

# Field Action Notes

**RADIOMETER** 

from **Radiometer Medical ApS**

**Product:** S4934 Rinse solution for ABL555, Lot LW-01

**October 8, 2014**

**Subject:** Rinse solution bottles have been produced with an incorrect adaptor at the top.

**Background:** RADIOMETER has recently become aware that one lot of Rinse solution bottles has been produced with an incorrect adaptor. The incorrect adaptor has an enzyme dispenser filled with enzyme attached to it. If the operator pushes the enzyme dispenser the enzyme will be released into the Rinse solution. The enzyme will degrade the enzyme in the glucose and lactate membrane units. This causes the glucose and lactate results to be gradually affected and potentially false low results may be reported. The false low results will potentially be obtained in the timespan from where the degradation has led to a too low sensitivity of the glucose and lactate electrodes to the next calibration. This timespan will be maximum 4 hours. Upon a calibration with low sensitivity the analyzer will report an error for the glucose and lactate electrodes.



Correct adaptor

Incorrect adaptor

**Affected Product:** S4934 Rinse solution for ABL555, 944-032, Lot LW-01.

- User Action:** As per the customer letter the users are requested to carry out the following actions:
- Please check your inventory and remove any S4934 Rinse solution bottles from the affected lot
  - Please check the Rinse solution bottles installed on your analyzers.  
In case a Rinse solution bottle of the affected lot is installed **and** the enzyme has been released, then:
    - Replace the Rinse solution bottle with one from a different lot
    - Replace the glucose or lactate membrane unit on this analyzer
    - Review glucose and lactate patient results measured while this bottle has been installed as the results may be affected
  - Affected Rinse solution bottles may be used on the analyzer until a replacement supply has been received provided that the enzyme is not released
  - Once the replacement supply has been received please discard all remaining S4934 Rinse solution bottles from the affected lot in your possession

- Action:** **Please carry out the following actions:**
1. Translate the customer information letter into your local language(s) and print it on your official company paper.
  2. For all affected customers compose the information requested under 'Regulatory' and email to RMED
  3. Contact each affected customer as follows,
    - Submit the customer information letter to the customers, or
    - Visit the customer to hand over the appropriate letter and explain the problem.
  4. Exchange the customers rinse solution bottles of the affected lot with ones from a different lot.

**Completion Date:** Action #3 must be completed and confirmed to RMED (Confirmation Fax #1) by **October 15<sup>th</sup>, 2014.**  
Action #4 must be completed and confirmed to RMED (Confirmation Fax #2) by **October 31<sup>th</sup>, 2014.**

**Tools:** Customer information letter.

S4934 Rinse solution for ABL555, 944-032, of a different Lot

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

Email: [technical.support@radiometer.dk](mailto:technical.support@radiometer.dk) or

Telephone: +45 4010 8827

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