

# Correct Use of PressureWire™

For Calculating Fractional Flow Reserve



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# Equipment for FFR Calculation



PressureWire



Hyperemia

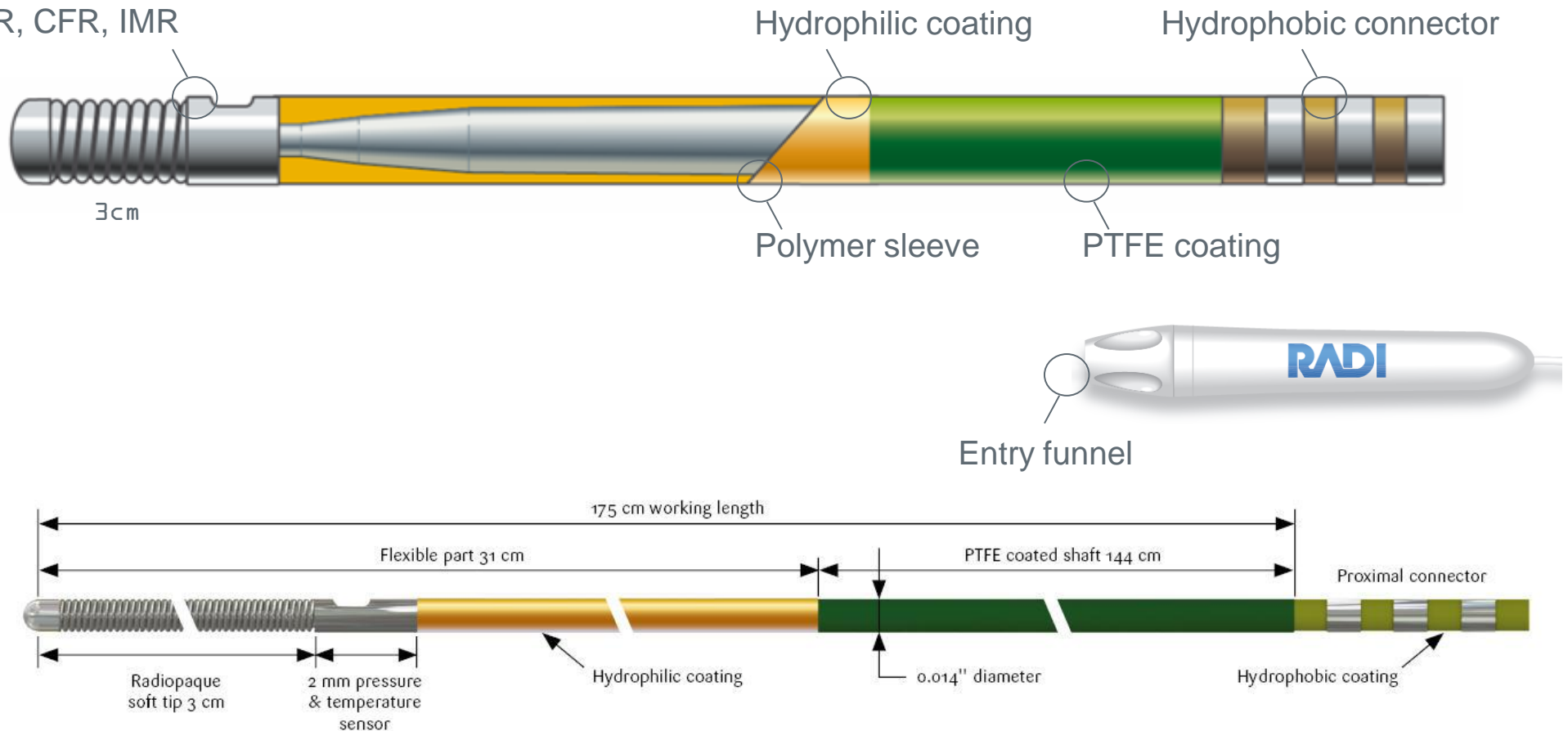


RadiAnalyzer™ Xpress



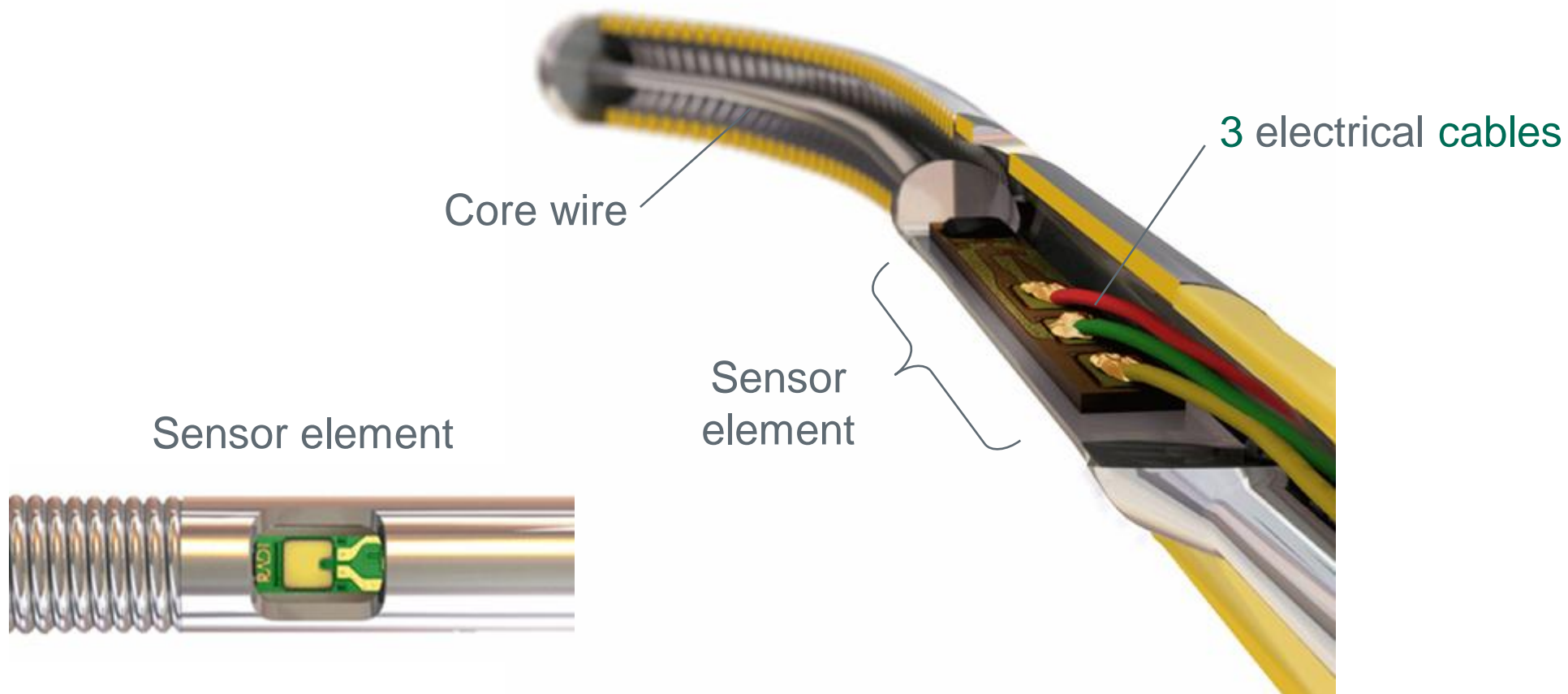
# PressureWire™ Certus™ - Overview

Multi-function sensor:  
FFR, CFR, IMR



# PressureWire Certus

Detailed close-up



# RadiAnalyzer Xpress - Overview



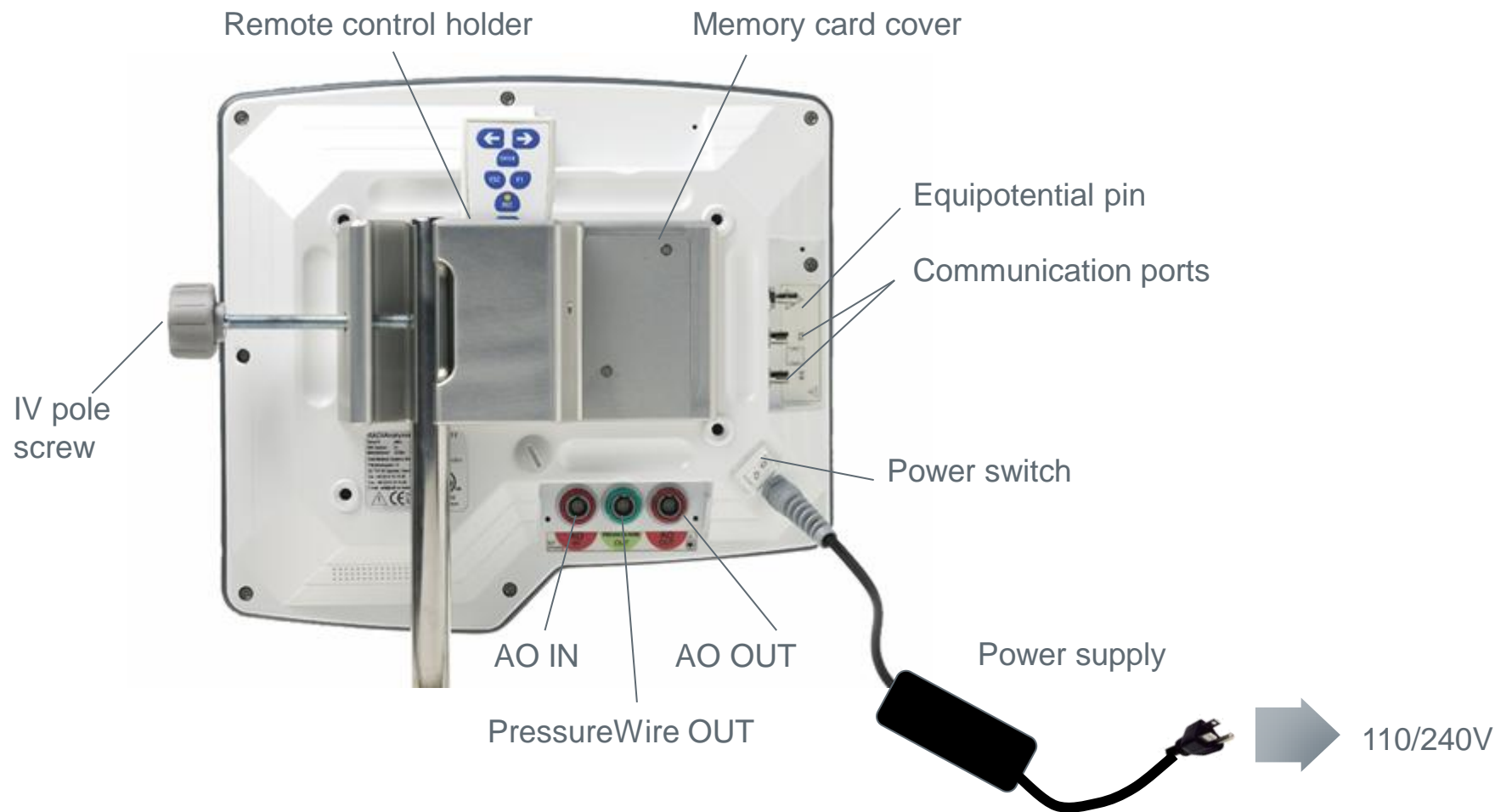
Remote control



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# RadiAnalyzer Xpress



# Hyperemia



Hyperemia is a pre-requisite for FFR.

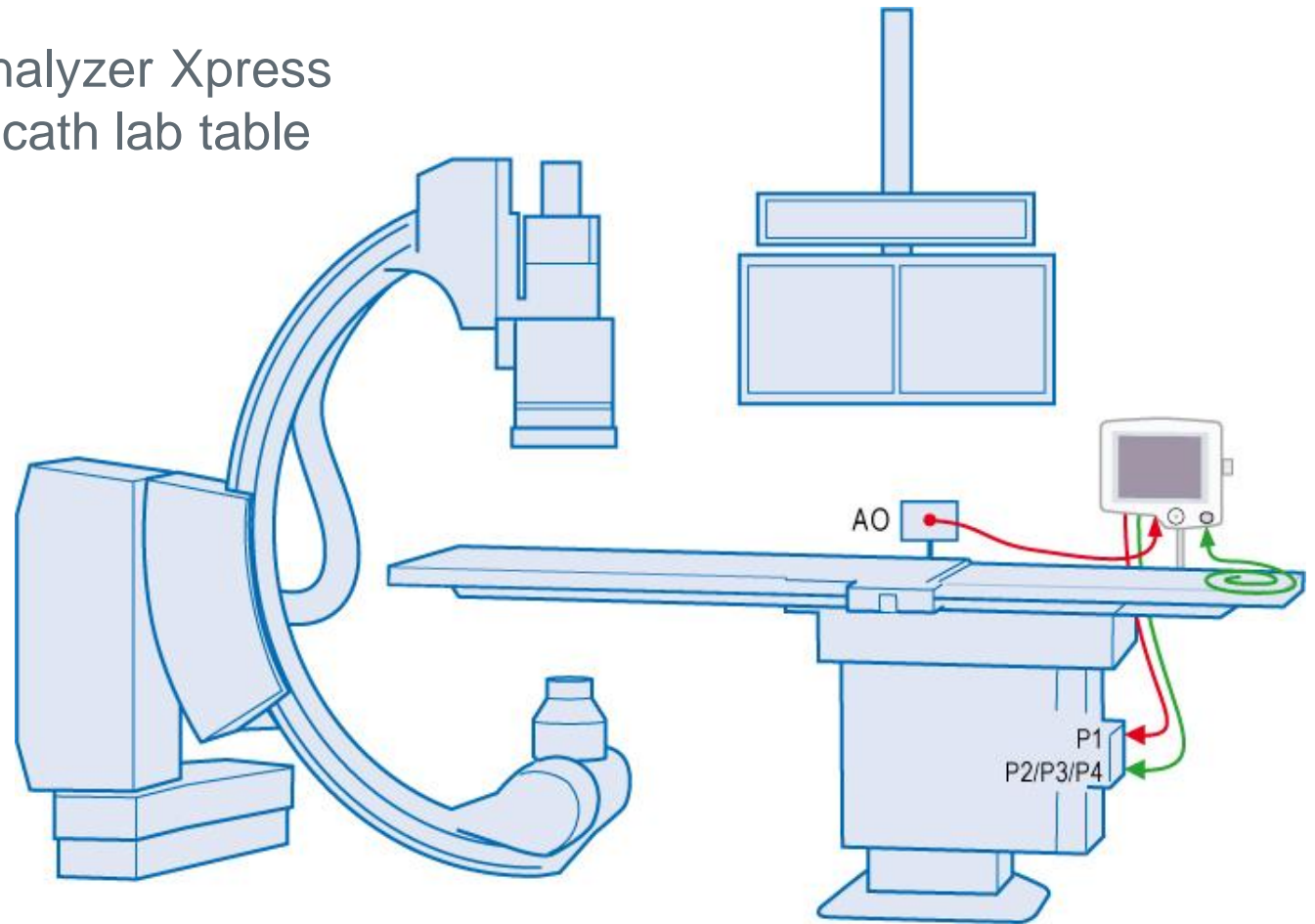
A high volume infusion pump is required for I.V. administration of hyperemic drugs





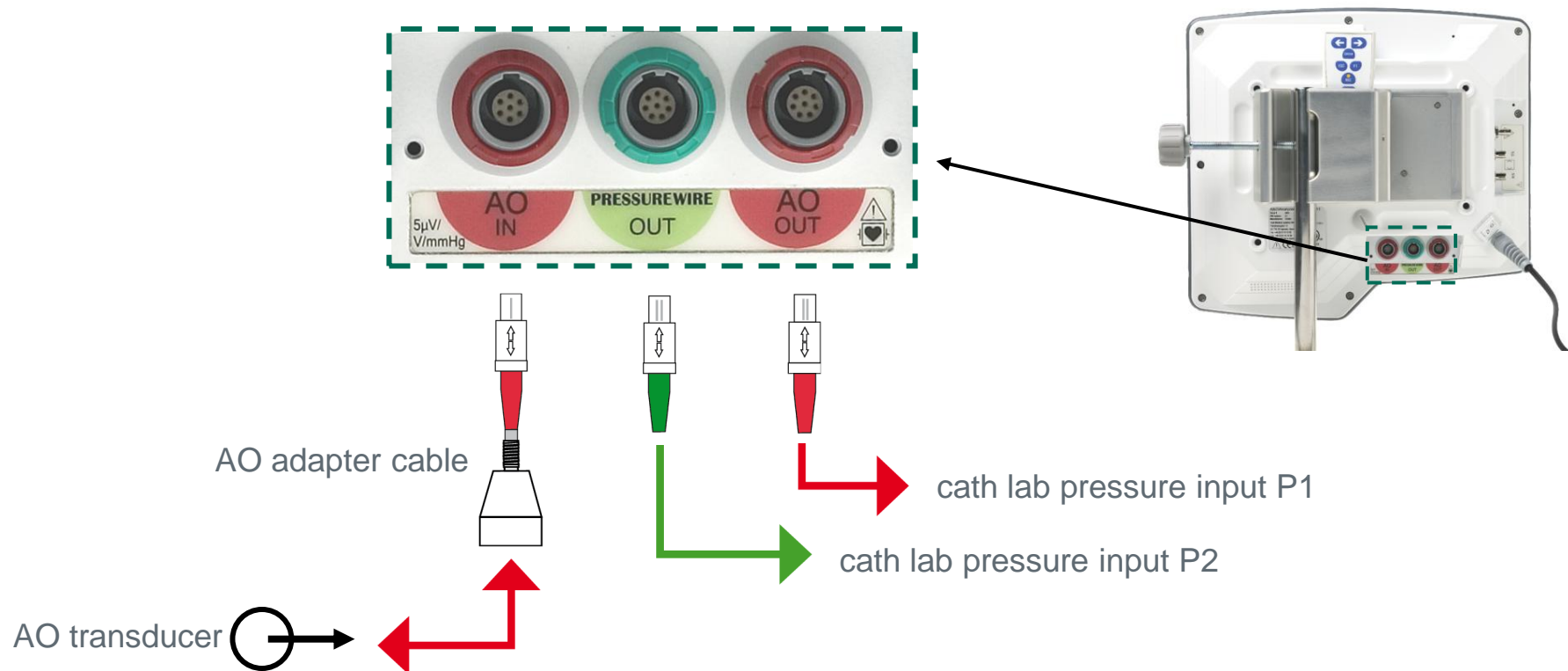
# Basic Set-up

For ease of use, RadiAnalyzer Xpress can be mounted on the cath lab table rail



# Connect Cables – Standard Set-up

1. Connect AO transducer to AO adapter cable
2. Connect AO adapter cable to AO IN port (**red**)
3. Connect AO OUT port (**red**) to cath lab recording system (P1)
4. Connect PressureWire OUT (**green**) to cath lab recording system (P2)



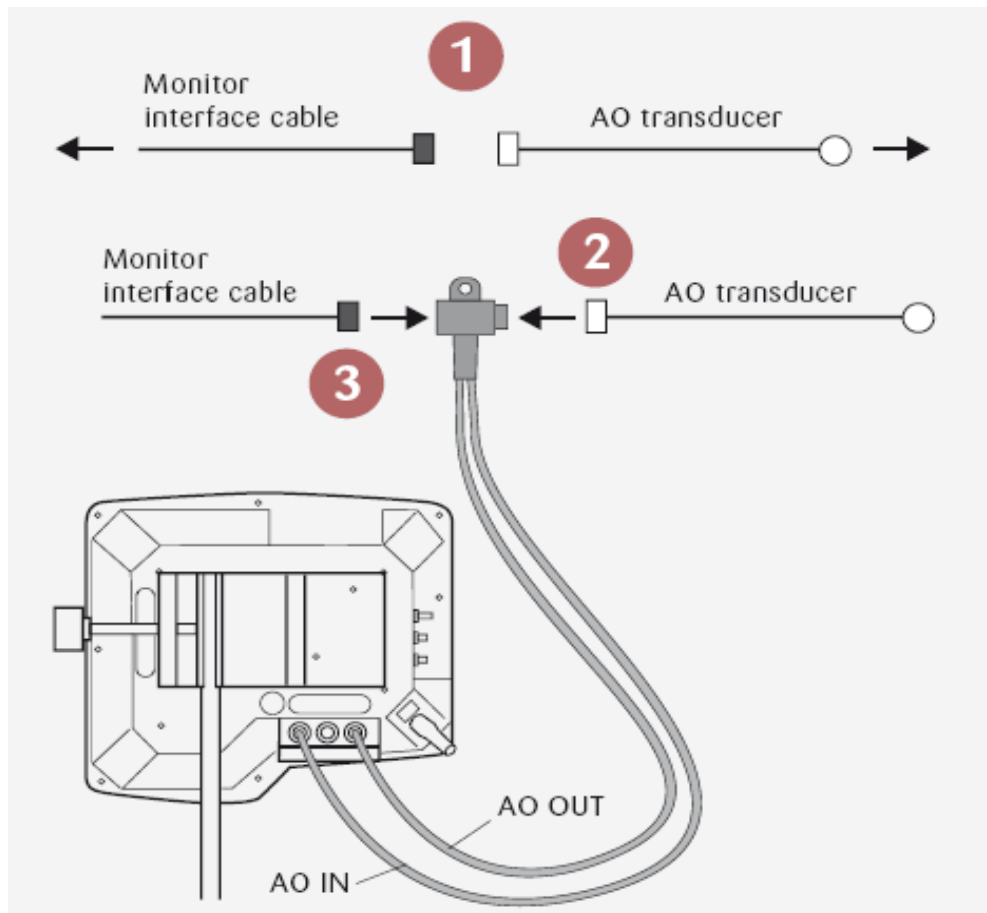
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# Connect Cables – Namic™ Adapter Cable

1. Disconnect the Namic® AO transducer from its monitor interface cable.
2. Connect the Namic AO transducer to the Namic adapter cable.
3. Connect the monitor cable to the Namic Adapter cable.

The Namic adapter cable should stay connected to RadiAnalyzer Xpress AO IN and AO OUT



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# Power On



After cables are connected, switch RadiAnalyzer Xpress to ON.

RadiAnalyzer Xpress will perform a system check then take you to the auto set-up sequence screen.



# Automatic Set-up Sequence

- The automatic set-up sequence is a on-screen step-by-step guide that runs through the three main set-up steps.
- The sequence is enabled/disabled in the **OPTIONS** submenu.
- If enabled the sequence starts automatically when the instrument is turned on.
- The sequence can be aborted by pressing **ESC**.
- It is possible to advance/go back using **LEFT** and **RIGHT** buttons.
- The sequence can always be started from the **MAIN** menu by keeping **F1** pressed for more than 2 seconds.

# Auto Set-up Procedure

## step 1: ZERO cath lab channels



"ZERO" both pressure channels on cath lab recording system, press ENTER when done.

(Optional: Press LEFT/RIGHT to test AO/PressureWire OUT).

# Auto Setup Procedure

## step 2: ZERO AO

1. ZERO	OPEN AO TRANSDUCER TO AIR AND PRESS ENTER
2. AO	
3. WIRE	
	<div>CAL</div>

Open AO TRANSDUCER TO AIR and press ENTER.

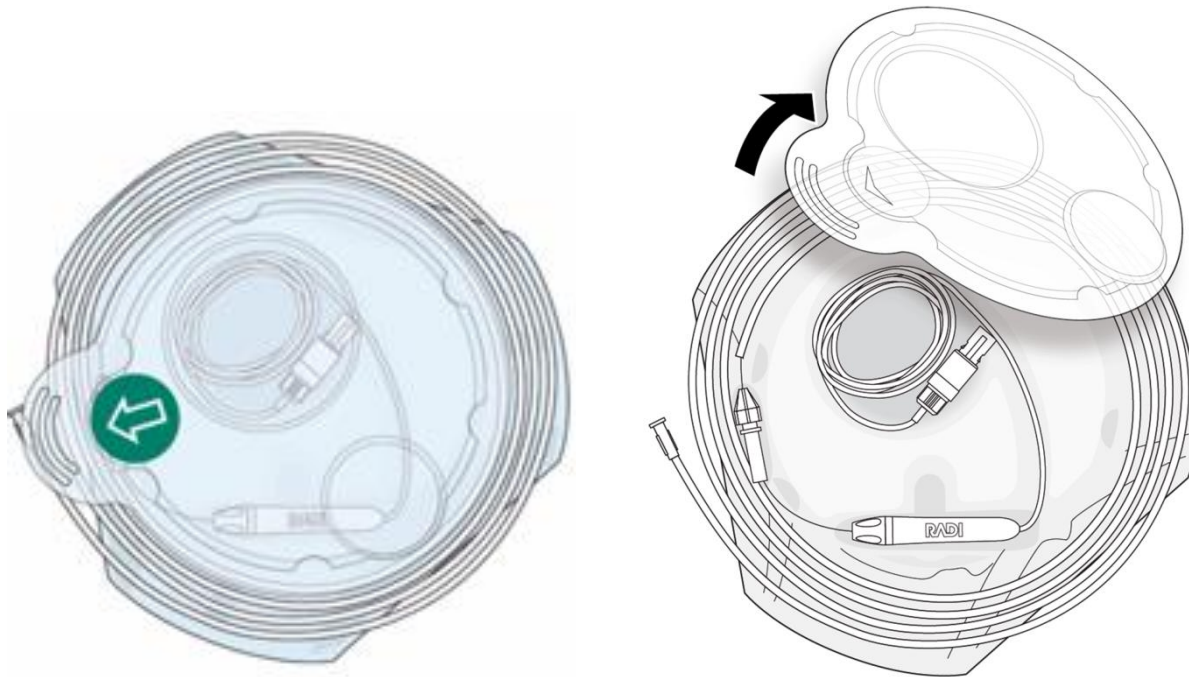
Close valve to resume pressure reading.



# Before Proceeding to Step 3

## Prepare PressureWire

1. Remove tray from sterile pouch using standard sterile technique
2. Place tray on cath lab table sterile dressing
3. Flush packaging coil with saline
4. Remove lid by pulling where indicated by arrow
5. Pull out instrument connector and connect to RadiAnalyzer Xpress, keep a finger on the white proximal connector to avoid the wire sliding out of the coil





# Auto Setup Procedure

## step 3: Calibrate PressureWire

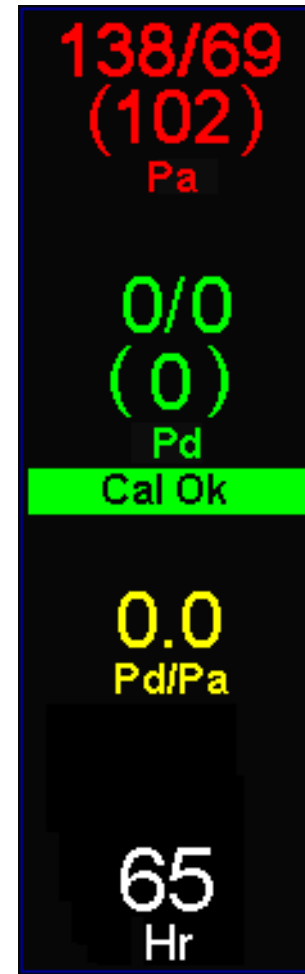
1. ZERO 2. AO 3. WIRE	FLUSH WIRE COIL, PLACE FLAT AND PRESS ENTER <div>CAL</div>
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Place coil flat, and flush to fill the coil with saline.

Press ENTER.



PressureWire is Now  
Calibrated and Ready for Use



# Things to Remember When Handling PressureWire

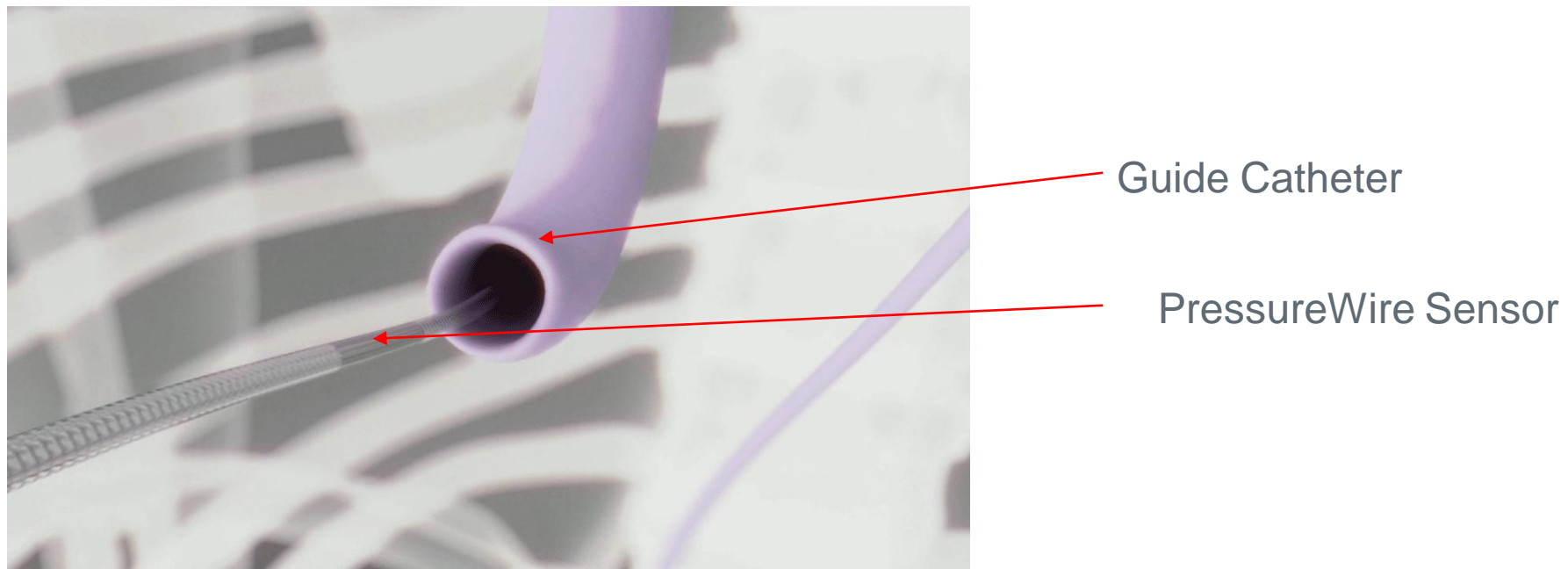
- Avoid kinking when removing PressureWire from packaging coil
- Do not damage sensor element when shaping tip
- Tighten torque device properly so that it does not slip on wire shaft
- Disconnect wire from white proximal connector for improved torque
- Tighten proximal connector securely
- Always keep PressureWire connectors dry
- Wipe proximal 7 cm of wire clean, and dry before reconnecting



# Verifying Equal Pressures


Advance sensor element just outside guide catheter opening.

Verify that AO ( $P_a$ ) and PressureWire pressures are equal at this position.



# Equalize

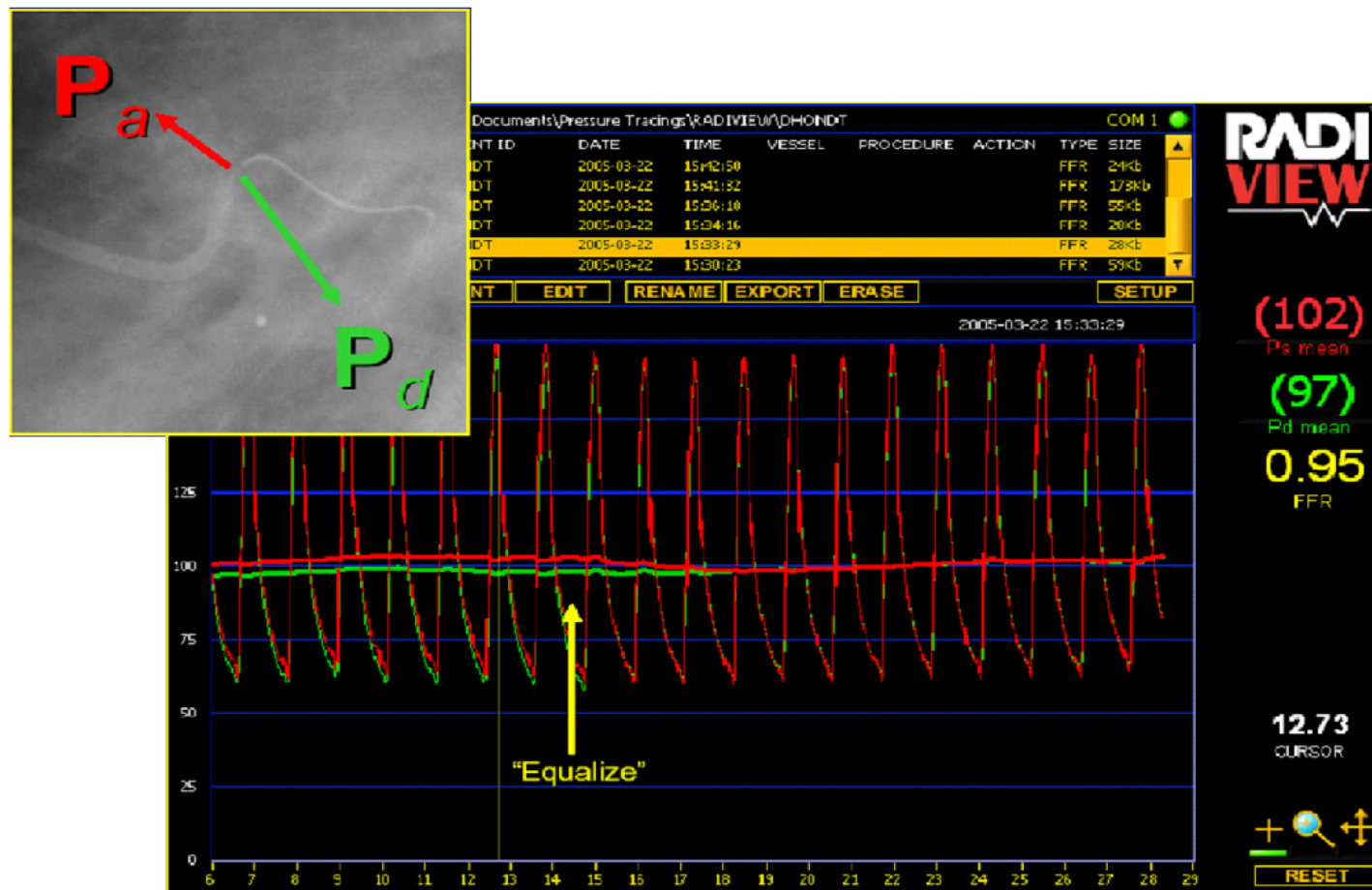
If pressures are NOT equal:

1. Position AO transducer at patient's heart level.
2. Remove guidewire introducer needle and close valve tightly.
3. Flush any contrast remnants.
4. Press Equalize  button and hold for 3 seconds.

Any small pressure difference is removed electronically and will be displayed on the monitor.

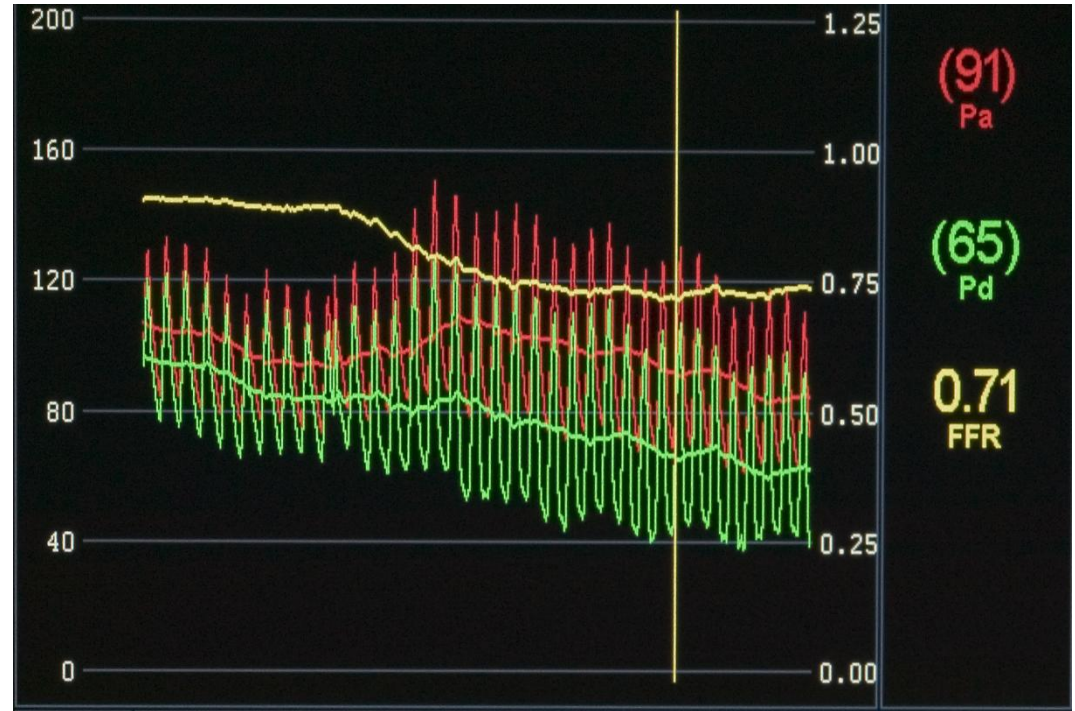


# Equalize



# Record and Calculate FFR

1. Advance sensor element distal to the lesion site.
2. Wait for stable baseline pressure values.
3. Induce maximum hyperemia.
4. Press REC to start recording.
5. When maximum hyperemia is reached, press Stop/View to stop recording.  
The instrument then calculates FFR automatically.



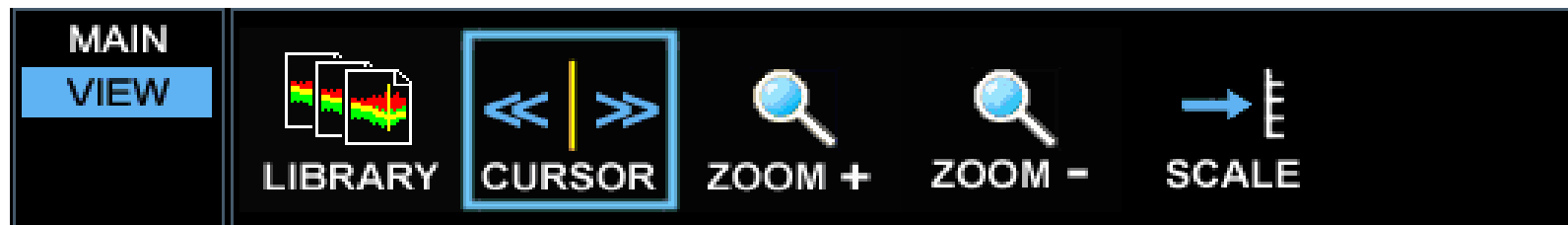
$$FFR_{\text{myo}} = P_d / P_a$$

At maximum hyperemia



# Review Pressure Recordings

Use cursor to analyze recording.



Select CURSOR and press ENTER.



Move CURSOR with LEFT and RIGHT buttons.

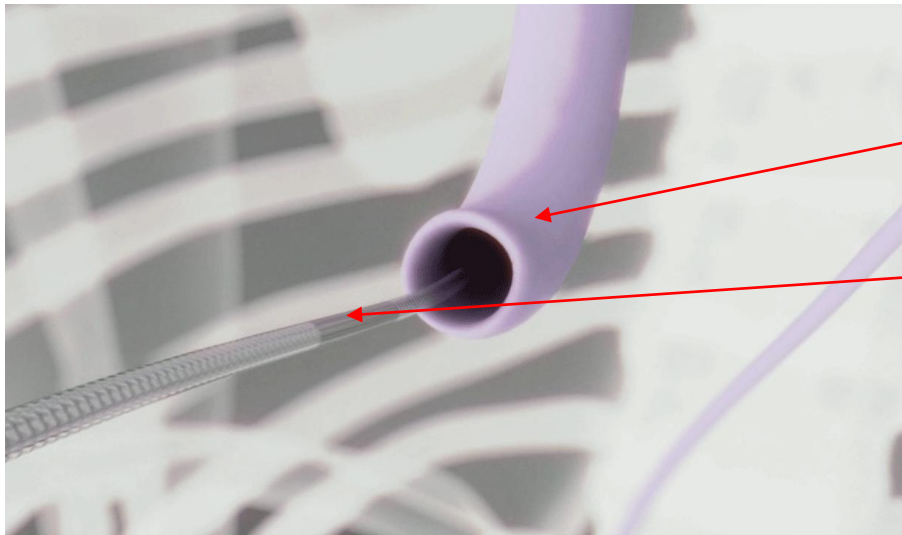
Press ENTER to save new position and leave menu.

Press ESC to leave without saving position.



# Verify Equal Pressures Post-Procedure

- After procedure – verify equal AO and PressureWire pressures.
- Withdraw PressureWire sensor so that the element is just outside the guide catheter opening.
- Verify that AO (Pa) and PressureWire (Pd) pressures are equal (difference  $\leq 5$  mmHg) at that position.



Guiding catheter

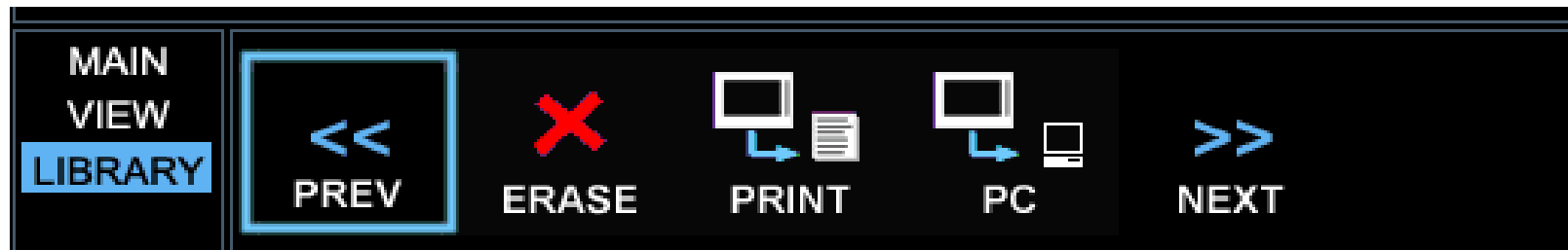
PressureWire sensor

# Review Previous Recordings



Press STOP/VIEW

Select LIBRARY and press ENTER



Browse through recordings using PREV and NEXT.

# Summary

## FFR Measurement (1/2)

1. Verify equal signals when sensor is just outside the guide catheter opening.
2. Advance wire; the sensor crosses the lesion.
3. Induce maximum hyperemia and measure FFR.
4. Because sensor is 3 cm from tip, easily pull-back and push-up for exact spatial information.  
If desirable, perform a pull-back recording.

# Summary

## FFR Measurement (2/2)

5. Perform PCI if indicated. If needed, perform optional wedge pressure measurement for collateral flow assessment.
6. Repeat post PCI, FFR measurement to check result.  
If desired, perform hyperemic pull-back recording.
7. Verify absence of drift at the end of procedure or between measurements in several vessels.

# RX Only

Product referenced is approved for CE Mark

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The products are designed, developed and manufactured by St. Jude Medical Systems AB. Unless otherwise noted, <sup>™</sup> indicates a registered or unregistered trademark or service mark owned by, or licensed to, St. Jude Medical, Inc. or one of its subsidiaries. PressureWire, Certus, Aeris, RadiAnalzyer, RadiView, RADI, ST. JUDE MEDICAL, the nine-squares symbol, and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.

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