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	Notification of change	

ECR number	ECR-20190312 Coatron-X Software	Date of notify: Jun 3th, 2019
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Affected system	Coatron X family and OEM				Old release	New Release	Date of Release
	ECO	PRO	TOP	OEM			
Software	☒	☒	☒	all	1.02.46	1.02.47	Jun 3th, 2019

New firmware release fixes a major problem regarding the system stability and need to be installed as soon as possible on all instruments in the field.

Download firmware available under
<https://1drv.ms/f/s!AoYVax1r2TZdZ5rkjiVSoyHundQ>

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

Corrective or preventive measure and solution	Related product	Risk of bleeding/thrombosis
Eeprom device problems discovered during writing process, which may impact the shelf life of component. The new firmware is intended for a) Detecting defective Eeprom. In this case the mainboard must be replaced. For warranty or goodwill issue - failure must be reported latest until 9-2019 to http://teco-medical.com/support.html - defective board must be returned b) Preventing failure of Eeprom as well as other internal components.	☒ Coatron X All versions	No risk. In case of a defect EEPROM no data can be changed nor saved, but the stored data keep valid and can be read correctly. In worst case results are based on older calibration data. If the daily quality control is out of range, than a patient run is not allowed and system & calibration data must be checked. Latest at this point, the EEPROM problem will be discovered and must be solved by replacement.
Under specific conditions system may freeze, if it is online with TECAM smart software. The new firmware fixes this problem. An update of TECAM Smart to V7.06.0 is not required but recommended, because of new features. TECAM setup and changelog can be downloaded from https://1drv.ms/f/s!AoYVax1r2TZdZ5rkjiVSoyHundQ	☒ Coatron X Since Build-45	No risk. TECAM function has not impact to result.

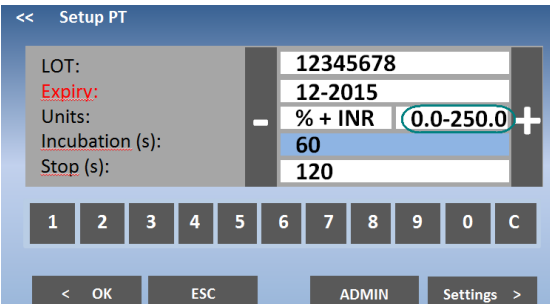
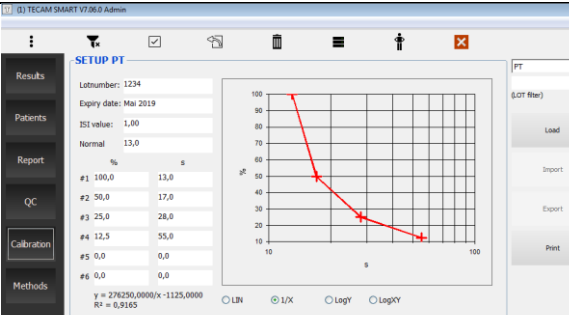
Datum <.....>	Unterschrift GL/CEO <>
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Plan of implementation					
Update firmware	☒ Immediate	☐ At next service	☐ optional	☐ No	immediate for all instruments.
Update components	☐ Immediate	☐ At next service	☐ optional	☒ No	
Update consumables	☐ Immediate	☐ 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	
Remove from field	☐ Immediate	☐ At next service	☐ optional	☒ No	
Remove from stock	☐ Immediate	☐ At next service	☐ optional	☒ No	FW update required

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: _____			

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List of further modifications																																	
ID	Change	Description	Impact to OEM																														
#1	Extrapolate chromogenic test through zero point. A zero optical signal (0.000E) will give a zero result (0%, 0ng).	This function was only enabled for immune assays, but it is also helpful for chromogenic tests. It improves accuracy below lowest calibration point.	All																														
#2	Results out of calibration range are extrapolated linear for DTI assays	Direct Thrombin Inhibitors need linear extrapolation in the low dose area to ensure accurate results	1																														
#3	New test setting: Select with result unit also range limitation to calibration range. (no extrapolation) or unit range Example: the unit range of PT-% is 0 – 250% →PT = 11.6s 118.1% 0.89INR the calibration range is 12.5 – 100% →PT = 11.6s >100% 0.89INR	Feedback from market 	All																														
#4	Add Polish dialogue language	Asked by Polish distributor	All																														
#5	D-dimer default protocol on COATRON X ECO switched from BLUE to RED DD reagent. The Blue DD reagent can be still used, but after update the protocol must be changed back to DD Blue. <table><tr><th>Setup DD Blue</th><th>Setup DD RED</th></tr><tr><td>1: 3300ng/mL=0.260E</td><td>1: 3400ng/mL=0.200E</td></tr><tr><td>2: 1650ng/mL=0.190E</td><td>2: 1700ng/mL=0.140E</td></tr><tr><td>3: 2ng/mL=0.002E</td><td>3: 2ng/mL=0.002E</td></tr><tr><td>4: 0ng/mL=0.000E</td><td>4: 0ng/mL=0.000E</td></tr><tr><td>5: 0ng/mL=0.000E</td><td>5: 0ng/mL=0.000E</td></tr><tr><td>R²=0.951 Math=lin</td><td>R²=0.963 Math=lin</td></tr><tr><td>Method=Chrom</td><td>Method=Chrom</td></tr><tr><td>Limit=50mE</td><td>Limit=100mE</td></tr><tr><td>Incubation=60s</td><td>Incubation=60s</td></tr><tr><td>Start=60s</td><td>Start=15s</td></tr><tr><td>Stop=180s</td><td>Stop=90s</td></tr><tr><td>Autostart=500</td><td>Autostart=500</td></tr><tr><td>T-Corr=0</td><td>T-Corr=0</td></tr><tr><td>S-Corr=0</td><td>S-Corr=0</td></tr></table>	Setup DD Blue	Setup DD RED	1: 3300ng/mL=0.260E	1: 3400ng/mL=0.200E	2: 1650ng/mL=0.190E	2: 1700ng/mL=0.140E	3: 2ng/mL=0.002E	3: 2ng/mL=0.002E	4: 0ng/mL=0.000E	4: 0ng/mL=0.000E	5: 0ng/mL=0.000E	5: 0ng/mL=0.000E	R²=0.951 Math=lin	R²=0.963 Math=lin	Method=Chrom	Method=Chrom	Limit=50mE	Limit=100mE	Incubation=60s	Incubation=60s	Start=60s	Start=15s	Stop=180s	Stop=90s	Autostart=500	Autostart=500	T-Corr=0	T-Corr=0	S-Corr=0	S-Corr=0	Higher analytical performance, because optical signals are 2-3x stronger on ECO.	All
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#6	Transmit calibration curve to TECAM Smart		All																														