

ECR number	ECR-202001002					Date of notification: October 19., 2020		
Product identification:	Coatron: X-Series ☒ A-Series ☐					Type of change		
	ECO	PRO	TOP	PLM	LM			
	☒	☒	☒	☒	☒	☒ Software ☐ Hardware ☐ Labeling		

Change Description:

A new software **V1.03.51** is released for Coatron X and its derivate

Reason:

Since October the affected instruments reset the system date to 1.1.2020 12:00 and report error "Clock" + "System not ready!"



Affected instruments:

Software version: Only version V1.03.50
Serial numbers: SIN = XXXXX – 01270 until XXXX – 01636

Risk of health:

None.

Update and compatibility information:

New firmware can be install on all Coatron X and its derivate without any limitation. Please follow steps below

- 1) Save test calibration data to paper before update
- 2) Download and execute flashdisk_cmx_10351 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

Date < 19.10.20 >	Signed by CEO <  >
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List of modifications

ID	Change	Description	Impact to LM/OEM Variants
#1	Fix for system date problem	Problem causes error message "System not ready !"	all
#2			
#3			

Plan of implementation

Update firmware	☒ Immediate	☐ At next service	☐ optional	☐ No	for 1.03.50
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	

Notification to competent authority

☐ Yes

☒ No

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	China CFDA	☐ Yes ☒ No	Number of reports: _____
Notified to	other _____	☐ Yes ☒ No	Number of reports: _____