

## Urgent Field Safety Notice

<b>Notice Ref No:</b>	<b>FSN_SB_RPD_2013_09</b>
<b>Document Date:</b>	<b>27-06-2012</b>

<b>PRODUCT AFFECTED:</b>	<b>cobas b 123 SENSOR CARTRIDGE BG/ISE/GLU/LAC</b>
<b>SYSTEM AFFECTED:</b>	<b>&lt;cobas b 123 POC system&gt;</b>
<b>MATERIAL NUMBER:</b>	<b>05170478001</b>
<b>LOT NO (IF APPLICABLE):</b>	<b>21531284</b>
<b>SUMMARY OF ISSUE:</b>	<b>Glucose/Lactate Calibration Failure</b>
<b>ACTION REQUIRED:</b>	<b>Do not use and exchange the affected sensor lot</b>
<b>CONTACTS:</b>	<b>Technical Services: Country:</b>

### **Reason for notice:**

Incorrect chip parameters cause the calibration of Glucose/Lactate to fail, if an affected **cobas b 123 SENSOR CARTRIDGE BG/ISE/GLU/LAC** is inserted to the analyzer. There may be a medical risk, due to the delay of results, caused by waiting times for new sensor cartridge insertion and calibration.

Dear Customer,

We regret to inform you that, due to incorrect chip parameters, Glucose and Lactate calibration will fail when a **cobas b** 123 sensor cartridge (BG/ISE/GLU/LAC), from the following single lot, is inserted into a **cobas b** 123 POC system.

**(Lot number and GMMI/Ref. No. have to match)**

GMMI / Ref. No.	Product Description	Lot No.
05170478001	cobas b 123 SENSOR CART. BG/ISE/GLU/LAC	21531284

The root cause analysis revealed that all sensors from this lot number have incorrect parameters stored on the chip, which contains all sensor specific data. These incorrect chip parameters are what cause the Glucose and Lactate calibration to fail.

For the affected lot number, Glu/Lac cannot be calibrated. It can take approximately 60 to 90 min for a replacement sensor to be ready for use. As a consequence, this may lead to a delay in diagnosis and/or treatment of 60 – 90 min, for glucose and lactate only.

**No incorrect results can be generated, due to this calibration failure. Other parameters, with the exception of Glucose and Lactate, remain unaffected.**

All lots which are now available in the Roche warehouse are tested and can be used without constraints. The same applies to all sensors from alternative lots and parameter configurations.

**Actions required:**

- Do not use the affected sensor lot number mentioned in the table above and remove this single lot from your inventory
- Immediately order new sensor cartridges to replace your inventory of this single sensor lot.

We sincerely apologize for any inconvenience caused by this issue.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency  
(Closing paragraph)  
Signature