IMPORTANT PRODUCT NOTICE
ROTEM® *sigma* complete Part No. 555501
ROTEM® *sigma* complete + hep Part No. 555502

May 12, 2025

ATTENTION: Lab Director, Clinical Laboratory Manager, or Point of Care Coordinator

Dear Valued Customer:

This notification is intended to advise your facility regarding a potential issue identified with ROTEM *sigma* complete and ROTEM *sigma* complete + hep cartridges for the lot numbers identified in the table below.

The table below identifies the LOT numbers per product.

Product Name	Part No.	Lot No.	Expiration Date (YYYY-MM-DD)	UDI-DI
ROTEM *sigma* complete	555501	S240507	2025-11-30	04260160470310
		S240603	2025-12-31	
		S240701	2026-01-31	
		S240707	2026-01-31	
		S240709	2026-01-31	
ROTEM *sigma* complete + hep	555502	S240607	2025-12-31	04260160470327
		S240608	2025-12-31	
		S240706	2026-01-31	
		S240708	2026-01-31	
		S240804	2026-02-08	

- **Issue Description and Impact**

Werfen has identified that the above-mentioned lots of ROTEM *sigma* cartridges have a higher than expected likelihood of generating pressure errors during the ROTEM *sigma* functional checks. These functional checks take place before and after the screen notification to add a sample. If this pressure error is identified after the sample has already been inserted, it will require sample recollection. To minimize the waste of patient samples, we ask that you follow the below listed procedure to allow the full functional checks to complete before sample insertion.

- **Risks to Health:**

After the error occurs, the ROTEM *sigma* is not able to produce patient results and complaints have required recollection of multiple patient blood samples to produce a result or, in some instances, the need to transfuse in the absence of ROTEM guided bleeding management and potentially inappropriate transfusion based on the delay to obtain results.

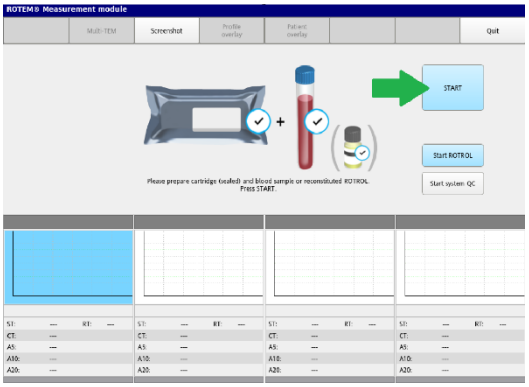
A corrective action has been opened to identify mitigations to prevent this problem from reoccurring in the future.

- **Mandatory Customer Actions**

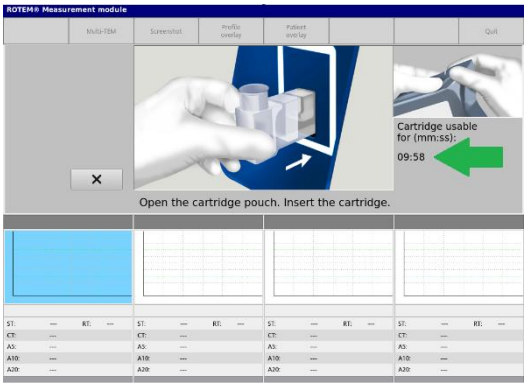
Based on the above, please take the following **immediate** actions:

- **If** you are using the affected lot numbers identified above in your facility, please review the provided guidance and adapt your workflow accordingly.

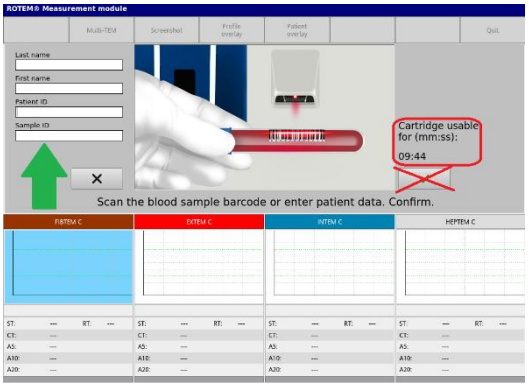
1. Press the start button:



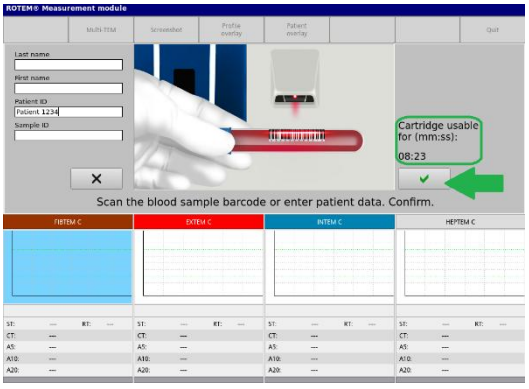
2. Follow the instructions on the screen and remember the time on the clock when cartridge was inserted:



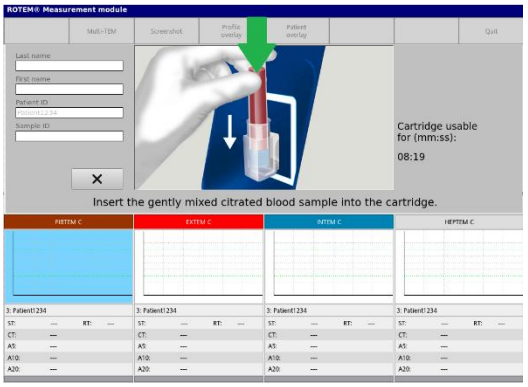
3. Enter or scan patient data and **do not confirm:** (Confirmation will hide the countdown)



4. 90 seconds after the cartridge was inserted confirm patient data:



5. Insert Sample:



- **Document** the acknowledgement on the Customer Reply Form and **return** the completed and signed form to the fax number or e-mail address listed.
- **Share** this information with your clinical users and laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Report** all device-related suspected serious incidents to the manufacturer, distributor, local contact point, and, if appropriate, the National Competent Authority.
- **Retain** a copy of this notification for your records.

- **Customer Reply Form**

The customer reply form can be communicated to Werfen via the below options:
- e-mail address: tem-ra@werfen.com
- Fax no.: + 49-89-45429522

- **Contact information for questions**
  - For technical questions please contact your local Werfen representative

We appreciate your prompt attention to this Important Product Notice.

Sincerely,

David Jacob

Director of Quality Assurance and Regulatory Affairs, PBM
PRRC
Tem Innovations GmbH
SRN: DE-MF-000012176