ACIST | CVi®

ACIST | CVi®
Contrast Delivery System
User's Guide

Bracco Group
901479-002,01 2019-08 English, OUS

ACIST®

Proprietary Information Notice

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

Contents

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1 Introduction

Intended Use

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

Contraindications

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

Any applications of the system, other than those described in this manual, are inappropriate and should not be attempted.

Do not add any components to the consumable kits or in conjunction with the catheter. No valves or other manifolds may be placed in-line between the ACIST-provided consumable kit and the catheter. ACIST-provided consumable kits are designed, manufactured, and tested for connection to catheters used in angiographic procedures.

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

Requirements for Use

For safe use and optimal operation of the ACIST | CVi Contrast Delivery System (CVi System), observe the following guidelines:

- 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 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.

Requirements for Use (continued)

- 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.

About This User's Guide

This User's Guide provides instructions for setting up and using the ACIST | CVi Contrast Delivery 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.

Section	Purpose
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 cause serious injury or death.

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2 Warnings, Cautions, and Symbol Definitions

Warnings

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

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 injecting, 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

When using a blood pressure monitor, be sure to clear the monitoring line of all air to avoid producing an inaccurate blood pressure reading.

Air Column Detect Sensor

The ACIST 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 high-pressure tubing past the sensor. This sensor is designed to aid the user in the detection of air columns in the injection line, but it is not designed to replace the vigilance and care required of the operator in visually inspecting for air and clearing air 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.

Warnings (continued)

Use of Patient Kits

Failure to observe the following guidelines can result in patient injury or equipment damage:

- Do not use a patient kit on more than one patient.
- Do not allow any consumable to sit unused for more than the maximum time recommended by the contrast manufacturer.
- Do not allow a syringe kit that is loaded with contrast to sit longer than the maximum time recommended by the contrast manufacturer.
- Do not use a multi-procedural syringe kit for more than five cases.
- Dispose of all single-use components after every case.
- Properly discard consumables 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 ACIST 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. 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. 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.

Warnings (continued)

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 patient catheter's pressure rating.

Injection System Setting

Check the ACIST 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.

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 ACIST | CVi Contrast Delivery System may only be interfaced with X-ray equipment that is certified to be in compliance with IEC 60601-1, second or 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 ACIST | CVi Contrast Delivery 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.

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.

Contrast Viscosity

To ensure proper operation of the syringe, viscosity limits must be observed. Refer to the IFU that was shipped with the syringe kit for viscosity limits.

Control Panel Touch Screen

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

Electromagnetic/Electrostatic Interference

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.

Cautions (continued)

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 patient 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.

Cautions (continued)

- 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 consumables, make sure the contrast spike is removed from the contrast container prior to opening the syringe chamber.

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 Input Cable

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

Symbol Definitions

The following symbols are used on the CVi System components and throughout this manual:

Symbol	Definition
	Patient applied part, degree of protection against electrical shock, type CF defibrillation proof
	Alternating current
	Equipotentiality
	Pushing prohibited
	Consult instructions for use
	Consult the instructions for use for important cautionary information
	Do not reuse
	Keep dry
	Humidity limitation
	Pressure limitation
	Temperature limitation
	Fragile, handle with care
	Non-pyrogenic
	Manufacturer, Date of manufacture
	Date of manufacture

Symbol Definitions (continued)

Symbol	Definition
SN	Serial number
REF	Catalog number
LOT	Lot number
	Packaging Unit
	Dangerous voltage
	Explosion hazard
	Do not tip
EC REP	European representative
	Contact for service
	This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419). In accordance with European Union WEEE Directive 2002/96/EC, ACIST Europe B.V. will be fully responsible for the coordination, logistics, and costs of the WEEE process.
	With respect to electrical shock, fire, mechanical, and other specified hazards, only in accordance with IEC 60601-1, second and third editions.
	Complies with European Directive 93/42/EEC, Medical Device Directive.
	Do not use if packaging is damaged
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation

Symbol Definitions (continued)

Symbol	Definition
	Contains DEHP
IP21	Environmental enclosure rating, protected against objects greater than 12 mm and protected against dripping water, injector head
	General warning

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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- 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 consumable kits. The consumable 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 from Siemens, Toshiba, GE, and Philips. Synchronization is only possible provided the proper X-ray interface cable is also purchased and installed.

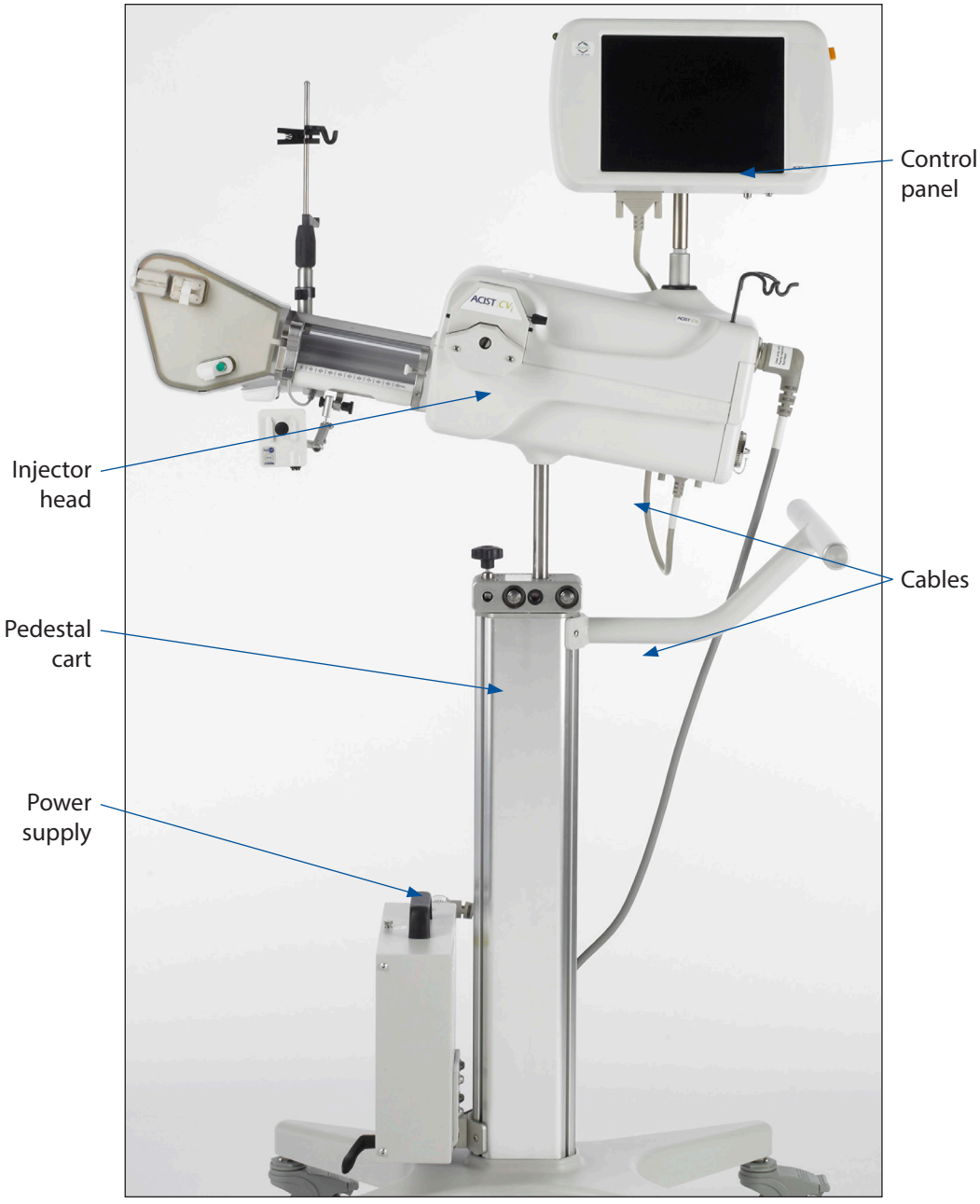
System Hardware

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)



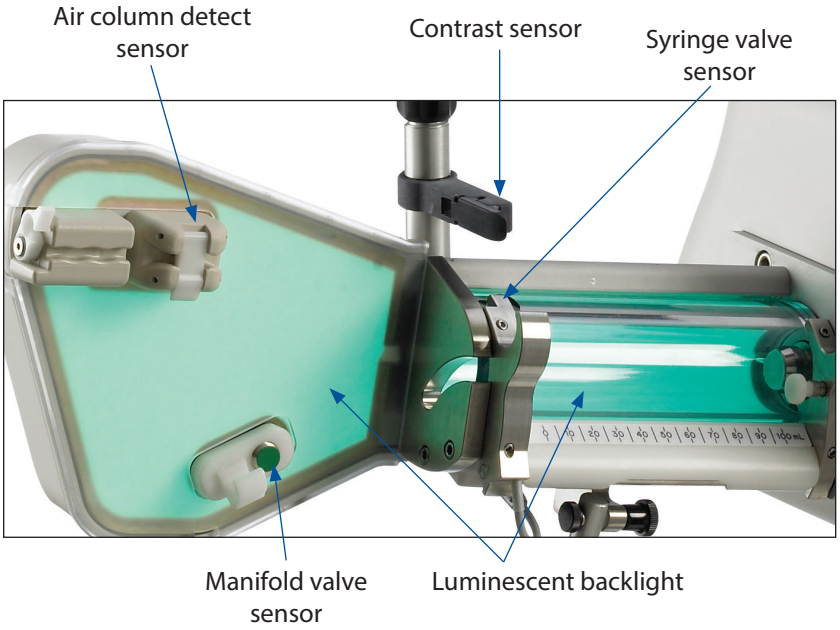
Power Supply

The power supply is the only connection to mains power and provides power to all subsystems of the CVi System. The power supply also provides the data interface connections between subsystems, and the connection to the remote X-ray imaging system (if applicable).

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
- Contrast sensor
- Manifold valve sensor—automatically switches between high- and low-pressure ports for delivery of contrast and saline. Ensures patient blood pressure is monitored any time fluid is not being dispensed, if the optional pressure transducer is used.
- Syringe valve sensor
- Luminescent backlight, located behind the syringe chamber and the consumable connections, to facilitate visual air column detection



Mounting

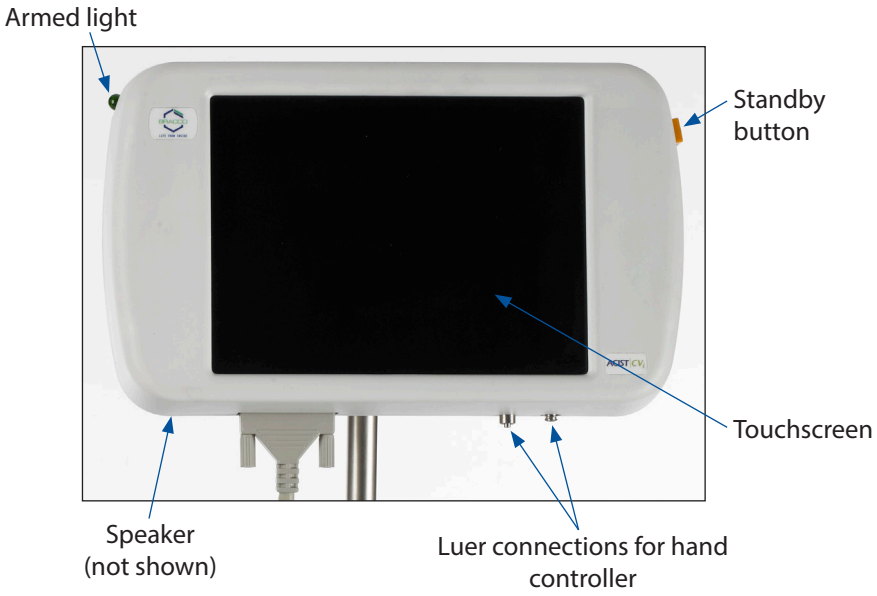
The injector head can be mounted in the following ways:

- 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
- Armed mode indicator light, which is lit when the system is ready to perform an injection
- Standby button, which is used to pause system operation
- Speaker, for audible alerts
- Luer connections, for the AngioTouch® hand controller
- A swivel base, which allows the control panel to be easily rotated to a position for optimal viewing



Touchscreen

The touchscreen provides user prompts throughout the setup procedure. During operation, the touchscreen provides status information, alert messages, and controls for configuring injection parameters and device states.

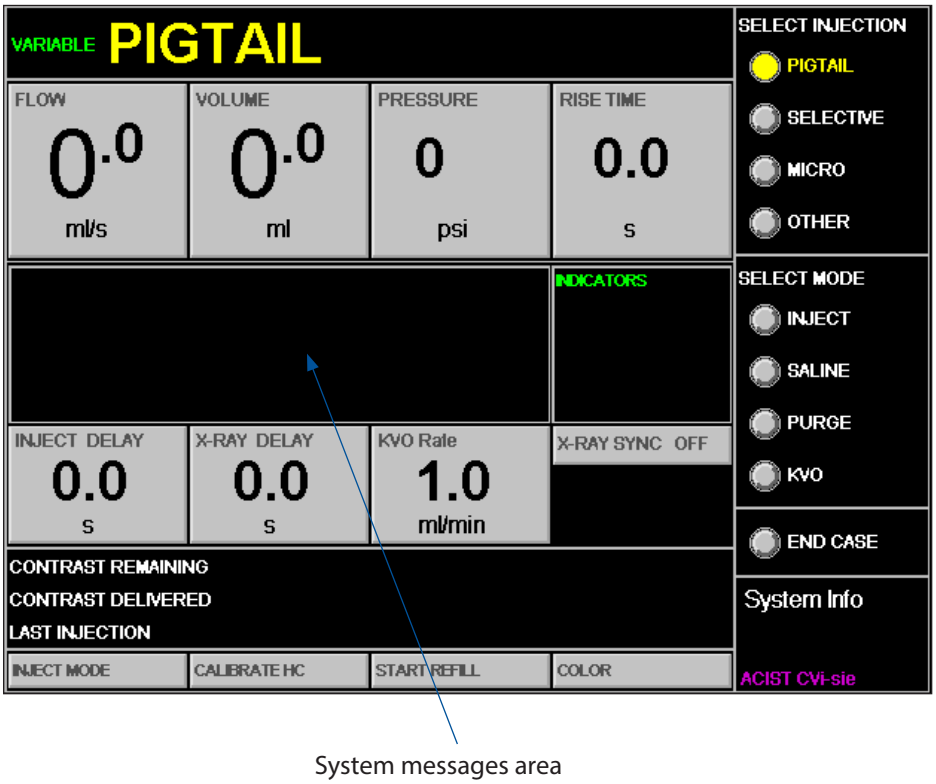
Audible Indicators

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 message	Beep
Injecting contrast	Repeating beep

Touchscreen Functions

The major functional areas of the touchscreen are shown in the following 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.

Touchscreen Functions (continued)

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 hard the contrast (C) button on the hand controller is pressed.
- 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

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 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.

Consumable Patient Kits

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

The CVi System currently uses the following consumable patient kits:

Model Number	Model Name	Uses
BT2000	Automated Manifold Kit	Single use
AT P54 AT P65	AngioTouch® Kit	Single use
A2000 A2000V	Multi-Use Syringe Kit	Up to five cases

Consumable kit availability varies by world area. Some locally-approved kits may not be listed above. Contact a local ACIST representative for more information.

Note

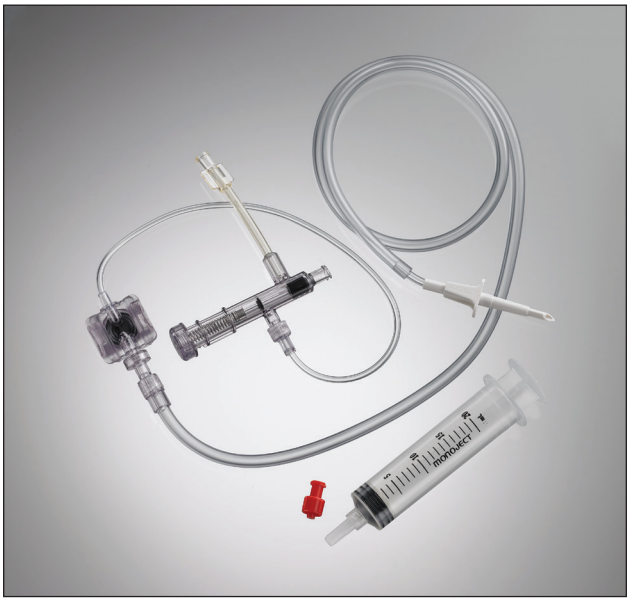
Product availability may vary in different global markets.

CAUTION

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

Automated Manifold Kit (BT2000)

The kit includes a manifold, saline tubing, a saline spike, and a hand syringe. The kit is available with or without a pressure transducer cartridge.



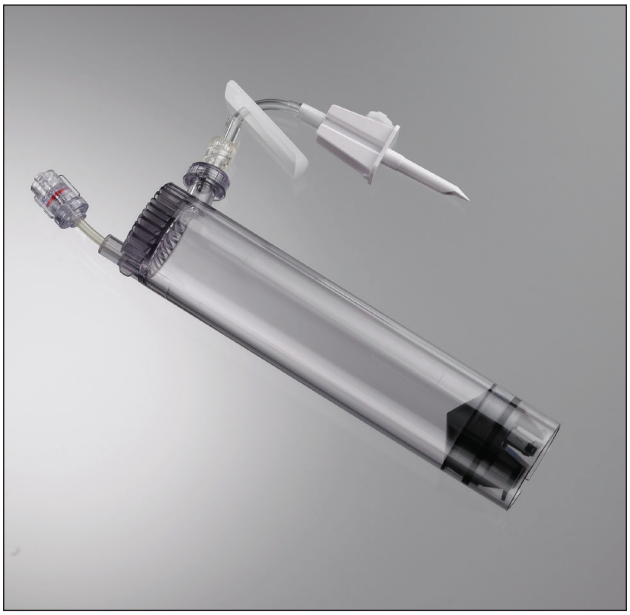
Consumable Patient Kits (continued)

AngioTouch® Kit (AT P54 or AT P65)

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

Multi-use Syringe Kit (A2000 or A2000V)

The kit includes a 100 ml syringe, a contrast spike, contrast tubing, and a slide clamp.



AngioTouch Hand Controller

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.

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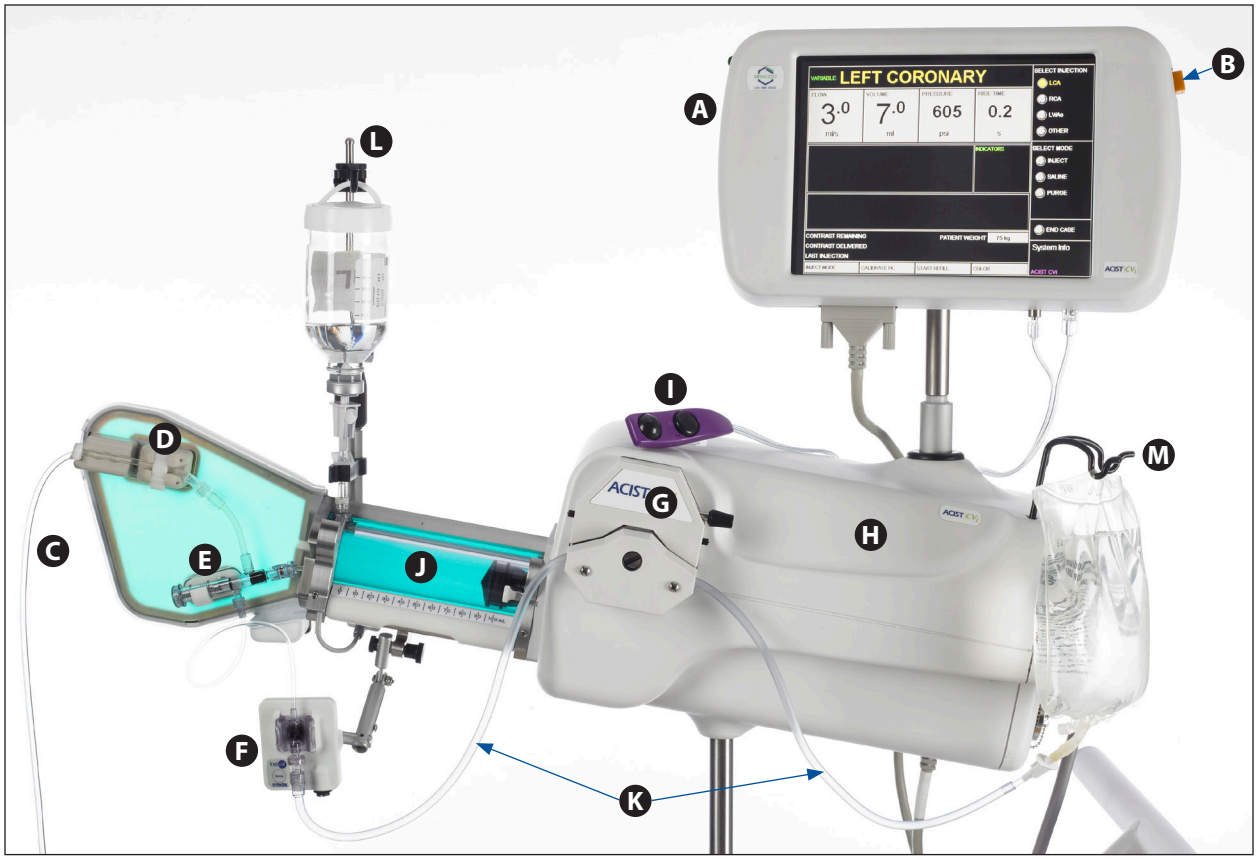
4 Setup



A. Control panel
B. Standby button
C. High-pressure 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 supply hanger
M. Saline bag hanger

Setup Overview

The setup procedure involves the following general steps:

1. Supplying power to the system.
2. Installing consumable kits.
3. Removing air from all system components and from the entire patient catheter.

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

Aseptic technique must be followed when performing setup.

Power On

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

Load the Syringe

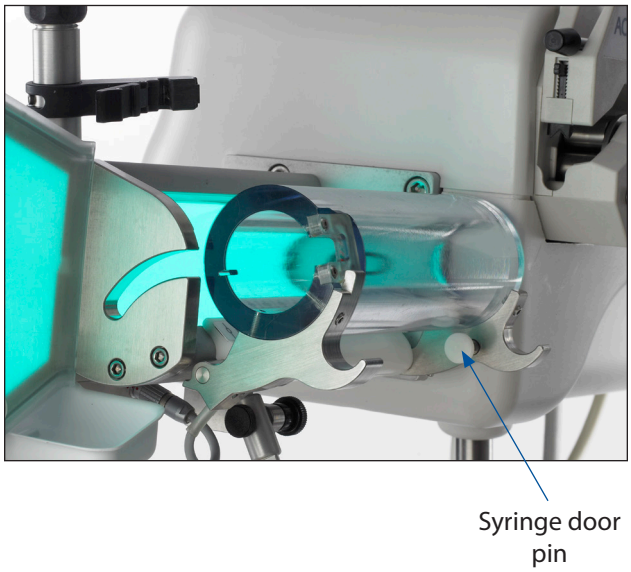
1. On the control panel, press START.
2. Press CARDIAC or PERIPHERAL to select the procedure mode.

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

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

Load the Syringe (continued)

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



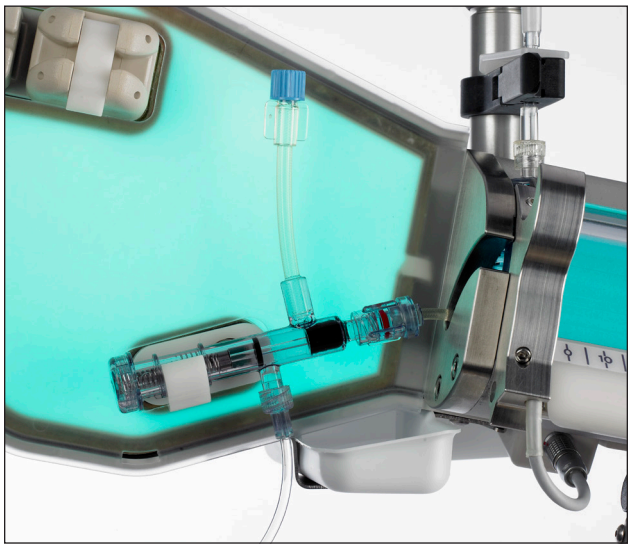
4. Open the Multi-Use Syringe Kit and remove all the end caps.
5. Tighten the contrast spike tubing on the syringe.
6. Insert the syringe into the syringe chamber.
7. Close the chamber. Make sure the syringe door pin locks into place.
8. Press DONE.
9. The plunger will move to the fill syringe position.

Load Contrast

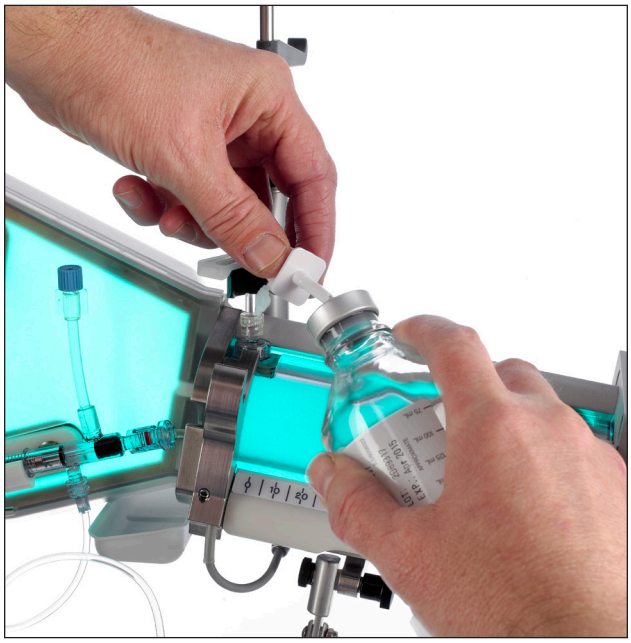
1. Open the Automated Manifold Kit and remove all the end caps.
2. Connect the manifold to the syringe. Tighten by turning the syringe side of the luer connection.

Load Contrast (continued)

3. Clip the manifold into the manifold valve sensor.



4. Swab the stopper/closure of a contrast supply container with the appropriately safe and potent antiseptic agent approved for your institution's use. Insert the contrast spike into the stopper/closure of the contrast supply container. To avoid spilling contrast, hold the contrast supply container with the stopper/closure facing up, as shown.



Load Contrast (continued)

5. Hang the contrast supply container.

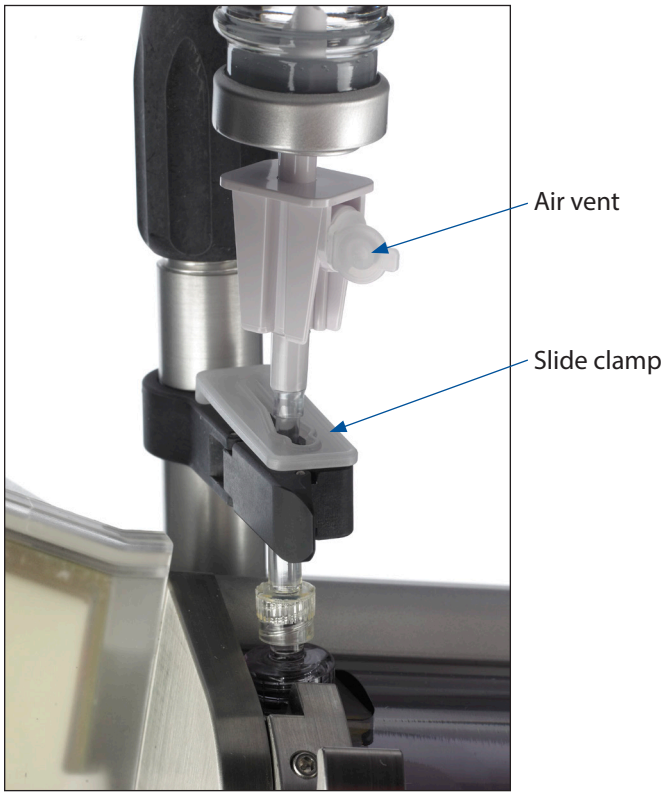
6. Keeping the white slide clamp above the contrast sensor, insert the contrast spike tubing into the contrast sensor and close securely.

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.

Load Contrast (continued)

7. Open the air vent on the contrast spike and make sure that the white slide clamp is open.



8. Press DONE.

Load Saline

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

Load Saline (continued)

2. Insert the saline spike into a saline bag. Hang the saline bag on the saline hanger.

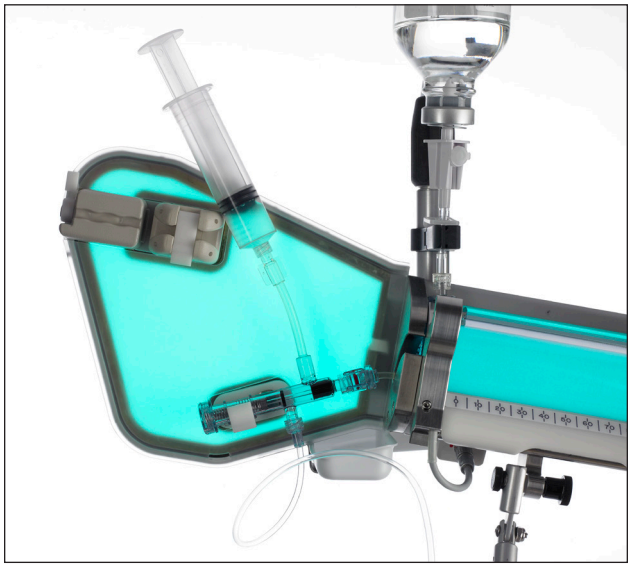
Important

Make sure the saline bag is fully spiked. If it is not fully spiked, air will be introduced into the tubing.

3. Connect the hand syringe to the manifold.
4. Slowly draw saline through the saline tubing using the hand syringe. Continue drawing saline until all air is removed from the saline tubing, the transducer, and the manifold.

Tip

Draw saline two times. After the first draw, disconnect and empty the hand syringe. Reconnect the hand syringe and draw saline a second time.



5. Open the saline pump and place the saline tubing inside.

   Center the tubing in the pump so that equal amounts of tubing remain on either side of the pump.

Load Saline (continued)

6. Raise both tubing guides all the way to the top.

Front tubing guide

Rear tubing guide

7. Verify that the teeth of the tubing guides are centered over the tubing.
8. Close the saline pump.
9. Lower the rear tubing guide until it is stopped by the tubing. The tubing guide should be low enough to secure the tubing without crimping the tubing.

Move rear tubing guide downward

Note

The rear tubing guide should not restrict the flow of saline through the tubing.

10. Press DONE.

Purge Contrast

1. Disconnect and empty the hand syringe.
2. Reconnect the hand syringe to the manifold.
3. Press and hold PURGE for 1–2 seconds. Contrast will run through the manifold and into the hand syringe, purging the small amount of air from the manifold.

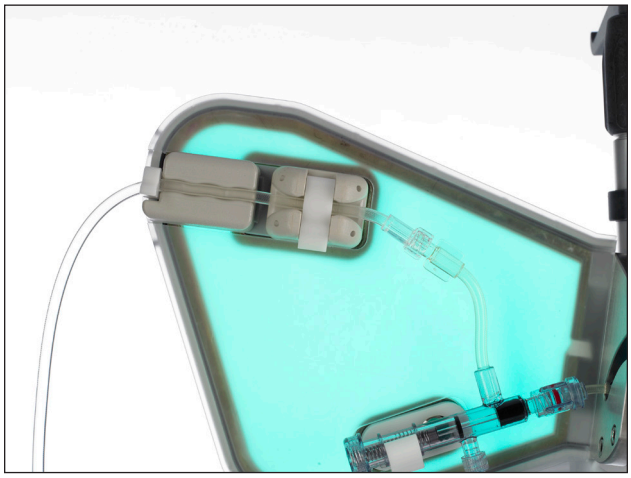
Tip

The amount of air that needs to be purged is very small. Holding the PURGE button too long can use an excessive amount of contrast.

4. Check for air. If necessary, press and hold PURGE again.
5. Press DONE.

Flush Saline

1. Disconnect the hand syringe.
2. Open the AngioTouch Kit and empty its contents onto the sterile field.
3. Connect the stopcock to one end of the high-pressure tubing, and connect the other end of the high-pressure tubing to the manifold.
4. Place the high-pressure tubing into the strain relief and air column detect sensor. Fully close both latches.



5. Open the stopcock and position it over a waste receptacle to catch the saline overflow.
6. Press FLUSH. The CVi System will automatically stop the saline flush after 10 seconds.

Flush Saline (continued)

7. Completely flush the high-pressure tubing. Dislodge air as necessary from the saline spike, tubing, stopcock, manifold, and pressure transducer cartridge.

Tip

Flush twice. During the first flush, use the supplied mallet to tap on the saline tubing. During the second flush, use the mallet to tap on the pressure transducer and manifold.

8. Press DONE.
9. Inspect all components for air.

WARNING

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 injecting, 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.

10. Press DONE.

Connect and Calibrate the AngioTouch® Hand Controller

1. Connect the luer connections on the hand controller to the control panel. Tighten each luer connection until it is airtight.

2. Press DONE.
3. Press OK to start the hand controller calibration.
4. Fully depress the contrast (C) button on the hand controller within 4 seconds.

Connect and Calibrate the AngioTouch® Hand Controller (continued)

Tip

If the hand controller calibration fails, try the following:

- *Recheck the luer connections on the hand controller and make sure they are securely connected to the control panel.*
- *Make sure to press OK on the control panel to start calibration before pressing the C button on the hand controller.*
- *Calibration can fail if too much time lapses between starting the calibration and pressing the C button on the hand controller, or if insufficient pressure is applied to the C button.*
- *Make sure the tubing for the hand controller is not kinked.*
- *Press OK and then press CALIBRATE HC (on the bottom of the control panel screen) to retry the calibration procedure.*

If the hand controller becomes disconnected during a case or needs to be replaced, perform the following steps:

1. Connect the new hand controller as in Step 1 above.
2. Press CALIBRATE HC on the control panel to initiate the calibration procedure.

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.

Repurge Contrast

1. Turn the stopcock so that the patient is disconnected from flow.
2. Press and hold PURGE to purge additional contrast, if necessary, until contrast flows out of the stopcock.
3. When no further purging is required, press CANCEL.

Important

Make sure that the connection between the high-pressure tubing and the catheter is purged of air.

Zero the Pressure Transducer

When using a 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 high-pressure tubing. Contrast in the high-pressure tubing will damp the pressure signal.

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.
   - In cardiac procedure mode, press LCA, RCA, LV/AO, or OTHER.
   - In peripheral procedure mode, press PIGTAIL, SELECTIVE, MICRO, or OTHER.

   The procedure mode (cardiac or peripheral) is chosen during startup. See page 32.
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	Pressing the contrast (C) button on the hand controller causes the CVi System to inject contrast at the exact parameters on the control panel.
Variable	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 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 page 25.

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 device.
    - 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 C button in fixed rate mode and variable rate mode.

Inject Contrast (continued)

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 supply 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	Contrast injection is initiated from the X-ray device.
OFF	Contrast injection is controlled by the CVi System using the hand controller.

Notes

- *Injections initiated by an X-ray imaging device always use fixed injection rate mode.*
- *Depending on the X-ray imaging device, the hand controller may be disabled.*
- *X-ray Sync is available only with peripheral mode injections.*

Purge Air from Contrast Components

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.

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

When the CVi System is in Standby mode, all functions are paused.

6 End a Case

End the Case

1. Disarm the system from inject mode.
2. Record all relevant case information (for example, Contrast Delivered, Last Injection).

   When recording patient doses, account for the 6–7 ml of contrast remaining in the injection tubing and any contrast that was used in setup purges. 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.

3. Press END CASE.
4. Press OK.
5. At the Shut Down System prompt, press YES, NO, or CANCEL.

YES	End the case and shut down the CVi System.
NO	End the case and start a new case. The CVi System displays the number of cases for which the syringe has been used. Press YES or NO to replace the syringe. YES: Start a new case with a new syringe. NO: Start a new case with the current syringe.
CANCEL	Do not end the case.

Remove Single-Use Consumables

All single-use consumables must be removed and properly discarded after every case.

1. If the syringe will be replaced, or if the system will be shut down, remove the contrast supply container.
2. Remove and discard the following components:
   - High-pressure tubing and stopcock
   - Saline tubing and saline bag
   - Hand controller
   - Manifold
3. Before removing the syringe from the chamber, close the white slide clamp below the contrast supply container.
4. Press OK.

Start a New Case

Start a New Case with the Current Syringe

To start a new case with the current syringe, perform the following steps:

1. Press CARDIAC or PERIPHERAL to select the procedure mode.
2. Open a new Automated Manifold Kit.
3. Connect the manifold to the syringe.
4. Clip the manifold into the manifold valve sensor.
5. Continue the setup procedure at “Load Saline” on page 36.

Start a New Case with a New Syringe

To start a new case with a new syringe, perform the following steps:

1. Wait until the syringe plunger has disengaged.
2. Open the syringe chamber.
3. Remove the syringe.
4. Press RESTART.

Shut Down the System

To shut down the system, perform the following steps:

1. Wait until the syringe plunger has disengaged.
2. Open the syringe chamber.
3. Remove all consumables used.
4. Turn off the power switch on the power supply.

7 Supplementary Procedures

Decontamination

If the CVi System needs to be cleaned of biohazards (such as blood), ACIST recommends using a non-alkaline cleaner.

Wear protective gloves. Apply the solution to a soft cloth and wipe down the system. 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 above. 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.*

Daily Cleaning and Maintenance

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.
- Use a soft cloth or sponge moistened with warm water.
- Never spray water or cleaning agents directly on the CVi System.
- Do not use detergents.
- Do not immerse any component in water, or allow water to drip inside the injector head or control panel.
- Do not use sharp objects.

Daily Cleaning and Maintenance (continued)

Cleaning After Every Use

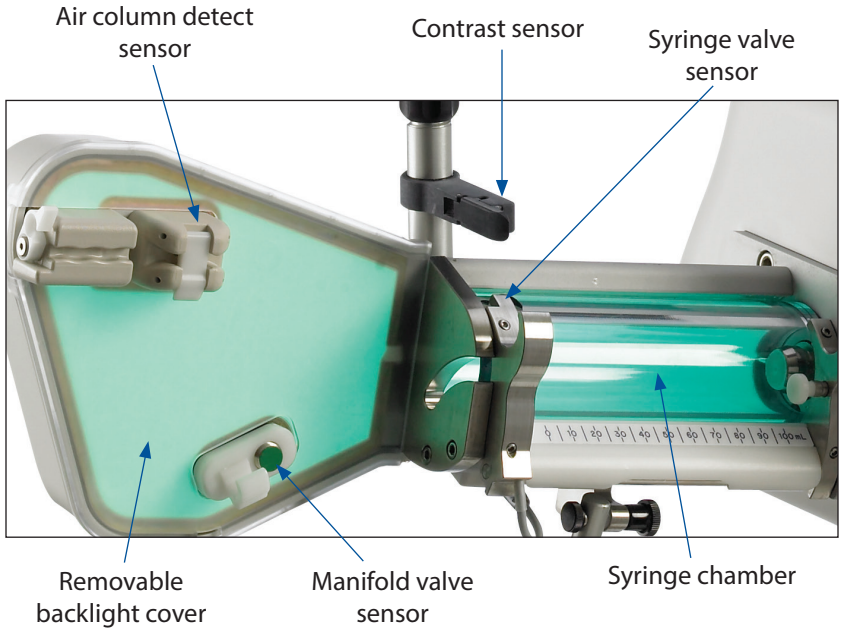
After every patient procedure, use a towel or sponge moistened with warm water to clean spilled contrast in and around the syringe chamber. Pay particular attention to the lower edge by the drain and the edge along the front of the chamber.

Injector Head

Clean the entire injector head with a soft cloth moistened with warm water.

Sensors and Components

Clean the following sensors and components with a soft cloth moistened with warm water:



To remove the backlight cover, pull gently around the edges of the cover and lift it over the air column detect sensor and manifold valve sensor.

Daily Cleaning and Maintenance (continued)

To reattach the backlight cover, snap the outer edge of the backlight into the channel around the edge of the cover. Start with the upper-right corner and work all around the perimeter.

Pressure Transducer

If the pressure transducer requires cleaning, be careful not to soak the cartridge or backplate. Do not expose any of the pressure transducer components to cleaning agents. Doing so may degrade the transducer and result in poor pressure waveforms.

Daily Inspection

- Inspect the syringe chamber for cracks or deterioration. Do not use the system if the syringe chamber is damaged in any way.
- Press the calibration button on the pressure transducer backplate, and verify that this produces a signal equal to 100±3 mmHg. If the signal is not within this range, the backplate should be replaced.
- Cover the system with a dust curtain when not in use.

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.

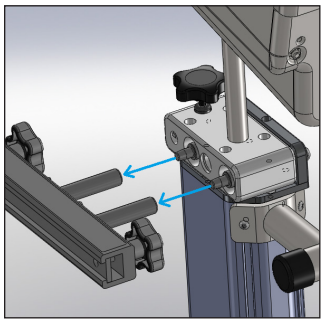
Storage of Cart-Mounted Systems

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.

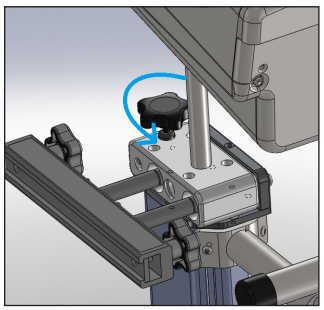
Transfer the Injector Head to/from a Pedestal Cart

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

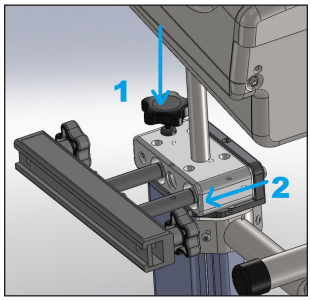
1. Align the pins on the cart with the pins on the bed rail mount.



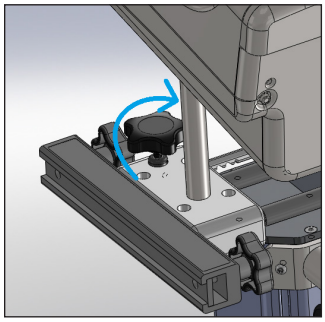
2. Loosen the lock knob.



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

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

Cabling (continued)

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

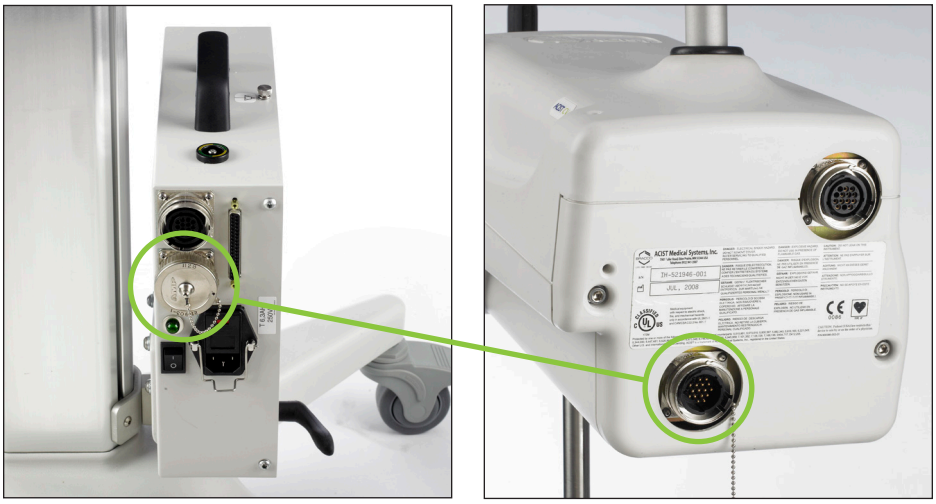
CAUTION

To avoid damaging the X-ray imaging equipment, make sure that the connector on the X-ray imaging device 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 device.

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 input cable between the power supply and the Siemens X-ray device.



Power supply | Injector head

CAUTION

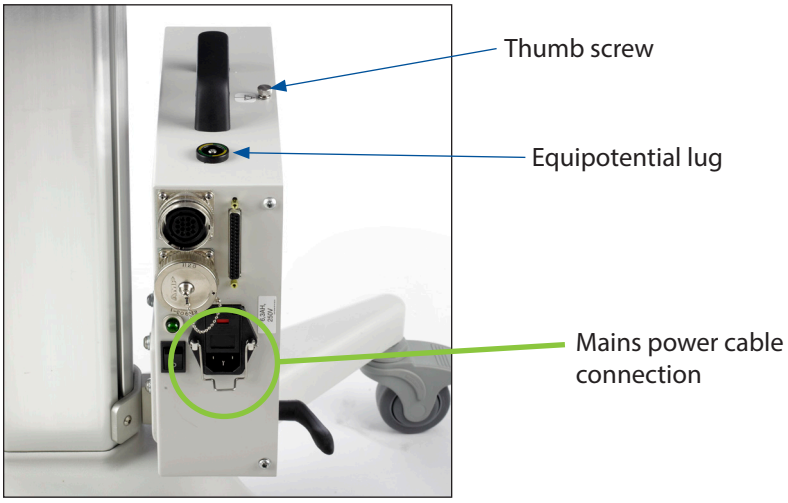
To avoid damaging the X-ray imaging equipment, make sure that the connector on the X-ray imaging device is properly configured before the input cable is connected to the CVi System.

Cabling (continued)

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 IEC60601-1 clause 8.6.7.

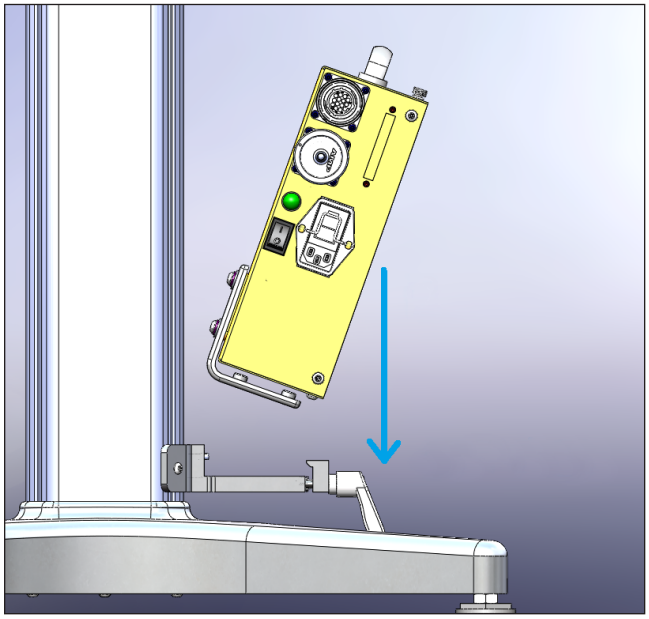


Notes

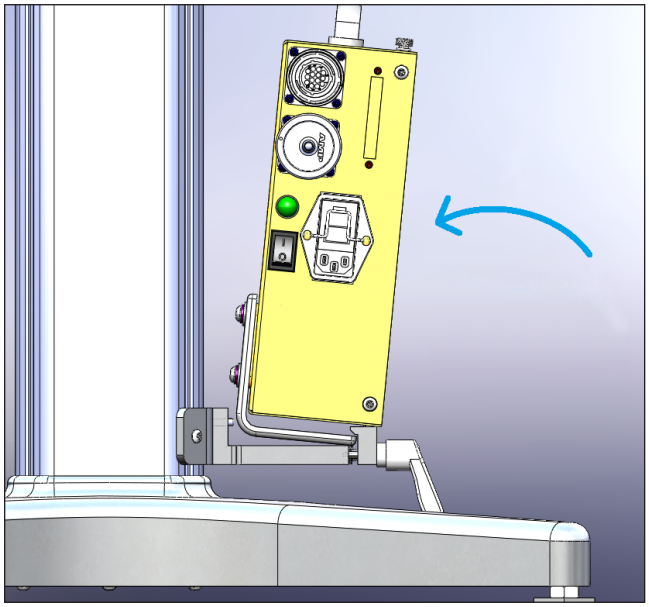
- *The power cable may only be substituted with an equivalent medical-grade power cable.*
- *The power supply must be positioned to provide easy access to either or to both ends of the line power cable for disconnection from mains power.*
- *For systems connected to a Philips or Siemens X-ray imaging 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.

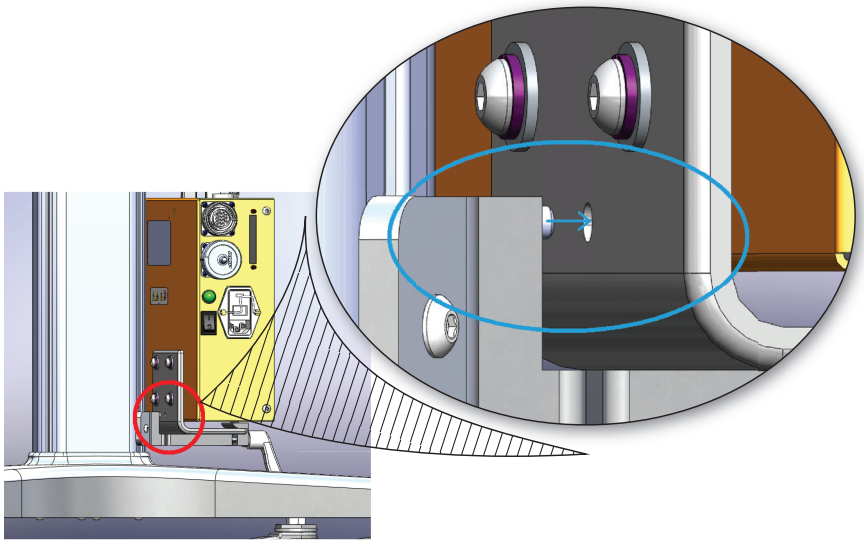


3. Rotate the power supply into the clamp.



Mount the Power Supply on a Cart (continued)

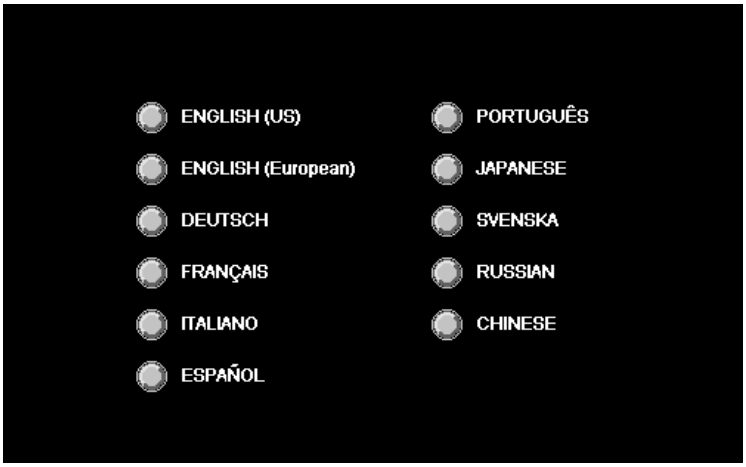
4. Position the hole on the power supply so that it mounts onto the peg on the power supply clamp.



5. Hand-tighten the power supply clamp.

Change the Display Language and Pressure Units

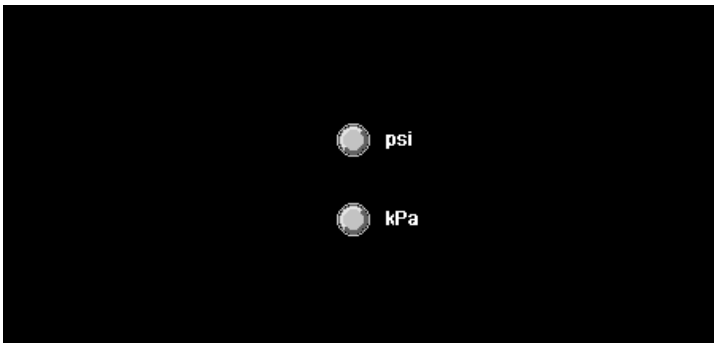
During system startup, the CVi System presents a list of languages. Press the button next to the desired language. If no language selection is made within 5 seconds, the system defaults to the last selected language.



Change the Display Language and Pressure Units (continued)

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.



Resume an Interrupted Case

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

RESUME	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.
RESTART	Abandon the interrupted case and start over.

Calculate Parameters from Patient Weight

In cardiac procedure mode, the CVi System can automatically calculate suggested flow, volume, pressure, and rise time values based on patient weight. Press PATIENT WEIGHT and enter the patient's weight in kg.

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 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 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.

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 0.1–10 ml/min.

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8 Troubleshooting

Frequently Asked Questions

Pressure tracing is damped. How can this be improved?

- When the tubing is 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 high-pressure 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 supply 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.

Frequently Asked Questions (continued)

What can be done about air in the high-pressure 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 high-pressure 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?

- 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.
- Check for kinks in the hand controller tubing.
- Replace the hand controller.

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 page 58.

Frequently Asked Questions (continued)

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

The tubing guides may not be positioned correctly. Refer to the instructions on page 38.

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 CVi System Issues

Air Column Detected

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

To avoid false detection of air columns:

- Make sure that the high-pressure 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 high-pressure tubing is secured in the strain relief, and that the latch on the strain relief is closed.

Contrast Empty/No Contrast

- The contrast supply 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.
- The contrast (C) button on the hand controller must be pressed within 4 seconds of starting the hand controller calibration.
- Insufficient pressure may have been applied to the contrast (C) button during calibration.

Troubleshooting CVi System Issues (continued)

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:

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

Manifold valve failed to close *n* times using current syringe. Contrast may be contaminated. 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.

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

Troubleshooting CVi System Issues (continued)

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.

- 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.

Troubleshooting Hemodynamic Issues

Zero Fluctuations

- Was zero set up at midaxillary?
  - An elevation difference between the transducer and stopcock can cause an offset of 7–10 mmHg.
  - Zero with saline in the high-pressure 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.

Troubleshooting Hemodynamic Issues (continued)

- Did the zero change after a saline flush?
  - An elevation difference between the transducer and stopcock can cause an offset of 7–10 mmHg.
  - Zero with saline in the high-pressure tubing, the stopcock open to air, and the stopcock and transducer located at midaxillary.
  - Ensure that there is saline and/or contrast in the high-pressure 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.

Troubleshooting Hemodynamic Issues (continued)

- 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 manifold is free of all air.
  - Purge the tubing to remove air. Press PURGE, and then press TUBING.
- 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 cartridge may be faulty. Clamp the low-pressure tubing with a hemostat just behind the transducer, and then re-zero. If this improves the waveform, replace the manifold/transducer kit.
- Check the transducer backplate for the following issues:
  - The backplate is rated for 500 cases.
  - 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.
- 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 and smaller) 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 high-pressure tubing. Make sure the stopcock is not open to the patient, and purge the high-pressure tubing to see if the message is cleared. The air column detect sensor can be triggered if the high-pressure tubing is pulled. Make sure that the high-pressure 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 high-pressure tubing. Make sure the stopcock is not open to the patient, and purge the high-pressure tubing to see if the error is cleared. The air column detect sensor can be triggered if the high-pressure tubing is pulled. Make sure that the high-pressure 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 start-up 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.

System Messages (continued)

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 start-up 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 supply container. If the contrast supply container is empty, replace it with a new supply container. If there is contrast remaining in the supply 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.

System Messages (continued)

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.

System Messages (continued)

Message	Recommendation
Invalid Calibration Data	The system detected a problem with the start-up 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 start-up 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. Contrast may be contaminated!	The manifold is designed to prevent reverse flow by automatically closing when fluid flow stops. If the manifold failed to close, then the contrast may have become contaminated. When starting a new case, use a new syringe and a new contrast supply container.
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. • Make sure that the white slide clamp on the contrast tubing is open. • Press the Standby button to relieve back-pressure on the manifold. • Try purging the tubing. • Replace the patient kit.
Motor Speed Incorrect	Try cycling power to the system.

System Messages (continued)

Message	Recommendation
No Contrast	The system was unable to fill the syringe from the contrast supply container. If the contrast supply container is empty, replace it with a new supply container. If there is contrast remaining in the supply 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.

System Messages (continued)

Message	Recommendation
Remove tubing from, and clean contrast sensor	The system displays this alert when it detects contrast during start-up 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.

System Messages (continued)

Message	Recommendation
Syringe Valve Open	The system displays this alert when it detects a syringe already in the chamber during start-up 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.

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.

Viscosity

Refer to the IFU shipped with the syringe kit for viscosity limits.

Injection Parameters

Injection parameter ranges for 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

Injection parameter ranges for 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.

Injection Parameters (continued)

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 $V_D > \left(V_S - \left(0.75 \times \sqrt{V_S}\right)\right)$ *OR* $(V_S - 3\ ml)$ *AND* one of the two formulas below, whichever is larger $V_D < \left(V_S + \left(0.75 \times \sqrt{V_S}\right)\right)$ *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	21 x 25 in (53.3 x 63.5 cm)
Height	36 in (91.4 cm)

Weight

Weight of system components are as follows:

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

Environmental Limits

Transportation:

Type	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	10% to 85% non-condensing
	Patient Kits	10% to 85% non-condensing
Atmospheric pressure	Injection System	60 kPa to 106 kPa (9 psi to 15 psi)

Operating and storage 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: 12 ft (3.7 m)

Electrical Leakage

Less than 10 µA for patient connection

Less than 100 µA for chassis

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

Patient Kits

The CVi System uses the following patient kits:

Model Number	Model Name	Uses
BT2000	Automated Manifold Kit	Single use
AT P54 AT P65	AngioTouch® Kit	Single use
A2000 A2000V	Multi-Use Syringe Kit	Up to five cases

Hemodynamic Transducer

Refer to the following specifications for Smiths Medical LogiCal® Pressure Transducer product code MX960. The following specifications are current as of 18 May 2012 and are subject to change by the manufacturer.

Specification	Range
Pressure measurement	–30 to +300 mmHg
Sensitivity	5 µV / V / mmHg nominal
Output impedance	300 Ohm ± 10%
Input impedance	630 Ohm nominal
Balance	0 ± 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 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
Siemens	AXIOM Artis BA/dBA
	AXIOM Artis BC/dBC
	AXIOM Artis FA/dFA
	AXIOM Artis FC/dFC
	AXIOM Artis MP/dMP
	AXIOM Artis TA/dTA
	AXIOM Artis TC/dTC
	AXIOM ZEE
	AXIOM ZEEGO
GE	Advantx Series
	Innova Series
	9600, 9800, and 9900
Philips	Allura Xper FD10
	Allura Xper FD20
	Integris Allura Series
Toshiba	Infinix
	Infinix i-series
Shimadzu	Bransist Safire Series
	Digitex Safire Series
	Heart Speed 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	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.

Collect Separately

This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, residents of the European Union must follow specific disposal or recycling instructions for this product. ACIST Europe BV is fully responsible for the coordination, logistics, and costs of the WEEE process. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

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

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

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

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

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