



Munich, March 14, 2017

## **IMPORTANT CUSTOMER INFORMATION**

**To all ROTEM® *delta* Thromboelastometry System users**

**In reference to IvD product r ex-tem, ref. # 000503-05, lot 21734044 with prolonged CT values**

Dear Customer,

Internal and external observations with some vials of r ex-tem, lot 21734044 (expiration 10/2017) demonstrated prolonged CT values. In testing, some whole blood patient samples have shown CT values up to 4 times longer than expected. QC measurements with ROTROL N or P have also produced longer CT's as compared to other lots; these CT values have at times exceeded the target ranges.

All other parameters and functions such as heparin neutralization or sensitivity to factor deficiencies remain unaffected.

While the root cause of these observations is currently under investigation, we have taken the decision to recall this lot.

**The following recall procedure must be followed:**

**Do not use any remaining vials of r ex-tem, lot 21734044!**

1. Destroy all remaining material according to local waste regulations.
2. Inform your local supplier of the quantity of kits to be replaced free of charge.
3. Complete the enclosed CONFIRMATION OF IMPORTANT CUSTOMER INFORMATION form
4. Before March 31<sup>st</sup> 2017, fax the completed form to +49 89 45 42 95 22 or e-mail to [hgtietz@ilww.com](mailto:hgtietz@ilww.com)

We apologize for the inconvenience this may cause and thank you in advance for your cooperation.

Kind regards,

**Tem Innovations GmbH  
Instrumentation Laboratory**

**Our Passion.  
Your Results.**

**CONFIRMATION OF IMPORTANT CUSTOMER INFORMATION**

**Prolonged CT values with r ex-tem, ref. # 000503-05, lot 21734044  
from March 14, 2017**

I have acknowledged receiving and reviewing the important customer information  
"r ex-tem, ref. # 000503-05, lot 21734044 with prolonged CT values" from March 14, 2017.

I have disposed of our remaining stock of #\_\_\_\_\_ kits of r ex-tem lot 21734044.

I have informed all users of this reagent lot regarding this recall action.

**Date:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

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

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

**Company/Institute:** \_\_\_\_\_

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

Please e-mail the completed form as soon as possible to:

[hgtietz@ilww.com](mailto:hgtietz@ilww.com)

or

fax to: +49 89 45 42 95 22