Operation Manual

MEDRAD® Stellant FLEX
CT Injection System

MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation

Operation Manual

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation 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 FLEX CT Injection System with Certegra® Workstation can be found in Section 2 of this manual.

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1 Introduction

This manual applies to the MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation (Stellant FLEX with Certegra Workstation), also referred to as the system throughout this document, Catalog Numbers: FLEX. Read all the information contained in this manual. Understanding this information will assist users in operating the Stellant FLEX with Certegra Workstation in a safe manner.

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

1.1 Certifications

This device is equipped to operate at 100-240 VAC, 50/60 Hz, 300 VA and is designed to comply with IEC 60601-1 (3rd Edition Amendment 1) and IEC 60601-1-2 (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 18 - Addendum – Compliance to IEC 60601-1-2: 3rd and 4th Editions.

1.2 Intended Patient Population

This device is intended for use on the general patient population. Patient physiology and institutional guidelines should be considered when selecting catheter sizes and injection protocol parameters.

1.3 Indications For Use

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation, including Stellant FLEX CT Syringe Kits and Connector Tubing, is indicated for the specific purpose of injecting intravenous imaging agents, including saline, into humans for diagnostic studies in computed tomography (CT) and mammography. For complete prescribing information, refer both to the current drug labeling and to the device labeling for information relating to “imaging agent”.

1.4 Contraindications

None known.

1.5 Restricted Sales

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

1.6 Required Training

The device is intended to be used by trained personnel with experience in diagnostic imaging studies.

1.7 Training Information

This manual is intended as an extension of the user interface of the Stellant FLEX with Certegra Workstation to provide procedural and technical information. Additional Stellant FLEX with Certegra Workstation training information will be available in the following formats:

- On-site initial installation and additional training as requested
- Stellant FLEX Quick Use Guide
- Instructions for use (IFU)

Please contact Bayer or your local Bayer representative if any of these resources are needed. Refer to your imaging equipment labeling for specific instructions on scanner use. Handle and use contrast media and saline per the manufacturers’ instructions.

1.8 Disclaimers

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

Anyone who connects additional equipment to the device or configures a medical system is responsible that the system complies with the relevant requirements of IEC 60601-1. 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.

1.9 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.

1.10 Installation

Contact Bayer for installation information.

1.11 WEEE

Refer to the following website for additional information. www.weee.bayer.com

1.12 REACH Compliance

REACH compliance information can be found at www.REACH.bayer.com

2 Symbols

2.1 General Symbols

⚠ **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 minor or moderate injury to the patient or operator. Read and understand the cautions before operating the injection system.
NOTICE:	Indicates that the information is a notice. Notices advise you of circumstances that could result in damage to the device. Read and understand the notices 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 reference to related information within the manual.
	To signify a general warning. (General warning sign, ISO 7010, W001)
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. (Caution, ISO 15223-1, 5.4.4)
	To identify equipment, for example, the welding power source, that has risk of electric shock. (Caution, risk of electrical shock, IEC 60417-1, 6042)
	To prohibit pushing against an object. (No pushing, IEC 60601-1, Table D2, Safety Sign 5)
	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment. (MR Unsafe, IEC 62570, 7.3.3)
	To signify that the instruction manual/booklet must be read. (Refer to instruction manual/booklet, IEC 60601-1, Table D2, Safety Sign 10)
	Indicates the need for the user to consult the instructions for use. (Consult instructions for use or consult electronic instructions for use, ISO 15223-1, 5.4.3)
	Indicates the medical device manufacturer (Manufacturer, ISO 15223-1, 5.1.1))
	Indicates the authorized representative in the European Community/ European Union (Authorized representative in the European Community / European Union, ISO 15223-1, 5.1.2)

Indicates the entity importing the medical device into the locale.
(Importer, ISO 15223- 1:2020(E), 5.1.8)

Indicates the entity distributing the medical device into the locale.
(Distributor, ISO 15223- 1:2020(E), 5.1.9)

To identify the country of manufacture of products.
(Country of manufacture, ISO 15223- 1:2020(E), 5.1.11)

CE 2797

Means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, and other applicable Union harmonization legislation providing for its affixing (for Class II medical devices).
(CE Mark, EU Directive 2017-745, Annex V)

To identify UL Certification to IEC 60601-1 (3rd edition).
(UL Certification, IEC 60601-1, 3rd Edition)

Indicates the manufacturer's serial number so that a specific medical device can be identified.
(Serial number, ISO 15223-1, 5.1.7)

Indicates Bayer-specific part number.
(Part number)

Indicates the manufacturer's catalog number so that the medical device can be identified.
(Catalog number, ISO 15223-1, 5.1.6)

Indicates a carrier that contains Unique Device Identifier information.
(Unique Device Identification, ISO 15223- 1:2020(E), 5.7.10)

Indicates the item is a medical device.
(Medical device, ISO 15223- 1:2020(E), 5.7.7)

Indicates the date when the medical device was manufactured.
(Date of manufacture, ISO 15223-1, 5.1.3)

To indicate that stacking possibilities are limited because of the nature of the transport package.
(Maximum stacking load, ISO 7000, 0630)

Indicates the temperature limits to which the medical device can be safely exposed.
(Temperature limit, ISO 15223-1, 5.3.7)

Indicates the range of humidity to which the medical device can be safely exposed. (Humidity limitation, ISO 15223-1, 5.3.8)

Indicates the range of atmospheric pressure to which the medical device can be safely exposed. (Atmospheric pressure limitation, ISO 15223-1, 5.3.9)

To indicate correct upright position of the transport package.
(This way up, ISO 7000, 0623)

Indicates a medical device that needs to be protected from moisture.
(Keep dry, ISO 15223-1, 5.3.4)

Indicates a medical device that can be broken or damaged if not handled carefully.
(Fragile, handle with care, ISO 15223-1, 5.3.1)

To indicate mass. To identify a function related to mass.
(Net weight, ISO 7000, 1321B)

Maximum weight of the injection system and accessories during normal use.
(Net weight, ISO 7000, 1321B)
(Consult instructions for use or consult electronic instructions for use, ISO 15223-1, 5.4.3)

To identify a type BF applied part complying with IEC 60601-1.
(Type BF Applied Part, IEC 60601-1, Table D1, Symbol 20)

To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge.
(Electrostatic sensitive device, IEC TR 60878, 5134)

CLASS 1

To indicate the system is "Class 1" medical equipment as defined by IEC 60601-1 standards.
(Class 1, IEC 60601-1)

To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
(Class II equipment, IEC 60417-1, 5172)

IPX1

Protection against vertically falling water drops.
(Degree of protection, IEC 60601-1, Table D3, Ref. No. 6.3)

Separate collection for waste of electrical and electronic equipment.
(Collect separately, Directive 2012/19/EU [WEEE]).

Indicates 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 symbol). This product should be recycled immediately after its environmental protection use period has expired.
(Environmental protection use period)

To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
(Alternating current, IEC 60601-1, Table D1, Symbol 1)

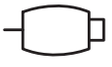
To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
(Direct current, IEC 60601-1, Table D1, Symbol 4)

To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.
(Stand-by, IEC TR 60878, 5009)

To identify the computer network itself or to indicate the connecting terminals of the computer network.
(Computer network, IEC 60417-1, 5988)

To identify connecting means (e.g. plug or cord) to the power source (mains) or to identify the storage place for the connecting means.
(Power Plug, IEC TR 60878, 5534)

To identify the control to transfer the displayed image to a second screen.
(Image transferred to second screen, IEC 60417-1, 5892)



To identify controls or connection points associated with hand-held switches.
(Handswitch, IEC TR 60878, 5322)

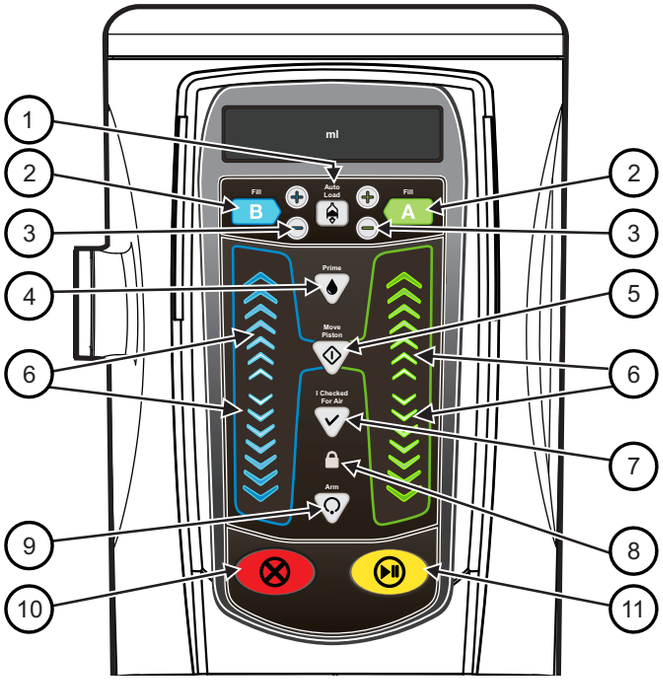
To identify an input terminal when it is necessary to distinguish between inputs and outputs.
(Input, IEC TR 60878, 5034)

To identify an output terminal when it is necessary to distinguish between inputs and outputs.
(Output, IEC TR 60878, 5035)

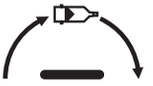
To indicate that the assistance of a servicing engineer should be obtained before further operation of the machine is attempted.
(Call for maintenance, IEC TR 60878, 0717)

2.2 Injection System Buttons and Icons

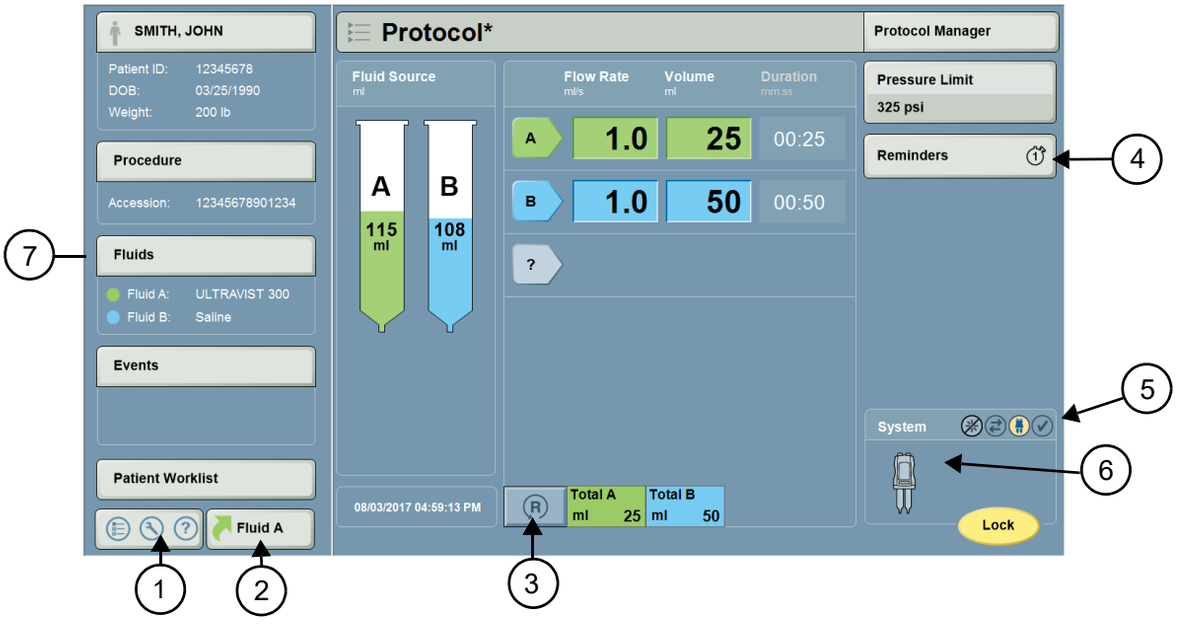
2.2.1 Injector Head Icons



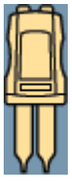
#	Button/Icon	Description	#	Button/Icon	Description
1		Activates the Fill buttons.	2		Fill buttons: ◆ Syringe A (green) ◆ Syringe B (blue)
3		Adjusts volume to the desired amount in small increments/ decrements.	4		Prime button
5		Activates the forward and reverse piston controls. Illuminates when pressed.	6		Forward and reverse piston controls
7		I Checked for Air confirmation button. Illuminates after the operator has confirmed inspection of the fluid path for air.	8		Indicates the protocol is locked. Illuminates after the protocol has been locked.
9		Arms the injector. Illuminates after the injector has been armed.	10		Terminates the injection and disarms the system.

#	Button/Icon	Description	#	Button/Icon	Description
11		Initiates the injection. Holds the injection for a maximum of 20 minutes.			Manual knob indicators (not shown): ◆ Syringe A (green) ◆ Syringe B (blue)
		Identifies heat maintainer connection on underside of injector head (not shown).			Identifies handswitch connection on underside of injector head (not shown).

2.2.2 Display Buttons and Icons



#	Button/Icon	Description	#	Button/Icon	Description
1		Accesses the system settings.	2		Displays most recent Fluid A values entered. Press **OK** to select again or cancel to choose new values.
3		Resets the protocol to the factory default values.	4		Displays the remaining number of set Reminders.
4		Displays that no Reminders are set.	5		Indicates status of communication with injector head.
5		If ISI is available, indicates status of communication with ISI.	5		I Checked for Air confirmation icon. Displays prior to the operator confirming inspection of the fluid path for air.

#	Button/Icon	Description	#	Button/Icon	Description
5		I Checked for Air confirmation icon. Illuminates yellow after the operator has confirmed inspection of the fluid path for air.	5		If XDS is available, indicates the status of the XDS accessory.
6		The Injector icon identifies various states of the injector: ◆ Illuminates yellow and flashes when the system is armed. ◆ Illuminates solid yellow when the system is injecting. ◆ Not illuminated when system is idle.	7	Informatics Panel and Modality Worklist	Indicates that the Informatics Panel and Modality Worklist accessories are enabled. Refer to the Certegra® Applications and Workstation Accessories operation manual for more information.

2.2.3 Base Unit Icons

Identifies the Equipotential connection. (IEC TR 60417, 5021)

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

2.2.4 Overhead IV Track System

The Overhead IV Track System is only intended for hanging IV fluids. Do not hang more than 50lbs/23kg of weight on the hooks.

3 Warnings, Precautions, and Notices

3.1 Warnings

⚠ WARNINGS

Air Embolism Hazard - Serious patient injury or death may result.

- Use only disposables or accessories supplied by Bayer. Refer to 16.6 - Sterile Disposables.
- Use catheters and connectors with pressure ratings compatible with this system. Refer to 17.7.2 - Maximum Flow Rate Performance and 17.7.3 - Programmable Pressure System Performance.

Environmental Contamination Hazard - Serious patient or worker injury or death may result.

- Visually inspect all components before use.
- Do not use damaged components.

Electric Shock Hazard - Serious patient and/or worker injury or death may result.

- The system should be opened and serviced by qualified service personnel only.
- Only use the power cord supplied with the system.
- Equipment must only be connected to a supply mains with protective earth.

Fire hazard - Serious patient and/or worker injury or death may result.

- Use the correct fuse type replaced by Bayer or personnel trained by Bayer.

Applicable Restrictions - Serious patient injury or death may result.

- Do not use this system to deliver any fluid other than intravenous contrast media and common flushing solutions.
- This device is not intended for drug infusions, chemotherapy, or any other use for which the device is not indicated.
- Handle and use contrast media and saline per the manufacturers' instructions.

Hazard

- Do not service or perform maintenance on the injection system while in use with a patient.

Reuse of single-use fluid sources may result in biological contamination.

- Refer to the fluid source manufacturers' Instructions for Use.

Mechanical Hazard – Serious patient injury could result from leaks or ruptures during an injection.

- Use only disposables supplied by Bayer. Refer to 16.6 - Sterile Disposables.
- Use only syringes and connector tubing with a pressure rating greater than the maximum programmable pressure limit of the injection system, which is 325 psi (2241 kPa).
- Use catheters with pressure ratings compatible with this system. Refer to 17.7.2 - Maximum Flow Rate Performance and 17.7.3 - Programmable Pressure System Performance.

⚠ WARNINGS

Hot surface

- Do not touch.

Hazard

- Do not lean against the injection system when installed on any type of mounted configuration.

3.2 Cautions

⚠ CAUTIONS

Mechanical Hazard - Minor or moderate patient and/or worker injury may result.

- Only use the system as defined in this manual. Follow the system communication if a system fault is communicated or in the event of a system malfunction. Follow the fault message.
- Do not use the system in the presence of flammable (such as anesthetics) or combustible gases or other agents.

Electric Shock Hazard - Minor or moderate patient and/or worker injury may result.

- Only plug the system into a direct mains access point. Do not plug the system power cord into an extension cord or multi-outlet power strip.

Procedure Delay Hazard - Serious patient and/or worker injury or death may result.

- Turn off any equipment that could generate a high level electrostatic discharge.

Hazard

- Do not connect or disconnect an accessory to the system while in use with the patient.

3.3 Notices

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Allow the system to stabilize at room temperature before use due to condensation that may cause electrical damage.

Mechanical Hazard - Equipment damage may result.

- Do not touch the display screen with a sharp object in order to perform the calibration.
- Component damage may occur if not installed properly. Ensure all connections are secure; do not overtighten. This will help minimize leaks, disconnection, and component damage.
- Do not strike syringes to remove air. Striking the syringes may cause component damage.

4 System Overview

This section describes:

4.1 System Diagram

The system is comprised of the injector head, a workstation, and base unit. The three components are connected by a communications link.

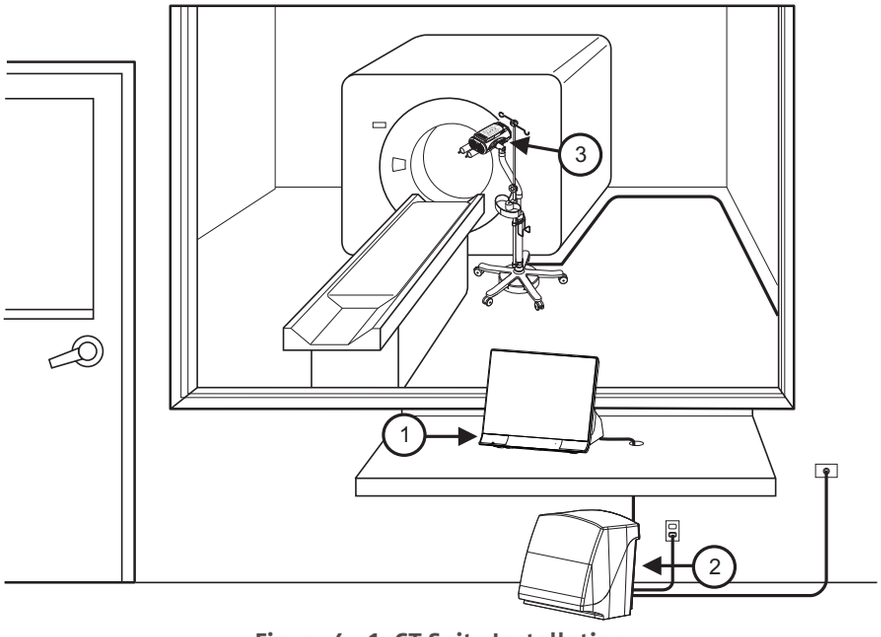


Figure 4 - 1: CT Suite Installation

1	Workstation	2	Base Unit	3	Injector Head

NOTE: The workstation is not for use in the scan room.

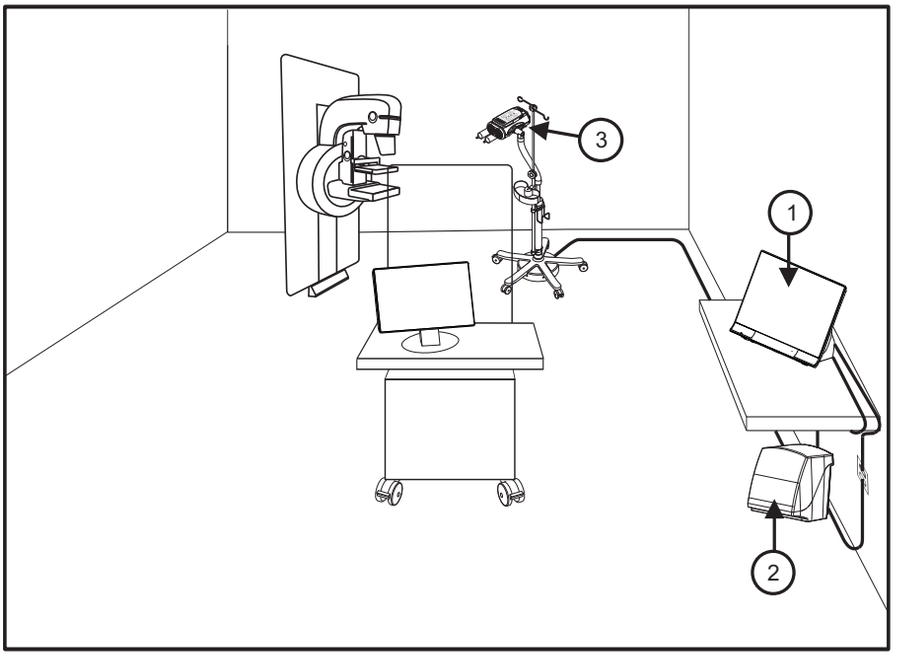


Figure 4 - 2: Mammography Suite Installation

1	Workstation	2	Base Unit	3	Injector Head

⚠ CAUTION

Electric Shock Hazard - Minor to moderate patient injury may result.

- Maintain a 4.9 ft (1.5 m) safe distance between the patient and non-patient devices.
- Install the Workstation (non-patient device) a minimum of 4.9 ft (1.5 m) from the injector head.

4.1.1 Moving the System Within the Room

When moving the system, hold the pedestal below the point indicated by the label on the pedestal arm. If the pedestal does not contain this label, hold the pedestal no higher than 36 inches above the floor.

4.2 Contrast Imaging Agent Use in Contrast Enhanced Mammography

Contrast-enhanced mammography (CEM) is the combination of dual energy X-ray mammography with intravenous administration of an iodinated contrast agent. Stellant FLEX with Certegra Workstation may be used for CEM studies on the prescription of and under the supervision of appropriately licensed healthcare professionals.

CEM is commonly performed using low-osmolar iodinated contrast media (LOCM). A variety of intravenous injection protocols are used with different LOCM volumes, flow rates, and scan delays. Example protocols described in Zanardo 2019[1] have utilized different available non-ionic LOCM concentrations in dose ranges between 1-2 mL/kg. Injector flow rates between 1.5 - 5 mL/s and iodine concentrations of 300 mg I/mL or higher were used. Of the studies that included a specification of the contrast injection modality, automated power injectors were used in 85% of the studies (90% of the patients). Of the total patient population from the study, 62% of the patients received a saline flush. The scan delay between completed injection and start of the imaging sequence ranged from 0.5 to 5 minutes, most commonly 2 minutes.

Stellant FLEX with Certegra Workstation may be used to deliver an iodinated X-ray contrast agent within its approved dose range and route of administration. In addition to the example protocols from Zanardo 20191 and other literature or

guidelines, the injector can deliver protocols prescribed by the licensed healthcare professional if those are within the injector specifications.

Stellant FLEX with Certegra Workstation is intended only for use with approved contrast agents. For complete prescribing information, refer to current drug labeling.

4.2.1 References

1. Zanardo, M, et al. (2019) Technique, protocols and adverse reactions for contrast-enhanced spectral mammography (CESM): a systematic review. Insights into Imaging 10:76.

4.3 Fluid Delivery Basics

The system is a programmable power injector that enables the operator to generate a defined fluid delivery protocol and execute a fluid injection.

4.3.1 Protocol

A protocol defines how the fluid injection procedure will proceed and is comprised of three elements: phases, a pressure limit, and an optional number of reminders. Phases are steps that define the actual movement of fluid. The pressure limit is a setting that governs the fluid pressure generated within the system during the injection sequence. Reminders are user-determined timing notifications to be generated during the injection sequence.

4.3.1.1 Phase

There are three types of phases:

- **Fluid Delivery Phase:** Defines the flow rate, volume, and duration of a fluid to be injected.
- **Programmable Pause Phase:** Defines a set amount of time the fluid injection will be paused. The next phase will execute once the set time has elapsed.
- **Hold Phase:** Places the fluid delivery in Hold. The user must actively re-engage the system to advance to the next phase.

4.3.1.2 Pressure Limit

Defines the maximum fluid pressure the system is permitted to generate during the execution of the protocol. The maximum pressure limit is 325psi (2,241 kPa) when using disposable syringes from Bayer.

This limit may be reduced based on the indication and patient-based considerations.

4.3.1.3 Reminder

An operator-defined request for the system to provide a notification after a defined time has elapsed during the protocol execution.

4.3.2 Protocol Manager

Once the phases, pressure limit, and optional reminders are configured, the protocol is complete and can be saved and recalled for later use. Through the Protocol Manager, protocols with unique operator-defined names can be sorted. These protocols can then be recalled at a future point for repetitive use.

4.3.3 Fluid Delivery System Design

The system is flow-controlled. The flow rate specified in a phase is the value the system targets to deliver during the injection until the defined phase volume is delivered. The duration is the defined time the phase will take to perform the volume injection at the stated flow rate. The system permits any two of these three parameters to be defined with the third calculated.

4.3.4 Fluid Pressure and Pressure Limiting

The fluid pressure is measured by the system during the execution of a phase and ensures the protocol pressure limit is not exceeded. Fluid pressure is generated by delivering fluid through the attached disposable system at the desired flow rate. The resulting measured fluid pressure is dependent on the following:

- Flow Rate
- Fluid Properties
- Fluid Temperatures
- Attached Disposables
- Catheter Type/Size

Pressure Limiting occurs when the above conditions result in the measured fluid pressure exceeding the protocol Pressure Limit setting. If this occurs, the system displays a notification of the condition and initiates Flow Rate Reduction for the phase to reduce the fluid pressure.

4.3.4.1 Flow Rate Reduction

As flow rate is reduced, the resulting measured fluid pressure is decreased. The system continues to deliver the phase volume at this reduced flow rate resulting in a phase duration exceeding the targeted duration.

4.3.5 Response to Occlusions

When injecting into an occlusion, a stall condition or high pressure disarm results. If a stall or high pressure disarm occurs, check the fluid path for blockage and inspect the disposable set for damage. If no issue is found, consider increasing the catheter size or decreasing the flow rate.

NOTE: A stall condition occurs when the actual flow rate is less than 10% of the defined rate.

NOTE: A high pressure disarm condition occurs when the system pressure is 50 psi (345 kPa) above the programmed pressure limit. Refer to Table 17 - 3.

4.3.6 Volume and Flow Rate Protection

The system provides the following protection against over and under volume or flow rate conditions:

- Warnings display on the Safety screen as a reminder to check the programmed injection parameters prior to the system being armed.
- On-screen indications of insufficient volume 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 is stopped.

4.4 Syringe Installation Features

⚠ CAUTION

Mechanical Hazard - Minor or moderate patient and/or worker injury may result.

- Ensure the syringe is properly snapped into the front of the injector head before injecting. Improper engagement or rotating syringe may cause the syringe to leak, to become damaged, or to come off during the injection, and can result in an under-volume delivery and the syringe becoming a projectile.

The injection system is designed with five features to decrease the amount of time and steps to load disposable syringes:

1. **Easy Installation:** Syringe is inserted straight into the injector without twisting.

2. **Auto Engage/Lock:** Once the syringe is inserted straight into the injector, the injector automatically rotates and locks the syringe in place. No twisting is required.
3. **Auto Dock:** Once a syringe is installed, the injector piston advances, finds and docks with the syringe plunger. If the syringe was previously filled with fluid, no further action is initiated at this time.
4. **Auto Advance:** When an empty syringe is removed from its packaging and installed on the injector, the piston automatically docks with the plunger and then advances it to the full forward position.
    - When Auto Advance is configured to ON through the configuration screen, both Auto Dock and Auto Advance are enabled. The injector determines whether a syringe was on the unit or not by the position of the syringe plunger.
    - If Auto Advance is ON, then the plunger automatically advances when a new syringe is installed.
5. **Auto Retract:** When the syringe is removed, the piston rod will automatically retract (if enabled).

The disposable syringes also include six identical barcodes at the bottom of the barrel. The syringe can be installed without aligning the barcodes. When a syringe is installed, the system reads one of the barcodes to identify the syringe size and if the syringe has expired or has been installed multiple times.

4.5 Programming Mode

After values for any two parameters are entered, the system calculates the value for the third. By default, values for flow rate and volume are entered, and the system calculates the duration. Use Programming Mode to toggle the value calculated by the system. The system can calculate the flow rate, volume, or duration. To enable Programming Mode, refer to 13.4 - Fluid Delivery Setup for more information.

4.6 Basic Informatics

If an optional Informatics platform is included with the system, refer to the Certegra® Applications and Workstation Accessories operation manual for overview and functionality.

4.7 Using the Pedestal with Integrated IV Pole

The pedestal is intended to support the injector head in a CT scan room. Do not attempt to use the pedestal for any other purpose.

⚠ CAUTIONS

Mechanical Hazard - Minor or moderate patient and/or worker injury may result.

- Tighten all screws, clamps, and knobs during assembly and as needed during use. Loose components may cause the pedestal to collapse.
- Do not move or manipulate the injector mount by pulling or pushing the integrated IV pole. Using the pole to maneuver the injector could bend the pole or cause an imbalance of the system. Maneuver the injector as recommended in 4.1.1 - Moving the System Within the Room.
- Do not adjust the integrated IV pole or move the injector when anything is hung from the pole.
- Use care and diligence in folding and unfolding the hooks, raising and lowering the pole, and tightening the adjustment knob. Keep hands and fingers clear of all pinch point areas.
- The folding hooks are designed to hold a maximum weight of 5 lbs / 2,265 grams each. Do not exceed the weight limits.
- Use extreme care in raising and lowering the integrated IV pole. The pole should raise and lower easily without force. If raising and lowering becomes difficult, clean the pole as described in 15.3.4 - Cleaning the Pedestal With Integrated IV Pole, Overhead Counterpoise System (OCS), and Base.

⚠ CAUTIONS

Electric Shock Hazard - Minor or moderate patient and/or worker injury may result.

- Only plug the system into a direct mains access point. Do not plug the system's power cord into an extension cord or multi-outlet power strip.

Procedure Delay Hazard - Serious patient and/or worker injury or death may result.

- Turn off any equipment that could generate a high level electrostatic discharge.

4.7.1 Pedestal Operating Instructions

- **To extend Integrated IV Pole:** Turn adjustment knob counter-clockwise to loosen, then raise the top of the Integrated IV Pole to the desired height.
- **To lock the Integrated IV Pole:** Turn the adjustment knob clockwise until tight. Do not overtighten.
- **To store:** Turn the adjustment knob counter-clockwise and retract the Integrated IV Pole.

5 Understanding the Display and Workstation

5.1 Home Screen

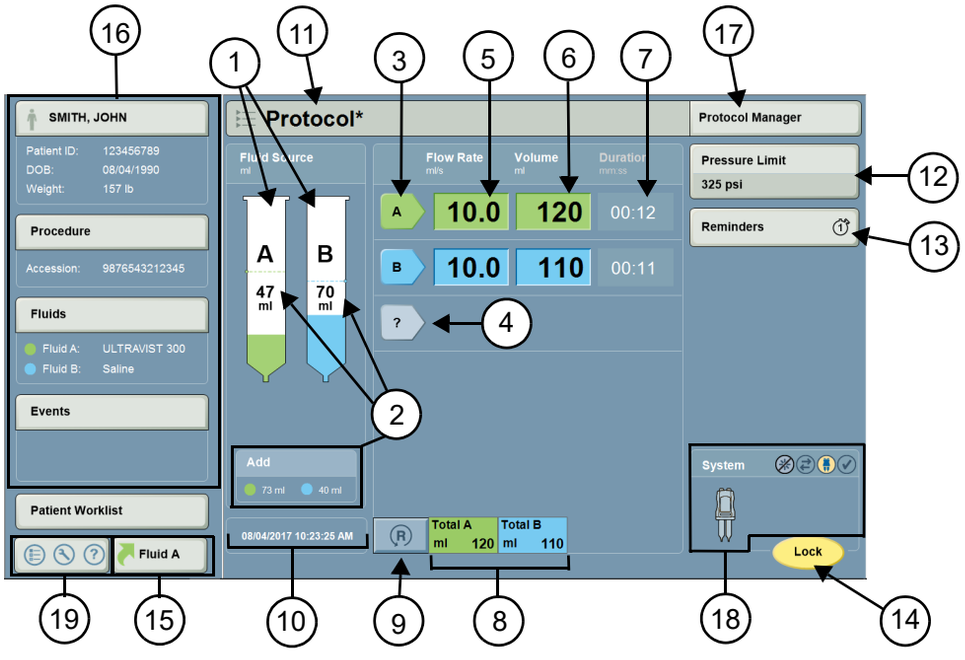


Figure 5 - 1: Home Screen

#	Name	Description
1	Volume Remaining	Shows the volume in the syringes. An outline of the syringe displays if no syringe is present.
2	Add Volume Indicators (if applicable)	A dotted line displays on the syringe graphic to indicate that there is not enough volume in the syringe to complete the current protocol. An Add box displays the volume that needs to be added to complete the current protocol.
3	Phase button (edit phase)	Select to edit a phase type.
4	Phase button (new phase)	Select to enter a new phase type.
5	Flow Rate	Displays the programmed flow rate. Select to modify (if enabled).
6	Volume	Displays the programmed volume. Select to modify (if enabled).
7	Duration	Displays the programmed duration. Select to modify (if enabled).
8	Total Volume	Displays the total programmed volume per syringe or the total combined volume in both syringes. Refer to 13.4 - Fluid Delivery Setup for more information.
9	Reset	Resets the protocol to the default factory values.

#	Name	Description
10	Date and Time	Shows the current date and time.
11	Protocol Name	Displays the name of the protocol.
12	Pressure Limit	Displays the current pressure limit. Select to modify.
13	Reminders	Displays the number of set reminders. Select to add or modify.
14	Lock/Arm/Disarm	Select to lock a protocol, arm the injector, or disarm the injector.
15	Fluid A	Displays most recent Fluid A values entered.
16	Informatics Panel	Displays Informatics panel. Refer to the Certegra® Applications and Workstation Accessories operation manual.
17	Protocol Manager	For more information, refer to Figure 5 - 3: Protocol Manager.
18	System Information	For more information, refer to Figure 5 - 2: System Information.
19	Launch Menu	For more information, refer to Figure 5 - 4: Launch Menu.

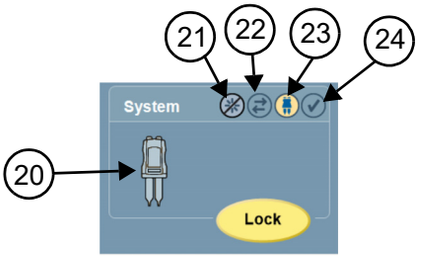


Figure 5 - 2: System Information

#	Name	Description
20	Injector icon	The Injector icon identifies various states of the injector: ◆ Not illuminated when the system is in the idle state. ◆ Illuminates yellow and flashes when the system is armed. ◆ Illuminates solid yellow when the system is injecting.
21	XDS Communicator	Indicates status of XDS accessory if XDS is available. Refer to the XDS operation manual.
22	ISI Communicator	Indicates active communication with ISI if ISI is available. Refer to the appropriate ISI operation manual.
23	Injector Communicator	Illuminated yellow when in active communication with injector head.
24	I Checked for Air icon	Illuminates yellow when the operator has confirmed inspection of the fluid path for air.

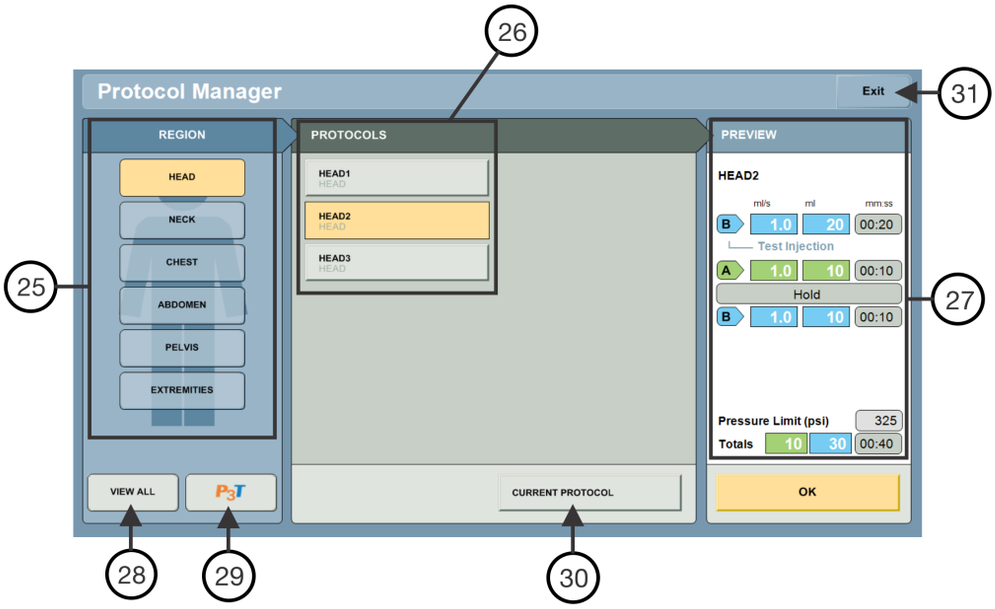


Figure 5 - 3: Protocol Manager

#	Name	Description
25	Region of Interest	Shows list of folders in which protocols are stored.
26	Protocol List	List of protocols stored in the highlighted Region of Interest.
27	Protocol Preview	Displays details of selected protocol.
28	View All	Displays all stored protocols.
29	P3T	Displays only stored presets of P3T.
30	Current Protocol	Shows details for current protocol in use.
31	Exit	Returns to the Home screen with no protocol selected.

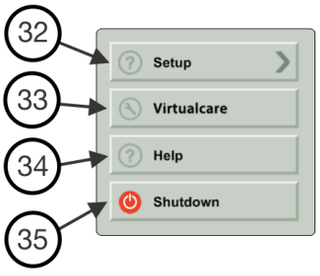


Figure 5 - 4: Launch Menu

#	Name	Description
32	Setup	Accesses the Setup options. Refer to 13.1 - System Setup for more information.
33	VirtualCare	Displays the contact information for Bayer.

#	Name	Description
34	Help	Launches the Help system. Refer to 13.6 - Help for more information.
35	Shutdown	Accesses the Shutdown options.

5.2 Workstation Descriptions

NOTE: Two models of the Certegra® Workstation can operate with the system. Buttons and icons will differ slightly with each model.

5.2.1 Workstation Buttons and Icons

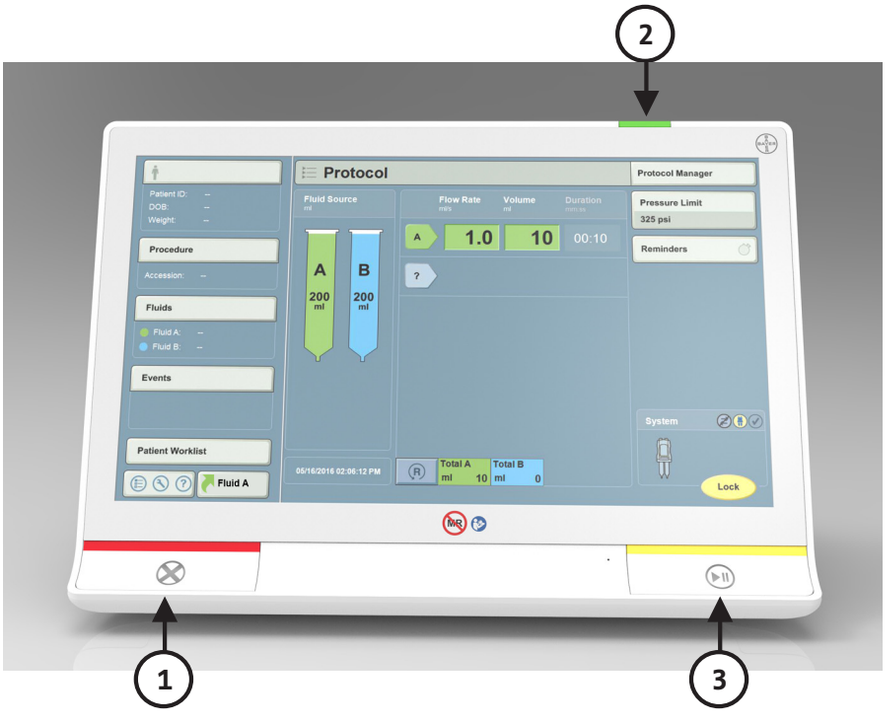


Figure 5 - 5: Workstation, Front View

#	Button/Icon	Description	#	Button/Icon	Description
1		Terminates the injection and disarms the system.	2		Powers the system On or Off. Blinks or continuously illuminates amber or green, based on power status. Refer to 7 - Powering Up and Shutting Down the System for more information.
3		Initiates the injection. Holds the injection for a maximum of 20 minutes.			

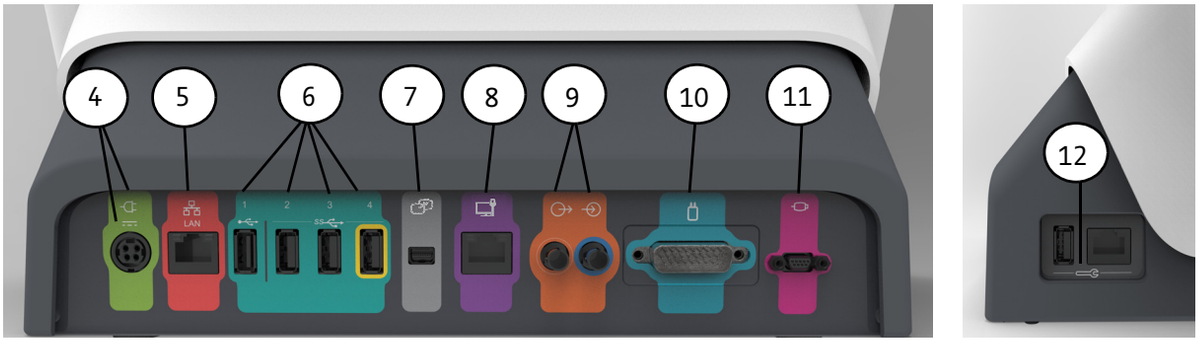
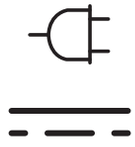
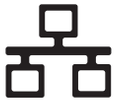
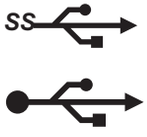
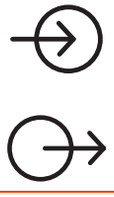


Figure 5 - 6: Workstation, Rear and Side Port View

#	Icon	Description	#	Icon	Description
4		Identifies power input and supply connection.	5		Identifies computer network connection.
6		Identifies USB connections. Port 4, identified with yellow outline, always remains on.	7		Identifies connection for screen extension or transfer to a second display. For Bayer use only.
8		Identifies a connection not applicable for MEDRAD® Stellant FLEX. Not for use with the system.	9		Identifies input and output connections not applicable for MEDRAD® Stellant FLEX. Not for use with the system.
10		Identifies injector head connection.	11		Identifies handswitch connection.
12		Identifies service ports. For Bayer use only.			

5.2.2 Workstation with Pod Buttons and Icons

Figure 5 - 7: Workstation with Pod

NOTE: Pod and display connection icons not shown. Refer to 17.2.2 - Workstation with Pod, Pod Connections and 17.2.3 - Workstation with Pod, Display Connections for more information.

#	Button/Icon	Description	#	Button/Icon	Description
1		Terminates the injection and disarms the system.	2		Powers the system On or Off. Refer to 7 - Powering Up and Shutting Down the System for more information.
3		Launches the Help system. Refer to 13.6 - Help for more information.	4		Initiates the injection. Holds the injection for a maximum of 20 minutes.
5		Blinks or continuously illuminates amber or green, based on power status.			

6 Understanding the Injector Head and Handswitch

6.1 Injector Head Control

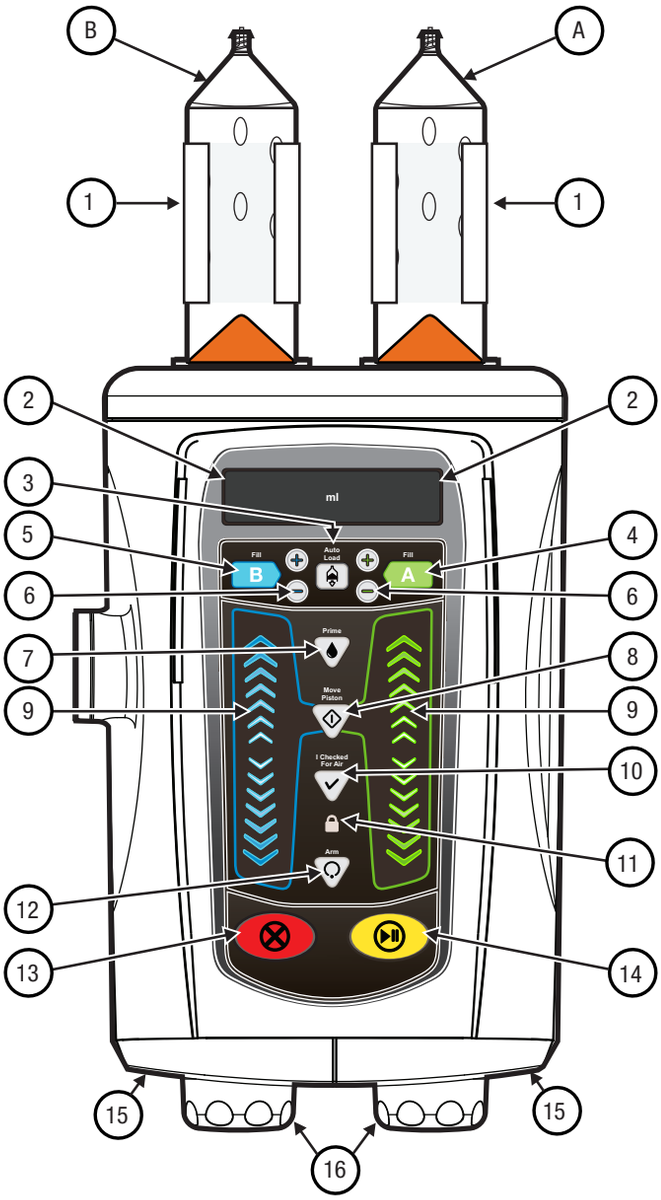


Figure 6 - 1: Injector Head Control

#	Name	Description
A	Syringe A	Contrast Syringe (150 mL or 200 mL)
B	Syringe B	Saline Syringe (150 mL or 200 mL)

#	Name	Description
1	Heat Maintainer (Side A or B)	Refer to 6.2.1 - Syringe Heat Maintainer for more information.
2	Volume (Side A or B)	◆ *Syringe Installed* - Indicates the volume loaded in the syringe. ◆ *Auto Load Active* - Indicates the volume to be loaded into the syringe. ◆ *Syringe Not Present* - No indicator.
3	Auto Load	Activates the Fill A, Fill B, and the +/- buttons.
4	Fill A	Fills Syringe A to the displayed volume.
5	Fill B	Fills Syringe B to the displayed volume.
6	+/- (Side A or Side B)	Adjusts the Auto Load volume to the nearest multiple of 5 mL, and then in increments/decrements of 5 mL.
7	Prime	Activates the tube priming function.
8	Move Piston	Activates the forward and reverse piston controls. Times out after ten seconds of inactivity.
9	Piston Control (Side A or B)	Advances and retracts the piston (variable speed).
10	I Checked for Air	Reminds user to verify that air is purged from the syringe and tubing. (Must be lit to enable arming.)
11	Protocol Lock	Indicates the protocol lock on display is enabled. (Must be lit to enable arming.)
12	Arm	Arms the system.
13	Abort	Terminates injection and disarms injector.
14	Start/Hold	Initiates injection. Holds injection for a maximum of 20 minutes.
15	Arm Lights	Refer to 6.2.3 - Arm Lights for more information.
16	Manual Knob (Side A or B)	Permits manually moving the piston when the injector is not armed.

6.2 Injector Head Components

6.2.1 Syringe Heat Maintainer

⚠ CAUTION

Mechanical Hazard - Minor or moderate patient and/or worker injury may result.

- Do not use the syringe heat maintainer if the fault indicator light is illuminated.

It is recommended that contrast be at 35 degrees Celsius prior to being loaded into the syringe. Once the syringe is loaded, use the syringe heat maintainer to maintain the contrast temperature.

6.2.2 Manual Knob

⚠ WARNING

Air Embolism Hazard - Serious patient injury or death may result.

- Ensure patient is not connected while purging air from syringe, or engaging or advancing plunger

Use the manual knob to purge air, check backflow of blood, and assist in ensuring correct catheter placement.

NOTE: For all non-automatic movements, it is critical for volume accuracy to ensure that the manual knob is turned one full turn clockwise after every reverse movement.

Adjust the amount of resistance on the manual knob from the Fluid Control option. This feature minimizes the draw-back of air or fluid after automatic piston movement, such as during Prime or at end of an injection. A setting of Low or Off increases the likelihood of draw-back during these conditions. Refer to Fluid Control in 13.4 - Fluid Delivery Setup for more information.

6.2.3 Arm Lights

The injector head has two arm lights that illuminate or flash depending on the conditions listed in Table 6 - 1:

Table 6 - 1: Arm Light Functionality

Condition	Arm Light Description
Armed	The light corresponding to the syringe to be used for the protocol flashes.
Injecting	The light corresponding to the syringe that is moving remains solid. Syringe A illuminates green, and Syringe B illuminates blue.
Hold	The light corresponding to the syringe to be used for the protocol flashes.

6.3 Handswitch

The handswitch enables the starting, holding, and stopping of an injection. The handswitch contains a light that identifies the state of the injector. This light illuminates or flashes depending on the conditions listed in Table 6 - 2:

Table 6 - 2: Handswitch Light Functionality

Condition	Arm Light Description
Armed	The light flashes.
Injecting	The light illuminates.
Hold	The light flashes.

NOTE: Handswitch light functions the same whether it is connected to the injector head or the workstation.

7 Powering Up and Shutting Down the System

7.1 Power Up the System

⚠ CAUTION

Electric Shock Hazard - Minor or moderate patient and/or worker injury may result.

- Verify the voltage and frequency as labeled matches the voltage and frequency of the electrical outlet.

1. Press the **Power** button on the workstation. The injector and the workstation power up.
2. Read the warnings, and press **Continue**. The Home screen displays.

7.2 Shut Down the System

The system provides two options for shutting down the system: Full System Shutdown and Injector Shutdown.

1. From the Launch menu, select a **Shutdown** option or press **Power** button on workstation.
2. Select from the following (Figure 7 - 1: Shutdown Options):
   - **System Shutdown:** Both the workstation and injector shut down.
   - **Injector Shutdown:** The injector shuts down, the display screen is blank, and Informatics operations remain running on the display.

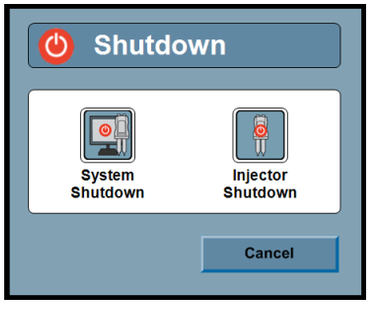


Figure 7 - 1: Shutdown Options

7.2.1 Hard Shutdown

To perform a hard shutdown, either:

- Press and hold the **Power** button on the Workstation or Workstation with Pod.
- Turn the power switch to Off on the Workstation with Pod (in the event that the graphical display is unresponsive).
- Unplug the power cord to the Workstation or Workstation with Pod (in the event that the graphical display is unresponsive).

7.3 Restore from Injector Shutdown

When the system is in Injector Shutdown mode, the injector is shut down, the display screen is blank, and the Informatics operations remain running in the background.

1. Press the **Power** button on the workstation. The injector powers up, and the display screen becomes active.
2. Read the warning, and press **Continue**. The Home screen displays.

8 Protocol Management

⚠ WARNING

Vessel Hazard - Serious patient injury or death may result.

- Ensure the programmed flow rate meets facility guidelines.

8.1 Create or Edit a Protocol

Create and edit protocols from the Home screen.

1. Select an arrow (1) to create or edit a protocol (Figure 8 - 1: Select Phase Type).

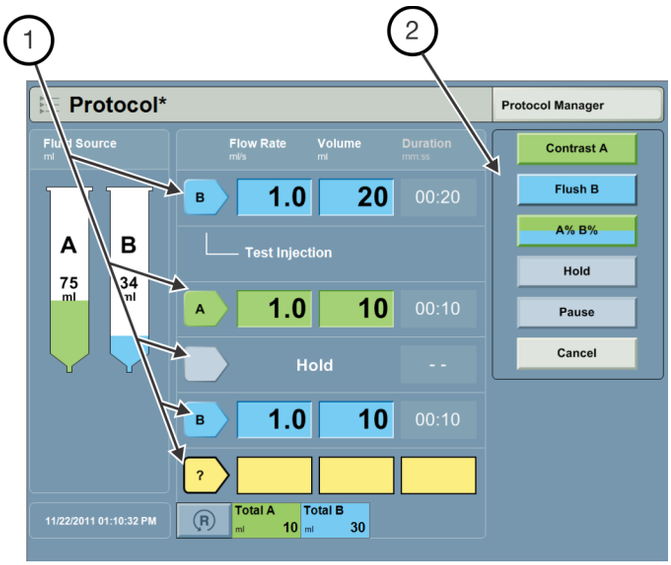


Figure 8 - 1: Select Phase Type

   a. Define the phase type from the list (2) on the right of the display.

Table 8 - 1: Phase Types

Phase Type	Description
Test Inject A	Injects a programmed phase from Syringe A followed by a hold phase.
Test Inject B	Injects a programmed phase from Syringe B followed by a hold phase.
Contrast	Injects a programmed phase from Syringe A.
Saline	Injects a programmed phase from Syringe B.
Dual Flow	Injects a DualFlow phase from Syringe A and Syringe B. Refer to 8.4 - DualFlow.

Table 8 - 1: Phase Types

Phase Type	Description
Hold	Phase where the injection is stopped until it is restarted.
Pause	Phase where the injection is stopped for a programmed amount of time. The injection resumes when the pause time elapses.

NOTE: A test injection can be used to confirm that the catheter is properly placed.

NOTE: A test injection can only be the first phase in a protocol.

NOTE: Phases may be deleted from a protocol. The Delete functionality is only available when editing a protocol with more than one phase.

NOTE: A hold phase cannot be the first phase in a protocol.

b. Select a parameter (3) and enter the values (4) (Figure 8 - 2: Enter Parameters).

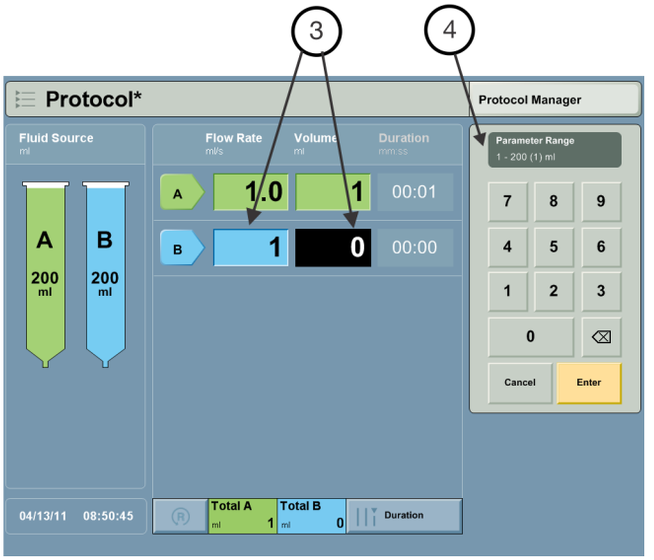


Figure 8 - 2: Enter Parameters

c. Select **Enter** to confirm the parameter, or select **Cancel** to disregard.

2. Repeat step **1** to add additional phases.

NOTE: If the programmed volume exceeds the amount of volume in the syringe(s), the system provides an on-screen indication and displays how much fluid needs to be added in each syringe.

NOTE: When modifications have been made to a protocol, an asterisk displays to the right of the protocol name.

3. If a protocol is entered that requires more than 150 mL, a yellow indication will appear and blink on the screen (Figure 8 - 3: Insufficient Syringe Volume). The indication is removed once a syringe is installed on the injector.

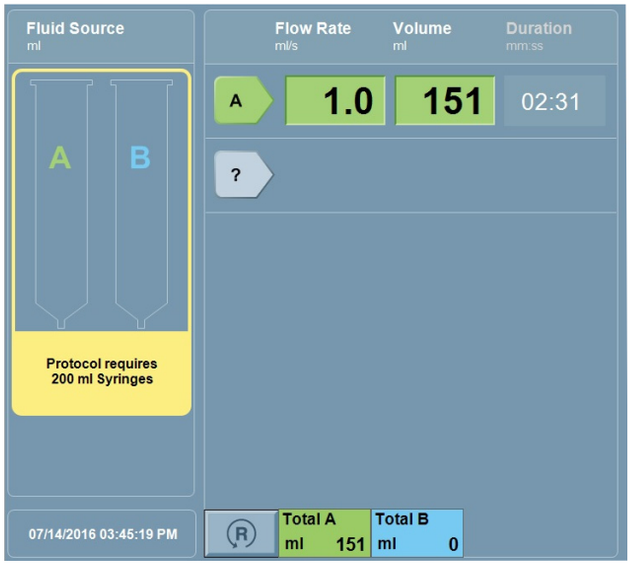


Figure 8 - 3: Insufficient Syringe Volume

4. Optionally, modify the default pressure limit.

   a. Select **Pressure Limit**.

   b. Select a pressure limit from the pick list.

   NOTE: Ensure that the pressure is set for the patient per facility guidelines.

   NOTE: Ensure the proper pressure is set for the catheter and other disposables connected to the system.

5. Optionally, set or modify a reminder.

   Reminders are alerts that display after an operator-programmed amount of time. The system stores reminders as part of the protocol.

   NOTE: A reminder dialog displays when the reminder is initiated.

   NOTE: If the reminder dialog is not acknowledged, the dialog will remain open.

   a. Select **Reminders** (1) (Figure 8 - 4: Enter Reminders).

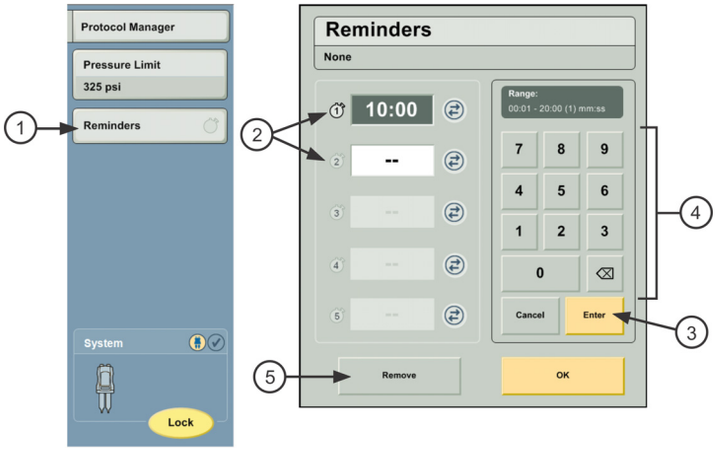


Figure 8 - 4: Enter Reminders

b. Select an empty reminder slot (2) to enter additional reminders, or select an existing reminder (2) to modify the parameter.

c. Select **Enter** (3) when all reminders are entered.

d. Enter the time (4) for the reminder in minutes and seconds.

e. Optionally, select **Remove** (5) to delete a reminder.

The protocol can be saved (refer to 8.2 - Save a Protocol) or used for an injection (refer to 10 - Arming and Injecting).

8.2 Save a Protocol

Protocols that have been created or edited on the Home screen can be saved.

NOTE: Unique protocol names are required within the same region.

NOTE: The system can store up to 250 protocols.

1. Select **Protocol Manager**.
2. Under *Region*, select the folder in which to store the protocol (Figure 8 - 5: Protocol Manager).
3. Under *Preview*, select **Store in <Region>**.

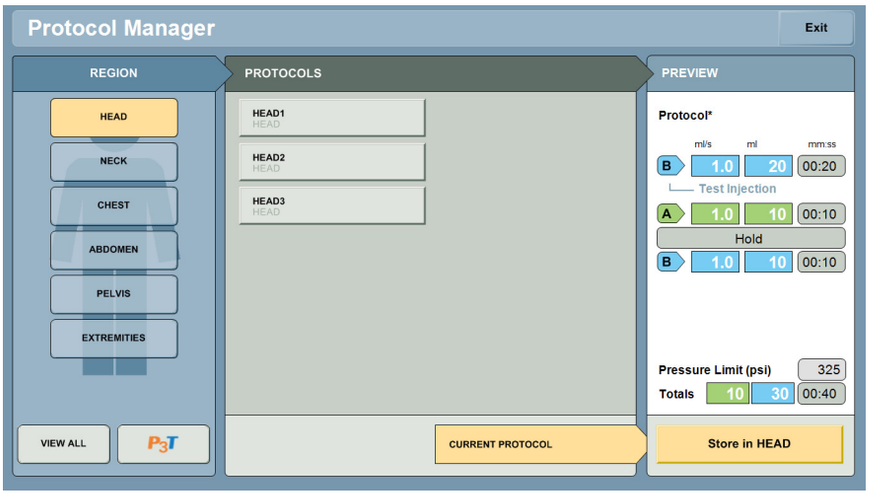


Figure 8 - 5: Protocol Manager

4. Enter a Name for the protocol, and select **Enter**.

8.3 Recall a Saved Protocol

1. Select **Protocol Manager.**
2. Select the desired region or select **View All** (1) (Figure 8 - 6: Recall Protocol).
3. Select the protocol name (2).
4. Select **OK** (3). The Home screen displays the selected protocol.

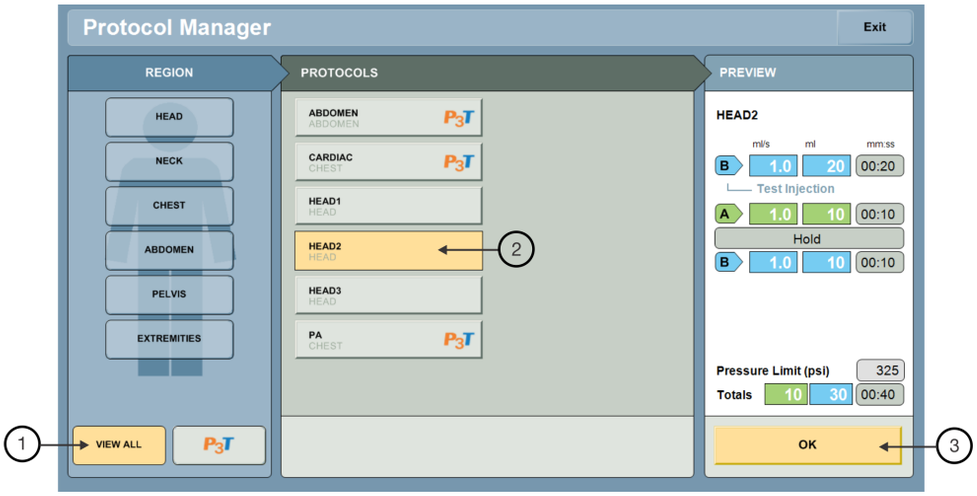


Figure 8 - 6: Recall Protocol

To edit the protocol, refer to 8.1 - Create or Edit a Protocol. To use the protocol for an injection, refer to 10 - Arming and Injecting.

NOTE: Presets for P3T will be indicated with the P3T logo. For more information regarding P3T Presets, refer to the appropriate Certegra® Workstation Personalized Patient Protocol Technology (P3T) module operation manual: P3T Cardiac, P3T Abdomen, or P3T Pulmonary Angiography (PA).

8.4 DualFlow

8.4.1 Essential Claims

The system provides the capability to program the contrast and saline syringe plungers to move simultaneously. The user can program various ratios to achieve the desired volumetric delivery of the media. Always refer to the specific contrast media manufacturer's labeling.

8.4.2 Programming a DualFlow Phase

1. Select a Phase button (1).

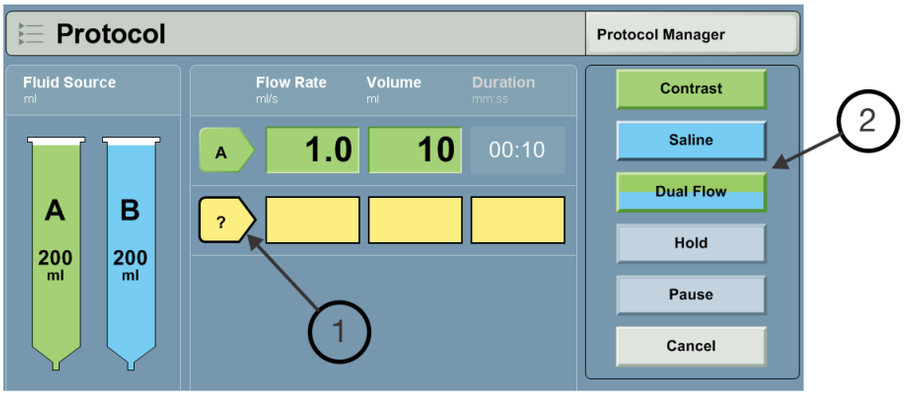


Figure 8 - 7: Select Phase Button

2. Select **DualFlow** (2).
3. Enter the percentage of Contrast to be injected during the DualFlow phase. The system automatically calculates the percentage of Saline.

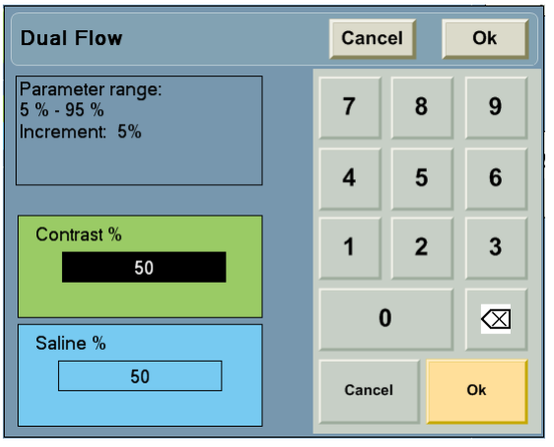


Figure 8 - 8: DualFlow Keypad

4. Enter the parameters for the phase.

   Depending on the Programming Mode, enter the Flow Rate, Volume (combined total volume of Contrast and Saline), or Duration. Regardless of the parameters entered, the Contrast and Saline percentages are calculated based on the Volume and Flow Rate. For more information on Programming mode refer to 4.5 - Programming Mode.

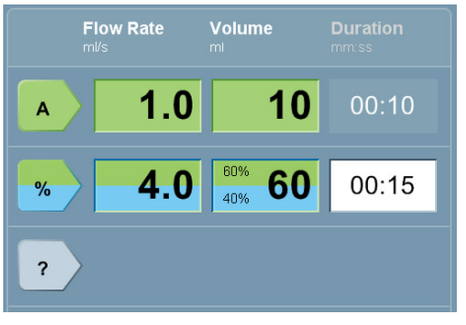


Figure 8 - 9: DualFlow Phase

DualFlow automatically determines the individual volumes of Contrast and Saline and the individual flow rates needed for the Contrast and Saline portions of the DualFlow phase.

For example, if the user enters a total Flow Rate of 4.0 mL/sec and a total Volume of 60 mL, the individual volume and flow rate of Contrast and Saline for the DualFlow phase would be as follows (based on the sample percentages of Contrast):

Sample Ratio	Syringe A	Syringe B
A90% B10%	54 mL @ 3.6 mL/sec	6 mL @ 0.4 mL/sec
A80% B20%	48 mL @ 3.2 mL/sec	12 mL @ 0.8 mL/sec
A75% B25%	45 mL @ 3.0 mL/sec	15 mL @ 1.0 mL/sec
A70% B30%	42 mL @ 2.8 mL/sec	18 mL @ 1.2 mL/sec
A65% B35%	39 mL @ 2.6 mL/sec	21 mL @ 1.4 mL/sec
A60% B40%	36 mL @ 2.4 mL/sec	24 mL @ 1.6 mL/sec
A50% B50%	30 mL @ 2.0 mL/sec	30 mL @ 2.0 mL/sec

NOTE: To change the ratio once the phase has been programmed, re-select the phase and enter the new ratio values per step **3**.

9 Preparing for Injection

9.1 Control Room Preparation

WARNING

Vessel Hazard - Serious patient injury or death may result.

- Ensure that the programmed flow rate meets facility guidelines.

CAUTION

Minor or moderate patient injury may result.

- Confirm that the programmed protocol is correct prior to selecting Lock on the display.

9.1.1 Informatics Panel

Refer to the Certegra® Applications and Workstation Accessories operation manual.

9.1.2 Prepare Injection Protocol

1. Set protocol.
   a. To recall a protocol:

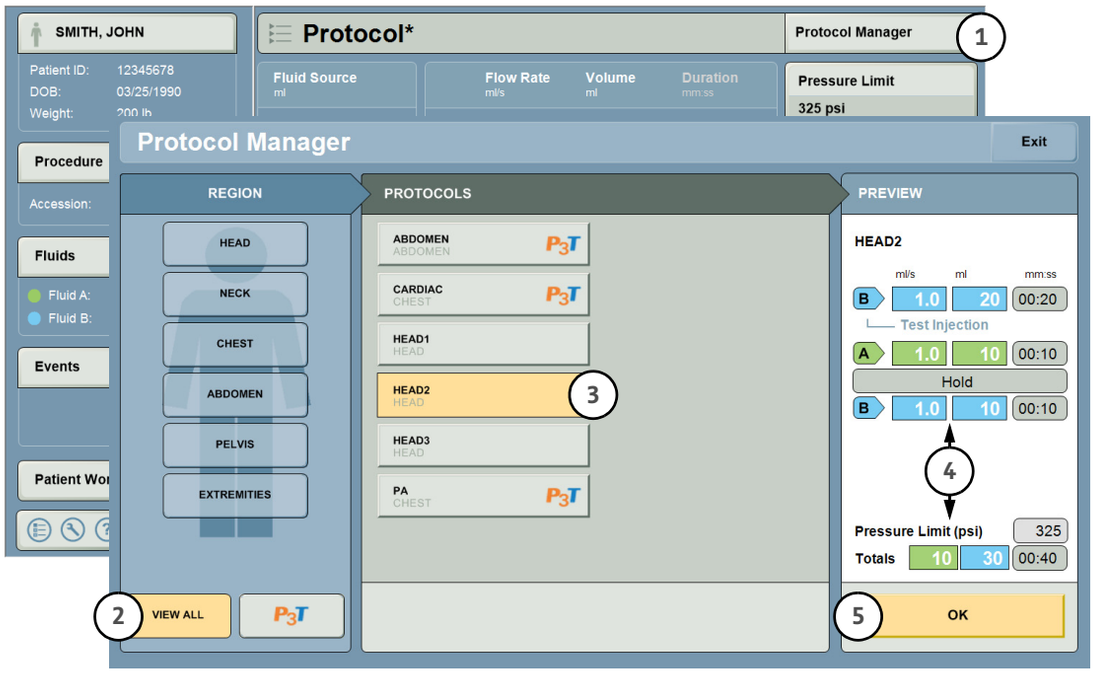


Figure 9 - 1: Recall a Protocol

i. On the Home screen, select Protocol Manager. **(1)**

ii. Select View All to see all saved protocols. **(2)**
iii. Select applicable protocol from list. **(3)**
iv. Review all protocol values. **(4)**
v. Select OK to use or edit the protocol. **(5)**
vi. Refer to 8.3 - Recall a Saved Protocol for further information.

b. To create or edit a protocol:

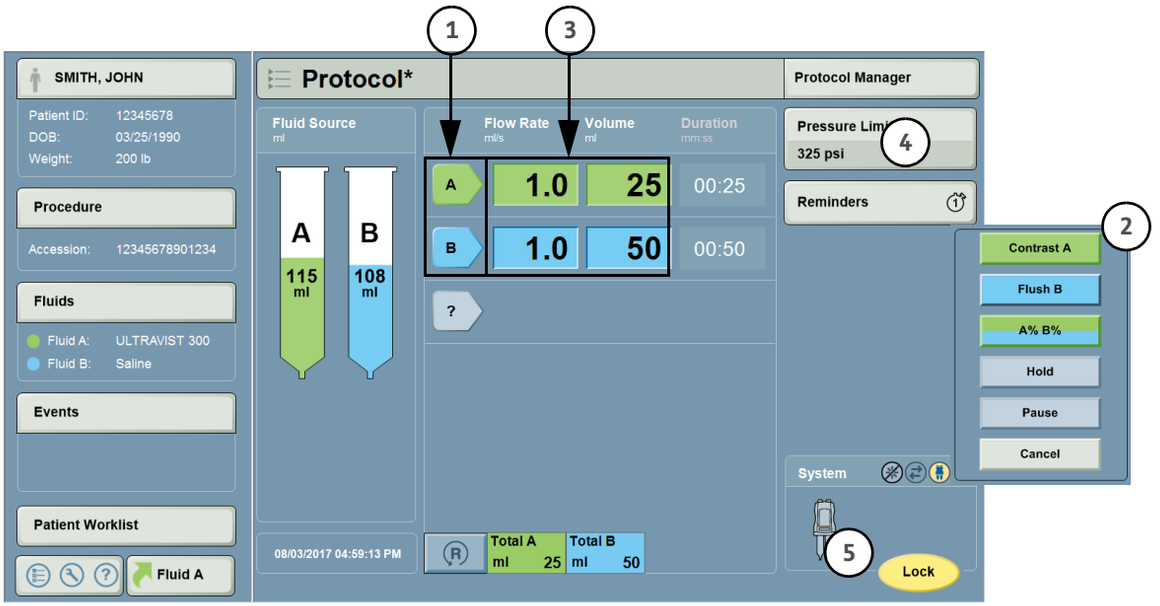


Figure 9 - 2: Create a Protocol

i. Select an arrow to create a phase. **(1)**
ii. Choose a phase type from the list. **(2)**
iii. Add/edit volumes and flow rates. **(3)**
iv. Select a pressure limit. **(4)**
v. Press Lock to lock the protocol. **(5)**
vi. Refer to 8.1 - Create or Edit a Protocol for further information.

NOTE: A blinking yellow indication will appear if a protocol is entered that requires more than 150 mL. Refer to 8.1 - Create or Edit a Protocol for further information.

2. Select **Lock** on the display.

NOTE: The icon on the display changes to ***Arm***, and the injector head ***Protocol Lock*** indicator illuminates.

9.2 Scan Room Preparation

⚠ WARNINGS

Air Embolism Hazard - Serious patient injury or death may result.

- Expel all trapped air from the syringe(s), connectors, tubing, and catheter before connecting the system to the patient. Carefully read the instructions for loading and the use of the syringe Beacon and MEDRAD® FluiDots (where applicable) to reduce the chance of air embolism.
- The presence of a syringe Beacon or rounded FluiDots does not indicate the total absence of air bubbles in the syringe tip. FluiDots 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.
- To minimize the possibility of inadvertent aspiration and injection, ensure the patient is disconnected from the injector when utilizing the forward and reverse piston controls.

Biological Contamination Hazard - Serious patient and/or worker injury or death may result.

- Properly discard fluid source containers and disposable items after use (refer to disposable label for specifics), or if there is any possibility that contamination may have occurred.
- Do not reuse single-use fluid sources. Refer to the fluid source manufacturers' instructions for use.

Environmental Contamination Hazard - Serious patient or worker injury or death may result.

- Follow aseptic technique when handling disposable components. Specifically, maintain sterility of all disposable components.
- Do not disassemble any disposable components.
- Visually inspect contents and package before each use.

Bacterial Contamination Hazard - Serious patient and/or worker injury or death may result.

- Syringes are not intended to be used as storage containers. Do not use syringes to store fluids.

Mechanical Hazard - Serious patient injury could result from leaks or ruptures during an injection.

- Use only disposables supplied by Bayer. Refer to 16.6 - Sterile Disposables.
- Use only syringes and tubing with a pressure rating greater than the maximum programmable pressure limit of the injection system, which is 325 psi (2241 kPa).
- Use catheters with pressure ratings compatible with this system. Refer to 17.7.2 - Maximum Flow Rate Performance and 17.7.3 - Programmable Pressure System Performance.

Adverse Reaction Hazard - Serious patient injury or death may result.

- Check the patient history for any evidence of allergy to injectable fluid sources.

Compromised Efficacy - Serious patient injury may result

- Programming or loading an incorrect fluid source or concentration may result in patient injury or suboptimal imaging.

Vessel Hazard - Serious patient injury or death may result

- Use catheters and connectors with pressure ratings compatible with this system. Refer to 17.7.2 - Maximum Flow Rate Performance and 17.7.3 - Programmable Pressure System Performance.

⚠ CAUTION

Mechanical Hazard - Patient injury could result if the syringe is not properly engaged.

- Ensure the syringe is properly snapped into the front of the injector head before injecting. Improper engagement or rotating syringe may cause the syringe to leak, to become damaged, or to come off during the injection, and can result in an under-volume delivery and the syringe becoming a projectile.

9.2.1 Fluid Detection Methods

The Stellant FLEX syringe aids in determining the presence of fluid by using three methods:

- The use of clear material allows visual detection of air inside of the syringe.
- MEDRAD® FluiDots on the syringe's wall appear round when the syringe is full of fluid and oval when the syringe is empty.
- MEDRAD® Beacon technology indicates the presence of fluid in an upright syringe by reflecting the plunger color at the syringe's tip unless 5 mL or more of air is present.

9.2.1.1 Using MEDRAD® FluiDots

NOTE: If using the optional heat maintainer, ensure that the heat maintainer is positioned in such a way that the Beacon and at least one of the FluiDots is visible.

FluiDots should be observed as part of an arming procedure. When the FluiDots are viewed through an empty syringe, the dots appear as small, narrow ellipses, as illustrated in Figure 9 - 3: FluiDots. When viewed through a full syringe, the dots become larger, almost round.

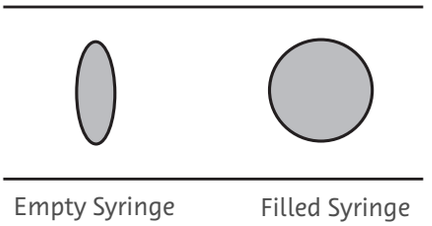


Figure 9 - 3: FluiDots

FluiDots must be viewed through fluid in the syringe. If viewed through an empty syringe, they will not change shape. FluiDots must be viewed in a properly illuminated environment providing enough light to permit easy viewing.

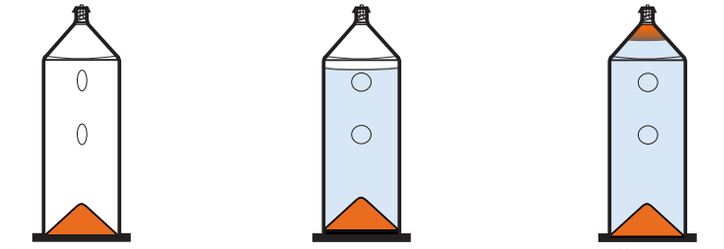
Figure 9 - 4: Properly Illuminated FluiDots

9.2.1.2 Using the Syringe Beacon

MEDRAD® Beacon technology indicates the presence of fluid in an upright syringe by reflecting the plunger color at the syringe's tip unless 5 mL or more of air is present. (Refer to Figure 9 - 5: Beacon Visibility).

NOTE: When there is 5 mL or more of air in the syringe, the Beacon reflection will not appear.

To get the best visibility of the Beacon, the syringe should be viewed from an angle perpendicular to the syringe barrel, and the injector head must be in the upright (fill) position.

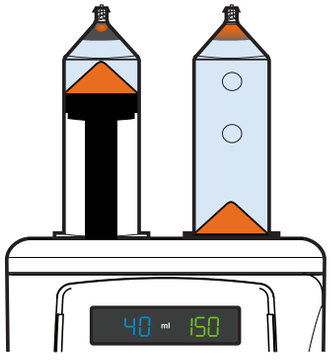


Empty Syringe | Partially Empty Syringe (5 mL or more of air) | Full Syringe

Figure 9 - 5: Beacon Visibility

NOTE: Beacon color will darken as the fluid volume in the syringe decreases. (Refer to Figure 9 - 6: Syringe Beacon Colors).

- When there is 5 mL or more of air in the syringe, the Beacon reflection will not appear.
- When the syringe is filled with more than about 50 mL of fluid and less than 5 mL of air, the Beacon appears orange.
- When the syringe is filled with less than about 50 mL of fluid and less than 5 mL of air, the Beacon begins to transition from orange to black.



Syringe Beacon colors at less than about 50 mL fluid (left) and greater than 50 mL fluid (right).

Figure 9 - 6: Syringe Beacon Colors

9.2.2 Install and Fill a Syringe

NOTICE:

Mechanical Hazard - Equipment damage may result.

- Do not install disposables with excessive force.
- Do not strike syringes to remove air. Striking the syringes may cause component damage.

1. Install a new syringe by inserting it straight into the injector head in one motion and release. The injector will automatically rotate and lock the syringe in place.

   NOTE: If the syringe is not engaged in one straight motion, the Auto Advance may be interrupted. In order to recover, re-insert syringe and check for an error message on the display.

NOTE: Twisting the syringe during installation may interrupt Auto Advance. In order to recover, re-insert syringe and check for an error message on the display.

NOTE: The syringe can be installed without aligning the barcodes.

NOTE: Syringes can be loaded with any of the following four configurations:

- One (1) 150 mL syringe
- Two (2) 150 mL syringes
- One (1) 200 mL syringe
- Two (2) 200 mL syringes

NOTE: If performing a contrast-only injection, place syringe onto Side A.

NOTE: The system typically takes a few seconds to read the barcode on the inserted syringe.

NOTE: When two syringes are installed at the same time, one piston will advance before the other.

2. If Auto Advance is enabled, the piston automatically advances and engages the syringe plunger and then advances it to the full forward position.

   NOTE: If Auto Advance is not enabled, advance plunger to the end of the syringe using the piston controls on the injector head or manual knobs.

3. Install the filling device (e.g. spike, Quick Fill Tube) onto the end of the syringe.
4. Insert the filling device into the fluid source.

   NOTE: Refer to fluid manufacturer's instructions for use and/or package insert.

5. Fill syringe using Auto Load or manually.

   NOTE: Syringe A is the contrast syringe, and Syringe B is the saline syringe.

   NOTE: Using Auto Load feature may reduce the amount of air bubbles present when filling syringes.

   a. Auto Load:

      i. Press **Auto Load** on the injector head.

         - The volume indicators on the injector head indicate how much fluid needs to be loaded to support the displayed protocol including the amount necessary to prime the patient tubing.
         - Optionally, press the +/- keys to increase or decrease the amount of volume loaded.

      ii. Press **Fill**.

   NOTE: **Auto Load** disables after 10 seconds of inactivity.

   NOTE: The system draws in the configured Auto Load Purge Volume and then expels this volume. The Auto Load Purge Volume should be set to 30, 20, 10, or 0 mL, depending on the filling device. Instructions for selecting the correct volume are contained in 13.4 - Fluid Delivery Setup.

   b. Manually:

      i. Press **MOVE PISTON** and use the reverse piston control to fill the syringe with the desired amount of fluid.

   NOTE: **MOVE PISTON** disables after 10 seconds of inactivity.

   NOTE: If protocol volume is greater than fill volume, an insufficient volume communication will display prior to ability to inject.

6. Expel any remaining air from syringe.

a. Proper method to expel air:

i. Do not strike the syringe to remove air.
ii. Reverse the plunger 3-5 ml.
iii. Rock the injector head on the pivot, keeping syringes mostly upright. This action will gather and accumulate bubbles toward the top of the syringe(s).
iv. Expel the remaining bubbles by advancing the plunger.

7. Remove filling device.
8. Connect the disposable tubing as outlined in 9.2.3 - Attach and Prime the Tubing.

9.2.3 Attach and Prime the Tubing

NOTICE:

Mechanical Hazard - Equipment damage may result.

- Do not install disposables with excessive force.

1. Remove the connector tube from the package.
2. Remove the dust covers.
3. Ensure all air is purged from the syringe.
4. Securely attach the connector tube luer fitting to the syringe tip.

NOTE: If using a connector tube with a T-connector, first attach the straight portion to the contrast (A) syringe and then the extension to the saline (B) syringe (Figure 9 - 7: T-connector).

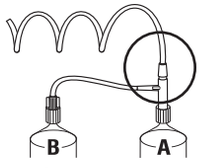


Figure 9 - 7: T-connector

5. Verify that the tubing is not kinked or obstructed.
6. Connect the Prime Tube (1) to the patient end of the tubing set (Figure 9 - 8: Prime Tube).

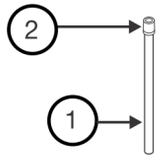


Figure 9 - 8: Prime Tube

7. Hold the Prime Tube higher than the patient's position, and ensure that the filter (2) is pointing upward.
8. Prime the tubing with fluid:

a. Prime Function:

i. Press **Prime** on the injector head.

NOTE: Selecting the Standard LPCT configuration setting will provide the prime fluid to prime the LPCT tubing included with Stellant FLEX disposable sets.

NOTE: Selecting the Other LPCT configuration setting will provide about 6 mL of prime fluid when using one syringe, or about 6.5 mL when using two syringes.

b. Manual Prime:

i. Turning the manual knob to advance the piston to prime the tubing.

NOTE: Use the appropriate fluid to prime the tubing. (Syringe A is the contrast syringe and syringe B is the saline syringe.)

c. Move Piston Prime (not recommended):

i. Press **Move Piston** and use the piston controls to prime the tubing.

NOTE: Leave the Prime Tube attached until immediately prior to patient connection.

9.2.4 Connect the Tubing to Patient

⚠ WARNING

Air Embolism Hazard - Serious patient injury or death may result.

- Before connecting the tubing to the patient, visually inspect the syringe and tubing to confirm that all air is purged.

NOTE: If required, turn the manual knobs to remove any remaining air before connecting to the patient.

1. Rotate the injector head downward.
2. Remove the Prime Tube.
3. Press **I Checked for Air**, confirming that the operator checked the fluid path for the presence or air.

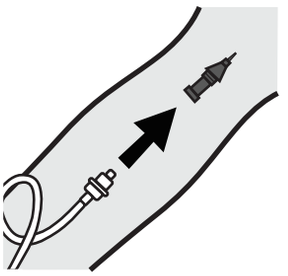


Figure 9 - 9: Connect Tubing to the Patient

4. Connect the tubing to the patient.

NOTE: Antecubital or large forearm veins are the preferred venous access sites for power injections. Alternatively, veins on back of the hand or foot can be selected. Choose a suitable catheter size and adjust flow rates accordingly. Refer to 17.7.2 - Maximum Flow Rate Performance.

10 Arming and Injecting

10.1 Add Volume Indicator

Whenever the Total Volume is greater than the Volume Remaining, the Home Screen provides on-screen Add Volume indicators to communicate how much fluid should be added to perform the protocol (Figure 10 - 1: Add Volume Indicators).

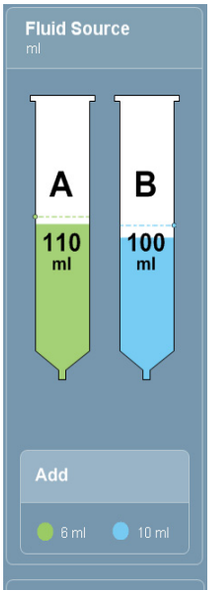


Figure 10 - 1: Add Volume Indicators

NOTE: It is recommended that this condition be resolved prior to arming the injector by either adding more fluid to the syringe or modifying the protocol.

10.2 Arm the Injector

The system can be armed from either the control room or the scan room.

10.2.1 Arm from the Control Room

1. Select **Arm** on the display.

   NOTE: If the last piston movement was a reverse movement or a syringe required by the protocol is not present, the system does not permit arming and communicates this.

2. Perform the I Checked for Air confirmation (Figure 10 - 2: I Checked for Air Confirmation):

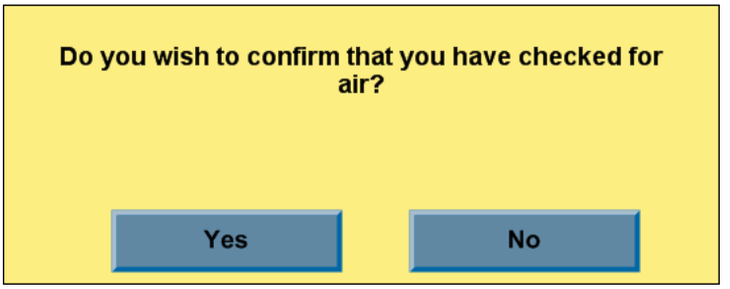


Figure 10 - 2: I Checked for Air Confirmation

a. Select **Yes** to acknowledge that the user has confirmed that all air has been expelled from the syringe and tubing.

NOTE: On the display, the I Checked for Air icon illuminates, and on the injector head, **I Checked for Air** confirmation button illuminates.

b. Select **No** if the user has not checked that all air has been expelled from the syringe and tubing. The system does not arm.

NOTE: The system monitors the syringe presence and piston movement after the I Checked for Air has been confirmed. If the syringe is removed or the piston is reversed, the system resets the I Checked for Air confirmation.

3. If the Add Volume Indicator was not corrected prior to Arming, the Insufficient Volume message is displayed (Figure 10 - 3: Insufficient Volume - Accept Modified Protocol).

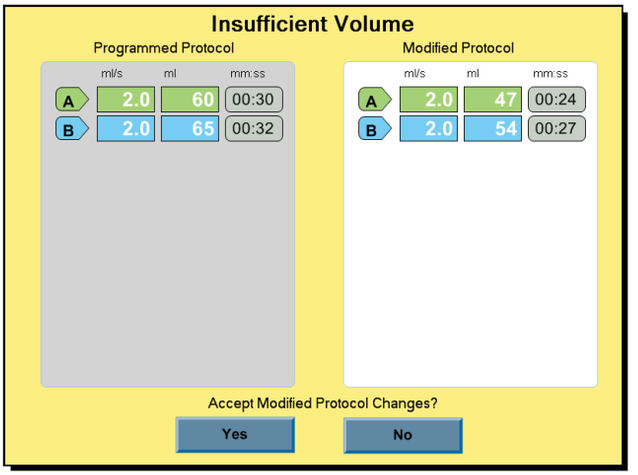


Figure 10 - 3: Insufficient Volume - Accept Modified Protocol

The system generates a modified protocol based on the available Volume Remaining.

a. Select **Yes** to accept the system-modified protocol. The system continues with the arming process. Refer to 10.3 - Initiating an Injection.

b. Select **No** to reject the system-modified protocol. The system does not arm.

The system remains armed until one of the following conditions are met:

- **Disarm** is selected on the display.
- **Abort** is pressed.
- Any injector head controls other than **Start/Hold** are activated.
- A 20 minute time-out occurs.

- An injection has completed.

NOTE: When armed, the injector head **Arm** button illuminates, the injector head Arm Lights blink, and the display shows a **Disarm** icon.

10.2.2 Arm from the Scan Room

1. Press the **I Checked for Air** confirmation button on the injector head to acknowledge that the user has confirmed that all air has been expelled from the syringe and tubing.

   NOTE: If the last piston movement was a reverse movement, or if a syringe required by the protocol is not present, the system does not permit arming and communicates this.

   NOTE: On the display, the I Checked for Air icon illuminates, and on the injector head, **I Checked for Air** confirmation button illuminates.

2. Press the **Arm** button on the injector head.

   a. If a protocol has not been locked, the Lock icon blinks, and the system does not arm. Refer to 9.1 - Control Room Preparation for more information.

   b. If the I Checked for Air has not been confirmed, the **I Checked for Air** button blinks, and an audible tone sounds.

   c. If an insufficient volume condition exists, the injector head LED flashes. Refer to 10.2.1 - Arm from the Control Room for more information on insufficient volume.

      i. Press **Arm** on the injector head to accept the system-modified protocol, or
      ii. Wait until Volume indicator stops flashing and address insufficient volume.

The system remains armed until one of the following conditions are met:

- **Disarm** is selected on the display.
- **Abort** is pressed.
- Any injector head controls other than **Start/Hold** are activated.
- A 20 minute time-out occurs.
- An injection has completed.

NOTE: The icon changes to indicate **Disarm**, the injector head **Arm** button illuminates, and the injector head Arm Lights blink.

10.3 Initiating an Injection

⚠ WARNING

Vessel Hazard - Serious patient injury may result.

- Follow institutional extravasation minimizing techniques.
- A small volume test injection may be utilized to confirm venous access.
- It is recommended that the operator stay by the patient's side at the beginning of the injection and to instruct the patient to communicate immediately any pain or change in feeling during the injection.
- Check for extravasation of contrast or saline during injection.
- If an extravasation is detected, stop the injection and refer to respective facility policy regarding treatment.

1. Press **Start/Hold** on the injector head, the workstation, or the handswitch.

NOTE: Refer to Table 6 - 1 for description on how the Arm Lights function while armed, injecting, and/or during a hold.

NOTE: If a Reminder is set, a communication appears once the Reminder elapsed time equals the setting. If a test inject phase is programmed, the Reminder elapsed time begins with the start of the first phase after the test inject.

NOTE: The Reminder communication is removed when either the communication is acknowledged or another communication is activated.

NOTE: **Test Injection -** an injection phase followed by a hold phase. After the injection phase, the system holds the injection until **Start/Hold** is pressed on the injector head, workstation, or handswitch to resume the protocol.

NOTE: **Hold Phase -** If the protocol contains a Hold Phase, the system holds the injection until **Start/Hold** is pressed on the injector head, workstation, or handswitch to resume the protocol.

10.4 Operator-Initiated Hold

If **Start/Hold** is pressed during an injection phase, the system holds the injection until **Start/Hold** is pressed on the injector head, workstation, or handswitch to resume the protocol.

NOTE: If a hold is initiated, the Reminder elapsed time is halted. The Reminder elapsed time starts when the protocol is reinitiated.

NOTE: If the system remains in a hold condition for (20) minutes, the system aborts the injection automatically.

10.5 Injection Aborted

At any time, press the **Abort** button or any other button on the injector head (other than **Start/Hold**) to abort the injection.

10.6 Viewing Injection Progress

During an injection, the system displays the following:

NOTE: If the injection is aborted, all remaining reminders are ignored.

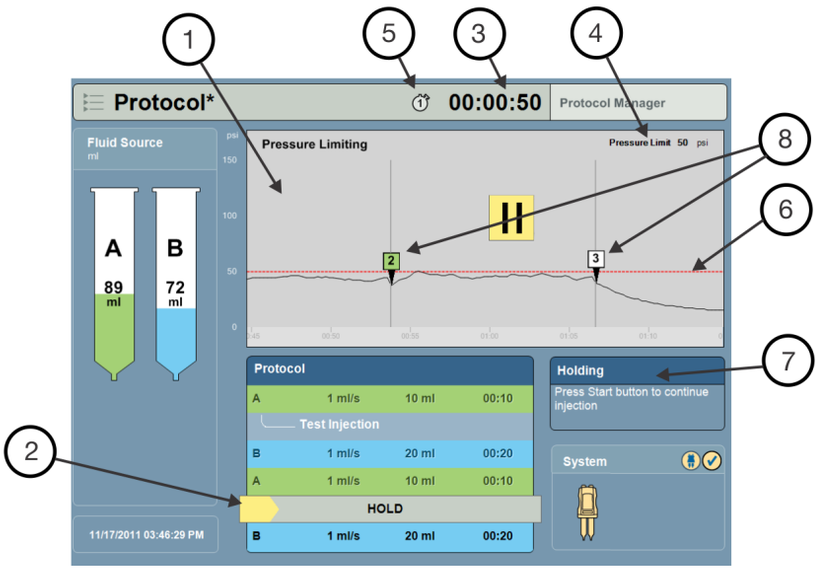


Figure 10 - 4: Injection Views

#	Name	Description
1	Pressure Graph	The graph shows the pressure sensed by the system during an injection.
2	Phase View	The system highlights each phase as it starts.
3	Elapsed Time	Shows the duration of the injection. ◆ If a test injection is programmed, the elapsed time begins after the test injection.
4	Pressure Limit	Shows the programmed pressure limit.
5	Reminders	Indicates the number of set reminders.
6	Pressure Limit Line	Displays the programmed pressure limit on the pressure graph.
7	Injection Information	Displays the injection.
8	Indicators of Start of Phase	Shows the start of each phase.

NOTE: Elapsed time continues during an operator-initiated hold.

NOTE: The Pause symbol and Injector icon will blink during either an operator-initiated hold or a Programmed Hold.

10.7 Viewing Reminders

A Reminder alert will display after the programmed time for the Reminder has elapsed.

1. Press **OK** to dismiss a Reminder (Figure 10 - 5: Reminder Communication).

Figure 10 - 5: Reminder Communication

11 Completing an Injection

11.1 Injection Complete

When an injection completes,

- the workstation and the injector head emit an audible tone,
- the Injection Completed screen displays a summary of injection parameters and the actual parameters delivered (Figure 11 - 1: Injection Complete - Summary), and
- the elapsed time of the injection continues to increment until the Injection Completed screen is exited.

NOTE: Any remaining Reminders will display as they are triggered.

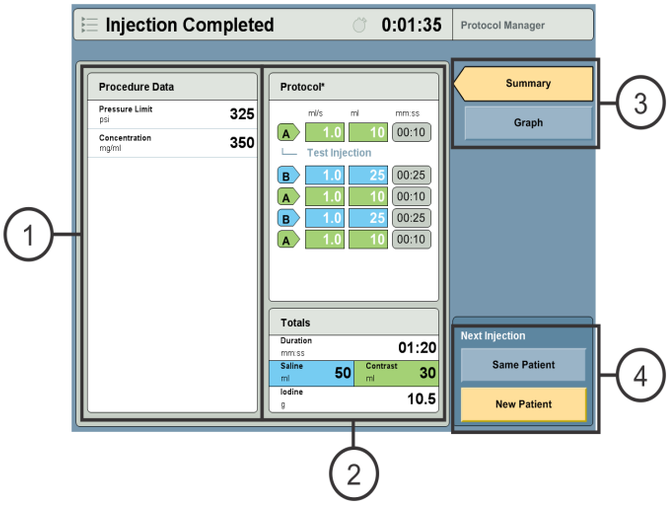


Figure 11 - 1: Injection Complete - Summary

1. **Procedure Data:** Displays operator-defined parameters at the procedural level.
2. **Protocol Summary:** Displays details of the completed protocol.
3. Toggles between Summary view and Graphical view.
4. Allows the selection of the next injection to be for either the same patient or a different patient.

NOTE: Elapsed time continues while this screen is displayed.

Select **Graph** (3) to view a graphical representations of the injection.

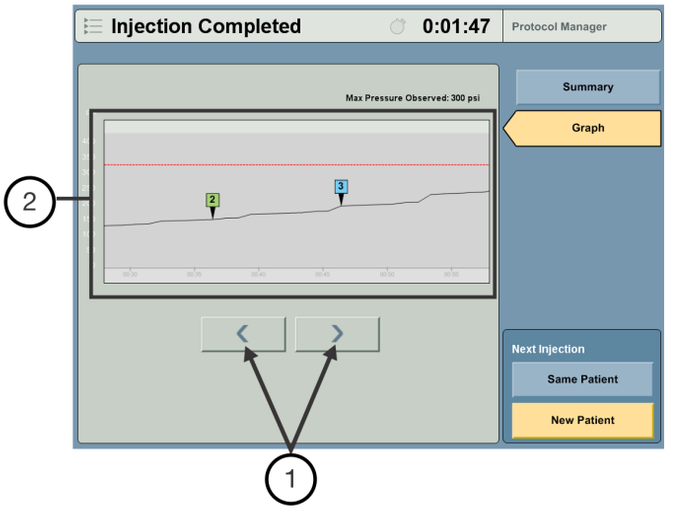


Figure 11 - 2: Injection Complete - Graph

1. Select the left or right arrow to scroll through the injection history.
2. Displays a graphical representation of the phases and pressure limits of the completed injection.

   NOTE: Elapsed time continues while this screen is displayed.

11.2 Injection Aborted

If the injection was halted, the Injection Aborted screen displays.

1. The system displays a reason why the injection aborted at the top of the screen (Figure 11 - 3: Injection Complete - Injection Aborted).
2. Displays the procedure data for the aborted injection.
3. Displays information for how much of the protocol was completed.

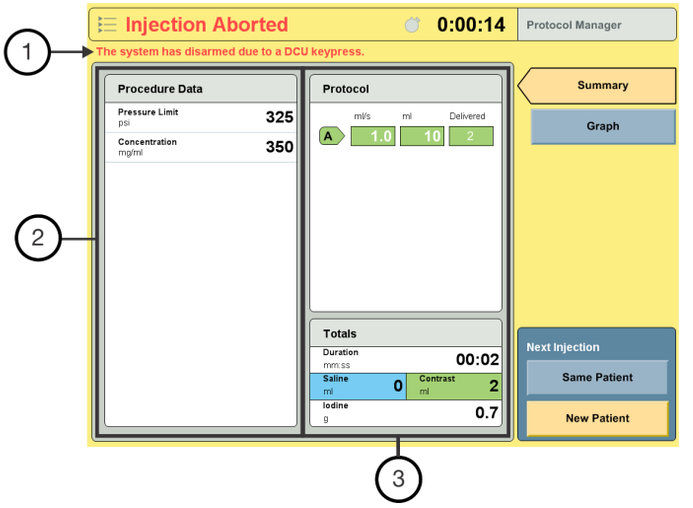


Figure 11 - 3: Injection Complete - Injection Aborted

11.3 Exiting Injection Complete

11.3.1 Conducting Another Injection

NOTE: The system resets the Reminders to zero when the Injection Completed screen is exited.

NOTE: Depending on how Fluid Delivery Setup is configured, the protocol may reset after the injection. By default, the system keeps the previous protocol for the next injection.

1. Select **Same Patient**.
   a. The Home screen displays.
   b. Refer to 8 - Protocol Management to create or edit a protocol, or repeat the steps for 10 - Arming and Injecting.
2. Select **New Patient** (Figure 11 - 4: Conducting Another Injection).
   a. The Home screen displays.
   b. Refer to 9 - Preparing for Injection for further instructions.

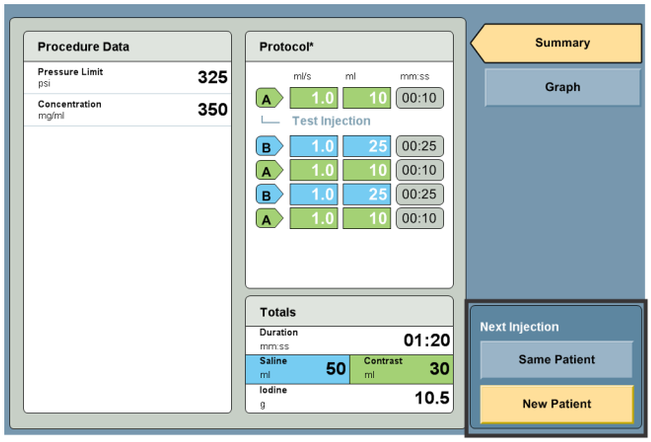


Figure 11 - 4: Conducting Another Injection

12 Removing Disposables

⚠ WARNING

Biological Contamination Hazard - Serious patient and/or worker injury or death may result.

- Properly discard fluid source containers and disposable items after use (refer to disposable label for specifics), or if there is any possibility that contamination may have occurred.
- Do not reuse single-use fluid sources. Refer to the fluid source manufacturers' instructions for use.

1. Disconnect the disposable tubing set from the catheter.

   NOTE: The disposable tubing set does not need to be disconnected from the syringe.

2. Remove the syringe by twisting counterclockwise ¼ turn and pulling out.

   NOTE: If the syringe cannot be removed, rotate the injector head manual knob approximately two revolutions in the reverse direction, then repeat step 2 above.

   NOTE: Once syringe has been removed, the piston automatically retracts to the start position (if enabled).

3. Discard fluid source containers and all used disposable items in accordance with facility policy.

13 Advanced Operations

13.1 System Setup

System Setup enables the configuration of settings that affect operation of the overall system.

1. From the launch menu, select **Setup**.
2. Select **System Setup** (Figure 13 - 1: Setup Categories (System Setup)).

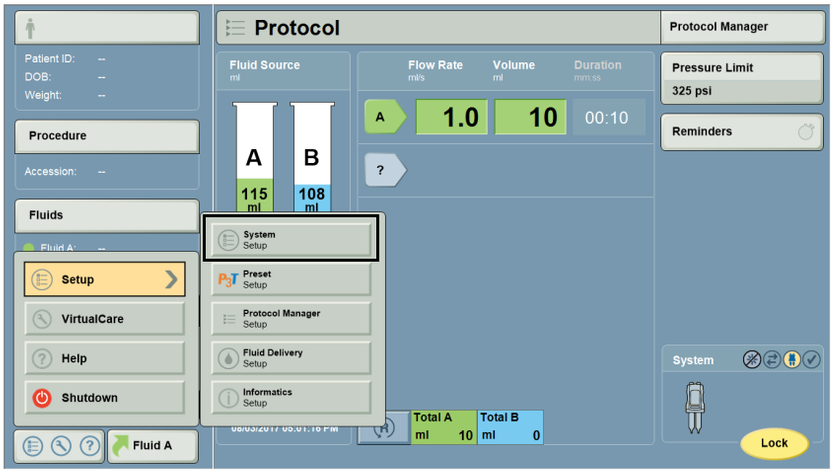


Figure 13 - 1: Setup Categories (System Setup)

3. Select a System Setup Option (Figure 13 - 2: Setup Screen (System Setup Screen Shown)).

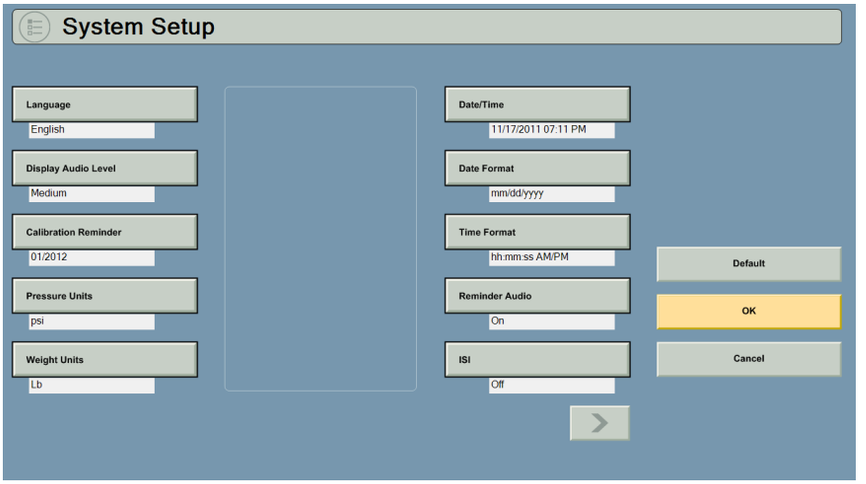


Figure 13 - 2: Setup Screen (System Setup Screen Shown)

4. Set the parameter for the selected option (Figure 13 - 3: Option Parameters (System Setup Screen Shown)).

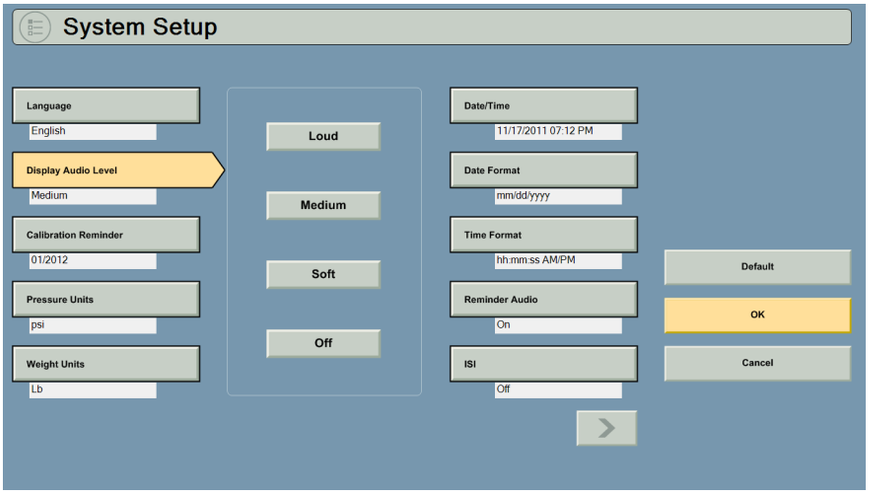


Figure 13 - 3: Option Parameters (System Setup Screen Shown)

5. Select **OK**.
6. Select **Yes** to confirm the changes.

13.1.1 System Setup Configurable Items

Table 13 - 1: Configurable Items

Configurable Item	Description
Language	Sets the display language.
Display Audio Level	Sets the audio volume for the display.
Calibration Reminder	Set the date for a calibration reminder.
Pressure Units	Sets the pressure measurement to PSI or kPa.
Weight Units	Sets the weight units.

Table 13 - 1: Configurable Items

Configurable Item	Description
Date/Time	Sets the system date and time.
Date Format	Sets the date format.
Time Format	Sets the time format.
Reminder Audio	Enables or disables audio for Reminders.
ISI	Enables ISI if ISI is available.
XDS	Enables XDS if XDS is available.
Injector Shutdown Display Mode	Sets Display mode during Injector Shutdown.
Display Brightness Level	Sets the brightness level for the display.

13.2 Setup of P3T Software Functionality

NOTE: The P3T functionality described in this section are separately licensable and purchasable options.

1. From the launch menu, select **Setup**.
2. Select **P3T Preset Setup** (Figure 13 - 4: Setup Categories (P3T Setup).

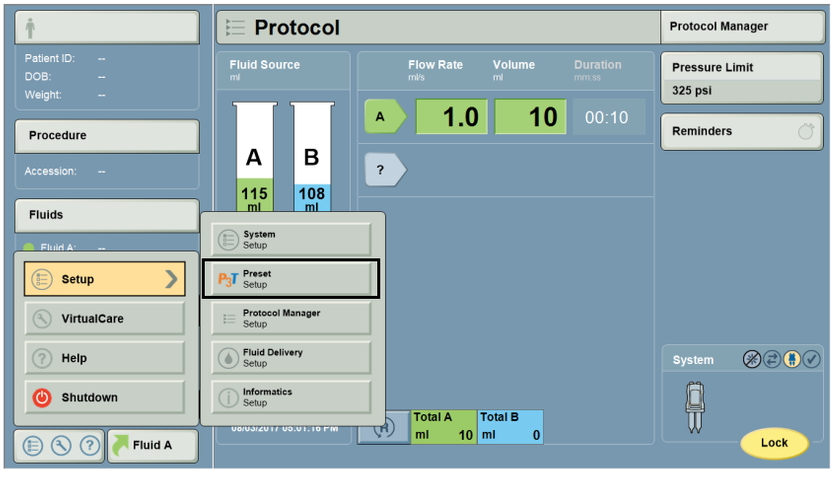


Figure 13 - 4: Setup Categories (P3T Setup)

13.2.1 P3T Setup Configurable Items

Table 13 - 2: Configurable Items.

Configurable Item	Description
P3T	Create and edit individual patient protocols. Refer to the appropriate Certegra® Workstation P3T module operation manual: P3T Cardiac, P3T Abdomen, or P3T Pulmonary Angiography (PA).

13.3 Protocol Manager Setup

Protocol Manager Setup manages the organization and display of protocols that are stored in the Protocol Manager. To create or edit a specific protocol, refer to 8.1 - Create or Edit a Protocol.

1. From the launch menu, select **Setup**.
2. Select **Protocol Manager Setup** (Figure 13 - 5: Setup Categories (Protocol Manager Setup)).

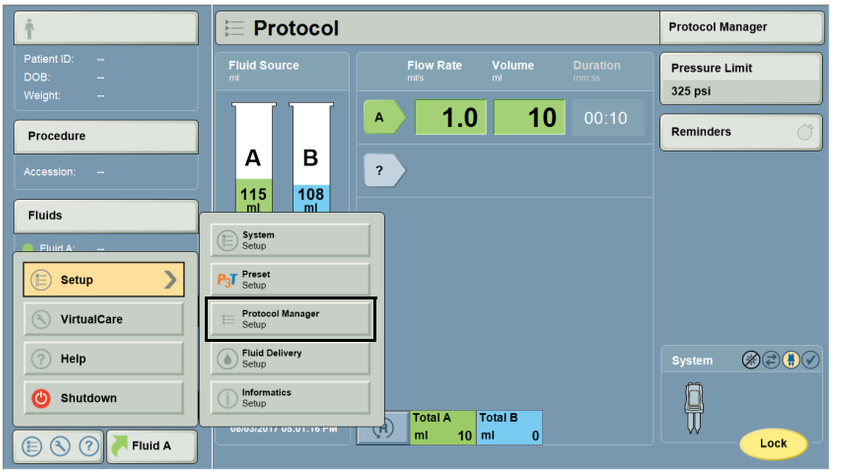


Figure 13 - 5: Setup Categories (Protocol Manager Setup)

13.3.1 Delete a Protocol

1. Go to **SETUP > PROTOCOL MANAGER SETUP** and select the protocol to delete.
2. Select **Delete** (Figure 13 - 6: Delete a Protocol).
3. Select **Yes** on the confirmation window to delete the protocol.

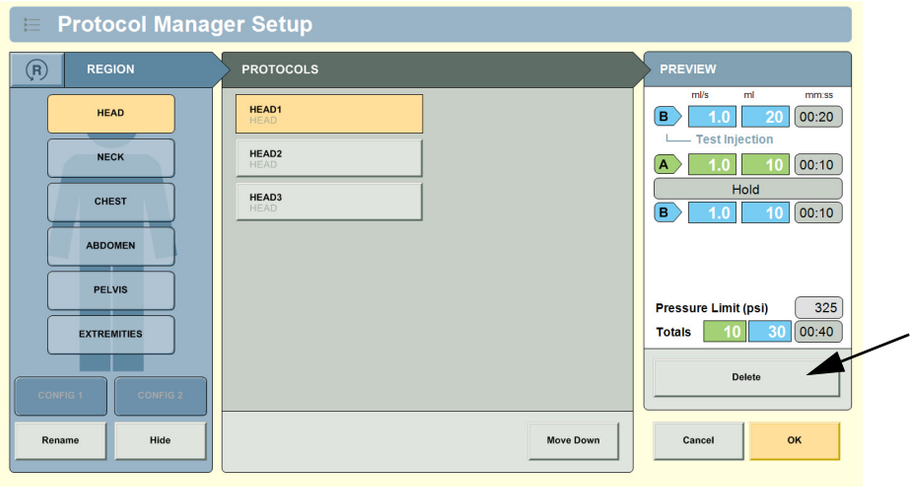


Figure 13 - 6: Delete a Protocol

13.3.2 Rearrange Protocol List

1. Go to **SETUP > PROTOCOL MANAGER SETUP** and select the protocol to move.
2. Select **Move Up** or **Move Down** (Figure 13 - 7: Rearrange Protocol List).

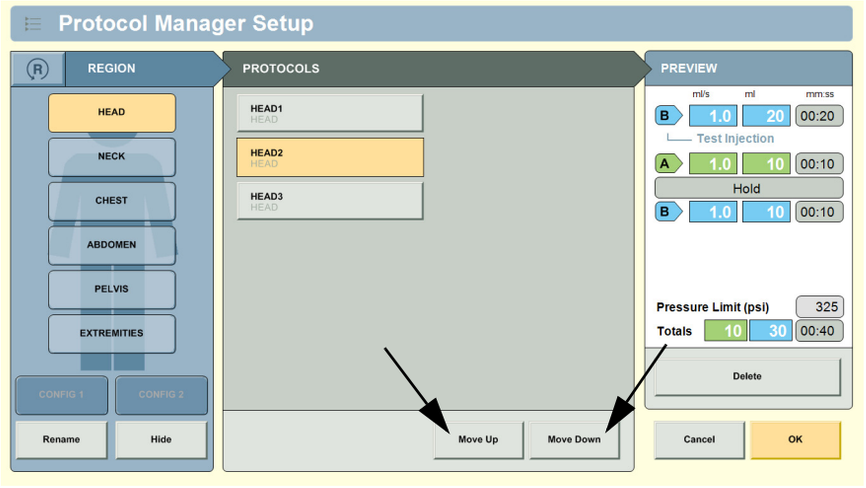


Figure 13 - 7: Rearrange Protocol List

13.3.3 Move Protocol to a New Region

1. Go to **SETUP > PROTOCOL MANAGER SETUP** and select the protocol to move.
2. Select **Change Region**.
3. Select the desired new region.

   NOTE: Configurable region(s) will not be accessible unless default name(s) replaced.

4. Select **Yes** on the confirmation window.

13.3.4 Hide/Show a Region

1. Go to **SETUP > PROTOCOL MANAGER SETUP** and select the region to hide/show.
2. Select **HIDE** to hide a region (Figure 13 - 8: Hide a Region), and select **SHOW** to display a hidden region.

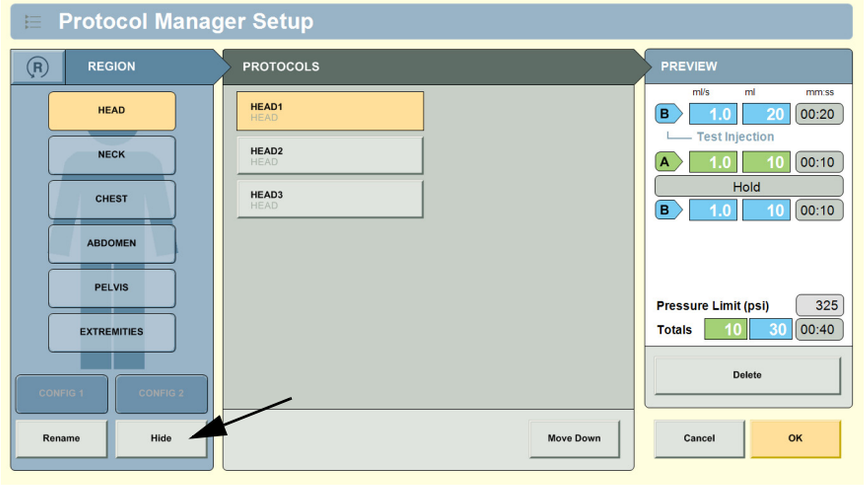


Figure 13 - 8: Hide a Region

13.3.5 Rename a Region

1. Go to **SETUP > PROTOCOL MANAGER SETUP** and select the region to rename.
2. Select **RENAME** (Figure 13 - 9: Rename a Region).

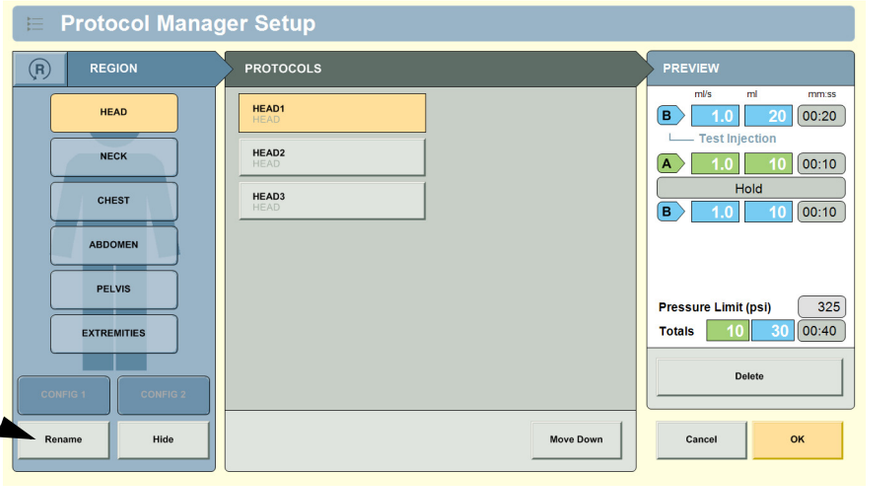


Figure 13 - 9: Rename a Region

3. Enter the name, and select **Enter**.
4. Select **OK**, and select **Yes** on the confirmation window to rename a region.

13.4 Fluid Delivery Setup

Fluid Delivery Setup configures settings that affect the operation of the fluid delivery system specifically.

1. From the launch menu, select **Setup**.
2. Select **Fluid Delivery Setup** (Figure 13 - 10: Setup Categories (Fluid Delivery Setup)).

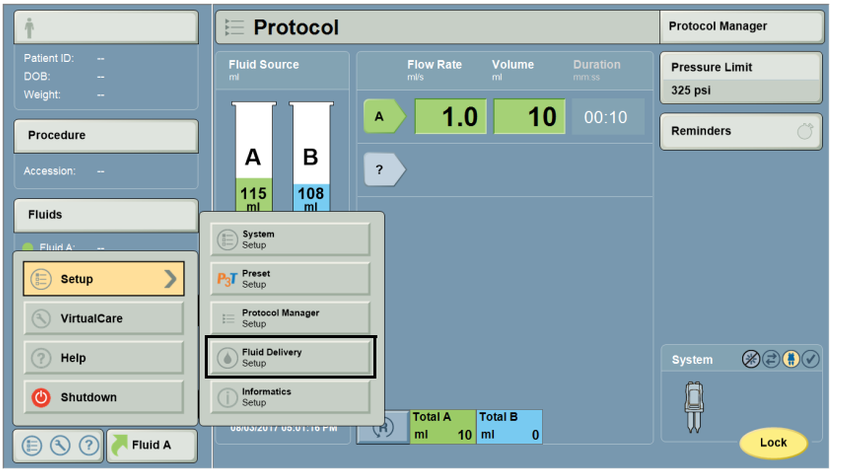


Figure 13 - 10: Setup Categories (Fluid Delivery Setup)

13.4.1 Fluid Delivery Setup Configurable Items

Table 13 - 3: Configurable Items

Configurable Item	Description
Priming Mode	Sets the injector to prime both syringes simultaneously or one after the other. The Simultaneous mode controls fluid movement through the union connector, moving both saline and contrast simultaneously during the priming process. The Sequential mode controls fluid movement through each branch of the union connector, moving saline and contrast separately, one after the other during the priming process.
Priming Source	Sets the syringe to be used for priming the tubing. Both syringes are primed. For a test inject, the operator may want to select the saline syringe as the priming source.
LPCT Type	Sets the type of Low Pressure Connector tubing being used. **NOTE:** Selecting the Other LPCT configuration setting will provide about 6 mL of prime fluid when using one syringe, or about 6.5 mL when using two syringes.
Test Inject Source	Sets the default syringe source for the test injection.
Test Inject Volume	Sets the default test injection volume.
Test Inject Rate	Sets the default flow rate for the test injection.
Protocol Programming Mode	The system calculates values for the displayed parameter. Sets the Programming Mode to enable the system to calculate the duration, flow rate, or volume. The Programming Modes follow: ◆ Calculate Flow Rate: SYSTEM CALCULATES THE FLOW RATE based on volume and duration. ◆ Calculate Volume: SYSTEM CALCULATES THE VOLUME based on flow rate and duration. ◆ Calculate Duration: SYSTEM CALCULATES THE DURATION based on flow rate and volume.
Total Volume Display	Sets the total volume to display the volumes in Syringe A and Syringe B, or the total in Syringe A and B combined.
Auto Retract	Enables or disables the Auto Retract feature to retract the piston after a syringe is removed.
Auto Advance	Enable or disables the Auto Advance feature to advance the piston after a syringe is installed.
Auto Load Purge Volume	When using filling devices from Bayer, choose one of the four volume selections based on the following guidelines: ◆ 30 mL for QFT ◆ 20 mL for short transfer sets (23” / 58 cm) ◆ 10 mL when loading through a spike only ◆ 0 mL (OFF) when loading through a filling device that has a check valve For other filling devices, consult manufacturer’s instructions for use.
Fluid Control	Sets the resistance level on the manual knobs.
Contrast Types	Set or add types of contrast.

Table 13 - 3: Configurable Items

Configurable Item	Description
Reset Protocol after Injection	Sets whether or not the protocol is reset to the factory default protocol after an injection completes.

13.5 Informatics Setup

Refer to the Certegra® Applications and Workstation Accessories operation manual for instructions on Informatics setup.

13.6 Help

This section provides instructions on how to access and use the Help System from the Launch Menu.

13.6.1 Accessing the Help System

1. Access the system settings by opening the **Launch Menu** (1) (Figure 13 - 11: Help System).
2. From the Launch Menu, select **Help** (2).

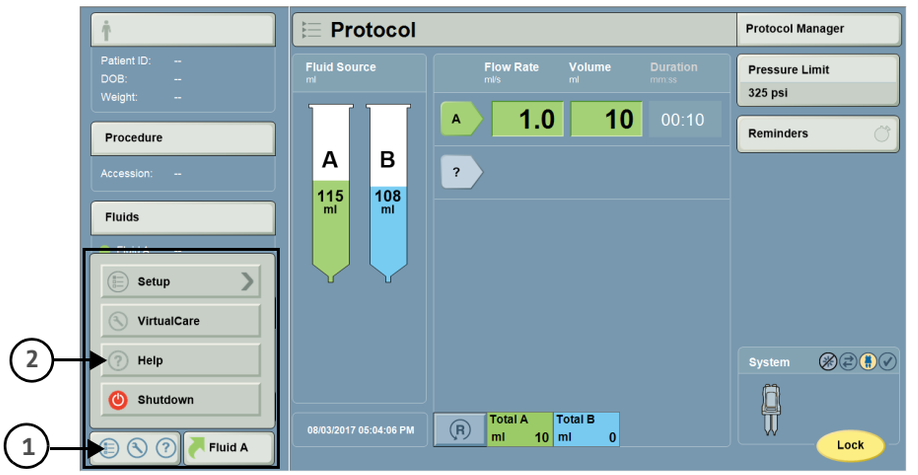


Figure 13 - 11: Help System

3. The Help screen will display (Figure 13 - 12: Help System Navigation).

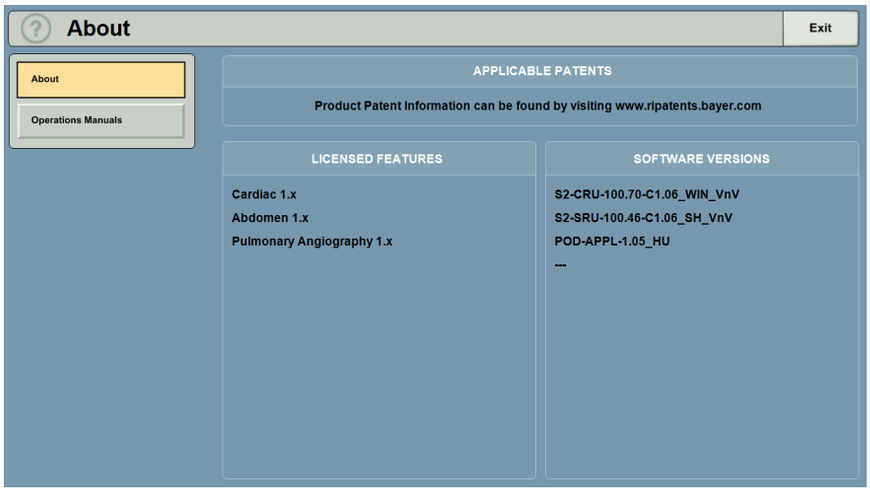


Figure 13 - 12: Help System Navigation

13.7 Fluid A

Select the Fluid A button to open a pop-up window that shows the most recent Fluid A (contrast) values entered. Keep these values by pressing **OK**, or select and enter new values by pressing **Cancel**. Refer to Figure 13 - 13: Fluid A Value Selection. Refer also to Certegra® Applications and Workstation Accessories manual.

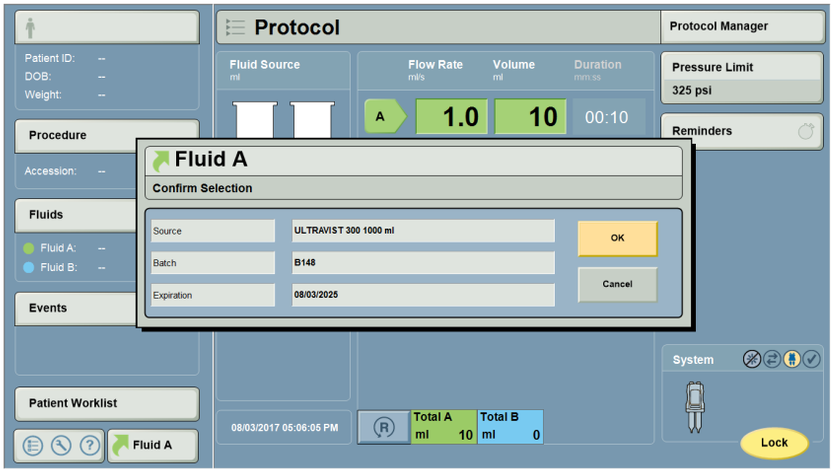


Figure 13 - 13: Fluid A Value Selection

14 Troubleshooting

14.1 Injector Head Error Indication

The LEDs on the injector head will blink when the system encounters an error. Refer to any error messages that appear on the workstation to recover from the error.

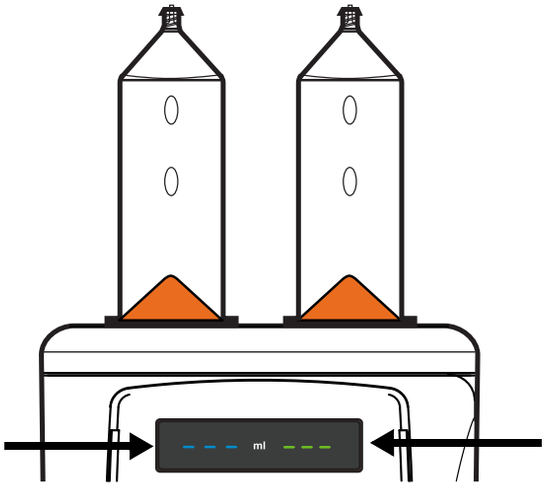


Figure 14 - 1: Injector Head Error Indication

14.2 Error Screen

An Error screen displays a unique error code or keywords for a Services Representative to categorize the problem and error text for the operator.

14.2.1 Error Recovery and Error Screen Messages

There are two types of errors: User Recoverable and Critical Error. User Recoverable errors can be fixed by following the prompted instructions or consulting Table 14 - 1. If a Critical Error occurs, record the error code and message, and try to reboot. If the error persists, contact Bayer.

The following is a list of error messages the injection system could display and corrections for those issues.

Table 14 - 1: Error Screen Messages

Error Message	Related Warning	Explanation
Expired syringe detected on side <A or B>.		The system compares the syringe manufacturing date to the date the syringe is installed on the system. When a syringe is past the expiration date, an error message informs the user. If an expired syringe is installed and the error message occurs, then: ◆ Confirm that the system's date and time are correct. Refer to 13.1 System Setup for further instructions. ◆ Remove the existing syringe and install a new syringe that is not expired, or ◆ Press **OK** to override the message and use the current syringe.
Previously installed syringe detected on side <A or B>.	WARNING: Syringe reuse may result in biological contamination, product degradation, and/or product performance issues.	The system tracks the number of times a syringe has been installed. If a syringe has been installed and removed multiple times, an error message occurs. To correct the error: ◆ Confirm that the syringe is being installed correctly. Refer to 9.2.2 Install and Fill a Syringe for instructions on how to correctly install a syringe, or ◆ Remove the existing syringe and install a new syringe. Properly discard disposable items after use, or if there is any possibility that contamination may have occurred, or ◆ Press **OK** to override the message and use the current syringe.
Syringe interface error on side <A or B>.		An error message can occur for any of the following reasons: ◆ A defective syringe is used, ◆ A syringe is incorrectly inserted on the system, or ◆ The injector is not correctly identifying the syringe. To correct the error: ◆ Remove the existing syringe and install a new syringe. Refer to 9.2.2 Install and Fill a Syringe for instructions on how to install a syringe. ◆ A software update may be required. Contact Bayer. If installing a new syringe from Bayer does not correct the problem, record the error code and contact Bayer.
Syringe set installed is not allowed.		The system is intended to be used with contrast and saline syringes that are the same volume for a patient injection. If a 150 mL syringe and a 200 mL syringe are both inserted on the system, an error message occurs. To correct the error: ◆ Remove the installed syringes and replace with two syringes that are the same volume, either (2) 150 mL or (2) 200 mL syringes.

Table 14 - 1: Error Screen Messages

Error Message	Related Warning	Explanation
Unable to identify genuine Bayer syringe on side <A or B>.	WARNING: Serious patient injury or death may result. Use only Bayer approved disposable products.	Genuine syringes from Bayer are marked with a digital signature. Stellant FLEX reads this signature, and an error message occurs if the installed syringe is not a genuine Bayer syringe. To correct the error: ◆ Remove the existing syringe and install a new syringe from Bayer, or ◆ Press **OK** to override the message and use the current syringe. If a genuine syringe from Bayer was installed and an error message occurs, the light pipe in the syringe interface needs to be cleaned. To correct the error: ◆ Remove the existing syringe. Clean the light pipe (refer to 15.3.3.2 Syringe Interface and Light Pipe), and install a new syringe, or ◆ Press **OK** to override the message and use the current syringe.
Syringe piston disengaged on side <A or B>. Turn knob two full rotations to move piston forward.		To arm the system for an injection, the last piston movement must be forward. An error message occurs when the system detects that the last piston movement was in reverse. To correct the error: ◆ Turn the knob of the side identified in the error message two full rotations to move the piston in the forward direction.
Multiple syringe errors detected.		An error message occurs when there are two or more issues with the syringe installed on the system. The issues possibly causing the error message are any combination of 1) an expired syringe, 2) a syringe not manufactured by Bayer, or 3) a previously used syringe. If this error message occurs, then: ◆ Remove the existing syringe and install a new syringe, or ◆ Press **OK** to override the message and use the current syringe.
Syringe barcode reader is unresponsive on side <A or B>. Press and select Injector Shutdown, then restart injector.		An error message occurs if the system was unable to read the barcode on a syringe from Bayer. To correct the error: ◆ Press Shutdown on the Launch menu. Select “Injector Shutdown” on the system display. Refer to 7.2 Shut Down the System. ◆ Press the power button on the workstation.

14.3 Other Troubleshooting Tips

- If a syringe with a corrupt barcode is inserted, the system may not be able to detect that the syringe has been inserted because one of the six barcodes may be unreadable. If the system cannot read the barcode, an error message may occur, and the automated features will not function. Remove, rotate, and re-insert the syringe to enable the system to read one of the other six barcodes on the syringe.
- If filling the syringe manually is causing an excess of air bubbles present in the syringe, try using the Auto Load feature of the injector. This may reduce the presence of air bubbles in the syringe.

- If the syringe size is not recognized, remove the installed syringes and replace with two syringes that are the same volume, either (2) 150 mL or (2) 200 mL syringes.
- If the syringe cannot be easily removed from the system, retract the injection system syringe piston by rotating the knob on the head counter-clockwise approximately two turns. Remove the syringe after retracting the syringe piston. If the syringe remains stuck in the injector: Promptly contact Bayer.
- If the system takes too long to identify a syringe and automatically advance the piston, then the light pipe in the syringe interface may be dirty. The system may take as long as five seconds to detect a syringe. To return the system to normal operation, clean the light pipe (refer to 15.3.3.2 Syringe Interface and Light Pipe).
- If a new syringe is installed and Auto Advance does not initiate, the syringe may not have been correctly inserted into the injector. The syringe plunger can be manually advanced using the Forward Piston controls. Refer to 9.2.2 Install and Fill a Syringe for instructions on how to correctly install a syringe.

14.4 System Tones

Both the Certegra® Workstation and the injector head are capable of emitting tones. These tones fall into two categories: General Tones and Notification Tones. The following is an identification of several interactions and events that may generate tones.

14.4.1 General Tones

Both the Certegra Workstation and the injector head produce General Tones as a result of key presses and soft button interaction. In many cases, these tones have system settings that can control the volume, and in some cases, these General Tones may be turned off. General Tones are used as indicators of an action being taken and do not denote a Notification.

14.4.2 Notification Tones

Notification Tones are also generated by both the Certegra Workstation as well as the injector head. These tones are intended to provide a notification of items requiring attention or an action to be taken, with few exceptions. These tones cannot be turned off or reduced in volume.

Notification Tones take many forms, including multi-pitch tones, multiple tones, and tones of differing duration. Notification Tones are distinctly different from General Tones and are designed to capture and direct attention to either the Certegra Workstation or the injector head as needed.

Tone Name	Where Encountered
Armed	Certegra Workstation and Injector Head
Prime Complete	Injector Head
Countdown to Scanner use	Injector Head
Critical Error	Certegra Workstation and Injector Head
Delay Expired	Certegra Workstation and Injector Head
Delay Warn	Certegra Workstation and Injector Head
Disarm	Certegra Workstation and Injector Head
Injection Complete	Certegra Workstation and Injector Head
Power Up	Certegra Workstation and Injector Head
Warning	Certegra Workstation and Injector Head

NOTE: Notification Tones are intended to draw attention to the injector head and/or the Certegra Workstation as indicated. Upon hearing a Notification Tone, refer to the area of interest as important safety or system information may be displayed

NOTE: The provision of Notification Tones should not take the place of active attention to the systems in use or the condition of the patient.

15 Cleaning and Maintenance

⚠ WARNINGS

Electro-Mechanical Hazard - Serious injury or death may result from exposure to hazardous voltages existing within the system.

- 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 or a local dealer for service or repairs.
- Do not expose system components to excessive amounts of water or cleaning solutions.
- Disconnect the system from line power when cleaning.

Hazard

- Do not service or perform maintenance on the injection system while in use with a patient.

Performance Hazard - Serious injury or death may result from not maintaining the injection system per instructions from Bayer.

- System may not perform to specifications if not calibrated or maintained per instructions by Bayer.

⚠ CAUTION

Environmental Hazard - Patient injury could result from potentially hazardous system electronic assembly material.

- Dispose of system components or accessories properly. Follow local regulations for proper disposal or contact Bayer for assistance.

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not soak or immerse any components in water or cleaning solution.
- Do not expose system components to excessive amounts of water or cleaning solutions.
- Perform routine cleaning and maintenance.

This section contains the recommended procedures for maintenance and an operational checkout of the system. Routine maintenance and inspection:

- Ensures continued performance of the injection system
- Reduces the possibility of equipment malfunction

The system must be properly maintained to ensure it is in peak operating condition.

NOTE: If contrast media has leaked inside any component of the system, contact Bayer for service.

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

NOTE: Bayer will make available upon request:

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

15.1 In the Case of Saline or Contrast Media Spills

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not use cleaning agents containing quaternary ammonium compounds (e.g. dimethyl ethylbenzyl ammonium chloride), such as Sani-Cloth® Plus, CaviWipes™, and ZEP® brand cleaners, and/or ethyl alcohol, such as Lysol® and Clorox® on the syringe pistons, syringe interface, or light pipe.

NOTE: To clean the syringe piston or syringe interface, refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe for instructions.

15.1.1 Cleaning the Injector Head

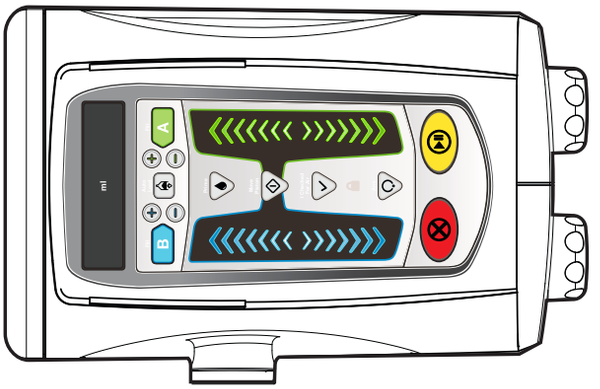


Figure 15 - 1: Injector Head

Frequency: In the Case of Saline or Contrast Media Spills

Materials:

- Clean, soft, non-linting wipe
- Warm water
- Cleaning Agent
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth (EPA registration # 9480-6) or CaviWipes™ Disinfecting Towelettes (EPA registration # 46781-8) within the United States except where noted.
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth or CaviWipes™ Disinfecting Towelettes in all other countries except where noted. If neither Sani-Cloth® Plus Germicidal Disposable Cloth nor CaviWipes™ Disinfecting Towelettes are available within your country, then use a disinfectant with 0.25% - 0.30% quaternary ammonium compounds and 14.8% - 20% isopropanol.

1. Turn off power to the injector.
2. Clean the injector head surfaces (excluding pistons and syringe interface, refer to Figure 15 - 3: Piston) with a clean, soft, non-linting wipe dampened with warm water (wet, but not dripping) for a minimum of 1 minute and until visibly clean. Replace wipe if it becomes visibly soiled. During the 1 minute cleaning time, make certain that all seams, recessed, areas and buttons are clean. Refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe to clean the syringe pistons and syringe interface.
3. Thoroughly dry the injector head using a dry, clean, soft, non-linting wipe.
4. Wipe all external surfaces with the exception of the syringe pistons and syringe interface (refer to Figure 15 - 3: Piston) with Sani-Cloth® Plus or CaviWipes™ for 1 minute or until visibly clean. Make certain that all seams, recessed areas, and buttons are clean. Refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe to clean the syringe pistons and syringe interface.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent cleaning agent (refer to the materials listed above), follow the same instructions specified in step 4.
5. Allow the injector head to thoroughly air dry.
6. Inspect the injector head to ensure all surfaces are clean.
7. If any visible contrast media or other debris is evident, repeat cleaning instructions steps 2 through 6 until no visible soil is detected.

15.2 Daily and In the Case of Visible Contamination

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not use cleaning agents containing quaternary ammonium compounds (e.g. dimethyl ethylbenzyl ammonium chloride), such as Sani-Cloth® Plus, CaviWipes™, and ZEP® brand cleaners, and/or ethyl alcohol, such as Lysol® and Clorox® on the syringe pistons, syringe interface, or light pipe.

NOTE: To clean the syringe pistons or syringe interface, refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe for instructions.

15.2.1 Cleaning the Injector Head

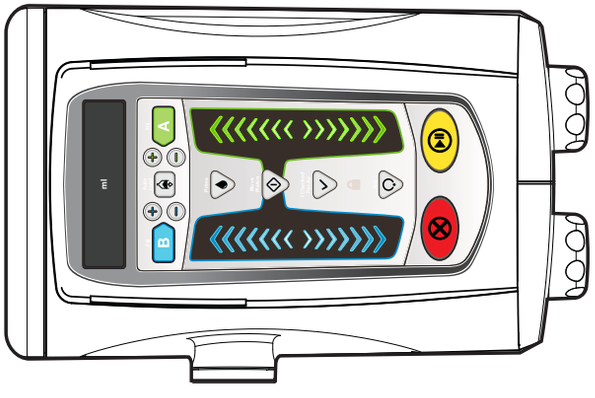


Figure 15 - 2: Injector Head

Frequency: Daily and In the Case of Visible Contamination

Materials:

- Clean, soft, non-linting wipe
- Warm water
- Cleaning Agent:
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth (EPA registration # 9480-6) or CaviWipes™ Disinfecting Towelettes (EPA registration # 46781-8) within the United States except where noted.
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth or CaviWipes™ Disinfecting Towelettes in all other countries except where noted. If neither Sani-Cloth® Plus Germicidal Disposable Cloth nor CaviWipes™ Disinfecting Towelettes are available within your country, then use a disinfectant with 0.25% - 0.30% quaternary ammonium compounds and 14.8% - 20% isopropanol.

1. Turn off power to the injector.
2. Clean the injector head surfaces (excluding pistons and syringe interface, refer to Figure 15 - 3: Piston) with a clean, soft, non-linting wipe dampened with warm water (wet, but not dripping) for a minimum of one 1 minute and until visibly clean. Replace wipe if it becomes visibly soiled. During the 1 minute cleaning time, make certain that all seams, recessed areas, and buttons are clean. Refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe to clean the syringe pistons and syringe interface.
3. Thoroughly dry the injector head using a dry, clean, soft, non-linting wipe.
4. Wipe all external surfaces with the exception of the syringe pistons and syringe interface (refer to Figure 15 - 3: Piston) with Sani-Cloth® Plus or CaviWipes™ for 1 minute or until visibly clean. Make certain that all seams, recessed areas, and buttons are clean. Refer to 15.3.3 - Cleaning the Pistons, Syringe Interface, and Light Pipe to clean the syringe pistons and syringe interface.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent cleaning agent (refer to the materials listed above), follow the same instructions specified in step 4.

5. Allow the injector head to thoroughly air dry.
6. Inspect the injector head to ensure all surfaces are clean.
7. If any visible contrast media or other debris is evident, repeat cleaning instructions steps 2 through 6 until no visible soil is detected.

15.2.2 Disinfecting the Injector Head

Frequency: Daily and In the Case of Visible Contamination

Material:

- Disinfecting Agent:
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth (EPA registration # 9480-6) or CaviWipes™ Disinfecting Towelettes (EPA registration # 46781-8) within the United States except where noted.
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth or CaviWipes™ Disinfecting Towelettes in all other countries except where noted. If neither Sani-Cloth® Plus Germicidal Disposable Cloth nor CaviWipes™ Disinfecting Towelettes are available within your country, then use a disinfectant with 0.25% - 0.30% quaternary ammonium compounds and 14.8% - 20% isopropanol.

1. Ensure the injector head has been thoroughly cleaned. Refer to 15.2.1 - Cleaning the Injector Head.
2. Use Sani-Cloth® Plus or CaviWipes™ to thoroughly wipe all external surfaces with the exception of the syringe pistons and syringe interface. Make certain that all seams, recessed areas, and buttons are clean.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent disinfecting agent (refer to the materials listed above), follow the same instructions specified in step 2.

3. Using Sani-Cloth® Plus or CaviWipes™, allow surfaces to remain visibly wet for 3 minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent disinfecting agent (refer to the materials listed above), allow the surface to remain visibly wet per the manufacturer's instructions.

4. Allow the injector head to thoroughly air dry.

15.3 Daily

The following procedures are recommended for daily inspection of the system.

Before use each day, the system should be visually inspected, using the procedures outlined in this section, to ensure that all surfaces are free from defects and visible contamination. If any defects are detected, either repair the system, or call the local office for Bayer or the local authorized dealer for service. Do not use the system until the problem is corrected. If visible contamination is evident on any surface of the device, follow the cleaning process outlined below before using the system.

15.3.1 Inspecting the Injection System

Frequency: Daily

- Inspect the housing for any damage or cracks that could allow fluid to leak inside or weaken the structural integrity of the unit.
- Inspect all cables connected to the system. Look for cuts, cracks, worn spots, or other obvious damage to the cables. Ensure all connectors are properly seated.
- Inspect the pedestal, base, overhead counterpoise system, and support arm for cracks and other defects that could weaken the structure.
- Ensure all mounting bolts and screws are secure.
- Inspect the pivot points. The head and support arm must pivot freely. The injector head should rotate on the support arm no more than 270°. The support arm should not rotate on the center post more than 350°.
- Ensure the casters roll smoothly with no binding or scraping.
- Ensure all locking mechanisms on the casters are functional.

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

  NOTE: Contact Bayer or a local dealer for service or repairs.

15.3.2 Cleaning and Disinfecting the injector Head

Frequency: Daily

1. Ensure the injector head has been thoroughly cleaned. Refer to 15.1.1 - Cleaning the Injector Head.
2. Ensure the injector head has been thoroughly disinfected. Refer to 15.2.2 - Disinfecting the Injector Head.

15.3.3 Cleaning the Pistons, Syringe Interface, and Light Pipe

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not use cleaning agents containing quaternary ammonium compounds such as Sani-Cloth® Plus and/or ethyl alcohol, such as Lysol® on the syringe pistons, syringe interface, or light pipe.

Frequency: Daily

15.3.3.1 Pistons

Figure 15 - 3: Piston

Materials:

- Clean, soft, non-linting wipe
- Cotton swab
- Warm water

1. Place the injector head in the vertical position.
2. Fully advance both pistons using the forward piston controls.
3. Turn off power to the injector.
4. Clean all surfaces of pistons at least 1 time with a clean, soft, non-linting wipe dampened with warm water (wet, but not dripping) until visibly clean from contrast media and other debris.

5. Thoroughly dry the pistons using a dry, clean, soft, non-linting wipe.
6. Inspect the syringe pistons to ensure all surfaces are clean.
7. If any visible contrast media or other debris is evident, repeat cleaning instructions steps 4 through 6 until no visible soil is detected.

15.3.3.2 Syringe Interface and Light Pipe

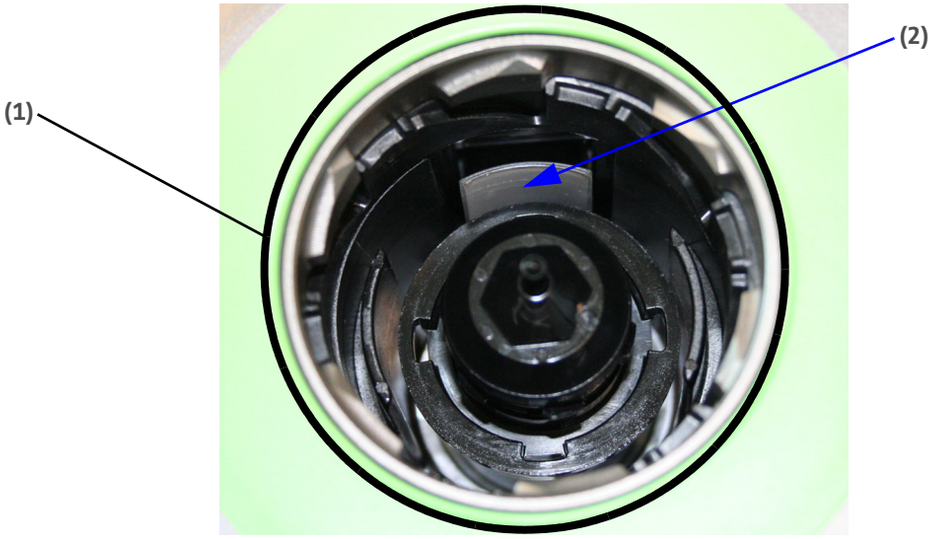


Figure 15 - 4: Syringe Interface (1) and Light Pipe (2)

Materials:

- Clean, soft, non-linting wipe
- Cotton swab
- Warm water

1. Turn on the power to the injector.
2. Fully retract both pistons using the reverse piston controls.
3. Turn off power to the injector.
4. Rotate the injector head to have access into the syringe interface.
5. Clean all surfaces of the inner area of both syringe interfaces at least 1 time with a clean, soft, non-linting wipe dampened with warm water (wet, but not dripping) until visibly clean from contrast media and other debris.
6. Clean both light pipes at least 1 time using a cotton swab dampened with warm water until visibly clean from contrast media and other debris (Figure 15 - 4: Syringe Interface (1) and Light Pipe (2)).
7. Dry both light pipes with dry cotton swabs.
8. Inspect the syringe interfaces and light pipes to ensure all surfaces are clean.
9. If any visible contrast media or other debris is evident, repeat cleaning instructions steps 5 through 8 until no visible soil is detected.

15.3.4 Cleaning the Pedestal With Integrated IV Pole, Overhead Counterpoise System (OCS), and Base

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not use chlorine bleach or bleach equivalents on the pedestal.

Frequency: Daily

Material:

- Clean, soft, non-linting wipe
- Warm water
- Cleaning Agent:
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth (EPA registration # 9480-6) or CaviWipes™ Disinfecting Towelettes (EPA registration # 46781-8) within the United States.
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth or CaviWipes™ Disinfecting Towelettes in all other countries. If neither Sani-Cloth® Plus Germicidal Disposable Cloth nor CaviWipes™ Disinfecting Towelettes are available within your country, then use a disinfectant with 0.25% - 0.30% quaternary ammonium compounds and 14.8% - 20% isopropanol.

1. Turn off power to the injector.
2. Wipe the pedestal with integrated IV pole, OCS, and base with a clean, soft, non-linting wipe dampened with warm water for 1 minute.
3. Wipe the pedestal with integrated IV pole, OCS, and base with Sani-Cloth® Plus or CaviWipes™ for 1 minute or until visibly clean.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent cleaning agent (refer to the materials listed above), follow the same instructions specified in step 3.

4. Inspect the pedestal with integrated IV pole, OCS, and base to ensure all surfaces are clean.
5. If any visible contrast media or other debris is evident, repeat the cleaning instructions steps 2 through 4 until no visible soil is detected.

15.3.5 Cleaning the Workstation Screen

Frequency: Daily

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- Do not spray cleaning solutions directly onto the workstation screen.
- Do not spray water or cleaning solutions onto the rear surface of the workstation.
- Do not use cleaning agents that contain phenol.
- Do not use cleaning agents that contain ethanol.
- Do not use cleaning agents that contain strong aromatic, chlorinated, ketone, or ether solvents.

Material:

- Clean, soft, non-linting wipe
- Warm water
- Cleaning Agent:
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth (EPA registration # 9480-6) or CaviWipes™ Disinfecting Towelettes (EPA registration # 46781-8) within the United States.
  - Use either Sani-Cloth® Plus Germicidal Disposable Cloth or CaviWipes™ Disinfecting Towelettes in all other countries. If neither Sani-Cloth® Plus Germicidal Disposable Cloth nor CaviWipes™ Disinfecting Towelettes are available within your country then use a disinfectant with 0.25% - 0.30% quaternary ammonium compounds and 14.8% - 20% isopropanol.

1. Wipe the workstation screen with a clean, soft, non-linting wipe dampened with warm water for 1 minute.
2. Wipe the workstation screen with Sani-Cloth® Plus or CaviWipes™ for 1 minute or until visibly clean.

   NOTE: If in a country where Sani-Cloth® Plus or CaviWipes™ are not available, and using an equivalent cleaning agent (refer to the materials listed above), follow the same instructions specified in step 2.
3. Inspect the workstation screen to ensure all surfaces are clean.
4. If any visible contrast media or other debris is evident, repeat the cleaning instructions steps 1 through 3 until no visible soil is detected.

15.4 Monthly

Once a month, perform an operational checkout.

15.4.1 Operational Checkout

A basic functional checkout of the system should be included as part of regular maintenance. Verifying proper operation of the 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, call your Services Representative.

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

System Labels

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

Power Up

1. Apply power to the system.
2. Verify the Safety screen displays.
3. Press **CONTINUE** to acknowledge the messages on the Safety screen.
4. Verify proper audible tones are functioning on the workstation and injector head.
5. Verify all displays and indicators are functioning properly.
6. Verify the arm lights on the injector head are functioning.

Programming

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

1. Ensure the heat maintainers are connected.

2. Fully advance and reverse the pistons by using the **Move Piston** button and the forward/reverse piston controls.
3. Ensure Auto Advance and Auto Retract are enabled.
4. Enter and lock the following protocol:

		Flow Rate	Volume
Phase 1:	Syringe A:	10 mL/s	70 mL
Phase 2:	Syringe B:	2.5 mL/s	29 mL
Phase 3:	Syringe A:	5.0 mL/s	100 mL
Phase 4:	Syringe B:	0.1 mL/s	1 mL

5. Install syringes and ensure the piston automatically docks and fully advances the syringe plungers.
6. Perform Auto Load.
7. Arm and initiate an injection.
8. In one of the phases, activate the HOLD feature for at least 10 seconds.
9. Resume the injection, and verify that the injection completes normally and that the Injection Complete screen displays the results.
10. Advance plungers to the full forward position, remove syringes, and ensure the pistons automatically retracts.
11. Inspect the heat maintainer. Make sure it is warm and the fault indicator is not illuminated.
12. Ensure all injector functions (such as filling, priming, reset, etc.) are working correctly.

15.5 Annually

Bayer offers Preventative Maintenance Programs. These annual programs greatly assist in maintaining accuracy and reliability, and can also extend the life of the system. Contact a local office for Bayer or a local authorized dealer for further information. Refer to the back cover of this manual for address, telephone, and fax information.

15.5.1 Injection System Calibration

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

15.5.2 Checking Leakage

As part of an annual maintenance program performed by a qualified services representative or authorized dealer, both electrical leakage and protective earth ground continuity checks should be performed.

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

15.6 Reinstalling the System in Another Room

If re-installing the system in another room, disconnect the cable, lower the IV pole, and fold in the hooks. Position the injector head vertically. When moving the injector, hold the pedestal below the point indicated by the label on the pedestal arm. If the pedestal does not contain this label, hold the pedestal no higher than 36 inches above the floor. Maintain a grip on the injector when moving it across a threshold or over other obstacles in the path of travel.

16 Options and Accessories

NOTICE:

Equipment damage may result or system may fail to operate.

- The system is meant to connect with the specific devices listed in 16 - Options and Accessories, and should not be used with other medical devices or medical device technologies.

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

16.1 Mounting Options

Catalog Number	Description
SHP 800	TALL FIXED HEIGHT PEDESTAL
OCS CEIL 58-S	OCS, 580MM CEILING MOUNT, PORTEGRA2
OCS CEIL 85-S	OCS, 850MM CEILING MOUNT, PORTEGRA2
OCS CEIL 100-S	OCS, 1000MM CEILING MOUNT, PORTEGRA2
OCS TRACK 58-S	OCS 580MM TROLLEY MOUNT, PORTEGRA2
OCS TRACK 80-S	OCS, 800MM TROLLEY MOUNT, PORTEGRA2
OCS WALL-S	OCS WALL MOUNT, PORTEGRA2
OCA PLATE CEIL	CEILING MOUNTING PLATE, PORTEGRA2
OCS CEIL 70Si	OCS,696MMCEILING MOUNT,PORTEGRA2I
OCS CEIL 97Si	OCS,996MMCEILING MOUNT,PORTEGRA2I
SCT MK	ASSY, FINAL, KIT, MOBILE, MBL KT

16.2 Injector Head Extension Cables

Catalog Number	Description
SHC 700 25	25 ft. (7.6 m) cable
SHC 700 50	50 ft. (15.2 m) cable
SHC 700 75	75 ft. (22.9 m) cable
SHC 700 100	100 ft. (30.5 m) cable

16.3 Workstation Extension Cables

Catalog Number	Description
SDC 700 5	5 ft. (1.52 m) cable
SDC 700 25	25 ft. (7.6 m) cable

16.4 Accessories

Catalog Number	Description
SSH 200F	Syringe Heat Maintainer
SHS 700 05	Handswitch
ISI 700	Imaging System Interface Device
ISI 800	Imaging System Interface Device
ISI 900H	Imaging System Interface Device (Hitachi)
ISI 900G	Imaging System Interface Device (General Electric)
ISI 900S	Imaging System Interface Device (Siemens)
ISI 900T	Imaging System Interface Device (Toshiba)
ISI 900U	Imaging System Interface Device (United Imaging)
ISI2	Imaging System Interface Device
BCRFLEX	MEDRAD® Stellant FLEX with Certegra® Workstation Barcoding Accessory

16.5 Manuals

Catalog Number	Description
SSM 700 1	Service Manual

16.6 Sterile Disposables

Catalog Number	Description
FLEXS-150-SPK	Single 150 mL Syringe with Spike
FLEXD-150-SPK	Dual 150 mL Syringe with Spikes
FLEXS-200-SPK	Single 200 mL Syringe with Spike
FLEXD-200-SPK	Dual 200 mL Syringe with Spikes
FLEXS-150-QFT	Single 150 mL Syringe with Quick Fill Tube
FLEXD-150-QFT	Dual 150 mL Syringe with Quick Fill Tube
FLEXS-200-QFT	Single 200 mL Syringe with Quick Fill Tube
FLEXD-200-QFT	Dual 200 mL Syringe with Quick Fill Tube
FLEXD-150-SCS	Dual 150 mL Syringe with Large Saline Spike and Small Contrast Spike
FLEXD-200-SCS	Dual 200 mL Syringe with Large Saline Spike and Small Contrast Spike

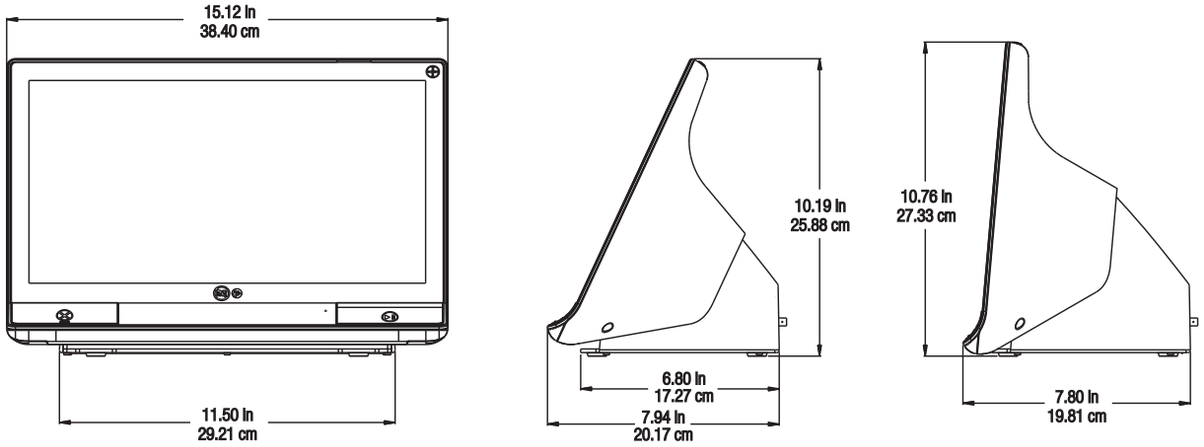
Catalog Number	Description
SSS-LP-60	60” Low Pressure Connector Tubing with Prime Tube
SSS-LP-60-T	60” Low Pressure Connector Tubing with 6” “T” Connector and Prime Tube
SJS-LP-60-T-J	60" Low Pressure Connector Tubing with 14" "T" Connector and Prime Tube
LP-96-T-CV	96" Low Pressure Connector Tubing with "T" Connector and Check Valve

17 Specifications

17.1 Workstation Specifications

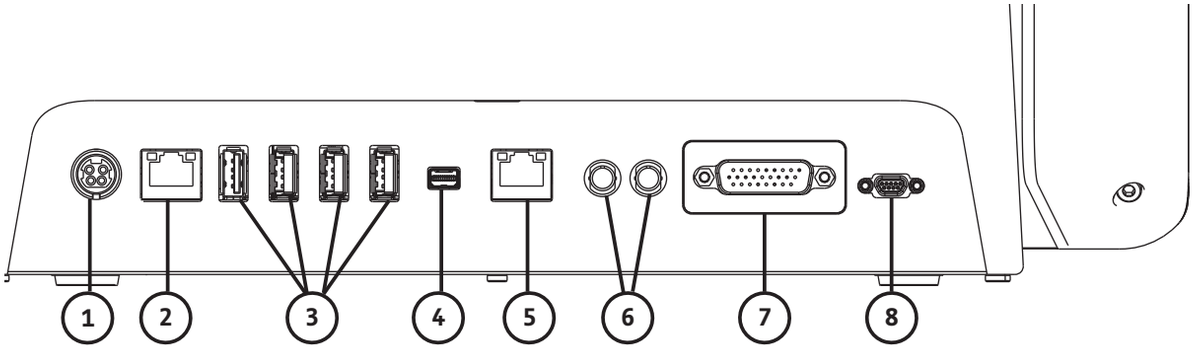
17.1.1 Workstation Dimensions and Weight

NOTE: Listed weight and dimensions are approximate.



Weight: 15.8 lbs (7.2 kg)

17.1.2 Workstation Connections



#	Description	#	Description
1	Power input and supply connection **NOTE:** For the power input and supply connection, the Workstation requires use of a Listed Class 2, LPS, or Listed Information Technology Equipment (ITE) power supply with output rated 12Vdc, minimum 6A, marked LPS. Use only Bayer P/N: 86100134.	2	Computer network connection
3	USB connections	4	Connection for screen extension/transfer to a second display (for Bayer use only)
5	Connection not applicable for system	6	Connections not applicable for system
7	Injector head connection	8	Handswitch connection
	Service ports - not shown (for Bayer use only)		

17.1.3 Workstation Input Power Requirements

100-240 VAC

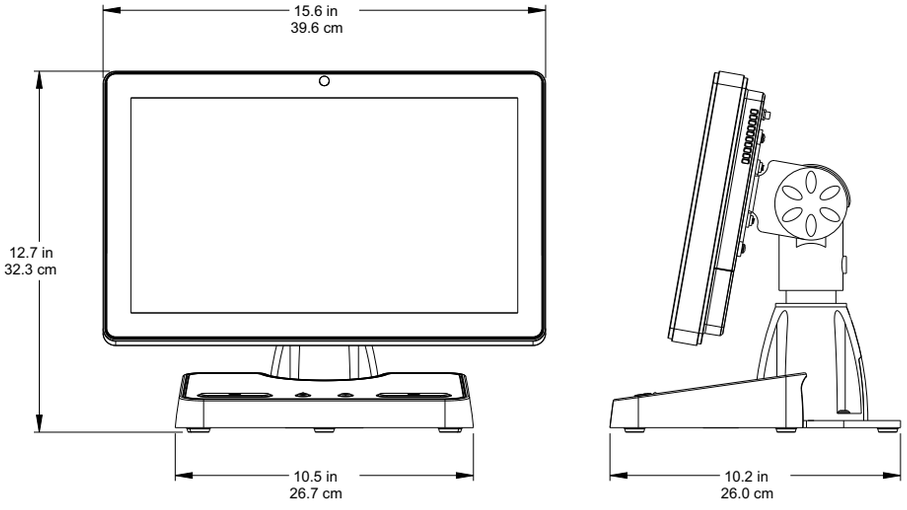
50-60 Hz

1.3A

17.2 Workstation with Pod Specifications

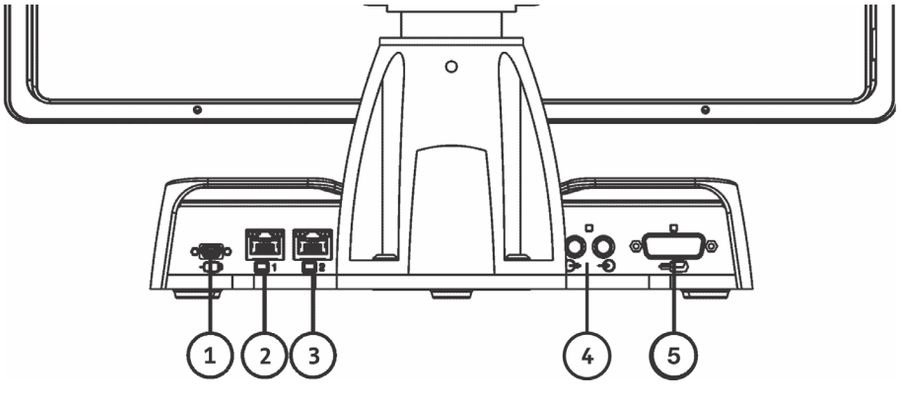
17.2.1 Workstation with Pod Dimensions and Weight

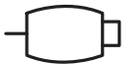
NOTE: Listed weight and dimensions are approximate.



Weight: 17.6 lbs (8.0 kg)

17.2.2 Workstation with Pod, Pod Connections

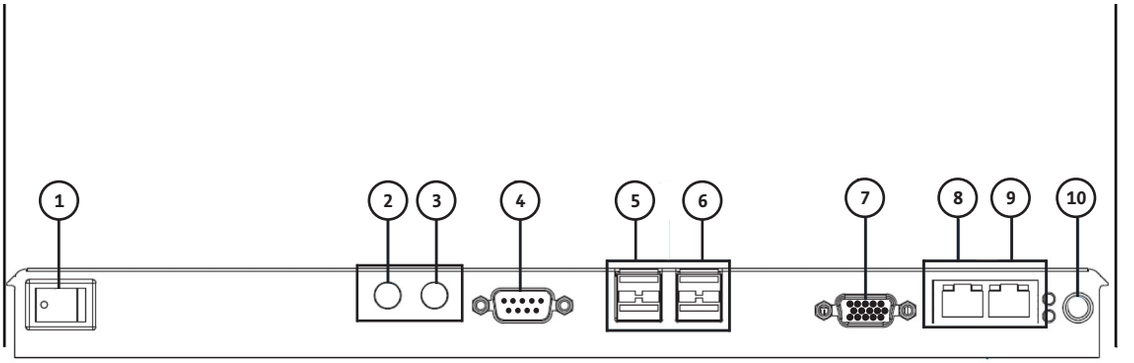


#	Icon	Description	#	Icon	Description
1		Identifies handswitch connection.	2		Identifies ethernet connection (for Bayer use only).
3		Identifies ethernet connection (for connecting to the display).	4		Identifies input and output connections not applicable for MEDRAD® Stellant FLEX. Not for use with the system.

5		Identifies injector head connection			

17.2.3 Workstation with Pod, Display Connections

NOTE: Display connections shown are for Bayer use only.



#	Icon (if applicable)	Description	#	Icon (if applicable)	Description
1		Indicates power switch for display.	2		Connection not applicable for MEDRAD® Stellant FLEX. Not for use with the system.
3		Connection not applicable for MEDRAD® Stellant FLEX. Not for use with the system.	4		COM1 connection
5		USB connection	6		USB connection
7		VGA connection	8		LAN 2 connection
9		LAN 1 connection	10		12V DC-IN connection

17.2.4 Workstation with Pod, Display Input Power Requirements

100-240 VAC

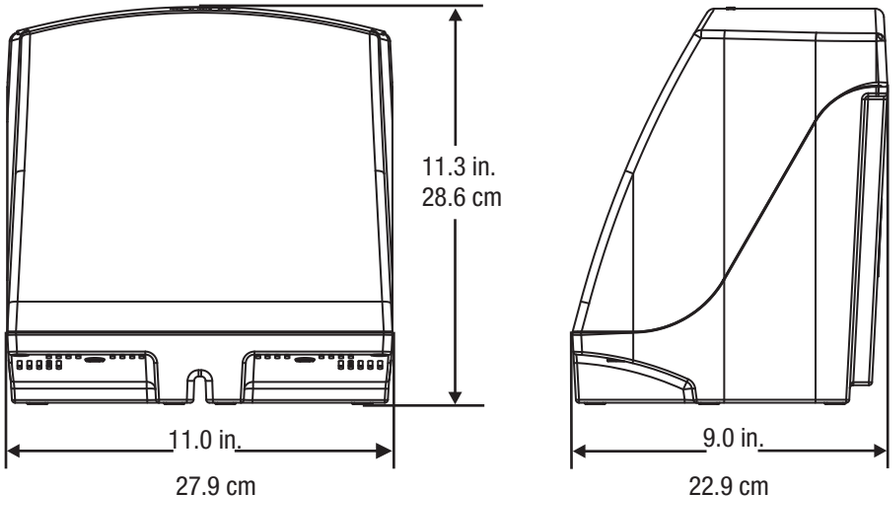
47-63 Hz

1.6A

17.3 Base Unit Specifications

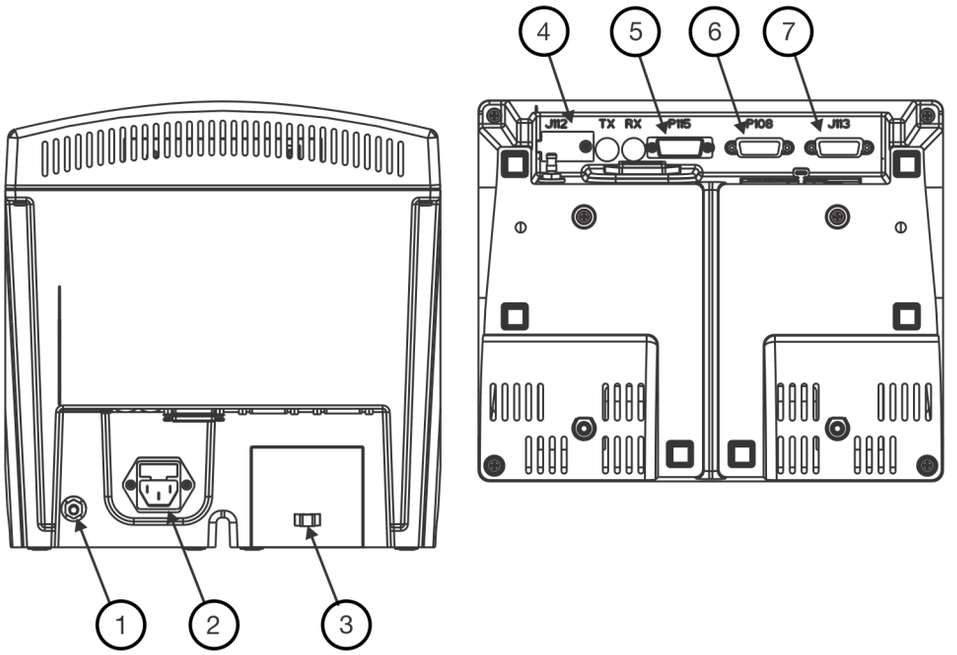
17.3.1 Base Unit Dimensions and Weight

NOTE: Listed weight and dimensions are approximate.



Weight: 13.6lbs (6.17 kg)

17.3.2 Base Unit Connections



1	Equipotential connection	2	Power connection	3	Injector head cable clamp
4	Service connection (J112)	5	Future use (P115)	6	Workstation connection (P108)
7	Injector head connection (J113)				

17.3.3 Base Unit Input Power Requirements

NOTE: Base unit input power requirements apply to the system as the system receives its power through the base unit.

100-240 VAC

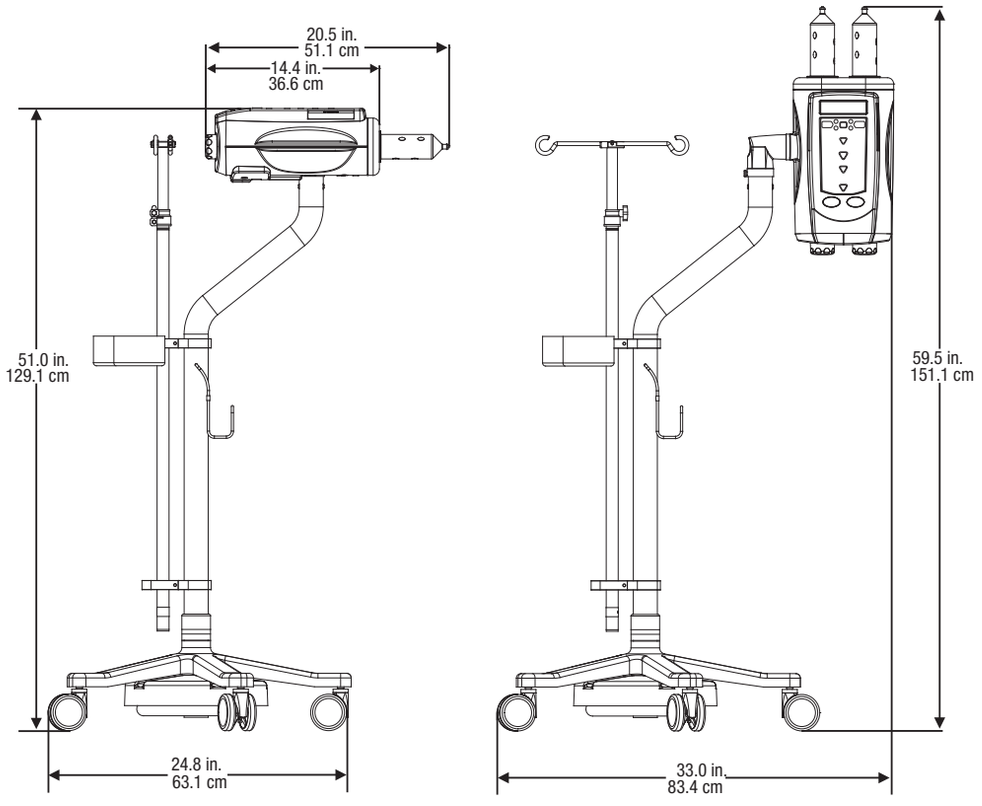
50-60 Hz

300 VA

17.4 Injector Head Specifications

17.4.1 Injector Head Dimensions and Weight

NOTE: Listed weight and dimensions are approximate.



Weight: 76 lbs (34.5 kg)

17.5 Environmental Specifications

17.5.1 Non-Operating (Transportation and Storage)

Temperature:	-20° C to 60° C (-4° F to +140° F)
Humidity:	10% to 95% R.H., non-condensing
Air Pressure:	57 kPa to 106 kPa

17.5.2 Operating

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

Temperature:	+15° C to + 30° C (+59° F to +86° F)
Humidity:	20% to 90% R.H.
Air Pressure:	70 kPa to 105 kPa

17.5.3 Protection Against Electrical Shock

Per IEC 60601-1, the system is designed as a Class 1 or 2 Medical Device with a type BF applied part.

Type BF corresponds to the degree of protection against electrical shock by the applied part of the Medical Device. Class 1 Equipment requires a protective earth connection (electrical grounding) to ensure protection against electrical shock in the event of a failure of the basic insulation system. The following are requirements for a Class 1 type BF Medical Device.

17.5.3.1 Electrical Leakage

Complies with EN, 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)
Patient Connection Leakage Current:	< 100 microamps (NC)

17.5.3.2 Ground Continuity

< 0.2 ohms from power cord ground pin to base, workstation, or head enclosure.

17.5.4 EMI/RFI

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

17.5.5 Protection Against the Ingress of Fluids

Per IEC 60601-1, the injector head has been classified as drip-proof equipment. This component of the system is 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. This is indicated by the IPX1 designation on the injector head.

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 Service personnel for performing appropriate electrical safety and operational checks prior to use.

17.5.6 Mode of Operation

Per IEC 60601-1 the mode of operation for the base and the display is continuous operation. They are capable of operation under normal load for an unlimited period, without excessive temperature being developed.

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

17.5.7 Fluid Delivery Performance

Table 17 - 1: Fluid Delivery Performance

Description	Specification
Volume Range	1 mL to maximum syringe capacity in 1 mL increments
Flow Rate Range	0.1 to 10 mL/sec in 0.1 mL/sec increments
Programmable Pressure limit (PSI / kPa)	Pressure Limit selections (PSI / kPa): Choice of 50/345, 100/689, 150/1034, 200/1379, 225/1551, 250/1724, 300/2068, 325/2241

Table 17 - 1: Fluid Delivery Performance

Description	Specification
Pause	1 second to 900 seconds in 1 second increments
Hold	Maximum Hold time is 20 minutes
Syringes (Volume Capacity)	Maximum two (150 mL or 200 mL)
Injection Capabilities	Maximum 6 phases per protocol
Elapsed Injection Time	Minimum of 0 - 999 seconds
Flow Rate Accuracy	**NOTE:** The injection system performs within the defined accuracy specifications over steady state. Steady state is averaged over: - a 2 second interval for flow rates > 5 mL/s, or - a 10 mL volume for flow rates ≤ 5 mL/s Single Syringe Injection: ◆ +/- (5% + 0.1) mL/s Simultaneous (DualFlow) Injection: ◆ +/- 25% for flow rates < 1 mL/s ◆ +/- 15% for flow rates >= 1 mL/s and < 2 mL/s ◆ +/- 10% for flow rates >= 2 mL/s
Volume Delivered Accuracy	Single Syringe Injection: ◆ +/- (2% + 1 mL) Simultaneous (DualFlow) Injection: ◆ +/- (4% + 2 mL)

17.6 Over and Under Infusion Protection

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

- Warnings displayed on the Safety screen act as a reminder to check the programmed injection parameters prior to the injector being armed.
- An on-screen indication of insufficient volume is provided whenever the total volume programmed to be delivered is greater than the amount of fluid in the syringe.
- Injection monitoring is performed in the injector head to detect over rate or over volume conditions due to system faults. The delivered volume is also monitored against the total programmed volume for the injection.
- When a fault condition, hold, or stop is detected, the injection will stop within 5 mL.
- Once the system has disarmed, a tone sounds, and a stall message displays on the display screen.

17.7 System Fluid Performance

The performance of the injection system has been tested with disposables supplied by Bayer with a pressure rating greater than 325 psi (2241 kPa) and the catheters in Table 17 - 2.

17.7.1 Factors Affecting Flow Rates

An injector's ability to generate pressure is only one factor affecting maximum flow rates. Other factors include:

- Catheter diameter
- Viscosity (thickness) of the fluid
- Tube length
- Number of tubing sections
- Tube diameter
- Temperature of the fluid, tube, and syringes during the injection
- Maximum pressure setting on the injector

If problems are experienced achieving the desired flow rate, please contact a Clinical representative for suggestions that may increase it.

17.7.2 Maximum Flow Rate Performance

Maximum flow rates were achieved using the following catheters, with inner diameters (ID) and lengths as noted. Contrast was heated to 37° C ± 1° C. System programmable pressure limit of 325 psi (2241 kPa) was used for testing.

NOTE: Individual results may vary. Maximum flow rate performance results were met using the components and conditions described in this section. Different components and/or conditions may lead to different results.

Table 17 - 2: Steady State Maximum Flow Rate Using 60-inch LPCT from Bayer

	Catheter			
Fluid	**18 Gauge** **ID:** 0.876 mm – 0.978 mm **Length:** 2.95 cm (1.16 in.)	**20 Gauge** **ID**: 0.800 mm **Length**: 2.54 cm (1.00 in.)	**22 Gauge** **ID**: 0.546 mm – 0.648 mm **Length**: 2.54 cm (1.00 in.)	**24 Gauge** **ID**: 0.445 mm – 0.521 mm **Length**: 1.91 cm (0.75 in.)
Ultravist 300	8.5 mL/s	7.0 mL/s	6.0 mL/s	4.0 mL/s
Ultravist 370	8.5 mL/s	7.0 mL/s	5.0 mL/s	3.0 mL/s
0.9% Saline	8.5 mL/s	7.0 mL/s	6.0 mL/s	4.0 mL/s

17.7.3 Programmable Pressure System Performance

Table 17 - 3: Programmable Pressure System Performance

Programmed Pressure Limit	High Pressure Disarm
325 psi (2241 kPa)	375 psi (2586 kPa)
300 psi (2068 kPa)	350 psi (2413 kPa)
250 psi (1724 kPa)	300 psi (2068 kPa)
225 psi (1551 kPa)	275 psi (1896 kPa)
200 psi (1379 kPa)	250 psi (1724 kPa)
150 psi (1034 kPa)	200 psi (1379 kPa)
100 psi (689 kPa)	150 psi (1034 kPa)
50 psi (345 kPa)	100 psi (689 kPa)

17.8 Power Cable Specifications

The specifications required by the 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.

17.9 Cybersecurity and IT Network Connection

17.9.1 System Cybersecurity Protection

System software cybersecurity controls include:

- Internal data integrity checks
- Remote access requires valid credentials and a user at the workstation to approve a remote connection
- Service access requires valid credentials
- Access to the Operating System is restricted
- Firewall and Anti-Virus
- (Configurable) Masking Protected Health Information (PHI) when sharing with external systems
- Network settings can only be configured by Bayer
- Data Manager website access requires valid credentials
- Certegra database encrypted and access restricted

17.9.2 Certegra® Workstation Cybersecurity

When Informatics is enabled, the Certegra® Workstation hard drive can contain PHI. The security and privacy of this information must be safeguarded by all individuals interacting with the device. Prior to disposing of the workstation, this information must be removed from the hard drive inside the system. Contact Bayer or a local authorized dealer for further information. Refer to the back cover of this manual for contact information.

NOTE: In the event of a suspected or known cybersecurity breach, or for any cybersecurity related questions, please contact Bayer Service at radiology.bayer.com/contact.

17.9.3 IT Network Connection

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

17.10 Fuse Specification

FUSE,3.15A,250V,5X20MM,IEC TYPE T, HIGH.

18 Addendum – Compliance to IEC 60601-1-2: 3rd and 4th Editions

The MEDRAD® Stellant FLEX CT Injection System with Certegra® Workstation 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 61000-4-2:** 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. Failure to follow these instructions may result in loss or degradation of the essential performances of the system as described in the table below. Detailed EMC information contained in this addendum is intended to reflect conformance to IEC-60601-1-2 / 2nd, 3rd, and 4th edition standards.

Essential performance description	Potential effects if essential performance is lost or degraded due to electromagnetic disturbances
Provide the accurate delivery of fluid to the patient.	Delivered flowrate and volume may fall outside of the fluid delivery performance specifications. Test injections may not be delivered correctly, preventing confirmation of catheter placement. Unintended excessive flow rates may cause disposable damage, leading to contamination.
Prevent or detect the inadvertent delivery of fluid as well as unintended reverse motion while a patient is connected to the injector.	Delivered flowrate and volume may fall outside of the fluid delivery performance specifications. Unintended mixing of contrast and saline could occur. Blood may be unintentionally drawn out of the patient.
Ensure the operator can stop an injection when needed.	Delivered flowrate and volume may fall outside of the fluid delivery performance specifications.
Ensure that the syringe heat maintainer does not overheat the fluid. **NOTE:** This essential performance only applies to systems when a heat maintainer is in use.	High fluid temperature may result.

Essential performance description	Potential effects if essential performance is lost or degraded due to electromagnetic disturbances
Provide intended scanner communication and synchronization. **NOTE:** This essential performance only applies to systems that are configured to communicate with a scanner.	Communication with the scanner may occur inadvertently or at the wrong time.

⚠ WARNING

Electro-Magnetic Hazard - Serious injury or equipment damage may result.

- 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.
- 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.
- 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

Electro-magnetic Hazard - Equipment damage may result or system may fail to operate.

- 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.

Recommended separation distances between portable and mobile RF communications equipment and the system

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{p}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{p}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{p}$
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.

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**

Guidance and manufacturer's declaration - electromagnetic immunity

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:

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

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

$d = 1.17\sqrt{p}$

Radiated RF IEC 61000-4-3

3Vrms from 80 MHz to 2.7 GHz at 80% AM 1kHz and specific ISM bands listed below:

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

$d = 1.17\sqrt{p}$ 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)

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.

Guidance and manufacturer's declaration - electromagnetic immunity
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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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.

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