Operation Manual

MEDRAD® Centargo
CT Injection System

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Operation Manual

The MEDRAD® Centargo CT Injection System has an expected service life* of 8 years from the date of product installation when operated according to the instructions provided with this device. These 8 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 symbols can be found in Section 2 of this manual.

1 Introduction

This manual applies to the MEDRAD® Centargo CT Injection System (Centargo), also referred to as the system throughout this document, Catalog Numbers: CENT-SYS-PED (pedestal) and CENT-SYS-BAT (pedestal with battery). Read all of the information contained in this manual. Understanding this information will assist users in operating the system in a safe manner.

NOTE: Operating specifications and feature availability may vary by country. Check with local product representatives and refer to country-specific operating instructions.

1.1 Certifications

This device is equipped to operate at 100-240 VAC, 50/60 Hz, 336-377 VA and is designed to comply with IEC 60601-1 (3rd Edition Amendment 1) and IEC 60601-1-2 (2nd, 3rd, and 4th Edition) standards, including national differences. Special precautions regarding Electro-magnetic Compatibility (EMC) are required for installation and use of this injection system. Detailed EMC information can be found in 14 Compliance to IEC 60601-1-2 / 2nd, 3rd, and 4th Editions.

1.2 Indications for Use

The system is indicated for the specific purpose of injecting intravenous contrast media and flushing solutions into humans for diagnostic studies in x-ray applications.

1.3 Training Information

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

- On-site initial installation and additional training as requested
- Video training accessible on the control room unit (CRU) display
- Instructions for use (IFU)

Please contact Bayer or your local Bayer representative if any of these resources are needed.

1.4 Contraindications

None known.

1.5 Restricted Sales

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

1.6 Required Training

This device is intended to be used by individuals with adequate training and experience in diagnostic studies in x-ray applications.

1.7 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 to ensure 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.

1.8 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 to form a medical system. 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.

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

1.9 Installation

Contact Bayer for installation information.

2 Symbols

2.1 General Symbols

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

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

Warning: Indicates a pinch or crush hazard. (ISO 7000, W024)

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

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

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

Indicates alternating current. (IEC 60417, 5032)

Identifies the Equipotential connection. (IEC TR 60878, 5021)

Identifies the Earth Ground point. (IEC TR 60878, 5017)

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

CLASS 1

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

Class II Equipment, Double Insulated. (IEC 60417, 5172)

CE 2797

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

Indicates separate collection for Electrical and Electronic Equipment per Directive 2012/19/EU. Refer to the following website for additional information: http://www.weee.bayer.com.

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

Identifies a power switch for equipment. (IEC TR 60878, 5009)

Symbols on the Power Switch (IEC TR 60878: 5007, 5008):
O - Off
I - On

Stop button. (IEC TR 60878, 5110A)

Identifies a computer network. (IEC TR 60878, 5988)

Identifies a power supply connection. (IEC TR 60878, 5534)

Identifies a terminal suitable for direct current. (IEC TR 60878, 5031)

Identifies a transfer of displayed image to a second screen. (IEC TR 60878, 5892)

Identifies a handswitch connection. (IEC TR 60878, 5322)

Identifies an input terminal. (IEC TR 60878, 5034)

Identifies an output terminal. (IEC TR 60878, 5035)

Identifies service assistance. (IEC TR 60878, 0717)

Manufacturer (ISO 15223-1, 5.1.1)

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

Date of manufacture (ISO 15223-1, 5.1.3)

Temperature range (ISO 15223-1, 5.3.7)

Humidity range (ISO 15223-1, 5.3.8)

Atmospheric pressure range (ISO 15223-1, 5.3.9)

Serial number (ISO 15223-1, 5.1.7)

Part number

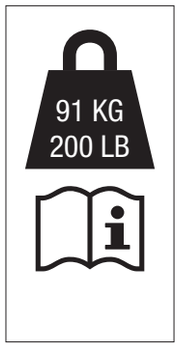
Catalog number (ISO 15223-1, 5.1.6)

This side up (ISO 7000, 0623)

Keep dry (ISO 15223-1, 5.3.4)

Fragile (ISO 15223-1, 5.3.1)

Quantity (IEC TR 60878, 2794)



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

Net Weight (ISO 7000, 1321B)

Hand wash only. (ISO 7000, 3125)

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

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

3 Warnings, Cautions, and Notices

3.1 Definitions

⚠ **WARNING**	Indicates that the information is a warning. Warnings advise of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the injection system.
⚠ **CAUTION**	Indicates that the information is a caution. Cautions advise of circumstances that could result in 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 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, a tip that helps with recovery from an error, or a reference to related information within the manual.

3.2 Warnings

⚠ **WARNING**

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

- Follow aseptic technique at all times. Improper handling can cause infection.

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

- Use only disposable products, accessories, and options compatible with this system. Use catheters and connectors with pressure ratings compatible with this system. Patient injury could result from leaks or ruptures during an injection.
- Do not pull the injector with excessive force. Injector could fall and result in patient or operator injury.

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.
- Only plug the system into a direct mains access point. Do not plug the system power cord into an extension cord of multi-outlet power strip.
- Do not touch the patient while pressing the Power, Unlock Door, or Advance Saline button.

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

- The system contains a lithium ion batteries. Replacement and disposal should be performed only by a qualified service engineer. Contact Bayer for assistance.

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

- Do not modify this equipment without authorization of the manufacturer. Patient or operator injury could result from unauthorized modification to the equipment.
- Do not service or perform maintenance on the injection system while in use with a patient.

4 System Overview

The system is comprised of the injector with a touchscreen display and the control room unit (CRU). The two components are connected by a wired or wireless communications link.

4.1 Power On and Shut Down

Power On

- Injector: Push power switch at the base of the injector to ON position (Figure 4 - 3: Injector Base). Press the **Power** button on the side of the injector.
- CRU: Press the power button (Figure 4 - 4: Control Room Unit).

Restart

- Press the **Restart** button in the shutdown menu.

Shutdown

- Press the **Shutdown** button in the shutdown menu. Press and hold the power button on the side of the injector.

4.2 Injector

Table 4 - 1: Injector Icons

#	Icon	Name
1		Advance Saline button
2		Unlock Door button
3		Power button (other side)
4		All-Stop button
5		Barcode Reader
6		Patient Line port
7		Power switch (4.2.4 Injector Base)

4.2.1 Fluid Loading Area

The injector can support 50 mL to 500 mL of contrast bottles and 50 mL to 1000 mL of saline.

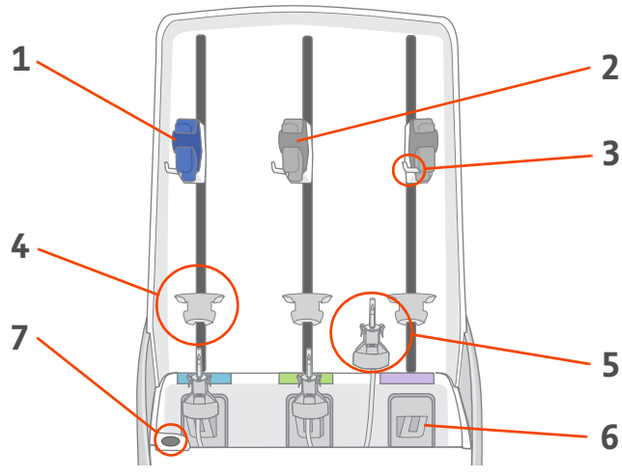


Figure 4 - 1: Fluid Loading Area

#	Name	Function
1	Saline Clamp	Secure saline bottles.
2	Contrast Clamp	Secure contrast bottles.
3	Clamp Hook	Secure fluid bags.
4	Bottle Holder	Hold fluid bottles in place and ease spiking (removable).
5	Spike & Spike Adapter	Spike fluid for loading into the Day Set.
6	Inlet Air Sensor	Detect air in Day Set tubing and lock spike adapter into the injector.
7	Advance Saline button	Push a small amount of saline through an installed Patient Line.

4.2.2 Day Set Install Area

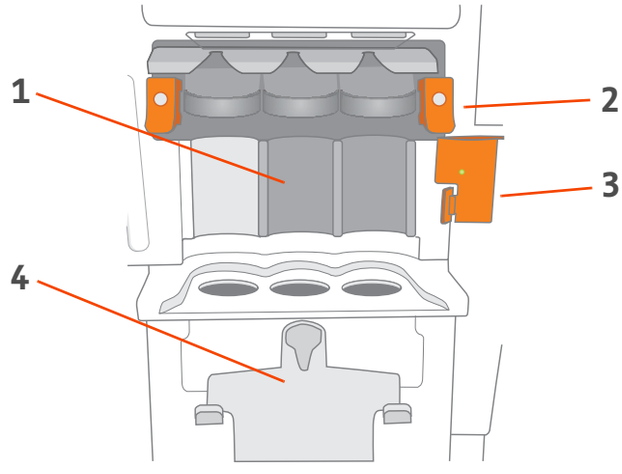


Figure 4 - 2: Day Set Install Area

#	Name	Function
1	Day Set location	Store and administer saline and up to two contrast fluids.

#	Name	Function
2	Lock Levers	Lock Day Set in place.
3	Outlet Air Sensor	Detect air within fluids.
4	Prime Container	Store discarded fluids.

4.2.3 Heat Maintainer

It is recommended that contrast be at 37 °C prior to being loaded into the Day Set. Once contrast is loaded into the Day Set, the heat maintainer will maintain the contrast temperature.

4.2.4 Injector Base

Figure 4 - 3: Injector Base

#	Icon	Name
1		Power switch
2		Mains (AC power)
3		Battery circuit breakers
4		Network connection

4.2.5 Lights

The injector has various sets of lights that aid in providing instruction, depicting system status, and enhancing aesthetics.

4.2.5.1 Fluid Loading Area Lights

The fluid loading area lights are located within the fluid loading area and provide instruction and fluid status.

Light Display	Condition
Off	Day Set is not installed.
Flashing white	Day Set is installed, but spike is not.
White	Day Set and spike are installed, but no fluid is loaded.
Flashing fluid color	Filling Day Set is in progress.
Fluid color	Fluid is loaded into Day Set.
Orange	Fluid supply is empty.

4.2.5.2 Patient Line Port Lights

The Patient Line port lights surround the Patient Line port and provide instruction and fluid status.

Light Display	Condition
Flashing white	System is ready for patient line installation.
Red	Do not connect to a patient. ◆ Day Set is purging air. ◆ Installed Patient Line is not primed.
Flashing fluid color	Specified fluid is being primed or injected.
Fluid color	Fluid is successfully primed and/or fluid is being injected. **NOTE:** The fluid color light will display even if the injection is on hold or paused.
Orange	Patient Line is used and needs to be replaced with a new Patient Line.

4.2.5.3 Door Lights

The door lights provide injection status and aesthetic lighting.

Light Display	Condition
Mood lighting	Day Set is not installed.
Off	Day Set is installed.
Flashing yellow	Injector is armed.
Flashing fluid color	Injection is in progress.
Fluid color	Fluid is successfully primed and/or fluid is being injected.

4.2.5.4 Door Open Button Lights

Light Display	Condition
Blue	Door can be opened.
Off	Door cannot be opened.

4.2.5.5 Outlet Air Sensor Light

Light Display	Condition
Flashing orange	Outlet air sensor door is open.
Green	Outlet air sensor door is closed.

4.2.6 Moving the Injector

Unlock the wheels by pressing up on the brakes. Hold the handles located on the back of the injector and push in any direction.

Re-lock the wheels by pressing down on the brakes.

NOTE: The injector power cord is the mains (AC power) disconnection device that isolates and removes AC power from the injector. Do not place the injector in front of AC wall outlets to prevent access to the supply mains.

4.3 Control Room Unit

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

NOTE: The CRU power cord is the mains (AC power) disconnection device that isolates and removes power from the CRU. Do not place the CRU in front of AC wall outlets and prevent access to the supply mains.

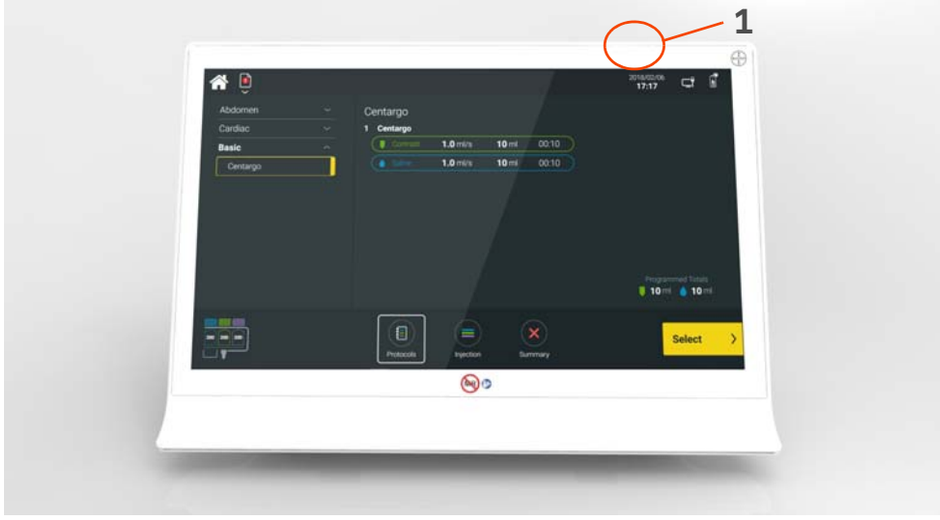


Figure 4 - 4: Control Room Unit

#	Icon	Name
1		Power On/Off

4.3.1 Control Room Unit Symbols

Figure 4 - 5: Control Room Unit, Rear and Side Port View

#	Icon	Function	#	Icon	Function
1		Identifies power input and supply connection.	2		Identifies computer network connection.
3		Identifies USB connections. Port 4, identified with yellow outline, always remains on.	4		Identifies connection for screen extension or transfer to a second display. For Bayer use only.
5		Identifies a network connection.	6		Identifies input and output connections. Not for use with this system.
7		Identifies injector head connection. Not for use with this system.	8		Identifies handswitch connection. Not for use with this system.
9		Identifies service ports. For Bayer use only.			

4.4 Display

NOTE: Saline will always show as blue, Contrast 1 as green, and Contrast 2 as purple. If the same type and concentration is loaded into both contrast reservoirs, both will show as green.

NOTE: Certain functions are available only on the injector or CRU display.

4.4.1 Home Screen

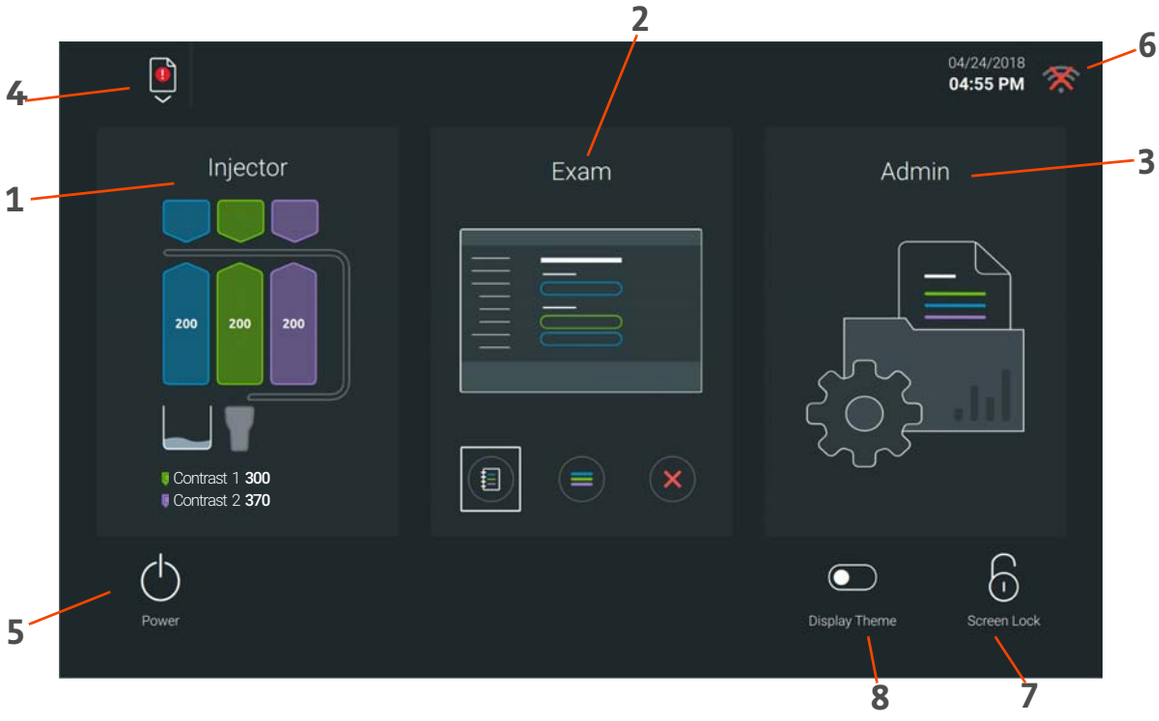


Figure 4 - 6: Home Screen

#	Name	Function
1	Injector	Load contrast and saline into Day Set and view status of Day Set and other fluid-loading components. View contrast(s) loaded into the Day Set. Refer to 5 Prepare Injector.
2	Exam	Select a protocol from the protocol library and deliver injections. Highlighted icon below indicates exam progress. Refer to 6 Perform Exam.
3	Admin	Manage the protocol library and contrast information, configure system settings, and perform other administrative tasks. Refer to 8 Administrative Operations.
4	System Alerts	Display a list of system alerts. Refer to 10.2 System Alert Recovery and Error Screen Messages.
5	Power button	Open shutdown menu.
6	Status Icons	Press icons on user interface for more information on injector battery status, wireless connection, and network connection status.
7	Screen Lock	Lock screen.
8	Display Theme	Switch themes.

4.5 Day Set and Patient Line

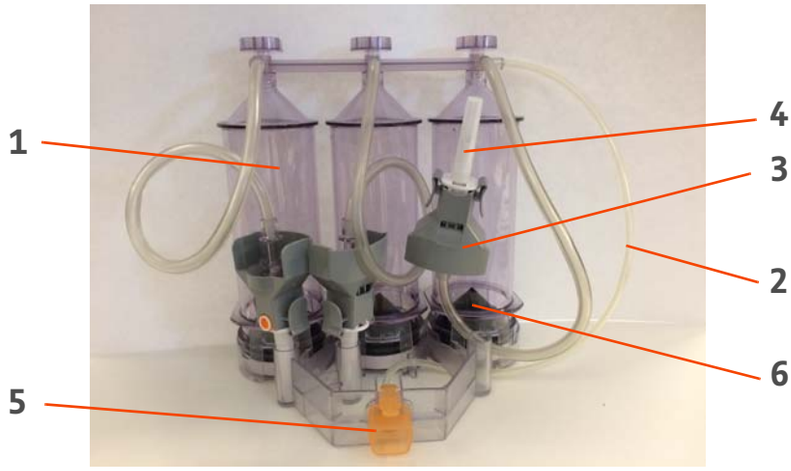


Figure 4 - 7: Day Set

#	Name
1	Reservoir
2	Air Sensor Tube
3	Spike Adapter
4	Spike (dust cap on)
5	Patient Line Connection (Day Set cap in)
6	Plunger

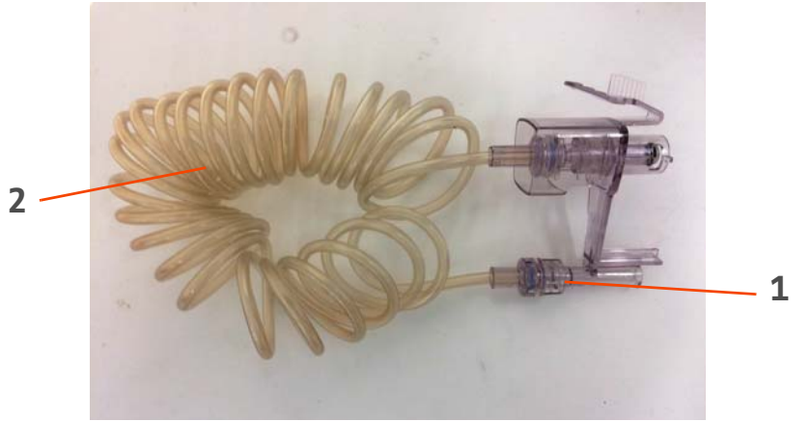


Figure 4 - 8: Patient Line

#	Name
1	Patient end
2	Tubing

5 Prepare Injector

⚠ WARNING

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

- For Patient Line and replacement spike, inspect contents and package prior to use. Do not use if sterile package is opened or damaged. Patient or operator injury may result.
- For Day Set, inspect components prior to use. Do not use if any dust caps are missing or displaced. Do not remove dust caps until ready to make connections. Early removal of dust caps can result in contamination.
- Do not reinstall, re-sterilize, or reprocess Day Set. Potential device failure includes significant component deterioration and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be reinstalled, re-sterilized, or reprocessed.
- Do not use the Day Set for longer than 24 hours. Over-use poses risks to the patient, including contamination and injury due to device failure.
- Do not remove dust caps until ready to make connections. Early removal of dust caps can result in contamination.

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

- Use care in handling and inserting spikes into saline and contrast. The spikes are sharp and may cause injury.

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

- Do not modify or attempt to circumvent the operation of the air sensors.

5.1 Install Day Set

1. Press **Unlock Door** button to unlock injector door.

   NOTE: Injector door will not open if Patient Line is inserted.

2. Insert new Day Set straight into the injector.

   NOTE: Maximum use time for the Day Set is 24 hours.

3. Push down on lock levers. Lock levers click when Day Set is locked into place.
4. Push small-diameter tube into the outlet air sensor and close the outlet air sensor door.
5. Snap on spike adapters from Day Set onto assigned inlet air detectors.

   NOTE: Ensure spike adapters are aligned with corresponding fluid reservoirs.

   NOTE: Ensure adapters are fully inserted. Adapters click when locked into place.

6. Ensure the air detector door is closed.
7. Close the injector door.

   NOTE: Do not pinch tubing.

5.2 Load Fluids into Day Set

Select **Injector** from the system Home screen to load contrast and saline into the Day Set.

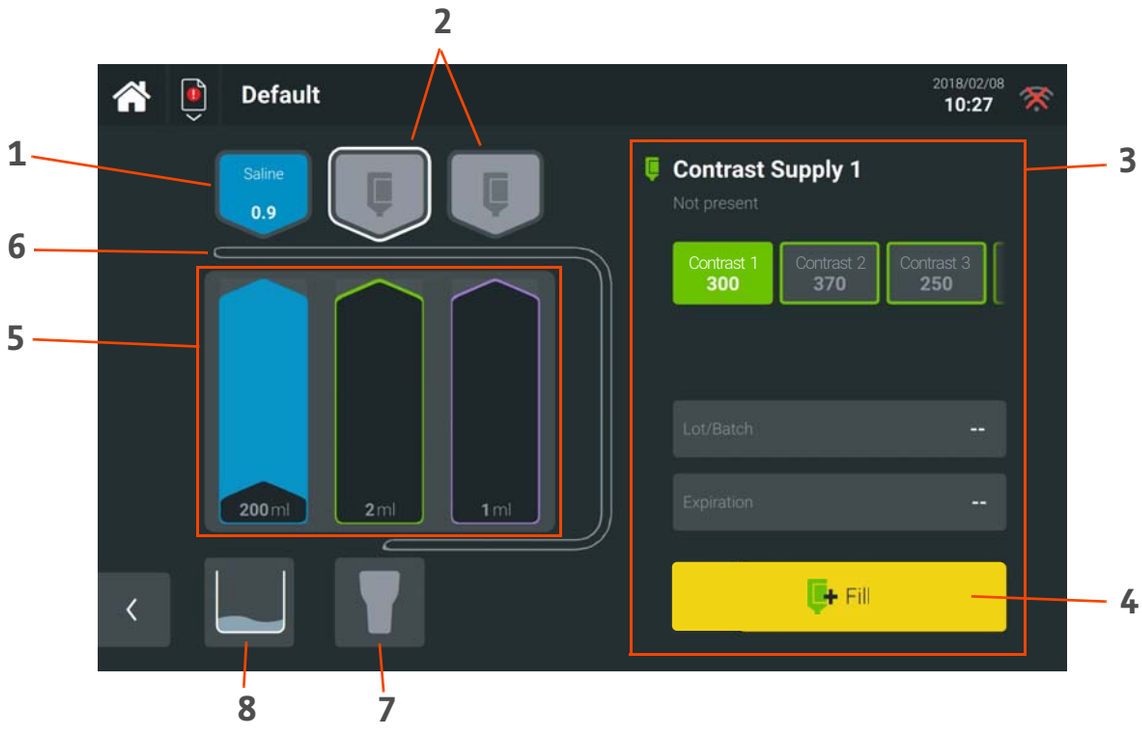


Figure 5 - 1: Injector Screen

#	Name	Function
1	Saline Icon	View saline installed or to be installed into the Day Set.
2	Contrast Fluid Icons	View contrast(s) installed or to be installed into the Day Set.
3	Side Panel	Select and edit information for reservoir selected or view details of selected fluid loading area.
4	Fill button	Load selected and installed fluid into the corresponding fluid reservoir within the Day Set. **NOTE:** Pressing **Fill** activates an expiration timer for each fluid loaded into the Day Set.
5	Day Set	When Day Set is installed, fill Day Set with fluid or empty/eject Day Set. When Day Set is not installed, activate piston moving for cleaning; refer to 11.2 Clean Fluid Spills or Debris.
6	Outlet Air Sensor Tubing	View outlet air sensor tubing status (primed, not primed).
7	Patient Line	View Patient Line status (primed, not primed).
8	Prime Container	View status of fluid volume level within prime container.

1. Select one fluid icon.
   a. For contrast, use the middle or far right icon.
   b. For saline, use the far left icon.
2. Set fluid type and information by selecting the type on the display or scanning the barcode.

NOTE: Contrast barcodes must first be defined in the system for successful scanning. Refer to 8.3 Contrast Management.

NOTE: If it is a different fluid from what is currently loaded in the reservoir, on-screen prompts will provide instructions for emptying and re-filling the reservoir.

3. Remove the spike dust cap (if present).
4. Spike the bottle or bag.

   NOTE: Spike adapter may be removed from holder to ease spiking.

   NOTE: Bottle holder may also be removed from injector to ease spiking; hold and slide bottle holder up to remove.

   a. For bottles, use clamp to secure. Pinch clamp and adjust position as needed.

   b. For bags, use clamp hook to hang.
5. Press **Fill**.

   NOTE: To set up a second contrast source if desired, repeat the steps in this section.

5.3 Install, Prime, and Connect Patient Line

⚠ WARNING

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

- Do not connect the Patient Line to the patient until all trapped air has been cleared.

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

- The Patient Line is intended for single use only. Do not re-sterilize, reprocess, or reuse. Potential device failure includes significant component deterioration and system failure. Potential risks to the patient include injury due to device malfunction or infection as the device has not been validated to be re-sterilized, reprocessed, or reused.
- Do not reuse or reconnect the Patient Line. Cross-contamination can cause infection.

1. Remove orange Day Set cap (if present).
2. Insert Patient Line until it clicks.

   NOTE: The system primes the Patient Line automatically. If lights are solid blue, the Patient Line is primed and ready. If lights are red, the Patient Line is not primed. Refer to 10 Troubleshooting.
3. Check Patient Line for air.

   NOTE: If additional prime fluid is needed, press and hold the **Advance Saline** button on the injector. Saline will be pushed through the Patient Line.
4. Disconnect the patient end of the Patient Line from the injector.
5. Connect the Patient Line to the patient.

5.4 Within 24 Hours

5.4.1 Replace Fluids As Needed

For additional contrast and saline, repeat steps in 5.2 Load Fluids into Day Set.

5.4.2 Remove And/Or Replace Spikes If Required

To remove a spike from the spike adapter, press both levers on either side (left and right) of the spike adapter. While pressing, pull spike out and discard per facility guidelines.

To replace a spike in a spike adapter:

1. Press both levers on left and right side of spike adapter.
2. While pressing, remove used spike.
3. Insert new spike into spike adapter.

   NOTE: When installing a new spike, the circular orange vent must align with the indent on the back of the adapter.

5.4.3 Empty Prime Container As Needed

1. Press **Unlock Door** button to unlock injector door.
2. Remove prime container, and dispose of fluids per facility guidelines.
3. Reinsert prime container, and close injector door.

6 Perform Exam

Select **Exam** from the system Home screen to begin an exam and deliver injections.

6.1 Select Protocol

Select a protocol from the left side panel, and press **Select**.

NOTE: Deselect any open protocol folder or protocol and the routine protocol displays. Refer to 8.2.2.3 Routine Protocol for more information.

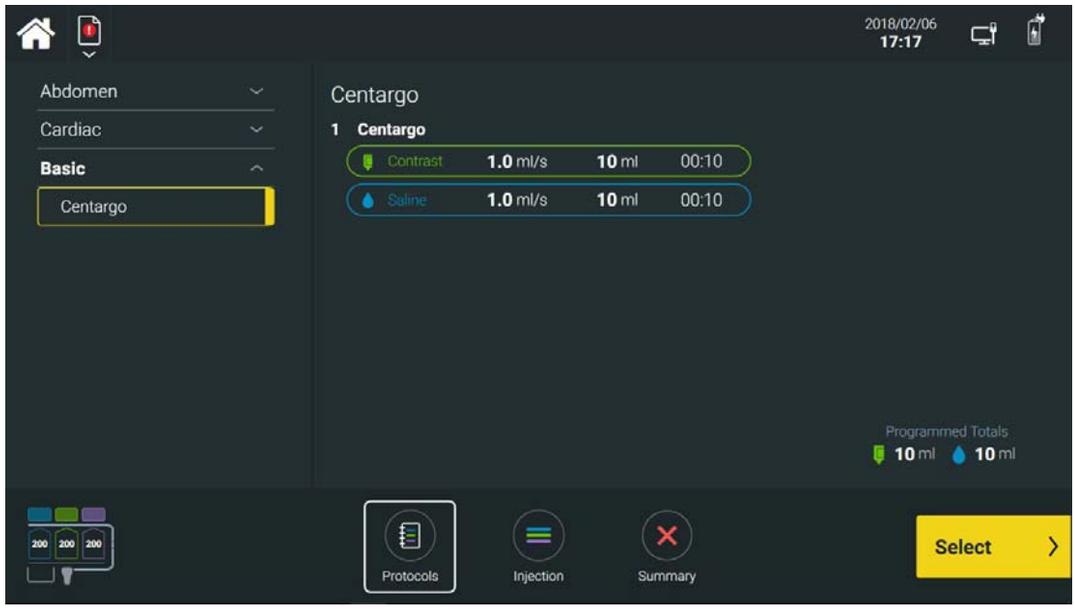


Figure 6 - 1: Select Protocol

6.2 Edit Protocol

Values for flow rates and volumes can be edited by touching the values; a keypad will display. Add injections and phases using the edit panel on the right side.

NOTE: Refer to 8.2.2 Protocol for more information on injections and phases.

NOTE: During protocol selection, any edits made to a protocol will not be saved when the exam is completed. Refer to 8.2.2.2 Edit Protocol to implement changes to a saved protocol.

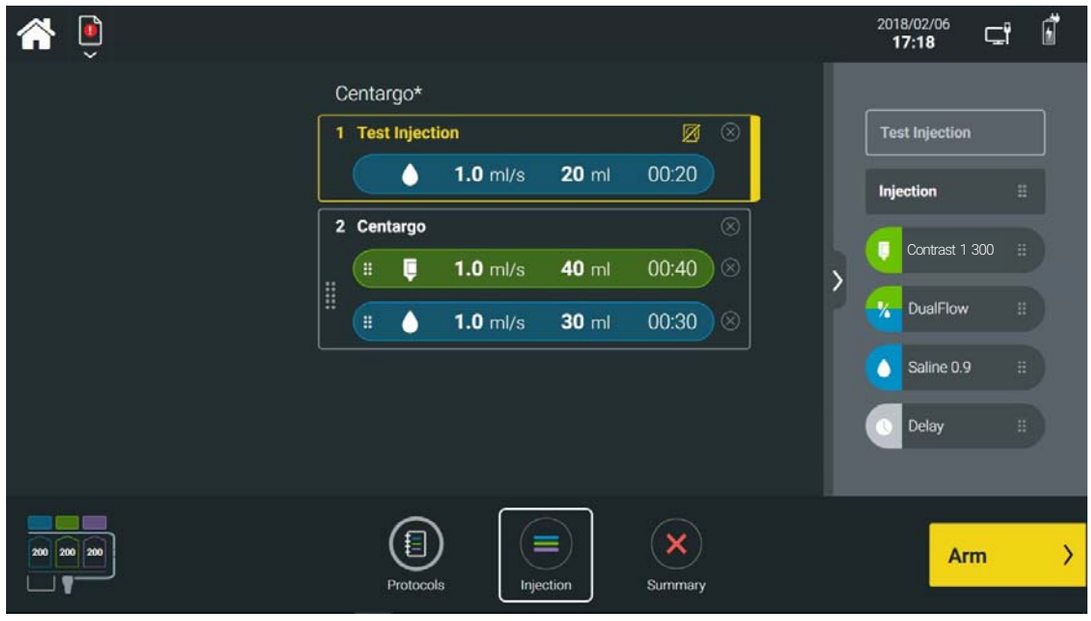


Figure 6 - 2: Edit Protocol

6.3 Arm Injector and Confirm Check for Air

The system must be armed prior to performing any injection in a protocol. Press **Arm** to arm the system.

For the first injection of an exam, a message displays asking for confirmation the Patient Line has been checked for air.

- Press **Yes** to confirm all air has been expelled and no air is visible in the Patient Line.
- Press **No** if the Patient Line has not been checked for air. The system will not arm.

6.4 Perform Injection(s)

- **Start Injection:** Once the system is armed, press the **Start** button to begin an injection.

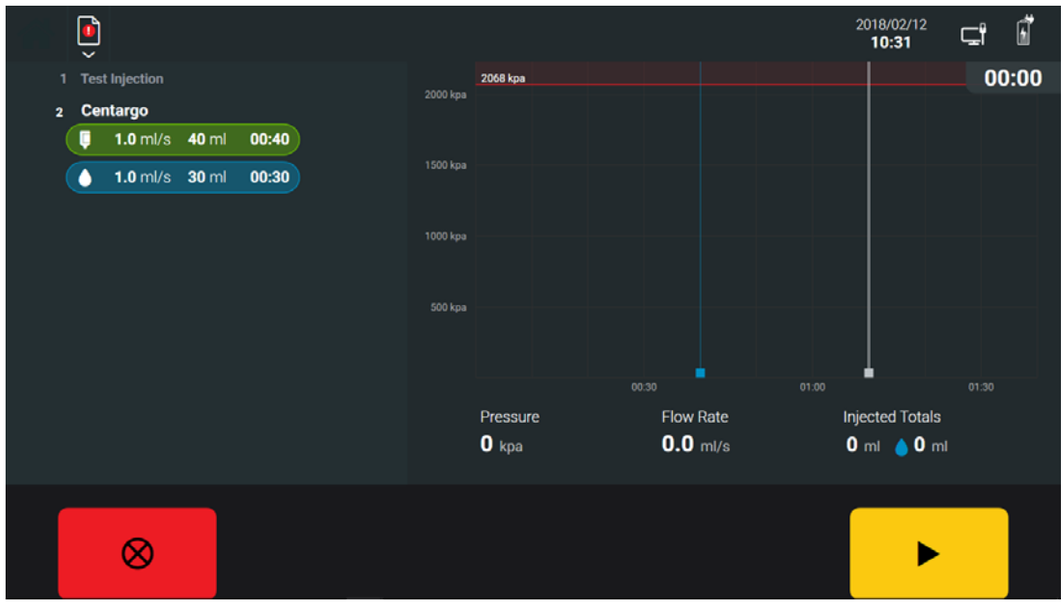


Figure 6 - 3: Start Injection

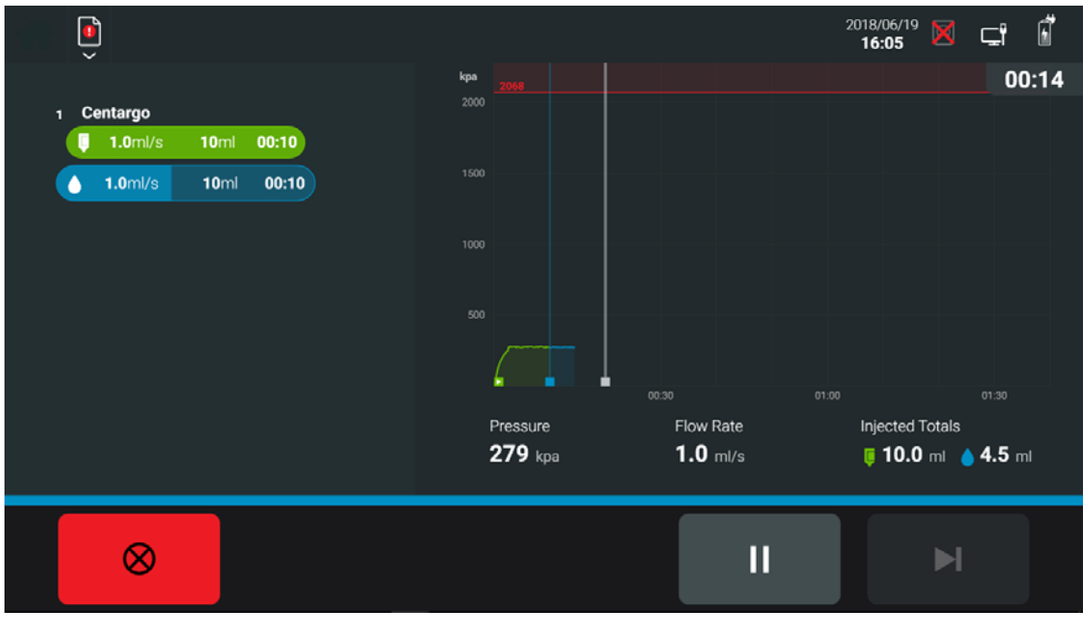


Figure 6 - 4: Injection in Progress

- **Pause Injection:** Press the **Pause** button. The system holds the injection until the **Start** button is pressed again to resume to protocol.

  NOTE: The system holds the injection for 20 minutes, after which time the injection is stopped.

  NOTE: If **Pause** button is selected, the reminder elapse time is halted and started again when the protocol is resumed.

- **Skip to Next Phase:** Press the **Skip to Next Phase** button to stop the current phase of an injection and start the next phase. The button is disabled during the last phase of an injection.
- **Stop Injection:** Press the **Stop** button on the display or the **All-Stop** button on the injector at any time to stop the injection.

  NOTE: Pressing the **All-Stop** button also causes the injection summary panel and the protocol to display.

- **Adjust Flow Rate**: Press the **+/-** buttons to adjust the flow rate in 0.1 mL/sec increments. Available only for test injections.

6.5 View Protocol and Perform Additional Injections

When an injection is completed, the injection summary panel and the protocol display. The injection summary panel includes further details on the last performed injection. The protocol includes previously completed injections and/or injections not yet started.

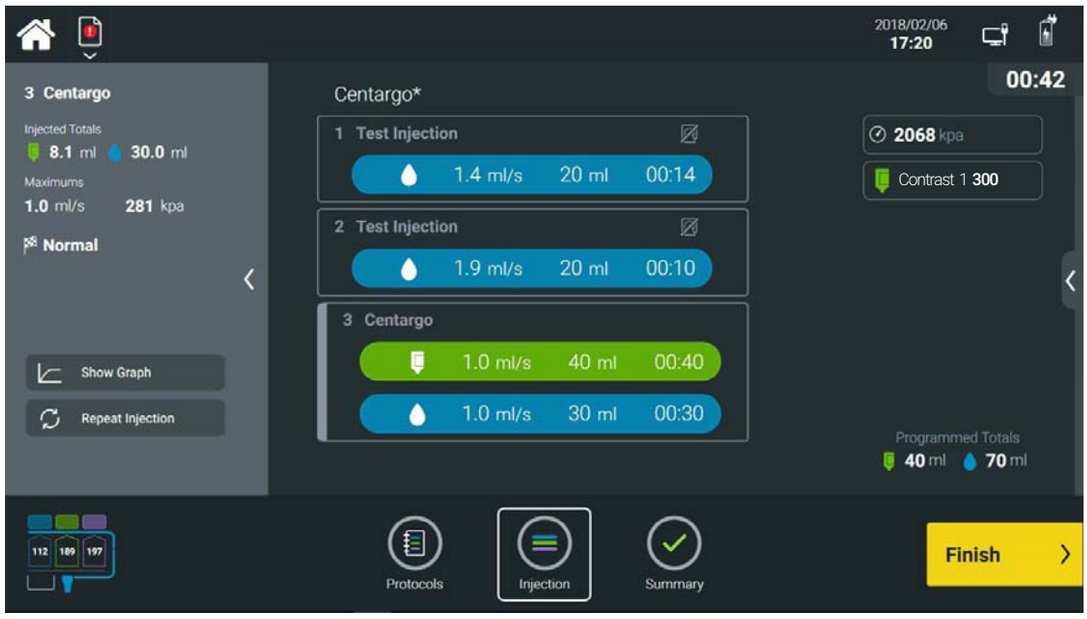


Figure 6 - 5: Protocol

- **Perform Additional Injections:** Add additional injections to the protocol by unhiding the edit panel on the right side, and then selecting and/or dragging and dropping injection(s) into the protocol.
- **Repeat Injection:** The last performed injection can be repeated by pressing **Repeat Injection** on the injection summary panel. The last performed injection is automatically duplicated in the protocol; press **Arm** to start the injection.

  NOTE: The pressure graph of the last performed injection can be viewed by pressing **View Graph** in the injection summary panel.

6.6 Insufficient Volume

If there is not enough available volume to fill the Day Set and complete the injection, an insufficient volume message displays. Press **Yes** for the system to automatically adjust the volume to be delivered in the injection, or press **No** to load more contrast and saline.

6.7 Finish Patient Exam

When all injections are completed, press **Finish** to exit the protocol screen.

At the end of the exam, the injection details are combined into a summary that displays. Press **End Exam** to end the exam.

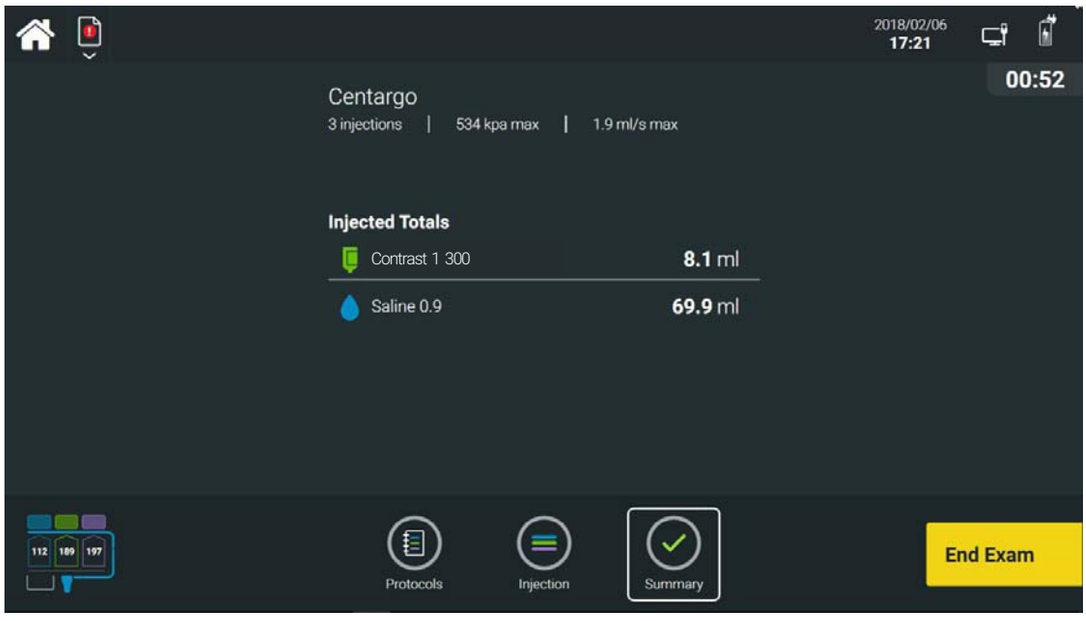


Figure 6 - 6: End Exam

6.8 Remove Patient Line

NOTE: Patient Line is single-use only.

When an exam is completed, disconnect used Patient Line from the injector and the patient, and discard per facility guidelines.

7 Empty and/or Eject Day Set

NOTE: Maximum use time for the Day Set is 24 hours.

Select **Injector** from the system Home screen, then select the Day Set reservoirs to:

- (Optional) Empty contrast and saline remaining in the Day Set and/or
- Eject and remove the Day Set from the injector.

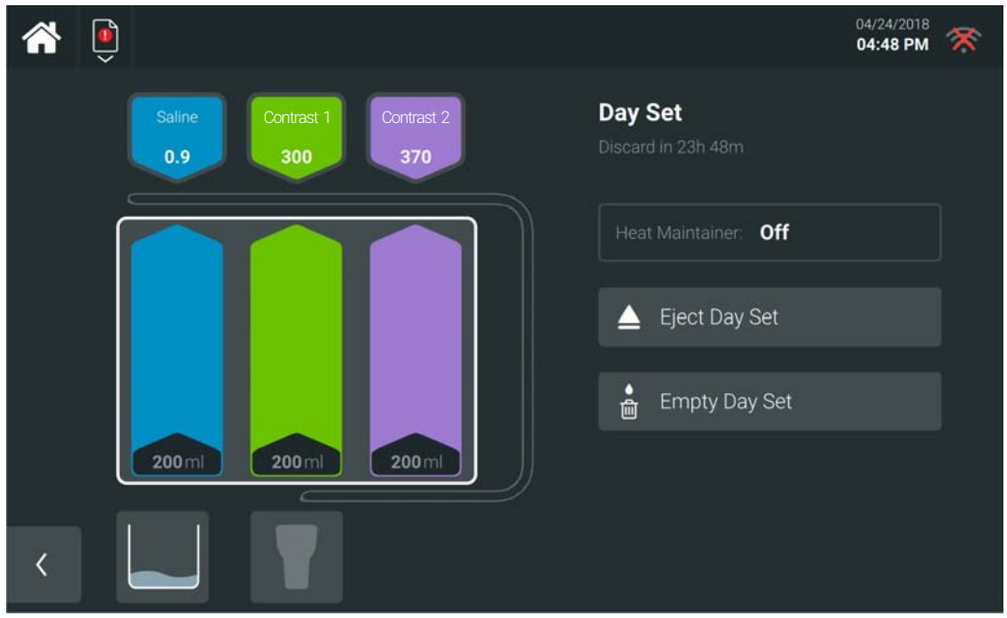


Figure 7 - 1: Empty and/or Eject Day Set

7.1 Empty Day Set (Optional)

Empty the Day Set reservoirs of remaining contrast and saline in order to dispose of fluids separately from the Day Set. Contrast and saline will remain in the inlet lines.

1. Press **Empty Day Set**, and follow the prompts on the user interface.
2. Once finished, disconnect and discard Patient Line.
3. Dispose of fluids per facility guidelines.

7.2 Eject Day Set

1. Press **Eject Day Set**.
2. A message displays asking for confirmation:
   - Press **Yes** to confirm the Day Set should be ejected. The pistons will begin retracting.
   - Press **No** if the Day Set should remain installed.
3. Open the injector door.
4. Lift the lock levers.
5. Open the outlet air sensor door, remove the small-diameter tube, and close the outlet air sensor door.
6. Remove contrast, saline, and spike assemblies from spike adapters.
7. Remove the Day Set and discard per facility guidelines.

8 Administrative Operations

Select **Admin** from the system Home screen to manage the protocol library and contrast information, configure system settings, and perform other administrative tasks.

8.1 Administration Menu

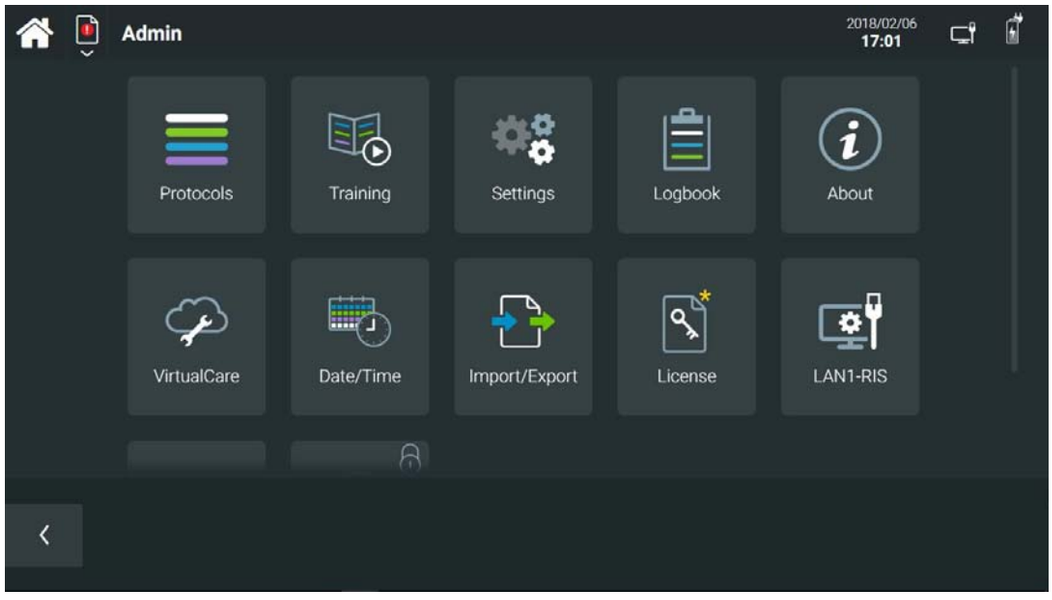


Figure 8 - 1: Administration Menu

Tile	Function
Protocols	Create, modify, and delete protocols. Refer to 8.2 Protocol Management.
Contrasts	Manage saved contrasts. Refer to 8.3 Contrast Management.
Settings	Manage system settings. Refer to 8.4 Settings.
Logbook	View exam, injector, and fluid activity.
About	View system information, including manufacturer, model and serial number, and current software version.
Training	View supplemental training material and videos. Refer to 8.5 Training.
VirtualCare	Access remote service capabilities. Refer to 10.4 VirtualCare.
Date/Time	Program displayed date and time.
Import/Export	Manage transfer and storage of system and exam information.
License	View available programmed licenses. Refer to 8.7 Licensing.
LAN1-RIS	View and configure network connection status.
Proxy Settings	Configure network settings.
Service	For Bayer use only.

8.2 Protocol Management

Under Admin, select **Protocols** to manage the organization and display of protocols stored in the system.

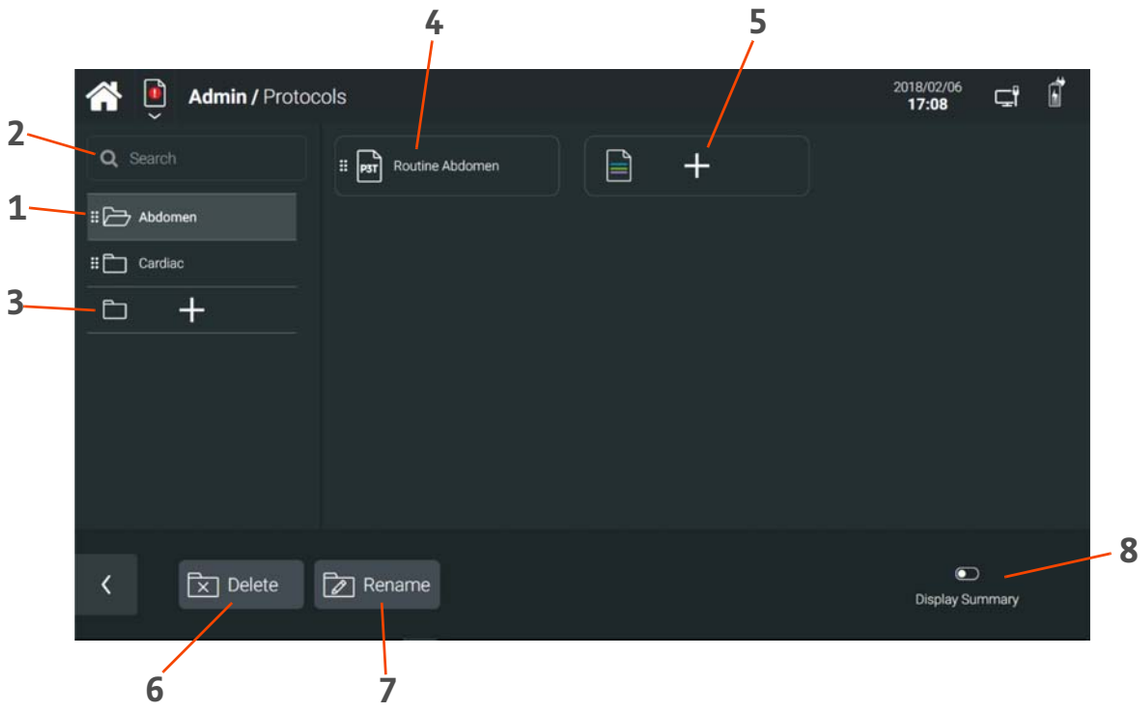


Figure 8 - 2: Protocols

#	Name
1	Protocol Folder
2	Search Protocols
3	Add Protocol Folder
4	Protocol
5	Add Protocol
6	Delete Protocol Folder
7	Rename Protocol Folder
8	Display Summary

8.2.1 Protocol Folder

Protocols are organized by and stored in folders, shown on the left side panel. View the protocols in each folder by selecting a folder.

NOTE: A protocol must be stored in a folder. The only exception is the routine protocol (8.2.2.3 Routine Protocol).

8.2.2 Protocol

A protocol is an injection or set of injections to be performed in an exam. It is comprised three elements:

1. **Phase(s)**: Delivery of individual volumes of fluid or duration of a pause within an injection. Phase types include:
   a. Contrast: Injects a programmed volume of contrast.
   b. DualFlow: Simultaneously injects a programmed volume of contrast and saline.

   NOTE: The system automatically determines the individual volumes of contrast and saline and the individual flow rates needed for each portion of the DualFlow phase.

   c. Saline: Injects a programmed volume of saline.
   d. Delay: Stops injection of fluids for a programmed amount of time.
2. **Pressure Limit**: Maximum pressure limit not to be exceeded during the injection.

   NOTE: The maximum pressure limit is 300 psi (2,068 kPa) when using disposables from Bayer. This limit may be reduced based on the indication and patient-based considerations.
3. **Reminder(s)** (optional): Timers that display after a programmed amount of time. The system stores timers as part of the protocol. Refer to 8.2.2.4 Configure Reminders.

8.2.2.1 Create Protocol

1. Select a protocol folder.
2. Press the **Add Protocol** button.
3. Enter a name using the displaying keyboard, and press **OK**.
4. Select and/or drag and drop injection(s) to the center panel:
   a. **Test Injection**: An injection of flush phases that will not generate an ISI trigger. A test injection can be used to confirm the catheter is properly placed.

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

   b. **Injection**: A sequence of phases within a protocol.
   c. **P3T Injection**: An individualized contrast injection based on specified input. Refer to 9 Personalized Protocols.
   d. **Phases**
5. Modify parameters as needed.
6. Press **Save** when completed.

8.2.2.2 Edit Protocol

When **Display Summary** is off, select a protocol. An editable protocol displays.

When **Display Summary** is on, select a protocol and press **Edit** in the right side panel. An editable protocol displays.

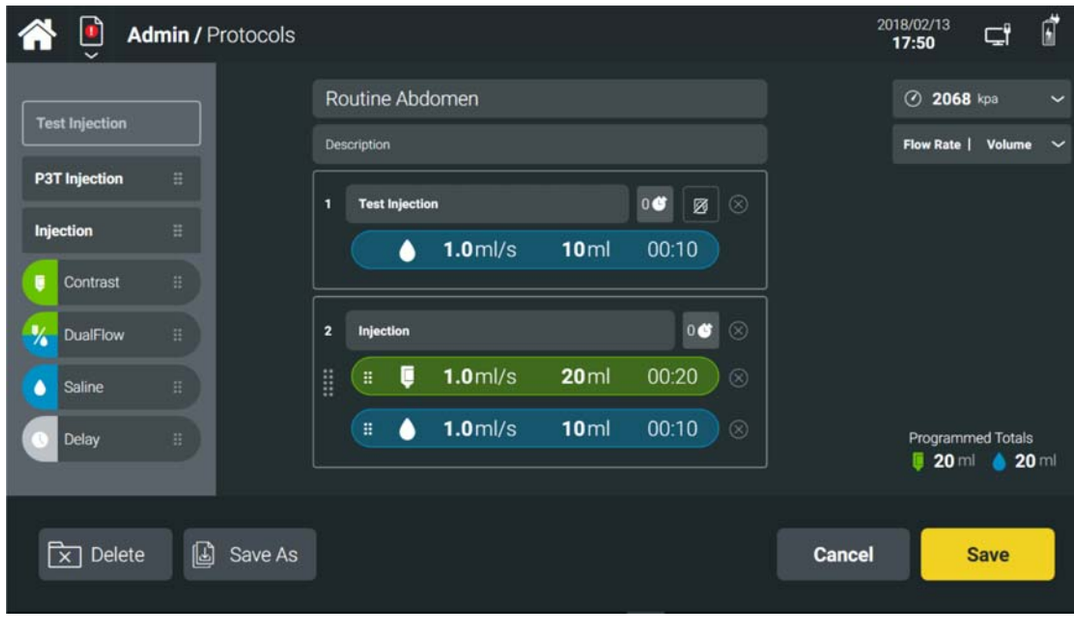


Figure 8 - 3: Edit Protocol

8.2.2.3 Routine Protocol

The routine protocol is the default protocol that displays when starting an exam.

The routine protocol displays when no protocol group is selected. Like any other protocol, the routine protocol can be edited from the Admin / Protocols section. To edit, select and edit as if any other protocol (8.2.2.2 Edit Protocol).

8.2.2.4 Configure Reminders

Within a selected protocol, select the **Reminders** button next to the injection name. Select and enter parameters:

- **Time**: Determine when the timer displays.
- **Begin Timer At**: Determine if timer begins during the start of injection or when injection is completed.
- **Message**: Determine if a message displays with reminder timer.

Press **Save** when completed.

8.3 Contrast Management

⚠ WARNING

Exposure to Unintended Contrast Hazard - Serious patient injury or death may result.

- Do not configure contrast media with different active pharmaceutical ingredients (APIs) into the same contrast group. Small residual amounts of contrast media within the Day Set could lead to dose-independent reactions. Refer to the contrast media manufacturer's package insert for specific indications and use time.

Under Admin, select **Contrasts** to manage the organization and display of contrasts stored in the system.

NOTE: Contrast agents of the same brand, including different concentrations, should be grouped together. The system will not allow contrast agents from different groups to be loaded together into the Day Set.

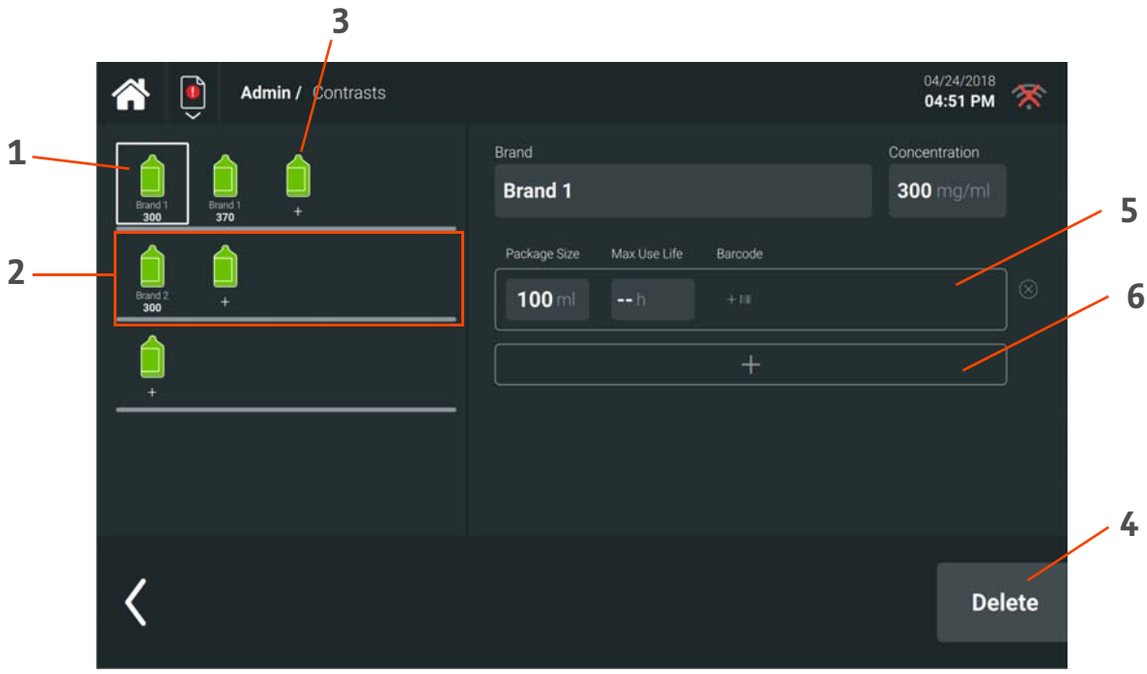


Figure 8 - 4: Contrasts

#	Name/Function
1	Contrast (by brand and concentration)
2	Contrast Group
3	Add Contrast
4	Delete Contrast
5	Define contrast barcode (barcodes for each package size).
6	Add another contrast package size for the same brand and concentration.

8.4 Settings

Under Admin, select **Settings** to configure system settings.

8.4.1 Networking

Under Admin, select **Networking** to configure a wireless communication between the injector and the CRU. Enter the injector serial number. This enables the specified injector to establish a wireless connection to the CRU.

If the configuration is successful, the wireless symbol will appear on the user interface. If the configuration is not successful, refer to 10 Troubleshooting.

8.4.2 Scanner Suite Name

Enter the name of the scanner suite to identify the injector and CRU pairing. This name will appear on the both injector and CRU user interface.

Under Admin, select **General**, then select the name listed for Scanner Suite Name. Enter a name using the displaying keyboard. Press **Save** when completed.

8.4.3 Administration Passcode and Protected Tasks

Set a passcode for certain administrative tasks to prevent any unauthorized changes.

To configure the passcode:

1. Select **Admin**, then **Admin Passcode**.
2. Enter a passcode, and select **OK** when finished.

To select which tasks(s) require passcode entry:

1. Select **Admin** and then **Admin Protected Tasks**.
2. Select the task(s), and select **Done** when finished.

8.5 Training

Under Admin, select **Training** to view training videos.

8.6 Import and Export

Under Admin, select **Import/Export** to perform the following data management activities from the system:

- **Import**: Import specified content from a previously exported file.
- **Export**: Export specified content for use on another system.
- **Backup**: Creates a system backup file, including injection history.
- **Restore**: Restores a previously created backup file, preferably from the same unit; a restart is required when restoration is complete.
- **Initial Setup**: Partially restores a different system's backup file (excluding injection data) when a new suite is setup.
- **Stellant Import**: Set up a new suite being upgraded from a MEDRAD® Stellant or MEDRAD® Stellant with Certegra® Workstation.
- **Bayer Barcodes**: View and update the saved Bayer barcodes and defined contrast information for the system.

8.7 Licensing

Under Admin, select **License** to activate or enable specific features for the injection system. A license must be obtained and applied to the system. When the license is successfully installed, a restart is required. Contact Bayer or your local representative from Bayer for further details.

9 Personalized Protocols

If the feature is licensed, Personalized Patient Protocol Technology (P3T®) Software can be used to generate personalized injection protocols.

NOTE: Not all algorithms are available in all markets. Check with local product representatives.

Depending on the algorithm, the personalized protocol may include the following injection types:

- **Test Injection**: In order to check the patency of the vein, a small amount of saline can be injected as the first injection in a protocol. With a personalized protocol, the test injection flow rate will be calculated to match the diagnostic injection.
- **Transit Bolus Injection**: For some algorithms, an optional transit bolus of contrast followed by saline can be added to the protocol. This is also referred to as a timing bolus or test bolus, and is used to determine scan timing or to make adjustments to the diagnostic injection protocol.
- **Diagnostic Injection**: This is the main injection of the protocol and may be adjusted based on additional parameters entered after a transit bolus.

Available algorithms with their claims, indications for use, and available configuration parameters are listed in 9.3 P3T® Cardiac Software, 9.4 P3T® Pulmonary Angiography (PA) Software, and 9.5 P3T® Abdomen Software.

9.1 Create and Edit Personalized Protocols

Under Admin / Protocols, personalized protocols can be created, edited, and organized similar to standard protocols (8.2.2 Protocol).

For each personalized protocol, configuration parameters, such as minimum and maximum flow rates or dosing factors, are set. Default values for input parameters are set as well. When a personalized protocol is selected for an exam, those default parameters are updated with the current patient and procedure information.

1. Select a protocol folder.
2. Press the **Add Protocol** button to add a new protocol.
3. Enter a name using the displaying keyboard, and press **OK**.
4. Select and/or drag and drop the **P3T Injection** button to the center panel. This will create a diagnostic injection.

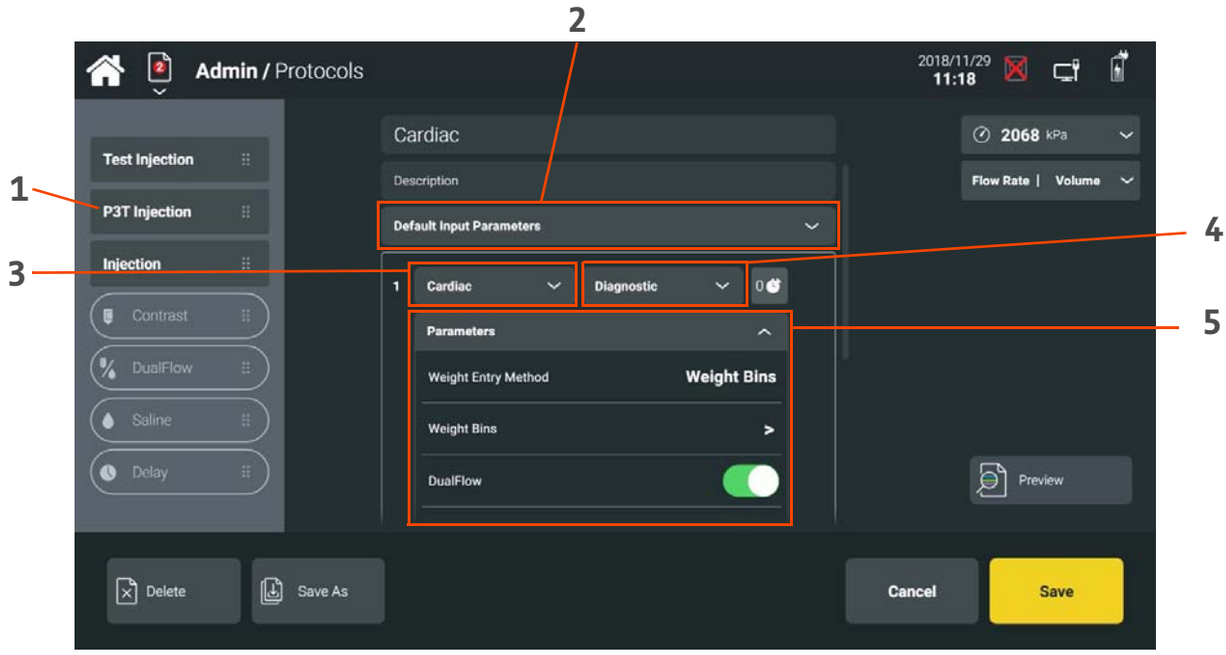


Figure 9 - 1: Create/Edit Personalized Protocol

#	Name	Function
1	P3T Injection Button	Adds personalized injections to the protocol.
2	Default Input Parameters	Defines default values for patient/procedure-specific inputs. Refer to the applicable algorithm's Default Input Parameters section within this chapter.
3	Algorithm	Defines the P3T or PAT algorithm used for the calculation. **NOTE:** Only one algorithm can be used per protocol.
4	Injection Type	Defines the injection type (Test Injection, Transit Bolus, Diagnostic Injection).
5	Configuration Parameters	Defines the configuration parameter values for the personalized protocol. Refer to the applicable algorithm's Configuration Parameters section within this chapter.

5. To add a Test Injection and/or Transit Bolus Injection, select and/or drag and drop the **P3T Injection** button to the center panel again. Set the Injection Type accordingly.
6. Set values for Default Input Parameters and Configuration Parameters.
7. To preview the calculated protocol based on the selected values, press the **Preview** button.
8. Press **Save** when completed.

9.2 Using Personalized Protocols

⚠ WARNING

Extravasation Hazard - Serious patient injury or death may result.

- Ensure the programmed flow rate meets hospital guidelines.

Hazard - Serious patient injury or death may result.

- Patient injury could result if personalized protocols are used with patients with compromised renal function or other contrast-adverse related health issues. Personalized protocols are not recommended if performing a procedure on a patient with compromised renal function or some other contrast-adverse related health issues.

Hazard - Serious patient injury or death may result.

- Patient injury or an image that is not sufficient for diagnosis could result if the protocol is not confirmed by the user. The user is responsible for confirming that the personalized protocol generated does not compromise the safety of a particular patient and will result in an image sufficient for diagnosis, prior to injection.

NOTE: Personalized protocols can only be used when the CRU is on and connected (wired or wirelessly) to the injector.

Personalized protocols that have been saved are available for selection in the protocol library under Exam / Protocols. In the library, a preview displays of the calculated protocol, generated based on the Default Input Parameters.

After the personalized protocol has been selected, the Input Parameters should be updated based on the current values for this exam. For example, if the Scan Duration differs from the stored default, the user should edit that value to recalculate the protocol.

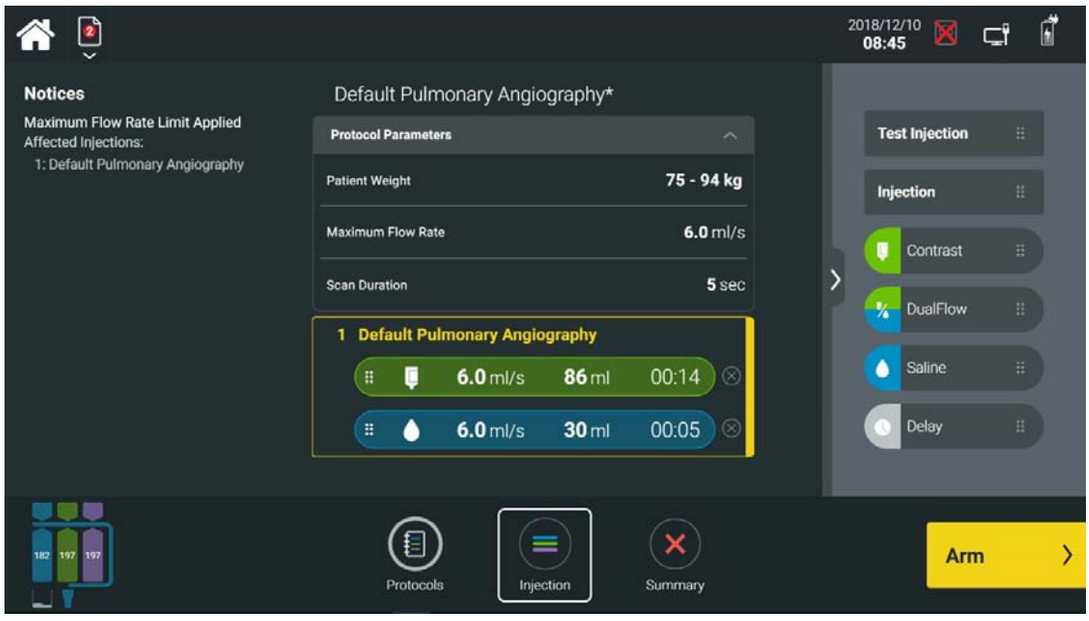


Figure 9 - 2: Edit Personalized Protocol

Prior to arming, review the calculated protocol to confirm none of the values are outside of acceptable ranges given the condition of the patient. All flow rates and volumes are editable if necessary.

NOTE: During protocol selection, any edits made to a personalized protocol will not be saved when the exam is completed. Refer to 9.1 Create and Edit Personalized Protocols to implement changes to a saved personalized protocol.

When finished selecting and editing protocol (as applicable), perform exam, following steps in 6 Perform Exam.

9.3 P3T® Cardiac Software

P3T Cardiac is an algorithm that creates personalized protocols intended for CT angiography of cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, and thoracic and abdominal aorta.

9.3.1 Essential Claims

- P3T Cardiac computes individual contrast injection protocols and scan timing for individualized dosing.
- P3T Cardiac increases the consistency of individualized injection protocols amongst clinicians.

9.3.2 Indications for Use

P3T Cardiac is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, and thoracic and abdominal aorta. P3T Cardiac computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters and contrast concentration.

9.3.3 Default Input Parameters

Table 9 - 1: P3T Cardiac Default Input Parameters

Name	Description	Default Value	User-Selectable Values
Contrast Concentration	Defines the contrast concentration value used for the protocol.	350 mg/mL	300 - 450 mg/mL in increments of 1 mg/mL
Patient Weight	Sets either the exact patient weight or the weight bin, depending on the Weight Entry Method parameter. Units can be in pounds or kilograms.	75 - 94 kg	≤ 39 kg 40 - 59 kg 60 - 74 kg 75 - 94 kg 95 - 109 kg 110 - 125 kg > 125 kg
Maximum Flow Rate	Sets the maximum flow rate allowed for the protocol. If the P3T protocol is generated such that it exceeds the maximum flow rate value, the protocol will automatically be adjusted so that the maximum flow rate value is not exceeded and the user is notified of the protocol adjustment.	6.0 mL/s	5 mL/s - 10 mL/s in increments of 0.1 mL/s
Scan Duration	Identifies the length of time for the Diagnostic portion of the scan acquisition.	10 sec	1 - 40 seconds in increments of 1 second
Maximum Contrast Volume	Sets the maximum contrast volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the max contrast volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	79 mL - 194 mL in increments of 1mL
Maximum Saline Volume	Sets the maximum saline volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the maximum saline volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	0 mL - 194 mL in increments of 1 mL

9.3.4 Configuration Parameters

Table 9 - 2: P3T Cardiac Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Test Injection Delivery Method	Selects the way the test injection is calculated and delivery - by volume or duration.	Volume	Volume, Injection Duration
Test Injection Volume	Sets the volume for the test injection when the Test Inject Delivery Method is set to Volume.	20 mL	10 mL- 50 mL in increments of 1 mL
Test Injection Duration	Sets the duration of the test injection when the Test Inject Delivery Method is set to Duration.	5 seconds	3 seconds -15 seconds in increments of 1 second
Transit Bolus Contrast Volume	Sets the default volume for a contrast bolus portion of the Transit Bolus if the Transit Bolus parameter is set to Yes.	20 mL	10 - 25 mL in increments of 1 mL
Transit Bolus Saline Volume	Sets the default volume for a saline bolus portion of the Transit Bolus if the Transit Bolus parameter is set to Yes.	40 mL	0 - 50 mL in increments of 1 mL
Weight Entry Method	Defines the way in which the user enters patient weight. For Weight Bins, the system displays five defined weight ranges for the patient. For Exact Weight, the system displays a numeric keypad for patient weight entry. **NOTE:** If the user configures the Weight Entry Method to use Weight Bins, a representative weight within the selected range will be used to calculate the contrast dosage. As a result, the Exact Weight weight entry method is more accurate compared to the Weight Bin entry method.	Weight Bins	Weight Bins, Exact Weight
Weight Bins	Enables a user to create seven custom weight bins. Units can be in pounds or kilogram depending on system settings.	≤ 39 kg 40 - 59 kg 60 - 74 kg 75 - 94 kg 95 - 109 kg 110 - 125 kg > 125 kg	User defined. Each bin can be 3-31 kg (3-71 lbs) wide
DualFlow	Enables the use of DualFlow for the P3T Preset. When Yes is selected, the underlying algorithm will consider a contrast dilution phase for the protocol. In some cases, even through the Preset may include DualFlow, the algorithm may not generate a protocol with a DualFlow phase (for example, when scan durations are short and the scan is completed before the time of the injection of the DualFlow phase).	Yes	Yes, No

Table 9 - 2: P3T Cardiac Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Duration Adjustment	Used to calculate the duration for the first phase of the diagnostic protocol. The Duration Adjustment is added to the Scan Duration to determine the injection duration of the first phase. Contrast injection durations should be sufficiently long to account for the dispersive effects of the cardio pulmonary system. It is therefore advisable to include additional injection duration to the bolus to avoid suboptimal enhancement towards end of the scan. The Duration Adjustment setup option enables the user to configure this additional injection duration. Since P3T computes the flow rate of the contrast phase in the Diagnostic Protocol based on contrast volume and injection duration, a larger value of Duration Adjustment results in a longer injection duration and a lower flow rate.	4 seconds	0 -10 seconds in increments of 1 second
Minimum Injection Duration	Specifies the minimum injection duration of the diagnostic contrast phase. In order to reduce contrast volume, short minimum injection duration value may be desired for very fast scans (3-5 seconds) when the user is comfortable with higher flow rates for a patient. The minimum injection duration requirement is enforced after the Duration Adjustment is added to the Scan Duration. For example, in the case of a 5 second Scan Duration, a 4 second Duration Adjustment, and a Min Injection Duration of 10 seconds: the calculated injection duration of the first phase of the P3T protocol is 9 seconds, but would be increased to 10 seconds based on the Min Injection Duration specified.	16 seconds	6 - 16 seconds
Weight Factors	Enables the user to edit the default weight factors, which determine the gI/kg used in the first contrast phase of the diagnostic protocol.	0.5, 0.4, 0.375, 0.35, 0.31, 0.30 gI/kg	0.05 - 1.0 gI/kg in increments of 0.001 gI
Minimum Iodine Load	Sets the minimum volume for iodine load. If the P3T protocol is generated such that it is less than the Minimum Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the minimum iodine load value is not less than the Minimum Iodine Load limit and the user is notified of the protocol adjustment.	20 gI	0 gI - 50 gI in increments of 1 gI
Maximum Iodine Load	Sets the maximum volume for iodine load. If the P3T protocol is generated such that it exceeds the Max Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the max iodine load value is not exceeded and the user is notified of the protocol adjustment.	38 gI	20 gI - 80 gI in increments of 1 gI
Saline Flush Volume	Sets the volume for the saline flush phase. Set the volume to zero to eliminate the saline flush phase	30 mL	0 mL- 50 mL in increments of 1 mL

9.4 P3T® Pulmonary Angiography (PA) Software

P3T PA is an algorithm that creates personalized protocols intended for CT angiography of pulmonary vasculature.

9.4.1 Essential Claims

- P3T PA computes individual contrast injection protocols and scan timing for individualized dosing.
- P3T PA increases the consistency of individualized injection protocols amongst clinicians.

9.4.2 Indications for Use

P3T PA is indicated for use with CT Angiography of the cardiac structures, coronary arteries, chambers of the heart, pulmonary vasculature, and thoracic and abdominal aorta. P3T PA computes individual contrast injection protocols and scan timing, based on patient characteristics, scanner parameters, and contrast concentration.

NOTE: P3T PA has not been validated for anatomical regions outside of the stated Indications For Use.

9.4.3 Default Input Parameters

Table 9 - 3: P3T PA Default Input Parameters

Name	Description	Default Value	User-Selectable Values
Contrast Concentration	Defines the contrast concentration value used for the protocol.	350 mg/mL	300 - 450 mg/mL in increments of 1 mg/mL
Patient Weight	Sets either the exact patient weight or the weight bin, depending on the Weight Entry Method parameter. Units can be in pounds or kilograms.	75 - 94 kg	≤ 39 kg 40 - 59 kg 60 - 74 kg 75 - 94 kg 95 - 109 kg 110 - 125 kg > 125 kg
Maximum Flow Rate	Sets the maximum flow rate allowed for the protocol. If the P3T protocol is generated such that it exceeds the maximum flow rate value, the protocol will automatically be adjusted so that the maximum flow rate value is not exceeded and the user is notified of the protocol adjustment.	6.0 mL/s	5 mL/s - 10 mL/s in increments of 0.1 mL/s
Scan Duration	Identifies the length of time for the Diagnostic portion of the scan acquisition.	5 sec	1 - 40 seconds in increments of 1 second
Maximum Contrast Volume	Sets the maximum contrast volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the max contrast volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	79 mL - 194 mL in increments of 1mL
Maximum Saline Volume	Sets the maximum saline volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the maximum saline volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	0 mL - 194 mL in increments of 1 mL

9.4.4 Configuration Parameters

Table 9 - 4: P3T PA Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Test Injection Delivery Method	Selects the way the test injection is calculated and delivery - by volume or duration.	Volume	Volume, Injection Duration
Test Injection Volume	Sets the volume for the test injection when the Test Inject Delivery Method is set to Volume.	20 mL	10 mL- 50 mL in increments of 1 mL
Test Injection Duration	Sets the duration of the test injection when the Test Inject Delivery Method is set to Duration.	5 seconds	3 seconds -15 seconds in increments of 1 second
Transit Bolus Contrast Volume	Sets the default volume for a contrast bolus portion of the Transit Bolus if the Transit Bolus parameter is set to Yes.	20 mL	10 - 25 mL in increments of 1 mL
Transit Bolus Saline Volume	Sets the default volume for a saline bolus portion of the Transit Bolus if the Transit Bolus parameter is set to Yes.	40 mL	0 - 50 mL in increments of 1 mL
Weight Entry Method	Defines the way in which the user enters patient weight. For Weight Bins, the system displays five defined weight ranges for the patient. For Exact Weight, the system displays a numeric keypad for patient weight entry. **NOTE:** If the user configures the Weight Entry Method to use Weight Bins, a representative weight within the selected range will be used to calculate the contrast dosage. As a result, the Exact Weight weight entry method is more accurate compared to the Weight Bin entry method.	Weight Bins	Weight Bins, Exact Weight
Weight Bins	Enables a user to create seven custom weight bins. Units can be in pounds or kilogram depending on system settings.	≤ 39 kg 40 - 59 kg 60 - 74 kg 75 - 94 kg 95 - 109 kg 110 - 125 kg > 125 kg	User defined. Each bin can be 3-31 kg (3-71 lbs) wide

Table 9 - 4: P3T PA Configuration Parameters

Name	Description	Default Value	User-Selectable Values
DualFlow	Enables the use of DualFlow for the P3T Preset. When Yes is selected, the underlying algorithm will consider a contrast dilution phase for the protocol. In some cases, even through the Preset may include DualFlow, the algorithm may not generate a protocol with a DualFlow phase (for example, when scan durations are short and the scan is completed before the time of the injection of the DualFlow phase). Since DualFlow is primarily beneficial for maintaining opacification of the right heart structures, it may not be required for pulmonary angiography studies. Also, by configuring the Preset for P3T PA to not include DualFlow, initial contrast volume calculation could be lower than if it were included.	No	Yes, On
Duration Adjustment	Used to calculate the duration for the first phase of the diagnostic protocol. The Duration Adjustment is added to the Scan Duration to determine the injection duration of the first phase. Contrast injection durations should be sufficiently long to account for the dispersive effects of the cardio pulmonary system. It is therefore advisable to include additional injection duration to the bolus to avoid suboptimal enhancement towards end of the scan. The Duration Adjustment setup option enables the user to configure this additional injection duration. Since P3T computes the flow rate of the contrast phase in the Diagnostic Protocol based on contrast volume and injection duration, a larger value of Duration Adjustment results in a longer injection duration and a lower flow rate.	4 seconds	0 -10 seconds in increments of 1 second
Minimum Injection Duration	Specifies the minimum injection duration of the diagnostic contrast phase. In order to reduce contrast volume, short minimum injection duration value may be desired for very fast scans (3-5 seconds) when the user is comfortable with higher flow rates for a patient. The minimum injection duration requirement is enforced after the Duration Adjustment is added to the Scan Duration. For example, in the case of a 5 second Scan Duration, a 4 second Duration Adjustment, and a Min Injection Duration of 10 seconds: the calculated injection duration of the first phase of the P3T protocol is 9 seconds, but would be increased to 10 seconds based on the Min Injection Duration specified.	13 seconds	6 - 16 seconds in increments of 1 second
Weight Factors	Enables the user to edit the default weight factors, which determine the gI/kg used in the first contrast phase of the diagnostic protocol.	0.5, 0.4, 0.375, 0.35, 0.31, 0.30 gI/kg	0.05 - 1.00 gI/kg in increments of 0.001 gI

Table 9 - 4: P3T PA Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Minimum Iodine Load	Sets the minimum volume for iodine load. If the P3T protocol is generated such that it is less than the Minimum Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the minimum iodine load value is not less than the Minimum Iodine Load limit and the user is notified of the protocol adjustment.	20 gI	0 gI - 50 gI in increments of 1 gI
Maximum Iodine Load	Sets the maximum volume for iodine load. If the P3T protocol is generated such that it exceeds the Max Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the max iodine load value is not exceeded and the user is notified of the protocol adjustment.	38 gI	20 gI - 80 gI in increments of 1 gI
Saline Flush Volume	Sets the volume for the saline flush phase. Set the volume to zero to eliminate the saline flush phase	30 mL	0 mL- 50 mL in increments of 1 mL

9.5 P3T® Abdomen Software

P3T Abdomen is an algorithm that generates personalized protocols intended to enhance the abdominal region (liver, pancreas, kidneys, etc.). An overview of the relevant clinical literature with regards to the practice of patient-based dosing for abdominal studies is available in 9.5.6 Clinical Literature Summary.

9.5.1 Essential Claims

- P3T Abdomen automates calculation of individualized injection protocols.
- P3T Abdomen increases consistency of individualized protocols amongst clinicians.
- P3T Abdomen provides multiple options for contrast dosing for CT imaging of the abdominal region.
- P3T Abdomen makes these options available through an easy to use interface.

9.5.2 Indications for Use

P3T Abdomen is indicated for use with CT imaging of abdominal organs (i.e., liver, pancreas, kidneys). P3T Abdomen automates the calculation of individual contrast injection protocols, based on patient characteristics and contrast concentration.

9.5.3 Default Input Parameters

Table 9 - 5: P3T Abdomen Default Input Parameters

Name	Description	Default Value	User-Selectable Values
Contrast Concentration	Defines the contrast concentration value used for the protocol.	300 mg/mL	200 - 450 mg/mL in increments of 1 mg/mL
Patient Weight	Sets either the exact patient weight or the weight bin, depending on the Weight Entry Method parameter. Units can be in pounds or kilograms.	85 kg	20-320 kg
Maximum Flow Rate	Sets the maximum flow rate allowed for the protocol. If the P3T protocol is generated such that it exceeds the maximum flow rate value, the protocol will automatically be adjusted so that the maximum flow rate value is not exceeded and the user is notified of the protocol adjustment.	6.0 mL/s	4 mL/s - 7mL/s in increments of 0.1 mL/s
Maximum Contrast Volume	Sets the maximum contrast volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the max contrast volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	99 mL - 194 mL in increments of 1mL
Maximum Saline Volume	Sets the maximum saline volume allowed for the diagnostic portion of the protocol. If the P3T protocol is generated such that it exceeds the maximum saline volume value, the protocol will automatically be adjusted so that the max volume is not exceeded and the user is notified of the protocol adjustment.	194 mL	0 mL - 194 mL in increments of 1 mL

9.5.4 Configuration Parameters

Table 9 - 6: P3T Abdomen Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Test Injection Fluid	Defines the fluid to be used during the test injection.	Saline	Contrast, Saline
Test Injection Delivery Method	Selects the way the test injection is calculated and delivery - by volume or duration.	Volume	Volume, Injection Duration
Test Injection Volume	Sets the volume for the test injection when the Test Inject Delivery Method is set to Volume.	20 mL	10 mL- 50 mL in increments of 1 mL
Test Injection Duration	Sets the duration of the test injection when the Test Inject Delivery Method is set to Duration.	5 seconds	3 seconds -15 seconds in increments of 1 second
Weight Entry Method	Defines the way in which the user enters patient weight. For Weight Bins, the system displays five defined weight ranges for the patient. For Exact Weight, the system displays a numeric keypad for patient weight entry. **NOTE:** If the user configures the Weight Entry Method to use Weight Bins, a representative weight within the selected range will be used to calculate the contrast dosage. As a result, the Exact Weight weight entry method is more accurate compared to the Weight Bin entry method.	Exact Weight	Weight Bin, Exact Weight
Weight Bins	Enables a user to create seven custom weight bins. Units can be in pounds or kilogram depending on system settings.	≤ 39 kg 40 - 59 kg 60 - 74 kg 75 - 94 kg 95 - 109 kg 110 - 125 kg > 125 kg	User defined. Each bin can be 3-31 kg (3-71 lbs) wide
Minimum Flow Rate	Sets the minimum flow rate allowed for the protocol. If the P3T protocol is generated such that it is less than the minimum flow rate value, the protocol will automatically be adjusted so that the minimum flow rate value is not less than the Minimum Flow Rate limit and the user is notified of the protocol adjustment.	0 mL/s	0 mL/s - 4 mL/s in increments of 0.1 mL/s
Delivery Method	Configures the module to generate a protocol based on a fixed flow rate or fixed injection duration (time).	Flow Rate	Injection Duration, Flow Rate
Delivery Method: Flow Rate	Sets the flow rate for the generated P3T protocol if the Delivery Method is set to Flow Rate.	4 mL/s	1 mL/s - 7 mL/s in increments of 0.1 mL
Delivery Method: Duration	Sets the injection duration for the generated P3T protocol if the Delivery Method is set to Duration.	30 seconds	1 second - 3 minutes in increments of 1 second

Table 9 - 6: P3T Abdomen Configuration Parameters

Name	Description	Default Value	User-Selectable Values
Dosing Method	Sets the Dosing Method for calculating contrast volumes to Weight, Volume, or Iodine Load.	Weight	Weight, Volume, Iodine Load
Dosing Method: Weight	Configures the module to calculate the contrast volume based on patient weight in terms of grams of Iodine per kilogram of patient weight (gI/kg). Contrast volume is calculated by: Contrast volume = (Dosing Factor * Patient Weight) / (Iodine Concentration * 1000)	0.5 gI/kg	One value per bin. 0.4 gI/kg - 0.6 gI/kg in increments of 0.01 gI/kg
Dosing Method: Volume	Configures the module to calculate the contrast volume based on patient weight in terms of milliliters of contrast per kilogram of patient weight (mL/kg). Contrast volume is calculated by: Contrast volume = Dosing Factor * Patient Weight	1.6 mL/kg	One value per bin. 1.0 mL/kg - 2.5 mL/kg in increments of 0.1 mL/kg
Dosing Method: Iodine	Configures the module to calculate the contrast volume based on grams of iodine. Contrast volume is calculated by: Contrast volume = Dosing Factor * Iodine Concentration * 1000. **NOTE:** Patient weight is not considered when Iodine Load dosing method is used.	40 gI	One value per bin. 18 gI - 70 gI in increments of 1 gI
Minimum Iodine Load	Sets the minimum volume for iodine load. If the P3T protocol is generated such that it is less than the Minimum Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the minimum iodine load value is not less than the Minimum Iodine Load limit and the user is notified of the protocol adjustment.	0 gI	0 gI - 50 gI in increments of 1 gI
Maximum Iodine Load	Sets the maximum volume for iodine load. If the P3T protocol is generated such that it exceeds the Max Iodine Load value, the protocol's contrast volume will automatically be adjusted so that the max iodine load value is not exceeded and the user is notified of the protocol adjustment.	60 gI	20 gI - 80 gI in increments of 1 gI
Saline Flush Volume	Sets the volume for the saline flush phase. Set the volume to zero to eliminate the saline flush phase	40 mL	0 mL- 50 mL in increments of 1 mL

9.5.5 Dosing Methods

P3T Abdomen offers flexibility with the choice of three dosing methods: Weight Factor, Volume Factor and Iodine Load. The dosing methods primarily differ in the variables used for calculating the individualized contrast volume: Patient Weight and Concentration. Weight Factor method uses both Patient Weight and Concentration for determining an individualized contrast dose. Volume Factor takes into account Patient Weight only, and Iodine Load takes into account Concentration only for determining an individualized contrast dose.

Table 9 - 7: Three Dosing Methods: Weight Factor, Volume Factor, and Iodine Load

Dosing Method	Parameter	Dependent Variables		Formula
		Patient Weight	*Concentration*	
Weight Factor	gI/kg	Yes	Yes	Volume = Weight*Weight Factor/ Concentration
Volume Factor	mL/kg	Yes	No	Volume = Weight*Volume Factor
Iodine Load	gI	No	Yes	Volume = Iodine Load/Concentration

For example, when using a contrast concentration of 300 mg/mL, a Volume Factor of 1.5 mL/kg is equivalent to specifying a Weight Factor of 0.45 gI/kg.

The following table shows the equivalent weight factor values (gI/kg) for each volume factor –contrast concentration pair. The entries in gray are weight factors that are either smaller or larger than the minimum and maximum values found in clinical literature and hence would not be typically used for a CT Abdomen protocol. Using these results, it is possible to summarize the most commonly used volume factor and contrast concentration pairs.

Table 9 - 8: Weight Factors Corresponding to Volume Factor-Concentration Pairs

Volume Factor / Concentration	1.0 mL/kg	1.3 mL/kg	1.6 mL/kg	2.0 mL/kg	2.5 mL/kg
300 mg/mL	0.30	0.39	0.48	0.60	0.75
320 mg/mL	0.32	0.42	0.51	0.64	0.80
350 mg/mL	0.35	0.46	0.56	0.70	0.88
370 mg/mL	0.37	0.38	0.59	0.74	0.93
400 mg/mL	0.40	0.52	0.64	0.80	1.00

Table 9 - 9: Weight Factors Corresponding to Volume Factor-Concentration Pairs

Volume Factor / Concentration	1.0 mL/kg	1.3 mL/kg	1.6 mL/kg	2.0 mL/kg	2.5 mL/kg
300 mg/mL		X	X	X	X
320 mg/mL		X	X	X	
350 mg/mL	X	X	X	X	
370 mg/mL	X	X	X	X	
400 mg/mL	X	X	X		

The following graph shows the variation of iodine delivered with Weight Factor for different patient weights. Iodine dose increases linearly with large weight factors and heavy patients.

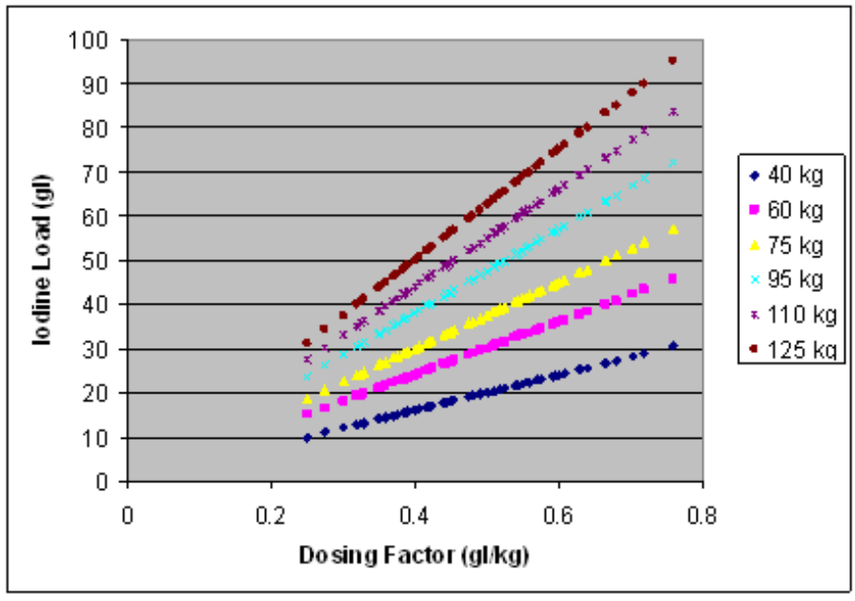


Figure 9 - 3: Relationship Between Iodine Load and Weight Factor

NOTE: If different contrast concentrations are routinely used for abdomen studies, the Weight Factor method is recommended since it takes into account both varying iodine content across contrast products as well as patient weight.

NOTE: The Volume Factor method is superior to the Weight Factor method if the clinician prefers higher dosing factors (the maximum Weight Factor value that can be configured is 0.6 gI/kg, but it is possible to generate weight factors of up to 0.875 gI/kg when using Volume Factor with a contrast concentration of 370 mg/mL).

NOTE: The total iodine delivered in a protocol with any of the three methods will always be limited by the value set with the Max Iodine Load setup option. Max Iodine Load provides the clinician with the flexibility of setting an upper limit for contrast volume in the interest of patient safety.

9.5.6 Clinical Literature Summary

P3T Abdomen is designed to provide the clinician with flexibility in contrast dosing options for abdominal imaging. These options are intended to reflect the range of clinical care currently practiced and described in the literature. A summary of relevant clinical literature that was used to determine the different setup options and range of values is presented below.

9.5.6.1 Individualized Dosing

Literature references support the use of the following ranges to configure the dosing factor values:

- Weight Factor: 0.4 gI/kg – 0.6 gI/kg in 0.01 gI/kg increments
- Volume Factor: 1.0 mL/kg – 2.5 mL/kg in 0.1 mL/kg increments
- Iodine Load: 18 g – 60 g in 1 g increments

Arana et al. analyzed the influence of contrast dose adjusted by weight vs. fixed contrast dose in the attenuation and cost of abdominal CT and determined that aortic attenuation was significantly superior when contrast was tailored to the patient weight. They concluded that when dose was tailored to patient weight, the use of 1.75 mL/kg of 320 mg/mL concentration contrast material (or 0.56 gI/kg) with saline flushing in abdominal SDCT allowed a reduction of contrast material dose.

Yanaga et al. prospectively compared the effect of a protocol with a fixed contrast material injection dose and one with a dose tailored to patient body weight on pancreatic enhancement. They concluded that injection protocols with doses tailored to patient weight (2.0 mL/kg; 300 mg/mL concentration or 0.6 gI/kg) and fixed injection duration may help reduce variations in pancreatic enhancement.

Heiken et al. determined a relationship linking per-patient contrast dosing and hepatic enhancement. They found that the iodine doses required for desired hepatic parenchymal enhancement levels of 40, 50, 60, and 70 HU are 0.417, 0.521, 0.625, and 0.729 gI/kg. They also recommended against using contrast material of concentration of 240 mg/mL for dynamic incremental hepatic CT except in small patients.

Yamashita et al. studied the optimal dose of intravenous contrast material for CT of the abdomen based on patient weight. When dose was tailored to patient weight, they determined that 2.0-2.5 mL/kg of 300 mg/mL contrast (0.6-0.75 gI/kg) produced better results than did 1.5 mL/kg or a fixed dose for both arterial and hepatic parenchymal enhancement. Arterial enhancement did not differ among the 2.0 mL/kg, 2.5 mL/kg, or fixed-dose groups when contrast was administered at a rate of 3 mL/s.

Megibow et al. studied the minimum optimal dose of contrast medium for helical CT that can preserve image quality while reducing cost. In a prospective trial, they assessed the acceptability of scans for different dose categories of 1.25, 1.5, 1.75, and 2.0 mL/kg with 300 mg/mL contrast. They concluded that a weight based dose at 1.5 mL/kg of low osmolality contrast medium (0.45 gI/kg) can provide acceptable scans in most patients.

Brink et al. assessed the potential for reduction of contrast material dose in hepatic by prospectively studying maximum hepatic enhancement and contrast enhancement index for iodine loads varying from 18 g to 44 g. They found that in heavy patients, a dose of 38 g of iodine produced adequate enhancement whereas, doses as small as 26 g may be sufficient for lighter patients.

Ichikawa et al. studied the technical factors employed in an injection protocol for multiphasic contrast enhanced MDCT of the liver. They determined that the use of a fixed injection duration (30 s) and a body-weight adapted contrast protocol (2 mL/kg with 300 mg/mL contrast or 0.6 gI/ kg), achieves similarity of time density curves of each organ in shape and pattern across different patient weights. With fixed injection duration, the peak enhancement of the aorta, portal vein, and liver constantly appear approximately at 10, 20, and 30 s after the injection is completed.

9.5.6.2 Delivery Method (Injection Duration or Flow Rate)

Awai et al. studied the effect of contrast material injection duration and rate for weight based injection protocols and concluded that aortic peak time and peak enhancement are closely related to injection duration.

Bae et al. investigated the effect of injection rate of contrast medium on aortic and hepatic peak enhancement using pharmokinetic analysis. They concluded that while the use of injection rates above 2 mL/s did not substantially increase hepatic enhancement, higher flow rates helped increase the magnitude of arterial enhancement and temporal separation of arterial and venous phases of enhancement.

9.5.6.3 Saline Flush

The benefits of including a saline flush following the diagnostic contrast injection phase for abdomen studies has been cited in several literature references.

Schoellnast et al. reported that a saline flush statistically significantly improved enhancement of the liver, pancreas, portal vein, and abdominal aorta for contrast enhanced abdominal multidetector CT.

Dorio et al. compared hepatic tumor conspicuity on CT after injection of either 150 mL or contrast or 100 mL of contrast followed by 50 mL of saline. They determined that the two injection protocols did not result in meaningful difference in liver parenchyma attenuation or lesion conspicuity. They also concluded that the routine use of saline flush potentially yields cost savings and also decreases risk of contrast nephropathy.

Murakami et al. studied CT imaging of the hepatic artery and concluded that peak enhancement and duration of the plateau of enhancement were greater when a saline flush is included in the injection protocol.

9.5.7 References

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6. Heiken, J et al. Dynamic Incremental CT: Effect of Volume and Concentration of Contrast Material and Patient Weight on Hepatic Enhancement. Radiology 1995; 195:353–357.
7. Ichikawa et al. Multiphasic contrast-enhanced multidetector-row CT of the liver: Contrast enhancement theory and practical scan protocol with a combination of fixed injection duration and patients' body-weight tailored dose of contrast material. EJR 2006; 58:165–176.
8. Megibow et al. Quantitative and Qualitative Evaluation of Low Osmolality Contrast Medium needed for Routine Helical Abdominal CT. AJR 2001; 176:583–589.
9. Murakami, T et al. Determining the Optimal Timing for Early Arterial Phase Hepatic CT Imaging by Measuring Abdominal Aortic Enhancement in Variable Contrast Injection Protocols. JCAT 2006; 30:206–211.
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10 Troubleshooting

If the problem is not resolved after trying the listed potential solutions, restart the system and try again. If the problem persists, contact Bayer.

10.1 Troubleshooting Tips

Table 10 - 1: Troubleshooting Tips

Problem	Potential Solution
Advance Saline button is not priming tubing/pushing out any saline.	◆ Ensure saline is loaded into the Day Set. ◆ Press and hold the **Advance Saline** button until saline is pushed through.
Outlet air detector is detecting air.	Remove small-diameter tubing from the outlet air sensor and push back in. Ensure outlet air detector door is firmly latched.
The system does not detect installed fluid source.	◆ Ensure spike adapters are fully inserted onto inlet air sensors; spike adapters will click when locked in place. Ensure spikes are fully inserted into fluid bottles and/or bags. ◆ If problem persists, remove spike adapters from inlet air sensors and restart the injector. Clean fluid loading area if necessary, and reinstall spike adapters.
Wireless connection is not working.	Refer to 10.3 Communication Loss Between Injector and Control Room Unit.
Injector door will not open.	◆ Ensure injector is powered on. ◆ Ensure Patient Line is not inserted. Insert a screwdriver into the manual release hole located next to the Unlock Door button.
Patient Line is not primed; injector lights are red.	◆ Ensure saline is loaded into the Day Set. ◆ Check for occlusions. ◆ Press and hold the **Advance Saline** button until the Patient Line is primed.
Prime container is displaying as missing when installed.	Ensure prime container presence sensor is clean and clear of obstructions. Refer to 11.2.3 Clean Prime Container.
Injector is not powering on.	◆ Plug in injector power cord. Turn on power switch at the base of the injector, then press the **Power** button. Refer to 4.1 Power On and Shut Down. ◆ (If applicable) Ensure battery circuit breakers are not disengaged (Figure 4 - 3: Injector Base). If disengaged, push back in. Power on injector.

10.2 System Alert Recovery and Error Screen Messages

On-screen alert messages can occur and will provide instruction on resolving issues. If unable to resolve the issue, restart the system and try again. If the issue persists, contact Bayer or qualified service personnel.

10.3 Communication Loss Between Injector and Control Room Unit

The injector can operate separately of the CRU should communication between the two be disrupted or lost.

NOTE: The exception is personalized protocols, which can only be used when the CRU is on and connected (wired or wirelessly) to the injector.

However, should the communication between the injector and CRU be lost, the CRU will prevent access to Exam. If communication was lost during an injection, the CRU will redirect to the Home screen and a notification displays to continue from the injector.

Set up a wired connection if possible. On the injector, go to Admin / Settings / Networking, and select **Wired**. Plug in ethernet cable from the base of the injector (Figure 4 - 3: Injector Base) to the CRU. Contact Bayer.

10.4 VirtualCare

VirtualCare™ Remote Support allows the user to request service and provides remote service support. The CRU must be connected to the network and able to reach the internet for VirtualCare to operate.

VirtualCare creates help reports to be copied to a USB, which can be sent to Bayer for review. There are two types of help reports that can be created:

- **Technical Assistance Center (TAC) Report** is intended for use by internal service engineers from Bayer and contains detailed logs for debugging.
- **Fight Recorder Activity (FRA) Report** contains simple human readable data in the form of English-only Microsoft Excel files (one per day) that can be opened and reviewed; these files contain a timestamped listing of all system activity.

  NOTE: Neither a TAC nor FRA report contains patient information.

If connected to the internet, VirtualCare allows the user to request support. When support is requested, Bayer will contact the user using the site information provided. Access can be granted to enable remote connection to the CRU for the duration of the service session. (During normal use, remote access is disabled.) The injection system cannot be used for patient exams during this time.

In order to connect the system to the VirtualCare server, LAN1-RIS must be configured (under Admin / LAN1-RIS), and a network cable must be connected. If a proxy server is used for internet, configure the connection under Admin / Proxy Server. Contact the hospital IT department for help with configuring network settings.

11 Cleaning and Maintenance

⚠ WARNING

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

- The system should be opened and serviced by qualified service personnel only.
- Do not remove any covers or disassemble the injector.
- Do not expose system components to excessive amounts of water or cleaning solutions.
- Disconnect the injector before cleaning near power switch (AC power); dry thoroughly before reconnecting.

Pinch Hazard - Serious injury may result from moving pistons.

- Do not insert fingers or hands into the Day Set install area when pistons are advancing or retracting.

This section contains recommended procedures for maintenance and an operational checkout of the injection system. Routine maintenance and inspection ensures continued performance of the injection system and reduces the possibility of equipment malfunction.

The system must be properly maintained to ensure it is in peak operating condition. The individual maintenance schedule depends upon how each injection system is used, the type of procedures performed, and the frequency of use.

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

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

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 in repairing components classified as repairable.
- Instructions and training for correct replacement of interchangeable or detachable parts Bayer specifies as replaceable by service personnel.
- On-site consulting or consulting references.

11.1 Daily Maintenance

Before use each day, the system should be inspected as needed using the procedures outlined in this section. Ensure all system safety and warning labels are in place and are legible. If cleaning is required, follow procedures outlined in 11.2 Clean Fluid Spills or Debris.

The following procedures are recommended for inspection of all components in the system. If any defects are detected, contact a qualified service representative for service. Do not use the system until the problem is corrected.

11.1.1 Inspect Injector

- Inspect the injector body for any cracks that could allow fluid to leak inside the system or weaken the structural integrity of the unit.
- Inspect all connected cables. Look for cuts, cracks, worn spots, or other obvious damage. Ensure all connections are properly seated.
- Inspect the Day Set area for contrast media build-up. Follow the cleaning guidelines outlined in 11.2 Clean Fluid Spills or Debris.
- Make note of any loose exterior mounting bolts and screws, and contact Bayer for servicing.
- Ensure the Day Set lock levers, door latch, and fluid loading mechanisms are functioning.

- For pedestal units, ensure the wheels roll smoothly without binding or scraping and the brakes work.
- Confirm operation of the **All-Stop** button by pressing it; a tone will emit.

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.

11.1.2 Inspect Control Room Unit

- Inspect all cables connected to the unit. Look for cuts, cracks, worn spots, or other obvious damage. Ensure all connectors are properly seated.
- Inspect the housing for any damage or cracks that could weaken the structural integrity of the unit.

11.2 Clean Fluid Spills or Debris

NOTICE:

Electro-Mechanical Hazard - Equipment damage may result.

- The system has been tested for chemical resistance to the following cleaning agents: 96% ethanol, 70% isopropyl alcohol, chlorine bleach diluted 1:10, 3% hydrogen peroxide, PDI Super Sani-Cloth®, and Lysol® Brand II Disinfecting wipes. Use of other cleaning agents may cause equipment damage.
- Do not spray cleaning solutions directly onto the display screen. Refer to cleaning instructions for details.
- Do not pour water directly onto the system; instead, dampen wipe with water.

Refer to the following instructions when cleaning off visible contamination on the system. Exceptions include the following; refer instead to the referenced sections for cleaning instructions:

- inlet/outlet air sensor and barcode reader (11.2.1 Clean Inlet/Outlet Air Sensor and Barcode Reader),
- pistons (11.2.2 Clean Piston Area), and
- prime container (11.2.3 Clean Prime Container).

1. Power off the system.
2. Clean the system:
   a. In the case of contrast media spills, clean the system with a clean and soft non-linting wipe dampened with warm water (wet but not dripping) until visibly clean (minimum of one minute). Replace wipe if it becomes visibly soiled.
   b. In the case of other debris, wipe all external surfaces with cleaning agent (alcohol-based quaternary ammonium cleaning agent, such as PDI Super Sani-Cloth®) for one minute or until visibly clean.
3. Ensure all seams, recessed areas, and buttons are clean. If any visible contrast media or other debris is evident, repeat step 2 until no visible soil is detected.

11.2.1 Clean Inlet/Outlet Air Sensor and Barcode Reader

If necessary, clean using a dry, clean, and soft non-linting wipe and warm water. Finish with isopropyl alcohol (IPA).

11.2.2 Clean Piston Area

1. Power on the system.
2. Ensure the Day Set is not installed.
3. Select **Injector** from the system Home screen, then select the Day Set reservoirs.
4. Press **Clean Piston Area**.
5. Select the **Forward** button once. The pistons will partially advance for access to the piston tips.

Figure 11 - 1: Piston Area

#	Name
1	Piston tip
2	Piston shaft

6. Open the injector door and clean the piston tips.
   a. In the case of contrast media spills, clean the area with a clean and soft non-linting wipe dampened with warm water (wet but not dripping) until visibly clean (minimum of one minute). Replace wipe if it becomes visibly soiled.
   b. In the case of other debris, wipe all external surfaces with cleaning agent (alcohol-based quaternary ammonium cleaning agent, such as PDI Super Sani-Cloth®) for one minute or until visibly clean.
7. Press the **Forward** button again. The pistons will fully advance for access to the piston shafts.
8. Clean the piston shafts.
9. Press the **Reverse** button once. The pistons will retract to their original position.
10. Clean the Day Set area.
11. When finished, shut injector door.

11.2.3 Clean Prime Container

Discard fluids per facility guidelines. Only hand wash the prime container using warm water, a mild soap solution, and a dry, clean, and soft non-linting wipe. When finished, place prime container back into injector. Ensure prime container presence sensor is clean and clear of obstructions.

Figure 11 - 2: Prime Container Presence Sensor

11.3 Disinfect System

1. Ensure the system has been thoroughly cleaned. Refer to 11.2 Clean Fluid Spills or Debris.

2. Use an alcohol-based quaternary ammonium disinfection agent, such as PDI Super Sani-Cloth®, following (as applicable) the manufacturer's instructions to thoroughly wipe all external surfaces. Ensure all seams, recessed areas, and buttons are clean.
3. Allow surface to remain visibly wet for the contact time specified by the manufacturer for disinfection. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.
4. Allow surfaces to thoroughly air dry.

11.4 Annual Maintenance

Once a year, a system calibration and leakage check should be performed by a qualified service representative. Bayer offers preventative maintenance programs. These annual maintenance programs greatly assist in maintaining accuracy and reliability and can extend the life of the system. Contact Bayer for information.

11.4.1 Injection System Calibration

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

11.4.2 Check Electrical Leakage

As part of an annual maintenance program performed by a qualified service representative or authorized dealer, both electrical leakage and protective earth ground continuity checks should be performed. Refer to 13.3.4.1 Electrical Leakage for leakage specifications.

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.

12 Options and Accessories

⚠ WARNING

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

- Only connect items that have been specified as part of or as compatible with the system.

12.1 Ethernet Cables

Catalog Number	Description
CENT-ETH-20	20 m (65.61 ft.) cable

12.2 Sterile Disposables

Catalog Number	Description
CENT-DS	Day Set
CENT-PL	Patient Line
CENT-RS	Replacement Spike

12.3 Accessories

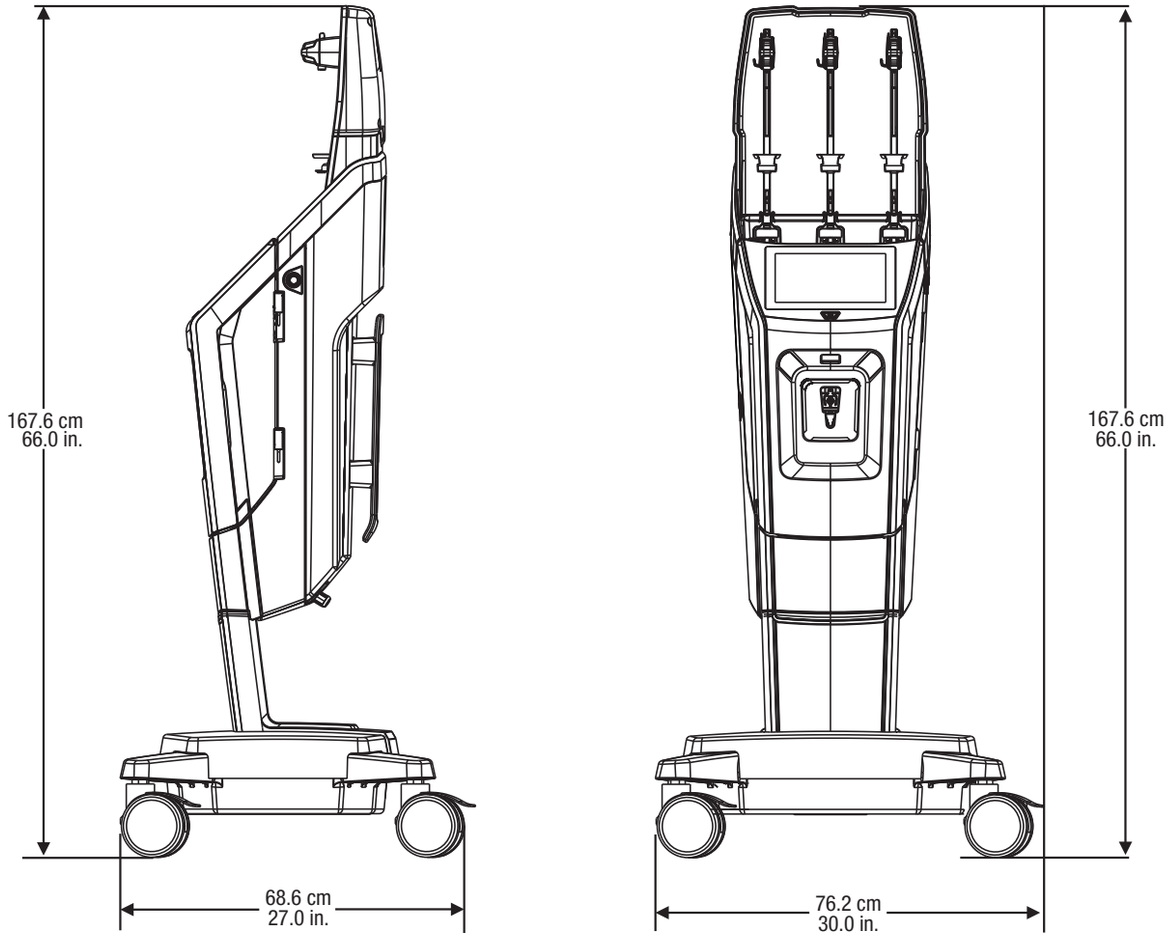
Catalog Number	Description
CENT-PC	Prime container

13 Specifications

13.1 Injector Specifications

13.1.1 Injector Dimensions and Weight

NOTE: Listed weight and dimensions are approximate.



Weight: 74.5 kg (164.2 lbs)

13.1.2 Injector Power Requirements

100-240 VAC

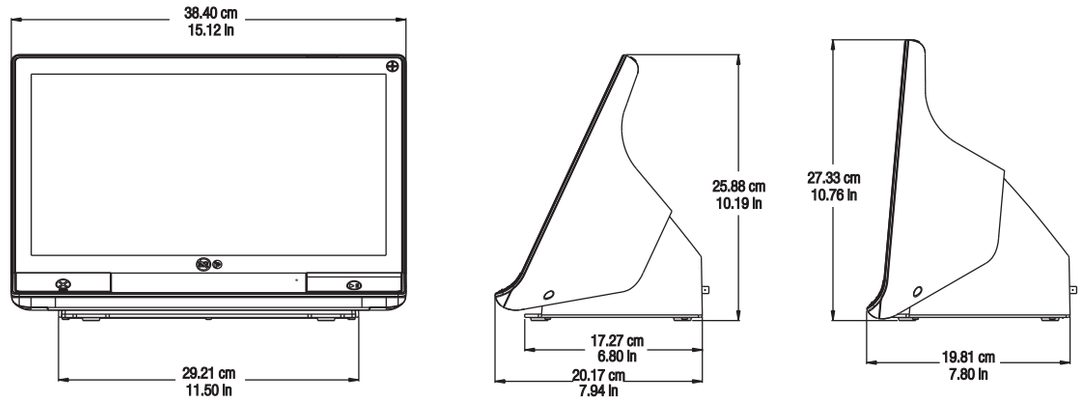
50/60 Hz

336-377 VA

13.2 Control Room Unit Specifications

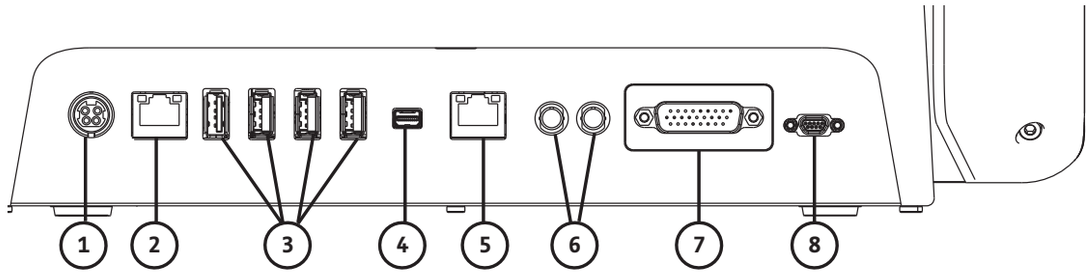
13.2.1 Control Room Unit Dimensions and Weight

NOTE: Listed weight and dimensions are approximate.



Weight: 7.2 kg (15.8 lbs)

13.2.2 Control Room Unit Connections



#	Description	#	Description
1	Power input and supply connection **NOTE:** For the power input and supply connection, the CRU 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 part number from Bayer for power supply.	2	Computer network connection
3	USB connections	4	Connection for screen extension/transfer to a second display
5	Network connection	6	Connections not applicable for system
7	Injector head connection not applicable for system	8	Handswitch connection not applicable for system
	Service ports - not shown (for Bayer use only)		

13.2.3 Control Room Unit Power Requirements

100-240 VAC

50-60 Hz

1.3A

13.3 Injector Environmental Specifications

13.3.1 Non-Operating (Storage)

Temperature:	0 °C to 40 °C with a mean kinetic temperature of ≤ 25 °C (32 °F to 104 °F with a mean kinetic temperature of ≤ 77 °F).
Humidity:	10% to 90% R.H., non-condensing

13.3.2 Non-Operating (Transport)

Extreme Cold:	-29 °C (-20 °F) at uncontrolled RH, for 72 hours.
High temperature and humidity:	38 °C (100 °F), 85% RH for 72 hours
Extreme Heat:	60 °C (140 °F) for 16 hours

13.3.3 Operating

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

Temperature:	+16 °C to + 28 °C (+61 °F to +82 °F)
Humidity:	20% to 90% R.H.
Air Pressure:	70 kPa to 106 kPa

13.3.4 Protection Against Electrical Shock

Per IEC 60601-1, the system is designed as a Class 1 Medical Device and Internally Battery Powered 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.

13.3.4.1 Electrical Leakage

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

Earth Leakage Current:	< 500 microamps (NC)
Chassis (Touch) Leakage Current:	< 100 microamps (NC)
Patient Connection Leakage Current:	< 100 microamps (NC)

13.3.4.2 Ground Continuity

< 0.2 Ohms from power cord ground pin to metal components of the pedestal base.

13.3.5 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.

13.3.6 Protection Against the Ingress of Fluids

The injector has not been classified for protection against the ingress of fluids.

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.

13.3.7 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 is continuous operation with intermittent loading. Although power is applied 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 will not raise enough to degrade safety, system performance, or reliability.

13.3.8 Fluid Delivery Performance

Description	Specification
Volume Range	1 mL to 200 mL for contrast and flush phases, 1 mL to 400 mL for DualFlow phases, in 1 mL increments A total of 400 mL of contrast can be delivered in the same injection if both contrast reservoirs contain the same type and concentration.
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 ◆ Configured for kPa: from 345 kPa to 2068 kPa in 1 kPa increments. ◆ Configured for psi: from 50 psi to 300 psi in 1 psi increments. ◆ Configured for kg/cm^2: from 3.5 kg/cm^2 to 21.1 kg/cm^2 in 0.1 kg/cm^2 increments.
Programmable Delay	1 second to 900 seconds in 1 second increments
Pause	Maximum pause time is 20 minutes
Reservoirs (Volume Capacity)	Maximum three (200 mL)
Injection Capabilities	Maximum 6 phases per injection. Maximum of 10 injections per patient exam.
Flow Rate Accuracy	**NOTE:** The injection system performs within the defined accuracy specifications: - a 2 second interval for flow rates > 5 mL/s, or - a 10 mL volume for flow rates ≤ 5 mL/s ◆ +/- (5% + 0.1) mL/s

Description	Specification
Volume Delivered Accuracy	Contrast or Saline Phase: ◆ +/- (2% + 1 mL) Simultaneous (DualFlow) Phase: ◆ For a DualFlow phase with a ratio of less than 80%, or that occurs following a contrast phase of 20 mL or greater: • Contrast: +/- (4% + 2 mL) • Saline: +/- 4% + 2 mL) • Combined fluid volume: +/- (4% + 2 mL) ◆ For a DualFlow phase with a ratio of 80% or greater that occurs without a preceding contrast phase of 20 mL or greater: • Contrast: +/- (4% + 2 mL) • Saline: + (4% + 7 mL) / - (4% + 2 mL) • Combined fluid volume: + (4% + 7 mL) / - (4% + 2 mL) Multi phase injection: ◆ The total volume of fluid will be within the combined accuracy limits of the individual phases.

13.4 Control Room Unit Environmental Specifications

13.4.1 Non-Operating (Transportation and Storage)

Temperature:	-20 °C to + 60 °C (-4 °F to +140 °F)
Humidity:	5% to 100% R.H., non-condensing
Air Pressure:	57 kPa to 106 kPa

13.4.2 Operating

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

Temperature:	+10 °C to + 40 °C (+50 °F to +104 °F)
Humidity:	20% to 90% R.H.
Air Pressure:	70 kPa to 105 kPa

13.5 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.
- If the required fluids are available, the injector will automatically refill the reservoirs when they do not contain sufficient fluid to complete the next programmed injection. If the fluids are not available, the insufficient volume condition will be indicated when arming is requested.
- Injection monitoring is performed in the injector to detect system faults that could result in over rate or over volume conditions. The delivered volume is also monitored against the total programmed volume for the injection.
- When a fault, pause, abort, or stop request is detected, the injection will stop within 10 mL.
- Once the system has disarmed, a tone sounds, and a message displays on the display screen.

13.6 System Fluid Performance

13.6.1 Factors Affecting Flow Rates

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

- Catheter diameter and length
- Viscosity (thickness) of the fluid
- Temperature of the fluid, Day Set, and Patient Line 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.

13.6.2 Maximum Flow Rate Performance

NOTE: Use of an extension set may compromise fluid delivery performance.

Fluid	Catheter (18 Gauge)
UV 370	8 mL/s
0.9% Saline	8 mL/s

NOTE: The injection system was designed to use the Day Set and Patient Line to operate in a safe and effective manner. The performance of the injection system has been tested with Bayer supplied disposables, with a maximum pressure rating of 300 psi (2068 kPa), and the following plastic catheters:

18 Gauge	◆ Inner diameter: 0.876 mm – 0.978 mm ◆ Length: 1.16 in

13.7 Power Cable Specifications

The specifications required by the Centargo injection system relative to the power cable (plug, receptable, and cord) are:

- Rated 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.

13.8 Cybersecurity and IT Network Connection

13.8.1 System Cybersecurity Protection

System software cybersecurity controls include:

- Internal data integrity checks
- Remote access requires valid credentials and a user at the CRU 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
- Data Manager website access requires valid credentials
- Certegra® database is access restricted
- The virtual wireless access point in the CRU is protected via WPA2 Encryption

13.8.2 Control Room Unit (CRU) Cybersecurity

When Informatics is enabled, the CRU 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 CRU, 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

13.8.3 IT Network Connection

Connecting the system to a 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 network.

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

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

13.9 Mains (AC) Fuse Specifications

FUSE, 2AH, 250V, 5X20MM, IEC TYPE T

13.10 Wireless Communication Specification

The injector can communicate with the CRU via a wireless connection. The wireless radio specifications used in Centargo are:

Standard	IEEE 802.11 b/g/n Standard ◆ Supports 2.4 GHz only
Frequency Range	IEEE 802.11b/g, 802.11g/n HT20: 2412 MHZ ~ 2472 MHz
Transmit Power (EIRP)	IEEE 802.11b: 17.13 dBm
	IEEE 802.11g: 19.22 dBm
	IEEE 802.11g/n HT20: 19.34 dBm
Channel Number	IEEE 802.11b/g, 802.11g/n HT20: 13 channels
Security	WPA2

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

The MEDRAD® Centargo CT Injection System complies with the requirements of:

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

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

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

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

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

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

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

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

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

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

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

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

⚠ WARNING

Electromagnetic Interference Hazard - Serious patient and/or worker injury or death 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 the 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

Electromagnetic 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.

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 2.7 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.

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

Guidance and manufacturer's declaration - electromagnetic emissions

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

Guidance and manufacturer's declaration - electromagnetic immunity

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

<table><tr><th>Frequency (MHz-ISM List)</th><th>Test Level (Vrms)</th></tr><tr><td>1.8 - 2.0</td><td>6</td></tr><tr><td>3.5 - 4.0</td><td>6</td></tr><tr><td>5.3 - 5.4</td><td>6</td></tr><tr><td>6.765 - 6.795</td><td>6</td></tr><tr><td>7.0 - 7.3</td><td>6</td></tr><tr><td>10.1- 10.15</td><td>6</td></tr><tr><td>13.553 - 13.567</td><td>6</td></tr><tr><td>14.0 - 14.2</td><td>6</td></tr><tr><td>18.07 - 18.17</td><td>6</td></tr><tr><td>21.0 - 21.4</td><td>6</td></tr><tr><td>24.89 - 24.99</td><td>6</td></tr><tr><td>26.957 - 27.283</td><td>6</td></tr><tr><td>28.0 - 29.7</td><td>6</td></tr><tr><td>40.66 - 40.70</td><td>6</td></tr><tr><td>50.0 - 54.0</td><td>6</td></tr></table></td><td>WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the injection system unless a greater separation distance is required as indicated by the equation. Otherwise, degradation of the performance of this equipment could result.

Recommended separation distance

$d = 1.17\sqrt{p}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3Vrms from 80 MHz to 2.7 GHz at 80% AM 1kHz and specific ISM bands listed below:

<table><tr><th>Frequency (MHz)</th><th>Modulation Type</th><th>Modulation Frequency</th><th>Field Strength (Volts/meter)</th></tr><tr><td>385</td><td>Pulse</td><td>18 Hz</td><td>27</td></tr><tr><td>450</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>710</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>745</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>780</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>810</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>870</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>930</td><td>Pulse</td><td>18 Hz</td><td>28</td></tr><tr><td>1720</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>1845</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>1970</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>2450</td><td>Pulse</td><td>217 Hz</td><td>28</td></tr><tr><td>5240</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>5500</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr><tr><td>5785</td><td>Pulse</td><td>217 Hz</td><td>9</td></tr></table></td><td>$d = 1.17\sqrt{p}$ 80 MHz to 800 MHz

$d = 2.33\sqrt{p}$ 800 MHz to 2.7 GHz
Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
 
Non-ionizing Radiation Symbol
(IEC TR 60878, 5140)</td></tr>
</table>

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

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.

15 Country-Specific Information

The following information is country-specific. The information within each section pertains only to that country.

15.1 Australia and New Zealand

Australian Communications and Media Authority (ACMA) Regulatory Compliance Marking (RCM)

15.2 Canada

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

IC RSS(Gen, 210 (UNII-1/2/2Ext/3))
ID:4608A-SXPCEAN2

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

15.3 European Union (EU)

15.3.1 Declaration of Conformance

Hereby, Imaxeon Pty Ltd declares that the radio equipment type MEDRAD® Centargo CT Injection System is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: https://radiology.bayer.com/contact

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

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