Heartflow

Sample Plaque Analysis

Example Overview. Not For Clinical Use.

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tel: +1.650.241.0500 | support@heartflow.com | **heartflow.com**

206314436 v8

Heartflow

Plaque Overview

Jane Doe

Birth Date: 06/05/1968 (55 years)
Sex: Female
CT Study Date: 06/26/2023

Heartflow ID: ANYH-23FQRD-KRNT
Patient ID: 111ECAA13D2C4F5498305
Referring Physician: John Smith

Total Plaque Summary

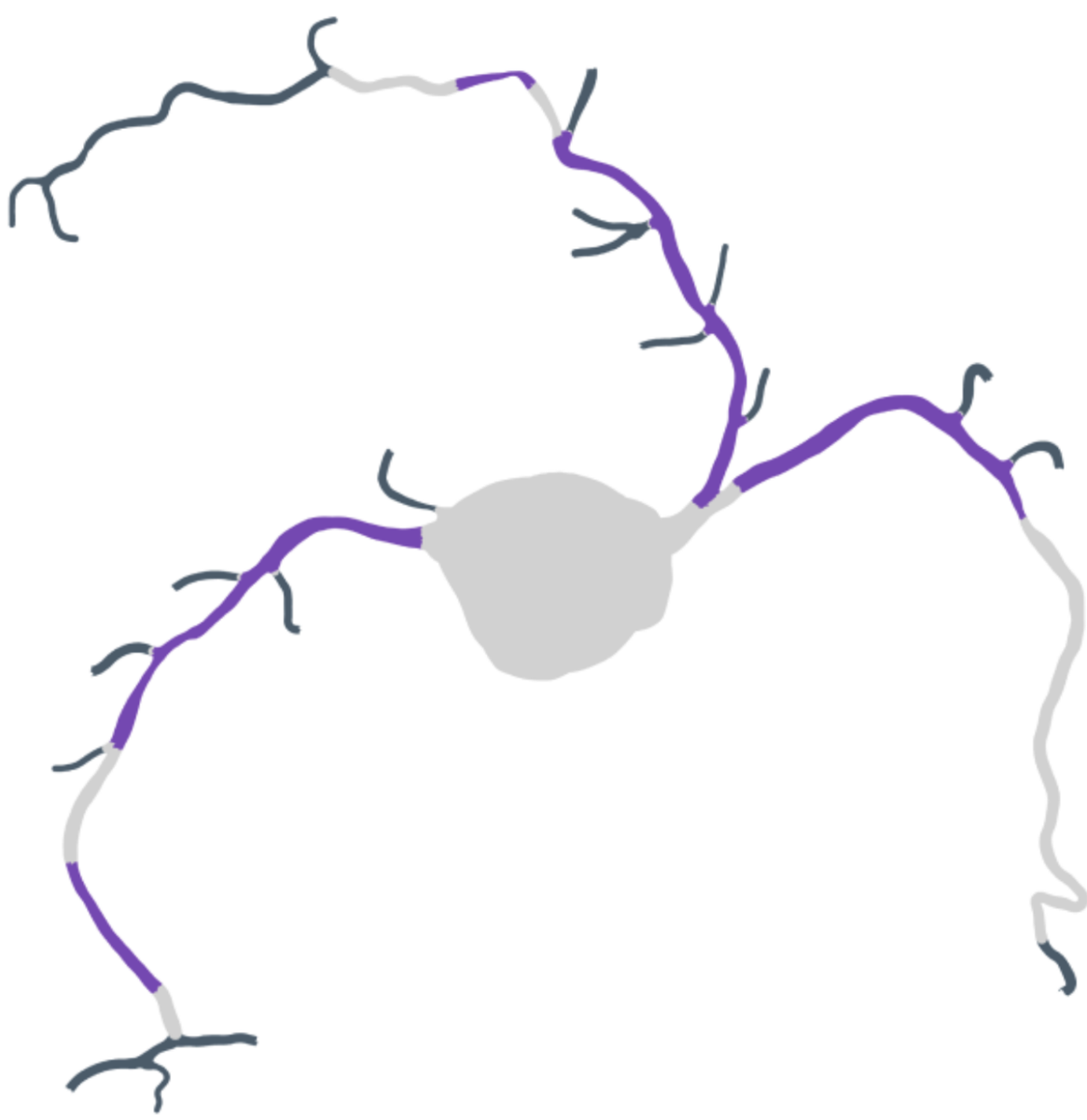
728 mm³
Total Plaque Volume

98th
Patient Percentile[1]

Plaque Types

Calcified	336 mm³	(46%)
Non Calcified	392 mm³	(54%)
Low attenuation	0 mm³	(0%)

2D Model - Plaque Volume by Vessel Territory



LM
9 mm³

LAD
298 mm³

RCA
218 mm³

LCX
203 mm³

Legend

- Regions of identified plaque
- Lumen
- Non-reportable

Jane Doe

Birth Date: 06/05/1968 (55 years)
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Patient ID: 111ECAA13D2C4F5498305

LM and LAD Vessel Territory Analysis

9 mm³
LM Total Plaque Volume

298 mm³
LAD Total Plaque Volume

Plaque Types

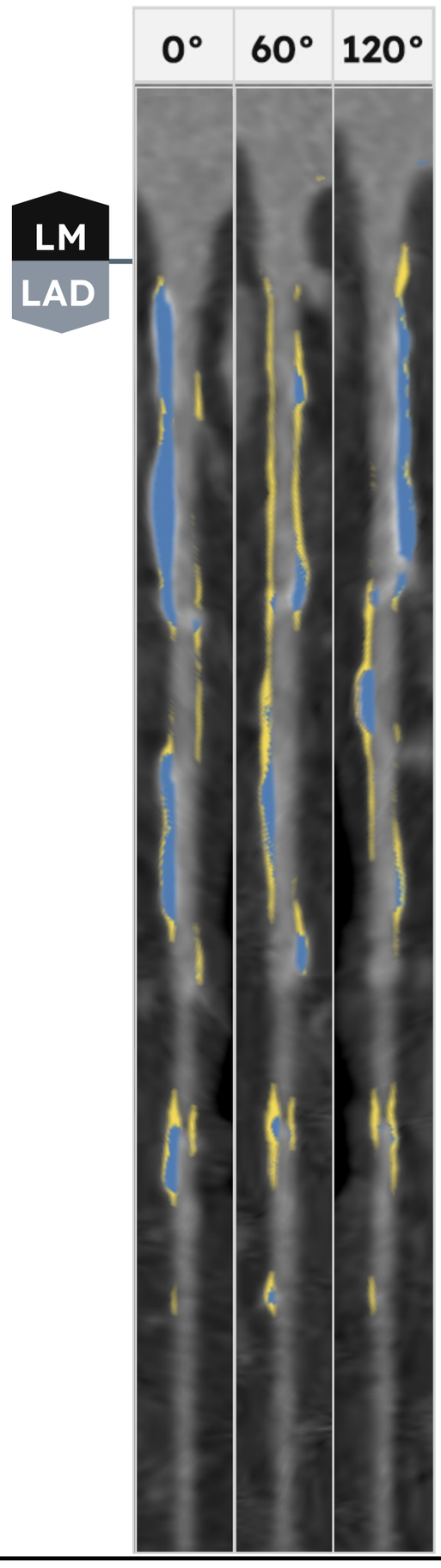
Calcified	6 mm³	(67%)
Non Calcified	3 mm³	(33%)
Low attenuation	0 mm³	(0%)

Plaque Types

Calcified	177 mm³	(59%)
Non Calcified	121 mm³	(41%)
Low attenuation	0 mm³	(0%)

2D Model

sCPR



Legend

2D Model legend

- Regions of identified plaque
- Lumen
- Non-reportable

Jane Doe

Birth Date: 06/05/1968 (55 years)
CT Study Date: 06/26/2023

Heartflow ID: ANYH-23FQRD-KRNT
Patient ID: 111ECAA13D2C4F5498305

LM and LCX Vessel Territory Analysis

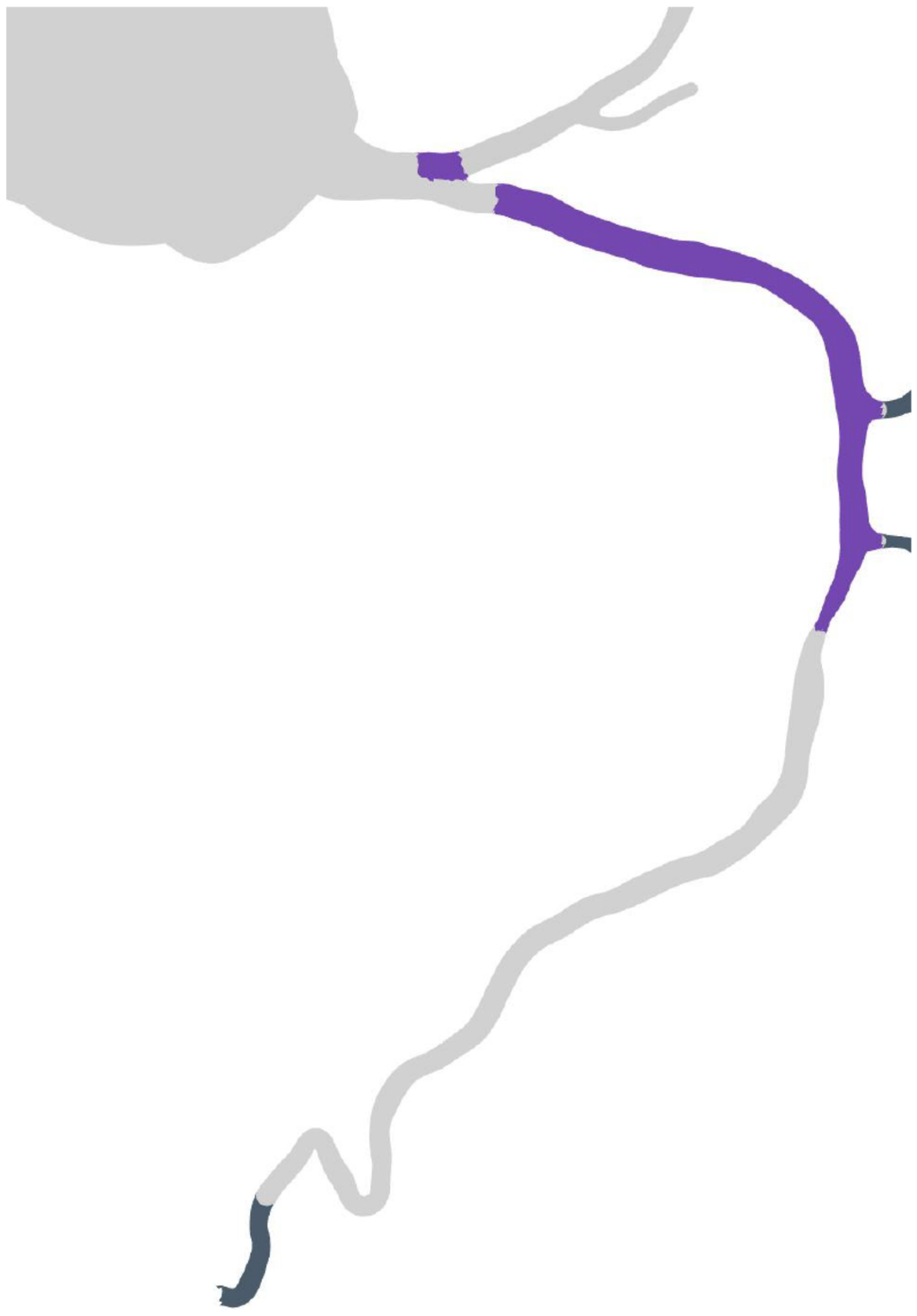
9 mm³
LM Total Plaque Volume

203 mm³
LCX Total Plaque Volume

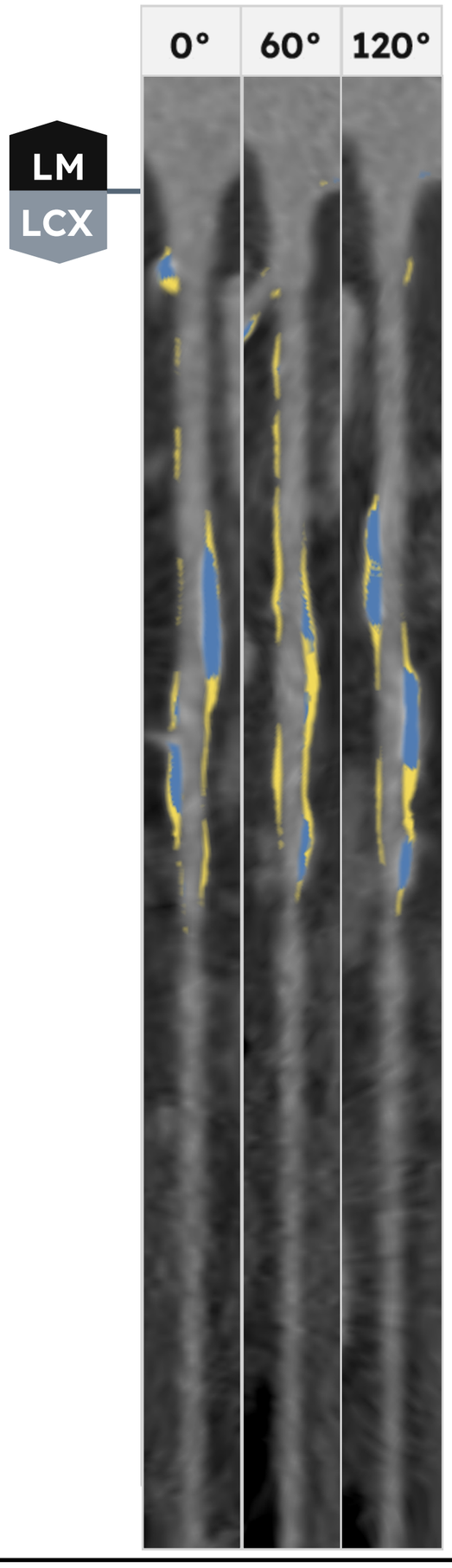
Plaque Types		
Calcified	6 mm³	(67%)
Non Calcified	3 mm³	(33%)
Low attenuation	0 mm³	(0%)

Plaque Types		
Calcified	84 mm³	(41%)
Non Calcified	119 mm³	(59%)
Low attenuation	0 mm³	(0%)

2D Model



sCPR



Legend

2D Model legend

- Regions of identified plaque
- Lumen
- Non-reportable

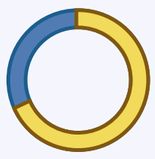
EXAMPLE OVERVIEW. NOT FOR CLINICAL USE. Mockup for visualization and actual appearance may change. Clinical information is for illustrative purposes only.

Jane Doe

Birth Date: 06/05/1968 (55 years)
CT Study Date: 06/26/2023

Heartflow ID: ANYH-23FQRD-KRNT
Patient ID: 111ECAA13D2C4F5498305

RCA Vessel Territory Analysis



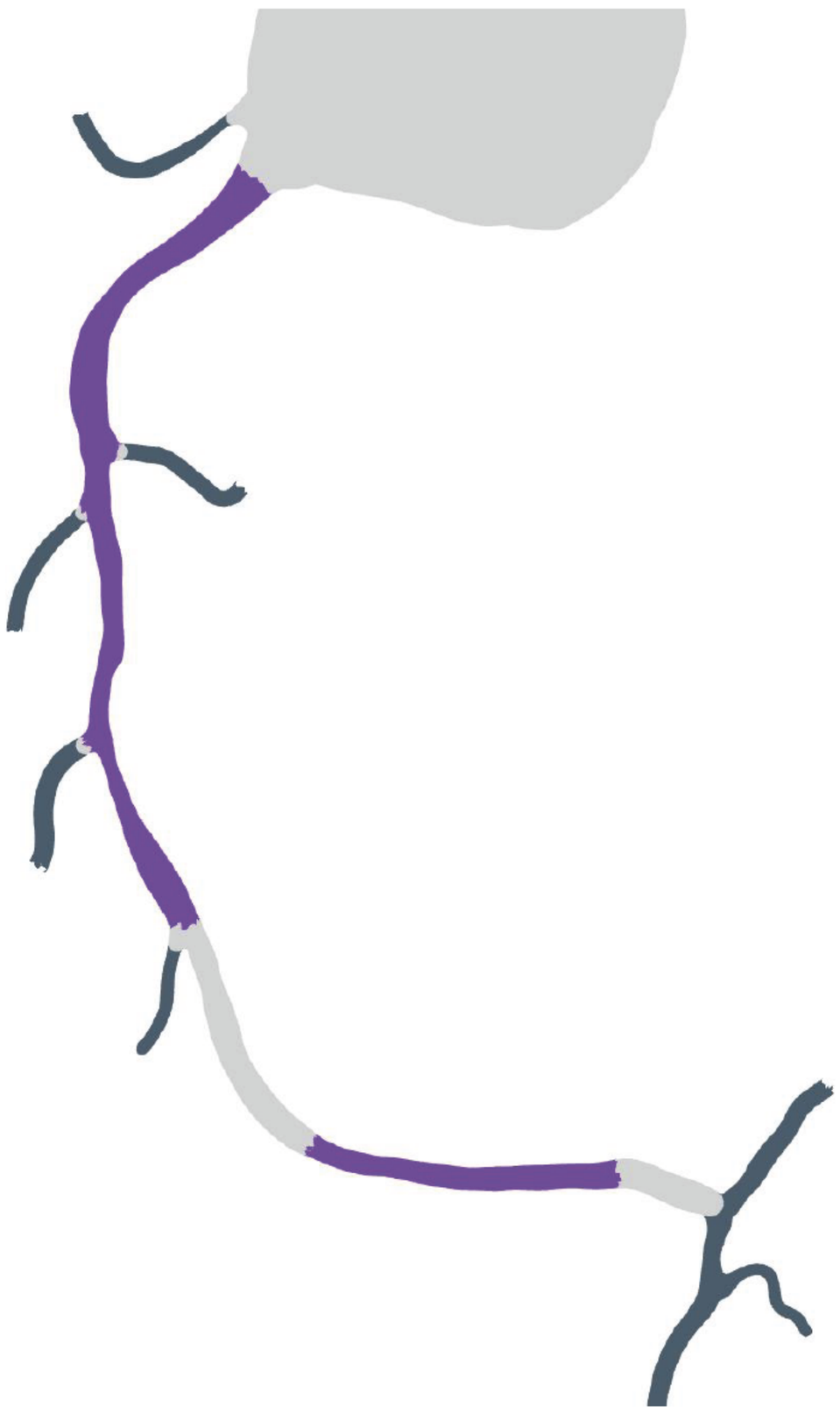
218 mm³

RCA Total Plaque Volume

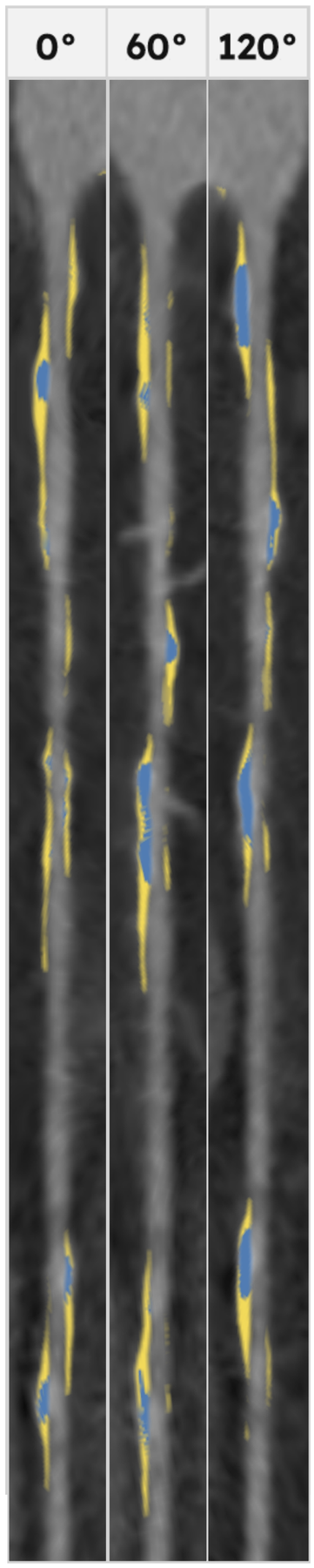
Plaque Types

Calcified	69 mm³	(32%)
Non Calcified	149 mm³	(68%)
Low attenuation	0 mm³	(0%)

2D Model



sCPR



Legend

2D Model legend

- Regions of identified plaque
- Lumen
- Non-reportable

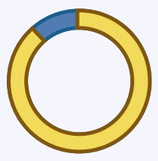
EXAMPLE OVERVIEW. NOT FOR CLINICAL USE. Mockup for visualization and actual appearance may change. Clinical information is for illustrative purposes only.

Jane Doe

Birth Date: 06/05/1968 (55 years)
CT Study Date: 06/26/2023

Heartflow ID: ANYH-23FQRD-KRNT
Patient ID: 111ECAA13D2C4F5498305

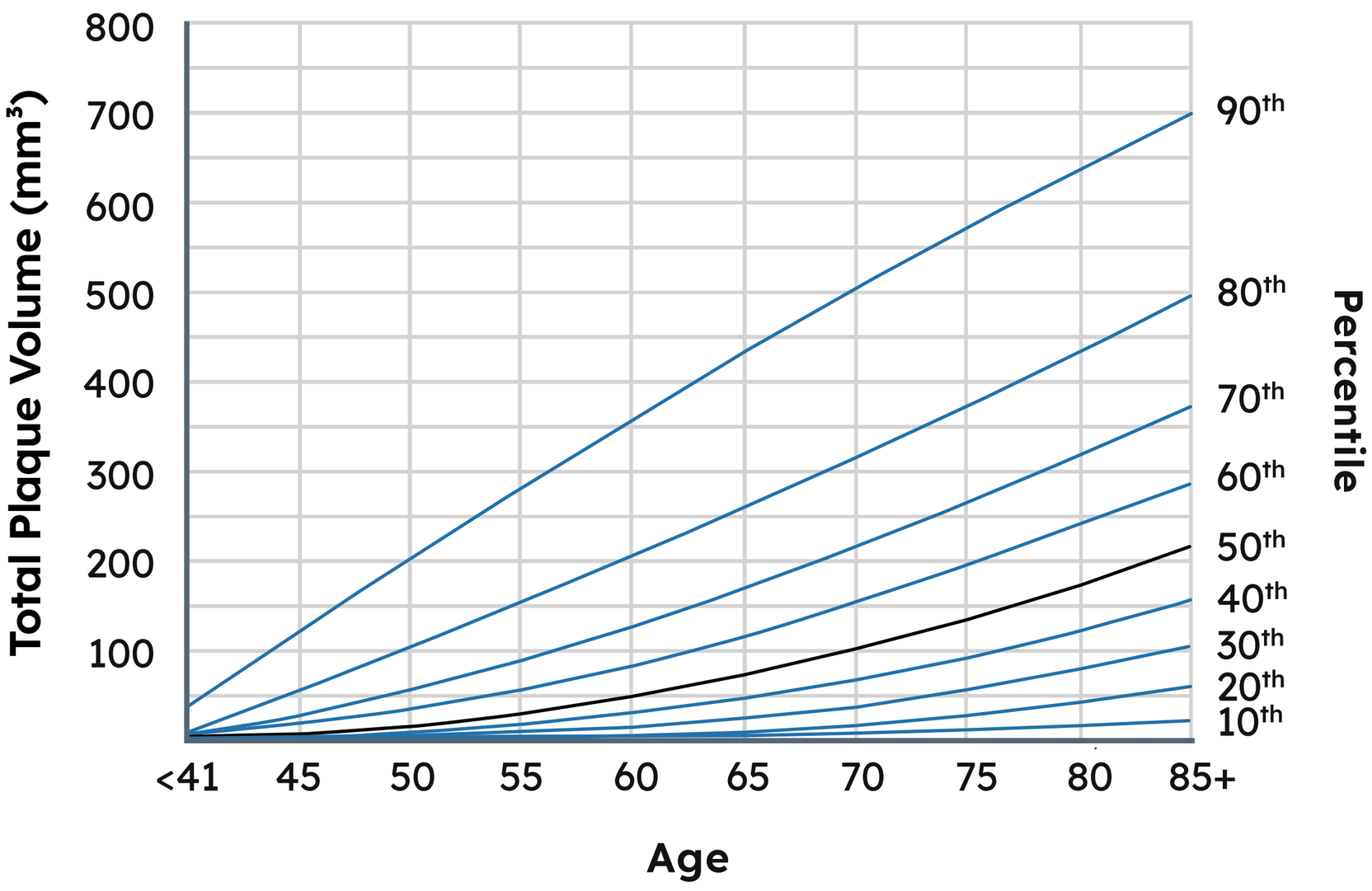
Nomogram[1]



728 mm³
Total Plaque Volume

98th
Patient Percentile[1]

Female Plaque Volume Nomogram



HeartFlow®

Sample FFR_{CT} Analysis

EXAMPLE OVERVIEW. NOT FOR CLINICAL USE.

This document provides a sample HeartFlow FFR_{CT} Analysis that is not intended for clinical use.

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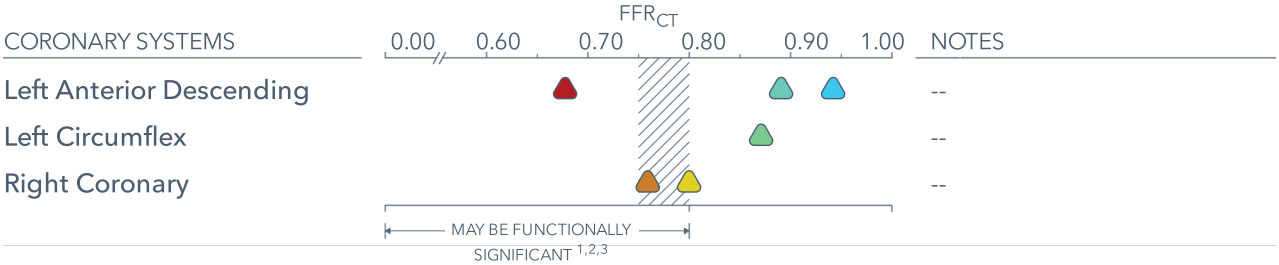
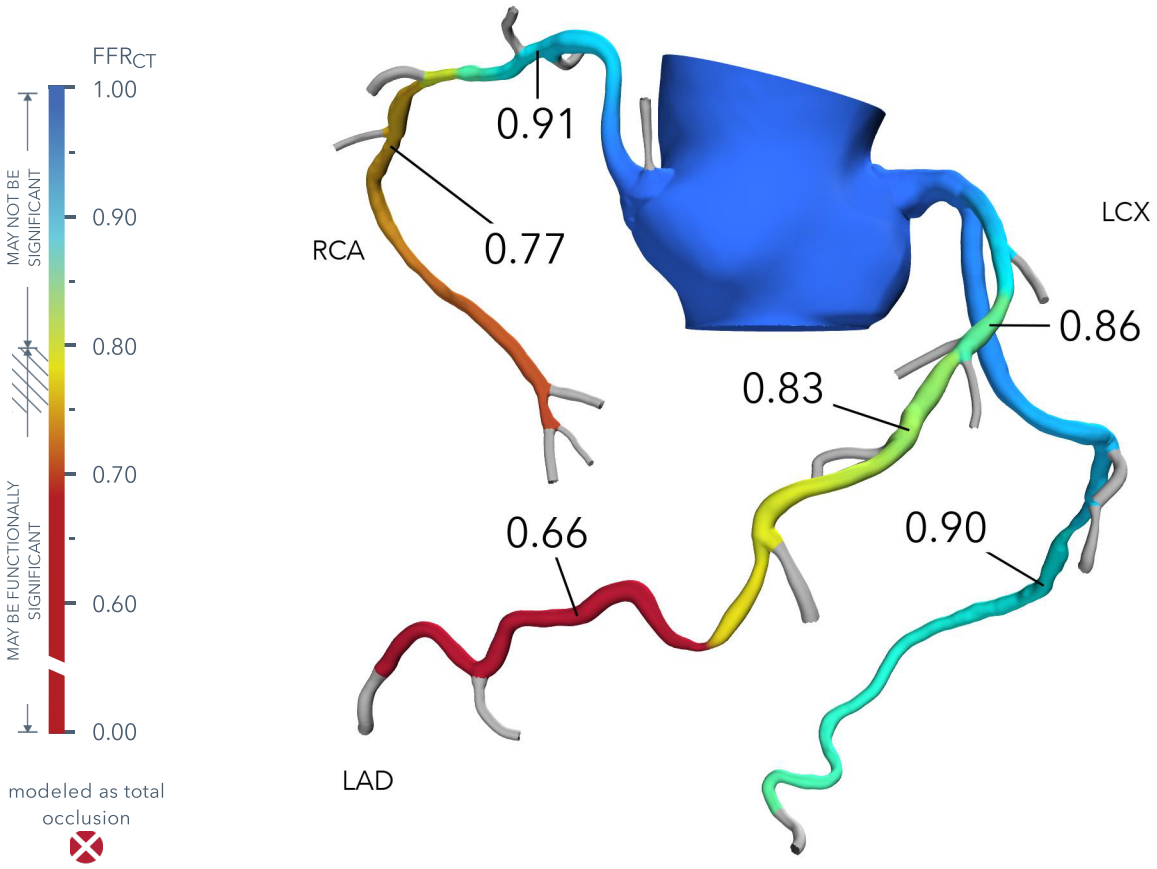
206314440 v1

Doe, Jane

Patient ID	111ECAA13D2C4F5498205	CT Study Date	06/26/2023
Birth Date	06/05/1968	Referring Physician	John Smith
HeartFlow ID	ANYH-23FQRD-KRNT	Institution	Anytown Hospital

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



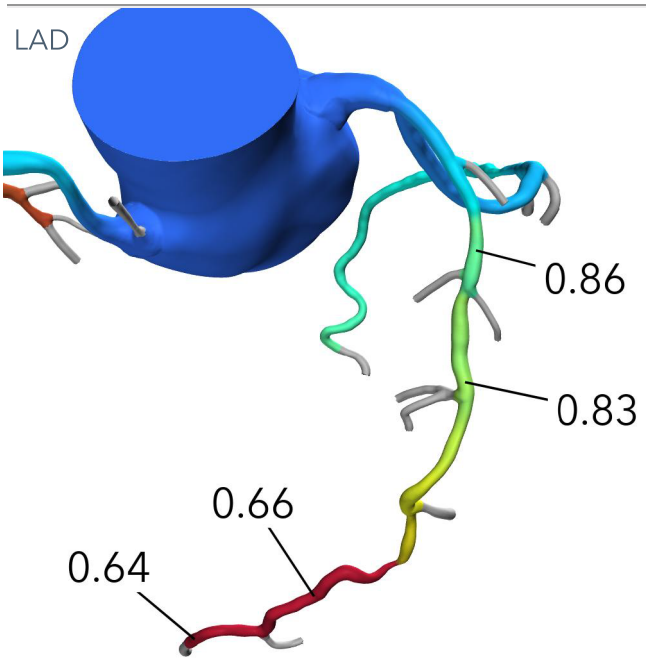


FFR_{CT} values are specified distal to modeled stenoses > 30%. Some modeled stenoses in the 30-40% range may not have pins present; pins are not displayed on acute marginal or septals.

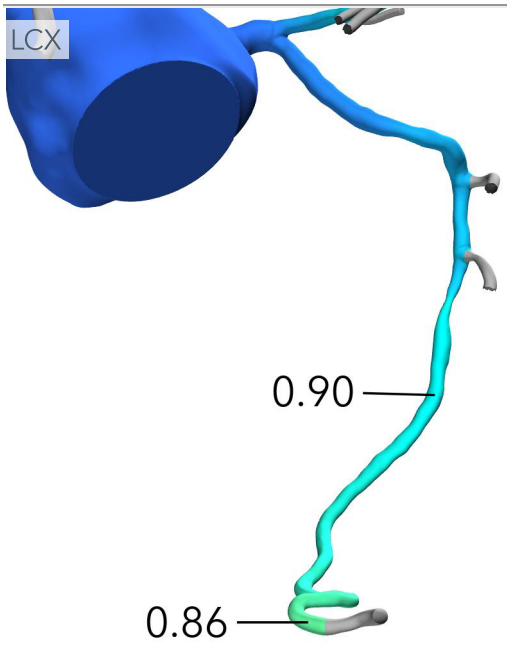
Doe, Jane

Patient ID	111ECAA13D2C4F5498205	CT Study Date	06/26/2023
Birth Date	06/05/1968	Referring Physician	John Smith
HeartFlow ID	ANYH-23FQRD-KRNT	Institution	Anytown Hospital

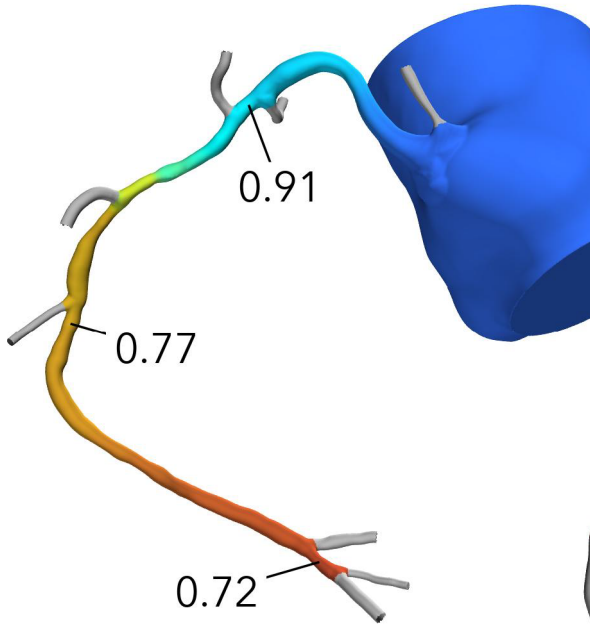
LAD



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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