Field Action Notice

RADIOMETER

Product:	**ABL90 FLEX and ABL90 FLEX PLUS**	**June 4, 2025**

Subject: Analyzer may cease to perform calibrations upon restart

Background: Radiometer has become aware of a potential issue with ABL90 FLEX and ABL90 FLEX PLUS analyzers upon restart. Specifically, the analyzer may fail to initialize the calibration schedule, which means that the sensors will not be calibrated.

The calibration schedule will most likely be initialized by restarting the analyzer.

The default setup for internal quality control measurements will flag out-of-specification sensor performance; hence, the described error does not impact analyzer performance.

Affected Product: ABL90 FLEX and ABL90 FLEX PLUS analyzers with software version 3.5 MR11 and below. Hence, new analyzer installations are also affected.

User Action: Per the customer advisory letter:
Since the automatic internal quality control is running by default, there are no actions for you related to the affected product.
Please complete the Recall Response Form (on the last page of this letter) and return it to your Radiometer representative within a week of receiving this letter.

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. Compose a complete list of affected customers.
3. Provide the customer advisory letter to each affected customer as follows,
   - Submit the customer advisory letter to the customers, or
   - Visit the customers to hand over the customer advisory letter and explain the problem.
4. Collect and consolidate recall response forms in the “Field Action Effectiveness Data Sheet” (excel) enclosed with this FAN.

Please carry out the following actions for <u>new</u> customers:
(New customers are defined as customers who take an analyzer into use.)

- Hand over a copy of the customer advisory letter to the customer
- Update the list of affected customers with the new installation (as per step 2 above)

Update the list of received recall response forms once received from the new customer (as per step 4 above)

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

- **Actions #1, #2, and #3** must **before June 17, 2025**, be completed and confirmed to RMED by submitting the following:
  - Translated customer advisory letter
  - List of affected customers using the "Field Action Effectiveness Data Sheet"
  - "**FAC1** - Customer advisory letter"

- **Action #4** must before **July 17, 2025**, be completed and confirmed to RMED by submitting the following:
  - "Field Action Effectiveness Data Sheet"
  - "**FAC2** – Customer response"

Tools: **The following tools are available:**

- Customer advisory letter
- Field Action Effectiveness Data Sheet

Inquiries: Please refer to the below departments for inquiries related to this Field Action Note:

- For technical, commercial, and practical questions, please contact RMED Technical Product Support and Service:

  CRM users: Escalate a support request in CRM

  Non-CRM users: Send an email to product.support@radiometer.dk

- For questions from your local national competent authorities, please contact RMED Vigilance:

  Email: vigilance@radiometer.dk

- To confirm receipt and submit customer lists, translated letters, FACs, Customer Response Sheets, etc., please use:

  Email: fan@radiometer.dk

Regulatory: For regulatory reasons, you must email a complete list of affected customers to RMED.

USA: The Field Action is not reportable in the US.

Canada: The Field Action is not reportable in Canada.

EEA and UK: The field action is not a Field Safety Corrective Action and will thus not be reported to European Health Authorities.

Japan, South Korea, Australia, New Zealand, South Africa, India, Hong Kong, and Malaysia:
The affected product has been distributed to these countries. The local Subsidiary will assess if reporting is required locally.

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