

 Medical Instruments Production + Trading GmbH	Product Change Notification	FB208 Page: 1 of 2
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ECR number	ECR-20240325-TECO	Date of notification: Jul 17th, 2024
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Product identification:	Coatron: X-Series ☒ A-Series ☐					Type of change	
	ECO	PRO	TOP	PLM	LM	☒ Software: V1.04.52 (1F)	
	☒	☒	☒	☒	☒	☐ Hardware ☒ Labeling: User manual Rev9	

Subject:
A new software is available. It can be install without any limitation on all instruments. The update should be performed asap or latest after end of ‘Code20’ support, which will end 2025/03/30.

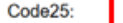
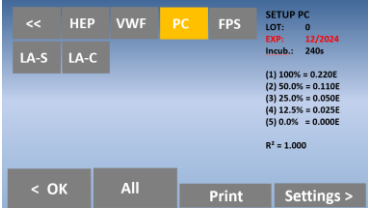
- Quick instruction
- You need a USB A-to-B cable
 - Download the flashdisk from our website
 - Save instrument test calibration data to paper before the update
 - Run flash-disk and follow the instructions
 - After update restore calibration data
 - Check system date and temperature

PDF instruction



Video instruction



ID	Change	Description	Impact to LM/OEM Variants
CR1	support of new vouchers type 72 Voucher Single Cuvettes VIN: 72  PIN:   500	TECO will roll out new vouchers (type ‘72’) for single cuvettes. You can identify the new voucher series on the first two digits of VIN number.	All
CR3	support of code25 encryption Ticket Information Product: Single Cuvette Sin:  Quantity:  VIN:  Code25: 	The new encryption is intended to prevent from product piracy. Ticket Information Product: Single Cuvette Sin:  Quantity:  VIN:  Code20:  Code25:  Until 2025/03/30 both Code20 & Code25 will be supported on ticket. Afterwards older instruments need a SW-update.	All
CR3	Improved statistics of QC-results 	The memory space of 180 results is split into recent 60 patient results and 120 quality control results. The result history screen allows to filter, scroll and show statistics of patient or QC results. Procedure: - Measure control plasma. Input QC1 or QC2 as PID - Open screen to display recent result - Select filter and scroll correct result - Press on statistics to print and display average and SD.	All
CR4	New test methods 	VWF von Willebrand Factor (antigen) PC Protein-C (chromogen) FPS free Protein-S (antigen) Contact us for reagent and application information.	TECO only
CR5	Display “TAG” within status screen	The Service Tag will be required for service requests/complaints in future.	All
CR6	Hi-Dose option button for immuno assays	Hi-Dose means half start-end time to improve Hook Effect. Eg. DD 20-180s in Hi-Dose 10 – 90s	TECO only

Impacts

Impact to products in the field:

- All older vouchers of type '71' can be used unlimited on all instruments and versions.
- Our voucher system will provide cuvette tickets with both Code20 and Code25 information until 2025/03/30. Afterwards the support of Code20 will end and older instruments will require a software update.
- The new vouchers of type 72 can be used only on instruments with new software.

Affected instruments:

Software version: V1.03.51 or below

Date of production: 2024/05/30 or older

Regulatory issues:

- Update analytical performance: ☒ no ☐ yes
- Update user manual: ☐ no ☒ yes, changed to Rev-9
- Update safety (Risk reduction) ☒ no ☐ yes

Risk of health:

None.

Actions:

Update firmware	☒ Immediate	☒ At next service	☐ optional	☐ No	Update required for use of new vouchers – latest 2025/03/30
Update user manual	☐ Immediate	☐ At next service	☒ optional	☐ No	Update section about result statistics
Inform end-user	☐ Immediate	☐ At next service	☒ optional	☐ No	Done by directly by voucher system after login.

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:_____

Date <.....>

Director RD<

(document release by manual or digital signature with date & name)