

User Manual

Coatron X Series Eco / Pro / Top



Instructions intended for instruments
REF 8110110|8110120|8110140
Basis UDI-DI 426018278CMX81152

EN ISO 15223-1 EN ISO 18113-3



For In-Vitro Diagnostic use

Versions

User manual	Instrument Software
1	1.01.42 (first release)
2	1.01.43
3 (minor correction on OPM)	1.01.43
4	1.01.44
5	1.01.47 + 1.02.48
6	1.03.49
7	1.03.50
8	1.03.51 and higher

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Warranty

The Coatron X Coagulometer is warranted for a period of one year after delivery or first installation unless agreed in written for a different period of warranty. It covers any defects in material, functionality or workmanship. For first installation the device must be registered online via www.teco-reg.com (- see chapter 2.9 page 21 - "Registration")

The warranty expires in case of failures caused by

- Accident, neglect of maintenance & service, abuse or misuse.
- Using unauthorized reagents, consumables or spare parts
- Unauthorized service. Any repair or service must be performed by authorized persons.

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1. INTRODUCTION

This device left the factory in fault-free certified condition regarding its safety and engineering functionality. To maintain this condition and ensure risk-free operation, the operator must comply with the safety warnings and information in this User Manual. (see Chapter 1.5 page 14 – “Safety information”)



Use the Coatron X only in compliance with the instructions in this User Manual. Otherwise, the manufacturer shall exclude the liability for any damages to the Coatron X, patients or operators.

1.1 SYMBOLS

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
Courier	Info	Key on keypad.
CAPS	Info	Screen message.
	Read	Indicates <u>important information</u> and tips.
	Info	Describes reaction of Coatron X to operator input.
	Warning	Risk of possible health damage or considerable damage to equipment, if warning is not heeded.
	Danger	Potential risk to operating personnel or equipment due to electric shock.
	Biohazard	Equipment can be potentially infectious due to the samples and reagents used.
	Laser Radiation	Avoid direct eye exposure

1.2 VIEWS OF THE DEVICE



Home Screen

Coloured Touch Display

Complete area is prewarmed to 37°C

1 x Reagent position Ø24mm

1 x Reagent position Ø22mm

1 x Reagent position Ø22mm, stirred

2 x Reagent positions Ø13mm

20 x Cuvette incubation positions

4 x Cuvette measurement positions
(depends on ECO/PRO/TOP version)

FIGURE 1: TOP VIEW



5V: Power in

PC: LIS or PC

SERVICE: Software update

PRINTER: Serial printer

BARCODE: Handheld barcode scanner

FIGURE 2: REAR VIEW



FIGURE 3: SIDE VIEW

1.3 CONSUMABLES / FURTHER EQUIPMENT

Detailed informations are available with the product pricelist or Leaflet or website

Consumables, laboratory equipment	Cuvettes for Coatron X	Box of 500 or 5000 pieces including one Voucher ticket
	Reagent adapter Ø 24,5 → 22,5 mm	Helps to place vials with different sizes on device
	Stirring magnets, P=4	Required to mix PT reagent. (only on Coatron Pro and Top)
additional technical equipment	External QR barcode reader	To read 1D or QR code for Patient-ID, Reagent and Tickets
	Glass Protection Foil Kit	Safe display glas from scratches. Kit includes foil, clean tissues & remover tool
	Thermal printer 60mm (Optional)	Print test results, Calibration data or System information
	TECAM Smart Software (Optional)	Patient management, Reagent Calibration management, Monitoring, Research, Statistics, Mirror print function, LIS communication (ASTM-1394)

1.4 INTENDED USE



The **Coatron X Family** is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immunoturbidimetric tests (for instance Antithrombin, D-dimer etc.) on human citrated plasma. The instrument has to be used for the expected purposes and in perfect technical condition, by qualified personnel, in working conditions and maintenance operations as described in this document. It is designed for laboratory use or clinical environment and trained users. It is not intended for home use.

1.4.1 COMPARISON OF COATRON-X SERIES

The Coatron X Series includes three different versions called ECO, PRO, TOP

	ECO	PRO	TOP
Coatron X Series			
Reagent and Optic block	Prewarmed to 37°C		
Cuvette prewarm	10x	20x	20x
Reagent prewarm, 24mm	1x	1x	1x
Reagent prewarm, 22mm	2x	2x	2x
Microtubes prewarm	2x	2x	2x
Reagent stirrer	No	1x	1x
Printer, RS232	Yes		
Barcode Scanner, RS232	Yes, external handheld barcode scanner for 1D or QR labels to read patient-ID, reagent information or vouchers.		
LIS, USB	Yes		
Firmware Update, USB	Yes		

Measurement	ECO	PRO	TOP
Optic channels	1	2	4
Optic wavelength	620nm (RED)	405nm (UV)	405nm (UV)
Cuvette, total volume	Single, 75µL	Single, 75µL	Single, 75µL
Global Clotting Assays	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT	PT+aPTT+Fib+TT
Special Clotting Assays	-	All factors PS, LA	All factors PS,LA
Chromogenic Assays	-	AT, PC,HEP	AT, PC,HEP,AF10,
Latex enhanced Assays	D-Dimer	D-Dimer Free PS	D-Dimer Free PS
Whole Blood Testing	Yes (PT INR+%)	No	No
Software features			
Reagent Dual LOT manage two different lots for each test	No	Yes	Yes
Test Calibration LOT, expiry and upto 5 points for each test	Yes	Yes	Yes
Reagent Barcode Input LOT+Expiry or Positive LOT detection	Yes	Yes	Yes
Patient Barcode Input patient ID by barcode scanner upto 16char	Yes	Yes	Yes
System Barcode Input voucher tickets by barcode scanner directly from display of smart device	Yes	Yes	Yes
Result Database save recent 180 results onboard	Yes	Yes	Yes
Double Determination Run patient twice and display mean value	No	Yes	Yes
Stopwatch function count up or down incubation time	1x	2x	4x
Result Identification Patient ID or sample ID or Auto ID	Yes	Yes	Yes
Real Time Clock	Yes	Yes	Yes
Change language EN, ESP, ITA, FR, DE - further on option	Yes	Yes	Yes
Start test at reagent addition No expensive starter pipette required	Yes	Yes	Yes
Visualize Reaction Curve Tecmoni Software required	Yes	Yes	Yes
Link to LIS over USB or network/ASTM TECAM SMART Software required	Yes	Yes	Yes

1.4.2 TEST METHODS

Following test are provided to detect of the human coagulation system, which can be bleeding or thrombosis and the monitoring of anti-coagulation drugs like Heparin or Marcumar.

Test	Name	Specimen	Method	Coatron X		
				Eco	Pro	Top
PTB	Prothrombin Time	blood	clot	Yes	No	No
PT	Prothrombin Time	plasma	clot	Yes	Yes	Yes
APTT	Activated Partial Thromboplastin Time	plasma	clot	Yes	Yes	Yes
FIB	Fibrinogen	plasma	clot	Yes	Yes	Yes
TT	Thrombin Time	plasma	clot	Yes	Yes	Yes
AT	Antithrombin	plasma	chromogen	No	Yes	Yes
DD	D-Dimer	plasma	immuno	Yes	Yes	Yes
Factors	Factors II, V, VII, VIII, IX, X, XI, XII	plasma	clot	No	Yes	Yes
HEP	Heparin (anti Xa)	plasma	chromogen	No	Yes	Yes
PC	Protein C	plasma	chromogen	No	Yes	Yes
PS	Protein S	plasma	clot	No	Yes	Yes
PSF	Free Protein-S	plasma	immuno	No	Yes	Yes
LA-S	Lupus Screen	plasma	clot	No	Yes	Yes
LA-C	Lupus Confirm	plasma	clot	No	Yes	Yes

1.4.3 SPECIMEN COLLECTION

Type:	Human citrated plasma
Collection:	Veinvein puncture, 1:10 mixed sodium citrate 3.2% (0.105M)
Centrifugation:	10min at 1500g
Storage:	Max 4h after collection at room temperature
Bilirubin:	< 50mg/dl
Hemoglobin:	< 9000mg/l
Triglyceride:	< 2500g/l

Intended specimen for PTB (Coatron X Eco)

Type:	Capillary blood from puncture of finger or citrated whole blood
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In case of differences to the boxinserts of the reagent, always follow the instructions on the box insert.

1.4.4 PRINCIPLE OF MEASUREMENT

The detection of plasma clotting is based on a photometric principle. No mechanical aids like mixing bars are required. Blood plasma is filled into a cuvette. Special reagents are added, which initiate the blood coagulation. The cuvette is transmitted by ultra violet light during the coagulation process. When the sample starts to clot a change of light absorbance is measured. The time from measurement start to change of light (turning point) is called clotting time and expressed in seconds [s].

The conversion of coagulation time into a specific test unit is one using a linear, hyperbolic, semi-logarithmic or double-logarithmic interpolation of the stored calibration points. The current mathematical model is printed out in "TEST SETUP." Values outside the calibration range are calculated by extrapolation and flagged as " * ".

Unit	Info	Decimal places	Maximum value
s	seconds	1	-
%	activity	1	250.0
U	units	0	29999
INR	Int. ratio	2	99.00
R	ratio	2	99.00
NR	polish ratio	0	250
mg/dl		0	999
g/l		2	99
IE/ml	Int. Units	2	99
mg/l		2	999
µg/ml		3	9.000
ng/ml		0	27500
µg/l		0	27500
IU/mL	Int. Units	2	99.00

R = clotting time / normal time

NR = 100 *(normal time/clotting time)

INR = Ratio ^{ISI} (International Normal Ratio)

IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

1.4.5 CLOTTING METHOD (PT, APTT,..)

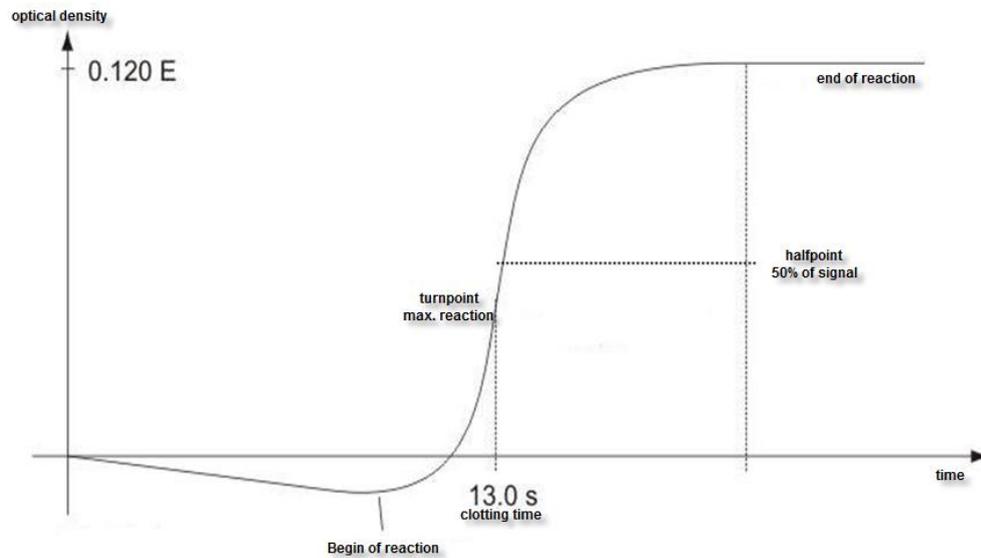


FIGURE 4: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

The final reaction in the coagulation cascade is the transformation of fibrinogen into fibrin catalyzed by thrombin. Fibrin formation results in clouding (higher turbidimetric level) in the sample, which is measured by the photometer and stored as the extinction. The result in seconds is the time from the start of the reaction to the time of half rate of change (halfpoint).

1.4.6 CHROMOGENIC METHOD (ANTITHROMBIN):

The change of optical signal is not caused by clot reaction, but by the release of color particles (pNA) which causes a yellow color. The change of color is measured at 405nm and expressed as "dE/60sec" and proportional to the concentration or activity of analyte.

1.4.7 IMMUNTURBIDIMETRIC METHOD (D-DIMER):

The change of light is caused by Antigen – Antibody reactions, which scatter the light. The antibodies are linked to latex particles to amplify the optical reaction. The change of light is proportional to the concentration of antigen like D-Dimer and expressed as dE/120sec

1.5 SAFETY INFORMATION



No liability is assumed, if this product is not purchased from any other than the manufacturer or an authorized distributor.

A. General use

A.1 This device must be installed at professional laboratories where a quality management system is established and good laboratory practice (GLP) is applied. The laboratory must follow local regulations about operating medical products.

A.2 This device must be operated by a professional user only. It is not intended for point of care or home testing.

A.3 Read user manual in its entirety prior first operation.

A.4 Install device according to electrical and environmental conditions stated in chapter "Installation" of user manual.

A.5 Operate the instrument as intended and instructed in the User Manual.

A.6 Follow always product labeling and manufacturer's recommendations.

A.7 Use only materials, consumables and (spare)parts such as reagent or cuvettes, which are intended or recommended for use on this instrument. Always contact manufacturer or local authorized distributor in case of doubts.

A.8 Do not use materials after their expiry date or assigned shelf life.

B. Laboratory use

B.1 Check correct function of instrument by performing quality control before running a series of patient samples or after test calibration.

B.2 Do not operate the instrument after spilling reagent or liquids into the analyser. Contact local authorized distributor for servicing.

B.3 Never use cuvettes more than once. Do not wash cuvettes. They are for single use only.

C. Risk of infection

C.1 Consider all surfaces and materials, which might be in contact with plasma or other biological liquid as potentially infectious.

C.2 Avoid direct contact with potential infectious materials or surfaces by wearing appropriate protective clothing.

C.3 Follow the laboratory hygienic procedures during and after completion of work.

D. Maintenance and Service

D.1 Only an authorized customer service may carry out any servicing.

D.2 Decontaminate instrument before doing any servicing or shipment.

D.3 Recycle instrument according to WEEE or local regulations for electronic equipment.

2. INSTALLATION OF THE **COATRON X**

2.1 SCOPE OF DELIVERY

Contents of standard delivery package:

- 1 Pc **Coatron X**
- 1 Pc Power Supply
- 200 Pcs Single cuvettes
- 5 Pcs Reagent container, $\varnothing 22,5\text{mm}$
- 5 Pcs Reagent tubes, $\varnothing 11\text{mm}$
- 1 Pc User Manual (not on picture below)
- 1 Pc Brochure with Safety Information (not on picture below)
- 1 Pc Display protection foil



FIGURE 5: STANDARD DELIVERY PACKAGE

2.2 CONDITIONS OF OPERATION

Ambient conditions:

Operating Temperature	15 to 30 °C
Humidity	< 70% rel. humidity
Elevation above NN sea level	< 3,000m
Free of dust	Grade 2
Impact resistance	According to IEC/EN 61010-1, 8.2.2
Not allowed	Vibrations, direct sun light and direct exposure to air condition.

Electrical conditions:

100-240 VAC, 47 - 63Hz, no earthing required (Class-2)

Electrostatic Discharge (ESD):

No special requirements for ESD protection (shoes etc.)

Storage conditions:

0 - 50°C, max. 12 months in original package.

Transport conditions:

No special conditions required. The general regulations for transport can be used.

Hygienic conditions:

Validate your hygienic management system according to international applied Good Laboratory Practice (GLP) or similar quality standard. Any waste material must be considered as potentially infectious. Direct contact must be avoided. Protective gloves during operation, service or cleaning are required.

Device environment:

No special requirements. Instruments is suitable for or use in domestic and industrial establishments.

2.3 FIRST INSTALLATION

Inspect the packaging of the **Coatron X** and accessories for any visible external damage. If the packaging is damaged, contact the transport company so that any damage to the device or accessories can be assessed.

The instrument is ready to use and don't need a specific procedure.

First installation procedure:

1. Unpack and place instrument in conformity with conditions of operation (see previous chapter).
2. Install accessory (Protection foil, printer, barcode, Tecam – see next chapters)
3. Plug in power 5V.
4. Wait until green Status (approx. 15 min). The instrument is now ready to use.
5. Register instrument online for start of warranty period.
6. Activate 500 cuvettes (see chapter-5 "ticket system").



Keep the original packaging material for purposes of later transport



maximum length of cables to external devices like printer, barcode or LIS must be less than 3m to keep compliance with EMC

2.4 SWITCHING ON AND OFF

Switching on

Connect with power supply

Important Information:

The instrument requires about 15 minutes to heat up the optic block to 37°C. Afterwards it is ready for measurement, indicated by a green dot in the top right corner of the display. If the status symbol does not turn green, even after waiting for 25 minutes, press the status symbol to see the device status to identify the problem.

Switching off

The device supports no power switch. It must be disconnected from power. To do this, unplug the power adapter from the socket on the device first and then disconnect the power supply.

Standby

The system switches to standby after 2 minutes of idle operation. In standby mode, the display brightness is reduced to save display life time and reduce power consumption. The next touch anywhere on the display disables the standby mode.

Sleep

Open menu and touch the “sleep” button: 

The menu bar is displayed on top of screen and only available, if no measurement is ongoing. The power consumption during sleep is 0,2W.

Wakeup

To wake the device up from sleep, touch the display.



The system can be disconnected under any operation situations. There is no risk of system damage

2.5 DISPLAY PROTECTION FOIL

Requirements:

Type: Touchsensitive Protection foil, clean tissue wet and dry, Pick-off
Size: same as Display (4,3")

Installation:

Ready to fix on display, as described in the Inlay
(clean display with clean tissues wet and dry and fix protection foil carefully)

2.6 EXTERNAL THERMAL PRINTER

Requirements:

Type: Serial RS232 Printer
Power: external supply, 24V 1.5A
Cable: 2 x Sub D9, female, straight, max length 3m
Interface: RS232, 9600 Baud, 8, 1, No

Installation:

The printer is ready to plug in. No settings are required.



Do not plug power supply of printer (24V) to Coatron-X. It will destroy the instrument! Double check before you plug-in.

2.7 EXTERNAL BARCODE SCANNER

Requirements:

Type: Serial handheld scanner
Power: 5V DC over cable, PIN-9
Cable: Included to scanner
Interface: RS232 9600 Baud, 8, 1, No
Setting: No handshake or protocol. Barcode must be finished with carriage return.

Installation:

The scanner is ready to plug in. no settings are required.

2.8 TECAM SMART

Requirements:

License:	TECAM SMART fingerprint and activation code.
Cable:	USB, type A to B, max 3m
Interface:	USB
Setting:	no handshake or protocol. Barcode must be finished with carriage return.

Installation:

- a) Disconnect the device from PC.
- b) Run setup.exe.
- c) Confirm when asked to install Coatron X driver.
- d) Connect device with PC.
- e) Start TECAM

Further information available in chapter "7" or online help file of TECAM.

2.9 REGISTRATION

The instrument must be registered online for warranty or service issues

- 1) Open weblink www.teco-reg.com or scan QR Code →
- 2) Enter **SIN + PIN** of device

Both can be seen on instrument license plate (Type label) or during startup or on info screen (touch green or red LED on home screen)

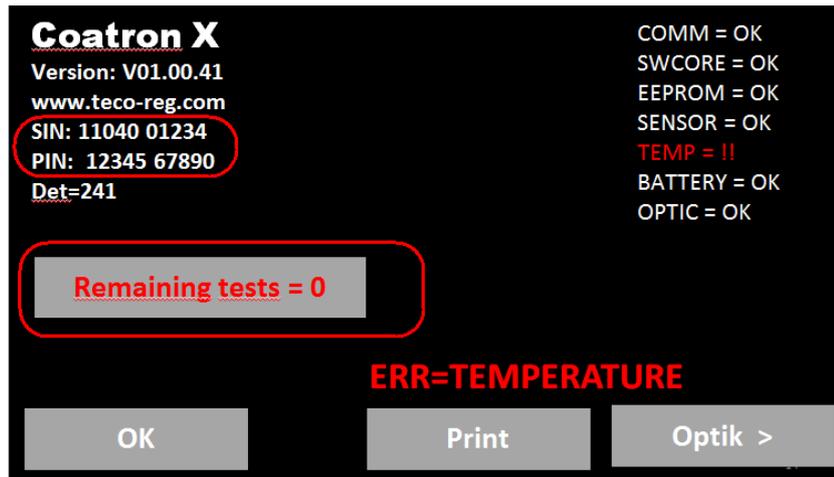


FIGURE 6: SYSTEM INFORMATION

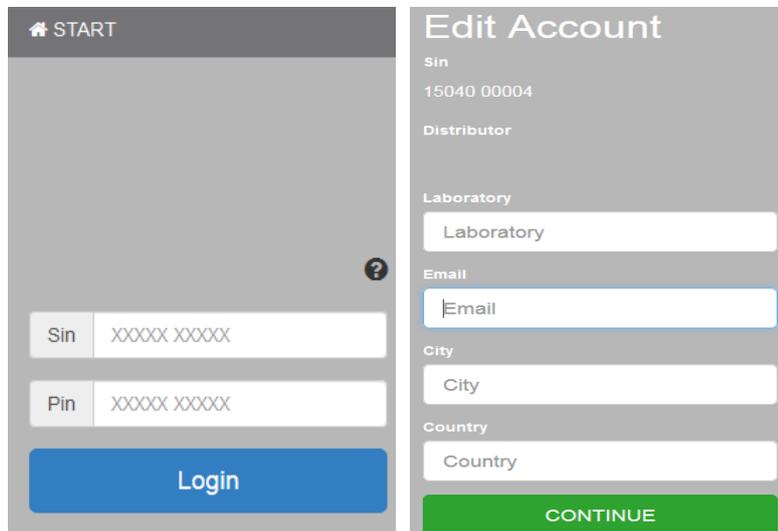


FIGURE 7: REGISTRATION OF COATRON-X

3. OPERATION OF THE COATRON X

3.1 HOMESCREEN

After boot or home button following screen is displayed

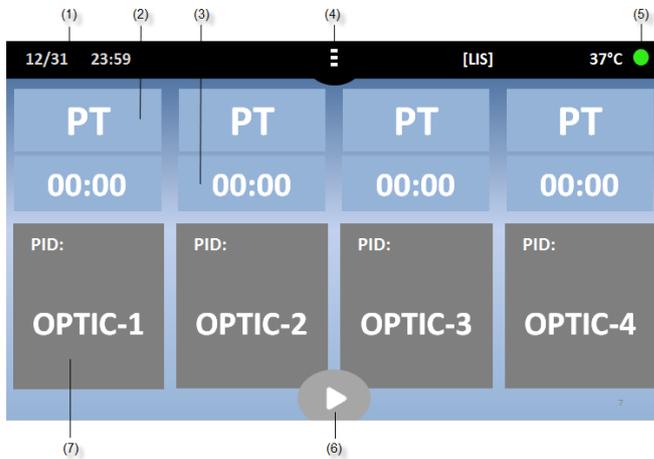


FIGURE 8: HOMESCREEN COATRON X TOP

UI Element	Element Name	Use Function
(1)	Date & Time	Edit date
(2)	Current test	Change test
(3)	Stopwatch	Start/Reset stopwatch or countdown
(4)	Menu or Home	Open menu or return to main
(5)	Status Dot	Show device status/Open system information
(6)	Multistart	Activate all channels
(7)	Optic-Button	Channel-1 is idle. Touch to enter new PID and activate
	Active	Channel is active. Touch or add reagent to start
	Blinking green	Ongoing measurement. While green state it is allowed to touch, mix or move cuvette.
	Blinking orange	Ongoing measurement. Don't move nor touch cuvette. Touch button to stop measurement
	Current result	Touch to enter new PID

Other functionality:

[LIS]	Visible, if connected with LIS
Green LED	System is ready for measurement
Red LED	Indicate system problems. No measurement is possible.
37.0°C	Temperature on reagent block.
Grayed buttons	Use function is not possible during measurement.
Reduced brightness	Screensaver mode. Touch to reactivate.
Long touch	Repeat current function
Green	Green = Ready to measure, no problems
Yellow	Yellow = Ready to measure, minor problems
Red	Red = Not ready to measure, major problems

3.2 INPUT PATIENT IDENTIFICATION

Call: Homescreen/Optic button

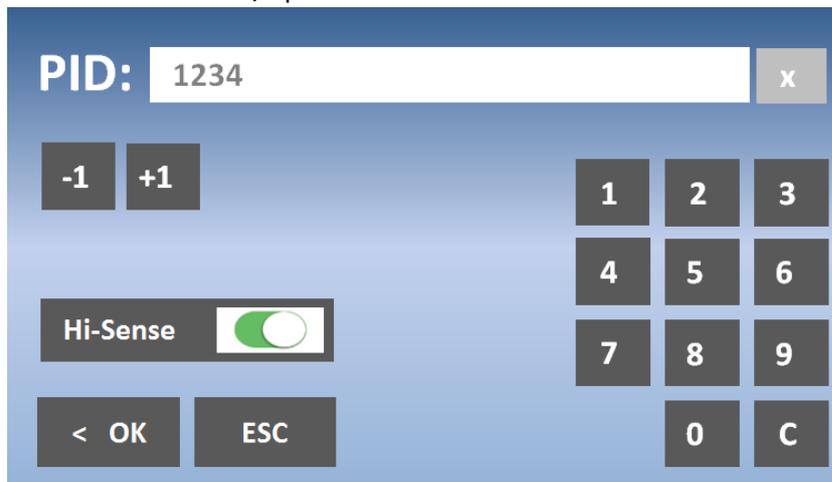


FIGURE 9: INPUT PATIETN ID

Button	UI Element	Use Function
Numeric keys	0-9, C, X	Change or delete PID.
Increment	-1 / +1	Increment PID. Use long touch feature for easy change.
Hi-Sense	Hi-Sense	Enable very high detection sensitivity. Useful for high diluted or lipemic samples or "+++" results.
Additional:		
Long touch	-	Press button > 2sec.
Sample barcode	-	Set PID to barcode.

3.3 TEST SELECTION

Call: Homescreen/Test button

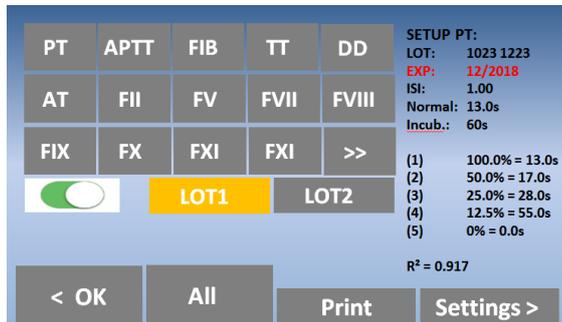


FIGURE 10: TEST SELECTION COATRON X PRO/TOP

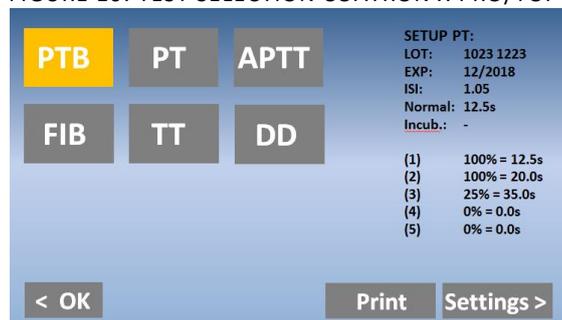


FIGURE 11: TEST SELECTION COATRON X ECO

Button	UI Element	Use Function
Test keys	PT – F12	Select test.
	>> <<	Change test table
On / Off	On / Off	Activate two LOTs per test (not available for Coatron X Eco).
LOT 1/2 (not visible for DOACs)	LOT 1 / LOT 2	Load calibration of LOT 1 or LOT 2 from memory.
OK	< OK	Confirm test for current channel.
All	All	Confirm test for all channels.
Settings	Settings >	Change test calibration.
Print	Print	Print current test setup.
Scan reagent barcode	-	Select current test and lot. A long beep indicates an invalid barcode or LOT.
SETUP PT	Test Information Box	Calibration data of current lot and test. Red values indicate invalid data.

About reagent barcode:

The barcode on reagent label can be used to switch to correct Test and LOT. Before use of barcode, the test LOT + Calibration must be entered in calibration menu (see chapter test setting)

3.4 MEASUREMENT



FIGURE 12: SCREEN DURING MEASUREMENT

Button (7) during measurment	
PID	Patient identification number (max 16 numbers).
Result	PT = 12.5s, 115% 0,91 INR.
Flag	f = very low fibrinogen (weak clot). F = very high fibrinogen (strong clot). * = Result is out of calibration. X = double value deviate more than 15%.
Err	T = temperature not 36 - 38°C. E = reagent expired. S = light intensity very low; caused by turbid reagent and or high lipemic or icteric samples.
mOD	Current optical absorbance. A change of value > 50mOD indicates an ongoing clot reaction.
Timer	Current time of measurement.
Grey blinking	Optic is ready for start of measurement
Green blinking	Measurement is started, but cuvette can be mixed or touched.
Orange blinking	Stop mixing and don't touch cuvette anymore

3.5 SYSTEM SETTINGS

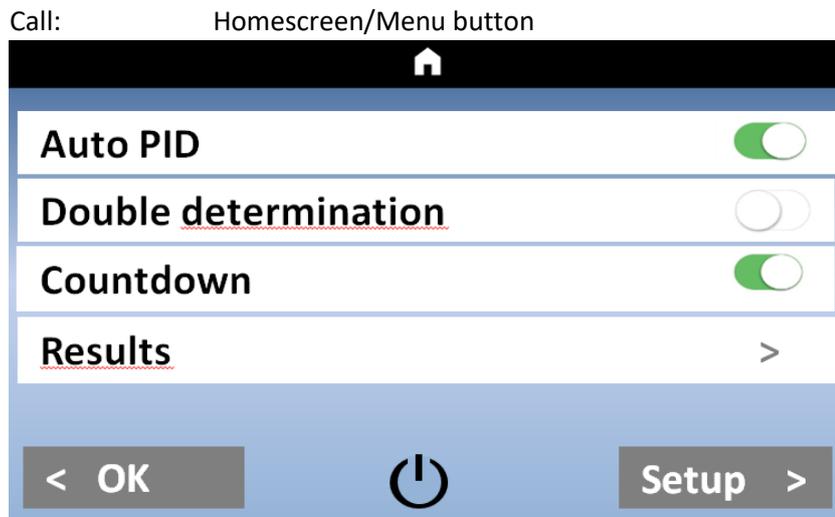


FIGURE 13: QUICKMENU COATRON X

Button	Use Function
Auto PID	Enable/Disable the Auto PID feature.
Double determination (not visible for Coatron ECO)	Enable/Disable Double determination
Countdown	Switch between Stopwatch and Countdown mode.
Results	Open the result history.
Setup	Open the system setup.
	Put the device into sleep mode.
OK /	Return to the home screen.

Auto PID:

Using the Auto PID mode enables the user to let the device choose a consecutively numbered ID for every measurement. By setting the ID manually you set the start ID. Every new channel activation automatically sets the ID to the next higher number.



Auto PID mode must be enabled to use the Multistart feature!

Double determination:

When using double determination mode, the channels 1 / 2 (Coatron X Pro) respectively channels 1 / 2 and 3 / 4 (Coatron X Top) are combined to perform a test using the same ID twice. Both results are combined by calculating the mean value.

Countdown:

Use the stopwatches in countdown mode. The period of countdown is defined by incubation time of test (see “test settings”). When Countdown mode is enabled, the stopwatches count down give alarm 5sec before zero.

Results:

Pressing the Results button opens the result history screen.

Setup:

Pressing the Setup button opens the system settings.



Pressing the Sleep Button sends the device into the sleep mode. To wake the device up, touch anywhere on the screen.

OK Button /  :

Pressing the OK or Home Button returns to the home screen.

Call: Homescreen / Menu / Setup

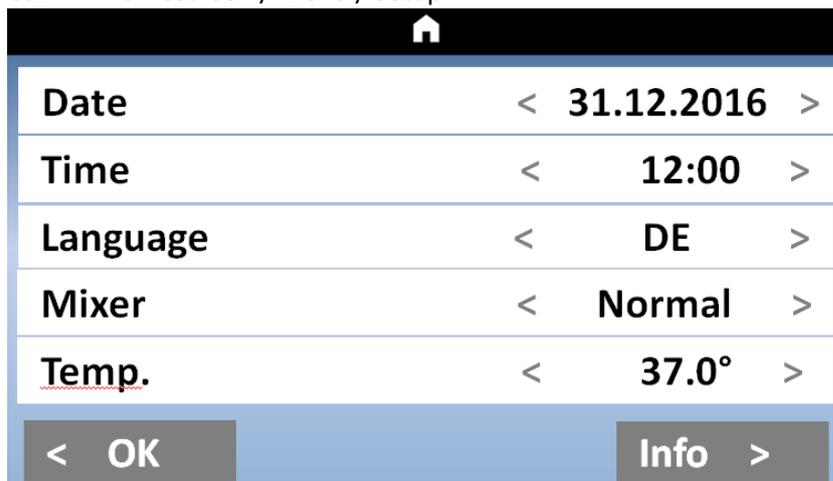


FIGURE 14: SYSTEM SETTINGS COATRON X PRO/TOP

Setting/Buttons	Use Function																																								
Date	Set system date, use long touch on “<” “>” to scroll through the values faster. Short touch on date change the format (EU / US) Long touch on date reset to default date																																								
Time	Set the system clock. Long Touch the time to reset to default.																																								
Language	Select the system language DE/EN/ESP/ITA/FR/RO/PL. <table border="1" data-bbox="625 1093 1072 1505"> <tbody> <tr> <td>EN,</td> <td>English,</td> <td>FI,</td> <td>Suomi,</td> </tr> <tr> <td>DE,</td> <td>Deutsch,</td> <td>HR,</td> <td>Hrvatski,</td> </tr> <tr> <td>ESP,</td> <td>Espanol,</td> <td>LV,</td> <td>Latviesu,</td> </tr> <tr> <td>ITA,</td> <td>Italian,</td> <td>LT,</td> <td>Lietuviu,</td> </tr> <tr> <td>FR,</td> <td>Francais,</td> <td>PT,</td> <td>Portugues,</td> </tr> <tr> <td>RO,</td> <td>Romana,</td> <td>SE,</td> <td>Svenska,</td> </tr> <tr> <td>PL,</td> <td>Polski,</td> <td>SK,</td> <td>Slovensky,</td> </tr> <tr> <td>DA,</td> <td>Dansk,</td> <td>SI,</td> <td>Slovenscina,</td> </tr> <tr> <td>NL,</td> <td>Nederlands,</td> <td>CS,</td> <td>Cestina,</td> </tr> <tr> <td>SR</td> <td>Srpski</td> <td>HU,</td> <td>Magyar,</td> </tr> </tbody> </table>	EN,	English,	FI,	Suomi,	DE,	Deutsch,	HR,	Hrvatski,	ESP,	Espanol,	LV,	Latviesu,	ITA,	Italian,	LT,	Lietuviu,	FR,	Francais,	PT,	Portugues,	RO,	Romana,	SE,	Svenska,	PL,	Polski,	SK,	Slovensky,	DA,	Dansk,	SI,	Slovenscina,	NL,	Nederlands,	CS,	Cestina,	SR	Srpski	HU,	Magyar,
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PL,	Polski,	SK,	Slovensky,																																						
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NL,	Nederlands,	CS,	Cestina,																																						
SR	Srpski	HU,	Magyar,																																						
Mixer (not visible for Coatron ECO)	Some reagents like PT sediment and need to be stirred Select here the mixer intensity (Low/Normal/High). Insert vial and magnetic stirbar into middle position. Change speed until stirbar ensures proper mixing.																																								
Temp	Correct the actual current temperature of the reagent block. Long touch the temperature value will reset to default. Detailed information can be read in chapter “Adjust temperature”.																																								
OK / 🏠	Return to the home screen.																																								
Info	Open system information.																																								
< / >	In or decrement value. Use long touch to scroll																																								

3.6 TEST SETTINGS

Call: Homescreen / Test button / Settings

FIGURE 15: TEST SETTING 1

Setting/Buttons	UI Element	Use Function
LOT	LOT Number field	Press the LOT text field to enter or change LOT number.
Expiry	Expiry date field	Press the expiry date value to select the field
Units	mg/dl 0-999 63 - 500	Press to change unit Result limited to unit range (min, max) Result limited to calibrated range
Incubation	Incubation time field	Press the incubation value to select the field.
Stop	Stop time field	Press the stop time value to select the field.
In/Decrement	+ or -	Change the value of the selected field.
Numeric keys	0 – 9 and C	Keys for LOT entry. C=Clear
OK	< OK	Save settings and exit screen.
ESC	ESC	Exit to test selection without saving.
Admin	Admin	Open advanced test settings. Only visible for administrator user.
Settings	Settings >	Open test calibration settings (Screen test settings 2)
Barcode:	LOT barcode entry	Scan reagent barcode to input LOT and expiry.

LOT:

Enter the LOT of the used reagent for the selected test. If dual LOT is used, use the test selection screen to choose LOT 1 or LOT 2. Both LOT numbers have individual test settings.

Expiry:

Enter the expiry date of the reagent for the selected test (and LOT).

Units:

Value: Select the units used for the test results. The available unit is predefined for each test.

Range: Limit results to unit or calibration range. Results out of range are reported as ">Max" or "<Min".

Incubation:

Required waiting time until adding final reagent and start measurement. The time is used for countdown.

Stop:

Some samples do not clot. After stop time instrument breaks measurement and reports “+++” (no clot detected)

Call: Homescreen / Test button / Settings / Settings

The screenshot shows the 'Setup PT' screen with the following data and controls:

	[%]	[s]
1:	100	13.0
2:	50	17.0
3:	25	28.0
4:	13	55.0
5:	0	0.0

Normal (s): 13.0
ISI: 1.00

DEL - +
0.5x 2x -- ++

R²= 0.917 Y=1/X

< OK ESC CAL Reset

FIGURE 16: TEST SETTING 2

Setting/Buttons	UI Element	Use Function
Calibration curve values	Value fields	Press a calibration value to select the field.
Increment Decrement	+, -, ++, --	Change values in small or big steps. Use long touch to repeat change
Double/Half	0.5x 2x	Half or duplicate values
Delete	DEL	Delete the selected value.
Reset	Reset	Reset all values to default.
Calibrators	CAL	Shift all calibration points according to serial dilution (1:1 1:2 1:4 ...)
OK	< OK	Save settings and exit screen.
ESC	ESC	Exit screen without saving.

Calibration curve:

Input of Calibration points. Minimum 2 points, maximum 5 points.

Normal:

Reference value for normal clotting time like for PT (MNPT). Only shown, if unit is selected.

ISI:

International sensitivity index of PT reagent. Value is stated on reagent label.

R²:

Linearity of calibration depending on mathematic

R ² <0.5	not linear	Y=LIN	linear interpolation
R ² <0.9	moderate linear	Y=1/X	reciprocal linear interpolation
R ² >0.9	high linear	Y=logXY	double logarithm interpolation

3.7 REVIEW RESULTS

The device holds automatically the recent 180 results into EEPROM memory. The most recent result is shown first. If the result history exceeds the memory, then the oldest measurement result is overwritten.

Call: Homescreen / Menu / Results

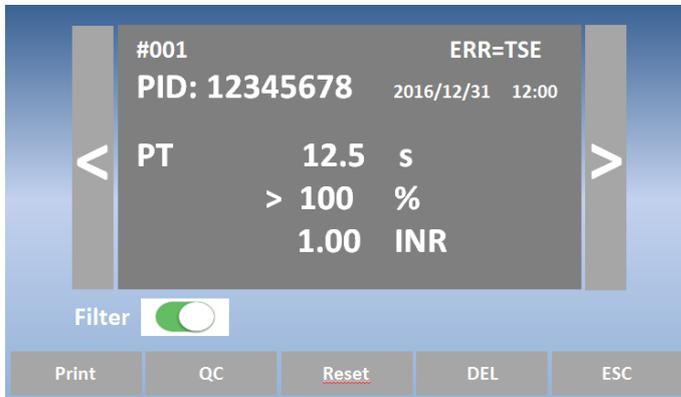


FIGURE 17: REVIEW RESULTS

Setting/Buttons	Use Function
< >	Scroll the results.
Filter (on,off)	Scroll only current PID+Test
Print	Print the shown result.
QC	Print & display max. 14 values of current PID+Test including mean and C.V. value.

FIB: PID=20190929, n=7

Mean:	16.6s	162 mg/dl
C.V.:	2.1%	2,9%

QC REPORT
26.09.2019

System:	Coatron X	
SIN :	01040 01234	
Test:	FIB	
PID:	20190929	

1	16.8s	159 mg/dl
2	17.1s	154 mg/dl
3	16.9s	157 mg/dl
4	16.2s	166 mg/dl
5	16.5s	163 mg/dl
6	16.4s	164 mg/dl
7	16.1s	168 mg/dl

-

Mean:	16.6s	162 mg/dl
C.V. :	2.1%	2.9%

Reset	Reset the result view to most recent result.
DEL	Delete current result
ESC	Exit screen.

4. BASIS COAGULATION TESTS



This section describes only rudimental how to run basic clotting tests on Coatron. Correct procedure may be different for specific reagents. Read and follow always the procedure in boxinsert of reagent kit.

4.1 QUICKGUIDE OF PT DETERMINATION

How to run a PT measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Reconstitute PT reagent and wait 30-60 min before next step.
3. Place PT vial into reagent block + stirring bar and let incubate for at least 5min.
4. Change test of channel 1 to "PT" by pressing on the current test.
5. Place empty cuvette into optic.
6. Pipet 25µL of sample into cuvette.
7. Press "00:00" to start the stopwatch and wait 30 seconds.
8. Press specific "OPTIC" and enter a PID or scan a sample barcode.
9. Add 50µL PT reagent, when "Active" is blinking. The measurement will start automatically when adding the reagent.
10. Wait for result or touch optic button to abort.

Multi-Activation (not for Coatron ECO)

1. Open menu and set Auto PID = On.
2. Place empty cuvettes into each channel and pipet 25µL of sample to each cuvette.
3. Press button multistart.
4. Add 50µL PT in to each cuvette from left to right.

How to calibrate a PT

1. Reconstitute calibrator and wait 15-30min before continue with next step
2. Calibrators
The target value of calibrator is state at certificate. I assume 100% as example
IBS, Owrens or NaCl₂ solution can be used as sample diluent
 - a. 100%: Pipet 100µL calibrator into empty tube
 - b. 50%: Pipet 100µL 100% calibrator + 100µL diluent into empty tube
 - c. 25%: Pipet 100µL 50% calibrator + 100µL diluent into empty tube
 - d. 12.5%: Pipet 100µL 25% calibrator + 100µL diluent into empty tube
3. Run all 4 calibrators like patients and write down the clotting time
(double determination is recommended)
4. Enter PT settings and enter
 - a. correct LOT, Exp (read Barcode of vial label)
 - b. set UNITS to "INR + %"
 - c. Input Normal Time (=100% result) + ISI (see vial)
 - d. Input % calibration

4.2 QUICKGUIDE OF PT-B DETERMINATION

How to run a PT-B measurement from finger blood:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to "PTB" by pressing on the current test.
3. Reconstitute PT-B with component-1 (Diluent) and wait 30-60 min before next step.
4. Add component-2 (CaCl₂) to PT-B and wait again for 30-60 min before next step.
5. Place empty cuvette into optic or pre-incubation.
6. Pipet 150µL of PT-B into cuvette. The cuvette must be used within the next 10min.
7. Close PT-B vial and store in the refrigerator until next use. The reagent is stable for 30 days.
8. Press "OPTIC-1" and enter a PID or scan a sample barcode.
9. When "active" is blinking, pierce the finger and pipet 15µL capillary blood from finger into cuvette.
10. Measurement should start. It is important to mix in the cuvette. For this lower the pipet into cuvette and pump 10-15x up and down. Stop mixing latest when countdown is zero.

How to calibrate a PTB

1. Reconstitute calibrator with 1.7mL and wait 15-30min
2. Calibrators
The target value of calibrator is state at certificate. I assume 100% as example
IBS, Owrens or NaCl solution can be used as sample diluent
 - a. 100%: Pipet 100µL calibrator into empty tube
 - b. 25%: Pipet 100µL 100% calibrator + 500µL diluent into empty tube
3. Run all calibrators like patients and write or print the clotting time
4. Enter PTB settings and enter
 - a. correct LOT, Exp
 - b. set UNITS to "INR + %"
 - c. Input Normal Time (=100% result) + ISI (see vial)
 - d. Input % calibration

4.3 QUICKGUIDE OF APTT DETERMINATION

How to run an aPTT measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to "APTT" by pressing on the current test.
3. Place CaCl into instrument let incubate for at least 5min.
4. Place empty cuvette into optic or pre-incubation.
5. Pipet 25µL of sample into cuvette.
6. Pipet 25µL of cold aPTT reagent into cuvette.
7. Press "00:00" to start the stopwatch and wait 180 seconds.
8. Short before end of incubation press "OPTIC-1" and enter a PID or scan a sample barcode.
11. Add 25µL CaCl, when "Active" is blinking. The measurement will start automatically.
12. Wait for result or touch optic button to abort.

4.4 QUICKGUIDE OF FIB DETERMINATION

How to run a FIB measurement:

1. Switch on instrument and wait for green state (~ 15min until 37°C).
2. Change test to "FIB" by pressing on the current test.
3. Reconstitute FIB reagent and wait 30-60 min before next step.
4. Place FIB vial not into reagent block. Room temperature is ok.
5. Place empty cuvette into optic.
6. Pipet 10µL of sample into cuvette.
7. Pipet 90µL of IBS buffer into cuvette.
8. Press "00:00" to start the stopwatch and wait 30 seconds.
9. Press "OPTIC-1" and enter a PID or scan a sample barcode.
10. Add 50µL FIB reagent, when "Active" is blinking. The measurement will start automatically when adding the reagent.
11. Wait for result or touch optic button to abort.

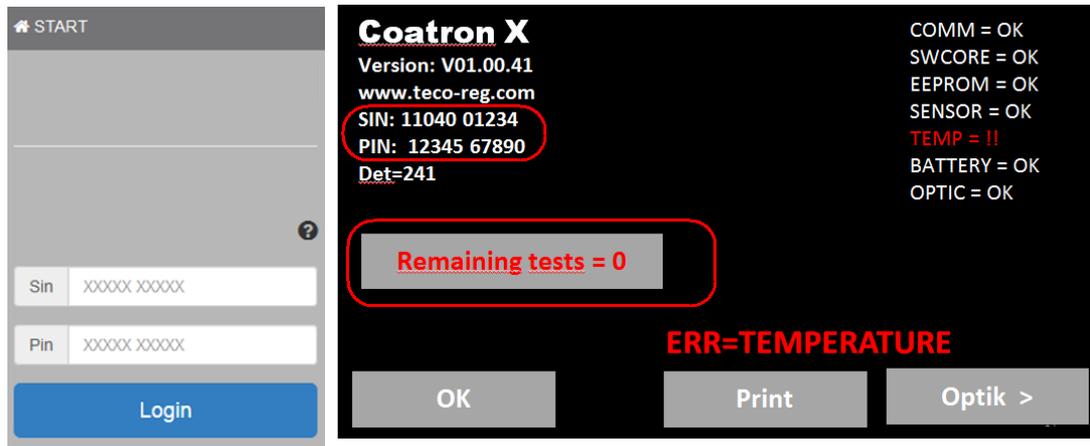
How to calibrate a FIB

1. Reconstitute calibrator and wait 15-30min before continue with next step
2. Calibrators
The target value of calibrator is state at certificate. I assume 300mg/dL as example
 - a. 600mg/dL: Pipet 50µl calibrator + 200µL IBS buffer into empty tube
 - b. 300mg/dL: Pipet 50µl calibrator + 4500µL IBS buffer into empty tube
 - c. 150mg/dL: Pipet 50µl calibrator + 950µL IBS buffer into empty tube
 - d. 75mg/dL: Pipet 50µl calibrator + 1950µL IBS buffer into empty tube
3. Run all 4 calibrators
 - a. Add 50µL of calibrator into cuvette
 - b. Add 25µL of FIB reagent to start measurement. Write clotting times to paper or print,
4. Enter FIB settings and enter
 - a. correct LOT, Exp
 - b. set UNITS to "mg/dL"
 - c. Input mg/dl calibration

5. TICKET SYSTEM

1) Login to ticket system

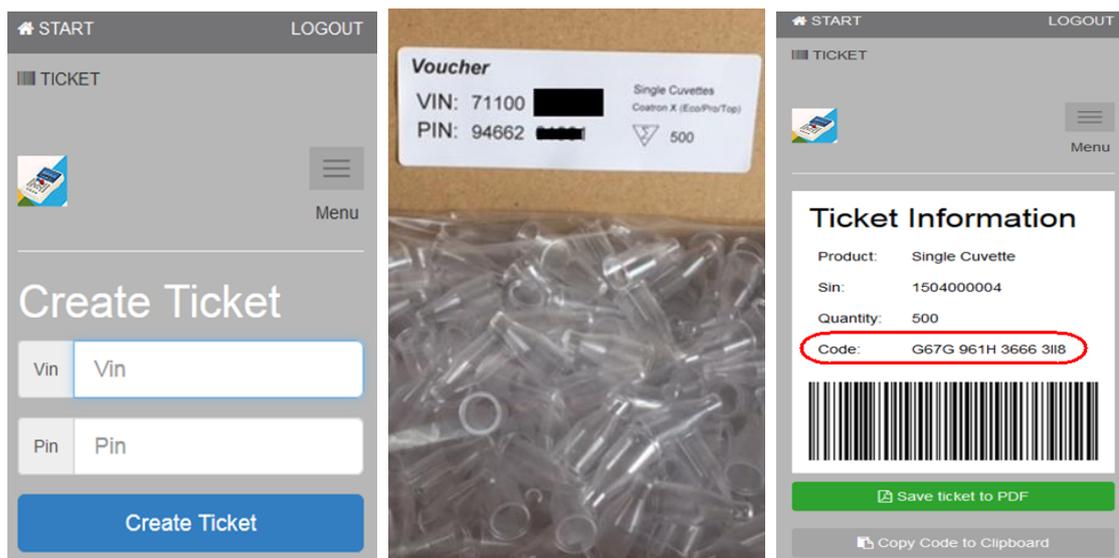
webpage: www.teco-reg.com



Enter SIN and PIN of instrument! This information can be found on instrument license plate (Type label) or on info screen.

FIGURE 19: TICKET SYSTEM, LOGIN

2) Input Voucher



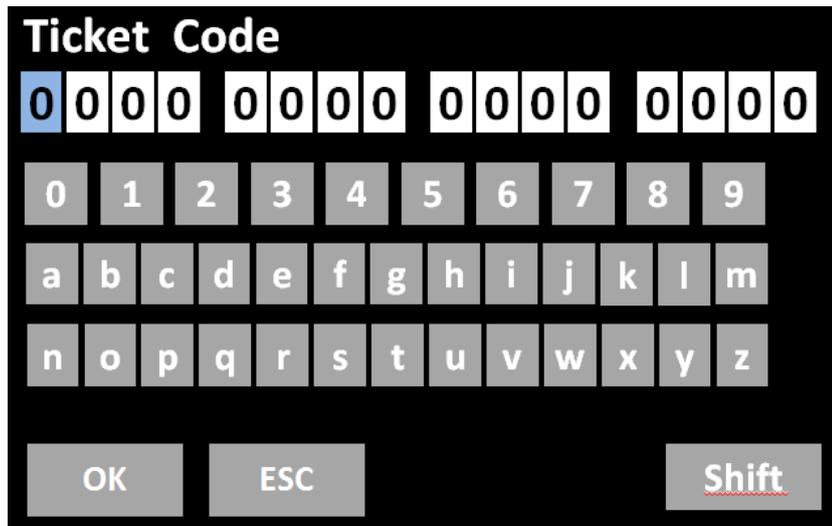
Enter VIN and PIN
of voucher

Voucher is inside of
cuvette box

Transfer Ticket code
to instrument

FIGURE 20: TICKET SYSTEM, VOUCHER

3) Transfer ticket code to instrument



Open info screen (touch blinking RED LED) and then “Remaining tests=0”. The code can be transferred by manual input, barcode scanner or TECAM SMART software.

FIGURE 21: TICKET SYSTEM, INPUT CODE

4) Using TECAM SMART software



FIGURE 22: TICKET SYSTEM, TECAM SMART

- a) Use your mobile device and scan QR code or “Get ticket”, if TECAM is connected to internet
- b) Follow dialogue according to chapter (1)
- c) Copy Paste the code and “send” to instrument

6. SERVICE FUNCTIONS



Only for authorized and trained persons. Unqualified modifications can cause troubles and misfunction of the system!

6.1 SYSTEM INFORMATION

Call: Homescreen / green or red LED

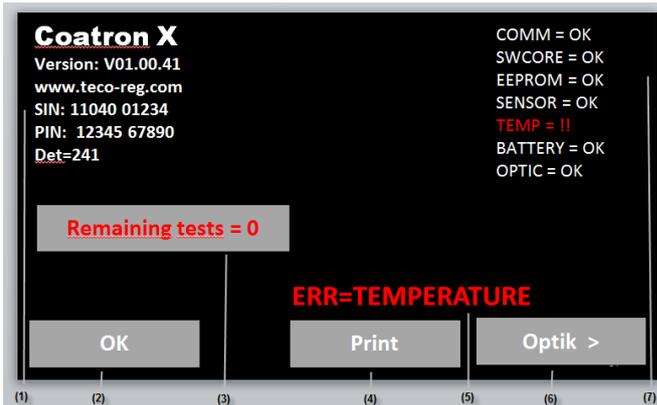


FIGURE 23: SYSTEM INFORMATION

UI Element	Element Name	Use Function
(1)	-	System version information
(2)	OK	Return to homescreen
(3)	Remaining tests	Number of activates cuvettes. Touch to activate new cuvettes
(4)	Print	Print out of system information
(5)	ERR message	Show current error
(6)	Optik	Check optic system
(7)	-	System error information

System information

Version of software, URL link to register or ticket system, system ident number (SIN), product ident number (PIN). SIN+PIN is required for login to ticket system.

Remaining tests=0:

Latest at zero the system will stop operation and require to activate new cuvettes.

YELLOW warnings

Minor problems

Reagent expired	Check expiry date of test
Remaining tests < 100	Activate cuvettes soon

RED warnings

System is not ready to measure

COMM= communication to LIS	SWCORE = software memory overflow
EEPROM= EEPROM/memory error	SENSOR = temperature sensor
TEMP= temperature not 36-38°C	BATTERY = CR2032 on mainboard below 3V
OPTIC= optical system out of range	

6.2 OPTIC CHECK

Call: Homescreen / green or red LED / Optic

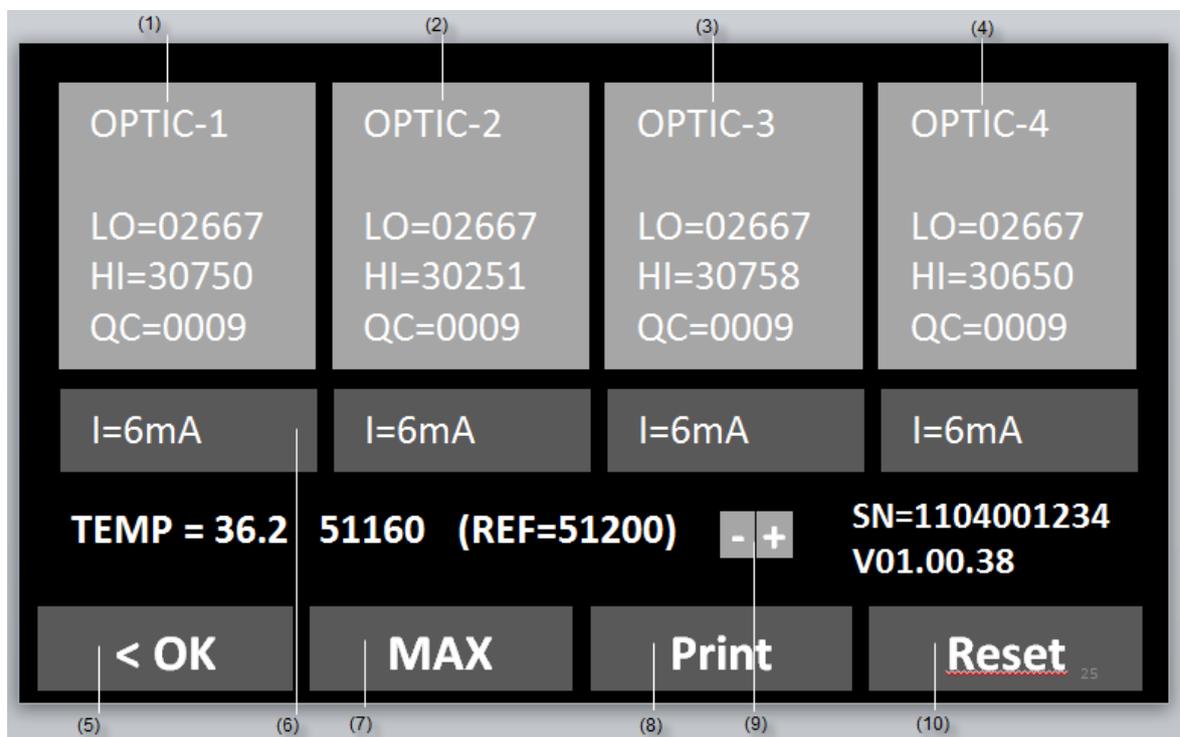


FIGURE 24: OPTIC CHECK

Button	Caption	Use Function
(1)-(4)	OPTIC xx	Reset QC value
(5)	I=mA	Display and change intensity of LED
(6)	OK	Return to homescreen
(7)	MAX	Set all LED to max. intensity (42mA)
(8)	Print	Print system report (see next chapter)
(9)	+ / -	Change temperature
(10)	Reset	Reset all channels and re-calibrate optic

Informations on screen	Fault condition	Troubleshoot
LO optic signal, when LED is off	> 2900	Replace optic board
HI optic signal, when LED is on	< 25000	Remove cuvette and touch "RESET"
QC noise of optic signal	> 30	Touch button "OPTIC"
mA power of LED (intensity)	not [3 - 12mA}	Remove cuvette and touch "RESET"
TMP temperature in °C	not [36.0 - 38.0°C]	wait 15min
REF signal of temperature sensor	not [48000 - 52000]	adjust temperatur or replace sensor

6.3 SYSTEM REPORT

Call: Homescreen / green or red LED / Print

SYSTEM REPORT				
08.10.2019				
System:	Coatron X			
Version:	V01.03.49 (OEM-1D)			
SIN :	01040 01234			
PIN:	12345 67890			
TEMP:	37.0°C			
	50981 (target=51000)			
Optic:				
Lo	Hi	mA	Qc	

1:2698	28822	5	1	OK
2:2698	29822	6	1	OK
3:2698	30822	7	1	OK
4:2698	29822	6	1	OK
PT=	123			
aPTT=	102			
FIB=	100			
DD=	0			
AT=	0			
TOTAL	325			

Date of report

name of system

software version and OEM Index

system ident number

product ident number

temperature of optic and digital value
of thermosensor

Optical values

Lo= LED off

Hi= LED on

mA= LED power

Qc= noise of optic

OK= no fault

!!= fault condition

count of performed tests

Fault condition are described in chapter "optic check"

6.4 ADJUST TEMPERATURE

Call: Homescreen / Menu / Temperature

1. Switch on device and wait approx. 15min until system show 37°C on screen.
2. Fill a reagent tube/vial with 2 ml water and place it in a reagent position. Place a digital thermometer in the reagent tube and let warm-up for approx. 10 min.
3. Press menu
Change current system temperature to value of thermometer. Wait 10min and repeat procedure.

Typical problems:

Malfunction / Error	Possible cause	Measures
System heat not up to 37°C	Sensor calibration is out of range	Reset to factory default as described in chapter "Hidden Function"
System show 0.00°C	Sensor is out of range	Ambient temperature must be 0 – 45°C.
	Sensor or optic LED board is defect	Replace LED board.

6.5 FIRMWARE UPDATE



Only for authorized and trained persons. Sudden interruption of power or data communication during update procedure will cause device not to boot anymore. In this case, the instrument can be restored only by JTAG interface.

1. Download flashdisk.exe from manufacturer website. Contact local distributor to receive correct URL address.
2. Flashdisk.exe is a selfrunning Winzip archive. A double click will start the update dialogue. Some antivirus software may block selfrunning archiv. In this case extract the file to your desktop and execute "XFlash.exe"

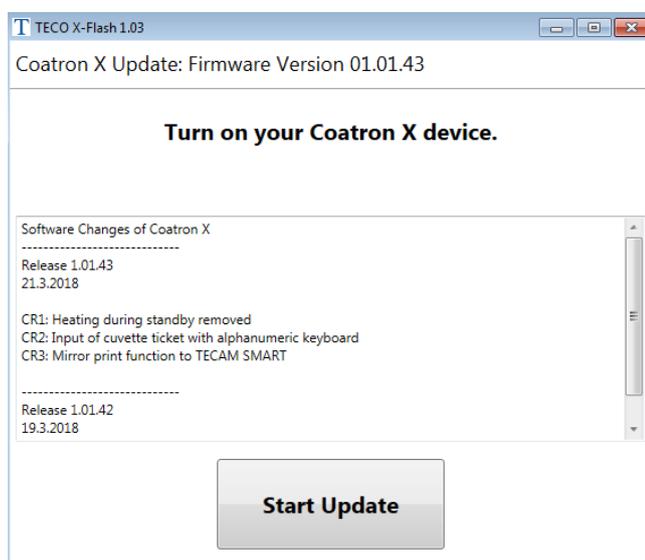


FIGURE 25: SCREENSHOT OF XFLASH TOOL

3. Confirm "Start Update"
4. Remove USB cable from instrument and confirm
5. Connect USB cable to instrument USB "Service" (=second USB port from left)

XFlash will now identify the instrument and display "CONTINUE". Abort XFlash, if no instrument is found and install device driver "FT232.exe" manually. The file is included in the flashdisk archive.

6. Confirm "Start Update". After this command the firmware will be transmitted to instrument. There is no way to interrupt. After around 120s the update will be finished.
7. Remove power and afterward USB cable from service port. Now connect power to instrument. It should boot and show correct firmware version.

6.6 OVERVIEW OF MAINBOARD

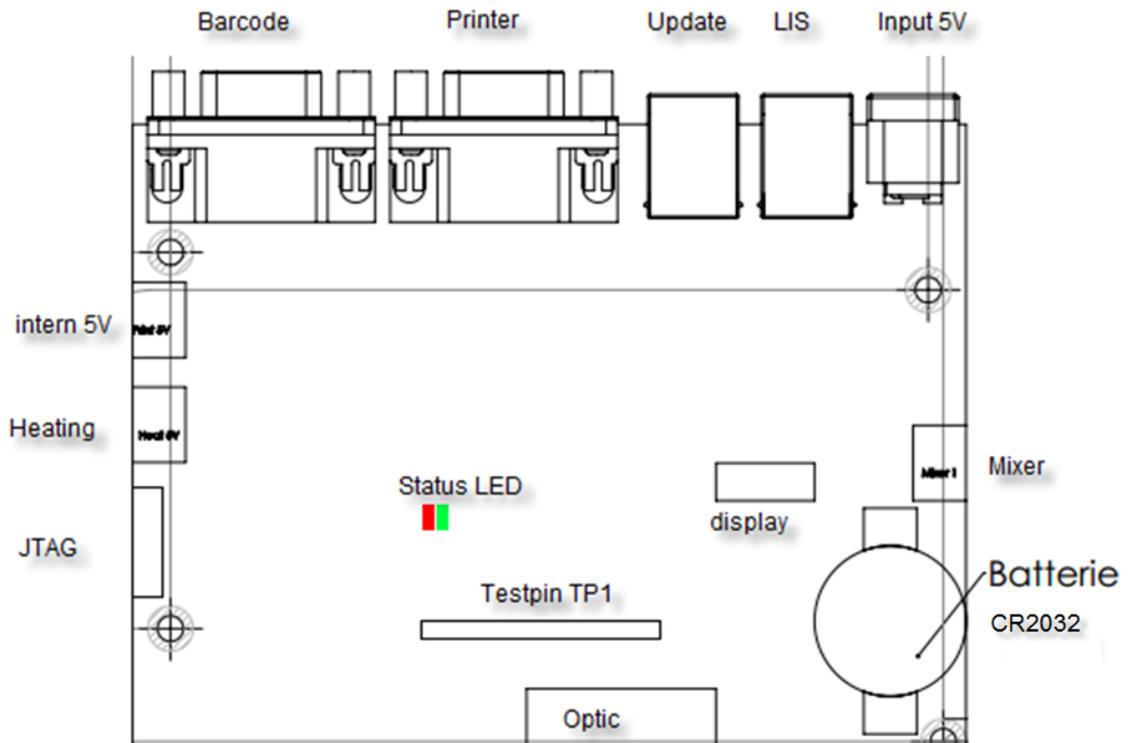


FIGURE 26: MAINBOARD

Testpin Function:

- TP1 = Systick Interval, must toggle each 1ms
- TP2 = indicate reading of SD24
- TP3 = draw homescreen
- TP4 = Write to EEprom
- TP5 = Read from to EEprom
- Other = not used

Status LED:

- | | | |
|------------------|------------------|------------------------------------|
| green, permanent | = everything OK | |
| red, permanent | = EEPROM error | defect optic unit and/or mainboard |
| green, blink | = Battery < 3.0V | battery expired |
| red, blink | = Temp sensor | Optic not connected |

6.7 TYPICAL FAILURES

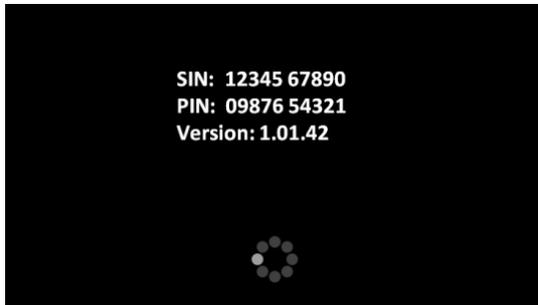
Malfunction / Error	Possible cause	Measures	By
System not ready	different	Open system info and check red errors	User
Remaining tests = 0	No cuvette activated	Create a ticket	User
ERR=Comm	Mainboard defect	replacement	Authorized service
ERR=SWCORE	Software failure or bug	Update firmware	User
ERR=Sensor	Temp sensor defect	Replacement of optic	Authorized service
ERR=Temp	Temperature out of 36-38°C	Wait 15min	User
ERR=Optic	Optic channel blocked or LED defect	Remove cuvette from optic or clean optic or replace optic	Authorized service
ERR=Battery	Battery low power	Replacement	Authorized service

False results	Possible cause	Measures
No or false clot detected	True, patient anti coagulated or bleeding	Remove cuvette and check with needle for clot
	Reagent defect	Check reagent with eyes for flakes or clots. Run control plasma to verify. Prepare new vial. Check diluent/water
	Instrument missed clot	Increase MAX time
	Low fibrinogen or optical interference (lipemic, bilirubin, haemolytic)	Repeat but activate hi-sense option
False result (INR, %, mg/dl, ...)	Method not correct calibrated	Check calibration data and correct LOT

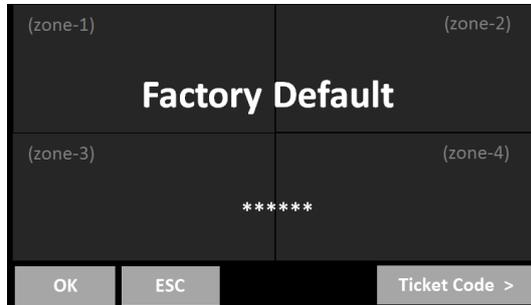
Invalid cuvette ticket	Possible cause	Measures
LOT invalid	The voucher ticket already has been used on system.	Use a new voucher www.teco-reg.com
S/N invalid	The SIN number of voucher ticket information is not equal to S/N of instrument	Enter the voucher ticket code only on the correct target device
Code16 invalid	System does not accept Code16	Re-use voucher @ (www.teco-reg.com) to obtain Code20 voucher tickets.
Invalid	System does not accept voucher ticket for an unknown reason	Visit www.teco-medical.com/support and "report a problem". Provide information about VIN , SIN and Code20.

7. RESET TO FACTORY DEFAULT

System factory reset procedure:



WELCOME SCREEN +



FACTORY DEFAULT

How to reset to factory default:

1. Press 3sec to spinner during boot up
2. Select "OK" Switch on device and switch to home screen
3. Confirm the reset

⇒ Date, temperature and test calibration must be adjusted after a factory reset!!

Default values:

- Temperature sensor = 51000
- Mixer = 1;
- Language = EN;
- Double determination = OFF;
- Auto PID = ON;
- Countdown = OFF;
- All results stored on board are deleted
- All test calibration data are reset to default

Test calibration:

How to reset to factory input a PT calibration:

1. Switch on device and switch to home screen
2. Touch any test button
3. Change test to "PT" and touch "Setup" or scan barcode of PT vial
4. Enter LOT, expiry and select Units to "% + INR"

8. WORKING WITH TECAM SMART

⇒ Detailed information about installation and operation be be read in the online manual of TECAM. This is just a quick overview.

TECAM software is a small local LIS and combines laboratory data management, quality control and research purpose in one. It connects the Coatron to the “big” LIS and and manage results in an own local database. Flexible filters allow QC with Levey-Jennings graph and Westgard analysis. Each result can be traced back to reagent lot and calibration.

Features	Smart
Receive result from analyser	The results can be reported and manage in a local database
Receive calibration curve from analyser	Visualize and manage calibration data for all reagents and LOT.
Receive reaction curve	Visualize the optical reaction for research, result verification or failure analysis
Patient information	Connect Patient-ID with name and other information.
LIS communication	Talk to LIS with ASTM-1394 standard protocol Receive from LIS: Patient information Send to LIS: Results
Statistical analyze (QC)	Power filters allow quality evey-Jennings graph and Westgard analysis for controls as well as for patients
integrated TECMONI	This is a powerful research tool to visualize reaction curve in real time. It is a great tool for reagent development or adapting new tests to instrument
Mirror print	Instead of expensive portable thermo printer, use TECAM as printer
Ticket system	Activation of cuvette in its easiest way. Connect to ticket system, receive ticket and send to instrument

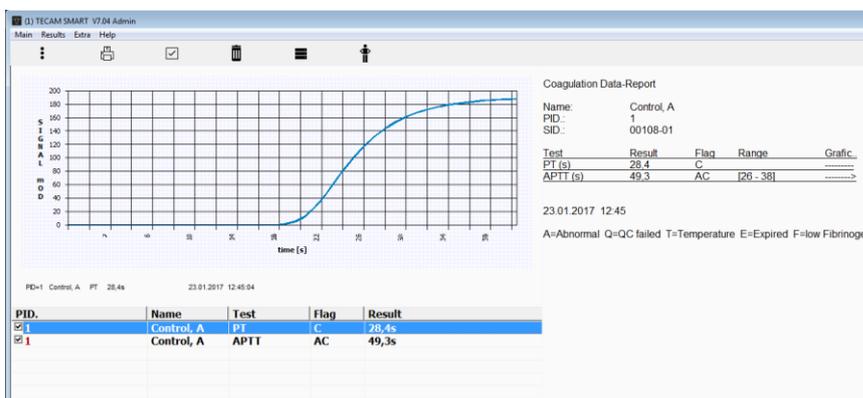


FIGURE 27: TECAM SMART

9. CLEANING AND MAINTENANCE

9.1 GENERAL CLEANING INFORMATION

- Clean with a lint free cotton cloth or stick
- Never pure any liquid into optic, working area or touch display
- Keep the device free of dust and moisture.
- If the device is soiled with liquids, remove the soiling with an absorbent cloth.
- If a liquid has accidentally been spilt or pipetted into a measurement channel, remove power immediately and clean the measurement channel with pipette and a lint-free cloth. Check the function of the optics in the menu SERVICE



Regard all surfaces and materials, which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.



Avoid any direct contact with decontaminants or disinfections.

9.1 CLEANING

- Use microfiber tissue only and no liquid to clean the screen
- Clean and wipe up all spills around the working area with 5-10% diluted bleach detergent or water.

9.2 DECONTAMINATION

- Use 30% diluted bleach and commercial disinfectant (e.g. BacilloI®AF)
- Decontaminate working area. Don't apply liquid on display.

9.3 REGULAR MAINENTANCE

- No maintenance required

10. TECHNICAL DATA

Analyzer		
Display		capacitive touch sensitive TFT 4.3" 480x272
Measurement system		1-4 independent measurement channels wavelength of LED 405 nm / 620 nm
Cuvette		single channel cuvette for optical detection
Positions (prewarmed)		5 reagent positions at 36.5 – 37.5 °C 20 cuvette positions at 36.5 – 37.5°C
Reaction volumes		Minimum total volume is 75 µl
Power supply		
Input Power		100 – 240VAC/50-60Hz/600-300mA
Output Power		5V DC, 5A
Batterie (mainboard)		Lithium CR2032 3V
Power consumption		max. = 14W sleep < 0.5W
Dimensions		
Size (W x D x H)		225 x 150 x 90 mm
Weight		1.04 kg (without power supply)
Ambient conditions		
See chapter "Installation"		
Noise output		
Operating noise		max. 50 dBA
Interfaces		
RS232 (Barcode)		Sub-D9, female; 9600 Baud/8/1/N; Pin-9 powered with 5V DC. For external handheld barcode scanner, serial printers
RS232 (Printer)		Sub-D9 female; 9600 Baud/8/1/N; For serial printers
USB (Service, Firmware Update)		Type-B, female, 115200 Baud/8/1/N
USB (LIS)		Type-B, female, 115200 Baud/8/1/N; For LIS communication
Typical performance data		
Test	CV.	Range
PT	<3%	0-30 INR
APTT	<3%	15 – 420s
FIB	<7%	50-999mg/dL

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