Instrumentation Laboratory
A Werfen Company

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

Urgent Field Safety Notice (FSN)

ROTEM Rex-tem, PART No. 503-05,
LOT No. 42255701

FSCA: 600000957 **Munich, July 22, 2019**

For Attention of Werfen Affiliates and Distributors (list enclosed)

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	ROTEM r extern reagent for lvD
1.	2. Commercial name(s)
	rex-tem
1.	3. Primary clinical purpose of device(s)*
	(r) ex-tem is a ROTEM system reagent for the assessment of the extrinsic coagulation pathway and its interaction with thrombocytes in citrated blood. It is always used in combination with star-tem.
1.	4. Device Model/Catalogue/part number(s)*
	000503-05
1.	5. Affected serial or lot number range
	42255701
1.	6. Associated devices
	ROTEM delta thromboelastometry system.

	2 **Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	We have received customer complaints on Lot No. 42255701 of ROTEM r ex-tem, reporting prolonged clotting times (CT) with multiple lots of ROTROL N controls. To date, no complaints have reported erroneous patient results.
2.	2. Hazard giving rise to the FSCA* Internal
	testing has demonstrated prolonged ex-tem CT results outside of the normal range for healthy donor whole blood samples. This could potentially results in patients being inappropriately transfused with fresh frozen plasma (FFP) or prothrombin complex concentrate (PCC).
2.	3. Predicted risk to patient/users
	Severity: Temporary or reversible health/safety consequences to patient
2.	4. Further information to help characterise the problem
	As long as mandatory quality control is performed in the laboratory the risk to create wrong patient results is excluded, because failed QC will not allow to use this reagent batch on the analyser. Results must always be interpretated with other laboratory results.
2.	5. Background on Issue
	Root cause was investigated by the contract manufacturer, DSM, and found as impurity of the NaOH/HCL solutions used for the adjustment of the pH during production of the product. This impurity has an impact on the performance of the final product reflected by increased levels of CT values in quality control material ROTROL **N.**

Instrumentation Laboratory
instrumentationlaboratory.com

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

www.rotem.de
Phon e: +49 (0) 89 45 42 95 O
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.-ldNr .: DE 209487304
St.-Nr.: 143/185/60952

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** Identify Device D Quarantine Device D Return Device Destroy Device D On-site device modification/inspection D Follow patient management recommendations D Take note ofamendment/reinforcement of Instructions For Use (IFU) Other D None • **Provide** this information to your customers/distributors in local languages if required • **Inform your local authorities according your local procedures about this FSA.** • **Retain** a copy of this notification for your records.	
3.	2. By when should the action be completed?	October 29, 2019
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	**3.** Manufacturer information	
	a. Company Name	**Tem Innovations GmbH**
	b. Address	**Martin-Kollar-Strasse 15, 81829 Munich**
	c. Website address	**www.instrumentationlaboratory.com**
4.	4. The Competent (Regulatory) Authority of your country must be informed about this communication to customers by you or distributors acc. to the Quality Service Agreement. The competent (regulatory) Authority of the manufacturer, BfArM, will be informed by the manufacturer.	
4.	5. List of attachments/appendices:	**Mandatory Response Tracking Form**
4.	6. Name/Signature	**……**

	Transmission of this Field *Safet {* Nc tice
	This notice needs to be passed on all those who need to be\ç are within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Author ity if appropriate, as this provides important feedback.*

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