

Urgent Field Safety Notice

SBN-CPS-2018-001

CPS / Blood Gas & Electrolytes
Version 1
09-Feb-2018

cobas b 221 AutoQC scheduler issue

Product Name	cobas b 221 <2> system cobas b 221 <4> system cobas b 221 <6> system AutoQC module complete cobas b 221
GMMI / Part No	03337111001
Device Identifier	03337138001 03337154001 03313522001
Product Description	cobas b 221 <2> equipped with AutoQC module cobas b 221 <4> equipped with AutoQC module cobas b 221 <6> equipped with AutoQC module AutoQC module complete cobas b 221
Production Identifier (Lot No./Serial No.)	All
SW Version	All
Type of Action	Field Safety Corrective Action (FSCA)

Dear valued **cobas b 221** Customer,

We are informing you about a software limitation that can affect automatic QC (AutoQC) measurements on the **cobas b 221** instrument under specific circumstances. This phenomenon could occur on the following **cobas b 221** instruments (types <2>, <4> and <6>) equipped with AutoQC modules.

Description of Situation

Based on three recent complaints, we have become aware of an issue that affects automatic QC (AutoQC) measurements. The QC setup wizard user interaction can create a situation whereby specific user interaction causes the internal timers (scheduler) no longer perform previously scheduled automatic QC measurements.

The QC setup wizard consists of a sequence of 5 windows that comprise the workflow. In the last of these 5

cobas b 221 AutoQC scheduler issue

windows, the “AutoQC timing,” the operator can use the buttons “Return to Setup” (1) and “Exit” (2) (Fig. 1) to exit the QC setup Wizard and save the input as described in the Instructions For Use (IFU) (V17.0, chapter “Quality control”) (Fig. 2).

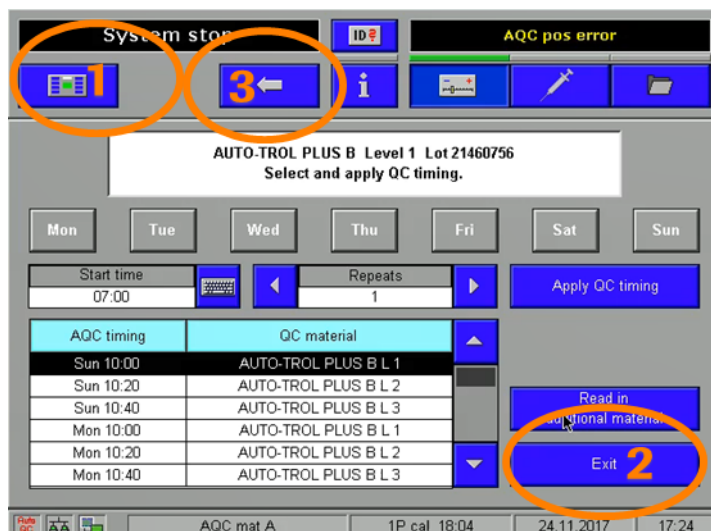


Fig. 1: Last “AutoQC timing” window in the QC setup wizard workflow.

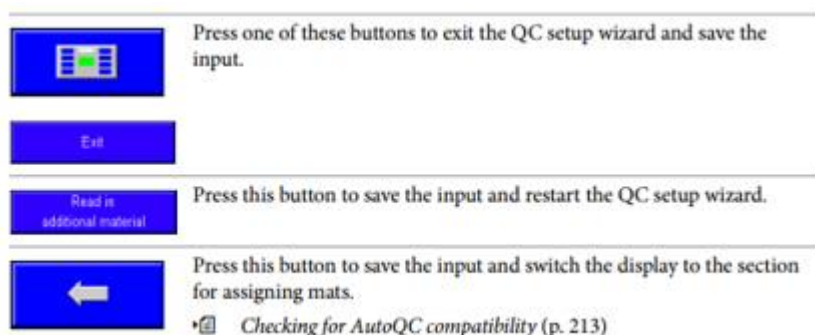


Fig. 2: Excerpt from IFU for the **cobas b 221** (V17.0, chapter “Quality control”).

The “Back” button (3) (Fig. 1) allows the operator to navigate back through the QC setup wizard workflow. When the operator uses the “Back” button 5 times consecutively to navigate backwards through the workflow and finally closes the QC setup wizard, the software responsible for starting scheduled AutoQC measurements (scheduler) is not activated. Consequently, from this time on, no more automatic QC measurements will be performed. This situation can only be detected by reviewing AutoQC results in the instrument’s data manager or in a connected LIS/HIS.

The situation persists until the QC setup wizard is opened and closed properly, using the “Return to Setup” (1) or “Exit” (2) button.

In this case, there is no direct influence on patients’ results. However, in the absence of QC measurements, erroneous results caused by another independent issue might remain undetected. Considering the unreliable detectability of the issue, medical risk for the population at the greatest risk cannot be entirely excluded. To date, there are no known cases or complaints where this issue caused any adverse events to patients.

cobas b 221 AutoQC scheduler issue

Actions taken by Roche Diagnostics

Roche has developed a workaround which describes how to exit the QC setup wizard to ensure the AutoQC scheduler is working as expected. Please refer to the “Actions to be taken by the customer/user” section. This issue will be fixed in an upcoming software patch, expected to be available in May 2018. Until the software patch has been installed on the instruments, the workaround must be performed.

Actions to be taken by the customer/user

Until the software patch is available and has been installed, the following workaround must be used: Do not use the “Back” button to exit the QC setup wizard workflow. Instead, use the “Return to Setup” (1) and “Exit” (2) (Fig. 1) buttons to ensure execution of scheduled automatic QC measurements. Whenever the QC setup wizard workflow has been used on an instrument, check whether the next scheduled AutoQC measurement is performed to ensure the AutoQC scheduler is working as expected.

Communication of this Field Safety Notice (if appropriate)

<If the recipient needs to forward the FSN to additional organizations/individuals then one or more of the following statements may be included:

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied. (If appropriate).

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

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

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

<closing salutations>,

Contact Details

To be completed locally:

Name

Title

Company Name

Address

Tel. +xx-xxx-xxxx xxxx

Email name@roche.com