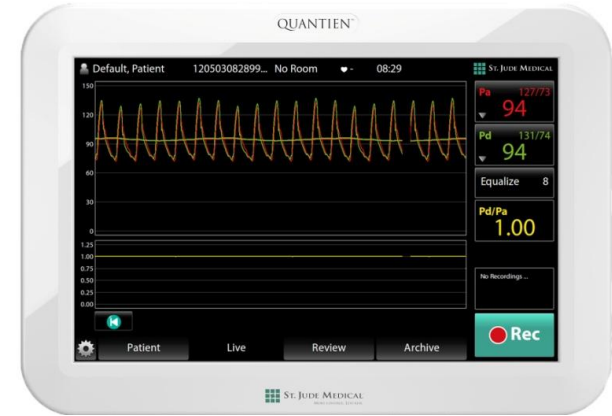


Introducing

QUANTIEN™

Integrated FFR Platform



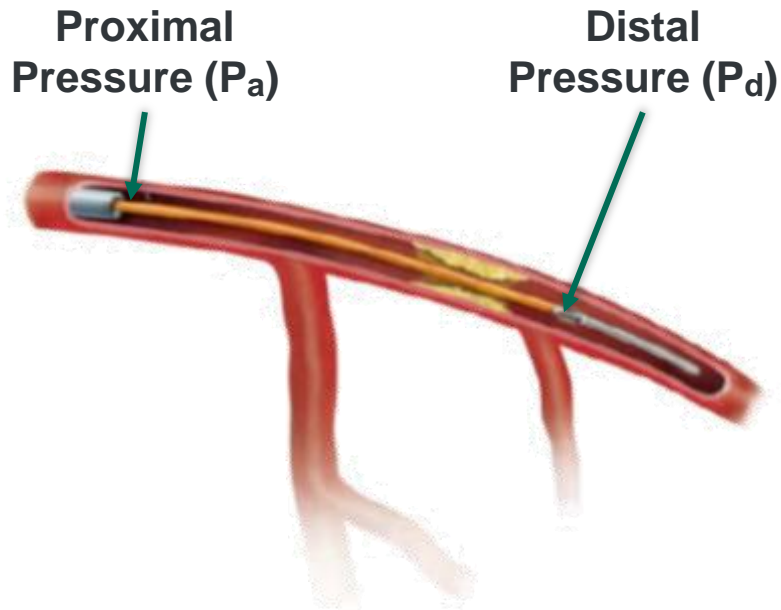
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Fractional Flow Reserve (FFR)

Definition of FFR

Maximum achievable blood flow in stenotic coronary artery divided by maximum blood flow in the same artery without stenosis.

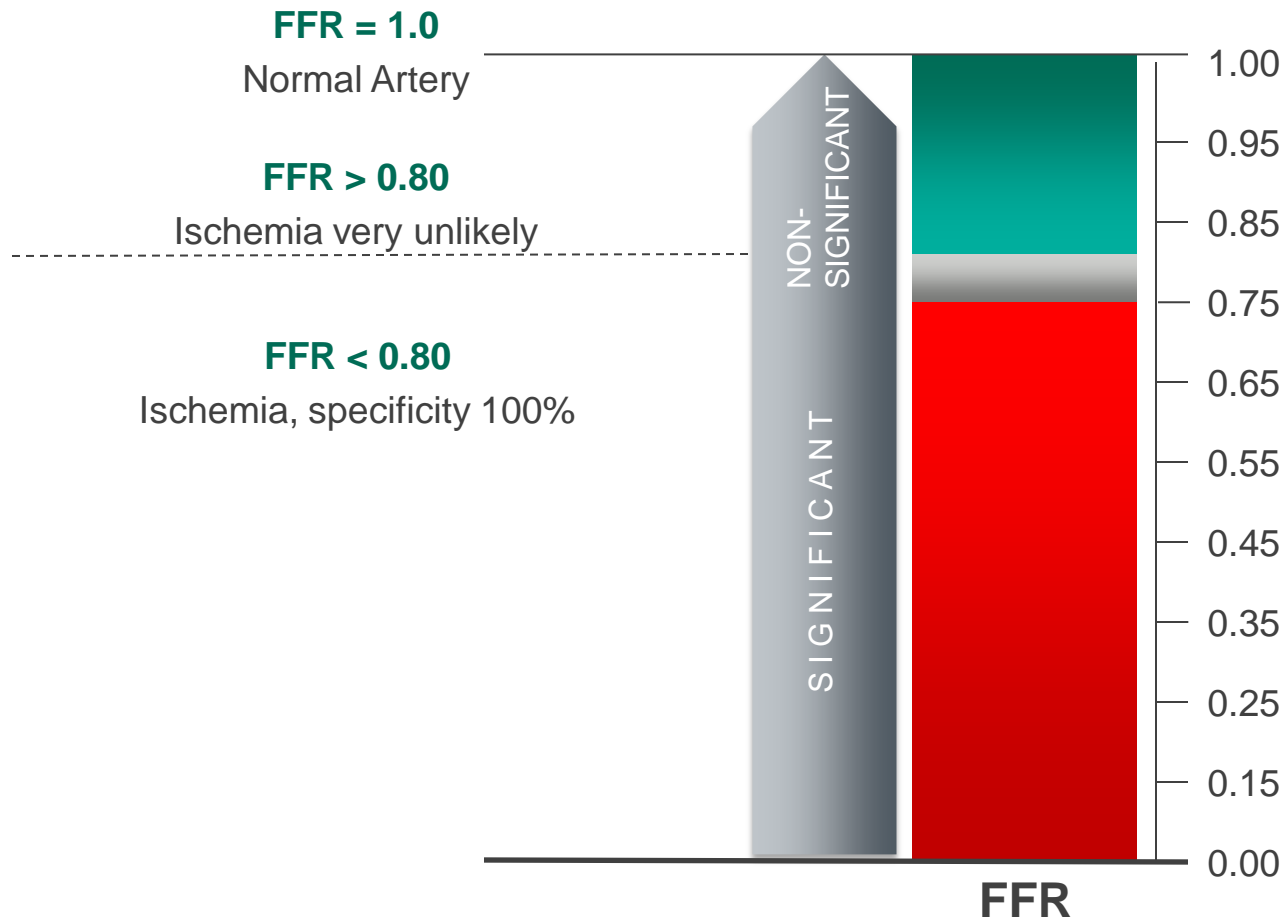


$$\text{FFR} = \frac{\text{Distal Pressure (} P_d \text{)}}{\text{Proximal Pressure (} P_a \text{)}}$$

(During Maximum Hyperemia)

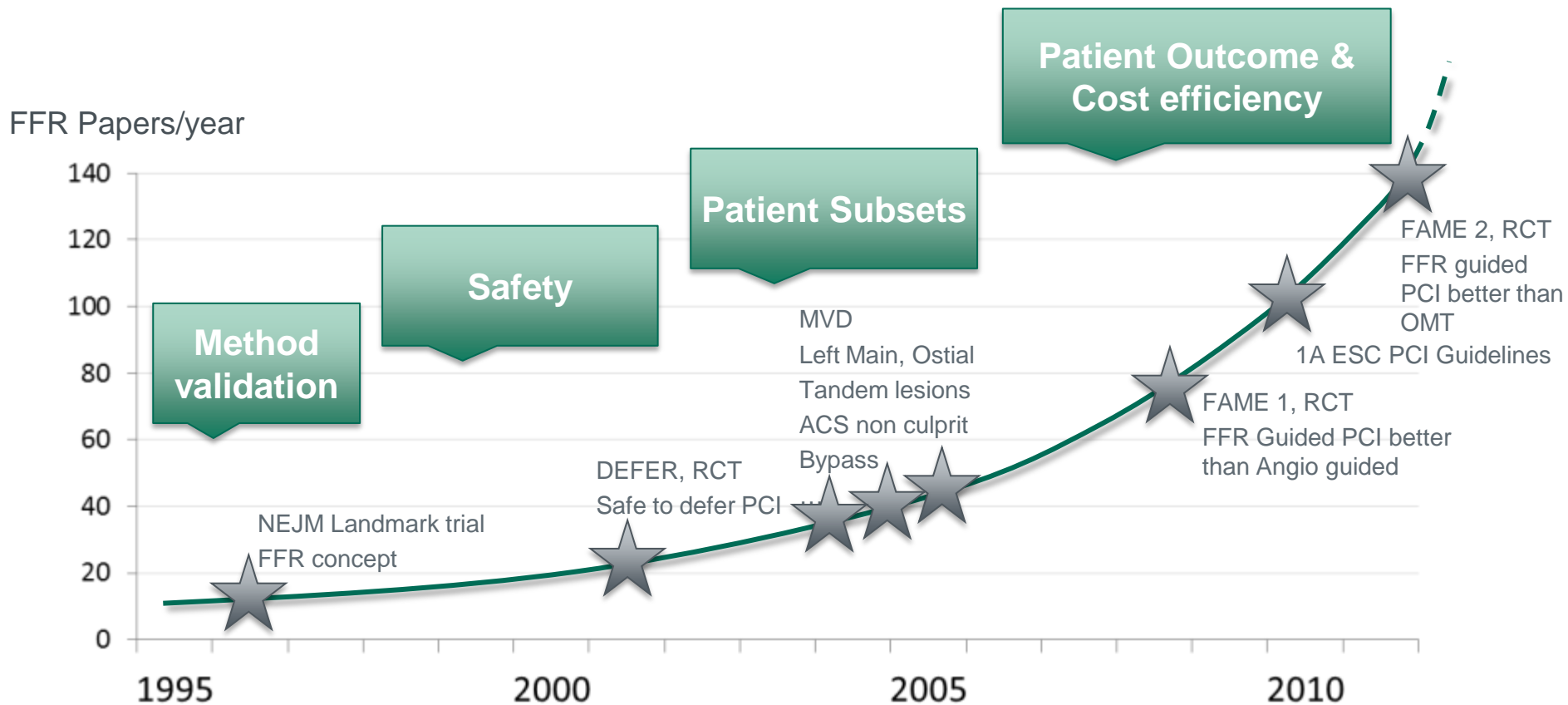


FFR Correlation to Ischemia



Pijls NH, De Bruyne B, Peels K, et al. Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenoses. *N Engl J Med.* 1996;334(26):1703-8.

FFR – A History of Gradual and Strategic Method Development



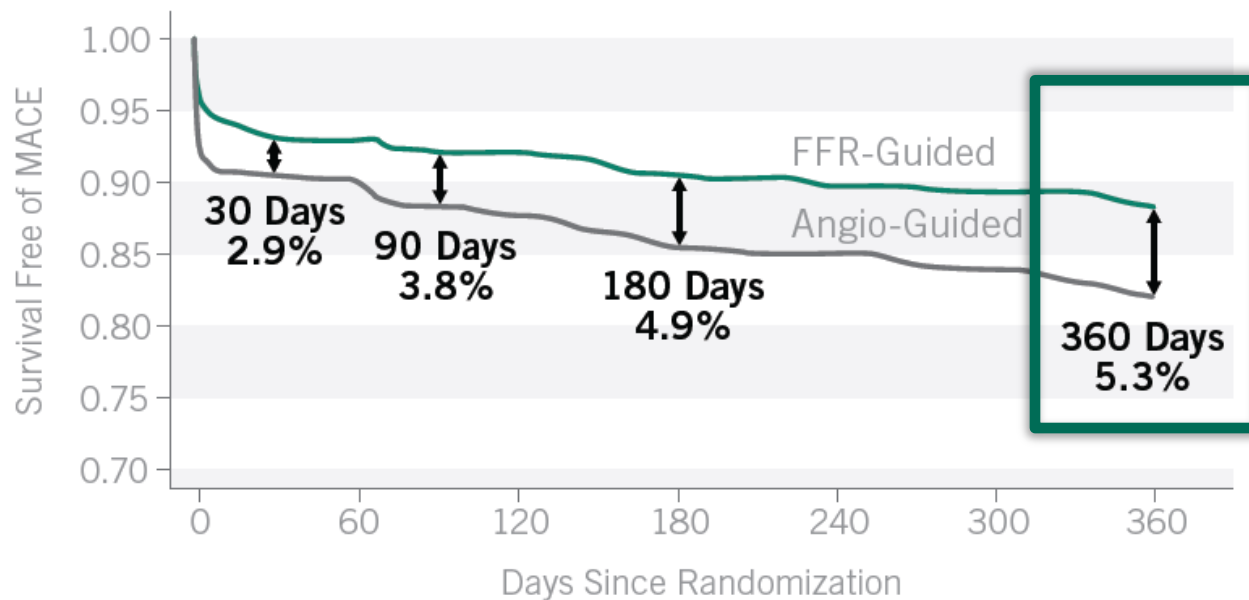
FAME 1: PCI-Guided FFR Vs. Angio Guided Only

Prospective randomized multi-center study, patients with multi-vessel disease. As compared to Angio guided only, FFR Guided PCI resulted in:

-28% Reduced composite rate of death, MI and repeat revascularization

-34% Relative reduction in mortality and MI

FFR Guided PCI was additionally found to save costs without increasing procedure time



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.



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FAME 2: FFR Guided PCI Vs. Medical Therapy

Prospective randomized multi-center study with patients with stable coronary artery disease. As compared to medical therapy only, FFR Guided PCI plus medical therapy resulted in:




-86% Relative Risk Reduction for Urgent Revascularization

Event	FFR-Guided PCI+MT (%, n=447)	MT Alone (%, n=441)	P-Value
Primary Endpoint	4.3	12.7	<0.001
▪ Death	0.2	0.7	0.31
▪ Myocardial Infarction	3.4	3.2	0.89
▪ Urgent Revascularization	1.6	11.1	<0.001
Free from Angina (1 month)	71	48	<0.001

De Bruyne, et al. New Engl J Med 2012;367:991-1001

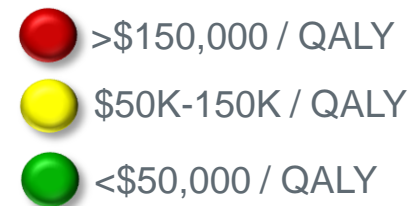
Cost-Effectiveness FAME 1 & FAME 2

- FAME 1 showed that FFR both improves patient outcome and lower procedural costs - FFR is cost saving when used to guide PCI in MVD.
- FAME 2 demonstrated that angina and quality of life are significantly improved by FFR-Guided PCI as compared to medical therapy and that FFR Guided PCI is cost efficient with ICER \$32,000/QALY.

Study	Comparators	Cost Efficiency Ratio	Result
COURAGE	Angio-Guided PCI vs Medical Therapy	≥ \$168,000 / QALY	
FAME 1	Angio-Guided PCI vs FFR-Guided PCI	FFR-Guided PCI is Dominant (Reduces cost AND Increases QALY)	
FAME 2	FFR-Guided PCI vs Medical Therapy	\$32,000 / QALY	

Cost Efficiency Benchmarks:

- Hemodialysis ≈ \$50,000 / QALY
- WHO GDP std ≈ \$150,000 / QALY

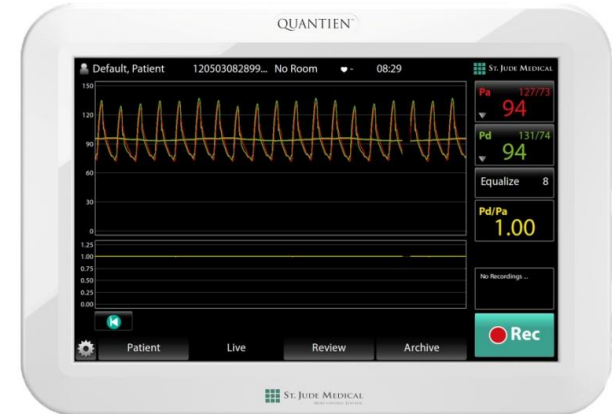


Fearon et.al TCT 2012

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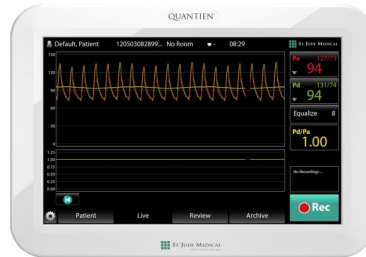


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SJM PCI Optimization Portfolio

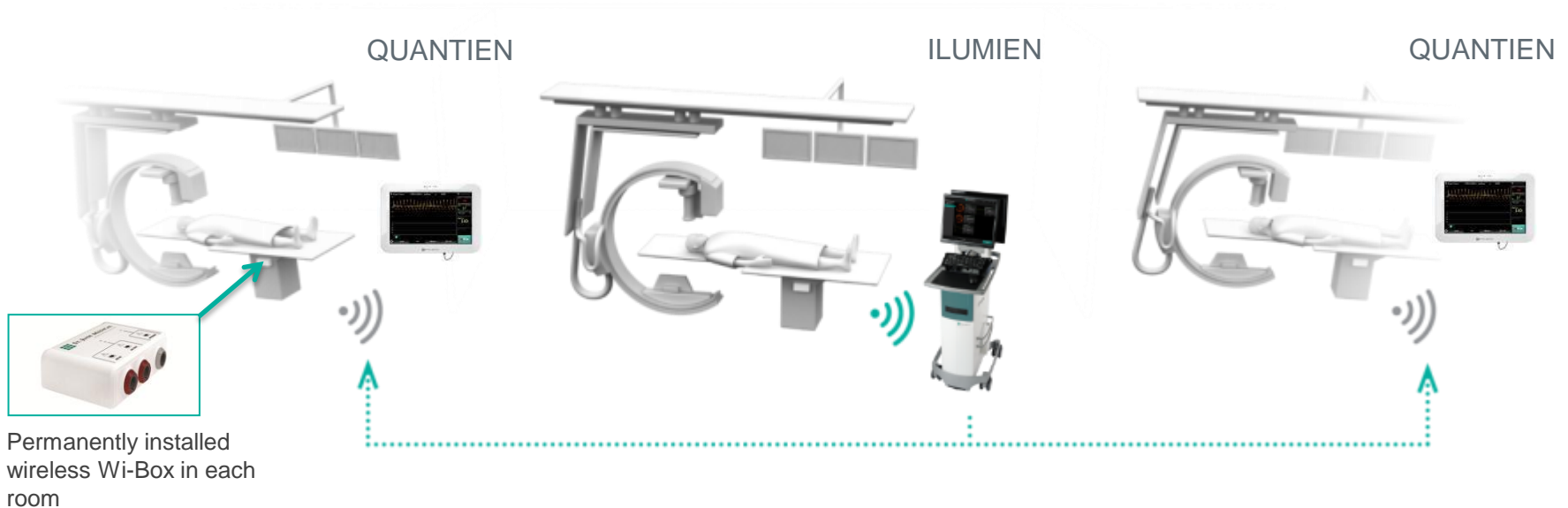
- FFR/OCT Solutions for all cathlab configurations and needs
- Integrated or Mobile configuration
- Wireless connectivity



	QUANTIEN™	ILUMIEN™
PressureWire™ Receiver™	QUANTIEN™ Wi-Box™ AO Interface	OCT Wi-Box AO Interface
Wireless FFR	Wireless FFR	Wireless FFR
Integrated	Integrated/Mobile	Mobile

All Room FFR/OCT Coverage

- Wi-Box Wireless Connectivity
- System inter compatibility gives flexible all room coverage
- Room Integration or Mobile Integration™



QUANTIEN – Wireless FFR Integration

Flexible Lab Integration

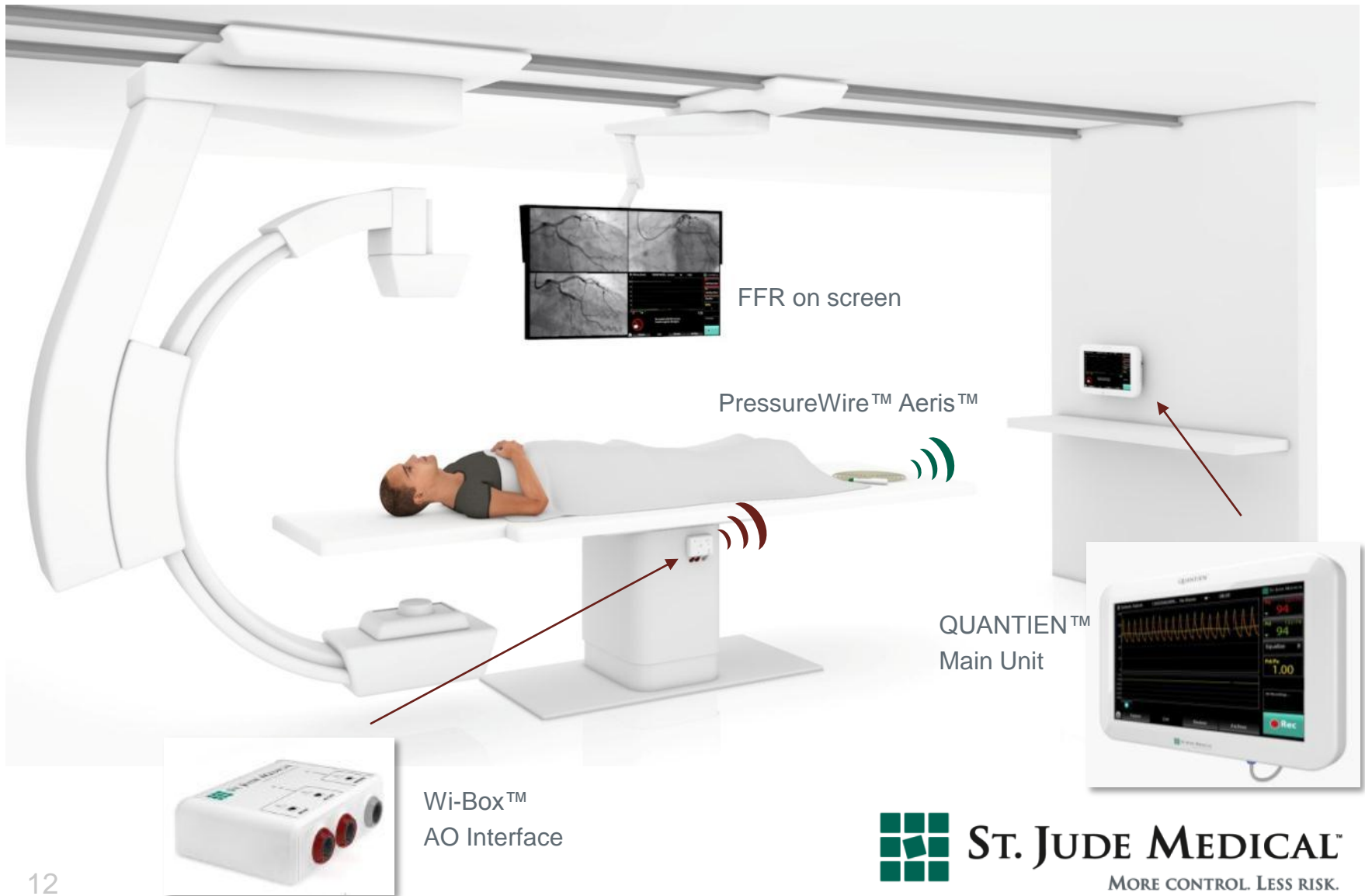
Wireless Connectivity

Hospital Data Integration

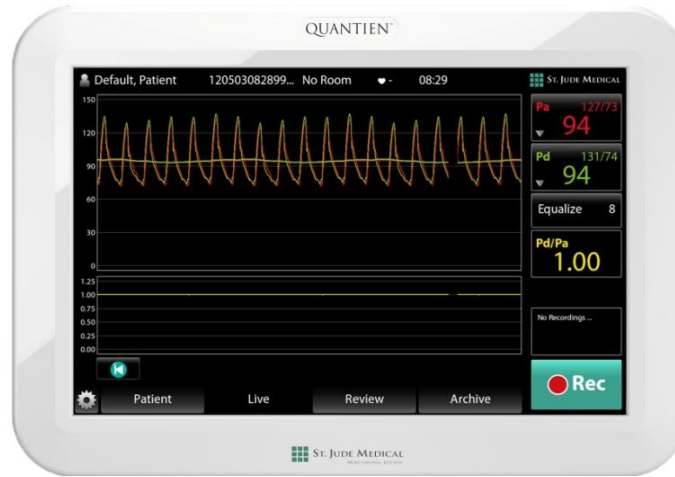
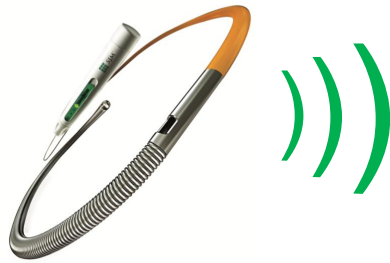
Fast & Easy Workflow



QUANTIEN – Wireless FFR Integration

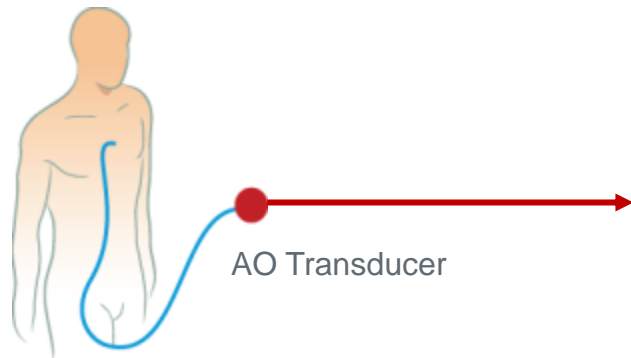


QUANTIEN System Components



QUANTIEN

PressureWire Aeris (Wireless)
PressureWire™ Certus™ (Wired)



Hemodynamic Recording System



Flexible Lab Integration

- Quick Installation without complicated cabling and cath lab downtime.
- Only installed equipment in patient environment is Wi-Box, one per room.
- QUANTIEN main unit placed anywhere in cath lab: Desktop, Table, Wall, Mobile.
- Instrument controlled by sterile or non-sterile staff.
- Remote control and touch screen.
- QUANTIEN screen can be displayed on existing cath lab monitors through DVI interface.

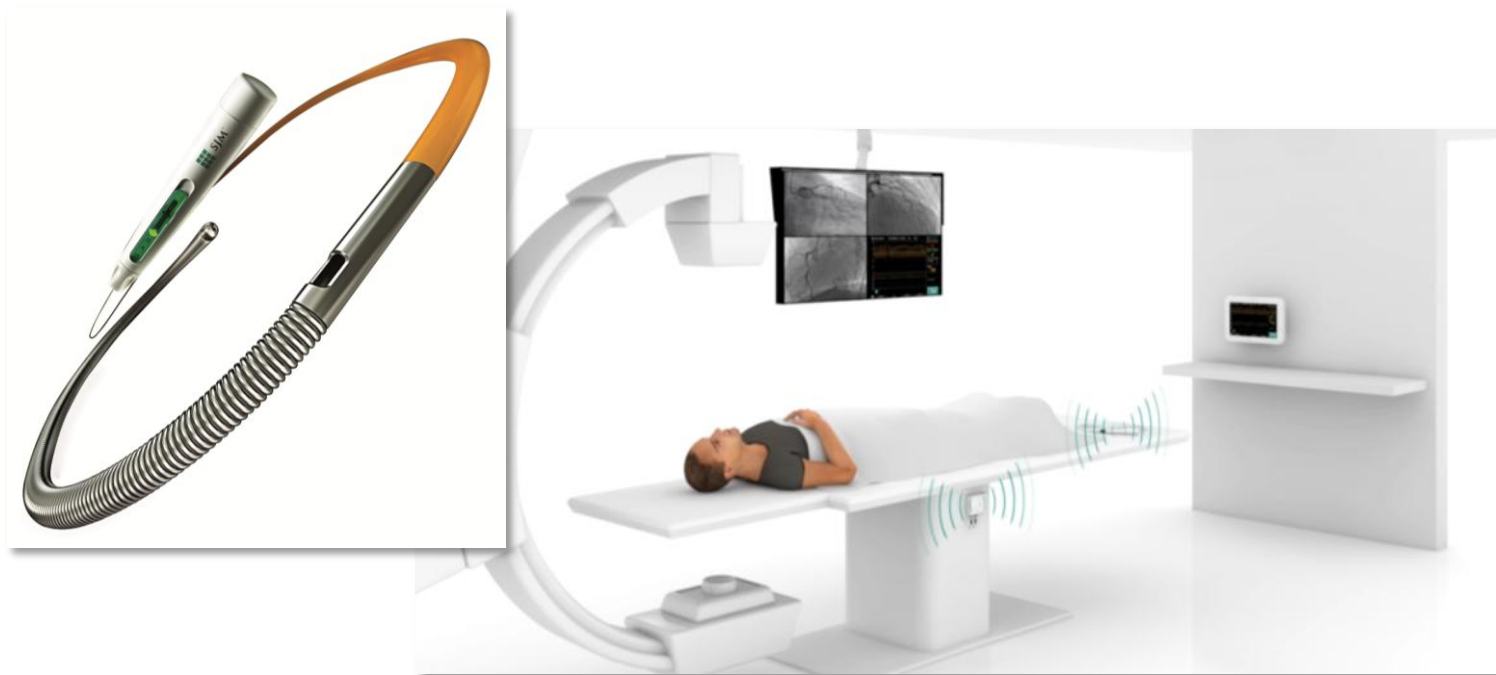


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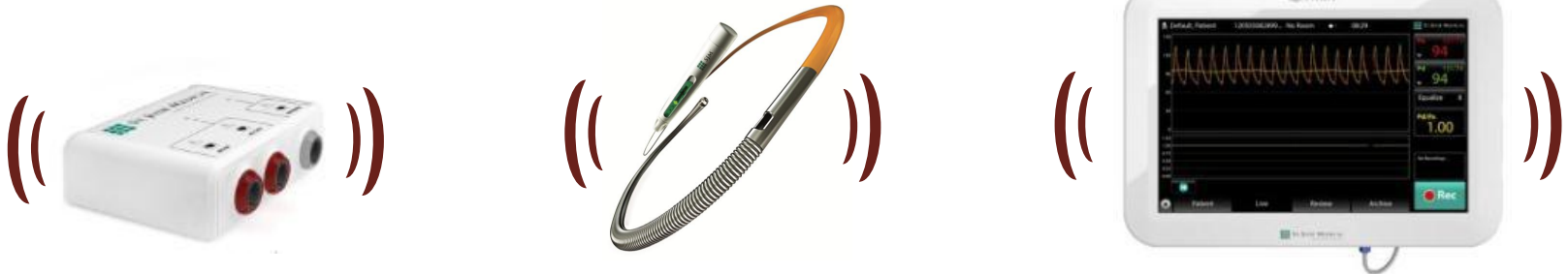
Wireless Connectivity – Free Your Lab From Cables

- Wireless patient environment for all FFR Procedures
- Clean table with no clutter of cables crossing the sterile barrier
- Wireless PressureWire AERIS – no cables limiting movement



Wireless Connectivity – Secure Communication

- QUANTIEN utilizes an advanced radio technology which gives fast, robust and secure radio communication.
- Each device locks to its receiver and is not disturbed by other devices used in the same environment.
- The system is designed not to disturb, or be disturbed by, for instance Wi-fi networks or cellular phones.
- The technology has passed all radio acceptance tests by US FCC and EU R&TTE and is well proven in cath labs around the world.



Seamless Hospital Data Integration

Patient Info



Documentation

Patient Demographics

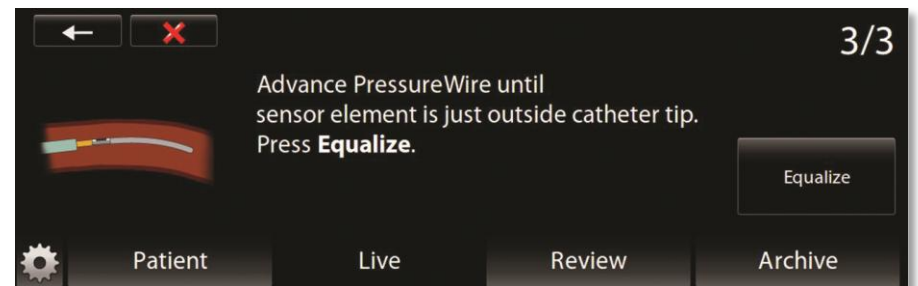
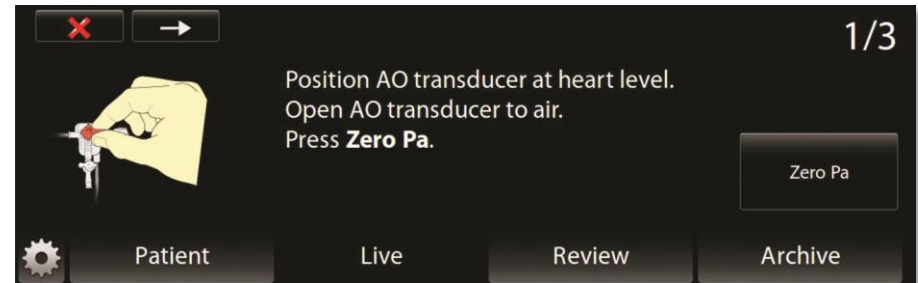
- Loaded from hospital planning system
- Select from list of scheduled patients
- Standard DICOM worklist interface

Case Documentation

- Multiple data export possibilities
- DICOM image archive with Angio
- RadiView™ for scientific analysis
- Network or USB quick export

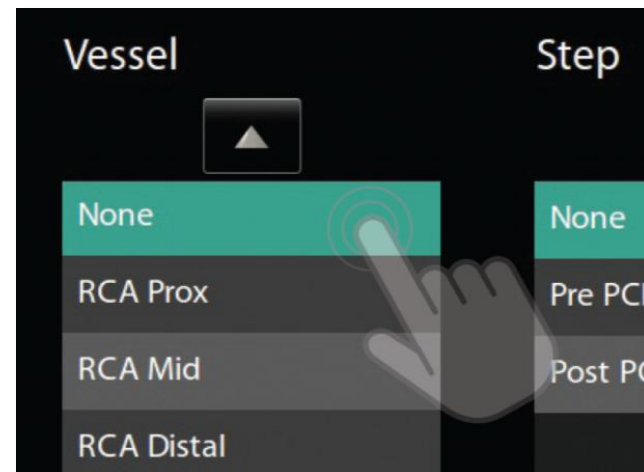
Fast and Easy FFR Workflow

- No cables to connect
- Patient data from hospital planning system
- Intuitive and illustrated step-by-step guide
- All features at your fingertips through touch screen display
- Remote control for hands-off access



Quick and Easy Case Annotation

- Annotation of Vessel/Drug/Pre/Post PCI simplifies FFR assessment and documentation of patients with multiple vessel disease.
- All settings are easily accessible through the touch screen interface.



Flexible Lab Integration

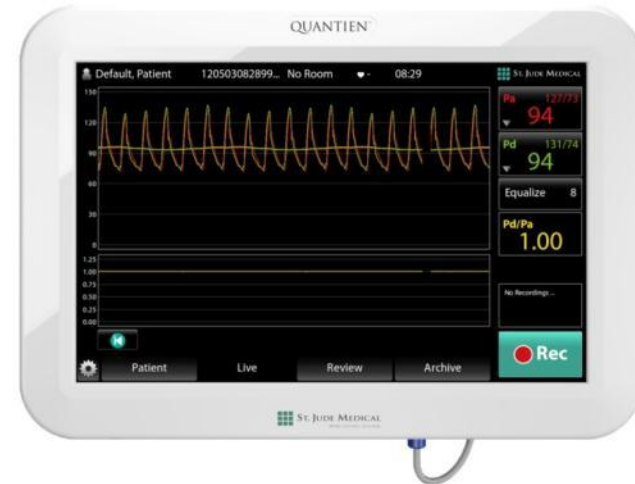
Wireless Connectivity

Hospital Data Integration

Fast & Easy Workflow

QUANTIEN

Integrated FFR Platform



Product referenced is approved for CE Mark.

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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