

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: |  |