

Qlvus Research Edition 3.1

Quick Start Manual

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Disclaimer

QIvus Research Edition is for research purposes only. It may not be used for clinical decision making.

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Conventions Used

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

Mouse

Click	Press and release the left 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 right 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 left mouse button twice. If you are left-handed, the right mouse button can be used.

Keyboard

CTRL+click	Press and hold down the CTRL key on your keyboard while you click an object.
CTRL+O	Press and hold down the CTRL key on your keyboard while you press O, then release both keys. This example opens the dialog window for opening a study.

Typographical Conventions

On the Segment tab, click Apply .	Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold.
File > Browse for DICOM...	A sequence of menu options that you select to perform a specific task, is indicated by angular brackets.
Double-click <code>New analysis</code> .	Text that you type or that appears on the screen, such as file names and file locations, is displayed in <code>Courier New</code> .

Symbols Used



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



Tip. Provides helpful information or an alternative working method.



Note. Brings additional information to your attention.



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



Warning. Warns you for 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 Qlvus Research Edition

Qlvus Research Edition is the Medis software solution for reviewing and analyzing IVUS and OCT studies of the coronary arteries.

Qlvus Research Edition enables you to view and analyze both IVUS and OCT studies, including tissue characterization as performed by the data provider. Qlvus Research Edition currently supports Boston Scientific Corporation's iMap™, Volcano® VH® (Virtual Histology) IVUS, Infraredx TVC™ (True Vessel Characterization) tissue characterization and Terumo TCP (Terumo Color Processing).

 The tissue characterization and OCT features are only active in Qlvus Research Edition if you have the appropriate license(s).

For IVUS studies, Qlvus Research Edition features rapid automatic detection of lumen, stent and vessel borders over the entire pull-back run, as well as powerful and intuitive editing, which saves you valuable time. Analysis results not only include 2D measurements, but also provide 3D data—lumen, stent, and vessel volumes. You can print the results in a one-page report or export them for further analysis.

For OCT studies, Qlvus Research Edition features fast automatic detection of lumen contours, semi-automatic detection of stent contours and automatic detection of stent struts. You can export stent strut data for further analysis.

2 System Requirements

2.1 Hardware

QIvus Research Edition:

- Intel or compatible processor with a minimum speed of 2.8 GHz
- 2 GB of RAM
- 2 GB of available hard disk space (if you want to store images locally, make sure you have enough disk space)
- 3-button mouse required, scroll-wheel recommended
- DVD- or CD-ROM drive
- Color monitor supporting a minimum resolution of 1280x1024 pixels (S-XGA color monitor recommended)
- Video card supporting 1280x1024, 64 MB memory with a color depth of 32 bits.
- Network interface card (required if you will be using floating licenses)

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

QIvus Research Edition:

- Microsoft Windows 7, SP1 or higher, 32 or 64 bit version
- Microsoft Windows 8.1, 32 and 64 bit version
- Microsoft Windows 10, 32 and 64 bit version
- Microsoft Windows Server 2016, 64 bit version

NOTES:

- To work efficiently with large datasets, a 64 bit operating system operating the 64 bit version of QIvus Research Edition and at least 8 GB of RAM is recommended.
- VH data cannot be read and analyzed with the 64 bit version of QIvus Research Edition or on Windows 10 and Windows Server 2016.

Medis System Tools and Sentinel license server:

- Microsoft Windows 7, SP1 or higher, 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 or higher, 64 bit version
- Microsoft Windows Server 2012 R2, 64 bit version
- Microsoft Windows Server 2016, 64 bit version

2.3 Dependencies on Other Software

Qlvus Research Edition is capable of creating detailed reports in Microsoft Excel format. To make use of this functionality, the Microsoft Excel software needs to be installed on the machine that runs Qlvus. The following versions of Microsoft Excel are supported:

- Microsoft Excel 2010, 32 or 64 bit version
- Microsoft Excel 2013, 32 or 64 bit version
- Microsoft Excel 2016, 32 or 64 bit version

NOTE:

- Without Microsoft Excel installed on the machine, Qlvus Research Edition will still be able to perform analyses that can be reviewed on screen, but it will only be able to create simple single page reports and print these on paper.

3 Support

For quick and easy Qlvus Research Edition support, you can go to the menu bar (on top of the program), click **Help** and choose one of the three options:

- 1) **User Manual** for a simple explanation on all available Qlvus Research Edition functions (this document).
- 2) **Instruction Movies** for a visual explanation on several topics, including the graphical user interface, contour detection, and analysis results.
- 3) **About...** for general package information, like the Qlvus Research Edition version number, License Information, Legal Notices, and Contact Information.

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. The Qlvus Research Edition version number is displayed in the title bar.

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4 Starting Qlvus Research Edition and Opening Studies

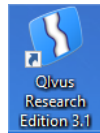
4.1 Starting Qlvus Research Edition

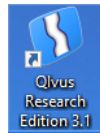
Qlvus Research Edition and its licenses must be installed before you can start the application.



For instructions on installing Qlvus Research Edition and managing licenses, we refer to the Qlvus Research Edition Installation Manual.

To start Qlvus Research Edition



- Double-click  on your desktop.

Or,


- Select **Start > (All) Programs > Medis Qlvus Research Edition > Qlvus Research Edition 3.1.**

4.2 Opening Image Runs

After starting Qlvus Research Edition, you open the image run that you want to analyze in the two-step File Browser as follows:

To open an image run



1. Click  or select **File > Browse for DICOM...**
2. In the Image Browser, browse the directory structure on the left and select the directory in which the image run is located. In the right-hand pane, select the image run and click **Next**, or double-click the image run.
3. In the next step, in the lower pane, select `New analysis` and click **OK**, or double-click `New analysis`.

To resume the last analysis, select `Last analysis` in the lower pane and click **OK**, or double-click `Last analysis`.

To review or continue an older analysis, select the analysis in the lower pane based on the date, time and analyst name and click **OK**, or double-click the analysis of your choice. Analyses created with a previous version of Qlvus will be displayed in red. These can still be read and modified, but some results may differ because of improved algorithms in Qlvus Research Edition 3.1.

4. If you are loading IVUS grayscale or OCT images, you can limit the number of frames that are loaded into Qlvus Research Edition in the **Image Subset Selection** dialog window. With large image runs, limiting the number of frames ensures that the image run is loaded quickly and that analyses are performed efficiently. You can do this in two ways: under **Enter Frame Number**, select a range of frames to be loaded, or specify a subset selection number, which loads just one frame out of the specified number of frames (also known as subsampling).



In case of long pullbacks, it is recommended to load sufficient frames to maintain a slice thickness of 0.1 mm or less.

If you are loading images with tissue characterization data, the data set is limited by default to the frames that show tissue characterization.

5. If the image run is raw OCT, two extra options are present:
 - Radio boxes to switch between loading only the center **7 mm diameter** of the images and loading the **full depth** of the image.
 - The checkbox **Load Z-offsets**. If the image run already has Z-offsets from the acquisition system, it is recommended to use those instead of performing the Z-offset correction later in Qlvus Research Edition.
6. Click **OK**. Qlvus Research Edition now starts to load the image run and creates the longitudinal images.
7. In the General Information dialog window, check the DICOM properties.




Make sure to check the catheter type, the pull-back speed, and the frame rate. The correctness of this information is very important, because it is used to accurately calculate the volume measurements and all other measurements in the longitudinal view.

Click **OK** to close the General Information dialog window.

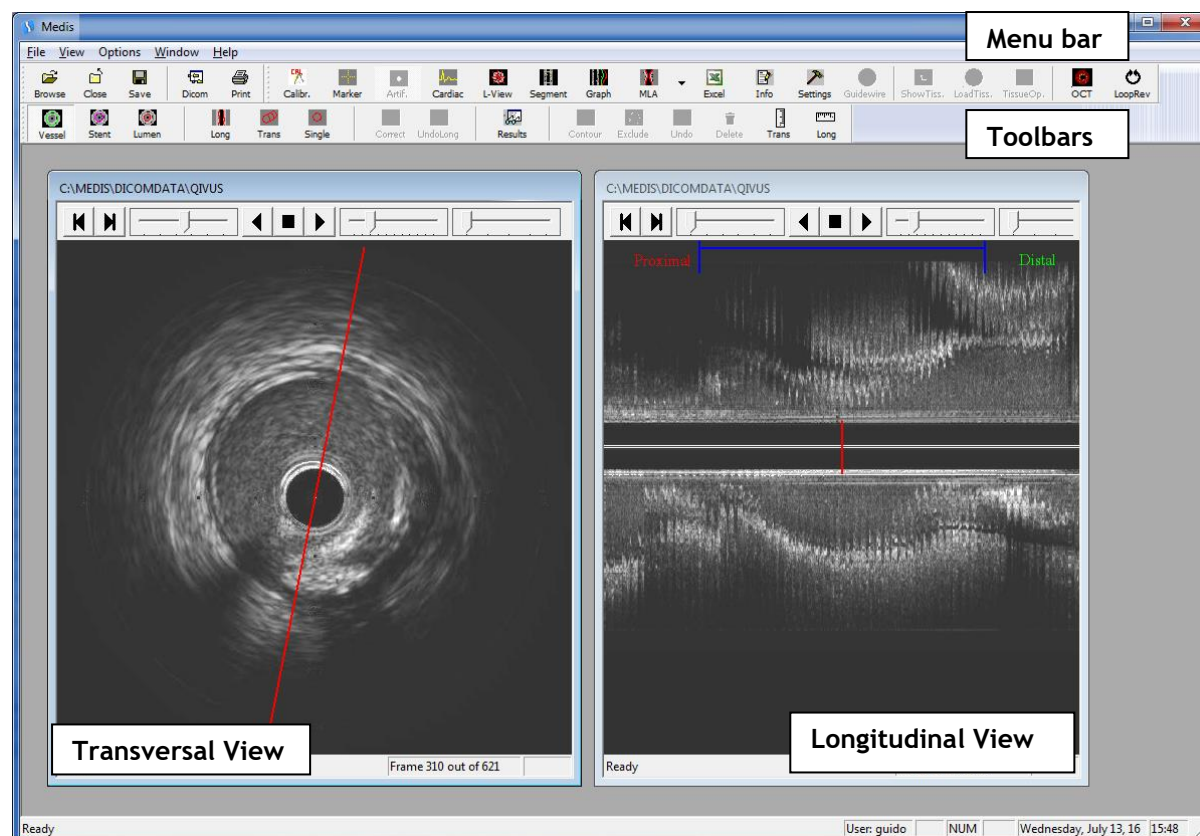
4.3 Closing Image Runs



- Click , when you are done reviewing and/or analyzing the image file.
- During the closure procedure, all analysis settings and results are automatically saved.

5 The Qlvus Research Edition Workspace



The Qlvus Research Edition main workspace consists of a menu bar, a set of toolbars and a canvas that presents the transversal and the longitudinal views.

















❗ The version number of Qlvus Research Edition is displayed in the title bar (not shown in screenshot above).










❗ The name of the user currently logged on to Windows is displayed in the status bar.












5.1 Toolbars






Tool Icon	Description
File Toolbar	
	Browse for all types of image data that can be read in by Qlvus Research Edition and start analysis.
	Close the currently active image file.

Tool Icon	Description
 Save	Save the current image run or part of the current image run as an AVI file, or save the currently selected frame or multiple frames as a BMP or JPG file.
 Dicom	Hide or show the DICOM info.
 Print	Print a one-page report with analysis results.
General Toolbar	
 Calibr.	Perform manual calibration and check the catheter and artifact circles.
 Marker	Semi-automatically remove calibration markers.
 Artif.	Automatically remove artifacts.
 Cardiac	Correct for cardiac motion.
 L-View	(Re-)creates longitudinal images.
 Segment	Specify the segment(s) and/or subsegments of interest for contour detection and reporting.
 Graph	Hide or show the area graph in the longitudinal view.
 MLA	<p>Jump to the frame with the minimum lumen area in the selected segment.</p> <p>ⓘ Click the arrow next to this icon to select other types of frames. For example, you can select the frame with the smallest or largest lumen area in the current segment, the largest calcium area in the current segment, or the largest area of malapposition in the current segment.</p>

Tool Icon	Description
	Export the results of the selected analysis to Microsoft® Excel®.
	<p>Open the General Information dialog window, in which you can view and edit basic details about the patient, intervention, catheter and stent.</p> <p>ⓘ The changes you make to the properties are only stored with the QIvus Research Edition analysis results, not in the original DICOM file. Your changes are stored with the current analysis and shown in reports.</p>
	<p>Open the Settings dialog window.</p> <p>In this dialog window, you can specify the scroll step and the loop interval.</p> <p>The other settings in this dialog window show the characteristics of the image run as detected by QIvus Research Edition. The contour detection is optimized for each specific catheter type.</p>
	Open the guidewire detection dialog window for iMap or VH-Revolution IVUS images.
 or  or  Or 	<p>Hide or show iMap, VH, TVC or TCP IVUS tissue characterization.</p> <p>ⓘ One of these icons is active if you have the appropriate license, if an image run set of the corresponding IVUS manufacturer is loaded, and if tissue characterization data and contours are available.</p>

Tool Icon	Description
 or  or  Or 	<p>Display iMap, VH, TVC or TCP IVUS tissue characterization data or re-perform tissue characterization.</p> <p>⚠ One of these icons is active if you have the appropriate license, if an image run set of the corresponding IVUS manufacturer is loaded, and if tissue characterization data is available for the image run.</p>
 or  or 	<p>Open the tissue characterization options of the iMap Analysis, VH IVUS Analysis, TVC Chemogram Analysis or TCP Analysis dialog window, respectively.</p> <p>Using the options in this dialog window for iMap, VH or TCP, you can add a pie chart and a legend to the transversal view, you can change the transparency of the tissue characterization overlay, and you can select the tissues that must be shown in the overlay.</p> <p>If you are reviewing iMap or VH-Revolution images, you can also filter out black pixels using this dialog window, you can display the level of confidence with which the pixels are characterized as belonging to a tissue type, and you can mask specific areas.</p> <p>If you are reviewing TVC data, you can view the chemogram map and crosshair information, and you can detect the mxLCBI.</p> <p>If you are reviewing TCP data, you can set values for start position, gain , noise correction, smoothing and purple threshold.</p> <p>⚠ One of these icons is active if you have the appropriate license, if an image run set of the corresponding IVUS manufacturer is loaded, and if tissue characterization data is displayed.</p>
	<p>Open the OCT analysis dialog window.</p> <p>⚠ This icon is only active if you have the appropriate license.</p>
	<p>Open the Loop Viewer window.</p>

Tool Icon	Description
	Open the OCT Raw Loop Viewer window.
Analysis Toolbar	
	Indicate that you want to create or edit vessel contours.
	Indicate that you want to create or edit stent contours.
	Indicate that you want to create or edit lumen contours.
	Detect longitudinal contours in the segment(s) of interest.
	Detect transversal contours in the segment(s) of interest.
	Detect a transversal contour in a single frame.
	Place a correction point and correct the currently active contour in only the current transversal image.
	Undo your changes to the positions of the attraction points.
	Open a dialog window with analysis results. Depending on the analyses performed, area, volume, diameter and tissue results may be presented.
	Hide or show the transversal contour of the selected contour type.

Tool Icon	Description
 Exclude	Exclude or re-include the current frame in the analysis.
 Undo	Undo only the last manual transversal contour edit. After use, the icon it becomes inactive until an additional manual edit is applied.
 Delete	Open the Delete Contour dialog window, in which you can choose to delete either the selected contour in the current frame or in all frames.
 Trans	Perform caliper measurement on the transversal image.
 Long	Perform caliper measurement on the longitudinal image.

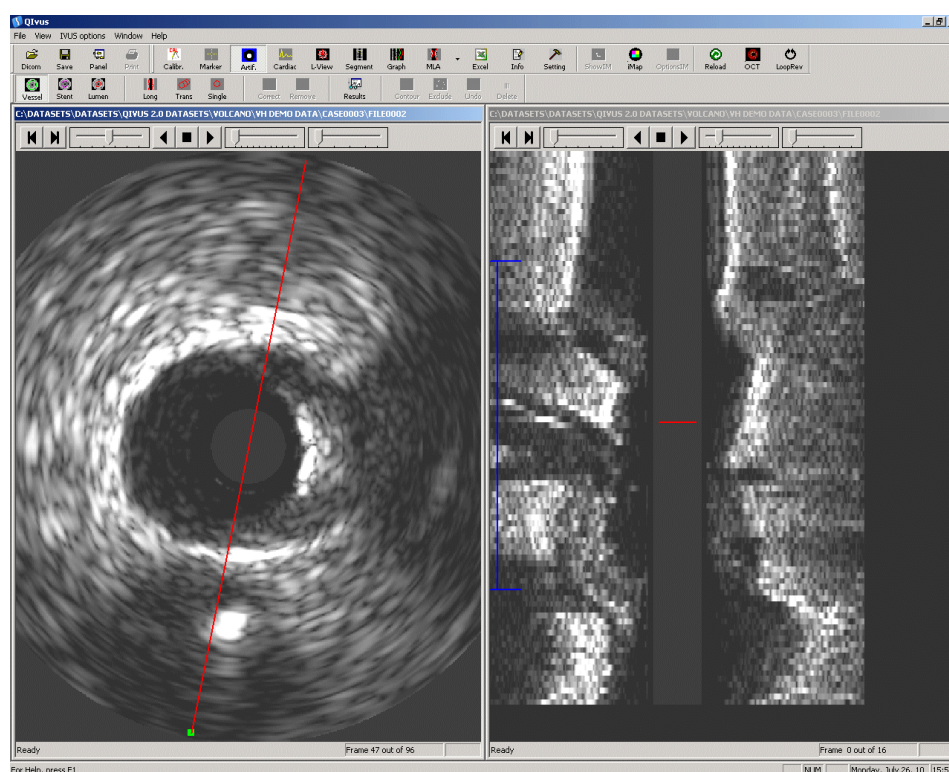
Working With Qlvus Research Edition

6 Reviewing

6.1 Customizing the Canvas and the Views

The large canvas gives you space to review the transversal and longitudinal views, which you can tile horizontally or vertically. You can also maximize the transversal view or the longitudinal view.

The following illustration shows a Qlvus Research Edition window with maximized canvas and vertically tiled views.



To tile the transversal and longitudinal views

- Select **Window > Tile Horizontally** or **Window > Tile Vertically**.

To maximize the transversal or longitudinal view

- Double-click the title bar of the view.

To return to the standard view, click  in the upper right corner of the menu bar.


6.2 Reviewing Image Runs


When you review image runs, you use the movie controls and sliders at the top of the transversal view and the longitudinal view.

The sliders are used respectively to select frames, to change the speed with which the image run is played, and to zoom in or out.



To play an image run

- Click  to start playing the image run.

This plays the image run until the end of the pull-back run and then restarts at the beginning.
- Click  to play the image run backward.

This plays the image run from the end of the pull-back run to the beginning, and then restarts at the end.

6.3 Adjusting Contrast and Brightness

You can manually adjust the contrast and brightness for the current image run.

- ! These adjustments only affect the representation on the screen. They do not affect the actual image properties or the outcome of the analyses.

To adjust contrast and brightness

- In the transversal, longitudinal image or loop view, click the right or middle mouse button or the wheel button, hold the mouse button or wheel button down and drag.

Drag right to increase contrast. Drag left to decrease contrast.

Drag down to increase brightness. Drag up to decrease brightness.

To return to the original contrast and brightness settings

- Double-click the right or middle mouse button or mouse wheel.

7 Performing Analyses in IVUS Images

7.1 Pre-Analysis Actions

In order to perform an accurate analysis, all analyses should start with a precise calibration and a suitable artifact removal of image structures that might diverge the automatic contour detection.

To check the calibration and remove obstacles for automatic detection

Normally, the calibration factor is included in the DICOM file. You must check if this information is available and in the range you expect, and perform manual calibration if needed.

If automatic calibration was performed, you must verify that it was performed correctly and that any obstacles for the automatic detection have been removed, marked for exclusion, or corrected.

Next, you must position the catheter circles over the catheter and the artifact circle. This ensures that the catheter, the calibration markers, and the artifact areas do not affect the automatic contour detection.



1. Click **Calibr.**, and check if the **Average calibration factor** field shows a calibration factor. If it does, click **Close** and continue with step 3 of this instruction.

If there is no calibration factor or when the calibration factor is not correct, you must now manually calibrate the image run.

Browse to the first image that shows the calibration markers. You can do this using the Frame slider, which is the first slider in the image control toolbar.

Check the horizontal or vertical marker line in the transversal view to see how long the maximum distance is that you can mark.

2. In the Calibration dialog window, fill in the distance (in mm) under **Actual diameter** and click **Indicate distance**.

Click and drag in the transversal view, to draw a marker line from the first marker to the last marker. Mid- or right-click in the image to accept the calibration line. In the Calibration dialog window, click **Accept**.

Repeat this step for the other marker line, so that the calibration factor is based on two distances (one in the horizontal and one in the vertical direction).

3. Then, in the transversal view, click on the red **catheter circle** or circle center point to activate the catheter circle in the image for editing. Subsequently, you can click and move the circle center point to reposition the catheter circle and/or you can click and move the catheter circle itself towards the inner- or outer border to resize the catheter circle, until the catheter circle is just around the black catheter circle on the white edge. Middle- or right-click to accept.

In the **Calibration** dialog window, click **Ok**.

4. If the calibration markers are still shown in all images of the image run, click



Under **Horizontal line**, click **Indicate**.

Under **Markers**, check the number of markers specified and correct it if necessary. If needed, adjust the size of the boxes to be drawn around the markers, then click **Draw markers**. This outlines the markers in the images.

Under **Vertical line**, click **Indicate**, and repeat the steps for the vertical markers.

Click **Remove markers**.

This removes the calibration markers from all images except the first.

Click **Exit** to close the dialog window.

5. If digital artifact removal has not been performed already and digital artifacts are still

present in the images, click



6. If the image run must be corrected for cardiac motion, click



7. By default, Qlvus Research Edition creates 16 longitudinal images. If you require fewer or more longitudinal images, you can re-create the longitudinal images before you start the analysis.

Click





In the dialog window that opens, select the number of longitudinal images you require. Click **OK**.

7.2 Performing Caliper Measurements

Qlvus Research Edition enables you to perform various caliper measurements: distance measurements, angle measurements, line, and area measurements. These caliper measurements cannot be saved or exported.

To perform a caliper measurement

1. Select  or  to perform a caliper measurement in the transversal or longitudinal view respectively.
2. Select in the **Transversal Caliper dialog** window the type of caliper measurement you want to perform: **Indicate distance**, **Indicate angle**, **Indicate line**, or **Indicate area**.

Or, select in the **Longitudinal Caliper dialog** window the type of caliper measurement you want to perform: **Indicate distance**, or **Indicate angle**.

3. If you want to measure an angle, pick up and move the measurement overlay in the image and position it over the right area. Pick up and drag the angle legs into the correct position. This displays the angle in the image and in the dialog window.

If you want to measure a distance, a free-form line length or an area, click to place the starting point of the distance measurement in the image, and drag to the end point. Release the mouse button. This displays the distance in mm or the area in mm² in the image.

4. You can add other caliper measurements, or perform the caliper measurement again.
5. Click **Finish** to close the dialog window. Note that these measurements are lost when the dialog is closed.


7.3 Performing Single-Slice Analyses

An analysis in a single slice provides you with a number of 2D analysis results: area and diameter results, and a symmetry indicator. With a single-slice analysis, you can focus on the vessel, the lumen, or the stented area, or a combination of these areas.

To perform a single-slice analysis

1. Open an image run and make sure to start with the pre-analysis actions.
2. Using the movie controls, select your frame of interest.
3. Select the type of contour for which you want to obtain analysis results: a vessel, stent, or lumen contour.



4. The contour detection needs a circular model that is created manually. Click , then click at the center of the contour you want to detect and drag until the circle matches the contour as closely as possible. After releasing the mouse button you can still move the complete circle by dragging the center point or resize the circle by dragging the outline.



Make sure the input model fits in a general manner, because this will improve your contour detection and decrease the need for contour editing.

5. Middle- or right-click to accept the input model.

The contour is now automatically detected.



To ensure that the analysis results are accurate, all automatically detected contours must be reviewed and edited where necessary.



6. Click **Results** to view the analysis results for this slice.

The contour and analysis results are saved automatically with the current image run.

7.4 Performing Segment Analyses

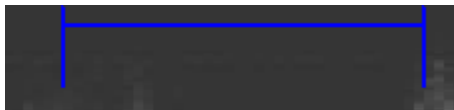
A quantitative analysis of a vessel segment of interest provides you with area, diameter and volumetric analysis results for an entire segment.

- Open an image run and make sure to start with the pre-analysis actions

To perform the segment analysis

1. Indicate your segment of interest using the blue segment marker in the longitudinal view.

You can select and drag the end-points of the marker, and you can move the entire marker by selecting and dragging the horizontal bar.



2. If you also want to obtain analysis results for the edge segments and for the reference segments, you can add more vessel segments to the analysis.

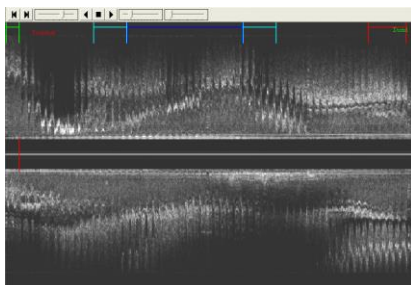


Click **Segment**.

In the **Segment Definition** dialog window, select the check boxes of the segments you want to add.

Click **Apply**, and then click **Close**.

The longitudinal view now looks similar to the following.




3. If you want to obtain analysis results for subsegments of the segment of interest, you can define the subsegments. Results for the subsegments are included in the MS Excel report.



Click **Segment**.

In the Segment Definition dialog window. If the list of subsegments is not shown, click **Define subsegments** to show it. Press **Add** to add a subsegment.

Enter the start frame and end frame of each subsegment. You can also enter a name for each subsegment, or select it from the drop-down list.

 When identical frames are used as start and end frame, the (sub)segment can have a segment length of 0.00mm.

Click **Close**.

4. Select the type of contour for which you want to obtain analysis results: vessel, stent, or lumen contours.



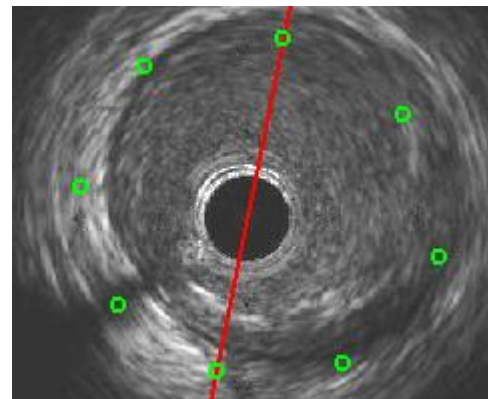
By default, the vessel contour is selected.

5. Click  **Long**.

This detects the longitudinal contour in the segment of interest.

6. Review the attraction points (represented by small green circles) in the **transversal view** by dragging the cross-sectional (red) marker line through the entire segment in the **longitudinal view**.

You can move an attraction point by picking it up in the **transversal view** and dragging it to its new location. At the same time, an attraction point is added to its new location in the **longitudinal view**, and followed with a redetection of the longitudinal contour, whereby the new longitudinal contour is obliged to go through (all) the added attraction point(s); a global editing effect.




7. Click  **Trans**.

This detects all the transversal contours in the segment of interest.

8. Review the transversal contours in the entire segment.

You can do this in three ways: 1) drag the Frame slider in the transversal view, 2) review

the area graph in the longitudinal view, or 3) click the arrow next to  **MLA** and select e.g. **Smallest vessel area in segment**, and then **Largest vessel area in segment**.

9. Edit the contours in the transversal view if needed.



To ensure that the analysis results are accurate, all automatically detected contours must be reviewed and edited where necessary.

10. If needed, repeat steps 4 through 9 to obtain the stent contours and then the lumen contours, (or in case of Volcano Eagle-Eye, the vessel contours and then the lumen contours).
11. You can define specific frames of interest.

The user-defined frames of interest are included in the Excel report, in which they replace the by default used frames.

- Select **Options > Define frames of interest** to open the **Frame navigation** dialog window.
- Press on one of the **Go to** buttons, to immediately go to the retained transversal or longitudinal frame.
- Select a specific transversal frame and press **D** (Define) on the corresponding **Go To** transversal frame type (i.e., Distal, Segment, and Proximal) to retain.

You can select a specific longitudinal frame as well, by pressing **D** on the corresponding **Go To** longitudinal frame type (i.e., Long 1 or Long 2) retain.

Press **R** (Remove) to release the corresponding specific frame. The placeholder for this image in the Excel report will be empty.



12. You can view the analysis results by clicking

The contours and analysis results are saved automatically with the current image run.

You can export a frame, part of the image run or the entire image run as a BMP, JPG or AVI file. You can also print a report or export the results to MS Excel.

7.5 Editing Contours

There are three ways to edit.


- you can *move an attraction point*
- you can *insert a correction point* that forces the contour through a specific location
- you can *manually re-trace part of the contour*

Moving an attraction point is the most powerful editing option. This redetects the longitudinal and transversal contour.

To move an attraction point

1. Pick up and drag the attraction point in the transversal view to its new location.
This redetects all (longitudinal and transversal) contours near the attraction point.
2. To **undo** your **manual attraction point change** in the transversal view one by one, click

**To insert a correction point**

1. Click  or press C, and then click in the transversal view to place the correction point.

The contour snaps to the correction point.


2. If you are not satisfied with the new transversal contour, you can pick up the correction point and drag it to a new location.

You can selectively remove the correction point by clicking it with the left and right mouse button simultaneously.

To manually re-trace part of a contour

1. Select the **transversal contour** and start re-tracing the contour using the left mouse button, and release to accept the manually corrected part of the contour.
2. The **longitudinal contour** can be manually corrected as well. Select the longitudinal contour, start re-tracing the contour (in fact you reposition the contour points / attraction points), and release to accept. Because the positions of the corresponding attraction points in the transversal view are changed, the transversal contours will be redetected.

Redetecting longitudinal contours

If you are not satisfied with your manual edits of the longitudinal contour or support points in the transversal image(s), you can redetect the selected longitudinal contour by clicking . The

actual effect depends on the options "Multiple longitudinal vessel", "Multiple longitudinal lumen" and "Multiple longitudinal stent" that can be set via the main menu (Options). When the option is ON, the contours in all the 4 predefined longitudinal views are updated. When the option is OFF, only the two contours in the current longitudinal view are updated (one cross-section). The first option (ON) is useful when user wants to redo the entire contour detection. The second option (OFF) can be useful when additional support points are needed in the transverse image, in case of poor image quality or difficult analyses.

8 Viewing Tissue Characterization

QIvus Research Edition can display tissue characterization overlays in image runs that provide this information. Currently, QIvus Research Edition supports Boston Scientific iMap, Volcano VH IVUS, Terumo Color Processing (TCP) and Infraredx TVC tissue characterization.

ⓘ Viewing Boston Scientific iMap, Volcano VH-Eagle Eye IVUS, Volcano VH-Revolution IVUS, Infraredx TVC, and Terumo TCP data sets requires special licenses.

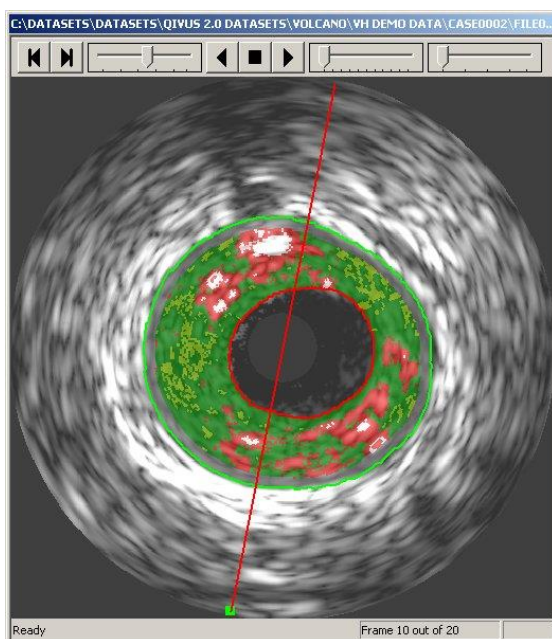
Contact your Medis account manager or send a mail to sales@medis.nl for more information.

If you are reviewing iMap, VH, TCP or VH-Revolution data sets, you can change the level of transparency of the tissue overlay and hide individual tissue types from the overlay. In the transversal view, you can also add a legend and a pie chart.

If you are reviewing iMap data sets, you can display the confidence level of the tissue types with the brightness of the pixels color and exclude low or high confidence pixels from the tissue characterization results.

If you are reviewing iMap or VH-Revolution data sets, you can also filter out guidewire pixels (low-intensity pixels) from the tissue characterization results.

The following images show examples of a transversal view with Volcano's VH IVUS and Boston Scientific's iMap IVUS tissue characterization, respectively.

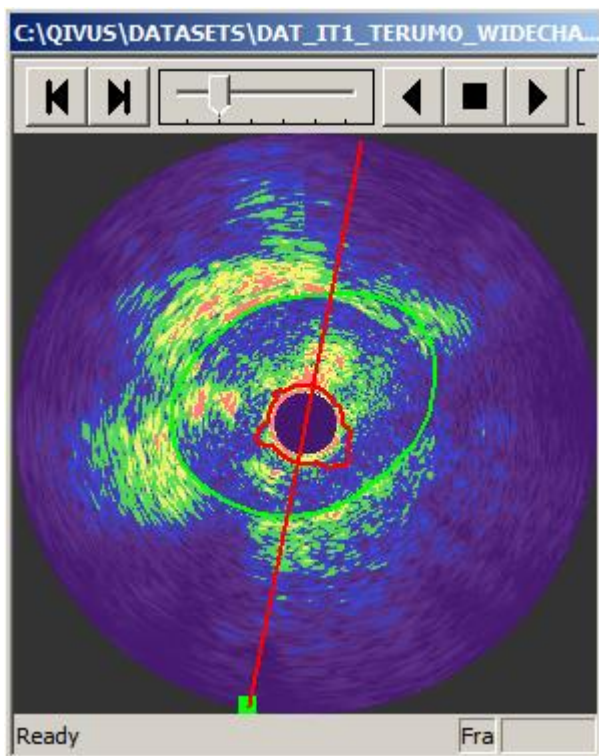


VH tissue characterization



iMap tissue characterization

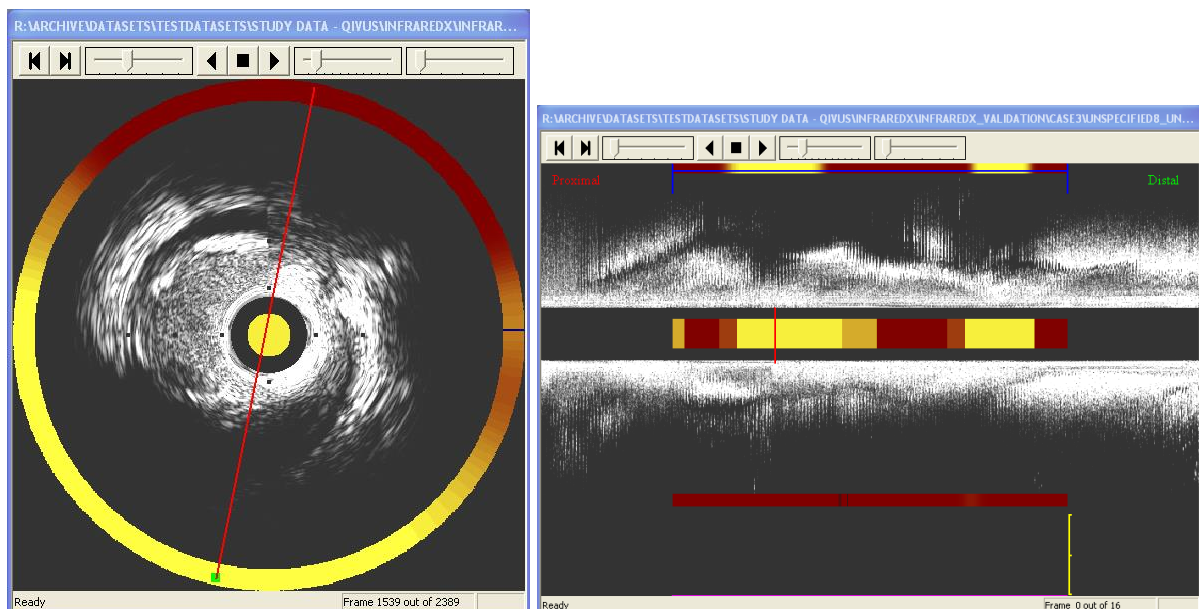
Next image shows an example of Terumo Color Processing



Terumo Color Processing

If you are reviewing Infraredx TVC images, the TVC Chemogram Analysis will display the Chemogram map in which you can automatically detect the maximal LCBI (Lipid-Core Burden Index).

The first of following images shows an example of a transversal view with Infraredx TVC tissue characterization with its chemogram Halo around the gray scale IVUS image. In the center of the image (inside the catheter artifact) you can see the Block-Index chemogram circle.

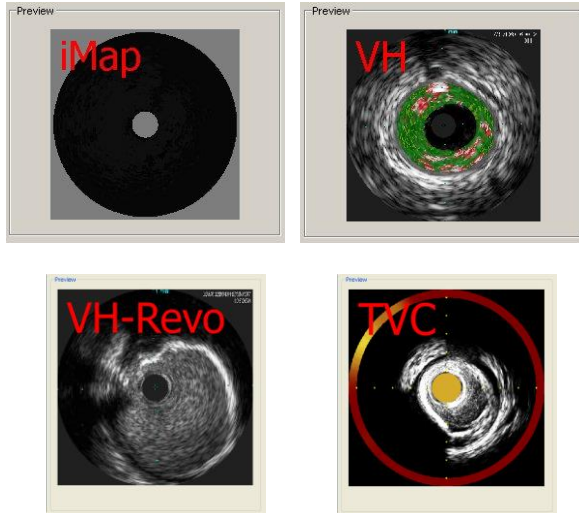




The second image shows an example of the longitudinal view with Infraredx TVC tissue characterization, with in the middle of the image the Block-Index chemogram bar that corresponds to the Block-Index chemogram circle. The colored bars at top and bottom of the image correspond to the chemogram Halo in the transversal view.

To view tissue characterization

1. Open the image run with tissue characterization.

In the File Browser, the image run preview is marked **iMap**, **VH**, **VH-Revo** or **TVC** if tissue characterization is available. The following illustrations show examples.



2. When the gray-scale images are loaded in Qlvus Research Edition, click  ,  ,



This displays the tissue characterization in the transversal and longitudinal views. If no lumen and vessel contours were previously detected on Qlvus Research Edition, this also loads contours that were created on the acquisition system (not applicable for TVC and TCP).





⚠ In case the contours were created on the Boston Scientific's iLab system, the labels **iLab Lumen** (in red) and **iLab Vessel** (in green) are displayed in the top left corner of the transversal view.

⚠ In case the contours were created on the Volcano VH IVUS imaging system, the labels **s5 Lumen** (in red) and **s5 Vessel** (in green) are displayed in the top left corner of the transversal view.

📄 If the tissue characterization is not displayed, no lumen and vessel contours from the acquisition system were available. Detect lumen and vessel contours in Qlvus Research Edition first. We refer to section 7 for instructions.

To hide or show tissue characterization

You can temporarily hide the tissue characterization to view the underlying images.

- Click  ,  ,  or  to hide the tissue characterization.

Click the icon again to show the tissue characterization.

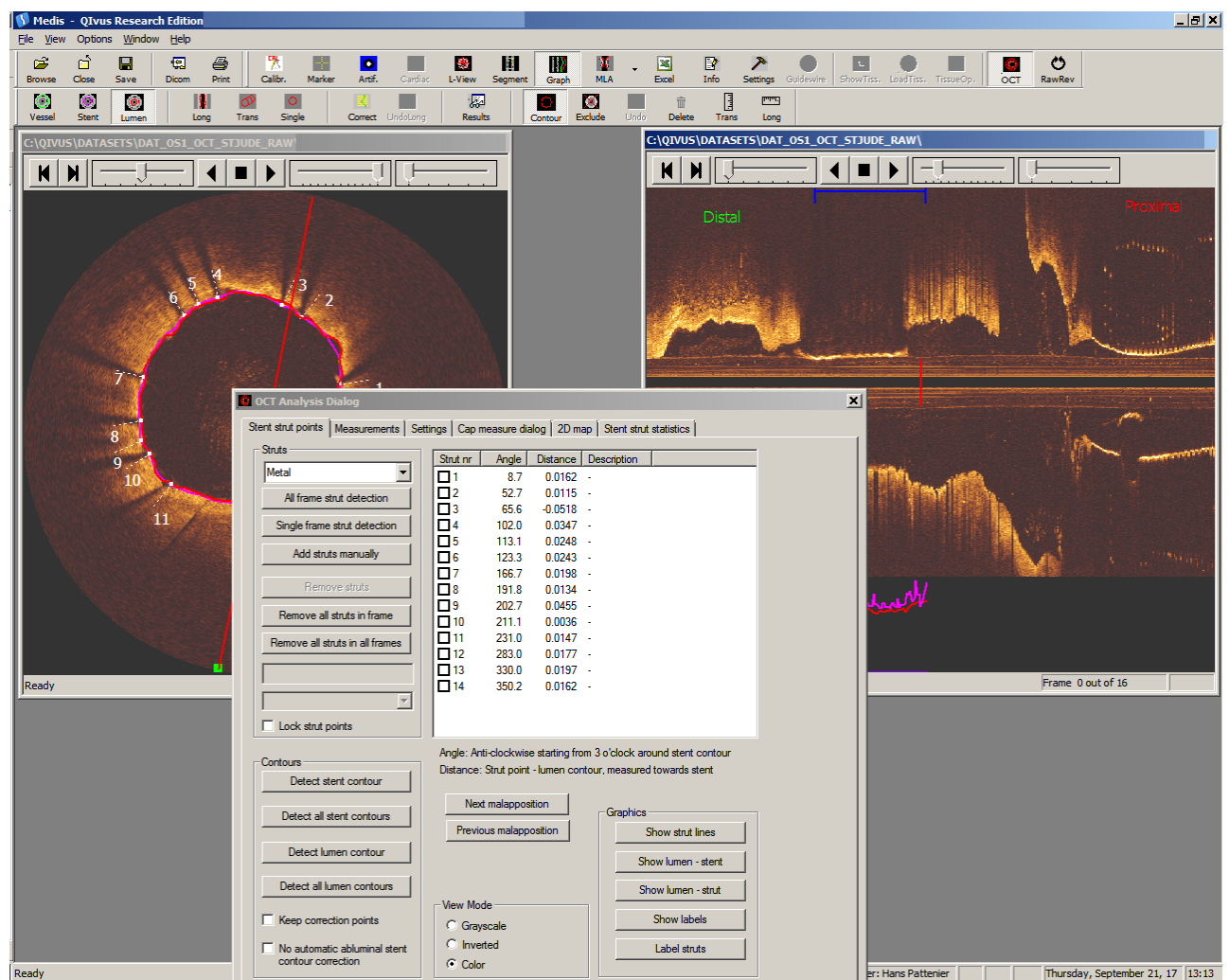
9 Performing Analyses in OCT Images

Qlvus Research Edition can automatically detect stent struts in raw St. Jude Medical OCT and raw Terumo OFDI image data. Additionally, Qlvus Research Edition can read, display and perform manual analyses on St. Jude Medical (formerly known as LightLab) Optical Coherence Tomography (OCT) and Terumo Optical Frequency Domain Imaging (OFDI) raw and DICOM image data. Additionally,.

! Performing analyses in OCT images requires a special license.

Contact your Medis account manager or send a mail to sales@medis.nl for more information

The following image shows an example of an OCT analysis.



To change the display color of the OCT image run

By default, St. Jude Medical OCT image runs are displayed in "gold" color. You can change this to grayscale or inverted grayscale.

By default, Terumo OFDI image runs are displayed in grayscale. You can only change this to inverted.

- Click  to open the **OCT Analysis Dialog** window and select the **Stent strut points** Tab.

Go to the **View Mode** box at the bottom of the window, select **Grayscale, Inverted or Color**, and then click **Close**.

9.1 Pre-Analysis Actions OCT

To perform z-offset correction

In OCT image runs, the z-offset in the transversal images can change over the length of the image run. You can correct for this change using the z-offset correction.

1. Select **Options > Change Z-offset**.

This opens the z-offset dialog window.

2. Go to the first distal frame of the image run.
3. Usually, the appropriate sheath size is given by default.

However, if it is necessary, change the sheath size at **Size of the sheath** into the appropriate one, and click **Change circle** to accept.

4. In the transversal view, pick up the center of the circle and move the red circle over the guiding sheath in the image until their centers coincide.
5. Use the slider to change the Z-Offset such that the guiding sheath and red circle coincide.
6. Click **Update**. This updates all images from the first frame to the end frame of the image run with the present z-offset factor zero.
7. Scroll through the image run from start to end and check whether the sheath keeps fitting the red circle. Stop scrolling when there is no fit anymore.

Enter a z-offset correction factor at **Z - Offset** and click **Test** to show the correction in the current frame, or drag the slider to change the **z-offset correction factor** until there is a perfect fit of the outer edge of the guiding sheath against the circle again.

8. Click **Update**. This updates all images from the current frame to the end of the image run with the new z-offset factor.
9. Click **Close** when the end frame is reached.

9.2 Performing OCT Analyses

Qlvus Research Edition supports the analysis of metal stent struts as well as the struts of a biodegradable vascular scaffold (BVS).


- Metal stent struts:
 - Represented by a single point in the transversal image.

- Typically only one stent contour is detected per frame. Abluminal distance from strut is configurable in the settings (see section 9.1)
- BVS struts:
 - Represented by a small box-shaped area in the transversal image
 - Typically two stent contours are detected per frame: one that touches the adluminal side of the strut boxes and one that touches the abluminal side of the strut boxes.

To automatically detect stent struts

1. Indicate your segment of interest (stent segment) by using the blue segment marker in the longitudinal view or use the **Segment Definition** dialog window to fill in the start- and end frame.




2. Click  to open the **OCT Analysis Dialog** window and select the **Stent strut points** Tab.
3. In the dropdown list at the top of the **Struts** box, you can select the type or stent you want to analyze: **Metal**, **BVS Follow-up**, **BVS Baseline**.
4. In order to detect BVS struts, first press **Detect all lumen contours**.
5. To start the automatic stent strut detection in the target segment, click **All frame strut detection** in the **Struts** box.

The struts are detected in all frames of the target segment of the transversal view.

6. All the detected stent struts are listed in the **Struts** table.

To manually add, edit and delete stent struts



1. Click  and select the **Stent strut points** Tab.
2. Use the Frame slider to scroll through the image run in the transversal view. Browse to the image that you want to analyze.
3. Before setting BVS strut points, make sure the lumen contour is present, e.g. by pressing **Detect lumen contour** or **Detect all lumen contours**.
4. To add a stent strut marker point, click **Add struts manually** in the **Struts** box of the **Stent struts points** Tab, then click to place the new point or points in the transversal image. Middle- or right-click to accept your strut point edits (yellow color becomes white).
5. To edit the position of a stent strut marker point, select the target point in the transversal image (color becomes yellow) and drag it to a new position. Middle- or right-click to accept your strut point edits (color becomes Blue).
6. To edit the shape of a BVS stent strut marker, click on its contour and draw the change. It might be useful to zoom-in as the struts are quite small.
7. To delete a stent strut marker point, select its **Strut nr** in the strut list from the **Struts** table and click **Remove strut**.


To add stent strut descriptions

Strut descriptions are shown in the results pane and in reports. The strut descriptions also define the color of the strut points in the transversal image and in the 2D view. By default there are four descriptions to choose from: **Covered** (green), **Uncovered** (yellow), **Malapposed** (red) and **Artefact** (blue).

Add stent strut descriptions automatically

As of version 3.1 QIvus Research Edition can label the struts automatically. First make sure the settings are to your liking:



1. Click  and select the **Settings** Tab.
2. In the section for Strut thickness there are two options that affect the automatic strut labelling:
 - a. Minimal malapposition distance in mm.
If the strut is inside the lumen and the distance to the lumen contour is larger than this value, it will be labelled “Malapposed”.
 - b. Minimal coverage distance in mm.
If the strut is more than this distance from the lumen, it will be labelled “Covered”.
3. Select the **Stent strut points** Tab
4. Make sure that in the OCT dialog, both lumen as stent contours have been detected.
5. Click the **Label struts** button to perform the automatic strut labelling.
6. After the automatic labelling, you can always change the labels manually. (See next section)

To show or hide stent strut descriptions in the transversal view

You can show the stent strut descriptions you have added in the image, or hide them again.

- In the **Stent strut points** Tab, click **Show Labels** in the **Graphics** box.
This changes the text on the button to **Hide Labels**.
- Click **Hide Labels** to hide the descriptions from the view.


To lock or unlock stent points

You can lock the positions of the stent strut points, to make them un-editable during the stent contour editing process.


In the **Stent strut points** Tab, check **Lock strut points** in the **Struts** box.

- To enable the editing of the stent strut points, un-check **Lock strut points**.

To detect the stent and lumen contours

 Although the IVUS longitudinal and transversal contour detection buttons are active during OCT analysis, the user should be aware that the processing of the IVUS and OCT contour detection is very different (e.g., with respect to attraction points, kernels, contour smoothing, etc.). Therefore, it is not advised to use the IVUS contour detection for the OCT analysis, unless the vessel is filled with blood.



- Click  and select the **Stent strut points** Tab.
- Click **Detect stent contour** in the **Contours** box.

This creates a spline fit contour through the stent strut markers.

- Click **Detect lumen contour**.

This performs the contour detection and adds the analysis results to the **Struts** table.



You can re-use the indicated correction points, when you want to redetect the stent contour(s).

- In the **Stent strut points** Tab, check **Keep correction points** in the **Contours** box.

To edit the stent and lumen contours

You can edit the transversal contours by placing correction points and by manually redrawing part of the contour.





1. Click , or  to specify the contour type you want to edit.
2. Now you can edit the contour in 3 ways:
 - By placing a correction point: Press the C key on your keyboard and then click at the right location in the transversal image.
 - By removing a correction point: Press the left mouse button down on the point in the transversal image and then click the right mouse button.
 - By manually redrawing part of the contour: Click and hold left mouse button on the contour and then move the mouse. Release the mouse button to accept the change.


To delete the stent and lumen contours

The OCT stent and lumen contours can be deleted.



1. Click , or  to specify the contour type you want to delete.



2. Next, click  to open the **Delete contour** window.

The opened Delete contour window shows the selected contour type.

3. Specify if you want to **Delete current transversal contour**, **Delete multiple contours** or **Cancel**.

To show or hide the areas inside and the areas outside the stent

You can show all the plaque areas inside the stent and the lumen areas outside the stent in the transversal view.

- In the **Stent strut points** Tab, click **Show lumen - stent** in the **Graphics** box.

This marks the **areas inside** in green and the **areas outside** in red in the transversal view. It also changes the text on the icon to **Hide lumen - stent**.

- Click **Hide lumen - stent** to hide the areas from the view again.

To show or hide lines between the lumen and the struts

In the transversal view, you can also display lines that run from each stent strut to the lumen.

- In the **Stent strut points** Tab, click **Show lumen - strut** in the **Graphics** box.

This adds the lines to the transversal view. It also changes the text on the icon to **Hide lumen- strut**.

- Click **Hide lumen - strut** to hide the lines from the view again.

To show or hide the strut lines of the area between the struts

In the transversal view, you can display strut lines that run from the struts to the center of the stent contour.


- In the **Stent strut points** Tab, click **Show strut lines** in the **Graphics** box.

This adds the lines to the transversal view. It also changes the text on the icon to **Hide strut lines**.

- Click **Hide strut lines** to hide the lines from the view again.


To view stent strut statistics



1. Click  to open the **OCT Analysis Dialog** window and select the **Stent strut statistics** Tab.
2. When stent struts are detected, the following data will be shown: the **Nr. of frames with struts**, the **Tot. nr. of struts**, and the **Average nr. of struts per frame**.
3. When the lumen contours are detected, the following data will be shown: the **Nr. of struts with positive distance** and the **Nr. of struts with negative distance**.
4. When strut descriptions are added, the **Nr. of struts per label** table will show: the **Number** of struts per strut description and the **Percentage** of struts per strut description.

To view a 2D representation of the stent struts (carpet view)




1. Click  to open the **OCT Analysis Dialog** window and select the **2D** Tab.
2. Click the **Show struts** button => Dots will appear in the black area. Note that for each change in the settings of this tab, you need to click the **Show struts** button to see the effect.
3. **Use stent center** (followed by **Show struts**): Default, the catheter center is used to resample the image into 360 degrees. When the option “Use stent center” is selected, the center of the stent is used. Especially when the catheter is eccentric, this gives a better image with respect to the strut distribution. If no stent contour is present, but the lumen is present, the lumen center is used. If both are absent, the catheter is used
4. If the struts have been labeled, the struts are shown in color. These colors correspond to the ones you see on the tab **Stent strut statistics** and in the transversal image. You can switch to white spots by selecting **Show in white**, followed by **Show struts**.
5. You can save an image of the 2D view as .png by clicking **Save image**.

9.3 Performing OCT Caliper Measurements

To add distance measurements

This measurement tool can be used to determine individual distances, such as the distance of the stent strut towards the lumen edge (e.g., malapposed stent strut) or the plaque thickness (e.g. of plaque covered strut).



1. Click  to open the **OCT Analysis Dialog** window and select the **Measurements** Tab.
2. Use the frame slider to scroll through the image run in the transversal view. Browse to the image in which you want to measure.
3. For administrative purposes, you are able to specify on which strut number the distance measurement is performed on. Browse **Measurements on** to select the corresponding **Strut number**, or **Frame** when the distance measurement is not linked to a strut.
4. To add a distance measurement, click **Add Distance** in the **Distance measurements** box, then indicate the start position in the transversal view by pressing the left mouse button, draw a line and release the left mouse button at the end position in the image.
5. To edit a distance measurement, click on the start- or end point of the distance line and drag it to a new position. Release mouse to accept.
6. To delete a distance measurement, select it in the list of the **Distance measurements** table and click **Remove selected distance(s)**.

To add distance measurement descriptions

Distance descriptions are shown in the results pane and in reports. For the Strut related distance descriptions you can choose by default from: **Abluminal** and **Adluminal**, and for the Frame related


distance descriptions you can choose by default from: **Abluminal**, **Adluminal**, **Rupture** and **Sidebranch**.

- In the **Measurements** Tab, select a **Distance Nr** in the **Distance measurements** table, and then select a description from the description drop-down list, or right-click on a **Distance Nr** in the list and select a description in the displayed menu.

To add area measurements

This measurement tool can be used to determine individual areas, such as the area of the stent strut (e.g., biodegradable stent) or the plaque size (e.g. of plaque covered strut).



1. Click  and select the **Measurements** Tab.
2. Use the Frame slider to scroll through the image run in the transversal view. Browse to the image that you want to measure.
3. For administrative purposes, you are able to specify on which strut number the area measurement is performed on. Browse **Measurements on** to select the corresponding **Strut number**, or **Frame** when the area measurement is not linked to a strut.
4. To add an area measurement, click **Add Area** in the **Area measurements** box, then click in the transversal image to indicate the start position. Draw the contour and release the mouse button at the end position of the area contour. Subsequently middle-click to close and accept the area contour.

To edit an area measurement, click on the part of the contour that needs editing and re-draw the area contour. Middle- or right-click to close and accept the edited area contour.

To delete an area, select it in the list of the **Area measurements** box and click **Remove selected area(s)**.

To add area measurement descriptions


Area descriptions are shown in the results pane and in reports. For the Strut related area descriptions you can choose by default from: **StentArea**, **AbluminalPlaque** and **AdluminalPlaque**, and for the Frame related distance descriptions you can choose by default from: **Thrombus**, **Calcified**, **LipidPool**, **Artefact**, **GuideWire**, **FalseLumen** and **NecroticCore**.

- In the **Measurements** Tab, select an **Area Nr** in the **Area measurements** table, and then select a description from the description drop-down list, or right-click on an **Area Nr** in the list and select a description in the displayed menu.

To add angle measurements

This measurement tool can be used to determine individual angles.



1. Click  and select the **Measurements** Tab.
2. Use the Frame slider to scroll through the image run in the transversal view. Browse to the image that you want to measure.

3. Make sure that **Frame** is detected in the dropdown after **Measurements on:**
4. To add an angle measurement, click **Add angle** in the **Angle measurements** box. A default angle is drawn.
5. Edit the angle by dragging its arms or center. Middle-click to close and accept the angle.

To delete an angle, select it in the list of the **Angle measurements** box and click **Remove selected angle(s)**.

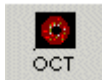
To add angle measurement descriptions

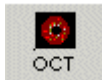
Angle descriptions are shown in the results pane and in reports.

- In the **Measurements** Tab, select an **Angle Nr** in the **Angle measurements** table, and then select a description from the description drop-down list, or right-click on an **Area Nr** in the list and select a description in the displayed menu.

9.4 Performing Thin Cap Analysis

The option to perform cap measurements is a semi-automatic procedure. The user is responsible for selecting the location of the fibrous cap and then the software automatically determines the distances between both contours, translated as thickness.



1. Click  to open the **OCT Analysis Dialog** window and select the **Cap measure dialog** Tab.
2. Use the frame slider to scroll through the image run in the transversal view. Browse to the image in which you want to measure.
3. Make sure the lumen contour is present. If there is no lumen contour present, detect the lumen contour by pressing **Detect lumen** and correct it if necessary.
4. Next indicate the start and end angle of the fibrous cap by pressing **Indicate cap**. A default angle is drawn in the transversal image, typically with arms at the wrong location, so:
5. Modify the two “legs” of the triangle by selecting the endpoints with the left mouse point and move it to the appropriate position. The part indicated by the yellow arc, is the region of interest.
6. Next press the **Detect cap** button to get the abluminal cap contour.
7. This contour can be modified by selecting it with the left mouse button and redrawing parts with the left mouse button hold down.
8. The image shows also a red and a green line between. The red one is the shortest distance between the lumen and the cap contour, the green line is the largest distance between the lumen and cap contour. The distance between the contours is based on the shortest distance to the other contour based on individual points.
9. Multiple caps can be drawn in one image.
10. To delete a cap, select it in the dialog and then click **Delete cap**.

11. In case a guide wire is defined, the guide wire region is excluded from the thickness measurements.

10 Creating Reports


10.1 Printing a One-Page Report

You can print a one-page report for inclusion into a patient's file. The report contains patient and study details, and analysis results. It also provides fields for comments, approval signature and date.

To print a one-page report

- Select **File > Print...** to open the Print dialog window.

Or,

- Click  to directly print the one-page report.

10.2 Customizing Image Display in Reports

You can customize how some of the image elements are displayed in images in the one-page reports and in the MS Excel reports.

You can modify the colors used for the vessel, lumen or stent contours and for the slice indicators that mark the proximal, target, and distal slices in the image. You can also change the thickness of the contour lines, and hide any of the detected vessel, lumen or stent contours, or show the slice indicators.

The changes you make only apply to the currently selected image run.

To customize image display in reports

1. Select **Options > Print Options**.
1. In the IVUS Print Options dialog window, remove the check mark from the **Visible** check box for the Vessel Contour, Lumen or Stent options. The slice indicators that mark the proximal, target, and distal slices are hidden by default.

Under **Print Color** you can select another color for the various contours.

After **Line** you can select a different contour line thickness.

2. Click **OK**.

This instantly applies your changes.

11 Exporting Results

11.1 Export Images and Image Runs


You can export the current image run or part of the current image run as an AVI file, or export the currently selected image or multiple images as a BMP or JPG file.

You can choose to save contours with the images, and gray-scale or tissue characterization images.

To export an image or image run

1. Select the transversal or longitudinal view, to specify image view frames that need to be exported.



2. Click  or select **File > Save...**

This opens the Save As dialog window.

3. The directory shown by default is the directory in which the image run is stored.
4. Type a name for the image or image run in the **File name** field, select the file format from the **Save as type** field, and click **Save**.

This opens a dialog window, in which you can indicate if you want to save a single image or the entire image run (BMP or JPG) or part of the image run or the entire image run (AVI). You can also choose to save contours or tissue characterization with the images.

Click **Save**.

11.2 Exporting Results

To export results to Excel

You can export your Qlvus Research Edition results to Microsoft Excel for further analysis.



1. Click .

This starts the export process and opens the Save As dialog window.

2. Type a name for the Excel report file in the dialog window, and click **OK**.

This creates the Excel spreadsheet and displays it.

To modify the cross-sectional area graph settings

1. Select the **OrgSheet** Tab.

2. Click **Graph Settings**.

This opens the **Select Graphs to Display** dialog window.

3. Select the graph lines that need to be displayed in the **Cross-Sectional Area** graph.

There are eight graph lines to choose from: **Vessel CSA, Lumen CSA, Stent CSA, Vessel CSA-Lumen CSA, Vessel CSA-Stent CSA, Stent CSA-Lumen CSA, Abluminal Stent CSA** and **Reference CSA**. See the legends for the colors.

To define the reference area method

1. Select the **OrgSheet** Tab.

2. Click **Reference Area**.

This opens the **Select References Area Method** dialog window.

3. Select the reference area calculation method you want to use.

There are eight calculation methods to choose from: **Interpolation using Proximal and Distal Vessel Areas, Average of Distal Vessel Areas, Average of Proximal Vessel Areas, Interpolation using Proximal and Distal Lumen Areas, Average of Distal Lumen Areas, Average of Proximal Lumen Areas, Vessel Area at same location as Lumen Area, and Interpolation of Vessel Areas in Analyzed Part only.**

To define the remodeling index method

1. Select the **OrgSheet** Tab.

2. Click **Remodeling Index**.

This opens the **Select Remodeling Method** dialog window.

3. Select the remodeling index calculation method you want to use.

There are three calculation methods to choose from: **Interpolation using Proximal and Distal Vessel Areas, Average of Distal Vessel Areas, and Average of Proximal Vessel Areas.**

4. Select the position where you want to calculate the remodeling index for.

There are two positions to choose from: **At position of minimum lumen area (MLA)** and **At position of maximum area stenosis.**

The remodeling index data is displayed in the **Reference Area Calculation Based on Vessel Area at Same Location as Lumen Area** box.

To select result pages to print

1. Select the **OrgSheet** Tab.

2. Click **Print Results**.

This opens the **Select Pages to Print** dialog window.

3. Select the pages you want to be printed.

There are six pages to choose from, that refer to the **Excel Tabs**: “**OrgSheet**”, “**Images**”, “**Edge Segments**”, “**TissueAnalysis**”, “**TissuelImages**”, and “**OCTResults**”.

4. Click **All Pages** or **Selected Pages** to print.