

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: AUTOCHECK 5+ Level 2 lot 0689

Priority Level: Urgent

Dear Customer

Radiometer has recently become aware of AUTOCHECK 5+ level 2 ampoules, may give incorrect results for pO_2 .

A defective QC ampoule may for pO_2 give a considerable higher result than the expected assigned value of 13.9 -14.3 kPa (104-107 mmHg)

Risk for the patient

Delayed medical treatment. Whilst the patient result may be correct, an erroneous QC result may lead to troubleshooting of the analyzer and therefore affect its availability for clinical use.

Affected product:

Only the following Lot of AUTOCHECK 5+ Level 2 is affected:

Item no	Item name	Lot number
944-075	AUTOCHECK 5+ Level 2	0689

What you should do:

1. Please check your inventory and analyzers for any boxes and ampoules of above mentioned QC.
2. Discard all Boxes and ampoules of this lot.
3. Complete the form overleaf and submit to your Radiometer representative.

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.

Best regards,
<Radiometer distributor>

Recall Response Fax Form no. 1

Fax No.:

Concerning:

AUTOCHECK 5+ Level 2 lot 0689

- I have received the customer letter and carried out the action mentioned.
- No boxes or ampoules found.

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