FRACTIONAL FLOW RESERVE STANDARDIZED

Measure Accurately \(^1,^2\) with PressureWire™ Guidewire
Standardization of FFR

STEP-BY-STEP PROCEDURE FOR PRESSUREWIRE™ GUIDEWIRE

FFR is considered the reference standard for the evaluation of ischemic stenosis and the expected benefit from revascularization. The FFR standardization publication from Toth et al., 2016 in Journal of the American College of Cardiology proposed a standardized way of acquiring, recording and interpreting FFR in daily practice to ensure accurate and reproducible measurements.

FFR AT MAXIMUM HYPEREMIA IS THE GOLD STANDARD FOR ACCURACY

Contrast FFR (Single Cutoff)

Pd/Pa and iFR™ (Single Cutoff)

Hybrid Approach (Pd/Pa + FFR or Contrast FFR + FFR)

Angiography Alone (QCA)

Diagnostic Accuracy

85-95%

85%

80%

65%

100%

FFR (IV/IC Adenosine*) - Standard of Reference

*Prior to using hyperemic agents, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions.

MATERIALS AND PRACTICALITIES TO MEASURE FFR:

- Proper anticoagulation (i.e. ≥ 50 U/kg unfractionated heparin)
- Intracoronary administration of nitrates (200 µg)
- Guiding catheters: any size can be used, but consider the following standard steps:
  - Larger catheters: slightly disengage the guiding catheter from the ostium as they can impede the flow
  - Smaller catheters (i.e. 5 F): adequately flush the guiding catheter with saline to remove residual contrast medium
  - Not recommended: guiding catheters with side holes and diagnostic catheters
  - PressureWire™ guidewire in combination with St. Jude Medical™ FFR platform (QUANTIEN™ Measurement System, OPTIS™ Mobile, OPTIS™ Integrated, RadiAnalyzer™ Xpress systems)
STEP 1: **CALIBRATION**

*Standard steps relating to zeroing the aortic transducer to atmospheric pressure*²,³

- Position the transducer at the patient’s heart level.
- Purge the aortic transducer system, zero the catheter tubing system and obtain an optimal aortic pressure waveform prior to FFR measurement. This prevents fluctuations in FFR measurement due to air bubbles shifting.
- When a contrast injector pump is used, ensure that the three-way stopcock and the aortic transducer are both positioned at the heart’s level.

*Standard steps relating to zeroing the PressureWire™ guidewire to atmospheric pressure*²,³,⁵

- Place package coil flat and then flush with 10 mL saline and wait 1 minute.
- Check pressure wire is correctly seated in the handle and the wire connector is tightened to ensure signal reliability.
- Press the connect button on the PressureWire™ receiver/QUANTIEN™ system/OPTIS™ system. **This must be done before** the PressureWire guidewire is turned on.
- Slide the green slide on the PressureWire guidewire handle forward to turn on. During this step the PressureWire guidewire is zeroed upon connection. The PressureWire guidewire should stay in the package coil until Pd = 0.

STEP 2: **EQUALIZATION**

*Standard steps relating to equalization of aortic pressure and PressureWire™ guidewire*¹-³

- The sensor of the PressureWire guidewire should be advanced a few millimeters beyond the tip of the guiding catheter.
- Remove introducer needle and close hemostatic valve.
- For aorto-ostial lesions, this should be performed with the disengaged catheter in the ascending aorta.
- Equalize the pressures registered by the guiding catheter and the pressure wire and observe for 1 minute. If the signal is not stable, re-equalize prior to FFR measurement.

STEP 3: **MEASUREMENT**

*Standard steps relating to the advancement of PressureWire™ guidewire sensor distally*¹-³

- As per any intracoronary manipulation, proper anticoagulation and intracoronary nitrates (200 µg) should be administered prior to entering the coronary circulation.
- The sensor should be advanced to the distal two-thirds part of the coronary artery and at least 2 to 3 cm distal to the lesion (Figure 2).
- Ensure that the wire tip is rotating freely and no resistance is felt when torque is applied.
If additional wire torque is required to position the PressureWire guidewire, loosen the wire connector on the PressureWire™ transmitter and remove transmitter. Do not turn off PressureWire™ guidewire to prevent repeat zeroing PressureWire guidewire to atmospheric pressure and Equalization steps.

Dry proximal end of wire with dry gauze and re-connect transmitter prior to FFR measurement. Tighten wire connector to ensure signal reliability.

**Standard steps to induce hyperemia**

- When the sensor has been optimally positioned distal to the stenotic region, administer the hyperemic agent.
- Check that pressure measurement is stable and steady-state maximal hyperemia is achieved.

**Standard steps to measure FFR**

- Record the pressure tracing encompassing the baseline (10 beats), the beginning of the hyperemic phase and the recovery phase. The total recording duration will vary from the hyperemic agent used.
- Slightly reposition the PressureWire guidewire if spikes in the signal are seen due to the PressureWire guidewire sensor touching the vessel.
- Determine the lowest FFR value.

**STEP 4: VERIFICATION**

**Standard steps to check for drift**

- Pull back PressureWire™ guidewire sensor to guiding catheter tip to verify equal pressures.
- If a drift larger than > 3 mmHg is seen, re-equalize and repeat the FFR measurement.

**Drift-related troubleshooting questions to ask:**

- Has the guiding catheter been adequately flushed with saline prior to equalization/prior to FFR measurement/and prior to checking for drift?
- Is the PressureWire guidewire checked at the same position as during equalization?
- Has the height of the aortic transducer been altered after equalization?
- Is the guiding catheter position in the coronary ostia different from equalization?
- Is the needle left in the Y-connector?
- Does the guide catheter have side-holes?
- Was the PressureWire guidewire prepared correctly (placed flat and flushed with 10 ml saline connected correctly)?
- Was the proximal end of the PressureWire guidewire cleaned before reseating into the transmitter/handle?

The procedure settings during equalization and verification need to be exactly the same to rule out any drift.
PATIENTS AND VESSEL SELECTION FOR FFR

<table>
<thead>
<tr>
<th>INDICATIONS FOR FFR-BASED DECISION MAKING*</th>
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<tbody>
<tr>
<td>Stable CAD</td>
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<tr>
<td>Clear culprit</td>
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<tr>
<td>Non-culprit</td>
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PHARMACOLOGIC AGENTS FOR INDUCING HYPEREMIA IN THE CATH LAB

<table>
<thead>
<tr>
<th>ADMINISTRATION</th>
<th>AGENT</th>
<th>DOSE</th>
<th>EFFECT</th>
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</thead>
<tbody>
<tr>
<td>Intravenous (Preferably Central Venous)</td>
<td>Adenosine*</td>
<td>Infusion: 140 µg/kg/min</td>
<td>Duration: Infusion length</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Peak: ~ 1 min</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Wear-off: ~ 1 min</td>
</tr>
<tr>
<td>Intracoronary</td>
<td>Adenosine*</td>
<td>LCA: 200 µg RCA: 100 µg</td>
<td>Duration: &lt; 20 sec</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Peak: &lt; 10 sec</td>
</tr>
<tr>
<td>Intracoronary</td>
<td>Papaverine*</td>
<td>LCA: 16-20 mg RCA: 100 µg</td>
<td>Duration: 45-60 sec</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Peak: 10-30 sec</td>
</tr>
<tr>
<td>Intravenous (Central Venous or Peripheral)</td>
<td>Regadenoson*</td>
<td>Bolus: 400 µg Bolus</td>
<td>Duration: Avg 2.5 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wear-off: Potentially &gt; 10 min</td>
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