

# Field Safety Notice

## SBN-RPD-2015-019

RPD / Blood Gas & Electrolytes  
Version 1  
04-Sep-2015

### cobas b 123: Interference of *PCO2* on Sodium Results in Patient Samples

<b>Instrument/System Affected</b>	<b>cobas b 123 &lt;1&gt;</b> <b>cobas b 123 &lt;2&gt;</b> <b>cobas b 123 &lt;3&gt;</b> <b>cobas b 123 &lt;4&gt;</b>
<b>Product Name</b>	<b>cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC</b>
<b>GMMI / Part No</b> <b>Device Identifier</b>	05170478001
<b>Production Identifier</b> <b>(Lot No./Serial No.)</b>	See Table 1
<b>Type of Action</b>	Field Safety Corrective Action

Affected lots are not available in Singapore

Dear Valued **cobas b 123** Customer,

We regret to inform you about an issue affecting **cobas b 123** POC systems whereby interference of *PCO2* on sodium ( $\text{Na}^+$ ) results (positive bias) is observed in whole blood samples. The issue occurs when specific lots of **cobas b 123** Sensor Cartridges BG/ISE/GLU/LAC are used. Customers who want to measure  $\text{Na}^+$  must not use **cobas b 123** Sensor Cartridge BG/ISE/GLU/LAC lots listed in Table 1 and must use **cobas b 123** Sensor Cartridges from unaffected lots.

# cobas b 123: Interference of $PCO_2$ on Sodium Results in Patient Samples

## Affected cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC Lots

The following lots show interference of  $PCO_2$  on sodium ( $Na^+$ ) results (positive bias):

05170478001 cobas b 123 SENSOR CART. BG/ISE/GLU/LAC Lot Nr
21551691
21552091
21552191
21552491
21552492
21552591
21552691
21552692
21552791
21552792

Table 1: List of affected **cobas b** 123 Sensor Cartridge BG/ISE/GLU/LAC lots.

## Description of Situation

Recently we have become aware during internal tests that specific lots (see Table 1) of **cobas b** 123 Sensor Cartridge BG/ISE/GLU/LAC show interference of  $PCO_2$  on sodium ( $Na^+$ ) results in whole blood samples. The bias increases with the  $PCO_2$  (partial pressure of carbon dioxide) values of the sample.

Other current lots of cobas b 123 Sensor Cartridges have been re-tested and perform within specifications. There are no cases known where this issue caused any serious adverse events to patients.

## Actions taken by Roche Diagnostics

Roche Diagnostics will further investigate this issue in order to implement corrective and preventive actions.

Roche has developed a workaround which describes how to deactivate the parameter  $Na^+$  (see "Appendix 1: Deactivation of  $Na^+$ ").

Roche Diagnostics will replace affected **cobas b** 123 Sensor Cartridges BG/ISE/GLU/LAC.

# cobas b 123: Interference of *PCO*<sub>2</sub> on Sodium Results in Patient Samples

## Actions to be taken by the Customer/User

Customers who want to measure Na<sup>+</sup> must use **cobas b 123** Sensor Cartridges BG/ISE/GLU/LAC of unaffected lots. Affected lots are listed in Table 1; all other lots including upcoming lots are unaffected.

Whenever a **cobas b 123** Sensor Cartridge BG/ISE/GLU/LAC of the affected lots listed in Table 1 is used, the parameter Na<sup>+</sup> must be deactivated in order to avoid any risk of reporting too high sodium results.

For details regarding the deactivation of Na<sup>+</sup>, see Appendix 1.

Alternatively affected Sensor Cartridges currently in-use on-board the analyzer may be replaced by a Sensor Cartridge from an unaffected lot.

**cobas b 123** Sensor Cartridges BG/ISE/GLU/LAC of the affected lots may be discarded locally.

## Communication of this Field Safety Notice

Please transfer this notice to other organizations/individuals on which this action has an impact.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologize for any inconvenience caused by this issue and hope for your understanding and support.

Sincerely,

**Roche Diagnostics Asia Pacific Pte Ltd**

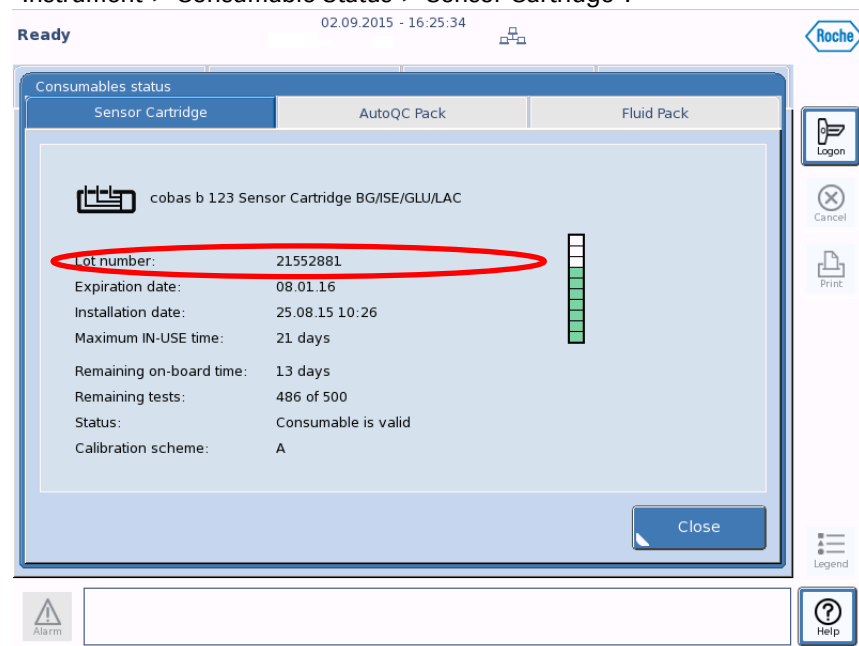
Email: [sg.regulatory@roche.com](mailto:sg.regulatory@roche.com)

# cobas b 123: Interference of *PCO<sub>2</sub>* on Sodium Results in Patient Samples

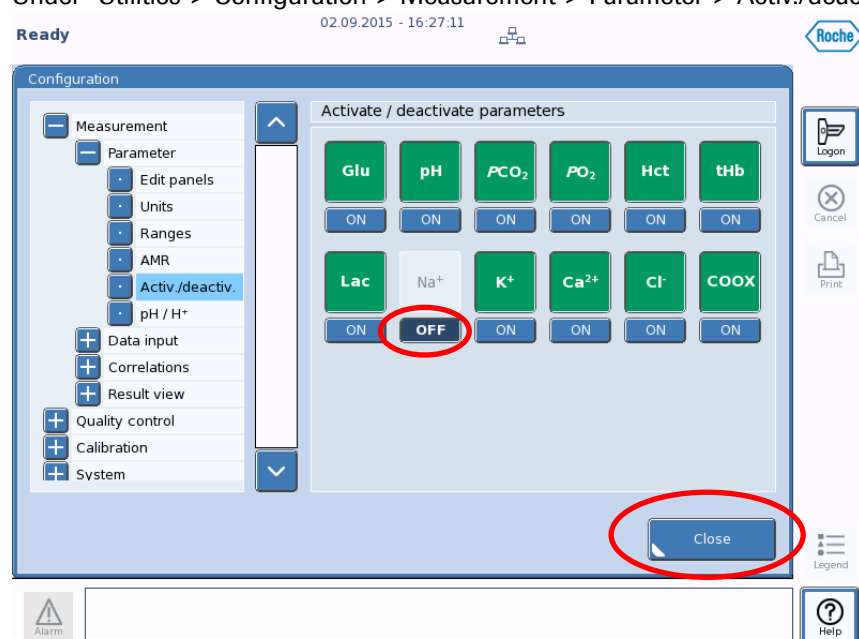
## Appendix 1: Deactivation of Na<sup>+</sup>

Whenever a **cobas b 123** Sensor Cartridge of the potentially affected lots listed in Table 1 is used, **the parameter Na<sup>+</sup> must be deactivated**.

The lot number of the currently installed Sensor Cartridge can be checked in **cobas b 123** system software under “Instrument > Consumable Status > Sensor Cartridge”:

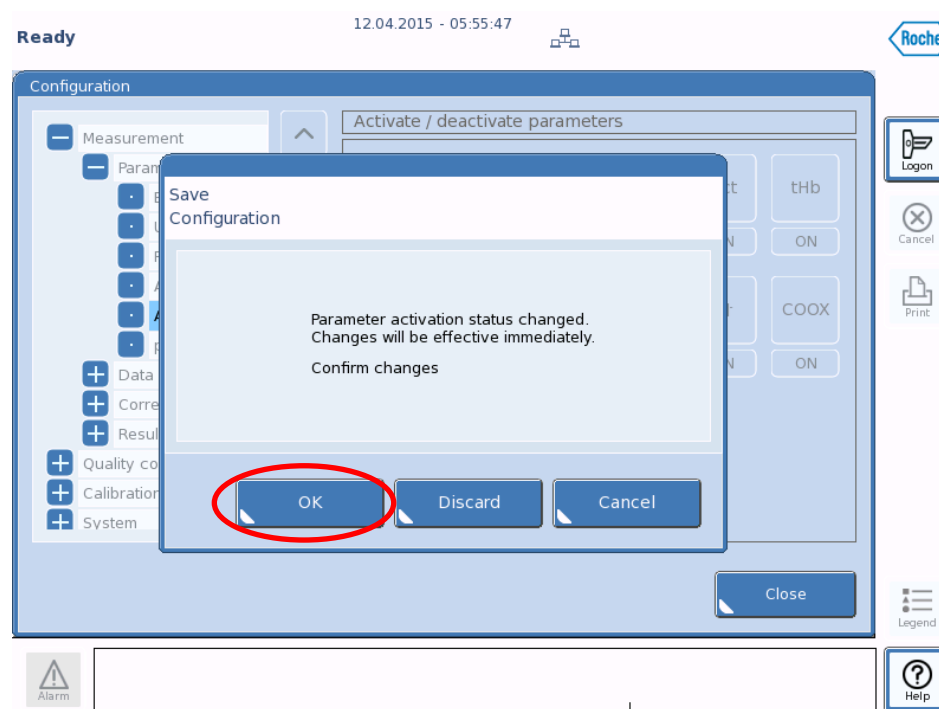


If the lot number of the Sensor Cartridge is listed in Table 1, the parameter Na<sup>+</sup> must be deactivated. Under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set Na<sup>+</sup> to “OFF”:



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After selecting “Close”, confirm the change by selecting “OK”:



In the overview screen  $\text{Na}^+$  is then shown as greyed out, and the parameter is no longer active.



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## Re-activation of Na<sup>+</sup>:

Before the installation of a new, unaffected Sensor cartridge (lot number **not** listed in Table 1), re-activate Na<sup>+</sup>:

Under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set Na<sup>+</sup> to “ON”:

