation, or to related sections in this document, that may be relevant to your situation.



Tip: Provides helpful information or an alternative working method.



Note: Promotes additional information.



Caution: Tells you to be careful when performing a task.



Warning: Warns you of a potentially dangerous situation in the image representation or analysis, which may lead to incorrect results. You are advised to follow the instructions to avoid this.

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1 About QTavi

QTavi is the Medis software solution designed to support the planning or evaluation of TAVI or TAVR procedures.

QTavi supports cardiologists, radiologists, or trained technicians, to select the appropriate oblique views of the Aortic root, before defining anatomical measurements that are required both for planning and/or evaluation of Aortic Root procedures.

QTavi runs as an app in the Medis Suite product. The functionality of Medis Suite, including instructions on how to start QTavi and load image data, is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Click F1.
- Pushing the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help > User Documents**

1.1 QTavi Usage

QTavi allows the quantification of the following anatomical entities.

- Aortic Annulus / annular plane and dimensions (area, diameter)
- The angle from the horizontal plane to the Annulus plane.
- Angulation: Coronary angiography angles.
- Distance of the Coronary Ostia (LCO and RCO) to the Annulus plane.
- Left Ventricular Outflow Tract (LVOT) (area, distance)
- Sinus of Valsalva (area, distances).
- Sinus distances (LCS, RCS and NCS)
- Sinotubular junction (area, diameter)
- Distances (LCC, RCC and NCC) from the top of the cusps to the Annulus plane.
- Ascending aorta (area, diameter)

2 System Requirements

2.1 Hardware

QTavi:

- Intel or compatible quad-core processor
- 4 GB of RAM
 - If you are using larger image sets, particularly with multiple time points, please ensure you have adequate memory.
- 250 GB of available hard disk space
(if you want to store images locally, make sure you have enough disk space)
- 3-button mouse, scroll-wheel recommended
- A USB port or network connection to transfer the installer to the system
- Widescreen monitor supporting a minimum resolution of 1920x1080 pixels
- Video card supporting OpenGL and with 512 MB memory
- Network interface card of at least 100MBit/s to access, receive, and send images over the network

Sentinel license server:

- Intel or compatible processor with a minimum speed of 550 MHz
- 128 MB of RAM
- 1 GB of available hard disk space
- Network interface card

NOTES:

- All hardware must be compliant with the operating system
- For the license server, a PC with a fixed IP address or a reserved IP address in the DNS server is strongly recommended

2.2 Operating System

QTavi: 64 bit version is the preferred configuration


- Microsoft Windows 7, SP1, 32 and 64 bit version
- Microsoft Windows 8.1, 32 and 64 bit version
- Microsoft Windows 10, 32 and 64 bit version
- Microsoft Windows Server 2008 R2, SP1, 64 bit version
- Microsoft Windows Server 2012 R2, 64 bit version
- Microsoft Windows Server 2016, 64 bit version

Sentinel license server:

- Microsoft Windows 7, 32 and 64 bit version
- Microsoft Windows 8, 32 and 64 bit version
- Microsoft Windows 8.1, 32 and 64 bit version
- Microsoft Windows 10, 32 and 64 bit version
- Microsoft Windows Server 2008, 32 and 64 bit version
- Microsoft Windows Server 2008 R2, 64 bit version
- Microsoft Windows Server 2012, 64 bit version
- Microsoft Windows Server 2012 R2, 64 bit version
- Microsoft Windows Server 2016, 64 bit version

3 Support

Medis is committed to offering high-quality products and services. If you have questions about the software, or if you would like to make suggestions for improvements in the software or in the documentation, please contact the Medis helpdesk.

If you contact the Medis helpdesk by e-mail, mention the name of the software and the version number in the subject field. To look up the version number of your software, select  > **Help** > **About...**

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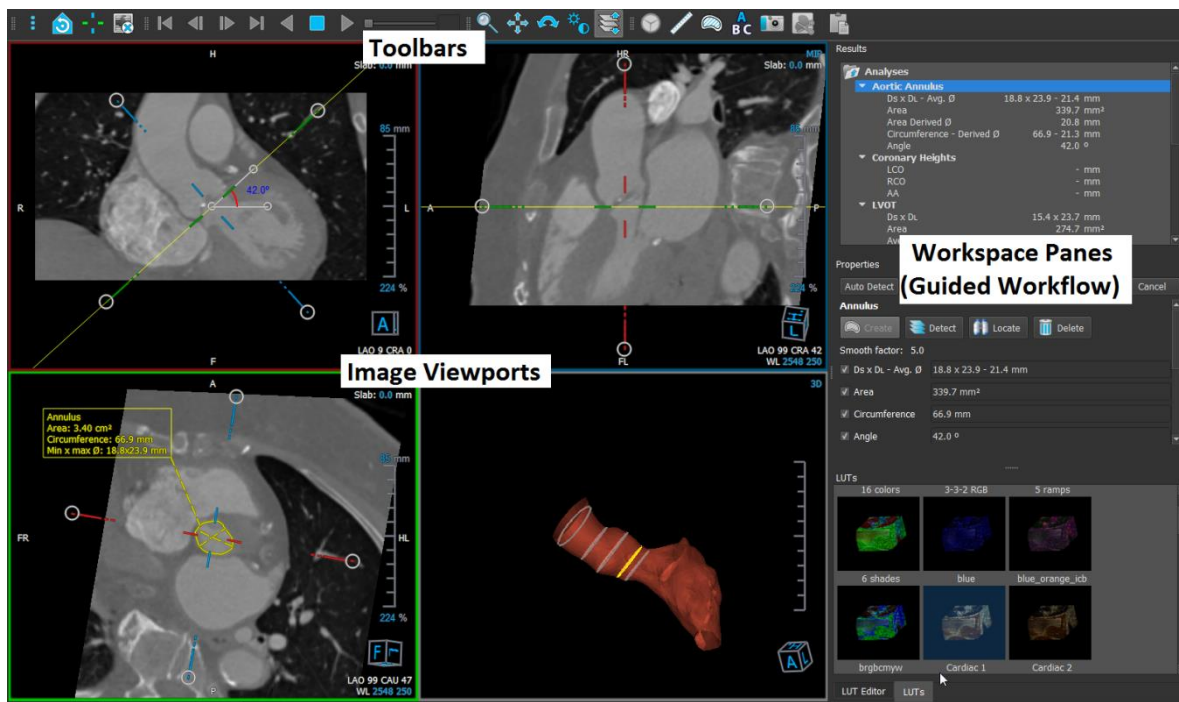
4 The QTavi Workspace

This chapter covers the following topics:

- Overview
- Menu bar
- Toolbars
- Workspace panes
- Viewing

4.1 Overview

The main workspace consists of a menu bar, toolbars, several workspace panes, and the central window area with Double Oblique/3D/MIP/VR image viewports.



You can customize the workspace by hiding, resizing or moving the workspace panes and toolbars. Any changes that you make to the workspace are saved for each individual Windows user.

4.2 Menu


The menu contains commands to activate the application functionality.

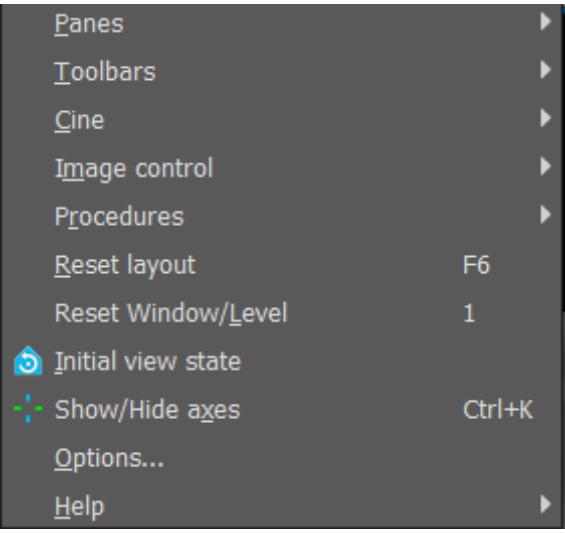
To make the menu visible:

- Click on the menu icon  in the **General** toolbar.

The menu commands are organized into the following main menus; **Panes**, **Toolbars**, **Cine**, **Image Control**, **Procedures** and **Help**.

In addition there are menu items; **Reset layout**, **Reset Window/Level**, **Initial View State**, **Show/Hide axes** and **Options**. For some of these commands, tool buttons are available in the toolbars as shortcuts.

 Menu commands may be grayed out when you are performing a procedure, such as a single vessel analysis. You can make the menu commands active by canceling or finishing the procedure.


Menu	Command	Description
	Panes	Show or hide a workspace pane
	Toolbars	Show or hide a toolbar
	Cine	Control the frame selection
	Image Control	Control the image display
	Procedures	Start a new procedure
	Help	User documentation and About
	Reset layout	Reset the default layout
	Reset Window/Level	Reset the default window/level
	Initial view state	Reset the view state
	Show/Hide axes	Enable/disable crosshair axes
	Options	Application default settings

4.3 Toolbars

You can move toolbars to another part of the main window. You can also show or hide toolbars.




To move a toolbar:

- Click on the double-bar grip handle  of the toolbar and drag it.

You can now move the toolbar to any location on the sides of the main window. Simply click and drag the toolbar to its new position. The position of the toolbar is saved when you close the application.





To show or hide a toolbar:








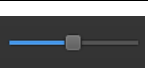





- Select  > Toolbars.
- Select a check box to show the toolbar, clear a check box to hide the toolbar.







Or,

- Right-click in the toolbar area. This opens a context menu.
- Select a check box to show the toolbar, clear a check box to hide the toolbar.

The state of the toolbars is saved when you close the application.

Icon	Function
General Toolbar	
	Show the menu
	Go to the initial view state, reset zoom \ pan \ window width \ window level
	Crosshair Axes. Indicates the relative position of the other oblique viewports
	Toggle image overlay

Icon	Function
Cine Toolbar	
	Go to the first frame
	Go to the previous frame
	Go to the next frame
	Go to the last frame
	Play a cine in backward direction
	Stop the cine
	Play a cine in forward direction
	Set the cine playback speed
Mouse Controls Toolbar	
	Stack
	Zoom
	Pan
	Window width and window level
	Rotate (only if the 3D viewport is selected)

Icon	Function
Procedures Toolbar	
	Start an Aortic Root procedure
	Create a distance measurement
	Create an area measurement
	Create a text annotation
	Create a snapshot
	Copy all measurement results to the clipboard


4.4 Workspace Panes

By default, the workspace displays the following panes to the right of the image viewports:

- Results
- Properties
- LUTs
- LUT Editor

You can show or hide panes, dock panes, combine panes into one tabbed panel and remove panes from a panel.

To show or hide a pane:

- Select  > **Panes**, and select a hidden pane to show it, or select a visible pane to hide it.

To dock a pane:

1. Click and drag the title bar of the pane.
2. Move the pane to the sides of the viewer window to select one of the dock areas.

As the pane approaches a dock area, the area is highlighted with a dotted line. The pane can be combined with another pane or inserted separately.

3. When the dock area of your choice appears highlighted, release the mouse button.

This docks the pane into the selected position.

To combine panes into one tabbed panel:

- Click and drag the title bar of the pane to the title bar of the pane with which you want to combine it.

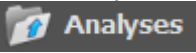
This creates a tabbed panel.

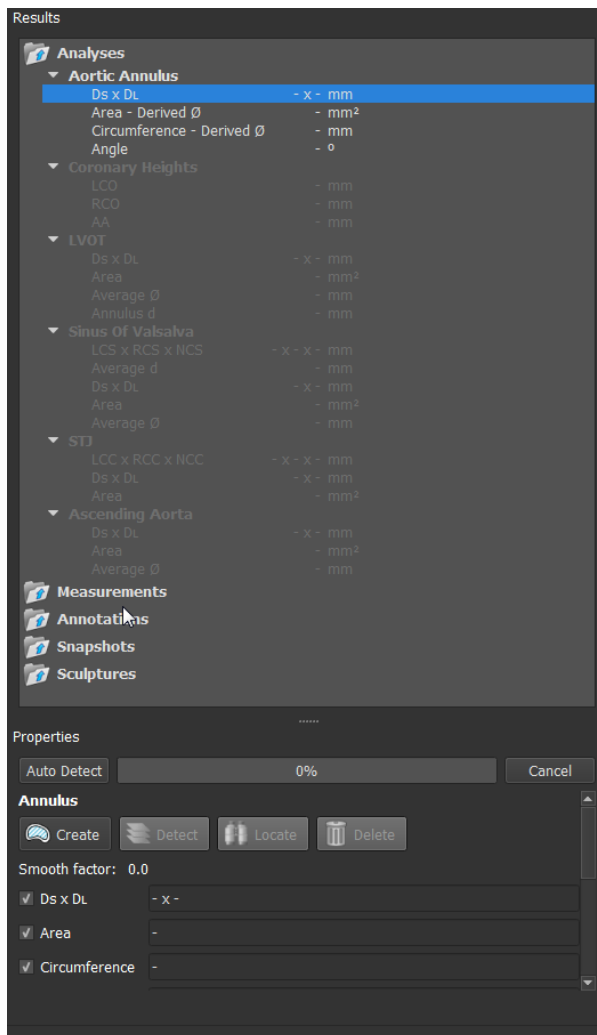
To remove panes from a panel:

- Click and drag the title bar of the pane away from the panel.

4.4.1 Results pane

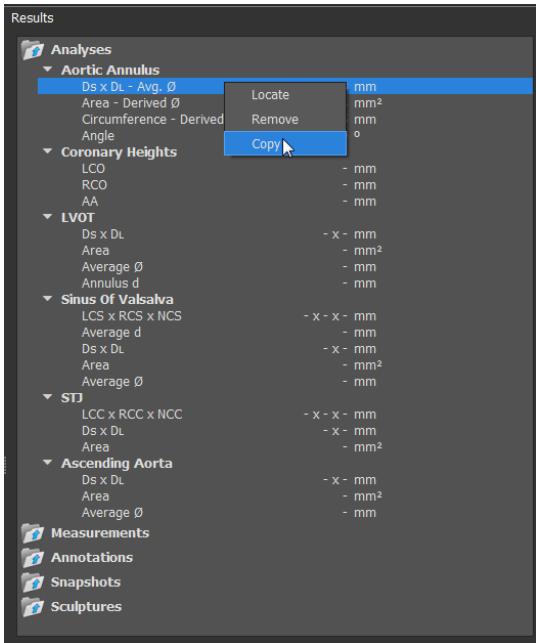
The **Results pane** has two purposes in QTavi.

- It shows standard procedures, i.e. measurements, annotations and snapshots performed on the series that is loaded in the viewport.
- Under the Analyses folder  the Aortic Root procedure can be managed by selecting one of the top down guided workflow Aortic Root analysis steps.



You can collapse and expand an item by clicking it.

You can right-click a procedure to perform actions on the procedure. Depending on the type of procedure, you will get a context menu with several options. The options are only enabled when the measurement for that procedure or guided workflow results exists.



Locate: The image and the image orientation at which the procedure was originally performed will be activated. Locate is automatically done for QTavi analysis steps when you select a step.

⚠ **Locate** may be grayed out. This menu item is activated by cancelling or finishing the active procedure.

Copy: The annotation label, distance measurement and value, area measurement and values, or the snapshot image is copied to the clipboard.

Remove: The procedure is deleted.

Activate analysis step: Click on the desired analysis step, in the **Results** pane.

4.4.2 Properties Pane

The **Properties** pane shows the properties of the selected procedure. You can modify the QTavi analysis steps or the standard procedures, i.e. measurements, annotations or snapshot procedures.

Using the **Properties** pane you can edit the properties of the measurements, annotations and snapshots in addition to editing properties of the actively selected step of the QTavi analysis.

4.4.2.1 Properties: Aortic Root analysis

QTavi analysis steps are individually activated by clicking the step in the Results pane. Once selected, the corresponding **Properties** pane is shown.

From the **Properties** pane of the active step, all the measurements can be created, located or deleted. The **Properties** pane shows all measurement details that pertain to that step.

The **Properties** pane allows you to choose whether to display or hide the details of measurements that are to be shown in the **Procedures** (Results) pane.

ⓘ All steps of the guided workflow will be activated once the Annulus plane contour is drawn.

To start and to modify a step in the Aortic Root analysis steps:

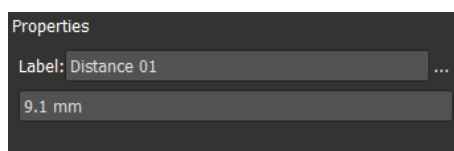
1. On the **Results** pane, select the appropriate analysis step.

4.4.2.2 Properties: Calipers, Annotations and Snapshots

The **Properties** Pane defines both labels and details of the procedure.

To modify a label (Measurements, Annotations and Snap-Shots):

1. On the **Results** pane, select the procedure.
2. On the **Properties** pane, click the ellipsis **...** on the right of the **Label** field and select a predefined label, or type a custom label and press Enter.



Properties

Label: Stent_MPA (2)

29.8 mm

- PV annulus (1)
- PV annulus (2)
- TV annulus (1)
- TV annulus (2)
- MV annulus (1)
- MV annulus (2)
- AV annulus (1)

- Veins ▶
- Pulmonary ▶
- Aorta ▶
- Valves ▶**
- RVOT ▶
- Defects ▶
- Coronaries ▶
- Stents ▶
- Pericardial Thickness ▶

5 Viewing

5.1 Loading Images

Images can be loaded into QTavi from the **Series Browser** of Medis Suite. Refer to the Medis Suite user manual for detailed instructions.


To load images from the Series Browser of Medis Suite

1. Click an item in the image view or text view of the Medis Suite **Series Browser** to select it.
2. Click and drag the selected item onto any viewport.

Or,

1. Double click an item in the image view or text view of the Medis Suite **Series Browser**.


This will load the image into the viewport. A Cine will start playing to present all individual image frames.

 QTavi only loads CT DICOM images.

5.2 Viewports

The viewport text overlay displays detailed information about the patient, the hospital, the image acquisition, and the display settings.

To show or hide the patient and image information:

- Select  > **Options, Hangings**.
- Select or deselect **Show patient information** or **Show image information**.

To maximize an image in the viewport:

- Double-click the image.

This maximizes the image, so that it takes up the entire viewport.



To return to the original viewport layout, double-click the image again.

 Interactive graphics are displayed in blue color  and allow you to change image or display properties with your mouse.




5.3 Frame selection

You can move forward or backward through frames in the image in several ways.



Moving through frames can be done by using buttons:

- Click  or  on the Viewing toolbar to move to the previous or next frame.

Or,

- Click  or  on the Viewing toolbar to play a cine through the frames in backward or forward direction. Click  to stop the cine.

Or,

- Click  or  on the Viewing toolbar to move to the first or last frame.

Moving through frames can be done by using keys:

- Press the left or right arrow key to move to the previous or next frame.

Or,

- Press CTRL + left arrow, CTRL + right arrow to play a cine through the frames in backward or forward direction. Press Esc to stop the cine.

Or,

- Press HOME or END to move to the first or last frame.

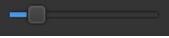
Moving through frames can be done by using interactive graphics:

- Click the interactive graphics for frame selection ('Frame') on the viewports to move to the next frame.

Or,

- Right-click the interactive graphics for frame selection ('Frame') and enter the desired frame number.




The cine speed can be modified with the slider  in the Viewing toolbar.

5.4 Mouse Controls

5.4.1 Stacking

You can move through the frames using **Stacking** when you see the stack cursor .

To activate the stacking mouse control:

- Click  in the mouse controls toolbar.

Or,


- Select **Stacking** from the viewport context menu.

To stack forward or backward through frames:

- Click and drag the mouse left and right or down and up to scroll through the frames. It will loop to the first or last frame.

Or,


- Independent of the stacking mouse control status, you can scroll the mouse wheel to stack through the frames. It will stop at the first or last frame.

 The current frame number is displayed on the overlay graphics in the viewport ('Frame:').

5.4.2 Zooming

You can zoom in and out of the viewport using **Zooming** when you see the magnify cursor .

To activate the zooming mouse control:

- Click  in the mouse controls toolbar.

Or,

- Select **Zooming** from the viewport context menu.

To zoom in and out:

- Click and drag the mouse forward and backward to zoom in and out.

Or,


- Independent of the zooming mouse control status, you can click and drag on the interactive zoom scale graphics, or hold Ctrl and scroll the mouse wheel up and down, to zoom in and out.




The current zoom factor is displayed on the scale graphics in the viewport. The value above the scale is the physical size of the scale. The number below the scale indicates the relative zoom: 100% means one display pixel equals one acquisition pixel.



5.4.3 Panning

You can move the image within the viewport left, right, up and down using **Panning** when you see the hand cursor .

To activate the panning mouse control:

- Click  in the mouse controls toolbar.

Or,

- Select **Panning** from the viewport context menu.


To pan the image:

- Click and drag the mouse in any direction.


Or,

- Independent of the panning mouse control status, you can middle-click and drag the mouse in any direction to pan the image.

5.4.4 Window Width and Level

You can adjust the window width and level (WWL) when you see the WWL cursor .

To activate the window/level mouse control:

- Click  in the mouse controls toolbar.

Or,

- Select **Window/Level** from the viewport context menu.

To adjust the window width and level:

- Click and drag
 - Right or left to increase or decrease the width.
 - Down or up to increase or decrease the level.

Or,


- Independent of the window/level mouse control status, right-click and drag
 - Right or left to increase or decrease the width.
 - Down or up to increase or decrease the level.

Or,

- Independent of the window/level mouse control status, click on the window width or level interactive graphics and drag up or down to increase or decrease the window width or level.


Or,

- Independent of the window/level mouse control status, right-click on the window width or level interactive graphics and enter the desired values.

 The current window width and level values are displayed in the lower-right overlay graphics in the viewport.

5.4.5 Initial View State

To reset the zooming, panning and window width and level settings to the initial view state:

- Click  to reset the zooming, panning and window width and level.

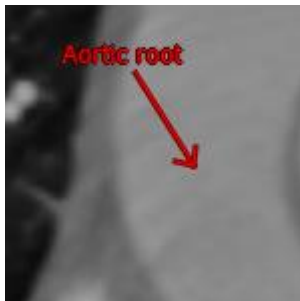
6 Standard measurements


QTavi supports the following standard measurements:

- Annotations,
- Distance measurements,
- Area measurements,
- Snapshots.

6.1 Annotations

You can add annotations to a viewport to mark it for analysis or to draw attention to specific details. Annotations are displayed in the viewport. All annotations of the active study are listed on the **Results pane**.

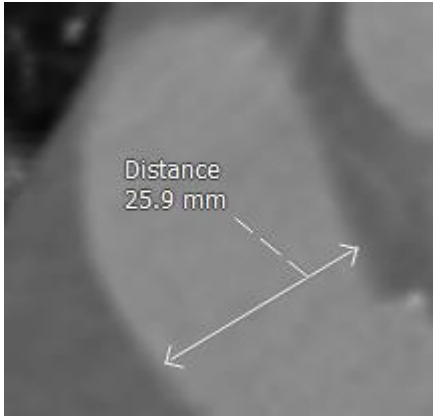



 When you select another series or navigate to another time point in the active series, your annotation is no longer displayed in the viewport. This is because the point to which the annotation refers does not lie on the currently visible image. To see your annotation again, right-click on the annotation on the **Results pane** and select **Locate**; or double-click on the annotation on the **Results pane**.

For details on creating, editing and deleting annotations, see the *Medis Suite User Manual*.

6.2 Distance Measurements

You can measure the distance from one point to another. When you have measured a distance, you can modify the annotation and the end points of the measurement. All distance measurements of the active study are listed on the **Results pane**. All distance measurements of the active session are listed on the **Results pane** of *Medis Suite*.




 When you select another series or navigate to another time point in the active series, your distance measurement may not be displayed on the viewport. This is because the points between which you measured do not lie on the currently visible image. To see your measurement again, right-click on the measurement on the **Results pane** and select **Locate**; or double-click on the measurement on the **Results pane**.

For details on creating, editing, and deleting distance measurements and copying the results to clipboard, see the Medis Suite User Manual.

6.3 Area Measurements

You use the area measurement tool to draw and measure 2D areas. When you have measured an area, you can modify the area contour or annotation. All area measurements of the active study are listed on the **Results pane**. All area measurements of the active session are listed on the **Results pane** of Medis Suite.




 When you select another series or navigate to another time point in the active series, your area measurement may not be displayed on the viewport. This is because the image on which you measured the area is not the same as the currently visible image. To see your measurement again, right-click on the measurement on the **Results pane** and select **Locate**; or double-click on the measurement on the **Results pane**.

For details on creating, editing, and deleting area measurements and copying the results to clipboard, see the Medis Suite User Manual.

6.4 Snapshots

You can save snapshots as evidence of an analysis or diagnosis. Snapshots are displayed on the **Properties** pane, and are listed on the **Results** pane. When a snapshot is created, you can modify the name at any time.

 When you select another series or navigate to another time point in the active series, the annotations and measurements shown in the snapshot may not be displayed on the viewport. This is because the points at which the annotations and measurements were created do not lie on the currently visible image. To return to the same series and time point where a snapshot was created, right-click on the snapshot on the **Results** pane and select **Locate**; or double-click on the snapshot on the **Results** pane.


6.4.1 Creating Snapshots

You can create a snapshot of the current state of a viewport.

To create a snapshot:

1. Click  in the toolbar, or press the S key, or select  > **Procedures** > **Snapshot**.

A snapshot is taken of the active viewport.

2. On the **Properties** pane, click the ellipsis  on the right of the **Label** field and select a predefined label, or type a custom label and press Enter.

6.4.2 Deleting Snapshots

You can delete any snapshot that was created.

To delete a snapshot:

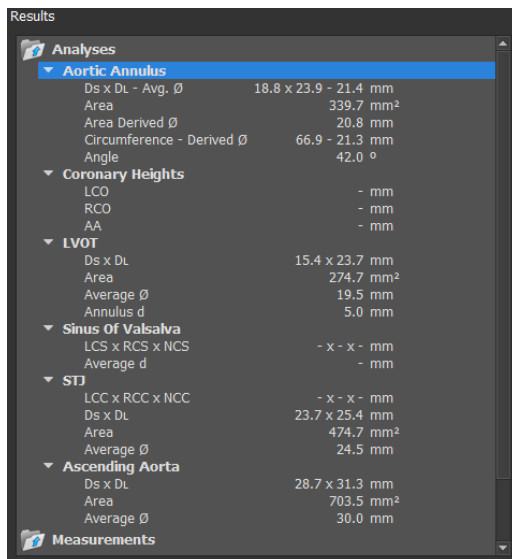
1. Select the snapshot in the Snapshots list on the **Results** pane.
2. Press Delete on your keyboard or right-click and select **Remove**.

This deletes the snapshot.

7 Performing an Aortic Root analysis

The QTavi analysis consists of multiple steps. Each Aortic root analysis step is defined in the **Results** pane.

The sequence begins with the Aortic Annulus step at the top of the pane and continues working downward. The Results pane offers a top-down guided workflow to complete an Aortic Root analysis. When an Aortic root analysis step is selected all the measurements and visibility of results of the selected step is managed from the **Properties** pane.



! All steps of the guided workflow will be activated once the Annulus plane contour is drawn.

The list of steps is as follows;

- Aortic Annulus
- Coronary Heights
- LVOT
- Sinus Of Valsalva
- Sinotubular Junction
- Ascending Aorta

7.1.1 Define the Aortic Annulus

To activate the Aortic Annulus step:

1. Click on **Aortic Annulus** in the **Results** pane.
2. Determine the position of the Annulus in the Axial viewport.

To determine the desired view state of the plane,

- Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- In the Axial viewport, scroll through the images to find the correct plane.

To define the Annulus Plane:

In the **Properties** pane,

Create the Annulus contour. See chapter 7.2 on Contour Management.

- Select or deselect a contour measurement to include or exclude it from the Results.

The Annulus contour provides the following measurements:


- **Ds x DI** : The minimal and maximal diameter of the plane.
- **Area** : The area of the plane
- **Circumference** : The circumference of the plane
- **Angle** : The angle between the horizontal plane and the Annulus plane.

7.1.2 Define Coronary Heights

To activate Coronary Heights step:

1. Click “Coronary Heights” in the **Results** pane.

To define the Measurements (LCO, RCO, and AA):

1. Determine the desired location of the LCO|RCO|AA in the Sagittal or Coronal viewport
2. In the **Properties** pane, click on  to create LCO, RCO or AA.
3. Click the position of the measurement.


A perpendicular line will be drawn from the clicked position to the Annulus plane.

To locate the Measurements (LCO, RCO, and AA):

1. In the **Properties** pane, click  to locate the view-state of the LCO, RCO or AA.

The measurement will be shown in the original orientation it was drawn.

To delete the Measurements (LCO, RCO, and AA):

1. In the **Properties** pane, click  to delete the view-state of the LCO, RCO or AA.

7.1.3 Define LVOT

To activate LVOT step:

1. Click on LVOT in the **Results pane**.
2. Determine the position of the LVOT in the Axial viewport.

To determine the desired view state of the plane,

- Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- In the Axial viewport, scroll through the images to find the correct plane.

To define the LVOT Plane:

In the **Properties** pane,

Create the LVOT contour. See chapter 7.2 on Contour Management.

- Select or deselect a contour measurement to include or exclude it from the Results.

The LVOT contour has the following measurements:

- **Ds x DI** : The minimal and maximal diameter of the plane.
- **Area** : The area of the plane
- **Circumference** : The circumference of the plane
- **Average Ø** : The average diameter.
- **Annulus d** : The distance from the LVOT plane to the Annulus plane.

7.1.4 Define Sinus Of Valsalva

To activate Sinus Of Valsalva step:

1. Click “Sinus Of Valsalva” in the **Results pane**.
2. Determine the position of the Sinus-Of-Valsalva in the Axial viewport.

To determine the desired view state of the plane,

- Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- In the Axial viewport, scroll through the images to find the correct plane.

To define the Sinus Of Valsa Plane:

In the **Properties** pane,


Create the Sinus Of Valsalva contour. See chapter 7.2 on Contour Management.

- Select or deselect a contour measurement to include or exclude it from the Results.

The Sinus Of Valsalva contour provides the following measurements:

- **Ds x DI** : The minimal and maximal diameter of the plane.
- **Area** : The area of the plane
- **Circumference** : The circumference of the plane
- **Average Ø** : The average diameter.

To define the Measurements (LCS, RCS, and NCS):

1. In the **Properties** pane, click on  to create LCS, RCS or NCS.
2. Determine the desired location of the LCS|RCS|NCS in the Axial viewport
3. Draw the distance of the Sinus.

A distance line will be drawn.

To locate the Measurements (LCS, RCS, and NCS):

1. In the **Properties** pane, click  to locate the view-state of the LCS, RCS or NCS.

The Cusp will be shown in the original orientation it was drawn.

To delete the Measurements (LCS, RCS, and NCS):

1. In the **Properties** pane, click  to delete the view-state of the LCS, RCS or NCS.

7.1.5 Define Sinotubular Junction

To activate STJ step:

2. Click “STJ” in the **Results** pane.
3. Determine the position of the STJ in the Axial viewport.

To determine the desired view state of the plane,

- Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- In the Axial viewport, scroll through the images to find the correct plane.

To define the STJ Plane:

In the **Properties** pane,

Create the STJ contour. See chapter 7.2 on Contour Management.

- Select or deselect a contour measurement to include or exclude it from the Results.

The STJ contour has the following contour measurements:

- **Ds x DI** : The minimal and maximal diameter of the plane.
- **Area** : The area of the plane
- **Circumference** : The circumference of the plane
- **Average Ø** : The average diameter.

To define the Measurements (LCC, RCC, and NCC):


1. Determine the desired location of the LCC|RCC|NCC in the Sagittal or Coronal viewport

2. In the **Properties** pane, click on  to create LCC, RCC or NCC.

3. Click the position of the Cusp.


A perpendicular line will be drawn from the clicked position to the Annulus plane.

To locate the Measurements (LCC, RCC, and NCC):

1. In the **Properties** pane, click  to locate the view-state of the LCC, RCC or NCC.

The Cusp will be shown, in the original orientation it was drawn.

To delete the Measurements (LCC, RCC, and NCC):

1. In the **Properties** pane, click  to delete the view-state of the LCC, RCC or NCC.

7.1.6 Define Ascending Aorta

To activate Ascending Aorta step:

1. Click “Ascending Aorta” in the **Results** pane.
2. Determine the position of the Ascending Aorta in the Axial viewport.

To determine the desired view state of the plane,

- Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- In the Axial viewport, scroll through the images to find the correct plane.

To define the Ascending Aorta Plane:

In the **Properties** pane,

Create the Ascending Aorta contour. See chapter 7.2 on Contour Management.

- Select or deselect a contour measurement to include or exclude it from the Results.

The Ascending Aorta contour has the following measurements:

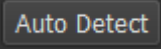
- **Ds x DI** : The minimal and maximal diameter of the plane.
- **Area** : The area of the plane
- **Circumference** : The circumference of the plane
- **Average Ø** : The average diameter.

7.2 Contour Management

A contour defines a plane. The following methods are available for creating contours.

- **Auto Detect:**
 - Creates both a detailed mesh representation of the Aortic Root, in addition to creating all contours that define all planes, e.g. Annulus plane contour.
 - Auto Detection can run prior starting QTavi, as a background process on the selected data. See chapter 9 on AutoQ preprocessing functionality for more details.
 - ❗ The user must check all automatically generated data and results.
- **Detect:**
 - From any view orientation you can “Detect” a contour for a plane.
 - ❗ Detect replaces existing contours.
Detect is only enabled after automatic detection has been run manually or via AutoQ preprocessing.
 - ❗ The user must check all automatically generated data and results.
- **Draw Contour.**
 - Hand drawn contour.

7.2.1 To Auto Detect contours

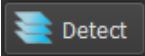
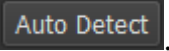
1. Click on  in the **Properties** pane.

The results of automatic detection are visible in both the 3D Viewport and the 2D viewport.

❗ To increase the speed of contour detection, you can pre-detect the contour automatically. See chapter 9 on AutoQ preprocessing functionality for more details.

❗ The user must check all automatically generated data and results.

7.2.2 To Detect a contour


The  button is enabled after the automatically generated mesh has been created by running .

- 1) Determine the desired view state of the plane,

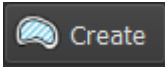
- (1) Change the view state orientation by dragging the Axes toggles in the Sagittal or Coronal viewports.
- (2) In the Axial viewport, scroll through the images to find the correct plane.

- 2) Click on  in the **Properties** pane.

The results of detection will be automatically filled in both the 3D Viewport and the 2D viewport.

 The user must check all automatically generated data and results.

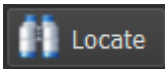
7.2.3 To draw a contour

1. Click on  in the **Properties** pane.
2. On any viewport, hold the Right mouse button down and drag to draw a contour.

7.2.4 To delete a contour

1. Click on  in the **Properties** pane.


7.2.5 To locate a contour

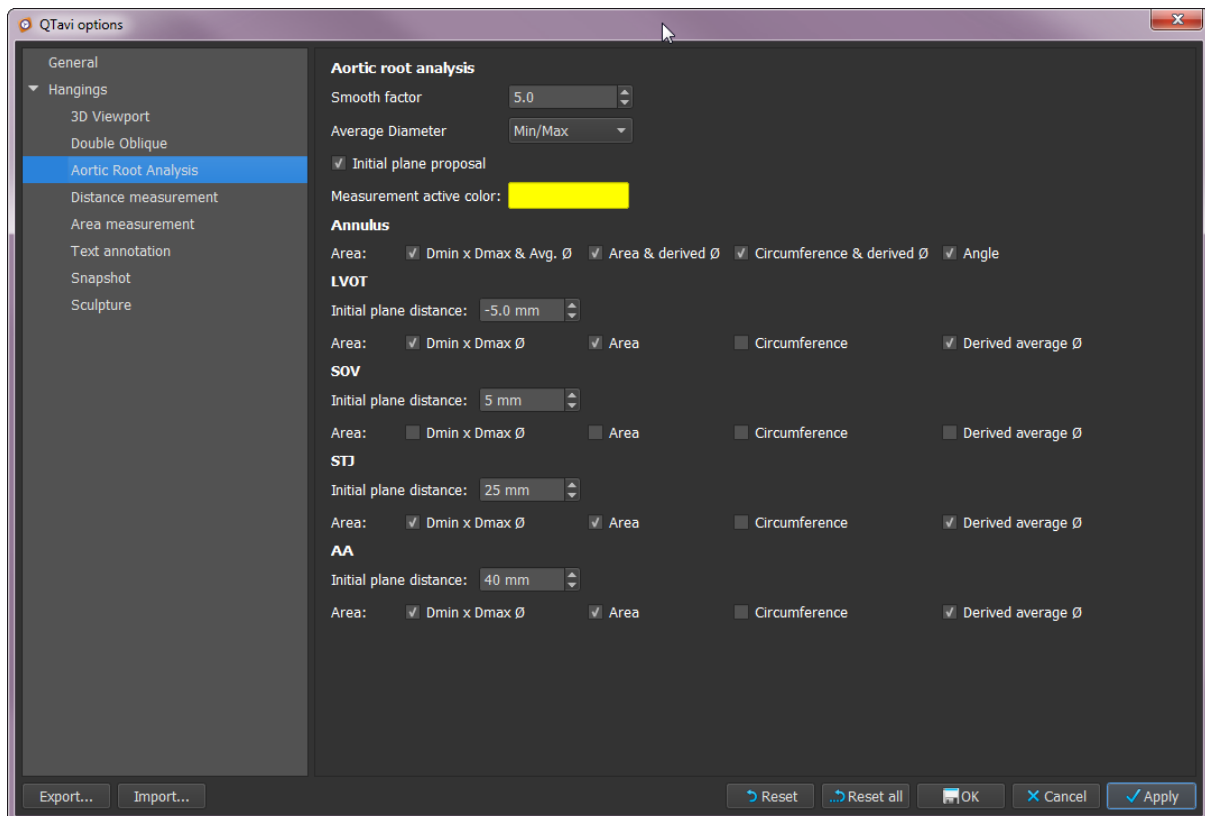
1. Click on  in the **Properties** pane.

8 Aortic Root Analysis Options

QTavi has Aortic Root Analysis specific options.

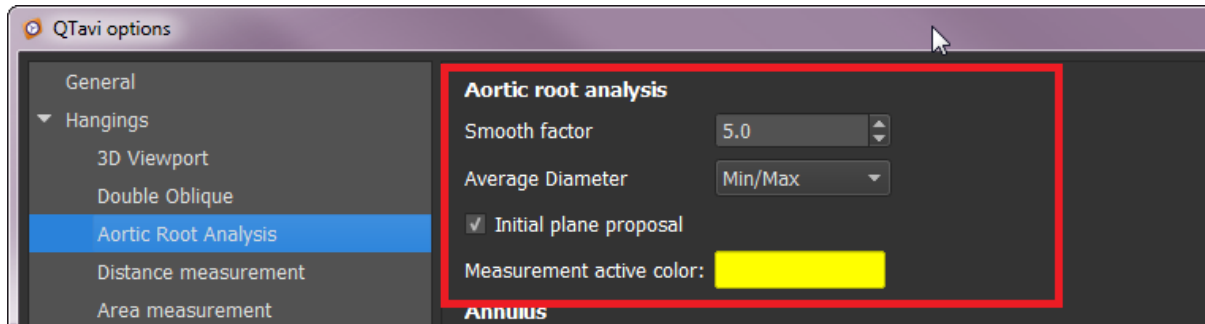
To access the Aortic Root Analysis Options:

Click on the menu icon  in the **General** toolbar of QTavi and select **Options** and choose **Aortic Root Analysis**. This will open the QTavi Options dialog.



8.1 Options for all Aortic Root Analysis steps

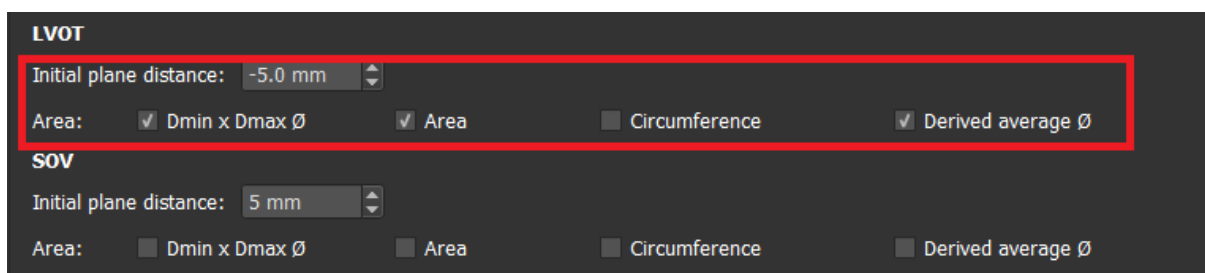
Below is a list of options that are applicable to all QTavi Aortic root analysis steps. For example, if the smoothing factor of a contour is modified, then it is modified for all contours in the Aortic root analysis.



Title	Default	Description
Smooth Factor	5.0	Contours are smoothed after been drawn or generated. A perfect circular contour would have a high smoothing factor and a rippled contour would have a long factor.
Average Diameter method	Circumference based	Area based average diameter. Circumference based average diameter. Min/Max based average diameter.
Initial plane proposal	On	When an Aortic Root Analysis step is activated, the viewports will be adjusted to a proposed view-state. The view-state is an approximation of the position and orientation of where that plane should be.

8.2 Contour Measurement Options

Every Aortic Root Analysis step with a contour measurement has the following options. The list below describes each option.

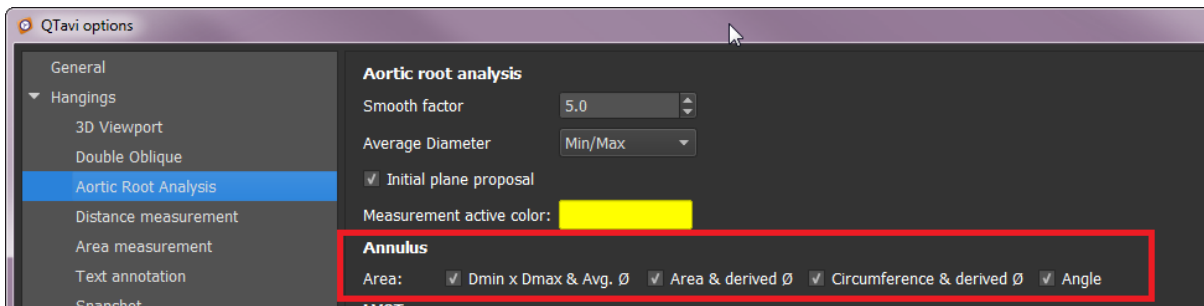


Title	Default	Description
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Initial plane distance		The desired distance of a plane from the annulus. This is used in conjunction with the initial plane proposal. Negative numbers implies the new plane is below the Annulus plane, such as the LVOT.
Area: Dmin x Dmax	On	Show/Hide the average of the min/max diameter.
Area	On	Show/Hide the area of the contour.
Circumference	Off	Show/Hide the circumference of the contour.
Derived average	On	Show/Hide the derived average. This number is calculated based on the Average diameter method selection.

8.3 Aortic Root Annulus step Options

The Aortic Root Annulus step has the following options. The list below describes each option.



Title	Default	Description
Area: Dmin x Dmax & Avg	On	Show/Hide the average of the min/max diameter.
Area & derived average	On	Show/Hide the area of the contour and the derived average of the contour.
Circumference & derived average	On	Show/Hide The circumference and the derived average of the contour.
Angle	On	Show/Hide angle results.

9 AutoQ preprocessing

AutoQ is a preprocessing functionality feature of Medis Suite which enables QTavi Automatic Detection to be run without any user interaction as a background process prior to starting QTavi.

When AutoQ has run, the Auto Detection results are placed in a new series, which appears in the Series Browser. The newly generated AutoQ series will contain a fully segmented mesh representation of the Aortic root in addition to contours representing the TAVI planes. The AutoQ series can then be loaded into QTavi with the original data.



The user must check all automatically generated data and results.

9.1 Running AutoQ

To generate an AutoQ series do the following.

1. Start Medis Suite and select a patient from a repository.
2. Select one or more series in the Browser, “Series info” panel.
3. Right click on the selected series.
4. In the context menu, Select AutoQ > QTavi Aortic Root Segmentation

A separate entry will appear in the series list that shows the progress and status message of the AutoQ process. The process will run in the background and may several minutes.

A new Series will be added to the ‘Series info’ panel.

9.2 Loading AutoQ results

AutoQ series can be loaded into QTavi into QTavi similar to loading a standard series, but selecting the AutoQ series and loading it, or by dragging the AutoQ series onto QTavi.

To use AutoQ results:


1. Select a patient from a repository, whereby AutoQ results have been generated.
2. In the Series info panel of the Study Browser, load both the original data and the AutoQ series.

Then, either load the series into QTavi, or drag & drop the series in QTavi.

To load AutoQ series into QTavi:

1. From the Series Browser, select the original data and the AutoQ series.
2. Right click the mouse and select QTavi

Or:

1. Start QTavi
2. From the Series Browser, select the original data and AutoQ series.
3. Drag & Drop the original image original data and the AutoQ series on QTavi
 The user must check all automatically generated data and results.



10 Reporting

QTavi results are made available in the Medis Suite Results pane and in the Medis Suite report.

The screenshot displays the Medis Suite Results pane with a sidebar on the left and a main report area on the right. The sidebar contains a tree view of analysis categories, including Manual Calipers, Aortic Root Analysis 02 (QTavi Stable Daily 1.0...), Analysis Information, Aortic Annulus, Coronary Heights, LVOT, Sinus Of Valsalva, STJ, and Ascending Aorta. The main report area shows the following data:

Reason for Referral	
Viewer	
Annulus Diameter dist	38.5 mm
Annulus area	8.01 cm ²
Aortic Root Analysis 02 (QTavi Stable Daily 1.0 #1)	
Analysis Information	
Average Diameter	Min/Max
Smoothing factor	5 mm/pixel
Aortic Annulus	
Ds x Dd - Avg. Ø	18.8 x 23.9 - 21.4 mm
Area	339.7 mm ²
Area Derived Ø	20.8 mm
Circumference - Derived Ø	66.9 - 21.3 mm
Angle	42.0 °
Coronary Heights	
LCO	- mm
RCO	- mm
AA	- mm
LVOT	
Ds x Dd	15.4 x 23.7 mm
Area	274.7 mm ²
Average Ø	19.5 mm
Annulus d	5.0 mm
Sinus Of Valsalva	
LCS x RCS x NCS	- x - x - mm
Average d	- mm
STJ	
LCC x RCC x NCC	- x - x - mm
Ds x Dd	23.7 x 25.4 mm
Area	474.7 mm ²
Average Ø	24.5 mm
Ascending Aorta	
Ds x Dd	28.7 x 31.3 mm
Area	703.5 mm ²
Average Ø	30.0 mm
Conclusions	



The Reporting functionality of Medis Suite is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Click F1.
- Pushing the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help > User Documents**

11 Sessions

The QTavi state can be saved in a Medis Suite session. The session can be reloaded to continue or review the analyses.

The session functionality in Medis Suite is described in the Medis Suite user manual. The Medis Suite documentation is available from the User documents tab, which can be opened as follows;

- Click F1.
- Pushing the  help button.
- Select the Medis Suite main menu button in the upper right corner  > **Help > User Documents**

12 Shortcut Keys

When you are working with QTavi, you can use several combinations of keys on your keyboard and mouse actions to quickly perform the following tasks.

Press	To
Layout	
F11	Show or hide the workspace window panes
Image control	
Middle-click and hold	Hide all graphics
Middle-click and drag, or Ctrl and drag	Pan
Ctrl+Shift and drag	Zoom
Alt+Shift and drag	Stack
Procedures	
A	Create an area measurement
D	Create a distance measurement
S, or CTRL+SPACE	Create a snapshot
Esc	Stop editing the procedure
Delete	Delete the currently selected procedure

Press	To
SHIFT+Delete	Delete all procedures
Navigation Controls	
HOME	Display the first time point
END	Display the last time point
Arrow up	Display the previous slice
Arrow down	Display the next slice
Arrow left	Display the previous time point
Arrow right	Display the next time point
CTRL+arrow left	Play cine backward
CTRL+arrow right	Play cine forward
Esc	Stop playing cine
Page Up	Display the previous series
Page Down	Display the next series

13 General References

QTavi runs as an application in Medis Suite. Please refer to the Medis Suite user documentation for detailed descriptions of Medis Suite functionality.

Aortic Root anatomy references:

RCO Right Coronary Cusps Ostium

LCO Left Coronary Cusps Ostium

NCO	Non Coronary Cusps Ostium
RCS	Right Coronary Sinus
LCS	Left Coronary Sinus
NCS	Non Coronary Sinus
RCC	Right Coronary Cusps Sinus
LCC	Left Coronary Cusps Sinus
NCC	Non Coronary Cusps Sinus

14 Troubleshooting

Missing results although Auto Detection is complete

After a successful Auto detect, there are no contours are visible. This may occur when multiple time points are loaded. It is then possible that for the current time-point there are no contours detected, while contours have been detected for other time-points.