



Legal Statements

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

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

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8.25.220.22.1



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QFR[®] 2.2

The Medis QFR (Quantitative Flow Ratio) is the X-ray image-based solution for the assessment of the coronary physiology of selected coronary segments. It is based on 3D QCA from 2 angiographic views combined with the patient-specific flow velocity in that vessel. It can replace the invasive FFR-wire approach, at the same time providing multiple additional features, which are further described in this product sheet.

CLINICAL EVIDENCE

- The angio-based solution supported by the greatest number of peer-reviewed scientific publications

TIME & COST EFFICIENCY

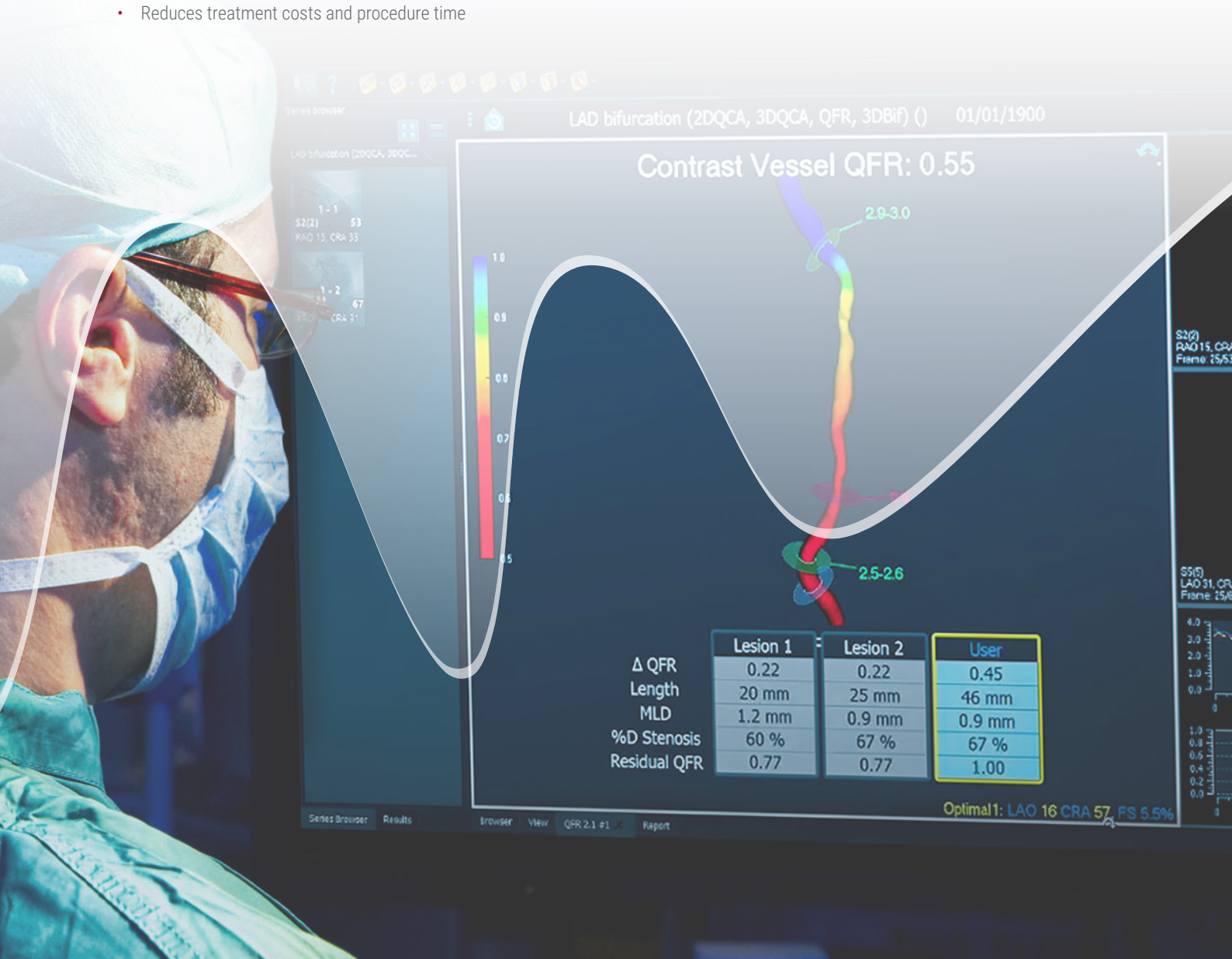
- No pressure wire, no adenosine
- Reduces treatment costs and procedure time

USER FRIENDLY

- Simple & intuitive workflow, applicable for in-procedure as well as offline usage

ECCENTRIC LESIONS

- Accurate even in the case of eccentric lesions



Product Specification Sheet

QFR (POWERED BY QANGIO XA 3D)

QFR is a proven non-invasive coronary physiology measurement that supports better clinical decisions. Extensive use of Artificial Intelligence (AI) in QFR 2.2 has made the tool even simpler and faster.

PROVEN CLINICAL EVIDENCE:

- The accuracy of QFR® has been demonstrated in 185+ peer-reviewed scientific publications
- 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 <1 minute
- No need to introduce invasive instrumentation/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:

- Clinical evidence has demonstrated that >60% of lesions are eccentric, requiring 2 views for accurate 3D QCA
- Guidance of the user in the acquisition of proper views for the QFR analysis
- 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
- Very fast automated selection of optimal ED frame for analysis
- Matching of 2 views now automated (offset correction)
- 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
- Highly improved 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 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 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
 - Δ (delta) QFR: The pressure drop over the selected lesion

NEW:

- **dQFR/ds objectively describes the positions of focal stenoses**
- **Residual QFR predicts the vessel QFR assuming optimal treatment of 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
- 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

