

Notification of change

FB204_Rev1

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Ref: QMV-07-38

ECR number

ECR-20190925 Coatron-X Software

Date of notify: Nov 12th, 2019

Affected system	Coatron X family and OEM				Previous version	New Release	Date of Release
	ECO	PRO	TOP	OEM			
Software	☒	☒	☒	all	1.02.48	1.03.49	Nov 12th, 2019

A new firmware is released with improvements, new functions and minor fixes.

New firmware can be downloaded here

<https://1drv.ms/f/s!AoYVax1r2TZdZ5rkjiVSoyHundQ>

Forced update:

Must instruments in the field be updated ? ☐ Yes, Immediate ☐ Yes, at next service ☐ No

Modifications:

The full list of modifications and description is added on second page !

- New: Print mean and CV. value of a series of results.
- New: Scroll AF10 results through the anti-Xa agents - Apixaban, Rivaroxaban, Edoxaban

Compatibility information:

The new firmware can be install on all Coatron X and its OEM versions without any limitation.

Update information:

- 1) Save test calibration data to paper before update
- 2) Restore test calibration after update
- 3) Check system date and temperature after update

Corrective or preventive measures

Related product

Risk of bleeding/thrombosis

There is no measure to reduce medical risk

☒ Coatron X + OEM
Version 1.02.48

no

Datum < 12.11.19 >

Unterschrift GL/CEO < [Signature] >

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List of modifications

ID	Change	Description	Impact to OEM
#1	Coatron X ECO can now hold the recent 180 results in storage like the PRO and TOP version.	With former firmware, the result storage was reserved for PRO & TOP device.	All
#2	New "QC" button including result filters. (Call: Goto menu and select "Results".)	The instrument holds automatically the recent 180 results in storage. The filter buttons allow to scroll through selected PID or TEST. The QC button print the recent 14 results of shown PID+Test including mean and C.V. value	All
#3	"DOAC scroll button" (Only available for Coatron X TOP)	The test method "AF10" is intended to screen for anti-Xa agents with new TECO reagent "TECHROM AF10". Only with test "AF10" there is a DOAC unit scroll button, which allows to convert the AF10 results to concentration of the specific agent like Apixan, Rivaroxaban or Edoxaban	No, Only TECO
#4	The optic button blink green after start of measurement and change to red color after some time	Green blinking= you can touch, move or mix cuvette. Red blinking= don't touch cuvette	All
#5	System accepts now alphanumeric Patient-ID, if input by barcode scanner	Some laboratories are using alphanumeric PID like "ABCD01234..". This is not possible before.	All
#6	Minor fix: Temperature is now more stable	Temperature drifted occasional between 36-37°C. Now it is stable between 36.8 – 37.0°C	All
#7	Minor fix: Calibration curve is now print with correct precision	Before the pojits were printed rounded like 3g/l instead of 2.9g/l	All

Plan of implementation

Update firmware	☐ Immediate	☐ At next service	☒ optional	
Update components	☐ Immediate	☐ At next service	☐ optional	☒ No
Update consumables	☐ Immediate	☐ At next service	☐ optional	☒ No
Update reagent	☐ Immediate	☐ At next service	☐ optional	☒ No
Update Tecam	☐ Immediate	☐ At next service	☐ optional	☒ No
Update Technical File	☐ Immediate	☐ At next service	☐ optional	☒ No
Update user manual	☐ Immediate	☐ At next service	☒ optional	☐ No
Inform end-user	☐ Immediate	☐ At next service	☐ optional	☒ No
Train end-user	☐ Immediate	☐ At next service	☐ optional	☒ No
Remove from field	☐ Immediate	☐ At next service	☐ optional	☒ No
Remove from stock	☐ Immediate	☐ At next service	☐ optional	☒ No

☐ Yes ☒ No

Notification to competent authority

Corrective measure	☐ Yes ☒ No	Bleeding	☒ No ☐ not serious	☐ serious
Preventive measure	☐ Yes ☒ No	Thrombosis	☒ No ☐ not serious	☐ serious

Notified to German BfArm	☐ Yes ☒ No	Number of reports: _____
Notified to other _____	☐ Yes ☒ No	Number of reports: _____