Your Cath Lab **Knowledge Catalysts**

It's how you know.

From helping to reduce and track contrast delivery[1] to enabling physicians to use their 0.014” guidewire of choice, to optimized imaging.[2]

ACIST gives you the power to make those critical decisions.

Beyond their clinical effectiveness, our diagnostics also validate the appropriateness of therapeutic intervention to improve patient outcomes.

ACIST®

ACIST informs interventional decisions during peripheral, cardiovascular disease and structural heart procedures.

Physicians worldwide rely on our diagnostic technologies to give them the power to visualize, assess and inform patient treatment. Economic decision-makers appreciate our ability to demonstrate the value of therapeutic intervention.

How much contrast have I delivered?

ACIST **CVi**®

Is an intervention needed?

ACIST **RXi**®

Have I optimized my intervention?

ACIST **HDi**®

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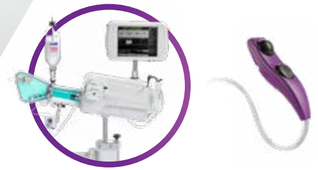
ACIST is **YOUR** diagnostic partner providing you clinical and economic value every day.

ACIST **CVi**®

Contrast Delivery System



Increase safety and operational efficiency

ACIST CVi delivers the power to reduce delivered contrast, minimizing the risk of contrast-induced acute kidney injury (CI-AKI).*

ACIST AT X65 provides a more defined hemodynamic signal, without using a hand manifold.

*When compared to manual injection of contrast media: 22% reduction in contrast use without compromising image quality[1]

Clinical and Economic Value

CVi

- Up to **30%** reduction in CI-AKI vs. manual injection[1,2]
- **49.4%** of Interventional Cardiologists have experienced at least one orthopedic injury.[3] CVi may reduce repetitive stress injuries that can be caused by manual contrast injection.
- Average CI-AKI cost to the hospital: **$9,448**[4]
- Up to 50% reduction in clinician radiation exposure by stepping back.[5]
- Average **5 min** faster per procedure, which may allow for additional procedures to be performed in a day[6]

CVi Consumable Kits

ATX and ATP Simplicity Sets • ATX and ATP Pressure Monitoring Sets Multi-use Syringe • Automated Manifold • Single-Use Syringe

ACIST **RXi**®

Rapid Exchange FFR System

Medis **QFR**®
Quantitative Flow Ratio

Efficiently assess, and confirm coronary artery disease, even in the most complex cases

RXi and the ultra-thin Navvus®II MicroCatheter provides you with the power to simplify assessment of complex coronary artery disease using your 0.014"guidewire of choice.

QFR® is Medis' proprietary solution delivering image-based functional assessment of coronary obstructions from standard coronary angiograms.

ACIST NavvusII Rapid Exchange FFR MicroCatheter

- **13%** reduced lesion entry profile[7,8] to streamline contouring in allowing navigation of complex diseases.
- **28%** improved flexibility[9]
- Maximize control by enabling you to use the **0.014" guidewire of choice** to maintain wire position
- **Consistent and reliable**[10] fiber optic technology may be less susceptible to clinically significant drift compared to traditional pressure wire.*

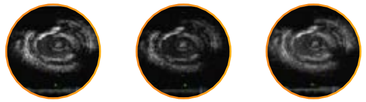
RXi System

- Requires zeroing only once, at initial install, when in stationary mode
- Ready when you are, displaying patient's aortic pressure

* Difference did not reach statistical significance in clinical trial

ACIST **HDi**®

HD IVUS System



LumenView™
For a better defined lumen border visualization*

SilkView™
For a softer gray scale and more defined plaque visualization*

ClassicView™
Utilizes blood speckle to define the intravascular space*

*Data on file - TR-07057 – Internal Testing

The system of choice for optimized imaging in percutaneous coronary and peripheral interventions

ACIST HDi with advanced imaging modes provides a better defined IVUS image for pre procedural planning and post procedural assessment.[2]

HDi High-Definition IVUS System with Extended Field of View Kodama IVUS Catheter

- Improved deliverability[11] and optimized imaging[2] with the offset distal tip
- High-speed pullback – **10x** faster pullback; 90%-time reduction[12]
- **Better visualization** of media with 60 MHz IVUS than OCT for optimizing stent sizing[13]
- **Interactive** compact HDi console with touch screen for rapid analysis and small footprint
- 0.014" guidewire compatible; 20 mm max imaging diameter

IVUS Benefits

- IVUS use changed the treatment strategy during the procedure **74% of the time**[13]
- IVUS-guided PCI was significantly associated with lower risk of death, myocardial infarction, revascularization, and stent thrombosis[14]
- IVUS is less expensive and more effective than angiography in **71% of PCI procedures**[15]

Over the last **20 years**, we've helped improve the lives of **35 million** patients and counting in over **75 countries** around the world

Since then, ACIST has become a knowledge catalyst, helping interventional cardiologists quickly visualize, assess and improve patient treatment globally with over 400+ employees worldwide.

Acquired in 2001 and backed by the power of Bracco, a world-class leader in diagnostic imaging, our expanding product and service offering delivers the flexibility clinicians want to get the insights they need.

ACIST CVi
Rx Only

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

Indications for Use (Multi-Use): The ACIST CVi® Contrast Delivery System is indicated for controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The ACIST CVi® Contrast Delivery System is specifically indicated for use in angiographic procedures for the delivery of ISOVUE® (iopamidol injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of ten (10) hours. The Syringe Kit must be discarded after six (6) patient procedures. The Manifold Kit and AngioTouch® Hand Controller Kit must be discarded after each patient procedure.

The ACIST CVi® Contrast Delivery System is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

Indications for Use (Single-Use): The ACIST CVi® Contrast Delivery System is indicated for controlled administration of radiopaque contrast media and saline to human subjects while undergoing angiographic procedures. The CVi®1 Syringe Kits, Manifold Kit and AngioTouch® Hand Controller Kit must be discarded after each patient procedure. The CVi1 Syringe Kits are also indicated for single patient use with ACIST CVi® Contrast Delivery Systems. The ACIST CVi® Contrast Delivery System is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

Contraindications: The ACIST CVi® Contrast Delivery System (CVi system) is not intended for use as a long-term infusion pump. The system is not intended to be used to inject any agents other than contrast media. The system should not be used to inject substances into nonvascular body cavities.

Important Safety Info: The CVi System is designed to aid the physician in the injection of contrast media and saline during angiography. It should be used with adequate radiographic imaging and where monitoring equipment for blood pressure and the electrocardiogram is available. Additionally, standard equipment for cardiopulmonary resuscitation and drugs for the treatment of contrast media-induced drug reactions should be present. It is necessary that the CVi system be operated by, or be under the immediate and direct supervision of a physician who is specifically trained in angiography and in the operation of this unit. System operation must be monitored at all times, and specific operational and mechanical integrity must be maintained to ensure patient safety. For proper operation and to ensure equipment compatibility, use only accessories and options provided or specified by ACIST Medical Systems for use with the CVi system. For Single-Use Patient Kits, use of an incorrect combination of contrast media and syringe kit may cause the system to fail to operate correctly and may result in procedural delay. Contamination of patient kits or the contrast container septum presents a risk of serious patient injury due to infection. Aseptic technique must be employed. If suspected contamination has occurred, replace the affected item. An air embolism can cause patient injury or death. Operator vigilance and care, along with a defined procedure, are essential to avoid injecting air and causing an air embolism. Before injections, clear all air from the entire patient kit and the angiographic catheter. Make sure that the exterior of the tubing is dry before inserting it into the air column detect sensor. If any fluid is present on the tubing's exterior surface, the sensor may be unable to detect air. Use extreme care when setting the flow rate. High flow rate injections can cause patient injury or death. When high flow rate injection is required, select a pressure setting that does not exceed the catheter's pressure rating. The maximum pressure rating of the CVi system is 1200 psi.

ACIST RXi & RXi Mini
Rx Only

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

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

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

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

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

This product should not be used in rooms containing magnetic resonance imaging (MRI) equipment.

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

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

ACIST HDi
Rx Only

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

Indications for Use: The ACIST HDi® System is intended to be used for the ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. The ACIST Kodama Intravascular Ultrasound Catheter is intended for use with the ACIST HDi System.

Contraindications: Contraindicated for patients with: bacteremia or sepsis; arterial spasm; major coagulation system abnormalities; mechanical heart valves that would be crossed by the catheter; severe hemodynamic instability or shock; total vessel occlusion (prior to initial stages of revascularization). Contraindicated for use in the cerebrovascular arteries. In coronary procedures, the product is also contraindicated for patients who are: disqualified for revascularization surgery; disqualified for balloon angioplasty (PTCA).

Important Safety Info: Intravascular ultrasound studies using this product should be performed only by physicians and other medical professionals fully trained in the required techniques and procedures.The Kodama catheter contains a short monorail guidewire engagement system. As such, it is susceptible to guidewire entanglement and/or prolapse during catheter deployment and withdrawal. Before use and when possible during use, inspect the Kodama catheter carefully for kinks or any other damage. Do not use a kinked or damaged catheter because vessel damage and/or the inability to advance or withdraw the catheter may occur.

Never advance or withdraw the Kodama catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in elongation or separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

When advancing the Kodama catheter through a stented vessel, short monorail catheter designs are susceptible to guidewire/ catheter entrapment, catheter tip separation, and/or stent dislocation.

Adverse events that may occur as a consequence of intravascular ultrasound imaging include (but are not limited to): vessel occlusion and/or abrupt closure; air embolism; vessel dissection, injury, or perforation; vessel rupture, injury, or perforation; acute myocardial infarction; cardiac arrhythmias including but not limited to ventricular tachycardia, ventricular fibrillation, and complete heart block; cardiac tamponade; catheter/guidewire entrapment; catheter induced ischemia; death; vessel trauma requiring treatment/surgical intervention, including angioplasty/stent; infection; stent strut damage; stroke (including cerebral vascular accident and transient ischemic attack); thrombus formation or thromboembolism; vasospasm.

Medis QFR
Rx Only

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

Indications for Use: QAngio XA 3D is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease. When the quantified results provided by QAngio XA 3D are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible clinicians. Warnings: QAngio XA 3D must be used by cardiologists or trained technicians who are qualified to perform cardiac analysis. If the analysis results are used to reach a diagnosis, the results must be interpreted by a qualified medical professional. Users must have sufficient proficiency in the selected operating language, read this manual, become familiar with the software, and must be certified by Medis before using QAngio XA 3D in a clinical environment in order to obtain reliable analysis results. Limitations: The two 2D angiographic images used for the 3D vessel reconstruction need to be taken with at least 25 degrees difference in viewing angle. QFR measurements have not been evaluated for non-coronary arteries, pediatric patients, and cardiac patients with the following conditions: tachycardia with frequency above 100 bpm, systolic aortic resting blood pressure below 75 mm Hg, atrial fibrillation.

Additionally, QFR measurements have not been evaluated for the following lesions and vessels: culprit lesions in Acute Coronary Syndrome, bifurcation lesions with 1,1,1 Medina classification , aorto-ostial artery stenoses or ostial right coronary artery stenoses, distal Left Main lesions in combination with a proximal circumflex lesion, vessels with retrograde fillings, bypass grafts, grafted coronary arteries, myocardial bridging.

QFR measurements cannot be performed accurately under the following conditions: when no nitroglycerin has been administered either systemic nor intracoronary; too much overlap of other vessels with the lesion or areas just around the lesion in the target vessel in one or both angiographic acquisitions, too much foreshortening of the target coronary artery in one or both angiographic acquisitions.

Note on Monitor Aspect Ratio and Resolution: The shapes of objects and calipers displayed may get slightly distorted when the resolution is set to an aspect ratio different than the monitor's physical aspect ratio. This distortion does NOT affect the accuracy of measurements or analyses. To avoid distortion, set the resolution of the monitor to an aspect ratio equal to the physical aspect ratio. LCD monitors typically operate best at their native resolution. Microsoft Windows recommends a resolution when it has sufficient information to do so.

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8. TR-07888: Compared with Navvus. FFR MicroCatheter internal testing. Data on file at ACIST. May not be indicative of clinical performance.
9. TR-07888: Compared with Navvus. FFR MicroCatheter in benchtop testing. Data on file at ACIST. May not be indicative of clinical performance.
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