

ECR number	ECR-20200707 Coatron A Software	Date of notify: 30. Jul 2020
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Products affected	Coatron A6 Plus	Coatron 5000	Coatron A6	Coatron 3000	Coatron A4	Coatron 1800	TECAM Pro/Prolis
New Firmware	1.03.06a	6.03.06a	1.03.05a	6.03.05a	1.07.05a	6.07.05a	V7.08.8
Build Index	53	53	106	106	261	261	

A new software is released

Modifications:

System self-rebooted occasional after a missing liquid level (out of liquid), instead of returning to main menu. This minor bug is since mar-2019 and fixed now.

Update and compatibility information:

Instruments in the field don't need to be updated, but the new firmware can be install on all Coatron nd its OEM versions without any limitation.

Download and execute flashdisk here

<https://1drv.ms/f/s!AoYVax1r2TZdZ5rkjiVSoyHundQ>

New firmware has impact to:

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

Measure(s) are released

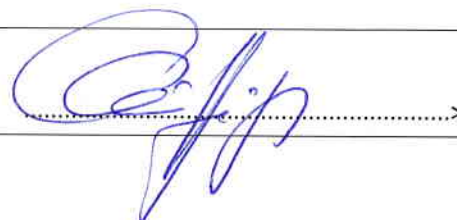
☒ Yes

☐ No

Limitations: none

Datum < 30.7.20 >

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Plan of implementation

Update firmware	☐ Immediate	☐ At next service	☒ optional	☐ No
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 enduser	☐ Immediate	☐ At next service	☐ optional	☒ No
Inform service engineer	☐ 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:	_____