



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[®] 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 12.000+ patients and 15.000+ lesions in 110+ 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



Product Specification Sheet

MEDIS SUITE PLATFORM (VIEWER, CONNECTIVITY, REPORTING)

- **New:** User login
- **New:** Role Based Access Control
- Support for coronary angiograms of all major X-ray vendors
- Import of coronary angiograms from local storage media (hard disk, USB, and CD/DVD)
- DICOM connectivity, receiving cases, query and retrieve, pushing results to PACS
- Centralized and/or local data repositories
- Review angiograms side by side, drag 'n drop angiograms into the viewer, fast paging through all angiograms, simple calliper measurements and annotations
- Different calibration options in the viewer (isocenter, catheter, sphere/circle, manual calibration)
- **New:** line calibration
- Anonymization of studies
- Loading prior examinations in parallel
- Stored results can be reviewed and/or edited
- Enhanced clinical report, combining all measurements in a single report, snapshots, editable comment fields, save as PDF, to be viewed in graphic or text formats.
- Clinical XML or JSON output
- Audit trailing

QFR (POWERED BY QANGIO XA 3D)

- Automatic angiographic series loading into the application
- Automatic calibration, based on isocenter calibration data in the DICOM files
- Screen can be duplicated to the monitor in the cath.lab.
- Full-screen application during the analysis
- 2D and 3D viewing of arteries and lesions
- ECG display and synchronization with 2D angiographic views
- Automatic ED phase detection in available ECG
- Marker synchronization between 3D QCA and QFR "pull-back" graphs, and in the 2D and 3D angiographic views

QFR ANALYSIS WORKFLOW

- Full analysis workflow is visible during all analysis steps
- Acquisition aid is visible 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° apart
- Automated optimal viewing angles calculation
- Offset correction
- **NEW:** Improved automatic countour detection, especially on low dose images
- Automated 3D reconstruction of the arterial contours
- Automated 2D and 3D reconstruction of reference contours and surface
- Automated 3D lesion quantification
- Lesion foreshortening calculation for the original 2D projections and the current 3D view
- **NEW:** Automatic Frame Counting

3D QCA ANALYSIS RESULTS

- Results of the 3 most severe lesions are automatically shown. And additional user-defined region 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;
 - (Behind a separate research license: Adenosine-induced maximum hyperemia using contrast frame count: hyperemic QFR).
- Three 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.

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 or export function.
- 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.
- **NEW:** Improved lesion image export

