

QAngio XA 3D 2.1

Quick Start Manual



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<https://www.medisimaging.com>

On the Medis website, select “Products” and then the applicable product group. The user documentation can be found on that page.

A PDF reader is required to access the user documentation. If a PDF reader is not installed on the system, you can download the free Adobe reader. Visit the Adobe website at <https://get.adobe.com/reader/> and click "Download Adobe Reader" to download the PDF reader.

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Regulatory Information

Intended Use

QAngio XA 3D is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. These calculations are based on contours which are automatically detected in two angiographic views of the same vessel.

QAngio XA 3D enables interventional cardiologists and researchers to obtain accurate anatomical quantifications of one or more lesions in the analyzed coronary vessel segment, to determine the functional significance of the individual and consecutive multiple lesions, and to assess the best viewing angles which can be helpful for optimal visualization of the lesion during PCI (percutaneous coronary intervention) treatment.

The analysis results obtained with QAngio XA 3D are intended for use by cardiologists and researchers:

- to provide quantitative results of coronary vessel segments based on a 3D reconstructed model;
- to inform the clinical decision making process with respect to the diagnosis and possible PCI treatment options of the coronary vessels;
- to evaluate the procedural success of such coronary interventions.

Indications For Use

QAngio XA 3D is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease.

When the quantified results provided by QAngio XA 3D are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decisions making for the diagnosis of the patient or the evaluation of the treatment applied. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.

QFR Usage

QFR results needs to be used in a “hybrid” QFR - FFR decision making approach:

- $QFR < 0.78$ sufficiently high sensitivity to treat the patient in the cathlab;
- $QFR > 0.84$, sufficiently high specificity to follow the patient medically;
- QFR in the gray zone $[0.78, 0.84]$: use pressure wire and FFR measurement following the associated medical guidelines.

In order to obtain a correct QFR result, users need to be trained and certified by Medis Medical Imaging Systems.

Limitations

The two 2D angiographic images used for the 3D vessel reconstruction need to be taken with at least 25 degrees difference in viewing angle.

QFR measurements have not been evaluated for non-coronary arteries, pediatric patients, and cardiac patients with the following conditions:

- Tachycardia with frequency above 100 bpm
- Systolic aortic resting blood pressure below 75 mm Hg
- Atrial fibrillation


nor for the following lesions and vessels:


- Culprit lesions in Acute Coronary Syndrome
- Bifurcation lesions with 1,1,1 Medina classification
- Aorto-ostial artery stenoses or ostial right coronary artery stenoses
- Distal Left Main lesions in combination with a proximal Circumflex lesion
- Vessels with retrograde fillings
- Bypass grafts
- Grafted coronary arteries
- Myocardial bridging

QFR measurements cannot be performed accurately under the following conditions:


- When no nitroglycerin has been administered either systemic nor intracoronary;
- Too much overlap of other vessels with the lesion or areas just around the lesion in the target vessel in one or both angiographic acquisitions;
- Too much foreshortening of the target coronary artery in one or both angiographic acquisitions.

WARNINGS


 QAngio XA 3D must be used by cardiologists or trained technicians who are qualified to perform cardiac analysis. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. In clinical practice QAngio XA 3D should not be used for purposes other than those indicated in the section Intended Use.

 Users must have sufficient proficiency in the selected operating language, read this manual, become familiar with the software, and must be certified by Medis before using QAngio XA 3D in a clinical environment in order to obtain reliable analysis results.

Note on Monitor Aspect Ratio and Resolution

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

European Regulations

| | |
|---|---|
|  <p>1639</p> | <p>QAngio XA 3D is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.</p> |
|---|---|

North American Regulations

QAngio XA 3D complies with the requirements of the Canadian Medical Devices Regulations and has been licensed as a Class II medical device.

South American Regulations

QAngio XA 3D complies with the requirements of the Brazilian National Health Surveillance Agency and has been licensed as a Class II medical device.

Asia-Pacific Regulations

QAngio XA 3D complies with the requirements of the Australian Therapeutic Goods Administration and has been licensed as a Class IIa medical device.

QAngio XA 3D complies with the requirements of the Singapore Health Sciences Authority and has been licensed as a Class B medical device.

QAngio XA 3D complies with the requirements of the Indonesian National Agency of Drug and Food Control and has been licensed as a Class IIa medical device.

QAngio XA 3D complies with the requirements of the Malaysian Medical Device Authority and has been licensed as a Class B medical device.

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 primary mouse button. If you are left-handed, you may have set the right mouse button as your primary mouse button. |
| Click and drag | Press and hold the primary mouse button. Drag the mouse to perform a function. Release the primary mouse button. If you are left-handed, you may have set the right mouse button as your primary mouse button. |
| Right-click | Press and release the secondary mouse button. If you are left-handed, you may have set the left mouse button as your secondary mouse button. |
| Middle-click | Press and release the wheel button or the middle mouse button. If you have a two-button mouse, press and release the left and the right mouse button simultaneously. |
| Double-click | Press and release the primary mouse button twice. |
| Wheel | Rotate the mouse scroll wheel. |

Keyboard

| | |
|-------------|--|
| SHIFT+click | Press and hold down the SHIFT key on your keyboard while you click a button or object. |
| CTRL+K | Press and hold down the CTRL key on your keyboard while you press K, then release both keys. |

Typographical Conventions

| | |
|---|---|
| On the Annotations node of the Procedures pane... | Names of buttons, fields, menus, menu options, and tab names are capitalized and in bold. |
| Procedures > Text Annotation | A sequence of menu options that you select to perform a specific task is indicated by angular brackets. |
| Label: <code>Aortic root</code> | Text that you type or that appears on the screen, such as annotation labels, is displayed in <code>Courier New</code> . |

Symbols Used



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 QAngio XA 3D

QAngio XA 3D is the Medis software solution for the quantification of coronary vessels in 3D using two angiographic projections.

2 System Requirements

2.1 Hardware

QAngio XA 3D:

- Intel or compatible quad-core processor
- 4 GB of RAM
- 250 GB of available hard disk space
(if you want to store images locally, make sure you have enough disk space)
- 3-button mouse, scroll-wheel recommended
- CD-ROM player to install the software from CD-ROM
- Widescreen monitor supporting a minimum resolution of 1920x1080 pixels
- Video card supporting OpenGL and with 512 MB memory
- Network interface card of at least 100MBit/s to access, receive, and send images over the network

Sentinel license server:

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

NOTES:

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

2.2 Operating System

QAngio XA 3D:


- Microsoft Windows 10, 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows Server 2012 R2, 64-bit
- Microsoft Windows Server 2016, 64-bit
- Microsoft Windows Server 2019, 64-bit

Sentinel license server:

- Microsoft Windows 10, 32-bit and 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows Server 2012 R2, 64-bit
- Microsoft Windows Server 2016, 64-bit
- Microsoft Windows Server 2019, 64-bit

3 Support

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

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

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4 Startup from Medis Suite

To enhance your image processing workflow, QAngio XA 3D is launched from Medis Suite in different analysis modes. Each launch mode will provide a different image analysis option, with dedicated functionality and viewport layouts.

The following launch modes for QAngio XA 3D are available in Medis Suite:



QFR: Quantitative Flow Ratio analysis



3D Single vessel analysis



3D Bifurcation vessel analysis

Detailed information on how to start the QAngio XA 3D app and load images is described in the Medis Suite user manual.



Availability of the launch modes is dependent on the available licenses. If you would like to purchase a license for one or more of the QAngio XA 3D analysis modules, please contact Medis.

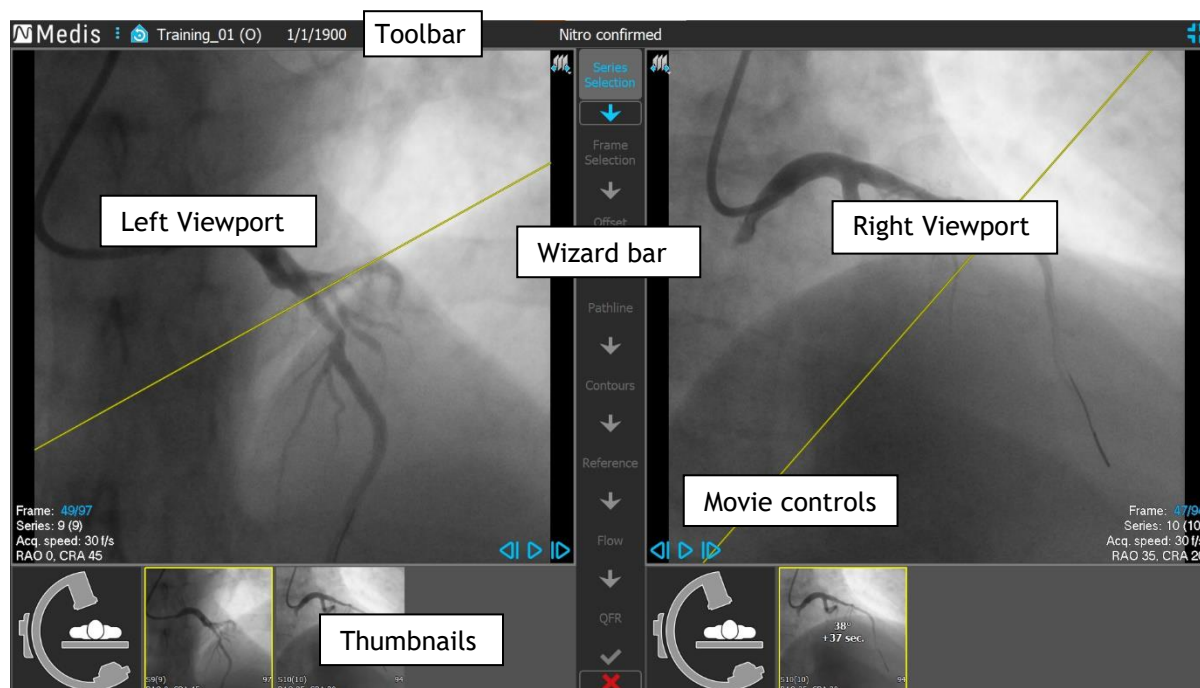


You can load the patient images before or after starting QAngio XA 3D. In both cases the images will automatically be loaded into QAngio XA 3D.

5 QAngio XA 3D Workspace

5.1 Overview


The main workspace of QAngio XA 3D consists of viewports, a toolbar, a wizard bar and optional thumbnails.



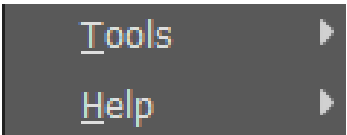
5.2 Menu

The main menu contains commands to activate the application functionality.





To make the menu visible:

- Click on the menu icon  in the toolbar of the QAngio XA 3D app.

The menu commands are organized into two main menus: **Tools** and **Help**. For some of these commands, tool buttons are available in the toolbars as shortcuts.

| Menu | Command | Description |
|---|---------|---|
|  | Tools | Access to options and tools |
| | Help | Access to user documentation and information about Medis Suite and QAngio XA 3D |

5.3 Toolbar

| Icon | Function |
|---|--|
|  | Show the menu |
|  | Go to the initial view state, reset zoom \ pan \ window width \ window level |
|  | Show the application in full screen mode. Only present if application is in windowed mode. |
|  | Show the application in windowed mode. Only present if application is in full screen mode. |

Besides these icons the toolbar also shows the patient's name, gender and birthdate.

The toolbar is also used for interactive text messages and resulting status.

E.g. After selecting the series in a QFR analysis, it blinks in orange: "Click here to confirm nitro has been administered. After confirmation this changes to "Nitro confirmed" (not blinking).

5.4 Wizard bar

The vertical wizard bar is shown between the two viewports and represents the steps required to perform the analysis. The content of the wizard bar is dependent on the analysis you are performing: 3D single vessel, 3D bifurcation, or QFR.

5.5 Context menu

A context menu can be activated by clicking the right mouse button in a viewport, diagram or table. The contents of this menu is dependent on the analysis you are performing, the clicked item, the wizard step and the state within a step.

6 Viewing

6.1 Image viewports

Many analysis wizard steps have two image viewports that can display two matching images of the same study. See section 7.1 Series selection for info about the image requirements.

6.1.1 Resizing a viewport

To maximize a viewport:

- Double-click the viewport.

This maximizes the viewport, so that it takes up the maximum space.

To return to the original viewport layout:

- Double-click the image again.

6.1.2 Mouse mode







The behavior of the left mouse button depends on the mouse mode: cine, zooming, panning, or window width and level. The active mouse mode is displayed in the mouse mode icon in the top corner of the image viewport.

To cycle through the different mouse modes:

- Select the mouse mode icon to activate the next mouse mode.


6.1.3 Frame selection


You can move forward or backward through frames in the image in several ways. Moving through frames only applies to the selected viewport, unless synchronization is active, see 6.1.4 Synchronization. The active frame number is shown at the bottom of the viewport.

| Action | Button in Viewport | Key on keyboard | Mouse scroll wheel | Left mouse button (cine mode) |
|------------------------|--|-----------------|--------------------|-------------------------------|
| Select next frame |  | → | Scroll down | Mouse drag right or down |
| Select previous frame |  | ← | Scroll up | Mouse drag left or up |
| Select first frame | | Home | | |
| Select last frame | | End | | |
| Play the cine forward |  | Ctrl + → | | |
| Play the cine backward | | Ctrl + ← | | |
| Stop playing the cine |  | | | |
| Toggle synchronization |  | | | |
| Select frame | Right click on the frame number in bottom corner of the viewport and enter the frame number. E.g.  | | | |

6.1.4 Synchronization

Frame synchronization helps you to simultaneously navigate through images in both viewports. The image in the left viewport is considered as the primary image, and the image in the right viewport is considered secondary.


When synchronized, the  icon is shown at the lower part of the viewport. Both viewports will always show the image with the same frame number.

When not synchronized, the  icon is shown at the lower part of the viewport or no icon is shown at all. Changing the frame selection in one viewport does not affect the other viewport.




Frame synchronization is only available for corresponding biplane images.

To switch synchronization off:

- Click the  icon in the image overlay to switch off synchronization.

To switch synchronization on:

- Click the  icon in the image overlay to switch on synchronization.


6.1.5 Invert Image

To invert the image view, i.e. turn blacks to whites and whites to blacks:

- Select “Invert image” from the viewport context menu to toggle the image inversion.

6.1.6 Initial View State

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

- In the toolbar, click  to reset the zooming, panning, window width and level, and image inversion.




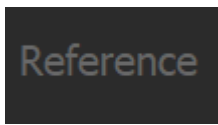



7 Performing an Analysis

QAngio XA 3D supports the analysis of single vessel segments in 3D, bifurcation vessel segments in 3D, and the analysis of the Quantitative Flow Ratio (QFR).

To start an analysis, select the appropriate launch mode in Medis Suite (see also Chapter 4). Any images loaded in Medis Suite will be loaded automatically in QAngio XA 3D, and the analysis will be started.

For a new analysis, QAngio XA 3D will by default switch to full screen layout, providing you with the best window layout for the subsequent analysis steps. If you reload a Medis Suite session that has QAngio XA 3D analyses, they will be restored and activate QAngio XA 3D in review mode.

A wizard will guide you through the steps necessary to perform the analysis. The wizard steps are represented by the wizard bar between the two images. The wizard steps depend on the type of the analysis.

| Wizard bar | |
|---|---|
|  | Buttons with blue text on a dark background indicate completed steps. Any of these buttons can be pressed to jump to the corresponding wizard step. |
|  | The Button with blue text on a grey background indicates the active step. |
|  | The button with the blue arrow can be pressed to proceed to the next step of the analysis. This button is only enabled when all required data for the active wizard step is available. |
|  | Buttons with grey text on a dark background are disabled. The wizard step has not been performed. |
|  | Cancel button. Select the button to cancel the analysis and discard all changes. For a new analysis, cancelling the analysis will close the QAngio XA 3D app and remove it from the Medis Suite session. |
|  | Finish button. Select the button to complete the analysis. The wizard will be closed and QAngio XA 3D will show the analysis in review mode. The analysis results will become available in the Medis Suite report. |
|  | When you have passed the Frame Selection step and activate another frame than the one used for the analysis, the wizard will be paused. All buttons in the wizard bar will be disabled except for a Resume button which will be displayed at the bottom of the wizard bar. Select the Resume button to activate the analysis frames, and resume the analysis. |

7.1 Series selection

The analysis starts with the series selection step. The objective of this step is to obtain two appropriate images to be used in the 3D reconstruction of the vessel segment.

7.1.1 Image requirements

QAngio XA 3D only loads DICOM greyscale XA images with square pixels (pixel aspect ratio 1:1) that include isocenter calibration data.

To perform the QFR analysis, it is advised to use non-hyperemic contrast images. If you need to perform QFR analysis on hyperemic images, please contact Medis to obtain a special license for that purpose.

Once an image is loaded into the left-hand viewport, only images that will make a suitable analysis pair can be loaded into the right-hand viewport. The acquisition angle of the two images must be larger than 25°, and the images must be acquired less than 120 minutes apart.

7.1.2 Selecting from existing series

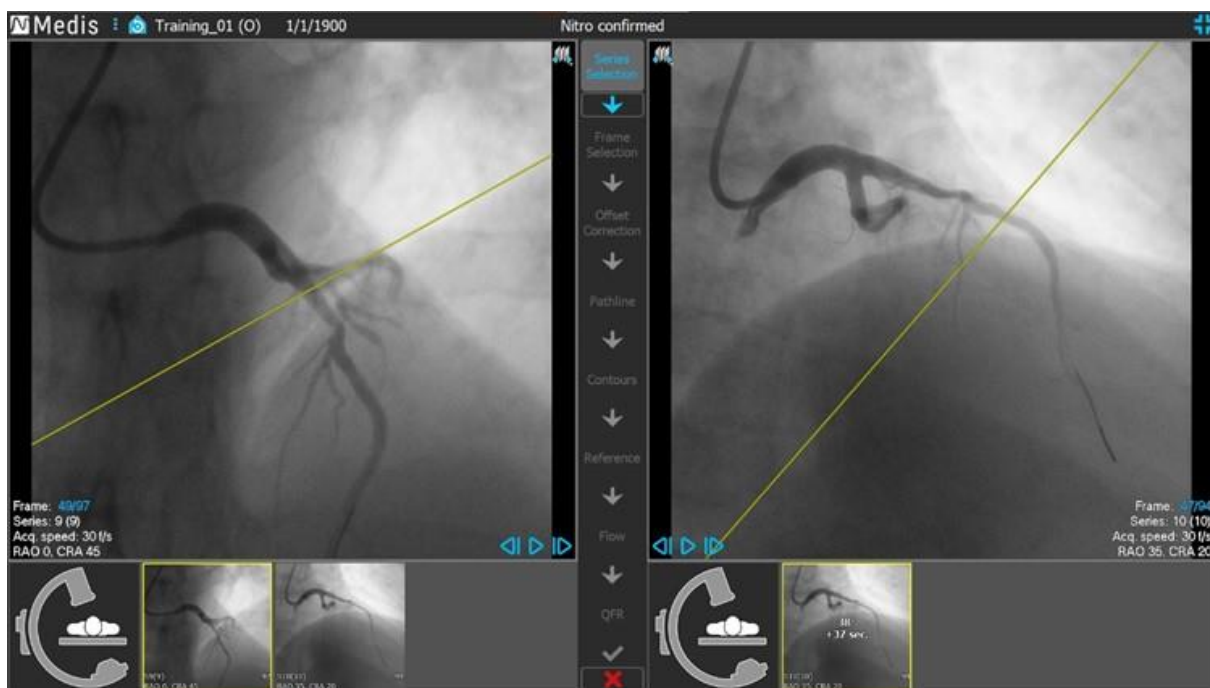
To select the two series for analysis:

1. Click on a thumbnail under the left viewport.
 - The image will be loaded in the left viewport.
 - Thumbnails of matching images appear under the right viewport.
2. Click on a thumbnail under the right viewport (not needed if already loaded)
 - The image will be loaded in the right viewport
3. In case of a QFR analysis click on the blinking text in the toolbar to confirm that nitroglycerin has been administered.

If only one image is loaded (in the left-hand viewport), the yellow line indicates the projection of an image with acquisition angles as set in the **Acquisition** guide.

If both images are loaded, on each image the projection line of the other image is shown. The projection line represents the X-ray beam that hits the center of the other image.

Best results are obtained when this line is perpendicular to the vessel of interest.




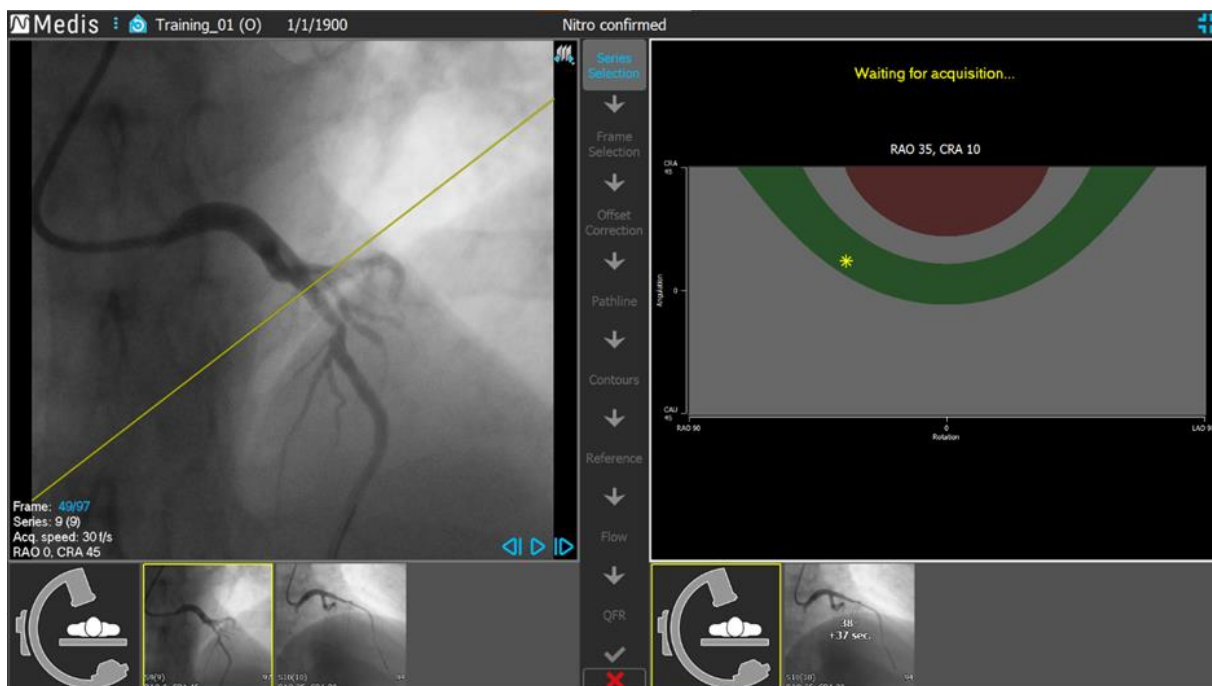
7.1.3 Acquisition Guide

The **Acquisition Guide** helps to find suitable rotation and angulation angles for a matching second acquisition if the first acquisition is loaded in the left-hand viewport.


To view the acquisition guide:


- Click on the thumbnail with the C-arm image under the right viewport

For the selected rotation and angulation angle, marked with , the projection line is shown on the image in the left-hand viewport:



To change the rotation and angulation angle:

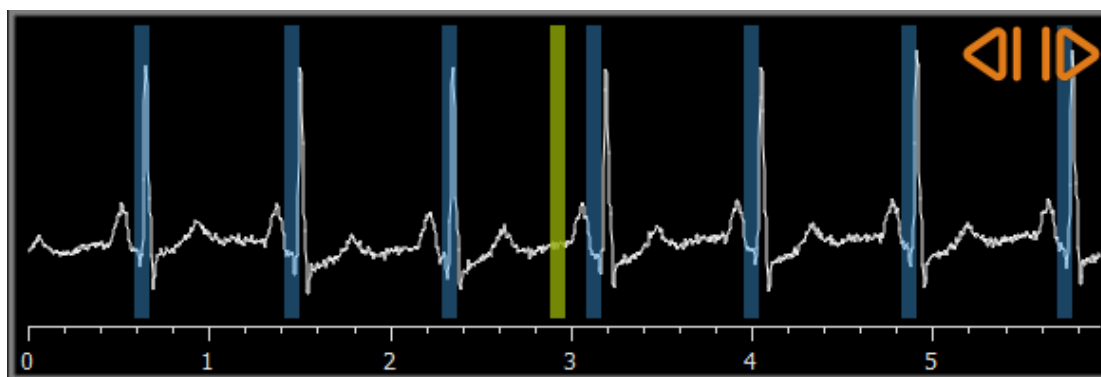
- Drag the marker  to the desired rotation and angulation.

Press  to proceed to the next step.

7.2 Frame selection

The objective of the frame selection step is to select a pair of frames to be analyzed. It is advised to select frames that are on (or just before) the end diastolic (ED) phase of the heart cycle.

The frame selection control is shown below each image viewport. On the x-axis, time is displayed in seconds. The yellow/green vertical bar indicates the selected frame, visible in the corresponding image viewport. If ECG data is included with the image data, the ECG curve is shown in the frame selection control.



The blue bars indicate the frames that correspond to the automatically detected ED phases. By default, the ED phases are automatically detected from the ECG signal if this is available. Only for the QCA Single Vessel analysis, if no ECG signal is available, ED phases are detected from the image information using AI technology.



To select a frame using the frame selection control:

- Drag the yellow/green vertical bar to the desired location.


Or,

- Click in the frame selection control to place the vertical bar and select the corresponding frame at the desired location.

Or,

- Click on  to select the same phase in the previous cardiac cycle.
- Click on  to select the same phase in the next cardiac cycle.

If no ED phases have been detected from either the ECG or the image information, you have to find the proper ED phase for the analysis manually. The 'QAngio XA 3D Image Analysis' white paper explains in more detail how to find the proper ED phases based on the image characteristics.

Press  to proceed to the next step.

7.3 Offset correction

The objective of the offset correction step is to provide an accurate image offset correction, allowing QAngio XA 3D to create a 3D space from the two images.

To apply offset correction:

1. In the left-hand viewport, click on an anatomical landmark.

This will mark the landmark in the left viewport and display a corresponding projection line of this landmark in the right-hand viewport.

2. In the right-hand viewport, click on the same anatomical landmark.

This will mark the landmark in the right-hand viewport and display a corresponding projection line in the left-hand viewport. The offset correction is now performed automatically.

To verify successful image offset correction:


- Click in the left-hand or right-hand viewport to select a landmark.

This will display a corresponding projection line in the other viewport, which can be checked with the anatomical landmark.

To delete a checkpoint:

- With the right mouse button click on the circle in the image.

The circle and projection line in the other viewport will be removed.

Press  to proceed to the next step.

7.4 Pathlines

The objective of the pathline step is to create a set of pathlines that define the vessel segment of interest.

To create pathlines:

- Click in the left-hand viewport to mark the proximal point of the vessel segment.
- For a single vessel analysis, click once in the left-hand viewport to mark the distal point of the vessel segment.

For a bifurcation analysis, click twice in the left hand viewport to mark both distal points of the bifurcated vessel segments.

QAngio XA 3D will automatically detect the pathlines and contours in both viewports.

- If needed, drag the proximal or distal point(s) of the vessel segment in either the left- or right-hand viewport to correct their locations.


To edit a pathline:

It might be that a wrong pathline is found (e.g. when the vessel is crossed by another vessel). In that case you can add one or more support points to guide the pathline through the segment of interest. If editing is required, correct the pathline before making corrections to the contours.

- Click a point on the pathline and drag it to the correct position.
This creates a support point and redetects the pathline and the contours.
- If needed add more support points or drag existing support points to better locations.

To delete a pathline support point:

- Right-click on the support point to delete it.
The pathlines between the proximal and distal points and the contours are redetected automatically.

Press  to proceed to the next step.

7.5 Contours


The objective of the contour step is to assert that the vessel contours are correct. You can verify and optionally correct the automatically detected contours. On entering the contour step for the first time, the image will be zoomed for a better look at the contours.

To edit a contour:

- Click a point on the contour and drag it to the correct position.
This will create a contour support point and redetect the corresponding contour.
- If needed add more support points or drag them to better locations.

To delete a contour support point:

- Right-click on the support point.
The point is deleted, and the corresponding contour is redetected.

Press  to proceed to the next step.

7.6 Correspondence

The objective of the correspondence step is to assert that the correspondence between the diameter functions of the left and right projections is correct. If needed, the correspondence can be corrected. This step is only available in the **3D Bifurcation** analysis.

In the correspondence step two extra viewports are displayed: a 3D model of the analyzed vessel segment and two diagrams with the minimum and maximum diameters of the 3D model. This diagram is very useful to evaluate how well the diameters correspond between the two images. The left viewport shows a blue correspondence marker in the vessel. This marker is also present in the diagram, but not yet in the right viewport.

To evaluate the correspondence:

- Examine the diameter functions in the diagram.
- Drag the correspondence marker in the left viewport or in the diagram.

A correspondence marker in the right viewport is created and moves along while you drag the marker in the left viewport, indicating how the two markers correspond.




The correspondence markers will make one marker pair if they are placed in the proximal segment. They will make two marker pairs if they are placed in the distal segments, but they cannot be set independently from each other. The correspondence markers cannot be placed in the bifurcation core.

If you are not satisfied with the correspondence of the markers in the left and right viewport, you can correct the correspondence by forcing a corresponding location in the vessel.

To force a corresponding location in the vessel:

- Drag the correspondence marker in the left viewport to a position you want to correct, preferably an anatomical landmark that is also visible in the right image.
- Drag the correspondence marker in the right viewport to the same anatomical landmark.

The correspondence markers turn orange to indicate that a corresponding location has been forced by the user. The diameter functions are recalculated. The 3D model and the diameter functions in the diagram are updated as result of the newly calculated diameter functions.

Press  to proceed to the next step.

7.7 Reference

The objective of the reference step is to obtain correct reference diameter functions and lesions markers.

QAngio XA 3D will determine and display the following:

- The 3D vessel model, including optimal viewing angles and foreshortening.
- The 2D and 3D reference contours, indicating the vessel contours had the vessel been healthy.
- One or more lesions, each having a table displaying the following lesion parameters: percentage diameter stenosis, minimal lumen diameter (MLD), and the lesion length.



In a **3D Single Vessel analysis or QFR analysis**, up to 3 lesions are automatically detected, and you will have an option to define a custom lesion.

In a **3D Bifurcation analysis**, up to 4 lesions are automatically detected, with a minimum of 1 and a maximum of 3 per bifurcation branch. There is no option for a custom lesion. No lesions will be automatically detected in the bifurcation core. The lesion identifier shows in which bifurcation branch the lesion was detected (e.g. “Lesion 1 (A)” is the first lesion that was detected in branch A).

For the selected lesion, QAngio XA 3D will display the following:

- The proximal (P) and distal (D) lesion markers, indicating the start and end of the detected lesion.
- The obstruction (O) marker, indicating the maximal obstruction in the lesion.

7.7.1 Correcting Reference Contours

3D Single Vessel and QFR Analyses

There are two ways for correcting the reference contour:

- You can mark two healthy parts of the vessel segment as “normal areas”.

Or:

- You can set a fixed reference diameter for the proximal part of the vessel in combination with a ‘normal area’ for the distal part.

To correct the reference contours by normal areas:

- Click the button **Normals** (above the diagram) to put the reference contours in normal area mode. Two normal areas will appear in the image and in the diagram.
- Click and drag the areas to the required positions, either in an image or in the diagram. You can resize the areas by dragging an edge. The reference contours will be recalculated automatically.

To correct the reference contours by a fixed proximal reference diameter:

- Click the button **Fixed prox** (above the diagram) to put the reference contours in fixed proximal reference mode. A marker (proximal) and a normal area (distal) will appear in the image and the diagram.
- Adjust the normal area either in an image or in the diagram by:
 - Dragging the area to the desired position and/or
 - Resizing the area by dragging an edge.The reference contours will be recalculated automatically.
- Adjust the reference diameter value at the position of the proximal marker by selecting a value in the dropdown menu.

3D Bifurcation Analysis

For the 3D bifurcation analysis, you can set a fixed reference diameter for the proximal and two distal sections of the bifurcation.

To correct the reference contours by a fixed proximal or distal reference diameter:

- Adjust the reference diameter value for the proximal section, or either of the two distal sections by selecting a diameter value from the dropdown menu.

Based on the selected reference diameters in the proximal segment and the two distal segments, the HK reference ratio is calculated and displayed. In healthy bifurcations, the value is approximately 1.00.

7.7.2 Correcting Lesion Markers

Multiple lesions can be detected in a single vessel segment. The maximum number of automatically detected lesions can be set in the options.

To correct the lesion markers:

- If needed, select the desired lesion by clicking on its lesion table.
- Click and drag the obstruction (O) marker to the required position.
- Click and drag the proximal (P) and distal (D) markers to the required positions.

To reset the lesion markers to the automatically detected position:

- Select **Reset lesion** from the lesion table's context menu.

To reset all lesion markers to the automatically detected position:

- Select **Reset all lesions** from the lesion table's context menu.

To delete a lesion:


- Select **Delete lesion** from the lesion table's context menu.


In a QFR or 3D Single Vessel analysis, a user defined (custom) lesion can be added.

To create an user defined (custom) lesion:

- Click on the **User (+)** table.
- Drag the obstruction marker (O) to the required position
- Optionally correct the proximal (P) and distal (D) markers.

7.7.3 Accept the analysis results

In a **3D Single Vessel analysis** or a **3D Bifurcation analysis**, this is the last wizard step. Press  to end the wizard. The analysis results will now become available in the Medis Suite report and will be stored if the Medis Suite session is saved. QAngio XA 3D will enter the review state of this analysis.

In a **QFR analysis** two more wizard steps are present. Press  to proceed to the next step.

7.8 Flow

The objective of the flow step is to determine flow velocity of the blood through the vessel segment being analyzed. This step is only present in QFR analyses.

The calculation of the QFR values is dependent on the vessel segment type. The type must be specified in the Flow step.

To select the segment type:

- Click on the appropriate button: **'Left Main / LAD'** or **'Other coronary'**



After your initial selection of the segment type, the selection can be changed through the context menu in the 3D viewport.

QAngio XA 3D will attempt to perform and apply an **Automatic Frame Count**. This will automatically track the contrast through the vessel segment and determine the flow velocity.

If the Automatic Frame Count could be performed successfully it will be applied, and the analysis will automatically proceed to the next and final step of the analysis. If you want to activate another option to determine the flow velocity, you can return to the Flow step and select one of the alternative options.

If automatic frame count could not be performed successfully, the **Manual Frame Count** mode will be activated. The manual frame count should be completed to be able to proceed to the next and final step of the analysis. If manual frame count cannot be performed, it is possible to activate the **Fixed Flow** option.



Availability of the **Fixed Flow** state requires a specific license. If the license is not available, either automatic or manual frame counting must be applied.

To activate the automatic frame count:

- Click the button **Automatic Frame Count** to enable automatic frame counting. The flow velocity that was the result of the Automatic Frame Count will be applied.

To activate the manual frame count:

- Click the button **Manual Frame Count** to enable manual frame counting. Frame counting is performed on the image displayed in the large viewport. Perform manual frame count to determine and apply the manually determined flow velocity.

To activate the fixed flow velocity:

- Click the button **Fixed Flow** to enable the fixed flow. The fixed flow velocity will be applied.

To change the automatic or manual frame count image:

- Double click on one of the analysis images, presented by thumbnails at the right side of the wizard bar.

Or,

- Click on one of the images, presented by thumbnails under the large viewport.


To perform manual frame count:

- Navigate through the frames until the start of the contrast bolus reaches the end of the analyzed segment, indicated by the distal frame count marker (e). Drag the distal frame count marker if the exact arrival of the contrast bolus does not match the initial location.

Press **End frame**.

- Navigate through the frames until the start of the contrast bolus reaches the start of the analyzed segment, indicated by the proximal frame count marker (s). Drag the proximal frame count marker if the exact arrival of the contrast bolus does not match the initial location.

Press **Start frame**.

Press  to proceed to the next step.

7.9 QFR

The QFR wizard step calculates the QFR value and summarizes all analysis results. This step is only available in the QFR analysis, and is the final wizard step.

To determine the QFR value at a specific location in the vessel segment:

- Drag the index marker (i) in an image or in the diagram.
While dragging the QFR value at the index marker is displayed in the 3D viewport.



QFR results needs to be used in a “hybrid” QFR - FFR decision making approach:

- QFR < 0.78 sufficiently high sensitivity to treat the patient in the cath lab;
- QFR > 0.84, sufficiently high specificity to follow the patient medically;
- QFR in the gray zone [0.78, 0.84]: use pressure wire and FFR measurement following the associated medical guidelines.


Now that the QFR results are available, you may decide that another lesion is more significant. Selecting lesions and editing/reverting lesion markers is the same as in the reference step, 7.7.

To create an extra lesion:

- Click on the **User** table (+)
- Drag the obstruction marker (O) to the required position
- Optionally correct the proximal (P) and distal (D) markers

To delete a lesion:

- Click right mouse button on lesion table and select **Delete lesion**

Press  to end the wizard. The analysis results will now become available in the Medis Suite report and will be stored if the Medis Suite session is saved. QAngio XA 3D will enter the review state of this analysis.

7.10 Review mode

The review mode shows the relevant values, images and diagrams of an analysis. The review mode is activated after completing an analysis, or when an analysis is restored from a Medis Suite session.

To determine the QFR value at a specific location in the vessel segment:

- Drag the index marker (i) in an image or in the diagram.

The QFR value at the index marker is displayed in the 3D viewport.

To select another lesion:


- Click on the corresponding lesion table in the 3D viewport.

The lesion markers in all images and diagrams will be updated.

To View any image in the large viewport:

- Double click in the viewport you want to be enlarged.

To edit the analysis:

- Click  in the toolbar.

7.11 Report

After completing an analysis, the report in Medis Suite will include all analysis information. While editing an analysis, the report content is removed from the report and re-added after completion.

Details on the reporting functionality can be found in the Medis Suite user manual.