

QAngio XA 8.1

User Manual

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Regulatory Information

Intended Use

QAngio XA is software intended to be used for performing calculations in X-ray angiographic images of the chambers of the heart and of blood vessels. These calculations are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing. QAngio XA is also intended to be used for performing caliper measurements. The results obtained are displayed on top of the images and provided in reports.

The analysis results obtained with QAngio XA are intended for use by cardiologists and radiologists:

- · to support clinical decisions concerning the heart and vessels
- to support the evaluation of interventions or drug therapy applied for conditions of the heart and vessels

Indications for Use

QAngio XA is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the calculations in X-ray angiographic images of the chambers of the heart and of blood vessels, for use on individual patients with cardiovascular disease.

When the quantified results provided by QAngio XA 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.

WARNINGS

- QAngio XA 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 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, and become familiar with the software before using QAngio XA in a clinical environment in order to obtain reliable analysis results.
- Inherent to the angiographic method and the ventricular volume modeling, QAngio XA may severely overestimate the end-diastolic right ventricle volume in case of enlarged left ventricles.
- QAngio XA may underestimate the volumes of large right ventricles with extensive trabeculae in case of bad contrast fillings.

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



QAngio XA 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.

North American Regulations

QAngio XA 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.

Caution

Federal law restricts this device to sale by or on the order of a physician.

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

Asia-Pacific Regulations

QAngio XA complies with the requirements of the Japanese Pharmaceutical and Medical Device Law and has been licensed as a Class II medical device.

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一般的名称:汎用画像診断装置ワークステーション用プログラム

販売名:心臓血管画像解析ソリューション Medis Suite

管理医療機器:227AFBZI00140000



(01)08720892272522 (17)301031 (10)4.0.70.8A

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

QAngio XA complies with the requirements of the South Korean Medical Device Act and has been licensed as a Class II 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

General > Tools > Options A sequence of menu options that you select to perform a

specific task is indicated by angular brackets.

Label: Aortic root Text that you type or that appears on the screen, such as

annotation labels, is displayed in Courier New.

Symbols Used



Tip: Provides helpful information or an alternative working method.

1

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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Introduction

1 About QAngio XA

QAngio XA is the Medis solution for the quantification of coronary and peripheral vessels and ventricles of the heart in X-ray angiograms.

This software solution offers quantification results that enable interventional cardiologists and radiologists to review X-ray angiograms, and it provides a solid basis for the assessment of new therapies.

2 System Requirements

2.1 Hardware

QAngio XA:

- A 64 bit processor
- 8 GB RAM
- 10 GB free disk space after the software is installed
- A monitor with a screen resolution of 1.3 Megapixels (e.g. 1280 x 1024 pixel for a display ratio 4:3, 1600 x 900 pixels for display ratio 16:9)

Sentinel license server:

- A 32 or 64 bit processor
- 4 GB RAM
- 5 GB of available hard disk space

NOTES:

- All hardware must be compliant with the operating system.
- The requirement for the disk space does not take storage space for image data into account. If you want to store images on the local machine, make sure that sufficient disk space is available. Also note that client machines will cache image data from the server temporarily on the local machine.
- To view image data a dedicated graphics card supporting OpenGL and at least 512 MB memory is recommended.
- To connect your workstation with other machines in the network (e.g. a client-server configuration, or receive and send images to a remote DICOM node) a network connection will be required. A network interface card supporting at least 100 mbps is recommended.
- For the license server, a workstation with a fixed IP address or a reserved IP address in the DNS server is recommended.

2.2 Operating System

QAngio XA:

- 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
- Microsoft Windows Server 2022, 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
- Microsoft Windows Server 2022, 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 is launched from Medis Suite in different analysis modes. Each mode will provide you with different image analysis functionality with dedicated functionality and viewport layouts.

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



QCA Single Vessel

Coronary single vessel analysis on monoplane XA image acquisitions



QVA Single Vessel

Peripheral single vessel analysis on monoplane XA image acquisitions



LV Monoplane

Left ventricle analysis on monoplane XA image acquisitions



LV Biplane

Left ventricle analysis on biplane XA image acquisitions



RV Biplane

Right ventricle analysis on biplane XA image acquisitions



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



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

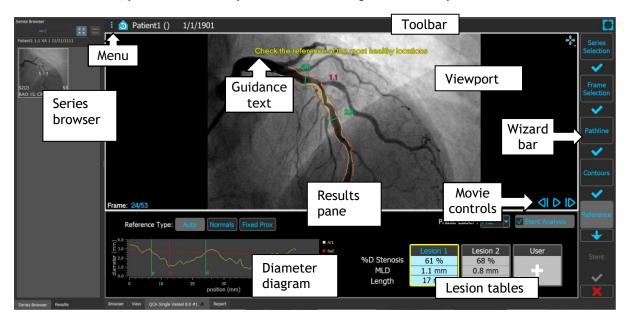
Detailed information on how to start the QAngio XA app and load images is described in the Medis Suite user manual.

5 QAngio XA Workspace

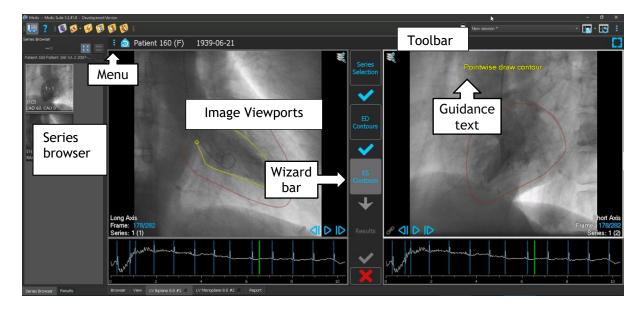
5.1 Overview

The main workspace window of QAngio XA consists of toolbars, workspace panes, and the central window area with the image viewport(s). The layout of the workspace window differs between the different QAngio XA launch modes; it is dependent on the type of acquisitions used as input for the analyses (monoplane or biplane), and the analysis module that was selected.

In this screenshot, you can see the layout for the QCA Single Vessel analysis:



In this screenshot, can see the layout for the Left Ventricle Biplane analysis:



5.2 Menu

The menu contains commands to activate the application functionality.

To make the menu visible:

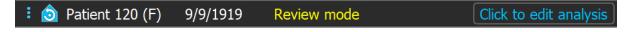
• Click on the menu icon in the toolbar of the QAngio XA app.

The available menu commands are dependent on the launch mode you selected. The table below shows information of the menu.

Menu	Command	Description
•	Tools	Access to options and tools
<u>T</u> ools <u>H</u> elp	Help	Access to user documentation and information about Medis Suite and QAngio XA

5.3 Toolbar

The image below shows the toolbar that is available in QAngio XA.



The toolbar contains the button to show the menu, the patient name and birthdate and optional info and/or buttons.

Icon	Function
•	Show the menu
(3)	Go to the initial view state, reset zoom / pan / window width / window level
Patient 120 (F)	Name and gender of the patient
9/9/1919	Birthdate of the patient
Review mode	Example of additional info.

Icon	Function
Click to edit analysis	Example of an optional button
	Show the app in full screen mode
45	Show the app in the windowed mode

5.4 Wizard bar

The vertical wizard bar is shown between the two viewports or right of a viewport if only one viewport is present. It represents the steps required to perform the analysis. The content of the wizard bar is dependent on the analysis you are performing: single vessel, monoplane LV, biplane LV or biplane RV. See chapter 7 for details.

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.

Working with QAngio XA

6 Viewing

This chapter handles functionality for viewing images that is present in most wizard steps.

6.1 Monoplane and biplane viewing

QAngio XA can be started in different analyses modes. The QCA Single Vessel analysis, the QVA Single Vessel analysis and the LV Monoplane analysis require one single monoplane acquisition as input, and therefore provide a single viewport. The LV and RV Biplane analyses require a biplane acquisition (or two matching monoplane acquisitions) and therefore provide two viewports.

6.2 Image viewports

Interactive graphics are displayed in blue color, e.g. Frame: 21/53 and allow you to change image or display properties with your mouse.

The guidance texts are displayed in yellow color at the top of the viewport. They provide information about the current wizard state.

6.2.1 Biplane viewing

To maximize an image in the viewport:

Double-click the image.

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

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

6.2.2 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.

To activate a specific mouse mode:

• Select and hold the mouse mode icon until it shows the mouse mode menu, and select the requested mouse mode.

Or;

• Right click in the image viewport to activate the viewport context menu, and select the requested mouse mode from the menu.



Although each viewport in the biplane mode has its own icon, the mouse mode for the different viewports is synchronized, changing the mode in one viewport will also change it in the other viewport.

		Result of dragging the mouse				
Icon	Function	Up	Down	Left	Right	
M	Cine	Previous frame	Next frame	Previous frame	Next frame	
	Zooming	Zoom in	Zoom out	-	-	
+	Panning	Image up	Image down	Image left	lmage right	
***	Window width/level	Decrease level (darker)	Increase level (brighter)	Decrease window (more contrast)	Increase window (less contrast)	



The result of dragging the middle or right mouse button is independent of the mouse mode:

Panning: Drag middle mouse button
 Window width/level: Drag right mouse button

6.2.3 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. 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		\rightarrow	Scroll down	Mouse drag right or down
Select previous frame	۵۱	←	Scroll up	Mouse drag left or up
Select first frame		Home		
Select last frame		End		
Play the cine forward	D	Ctrl + →		
Play the cine backward		Ctrl + ←		
Stop playing the cine				
Synchronization	B			
Select frame	Right click on the frame number in bottom corner of the viewport and enter the frame number. E.g.			

6.2.4 Synchronization of corresponding biplane images

Frame synchronization helps you to simultaneously navigate through images in both viewports. This is only available in biplane acquisitions.

When synchronized, the sicon 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.

In the LV biplane and RV biplane modes, synchronization cannot be switched on or off. It is always on for biplane acquisitions and always off for monoplane acquisitions.

6.2.5 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.

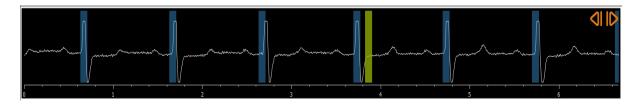
6.2.6 Initial View State

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

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

6.3 ED Phase Detection and ED Frame Selection

In the frame selection step of the QCA Single Vessel wizard, the Landmarks and Contour steps of the LV Monoplane wizard and the Contours steps of the LV and RV Biplane wizards, the frame selection control is shown below the image. 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.



The method for ED phase detection can be set in the options for the QCA Single Vessel analysis.

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,

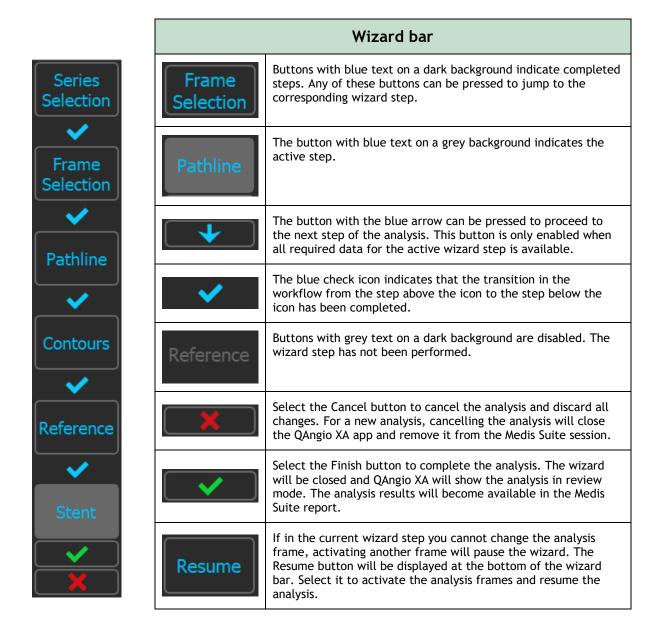
- Click on to select the same phase in the previous cardiac cycle.
- Click on to select the same phase in the next cardiac cycle.



7 Performing an analysis

To start an analysis, select the corresponding launch mode in Medis Suite (see also Chapter 4). All XA images available in Medis Suite that are suitable for the analysis are loaded automatically in QAngio XA. The analysis starts in the Series Selection step, that shows the available calibrated XA images as thumbnails under the image viewport.

In all analyses, a wizard bar is displayed, showing the steps of the analysis. For example, the wizard bar of the QCA and QVA single vessel analysis is:



If you reload a Medis Suite session that has QAngio XA analyses, they will be restored and activate QAngio XA in review mode.

Accuracy of Methods Used

The methods and algorithms used in QAngio XA to obtain quantification results and to determine the accuracy of those results have all been published in literature. In this section, you will find a brief overview of the origin of the methods and their accuracy. The references to literature can be found in Chapter 11. Refer to the Medis Suite user manual for references related to XA image calibration.

- A method paper on how QCA systems should be validated can be found in [1]
- QCA single vessel analysis: The method for the automated detection of the vessel boundaries and its accuracy has been described in [2, 3]. Validation of the QCA quantification results have been published extensively over the years. The latest results can be found in [4].
- Ventricle analysis: The method for automated segmentation of the left ventricle and its validation can be found in [7]. QAngio XA supports the calculation of ventricular volumes by means of the Area Length calculation. This method and its accuracy is described in [5, 6]. For the results of the left ventricular wall motion models the Centerline model is available. The Centerline model and derived results are described in [8, 9]. For biplane and right ventricle analyses, QAngio XA supports manual segmentation. This method and its accuracy is described in [10, 11, 12].

Numerical analysis results	Expected accuracy
Single Vessel Lesion Results	
Lesion length	0.4 mm
Lesion start	0.2 mm
Diameter stenosis	5%
Area stenosis	10%
Proximal diameter	.15 mm
MLD	.15 mm
Distal diameter	.15 mm
Reference diameter	.15 mm
Area at MLD	Derived from diameter
Reference area	Derived from diameter
Proximal area	Derived from diameter
Distal area	Derived from diameter
Single Vessel Segment Results	
Minimum Diameter	.15 mm
Maximum Diameter	.15 mm
Mean Diameter	.15 mm
St.dev. Diameter	0.1
Minimum Area	Derived from diameter
Maximum Area	Derived from diameter
Mean Area	Derived from diameter
St.dev. Area	Derived from diameter
Segment Length	0.4 mm

Proximal position of segment	0.2 mm
Distal position of segment	0.2 mm
Position of minimum diameter in segment	0.2 mm
Position of maximum diameter in segment	0.2 mm
Single Vessel Stent Results	
Lesion length	0.4 mm
Diameter stenosis	5%
Area stenosis	10%
MLD	0.15 mm
Reference diameter	0.15 mm
MLD position	0.2 mm
Mean diameter	0.15 mm
Segment start	0.2 mm
Segment length	0.2 mm
Distance MLD to stent	0.2 mm
Ventricle Results	
Regression Slope (not a result, input parameter)	-user input-
Regression Offset (not a result, input parameter)	-user input-
Ejection Fraction	15%
Height (not a result, input parameter)	-user input-
Weight (not a result, input parameter)	-user input-
BSA	0.01 m ²
Heart Rate (not a result, input parameter)	1
Cardiac Output	15%
Cardiac Index	15%
ED Volume	SEE = 4-8%
ES Volume	SEE = 4-8%
Stroke Volume	15%
ED Volume Index	8%
ES Volume Index	8%
Stroke Volume Index	15%
Centerline Dyskinetic Results	
Chords	± 2
Severity	1 mm
Depth	0.5
<u>Miscellaneous</u>	
Acquisition Speed (input from DICOM file)	1
Calibration Factor (input from Medis Suite or calculated)	0.01

8 Single Vessel Analysis

QAngio XA supports the analysis of a single vessel segment.

The QCA and QVA single vessel analysis have the following steps:

- 1. Series selection
- 2. Frame selection
- 3. Pathline detection
- 4. Contour detection
- 5. Reference
- 6. Stent (optional)

8.1 Wizard Step 1: Series selection

The analysis starts with the series selection step. The objective of this step is to select an appropriate image for the analysis.

8.1.1 Image requirements

QAngio XA only loads DICOM greyscale XA images with square pixels (pixel aspect ratio 1:1) that are either manually calibrated in Medis Suite or include isocenter calibration data.

8.1.2 Selecting from existing series

To select the series for analysis:

• Click on a thumbnail under the viewport.

The image will be loaded in the viewport.

All images loaded into Medis Suite and that are suitable to be analyzed will automatically be displayed in the list of thumbnails under the viewport. Be sure to load all images of the study in Medis Suite. If images are loaded into Medis Suite afterwards, or when uncalibrated images are manually calibrated in Medis Suite, the list of thumbnails will automatically update.

Press to proceed to the next step.

8.2 Wizard Step 2: Frame selection

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

If an ECG signal is available with the image data, it will be displayed in the frame selection control underneath the image viewport.

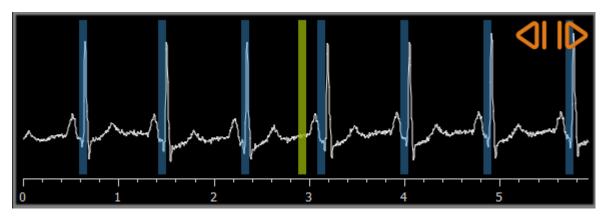
If ED phases have been detected from the ECG signal or from the gray-scale image information, one of the ED phases is automatically selected:

- In the QCA single vessel analysis, all available ED phases will be evaluated and the ED phase that shows the best contrast filling of the vessels will be selected automatically.
- In the QVA single vessel analysis, the middle ED phase is selected automatically.

If no ED phases are detected, the middle frame will be selected automatically.

Evaluate the frame that was automatically selected by the system, and make sure that it is suitable to be used as input for the analysis. If needed, you can select another frame.

For more information on frame selection, see sections 6.2.3 and 6.3.



After a suitable analysis frame has been selected, press

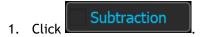


to proceed to the next step.

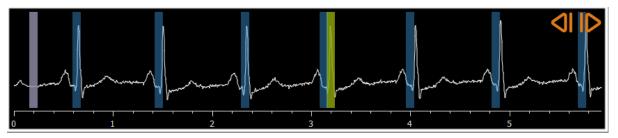
8.2.1 Subtraction

In the QVA single vessel analysis, it is possible to perform subtraction on the analyzed image. Another image (the mask image) of the same series is subtracted from the analysis image, optionally with pixel shift.

To apply subtraction:



Mask frame: 1 2. Select the proper mask frame, either by or by dragging the purple mask frame bar in the frame selection control:



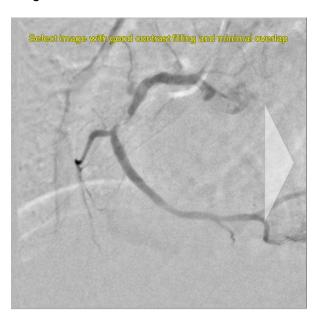
9

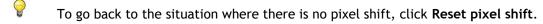
To make the currently selected frame the mask frame and select the original mask frame as analysis frame, click **Swap frames**.

3. If needed, change the pixel shift, either:



- by using the controls
- by using the CTRL+arrow keys on your keyboard, or
- by clicking with the left mouse key in the image near a border (top, bottom, right, or left border). An arrow will appear on the image when the mouse hovers over the image near a border:







To switch off subtraction, click



8.3 Wizard Step 3: Pathline

The objective of the pathline step is to create a pathline in the vessel segment of interest.

To create a pathline:

- 1. Click in the viewport to mark the proximal point of the vessel segment.
- 2. Click in the viewport to mark the distal point of the vessel segment.

QAngio XA will automatically detect the pathline and contours.



If the option 'Automatically proceed to the contour step' is on, the wizard will now automatically proceed to the contour step.

3. If needed, drag the proximal or distal point of the vessel segment to correct their location.

In the QVA single vessel analysis, QAngio XA automatically detects a dark vessel on bright background or a bright vessel on dark background. If this is not correct, right-click in the image and select the right 'Vessel detection type' from the context menu.

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 maximal five 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 pathline 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 pathline between the proximal and distal points and the contours are redetected automatically.
- ① The contours cannot be edited in the pathline step.
- To hide all image viewport graphics, press the middle mouse button or the H key.
- Undo (Ctrl + Z) and Redo (Ctrl + Y) are available to undo or redo the last action.

To change the option to automatically proceed to the contour step:

• Select > Tools > Options > Single vessel: Automatically proceed to contour step

Press to proceed to the next step.

8.4 Wizard Step 4: 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.
- To hide all image viewport graphics, press the middle mouse button or the H key. This might help to examine if the detected contours correspond with the vessel border.
- Undo (Ctrl + Z) and Redo (Ctrl + Y) are available to undo or redo the last action.

Press to proceed to the next step.

8.5 Wizard Step 5: Reference

The objective of the refence step is to obtain a correct reference diameter function and lesions markers.

QAngio XA will determine and display the following:

- The 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, reference diameter, minimal lumen diameter (MLD), and the lesion length.

For the selected lesion, QAngio XA 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.
- You can select a lesion by clicking on its lesion table under the diagram. The lesion markers in the images and diagram will be updated.
- You can toggle the display of plaque areas from the viewport's context menu: **Hide plaque** or **Show plaque**.

8.5.1 Correcting Reference Contours

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 the 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 the image or in the diagram by:
 - o 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.
- To revert the selected areas and/or markers to their initial positions: Select **Reset** reference from the context menu in the diagram.
- To enable dragging normal area or marker: Select **Enable normal markers** from the context menu in the diagram. This might be needed after correcting the lesion markers.

8.5.2 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 enable dragging the lesion markers: Select **Enable lesion markers** from the context menu of the diagram. This might be needed if Normals or Fixed prox is used.

To correct the lesion markers:

- If needed, select the desired lesion by clicking on its lesion table.
- Click and drag the obstruction (0) 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.

8.5.3 Deleting and Adding Lesions

To delete a lesion:

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

To create a user defined (custom) lesion:

- Click on the **User** (+) table.
- Drag the obstruction marker (0) to the required position
- Optionally correct the proximal (P) and distal (D) markers.



Lesion table before setting a user defined lesion



Lesion table after setting a user defined lesion.

8.5.4 Accept Analysis Results or Continue with Stent Analysis

In a single vessel analysis without stent 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 will enter the review state of this analysis.

If you also want to perform a stent analysis, press analysis workflow step to the wizard bar, and you must complete the stent analysis step before you can close the analysis.

If you press again, the Stent analysis workflow step will be removed from the wizard bar.

Press to proceed to the next step.

8.6 Wizard Step 6: Stent

The objective of the stent step is to add stent parameters to your analysis.

QAngio XA will automatically place the stent markers at the proximal and distal end of the vessel segment, they need to be placed on the correct locations manually.

To place the stent markers or the correct locations:

- Click and drag the stent markers (S) to the required positions.
- Click and drag the stent edge regions to the required position.
- To enable dragging the lesion markers: Select **Enable lesion markers** from the context menu of the diagram or the image viewport. When the lesions markers are placed on the correct position, select **Enable stent markers** from the context menu to enable dragging the stent makers again.
- ho You can drag a marker in the image or in the diameter diagram.
- ho The default stent edge length can be set in the options.

After completing the stent step in the analysis wizard, 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 will enter the review state of this analysis.

8.7 Report

The report in Medis Suite is extended with a single vessel analysis section as soon as the analysis is finished. During editing of an analysis, the section is removed from the report and re-added after completion.

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

9 Monoplane Ventricle Analysis

QAngio XA supports the analysis of left ventricles in monoplane acquisitions.



Availability of the analysis is dependent on a license. If you would like to purchase a license for the left ventricle analysis module, please contact Medis.

The monoplane LV analysis has the following steps:

- 1. Series selection
- 2. ED landmarks
- 3. ES landmarks
- 4. ED contour
- 5. ES contour
- 6. Results

9.1 Wizard Step 1: Series selection

The analysis starts with the series selection step. The objective of this step is to select an appropriate series for the analysis.

9.1.1 Image requirements

QAngio XA only loads DICOM greyscale XA images with square pixels (pixel aspect ratio 1:1) that are either manually calibrated in Medis Suite or include isocenter calibration data.

9.1.2 Selecting from existing series

To select the series for analysis:

• Click on a thumbnail under the viewport.

The series will be loaded in the viewport.



The images for the left ventricle analysis are expected to be acquired at RAO 30 (±10) which is perpendicular to the long axis of the heart in the majority of cardiac anatomies.

When you load images that have been acquired outside the range between RAO 20 and RAO 40, a warning message will be displayed in the series thumbnails. When you attempt to analyze these images, a warning message will be displayed in the analysis viewport. In this case, before continuing the analysis, make sure that the images are suitable to be used as

input for the left ventricle analysis, having a view perpendicular to the long axis of the heart.



All series loaded into Medis Suite and that are suitable to be analyzed will automatically be displayed in the list of thumbnails under the viewport. Be sure to load all series of the study in Medis Suite. If series are loaded into Medis Suite afterwards, or when uncalibrated series are manually calibrated in Medis Suite, the list of thumbnails will automatically update.

Press to proceed to the next step.

9.2 Wizard Step 2: ED Landmarks

The objective of the ED Landmarks step is to select the End Diastolic frame and set landmarks for automatic contour detection.



If the option 'Include ED and ES landmark steps in the analysis workflow' is off, the ED Landmark and ES Landmark steps are not visible in the wizard bar.

9.2.1 Manual contours

The Landmarks steps can be skipped to draw manual contours. In that case just press in the ED Landmarks step and the wizard will automatically proceed to the ED Contour step.

9.2.2 ED frame selection using ECG

If an ECG signal is available with the image data, it will be displayed in the frame selection control underneath the image viewport. If ED phases have been detected, the middle ED phase is automatically selected.

For information on frame selection see 6.2.3 and 6.3.

9.2.3 Setting landmarks

Once the End Diastolic frame is selected, place the landmark points of the two valve points and the apex point by clicking in the image.



If the option 'Automatically proceed after setting 3 landmarks' is on, the wizard will now automatically proceed to the next step.

To change the end diastolic frame

- In the context menu in the image viewport, select 'Delete landmarks',
- Navigate to the desired End Diastolic frame,

Place new landmarks.

Press to proceed to the next step.

9.3 Wizard step 3: ES Landmarks

The objective of the ES Landmarks step is to select the End Systolic frame and set landmarks for automatic contour detection. If ED landmarks are set, ES landmarks must also be set to generate automatic contours.

9.3.1 ES frame selection

If an ECG signal is available with the image data, it will be displayed in the frame selection control underneath the image viewport, similar to the ED Landmarks step. There are no buttons to go to the next or previous cardiac phase.

It is advised to select the ES frame in the same cardiac cycle as the ED frame. If ED frames were automatically detected, and in the ES Landmarks step a frame outside this cardiac cycle is selected, a warning text is displayed on the image.

It is not possible to select the ES frame the same as the ED frame.

9.3.2 Setting landmarks

Once the End Systolic frame is selected, place the landmark points of the two valve points and the apex point by clicking in the image.



If the option 'Automatically proceed after setting 3 landmarks' is on, the wizard will now automatically proceed to the next step.

To change the End Systolic frame

- In the context menu in the image viewport, select 'Delete landmarks',
- Navigate to the desired End Systolic frame,
- Place new landmarks.

Press to proceed to the next step.

9.4 Wizard Step 4: ED Contour

The objective of the ED Contour step is to draw or correct the ED contour. If ED and ES landmarks have been set in the ED and ES Landmarks steps, automatic contours are calculated and displayed in this step.

9.4.1 Manual contours

If no ED and ES landmarks have been set, select the ED frame (see 9.2.2) and pointwise draw the contour: click on multiple locations on the image and accept by a double click at the last point. A smooth contour through the clicked locations will be generated.

9.4.2 Editing contours

Contours that were automatically generated or manually drawn can be corrected in the following ways:

 Near the existing contour click and drag an altered contour. The alteration will be combined with the original.

Or,

Right-click on the contour and drag it, using the rubber-band tool



Contours can be deleted by 'Delete contour' in the context menu in the image viewport.



Undo (Ctrl + Z) and Redo (Ctrl + Y) are available to undo or redo the last action.

When the contour is correct, press to proceed to the next step.

9.5 Wizard step 5: ES Contour

The objective of the ES Contour step is to draw or correct the ES contour. If ED and ES landmarks have been set in the ED and ES Landmarks steps, automatic contours are calculated and displayed in this step.

9.5.1 Manual contours

If no ED and ES landmarks have been set, select the End Systolic frame (see 9.3.1) and pointwise draw the contour: click on multiple locations on the image and accept by a double click at the last point. A smooth contour through the clicked locations will be generated.

9.5.2 Editing contours

Contours that were automatically generated or manually drawn can be corrected in the following ways:

 Near the existing contour click and drag an altered contour. The alteration will be combined with the original.

Or,

Right-click on the contour and drag it, using the rubber-band tool



Contours can be deleted by 'Delete contour' in the context menu in the image viewport.



Undo (Ctrl + Z) and **Redo** (Ctrl + Y) are available to undo or redo the last action.

When the contour is correct, press to proceed to the next step.

9.6 Wizard step 6: Results

The objective of the Results step is to view the calculated results and enter additional patient data. The calculated Ejection Fraction, ED Volume and ES Volume are displayed to the right of the image. Additional patient data can be entered below the table with results.

To calculate indexed values:

- Enter the Height of the patient and press Enter,
- Enter the Weight of the patient and press Enter.



The default values for patient height and weight will be taken over from your DICOM data file.

To calculate cardiac output:

• Enter the Heart Rate and press Enter

To hide the centerline information on the image:

• Select 'Hide Centerline graphics' from the image context menu.

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 will enter the review state of this analysis.

9.7 Report

The report in Medis Suite is extended with a Left Ventricle analysis section as soon as the analysis is finished. During editing of an analysis, the section is removed from the report and re-added after completion.

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

10 Biplane Ventricle Analyses

QAngio XA supports the analysis of left- and right ventricles in biplane image acquisitions (or two matching monoplane acquisitions).

Availability of the analyses is dependent on licenses. If you would like to purchase a license for the left- or right biplane ventricle analysis module, please contact Medis.

The biplane LV or RV analysis has the following steps:

- 1. Series selection
- 2. ED contours
- 3. ES contours
- 4. Results

For the LV biplane analysis, several regression methods are supported for pediatric or adult patients. For pediatric patients the supported methods are Graham (default), Lange, and Dodge, all using the Area Length method. For adult patients the supported methods are Lange (default), Dodge, and Wynne, all using the Area Length method.

The choice of the regression method for adult or pediatric patients can be set in the options dialog of QAngio XA.

For the RV biplane analysis, there is no option to choose a different regression method for the pediatric and adult patients. For pediatric patients the method is based on Graham and Simpson Rule. For adult patients the method is based on Lange and Area Length.

10.1 Wizard Step 1: Series selection

The analysis starts with the series selection step. The objective of this step is to select an appropriate image for the analysis.

10.1.1 Image requirements

QAngio XA only loads DICOM greyscale XA images with square pixels (pixel aspect ratio 1:1) that are either manually calibrated in Medis Suite or include isocenter calibration data.

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 angle between the two images must be 90° (±10), and the images must be acquired less than 120 minutes apart.

10.1.2 Patient type

The proper patient type needs to be selected in the bar that is displayed at the top; either 'Pediatric' or 'Adult'.



The default patient type can be set in the options.

10.1.3 Selecting series for the long- and short axis view



All series loaded into Medis Suite and that are suitable to be analyzed will automatically be displayed in the list of thumbnails under the viewports. Be sure to load all series of the study in Medis Suite. If series are loaded into Medis Suite afterwards, or when uncalibrated series are manually calibrated in Medis Suite, the list of thumbnails will automatically update.

From all available series, the proper series that will be used for the analysis must be selected.

- The series for the long axis must be loaded into the left hand viewport.
- The series for the **short axis** must be loaded into the **right hand** viewport.

To select the two series for analysis:

- Click on a thumbnail under the left viewport to load the long axis series.
 - The series will be loaded in the left viewport.
 - Thumbnails of matching series appear under the right viewport.
- Click on a thumbnail under the right viewport to load the short axis series (not needed if already loaded)
 - The series will be loaded in the right viewport

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The series are expected to be acquired at specific angles to have a proper view on the longand short axis of the heart. The expected angles are dependent on the regression method that is used:

Analysis	Patient Type	Regression Formula	Expected Angle	
			Long Axis	Short Axis
LV Biplane	Adult	Lange (default)	RAO 30 RAO 0	LAO 60 LAO 90
		Dodge	RAO 0	LAO 90
		Wynne	RAO 30	LAO 60
	Pediatric	Graham (default)	RAO 0	LAO 90
		Lange	RAO 30 RAO 0	LAO 60 LAO 90
		Dodge	RAO 0	LAO 90
RV Biplane	Adult	Lange	LAO 90	RAO 0
	Pediatric	Graham	LAO 90	RAO 0

- When you load images that have been acquired outside the range of expected angles for the selected regression method, a warning message will be displayed in the series thumbnails. When you attempt to analyze these images, a warning message will be displayed in the corresponding image viewport. In this case, before continuing the analysis, make sure that the images are suitable to be used as input for the ventricle analysis, and have a proper and clear view on the long- and short axis of the heart. Unexpected angles may still be valid when the patient is having an abnormal anatomy.
- If one of the images of a biplane acquisition is loaded into the left-hand viewport, the other image of the biplane acquisition is automatically loaded into the right-hand viewport.
- If an image is loaded into the left-hand viewport and there is only one other image that matches with this image, it is automatically loaded into the right-hand viewport.
- It is possible that QAngio XA receives a series from Medis Suite e.g. one captured by an X-ray device. Such a series will be automatically added to the list of thumbnails under the viewports.

Press to proceed to the next step.

10.2 Wizard Step 2: ED contours

The objective of the ED Contours step is to select the End Diastolic frame and draw the ED contours in both the Long Axis image and the Short Axis image.

10.2.1 ED frame selection using ECG

If an ECG signal is available with the image data, it will be displayed in the frame selection control underneath the image viewport. If ED phases have been detected, the middle ED phase is automatically selected.

For information on frame selection, see 6.2.3 and 6.3.

10.2.2 Draw contours

When the End Diastolic frame has been selected, pointwise draw the contours in both the Long Axis and the Short Axis images: click on multiple locations on the image and accept by a double click at the last point. A smooth contour through the clicked locations will be generated.

10.2.3 Editing contours

Contours can be corrected in the following ways:

 Near the existing contour click and drag an altered contour. The alteration will be combined with the original.

Or,

- Right-click on the contour and drag it, using the rubber-band tool
- Contours can be deleted by 'Delete contour' in the context menu in the image viewport.
- Undo (Ctrl + Z) and Redo (Ctrl + Y) are available to undo or redo the last action.

When the contours are correct, press to proceed to the next step.

10.3 Wizard step 3: ES contours

The objective of the ES Contours step is to select the End Systolic frame and draw the ES contours in both the Long Axis image and the Short Axis image.

10.3.1 ES frame selection

If an ECG signal is available with the image data, it will be displayed in the frame selection control underneath the image viewport, similar to the ED Contours step. There are no buttons to go to the next or previous cardiac phase.

It is advised to select the ES frame in the same cardiac cycle as the ED frame. If ED frames were automatically detected, and in the ES Contours step a frame outside this cardiac cycle is selected, a warning text is displayed on the image.

It is not possible to select the ES frame the same as the ED frame.

10.3.2 Draw contours

When the End Diastolic frame has been selected, pointwise draw the contours in both the Long Axis and the Short Axis images: click on multiple locations on the image and accept by a double click at the last point. A smooth contour through the clicked locations will be generated.

10.3.3 Editing contours

Contours can be corrected in the following ways:

 Near the existing contour click and drag an altered contour. The alteration will be combined with the original.

Or,

Right-click on the contour and drag it, using the rubber-band tool



Contours can be deleted by 'Delete contour' in the context menu in the image viewport.



Undo (Ctrl + Z) and **Redo** (Ctrl + Y) are available to undo or redo the last action.

When the contour is correct, press to proceed to the next step.

10.4 Wizard step 4: Results

The objective of the Results step is to view the calculated results and enter additional patient data.

The calculated Ejection Fraction, ED Volume and ES Volume are displayed below the images. Additional patient data can be entered there.

To calculate indexed values:

- Enter the Height of the patient and press Enter,
- Enter the Weight of the patient and press Enter.



The default values for patient height and weight will be taken over from the DICOM data.

To calculate cardiac output:

• Enter the Heart Rate and press Enter

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 will enter the review state of this analysis.

10.5 Report

The report in Medis Suite is extended with a Left or Right Ventricle analysis section as soon as the analysis is finished. During editing of an analysis, the section is removed from the report and readded after completion.

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

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11 Literature

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12 Shortcut Keys

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



Medis Suite and apps may use the same shortcut key for different functionalities. Which application handles your shortcut key is dependent on which application has 'focus'.

Press	То			
Image control				
Drag middle mouse button	Pan			
or Ctrl and left mouse button drag				
Ctrl + Shift and left mouse button drag	Zoom			
Alt + Shift and left mouse button drag	Cine			
Н	Hide all graphics			
or hold middle mouse button down				
Ctrl and left mouse button move	Enable pixel spy			
Wizard				
Esc	Cancel the analysis			
Ctrl + Z	Undo (only in pathline and contour steps)			
Ctrl + Y	Redo (only in pathline and contour steps)			
Navigation Controls				
Home	Display the first time point			
End	Display the last time point			
Arrow up	Display the previous slice			
Arrow down	Display the next slice			
Arrow left	Display the previous time point			
Arrow right	Display the next time point			
Ctrl + arrow left	Play cine backward			
Ctrl + arrow right	Play cine forward			
Page Up	Display the previous series			
Page Down	Display the next series			

13 Troubleshooting

Menu commands or toolbar buttons are disabled

• An interactive control in the guidance text or toolbar is waiting for input.

Or

 Menu commands or toolbar buttons may be grayed out when you have changed the active frame in the analysis. You can make them active pressing the resume button: