Hofspoor 3
3994 VZ Houten
The Netherlands
www.icumed.com

URGENT: FIELD SAFETY NOTICE

Discolouration in Certain IV Tubing Set Drip Chambers

14th August 2026

Dear Valued Customers:

ICU Medical is issuing this Field Safety Notice to inform you that reports of discolouration have been received concerning the drip chambers of certain IV sets. This letter details the investigational findings and the required actions for users to perform.

Issue:
ICU Medical received reports of discolouration observed in the drip chambers of certain IV tubing sets. There were six (6) complaints in the EMEA region between 2022-2025.

Summary of Investigation Findings:
ICU Medical has completed its investigation of reported discolouration observed in certain IV tubing set drip chambers. The investigation confirmed that the observed discolouration is characteristic of the drip chamber material, does not enter the fluid path, and does not affect device safety, performance, or intended use.

Based on these findings, products should continue to be used as intended and per facility protocol.

Investigation Details
To further evaluate the reported observations, ICU Medical conducted an extensive investigation that included evaluation of returned samples, laboratory analysis, simulated-use testing, and inspection of product inventory, and has determined that the reported discolouration is intrinsic to the PVC used to manufacture the drip chamber and remains embedded within the drip chamber wall. The investigation demonstrated that the reported observations represent discolouration of the drip chamber material itself and the discolourations:

- Are not biological contamination
- Are not foreign material
- Do not enter the fluid path
- Do not dislodge under expected use conditions
- Do not affect the structural integrity or performance of the drip chamber

Given these findings, products should continue to be used as intended and per facility protocol.

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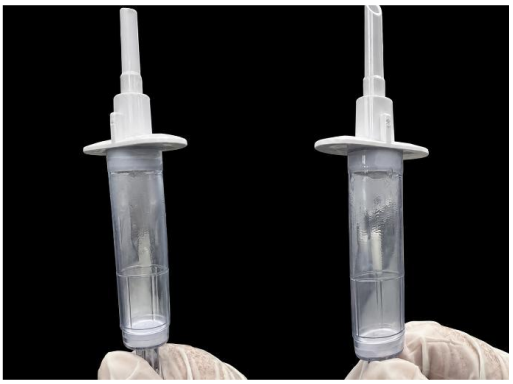
Example images of discolourations are shown below:

Pronounced Dark Discolouration

Small Dark Discolouration



White Hazy Discolouration

The investigation confirmed that the reported discolouration does not affect device safety or performance and is a known characteristic associated with PVC injection molding processes used throughout the medical device industry. In alignment with our continuous improvement initiatives, ICU Medical implemented additional process controls and continues to pursue manufacturing enhancements to further reduce the already rare occurrence of discolouration.

Given these findings, products should continue to be used as intended and per facility protocol.

Potential Risk:

The investigation identified no direct patient risk associated with use of affected products. In some circumstances, a healthcare provider who observes discolouration may elect to replace a product before use, which could result in a delay in therapy. These delays could be clinically significant, especially for time-sensitive, life-saving infusions or when a replacement cannot be readily obtained.

Affected Products:

All ICU Medical IV Tubing sets with a drip chamber that are within their expiration date are covered by this communication, including Plum Administration Sets with drip chambers, IV Non-Dedicated Gravity Administration Sets with drip chambers, IV Sets with drip Chambers and Oncology sets with drip chambers.

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Customer Required Actions

The completed investigation supports continued use of products in accordance with their intended use and standard clinical practices.

Healthcare providers should therefore continue using products in accordance with the Instructions for Use and established clinical procedures per facility protocol. No product returns are necessary

1. Share this communication with the appropriate personnel within your organization.
2. Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.
3. Continue using products as intended and per facility protocol
4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further information contact ICU Medical using the details below:

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	Regional Support | ICU Medical	Additional information or technical assistance.

Your country regulatory agency has been notified of this action

ICU Medical appreciates your partnership throughout this investigation. Based on the completed evaluation, customers should continue to use IV tubing sets with drip chambers as intended and without additional inspection requirements beyond routine clinical practice. We remain committed to delivering safe, reliable products and to communicating transparently with our customers.

Sincerely,

Corine Broekhuizen
Director of Quality, ICU Medical BV

See below:
Customer Response Form

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM
Discolouration in Certain IV Tubing Set Drip Chambers

14th August 2026

Check your inventory and complete the information below, even if you do not have the affected product. Complete this form and return it to EMEA-FSN@icumed.com. If you have questions about this form please contact ICU Medical using the contact provided.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If affected product was purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to the e-mail address provided above)

Adverse events and complaints associated with the use of these products should be reported and emailed to ProductComplaintsPP@icumed.com.