

Field Safety Notice

SBN-RPD-2015-010

RPD / Blood Gas & Electrolytes
Version 1
24-Jun-2015

Low *PO2* patient sample and QC results

Instrument/System Affected	cobas b 123 <1> cobas b 123 <2> cobas b 123 <3> cobas b 123 <4>
Product Name	cobas b 123 FLUID PACK COOX 400
GMMI / Part No	05170036001
Device Identifier	
Production Identifier (Lot No./Serial No.)	21446113 21446153 21446163 21446173
Type of Action	Field Safety Corrective Action

Dear Valued **cobas b 123** Customer,

We regret to inform you about an issue on **cobas b 123** POC systems causing low *PO2* results for patient samples and QC material. It may occur when specific **cobas b 123** Fluid Packs, identifiable by Lot number, are used.

In order to avoid any risk of reporting too low *PO2* results, the parameter *PO2* must be deactivated on the **cobas b 123** systems whenever Fluid Packs from affected lot numbers are being used.

Description of Situation

Recently, several customers reported QC failures (QC values below the target values) of parameter *PO2* on **cobas b 123** POC systems, affecting primarily Level 1 and 2.

We found these QC failures to be caused by a calibration issue with the *PO2* parameter. Detection of this issue is not guaranteed given QC results can be below mean values but still within 2 standard deviations (SD) limits. Therefore there is a potential for erroneously low *PO2* results in patient samples, especially in blood samples with *PO2* values

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below 50 mmHg.

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 *PO2* (see “Appendix 1: Description of the Workaround”).

Roche Diagnostics will replace affected **cobas b** 123 Fluid Packs.

Actions to be taken by the customer/user

For **cobas b** 123 Fluid Packs of the affected lots currently in use, **the parameter *PO2* must be deactivated**. Please kindly follow the detailed workaround given in Appendix 1.

Unused **cobas b** 123 Fluid Packs 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.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action.

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

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

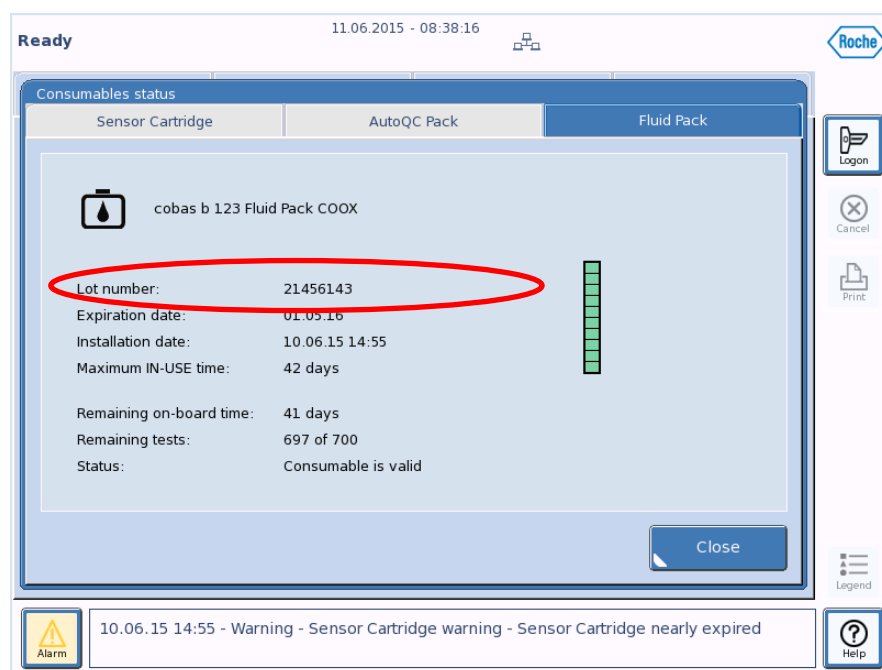
Email: sg.regulatory@roche.com

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Appendix 1: Description of Workaround

Whenever a **cobas b** 123 Fluid Pack of the potentially affected lots is used, **the parameter *PO2* must be deactivated.**

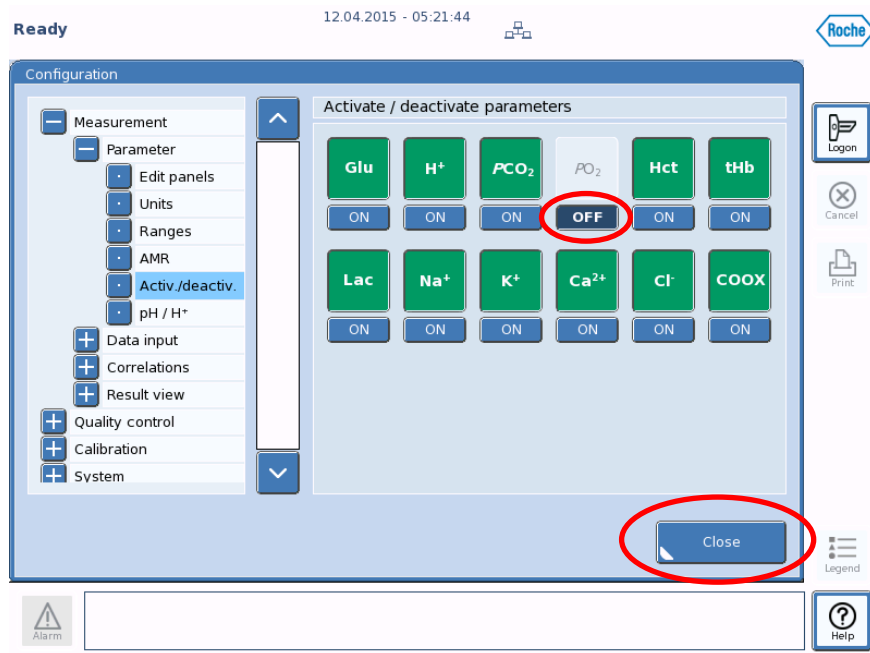
The lot number of the currently installed Fluid Pack can be checked in **cobas b** 123 system software under “Instrument > Consumable Status > Fluid Pack”:



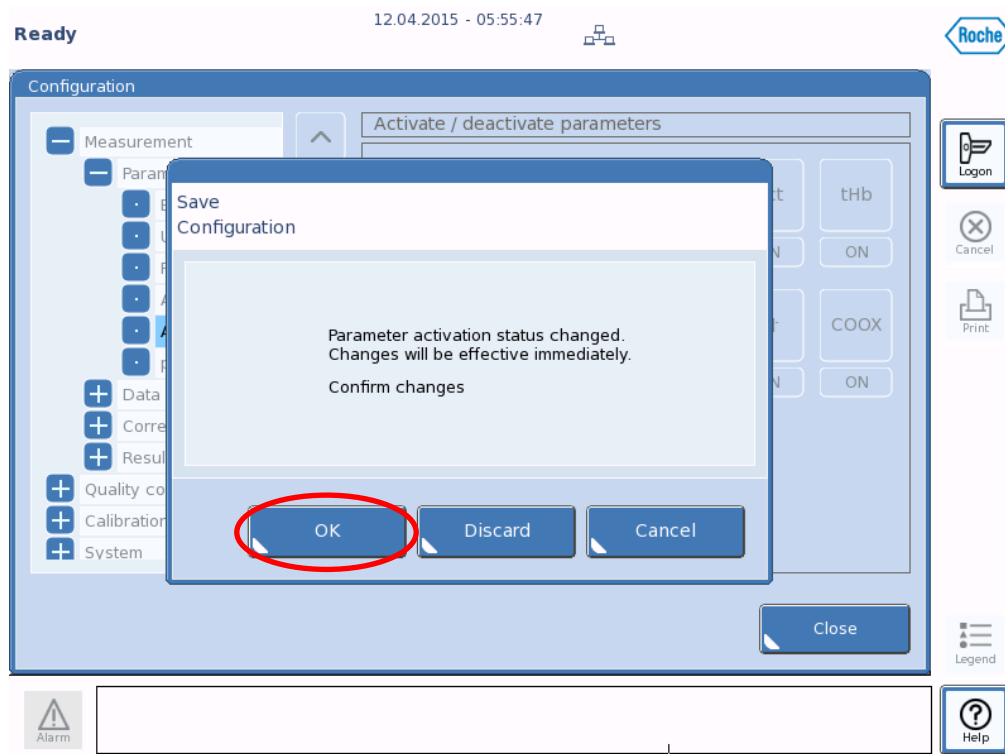
If the Lot number of the Fluid Pack is the affected lot, the parameter *PO2* must be deactivated.

Under “Utilities > Configuration > Measurement > Parameter > Activ./deactiv.” set *PO2* to “OFF”:

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After selecting "Close", confirm the change by selecting "OK":



In the overview screen PO_2 is then shown as greyed out, and the parameter is no longer active.

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Ready 12.04.2015 - 05:23:15

Overview Workplace Instrument Utilities

Cal. Not activated
AutoQC Not scheduled

19 days 500 tests
41 days 24 AutoQC's
20 days 700 tests

Full panel BG only BG + ISE BG + ISE + Glu

Glu H⁺ PCO₂ PO₂ Hct tHb
Lac Na⁺ K⁺ Ca²⁺ Cl⁻ COOX

Start capillary measurement Start syringe measurement

Alarm

Logon Cancel Print Legend Help

Re-activation of PO_2 :

Before the installation of a new, unaffected Fluid Pack lot, re-activate PO_2 :

Under "Utilities > Configuration > Measurement > Parameter > Activ./deactiv." set PO_2 to "ON":

Ready 12.04.2015 - 06:00:34

Configuration

Measurement
Parameter
Edit panels
Units
Ranges
AMR
Activ./deactiv.
pH / H⁺
Data input
Correlations
Result view
Quality control
Calibration
System

Activate / deactivate parameters

Glu H⁺ PCO₂ PO₂ Hct tHb
ON ON ON ON ON ON
Lac Na⁺ K⁺ Ca²⁺ Cl⁻ COOX
ON ON ON ON ON ON

Close

Alarm

Logon Cancel Print Legend Help



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ACKNOWLEDGMENT RECEIPT

This is to acknowledge the receipt of Roche Safety Board Advisory Notice: SBN-RPD-2015-010, dated 24-Jun-2015, regarding cobas b 123 POC systems causing low *PO2* results for patient samples and QC material

Received by:

Name & Signature

Hospital & Stamp

Date