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## **Urgent Field Safety Notice**

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

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October, 2012

### **Customer Name/Address**

Dear **Customer Name**:

### **Details on affected devices:**

This Field Safety Notice is applicable to the following *Radiometer product*:

***Lactate membrane units, ordering number 942-066***

### **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  $\pm 1.8$  mmol/L to  $\pm 1.3$  mmol/L.**

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

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

If you have any questions regarding this letter please contact your Radiometer distributor.

We sincerely apologize for the inconvenience this may cause.

Regards,

**FAX RETURN FORM**

Product Description

Lactate membrane units, ordering number 942-066

- We acknowledge receipt of the urgent field safety notice.***
- Furthermore, we acknowledge that Lactate results over 7.0 mmol/L must NOT be reported unless the requested procedure is followed.***

***Please print the following information:***

\_\_\_\_\_  
Hospital

\_\_\_\_\_  
Address

\_\_\_\_\_  
Contact Person

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

***Additionally, please fax this form to the following number:  
(Insert Fax number here)***