Management Cover

RADIOMETER

for Field Action Notes

Product: **ABL90 FLEX Analyzer** **February 6, 2015**

Subject: Release of new software version, V3.1 MR3.

Background: Revision 1 of this Field Action Note informed about the risk of biased results when the inlet is left open after aspiration of the patient sample, for more than 30 seconds.
It also stated a short term corrective action (ensuring that the inlet is closed when prompted by the analyzer) and announced the final solution, which is to implement a mechanism in the analyzer software to eliminate the risk of this error.

Affected product: ABL90 FLEX analyzers with software versions V3.1 MR1 and below.

Revision 2: The mechanism which ensures that reported results are not affected by leaving the inlet open more than 30 seconds has now been implemented in the software.

Furthermore the following new features have been implemented:

New lower Range of Indication for Ca^{++}
The lower Range of Indication for Ca^{++} has been changed from 0.2 mmol/L to 0.1 mmol/L.
Please note that the default reportable range has NOT been changed. The lower reportable range can now be set to 0.1 mmol/L instead of 0.2 mmol/L.

Guided troubleshooting optimization
Based on external and internal feedback, we have optimized the guided troubleshooting.
The two major changes are:

- If a clot error is present, the instrument will no longer suggest a replacement of the Solution Pack, but will suggest a manual backflush.
- If error message 1324 “inhomogeneous rinse solution” is the only fluid transport error, the instrument will no longer suggest a replacement of the solution pack, but will suggest a manual backflush.

Fluid transport robustness
In order to increase the fluid transport robustness we have further improved how the air segmentation is made and handled.

Printout of PER report changed
The PER report has been improved.

Finally, various issues have been corrected:

- Analyzer freezes and becomes unresponsive,
- Operator unable to exit login screen if attempted to login to service with incorrect password
- SP replacement date stated was after the expiry date

Please refer to separate email for details.

Action: **Please carry out the following actions:**

1. Print the customer information letter on your official company paper.
2. Contact each affected customer to arrange a visit to;
   - Hand over the customer information letter and explain the corrective action.
   - Upgrade the analyzer software to V3.1 MR3

Completion Date: The actions must be completed and confirmed to RMED by **July 31, 2015**.

Tools: ***Software:***
Please refer to separate email including a link for download of the software.
Additionally, the software will become available on CD under part number 933-331.

Customer information letter

Inquiries: Please refer all inquiries related to this Field Action Note to RMED Technical Product Support and Service:

Email: technical.support@radiometer.dk or

Telephone: +45 4010 8827

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 **February 13, 2015**.

USA/Canada: The field action is a class II Recall. This means that the action has been reported to the FDA and Health Canada by RMED as manufacturer and by RAME as importer.

Europe: The field action is a Field Safety Corrective Action. This means that RMED has reported the action to all affected European Health Authorities.

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 **February 13, 2015**.

Note that any distributor within the EEA may receive requests for additional information from their Competent Authority. Please forward such requests (translated into English) to RMED before answering so that we can coordinate the answer.

Australia/NZ: The field action was reported as a "Recall". RPAC RA must submit a final Recall Report to TGA and Medsafe.

Accounts: Distributors covering more than one country must generate separate lists of accounts for each country.

Mail to: The above requested information must be mailed to:

Mail to: FAN@radiometer.dk

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