

Field Action Notice



Product: ABL90 FLEX

May 25, 2018

Subject: ABL90 FLEX wrong results

Background: Radiometer has recently become aware that the ABL90 FLEX in a very rare specific situation can aspirate Cal 2 solution instead of rinse solution. The specific situation can occur when the following take place:

- The analyzer is in ready mode
- Operator lifts the inlet and then closes it again, thereby initiating a rinse
- Immediately after lifts the inlet and quickly closes it again

In this situation, it will lead to several parameters reported wrong (see table 1 in revision 1 of this Field Action Note) during the following measurements. Some of the parameters will not have an error message or question mark indicating a problem with the result.

The wrong reporting will continue until the analyzer flow selector has reset. The flow selector will reset as part of the automatic error removal process performed during repeated automatic calibrations, QC measurements or during installation of the solution pack.

Revision 2: Radiometer has now released a new software version 3.4 (933-470) for the ABL90 FLEX analyzer, which correct this issue.

Affected Product: All ABL90 FLEX (393-090) analyzers running software versions 3.3 MR1 or lower.

User Action: No additional actions, compared to what was communicated with revision 1 of this FAN.

Action: **Please carry out the following actions for existing customers:**

1. Translate the customer advisory letter into your local language(s) and print it on your official company paper.
2. Contact each affected customer to schedule a visit to perform the following actions:
 - Hand over the customer advisory letter to the customer,
 - Hand over the the required copies of the revised instructions for use
 - Upgrade the ABL90 FLEX software to version 3.4.
3. Visit the customer to perform the actions in step 2 above.

Please carry out the following actions for new customers:

1. Ensure that the ABL90 FLEX software is upgraded to version 3.4 prior to installation.

Completion Dates: The following actions must be completed by the dates stated:

- Action #1 must be completed and confirmed to RMED (by submitting the translated customer letter) before **June 6, 2018**.
- Action #2 and #3 must be completed and confirmed (by submitting **FAC1**) to RMED before **May 31, 2019**.

For new customers:

This is an ongoing activity for which no confirmation and data is to be submitted to RMED.

Tools:	Customer advisory letter. Revised instructions for use ABL90 FLEX software version 3.4 (933-470)
Inquiries:	<p>Please refer to the below departments for inquiries related to this Field Action:</p> <ul style="list-style-type: none">Regarding technical, commercial, and practical questions please contact RMED Technical Product Support and Service: Email: technical.support@radiometer.dk or Telephone: +45 4010 8827Regarding questions from your local national competent authorities please contact RMED Vigilance: Email: vigilance@radiometer.dk <p>Please confirm receipt and send the completed FAC to: Email: fan@radiometer.dk</p>
Regulatory:	For regulatory reasons the following, additional actions apply for the different countries. All subsidiaries and distributors must email complete customer lists for each country to RMED before June 6, 2018 .
USA/Canada:	The affected product has been distributed to USA and Canada and will be reported to the FDA and Health Canada.
Europe:	<p>The field action is a reportable recall action and is thus reported to European Health Authorities.</p> <p>All distributors in EEA member states receiving this FAN must mail the translated copy of the customer information letter (for distributors serving different regions with different languages we will need a copy in each language) to RMED before June 6, 2018.</p>
Australia/NZ:	The affected product has been distributed to Australia/NZD.
Accounts:	Distributors covering more than one country must generate separate lists of accounts for each country.
Mail to:	<p>The above requested information must be mailed to:</p> <p>Mail to: FAN@radiometer.dk</p>

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