

	TECO GMBH, GERMANY www.teco-gmbh.com	Rev.: 1 Page: 1 of 2
	Notification of change	

ECR number	ECR-20191128 Coatron A Software	Date of notify: 20. Dec 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	1.03.06a	6.03.05d	1.03.05a	6.03.05a	1.07.05a	6.07.05a	V7.08.6
Build Index	52	52	105	105	260	260	

A new software version has been released. It is helpful to extend lifetime of valve and reduce consumption of rinse solutions. It has no impact to analytical performance nor does change and EEPROM data stored on mainboard. The update is optionally and can be installed on all instruments and versions.

	Related product	Risk of bleeding/thrombosis
Back wash of filter inside of rinse tank Remove particles from filter and avoid clogging	☒ A4/1800 all version ☒ A6/3000 all version ☒ A7/5000 all version	No risk.
Apply high pump pressure during boot-up Identify leaky valves, if many air bubbles are visible inside of syringe. In this case the valve must be replaced.	☒ A4/1800 all version ☒ A6/3000 all version ☒ A7/5000 all version	No risk.
Wash sample out of needle probe inside of the dome. -This wash needle probe inside+outside -This extend lifetime of valve -This reduce consumption of rinse tank	☒ A4/1800 all version ☒ A6/3000 all version ☒ A7/5000 all version	No risk.

Measure(s) are released	☒ Yes ☐ No
Limitations: none	
Datum < 20.12.19 >	Unterschrift TECO <  >

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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:	_____