Operation & Installation Manual

MEDRAD® Stellant Imaging System Interface (ISI)
800 Module

MEDRAD® Stellant
CT Injection System

MEDRAD® Stellant FLEX
CT Injection System

MEDRAD® Stellant Imaging System Interface (ISI) 800 Module

Operation and Installation Manual

Operating specifications, options, accessories, and feature availability may vary by country. Check with local product representative and country-specific operating instructions.

The MEDRAD® Stellant Imaging System Interface (ISI) 800 Module has an expected service life* of 7 years from the date of product installation when operated according to the instructions provided with this device. These 7 years include suggested or mandatory actions of preventative maintenance and repair activities, as well as required calibration(s) that are needed. Required reading includes the instructions for use and other materials provided with the device. This also includes any hardware and software updates that may be required.

* Expected Service Life: The length of time that an individual unit, lot, or batch of devices is expected to remain functional after it is placed into use.

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

A glossary of the symbols used on the MEDRAD® Stellant Imaging System Interface (ISI) 800 Module can be found in Section 1 of this manual.

1 - Introduction

This manual contains important information about use of the MEDRAD® Stellant Imaging System Interface (ISI) 800 Module (Catalog Number: ISI 800).

Read all the information contained in this manual. Understanding this information will assist the user in safely operating the System.

Installation

Contact Bayer for Installation information.

Important Safety Notice

The ISI 800 Module is an option that allows an injector from Bayer to interface with a CT scanner. It obtains its power from a hospital grade wall outlet. It interacts with an injector and scanner through direct cable connection. Once the ISI 800 Module is installed and configured on the injector, it allows the scanner and injector to interact with each other and provide functionality as outlined in this manual. The ISI 800 Module supports the Class 1 standard of the CAN Open for add-on Medical Devices.

Indications For Use

The ISI 800 Module option is indicated for the specific purpose of allowing an injector to interface with a CT scanner.

Certifications

This device is equipped to operate at 100-120 / 200-240 VAC, 50/60 Hz, 40 VA, and is designed to comply with IEC 60601-1 (2nd and 3rd Edition Amendment 1)and IEC 60601-1-2 (2nd, 3rd, and 4th Edition) standards, including national differences. Special precautions regarding Electro-magnetic Compatibility (EMC) are required for installation and use of this injection system. Detailed EMC information can be found in Appendix A of this manual.

Contraindications

None.

Restricted Sale

Federal (USA) law restricts these devices for sale except by or on the order of a physician.

Disclaimers

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

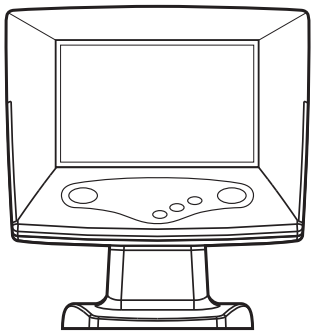
Anyone who connects additional equipment to the device or configures a medical system is responsible that the system complies with the relevant requirements of IEC 60601-1. Any accessory or equipment connected to the device must be certified to either IEC 60601-1 (Operator or Patient Environment Use)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

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

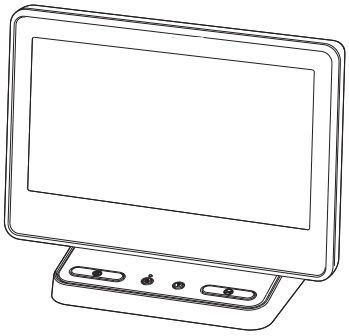
Monitors

In some countries, the MEDRAD® Stellant CT Injection system may be purchased with a choice of two monitors, shown below - "Display and Control Unit (DCU)" and "Certegra® Workstation." The Certegra Workstation comes in two models, shown below as Model 1 and Model 2. The Certegra Workstation hardware buttons differ slightly between Models but the screen/monitor information remains the same.

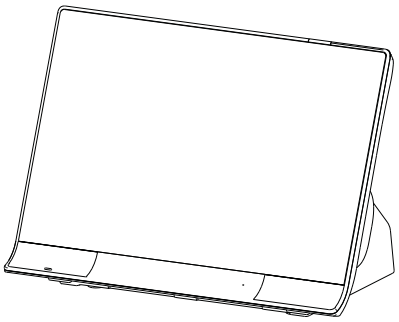
Throughout the manual, "Display and Control Unit (DCU)" and "Certegra Workstation" will be used to refer to the two when there are differences in how information is presented on the screens.



Display and Control Unit (DCU)



Certegra® Workstation (Model 1)



Certegra® Workstation (Model 2)

Symbols

The following symbols are used on the ISI 800 Module and its components:

Icon	Meaning
CE 2797	Indicates that this device conforms to the requirements of the European Medical Device Directive 93/42/EEC.
	Attention: Refer to warnings and cautions on Instructions for Use packaged in each carton. (ISO 15223-1, 5.4.4)
	Warning: Indicates hazardous voltages. (ISO 7010, W012)
	Indicates alternating current. (IEC 60417, 5032)
	Indicates scanner connection.
	Identifies a terminal suitable for direct current. (IEC TR 60878, 5031)
	Indicates injector connection.
	Identifies the Equipotential connection. (IEC TR 60878, 5021)
TX	Identifies the CAN Interface TRANSMIT LED.
RX	Identifies the CAN Interface RECEIVE LED.

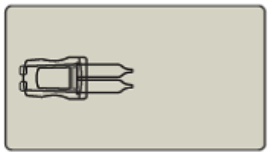
LK	Identifies the Ethernet LINK LED.
AT	Identifies the Ethernet ACTIVITY LED.
CLASS 1	Indicates the ISI 800 Module is Class 1 medical equipment as defined by IEC 60601-1 standards.
IPX 1	IPX1 Code that specifies the degree of protection provided by the enclosure against vertically falling water drops (IEC 60529)
	Identifies the Protective Earth Ground point. (IEC TR 60878, 5019)
	Indicates separate collection for Electrical and Electronic Equipment per Directive 2002/96/EC. Refer to the following website for additional information: www.weee.bayer.com
I **0**	Symbols on the Power Switch: (IEC TR 60878: 5007, 5008) I - On O - Off
	Authorized representative in the European community. (ISO 15223-1, 5.1.2)
	Manufacturer. (ISO 15223-1, 5.1.1)
	Date of Manufacture. (ISO 15223-1, 5.1.3)
	Catalog Number. (ISO 15223-1, 5.1.6)
	Serial Number. (ISO 15223-1, 5.1.7)
PN	Part Number.
	This side up. (ISO 7000, 0623)
	Keep dry. (ISO 15223-1, 5.3.4)
	Fragile, handle with care (ISO 15223-1, 5.3.1)

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).

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

Consult instructions for use (ISO 15223-1, 5.4.3)

The following icons may appear on the injector screen:

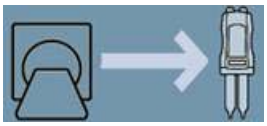
Icon	Meaning
	Communication between the injector and the scanner has been established via the ISI 800 Module, which means it is communicating with both the scanner and the injector.
	The ISI 800 Module is communicating with the injector.
	The ISI 800 Module is not communicating with the injector.
	This icon indicates the injector and scanner are functioning independently. This icon is also used when the injector is operating without an ISI 800 Module. The Display and Control Unit (DCU) icon is shown. On the Certegra® Workstation, the icon is the same but is vertical.

The configurations below are determined by the scanner manufacturer. Refer to the scanner manufacturer instructions for further information. The following description applies to the four icons below.

1. If the injector and/or scanner icon is gray, as shown below, it is not ready.
2. If the injector icon is yellow but not flashing, it is ready but is waiting for the scanner to be ready.
3. If the scanner icon is yellow but not flashing, it is ready but is waiting for the injector to be ready.
4. If the injector icon is yellow and flashing, an injection can be initiated whether or not the scanner is ready.
5. If the injector and scanner icons are yellow and flashing, the procedure (injection plus scan) can be initiated by pressing the start button specified below.

When no arrow is shown between the injector and the scanner, a test injection is programmed -- a test injection can be started only from the injector. When the injector icon is highlighted in yellow and blinking, the injector is ready and the test injection can proceed. After the test injection is completed, one of the three arrows, as shown below, will appear.

The procedure (injection plus scan) can only be initiated by pressing the start button on the injector.



The procedure (injection plus scan) can only be initiated by pressing the start button on the scanner.

The procedure (injection plus scan) can be initiated by pressing the start button on EITHER the scanner or the injector.

The following icons may appear on the Display and Control Unit (DCU) only.

Icon	Meaning
	When the icon is yellow, as shown, the injector is working in conjunction with the scanner – it is "coupled". This symbol will only appear on the screen when the system is in Control or Tracking modes.
	When the icon is gray, as shown, the protocol has not been locked. When the icon is highlighted in yellow, the protocol has been locked.

Labels on ISI 800 Module 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 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 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 the user to recover from an error or point to related information within the manual.

Warnings

Improper installation of the ISI 800 Module may cause it to fail. Installation must be completed by properly trained personnel. Contact your scanner manufacturer for configuration and installation assistance.

Patient injury could result from using improper accessories. Use only accessories and options provided by Bayer and designed for the ISI 800 Module.

Patient injury could result from a system malfunction. If a system malfunction occurs, immediately remove injector power by pressing the power switch and disconnect the injector from the patient. If a fault message is displayed that cannot be corrected, and/or the system is not operating correctly, do not use the injection system. Call Bayer or your local dealer for assistance.

Explosion hazard: Patient injury could result from using the injection system in the presence of flammables (such as anesthetics). Do not use the system when flammables are present.

Fire hazard: Patient injury could result from using incorrect fuses. To avoid an electrical fire, ensure the correct type of fuse is used for replacement. The fuse must be replaced with Type T, 250 V, 2 A fuse by qualified personnel only.

Shock hazard: Patient injury could result from worn cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, do not disassemble the ISI 800 Module in any way. Worn cabling also creates hazards. If any worn or damaged cables are detected, do not use the ISI Module. Contact Bayer or your local dealer for service or replacement.

Only use the power cord supplied with the system. Do not plug the power cord into an extension cord or multi-outlet power strip. The power cord should be connected to an appropriate grounded hospital grade AC receptacle. Confirm system grounding in relationship to the CT Suite Grounding diagram.

Patient or operator injury may result if damaged components are used. Do not use damaged components. Visually inspect all components before use.

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

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

Cautions

Damage can occur as a result of incorrect voltage. Verify that the voltage and frequency marked on the serial tag on the back of the unit matches the voltage and frequency of the electrical outlet.

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

Do not expose system components to excessive amounts of water or cleaning solutions. Disconnect power before cleaning. 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 are required to clean the ISI 800 Module. Do not use strong industrial cleaning solvents such as acetone.

Damage can occur to the system if it is subjected to excessive shock. Do not subject the system to excessive shock.

Equipment damage may result or system may fail to operate. The system is meant to connect the following CT injection systems with a CT scanner and should not be used with other medical devices or medical device technologies. Catalog Numbers:
SCT 110, SCT 111, SCT 112, SCT 120, SCT 121, SCT 122, SCT 210, SCT 211, SCT 212, SCT 220, SCT 221, SCT 222, SCT-310, SCT-321, SCT-322, FLEX, and FLEX UPG.

Notes

NOTE: Bayer can only be responsible for proper injector and scanner interaction if they are configured exactly as specified. The injector and scanner will operate as described in this section only if the ISI 800 Module is installed according to this manual and the scanner is capable of accepting these signals via the interface.

NOTE: The scanner **CANNOT** override any injector operation that is considered safety critical; for example, check for air, hold during an injection or stopping an injection.

System Overview

The ISI 800 Module acts as a communication interface between the MEDRAD® Stellant CT Injection System and the imaging system. When the ISI 800 Module is installed, the injector can function either independently or linked to the imaging system. When "coupled" with all operational conditions met, the imaging system can request an injection to start, and alternately, the injector can request the initiation of a procedure.

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

NOTE: The scanner **CANNOT** override any injector operation that is considered safety critical; for example, check for air, hold during an injection or stopping an injection.

CiA 425 Standard.

The ISI 800 Module communication interface is based upon Controller Area Network, or CAN, which is a standard from the CAN in Automation (CiA) standards body. The specific definition of Injector / Scanner Interfacing is described in:

- CiA 425 Part 1 - Application Profile for Medical Diagnostic Add-On Modules, Part 1: General Definitions. CiA 425 Part 1 specification defines a number of physical aspects of the interface as well as the functionality provided by each device class.
- CiA 425 Part 2 - Application Profile for Medical Diagnostic Add-On

Modules. CiA 425 Part 2 specification defines a standard way for an injector to behave.

Classes

The CiA 425 specification defines how a scanner controls an injector. In this definition they specify 6 "classes" or levels of control. Each higher number offers more features and includes all features of the previous classes. The actual class for a pairing is derived from the class of the least capable component in a pair.

- Class 0 - scanner can monitor the "state" of the injector
- Class 1 - triggering interface (each device can request the initiation of the other)
- Class 2 - injector can provide injection summary data to the scanner
- Class 3 - scanner can read injection protocol configuration from injector
- Class 4 - scanner can write injection protocol to injector
- Class 5 - scanner can control flow rate of injection in real time

The ISI 800 Module currently conforms to Class 1.

Injector Modes

There are 3 available ISI Modes; which are determined by the scanner:

- Monitor Mode - The scanner can monitor but not influence the injector.
- Tracking Mode - The injector cannot start an injection when the scanner is not ready.
- Control Mode - Either the Scanner or the Injector can request the initiation of a procedure.

Lockouts

The scanner can lockout the following injector operations:

- Arm Lockout - the injector will not allow local arming (at the injector).
- Start Lockout - the injector will not allow local starting.
- Resume Lockout - the injector will not allow local resume if the injector is in a hold condition.
- Protocol Configuration - the injector protocol configuration cannot be changed. (Protocol Config Lockout does not affect the ability to use the setup screen).

NOTE: This last bullet applies only to the Display and Control Unit (DCU).

2 - Operation

Overview of Operation

With the ISI 800 Module installed, the injection system can function independently or coupled to the scanner. Depending upon what mode of operation the scanner is in, this link can allow the scanner to automatically request the initiation of an injection, or permit the injector to automatically request the initiation of a scanning procedure.

NOTE: The scanner **CANNOT** override any injector operation that is considered safety critical; for example, check for air, hold during an injection or stopping an injection.

NOTE: The scanner manufacturer and/or user must make the final determination of the mode of operation for the coupled injector and scanner. The scanner manufacturer is responsible for providing operation instructions for their system.

The ISI 800 Module gives the scanner the ability to lockout the following injector local operations:

- Arm - the injector can not be armed at the injector
- Start - the injector can not be started by the injector's controls
- Resume - the injector will not resume the injection if Hold button is pressed during the injection.
- Protocol Configuration - the injector protocol configuration cannot be changed. (Protocol Config Lockout does not affect the ability to use the Setup screen).

NOTE: This last bullet applies only to the Display and Control Unit (DCU).

Injector Head Indicator Lights

For the Certegra® Workstation, some behaviors of the injector head arm indicator lights (the blue and green indicator lights around the manual fluid movement knobs) have been modified.

In independent and monitored operation, where the injector cannot request the scanner to start, the arm lights on the injector head flash once per second when the injector is armed.

In coupled operation with the scanner where the injector may request the scanner to start (the injector will be labeled as described in the symbols section), the arm lights flash approximately twice per second with a "short flash, long flash" pattern.

Details of Operation (Monitor Mode)

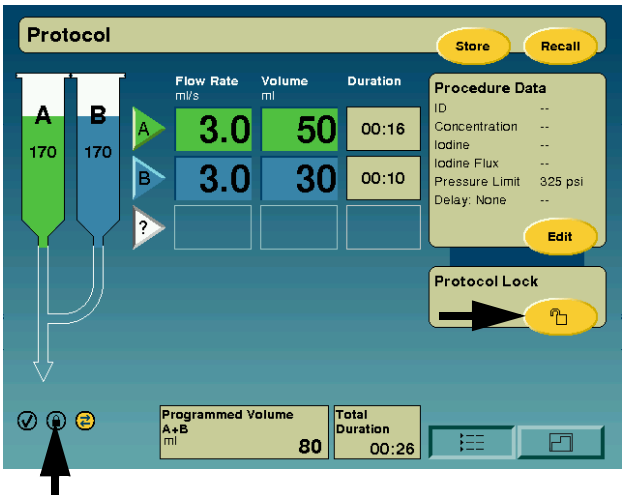
The following instructions apply when the system is in Monitor Mode.

NOTE: When in Monitor Mode, the injector operates independently. Communication must be established between the injector and the scanner in order for monitoring to take place. The scanner icon will not show when the system is in Monitor Mode.

NOTE: The Display and Control Unit (DCU) screenshots used in this section show a mixture of Protocol and Profile views.

1. Program the scanner.
2. Program the injection protocol into the injector. Once the protocol has been programmed, press the Protocol Lock button.

Display and Control Unit (DCU)



Protocol Lock Status Icon (Shown Unlocked)

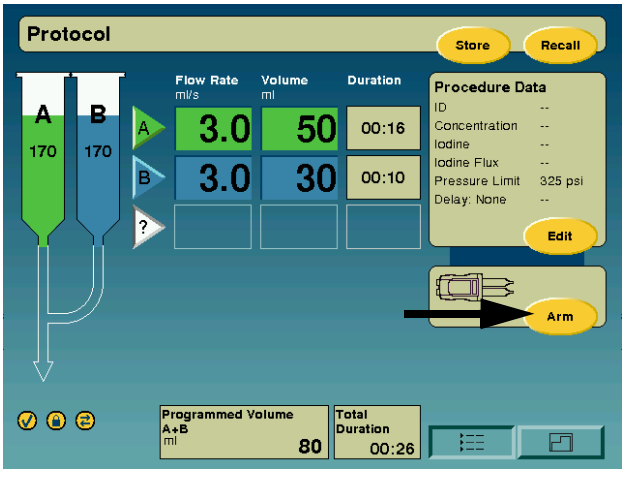
Certegra Workstation

NOTE: The Protocol Lock button **MUST** be pressed before the injector can be armed.

NOTE: Once the Protocol Lock button has been pressed, the Protocol Lock icon in the lower left corner of the screen will be highlighted in yellow.

3. Check the fluid pathway for air. Once any air has been purged, press the Check For Air button on the injector head.
4. Press the Arm button to arm the injector.

Display and Control Unit (DCU)



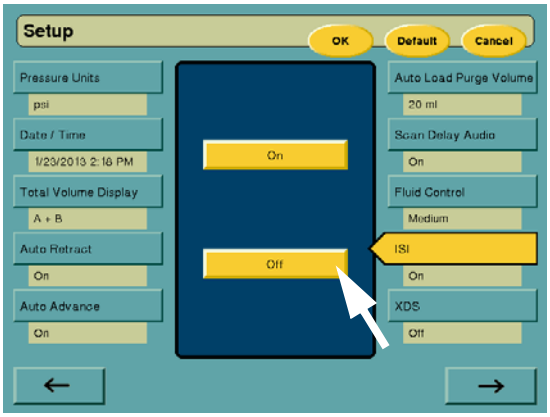
Certegra Workstation

Monitor Mode - Injector Not Ready

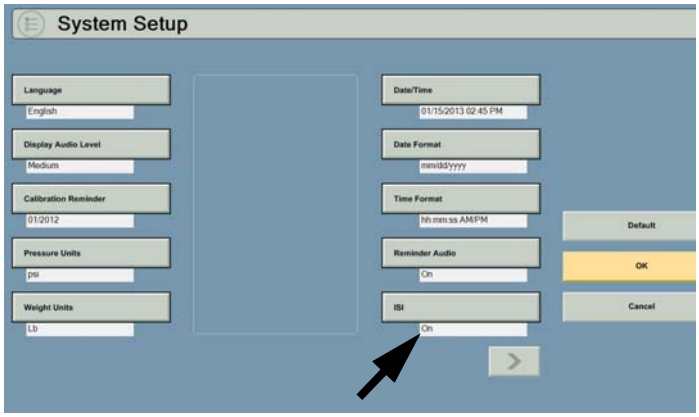
NOTE: For specific information about programming, arming and injecting, refer to the MEDRAD® Stellant CT Injection System Operation Manual.

NOTE: If the injector is configured to use the ISI 800 Module and fails to "Arm" or "Disarms", check the ISI Communication icon located at the bottom left of the Monitor. If the icon is not highlighted with a yellow background or indicates a communication problem with the module, the ISI can be disabled so that the injector can be used stand-alone. To do this go to the ISI Setup screen in System set-up Menu and select ISI Off.

Display and Control Unit (DCU)



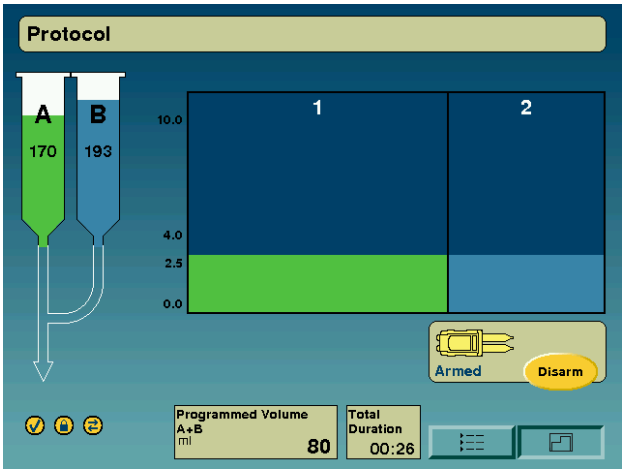
Certegra Workstation



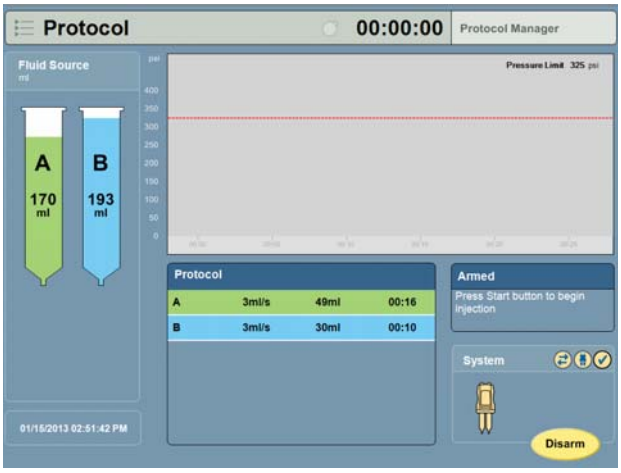
System Set-up Menu - ISI Set-up Screen

5. Wait until the Injector icon is flashing and highlighted in yellow before proceeding.

Display and Control Unit (DCU)



Certegra Workstation



Monitor Mode - Injector Ready

6. Execute the procedure.

NOTE: The injection will continue normally unless the communication link between the scanner and the injector fails.

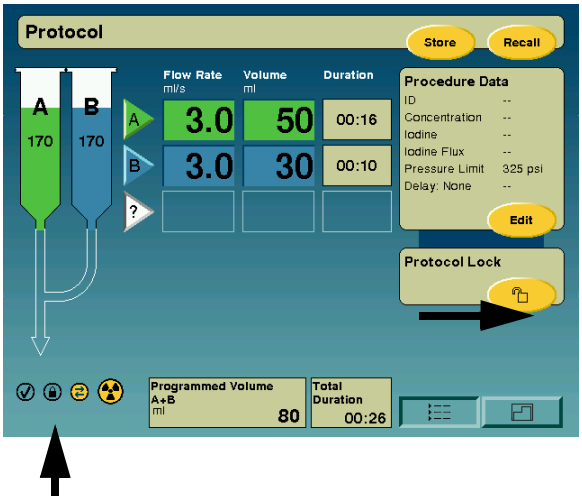
Details of Operation (Tracking and Control Modes)

The following operating instructions apply when the system is in either Tracking Mode (shown by an arrow pointing towards the scanner) or Control Mode (shown on the Monitor by a bi-directional arrow).

NOTE: The Display and Control Unit (DCU) screenshots used in this section show a mixture of Protocol and Profile views and Tracking and Control modes.

1. Program the scanner.
2. Program the injection protocol into the injector. Once the protocol has been programmed, press the Protocol Lock button.

Display and Control Unit (DCU)



Protocol Lock Status Icon (Shown Unlocked)

Certegra Workstation

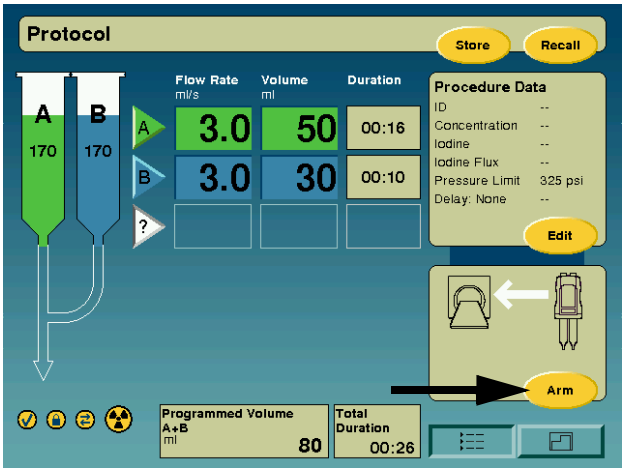
NOTE: The Protocol Lock button **MUST** be pressed before the injector can be armed.

NOTE: Once the Protocol Lock button has been pressed, the Protocol Lock icon in the lower left corner of the screen will be highlighted in Yellow.

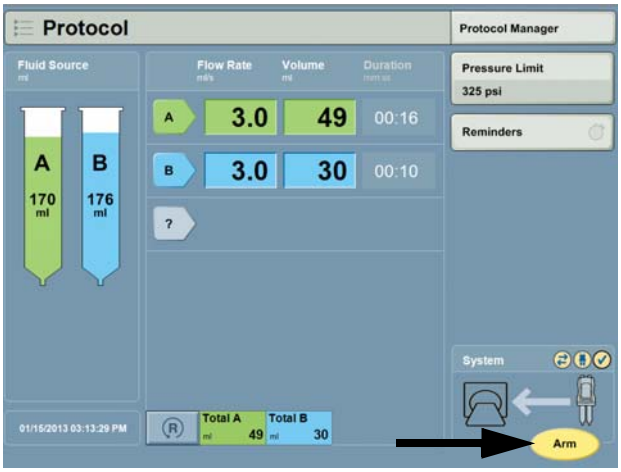
3. Check the fluid pathway for air. Once any air has been purged, press the Check For Air button on the injector head.

4. Press the Arm button to arm the injector.

Display and Control Unit (DCU)



Certegra Workstation

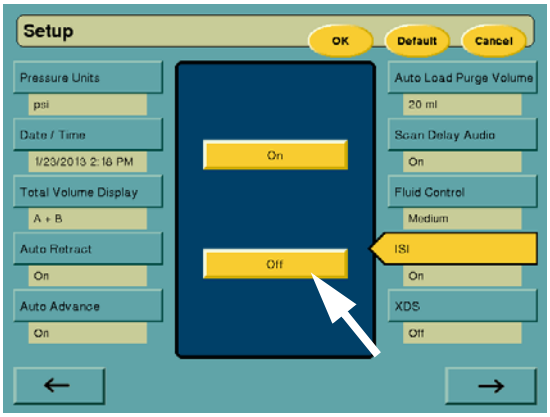


Tracking Mode - Scanner and Injector Not ready

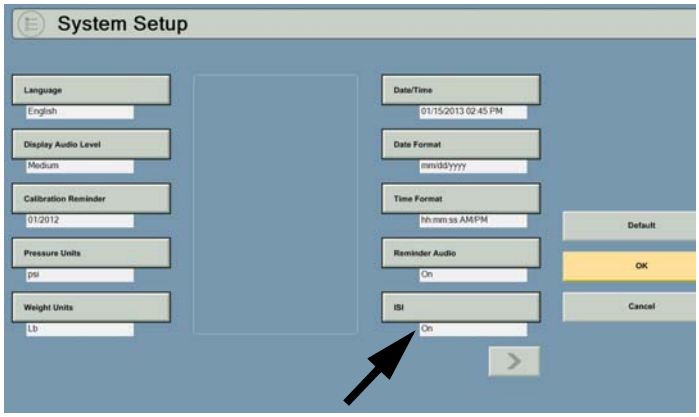
NOTE: For specific information about programming, arming and injecting, refer to the MEDRAD® Stellant CT Injection System Operation Manual.

NOTE: If the injector is configured to use the ISI 800 Module and fails to "Arm" or "Disarms", check the ISI Communication icon located at the bottom left of the Monitor. If the icon is not highlighted with a yellow background or indicates a communication problem with the module, the ISI can be disabled so that the injector can be used stand-alone. To do this go to the ISI Setup screen in System set-up Menu and select ISI Off.

Display and Control Unit (DCU)



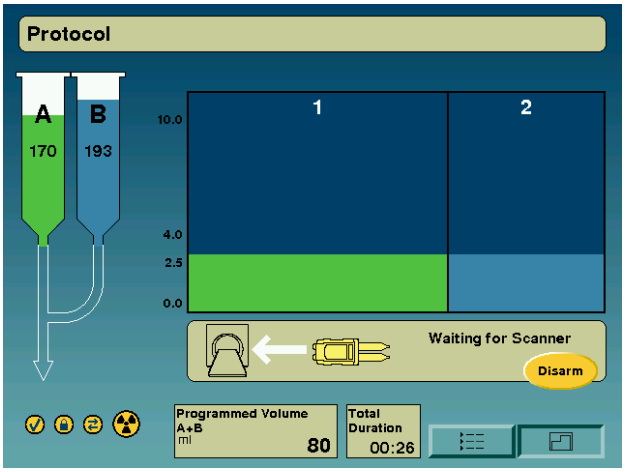
Certegra Workstation



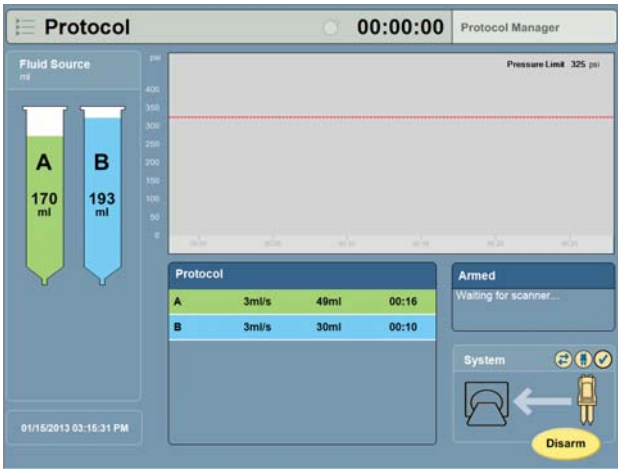
System Set-up Menu - ISI Set-up Screen

5. Wait until both the Injector and Scanner icons are flashing and highlighted in yellow before proceeding.

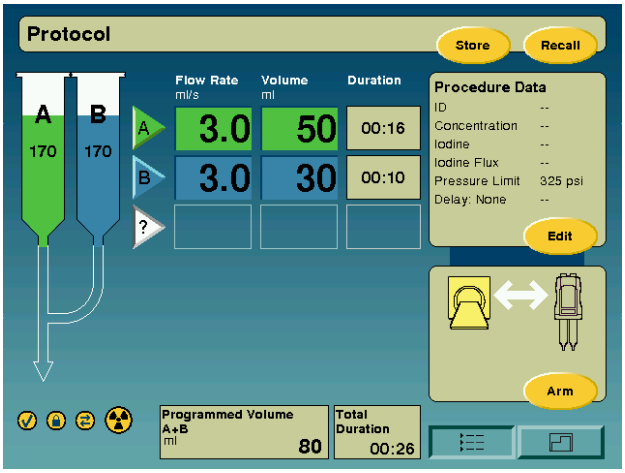
Display and Control Unit (DCU)



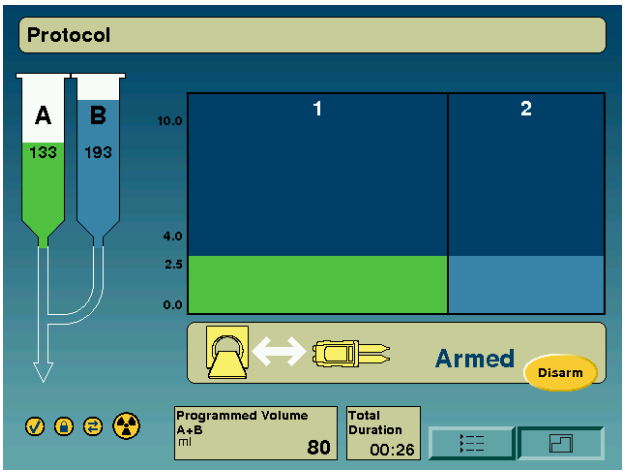
Certegra Workstation

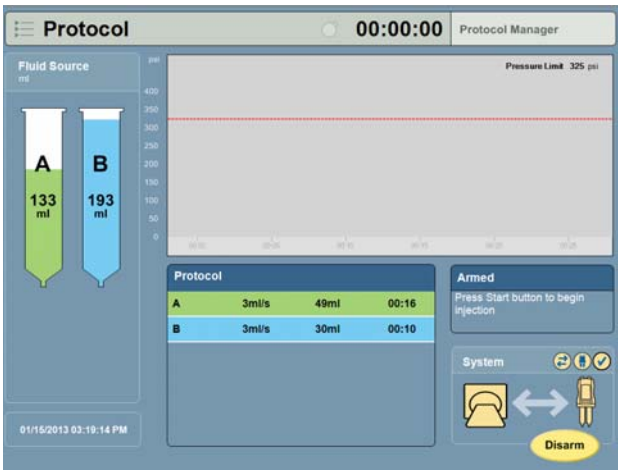


Tracking Mode - Injector Ready - Scanner Not Ready



Control Mode - Scanner Ready - Injector Not Ready





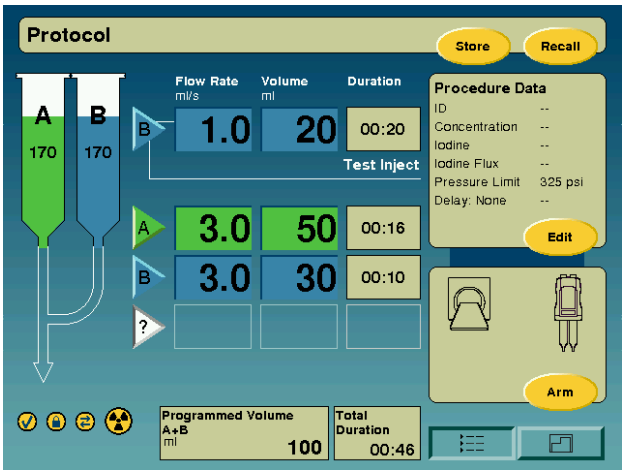
Control Mode - Injector and Scanner Ready

6. Execute the procedure by pressing the start switch on either the scanner or injector (as determined by the scanner's configuration of the injector).
   - When in Control Mode: Press start switch on either the scanner or the injector (unless local start is locked out by the scanner) to request the initiation of the scan/inject sequence.
   - When in Tracking Mode: Press the start switch on the injector to request the initiation of the scan/inject sequence.

Test Inject

7. When using the ISI 800 Module test inject is not part of the actual diagnostic injection procedure, therefore Scanner Ready is not required to initiate a test inject. This is considered an injector local operation similar to priming and is denoted in Control and Tracking Modes by the lack of an arrow between the Scanner Icon and the Injector Icon. The injector does not notify the scanner that it is armed until after the test inject is complete; however, the injector does show locally that it is armed.

Display and Control Unit (DCU)



Certegra Workstation

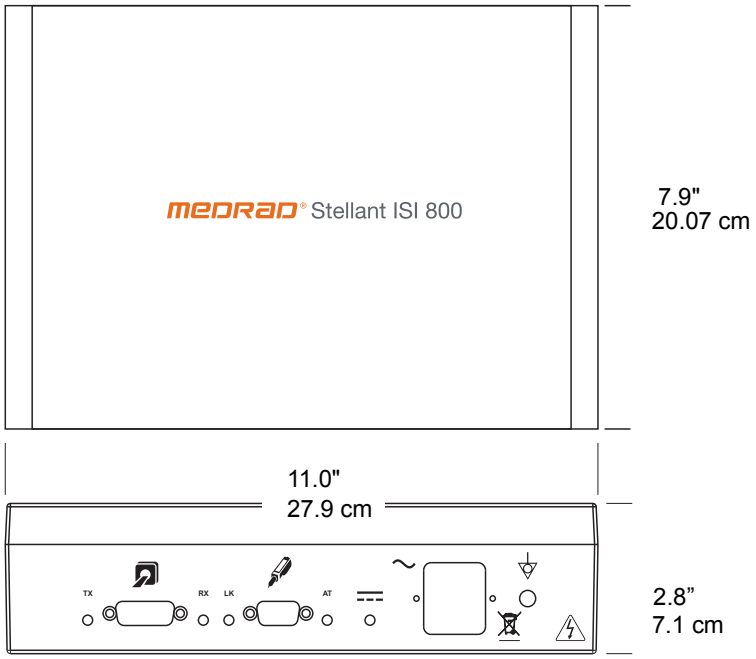
Control Mode - Test Injection

NOTE: The arrow will appear between the Scanner and Injector icons after the test injection is complete.

3 - Specifications

ISI 800 Enclosure Dimensions

Weight: 4.5 lbs. (2.04 kg)



Power Cords

The specifications required by the MEDRAD® Stellant Imaging System Interface (ISI) 800 Module 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.

Environmental Specifications

Non-Operating: (Transportation and Storage)

Temperature: -25^{o} C to 70^{o} C (-13^{o} F to +158^{o} F)

Humidity: 5% to 100% R.H., condensing

Air Pressure: 48 kPa to 110 kPa

Operating

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

Temperature: +10^{o} C to + 40^{o} C (+50^{o} F to +104^{o} F)

Humidity: 20% to 90% R.H.

Air Pressure: 69 kPa to 110 kPa

Protection Against Electrical Shock

The ISI 800 Module is designed per IEC 60601-1.

EMI/RFI

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

Electrical Leakage

Complies with UL, CSA and IEC requirements for safe Electrical Leakage Current limits for Medical Equipment:

Earth Leakage Current:	< 300 microamps (NC)
Chassis (Touch) Leakage Current:	< 100 microamps (NC)

Ground Continuity

< 0.2 ohms from power cord ground pin to enclosure.

Protection Against the Ingress of Fluids

Per IEC 60529, the ISI 800 Module has been classified as drip proof. This is indicated by the IPX1 designation on the ISI 800 Module.

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 or contact Bayer for performing appropriate electrical safety and operational checks prior to use.

Mode of Operation

Per IEC 60601-1 the mode of operation for the ISI 800 Module is continuous. It is capable of operation under normal load for an unlimited period, without excessive temperature being developed.

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

The MEDRAD® Stellant Imaging System Interface (ISI) 800 Module 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 injection 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.

<table>
<tr><th>Immunity test</th><th>IEC 60601 Test Compliance Level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3Vrms from 150kHz to 80 MHz at 80% AM 1kHz
6Vrm, 80% AM 1kHz at ISM frequencies listed below:

<table><tr><th>Frequency (MHz-ISM List)</th><th>Test Level (Vrms)</th></tr><tr><td>1.8 - 2.0</td><td>6</td></tr><tr><td>3.5 - 4.0</td><td>6</td></tr><tr><td>5.3 - 5.4</td><td>6</td></tr><tr><td>6.765 - 6.795</td><td>6</td></tr><tr><td>7.0 - 7.3</td><td>6</td></tr><tr><td>10.1- 10.15</td><td>6</td></tr><tr><td>13.553 - 13.567</td><td>6</td></tr><tr><td>14.0 - 14.2</td><td>6</td></tr><tr><td>18.07 - 18.17</td><td>6</td></tr><tr><td>21.0 - 21.4</td><td>6</td></tr><tr><td>24.89 - 24.99</td><td>6</td></tr><tr><td>26.957 - 27.283</td><td>6</td></tr><tr><td>28.0 - 29.7</td><td>6</td></tr><tr><td>40.66 - 40.70</td><td>6</td></tr><tr><td>50.0 - 54.0</td><td>6</td></tr></table></td><td>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 injection 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
$d = 1.17\sqrt{p}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3Vrms from 80 MHz to 2.7 GHz at 80% AM 1kHz
and specific ISM bands listed below:

<table><tr><th>Frequency (MHz)</th><th>Modulation Type</th><th>Modulation Frequency</th><th>Field Strength (Volts/meter)</th></tr><tr><td>385</td><td>Pulse</td><td>18 Hz</td><td>27</td></tr><tr><td>450</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>710</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>745</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>780</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>810</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>870</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>930</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>1720</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>1845</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>1970</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>2450</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>5240</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>5500</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>5785</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr></table></td><td>$d = 1.17\sqrt{p}$ 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)</td></tr>
</table>

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 Bayer representative for the most current information.

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

86417308 Rev. E February 27, 2019

Bayer 拜耳 バイエル بایر Байер

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

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