

Customer
Hospital
City
Postal code
Country
Attn.: XXX

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

Dear Customer

This is a follow-up to previous communication regarding ABL800 analyzers with low cCrea results on patient samples issued June 2018.

Radiometer has now updated the software on your analyzer, so it is no longer necessary to manually adjust the cCrea lower limit for S7835 AutoCheck 6+, level 1 by +20 µmol/L. With the new software this will happen automatically when you install a new lot of S7835 AutoCheck 6+ level 1 (the limits for a Lot installed prior to the software update are not affected by the software update).

Affected product:

All ABL800 analyzers measuring cCrea.

What you must do:

1. Until further notice, continue carry out the following every 24 hours and upon replacement of Crea A and Crea B membranes:
 - Perform one quality control (QC) measurement using S7835 AutoCheck 6+, level 1, to verify the cCrea performance.
If the cCrea QC result is out of range, you must install new Crea A and Crea B membranes.
2. Read the "Important Notes" on pages 2 and 3 of this letter.
3. Please complete the recall response form (last page of this customer advisory letter) as soon as possible and submit to your Radiometer representative

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.

Important Notes:

AutoCheck 6+ level 1 control ranges

When installing a new Lot of AutoCheck 6+, please be informed that:

- For AutoCheck 6+ level 1 below Lot 0135 there will be a difference between the ranges stated on the insert and the ranges shown on the analyzer.
- For AutoCheck 6+ level 1 of Lot 0135 and onwards the range stated on the insert has been updated and is listed in the column named “≥SW 6.18 MR2”.

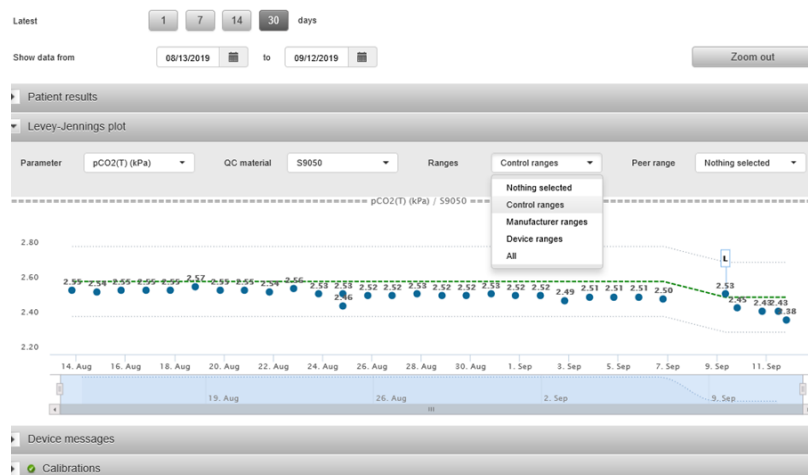
Please note that for technical reasons the upper limit for AutoCheck 6+ of Lots 0135 and onwards has been decreased by 20 µmol/L, so the complete control range will be +/- 20 µmol/L.

AQURE users

For analyzers connected to AQURE, where the AutoCheck 6+ level 1 installed is below Lot 0135, please note that when viewing QC results, it is possible to select between different ranges.

- If selecting the “Manufactures ranges”, the displayed range is the range from the insert.
- If selecting the “Control ranges”, the displayed range is the manually adjusted range.

Radiometer recommends to select “Control ranges”, until an AutoCheck 6+ level 1 from Lot 0135 and onwards is installed.



QA portal users

For analyzers where the QC results are reported to the QA portal, please note that the control ranges displayed are following the insert ranges, which means that you will only see the tighter control ranges displayed on your reports when using AutoCheck 6+ level 1 of Lot 0135 and onwards.

Rilibäk range users

The current default Rilibäk range is ± 11.5%. With the new narrow control range for AutoCheck 6+ level 1, the Rilibäk range is to be changed to ± 8% (± 20 µmol/L) or less in order to comply with the Rilibäk regulations.

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 Form

Concerning:

ABL800 Analyzers; Low cCrea results on patient samples

☐ I have received the customer advisory letter

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