

# Field Safety Notice

## SBN-CPS-2016-008

CPS / Blood Gas & Electrolytes  
Version 1  
29-Apr-2016

### 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</b>
<b>GMMI / Part No</b>	05170460001
<b>Device Identifier</b>	
<b>Production Identifier (Lot No./Serial No.)</b>	Lot 21560881 / Serial Numbers 00200076 – 00200176
<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 Lot 21560881 with SN 00200076 to SN 00200176 of **cobas b 123** Sensor Cartridges BG/ISE are used.

Users who want to measure  $\text{Na}^+$  must not use **cobas b 123** Sensor Cartridge BG/ISE lot 21560881 with SN 00200076 to 00200176 and must use **cobas b 123** Sensor Cartridges from unaffected lots.

Whenever a **cobas b 123** Sensor Cartridge BG/ISE of the affected lot **21560881** - with SN 00200076 to SN 00200176 is used, **the parameter  $\text{Na}^+$  must be deactivated** in order to avoid any risk of reporting too high sodium results.

### Description of Situation

Recently we have become aware during internal tests that the specific lot 21560881 with SN 00200076 to SN 00200176 of **cobas b 123** Sensor Cartridge BG/ISE show interference of *PCO2* on sodium ( $\text{Na}^+$ ) results in whole blood samples. The  $\text{Na}^+$  bias increases with the *PCO2* (partial pressure of carbon dioxide) values of the sample.

The interference of *PCO2* on  $\text{Na}^+$  in patient samples causes medical risks only for patients with increased *PCO2*, or with *PCO2* at the very upper end of normal range.

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

The positive bias of  $Na^+$  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  $Na^+$  (see "Appendix 1: Deactivation of  $Na^+$ "). Roche Diagnostics will replace affected **cobas b 123** Sensor Cartridges BG/ISE.

## Actions to be taken by the Customer/User

Users that want to measure  $Na^+$  must use unaffected lots of **cobas b 123** Sensor Cartridges BG/ISE. Whenever the affected **cobas b 123** Sensor Cartridge BG/ISE lot 21560881 with SN 00200076 to SN 00200176 is used, the parameter  $Na^+$  must be deactivated in order to avoid any risk of reporting too high sodium results. For details regarding the deactivation of  $Na^+$ , see Appendix 1. **cobas b 123** Sensor Cartridges BG/ISE 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.

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

Sincerely,

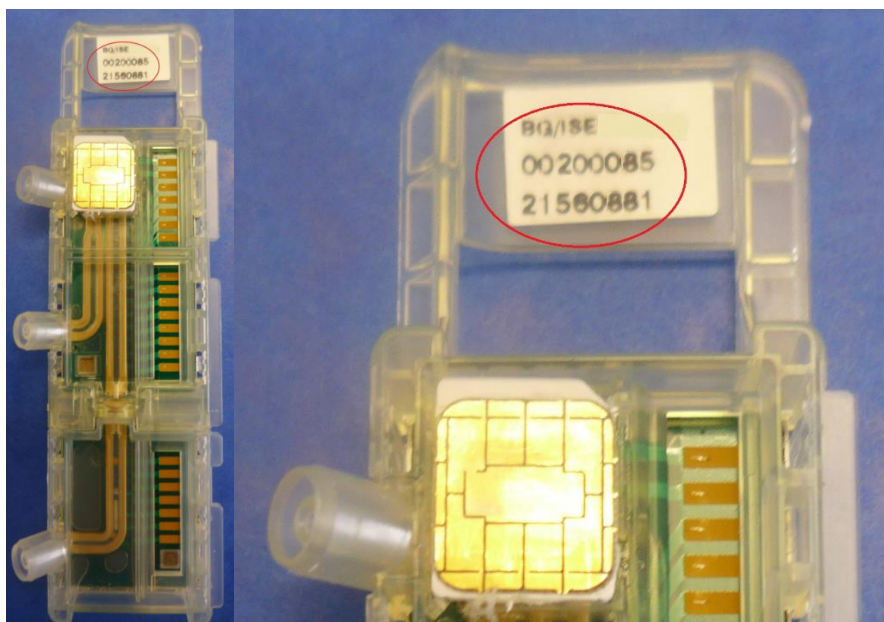
**Roche Diagnostics Asia Pacific Pte Ltd**

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

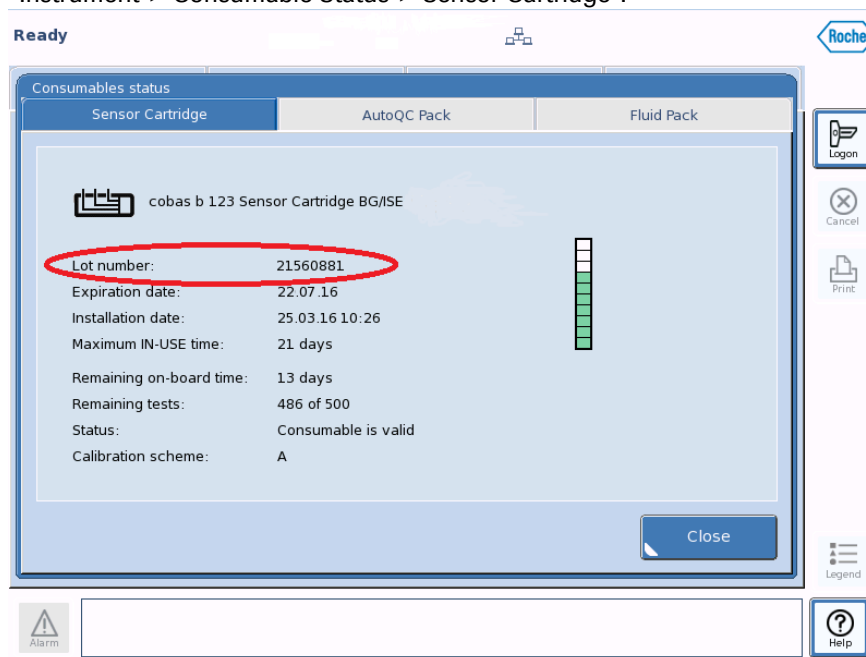
# cobas b 123: Interference of *PCO2* on Sodium Results in Patient Samples

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

- 1) Lot and SN of a Sensor Cartridge BG/ISE - Lot 21560881 - SN 00200085

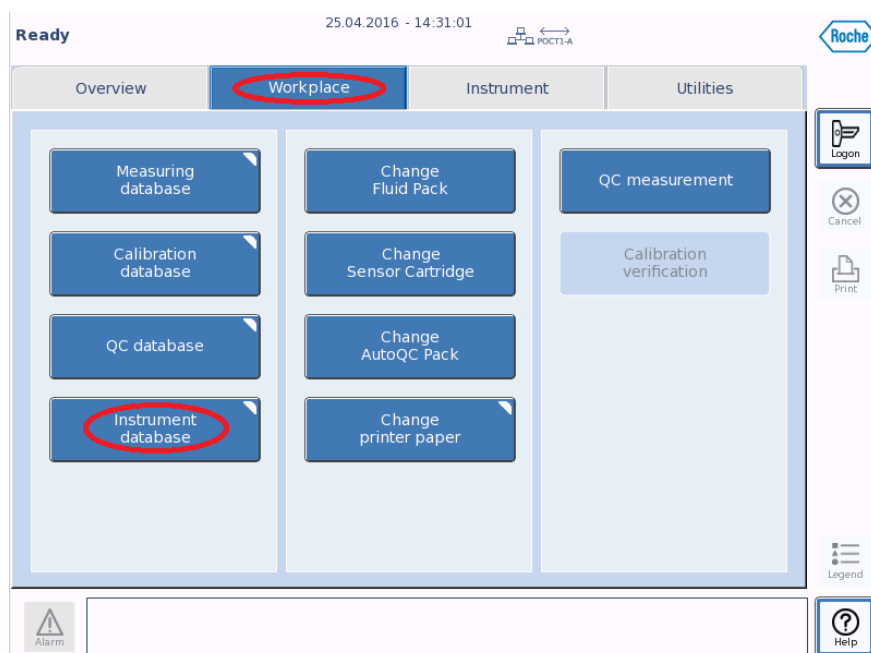


- 2) The lot number of an installed Sensor Cartridge can be checked in **cobas b 123** system software under “Instrument > Consumable Status > Sensor Cartridge”.

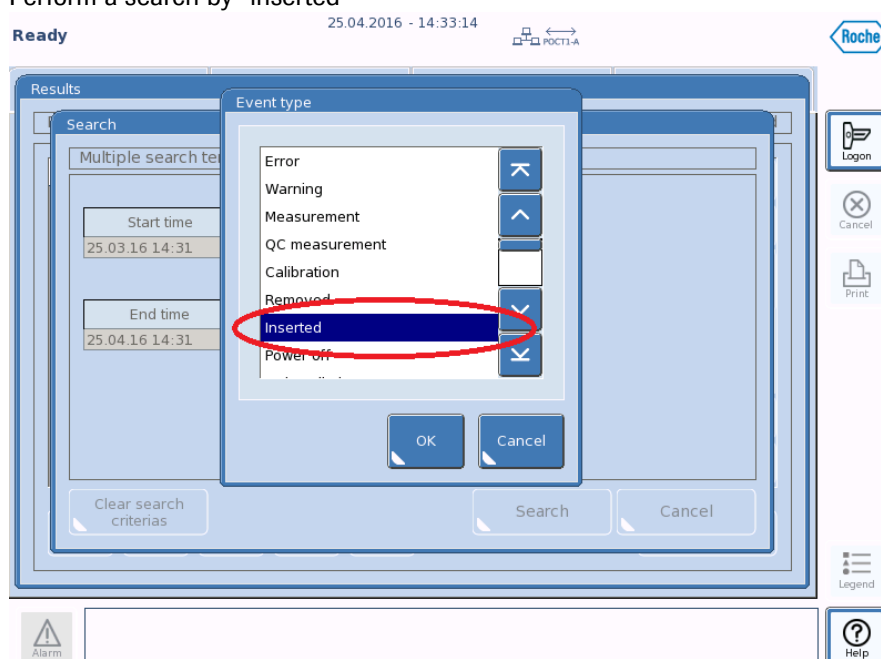


# cobas b 123: Interference of *PCO2* on Sodium Results in Patient Samples

If this is an affected sensor from lot 21560881, 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”



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

Choosing the affected sensor lot and select detailed view:

Ready 25.04.2016 - 14:34:19 POCT3-A

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)	21560881
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 25.04.2016 - 14:34:56 POCT3-A

Results

Consumable inserted

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

Serial number: 200096  
Lot number: 21560881  
Expiration date: 12.08.2016 00:00:00

Close

Alarm

Legend

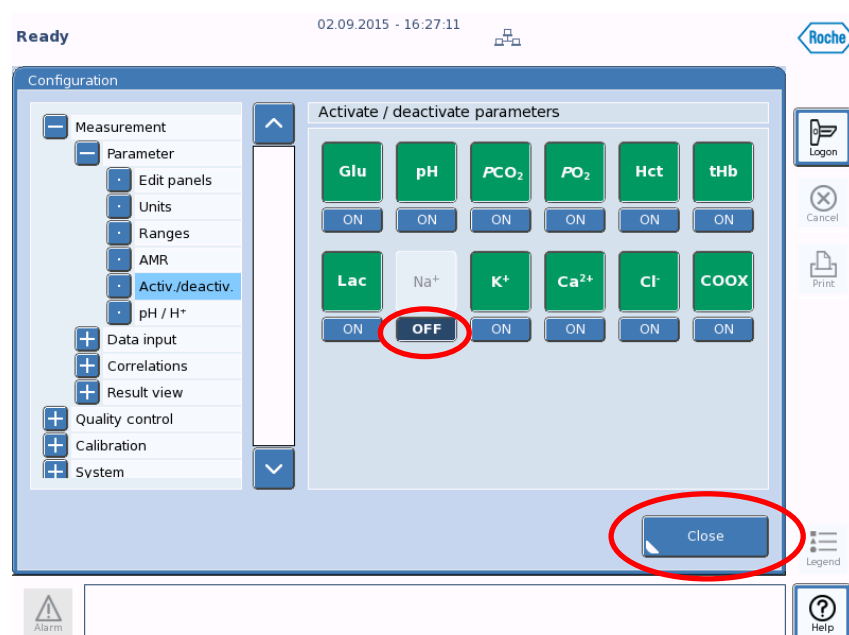
Help

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

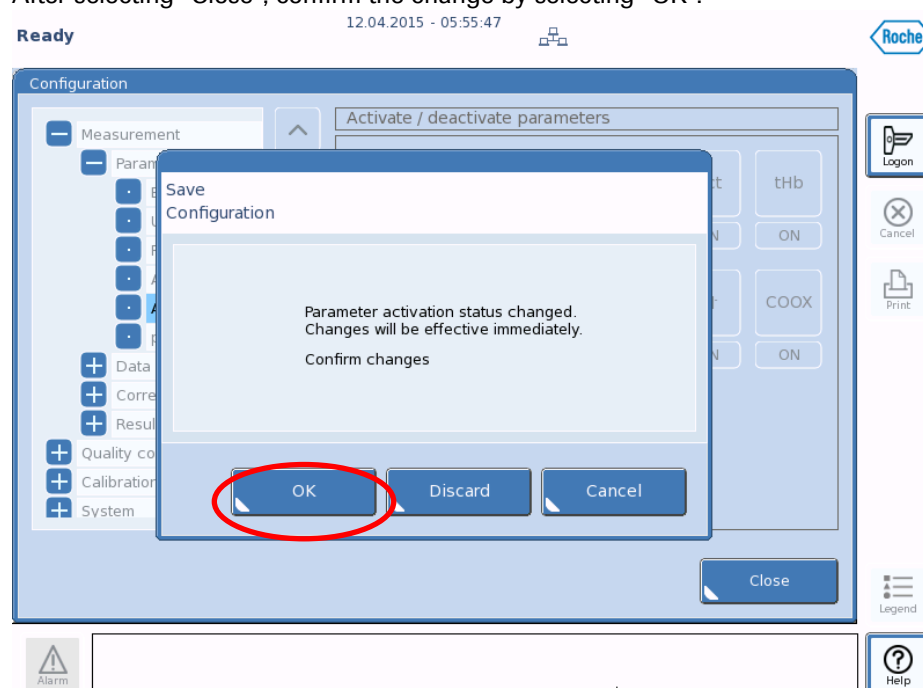
## Appendix 1: Deactivation of $Na^+$

So, whenever a customer intends to use a **cobas b 123** Sensor Cartridge of the affected lot 21560881 with SN 00200076 to SN 00200176, **the parameter  $Na^+$  must be deactivated.**

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



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



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

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



## Re-activation of $\text{Na}^+$ :

Before the installation of a new, unaffected Sensor cartridge (lot number **different** from **lot 21560881** with **SN 00200076 to SN 00200176**), you can re-activate  $\text{Na}^+$  under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set  $\text{Na}^+$  to “ON”:

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

