Operation Manual

MEDRAD® Spectris Solaris EP

MR Injection System

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The MEDRAD® Spectris Solaris EP MR 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.

EU Customers: Please report any serious incident that has occurred in relation to this device to Bayer (radiology.bayer.com/contact) and your local competent authority.

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1 - Introduction

This manual applies to the MEDRAD® Spectris Solaris EP MR Injection System, Catalog Number 3012011. Read all of the information contained in this section. Understanding the information will assist you in operating the device in a safe manner.

Important Safety Notice

This device is intended to be used by medical professionals with adequate training and experience in magnetic resonance imaging (MRI) studies.

Certifications

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

Indications for Use

This system is intended for the purposes of injecting intravenous MR contrast media and common flushing solutions into the human vascular system for diagnostic studies in magnetic resonance imaging (MRI) procedures.

Contraindications

This device is not to be used in the arterial side of the vascular system, for drug infusion, chemotherapy, or any other use for which the device is not indicated. The system should not be used with a magnetic resonance imaging scanner having a magnetic field strength greater than 3.0 Tesla.

Restricted Sale

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

Required Training

This device is intended to be used by individuals with adequate training and experience in diagnostic image studies.

Disclaimers

External wiring and modifications disclaimers: Bayer disclaims liability for any modifications or interfaces with other equipment which 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.

The MEDRAD® Spectris Solaris EP MR Injection System is not intended for portable use.

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

The Equipotential Connector (EPC)

The Equipotential Connector (EPC) is an electrically bonded terminal on the injector that is used as a connection point between other medical electrical equipment. The EPC's function is to minimize any voltage potentials differences between all connected equipment. The EPC is not designed to be an electrical safety ground.

Understanding Symbols

The following symbols are used on the MEDRAD® Spectris Solaris EP MR Injection System and components.

Warning: Refer to warnings and cautions on Instructions for Use packaged in each carton. (ISO 7010, W001)

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

Indicates that this device conforms to the requirements of the European Medical Device Directive 93/42/EEC.

Indicates on/off switch for the Control Room Unit. (IEC TR 60878: 5010, 5265)

Warning: Indicates hazardous voltages. (ISO 7010, W012)

Indicates alternating current. (IEC 60417, 5032)

Identifies a type BF applied part complying with IEC 60601-1 standards. (IEC 60417, 5333)

CLASS 1

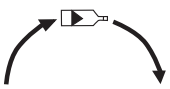
Indicates the injection system is Class 1 medical equipment as defined by IEC 60601-1 standards.

IPX1

IPX1 Code that specifies the degree of protection provided by the enclosure against vertically falling water drops (IEC 60529)

Identifies connection of the handswitch. (IEC TR 60878, 5322)

Identifies injector head forward and reverse piston control keys.



Identifies the direction of manual knob rotation relative to plunger movement.

Identifies the ENABLE key. (IEC TR 60878, 5104)

Identifies polarity of the battery pack terminals. (IEC TR 60878: 5005, 5006)

Indicates DC power supply. (IEC TR 60878, 5031)

Indicates the current charge level of the system battery.

Identifies Integrated Continuous Battery Charger system activity on Graphical User Interface. When illuminated yellow this indicates that the Continuous Battery Charger system is present and functioning.

Indicates the AIR EXPELLED button on the injector head. When illuminated yellow on the touch screen, also indicates that the operator has acknowledged inspecting the fluid path for air.

Identifies the Equipotential connection. (IEC 60417, 5021)

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

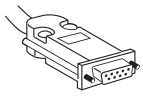
IOIO Identifies the Service Connection Port.

Identifies the Locking Bracket. Indicates which direction to turn Locking Bracket knob to “lock” and “unlock” the bracket.

TX Identifies the Communication Cable Transmit connection.

RX Identifies the Communication Cable Receive connection.

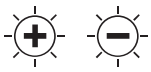
Indicates design for indoor use only. (Based on IEC TR 60878, 5957)



Identifies the Integrated Continuous Battery Charger System power supply connection.

Indicates the presence of no serviceable parts.

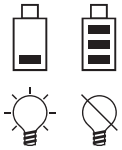
Indicates the presence of AC power at the battery charger.



Identifies the Control Room Unit brightness controls. (IEC TR 60878, 5056)
Brightness Up (+) and Down (-)

P109

Reserved for future use.



Indicates the status of the battery charger. When a battery is properly inserted, the LED will illuminate while charging, and extinguish when the battery is fully charged.

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

Consult instructions 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)

Maximum weight of the injector system and accessories during normal use:

SSEP, Total Weight: 35 kg/77 lbs
SSEP CRU Pedestal: 23 kg/50 lbs
(ISO 7000, 1321B; ISO 15223-1, 5.4.3)

Manufacturer (ISO 15223-1, 5.1.1)

Date of Manufacture (ISO 15223-1, 5.1.3)

Authorized representative in the European community (ISO 15223-1, 5.1.2)

Temperature range (ISO 15223-1, 5.3.7)

Humidity range (ISO 15223-1, 5.3.8)

Atmospheric pressure range (ISO 15223-1, 5.3.9)

This side up (ISO 7000, 0623)

Keep dry (ISO 15223-1, 5.3.4)

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

Part Number

Serial Number (ISO 15223-1, 5.1.7)

Catalog Number (ISO 15223-1, 5.1.6)

MR Conditional (IEC 62570, 7.3.2)
Has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use as defined by the ASTM International Standards for MRI Device Marking.

MR Unsafe (IEC 62570, 7.3.3)
Known threat or poses a hazard in all MR environments as defined by the ASTM International Standards for MRI Device Marking.

This product contains certain toxic or hazardous substances or elements and can be used safely during its environmental protection use period (indicated by the number in the middle of the logo). This product should be recycled immediately after its environmental protection use period has expired.

This manual contains important information about use of the MEDRAD® Spectris Solaris EP MR Injection System.

Bayer urges you to read this manual carefully, become familiar with the procedures and system functions that it describes, and follow its recommendations to assure proper use of the system.

Labels on the system or statements in this manual preceeded by any of the following words and/or symbols are of special significance, intended to help you to operate the system in a safe and successful manner:

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.

Warnings

Patient injury may result from a system malfunction. If a system malfunction occurs, immediately remove unit power (by pulling the battery from the Scan Room Unit), and disconnect 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 for assistance.

Patient injury could result from leaks or ruptures during an injection. To prevent leaks or ruptures in the event of a blockage, use only catheters and connectors with pressure ratings compatible with this system.

Explosion hazard. The MEDRAD® Spectris Solaris EP MR Injection System is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Fire hazard. To avoid an electrical fire, ensure the correct type of fuse is used for replacement. The fuse must be replaced by qualified personnel only. Refer to Appendix C for fuse type.

Electrical shock hazard. Hazardous voltages exist within system components. Do not remove or open any enclosure.

Electrical shock hazard. Avoid fluid entry into system components. Do not immerse any components in water or cleaning solutions. Use a damp cloth when cleaning on or around the battery and the Integrated Continuous Battery Charger system power supply.

Electrical shock hazard. Serious injury or death may result from exposure to hazardous voltages existing within the system. Disconnect the Battery Charging System from line power and remove the battery from the Scan Room Unit before cleaning.

Electrical shock hazard. Equipment must only be connected to a supply mains with protective earth.

Ventilation hazard. To avoid a build up of hydrogen gas from the battery, assure the room is well ventilated while battery is charging.

Improper disposal of the battery pack may result in explosion, leakage, or personal injury. Do not open, or dispose of in a fire! Follow all local regulations concerning the disposal of spent lead-acid based batteries, or contact Bayer for assistance.

System electronic assemblies contain potentially hazardous materials. Dispose of system components or accessories properly. Follow local regulations for proper disposal or contact Bayer for assistance.

Unsafe operation may result from using improper accessories. Use only accessories and options provided by Bayer designed for this system.

Chemical burn hazard. Always carry the battery pack firmly by the battery pack hand grips. Damage to the housing may result in a chemical burn hazard. Do not use if the housing is severely cracked or damaged.

Voltage hazard 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 for service or replacement.

The MEDRAD®Spectris Solaris EP MR Injection System is a dual syringe system. Always ensure that the proper syringes are loaded with contrast media and flush solution prior to the injection. Failure to properly load and install the syringes may require the procedure to be repeated. Syringe A is designated for contrast agent use only. Syringe B is designated for flush solutions only.

Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/ magnet room components.

Patient injury and/or catheter damage may result from using connector tubing (LPCT) that is too short. Operator must consider tubing length and stretch limitations when moving the injector or the patient.

Serious injury or death may result from syringe failure. Do not retract pistons with connector tubing installed. Retracting the pistons with the connector tubing installed on syringes will create a vacuum in the syringe due to the check valve in the connector tubing. This vacuum may accelerate the plunger rapidly toward the tip of the syringe when it is removed from the injector causing the syringe to break.

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

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.

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.

Cautions

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.

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.

This injection 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 injection system. Detailed EMC information can be found in Appendix F of this manual.

Damage can occur as a result of incorrect voltage. Before plugging in the system, check the following:

- Verify that the voltage and frequency marked on the serial tag on the back of the unit matches the voltage and frequency of the electrical outlet.
- Verify that the Control Room Unit and the Battery Charger power supply have the appropriate power cord plugs for the power outlet.

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

2 - System Basics

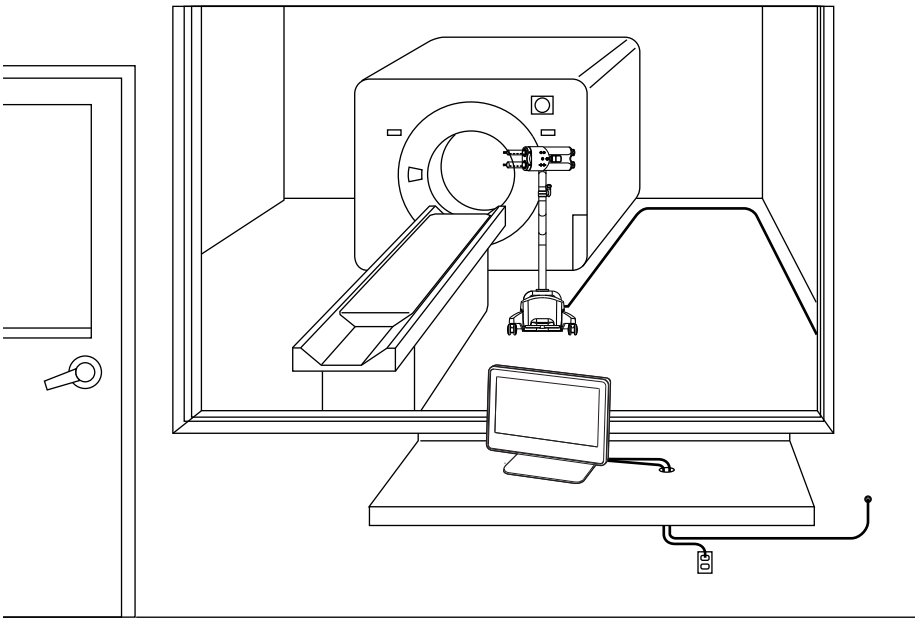
About the Injection System

The MEDRAD® Spectris Solaris EP MR Injection System is a programmable, dual syringe system, designed to accurately administer controlled doses of intra-venous MR contrast agents and common flushing solutions to patients undergoing a contrast enhanced MR scan.

The system consists of two basic components that communicate by a direct connection of fiber optic lines.

- The Control Room Unit houses the Touch Screen and electronic components used to program the injection system.
- The Scan Room Unit, positioned near the magnet bore, contains the Injector Head, system battery pack, and the mechanical assemblies required for fluid delivery.

A battery charger is also supplied with the system, used to charge the Scan Room Unit battery pack. For convenience, the charger can be used in the control room, but should never be installed or operated in the scan room.



Note: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Pressure Safety Limit

The MEDRAD® Spectris Solaris EP MR Injection System is designed to allow varied flow rates for contrast injections. By automatically reducing the flow rate, the system can limit the pressure produced during an injection to prevent damage or failure of any connecting devices or tubing. This feature is called *Pressure Safety Limit*.

Inability to maintain the desired flow rate while remaining below the Pressure Safety Limit can be caused by various conditions including contrast viscosity, catheter sizing, connector tube sizing, and stopcock restrictions. If the system is unable, for a period of three seconds, to maintain a flow rate of at least 10% of the programmed rate, the system will disarm due to a stall condition.

If unable to automatically achieve the required level of flow rate reduction, thus reaching the Pressure Safety Limit, the system will terminate the injection and move to a disarm state.

Response to Occlusions

When injecting into an occlusion, a stall condition (flow rate less than 10% of programmed rate) will result. A stall condition lasting more than 3 seconds (3 minutes for programmed rates less than 0.1 ml/sec) will result in the injection being automatically terminated.

If an occlusion occurs during KVO (Keep Vein Open) the system will detect the condition after 4 or less KVO boluses fail to be delivered. This will correspond to from 1 minute with a KVO interval of 15 seconds configured, to 5 minutes with a KVO interval of 75 seconds. Refer to the Setup screen to determine the current KVO setting.

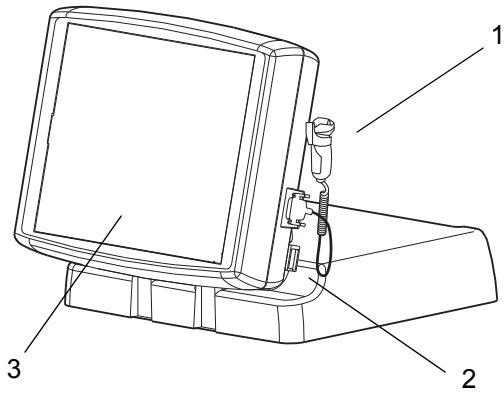
If a stall occurs due to an occlusion, and the blockage is subsequently removed, less than 10 ml will be delivered as the pressure in the administration set dissipates.

Volume and Rate Protection

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

- Warnings displayed on the Safety screen and during the arming sequence remind the operator to check the programmed injection parameters prior to the system being armed.
- An onscreen 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 before an additional 10 ml of fluid above programmed volume is delivered.

Control Room Unit



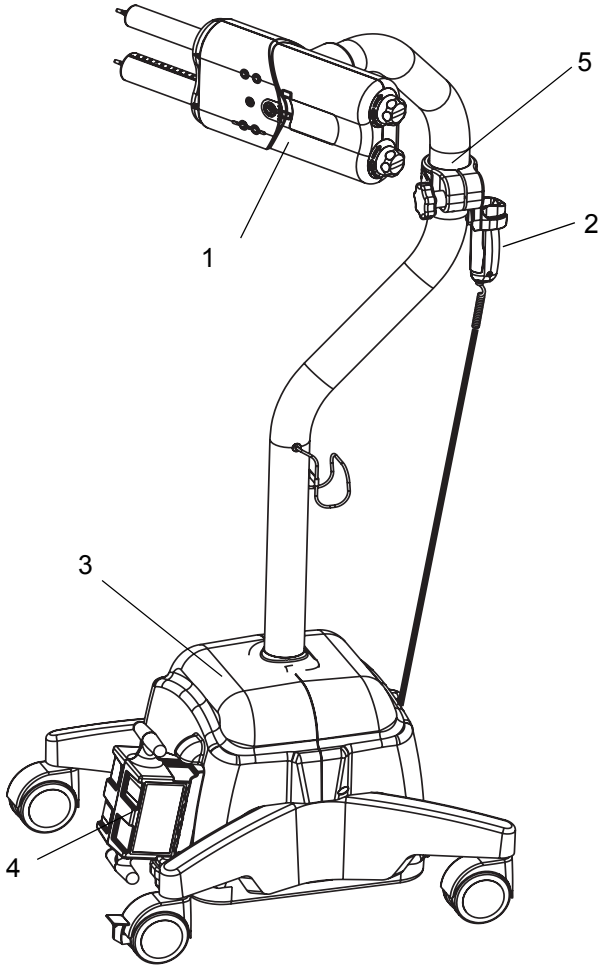
1. Handswitch

2. System Power Switch

3. Touch Screen

At rear of Touch Screen Assembly - Display Contrast Controls

Scan Room Unit



1. Injector Head

2. Handswitch

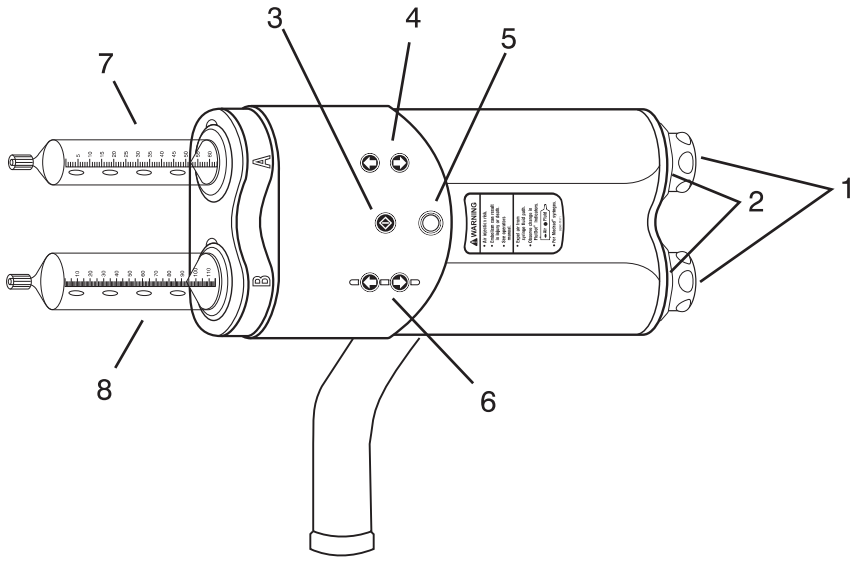
3. Lower Console

4. System Battery Pack

5. Middle Pivot Clamp

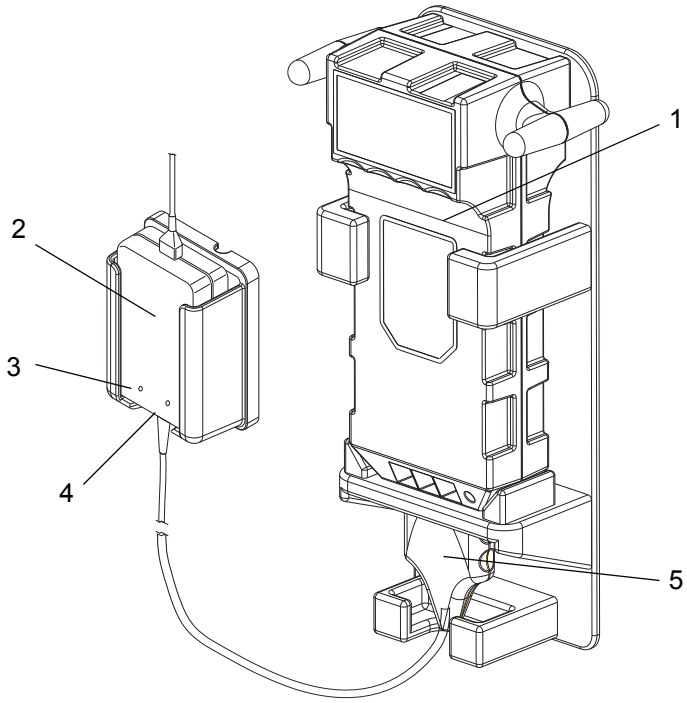
Not shown - Contrast Holder (optional)

Injector Head



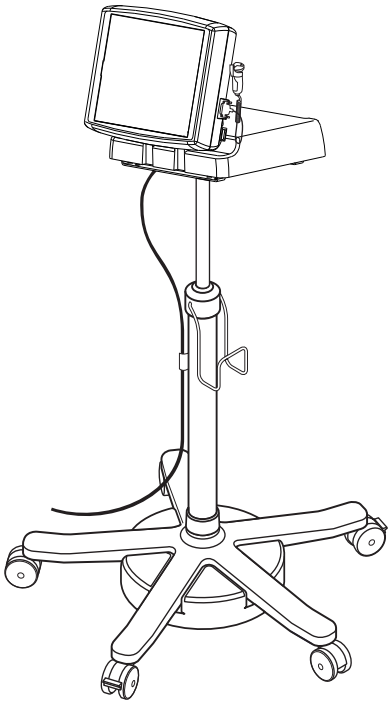
1. Manual piston movement knobs
2. Armed indicator lights
3. ENABLE button - Used to activate the forward/reverse controls - the appropriate direction must be selected within 5 seconds.
4. Syringe A forward/reverse controls
5. AIR EXPELLED button/indicator
6. Syringe B forward/reverse controls
7. Syringe A: Contrast agent
8. Syringe B: Flush solution

Battery Charger



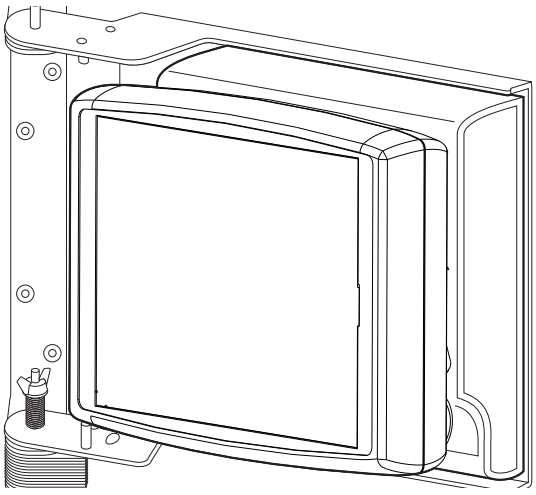
1. Battery Pack
2. Battery Charging Unit
3. Charging Indicator - Amber
4. Power Indicator - Green
5. Battery Charger Head

Optional Control Room Unit Accessories



Adjustable Height Pedestal

WARNING: Injury or equipment damage may result if the adjustable height pedestal is taken into the scanner room. Do not take the adjustable height pedestal in the scanner room. It contains ferrous material that could be attracted toward the magnet.



Wall Mounting Bracket

Note: These accessories contain ferrous material and are designed to be used in the Control Room only. Do not install or operate in the Scan Room.

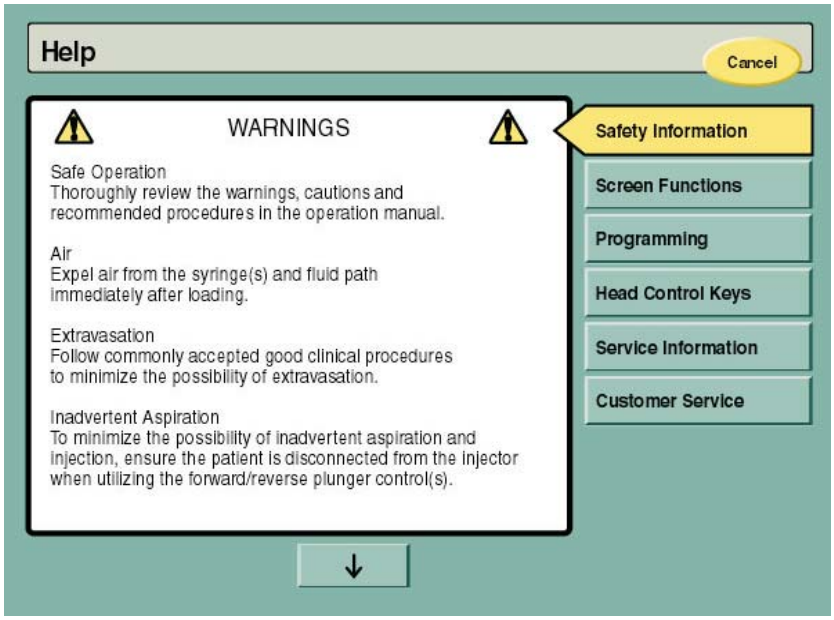
Touch Screen Calibration

To enter Touch Screen Calibration mode, simultaneously press both the Contrast UP and DOWN keys on the rear of the touch screen housing. A series of screens with instructions to press the appropriate calibration circles will appear.

CAUTION: Do not touch the screen with a sharp object in order to perform the calibration.

Help Mode

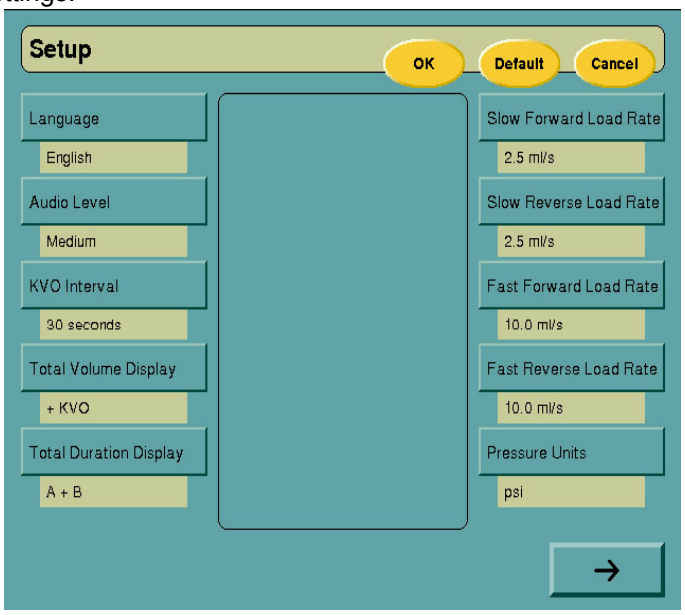
The Help screen can be accessed by pressing the HELP button on the lower right corner of the Main screen. Besides safety information, the Help screen displays a variety of topics as displayed below.

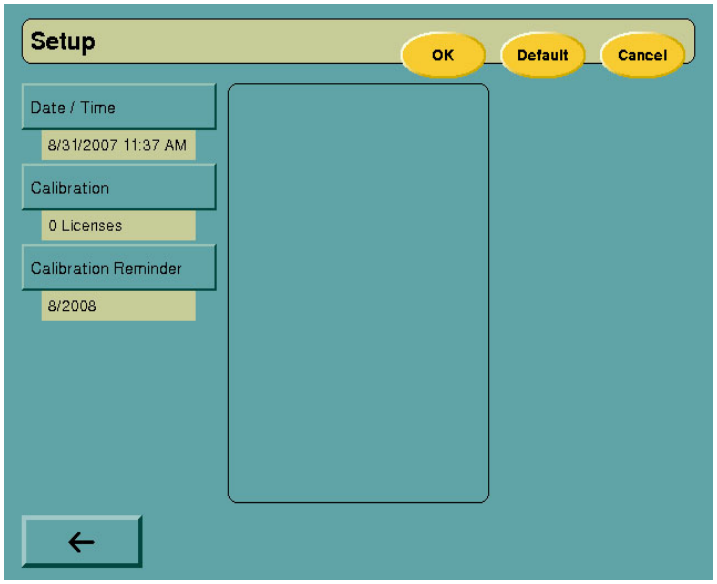


Setup Mode

The Setup screen can be accessed by pressing the SETUP button at the lower right corner of the Main screen. The Setup screen allows user configurable options and preferences to be selected, along with setting of date and time parameters.

Select the appropriate option, then choose from the available selections in the display window. Select the DEFAULT key to return all options to original factory settings.





The system provides a calibration and maintenance reminder. This reminder will be displayed on the System Logo screen at each startup, beginning 30 days before the system is due to be recalibrated. The duration of time from one calibration to the next is programmed during system installation or by selecting the Calibration Reminder key and entering the correct due date.

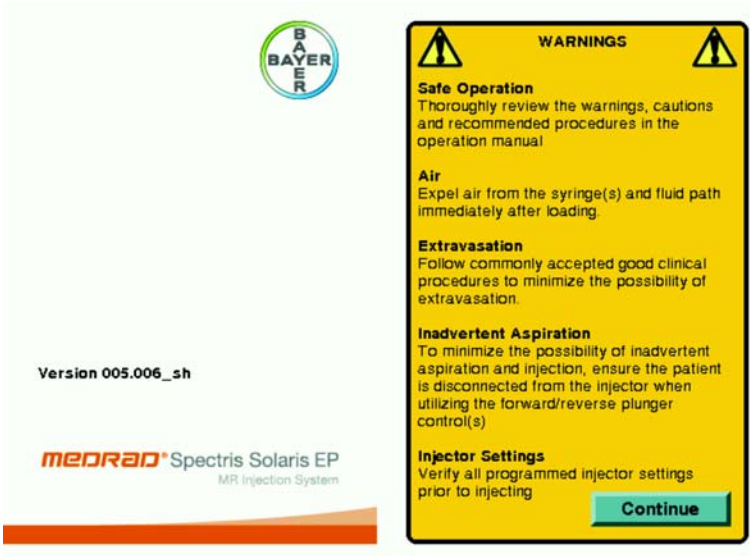
3 - Preparing to Inject

Applying Power

Place the power switch located on the right side of the Control Room Unit in the ON position. The System Logo screen will appear while the system performs a series of self diagnostic tests.

Note: Do not touch the screen or activate any controls while self diagnostics are in progress. If this occurs, diagnostic tests will interpret this activity as a hardware failure and halt the system. The system must then be powered down/up to reset the error.

After diagnostics have successfully completed, the System Logo screen will be replaced by the Safety screen



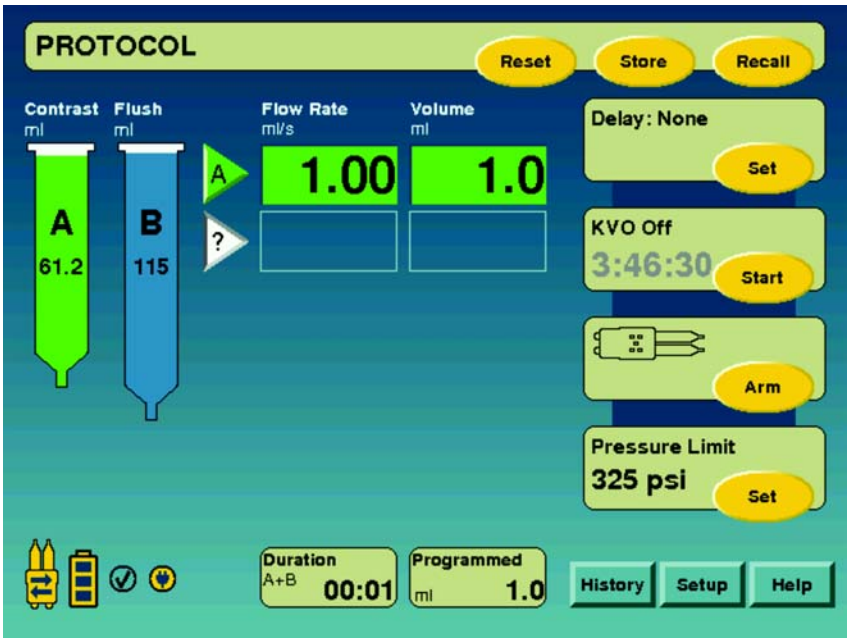
After reading the Safety screen, press CONTINUE to view the Main screen.

Apply power to the Scan Room Unit by inserting the battery into the receptacle on the bottom of the Scan Room Unit. Upon power up of the CRU and SRU, verify that the indicators, lamps, and speaker are operational.

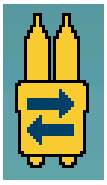
Note: The Control Room Unit can be programmed for an injection without power applied at the Scan Room Unit.

Main Screen

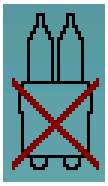
The Main screen is entered from the Safety screen after power-up. The Main screen is used during programming, arming, and injecting, with applicable screen controls made visible based on the task currently being performed.



The Communication Status will be shown in the lower left corner of the Main screen. The Communication Status icon will contain two arrows when communication is up or a red “X” when communication is down.



Communication Up



Communication Down

Battery Maintenance

WARNING: Explosion Hazard. Serious injury or death may result from improper use of the battery charger. The battery charger, Bayer Catalog Number 3012424, is intended for use in a well ventilated area, with the injection system battery, Bayer Catalog Number 3012070, only. Do not use the charger with non-rechargeable batteries.

When the Main screen appears, check the status of the system battery in the lower left corner of the screen. The battery icon will contain three horizontal bars when indicating full charge, two when indicating medium charge, one for low charge, and no indicators in the icon when the battery is fully depleted, not connected, or communication is not detected between the Control Room and Scan Room Units.

- Full Charge

- Medium Charge

- Low Charge

- Fully Depleted
- Not Connected
- Communication Not Detected

If the depleted battery is not replaced when only one bar is displayed, the system will complete any injection that is in progress. However, the system may not initiate a single or multi arm injection, the forward and reverse controls on the injector head may not function and system communications may be lost.

Each battery pack should last for 4 to 6 typical injections using a 20 minute KVO, or approximately 5 hours in an idle state before requiring a recharge. Monitor battery status per injection and on a daily basis. Each battery is capable of being recharged approximately 300 times. When the life of a battery pack becomes shortened, noticeably sustaining fewer injections per charge, this signals that battery life is expiring and the battery pack should be replaced. Call Bayer for battery pack replacement.

To charge the battery, place the 3-pronged, charging head into the battery, then connect the charger to AC power. A green LED on the charger indicates that AC power is applied. An amber LED indicates that the battery is charging. The amber LED will turn off when full charge is reached. Battery charge time is approximately 5 hours.

Syringe and Disposable Accessory Installation

Retracting the Pistons

Fully retract each piston by using the reverse switches on the injector head.

Note: When using the reverse switches, first press the Enable switch; then within 5 seconds, press the reverse switch(es). Both pistons may be reversed simultaneously.

The forward and reverse switches have dual speed capabilities:

When the switches are partially depressed, the pistons will move slowly. When fully depressed, the pistons will move quickly. Forward and reverse piston speeds are fully configurable (1 to 10 ml/sec) in the Setup mode.

The manual knobs may also be used to move the pistons in the forward or reverse direction. Turn the knobs clockwise to advance the piston, counterclockwise to retract.

Installing a Syringe

WARNINGS:
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.

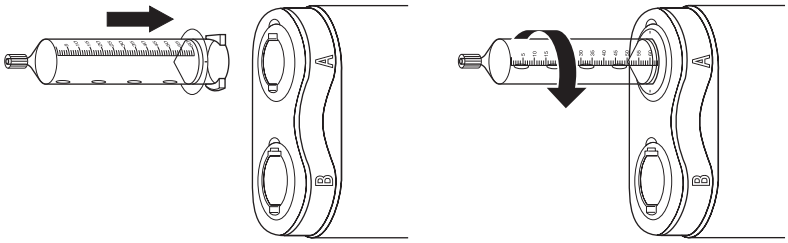
Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components. Do not store pre-loaded syringes.

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.

Patient injury could result if the syringe is not properly engaged. Ensure the alignment marks on the syringe and injector head are properly aligned, and the piston and plunger are interlocked. Improper engagement may cause syringe damage or under-volume delivery.

CAUTION: Improperly engaged syringes may leak or be damaged. Ensure proper engagement of syringe and injector. Syringe and injector engagement points must align.

Note: Syringe A is intended for contrast media, and Syringe B is intended for flushing solution only.



1. Align the flanges on the syringe with the notches in the injector head. (The syringe is keyed to properly fit in only one way.)
2. Insert the syringe.
3. Twist 1/4 turn clockwise until the syringe snaps into place. (Graduations will be facing the front of the injector head.)

WARNING: Air embolism can cause patient injury or death. Expel all trapped air from the syringe(s), connectors, tubing, and catheter-over-needle before injecting.

Note: Do not hit or tap the syringe to remove air bubbles.

To reduce the volume and size of air bubbles drawn into the syringe during loading, a Fluid Dispensing Device (FDD or “spike”) from Bayer is recommended. Air removal from the syringe(s) will be much more difficult if a small diameter tube, such as a catheter-over-needle, needle, or a tube longer than 10 inches (25 cm), is used for loading.

Operator vigilance and care, coupled with a set procedure, is essential to minimizing the possibility of an air embolism. The injector head should be pointed upward during loading, enabling any air to accumulate at the syringe tip and to be expelled. The injector head should be pointed downward during an injection, enabling any small air bubbles which could still be in the fluid to float to the rear of the syringe(s).

To help avoid air injection, syringes from Bayer are equipped with MEDRAD® FluiDots indicators. These MEDRAD® FluiDots indicators should be observed as part of an arming procedure. When the MEDRAD® FluiDots are viewed through an empty syringe, the dots appear as small narrow ellipses as illustrated below in figure 1. However, when viewed through a full syringe, the dots become larger, almost round (or wider than round) as illustrated below in figure 2.

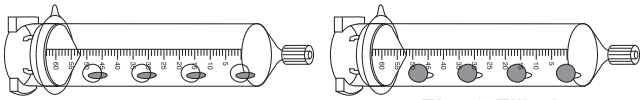


Fig. 1 Empty

Fig. 2 Filled

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.

To minimize air embolization risks, ensure that one operator is designated the responsibility of filling the syringe(s). Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that the fluid path is purged of air.

WARNING: If a blockage occurs, disposable components with a lower pressure rating may leak or rupture. Use only catheter and connectors with ratings that are compatible with the MEDRAD® Spectris Solaris EP MR Injection System.

During installation of the low pressure connector tubing (LPCT) with T-connector to the syringe(s), and before arming, manually advance the syringe plunger(s) to provide a very slow flow of fluid at the connection. An absence of flow is an obvious indication of air or a blockage in the fluid path.

Loading a Syringe

WARNINGS:
Remove all trapped air from the syringe, connector tubing, and catheter-over-needle before connecting the patient to the injector.

Syringe sterility will be compromised, and patient infection may result, if the plunger is removed from the syringe. Do not remove the plunger to fill the syringe.

Bacterial contamination can occur if syringes are used to store contrast media. Use loaded syringes immediately. Do not store loaded syringes for later use. Discard any unused syringes.

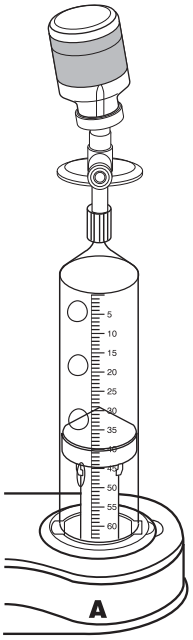
Note: The presence of rounded MEDRAD® FluiDots indicators does not indicate the total absence of air bubbles in the syringe tip.

Note: 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.

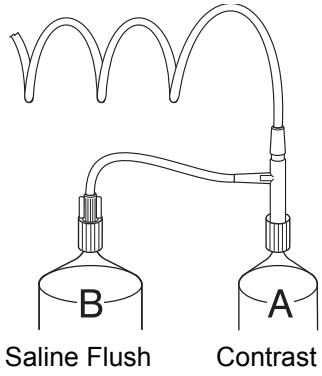
1. Position the injector head so that the syringes are pointing upward.
2. Fully advance each piston plunger. The plungers may be advanced simultaneously after pressing ENABLE.
3. Attach a sterile filling device (spike or Female-to-Female Adaptor - *Bayer Catalog Number FFA 50*) onto the tip of the syringe. If loading contrast media and/or saline from a bag or bottle, use a spike. If loading contrast media from a pre-filled syringe, use an FFA 50.

   A. If using a spike, open the bottle(s) of contrast and/or bag(s) of flushing solution, then draw the contents (contrast for syringe A; flush for syringe B) into the syringe(s) by depressing ENABLE, and then the reverse load button for each syringe.

   B. If using the FFA 50, attach it to the tip of syringe A, then attach the pre-filled syringe to the FFA 50. Draw the contents from the prefilled syringe into syringe A by pressing ENABLE, then the reverse load button.
4. With the filling device still attached, advance the plunger to expel any air that may remain in the top of the syringe; then, if necessary, draw more fluid into the syringe to replace fluid loss.
5. Remove the filling device and expel any air bubbles from the syringes.



6. Attach the long end of the T-connector to syringe B.
7. While the injector head is still in a vertical position, attach the short section of the T-connector to syringe A.
8. Starting with syringe A, then syringe B, prime the T-connector, then fill the connector tubing with the appropriate fluid. Ensure that all air is expelled from the entire length of the tubing.



Note: A MEDRAD® SSIT 96VLD low pressure connector tube (LPCT) holds approximately 7 ml of fluid. If syringe B is used to flush, use at least 8 ml of flush to deliver this volume to the patient.

Note: If the connector tube is filled with saline, contrast will be delivered to the patient with a delay dependent on the flow rate selected for syringe A.

Note: When the connector tube is filled with contrast the volume remaining displayed on the protocol screen is approximately 7 ml less than what was loaded into the syringe.

9. *Tilt the injector head downward* before attaching to the vascular entry device in the patient. After attaching the connector tube to the vascular entry device verify that the connector luer fittings are secured. The injector head must be maintained in this position during the injection.

WARNINGS:
Patient injury could result from movement of the Scan Room Unit after the patient is connected to the fluid path. Lock the casters at the base of the unit and the Middle Pivot Clamp to prevent unintended movement.

Patient injury and/or catheter damage may result from using connector tubing (LPCT) that is too short. Operator must consider tubing length and stretch limitations when moving the injector or the patient.

10. Secure the Scan Room Unit by locking the casters and the Middle Pivot Clamp, then verify that all air has been expelled from the fluid path by carefully inspecting all tubing and syringe(s). Acknowledge that the inspection has occurred by pressing the AIR REMOVED confirmation button/indicator on the injector head. The Air Removed Indicator will then illuminate yellow on the touch screen.

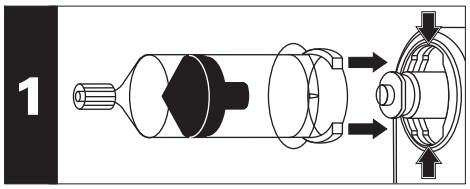
Note: Reverse movement of the pistons after the AIR EXPELLED button has been pressed will cancel the Air Expelled status. Re-check the fluid path for air, then press the AIR EXPELLED button again to continue.

Reinstalling a Syringe

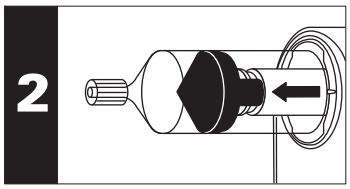
WARNING: Patient injury could result if the syringe is not properly engaged. Ensure the alignment marks on the syringe and injector head are properly aligned, and the piston and plunger are interlocked. Improper engagement may cause syringe damage or under-volume delivery.

If you remove a syringe from the injector, and then wish to reinstall it, perform the following steps:

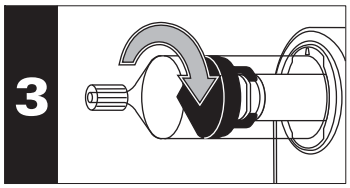
1. Insert the end of the syringe in the horizontal cutouts in the injector head.



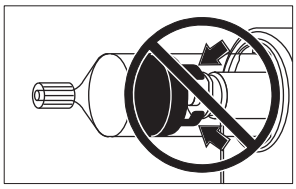
2. Advance the piston until it is past the plunger feet and the piston/plunger interlock.



3. Rotate the syringe 1/4 turn clockwise until the syringe locks and alignment marks are positioned.



4. Proceed as normal by aspirating and dislodging any air bubbles.



Note: If bubbles appear in the syringe **DO NOT** hit the syringe to remove them. Reverse the plunger 3 to 5 ml, then rock the head on the pivot to gather and accumulate the small bubbles. Expel the remaining air.

Programming

If a program has not been previously entered or stored on the Main screen when the unit is powered up, the Main screen will display default settings; 1.0 ml/s flow rate and 1.0 ml volume, KVO off and No Delay.

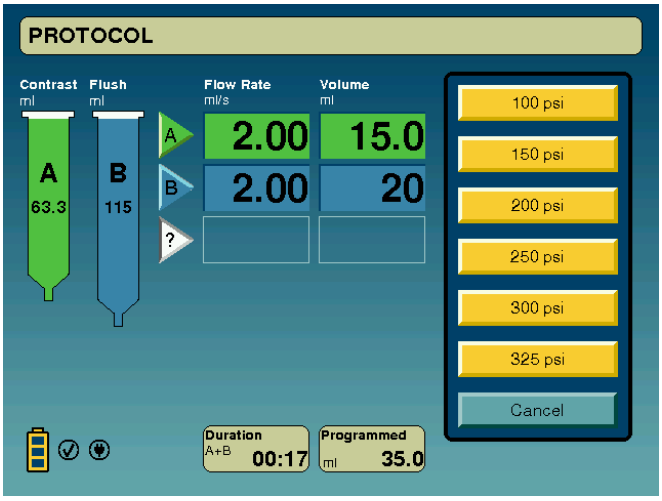
Flow Rate and Volume

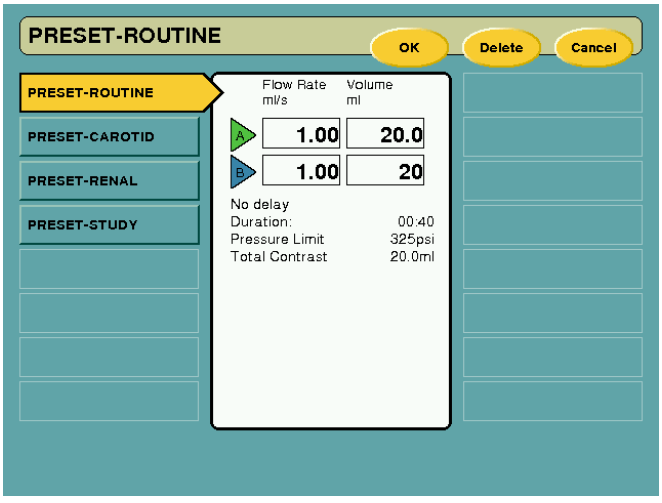
Begin programming by selecting any programmable block, such as FLOW RATE or VOLUME. When a programmable block on the screen is touched, a keypad will be displayed to permit the selection of numeric values. The numeric keypad is displayed when a Flow Rate, Volume or Delay value is selected. The keypad window will also display the appropriate programmable range for the parameter selected. To lock in values, press ENTER. Press << to edit a selection, or CANCEL to eliminate a selection if an error is made.

Pressure Limit

The pressure limit can be programmed by choosing a value between 100-325 PSI up to the greater of the syringes' maximum pressure.

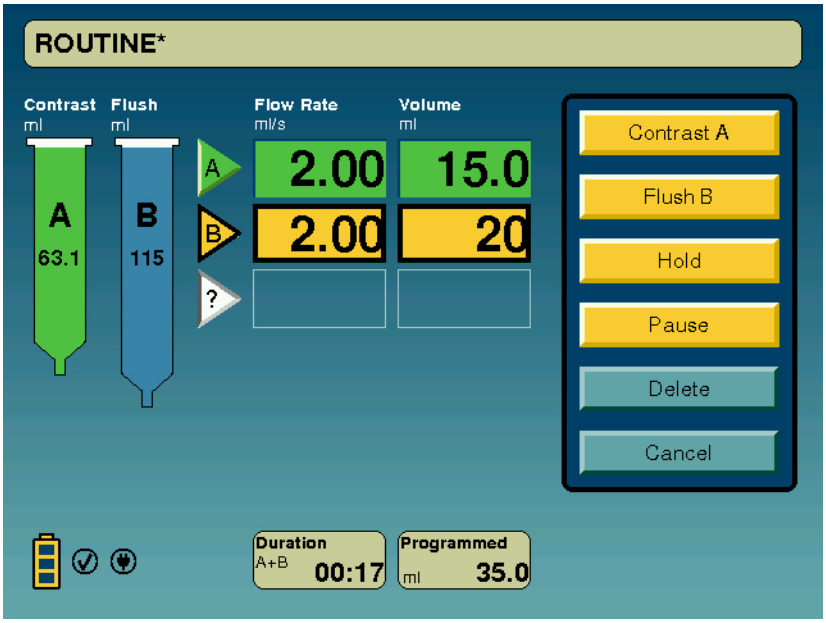
The Set Pressure Limit is associated with protocols. The pressure limit set for a protocol will reset the current pressure limit when that protocol is recalled. The pressure limit set with a protocol will display on the Protocol Recall screen.





Multiple Phases

If appropriate, select a second phase for the injection protocol by pressing the triangle block below the first phase of the injection. The Phase Type selector will appear in order to select the function of the new phase.



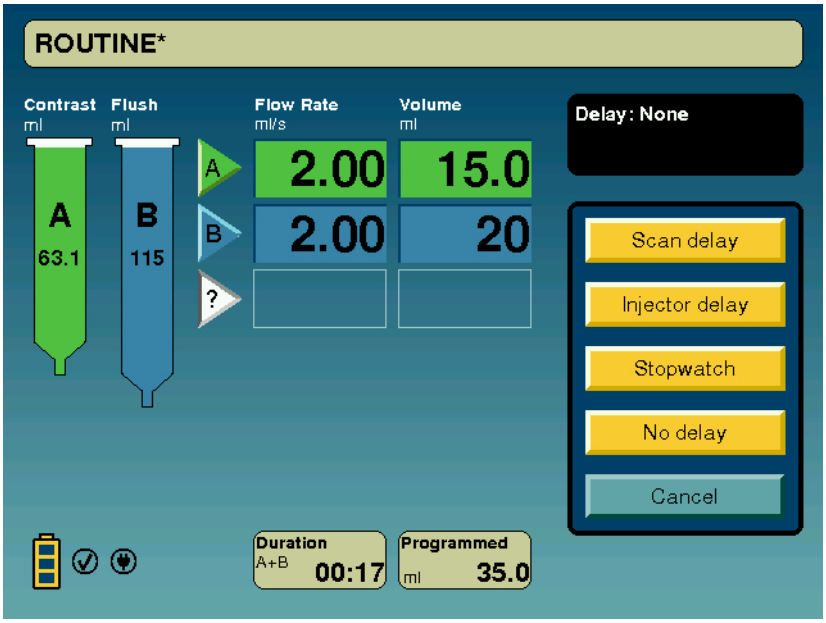
Hold and Pause Phases

A Hold or Pause phase can be programmed into a multi-phase injection. A Pause phase will stop the total injection process for a preprogrammed length of time, while the Hold phase will stop the injection until input from the operator resumes the injection. A Hold phase can be maintained for up to 20 minutes, at which time the system will disarm.

After selecting the phase type, continue programming by entering Flow Rate and Volume values for the new phase.

Programmed Delay

After entering Flow Rate and Volume parameters, press SET in the Delay Timer field to select the delay type (Scan Delay, Inject Delay, Stopwatch, or No Delay.)



Note: There is no direct interface between the scanner and the injector. The scanner cannot trigger the injector, nor can the injector trigger the scanner.

Scan Delay

Scan Delay time will elapse in the timer block on the screen. The time remaining before the scan should be activated will decrement in one second intervals. (The scan delay countdown will continue through multiple arm injections.) When countdown is complete, the system will emit 5 beeps.

Inject Delay

Inject Delay will also countdown in one second intervals, commencing when the handswitch is pressed. The clock will display, in one second decrements, the time remaining before the injection will begin. *When inject delay is chosen and the handswitch is pressed, the injection will automatically occur unless the injector is disarmed.* When countdown is complete, the system will emit 5 beeps and the injection will automatically begin.

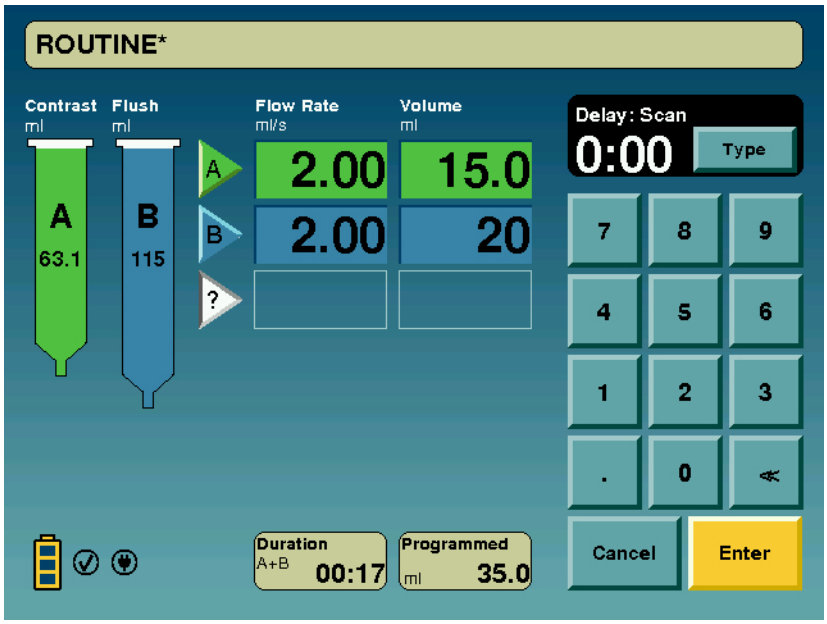
If Hold is activated during an inject delay or a scan delay, the timer will stop during the hold interval and resume when the handswitch is pressed.

For scan or inject delays that are longer than 3 minutes, the unit will beep 30 seconds before the delay is to terminate, then will beep every second from 5 seconds through 1 second before the delay is due to terminate.

Stopwatch

The Stopwatch function initiates an incremental count of elapsed time from initial fluid injection.

After selecting the delay type, enter the delay duration on the numeric keypad. To lock in values, press ENTER. Press CANCEL to eliminate a selection if an error is made.



KVO (Keep Vein Open)

The KVO function delivers small boluses of fluid from syringe B at configurable intervals. KVO can run during:

- Programming
- Pre and post injection
- Between multiple injections
- During Pause and Hold

The delivery interval can be selected in the Setup mode, which is accessed using the Setup button on the Main Screen.

After an initial KVO pulse of 2 ml, KVO delivery intervals include 0.25 ml pulsed every:

- 15 seconds
- 20 seconds
- 30 seconds (default)
- 45 seconds
- 60 seconds
- 75 seconds

The KVO field displays the time available to support KVO based on the configured interval and the volume remaining in syringe B less any volume programmed from syringe B in the protocol.

Starting KVO:

On the Main Screen, press START in the KVO field to initiate KVO. When KVO is running, “KVO” will appear, and the KVO Injecting arrows will flash in the Syringe B touch screen indicator.

KVO will function during Pause, Hold and/or inject delay periods. KVO will resume post-injection until no fluid remains in syringe B, or until STOP KVO is pressed in the Injection Complete window.

Note: Volume displayed in the Volume Delivered window can be configured in the Setup mode to include the total KVO volume delivered in addition to volume delivered by the programmed injection.

KVO may be stopped at any time by pressing STOP in the KVO field, or by pressing any injector head control button (this will also disarm the system and terminate any injection in progress). Other actions that disarm the injector, such as syringe removal, disarm button press and injection stall, will also stop KVO.

KVO and Occlusions:

If an occlusion occurs during KVO the system will detect the condition after 4 or less KVO boluses fail to be delivered. This will correspond to from 1 minute with a KVO interval of 15 seconds configured, to 5 minutes with a KVO interval of 75 seconds. Refer to the Setup screen to determine the current KVO setting.

Storing a Protocol

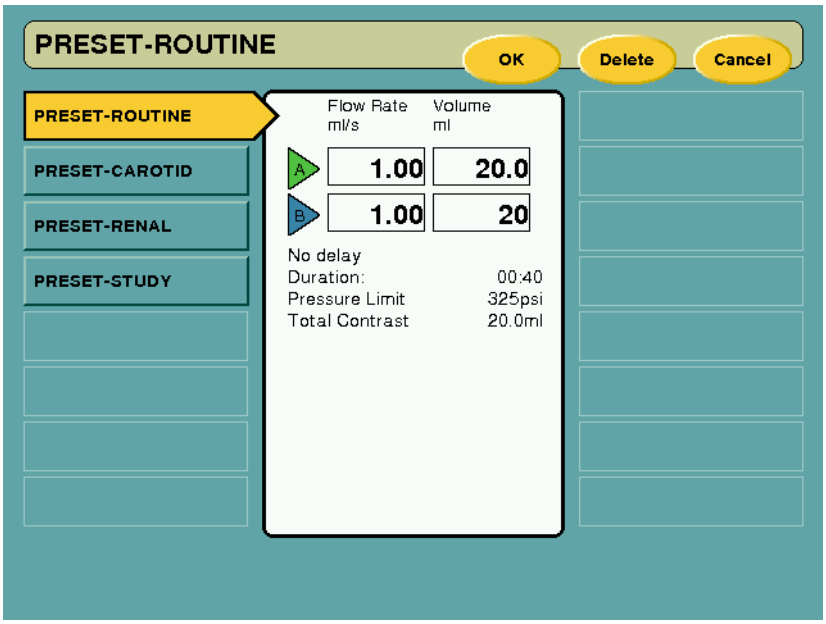
To store a protocol for future use, press the STORE button on the upper right corner of the Main screen.

An alpha-numeric keypad will appear with a flashing cursor in the title block. Type in a title of up to 20 characters, including spaces. Use the arrow key to backspace, individually erasing characters, and the CLEAR key to clear a string of text. When title entry is completed, press ENTER.

To exit the Store screen without making changes, press the CANCEL button in the upper right corner.

Recalling a Stored Protocol

To access program memory, press RECALL on the Main screen.



Select a previously stored injection protocol by pressing one of the names on either side of the screen. Key parameters of the selected injection will be displayed in the center of the screen. Once selected, the protocol can be deleted by selecting DELETE at the upper right corner of the screen, or brought to the Main screen by selecting OK.

4 - Arming and Injecting

Before beginning the arming process, ensure that the casters on the Scan Room Unit are locked, verify that all air has been expelled from the fluid path, and that the programmed parameters are correct. Carefully inspect all tubing and syringe(s), then acknowledge that the inspection has occurred by pressing the AIR EXPELLED button/indicator on the injector head. A yellow illuminated Air Expelled Indicator on the touch screen confirms that the button has been pressed.

WARNINGS:
Air embolization can cause death or serious injury to the patient. Do not connect a patient to the injector until all trapped air has been cleared from the syringe and fluid path.

Patient injury could result from high flow rate venous injections. Use extreme care when selecting flow rate and duration. Before arming the injector, verify that high flow rate injection parameters have not been unintentionally programmed.

Patient injury could result from inadvertent aspiration. To minimize the possibility of inadvertent aspiriation and injection, ensure the patient is disconnected from the injector when utilizing the forward/reverse plunger control(s).

Extravasation can cause injury to the patient. Follow commonly accepted good clinical procedures to minimize the possibility of extravasation.

Arming

To begin the arming and injecting process, press ARM on the Main screen. If necessary, changes can be made to programmed injection parameters after the arming sequence is complete. Select the required parameter, then enter the correct value with the on-screen keypad. Pressure safety limit programmed by the user is indicated to the user and cannot be changed when the injector is armed.

Note: If the AIR EXPELLED button on the injector head has not been pressed, the system will request user confirmation that air has been expelled before proceeding.

Single and Multi-Arm

Select either a Single or Multiple arming sequence by pressing either SINGLE or MULTI. (The default is Single arm.)

A *single arm* injection will perform the protocol once, then disarm.

A *multi-arm* injection allows the protocol to be repeated, creating a series of injections. After the protocol is completed, the system will automatically re-arm in preparation for the protocol to be repeated. Each injection in the series must be started with the handswitch.

Insufficient Volume

If an insufficient volume condition occurs during a multi arm sequence, the system will remain armed to permit the injection of the remaining volume. However, the screen will update to display only the phases that are achievable with the volume that remains. In a single arm sequence, the screen will update when arming occurs to display only the phases that are achievable.

While the system is armed, pressing DISARM or activating any injector head controls will return the system to the idle state.

Injecting

After the system has been armed, press the handswitch to begin the injection. Additional presses of the handswitch will alternately “hold” and resume the injection. The maximum duration for Hold is 20 minutes. If the maximum hold time is exceeded the injection will abort automatically.

If an inject delay has been programmed, pressing the handswitch will activate the countdown timer. The programmed injection will automatically begin when the timer counts down to zero. If the handswitch is pressed during an inject delay, the countdown timer will stop counting until the switch is pressed again, or the Hold time is exceeded.

If a scan delay is programmed*,* the scan delay countdown and the injection will start simultaneously. During the injection, additional presses of the handswitch will alternately “hold” and resume the injection and the scan delay timer.

If KVO is running: KVO will function during Pause, Hold and/or inject delay periods as long as sufficient fluid remains in syringe B to complete the programmed injection. KVO will run post-injection until no fluid remains in syringe B, or until STOP KVO is pressed in the Injection Complete window. To stop KVO the operator can also press any injector head control buttons.

If a Hold phase is entered, parameters for the remaining portion of the injection protocol can be altered.

On the Injecting Screen:

- As each phase is activated, the phase parameters will be highlighted to display injection progress.
- The Duration window will also increment to display elapsed time.
- The Delivered window will increment as the injection proceeds to display volume delivery (including KVO volume, if selected in Setup mode).
- The Volume Remaining display will decrement.
- The Programmed pressure limit and the current pressure will be indicated on the display. If a pressure limit condition occurs, it will indicate on the display.
- If KVO is selected, the time available for KVO will decrement in the KVO

Time Remaining window while KVO is active. (During an injection, KVO will stop and the time display will not count-down.)

On the Injector Head:

- While injecting, indicator lamps on the back of the injector head will be illuminated (white for syringe A, blue for syringe B). The appropriate lamps will be lit solid while injecting, and flash while either Armed or on Hold.
- If multi-arm is selected, the indicator lamps will flash when the system rearms.
- During KVO the blue indicator lamp for syringe B is illuminated.
- AIR EXPELLED Indicator is illuminated.

Disarming

Pressing DISARM, activating any injector head controls, or touching any portion of the touch screen while the system is injecting, will cause the system to disarm.

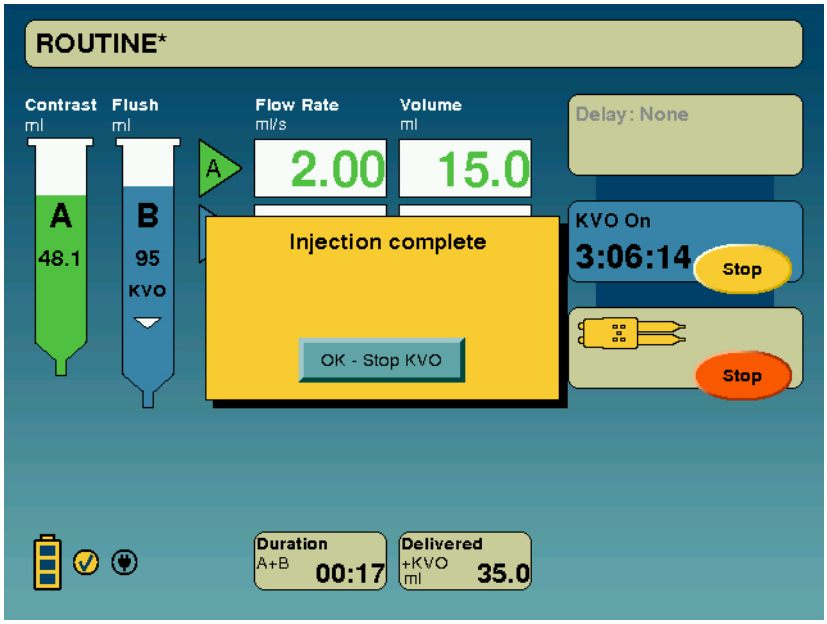
The Hold mode can be entered at any time during an injection by pressing the handswitch. The system will remain in this state until the handswitch is pressed a second time, or the maximum hold time of 20 minutes is exceeded.

Note: A MEDRAD® SSIT 96VLD low pressure connector tube (LPCT) holds approximately 7 ml of fluid. If syringe B is used to flush, use at least 8 ml of flush to deliver this volume to the patient.

Note: If the connector tube is filled with saline, contrast will be delivered to the patient with a delay dependent on the flow rate selected for syringe A.

Note: When the connector tube is filled with contrast, the volume remaining displayed on the screen is approximately 7 ml less than what is present in the system.

When an injection (single or all multi-arm sequences) is completed, the following window, with a brief summary of the injection parameters, will be displayed.

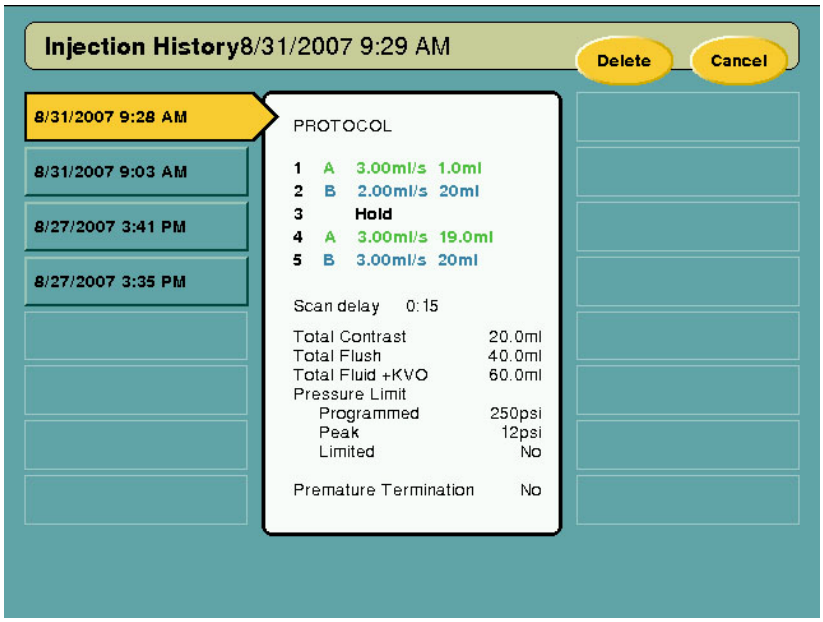


Injection History

To review injection parameters used in a procedure, along with actual achieved values for the injection, press the HISTORY button on the Main screen.

The Injection History screen displays an injection summary block containing the following data:

- Time and Date Started
- Programmed Flow Rate
- Programmed Volume
- Programmed Protocol
- Total Fluid (plus KVO)
- Delay Type
- Delay Duration
- Pressure Limit Programmed
- Peak Pressure
- Pressure Limit Status (YES/NO)
- Premature Termination Status (YES/NO)



The system maintains status information of the 20 most recent injections, sorted by date and time.

To delete any injection protocol history from the system, press DELETE while the protocol is selected. To scroll to the next page of protocols, press the ARROW key. To exit the Injection History screen, press CANCEL.

Clean Up

Note: Do not resterilize or reuse any disposable items.

When cleaning the injector, remove and discard all used disposable items. (Syringes ***should*** be removed without retracting the pistons.) It is not necessary to remove the connector tubing when removing and discarding syringes.

WARNING:
Serious injury may result from syringe failure. Do not retract pistons with connector tubing installed.

- Disconnect the Control Room Unit from line power and remove the battery from the Scan Room Unit before 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.
- Retracting the pistons with the connector tubing installed on syringes will create a vacuum in the syringe due to the check valve in the connector tubing. This vacuum may accelerate the plunger rapidly toward the tip of the syringe when it is removed from the injector causing the syringe to break.

CAUTIONS:
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 Appendix B of this manual or contact Bayer for additional information.

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.

Note: For all body fluid spills, follow institutional decontamination procedures.

Note: 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.

Scan Room Unit

Using a soft non-abrasive cloth, warm water, and a mild disinfectant, carefully clean the assembly, paying particular attention to the following:

- Injector Head
- Syringe Piston Plunger
- Syringe Interface
- SRU Lower Console covers

To clean the injector head, piston, and syringe interface:

1. Fully advance the piston.
2. Remove the battery from the Scan Room Unit.
3. Place the injector head in a vertical position.
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. Re-install the system battery, then fully retract the piston.
7. Remove the battery from the Scan Room Unit again.
8. Clean the inner area of the syringe interface with a soft cloth or paper towel dampened with cleaning solution.
9. Wipe the injector head case and control panel with a soft cloth or paper towel dampened with cleaning solution.
10. Thoroughly dry the injector head case and control panel with a paper towel.

Control Room Unit

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

Appendix A: System Messages

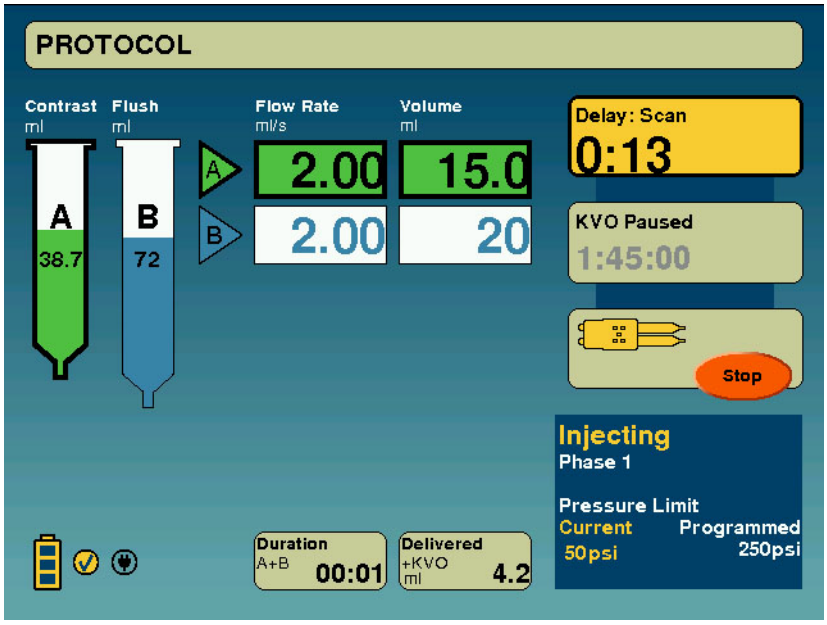
The system will display messages on the screen as conditions or events occur. There are three basic types of messages:

WARNING: Patient injury may result from a system malfunction. If a system malfunction occurs, immediately remove Scan Room Unit power (by pulling the battery from the head stand), and disconnect the system 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 for assistance.

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

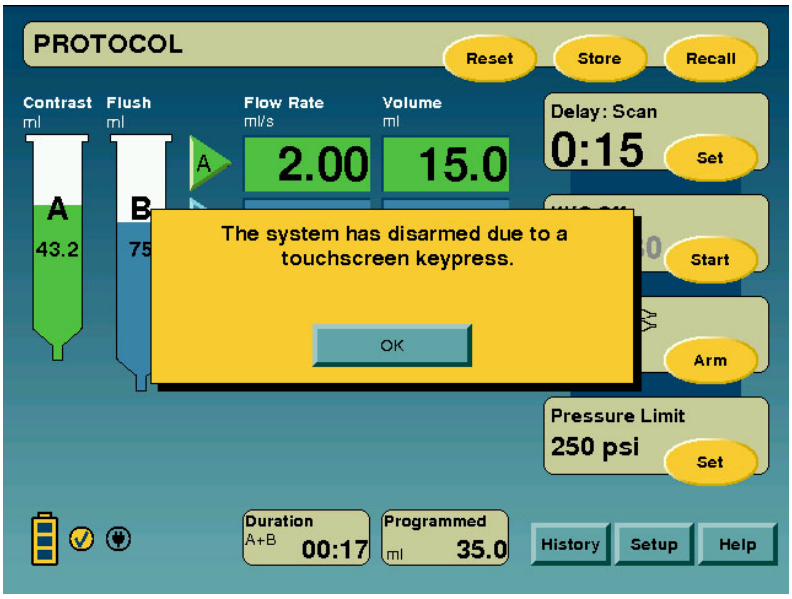
Type 1 Messages

Type 1 messages are messages which provide information regarding the current status of the system, and will clear automatically from the screen. These messages are typically displayed in the lower right corner of the screen.



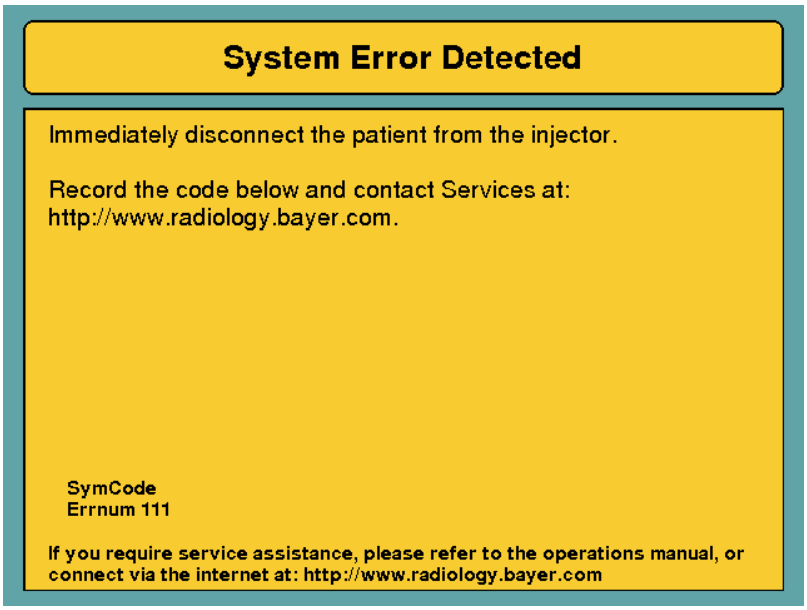
Type 2 Messages

Type 2 messages are messages that convey information that must be explicitly acknowledged before proceeding. The message is displayed within a yellow dialog box - a button (or buttons) must be pressed to acknowledge and remove the message from the screen.



Type 3 Messages

Type 3 messages are system malfunction messages which require power to be removed from the system. Some Type 3 messages provide suggestions to prevent the condition from recurring. If the condition cannot be corrected, record the code and number from the lower left corner of the dialog box, then call Bayer for assistance.



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

Appendix B: Maintenance and Checkout

This section contains recommended procedures for maintenance, and an operational checkout of the MEDRAD® *Spectris Solaris EP MR Injection System.* Routine maintenance and inspection will:

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

Recommended Maintenance Schedule

Your MEDRAD® Spectris Solaris EP MR 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:

Daily:

The piston rod should be thoroughly cleaned after each use. 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.

Monthly:

Once a month, the entire system should be thoroughly inspected and cleaned, and an Operational Checkout should be performed.

Annually:

As part of an annual maintenance program performed by a qualified Services Representative or authorized dealer, 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 dealer authorized by Bayer for complete details.

In the United States, Canada, and Europe, 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 dealer authorized by 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.

Bayer

Bayer will make available upon request:

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

Inspection Procedures

The following procedures are recommended for *daily* inspection of all components in the MEDRAD® Spectris Solaris EP MR Injection System. If any defects are detected, either repair the system, or call Bayer for service. Do not use the system until the problem is corrected.

Scan Room Unit

1. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
2. 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.
3. Inspect for contrast media build-up in the syringe interface area. Follow the cleaning guidelines outlined in this section.
4. Inspect the stand, base, and support arm for cracks and other defects that could weaken the structure.
5. Ensure that all mounting bolts and screws are secure.
6. Ensure that all locking mechanisms on the casters are functional.
7. Inspect the pivot points. The head and support arm must pivot freely. The injector head should rotate on the support arm no more than 330°. The support arm should not rotate on the center post more than 350°.

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

Control Room Unit

1. Inspect *all* cables connected to the unit: Look for cuts, cracks, or worn spots, or other obvious damage. Ensure that all connectors are properly seated.
2. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.

Wall Mount Bracket

1. Inspect all parts of the bracket for cracks and other defects that would weaken the assembly.
2. Ensure that the bracket is securely attached to the wall.
3. Ensure that all cables are secured to the display control unit and do not interfere with the movement of the mounting bracket.

Height Adjustable Pedestal

1. Inspect the stand, base and support arm for cracks and other defects that could weaken the structure.
2. Ensure all mounting bolts and screws are secure.
3. Ensure that the casters roll smoothly with no binding or scraping.
4. Ensure all locking mechanisms on the casters are functional.
5. Verify that the vertical height adjustment of the column shaft moves freely without binding or scraping.

Battery Charger

1. Inspect *all* cables connected to the unit: Look for cuts, cracks, or worn spots, or other obvious damage. Ensure that all connectors are properly seated.
2. Inspect the housing for any damage or cracks that could allow fluid to leak inside, or weaken the structural integrity of the unit.
3. Inspect all parts of the wall mounting bracket for cracks or other defects that would weaken the assembly. If applicable, ensure that the bracket remains firmly attached to the wall.

Communication Link

1. Inspect the cables for cuts, cracks or worn spots. Ensure that the connectors are properly seated.

Cleaning Guidelines

Deposits of contrast media can interfere with proper operation of the MEDRAD® Spectris Solaris EP MR Injection System. The following guidelines should be followed when removing deposits, or cleaning any portion of the system.

WARNING: Serious injury or death may result from exposure to hazardous voltages existing within the system. Disconnect the system from line power before cleaning or attempting to perform any maintenance. Ensure that the system is completely dry before connecting to the power source and applying power.

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

•If contrast medium has leaked inside any component of the system, the affected subassembly should be disassembled and cleaned. This cleaning procedure can be done in the field by trained Services personnel, or returned to Bayer. If the cleaning will be performed in the field, do not disturb any internal wiring or components.

- Care must be taken not to get water or cleaning solutions inside any system components. Do not use strong industrial cleaning agents or solvents such as acetone. Warm water and a mild disinfectant such as antibacterial hand soap are all that is required.

- To clean the syringe interface area of the injector head, fully retract the piston. Using a paper towel moistened with warm water or a mild disinfectant, gently wipe the inner syringe installation area. Do not insert any sharp instruments into this area during the cleaning process.

- Check all System Safety and Warning Labels for legibility. Ensure that the labels are not damaged or missing.

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.

Operational Checkout

A basic functional checkout of the MEDRAD® Spectris Solaris EP MR 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 encompass typical operation of the system. Read the following procedure carefully before beginning the checkout. If problems are detected, contact Bayer.

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

System Labels

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

Power Up

Apply power to the system. Verify that the Safety screen is displayed after system diagnostics occur. Press OK to acknowledge the messages on the Safety screen. Upon power up of the CRU and SRU, verify that the indicators, lamps, and speaker are operational.

Programming

After the Main screen is displayed, verify that the following controls are functioning properly.

At the rear of the Control Room Unit, Press the **Lighten Display Contrast** key until the screen is lightened to its fullest extent. Press the **Darken Display Contrast** Key until the screen is darkened to its fullest extent. Adjust the screen appearance to return to a desirable contrast level.

Fully advance and reverse the pistons by using the ENABLE key and the forward/reverse controls. Verify that both pistons respond to the forward and reverse controls.

Enter the following protocol:

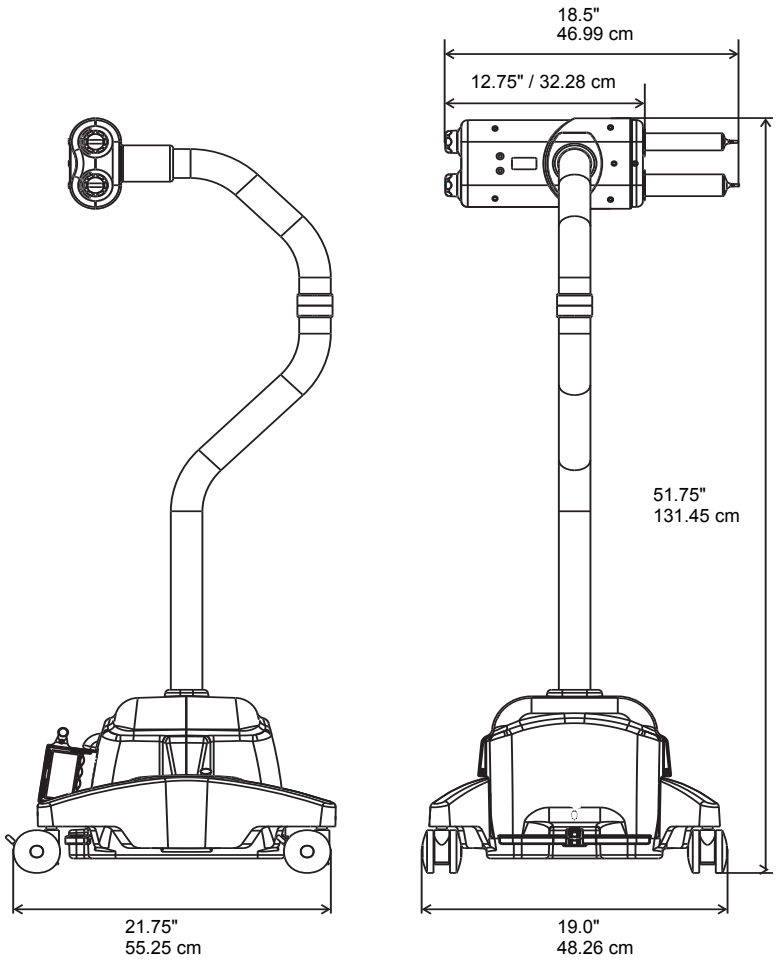
		Flow Rate	Volume
Phase 1:	**Syringe A:**	10 ml/s	20 ml
Phase 2:	**Syringe B:**	2.5	10
Phase 3:		PAUSE	5 seconds
Phase 4:	**Syringe A:**	5.0	10
Phase 5:	**Syringe B:**	0.1	1
		No Delay	
		KVO Off	

1. Arm in single injection mode and inject. In one of the phases, activate the HOLD feature for at least 10 seconds.
2. Verify that the injection completes normally.
3. When the injection is complete, access the Injection History screen and verify volume accuracy; actual volume and programmed volume should be the same (41 ml).
4. Add a 15 second inject delay to the program and activate KVO.
5. Install syringes and fill them with water.

6. Arm in single injection mode and inject.
7. Verify that:
   A. When the handswitch is pressed, the inject delay begins counting down.
   B. The inject delay beeps 5 times when the delay timer elapses and that the injection begins automatically at that time.
8. Verify that when the injection completes, KVO resumes.
9. Remove and discard the syringe.
10. Remove power from the system.

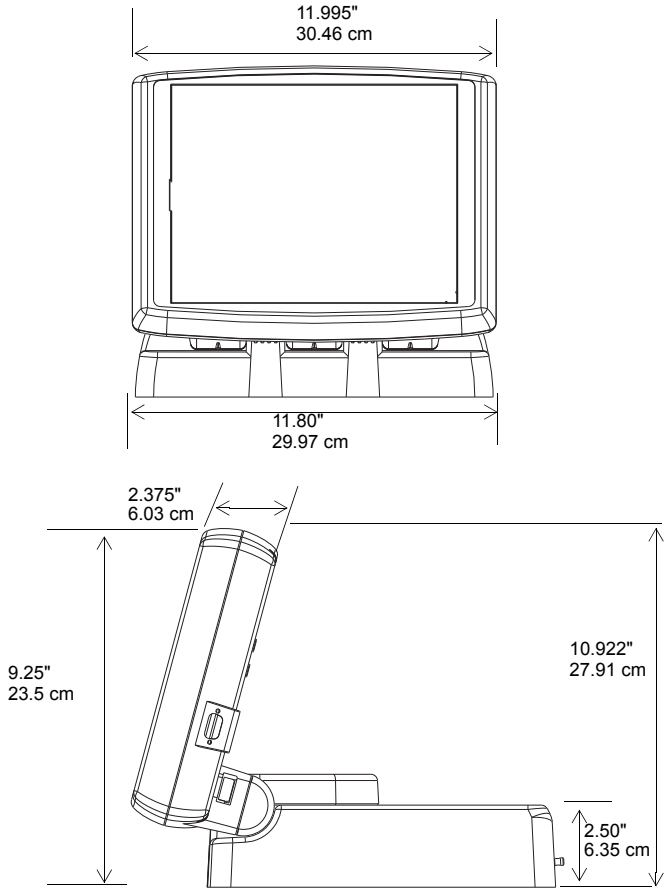
Appendix C: Specifications

Scan Room Unit Weight: 60 lbs. (27.3 kg.)



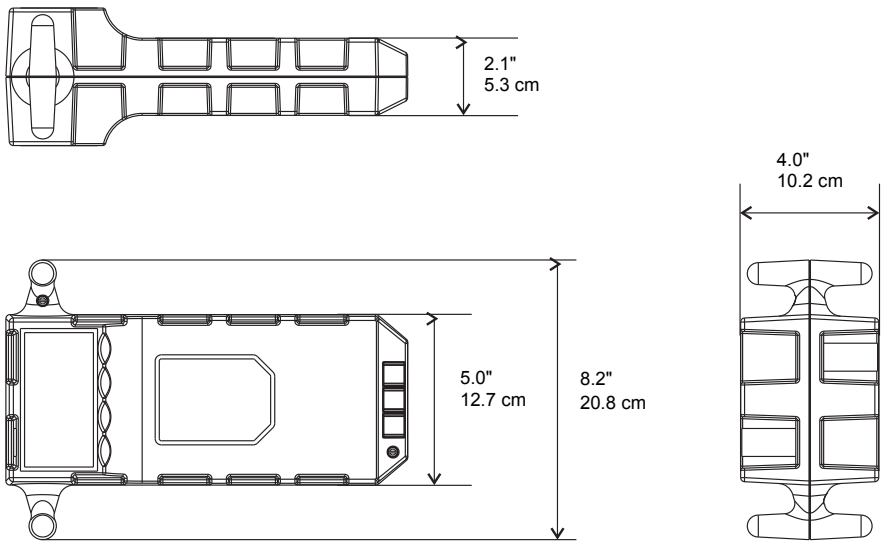
Control Room Unit

Weight: 15 lbs. (6.8 kg.)



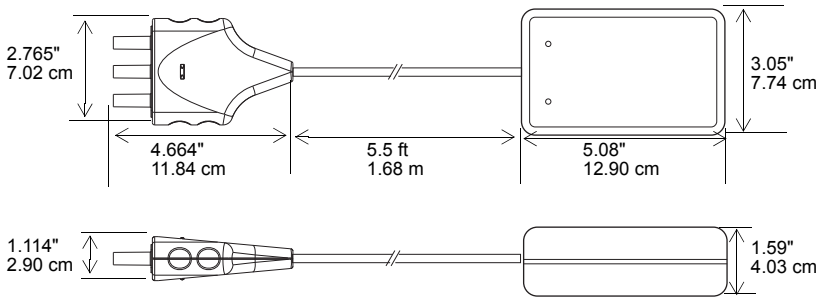
Battery Dimensions

Weight: 7.7 lbs. (3.5 kg.)



Battery Charger

Weight: 2 lbs. (0.9 kg.)



Power Cords

American 12 ft. (3.6 m), Continental 9.8 ft. (3 m)

System Capabilities

SYRINGE A:		Disposable 63 ml
SYRINGE B:		Disposable 115 ml
VOLUME:	Syringe A:	0.5 ml to max. syringe volume in:
		0.1 ml increments between 0.5 and 31 ml
		1 ml increments for 31 ml and above
	Syringe B:	1 ml to max. syringe volume in 1 ml increments
FLOW RATE (Programmable):		0.01 to 10 ml/s in:
		0.01 ml/s increments between .01 and 3.1 ml/s
		0.1 ml/s increments between 3.1 and 10 ml/s
KVO (Programmable):		15 seconds
		20 seconds
	0.25 ml pulsed every:	30 seconds (default)
		45 seconds
		60 seconds
		75 seconds
PRESSURE SAFETY LIMIT:		Factory set below 325 psi (2240 kPa)
PROGRAMMABLE PRESSURE LIMIT (PSI/kPa):		100/690
		150/1035
		200/1380
		250/1725
		300/2070
		325/2240 (default)
DELAY:		1 to 300 seconds in 1 second increments
PAUSE PHASE:		1 to 900 seconds in 1 second increments
INJECTION CAPABILITIES		6 phases per protocol
STORAGE CAPACITY		32 Protocols of up to 6 phases each

Protocol and User Configuration memory is maintained when system power is off.

Executable Flow Rates

These Flow Rates, with pressure safety limit set to 325psi/2240kPa, are achievable with the MEDRAD® Spectris Solaris EP MR Injection System, using the Becton Dickinson catheters listed below and the MEDRAD® SSQK 65/115VS Syringe/Disposables Kit.

	18 g IV Catheter BD pn 381144	20 g IV Catheter BD pn 381134	22 g IV Catheter BD pn 381123	24 g IV Catheter BD pn 381112
Multihance	7.0	5.8	4.0	2.6
Gadovist	7.3	6.0	4.2	2.7
Magnevist	9.0	7.2	5.2	3.2
Optimark	9.7	7.8	5.5	3.7
Prohance, Omniscan	10.0	8.3	5.8	4.0
Saline	10.0	9.1	6.1	4.3

System Performance

Volume Accuracy:	Syringe A:	+/- (1% + 0.1 ml)
	Syringe B:	+/- (5% + 0.1 ml)
Flow Rate Accuracy		+/- (10% + 0.005 ml/s) when rate is 0.01 to 0.99 ml/s +/- (10% + 0.02 ml/s) when rate is 1 to 10 ml/s
Programmed Delay/ Pause Accuracy		+/- (5% + 0.2 second)
KVO Volume Accuracy		+/- 0.05 ml, averaged over 10 consecutive boluses
KVO Flow Rate Accuracy		1 ml/s +/- 0.2 ml/s

Forward and Reverse Controls

Low Speed: 2.5 ml/s (default)

High Speed: 10 ml/s (default)

Low speed is selectable from 1.0 to 10.0 ml/s in 0.5 ml/s increments

High speed is selectable from 1.0 to 10.0 ml/s in 0.5 ml/s increments

EMI/RFI

The MEDRAD® Spectris Solaris EP MR Injection System is designed to be in compliance with IEC 60601-1-2 2nd, 3rd, and 4th Editions. Refer to Appendix F of this Manual.

Electrical Requirements

100-240 VAC
50/60 Hz
Scanner Room Unit (Powered by Integrated Continuous Battery Charger): 100VA
Control Room Unit: 50VA

Fuse

2.5A, 250V, 5X20MM, IEC TYPE F, HIGH

Power Supply DC Output Voltage

Nominal 15.5 VDC

Electrical Leakage

Unit < 100 microamperes
Patient < 10 microamperes

Ground Continuity

The resistance from the earth ground connector at the plug-end of the AC mains power cord to any exposed metal on the Control Room Unit shall be less than 0.2 ohms.

Environmental Specifications

Non-Operating: (Transportation and Storage)

Temperature:	-25° C to 70°C (-13°F to +158°F)
Humidity:	5% to 100% R.H.
Air Pressure:	48kPa to 110 kPa (6.96 psi-16 psi)

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

Temperature:	+10°C to + 40°C (+50°F to +104°F)
Humidity:	20% to 90% R.H., non-condensing
Air Pressure:	69 kPa to 110 kPa

Classifications

Protection Against Electrical Shock: Per EN 60601-1, the MEDRAD® Spectris Solaris EP MR Injection System is designed as Class 1 equipment with Type BF applied parts.

Type BF corresponds to the degree of protection against electrical shock via the applied parts. Class 1 applies to equipment which includes a means for the connection of the equipment to protective earth in such a way that accessible metal parts cannot become live in the event of failure of basic insulation.

Flammable Anesthetics: The MEDRAD® Spectris Solaris EP MR Injection System is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Protection Against Ingress of Fluids: Per EN 60601-1, the Scan Room and Control Room Units have been classified as drip proof equipment. The components of the MEDRAD® Spectris Solaris EP MR Injection System Scan Room and Control Room Units are provided with an enclosure that prevents the entry of such an amount of falling liquid as might interfere with the safe operation of the injector, indicated by the IPX1 designation. The battery charger is not classified for protection against the ingress of fluids.

Mode of Operation: Per EN 60601-1 the mode of operation for the Control Room Unit is continuous operation. It will operate under normal load for an unlimited period, without excessive temperature being developed.

The Integrated Continuous Battery Charger power supply will operate under normal load for an unlimited period, without excessive temperature being developed.

The mode of operation for the Scan Room Unit is continuous operation with intermittent loading. Although power is applied to the Scan Room Unit continuously, intermittent use for loading and injecting will result in an internal temperature less than continuous load operating temperatures, but greater than no-load operating temperatures. Under normal operating conditions with a minimum of 10 minutes between injections, the internal temperature of the Scan Room Unit will not rise enough to degrade system performance or reliability.

Power Cable Specifications

The specifications required by the MEDRAD® Spectris Solaris EP MR 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.

MEDRAD® Spectris Solaris EP MR 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

Appendix D: Options and Accessories

		Catalog Number
Power Cord	American	SPC 300A
	Continental	SPC 300C
Integrated Continuous Battery Charger System		3012080
Battery Charger Kit		3012424
Enhanced Battery Pack		3012070
Handswitch		SSMR START
Contrast Holder		CHD 100 MR
Tray (optional)		CHD 400 MR
Control Room Unit Mounting System		
Height Adjustable Pedestal		SDP 300
Wall Mounting Bracket		SDW 300
Service Manual		SSMR-SERV

Appendix E: System Installation

Note: Contact Bayer for installation information.

WARNINGS:

Serious injury or death may result from exposure to hazardous voltages existing within the system. Use of an unapproved extension cord, adapter, inverter, or multi-outlet strip may compromise electrical safety. Plug the system directly into a properly grounded AC outlet or contact Bayer for installation assistance.

Injury or equipment damage may result from improper placement of the Battery Charger. Do not install the Battery Charger in the Scan Room. Install the Battery Charger in the Control Room, or any convenient location other than the Scan Room.

Serious injury or death can result from placing the Adjustable Height Pedestal in the Scan Room. Do not install or operate the Adjustable Height Pedestal in the Scan Room.

Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/magnet room components

CAUTIONS:

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.

Damage can occur as a result of incorrect voltage. Before plugging in the system, check the following:

- Verify that the voltage and frequency marked on the serial tag on the back of the power supply matches the voltage and frequency of the electrical outlet.
- Verify that the injector has the appropriate power cord plug for the power outlet.

Damage can occur to fiber optic cabling due to mishandling during installation. Install following proper handling procedures or contact Bayer for further assistance.

Unpacking the Injection System

The entire standard configuration of the MEDRAD® Spectris Solaris EP MR Injection System is shipped in one shipping carton. The optional Control Room Unit mounting accessories, the Adjustable Height Stand and the Wall Mounting Bracket, along with the optional IV Pole, are packaged individually and shipped in separate cartons. Prior to beginning installation, verify that the following items are present:

Standard:

- Scan Room Unit
- Control Room Unit and power cord (110V or 220V)
- Fiber Optic Interconnection Cable - 200 ft. (60.96 m)
- Battery Charging Unit and power cord (110V or 220V) - with mounting bracket and all hardware
- System Batteries (2)
- Handswitch - with mounting bracket and all hardware
- Syringe Kit (w/ 65 and 115 ml syringes)
- Operation Manual

Optional*:

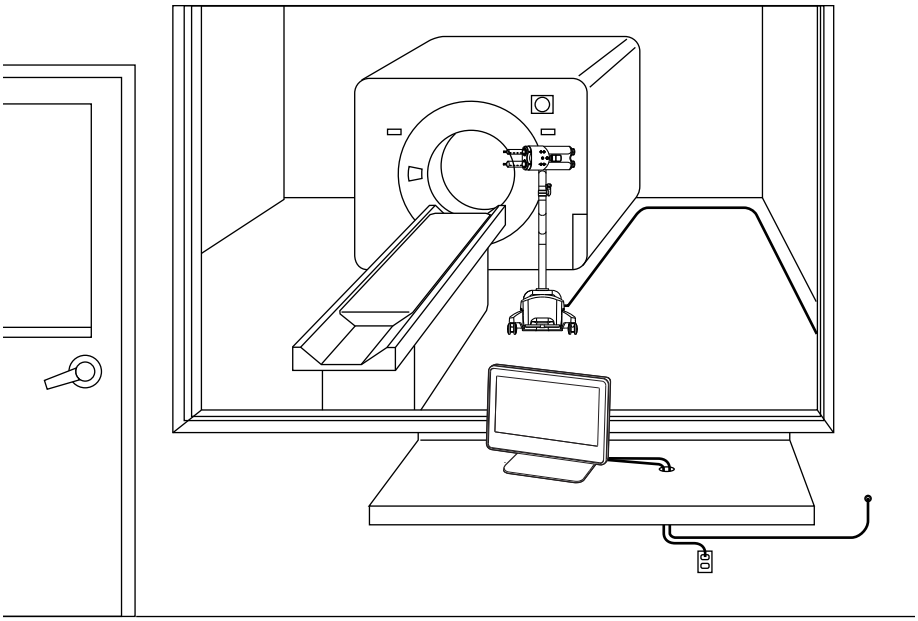
- Additional Battery Charging Unit and power cord (110V or 220V) - with mounting bracket and all hardware
- Additional System Battery
- Additional Handswitch - with mounting bracket and all hardware
- Service Manual

Optional (packaged separately)*:

- Adjustable Height Pedestal for Control Room Unit
- Wall Mounting Bracket for Control Room Unit
- IV Pole for Scan Room Unit Mounting
- Integrated Continuous Battery Charger System

* Refer to "Instructions For Use" sheets for accessory and optional equipment installation.

Installation Considerations



WARNING: Injury or equipment damage may result from use of tools containing ferrous materials. Use only non-magnetic tools to install any scanner/magnet room components.

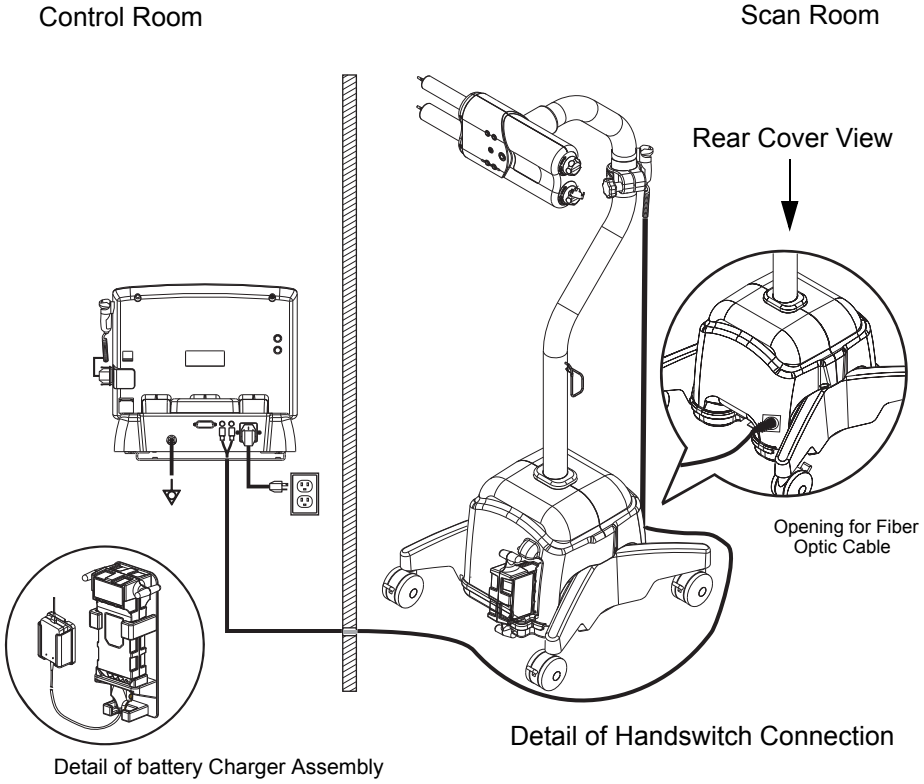
Note: System Installation requires that the suite have a 1.5 inch (3.81 cm) minimum tuned port (either separate or within the penetration panel) available for connections between the Scan and Control rooms.

Note: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Tools Required: Non-magnetic #2 Phillips Head Screwdriver

Review the following general connections prior to installing the MEDRAD® Spectris Solaris EP MR Injection System. Be sure to consider all specifications and requirements outlined in Appendix C of this manual, and follow all applicable regulations of your locality.

Note: When using the MEDRAD® Spectris Solaris EP MR Injector with a Siemens MR Scanner up to 3.0T, it is recommended that the MEDRAD® Spectris Solaris EP be placed a minimum of 18 inches (46 cm) from the facade of the scanner.



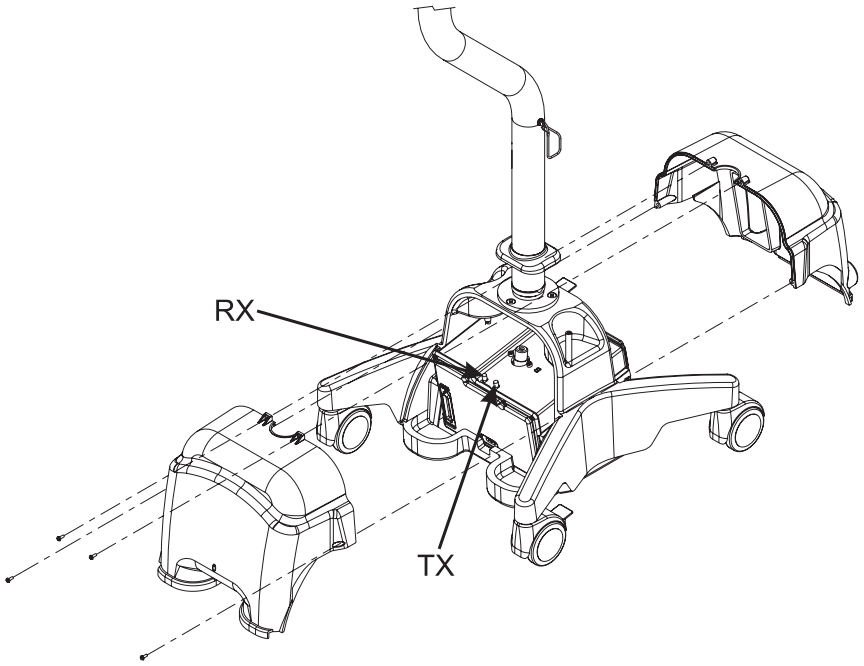
Fiber Optic Cable Installation

Connection at the Scan Room Unit:

Special care should be taken with routing the fiber optic cable to ensure:

- there is no bend radius less than 1 in. (2.54 cm)
- the connector dust caps are not removed until connections are made
- the cable does not run across any sharp edges
- the cable is run across a low traffic area of the floor
- established standards for fiber optic cabling installation should be followed if routing through conduit.

1. Remove the four screws that secure the covers to the lower console of the Scan Room Unit.



2. Install the strain relief 17 inch (43 cm) from the tip of the fiber optic cable.

3. Route the fiber optic cable (the end with the strain relief) through the hole in the lower corner of the rear console cover and snap the strain relief into the hole.

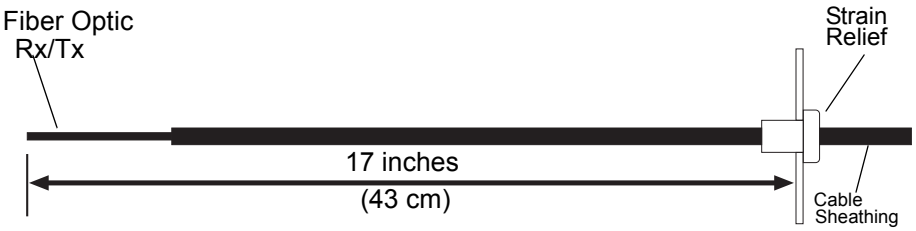
4. Remove the caps from the fiber optic cable connectors, then establish the connections at the lower console - TX to TX, and RX to RX.

5. Carefully re-position the covers on the lower console and secure with the four screws previously removed. Ensure that there are no tight bends in the fiber optic cable.

6. Gather and loop any extra fiber optic cable, then hang the loop from the cable hanger on the Scan Room Unit column.

Strain Relief Location

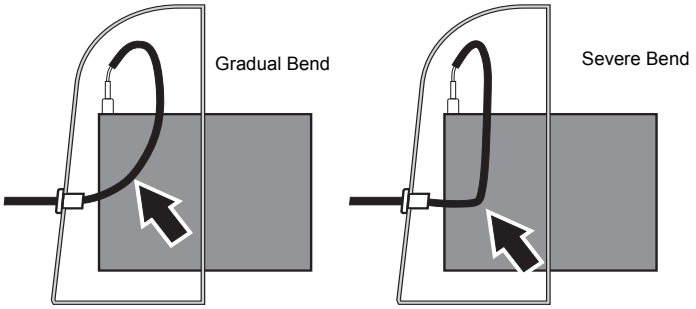
The strain relief should be placed 17" (43 cm) inches form the end of the Fiber optic connectors. This ensures there is sufficient length to maneuver the cable and minimize severe cable bends, which may damage the Fiber Optic cable.



Recommended Routing

The recommended Routing of the FO cable after it enters the SRU rear cover is as follows:

1. Route the cable to the right side of the Electric box
2. Next, route the cable up about 4-6 inches (10-15 cm).
3. Make a gradual bend and connect the FO cable to the Electronic box. (left side of drawing shows a gradual bend, right side of drawing shows a severe bend)



Cable Routing:

Route the fiber optic cable from the Scan Room Unit through the tuned port in the wall between the Scan and Control Rooms. (The tuned port may be part of the penetration panel connecting the two rooms).

Note: Follow all institutional, local, or national safety regulations related to routing cabling on the floor.

Control Room Unit Setup

1. Position the Control Room Unit near an appropriate AC power outlet.
2. Remove the caps from the fiber optic cable connectors, then establish the connections at the rear of the Control Room Unit - TX to TX, and RX to RX.
3. Connect the Handswitch at either the Scan Room Unit, or Control Room Unit Handswitch connection port.

   Note: Refer to the following procedure for Handswitch mounting hardware installation instructions.
4. Attach the power cord to the Control Room Unit power inlet.
5. If required by local codes, connect the optional equal potential cable to the equal potential stud, and the equal potential bus.

6. Plug the AC power cord into an appropriate AC power outlet.
7. Insert a fully charged system battery in the Scan Room Unit battery receptacle
8. Apply system power at the Control Room Unit power switch, then perform an system operation checkout as outlined in Appendix B of this manual.

Handswitch Mounting

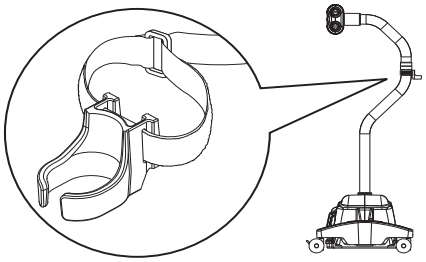
To allow convenience in use, the handswitch mount can be mounted in one of the following ways:

On the wall:

Attach the mount to the bracket using the two screws supplied. Apply the supplied double sided adhesive tape to the back of the solid side (without holes) of the mounting bracket. Affix the mount/bracket assembly to a properly primed wall to ensure maximum adhesion.

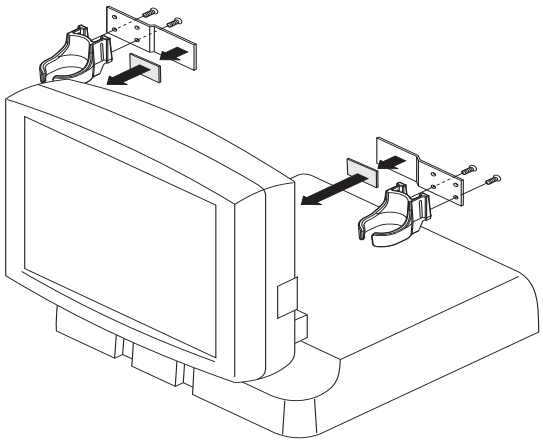
On the Scan Room Unit:

Route the supplied strap through the recesses in the back of the mount. Secure the mount and strap to the upright column of the Scan Room Unit.



On either side of the Control Room Unit:

Determine which side of the unit the mount and bracket will be attached to. Secure the mount to the bracket using the two screws supplied. Apply the supplied double sided adhesive tape to the front of the solid side (without holes) of the mounting bracket. Affix the mount/bracket assembly to the backof the Control Room Unit display.



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

The MEDRAD® Spectris Solaris EP MR 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.

Bayer reserves the right to modify the specifications and features described herein or to discontinue any product or service identified in this publication at any time without prior notice or obligation. Please contact your authorized representative from Bayer for the most current information.

All patient data that appear in this document are fictitious. No actual patient information is shown.

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To provide feedback or request support, please use the contact form provided on radiology.bayer.com/contact

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