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ECR number	ECR-20190702 Coatron-X Software	Date of notify: Jul 9th, 2019
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Affected system	Coatron X family and OEM				Previous version	New Release	Date of Release
	ECO	PRO	TOP	OEM			
Software	☒	☒	☒	all	1.02.47	1.02.48	Jul 9th, 2019

New firmware release fixes a minor problem since previous version 1.02.47

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 to paper before update
- 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
Test calibration is reset to default, when reagent become expired.	☒ Coatron X + OEM Version 1.02.47	No risk. The instrument is not intended to work with expired reagent. But in worst case patients results were calculated with default calibration data. With TECO reagent this will cause less than 15% deviation from true results in compare to LOT specific calibration curve. This is acceptable and classified by TECO as "no bleeding/thrombosis risk"

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: _____			

List of further modifications			
ID	Change	Description	Impact to OEM
#1	Don't init test, if expiry date becomes expired	Bug since Build-47	All