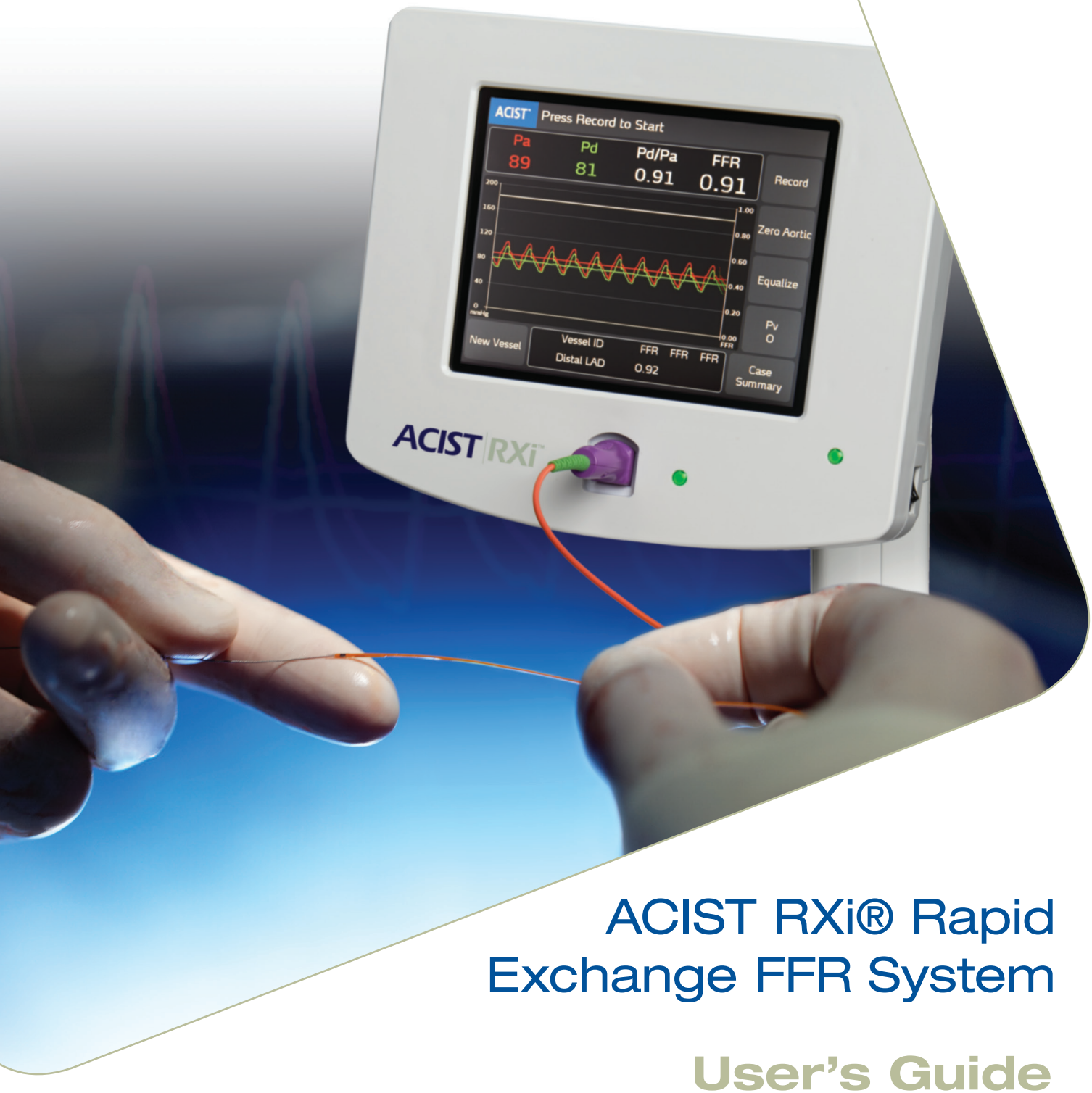
ACIST **RXi®**



ACIST RXi® Rapid Exchange FFR System

User's Guide

Bracco Group
901700-001,01 2019-09 English

ACIST®

Proprietary Information Notice

Contact Information

Web site (worldwide)	acist.com
USA	ACIST Medical Systems, Inc. 7905 Fuller Road Eden Prairie, MN 55344 USA
	Technical Support: 1-888-670-7701 or 952-941-3507 Fax: 952-941-4648 Email: customer.support@acistmedical.com

In other areas of the world, contact your local distributor or representative.

Contents

1 Introduction

Indications for Use/Intended Use

The ACIST RXi® System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus® MicroCatheter is intended for use with the ACIST RXi System.

Note

The RXi System is for use only on the 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.

Intended Patient Population

This product is designed for use in adult patients identified by a physician as suitable candidates for vascular pressure measurement, taking into consideration the patient's anatomy and health status.

Device Description

The ACIST RXi System is designed to provide hemodynamic information for the diagnosis and treatment of coronary and peripheral artery disease. The system is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display fractional flow reserve (FFR) and resting Pd/Pa.

FFR and resting Pd/Pa supplements the visual data provided by angiography and provides an assessment of the lesion severity.

Measurement of FFR and resting Pd/Pa requires simultaneously monitoring the blood pressures proximal and distal to a lesion. The ACIST RXi System includes a single-use microcatheter with a pressure sensor for acquisition of the distal pressure. The proximal pressure is acquired via the guide catheter which is monitored by the ACIST RXi System via an interface to the hospital's hemodynamic monitor.

Pd/Pa is the ratio of distal coronary arterial pressure to aortic pressure, measured at resting conditions. The physician may then use the resting Pd/Pa value, along with knowledge of patient history, medical expertise and

clinical judgment to determine if an additional measurement of FFR during hyperemia or therapeutic intervention is indicated.

About this User's Guide

This user's guide provides instructions for setting up and using the ACIST RXi System. It includes the following sections:

Section		Purpose
1	Introduction	Defines the indications for use and provides a description of the RXi System. Provides an overview of the purpose and structure of this user's guide.
2	Warnings, Cautions, and Symbol Definitions	Users must read and understand this section thoroughly before using the RXi System.
3	System Overview	Describes the system components and functions.
4	Installation Instructions	Explains how to install the system.
5	Basic Operating Procedures	Provides instructions for preparing and using the RXi System for obtaining FFR recordings during angiographic procedures.
6	System Information and Settings	Provides instructions for reviewing system information and changing system settings.
7	Maintenance	Provides instructions for care and cleaning.
8	Troubleshooting and Support	Provides suggested corrective actions in response to system messages and conditions.
9	Glossary	Provides definitions of terms and acronyms.
10	Technical Specifications	Provides technical specifications and reference information.
11	Limited Warranty	Provides warranty information.
	Appendix: Ao Interface Box	Provides instructions for installation, operation, and maintenance of the Ao Interface Box.

Manual Conventions

This manual uses the following conventions:

Note

Notes are used to highlight important information from the rest of the text.

CAUTION

Cautions alert the user to a possible hazard that may result in equipment damage or personal injury.

WARNING

Warnings alert the user to a possible hazard that may cause serious injury or death.

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2 Warnings, Cautions, and Symbol Definitions

Read this First!

Before using the ACIST RXi® System, please read and fully understand this entire section. Failure to do so may result in serious injury to the patient or the user, or damage to the ACIST RXi System or other equipment. If you have any questions after reading this section, please contact ACIST Medical Systems, Inc. Technical Services.

Warnings

The following warnings refer to hazards that can cause serious injury or death. Read this section carefully.

- To avoid the risk of electric shock, this equipment must only be connected to a supply mains power outlet with protective earth.
- No modification of this equipment is allowed.
- In order to avoid the potential for electric shock to the patient, do not simultaneously touch the patient and either the system console screen, USB, Ethernet or hemodynamic connectors located behind the sterile drape.
- Prior to use and whenever possible during the procedure, carefully inspect the Navvus MicroCatheter for kinks or any other damage. Do not use a kinked or damaged microcatheter as vessel damage and/or the inability to advance or withdraw the microcatheter may occur.
- The Navvus MicroCatheter is supplied sterile in a protective carton containing a sterile barrier tray. Sterility is indicated by a chemical process 'dot' label, which during successful sterilization turns green. Verify package integrity before use. If the sterile barrier package is damaged or the seal is not intact, or if the dot is not green, DO NOT use the product. Contact an ACIST representative to return damaged product. Do not use this product beyond the 'Use by' date indicated, as product integrity and sterility cannot be guaranteed.
- Any serious incidents related to the product or its use must be reported to ACIST Medical Systems, Inc., as well as the competent authority of the Member State or country in which the user and/or patient is established.

- Improper technique may damage ~~a~~ the Navvus MicroCatheter. Exercise care in handling the microcatheter during a procedure to reduce the possibility of accidental breakage or kinking.
- Do not disturb pressure sensing system elements during equalization or FFR recording.
- If a broken fiber optic is detected within the Navvus MicroCatheter, a visual and auditory technical alarm condition is triggered. The defective microcatheter, along with the guide catheter, must be immediately removed and replaced.
- If the system is set to Stationary mode and you move the system from one lab to another, you must manually zero the RXi aortic pressure after you zero the hemodynamic monitoring system or an incorrect FFR or resting Pd/Pa value may result.
- To prevent electric shock, always turn off power to the system and disconnect the power cord from the main power source before performing any cleaning or service procedure.
- Never touch any pins on connectors or cables that have become disconnected from a system while power is on.
- Never immerse any system component in water or in a cleaning solution.
- This equipment is not suitable for use in the presence of flammable anesthetic agents.
- The RXi system should not be used in rooms containing magnetic resonance imaging (MRI) equipment.

Cautions

The following cautions refer to hazards that could result in minor injury or damage to the system or other equipment. Read this section carefully.

- This system is not intended for use as a blood pressure monitoring system.
- Use only the supplied medical grade power converter (Model MENB1030A1249F02) to ensure safe operation of the ACIST RXi System.
- To prevent equipment damage, accessory equipment connected to the analog or digital interfaces on the RXi System must be certified to the respective IEC standard UL/IEC 60601-1 for medical equipment. Any person who connects equipment to the input or output signal port is configuring a medical system. Therefore, this person is responsible for ensuring that the system complies with the requirements of the system standard UL/IEC 60601-1. If in doubt, consult ACIST Medical Systems Technical Services or your local ACIST representative for assistance.
- Mains power quality should be that of a typical commercial or hospital environment. To ensure that the RXi System remains operational during power mains interruptions, ACIST recommends that an uninterruptible power supply or battery backup be used to power the system.
- Connect only to certified hemodynamic systems that have no more than 36 VDC output voltage.
- Ensure aortic pressure is correctly set to zero on the ACIST RXi System. Always verify that the Pa value is zero.
- Only qualified medical professionals may use the ACIST RXi System. User vigilance is required at all times when using the system.
- To avoid inaccurate arterial pressure measurements, the use of guide catheters larger than 8F or guide catheters with side holes are not recommended. Avoid blocking blood flow to the selected artery. Do not wedge the guide catheter in the selected artery.
- Carefully place the Navvus MicroCatheter on the guidewire to avoid damage to the tip. Avoid contact between the guidewire and the small pressure sensor that is just proximal to the microcatheter tip.
- Tighten the Tuohy Borst adapter on the guide catheter after placing the Navvus MicroCatheter distal shaft inside the guide catheter, or false low aortic pressure readings may result.
- Open the hemostasis valve fully to avoid damage to the Navvus MicroCatheter tip.
- Do not perform high pressure (greater than 600 psi) fluid injections while the Navvus MicroCatheter tip is inside a guide catheter.
- Observe all Navvus MicroCatheter movement in the vessel. When the microcatheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter without observing the resultant tip response.

- Always advance or withdraw a Navvus MicroCatheter slowly and carefully.
- Verification of aortic and distal pressures is very important for the upcoming pressure recordings. If the baselines are not equal at this point, a systematic error will be created throughout the FFR calculations.
- Always wear protective gloves and eye protection when cleaning or decontaminating the system.
- Never allow oil or materials containing oil to come in contact with any part of the system console.
- Never spray or pour any liquid directly onto the power supply, system console, or control panel.
- Do not use any sharp objects or apply excessive pressure to any component.
- Discard all cleaning materials in accordance with all local, state, and federal regulations, codes, and directives.
- Inaccurate measurements from the hemodynamic pressure transducer may result if the transducer is not prepared and connected correctly.
- With the stopcock at the midaxillary position, zero the hemodynamic transducer at the start of each patient case by using atmospheric pressure as a zero pressure reference. Zeroing the transducer ensures that the pressure values measured are only from within a blood vessel or from within the heart. Periodically re-zeroing the transducer ensures the continued accuracy of blood pressure readings. If hemodynamic signal drift is suspected, re-zero the transducer.
- Prior to recording physiological blood pressures with the hemodynamic pressure transducer, re-zero the transducer at the patient midaxillary position to establish a clear baseline. (Changes in bed height, atmospheric pressure, catheter hub position, fluid density, and so on, may affect the baseline pressure.)
- The blood pressure waveform may be dampened significantly when using very small diameter catheters filled with contrast. Perform a saline flush before recording physiological waveforms with the transducer system.
- When using an ACIST or a third-party hemodynamic transducer, clear all tubing of air to avoid producing an inaccurate reading.
- Whenever the hemo system is "zeroed", ensure the stopcock is open and actively zero RXi using the **Zero Pa** button.

Symbol Definitions

Symbol	Definition
	Caution
	Type CF applied part
	Defibrillation-proof type CF applied part
	Manufacturer, Date of manufacture
	Date of manufacture
	Serial number
	Catalog number
	Collect separately
	With respect to electrical shock, fire, mechanical, and other specified hazards, only in accordance with IEC 60601-1, second and third editions.
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Do not re-sterilize
	Quantity
	Use-by date
	Sterilized using ethylene oxide
IPX0	IEC 60529 European (ECC) Water Protection Specifications.
	Direct Current (5031)
	Class II equipment
	Keep dry
	Consult instructions for use or consult electronic instructions for use

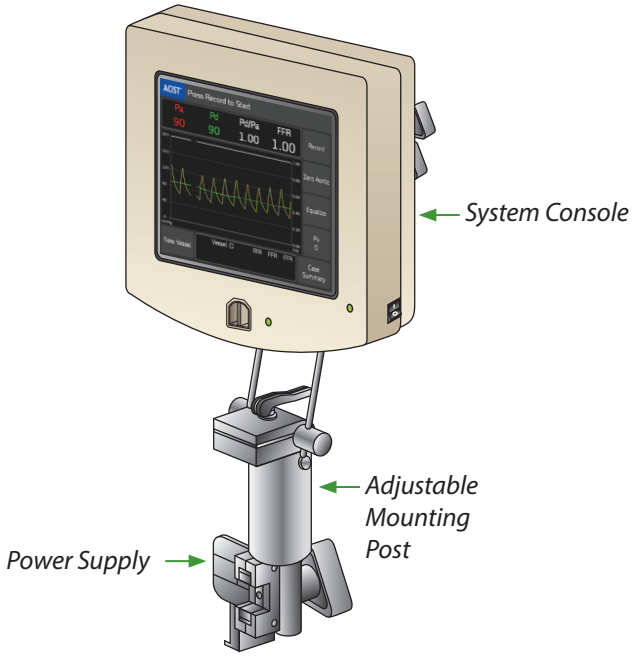
Symbol	Definition
	On power
	OFF power
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Refer to instruction manual/booklet
	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.
	Non-pyrogenic
	Not made with natural rubber latex
	Fragile; handle with care
	Connector #1 for the BNC connector on the RXi Ao input cable
	Connector #2 for the cath lab invasive blood pressure transducer cable
	Connector #3 for hemo system cable
	MR unsafe
	Medical device
	Single sterile barrier system
	Single sterile barrier system inside protective packaging

3 System Overview

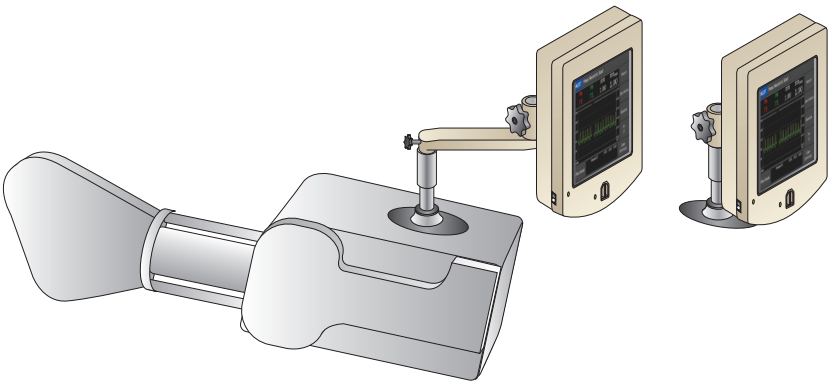
System Hardware

The ACIST RXi® System includes three main hardware components:

- system console
  displays blood pressure and computes the FFR value
- power supply
  attaches to the mounting post and provides power to the system console
- one of two mounting systems that supports the system console:
  - Stationary Mount System that attaches to the bed rail
  - Pivoting Mount System that attaches to the ACIST CVi® Injector



Stationary Mount System that attaches to the bed rail



Pivoting Mount System that attaches to the ACIST CVi Injector

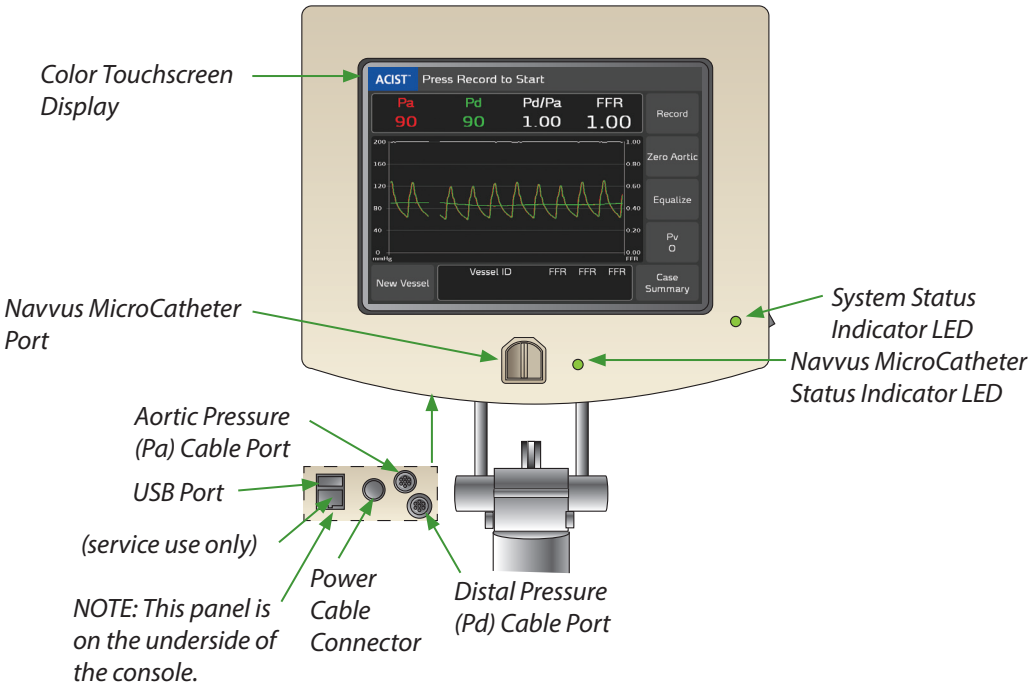
The system hardware also includes the following:

- power and communication cables
- hemodynamic monitor cables

System Console

The system console provides the main user interface for the ACIST RXi System, and includes the following features:

- color touchscreen display, which provides pop-up message notifications and button touch feedback
- Navvus® MicroCatheter port
- speaker, which provides audible alerts
- USB port used for installing software updates and exporting screenshots of FFR results
- hemodynamic cable ports
- power cable



System Power Supply

The power supply, which provides power to the ACIST RXi System, is the only connection to mains power. A green system status indicator light illuminates when power to the system is on and ready for use.

CAUTION

Use only the supplied medical grade power converter (Model MENB1030A1249F02) to ensure safe operation of the RXi System.

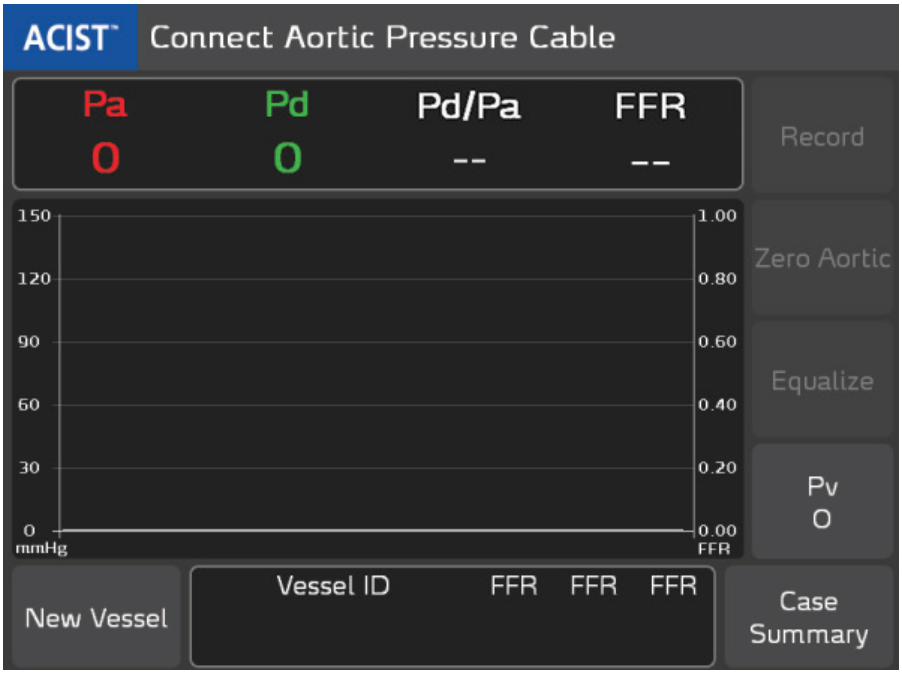
Touchscreen User Interface

Purpose of the Touchscreen

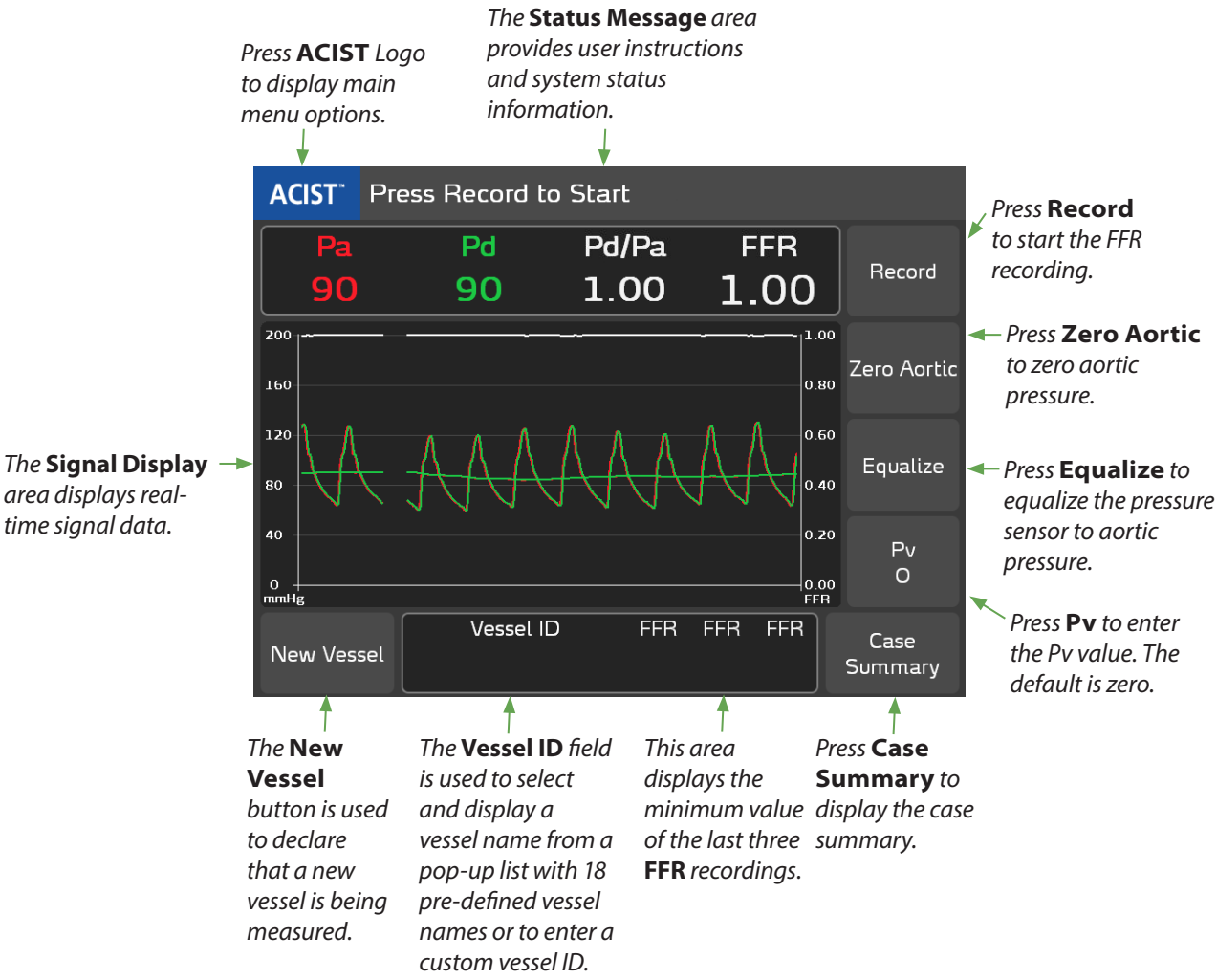
The console touchscreen is the main user interface for the ACIST RXi System and provides the following functionality:

- guides the user in system operation
- zeros the aortic pressure signal
- equalizes the RXi pressure sensor and aortic pressure signals
- adjusts the Pv value
- displays the mean Pa, Pd, Pd/Pa, and FFR values
- identifies the vessel
- shows the last three FFR recorded values
- enables access to system settings via a main menu
- enables viewing the case information
- calibrates the RXi Pa signal to the hospital's hemodynamic system signal

The following example of the console touchscreen shows the user interface upon initial startup.



Functional Areas of the Touchscreen



Navvus® MicroCatheter

Use only an ACIST Navvus MicroCatheter with the ACIST RXi System.

The Navvus MicroCatheter is a single-lumen monorail microcatheter designed for use with 0.014 in. guidewires in the arterial vasculature.

The pressure sensor utilizes optical sensing technology. A single connection between the Navvus MicroCatheter and the ACIST RXi System incorporates the optical connection. An electrical interface provides sensor-specific calibration information. The sensor pressure signals are processed by the ACIST RXi System console, which displays Pd/Pa, FFR, Pa, and Pd values in real time.

4 Installation

Unpacking

Preliminary Inspection

After receiving the ACIST RXi® System, check the packaging and inform ACIST Technical Services of any damage. Perform the following steps while unpacking the unit:

- Strip the tape from the carton by hand. Do not use a knife or any other sharp instrument.
- Carefully examine all components for damage.
- If any damage is found, save the box and the packaging materials.

Package Contents

The ACIST RXi System is shipped in one box. The individual packages within that box contain the following items:

- Package 1 contains the system console, power supply and cable, and a literature reference card.
- Package 2 contains the mount and hardware, and a hook and loop fastener strap.
- Package 3 contains accessories (hemo system input and output cables).

Note

This user's guide is supplied using a variety of methods, including via a provided link to a website, on a CD supplied with the product, etc. For additional copies, contact ACIST Medical.

Carefully inspect the contents to ensure everything is included. If any contents are missing, call ACIST Technical Services.

Installation Precautions

ACIST Medical Systems recommends that you not remove package contents until instructed to do so. This prevents damaging or misplacing any equipment or hardware.

CAUTION

To prevent equipment damage, accessory equipment connected to the analog or digital interfaces on the RXi System must be certified to the IEC standard UL/IEC 60601-1 for medical equipment. Any person who connects equipment to the input or output signal port is configuring a medical system. Therefore, this person is responsible for ensuring that the system complies with the requirements of UL/IEC 60601-1. If in doubt, consult ACIST Medical Systems Technical Services or your local ACIST representative for assistance.

CAUTION

Mains power quality should be that of a typical commercial or hospital environment. To ensure that the RXi System remains operational during power mains interruptions, ACIST recommends that an uninterruptible power supply or battery backup be used to power the system.

Before beginning installation, perform the following steps:

- Review possible mounting locations to ensure that the console touchscreen can be easily reached and viewed by the user.
- Verify that the mounting plate on the mounting post is securely fastened to the console. Tighten the screws if necessary.
- Ensure that the selected location of the ACIST RXi System is appropriate for the user's needs.
- Review the access to the AC main power source. The power supply must be placed close to an outlet under the bed. Its AC line cord measures approximately 8 feet (2.5 meters).
- Ensure the host hemodynamic system has an available Pa output of 100 mmHg/V or 20 mmHg/V signal.

Installation Procedures

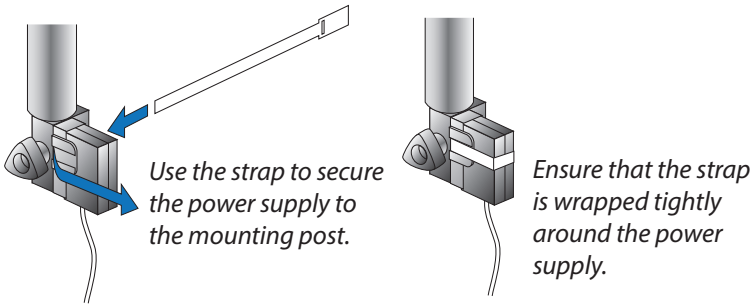
The ACIST RXi System installation includes the following procedures:

- How to mount the system on a bed rail or an ACIST CVi® Injector
- How to connect the ACIST RXi System to the hospital's hemodynamic system
- How to zero the aortic pressure
- How to enter the Facility Name and the Lab ID (optional)
- How to perform Pa Scaling (adjusting the aortic pressure value to match the value on the hemodynamic system)

Mount the ACIST RXi® System on a Bed Rail

To mount the ACIST RXi System on a bed rail:

1. Attach the power supply to the bed rail mounting post. Use the hook and loop fastener strap to secure the power supply, as shown below:



2. Ensure that the system console is securely attached to the plate on the mounting post.

3. Attach the mounting post to the desired location on the bed rail:
   - Turn the lower knob counter-clockwise to open the brackets wide enough to fit over the bed rail, as shown in Figure A.
   - Place the mounting post's brackets on the bed rail.
   - Turn the lower knob clockwise to tighten the brackets on the bed rail, as shown in Figure B.

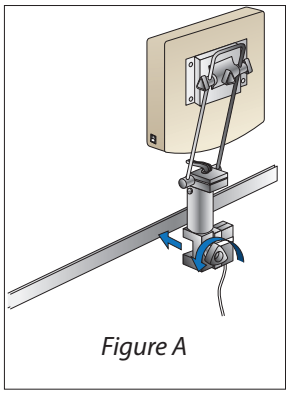


Figure A

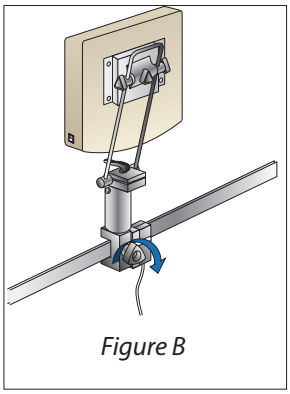
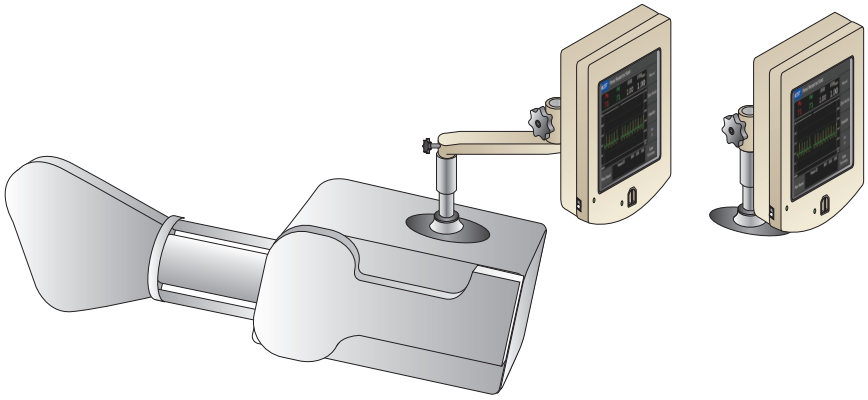


Figure B

4. Ensure that the mounting post is securely fastened on the bed rail.
5. Use the vertical and horizontal adjustment knobs to customize the orientation of the system unit on the bed rail.
6. Connect the power supply cable to the system console.
7. Connect the power cord to an AC mains power source. The power supply must be positioned to provide easy access to either or both ends of the line power cable for disconnection from mains power.

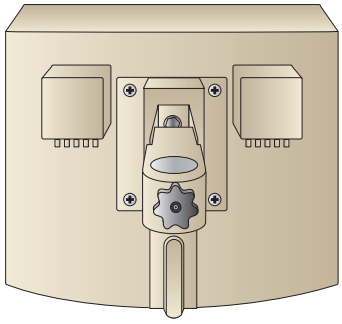
Mounting the ACIST RXi® System to the ACIST CVi® Injector with the Pivoting Mount System

The Pivoting Mount System is used to attach the ACIST RXi System onto the ACIST CVi Injector with or without the optional extension arm as shown below.

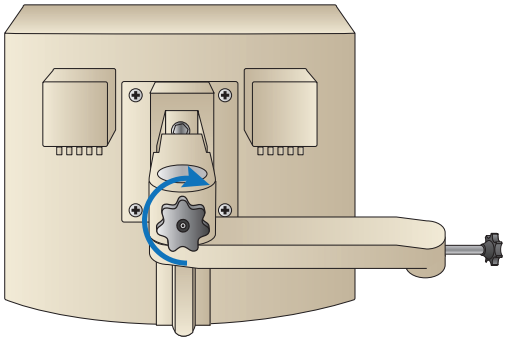


To mount the ACIST RXi console on an ACIST CVi Injector:

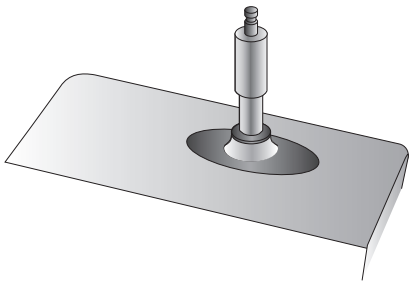
1. Connect the pivot bracket to the ACIST RXi console with four Phillips head screws. Ensure that the pivot bracket is securely fastened to the console.



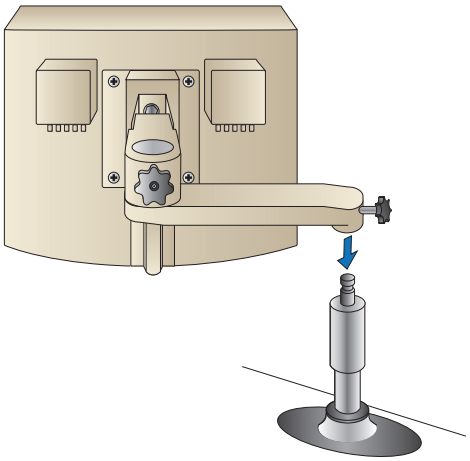
2. If using the optional extension arm, insert it into the pivot bracket and turn the knob on the pivot bracket clockwise to tighten.



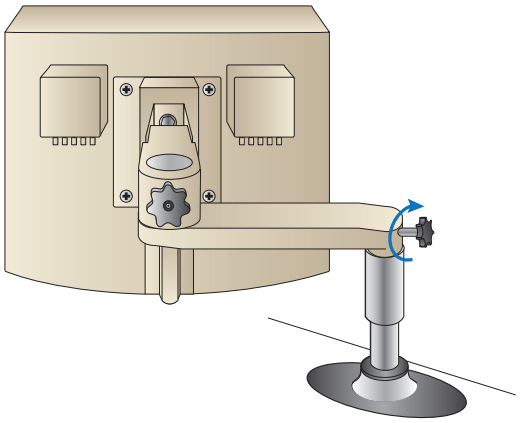
3. Insert the adapter pin in the display arm socket on the Injector, ensuring that the notch in the pin is properly aligned and the adapter pin is fully seated in the socket.



4. Attach the pivot bracket or the optional extension arm to the adapter pin.



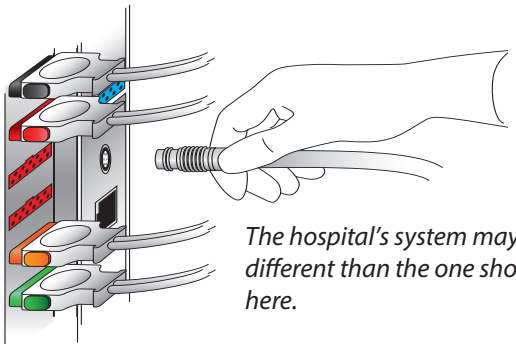
5. Turn the knob on the pivot bracket or the extension arm clockwise to tighten.



Connect the ACIST RXi® System to the Hospital's Hemodynamic System

To connect the ACIST RXi System to the hospital's hemodynamic system:

1. Ensure that the ACIST RXi System has been properly installed on a bed rail or an ACIST CVi Injector and is connected to the main power source.
2. Turn the system on as follows:
   - Facing the RXi touchscreen display, use the switch on the right side of the unit to turn on the ACIST RXi System.
   - Confirm that the front right green LED is illuminated.
3. Connect the RXi aortic pressure cable to the analog output port on the hemodynamic system, as shown below:



The hospital's system may be different than the one shown here.

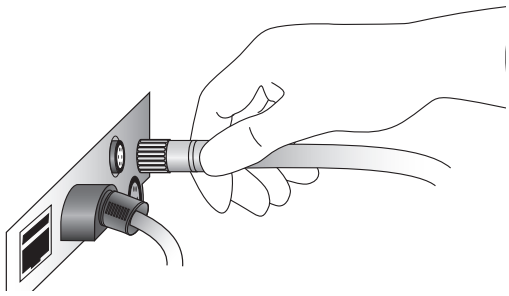
Note

Ensure that you have the correct aortic pressure cable for the hospital's hemodynamic system.

CAUTION

Connect only to certified hemodynamic systems that have no more than 36 VDC output voltage.

4. Connect the other end of the RXi aortic pressure cable to the round port (the one closest to the power cable) on the bottom of the ACIST RXi System as shown below:



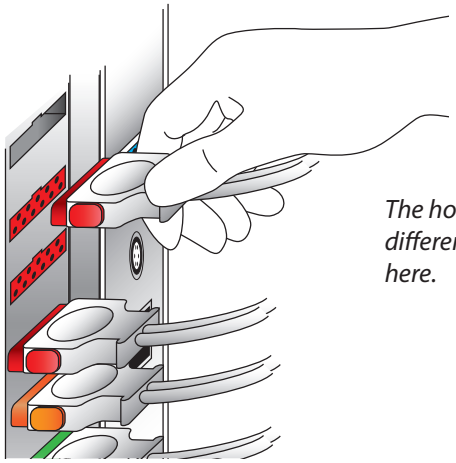
Note

This task of connecting the aortic pressure cable typically needs to be done only at installation or when connecting to a new hemodynamic monitor. You must verify that the aortic pressure zero is correct for each new patient case.

5. *Optional:* You may connect the RXi pressure output cable to an available pressure input on the hemodynamic system.

Note

This connection is not required, but it allows you to view and record the pressure waves on the hemodynamic system.

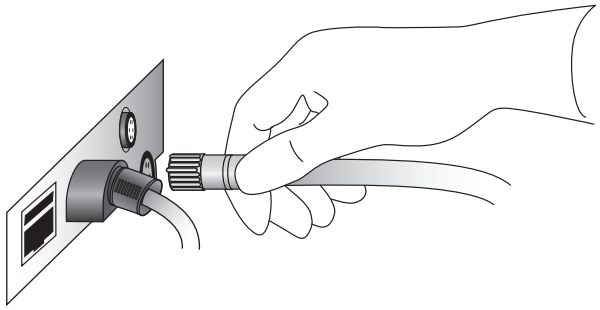


The hospital's system may be different than the one shown here.

Note

Ensure that you have the correct pressure output cable for the hospital's hemodynamic system.

6. Connect the other end of the RXi pressure output cable to the ACIST RXi System, as shown below:



Zero the Aortic Pressure on the ACIST RXi® System

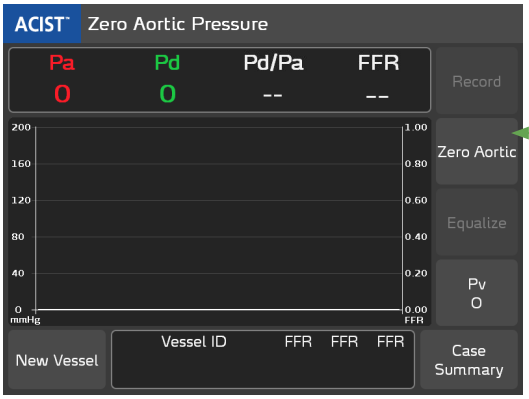
To ensure that the hemodynamic monitoring system is reading a zero value:

- Turn on power to the system. (Refer to page 30 for instructions.)
- With the stopcock at the midaxillary position, open the stopcock to expose the hemodynamic sensor to atmospheric pressure at the patient midaxillary position.
- Zero the hemodynamic monitor.

Zero the aortic pressure on the ACIST RXi System:

1. When the following status message appears on the touchscreen, press Zero Aortic:

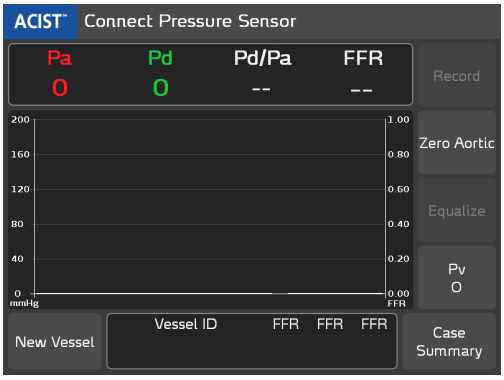
Zero Aortic Pressure



Press **Zero Aortic** *at the system prompt.*

2. Verify that the aortic signal (Pa) is showing zero (0) in the display area. Also verify that the hemodynamic monitor is showing zero (0).

In this example, the aortic signal **(Pa)** *is zero.*



Enter the Facility Name and Lab ID (Optional)

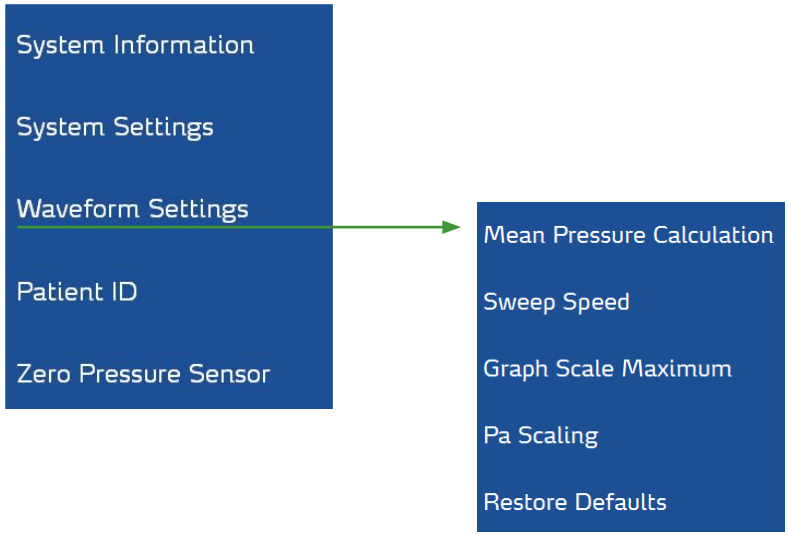
When entered, the Facility Name appears in the exported patient case summary, while the Lab ID appears in the case summary and in the exported case summary.

You may enter or change the Facility Name and Lab ID information at any time, but ACIST Medical Systems recommends that you do this during system installation.

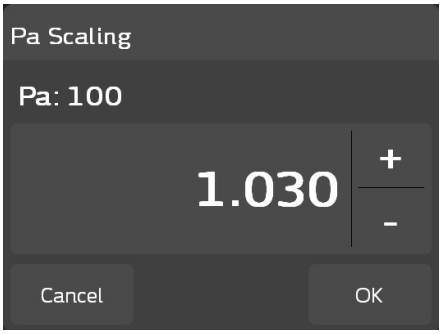
Instructions for using these options are provided in Section 6, *System Information and Settings*. Refer to page 54 for instructions on entering or changing a Facility Name. Refer to page 56 for instructions on entering or changing a Lab ID.

Perform Pa Scaling

Select the **Waveform Settings** option on the ACIST Main Menu, which provides a submenu of waveform configuration options. From this submenu, select Pa Scaling.



After selecting Pa Scaling, the following screen is displayed.



After zeroing the aortic pressure, Pa scaling must be performed if the value on the hemodynamic system is different from the Pa value that appears on the RXi touchscreen. If the two values are equal or within ±1 mm Hg, it is not necessary to perform this procedure.

Note

The signal from the hemodynamic system must be something other than zero before this procedure can be performed.

If the transducer has a backplate that creates a steady test pressure, use this to artificially apply a steady test pressure of 100 mm Hg. This is preferable to using a live pressure. However, if unable to send a steady pressure, getting the two values to match can be achieved, but may require more effort.

Use the + and – buttons on the RXi screen to adjust the signal from the hemodynamic system (1.030 was used in this example) to match the RXi Pa value displayed on the hemodynamic system screen. When these are equal, press **OK**.

Note

If the Pa value on the RXi system no longer equals the value on the hemodynamic system, this procedure must be repeated.

Note

If the RXi System is connected to a different hemodynamic system, this procedure may need to be repeated.

5 Basic Operating Procedures

Before Using the ACIST RXi® System

Before using the ACIST RXi® System:

- Read the warnings and cautions in Section 2.
- Complete the training provided by an ACIST Medical Systems representative before using the System for any patient procedures.
- Review the maintenance requirements and ensure they are performed on schedule as discussed in Section 7, *Maintenance*.
- As an option, use the system settings to adjust the system to specific parameters. Refer to Section 6, *System Information and Settings*, for more information.
- If used in a sterile field, ensure that the ACIST RXi System console is draped with a sterile barrier.

CAUTION

Ensure aortic pressure is correctly set to zero on the RXi System. Always verify the Pa value is zero on the hemodynamic system when zeroing the RXi Pa signal.

Only qualified medical professionals may use the ACIST RXi System. User vigilance is required at all times when using the system.

Start the ACIST RXi® System

Power On

WARNING

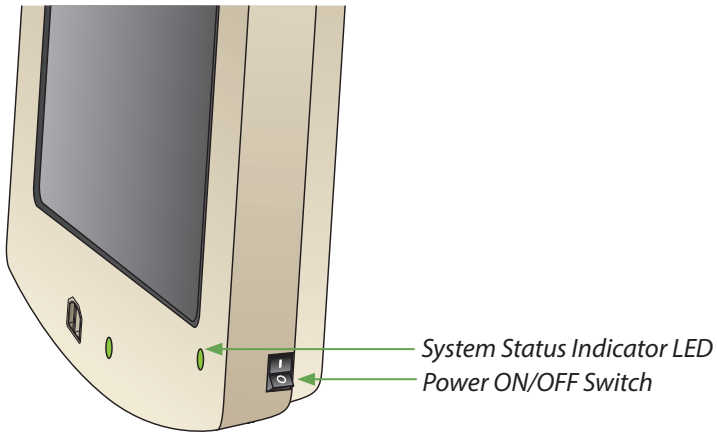
In order to avoid the potential for electric shock to the patient, do not simultaneously touch the patient and either the system console screen, USB, Ethernet or hemodynamic connectors located behind the sterile drape.

Start the ACIST RXi System:

1. Ensure the ACIST RXi System has been properly installed and securely attached on the bed rail or an ACIST CVi® Injector.
2. Turn on the system:
   - Facing the RXi console, use the switch on the right side of the unit to turn on the ACIST RXi System.

     | ON power

     ◯ Off power
   - The green system status indicator LED located on the console's front right side shows that power is on.



3. Wait approximately 30 seconds for the system to start. The main screen is displayed when the system is ready for setup. The status line provides instructions to start the setup procedures. If errors are detected during startup, the touchscreen displays an error message.

Verify that the Aortic Pressure is Zero

Zero Aortic Pressure

CAUTION

Ensure aortic pressure is correctly set to zero on the RXi System. Always verify that the Pa value is zero.

If the system has been set up as a mobile device, you must zero the aortic pressure signal before each case.

With the hemodynamic monitor still reading zero, re-zero the RXi aortic pressure if necessary. If using the Mobile setting for the Lab ID (as described on page 55):

- Press the **Zero Aortic** button.
- If zeroing was previously performed, the system confirms the action by displaying the following message:

  Do you want to zero the aortic pressure?
- Press **OK**.

Note

If the Ao Interface Box is connected to the RXi System, refer to Appendix A for additional information on zeroing.

Identify the Patient ID and the Vessel ID for the Case

Patient ID

To associate a Patient ID with the case, provide a Patient ID using the ACIST menu. For detailed instructions, refer to *Enter a Patient ID* on page 64.

Vessel ID

Provide a Vessel ID to identify the vessel being examined. For detailed instructions, refer to *Define a Vessel ID using the New Vessel Button* on page 67.

Unpack and Prepare the Navvus® MicroCatheter

Preparation Needed

The following instructions provide technical direction, but do not eliminate the need for formal training in the use of the Navvus MicroCatheter and the ACIST RXi System. The techniques and instructions provided here do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient.

Required Materials

Each Navvus MicroCatheter package contains the following components:

- one single-use disposable microcatheter
- one dispenser coil
- one monorail stylet

Other materials that are required ***but not supplied*** include the following:

- 5F to 8F guide catheter
- standard guidewire
- hand syringe used for flushing the dispenser coil and catheter
- sterile saline solution

CAUTION

To avoid inaccurate aortic pressure measurements, the use of guide catheters larger than 8F or guide catheters with side holes are not recommended. Avoid blocking blood flow to the selected artery. Do not wedge the guide catheter in the selected artery.

WARNING

Prior to use and whenever possible during the procedure, carefully inspect the Navvus MicroCatheter for kinks or any other damage. Do not use a kinked or damaged microcatheter because vessel damage and/or inability to advance or withdraw the microcatheter may occur.

The Navvus MicroCatheter is supplied sterile. If the sterile package is damaged or the seal breached, discard the product. Do not re-sterilize the microcatheter. Do not use the product beyond the expiration date indicated on the product packaging.

Improper technique may damage the Navvus MicroCatheter. Exercise care in handling the microcatheter during a procedure to reduce the possibility of accidental breakage or kinking.

Unpack and prepare the Navvus MicroCatheter by performing these steps:

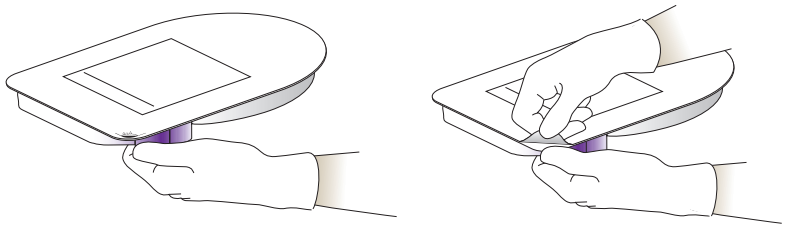
1. Carefully inspect the Navvus MicroCatheter packaging and components for damage prior to use.
2. Using sterile technique, open the Navvus MicroCatheter package as shown:

   Technician:

   a. Place your left thumb on the plastic corner just under the "Open" symbol and grip the underside of the tray at the corner with your fingers.

   b. Hold the tray securely with your left hand and use your right hand to peel the cover back and off the tray.

   c. Present the opened tray to the scrubbed and sterile physician. Continue to hold the opened tray for the scrubbed and sterile physician until the product is removed from the tray as described below.

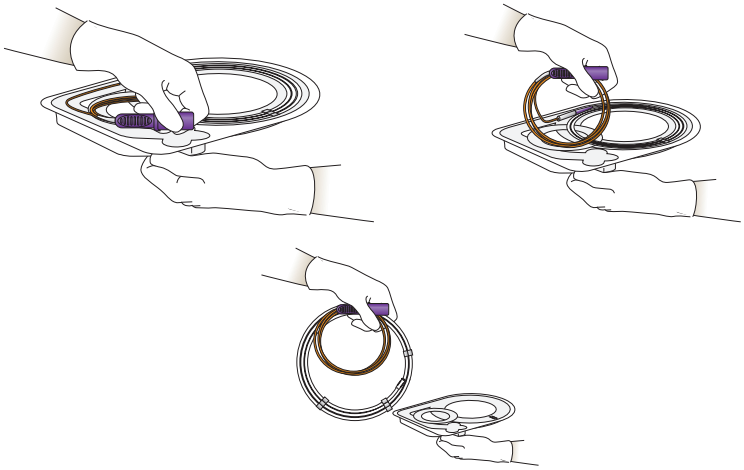


   Physician/Technician:

   d. Grasp the purple handle assembly.

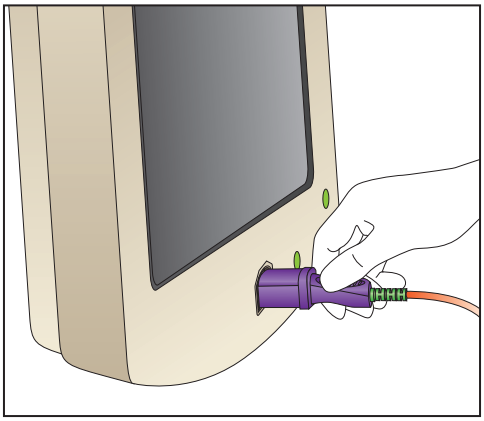
   e. Using the same hand and while still holding the purple handle, grasp the orange coil.

   f. Using the same hand and while still holding the purple handle and orange coil, finally grasp the dispenser coil.



7. Place the dispenser coil and the handle assembly cable in the sterile field. Ensure the handle assembly does not get wet.

8. Attach the Navvus MicroCatheter's handle assembly to the ACIST RXi System, as shown in the illustration below:



Note

When manipulating the Navvus MicroCatheter, avoid creating a knot in the cable.

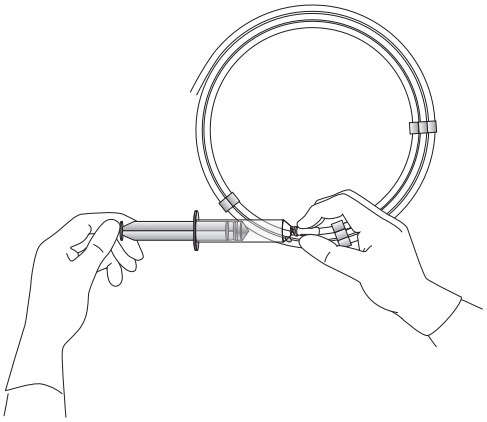
The Navvus MicroCatheter pressure sensor is automatically zeroed when the handle assembly is inserted into the ACIST RXi System console. Therefore, the tip should be outside the patient when this handle assembly is inserted into the system console.

Once inserted, do not remove the Navvus MicroCatheter from the system throughout the procedure.

The Navvus MicroCatheter status indicator LED illuminates GREEN when the handle assembly is properly inserted. If the LED illuminates RED, re-insert the handle assembly or replace the microcatheter.

9. Using sterile technique, attach a new, sterile hand syringe filled with sterile saline solution to the flushing Luer entry port of the dispenser coil.

   Thoroughly flush the Navvus MicroCatheter.



10. Using sterile technique, remove the Navvus MicroCatheter from the dispenser coil and inspect it for any damage or kinks. If damage or kinks exist, discard the microcatheter and use another.

Deliver the Navvus® MicroCatheter, Equalize Signals, and Enter Venous Pressure

Equalize Signals and Adjust Pv

The following steps assume a standard Percutaneous Coronary Intervention (PCI) protocol that uses the following items:

- an inserted 5F to 8F guide catheter
- an inserted 0.014 in guidewire
- a hemostasis valve

As with any interventional procedure, proper anticoagulation and antiplatelet therapy should be used before beginning the procedure.

WARNING

Prior to use and whenever possible during the procedure, carefully inspect the Navvus MicroCatheter for kinks or any other damage. Do not use a kinked or damaged microcatheter as vessel damage and/or inability to advance or withdraw the microcatheter may occur.

CAUTION

Carefully place the Navvus MicroCatheter on the guidewire to avoid damage to the tip. Avoid contact between the guidewire and the small pressure sensor that is just proximal to the microcatheter tip.

Tighten the Tuohy Borst adapter on the guide catheter after placing the Navvus MicroCatheter distal shaft inside the guide catheter, or false low aortic pressure readings may result.

Open the hemostasis valve fully to avoid damage to the Navvus Catheter tip.

Do not perform high pressure (greater than 600 psi) fluid injections while the Navvus MicroCatheter tip is inside the guide catheter.

Observe all Navvus MicroCatheter movement in the vessel. When the microcatheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter without observing the resultant tip response.

Always advance or withdraw the Navvus MicroCatheter slowly and carefully.

To deliver the Navvus MicroCatheter, equalize the signals, enter the venous pressure, and perform the following:

1. Verify that the system is displaying the following message:
   Ready to Equalize.
2. Remove the stylet from the end of the Navvus MicroCatheter. Do not discard.
3. On the guide catheter, tighten the Tuohy Borst adapter. Failure to do so may result in a false low aortic pressure reading.
4. Advance the Navvus MicroCatheter over the guidewire that is already in place in the distal vasculature.

Note

Carefully place the Navvus MicroCatheter on the guidewire to avoid damage to the tip. Avoid contact between the guidewire and the small pressure sensor that is just proximal to the microcatheter tip.

Open the hemostasis valve fully to avoid damage to the Navvus MicroCatheter tip.

5. Advance the Navvus MicroCatheter over the wire and position it with the radiopaque marker in the coronary ostium, 3 mm outside the tip of the guide catheter.

WARNING

Do not disturb pressure sensing system elements during equalization or FFR recording.

6. Equalization must take place with the Navvus MicroCatheter distal tip just distal to the guide catheter tip. Pressure is measured less than 3 mm proximal from the marker band that is visible under fluoroscopy:
   - Flush the guide catheter with saline solution.
   - Verify that the Pa displayed on the ACIST RXi System matches the reading on the hemodynamic monitor.
   - Press the **Equalize** button.
   - After equalization, the red and green waveforms should be superimposed and the displayed Pd/Pa value should be stable at 1.00.

CAUTION

Verification of aortic and distal pressures is very important for the upcoming pressure recordings. If the baselines are not equal at this point, a systematic error will be carried through the FFR calculations.

7. Review and adjust the venous pressure value if necessary. (The default value for the venous pressure on the ACIST RXi System is 0 mmHg.)

   All displayed calculations of resting Pd/Pa and FFR include a correction for the current Pv setting as shown in the following equation:

$$FFR = \frac{Pd - Pv}{Pa - Pv}$$

   The variables in this equation represent the following values:

   - **FFR** is the fractional flow reserve.
   - **Pd** is the mean arterial pressure distal to the stenosis as measured by the Navvus MicroCatheter.
   - **Pv** is the systemic venous pressure.
   - **Pa** is the mean aortic pressure at the ostium.

   High venous pressure (above 8 mmHg) will have a significant impact on FFR and resting Pd/Pa values. A high Pv value results in lower FFR and resting Pd/Pa values.

   To change the venous pressure value, perform these steps:

   - Press the **Pv** button on the main screen.
   - Enter the Pv value using the plus (+) or minus (-) buttons.

   The Pv value entered is displayed in the main screen.

Note

The Pv value will revert to the default value after the procedure for the current patient is completed. See page 73 for detailed instructions for changing the default Pv value.

Detection of Broken Navvus® MicroCatheter

WARNING

If a broken fiber optic is detected within the Navvus MicroCatheter, a visual and auditory technical alarm condition is triggered. The defective microcatheter, along with the guide catheter, must be immediately removed and replaced.

The Catheter Malfunction alarm, distinguishable from all other system information signals, sounds immediately, and consists of a series of repeated tones at a maximum volume of 80 dB ±5%. (Other auditory signals are a single short pulse at low volume.) Simultaneously, the following flashing message is displayed:

Warning!

Catheter malfunction detected.

Stop procedure immediately and replace catheter with a new one.

The alarm continues to sound and the message displayed until the defective Navvus MicroCatheter is disconnected.

Record the FFR for the First Vessel

Record

Note

Before recording the FFR, ensure that system settings are correct and the Navvus MicroCatheter was properly delivered as described in the previous sections.

WARNING

Do not disturb pressure sensing system elements during equalization or FFR recording.

Record the FFR:

1. Verify the system is displaying this message.

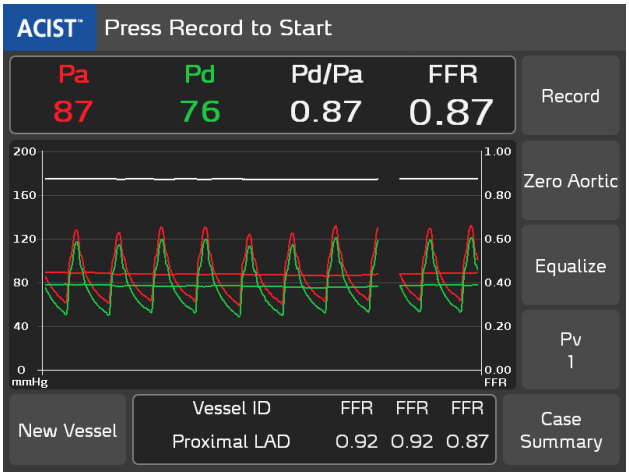
   Press Record to Start

2. Ensure the **Vessel ID** is correct (in the example below, Proximal LAD is selected).
3. With the Navvus MicroCatheter tip still present just outside the guide catheter tip, ensure the Pa and Pd values are equal (Pd/Pa = 1.00).
4. To properly position the pressure sensor, carefully advance the Navvus MicroCatheter until the marker band at the distal tip is 1-2 cm distal to the lesion being evaluated.

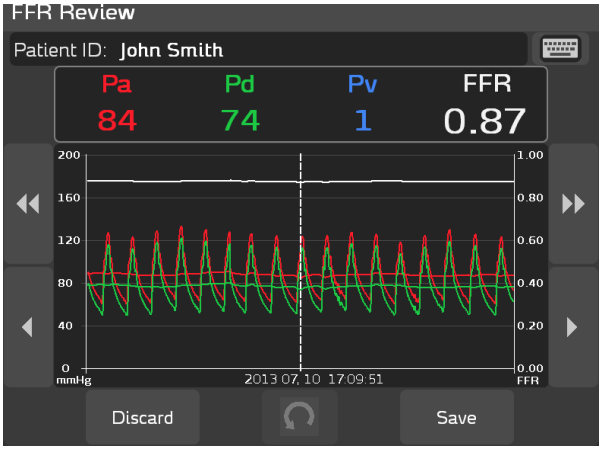
Note

When performing a resting Pd/Pa assessment, the live resting Pd/Pa value is available on the main screen (as shown below). If a recording of the resting Pd/Pa value is desired, without administering the vasodilator press **Record** *and the FFR value represents the resting Pd/Pa.*

5. Administer Adenosine (or another vasodilator) and press the **Record** button before or during maximum hyperemia.



6. After **Record** is pressed, it changes to a **Stop** button. Press **Stop** any time within the 10-minute maximum recording time to end the recording. When you press **Stop** (or when 10 minutes have lapsed), the FFR Review screen is automatically displayed as shown below:



7. Review the information displayed on the **FFR Review** screen. (Refer to page 71 for details regarding this screen.)

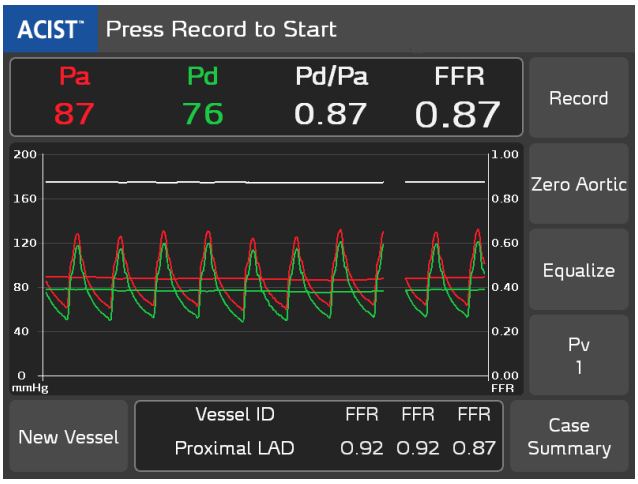
   The system has pre-selected the minimum FFR value present in the recording.

   - Use the scrolling arrows on either side of the screen to shift the position utilized for the minimum FFR value.
   - Use the **Revert** button to return to the system-selected value.

8. Press either **Discard** or **Save**.

   If you press **Discard**, the system permanently deletes the recording once you confirm.

   If you press **Save** recorded values are added to the Vessel ID display area, as shown in the example below (up to three FFR recording values can be displayed in this area):



For each case, you can save up to 10 FFR recordings per vessel. The oldest saved value will be overwritten if additional recordings are saved without changing the vessel.

You can save recordings for a maximum of 10 vessels per case. The oldest saved recording will be overwritten if additional vessels are selected.

You can save up to 10 cases on the system. The oldest case is overwritten if additional cases are started. Overwriting takes place when the next FFR recording is initiated after 10 recordings have been saved.

Note

The system saves 10 seconds of data prior to and after the location selected when the **Save** *button is pressed.*

Record the FFR for Another Vessel

New Vessel

Start an FFR Recording for a new vessel:

1. Re-equalize the signals if needed. (Refer to page 72 for detailed instructions.)
2. Identify the new vessel ID. (Refer to page 67 for detailed instructions.)
3. Deliver the Navvus MicroCatheter over the guidewire that has been placed in the vessel and, if needed, adjust the venous pressure. (Refer to page 37 for detailed instructions.)
4. Record the FFR. (Refer to page 41 for detailed instructions.)

Review the Case Summary and Export Data

Case Summary

Assuming that you saved a recordings for at least one vessel for one patient case, you may review the case summary. Press the **Case Summary** button. Refer to page 70 for detailed instructions on using the Case Summary window to review a case and export case summary data.

Note

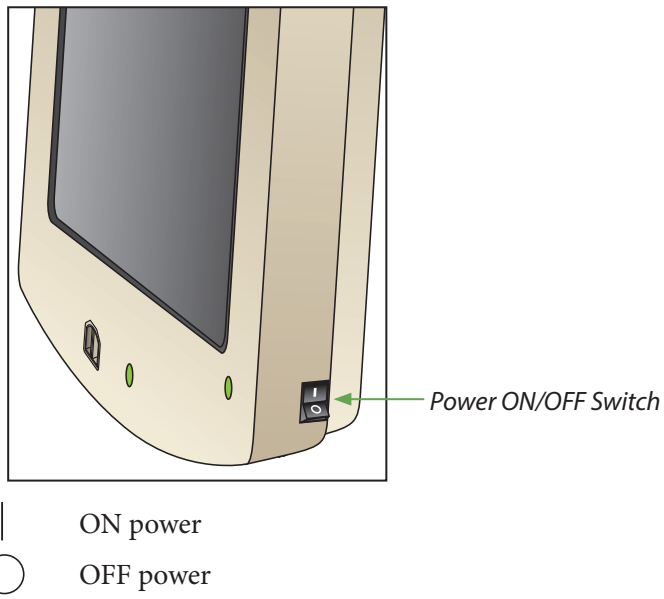
If a USB memory device is connected when an FFR recording is saved, the FFR data is automatically exported to the memory device as a picture in JPG format.

The Patient ID is stored only while the current Navvus MicroCatheter is connected. Data exported after the micocatheter is disconnected will not include the Patient ID.

Shutting Down the ACIST RXi® System

Power Off

Shut down the ACIST RXi System by using the switch on the right side of the unit.



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6 System Information and Settings

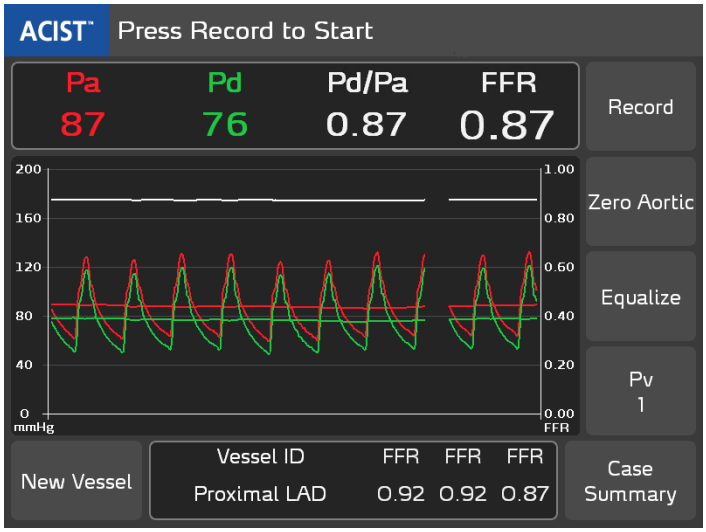
About the ACIST Menu

The ACIST menu provides access to system information, system settings, and menu options. These allow the user to view and/or adjust the following settings, or to perform the following tasks:

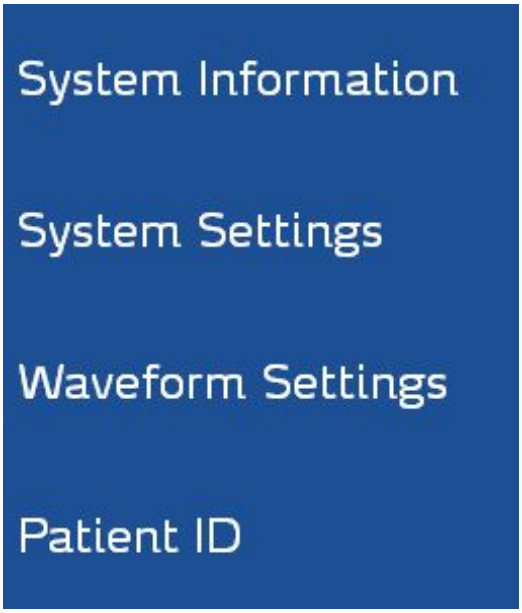
- View the software version of the system.
- View the current date and time.
- View or adjust system settings. These settings include:
  - » language for the user interface
  - » date
  - » time
  - » facility name
  - » lab ID
  - » monitor output sensitivity
  - » audio volume
  - » touchscreen calibration
- View or adjust waveform settings. These settings include:
  - » mean pressure calculation
  - » sweep speed
  - » graph scale maximum
  - » Pa scaling
  - » restore default settings for the waveform display
- Enter a patient ID.
- Zero the pressure sensor.

When you press the ACIST logo on the main screen, the ACIST menu is displayed:

Press the **ACIST** *logo to view the ACIST menu*



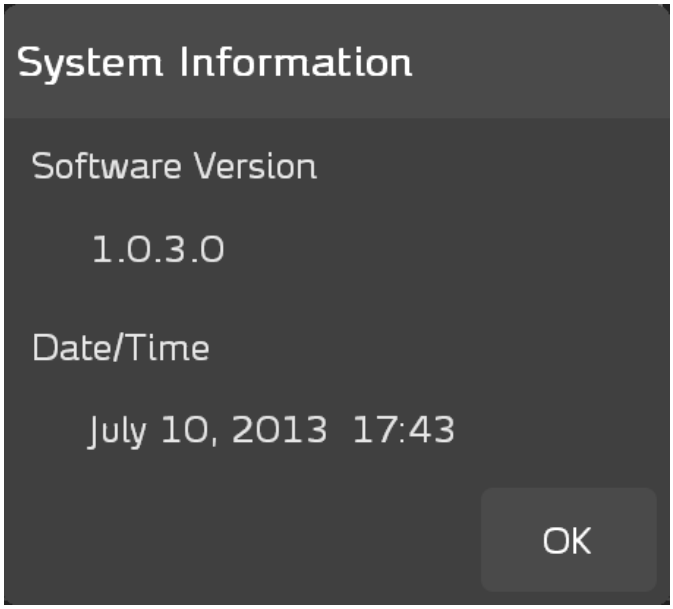
The ***ACIST*** *menu*



System Information

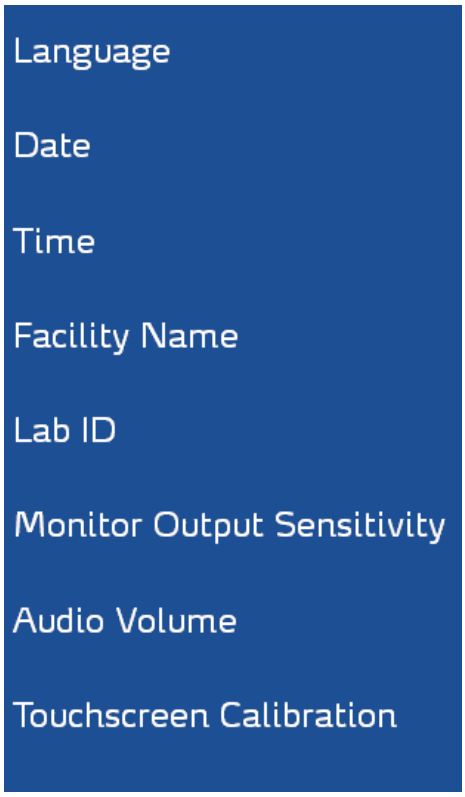
System Software Version, Date, and Time

To view the system software version and the system date and time, press **ACIST > System Information**. The System Information pop-up window appears as shown below. Note that the Software Version displayed on your system will not match the one shown here.



System Settings

The ACIST Main Menu provides the **System Settings** submenu:



Note

These settings cannot be adjusted while the system is recording the FFR.

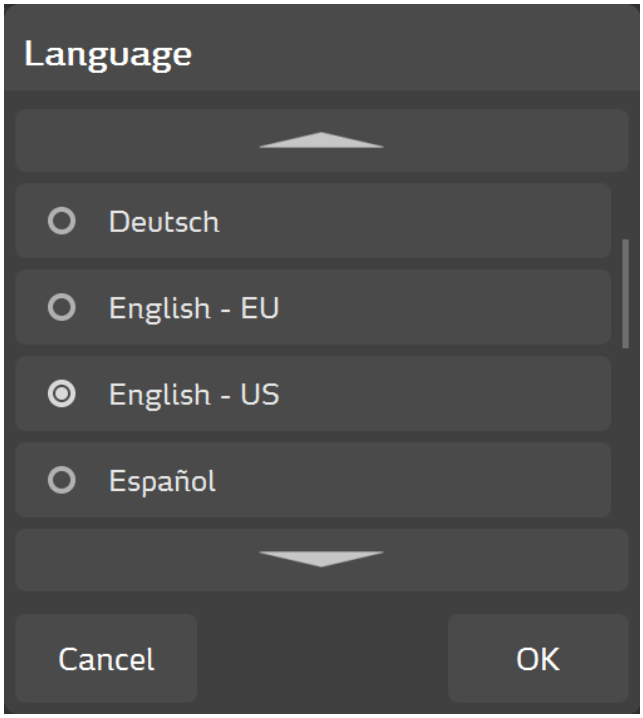
All saved system settings are automatically restored at system startup.

Change the Language Displayed in the System Software

Press **ACIST** > **System Settings** > **Language** to display the language options of the system software. Use the Language pop-up window, (shown below), to view or change the language of the software user interface.

Note

The language selection also sets the decimal delimiter to a dot or a comma, whichever is correct for the selected language. English - EU uses the comma delimiter instead of the dot.

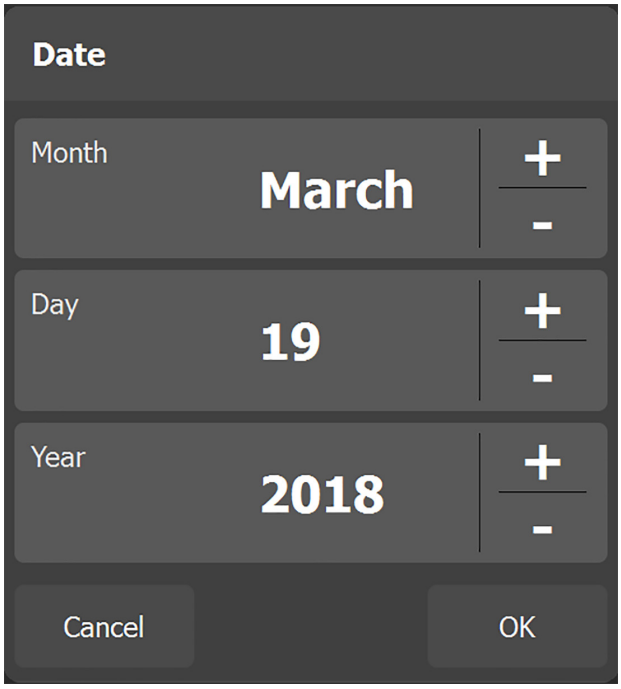


To change the language, use the arrows to scroll to the desired language and press the desired language (the radio button next to the language you selected activates, then press **OK** (or press **Cancel** to exit with no changes). The software user interface now appears in the language selected.

Adjust the Date Setting

The current date is displayed in the Date/Time field of the System Information pop-up window. To adjust the date, press **ACIST > System Settings > Date**.

Use the plus (+) and minus (-) buttons to adjust the Month, Day, and/or Year settings, then press **OK** to accept the new date, or **Cancel** to exit without making changes.



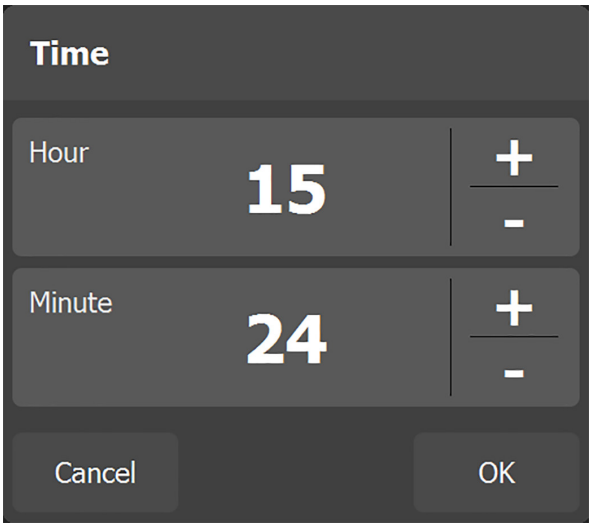
Adjust the Time Setting

The local time setting is displayed in the Date/Time field of the System Information pop-up window. The time is based on a 24-hour clock (00:00 to 23:59, with 00:00 representing 12 a.m.)

Note

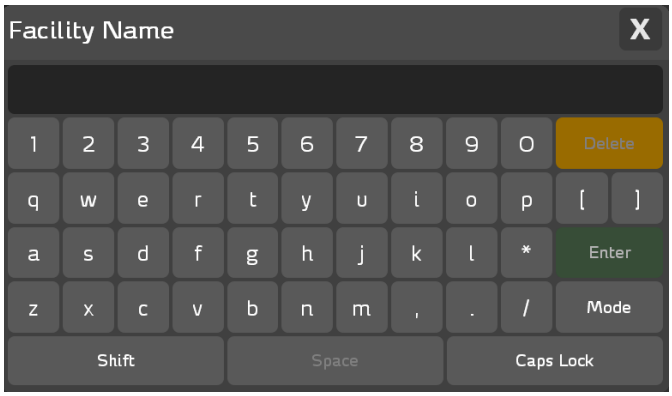
The RXi System time is not adjusted automatically for daylight savings time.

Use the plus (+) and minus (-) buttons to adjust the Hour and Minute settings, then press **OK** to save the new time, or **Cancel** to exit without making changes.



Enter or Modify the Facility Name

To associate a Facility Name, such as the hospital's name or hospital's ID number, with an FFR patient recording case, press **ACIST > System Settings > Facility Name**. The Facility Name pop-up keyboard appears as shown below:

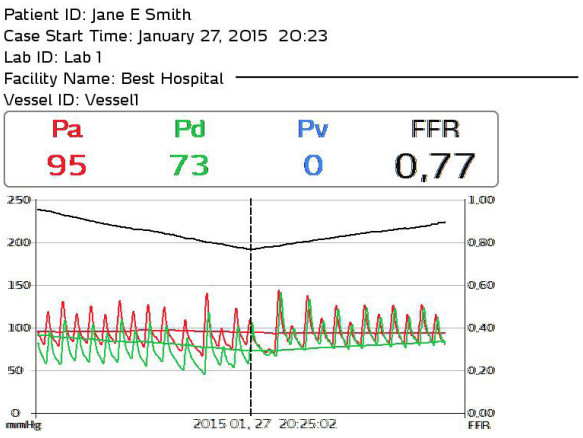


Use the keyboard to enter the Facility Name. Use the buttons listed below to perform the task associated with each button:

- the **Delete** button to delete a character
- the **Shift** button to enter a capital letter
- the **Space** button to enter a blank space
- the **Caps Lock** button to enter characters in all caps
- the **Mode** button to select alternate keyboard characters

When you have finished entering the Facility name, press **Enter** to close the Facility Name pop-up keyboard. To close without making any changes, press the **X** in the upper-right corner.

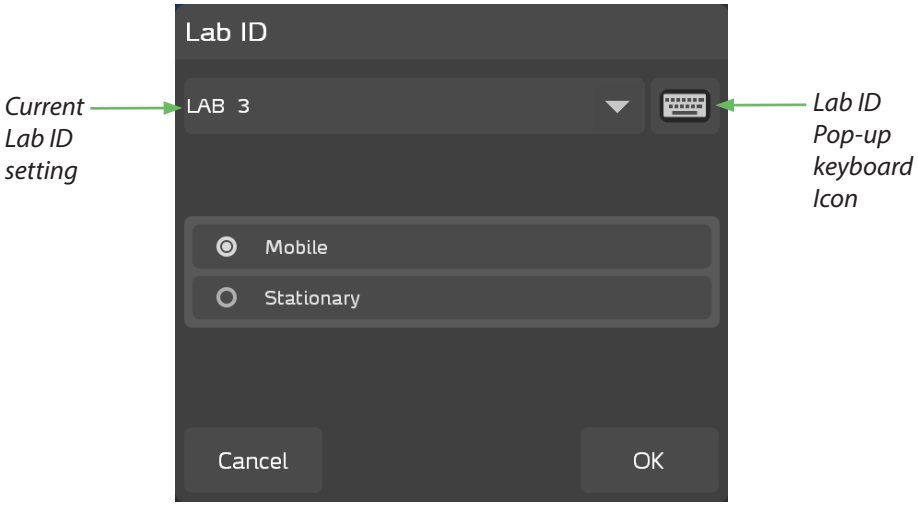
The Facility Name does not appear in the Case Summary. The Facility Name displays only in the Exported Case Summary as shown in the example below:



The Facility Name displays in the Exported Case Summary, which is exported in JPG file format

Lab ID, Mobile or Stationary

Press **ACIST** > **System Settings** > **Lab ID** submenu to view the Lab ID settings screen, as shown below:



Press **Mobile** or **Stationary** to select the desired mode depending on the method of installation of the ACIST RXi® System at your facility.

- In Mobile mode, the ACIST RXi System is designated as a mobile device. In this mode, the system prompts you to zero the aortic pressure on the ACIST RXi System for every patient case.
- In Stationary mode, the ACIST RXi System is designated as a stationary device, and is intended to remain installed in one room. In this mode, zeroing the aortic signal input on the ACIST RXi System is only required at installation.

WARNING

If the system is set to Stationary mode and you move the system from one lab to another, you must manually zero the RXi aortic pressure after you zero the hemodynamic monitoring system or an incorrect FFR value may result.

Enter or Modify a Lab ID

Note

Enter the Lab ID at the start of a patient case.

Press the Lab ID pop-up keyboard icon in the upper right corner of the Lab ID settings screen. The Lab ID pop-up keyboard appears as shown below:

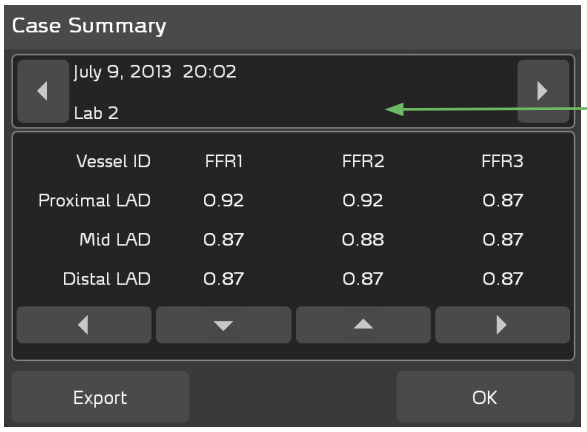
Use the keyboard to enter the Lab ID. Use the buttons listed below to perform the task associated with each button:

- the **Delete** button to delete a character
- the **Shift** button to enter a capital letter
- the **Space** button to enter a blank space
- the **Caps Lock** button to enter characters in all caps
- the **Mode** button to select alternate keyboard characters

When you have finished entering the Lab ID, press **Enter** to close the Lab ID pop-up keyboard or press the **X** in the upper right corner to close without saving.

Lab ID in the Case Summary

The Lab ID appears in the Case Summary, as shown below:



Use the arrow buttons as needed to scroll through the study dates, as well as the list of studies.

Monitor Output Sensitivity Setting

Contact your ACIST Service Representative for assistance in adjusting the Monitor Output Sensitivity setting.

This setting is adjusted at installation to match the system output voltage to the hospital's hemodynamic monitor, and should not be changed. It should be modified only if necessary for compatibility to non-standard systems.

Adjust the Audio Volume

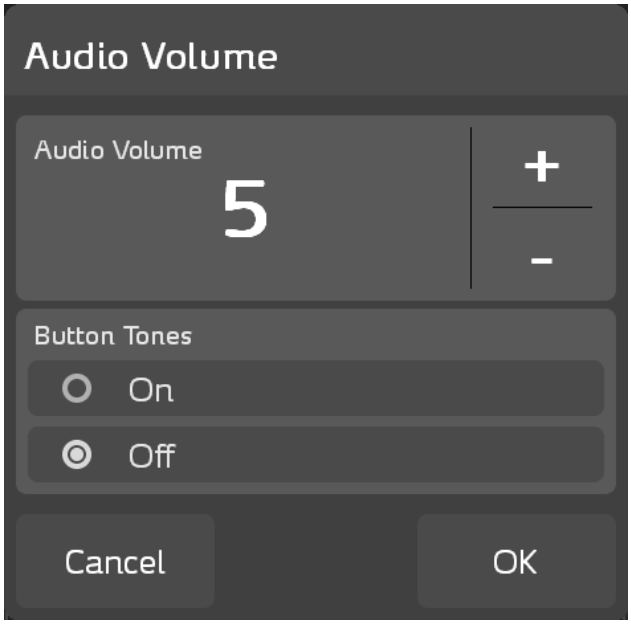
To adjust the audio volume of the system's alarms and button tones, press **ACIST > System Settings > Audio Volume**. The Audio Volume pop-up window displays the current audio volume settings.

Use the plus (+) and minus (-) buttons to adjust the audio volume settings.

Note

The audio volume cannot be completely silenced.

The Button Tones setting determines if a noise accompanies pressing any of the touchscreen buttons. Press the corresponding radio button to set button tones to **On** or to **Off**.



Touchscreen Calibration

To recalibrate the console panel touchscreen press **ACIST > System Settings > Touchscreen Calibration** and perform the following steps:

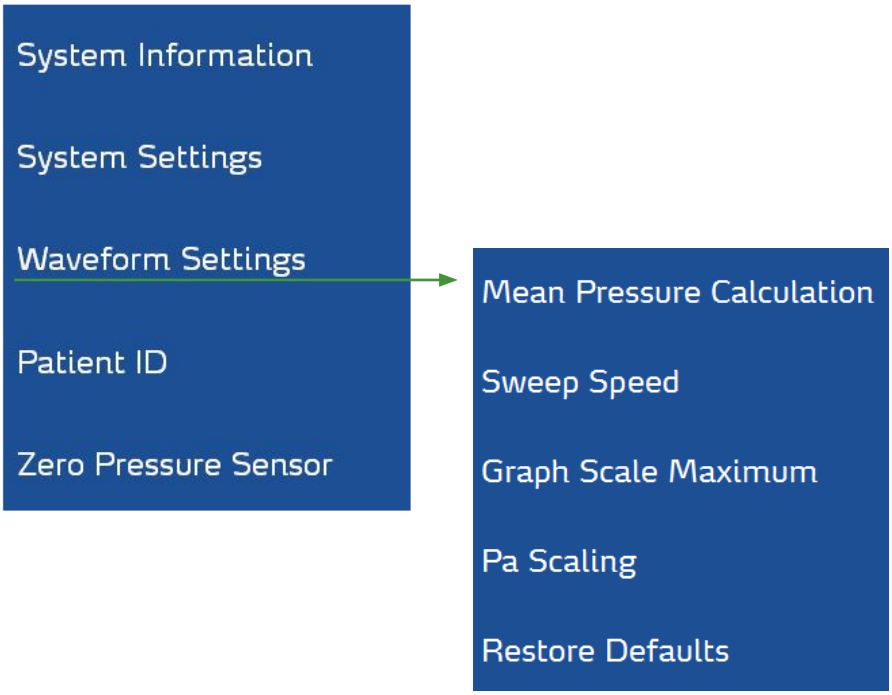
1. Touch the calibration target on the screen to start the four-point calibration.
2. Touch the target as it moves around the screen. A confirmation message window opens when calibration is complete.
3. Press **OK** in the confirmation message window to save the calibration data and ~~to~~ end the calibration session.

Note

If touching a field on the screen does not produce a response, recalibrate the touchscreen.

Adjust the Waveform Settings

The **Waveform Settings** option on the ACIST Main Menu provides a submenu of waveform configuration options:



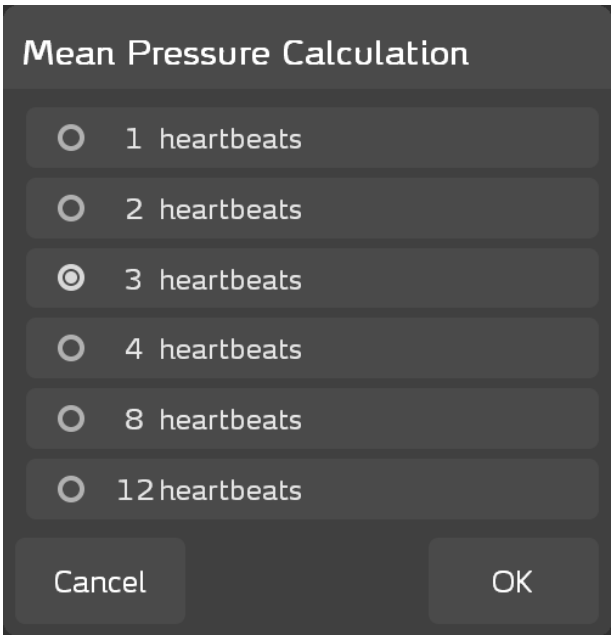
Adjust the Number of Heartbeats Used for Mean Pressure Calculation

To change the number of heartbeats used to calculate the mean pressure, press **ACIST > Waveform Settings > Mean Pressure Calculation**. The default setting is 3 heartbeats.

In the case of intracoronary administration of the vasodilator, the default setting of 3 heartbeats is recommended.

Note

This setting can affect the resting Pd/Pa or FFR value. For FFR, this is dependent on the amount of time maximum hyperemia is maintained in an individual patient.

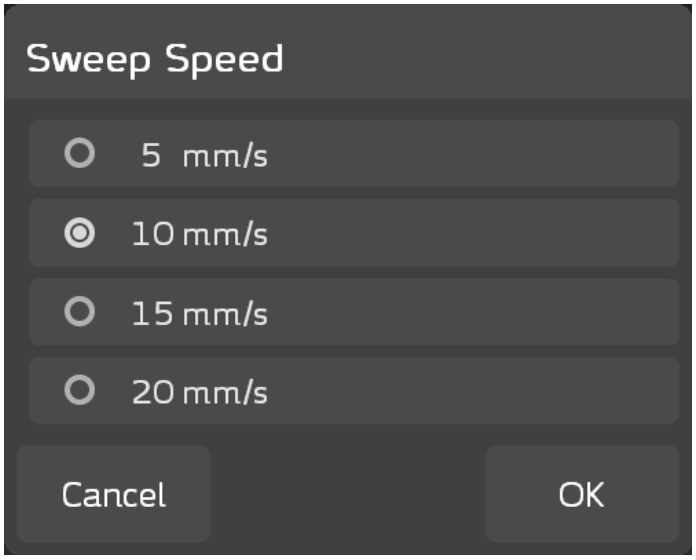


To change the number of heartbeats setting, press the radio button next to the preferred number of heartbeats, then press **OK**. The system calculates the mean pressure based on the adjusted setting. Press **Cancel** to exit without making changes.

Adjust the Screen Sweep Speed

Sweep speed is the range of hemodynamic waveform speeds selected by the user.

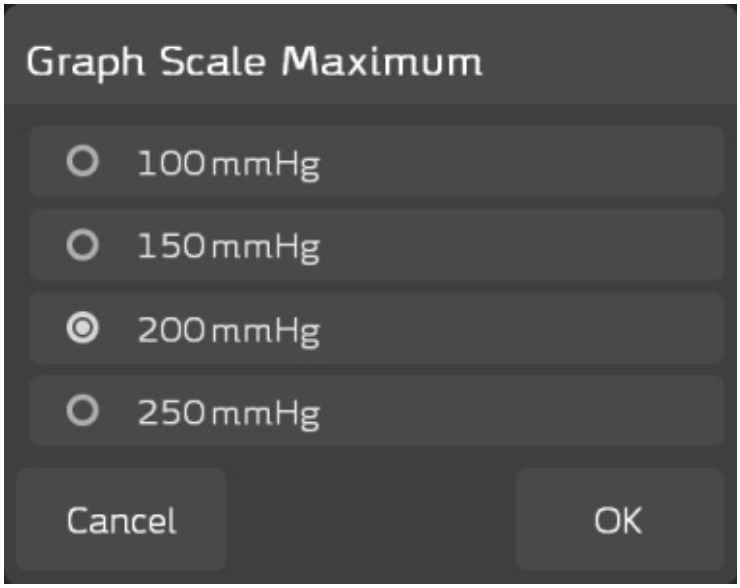
Press **ACIST > Waveform Settings > Sweep Speed** to view the Sweep Speed pop-up window enabling you to adjust the sweep speed in the waveform display area of the screen. Sweep speed options include 5, 10, 15, or 20 mm/s. The default is 10 mm/s.



To change the sweep speed setting, press the radio button next to the preferred sweep speed, then press **OK**. The system displays the pressure waveform based on the adjusted setting. Press **Cancel** to exit without making changes.

Adjust the Graph Scale Maximum

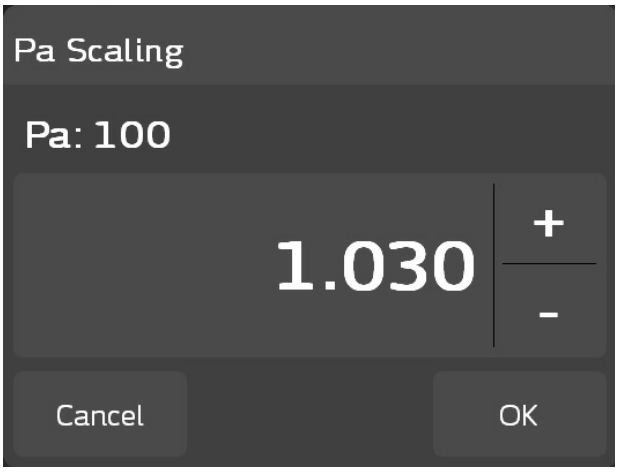
Press **ACIST > Waveform Settings > Graph Scale Maximum** to view the Graph Scale Maximum pop-up window. This window enables you to adjust the maximum mmHg units displayed in the waveform graph. The default is 200 mmHg.



To change the graph scale maximum setting, press the radio button next to the preferred setting, then press **OK**. The system displays the pressure waveform based on the adjusted setting. Press **Cancel** to exit without making changes.

Pa Scaling

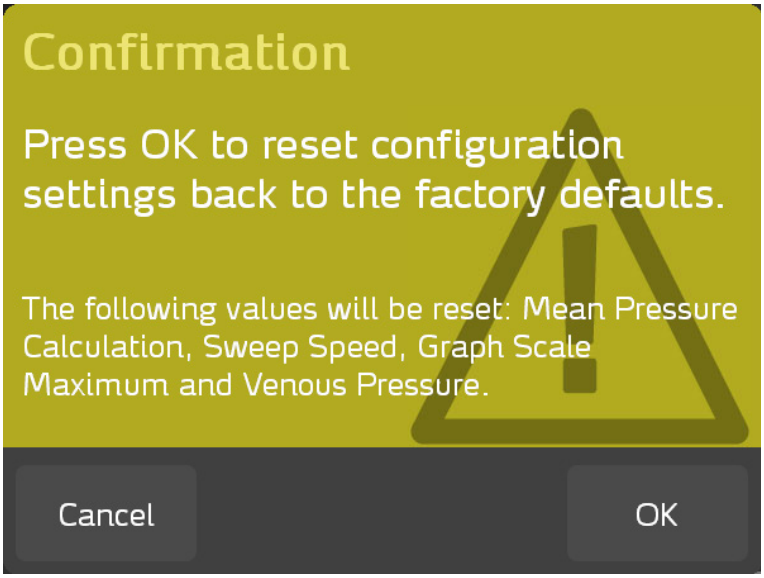
Press **ACIST > Waveform Settings > Pa Scaling** to view the Pa Scaling pop-up window. This window enables you to perform Pa Scaling (if required).



If the Pa value displayed is equal to or within ± 1 mm Hg of the Pa value on the hemodynamic system, it is not necessary to perform Pa scaling (press **Cancel** to exit). If the difference in these values is greater than 1 mm Hg, Pa Scaling is required. Refer to page 27 for detailed instructions on performing Pa Scaling.

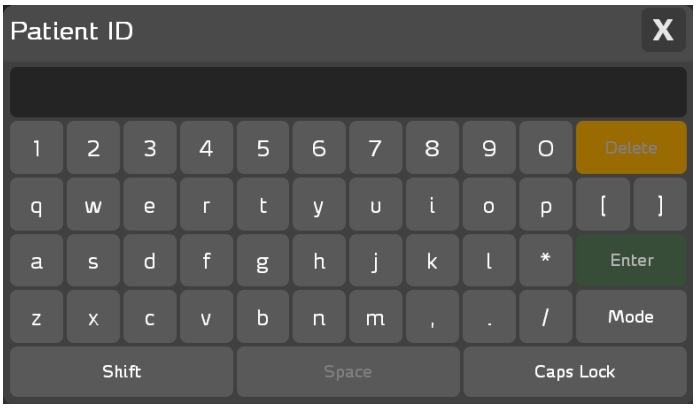
Restore the System Defaults for the Waveform Display

Press **ACIST > Waveform Settings > Restore Defaults** to view the Restore Defaults pop-up window. This window enables you to restore all the waveform display parameters (mean pressure calculation, sweep speed, and graph scale maximum), as well as venous pressure, to the factory default settings.



Create a Patient ID

To associate a patient ID such as the patient's name or hospital ID number with a patient's case, press **ACIST > Patient ID**. The Patient ID pop-up keyboard appears as shown below:

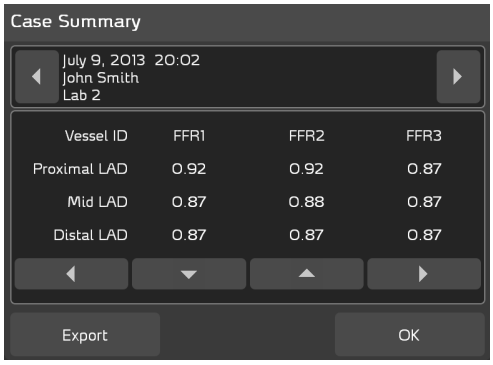


Use the keyboard to enter the Patient ID. Use the buttons listed below to perform the task associated with each button:

- the **Delete** button to delete a character
- the **Shift** button to enter a capital letter
- the **Space** button to enter a blank space
- the **Caps Lock** button to enter characters in all caps
- the **Mode** button to access an alternate character set

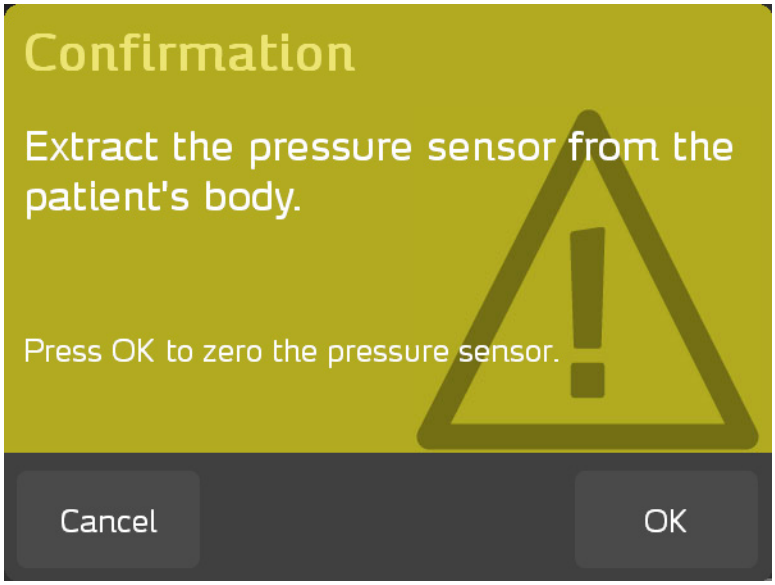
When you have finished entering the Patient ID, press **Enter** to close the Patient ID pop-up keyboard. To close the keyboard without making any changes, press the **X** in the upper right corner.

The Patient ID, which is the patient's name (John Smith) in this case, appears in the Case Summary, as shown below. Note that the Patient ID is displayed only while the case is active.



Zero the Pressure Sensor

The **Zero Pressure Sensor** option is available when the pressure sensor on the Navvus MicroCatheter is connected to the ACIST RXi System and the microcatheter is extracted from the patient's body. Press **ACIST > Zero Pressure Sensor** and the following confirmation message appears:



Note

The Navvus MicroCatheter pressure sensor is automatically zeroed when the purple handle is inserted into the ACIST RXi System.

Summary of ACIST Menu Options

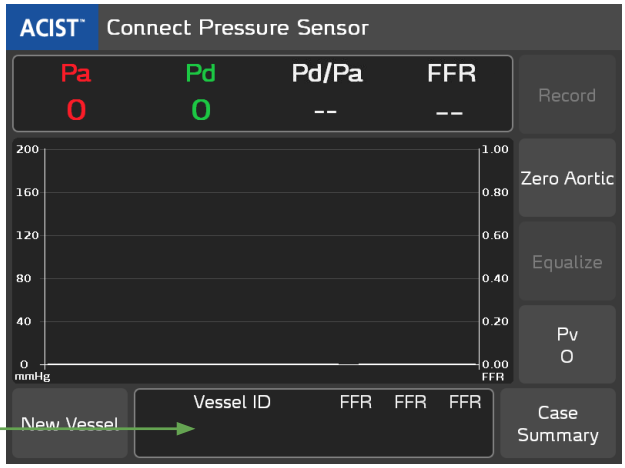
The following table summarizes the System Settings available through the ACIST menu.

Menu Option	Purpose
System Information	Displays Software Version Number, Date, and Time
System Settings: Language	To select a supported language
System Settings: Date	To change the system date (month, day and year)
System Settings: Time	To change the system time (hours and minutes)
System Settings: Facility Name	To enter a facility name
System Settings: Lab ID	To provide a Lab ID and indicate if the system is stationary or mobile
System Settings: Monitor Output Sensitivity	To change the monitor output sensitivity
System Settings: Audio Volume	To change the audio volume setting and decide if a sound should accompany button presses on the touchscreen
System Settings: Touchscreen Calibration	To calibrate the touchscreen
System Settings: Install Software	To install software upgrades from a USB memory device that has valid software
Waveform Settings: Mean Pressure Calculation	To change the current heartbeat count used for the mean pressure calculation
Waveform Settings: Sweep Speed	To change the current sweep speed
Waveform Settings: Graph Scale Maximum	To change the graph scale maximum
Pa Scaling	To adjust the aortic pressure value to match the value on the hemodynamic system
Waveform Settings: Restore Defaults	To restore the factory settings for Waveform Settings (Mean Pressure Calculation, Sweep Speed, and Graph Scale Maximum) as well as Venous Pressure
Patient ID	To enter a patient ID
Zero Pressure Sensor	To set the current pressure value to zero

Additional Settings

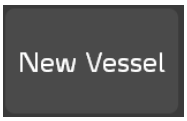
Define a Vessel ID using the New Vessel Button

At the beginning of a new patient case, the Vessel ID field is blank, as shown below:

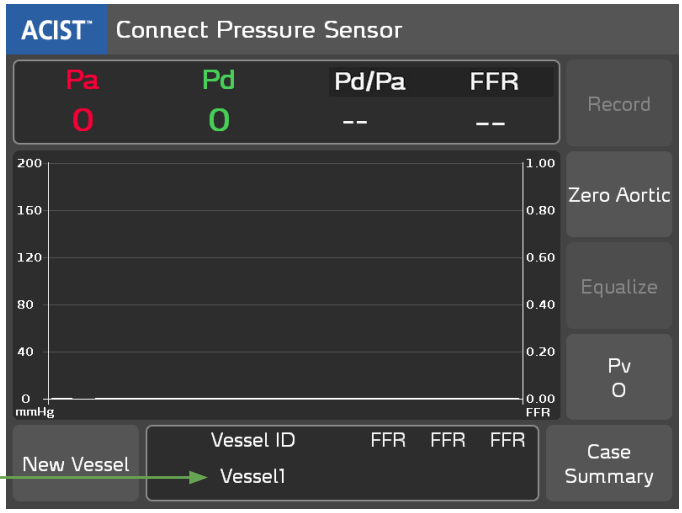


In this example, the Vessel ID field is blank.

Press the **New Vessel** button to define a new Vessel ID:



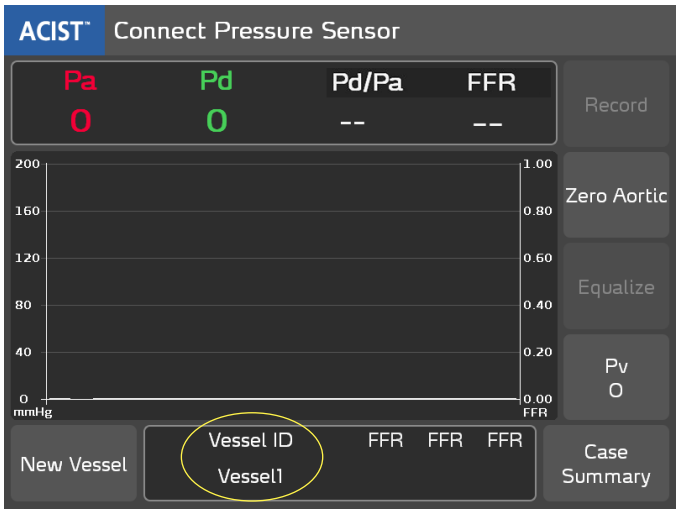
The system displays **Vessel1** as the default Vessel ID, as shown in the example below:



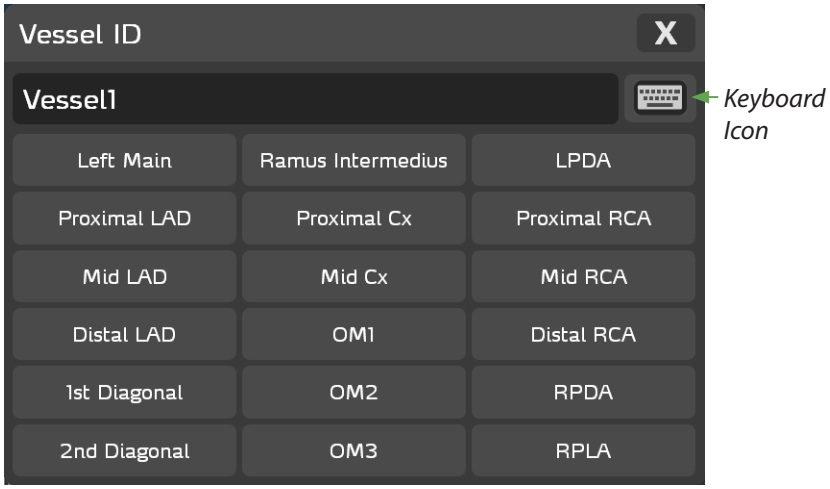
In this example, the Vessel ID field displays Vessel1.

Select the Vessel ID Name

Press the **Vessel ID** field.



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:



Press a Vessel ID from the displayed list to select a Vessel ID and close the pop-up window. Or, press the keyboard icon and create a Vessel ID name as described in the next section.

Create the Vessel ID Name using the Keyboard

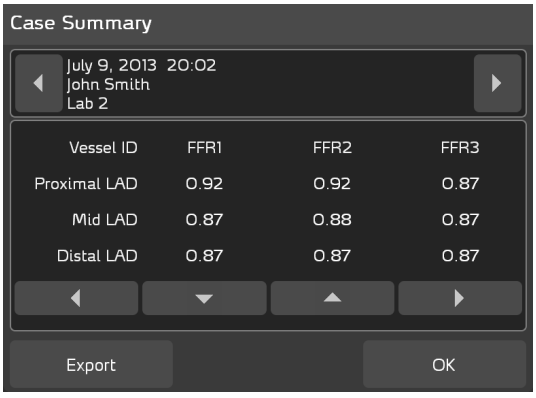
When you press the keyboard icon from the Vessel ID pop-up window, the Vessel ID pop-up keyboard is displayed, as shown below:

Use the keyboard to create the Vessel name or identifier. Use the buttons listed below to perform the task associated with each button:

- the **Delete** button to delete a character
- the **Shift** button to enter a capital letter
- the **Space** button to enter a blank space
- the **Caps Lock** button to enter characters in all caps
- the **Mode** button to use an alternate character set

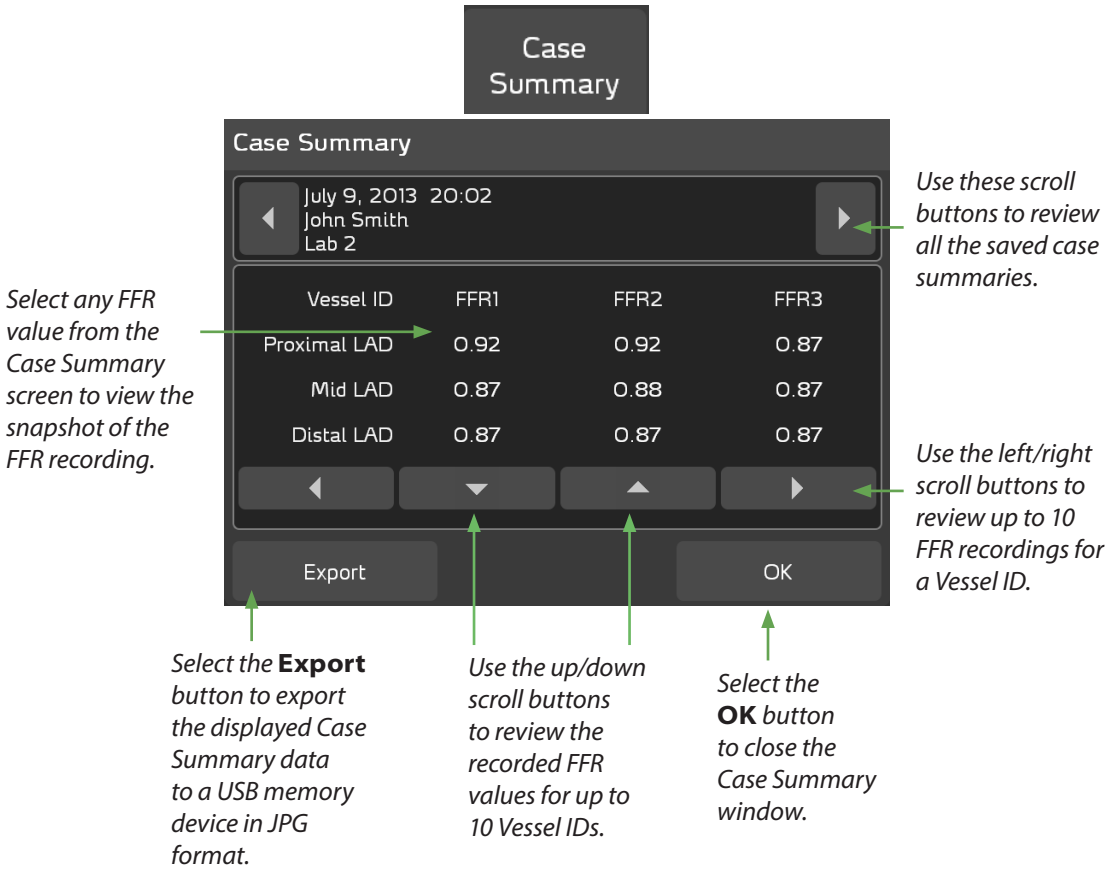
When you have finished creating the Vessel name, press **Enter** to close the keyboard, or press the **X** in the upper right corner to close without saving.

Following recordings, the Vessel name is also displayed in the Vessel ID field of the main screen and in the Case Summary, as shown below:

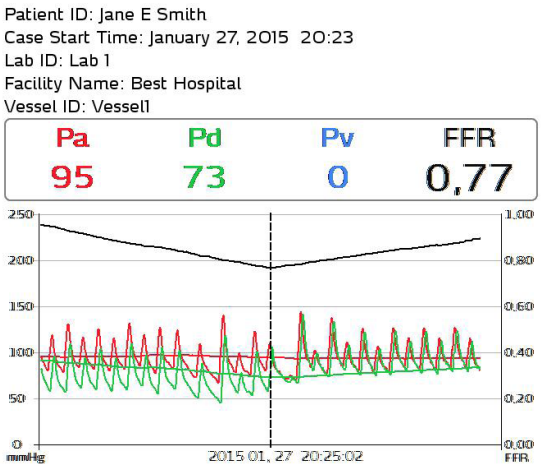


Review the Case Summary

Press the **Case Summary** button on the main screen to view currently saved FFR information, as shown below:



An example of an exported case summary for a Vessel ID is shown below:



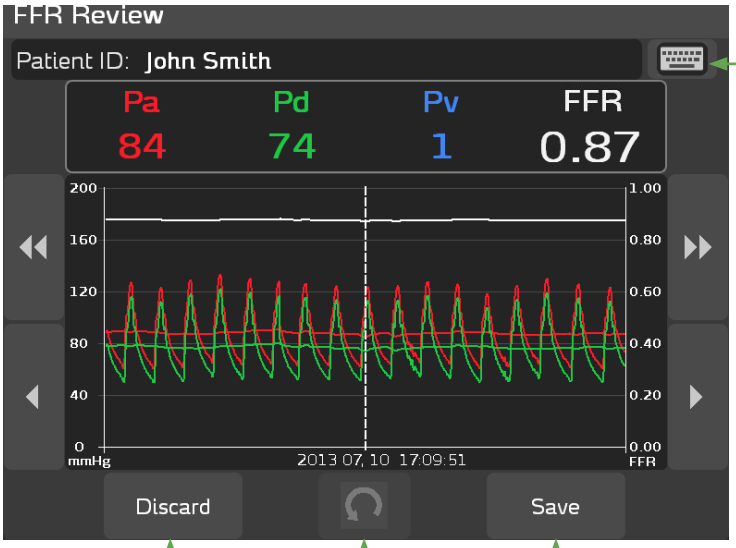
Review the FFR Recording (FFR Review)

The FFR Review screen displays when you press the **Stop** button to stop the recording. The FFR Review screen enables you to view a snapshot of the FFR data, which includes:

- aortic pressure (Pa)
- distal pressure (Pd)
- venous pressure (Pv)
- FFR

The date and the time of the recording displays at the bottom of the FFR Review screen. If a patient ID is associated with the recording, the patient's ID will also display at the top of the screen. To add a patient ID to the FFR Review screen, press the keyboard icon in the upper right corner of the FFR Review screen.

The FFR minimum location is indicated by a white vertical line. Ten seconds of the recorded waveform (if available) before and after the FFR minimum location is displayed, as shown in the example below:



Press the keyboard icon to enter the Patient ID on the FFR Review screen.

Press the arrow keys on either side of the signal display area to scroll forward and backward through the recorded waveform.

Press **Discard** *to discard the recording.*

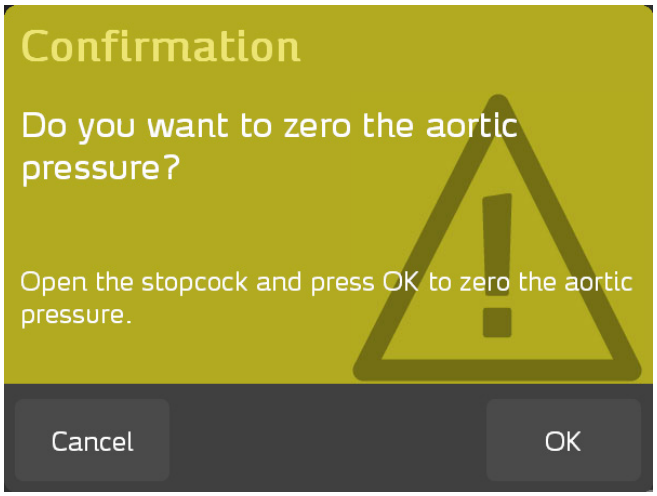
Press the **Revert** *button to reset the FFR Marker to the original FFR minimum value chosen by the system.*

Press **Save** *to save the recording.*

Zero the Aortic Pressure

Press the **Zero Aortic** button on the main screen to zero the aortic signal.

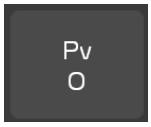
When you press **Zero Aortic**, a confirmation pop-up window instructs you to open the stopcock and press **OK** to zero the aortic pressure.



Press **OK** to zero the aortic pressure or press **Cancel** to return to the ACIST RXi System's main screen. You may be prompted to re-equalize.

Adjust the Venous Pressure

To adjust the venous pressure, press the **Pv** button from the main screen:



Use the plus (+) and minus (–) buttons in the Venous Pressure pop-up window to adjust the venous pressure setting, within the range of 0 to 40 mmHg:

Note

All displayed calculations of resting Pd/Pa and FFR will include a correction for the venous pressure (Pv) setting.

High venous pressure, which is a setting above 8 mmHg, will have a significant impact on FFR or resting Pd/Pa values.

A high Pv value results in lower FFR or resting Pd/Pa:

$$FFR = \frac{Pd - Pv}{Pa - Pv}$$

Note

Resting Pd/Pa uses the same governing equation as FFR under a non-hyperemic state.

Press **OK** to use for the current case only, or press **Save as default** to use the displayed setting for the current and future cases. Press **Cancel** to return to the ACIST RXi System's main screen.

Note

Every new case reverts to the default value, which is zero, unless it has been changed to a different value.

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7 Maintenance

Cleaning and Maintenance

Routine maintenance is required to keep the ACIST RXi® System in good working order. This section provides thorough instructions for performing the following:

- daily maintenance items
- monthly maintenance and inspection items

Prevent Equipment Damage

To prevent equipment damage, adhere to the following requirements:

- Do not clean inside the Navvus MicroCatheter connection port without the proper cleaning tools. Refer to *Optional Fiber Optic Cleaning Process* on page 78.
- Use only a soft cloth dampened with water to clean the system. Do not use detergents, cleaning solutions, isopropyl alcohol, or steam to clean the system.
- Never spray or pour any liquid directly onto the power supply or the system console.
- Never allow oil or materials containing oil to come in contact with any part of the system console.
- Do not use any sharp objects.
- Discard all cleaning materials in accordance with all local, state, and federal regulations, codes, and directives.

Decontamination Procedure

Use this procedure to remove biohazardous materials such as blood from the ACIST RXi System.

WARNING

To prevent electric shock, always turn off power to the system and disconnect the power cord from the main power source before performing any cleaning or service procedure.

Never touch any pins on connectors or cables that have become disconnected from a system while power is on.

Never immerse any system components in water or in a cleaning solution.

CAUTION

Always wear protective gloves and eye protection when cleaning or decontaminating the system.

CAUTION

Never allow oil or materials containing oil to come in contact with any part of the system console.

Never spray or pour any liquid directly onto the power supply, system console, or control panel.

Do not use any sharp objects or apply excessive pressure to any component.

Discard all cleaning materials in accordance with all local, state, and federal regulations, codes, and directives.

For decontamination, use a 10% bleach solution.

To decontaminate the ACIST RXi System, perform the following tasks:

1. Turn off power to the system.
2. Disconnect the power cord from the main power source.
3. Wipe down the system with a soft cloth dampened with the 10% bleach solution.
4. Discard all materials used to decontaminate the system according to all local, state, and federal regulations, codes, and directives.

Daily Cleaning

Daily cleaning is required for optimal operation.

WARNING

To prevent electric shock, always turn off power to the system and disconnect the power cord from the main power source before performing any cleaning or service procedure.

Never touch any pins on connectors or cables that have become disconnected from a system while power is on.

Never immerse any system component in water or in a cleaning solution.

CAUTION

Always wear protective gloves and eye protection when cleaning or decontaminating the system.

CAUTION

Never allow oil or materials containing oil to come in contact with any part of the system console.

Never spray or pour any liquid directly onto the power supply, system console, or control panel.

Do not use any sharp objects or apply excessive pressure to any component.

Discard all cleaning materials in accordance with all local, state, and federal regulations, codes, and directives.

1. Turn off power to the system.
2. Disconnect the power cord from the main power source.
3. Clean the system console with a soft cloth moistened with warm water. Pay special attention to the system console and power supply where fluids may have dripped.

Optional Fiber Optic Cleaning Process

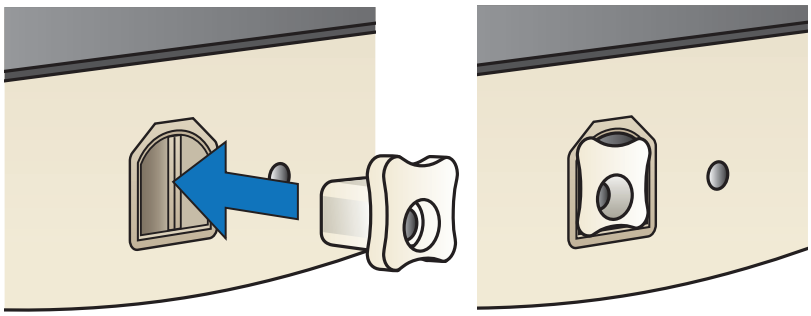
To perform this procedure, you will need the Senko Smart Cleaner or equivalent fiber optic cleaning tool and the RXi PIM Door Opener. These can be obtained by contacting your ACIST representative or contacting ACIST Customer Service.

Note

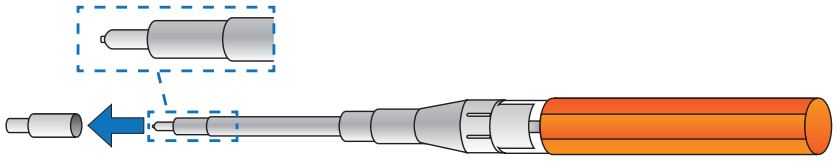
For these instructions, the Senko Smart Cleaner is shown, but any equivalent off-the-shelf dry cleaning tool for use with fiber optic LC, MU, and APC connections can be used.

Perform the following steps to clean the Patient Interface Module (PIM).

1. Turn off power to the system.
2. Insert the PIM Door Opener completely into the PIM assembly.



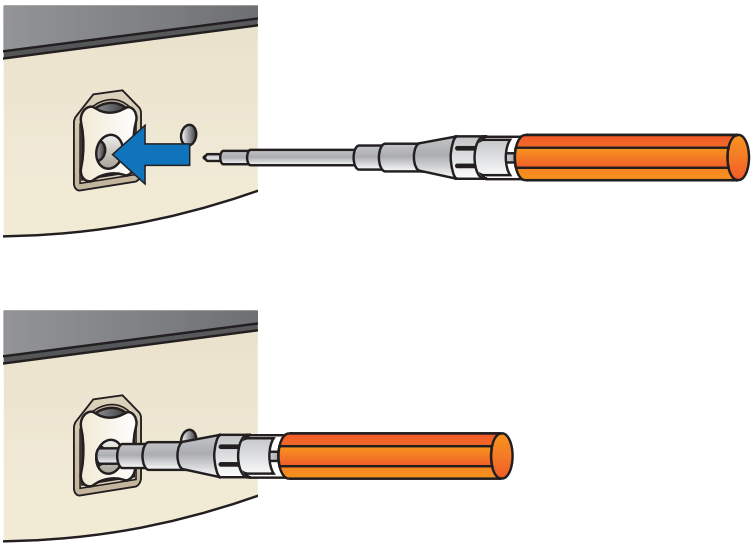
3. Remove the white adapter cap on the Senko Smart Cleaner to expose the cleaning filament.



4. Insert the exposed filament into the PIM assembly with the door open. While keeping the cleaner as straight as possible, depress the cleaner fully until it stops moving. A click may be heard.
5. Rotate the cleaner 90° and depress fully again.

Note

It is important to fully depress the cleaner to ensure the cleaning filament works properly.



6. Remove the fiber optic cleaner from the PIM assembly.
7. Clean and disinfect the filament and any portion of the cleaner that potentially came in contact with the PIM assembly.
8. Replace the white adapter cap on the cleaner.
9. Remove the PIM door opener from the PIM assembly.

Monthly Inspection and Maintenance

Monthly inspection and maintenance are required to keep the ACIST RXi System in optimal working condition.

WARNING

To prevent electric shock, always turn off power to the power supply and disconnect the power cord from the main power before starting any maintenance procedure.

Never touch any pins on connectors or cables that have become disconnected from a system while power is on.

Never immerse any component in water or in cleaning solution.

CAUTION

Always wear protective gloves and eye protection when cleaning or decontaminating the system.

CAUTION

Never allow oil or materials containing oil to come in contact with any part of the system console.

Never spray or pour any liquid directly onto the power supply, or system console, or control panel.

Do not use any sharp objects or apply excessive pressure to any component.

Discard all cleaning materials in accordance with all local, state, and federal regulations, codes, and directives.

Perform these inspection and maintenance items monthly:

1. Turn off power to the system.
2. Disconnect the power cord from the main power source.
3. Inspect the ACIST RXi System console and power supply. Check the housings for damage.
4. Inspect power cords and cables for cuts, nicks, and openings in the cable insulation. Check cable connections to make sure cables and connectors have not separated. Replace any cables or cords that are damaged.
5. Check all mounting fixtures, making sure they are tight and secure.

8 Troubleshooting and Support

General Troubleshooting

This section provides troubleshooting guidance for the ACIST RXi® System, including general troubleshooting information, resolution of hemodynamic monitoring problems, and resolution of specific problem conditions.

LED Indicator Lights

A table on page 83 explains how to interpret the LED indicator lights on the ACIST RXi System.

System Status Messages

The ACIST RXi System is designed to provide trouble-free operation. System status messages guide the user, provide instructions, and display system information. A guide to interpreting system status messages is provided on page 86.

Pop-up Message Windows

Pop-up message windows display messages to inform or warn you to follow the instructions in the window. Use information in the table on page 88 to help determine the probable cause and the corrective action for the messages displayed in the pop-up message windows.

General Troubleshooting Procedures

Before contacting ACIST Medical Systems about a problem, perform the following steps:

1. Follow instructions in the message displayed on the system console display. If you cannot clear the message, continue to step 2.
2. Turn off power to the ACIST RXi System at the main power supply.
3. Unplug the power cord at the power supply from main power.
4. Check for damaged or loose connections.
5. Check the integrity of main power and the main power connection.
6. Perform routine system maintenance and cleaning.
7. With the Navvus® MicroCatheter disconnected from the system, turn on power to the ACIST RXi System at the power switch.

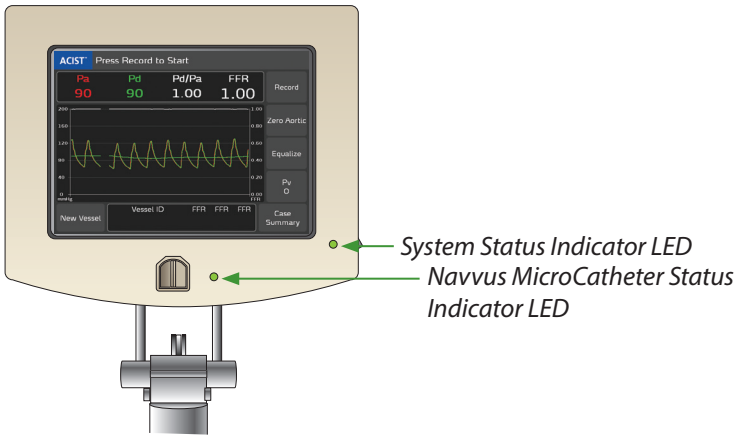
8. Resume operation.

If you are unable to resolve a problem or if you have any problems or concerns, contact an ACIST Medical Systems service representative.

Interpreting LED Indicator Lights

The ACIST RXi System has two LED indicator lights:

- Navvus MicroCatheter Status Indicator LED located next to the connection port for the Navvus MicroCatheter.
- ACIST RXi System Status Indicator LED located next to the power switch on the right side of the ACIST RXi System.



Navvus® MicroCatheter Status Indicator LED

LED State	Condition
Off	The Navvus MicroCatheter is not connected to the RXi System.
On (Blue)	The Navvus MicroCatheter is connected to the RXi System and the system is checking the functionality of the sensor.
On (Green)	The Navvus MicroCatheter is connected to the RXi System and is functioning properly.
On (Red)	The Navvus MicroCatheter is connected to the RXi System and software detects an error with the pressure sensor.

ACIST RXi® System Status Indicator LED

LED State	Condition
Off	The RXi System is not turned on.
On (Green)	The RXi System is on and functioning properly.
On (Red)	The RXi System is in an error state as detected by the system software.

Hemodynamic Pressure Monitoring

CAUTION

Inaccurate measurements from the hemodynamic pressure transducer may result if the transducer is not prepared and connected correctly.

With the stopcock at the midaxillary position, zero the hemodynamic transducer at the start of each patient case by using atmospheric pressure as a zero pressure reference. Zeroing the transducer ensures that the pressure values measured are only from within the blood vessel or from within the heart. Periodically re-zeroing the transducer ensures the continued accuracy of blood pressure readings. If hemodynamic signal drift is suspected, re-zero the transducer.

Prior to recording physiological blood pressures with the hemodynamic pressure transducer, re-zero the transducer at the patient midaxillary position to establish a clear baseline. (Changes in bed height, atmospheric pressure, catheter hub position, fluid density, and so on, may affect the baseline pressure.)

The blood pressure waveform may be dampened significantly when using very small diameter catheters filled with contrast. Perform a saline flush before recording physiological waveforms with the transducer system.

When using an ACIST or a third-party hemodynamic transducer, clear all tubing of air to avoid producing an inaccurate reading.

Pressure Waveform Accuracy

To ensure accurate waveforms, zero the hemodynamic transducer with both the transducer and the stopcock at the midaxillary position. Check the hemodynamic zero before recording any pressures.

Dampened Pressure Tracing

The waveform may be damped when the guide catheter or tubing is filled with contrast. To obtain the clearest waveform:

- Check the entire fluid pathway for air bubbles and purge the patient tubing if necessary.
- Remove contrast from the guide catheter with a hand syringe attached to the high-pressure stopcock and hand flush it with saline.
- Zero the hemodynamic transducer with both the transducer and the stopcock at the midaxillary position.
- If you have signal problems, inspect both hemodynamic connectors for presence of contaminating materials.
- Ensure that you do not wedge the guide catheter in the selected artery or create any kink in the guide catheter. Do not adjust any kink. If you discover a kink, do not use the guide catheter.

Power Interruption

Note

If an uninterruptible power supply or battery backup is not used to power the ACIST RXi system, and a power interruption for any length of time is experienced, the RXi system will power on once power is resumed if the power on/off switch remains in the on position. If a Navvus MicroCatheter is present during the power on, a new case is also initiated. For this reason, it is necessary to flip the switch to the off position and remove the catheter once a power interruption occurs. Turning power off ends the case.

Auditory and visual alarming and information signals are disabled while the system is powered down. Upon resumption of power, if a defective microcatheter with a broken fiber optic cable remains connected to the system, the system resumes alarming.

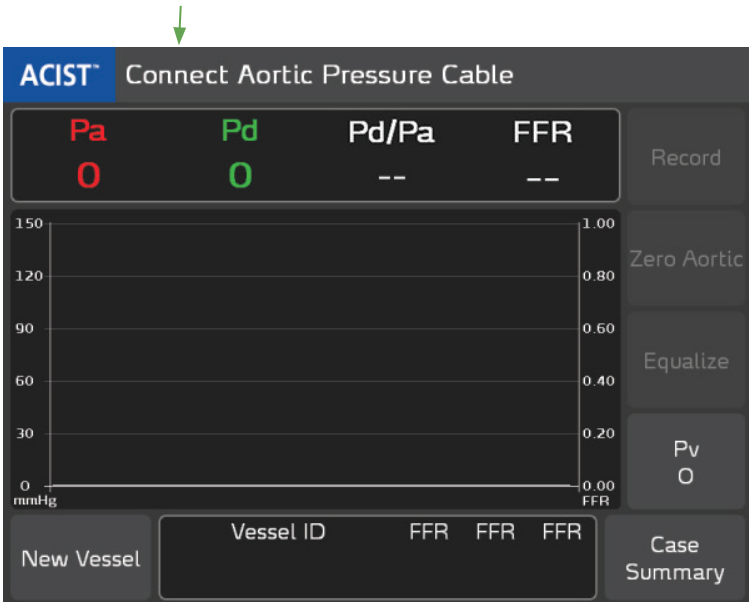
Following a power interruption (no matter how brief), if the ACIST RXi System has been set up as a mobile device, aortic pressure must be zeroed. Refer to page 72 for instructions on performing this procedure. If it has been set up as a stationary device, it does not need to be zeroed. For all ACIST RXi Systems, signals must be equalized following a power interruption. See page 37 for instructions on equalizing.

All data from previous cases is saved. However, if a ~~case~~ recording was in progress when the power was interrupted, this data is lost. Any saved recordings for the case are still saved. In addition, if a Patient ID and/or Vessel ID had been entered, these settings will have been lost and will need to be re-entered. If the case summary was exported to a USB memory device, this data will be saved, along with the Patient ID.

Interpreting Status Messages

Status messages appear at the top of the main screen:

The Status Message area of the window provides user instructions and system status information



The following table provides a summary of the status messages, the purpose of each message, and the recommended user response.

Status Message	Purpose	User Response
Zeroing...	Informs that the system is zeroing the aortic or pressure sensor.	Wait for zeroing to complete.
Connect Aortic Pressure Cable	Instructs you to connect the aortic pressure cable.	Ensure that the aortic pressure cable is connected to the hemodynamic system and the RXi console.
Check Aortic Pressure Cable	Displays when an aortic pressure input failure has been detected.	Check the aortic pressure cable connections to the hemodynamic system and the RXi system
Aortic Pressure Out of Range	Informs that the aortic pressure signal is out of range.	If performing a flush, wait until flush is complete. If this message is still present, check to see if the hemodynamic system is sending correct signal.
Zero Aortic Pressure	Instructs you to zero the aortic pressure signal.	This step is done at system installation and again before each case. Prior to each case, open the stopcock at the midaxillary position, zero the hemodynamic system, and press the zero aortic button.
Connect Pressure Sensor	Instructs you to connect the Navvus MicroCatheter to the RXi System.	Insert the handle assembly of the catheter in the Navvus MicroCatheter connection port of the RXi System Console.
Equalizing...	Informs that the RXi System is equalizing the aortic pressure and the pressure sensor signals.	Wait for the signals to equalize.
Equalization Requires Positive Pa	Informs that the Pa value is too low (0 mmHg or less) to equalize.	Adjust the aortic pressure.
Ready to Equalize	Displays when the aortic pressure is connected and zeroed, the pressure sensor is connected, and the pressures have not been equalized.	Select the **Equalize** button on the RXi main screen. The RXi System will then equalize the pressure signals.
Press Record to Start	Displays when the aortic pressure and the pressure sensor signals have been equalized.	The system is ready to record. Select the **Record** button on the RXi main screen to start the recording.
Press Stop to Finish	Displays when the RXi System is actively performing an FFR recording.	Select **Stop** to stop the recording.

Color-coded Pop-up Messages and Problem Conditions

The following table describes messages displayed in response to system conditions. All messages in the ACIST RXi System are color-coded as follows according to their severity:

- Red — warning or error
- Yellow — information; user input required
- Blue — information only

Color	Message	Corrective Action or Explanation
Red	**Invalid installation software.** **Please remove the USB memory stick and restart the system.**	The system does not recognize the installation program on the USB memory device. Remove the USB memory device and restart the system.
Red	**Please restart the system.** **If the problem persists, please contact your service representative.**	The software installation has failed. Restart the system. **If the problem persists, please contact your service representative.**
Red	**The case failed to export, due to insufficient available memory on the USB memory stick.**	There is insufficient room on the USB memory device. Use a different USB memory device to transfer the FFR data.
Red	**The case failed to export.**	Check the connection of the USB memory device.
Red	**The system detected non-recoverable error number XXXXX.** **Please record the error number and contact your service representative.**	Contact your ACIST service representative and provide the error message number displayed in the message.
Red	**The system has detected a problem with the pressure sensor.**	There is a problem with the pressure sensor. Remove and discard the Navvus MicroCatheter and try a new one.
Red	**Warning!** **Catheter malfunction detected** **Stop procedure immediately and replace catheter with a new one.**	Immediately remove and replace the Navvus MicroCatheter.
Yellow	**Software installation files have been detected.** **Press OK to start the software installation.**	Press **OK** to confirm and close the message. The system starts the software installation process.
Yellow	**Are you sure you want to discard this record?** **Press OK to discard this Record.**	Press **OK** to confirm and close the message. The system discards the recording.
Yellow	**Do you want to zero the aortic pressure?** **Open the stopcock and press OK to zero the aortic pressure.** *If system is equalized, this message will appear:* **It is recommended to equalize after zeroing.**	Open the stopcock at patient midaxillary position press **OK** to confirm and close the message. The system zeroes the aortic pressure signal. It is recommended to re-equalize to ensure equal pressures.
Yellow	**Extract the pressure sensor from the patient's body.** **Press OK to zero the pressure sensor.**	Remove the Navvus MicroCatheter from the patient. Press **OK** to confirm and close the message. The system zeroes the pressure sensor.
Yellow	**Press OK to reset configuration settings back to the factory defaults.** **The following values will be reset: Mean Pressure Calculation, Sweep Speed, Graph Scale Maximum, and Venous Pressure.**	Press **OK** to confirm and close the message. The system resets the default parameters for mean pressure calculation, sweep speed, graph scale maximum, and venous pressure.
Blue	**Do not remove USB memory stick.**	Wait until the software is installed.
Blue	**Exporting case data requires the insertion of a USB memory stick.**	Insert a USB memory device into the USB port.

Color	Message	Corrective Action or Explanation
Blue	**The case was successfully exported.**	The FFR data was successfully exported. You may remove the USB memory device.
Blue	**The FFR recording has been discarded. Please check the aortic pressure cable.**	Press **OK** to confirm and close the message. This is a notification that the FFR data has been interrupted because there is a problem with the aortic cable. Check the aortic cable connection.
Blue	**The FFR recording has been discarded. The system has detected a problem with the pressure sensor.**	Press **OK** to confirm and close the message. This is a notification that the FFR data has been interrupted because there is a problem with the pressure sensor (located within the Navvus MicroCatheter). Inspect the microcatheter, unplug and plug in if needed, or replace the microcatheter. Note: If you unplug the microcatheter it ends the case.
Blue	**The FFR recording has been discarded. The aortic pressure is out of range.**	Press **OK** to confirm and close the message. This is a notification that the FFR data has been interrupted because the aortic pressure was out of range. Determine why aortic pressure is reading high or low.
Blue	**The software installation completed successfully. Please remove the USB memory stick and restart the system.**	The software download is complete. Remove the USB memory device and restart the system.

9 Glossary

Acronyms and Abbreviations	
Pa	mean aortic pressure
Pd	mean arterial pressure distal to the stenosis
Pv	venous pressure
FFR	fractional flow reserve

Glossary Term	Definition
Aortic Pressure	The pressure exerted by the blood within the aorta, the body's largest artery that extends out from the heart.
Audio Volume	The audio volume of the system's button tones can be adjusted from a range of 1 to 10, using the plus (+) or minus (-) buttons to change it from the current setting on the Audio Volume window. This window also allows you to turn the button tone either **On** or **Off**.
Case Summary Button	The **Case Summary** button is used to view currently saved FFR data. Any FFR value can be selected to view the snapshot of the FFR recording. Also included in the Case Summary are the date and start time, lab ID, and facility name (facility name is only displayed in exports). If a patient ID was entered, it is only stored while the current Navvus MicroCatheter is connected and is not be exported with the other data in the Case Summary once the microcatheter has been disconnected.
Date	Selecting Date on the System Settings screen brings up the current date. Use the plus (+) or minus (-) buttons to change to a different Month, Day, or Year.
Distal Pressure (Pd)	Mean arterial pressure distal to the stenosis as measured by the Navvus MicroCatheter.

Glossary Term	Definition
Equalize Button	After verifying that the aortic pressure displayed on the RXi System matches the reading on the hemodynamic monitor, pressing **Equalize** produces a Pd/Pa of 1.00. Equalizing shifts the mean distal pressure so it equals the mean aortic pressure, and additionally adjusts for phase shift between the distal and aortic signals.
Export Button	Press the **Export** button to transfer Case Summary information for the case currently being viewed to a USB memory device.
Facility Name	Identifies the hospital's name or ID where the RXi System is installed. Up to 20 characters can be used.
Fractional Flow Reserve (FFR)	The measurement of pressure differences across an arterial stenosis at maximum hyperemia. It is calculated as FFR = (Pd - Pv) / (Pa - Pv).
FFR FFR FFR	The RXi Main screen displays the FFR for the last three recordings in the current case.
FFR Review Screen	Provides a snapshot of the FFR data, including Aortic pressure (Pa), Distal pressure (Pd), Venous pressure (Pv) and FFR. Included on this screen is the date and time of the recording, along with the patient ID, if entered.
Graph Scale Maximum	Pop-up window allows adjustment of the maximum pressure value displayed on the waveform graph. The allowable values are 100 mmHg, 150 mmHg, 200 mmHg, and 250 mmHg, with default being 200 mmHg. To provide the most legible curve, the smallest value suitable for the patient should be used.
Install Software	Allows installation of software upgrades via a USB memory device that has valid software installed on the device.
Lab ID	Identifies the lab where the RXi System is installed. Up to 20 characters can be used, which appear in the FFR Patient Recording Case Summary. Also included on the Lab ID screen are buttons to select whether the system is Mobile (moved from room to room) or Stationary (used in only one room).
Language	Selecting Language provides the option of choosing from all the supported languages.
Mean Aortic Pressure	The average pressure within the aorta over a complete cycle of one heartbeat.
Mean Pressure Calculation	The number of heartbeats selected on the Mean Pressure Calculation window is used in calculating the mean pressure. The allowable values are 1, 2, 3, 4, 8, and 12, with the default value being 3 heartbeats.
Message Bar	Area of the Main screen that displays instructions and information.
Midaxillary Position	The aortic transducer must be placed in the midaxillary position, which follows an imaginary line through the axilla parallel to the long axis of the body and midway between its ventral and dorsal surfaces.

Glossary Term	Definition
Mobile Mode	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 manner, the aortic pressure on the RXi must be zeroed at the beginning of every patient case.
Monitor Output Sensitivity	An adjustment to ensure that the output voltage of the RXi System matches that of the hemodynamic monitor. This procedure should only be performed at installation or if necessary to adjust for compatibility to non-standard systems. Only an ACIST Service Representative should perform this procedure.
New Vessel Button	The **New Vessel** button is selected to declare that a new vessel is being measured.
Pa Scaling	Adjustment of the aortic pressure value to match the value on the hemodynamic monitor.
Patient ID	Up to 20 characters can be used to identify the patient.
Pv Button	Press **Pv** to open a pop-up window that enables changes to the venous pressure parameter displayed on the touchscreen.
Record Button	Press **Record** when the system is ready to start the FFR recording.
Stationary Mode	In the Stationary mode, the RXi System is set up as a stationary device, which means it will remain installed in one room. The aortic signal input only needs to be zeroed at installation or if it is connected to a different hemodynamic system.
Stop Button	When recording is started, the **Record** button changes to a **Stop** button, which stops recording at any time within the 10-minute recording time. Once pressed, the FFR Review screen is displayed.
Sweep Speed	A range of hemodynamic waveform speeds that may be selected by the user. Available values are 5, 10, 15, and 20 mm/s, with the default being 10 mm/s.
System Information	Displays the Software Version installed on the system and the Date/Time (displayed in real time).
Time	Used to change the system time in Hours (using a 24-hour clock) and Minutes.
Touchscreen Calibration	Allows you to re-calibrate the console panel touchscreen.
Venous Pressure (Pv)	Venous pressure is the estimated right atrial pressure. The venous pressure setting can be adjusted within the range of 0 to 40 mmHg by pressing the **Pv** Button. This opens a window where you can adjust the value using the plus (+) and minus (-) buttons. The default is 0.
Vessel ID	Identifies the vessel that is being examined. Select from a list of 18 pre-defined vessels or input a custom vessel ID of up to 20 characters.

Glossary Term	Definition
Zero Aortic Button	Press **Zero Aortic** when the aortic pressure transducer is reading atmospheric pressure at patient midaxillary height. Pressing this button zeroes the Aortic Pressure on the RXi System.
Zero Pressure Sensor Option	Select this option on the ACIST Menu when the Navvus MicroCatheter pressure sensor is connected to the RXi System. This option should only be used when the microcatheter pressure sensor is reading atmospheric pressure. Your are prompted to remove the microcatheter from the patient's body when this option is selected.

10 Technical Specifications

Electrical Specifications

Power Requirements

Power	Requirements
Standard voltage	100-240 VAC (±10%) with the specified external switching power supply
AC amps	1.41 A DC maximum
Wattage	17 watts maximum
Frequency	47 to 63 Hz (includes ±5% tolerance)
RXi System voltage	12 VDC for the specified external switching power supply
RXi System DC amps	0.9 A DC maximum

Note:

The power supply must be positioned to provide easy access to either or both ends of the line power cable for disconnection from mains power.

Electrical Leakage

Current	Amount
Patient leakage current	Less than 10 µA
Enclosure leakage current	Less than 100 µA
Earth leakage current (ground)	Less than 500 µA

UL Classification

Area	Classification
Type of protection against electric shock	Class II
Degree of protection against electric shock	Defibrillation-proof type CF applied part
Degree of protection against ingress of water	IPX0
Methods of sterilization or disinfecting	None
Mode of operation	Continuous

WARNING

This equipment is not suitable for use in the presence of flammable anesthetic agents.

For UL labeled product:

C-UL Classified Mark, Medical Electrical equipment, Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with IEC 60601-1.

Other Specifications

Transportation and Storage Requirements

Requirement	Range - System	Range - Catheter
Ambient Temperature	-20° to 140°F -29° to 60°C	-20° to 140°F -29° to 60°C
Relative Humidity	5 to 95% Non-condensing	5 to 85% Non-condensing
Atmospheric Pressure	7 to 15 psi 50 to 106 kPa	11 to 15 psi 77 to 106 kPa

Operating Environment Requirements

Requirement	Range - System	Range - Catheter
Ambient Temperature	64° to 86°F 18° to 30°C	64 to 86°F 18 to 30°C
Relative Humidity	10 to 95% Non-condensing	10 to 95% Non-condensing
Atmospheric Pressure	11 to 15 psi 77 to 106 kPa	11 to 15 psi 77 to 106 kPa

Weight

Component	Weight
System console (with power supply and cables)	20 lb (9.1 kg)

Dimensions

Component	Dimensions
System console (without power supply and cables)	Depth: 3.5 in (8.9 cm) Width: 10.7 in (27.2 cm) Height: 9.2 in (23.4 cm)

Cable Lengths

Cable	Length
Power cable (power supply to main power)	8.2 to 10 feet (2.5 to 3 meters)
System console to power supply	5 feet (1.5 meters)

Pressure Signal Input

Signal Type	Specification
Pressure range	-30 to +300 mmHg relative atmosphere thoughout 580 to 800 mmHg absolute atmospheric pressure
Pressure accuracy	±3% of reading or ±3 mmHg of reading over pressure range, whichever is greater, including the combined effects of sensitivity, repeatability, non-linearity, and hysteresis
Pressure drift	<7 mmHg over 1 hour
Frequency response	Response at 10 Hz within 3 dBA of the response at 1 Hz
Input sensitivity	Compatible with 20 mmHg/V or 100 mmHg/V Pa signal input

Pressure Signal Output

Signal Type	Specification
Output sensitivity	5 uV/V/mmHg nominal scale strain gauge bridge (ANSI/AAMI BP22)

Clinical Guidance for Use of Pd/Pa to FFR Measurements

As stated previously, the ACIST RXi System is designed to provide hemodynamic information for the diagnosis and treatment of coronary and peripheral artery disease. The system is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display fractional flow reserve (FFR) and resting Pd/Pa.

The expected FFR value in a normal vessel without a stenotic lesion or obstruction to blood flow is a value of 1.0. Based on clinical evidence, a threshold or cutpoint value of ≤ 0.80 is commonly considered for treatment with a therapeutic intervention, while a value > 0.80 is commonly considered for deferment. An established, clinically evident Pd/Pa threshold or cutpoint such as this is indeterminate, but guidance for use of Pd/Pa for clinical decision making may be considered by referring to the existing, supportive clinical evidence from multiple diagnostic accuracy studies performed on resting Pd/Pa.

A recent meta-analysis was reported by Maini et al., based on published resting Pd/Pa diagnostic accuracy studies[1] which examined the overall diagnostic accuracy of Pd/Pa compared to FFR. The meta-analysis reported on 14 studies with an optimal cutpoint ranging from 0.875 to 0.96 and resulted in cutpoints from 0.91 to 0.93 in 12 of the 14 studies in the meta-analysis.

The ACIST-FFR Pd/Pa Post-hoc Sub-Group Analysis[2] identified an optimal cutpoint of 0.91. The cutpoint was derived from a post-hoc receiver operating characteristic (ROC) curve analysis using an FFR cutoff value of ≤0.80 measured with the ACIST Navvus® MicroCatheter to define stenosis. The 0.91 cutpoint is within the range of 0.91 to 0.93 as was reported in 12 of the 14 studies in the Maini et al., meta-analysis.

Clinical Guidance for use of FFR and Pd/Pa physiologic measurements by the physician may be considered as the resting Pd/Pa value, along with patient history, medical expertise and clinical judgement to determine if an additional measurement of FFR during hyperemia or therapeutic intervention is indicated.

1. Maini R, Moscona J, Sidhu G, Katigbak P, Fernandez C, Irimpen A, Mogabgab O, Ward C, Samson R, LeJemtel T. **Pooled diagnostic accuracy of resting distal to aortic coronary pressure referenced to fractional flow reserve: The importance of resting coronary physiology.** *J Interv Cardiol.* 2018 Oct; 31(5): 588-598.

2. Thackery, Lisa.; Rorke, Becky; Larson, Janet A. Post-hoc analysis of data from the **ACIST-FFR clinical study which assessed catheter based interrogation and standard techniques for Fractional Flow Reserve Measurement.** Original data set analysis published in: *Circ Cardiovasc Interv.* 2017 Dec; 10 (12). e005905.

EMC Tables

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The ACIST RXi® System is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions EN 55011:2009/A1:2010 (CISPR 11:2009/A1:2010)	Group 1, Class B*	The RXi System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2:2006 + A1:2009 +A2:2009	Class B	—
Voltage fluctuations / flicker emissions IEC:61000-3-3: 1995 + A1:2008 +A2:2005	Complies	—

* The ACIST RXi System is in compliance with Class A RF emissions when the Ao Interface Box is attached.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ACIST RXi System is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2: 2008 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	±8 KV contact ±15 KV air	Criterion A Criterion A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4:2012 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	±2 KV for power supply lines ±1 KV for input/ output lines	Criterion B Criterion B	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5:2005 + Cor 1:2009 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	±1 KV differential mode ±2 KV common mode	Criterion A Criterion A	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field EN/IEC 61000-4-8 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	3 A/m	Criterion A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN/IEC 61000-4-11:2004 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	100% of VNOM for 8.3 mSec (0.5 Line Cycles at 0, 45, 90, 135, 180. 225, 270, 315 100% of VNOM for 20 mSec (1 line cycle) at 0 60% of VNOM for 500 mSec (30 Line Cycles) at 0 30% of VNOM for 500 mSec (30 Line Cycles) at 0 0% of VNOM for 5000 mSec (300 Line Cycles)	Criterion A Criterion A Criterion A Criterion A Criterion C	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RXi System requires continued operation during power mains interruptions, it is recommended that the RXi System be powered from an uninterruptible power supply or battery.
Note: Ut is the AC mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF Immunity EN/IEC 61000-4-6:2013 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	6 Vrms 150kHz to 80MHz	Criterion A	Portable and mobile RF communications equipment should be used no closer to any part of the RXi System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3:2006 + A1:2007 + A2:2010 per IEC 60601-1-2:2014 and EN 60601-1-2:2015 4th Edition	3 V/m 80 MHz to 2.7 GHz	Criterion A	$d = 1.2 \sqrt{P}$
	9 V/m 704-787MHz 5.1-5.8GHz	Criterion A*	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
	27 V/m 380-390 MHz	Citerion A	Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:
	28 V/m 430-470 MHz 800-900 MHz 1.7-1.99 GHz 2.4-2.57 GHz	Criterion A*	

Note 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RXi System is used exceeds the applicable RF compliance level above, the RXi System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation of the RXi System.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

* The ACIST RXi System meets Criterion B when the Ao Interface Box is attached.

Criteria Definitions

Criterion A - EUT operated as intended during and after the test. No degradation of performance or loss of function.

Criterion B - Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention;

Criterion C - Temporary loss of function or degradation of performance, the correction of which requires operator intervention

Criterion D - Loss of function or degradation of performance which is not recoverable, owing to damage to hardware or software, or loss of data.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ACIST RXi® System

The ACIST RXi System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RXi System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*			
Note 2 *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			

	Essential Performance	
	Measure blood pressure with Navvus® MicroCatheter. The pressure static accuracy shall be ±3% of reading or ±3 mmHg of reading over operating range of -30 mmHg to 300 mmHg.	The RXi System to begin alarming when a broken fiber optic condition occurs.
Immunity Tests	During test, the system is set to read a positive value (~20 mmHg on the screen) with a 0.5 Hz square 5 mmHg wave imposed on it. The pressure is monitored during testing to ensure compliance with the Essential Performance.	
Electrostatic Discharge (ESD)	4th Edition: Criterion A	The system continuously monitors for a broken fiber. No specific testing was performed during EMC-EMI testing to validate broken fiber detected during testing.
Electrical Fast Transient / Burst	4th Edition: Criterion B	
Surge	4th Edition: Criterion A	
Voltage dips, short interruptions and voltage variations on power supply input lines	4th Edition: Criterion A 4th Edition: 250/300 cycle dip Criterion C 4th Edition additional Phase angles Criterion A	
Power Frequency (50/60 Hz) Magnetic Field	4th Edition: Criterion A	
Conducted RF Susceptibility	Criterion A	
Radiated RF Susceptibility	Criterion A	
Radiated RF 4th Edition spot	Criterion A	
Emissions Test		
RF Emissions	Passes class B emissions* per TÜV SÜD America, Inc. NOTE: The RXi System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF Emissions Conducted	Class B	

* The ACIST RXi® System is in compliance with Class A RF emissions when the Ao Interface Box is attached.

11 Limited Warranty

ACIST Medical Systems, Inc. ("ACIST") warrants that the ACIST RXi® System will be free of defects in material and workmanship for a period of one (1) year following installation. This warranty is available and extended only to the original end-user purchaser of the ACIST product. The foregoing is the sole warranty of ACIST.

Any part or component of the ACIST RXi System that is judged to be covered under this warranty by ACIST during the warranty period will be repaired or replaced by ACIST at its option and its expense. Remedies available to the purchaser under this warranty are limited to repair or replacement of malfunctioning parts or System replacement with the specific remedy subject to determination by ACIST in its sole and reasonable judgment. Application for warranty coverage and remedy must be made to ACIST within ten (10) days of the apparent malfunction.

This warranty is void if the product has been (a) repaired by someone other than ACIST or its authorized agent; (b) modified or altered in any way as to, in the judgment of ACIST, affect its function (c) misused; or (d) damaged by negligence, accident, or intent.

This warranty does not cover routine wear and tear on the product.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE GOODS SOLD HEREUNDER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, ACIST MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, ORAL, WRITTEN OR OTHERWISE, WITH RESPECT TO THE PRODUCT(S) SOLD HEREUNDER, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. DUE TO DIFFERENCES IN PATIENTS AND OTHER FACTORS BEYOND THE REASONABLE CONTROL OF ACIST, AND BECAUSE ACIST HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH PRODUCTS ARE USED AFTER THEY LEAVE THE POSSESSION OF ACIST, ACIST DOES NOT WARRANT EITHER A GOOD EFFECT OR AGAINST ILL EFFECT FOLLOWING THE USE OF THE ACIST PRODUCT AND ACIST MAKES NO WARRANTY AS TO WHETHER OR NOT ANY

PARTICULAR OR DESIRED RESULT IS OBTAINABLE BY APPLICATION OR USE OF THE ACIST PRODUCT.

ACIST SHALL UNDER NO CIRCUMSTANCES BE LIABLE TO THE PURCHASER OR ANY THIRD PARTY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES OF ANY NATURE, WHATSOEVER, INCLUDING, BUT NOT LIMITED TO, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR REVENUE, REAL OR PERCEIVED LOSS OF USE, LOSS ARISING FROM A DEFECT IN DESIGN, MATERIAL AND/OR MANUFACTURE OR WORKMANSHIP AND/OR THE FAILURE OF THE PRODUCT(S) TO PERFORM AS SPECIFIED, EVEN IF ACIST SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

IT IS REQUIRED THAT THE ACIST PRODUCT BE OPERATED BY OR UNDER THE IMMEDIATE, DIRECT SUPERVISION OF A LICENSED DOCTOR OR OTHER LICENSED HEALTH CARE PROFESSIONAL QUALIFIED TO USE THE PRODUCT AND PERFORM THE PROCEDURE. ACIST DISCLAIMS LIABILITY FOR ALL INJURIES, DEATHS, OR PROPERTY DAMAGE ARISING FROM THE USE OF THE PRODUCT BY ANYONE, OTHER THAN QUALIFIED PERSONNEL DESCRIBED ABOVE, OR THE IMPROPER, NEGLIGENT OR RECKLESS USE OF THE PRODUCT, OR THE USE OF THE PRODUCT FOR ANY UNAPPROVED INDICATION OR FOR ANY USE NOT SPECIFICALLY INDICATED IN THE OWNER'S MANUAL OR OTHER PRODUCT INSTRUCTIONS.

A charge will be applied for all repair service not covered under this limited warranty.

Appendix: Ao Interface Box

Package Contents

The RXi Ao Interface Box is shipped in one box. The pouch contains the following items:

- one Ao interface box assembly, which also includes the RXi mounting bracket
- one remote mounting bracket
- two cables
- two hook and loop fastener straps

Carefully inspect the contents to ensure that all contents are included. If any contents are missing, call ACIST Technical Services.

Device Description

The RXi Ao Interface Box is a signal splitter that allows the ACIST RXi system to receive Ao (aortic) input from transducers that would otherwise be connected to the hemodynamic system.

Note

With the Ao Interface Box attached, the RXi System is in compliance with Class A RF emissions.

Indications for Use/Intended Use

The RXi Ao Interface Box is indicated for use with the RXi System in order to receive aortic pressure input from transducers that are connected to:

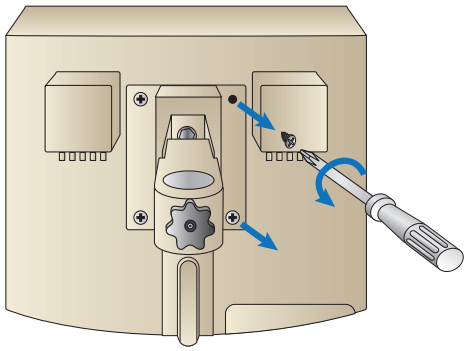
- An older hemodynamic system that does not have a compatible Ao output
- A hemodynamic system that is not accessible to the RXi system because it is located in the control room or remote from the patient
- Additional products that require an Ao input and cannot pass on that signal for use by RXi

- Hemodynamic systems where the output channels are dedicated to other cath lab equipment

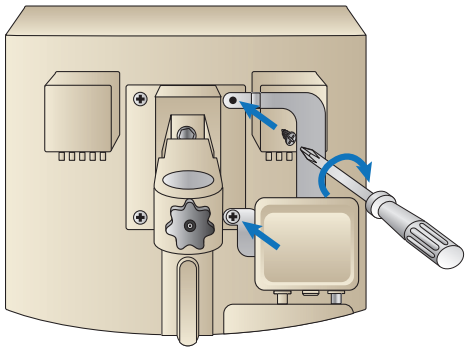
The Ao interface box is intended to connect to the transducer, RXi, and the hemodynamic system.

Option 1: Installation of Ao Box on the RXi Console

Using a Phillips head screwdriver, remove the two screws on the right side of the console Vesa mount.



Position the mounting holes on the Ao Box assembly bracket over the holes in the RXi mount flange and reattach the screws.

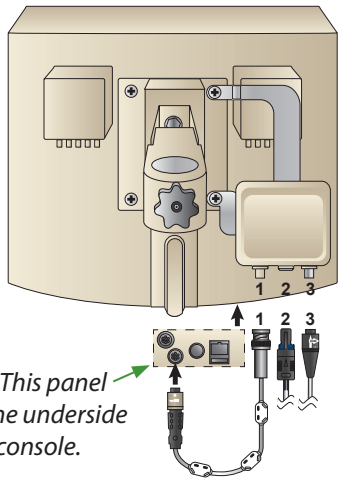


Note

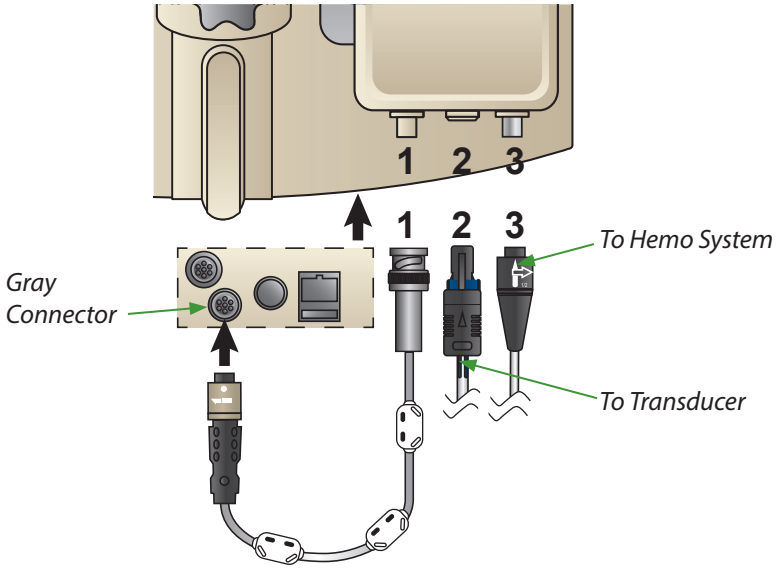
If using the remote mounting option, refer to the section, "Ao Interface Box Installed with Remote Mounting Bracket".

Cable Connections to Ao Interface Box

The following illustration shows the cable connections to the Ao Interface Box when installed on the console.



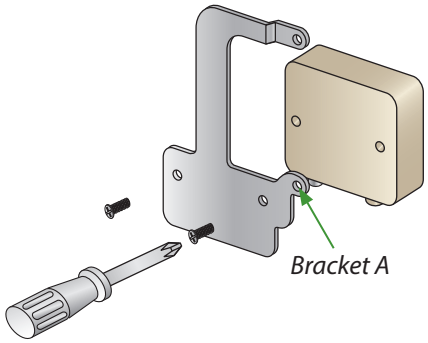
1. Insert the metal BNC connector (#1) on the short cable (PN 301764) to connector #1 on the interface box. Twist to lock it in place.



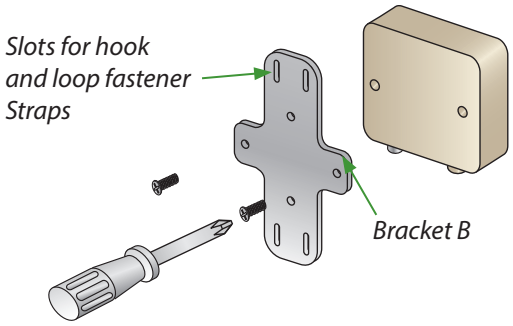
2. Connect the other end of the cable to the RXi Ao input connector as shown in the illustration above. **Push the connection until it clicks to lock** it in place.
3. **Pull gently on each end of the cable to ensure they are fastened securely**.
4. Attach the cable with the gray and blue connector to the middle connector on the interface box (#2). Align the black arrow on the female end of the cable connector with the gray arrow on the male connector on the box. Push the connector in until it clicks to make the attachment secure. **Pull gently on the cable to ensure it is fastened securely**.
5. Connect the other end of the cable to the cath lab invasive blood pressure (IBP) transducer that would normally connect to the hemo system. **After making the connection, tug slightly on the connector (but do NOT twist) to ensure the connection is locked**.
6. Insert the black connector (#3) on the hemo cable into the rightmost connector on the box by aligning the arrows on the connectors and pushing to lock it into place. **After making the connection, tug slightly on the connector (but do NOT twist) to ensure the connection is locked**.
7. Connect the other end of the cable to the hemo system into the position that the aortic pressure input would normally connect.

Option 2: Ao Interface Box Installed with Remote Mounting Bracket

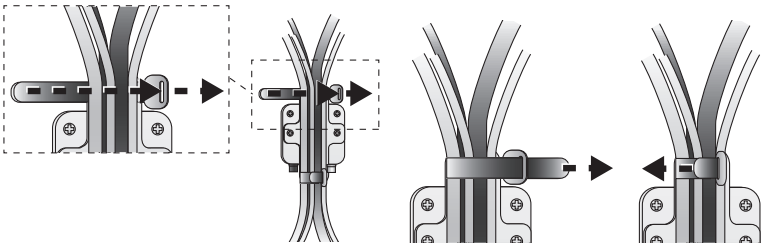
An alternative method of installing the Ao Interface Box is to attach it to existing cath lab equipment. Remove Bracket A from the Ao Interface Box that is connecting the Ao Interface Box to the RXi console by removing the two screws as illustrated below.



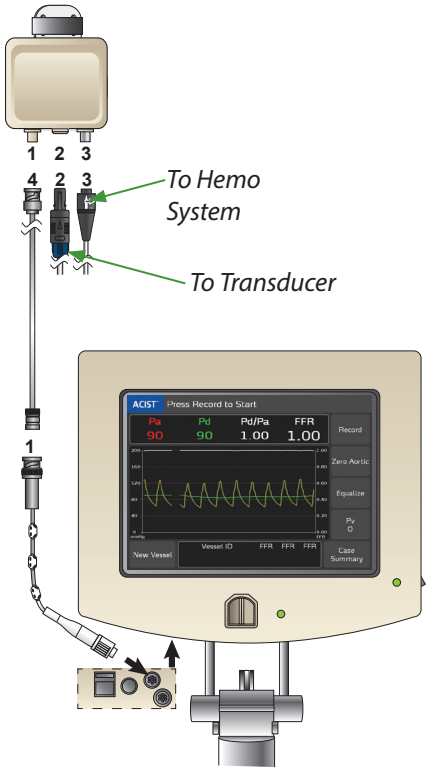
Reuse the same screws to attach the remote mounting bracket (Bracket B) to the Ao Interface box.



This assembly can now be used with the supplied hook and loop fastener straps to attach the Interface Box to other equipment in the cath lab (such as cables shown in the illustration below).



The following illustration shows the cable connections to connector #1 on the Ao Interface Box when installed using the remote mounting bracket.



1. Connect the male end of the long cable with the BNC to BNC connectors (#4) to connector #1 on the Ao Interface Box, which has been installed remotely.
2. Connect the female end of this cable to the BNC connector (#1) on the short cable (PN 301764). Connect the other end of the short cable to the RXi Ao input connector as shown in the above illustration.

Connect remaining cables as described in the previous section, "*Cable Connections to Ao Interface Box*".

Calibration

1. Ensure that both the hemo system and the RXi system are powered on. Confirm that the RXi System is set to the Mobile mode. Refer to *"System Settings"* in Section 6 *System Information and Settings*.
2. Ensure that the transducer stopcock is open to atmosphere.
3. Wait until the aortic pressure (Pa) signal is displaying a steady state value on the hemo system. If the hemo system does not display zero, actively zero the hemo system, and then actively zero Pa on the RXi system. Refer to the section, "*Zero the Aortic Pressure on the ACIST RXi® System*" in Section 5 *Basic Operating Procedures*.
4. If the Ao Box is disconnected for more than 5 seconds, you may need to re-establish connection with the hemo system and repeat the zeroing process.
5. Verify a non-zero pressure value in one of the following ways.
   - If a Medex Back Plate is present, press and hold down the 100 mmHg button.

   - Connect a calibrated variable pressure gauge and manually supply a value of 100 mmHg to an attached internal blood pressure transducer.
   - Attach a syringe to a stopcock connected to the pressure transducer and depress plunger to apply a non-zero pressure value. Close the stopcock to hold pressure during calibration.
6. Confirm that both the hemo system and the RXi System are reading the same non-zero value (100 mmHg in this example).
7. If the hemo system is not reading 100 mmHg while a known (for example, from the Medex backplate) 100 mmHg of pressure is supplied to the transducer, re-calibrate the hemo system to 100 mmHg. Refer to the hemo system user's guide for calibrating the pressure channels.
8. The hemo system should always read 100 mmHg when a 100 mmHg signal is sent via the Medex backplate from the transducer unless:
   - The transducer is raised or lowered with respect to its original height when the transducer was previously calibrated.
   - The hemo system is recalibrated with an incorrect zero offset or inaccurate non-zero value.

9. If the RXi system is not reading 100 mmHg while 100 mmHg is supplied to the transducer, use the Pa Scaling function on the RXi software to adjust the signal gain up or down to match 100 mmHg. Refer to "*Perform Pa Scaling*" in Section 4 *Installation*.

Performing a Case

After ensuring that the signal is calibrated correctly on both the hemo system and RXi, perform the following steps.

1. Check the zero pressure value on both the hemo system and RXi while ensuring that the guide catheter stopcock is open.
2. If dissimilar, re-zero both the hemo system and RXi.
3. Close the stopcock.
4. Continue the case as described in Section 5 *Basic Operating Procedures*.

CAUTION

Whenever the hemo system is "zeroed," ensure the stopcock is open and actively zero RXi using the **Zero Aortic** *button.*

Cleaning and Maintenance

Routine inspection is required to keep the Ao interface box in optimal working condition. Inspect cables for cuts, nicks, and openings in the cable insulation. Check cable connections to make sure cables and connectors have not separated. Replace any damaged cables. Check the mount to ensure a tight and secure fit.

When cleaning is needed, wipe down using 70% isopropyl alcohol.

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ACIST Medical Systems, Inc.
7905 Fuller Road
Eden Prairie, MN 55344 USA

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