951 Calle Amanacer
San Clemente, CA 92673
www.icumed.com

URGENT: FIELD SAFETY NOTICE

Affected Device(s): Monitoring Kit Transpac® IT

Date: 03-May-2018

Dear Valued Customer:
Director of Risk Management
Director of Nursing
Director of Materials Management

ICU Medical Inc. has identified a potential for separation of pressure tubing on some of the monitoring kits mentioned in the table below.

ICU Medical has received reports of separation of pressure tubing and there is a potential for delay, interruption and/or erroneous measurement of blood pressure, air embolism or blood loss to occur as a result. Out of an abundance of caution, ICU Medical Inc. is voluntarily recalling the affected devices.

Product Affected

Our records indicate that you have received some of the affected products, which were distributed in Switzerland between August 2017 and October 2017. The affected item numbers and lots are provided in Table 1. Alternate product choices are provided in Table 2.

Action Required

To ensure the affected devices are accounted for, removed from use and returned to ICU Medical Inc., please follow the instructions below:

Step	Action	
1	Inspect your inventory for the specific product and their lot numbers listed in Table 1.	
	If…	**Then…**
	No affected devices are found:	• Complete sections A & B of the Field Safety Notice Response Form and return to ICU Medical, see Step 2 below.
	Affected devices are found:	• Quarantine all affected devices • Complete sections A & C of the Field Safety Notice Response Form as applicable and return to ICU Medical per the instructions in Step 2 below. • Contact ICU Medical Customer Care for a Return Goods Authorization ○ E-mail: DistributorsEurope@icumed.com
2	Return completed Field Safety Notice Response Form to ICU Medical via • E-mail: DistributorsEurope@icumed.com	

Upon receipt of the completed Response Form and return of the recalled devices, ICU Medical, Inc. will credit you for any product returned. You will only receive credit for recalled product that you return. NOTE: Credits for product purchased through distributor will be credited by the distributor.

951 Calle Amanacer
San Clemente, CA 92673
www.icumed.com

This recall should be carried out to the user level and passed on to all those who need to be aware within your organization or any other organization to which the device may have been transferred. Please forward this Field Safety Notice to your customers and on to any end users of the devices.

For further inquiries, please contact ICU Medical Inc. using the information provided below:

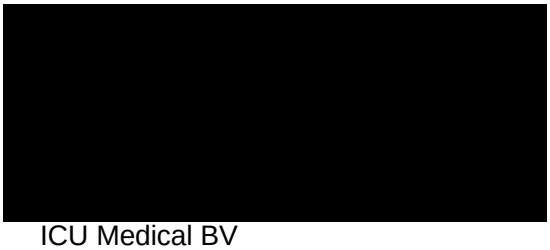
Country	Contact Information	Areas of Support
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
ICU Customer Service	DistributorsEurope@icumed.com	Additional information or assistance relating to this recall including availability of replacement product

This recall is being conducted with the knowledge of SwissMedic and Bfarm.

Please complete the attached Field Safety Notice Response Form and e-mail to DistributorsEurope@icumed.com. Please include the words **"Separation of Pressure Tubing, Lot No 3451008"** in the subject line.

ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



ICU Medical BV

Enclosures:

- Affected Product and Lot Numbers
- Response Form

icumedical
human connections

951 Calle Amanacer
San Clemente, CA 92673
www.icumed.com

Table 1. Affected Product and Lot Numbers

Item No.	Description	Lot No.
011-46112-28	Transpac® IT w/91 INCH (232 CM), 3 ML/HR Macrodrip	3451008

Table 2. Alternate Product Choices

Item No.	Description
011-0P240-01	1 LINE, 1 TRANSDUCER 72 INCH (182 CM), 3 ML/HR MACRODRIP
011-0P240-01S	Transpac® IT, 3ML/HR 72” (182 CM) Blue Stripe Pressure Tubing Macrodrip

951 Calle Amanacer
San Clemente, CA 92673
www.icumed.com

URGENT: FIELD SAFETY NOTICE RESPONSE FORM

Affected Device(s): Monitoring Kit Transpac® IT

Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Section B

[ ] I have read and understood the contents of this Field Safety Notice and confirm that our inventory has been checked and we have no inventory of the listed products.

Section C

[ ] I have read and understood the contents of this Field Safety Notice and confirm that our inventory has been checked, Quarantined, and returned to ICU Medical Inc.:

Item #	Lot #	Quantity Returned (please specify if quantity returned is each device or cases)	ICU RGA Number

Please return to:
ICU Medical Recall Coordinator
E-mail: DistributorsEurope@icumed.com. Please include the words **"Separation of Pressure Tubing, Lot No 3451008"** in the subject line.