

TECO

TECO GMBH, GERMANY

www.teco-gmbh.com**Notification of change**

Rev.: 1

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ECR number

ECR-20191021 Coatron A Software

Date of notify: 12. Nov 2019

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	V7.08.5
Build Index	51	51	104	104	259	259	

A new software version has been released. The update is optionally and can be installed on all instruments and versions.

Related product

Risk of bleeding/thrombosis

Default protocols changed for

- Protein-S (new clotting assay),
- von Willebrand Factor (new immuno assay)
- Dabigatran (new clotting assay)
- anti Xa (new chromogenic assays for DOAC)

- ☒ A4/1800 all version
- ☒ A6/3000 all version
- ☒ A7/5000 all version

No risk.

Some enduser have been confused, that system switches automatically to special simulator mode after errors caused by robotic systems. Now, the system performs automatically a reboot.

- ☒ A4/1800 all version
- ☒ A6/3000 all version
- ☒ A7/5000 all version

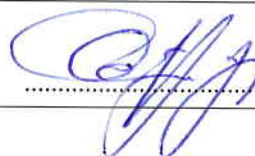
No risk.

Measure(s) are released☒ Yes☐ No

Limitations: none

Datum < 12.11.19 >

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: _____