



#### 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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# QFR<sup>®</sup> 2.1

## Proven image-based coronary physiology for better clinical decisions

QFR<sup>®</sup> (Quantitative Flow Ratio, the functional angiography solution by Medis) is based upon the accurate 3D QCA reconstruction of the coronary anatomy and subsequent frame counting for the assessment of the flow velocity of the contrast medium through the target vessel. This document contains the description of the functionalities of the application and the underlying Medis Suite platform.

### PROVEN ACCURACY

- QFR<sup>®</sup> is proven to have excellent correlations and agreements with wire based FFR, represented by 15.000+ patients and 17.000+ lesions in 160+ scientific publications in high ranking journals

### TIME & COST EFFICIENCY

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

### USER FRIENDLY

- Simpler intuitive workflow, applicable for in-procedure and offline usage



**AI DEEP LEARNING  
IN MEDIS QFR<sup>®</sup>**

# 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:

- The accuracy of QFR® has been demonstrated in 160+ peer-reviewed articles, representing 15.000+ patients and 17.000+ lesions.
- In the FAVOR III China outcome study, QFR® proved to reduce relative risk of MACE after 2 years by 32% compared with the standard visual interpretation (8.5% vs 2.5%).

### Time & Cost Efficiency:

- Offers physiological assessment in <3 minutes
- No need to introduce invasive medical device/drug

### User Friendly:

- Only 2 angiograms at least 25° apart are needed
- Compatible with any OEM X-Ray vendor
- Can be used pre-, during- and post- PCI

## QFR ANALYSIS WORKFLOW

### Image Acquisition:

- Guidance of the user in the acquisition of proper views for the QFR analysis
- Acquisition guide suggesting optimal viewing angle for the second acquisition in in-procedure situations
- Efficient pre-selection of angiographic series, showing only series at least 25° apart
- Automated optimal viewing angles calculation

### Image Analysis:

- Offset correction to match the same vessel point on the 2 angiograms
- Auto selection of optimal ED frame for analysis
- Improved automatic contour detection, especially on low dose images
- Excellent pathline detection of vessel segment of interest
- Automated 3D reconstruction of the arterial contours and 3D lesion quantification
- Enhanced Automatic Frame Counting workflow to assess 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 2 different flow velocity models:
  - Fixed flow velocity: fixed flow QFR
  - Basal flow without hyperemia using contrast frame count: basal QFR
- Two different QFR indices along the analyzed coronary segment:
  - Vessel QFR: The QFR value at the distal location of the analyzed vessel segment
  - $\Delta$  (delta) QFR: The pressure drop over the selected lesion

## 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
- **NEW: Structured clinical report**

### 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
- Audit Trailing

