Medis
Medical Imaging Systems

QAngio XA 8.0

Quick Start Manual

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Legal Notices

Copyright Notice

Trademark Acknowledgments

QAngio is a registered trademark of Medis Associated bv. DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information. Microsoft and Windows are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries. All other brand, product, and company names mentioned in this document are trademarks or registered trademarks of their respective owners.

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 English 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

$C\,\epsilon$ 1639	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 Australian Therapeutic Goods Administration and has been licensed as a Class IIa medical device.

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

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: `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.

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.

Table of Contents

1   About QAngio XA

QAngio XA is the Medis solution for the quantification of coronary 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:
- 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:
- Microsoft Windows 7, SP1, 32 and 64 bit version
- Microsoft Windows 8.1, 32 and 64 bit version
- Microsoft Windows 10, 32 and 64 bit version
- Microsoft Windows Server 2008 R2, SP1, 64 bit version
- Microsoft Windows Server 2012 R2, 64 bit version
- Microsoft Windows Server 2016, 64 bit version

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

3 Support

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

If you contact the Medis helpdesk by e-mail, mention the name of the software and the version number in the subject field. To look up the version number of your software, select > **Help** > **About** 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 launch mode will provide you with different image analysis functionality with dedicated functionality and layout.

💡 Availability of the 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.

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

QCA Single Vessel: 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

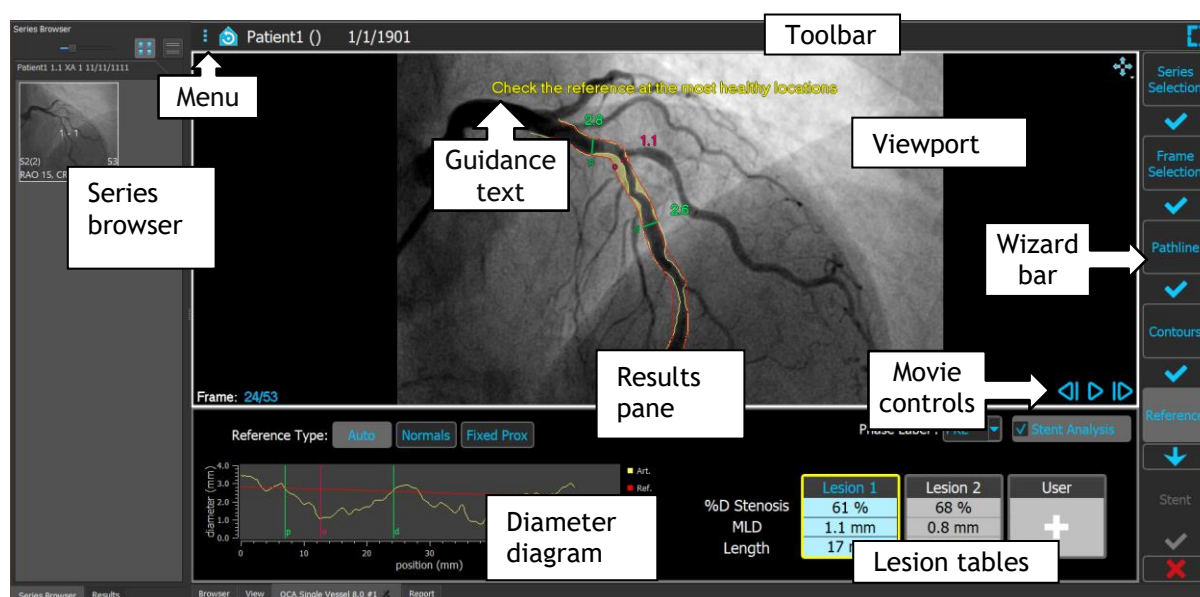RV Biplane: right ventricle analysis on biplane XA image acquisitions

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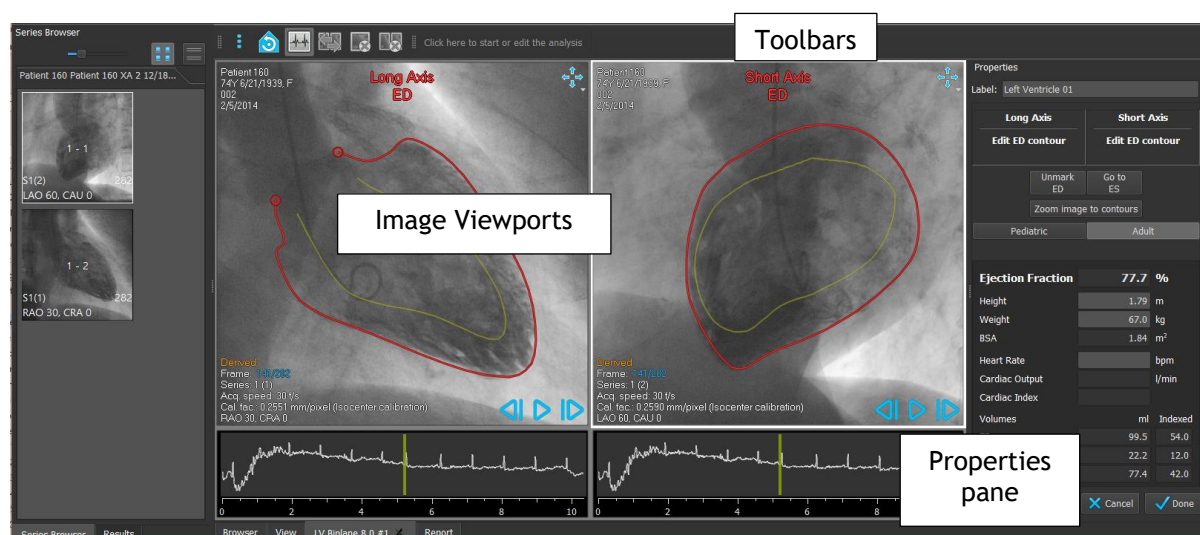
5   QAngio XA Workspace

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:

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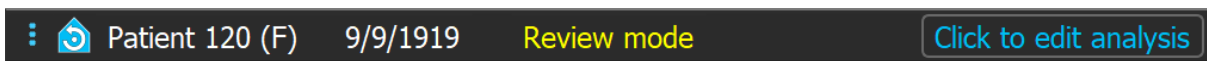
5.2   Menu

The menu contains commands to activate the application functionality.
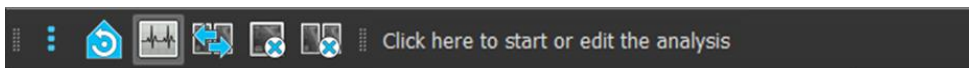
To make the menu visible:

- Click on the menu icon in the **General** toolbar of the QAngio XA app.

5.3   Toolbars

The available toolbars are dependent on the launch mode you selected. The image below shows the toolbar that is available for the QCA Single Vessel launch mode.

The image below shows the toolbar available for the Left Ventricle Biplane launch mode. Similar toolbars are available in the other ventricle analysis launch modes.

6   Viewing

6.1   Monoplane and biplane viewing

QAngio XA can be started in different analyses modes. The **QCA 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: stacking, 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.

6.2.3   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 (stacking 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. Frame: 26/90 5			

If an ECG diagram is present, you can also select frames by dragging the ECG marker or by clicking in the ECG diagram.

6.2.4   Synchronization of corresponding biplane images

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.
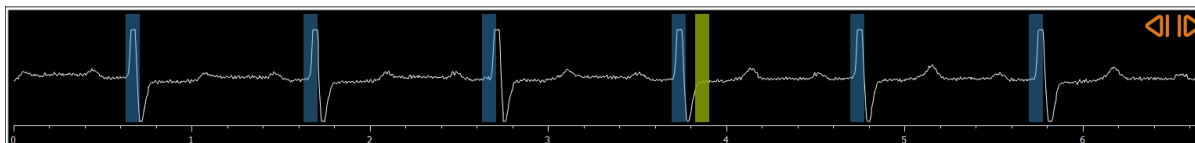
6.2.5   Initial View State

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 and window width and level.

6.3   ECG

In the frame selection steps, the ECG diagram is shown below the image. If ECG data is included with the image data, the ECG curve is shown in the diagram.

On the x-axis, time is displayed in seconds. The green vertical bar indicates the selected frame, visible in the corresponding image viewport. The blue bars indicate the frames that correspond to the automatically detected ED phases.

To select a frame using the ECG diagram:

*   Drag the green vertical bar to the desired location.

Or,

*   Click in the ECG diagram to place the vertical bar (and thus select the related frame) directly 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 Single Vessel Analysis

7.1 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.

7.1.1 Image requirements

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

7.1.2 Selecting from existing series

To select the series for analysis:

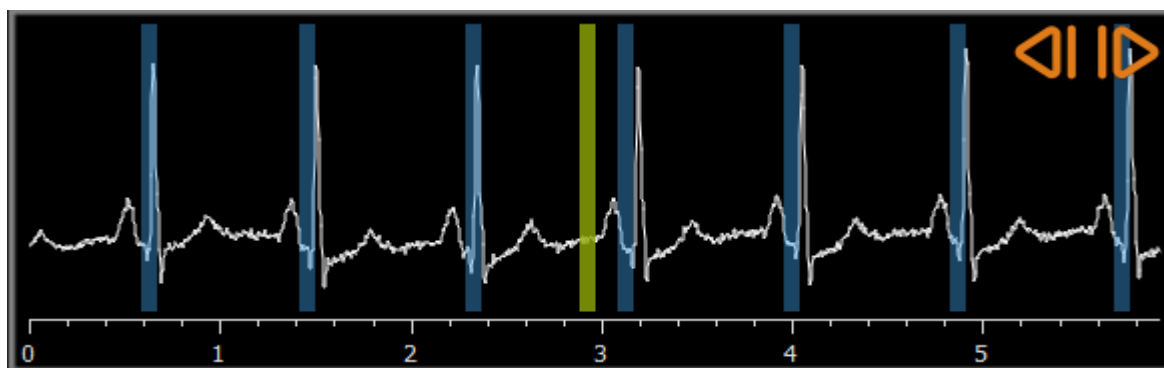1. Click on a thumbnail under the viewport.

   The image will be loaded in the viewport.

Press [↓] to proceed to the next step.

7.2 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 a diagram underneath the image viewport.

To select a frame using the ECG diagram:

- Drag the green vertical bar to the desired location.

Or,

- Click in the ECG diagram to place the vertical bar (and thus select the related frame) directly at the desired location.

Or,

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

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

Press [↓] to proceed to the next step.

7.3   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.

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

To edit a pathline:

- 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.

Press [↓] to proceed to the next step.

7.4   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.

Press [↓] to proceed to the next step.

7.5   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, minimal lumen diameter (MLD), and the lesion length.

7.5.1   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:
  - Dragging the area to the desired position and/or
  - Resizing the area by dragging an edge.

  The reference contours will be recalculated automatically.

7.5.2   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 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.

7.5.3   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 (O) to the required position

- Optionally correct the proximal (P) and distal (D) markers.

7.5.4   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 [Stent Analysis]. This will add the Stent analysis workflow step to the wizard bar, and you must complete the stent analysis step before you can close the analysis.

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

Press [↓] to proceed to the next step.

7.6 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.

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.

7.7 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.
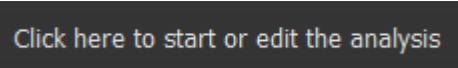
8 Monoplane Ventricle Analyses

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

8.1 Performing a Left Ventricle Analysis

To start a Left Ventricle analysis:

- Click **Click here to start or edit the analysis** in the toolbar.

Or,

- Select **⋮** > **Procedures > Click here to start or edit the analysis.**

Or,

- Press 'L'.

To perform the left ventricle analysis with automatic contour detection:

- Navigate to the End Diastolic (ED) frame, click **Mark ED** to mark the current frame as End Diastolic.

- Place the landmark points of the two valve points and the apex point.

- Navigate to the End Systolic (ES) frame, click **Mark ES** to mark the current frame as End Systolic,

- Place the landmark points of the two valve points and the apex point.

To perform the left ventricle analysis with manual contour drawing:

- Navigate to the End Diastolic (ED) frame, click **Mark ED** to mark the current frame as End Diastolic.

- Create the ED contour by clicking on multiple locations on the image and accepting by a double click at the last point. A smooth contour through the clicked locations will be generated.

- Navigate to the End Systolic (ES) frame, click **Mark ES** to mark the current frame as End Systolic,

- Create the ES contour on the image.

To edit a contour:

- Navigate to the ED or ES frame,

- In automatic contour detection mode, drag a valve or apex landmark point to recalculate the contours.

  Or,

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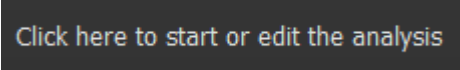
  Or,

- Right-click on the contour and drag it, using the rubber-band tool ⟨icon⟩.

To finish the analysis:

- Click ✓ Done to finish the analysis and make the results available in the report.

8.2   Editing a Left Ventricle Analysis

To edit a left ventricle analysis:

- Click Click here to start or edit the analysis in the toolbar.

Or,

- Select ⋮ > **Procedures > Click here to start or edit the analysis.**

Or,

- Press 'L'.

Make your changes to the analysis based on the instructions for performing a new analysis.

8.3   Deleting a Left Ventricle Analysis

To permanently remove the Ventricle analysis section from the Medis Suite report and session, close the Ventricle app by selecting the close icon on the tab.

8.4   Report

The report in Medis Suite is extended with a Ventricle analysis section as soon as the analysis is finished. Details on the reporting functionality can be found in the Medis Suite user manual.

During editing of an analysis, the section is removed from the report and re-added after completion.

9   Biplane Ventricle Analyses

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

A biplane analysis can only be started if both viewports contain a calibrated image. Also, the images must have been acquired with the following acquisition angles for left ventricle analyses:
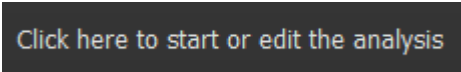
- RAO 30, LAO 60

And the following acquisition angles for right ventricle analysis:

- RAO 30, LAO 60
- RAO 0, LAO 90

9.1   Performing a Biplane Ventricle Analysis

To start a ventricle analysis:

- Click Click here to start or edit the analysis in the toolbar.

Or,

- Select ⋮ > **Procedures** > **Click here to start or edit the analysis**.

Or,

- Press 'L'.

The ventricle analysis is started. Based on the image acquisition angles, the images will be automatically marked as 'short axis' or 'long axis' images.

Left Ventricle analysis:

LAO 60 (±10) is used as short axis image

RAO 30 (±10) is used as long axis image

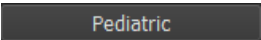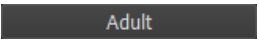Right Ventricle analysis:

LAO 90 (±10) or LAO 60 (±10) is used as long axis image

RAO 0 (±10) or RAO 30 (±10) is used as short axis image

The properties pane shows the controls to perform the analysis.

To perform the ventricle analysis:

- Navigate to the End Diastolic (ED) frame for the Long Axis image, click [Mark ED] to mark the current frame as End Diastolic.

- Create the End Diastolic contour in the Long Axis image by clicking on multiple locations on the image and accepting by a double click at the last location. A smooth contour through the clicked locations will be generated.

- If no synchronization is active, navigate to the End Diastolic (ED) frame for the Short Axis image, click [Mark ED] to mark the current frame as End Diastolic.

- Create the End Diastolic contour in the Short Axis image by multiple clicks and accepting by a double click.

- Navigate to the End Systolic (ES) frame for the Long Axis image, click [Mark ES] to mark the current frame as End Systolic,

- Create the contour in the Long Axis image.

- If no synchronization is active, navigate to the End Systolic frame for the Short Axis image, click [Mark ES] to mark the current frame as End Systolic,

- Create the contour in the Short Axis image.

- Select [Pediatric] or [Adult]

To edit a contour:

- Navigate to the ED or ES frame,

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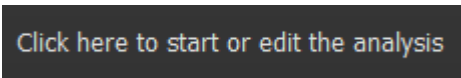
Or,

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

To finish the analysis:

- Click [✓ Done] to finish the analysis and make the results available in the report.

9.2   Editing a Biplane Ventricle Analysis

To edit a ventricle analysis:

- Click Click here to start or edit the analysis   in the toolbar.

Or,

- Select ⋮ > **Procedures** > **Click here to start or edit the analysis.**

Or,

- Press 'L' or 'R'.

Make your changes to the analysis based on the instructions for performing a new analysis.

9.3   Deleting a Biplane Ventricle Analysis

To permanently remove the Ventricle analysis section from the session and report, close the Ventricle app by selecting the close icon on the tab.

9.4   Report

The report in Medis Suite is extended with a Ventricle analysis section as soon as the analysis is finished. Details on the reporting functionality can be found in the Medis Suite user manual.

During editing of an analysis, the section is removed from the report and re-added after completion.