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	Notification of change	

ECR number	ECR-20190304 Coatron-A Software.docx	Date of notify: 4. April 2019
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Products affected	Coatron A6 Plus	Coatron 5000	Coatron A6	Coatron 3000	Coatron A4	Coatron 1800	TECAM Pro/Prolis
New Firmware	1.03.05d	6.03.05d	1.03.04d	6.03.04d	1.07.04d	6.07.04d	V7.08.4
Build Index	50	50	102	102	258	258	

A new firmware release + TECAM is available. It fixes recent problems on Coatron-5000 with barcode scanner and optic check during service menu.

Update information:

- 1) Print test calibration data or send to TECAM, because system will reset all test settings to default after update
- 2) After upgrade check adjustment of cuvette and XYZ. It is essential for high accuracy
- 3) Run autocalibration for AT,DD,FIB,FDP,PSF

Corrective or preventive measure and solution	Related product	Risk of bleeding/thrombosis
System displays barcode information sometimes with missing characters, which requires re-reading.	☐ A4/1800 ☐ A6/3000 ☒ A7/5000 since build-48	No risk.
Optic check at 30.000 digits sometimes out of range	☒ A4/1800 build-255 ☒ A6/3000 since build-97 ☒ A7/5000 since build-46	No risk.

Measure(s) are released ☒ Yes ☐ No	
Limitations: none	
Datum <.....>	Unterschrift TECO <>

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Plan of implementation					
Update firmware	☒ Immediate	☒ At next service	☒ optional	☐ No	For Coatron A6Plus/5000 , if patient barcode are used. Optional for Coatron A4/A6
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	Yes, if TECAM is older than 7.08.2
Update Technical File	☒ Immediate	☐ At next service	☐ optional	☐ No	Yes, new optic check ranges
Update user manual	☒ Immediate	☐ At next service	☐ optional	☐ No	Yes, new optic check ranges
Inform enduser	☐ Immediate	☐ At next service	☐ optional	☒ No	
Inform service engineer	☒ Immediate	☐ At next service	☐ optional	☐ No	Yes, new optic check ranges
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: _____			

List of modifications					
ID	Change	Reason	A4	A6	A7
CR1	Improvement of barcode reading	Barcode reading sometimes with missing characters	☒	☒	☒
CR2	Optic Check changed to target=10.000 digit New Optic range is ON: 9000 – 11000 OFF: 50 – 350 AMP: 100 –3000	Adjustment to production process (QCR-report)	☒	☒	☒