



Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details		
Device Name	Cobas pro	
Device Model	09719385001	
Manufacturer	Roche Diagnostics	
Country of Origin	Germany	
Reference	attached	
Reason of Alert	NHRA initiates this FSN due to an error in the update registration process of ClinChem	
	application parameter download with Partial Overwrite.	
Action should be	e Please refer to "Actions to be taken by Customer/ User" in the attached FSN	
taken	And for more information please contact the authorized representative General medical W.L.L.	
	at <u>registration.medics@intercol.com</u>	

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

FSCA 2023 0011 8/Mar/2023



Quality Notification

15 February 2023

Subject: Calibration Update Point not overwritten by Partial Overwrite on cobas c 503

Dear Valued Customer,

Product	Quant. GMMI	
cobas pro INSTALL SW V 02-03	1 09719385001	
Instrument/System	cobas® c 503 analytical unit cobas® pro sample supply unit cobas® pro SSU	
Component	Software	

Application Service

Units Concerned

Target Group

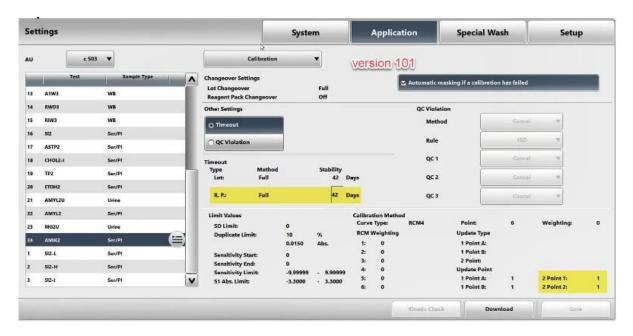
cobas pro systems running AMIK2 (ACN 20150) on c 503 with all software versions

Subject

For AMIK2 (ACN 20150) application parameter, there is an update from version 101 to 102 recently.

In the **parameter version 101**, the Timeout calibration for reagent packs is defined as:

- Method: Full
- Stability: 42 Days
- Update Points: 1 (2 Point1) and 1 (2 Point2)



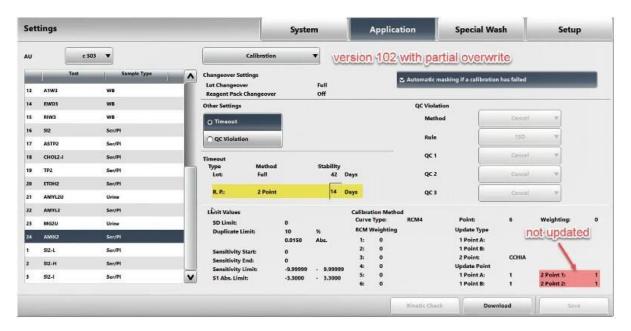
In the **parameter version 102**, the Timeout calibration for reagent packs is defined as:

- Method: 2 PointStability: 14 Days
- Update Points: 2 (2 Point1) and 6 (2 Point2)



Due to a software issue, if version 102 is downloaded with Partial Overwrite, the Update Points "2 Point1" and "2 Point2" are not overwritten and both are kept as 1.

Timeout Calibration Method and Stability are not affected by the issue and overwritten successfully.



As a consequence, the system only accepts calibrator 1 and performs a 1 point calibration update when a R.Pack calibration timeout occurs,

Only Update Point "2 Point1" and "2 Point2" among all parameter settings are affected by this issue. The only affected assay is AMIK2 (ACN 20150).

Workaround

Choose the Overwrite function for the update of the AMIK2 (ACN 20150) application parameter to version 102.

If Partial Overwrite has already been chosen, download version 102 again by choosing Overwrite.

Root Cause

The issue is caused by an error in the update registration process of ClinChem application parameter download with Partial Overwrite.

Risk Assessment

The issue does not have an impact on the patient's results, even though the calibration curve is updated with a 1- point calibration only.

Severity

No patient or diagnostic test results are affected and a medical risk to patients and users can be excluded. Therefore, an HHE is not required.

Customer Details:
Facility Name: Contact Name: Position: Phone: Date: Signature and Stamp:
If you have any questions, please do not hesitate to contact our Application Support Team or your local Account Manager.
Yours sincerely,
For on behalf of Roche Diagnostics Middle East FZCO
V. Vergrime

Hassan Kassem

Middle East

Regional Quality & Product Safety Lead,

Venkatesan Veeraraghavan

Regional Quality Manager