
Urgent Field Safety Notice

***Ca++ membrane units, ordering numbers 942-046 and 942-060
Used with ABL505/555, EML105, ABL600, ABL700 Series, and ABL800 Analyzers***

April, 2011

Customer Name/Address

Dear **Customer Name**:

Details on affected devices:

This Field Safety Notice is applicable to the following **Radiometer product**:

Ca++ membrane units, ordering numbers 942-046 and 942-060

Description of the problem:

RADIOMETER recently became aware that wrinkles might arise on the outer membrane of these membrane units upon installation. Retention of fluids between the wrinkles can cause a positive bias of approx. 14% when measuring on whole blood at a level of approx. 0.80 mmol/L.

The bias will be towards the Ca++ value of the rinse solution, and will therefore be positive on low levels of ionized calcium and negative on levels higher than the normal range. The error is most significant for samples with Ca++ levels far away from the normal range. This may pose a risk to the safety of patients, particularly when measurement results are used for diagnosis and therapy of hypocalcemia Calcium levels lower than the normal range.

Request on action to be taken by the user:

We request that Ca++ results below 1.00 mmol/L are NOT reported until the following is performed:

1. Remove and discard the existing Ca membrane
2. Fill a small beaker with rinse solution (for the analyzer in question)
3. Click the electrode into the new membrane unit
4. Immerse the membrane into the beaker with rinse solution for five seconds and move the electrode from side to side ("stir")
(this softens the membrane and prevents wrinkles)
5. Remove droplets of rinse solution on membrane
6. Install the electrode in the analyzer
7. Wait for the analyzer to complete calibration
8. Verify the Ca performance using one of the QC solutions listed below
9. If the Ca verification fails the membrane must be replaced

Until further notice the above must be carried out when replacing the Ca membrane.

Verification of Ca performance:

The Quality Control products listed below contain low levels of Ca⁺⁺ and will detect if a bias is present:

Qualicheck4+:	S7440 (Level 2) and S7450 (Level 3)
Qualicheck5+:	S7740 (Level 2) and S7750 (Level 3)
Autocheck5+:	S7745 (Level 2) and S7755 (Level 3)
Autocheck6+:	S7845 (Level 2) and S7855 (Level 3)

One of the above must be used for Ca verification.

Important:

Since the positive bias of a Ca-unit with wrinkles on whole blood is larger than on the aqueous QCs, **it is required to manually adjust the upper and lower limits on the analyzer in relation to the limits printed on the insert as follows:**

- **Adjust the upper limit by – 0.02 mmol/L**
- **Adjust the lower limit by + 0.02 mmol/L**

This must be done for every lot of QC ampoules used, and for any new lot of QC ampoules installed.

Please note that manually adjusting the QC limits on ABL505/555 and ABL600 will delete the QC statistics for that level.

Please complete and return the attached fax form, with your signature.

If you have any questions regarding this letter, or the upgrade, please contact your Radiometer distributor.

We sincerely apologize for the inconvenience this may cause.

Regards,

FAX RETURN FORM

Product Description

Ca++ membrane units, ordering numbers 942-046 and 942-060

- We acknowledge receipt of the urgent field safety notice.***
- Furthermore, we acknowledge that Ca++ results below 1.00 mmol/L must NOT be reported unless the requested procedure is followed.***
- We have instructed the operators in how to install Ca++ membrane units and verify Ca++ performance.***

Please print the following information:

Hospital

Address

Contact Person

Signature

Date

***Additionally, please fax this form to the following number:
(Insert Fax number here)***