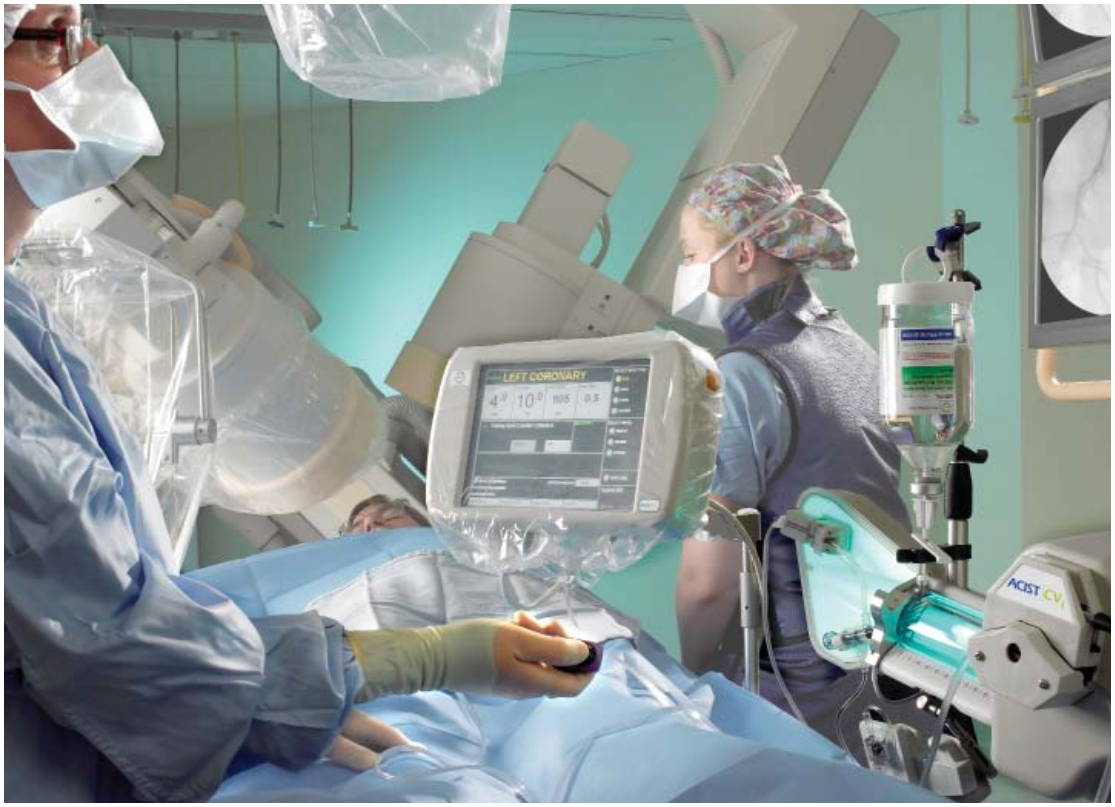
ACIST Contrast Delivery System User Manual

ACIST CV$_i$™



and CMS2000 and E2000Voyager™

ACIST®

BRACCO

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Information & Warnings

Contact Information

Contact Information			
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FAX Number	1-866-272-1619	+ 31.43.328.1329	Contact your local ACIST distributor
Ordering systems and accessories	Call 952-941-3507 or 952-995-9300 for Representative nearest you	00800.2247.8387 + 31.43.328.1318	Contact your local ACIST distributor
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About this manual

This manual is intended to guide you in the proper installation, use, and care of the ACIST® injection system. The manual contains information for all users of ACIST injection systems, whether you set the controls, direct its use, or interpret its results.

Also refer to the Instructions for Use provided with ACIST patient kits (the syringe, manifold, tubing, hand controller, etc.) for setup instructions and specific warnings and cautions.

Product Definition

The ACIST injection system is an angiographic injection system that supplies radiopaque contrast media to a catheter at a user-determined variable flow rate and volume which can be instantaneously and continuously varied.

The ACIST injection system is designed to comply with MDD/93/42 EEC and EN 60601-X series of safety standards for medical electrical equipment.

Intended Use

The ACIST injection system is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Disclaimers

ACIST Medical Systems reserves the right to change specifications and contents of this manual without obligation.

Protected by one or more of the following U.S. patents and international counterparts: 5,515,851; 5,573,515; 5,800,397; 5,882,343; 5,916,165; 6,221,045; 6,344,030; 6,447,481; 6,626,862; 6,656,157; 6,673,048; 6,746,427; 6,752,789; 6,945,959; 7,101,352; 7,128,729; 7,169,135; D404,717; D412,205. Other U.S. and international patents pending.

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CE
0086

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17ZM

ACIST is a trademark of ACIST Medical Systems, Inc., registered in the United States.

CAUTION: Federal Law (USA) restricts the sale of this device by or on the order of a physician (or properly licensed practitioner).

For proper operation, use only accessories and options provided by ACIST Medical Systems, which are designed specifically for the ACIST Angiographic Contrast Delivery System. This ensures compatibility with the injector. Do not use an accessory or option designed for another system on the ACIST Angiographic Contrast Delivery System.

SAFE USE

ACIST Angiographic Contrast Delivery System is designed to aid the physician in the injection of contrast media during angiography. It should be used with adequate radiographic imaging and where monitoring equipment for blood pressure and the electrocardiogram is available. Additionally, standard equipment for cardiopulmonary resuscitation and drugs for the treatment of contrast media-induced drug reactions should be present.

Due to the type of procedures in which the ACIST System is used, (angiographic studies of human cardiovascular and central venous systems) or procedures in interventional radiology or in endovascular surgery), it is necessary that the ACIST 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, defibrillation unit, etc.) is on site for immediate response to patient distress.

PHYSIOLOGICAL PRESSURE TRANSDUCER (OPTIONAL)

Attach the pressure transducer cartridge to the pressure transducer backplate before application of any pressure to the system. This prevents pressures from bursting the membrane and introducing air into the system.

Note: Prior to recording physiological blood pressures with the transducer system, re-zeroing of the transducer is recommended to establish a clear baseline. (Changes in bed height, catheter hub position, fluid density, etc. can affect the baseline pressure.)

Note: Prior to recording physiological waveforms with the transducer system, a saline flush is recommended to clear contrast from the tubing. (Any contrast in the tubing will damp pressure signals.)

Intended Use/ Indication

The ACIST Injection System is intended to be used for the controlled infusion of contrast media for angiographic procedures.

Contra-indications

ACIST Angiographic Contrast Delivery Systems are not intended for use as a long-term infusion pump nor is it intended to be used to inject any agents other than contrast media. ACIST Angiographic Contrast Delivery Systems should not be used to inject substances into nonvascular body cavities.

Any applications of the ACIST Angiographic Contrast Delivery Systems (other than those described in the user manual) are inappropriate and should not be attempted.

Do not add any components (e.g., manifolds, connector tubing) into the ACIST disposable kits or in conjunction with the catheter. No valves or other manifolds may be placed in-line between the ACIST Angiographic Kit and catheter. The disposable kits are designed, manufactured, and tested for connection to catheters used in angiographic procedures.

Do not use ACIST Angiographic Contrast Delivery Systems in the presence of flammable gases.

Please read and understand all the following warnings and precautions before proceeding with installation, setup and operation of the ACIST system.

Warnings

AIR COLUMN DETECT SENSOR

The ACIST System is equipped with an air column detect 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.

AIR EMBOLISM

An air embolism can cause patient injury or death. Operator vigilance and care, combined with a set procedure, are essential to avoid injecting air and causing an air embolism. Before injecting, be sure to clear air from the entire patient kit and angiographic catheter. Make sure the exterior of the tubing is dry before inserting it into the air column detect sensor; if any fluid is present, they may inhibit the ability of the sensor 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.

CABLES

Be sure to plug each cable into the correct connector. Never touch the pins on the connector or cable (See "Making Cable Connections on Page 18"). Do not use the ACIST system if any worn cords or cables are detected. For replacement information, Contact an ACIST representative.

CATHETERS

Connections to the patient are to be made from commercially available catheters that have been approved for angiographic studies. For information on pressure settings and limits, refer to instructions provided by the catheter manufacturers.

CLEANING

To avoid shock and prevent damage to the ACIST 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 ACIST system is completely dry before applying power. For more information, see “System Maintenance,” starting on page 51.

ELECTRICAL ISOLATION

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

FLAMMABLE GASES

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

HIGH FLOW RATE INJECTIONS

High flow rate injections can cause patient injury or death. Use extreme care when setting the flow rate to avoid unintentionally setting a high flow rate injection. When high flow rate injection is required, be sure to select a pressure setting that does not exceed the rated pressure of the selected catheter.

INJECTION SYSTEM SETTING

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

MOUNTING SYSTEM

The system must be mounted using ACIST approved mounting assemblies, such as the Pedestal cart (see page 12) or the Patient Table (Bed) Rail Mount (see page 12). Use of non-approved mounting equipment may cause injury.

PROPER USE OF PATIENT KITS

- Do not use the patient kits on more than one patient.
- Do not allow the disposables to sit, without use, for more than the maximum time recommended by the contrast manufacturer.
- Do not reuse the syringe kit with the CL100H system.
- Do not use the multi-procedural syringe kit with the CMS2000 or Voyager for more than five (5) procedures.
- Do not allow the syringe kit to sit loaded with contrast longer than the maximum time recommended by the contrast manufacturer.
- Do not use the multi-procedural syringe kit for more than five (5) procedures.
- Replace the automated manifold and hand controller kits after each procedure.
- Properly discard disposables in accordance with all local, state, and federal regulations, codes and directives.

SHOCK HAZARD

Hazardous voltage exists within the ACIST system. To avoid shock, only trained, qualified service personnel should service the ACIST system. Always disconnect the system from line power before attempting to perform any maintenance. Never touch any pins on connectors or cables that have become disconnected from a live system.

SYSTEM MESSAGES

Respond appropriately to all system messages. If the message cannot be cleared, contact an ACIST representative. For more information, see “Troubleshooting,” starting on page 58.

Precautions

ACCESSORIES

For proper operation, use only accessories and options provided or specified by ACIST Medical Systems which are designed specifically for the ACIST system. This ensures compatibility with the device.

PATIENT TABLE (BED) RAIL MOUNT

Failure to securely clamp the instrument to the patient table (bed) may result in serious injury. For optimal displacement of weight, the ACIST system should be mounted per the bed manufacturer’s recommended placement. Before mounting the ACIST system on the bed, consult bed specification to ensure that bed rails can support the system.

CONTROL PANEL TOUCH SCREEN

Touch the touchscreen in one place only when programming. If the touchscreen is touched in two places simultaneously, a selection located at the midpoint between them may be inadvertently activated or selected.

ELECTROMAGNETIC/ELECTROSTATIC INTERFERENCE

The ACIST system may fail to operate appropriately if exposed to high electromagnetic fields (which may be generated by sources such as radio transmitters and cellular phones), or to high levels of electrostatic discharge.

EXCESSIVE INJECTIONS

When doing a large number of high pressure, high-volume injections or a very large number of 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 this device.

INJECTION SYSTEM TEMPERATURE

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

LEAKAGE CURRENT

If the chassis leakage current is above 100 microamperes, do not use the ACIST system. Contact an ACIST representative.

LINE POWER

Check for proper voltage and frequency before plugging the ACIST system into an electrical outlet. Be sure the voltage selection plug on the power supply’s power entry module is in the correct position before plugging into a wall outlet.

LOCK BUTTON

The ACIST system is locked to its mount when the locking knob is fully clockwise. The system should always remain locked to its mount except during transfer between mounts, e.g., when transferring from the patient table (bed) to the cart. For more information, see “Mounting Configurations” on page 13.

LOCKING WHEELS

After moving the ACIST system using the pedestal cart, lock the wheels to prevent unintentional movement when the cart is stationary.

SALINE PUMP

The tubing must be properly installed in the injector head and the locking V-teeth engaged on the tubing for proper operation of the pump and system. (See page 28)

PRESSURE TRANSDUCER (OPTIONAL)

Attach the pressure transducer cartridge to the transducer backplate before application of any positive pressure to the system. This prevents pressures from bursting the dome membrane and introducing air into the system.

PREVENTATIVE MAINTENANCE

To ensure that your ACIST system is in optimal working condition, annual preventative maintenance is recommended. Contact ACIST Medical Systems for information on extended warranty options (see page 73).

PROPERTIES OF CONTRAST

For correct function of the ACIST system, make sure that the contrast has its viscosity maintained between 26.6 centipoise and 4.6 centpoise for all functions at the temperature used.

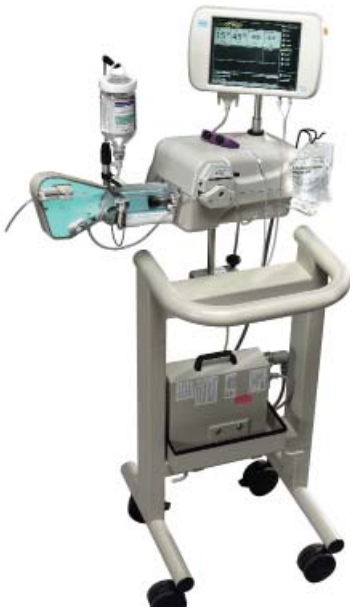
THE MOUNTED INSTRUMENT

Never lean, grab or place objects on the ACIST System. When transporting the system, guide it using the pedestal cart handrail only. Do not grab or push on the system itself. Make sure safety latch knob is tightened in the clockwise rotation and the unit is secure on the cart. For power supplies that are off the patient table (bed) mount, be sure that the power supply is in the cart tray during transportation.

TRAINING

ACIST Medical systems recommends instruction for all qualified persons prior to operating of the ACIST system. A certified ACIST Medical systems representative will conduct training.

Section 1: System Overview



Introduction

The ACIST® injection system is an angiographic injection system used in interventional cardiology, radiology, and vascular surgical procedures. The ACIST injection system supplies radiopaque contrast media to a catheter at a rate that can be instantaneously and continuously varied by the user. The ACIST injection system contains the following primary components:

- Power supply
- Control panel
- Injector head
- Cables

Angiographic patient kits (also referred to as the “disposables”) provide the interface between the ACIST injection system and the angiographic patient catheter. Patient kits consist of several components including a hand controller, high pressure (injection) tubing, a syringe assembly, and a manifold assembly. For more information on the patient kits used with the ACIST injection system, see page 11. The patient kits are sold separately and can be ordered from your ACIST distributor.

This document is designed to orient lab personnel in setting up, using, and troubleshooting the ACIST injection system. Each part of the system is described in detail in this manual. Step-by-step procedures for using the system are also presented.

A More Detailed Look

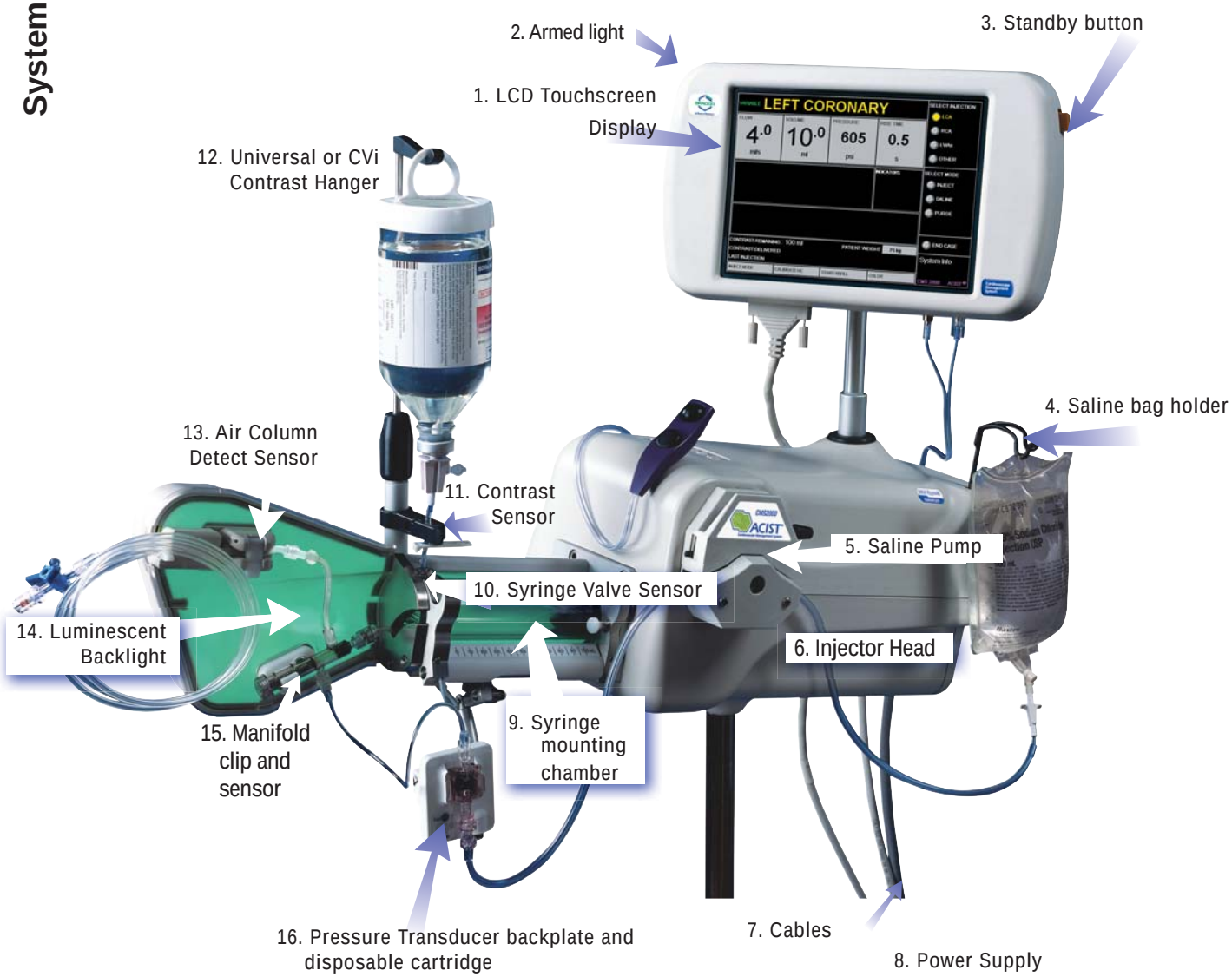
The ACIST injection system contains a motor-driven pump that delivers contrast media to a patient catheter. You can control the flow rate of the contrast media using a user-actuated proportional control device–the AngioTouch® Hand Controller. The hand controller enables you to provide variable or fixed rate control when dispensing contrast media. When using the variable rate feature, the system allows you to vary the flow rate of the contrast media from the injector while simultaneously observing the angiographic procedure on a angiographic monitor.

Before the system is used, the patient kit disposables are loaded onto the injector and the system is prepped with contrast and saline. A touchscreen control panel allows you to uniquely configure the various injection parameters.

The ACIST CMS2000, Voyager and CVi injection systems include disposables that are designed to be used for multiple procedures. A single syringe can be used in up to five cases. This reduces kit costs and saves contrast that would normally be discarded at the end of each procedure.

The ACIST Voyager and the ACIST CVi injection systems are able to synchronize with certain X-ray imaging systems from Siemens, Toshiba, GE, and Philips. (For specific models and series, refer to Section 11. When interfacing to Siemens X-ray systems, a special Siemens power supply is required (see “Making Cable Connections” on page 18).

System Components, Hardware

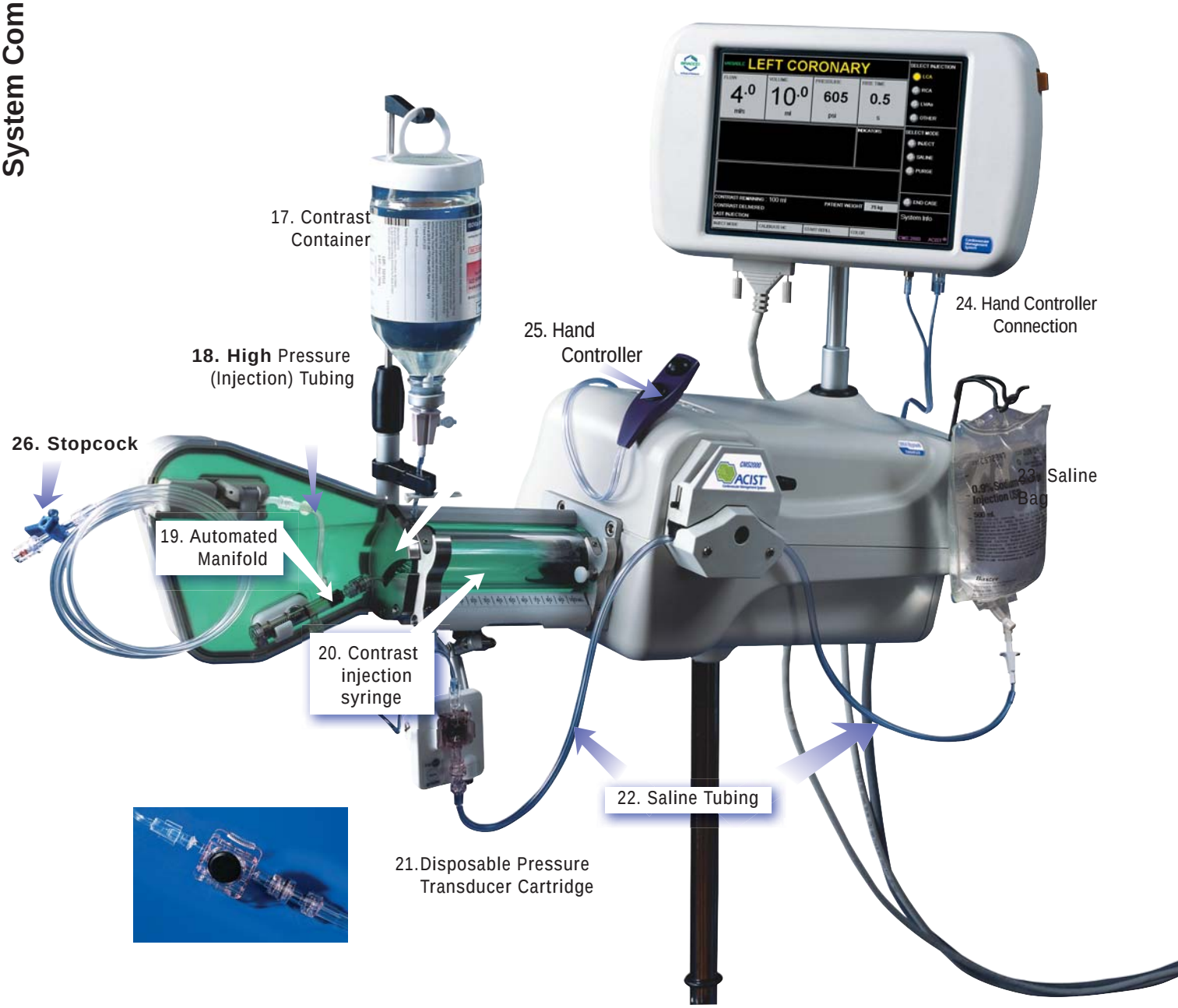


1. **Control Panel with LCD Display**
   This is an interactive screen used to control injection parameters and use of the device. This screen can be calibrated during setup if needed.
2. **Armed light**
   A green light on the top of the control panel that indicates the system is armed and ready to inject.
   (**Note:** On some systems, the armed light is on the right side of the control panel.)
3. **Standby button**
   When the Standby button is depressed, the system is immediately disabled. Pressing the Standby button again reverses the action.
4. **Saline bag holder**
   For hanging the saline bag.
5. **Saline (peristaltic) pump**
   Controls the flow of saline into the patient.
6. **Injector Head:** The part of the device that contains the electroics, including the computer system, the injection motor control, saline pump control, and the control panel.
7. **Cables:** Used to connect the various components of the system
8. **Power supply:** The power supply supplies power to the ACIST System, and provides electrical safety isolation between the main power and the ACIST System.
9. **Syringe mounting chamber**
   The mounting chamber has demarcations to assist you in determining the amount of contrast present in the syringe.
10. **Syringe valve sensor**
    (Located on top of the mounting chamber; connection is plugged in underneath) Detects if the system is ready to inject contrast to the patient.
11. **Contrast sensor**
    Detects if contrast remains for filling operations.
12. **Universal or CVi contrast hanger**
    Holds the contrast container.
13. **Air column detect sensor**
    An ultrasonic detection device used to aid the user in detecting and preventing air from being introduced into the patient.

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

14. **Luminescent back light**
    Located behind the syringe and disposable, the lighting facilitates visual air column detection.
15. **Manifold clip and sensor**
    Automatically switches between high and low pressure ports eliminating the need to switch manifold stopcocks. Ensures that the patient blood pressure is monitored any time fluid is not being dispensed (when using a pressure transducer).
16. **Pressure Transducer Backplate and Disposable Cartridge (Optional)**
    Used for pressure measurement when mounted in the backplate.

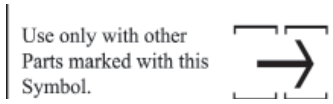
System Components, Disposables



17. **Contrast container**
    Contains the contrast media.
18 **High pressure (injection) tubing**
    Connects with patient catheters for contrast or saline injection.
19. **Automated Manifold**: Regulates the distribution of contrast media and saline.
20. **Contrast Injection Syringe**
    The contrast syringe is a self-purging syringe and has one port for filling of contrast and purging of air, and a second port for injection of contrast.
21. **Disposable Pressure Transducer Cartridge**
22. **Saline tubing**
    Carries saline from the saline bag.
23. **Saline bag**
    For flushing the system and catheters through the use of the saline pump.
24. **Hand controller connection**
    Connects the hand controller to the touchscreen
25. **Hand controller:** The device used to inject contrast and to dispense saline.
26. **Stopcock:** Regulates the flow of fluids to the patient.

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

In addition to the manufactured date label, newer model ACIST hardware components also will carry this label for easy identification:



The exception to this rule are the CVI Adjustable Arm, the CVi Utility Tray and the CVi Contrast Hangar. Instructions for installing these components on pages 16 and 17.

The CL100H disposables are designed to be used per procedure and this injection system does not have synchronization capability.

Available Models

- **CL100H:** This is an early model that is no longer available for sale.
- **CMS2000:** The ACIST CMS2000 system is designed for use in cardiac procedures to inject contrast into the patient's vasculature. **This model does not** synchronize with any X-ray system
- **Voyager™ E2000:** The ACIST Voyager E2000 is designed for use in peripheral vascular procedures to inject contrast into the patient's vasculature.This model does synchroize with certain X-ray systems. For specific models and series, refer to Section 9.

  Note: Syrchronization is only possible provided the proper x-ray interface cable is also purchased and installed with the Voyager E2000.
- **ACIST CVi™**: The latest model available from ACIST Medical Systems, the ACIST CVi combines the capabilities of the CMS2000 and the Voyager E2000 on the same device. The ACIST CVi may function in either in cardiac or peripheral modes Peripheral mode provides x-ray sychronization feature. For specific models and series of x-ray systems, refer to Section 9.

  Note: Synchronization is only possible provided the proper x-ray interface cable is also purchased and installed with the ACIST CVi.

Injector Head Electronics

The Computer System

The electrical control system includes a digital computer that receives input signals from the control panel and provides signals to display data, alerts, status information, and operator prompts.

The computer system consists of two microprocessors. Major functions such as the injection motor movement and saline pump motor movement are monitored by both microprocessors. The computer system controls the motion of the syringe plunger through a motor drive circuit that includes a motor, a motor amplifier, an optical encoder, a potentiometer, and an A/D converter.

Injection Motor Control

The injection motor amplifier provides a drive signal to the motor in response to a control voltage. Forward, reverse, and brake signals come from the computer, and a speed feedback signal from an optical encoder is used to control speed. The outputs of the optical encoder and potentiometer are supplied to the computer through an A/D converter as speed monitor and position monitor signals. These allow the computers to check motor speed, motor direction, and position (volume is a calculated value).

Saline Pump Control

The saline pump is driven under the control of the computers through the pump motor and the motor driver. The computer supplies a drive signal to the motor to operate the pump for saline flush and KVO operations.

The Control Panel

The control panel consists of the touchscreen, a standby button, audible indicators, and an armed light. It also has connectors for connection to the injector head and the hand controller. The control panel can be mounted on the injector head or on a patient table (bed) rail mount. The control panel has a swivel base, allowing it to be easily rotated to a position for optimal viewing.

Standby Button

When you press the Standby button it immediately disables the operation of the ACIST injection system. To re-enable the system you press the Standby button again, then press OK on the screen. When the Standby button is engaged the system will not inject contrast. This is indicated by the NO INJECTION icon on the face of the button.

Armed Light

A green light illuminates when the system is ready to perform an injection.

Control Panel Cable Connection

This connector is used to connect the injector head to the control panel.

Hand Controller Connection

These connectors are used to connect the hand controller to the control panel.

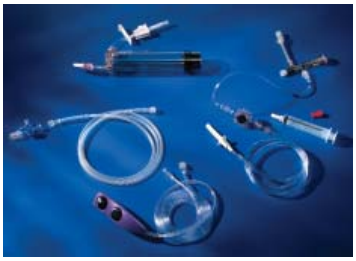
Touchscreen Display

The touchscreen serves as the user interface, providing operator prompts, status information, and alerts. The touchscreen also allows you to enter commands and to make various parameter selections.

The AngioTouch® Hand Controller

The AngioTouch Hand Controller lets you precisely control the volume and rate of contrast that is delivered to the patient. It does this by delivering an amount of contrast that is proportional to the amount of force exerted on the Contrast button. The hand controller eliminates the distractions that can occur with more traditional methods and it frees you to monitor the patient. The hand controller also allows you to step away from the table during the injection, thus reducing possible exposure to radiation.

The hand controller contains two buttons. The top button allows control of the contrast media and the bottom button allows control of saline.



The ACIST Angiographic Kit

For more information, see the Instructions for Use document packaged with each box of patient kits.

The patient kits are custom designed and manufactured. Each is provided sterile and pre-assembled, minimizing the possibility of interconnection in the wrong manner while ensuring positive connections. All patient kits are for single-use only, except for the multi-procedural use syringe assembly designed for the CMS2000, Voyager and ACIST CVi.

Kit components include:

1. Contrast spike
2. Hand syringe
3. Manifold
4. Saline spike and tubing
5. Disposable transducer cartridge (optional)
6. Dual port injection syringe
7. 3-way high pressure stopcock
8. High pressure (injection) tubing
9. AngioTouch Hand Controller

Contrast Media Requirements

The ACIST injection system is to be used with contrast media that has a viscosity between 26.6 and 4.6 centipoise. It also must be used with angiography catheters that are appropriately rated for pressure and flow rate, as indicated the Injection Parameter Table on page 36 In addition, follow the instructions for use provided by the catheter manufacturers.

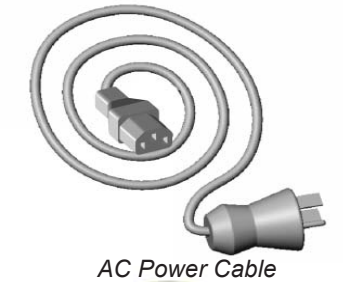
Cables

Cables for Standard Power Supply

The following cables are provided with an ACIST injection system that is using a standard power supply:

- Medical grade AC power cable to connect power supply and electrical outlet for 110V or 220V
- DC power cable to connect power supply and injector head.
- Cable to connect injector head and control panel.
- (Voyager and CVi only) X-ray Imaging system interface cable to connect injector head and the imaging system specific to the manufacturer.

Note: Specific cables may be needed, depending on the imaging system. For more information, contact an ACIST representative.

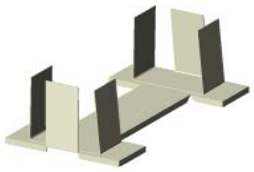


AC Power Cable

DC Power supply/injector head cable

Injector head/control panel cable

Acist pressure monitoring interconnect cable



Floor Stand for power supply

Cables for Siemens Axiom Artis Imaging System

The following cables are provided with an ACIST injection system (Voyager and CVi only) that is connected to a Siemens Axiom Artis imaging system:

- Cable from the power supply connecting the ACISt System to the Siemens X-ray equipment
- Cable to connect ACIST injector head to power supply, power
- Cable to connect ACIST injector head to control panel
- Cable from the power supply connecting the ACIST system to the Siemens X-ray equipment

The above cables are also used with other Siemens systems with the addition of an adaptor cable for cable from PS to X-ray to be used with older x-rays systems.

Description of Accessory Items

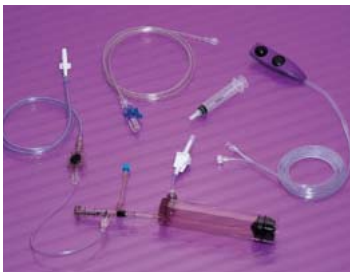
The following accessory items are used with the ACIST injection system and are described in the following sections.

- Disposable patient kits
- Power supply cables
- X-ray interface cables
- Pedestal cart
- CVi Utility Tray (standard on ACIST CVi models)
- CVi Adjustable arm -TABLE MOUNT ONLY (standard on ACIST CVi models)
- CVi Easy-adjust contrast hanger (standard on all ACIST CVi models)
- Cart tray to hold power supply
- Table mounting brackets (for control panel and injector head)
- Patient table (bed) rail mounts
- Pedestal cart
- Floor stand for power supply
- Acist pressure transducer backplate
- Pressure monitoring interconnect cable

Patient Kits

The patient kits are custom designed and manufactured. Each kit is delivered sterile and pre-assembled, minimizing the possibility of interconnection in the wrong manner while ensuring positive connections. All patient kits are for single-use only, with the exception of the multi-use syringe assemblies used with Models CMS2000, Voyager and ACIST CVi.

For more information, see the Instructions for Use document packaged with each box of patient kits.

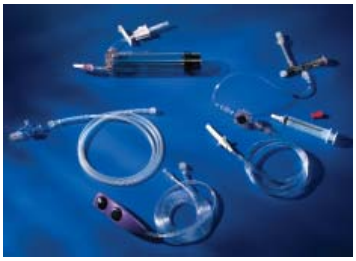


CL100H Patient Kit

Model CL100H

The following patient kit is required for use with the ACIST model CL100H:

- A single-use Syringe/Manifold Assembly Kit containing a contrast injection syringe, contrast spike, automated manifold, saline tubing, saline spike, pressure transducer cartridge, hand syringe.
- AngioTouch Hand Controller, high pressure (injection) tubing, and three-way high pressure stopcock.



CMS2000, Voyager and CVi Kit

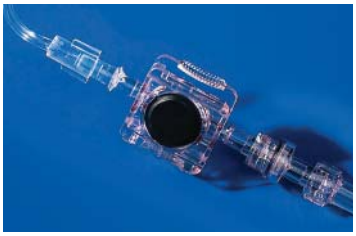
Models CMS2000, Voyager, and ACIST ACIST CVi

The following patient kits are required for use with the ACIST models CMS2000, Voyager, and ACIST CVi:

- A multi-use Syringe Assembly Kit containing a contrast injection syringe and a contrast spike assembly. This kit can be used for up to five procedures.
- An Automated Manifold Kit (with or without a disposable pressure transducer cartridge) containing an automated manifold, saline tubing, saline spike, and other components.
- An AngioTouch Hand Controller Kit containing a hand controller, high pressure (injection) tubing, and stopcock.

ACIST Pressure Transducer Cartridge

Some manifold kits contain a disposable “snap in” pressure transducer cartridge that can be used with pressure monitor to record pressure waveforms. The pressure transducer cartridge provides a sealed membrane barrier between the fluid path and the Acist pressure transducer backplate, allowing the transmission of pressure waveforms while maintaining a sterile barrier. The ACIST injection system can be ordered with a pressure transducer backplate sensor that is used to hold the disposable pressure transducer cartridge.



Disposable pressure transducer cartridge

Pressure Monitoring Interconnect Cable

A pressure monitoring interconnect cable provides the signal connection from the ACIST-supplied pressure transducer backplate to the monitor or trace equipment. The interconnect backplate cable part number depends on the make and model of the hemodynamic monitoring equipment used. Contact ACIST Medical Systems to obtain the pressure monitoring interconnect cable.

Pressure monitoring interconnect cable

Pedestal Cart

Utility Tray

Adjustable Arm

Cart Tray

Control Panel Patient Table Rail Mounting Bracket

Injector Head Patient table (bed) Rail Mount Bracket

CVi Adjustable Arm Bed Rail Mount Bracket

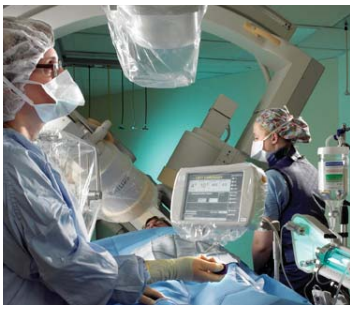
Pedestal Cart

The pedestal cart makes the system readily transportable.

Patient table (bed) Rail Mounts

Two patient table rail mounts allow flexible mounting configurations. The injector head mounting bracket allows the injector head, with or without a control panel to be mounted on a table (bed) rail.The control panel mounting bracket allows only the control panel to be mounted on a patient table (bed) rail. The CVi table rail mount allows the adjustable arm to be mounted on a bed rail.

Section 2: Installation



Setup

The ACIST injection system is an angiographic injection system that supplies radiopaque contrast media to a catheter at a user-determined variable flow rate and volume which can be instantaneously and continuously varied.

The ACIST injection system is designed to comply with the EN 60601-X series of safety standards for medical electrical equipment.

Review all Warnings and Cautions in the Information and Warnings section of this manual before setting up the system.

Installing the System

Upon system delivery:

- Inspect the packaging immediately upon receipt.
- Assembly and installation of the ACIST System are to be performed only by individuals trained and certified to perform this function by ACIST Medical Systems.

Mounting Configurations

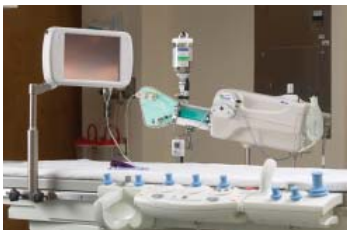
The ACIST injection system, injector head and control panel can be mounted in a variety of configurations:

- On a movable cart
- On a patient table (bed) rail

To give the operator control of all aspects of contrast delivery and to allow the lab staff easy access to the injector head for setup and troubleshooting, ACIST Medical Systems notes the following common installation configurations:

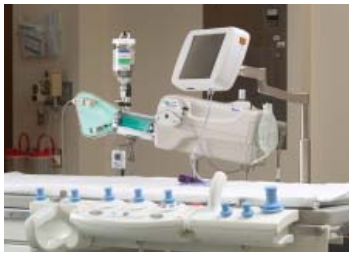
- The injector head located on the side opposite the operator, convenient for disposable tubing handling and viewing.
- The control panel mounted directly across the table from the operator of the control panel and hand controller.

Cart mount configuration



Control Panel on clinician's side of patient bed

Control Panel on top of injector

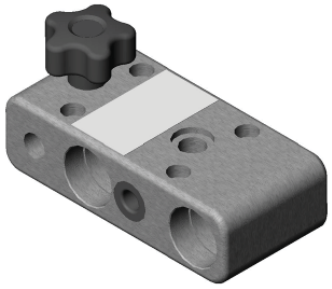


Control Panel on far side of patient bed.

CAUTION: Make sure power is off when moving the ACIST System. Before mounting the ACIST System on a patient table (bed), consult the patient table (bed) manufacturer's specification to ensure that patient table (bed) rails can support the weight. See "Weight" on page 71.

Failure to securely clamp the ACIST injector head to the patient table (bed) may result in serious injury.

CAUTION: If you are using a movable cart, after moving the system be sure to lock the wheels to prevent unintentional movement.



U-joint

Position cart in front of the bed rail on the patient table.

Lock wheels on the cart.

Unlock the knob on the U-Joint by turning it counter-clockwise and pressing down

Carefully slide the injector head onto the patient table.

Tighten the lock knob.

Injector Head from Pedestal Cart to Patient table (bed) Mount (2 Options)

Note: Before mounting the injector head to the patient table (bed), ensure that the patient table (bed) mount is correctly positioned on the patient table (bed) rail. The locking pin of the patient table (bed) rail will be situated to the right and the lock knobs tightened. The metal U-Joint is bolted to the shaft at the base of the injector head.

Option 1—When mounting the injector head to the patient table (bed) rail from the pedestal cart:

1 Maneuver the cart so it is positioned in front of the patient table (bed) rail. (See photo at left.)

2 Lock the wheels on the cart. (See photo at left.)

3 Raise or lower the patient table (bed) so the patient table (bed) rail is the same height as the U-Joint.

4 Unlock the knob on the U-Joint by turning it counter-clockwise and push down to disengage. (See photo at left.)

5 Carefully slide the injector head forward from the cart onto the patient table (bed) rail. (See photo at left.)

6 Ensure the U-Joint is correctly positioned and tighten the lock knob to secure it to the patient table (bed) mount. (See photo at left.)

Option 2—If the patient table (bed) is unable to be raised or lowered to match the height of the U-Joint of the cart mounted injector head.

(Transfer requires 2 people)

1 Maneuver the cart in an accessible position for transfer.

2 Lock the wheels on the cart.

3 Unlock the knob on the U-Joint by turning it counter-clockwise and push down to disengage.

4 Carefully remove it from the cart by cradling with your arms under the injector head.

5 Push it onto the patient table (bed) rail mount carefully.

6 After the U-Joint has engaged the patient table (bed) mount, secure it by tightening the lock knob.

For power supply off the Patient table (bed) Mount configuration: Remove the power supply, from the tray of the pedestal cart and place it on the floor on the power supply stand.

After docking has been successfully completed, unlock the casters on the pedestal cart and pull the cart away from the bedside and store it in a safe location.

Position cart in front of the bed rail on the patient table.

Lock wheels on the cart.

Unlock the knob by turning it counter-clockwise and pressing down

Carefully remove the injector head from the patient table bed raild by cradling it in your arms.

Push it onto the pedestal cart carefully.

Tighten the knob on the U-Joint

Transfer Injector Head from Patient table (bed) Mount to Pedestal Cart (2 Options)

Option 1—When mounting the injector head to the pedestal cart from the Patient table (bed) Mount:

1 Maneuver the cart so it is positioned in front of the patient table (bed) rail.

2 Lock the wheels on the cart.

3 Raise or lower the patient table (bed) so the patient table (bed) rail is the same height as the U-Joint on the pedestal cart.

4 Unlock the knob on the U-Joint by turning it counter-clockwise and push down to disengage.

5 Carefully slide the injector head forward from the patient table (bed) rail onto the pedestal cart.

6 Ensure the U-Joint is correctly positioned and tighten the lock knob to secure it to the pedestal cart.

7 Place the power supply on the cart.

8 If you need to move the cart, unlock the wheels, and lock them again after you have moved the cart.

Option 2—If the patient table (bed) is unable to be raised or lowered to match the height of the U-Joint of the pedestal cart

(Transfer requires two persons)

1 Maneuver the cart in an accessible position for transfer. (See photo at left.)

2 Lock the wheels on the cart. (See photo at left.)

3 Unlock the knob on the U-Joint by turning it counter-clockwise and push down to disengage. (See photo at left.)

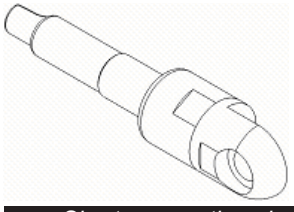
4 Carefully remove it from the patient table (bed) mount by cradling with your arms under the injector head. (See photo at left.)

5 Push it onto the pedestal cart carefully. (See photo at left.)

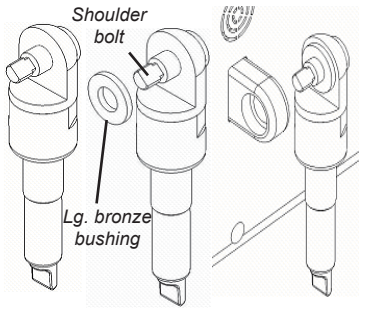
6 After the U-Joint has engaged the patient table (bed) mount, secure it by tightening the lock knob. (See photo at left.)

7 Place the power supply on the cart.

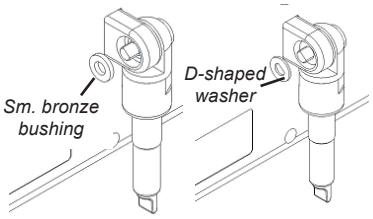
8 If you need to move the cart, unlock the wheels, and lock them again after you have moved the cart.



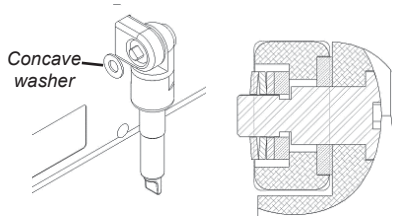
Shorter mounting shaft



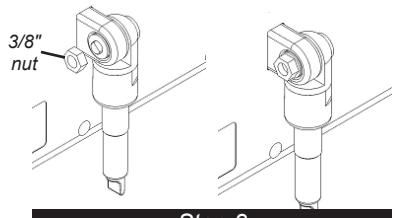
Steps 2, 3, 4



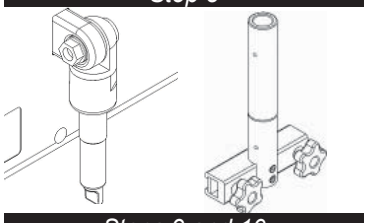
Steps 5 and 6



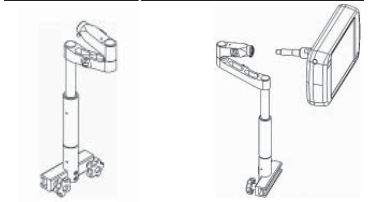
Step 7



Step 8



Steps 9 and 10



Steps 11 and 12

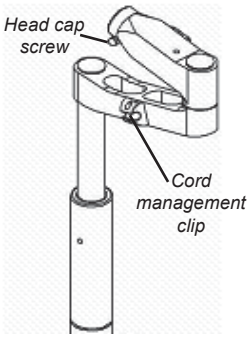
Installing the CVi Adjustable Arm with the Voyager, CMS2000, and CL100H ACIST Systems

CAUTION: For Table Mounting Only

If you elect to use the optional adjustable arm, you can install it by performing the following steps. All parts are provided in the adjustable arm accessory kit.

1. Remove the original mounting shaft from the control panel and dispose of all nuts, bolts, washers, and bushings.
2. Locate the new (shorter) mounting shaft.The original (longer) mounting shaft can be used, but the control panel will be extended approximately 6 inchs in from the retracted position of the arm.
3. Insert the shoulder bolt through the mounting shaft and then slide the large bronze bushing over the shaft of the bolt.
4. Insert the mounting shaft and shoulder bolt into the back of the control panel.
5. Slide the small bronze bushing and then the D-shaped washer onto the bolt.
6. Slide one concave washer onto the bolt, with the concave end towards the D-shaped washer.
7. Slide the other concave washer onto the bolt with the concave end away from the D-shaped washer.
   If installed correctly there should be a slight gap between the concave washers near their centers.
8. Place the 3/8” nut onto the bolt and tighten.

   Set the control panel aside for the moment.
9. Attach the patient table (bed) mount to the patient table (bed) rail.
10. Insert the height extension into the patient table (bed) mount.
11. Insert the adjustable arm into the extension piece.
12. Retrieve the control panel, insert the mounting shaft into the adjustable arm socket, and then tighten the bolt on the back of the control panel until the desired rotational stiffness is reached.
13. Lock the control panel into the adjustable arm by tightening the head cap screw (located below the adjustable arm socket).
14. Snap the control panel cord into both cord management clips.



Installing the CVi Adjustable Arm with the ACIST CVi

Follow steps 9-11 and 13-14 above.


Step 1


Step 2


Step 3


Step 4

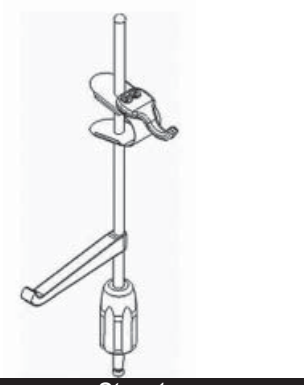
Installing the CVi Utility Tray on all ACIST Systems

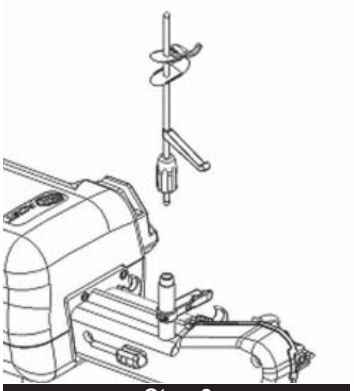
If you elect to use the optional utility tray, you can install it by performing the following steps. All parts are provided in the utility tray accessory kit.

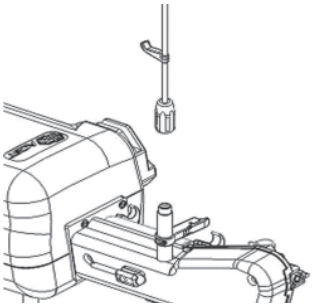
1. Clean the tray and the bracket with the alcohol wipe.
2. Place the tray on the bracket, aligning the embossed (molded) areas.
3. Remove the liner from the tape on the bracket.
4. Attach the bracket to the bottom of the injector head. Position it to the left side of the “V” formed by the bottom of the injector head.
5. Press and hold for 10 seconds.

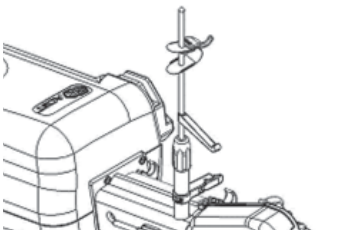
Installing the CVi Contrast Hanger on all ACIST Systems

1. Remove new hanger assembly from bag
2. Untighten and remove old hanger assembly from the injector head.
3. Install new hanger assembly.
4. Tighten.


Step 1


Step 3


Step 2


Step 4

Voltage Selection Plug

Voltage set to 110

Making Cable Connections

Power and communication between ACIST System components is provided by cables. How you make the cable connections depends on which of the two available power supplies you use:

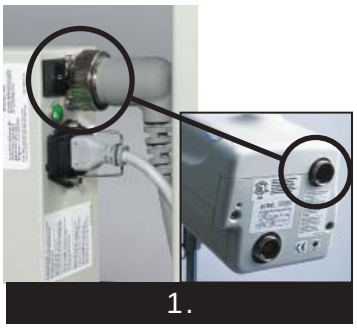
- Standard power supply
- Power supply configured for use with Siemens imaging systems

WARNING: You must make all cable connections before powering on the system.

WARNING: Because of safety considerations, be sure to insert each cable into its own proper connector. Never touch the pins on a connector or cable. Do not use the ACIST injection system if any worn cables are detected.

Standard Power Supply

CAUTION: The voltage selection plug, located on the power entry module, identifies the power supply selection (100-120 VAC or 200-240 VAC). Be sure the voltage selection plug is in the correct position before plugging the system into a wall outlet. If possible, use a separate circuit for the ACIST system. Extension cords are not recommended for use with the system.



1. With the DC power cable, connect the injector power supply cable to the injector head
   - The DC power cable, with circular connectors and pins, connects from the power supply to the back upper right corner of the injector head.
   - Put lock ring on DC power cable before connection.

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

   The cable interface with circular connectors and sockets connects from the X-ray system to the lower left corner of the injector head.

3.

3. Connect the injector head to the control panel.
   The cable with the rectangular connectors connects from the bottom of the injector head to the bottom of the control panel.

Important: Be sure that the cable from the control panel is not kinked or sharply bent.

4.

Note: Securely tighten the cable screws to the control panel.

4. Connect the AC line power cable to the power entry module on the power supply.

   The appropriate medical grade power cable is supplied with the ACIST injection system. This cable may only be substituted with an equivalent medical-grade power cable.

   Note: On systems interfacing to Philips x-ray systems, the power cord is part of the imaging system interface cord.

Power Supply Configured for Use with Siemens Systems

If using an ACIST injection system to interface with Siemens systems, you must use the ACIST power supply specially configured for Siemens systems, available only in 200-240 VAC (5 amp). This power supply allows the Siemens imaging system to control power to the injector head. With this power supply, input power comes from the input cable (configured for Siemens).

1. Injector head power cable connector
2. Power switch
3. Imaging system interface cable
4. “Power on” light
5. Fuses
6. Connector for input cable to X-ray table

1.

Steps to set up the Siemens Axiom Artis Systems

1. With the DC power cable, connect the injector power supply cable to the injector head
   - The DC power cable, with circular connectors and pins, connects from the power supply to the back upper right corner of the injector head.
   - Put lock ring on DC power cable before connection.

2.

2. Connect the X-ray system interface cable from the injector head to the power supply.

   Put lock ring on DC Cable before conecting

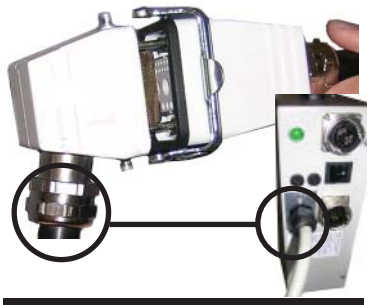
   The cable with circular connectors and sockets connects from the power supply (center right) to the lower left corner of the injector head.

3. Connect the control panel cable to the injector head.

   The cable with the rectangular connectors connects from the bottom of the injector head to the bottom of the control panel.

   Note: Securely tighten the cable screws to the control panel.

3.



4.

4. Connect the input cable to the X-ray table with the attached connector or with the supplied adaptor.

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Section 3: System Setup

Note: The setup example illustrated in this section is based on the ACIST CVi. The setup procedures for other models may be slightly different where noted.

During the setup procedure:

- The ACIST injection system is powered on.
- Disposable patient kits are installed, which includes inserting the syringe assembly, filling the system with contrast, attaching the automated manifold kit and saline bag and contrast tubing and stopcock.
- All lines are purged of air.
- Several items are placed in the sterile field, including:
  (1) the 3-way stopcock;
  (2) the hand controller; and
  (3) the high-pressure injection tubing that will be connected to the system and to a catheter.

The ACIST injection system is designed to prompt you through the setup process. When system power is applied, prompts are displayed on the touchscreen control panel that will guide you through the setup procedure.

Note: Do not power on the system with a disposable patient kit installed. If a kit is installed, an error message will appear instructing you to remove the kit.

1. Use the power switch to turn the system power on.

   The system will take about one minute to boot up. When the power is on, the power indicator (green light) located next to the power switch is also on.

WARNING! In the case of power blackouts, power brownouts, or voltage surges, immediately follow the Emergency Shutdown steps on page 55.

The system starts and the “power-up” screen is displayed

Power Up Screen

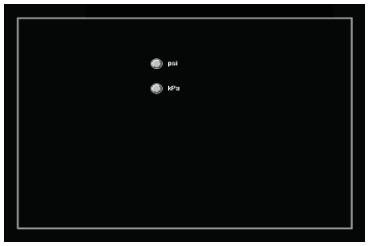
2. Touch the screen **within five seconds** to calibrate the touchscreen.

   If you do not touch the screen within five seconds the calibration step is skipped and you will proceed directly to the language selection screen (Step 4). To return to the Power On screen, simply power the system off and then on again.

Note: It is recommended that you calibrate the touchscreen regularly, approximately once per month or when any shift in sensitivity of the screen is noted.

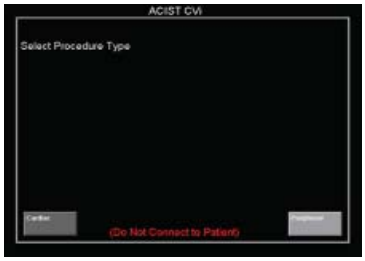
3. To perform the calibration, carefully touch the screen directly on the plus signs (+) that will appear in three separate corners of the screen.
   It is important to touch the three calibration points with precision for an accurate calibration. If calibration is not performed correctly or completely, the calibration will be invalid.

Language selection screen

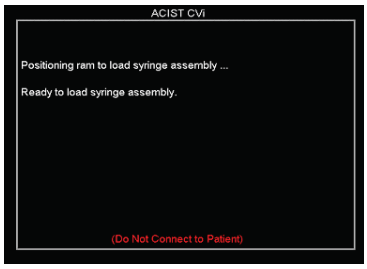


Pressure selection screen

Start screen



CVi Cardiac or Peripheral selection screen



CVi Ready to load syringe screen

Positioning Ram to hold syringe assembly

When the calibration is complete the language selection screen is displayed.

Language Selection Screen

4. To switch to a different language, press the appropriate language button within 5 seconds.

   The software defaults to the last selected language if none is selected in 5 seconds.

   (Optional) If you select a language other than US English, the Pressure Selection screen is displayed. You can select the unit of measure used for pressure: Pounds per square inch (psi) or Kilopascals (kPa). After you select psi or kPa, this unit of measure will continue to display until you change it. The system defaults to the last selected pressure unit if none is selected within 5 seconds.

   The Start screen is displayed.

5. Press START to continue with system setup.

   Note: Do not place the syringe assembly into the chamber until the system completes the calibration process.

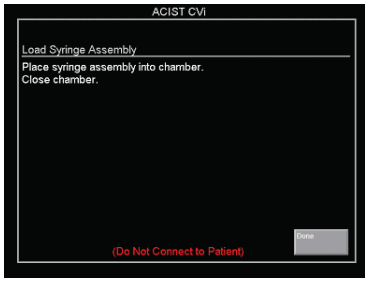
   The Cardiac/Peripheral selection screen is displayed:

6. Select the type of procedure you wish to perform.

   Your selection dictates the set of pre-defined paramater selections that will be loaded into the machine.

   - Cardiac: This option is best suited for heart-related procedures. The following injection types will be made available: LCA, RCA, LV/Ao, and Other.
     X-ray functions are not available.
   - Peripheral: This option is best suited for procedures not related to the heart (for example: arms, legs, kidneys, carotid artery, etc). The following injection types will be made available: Pigtail, Selective, Microcatheter, and Other.
     X-ray system synchonization is available, provided the proper X-ray interface cable is installed.

After selecting the procedure type, ram calibration will begin. After ram calibration the “Ready to load syringe” screen is displayed.



Load syringe assembly screen

The Load Syringe Assembly Screen is displayed when the system is ready to load the syringe assembly:

7. Open the angiographic patient kits
   - Tighten the contrast spike to the syringe assembly.
   - Set aside the package containing the hand controller, high-pressure injection tubing and high-pressure 3-way stopcock. Place these items in the sterile field.
   - Take the syringe and automated manifold kit components from their sterile pouches and remove all caps.

Tighten contrast spike on syringe assembly

8. Open the rotating chamber door by pulling on the white pin and lowering the door.

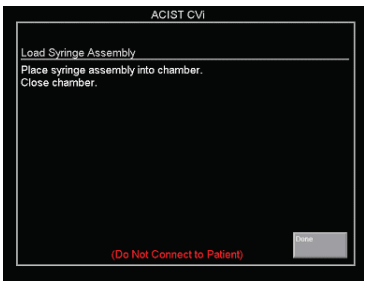
Open the chamber by pulling the white button

9. Insert the syringe into the chamber and then close the chamber door completely, ensuring that the chamber is locked (make sure the white latch pin clicks into place).

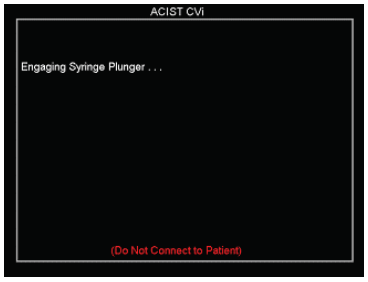
   The chamber door must be closed for the system to function.

Insert the syringe in chamber and close the chamber door completely

10. On the Load Syringe Assembly screen, press DONE.



Load syringe assembly screen



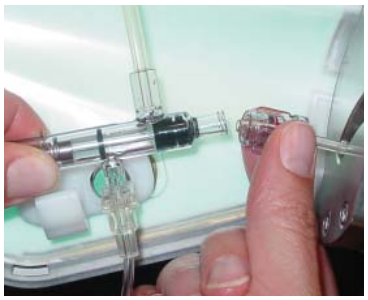
Engaging Syringe Plunger

The Engaging Syringe Plunger screen is displayed.

The plunger will move to the fill syringe position. You may hear motor noise as the plunger advances.

Spike contrast screen

The Spike Contrast screen is then displayed.



Connect manifold to syringe assembly

11. Connect the automated manifold to the syringe assembly.

Clip manifold assembly into the manifold valve sensor

12. Clip the manifold assembly into the manifold valve sensor by rotating the manifold down and inserting it into the manifold clip.

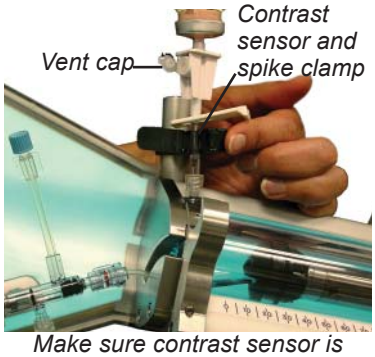
Spike contrast

13. Spike the contrast container, holding the container at downward angle, as shown. When finished, hang the contrast container on the hanger.

    (The contrast hanger rotates to the left and right making it easier to hang the container.)

The Easy-Adjust Contrast Hanger

Note: If your system is equipped with the CVi Easy-Adjust Contrast hanger. one-handed height adjustments can be made to accomodate different bottle sizes. A "light touch" only is needed when pressing the clip and sliding up or down.

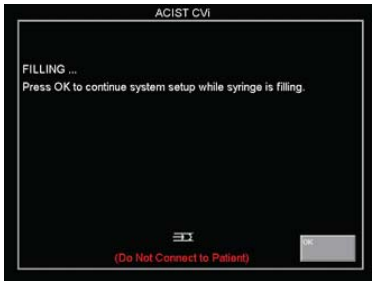


Make sure contrast sensor is securely placed around the spike tubing

14. Place the spike tubing in the contrast sensor.

Important: Note position of the contrast sensor. If you do not place the contrast sensor around the spike tubing and close the latch securely, this will interfere with the ability of the sensor to detect the presence of contrast.

Note: The vent cap on the spike should be open at all times. Also, the white contrast spike clamp should be open whenever the syringe is in use. This will not be prompted by a screen, but it is very important to remember to do so. A closed spike tuing will prevent proper syringe function.



Syringe filling screen

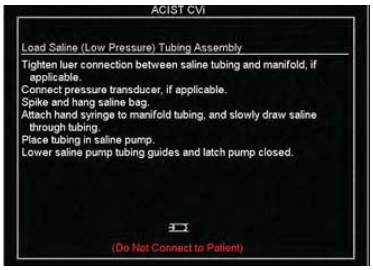
15. To begin filling the syringe, press DONE.

An audible sound will notify you that the system is filling. The Syringe Filling screen is displayed.

16. Press OK.

The Load Saline screen appears. You can read the instructions on the screen and continue with the set-up process while the syringe is filling. After the syringe is filled with at least 25ml of contrast, the Back and Done buttons are added to the screen.

Important: If the syringe does not fill, the screen will say "Purging" and the ram will move a small distance forward and back as the system checks to see if contrast is detected. This occurs when the contrast sensor does not detect the contrast. Make sure the contrast sensor is around the spike tubing and that the tubing is and sensor are clean.



Load saline screen

Note: When using the Syringe Kit on the CL100H, check to see that the luer connection between the saline tubing and the manifold is tight.

17. If you are using the Acist disposable pressure transducer cartridge, connect it to the transducer sensor backplate.

If using a transducer cartridge, connect it to the transducer backplate.

Spike and hang saline bag

18. Connect the spike from the saline tubing to the saline bag and hang the saline bag on the hanger located on the right upper corner of the injector head.

    Important: Make sure the saline bag is fully spiked. Otherwise, air will be introduced into the tubing.

Attach the hand syringe to the manifold and slowly draw saline through the tubing

19. Attach the hand syringe to the manifold and slowly draw saline through the tubing to make sure all air is removed from the lines, the transducer cartridge, and the manifold.

    Tip: The “start, stop, and go” technique often works well for this. Start drawing saline until about 6 inches of saline is in the tubing and then stop. After a brief pause, continue slowly drawing the saline until the entire tubing is full. Remember, drawing at a slow rate will help avoid the formation of air bubbles in the tube.

Place the saline tubing in the saline pump, making sure the black v-teeth guides are lowered on each side and centered over the tubing

20. Open the saline pump door by raising the pump handle and moving it counterclockwise from the right side of the pump to the left side.
21. Place the tubing in the saline pump, leaving some slack on either side of the pump.
22. Position the black v-teeth guides all the way to the bottom and then move them up to the next highest locking position. Verify that the v-teeth are centered over the tubing. The guides hold the tubing in place and prevent kinking.
23. Close the saline pump door by moving the handle from the left side to the right side to its locked position.
24. Remove the hand syringe and empty it into a waste container.
25. Press DONE on the touchscreen.

Purge tubing screen

The Purge Tubing screen is displayed:

26. Re-connect the hand syringe to the manifold tubing or direct the tubing into a waste container.
27. Lightly tap the PURGE button to purge air from the the short section of contrast tubing between the syringe and the manifold.

    Important: The PURGE button is only engaged when pressed.

    The PURGE button is very sensitive and slight taps are sufficient for purging. Removing 2 – 3 cc of fluid is typically sufficient for purging any air.

    While purging, check the tubing and connections for air bubbles. If needed, purge a second time.
28. When the tubing is free of air, press DONE.

Inspect the tubing and make sure it contains no air bubbles

Flush saline tubing screen

The Flush Saline Tubing screen is displayed:

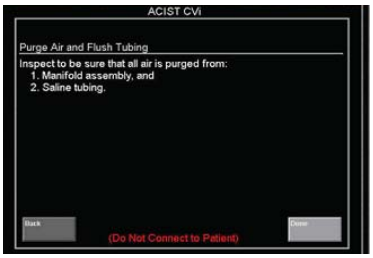
29. Place the tubing end over a waste container or place the hand syringe on the tip of the high pressure (injection) tubing and then press FLUSH. When you have determined that the system is free of air, press CANCEL to stop the process.

    Important: If you are using a hand syringe to collect the saline, you must remember to stop the flushing process before the syringe overfills.

    While the system is flushing, check the saline tubing for air bubbles. Tap on the tubing, the connections, the manifold, and the disposable transducer cartridge as needed to free air bubbles. The system will flush for 10 seconds at 1.66 cc/sec or until the CANCEL button is pressed.

    You can use the small mallet provided on the back of the pump to tap the tubing.
30. Press DONE.

Tap the tubing with the provided mallet or a hemostat



Purge and flush verification screen

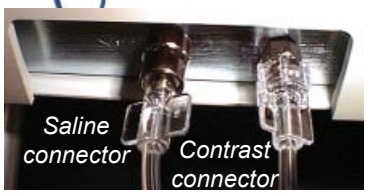
The Purge and Flush Verification screen is displayed.

31. Do a final inspection of the system to make sure that no air is present and then press DONE.

Important: The remaining steps of the setup require a tech or operator to be scrubbed in.

AngioTouch Hand Controller setup screen

High pressure (injection) tubing placed in air column detect sensor



Connect the hand controller to the control panel

The AngioTouch Hand Controller Setup screen is displayed:

32. Apply a sterile drape over the touchscreen.

    This enables the operator or scrub tech to continue the screen setup in the next section.

33. Empty the contents of the hand controller package on the sterile field.

    This package contains the pneumatic AngioTouch hand controller tubing, high-pressure(injection) tubing, and high-pressure 3-way stopcock.

34. The scrub person should hand one end of the high-pressure (injection) tubing to someone outside the sterile field. That person should then attach it to the manifold tubing and then place the tubing through the air column sensor. At the same time the scrub person can connect the 3-way stopcock to the other end of the tubing.

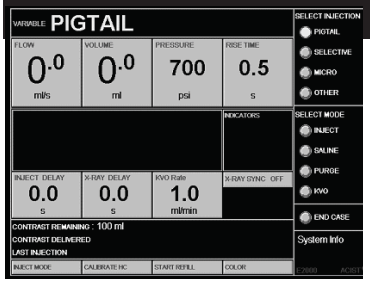
    Note: The air column detect sensor is not a substitute for user vigilance.

35. The scrub person should hand off the two connectors from the end of the pneumatic hand controller so that they can be connected to the control panel.

    The two lines are connected to the bottom right side of the control panel. The control panel can be tipped back for easier access to the connectors.

    Important: Make sure the connections are screwed on straight and tight. Do not over-tighten.

The person who is scrubbed in will complete the following steps. Make sure hand controller connections are tight.



Main Screen

A screen similar to the Main Screen shown at the left is displayed:

Status Window

The black section in the middle of the screen is the Status Window, and is used to display system messages. Interactive messages such as the calibration message shown here are displayed in this section. These messages require a response.

Contrast button

36. To calibrate the hand controller, hold the hand controller in one hand with the thumb in a comfortable position, and with the other hand press OK.
37. Within four seconds, completely depress the top “C” (Contrast) button.

Important: The hand controller must be recalibrated at the beginning of each case.
You have four seconds to calibrate the hand controller before the “calibration failed” message is displayed.

If the hand controller calibration fails, check the tubing connections to make sure they are straight and the tubing to see that there are no kinks in it.

Pressing the contrast button prior to selecting the OK button on the touch screen will also cause a calibration
failure.

Repeat calibration by pressing the Calibrate HC button. This is the second button from the left on the bottom row of the control panel screen.

Calibration failed screen; Calibrate HC button

Purge Air screen

After hand controller calibration and before the first injection of each case, the Purge Air screen is displayed as a reminder to purge fluid and air.

Note: Air in the system can also be removed by flushing with saline.

38. The scrub person flushes the high-pressure (injection) tubing and stopcock with saline to flush air from system.
39. When using a pressure transducer, zero the system with stopcock and transducer at the patient’s mid-axillary (i.e. mid-heart) level.
Open the 3-way stopcock to air and hold it at the patient’s mid-axillary line in order to zero the transducer.

WARNING! Never inject with the stopcock closed.

Setup of the ACIST injection system is now complete

Refer to “Performing Patient Procedures” to purge system with contrast and connect catheter and begin the procedure.

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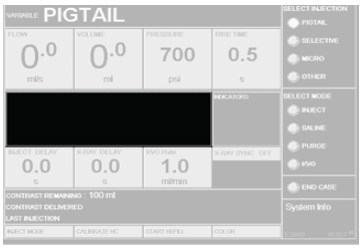
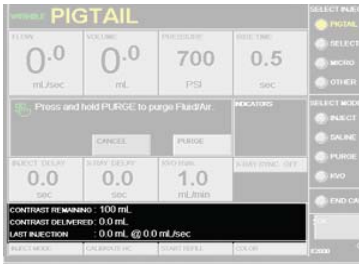
Section 4: About the Touchscreen

1. Injection Parameters



2. Status Window



3. Contrast Remaining
4. Contrast Delivered
5. Last Injection

6. Option Buttons

7. Injection Type Buttons

The touchscreen allows you to select the appropriate injection parameters for each individual patient. You also can select other modes of operation as needed during the procedure. The areas of the touchscreen include:

- Top of screen: Used to select injection parameters and limits.
- Right side of screen: Controls the injection type and the mode of operation.
- Center of screen: Contains the message display area and synchronization functions.
- Bottom of screen: Contains the user option buttons..

The sections of the touchscreen include:

1. Parameter Buttons: Display the default injection parameters and limits associated with the option currently selected in the SELECT INJECTION box. The parameters can be changed while the status window is clear (empty).
2. Status Window: Displays system messages and provides feedback on the state of system operations.

Contrast Usage Feedback Display

3. Contrast Remaining: Displays the amount of contrast remaining in the syringe.
4. Contrast Delivered: Displays the total amount of contrast injected during the current case.

   Important: When documenting the total contrast dose delivered to the patient, you should take into account the contrast remaining in the tubing (6-7 ml) and any contrast that has been used in purges.

5. Last Injection: Indicates the volume and flow rate used during the most recent injection.

6. Option Buttons: Allow you to specify if the injection will be variable or fixed, to initiate a calibration of the hand controller, to refill the syringe with contrast media, and to modify the background color of the buttons

7. Injection Type Buttons: Allows you to select the type of injection you wish to perform.

8. Status Indicators

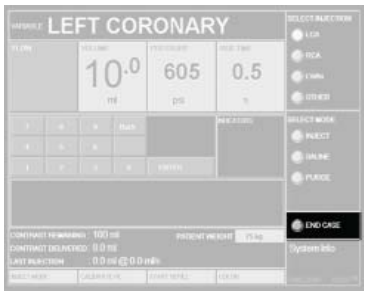
8. Status Indicators: Display key system sensors when they are active.

9. Function Buttons

9. Function Buttons: Enable you to select which function to perform (inject contrast, flush with saline, purge tubing with contrast, or keep a vessel open).

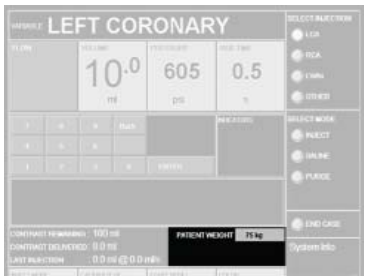
10. X-Ray and KVO Parameters

10. X-ray and KVO Parameters: Enable you to set the x-ray interface or KVO parameters (available only with the Voyager and CVi [peripheral mode] models).



11. End Case

11. End Case: Leads you through the proper steps to end the current case.

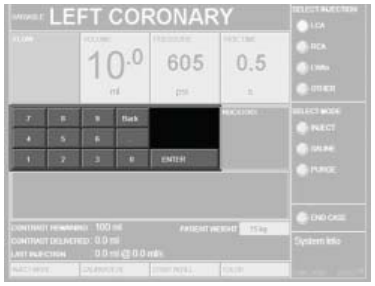


12. Patient Weight Button

12. Patient Weight (not available on Voyager and in Peripheral Mode on CVi models): Used to enter the patient's weight, if desired. The parameter options (flow, volume, pressure, and rise time) will be recalculated automatically by the system.

Select Injection: Pigtail option selected

Injection Parameters



Keypad to change parameters

Select Injection

An injection type must be selected before initiating an injection. The following injection types are available:

- If the system is setup for cardiac procedures the options displayed (based on the procedure) are LCA, RCA, LV/Ao, and OTHER.
- If the system is setup for peripheral (non cardiac) procedures the options displayed (based on the catheter used) are PIGTAIL, SELECTIVE, MICRO, and OTHER.

Each option will provide a different set of default values for the corresponding injection parameters and limits.

Once an option is selected, the button next to the option is highlighted and the selection is identified at the top of the display screen. The injection parameter values are changed to the default values for that injection mode or to the last values selected for that injection during the current case or since start-up.

Injection Parameters

You can set the following four parameters:

- FLOW: Displays the greatest flow rate (ml/sec) obtainable if the hand controller button is completely depressed.
- VOLUME: Displays the total volume (ml) limit that can be injected during a single injection.
- PRESSURE (limit): Displays the maximum pressure (psi) allowed at the syringe tip during an injection. If this pressure is reached, a warning indicator will display and the injection flow rate will be limited to the indicated pressure.
- RISE TIME: Displays the maximum rise time (sec.) allowed during an injection.

  To change these parameters, touch the desired parameter on the touchscreen. A parameter selection keypad will pop up in the status window. Use this to enter a new parameter value.

  If you select a value outside the range of allowable values, an error message will indicate the appropriate range of values.

Injection Parameter Ranges

Parameter ranges for each injection type are shown in the table below

Injection Parameter Ranges Table

System	Injection type	FLOW[1] (ml/s)	VOLUME[2] (ml)	PRESSURE[3] Pounds per square inch – psi (Kilopascals–kPa)	RISE TIME[4] (Sec)
CL100H, CMS2000, and CVi (Cardiac mode)	LCA	0.8 – 10.0	0.8 – 20.0	200 –1,200 (1,379 – 8,274)	0.0-1
	RCA	0.8 – 10.0	0.8 – 20.0		
	LV/Ao	0.8 – 40.0	0.8 – 99.9		
	Other	0.8 – 40.0	0.8 – 99.9		
Voyager and CVi (Peripheral mode)	Pigtail	0.8 – 40.0	0.8 – 99.9	200 –1,200 (1,379 – 8,274)	0.0–1
	Selective	0.8 – 15.0	0.8 – 99.9	200 –1,200 (1,379 – 8,274)	
	Microcatheter	0.8 – 3.0	0.8 – 10.0	200 –300 (1,379 – 2,068)	
	Other	0.8 – 40.0	0.8 – 99.9	200 –1,200 (1,379 – 8,284)	

1. In 0.1 ml/sec increments.
2. In 0.1 ml increments.
3. In 1 psi (1 kPa) increments.
4. In 0.1 sec. increments.

Select Mode

Select Mode

- INJECT: Arms the system, readying it to inject contrast.
- SALINE: Enables you to flush saline through the system at a rate of 1.66 ml per second. There is a 10 second timeout on saline flushes.
- PURGE: Enables you to purge either the syringe or the high-pressure tubing.
  - Purging the syringe clears the air from the syringe through the contrast valve and into the contrast container.
  - Purging the high pressure (injection) tubing requires turning the 3-way stopcock off to the patient.
- KVO (Keep Vein Open, or Keep Vessel Open): Available only on Voyager and CVi (peripheral mode) models. Provides a periodic pulse of saline to keep the fluid pathway open to the patient during delays between injections. This feature consists of two screen controls.

  To use KVO, first specify the amount of saline to be dispensed during each pulse by pressing the KVO Rate parameter. The available range for this parameter is 0.1 – 10 ml/min. There is a 20-minute timeout on the KVO function, meaning a maximum of 200 ml of saline can be dispensed during any single activation.

KVO Function Mode Screen

When you are ready to activate KVO, press the KVO button from within the SELECT MODE box. The following prompt will be displayed: Press KVO to start Keep Vessel Open function.

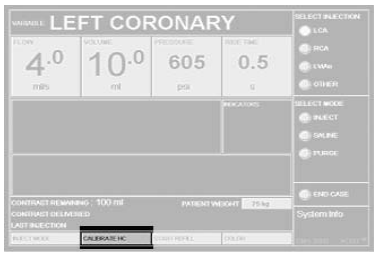
To start the KVO process press KVO; to cancel the KVO process press CANCEL.

Fixed rate screen

Option Buttons

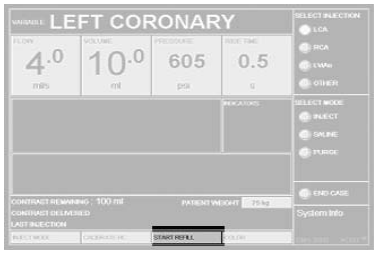
- INJECT MODE: This button allows you to specify whether the injection will be at a variable rate or at a fixed rate.
  - In FIXED RATE mode, pressing the Contrast button on the hand controller will cause an injection of contrast exactly equal to the amount specified on the FLOW parameter. Also, the display area will change to an amber colored background.
  - In VARIABLE RATE mode, pressing the Contrast button will cause an injection proportional to the pressure applied to the button. VARIABLE RATE injections will always remain within the injection parameters (limits) defined on the touchscreen.

Variable rate screen



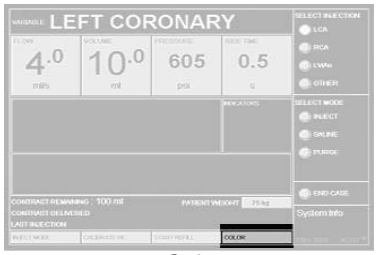
Calibrate Hand Controller

- CALIBRATE HC: This button allows you to recalibrate the hand controller.



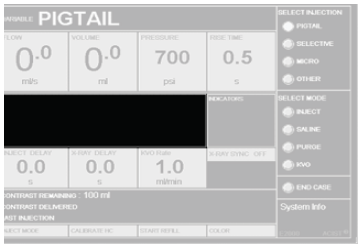
Start/stop Refill

- START REFILL/STOP REFILL: This button allows you to refill the contrast syringe. When the syringe starts to refill, the STOP REFILL button is displayed.



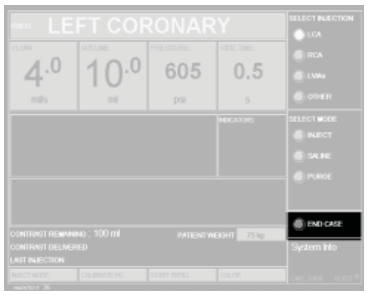
Color

- COLOR: You can select the background color of the buttons on the touchscreen. Repeatedly tap the button to cycle through the color choices.

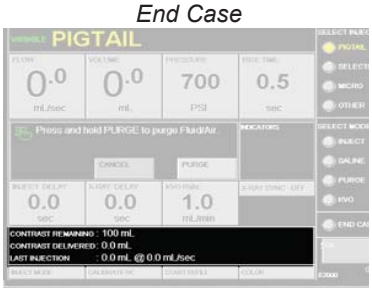


Status Window

Status Indicators



End Case



Case Information

Message Windows

There are two message windows on the touchscreen.

- Status Window: This is a blank window in the middle of the screen that displays messages about system functions. This window will provide prompts instructing you on how to correct any errors with the system.

- INDICATORS: This window notifies you of any indicators that are currently active. The following indicators may appear in this window:

  - **Contrast Empty Sensor**
    Indicates whether fluid is present at the contrast sensor. If contrast is not present, the computer will disable the fill operation.

  - **Limit Switches**
    Monitors the forward limit and reverse limit positions of the contrast injection syringe.

  - **Revolving chamber sensor**
    Indicates if the syringe chamber is closed. All functions are disabled when the chamber is open.

  - **Manifold Sensor and Syringe Valve Open Sensor**
    Determines the state of the manifold valve and sryinge valve. If the sensors show the valves in an incorrect position, the system software will display an appropriate warning message.

  - **Air Column Detector**
    Senses air in the proximal end of the high-pressure (injection) tubing. If air is detected in the tubing, all fluid delivery functions are disabled.

WARNING! Do not depend solely on this sensor. You should routinely perform a visual inspection for the presence of air.

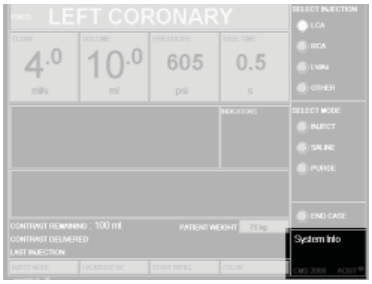
  - **Pressure Limit**
    This is displayed during an injection if the system is trying to limit the pressure by decreasing the motor speed.

Case Information

Information about the amount of contrast used by the system is displayed at the bottom of the screen. Because this information is not stored from case to case, if you wish to save any of this information be sure to record it before you select END CASE.

NOTE: When documenting patient doses, you must account for the contrast remaining in the injection tubing (6-7 ml) and for any contrast that has been used in setup purges.

- CONTRAST REMAINING: Displays the amount of contrast remaining in the syringe.
- CONTRAST DELIVERED: Displays the total amount of contrast injected during the current case. This does not include any contrast used while purging the tubing during setup.



System Information

- LAST INJECTION: Indicates the volume and highest flow rate achieved during the most recent injection.

System Info

Located in the bottom right corner of the screen, this box displays the company logo and system model number. If you repeatedly touch this area of the screen you can scroll through the following data:

- Hardware Configuration, including Board ID, Control Panel ID.
- Software Configuration, including the software version and firmware version.
- Current Session Info, including case number and the number of manifold valve failures with this syringe.
- Number of power ups and total cases since the NVRAM (memory) was cleared.

Audible Indicators

Audible indicators are used to notify you of certain conditions. The audible indicators are identified in the table below

Type of Message	Event	Audible Indicator
System Messages	Start Refill	Series of tones to alert user
Warning Messages	Refilling	Repeating click
	Injecting	Repeating click
	Warning is displayed	Beep
Touchscreen Messages	Touchscreen key is pressed	Click

Inject Delay

X-Ray Delay

X-Ray Sync

X-Ray Interface Parameters

The following x-ray parameters are available on the Voyager and CVi (peripheral mode) models:

- INJECT DELAY and X-RAY DELAY
  Inject Delay is used with the “injector start” input to delay the beginning of the injection. X-Ray Delay is used with the “X-ray trigger out” output and is used to delay the operation of the X-ray equipment until after an injection has begun. These two parameters are mutually exclusive, meaning you can define values for one or the other (but not both). Valid values for these two parameters are 0 - 99.9 seconds.

  X-ray imaging systems (such as GE, Toshiba) may handle the delay functions directly. Always refer to the X-ray manufacturers’ user manual for instructions
- X-RAY SYNC
  This button allows you to specify whether the imaging system interface is enabled or disabled. This allows the system to be controlled by the imaging system or by the hand controller without disconnecting the interface cable. Repeatedly press this button to toggle between Xray Sync On and Xray Sync Off.

Imaging System Status and Control Lines

The imaging system (or x-ray) interface is a general group of status and control lines that allow for a wide variety of interface configurations with film changers, programmers, or digital imaging systems. The lines are described in the following tables.

Status Output Lines

Injecting	This output is active anytime the injection system is injecting contrast.
Armed Status	This output is active while the injection system is armed and ready for an injection.
X-ray trigger out This trigger signal is set as active by the injector as a trigger to the imaging system.	There are several conditions that must be met before this signal is active. 1. The injector must be armed. 2. The injector start must be active 3. The X-ray delay has passed.
Hand Controller Pressed (only for CVi standard and Voyager-Philips Alura FD10 and FD 20)	There are several conditions that must be met before this signal is active. 1. The injector must be armed. 2. The hand controller disable is active. 3. The hand controller contrast button has been pressed.

Input Control Lines

Disarm/Disable	When this signal is set active from an external device, the injection system will disarm (if armed), and will be prevented from arming or injecting until the signal is cleared.
Injector Start	When this input is active, starts the programmed injection process.
Hand Control Disable	Disarms the hand controller inject function when X-ray Sync is ON.

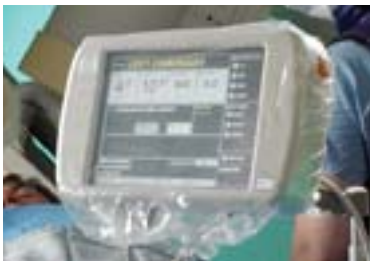
Section 5: Performing Patient Procedures

Contrast button

Saline button

AngioTouch Hand Controller

Control Panel with LCD Touchscreen display



Cotnrol panel with touchscreen display sterile draped

Interface Devices

There are two interactive components used during a typical procedure:

- AngioTouch Hand Controller

  The hand controller is a variable rate controller that gives you complete control of contrast injections and saline distribution. It also allows you to stand back from the table during procedures, which can help minimize exposure to nearby radiation sources.

  The AngioTouch Controller allows you to instantaneously and contiuously vary the flow rate and volume of contrast delivered,

- Control Panel with LCD touchscreen display

  The touchscreen is an interactive screen that is used to control what is performed and how it is performed.

Operating the AngioTouch Hand Controller

During injections in VARIABLE RATE injection mode, pressing and holding the Contrast button will cause an injection flow rate proportional to the pressure applied to the button. The injection will always remain within the injection parameters and limits defined on the touchscreen. The injection can be stopped at any point in the procedure by simply releasing the button.

Important: There is a quick response time between pressing the button and seeing contrast on the fluoroscopy screen.

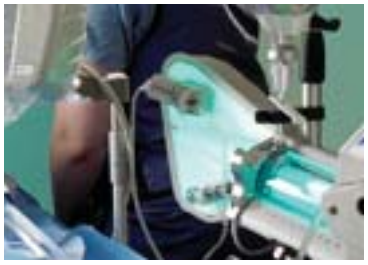
In a FIXED RATE injection mode, pressing the Contrast button will cause an injection equal to the amount specified by the “Flow” and “Rise Time” parameters on the touchscreen.

The Saline button on the hand controller is marked with an “S” and is used to flush the entire system with saline. Press the button and saline will be flushed from the saline bag through the disposable system. The flush will continue until either the button is pressed again or the 10 second limit is reached.

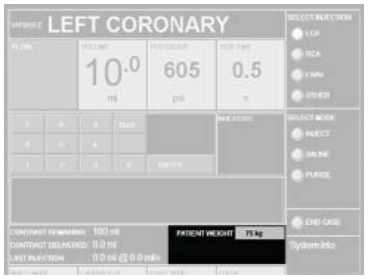
Pre-Procedure Tasks

To prepare for a patient procedure:

1. Verify that all system connections have been made and that a sterile drape is placed over the control panel (see previous section).
2. Verify that the system set-up steps have been done as directed in “System Setup”



Purge the high pressure (injection) tubing and stopcock



Patient Weight Button

Injection Type Buttons

3. Purge the high pressure (injection) tubing and stopcock with contrast to clear the saline from tubing. In using a pressure transducer, ensure that it has been set up properly as described in the “System Setup “ section.
4. Connect the 3-way stopcock to the patient catheter. Use good clinical practices to ensure there is no air in the tubing.
5. If using a CL100H, CMS2000 or CVi in cardiac mode, enter the patient’s weight.:

   - Press PATIENT WEIGHT to display the keypad.

   - Type the patient’s weight (in kg) and then press Enter.

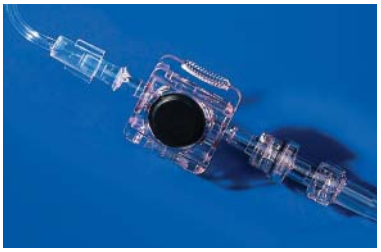
   The settings for the parameters (flow, volume, pressure, and rise time) will be calculated automatically by the system.
6. Select injection type by pressing the desired selection on the touchscreen. Injection types include:

Cardiology (CL100H,CMS2000, CVi - in cardiac mode)
LCA (left coronary artery)
RCA (right coronary artery)
LV/Ao (left ventricle, aorta)
Other

Peripheral (Voyager, CVi-in peripheral mode)
Pigtail
Selective
Microcatheter
Other

   When a new injection type is selected, default parameters will be displayed.
7. Review and revise injection parameters as clinically indicated for the patient.

The system is now ready for patient injections.



Disposable Pressure Transducer

saline button

Select the Saline Option

Pressure Monitoring

Blood pressure is monitored directly through the system in conjunction with the monitoring equipment in the lab. Not all procedures are performed with pressure monitoring. If pressure monitoring is desired, the BT2000 low pressure disposable kit must be used.

Important: Remember, following an injection, the catheter and high-pressure tubing will be filled with contrast, which dampens pressure transmission. To decrease dampening, the system should be flushed with saline.

Pressure dampening can be minimzed in using the following steps:

- An acceptable waveform can be achieved by chasing the contrast from the catheter only, by using a saline filled hand syringe connected to the high pressure stopcock at the catheter connection.
- Optimal waveform characteristics can only be achieved with saline in the high pressure (injection) tubing. This can be completed by first chasing the contrast from the catheter (previous step) then closing the stopcock to patient, opening to a syringe or waste container and flushing the injection line (high pressure) with saline.
- Press the Saline button on the hand controller to flush the entire tubing with saline. This is a Start - Stop button.
- Press the SALINE button in the SELECT MODE section of the touchscreen. The status window will display the following message: Press and Hold Flush to flush tubing. The tubing will be flushed with saline for as long as the button is pressed. If an additional flush is desired, press and hold the button again.
- Open the stopcock and attach a hand syringe. Draw the contrast.

Injecting Contrast

This section describes the steps required to inject contrast during a diagnostic or interventional angiography procedure.

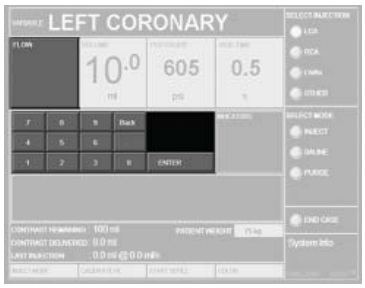
Important: Make sure that the connection between the high-pressure tubing and the catheter is purged of air.

a. Open the stopcock to the patient and aspirate blood with the hand syringe to clear any air that may be in the catheter connection.

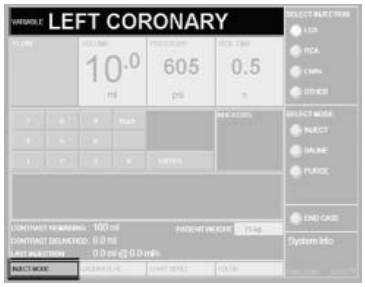
b. Turn the stopcock off to the patient by flipping the lever on the stopcock 180°.This opens the port to the high-pressure (injection) tubing.

c. Flush contrast through the high-pressure (injection) tubing (until contrast comes out of the stopcock) using the “C” button on the hand controller (this uses approximately 7cc of contrast for the first injection of the case).

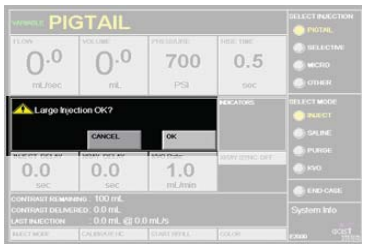
Peripheral has been selected



Screen to input flow rate



Press INJECT MODE for variable or fixed rate



Large injection confirm screen

Armed Light

1. Select the injection type in the SELECT INJECTION section of the touchscreen:

   When you select an injection type, default parameter values are displayed in the parameter buttons on the touchscreen.

Cardiology (CL100H,CMS2000, CVi - in cardiac mode)
LCA (left coronary artery)
RCA (right coronary artery)
LV/Ao (left ventricle, aorta)
Other

Peripheral (Voyager, CVi-in peripheral mode)
Pigtail
Selective
Microcatheter
Other

2. To make changes to the injection parameters, touch the desired parameter on the touchscreen.

   For example, if you press FLOW on the touchscreen, a keypad is displayed in the Status window. Simply press the numbers corresponding to the desired flow rate and then press ENTER. The keypad is used to make changes to all numeric parameters including FLOW, VOLUME, PRESSURE, and RISE TIME.

   If the specified value is out of the acceptable range a message is displayed in the Status window. Press CANCEL to return to the previous value.

3. Press the INJECT MODE button in the lower left corner of the screen to select either a VARIABLE or FIXED RATE injection.

   Repeatedly press the button to toggle between VARIABLE RATE and FIXED RATE.

- Selecting a VARIABLE RATE injection mode causes an injection flow rate that is proportional to the pressure applied to the Contrast hand controller button. A VARIABLE RATE injection will always remain within the injection parameters defined on the touchscreen.
- Selecting a FIXED RATE injection causes the injection to provide the exact flow parameters selected, regardless of how much pressure is applied when the Contrast hand controller button is pressed.

4. Select INJECT in the SELECT MODE section of the touchscreen.

   Special note if performing large injections: A large injection is any flow rate greater than 10 ml/sec, or volume greater than 20 ml. If injection parameters are set to perform a large volume injection, the status window will show a message asking you to confirm the large injection. For each subsequent

large injection, the system will require confirmation of the large injection.

5. At the “OK to arm injection?” prompt, press OK.

   The green armed light on the control panel comes on indicating that the system is armed. The message Ready to Inject is displayed. For large injections, the backlight will flash on and off.

6. Press the Contrast button on the hand controller to initiate the injection.

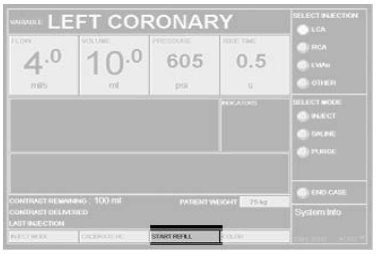
   Note: If you have enabled the X-Ray Sync button so that the system is used in conjunction with an X-ray imaging system, press the triggering switch on the imaging system. Only a fixed flow injection can be delivered with the imaging system.

7. After the injection is complete, release the hand controller button.

   A new injection cannot be started until the pressure on the hand controller button has been released.

   Note: If using an X-ray imaging system, a new injection cannot be started until the imaging system releases the triggering switch.

   The system will remain armed until a parameter or injection mode is changed. You may continue to make injections until they are completed.



Start/stop Refill

Press the contrast button to stop the automatic refill.

Refilling the Syringe with Contrast

Automatic Refill

The system monitors the amount of contrast in the syringe to make sure there is always contrast available for the next injection. When the system detects that there is an insufficient amount of contrast, the refill function begins automatically. The automatic refill function can be stopped in two ways:

To stop the refill:

- Press the STOP REFILL button.

  The STOP REFILL button will end the current fill and will start a syringe purge to remove any remaining air from the syringe.

- Press the Contrast button on the hand controller.

  This will stop the automatic refill. This feature will work when sufficient contrast has been loaded into the syringe for the currently programmed injection, and the system refills from the “armed” state. The system automatically purges the syringe after refill.

Manual Refill

You can manually refill the syringe at any time during a procedure. If a refill is initiated while the system is armed, the system will return to the armed mode after the refill is complete.

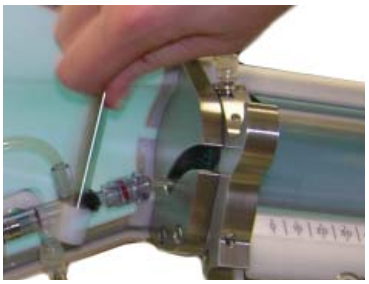
To start a manual refill:

1. Press the START REFILL button located at the bottom of the screen.

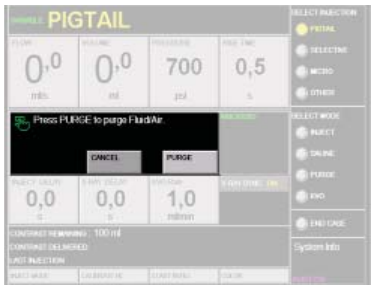
   The system will automatically start to refill the syringe and the name of the button changes to STOP REFILL.

Select the Saline Option

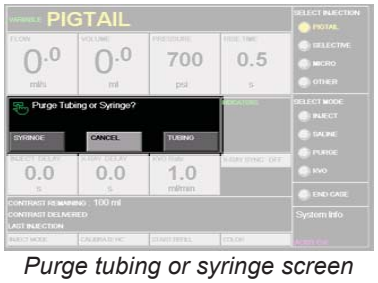
Press FLUSH



Tap tubing and connections to make sure all air is removed.



Press the PURGE button to purge air from contrast tubing



Purge tubing or syringe screen

2. To stop filling the syringe, press STOP REFILL.

   You can partially fill the syringe or wait for it to fill completely. As the syringe is being filled, the Status window displays the amount of contrast being dispensed into the syringe. The system automatically purges the syringe after refill.

Flushing Air from Saline Components

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

The Flush function removes air from the saline tubing.

1. Select SALINE in the SELECT MODE box of the touchscreen.

   The SALINE FLUSH window is displayed.

2. Perform the flush using either the touchscreen or the hand controller.

   - Touchscreen: To flush using the touchscreen, press and hold FLUSH. The tubing will be flushed with saline until the FLUSH button is released or until a 10-second timeout is reached.
     If prior to the flush the system was armed to complete an injection, the message OK to arm injection? is redisplayed.
   - Hand Controller: To flush using the hand controller, press and release the Saline button on the hand controller. The tubing will be flushed with saline for 10 seconds. To stop flushing before the 10-second timeout, press the Saline button again, or press CANCEL.
     If prior to the flush the system was armed to complete an injection, the message Ready To Inject is redisplayed.

3. During the flush, check for air bubbles and, if needed, tap the tubing and connections to make sure you have removed all air from the following components:

   - Saline spike
   - High pressure (injection) tubing and saline (low pressure) tubing
   - Transducer cartridge
   - Manifold
   - Stopcock
   - Catheter luer fitting

Purging Air from Contrast Media Components

The Purge function purges air from the syringe, manifold, high pressure (injection) tubing, and catheter.

Note: Make sure the outlet is pointed into an appropriate waste container.

1. Select PURGE in the SELECT MODE box of the touchscreen. The PURGE status window is displayed.

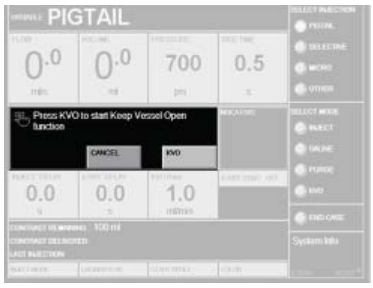
2. You can purge air either from the syringe or from the tubing.

   Note: If Syringe Valve Open is displayed in the indicator box, a syringe purge occurs automatically.

Turn stopcock off to patient screen

1. KVO Rate button

2. Select KVO in the SELECT MODE box.



3. Press KVO to start the saline.

a. To purge air from the syringe:

(1) On the touchscreen press SYRINGE.

(2) Press PURGE. The purge function automatically discontinues when air has been purged from the syringe and contrast has pushed the syringe check valve closed.

b. To purge air from the tubing:

(1) On the touchscreen press TUBING.

(2) Turn the stopcock off to patient.

(3) Select OK to confirm that a patient is not connected.

(4) Press PURGE. The purge function continues until you release the button or until the 10-second timeout is reached.

KVO Injection

KVO (Keep Vessel Open) mode is available on Voyager and CVi (Peripheral mode) models. This function allows the physician to periodically provide a pulse of saline to keep the fluid pathway open to the patient during delays between injections.

To use the KVO function:

1. If you want to use a value for KVO that is different from the default value (1.0 ml/min.), press the KVO Rate button and specify a new rate.

   The available range is 0.1 – 10 ml/min. There is a 20-minute timeout on the KVO function, providing for a maximum of 200 ml of saline to be dispensed during any single activation.
2. Select KVO in the SELECT MODE box.
3. This screen is displayed. To start the KVO process, press KVO.

   The touchscreen will display a running total of the volume of saline dispensed in the KVO function.
4. To stop the KVO process, press CANCEL.

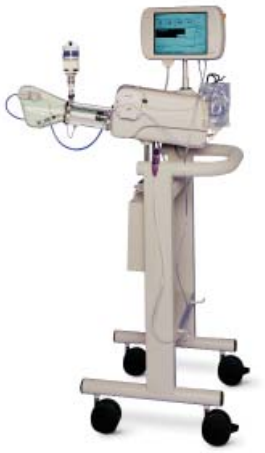
Resuming an Interrupted Case

The RESUME function allows a quick recovery from an interrupted case without losing the current patient kit setup. If the system detects a RESUME is possible, you will be presented with the following two options: RESUME and RESTART.

- RESUME – Depending on where you are in the software, pressing the RESUME button will bring you back to the following points:

If system shutdown occurred…	RESUME brings you to this point:
After the Spike Contrast screen (during setup)	RESUME returns you to the Load Saline (Low Pressure) Assembly screen (setup)
After the Main screen is displayed	RESUME returns you to the Starting Hand Controller Calibration screen

- RESTART – The RESTART button will typically take you back to the startup screens as though you were turning the power on for startup. **You will need to load a new patient kit in the system.**



Model CL100H

CMS2000

The exception to this is if the system sensors detect that a manifold or syringe is still connected; in this case a screen providing appropriate instructions will be displayed.

This screen also gives you a second chance to resume a case in the event that you initially pressed the RESTART button by mistake.

Ending a Case when using a Model CL100H

To end a case with the CL100H:

1. Record all case information before ending the case (for example, CONTRAST DELIVERED, LAST INJECTION, etc.).

   This information is cleared after the case is ended.
2. Press END CASE.
3. Press OK.

The message Shut Down System? is displayed.

4. If you want to keep the machine on, press NO. If you want to turn off the machine, press YES.
5. Disconnect the high pressure (injection) tubing from the injection system, and remove the contrast container from the contrast holder.

CAUTION: Make sure the contrast spike is removed from the contrast container prior to opening the chamber.

6. After the syringe plunger has disengaged, remove the syringe by rotating the chamber to the open position.
7. Disconnect and discard the patient kit (hand controller, high-pressure injection tubing, high-pressure 3-way stopcock. contrast syringe and automated manifold kit components). Properly discard disposables in accordance with all local, state, and federal regulations, codes and directives.
8. Turn off the power switch or press RESTART to begin another procedure.

Ending a Case when Using a Model CMS2000, Voyager, or CVi

When ending a case with the CMS2000, Voyager, or CVi, you can select from three paths:

- End the current case and start a new case using the existing contrast syringe kit, which is designed to be used for up to five cases. See “Starting a New Case with the Existing Syringe” on the next page.
- End the current case and start a new case with a new syringe kit. See “Starting Another Case with a New Syringe” on the next page.
- End the current case and shut down the system. See “System Shutdown” on page 55.

Starting a New Case with the Existing Syringe

The CMS2000, Voyager, and CVi systems are designed to allow the use of the multi-procedural syringe kit for up to five (5) procedures within 12 hour period. This allows you to save the contrast that remains in the syringe at the end of a case.

Note: The CL100H is not designed for re-use of the syringe kit beyond a single procedure.

End Case? screen

To end a case and start a new case using the same syringe:

1. Before ending the previous case, record all case information (for example, CONTRAST DELIVERED, LAST INJECTION, etc.).

   This information is cleared after the case is ended.
2. Press END CASE.
3. Press OK.

   The following prompt is displayed: Shut Down System?
4. Press NO.

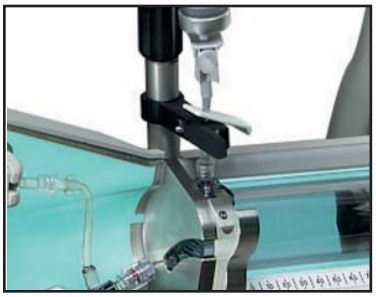
   The screen displays the following information:

   Maximum recommended cases per syringe : 5

   Number of cases this syringe: X
   (X= number of cases counted by the system)

   The system will recommend using a new syringe if the current number of cases equals or exceeds the recommended number of cases per syringe.
   If you exceed the recommended number of cases, the performance of the patient kit may be degraded.

   The following prompt is displayed: Use new syringe?
5. Press NO.
6. Close the white contrast slide clamp.



Close the white contrast slide clamp

7. Disconnect and discard the catheter, high pressure (injection) tubing and stopcock, and the automated manifold kit, including the manifold, saline connection tubing to the syringe and high pressure (injection) tubing.

   Properly discard disposables in accordance with all local, state, and federal regulations, codes and directives.

   Note: If the syringe will not be used immediately, place the pre-sterile cap (provided in the automated manifold kit) on the syringe and tighten it.
8. Connect the new automated manifold and hand controller kit assemblies to the syringe.
9. Continue with the rest of the message prompts to start a new case using the existing syringe.

Use new syringe? screen

Starting Another Case with a New Syringe

To end a case and start another case with a new syringe:

1. Before ending the previous case, record all case information (for example, CONTRAST DELIVERED, LAST INJECTION, etc.).

   This information is cleared after the case is ended.

End Case? screen

Use new syringe? screen

2. Press END CASE.
3. Press OK.

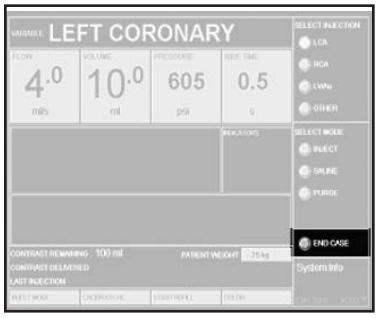
   The following message is displayed: Shut Down System?
4. Press NO.

   This prompt is displayed: Use new syringe?
5. Press YES.
6. Disconnect the high pressure (injection) tubing from the injection system.
7. Remove the contrast container from the contrast holder, close the white contrast spike clamp, and then press OK.

CAUTION: Make sure the contrast spike is removed from the contrast container prior to opening the chamber.

   The message Disengaging Syringe Plunger . . . Please Wait is displayed.
8. After the syringe plunger has disengaged, remove the syringe.
9. Disconnect and discard all disposables and the catheter.

   Properly discard disposables in accordance with all local, state, and federal regulations, codes and directives.
10. When prompted, press RESTART to begin the setup for the next case.



Select End Case

End Case? screen

System Shutdown

To shut down the system:

1. Record all case information (for example, CONTRAST DELIVERED, LAST INJECTION, etc.) before ending a case.

   This information is cleared after the case is ended.
2. Press END CASE.
3. Press OK.

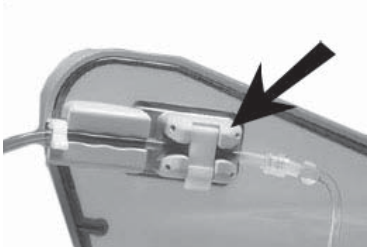
The following message is displayed: Shut Down System?

4. Press YES.
5. Disconnect the high pressure (injection) tubing from the injection system.
6. Remove the contrast container from the contrast holder, close the white contrast spike clamp and then press OK.

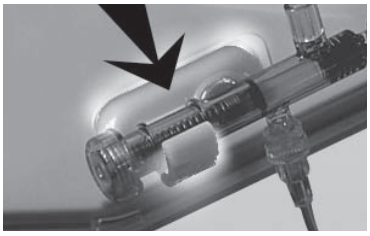
CAUTION: Make sure the contrast spike is removed from the contrast container prior to opening the chamber.

   The message Disengaging Syringe Plunger . . . Please Wait is displayed.
7. After the syringe plunger has disengaged, remove the syringe.
8. Disconnect and discard the entire patient kit and the catheter. Properly discard disposables in accordance with all local, state, and federal regulations, codes and directives.
9. When the message OK to turn power off or Restart is displayed, turn off the power switch.

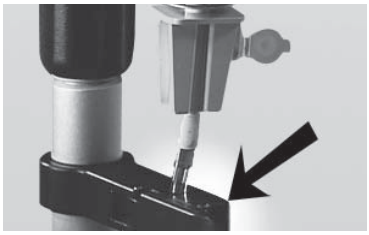
Section 6: System Maintenance



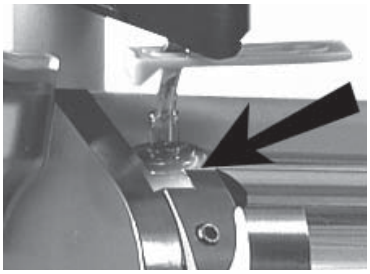
Air column detect sensor



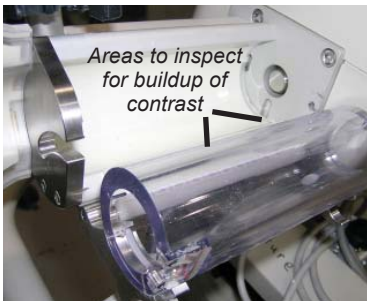
Manifold valve sensor



Contrast sensor



Syringe valve sensor



Chamber sleeve in open position

The ACIST injection system will function best if it is cleaned on a regular basis. This section describes the care and cleaning procedures that should be carried out in order to keep the system running at peak efficiency.

When cleaning the system:

- Use a soft cloth or sponge moistened with warm water
- Never spray anything directly on the system
- Do not use detergents
- Do not use any sharp objects

Daily Cleaning

Buildup of contrast is one of the major causes of malfunctions. Perform the following procedures daily for optimal operation.

Clean the Sensors

Using a soft cloth and warm water, clean the following:

- Air column detect sensor
- Manifold valve sensor
- Contrast empty sensor
- Syringe valve sensor (located on chamber sleeve)

Clean and Inspect the Chamber Sleeve

After each use, clean the syringe chamber and inspect it for cracks, crazing, or other deterioration. Use of a damaged chamber sleeve may result in its rupture during injection. If any irregularities are observed, do not use the ACIST injection system. Call ACIST Technical Services to report the problem.

What to Clean in the Chamber

After wiping down the entire chamber, you should inspect the following areas for a buildup of contrast:

- The lower edge by the drain
- The edge along the front of the chamber

If You Choose to Remove the Chamber Sleeve

The chamber sleeve can be removed to facilitate cleaning of the sleeve and of the syringe valve sensor.

Note: You should typically leave the chamber sleeve attached to the system when cleaning. Only remove the sleeve if you are unable to clean it properly while it is installed on the system.

Do not allow water to come in contact with the cable during cleaning

To remove the chamber sleeve:

1. From an open position, gently pull down on the sleeve until it pops out from its guides.
2. Detach the cable from the system.

   If you wish to clean the chamber sleeve by holding it under a faucet, be sure you hold the attached cable a safe distance from the water.

CAUTION: Do not immerse or expose the cable to water. Electrical connections from the syringe valve sensor are attached to the chamber and may produce "Syringe Valve Open/Closed" messages if the cable is damaged by exposure to water.

Cleaning the Removable Backlight Cover

ACIST injection systems manufactured after mid-2003 have a removable backlight cover that should be removed and cleaned at the end of each day.

To clean the removable backlight cover:

1. Turn off the power.

   Make sure the power is off whenever you remove the backlight cover or clean the system.

Turn off the power

2. Remove the backlight cover.

   Be sure that the air column detect sensor door is not latched, so that it will not catch on the removable cover. Carefully pull the backlight cover away from the outside edge of the backlight, pulling all the way around the perimeter of the cover. Lift the cover off the syringe chamber, allowing the manifold sensor and the air column detect sensor to go through the appropriate cutout holes.

Remove the backlight cover and clean with a soft cloth and warm water

3. Clean the backlight cover and the backlight area using a soft cloth and warm water.

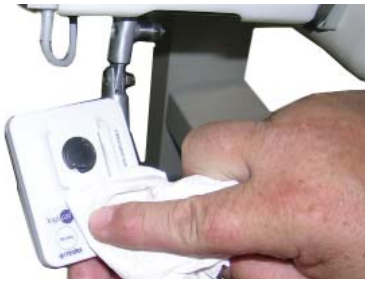
   If decontamination is necessary, you can use a bactericide on the removable backlight cover, but use only warm water to clean the backlight area and the rest of the ACIST injection system.

4. Reattach the backlight cover.

   Position the backlight cover over the backlight, lining up the cutouts for the manifold sensor and the air column detect sensor. Be sure the air column detect sensor door is positioned out of the way so it does not catch on the backlight cover. Secure the backlight cover by snapping the outer edge of the backlight into the "channel" around the edge of the cover. Start by snapping the cover into the upper-right corner of the backlight and work all around the perimeter of the backlight cover until the entire cover is securely in place.

Reattach the backlight cover

Use a soft cloth moistened with warm water to clean the injector head



Clean the transducer backplate membrane with a damp cloth

Cleaning the Injector Head

1. Make sure system power is turned off.
2. Clean the entire injector head using a soft cloth moistened with warm water.

CAUTION: Be careful not to get the injector head so wet that water drips inside. Do not immerse the injector head in water. Do not spray or pour liquid directly onto the display panel. Do not use excessive pressure.

Pressure Transducer Cartridge and Backplate

The disposable pressure transducer cartridge and the backplate it mounts to both have rubber membranes. When cleaning these components you can wipe them with a damp cloth, but be careful not to soak these components or expose them to bleach or other cleaning agents. If the backplate's rubber membrane looks white or dull you can try applying a small amount of mineral oil. If a good pressure waveform cannot be achieved, one possible cause may be a worn or damaged rubber membrane.

Important! Do not soak the rubber membrane or expose it to bleach or other cleaning agents.

Decontamination

If the system needs cleaning to remove any biohazardous materials (blood, etc.), the following are acceptable solutions to use.

- A 12% bleach solution (only on plastic components)
- Hospital grade disinfectant
- An alcohol pad

Wear protective gloves. Apply the solution to a soft cloth and wipe down the system. Discard all materials used to decontaminate the product in accordance with all local, state, and federal regulations, codes and directives.

CAUTION: Do not apply these solutions to the rubber membrane of the pressure transducer backplate because this may cause the transducer to degrade, resulting in poor pressure waveforms.

Daily Status Inspection and Prevention

- The electrical integrity of the pressure transducer backplate should be checked daily by pushing the cal button located on the front of the backplate. This will produce a signal equal to 100 mmHg ± 3 mmHg on the pressure monitor. If the signal does not fall into this range the backplate should be replaced. Check the backplate signal anytime there is zero drift or questionable pressures.
- Cover the system with a dust curtain when not in use.

Monthly Status Inspection

Complete the following inspection on a monthly basis:

- Inspect cables for cuts, nicks and openings in cable insulation, as well as separation of cables and connectors. Replace damaged cables.
- Check for poor contact between male/female, single/multi-pin connectors.
- Check chamber sleeve for cracks, opacity, scratches, or other damage. Replace all faulty items.
- Check the wheels on the cart used to transport the system in the lab. Check for wheel damage and make sure the wheels are securely fastened to the cart.

For replacement parts, call ACIST Technical Services.

Annual Preventive Maintenance Inspection

To keep an ACIST injection system in optimal working order, make sure that the system goes through a preventive maintenance inspection each year. This service is scheduled and performed by ACIST Medical Systems at no additional charge for customers who have purchased an extended warranty plan. For customers not covered by an extended warranty plan, contact ACIST Technical Services for information on out-of-warranty services or extended warranty plans.

Storage of Cart Mounted Systems

When storing the system, make sure the power cord is wrapped or attached to the cart to avoid accidents caused by loose cords. Make sure to lock both wheels to prevent unintentional movement of the device when stored.

Section 7: Troubleshooting

The ACIST injection system is designed to provide trouble-free operation. However, if problems do occur consider the following options:

- If an alert message displays in the status window, follow the instructions provided in the window. Also use the Troubleshooting Table on page 59 to aid in determining probable cause and corrective action.
- For other problems, use Table 7-2 to aid in determining probable cause and corrective action. (See “Functional Errors” on page 57.)

WARNING! In the case of power blackouts, power brownouts, or voltage surges resulting in abnormal system operation of any kind, immediately follow the emergency shutdown steps to ensure patient safety. (See “Emergency Shutdown Procedure” below).

General Troubleshooting

Many problems can be resolved by performing the following steps:

1. Turn off the power.
2. Unplug the system.
3. Check for damaged or loose connections.
4. Check the integrity of the wall power outlet.
5. Perform system cleaning.

For failures or problems that cannot be resolved, contact an ACIST Medical Systems representative.

Emergency Shutdown Procedure

1. Turn the power switch off. The power switch is located on the power entry module on the side of the power supply.
2. Detach from the patient.
3. Turn the power switch on to reboot the system.

   If the system detects a RESUME is possible, you will be presented with the following two options: RESUME and RESTART.

   - **RESUME** – Depending on where you are in the software, pressing the RESUME button will bring you back to the following points:

If system shutdown occurred…	RESUME brings you to this point:
After the Spike Contrast screen (during setup)	RESUME returns you to the Load Saline (Low Pressure) Assembly screen (setup)
After the Main screen is displayed	RESUME returns you to the Starting Hand Controller Calibration screen

Snap the transducer cartridge into the transducer backplate

Connect the hand syringe to the high-pressure tubing that is exiting the manifold.

Slowly aspirate (pull) fluid from the saline container to the hand syringe, removing air from the lines.

Place tubing in saline pump.

- **RESTART** – The RESTART button will take you back to the start-up screens as though you were turning the power on for start-up. *You will need to load a new set of disposables into the system.*

If problems persist, call ACIST Medical Systems Technical Support.

Problems with ACIST In-Line Pressure Monitoring

The following steps should be followed to assure accurate waveforms when using the Acist pressure transducer cartridge and backplate:

A. Properly optimize the setup.

1. Perform complete setup prior to adjusting/setting the zero pressure level.
2. Snap the disposable transducer cartridge into the pressure transducer backplate.
3. Connect the hand syringe to the high pressure (injection) tubing that is exiting the manifold.
4. Slowly aspirate (pull) fluid from the saline container to the hand syringe making sure all air is removed from the lines, transducer cartridge, and manifold.
5. Remove slack from the tubing between the saline pump and the transducer cartridge and then clamp the tubing by placing the tubing in the roller pump, verifying that the pump door is completely closed. Check to see that all air has been removed from the tubing, spike and valves.
6. Remove the hand syringe from the high pressure (injection) tubing.
7. Examine all joints and areas susceptible to air entrapment. Double check the transducer cartridge, the manifold, and tubing connections.
8. Make sure all connections are straight and tightened securely.

B. Make sure the system is zeroed

1. Move the transducer backplate to the mid-axillary position.
2. Zero the transducer at the mid-axillary position.

   If using two transducers, make sure both transducers are at the same level and zero both through the 3-way stopcock.

3. Check the hemodynamic zero point before recording pressures.

Note: Leave the same transducers in the same rooms. For example, when moving the system to other rooms, do not move the transducers with the system.

C. Make sure any small bubbles are purged.

Frequently Asked Questions

Question	Answer
The pressure tracing is damped—what can I do to improve it?	Remember that the tubing filled with contrast will always result in a damped pressure waveform. (You can save contrast by flushing forward into a syringe.) If you need to see a better pressure tracing you will need to flush the tubing with saline. This can be done in several ways. • Check that the disposable pressure transducer cartridge is properly seated in the backplate sensor. • Check the system for air bubbles. • Aspirate fluid from the catheter with a hand syringe attached to the high-pressure stopcock and hand flush the catheter with saline. • Press the Saline button on the hand controller to flush the entire tubing with saline. • Press the FLUSH button in the SELECT MODE box of the touchscreen. The Status window will show the following message: Press and Hold Flush to flush tubing. While the FLUSH button is held down, the tubing will be flushed with saline for a maximum of 10 seconds. If more flush is desired, press and hold the FLUSH button again. • Zero the in-line ACIST-supplied pressure transducer to the system.
The hand controller is not working. What should I do?	Check the following items. 1. Check the hand controller connections on the bottom of the control panel to be sure they are attached properly. You may need to tighten them or disconnect them and then connect them again. 2. Check for kinks in the tubing. 3. If the hand controller still will not calibrate, replace it.

Functional Errors

Functional errors occur during a procedure and are displayed in the status window. Sensors within the system are activated when functional errors occur. An error message will be displayed in the Status window. Follow the directions given in the window to clear the problem.

Problem	Corrective Action
Air column detect messages are not displayed when expected (for example, when there are air bubbles present)	Wetness on the exterior of the tubing may interfere with the air column detect sensor's ability to detect air bubbles. Fluids that are present on the exterior of the tubing—such as contrast, normal saline, gels or cleaning solutions—can present a "masking" barrier for the sensor. Be sure to wipe the sensor and the exterior tubing dry before beginning a case.
Contrast empty message is given in error.	Make sure the contrast sensor is clipped around the spike tubing and that the sensor is clean. If contrast build up occurs on the sensor you may get a false reading.
Contrast is leaking from syringe or contrast spike	1. Close the white contrast spike clamp before changing the patient kit. 2. Press the Standby button and check the connection of the contrast spike.

Problem	Corrective Action
Control panel display is blank.	Do not leave the system power on for more than 24 continuous hours. Leaving the system on for more extended periods of time can cause screen burnout, requiring the system to be repaired. 1. Check cable connections between the control panel and the injector head. 2. Call a service representative.
Saline button on hand controller not working.	1. Make sure the saline pump is closed and the v-teeth are down. 2. Make sure the tubing is not bunched up in the pump. 3. Make sure the stopcock is open. 4. Check the connection between the hand controller connection and the bottom of the control panel. Try reconnecting the hand controller – it takes two or three turns to make a good connection (but do not overtighten). If you reconnect the hand controller, remember to calibrate it again.
The touchscreen is not responding.	Try pressing different areas around the button to see if another spot works. The screen may need to be recalibrated. Screen recalibration can be done the next time the system is powered on (see page 23). Also, check to see if the Standby button is engaged and that all cable connections are tight.
The saline tubing is moving forward (or backward) in the saline pump or the message Saline Pump Malfunction (OT) is displayed on the screen.	Adjust the saline pump guide teeth up or down as needed. Adjust by pressing small black buttons on the side of the pump and moving them up or down. For saline pump malfunction (OT), raise the top part of the pump, begin to flush and lower the top portion of the pump again during the flush process.
There is air in the high-pressure tubing beyond the air detect sensor.	Beyond the high pressure (injection) tubing you can use saline or contrast with the hand controller. Make absolutely certain that the stopcock is turned off to the patient before purging the tubing.
There is air in the high-pressure tubing before the air detect sensor	Purge the syringe and the high pressure (injection) tubing. • Turn the stopcock off to the patient and purge the tubing. • Press the PURGE button in the SELECTION MODE box of the touchscreen. • Select Purge Tubing from the Status window.
Unnecessary movement of catheter at beginning of injection.	1. Increase the rise time. 2. Use less pressure when pressing the injection button. 3. Reduce the flow rate

Alert Messages

The table on the next few pages identifies alert messages, their probable causes, and corrective action. Messages are displayed in the Status Window area of the screen, unless otherwise indicated (some messages display in the Indicators Box part of the screen).

If a message cannot be cleared, contact an ACIST service representative. If the “Report to Service” box is checked, write down the message (including any error numbers or other details), and call a service representative to report it.

Alert Messages and Corrective Action

Message	Probable Cause	Corrective Action	Report to Service
Actuator Calibration Failed.	Calibration was disrupted or there was an unexpected result.	Shut down the system and power up again.	
Air Column Detect Sensor Failure.	Communication with ACD board was interrupted.	1. If prompted, press OK, or shut down the system and power up again. 2. Call a service representative to report this message.	√
AIR COLUMN DETECTED! (Status window message) Air Detected (Indicators box message)	The air column detector has detected air. There are two possible reasons for the message. •. Air is detected in the high pressure (injection) tubing by the air column detector. • The high pressure (injection) tubing has been pulled and the air column detect has been triggered.	To clear air from the tubing: 1. Disconnect the system from the patient. Make sure the stopcock is not open to the patient. 2. Check the high pressure (injection) tubing for air bubbles. 3. Press PURGE to purge air from the high pressure (injection) tubing. If no air is in the tubing, make sure connections are secure: 1. Firmly place and secure the high pressure (injection) tubing in the Air Column Detect Sensor. 2. Make sure that Air Column Detect Sensor latch is closed. 3. Press **INJECT** and **OK** to arm the system and resume the procedure.	

Message	Probable Cause	Corrective Action	Report to Service
Chamber Not Closed (Status window message) Chamber Open (Indicators box message)	Chamber is open. The chamber must be fully closed for proper operation of the system. Injector motor moves (inject, syringe purge, tubing purge and refill) will not be performed if the chamber is not closed. A magnetic switch located in the chamber door triggers the sensor.	1. Rotate the chamber to the closed position. Make sure the white latch pin clicks into place. 2. If the door is closed and the problem persists, call a service representative.	
Check Manifold Valve. Remove syringe assembly from chamber …OR Check the manifold valve sensor.	This message displays during setup if the system detects a patient kit in place before system calibration.	Remove the syringe assembly from the chamber or check the Manifold Valve Sensor.	
Check Syringe Valve. Remove syringe assembly from chamber …OR Clean syringe valve sensor and check cable connection.	This message displays during setup if the system detects a patient kit in place before system calibration.	Remove the syringe assembly from the chamber or check the Syringe Valve Sensor.	
Communication Error Has Occurred. Communication Timeout!	Communications errors.	1. Shut down the system and power up again. 2. Call a service representative to report this message.	√
Contrast Empty (Indicators box message)	No contrast has been detected by the Contrast Sensor. This message is displayed in the Indicators Box (the message “No Contrast” is displayed in the Status Window).	1. Make sure the contrast spike tubing is in the Contrast Sensor. 2. Make sure there is contrast in the container, or connect a new container. 3. Make sure the Contrast Sensor (the black sensor that clamps around the contrast spike) is clean. 4. Make sure the Contrast Sensor is closed tightly. 5. Make sure the white contrast spike clamp is open. 6. Make sure there are no air bubbles trapped in the spike. 7. Call a service representative.	
Counter/Position Mismatch.	During an injection, the system monitors two separate components to determine location of the ram in the syringe. This message will be displayed if these two separate feedback loops do not agree.	Press **OK** to continue. If the problem persists, call a service representative.	

Message	Probable Cause	Corrective Action	Report to Service
Disarm (Indicators box message)	The imaging system has disarmed the Voyager injection system.	Check the imaging system manual to see how to correct this on the imaging system side.	
DISARMED! (Status window message) **Voyager and CVi only**	While the imaging system had disarmed the Voyager, an attempt was made to arm the Voyager system.	Check the imaging system manual to see how to correct this on the imaging system side.	
DOS unable to stop injection motor error!	Hardware error.	Call a service representative to report this message.	√
Error #		Write down the error number displayed on screen and call a service representative to report it. You can try to continue by shutting down the system and powering up again.	
Front Stop Reached. Forward Limit Reached.	The syringe actuator ram has reached the maximum forward position. The system will not allow any forward moves (such as purge or inject).	1. Press OK to continue. 2. Press START REFILL (reverse move) to get the actuator ram off the front stop, or 3. If the problem persists, call a service representative.	
Function Timeout!	Calibration error.	1. Press OK to retry calibration. 2. Shut down the system and power up again, or 3. If the problem persists, call a service representative.	
Hand Controller Disabled **Voyager and CVi only**	The imaging system is disabling hand controller injections via the X-ray interface. This is a status message.	Most imaging systems will disable the hand controller and control the injection from the imaging system.	

Message	Probable Cause	Corrective Action	Report to Service
Hand Controller Calibration Failed. Hand Controller requires Calibration.	These error messages can occur if: 1. You press the Contrast Button on the hand controller before the message prompts you to do this. 2. You accidentally press the Saline Button instead of the Contrast Button. 3. The hand controller was not calibrated at setup. 4. Connection to the touchscreen is not tight. 5. Defective hand controller.	1. Make sure you wait until the message displays on screen to press the Contrast Button (do not press the Saline Button). 2. Check to see if the hand controller attachments are secure (at bottom of the touchscreen), or 3. To retry hand controller calibration, press the CALIBRATE HC key. **NOTE:** The hand controller must be calibrated successfully each time you begin a case. If you disconnect or change a hand controller at any time during a case, you must calibrate it.	
Injection Motor Malfunction (OS). Injection Motor Malfunction (OT).	1. Internal error. 2. For OT errors, there may be a restriction in the fluid flow.	1. Make sure the stopcock is open and that fluid flow is not restricted in any part of the system or patient kit. 2. Write down the screen message (and whether it says “OS” or “OT”), and call a service representative to report this message.	√
Interprocessor Ping Error.	Communications error.	1. Turn system power off and on again. 2. If the problem persists call a service representative to report this message.	√
Invalid calibration data.	During initial startup calibration, the system checks the calibration data. If an error is detected, this message is displayed. In addition to the error message, an error description, error value, and expected value will be displayed.	1. Press OK to retry calibration. 2. Write down the error message displayed on screen and call a service representative to report it.	√

Message	Probable Cause	Corrective Action	Report to Service
Invalid calibration data. Can't Resume!	During the RESUME function, the system checks the calibration data. If an error is detected, this message is displayed.	1. Press OK to continue, or turn system power off and on to restart. 2. If the problem persists, call a service representative.	
Invalid HC16 Response! Restart Setup: turn power OFF and ON again. 0x0, 0x0, 0x0, 0x0	Communications error. The 0x0 represents code numbers that correspond to the problem.	Write down the error number displayed on screen and call a service representative to report it. You can try to continue by turning system power off and on again.	
Manifold Valve Closed.	The manifold valve was detected as closed when it should have been open.	During startup, make sure there is no patient kit in the chamber.	
Manifold valve failed to close X times using current syringe. Contrast may be contaminated! **CMS2000, Voyager and CVi only**	This message may be displayed if you are using the CMS2000 for multiple cases. The message will display after you end a case, if the "Manifold Open" message occurred anytime during the case.	If you start a new case, use a new patient kit and a new container of contrast.	

Message	Probable Cause	Corrective Action	Report to Service
Manifold Valve Open. (same message displayed in Status window and Indicators box)	The manifold valve, located inside the manifold, is designed to open at the beginning of an injection and close when an injection is complete. Therefore, you will see “Manifold valve open” displayed as an informational message in the Indicators box. However, if the manifold valve stays open after an injection, pressure needs to be released from the manifold. You may still be able to inject, so you may continue the procedure. The message indicates that this valve is out of position due to: 1. The manifold has not been properly placed in the holder. 2. The manifold remains in an open position due to pressure from the Ram. 3. The patient kit is defective. 4. Special Case: Manifold Valve and Syringe Valve are Open at same time.	1. Check the manifold and make certain that it has been secured into the holder, or 2. Press the Standby button on the side of the screen to allow the manifold to close, or 3. Make sure the contrast spike clamp is open, or 4. Try performing a tubing purge, or 5. Replace patient kit with a new kit.	
Motor Speed Incorrect.	Internal error.	1. Press OK to continue, or turn system power off and on to restart. 2. If the problem persists, call a service representative.	
No Contrast (Status window message)	See “Contrast Empty.”	See “Contrast Empty.”	
No X-ray Interface (Indicators box message) **Voyager and CVi only**	A connection on the internal X-ray interface board is not connected, or there is a wiring problem.	Call a service representative.	

Message	Probable Cause	Corrective Action	Report to Service
Non-system disk or disk error	System is experiencing problem reading the software chip.	Call a service representative.	
NVRAM Failure!	The NVRAM failed a self-test during startup.	Call a service representative.	
Pressure Limit (Indicators box message)	The system is limiting the pressure by decreasing the motor speed (flow rate).	Because the system automatically limits the pressure, the selected flow rate may not be reached. Otherwise, you do not need to take any corrective action unless you see the "Pressure Limit Exceeded" message (see below).	
Pressure Limit (Indicators box message)	The system is limiting the pressure by decreasing the motor speed (flow rate).	Because the system automatically limits the pressure, the selected flow rate may not be reached. Otherwise, you do not need to take any corrective action unless you see the "Pressure Limit Exceeded" message (see below).	
Pressure Limit Exceeded (1) Pressure Limit Exceeded (2) NOTE: Use the corrective actions for either of these messages. The notations (1) and (2) are useful to report to a service representative, if a call for service is needed.	•Stopcock is not open to allow injection. •Catheter is kinked. •Preset pressure is too low for required injection.	1. Make sure stopcock is open and catheter is not kinked. 2. Increase the preset pressure. 3. Decrease the flow rate. 4. Increase the rise time.	
PURGE is Incomplete.	The front stop is reached before the syringe valve closes. The syringe purge function removes air from the syringe. When all air is removed, contrast will force the syringe valve closed, triggering a successful purge. If the purge fails to close the syringe valve, this message is displayed.	1. Do a refill (press START REFILL), and then Purge. 2. Retry syringe purge. After the purge is complete, the system is ready to be armed for the next series of injections, or 3. Replace patient kit, or 4. Call a service representative (syringe valve sensor may be defective).	
Ram Forward (Indicators box message)	Ram has reached the forward position.	Informational only.	
Ram Reverse (Indicators box message)	Ram has reached the reverse position.	Informational only.	

Message	Probable Cause	Corrective Action	Report to Service
Release trigger for new injection.	Displayed after an injection that was initiated from the hand controller.	Release the Contrast Button on the hand controller and press it again to begin a new injection. Note: If the message is displayed after a large injection (any flow rate more than 10 ml/s, or volume more than 20 ml), you must press OK on the screen to confirm the large injection before continuing.	
Reverse Limit Reached	Ram has reached the reverse position.	Press OK to continue.	
Reset X-ray interface for new injection **Voyager and CVi only**	Displayed after an injection that was initiated from the imaging system.	Release the x-ray trigger on the imaging system before the next injection	
Saline Pump Malfunction (OS).	Internal error.	1. Press OK to continue. 2. Write down the screen message, and call a service representative to report the message.	√
Saline Pump Malfunction (OT).	Soft saline tubing is obstructed or pinched. The saline pump pressure required to dispense saline is greater than the internally set safety limit.	1. Make sure the tubing is properly seated and latched in the saline pump. Open the roller pump. Align the soft saline tubing and adjust the tubing guides (V-teeth). The tubing guides should hold the tubing but not pinch the tubing off to restrict flow. 2. Check the saline tubing for blockage, replacing this portion of the patient kit if necessary. 3. If the problem persists, write down the screen message, and call a service representative to report this message.	√

Message	Probable Cause	Corrective Action	Report to Service
Standby!	The screen is locked and “Standby” is displayed. If the Standby button is depressed, all system activity is suspended.	1. Check the cable connections between the control panel and the injector head. 2. Assess your situation in the procedure. If you are prepared to continue with the procedure, release the Standby button (located on right side of the control panel) and press OK to continue.	
Start Injection **Voyager and CVi only**	Indicators box message. This message will display when the injection is initiated from the imaging system, even if the “Inject Delay” setting delays the actual start of the injection.	Informational only.	
Syringe Not Detected	An installed syringe was not detected, or the small metallic ball in the top of the syringe is stuck in the up position. This error message will occur if you try to go past the first step in the setup process without inserting the syringe into the syringe chamber.	1. Install a syringe. Load syringe into chamber when screen displays “Load Syringe” (but not before this). 2. Clean the Syringe Valve Sensor. 3. Use a new patient kit. 4. Call a service representative (sensor may require replacing).	
Syringe Valve Closed	The small metallic ball in the top of the syringe is stuck in the up position, or the Syringe Valve Sensor needs cleaning.	1. Do a refill to pull the ball down. 2. Clean the sensor. Make sure the gray wire connection for the Syringe Valve Sensor is clean and plugged in, or 3. If the problem persists, change the disposable syringe. 4. Call a service representative.	

Message	Probable Cause	Corrective Action	Report to Service
Syringe Valve Open (same message displayed in Status window and Indicators box)	The small metallic ball in the top of the syringe is in the down position, or the Syringe Valve Sensor needs cleaning.	1. During startup, make sure there is no disposable in the chamber before “Start” is displayed on screen. 2. Press Purge, Syringe to purge the syringe and close the valve, or 3. Clean the sensor. Make sure the gray wire connection for the Syringe Valve Sensor is clean and plugged in, or 4. Call a service representative.	
There is a 10 second limit for Flush.	The internal timeout for the flush function is 10 seconds. The system automatically stops the flush function after this time.	The timeout serves as a safety feature. The function can be repeated.	
There is a 10 second limit for Purge.	The internal timeout for the purge function is 10 seconds. The system automatically stops a purge function after this time: •If tubing purge, the timeout expired. •If syringe purge, the ball was not seated properly before the timeout expired.	The timeout serves as a safety feature. Press Purge to continue.	
There is a 20 minute limit for KVO. **Voyager and CVi only**	The internal timeout for the KVO function is 20 minutes. The system automatically stops the KVO function after this time.	The timeout serves as a safety feature. The function can be repeated.	
Values Out of Range!	Communications error.	1. Turn system power off and on again. 2. Call a service representative to report this message.	√

Section 8: Specifications

System Control

User selectable dual mode control:

- Interactive control
- Pre-programmed microprocessor control.

You have constant interactive control via a continuously variable hand controller within the limits that you set. The microprocessor monitors operation of the system and acts to limit the system when parameters have been met.

Power Requirements

Standard: 100–120 VAC ~ factory selectable, 50–60 Hz, 10 A maximum

Optional: 200–240 VAC ~ factory selectable, 50–60 Hz, 5 A maximum

Electrical Leakage

Less than 10 µA (microamperes) for patient connect

Less than 100 µA (microamperes) chassis

The devices comply to ISO 60601-1 and UL 2601-1.

Load Rate

Fill 1 - 2 ml/sec, syringe air purge 6 ml/s.

Safety and Sensor Checks

Safety and Sensor checks

Limit Switches	**Fixed Position forward and reverse limit switches**	
Flow rate (speed)	For any selected flow rate, the injector will not allow an over speed of greater than 25% of the selected (input) flow rate for a duration greater than 4 ms.	
Accuracy of over pressure limit	Accuracy	Pressure Limit Setting
	± 100 psi (690 kPa)	Pressure limit ≤ 500 psi (3,447 kPa)
	± 30% of setting	500 psi (3,447 kPa) < Pressure limit ≤1,250 psi (8,618 kPa)
Air column detect	User aid for detection of air columns	
Chamber open	Detects that the chamber is open	

Injection Parameter Ranges

System	Injection type	FLOW[1] (ml/s)	VOLUME[2] (ml)	PRESSURE[3] Pounds per square inch – psi (Kilopascals–kPa)	RISE TIME[4] (sec)
CL100H, CMS2000, and CVi (Cardiac mode)	LCA	0.8 – 10.0	0.8 – 20.0	200 –1,200 (1,379 – 8,274)	0.0-1
	RCA	0.8 – 10.0	0.8 – 20.0		
	LV/Ao	0.8 – 40.0	0.8 – 99.9		
	Other	0.8 – 40.0	0.8 – 99.9		
Voyager and CVi (Peripheral mode)	Pigtail	0.8 – 40.0	0.8 – 99.9	200 –1,200 (1,379 – 8,274)	0.0–1
	Selective	0.8 – 15.0	0.8 – 99.9	200 –1,200 (1,379 – 8,274)	
	Microcatheter	0.8 – 3.0	0.8 – 10.0	200 –300 (1,379 – 2,068)	
	Other	0.8 – 40.0	0.8 – 99.9	200 –1,200 (1,379 – 8,284)	

1. In 0.1 ml/sec increments.
2. In 0.1 ml increments.
3. In 1 psi (1 kPa) increments.
4. In 0.1 sec. increments.

Saline Rate

Automated fixed flow rate of 100 ml/min.

Status Readouts

Contrast Remaining: Real time, total volume in Injection Syringe

Contrast Delivered: Real time, cumulative volume of contrast delivered per case in ml; reset with each new case. Also reset if power is turned off and on again.

Last Injection: 0-99.9 ml @ 0-40 ml/sec (real time, peak/injection; reset each injection)

Program Control

- Infinite single level injections
- Variables entered through keypad on display screen for fixed rate injections

Height

User-configurable positioning system.

May be used as a cart and/or patient table (bed)-mounted system with remote control console.

Weight

Standard Power Supply: .. .. 28.0 lbs. (12.7 kg.)

Siemens Power Supply: . .. . 36.0 lbs. (16.3 kg.)

Control Panel and Stem: .. .. 7.5 lbs. (3.4 kg.)

Pedestal Cart: . .. . 52.0 lbs. (23.6 kg.)

Injector Head: . .. . 45.0 lbs. 20.4 kg.)

CVi Adjustable Arm: . .. . 1.45 lbs (0.66 Kg.)

CVi Control Panel and Stem: .. .. .. 7.0 lbs. (3.18 Kg.)

Cord Lengths

Power cord: .. .. 12 feet (3.7 meters)

Control console:.. .. .. 10 feet (3 meters)

Injector Head power: .. .. 5 feet (1.5 meters)—mobile cart mounted

Specifications that Apply to UL Labeled Product

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: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Transportation and Storage Requirements

Type of Temperature Range	Injection System	Patient Kits
Ambient temperature range	-40º to 122º F (-40º to 50º C)	0º to 122º F (-18º to 50º C)
Relative humidity range	10 to 95% non-condensing	Same
Atmospheric pressure range	7 to 15 psi (50 to 106 kPa)	10 to 15 psi (70 to 106 kPa)

Operating Environment Requirements

Type of Temperature Range	Injection System	Patient Kits
Ambient temperature range	18º C to 29.4º C (64º F to 85ºF)	Same
Relative humidity range	10 to 95% non-condensing	Same
Atmospheric pressure range	10 to 15 psi (70 to 106 kPa)	Same

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

Section 9: Voyager and ACIST CVi
Supported Imaging Systems

The Voyager and CVi models synchronize with the following X-Ray imaging systems.

		CVi	Voyager
Siemens	AXIOM Artis BA/dBA	p	✓
	AXIOM Artis BC/dBC	p	✓
	AXIOM Artis FA/dFA	p	✓
	AXIOM Artis FC/dFC	p	✓
	AXIOM Artis MP/dMP	p	✓
	AXIOM Artis TA/dTA	p	
	AXIOM Artis TC/dTC	p	
	Iconos R200		✓
	Sireskop		✓
	Bicor		✓
	Coroskop		✓
	Neurostar		✓
	Multistar		✓
	Angiostar		✓
	Polystar		✓
GE	Advantx Series	p	✓
	Innova Series	p	✓
Philips	Allura Xper FD10	p	✓
	Allura Xper FD20	p	✓
	Integris Allura Series	p	✓
Toshiba	Infinix i-series	p	✓
p = pending			

This table reflects current interface capabilities as of this revision. Please contact the manufacturer for any updates if your system is not identified here.

Section 10: Warranty Information

CL100H/CMS2000 Limited Warranty

ACIST Medical Systems (“ACIST”) makes no representations or warranties concerning its procedures and services, express or implied, written or oral, except those set forth herein. This warranty is available and extended only to the original end-user purchaser. ACIST Medical Systems, makes NO WARRANTY as to whether or not any particular or desired result is obtainable by application and use of the ACIST System.

ACIST Medical Systems warrants that the ACIST System will be free of defects in material and workmanship for a period of one (1) year following installation, subject to the following exceptions:

1. Misused
2. Abused
3. Altered

Any part or component of the ACIST System that is judged to be defective by ACIST Medical Systems in material or workmanship during the warranty period will be repaired or replaced by ACIST Medical Systems at its option and its expense. Remedies available to the purchaser under this warranty are limited to repair or replacement of malfunctioning parts, system replacement, or refund of the purchase price with the specific remedy subject to election by ACIST Medical Systems in its sole and reasonable judgment.

ACIST Medical Systems shall under no circumstances be liable for special, indirect, incidental or consequential damages including without limitation, any real or perceived loss of use, revenue, or profit.

Application for warranty remedy must be made to ACIST Medical Systems within thirty (30) days of the apparent malfunction.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, ACIST MEDICAL SYSTEMS MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE ACIST SYSTEM, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTIBILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. ACIST MEDICAL SYSTEMS SHALL NOT BE LIABLE FOR ANY OTHER DAMAGES, INCLUDING, BUT NOT LIMITED TO, SPECIAL INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE ACIST SYSTEM.

NOTWITHSTANDING ANYTHING CONTAINED IN THIS MANUAL TO THE CONTRARY, ACIST MEDICAL SYSTEMS SHALL UNDER NO CIRCUMSTANCES BE LIABLE TO THE PURCHASER OR ANY THIRD PARTY FOR SPECIAL, 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 OR ARISING OUT OF THE PURCHASER’S FAILURE TO COMPLY WITH ALL OR ANY OF THE PROVISIONS OF THIS MANUAL AND/OR THE FAILURE OF THE ACIST SYSTEM TO PERFORM AS SPECIFIED, EVEN IF ACIST MEDICAL SYSTEMS SHALL HAVE BEEN ADVISED TO THE POSSIBILITY OF SUCH DAMAGES.

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The representations and warranties contained in this manual, may be changed, modified or amended only by an agreement signed by an authorized representative of ACIST Medical Systems.

Voyager™ E2000 and ACIST CVi Limited Warranty

ACIST Medical Systems (“ACIST”) makes no representations or warranties concerning its procedures and services, express or implied, written or oral, except those set forth herein. This warranty is available and extended only to the original end-user purchaser. ACIST Medical Systems, makes NO WARRANTY as to whether or not any particular or desired result is obtainable by application and use of the ACIST Voyager Model E2000 Contrast Delivery System (“Voyager System”).

ACIST Medical Systems warrants that the Voyager System will be free of defects in material and workmanship for a period of one (1) year following installation, subject to the following exceptions:

1. Misused
2. Abused
3. Altered

Any part or component of the Voyager System that is judged to be defective by ACIST Medical Systems in material or workmanship during the warranty period will be repaired or replaced by ACIST Medical Systems at its option and its expense. Remedies available to the purchaser under this warranty are limited to repair or replacement of malfunctioning parts, system replacement, or refund of the purchase price with the specific remedy subject to election by ACIST Medical Systems in its sole and reasonable judgment.

ACIST Medical Systems shall under no circumstances be liable for special, indirect, incidental or consequential damages including without limitation, any real or perceived loss of use, revenue, or profit.

Application for warranty remedy must be made to ACIST Medical Systems within thirty (30) days of the apparent malfunction.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, ACIST MEDICAL SYSTEMS MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE VOYAGER SYSTEM, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTIBILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. ACIST MEDICAL SYSTEMS SHALL NOT BE LIABLE FOR ANY OTHER DAMAGES, INCLUDING, BUT NOT LIMITED TO, SPECIAL INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR PERFORMANCE OF THE VOYAGER SYSTEM).

NOTWITHSTANDING ANYTHING CONTAINED IN THIS MANUAL TO THE CONTRARY, ACIST MEDICAL SYSTEMS SHALL UNDER NO CIRCUMSTANCES BE LIABLE TO THE PURCHASER OR ANY THIRD PARTY FOR SPECIAL, 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 OR ARISING OUT OF THE PURCHASER’S FAILURE TO COMPLY WITH ALL OR ANY OF THE PROVISIONS OF THIS MANUAL AND/OR THE FAILURE OF THE VOYAGER SYSTEM TO PERFORM AS SPECIFIED, EVEN IF ACIST MEDICAL SYSTEMS SHALL HAVE BEEN ADVISED TO THE POSSIBILITY OF SUCH DAMAGES.

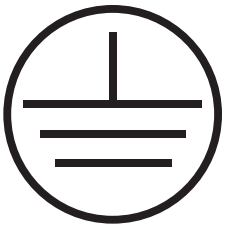
IT IS REQUIRED THAT THE VOYAGER SYSTEM BE OPERATED BY OR BE UNDER THE IMMEDIATE, DIRECT SUPERVISION OF AND CONTROLLED BY A BOARD-CERTIFIED CARDIOLOGIST AND SUPPORTED BY OTHER QUALIFIED PERSONNEL, ALL TRAINED IN ANGIOGRAPHIC CATHETERIZATION. THEREFORE, ACIST MEDICAL SYSTEMS DISCLAIMS LIABILITY FOR AND THE PURCHASER AGREES TO INDEMNIFY AND HOLD HARMLESS ACIST MEDICAL SYSTEMS FROM ALL INJURIES, DEATHS, OR PROPERTY DAMAGE AND ALL CLAIMS, SUITS, COSTS, JUDGMENTS, OR LEGAL FEES ARISING FROM SAME OCCURRING

IN CONNECTION WITH THE USE OF THE VOYAGER SYSTEM BY ANYONE OTHER THAN QUALIFIED PERSONNEL DESCRIBED ABOVE.

The representations and warranties contained in this manual, may be changed, modified or amended only by an agreement signed by an authorized representative of ACIST Medical Systems.

Section 11: Symbols

Alternating current



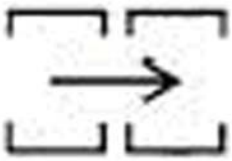
Protective earth ground

Attention: Consult accompanying documents

On

Off

Type CF Equipment



Use only with other parts marked with this symbol

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