

# PRODUCT INFORMATION NOTICE

## ACTION REQUIRED

Information Ref No: NPCI Launch of cobas® b 101 software version 3.0.0 to achieve compatibility with upcoming cobas® click tests SN-RDS-NPC-2025-082 **version 2**

Date: 08/05/25

**Updated information is highlighted in yellow**

System Affected: cobas® b 101

Software Version: 3.0.0

### Summary of Notice Information

Launch of cobas® b 101 software version 3.0.0 to achieve compatibility with upcoming cobas® click tests

**Updated notice version to correct for typo in customer service email address**

### Reason for Notice

Roche would like to inform you about the launch of software (SW) version 3.0.0 for the cobas® b 101 instrument.

Main goals of this software version are:

- Enable cobas® b 101 instruments to measure cobas click discs (planned to be launched during 2025)
- Enable cobas® b 101 instruments to use the new cobas click QC concept
- Support of additional printer and external barcode scanner
- Bug fixes

This SW update is mandatory in order to continue using the cobas® b 101 in the future. It allows the new second generation (Gen. 2) discs, which are used in the new cobas click instrument, to be used in the cobas® b 101 instrument. As a result, the current discs will be

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phased out. Until the current discs are phased out they can still be used in the cobas® b 101 after updating to SW version 3.0.0.

Therefore, to continue using the cobas® b 101 instrument after 2025, this SW update is required. If a new cobas click (Gen.2) disc is inserted into a cobas b® 101 instrument running on SW version 2.0.5 or earlier, the cobas b® 101 will show an error message (I-302 Invalid Disc).

All existing cobas® b 101 SW versions can directly be updated to version 3.0.0.

### Detailed overview of changes and bug fixes

#### **Application / User Interface (Changes)**

#	Description
1	Support the cobas click (Gen.2) discs and cobas click QC materials (Gen.2). See information above.
2	Support of printer Citizen CT-E301  Due to the discontinuation of other supported printers, the cobas b 101 will in addition to the current printers support the new model Citizen CT-E301.
3	Support of successor barcode scanner QD2590  The cobas b 101 will in addition support the 2D scanner Datalogic QD2590 (which is the successor model of the QD2430).

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### Application / User Interface (Resolved issues)

#	Description
1	<p>Under the very rare conditions it is possible that the cobas b 101 incorrectly releases a QC lockout.</p> <p><b>Condition 1:</b></p> <ul style="list-style-type: none"> <li>Parameter <ul style="list-style-type: none"> <li>Lipid CHOL : Disabled</li> <li>TG: Disabled</li> <li>HDL: Enabled</li> </ul> </li> <li>Lipid patient test is locked (e.g. due to Failed QC lockout, interval lockout, and/or new lot lockout).</li> </ul> <p>If a lipid QC test is performed using a sample with “TG value is greater than 650 mg/dL”, the QC lockout is incorrectly released.</p> <p><b>Condition 2:</b></p> <ul style="list-style-type: none"> <li>Parameter <ul style="list-style-type: none"> <li>Lipid CHOL : Enabled</li> <li>TG: Disabled</li> <li>HDL: Enabled</li> </ul> </li> <li>Lipid patient test is locked (e.g. due to Failed QC lockout, interval lockout, and/or new lot lockout).</li> </ul> <p>This issue has been fixed in software version 3.0.0.</p>
2	<p>Communication issues when using more than 1 cobas b 101 instrument at the same Base Unit Hub (BUH)</p> <p>Due to a software issue in the cobas b 101 software, the Base Unit Hub cannot differentiate more than 1 cobas b 101 instrument. This prevents the usage of the multi-slot configuration of the Base Unit Hub when attached cobas b 101 instruments shall synchronize with the data management systems on different ports.</p> <p>The software issue is fixed in software version 3.0.0.</p>
3	<p>Incorrect date/time format on printouts of QC, proficiency and optical check disc results</p> <p>cobas b 101 software version 2.0.0 and later prints the measured date and the print date on QC results, optical check results, and proficiency test results with the date format “DD.MM.YYYY” and the time format “24 h”, not following the “Date Format” setting and the “Time Format” setting.</p> <p>Software version 3.0.0 follows the “Date Format” setting and the “Time Format” setting.</p>

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### POCT1-A Communication Interface (Changes)

There are no changes in the POCT1-A communication protocol between the recent version 2.0.5 and the new version 3.0.0.

### **POCT1-A Communication Interface (Resolved issues)**

#	Description
1	<p>Issue of DMS connection related to event log</p> <p>During the global investigation CN-603737, it was discovered that an event log message contained an ASCII control code (the "STX" character, 0x02) that the DMS cannot process. As a result, the DMS is unable to retrieve the event log from the cobas b 101 instrument.</p> <p>So far only one case was observed globally and no reason why the control code was stored in the event log was found.</p> <p>Software version 3.0.0 improves the robustness by ensuring that messages sent to the DMS do not contain ASCII control codes.</p>

Further information about the launch of the cobas click and availability of the new second generation (Gen. 2) discs will be communicated via customer notifications over the coming months.

### Action Required

Customers will need to update their cobas® b 101 SW using a pre-loaded USB flash drive and inserting it into the instrument. To receive the USB customers should contact our customer services team via telephone on 0808 100 99 98 (UK) or 1800 509 586 (Ireland) or via email [burgesshill.customerservice@roche.com](mailto:burgesshill.customerservice@roche.com) and provide the following information:

- Customer contact name
- Account number
- Account name
- Serial numbers of all cobas® b 101 instruments

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- Number of USB sticks required
- Address and contact name for USB stick(s) to be sent to

USB sticks will be sent out with instructions on how to load the new SW. The SW update to version 3.0.0 takes approx. 5 minutes per instrument.

In addition all cobas® b 101 consumable deliveries will be sent out with a letter informing customers of the requirement to load SW 3.0.0 onto their cobas® b 101 instruments as a reminder.

Should customers have any queries about this notice or require technical support please contact technical services using the telephone numbers provided in the box below or email [burgesshill.npc@roche.com](mailto:burgesshill.npc@roche.com)

Updated cobas® b 101 Quick reference guide and User Assistance are available from eLabDoc on the Roche navify Portal.

### Attachments

None

A copy of this notice can also be found on the [Roche navify® portal](#)

If you have any questions in relation to this notice or require any further information please raise a case via Online Support on the [Roche navify® portal](#)

Alternatively contact our Technical Support Hotline

UK: 0808 100 19 20  
Ireland: 1800 40 95 64

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Option 2 – Near Patient care devices for Health Care Professionals

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