

Sample FFR_{CT} Analysis

Not For Clinical Use. Demonstration Only.

This document provides a sample or demonstrative Heartflow FFR_{CT} Analysis that is not intended for clinical use. The processes used to obtain the subject's CT data for this case and to generate the Heartflow Analysis may not comply with Heartflow's standard commercial processes. Please refer to the enclosed product warnings applicable to this analysis.

Jane Doe

Patient ID: 111ECAA13D2C4F5498305

Birth Date: 06/05/1968

Heartflow ID: ANYH-23FQRD-KRNT

CT Study Date: 06/26/2023

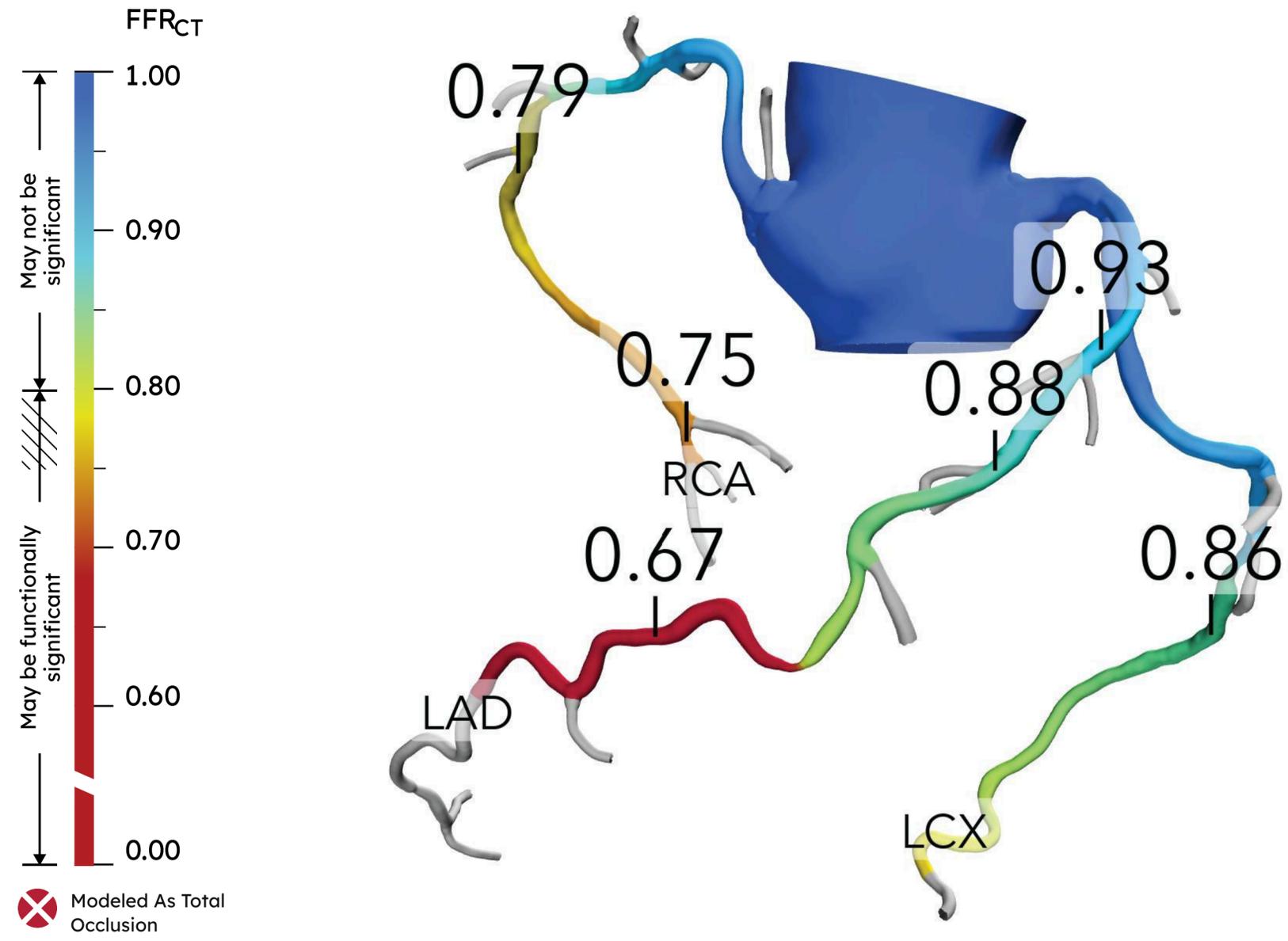
Referring Physician: John Smith

Institution: Anytown Hospital

FFR_{CT} is ≤ 0.80 and may indicate functional significance.^{1,2,3}

Coronary Systems	FFR _{CT}	Notes
Left Anterior Descending	0.79, 0.93, 0.95	--
Left Circumflex	0.88, 0.93	--
Right Coronary	0.67, 0.75	--

May be functionally significant^{1,2,3} (range 0.70-0.80)



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.

Jane Doe

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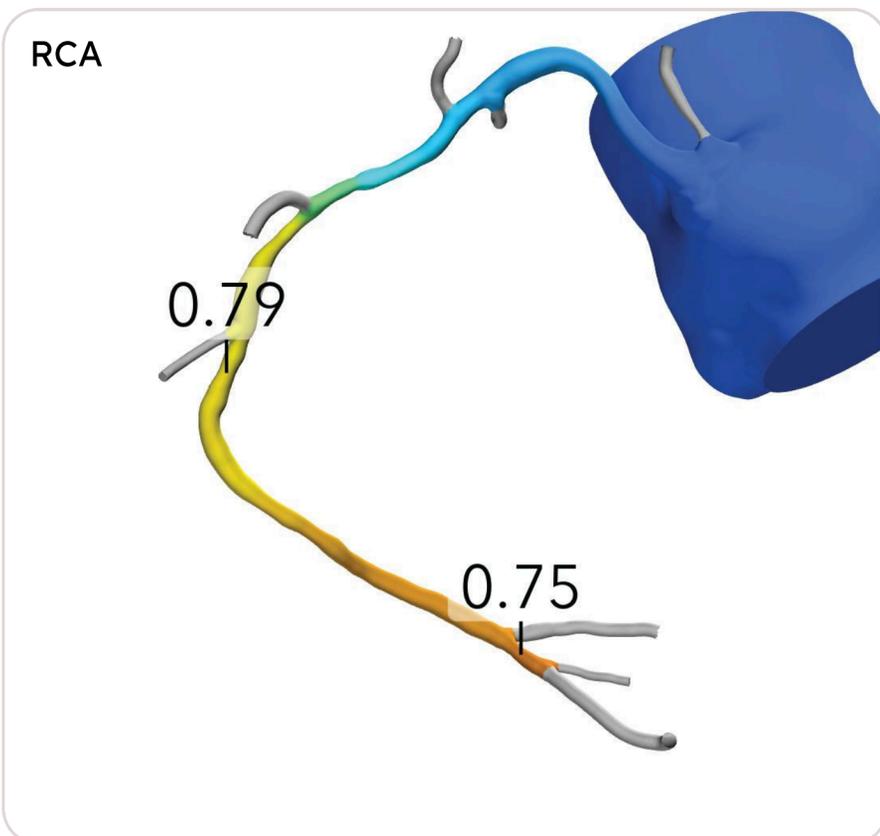
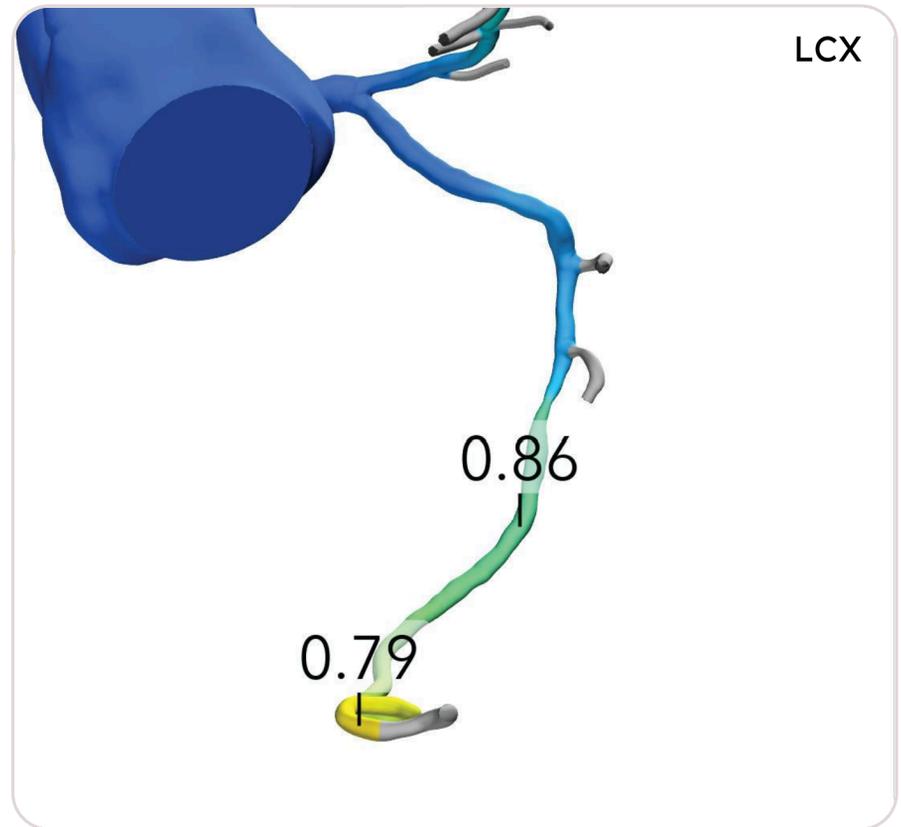
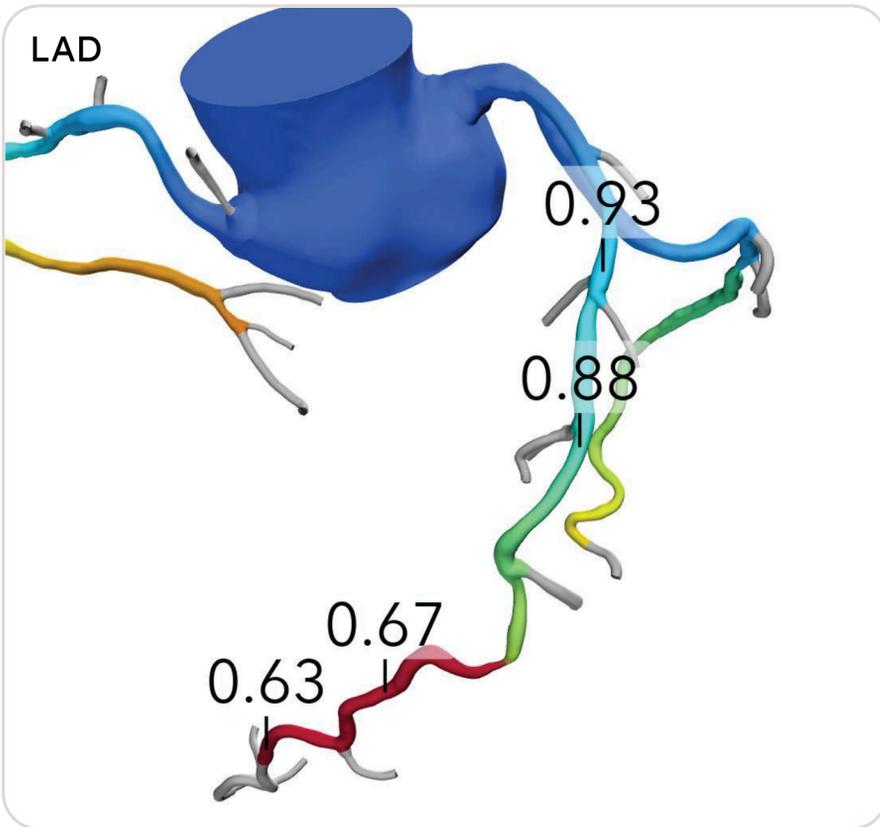
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Warnings

- ⚠️ 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} Errors

FFR _{CT}	Color	Average error to Invasive FFR ± 1 SD
≤ 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.

331 E Evelyn Ave | Mountain View, CA 94041 USA
 Tel: +1.650.241.0500 | support@heartflow.com | www.Heartflow.com

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