

<Contact Name>  
<Account 2>  
<Department>

ID: <ID>

**Priority Level: Recall**

**Date: --/--/2018**

**ABL800 analyzers; Low cCrea results on patient samples**

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Dear Customer

Radiometer has recently become aware that the ABL800 FLEX analyzer can potentially report lower than expected cCrea results on patient samples. The difference has been reported to be as high as -28%. The issue may not be caught by running QC, as the QC will be lower, but still within range.

**Risk for the patient**

The described error may potentially lead to an underestimation of the actual serum creatinine concentration (cCrea) of up to 28% or erroneous measurement values for cCrea, resulting in no detection of renal insufficiency or underestimation of moderate to severe renal failure.

In case of a non-detected minor renal insufficiency, the patient may be subjected to diagnostic imaging procedures involving intravenous injection of contrast, which may, in a worst-case scenario, lead to acute renal failure (contrast-induced nephropathy, CIN).

**Affected product:**

All ABL800 FLEX analyzers measuring cCrea.

**Interim Countermeasure**

Before reporting cCrea results, verify the performance of the membrane units as described below:

- If not already installed, install S7835 Autocheck 6+. Level 1 (#944-094)
- Manually adjust the cCrea lower limit for S7835 AutoCheck 6+, level 1 by +20 µmol/L (example: Adjust from 210 µmol/L to 230 µmol/L).  
You must do this for every lot of QC ampoules used for the verification.
- Perform one quality control measurement using S7835 AutoCheck 6+, level 1 on already installed Crea membrane units to verify the cCrea performance.  
If the QC result is out of range, install new Crea A and Crea B membranes.

Until further notice, follow the procedure every 24 hours and upon replacement of Crea A and Crea B membranes:

- Perform one quality control measurement using S7835 AutoCheck 6+, level 1, to verify the cCrea performance.
- If the QC result is out of range, install new Crea A and Crea B membranes

The above countermeasures are to be considered as an interim change of labeling.

**Permanent Countermeasure provided by Radiometer:**

Radiometer is working on improving the Crea membranes, and will inform you accordingly when the QC verification is no longer needed.

**We ask that you please complete the attached response form and send it to the number at the bottom of the form.**

**Please Note:**

If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact Technical Support at 800-736-0600 opt 4, or via email: [support@radiometeramerica.com](mailto:support@radiometeramerica.com)

Best regards,

A handwritten signature in blue ink, appearing to read 'Matthew R. Ackerman', with a stylized flourish at the end.

Matthew R. Ackerman  
Radiometer America, Inc.  
Quality Assurance/ Regulatory Affairs Manager  
1-800-736-0600 opt.4

# Response Form

## ABL8x7 Flex analyzers

### ACKNOWLEDGEMENT FORM

Product Description	Part Number	Lot Number(s)/Serial Number(s)
ABL8x7 Flex	All	All

- I have received the customer advisory letter
- I acknowledge that cCrea results must NOT be reported unless performance of the membrane units has been verified as requested.

Contact Person (please print)

Facility

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Signature

Date

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ID:<ID>

WE ALSO KINDLY REQUEST YOUR COOPERATION IN FAXING THIS ACKNOWLEDGEMENT TO THE FOLLOWING NUMBER SO WE MAY UPDATE OUR RECORDS.

**FAX Number: 714 582 0806**