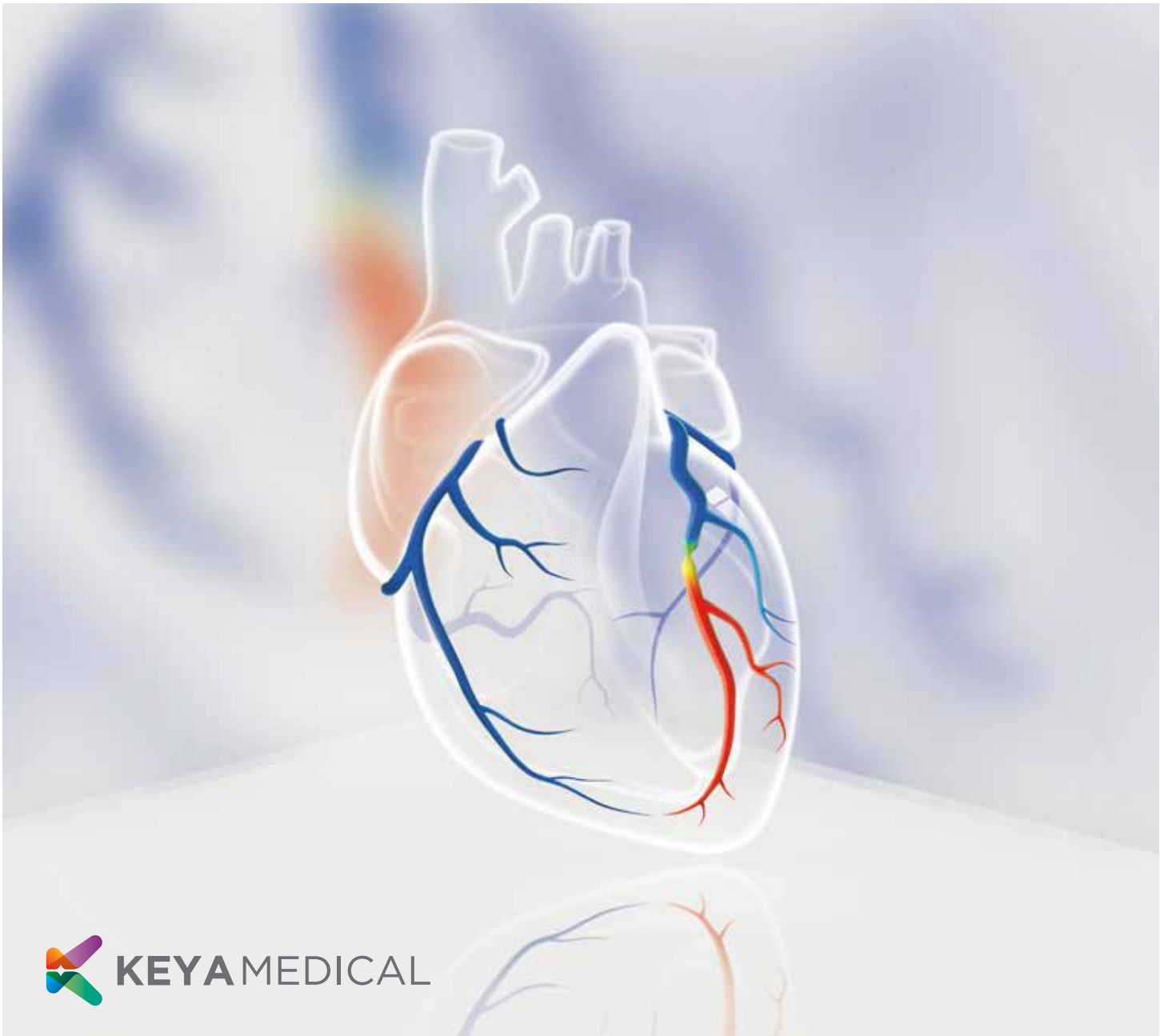
DEEPVESSEL®

Unlocking the **non-invasive** FFR era

DeepVessel® FFR

Non-Invasive Coronary Artery Functional Assessment



KEYA MEDICAL

Non-invasive FFR CT Technique with AI

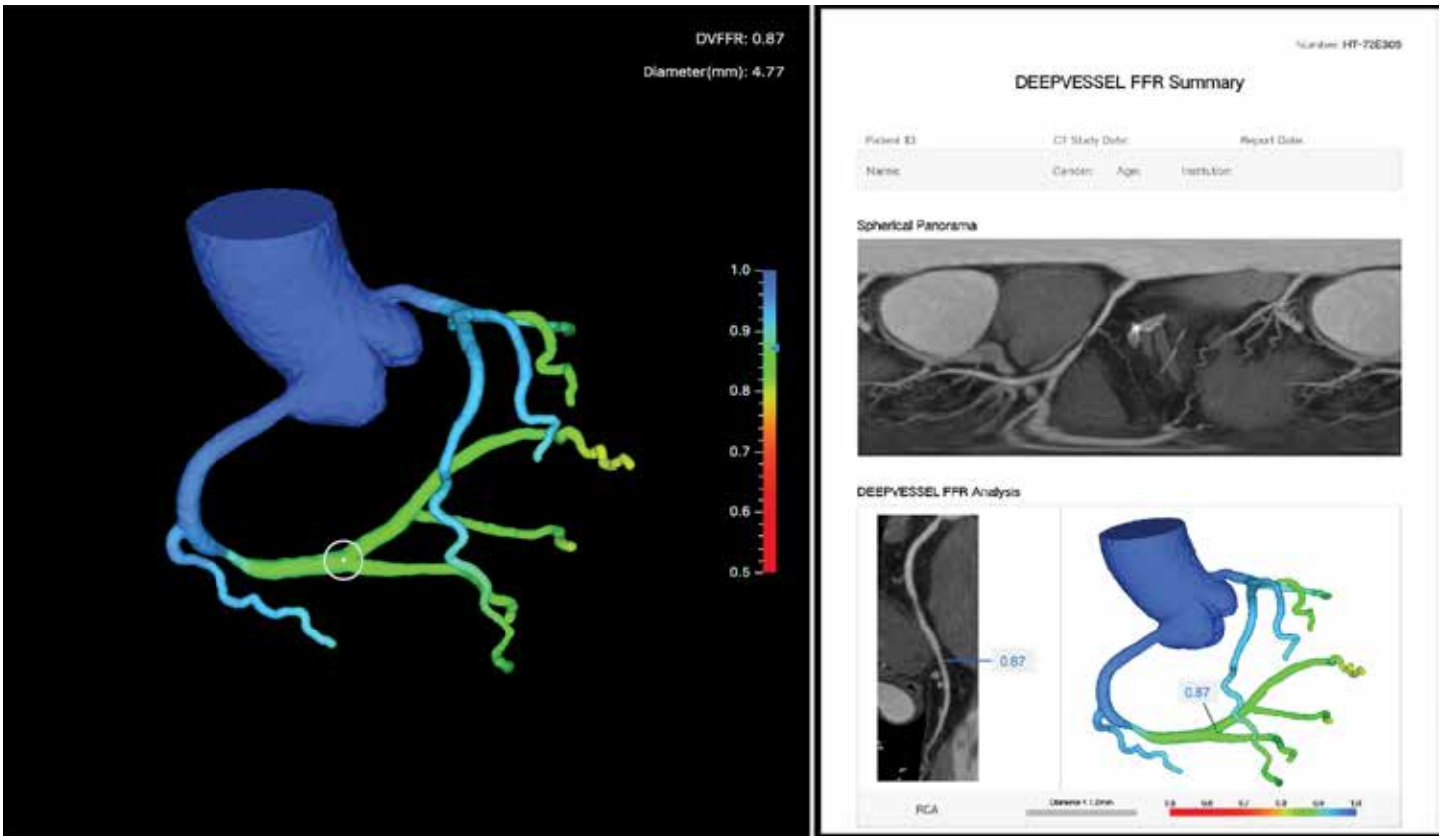
Coronary artery disease (CAD) is the most common type of heart disease, and it is the leading cause of death worldwide in both men and women. CAD happens when the coronary arteries become hardened and narrowed, which is due to the buildup of cholesterol-containing deposits (plaque) on the inner vessel wall. As the plaque grows, less blood can flow through the arteries due to the vessel narrowing. Decreased blood flow can lead to chest pain (angina), shortness of breath or even a heart attack.

Fractional flow reserve (FFR), which measures the blood flow reduction caused by vessel narrowing, is accepted as the reference standard for assessing the functional significance of the stenotic lesions. However, FFR is measured invasively through a guidewire-based cardiac catheter procedure. Current guidelines recommend assessing myocardial ischemia of stable patients with CAD through non-invasive functional testing before considering invasive coronary angiography (ICA) or conducting myocardial revascularization[1,2].

DEEPVESSEL FFR (DVFFR)

DEEPVESSEL FFR is a software medical device that uses deep learning technology to perform a non-invasive physiological functional assessment of the coronary arteries using CCTA. The software processes CCTA images semi-automatically, of the derived information is sent electronically to physicians. DEEPVESSEL FFR is intended to support the functional evaluation of CAD. DEEPVESSEL FFR applies Keya Medical's proprietary deep learning technologies built on the latest advances in computer vision and medical image analysis.

The 2021 ACC and AHA Guidelines for the Evaluation and Diagnosis of Chest Pain highlight use of Coronary CTA + FFR CT as a front-line pathway [3].



1 Montalescot G, Sechtem U, Achenbach S, et al. 2013 ESC guidelines on the management of stable coronary artery disease: the Task Force on the management of stable coronary artery disease of the European Society of Cardiology. Eur Heart J 2013;34:2949–3003.
2 Neumann, F, Sousa-Uva, M, Ahlsson, A, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J 2018;40:87-165.
3 Gulati, et al. 2021 AHA/ACC/ASE/CHES/SAEM/SCCT/SCMR Guideline for the Evaluation & Diagnosis of Chest Pain. Circulation.

Novel FFR CT product driven by deep learning technologies

- Non-invasive functional assessment from coronary computed tomography angiography (CTA) scans
- Enables accurate and fast FFR CT analysis
- Provides both anatomical and functional information to improve clinical decision-making and reduce medical cost
- The first AI-based medical product that has been approved by NMPA (Class III device)
- Available in the USA, Europe, and China

DEEPVESSEL FFR Diagnostic Performance

On-going multi-national multi-center retrospective clinical trial ADAPT [1], 2021

- DVFFR analysis was conducted on a total of 269 patients with 358 target vessels from 10 clinical sites (5 from the US and 5 from the EU).
- The primary endpoint was per-vessel sensitivity and specificity of DVFFR to detect ischemic condition compared with invasive FFR measurement
- The study demonstrated that DVFFR yielded good diagnostic performance and met pre-specified criteria for study success.

PER-VESSEL	Estimate, %	2-Sided 95% CI (lower bound)	Target Rate	Met/Not Met
Sensitivity	86.9%	80.6%	75%	Met
Specificity	86.7%	82.0%	70%	Met

PER-VESSEL	Estimate, % (95% CI)
Accuracy	86.8% (83.0-90.4%)
PPV	79.4% (71.8-86.2%)
NPV	91.9% (87.7-95.6%)

PER-PATIENT	Estimate, % (95% CI)
Sensitivity	87.4% (79.4-93.1%)
Specificity	83.7% (76.5-89.4%)
Accuracy	85.2% (80.2-89.4%)
PPV	79.6% (71.0-86.6%)
NPV	90.1% (83.6-94.6%)

1 https://clinicaltrials.gov/ct2/show/NCT04828590

Advantages of DEEPVESSEL FFR

Non-Invasive
Calculates non-invasive FFR from CCTA

Accurate
Achieves high diagnostic accuracy using invasive FFR as the ground truth

Comprehensive
Calculates FFR values at any location in the coronary tree

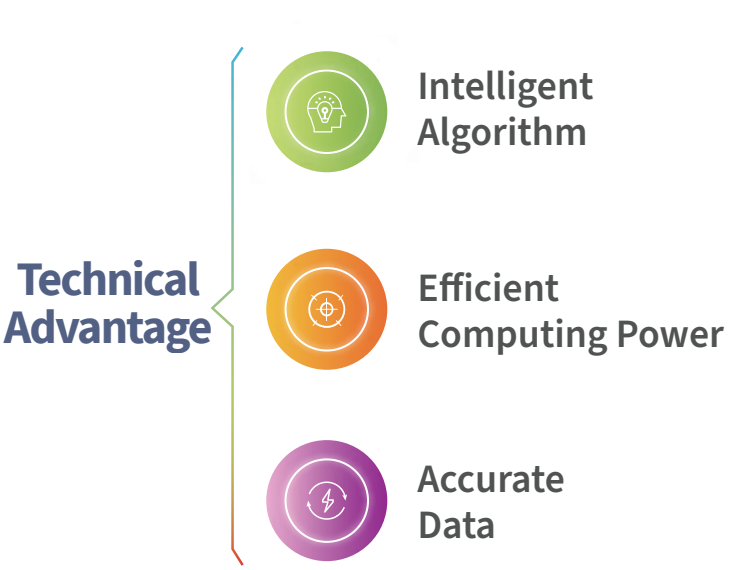
Efficient
Provides fast results

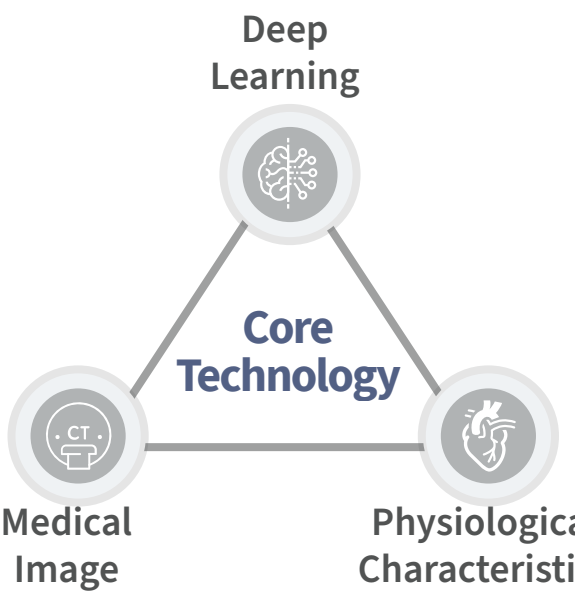
Affordable
Optimizes hospital resources by reducing unnecessary invasive procedures

Accessible
Delivers results that can be viewed on PCs, tablets, and mobile devices

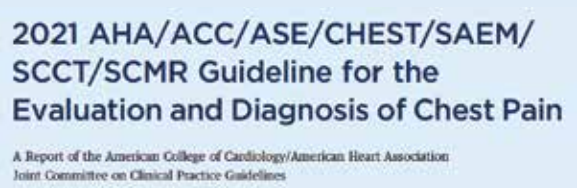
Core Technology

DEEPVESSEL FFR uses deep learning technology to integrate key technologies in artificial intelligence, medical imaging, biomedical engineering and other related disciplines, covering a number of independently developed cutting-edge deep learning algorithms, from medical image processing, model reconstruction to FFR calculation Intelligent optimization. Processing is carried out in each link, which improves the accuracy, robustness of segmentation, and the processing speed.





ACC/AHA Guideline Recommends CCTA + FFR CT Pathway



The 2021 American College of Cardiology (ACC) and American Heart Association (AHA) Guideline for the Evaluation and Diagnosis of Chest Pain encourages the use of CCTA as a first-line test for patients with stable heart pain, and, for some patients, the addition of CT-derived FFR simulation algorithms to non-invasively assess functional ischemia from the CT images.

CCTA is recommended for intermediate and high-risk patients with stable chest pain and no known CAD. For the first time in an ACC/AHA guideline, FFR CT is officially recommended as a front-line pathway[4] for the diagnosis of vessel-specific ischemia, and to guide decision-making for coronary revascularization.

CTA Image Acquisition Requirements & Clinical Recommendations

DEEPVESSEL FFR is clinically applicable to patients with stable coronary heart disease (SCAD) with 30-90% coronary stenosis based on CTA examination.

Input CTA Image Requirement

- Input coronary CTA images need to be acquired by a CT scanner with at least 64 detector rows.
- Input coronary CTA images with any of the following conditions may NOT be eligible for DVFFR analysis and should be excluded:
  - Unsuitable imaging parameters:
    - Slice thickness >1 mm;
    - Slice spacing >1 mm;
    - In-plane pixel spacing >0.5 mm;
    - KVP <70;
  - Unsuitable image quality
    - Images with severe imaging artifacts, including motion artifact, misalignment, calcium blooming, low contrast and high noises.

Intended Patient Population

- The targeted patient population are adult patients with clinically stable coronary artery diseases.
- The coronary CTA image shows at least one vessel segment (≥2 mm diameter) with a diameter stenosis of 30%–90%.

DVFFR analysis is **NOT** intended for patients with any of the following conditions (the clinical performance on those patient population have not been clinically validated):

- Acute myocardial infarction;
- Unstable angina;
- Pulmonary edema;
- Heart function classification level III and IV (NYHA heart function classification);
- Implantable cardioverter defibrillator (ICD);
- Prior PCI or pacemaker surgery;
- Prior coronary artery bypass grafting (CABG) surgery;
- Prior heart valve replacement;
- Prior history of complex congenital heart disease;
- Prior history of cardiomyopathy;
- BMI >35;
- Coronary total occlusion.

Regulatory Compliance

DEEPVESSEL FFR is FDA-Cleared, CE-Marked, and NMPA-Approved. DEEPVESSEL FFR is commercially available in the USA, EU, and China. DEEPVESSEL FFR is a registered trademark in the People's Republic of China.

3 Gulati, et al. 2021 AHA/ACC/ASE/CHES/SAEM/SCCT/SCMR Guideline for the Evaluation & Diagnosis of Chest Pain. Circulation.

Clinical Workflow

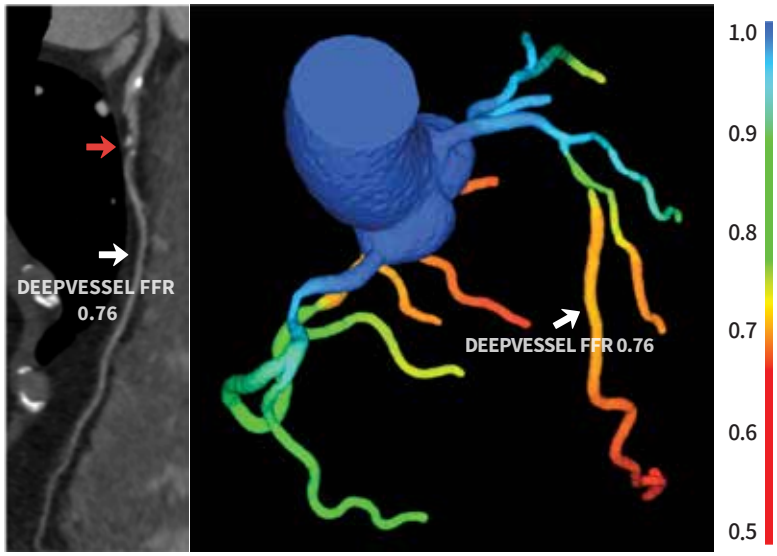
Imaging centers send de-identified CCTA images through a secure AWS web portal

DVFFR algorithms and Keya Medical analysts perform the image analysis

Clinicians receive an interactive 3D heart model and PDF report electronically

Case Studies

DV FFR positive — invasive FFR shows functional ischemia



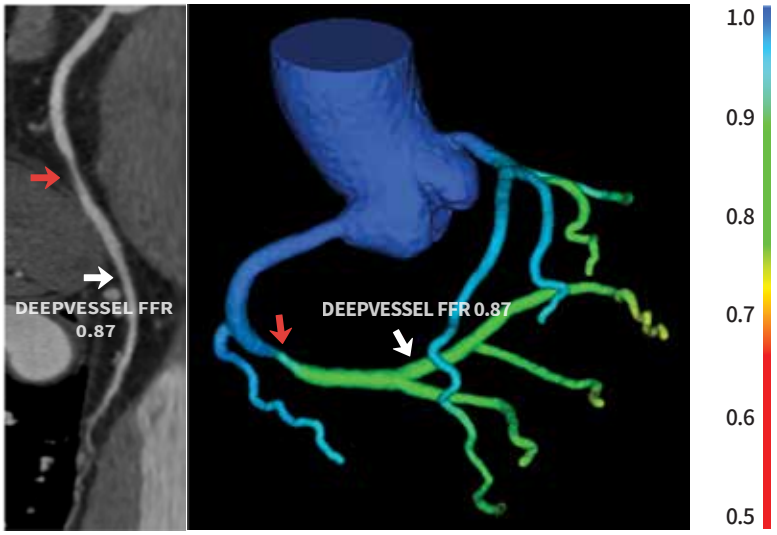
CASE ANALYSIS:

Left: Reconstruction of the anterior descending branch curve. Coronary CTA images report about 80% stenosis in the middle segment (red arrow);

Right: The calculation result of non-invasive DEEPVESSEL FFR based on coronary CTA shows functional ischemia (the white arrow is at the measurement point with non-invasive DEEPVESSEL FFR=0.76);

Invasive blood flow reserve measurement verifies a functional ischemia (invasive FFR=0.75 at the measurement point).

DV FFR negative — invasive FFR shows no obvious functional ischemia



CASE ANALYSIS:

Left: The curved surface of the right coronary artery is reconstructed. The coronary CTA image reports that the stenosis at the second turning point is about 70% (red arrow);

Right: The calculation result of non-invasive DEEPVESSEL FFR based on coronary CTA shows that there is no obvious functional ischemia (white arrow, non-invasive DEEPVESSEL FFR=0.87 at the measurement point);

Invasive blood flow reserve measurement verifies that there is no obvious functional ischemia (invasive FFR=0.88 at the measurement point).

About Keya Medical

Keya Medical is an international medical technology company developing deep learning-based medical devices for disease diagnosis and treatment. The company is committed to creating solutions that deliver clinical value at all stages in the patient care process, covering specialties including cardiology, neurology, pulmonology, pathology, and surgery.

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