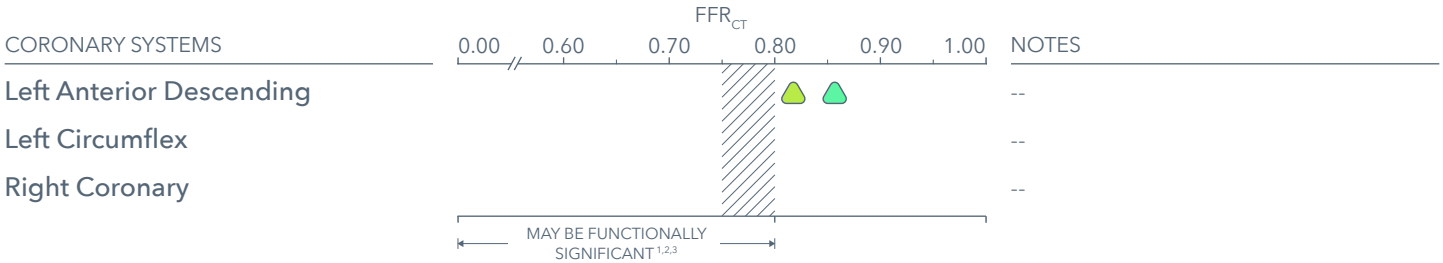
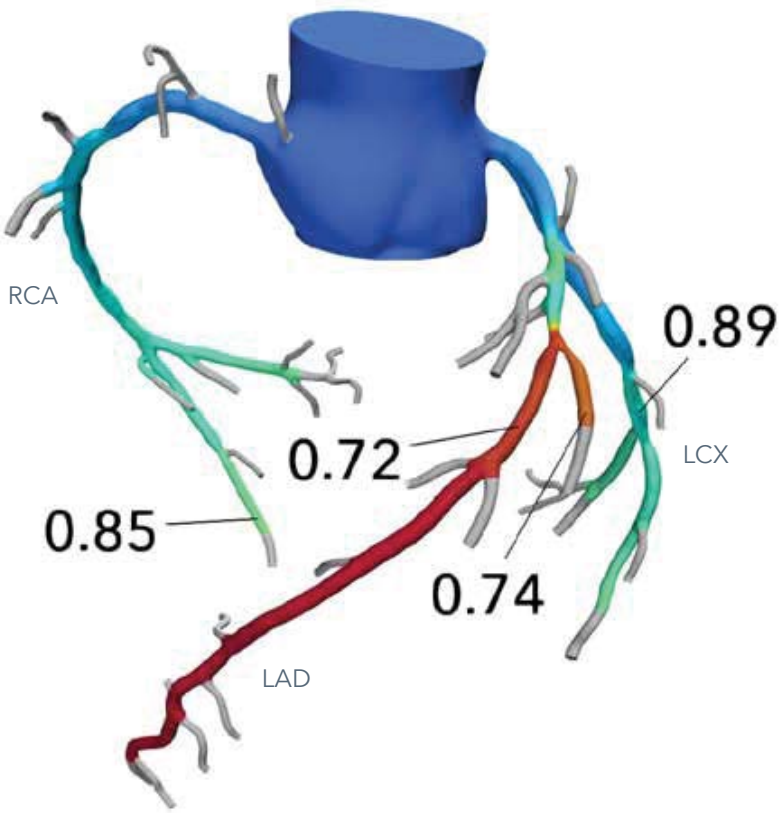
Doe, John

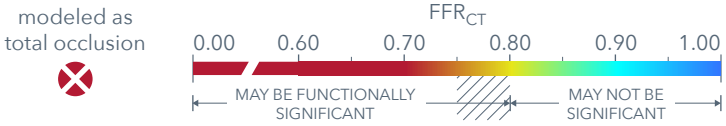
Patient ID	10-028-KHE	CT Study Date	06/20/2016
Birth Date	07/24/1961	Referring Physician	Dr. Jim Cardiologist
HeartFlow ID	ANYT-160620-JKD7	Institution	Anytown Cardiology

FFR_{CT} is > 0.80 distal to all modeled stenoses. FFR_{CT} is ≤ 0.80 at the end of the modeled vessel(s).





FFR_{CT} values are specified distal to modeled stenoses > 30%. Some modeled stenoses in the 30-40% range may not have pins present; pins are not displayed on acute marginal or septals.



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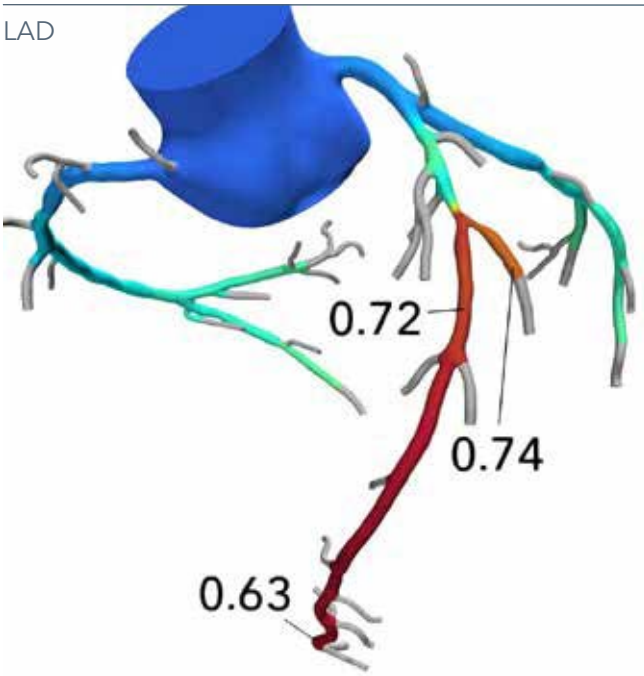
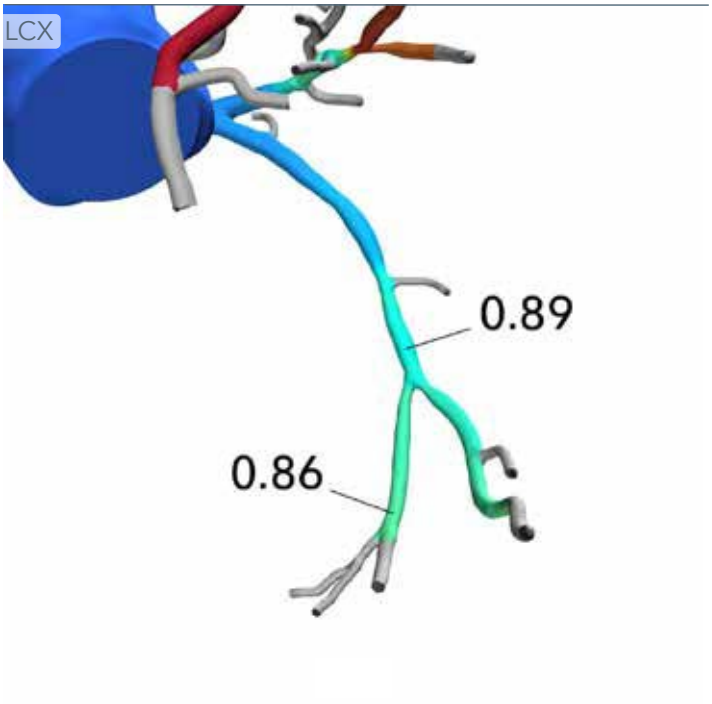
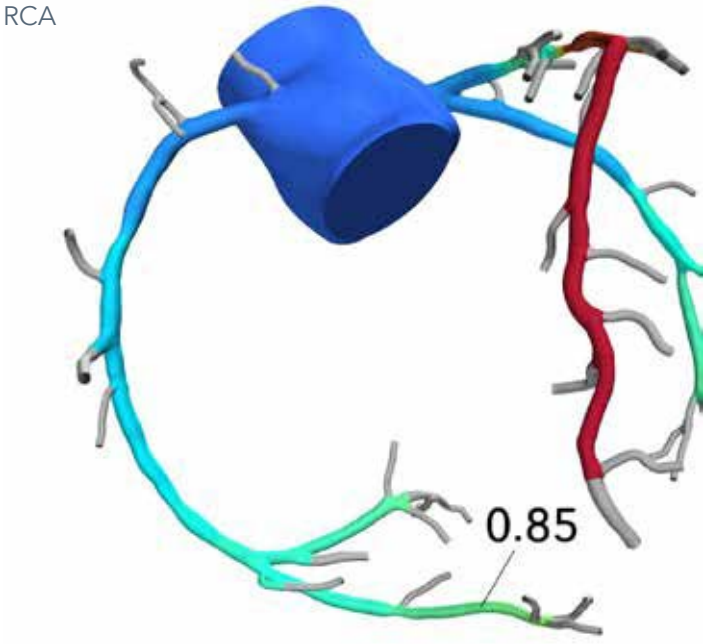
LAD



LCX



RCA



WARNINGS

- Absence of nitrate administration during coronary CTA acquisition may adversely affect the accuracy of the HeartFlow FFR_{CT} Analysis. The HeartFlow Analysis simulates maximal coronary hyperemia. Induction of coronary hyperemia commonly includes vasodilation of the epicardial coronary arteries via nitrate administration. Therefore, HeartFlow recommends following SCCT Guidelines for coronary CTA acquisition, which include the use of sublingual nitrates at the time of image acquisition.[4]
- The HeartFlow Analysis represents patient conditions at the time of CT acquisition. The duration of time and changes to patient health after CT acquisition must be assessed during interpretation. Clinical validation that supports FFR_{CT} values was limited to subjects whose CT acquisition occurred within 60 days of invasive FFR (mean 18 +/- 13 days).
- Qualitative anatomical information presented on the 3D/2D computer generated anatomical models is for orientation purposes only. Quantitative lumen diameter is representative of the geometric model, and the accuracy is dependent on the quality of the CT data provided. It does not represent artery diameter and should not be used for treatment decisions.
- Diagnostic performance of FFR_{CT} using invasive FFR as the reference standard is: 84% accurate, 82% sensitive, and 85% specific. Refer to product Instructions For Use for patient populations in which FFR_{CT} has been clinically evaluated, relevant clinical data, and product warnings.
- The performance of the HeartFlow Analysis has not been fully characterized in small vessels. Vessels with modeled lumen diameters less than 1.8 mm are grayed, and FFR_{CT} values are unavailable. When modeled lumen diameter decreases below 1.8 mm due to disease, but distally recovers to 1.8 mm or greater, FFR_{CT} values remain available. In some instances, continued distal disease and/or recovery may not be presented in the model.
- The HeartFlow Analysis has been studied in patients with prior PCI, but the FFR_{CT} values have only been validated in vessels without metallic stents.
- Because of physiologic changes in pressure and flow within regions of complex or turbulent flow (i.e. stenosis, bifurcations), pressure measurements may vary, potentially affecting measured FFR. Similarly, computed FFR_{CT} values may be affected by flow disturbances in stenoses and bifurcations.

FFR_{CT} ERROR

FFR_{CT}	COLOR	AVERAGE ERROR TO Invasive FFR † ± 1SD
≤ 0.70		-0.07 ± 0.12
0.71 - 0.75		-0.07 ± 0.12
0.76 - 0.80		-0.06 ± 0.07
0.81 - 0.85		-0.04 ± 0.05
0.86 - 0.90		-0.02 ± 0.07
0.91 - 1.0		-0.01 ± 0.04
0.0 - 1.0		-0.03 ± 0.07

† Error from the FFR_{CT} v3.0 Clinical Validation Population. Not indicative of all patient populations. Please refer to complete summary of clinical data provided in the Instructions For Use to determine the population in which the FFR_{CT} technology has been clinically validated.

REFERENCES

1. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. Tonino PA, et al. NEJM 2009; 360:213-224.
2. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. De Bruyne B, et al. NEJM 2012; 367:991-1001.
3. Diagnostic performance of non-invasive fractional flow reserve derived from coronary CT angiography in suspected coronary artery disease: The NXT Trial. Norgaard B, et al. JACC 2014; 63(12):1145-1155.
4. SCCT guidelines for the performance and acquisition of coronary computed tomographic angiography. Abbara S, et al. JCCT 2016; DOI: 10.1016/j.jcct.2016.10.002.

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HeartFlow®

Product Warnings

PATIENT POPULATION

The following warnings provide clarification as to which patient populations should be considered for the HeartFlow FFR_{CT} Analysis.

⚠ The safety and effectiveness of the HeartFlow Analysis has not been evaluated for the following populations:

1. Suspicion of acute coronary syndrome (where acute myocardial infarction or unstable angina have not been ruled out)
2. Recent prior myocardial infarction within 30 days
3. Complex congenital heart disease
4. Prior coronary artery bypass graft (CABG) surgery
5. Patients with a Body Mass Index >35
6. Patients who require emergent procedures or have any evidence of ongoing or active clinical instability, including acute chest pain (sudden onset), cardiogenic shock, unstable blood pressure with systolic blood pressure <90 mmHg, severe congestive heart failure (New York Heart Association [NYHA] III or IV) or acute pulmonary edema

Due to the potential for artifacts in the CT data or degradation of CT data quality, the safety and effectiveness of the HeartFlow Analysis has not been clinically evaluated for the following populations:

1. Patients with intracoronary metallic stents
2. Patients with prior pacemaker or internal defibrillator lead implantation
3. Patients with prosthetic heart valves
4. Patients with significant arrhythmias or tachycardia (uncontrolled by medication) that would preclude CT acquisition
5. Coronary vessels with excessive calcification

⚠ The HeartFlow Analysis has been studied in patients with prior PCI, but the FFR_{CT} values have only been validated in vessels without metallic stents.

⚠ The diagnostic performance of the HeartFlow Analysis has been validated in patients who are candidates for invasive coronary angiography based on clinical presentation and/or non-invasive testing.

PROVISION OF DATA

The following warnings identify anatomy or image acquisition factors that may impact the HeartFlow Analysis.

⚠ The HeartFlow Analysis may be adversely affected by the following:

1. Marginal quality of the submitted imaging data (motion, blooming, misalignment, etc.)
2. Regionalized or global myocardial dysfunction
3. Myocardial mass abnormalities (hypertrophic right ventricle for example)
4. Abnormal patient physiology (e.g. severe congenital disease or excess calcification)

⚠ The HeartFlow Analysis has not been validated with software-based motion correction algorithms. CT datasets with significant coronary motion may require application of software-based motion correction algorithms which use information from multiple phases (time points) to recreate the lumen and correct for motion. Motion correction algorithms improve acceptability for standard visual interpretation, however they may distort the anatomy such that it is no longer representative of actual patient anatomy. The HeartFlow Analysis is for the anatomy in the provided data, which may not represent actual patient anatomy.

⚠ The HeartFlow Analysis simulates maximal hyperemia, which results in vasodilation of the epicardial coronary arteries. This condition is commonly induced using nitrates. Therefore, HeartFlow recommends following SCCT guidelines for coronary CTA acquisition, which recommends the use of sublingual nitrates at the time of image acquisition unless contraindicated. Absence of nitrates during coronary CTA may adversely affect the HeartFlow Analysis.

⚠ The HeartFlow Analysis has been clinically validated using DICOM data acquired from the following CT scanner manufacturers: Siemens Healthineers, Toshiba (now Canon Medical Systems), GE Healthcare, and Philips. Performance of the HeartFlow Analysis using DICOM data acquired from scanners for which it has not been clinically validated is unknown, and therefore the safety and effectiveness of its use has not been established.

⚠ The HeartFlow Analysis provision timeframes are contractually defined and are subject to delay. The HeartFlow Analysis should not be used for patients with unstable coronary syndromes, or in patients where urgent and timely workup and evaluation is critical.

REVIEWING THE HEARTFLOW ANALYSIS

The following warnings provide cautionary guidance for viewing and interpretation of the HeartFlow Analysis.

- Due to the variability in the HeartFlow Analysis, the FFR_{CT} values should be reviewed as one of several clinical data points to be used in conjunction with the patient's original CT images, clinical history, symptoms and other diagnostic tests, as well as an appropriately trained clinician's clinical judgment, to evaluate the patient.
- The HeartFlow Analysis process is dependent on the quality of the imaging data provided. FFR_{CT} values may be affected by assumptions needed to resolve anatomy in areas of uncertainty, whether provided by the physician or made by HeartFlow Case Analysts.
- The HeartFlow Analysis represents patient conditions at the time of CT acquisition. The duration of time and changes to patient health after CT acquisition must be assessed during interpretation. Clinical validation that supports FFR_{CT} values was limited to subjects whose CT acquisition occurred within 60 days of invasive FFR (mean 18 +/- 13 days).
- The HeartFlow FFR_{CT} Overview provides images based on vessel view. If a vessel of interest is obscured, FFR_{CT} values may be interrogated with the Interactive Model.
- Use of an unsupported Operating System (OS) and/or browser may compromise website functionality and/or content presentation. A warning will be displayed on the login page if the application detects you are using an unsupported OS or browser. Please refer to the "Product Use Requirements" section of the Instructions for Use for a list of supported OS, browser, and browser versions.
- Because of physiologic changes in pressure and flow within regions of complex or turbulent flow (i.e. stenosis, bifurcations), pressure measurements may vary, potentially affecting measured FFR. Similarly, computed FFR_{CT} values may be affected by flow disturbances in stenoses and bifurcations. This is representative of physiology and is not a product limitation.
- Qualitative anatomical information presented on the 3D/2D computer generated anatomical models is for orientation purposes only. Quantitative lumen diameter is representative of the geometric model and the accuracy is dependent on the quality of the CT data provided. It does not represent artery diameter and should not be used for treatment decisions.
- The performance of the HeartFlow Analysis has not been fully characterized in small vessels. Vessels with modeled lumen diameters less than 1.8 mm are grayed, and FFR_{CT} values are unavailable. When modeled lumen diameter decreases below 1.8 mm due to disease, but distally recovers to 1.8 mm or greater, FFR_{CT} values remains available. In some instances, continued distal disease and/or recovery may not be presented in the model.
- The HeartFlow FFR_{CT} Overview provides selected FFR_{CT} values. To interpret the FFR_{CT} values, please review the color images of the FFR_{CT} model and/or the Interactive Model to evaluate FFR_{CT} changes in the modeled vessel systems. Refer to the Instructions For Use for details on the selection of FFR_{CT} values.

PRECAUTIONS

The following precautions provide guidance for use of the HeartFlow Analysis.

- If the DICOM Patient Name or Patient ID displayed in the web application exceeds the available display space, the data will be truncated and displayed with an ellipsis (…). Hovering the cursor over the field will display the full information.
- Display of the visual color model/images in the HeartFlow Analysis is dependent on monitor and/or printer settings, and individual ability to interpret shades of color.

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