QAngio XA 3D 1.2

Quick Start Manual

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Regulatory Information

Intended Use

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

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

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

- to provide quantitative results of coronary vessel segments based on a 3D reconstructed model;

- to inform the clinical decision making process with respect to the diagnosis and possible PCI treatment options of the coronary vessels;

- to evaluate the procedural success of such coronary interventions.

Indications For Use

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

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

QFR Usage

QFR results needs to be used in a "hybrid" QFR – FFR decision making approach:

- QFR < 0.78 sufficiently high sensitivity to treat the patient in the cathlab;

- QFR > 0.84, sufficiently high specificity to follow the patient medically;

- QFR in the gray zone [0.78, 0.84]: use pressure wire and FFR measurement following the associated medical guidelines.

In order to obtain a correct QFR result, users need to be trained and certified by Medis medical imaging systems.

Limitations

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

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

- Tachycardia with frequency above 100 bpm

- Systolic aortic resting blood pressure below 75 mm Hg

- Atrial fibrillation

nor for the following lesions and vessels:

- Culprit lesions in Acute Coronary Syndrome

- Bifurcation lesions with 1,1,1 Medina classification

- Ostial left main coronary artery or ostial right coronary artery stenoses

- Vessels with retrograde fillings

- Bypass grafts

- Grafted coronary arteries

QFR measurements cannot be performed accurately under the following conditions:

- Too much overlap of other vessels with the lesion or areas just around the lesion in the target vessel in one or both angiographic acquisitions;

- Too much foreshortening of the target coronary artery in one or both angiographic acquisitions.

WARNINGS

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

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

Note on Monitor Aspect Ratio and Resolution

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

European Regulations

CE 0120	QAngio XA 3D is qualified as a class IIa medical device. It complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Stb. 243/1995) and the European Medical Device Directive 93/42/EEC.

North American Regulations

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

Other Regulations

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

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 3D

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

2 System Requirements

2.1 Hardware

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

Sentinel license server:
* Intel or compatible processor with a minimum speed of 550 MHz
* 128 MB of RAM
* 1 GB of available hard disk space
* Network interface card

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

2.2 Operating System

QAngio XA 3D:
* Microsoft Windows 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

QAngio XA 3D is launched from the app toolbar, app context menu, or app pane of Medis Suite, by

selecting the QAngio XA 3D app icon ![icon] . Detailed information on how to start the QAngio XA 3D
app and how to load images into the app, is described in the Medis Suite user manual.

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

5   QAngio XA 3D Workspace

5.1   Overview

The main workspace of QAngio XA 3D consists of toolbars, several workspace panes, and the central window area with the image viewports.
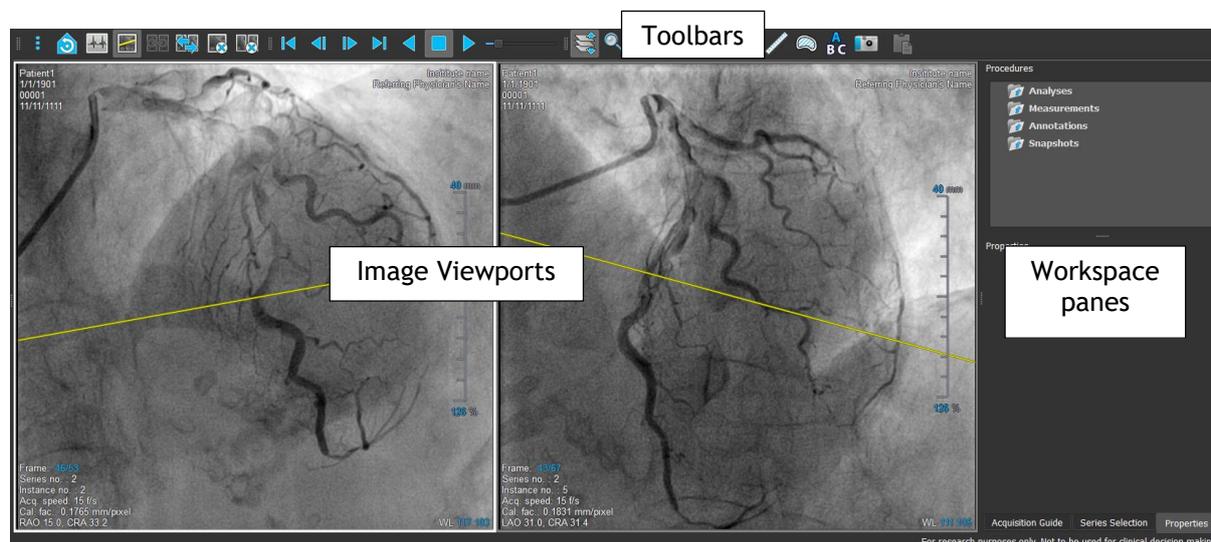
You can customize the workspace by hiding, resizing or moving the workspace panes and toolbars. Any changes that you make to the workspace are saved for each individual Windows user.

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.

5.3   Toolbars

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

5.4 Workspace Panes

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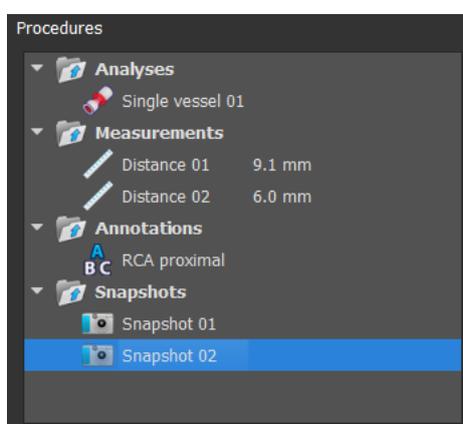
You can collapse and expand the branches of the tree by double-clicking the top-level nodes.

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:

- On the **Procedures** pane, select the procedure.

- 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.

Or,

1. On the **Procedures** pane, right-click on the procedure and select **Label**.

2. Select a predefined label, or type a custom label and press Enter.

5.4.3   Acquisition Guide Pane

The **Acquisition Guide** pane provides a guide to find suitable rotation and angulation angles for a matching second acquisition if the first acquisition is loaded in the left-hand viewport.
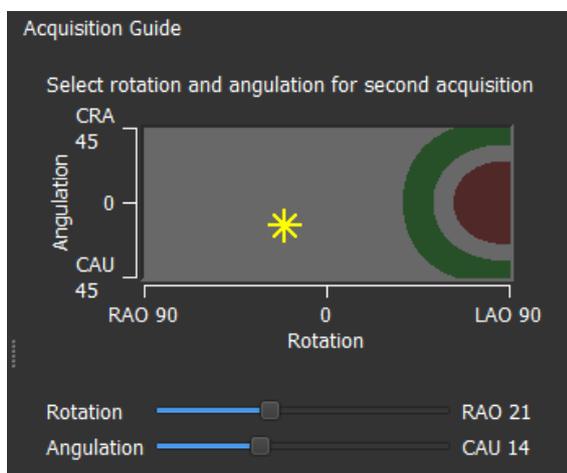
For the selected rotation and angulation angle, marked with ✳, the projection line is shown on the image in the left-hand viewport:
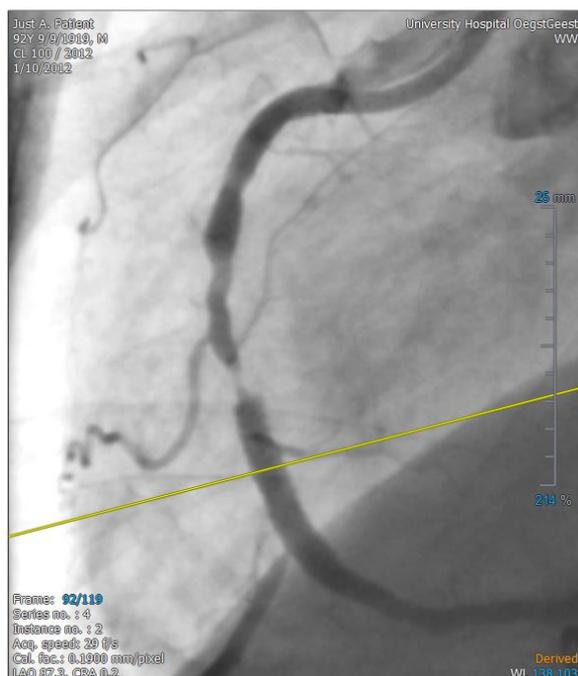

💡 It is advised to select acquisition angles such that the projection line is perpendicular to the vessel that will be analyzed.

💡 The acquisition guide is available if only one image is loaded in the left-hand viewport.

To change the rotation and angulation angle:

- Drag the marker to the desired rotation and angulation.

Or,

- Use the rotation and angulation sliders to set the desired rotation and angulation.
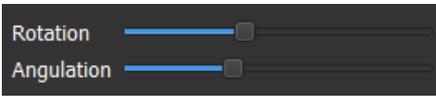
In the rotation/angulation diagram, special angles are indicated:

- The red area in the diagram indicates angles that are not allowed to create a matching acquisition, since an image acquired from these angles will have an angle of less than 25˚ with the loaded image.

- The green area in the diagram indicates acquisitions that have preferred angles (between 35˚ and 50˚) with the loaded image.

💡 The minimum angle and preferred angle range can be configured in the options. Select ⋮ > **Tools** > **Options** > **General** and enter a minimum angle or preferred angles.

5.4.4 Series Selection Pane

The **Series Selection** pane provides a guide to support the selection of matching images in the active study. The **Series Selection** guide shows all images that match with the image loaded in the left-hand viewport. Two images match if their mutual angle is larger than 25˚ and the difference in acquisition time is less than 120 minutes.
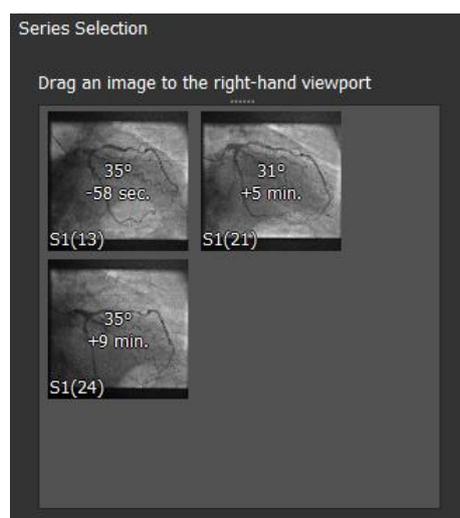
🛈 The images in the **Series Selection** guide form a subset of those loaded in Medis Suite. Be sure to load all images of the study in Medis Suite.

On each of the thumbnails in the Series Selection guide, the angle and time difference with the image in the left-hand viewport are shown. The series number and instance number are shown in

the bottom left corner. If an image is loaded in the right-hand viewport, this image has a white border.

To load an image from the series selection guide:

- Click an item in the thumbnail view of the series selection guide and drag it into the right-hand viewport.

It is not possible to drag images from the **Series Selection** guide to the left-hand viewport. To load images into the left-hand viewport, use the Medis Suite **Series Browser.**

6 Viewing

6.1 Loading Images

Images can be loaded into QAngio XA 3D 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.

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.

To unload an image from a viewport:

1. Click in the viewport to select it.

2. Click on the **Viewing** toolbar.

To unload images from both viewports:

- Click on the **Viewing** toolbar.

6.2 Viewports

The image viewports can display two matching images of the same study. The images must have a mutual angle larger than 25˚ and the acquisition times must differ less than 120 minutes.

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.

6.3   ECG

If available, the ECG diagram of an image is shown below the image.
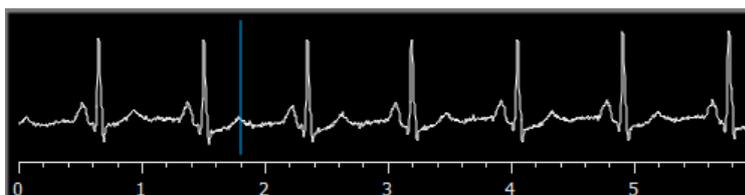
On the x-axis, time is displayed in seconds. The blue vertical line indicates the selected frame.

To show or hide the ECG diagrams:

1. Click [icon] on the Viewing toolbar to show or hide the ECG diagrams.

To select a frame based on the ECG diagram:

1. Click and drag in the ECG diagram to set the blue vertical frame marker.

6.4   Frame Selection

You can move forward or backward through frames in the image in several ways. Moving through frames only applies to the selected viewport, unless synchronization is active, see 6.4.1.

Moving through frames can be done by using buttons:

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

Or,

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

Or,

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

6.4.1 Synchronization

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

To switch synchronization on or off:

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

6.5 Mouse Controls

6.5.1 Stacking

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

To activate the stacking mouse control:

- Click [icon] in the mouse controls toolbar.

Or,

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

6.5.2 Zooming

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

To activate the zooming mouse control:

- Click [icon] in the mouse controls toolbar.

Or,

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

6.5.3 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.

6.5.4 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.

6.5.5 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   Simple measurements

7.1   Annotations

You can add annotations to a viewport to mark it for analysis or to draw attention to specific details. Annotations are displayed in the viewport. All annotations of the active study are listed on the **Procedures** pane.
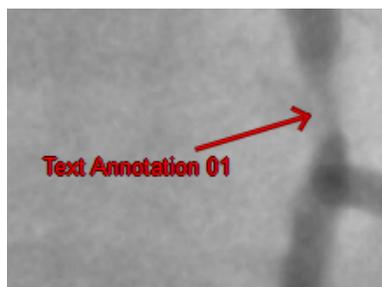
For details on creating, editing and deleting annotations, see the Medis Suite User Manual.

7.2   Distance Measurements

You can measure the distance from one point to another. When you have measured a distance, you can modify the annotation and the end points of the measurement. All distance measurements of the active study are listed on the **Procedures** pane. All distance measurements of the active session are listed on the **Results** pane of Medis Suite.
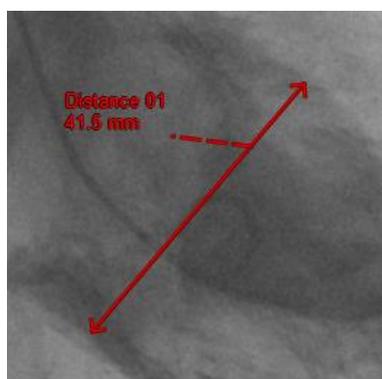
For details on creating, editing, and deleting distance measurements and copying the results to clipboard, see the Medis Suite User Manual.

7.3   Area Measurements

You use the area measurement tool to draw and measure 2D areas. When you have measured an area, you can modify the area contour or annotation. All area measurements of the active study are listed on the **Procedures** pane. All area measurements of the active session are listed on the **Results** pane of Medis Suite.
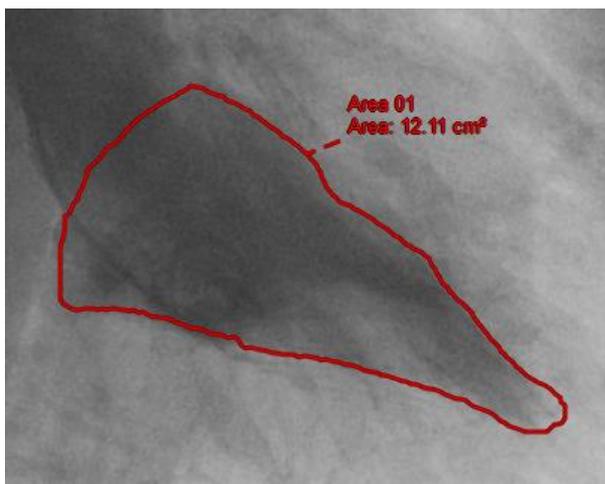
For details on creating, editing, and deleting area measurements and copying the results to clipboard, see the Medis Suite User Manual.

7.4   Snapshots

You can save snapshots as evidence of an analysis or diagnosis. Snapshots are displayed on the **Properties** pane, and are listed on the **Procedures** pane. When a snapshot is created, you can modify the name at any time.

7.4.1   Creating Snapshots

You can create a snapshot of the current state of a viewport.

To create a snapshot:

1. Click [camera icon] in the toolbar, or press the S key, or select [menu icon] > **Procedures > Snapshot**.

2. Click in the viewport where you want to take a snapshot.

3. 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.

8   Single Vessel Analysis

8.1   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.

8.2   Start a Single Vessel Analysis

To start a single vessel analysis:

* Click in the Procedures toolbar.

8.3   Wizard Step 1: Offset correction

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

To apply offset correction:

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

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

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

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

The offset correction is now performed automatically.

8.4   Wizard Step 2: Pathline and Contours

The second wizard step is to define the pathlines and contours of the vessel segment of interest, allowing QAngio XA 3D to create a 3D model of the vessel segment.

To create pathlines and contours:

* Click in the left-hand viewport to mark the proximal point of the vessel segment.

* Click in the left-hand viewport to mark the distal point of the vessel segment.

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

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

8.5　Wizard Step 3: Lesion

The third wizard step is to review the lesion parameters of the vessel segment.

Upon entering the third wizard step, QAngio XA 3D will determine and display the following items:

- The 3D vessel model, including optimal viewing angles to obtain minimal foreshortening and some relevant clinical parameters.

- The 2D and 3D 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).

To view the 3D vessel model in different orientations:

- Click and drag in the 3D viewport to change the orientation.

8.5.1　Force Corresponding Point

You can improve alignment of the two 2D contours in the 3D model by forcing a corresponding point.

To force a corresponding point:

- Click the checkbox **Corresponding points** to enable the corresponding point mode.

- Set a point in the left-hand and right-hand viewports.

8.5.2　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.

8.5.3   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.

8.6   Wizard Step 4: QFR Calculation

The fourth wizard step is to perform the QFR calculations.

ⓘ QFR values can only be calculated reliably for images that were captured after nitro has been administered to the patient.

To perform Fixed Flow QFR calculations:

- Select the radio button to specify whether nitro has been administered before image acquisition.

- Select the radio button to specify the analyzed vessel segment.

8.6.1   Frame Count

In some cases, you may obtain more accurate values for the QFR if the blood flow is based on the actual blood flow, which can be determined by frame counting.

To perform frame count:

- Click the checkbox **Frame counting** to enable the frame count

- The frame counting needs to be performed on the image displayed in the bottom right-hand viewport. By default, this viewport takes over the image displayed in the top-right-hand viewport.

Select the radio button to specify which image should be used for frame counting.

- o Left: The image from the upper left-hand viewport will be used for frame counting.

- o Right: The image from the upper right-hand viewport will be used for frame counting.

- o Other: The bottom right-hand viewport is cleared. Drag an image from the series browser into the viewport to use it for frame counting.

- Dependent on the available licenses, select the radio button to specify the patient state: Hyperemic or Contrast.

- Navigate through the frames until the start of the contrast bolus reaches the start of the analyzed segment, indicated by the proximal frame count marker.

  Drag the proximal frame count marker if the exact arrival of the contrast bolus does not match the initial location.

- Press **Start frame**.

- Navigate further through the frames until the start of the contrast bolus reaches the end of the analyzed segment, indicated by the distal frame count marker.

  Drag the distal frame count marker if the exact arrival of the contrast bolus does not match the initial location.

- Press **End frame**.

8.7   Wizard Step 5: QFR Results

The last wizard step summarizes all analysis results.

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

- Drag the index marker (I) in an image or the diagram. The Index QFR value is updated in the properties pane.

Now that the QFR results are available, you may decide that another lesion is more significant. Click and drag the lesion markers to this new location. The lesion parameters are updated.

Press **Done** to finish the analysis and make the results available in the report.

8.8   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.