Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice:
ABL80 FLEX Analyzers configured with either FLEX or BASIC software

Priority Level: High

Dear Customer

We have recently become aware of a possible condition in a limited number of ABL80 FLEX analyzers configured with either FLEX or BASIC software, which can cause the analyzer to report values outside the published performance specifications for pH, pCO_2, cNa^+, cK^+, cCa^{2+} and cCl^-.

This condition can occur without indication to the user.

The root cause of this condition is related to the analyzer hardware.

Radiometer will be contacting you as soon as possible to perform the necessary corrective actions to return your analyzers to proper working order.
Please contact Radiometer if you have any questions in relation to this matter.

According to our records, the following affected analyzers are at your facility.

Description	Serial Number
ABL80 FLEX analyzer configured with either FLEX or BASIC software	xxxxxx xxxxxx

Request on action to be taken by the user:

Due to this possibility of reporting incorrect sample measurement results, Radiometer requests that you immediately implement either Alternative 1 or Alternative 2 below:

Alternative 1
Stop the use of all affected analyzers until corrective actions can be performed on these analyzers.

Alternative 2
Verify proper function of the affected analyzers immediately following **every** patient sample measurement by measuring a manual QC sample. Performing this short-term workaround is described in the following table.

Step	Action
1	Perform patient sample analysis
2	Perform manual QC analysis using QUALICHECK4+ Level 3 (REF 944-055; Solution ID S7450)
3	• If manual QC results fall within the package insert ranges then patient sample analysis results may be used to assess a patient's condition • If manual QC results fall outside the package insert ranges then patient sample analysis results may NOT be used to assess a patient's condition
4	If manual QC results fall outside package insert ranges, perform the following steps: • Power cycle the analyzer (see chapter 2 in the operator's manual) o Turn the analyzer power off by selecting ***Menu > Shutdown*** then responding "***Yes***" to the question, "Are you sure you want to shutdown?" o Turn the analyzer power on, using the power switch at the rear of the analyzer • Manually initiate a calibration by selecting o ***Menu > Manual System Cycle*** (in analyzers with QC^3) o ***Menu > 2 Point Cal*** (in analyzers without QC^3)

Furthermore, we kindly request that you complete the fax form on the following page, acknowledging your receipt of this letter and confirming that the subject analyzers listed above are no longer being used for patient sample measurements or that the short-term workaround will be performed.
Please return the completed form to <Radiometer distributor> using the fax number printed.

We realize this action will likely cause significant disruption to your facility. We sincerely apologize for this inconvenience.

Best regards,
<Radiometer distributor>

FAX FORM

Fax Number: <FAX number>

Concerning:

The possibility of incorrect sample measurement results when using some ABL80 FLEX analyzers configured with either FLEX or BASIC software.

☐ **I have received the customer letter and acknowledge that the ABL80 FLEX analyzers listed in the customer letter have been taken out of service as per Alternative 1.**
These analyzers will not be used until corrective actions have been performed by Radiometer.

☐ **I have received the customer letter and acknowledge that the short-term workaround described in the customer letter will be performed when using the ABL80 FLEX analyzers listed in the customer letter as per Alternative 2.**
The short-term workaround will be performed until corrective actions have been performed by Radiometer.

Date: _____

Hospital: _____

Address: _____

_____

Name: _____

Title: _____

_____