Instrumentation Laboratory
A Werfen Company

Instrumentation Laboratory
Tem Innovations GmbH • Martin-Kollar-Strasse 15 • 81829 Munich/Germany

URGENT FIELD SAFETY NOTICE
ROTEM ex-tem, PART NO. 503-05, LOT NO. 42255701

July 22, 2019

Dear Valued ROTEM ex-tem Customer:

This notification is intended to advise your facility regarding a performance issue identified with the following product lot of ROTEM ex-tem:

Product Name	Part No.	Lot No.	Exp. Date
ROTEM ex-tem	503-05	42255701	3/31/2020

• Issue Description and Impact

We have received customer complaints on Lot No. **42255701** of ROTEM ex-tem, reporting prolonged clotting times (CT) with multiple lots of ROTROL N controls. To date, no complaints have reported erroneous patient results.

Internal testing has also demonstrated prolonged ex-tem CT results outside of the normal range for healthy donor whole blood samples. This could potentially result in patients being inappropriately treated.

Accordingly, we are removing Lot No. **42255701** of ROTEM delta ex-tem from the field.

• Mandatory Customer Actions

Based on the above**,** please take the following ***immediate*** actions:

- **Check** your inventory for **Lot No. 42255701** and **destroy** all remaining material.
- **Document** the destruction on the Customer Reply Form and **return** the completed and signed form to the fax number or e-mail address listed on the next page.

Instrumentation Laboratory
instrumentationlaboratory.com

Tem Innovations GmbH
Martin-Kollar-Strasse 15
81829 Munich, Germany

www.rotem.de
Phone: +49 (0) 89 45 42 95 0
Fax: +49 (0) 89 45 42 95 22
E-Mail: rotem.info@ilww.com

CEO: Hans-Martin Combé/Javier Gomez
HRB: 132082 Amtsgericht München
Ust.-IdNr.: DE 209487304
St.-Nr.: 143/185/60952

- **Contact** your local representative for an alternative product lot of ROTEM ex-tem, Part No. 503-05.
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

We appreciate your prompt attention to this Field Safety Notice.

Sincerely,

[redacted]

Instrumentation Laboratory
A Werfen Company

Instrumentation Laboratory
Tem Innovations GmbH • Martin-Kollar-Strasse 15 • 81829 Munich/Germany

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	600000957
FSN Date*	July 22, 2019
Product/ Device name*	ex-tem
Product cat. No.	503-05
Batch/Serial Number (s)	42255701

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 destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number: 42255701
		Date completed	
☐	No affected devices are available for return/ destruction		

Our Passion.
Your Results.

Instrumentation Laboratory
A Werfen Company

☐	I do not have any affected devices.	Customer to enter contact details if different from above and brief description of query
☐	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 Werfen affiliate or distributor
Customer Helpline	Pre-filled by Werfen affiliate or distributor
Postal Address	Pre-filled by Werfen affiliate or distributor
Web Portal	Pre-filled by Werfen affiliate or distributor
Fax	Pre-filled by Werfen affiliate or distributor
Deadline for returning the customer reply form*	Pre-filled by Werfen affiliate or distributor

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.