CE 2797

Product Catalog		
Product	**Specification**	**Picture**
FlashAngio™ caFFR™ System	ASC15	
FlashPressure™ Transducer	CPT-1200	
	CPT-1500	
	CPT-2000	

For further information and contact us

For more information and a demonstration, please send email to InternationalBD@rainmed.com or visit www.rainmed.com.

Reference list

1. Tonino PA, De Bruyne B, Pijls NH, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. FAME study. N Engl J Med. 2009;360(3):213-24.
2. Angiographic Versus Functional Severity of Coronary Artery Stenoses in the FAME Study : Fractional Flow Reserve Versus Angiography in Multivessel Evaluation. Journal of the American College of Cardiology, 2010, 55(25):2816-21
3. Fearon WF. FAME 2 Cost-effectiveness: A Prospective, Randomized Trial Evaluating the Cost-effectiveness of FFR-Guided PCI in Patients with Stable Coronary Artery Disease Presented at Late Breaking Clinical Trials 1 at TCT 2012, Miami, Florida, October 24, 2012.
4. De Bruyne B, Pijls N, Kalesan B, et al. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. N Engl J Med. 2012;367(11):991-1001.
5. 2018 ESC/EACTS Guidelines on myocardial revascularization： The Task Force on myocardial revascularization of the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS). European Heart Journal (2019) 40, 87–165
6. Kushner FG, hand M, smith sC Jr, et al. 2009 focused updates: aCC/aha guidelines for the management of patients with st-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and aCC/aha/sCaI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update)
7. Jelmer Westra,Diagnostic Accuracy of On-line Quantitative Flow Ratio Functional Assessment by Virtual Online Reconstruction: FAVOR 2 Europe-Japan,2017.
8. Jianping Li, Huo Yong, Ziad Ali et.al. Accuracy of computational pressure-fluid dynamics applied to coronary angiography to derive fractional flow reserve: FLASH FFR European Society of Cardiology:Cardiovasc Res. 2019 Nov 5. pii: cvz289. doi: 10.1093/cvr/cvz289

Please check with your RainMed Medical representative for product availability in your country.
Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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INTRODUCING

FlashAngio™ caFFR™

Novel Platform for Coronary Physiologic Guidance

RainMed

caFFR™

New approach getting precision FFR

Empowering Guidance

- Used for more applications easier than ever
- Adjusted based on Medina bifurcation classification
- Simplified Multivessels interrogation

Superior Accuracy

Accuracy Comparison	Rainmed CAFFR	Cathworks FFRangio	Medis QFR
	95.7%[8]	**92%**	**86%**[7]

89.9% accuracy when FFR between 0.75 - 0.85

Integrated Workflow

- Non Invasive, No adenosine
- Liberate Cardiologists to more comprehensive vision with Physicians/Assitants help

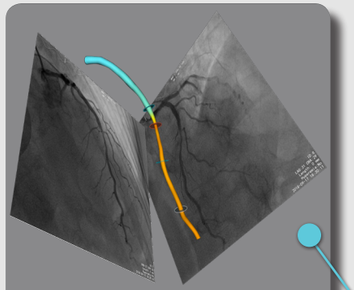
Free Up Your Time

- Dedicated designed CFD algorithm offers accurate resolution to Navier–Stokes formula in 10 seconds

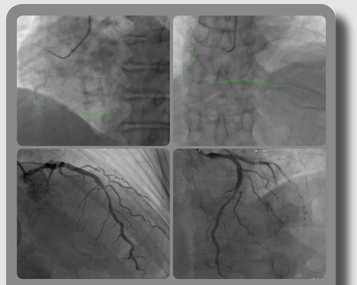
RainMed

caFFR™

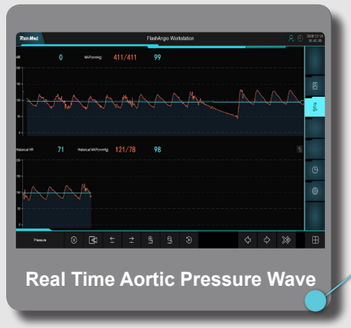
A Milestone of FFR Measurement



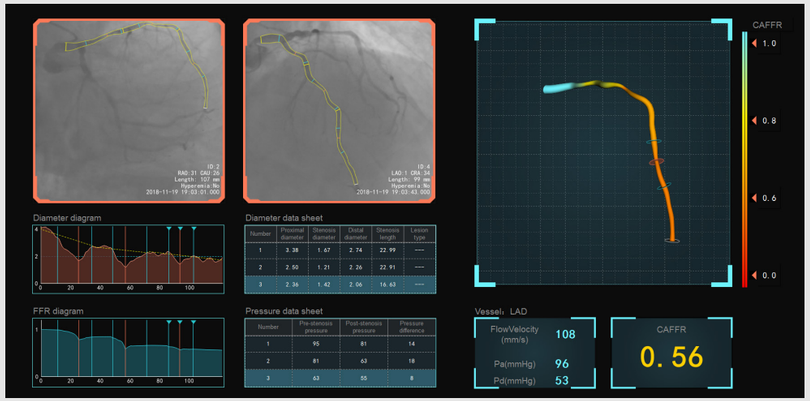
Vessel 3D Reconstruction



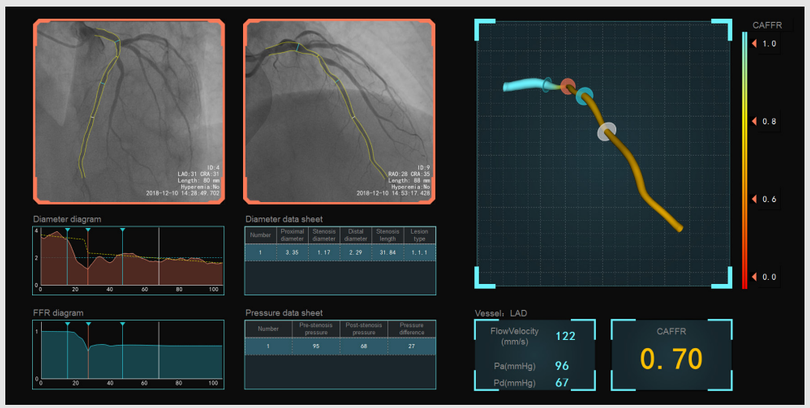
TIMI Frame Blood Flow Velocity



Real Time Aortic Pressure Wave



Multiple Lesions



Bifurcation Lesion

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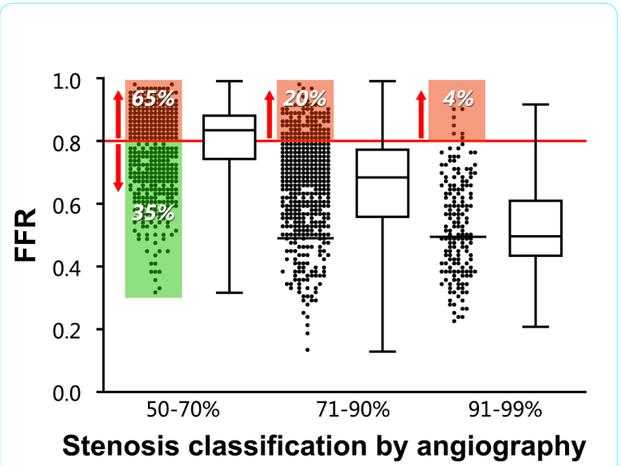
Physiology-guide Revascularizaiton Decision Making

FAME & FAME Ⅱ

- Allows more accurate identification of hemodynamically relevant stenosis.[1]
- Reduces mortality and myocardial infarction by 34% at two years.[2]
- The MACE happened to FFR-guided PCI group were significantly lower than the medical therapy group.[3-4]
- 86% relative reduction in the risk for ACS requiring unplanned hospital readmission with urgent revascularization.
- Cost-effectiveness-ICER of $32,000 per QALY.



Study Result

- Patients with moderate stenosis (50-70% Stenosis) . 1/3 of them will be ignored if by angiography alone.
- Patients with severe stenosis (>70% Stenosis). 20% of them might be over-treated if decided by angiography alone.

Supported By Guidelines

- FFR is awarded the highest level of evidence, Class I, level of Evidence a, by the European society of Cardiology (ESC) and the European association for Cardio-thoracic surgery (EACTS).[5]
- The ACC/AHA/SCAI guidelines are Class II a, level of Evidence a, for determining whether PCI of a specific coronary lesion is warranted.[6]

ESC European Society of Cardiology
Cardiovascular Research
doi:10.1093/cvr/cvz289

Accuracy of computational pressure-fluid dynamics applied to coronary angiography to derive fractional flow reserve: FLASH FFR

Jianping Li[1†], Yanjun Gong[1†], Weimin Wang[2], Qing Yang[3], Bin Liu[4], Yuan Lu[5], Yawei Xu[6], Yunlong Huo[7*], Tieci Yi[1], Jian Liu[2], Yongle Li[3], Shaopeng Xu[3], Lei Zhao[4], Ziad A. Ali[8,9,10], and Yong Huo[1*]

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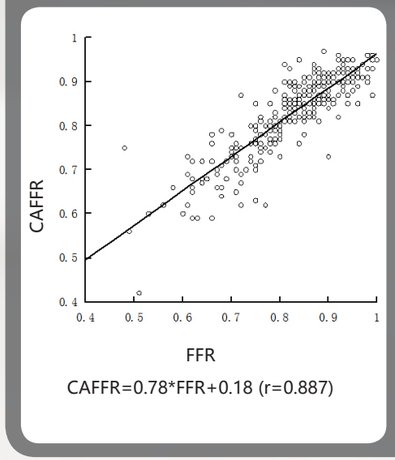
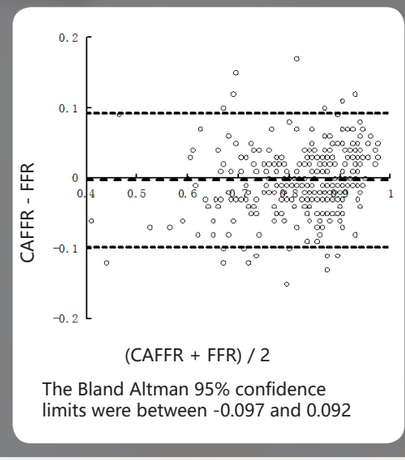
Diagnostic Characteristics of caFFR

All Interrogated Vessel No.	328
Diagnostic accuracy	95.7 %
Sensitivity	90.4 %
Specificity	98.6 %
Positive Predictive Value	97.2 %
Negative Predictive Value	95.0 %

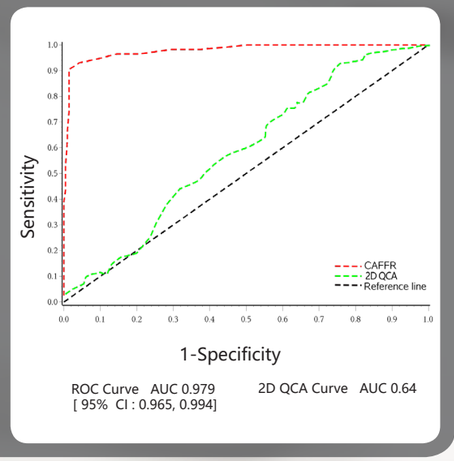
Relevance and Consistency of CAFFR and FFR



CAFFR=0.78*FFR+0.18 (r=0.887)



The Bland Altman 95% confidence limits were between -0.097 and 0.092



ROC Curve AUC 0.979
[95% CI : 0.965, 0.994]

2D QCA Curve AUC 0.64

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