

Notification of change

FB204_Rev1

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Ref: QMV-07-38

Affected system	Coatron X family and OEM				Version shown on screen depending of OEM	Date of notify
	ECO	PRO	TOP	OEM		
Software	☒	☒	☒	all	1.03.50 (1E) 1.03.50 (5B), 1.03.50 (11C) 1.03.50 (15E)	Mar 31th, 2020

A new software is released

Modifications:

- Easier input of calibration curves.
- Some minor fixes
- New languages are available

ID	Name	ID	Name
DA,	Dansk,	LT,	Lietuviu,
NL,	Nederlands,	PT,	Portugues,
SR	Srpski	SE,	Svenska,
ET,	Eesti keel,	SK,	Slovensky,
FI,	Suomi,	SI,	Slovenscina,
HR,	Hrvatski,	CS,	Cestina,
LV,	Latviesu,	HU,	Magyar,

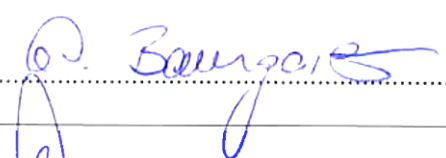
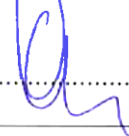
Update and compatibility information:

Instruments in the field don't need to be updated, but the new firmware can be install on all Coatron X and its OEM versions without any limitation. Please follow steps below

- 1) Save test calibration data to paper before update
- 2) Download and execute flashdisk_cmx_10350 here <https://1drv.ms/f/s!AoYVax1r2TZdZ5rkjiVSoyHundQ>
- 3) Restore test calibration after update
- 4) Check system date and temperature after update

New firmware has impact to:

- Analytical performance: ☒ no ☐ yes
- User manual: ☐ no ☒ yes
- Risk reduction: ☒ no ☐ yes

Datum ► 31.3.2020 ◀	Unterschrift ►  ◀ (Director RD)
Datum ► 31/3/20 ◀	Unterschrift ►  ◀ (GL/CEO)

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List of modifications

ID	Change	Description	Impact to OEM
#1	In total 21 European languages are now available		All
#2	Easier input of calibration curves. Insert first calibration point. The next points will be proposed by instrument values based on serial dilution		All
#3	Test protocol LIMIT=0% is now possible. This breaks the measurement very close to start of clotting reaction and reports the clotting time , when signal break through 35mE. Helpful for clot reactions with no clear endpoint like with Protein-S		All
#4	Test protocol START=2s is now possible Helpful for assays like FIB, where clot reaction starts before 3s		All
#5	Minor fix: Sometimes only clotting time, but no unit result was not displayed. This happened , when result was out of unit range like >250%		All
#6	Minor fix: Sometimes valid barcode tickets were rejected.		All

Plan of update

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 Update to REV-7
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

Notification to competent authority

☐ Yes

☒ No

Urgent field corrective measure ☐ Yes ☒ No
Urgent filed preventive measure ☐ Yes ☒ No

Bleeding ☒ No ☐ not serious ☐ serious
Thrombosis ☒ No ☐ not serious ☐ serious

Notified to German BfArm ☐ Yes ☒ No
Notified to other _____ ☐ Yes ☒ No

Number of reports: _____
Number of reports: _____