

March 11, 2016

## **Urgent Important Customer Information (Please Read Immediately!)**

**Subject: Information about inconsistent heparin neutralization in the EXTEM C and the FIBTEM C tests in the ROTEM<sup>®</sup> sigma complete + hep cartridge (Art. No. 555502) and EXTEM C, FIBTEM C and APTTEM C in the ROTEM<sup>®</sup> sigma complete cartridge (Art. No. 555501) and recall of all ROTEM<sup>®</sup> sigma complete cartridges (Art. No. 555501)**

Dear Customer,

we must inform you that the current lots of cartridges ROTEM<sup>®</sup> sigma complete (Art. No. 555501) and cartridges ROTEM<sup>®</sup> sigma complete + hep (Art. No. 555502) do not longer consistently fulfill the requirement of neutralizing heparin up to 3 IU UFH /ml whole blood as indicated in the package insert. Whole blood samples containing heparin will show unexpected increased CT-values and decreased amplitudes in the tests EXTEM C, APTTEM C and FIBTEM C.

Following lots are affected:

Art. No. 555501: lot KS150602 (exp. date: 31.03.2016)  
lot KS150701 (exp. date: 30.04.2016)  
lot KS150801 (exp. date: 31.05.2016)  
lot KS151003 (exp. date: 31.07.2016)  
Art. No. 555502: lot KS150603 (exp. date: 31.03.2016)  
lot KS150703 (exp. date: 30.04.2016)  
lot KS150802 (exp. date: 31.05.2016)  
lot KS151201 (exp. date: 30.09.2016)

as well as all future ROTEM<sup>®</sup> sigma complete + hep cartridge (Art. No. 555502) lots until Tem informs that heparin neutralization has been improved consistently.

**Please stop the use of cartridges ROTEM<sup>®</sup> sigma complete (Art. No. 555501) and contact us for replacement free of charge by indicating the quantity to be replaced in your response to the attached confirmation letter! The lots of cartridges ROTEM<sup>®</sup> sigma complete (Art. No. 555501) should be sent back to Tem or discarded according to your institution's procedures for reagent disposal.**

**ROTEM<sup>®</sup> sigma complete + hep cartridges can still be use in patients without therapeutic anticoagulation with unfractionated heparin (UFH) and if the comparison of HEPTEM C with INTEM C and EXTEM C results don't show any significant heparin effects (see attached algorithm). Please make this algorithm visible at any place where ROTEM<sup>®</sup> sigma analyses are performed or displayed.**

Please fill out the CONFIRMATION OF COMPLIANCE letter enclosed and send the signed letter back by e-mail **not later than March 24<sup>th</sup>, 2016** to:

[hans-guenther.tietz@tem-innovations.de](mailto:hans-guenther.tietz@tem-innovations.de) or +49 89 45 42 95 22.

For questions or remarks, please contact our customer service team at:  
+49 89 45 42 95 45 or [support@tem-international.de](mailto:support@tem-international.de)

*The ROTEM® support team*

We kindly ask to excuse this inconvenience.

With kind regards,



Dr. Volker-Joachim Friemert  
Head of Quality Assurance and Regulatory Affairs  
TEM Innovations GmbH

**CONFIRMATION OF COMPLIANCE  
URGENT IMPORTANT CUSTOMER INFORMATION**

Dated on 2016-03-11

Information about inconsistent heparin neutralization in the EXTEM C and the FIBTEM C tests in the ROTEM<sup>®</sup> *sigma* complete + hep cartridge (Art. No. 555502) and EXTEM C, FIBTEM C and APTEM C in the ROTEM<sup>®</sup> *sigma* complete cartridge (Art. No. 555501) and recall of all ROTEM<sup>®</sup> *sigma* complete cartridge (Art. No. 555501)

Hereby we confirm that we have sent back to Tem or discarded our remaining inventory of the lots **ROTEM<sup>®</sup> *sigma* complete (Art. No. 555501)** according to the Urgent Important Customer Information (2016-03-11) and noticed the instructions for use for the **ROTEM<sup>®</sup> *sigma* complete + hep (Art. No. 555502)**.

We have informed all users, who have received these lots.

Date: \_\_\_\_\_

Number of boxes sent back or discarded: \_\_\_\_\_

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Company: \_\_\_\_\_

Signature: \_\_\_\_\_

**Please send this completed document as soon as possible to:**

[hans-guenther.tietz@tem-innovations.de](mailto:hans-guenther.tietz@tem-innovations.de) or fax to +49 89 45 42 95 22.