

QAngio XA 8.0

Quick Start Manual



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Legal Notices

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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 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

 <p>0120</p>	<p>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.</p>
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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: <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

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



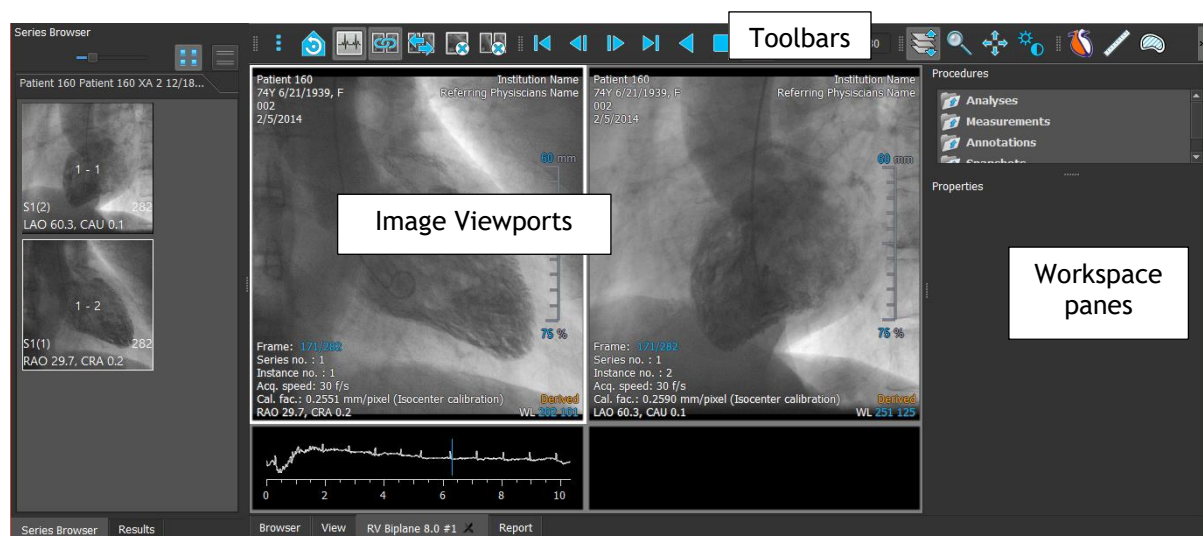
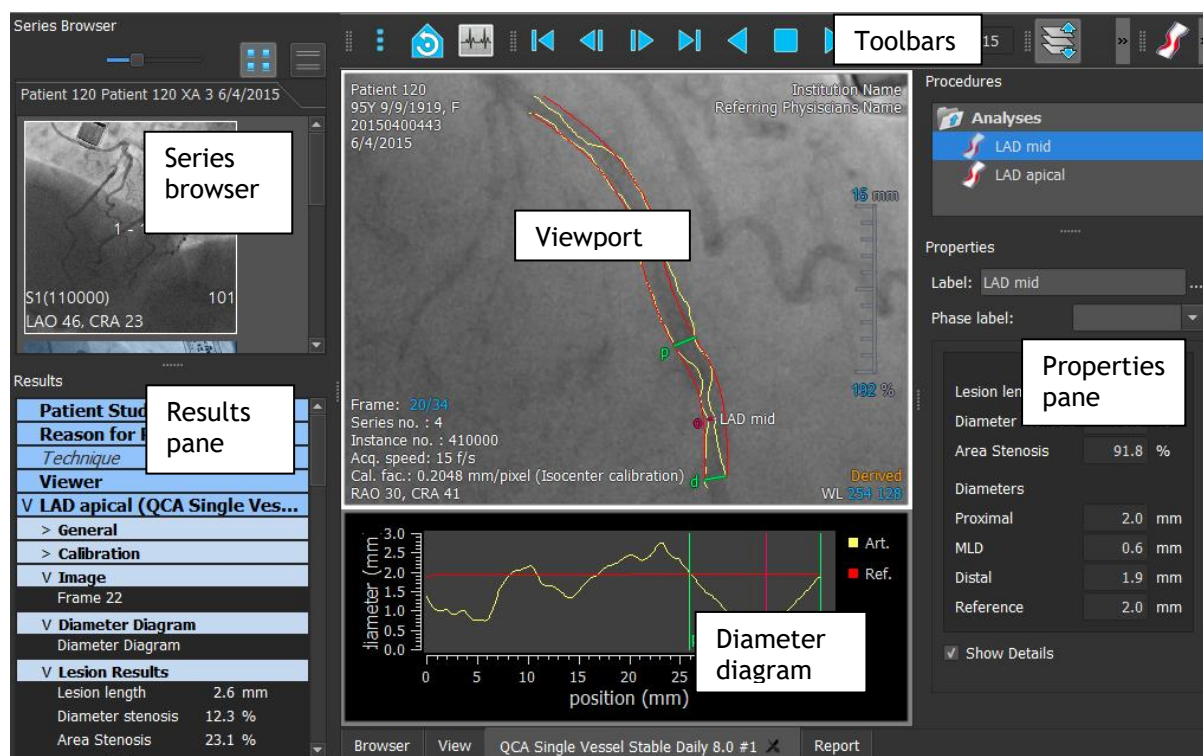
RV Biplane: right ventricle analysis on biplane XA image acquisitions

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, several 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 the screenshots below, you can see the layout for the QCA Single Vessel analysis, and the Right 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

You can move toolbars to another part of the main window. You can also show or hide toolbars.



To move a toolbar:


- Click on the double-bar grip handle  of the toolbar and drag it.

You can now move the toolbar to any location on the sides of the main window. Simply click and drag the toolbar to its new position. The position of the toolbar is saved when you close the application.

5.4 Workspace Panes

By default, the workspace displays the **Procedures** and **Properties** panes to the right of the image viewports. You can show or hide panes, dock panes, combine panes into one tabbed panel and remove panes from a panel.

To show or hide a pane:

- Select  > **Panes**, and select a hidden pane to show it, or select a visible pane to hide it.

5.4.1 Procedures Pane

The **Procedures** pane lists the analyses, measurements, annotations and snapshots performed on the series that is loaded in the viewport.


You can collapse and expand the branches of the tree by double-clicking the top-level nodes.

You can right-click a procedure to perform actions on the procedure. Depending on the type of procedure, you will get a context menu with several options.

5.4.2 Properties Pane

The **Properties** pane shows the properties of the selected procedure.

To modify a label:

1. On the **Procedures** pane, select the procedure.
2. On the **Properties** pane, click the ellipsis  on the right of the **Label** field and select a predefined label, or type a custom label and press Enter.

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 Loading Images

Images can be loaded into QAngio XA from **Series Browser** of Medis Suite. Refer to the Medis Suite user manual for detailed instructions.

To load images from the **Series Browser** of Medis Suite

1. Click an item in the image view or text view of the Medis Suite **Series Browser** to select it.
2. Click and drag the selected item to the desired viewport.

Or,

1. Double click an item in the image view or text view of the Medis Suite **Series Browser**.

This will load the image into the viewport. A cine will start playing to present all individual image frames.

6.2.1 Monoplane viewing

To review all images in the active study:

1. Press **Page Down** on your keyboard to load the next image.
2. Press **Page Up** on your keyboard to load the previous image.

6.2.2 Biplane viewing

To review all images in the active study:


1. Click in the viewport to select it.
2. Press **Page Down** on your keyboard to load the next image into the selected viewport.

3. Press **Page Up** on your keyboard to load the previous image into the selected viewport.

6.3 Viewports

The viewport text overlay displays detailed information about the patient, the hospital, the image acquisition, and the display settings.

To show or hide the patient and image information:

- Select  > Tools > Options, Viewer.
- Select or deselect **Show patient information** or **Show image information**.

6.3.1 Biplane viewing

To maximize an image in the viewport:

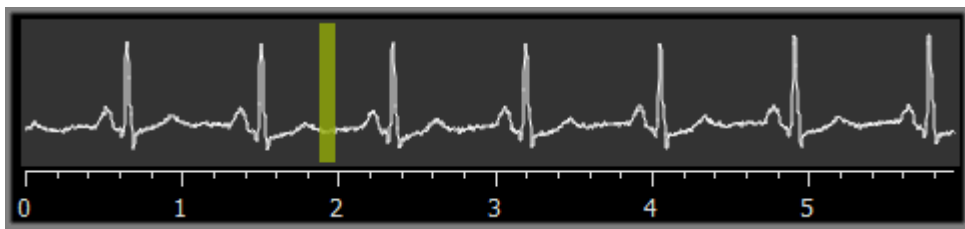
- Double-click the image.

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

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

6.4 ECG

If available, the ECG diagram of an image is shown below the image.



On the x-axis, time is displayed in seconds. The blue vertical line indicates the selected frame.




6.5 Frame Selection

You can move forward or backward through frames in the image in several ways. In biplane viewing, moving through frames only applies to the selected viewport, unless synchronization is active, see 6.5.1.



Moving through frames can be done by using buttons:

- Click  or  on the Viewing toolbar to move to the previous or next frame.

Or,

- Click  or  on the Viewing toolbar to play a cine through the frames in backward or forward direction. Click  to stop the cine.


Or,

- Click  or  on the Viewing toolbar to move to the first or last frame.

6.5.1 Biplane Viewing: Synchronization

In biplane viewing, moving through frames only applies to the selected viewport. However, if the two images of a biplane acquisition are loaded, frame selection is synchronized: the same frame is selected in both viewports.

To switch synchronization on or off:


- Click  on the Viewing toolbar to switch on or off synchronization.

6.6 Mouse Controls

6.6.1 Stacking

You can move through the frames using **Stacking** when you see the stack cursor .

To activate the stacking mouse control:

- Click  in the mouse controls toolbar.


Or,

- Select **Stacking** from the viewport context menu.

6.6.2 Zooming

You can zoom in and out of the viewport using **Zooming** when you see the magnify cursor .


To activate the zooming mouse control:

- Click  in the mouse controls toolbar.


Or,

- Select **Zooming** from the viewport context menu.

6.6.3 Panning

You can move the image within the viewport left, right, up and down using **Panning** when you see the hand cursor .


To activate the panning mouse control:

- Click  in the mouse controls toolbar.


Or,

- Select **Panning** from the viewport context menu.

6.6.4 Window Width and Level

You can adjust the **window width and window level** when you see the window width and window level cursor .

To activate the window width and window level mouse control:


- Click  in the mouse controls toolbar.

Or,

- Select **Window/Level** from the viewport context menu.

6.6.5 Initial View State

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

- Click  to reset the zooming, panning and window width and level.


7 Single Vessel Analysis

7.1 Analysis Wizard

The analysis is guided by a wizard, which is displayed in the **Properties** pane. The basic functionality of the wizard is provided by buttons at the bottom of the wizard.

7.2 Start a Single Vessel Analysis

To start a single vessel analysis:

- Make sure an appropriate image is present in the viewport.
- Select the frame that provides you with an accurate view on the vessel segment of interest
- Click  in the Procedures toolbar.

7.3 Wizard Step 1: Pathline and Contours

The first wizard step is to define the pathlines and contours of the vessel segment of interest.

To create pathlines and contours:

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 locations.

7.4 Wizard Step 2: Lesion

The second wizard step is to review the lesion parameters of the vessel segment. Upon entering the second wizard step, QAngio XA will determine and display the following items:

- The reference contours, indicating the vessel contours had the vessel been healthy.
- 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.
- Lesion parameters, including lesion length, stenosis % based on diameter and area, and the minimal lumen diameter (MLD).

- The diameter function along the vessel of both arterial and reference diameters. These are shown in a diagram.

7.4.1 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 radio button **Normals** 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 radio button **Fixed prox** 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.
- Click and drag the marker or the area to the required position, either in the image or in the diagram. You can also resize 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.

7.4.2 Correct Lesion Markers

To correct the lesion markers:

- 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.

7.4.3 Stent Analysis

To add stent analysis to the single vessel analysis:

- Enable the checkbox **Stent analysis** in the wizard pane

This will add proximal and distal stent edge regions and markers.

- Click and drag the stent edge region marker to the required position.
- Click and drag the stent edge markers (S) to the required positions.

After completing the lesion step in the analysis wizard, press **Done** to end the analysis and make the results available in the report.

7.5 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  in the toolbar.

Or,



- Select  > Procedures > Left Ventricle Volume.

Or,



- Press 'L'.

The left ventricle analysis is started, and the properties pane shows the controls to perform the analysis.

To perform the left ventricle analysis with automatic contour detection:

- Navigate to the End Diastolic (ED) frame, click  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  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  to mark the current frame as End Diastolic.
- Draw the ED contour on the image.
- Navigate to the End Systolic (ES) frame, click  to mark the current frame as End Systolic,

- Draw the ES contour on the image.

To view the centerline wall motion:

- Select the checkbox **Show Centerline wall motion**.

To finish the analysis:

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

8.2 Report

The report in Medis Suite is extended with a 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.

9 Biplane Ventricle Analyses

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

9.1 Performing a Biplane Ventricle Analysis

To start a **Left Ventricle analysis** (only available if you launched 'LV Biplane' from Medis Suite):

- Click  in the toolbar.

Or,

- Select  > **Procedures** > **Left Ventricle Volume**.

Or,

- Press 'L'.

To start a **Right Ventricle analysis** (only available if you launched 'RV Biplane' from Medis Suite):

- Click  in the toolbar.

Or,



- Select  > **Procedures** > **Right Ventricle Volume**.



Or,

- Press 'R'.

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

To perform the ventricle analysis:


- Navigate to the End Diastolic (ED) frame for the Long Axis image, click  to mark the current frame as End Diastolic.
- Draw the End Diastolic contour in the Long Axis image.
- If no synchronization is active, navigate to the End Diastolic (ED) frame for the Short Axis image, click  to mark the current frame as End Diastolic.
- Draw the End Diastolic contour in the Short Axis image.

- Navigate to the End Systolic (ES) frame for the Long Axis image, click  to mark the current frame as End Systolic,
- Draw the contour in the Long Axis image.
- If no synchronization is active, navigate to the End Systolic frame for the Short Axis image, click  to mark the current frame as End Systolic,
- Draw the contour in the Short Axis image.

To label the analysis:

- Enter text in the area after **Label**.

To finish the analysis:

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

9.2 Report

The report in Medis Suite is extended with a 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.