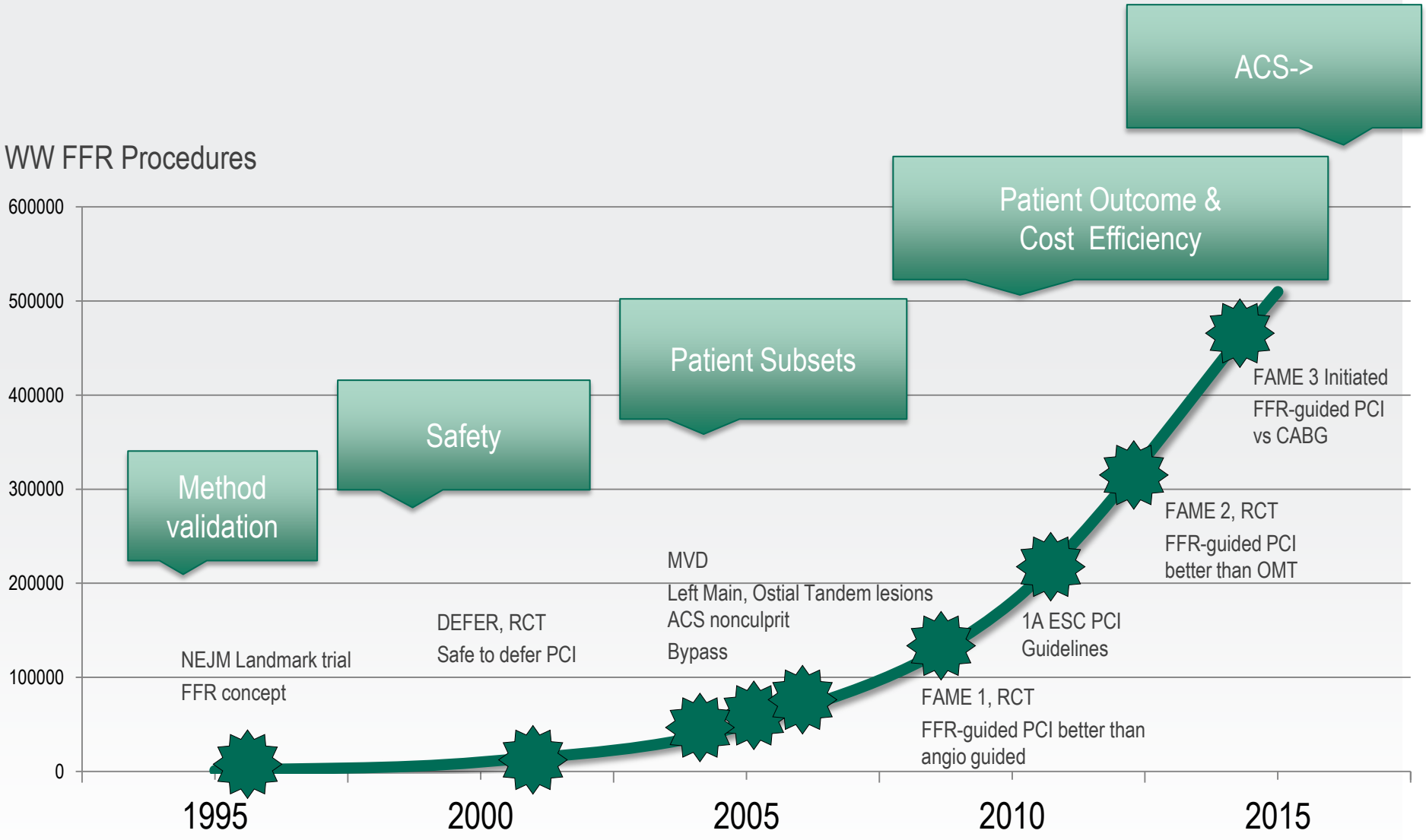
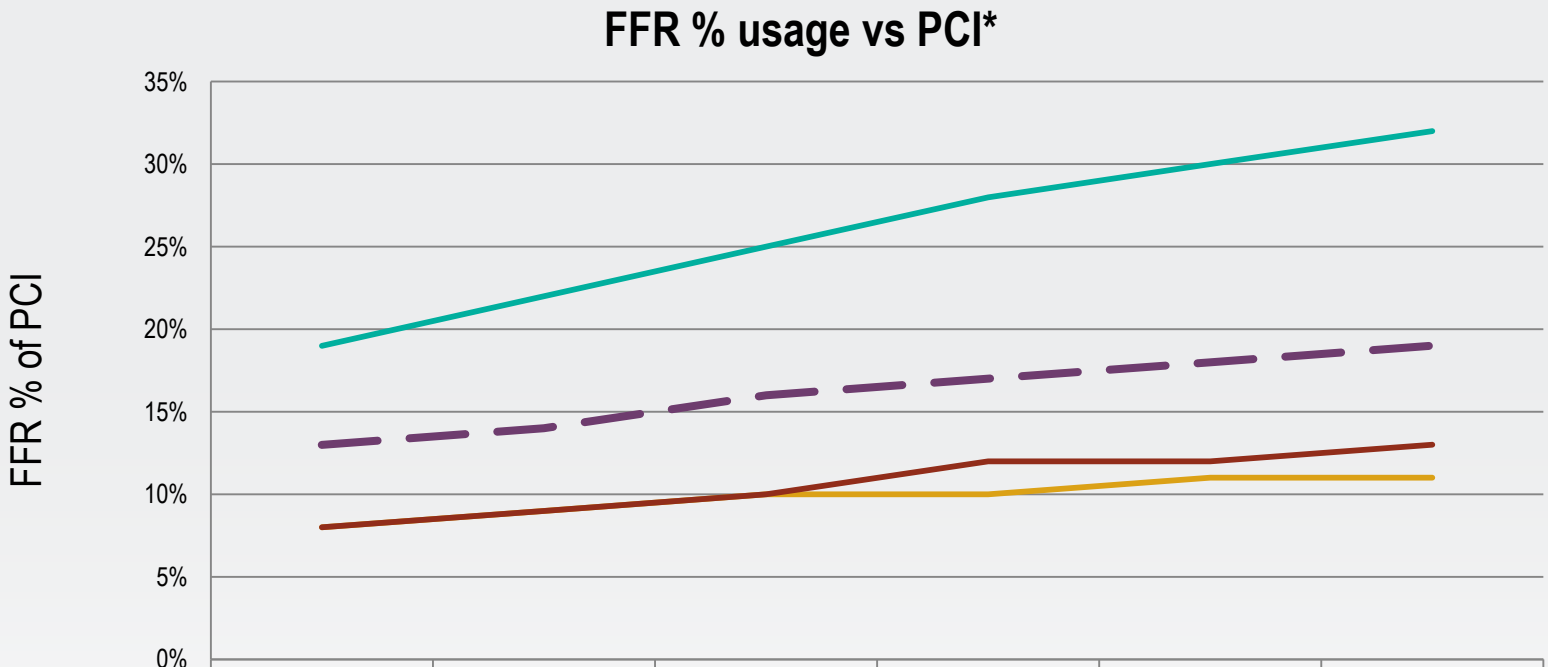
THE FUTURE IS HERE NOW, AND ITS ELECTRICAL

Johan Svanerud, St Jude Medical

FFR CLINICAL EVIDENCE DEVELOPMENT



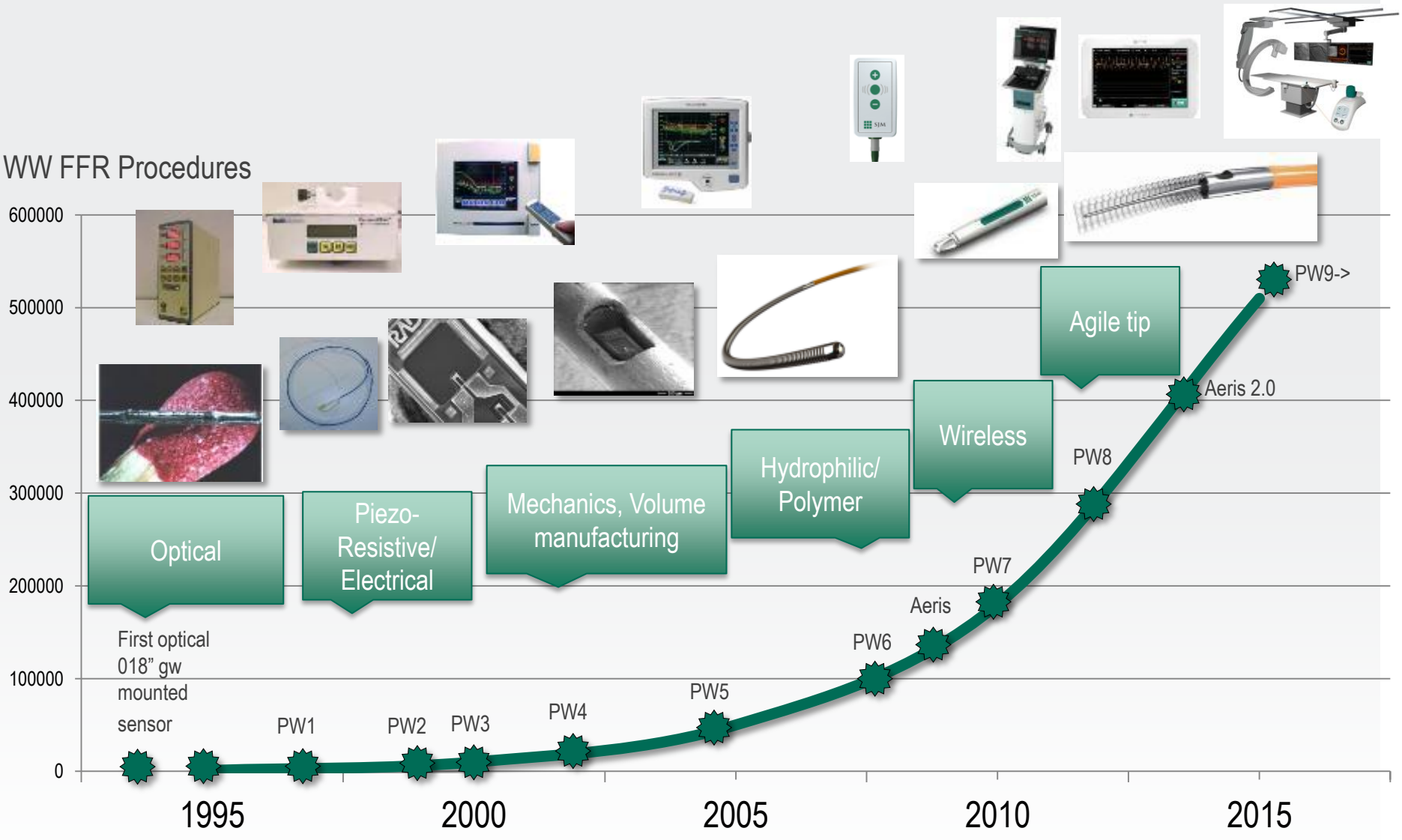
FFR USAGE IS GROWING. FAST



	2013	2014	2015	2016	2017	2018
US	19%	22%	25%	28%	30%	32%
Europe	8%	9%	10%	10%	11%	11%
Japan	8%	9%	10%	12%	12%	13%
WW (US,JPN,EU)	13%	14%	16%	17%	18%	19%

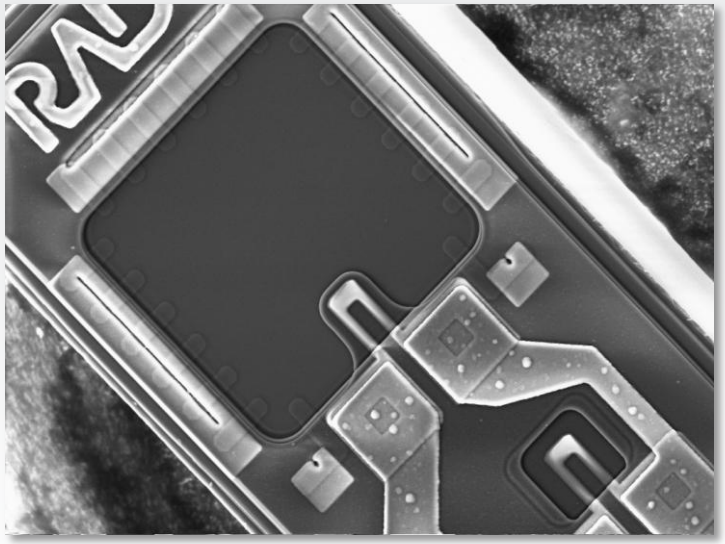
Total number of FFR Procedures divided by number of PCI
Source: Millennium Research Group (2013-2015)

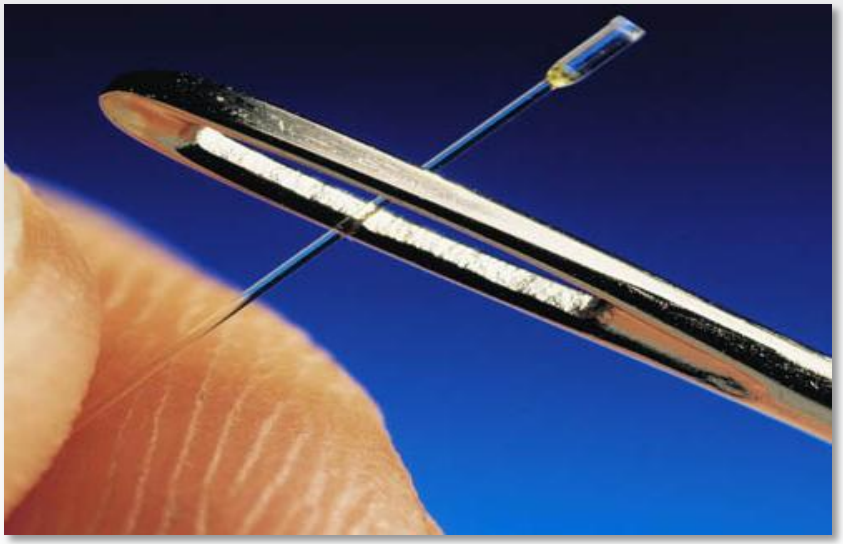
PRESSUREWIRE SYSTEM DEVELOPMENT



ELECTRICAL OR OPTICAL SENSORS?

- Emerging FFR Manufacturers (BSC, OPSENS, ACIST) All use similar optical pressure sensors
- Why does St Jude use Electrical (Piezo-Resistive) Sensors, and how are these being further developed?





1 ST JUDE'S ELECTRICAL SENSOR IS STABLE

REALLY?

- All FFR devices on the market has some level of measurement inaccuracy
- Not all vendors disclose this information publicly

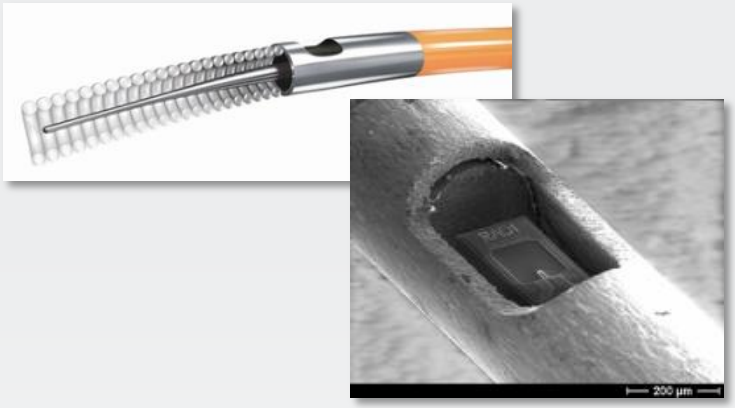
	St. Jude Medical PressureWire™ Pressure Guidewire	ACIST Navvus™ Pressure Catheter	Volcano Verrata™ Pressure Guidewire
Device	Pressure guidewire	Catheter	Pressure guidewire
Sensor technology	Piezo-resistive (Electrical)	Optical Fabry-Perot	Piezo-resistive (Electrical)
Pressure accuracy	+/-1 mmHg plus +/-3% of reading	+/-3% of reading or +/-3 mmHg, whichever is greatest	Not specified in IFU
Pressure range	-30 to 300 mmHg	-30 to 300 mmHg	Not specified in IFU
Frequency response	0-25 Hz	Not specified in IFU	Not specified in IFU
Zero thermal effect	< 0.3 mmHg/deg C	< 0.4 mmHg/deg C	Not specified in IFU
Zero drift	**< 7 mmHg/hour**	**< 7 mmHg/hour**	**Not specified in IFU Per FDA approval: <5 mmHg/10minutes**

WHAT IS THE CAUSE OF DRIFT?

Drift related to AO/Procedure

- Changing height of AO transducer
- Capillary forces in catheter
- Wedging guide in Ostium
- Needle in Y-connector
- Catheter with side-holes
- Contrast power injector

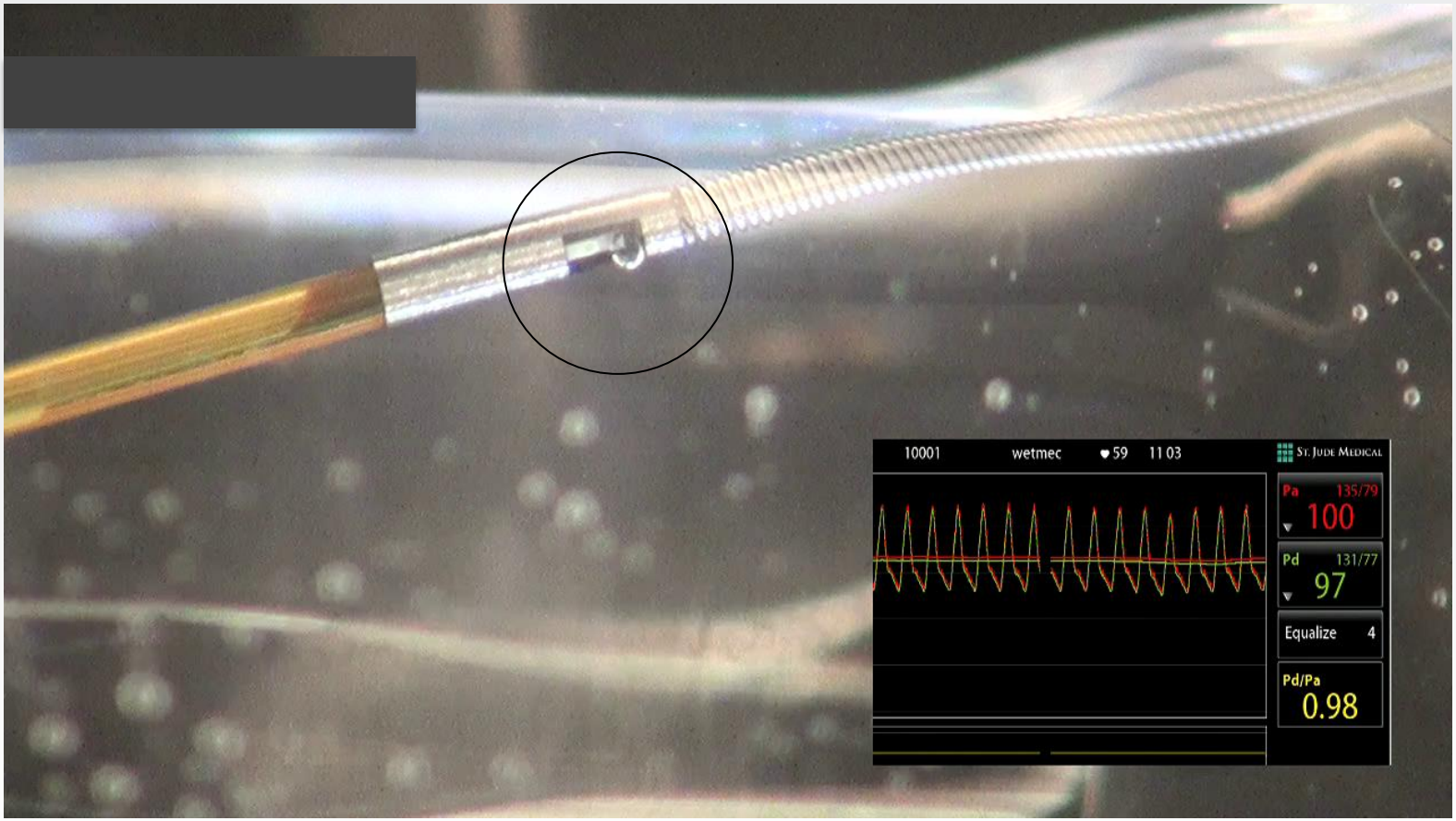
Drift related to PressureWire



- Temperature shift from room to patient
- Instrumentation calibration
- Blood/saline remnants on connector
- Microscopic-air bubbles trapped inside sensor capsule

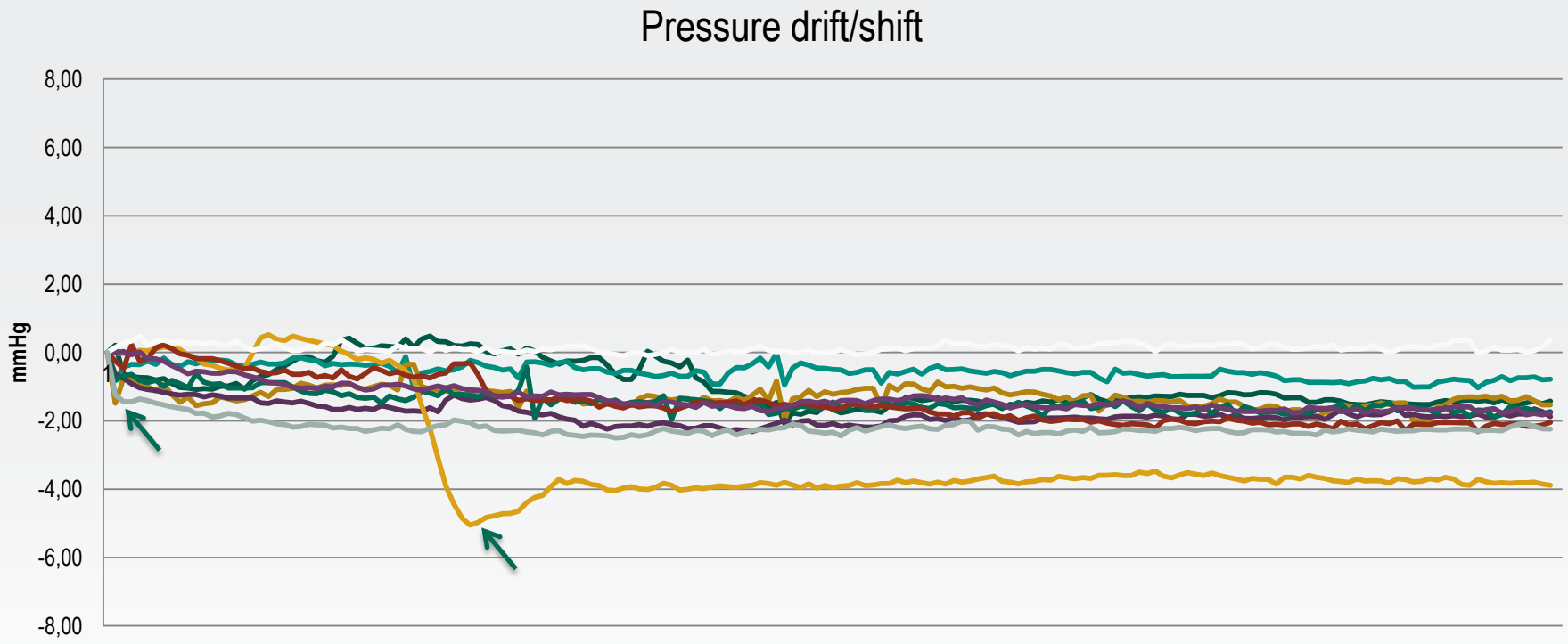
MICRO-BUBBLES?

Microscopic-volumes of encapsulated gas may cause pressure shift when dissolving from sensor housing



WHEN DO DRIFT OCCUR?

- If PW drift occurs it is most commonly early on in the procedure
- After initial pressure drift pressure measurement is normally stable



CAN WE REACH A DRIFT-FREE FFR PROCEDURE?

Improving procedure/accuracy of AO-pressure reading

- Repeated training of the cathlab staff
  - Adherence to protocol – need for standardization
- FFR Instrumentation
  - On-screen step-by-step procedure guide
  - Software automatic detecting and avoiding common artifacts/user mistakes

ST. JUDE MEDICAL™

2 ST JUDES'S ELECTRICAL SENSOR CAN BE MADE WIRELESS

WHY WIRELESS?

Ease of use

- Quick, wireless setup
- Cable free patient environment
- No cables crossing sterile barrier
- No cables to limit wire movement

WHY WIRELESS?

Accuracy

- New, calibrated, measurement electronics for every case – Accurate, no need for annual checkup or calibration
- Analog-Digital conversion at the wire – no transmission loss

WHY WIRELESS?

Flexibility

- All St Jude FFR systems share the same wireless AO source: Wi-box
- Allows a mix of Mobile or Integrated FFR/OCT systems, covering all cathlab rooms
- Minimal installation/cabling requirements

PressureWire™
Aeris

Wi-Box
AO-transmitter

PressureWire™
Receiver

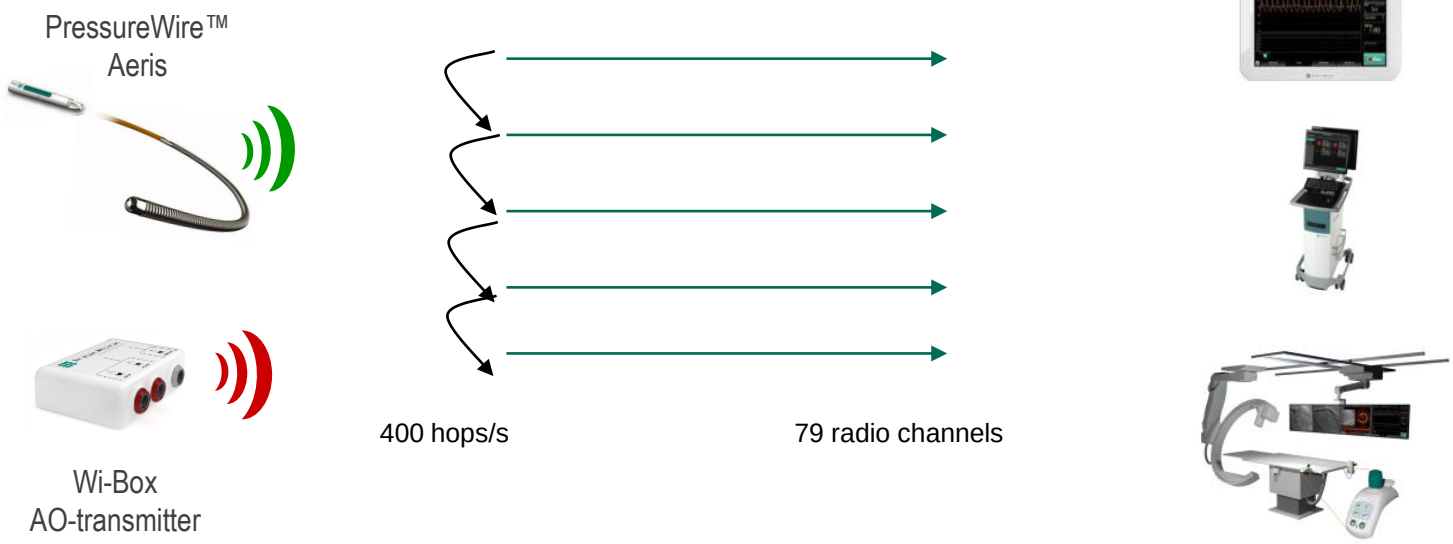
QUANTIEN™

ILUMIEN™
OPTIS™

OPTIS™
Integrated

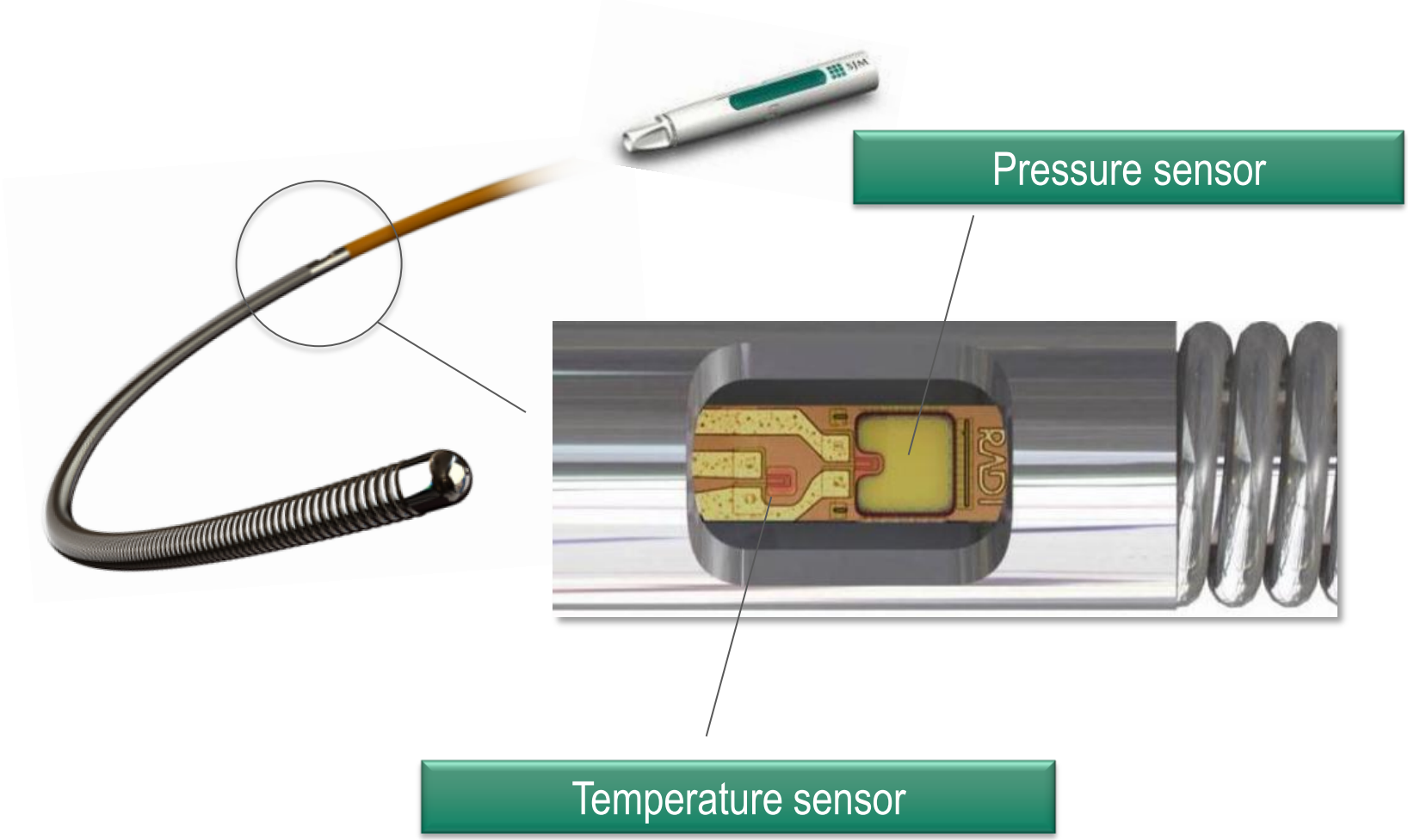
HOW DOES IT WORK?

1. Transmitters and Receivers lock to each other using unique identification codes
2. “Frequency-Hopping” technology change transmitting frequency 400 times/second
3. Stable and reliable communication also in instrumentation-packed cathlabs



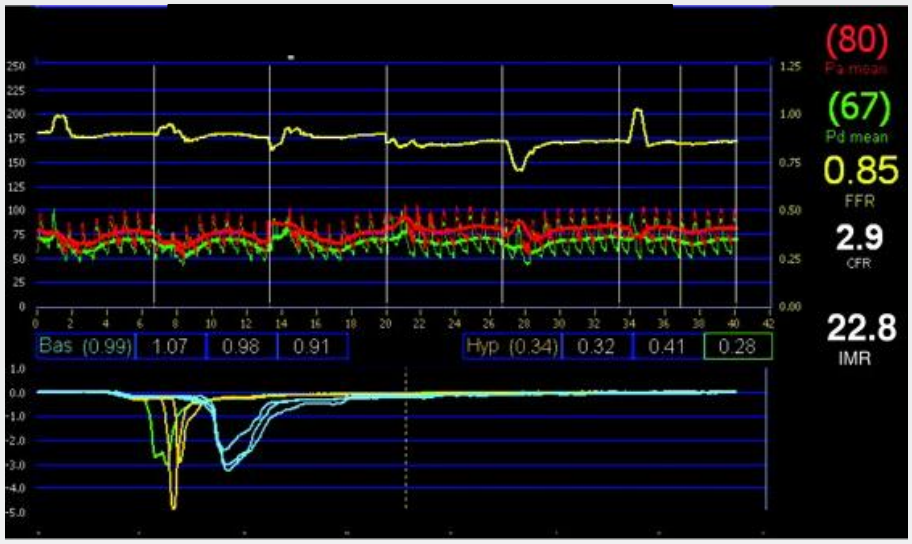
3 ST JUDE'S ELECTRICAL SENSOR CAN MEASURE FLOW

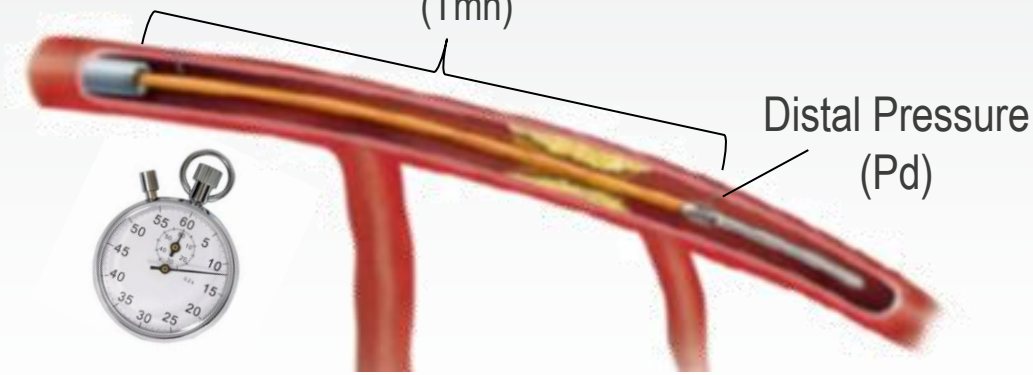
PRESSUREWIRE: PRESSURE & FLOW



HOW DO WE GET FLOW FROM TEMPERATURE?

1. THERMO-DILUTION - BOLUS





IMR - Index for microcirculatory Resistance

$$IMR = \frac{\Delta \text{ Pressure}}{\text{Flow}} = Pd \times Tmn$$

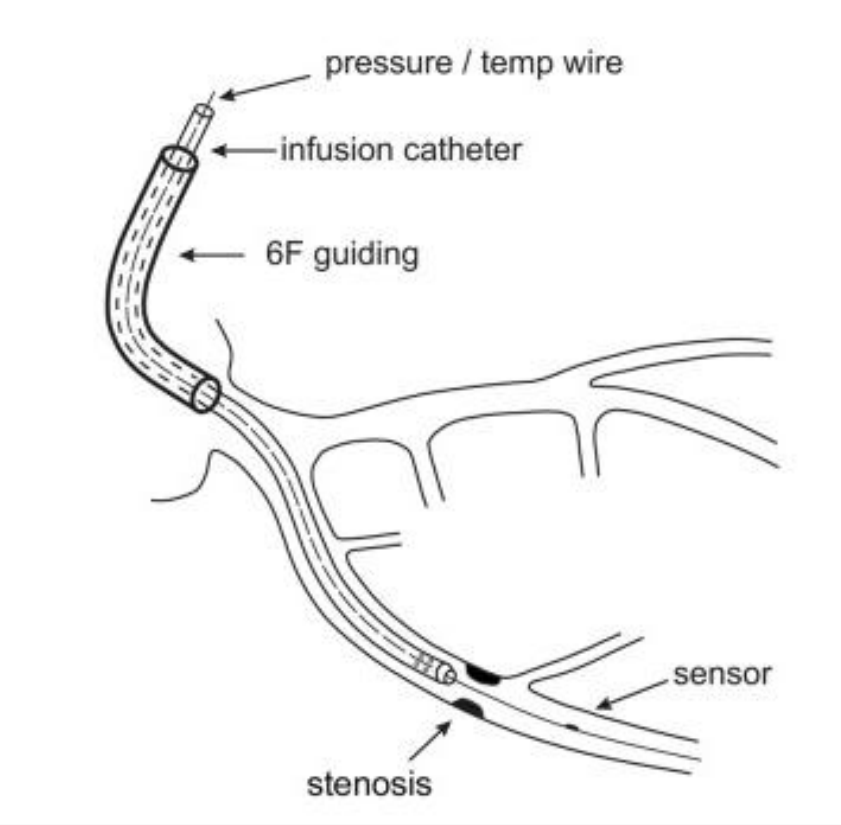
CFR – Coronary Flow Reserve

$$CFR = \frac{\text{Hyp flow}}{\text{Resting flow}} = \frac{1/Tmn\_Hyp}{1/Tmn\_Rest}$$

Novel Index for Invasively Assessing the Coronary Microcirculation, William F. Fearon, Circulation. 2003; 107: 3129-3132
Coronary Thermodilution to Assess Flow Reserve, Validation in Humans, Nico H.J. Pijls, Circulation. 2002;105:2482-2486.)

HOW DO WE GET FLOW FROM TEMPERATURE?

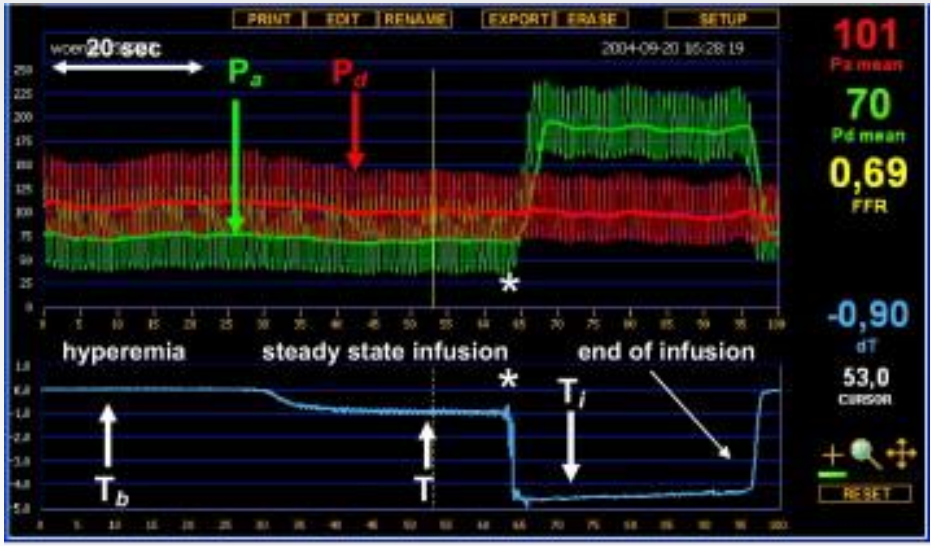
2. THERMO-DILUTION - INFUSION



Volumetric blood flow (ml/min)

Qb = Infusion.rate x (T_infusion/T_mix) x k

k=1.08

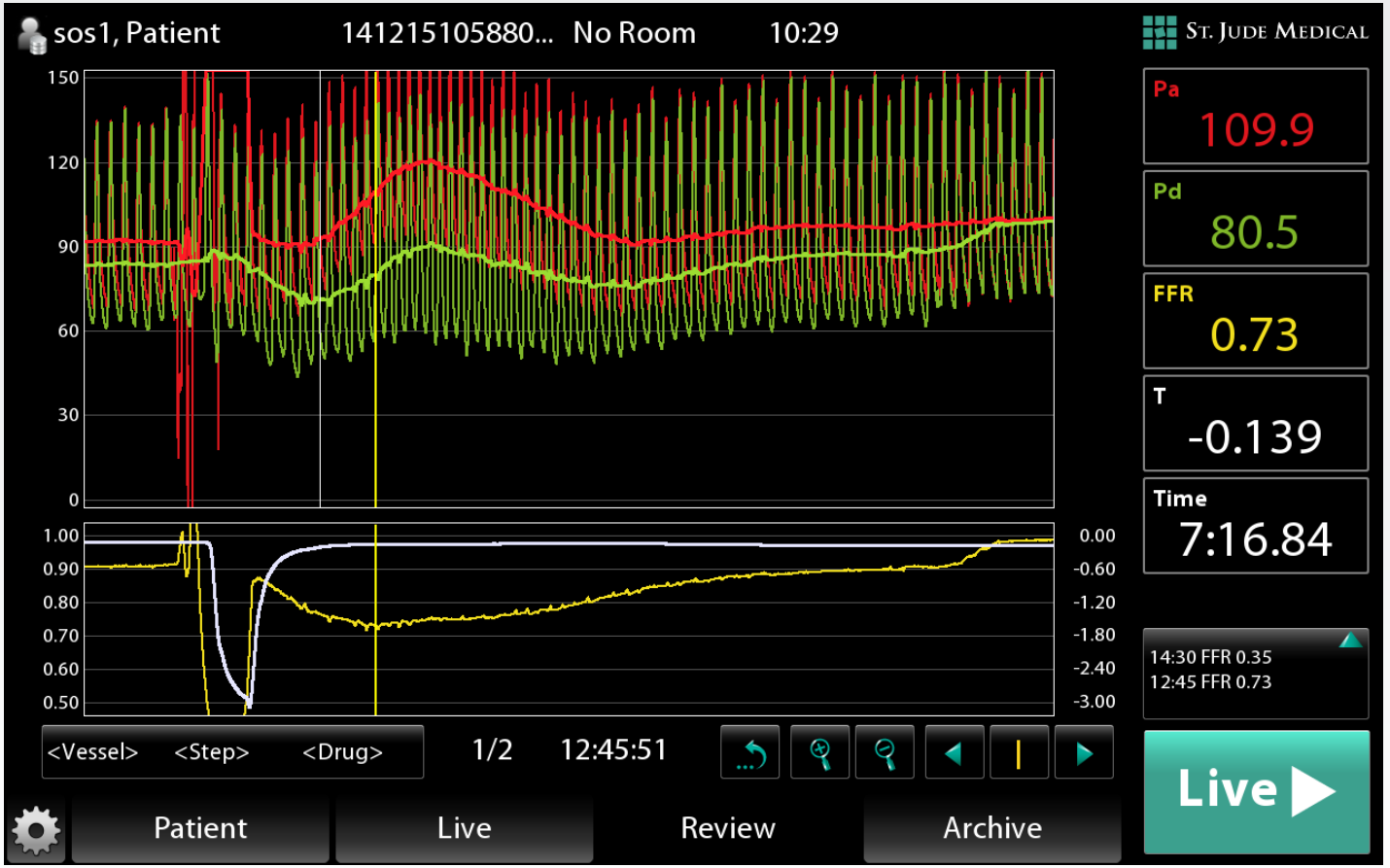


$Q_b = 15 \times (-4.5 / -0.9) \times 1.08 = 81$ ml/min

Direct Volumetric Blood Flow Measurement in Coronary Arteries by Thermodilution
Wilbert Aarnoudse et al Journal of the American College of Cardiology Volume 50, Issue 24, 11 Dec 2007, Pages 2294–2304

HOW DO WE GET FLOW FROM TEMPERATURE?

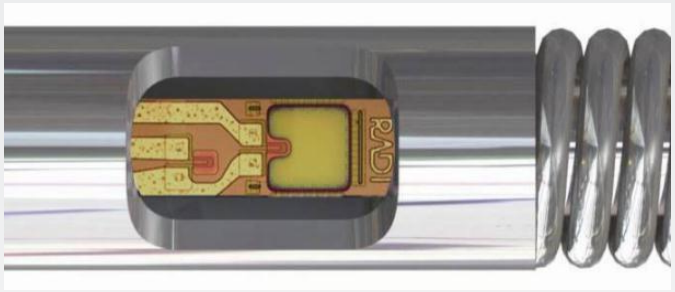
SENSOR AND CABLE TEMPERATURE FROM PW AERIS 2.0 ON QUANTIEN -WORK IN PROGRESS



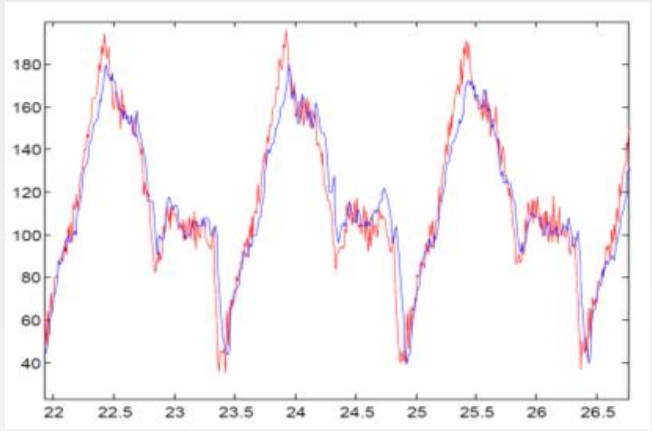
HOW DO WE GET FLOW FROM TEMPERATURE?

3. THERMO-CONVECTION FLOW VELOCITY

Elevated sensor temperature +5°C
Sensor housing +1-2°C



Blood flow cools sensor temperature proportionally to blood flow rate

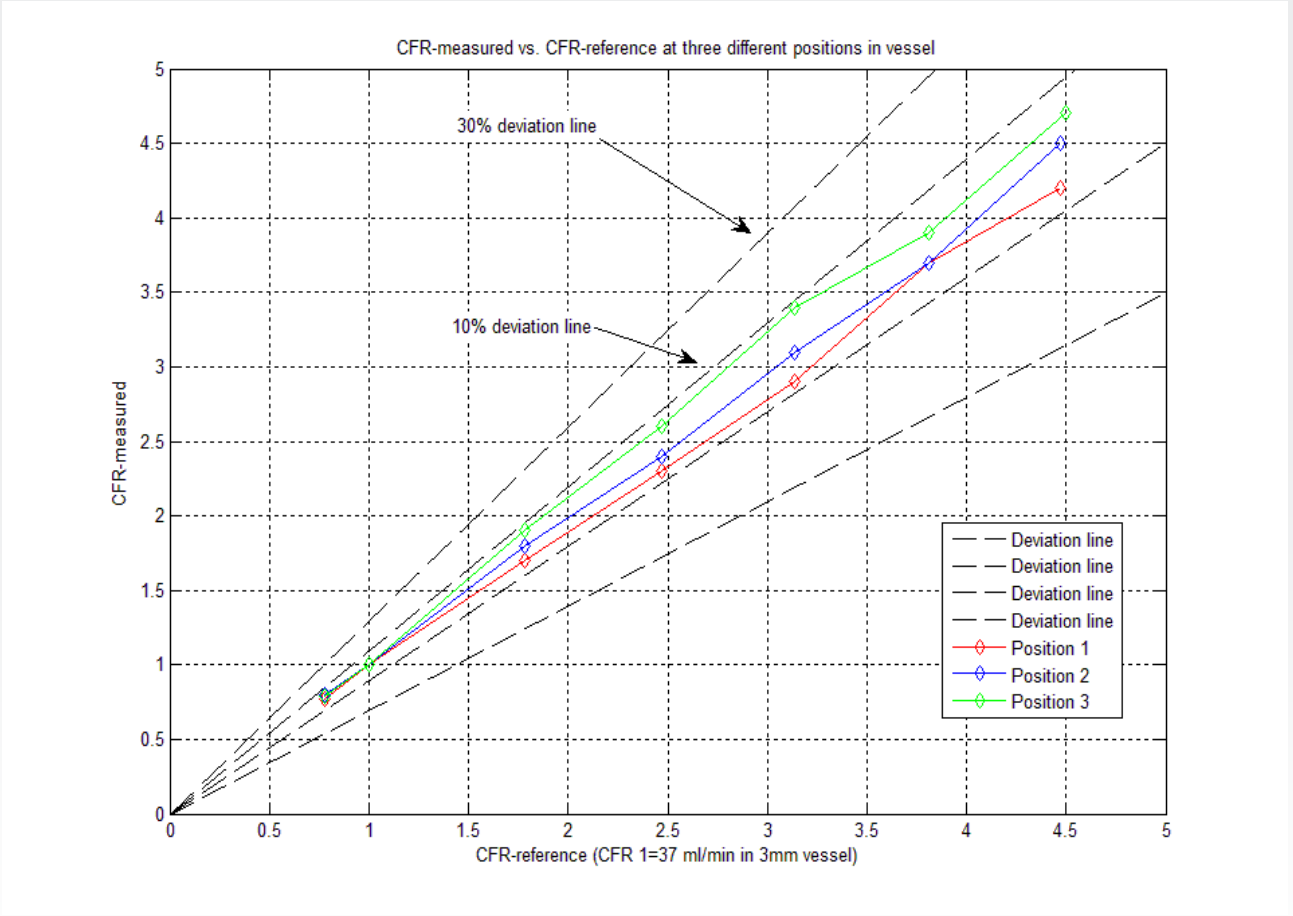


Red: Reference flow probe
Blue: PressureWire Thermo Convection flow

Internal St Jude Animal data
Thermal anemometric assessment of coronary flow reserve with a pressure-sensing guide wire: An *in vitro* evaluation.
Arjen van der Horst, Medical Engineering and Physics, July 2011 Volume 33, Issue 6, Pages 684–691

HOW DO WE GET FLOW FROM TEMPERATURE?

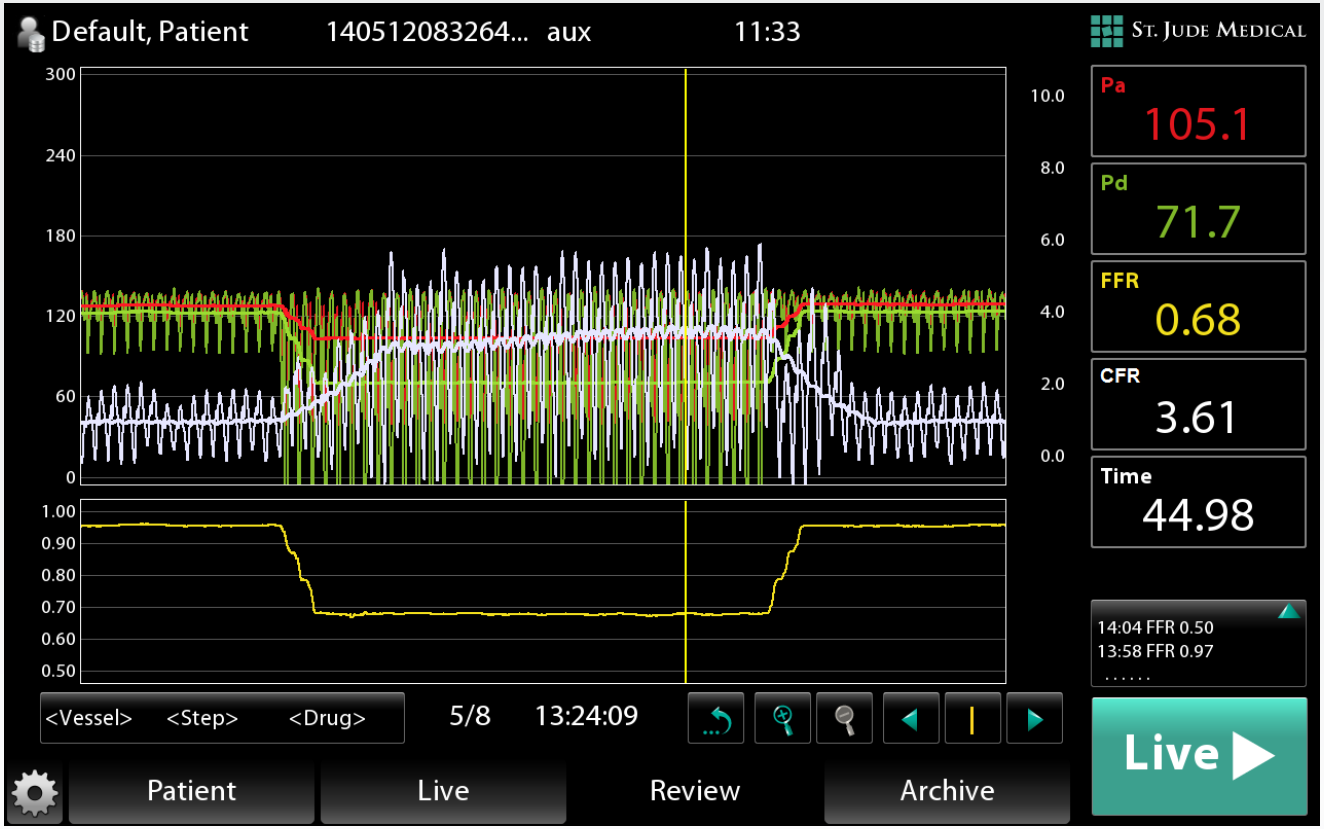
3. THERMO-CONVECTION FLOW VELOCITY



Internal St Jude in-vitro data

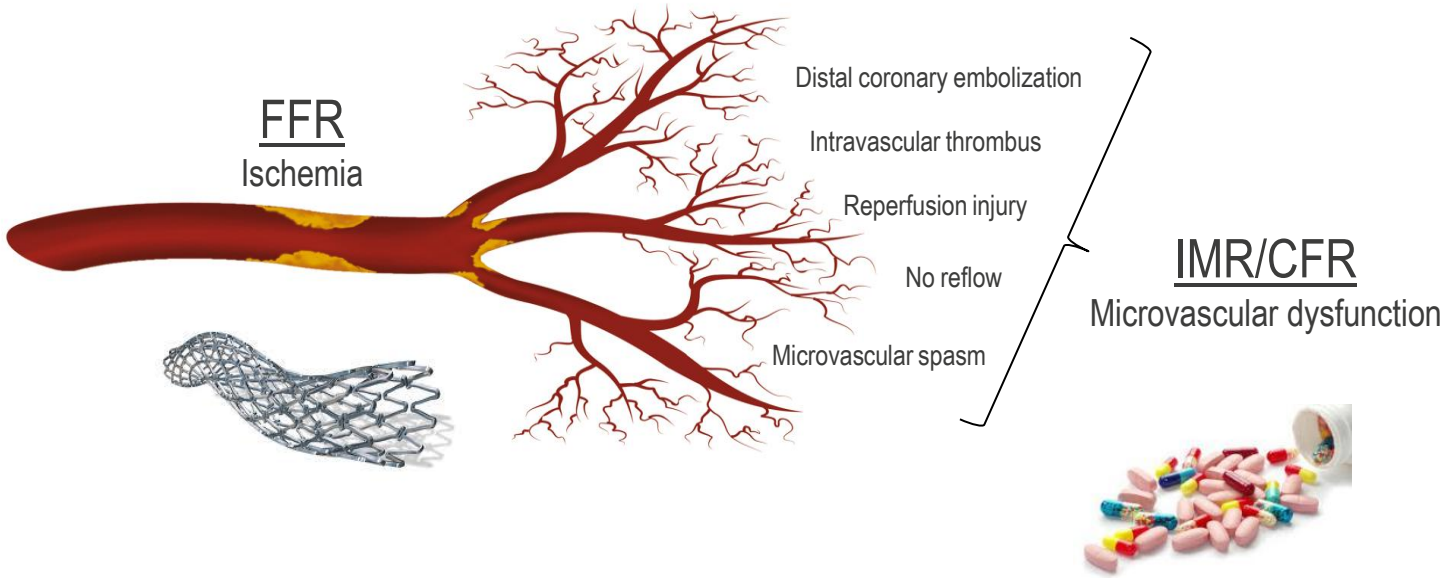
HOW DO WE GET FLOW FROM TEMPERATURE?

PRESSURE AND THERMOCONVECTION FLOW FROM PW AERIS 2.0 ON QUANTIEN – WORK IN PROGRESS



COMBINED LESION/MICROVASCULAR ASSESSMENT

- Combined assessment of Epicardial and Microvascular disease may lead to improved diagnosis and outcomes
- Enabling FFR and IMR/CFR on a FFR-guidewire designed for every day PCI usage may move combined assessment into every day clinical practice



CONCLUSION

THE ELECTRICAL SENSOR TECHNOLOGY USED IN ST JUDE'S PRESSUREWIRE ENABLES:

1. HIGH MEASUREMENT RELIABILITY

2. WIRELESS CONNECTIVITY

3. COMBINED ASSESSMENT OF FFR & IMR/CFR

THE FUTURE IS HERE NOW (ALMOST) AND ITS ELECTRICAL

THANK YOU FOR YOUR ATTENTION