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

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, changing the quality control schedule and decreasing the QC control ranges will be necessary.

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

Your actions

With immediate effect, Radiometer requests that you implement either "Procedure 1" for customers who run daily quality controls or "Procedure 2" for customers who do not.
The procedures are described on the subsequent pages of this letter.
This must be carried out regardless of which patient groups are measured on the analyzer. It will ensure that biased out-of-specification pH results that may lead to the risks above are not reported.

Further, Radiometer kindly requests that you complete the Recall Response Form (page 5 of this letter) and submit it to your Radiometer representative within two weeks of receiving the letter.

Solution provided by Radiometer

Radiometer is conducting further investigation to identify the causes for the issues and permanent countermeasures. Your Radiometer representative will contact you with further communication.

Radiometer will compensate for the potential increased consumption of CAL1 and CAL2 solution bottles.

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.

Best regards,
<State Radiometer distributor name>

PROCEDURE 1, for customers who run daily quality controls

The individual steps of the procedures are described in the Operators Manual.

Setup of quality controls (one-time action for each Lot)

The following two steps must be performed:

1. Ensure that one of the quality controls AutoCheck 3+, AutoCheck 5+, AutoCheck 6+, or QualiCheck 5, Levels 2 or 3, is run at least every 12 hours. You may choose to run the same type and level or any combination.
    a. Change the quality control schedule if the above is not fulfilled.

2. Manually adjust the pH upper limit (relative to the limit stated on the insert) for the quality controls used as follows:
    a. For quality controls of Level 2 adjust the pH upper limit by -0.005
    b. For quality controls of Level 3 adjust the pH upper limit by -0.007

    If taking a new Lot of quality control into use, Step 2 must be carried out again for the new Lot.

Daily actions 1

1. View the results for the quality controls
    - If the quality control results are within the reduced control range:
      No further actions are required

    - If the quality control results are out of the reduced control range:
      Proceed to Step 2 below

2. Enter the calibration log and find the latest 2-point calibration performed.

3. View the results screen and note the pH sensitivity.
    - If the pH sensitivity is in the range of 98.0%-100.0%
      Troubleshoot the quality control out of range as per the Operators Manual, and then continue performing the "Daily actions 1".

    - If the pH sensitivity is out of the range 98.0%-100.0%, proceed to step 4.

4. Check how much the pH sensitivity has drifted over the last 48 hours.

    - If the pH sensitivity has drifted by up to ±1.0%
      Troubleshoot the quality control out of range as per the Operators Manual, and then continue performing the "Daily actions 1".

    - If the pH sensitivity has drifted by more than ±1.0%
      Proceed to the "Countermeasure" below.

PROCEDURE 2, for customers who do not run daily quality controls

The individual steps of the procedures are described in the Operators Manual.

Daily actions 2 (to be performed at the same time every day):

1. Enter the calibration log and find the latest 2-point calibration performed.

2. View the results screen and note the pH sensitivity.
   - If the pH sensitivity is in the range of 98.0%-100.0%
     No further actions are required.

   - If the pH sensitivity is out of the range 98.0%-100.0%, proceed to step 3.

3. Check how much the pH sensitivity has drifted over the last 48 hours.

   - If the pH sensitivity has drifted by up to ±1.0%
     No further actions are required.

   - If the pH sensitivity has drifted by more than ±1.0%
     Proceed to the "Countermeasure" below.

COUNTERMEASURE:

The countermeasure is the same for both Procedure 1 and Procedure 2.

1. Replace both the CAL1 and CAL2 solution bottles and call a 2-point calibration
   - If the sensitivity is still out of the range 98.0%-100.0%
     Perform regular troubleshooting and then revert to:
     - "Daily actions 1" above if you run quality controls
     - "Daily actions 2" above if you do not run quality controls

   - If the sensitivity is now in the range of 98.0%-100.0%
     Proceed to Step 2 below

2. Call your Radiometer representative to schedule a visit by the representative to disinfect the analyzer (as per the procedure in the service manual).

3. If the analyzer cannot be taken out of service while waiting for the disinfection
   - Replace the CAL1 and CAL2 solution bottles every two days until the disinfection has been performed

4. Once the disinfection has been performed, revert to:
   - "Daily actions 1" above if you run quality controls
   - "Daily actions 2" above if you do not run quality controls.

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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 have implemented either Procedure 1, using quality controls, or Procedure 2, using the check of calibrations, as you requested.

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