Operation Manual

MEDRAD® Avanta

Fluid Management Injection System

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The MEDRAD® Avanta Fluid Management Injection System has an expected service life* of 7 years from the date of product installation when operated according to the instructions provided with this device. These 7 years include suggested or mandatory actions of preventative maintenance and repair activities, as well as required calibration(s) that are needed. Required reading includes the instructions for use and other materials provided with the device. This also includes any hardware and software updates that may be required.

*EXPECTED SERVICE LIFE - The length of time that an individual unit, lot, or batch of devices is expected to remain functional after it is placed into use.

Report any serious incident that has occurred in relation to this device to Bayer (radiology.bayer.com/contact) and to your local European competent authority (or, where applicable, to the appropriate regulatory authority of the country in which the incident has occurred).

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1 - Information



Important Safety Notice to Users of the MEDRAD® Avanta (Avanta) Fluid Management Injection System

This manual and the equipment it describes are for use only by qualified medical professionals with adequate training and experience in angiographic procedures and the use of the MEDRAD® Avanta Fluid Management Injection System. It is intended as a guide for using both the Injector and dedicated MEDRAD® Avanta disposables.

The Avanta Fluid Management Injection System contains a gross air detection feature which is intended to assist qualified medical professional users/operators during injections to detect gross air contained in the Multi-Patient Disposable Set. As noted throughout this manual, operator vigilance is always required to eliminate potential air hazards during use.

The safe and effective use of the Avanta Fluid Management Injection System to a large degree depends upon factors solely under the control of the medical professionals using the system. There is no substitute for a properly trained and vigilant angiographic team. It is important that the operating instructions and user warnings supplied with this Injection System be read, understood and followed.

Before starting any angiographic injection procedure the angiographic team should be trained in the particular angiographic procedures to be performed, and should be familiar with the medical literature related to angiographic procedures and the potential complications and risks versus the benefits of utilizing angiographic fluid injection procedures.

This manual is intended as an extension of the user interface of the MEDRAD® Avanta Fluid Management Injection System to provide procedural and technical information. Additional MEDRAD® Avanta training information is available in the following formats:

- On-site in-service sessions
- In-service video
- Service manual
- Package inserts (IFU)
- User Tips

Please do not hesitate to contact Bayer if any of these resources are needed.

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2 - About this Manual

This manual applies to the MEDRAD® Avanta Fluid Management Injection System, Catalog Numbers: AVA 500 PEDL, AVA 500 TABL.

Read all of the information contained in this manual. Understanding this information will assist you in operation of the MEDRAD® Avanta Fluid Management Injection System in a safe manner.

2.1 Certifications

This device is equipped to operate at 100-240 VAC, 50/60 Hz, 1200 VA, and is designed to comply with IEC 60601-1 (2nd and 3rd Edition Amendment 1) and IEC 60601-1-2 (2nd, 3rd, and 4th Editions) standards, including national differences.

2.2 Intended Use

The MEDRAD® Avanta is specifically intended for operation in the x-ray angiography environment. It is designed to administer intravascular radio-opaque contrast compounds, and common flushing agents at various volumes and flow rates into humans for use in diagnostic and interventional angiographic procedures performed in cardiology, radiology, and vascular surgery.

2.3 Contraindications

This device is not intended to be used for chemotherapy and is not intended to administer fluids other than intravascular contrast agents and common flushing solutions.

2.4 Restricted Sale

RX Only - Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

2.5 Disclaimers

External wiring and modifications disclaimers: Bayer disclaims liability for any modifications or interfaces with other equipment that are not in conformity with the specifications and information contained within this manual.

Anyone who connects additional equipment to the device or configures a medical system is responsible that the system complies with the relevant requirements of IEC 60601-1. An accessory or equipment connected to the device must be certified to either IEC 60601-1 (Operator or Patient Environment Use) or, outside the patient environment, the level of safety must be equivalent to equipment complying with their respective IEC or ISO safety standards, e.g. IEC 62368-1 or IEC 60950-1 (Operator Environment Use Only), and must comply with the relevant requirements according to IEC 60601-1. Consult Bayer for any modifications to the equipment.

Screen images in this manual are for illustration purposes only. Actual screens may vary.

3 - Symbols

The following symbols are used on the MEDRAD® Avanta Fluid Management Injection System and components:

3.1 Notified Body

CE 2797

Indicates that the device conforms to the requirements of the European Union Medical Device Regulation 2017/745

3.2 Regulatory Classifications

IPX1

Code that specifies the degree of protection provided by the enclosure against vertically falling water drops (IEC 60529)

Type Cardiac Floating (CF) Defibrillation-Proof applied part (IEC 60417-2, 5336)

3.3 Warnings



Air Warning Label

- Air Embolism Hazard: injury or death can result.
- Observe change in MEDRAD® FluiDots Indicators, for syringes from Bayer.
- Expel air from syringe/disposables.
- Read Operation Manual.

Attention: Refer to warnings and cautions on Instructions for Use packaged in each carton. (ISO 15223-1, 5.4.4)

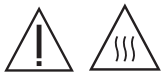
Warning: Indicates hazardous voltages (ISO 7010, W012)

Warning: Indicates a pinch or crush hazard. (ISO 7000, W024)
(Pedestal & Table Mount Bracket)

WARNING: Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the injection system.

CAUTION: Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device. Read and understand the cautions before operating the injection system.

NOTE: Indicates that the information that follows is additional important information or a tip that will help you recover from an error or point you to related information within the manual.



Caution: Indicates hot surface. Item can be hot and should not be touched without taking care. (ISO 15223-1, 5.4.4; IEC TR 60878, 5041)



IV pole volume limit. Less than or equal to 1000 mL for saline bag and contrast bottle.



Consult instruction for use. (ISO 15223-1, 5.4.3)



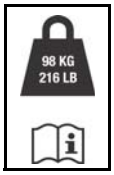
See accompanying documentation. This symbol indicates the user shall refer to the instructions-for-use to ensure safe operation. (ISO 7010, M002)



Medical - General Medical Equipment
As To Electrical Shock, Fire, and Mechanical Hazards Only
In accordance with ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012)
CAN/CSA-C22.2 No. 60601-1 (2014)



Pushing Prohibited. Do not push at or above this point on the Injector. (ISO 7010, P017)



Maximum weight of the injector system and accessories during normal use (ISO 7000, 1321B; ISO 15223-1, 5.4.3)

3.4 Buttons and Icons

The buttons on the Display Control Unit (DCU), Injector Head, and Power Unit allow operators to access functions on the injector system. The icons used on the DCU, Injector Head, Fluid Control Module, and Power Unit notify operators about system processes and identify connection ports.

3.4.1 Display Control Unit Buttons and Icons



Check for Air icon



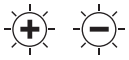
Fluid delivery indicator



Indicates on/off switch. (IEC TR 60878: 5010, 5265)



Service Port Connector



Brightness Up (+) and Down (-)
(IEC TR 60878, 5056)



Screen display: The injector is configured for ISI and it is operational.

3.4.2 Injector Head Icons



Syringe Heat Maintainer connection

3.4.3 Fluid Control Module Icons



Foot Switch connector (IEC TR 60878, 5114)



Connector, Hand Controller



Bottle Heat Maintainer

3.4.4 Power Unit Icons



Identifies the Equipotential connection. (IEC 60417, 5021)



Identifies the protective Earth Ground point (internal). (IEC TR 60878, 5019)



Connector, DCU interface cable



Service Port Connector



Head cable connector.



ISI connection



Data connection (future implementation)



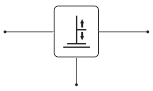
Indicates separate collection for Electrical and Electronic Equipment per Directive 2002/96/EC. Refer to the following website for additional information:
www.weee.bayer.com



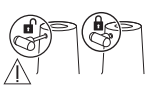
Indicates Alternating Current. (IEC 60417, 5032)

3.5 Mounting

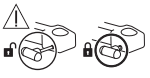
3.5.1 Pedestal



Pedestal height adjustment/range of motion. Raising/Lowering symbol on handle.



Lock and release for Pedestal



Lock and release for DCU arm

3.5.2 Table Mount



Lock and release for Table Mount Bracket

3.6 Packaging



Non-Pyrogenic (ISO 15223-1, 5.6.3)



Non-Pyrogenic Fluid Path (ISO 15223-1: 5.6.2, 5.6.3)



Do not use if package is opened or damaged. (ISO 15223-1, 5.2.8)



Single Use Only (ISO 15223-1, 5.4.2)



Do not exceed five patients per day usage.



Date of Manufacturer (ISO 15223-1, 5.1.3)



Use By (ISO 15223-1, 5.1.4)



Lot Number (ISO 15223-1, 5.1.5)



Catalog Number (ISO 15223-1, 5.1.6)



Sterilized with Ethylene Oxide (ISO 15223-1, 5.2.3)



Sterilized using irradiation (ISO 15223-1, 5.2.4)



Not made with natural rubber latex



Warning - Advises you of circumstances that could result in injury or death to the patient or operator.



Caution - Advises you of circumstances that could result in damage to the device.



Device contains phthalates (BS EN 15986:2011)



Do not resterilize (ISO 15223-1, 5.2.6)



Authorized Representative in the European Community (ISO 15223-1, 5.1.2)



Manufacturer (ISO 15223-1, 5.1.1)



This side up (ISO 7000, 0623)



Keep dry (ISO 15223-1, 5.3.4)

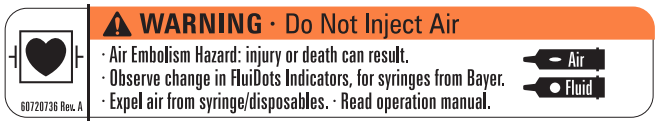


Fragile, handle with care (ISO 15223-1, 5.3.1)

4 - Warnings and Cautions

4.1 Warnings

Patient injury or death could result from an air embolism.



- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- To minimize air embolization risks, ensure that one operator is designated as being responsible for filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that air has been removed from the fluid path.
- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not fill or inject unless the syringe is properly engaged with the injector head. Improper engagement may cause an under volume delivery, air embolization or personal injury.
- Do not attempt to aspirate fluid from the waste port stopcock when open to the PIV. Doing so may increase the risk of inducing air into the fluid path.
- Do not attempt to aspirate fluid from the hemodynamic port. Doing so may increase the risk of inducing air into the fluid path.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.
- Verify no air is present in the tubing between the drip chamber and fluid source.
- Verify that the fluid path is open and free of air before attempting an injection.
- No modification of equipment is allowed.

Patient injury could result from leaks or ruptures during an injection. To prevent leaks or ruptures in the event of a blockage, use only disposable products from Bayer.

Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

Do not exceed the five patients per day usage for the Multi-Patient Disposable Set (MPAT). MPAT Integrity and performance could be affected if 5 patient usage is exceeded.

Do not use if sterile package is opened or damaged. Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually inspect contents and package before each use.

For devices labeled for single use, please note: This product is intended for single use only. Do not resterilize, reprocess or reuse. The disposable devices have been designed and validated for single use only. Re-use of the single use disposable devices pose risks of device failure and risks to the patient. Potential device failure includes significant component deterioration with extended use, component malfunction, and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be cleaned or re-sterilized.

For all body fluid spills/contamination, follow institutional decontamination procedures. If contrast medium has leaked inside any component of the system, the affected subassembly should be disassembled and cleaned by Services personnel or returned to Bayer.

Use of non-Bayer accessories, including heat maintainers, Foot Switch, cables and replacement parts may degrade system performance and cause equipment damage. Use only Bayer heat maintainers, Foot Switch, cables and replacement parts from Bayer.

Use of non-Bayer supplied disposables, including administration sets and additions to administration sets, such as but not limited to bleed back control devices and pressure transducers may cause patient injury if not properly connected or flushed. These devices must be compatible with your system. Refer to manufacturer's instructions for proper use of these devices.

Use of extension tubing connected to the Single Patient Disposable Set may cause patient injury and will degrade system performance. Do not connect extension tubing to the Single Patient Disposable Set.

Do not use the system to inject unintended media. The injection system has only been validated for its specified intended use. There may be additional risks associated with use of the system for other purposes due to insufficient performance specifications, or operational safeguards. Contact Bayer for additional information.

Use of non-Bayer supplied accessories, external components, and replacement parts for internal components may result in increased emissions or decreased immunity for the equipment or system. Use only accessories and replacement parts supplied by Bayer.



Explosion hazard: Explosion risk may exist if the system is used in the presence of flammable anaesthetic mixtures, and/or flammable agents for disinfection and/or skin cleaning.



Electrical Shock hazard: Serious injury or death may result from exposure to hazardous voltages existing within the system. Operator injury could result from worn cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, do not disassemble the injection system in any way. Worn cabling also creates voltage hazards. If any worn or damaged cables are detected, do not use the injection system. Contact Bayer or your local dealer for service or replacement.



Do not rotate the injector head by applying force at the syringe tip. Possible injury can occur if the injector head or stand falls on the patient or technologist. Move the injector by grasping the center of the handle, and by pulling or pushing the injector into place.



To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



Burn hazard: Operator injury may result if contact is made with the heater element. Do not touch the bottle or syringe heat maintainer heater elements.



Only use the power cord supplied with the system. Do not plug the MEDRAD® Avanta Fluid Management Injection System power cord into an extension cord or multi-outlet power strip.



Do not disassemble the Power Unit assembly. No user serviceable parts exist within the assembly.



Component damage may occur if disposables are not installed properly. Ensure all connections are secure. This will help minimize leaks, disconnections, air introduction, and component damage. Do not use tools to over tighten connections or to assist in removal of disposables.



The system is not to be serviced or maintained while in use with a patient.

4.2 Cautions



DO not hang items on the Display Control Unit, its mounting arm or any other component of the system. Hanging items on the Display Control Unit or other components may result in failure of the mounting system and can result in personal injury and/or equipment damage.



Do not remove any covers or disassemble any parts of the system. The system does not contain user serviceable parts. Refer to the MEDRAD® Avanta Fluid Management Injection System Service Manual (86498197) for information regarding replacement of the Power Unit air filter. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact Bayer for repairs.

Do not block Power Unit vents. Installation clearance should be a minimum of 3 to 5 inches (8 to 13 cm).

For proper operation, use only accessories and options provided by Bayer that are designed specifically for the injector system. Other non-Bayer approved accessories or options may cause equipment damage or may result in increased emissions or decreased immunity of the injector system. Injector system accessories listed in the operation manual comply with the requirements of electromagnetic emissions and immunity standards IEC 60601-1-2 / 2nd, 3rd, and 4th Editions.

System malfunction may be caused by failure to perform regular maintenance. Regular preventive maintenance is recommended to ensure that the system stays calibrated and functions properly. Refer to this manual or contact Bayer for additional information.

Condensation may cause electrical damage to the injection system. Do not use the system immediately after it has been brought indoors from extreme outside temperatures. Allow the system to stabilize at room temperature before use.

Additional warnings, cautions and notes are located throughout this manual, where applicable.

5 - System Basics

5.1 System Overview

The system configurations include table mount brackets for the Fluid Control Module/Injector Head and display components, as well as a movable pedestal mounting of the components. The power unit may be mounted directly to the moveable pedestal or used remotely.

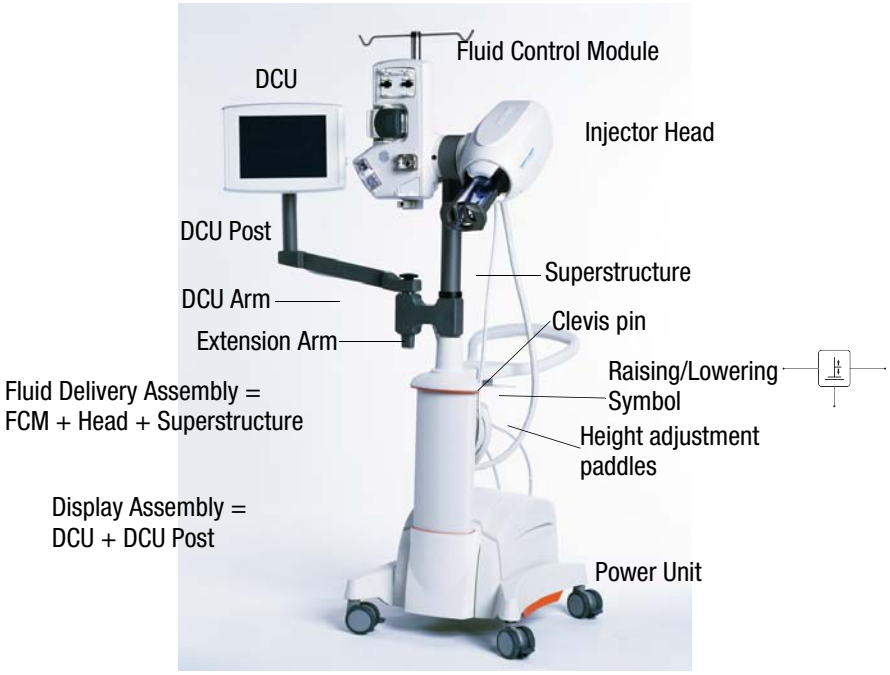
The MEDRAD® Avanta Fluid Management Injection System provides the following features:

- Variable rate which can be increased or decreased by the physician during the injection
- Fixed rate programmable flow of contrast up to 45 mL/sec.
- Variable rate programmable flow of contrast up to 10 mL/sec.
- Programmable filling and refilling of syringes during a procedure without requiring disconnection of the disposable set from the patient
- Fluid level sensing to ensure syringe filling and fluid delivery only when a fluid supply is available
- Hand Controller, enabling solo operation of the injector during a patient procedure
- Gross air detector
- Saline injection for purging and flushing
- Multi-Patient disposable components that may be used for up to five patients
- Disposable Hand Controller that provides control of contrast and saline injections
- Sharp bolus at the end of contrast injections.

The injection system does not control the imaging system via the ISI module. The ISI notifies the scanner of the injector status, which enables the scanner to synchronize the scan timing based upon when the injection started. The scanner controls the start of the scan sequence after it has received the injection start status and will not start the scan unless the scanner is in the correct state. The scanner system maintains full control of the radiation initiation.

5.2 Configurations

5.2.1 Pedestal Configuration



5.2.1.1 Pedestal Movement

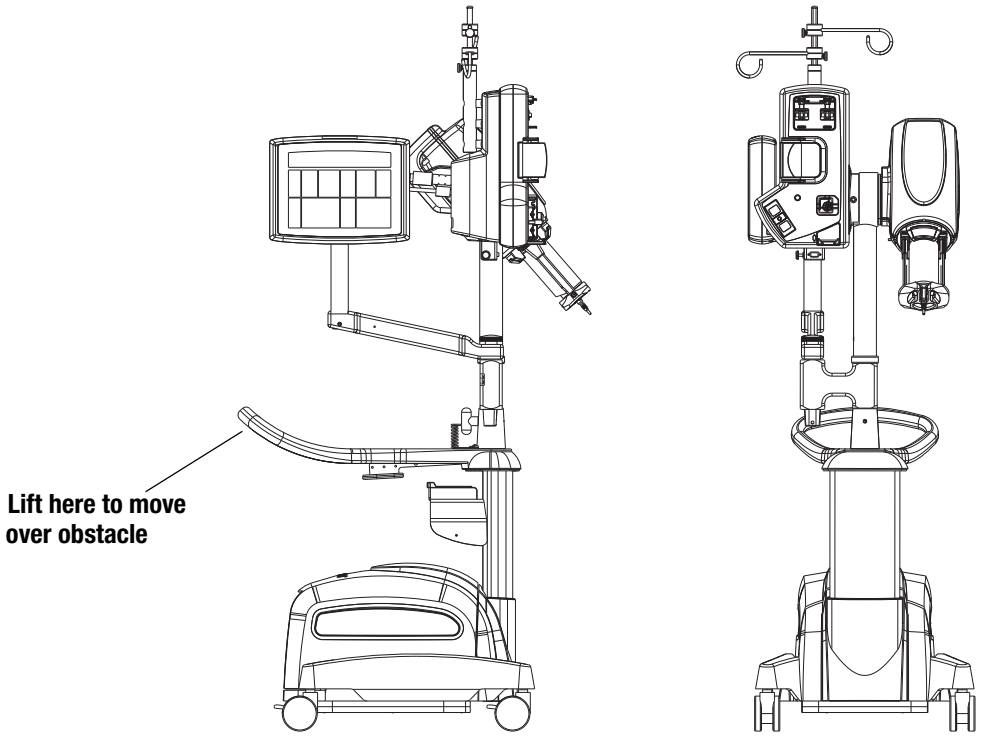
Warning: Patient or operator injury may result if the injection system is moved without locking the Superstructure and/or extension arm. Failure to do so may result in disengagement or adverse movement of the Superstructure or DCU. Do not move the injection system without locking the Superstructure to the pedestal and the DCU to the extension arm.

Warning: Patient injury may result if the injector head or pedestal is moved while the catheter is connected to the patient. Ensure the catheter is disconnected from the patient before moving the injector.

Warning: Do not position the injector by pulling on the head or cabling, or by applying force at the syringe tip. Possible injury can occur if the injector head or stand falls on the patient or technologist. Move the injector by grasping the center of the handle, and by pulling or pushing the injector into place.

Caution: Component damage could occur if the pedestal rolls over the cables. When moving the pedestal, ensure the cables are out of the way.

Place pedestal system components into the approximate positions shown below prior to moving the system. When necessary, lift pedestal by using the handle to move over obstacles.



5.2.2 Table Mount Configurations

Warning: Patient and/or operator injury or system malfunction may result if the exam table is not horizontal in both planes during an injection when using the Table Mount Bracket Configurations (1 and 2). Ensure that the table is horizontal in both planes at all times when using the Table Mount Bracket Configurations (1 and 2).

Table Mount Bracket Configuration
(2 Table Mount Brackets)

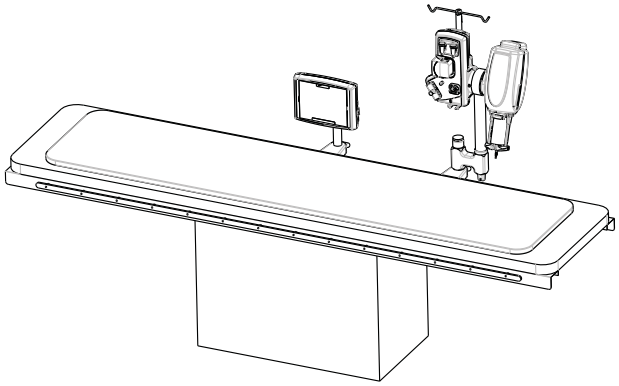
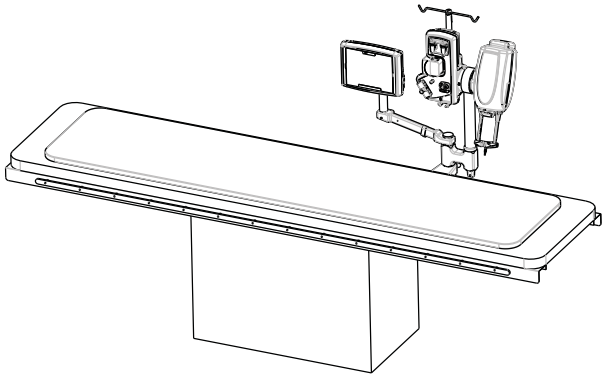


Table Mount Bracket Configuration
(1 Table Mount Bracket)



5.2.3 Table Mount Bracket Installation

Warning: Pinching can occur if the Superstructure and the table are not mated properly during transfer, installation and/or removal. To avoid pinch points and personal injury, use care and diligence while mating the Superstructure to the table and the Superstructure with the pedestal interface. Keep hands and fingers clear of all pinch point areas.

Caution: Component damage may occur if the table rail cannot withstand a minimum vertical static load of 36.3 kg (80 lbs.) Before installing the Table Mount Bracket, ensure the table rail can withstand a minimum vertical static load of 36.3 kg (80 lbs.) Refer to the table manufacturer documentation for weight load information.

Caution: Over tightening the knobs may cause the Table Mount Bracket to work improperly. Do not over tighten the knobs.

Caution: Forcing the Table Mount Bracket onto an incorrectly sized table rail could damage the bracket or table rail. Do not force the bracket onto the table rail.

Refer to installation instructions in section “Table Mount Bracket Installation” on page 103.

5.3 Transferring the system

5.3.1 Transfer from Pedestal to Table Mount

The following instructions describe how to transfer the system from the pedestal to the Table Mount Brackets.

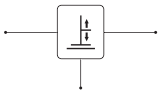


Ensure the following:

- Table Mount Brackets are mounted to table
- Table is horizontal and lift mechanism is operational
- System is mounted on pedestal
- Power outlet is within ten feet of the mounting location
- Power Unit is mounted on pedestal
- Display Assembly is mounted on

1. Position the table at it is lowest horizontal position and the superstructure at a higher horizontal position than the top of the Table Mount Bracket.

   NOTE: When raising or lower the pedestal ensure that your hands are placed in the area of the raising/ lowering symbol on the handle.



2. Remove the clevis pin from the DCU arm.
3. Remove the Display Assembly from the DCU arm.
4. Insert the Display Assembly into the DCU Table Mount Bracket and secure with clevis pin.
5. Remove the DCU arm from the superstructure.
6. Verify the male end of the knuckle support arm is aligned directly over the female mounting receptacle of the Table Mount Bracket.
7. Engage the handle height adjustment actuator paddle and push the superstructure downward so that the knuckle support arm is engaged to the Table Mount Bracket.
8. Secure the clevis pin to the Table Mount Bracket.
9. Remove the clevis pin from the pedestal.
10. Raise the table up to lift the superstructure from the pedestal.
11. Remove the Power Unit from the pedestal and place it in a desirable location within ten feet of both Table Mount Brackets.
12. Remove the pedestal and DCU arm from the immediate area for storage.
13. Plug the Power Unit into the wall outlet.
14. Complete the Inspection Procedure.

5.3.2 Transferring from Table Mount Brackets to the Pedestal

Caution: Component damage may occur if the Table Mount Bracket lock is not released prior to removal of components. Ensure lock is released before removal.

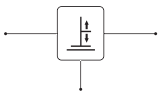
The following instructions describe how to transfer the system from the Table Mount Brackets to the pedestal. (Refer to the illustration in “Pedestal Configuration” on page 16.)

Ensure the following:

- Table is horizontal and lift mechanism is operational
- System is mounted on Table Mount Bracket
- Power Unit is in a nearby location
- Display Assembly is on Table Mount Bracket.

1. Place the pedestal next to the table.
2. Place the Power Unit onto the lower portion of the pedestal.
3. Lower the pedestal to the lowest position.

   NOTE: When raising or lower the pedestal ensure that your hands are placed in the area of the raising/ lowering symbol on the handle.



4. Position the table so that the knuckle support arm is at a higher horizontal position than the pedestal.
5. Verify the male end of the knuckle support arm is aligned directly over the female mounting receptacle of the pedestal.
6. Engage the handle height adjustment actuator paddle to raise the pedestal upward so that the knuckle support arm is engaged to the pedestal.
7. Secure the clevis pin to the pedestal.
8. Remove the clevis pin from the Table Mount Bracket.
9. Lower the table to disengage from the Table Mount Bracket. If lowering the table does not provide enough clearance, raise the pedestal.
10. Place the DCU arm onto the pedestal.
11. Remove the clevis pin from the DCU Table Mount Bracket.
12. Move the Display Assembly from the Table Mount Bracket to the DCU arm.
13. Insert the clevis pin into the DCU arm.
14. Plug cables into the Power Unit, if required.

5.4 Pressure Limit

The MEDRAD® Avanta Fluid Management Injection System is designed to allow varied and fixed flow rates for contrast injections. In order to understand this section on Pressure and Pressure Limiting, it is important to clarify the terminology that will be used in this section.

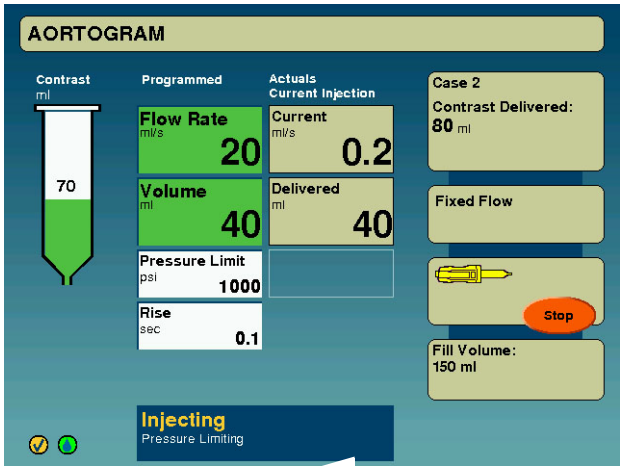
Pressure: Related to the amount of force which the injector head must develop in the syringe in order to move fluid at the selected Flow Rate.

Flow Rate: Selected on the Display Control Unit in units of mL/sec.

In order for contrast media to flow through the disposable system, the pressure in the syringe must exceed the resistance of the disposable system. Pressure in the syringe is generated by the force driving the syringe plunger. This pressure decreases over the entire length of the disposable system. As the fluid flows out the end of the catheter, there will be virtually no

pressure. Pressure will be essentially zero at the open (unrestricted) end of the catheter because there is no resistance to fluid flow. To achieve a selected Flow Rate, the pressure exerted by the plunger must be great enough to overcome the resistance of the disposable system. To do this, the force behind a fluid must be great enough to push it through a tube.

A pressure limit condition is indicated on the screen when it occurs as shown below.



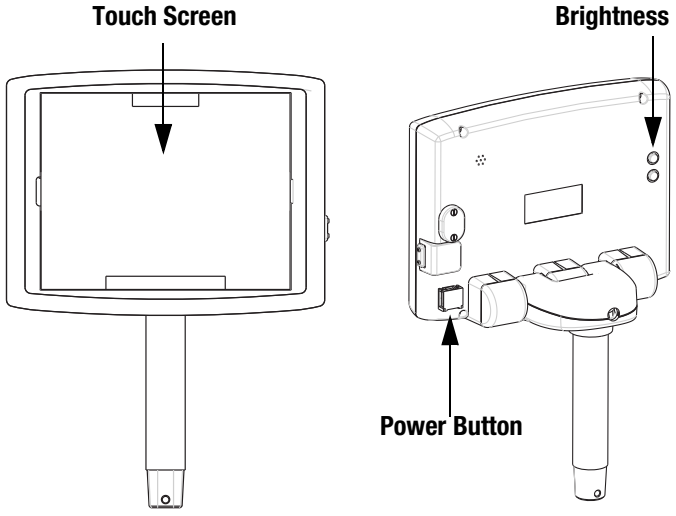
5.4.1 If a Restriction Occurs

Warning: Re-check the fluid path for air before arming.

When injecting into an occlusion or a restriction, if pressure higher than the set pressure limit is detected or a stall condition (flow rate less than 10% of programmed rate for 1 second) occurs, the injection will be terminated. If such a disarm occurs, check the fluid path for blockage and kinks. Inspect the disposable set for damage, and check the recommended catheter flow rates. If no blockage or restriction is found consider increasing the catheter size or decreasing the flow rate.

5.5 Display Control Unit

The Display Control Unit (DCU):



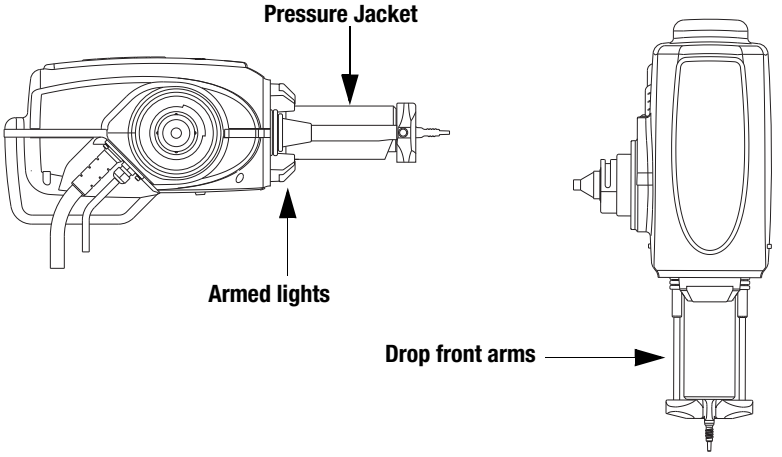
The DCU interface is designed as a color touch screen display.

Control	Function
Brightness Up (+)	Increases the display brightness.
Brightness Down (-)	Decreases the display brightness.
Power Button	Turns unit on and off.

5.6 Injector Head

The injector head pivots at least 90 degrees above the horizontal plane. This feature is to maximize the buoyancy force of air for purging. The head also pivots at least 70 degrees below the horizontal plane. This feature is to trap any remaining air in the back of the syringe during injection.

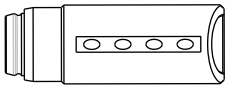
All lighting controlled by the head illuminates at power up to allow confirmation of operation. The lights stay on from two to ten seconds.



5.6.1 Pressure Jacket

Important Safety Notice: The MEDRAD® Avanta pressure jacket is intended to be used by medical professionals with adequate training and experience in the operation of the MEDRAD® Avanta Fluid Management Injection System and angiographic procedures and techniques.

The pressure jacket must be used to ensure the integrity of the syringe.



5.6.1.1 Pressure Jacket Storage

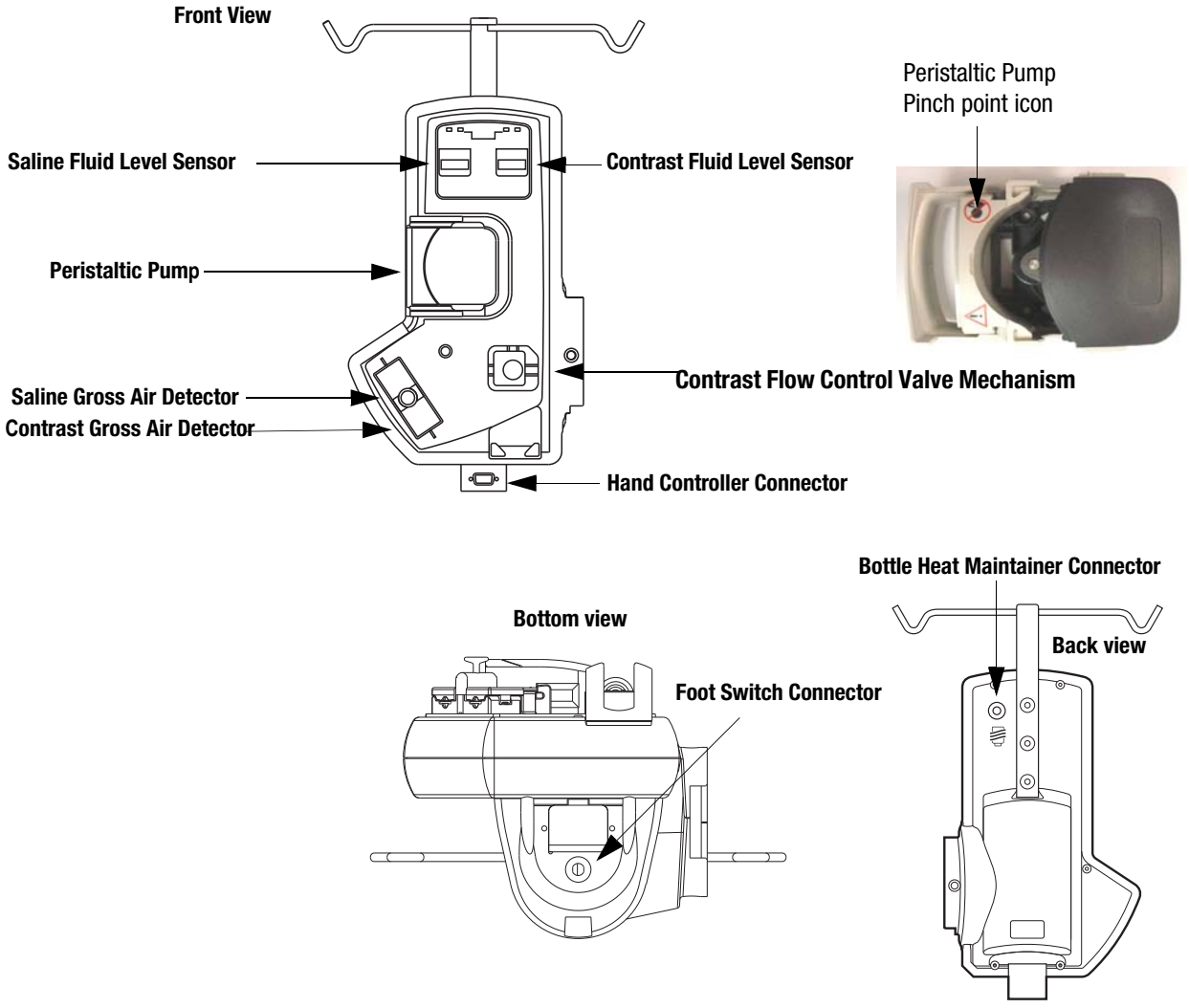
When not in use, the pressure jacket should remain securely attached to the injector head. Alternately, the pressure jacket may be wrapped in a cloth and stored where it will not be hit or dropped.

For cleaning and sterilization of the pressure jacket refer to "**Cleaning the Pressure Jacket**" on page 84 in the Cleaning and Maintenance section.

5.7 Fluid Control Module (FCM)

The Fluid Control Module (FCM) includes:

- Saline and contrast fluid level sensors
- Contrast Flow Control Valve Mechanism that directs the contrast for filling of the syringe, injection or closing of the contrast fluid path
- Gross air detector for both the MPAT contrast and saline delivery lines
- Peristaltic Pump that drives saline injection
- Connections for the installation and removal of disposable elements, Hand Controller, Foot Switch, and Bottle Heat Maintainer.



5.7.1 Fluid Level Sensors

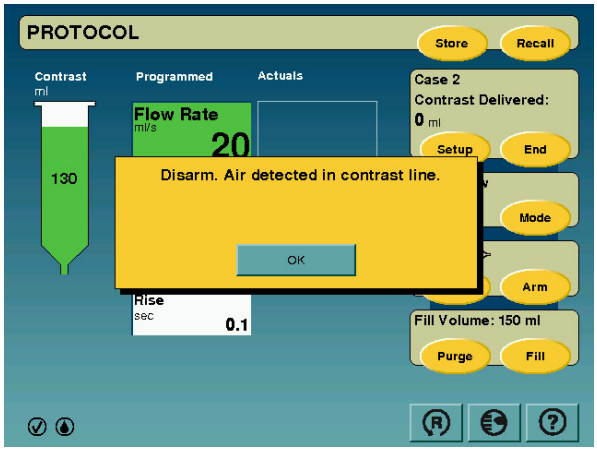
The FCM detects the absence of fluid in either the contrast or saline drip chamber. There is white lighting behind the drip chambers which flash when there is insufficient fluid.

5.7.2 Gross Air Detectors

Warning: The Avanta Fluid Management Injection System contains a gross air detection feature which is intended to assist qualified medical professional users/ operators during injections to detect gross air contained in the Multi-Patient Disposable Set. As noted throughout this manual, operator vigilance is always required to eliminate potential air hazards during use.

The FCM detects the presence of gross air in the contrast and/or saline delivery lines during injections and is intended to assist qualified medical professional users/operators during injections to detect gross air contained in the Multi-Patient Disposable Set.

The system disarms if air is detected in the contrast or saline fluid paths of the Multi-Patient Disposable Set to minimize the injection of an air bolus to the patient. The user or operator is responsible for making sure that the fluid path is free of air before injecting.



5.7.3 Contrast Flow Control Valve Mechanism (CFCV)

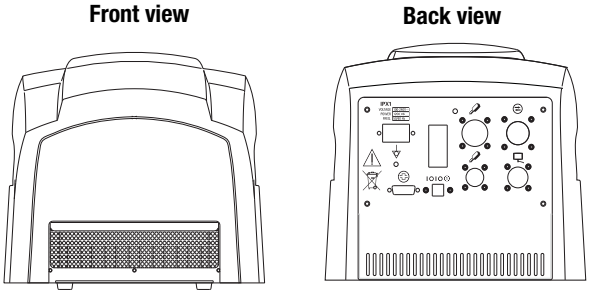
The contrast flow control valve mechanism (CFCV) allows the path of the contrast to change. The mechanism has three positions: inject (open to the patient and closed to the source), fill and closed (closed to the patient and open to the source).

5.7.4 Peristaltic Pump

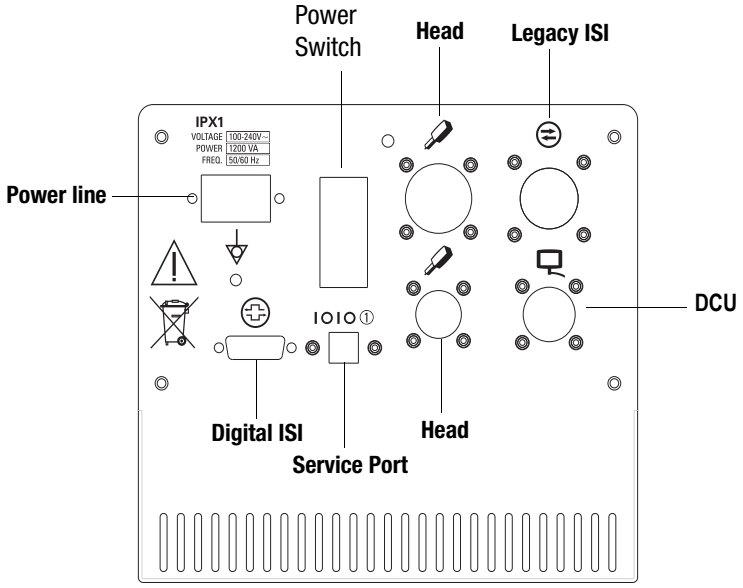
The Peristaltic pump delivers saline for flushing during imaging procedures.

5.8 Power Unit

The Power Unit is a self-contained unit that serves the injector system with system power conversion and distribution, power line switching and conditioning, a system grounding hub, an Ethernet 5 port switch, and Imaging System Interface (ISI) ports. The Power Unit can be mounted away from the procedure area, either under the patient bed or on a pedestal, reducing the amount of clutter in that area. The head, DCU and service communications links are 10/100BaseT Ethernet.



See enlarged view below.



5.8.1 Power indicator

The Power Unit has a green light indicating the power status. When illuminated, AC power is ON and when not illuminated, the AC power is OFF. The indicator is part of the master power switch on the Power Unit.

5.9 Accessories

5.9.1 Fluid Bags/Bottles

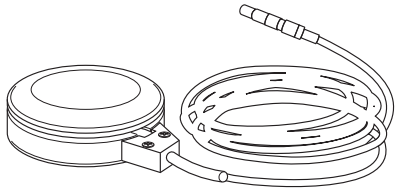
The FCM provides a means to hang saline and contrast bags and bottles to provide fluid to the drip chambers.

5.9.2 Contrast Heat Maintainers (option)

Refer to Bayer document number DN-229073 - MEDRAD® Avanta Bottle Heat Maintainer Instructions for Use or DN-229075 - MEDRAD® Avanta Syringe Heat Maintainer Instructions for Use.

5.9.3 Foot Switch (option)

Foot Switch



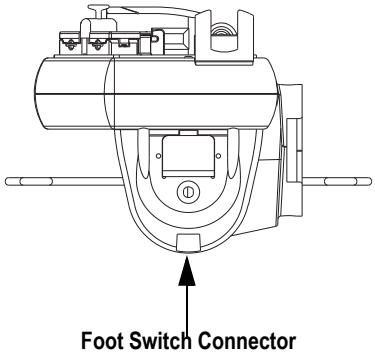
Contrast injections may be initiated by the optional Foot Switch. This device can only be used in the fixed rate injection mode. The Foot Switch does not support the variable rate injection mode. A fixed rate injection is initiated when the Foot Switch is depressed and stops the injection when released.

NOTE: The system is designed to ensure that once an injection is initiated by an injection device, no other injection device input will be acknowledged while that injection is in progress.

5.9.4 Foot Switch Installation

1. Ensure that the injector is in the disarmed state.
2. Open the Foot Switch box.
3. Remove the Foot Switch from the box.
4. Plug the Foot Switch into the Fluid Control Module – Foot Switch Connector (see drawing below).

Fluid Control Module - bottom view



Foot Switch Connector



Foot Switch symbol

NOTE: If the Foot Switch is damaged or does not work properly, discontinue use and discard.

5.10 System Technical Specifications

5.10.1 Input Power Requirements

100-240 VAC

50/60 Hz

1200 VA

5.10.2 Technical Specifications

Contrast Flow Rate:	**Variable Flow: 1.0 - 10.0 in 1.0 mL increments**
	Fixed Flow: 1.0 - 45.0 in 0.1 mL increments
Saline Flow Rate:	**Fixed Rate: 0.75 - 1.50 mL/sec**
Automated Saline Flush:	**1 - 20 min in 1 min increments**
	0.1 - 20 mL per/min in 0.1 mL increments
Volume:	**1-150 mL in 1 mL increments**
Pressure Limit (150 mL syringe):	**300-1200 psi in 1 psi increments**
Rise time:	**0.0-9.9 seconds in 0.1 increments**
Delay Time:	**0.0-99.9 seconds in 0.1 increments**
Fill Speed:	**Fixed**
Fill Volume:	**1-150 mL**
Syringe Size:	**150 mL**
Protocol Memory:	**40 Protocols**

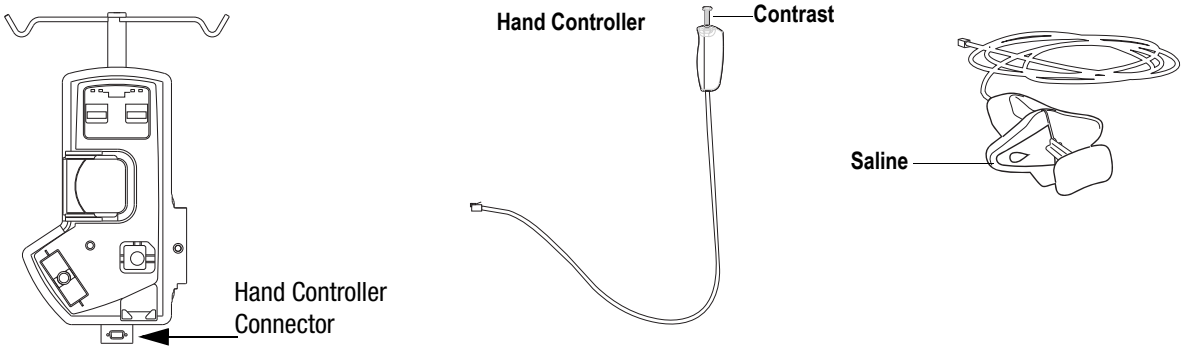
6 - Disposables

6.1 MEDRAD® Avanta Hand Controller

Caution: Component damage may occur if the MEDRAD® Avanta Hand Controller is immersed in fluid. Avoid immersion when using the Hand Controller unsheathed.

The MEDRAD® Avanta Sterile Hand Controller is a sterile device intended for single patient use. It can also be used multiple times for up to five patients when used with the MEDRAD® Avanta Hand Controller Sterile Sheath.

The Hand Controller works in two different modes, variable and fixed. When in the variable rate injection mode, the flow rate increases incrementally as the Hand Controller is depressed, and decreases as the Hand Controller is released. In the fixed rate injection mode, the Hand Controller acts as a start switch, and release of the device ceases all flow. The Hand Controller also allows the start and stop of the flow of saline. The Hand Controller is designed to be discarded after each patient or after every five patients, when used with a single-patient disposable sheath.



6.2 Sterile Sheaths

Warning: Biological contamination can result from reusing single use disposable items or failure to follow sterile technique during setup or use. Properly discard single use disposable items after use.

6.2.1 MEDRAD® Avanta Hand Controller Sterile Sheath

The transparent sterile sheath for the MEDRAD® Avanta Sterile Hand Controller allows the Hand Controller to be used for more than one patient. The sterile sheath is designed to fit over and around the Hand Controller and cable assembly without impairing operator functions, and is attached to the Fluid Control Module (FCM) at the cable/FCM interface using sterile technique. The MEDRAD® Avanta Hand Controller Sterile Sheath is intended for single patient use.

6.2.2 DCU Sterile Sheath

The MEDRAD® Avanta DCU Sterile Sheath is intended for single patient use. It is designed to quickly slip over the entire DCU using sterile technique, and allows complete access to the touch screen as well as the re-positioning of the DCU on its mounting structure.

6.3 Multi-Patient Disposables

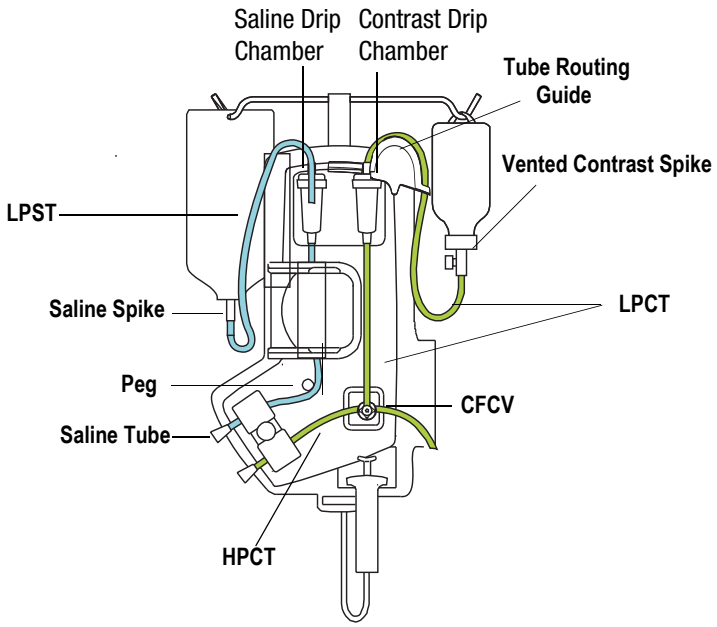
The Multi-Patient Disposable Set (MPAT) consists of a syringe, contrast tubing, and saline tubing:

Contrast Tubing

- Vented Contrast Spike with Low Pressure Contrast Tube (LPCT)
- Contrast Drip Chamber - clear, flexible reservoir that helps initiate the filling of the fluid pathway.
- High Pressure Contrast Tube (HPCT)
- Contrast Flow Control Valve (CFCV) - a stopcock that functions in three positions: inject, fill, and closed.
- Male Luer with multi-guard connector

Saline Tubing

- Saline Spike with Low Pressure Saline Tube (LPST)
- Saline Drip Chamber - clear flexible reservoir that helps initiate the filling of the fluid pathway.
- Female Luer with multi-guard connector



6.3.1 Syringe

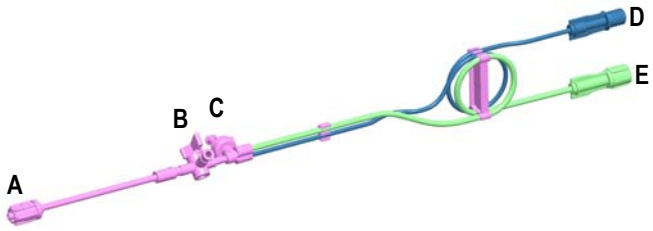
The syringe interface supports a single 150 mL contrast syringe. The head has a sensor that detects the presence of a syringe. A syringe is attached to the head from the front of the injector (front loading). The syringe locks into place when the drop front arms are locked. You can remove the syringe from the piston rod at any position within the normal travel of the piston. A syringe can also be removed with or without the injector head powered or without removing a disposable from the syringe. While the injector head is on, the syringe has white backlighting available to assist in visualization. The white backlighting is a selectable feature through the configurations menu.

6.4 Single-Patient Disposables

The Single-Patient Disposable Set AVA 500 SPAT L which is intended for use with a user attachable transducer, consists of the following items, all attached, to form a single complete element:

- Rotating luer **(A)**
- Waste port stopcock **(B)**
- Pressure Isolation Valve (PIV) Assembly / Hemodynamic pressure monitoring Port **(C)**
- High Pressure Saline tube with male Luer connector **(D)**
- High Pressure Contrast Tube with female Luer connector **(E)**.

Single-Patient Disposable Set (AVA 500 SPAT Angio) is indicated for use when a user does not need a transducer and does not contain item **(C)** pictured below.



7 - Powering Up and Shutdown the System

7.1 Powering Up the System

Warning: Injector may disarm or fail to operate upon exposure to high electromagnetic fields that may be generated by radio transmitters or cellular phones, or upon exposure to high levels of electrostatic discharge. Turn off any equipment that could generate an electrostatic discharge.

Warning: Explosion Hazard: Explosion risk may exist if the system is used in the presence of flammable anaesthetic mixtures, and/or flammable agents for disinfection and/or skin cleaning.

Warning: Electrical Shock Hazard: Operator injury could result from using an extension cord or power adaptor with the system. Plug the injector directly into a properly grounded AC power outlet. Since the injector power cord supplies a safety ground to the unit, using an extension cord will compromise the ground quality and the injector could become unsafe.

Warning: Only use the power cord supplied with the system. Do not plug the MEDRAD® Avanta Fluid Management Injection System power cord into an extension cord or multi-outlet power strip.

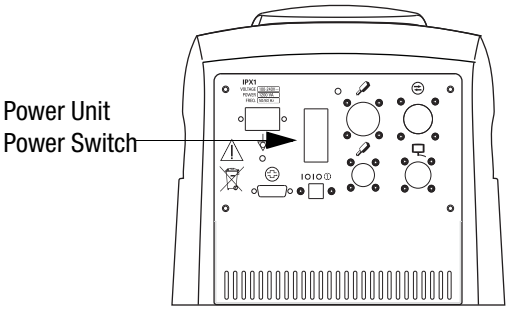
Caution: Damage can occur as a result of incorrect voltage. Verify that the voltage and frequency marked on the serial tag on the back of the Power Unit module matches the voltage and frequency of the electrical outlet.

Caution: Component damage may occur if fluid is pulled into the Power Unit vents. If the Power Unit is located remotely, ensure that it is placed away from any puddles of fluid or spills.

To power up the system:

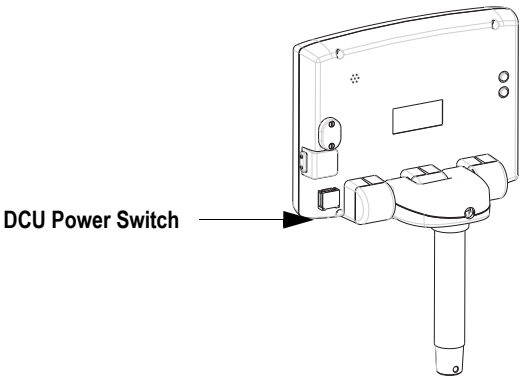
1. Turn on the master power switch on the Power Unit. The system responds by illuminating a green light on the Power Unit to indicate that the power is on and properly operating.

Back of Power Unit

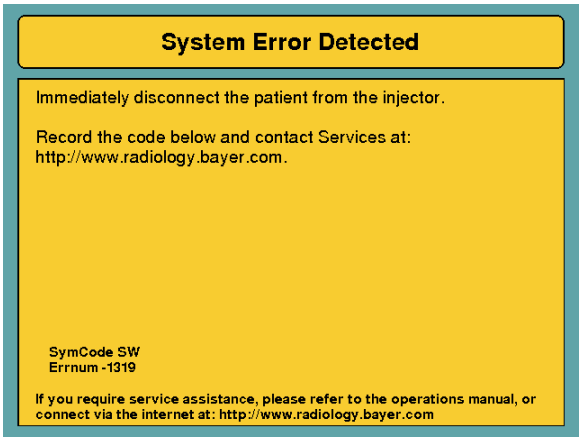


2. Turn the DCU on. The system responds by running self diagnostics.

Back of DCU



NOTE: If the system does not power up, or a system error is detected such as the one below, disconnect the patient, record the code and contact Bayer.



3. On the DCU, press “Continue.” The system displays the main screen, is powered-up and ready to use.

7.2 Emergency Shutdown

Warning: Patient injury may result from a system malfunction. If a system malfunction occurs, immediately remove unit power by pressing the On/Off switch on the Display Control Unit and disconnecting the unit from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the injection system. Call Bayer or your local dealer for assistance.

In the event of an emergency such as a fire, explosion, or electrical shock, the power can be shut down by disconnecting the power cord, or turning off the power switch on the Power Unit.

8 - Display Control Unit Functions

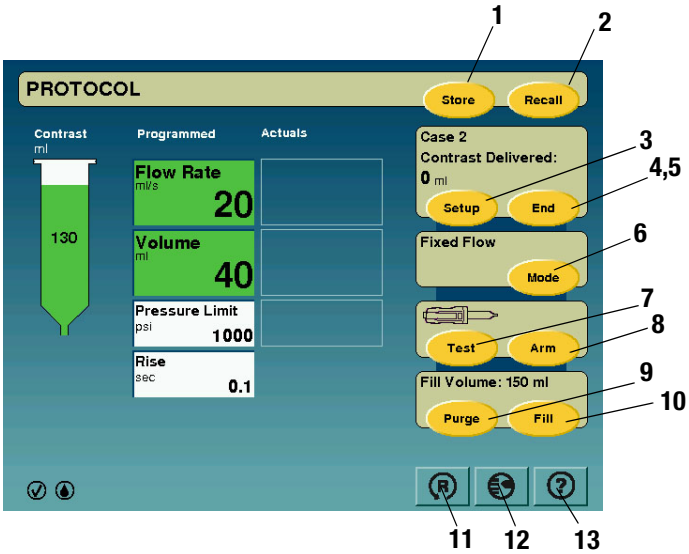
8.1 ⚠ System Safety Information

When power is applied to the system, the system Safety screen appears on the display, and a series of self-diagnostic tests are performed. The Safety screen provides information about safe operation of the injector and potential hazards associated with an injection procedure.



8.2 Main Screen

The Main screen is used during injection protocol programming, syringe refill, arming and injecting. Different options are visible based on the operation being performed and the screen configuration.



8.2.1 Screen functions

1. Store

To save a protocol, touch “Store” on the Main screen.

2. Recall

To access protocol memory, touch “Recall” on the Main screen.

3. Setup

Touch “Setup” on the Main screen to access functions to assist setup of the disposable components.

4. New

Touch “New” in the Case Panel to start a patient case.

5. End

Touch “End” in the Case Panel to end the patient case.

6. Mode

To select between Fixed and Variable Flow modes, touch “Mode” on the Main Screen.

7. Test

To arm in preparation for test injection, touch “Test” on the Main screen.

8. Arm

To arm in preparation for injection, touch “Arm” on the Main screen.

9. Purge

To access the Purge screen, touch “Purge” on the Main screen.

10. Fill

To fill the syringe with configured Auto Fill Volume, touch “Fill” on the Main screen.

11. Reset

To reset all parameters associated with the current injection protocol to default values, touch Reset on the Main screen.

12. Configuration

To configure the system for particular needs, touch Configuration on the Main screen.

13. Help

To access the Help screen, touch “Help” on the Main screen.

8.2.2 Reset

Pressing Reset returns all currently programmed parameters to the factory default settings.

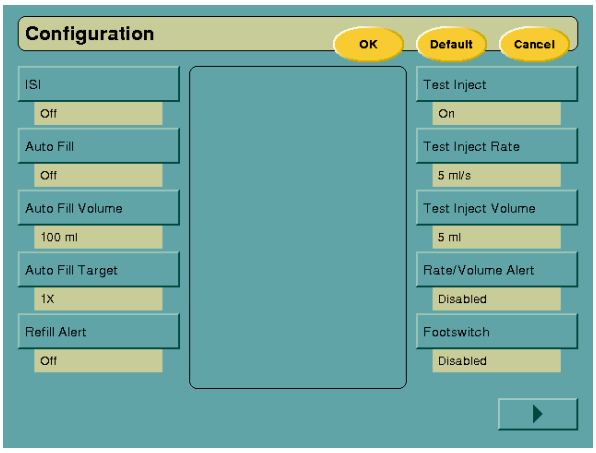
The following values are the factory default parameters:

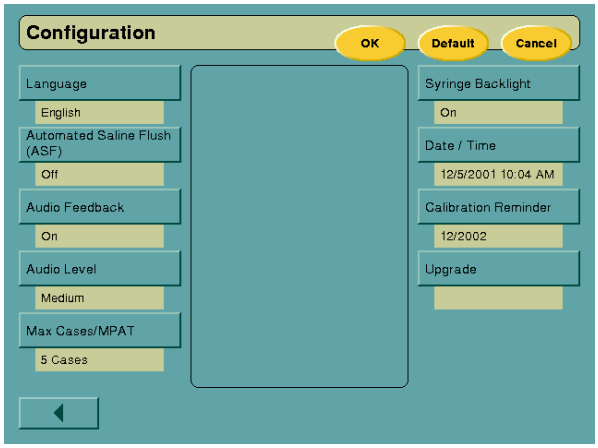
- Flow Rate: 1.0 mL/s
- Volume: 1 mL
- Rise time: 0.1 s
- Pressure limit: 1000 psi
- Delay Type: none
- Delay Duration: 0

8.2.3 Configuration Screen

The Configuration screen may be accessed by pressing Configuration located on the DCU touch screen display.

The Configuration screen allows the selection of configurable options and preferences, as well as the setting of date and time parameters.





The following table identifies the configurable items and their selectable values.

Configurable Item	Selectable Value
ISI	On, Off
Auto Fill	On, Off
Auto Fill Volume	25 mL, 50 mL, 75 mL, 100 mL, 125 mL, 150 mL
Auto Fill Target	1X, 2X, 3X
Refill Alert	Off, 25 mL, 50 mL, 75 mL
Test Inject	On, Off
Test Inject Rate	1 mL/s, 2 mL/s, 3 mL/s, 4 mL/s, 5 mL/s
Test Inject Volume	1 mL, 2 mL, 3 mL, 4 mL, 5 mL
Rate/Volume Alert	On, Off
Foot Switch	Enabled, Disabled

Configurable Item	Selectable Value
Language	Languages Available
Automated Saline Flush (ASF)	On, Off
Audio Feedback	On, Off
Audio Level	Loud, Medium, Soft
Max Cases/MPAT	1 - 5 Cases
Syringe Backlight	On, Off
Date / Time	Date, time
Calibration Reminder	Date
Upgrade	

8.2.4 Help

The Help screen may be accessed by pressing Help located on the DCU touch screen display. Descriptions are included below of each button on the Help screen



8.2.5 Touch Screen Calibration

To calibrate the touch screen, simultaneously press both the Brightness up (+) and Brightness down (-) buttons on the back of the DCU. A series of screens with instructions will appear.

NOTE: Calibration can only be performed from the system Safety screen.

8.3 Manage Protocols

8.3.1 Program a Protocol

Warning: Pressure settings must be lower than catheter and other disposables ratings. If a blockage occurs, tubing with a lower pressure rating may be subjected to pressure beyond its capability resulting in a failure. Always verify that the pressure setting on the injector is lower than the maximum ratings of any disposables.

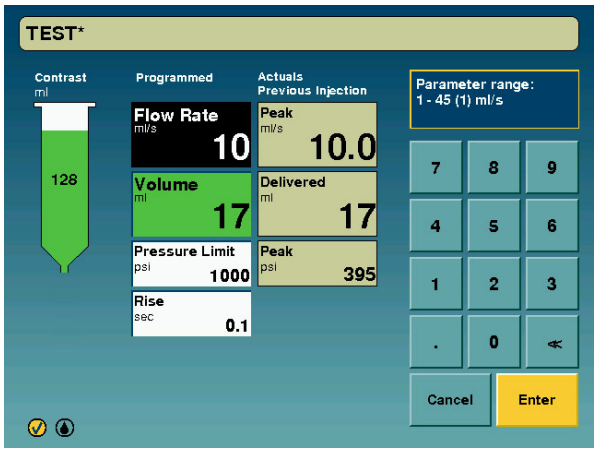
Warning: Patient injury could result from high flow rate injections. Use extreme care when selecting the flow rate. Before arming the injector, verify that high flow rate injection parameters are correct.

Programming a protocol is initiated at the Main screen.

1. Touch any programmable block, (such as Flow Rate or Volume). The selected block will be black. A numeric keypad and parameter range window appears.

2. Enter the desired Flow Rate, Volume, Pressure Limit and Rise Time (Fixed Rate Injection only).

3. Press “Enter” to lock in the value, press (<<) to edit the value, or “Cancel” to restore the original value if an error is made.



NOTE: You can also lock in a selected value by touching another parameter.

8.3.2 Storing a Protocol

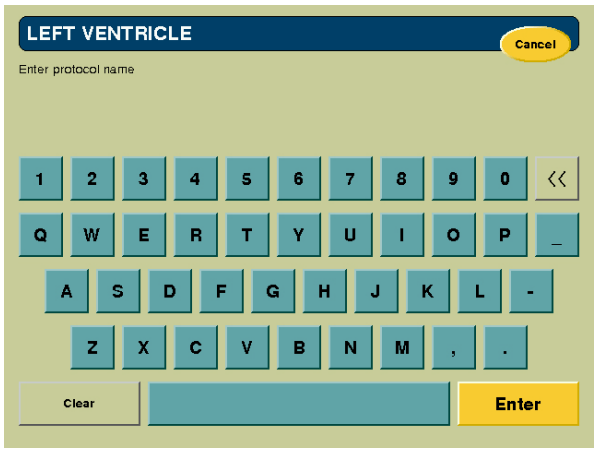
To store up to 40 commonly used protocols:

1. Enter the desired parameters on the main screen.

2. Touch “Store” located in the upper right corner of the Main screen. An alpha-numeric keypad appears with a flashing cursor in the title block.

3. Enter the desired name for the protocol. The name can be up to 20 characters long, including spaces. Use the arrow key to backspace and erase individual characters, or the clear key to erase a string of text.

4. Touch “Enter” when the entry is completed.

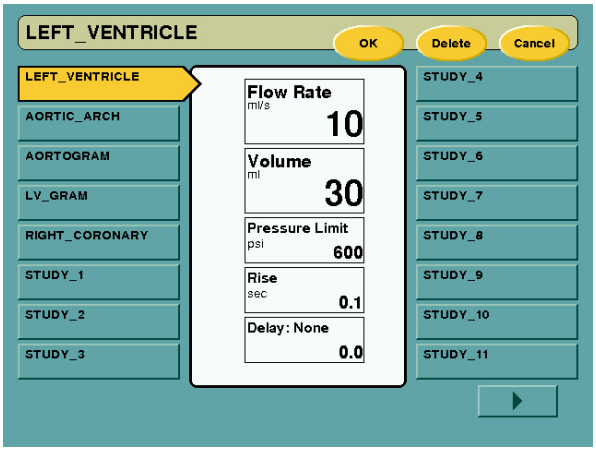


NOTE: To exit the Store screen without keeping your changes press Cancel in the upper right corner of the screen to return to the main menu.

8.3.3 Recalling a Protocol

To recall a protocol stored in memory:

1. Touch “Recall” on the upper right corner of the Main Screen.



NOTE: Protocols are ordered starting with the oldest protocol at the top left and continuing with subsequent protocols to the bottom

2. Select a previously stored injection protocol by touching one of the protocol titles on either side of the screen. Upon selection, key parameters of the injection protocol will be displayed in the center of the screen.
3. Touch “OK” to return to the main screen.

NOTE: If a protocol is recalled and then changed, an asterisk appears after the protocol name in the upper left of the screen, and is no longer the stored protocol.

8.3.4 Deleting a Protocol

To delete a protocol stored in memory:

1. Touch “Recall” on the upper right corner of the Main Screen.
2. Select a previously stored injection protocol by touching one of the protocol titles on either side of the screen. Upon selection, key parameters of the injection protocol will be displayed in the center of the screen.
3. Touch “Delete” to permanently erase the protocol from memory.
4. Acknowledge prompt.

9 - Setup

9.1 Minimizing Air Embolization Risks

Warning: **Patient injury or death could result from an air embolism.**



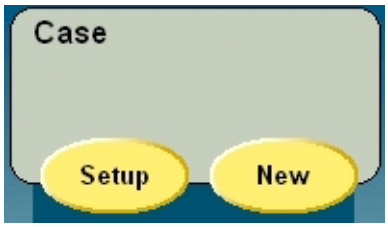
- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- To minimize air embolization risks, ensure that one operator is designated as being responsible for filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that air has been removed from the fluid path.
- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not fill or inject unless the syringe is properly engaged with the injector head. Improper engagement may cause an under volume delivery, air embolization or personal injury.
- Do not attempt to aspirate fluid from the waste port stopcock when open to the PIV. Doing so may increase the risk of inducing air into the fluid path.
- Do not attempt to aspirate fluid from the hemodynamic port. Doing so may increase the risk of inducing air into the fluid path.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.
- Verify no air is present in the tubing between the drip chamber and fluid source.
- Verify that the fluid path is open and free of air before attempting an injection.
- MEDRAD® FluiDots indicators are used on the pressure jacket to aid in confirming the presence of fluid in the syringe. MEDRAD® FluiDots indicators must be viewed in a properly illuminated environment, with a light source behind the operator, providing enough light to permit easy viewing.

- Operator vigilance and care, coupled with a set procedure, is essential to minimizing the possibility of an air embolism.

Warning: Air embolization can cause death or serious injury to the patient. Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path. Carefully read the instructions of the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.

9.2 Case Setup

Press “Setup” on the Main screen.



The DCU displays the Case Setup screen.

9.3 Disposable Sets

Warning: Blood can contaminate the Multi-Patient portion of the disposable set. Ensure that blood does not appear past the pressure isolation valve in the Single-Patient Disposable Set.

Warning: Patient injury could result if contrast crystallizes within the Multi-Patient or Single-Patient Disposable Sets. Regularly check the disposable sets for crystallized contrast and discard if present.

Warning: Do not use if sterile package is opened or damaged. Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually inspect contents and package before each use.

Warning: For devices labeled for single use, please note: This product is intended for single use only. Do not resterilize, reprocess or reuse. The disposable devices have been designed and validated for single use only. Re-use of the single use disposable devices pose risks of device failure and risks to the patient. Potential device failure includes significant component deterioration with extended use, component malfunction, and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be cleaned or re-sterilized.

Warning: Under certain misuse conditions biological contaminants can contaminate the Multi-Patient portion of the disposable set. Carefully follow all recommended steps in setup and use. Ensure that blood does not appear past the density loop in the Single-Patient Disposable Set.

Warning: Biological contamination can result from reusing single use disposable items or failure to follow sterile technique during setup or use. Properly discard single use disposable items after use. If there is any possibility that contamination may have occurred during set-up or use, disassemble and setup a new sterile product.

Warning: Use of extension tubing connected to the Single-Patient Disposable Set may cause patient injury and will degrade system performance. Do not connect extension tubing to the Single-Patient Disposable Set.

Warning: Component damage may occur if disposables are not installed properly.

Ensure all connections are secure. This will help minimize leaks, disconnections, air introduction, and component damage. Do not use tools to over tighten connections or to assist in removal of disposables.

Caution: Component damage may occur if excessive weight is hung on the IV pole hooks. Do not exceed a 1000 mL bag or bottle of saline or contrast on one hook of the IV pole.

Caution: Use of methyl alcohol will degrade the integrity of the disposable sets. Do not use methyl alcohol on disposable sets.

9.3.1 Install a Multi-Patient Syringe

Warning: Patient injury can result if the patient is connected when the "Engage Plunger" button is pressed. Ensure the patient is disconnected before pressing engage plunger button.

Ensure the following:

- System is on.

NOTE: To perform the following procedures, the operator must select the Case Setup screens on the DCU.

To install a Multi-Patient syringe:

1. On the Main screen, press "Setup."
2. Press "Multi-Patient Syringe."
3. Press "Retract Piston." The system retracts the piston.
4. Remove the syringe from the package, orient the syringe to fit the drop front housing, insert the syringe into the pressure jacket and raise drop front arms.



5. Close the drop front arms. Proper placement is denoted by an audible click.
6. Press "Engage Plunger." The system moves the piston to engage the plunger on the syringe. The piston travels the entire length of the syringe.

9.3.2 Install Multi-Patient Tubing

Warning: Patient injury or death could result from an air embolism.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Verify no air is present in the tubing between the drip chamber and fluid source.

Do not exceed the five patients per day usage for the Multi-Patient Disposable Set (MPAT). MPAT Integrity and performance could be affected if 5 patient usage is exceeded.

Warning: Patient or operator injury may result from mishandling of the sharp spike. Use care in handling and inserting the spike into the contrast bottle and the saline bag or bottle.

Warning: Ensure vent cap on contrast spike is open, if closed it may create a vacuum and air may be introduced.

Warning: Storage of filled syringes or disposables can promote bacterial growth. Avanta syringes and the Multi-Patient tubing components are designed to be used for up to five patient procedures but not for storage of contrast. Discard the syringe and Multi-Patient tubing after the fifth or the last patient of the day, whichever occurs first.

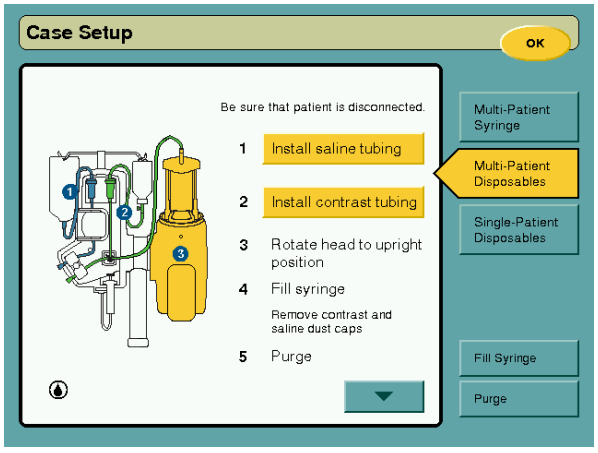
The system permits reuse of certain disposable components for up to and including five patients before disposal.

NOTE: Completely change or flush the disposable set when changing the contrast type.

Ensure the following:

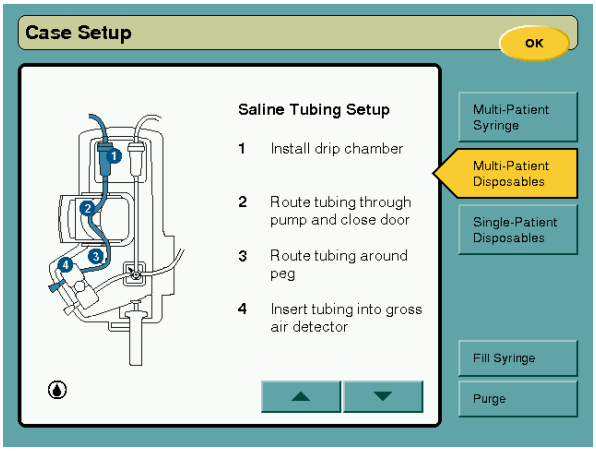
- Syringe installed and the DCU displays the Case Setup screen.

1. Press “Multi-Patient Disposables.” The DCU displays a graphic representation of the FCM, bottle holders, injector head, and installed Multi-Patient Disposable Set (blue represents saline, green represents contrast.)



2. Install saline tubing

a. Press “Install saline tubing.”



b. Hang saline bag or bottle.

c. Remove the saline portion of the disposable set from sterile package.

d. Install the saline drip chamber into the keyed interface and press firmly to engage.

e. Open the Peristaltic Pump door, route the tubing through the pump, and close the door.



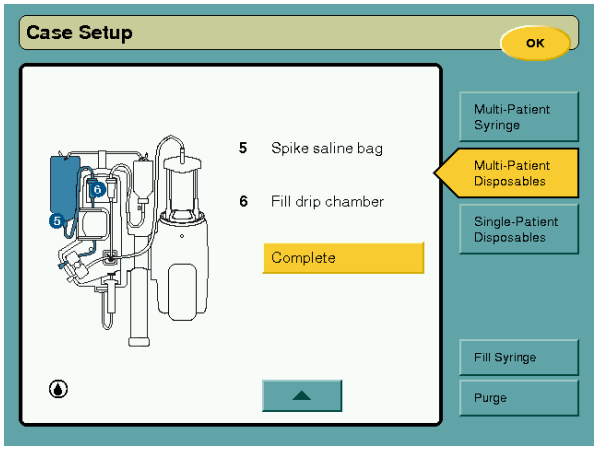
f. Route tubing around peg.



g. Insert the tubing into the gross air detector and close door.

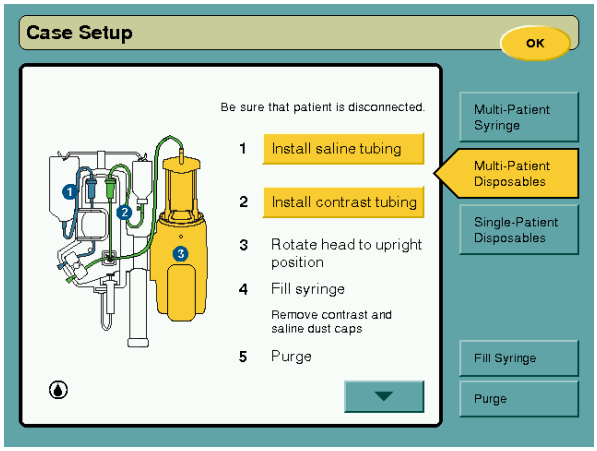
h. On the touch screen, select the down arrow.

i. Spike the saline bag or bottle.



j. Fill the saline drip chamber completely by repeatedly squeezing and releasing. Remove the drip chamber to aid in expelling air and replace when completed.

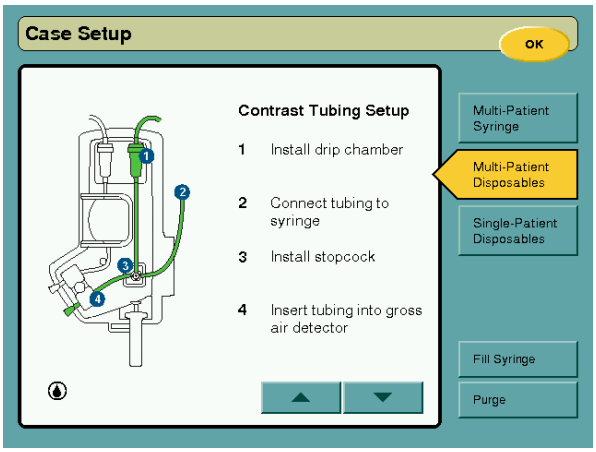
k. Press “Complete.” The DCU displays a graphic representation of the FCM, bottle holders, injector head, and installed Multi-Patient Disposable Set (blue represents saline, green represents contrast.)



3. Install contrast tubing

a. Press “Install contrast tubing.” The DCU displays an enlarged graphic representation of the FCM and contrast tubing setup (green) with a list of numbered

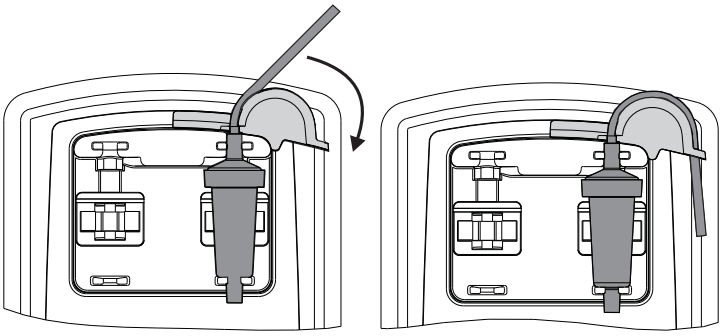
actions that correspond to the numbers on the image.



b. Hang the contrast bag or bottle.

c. Install the contrast drip chamber into the keyed interface and press firmly to engage.

d. Route tubing on tubing guide.



e. Remove dust caps from tubing (2) and syringe

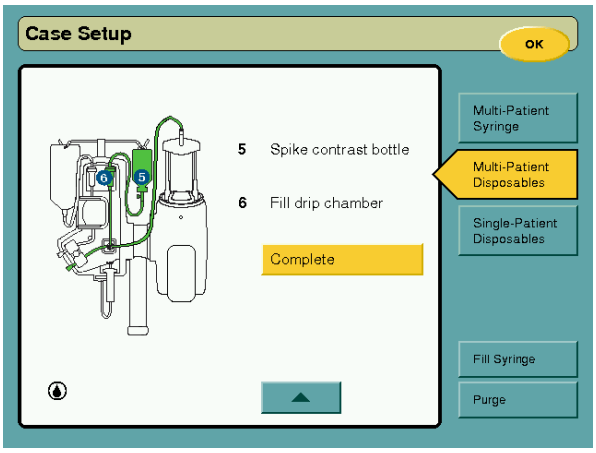
f. Connect the tubing to the syringe.

g. Install the stopcock into the CFCV mechanism.



h. Insert the tubing into the gross air detector and close door.

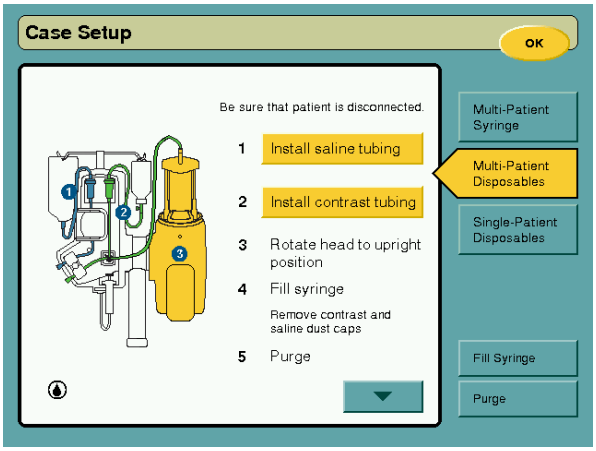
i. On the touch screen, select the down arrow.



j. Spike the contrast bottle or bag.

k. Fill the contrast drip chamber completely by repeatedly squeezing and releasing. Remove the drip chamber to aid in expelling air and replace when completed.

l. Press “Complete.” After completing the installation, you will see the following screen:



m. On the touch screen, go to step 3, rotate head to upright position.

9.3.3 Fill Syringe and Purge MPAT Contrast and Saline

Warning: Patient injury or death could result from an air embolism.

- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not fill or inject unless the syringe is properly engaged with the injector head. Improper engagement may cause an under volume delivery, air embolization or personal injury.
- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.

Warning: Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

Warning: Patient injury could result if contrast crystallizes within the Multi-Patient or Single-Patient Disposable Sets. Regularly check the disposable sets for crystallized contrast and discard if present.

Warning: All contrast media and flushing solutions should be used in accordance with the manufacturer's indication for use.

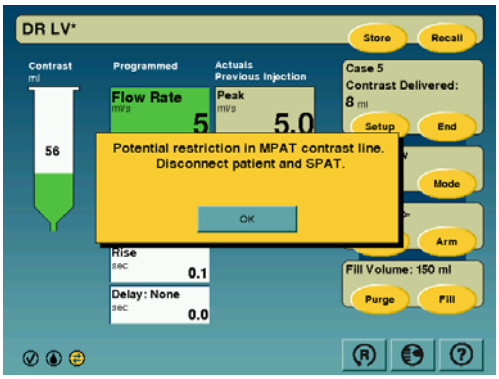
Warning: Patient injury may result from air injection. To minimize the risk of injecting air, remove air from the system prior to patient connection.

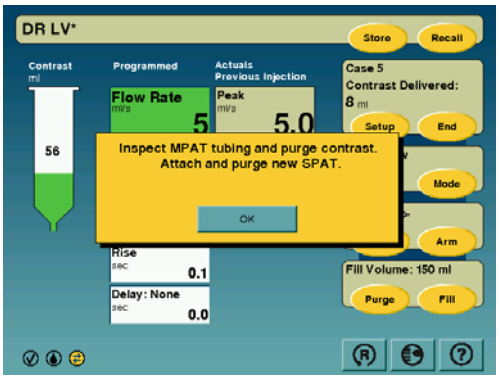
Warning: Operator injury may occur if Peristaltic Pump is operating with the door open. A pinch point exists due to rotating mechanical parts. Do not operate Peristaltic Pump with the door open.

Warning: Storage of filled syringes or disposables can promote bacterial growth. Avanta syringes and the Multi-Patient tubing components are designed to be used for up to five patient procedures but not for storage of contrast. Discard the syringe and Multi-Patient tubing after the fifth or the last patient of the day, whichever occurs first.

Warning: Inadvertent aspiration can occur if the Multi-Patient disposable contrast tubing set is kinked or blocked during a syringe fill process. Verify Multi-Patient contrast tubing is free of kinks before attempting to fill the syringe.

NOTE: To minimize the chance of aspiration caused by a trapped vacuum, the system will prompt the operator when a vacuum is detected in the syringe. If a vacuum is detected, the operator will be required to disconnect from the patient, remove SPAT and perform a contrast purge to relieve the vacuum and remove any potential air from the system disposables.



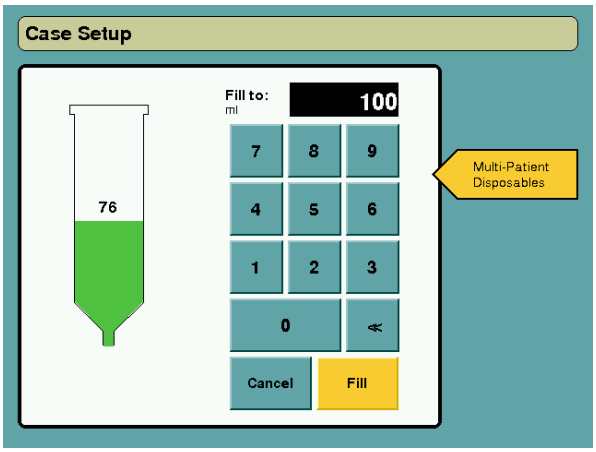


Ensure the following:

- A new Multi-Patient Disposable Set has just been installed.
- Ensure that the drip chambers are filled completely and snapped fully in position before use.
- The syringe plunger is engaged and in full forward position.
- Contrast tubing is straight and free of kinks.

1. Verify that the head is rotated to the upright position so that air can escape from the syringe. The syringe is now ready to be filled for the first time.
2. Press "Fill Syringe."

3. Enter the desired amount of contrast to fill the syringe.

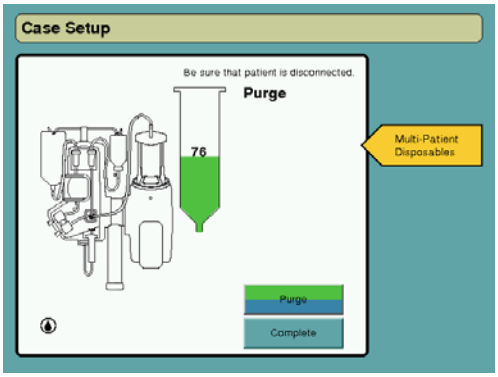


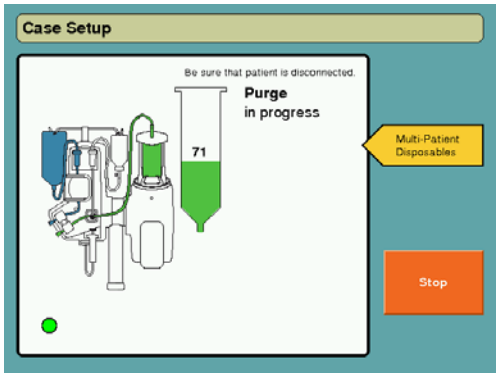
4. Press “Fill.” A graphic representation of the syringe filling is displayed on the screen.

5. Remove the contrast and saline dustcaps. On the touch screen, go to step 5, Purge contrast and saline.

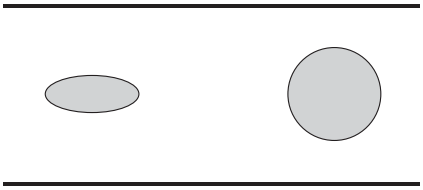
6. Purge Contrast and Saline.

   a. Press “Purge.”
   b. Press the blue and green “Purge” button.
   c. Catch the discharged fluid in a suitable container and tap disposable connection points and pressure jacket to remove air.





   d. Carefully observe the MEDRAD® FluiDots indicators to ensure that fluid is present in the syringe. Verify that the MEDRAD® FluiDots indicators are round in the filled portion of the syringe. The rounded shape of the MEDRAD® FluiDots indicators varies according to the type of contrast media, but an oblong shape indicates the presence of air. Rounded MEDRAD® FluiDots indicators do not indicate the total absence of air bubbles in the syringe tip.



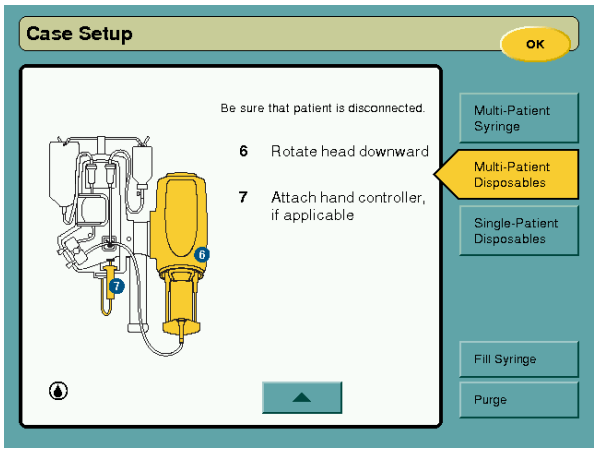
e. Remove CFCV (stopcock) and tap to dislodge air at the stopcock. Reinstall CFCV.

f. Repeat steps above as needed, until all air is removed.

g. During the purge process, press “Stop” when all visible air has been discharged.

NOTE: The system stops the purge operation automatically when approximately 8 mL of contrast/air and a minimal amount of saline/ air is expelled from the Multi-Patient Disposable Set.

h. Press “Complete”.After the contrast and saline disposable sets are adequately purged, select the down arrow on the touch screen and proceed to Step 6, on the touch screen Rotate head downward. You will see the following screen:



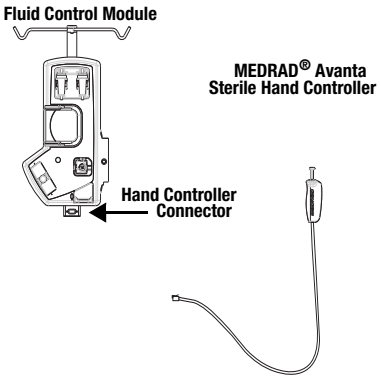
i. Replace the dust cap. Select, “OK.”

9.3.4 Install MEDRAD® Avanta Hand Controller

Caution: Component damage may occur if the MEDRAD® Avanta Hand Controller is immersed in fluid. Avoid immersion when using the Hand Controller unsheathed.

The MEDRAD® Avanta Sterile Hand Controller can be used for up to five patients. Sterility can be maintained between patients by using MEDRAD® Avanta Sterile Hand Controller Sheaths (available for purchase).

1. Ensure that the injector is in the disarmed state.
2. Open the Hand Controller package using sterile technique.
3. Using sterile technique, remove the Hand Controller from the package.
4. Plug the Hand Controller into the Fluid Control Module – Hand Controller Connector (see drawing below). Listen for an audible “click” to confirm proper connection.



NOTE: If the Hand Controller is damaged or does not work properly, discontinue use and discard.

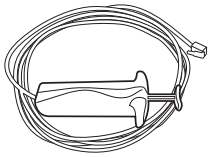
5. Place the Hand Controller sterile sheath over the Hand Controller, if applicable.

9.3.4.1 Install MEDRAD Avanta Hand Controller Sterile Sheath

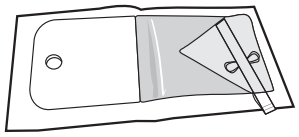
⚠ Warning: To prevent unintentional injection, avoid pressing the plunger or the saline button when installing the MEDRAD® Avanta Hand Controller Sterile Sheath.

NOTE: Contents are sterile. The MEDRAD® Avanta Hand Controller Sterile Sheath should be applied using sterile technique.

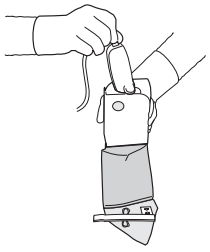
1. Ensure the Hand Controller is available.



2. Ensure that the injector is in the disarmed state.
3. Open the sheath packaging.

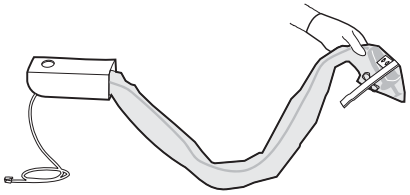


4. Drop the Hand Controller head first into the sheath.

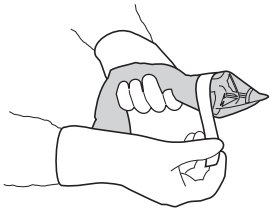


5. Hold the sheath with the Hand Controller inside and pull the sheath along the length of

the cord and secure.

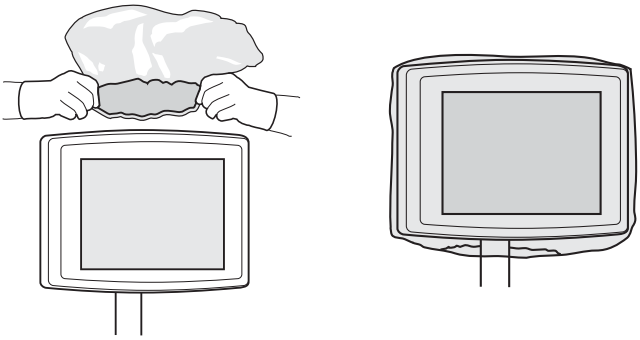


6. Wrap the tape (included) around the Hand Controller to secure it within the sheath. (Optional) Use the rubber bands to secure the Hand Controller.



9.3.5 DCU Sterile Sheath Installation

1. Using sterile technique, open the MEDRAD® Avanta DCU Sterile Sheath packaging.
2. Slip the sheath over the DCU.
3. Ensure that the sheath completely covers the DCU.



9.3.6 Install Single-Patient Disposable Set

Warning: Patient injury or death could result from an air embolism.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.

Warning: Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

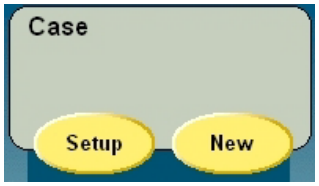
Ensure the following:

- The Multi-Patient Disposable Set is installed and properly purged, with injector head facing downward.
- Dustcaps are in place.
- The system is in a state that it is ready to accept the Single-Patient Disposable Set.
- The DCU sterile cover is on the DCU (optional.)

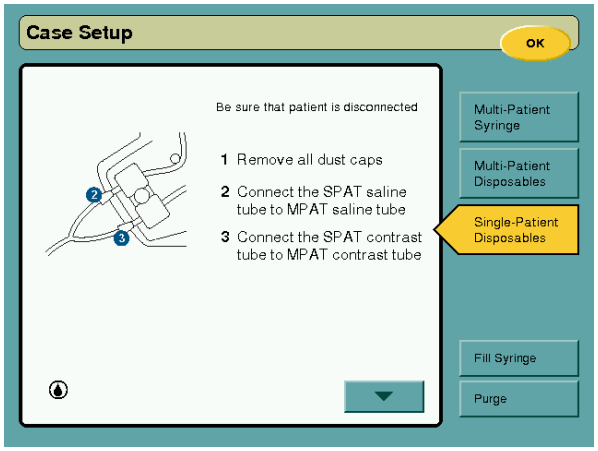
NOTE: The Single-Patient Disposable Set must be replaced after each patient use.

NOTE: Prior to attaching a new SPAT the user must select "New" Case.

1. Press "New."
2. Press "Setup."



3. Press "Single-Patient Disposables." The following screen appears.

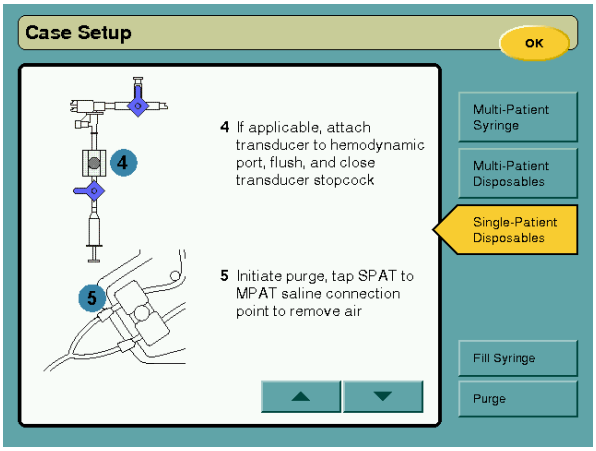


4. Remove all dustcaps.
5. Connect the SPAT saline tube to MPAT saline tube, ensuring that the connection is secure.

NOTE: For easier connection and to reduce twisting of the SPAT, slightly turn the saline luer connector counterclockwise before engaging the connector threads.

6. Connect the SPAT contrast tube to MPAT contrast tube ensuring that the connection is secure.

7. On the touch screen, select the down arrow.



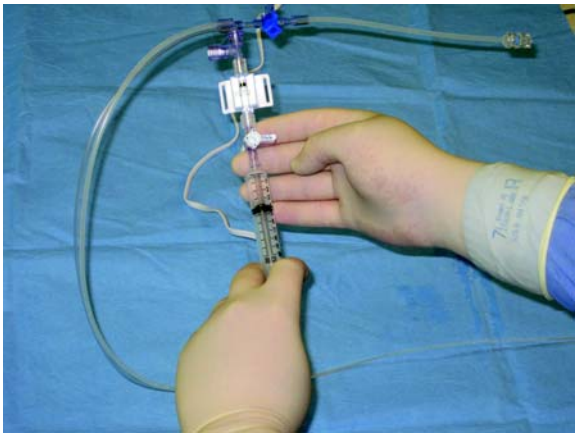
9.3.7 Setup and Flush Transducer

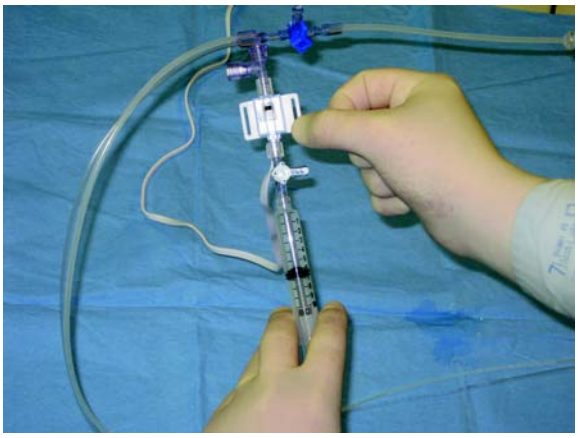
Warning: Patient injury or death could result from an air embolism.

- Do not attempt to aspirate fluid from the waste port stopcock when open to the PIV. Doing so may increase the risk of inducing air into the fluid path.
- Do not attempt to aspirate fluid from the hemodynamic port. Doing so may increase the risk of inducing air into the fluid path.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.

Warning: Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

1. Attach transducer to hemodynamic port, verify the transducer stopcock is open, and the waste port stopcock is off to waste port.
   a. Attach 20cc saline syringe to the transducer port.
   b. Hold SPAT parallel to the patient with the PIV and 20cc syringe connection facing upward at a 45° angle.





c. Forcefully flush through the transducer and PIV assembly until all air is removed from both components. Flick or tap PIV to facilitate air removal (Repeat as necessary).

d. Close transducer port stopcock. Remove 20cc syringe.

9.3.8 Purge Single-Patient Disposable Set

Warning: Patient injury or death could result from an air embolism.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- To minimize air embolization risks, ensure that one operator is designated as being responsible for filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that air has been removed from the fluid path.
- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not attempt to aspirate fluid from the waste port stopcock when open to the PIV. Doing so may increase the risk of inducing air into the fluid path.
- Do not attempt to aspirate fluid from the hemodynamic port. Doing so may increase the risk of inducing air into the fluid path.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.
- Verify no air is present in the tubing between the drip chamber and fluid source.

- Verify that the fluid path is open and free of air before attempting an injection.

1. Press “Purge.”

2. Press the blue and green “Purge” button to initiate contrast and saline purge. Flick the saline connection between the MPAT and SPAT and tap the waste port to remove any air while purge is in progress.

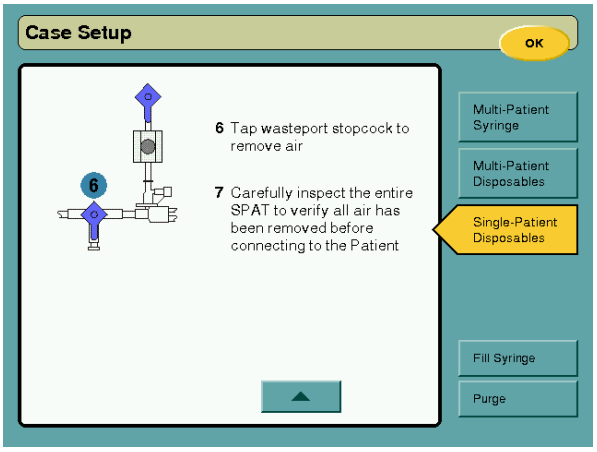


NOTE: To facilitate the removal of air in the saline SPAT to MPAT connection, remove the saline tubing from the gross air detector, hold the MPAT/SPAT connection upward at an angle greater than 30°, and while purging lightly tap the connection point. Reinstall the saline tube into the gross air detector and close the door.



3. Repeat steps above as needed, until all air is removed.

4. On the touch screen, select the down arrow.



5. Tap the wasteport stopcock to remove air.

6. Carefully inspect the entire SPAT and MPAT to verify all air is removed before connecting to patient.

7. Press "OK" to return the main screen.

NOTE: The system stops the purge operation automatically when approximately 8 mL of contrast/air and a minimal amount of saline/ air is expelled from the Single-Patient Disposable Set.

9.3.9 Calibrate (Zero) Hemodynamic Transducer



Warning: Patient injury or death could result from an air embolism.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- To minimize air embolization risks, ensure that one operator is designated as being responsible for filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that air has been removed from the fluid path.
- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not attempt to aspirate fluid from the waste port stopcock when open to the PIV. Doing so may increase the risk of inducing air into the fluid path.
- Do not attempt to aspirate fluid from the hemodynamic port. Doing so may increase the risk of inducing air into the fluid path. Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.
- The PIV with attached hemodynamic transducer allows you to accurately record and monitor invasive hemodynamic blood pressure waveforms through the Single-Patient Disposable Set.

NOTE: For more information about the hemodynamic transducer, refer to the manufacturer's guidelines.

9.3.9.1 Zeroing Transducer Outside the Patient's Body

This section demonstrates how to zero the transducer outside the patient's body and on the sterile field using the open end of the SPAT to zero.

1. Plug the transducer cable into the hemodynamic monitor cable.

2. Verify that the two-way stopcock on the transducer is closed to air and the waste port stopcock is off to the waste port.

3. With the tip of the SPAT open to air and placed at the mid-axillary level of the heart, have a non-sterile person zero the hemodynamic monitoring system.

NOTE: For more information about the hemodynamic transducer, refer to the manufacturer's guidelines.

9.3.9.2 Zeroing Transducer Inside the Patient's Body

This section demonstrates how to zero the transducer inside the patient's body and on the sterile field using the waste port stopcock on the SPAT to zero.

1. Plug the transducer cable into the hemodynamic monitor cable.

2. Verify the two-way stopcock on the transducer is closed to air.

3. Turn the blue stopcock on the SPAT off to the patient allowing the waste port to be open to air.

4. Have a non-sterile person zero the hemodynamic monitoring system.

5. After successfully zeroing the hemodynamic monitoring system, turn the blue stopcock on the SPAT back off to the waste port.

NOTE: For more information about the hemodynamic transducer, refer to the manufacturer's guidelines.

9.3.9.3 Zeroing off the table in the bracket

This section demonstrates zeroing at the side port of the transducer inside or outside the patient's body. This method requires manipulation of the transducer stopcock after the air has been removed from the transducer and SPAT. Manipulating the transducer stopcocks after the purge process can drain the transducer or SPAT, resulting in the possible introduction of air.

The preferred method is using the open end of the SPAT or waste port stopcock to zero the transducer.

1. Plug the transducer cable into the hemodynamic monitor cable.

2. Have a non-sterile person turn the three-way stopcock on the transducer off to the pressure monitor tubing to open the port to air.

3. Have a non-sterile person zero the hemodynamic monitoring system.

4. After successfully zeroing the hemodynamic monitoring system, have a non-sterile person turn the three-way stopcock back off to the side port on the transducer.

NOTE: For more information about the hemodynamic transducer, refer to the manufacturer's guidelines.

9.4 Disposable Troubleshooting and Replacement

This section describes how to remove and replace any disposable after the initial setup has been completed and during the procedure.

9.4.1 Replacing the Multi-Patient Syringe

Warning: **Patient injury or death could result from an air embolism.**

- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- To minimize air embolization risks, ensure that one operator is designated as being responsible for filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that air has been removed from the fluid path.
- The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip. Carefully read the instructions for use about filling the syringe and the use of MEDRAD® FluiDots indicators to reduce the chance of air embolism.
- Do not fill or inject unless the syringe is properly engaged with the injector head. Improper engagement may cause an under volume delivery, air embolization or personal injury.

Warning: Patient injury can result if the patient is connected when the "Engage Plunger" button is pressed. Ensure the patient is disconnected before pressing engage plunger button.

Ensure the following:

- System is on and the DCU displays the Case Setup screen.

  NOTE: To perform the following procedures, the operator must select the Case Setup screens on the DCU.

When changing a syringe during a procedure or after initial setup:

1. Always disconnect the patient from the Single-Patient Disposable Set (SPAT).
2. Disconnect the MPAT tubing from the syringe.
3. Release drop front arms and remove syringe by turning the syringe one quarter turn clockwise.
4. On the Main screen, press "Setup."
5. Press "Multi-Patient Syringe."
6. Press "Retract Piston." The system retracts the piston.
7. Remove the syringe from the package, orient the syringe to fit the drop front housing,

insert the syringe into the pressure jacket and raise drop front arms.



8. Close the drop front arms. Proper placement is denoted by an audible click.
9. Press “Engage Plunger.” The system moves the piston to engage the plunger on the syringe. The piston travels the entire length of the syringe.
10. Connect the MPAT contrast tubing to the syringe.
11. Rotate head to upright position.
12. Fill and purge the syringe, MPAT, and SPAT as described in sections “9.3.3 Fill Syringe and Purge MPAT Contrast and Saline” and “9.3.8 Purge SPAT.”

9.4.2 Replacing the Multi-Patient Tubing

Warning: Patient injury or death could result from an air embolism.

- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Verify no air is present in the tubing between the drip chamber and fluid source.

Do not exceed the five patients per day usage for the Multi-Patient Disposable Set (MPAT). MPAT Integrity and performance could be affected if 5 patient usage is exceeded.

Warning: Patient or operator injury may result from mishandling of the sharp spike. Use care in handling and inserting the spike into the contrast bottle and the saline bag or bottle.

Warning: Ensure vent cap on contrast spike is open, if closed it may create a vacuum and air may be introduced.

Warning: Storage of filled syringes or disposables can promote bacterial growth.

Avanta syringes and the Multi-Patient tubing components are designed to be used for up to five patient procedures but not for storage of contrast. Discard the syringe and Multi-Patient tubing after the fifth or the last patient of the day, whichever occurs first.

The system permits reuse of certain disposable components for up to and including five patients before disposal.

NOTE: Completely change or flush the disposable set when changing the contrast type.

Ensure the following:

- Syringe installed.

When changing the Multi-Patient (MPAT) tubing during a procedure or after initial setup:

1. Always disconnect the patient from the Single-Patient Disposable Set (SPAT).
2. Disconnect the SPAT from the MPAT tubing sets.
3. Disconnect the MPAT tubing from the syringe.
4. Remove the MPAT saline tubing.
5. Remove the MPAT contrast tubing.
6. Install the MPAT tubing as described in “Install Multi-Patient Tubing” on page 44.
7. Purge the MPAT as described in “Fill Syringe and Purge MPAT Contrast and Saline” on page 48.
8. Connect and purge the SPAT as described in sections “Install Single-Patient Disposable Set” on page 53 and “Purge Single-Patient Disposable Set” on page 56.

9.4.3 Replacing the Single-Patient Disposable Set



Warning: Patient injury or death could result from an air embolism.

- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Expel all air from the syringe, drip chambers, connectors, tubings, transducer, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Before connecting the Single-Patient Disposable Set (SPAT) to the patient, ensure all stopcocks and open ports are closed to air and all air has been removed from the fluid path before injection. Improper manipulation of the waste port stopcock as well as any fluid port left open to air may increase the risk of introducing air into the fluid path.



Warning: Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

Ensure the following:

- The Multi-Patient Disposable Set is installed and properly purged, with injector head facing downward.
- Dustcaps are in place.
- The system is in a state that it is ready to accept the Single-Patient Disposable Set.
- The DCU sterile cover is on the DCU (optional).

NOTE: Prior to attaching a new SPAT the user must select “New” Case.

When changing the Single-Patient Disposable Set (SPAT) during a procedure or after initial setup:

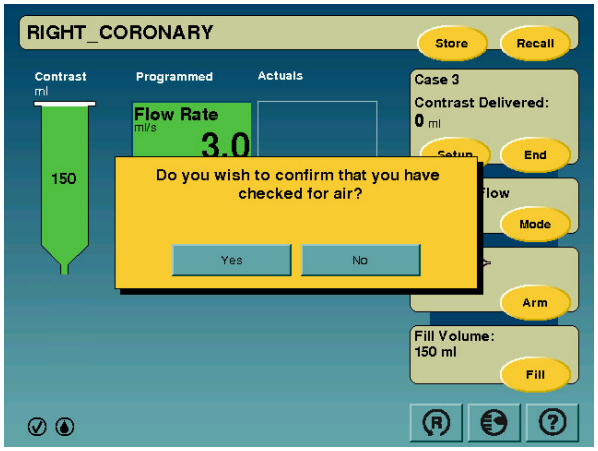
1. Always disconnect the patient from the SPAT.
2. Disconnect the SPAT from the MPAT.
3. Press “New.”
4. Install the SPAT as described in “Install Single-Patient Disposable Set” on page 53.
5. Purge the SPAT as described in “Purge Single-Patient Disposable Set” on page 56.

10 - Arming and Injecting Contrast and Saline

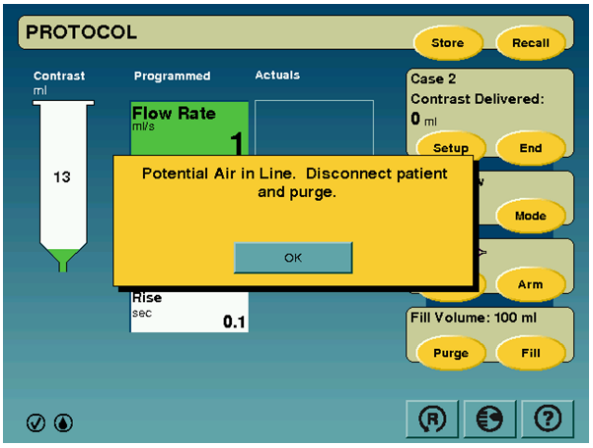
10.1 Confirm Air is Removed

Warning: Air embolization can cause death or serious injury to the patient. Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path. Carefully read the instructions of the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.

The system prompts the operator to check that air has been removed from the disposable set before an injection is started. Further injector operation that could potentially introduce air into the disposable set alerts the operator to reconfirm that air has been removed via a sentinal message on the main screen. Successful removal of air from the disposable set is the responsibility of the operator. The operator must verify that all air is successfully removed from the disposable set before contrast or saline is injected into the patient.



The Check for Air icon will highlight after the operator has confirmed air is expelled on touch screen prompt. The icon will remain highlighted until the system requires the operator to re-check for air.



To minimize the potential risk of air in the SPAT disposable due to a failure to purge, the user will be forced to purge when:

- A new case is selected.
- The Hand Controller is disconnected.

10.2 Volume and Rate Monitoring

The following means are provided to minimize over and under volume or rate conditions:

- Warnings displayed on the Safety screen remind the operator to check the programmed injection parameters prior to the system being armed.
- An on-screen indication of insufficient volume is provided whenever the total volume programmed to be delivered is greater than the amount of fluid in the syringe.

Injection monitoring is performed to detect over rate or over volume conditions due to system faults. If either of these conditions is detected, the injection will be stopped.

10.3 Arming the injector



Warning: Patient injury or death could result from an air embolism.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path.
- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.
- Verify no air is present in the tubing between the drip chamber and fluid source.
- Verify that the fluid path is open and free of air before attempting an injection.



Warning: Patient injury could result from high flow rate injections. Use extreme care when selecting the flow rate. Before arming the injector, verify that high flow rate injection parameters are correct.



Warning: Re-check the fluid path for air before arming.

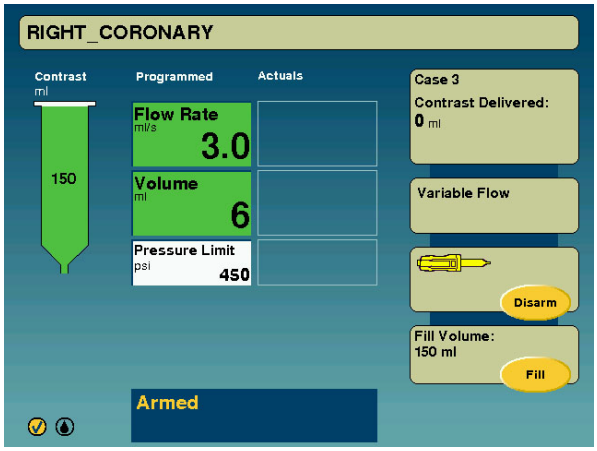


Warning: Replace the disposable set following a high pressure disarm condition.

Prior to injecting, the system requires you to place the system in a pre-injection (armed) condition during which the system determines if it is appropriate and safe to allow an injection. The system indicates it is in the armed state by an illuminated white light on the injector head. The system can be configured to issue an alert when armed for a high flow rate (greater than 10 mL/s) and/or high volume (greater than or equal to 20 mL) injection

1. Ensure the protocol parameters are set. See “Manage Protocols” on page 38 for more information.
2. Ensure proper flow mode (Variable Flow or Fixed Flow) is selected. See “Screen functions” on page 35” for more information.
3. Press “Arm.”

4. Go to “Perform an Injection.”



When injecting, the system returns to a disarmed state under the following conditions:

- Contact at any location on the touch screen
- When the system has determined that the injection cannot proceed safely (e.g. system sensor(s) feedback reporting a hazard condition)
- Overpressure condition
- When disposables have been removed from system
- At the end of a Fixed Rate injection.

Always verify the protocol prior to arming the injector or initiating an injection.

10.4 Perform an Injection

Warning: Patient injury or death could result from an air embolism.

- Verify that the fluid path is open and free of air before attempting an injection.
- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.

Warning: Patient or operator injury or component damage may occur if an injection is performed without pressure jacket in place. Ensure pressure jacket is in place before performing an injection.

Warning: Failure to properly install the pressure jacket may result in rupture of the syringe. Ensure that the pressure jacket has been properly installed prior to an injection.

The fluid delivery indicator flashes green when injecting contrast and flashes blue when injecting saline.

10.4.1 Variable Rate Injection

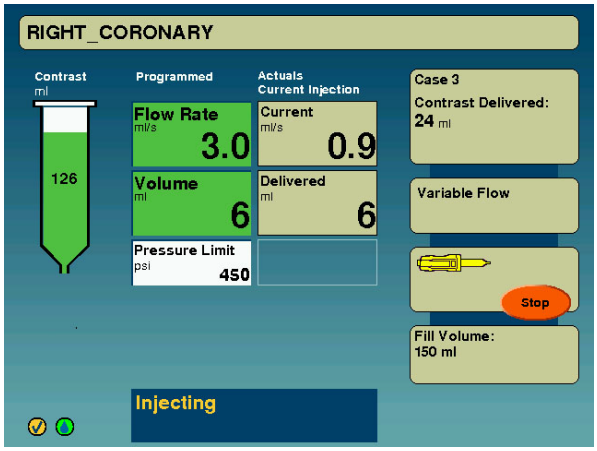
In the variable rate injection mode, the injector automatically re-arms after each injection. A variable rate injection can be initiated by the Hand Controller and ranges from 1 - 10 mL/sec in increments of 0.1 mL/sec. Variable rate is intended for use in those procedures where low volumes are injected and variable rate control is desired. The system has an option for receiving audible feedback when using the Hand Controller. The feedback indicates the flow rate.

To initiate a variable rate injection, ensure the following:

- Multi-Patient Disposable Set and Single-Patient Disposable Set installed

- All air has been removed from the fluid path
- Procedure parameters programmed
- Single-Patient Disposable Set connected to catheter
- System armed and ready to inject.
- The injector head is rotated downward.

1. Depress the plunger on the Hand Controller.



When in the variable rate injection mode, the flow rate increases incrementally as the Hand Controller is depressed, and decreases as the Hand Controller is released. Contrast flows until you release the plunger, or the programmed volume is injected. The system remains armed in preparation for the next variable rate injection.

2. Repeat injection as necessary. If injection is complete, go to “Injection Complete” on page 69.

10.4.2 Fixed Rate Injection

In the fixed rate injection mode, a single or multi-armed state can be selected.

A fixed rate injection can be initiated by the Hand Controller or the Foot Switch (option) and ranges from 1 - 45 mL/sec in increments of 1 mL/sec with the rate being constant throughout the injection. Fixed rate is intended for those procedures where variable rate is not desired and higher flow rates may be needed. You can program acceleration of fluid delivery through the input of rise time for fixed rate injections as follows: 0.0 to 9.9 seconds.

To initiate a fixed rate injection, ensure the following:

- Multi-Patient Disposable Set and Single-Patient Disposable Set installed
- All air has been removed from the fluid path
- Procedure parameters programmed
- Single-Patient Disposable Set connected to catheter
- System armed and ready to inject.
- The injector head is rotated downward.

When the system is armed for a single injection the injector disarms when the injection is complete. When multi-arm is selected, the injector automatically re-arms after each injection to allow the injection protocol to be repeated.

When the system is armed and not injecting, it will disarm under the following conditions:

- "Disarm" is pressed on the touch screen.
- The system has determined that the injection cannot proceed safely (e.g. system sensor(s) feedback reporting a hazard condition)
- The system is idle for longer than 30 minutes.

1. Depress the plunger on Hand Controller or depress the Foot Switch (option). The piston moves forward at the programmed rate (rate entered into the flow rate box on the set up screen). Contrast flows until you release the plunger, step off the Foot Switch (option), or the programmed volume is injected.

2. If injection is complete, go to "Injection Complete" on page 69.

10.4.3 Saline injection



Warning: Operator injury may occur if Peristaltic Pump is operating with the door open. A pinch point exists due to rotating mechanical parts. Do not operate Peristaltic Pump with the door open.

Saline Flush can be initiated via the Hand Controller or graphical user interface. The system injects saline at a rate of 0.75 - 1.50 mL/sec. Saline can be delivered using the grey saline button located on the Hand Controller. During a procedure saline can be requested and injected at anytime except when contrast injection is being performed.

10.4.3.1 Automated Saline Flush

Saline can also be delivered by activating an **Automated Saline Flush (ASF)** at the Main screen on the graphical user interface. ASF is a configurable feature that can be turned on or off via the configurations screen. The ASF feature can be programmed to deliver saline during idle periods when contrast is not being delivered. ASF is not available when the system is filling the syringe, armed for a contrast injection, or when contrast is actively being delivered. ASF rate can be programmed on the Main screen with a range of 0.1 - 20 ml/min in 0.1 ml/min increments. An injection duration can also be programmed with a range of 1 - 20 min(s) in 1 minute increments. If the combination of rate and duration would cause the delivery of more than 200 ml of fluid, the injector will stop ASF when 200 ml have been delivered and notify the user.

Automated Saline Flush will stop if:

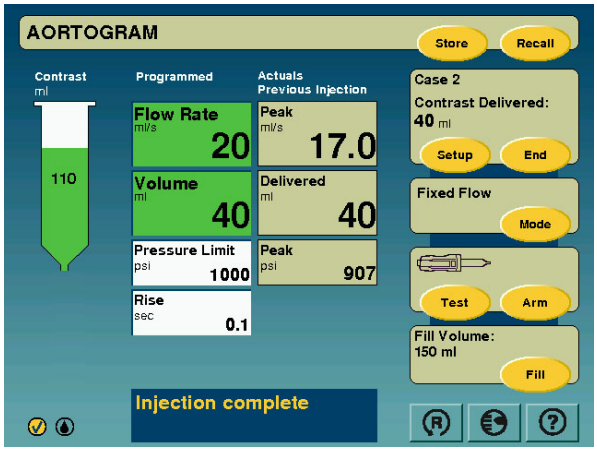
- The programmed protocol has been delivered
- A maximum allowable volume of 200 ml has been reached
- The saline fluid level sensor shows no fluid
- The operator stops Automated Saline Flush by pressing Stop or the hand controller saline button

10.5 Injection Complete

The system indicates the normal completion of an injection by:

- Displaying an injection completion indication on the display control unit

- Generating an audible injection complete tone at the display control unit.



NOTE: When variable rate and multi-arm fixed flow are selected, only the tone is heard whenever the injector returns to the arm state; the injection complete indication is not displayed.

11 - Refilling a Syringe

Warning: Air embolization can cause death or serious injury to the patient.

- Do not connect a patient to the injector, or attempt an injection until all air has been removed from the syringe and fluid path. Carefully read the instructions of the use of MEDRAD® FluiDots indicators (where applicable) to reduce the chance of air embolism.
- Disconnect the patient from the Avanta Single-Patient Disposable Set (SPAT) if a system malfunction occurs.

Warning: Blood can contaminate the Multi-Patient portion of the disposable set. Ensure that blood does not appear past the pressure isolation valve in the Single-Patient Disposable Set.

Warning: Do not exceed the five patients per day usage for the Multi-Patient Disposable Set (MPAT). MPAT Integrity and performance could be affected if 5 patient usage is exceeded.

Warning: Patient injury can result if the patient is connected during any contrast and saline purge. Ensure the patient is disconnected before any purge.

Warning: Patient or operator injury may result from mishandling of the sharp spike. Use care in handling and inserting the spike into the contrast bottle and the saline bag or bottle.

Warning: Patient injury may result from air injection. To minimize the risk of injecting air, remove air from the system prior to patient connection.

Warning: All contrast media and flushing solutions should be used in accordance with the manufacturer's indication for use.

Warning: Biological contamination can result from reusing single use disposable items or failure to follow sterile technique during setup or use. Properly discard single use disposable items after use. If there is any possibility that contamination may have occurred during set-up or use, disassemble and setup a new sterile product.

Warning: Patient injury could result if contrast crystallizes within the Multi-Patient or Single-Patient Disposable Sets. Regularly check the disposable sets for crystallized contrast and discard if present.

Warning: Inadvertent aspiration can occur if the Multi-Patient disposable contrast tubing set is kinked or blocked during a syringe fill process. Verify Multi-Patient contrast tubing is free of kinks before attempting to fill the syringe.

Warning: Operator injury may occur if Peristaltic Pump is operating with the door open. A pinch point exists due to rotating mechanical parts. Do not operate Peristaltic Pump with the door open.

Warning: Storage of filled syringes or disposables can promote bacterial growth. Avanta syringes and the Multi-Patient tubing components are designed to be used for up to five patient procedures but not for storage of contrast. Discard the syringe and Multi-Patient tubing after the fifth or the last patient of the day, whichever occurs first.

Warning: Do not use if sterile package is opened or damaged. Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually

inspect contents and package before each use.

Warning: For devices labeled for single use, please note: This product is intended for single use only. Do not resterilize, reprocess or reuse. The disposable devices have been designed and validated for single use only. Re-use of the single use disposable devices pose risks of device failure and risks to the patient. Potential device failure includes significant component deterioration with extended use, component malfunction, and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be cleaned or re-sterilized.

Warning: Component damage may occur if disposables are not installed properly. Ensure all connections are secure. This will help minimize leaks, disconnections, air introduction, and component damage. Do not use tools to over tighten connections or to assist in removal of disposables.

Caution: Component damage may occur if excessive weight is hung on the IV pole hooks. Do not exceed a 1000 mL bag or bottle of saline or contrast on one hook of the IV pole.

Caution: Use of methyl alcohol will degrade the integrity of the disposable sets. Do not use methyl alcohol on disposable sets.

The system can be configured to fill a syringe either manually or automatically. The system does not allow contrast injection while filling and returns to previous state when the fill completes. Saline flush is available while the syringe is filling. When Auto Fill is enabled, you can select Auto Fill volumes from 25 -150 mL, in increments of 25. You can also configure an Auto Fill volume threshold as a multiple of programmed volume on the main protocol screen (e.g. 2x multiplier on a 10 mL injection will refill when volume drops below 20 mL.) Auto Fill occurs when the volume in the syringe falls below the user-configured threshold. You can enter any desired fill volume when in the manual fill mode.

The Refill Alert can be configured to issue an audible indication when a preset volume is remaining.

NOTE: To minimize the chance of aspiration caused by a trapped vacuum, the system will prompt the operator when a vacuum is detected in the syringe. If a vacuum is detected, the operator will be required to disconnect from the patient, remove SPAT and perform a contrast purge to relieve the vacuum and remove any potential air from the system disposables.

11.1 Auto Fill

The syringe will automatically fill when the volume in the syringe falls below the user-configured threshold.

At the Main screen, a graphical representation of the volume in the syringe is displayed based upon the piston position.The system proceeds until the programmed fill volume is achieved.

Auto Fill will STOP if:

- The programmed fill volume has been achieved
- The fluid level sensor shows no fluid
- The operator stops the Auto Fill by pressing Stop or the Hand Controller plunger.

Auto Fill can also be initiated by pressing the Fill button on the Main screen.

11.2 Manual Fill

A manual fill can occur after the initial fill and when the Auto Fill function is configured off. You can initiate a manual fill at any time the system is disarmed. If you do not initiate a manual fill and program a fluid injection protocol that requires more contrast than what is available in the syringe, the system will prompt you to fill prior to achieving the armed state or ask you to continue with remaining volume. You can program fill volumes from 1 - 150 mL in increments of 1 mL.

Prior to refilling a syringe, ensure the following:

- Installation of the system has been verified and includes all components of the Multi-Patient Disposable Set
- Injector head piston is engaged with the Syringe Plunger
- Contrast volume is available
- Single-Patient Disposable Set may or may not be installed
- System is not armed or injecting
- No tubing kinks in contrast side of the MPAT

1. Select “Setup”.
2. Press “Fill Syringe.” The DCU displays a graphical representation of the volume in the syringe based on the piston position. Enter the desired volume and press “Fill.” The system proceeds until the total remaining volume in the syringe has reached the programmed volume or contrast volume is depleted from the bottle, whichever occurs first.

12 - End Case and Tear Down

Warning: Biological contamination can result from reusing single use disposable items or failure to follow sterile technique during setup or use. Properly discard single use disposable items after use. If there is any possibility that contamination may have occurred during set-up or use, disassemble and setup a new sterile product.

Warning: Storage of filled syringes or disposables can promote bacterial growth. Avanta syringes and the Multi-Patient tubing components are designed to be used for up to five patient procedures but not for storage of contrast. Discard the syringe and Multi-Patient tubing after the fifth or the last patient of the day, whichever occurs first.

12.1 Remove Single-Patient Disposable Set

After each case, immediately remove the Single-Patient Disposable Set from the Multi-Patient Disposable Set by disengaging the multi-guard connectors. In order to minimize the chance of cross contamination, do not allow the SPAT to fall below the table while still connected to the MPAT.

1. To disconnect the saline tube, rotate the wing.
2. To disconnect the contrast tube, rotate the wing and luer nut.
3. Replace the sterile caps on the MPAT multi-guard connectors to maintain sterility for the next case.

12.2 Touch End Case

Press “End.” The “New” button appears in place of the “End” button.

If five cases have not been completed, press “New” on the Case Setup screen.

If five cases (configurable) are completed, refer to “Install a Multi-Patient Syringe” on page 43 and “Install Multi-Patient Tubing” on page 44 to start a new case.

NOTE: Case numbers are noted in the counter.

12.3 Remove Multi-Patient Disposable Set

To remove the Multi-Patient Disposable Set:

1. **Saline**
   a. Open gross air detector doors.
   b. Open peristaltic pump door and remove saline tube.
   c. Remove saline drip chamber.
   d. Discard disposables.
2. **Contrast**
   a. Open gross air detector doors.
   b. Release drop front arms and remove syringe by turning the syringe one quarter turn clockwise.

NOTE: Opening the drop front can be difficult due to pressure within the system. In order to relieve this pressure, turn the CFCV stopcock off to the SPAT before attempting to open the drop front.

c. Remove stopcock.
d. Remove drip chamber.
e. Discard disposables.

12.4 Clean up

1. Wipe off contrast spills with warm water before they dry.
2. For all body fluid spills, follow institutional decontamination procedures.
3. Clean the Syringe Heat Maintainer. Remove the Syringe Heat Maintainer before cleaning. To clean the Syringe Heat Maintainer, refer to "**Clean the DCU, Syringe Heat Maintainer (option), Bottle Heat Maintainer (option), pedestal and Table Mount Brackets**" on page 85.
4. Clean the Pressure Jacket. Remove the Pressure Jacket from the syringe interface before cleaning. To clean Pressure Jacket, refer "**Cleaning the Pressure Jacket**" on page 84.
5. Clean the end of the piston ensuring that there is no contrast build-up, specifically in any recessed areas.

   NOTE: Clean the piston prior to fully retracting the piston.

6. Wipe main injector components (Display, Fluid Control Module, and Injector Head) with:

- a germicidal wipe, or
- a bleach wipe, for isolation patients

NOTE: If contrast media has leaked inside any system component, turn off the power immediately. The affected subassembly should be disassembled and cleaned by Services personnel or returned to Bayer.

13 - ISI

13.1 Introduction

The MEDRAD® Avanta Imaging System Interface (ISI) is an accessory that allows the MEDRAD® Avanta Fluid Management Injection System to interface with an imaging system. This feature provides for synchronization of the injection and the x-ray exposure.

13.2 Intended Use

The MEDRAD® Avanta ISI is intended for the specific purpose of allowing the MEDRAD® Avanta Fluid Management Injection System to interface with an imaging system.

13.3 ⚠ Important Safety Notice

The MEDRAD® Avanta ISI is intended to be used by medical professionals with adequate training and experience in the operation of the MEDRAD® Avanta Fluid Management Injection System and angiographic procedures and techniques.

13.4 Warnings

⚠ **Use of non-Bayer supplied accessories, external components, and replacement parts for internal components may result in increased emissions or decreased immunity for the equipment or system.** Use only accessories and replacement parts supplied by Bayer.

⚠ **Damaged cables may cause electrical shock.** Do not use the ISI option if cables are damaged. Contact Bayer or your local dealer for service or replacement.

13.5 Cautions

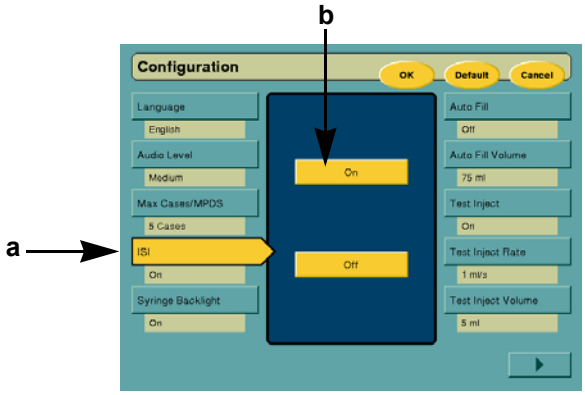
⚠ **System damage may occur if voltage is applied to ISI Pins 5, 6, 7, 8, or 9 in a Universal configuration or to ISI Pins 2, 3, 4, 5, 6, 8, 9, 10 in a Special/Siemens configuration.** Only connect these pins to isolated switch or relay contacts from the imaging system.

⚠ **Bayer can only be responsible for proper injector and imaging system interaction if they are configured exactly as specified.** The injector and imaging system will operate as described in this section only if the MEDRAD® Avanta ISI is installed according to this manual and the imaging system is capable of accepting these signals via the interface.

⚠ **Improper installation of the MEDRAD® Avanta ISI may cause it to fail. Installation must be completed by properly trained personnel.** Call Bayer or your local dealer for assistance.

13.6 ISI Configuration

1. The Configuration screen may be accessed by pressing “Configuration” located in the bottom right-hand corner of the Display Control Unit (DCU) touch screen display.



2. To turn the ISI option on, select “ISI” (a), then select “On” (b).

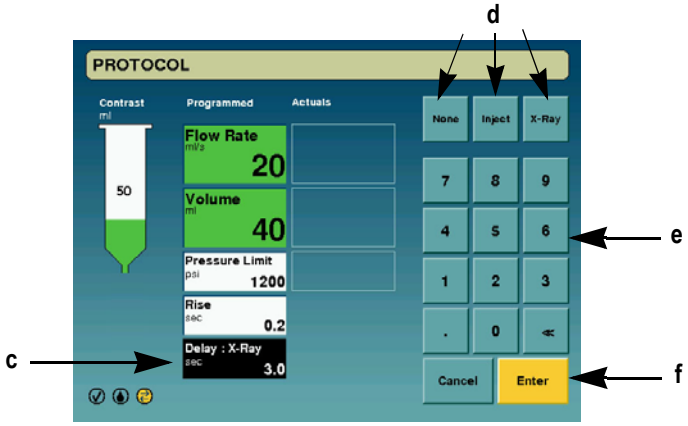
13.7 ISI Operation

To perform an injection using ISI:

- Ensure the ISI cable is attached to the Avanta Power Unit and to the imaging system.
- Ensure the injector is in a fixed flow mode and configured to use ISI (see “ISI Configuration” on page 78 above).

1. Set delay type (if desired).

- Programming a delay controls the timing of the injection in relation to the x-ray exposure. Either the x-ray exposure or the injection can be delayed.
- Touch the Delay programmable block to select delay type (c). Then touch “X-ray”, “Inject “or “None” above the keypad (d).



The available delays are:

None: A delay time has not been programmed. The injection and X-ray both occur when the appropriate start switch is pressed.

X-ray: The injector will start when the appropriate start switch is pressed. The X-ray begins after the programmed delay time has elapsed.

Inject: The X-ray will start when the appropriate start switch is pressed. The injection begins

after the programmed delay time has elapsed.

2. Set delay duration.

Enter the delay time (0 to 99.9 sec) by using the keypad (e) and press “Enter” (f) to set the value.

3. Arm the injector.

4. Activate the appropriate start switch on the injector or imaging system. See the chart for determining the appropriate start mechanism.

Determine the appropriate Start mechanism for the interface:

The functionality of the start switches on the injector and imaging systems is determined by the interconnecting cable and the configuration within the Imaging System. The typical operating scenarios are described in the following table. Consultation with the Field Engineer for the Imaging System may be required to confirm its internal configuration.

NOTE: Call Bayer to determine the compatibility of other imaging systems.

Imaging System OEM	*Bayer Catalog #	Pressing the Avanta start switch (Hand Controller or Foot Switch) results in:	Pressing the Imaging System start switch results in:	Pressing BOTH the AVANTA start switch and the Imaging System start switch results in:
GE	XMC 915R	No injection / No X-ray	Injection and X-ray	N/A
	XMC 917A	No injection / No X-ray	Injection and X-ray	N/A
GE/OEC	XMC 990R	Injection only (no X-ray)	Injection and X-ray	N/A
Philips	XMC 925A	No injection / No X-ray	No injection / No X-ray	Injection and X-ray
	XMC 927A	No injection / No X-ray	No injection / No X-ray	Injection and X-ray
	XMC 947R	No injection / No X-ray	No injection / No X-ray	Injection and X-ray
	XMC 945-S	No injection / No X-ray	Injection and X-ray	N/A
	XMC 945 40	No injection / No X-ray	Injection and X-ray	N/A
Siemens	XMC 977A	No injection / No X-ray	Injection and X-ray	N/A
	XMC 970A	No injection / No X-ray	Injection and X-ray	N/A
Canon	XMC 906i	Injection only (no X-ray)	Injection and X-ray	N/A
Ziehm	XMC 906i	Injection only (no X-ray)	Injection and X-ray	N/A
Shimadzu	XMC 906i	Injection only (no X-ray)	Injection and X-ray	N/A

***Note:** The catalog number is located on the cable near the MEDRAD® Avanta Power Unit.

13.8 ISI System Messages

The text box messages which may appear on the injector screen.

Text Box Message	What it means	Actions to be taken
"Imaging System not ready. (XX)"	When the Imaging System Interface (ISI) is configured "On", or when the user attempts to arm the injector, the system checks if the Inj_Start or Inj_Disarm signals are active. If either of these signals are active from the Imaging System, this message results.	Ensure the imaging system is ready. • Injector disarm is not activated. • Injector start is not activated.
"Internal ISI error. (XX)"	The injector is not communicating with the ISI. This message only appears when configuring the ISI, when arming the injector, or when an invalid condition is detected.	• Disable ISI. • Disconnect ISI cable. • Call Bayer. **Note:** Injection is possible without ISI synchronization.
"Disarm. Imaging System requested disarm. (XX)"	The Imaging System has taken an action that disarms the Injector. Typically this will be the removal of the Inj_Start signal during an injection. This can also be caused by a change in the Inj_Hand_Switch_Disable signal during an injection, or activating the Inj_Disarm signal.	If the disarm was intentional, no action is necessary; otherwise, ensure the Imaging System is configured and operating properly.
"Disarm. Injector - Imaging System Not Synchronized."	The Imaging System activated the Inj_Start signal prior to the Injector being armed.	• Ensure that the injector is armed before activating the Inj_Start signal from the Imaging System. • Acknowledge the message and continue. • If the message persists, call Bayer.

NOTE: Follow the error instructions on the display and/or contact Bayer for further support.

13.9 ISI Basic Functionality

The MEDRAD® Avanta ISI supports the following functions on the Injector:

- Allows the Injector to be "Disarmed" when "Armed" or "Injecting".
- Prevents the Injector from being "Armed".
- Allows the Injector to be "Started" from an Imaging System input when the Injector is in an armed state.
- Allows the Injector Hand Controller and Foot Switch to be disabled from directly initiating a contrast injection.

13.10 ISI Operational Checkout

A basic functional checkout of the ISI should be included as part of regular maintenance. Verifying proper operation of the ISI will help in detection of any problems that may not be noticed in day to day operation. The following procedure represents a suggested series of activities which encompass typical operation of the system. Read the following procedure carefully before beginning the checkout. If problems are detected, call your Services Representative.

NOTE: Any problems detected during this or any other procedure should be corrected before using the injection system in patient procedures.

1. Ensure that the interface cable is securely connected to both the imaging system and the injector.
2. Apply power to the system.
3. Refer to the Configuration and Operation sections in this manual.
    - Enable ISI and verify the ISI Active symbol appears in the lower-left corner.
    - Verify a fixed flow injection can be performed using the appropriate start mechanism for the specific OEM imaging system and the interface cable listed in the previous table.

14 - Cleaning and Maintenance

Warning: Explosion Hazard: Explosion risk may exist if the system is used in the presence of flammable anaesthetic mixtures, and/or flammable agents for disinfection and/or skin cleaning.

Warning: Electrical Shock Hazard: Serious injury or death may result from exposure to hazardous voltages existing within the system. Operator injury could result from work cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, do not disassemble the injection system in any way. Worn cabling also creates voltage hazards. If any worn or damaged cables are detected, do not use the injection system. Contact Bayer or your local dealer for service or replacement.

Warning: This system is not to be serviced or maintained while in use with a patient.

Caution: System malfunction may be caused by failure to perform regular maintenance. Regular preventive maintenance is recommended to ensure that the system stays calibrated and functions properly. Refer to this manual or contact Bayer for additional information.

Caution: Do not remove any covers or disassemble any parts of the system. The system does not contain user serviceable parts. Refer to the MEDRAD® Avanta Fluid Management Injection System Service Manual (86498197) for information regarding replacement of the Power Unit air filter. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact Bayer for repairs.

Caution: Use of methyl alcohol will degrade the integrity of the disposable sets. Do not use methyl alcohol on disposable sets.

14.1 Cleaning Guidelines

Warning: **Serious injury or death may result from exposure to hazardous voltages existing within the system.**

- Disconnect the system from line power when cleaning.
- Avoid fluid entry into system components. Do not immerse any components in water or cleaning solution.
- Do not remove any covers or disassemble the injector. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact Bayer for repairs.
- Do not expose system components to excessive amounts of water or cleaning solutions. Wipe components with a soft cloth or paper towel dampened with cleaning solution.
- Do not use strong cleaning agents and solvents. Warm water and a mild disinfectant are all that is required. Do not use strong industrial cleaning solvents such as acetone.

Warning: Electrical Shock Hazard: Operator injury could result from cleaning the unit while connected to line power. In order to avoid shock and prevent damage to the injector, always disconnect the unit from line power before cleaning. Remove unit power by pressing the On/Off switch at the rear of the Power Unit module or by disconnecting the power cord

from the wall outlet or from a power source. Ensure that the system is completely dry before connecting to a power source and applying power.

Warning: Do not spray industrial cleaning solvents such as acetone to clean the system or any parts. Use only warm water and a mild disinfectant to clean and wipe down.

Warning: Do not spray cleaning solutions directly onto the touch screen. To prevent damage, wipe down the touch screen with a soft non-abrasive cloth or paper towel dampened with water soluble cleaning solution.

Warning: For all body fluid spills/contamination, follow institutional decontamination procedures. If contrast medium has leaked inside any component of the system, the affected subassembly should be disassembled and cleaned by Services personnel or returned to Bayer.

Caution: Improper or careless cleaning methods may result in equipment damage. Do not soak or immerse any part of the injection system in water or cleaning solutions. While cleaning any outside portion of the system, avoid allowing any water or cleaning solutions to leak inside system components.

Remove any disposable components and discard these items according to institutional procedures. It is not necessary to remove the connector tubing from the syringe when removing and discarding the disposables unless institutional procedures require separate disposable processes for these items. Disposable components include syringes, connector tubing, sheaths, etc.

14.1.1 Clean the injector head, piston, and syringe interface

1. Turn the system main power supply off.
2. Place the injector head in a vertical position.
3. Remove the pressure jacket and clean with soft cloth or paper towel dampened with a cleaning solution. For more information about cleaning the pressure jacket refer to the subheading "**Cleaning the Pressure Jacket**" on page 84 in this section.
4. Clean the piston with a soft cloth or paper towel dampened with cleaning solution.
5. Thoroughly dry the piston with a paper towel.
6. Clean the inner area of the syringe interface with a soft cloth, paper towel or cotton-tipped applicator dampened with cleaning solution or warm water.
7. Wipe the injector head case with a soft cloth or paper towel dampened with cleaning solution or warm water.
8. Thoroughly dry the injector head case with a paper towel.
9. Re-install the clean pressure jacket.

14.1.2 Cleaning the Pressure Jacket

Warning: The pressure jacket should be replaced at the first sign of physical deterioration. Failure to do so may result in the pressure jacket fracturing during a high pressure injection.

The pressure jacket should be routinely cleaned to remove contrast media and other contamination. Some cleaning agents react with the plastic material and may cause structural degradation. Bayer recommends that the pressure jacket be washed in a solution of warm tap water (35° – 45° C) and mild detergent (neutral grade low pH, enzymatic cleaner). Then rinsed thoroughly and dried with a soft towel.

A solution of dishwashing detergent and water is compatible with the pressure jacket. If a germicidal cleaning agent is desired, contact the germicide manufacturer to check the recommended dilution and compatibility with polycarbonates. If the solution is acceptable, follow the manufacturer's directions exactly. Do not clean the pressure jacket with an automatic dishwasher. The pressure jacket is not dishwasher safe. Do not leave the pressure jacket in germicide for extended periods of time.

The pressure jacket should not be exposed to fluorocarbons (like Freon), or other solvents (acetone, benzol, carbon tetrachloride, MEK, MIBK, toluol, trichlor, and triclene). Gasses used to pressurize aerosol cans can be damaging to the pressure jacket. Therefore, do no use aerosols in or around the pressure jacket.

14.1.3 Sterilization of the Pressure Jacket

Normally, sterilization of the pressure jacket is not required, since it does not contact the contrast media to be injected. If sterilization is desired, cold chemical sterilization is recommended. Zephiran Chloride diluted as recommended by the manufacturer can be used with the pressure jacket; however, leaving the pressure jacket in cold chemical sterilization for extended periods of time reduces the pressure jacket's use life. Do not use gas sterilization (ethylene oxide).

Do not autoclave the pressure jacket. It will not withstand autoclaving temperatures without distortion.

14.1.4 Clean the DCU, Syringe Heat Maintainer (option), Bottle Heat Maintainer (option), pedestal and Table Mount Brackets

Turn power off. Wipe with a soft non-abrasive cloth or paper towel dampened with cleaning solution.

14.1.5 Clean the Fluid Control Module (FCM)

Wipe the FCM and its components with a soft non-abrasive cloth or paper towel dampened with cleaning solution. Pay particular attention to the fluid level sensors and the gross air detector ensuring that they are free of contrast or other performance diminishing contamination or buildup. The fluid control valve mechanism and peristaltic pump interfaces should also be free of contamination or buildup to ensure proper operation. A cotton-tipped applicator dampened with cleaning solution or warm water may be used to clean difficult to reach areas.

14.1.6 Clean the Power Unit

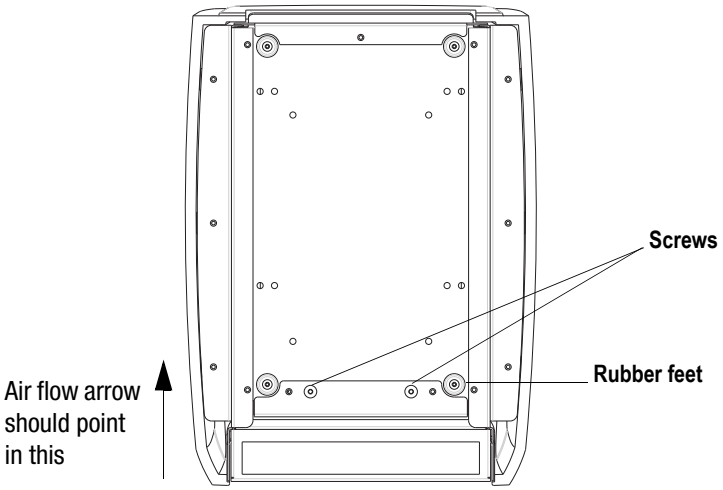
Turn power off. Wipe the Power Unit with a soft non-abrasive cloth or paper towel dampened with cleaning solution.

14.1.7 Clean the Internal Air Filter

1. Turn the Power Unit so that the bottom is accessible.
2. Remove the two screws as shown in the drawing below.
3. Pull the air filter out.
4. Vacuum or rinse the air filter with water and thoroughly dry before re-installing.
5. Replace the clean air filter (note direction arrow for air flow).
6. Replace the two screws.

NOTE: The internal air filter must be inspected monthly and cleaned at least

once per year (this can be done more frequently as needed.)



14.2 Recommended Maintenance Schedule

Warning: Electrical Shock Hazard: Operator injury could result from using an extension cord or power adaptor with the system. Plug the injector directly into a properly grounded AC power outlet. Since the injector power cord supplies a safety ground to the unit, using an extension cord will compromise the ground quality and the injector could become unsafe.

This section contains recommended procedures for maintenance, and an operational checkout of the MEDRAD® Avanta Fluid Management Injection System. Routine maintenance and inspection will:

- Ensure continued performance of the injection system
- Reduce the possibility of equipment malfunction.

Your MEDRAD® Avanta Fluid Management Injection System must be properly maintained to ensure that it is in peak operating condition. Your individual maintenance system and schedule depends upon how your injection system is used, the type of procedures performed, and frequency of use. The following maintenance schedule is recommended for the system:

14.2.1 Daily

Before use each day, the system should be cleaned and inspected, using the procedures outlined in this section. Ensure that all system safety and warning labels are in place and are legible.

14.2.2 Monthly

Once a month, the entire system should be thoroughly inspected and cleaned, and an Operational Checkout should be performed using the procedures outlined in this section.

14.2.3 Annually

As part of an annual maintenance program performed by a qualified Services Representative or authorized dealer of Bayer, both Electrical Leakage and Ground Continuity checks should be performed.

NOTE: Local regulations or hospital protocol may require electrical leakage checks at more frequent intervals. If this applies, local regulations for leakage must be followed.

Bayer also recommends that a complete system calibration and performance checkout be performed annually. Contact Bayer, or your local Bayer office for complete details.

In the United States, Canada, Japan, and Europe, the Bayer offers Preventive Maintenance Programs. These annual programs greatly assist in maintaining accuracy and reliability, and can also extend the life of the system. Contact Bayer for details. In Europe, contact your local authorized dealer of Bayer for further information. Refer to the back cover of this manual for address, telephone and FAX information.

NOTE: Failures which occur due to lack of proper maintenance will not be covered under warranty.

NOTE: Bayer will make available for purchase upon request:

- Circuit diagrams, components part lists, or other information that will assist qualified technicians to repair components classified as repairable.
- On-site consulting or consulting references upon request.

14.3 Pressure Jacket Use Life

The MEDRAD® Avanta pressure jacket is designed to withstand many pressure cycles; however, the exact life of a pressure jacket is difficult to determine and is a function of the number, duration, and the level of pressure cycles. In addition, handling, cleaning, and sterilization can significantly affect service life. Bayer therefore recommends following the procedures contained in this document to increase the useful life of the pressure jacket.

14.4 Inspection Procedures

The following procedures are recommended for daily inspection of all components in the MEDRAD® Avanta Fluid Management Injection System. If any defects are detected, either repair the system or call Bayer or the local authorized dealer of Bayer for service. Do not use the system until the problem is corrected.

14.4.1 Injector Head

- Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
- Inspect all cables connected to the unit: Look for cuts, cracks, worn spots or other obvious damage to the cables. Ensure that all connectors are properly seated.
- Inspect for contrast media build-up in the syringe interface area, including the Syringe Heat Maintainer (option) and the pressure jacket. Follow the cleaning guidelines outlined in this section.
- Inspect the Superstructure and DCU arm for cracks and other defects that could weaken the structure.
- Ensure that all mounting bolts and screws are secure.
- Ensure that all locking mechanisms on the casters are functional.
- Inspect the pivot points. The head and DCU must pivot freely. The injector head should rotate on the support arm no more than 160^{0}.

NOTE: All relevant guidelines for institutional, local, or national safety recommendations related to cable routing and installation should be followed.

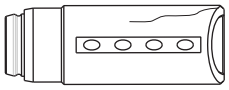
14.4.2 Pressure Jacket

Warning: The pressure jacket should be replaced at the first sign of physical deterioration. Failure to do so may result in the pressure jacket fracturing during a high pressure injection.

Prior to each procedure, inspect the pressure jacket for signs of deterioration or fatigue by looking through it with light shining through the pressure jacket. Carefully remove the pressure jacket. Rotate the pressure jacket while looking through it to view all areas. This includes the front edges, the entire cylindrical surface, and the grooves that interface with the injector head.

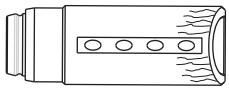
A pressure jacket should be rejected for cracks, crazing, scratches (if a fingernail can catch on the scratch), and opacity. These faults indicate that the pressure jacket has been weakened and may fracture during a high pressure injection. The pressure jacket should NOT BE USED if any of these conditions exist.

Cracks are usually the result of a sharp impact (such as from dropping). A crack may appear simply as a line, usually originating at the radius or edge and may also appear in conjunction with crazing.



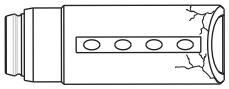
Cracks

Stress Cracks may appear after the pressure jacket has been subjected to a number of pressure cycles. These tiny cracks appear around the front area of the pressure jacket, and usually form a pattern around the jacket's circumference. Stress cracks are easiest to see while rotating the pressure jacket in front of a light source.



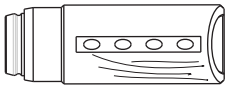
Stress cracks

Crazing can occur when non-compatible cleaning solutions or solvents are used on the pressure jacket. Crazing can also occur when the pressure jacket has reached the end of it's expected life. crazing appears as small lines that interfere with the transparency of the pressure jacket. Crazing usually appears several together or interconnected, localized to a point of impact or fatigue.



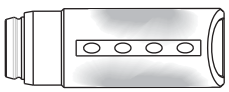
Crazing

Scratches result from objects striking or scraping the inside or outside surface of the pressure jacket. Scratches may occur when the pressure jacket is improperly handled. Check depth of scratches by pulling your finger across the scratch, perpendicular to the surface. If your fingernail catches on a scratch, The pressure jacket should NOT BE USED.



Scratches

Normally the pressure jacket is transparent, enabling you to clearly see through the barrel.



Opacity

The pressure jacket is manufactured from high impact resistant material; however, sharp

impacts such as from dropping may cause small barely visible cracks to form, which may propagate during subsequent pressure cycles.

14.4.3 Display Control Unit

- Inspect the cable connected to the unit: Look for cuts, cracks, or worn spots, or other obvious damage. Ensure that the connector is properly seated.
- Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
- The DCU arm should not rotate on the extension more than 90^{o}.
- If attached to a DCU arm, ensure the quick release pin is inserted completely.

14.4.4 Fluid Control Module

- Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
- Inspect components associated with the unit (includes the IV pole, gross air detector, fluid level sensors, CFCV and Peristaltic Pump): Look for cracks, worn spots or other obvious damage.
- Inspect any accessories connected to the unit (this could include the Bottle Heat Maintainer - option, Hand Controller, and/or Foot Switch - option.) Look for cuts, cracks, warn spots or other obvious damage. Ensure that all connectors are properly seated.

14.4.5 Table Mount Bracket

- Inspect all parts of the Table Mount Bracket for cracks and other defects that would weaken the assembly.
- Ensure that the Table Mount Bracket is securely attached to the table.
- Ensure that all cables are secured to the system and do not interfere with the movement of the Table Mount Bracket.
- Ensure the quick release pin is inserted completely.

14.4.6 Pedestal

- Inspect the base, column, casters and handle for cracks and other defects that could weaken the structure.
- Ensure all mounting bolts and screws are secure.
- Ensure the quick release pin is inserted completely.
- Ensure that the casters roll smoothly with no binding or scraping.
- Ensure all locking mechanisms on the casters are functional.
- Verify that the vertical height adjustment of the column shaft moves freely without binding or scraping.

14.5 Operational Checkout

A basic functional checkout of the MEDRAD® Avanta Fluid Management Injection System should be included as part of regular maintenance. Verifying proper operation of the injection system will help in detection of any problems that may not be noticed in day to day operation. The following procedure represents a suggested series of activities which encompasses typical operation of the system. Read the following procedure carefully before beginning the checkout. If problems are detected, call your Services Representative.

NOTE: Any problems detected during this or any other procedure should be corrected before using the injection system in patient procedures. It is assumed that the operator is familiar with the operation of the system as described in this manual.

1. System Labels

Ensure that all system safety and warning labels are in place and legible.

2. Power Up

a. Apply power to the system.

b. Verify that proper audible tones are functioning on the DCU.

c. Verify that all displays and indicators are functioning properly.

d. Verify that the armed lights on the injector head are functioning.

e. Verify that the Safety screen is displayed after system diagnostics occur.

f. Press CONTINUE to acknowledge the messages on the Safety screen.

g. At the rear of the Display Control Unit, press the DCU Brightness UP key until the screen is lightened to its fullest extent. Press the DCU Brightness DOWN key until the screen is darkened to its fullest extent. Adjust the screen appearance to return to a desirable contrast level.

NOTE: In the following procedure water or other readily available fluid such as saline may be used to perform this checkout. It is not required to use contrast for this checkout. All disposables must be properly disposed of at the conclusion of this checkout procedure.

NOTE: If the syringe has insufficient volume for a particular test, fill it prior to beginning the test.

3. Normal Fixed Injection/Flush

a Move to the Setup screen and prepare the system for fluid delivery with a full fluid filled Single-Patient Disposable Set/Multi-Patient Disposable Set. Aim the end of the Single-Patient Disposable Set/Multi-Patient Disposable Set in a beaker or other container so as to catch the test fluid. If care is taken, a Single-Patient Disposable Set is not necessary for this checkout procedure. Provide saline bags or other means as sources of fluid for both the contrast and saline channels of the system. Fill the drip chambers and, using the process outlined in this manual, fill a syringe with 150 mL of fluid. Purge the contrast and saline lines after the fill.

b. Program the system for 45 mL/s for 70 mL injection. Set the pressure limit to 1200psi.

c. Initiate the fixed rate injection via the Hand Controller. Volume delivered should indicate 70 mL. No pressure limiting should occur.

d. The armed light should switch from solid to flashing illumination during injection. The injection should complete and disarm. The DCU should display an injection complete dialog box.

e. Perform a saline flush using the Hand Controller. The system should pump saline into the saline line of the Single-Patient Disposable Set/Multi-Patient Disposable Set.

4. Normal variable Injection

a Program the system for 1 mL/s for 10 mL variable rate injection. Set pressure limit to 300psi.

b. Arm the system. The armed light should be solid while armed and the system should initially beep.

c. Initiate the variable rate injection via the Hand Controller. Vary the flow during the injection. Confirm that the rate can be varied from 0 to 1 mL/s. Volume delivered

should indicate 10 mL. No pressure limiting should occur.

d. The flow rate of the delivery should change in accordance with Hand Controller trigger position. The DCU should display instantaneous flow rate during injection.

e. The armed light should switch from solid to flashing illumination during injection. The injection should complete without error. If the system has sufficient fluid for another injection, the system should return to the armed state. If the system has insufficient fluid, the unit will display an injection complete dialog box.

5. Disarm Due to Air in Line

a Fill the syringe again with 150 mL of fluid. Purge the contrast and saline lines, if needed, after the fill.

b. Program the system for 5 mL/s for 40 mL fixed rate injection.

c. Arm the system. The armed light should be solid while armed and the injector should initially beep.

d. Start an injection and while injecting remove the contrast tubing from the contrast gross air detector mechanism.

e. The system should detect air in the line and disarm. A message should be displayed on the DCU stating air was detected. Acknowledgement of the message should return the system to the idle state.

f. Re-insert the contrast tubing into the gross air detector.

g. Re-arm the system.

h. The armed light should be solid while armed and the system must initially beep.

i. Initiate a saline flush using the Hand Controller and while delivering saline remove the saline tubing from the saline gross air detector.

j. The system should detect air in the line and disarm, stopping the saline flush. A message should be displayed on the DCU stating air was detected. Acknowledgement of the message should return the injector to idle state.

k. Re-insert the saline tubing into the gross air detector.

6. Disarm Due to Low Fluid Level

a Remove the fluid source from the saline side drip chamber. Initiate a saline flush using the Hand Controller.

b. The system should detect low fluid in the line and stop the flush. A message should be displayed on the DCU stating this. Acknowledgement of the message returns the system to the idle state.

c. Replace the fluid source to the saline side drip chamber, and remove the fluid source from the contrast side drip chamber.

d. Attempt to fill a syringe.

e. The system should detect low fluid in the line and stop the fill. A message should be displayed on the DCU stating this. Acknowledgement of the message returns the system to the idle state.

f. Replace the fluid source to the contrast side drip chamber.

7. Disarm Due to Drop Arm being Disengaged

a Program the system for 5 mL/s for 40 mL fixed rate injection. Disengage the Front Load Drop arm.

b. Attempt to arm the system. The system should detect the Front Load Drop arm is not in place. A message should be displayed on the DCU. Acknowledgement of the dialog box returns the system to the idle state.

c. Re-engage the Front Load Drop arm. Attempt to arm the system. The system

should arm normally.

d. Disengage the Front Load Drop arm. The system should detect that the Front Load Drop arm is not in place and disarm. A message should be displayed on the DCU. Acknowledgement of the error returns the system to the idle state.

8. Disarm Due to Syringe being Disengaged

a Remove the Syringe and hold the Front Loading Drop arm in the engaged position.

b. Attempt to arm the system. The system should detect that the syringe is not in place. A message should be displayed on the DCU. Acknowledgement of the error returns the system to the idle state.

c. Re-install the syringe.

9. Stopcock Removed

a Remove the Multi-Patient Disposable Set stopcock from the CFCV.

b. Attempt to fill the syringe. The system should detect that the stopcock is not in place. An error message should be displayed on the DCU. The acknowledgement of the error should not result in the system restarting.

c. Re-insert the Multi-Patient Disposable Set stopcock into the CFCV.

10. Foot Switch Function (if applicable) (option)

a Program the system for 25 mL/s for 40 mL fixed rate injection.

b. Arm the system.

c. Run the injection using the Foot Switch.

d. The DCU displays injection is complete.

11. Heat Maintainers (if applicable) (option)

a Connect the Syringe Heat Maintainer to the Head. Wait at least 1 minute for the maintainer to warm up.

b. Confirm that the Syringe Heat Maintainer is warm and the red fault indicating LED is not lit or flashing.

c. Connect the Bottle Heat Maintainer to the FCM. Wait at least 1 minute for the maintainer to warm up.

d. Confirm that the Bottle Heat Maintainer is warm and the red fault indicating LED is not lit or flashing.

12. Cleanup

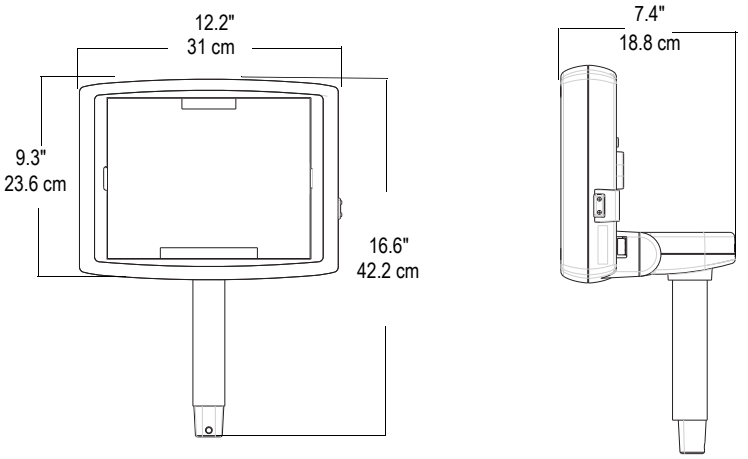
a Power down the system and remove all disposables including the syringe and dispose of these properly. Properly clean up any supporting equipment used in the checkout.

b. Clean the system, as required, per the instruction in this manual.

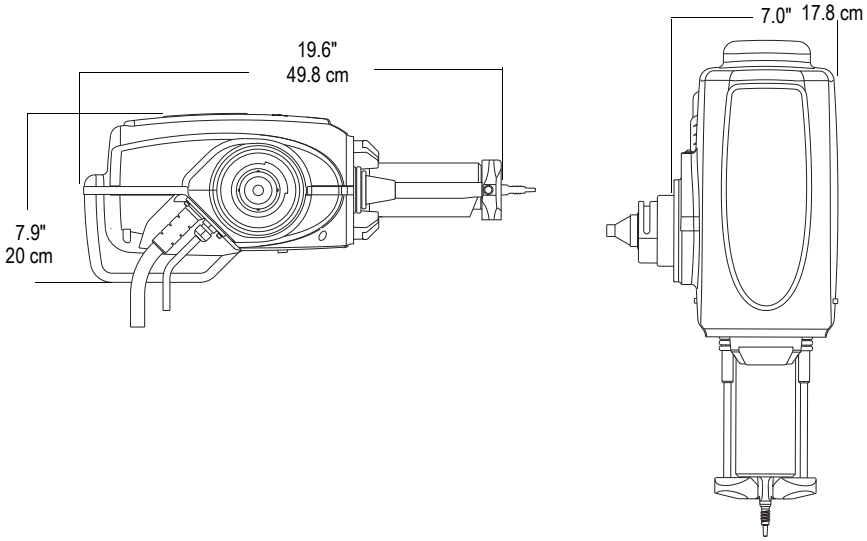
NOTE: In the event of fluid ingress or spillage on the injection system ensure all equipment and accessory connections are removed, dried, and inspected. Follow hospital policies and procedures or contact Bayer for performing appropriate electrical safety and operational checks prior to use.

15 - Specifications

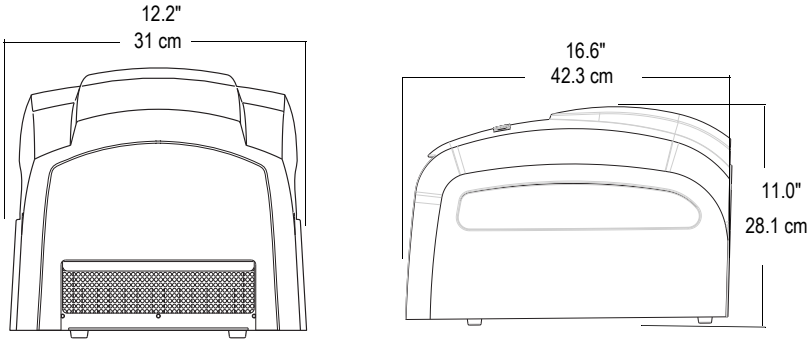
15.1 DCU



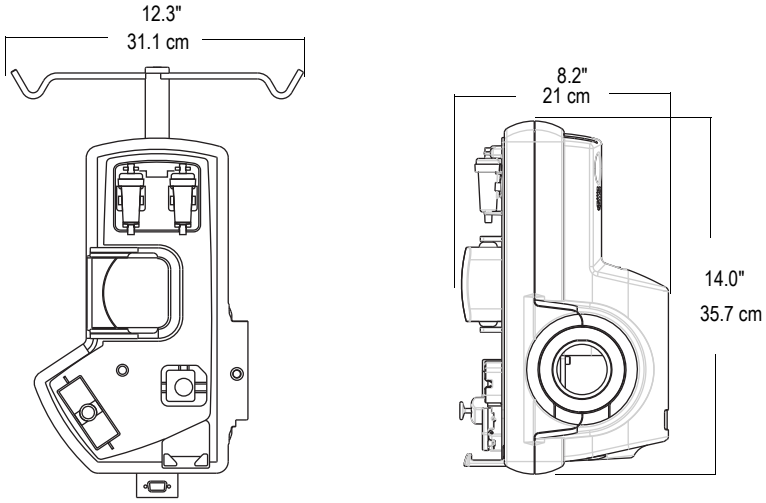
15.2 Injector Head



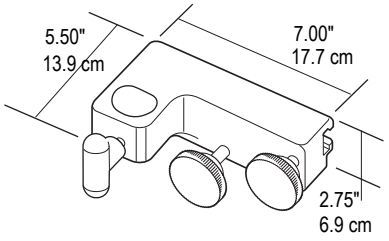
15.3 Power Unit

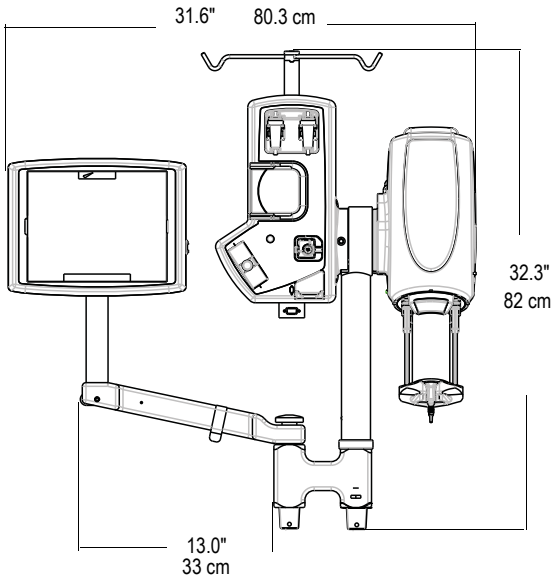


15.4 Fluid Control Module

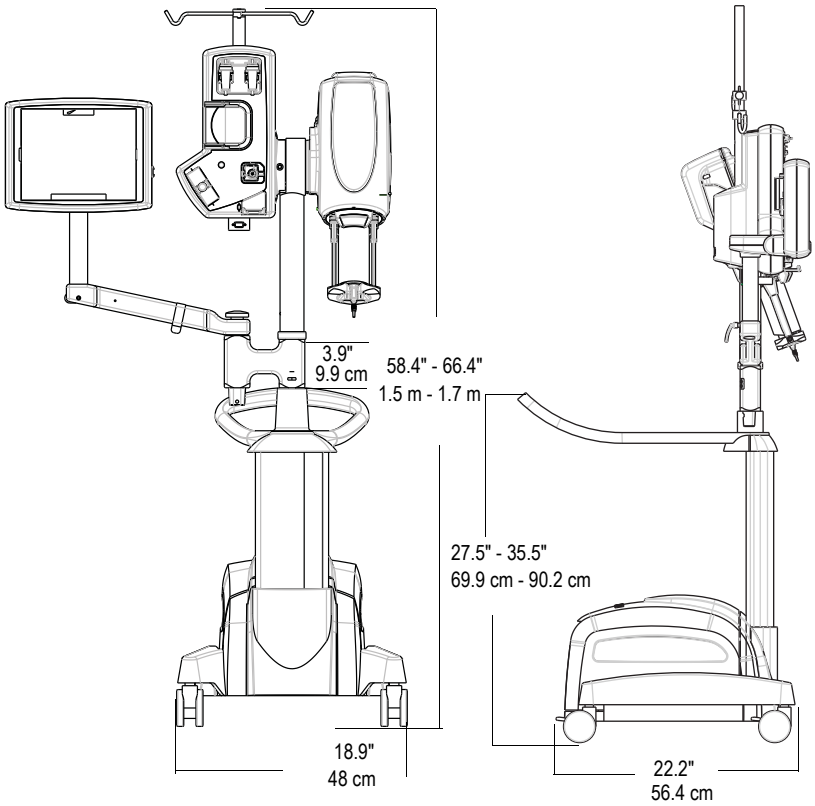


15.5 Table Mount Bracket





15.6 System



Component and Assembly weights:

Component or Assembly Description	Important Details	Weight
Pedestal System		190.5 lb. (86.4 kg)

Injector Head Assembly	Includes 10 ft. (3.05 m) of cable	25 lb. (11.3 kg)
FCM Assembly	Does not include IV pole	15 lb. (6.8 kg)
IV Pole Assembly	17 in. (43.18 cm) long	1.70 lb. (.77 kg)
DCU Assembly	Includes 10 ft. (3.05 m) of cable	7 lb. (3.2 kg)
Support Structure Assembly	Does not include DCU arm	11 lb. (5 kg)
Universal Table Mount Bracket		4.5 (2 kg)
DCU Support Arm		2.6 lb. (1.2 kg)
Extension Arm, Head and FCM		4.1 lb. (1.9 kg)
Knuckle, Head and FCM		2 lb. (.9 kg)
Support Column, Head and FCM		2 lb. (.9 kg)
Fixed DCU Mounting Post Assembly	Includes swivel housing	1.5 lb. (.7 kg)
Swivel, DCU Arm		.60 lb. (.27 kg)
Power Unit		22lb. (10 kg)

15.7 Environmental Specifications

15.7.1 Operating

(The system may not meet all performance specifications if operated outside of the following conditions.)

Temperature:	+10º C to + 40º C (+50º F to +104º F)
Humidity:	20% to 90% R.H.
Air Pressure:	69 kPa to 106 kPa after it has stabilized to within the operating pressure range

Syringe Heat Maintainer operating temperature: +15º C to +40º C (+59º F to 104º F)

Bottle Heat Maintainer operating temperature: +20ºC to +40ºC

Single and Multi-Patient Disposable Sets operating temperature: +15º C to +30º C (+59º F to 86º F)

15.7.2 Non-Operating: (Transportation and Storage)

Temperature:	-25º C to 70º C (-40º F to +158º F)
Humidity:	5% to 100% R.H., non-condensing
Air Pressure:	48 kPa to 106 kPa after it has stabilized to ambient conditions

15.7.3 EMI/RFI

The injector system is classified as Group 1, Class A equipment per the requirements of IEC 60601-1-2. Accessories provided by Bayer will also comply with this standard.

15.7.4 Equipment Classification

Type of protection against electrical shock: Class 1.

Degree of protection against electrical shock: Type CF Defibrillation-proof applied part.

Degree of protection against ingress of water: IPX1.

Degree of safety of application in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or with nitrous oxide.

Mode of operation: Continuous.

Class I product: A product that is provided with a reliable protective earth (PE) such that all accessible metal parts cannot become live in the event of a failure of basic insulation and therefore will provide protection against electric shock in the case of failure of basic insulation.

Type CF Defibrillation-proof Applied Part: The Injection System is Type CF Defibrillation-proof as the System may be utilized in a situation when the applied part is connected to the patient while defibrillation is applied. During the discharge of a cardiac defibrillator to a patient connected to the Defibrillation-proof applied part, hazardous energies do not appear on the enclosures, signal input and output parts.

IPX1: IEC 60529 classification of degree of protection (IP Code) provided by enclosures of electrical equipment against ingress of vertically dripping water with harmful effects

Continuous Mode of Operation: Operation under normal load for an unlimited period, without the specified limits of temperature being exceeded.

15.7.5 EU Directive

The MEDRAD® Avanta Fluid Management Injection System complies with the essential requirements of the Medical Device Directive 93/42/EEC and bears the CE Mark to show conformity with the provisions of this Directive

15.7.6 Fluid Delivery Performance

The system enables the operator to program the injector to perform a fixed flow rate injection at a constant rate between 1-45 mL/sec, in increments of 1 mL/sec. The system also enables the operator to program an injection at a rate between 1-10 mL/sec in increments of 0.1 mL/sec that can be modulated by operator input as the injection is being performed.

The system delivers saline at a rate of 0.75 - 1.50 mL/sec. Purging the disposable set with saline does not displace more than 5 mL of contrast. Saline cannot be delivered while a contrast injection is being performed. Initiation of saline delivery is by the operator command of the Hand Controller or from the display during setup.

15.7.7 System Response to Occlusions

When injecting into an occlusion, a stall condition (flow rate less than 10% of programmed rate) or at a very high pressure, a disarm will result. A stall condition lasting more than one second will result in the injection being automatically terminated.

15.7.8 Over and Under Infusion Protection

The following means are provided to protect against over and under infusions:

Warnings displayed on the safety screen and arming screen remind the operator to check the programmed injection parameters prior to the injector being armed.

An on-screen indication of insufficient volume is provided whenever the total volume programmed to be delivered is greater than the amount of fluid in the syringe.

Injection monitoring is performed in the injector head to detect over rate or over volume conditions due to system faults. The delivered volume is also monitored against the total programmed volume for the injection.

When a fault condition is detected, the injection will stop within 10 mL.

Once the system has disarmed a tone will sound and a stall message will be displayed on the Display Control Unit screen.

15.8 Power Cable Specifications

The specifications required by the MEDRAD® Avanta Fluid Management Injection System relative to the power cable (plug, receptacle, and cord) are:

- Operating Temperature: 60° C minimum
- Receptacle Type: IEC-60320 C13
- Normal Cord Voltage: 300 VAC minimum
- Wire Gauge: 1.00 mm^2 minimum
- Cord Type: IEC 60245-1, Annex A, Designation 53, or IEC 60227-1, Annex A, Designation 53 Certified
- Cord Length: 3 m maximum

The power cable must meet applicable plug, cord, and receptacle specifications including type, voltage, current, and safety approval markings for the country in which the power cable is being used.

15.9 Avanta Fluid Management Injection System to IT Network Connections

Connecting the system to an IT-Network that includes other equipment could result in unidentified risks to patients, operators, or third parties.

The organization responsible for managing the network should identify, analyze, evaluate, and control risks associated with connecting the equipment to the IT-Network.

Subsequent changes to the IT-Network could introduce new risks and require additional analysis. For example:

- Changes in the IT-network configuration
- Connecting additional items to the IT-Network
- Disconnecting items from the IT-Network
- Updating equipment connected to the IT-Network
- Upgrading equipment connected to the IT-Network

16 - System Installation

Warning: Explosion Hazard: Explosion risk may exist if the system is used in the presence of flammable anaesthetic mixtures, and/or flammable agents for disinfection and/or skin cleaning.

Warning: Electrical Shock Hazard: Serious injury or death may result from exposure to hazardous voltages existing within the system. Operator injury could result from work cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, do not disassemble the injection system in any way. Worn cabling also creates voltage hazards. If any worn or damaged cables are detected, do not use the injection system. Contact Bayer or your local dealer for service or replacement.

Warning: Pinching can occur if the Superstructure and the table are not mated properly during transfer, installation and/or removal. To avoid pinch points and personal injury, use care and diligence while mating the Superstructure to the table and the Superstructure with the pedestal interface. Keep hands and fingers clear of all pinch points.

Caution: Do not remove any covers or disassemble any parts of the system. The system does not contain user serviceable parts. Refer to the MEDRAD® Avanta Fluid Management Injection System Service Manual (86498197) for information regarding replacement of the Power Unit air filter. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact Bayer for repairs.

Warning: Personal injury and/or equipment damage may result if screws, clamps and knobs are not tightened on the pedestal. Loose components may cause the pedestal to collapse. Tighten all screws, clamps and knobs during assembly of the pedestal and as needed during use.

16.1 Unpacking the Injection System

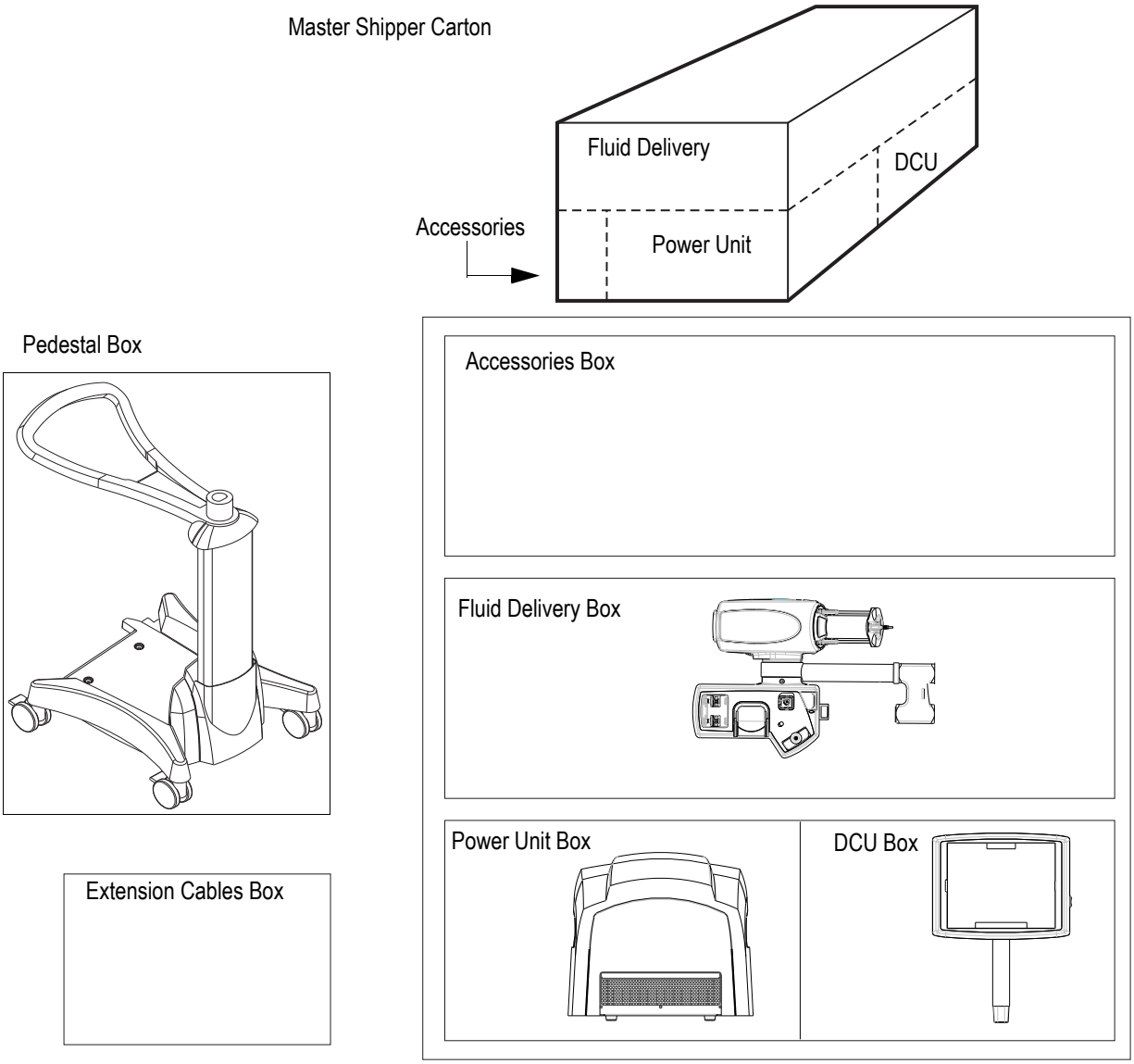
There are two master shipper cartons for the system. One master shipper carton for the injector, and one master shipper carton for the pedestal. If extension cables are purchased with the Table Mount Bracket system, they are in a separate shipper carton.

Warning: Do not use if sterile package is opened or damaged. Patient or operator injury may result if package is opened or damaged, or if damaged components are used. Visually inspect contents and package before each use.

There are two master shipper cartons for the system. One master shipper carton for the injector, and one master shipper carton for the pedestal. If extension cables are purchased with the Table Mount Bracket system, they are in a separate shipper carton.

NOTE: Contact Bayer for Installation information.

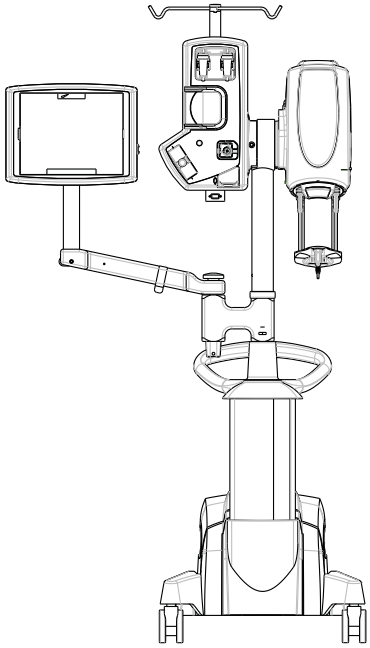
NOTE: Upon opening the cartons, inspect and verify the contents. Call Bayer if there is a problem.



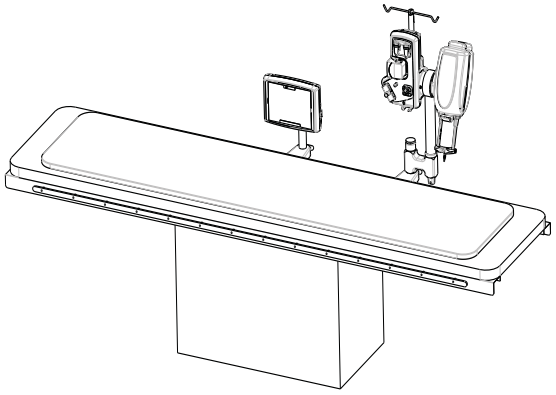
NOTE: Always use two persons to lift or move heavy, large or unwieldy packaging. Failure to do so may result in personal injury.

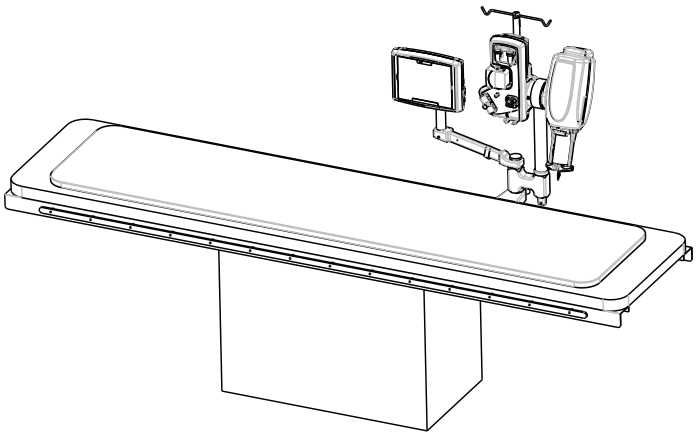
16.2 Installation Considerations

Below is a typical installation of the injection system with the pedestal.



Below are typical installations of the injection system with the Table Mount Bracket(s).





16.3 Injector Installation

Warning: Electrical Shock Hazard: Operator injury could result from using an extension cord or power adaptor with the system. Plug the injector directly into a properly grounded AC power outlet. Since the injector power cord supplies a safety ground to the unit, using an extension cord will compromise the ground quality and the injector could become unsafe.

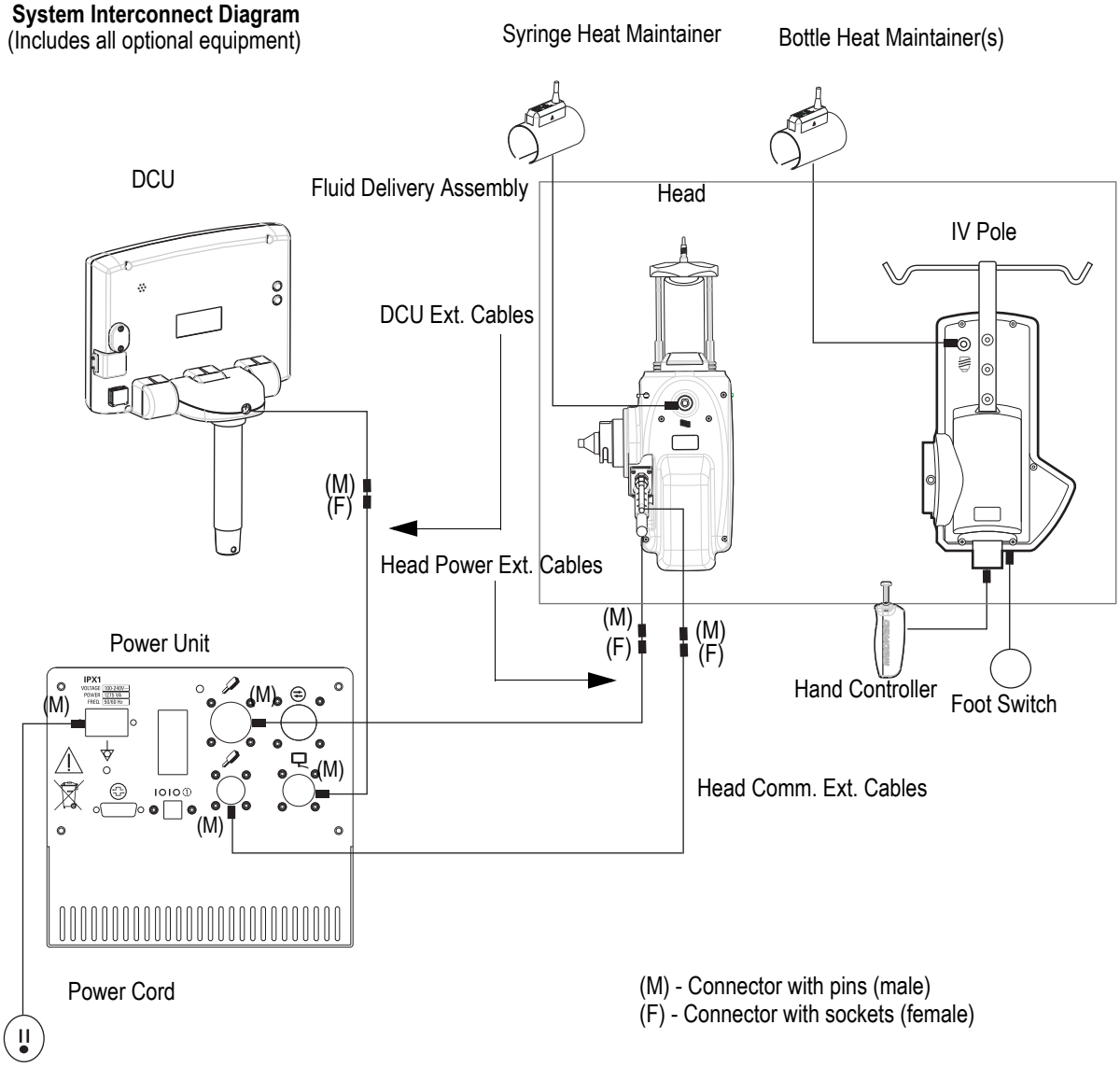
Warning: Use of non-Bayer accessories, including heat maintainers, Foot Switch, cables and replacement parts may degrade system performance and cause equipment damage. Use only heat maintainers, Foot Switch, cables and replacement parts from Bayer.

Warning: Only use the power cord supplied with the system. Do not plug the MEDRAD® Avanta Fluid Management Injection System power cord into an extension cord or multi-outlet power strip.

Follow the illustration below to install the cables that connect the MEDRAD® Avanta Fluid Management Injection System components. Be certain to tighten the screws that hold the cable connectors in place.

NOTE: All relevant guidelines for institutional, local, or national safety recommendations related to cable routing and installation should be followed.

System Interconnect Diagram
(Includes all optional equipment)



After installation, power-up the system, set the date and time, set the calibration interval, and perform the system check-out (see “Operational Checkout” on page 89) prior to use.

16.4 Pressure Jacket Installation

Install the MEDRAD® Avanta pressure jacket on to the front of the injector prior to installing a syringe. Align the slot in the pressure jacket with the protrusion on the front of the injector and push firmly on the face of the pressure jacket until it snaps on to the injector. Ensure that the syringe interface can close properly.

16.5 Table Mount Bracket Installation

The following instructions describe how to mount the system to the Table Mount Bracket(s).

NOTE: Ensure that the Table Mount Bracket(s) can be installed onto the table rail before installation. The Table Mount Bracket configuration

is compatible with the majority of exam tables produced by GE, Philips, Siemens, Canon, and others. Contact Bayer to verify your model.

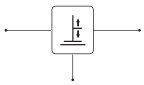
1. Remove the Table Mount Bracket from the box.
2. Assemble the Table Mount Bracket and attach to the table.
3. Remove the Fluid Delivery Assembly (including the FCM, head and superstructure) from the box and mount onto Table Mount Bracket. Secure with locking pin.
4. If using a DCU arm, remove the DCU arm from the box and mount onto the superstructure using threaded pin and knob.
5. Remove the DCU Final Assembly (including the DCU and DCU post) from the box.
6. Mount the DCU Final Assembly on the DCU arm or Table Mount Bracket and secure with locking pin.
7. Remove the Power Unit from the box and place in a desired location with connectors facing out.
8. Attach the cables to the appropriate Power Unit connectors, see System Interconnect Diagram.
9. Rotate the head unit to ensure that it has clearance to pivot into the vertical position, syringe up, and vertical position, syringe down, without interference.
10. Move the DCU to verify that it can be tilted or rotated in all directions without interference.
11. Attach the IV pole to the back of the FCM using the three screws provided.
12. Plug the Power Unit into the wall outlet.
13. Complete the inspection procedure.

16.6 Pedestal Installation

The following instructions describe how to mount the system to the pedestal.

1. Remove the pedestal from the box.
2. Remove the Fluid Delivery Assembly (including the FCM, head and superstructure) from the box and mount onto pedestal. Secure with locking pin.
3. Remove the DCU arm from the box and mount onto the superstructure using threaded pin and knob.
4. Remove the DCU Final Assembly (including the DCU and DCU post) from the box.
5. Mount the DCU Final Assembly on the DCU arm and secure with locking pin.
6. Remove the Power Unit from the box and place on the pedestal with connectors facing out.
7. Attach the cables to the appropriate Power Unit connectors, see System Interconnect Diagram.
8. Verify that the system can be raised or lowered without interference.

   NOTE: When raising or lower the pedestal ensure that your hands are placed in the area of the raising/lowering symbol on the handle

9. Rotate the injector head to ensure that it has clearance to pivot into the vertical position, syringe up, and vertical position, syringe down, without interference.
10. Move the DCU to verify that it can tilted or rotated in all directions without interference.
11. Attach the IV pole to the back of the FCM using the three screws provided.
12. Plug the Power Unit into the wall outlet.
13. Complete the Inspection Procedure.

16.7 ISI Installation (option)

Refer to the MEDRAD® Avanta Service Manual (86498197) for Installation instructions for the ISI option.

16.8 Catalog Numbers

Optional Accessories	Description	Catalog Number
Pedestal Mount		
	Assy, Pedestal, Adj Height	AVA 500 AJPED
	Assembly, Arm, DCU	AVA 500 DARM
Table Mount Bracket		
	Assembly, Table Mount Bracket	AVA 500 TMA
DCU - Power Unit Extension Cable		
	15 ft. (4.57 m)	AVA 500 D15
	50 ft. (15.2 m)	AVA 500 D50
	65 ft. (19.8 m)	AVA 500 D65
	90 ft. (27.4 m)	AVA 500 D90
Head - Power Unit Power Extension Cable		
	15 ft. (4.57 m)	AVA 500 HP15
	50 ft. (15.2 m)	AVA 500 HP50
	65 ft. (19.8 m)	AVA 500 HP65
	90 ft. (27.4 m)	AVA 500 HP90
Head - Power Unit Comm. Extension Cable		
	15 ft. (4.57 m)	AVA 500 HC15
	50 ft. (15.2 m)	AVA 500 HC50
	65 ft. (19.8 m)	AVA 500 HC65
	90 ft. (27.4 m)	AVA 500 HC90
Power Cords		
	North America and Japan	AVA 500 PC110V
	International	AVA 500 PC220V
	China	AVA 500 PCCHINA
	North America and Japan, 20 Ft	AVA 500 PP
	Brazil	AVA 500 PCBRAZIL
Miscellaneous		
	Pressure Jacket, 150 mL	AVA 500 PJ150
	Bottle Heat Maintainer (option)	AVA 500 BTLH-M AVA 500 BTLH-L
	Syringe Heat Maintainer (option)	AVA 500 SYRH
	Foot Switch (option)	AVA 500 FTC
	ISI Accessory Kit (option)	AVA 500 ISI
	Hand Controller	AVA 500 HC
	SPAT Long	AVA 500 SPAT L
	SPAT Angio	AVA 500 SPAT Angio
	MPAT	AVA 500 MPAT

17 - Compliance to IEC 60601-1-2 / 2nd, 3rd, and 4th Editions

The MEDRAD® Avanta Fluid Management Injection System complies with the requirements of:

IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

CISPR 11: Industrial, scientific and medical (ISM) radio-frequency equipment- Electromagnetic disturbance characteristics – Limits and methods of measurement

IEC 61000-3-2: Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (This does not apply to Class A equipment.)

IEC 61000-3-3: Electromagnetic compatibility (EMC)- Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connections) (This does not apply to Class A equipment.)

IEC 61000-4-2: Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test

IEC 61000-4-3: Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test

IEC 61000-4-4: Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test

IEC 61000-4-5: Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test

IEC 61000-4-6: Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio frequency fields

IEC 61000-4-8: Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity tests

IEC 61000-4-11: Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests

This system is in compliance to IEC-60601-1-2 / 2nd, 3rd, and 4th edition Standards. Special precautions regarding Electromagnetic Compatibility (EMC), are required for installation and use of this system. Detailed EMC information contained in this addendum is intended to reflect conformance to IEC-60601-1-2 / 2nd, 3rd, and 4th edition standards.



WARNING: For proper operation, use only accessories and options provided by Bayer that are designed specifically for the system. Other non-Bayer approved accessories or options may cause equipment damage or may result in increased emissions or decreased immunity of the system. System accessories listed in the operation manual comply with the requirements of electromagnetic emissions and immunity standards IEC-60601-1-2 / 2nd, 3rd, and 4th edition.



WARNING: Do not use system adjacent to or stacked with other equipment. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If adjacent or stacked use is necessary, the system and the other equipment should be observed to verify normal operation in the configuration in which it will be used.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the injector system unless a greater separation distance is required as indicated by the equation. Otherwise, degradation of the performance of this equipment could result.

CAUTION: System may disarm or fail to operate when exposed to high magnetic fields. Portable and mobile RF communications equipment can affect the system.

Recommended separation distances between portable and mobile RF communications equipment and the system			
The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = [3.5/V_1]\sqrt{p}$	**80 MHz to 800 MHz** $d = [3.5/E_1]\sqrt{p}$	**800 MHz to 2.7 GHz** $d = [7/E_1]\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***p*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency applies. **NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

THE SYSTEM REQUIRES SPECIAL PRECAUTIONS REGARDING EMC. Install and put into service according to the EMC information provided below:

Guidance and manufacturer's declaration - electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The emission characteristics of this system make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If the system is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity		
The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.		
Immunity test	**IEC 60601 Test Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for a.c. mains ±1 kV for I/O ports	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± -0.5 kV, ± -1 kV, ± -2 kV line to ground ± -0.5 kV, ± -1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	100% Vac for 0.5 cycles at 0°, 45°, 90°,135°,180°, 225°, 270°, 315	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continuous operation during power mains interruptions, it is recommended the system be powered from an uninterruptible power supply or battery.
	100% Vac for 1.0 cycles at 0°	
	30% Vac for 30 cycles at 0°	
	100% Vac for 250 (50Hz) cycles or 300 (60Hz) cycles at 0°	
Voltage interruptions IEC 61000-4-11	0% a.c. 250(50 Hz) or 300(60 Hz) at 0°	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 Test Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms from 150kHz to 80 MHz at 80% AM 1kHz 6Vrm, 80% AM 1kHz at ISM frequencies listed below:	**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the injector system unless a greater separation distance is required as indicated by the equation. Otherwise, degradation of the performance of this equipment could result. **Recommended separation distance** $d = 1.17\sqrt{p}$
Radiated RF IEC 61000-4-3	3Vrms from 80 MHz to 2.7 GHz at 80% AM 1kHz and specific ISM bands listed below:	$d = 1.17\sqrt{p}$ 80 MHz to 800 MHz $d = 2.33\sqrt{p}$ 800 MHz to 2.7 GHz Where ***p*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:  Non-ionizing Radiation Symbol (IEC TR 60878, 5140)

Frequency (MHz-ISM List)	Test Level (Vrms)
1.8 - 2.0	6
3.5 - 4.0	6
5.3 - 5.4	6
6.765 - 6.795	6
7.0 - 7.3	6
10.1- 10.15	6
13.553 - 13.567	6
14.0 - 14.2	6
18.07 - 18.17	6
21.0 - 21.4	6
24.89 - 24.99	6
26.957 - 27.283	6
28.0 - 29.7	6
40.66 - 40.70	6
50.0 - 54.0	6

Frequency (MHz)	Modulation Type	Modulation Frequency	Field Strength (Volts/meter)
385	Pulse	18 Hz	27
450	Pulse	18 Hz	28
710	Pulse	217 Hz	9
745	Pulse	217 Hz	9
780	Pulse	217 Hz	9
810	Pulse	18 Hz	28
870	Pulse	18 Hz	28
930	Pulse	18 Hz	28
1720	Pulse	217 Hz	28
1845	Pulse	217 Hz	28
1970	Pulse	217 Hz	28
2450	Pulse	217 Hz	28
5240	Pulse	217 Hz	9
5500	Pulse	217 Hz	9
5785	Pulse	217 Hz	9

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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(10) C

July 26, 2019

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