RADIOMETER
Legal Manufacturer: Radiometer Medical ApS
Åkandevej 21, 2700 Brønshøj, Denmark
Telephone: +45 38 27 38 27

Customer
Hospital
City
Postal code
Country
Attn.: XXX

URGENT Field Safety Notice

ABL800 Basic and ABL8XX FLEX analyzers – Risk of biased out-of-specification pH results

Dear Customer

This is a follow-up to the communication distributed in May 2024 and March 2025. (Appendix A, on pages 4 and 5 of this letter, provides an abstract of the May 2024 communication).

This follow-up relates only to ABL800 Basic and ABL8XX FLEX analyzers running with Windows XPE (and, hence, software versions below V6.20 MR2).

Solution provided by Radiometer

Radiometer is conducting further investigations to identify permanent countermeasures for analyzers running with Windows XPE.
Your Radiometer representative will contact you with further communication.

Your actions

For analyzers running with Windows XPE (and, hence, software versions below V6.20 MR2):

Radiometer requests that you continue using one of the manual procedures implemented per the communication distributed in May 2024 and March 2025.

Further, please complete the Recall Response Form on page 3 of this letter and submit it to your Radiometer representative within two weeks of receiving this letter.

Your help is appreciated

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 your Radiometer representative.

Radiometer sincerely apologizes for the inconvenience this situation may cause you.

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Best regards,
<Radiometer distributor>

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Recall Response Form

Concerning:

ABL800 Basic and ABL8XX FLEX analyzers
– Risk of biased out-of-specification pH results

☐ I have received the customer advisory letter and confirm that we will continue to use one of the manual procedures implemented as per the communication distributed in May 2024.

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

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Appendix A: Abstract of the May 2024 communication

Background

Radiometer has become aware of a potential issue with ABL800 Basic and ABL8XX FLEX analyzers.

An internal technical study was carried out based on reports from internal and external users regarding pH sensitivity and pH drift errors for calibrations and measured QC pH values out of range.

The study concludes that there is a remote probability of reporting biased out-of-specification pH results on blood samples.
This may occur if the calibration solution's pH value decreases during the in-use period due to bacterial growth in the calibration solution bottles CAL1 and/or CAL2.

In a worst-case scenario with bacterial growth in both calibration solution bottles, the pH bias may reach the following levels:

pH in the blood sample	6.850	7.000	7.200	7.400	7.700
Worst-case bias	+0.050	+0.060	+0.071	+0.084	+0.102

Affected product

All ABL800 Basic and ABL8XX FLEX analyzers.

FOR EU Countries only the following is to be included in the translated letter:

EU Basic UDI-DI: *ABL800 Basic 57006900036MW*

ABL8xx FLEX 57006900037MY

(UDI = Unique Device Identifier – DI = Device Identifier)

Risk for the Patient

- For fetal patients (population at greatest risk)

- There is a remote probability of permanent severe harm for this patient group when measuring pH on a scalp blood sample. These patients may be subject to delayed delivery and at risk of experiencing permanent organ damage.

- For patients other than fetal patients, (overall population at risk):

- There is a remote probability of reversible moderate harm for this patient group. These patients may experience tremors and/or delirium because of incorrect treatment.

- Please note that:

- For fetal patient scalp samples, running one of the quality controls below daily will eliminate the risk of reporting pH results with a bias of a magnitude that may lead to permanent severe harm. The quality controls will flag such biases when using the insert ranges.

- For patients other than fetal patients, the biases on pH results that may lead to reversible moderate harm are smaller. Hence, narrowing the quality control ranges will be necessary, and for some customers also changing the quality control schedule.

  Applicable quality controls and levels:
  Levels 2 or 3 of AutoCheck 3+, AutoCheck 5+, AutoCheck 6+, or QualiCheck 5.