IMPORTANT PRODUCT NOTICE
ROTEM® *sigma* ROTROL P Part No. 555202

August 14th, 2025

Dear Valued ROTEM Customer:

This notification is intended to advise your facility regarding a potential issue identified with ROTEM *sigma* ROTROL P lot 32400122.

The table below identifies the affected product:

Product Name	Part No.	Lot No.	Expiration Date (YYYY-MM-DD)	UDI-DI
ROTEM *sigma* ROTROL P	555202	32400122	2026-01-31	04260160470358

- **Issue Description and Impact**
  - Werfen has identified that the above-mentioned lot of ROTEM *sigma* ROTROL P has a higher than expected likelihood of generating quality control out of range results n INTEM C CT or HEPTEM C CT assays in conjunction with cartridge lots numbers between S240101 and S250209.

- **Risks to Health:**
  - In the setting where Rotrol P fails QC due to assigned values the system will be rendered unusable. Hence, the treating clinician will likely resort to clinical decision-making for bleeding management and transfusion decisions based on clinical expertise; other available laboratory and diagnostic results; real-time, specific patient considerations; and institution-specific transfusion guidelines/protocols. A subset of these clinical decisions may lead to transfusion decisions (packed red blood cells, fresh frozen plasma or equivalent, cryoprecipitate or equivalent, or platelets) that may differ from viscoelastic-guided driven decisions. 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 ROTEM *sigma* ROTROL P lot number identified above in your facility, please utilize the target range sheet received with this information for all ROTEM sigma cartridge complete and complete plus hep LOTs S240101 and higher for quality control measurements.
- **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

The information contained within this document is the confidential and proprietary information of Werfen / Tem Innovations GmbH, Martin-Kollar-Strasse 15, 81829 Munich, Germany

We appreciate your prompt attention to this Important Product Notice.

Sincerely,

Signed by David Jacob
David Jacob | I approve this document
2025-08-14 | 1:43:35 PM CEST
680C197BCA4643899FB4C4DDA06F4347

David Jacob
Director of Quality Assurance and Regulatory Affairs, PBM PRRC
Tem Innovations GmbH
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