The ACIST | RXi® System
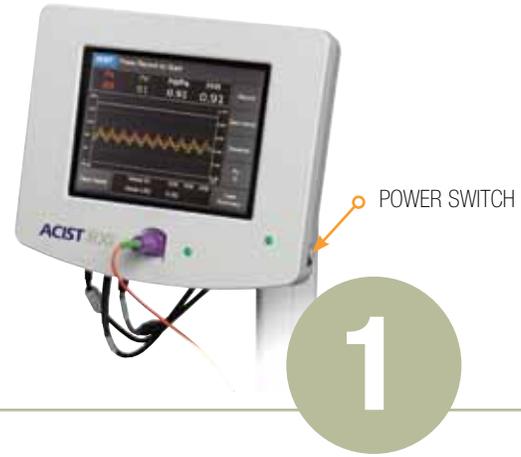# Quick Guide

ACIST®
the power to

The ACIST | RXi®
Rapid Exchange FFR System

The RXi system with the ultra-thin ACIST Navvus® Rapid Exchange FFR MicroCatheter gives you the freedom to quickly and easily assess FFR using your 0.014" wire of choice.

ACIST®
the power to

The plug-and-play
RXi System

POWER SWITCH

1

- Tableside, RXi is in a 'ready state' with the patient's aortic pressure displayed.

- The RXi system requires zeroing only once at initial install, when in the 'stationary mode.'

- The RXi System console does a self-check once the Navvus MicroCatheter is plugged into console.

Turn console power "ON"
- Zero the hemodynamic monitor

CATHETER INDICATOR LIGHT

Press the Zero Aortic button

NOTE: This step is done only once, at initial install, unless system is moved to another room. If system is moved, repeat Steps 1 and 2*.

- Verify aortic signal, (Pa) is showing zero (0) and hemodynamic monitor is showing zero (0)

- Using a sterile technique, open the Navvus MicroCatheter

  * The RXi system requires rezeroing when it is disconnected from the hemodynamic monitoring system and/or in 'mobile mode'.

Connect the purple-handled Navvus MicroCatheter assembly to the RXi console

NOTE: The catheter status indicator LED illuminates GREEN, when the handle assembly is fully inserted.

- Thoroughly flush the Navvus MicroCatheter (in dispenser coil) with sterile saline solution.

- Verify status message on RXi console is displaying: "Ready to Equalize"

- Advance the Navvus MicroCatheter over the guidewire and position radiopaque marker band 3mm outside the tip of the guiding catheter

Press EQUALIZE button

- Pd/Pa value should be stable at 1.00
- Position the Navvus MicroCatheter
  sensor 1-2 cm past the area of interest
- Administer Adenosine (or another vasodilator)

Press the RECORD button
(before or during maximum hyperemia)

- RECORD button changes to STOP button
- Press STOP any time within the 10 minute
  maximum recording time

Press the STOP button

- The FFR review screen will automatically display as shown at right

- Review screen information and use scrolling arrows to shift image, if desired

Press SAVE or DISCARD button

- SAVE button stores the FFR value and the FFR recorded value appears in the Vessel ID display area

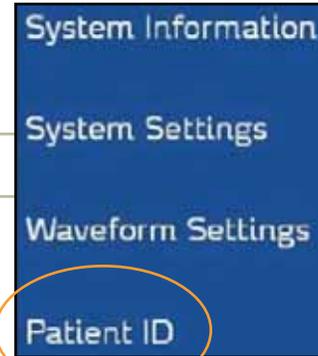- DISCARD button permanently deletes the recording after you confirm its selection

Frequently Used Console Setting Options

1

Enter facility name and patient ID

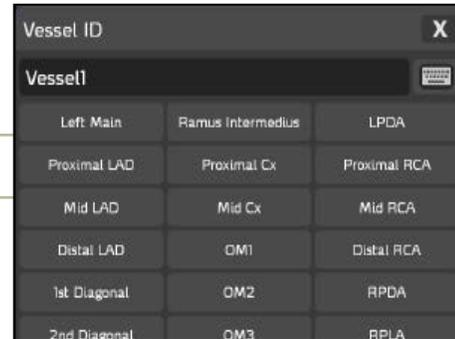- Pressing ACIST in the blue box on the main screen displays the menu screen

- Enter patient identification by selecting PATIENT ID and using pop-up keyboard

2

Enter Vessel ID

- Selecting the vessel ID field allows you to choose a new Vessel ID

- Selecting the "Vessel ID" field allows you to identify individual vessels

- The system displays VESSEL 1 as the default Vessel ID

- A pop-up window displays 18 pre-defined vessel names

- A pop-up keyboard allows you to enter a custom Vessel ID

RXi Troubleshooting Tips

The System has detected a problem with the Pressure Sensor

- *Has console interface frozen and no longer accepts touch commands?*
  - ► **Cycle power. Console boot sequence will take approximately 30 seconds. When system is fully operational, re-insert catheter**

- *Have you tried unplugging and reinserting the Navvus MicroCatheter?*
  - Catheter malfunction can occur when catheter is incorrectly seated or not fully engaged in console housing
  - ► **Unplug and firmly reinsert catheter, ensuring full contact with electrical and fiber optic components**

Indicator Light (no error message)

- *After plugging in the Navvus MicroCatheter, is indicator light following correct sequence of Blue to Green during system self-check?*
  - Absence of initial blue indicator light, persistent blue or intermittent blue indicator light may signal an issue with console's electrical components.
  - ► **Remove and reinsert Navvus to ensure correct catheter seating**

- *Was sensor pressurized when Navvus MicroCatheter was plugged in?*
  - May be caused by holding catheter (should be lying flat), flushing catheter with saline while plugging into console, or catheter already placed in patient.
  - IFU states to plug Navvus into console prior to flushing hoop
  - IFU states catheter tip should be outside patient when inserting catheter handle into system console.
  - ▶ **Remove Navvus from body or discontinue flushing during catheter system check.**

- *Have you tried cleaning fiber optic connection inside PIM door with an appropriate cleaning tool?*
  - Foreign material or debris, including fluid (saline, bodily fluids), can disrupt fiber optic signal and cause catheter error.
  - ▶ If contamination is suspected, utilize fiber optic cleaning tool (w/PIM door holder), or return console to ACIST for service.
  - ▶ When handling the Navvus catheter, ensure hub stays clean and dry. If hub is contaminated with fluid, replace catheter. Do not attempt to engage catheter in console after contamination.

(The situations above can also be identified as "THE SYSTEM HAS DETECTED A PROBLEM WITH THE PRESSURE SENSOR")

WARNING! Catheter malfunction detected. Stop procedure immediately and replace catheter with a new one.

- *Has Navvus MicroCatheter been replaced with a new catheter?*
  - RXi System does a self-check when catheter is plugged into console to ensure proper functioning of catheter prior to its use in patient.
  - ▶ **If warning message persists after replacing Navvus, return console and suspect catheter(s) to ACIST for investigation.**
  - ▶ **Reoccurring errors may indicate fiber optic mechanism in catheter part housing needs cleaning. Please contact your ACIST Sales Representative**

Error codes and self-checks are present to ensure proper functioning of Navvus catheter during procedure. When troubleshooting fails, the console and/or catheters should be returned to ACIST MEDICAL SYSTEMS for investigation.

"Connect Aortic Pressure Cable" status message

- *Connection issue with the RXi cable to the RXi console.*
  - ► **Ensure the aortic pressure cable is connected securely to the RXi console; gray sleeve to gray connector**

"Connect Aortic Pressure Cable" status message

- *Connection issue with the RXi cable to the hemodynamic system tram.*
  - ► **Ensure the aortic pressure cable is connected securely to the tram.**

"Connect Pressure Sensor" status message

STATUS MESSAGES
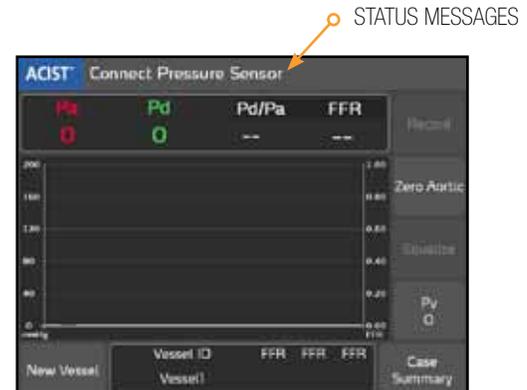
- *Indicates there are no cable connection issues.*

Equalization button is grayed out

- *Pa and/or Pd pressures are not present.*

  ▶ **Check both ends of cable connections to ensure connections are secure.**

  ▶ **Ensure the Pa cable is securely connected to the Pa connector; gray cable sleeve to gray connector.**

  ▶ **Ensure the Pd cable is securely connected to the Pd connector; black cable sleeve to black connector**

  ▶ **Gently rotate the collar clockwise to lock cable and ensure secure connection to the RXi console.**

Pa and Pd cable connections

▶ **Check both ends of cable connections to ensure connections are secure.**

▶ **Ensure the Pa cable is securely connected to the Pa connector; gray cable sleeve to gray connector.**

▶ **Ensure the Pd cable is securely connected to the Pd connector; black cable sleeve to black connector.**

▶ **Gently rotate the collar clockwise to lock cable and ensure secure connection to the RXi console.**

Notes

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Please contact your authorized ACIST representative for the most current information.

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