KEYA MEDICAL

DEEPVESSEL FFR

AI-Powered CT-Derived Fractional Flow Reserve for Functional Assessment of Coronary Artery Disease

Non-Invasive Functional Assessment Beyond Anatomy

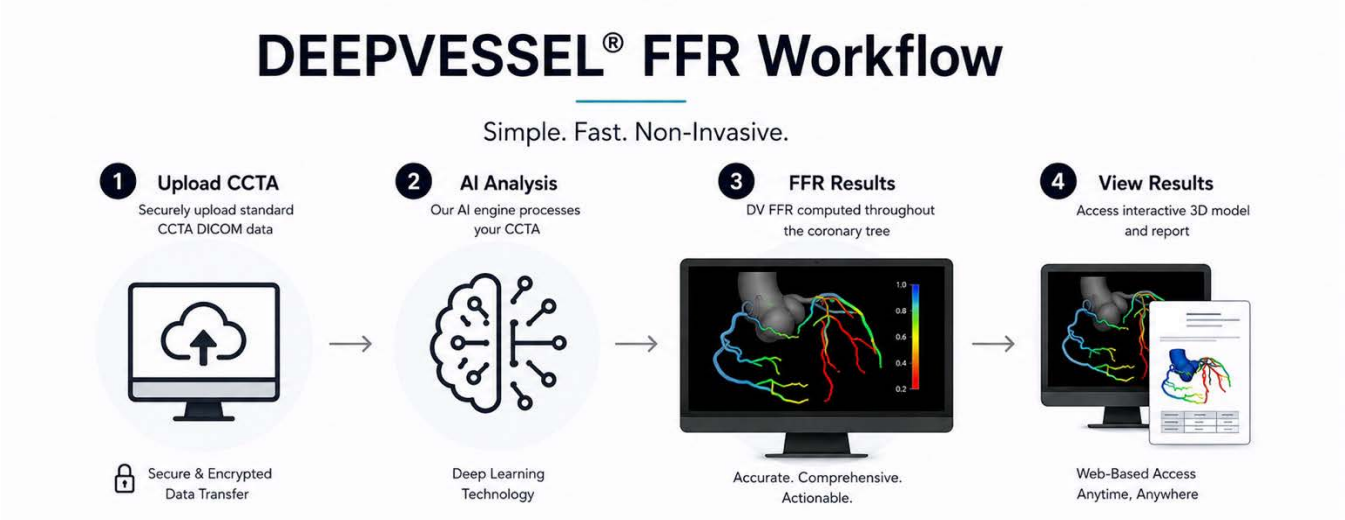
DEEPVESSEL® FFR (DVFFR) is an FDA-cleared, AI-powered software solution that derives fractional flow reserve from standard coronary CT angiography (CCTA) datasets. Using advanced deep learning technology, DEEPVESSEL FFR provides a non-invasive assessment of the physiological significance of coronary artery lesions, helping physicians identify which stenoses are most likely to cause ischemia.

By combining anatomical information from CCTA with functional assessment, DEEPVESSEL FFR supports more confident clinical decision-making and may reduce unnecessary invasive diagnostic procedures.

FDA Cleared	CE Marked	NMPA Approved	HSA Approved

WHY DEEPVESSEL FFR?

Accurate	Efficient	Accessible	Comprehensive	Cost Effective
Provides high diagnostic performance validated against invasive fractional flow reserve (FFR).	Rapid turnaround enables timely clinical decision-making and streamlined patient management.	Web-based platform accessible from standard workstations without additional on-site hardware requirements.	Calculates FFR values throughout the coronary tree, supporting vessel-level and lesion-specific functional assessment.	Provides a scalable CT-FFR solution designed to support broader access to coronary physiology assessment.



CLINICAL APPLICATIONS

DEEPVESSEL FFR may assist physicians in:

- Evaluating intermediate coronary stenoses identified on CCTA
- Assessing lesion-specific ischemia
- Supporting decisions regarding invasive coronary angiography
- Guiding revascularization planning
- Improving confidence in non-invasive CAD assessment

DEEPVESSEL FFR ANALYSIS REPORT

Comprehensive Functional Assessment

DEEPVESSEL FFR delivers a detailed PDF report featuring an interactive 3D coronary model, color-coded FFR mapping throughout the coronary tree, and branch-specific analysis of the LAD, LCX, and RCA. For each vessel, the software displays reconstructed vessel images and reports lesion-specific FFR values, including a recommended measurement point located approximately 2 cm distal to the stenosis.

DVFFR Summary

Report Number: –
Report Date: –

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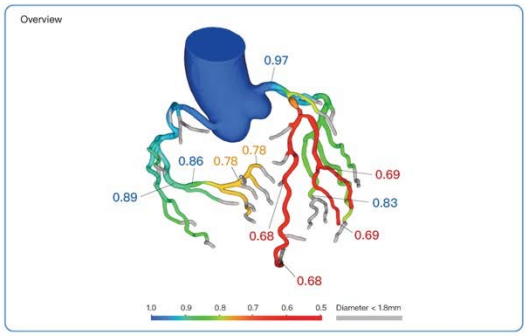
Patient Name –
Gender –
Age –
Patient ID –
CT Study Date –
Institution –

DVFFR Overview

Branch	Vessel	DVFFR *	Interpretation
	LAD	0.68	Supports hemodynamic significance
Left Coronary	D2	0.69	Supports hemodynamic significance
	LCX	0.83	No hemodynamic significance identified
Right Coronary	RCA	0.78	Borderline; correlate clinically

* Reported DVFFR: use the distal vessel value if there is no CAD-RADS 2+ stenosis; otherwise, use the value distal to the most distal CAD-RADS 2+ lesion.

Overview



DVFFR Summary

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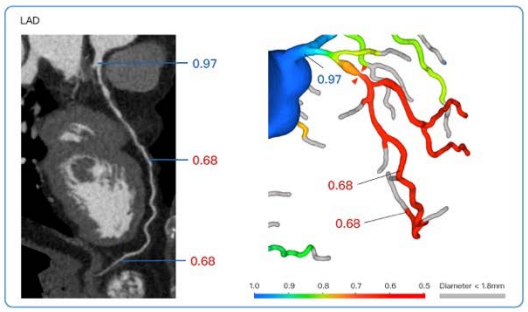
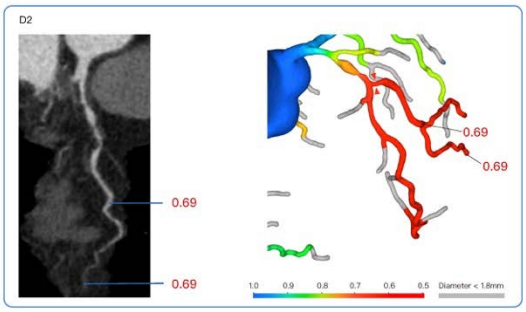
LAD



D2



DVFFR Summary

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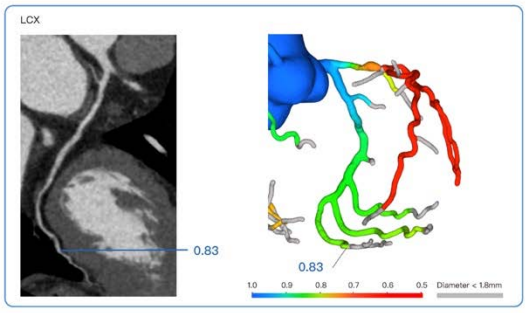
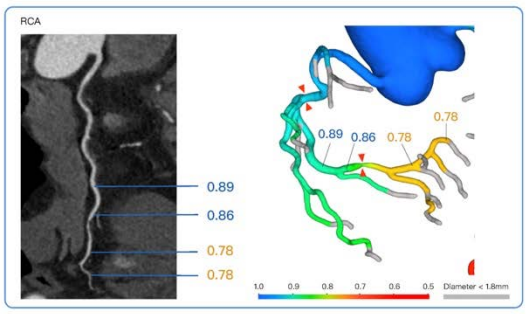
LCX



RCA



DVFFR Summary

Report Number: –
Report Date: –

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Warnings

⚠ 1. Degraded CCTA image quality may affect the accuracy of DVFFR analysis results. The SCCT guidelines for CCTA image acquisition are recommended . Image qualities are reviewed by trained image analysts before conducting DVFFR analysis, and the images with severe imaging artifacts, such as severe calcification, misalignment and poor contrast to noise ratio, are excluded from DVFFR analysis.

⚠ 2. The invasive measurement of fractional flow reserve (FFR) has been used as the clinical gold standard to determine the hemodynamic relevance of coronary artery stenoses. It has been shown that revascularization can be safely deferred if FFR is >0.80, while revascularization of stenoses with FFR values ⩽0.80 results in significantly lower event rates compared to medical treatment. However, invasive FFR procedure might not be applicable in certain scenarios, such as left main stenoses, aorto-ostial lesions as well as patients with left ventricular hypertrophy and severely-impaired ejection fraction. Therefore, clinical validation that support DVFFR (by comparing to the invasive FFR gold standard) may be limited to subjects excluding aforementioned specific diseased populations.

⚠ 3. The diagnosis performance of the DVFFR analysis is 93.9% sensitivity and 82.2% specificity*, based on the clinical validation study in which DVFFR has been evaluated and compared with the invasive FFR measurement.

⚠ 4. The DVFFR analysis has not been validated in patients with PCI history, coronary total occlusion and congenital coronary malformation at the time of coronary CT angiography imaging.

⚠ 5. This DVFFR report should be used in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the physician's professional judgment.

[1]Abbara S, et al. SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography: A report of the society of Cardiovascular Computed Tomography Guidelines Committee: Endorsed by the North American Society for Cardiovascular Imaging (NASCI), J Cardiovasc Comput Tomogr, 2016 Nov;10(6):435–449.
[2]Achenbach S, et al. Performing and Interpreting Fractional Flow Reserve Measurements in Clinical Practice: An Expert Consensus Document, Interv Cardiol. 2017 Sep;12(2):97–109.
*For conducting user study purposes, those numbers are estimated performances based on a preliminary study, and will be replaced by the reported performance numbers of the FDA-reviewed clinical validation study later.

CLINICALLY VALIDATED PERFORMANCE

ADAPT Multicenter Clinical Validation Study

DEEPVESSEL FFR was validated in the multicenter ADAPT study using invasive FFR as the reference standard.

Per-Vessel Performance

Metric	Performance
Sensitivity	**86.9%**
Specificity	**86.7%**
Accuracy	**86.8%**

Per-Patient Performance

Metric	Performance
Sensitivity	**87.4%**
Specificity	**83.7%**
Accuracy	**85.2%**

The ADAPT study successfully met all predefined performance endpoints, demonstrating robust diagnostic performance across a diverse patient population.

EVIDENCE SUPPORTING CLINICAL UTILITY

Improved Patient Selection

Functional assessment with CT-derived FFR provides information beyond stenosis severity alone, helping physicians identify lesions most likely to benefit from further intervention.

Reduced Unnecessary Invasive Procedures

Clinical studies evaluating CT-FFR have demonstrated the potential to improve patient selection for invasive coronary angiography while maintaining clinical outcomes.

Integrated Anatomical and Functional Assessment

DEEPVESSEL FFR complements CCTA by providing both anatomical and physiological information from a single non-invasive examination.

Supported by Clinical Guidelines and Expert Consensus

Coronary CTA combined with CT-derived FFR is recognized as an important non-invasive pathway for the evaluation of patients with suspected coronary artery disease.

DEEPVESSEL FFR is included among commercially available CT-derived FFR technologies referenced within contemporary cardiovascular imaging literature and expert consensus documents.

GLOBAL ADOPTION

DEEPVESSEL FFR is used by hospitals, imaging centers, and cardiovascular specialists across North America, South America, Europe, Asia, and the Middle East.

- Request Information
- Schedule a Product Demonstration

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