

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 taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative General medical W.L.L. at registration.medics@intercol.com

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

For more information please contact Medical_Devices@nhra.bh

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
Target Group	Application Service

Units Concerned

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)**

The screenshot shows the 'Settings' application window with the 'Application' tab selected. The 'Calibration' dropdown is set to 'version 101'. The 'Changeover Settings' section shows 'Lot Changeover' as 'Full' and 'Reagent Pack Changeover' as 'Off'. The 'Other Settings' section has 'Timeout' selected. The 'Timeout' table shows 'R. P.' as 'Full' and 'Stability' as '42 Days'. The 'Limit Values' section shows 'SD Limit' as 0, 'Duplicate Limit' as 10, and 'Sensitivity Limit' as -9.99999. The 'Calibration Method' section shows 'Curve Type' as 'RCM4' and 'RCM Weighting' as 1: 0, 2: 0, 3: 0, 4: 0, 5: 0, 6: 0. The 'QC Violation' section shows 'Method' as 'Cancel', 'Rule' as '1SD', and 'QC 1', 'QC 2', 'QC 3' as 'Cancel'. The 'Update Point' section shows '1 Point A: 1', '1 Point B: 1', '2 Point 1: 1', and '2 Point 2: 1'.

Test	Sample Type
13 A1W3	WB
14 RWD3	WB
15 R/W3	WB
16 SI2	Ser/PI
17 ASTP2	Ser/PI
18 CHOL2-I	Ser/PI
19 TP2	Ser/PI
20 ETOH2	Ser/PI
21 AMYL2U	Urine
22 AMYL2	Ser/PI
23 MG2U	Urine
24 AMIK2	Ser/PI
1 SI2-L	Ser/PI
2 SI2-H	Ser/PI
3 SI2-I	Ser/PI

Type	Method	Stability
Lot	Full	42 Days
R. P.	Full	42 Days

Limit Values	SD Limit	Duplicate Limit	Sensitivity Start	Sensitivity End	Sensitivity Limit	S1 Abs. Limit
0	10	0	0	0	-9.99999	-3.3000
%	0.0150	Abs.			9.99999	3.3000

Calibration Method	Curve Type	RCM4	Point	Weighting
RCM Weighting		1: 0	6	0
		2: 0		
		3: 0		
		4: 0		
		5: 0		
		6: 0		

QC Violation	Method	Rule	QC 1	QC 2	QC 3
	Cancel	1SD	Cancel	Cancel	Cancel

Update Point	1 Point A	1 Point B	2 Point
	1	1	
	1	1	

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

- **Method: 2 Point**
- **Stability: 14 Days**
- **Update Points: 2 (2 Point1) and 6 (2 Point2)**

The screenshot shows the 'Settings' application window with the 'Application' tab selected. The 'Calibration' dropdown is set to 'version 102 with overwrite'. The 'Changeover Settings' section shows 'Lot Changeover' as 'Full' and 'Reagent Pack Changeover' as 'Off'. The 'Other Settings' section has 'Timeout' selected. The 'Timeout' table shows 'R. P.' as '2 Point' and 'Stability' as '14 Days'. The 'Limit Values' section shows 'SD Limit' as 0, 'Duplicate Limit' as 10, and 'Sensitivity Limit' as -9.99999. The 'Calibration Method' section shows 'Curve Type' as 'RCM4' and 'RCM Weighting' as 1: 0, 2: 0, 3: 0, 4: 0, 5: 0, 6: 0. The 'QC Violation' section shows 'Method' as 'Cancel', 'Rule' as '1SD', and 'QC 1', 'QC 2', 'QC 3' as 'Cancel'. The 'Update Point' section shows '1 Point A: 1', '1 Point B: 1', '2 Point 1: 2', and '2 Point 2: 6'.

Test	Sample Type
13 A1W3	WB
14 RWD3	WB
15 R/W3	WB
16 SI2	Ser/PI
17 ASTP2	Ser/PI
18 CHOL2-I	Ser/PI
19 TP2	Ser/PI
20 ETOH2	Ser/PI
21 AMYL2U	Urine
22 AMYL2	Ser/PI
23 MG2U	Urine
24 AMIK2	Ser/PI
1 SI2-L	Ser/PI
2 SI2-H	Ser/PI
3 SI2-I	Ser/PI

Type	Method	Stability
Lot	Full	14 Days
R. P.	2 Point	14 Days

Limit Values	SD Limit	Duplicate Limit	Sensitivity Start	Sensitivity End	Sensitivity Limit	S1 Abs. Limit
0	10	0	0	0	-9.99999	-3.3000
%	0.0150	Abs.			9.99999	3.3000

Calibration Method	Curve Type	RCM4	Point	Weighting
RCM Weighting		1: 0	6	0
		2: 0		
		3: 0		
		4: 0		
		5: 0		
		6: 0		

QC Violation	Method	Rule	QC 1	QC 2	QC 3
	Cancel	1SD	Cancel	Cancel	Cancel

Update Point	1 Point A	1 Point B	2 Point
	1	1	
	1	1	

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.

The screenshot shows the 'Settings' application with the 'Application' tab selected. The 'Calibration' dropdown is set to 'c 503'. The 'Changeover Settings' section shows 'Lot Changeover' as 'Full' and 'Reagent Pack Changeover' as 'Off'. The 'Other Settings' section has 'Timeout' selected. The 'Timeout' section shows 'Type' as 'Lot', 'Method' as 'Full', and 'Stability' as '42 Days'. The 'R. P.' section shows '2 Point' and '14 Days'. The 'Limit Values' section shows 'SD Limit' as '0', 'Duplicate Limit' as '0.0150', 'Sensitivity Start' as '0', 'Sensitivity End' as '0', 'Sensitivity Limit' as '-9.99999', and 'S1 Abs. Limit' as '-3.3000'. The 'Calibration Method' section shows 'Curve Type' as 'RCM4' and 'RCM Weighting' as '1: 0, 2: 0, 3: 0, 4: 0, 5: 0, 6: 0'. The 'Update Point' section shows '1 Point A' as '1', '1 Point B' as '1', '2 Point 1' as '1', and '2 Point 2' as '1'. A red arrow points to the '2 Point 1' and '2 Point 2' fields, which are highlighted in red. A red box with the text 'not updated' is also present.

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



Venkatesan Veeraraghavan
Regional Quality Manager



Hassan Kassem
Regional Quality & Product Safety Lead,
Middle East