

	TECO GMBH, GERMANY www.teco-gmbh.com	Rev.: 1 Page: 1 of 3
	Notification of change	

ECR number	ECR- 20181109 Coatron-A Software.docx	Date of notify: 13. Feb 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	1.03.05c	6.03.05c	1.03.04c	6.03.04c	1.07.04c	6.07.04c	V7.08.2
Build Index	49	49	101	101	257	257	

A new firmware release + TECAM is available. It fixes recent problems and improves precision and accuracy of D-Dimer, AT, FDP and FIB testing. It must be installed on all instruments latest after 1.1.2020. 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
Occasional and random instrument self-reboot during sample measurement. The problem occurred with recent firmware and is fixed with this release.	☒ A4/1800 Vxx.07.04b SN: 1260 - 1295 ☒ A6/3000 Vxx.03.04b SN: 5222 - 5241 ☒ A7/5000 Vxx 03.05b SN: 7061 -7079	No risk. Self rebooting has no impact to health
Poor linearity of AT calibration ($R^2 < 0.985$)	TEChrom AT (anti Xa) Ref: C1000	No risk. Point to point interpolation ensure accurate results even with inlinear calibration curve.
Improvement of accuracy and imprecision of D-Dimer results in the area of CUT-OFF from 20% to below 15%	Teco Blue DD LC kit Ref: D2020	No risk. The current CUT-OFF value is assigned with regard of imprecision of max. 25% for safe exclusion of DVT.
Poor accuracy and imprecision of FIB results below 120mg/dL	All FIB reagent and instruments	No risk. A quantification below 120mg/dl FIB is not significant and means in any way a critical low FIB concentration in plasma
RS232 communication problems with some Chinese LIS. New TECAM provides more setting options	TECAM V7.06 or older	No risk.
False data transmission with TECAM , when orders at rack position P01b – P45b are transmitted	TECAM all versions before 7.08.2	No risk.

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

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Plan of implementation

Update firmware	☒ Immediate	☒ At next service	☐ optional	☐ No	Update immediate for all instrument installed in year 2018 Update all other instruments latest after 1.1.2020
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 orders P01b – P45b is applied
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	
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: _____

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List of modifications

ID	Change	Reason	A4	A6	A7
CR1	Bugfix: Remove self restart	Some users complaint occasional self reboots during operation after upgrading the firmware in year 2018	☒	☒	☒
CR2	No Simulator Mode after Reboot Error	Requested by users	☐	☐	☒
CR3	Improvement of optical detection system by recursive digital filter	Some users observe occasional peaks on the reaction curve. In worst case, this peaks can cause false results, especially for DD or FIB.	☒	☒	☒
CR4	Improvement of D-Dimer including new calibration procedure, new protocol and new detection algorithm	User complaint poor linearity beyond 1000ng/mL DDU and poor accuracy around CUT-OFF	☒	☒	☒
CR5	Improvement of accuracy by First shot a sample dilution is wasted	The first shot of sample dilution is contaminated with rinse solution and give slightly different signals than followed shots.	☒	☒	☐
CR6	Unit Reflex limit increased from factor 1.25 to 1.5 above highest cal-point.	Some user complaint too often reflex testing Especially for DD and FIB.	☐	☒	☒
CR7	New AT3 default protocol (only for Techrom AT C1000 and Chinese instruments)	Recent reagent LOT requires higher sample dilution to obtain linear calibration curve and accurate results	☒	☒	☒
CR8	Improvement of FIB	User observe sometimes 3-4s longer clotting time with low dose samples	☒	☒	☒
CR9	New worklist mode "QC"; The QC mode is intended to check system quality with FIB testing.	Asked by TECO QC department. It allows automatic check of pump, needle, optic and cuvette adjustment.	☒	☒	☒
CR10	Improvement of second worklist (P01b-P45b) (Bugfix versus UniCode problem)	Orders with position P35b – P45b (new function since TECAM 7.08.1) were performed on false rack position and later the result is missed at TECAM side.	☒	☒	☒
CR11	PUC (Product Unlock Code) Required to unlock account at Voucher system	Required if use of Voucher is blocked for this device. Can happen at false PIN entry or by important service recalls.	☒	☒	☒
CR12	Protect instrument from improper change of OEM version (hidden function)	An OEM change is only allowed for TECO	☒	☒	☒
CR13	More cleaning after PT reagent (only for Coatron A6P/5000)	Carryover of PT into aPTT can cause around 25% shorter aPTT results.	☐	☐	☒
CR14	Improve transmission of patient ID after scanning the racks	Sending of all PIDs was very often interrupted	☒	☒	☒
CR15	Start worklist always with a new cuvette , if the orders are sent cuvette wise.	In mode CUV (patients performed cuvette wise) the system must start with a new cuvette. Otherwise it would costs much more time and rinse solution.	☒	☒	☒
CR16	D-Dimer imprecision of low dose samples improved to below 15% C.V,	New requirement for Chinese registration	☒	☒	☒
CR17	Protocols of DD,FDP and PSF changed	Optimized to ensure best accuracy. Throughput will be around 20% lower	☒	☒	☒
CR18	Warning messages will blend out after 15s	Asked by Chinese hospitals to ensure safe walk away Working.	☒	☒	☒
CR19	Replace Rinse Tank within routine workflow	User complaint that they need always go to Service menu to replace the rinse tank. Now it is much easier (usability)	☒	☒	☒
CR20	Code20 syntax for Cuvette and Rinse Barcode	Teco will switch Voucher system to Code20 with 1.1.2020	☒	☒	☒