Rev 1: September 2018

FSN Ref: RYD-SA-2024-02

Date: 16.12.2024

# Urgent Field Safety Notice
# Medrad® Centargo CT Injection System

Dear Valued Customer,

We have identified an issue with the Patient Line sensor, a component of the Centargo CT Injection System which detects a Patient Line. Through the investigation of alleged air injection complaints, it was determined that under certain conditions the Patient Line sensor may not be reliably detecting the presence of a Patient Line.

A Patient Line sensor, which is not working as intended, may detect a Patient Line being installed without one being present. This situation would then trigger the injection system to auto prime saline (which, in this case, would be dispensed onto the floor) and it would also change the light display to Fluid color (Blue). Subsequent Patient Line installation would not be detected by the system and system auto prime would not occur, creating the potential for air injection, in extremely rare circumstances.

A combination of the following items may contribute to Patient Line sensor performance issues:

- Sensor assembly/ manufacturing issues
- Fluid/scuffing (potentially caused by bulk fluid spills or cleaning) of sensor lens

It is important to monitor the situation and rely on best practices when performing procedures; do NOT only rely on automatic system actions (e.g. auto prime).

Please take note of the following steps and adhere to guidance described in the Operations Manual and Instructions for Use (IFU):

- **Safety Check.** As a reminder the operator must always check Patient Line for air (follow the attached screenshots of the Operation Manual and IFU on how to check the Patient Line for air and the meaning of the Patient Line Port Light colors); insert Patient Line only when port light is flashing white.

- **Observe.** Inform Bayer, if you see spraying fluid/ auto priming with no Patient Line in place, or other suspect sensor behavior. This includes Patient Line Port Lights displaying a color other than flashing white when no Patient Line is installed.

- **Work Environment.** Contact Bayer Service if bulk fluid spill occurs with ingress into the injection system.

We appreciate your cooperation and sincerely regret any inconvenience caused by this situation. We maintain high standards of quality control and are committed to providing effective products and service to support patient care.

If you have any questions, pls contact the below manufacturer representative:

| Contact details of manufacturer representative (name, e-mail, telephone, address etc.)* |
| --- |
| Imaxeon<br>Rydalmere Metro Ctr U 1 38-46 South Street<br>Rydalmere New South Wales 2116<br>Contact: Dennis Balacano<br>Dennis.Balacano@bayer.com<br>+61 2 8845 4999 |

# Urgent Field Safety Notice (FSN)
# Medrad® Centargo CT Injection System
# Patient Line Sensor Performance Issues

| 1. Information on Affected Devices* | |
|---|---|
| 1. | 1. Device Type(s)* |
| | Medrad® Centargo CT Injection System |
| 1. | 2. Commercial name(s) |
| | Centargo CT Injection System |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | Basic UDI-DI: (8013)934539000TFCN-0099VY |
| 1. | 4. Primary clinical purpose of device(s)* |
| | To deliver contrast agents intravenously during computed tomography (CT) imaging to enhance the visibility of blood vessels, tissues, and organs for accurate diagnosis. |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | CENT-SYS-BAT (Part Numbers 85173278, 87202313, 87381390, 87977137, 88267303, 88628624, 88982797) and CENT-SYS-OCS (Part Number 87415945) |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | 100000 - 91000428 |
| 1. | 8. Associated devices |
| | N/A |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
|---|---|
| 2. | 1. Description of the product problem* |
| | There may be a performance issue with the Patient Line sensor, a component of the Centargo CT Injection System which detects a Patient Line. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | Possible Air Injection 1-20 mL |
| 2. | 3. Probability of problem arising |
| | The hazardous situation of air injection resulting from the identified problem above is associated with a Remote frequency (less than 1/1,000,000) |
| 2. | 4. Predicted risk to patient/users |
| | Hazardous situation associated with this condition exhibits a Medium residual risk for the Moderate severity level. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | Through the investigation of alleged air injection complaints, it was determined that under certain conditions the Patient Line sensor may not be reliably detecting the presence of a Patient Line. The unreliable detection presence in combination with user reliance on automated system actions (e.g. auto-prime) and suspected workflow errors leads to increased probability of air injections of 1 – 10 ml in volume. No single root cause for Patient Line sensor performance issues could be identified; A combination of the following items may contribute to Patient Line sensor performance issues: 1) Sensor assembly/ |

| | |
|---|---|
| | manufacturing issues, 2) Fluid/scuffing (potentially caused by bulk fluid spills or cleaning) of sensor lens. |
| 2. | 7. Other information relevant to FSCA |
| | See customer addendum for best practices and guidance document |

| | | |
|---|---|---|
| | **3. Type of Action to mitigate the risk*** | |
| **3.** | **1. Action To Be Taken by the User*** <br><br> ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device <br><br> ☐ On-site device modification/inspection <br><br> ☐ Follow patient management recommendations <br><br> ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) <br><br> ☐ Other ☐ None <br><br> Upon receipt refer to customer addendum for best practices and guidance as outlines in the operation manual and instructions for use. Return the customer acknowledgment form at earliest convenience. | |
| 3. | 2. By when should the action be completed? | This FSN is a reinforcement of IFU as per above letter. Return the customer acknowledgement form, upon receipt of FSN. |
| 3. | 3. Particular considerations for: Diagnostic Imaging device <br> Is follow-up of patients or review of patients' previous results recommended? <br> No <br><br> No impact to previously completed diagnostic imaging. | |
| 3. | 4. Is customer Reply Required? * <br> (If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer** <br><br> ☐ Product Removal ☐ On-site device modification/inspection <br> ☐ Software upgrade ☒ IFU or labelling change <br> ☐ Other ☐ None <br><br> Updates to in-service product training | |
| 3 | 6. By when should the action be completed? | Ongoing. |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |
| | No Not appended to this FSN | |
| | **4. General Information*** | |

| | | |
|---|---|---|
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | N/A | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | N/A | |
| 4 | 6. Anticipated timescale for follow-up FSN | No |
| 4. | 7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Imaxeon |
| | b. Address | Rydalmere Metro Ctr U-1 38-46 South Street, Rydalmere New South Wales 2116 |
| | c. Website address | N/A |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes, TGA will be notified. | |
| 4. | 9. List of attachments/appendices: | Attachment 1 – Best Practice & Guidance Document, Attachment 2 – Customer Acknowledgment Form |
| 4. | 10. Name/Signature | **Jeffrey Corrales**<br>**Product Supply Site Director**<br>**Jeffrey.Corrales@bayer.com** |
| | |  |

| | Transmission of this Field Safety Notice |
|---|---|
| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..* |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

**ATTACHMENT 1 TO CUSTOMER LETTER**
**RE: CENTARGO PATIENT LINE SENSOR FIELD CORRECTIVE ACTION**

*The following screenshots are excerpts from the Centargo Operations Manual and Disposables Instructions for Use (IFU), if you have any questions, please contact:*
*Bayer Technical Service – TAC@bayer.com*

## Centargo Operations Manual

- Section 4.2.6.2 (Patient Line Port Lights)
- Section: 5.3 (Install, Prime and Connect Patient Line)
- Section 6.4 (Arm Injector and Confirm Check for Air)
- Section 11.2 (Preloading a Protocol)

### 4.2.6.2 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.<br>◆ Day Set is purging air.<br>◆ 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.<br>**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. |

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## 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 use the Patient Line for more than one patient. Cross contamination can cause infection.
- Discard disposables in case of suspected fluid path contamination.

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

- Check the labeling of any disposables for their maximum pressures. If none are provided, do not use. Ensure that the programmed pressure limit does not exceed the maximum labeled pressures, but is not too low so as to compromise the quality of the study. Use of greater pressures can result in fluid leaks or tubing ruptures and patient or operator injury.

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 13 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.

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### 6.4 Arm Injector and Confirm Check for Air

**⚠ 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 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 protocol does not compromise the safety of a particular patient and will result in an image sufficient for diagnosis, prior to injection.

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.

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. Press **Arm** again after either reviewing the adjusted volumes or refilling has completed.

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### 11.2.2 Preloading a Protocol

**⚠ 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.


**Figure 11 - 2: Preloading Injection Protocol**

1. Select a protocol, then select the **Preload** button on the injector.

   **NOTE:** The **Preload** button will only be enabled if the protocol was configured to be preloadable.

2. The injector advances approximately 9mL of the programmed injection to the end of the Patient Line.

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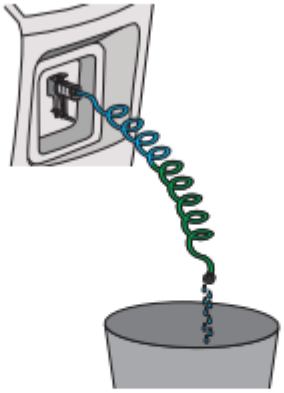

**NOTE:** This can include multiple phases if the first phase is less than the volume of the Patient Line.

3. Once the injection protocol is preloaded, the **Preload** button on the injector changes to a **Reprime**. In addition, an icon appears next to the injection name on both the injector and Control Room Unit.


**Figure 11 - 3: Protocol Preload Complete**

### 11.2.3 Repriming the Patient Line

To undo the preload, Press the **Reprime** button. The injector will reprime the Patient Line with saline. Refer to Figure 11 - 3: Protocol Preload Complete.

### 11.2.4 Modifying the Preloaded Protocol

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Once an injection protocol has been preloaded, any changes made to the protocol (e.g. adding a saline phase) will require the protocol to be preloaded again.

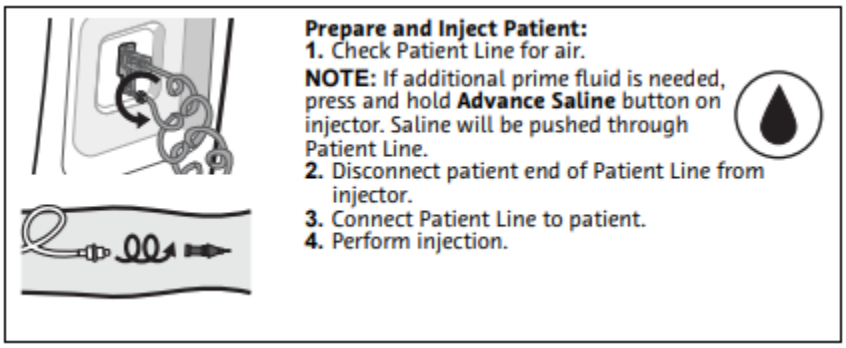
- Press **Preload** to perform the Preload operation again for the modified injection protocol.
- Press **Reprime** to undo the Preload and prime with saline.

### 11.2.5 Preload and Patient Line Lengths

The standard Patient Line (CENT-PL) is available in all markets. An extended length line may be available in some markets. To use the extended patient line with Preload, the user must first set Extended Patient Line Available under **Admin/System/ Configuration/Behaviors**. When preloading a patient's protocol, the choice of Standard (250cm)or Extended length (350cm) becomes available.

- The default setting for **Extended Patient Line Available** is **Off**.
- The default setting for **Default Patient Line Length** is for the Standard (250cm) line.

Disposables Instructions for Use (IFU)



**Prepare and Inject Patient:**
**1.** Check Patient Line for air.
**NOTE:** If additional prime fluid is needed, press and hold **Advance Saline** button on injector. Saline will be pushed through Patient Line.
**2.** Disconnect patient end of Patient Line from injector.
**3.** Connect Patient Line to patient.
**4.** Perform injection.

Associated warning:

**Do not connect the Patient Line to the patient until all trapped air has been cleared. Do not modify or attempt to circumvent the operation of the air sensors.** Air embolization can cause death or serious injury.

# Customer Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | RYD-SA-2024-02 |
| FSN Date* | 16.12.2024 |
| Product/ Device name* | Medrad® Centargo CT Injection System |
| Product Code(s) | CENT-SYS-BAT<br>CENT-SYS-OCS |
| Serial Number (s) | 100000-91000428 |

| 2. Customer Details | |
|---|---|
| Account Number | |
| Healthcare Organisation Name* | |
| Organisation Address* | |
| Department/Unit | |
| Shipping address if different to above | |
| Contact Name* | |
| Title or Function | |
| Telephone number* | |
| Email* | |

| 3. Customer action undertaken on behalf of Healthcare Organisation | | | | |
|---|---|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content. | Customer to complete or enter N/A | | |
| ☐ | I performed all actions requested by the FSN. | Customer to complete or enter N/A | | |
| ☐ | The information and required actions have been brought to the attention of all relevant users and executed. | Customer to complete or enter N/A | | |
| ☐ | I have returned affected devices - enter number of devices returned and date complete. | Qty: | Lot/Serial Number: | Date Returned (DD/MM/YY): |
| | | Qty: | Lot/Serial Number: | Date Returned(DD/MM/YY): |
| | | N/A | Comments: | |
| ☐ | I have destroyed affected devices – enter number destroyed and date complete. | Qty: | Lot/Serial Number: | |
| | | Qty | Lot/Serial Number: | |
| | | N/A | Comments: | |
| ☐ | No affected devices are available for return/ destruction | Customer to complete or enter N/A | | |
| ☐ | Other Action (Define): | | | |

| | | |
|---|---|---|
| ☐ | I do not have any affected devices. | Customer to complete or enter N/A |
| ☐ | I have a query please contact me (e.g. need for replacement of the product). | Customer to enter contact details if different from above and brief description of query |
| Print Name* | | Customer print name here |
| Signature* | | Customer sign here |
| Date* | | |

| **4. Return acknowledgement to sender** | |
|---|---|
| Email | Pre-filled by manufacturer/sender/requester |
| Customer Helpline | Pre-filled by manufacturer/sender/requester |
| Postal Address | Pre-filled by manufacturer/sender/requester |
| Web Portal | Pre-filled by manufacturer/sender/requester |
| Fax | Pre-filled by manufacturer/sender/requester |
| Deadline for returning the customer reply form* | As soon as possible, but before 31/01/2025 |

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.