Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE DATE]

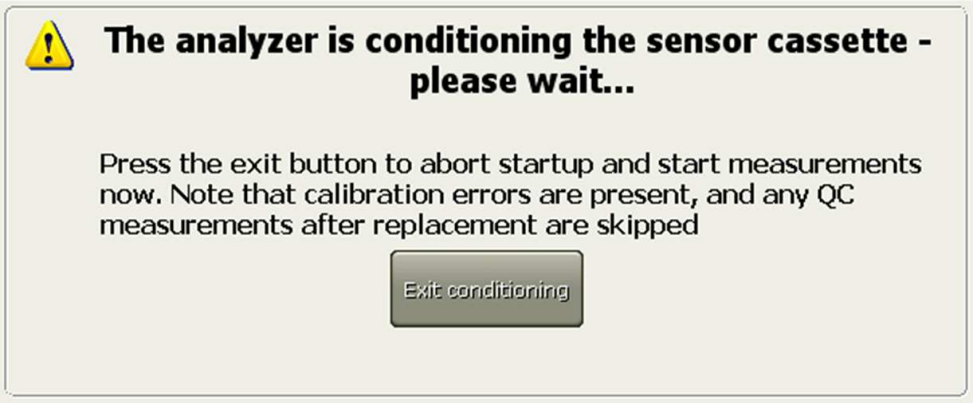
Field Safety Notice: ABL90 FLEX / ABL90 FLEX PLUS

Priority Level: Urgent

Dear Customer

Radiometer has recently become aware of a potential risk that the analyzer may report patient results although analyzer performance has not been verified by running quality controls. Ultimately this could lead to incorrect results being reported and these results will not be flagged.

The issue may occur if the operator manually exits the Conditioning mode, which is active during the initial startup of a new Sensor Cassette.
During the Conditioning mode the following is displayed on the screen:



If “Exit conditioning” is pressed to run an urgent sample the analyzer goes to “Ready” without performing three levels of quality control, which are run upon automatic exit. The regular QC schedule, one level every eight hours, will be effective, though.

As a result, no QCs are run during the period from where the conditioning was manually exited to when the first level of the regular QC schedule is run (default every eight hours). The analyzer does not indicate the exit from the Conditioning mode and the patient results are not flagged for QCs not being run.

Affected product:
ABL90 FLEX (393-090) and ABL90 FLEX PLUS (393-092)

What you should do (temporary countermeasure):

Either:

- Avoid exiting manually from the Conditioning mode

Or:

- If early exit from the Conditioning mode is required then manually run all three levels of QC upon exit **before** running patient samples.

And then:

- Please complete the last page of this letter and return to your Radiometer representative.

Long term solution provided by Radiometer:

Radiometer is currently investigating the issue and will revert with an update to inform about the long term solution which will be put in place to prevent the above situation from occurring. The long term solution is expected to be an update of the analyzer software and of the Instructions For Use.

Please Note:

If you are not the end-user of the affected product please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact your Radiometer representative.
Radiometer sincerely apologizes for the inconvenience this situation may cause you.

Best regards,
<Radiometer distributor>

Recall Response Fax Form no. 1

Fax No.:

Concerning:

ABL90 FLEX / ABL90 FLEX PLUS

□ I have received the customer letter.

□ I have instructed our staff as per the temporary countermeasure stated in the letter.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	