

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Urgent Field Safety Notice: ABL800 analyzers; Low cCrea results patient samples

Dear Customer

Radiometer has recently become aware that the ABL800 analyzer potentially could report lower than expected cCrea results patient samples. The difference has been reported to be as high as -28%.

This problem 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 immediate as well as long range adverse health consequences for the patient. The described error may lead to underestimation of the actual serum creatinine concentration (cCrea) of up to 28%. The described error may lead to erroneous measurement values for cCrea, and may lead to 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 analyzers measuring cCrea.

What you must do:

Radiometer requests that you do not report cCrea results until you have verified the performance of the membrane units as described below.

Carry out the following steps immediately on the affected product:

- If not already installed, install S7835 Autocheck 6+. Level 1 (#944-094)
- Manually adjust the lower limit for S7835 AutoCheck 6+, level 1 by +20 μM (example: Adjust from 210 μM to 230 μM).
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, you must install new Crea A and Crea B membranes.

Until further notice, carry out the following 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, you must install new Crea A and Crea B membranes.

Please complete the recall response fax form (last page of this customer advisory letter) as soon as possible and submit to your Radiometer representative

Until further notice, the above countermeasures are to be considered as an interim change of labeling.

Countermeasure provided by Radiometer:

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

Please Note:

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

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

Best regards,
<Radiometer distributor>

Recall Response Fax Form

Fax No.:

Concerning:

ABL800 Analyzers; Low cCrea results on patient samples

- 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.

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