Operation Manual

Prefilled Syringe Adapter (PFA)

MEDRAD® MRXperion

MR Injection System

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).

1 Overview

For complete operational information, warnings, and cautions, please refer to the MEDRAD® MRXperion MR Injection System operation manual.

This manual applies to the MEDRAD® MRXperion Prefilled Syringe Adapters (Catalog Numbers: MRXP PFA GN, MRXP PFA PE, MRXP PFA YW, MRXP PFA GY) for use with MEDRAD® MRXperion MR Injection System (Catalog Number: MRXP 200).

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

1.1 Indications for Use

This device is indicated for use with the MEDRAD® MRXperion MR Injection System, which is a syringe-based fluid delivery system indicated for delivery of contrast media and saline during MR procedures. This device is not to be used for any purpose other than those for which the device is indicated. Only trained healthcare professionals are intended to operate this device.

1.2 Contraindications

None known.

1.3 Symbols

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

Do not discard.

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

Manufacturer (ISO 15223-1, 5.1.1)

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

Temperature range (ISO 15223-1, 5.3.7)

Humidity range (ISO 15223-1, 5.3.8)

Atmospheric pressure range (ISO 15223-1, 5.3.9)

Date of manufacture (ISO 15223-1, 5.1.3)

Serial number (ISO 15223-1, 5.1.7)

Catalog number (ISO 15223-1, 5.1.6)

This side up (ISO 7000, 0623)

Keep dry (ISO 15223-1, 5.3.4)

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

Part number

Net weight (ISO 7000, 1321B)

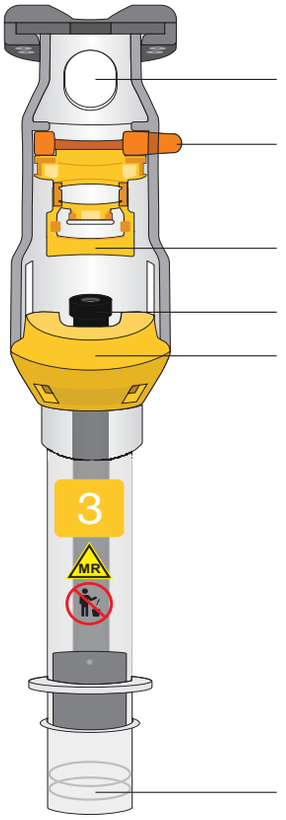
Quantity (IEC TR 60878, 2794)

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

Do not immerse.

⚠ **WARNING**	Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the injection system.
⚠ **CAUTION**	Indicates that the information is a caution. Cautions advise you of circumstances that could result in minor or moderate injury to the patient or operator. Read and understand the cautions before operating the injection system.
NOTICE	Indicates that the information is a notice. Notices advise you of circumstances that could result in damage to the device. Read and understand the notices before operating the injection system.
Note	Indicates that the information that follows is important information or a tip related to the proper functionality of the system that will help the operator to recover from an error or point to related information within the manual. Read and understand the notes before operating the system.

1.4 Prefilled Syringe Adapter (PFA) Components



Prefilled syringe removal access hole

Orange locking ring secures syringe

Cradle holds syringe in place

Adapter piston contacts syringe plunger

Pinch guard covers adapter piston

Optical sensing notifies injector which adapter is installed

NOTE: **Do not discard the prefilled syringe adapter after use.** The adapter is reusable. For cleaning instructions, refer to "Section 4.2 - Cleaning the PFA".

1.5 Prefilled Syringe Adapter Usage

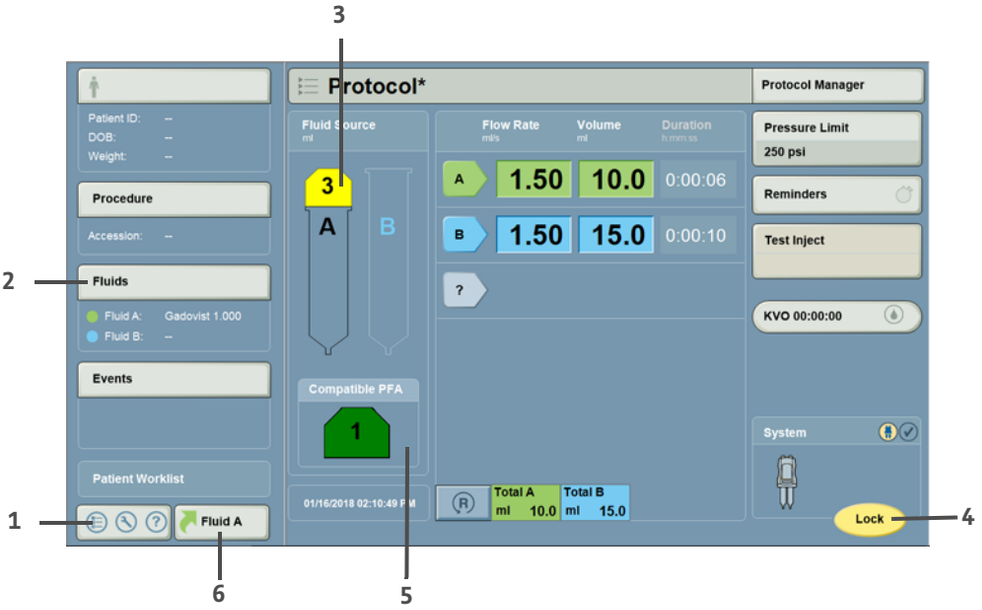
There are four color-coded prefilled syringe adapters available from Bayer:

Supplier	Name	PFA #	Volume (mL)
Bayer	Magnevist	1	5, 10
	Gadovist		5, 7.5, 10
	Primovist		5, 10
Eisai	Prohance[1]	2	13, 17
Bracco	MultiHance[2]		10, 15, 20
Bayer	Magnevist	3	15, 20
	Gadovist		15, 20
Bracco	ProHance[2]		10, 15, 17
Guerbet	Dotarem[2]		15, 20
GE	Clariscan		10, 15, 20
Guerbet Japan	Magnescope[1]	4	10, 11, 13, 15, 20

[1] Only available in Japan
[2] Not available in Japan

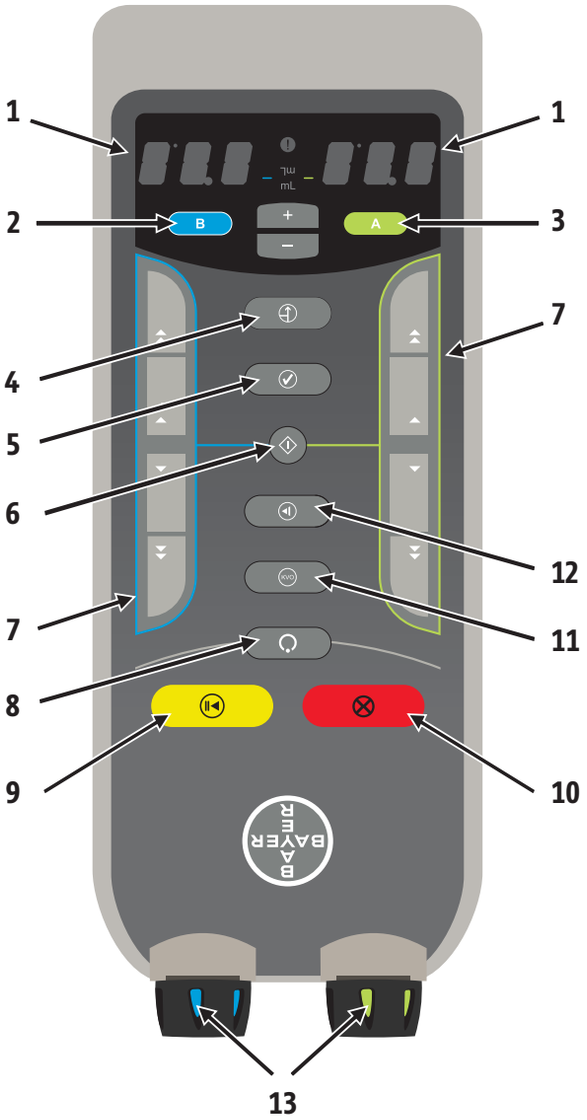
Figure 1 - 1: Compatible Prefilled Syringes

1.6 Home Screen



#	Name	Description
1	Launch Menu	Select to access Setup, Calculators, VirtualCare (if installed), Help, and Shutdown.
2	Fluids	Select to access the Information screen and choose the Fluid A source type (contrast).
3	PFA Status Indicator	When a PFA is installed, an adapter with the color and number of the installed PFA will display. If nothing is installed on Side A of the injector, ◆ a syringe outline will appear when: • PFA feedback is enabled, but “Use Prefilled Syringe with Adapter (PFA)” is unchecked OR • PFA feedback is disabled. ◆ a PFA outline will appear when: • PFA feedback is enabled and “Use Prefilled Syringe with Adapter (PFA)” is checked.
4	Lock/Arm/Disarm	Select to lock a protocol, arm the injector, and disarm the injector.
5	PFA Information	Applicable information related to PFA compatibility with the selected contrast will be shown if PFA Feedback is enabled.
6	Fluid A	Select to display most recent Fluid A values entered. Press OK to select again or Cancel to choose new values.

1.7 Injector Head Overview



#	Name	#	Name
1	Volume Indicator (Side A or B)	8	Arm Button
2	B Button	9	Start/Hold Button
3	A Button	10	Abort Button
4	Prime Button	11	KVO Button
5	I Checked for Air Confirmation Button	12	Test Inject Button
6	Enable Piston Control Button	13	Manual Knobs
7	Forward and Reverse Piston Controls (Side A or B)		

1.8 PFA Installation Features

The system is designed with four features that decrease the time and steps to install and remove the PFA to the injector head.

- **Non-rotational orientation:** When installing a PFA onto the injector head, alignment is unnecessary. Push the PFA into the Side A opening.
- **Auto Docking:** When Auto Advance is configured to be ON and a PFA is installed, the injector piston automatically advances and docks with the PFA piston.
- **Auto Advance:** When Auto Advance is configured to be ON and a PFA is installed, the injector piston automatically docks with the PFA piston and positions it level with the pinch guard.
- **Auto Retract:** When Auto Retract is configured to be ON and the PFA is removed, the injector piston rod will automatically retract into the injector head.

2 Configuration

2.1 Enabling Prefilled Syringe Adapter (PFA) Feedback

System Setup enables the operator to configure settings that affect operation of the overall system.

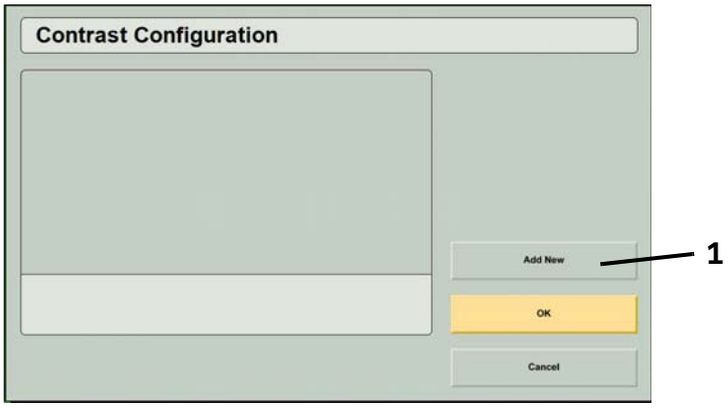
1. From the Launch Menu at the bottom left of the Home screen, select **Setup**, then select **System Setup**.
2. On the second page of System Setup, select **Prefilled Syringe Adapter (PFA) Feedback**.
3. Select **ON** or **OFF**:
   - When “Prefilled Syringe Adapter (PFA) Feedback” is turned ON: The system will recommend the compatible PFA for the selected contrast. The recommendation will be shown on the injector head and on the display.
   - When “Prefilled Syringe Adapter (PFA) Feedback” is turned OFF (Default): The system does not provide recommendations.
4. Select **OK**.
5. Select **Yes** to save changes.

2.2 Contrast Configuration

2.2.1 Adding a New Contrast Type

NOTE: If “PFA Feedback” is enabled, names of contrasts that are compatible with PFAs will be pre-populated.

1. From the Launch Menu at the bottom left of the Home screen, select **Setup**, then select **Fluid Delivery Setup**.
2. Select **Contrast Types** on the Fluid Delivery Setup screen.
3. Select **Add New** (1) on the Contrast Configuration screen.



4. Edit information for each of the following items by selecting a tab (2) on the left of the screen and entering the parameters:

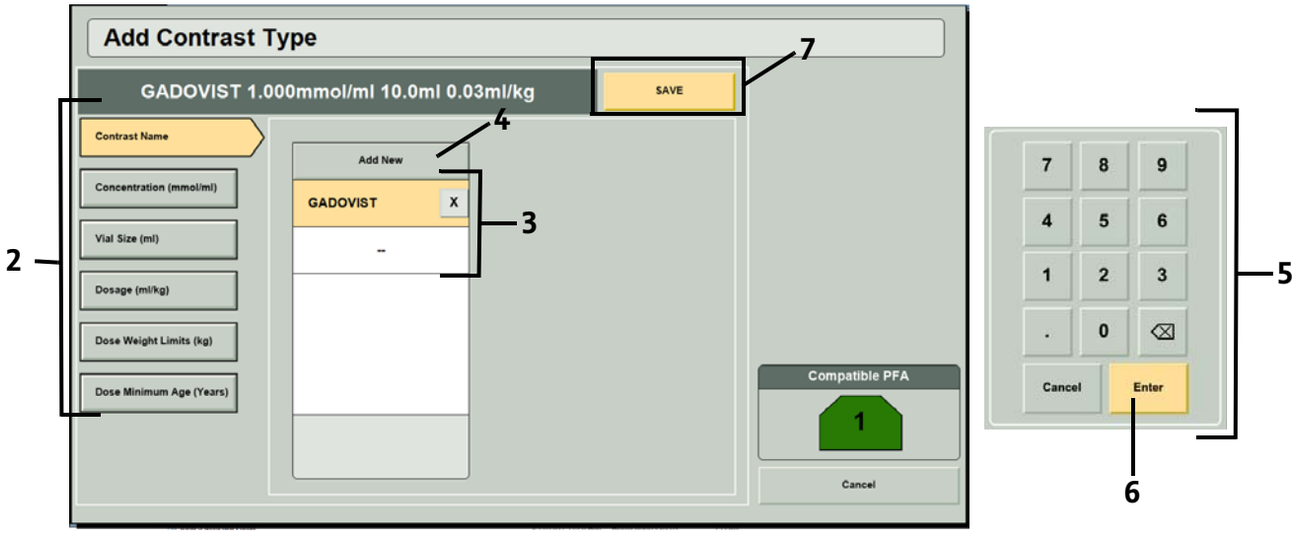


Figure 2 - 1: Adding a New Contrast Type

- Contrast Name: Select an existing contrast name from the list (3) or add a new contrast name by selecting **Add New** (4) and entering the name of the contrast using the keyboard window that will appear on the display. Select **Enter** to save the new contrast name to the list. Select the contrast name from the list.

NOTE: For Prohance, answer "Yes" or "No" when asked "Is this contrast media sold by Eisai?" This will determine which adapter is appropriate for the contrast media.

- Concentration: Select an existing concentration from the list (3) or add a new concentration by selecting **Add New** (4) and entering the concentration (5). Select **Enter** (6) to save the new concentration to the list. Select the concentration from the list.
- Vial Size: Select an existing vial size from the list (3) or add a new vial size by selecting **Add New** (4) and entering the vial size (5). Select **Enter** (6) to save the new vial size to the list. Select the vial size from the list.
- Dosage: Select an existing dosage from the list (3) or add a new dosage by selecting **Add New** (4) and entering the dosage (5). Select **Enter** (6) to save the new dosage to the list. Select the dosage from the list.
- Weight Range: Enter the weight range identified on the contrast package insert.
- Minimum Age: Enter the minimum age identified on the contrast package insert.

NOTE: A saved value can be deleted from the list by pressing the **X** button. Select **Yes** in the message window to confirm deletion. Deleting a value will also delete any saved contrast types using that value.

5. Once the contrast name, concentration, vial size, and dosage have been selected, a **Save** (7) button will appear at the top of the screen. Review the selections in the header and select **Save** to save the Contrast Type. Select **Yes** on the message window to confirm.
6. Select **OK** to save all changes and exit Contrast Configuration.

2.2.2 Editing an Existing Contrast Type

1. Select **Contrast Types** on the Fluid Delivery Setup screen.
2. Select a saved Contrast Type (1) on the Contrast Configuration screen and select **Edit** (2).

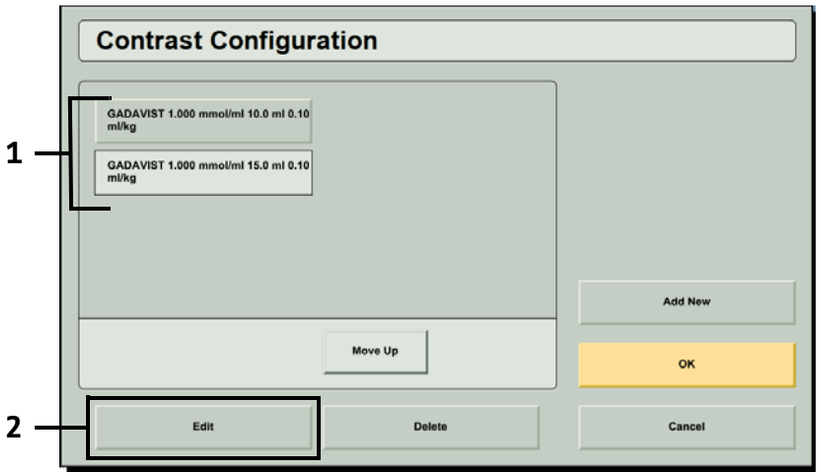


Figure 2 - 2: Select an Existing Contrast Type to edit

3. Edit information for each of the following items by selecting a tab on the left of the screen and entering the parameters (See Figure 2 - 3):

   - Contrast Name: Select an existing contrast name from the list (3) or add a new contrast name by selecting **Add New** (4) and entering the name of the contrast using the keyboard window that will appear on the display. Select **Enter** to save the new contrast name to the list. Select the contrast name from the list.

   NOTE: For Prohance, answer "Yes" or "No" when asked "Is this contrast media sold by Eisai?" This will determine which adapter is appropriate for the contrast media.

   - Concentration: Select an existing concentration from the list (3) or add a new concentration by selecting **Add New** (4) and entering the concentration (5). Select **Enter** (6) to save the new concentration to the list. Select the concentration from the list.
   - Vial Size: Select an existing vial size from the list (3) or add a new vial size by selecting **Add New** (4) and entering the vial size (5). Select **Enter** (6) to save the new vial size to the list. Select the vial size from the list.
   - Dosage: Select an existing dosage from the list (3) or add a new dosage by selecting **Add New** (4) and entering the dosage (5). Select **Enter** (6) to save the new dosage to the list. Select the dosage from the list.
   - Weight Range: Enter the weight range identified on the contrast package insert.
   - Minimum Age: Enter the minimum age identified on the contrast package insert.

   NOTE: A saved value can be deleted from the list by pressing the **X** button. Select **Yes** in the message window to confirm deletion. Deleting a value will also delete any saved contrast types using that value.

4. Once a contrast name, concentration value, vial size, and dosage have been selected, select **Save** (7) to save the Contrast Type. Select **Yes** on the message window to confirm.
5. Select **OK** to save all changes and exit Contrast Configuration.

   NOTE: If no changes were made, a message alerting the operator that a contrast type with those parameters already exists will display when attempting to save the contrast type. Select **OK** to close the message window. Edit a parameter to save the edited contrast type or select **Cancel** to return to the Contrast Configuration screen without making any changes.

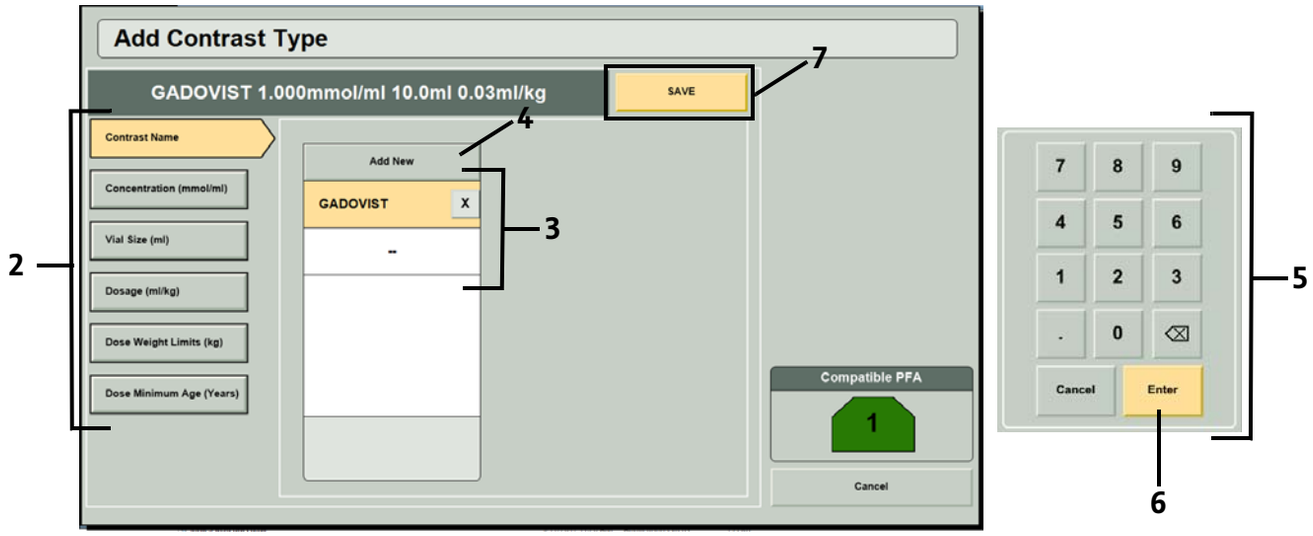


Figure 2 - 3: Editing an Existing Contrast Type

2.2.3 Contrast Type Management

- When two or more contrast types have been saved, the order can be changed by using the Move Up and Move Down buttons on the Contrast Configuration screen.
- To delete a saved contrast type, select the Contrast Type on the Contrast Configuration screen and select Delete. Select Yes to confirm deletion.

3 Preparing for an Injection, Arming, and Injecting

For complete operational information, warnings, and cautions, please refer to the MEDRAD® MRXperion MR Injection System operation manual.

⚠ WARNING

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

- Properly discard contrast and saline containers and disposable items after use (refer to disposable label for specifics), or if there is any possibility that contamination may have occurred.
- Do not reuse single-use fluid (contrast and saline) sources. Refer to the fluid source manufacturers' instructions for use.
- Re-using contrast and saline containers for more than one procedure may result in biological contamination. Discard contrast and saline containers after using syringes for a single procedure.
- Syringes and tubing sets from Bayer are for single use only.
- Use of the system is intended to be consistent with contrast package labeling.

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

- Expel all trapped air from the syringe(s), connectors, tubing, and catheter before connecting the system to the patient.
- To minimize air embolization risks, ensure that one operator is designated the responsibility of filling the syringe. Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that the fluid path is purged of air.
- To minimize the possibility of inadvertent aspiration and injection, ensure the patient is disconnected from the injector when using the forward and reverse piston controls.

Patient injury could result if syringe is not properly engaged.

- Do not load or inject unless the syringe is properly engaged.

Patient or operator injury may result from fluid leads or syringe or tubing ruptures.

- Ensure that the fluid path is open and use disposables that are rated to the set pressure limit. An occlusion in the fluid path and/or use of syringes or tubing rated below the set pressure limit may result in leaks or ruptures.

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

- Follow aseptic technique when handling syringe and connector tubing components. Specifically, maintain sterility of all syringe and connector tubing components.
- Do not disassemble any syringe or connector tubing components. Do not remove the plunger from the syringe.
- Visually inspect contents and package before each use. Do not use if sterile package is opened or damaged.

3.1 Control Room Preparation

1. Select **Fluids** from the informatics panel on the left side of the Home screen. The Information screen will display.

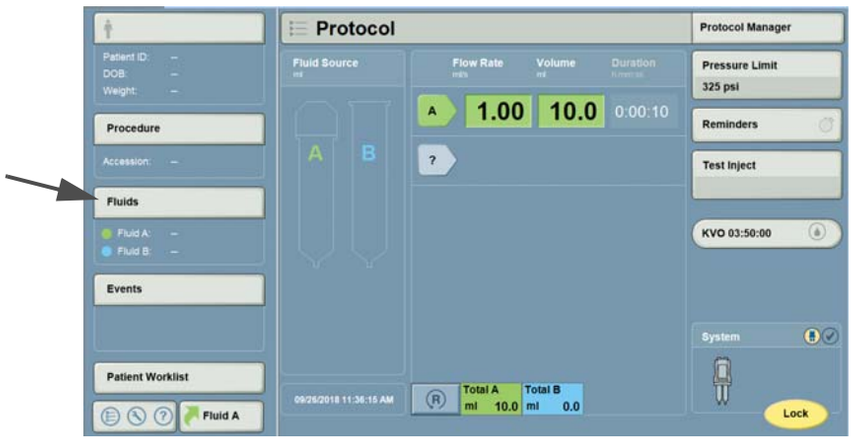


Figure 3 - 1: Select Fluids on the Home Screen

2. On the **Fluid A** tab (1) on the Information screen, select the **Source Type** field (2).
3. Select a configured contrast from the list on the right side of the screen (3). Once a contrast is selected, the compatible PFA will display (4). For more information about contrast configuration, refer to "Section 2.2 - Contrast Configuration".
4. If a PFA is not needed for the injection, uncheck the “Use Prefilled Syringe with Adapter (PFA)” check box (5) or install the contrast syringe. This will disable the additional PFA indicators (4).

   NOTE: When PFA Feedback is enabled, “Use Prefilled Syringe with Adapter (PFA)” is checked by default. See "Enabling Prefilled Syringe Adapter (PFA) Feedback" for more information.

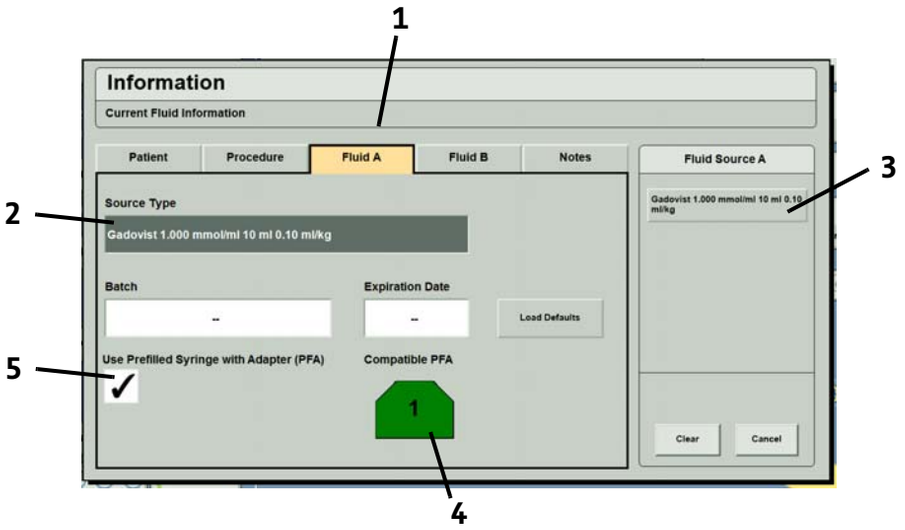


Figure 3 - 2: Information Screen

5. Select **OK** to save changes and return to the Home screen.

6. The Home screen will now show the compatible PFA to use with the selected contrast type (if PFA Feedback is enabled).

Figure 3 - 3: Compatible PFA Recommendation on Home Screen

7. When a PFA is installed on the injector, the PFA Status Indicator (1) on the Home screen will show the PFA installed on Side A.

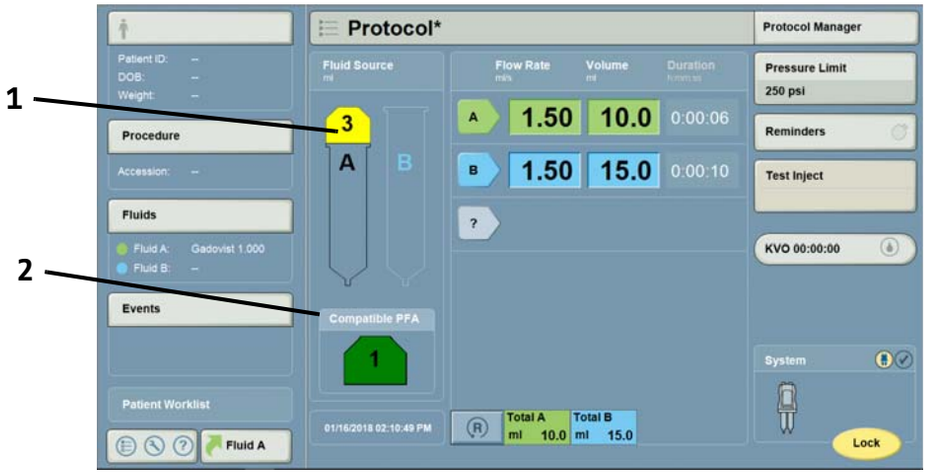


Figure 3 - 4: PFA Status Indicator on Home Screen: Incorrect PFA Installed

NOTE: If a user installs a PFA that is not compatible with the selected contrast type, the compatible PFA will be shown (2) and a message will appear that says "Incorrect adapter installed. Please install the [compatible] adapter." Install the compatible PFA, then select **OK** to proceed.

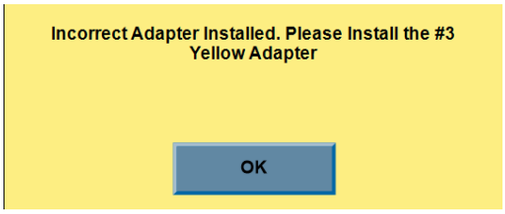


Figure 3 - 5: PFA Status Indicator on Home Screen: Incorrect PFA Installed

3.2 Injection Preparation

1. Set a protocol from the display.
2. Confirm the protocol, then select **Lock** on the display.

   NOTE: **Lock** on the display changes to **Arm** and the injector head Protocol Lock indicator illuminates.
3. Install the saline (Side B) syringe into the injector head.
4. Fill the saline syringe:
   a. Remove the spike luer dust cover.
   b. Install the spike onto the saline syringe.
   c. Remove the spike tip cover.
   d. Insert the spike into the saline source.
   e. Press the **B** button once to view saline volume and again to begin Auto Fill of Syringe B.
   f. Wait 3-5 seconds after Auto Fill is complete, then remove the spike and saline source.
5. Remove and discard the dust covers and syringe rod, if applicable, from the prefilled syringe (PFS). Connect the T-connector side of the tubing to the PFS.
6. Install the PFS into the PFA. Close the orange locking ring.

   NOTE: The PFS may move up and down until the Side A piston is advanced to meet the PFS plunger.
7. Install the PFS and PFA together onto Side A of the injector.

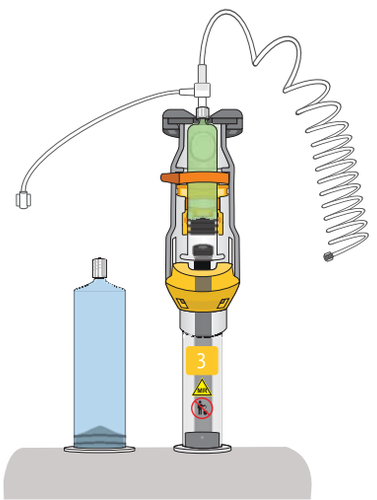


Figure 3 - 6: PFA Installed Into Side A of the Injector with the PFS Installed and Locking Ring Closed

8. Advance the adapter piston to the PFS plunger by pressing the Enable Piston Control button and using the Side A Low Speed Forward Piston Control. The top of the PFS should be in contact with the PFA.

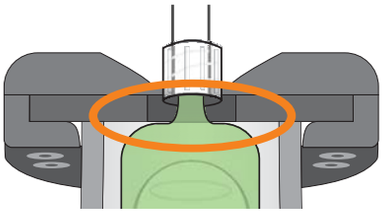
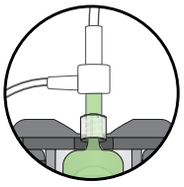


Figure 3 - 7: PFS in Contact with PFA

NOTE: Load rate will automatically adjust when a PFA is installed.

NOTE: The Side A Volume Indicator will blink the compatible PFA number until the PFA is installed into the injector. If a PFA that is not compatible with the selected contrast type is installed, the attention indicator will blink fast. Once a compatible PFA is installed, the Side A Volume Indicator will display "- - -".

3.2.1 Attach and Prime the Tubing



1. Remove the dust cover from the tubing and connect the tubing to the saline syringe.
2. Turn the manual knobs to advance the Side A piston to prime contrast to the T-connector.
3. Prime the tubing with saline manually or using the prime function.
   - Manual Prime: Turn the manual knob on Side B to advance the piston to prime the tubing with saline.
   - Piston Control Prime: Press the Enable Piston Control button to activate the piston controls. Then use the Side B Low Speed Forward Piston Control to prime the tubing with saline.
   - Auto Prime Function: Press the Prime button on the injector head. Prime source will be set to "B" when PFA is in use.
4. Press the I Checked For Air Confirmation button on the injector head to confirm that the syringes and tubing have been inspected for the presence of air.

   NOTE: If required, turn the manual knobs or repeat the priming steps to advance fluid and remove any remaining air.
5. Rotate the injector head downward until it stops and the volume indicators change direction.
6. Connect the tubing to the patient IV.
7. Press the **Test Inject** button to perform an optional test injection. (Fast blinking = test injection in progress.)
8. Press the **KVO** button to activate optional KVO (keep vein open). (Illuminated = KVO in progress.)

3.3 Arming and Injecting

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

NOTE: The injector head must be in the downward position prior to arming. The system prevents arming if the head is in the upright position.

1. Press the **Arm** button on the injector head or select **Arm** on the display to arm the injector.
2. Press the **Start** button on the injector head or workstation to start the injection.
3. To terminate the injection and disarm the injector, press the **Abort** button on the injector head or workstation.

3.4 Removing Disposables

1. Retract the adapter piston:
   - Press the **A** button on the injector head

     OR
   - Select **New Patient** and acknowledge the pop-up on the display.
2. Remove and discard disposables.

   NOTE: Do not discard the prefilled syringe adapter after use.

4 Inspection, Cleaning, and Disinfection of the PFA

NOTICE:

Electro-Mechanical Hazard - Equipment Damage may result.

- Do not soak or immerse the adapter in water. Immersing the adapter in water could damage the adapter.
- On the PFA, do not use cleaning agents containing quaternary ammonium compounds (e.g. dimethyl ethylbenzyl ammonium chloride), such as Sani-Cloth® and ZEP® brand cleaners.

The following procedures are recommended for inspection, cleaning, and disinfection of the prefilled syringe adapter (PFA). Before use, the PFA should be visually inspected using the procedures outlined in this section to ensure that all surfaces are free from defects and residue. If any defects are detected, call the local office for Bayer or the local authorized dealer for a replacement. Do not use the PFA until the problem is corrected. If residue is evident on any surface of the device, follow the cleaning procedures outlined in this section before using the PFA. If visible contamination is evident on any surface of the device, follow the cleaning and disinfection procedures outlined in this section before using the PFA.

4.1 Inspecting the PFA

Frequency: Daily

- Inspect the housing for any damage or cracks that could weaken the structural integrity of the unit.
- Inspect for residue. Follow the cleaning guidelines outlined below.

4.2 Cleaning the PFA

Frequency: As needed or when residue is visible

Materials:

- Clean, soft, non-linting wipe
- Warm water
- Disposable MR-safe soft bristle brush (if required)

1. Clean the PFA external surfaces with a clean, soft, non-linting wipe dampened with warm water (wet, but not dripping) for a minimum of 1 minute until visibly clean. Replace wipe if wipe becomes visibly soiled. During the one minute cleaning time, make certain that all seams and recessed areas are clean. If required, use a disposable MR-safe soft bristle brush to clean the seams of the adapter.
2. Thoroughly dry the PFA using a clean, soft, non-linting wipe.
3. Inspect the PFA to ensure all surfaces are clean.
4. If any residue is visible, repeat cleaning instructions steps 1 through 3 until no residue is detected.

4.3 Disinfecting the PFA

Frequency: As needed or when visibly contaminated

Material:

- Disinfection agent:
  - Use Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes (EPA registration #67619-25)
  - If Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes are not available within your country, then use a disinfectant with 1.4% - 3% hydrogen peroxide

1. Ensure the PFA has been thoroughly cleaned. Refer to "Section 4.2 - Cleaning the PFA".
2. Use the Clorox Healthcare wipes to thoroughly wipe all external surfaces. Make certain that all seams and recessed areas are clean.

   NOTE: If in a country where Clorox Healthcare wipes are not available and using an equivalent disinfecting agent (refer to materials listed above), follow the same instructions specified in step 2.

3. Using the Clorox Healthcare wipes, allow surfaces to remain visibly wet for 5 minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.

   NOTE: If in a country where Clorox Healthcare wipes are not available and using an equivalent disinfecting agent (refer to materials listed above), allow the surface to remain visibly wet per the manufacturer's instructions.

4. Allow the PFA to thoroughly air dry.

5 Troubleshooting

5.1 Selected Source Type Not Compatible with PFAs from Bayer

If the selected prefilled syringe is not compatible with PFAs, a message will appear on the screen that says “Prefilled Syringe not compatible with PFAs.”

For a list of compatible prefilled syringes, refer to "Figure 1 - 1: on page 1-4".

5.2 PFA Piston is Not Engaged with Prefilled Syringe Plunger

If the user has attempted to arm the system when the PFA piston is not advanced, a message will appear on the screen that says “The PFA piston is not engaged with the prefilled syringe plunger. Ensure the patient is disconnected and manually advance the Side A piston.”

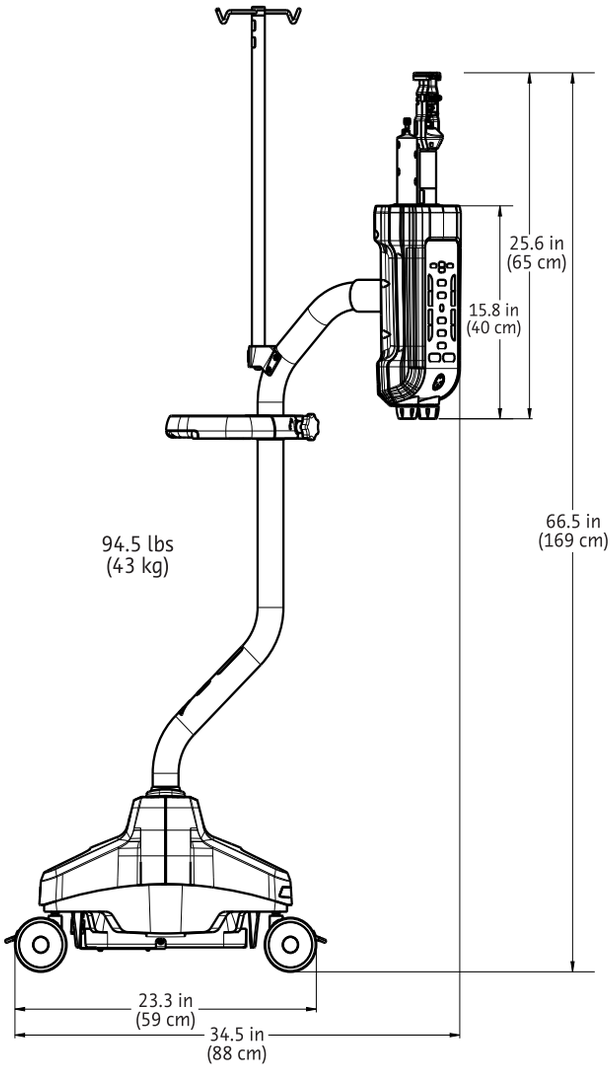
To remove the message,

- disconnect the patient tubing.
- ensure the prefilled syringe is installed in the PFA.
- advance the PFA piston to the prefilled syringe plunger.
- prime to the T-connector with contrast.

6 Specifications

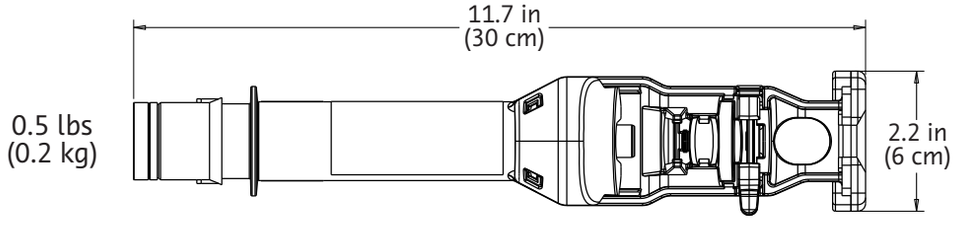
6.1 Injector (Scan Room Unit) Dimensions with PFA Installed

NOTE: Listed dimensions are approximate.



6.2 Prefilled Syringe Adapter (PFA) Dimensions

NOTE: Listed dimensions are approximate.



6.3 System Capabilities with PFA Installed

VOLUME (Programmable):	PFA (Side A)	0.5 mL to max. syringe volume in:
		0.1 mL increments up to 20mL
FLOW RATE (Programmable):	0.01 to 10 mL/s in:	0.01 mL/s increments between 0.01 and 3.1 mL/s
		0.1 mL/s increments between 3.1 and 10mL/s

The programmable pressure limit while a PFA is installed is adjustable in the following increments:

PROGRAMMABLE PRESSURE LIMIT (PSI/kPa):			
Installed PFA			
PFA #1 (Green)	**PFA #2 (Purple)**	**PFA #3 (Yellow)**	**PFA #4 (Gray)**
100/690	100/690	100/690	100/690
150/1035	150/1035	150/1035	150/1035
200/1380	200/1380	200/1380	200/1380
250/1725	250/1725	250/1725	250/1725
300/2070	300/2070	---	300/2070
---	325/2240	---	325/2240

6.4 Fluid Delivery Performance When a PFA is in Use

VOLUME ACCURACY:	**Single Syringe A Injection:** PFA (Side A): +/- (4% + 0.4ml) of the programmed contrast volume
FLOW RATE ACCURACY:	**Single Syringe A Injection:** +/- (25% + 0.005 mL/s) **NOTE:** The injection system performs within the defined flow rate accuracy specifications over steady state. Steady state is measured over at least 1 second.

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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