
Urgent Field Safety Notice

***ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers
Additional Labeling Instructions***

December, 2009

Customer Name/Address

Dear **Customer Name:**

Details on affected devices:

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

ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers

Description of the problem:

RADIOMETER recently became aware that the drug Irenat, which appears to be administered predominately in Germany, interferes with ionized calcium. It has been found that a level of 1.5 mmol/L per chlorate in the drug Irenat causes a negative bias of 0.20 mmol/L on ionized calcium (1.25 mmol/L level). Interference is present in the ***ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers.***

Advise on action to be taken by the user:

As a result of this situation, Radiometer is requesting your cooperation in inserting the enclosed "Note to Users" in front of your copies of the Operators' and Reference Manuals for the ***ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers.***

Transmission of this Field Safety Notice:

Kindly pass this notice on to all those within your organization who need to be aware of the additional labeling instructions as well as to any organization where the ***ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers*** have been transferred, if applicable.

If you have any questions, please contact your Radiometer distributor.

We sincerely apologize for the inconvenience this may have caused.

Regards,

FAX RETURN FORM

Product Description

ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers

- We acknowledge receipt of the ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX, and ABL800 BASIC Analyzers communication and have inserted the "Note to Users" in front of my copy of the Operators' and Reference Manual.***

Please print the following information:

Hospital

Address

Contact Person

Signature

Date

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