

ACIST | CVi® Contrast Delivery System

Standardizing contrast injection.



Standardizing contrast injection

The ACIST I CVi® System standardizes cardiovascular angiographic imaging across all procedures, from small injections in the coronaries to large volumes in the ventricles and peripheral vasculature. It's the advanced technology that physicians and staff can rely on for consistency and safety.

Protecting your patients

As interventional procedures become more complex, it's important to take steps to reduce the incidence of contrast-induced nephropathy; also called acute kidney injury (AKI). Lowering the contrast dose administered to the patient is one option to help reduce AKI.

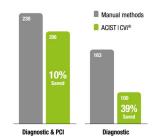
When compared to manual injection, automated contrast injection can:

- Decrease contrast dosage¹
- Reduce CIN incidence by 15%, based on meta-analysis²

Use of ACIST I CVI® has been shown to achieve a median contrast volume of 17.9 mL per procedure using an ultra low dose protocol. Posigned with safety in mind, its built-in features provide continuous automated monitoring of all critical systems functions including an air detect sensor that protects patients from air injection.

Reduce contrast volume by 40%5

Total mean contrast volume⁵ per patient in milliliters



Lab efficiencies

ACIST I CVi® shortens the procedure time (and turnaround time between patients) and decreases total contrast used per procedure, simplifying complex procedures and allowing for efficient workflow and operations.

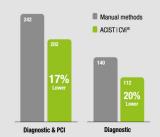
Improving safety for physicians and staff

ACISTI CVi® is a sophisticated system providing precise control of contrast injections for all your interventional and diagnostic angiographic procedures. Physicians and patients benefit from fast, safe procedures:

- Compared to hand injections, the AngioTouch® hand controller results in fewer images needed, using less fluoroscopy, and reducing radiation exposure for physicians and staff. It also enables the physician to take a step back from the radiation source, further reducing exposure
- Innovative system design makes ACIST | CVi®
 easy to use and simple to operate, eliminating
 hand injections and reducing wrist and back
 strain associated with manual injections.

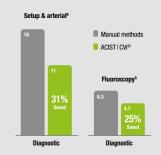
Lower contrast dosage by 20%1

Lower average contrast dose¹ per patient in milliliters



Reduce procedure time by 31%^{5,6}

Procedural time per patient in minutes







- The AngioTouch hand controller allows real-time, variable-flow control of the contrast injection rate for precise and consistent contrast administration, and has been shown to reduce per-patient contrast dosage by up to 20%1
- The touch screen monitor provides intuitive on-screen prompts for setup, adjustable injection volume and flow rate limits, contras tracking information, and real-time readout for continuous system and procedure monitorion.
- The built-in air column detection sensor alerts the clinician and stops the injection if air is detected in the single-use patient tubing connected to the catheter*
- The five-patient, isolated contrast syringe with rapid automatic refill can reduce
- 5 In-line, hemodynamic monitoring provided a real-time pressure reading, and the automated isolation manifold provides a barrier to the contrast syringe

*The air column detection sensor is designed to aid the user in the detection of air columns in the injection line, but it is not designed to replace the vigilance and care required of the operator in visually inspecting for air and clearing air

Product and Technical Specifications

	CVi system
Flow Dates	CVI System
Flow Rates Contrast: Saline:	User-Responsive, pre-set Variable and Fixed rates from 0.8 to 40 ml/sec, in 0.1 ml/sec increments Fixed rate: 1.6 ml/sec
Volume	User-Responsive, pre-set limits with variable range of 0.8 to 99.9 ml, in 0.1 ml increments
Pressure Limits	User defined from 200 to 1200 psi
Fill Rate	Manual or automatic refill of 3 ml/sec
Rise Time	User-defined 0 to 1 sec, in 0.1 sec increments
Program Routine Injection Modes	Cardiac: LCA, RCA, LV/Ao and User Defined Peripheral Vascular: Pigtail, Selective, Microcatheter and User Defined
Monitoring Sensors	Air Column Detect*, Isolation Manifold, Contrast Source Empty, Contrast Syringe Refill and Contrast Source Isolation
Imaging Interface Synchronization**	Able to synchronize with most brands of X-ray imaging equipment
Injection Delay** or X-ray Delay**	0-99.9 sec
KVO Feature***	Range of 0.1 to 10 ml/min with 20 min timeout; maximum of 200 ml of saline dispensed
Control Panel	27 cm (10.5 inches) Color Touch Screen
Flexible Mounting Configurations	Table Mount with adjustable arm or stationary stem Pedestal Cart
Pedestal Cart Dimensions	Wheelbase footprint 53.3×63.5 cm (21 \times 25 inches), height 91.4 cm (36 inches)
Contrast Syringe	100 ml
Consumable Kit Configurations Contrast Syringe (5 patient): AngioTouch Hand Controller & Tubing: Automated Isolation Manifold:	Contrast Syringe with contrast tubing spike and clamp (for use in up to 5 patient cases) AngioTouch hand controller, injection line tubing and 3-way stopcock Integrated system with automated isolation-manifold, low-pressure tubing and saline spike, and supplied pressure transducer cartridge
Component Weights	Power supply 5.5 kg (12 lb), control panel and stem 3.2 kg (7 lb), pedestal cart 10 kg (22 lb), injector head 20.4 kg (45 lb), adjustable arm 0.66 kg (1.45 lb)
Power Requirements	Factory selectable: 100 to 120 VAC, 50-60 Hz, 10 A maximum or 200 to 240 VAC, 50-60 Hz, 5 A maximum
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^{*} The air column detection sensor is designed to aid the user in the detection of air columns in the injection line, but it is not designed to replace the vigilance and care required of the operator in visually inspecting for air and clearing air

References

- 1. Anne G, Gruberg L, Huber A, et al. J Inv Cardiol. 2004;16(7):360-362.
- 2. Minsinger KD, Kassis HM, Block CA, et al. Am J of Cardiol. 2014;113(1):49-53.
- 3. Kelly SC, Li S, Stys TP, et al. J Invasive Cardiol. 2016;28(11):446-450.
- 4. 2011 ACIST Medical Systems Inc. interview with Joseph Tuma, MD, Rapid City Regional Hospital (Rapid City, SD).
- 5. Brosh D, Assali A, Vaknin-Assa H, et al. Int J Cardiovasc Int. 2005;7(4):183-187.
- 6. Lehmann C, Hotaling M. J Inv Cardiol. 2005;17(2):118-121.

The power to streamline your most complex interventional procedures.

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^{**} Available in synchronized peripheral mode

^{***} Available in peripheral mode

ACIST CVi°

Contrast Delivery System

CVi System Consumable Products

Designed to streamline set-up, manage contrast usage and provide enhanced control and consistency in your contrast delivery.

AngioTouch® Hand Controller

Indicated for single-patient use.

AngioTouch® Hand Controller Product includes: Hand controller, 3-way stopcock with

rotating end and standard 54"/65" high-pressure tubing.

SKU	Model Number	Qty/Case
014644	AT P54	10
014645	AT P65*	10



Multi-Use Syringe

Indicated for up to 5 patient cases.

Multi-Use Syringe Product includes:

100 ml contrast reservoir and tubing with contrast spike and clamp. For use with contrast media with viscosity range between 4.6 and 26.6 cP.

SKU	Model Number	Qty/Case
014612	A2000	10



*Not available in all markets

Bracco Group

NEW AngioTouch® Hand Controller

Indicated for single-patient use.

AngioTouch® Hand Controller Product includes: Hand controller, 3-way stopcock and 65" enhanced high pressure tubing with dual rotators.

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Multi-Use Syringe

Indicated for up to 5 patient cases.

Multi-Use Syringe Product includes:

100 ml contrast reservoir and tubing with contrast spike and clamp. For use with contrast media with viscosity range between 1 and 15.0 cP.

SKU	Model Number	Qty/Case
014113	A2000V*	10



Single-Use Automated Manifold

Indicated for single-patient use.

Automated Manifold Product includes:

Manifold with saline and contrast ports, saline tubing with spike, hand syringe and pressure transducer cartridge.

SKU	Model Number	Qty/Case
014613	BT2000	10



Pressure Monitoring Kit

Indicated for single-patient use.

Pressure Monitoring Kit Product includes: Transducer cartridge with high pressure tubing.

SKU	Model Number	Qty/Case
A30010	DPS564963	10



Contact your ACIST sales representative or ACIST Customer Support for more information.

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

Indications for Use: The ACIST CVi® Contrast Delivery System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

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. Any applications of the system, other than those described in this manual, are inappropriate and should not be attempted. Do not add any components to the consumable kits or in conjunction with the catheter. No valves or other manifolds may be placed in-line between the ACIST-provided consumable kit and the catheter. ACIST-provided consumable kits are designed, manufactured, and tested for connection to catheters used in angiographic procedures. Do not use the system in the presence of flammable gases.

Important Safety Info: The CVi System is designed to aid the physician in the injection of contrast media 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. To ensure proper operation of the syringe, viscosity limits must be observed. Do not allow the reusable syringe kit to sit loaded with contrast media longer than the maximum time recommended by the contrast manufacturer. Do not allow the reusable syringe kit to be used for more than five (5) procedures. Replace the automated manifold and hand controller kits after each procedure. Use of the syringe kit for more than five (5) procedures or re-use of the automated manifold and hand controller kits may result in cross contamination, risk of infection or device malfunction, for example, air ingress, leaks, or reduced performance. 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. High flow rate injections can cause patient injury or death. Use extreme care when setting the flow rate to avoid unintentionally setting a high flow rate injection. When high flow rate injection is required, be sure to select a pressure setting that does not exceed the rated pressure of the selected catheter.

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