tem®
Redefining Bleeding Control

Tem Innovations GmbH • Martin-Kollar-Strasse 13-15 • 81829 Munich/Germany

November 15, 2016

IMPORTANT CUSTOMER STATEMENT
Use of ROTEM® *sigma* cartridges complete + hep
Lot Numbers S160802 and S160905

We wish to inform you about this important change:

HEPTEM C is able to neutralize the heparin effect seen in INTEM C, up to 5 IU/ml unfractionated heparin spiked in whole blood. However, in experiments with citrated blood samples from 20 healthy donors spiked with 5 IU UFH per ml whole blood, in HEPTEM C the CT (clotting time) in lot S160802 and S160905 was in mean prolonged by 26.4% (range 5-50%).

HEPTEM C is able to neutralize the moderate effect of LMWH seen in INTEM C. The effect of danaparoid sodium seen in INTEM C cannot be neutralized. As no effect of fondaparinux in therapeutic dosage is seen in INTEM C, neutralization by HEPTEM C cannot be shown.

Experiments with citrated blood samples from 20 healthy donors spiked with 0 or 5 IU UFH per ml whole blood showed the following results:

FIBTEM C clot firmness parameter results (A5, A10, A20, A30 and MCF) can be up to 15% lower compared to the FIBTEM results measured with ROTEM® *delta* liquid reagents.

EXTEM C A5 (A10) results can be up to 15% (10%) lower compared to the EXTEM A5 (A10) results measured with ROTEM® *delta* liquid reagents.
The differences between EXTEM C A20, A30 and MCF results and the corresponding EXTEM results measured with ROTEM® *delta* liquid reagents are below 5%.

Please note:
HEPTEM C A5, A10 and A20 results can be reduced by in mean 10.6% (up to 30%), 5.8% (up to 15%) and 2.9% (up to 10%), respectively, in blood samples spiked with 5 IU UFH/ml. Accordingly, A5 values measured with the ROTEM® *sigma* cartridge complete + hep lot S160802 and S160905 have to be interpreted carefully in blood samples taken on cardio-pulmonary bypass, and HEPTEM C results assessed with these lots on cardio-pulmonary bypass can only be used for bleeding risk assessment, but not for final therapeutic decision-making. In cases of clinically relevant bleeding after weaning from cardio-pulmonary bypass and heparin-reversal with protamine, hemostasis should be re-assessed with a new blood sample and therapeutic decisions should be based on the results of this ROTEM® analysis.

For further information and support, our customer service will be happy to assist you at support@tem-international.de .

Sincerely yours,

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Dr. Volker-Joachim Friemert
Head of QA and RA

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CONFIRMATION OF KNOWLEDGE

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Lot Numbers S160802 and S160905

Dated on 2016-11-15

Hereby we confirm to have knowledge and understanding of the content of the Important Customer Statement "Use of ROTEM® *sigma* cartridges complete + hep, Lot Numbers S160802 and S160905" dated on 2016-11-15.

We have informed all colleagues dealing with ROTEM® *sigma* complete + hep cartridges.

Date: _____

Name: _____

Position: _____

Company: _____

Signature: _____

Please send this completed document as soon as possible to:

✉ Hans.Tietz@tem-innovations.de

or

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