

# **Qlvus® 3.0** Quick Start Manual

# Legal Notices

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# **Regulatory Information**

### Intended Use

Qlvus has been developed for the objective and reproducible analysis of intravascular ultrasound images. Its intended purposes are:

- supporting clinical diagnoses concerning stenoses and/or placement of interventional devices
- supporting subsequent clinical decision-making
- supporting clinical research trials that study changes in vessel condition over time as a result of interventions and/or medication

#### WARNINGS

QIvus must be used by cardiologists, radiologists, or trained technicians who are qualified to perform IVUS analyses. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. QIvus should not be used for purposes other than those indicated in the section Intended Use.

Users must make sure to read this manual to become familiar with the software and be able to obtain reliable analysis results.

### Indications for Use

Qlvus has been developed for the objective and reproducible analysis of tomographic images of both lumen and arterial wall of a coronary or vascular segment, in particular the assessment of a stenosis or artherosclerotic plaque. This information supports the possible placement of intervention devices in these vessels. Qlvus enables an advanced assessment of vessel, lumen, and stent morphology. It also avoids the very time-consuming conventional manual tracing of boundaries, which suffers from high intra- and inter observer variability. Qlvus can be used to control stent placement and to assess in-stent restenosis. Qlvus software package enables the automatic calculation and the display of various parameters such as: areas and diameters in individual slices; volumes over the segment of interest (Simpson's Rule) for the vessel, lumen and stent contours; plaque and in-stent restenosis parameters.

Qlvus analytical software is intended to support all clinicians, i.e. cardiologists, radiologists, and referring physicians involved in the assessment of ultrasound images. When interpreted by a trained physician these parameters may be useful in supporting the determination of a diagnosis.

## **European Regulations**

Qlvus 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.

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### North American Regulations

Qivus has 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.

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



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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 <b>Segment</b> tab, click <b>Apply</b> .	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 New analysis.	Text that you type or that appears on the screen, such as file names and file locations, is displayed in Courier New.

# Symbols Used

	<b>Reference.</b> Points to related documentation or to related sections in the document that may be relevant in your situation.
ę	<b>Tip.</b> 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.
	<b>Warning.</b> 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.

# **Table of Contents**

INTROE	DUCTION	۱1
1	About (	Qlvus1
2	Support	t2
3	Starting	g QIvus and Opening Studies5
	3.1	Starting Qlvus
	3.2	Opening Image Runs
	3.3	Closing Image Runs
4	The QI	us Workspace and Toolbars
WORKI	NG WITH	1 QIVUS 12
5	Review	ing 12
	5.1	Reviewing Image Runs12
	5.2	Adjusting Contrast and Brightness14
6	Perform	ning Analyses in IVUS Images16
	6.1	Pre-Analysis Actions16
	6.2	Performing Segment Analyses
	6.3	Editing Contours
7	Creatin	g Reports24
8	Exporti	ng Results25
TROUB	LESHOO	TING 26
REFERE	ENCE	

# Introduction

# 1 About Qlvus

 ${\rm QIvus}^{\circledast}$  is the Medis software solution for reviewing and analyzing IVUS studies of the coronary arteries.

Qlvus features rapid automatic detection of lumen, stent and vessel borders over the entire pullback 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.

# 2 System Requirements

### 2.1 Hardware

Qlvus:

- 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

#### Qlvus:

- 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

#### NOTES:

• To work efficiently with large datasets, a 64 bit operating system with 4 or 8 GB of RAM is recommended.

#### 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

### 2.3 Dependencies on Other Software

QIvus 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 QIvus. The following versions of Microsoft Excel are supported:

- Microsoft Excel 2003, 32 bit version
- Microsoft Excel 2007, 32 bit version
- 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, QIvus 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 support, you can go to the menu bar (on top of the program), click **Help** and choose one of the three options:

- 1) UserManual for a simple explanation on all available QIvus functions.
- 2) Instruction Movies for a visual explanation on 1) Getting Started, 2) Gui & Buttons, 3) Contour Detection, 4) Results, and 5) More Information.
- 3) About... for general package information, like the Qlvus version number, License Information, Legal Notices, and Contact Information (see also below).

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 QIvus version number is displayed in the title bar.

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# 4 Starting Qlvus and Opening Studies

### 4.1 Starting Qlvus

Qivus must be installed and the licensing mechanism must be enabled before you can start.



For instructions on installing QIvus and on enabling the license mechanism, we refer to the QIvus Installation Manual.

#### To start Qlvus



Double-click Qivus 3.0 on your desktop.

Or,

• Select Start > (All) Programs > Medis Qlvus > Qlvus 3.0.

### 4.2 Opening Image Runs

After starting QIvus, 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 Browse 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.

When you click on a folder in the directory structure, the Image Browser is immediately going to search for all files which QIvus can open. Therefore, clicking on a folder high in the directory structure can make the Image Browser slow. You can prevent this by clicking the [+] and [-] signs in the directory structure, in order to go down through the folder structure.

When the directory structure is not displayed, click **Folders** to display it.

To assist in the search for a specific image run, you can:

- o Click Preview, to display an image of the selected image run at the right.
- Click Screenshots, to display available screenshots of the selected image run at the bottom.

- You can add or remove the headings (searchable items) of the right-hand pane. Right-click on the headings and select or deselect the headings in the displayed menu.
- You can change the order of the headings in the right-hand pane. Click a heading, slide it to the left or right and release it at its new position.
- 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.

UAs location of the new analyses, you can select the Image Folder or the Analysis Storage Folder from the drop down menu.

To save new analyses to a different Analysis Storage Folder, click **Change Analysis Storage Folder**.... This opens a new dialog window. Browse the directory structure and select the directory where you want to store the analyses. Click **OK**.

4. If you are loading grayscale images, you can limit the number of frames that are loaded into Qlvus 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.

Click OK.

- 5. Qivus now starts to load the image run and creates the longitudinal images.
- 6. 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.

U The changes you make to the DICOM properties are only stored with the QIvus analysis results, not in the original DICOM file. Your changes are stored with the current analysis and shown in reports.

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

 $\bigcirc$  For easy comparison, it is possible to open multiple pullback at the same time. Repeat step 1 to 6 to add additional image runs.

## 4.3 Closing Image Runs

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

In both cases, whether it was opened for reviewing or analysis, an additional analysis will be added to the existing list of analyses.

# 5 The QIvus Workspace and Toolbars

The QIvus main workspace consists of a menu bar, a set of toolbars and a canvas that presents the transversal and the longitudinal views. Note that the QIvus appearance and functionality is influenced by the availability of the licenses.



0 The version number of QIvus is displayed in the title bar.

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

Tool Icon	Description
File Toolbar	
Browse	Browse for all types of image data that can be read in by QIvus and start analysis.
Close	Close the currently active image file.
<b>Save</b>	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.

Tool Icon	Description
년 Dicom	Hide or show the DICOM info.
- 🚑 Print	Print a one-page report with analysis results.
General Toolb	ar
Calibr.	Perform manual calibration and check the catheter and artifact circles.
Marker	Semi-automatically remove calibration markers.
Artif.	Automatically remove artifacts.
dan. Cardiac	Correct for cardiac motion.
Serview	(Re-)creates longitudinal images.
Segment	Specify the segment(s) and/or subsegments of interest for contour detection and reporting.
(11) Graph	Hide or show the area graph in the longitudinal view.
MLA	Jump to the frame with the minimum lumen area in the selected segment. 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.
Excel	Export the results of the selected analysis to Microsoft® Excel®.

Tool Icon	Description
De Info	Open the General Information dialog window, in which you can view and edit basic details about the patient, intervention, catheter and stent.
	① The changes you make to the properties are only stored with the QIvus analysis results, not in the original DICOM file. Your changes are stored with the current analysis and shown in reports.
7	Open the Settings dialog window.
Setting	In this dialog window, you can specify the scroll step and the loop interval.
	The other settings in this dialog window show the characteristics of the image run as detected by QIvus. The contour detection is optimized for each specific catheter type.
<b>O</b> LoopRev	Open the Loop Viewer window.
Analysis Toolbar	
Vessel	Indicate that you want to create or edit vessel contours.
Stent	Indicate that you want to create or edit stent contours.
Lumen	Indicate that you want to create or edit lumen contours.
Long	Detect longitudinal contours in the segment(s) of interest.
Market Constraints	Detect transversal contours in the segment(s) of interest.
Single	Detect a transversal contour in a single frame.
Correct	Place a correction point and correct the currently active contour in only the current transversal image.

Tool Icon	Description
UndoLong	Undo your changes to the positions of the attraction points.
Results	Open a dialog window with analysis results. Depending on the analyses performed, area, volume and diameter results may be presented.
Contour	Hide or show the transversal contour of the selected contour type.
<b>Exclude</b>	Exclude or re-include the current frame in the analysis.
<u>n</u> Undo	Undo only the last manual transversal contour edit. After use, the icon it becomes inactive until an additional manual edit is applied.
iii 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.

# Working With Qlvus

# 6 Reviewing

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 QIvus 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.

### 6.1 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.



• 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 I 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.

#### To play the loop viewer

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• Click LoopRev in the toolbar to open the Loop Viewer window.

In the Loop Viewer window, click . This starts playing the image run forward and backward around the current frame shown in the transversal view, over a number of frames specified in the settings.

#### Ö

To close the Loop Viewer window, click LoopRev again.

The loop view mode may be useful to get a clearer view of the lumen edge and of stent malapposition. The loop view mode shows all frames of the original image run in the transversal plane. So, this is the non-skipped and non-filtered image run.



To adjust the loop view interval, click Setting, and after Loop interval in the top right corner, specify the number of frames forward and backward that you want to view in the Loop Viewer.

#### To change the movie speed

• Drag the Speed slider to the right to increase movie speed, drag it to the left to decrease movie speed.

#### To change image selection

• Drag the Frame slider in one of the views.

Or,

• Use **M** and **M** to scroll the image run image for image in one of the views.

Or,

• In the longitudinal View, drag the red line to scroll through the images of the transversal image run.

• Use the left and right arrow keys or the Z and X keys to step through the images of the transversal image run at a specified interval, known as the scroll step. By default, the scroll step is 1 (image by image).

Pou can modify the scroll step. For instructions, we refer to the following section.

Or,

• Use the arrow up and arrow down keys to step through the images of the transversal image run five images at a time.

#### To modify the scroll step

To change the number of frames skipped in the scroll step:



This opens the Settings dialog window.

2. Fill in the scroll step in the Scroll step field in the top right corner.

The scroll step value can be based upon the pull-back speed, the number of frames per second and your protocol or standard operating procedure.

- 3. Click **OK**. This closes the Settings dialog window.
- 4. When you next use the Z and X keys or the left and right arrows on your keyboard, the specified scroll step is applied.

#### To zoom in

• Drag the Zoom slider in the transversal, longitudinal or loop view to the right.

#### To zoom out

• Drag the Zoom slider in the transversal, longitudinal or loop view to the left.

#### To pan the image

When the transversal, longitudinal or loop view image is zoomed in, you can re-position (pan) the image in the image viewer, to make sure the target area remains well in sight.

• Click somewhere in the image, move the cursor-hand to pan the image, release to accept.

### 6.2 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 or longitudinal image, 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.

U Make sure that the circle center point is positioned at the center of the catheter.

Next, click on the green **artifact circle** or circle center point to activate the artifact circle around the area with artifacts for editing. Subsequently, resize the artifact circle, until the artifact circle is just outside the major ring down artifact. Middle- or right-click to accept.

• Check the whole image run to make sure that no lumen is present within the artifact circle, to optimize the automatic contour detection results. Vice versa, enlarge (when possible) the artifact circle to include e.g. wire artifacts.

U The catheter- and artifact center points have the same position. Repositioning of the artifact center point will result in the repositioning of the catheter center point and circle (and vice versa).

 $\forall$  When the catheter center point is correctly positioned, there will be no need to reposition the artifact center point.

The following illustration provides an example.



In the Calibration dialog window, click Ok.

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

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.

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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 Artif.

You can view the uncorrected images in the Loop View window by clicking LoopRev

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

0 The cardiac motion button will be disabled when the contour detection is started.

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



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

### 7.2 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

For detailed instructions, we refer to section 4.2 and 6.1.

#### 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.



U When you edit the position of a marker end-point in the longitudinal view, the transversal view will automatically jump to the corresponding transversal frame (likewise the red cross-sectional marker line in the longitudinal view).

• The frame numbers shown in the status bar of the transversal view differ from those in the original data set if the number of frames has been limited. To view the original frame



numbers, open the Loop View window by clicking LoopRev.

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.



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.

For detailed instructions on exporting the MS Excel report, we refer to section 10.2.



In the Segment Definition dialog window, click **Define subsegments** and select the check boxes of the subsegments you want to add.

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.

U All (sub)segments are allowed to overlap with other (sub)segments.

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

Click Apply, and then click Close.

You can modify or add subsegment names if needed. To do this, browse to the Qlvus application folder. By default, this is C:\Program Files\Medis\Qlvus\3.0 or C:\Program Files(x86)\Medis\Qlvus\3.0. Open the file SubSegmentNames.xml and edit it using an XML editor to make the necessary changes.

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

① Make sure to create the contours in the order in which the icons are shown: first the vessel contour, then the stent contour, and finally the lumen contour.

• An exception to the previous note is a Volcano Eagle-Eye data set, which's contours can be better created in the following order: first the stent contour, then the vessel contour, and finally the lumen contour.



By default, the vessel contour is selected.



This detects the longitudinal contour in the segment of interest.

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

U An attraction point represents the cross-section of the longitudinal contour.

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.

You can take full advantage of this powerful editing option by starting with the longitudinal segment part that deviates most from what you expected. Make sure to start in the middle section of this deviating part of the segment.

U It is not necessary to extensively edit the transversal attraction points. Make sure that the longitudinal areas that are most off are corrected.



7. Click Trans .

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



Click Single when you only want to detect a single transversal contour 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

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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.

For detailed instructions on editing contours, we refer to section 7.3.

U 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 analysis results for the stented area and for the lumen area.
- 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.

U The five default frames are:

- 1) The middle frame between start- and end frame of the transversal distal reference segment;
- 2) MLA (when lumen contours are present) or the middle frame between start- and end frame of the transversal target segment;
- 3) The middle frame between start- and end frame of the transversal proximal reference segment;
- 4) The longitudinal frame number 0;
- 5) The longitudinal frame perpendicular to frame number 0 (e.g., 4 in case of 16 frames).
- Select Options > Define frames of interest to open the Frame navigation dialog window.
- 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.

- Press on one of the **Go to** buttons, to immediately go to the retained transversal or longitudinal frame.
- 12. You can view the analysis results by clicking Results.

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.

### 7.3 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.

• The first and second editing option override edits at a lower level. Make sure to start with the first editing option, then apply the second (if needed) or apply the third (if needed).

① Keep in mind that it is not necessary to manually edit the contours to perfection to obtain accurate results. You can check the analysis results in the meantime and see the impact of your

20 Results editing by clicking

#### To move an attraction point

① The attraction point of the transversal view works on multiple frames.

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.

igcup In the longitudinal image, the edited transversal attraction point will be displayed as a colored point (orange for vessel-, dark blue for stent, and light blue for lumen contours).

 $\left. \begin{array}{c} \mathbf{Q} \\ \mathbf{Q} \end{array} 
ight.$  The longitudinal attraction point can be dragged to a new position in the same frame or another frame as well.

2. To undo your manual attraction point change in the transversal view one by one, click NV

$\sim$	
UndoLong	

#### To insert a correction point

① The correction point of the transversal contour works on a single frame.



1. Click Correct 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

0 The manual re-tracing of the transversal contour works on a single frame, of the longitudinal contour on multiple frames.

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.



 $\stackrel{\bigvee}{=}$  To undo your manual correction in the transversal view one step back, you can click

once.

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.

U Be aware that the contour edges in the longitudinal view are less easy to read than the contour edges in the transversal view, and therefore less easy to edit accurately.

#### To delete contours

You can delete all IVUS contour types in the transversal and (when applicable) in the longitudinal view.

- 1. Click Vessel, Stent, or to specify the contour type you want to delete.
- 2. Next, click Delete 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**.

When you select **Delete current transversal contour**, the contour of the selected contour type will be removed from the current transversal image.

When you select **Delete multiple contours**, mark whether you want to delete contours of the selected contour type in the frames of a **Subsegment** or **All contours** of the selected contour type in all frames.

- In case of a Subsegment, fill in the Start and End frame.
- In case of All contours, it is possible to mark Delete longitudinal contours as well.
- 4. Click **Delete contours**, and the specified contours will be permanently deleted.

# 8 Creating Reports

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 Print to directly print the one-page report.

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.

# 9 Exporting Results

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.

U You can export transversal and longitudinal image (runs).

You can choose to save contours with the 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 <sup>Save</sup> 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 with the images.

U The final file name of the (BMP or JPEG) image will consist of the noted **File name** plus the concerning frame number. Click **Save**.

#### To export results to MS Excel

You can export your QIvus results to Microsoft® Excel® for further analysis.



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

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

This creates the MS Excel spreadsheet and displays it.

U By default, the XLS file is saved in the corresponding analysis/image subfolder in the Analysis Storage Folder.

 $\forall$  To make it easier to retrieve the saved XLS file, you can select a different folder location in the **Save in** box.

# Troubleshooting

# 10 Troubleshooting

#### My Image Browser is slow

When you click on a folder in the directory structure, the Image Browser is immediately going to search for all files which QIvus can open, in all subfolders. Therefore, clicking on a folder high in the directory structure can make the Image Browser slow. You can prevent this by clicking the [+] and [-] signs in the directory structure, in order to go down through the folder structure. See section 4.2 on page 5.

#### My directory structure is not displayed

In the Image browser you will see the directory structure. If this is not present you should click Folders to display it. See section 4.2 on page 5.

#### How can I see the original dataset?

Open the Loop view mode. The Loop view mode shows the non-skipped and non-filtered image run. See section 6.1 on page 12.

#### How can I change the scroll step?

In the settings you will find the option to set the Scroll step; the number of frames that are skipped using the Z and X or the left and right arrow keys on your keyboard. See section 6.1 on page 14.

#### Where can I find the original frame number if I loaded a subset?

Open the Loop view mode. The Loop view mode shows the non-skipped and non-filtered image run. The original frame number is displayed in the status bar. See section 6.1 on page 13 and section 7.2 on page 18.

#### My subsegment has a length of 0.00 mm

When identical frames are used as start and end frame, the subsegment can have a length of 0.00 mm. See section 7.2 on page 19.

#### How can I change the images in the Excel report?

Go to Options > Define frames of interest. Here you can change the default images that are included in the Excel report. See section 7.2 on page 20.

#### Why can't I calculate the remodeling index in the Excel sheet?

You will need both the proximal and distal reference segments to be able to calculate the remodeling index.

#### Floating license error after a crash of the software

In a floating license setup, licenses will be returned to the license server when Qlvus is closed. In case of a Qlvus software crash, the licenses will not be returned and remain locked on the license server. Restarting Qlvus will give a warning that the licenses are not available.

To solve this issue, you have to wait at most 2 minutes before you can start the software again. The license server checks every 2 minutes if the claimed licenses are still in use on the client machine. If the licenses are not in use, the license server will release the licenses.

#### Expiration date not updated after install non-expiring license

When you install a temporal license with CMS License Manager the license will be given an expiration date. You can see this expiration date in **View available licenses** in CMS License Manager. When you install a non-expiring license after you installed the temporal license the expiration date is not updated.

To see the correct expiration date of your licenses, you have to delete the expiring license before you install the non-expiring license. You can do this with the following steps:

- Start CMS License Manager (click Start, All Programs, Medis System Tools, CMS License Manager 2.5)
- Click Advanced...
- Click Delete licenses...
- Select all the expiring licenses
- Click Delete
- Click Close
- Click Close
- Click Install an additional license...
- Browse to the license file with the non-expiring license
- Make sure all licenses are selected
- Click Install
- Click Close

You are now able to see the licenses with their correct expiration date in View available licenses...

# Reference

#### Shortcut Keys

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

Press	То	
General		
F1	access the user manual.	
ALT+F4	close QIvus.	
Studies and Results		
CTRL+O	open a study.	
CTRL+P	print a one-page report with patient and analysis data.	
ALT+P	print a one-page report with patient and analysis data using the default printer.	
CTRL+S	save the current image run or part of the current image run as an AVI file, or save the currently selected frame as a BMP or JPG file.	
Images		
Right-click	accept edits.	
Click+right-click	remove a correction point.	
Z	move back the number of transversal slices defined in Setting > Scroll Step.	
x	move forward the number of transversal slices defined in Setting > Scroll Step.	

С	insert a correction point for the currently active contour.
w	move to the global minimum in the segment.
т	move to the global maximum in the segment.
E	move to the local minimum over a length of 21 slices.
Y	move to the local maximum over a length of 21 slices.
S	look for a distal area difference of more than 10%.
G	look for a proximal area difference of more than 10%.
1	move to the slice with the maximal in-stent re-stenosis.
U	move to the slice with the minimal in-stent re-stenosis.
Р	move to the slice with the maximal plaque area.
0	move to the slice with the minimal plaque area.
CTRL+T	rotate the image in the longitudinal view.