

# Field Action Notes



from **Radiometer Medical ApS**

915-302

Product: ABL80 FLEX and ABL80 COOX

June 6, 2012

**Subject:** Glucose measurements in samples with low  $pO_2$  levels

**Background:** Based on recent reports from a small number of ABL80 customers, it has come to our attention that the impact of low  $pO_2$  levels on the linearity characteristics of the glucose sensor is not always taken into consideration when interpreting the glucose results.

The linearity of the glucose sensor in the ABL80 FLEX and ABL80 FLEX CO-OX analyzers is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase during the glucose measurement. An insufficient level of oxygen will result in an underestimation of the glucose value. The greatest impact will be seen in samples with very high glucose levels in combination with very low  $pO_2$  levels.

The influence of low  $pO_2$  levels on the linearity of the glucose sensor is described by a table included in chapter 6 of the ABL80 FLEX Reference Manual. To provide greater clarity, this glucose linearity table has been updated as follows:

Impact of the $pO_2$ level on Glucose linearity	
<i>If the <math>pO_2</math> level in a sample is (mmHg):</i>	<i>Then cGlu linearity specifications only apply to cGlu values between (mmol/L):</i>
<20	Linearity not specified. Interpret all results with caution <sup>1)</sup>
20 – 40	0 – 10 <sup>2)</sup>
40 – 90	0 – 25 <sup>3)</sup>
≥ 90	0 – 40 <sup>4)</sup>

1. There are no linearity claims for glucose when the oxygen tension in the sample is less than 20 mmHg (2.7 kPa)
2. When the oxygen tension in the sample is between 20 and 40 mmHg (2.7 – 5.3 kPa), glucose linearity specifications only apply to glucose results up to 10 mmol/L (180.2 mg/dL)
3. When the oxygen tension in the sample is between 40 and 90 mmHg (5.3 – 12.0 kPa), glucose linearity specifications only apply to glucose results up to 25 mmol/L (450.4 mg/dL)
4. When the oxygen tension in the sample is 90 mmHg (12.0 kPa) or greater, glucose linearity specifications only apply to glucose results up to 40 mmol/L (720.6 mg/dL)

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**Action:**

1. Translate the customer letter into your local language, as necessary, and print on your official company paper.
2. Contact each customer with ABL80 FLEX (with FLEX software) and ABL80 CO-OX (with CO-OX software) and either submit the customer letter to the customer or visit the customer to hand over the letter and personally explain the issue.
3. Provide each customer with the Note to Users containing similar information which the customer should include with their operator's manual. There should be one Note to Users provided for every operator's manual at each customer site

**Tools:**

Customer letter.

Update kit for Operator's Manual:

Language	Order No.
English	995-236
Chinese	995-268
Czech	995-237
Danish	995-240
Estonian	995-246
French	995-247
German	995-241
Greek	995-242
Hungarian	995-248
Italian	995-255
Japanese	995-256
Latvian	995-258

Language	Order No.
Lithuanian	995-257
Norwegian	995-259
Polish	995-260
Portuguese	995-261
Romanian	995-262
Russian	995-263
Serbian	995-265
Slovak	995-264
Spanish	995-243
Swedish	995-266
Turkish	995-267

**Completion Date:** The actions must be completed and confirmed to RMED (Confirmation Fax) by **June 29, 2012.**

**Inquiries:**

Please refer all inquiries related to this Field Action Note to the technical services department at SenDx Medical:

Email: [techserv@sendx.com](mailto:techserv@sendx.com)

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