

Customer  
 Hospital  
 City  
 Postal code  
 Country

Attn.: XXX

**Urgent Field Safety Notice: Mandatory update of Operator's Manual for ABL8x7 analyzers**

Dear Customer,

Radiometer recently learned that the information regarding the recommended replacement intervals for the **Reference Membrane D711** in the manual for your **ABL8X7 Flex Creatinine Analyzer** needs to be corrected. In house analysis of customer data has shown that analyzers measuring Creatinine, ABL8x7, have a shorter in-use lifetime of the reference membrane than the currently recommended 1-month listed in the current Operators Manual. We have therefore made a change to the recommended replacement intervals in the Operators Manual to reflect this:

Samples per day	Replacement Interval
≤ 40	2 weeks
> 40	1 week

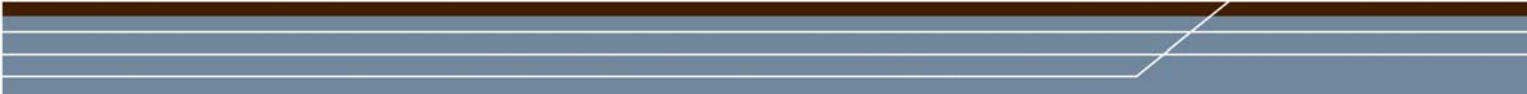
**Action:**

Enclosed is an insert for your manual with the revised replacement intervals. You should remove and destroy that page as it is now outdated and replaced with the enclosed page. It is important to immediately review the new recommended replacement intervals, as the new intervals may require you to replace the reference membrane in your ABL8X7 Flex Creatinine analyzer.

We ask that you complete and return the attached fax form, with your signature to <FAX number>.

We apologize for any inconvenience that this may have caused. If you have any questions regarding this letter, or the upgrade, please contact <Radiometer distributor>.

Kind Regards,  
 <Radiometer distributor>



**FAX FORM:**

**Fax Number:** <FAX number>

**Concerning:**

**Change to the Recommended Replacement Intervals for Reference Membrane D711 in the manual for your ABL8X7 Flex**

This is to confirm that the Field Safety Notice regarding the upgrade for the Operators manual has been received.

**I have received the letter and appropriate actions have been taken to ensure full compliance with the instructions outlined in this letter**

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

Hospital: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

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

Title: \_\_\_\_\_

