Medis
MEDICAL IMAGING

QFR

Version 3.1

User Manual

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https://www.medisimaging.com

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

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Legal Notices

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Patents

QFR is based on patented protected technology. Patents are registered in Europe under numbers NL2012459, NL2016787, NL20222109, NL20226137, EP3457945, EP3660858 and EP4231914. Patents are registered in the United States under numbers US 10,740,961, US 11,216,944 and US 11,741,602. Patents pending in Japan.

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Regulatory Information

Intended Use

QFR is a medical software device intended to be used for the visualization of X-ray angiographic images. Further, QFR is intended to be used for performing calculations in X-ray angiographic images of coronary vessel segments. The calculations are based on the contours that are automatically detected, in the images of coronary vessel segments, by the software and subsequently presented to the user for review and manual editing.

QFR provides 3D models of coronary vessel segments based on contours which are automatically detected in two angiographic views of the vessel. From these, accurate anatomical quantifications are calculated of one or more lesions in the analyzed vessel segment. Further, the device determines the functional significance of individual and consecutive multiple lesions in coronary vessel segments.

In summary, QFR provides:

- Cine loop and 2D review,
- Dimensions of the cardiovascular vessels, and lesions,
- Quantitative results of coronary vessel segments based on a 3D reconstructed model,
- Quantification of the pressure drop in coronary vessels.

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

- To support the clinical decision-making process with respect to the diagnosis and possible treatment options for the coronary vessels,
- To support the evaluation of interventions or drug therapy applied for conditions of the coronary vessels.

Indications for Use

QFR is indicated for use in clinical settings where validated and reproducible results are needed to quantitatively assess X-ray angiographic images of the blood vessels, for use on individual patients with cardiovascular disease.

The QFR measurements can be applied to intermediate coronary lesions in individual patients with stable angina.

When the quantified results provided by QFR are used in a clinical setting on X-ray images of an individual patient, they can be used to support the clinical decision-making process 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.

Contraindications

The QFR measurements have not been evaluated and therefore should not be applied to non-coronary arteries, in paediatric patients, and cardiac patients with the following conditions:

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

The QFR measurements have not been evaluated and therefore should not be used in the following lesions or vessel types:

- Culprit lesions in Acute Coronary Syndrome,
- Bifurcation lesions with 1,1,1 Medina classification,
- Ostial lesions in main stem or right coronary artery,
- Distal left main lesions in combination with a proximal circumflex lesion,
- Bypass grafts,
- Grafted coronary arteries,
- Myocardial bridging.

Limitations

QFR has the following known (technical) limitations.

Restrictions on X-ray angiographic images used for QFR measurements:

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

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.
- When no nitroglycerin has been administered either systemic or intracoronary,
- In vessels with retrograde fillings.

Rationale and Disclaimers

QFR must be used by cardiologists, trained technicians or trained nurses who are qualified to perform cardiac analysis. If the analysis results are used to reach a diagnosis or to guide treatment, the results must be interpreted by a qualified medical professional.

In clinical practice QFR should not be used for purposes other than those described in the sections Intended Use and Indications for Use.

Users must have sufficient proficiency in the language of the user manual, read the user manual, and become familiar with QFR to be able to obtain reliable analysis results.

European Regulations

CE 0476	Medis QFR XA complies with the requirements of the Dutch Medical Devices Decree (Besluit Medische Hulpmiddelen, Staatsblad 2022/190) and the European Medical Devices Regulation 2017/745. Medis QFR XA has been filed with KIWA CERMET ITALIA S.P.A. (0476).

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+Shift+Z	Press and hold down the Ctrl key and the Shift on your keyboard while you press Z, then release all keys.

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 QFR

QFR is a medical software device intended to be used for the visualization and analysis of X-ray Angiography (XA) images. It provides intuitive user workflows for loading, reviewing, and manipulating XA images in 2D, and provides tools for doing easy and quick measurements in XA images.

QFR supports the 3D analysis of anatomical and functional severity of lesions in coronary arteries from XA images. A 3D vessel model is reconstructed from the 2D contours of two angiographic projections with angles ≥25° apart, acquired by monoplane or biplane XA systems. End-diastolic image frames will be used as input for the analysis, where the vessel lumen is well filled with contrast. The start and end positions and the contours of the target vessel segment are automatically detected. The 3D vessel model is then used to calculate the QFR value, based on an automatically detected patient-specific volumetric flow rate, and an automatically detected reference diameter that takes side branches into account.

2 Quick Start

After a successful installation, configuration, and post install test, you can load DICOM X-Ray Angiographic (XA) images into the QFR application and perform a QFR analysis.

- Open a browser window and enter the QFR server address. Log on to QFR. If needed, enter your username and password.

- From the Studies page, find the study you want to analyze. If needed, query and retrieve the study from the PACS, or import data from your local computer. Double-click on the study or "New QFR Analysis" icon to load all XA series and start a QFR analysis.

- On entering the Vessel Selection step, QFR will automatically classify the coronary vessels that are visible and analyzable in each XA series. Select two series that provide a good view on the vessel you want to analyze. QFR will automatically detect the end diastolic (ED) phases of the heart cycle, and select the frame that corresponds to the optimal ED phase that can be used for the analysis. If available, the ECG signal will be displayed. Verify the ED frame selection, change the frame selection if needed, and click Next to proceed to the next step in the analysis.

- On entering the Contours step, QFR will automatically detect the start and end points of the target vessel, detect the pathline, and detect the vessel contours. Verify the start and end points, and make corrections if needed by dragging the points to the proper location. Verify the pathline and make corrections if needed by dragging the pathline to the proper location. Verify the contours and make corrections if needed by dragging the contours to the proper location. Verify that the correct vessel type is detected and make corrections if needed. Click Next to proceed to the next step in the analysis.

- On entering the Results step, QFR will automatically detect the lesions in the target vessel and calculate the QFR result. In the Physiology tab, you can verify the QFR diagram and the vessel QFR value, as well as the Delta QFR, Residual QFR, and Diameter Stenosis % values for each lesion. In the Morphology tab, you can verify the Diameter diagram, and the Minimal Lumen Diameter, the Reference Diameter and the Lesion Length for each lesion. Verify the detected lesions and make corrections to the lesion markers if needed by dragging them to the proper location. Click Finish to complete the QFR analysis.

- On entering the Review step, the report will be created and automatically saved to the QFR data repository, and automatically exported (if configured). Click the Show Report button to open the report. Click the Edit Analysis button to go back into the Results step of the QFR analysis where you can make changes to the analysis. Click the Start New Analysis button to start a new QFR analysis, for example on a different vessel type. Reload other previously created QFR analyses from the same study by selecting the analysis from the QFR analysis dropdown.

3 System Requirements

QFR is intended to be installed on a Windows-based server system and accessed from supported web browsers on client machines over the network.

If a dedicated server system is not available, QFR can also be installed on a standalone workstation or laptop, provided that the system meets the applicable requirements listed below.

QFR is **not** intended to serve as the permanent archive for images or results. Images and results must be stored in the organization's PACS, VNA, or other designated archive system.

QFR is a CPU-intensive server application. For best performance and predictable response times, deploy it on a high-performance Windows server with fast local SSD storage.

QFR Server Machine

The server machine is where the QFR software will be installed and run. The server can be a physical machine, or a virtual machine. A Windows operating system is required. Sufficient resources should be available to cache image data and results, and execute image processing algorithms.

Hardware

The following hardware configuration is required for a QFR server machine and is intended to support typical deployment scenarios.

- Processor: 64-bit CPU with at least 8 physical cores and 16 logical threads.
- Memory: Minimum of 32 GB RAM.
- Storage: SSD, with at least 20 GB free space, total capacity dependent on study data volume.
- Network: Minimum 100 Mbps bandwidth and maximum 50 ms latency between client and server.

Notes:

- Processor: QFR algorithm performance depends strongly on CPU capability. It is highly recommended to select **modern high-performance server processors** such as the AMD EPYC 4004 series, the Intel Xeon E-2400 series, or higher. Desktop equivalents include the AMD Ryzen 7 series, the Intel Core Ultra 7 series, or higher, preferably with a base frequency of 3.0 GHz or higher.
- Concurrent use: The server configuration supports up to 4 concurrent users performing QFR analyses under typical usage conditions. For higher concurrent usage, increase the number of CPU cores and overall CPU performance.
- Storage: The QFR server receives and caches (but does not archive) XA image data from the X-ray acquisition system or PACS to ensure fast access for review and analysis. Storage capacity should be sized to accommodate the operating system, the QFR software, and approximately 6 months of QFR study data. Actual storage needs depend on study volume. For performance

reasons, local SSD storage is recommended; storing QFR study data on a network drive is not recommended.

- Network: Network connectivity between QFR and any configured X-ray acquisition system, PACS system or other DICOM nodes must be available and correctly configured.
- Graphics: A dedicated graphics card is not required on the server machine.
- Display: A display is not required for normal server operation.
- Virtual machines: Allocated vCPU, RAM, and disk I/O performance must meet the same requirements as physical hardware.

Operating Systems

The following operating systems are supported by QFR:

- Microsoft Windows Server 2025, 64-bit
- Microsoft Windows Server 2022, 64-bit
- Microsoft Windows Server 2019, 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows 10, 64-bit

QFR Client Machines

The client machine is used to access QFR that runs on the server machine, using a web browser. No application modules or browser plugins will be installed, no data will be cached, and no algorithms will be executed on the client machine. QFR is designed to work on client machines with specifications and screen resolutions of a standard desktop computer or laptop.

Hardware

The following hardware configuration is required for QFR client machines:

- Processor: 64-bit CPU with at least 4 physical cores and 8 logical threads.
- Memory: Minimum of 16 GB RAM.
- Network: Minimum 100 Mbps bandwidth and maximum 50 ms latency between client and server.

Notes:

- On the QFR client machines, no applications will be installed and no data will be cached.
- Graphics card and display: The QFR application will work correctly when running in a web browser on a standard desktop-sized screen. A widescreen monitor with a resolution of at least 1920 x 1080 pixels (Full HD) is recommended. Scaling and zooming may affect the display of QFR.

Web Browsers

The following web browsers are supported by QFR:

- Microsoft Edge, version 143 or newer
- Google Chrome, version 143 or newer
- Safari, version 26.0 or newer

Web browser plugins and extensions may affect the operation of QFR and may have access to QFR web page content. Only enable plugins and extensions from a trusted source.

For optimal security and compatibility, keep the web browser updated to the latest supported version. Browser updates may include important security fixes, performance improvements, and compatibility updates that help ensure the QFR application continues to function as intended. Using an outdated browser version may reduce security and can affect the correct operation of QFR.

Web browsers may provide an option to automatically translate the contents of the QFR web pages. QFR will attempt to block these options, but in some cases the option might still be presented to you. It is advised not to use this automatic translation option, but use the official translations provided by the QFR application, configurable from the Settings screen.

QFR Standalone (Laptop) Machines

It is strongly recommended to install QFR on a server machine, which will unlock access to QFR from any client machine that has network access to it. However, if you are not able to arrange a dedicated QFR server machine and are considering installing and using QFR on a standalone (laptop) computer system, ensure that the selected system is suitable for both running QFR and viewing it in the web browser.

Hardware

The following hardware configuration is required for a standalone machine:

- Processor: 64-bit CPU with at least 8 physical cores and 8 logical threads.
- Memory: Minimum of 32 GB RAM.
- Storage: SSD, with at least 20 GB free space, total capacity dependent on study data volume.
- Network: Network communication between client and server is not applicable when installed on a standalone machine.

Notes:

- Processor: QFR algorithm performance depends strongly on CPU capability. It is highly recommended to select **modern high-performance processors** such as the AMD Ryzen 7 series, the Intel Core Ultra 7 series, or higher, preferably with a base frequency of 3.0 GHz or higher.
- Concurrent use: The standalone setup will only support a single-user profile.
- Network: Network connectivity between QFR and any configured X-ray acquisition system, PACS system or other DICOM nodes must be available and correctly configured.

- Graphics card and display: The QFR application will work correctly when running in a web browser on a standard desktop-sized screen. A widescreen monitor with a resolution of at least 1920 x 1080 pixels (Full HD) is recommended. Scaling and zooming may affect the display of QFR.
- Performance settings: Laptops must be **plugged in AC power** when using QFR and configured to **run at "Best performance"**.

Operating Systems

The following operating systems are supported by QFR:

- Microsoft Windows Server 2025, 64-bit
- Microsoft Windows Server 2022, 64-bit
- Microsoft Windows Server 2019, 64-bit
- Microsoft Windows 11, 64-bit
- Microsoft Windows 10, 64-bit

Web Browsers

The following web browsers are supported by QFR:

- Microsoft Edge, version 143 or newer
- Google Chrome, version 143 or newer
- Safari, version 26.0 or newer

Web browser plugins and extensions may affect the operation of QFR and may have access to QFR web page content. Only enable plugins and extensions from a trusted source.

For optimal security and compatibility, keep the web browser updated to the latest supported version. Browser updates may include important security fixes, performance improvements, and compatibility updates that help ensure the QFR application continues to function as intended. Using an outdated browser version may reduce security and can affect the correct operation of QFR.

Web browsers may provide an option to automatically translate the contents of the QFR web pages. QFR will attempt to block these options, but in some cases the option might still be presented to you. It is advised not to use this automatic translation option, but use the official translations provided by the QFR application, configurable from the Settings screen.

4 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 helpdesk.

If you contact the helpdesk by e-mail, mention “QFR 3.1.24.2” in the subject field.

North and South America

E-mail: support@medisimaging.com
Telephone: +1 919 278 7888 (working days 9.00-17.00 EST)

Japan

E-mail: support@medisimaging.com
Telephone: +81(0)3 6778 2589 (working days 9.00-17.00 JST)

Europe and other regions of the world

E-mail: support@medisimaging.com
Telephone: +31 71 522 32 44 (working days 9.00-17.00 CET)

Important Note to Users

When you experience any **serious incident** occurring in relation to the QFR device you **immediately** need to report this to the manufacturer (using the contact details above) and the competent authority of the EU Member State in which you and/or the patient are established.

5 Startup

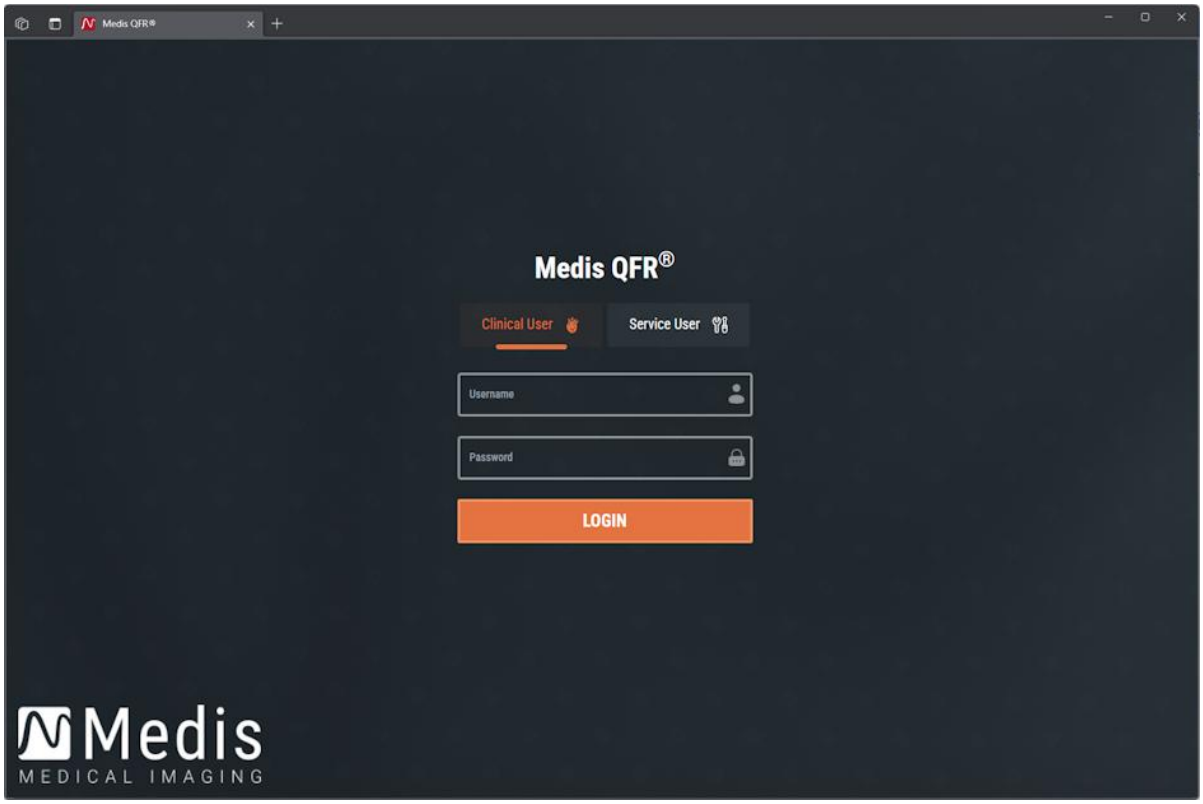
The QFR application is accessed from a web browser, by visiting or browsing to the QFR server address. The server address is dependent on the installation and configuration for your organization (e.g. https://qfr.myorganization.com).

QFR is running on a server machine in your organization network, it does not make use of a QFR server that runs in the cloud or internet.

To quickly reopen the QFR application, add a bookmark in your browser to save the QFR server address.

To run QFR full screen, press ‘F11’ (in Google Chrome and Microsoft Edge) or ‘Cmd+Ctrl+F’ (in Safari) on your keyboard.

The login screen of the QFR application will be presented.



To login to QFR:

- Select the **Clinical User** tab.
- Enter your **Username** and **Password**.
- Click the **Login** button to log on to QFR.

Depending on the configuration for your organization, the Username and Password edit fields may or may not be visible. The username and password may be identical to your organization Windows user account, or a dedicated QFR user account was created for you. Contact your system administrator to understand which user account can be used.

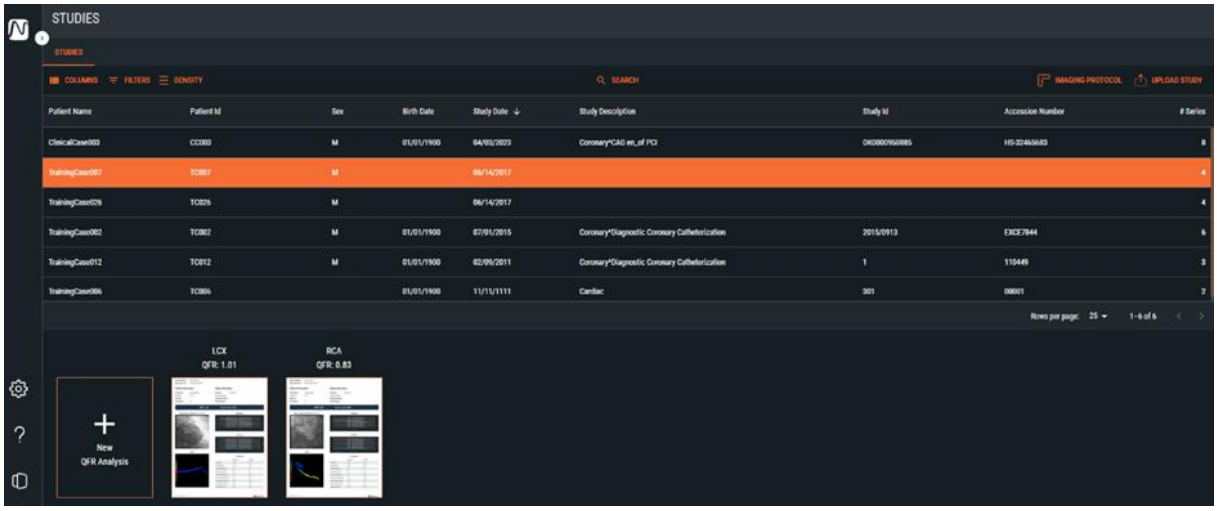
Even if you enter the correct username and password, you may not be authorized to work with QFR yet. In this case, contact your system administrator to request access to QFR.

After the initial configuration of QFR, the “Service User” option to logon to QFR is only available for Medis Installation and Support team members.

6 Workspace

After you have successfully logged on to QFR, the application workspace will be presented to you.

The default view will show you the **Studies** page, with an overview of all studies with X-Ray Angiography (XA) images and their QFR analyses.



QFR will only load studies with XA series. In case your study has image data from other modalities (such as MR or CT) they will not be visible in the list.

In the side bar on the left the following functionalities are available:

- to return to the **Main** screen (study browser or QFR analysis)
- to open the **Settings** screen, which includes basic settings (general application configuration, and the QFR 'post install test') as well as advanced settings (configuration of users and roles, DICOM connections, export settings, configuration of licenses and vouchers) that are only accessible for users with the Administrator role.
- to open the **Help** screen, which includes information on how to contact the support team, the QFR user documentation, and the QFR audit trail.
- to view the current user account details and log off from QFR.

7 Image Acquisition

7.1 Requirements for Image Acquisitions

DICOM XA image monoplane or biplane acquisitions can be used as input for the QFR analysis if they comply with the following criteria:

- The images are expected to be in grayscale (color images are not supported),
- The images must have square pixels (pixel aspect ratio 1:1),
- The images are accompanied by isocenter calibration data (manual calibration is not supported),
- The images are acquired at fixed angulations (rotational angiography is not supported),
- The images are expected to have at least 5 image frames. (This is to filter out single frame and other very short acquisitions such as balloon interventions, and wires without contrast. An acquisition suitable for the QFR analysis will include approximately 3 full heart cycles.)

XA images that do not comply to the above criteria will automatically be excluded from the QFR analysis, and they will not be visible as thumbnails in the Vessel Selection step.

7.2 Image Acquisition Guidelines

The QFR analysis is based on a 3D vessel reconstruction. To create a successful 3D vessel reconstruction, two XA acquisitions of the target vessel will be required, acquired from two different angles. The two acquisitions must have an angle difference of ≥ 25° (optimally between 35° and 50°). Also, the projections should be as perpendicular as possible to the target vessel (not parallel).

Recommendations for the angiographic procedure:

- Prior to the first angiographic acquisition to be used for QFR analysis, inject intracoronary nitroglycerin.
- Use a frame rate of at least 12.5 frames per second.
- Use a 4F catheter size or larger.
  5F or larger is recommended to support a brisk injection of the contrast.
- Make sure that the entire catheter is filled with contrast before the injection.
  Prevent premature contrast leakage.
- Use brisk, continuous and fast contrast injections.
  Aim for 3 full cardiac cycles (i.e. fully opacified target vessel).
- Minimize overlap of target segments (especially at the lesions).
- Avoid foreshortening of the target vessel.
- Prior to the acquisition, inject some contrast to check potential severe overlap and/or severe foreshortening. If any, rotate or angulate 5° more.
- Avoid moving the table early after injection (during acquisition).
- Ask the patient to hold their breath if possible (during acquisition).
- Make sure that the entire target vessel is visible in both image projections.

Recommendations for angulations:

The following table presents **recommendations** for the angulations of the first and second projection of a target vessel (all angles based on monoplane acquisitions). Minor adjustments of these angulations may be needed for individual patients to get an optimal view of the target vessel.

Target Vessel	1st View	2nd View
LAD + Diagonals	AP + CRA 45	RAO 35 + CRA 20
LM + Prox LAD, LCx + OMs	LAO 10 + CAU 25	RAO 25 + CAU 25
RCA	LAO 50 + CAU 0	LAO 30 + CRA 30

To analyze RCA+RPLA/RPDA use LAO 30 + CRA 30 view and AP + CRA25. It is important that the entire RCA is included in the RPLA/RPDA analyses.

QFR does not require image acquisitions of patients in hyperemic state as input for the analysis.

More detailed recommendations for the XA image acquisitions can be found in the QFR Imaging Protocol (PDF file), available in the User Documents page of QFR, and also accessible directly from the Studies page in QFR.

To open the QFR Imaging Protocol in a new browser window, select 

from the toolbar of the studies list.

8 Select Patient / Study

From the Studies page, find the study you want to analyze. If needed, query and retrieve the study from the PACS, or upload a study from your local computer. Double-click on the study or "New QFR Analysis" icon to load all XA series and start a QFR analysis.

8.1 Getting the XA Image Acquisitions

There are different ways to make the XA image acquisitions available for QFR.

QFR can receive the XA image acquisitions directly from the acquisition system, or you can query and retrieve images from your PACS system. These DICOM connections must be configured by your system administrator and/or PACS administrator:

- The XA image acquisitions can be 'pushed' directly from the X-Ray acquisition system to the QFR server. The 'push' can either be triggered automatically or manually, depending on your clinical practice and the functionality supported by your X-Ray acquisition system.

  In this workflow, no user interaction is needed in the QFR application to receive the images. After the images have been received by QFR, they will immediately be available in the studies page as input for the analysis.

- The acquisitions can be 'queried and retrieved' from your PACS system to the QFR server.

  In this workflow, from the QFR application, you query for a specific patient study in the PACS archive, and retrieve a copy onto the QFR server. After all images of the study have been received by QFR, they will be available in the studies page as input for the analysis.

  How to query and retrieve a study is described in section 8.2.

In case you have XA image acquisitions available in DICOM format on your local computer system, you can upload the acquisitions to the QFR server. After all images have been uploaded, they will be available in the studies page as input for the analysis.

How to upload data to the QFR server is described in section 8.3.

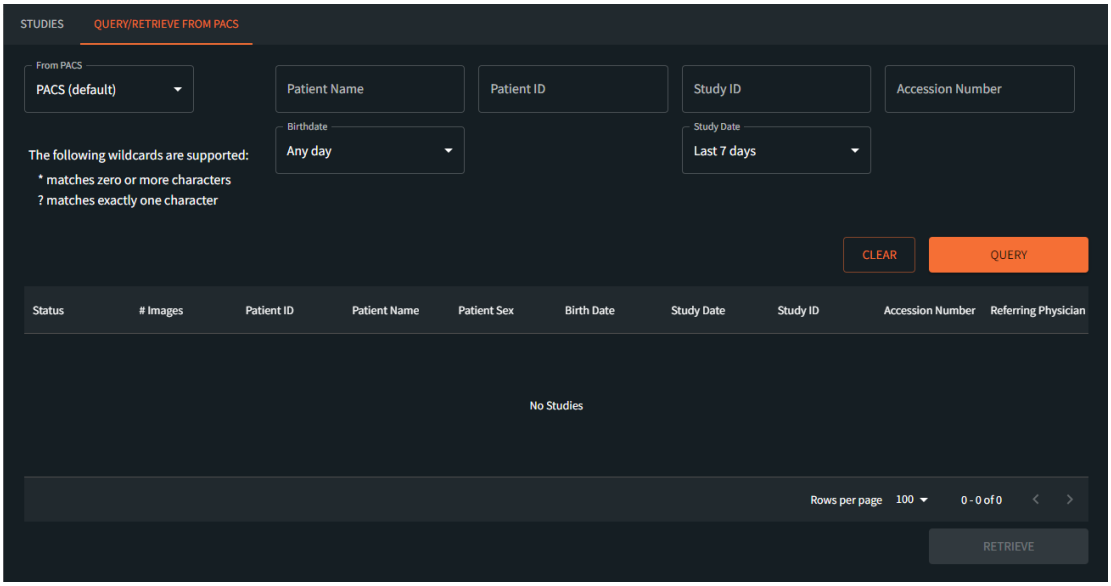
8.2 Query and Retrieve

To query and retrieve studies from the PACS:

- On the studies page, select the tab **Query / Retrieve from PACS**
- If multiple PACS systems are configured, select the PACS that holds the study that you want to retrieve in the drop-down box **From PACS**.
- Specify one or multiple of the query parameters:
  - Patient Name
  - Patient ID
  - Study ID
  - Accession Number
  - Study Date (default: last 7 days)
- Select **Query** to search for studies that match with the query parameters. The results of the search will be displayed in the study list.
- Select the study from the list that you want to retrieve to QFR.

- Select **Retrieve** to retrieve all information from the selected study to QFR.

  The status of the retrieve will be presented in the first column of the query result list.



The Query / Retrieve from PACS tab will be visible only if you have configured the DICOM connectivity and PACS in the Settings screen.

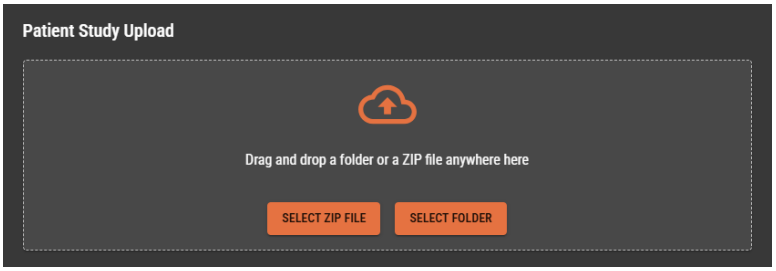
Make sure that you provide sufficient query fields to limit the search results from the PACS. Some PACS systems will support wild card characters (‘?’ to match any single character, and ‘*’ to match any multiple characters).

Some, but not all, PACS systems will also report the ‘Number of images in the study’ as part of the query result. If this information is available to QFR, it will be presented in the second column of the query result list.

8.3 Upload Study

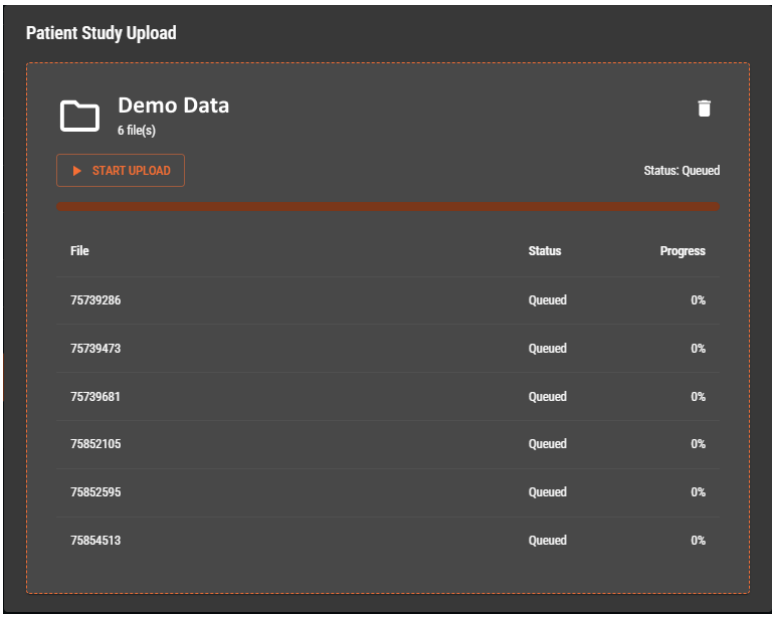
To upload XA image acquisitions of a study from your local computer system to the QFR server:

- On the studies page, select UPLOAD STUDY to open the upload dialog box.



- Drag a ZIP file (that contains DICOM files) or a folder (that contains DICOM files) from your local computer onto the dialog box. Alternatively, click on the associated buttons to browse and select a ZIP file or a folder on your local computer system.

- QFR will display the ZIP file, or parse the contents of the folder and present an overview of all DICOM files.

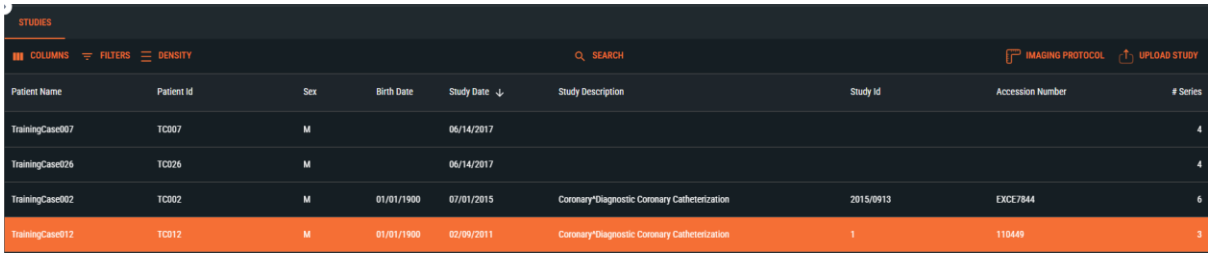


- Click the **Start Upload** button to start the upload process. Progress information will be provided during the upload process.
- After the upload process is completed, close the progress screen and close the upload dialog box. The QFR studies list will automatically update and show the uploaded data.

Only DICOM data can be uploaded to the QFR server. If you upload a folder, the non-DICOM data will automatically be filtered out and will not be displayed in the upload dialog box.

8.4 Studies List

After the X-Ray acquisitions have been pushed or retrieved to QFR, they will be presented in the Studies list. The studies list shows columns with the relevant patient and study information.



To show or hide columns from the studies list:

- Select COLUMNS and enable or disable the columns that you want to show or hide

If there are many studies available, it can become harder to find the study that you want to analyze. To help you find the study of interest, QFR provides search, filter and sort options.

To search for entries in the studies list:

- Click on the quick search bar SEARCH
- Enter the value you want to search for.

  The studies list will immediately update to show only the studies that contain your search value in any of the fields in the study list (patient name, patient ID, sex, birth date, study date, study description, study ID, accession number, and number of series in the study)

To filter the entries in the studies list:

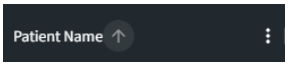
- Select FILTERS to activate the filter control.
- Select the column that you want to use in your filter.
- Enter the filter value, e.g. patient name “john” to only show the patients that have the characters “john” in their full name.

  You can filter on text values for patient name, patient ID, sex, study description, study ID, accession number and number of series in the study.

  You can filter on date values or date ranges for the patient birthdate and study date.

To sort the entries in the studies list:

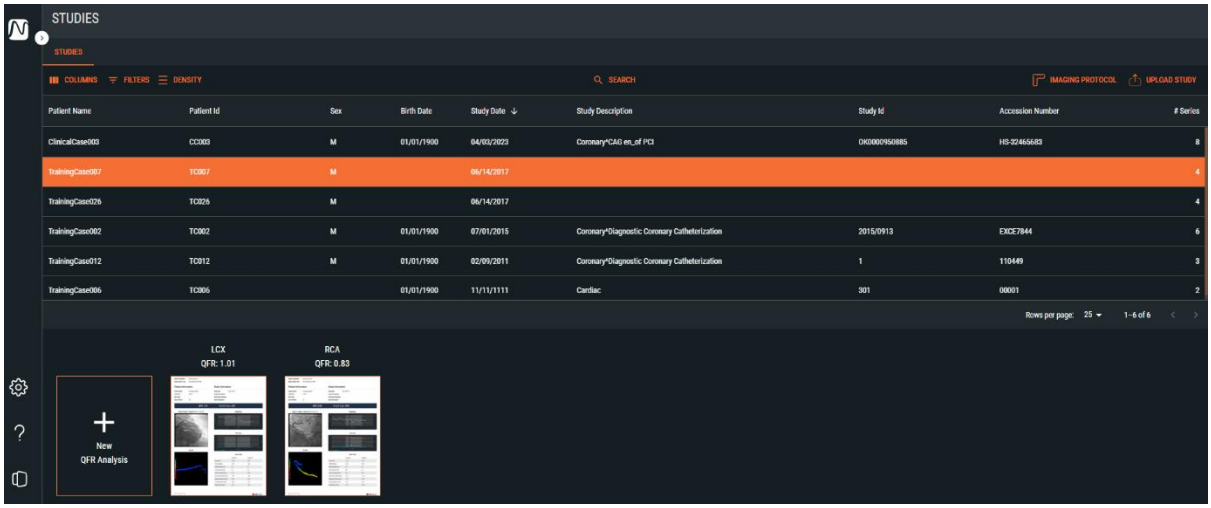
- Hover your mouse on one of the columns in the header of the study list, to show the sort icon (arrow up).

- Click on the arrow icon to sort the entries in the study list ascending (arrow up).
- Click on the arrow icon again to sort the entries in the study list descending (arrow down).

The options to show or hide columns, and filter and sort items in the list are also available from the menu in each column of the header.

If you select a study, the QFR analysis list will show the analyses that have been performed earlier for this particular study. The analysis can be reopened, reviewed, and edited.



The QFR analyses are sorted from the latest analysis (on the left) to the oldest analysis (on the right). Hover your mouse on top of the QFR analyses to see the name of the analyst, and the date and time the QFR analysis was created.

To load a study and start QFR analysis:

- Select a study entry in the Studies list
- Double-click on the study entry
- Or, right-click on the study entry, and select “New QFR Analysis”
- Or, double-click the “New QFR Analysis” icon from the analysis list

To load an existing QFR analysis:

- Select a study entry in the Studies list
- Double-click a QFR analysis in the analysis list
- Or, right click on the QFR analysis icon, and select “Load QFR Analysis”

Users that have been assigned the “Data Manager” role, can delete a study from the study list, or a QFR analysis from the analyses list.

To delete a study:

- Select a study entry in the Studies list
- Right-click on the study entry, and select “Delete Study”
- Click “Delete” in the confirmation dialog to delete the study entry

To delete an analysis:

- Select an analysis entry in the Analysis list
- Right-click on the analysis entry, and select “Delete QFR analysis”
- Click “Delete” in the confirmation dialog to delete the analysis entry

Users that have been assigned the “Data Manager” role, can download a copy of a study from the study list, or a QFR analysis from the analysis list.

To download a study:

- Select a study entry in the Studies list
- Right-click on the study entry, and select “Download Study”
- A copy of the study will be downloaded to your local computer in a zip file.
- Depending on your browser settings, the file will download directly to your Downloads folder, or the browser will ask where to save the file.

To download an analysis:

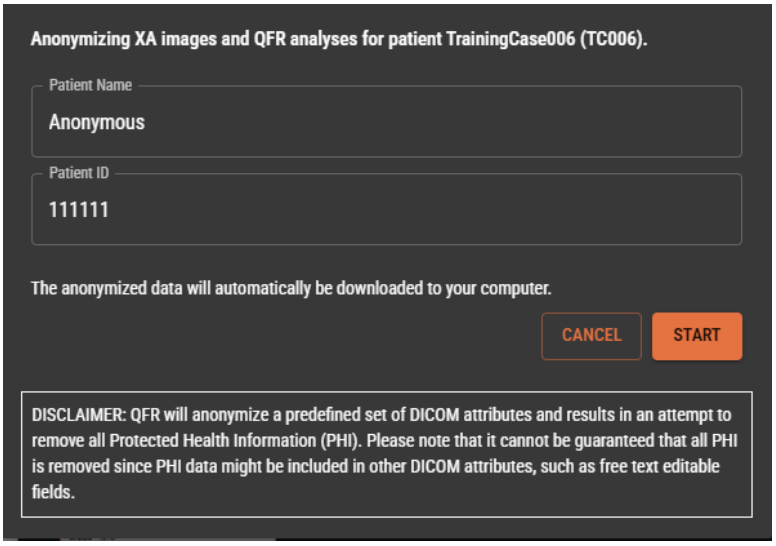
- Select an analysis entry in the Analysis list
- Right-click on the analysis entry, and select “Download QFR analysis”
- A copy of the study will be downloaded to your local computer as a DICOM file.
- Depending on your browser settings, the file will download directly to your Downloads folder, or the browser will ask where to save the file.

Users that have been assigned the “Data Manager” role, can download an anonymized copy of a study from the study list. All XA images and QFR analysis that are part of the study will be included in the anonymization, any other DICOM information (such as DICOM Secondary Capture images) will be excluded.

To download an anonymized copy of a study:

- Select a study entry in the Studies list
- Right-click on the study entry, and select “Anonymize Study”

- In the Anonymization dialog box, specify the values for “Patient Name” and “Patient ID” that should be applied to the anonymized study.



- Select START to start the anonymization process.
- An anonymized copy of the study will be downloaded to your local computer in a zip file.
- Depending on your browser settings, the file will download directly to your Downloads folder, or the browser will ask where to save the file.

Downloading a study or analysis, deleting a study or analysis, and anonymization of a study is only available for users that have been assigned the “Data Manager” role.

The downloaded ZIP file with the anonymized study can directly be uploaded on another QFR server; it is not required to unzip the file first.

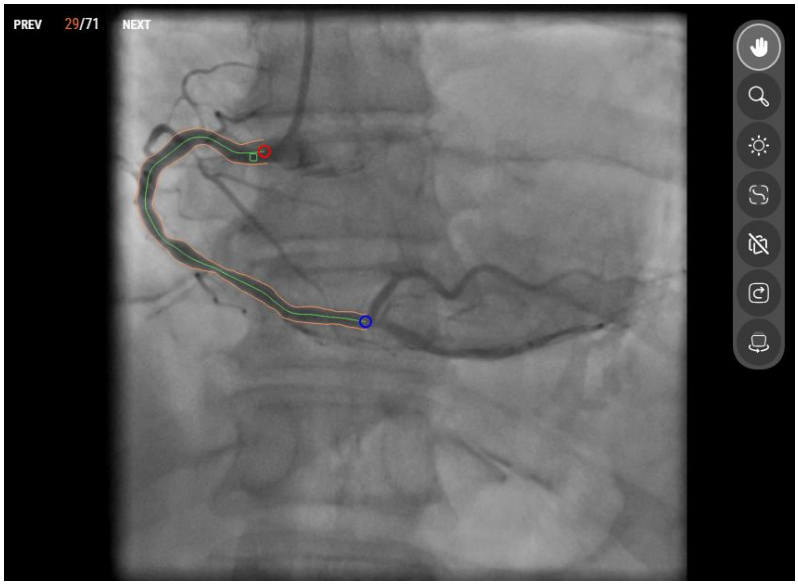
A QFR analysis that is included in the anonymization process contains (snapshots of) the report. This information will be removed from the analysis data, as it contains burned-in patient information. After uploading and reopening an anonymized QFR analysis, the (snapshots of) report will automatically be restored.

9 Viewing

This chapter describes the functionality for viewing images that is available in the QFR analysis steps.

9.1 Image Viewports

The QFR analysis workflow steps have two image viewports that display the XA image data. Each viewport has a viewport control toolbar. Some viewports have textual overlays that can also be interactive. An example of a viewport is given in the following image.



9.2 Mouse Mode

The behavior of the **primary mouse button** (the left button for a right-handed mouse) depends on the mouse mode: panning, zooming, or window width and level. The mouse mode can be set by using the buttons in the viewport control toolbar. The toolbar button that is highlighted indicates the active mouse mode.

To activate a mouse mode:

- Select the appropriate toolbar button:

   for panning

   for zooming

   for window width and window level

The behavior of the **secondary mouse button** (the right mouse button for a right-handed mouse) is always connected to the window width and window level functionality.

The mouse **scroll wheel** can be used to scroll through the individual frames of the acquisition. Scroll up to activate higher frame numbers, and scroll down to activate lower frame numbers.

Although each viewport has its own viewport toolbar, the mouse mode for the different viewports are synchronized; changing the mode in one viewport will also change it in the other viewport.

9.3 Mouse Actions

The image viewports also have mouse actions. The mouse actions can be activated using the buttons in the viewport control toolbar.

To activate a mouse action:

- Select the appropriate toolbar button (or shortcut key):

Zoom to contours (Ctrl+Shift+Z)

The zoom level and the panning of the image will be adjusted to have an optimal view on the full vessel. This action is only available in the Contours or Results step of the QFR analysis.

Hide overlay (press middle mouse button)

The graphics overlay displayed on top of the image will be hidden while the (mouse) button is pressed, and will be displayed again when the (mouse) button is released. This action is only available in the Contours or Results step of the QFR analysis.

Reset viewport state (Ctrl+Shift+S)

The default values for zoom, pan, and window width and window level will be applied to the viewport.

Reactivate analysis frame (Ctrl+Shift+F)

The analysis frame will be reactivated, showing the contours and analysis results. This action is only available in the Contours step of the QFR analysis.

10 Performing a QFR Analysis

When you load a study, the QFR analysis will automatically start. QFR will guide you through three workflow steps that are required to complete the analysis. You will be asked to provide manual input, or to verify and confirm the output of the QFR algorithms.

The following workflow steps are defined:

- Vessel Selection
- Contours
- Results

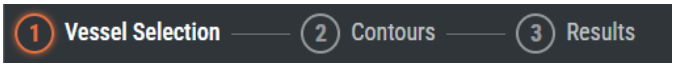
In the next sections, each workflow step will be described in more detail.

A license (and in some cases a voucher) will be required to perform a QFR analysis. The license will be in use from the start to the end of the QFR analysis.

A QFR analysis that is inactive will automatically be closed to free the license. The timeout value can be configured in the QFR Settings (default 60 minutes).

When you attempt to start a new QFR analysis and all licenses are in use, you can have the option to close one of the other QFR analyses – initiated by other users – to free the license and prioritize your QFR analysis. This functionality can be configured in the QFR settings (disabled by default).

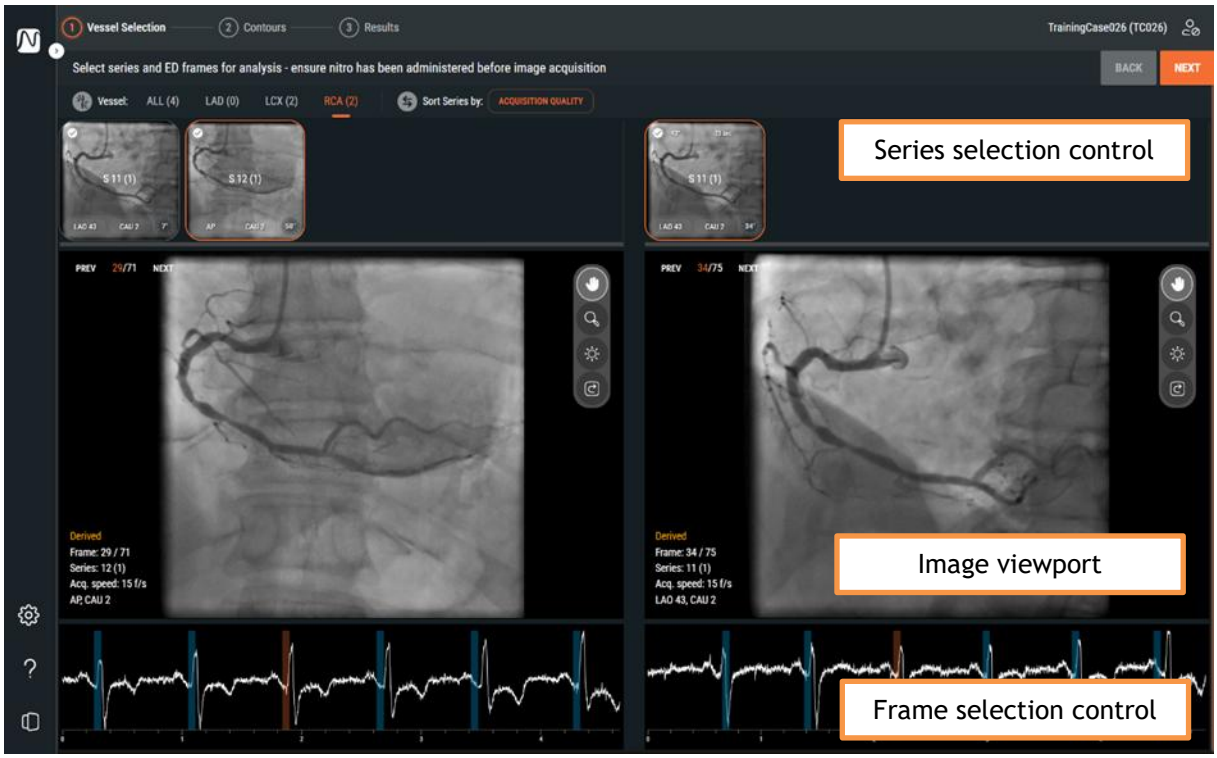
10.1 Vessel Selection



On entering the Vessel Selection step, QFR will automatically classify the coronary vessels that are visible and analyzable in each XA series. Select two series of the target vessel you want to analyze. QFR will automatically detect the end diastolic (ED) phases of the heart cycle, and select the frame that corresponds to the optimal ED phase that can be used for the analysis. Verify the ED frame selection, change the frame selection if needed, and click Next to proceed to the next step in the analysis.

In the Vessel Selection step of the QFR analysis, you need to select the coronary vessel that you want to analyze and select two XA series and ED image frames that have a proper view on this target vessel. The selected ED image frames will be used as the input ('analysis frames') for the QFR analysis.

In the Vessel Selection step, the screen shows the **series selection controls** at the top, the **frame selection controls** at the bottom, and the **image viewports** in the middle.



The series selection control, the image viewport and frame selection control will help you select the two XA acquisitions and ED image frames that will be the input for the QFR analysis. Both should have a proper view on the target vessel, they must be acquired at different angulations (at least 25° apart) and within a certain time frame (maximum 2 hours apart).

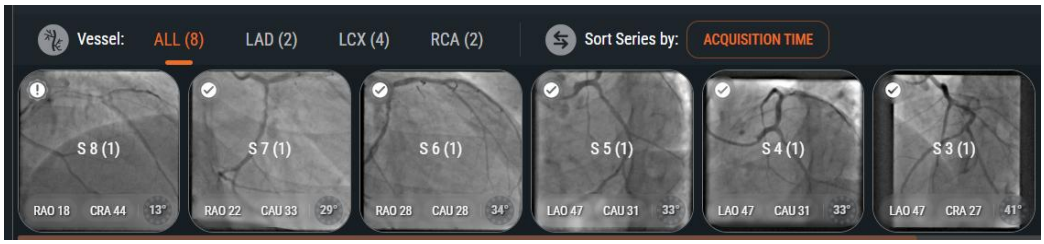
10.1.1 Series Selection Control

When you enter the Vessel Selection step, QFR will automatically process the XA series with an artificial intelligence (AI) algorithm to detect the most probable coronary vessel that is visible and analyzable in the image data. QFR can detect the following coronary vessels:

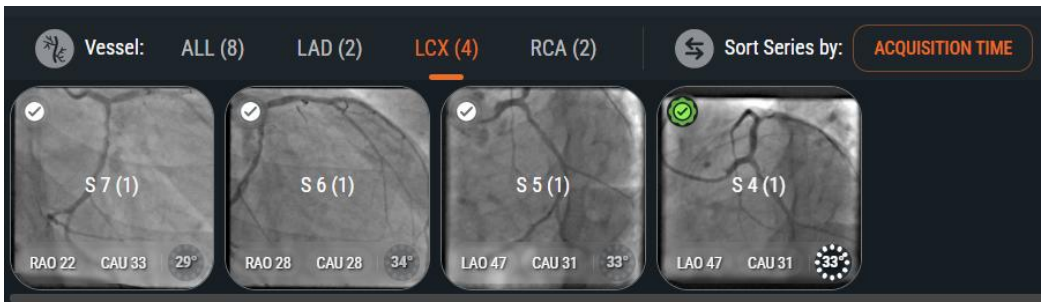
- Left Anterior Descending (LAD)
- Left Circumflex (LCX)
- Right Coronary Artery (RCA)

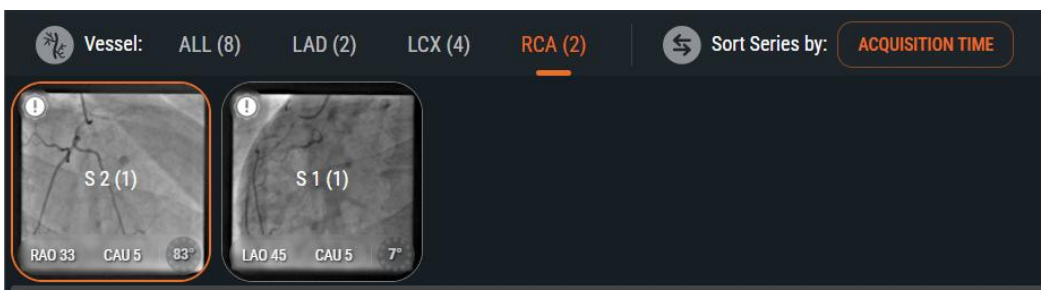
The XA series with the same vessel type are grouped together on a tab. The XA series are presented as thumbnails, with an overlay that shows the image quality, series number, instance number, and the angulation and rotation of the gantry during the acquisition.

The ALL tab displays all XA series of the study, independent of the detected vessel type, if they are suitable as input for the QFR analysis.



The LAD, LCX and RCA tabs will only display the XA series of the study with the corresponding image type that are suitable as input for the QFR analysis.





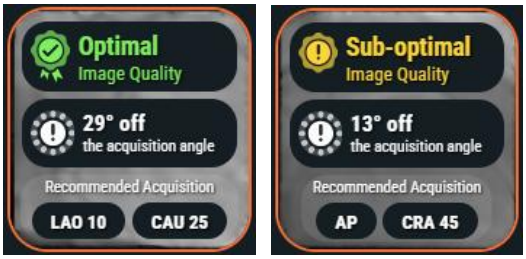
Not all XA series may be classified as LAD, LCX or RCA, for example if the algorithm is not able to detect a vessel type, or the XA image does not show one of the main vessel types. The ALL tab will show all XA series that are suitable as input for the analysis, independent of the automatically detected vessel type.

The series can be sorted by acquisition time or acquisition quality.

- Sorting on **acquisition time** is based on the time the series have been acquired by the acquisition system. The thumbnails will appear in the order of the acquisitions; first acquisition on the right, latest acquisition on the left.
- Sorting on **acquisition quality** is based on a combined measure:
    - The quality of the image acquisitions, measured by an AI algorithm, based on degree of contrast filling within the vessel and the clarity of the vessel edges. Series will be labeled as 'Optimal' or 'Sub-optimal' input for the QFR analysis.
    - The offset of the *actual* acquisition angles of the series against the *recommended* acquisition angles for the selected vessel type.

  The thumbnails will first show 'optimal' series and 'sub-optimal' series last. Within each category, acquisitions that are closest to the recommended acquisition angles are displayed first, and the series that have the largest deviation from the recommended acquisition angles are displayed last.

  The thumbnails will show an icon for 'Optimal' series and for 'Sub-optimal' series. Hover the mouse over the icon to see more details about the image quality of the series:



To switch between sorting options:

- Click the **Sort Series by** button to toggle between **Acquisition Time** and **Acquisition Quality**.
- If the button shows **Acquisition Time,** the series are sorted by acquisition time.
- If the button shows **Acquisition Quality,** the series are sorted by acquisition quality.

When you select a thumbnail in the series selection control, the corresponding XA series will be loaded in the image viewport below.

To select the two XA series as input for the QFR analysis:

- Select a vessel type tab in the left series control: All, LAD, LCX, or RCA.
- Select a series in the left series selection control. This will load the corresponding XA series in the left image viewport. The series selection control on the right will be populated with the XA series that could be a suitable matching pair; this includes only the series of the same vessel type, acquired at least 25° apart, and within a two hour timeframe.
- Select a series in the right selection control. This will load the corresponding XA series in the right image viewport.

The following image shows an example where two LAD series have been selected as input for the QFR analysis.

- The LAD tab is selected.
- On the left, series number 4 has been selected (LAO 0, CRA 45).
- On the right, series number 5 has been selected (RAO 35, CRA 20).
- Series numbers 4 and 5 have a 3D angle difference of 38°, and an acquisition time difference of 45 seconds.

If possible, QFR will automatically select the matching XA series in the right series selection control.

- If there are only 2 series available for a vessel type, selecting one series on the left will automatically load the other series on the right.
- If you select one series of a biplane acquisition on the left, the corresponding biplane series will automatically load on the right.

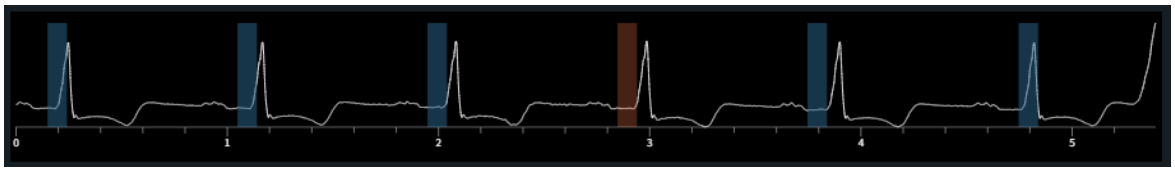
10.1.2 Frame Selection Control

After selecting the XA series, you need to select the appropriate image frames as input for the QFR analysis.

The QFR analysis should be performed on an image frame that is in the end diastolic (ED) phase of the heart cycle, where the heart is in a state of rest and the vessel is properly filled with contrast. QFR will automatically detect all image frames that are in an ED phase, by examining the electrocardiogram or by reviewing the image data. From all ED image frames, QFR will automatically

select the one that is considered to be optimal as input for the QFR analysis, by examining the contrast filling of the vessel.

The frame selection control is shown below each image viewport. On the x-axis, time is displayed in seconds. The orange vertical bar indicates the selected image frame, visible in the corresponding image viewport. The blue bars indicate the image frames that correspond to the automatically detected ED phases. If ECG data is included with the image data, the ECG curve is also shown in the frame selection control.



Verify the image frame that was automatically selected by the system is suitable to be used as input for the analysis. If needed, you can select another image frame in the ED phase of the cardiac cycle to be used as input for the QFR analysis.

To change the active image frame:

- Click in the frame selection control to select the image frame at the corresponding time point.
- Or, click and drag the mouse in the frame selection control to continuously update the active image frame.
- Or, click the frame selection controls in the angiographic viewport.
  - Click the **PREV** button (lower frame numbers)
  - Click the **NEXT** button (higher frame numbers)
- Or, use the arrow keys on your keyboard.
  - Use arrow keys left (lower frame number) and right (higher frame number) to change the active image frame in the **left** image viewport.
  - Use arrow keys down (lower frame number) and up (higher frame number) to change the active image frame in the **right** image viewport.

After you have selected two suitable image frames for the QFR analysis, click NEXT to proceed to the next workflow step of the QFR analysis.

Points of attention

- The frame for analysis must be in the ED phase of the cardiac cycle.
- The vessel and lesion(s) of interest should be clearly visible with good contrast filling and as little overlap as possible with other structures.

To verify if QFR automatically selected the proper end diastolic phase:

- The arteries are stretched as much as possible.
- For left and right coronaries arteries find the image in which the aortic valve opens and the accumulated contrast flushes into the aorta and then go backwards 2 or 3 frames.

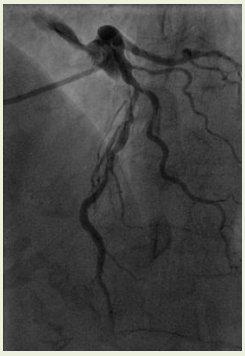
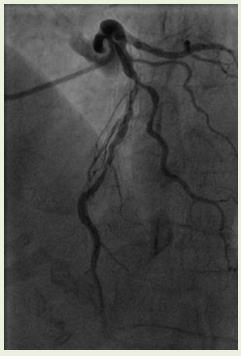
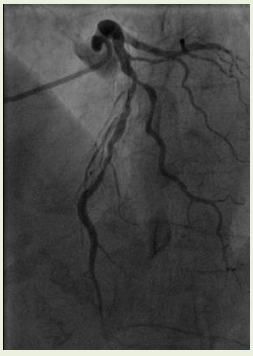
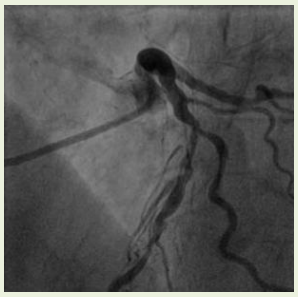
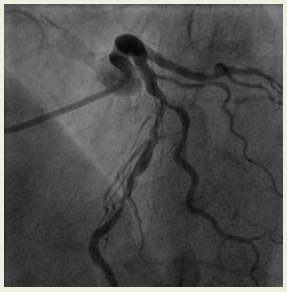
a)  b)  c) 

Figure a) shows the accumulated contrast flushing to the aorta, b) 1 frame earlier from frame a) and c) depicts the ED frame.

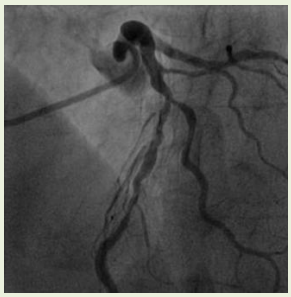
Another method to verify the end diastolic frame for left tree is when the vessel is in the most upper position of the image:



2 frames before ED

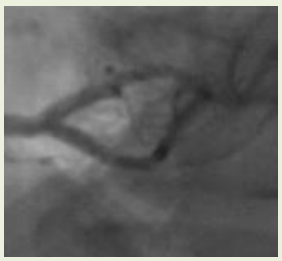


1 frame before ED

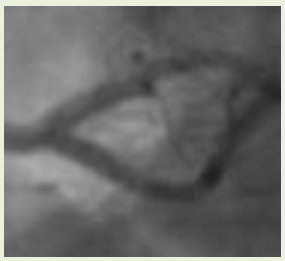


ED frame

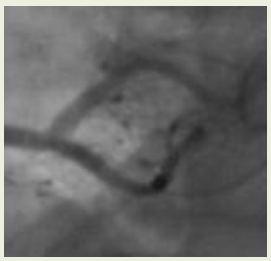
- For right coronary analysis, another way to find the ED frame is to look at moment where the angle formed by the posterior descending and posterolateral arteries widens.



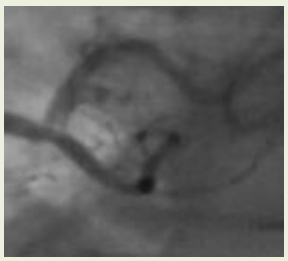
2 frames before ED



1 frame before ED



ED frame



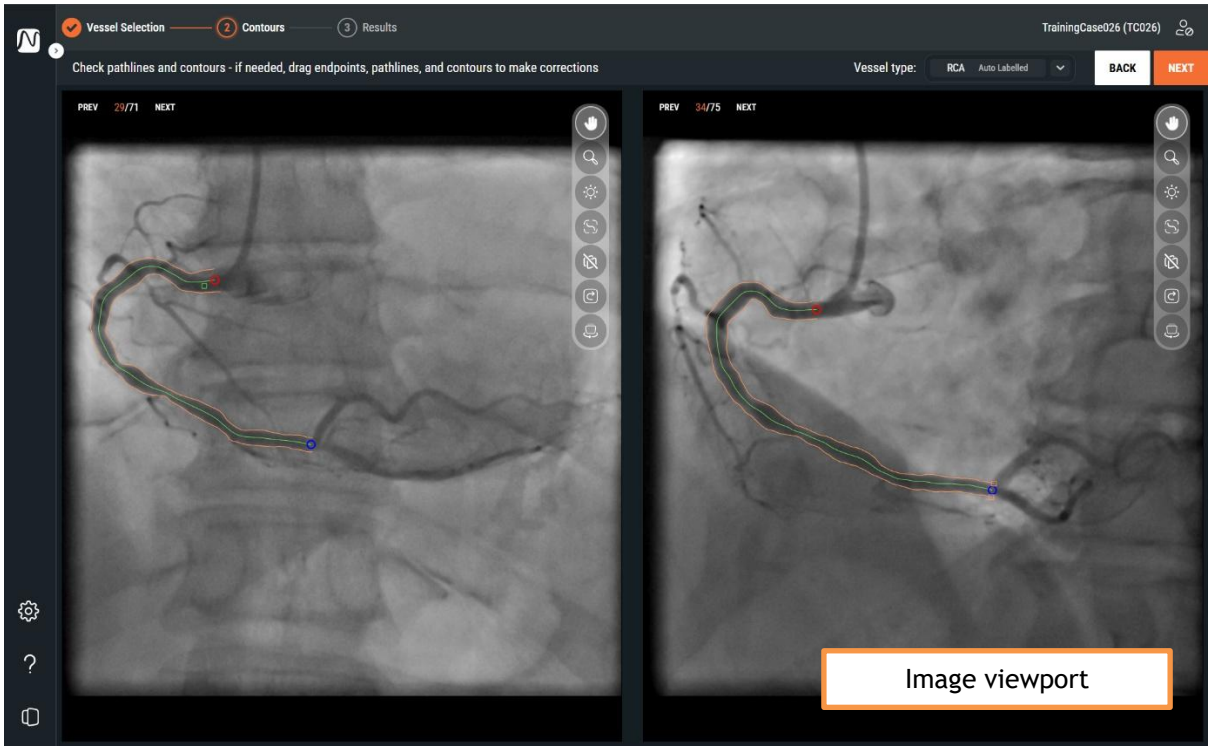
1 frame after ED

10.2 Contours

On entering the Contours step, QFR will automatically detect the start and end points of the target vessel, detect the pathline, and detect the contours. Verify the start and end points, and make corrections if needed by dragging the points to the proper location. Verify the pathline and make corrections if needed by dragging the pathline to the proper location. Verify the contours and make corrections if needed by dragging the contours to the proper location. Click Next to proceed to the next step in the analysis.

In the Contours step of the QFR analysis, you need to verify that QFR detected the correct start and end points of the target vessel, a pathline between them, and the contours of the vessel. If needed, you can make corrections manually.

In the Contours step, the screen only shows the two image viewports.



When you enter the Contours step, QFR will automatically detect the start and end points of the target vessel that is visible and analyzable in the XA series. Afterwards, it will detect the pathline from start to end point, and the contours of the target vessel. The contours from both views will be used as input for the 3D vessel reconstruction.

If the start or end point, pathlines, contours, or vessel type are not automatically detected properly, you can edit them manually.

To edit start or end points:

- Click and drag the start (red) and end (blue) points to the proper location.

  The pathlines and the contours are redetected automatically.

If editing of the start- or end points is required, apply the corrections to the points before making corrections to the pathline or the contours.

When the start- and end points have been placed correctly, click **Zoom to Contours** (shortcut key Ctrl+Shift+Z) to get an optimal view on the pathline and contours.

If QFR detects a possible mismatch in the start- or end point location in both views, a warning message will be displayed. Make sure that the start- and end points are placed on the same anatomical landmark in both views.

To edit a pathline:

In some cases with vessel overlap, it is possible that an incorrect pathline is detected. In this case you can add one or more support points to guide the pathline through the segment of interest.

- Click a point on the pathline and drag it to the correct position.

  This creates a support point and redetects the pathline and the contours.
- If needed, add more support points or drag existing support points to better locations.

If editing of the pathline is required, correct the pathline before making corrections to the contours.

To delete a pathline support point:

- Right-click on the support point to delete it.

  The pathlines between the proximal and distal points and the contours are redetected automatically.

To edit a contour:

In some cases with vessel overlap, it is possible that contours are not detected correctly along the entire length of the target vessel. In this case you can add one or more support points to the contours.

- 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.

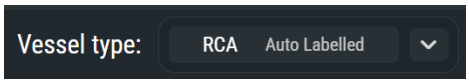
To delete a contour support point:

- Right-click on the contour support point.

  The point is deleted, and the corresponding contour is redetected.

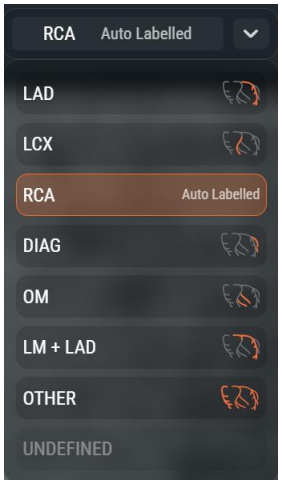
Use the **Hide Overlay** button  (press middle mouse button) to hide all graphics and have a clear view at the image data. This will help you to verify the correct placement of the contours.

The vessel type that is recognized by QFR is visible in the header of the QFR analysis window.

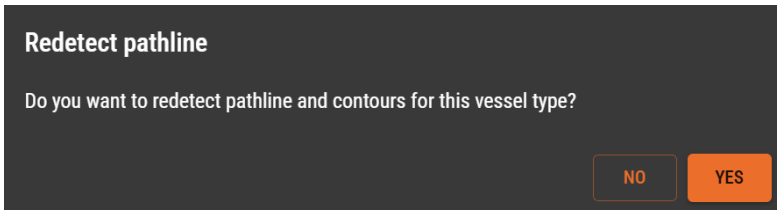


To correct the vessel type:

- Select the correct vessel type from the “Vessel type” dropdown:



- If you correct the vessel type to LAD, LCX, or RCA, QFR will provide an option to automatically re-detect the pathline and contours for this vessel type:



If corrections are needed in the Contour step, apply them in the following order to minimize the number of user interactions:

- Change the start- and end points;
- Change the pathline;
- Change the contours;
- Change the vessel type.

When you are confident that the start and end point, the pathline, and the contours of the target vessel have been placed correctly, and that the vessel type is set correctly, click 

to proceed to the next workflow step of the QFR analysis.

Points of attention

- Proximal and distal points must be placed in the same anatomical points in both views.
- The proximal point should be placed at the ostium of the target vessel.
- Avoid setting the proximal point on top of the catheter tip.
- The distal point must be placed distally in the vessel, where you normally will allocate a pressure wire.
- Verify that all the disease portions of the vessel are included in the vessel segment.
- Be sure to include all lesions and enough healthy areas in the vessel of analysis.

After checking the start and end points it is important to check the automatically generated contours as well. Therefore, pay attention to:

- Contours at the beginning and end of the pathline: the contour can be bent inwards creating a false lesion.
- Side branches.
- Overlapping vessels: this situation might cause diameter size overestimation.
- Low contrast acquisition also causes inwards bending.

Pitfalls and particularly difficult lesions

Left main artery (LM)

The LM and RCA ostia are difficult to assess due to the guiding catheter intrusion, or the back flow of contrast agent into the aorta overlapping the ostium. Currently, the presence of an ostial LM or RCA stenosis excludes the use of QFR (see also Regulatory section on page 4).

Left main artery (LM) + Left anterior descendent artery (LAD)

If there are stenoses in both the LM and LAD, it is very important to place the proximal point proximal to the stenosis in the LM.

Left circumflex artery (LCX)

The LCX ostium might be difficult to assess due to the requirement of two optimal projections. In many cases only one optimal projection can be acquired.

Left main artery (LM) + the ostium of the circumflex artery (CX)

This combination cannot be analyzed in one time, due to differences in physiological flow patterns in these vessel types. For the left main analysis you need to indicate the vessel type in the software LM/LAD and for circumflex analysis you need to select LCX.

In this case it is advised to first perform an analysis of the LM in the direction of the LAD and determine if the lesion in the LM is significant or not. The lesion in the CX needs to be analyzed in a separate analysis as well. But, as stated earlier, a lesion in the ostium of the CX is very difficult to visualize in two views with more than 25° difference in angiographic view.

10.3 Results

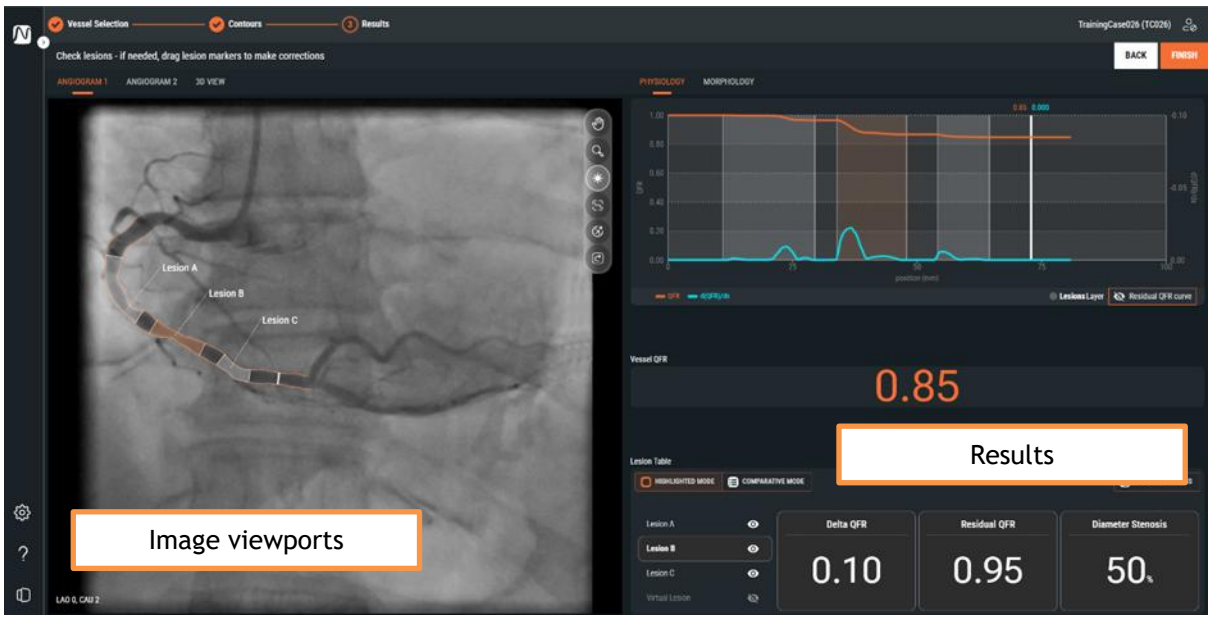
On entering the Results step, QFR will automatically detect the lesions in the target vessel and calculate the QFR result. In the Physiology tab, you can verify the Delta QFR, Residual QFR, and Diameter Stenosis % values. In the Morphology tab, you can verify the Minimal Lumen Diameter, the Reference Diameter and the Lesion Length. Verify the detected lesions and make corrections to the lesion markers if needed by dragging them to the proper location. Click Finish to complete the QFR analysis.

In the Results step of the QFR analysis, the Physiology and Morphology results will be calculated and presented on the screen. The screen shows the image viewports on tabs on the left:

- Angiogram 1
- Angiogram 2
- 3D View

and the results on tabs on the right:

- Physiology
- Morphology



10.3.1 Image Viewports

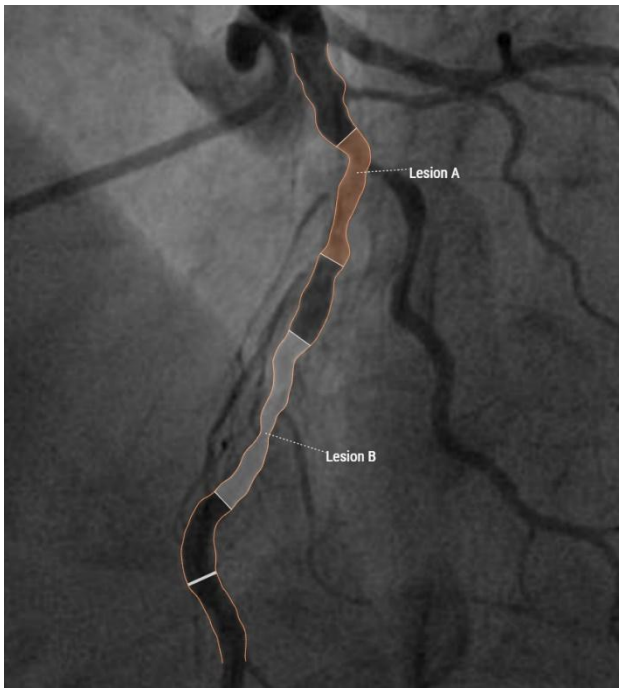
There are two image viewports that show the angiograms, and one viewport that shows the 3D vessel reconstruction.

To switch between the different image viewports:

- Click on the tab labels “Angiogram 1”, “Angiogram 2”, or “3D View”

The **angiogram image viewports** show the angiogram with the target vessel contours. All detected lesions are displayed, and each lesion is labeled with its lesion identifier. The most significant lesion (having the highest Delta QFR value) is automatically selected and highlighted. You can activate and verify the detailed parameters for each lesion.

Automatic lesion selection and orange highlighting are provided for visualization purposes only and must not be interpreted as a recommendation for treatment or clinical decision-making.



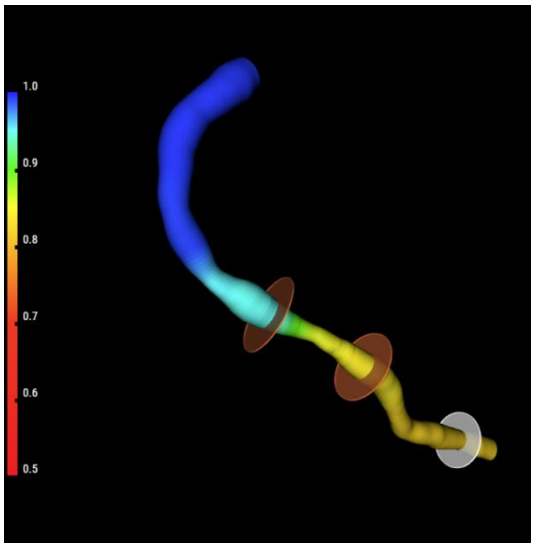
To activate the detailed lesion results in the angiogram image viewport:

- Hover your mouse on the lesion label.

  This will show a text box with the detailed lesion results. By default, this includes Delta QFR, Residual QFR, Diameter Stenosis %, Area Stenosis %, Minimal Lumen Diameter, Reference Diameter, and the Lesion Length.

In the QFR Settings you can configure which lesion results are presented in the text box.

The **3D View viewport** shows the 3D reconstruction of the target vessel. The 3D reconstruction is color coded based on the QFR values. In this view, only the lesion markers of the active lesion are visible, as well as the index marker.



10.3.2 Results

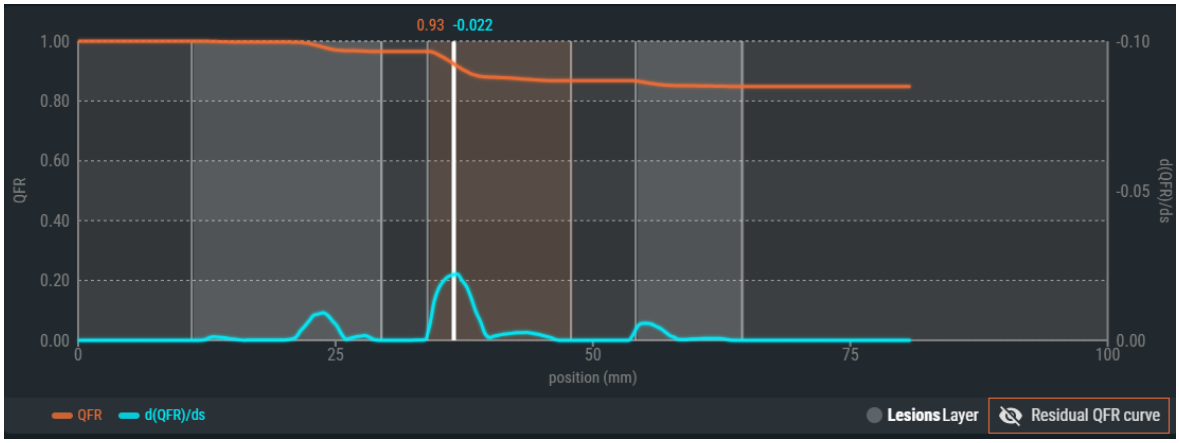
The results are presented in two tabs that are focused on the physiology results and morphology results.

To switch between the different results:

- Click on the tab labels “Physiology” or “Morphology”

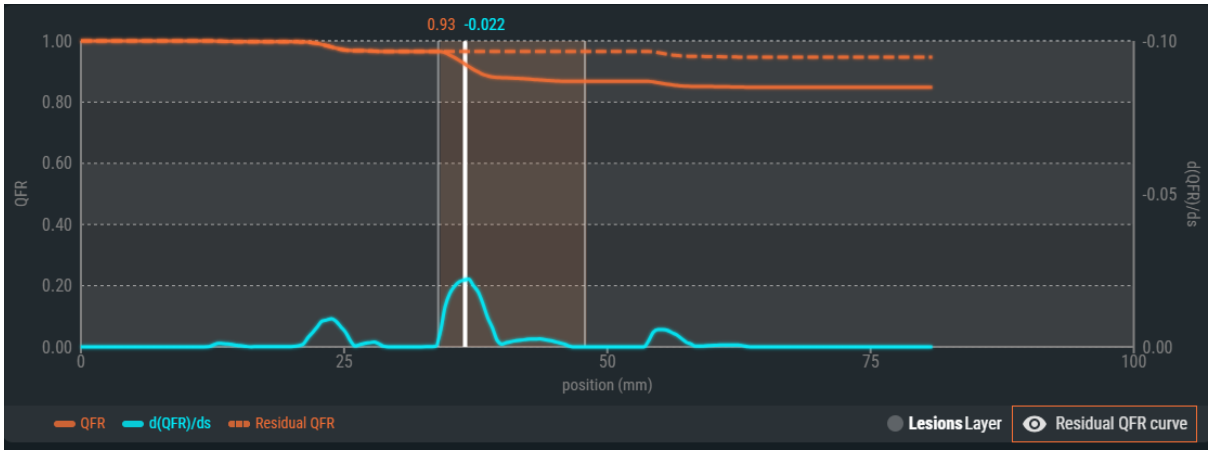
10.3.2.1 Physiology tab

In the **Physiology** tab, the QFR diagram is shown, with the curves for the QFR value and the d(QFR)/ds value across the length of the target vessel:

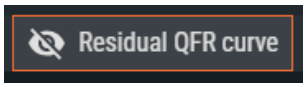


The QFR values are plotted on the left-hand y-axis. The d(QFR)/ds values are plotted on the right-hand y-axis.

The **Residual QFR** curve will show the expected QFR curve after the diameters of the active lesions have been restored to the reference diameters (by stent placement).



To show or hide the Residual QFR curve:

- Click on 

or 

to toggle the visibility of the Residual QFR curve in the QFR diagram.

The QFR diagram also shows the 'index marker' in white. The QFR and d(QFR)/ds values at the index marker are displayed at the top of the marker. You can select and drag the marker across the entire length of the target vessel.

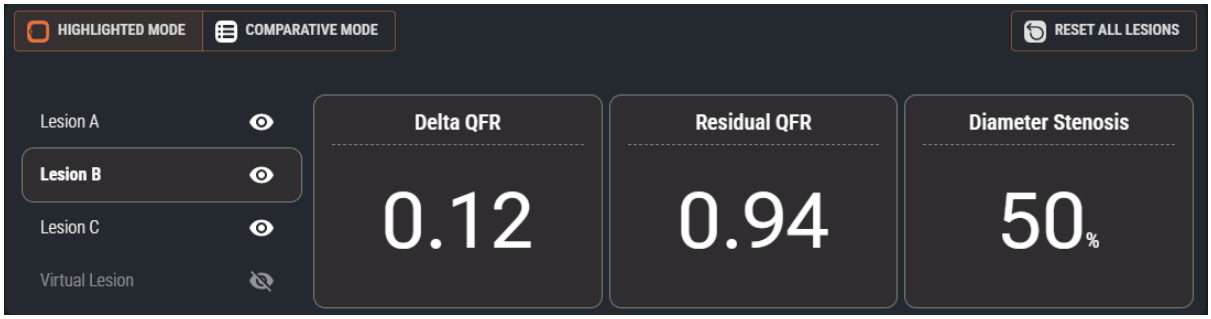
To change the location of the index marker:

- Click on the white index marker in the QFR diagram.
- Drag the marker to the desired location.

The index marker is also visible in the Diameter diagram, the angiographic views, and the 3D view. They will all be updated when you change the position of the index marker.

Below the QFR diagram, the vessel QFR result is displayed. The vessel QFR is the simulated relative residual pressure at the end of the target vessel (see also Chapter 14).

At the bottom of the page, the lesion table with the physiological parameters is displayed.



The following lesion results are displayed (see also Chapter 14):

- The **Delta QFR:** The relative change in pressure between the lesion proximal and distal marker.
- The **Residual QFR:** A predictive value of the Vessel QFR after treatment (revascularization) of the lesion.
- The **Diameter Stenosis %.** The ratio between the diameter reduction and the reference diameter.

In the QFR Settings you can configure which lesion results are presented in the lesion table.

Residual QFR is provided as a theoretical reference only and does not represent a prediction on the results of post-PCI functional outcome or physiological measurement. Real-world comparison to post-PCI QFR results may vary based on standards of care, disease type, and corresponding procedural details. Therefore, this value should not be used to make treatment decisions without supporting clinical evidence.

10.3.2.2 Morphology tab

In the **Morphology** tab the Diameter diagram is shown, with the curves for the minimal, maximal, and reference diameters.

The Diameter diagram also shows the ‘index marker’ in white. The minimal diameter and reference diameter values at the index marker are displayed at the top of the marker. You can click and drag the marker across the entire length of the target vessel.

To change the location of the index marker:

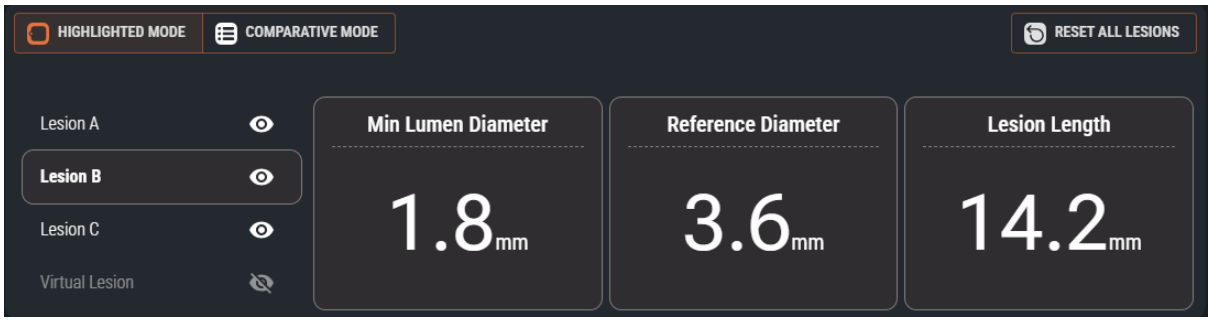
- Click on the white index marker in the Diameter diagram.
- Drag the marker to the desired location.

The index marker is also visible in the QFR diagram, the angiographic views, and the 3D view. They will all be updated when you change the position of the index marker.

If the reference diameters are outside the normal range (either very large or very small) a warning message will be displayed in the angiographic views. Make sure that the reference diameters are correct and suitable for this patient.

Below the Diameter diagram, the vessel QFR result is displayed.

And at the bottom of the page, the lesion table with the morphological parameters is displayed.



The following lesion results are displayed (see also Chapter 14):

- **Minimal lumen diameter**: The smallest lumen diameter of the lesion in mm.
- **Reference diameter**: The expected lumen diameter of a healthy vessel at the location of the minimal lumen diameter.

- **Lesion length**: The length of the lesion in mm, measured from the proximal lesion marker to the distal lesion marker, in the 3D vessel reconstruction.

In the QFR Settings you can configure which lesion results are presented in the lesion table.

10.3.3 Lesion Results

In both the Physiology and Morphology tabs, the lesion results can be verified in 'highlighted' and 'comparative' mode.

The default view mode for the lesion results can be configured in the Settings.

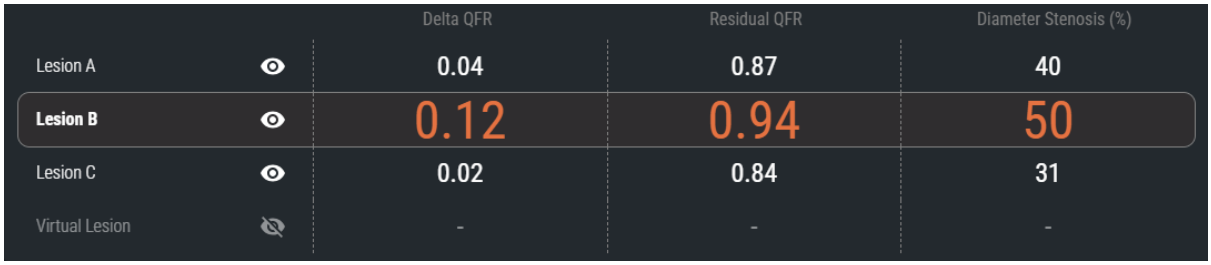
To switch the lesion results tables between the different modes:

- Click on the buttons to switch to 

or

In the highlighted mode, you can only see the results of the selected lesion.

In the comparative mode, you can see the results of all lesions in one overview, to make it possible for you to compare the values against each other. The values of the selected lesion have a different font color and font size.



10.3.4 Editing Lesions

The lesions that have been detected by QFR can be adjusted by dragging their proximal or distal markers. You can also disable a lesion, to hide it from the overlays, diagrams and report.

To adjust the lesion markers:

- Click and drag the proximal and/or distal markers to the required positions.

  The markers can be dragged in the angiogram viewports, in the QFR diagram, or in the Diameter diagram. The lesion results will be updated automatically.

When a lesion is enabled, it shows the visible icon  in the lesion results table. The enabled lesion is visible on the angiogram, the diagrams, and in the report.

When the lesion is disabled, it shows the hidden icon  in the lesion results table. The disabled lesion is not visible on the angiograms, the diagrams, or in the report.

To enable or disable a lesion:

- In the lesion results table, click on the visibility icon next to the lesion label.

  Lesion **enabled**: 

  Lesion **disabled**: 

10.3.5 Complete QFR Analysis

When you are confident that the lesions have been placed correctly, click 

to complete the QFR analysis.

Completing the analysis will automatically save the QFR analysis and report, and will automatically archive the QFR analysis and report on your PACS (if configured).

If you do not want to archive the QFR analysis, do not 

the QFR analysis, but close the study instead  .

Make sure to **Finish** the QFR analysis to save and export the QFR analysis and report. If you do not Finish the analysis and leave the QFR system inactive, by default your analysis will be cancelled automatically after 1 hour to free resources and the QFR license.

Points of attention

Please check that the reference diameter (red line in the diameter diagram) satisfies the following requirements:

- The reference diameter should always taper downward in the distal direction, or it should be horizontal.
- The reference diameter should follow the diameters of the healthy/normal areas.
- The reference diameter should not follow the diameters of the obstructed or aneurysmatic areas.
- The obtained reference diameter values should be realistic according to gender of the patient.

A proper reference diameter is crucial for a proper QFR calculation. The reference diameter determines the severity of the lesions along the target vessel, and the severities determine the final QFR results.

Most of the time having inaccurate contours will cause wrong reference diameters. If this occurs, go back to the Contour step and verify that the contours are defined correctly, modify them if needed. Alternatively, use another acquisition with better contour definition and less vessel overlap.

Not checking the reference diameter and correcting the contours (when necessary) can lead to wrong QFR results.

11 Review

The Review screen of the QFR analysis will show when a QFR analysis is closed, and when you reload a QFR analysis from the Studies page.

From this screen you can review the QFR analysis, including the contours, the lesions, and all physiological and morphological results. You cannot make any changes to the QFR analysis in this screen.

From the Review screen, you can also trigger the following actions:

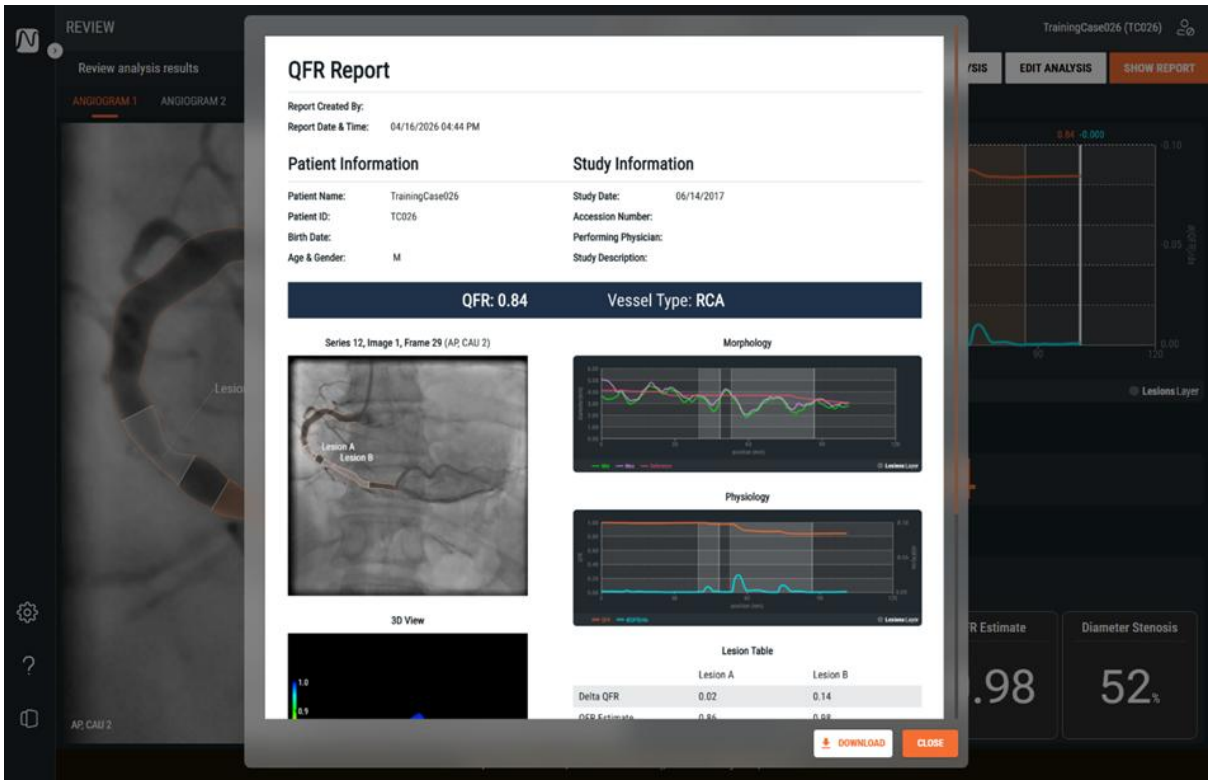
- Show the QFR report
- Edit the QFR analysis
- Start another (new) QFR analysis on the same study
- Reload another (existing) QFR analysis from the same study

The screen layout in the Review screen is exactly the same as the screen layout of the Results screen of the QFR analysis. See Chapter 10.3 and Chapter 14 for a detailed description of the available viewports and results.

In the Review screen, you cannot enable or disable the individual lesions, and not change the proximal and distal lesion markers.

11.1 Show Report

The QFR report will provide you with a one-page overview of the patient details, study details, and QFR results, including screenshots of the angiograms, the QFR diagram, and the diameter diagram. The QFR report can be downloaded in PDF format.



To show the QFR report:

- Click SHOW REPORT to show the Report screen.

To download the QFR report in PDF format:

- From the Report screen, click the Download button DOWNLOAD

11.2 Edit Analysis

To make changes to the QFR analysis, for example to make a correction to the detected contours or lesions, you can edit the QFR analysis.

To edit the QFR analysis:

- Click EDIT ANALYSIS to reactivate the QFR analysis guided workflow. You will enter the Results step (the last step of the workflow).
- If needed, click BACK to step back to earlier steps of the QFR analysis guided workflow.
- Make all required changes to the QFR analysis, as described in sections 10.1, 10.2 and 10.3.
- Click NEXT and/or FINISH to close the QFR analysis and save the modified QFR analysis.

When you edit a QFR analysis and finish it, it will always be saved as a 'new' analysis and not overwrite the 'old' analysis.

11.3 Start New Analysis

You can always start a new QFR analysis from the QFR Studies page, but this can also be started from the Review screen.

To start a new QFR analysis:

- Click + START NEW ANALYSIS
- QFR will load all XA series of the active study, and start a new QFR analysis, starting at the Vessel Selection screen.
- Make all required changes to the QFR analysis, as described in sections 10.1, 10.2 and 10.3.
- Click NEXT and FINISH to close the QFR analysis and save the new QFR analysis.

11.4 Reload Existing Analysis

You can always reload an existing QFR analysis from the QFR Studies page, but this can also be done from the Review screen.

To reload an existing QFR analysis:

- Open the QFR analysis dropdown list that is displayed in the center at the top of the screen. The available QFR analysis for the current study will be displayed, sorted by analysis date, the most recent analysis at the top. The text labels indicate the vessel type, the QFR value, and the analysis date and time. Hover your mouse on the text label to see the analyst's name. The QFR analysis that is currently active is highlighted.

- Select the QFR analysis you want to reload.

12 Close Study

When you have completed all QFR analyses, or want to cancel an open QFR analysis, you can return to the Studies page by closing the active study.

To close the active study:

- Click **Close Study** 

 Closing the study will cancel the open QFR analysis.

13 Sign Out

To end your active QFR session, you can sign out (log off). The state of the QFR analysis will be saved on the server, and will be restored when you log on again, from any computer.

To sign out from QFR:

- Click on the **User Profile** button 
- Click on the **Sign Out** button 

Signing out will not cancel an open QFR analysis, you can continue the QFR analysis when you log on to QFR later.

Do not leave QFR accessible for unauthorized users. When you leave your workstation, make sure that you sign out from QFR and lock the computer system.

14 Description of QFR Results

Delta QFR: The pressure drop over a lesion; the change in pressure between the proximal and distal marker.

Residual QFR: An estimate of the vessel QFR after treatment (revascularization) of a lesion. Residual QFR is provided as a theoretical reference only and does not represent a prediction on the results of post-PCI functional outcome or physiological measurement. Real-world comparison to post-PCI QFR results may vary based on standards of care, disease type, and corresponding procedural details. Therefore, this value should not be used to make treatment decisions without supporting clinical evidence.

Vessel QFR: The flow ratio value for the full length of QFR analysis; the QFR value from the start to the end of the defined target vessel.

Lesion length: The length of the lesion in mm, measured from the proximal lesion marker to the distal lesion marker, in the 3D vessel reconstruction.

Minimal Lumen Diameter: The smallest lumen diameter of the lesion in mm.

Reference diameter: The expected lumen diameter of a healthy vessel at the location of the minimal lumen diameter.

Diameter Stenosis %: The ratio between the diameter reduction and the reference diameter. For example, for a lesion with minimal lumen diameter of 1.0 mm and a reference diameter of 3.0 mm, the diameter reduction is 2.0 mm. The diameter stenosis % is 2.0 / 3.0 = 67%.

Area Stenosis %: The ratio between the area reduction and the reference area. For example, for a lesion with minimal lumen area of 1.0 mm^2 and a reference area of 7.0 mm^2, the area reduction is 6.0 mm^2. The area stenosis % is 6.0 / 7.0 = 86%.