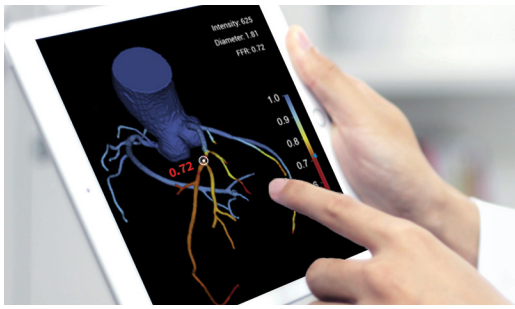


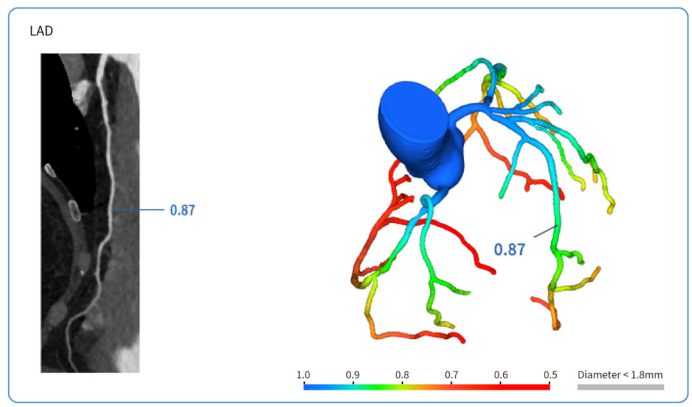
DEEPVESSEL® FFR

AI-Based CT-FFR Analysis with DEEPVESSEL FFR.

DEEPVESSEL FFR is FDA-cleared, CE-marked, and NMPA-approved.

DEEPVESSEL FFR (DVFFR) 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.

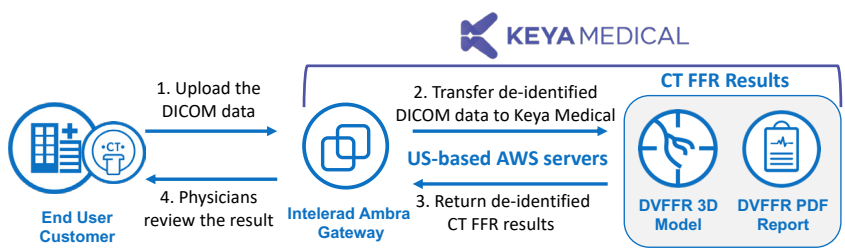
The 2021 ACC and AHA Guidelines for the Evaluation and Diagnosis of Chest Pain highlight the use of Coronary CTA + FFR CT as a front-line pathway[1].



AFFORDABLE	ACCURATE	EFFICIENT	NON-INVASIVE	COMPREHENSIVE
Optimizes hospital resources by reducing invasive procedures	Achieves high diagnostic accuracy using invasive FFR as the ground truth	Provides fast results	Calculates non-invasive FFR from CCTA	Calculates FFR values at any location in the coronary tree

Clinical Workflow

1. End User Customer uploads DICOM images to PIA (Intelerad Ambra). The Ambra algorithm de-identifies DICOM headers during upload. Any PHI on the images must be masked by End User Customer prior to upload.
2. De-identified DICOM data are sent to Keya Medical via Intelerad Ambra's US-based AWS servers.
3. Keya Medical-trained analysts, who may be working offshore, perform the analysis. A PDF reports and 3D interactive model are transferred to the End User Customer via Intelerad Ambra's servers.
4. Physicians review the CT FFR analysis results on the Intelerad Ambra platform.



Diagnostic Performance: Multi-national, multi-center clinical validation study ADAPT[2]

Per-Vessel	Estimate, %	One-Sided 95% CI (lower bound)	Target Rate	Met/Not Met
Sensitivity	86.9%	80.6%	75%	Met
Specificity	86.7%	82.0%	70%	Met
Accuracy	86.8% (82.5%-90.4%)			

Per-Patient	Estimate, %	Two-Sided 95% CI
Sensitivity	87.4%	79.4%–93.1%
Specificity	83.7%	76.5%–89.4%
Accuracy	85.2%	80.2%–89.4%

1 Gulati, et al. 2021 AHA/ACC/ASE/CHES/SAEM/SCCT/SCMR Guideline for the Evaluation & Diagnosis of Chest Pain. Circulation.
2. https://clinicaltrials.gov/ct2/show/NCT04828590

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