ACIST | CVi®

ACIST | CVi®
Contrast Delivery System

User's Guide

Bracco Group
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ACIST®

Proprietary Information Notice

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1 Introduction

Intended 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.

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.

Requirements for Use

For safe use and optimal operation of the CVi system, observe the following guidelines:

- **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use only accessories and options provided by ACIST Medical Systems, which are designed specifically for the CVi system. This ensures compatibility with the injector. Do not use an accessory or option designed for another system on the CVi system.
- The CVi system is designed to aid the physician in the injection of contrast media and 0.9% normal saline during angiography. The system should be used with adequate radiographic imaging, and where both blood pressure monitoring equipment and an electrocardiogram are available. 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.

- Support personnel must ensure that:
  - All system connections are in place, secure, and functional.
  - Proper grounding and isolation standards are maintained.
  - Operational and calibration checks are made prior to each use of the system.
  - Proper support equipment (for example, a defibrillation unit) is on site for immediate response to patient distress.

Aseptic Technique

Employ proper aseptic technique in the handling and use of all patient kits. Sterile openings must be handled with care to ensure contact with only sterile connections or a disinfecting cap. The use of gloves is preferred but not required.

About This User's Guide

This User's Guide provides instructions for setting up and using the CVi system. It includes the following sections:

Section		Purpose
1	Introduction	Identifies the purpose and structure of this guide.
2	Warnings, Cautions, and Symbol Definitions	Users must read and understand this section thoroughly before using the CVi system.
3	System Description	Provides an overview of the system, its components, and the touchscreen interface.
4	Setup	Describes the steps necessary to set up a new case.
5	Perform an Injection	Describes the steps for performing a contrast injection with the CVi system.
6	End a Case	Describes the steps for ending a case and, if desired, starting a new case or shutting down the system.
7	Supplementary Procedures	Provides instructions for cleaning, maintenance, and infrequently used options
8	Troubleshooting	Provides answers to frequently asked questions, as well as a list of system messages.
9	Specifications	Provides technical specifications for the CVi system.
10	EMC Tables	Provides EMC tables.
11	Limited Warranty	Describes the limited warranty for the CVi system.

Manual Conventions

This manual uses the following conventions:

Note

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

Tip

Tips are useful information that may make tasks easier to accomplish.

Important

Information marked as important is vital to the proper operation of the system.

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 can cause serious injury or death.

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2 Warnings, Cautions, and Symbol Definitions

Read this entire user guide prior to using the CVi system and patient kits to ensure proper understanding and use. Operate the device only in accordance with this user guide to ensure safe and effective use.

Upon arrival, inspect all packaging and the delivered items for signs of damage that may have occurred during transportation. If any item appears damaged, contact an ACIST service representative.

Warnings

The following warnings refer to hazards that can cause serious injury or death. Please read and understand all the following warnings before proceeding with installation, setup, and operation of the CVi system.

Aseptic Technique

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.

Air Embolism

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.

Air in the Monitoring Line

Clear the monitoring line of all air to avoid producing an inaccurate blood pressure reading.

Air Column Detect Mechanism

The CVi system is equipped with an air column detect sensor. The air column detect sensor cannot detect air in the patient catheter, the stopcock, or the patient tubing past the sensor. This sensor is designed to aid the user in the detection of air columns in the injection tubing, but it is not designed to replace the vigilance and care required of the operator in visually inspecting for air and clearing air from the entire patient kit and angiographic catheter. The air column detect mechanism is to be used in conjunction with and to complement the user's other procedures for preventing air injections.

Disconnect Before Flushing Air

When flushing air, be sure the tubing is disconnected from the patient.

Use of Patient Kits

ACIST-provided patient kits are designed, manufactured, and tested for connection to catheters used in angiographic procedures. Failure to observe the following guidelines can result in patient injury or equipment damage:

- Do not add any components to the patient kits or in conjunction with the catheter.
- No valves or other manifolds may be placed inline between the patient kit and the catheter.
- Do not use the single use kits on more than one patient.
- Do not allow any patient kit loaded with ISOVUE (iopamidol injection) contrast media to sit unused for more than 10 hours.
- Do not use a syringe kit for more than six cases.
- Dispose of all single use components, including the saline bag, Manifold Kit, and AngioTouch Hand Controller Kit after every case.
- Properly discard patient kits in accordance with all local, state, and federal regulations, codes, and directives.

Cables

Be sure to plug each cable only into the connector designed for it. To avoid the risk of electric shock, never touch the pins on the connector or cable. Do not use the CVi system if any worn or damaged cords, cables, or connectors are detected. For replacement information, contact an ACIST representative.

Catheters

Patient connections must be made using commercially available catheters that have been approved for angiographic studies. The system pressure limit should not be set higher than the rated pressure limit of the catheter. For information on catheter pressure settings and limits, refer to the instructions provided by the catheter manufacturer.

The CVi system was tested for use with 4 Fr–7 Fr catheter sizes. When using catheters 5 Fr or smaller with injection flow rates > 12 ml/s, the system may reduce the flow rate to prevent Pressure Limit while providing selected volume, or the system may Pressure Limit and stop the injection. To obtain the desired imaging outcome in the event of Pressure Limit, the user must either reduce the selected flow rate or use a larger size catheter to complete the injection.

Cleaning

- To avoid the risk of electric shock, and to prevent damage to the CVi system, always disconnect it from line power before cleaning.
- Do not use excessive water when cleaning.
- A disinfecting cap must be properly placed onto the multi-use syringe before cleaning.
- Do not immerse any components in water. Be sure that the CVi system is completely dry before applying power.

Closed Stopcock

Never inject with the stopcock closed.

DEHP (Phthalate)

Testing has shown that patient DEHP exposure for adults, children and infants are below levels identified with potential risk of toxicity to reproduction. Physicians should, however, weigh the benefit against the risk when considering use of this product in children and pregnant or nursing women.

Electrical Isolation

Connections to the patient are physically isolated from all CVi system power sources. Follow facility procedures to ensure that there is no degradation of CVi system electrical performance.

Emergency Shutdown

In the case of power blackouts, power brownouts, or voltage surges resulting in abnormal system operation of any kind, immediately turn off the power switch and detach from the patient.

Flammable Gases

Do not use the CVi system in the presence of flammable gases.

High Flow Rate Injections

Use extreme care when setting the flow rate. High flow rate injections can cause patient injury or death. When a 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.

Injection System Setting

Check the CVi system settings before injection, and verify the appropriateness of all injection parameters before injecting.

Mounting System

The use of non-approved mounting equipment can cause injury. Mount the CVi system using only mounting assemblies approved by ACIST Medical Systems.

Residual Contrast

Performing a saline flush following injection of contrast media will dispense residual contrast from the patient line to the patient. If it is suspected that such residue may adversely affect the patient, additional injections of contrast or saline should not be performed.

Shock Hazard

Hazardous voltage exists within the CVi system. To avoid the risk of electric shock, only trained, qualified personnel should service the CVi system. Disconnect the system from the power source before service. Do not touch the pins on the connectors or the cables.

System Messages

Respond appropriately to all system messages. If the message cannot be cleared, contact an ACIST representative.

Safe Use of Equipment

- No modification of equipment is allowed.
- The CVi system may only be interfaced with X-ray equipment that is certified to be in compliance with IEC 60601-1, third edition.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth ground.
- To avoid the potential for electric shock to the patient, X-ray equipment used in conjunction with the CVi system must provide two means of patient protection.
- To avoid the potential for electric shock to the patient, do not touch the patient while making connections to the injector head or to the power supply.
- To avoid the potential for electric shock, do not touch the patient and the X-ray interface connector pins simultaneously.
- To meet the defibrillator protection specified, the CVi system must be used only with accessories (including transducers and adapter cables) that are specified by ACIST Medical Systems.
- Never disconnect a CVi system from the mains power source while the main power switch is on. Make sure the main power switch is turned off before disconnecting.
- The CVi system should not be used in rooms containing magnetic resonance imaging (MRI) equipment.

Cautions

The following precautions refer to hazards that could result in injury to the patient or user or damage to the CVi system or other equipment. Read this section carefully.

Accessories

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.

Bed Rail Mount

Failure to securely clamp the CVi system components to the bed rail may result in serious injury or equipment damage. Mount equipment according to the bed manufacturer's recommendations. Before mounting the CVi system on a bed rail, consult the bed manufacturer's specifications to make sure that the rail can support the system's weight.

Cleaning

To avoid equipment damage:

- Do not apply bleach or other cleaners except as specified. Damage and degradation of the system and its parts can result if such solutions are applied.
- Do not apply cleaning solutions to the rubber membrane of the pressure transducer backplate. Applying cleaning solutions to the rubber backplate can degrade the transducer, resulting in poor pressure waveforms.

Control Panel Touch Screen

Touch the control panel screen in only one place at a time to avoid inadvertently activating buttons.

Electromagnetic/Electrostatic Guidance

- The CVi system may fail to operate correctly if exposed to certain electromagnetic fields (for example, radio transmitters, cell phones), or if exposed to high levels of electrostatic discharge. To avoid adverse events due to electromagnetic disturbances, ensure the system is properly connected to hospital ground and not subjected to electromagnetic/electrostatic environments that exceed compatibility limits as defined in IEC 60601-1-2. Refer to the compatibility ranges in Chapter 10.
- The use of accessories, transducers, or cables other than those specified and provided by ACIST Medical may result in increased electromagnetic emissions or decreased electromagnetic immunity of the CVi system.
- The CVi system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed prior to patient use to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the CVi system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Excessive Injections

When performing a large number of either high pressure, high volume injections or low pressure, low volume injections, the manifold valve may begin to stick when resetting or opening. If this occurs, replace the manifold kit.

Eye Protection

Always wear eye protection when using the CVi system.

Injection System Temperature

When the CVi system is brought in from extreme outside temperatures (hot or cold), allow it to stabilize at room temperature for approximately one hour before use.

Leakage Current

If the chassis leakage current is above 100 µA, do not use the CVi system.

Line Power

Before connecting the CVi system to an electrical outlet, check the power source for proper voltage and frequency.

Lock Button

The CVi system is locked to its mount when the locking knob is tightened fully clockwise. The system should remain locked to its mount except during transfer between mounts (for example, transferring between a bed rail and a wheeled cart).

Locking Wheels

To prevent unintentional movement of a CVi system that is mounted on a wheeled cart, lock the wheels.

Mixing Hardware Components

Never mix and match hardware components from different injector system models. Each model's components are designed to work together as a set.

Mounted System

Do not lean, grab, or place objects on the CVi system.

When transporting the CVi system on the pedestal cart, follow these guidelines:

- Make sure that the safety latch knob is tightened fully clockwise, and that the unit is secure on the cart.
- Make sure that the power supply is secured to the mounting bracket during transport.
- Guide the system using the cart handrail only. Do not push the CVi system.
- For power supplies that are off the patient table (bed) mount, be sure that the power supply is in the cart tray during transportation.

Pressure Transducer

To avoid bursting the dome membrane on the pressure transducer backplate and introducing air into the system, attach the disposable pressure transducer to the backplate before applying positive pressure to the system.

Preventive Maintenance

For optimal performance of the CVi system, annual preventive maintenance should be performed by an authorized ACIST Medical Systems representative.

Removing the Contrast Spike

When removing patient kits, make sure the contrast spike is removed from the contrast container prior to opening the syringe chamber.

Rx Only

Federal (USA) law restricts this device to sale by or on the order of a physician.

Saline Pump

The tubing must be properly installed in the injector head and the rear tubing guide must be lowered onto the tubing for proper operation of the saline pump and the system.

Training

All qualified personnel who will be operating the CVi system should be trained by a certified representative of ACIST Medical Systems.

X-Ray Cable

To avoid damaging X-ray imaging equipment, make sure the connector on the X-ray imaging system is properly configured before the input cable is connected to the CVi system.

Symbol Definitions

The following symbols are used on the CVi system, patient kits, and throughout this manual:

Symbol	Definition
	Manufacturer, Date of manufacture
	Use-by date
	Batch code
	Catalog number
	Serial number
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not reuse
	Consult instructions for use
	Caution
	Non-pyrogenic
	Alternating current

Symbol	Definition
	Protective earth; protective ground
	Equipotentiality
	Non-ionizing radiation
	Packaging unit
	Defibrillation-proof type CF applied part
	Locking
	Unlocking
	Refer to instruction manual/booklet
	No pushing
	General warning sign
	Warning: electricity
	Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)
IP21	Protection of equipment against ingress of solid foreign objects ≥ 12.5 mm diameter. Protection against access to hazardous parts with a finger. Protection against vertically falling water drops when equipment is tilted up to 15°.
	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.
	C-UL, US classification mark
	Do not tip
	No syringe
	Warning: explosive material
	MR Unsafe

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3 System Description

Introduction

The CVi system is an angiographic injection system used in interventional cardiology, radiology, or vascular surgical procedures utilizing an endovascular technique. The CVi system supplies radiopaque contrast media to a catheter at a user-determined variable flow rate that can be instantaneously and continuously varied.

The CVi system contains a motor-driven pump that delivers contrast media to a patient catheter. The flow rate of contrast media from the injector to the catheter can be controlled with a user actuated proportional control: the AngioTouch® Hand Controller. The hand controller allows variable rate or fixed rate control when dispensing contrast media. When using the variable rate feature, the CVi system allows the user to vary the flow rate from the injector while simultaneously observing the angiographic procedure (for example, on a fluoroscope monitor).

The hand controller and other components are provided in angiographic patient kits. The patient kits provide the interface between the CVi system and an angiographic patient catheter (not supplied by ACIST).

If desired, blood pressure may be monitored through the system in conjunction with the lab's monitoring equipment.

The CVi system is able to synchronize with certain X-ray imaging systems. See *Supported Imaging Systems* on page 85 for additional information. Synchronization is only possible provided the proper X-ray interface cable is also purchased and installed.

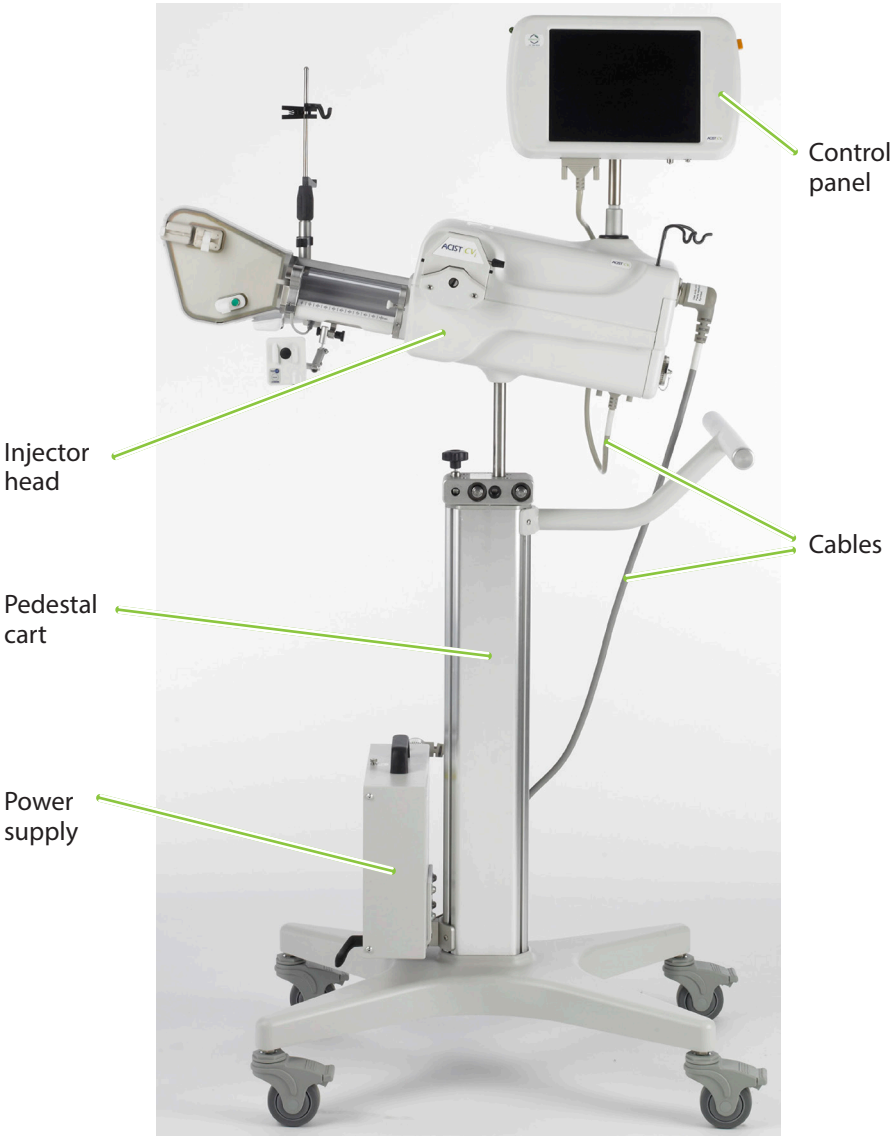
System Hardware

The CVi system, installed on a pedestal cart or bed rail, includes three main hardware components:

- Power supply
- Injector head
- Control panel

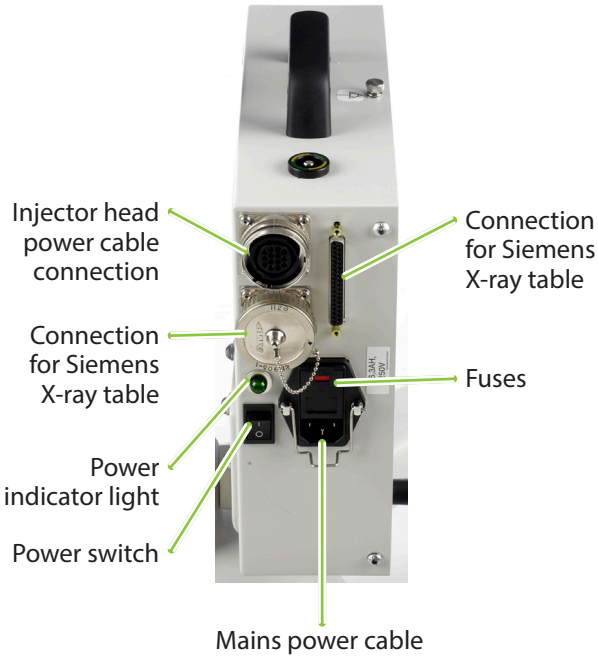
System hardware also includes the following components:

- Power and communication cables
- X-ray synchronization cable (optional)
- Pedestal cart (optional)



Power Supply

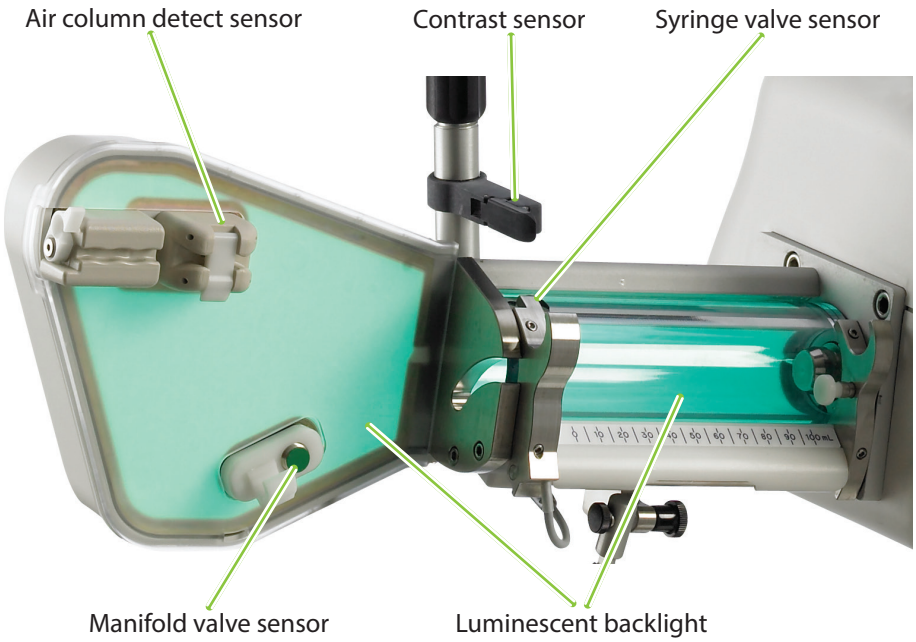
The power supply is the only connection to mains power and provides power to all subsystems of the CVi system. The power supply provides a data interface connection to some X-ray imaging systems.



Injector Head

The injector head houses the motors, pumps, sensing elements, and software that control the delivery of contrast and saline. The injector head includes safety features to support the safe delivery of angiographic fluid media, including the following:

- **Air column detect sensor** to aid the user in the detection of air being introduced into patient tubing.
- **Contrast sensor** for detection of contrast in the contrast tubing.
- **Manifold valve sensor** to detect manifold position.
- **Syringe valve sensor** for detection of the syringe valve ball position.
- **Luminescent backlight** to facilitate visual detection of air.



Mounting

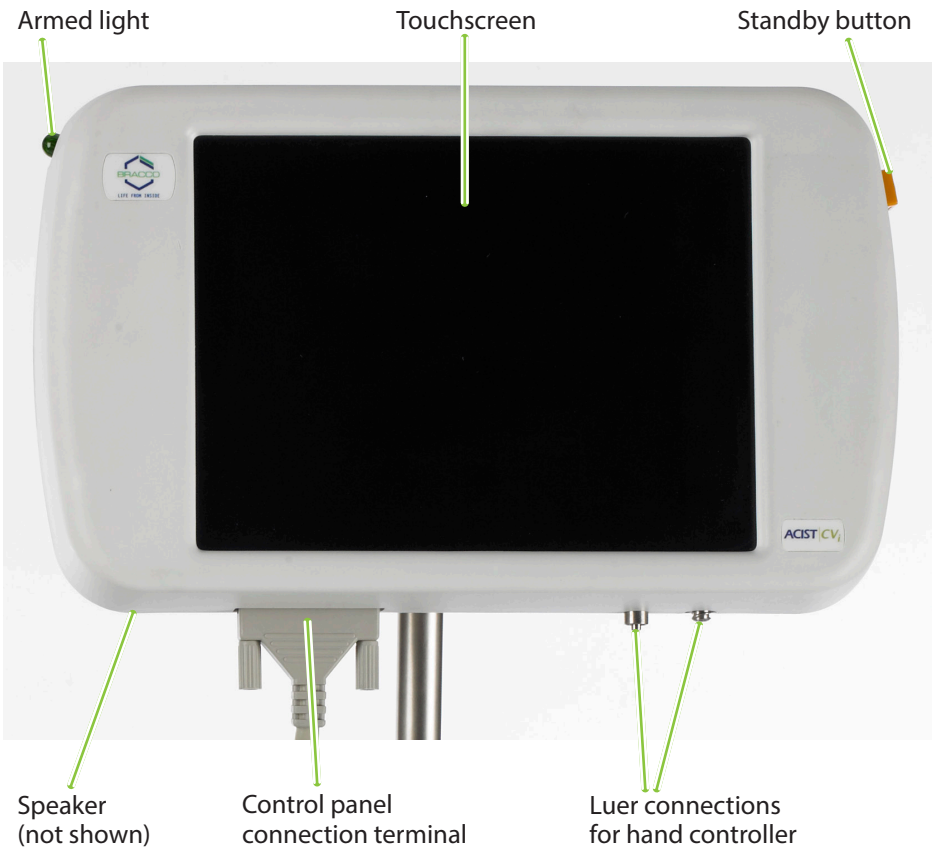
The injector head can be mounted in the following ways:

- On a movable pedestal cart, with the control panel mounted onto the injector head.
- On a bed rail, with the control panel mounted onto the injector head.
- On a bed rail, with the control panel mounted separately.

Control Panel

The control panel provides the main user interface for the CVi system. The main features of the control panel are as follows:

- **Touchscreen** provides user prompts throughout the setup procedure. During operation, the touchscreen provides status information, alert messages, and controls for configuring injection parameters and operation status.
- **Armed mode indicator light** to indicate when the system is ready to perform an injection.
- **Standby button** to allow the user to pause system operation.
- **Speaker** for audible alerts.
- **Luer connections** for the AngioTouch hand controller pneumatic tubing.
- **Control panel connection terminal** for connection of the control panel to the injector head.
- **Swivel base** to allow the control panel to be easily rotated to a position for optimal viewing.



Audible Indicators

The speaker on the control panel produces audible indicators to signal certain events, as follows:

Event	Audible Indicator
Pressing a button on the touchscreen	Click
Filling the syringe	Series of tones
Alert messages	Beep
Injecting contrast	Repeating beep

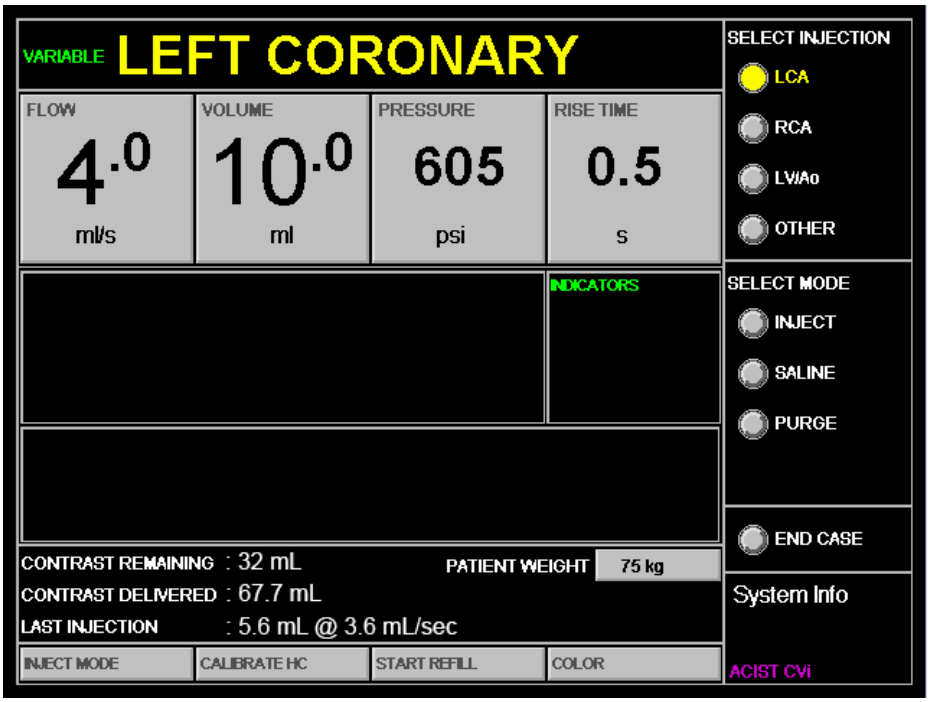
Touchscreen Functions and Sample Injection Images

The major functional areas of the touchscreen are shown in the following sample injection image:

Flow

Allows setting the contrast flow rate parameter, which is either:

- In variable rate mode, the highest flow rate attainable if the contrast **(C)** button on the hand controller is fully depressed.
- In fixed rate mode, the constant flow rate for each injection.



Volume

Allows setting the volume parameter, which is the maximum amount of contrast media that may be injected.

Pressure

Allows setting the pressure parameter, which is the maximum allowable injection pressure. If the injection pressure approaches this limit, the CVi system will either adjust the flow rate or stop the injection.

Rise Time

Allows setting the rise time parameter, which is either:

- In variable rate mode, the amount of time it takes the system to go from zero flow up to the requested proportional flow rate. The requested flow rate is based on how far the contrast **(C)** button on the hand controller is depressed.
- In fixed rate mode, the amount of time it takes the system to go from zero flow up to the flow rate configured by the flow parameter.

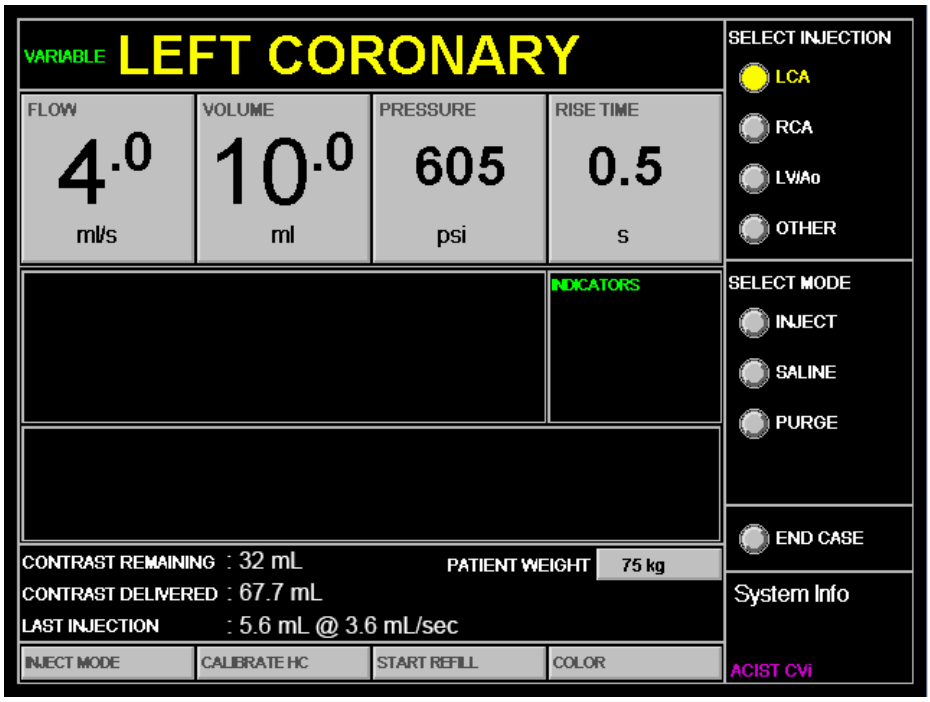
Select Injection

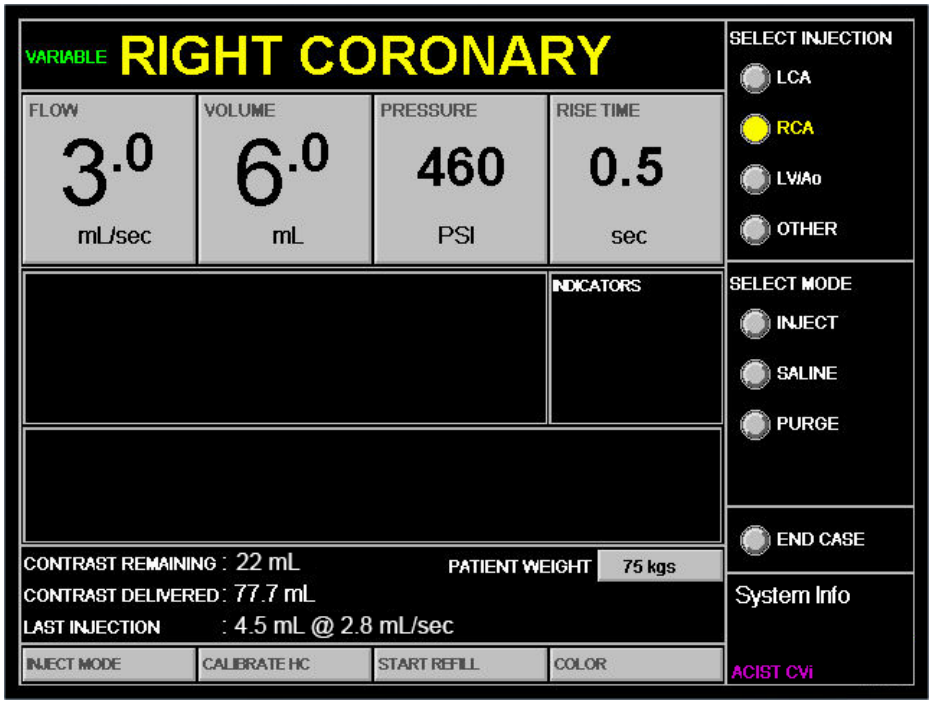
Allows selecting the desired injection type. The options shown will differ based on whether the CVi system is in cardiac procedure mode or peripheral procedure mode.

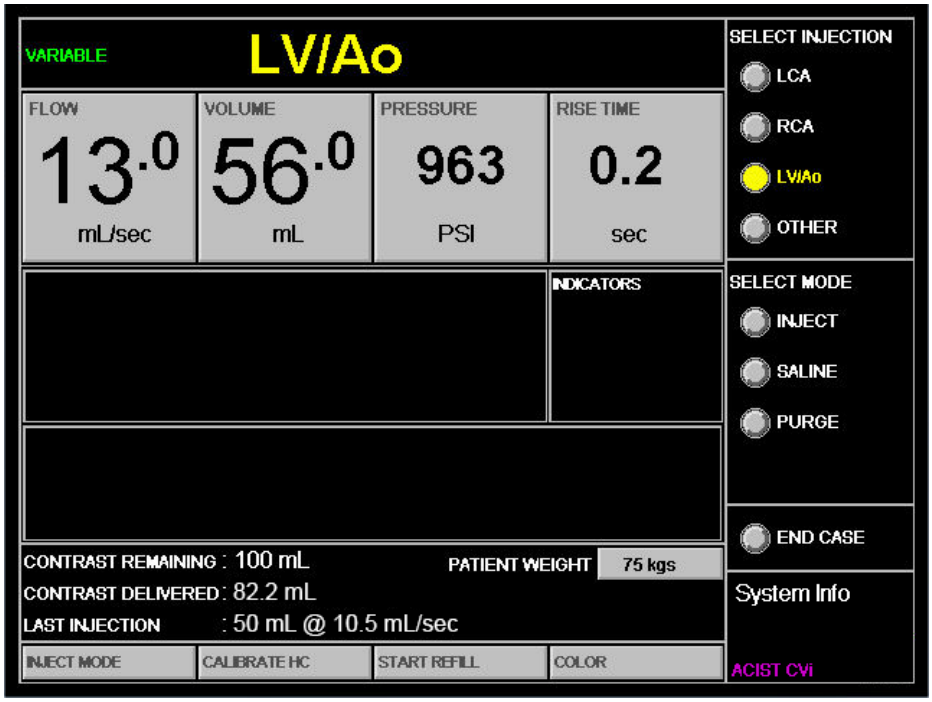
Cardiac Mode	Peripheral Mode
LCA (left coronary artery)	Pigtail
RCA (right coronary artery)	Selective
LV/Ao (left ventricle/aorta)	Micro
Other	Other

The available screens for cardiac procedure mode and peripheral procedure mode are displayed below.

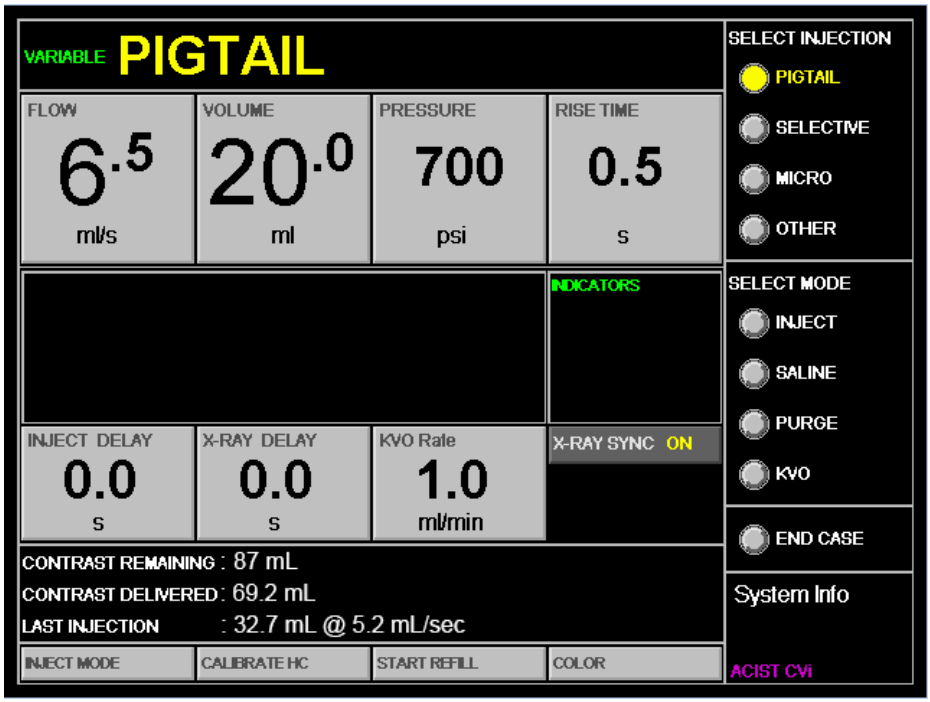
Cardiac Mode

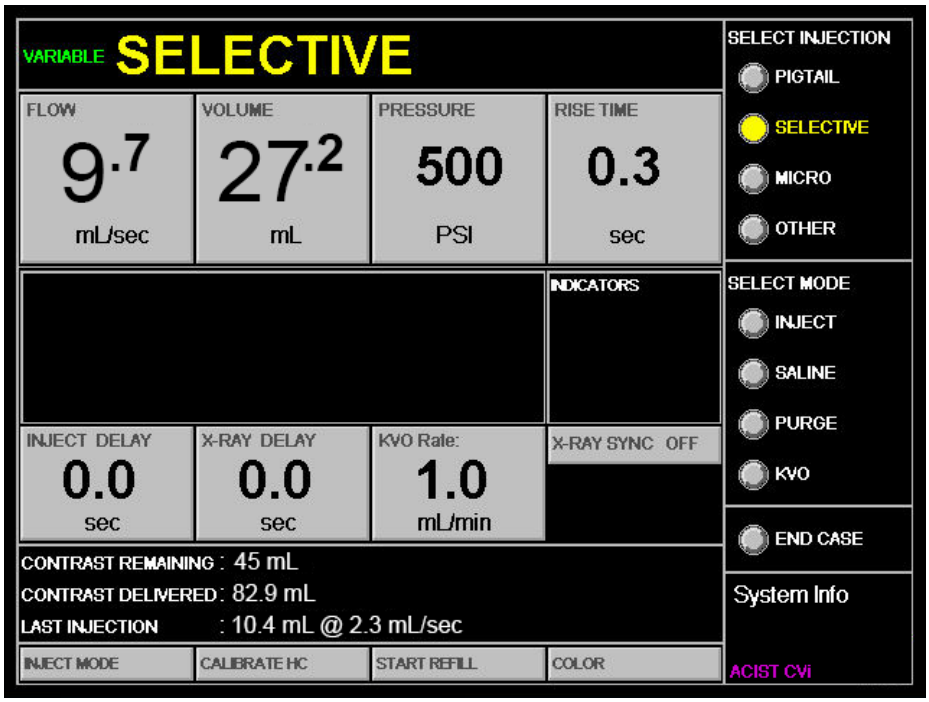


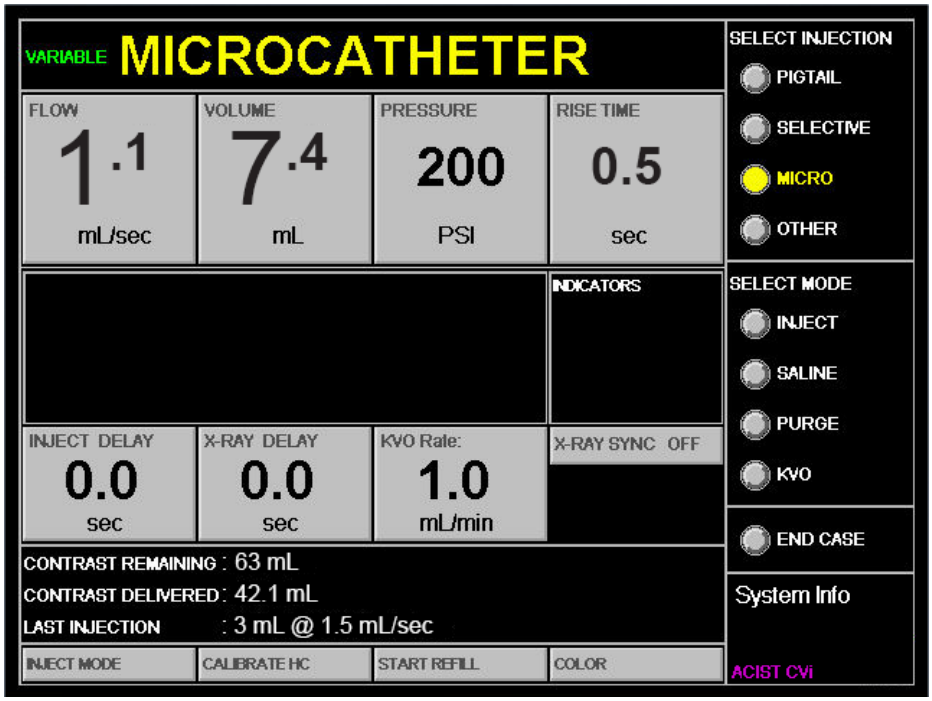

VARIABLE
RIGHT CORONARY
FLOW
3.0
mL/sec
VOLUME
6.0
mL
PRESSURE
460
PSI
RISE TIME
0.5
sec
INDICATORS
CONTRAST REMAINING : 22 mL
CONTRAST DELIVERED : 77.7 mL
LAST INJECTION : 4.5 mL @ 2.8 mL/sec
PATIENT WEIGHT
75 kgs
INJECT MODE
CALIBRATE HC
START REFILL
COLOR
SELECT INJECTION
LCA
RCA
LV/Ao
OTHER
SELECT MODE
INJECT
SALINE
PURGE
END CASE
System Info
ACIST CVi


VARIABLE
LV/Ao
FLOW
13.0
mL/sec
VOLUME
56.0
mL
PRESSURE
963
PSI
RISE TIME
0.2
sec
INDICATORS
CONTRAST REMAINING : 100 mL
CONTRAST DELIVERED : 82.2 mL
LAST INJECTION : 50 mL @ 10.5 mL/sec
PATIENT WEIGHT
75 kgs
INJECT MODE
CALIBRATE HC
START REFILL
COLOR
SELECT INJECTION
LCA
RCA
LV/Ao
OTHER
SELECT MODE
INJECT
SALINE
PURGE
END CASE
System Info
ACIST CVi

Peripheral Mode







Select Mode

Initiates the following three modes of operation:

- Inject – To arm the system in preparation for injecting contrast.
- Saline – To flush the system with 0.9% normal saline.
- Purge – To run contrast through the system in order to purge air.
- KVO – To initiate the KVO (keep vessel open) function, which provides a periodic pulse of saline between injections. The KVO function is available only in peripheral procedure mode.

End Case

Starts the end-of-case procedure for changing out single use components and, if desired, shutting down the system.

System Messages Area

System messages and alerts are displayed in this area of the screen.

Patient Kits

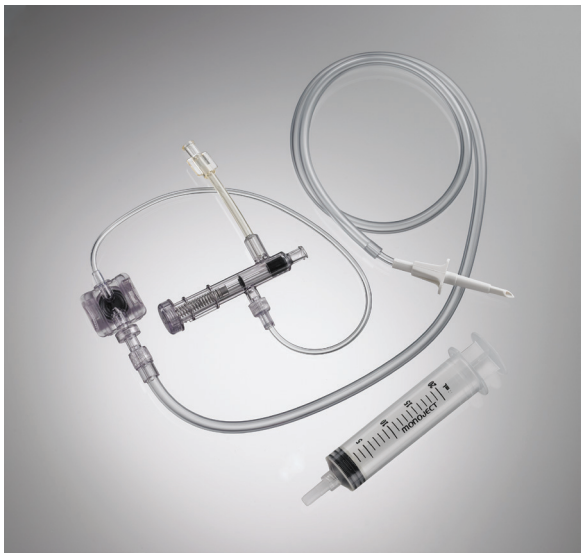
Before the CVi system is used, the patient kits are loaded onto the injector. The system is to be used only with ACIST-provided patient kits, and only those kits that are intended for use with the CVi system.

The CVi system currently uses the following patient kits:

Model Number	Model Name	Uses
BT2000	Manifold Kit	Single Use
AT P54 AT P65	AngioTouch Hand Controller Kit	Single Use
A2000	Syringe Kit	Up to six cases

BT2000 Manifold Kit

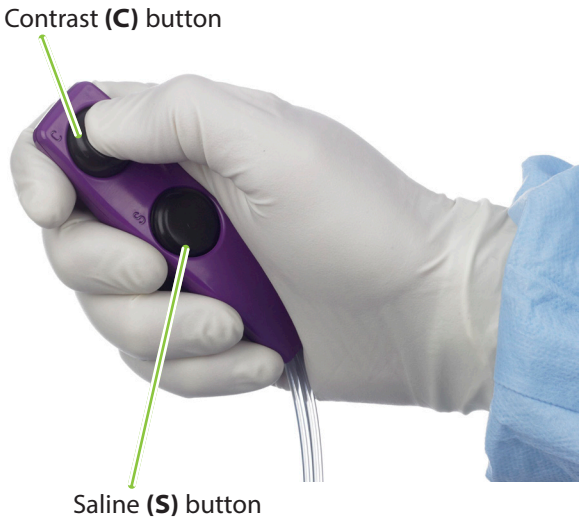
The kit includes a manifold, saline tubing, a saline spike, a hand syringe, and a pressure transducer cartridge.



AT P54 and AT P65 AngioTouch Kits

The kit includes an ergonomic AngioTouch hand controller, a 3-way high pressure stopcock with rotating end, and patient tubing.

The AngioTouch hand controller allows precise control over the flow rate and volume of contrast injections. It has two buttons. The top button, marked with a C, initiates and controls the flow rate of the contrast injection. The bottom button, marked with an S, starts and stops a saline flush.



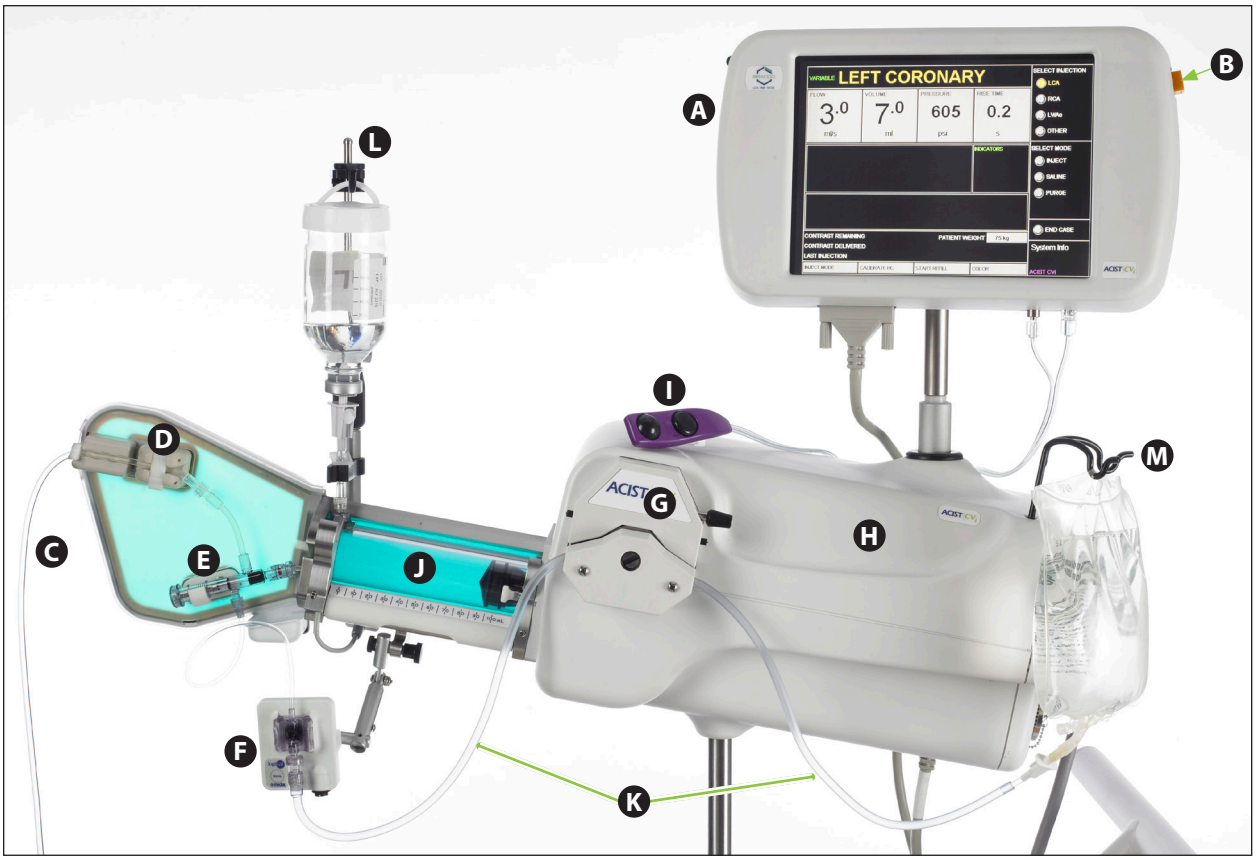
A2000 Syringe Kit

The kit includes a 100 ml syringe, a contrast spike, contrast tubing, a white slide clamp, and a strip of five disinfecting caps containing 70% isopropyl alcohol (IPA).

Note

The disinfecting caps in the A2000 Syringe Kit may differ from those shown above. Disinfecting caps may differ in color and shape. Disinfecting caps contained within the kit should be used according to the Instructions for Use that accompany the kit.

4 Setup



A. Control panel
B. Standby button
C. Patient tubing
D. Air column detect sensor
E. Manifold
F. Pressure transducer
G. Saline pump
H. Injector head
I. AngioTouch hand controller
J. Syringe chamber
K. Saline tubing
L. Contrast container hanger
M. Saline bag hanger

Setup Overview

The setup procedure involves the following general steps:

1. Supplying power to the system.
2. Installing patient kits.
3. Removing air from all system components and from the entire patient catheter. Air is removed from the system manually with a hand syringe and automatically using purge and flush functions via the control panel touchscreen and the hand controller.

After the system power is switched on, the control panel on the CVi system will provide guidance during the setup procedure by displaying onscreen prompts.

Aseptic technique must be followed when performing setup. Take particular care to protect connectors from incidental contact. See *Aseptic Technique* on page 6 for more information.

Note

Alternate setup workflows may be used depending on the specific requirements of your healthcare institution.

Power On

1. Turn the power switch on. The power switch is located on the power supply.

Power switch

2. On the control panel, press **START.**
3. Press **CARDIAC** or **PERIPHERAL** to select the procedure mode.

Cardiac	Peripheral
Heart-related procedures	Non-heart-related procedures
X-ray system integration not available	X-ray system integration available

After selecting the procedure type, the CVi system will perform a 60 second calibration routine.

4. Open the syringe chamber on the injector head by pulling on the white syringe door pin.

Prepare the Contrast Container

1. Remove the protective cover from the contrast container.
2. Following the contrast manufacturer's instructions, wipe the septum with a prepackaged 70% IPA wipe. Allow the septum to dry.

Warning

Contamination of the septum presents a risk of serious patient injury due to infection. Aseptic technique must be employed. If suspected contamination has occurred, replace the affected contrast container.

Load the Syringe Assembly

1. Open the syringe kit.
2. Remove the syringe and pouched disinfecting caps. Set the disinfecting caps aside.
3. Place the syringe assembly into the syringe chamber.
4. Close the chamber. Make sure the syringe door pin locks into place and press **DONE.** The plunger will move to the fill syringe position.
5. Open the disinfecting cap pouch and place the strip on the standby contrast or saline hook for use during case changeover.

Notes

- If a hook is not available, place the strip of disinfecting caps in an area that can be accessed easily during case changeover but outside of the sterile field.
- Do not discard the strip of unused disinfecting caps after the end of a case.
- Do not place the strip of unused disinfecting caps in the drip tray.

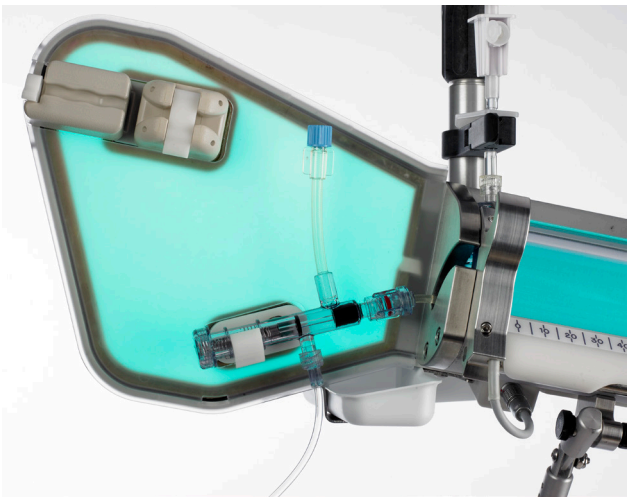
Load Contrast

1. Open the manifold kit.
2. Remove the luer cap from the syringe.
3. Remove the luer cap from the manifold contrast inlet and connect the manifold to the syringe assembly. Make sure the connection is secure.

Warning

Contamination of either luer presents a risk of serious patient injury due to infection. Aseptic technique must be employed. If suspected contamination has occurred, replace the affected kit or kits.

4. Clip the manifold assembly into the manifold valve sensor.

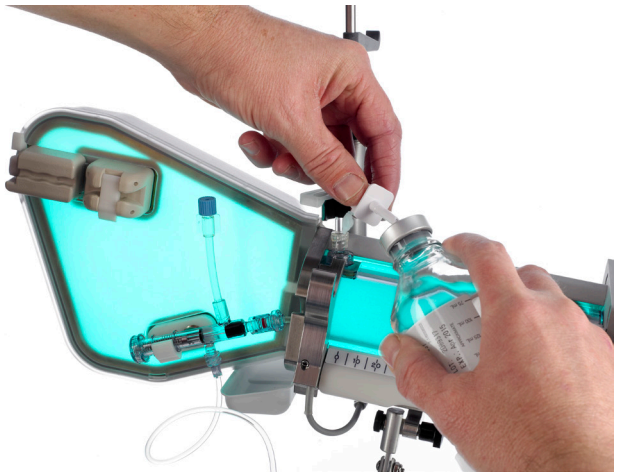


5. Remove the cover from the contrast spike. Ensure no hand contact is made with the tip or shaft of the contrast spike or septum.

Warning

Contamination of the contrast spike or septum presents a risk of serious patient injury due to infection. Aseptic technique must be employed. If suspected contamination has occurred, replace the affected kit and/or contrast container.

6. Hold the container at an angle away from the contrast sensor with the septum facing up. Insert the contrast spike into the septum of the contrast container. Ensure the air vent on the contrast spike is open.



7. Place the tubing in the contrast sensor and securely close the sensor latch.
8. Place the contrast container onto the hanger. Verify the white slide clamp is open and above the contrast sensor.

Important

- Make sure the contrast spike tubing is completely secured in the contrast sensor, and that the latch on the contrast sensor is fully closed. If the contrast spike tubing is not properly secured in the contrast sensor, the system may produce an error stating **No contrast.**
- If the air vent and the white slide clamp are not open, the system may produce an error stating **No contrast.**

9. Press **DONE** on the touchscreen to fill the syringe.

Load Saline Tubing Assembly

Warning

It is important to use aseptic technique throughout this procedure. See *Aseptic Technique* on page 6 for more information.

1. Remove the white protective cover from the BT2000 pressure transducer and connect the transducer cartridge to the transducer backplate sensor.

   Note

   A hemodynamic monitoring cable is required. The cable type is dependent upon the type of monitoring equipment used. Contact ACIST Medical to obtain the correct transducer interconnect cable.

2. Remove the spike cap from the saline tubing.
3. Spike and hang the 0.9% normal saline bag.

Warning

Contamination of the saline spike or saline bag presents a risk of serious patient injury due to infection. Aseptic technique must be employed. If suspected contamination has occurred, replace the affected kit and/or the saline bag.

4. Remove air by attaching the hand syringe to the manifold tubing and drawing saline slowly through the patient manifold. Disconnect the hand syringe and empty it. Repeat as necessary until all air has been removed from the saline tubing, including the transducer.

5. Open the saline pump door by rotating the pump handle counterclockwise.
6. Position both black tubing guides all the way to the top, then center the tubing in the pump. Verify that the teeth of the tubing guides are centered over the tubing.

7. Close the saline pump door by rotating the pump handle clockwise, locking it into position.
8. Adjust the rear tubing guide downward until it is stopped by the tubing.

Note

The rear tubing guide should not restrict the flow of saline through the tubing. If saline flow is restricted, the system may display a saline pump error. The saline flush button on the control panel and the saline button on the hand controller may not function as expected.

9. Press **DONE** on the touchscreen.

Purge the Tubing

Warning

It is important to use aseptic technique throughout this procedure. See *Aseptic Technique* on page 6 for more information.

1. Disconnect and empty the hand syringe.
2. Reconnect the empty hand syringe to the manifold tubing.
3. Press **PURGE** to remove air from the manifold tubing. Gently tap the tubing while purging.
4. Disconnect the hand syringe and empty it. Repeat purging as needed.
5. Press **FLUSH** for a 10 second saline flush.
6. Tap all tubing and fittings to remove trapped air.
7. Check the system thoroughly to ensure that all connections are in place and secure, and that all air is removed from the manifold assembly and saline tubing.
8. Leave the hand syringe in place until ready to connect it to the patient tubing.
9. Press **DONE** on the touchscreen.

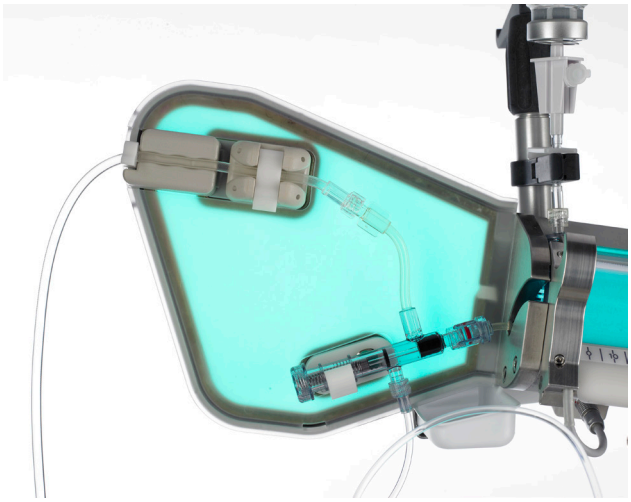
AngioTouch Hand Controller Setup

1. Disconnect and empty the hand syringe.
2. Open the AngioTouch kit and empty it contents onto the sterile field.
3. Connect the patient tubing to the manifold tubing.

Note

Make sure there are no sharp bends or kinks in the tubing.

4. Connect and tighten the stopcock to the patient tubing.
5. Place the patient tubing into the strain relief and air column detect sensor. Fully close both latches.



6. Connect the hand controller to the control panel using both luer fittings. Secure them tightly.

7. Calibrate the hand controller following the instructions on the control panel.

8. Press **PURGE** to automatically remove all air through the air column detect sensor.
9. Press **SALINE** to automatically flush all air through the patient tubing and stopcock.
10. Make sure the manifold valve closes and there is no space between the valve and the end of the manifold.
11. Do a final check to make sure all air has been removed from the entire fluid pathway.

Connect the Patient Catheter

1. Connect the patient catheter to the stopcock.
2. Connect the hand syringe to the stopcock.
3. Open the stopcock to the patient and aspirate blood with the hand syringe to clear any air that may be in the catheter connection.
4. Turn the stopcock so that the patient is disconnected from flow.
5. If necessary, press and hold **PURGE** to purge additional contrast until contrast flows out of the stopcock.
6. Press **CANCEL.**

Caution

Make sure the connection between the patient tubing and the catheter is purged of air.

Zero the Pressure Transducer

Zero the transducer before recording any pressure waveforms. To zero the pressure transducer:

1. Open the stopcock to air.
2. Hold the stopcock and pressure transducer at midaxillary.

Tip

Before recording pressure waveforms, flush saline through the patient tubing. Contrast in the patient tubing will damp the pressure signal.

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5 Perform an Injection

Adjust Parameters Based on Physician Preference

1. Select the injection type by pressing one of the four buttons in the **SELECT INJECTION** box. The procedure mode (cardiac or peripheral) is chosen during startup. See *Select Injection* on page 25.
   - In cardiac procedure mode, press **LCA, RCA, LV/AO**, or **OTHER.**
   - In peripheral procedure mode, press **PIGTAIL, SELECTIVE, MICRO,** or **OTHER.**
2. (Optional) Press the **INJECT MODE** button at the bottom of the control panel screen to toggle between fixed rate mode and variable rate mode.

Fixed	Variable
Pressing the contrast **(C)** button on the hand controller causes the CVi system to inject contrast at the parameters on the control panel.	Pressing the contrast **(C)** button on the hand controller causes the CVi system to inject contrast in proportion to the pressure applied to the contrast **(C)** button. The parameters on the control panel are maximum limits.

3. Press **FLOW, VOLUME, PRESSURE,** and **RISE TIME** on the control panel to modify each parameter according to physician preference. See *Touchscreen Functions* on page 24.
4. (Optional) Press **INJECT DELAY** and **X-RAY DELAY** on the control panel to modify how the CVi system interacts with a connected X-ray imaging system.
   - Inject Delay – Delays the start of contrast injection by the specified number of seconds.
   - X-Ray Delay – Delays the operation of X-ray equipment by the specified number of seconds after an injection has begun.
   - The Inject Delay and X-Ray Delay parameters are mutually exclusive. Setting one of these parameters automatically sets the other to 0.0 seconds.

Arm the Injector

1. In the **SELECT MODE** box, press **INJECT.**
2. Press **OK** to confirm arming the injector.

Large Injections

A large injection is defined as having a volume over 20 ml or a flow rate over 10 ml/s. The CVi system will request additional confirmation before initiating a large injection. For large injections, the luminescent backlight will flash on and off.

Disarm the Injector

Press **CANCEL** to disarm the injector.

Inject Contrast

Press and hold the contrast **(C)** button on the hand controller to inject contrast. Refer to page 43 for information about the behavior of the contrast **(C)** button in fixed rate mode and variable rate mode.

Automatic and Manual Refills

When the amount of contrast in the syringe is not enough for the next injection, the CVi system will automatically refill the syringe from the contrast container. To stop the system from refilling the syringe, press **STOP REFILL** on the control panel.

The syringe can also be manually refilled at any time by pressing **START REFILL** on the control panel. The system will continue to refill the syringe until either the syringe is full or **STOP REFILL** is pressed.

X-Ray Sync (Optional)

The **X-RAY SYNC** button toggles between sync modes.

ON	OFF
Contrast injection may be initiated from either the hand controller or the X-ray imaging system.	Contrast injection is controlled by the CVi system using the hand controller.

Notes

- Injections initiated by an X-ray imaging system always use fixed injection rate mode.
- The hand controller may be disabled with some X-ray imaging systems.
- X-ray imaging may be initiated by the CVi system with some X-ray imaging systems.
- X-Ray Sync is available only with peripheral mode injections.

Perform Contrast Purge

1. In the **SELECT MODE** box, press **PURGE.**
2. Press **SYRINGE** or **TUBING** to select the component to purge.
3. When purging the syringe, follow these steps:
   a. Press **PURGE.**
   b. The system automatically purges air from the syringe.
   c. Press **OK.**
4. When purging the tubing, follow these steps:
   a. Turn the stopcock off to the patient.
   b. Press **OK.**
   c. Press and hold **PURGE.**
   d. The system purges air as long as the **PURGE** button is held, to a maximum of 10 seconds.
   e. Press **CANCEL** to return to normal operation.

Perform Saline Flush using 0.9% Normal Saline

1. In the **SELECT MODE** box, press **SALINE.**
2. Press and hold **FLUSH.** The tubing will be flushed while the **FLUSH** button is held, to a maximum of 10 seconds.

Flush Saline Using the Hand Controller

Instead of using the control panel, a saline flush can be initiated using the hand controller.

1. Press the saline **(S)** button on the hand controller. The CVi system will begin a 10 second flush of the saline components.
2. To cancel the saline flush, press the saline **(S)** button on the hand controller a second time.

Standby

The Standby button immediately suspends operation of the CVi system. Press the **STANDBY** button once to place the CVi system into Standby mode. When the CVi system is in Standby mode, all functions are paused.

To enable the system, press the **STANDBY** button again and then press **OK** on the control panel touch screen.

6 End a Case

End the Case

Once a case is completed, end the case and follow one of the procedures below, depending on whether you will

- Begin a new case with the same syringe.
- Use a new syringe for a new case.
- Shut down the system.

End Case

1. Disarm the system from inject mode by pressing **CANCEL** in the system message area.
2. Record all relevant case information such as contrast delivered and last injection.

Note

Last Injection indicates the volume and highest flow rate achieved during the most recent injection.

Important

All case data are cleared when the case is ended.

If Beginning a New Case with the Same Syringe

Important

It is preferred to use the A2000 syringe for five patient procedures.

However, the system will allow one additional use to accommodate an emergency case. After a syringe has been used in six patient procedures, the system requires that a new syringe be used. The system software will prevent a user from beginning a new case until the syringe has been replaced. The A2000 Syringe Kit must be discarded after six cases. See *If Using a New Syringe* on page 48 to begin a new case with a new syringe.

1. On the touchscreen, press **END CASE,** then press **OK.** Select **NO** when prompted to shut down. Follow the screen prompts.
2. The system displays the number of cases for which the syringe has been used. Press **NO** to start a new case with the current syringe.
3. Close the white slide clamp on the contrast container tubing.

4. Disconnect and discard the patient tubing, saline tubing and bag, the hand controller and the manifold assembly.
5. Press **OK.**

Note

Patient kits must be removed before proceeding to the next step.

6. Remove a disinfecting cap from the strip included with the A2000 syringe kit.
7. To release the alcohol contained in the disinfecting cap, push and twist the cap onto the end of the syringe's male luer connector until the cap will turn no further. The disinfecting cap must remain firmly in place on the male luer for a minimum of 5 minutes to ensure proper disinfection.
8. *Software version 7 or higher only:* Press **DONE** after fully disinfected.
9. Leave the disinfecting cap in place until connecting a new manifold to the syringe.

Important

A new disinfecting cap must be placed on the male luer after each use.

10. Press **CARDIAC** or **PERIPHERAL** to select the procedure mode.
11. When ready for the next case, continue the setup procedure at *Load Contrast,* using the existing syringe assembly.

If Using a New Syringe

1. On the touchscreen, press **END CASE,** then press **OK** to confirm.
2. Select **NO** when prompted to shut down. The system displays the number of cases for which the syringe has been used.
3. Press **YES** to start a new case with a new syringe.
4. Close the white slide clamp on the contrast container tubing.
5. Remove and discard the patient tubing, saline tubing and bag, hand controller, and the manifold assembly.
6. Press **OK**.
7. Wait until the syringe plunger has disengaged, then open the syringe chamber.
8. Remove and discard the syringe.
9. Close the syringe chamber.
10. Press **RESTART.**
11. Follow the instructions beginning with *Load the Syringe Assembly* on page 34.

If Final Case

1. On the touchscreen, press **END CASE,** then press **OK.**
2. Select **YES** when prompted to shut down. Follow the screen prompts.
3. Close the white slide clamp below the contrast container.
4. Remove and discard the AT P54/AT P65 Hand Controller and patient tubing, the BT2000 manifold assembly, contrast container, and the saline bag.
5. Wait until the syringe plunger has disengaged, then open the syringe chamber.
6. Remove and discard the A2000 syringe.
7. Discard any remaining contrast media and saline in accordance with your institution's procedures.
8. Turn off the power switch on the power supply.
9. Refer to Chapter 7 *Supplementary Procedures* for detailed instructions on decontamination and daily cleaning.

Emergency Case

Important

It is preferred to use the A2000 syringe for five patient procedures.

However, the system will allow one additional use to accommodate an emergency case. After a syringe has been used in six patient procedures, the system requires that a new syringe be used. The system software will prevent a user from beginning a new case until the syringe has been replaced. The A2000 Syringe Kit must be discarded after six cases. See *If Using a New Syringe* on page 48 to begin a new case with a new syringe.

1. On the touchscreen, press **END CASE,** then press **OK.** Select **NO** when prompted to shut down.
2. Press **NO** to start a new case with the current syringe. The system displays the message below in the status area of the main screen.

3. Press **YES** to use a new syringe and refer to *If Using a New Syringe* on page 48. Press **NO** to use the syringe for one additional emergency case.

4. Close the white slide clamp on the contrast container tubing.
5. Disconnect and discard the patient tubing, saline tubing and bag, the hand controller and the manifold assembly.
6. Press **OK.**

Note

Patient kits must be removed before proceeding to the next step.

7. Remove a disinfecting cap from the strip included with the A2000 syringe kit.
8. To release the alcohol contained in the disinfecting cap, push and twist the cap onto the end of the syringe's male luer connector until the cap will turn no further. The disinfecting cap must remain firmly in place on the male luer for a minimum of 5 minutes to ensure proper disinfection.
9. *Software version 7 or higher only:* Press **DONE** after fully disinfected.
10. Leave the disinfecting cap in place until connecting a new manifold to the syringe.

Important

A new disinfecting cap must be placed on the male luer after each use.

11. Press **CARDIAC** or **PERIPHERAL** to select the procedure mode.
12. Open a new manifold kit.
13. Using aseptic technique, remove the disinfecting caps and connect the manifold to the syringe.
14. Clip the manifold into the manifold valve sensor.
15. Make sure the white slide clamp on the contrast container tubing is open.

Note

If the white slide clamp is closed, the system may display Manifold Valve Open or Syringe Valve Open indicators or messages.

16. Continue the setup procedure at *Load Saline Tubing Assembly* on page 37.

7 Supplementary Procedures

General Cleaning Instructions

Regular cleaning helps prevent contrast buildup, which can interfere with the operation of the system. When cleaning the system, observe the following guidelines:

- Turn off the power switch on the power supply before cleaning.
- Only use DisCide® ULTRA wipes and/or DisCide® ULTRA spray (Palermo Healthcare) as the cleaning/disinfection agent.
- Do not use detergents or other cleaning agents.
- Do not spray water directly on the CVi system.
- Do not immerse any component in water. Do not allow water to drip onto the injector head, control panel, power supply, or cables.
- Do not use sharp objects.

Warning

A disinfecting cap must be properly placed onto the multi-use syringe before cleaning.

After every patient procedure check to see if any contrast or other fluids spilled on the CVi system. If so, use the following procedure to clean and disinfect the CVi system.

Cleaning / Disinfection Procedure

If the CVi system needs to be cleaned of biohazards such as blood or other bodily fluids, ACIST recommends using DisCide ULTRA as a cleaning and disinfection agent. Wear protective gloves. Discard all materials used to decontaminate the system in accordance with all local, state, and federal regulations, codes, and directives.

CAUTION

To avoid equipment damage:

- Do not apply bleach or other cleaners except as specified. Damage and degradation of the system and its parts can result if such solutions are applied.
- Do not apply cleaning solutions to the rubber membrane of the pressure transducer backplate. Applying cleaning solutions to the rubber backplate can degrade the transducer, resulting in poor pressure waveforms.

Perform the following steps to clean and decontaminate the CVi system:

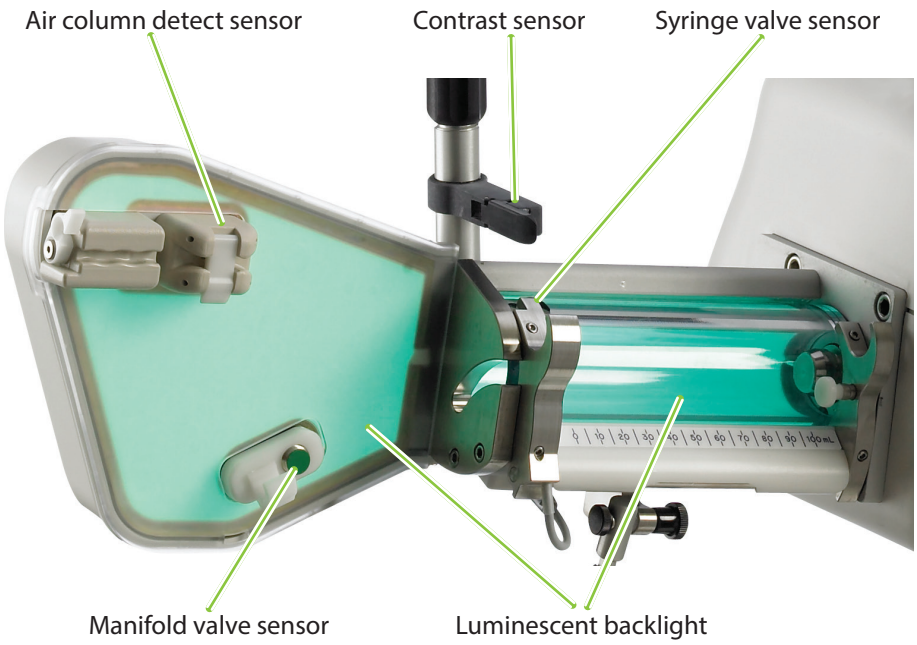
1. Turn off the power switch on the power supply before cleaning.
2. Remove all single-use patient kits from the equipment that was used in the previous case, if applicable.
3. Remove all excess material such as contrast, blood, or saline from the surfaces of the CVi injector using the DisCide ULTRA wipes. Use DisCide ULTRA spray and a soft bristle brush, as needed, to help remove any built up areas.

   Notes:

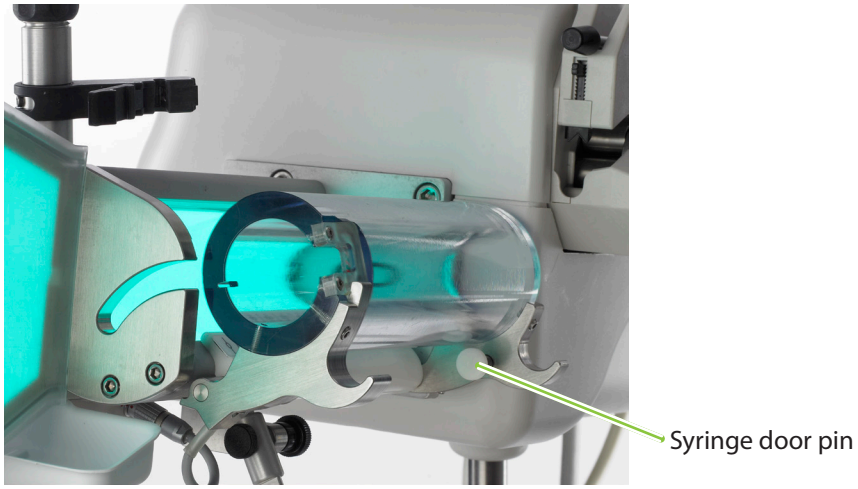
   - Do not use non-specified cleaning/disinfection agents or detergents.
   - Do not use sharp objects in the cleaning/disinfection.

4. Visually inspect the area that has been cleaned for any remaining soil or material. If there is visible soil, repeat the cleaning steps until all visible soil has been fully removed.

5. Apply DisCide ULTRA to all surfaces, including areas that do not have visible soil to ensure sufficient fluid has been applied. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions. Specific areas for biocidal agent application are in the following steps.



6. Apply DisCide ULTRA to the air column detect sensor by wiping or spraying, making sure to lift the securement latches on the proximal and distal end. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions.
7. Apply DisCide ULTRA to the manifold valve sensor and manifold holding latch, making sure both sides of the sensor and latch are fully covered. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions.



8. Open the syringe chamber using the syringe door pin. Apply DisCide ULTRA to the accessible syringe chamber surfaces and in particular, the metal syringe nozzle channel and the syringe door pin. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions. Slide the syringe chamber back into position
9. Apply DisCide ULTRA to the contrast sensor making sure both sides of the sensor are fully covered. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions.
10. Remove the backlight cover by applying light pressure to the top or bottom of the cover from the backside. Apply DisCide ULTRA to the cover making sure both sides fully covered. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions.
11. Open the peristaltic pump by using the pump door handle. Apply DisCide ULTRA to the peristaltic pump (saline pump) making sure both the pump door handle and retaining door latch are fully covered. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions. Close the pump door after cleaning/disinfecting.
12. Apply DisCide ULTRA to the control panel making sure both sides of the control panel are fully covered. Allow the material to remain moistened for a minimum of 1 minute prior to removal per the user instructions.

Monthly Inspection

Inspect the following on a monthly basis:

- Inspect all cables for cuts, cracks, or worn insulation, as well as separation of cables and connectors. Replace damaged cables.
- Check for poor contact on all connectors.
- Check the syringe chamber for cracks, opacity, scratches, and other damage. Replace if damaged.
- Check to make sure that the bed rail mount (if applicable) is securely fastened.
- Check for wheel damage on the CVi system cart (if applicable).

Annual Preventive Maintenance

For optimal performance, an ACIST Medical Systems representative should perform routine annual maintenance.

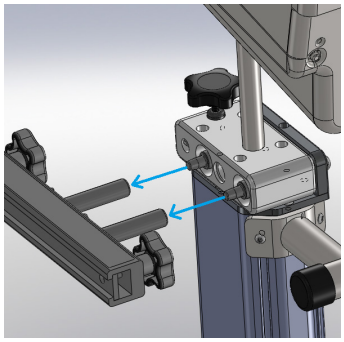
Storage of Cart-Mounted Systems

When storing a cart-mounted system, wrap or attach the power cord to the cart to avoid accidents caused by loose cords. Lock the wheels to prevent unintentional movement of the system.

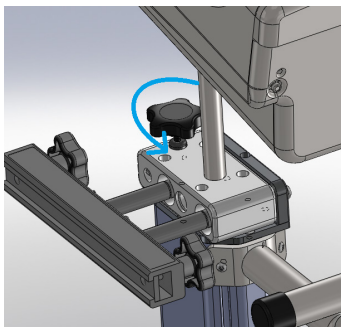
Transfer the Injector Head to/from a Pedestal Cart

To transfer the injector head between a bed rail and a pedestal cart, perform the following steps:

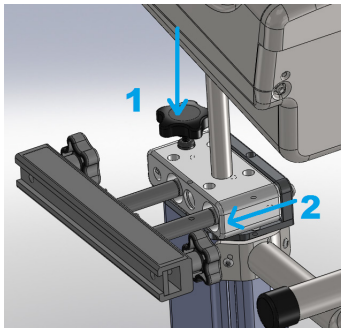
1. Align the pins on the cart with the pins on the bed rail mount.



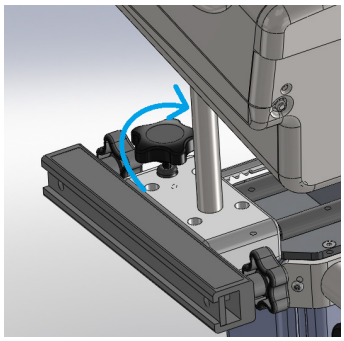
2. Loosen the lock knob.



3. Disengage the lock knob by pushing it down. Slide the injector head across until the injector head mount is fully transferred onto the desired mount (bed rail or pedestal cart).



4. Tighten the lock knob. Make sure the system is locked and secure.



Cabling

Cables between CVi system components are normally connected during installation by an approved representative or distributor. If it becomes necessary to connect the cables between components because the system was moved or serviced, follow the instructions below.

Connect the Injector Head Cable

Warning

To avoid the potential for electric shock to the patient, do not touch the patient while making connections to the injector head or to the power supply.

Connect the injector head cable from the power supply to the upper right port on the injector head.

Power supply

Injector head

Connect the Control Panel Cable

Connect one end of the control panel cable to the bottom of the control panel. Connect the other end of the control panel cable to the bottom of the injector head. Tighten the cable screws at both ends.

Control panel cable connected to control panel

Control panel cable connected to injector head

Connect the X-Ray Interface Cable on Standard Systems (Optional)

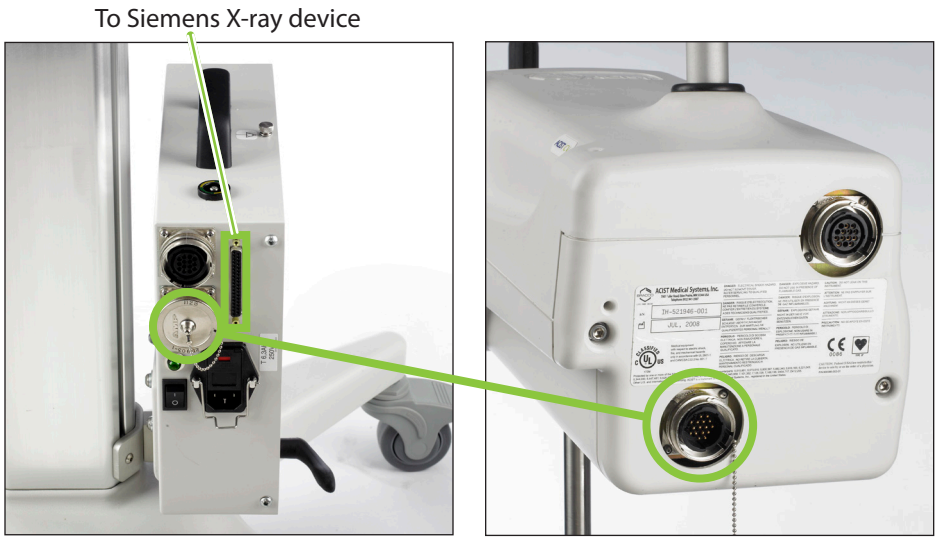
CAUTION

To avoid damaging the X-ray imaging equipment, make sure the connector on the X-ray imaging system is properly configured before the input cable is connected to the CVi system.

Connect the imaging interface cable from the injector head directly to the X-ray imaging system.

Connect the X-Ray Interface Cable on Siemens-Ready Systems (Optional)

Connect the imaging interface cable from the injector head to the power supply. Then connect the 37-pin Y cable between the power supply and the Siemens X-ray device.



Power supply Injector head

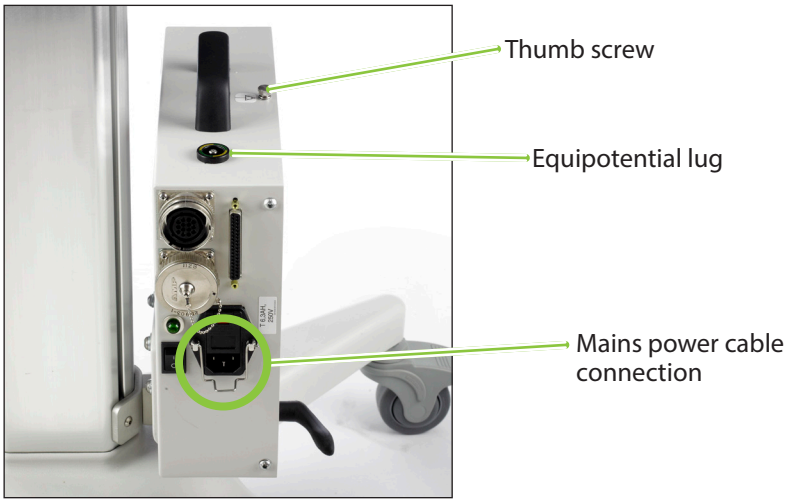
CAUTION

To avoid damaging the X-ray imaging equipment, make sure the connector on the X-ray imaging system is properly configured before the input cable is connected to the CVi system.

Plug In the Power Supply

Connect the power cord between the power supply and a wall outlet. The appropriate medical grade power cable is supplied with the CVi system.

In order to prevent voltage differential between medical equipment, an equipotential cable may be required. Ground equalization can be established by connecting the equipotential cable to either the equipotential lug or the thumb screw on the power supply. The other end of the equipotential cable must be attached to the appropriate location on the patient table. Both connections on the power supply are in compliance with IEC 60601-1 clause 8.6.7.

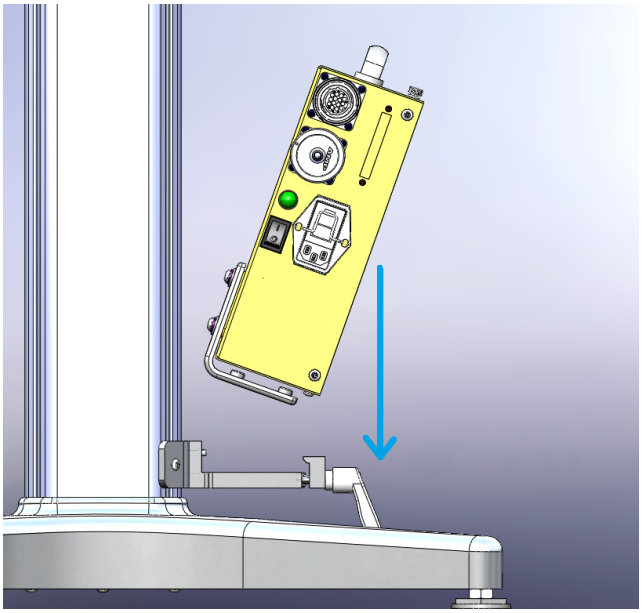


Notes

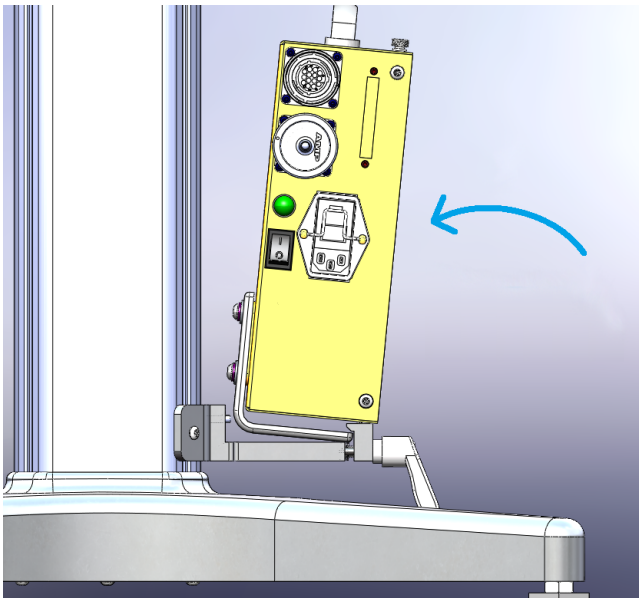
- The power cable may only be substituted with an equivalent medical grade power cable.
- The power supply must be positioned to provide easy access to either or to both ends of the line power cable for disconnection from mains power.
- For systems connected to a Philips or Siemens X-ray imaging system, a separate power cord is not required. Power is supplied from the imaging system connection.

Mount the Power Supply on a Cart (Optional)

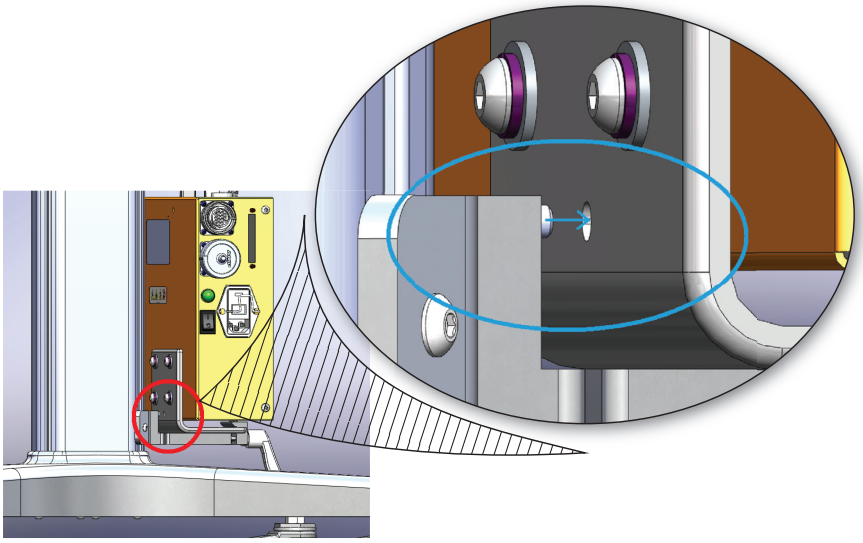
1. Loosen the power supply clamp on the pedestal cart.
2. Place the power supply in the clamp at an angle.



3. Rotate the power supply into the clamp.



4. Position the hole on the power supply so that it mounts onto the peg on the power supply clamp.



5. Hand tighten the power supply clamp.

Recalibrate Control Panel Screen

While the ACIST logo is being displayed during system startup, touch the control panel screen. When directed, touch each of the three points on the screen. It is important to touch the three calibration points with precision for an accurate calibration.

It is recommended that the control panel screen be calibrated approximately once per month.

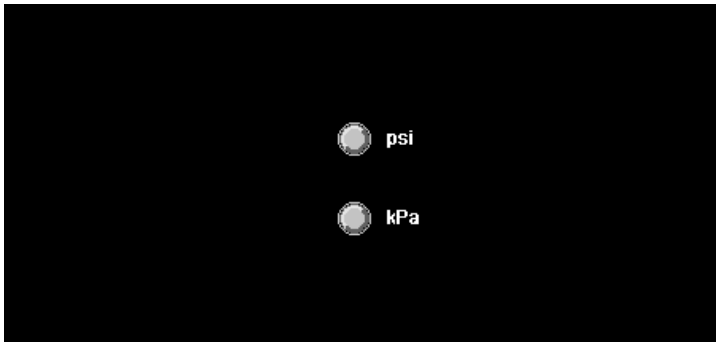
Change the Display Language and Pressure Units

Display Language

During system startup, the CVi system presents a list of languages. Press the button next to the desired language. If no language selection is made within 5 seconds, the system defaults to the last selected language.

Pressure Units

When a language other than English (US) is selected, the CVi system presents a second screen with a choice of pressure units (psi or kPa). Press the button next to the desired pressure unit.



Calculate Parameters from Patient Weight

In cardiac procedure mode, the CVi system can automatically calculate suggested flow, volume, pressure, and rise time values for each of the four injection types based on patient weight. Press **Patient Weight** and enter the patient's weight in kg.

Resume an Interrupted Case

If a previously interrupted case can be resumed, the CVi system will display the **RESUME** and **RESTART** buttons.

RESUME	RESTART
Resume the interrupted case. • If interruption occurred after the Spike Contrast setup screen, **RESUME** returns to the Load Saline (Low Pressure) Assembly setup screen. • If interruption occurred after reaching the main screen, **RESUME** returns to the Starting Hand Controller Calibration screen.	Abandon the interrupted case and start over.

Change Color Scheme

The color scheme of the buttons on the control panel can be changed by pressing COLOR. Toggling between Fixed rate mode and Variable rate mode always changes the color scheme.

System Info

Press **SYSTEM INFO** to cycle through CVi system data:

- HW Configuration – Board and control panel IDs
- SW Configuration – System software and firmware versions
- Current Session Info – Case number and patient manifold valve (pValve) failures
- System Info – Total number of power-ups and cases run since memory was cleared

Keep Vessel Open (KVO) Injection (Optional)

Note

The KVO function is available only with peripheral mode injections.

KVO Injection

A KVO injection periodically injects a pulse of saline to keep the fluid pathway open to the patient during delays between injections.

To initiate a KVO injection, press **KVO.**

KVO Rate

The default flow rate for KVO injections is 1.0 ml/min. Press **KVO RATE** to select a different flow rate for the KVO function. The available range is 0.1 ml/min–10 ml/min.

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8 Troubleshooting

Frequently Asked Questions

Pressure tracing is damped. How can this be improved?

- When the patient tubing and catheter are filled with contrast, the pressure waveform will always be damped. A saline flush may provide a better pressure tracing.
- Make sure that the pressure transducer is securely attached to the backplate.
- Check the system for air bubbles.
- Zero the pressure transducer.

Why are air column detect messages not being displayed when expected?

Wetness (for example, contrast, saline, gels, cleaning solutions) on the exterior surface of the patient tubing may interfere with the air column detect sensor. The sensor's effectiveness can also be reduced if it is not cleaned.

Clean the sensor with warm water. Wipe dry both the sensor and the tubing's exterior surface.

Note

The air column detect sensor is not a substitute for user vigilance.

A contrast empty error is displayed when the contrast container is not empty. Why?

- Make sure the white slide clamp is open.
- Make sure that the contrast tubing is secured in the contrast sensor.
- Make sure that the contrast sensor is clean.

Contrast is leaking from the syringe or contrast spike. Why?

- Close the white slide clamp before changing a patient kit.
- Press the **Standby** button and check the connection of the contrast spike.

What can be done about air in the patient tubing before or beyond the air column detect sensor?

1. Turn the stopcock so that the patient is disconnected from flow.
2. Press **PURGE** and then press **TUBING**.
3. Purge the patient tubing until all air has been removed.

Note

The air column detect sensor is not a substitute for user vigilance.

The saline tubing is being moved by the saline pump. How can I stop it?

- Lower the rear tubing guide so that it stops the saline tubing from advancing without crimping the saline tubing.
- Use only saline tubing from ACIST Medical Systems. The performance of other tubing cannot be guaranteed.

Why is the hand controller not working?

- Check for kinks in the hand controller tubing.
- Make sure that the luer connections on the hand controller are securely fastened to the control panel. The control panel can be rotated up for a better view of the luer connections. If the hand controller is disconnected, reconnect and recalibrate by pressing **CALIBRATE HC** on the control panel.
- The hand controller must be replaced. Connect a new hand controller and recalibrate by pressing **CALIBRATE HC** on the control panel.

The saline button on the hand controller is not working. Why?

- Make sure that the luer connections on the hand controller are securely fastened to the control panel. The control panel can be rotated up for a better view of the luer connections.
- If needed, reconnect the hand controller. Two to three turns are needed to make a good connection. If the hand controller is reconnected, calibrate it again.
- Make sure that the saline pump is closed and the rear tubing guide is lowered onto the saline tubing.
- Make sure that the saline tubing is not bunched up in the pump.
- Make sure that the stopcock is open.

The control panel touch screen is not responding. Why?

The CVi system may be in Standby mode. Check whether the **Standby** button has been pressed. If it has, press the **Standby** button again, and then press **OK** on the control panel.

The control panel is picking up button presses in the wrong location. Why?

The touch screen on the control panel needs to be recalibrated. See *Recalibrate Control Panel Screen* on page 61.

Why is the saline tubing moving forward in the saline pump?

The tubing guides may not be positioned correctly. Refer to *Load Saline Tubing Assembly* on page 37.

Why is the catheter moving at the start of each injection?

Try the following actions:

1. Increase the Rise Time.
2. Use less force when pressing the contrast **(C)** button on the hand controller.
3. Reduce the Flow rate.

Troubleshooting the CVi System

Air Column Detected

The air column detect sensor has detected air in the patient tubing. Perform the purging procedure described on page 45.

To avoid false detection of air columns:

- Make sure that the patient tubing is secured in the air column detect sensor, and that the latch on the air column detect sensor is fully closed.
- Make sure that the patient tubing is secured in the strain relief, and that the latch on the strain relief is closed.

Contrast Empty/No Contrast

- The contrast container may be empty.
- The contrast tubing may not be secured in the contrast sensor.
- The contrast sensor latch may be open.
- The contrast sensor may need to be cleaned with warm water.
- The white slide clamp may be closed, blocking the flow of contrast.
- The air vent on the contrast spike may be closed.
- There may be air bubbles trapped in the contrast tubing.

Hand Controller Calibration Failed

- The luer connections on the hand controller may not be firmly connected to the control panel. Rotate the control panel upwards for a better view of the luer connections.
- If the hand controller becomes disconnected during a case or needs to be replaced, connect a new hand controller and recalibrate by pressing **CALIBRATE HC** on the control panel.
- Make sure to press **OK** on the control panel to start calibration before pressing the contrast **(C)** button on the hand controller.
- Make sure the tubing for the hand controller is not kinked.
- The contrast **(C)** button on the hand controller must be pressed within 4 seconds of starting the hand controller calibration. Calibration can fail if too much time elapses.
- Insufficient pressure may have been applied to the contrast **(C)** button during calibration.
- Press **OK** and then press **CALIBRATE HC** on the bottom of the control panel screen to retry the calibration procedure.

Pressure Limit Exceeded

- The stopcock may be closed.
- The pressure, flow, or rise time parameters may be configured incorrectly.

If the **Pressure Limit** message appears, it means the configured pressure limit was nearly reached. The CVi system automatically adjusts to keep injection pressure beneath the configured limit by reducing or stopping the flow rate.

Standby!

The Standby button on the right side of the control panel has been pressed.

1. Press the **Standby** button again.
2. Press **OK.**

Manifold Valve Open

The manifold valve normally opens during an injection, which may cause this message to appear during normal operation. If this message appears while an injection is not in progress, check the following items:

- The manifold is not fully secured in the manifold valve sensor.
- Push the **Standby** button to pause the CVi system to allow the manifold valve to return to its home position.
- Continued pressure from the syringe may be keeping the valve open. A short purge may cause the manifold valve to return to its home position.
- The white slide clamp above the contrast sensor may be closed.
- The manifold may need to be replaced.

Important

If patient bodily fluids are observed in the patient tubing, or if the system displays both the Manifold Valve Open and Syringe Valve Open indicators along with any error message, replace the syringe when prompted at the end of the case.

Manifold valve failed to close *n* times using current syringe. Use new syringe?

The manifold valve failed to close at some point during the last procedure. Select either YES or NO when prompted to replace the syringe and the contrast.

Important

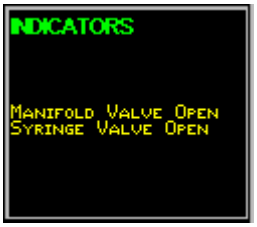
If patient bodily fluids are observed in the patient tubing, or if the system displays both the Manifold Valve Open and Syringe Valve Open indicators along with any error message, replace the syringe when prompted at the end of the case.

Yes	No
Replace the syringe and contrast container.	Continue using the current syringe and contrast.

Manifold Valve Open Conditions Requiring Syringe Replacement

The manifold valve open condition requires the replacement of the syringe if any of the following occur:

- If patient bodily fluids are observed in the patient tubing.
- If both the Manifold Valve Open and Syringe Valve Open indicators are on, as shown below, and any error messages are displayed, or



- If the system displays both the Manifold Valve Open error and the Syringe Valve Open indicator, as shown below.

Syringe Valve Closed

A sensor detects whether the syringe valve is in the correct position. A short refill may correct the valve position. Press **START REFILL.**

There is a gray wire underneath the syringe chamber. This wire may have been disconnected or may need to be cleaned.

Syringe Valve Open

A sensor detects whether the syringe valve is in the correct position.

- The sensor may need to be cleaned with warm water.
- A syringe purge may correct the valve position. Press **PURGE** and then press **SYRINGE.**

Note

Arming the injector will cause the CVi system to automatically purge if necessary.

- The white slide clamp above the contrast sensor may be closed.
- There is a gray wire underneath the syringe chamber. This wire may have been disconnected or it may need to be cleaned. If the gray wire is connected and clean, the presence of this error may mean the syringe chamber needs to be replaced. Contact a service representative.

Important

If patient bodily fluids are observed in the patient tubing, or if the system displays both the Manifold Valve Open and Syringe Valve Open indicators along with any error message, replace the syringe when prompted at the end of the case.

Injection Does Not Start

- Confirm hand controller is not damaged and is securely connected to control panel. Make secure connection or replace and recalibrate the hand controller.
- If using X-ray system for injection control, hand controller activation may be disabled. Use x-ray system for initiating injection or disable x-ray control to use hand controller.
- Verify system is not in Standby mode. Hit standby button to remove from Standby.
- Confirm the system is armed for injection. If not, arm the system for injection.
- If performing a large injection, confirm large injection.
- Cycle system power off and then on
- If problem fails to resolve, contact service representative

Power Failure

- Verify power switch has not inadvertently been turned off
- Verify power cord is securely connected to power outlet and power supply
- Verify power cable is securely connected to power supply and injector head
- Verify cable is securely connected between the injector head and control panel
- Cycle system power off and then on.
- If problem fails to resolve, contact service representative.

Troubleshooting Hemodynamic Issues

Zero Fluctuations

- Was zero set up at midaxillary?
  - An elevation difference between the transducer and stopcock can cause an offset of 7 mmHg to 10 mmHg (0.9 kPa to 1.3 kPa).
  - Zero with saline in the patient tubing, the stopcock open to air, and the stopcock and transducer located at midaxillary.
- Did the zero change after a large injection?
  - After a large injection, use a hand syringe filled with saline to flush contrast from the patient catheter. Then re-zero the transducer.
  - Re-zero the transducer before performing critical measurements.
  - Be sure to zero at midaxillary.
- Did the zero change after a saline flush?
  - An elevation difference between the transducer and stopcock can cause an offset of 7 mmHg to 10 mmHg (0.9 kPa to 1.3 kPa).
  - Zero with saline in the patient tubing, the stopcock open to air, and the stopcock and transducer located at midaxillary.
  - Ensure that there is saline and/or contrast in the patient tubing.
  - Manually flush the patient catheter with a hand syringe and re-zero the transducer when performing critical measurements.
- If a second transducer was added after the initial zero, re-zero the transducer. Ensure that the stopcock is open to air, and that the stopcock and transducer are located at midaxillary.
- Check the transducer for damage or dislodgement. If the transducer needs to be replaced, disconnect from the patient, replace the manifold/transducer kit, remove all air from the system, and resume the case.
- Check the transducer backplate:
  - The backplate is rated for 500 cases.
  - Make sure that the transducer is seated properly on the backplate.
  - Check the backplate connector.
  - Replace the backplate if it is worn out, cracked, or damaged. When inspecting the backplate, pay special attention to the condition of the membrane and to the rails that hold the transducer in place.

Cannot Obtain Zero or Lose Zero Before Procedure

- Check the transducer backplate for the following issues:
  - The backplate is rated for 500 cases.
  - Make sure that the transducer is seated properly on the backplate.
  - Check the backplate connector. Clean residual contrast with warm water.
  - Replace the backplate if it is worn out, cracked, or damaged. When inspecting the backplate, pay special attention to the condition of the membrane and the rails that hold the transducer in place.
- Check the transducer for damage or dislodgement. If the transducer needs to be replaced, disconnect from the patient, replace the manifold/transducer kit, remove all air from the system, and resume the case.
- The hemodynamic monitoring system may be receiving excessive noise. Make sure that the stopcock is stationary and located at midaxillary.

Waveform Dampened

- There may be small bubbles in the system.
  - Make sure that the system is free of all air.
  - Close the stopcock to the patient. Flush the air from the system by pressing the saline **(S)** button.
- High viscosity contrast in a small patient catheter will dampen the waveform. Flush the patient catheter with saline from the stopcock's side port.
- The transducer may be faulty. Replace the manifold kit.
- Replace the transducer backplate if it is worn out, cracked, or damaged. When inspecting the backplate, pay special attention to the condition of the membrane and the rails that hold the transducer in place.
- The manifold valve may be partially open. If it is, press the **Standby** button on the side of the control panel to pause the CVi system and allow the manifold valve to return to its home position.
- Check the patient catheter for the following issues:
  - A guidewire in the catheter will damp the waveform.
  - The catheter may be against a vessel wall. Reposition the catheter.
  - The catheter may be kinked. Replace the catheter if necessary.
  - Small catheters (4F) create a high impedance path in front of the transducer. Flushing the patient catheter with saline may help.
  - High viscosity contrast in the catheter may damp the waveform. Flush the patient catheter with saline.

System Messages

The following table lists all of the messages displayed by the CVi system. If the message cannot be cleared, contact an ACIST service representative.

Message	Recommendation
Actuator Calibration Failed	Try cycling power to the system.
Air Column Detect Sensor Failure	Try cycling power to the system.
AIR COLUMN DETECTED!	There may be air in the patient tubing. Make sure the stopcock is not open to the patient, and purge the patient tubing to see if the message is cleared. The air column detect sensor can be triggered if the patient tubing is pulled. Make sure that the patient tubing is secured in the strain relief, and that the latches on both the air column detect sensor and the strain relief are firmly closed.
Air Detected	There may be air in the patient tubing. Make sure the stopcock is not open to the patient, and purge the patient tubing to see if the error is cleared. The air column detect sensor can be triggered if the patient tubing is pulled. Make sure that the patient tubing is secured in the strain relief, and that the latches on both the air column detect sensor and the strain relief are firmly closed.
Chamber Not Closed	The syringe chamber door is not fully closed.
Chamber Open	The syringe chamber door is not fully closed.
Check Manifold Valve Remove syringe assembly from chamber…OR Check the manifold valve sensor	The system has detected a manifold in the manifold sensor during startup calibration. If there is a manifold in the sensor, remove it to continue the setup procedure. If this message appears when there is no manifold in the manifold sensor, the sensor may need to be cleaned.
Check Manifold Valve To reuse syringe, turn power OFF and ON again and press RESUME… OR Press OK to allow removal of syringe from chamber	The **RESTART** option was selected while a manifold was already in the manifold sensor. To start a new case, remove all components.

Message	Recommendation
Check Syringe Valve Remove syringe assembly from chamber…OR Clean syringe valve sensor and check cable connection	The system has detected a syringe in the chamber during startup calibration. If there is a syringe in the chamber, remove it to continue the setup procedure. Failure to remove the syringe will result in damage that makes the syringe unusable. If there is not a syringe in the chamber, the syringe valve sensor may need cleaning or may be blocked.
Check Syringe Valve To reuse syringe, turn power OFF and ON again and press RESUME… OR Press OK to allow removal of syringe from chamber	The **RESTART** option was selected while a syringe was already in the chamber. To start a new case, remove all components.
Communication Error Has Occurred	Try cycling power to the system.
Communication Timeout!	Try cycling power to the system.
Contrast Empty	The system was unable to fill the syringe from the contrast container. If the contrast container is empty, replace it with a new container. If there is contrast remaining in the container, make sure that the white slide clamp is open, that there are no air bubbles in the spike, that the contrast tubing is secured in the contrast sensor, and that the contrast sensor is clean.
Counter/Position Mismatch	There may be a problem with the components that drive the syringe ram. If the problem persists, contact a service representative.
Disarm	The connected X-ray imaging system has disarmed the CVi system. Consult the X-ray imaging system's instructions to determine how to correct the problem.
DISARMED!	Arming and disarming the system is controlled by the X-ray imaging system. Consult the X-ray imaging system's instructions to determine how to correct the problem.
DOS unable to stop injection motor error!	The system has experienced a hardware problem. Contact a service representative.

Message	Recommendation
Error *n*	Try cycling power to the system. If the problem persists, contact a service representative and report the error number.
Forward Limit (or Forward Stop) Reached	The syringe ram has reached its maximum forward position. Try pressing **START REFILL** to initiate a refill procedure.
Function Timeout!	The system experienced an error during calibration. Try cycling power to the system. If the problem persists, contact a service representative.
Hand Controller Disabled (or HC Disabled)	The connected X-ray imaging system has disabled the hand controller. Injections are controlled remotely from the X-ray imaging system. (Note: Philips X-ray imaging systems may still require the hand controller to be pressed to initiate an injection.)
Hand Controller Calibration Failed	The hand controller is a single use component and must be calibrated for every case. Check the following items if the hand controller calibration fails: • The hand controller luer connections are tightly connected to the control panel. • The **(C)** button on the hand controller was fully depressed. • The **(C)** button was not pressed within 4 seconds of starting the hand controller calibration. • The **(C)** button was pressed before pressing OK on the control panel.
Hand Controller Requires Calibration	The **INJECT** button was pressed before the hand controller was calibrated. Calibrate the hand controller before attempting to arm the injector.
Injection Motor Malfunction (OS/OT)	Make sure that the stopcock is open and that flow is not restricted in any part of the system or patient kit. If there are no flow restrictions and the error persists, contact a service representative.
Interprocessor Ping Error	Try cycling power to the system.

Message	Recommendation
Invalid Calibration Data	The system detected a problem with the startup calibration. Press OK to retry the calibration or try cycling power to the system. If the problem persists, contact a service representative.
Invalid Calibration Data. Can't Resume!	When trying to resume a previously interrupted case, the system detected a problem with the calibration data. Press OK to continue, or try cycling power to the system. If the problem persists, contact a service representative.
Invalid HC16 Response!	Try cycling power to the system.
Manifold Valve Closed	The system displays this alert when it detects a manifold in the manifold sensor during startup calibration. If there is a manifold in the sensor, remove it to continue the setup procedure.
Manifold valve failed to close *n* times using current syringe.	The manifold is designed to prevent reverse flow by automatically closing when fluid flow stops. Replace the syringe if: • Patient bodily fluids are observed in the patient tubing. • Both the Manifold Valve Open and Syringe Valve Open indicators are on and any error messages are displayed. • If the system displays both the Manifold Valve Open error and Syringe Valve Open indicator.
Manifold Valve Open	The manifold valve opens during an injection. Therefore, this alert sometimes appears for informational purposes. If the alert persists after an injection is complete, check for the following issues: • Make sure that the manifold is properly seated in the sensor. • Try purging. • Press the **Standby** button to relieve back pressure on the manifold. • Make sure that the white slide clamp on the contrast tubing is open. • Replace the patient kit.
Motor Speed Incorrect	Try cycling power to the system.

Message	Recommendation
No Contrast	The system was unable to fill the syringe from the contrast container. If the contrast container is empty, replace it with a new container. If there is contrast remaining in the container, make sure that the white slide clamp is open, that there are no air bubbles in the spike, that the contrast tubing is secured in the contrast sensor, and that the contrast sensor is clean.
Non-system disk or disk error	The system has experienced an internal fault that prevents it from starting up normally. Contact a service representative.
No X-ray Interface	The expected communication with a remote X-ray imaging system has failed.
NVRAM Failure	The system failed a self test during startup.
Pressure Limit	The system is adjusting the flow rate so that the injection pressure remains below the configured pressure limit.
Pressure Limit Exceeded	Make sure that the stopcock is open to allow injection and that the patient catheter is not kinked. If appropriate, increase the pressure limit, reduce the flow rate, or increase the rise time.
PURGE is Incomplete	The syringe ram has reached its maximum forward position before the purge could be completed. Try pressing **START REFILL** to initiate a refill procedure, then run the purge again. It may be necessary to replace the patient kit.
Ram Forward (or Ram Reverse)	This is an informational message indicating that the syringe ram has reached the forward or reverse position.
Ready to Inject Manifold Valve Open Press Standby to Release	The injector will not activate if the manifold valve is open. Press the **Standby** button to allow system pressure to relieve back pressure on the manifold.
Release Trigger for New Injection	Release the contrast **(C)** button on the hand controller to begin a new injection.

Message	Recommendation
Remove tubing from, and clean contrast sensor	The system displays this alert when it detects contrast during startup calibration. If there is contrast tubing in the sensor, remove it to continue the setup procedure.
Reset X-ray interface for new injection	Release the trigger on the connected X-ray imaging system before the next injection.
Reverse Limit Reached	The syringe ram has reached its rearmost position.
Saline Pump Malfunction (OS)	The saline pump has experienced an internal malfunction.
Saline Pump Malfunction (OT)	The saline tubing may be obstructed or pinched. Make sure the rear tubing guide is securing the tubing but not restricting flow of saline, and that the front tubing guide is positioned all the way up.
Standby!	The **Standby** button has been pressed, which has suspended all system functionality. To resume operation, press the **Standby** button and then press **OK** on the control panel.
Start Injection	This is an informational message displayed when an injection is initiated from a connected X-ray imaging system.
Syringe Not Detected	The system has not detected a syringe in the chamber. When prompted during setup, insert a syringe into the syringe chamber and fully close the chamber door. This message can also appear in error if the syringe valve sensor needs to be cleaned.
Syringe Valve Closed	The syringe valve may be stuck. Perform a short refill to try and correct the problem. If this alert occurs during setup, the syringe may be faulty and may need to be replaced. This alert can also occur if the syringe valve sensor needs to be cleaned.

Message	Recommendation
Syringe Valve Open	The system displays this alert when it detects a syringe already in the chamber during startup calibration. If there is a syringe in the chamber, remove the syringe to continue the setup procedure. If there is not a syringe in the chamber, the syringe valve sensor may need cleaning or the sensor may be blocked.
There is a 10 second limit for Flush	The system automatically stops a saline flush after 10 consecutive seconds as a safety feature.
There is a 10 second limit for Purge	The system automatically stops a purge after 10 consecutive seconds as a safety feature.
There is a 20 minute limit for KVO	The system automatically stops the KVO function after 20 consecutive minutes as a safety feature.
Values Out of Range	Try cycling power to the system.

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9 Specifications

Load Rate

Fill 1–2 ml/s
Syringe air purge 6 ml/s.

Saline Rate

Automated fixed flow rate of 1.6 ml/s.
Maximum saline injection volume of 16 ml per saline injection activation.

Contrast Injection Parameters

Cardiac procedure mode

Injection Type	Flow (ml/s)	Volume (ml)	Pressure		Rise Time (s)
			psi	kPa	
LCA	0.8–10.0	0.8–20.0	200–1200	1379–8274	0.0–1.0
RCA	0.8–10.0	0.8–20.0	200–1200	1379–8274	0.0–1.0
LV / Ao	0.8–40.0*	0.8–99.9	200–1200	1379–8274	0.0–1.0
Other	0.8–40.0*	0.8–99.9	200–1200	1379–8274	0.0–1.0

Peripheral procedure mode

Injection Type	Flow (ml/s)	Volume (ml)	Pressure		Rise Time (s)
			psi	kPa	
Pigtail	0.8–40.0*	0.8–99.9	200–1200	1379–8274	0.0–1.0
Selective	0.8–15.0*	0.8–99.9	200–1200	1379–8274	0.0–1.0
Microcatheter	0.8–3.0	0.8–10.0	200–300	1379–2068	0.0–1.0
Other	0.8–40.0*	0.8–99.9	200–1200	1379–8274	0.0–1.0

* When using 5Fr catheters, flow rate reduction may occur with > 15ml/sec flow rate settings and Pressure Limit may occur with flow rate settings > 20ml/sec. When using 4Fr catheters, flow rate reduction may occur with > 12ml/sec flow rate settings and Pressure Limit may occur with flow rate settings > 15ml/sec.

Accuracy

Parameter	Accuracy
Flow rate	Settable in 0.1 ml/s increments. Flow accuracy follows the formula $A = R \pm (0.5 \times \sqrt{R})$ where: • A is accuracy • R is the configured flow rate
Volume	Settable in 0.1 ml increments. Volume accuracy (see note) follows one of the two formulas below, whichever is smaller $V_D > \left(V_S - (0.75 \times \sqrt{V_S})\right)$ *OR* $(V_S - 3\ ml)$ *AND* one of the two formulas below, whichever is larger $V_D < \left(V_S + (0.75 \times \sqrt{V_S})\right)$ *OR* $(V_S + 1.5\ ml)$ where: • V_D is Volume delivered • V_S is Volume selected **Note** A high flow rate can create high injection pressure. Under these conditions, the delivered volume can be up to 4 ml less than the configured volume.
Pressure	Settable in 1 psi or 1 kPa increments
Rise Time	Settable in 0.1 s increments. Rise time accuracy is ± 0.1 s.

Pedestal Cart Dimensions

The dimensions of the pedestal cart are as follows:

Item	Dimensions
Wheelbase footprint	53.3 × 63.5 cm 21 × 25 in
Height	91.4 cm 36 in

Weight

Weight of system components are as follows:

Item	Weight
Power supply	5.5 kg 12.0 lb
Control panel and stem	3.2 kg 7.0 lb
Pedestal cart	10 kg 22.0 lb
Injector head	20.4 kg 45.0 lb
Adjustable arm	0.66 kg 1.45 lb

Environmental Limits

Transportation

Type	Product	Limit
Ambient temperature	Injection system	–29 °C to +60 °C –20 °F to +140 °F
	Patient kits	–18 °C to +29.4 °C 0 °F to +85 °F
Relative humidity	Injection system and patient kits	10 % to 85 % non-condensing
Atmospheric pressure	Injection system	60 kPa to 106 kPa 9 psi to 15 psi

Operating environment

Type	Limit
Ambient temperature	+18 °C to +29.4 °C +64 °F to +85 °F
Relative humidity	10 % to 85 % non-condensing
Atmospheric pressure	70 kPa to 106 kPa 10 psi to 15 psi

Power Supply

Standard

100–240 VAC

~50–60 Hz

6.3 A maximum

Power cord

3.7 m

12 ft

Electrical Leakage

< 10 µA for patient connection

< 100 µA for chassis

Complies with EN/IEC 60601-1, second edition and third edition, Amendment 1.

Patient Kits

The CVi system uses the following patient kits:

Model Number	Model Name	Uses
BT2000	Manifold Kit	Single Use
AT P54 AT P65	AngioTouch Hand Controller Kit	Single Use
A2000	Syringe Kit	Up to six cases

Hemodynamic Transducer

Refer to the following specifications for Smiths Medical LogiCal® Pressure Transducer product code MX960. The following specifications are current as of the date on this document and are subject to change by the manufacturer.

Specification	Range
Pressure measurement	–30 mmHg to +300 mmHg
Sensitivity	5 µV / V / mmHg nominal
Output impedance	300 Ohm ± 10%
Input impedance	630 Ohm nominal
Balance	0 mmHg ± 50 mmHg
Temperature sensitivity coefficient	0 ± 0.1% / °C
Temperature coefficient of calibration value	0 ± 0.3 mmHg / °C
Excitation	4–8 VDC to 5 kHz
Risk current	<5 µA at 115 VAC, 60 Hz
Overpressure withstand	–400 mmHg to +4000 mmHg
Defibrillation capacity	5 discharges in 5 min at 360 J
15% pressure transducer bandwidth	> 200 Hz

Supported Imaging Systems

The CVi system synchronizes with the following X-ray imaging systems. This table reflects current interface capabilities as of this revision. Please contact the manufacturer for any updates if your system is not identified here.

Manufacturer	Model
GE	Discovery Series
	Innova Series
	OEC 9x00 Series
	Optima Series
	Unity Series
Phillips	Allura Xper Series
Shimadzu	AngioSpeed Series
	Bransist Safire Series
	Digitex Safire Series
	Heart Speed Series
Siemens	AXIOM Series
Toshiba	Infinix Cleve I Series
	Infinix i-series

UL Approval

UL/c-UL Classified Mark, *Medical Electrical Equipment,* Control #17ZM, UL2601-1, CLASSIFIED BY UNDERWRITERS LABORATORIES INC. WITH RESPECT TO ELECTRICAL SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1, and CAN/CSA C22.2 NO. 601.1.

Item	Classification
Type of protection against electric shock	Class 1
Degree of protection against electric shock	Defibrillation-proof type CF applied part
Degree of protection against ingress of water	Ordinary
Methods of sterilization or disinfecting	None
Mode of operation	Continuous

Note

The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

10 EMC Tables

EMC Requirements

Caution

- The use of accessories, transducers, or cables other than those specified and provided by ACIST Medical may result in increased electromagnetic emissions or decreased electromagnetic immunity of the CVi system.
- The CVi system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed prior to patient use to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration—Emissions

The CVi system is intended for use in the electromagnetic environment specified below. The customer or user of the CVi system should ensure that it is used in such an environment.

Note

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11 EN 55011:2009/A1:2010 (CISPR 11:2009/A1:2010)	Group 1 Class A	The CVi 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 + A2:2010	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3:1995 + A1:2008 + A2:2013	Complies	

Guidance and Manufacturer's Declaration—Immunity

The CVi system is intended for use in the electromagnetic environment specified below. The customer or user of the CVi system should ensure 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 60601-2:2015 4th Edition	± 15 kV Air ± 8 kV Contact	Criterion A Criterion A	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h 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 A Criterion A	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 Hz 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 V_{NOM} for 10 mSec (0.5 line cycle) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% of V_{NOM} for 20 mSec (1 line cycle) at 0°. 30% of V_{NOM} for 500 mSec (25 line cycles) at 0°. 100% of V_{NOM} for 5000 mSec (250 line cycles)	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 CVi system requires continued operation during power mains interruptions, it is recommended that the CVi system be powered from an uninterruptible power supply or battery.
Power frequency 60 Hz 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 V_{NOM} for 8.3 mSec (0.5 line cycle) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% of V_{NOM} for 16.67 mSec (1 line cycle) at 0°. 30% of V_{NOM} for 500 mSec (30 line cycles) at 0°. 100% of V_{NOM} for 5000 mSec (300 line cycles)	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 CVi system requires continued operation during power mains interruptions, it is recommended that the CVi system be powered from an uninterruptible power supply or battery.
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	30 A/m	Criterion A	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration—Immunity

The CVi system is intended for use in the electromagnetic environment specified below. The customer or user of the CVi system should ensure that it is used in such an environment.

Caution

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the CVi system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Conducted RF EN/IEC 61000-4-6:2013 per IEC 60601-1-2: 2014 and EN 60601-1-2:2015 4th Edition	6 Vrms 150 kHz to 80 MHz	Criterion A	Portable and mobile communications equipment should be separated from the CVi system by no less than the distances calculated/listed below:
	3 V/m 80 MHz to 2.7 GHz	Criterion A	$D = (3.5/V1)\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF EN/IEC 61000-4-3:2006 + A1:2007 + A2:2010 per IEC 60601-1-2: 2014 and EN 60601-1-2:2015 4th Edition	9 V/m 704–787 MHz 5.1–5.8 GHz	Criterion A	$D = (3.5/E1)\sqrt{P}$ 80 MHz to 800 MHz $D = (7/E1)\sqrt{P}$ 800 MHz to 2.5 GHz
	27 V/m 380–390 MHz	Criterion C	where *P* is the max power in watts and D is the recommended separation distance in meters.
	28 V/m 430–470 MHz 800–900 MHz 1.7–1.99 GHz 2.4–2.57 GHz	Criterion C	Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (E1). Interference may occur in the vicinity of equipment containing a transmitter.

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 for the CVi System

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

Service	Band (MHz)	Maximum Power (W)	Separation (m)
TETRA 400	380 – 390	1.8	0.3
GMRS 460, FRS 460	430 – 470	2	0.3
LTE band 13, 17	704 – 787	0.2	0.3
GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	800 – 960	2	0.3
GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25 UMTS	1 700 – 1 990	2	0.3
Bluetooth, WLAN 802.11 b/g/n RFID 2450, LTE band 7	2 400 – 2 570	2	0.3
WLAN 802.11 a/n	5 100 – 5 800	0.2	0.3

11 *Limited Warranty*

ACIST Medical Systems, Inc. (“ACIST”) warrants that the ACIST CVi® Contrast Delivery 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 CVi® 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 including damage caused by contrast media or other substances.

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 BIOLOGICAL DIFFERENCES IN HUMAN PATIENTS AND BECAUSE ACIST HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH PRODUCTS ARE USED, DIAGNOSIS OF THE PATIENT, THE METHOD OR ADMINISTRATION OF THE PRODUCT OR THE HANDLING OF THE PRODUCT AFTER IT LEAVES THE POSSESSION OF ACIST, THE COMPANY 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.

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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.

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℞ Only

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ACIST|CVi® System User's Guide
English (USA)

ACIST®