

# Field Safety Notice

## SBN-CPS-2016-014

CPS / Blood Gas & Electrolytes  
Version 1  
09-Jun-2016

### cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC: Interference of PCO<sub>2</sub> 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>	05170478001
<b>Device Identifier</b>	
<b>Production Identifier (Lot No./Serial No.)</b>	Lot 21560883 / Serial Numbers 00200276 – 00200787
<b>Type of Action</b>	Field Safety Corrective Action

Affected lot is 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 PCO<sub>2</sub> on sodium (Na<sup>+</sup>) results (positive bias) is observed in whole blood samples. The issue occurs when Lot 21560883 with SN 00200276 to SN 00200787 of **cobas b 123** Sensor Cartridges BG/ISE/GLU/LAC are used.

Users who want to measure sodium must not use **cobas b 123** Sensor Cartridge BG/ISE/GLU/LAC lot 21560883 with SN 00200276 to 00200787 and must use **cobas b 123** Sensor Cartridges from unaffected lots.

Whenever a **cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC of the affected lot 21560883** - with SN 00200276 to SN 00200787 is used, **the parameter sodium (Na<sup>+</sup>) must be deactivated** in order to avoid any risk of reporting too high sodium results.

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## Description of Situation

Recently we have become aware during internal tests that the specific lot 21560883 with SN 00200276 to SN 00200787 of **cobas b** 123 Sensor Cartridge BG/ISE/GLU/LAC show interference of PCO<sub>2</sub> on sodium results in whole blood samples. The sodium bias increases with the PCO<sub>2</sub> (partial pressure of carbon dioxide) values of the sample.

The interference of PCO<sub>2</sub> on sodium in patient samples causes medical risks only for patients with increased PCO<sub>2</sub>, or with PCO<sub>2</sub> at the very upper end of normal range.

The positive bias of sodium falsifies either:

- hyponatremic values as normal results or
- normal values as hypernatremic results.

In case of false normal results the medical need to treat hyponatremia might be missed. Due to falsely high results above the upper normal range, unnecessary therapeutic body fluid correction might be initiated. However, to date, there are no known cases or complaints 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 sodium (see "Appendix 2: Deactivation of sodium [Na<sup>+</sup>]"). Roche Diagnostics will replace affected **cobas b** 123 Sensor Cartridges BG/ISE/GLU/LAC.

## Actions to be taken by the Customer/User

Users that want to measure sodium must use unaffected lots of **cobas b** 123 Sensor Cartridges BG/ISE/GLU/LAC. Whenever the affected **cobas b** 123 Sensor Cartridge BG/ISE/GLU/LAC lot 21560883 with SN 00200276 to SN 00200787 is used, the parameter sodium must be deactivated in order to avoid any risk of reporting too high sodium results.

For details regarding detection of the Sensor Lot and Serial Number, see Appendix 1.

For details regarding the deactivation of sodium, see Appendix 2.

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

# **cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC: Interference of PCO<sub>2</sub> on Sodium Results in Patient Samples**

## **Communication of this Field Safety Notice**

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

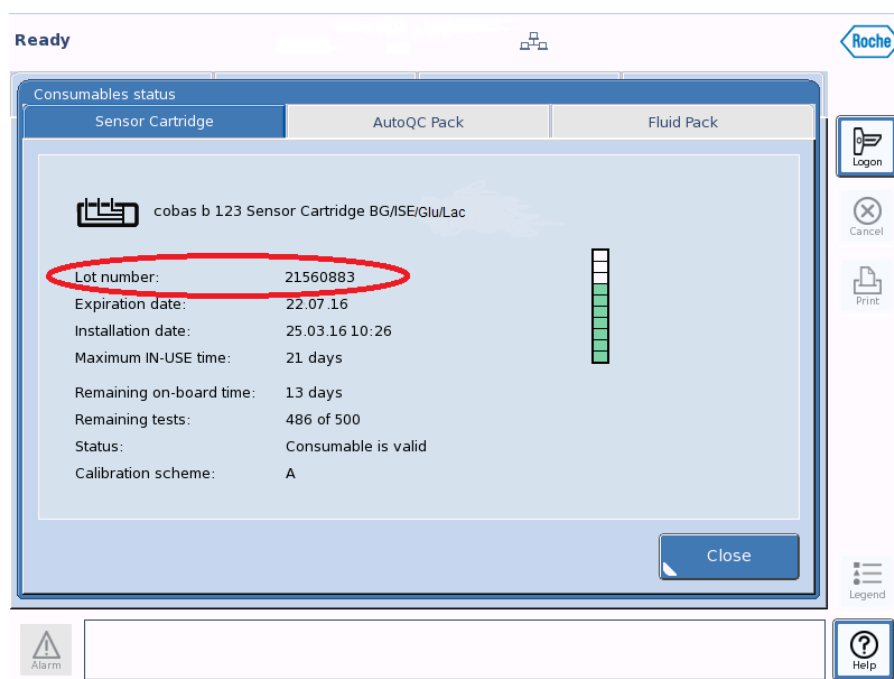
# cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC: Interference of PCO<sub>2</sub> on Sodium Results in Patient Samples

## Appendix 1: Detection of the Sensor Lot and Serial Number

- 1) Lot and SN of a Sensor Cartridge BG/ISE/Glu/Lac - Lot 21560883 - SN 00200296

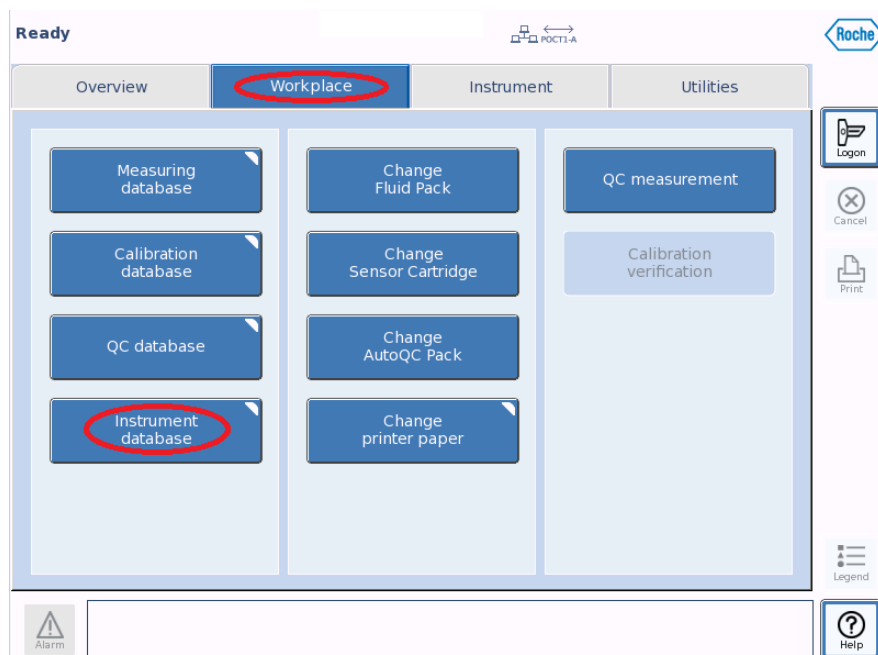


- 2) The lot number of an installed Sensor Cartridge can be checked in **cobas b 123** system software under "Instrument > Consumable Status > Sensor Cartridge".

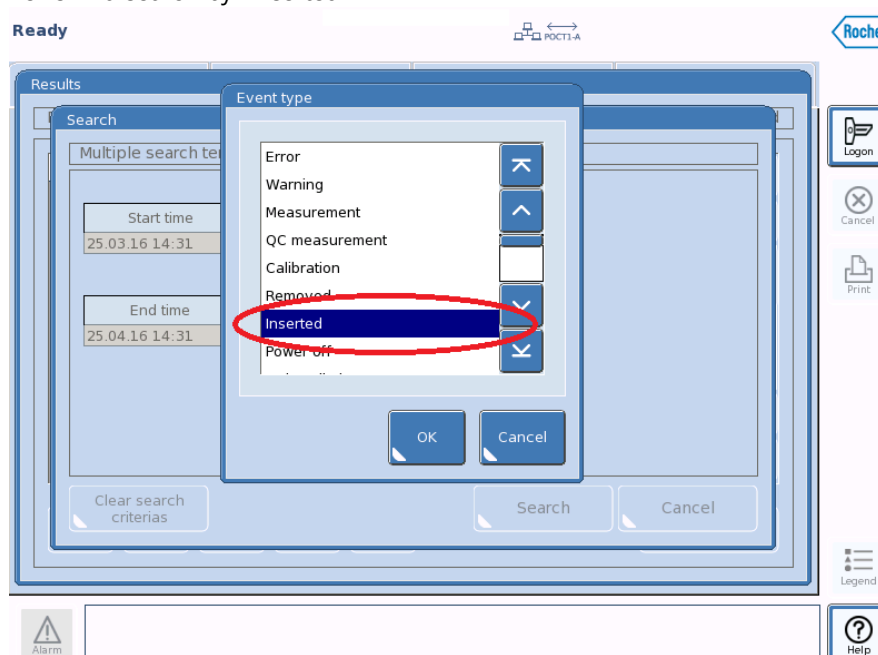


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If this is an affected sensor from lot 21560883, the serial number of this Sensor Cartridge can be found in **cobas b 123** system software under “Workplace>Instrument database> Results>Search”.

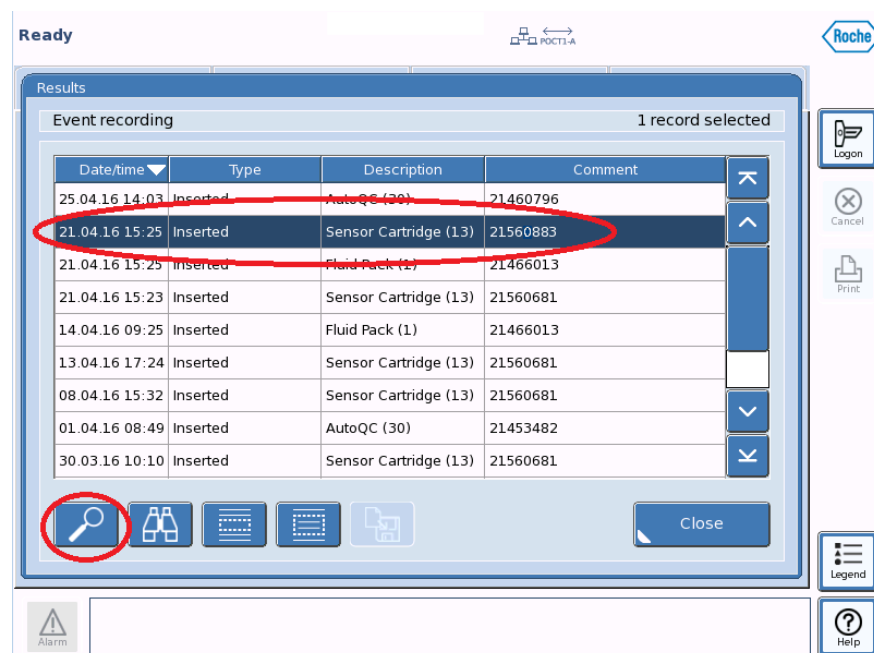


Perform a search by “inserted”



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Choosing the affected sensor lot and select detailed view:



Ready

POCT3-A

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Results

Event recording 1 record selected

Date/time	Type	Description	Comment
25.04.16 14:03	Inserted	AutoQC (30)	21460796
21.04.16 15:25	Inserted	Sensor Cartridge (13)	21560883
21.04.16 15:25	Inserted	Fluid Pack (1)	21466013
21.04.16 15:23	Inserted	Sensor Cartridge (13)	21560681
14.04.16 09:25	Inserted	Fluid Pack (1)	21466013
13.04.16 17:24	Inserted	Sensor Cartridge (13)	21560681
08.04.16 15:32	Inserted	Sensor Cartridge (13)	21560681
01.04.16 08:49	Inserted	AutoQC (30)	21453482
30.03.16 10:10	Inserted	Sensor Cartridge (13)	21560681

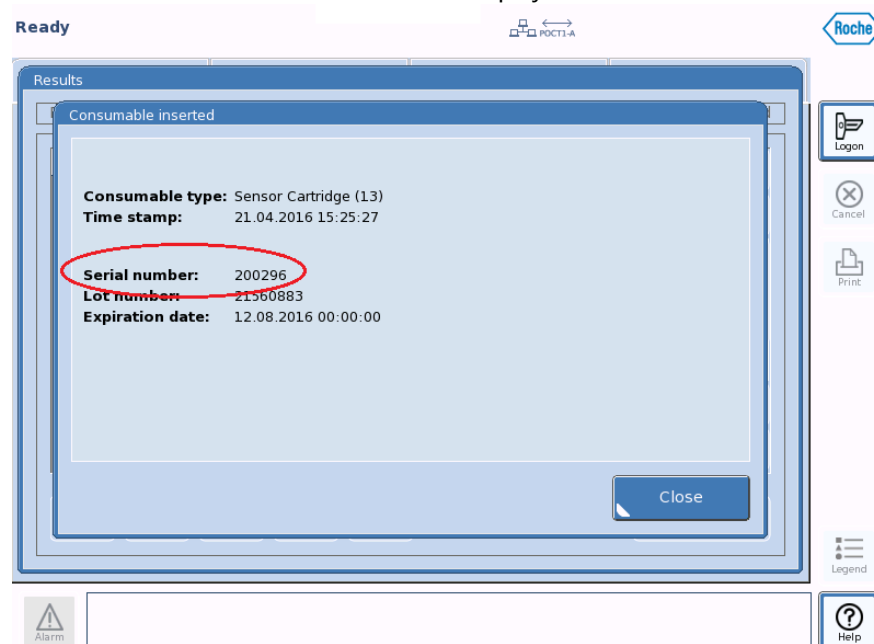
Close

Alarm

Legend

Help

The Serial Number will be shown on the display



Ready

POCT3-A

Roche

Results

Consumable inserted

Consumable type: Sensor Cartridge (13)  
Time stamp: 21.04.2016 15:25:27

Serial number: 200296  
Lot number: 21560883  
Expiration date: 12.08.2016 00:00:00

Close

Alarm

Legend

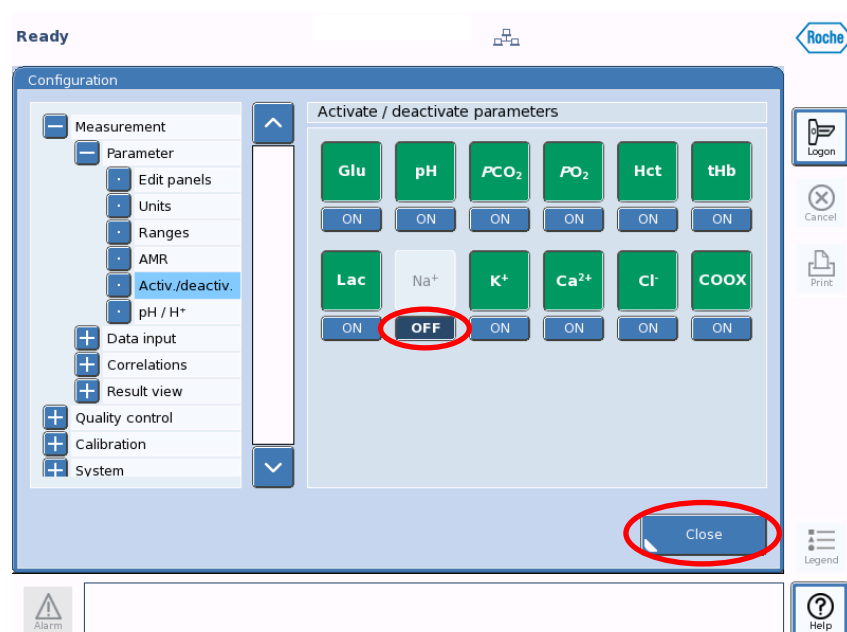
Help

# cobas b 123 Sensor Cartridge BG/ISE/GLU/LAC: Interference of PCO<sub>2</sub> on Sodium Results in Patient Samples

## Appendix 2: Deactivation of sodium (Na<sup>+</sup>)

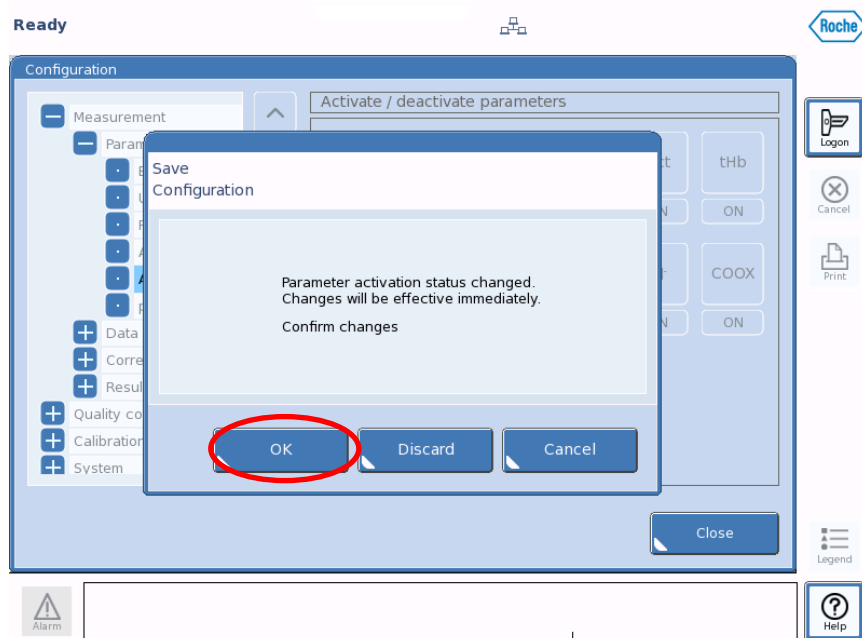
Whenever you intend to use a **cobas b 123** Sensor Cartridge of the affected lot 21560883 with SN 00200276 to SN 00200787, **the parameter sodium (Na<sup>+</sup>) must be deactivated.**

**Deactivation** can be done under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set Na<sup>+</sup> to “OFF”:

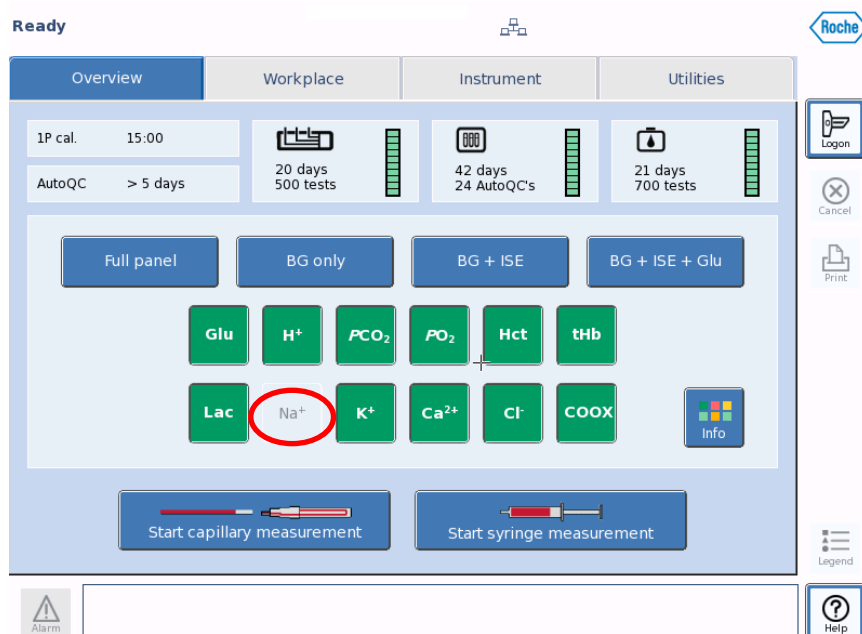


After selecting “Close”, confirm the change by selecting “OK”:

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In the overview screen Na<sup>+</sup> is then shown as greyed out, and the parameter is no longer active.





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

Before the installation of a new, unaffected Sensor cartridge (lot number **different** from **lot 21560883** with **SN 00200276 to SN 00200787**), you can re-activate sodium under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set Na<sup>+</sup> to “ON”:

