

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice: D999 Membrane Box, pO_2 , for ABL5/50/5XX

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware that one lot of membrane boxes has been produced using an incorrect electrolyte solution.

Some of these membranes have been found to calibrate and provide valid results on the analyzer for a few days (4-6 days), before Cal 2 fails on zero point. When this happens the membrane units will have a rapidly increasing positive bias until they are rejected by the following Cal 2. Cal 2 is run every 4 hours, and within this time slot there is a possible risk of obtaining wrong measuring results.

Affected product:

D999 Membrane box for E909 pO_2 electrode for ABL5/50/5XX, 942-042, R0971.

What you should do:

- Please check your inventory and remove any D999 Membrane Boxes from the affected lot
- Please discard all membrane boxes from the affected lot in your possession
- Complete page 2 of this letter and return to your Radiometer representative

RADIOMETER will provide compensation for all membrane boxes from the affected lot received at your institution.

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

Best regards,
<Radiometer distributor>

Recall Response Fax Form

Fax No.:

Concerning:

D999 Membrane Box, pO_2 , for ABL5/50/5XX

- I have received the customer letter and reviewed my current inventory of membrane boxes. All membrane boxes from 942-042, R0971 have been removed from stock and have been discarded.

- I have none of the affected stock on hand.

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