



Field Safety Notice

Name of the affected products:

3M™ Ranger™ Blood/Fluid Warming High Flow Sets, catalogue numbers 24355 and 24370 used with 3M™ Ranger Blood/Fluid Warming Unit Model 245, and 3M™ Ranger™ Fluid Warming Irrigation Set, catalogue number 24750 used with 3M™ Ranger™ Irrigation Fluid Warming Unit Model 247

FSCA-identifier: 2025-04 FSCA Ranger**Type of action:** Acknowledgement of additional information related to product use

Date: April 30th, 2025**Attention:** 3M Healthcare / Solventum Customers

Dear Customer,

3M and Solventum are notifying all customers and users regarding an update to the instructions for use with respect to flow rates and fluid temperature for the Ranger High flow sets and the Ranger Irrigation sets, as well as the user manuals for the corresponding warming units. The devices' user manuals and instructions for use (IFUs) will be updated to reflect these changes and this letter should be kept as it will take some time until the updated IFUs and user manuals are in the supply chain.

Description of the problem and potential hazard and risk for the patient/user:

There have been no changes to the design or composition of these products that prompted this notification. You may continue to use the products as indicated, considering the updated information provided below.

If the device is used at a flow rate outside of the updated information provided, there is a potential risk for the devices to administer the fluids at a lower temperature than indicated and cause a decrease in patient temperature. Under the dire circumstances of a massive rapid infusion where high flow rates outside of the updated ranges indicated below may be used, there is a potential for hypothermia. This risk remains remote and unlikely. There have been no hypothermia-related complaints reported associated with the use of the devices.

The modified section of the User Manual is provided below with updates underlined:

3M Ranger Blood/Fluid Warming Unit Model 245 used with 3M Ranger Blood/Fluid Warming High Flow Sets Catalog Numbers 24355 and 24370:**Product Description**

The Ranger blood/fluid warming system consists of a Model 245 warming unit and a sterile disposable fluid warming set.

The Ranger blood/fluid warming system is designed to warm blood, blood products, and liquids. Fluids can be warmed from 4°C-20°C inlet temperature to 33°- 41°C. It takes less than 2 minutes to warm up to the 41°C set point temperature and to begin infusion. An overtemperature alert point is set at 43°C and the under-temperature alert point is set at 33°C.

<u>Set</u>	<u>Inlet Fluid Temperature</u>	<u>Flow Rate</u>
<u>Pediatric</u>	<u>4°C-20°C</u>	<u>KVO – 100 mL/min</u>
<u>Standard flow</u>	<u>4°C-20°C</u>	<u>KVO – 150 mL/min</u>
<u>High flow</u>	<u>4°C</u>	<u>KVO – 167 mL/min</u>
<u>High flow</u>	<u>20°C (ambient temperature)</u>	<u>KVO – 333 mL/min</u>

3M Ranger Irrigation Fluid Warming Unit Model 247 used with 3M Ranger Fluid Warming Irrigation Set Catalog Number 24750:

Product Description

The Ranger irrigation fluid warming system consists of a Model 247 warming unit and a sterile disposable fluid warming set.

The 3M™ Ranger™ irrigation fluid warming system is designed to warm irrigation fluids and deliver these at flow rates under gravity up to 580 mL/min. Fluids can be warmed from 20°C inlet temperature to 33°C - 41°C. It takes less than 2 minutes to warm up to the 41°C set point temperature. An overtemperature alert point is set at 48°C and the under-temperature alert point is set at 33°C.

Details on affected devices:

See Tables 1 and 2 for impacted products and lot numbers.

Table 1: 3M Ranger Blood/Fluid Warming Sets

Cat. No.	Device Description	UDI-DI	Number
24355	3M™ Ranger™ Blood/Fluid Warming High Flow Set	Pouch: 10707387792685 Shipper: 50707387792683	All lots with a manufacturing date after March 2022.
24370	3M™ Ranger™ Blood/Fluid Warming High Flow Set	Pouch: 10707387792708 Shipper: 50707387792706	All lots with a manufacturing date after March 2022.
245XX	3M Ranger Blood/Fluid Warming Unit	-/-	All serial numbers

Table 2: 3M Ranger Fluid Warming Irrigation Set

Cat. No.	Device Description	UDI-DI	Number
24750	3M™ Ranger™ Fluid Warming Irrigation Set	Pouch: 10707387792722 Shipper: 50707387792720	All lots with a manufacturing date after March 2022.
247XX	3M Ranger Irrigation Fluid Warming Unit	-/-	All serial numbers

Action to be taken by all customers:

1. Ensure all your internal users are informed about this corrective action.
2. If you are a **distributor**, notify all customers who have purchased the affected products since March 2022 using this Field Safety Notice provided. Continue to provide the FSN to all new customers until Solventum notifies you that the IFUs and operator's manuals were updated.
3. Please inform us if you supplied the affected items to customers outside your home country.
4. Continue to use the products as indicated, considering the updated information provided.
5. Keep this notice on hand until the updated IFUs and operator's manuals are available.
6. Complete and return by e-mail to fsca-emea@solventum.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed.

This notification only applies to the 3M Ranger Blood/Fluid Warming High Flow Sets Catalogue Numbers 24355 and 24370 and 3M Ranger Fluid Warming Irrigation Set Catalogue Number 24750 and does not apply to any other 3M Ranger products.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:

If you have questions, please contact your local Solventum representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Dr. Marie Isabel Cobbers
Manager Complaint handling and Vigilance Reporting
Mail: fsca-emea@solventum.com

Acknowledgement Form – FSN 2025-04 FSCA Ranger**Email completed form to: fsca-emea@solventum.com**

Please check the box below to acknowledge that you have read and understood the clarified flow rates related to the inlet fluid temperature described below for the 3M™ Ranger™ Blood/Fluid Warming High Flow Sets Catalogue Numbers 24355 and 24370 used with 3M™ Ranger Blood/Fluid Warming Unit Model 245 and 3M™ Ranger™ Fluid Warming Irrigation Set Catalogue Number 24750 used with 3M™ Ranger™ Irrigation Fluid Warming Unit Model 247.

- ☐ End-user:
I have read and understood the letter and acknowledge the additional information provided in this notification. and will keep this notice on hand.
- ☐ Distributor:
I have read and understood the letter. I confirm that I have informed all customers who have purchased the affected products since March 2022 about this FSN and that I will continue to provide this FSN to all new customers until Solventum notifies me that the IFUs and operator's manuals were updated.

Email completed form to: fsca-emea@solventum.com

Person completing this form:

Name		Company /Hospital Name	
Signature		City, Country	
Date		Phone	
		E-mail	