

QFR[®] 2.1

No invasive pressure wire, no adenosine A proven coronary physiology for better clinical decisions

QFR (Quantitative Flow Ratio, the functional angiography solution of Medis) is based upon the accurate 3D QCA reconstruction and subsequent frame counting for the calculation of the flow velocity of the contrast through the target vessel. This document contains the description of the functionalities of the application and the underlying Medis Suite platform.

PROVEN ACCURACY

- QFR[®] is proven to have good correlation and agreement with FFR, by 14.000+ patients and 17.000+ lesions in 150+ peer-reviewed articles

TIME & COST EFFICIENCY

- No pressure wire, no adenosine, reduces treatment costs and procedure time

USER FRIENDLY

- Simpler Intuitive workflow, applicable for online and offline usage



**AI DEEP LEARNING
IN MEDIS QFR[®]**

Product Specification Sheet

QFR (POWERED BY QANGIO XA 3D)

QFR is a proven non-invasive coronary physiology measurement that supports better clinical decisions. Using Artificial Intelligence (AI) in QFR 2.1, QFR has become even simpler and faster.

Proven Accuracy:

- QFR® is proven by 14.000+ patients and 17.000+ lesions. With 130+ peer-reviewed articles
- In the FAVOR II Eu/Jp study, a good correlation and agreement between QFR® and FFR was observed
- In the FAVOR III China study, QFR® is proven to reduce relative risk of MACE by 34% compared with the angio-guided method. (5.5% vs 8.8%)

Time & Cost Efficiency:

- Offers physiological assessment in <5 minutes
- No need for invasive medical device/drug

User Friendly:

- Only 2 angiograms input needed
- Compatible with data from various vendors
- Can be used pre-, during, post- PCI

QFR ANALYSIS WORKFLOW

Image Acquisition:

- Acquisition aid upon app start-up to guide the user in the acquisition of good views for the QFR analysis
- Acquisition guide suggesting optimal viewing angle for the second acquisition in online situations
- Efficient pre-selection of angiographic series, showing only series being 25 degrees apart
- Automated optimal viewing angles calculation

Image Analysis:

- Offset correction to match the same vessel point on the 2 angiograms
- Improved automatic contour detection, especially on low dose images
- Automated 3D reconstruction of the arterial contours and 3D lesion quantification
- Enhanced Automatic Frame Counting workflow to calculate the flow velocity
- Automated Lesion foreshortening calculation for the original 2D projections and the 3D views

3D QCA Analysis Results:

- Results of the 3 most severe lesions are automatically shown and additional user-defined regions of interest can be added
- Lumen and plaque statistics:
 - Severity of stenosis (diameter and area)
 - Minimum lumen diameter (MLD)
 - Proximal and distal minimum and maximum diameters (at P- and D-marker positions)
 - Display of 3D reference volume along the entire segment
 - Lesion length
 - Bending angle
 - Five optimal views with minimum lesion foreshortening

QFR Analysis Results:

- QFR “pull-back” curve along the coronary segment for visual identification of pressure drops
- QFR values along the entire analyzed vessel segment calculated from 3D QCA according to 3 different flow velocity models:
 - Fixed flow velocity: fixed flow QFR
 - Basal flow without hyperemia using contrast frame count: basal QFR
 - With a separate research license: Adenosine-induced maximum hyperemia using contrast frame count: hyperemic QFR
- Two different QFR indices along the analyzed coronary segment:
 - Vessel QFR: The QFR value at the distal location of the analyzed vessel segment
 - Δ (delta) QFR: The percentual pressure drop over the selected lesion alone

MEDIS SUITE PLATFORM (VIEWER, CONNECTIVITY, REPORTING)

Viewer:

- User login
- Role-based Access Control
- Support for coronary angiograms of all major X-ray vendors
- Review angiograms side by side, drag 'n drop angiograms into the viewer
- Fast browsing through all angiograms, simple caliper measurements, and annotations
- Different calibration options in the viewer (Isocenter, Catheter, Sphere/circle, Manual calibration, Line calibration)

Connectivity:

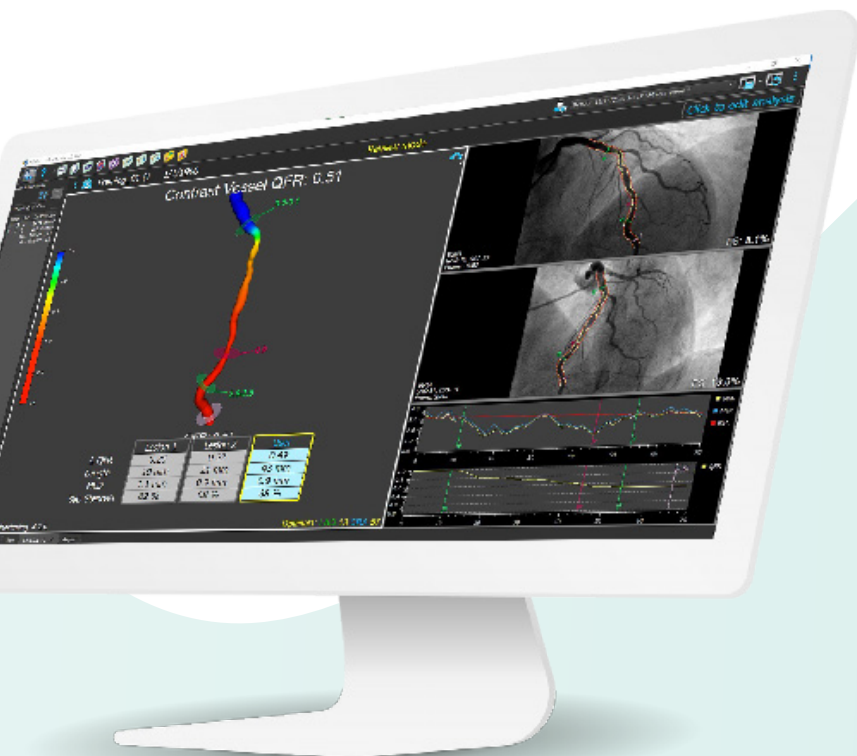
- DICOM connectivity, receiving cases, query and retrieve, pushing results to PACS
- Centralized and/or local data repositories
- Import of coronary angiograms from local storage media (hard disk, USB, and CD/DVD)
- Screen can be duplicated to the monitor in the cath lab

Reporting:

- Anonymization of studies
- Loading prior examinations in parallel

Data export:

- All analysis results including the 3D reconstruction data and the QFR data can be saved and reloaded again in the same application for reviewing, editing, and exporting
- Quantification results can be exported as a graphical report in PDF and DICOM PDF Secondary Capture format. Results can also be copied to the clipboard in textual format.
- Screenshots can be included in the report, exported to local storage media, or can be copied to the clipboard
- Improved lesion image export
- **NEW: Audit Trailing**





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Legal Statements

Medis Suite and QAngio XA have market clearance for USA, Canada, EU, Australia, Japan and South Korea.

QAngio XA 3D (incl. QFR) has market clearance for the USA, Canada, EU, Australia, Brazil, Malaysia, Singapore, Indonesia and South Korea. Market clearance in Japan is pending.

In China QFR is distributed by Pulse Medical Imaging Technology (Shanghai) Co., Ltd. as part of their AngioPlus system.

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