Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: Lactate membrane units, 942-066, when used with ABL700 and ABL800 Series Analyzers

Priority Level: Urgent

Dear Customer

Addendum:
This is an addendum to the letter distributed in October 2012.

Affected product:
Lactate membrane units, ordering number 942-066.

Resolution of the problem:
RADIOMETER has now implemented an end of production line test for lactate membrane units to ensure that lactate membrane units with the issue described on the next page are no longer released for sale.

Implementation:
The end of line production test has been implemented for lactate membrane units, 942-066, of **Lot 2192 onwards.**

Consequences:
With the implementation of the new end of production line test we will now have two populations of lactate membrane units, which must be handled differently as indicated below:

> ***For membrane units below Lot 2192:***
> Continue to perform the Quality Control verification of a new Lactate membrane as described overleaf (text copied from our October 2012 letter).
>
> ***For membrane units of Lot 2192 onwards:***
> It is not necessary to perform the Quality Control verification of a new Lactate membrane. Hence, the procedure given in the Operator's Manual applies.

Please complete and return the attached fax form, with your signature.

If you have any questions, please contact your Radiometer representative.

Best regards,
<Radiometer distributor>

The text below is copied from the original letter distributed in October 2012 and is still relevant for membrane units below Lot 2192.

Description of the problem:

RADIOMETER recently became aware that some membranes may have enzyme residues on the outer membrane. Upon replacement of the Lactate membrane the enzyme residue may cause an initial negative bias on the reported Lactate result. The bias decreases over the in-use time, and depending on the amount of residue it may take anything between hours and days for the bias to disappear.

Worst case the bias upon membrane replacement is -1.5 mmol/L at Lactate levels over 7.0 mmol/L. This is most apparent when comparing results measured before and immediately after membrane replacement.

User Action:
Until further notice the following steps must be carried out upon replacement of the Lactate membrane.

1. Wait for the analyzer to complete the startup calibration
2. Perform one quality control measurement (see “Preparation for Quality Control Verification” overleaf) to verify the Lactate performance.
   In case the result is out of the reduced limits subsequent patient results are questioned to indicate that the bias is present.

Please do not report Lactate results over 7.0 mmol/L unless the above is performed upon replacement of the Lactate membrane.

Preparation for Quality Control Verification:
Preparation for Quality Control verification of a new Lactate membrane:

1. Select one of the Quality Control products listed below to be used for Lactate verification:

   Qualicheck5+: S7750 (Level 3)
   Autocheck5+: S7755 (Level 3)
   Autocheck6+: S7855 (Level 3)

   These products contain high levels of Lactate and will detect if a bias is present.

2. Manually adjust the upper and lower limits for Lactate on the analyzer in relation to the limits printed on the insert as follows:

   - Adjust the upper limit by -0.5 mmol/L

   - Adjust the lower limit by +0.5 mmol/L

   I.e. the control ranges are decreased from ± 1.8 mmol/L to ± 1.3 mmol/L.

   This must be done for every lot of QC ampoules used for the verification.

Recall Response Fax Form

Fax No.:

Concerning:

Lactate membrane units, 942-066, when used with ABL700 and ABL800 Series Analyzers

□ We have received the customer letter, and:

□ We acknowledge that for Lactate membrane units **below Lot 2192** Lactate results over 7.0 mmol/L must NOT be reported unless the requested Quality Control Verification procedure is followed.

□ We acknowledge that for Lactate membrane units of **Lot 2192 onwards** the procedure remembraning the lactate electrode given in the Operator's Manual applies.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	