

Customer
Hospital
City
Postal code
Country
Attn.: XXX

Field Safety Notice:

942-063 $p\text{CO}_2$ Membrane Box (D788) used with ABL700 and ABL800 Series Analyzers

Priority Level: Urgent

Dear Customer

RADIOMETER has become aware that some $p\text{CO}_2$ membranes can cause a negative Bias, on both blood and QC measurement results.
The Bias can be seen after the replacement of the membrane.

Affected product

942-063 $p\text{CO}_2$ Membrane Box (D788)

What you should do:

The following steps must immediately be carried out on the affected product:

1. Adjust the QC ranges (see "Preparation for Quality Control Verification" overleaf)
2. Perform one quality control measurement on already installed membrane units to verify the $p\text{CO}_2$ performance. In case the result is out of the reduced QC limits, subsequent patient results are to be questioned to indicate that the bias is present. If the QC is out of range, a new membrane must be installed.

Until further notice the following must be carried out upon installation of a new $p\text{CO}_2$ membrane:

1. Wait for the analyzer to complete the startup calibration plus two extra automatic calibrations (will take approximately one hour).
2. After the third automatic calibration perform one quality control measurement as described above.
3. If the QC is out of range, a new membrane must be installed.

Please do not report $p\text{CO}_2$ results unless the membrane unit has been verified as described above.

You should re-evaluate relevant patients as previous $p\text{CO}_2$ results could also be affected.

Please complete and return the attached fax form, with your signature as soon as possible or within 7 days. If you have any questions, please contact your Radiometer representative.

We sincerely apologize for the inconvenience this may cause.

Best regards,
<Radiometer distributor>

Preparation for Quality Control Verification:

Preparation for Quality Control verification of a new $p\text{CO}_2$ membrane:

1. Select one of the Quality Control products listed below to be used for $p\text{CO}_2$ verification:

Qualicheck5+:	S7730 (Level 1)
Autocheck5+:	S7735 (Level 1)
Autocheck6+:	S7835 (Level 1)

These products can detect if a bias is present.

2. Manually adjust the upper and lower limits for $p\text{CO}_2$ on the analyzer in relation to the limits printed on the insert as follows:

For S7730 and ABL7xx

- Adjust the upper limit by **-0.6 mmHg (0.08 kPa)**
- Adjust the lower limit by **+1.4 mmHg (0.19 kPa)**

I.e. the control ranges are decreased from ± 5 mmHg to ± 4 mmHg, and the assigned value is changed by +0.4 mmHg.

For S7730 and ABL8xx

- Adjust the upper limit by **-1.8 mmHg (0.24 kPa)**
- Adjust the lower limit by **+0.2 mmHg (0.027 kPa)**

I.e. the control ranges are decreased from ± 5 mmHg to ± 4 mmHg, and the assigned value is changed by -0.8 mmHg.

For S7735 and S7835

- Adjust the upper limit by **-1 mmHg (0.13 kPa)**
- Adjust the lower limit by **+1 mmHg (0.13 kPa)**

I.e. the control ranges are decreased from ± 5 mmHg to ± 4 mmHg.

When installing a new QC ampoule lot, the above procedure should be repeated. The narrow QC ranges must be used until further notice.

Recall Response Fax Form

Fax No.:

Concerning:

942-063 pCO₂ Membrane Box (D788) used with ABL700 and ABL800 Series Analyzers

- We acknowledge receipt of the Field Safety Notice
- Furthermore we acknowledge that pCO₂ results must NOT be reported unless performance of the membrane unit has been verified as requested.

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