ACIST **RXi**®
ACIST **Navvus**®

Rapid Exchange FFR System
and MicroCatheter

QUICK GUIDE

Bracco Group

ACIST®

Know your ACIST RXi® System

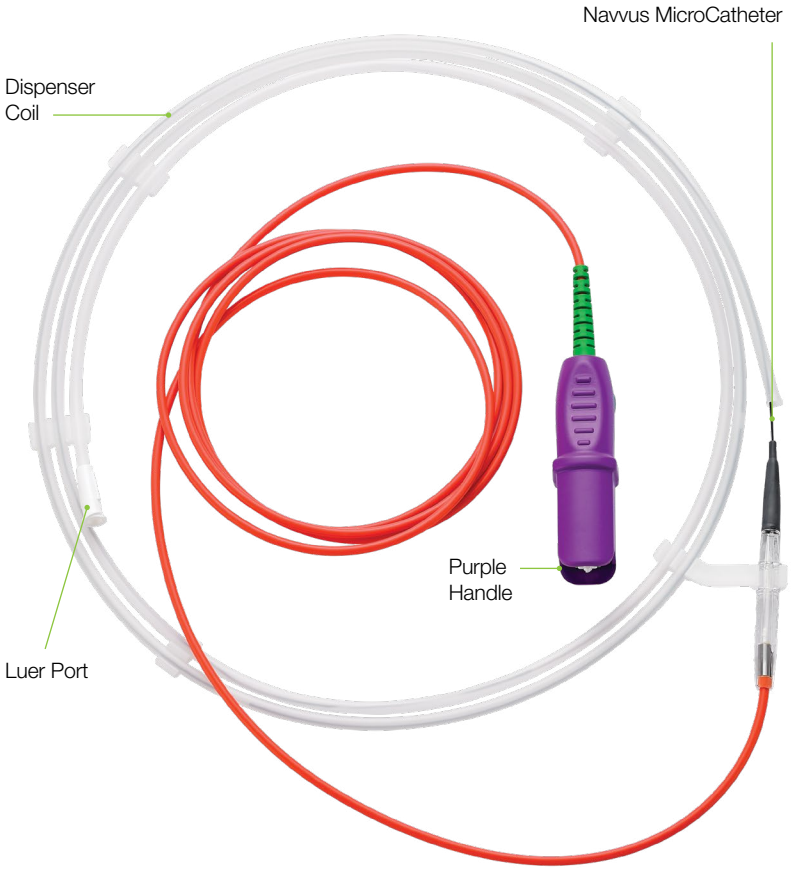
ACIST RXi®

Rapid Exchange FFR System

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

*This panel is on the underside of the console.

Navvus MicroCatheter



Functional Areas of the Touchscreen

The **Signal Display** area displays real-time signal data during recording.

The **ACIST Logo** button is used to display the main menu options.

The **Status Message** area provides user instructions and system status information.

The **Calculate dPR** button is used to start the dPR calculation*

The **Record** button is used to start the FFR recording.

The **New Vessel** button is used to declare that a new vessel is being measured.

This area displays the minimum value of the last three FFR recordings.

The **Vessel ID field** is used to select a vessel name from a pop-up list with 18 pre-defined vessel names or to enter a custom vessel ID.

The **Case Summary** button is used to display the case summary.

The **Pv** button is used for entering the Pv value. The default is zero.

The **Equalize** button is used to equalize the pressure sensor to the aortic pressure.

The **Zero Aortic** button is used to set the zero aortic pressure to zero.

*dPR calculation steps shown in Page 12

RXi Plug-and-Play System
Set Up & Use

Step 1

Turn console power “ON”

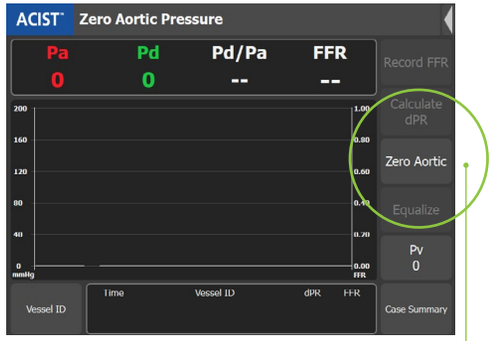
Power Switch

Step 2

Press the Zero Aortic button

NOTE: This step is done only once if the system is set up in Stationary mode at initial install, unless system is moved to another room.

In the Mobile mode, the RXi System is set up as a Mobile device, which means it is moved from room to room. When used in this matter, the aortic pressure on the RXi must be zeroed at the beginning of every patient case.



Zero Aortic button

Step **3**

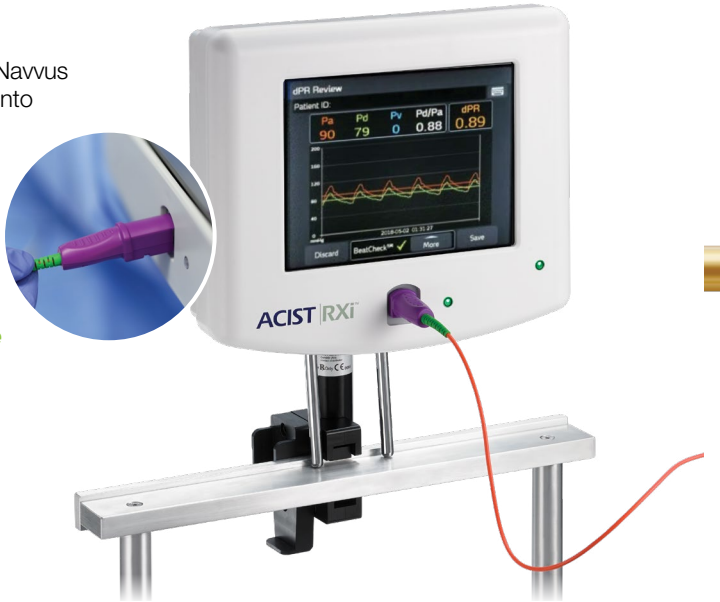
Using a sterile technique, open the Navvus MicroCatheter while being sure to maintain sterile condition.

Step **4**

Plug the purple-handled Navvus MicroCatheter assembly into the RXi system console.

MicroCatheter Status Indicator light is Green when the handle assembly is fully inserted.

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

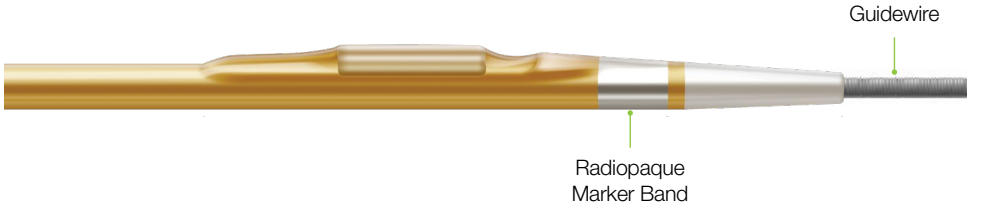


Step **5**

- Thoroughly flush the Navvus MicroCatheter with anticoagulated sterile solution.

Step **6**

Advance the Navvus MicroCatheter over the guidewire and position radiopaque marker band 3mm outside the tip of the guiding catheter, then flush the guide catheter with saline solution.

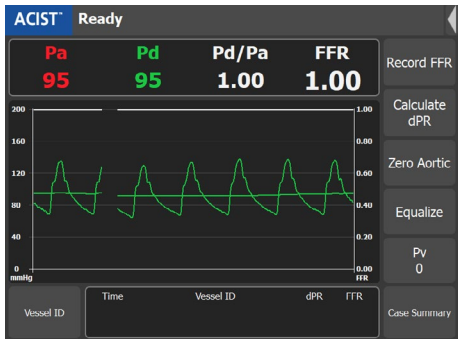


Step **7**

Press **EQUALIZE** button.

- Pd/Pa value should be stable at 1.00 after equalization.

*If **dPR calculation** is needed, please proceed to page 12*



Step **8**

Advance Navvus MicroCatheter until the marker band at the distal tip is 1-2cm distal to the lesion being evaluated.

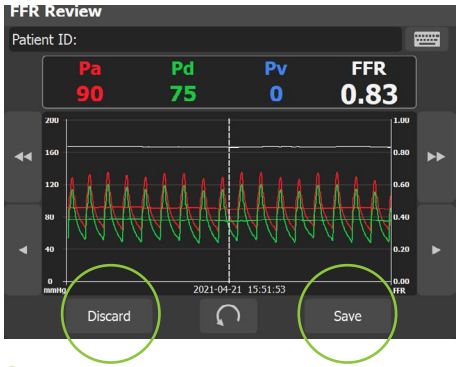
*NOTE: When performing a resting Pd/Pa assessment, the live resting Pd/Pa value is available on the main screen (as shown above). If a recording of the resting Pd/Pa value is desired, press **Record** and the FFR value represents the resting Pd/Pa.*

- Administrate Adenosine (or another vasodilator) and press **RECORD** button.

Step **9**

Press **STOP** any time within the 10 minute maximum recording time.

- The FFR review screen will automatically display.

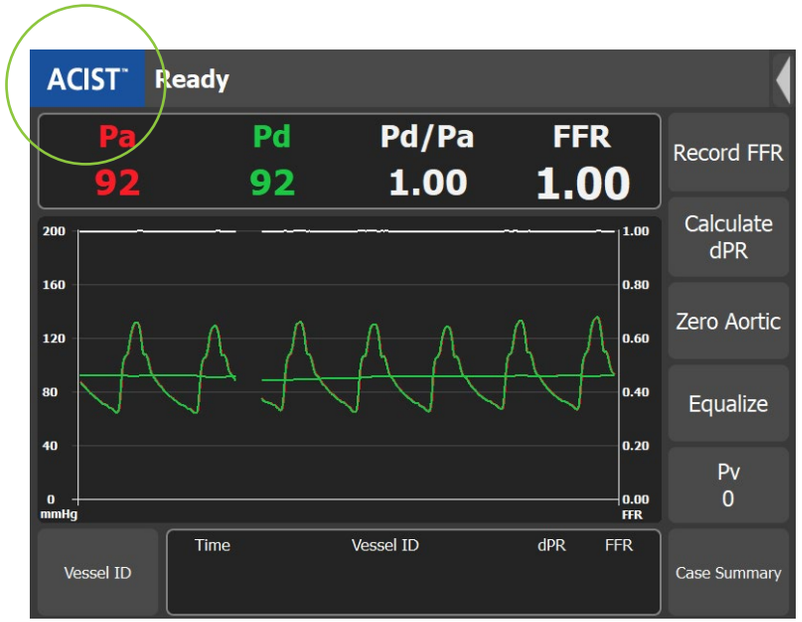


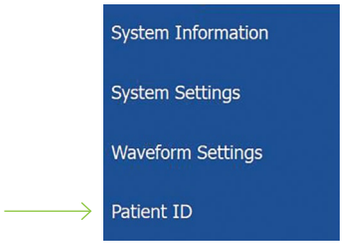
Step **10**

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

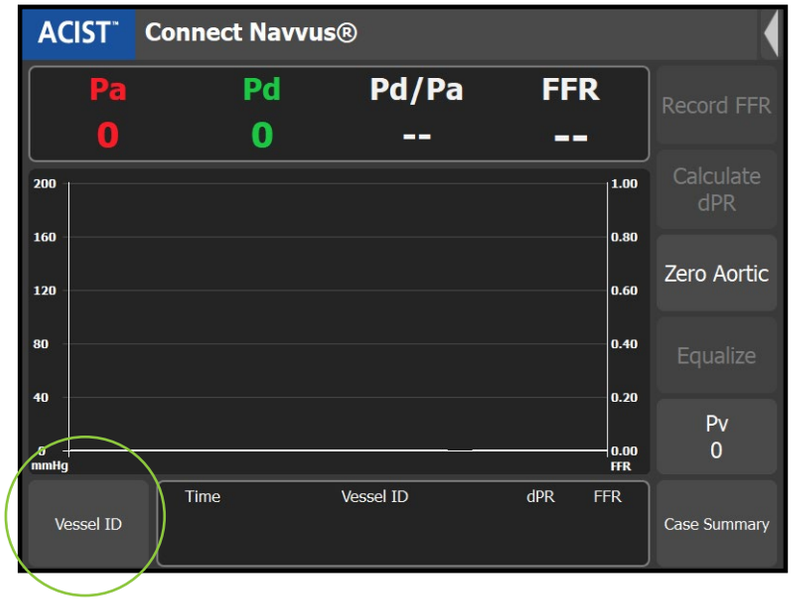




Patient ID

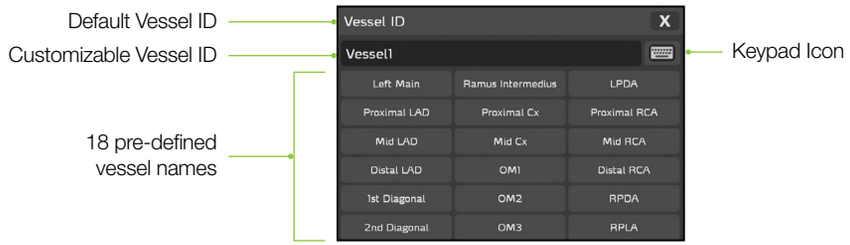
Press **ACIST** in the blue box on the main screen to display the menu screen.

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



Select Vessel ID

The Vessel ID pop-up window displays 18 pre-defined vessel names. It also provides a pop-up keyboard to enter custom vessel IDs, as shown below:



Select a Vessel ID from the displayed list of names, or select the keypad icon and enter a Vessel ID name for Vessel1.

To record another vessel re-equalize the signals (if required), select/create a new Vessel ID.

You can save up to 10 cases on the system.

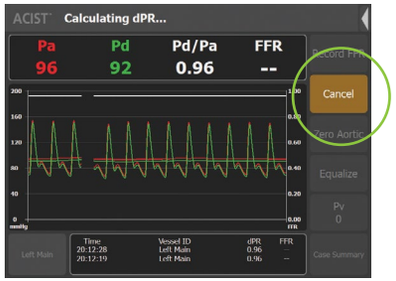
dPR Workflow

Step **1**

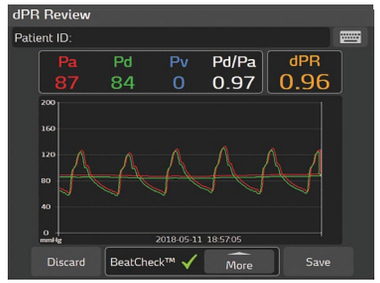
Zeroing and equalization have to be done prior to dPR calculation.

Once Navvus is positioned distal to the lesion, simply pressing the **CALCULATE dPR** button will begin the measurement.

- dPR will be calculated over the next 5 consecutive heartbeats.



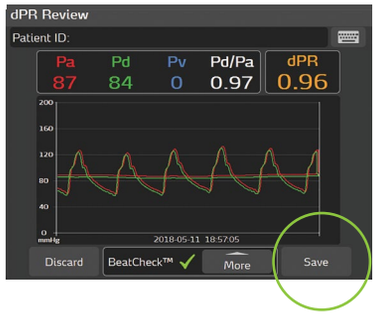
- If necessary, the dPR calculation can be cancelled at any time.



Step **2**

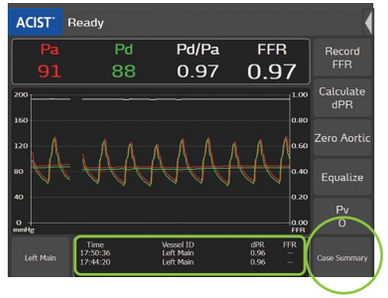
The review screen will show the dPR value and pressure waveforms for the assessment (along with Pd, Pa, Pv Values;* and Pd/Pa).

*Entering the Venous Pressure is specific to FFR recording. The Pv value has no effect on dPR value.



Step **3**

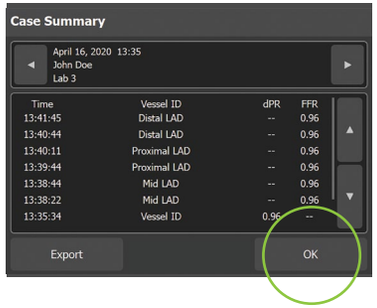
Pressing **SAVE** will retain the waveform, dPR value, and other assessment information in the case summary.



Step **4**

Pressing the **CASE SUMMARY** button will show all dPR and FFR values obtained during the case.

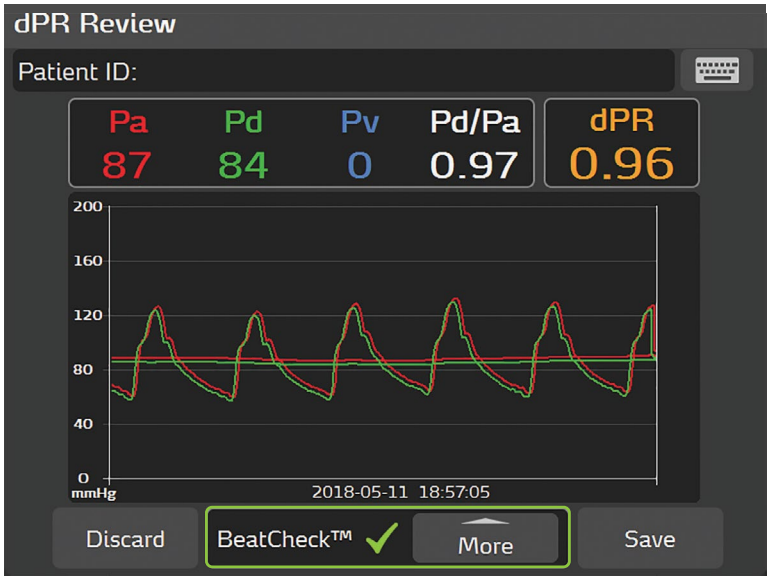
- The previous three dPR and FFR measurements will be shown chronologically top to bottom on the main screen.



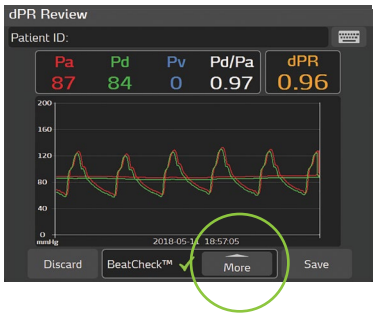
Step **5**

Pressing **OK** will exit this screen.

BeatCheck™



BeatCheck™ is a signal quality monitoring algorithm to identify ectopic rhythms that may impact the dPR measurement.

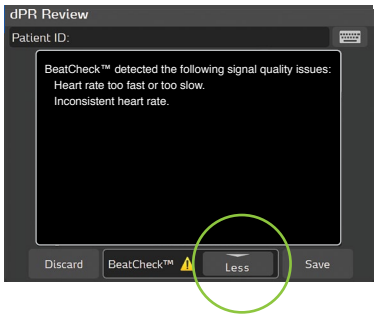


Step **1**

If ectopic rhythms are identified, a general warning alert will appear in order to notify the user.

Pressing the **MORE** button will provide additional information.

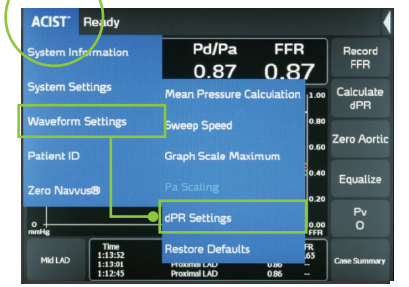
- See page 19 for detailed information on BeatCheck message.



Step **2**

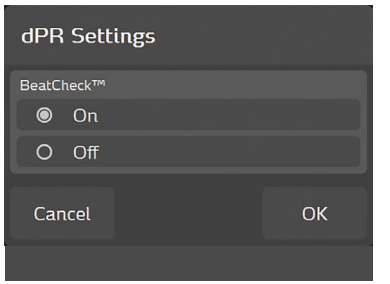
This screen will identify the BeatCheck parameter that was flagged as irregular.

Pressing the **LESS** button will exit this screen.



Step **3**

If preferred, dPR BeatCheck can be disabled by pressing the **ACIST** menu under **WAVEFORM SETTINGS >dPR SETTINGS.**



Step **4**

To toggle BeatCheck off, press the **OFF** button then press **OK.**

Messages & Errors Troubleshooting

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? If no:

Probable Cause(s)	Corrective Actions
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 MicroCatheter to ensure correct catheter seating.

The System has detected a problem with the Pressure Sensor

Probably Cause(s)	Corrective Actions
Console interface is frozen and no longer accepts touch commands.	• Cycle power (on weekly basis). Console boot sequence will take approximately 30 seconds. • When system is fully operational, re-insert catheter.
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.
Sensor was 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 inserted in patient.	• Remove Navvus MicroCatheter from body or discontinue flushing during catheter connection. • Plug Navvus MicroCatheter into console prior to flushing hoop. • Catheter tip should be outside patient when inserting catheter handle into system console.
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 (with PIM door holder), or return console to ACIST for service.

Note: *When handling the Navvus MicroCatheter, ensure hub stays clean and dry. If hub is contaminated with fluid, replace catheter. Do not attempt to connect catheter to console after contamination.*

WARNING! Catheter Malfunction Detected

Stop procedure immediately and replace catheter with a new one.

Probable Cause(s)	Corrective Actions
RXi System does a self-check when catheter is plugged into console to ensure proper functioning of catheter prior to its use in patient. Navvus MicroCatheter malfunction.	• Replace Navvus MicroCatheter with a new catheter. • If warning message persists after replacing Navvus MicroCatheter, return console and suspect catheter(s) to ACIST for investigation. • Reoccurring errors may indicate fiber optic mechanism in catheter port housing is malfunctioning. Return console to ACIST for investigation.

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

Status Message: "Connect Aortic Pressure Cable"

Probable Cause(s)	Corrective Actions
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.
Connection issue with the RXi cable to the hemodynamic system tram.	• Ensure the aortic pressure cable is connected securely to the tram.

Status Message: "Connect Pressure Sensor"

Probable Cause(s)	Corrective Actions
Indicates the Navvus MicroCatheter is not connected properly.	• Connect Navvus MicroCatheter and continue.

Messages & Errors Troubleshooting

Equalization Button is Grayed Out

Probable Cause(s)	Corrective Actions
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

Probable Cause(s)	Corrective Actions
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 able and ensure secure connection to the RXi console.

dPR BeatCheck™ Messages

BeatCheck™ detected the following signal quality issues:

When activated, BeatCheck performs quality checks on the signal quality of dPR recording calculations. Display the BeatCheck messages by pressing **MORE** on a dPR Review screen. The heading for all BeatCheck signal quality issues screen is:

Message		Corrective Actions
No issues detected.	✓	• No signal quality issues were detected.
Aortic signal out of range. Check zero or signal damping.	⚠	• Aortic signal is too high, too low, or the pulse pressure is too low. • Check the aortic zero to ensure that the signal is correctly zeroed. • Verify the aortic signal is not dampened.
Distal signal out of range. Check equalization or signal damping.	⚠	• Distal pressure is too high, too low, or the pulse pressure is too low. • Verify the signals were properly equalized. • Verify the distal signal was not dampened.
Distal signal greater than aortic signal. Check equalization or signal damping.	⚠	• Distal pressure is greater than aortic pressures. • Verify the signal was properly equalized, or if there is potential dampening (likely with aortic pressure).
Heart rate too fast or too slow.	⚠	• The patient's heart rate is too fast or too slow.
Inconsistent heart rate.	⚠	• The system verifies the heart rate of all beats used in the dPR calculation are consistent. This message indicates one or more beats have a significantly different duration (likely due to an arrhythmic beat). • Attempt the recording again.

Prior to use, reference Instructions for Use, inside the product carton (when available) or at acist.com for more detailed information on safe use of the device.

Indications for Use: The ACIST RXi® System and the RXi Mini are indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus® & Navvus® II MicroCatheter is intended for use with the entire family of ACIST RXi® Systems.

Contraindications: The ACIST Navvus® Catheters are contraindicated for use in the cerebral vasculature.

Important Safety Info: The RXi System is to be used only on order of a physician by medical professionals with adequate training and experience in the operation of the RXi System and angiographic procedures and techniques. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the patient catheter. Diligence on the part of the user is an essential requirement of overall device safety. The RXi System is not intended a use as a blood pressure monitoring system. Do not use for blood pressure monitoring. RXi Mini is not intended to be used with high frequency surgical equipment.

Prior to use and whenever possible during the procedure, carefully inspect the Navvus Catheter for kinks or any other damage. Do not use a kinked or damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur. When delivering the Navvus Catheter over the guidewire, ensure that the guidewire and the Navvus Catheter are freely moving within the vessel wall. Failure to do so may traumatize the vessel. The Navvus Catheter is not designed to be torqued. Do not excessively torque the catheter. Never advance or withdraw the Navvus Catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation. This product should not be used in rooms containing magnetic resonance imaging (MRI) equipment.

To avoid inaccurate arterial pressure measurements, the use of guide catheters larger than 8F or guide catheters with side holes are not recommended. The Navvus Catheter is not compatible with 4F guide catheters. Do not perform high pressure (> 600 psi) fluid injections while the Navvus Catheter tip is inside a guide catheter.

Potential complications that may be encountered during all catheterization procedures include but are not limited to: vessel dissection or occlusion, perforation, embolus, spasm, local and/or systemic infection, intimal disruption, distal embolization of blood clots and plaque, myocardial infarction, serious arrhythmias, or death.

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ACIST dPR is available in select markets.

Contact your authorized ACIST Medical Systems representative for the most current information.

Conforms to ANSI/AAMI STD ES60601-1, IEC STDS 60601-2-18 and 60601-2-37.
Certified to CSA STD C22.2 No. 60601-1.

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