

Operation Manual

Coatron X Series Eco / Pro / Top



For *In-Vitro* Diagnostic use



Instrumentation and reagents for human coagulation and hemostasis
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Warranty

The Coatron X is warranted for a period of one year after delivery or first installation. It covers any defects in material, functionality or workmanship. The first installation must be registered online to www.teco-reg.com (see chapter "Registration")

The warranty expires in case of failures caused by

- Accident, neglect 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 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 Operator's Manual.



Use the Coatron X only in compliance with the instructions in this Operator's 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
(depend 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 WITH BARCODE SLOT

1.3 CONSUMABLES / ACCESSORIES

| | |
|--|--|
| | Single cuvettes |
| | Reagent adapter \varnothing 24,5 \rightarrow 22,5 mm |
| | Stirring magnets, P=4 |
| | External CCD-Barcode Reader only connectable, if no internal Barcode-Reader is built-in |
| | Thermal printer 60mm |
| | TECAM Smart Software Patient management, Monitoring, Research, Statistics, Mirror print function, LIS communication (ASTM- 1394) |
| | Protection foil, Clean tissue, Pick-off |

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 COMPARE OF COATRON-X FAMILY

The Coatron-X family include three different versions called ECO, PRO, TOP

| | ECO | PRO | TOP |
|-------------------------|--|-----|-----|
| Coatron X Family | | | |
| 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 or integrated 1D Barcode scanner | | |
| LIS, USB | Yes | | |
| Firmware Update, USB | Yes | | |

| Measurement | | | |
|-------------------------|----------------|----------------|----------------|
| 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 | All factors |

| | | | |
|--|----------------|---------------------------------|---------------------------------|
| Chromogenic Assays | - | AT, PC | AT, PC |
| Latex enhanced Assays | D-Dimer | D-Dimer | D-Dimer |
| Whole Blood Testing | Yes (PT INR+%) | No | No |
| DOAC monitoring (based on anti IIa and anti Xa) | No | HEP,LMW,APIX, RIVX,EDOX,DABI | HEP,LMW,APIX, RIVX,EDOX,DABI |

Software features

| | | | |
|---|-----|-----|-----|
| Reagent Dual LOT manage two different lots for each test | No | Yes | Yes |
| Reagent Barcode Input LOT+Expiry or Positive LOT detection | Yes | Yes | Yes |
| Test Calibration LOT, expiry and upto 5 points for each test | Yes | Yes | Yes |
| Patient Barcode Input patient ID by barcode scanner upto 16char | Yes | Yes | Yes |
| Result Database save recent 200 results onboard | No | 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 |
| Test Calibration Service Calibrate new lot of reagents by barcode | 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 Prothrombin 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 |
| PC | Protein C | plasma | chromogen | No | Yes | Yes |
| Factors | Factors II, V, VII, VIII, IX, X, XI, XII | plasma | clot | No | Yes | Yes |
| AF2 | anti IIa | plasma | chromogen | No | Yes | Yes |
| AF10 | anti Xa | plasma | chromogen | No | Yes | Yes |
| HEP | Heparin | plasma | chromogen | No | Yes | Yes |
| LMH | Low molecular heparin | plasma | chromogen | No | Yes | Yes |
| APIX | Apixaban | plasma | chromogen | No | Yes | Yes |
| RIVX | Rivaroxaban | plasma | chromogen | No | Yes | Yes |
| EDOX | Edoxaban | plasma | chromogen | No | Yes | Yes |
| DABI | Dabigatran | plasma | chromogen | 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 |
|-------|---|



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 | 180.0 |
| U | units | 0 | 999 |
| INR | Int. ratio | 2 | 30.00 |
| R | ratio | 2 | 30.00 |
| NR | polish ratio | 0 | 180 |
| mg/dl | | 0 | 900 |
| g/l | | 2 | 10.00 |
| IE/ml | Int. Units | 2 | 10.00 |
| mg/l | | 2 | 10.00 |
| µg/ml | | 3 | 7.000 |
| ng/ml | | 0 | 7500 |
| µg/l | | 0 | 7500 |
| IU/mL | Int. Units | 2 | 10.00 |

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,..)

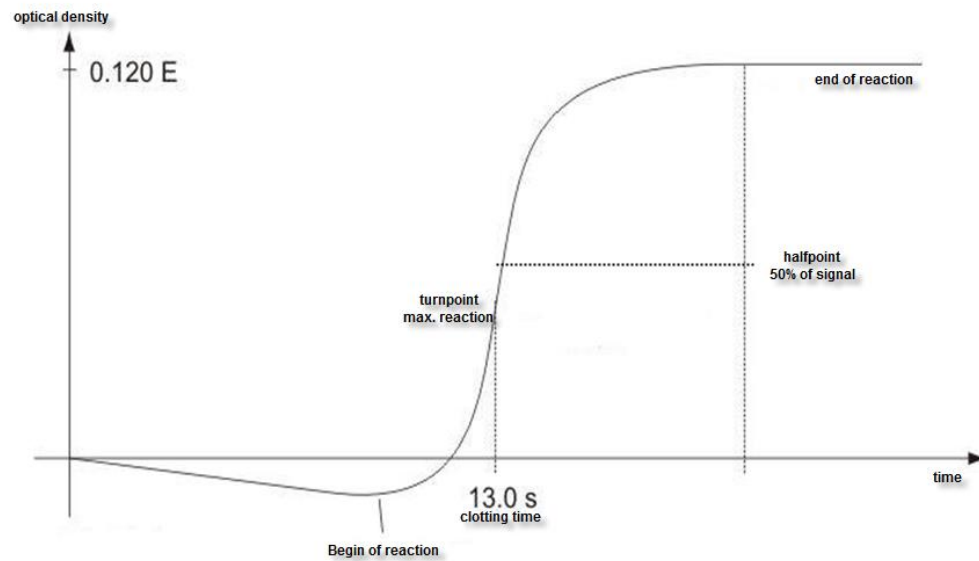


FIGURE 4: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

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

1.5.1 SAFETY INFORMATION FOR OPERATION



Use only the cleaning and rinsing liquids approved by the manufacturer. Failure to do so could result in faulty measurements or malfunctions of the **Coatron X**. Prevent reagents from leaking into the Analyzer. Failure to do so may result in damage to the instrument and result in expensive maintenance work!



Carry out control measurements at regular intervals to ensure that the analyzer continues to function faultlessly.



If the instrument is used in a manner not specified by the manufacturer, the protection impairment could be affected!



Please read the Operation manual in its entirety prior to operation, in order to ensure a high level of performance and to avoid errors by user.

1.5.2 SAFETY INFORMATION FOR MATERIALS



Use only TECO approved and labeled material like cuvettes, spare parts or reagents for which the instrument is intended and validated for.



Consumables like cuvettes or yellow tips are intended as single-use items. Multiple use may result in false results due to contamination. Follow the instructions on the reagent package circulars. Incorrect handling may result in falsified results.






Do not use materials after their date of expiry. Especially expired IVD reagents may cause false results.








Check correct function of manual pipette every year to ensure accurate results.





1.5.3 SAFETY INFORMATION REGARDING RISK OF HEALTH

| | |
|---|--|
|  | <p>Bleeding or Thrombosis Diagnosis and medication of human coagulation system based on false results may lead to critical bleeding or thrombosis. For risk reduction it is essential to follow the hints below.</p> <p>Regarding risks: <u>Caused by faulty condition of the instrument, reagent or calibration data:</u> Perform a quality control before running a series of patient samples or after reconstitution of a vial or after test calibration to eliminate failure of the instrument, reagent or calibration data. <u>Caused by imprecise pipet:</u> Validate your pipette every year and label it with the last date of validation. <u>Caused by false assignment of target values:</u> Run interlaboratory quality control standards. <u>Caused by purified water:</u> Use only high purified water to reconstitute controls or reagents. Check visually that the water is free of any particles. <u>Caused by expired reagent:</u> Do not use IVD reagents or other materials after their expiry date.</p> |
|  | <p>Infectious Material Consider all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.</p> <p><u>Avoid contact:</u> Wear medical infection grade protective gloves for all works involving potential contact with infectious material and use each pair of gloves only. Use a hand disinfectant product, e.g. Sterillium®, to disinfect your hands after completion of the work.</p> <p><u>Dispose:</u> Dispose infectious materials, such as cuvette waste and liquid waste, in compliance with your local regulations governing for infectious materials.</p> <p><u>Hygienic conditions:</u> Validate your hygienic management system according to German GLP federal bureau for good laboratory practice 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.</p> |
|  | <p>LED Light Radiation Avoid direct eye exposure. The internal CCD barcode scanner is assigned to EN 55022:2010 class B, EN 62471:2008.</p> |



1.5.4 SAFETY INFORMATION FOR CLEANING, MAINTENANCE AND SERVICING

| | |
|---|---|
|  | <p>Authorized service only! Carry out only the measures listed in this operator's manual for maintenance, repair and replacement. Improper manipulation of the device will void the manufacturer's liability obligations and may make service calls necessary, including payments which are not covered by warranty. Only the authorized Customer Service may carry out servicing. Only original replacement parts may be used. Before doing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts.</p> |
|  | <p>Cleaning and decontamination: Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. The procedure is described in chapter "Cleaning and maintenance" and should be performed by authorised well-trained personnel only, observing all necessary safety precautions</p> |
|  | <p>Cleaning certificate required! Instruments to be returned have to be accompanied by a decontamination certificate issued by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the service centre, or from authority's interventions.</p> |
|  | <p>Regard all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.</p> |
|  | <p>Avoid any direct contact with decontaminants or disinfections.</p> |

1.5.5 ELECTRICAL SAFETY

| | |
|---|---|
|  | <p>Precautions:</p> <ul style="list-style-type: none"> ▪ Avoid spilling liquids into system. In case of spilled liquids disconnect the system from power, then clean and dry all contaminated parts. ▪ Remove the power cord before opening the instrument. ▪ Do not touch any electronic parts during operation. ▪ Do not operate system without proper connection to grounding. ▪ Never intentionally interrupt protective ground contacts. ▪ Never remove housing elements, protective covers or secured structural elements, since doing so could expose parts carrying electric current. ▪ Make sure surfaces such as the floor and workbench are not moist while operating the device. ▪ Check electrical equipment regularly. Defective leads or socket must be replaced without delay. |
|  | <p>Connection to power:</p> <ul style="list-style-type: none"> ▪ Instrument is in compliance with IEC 61010-1 / 61010-2 and classified as portable instrument, class II. It does not require a safety connection to electrical earth. ▪ Make sure the operating voltage setting is correct before connecting the device to the power mains. Read chapter “installation” about electrical conditions. ▪ The power cord always has to be easily accessible during normal operation. |
|  | <p>EMC Statement:</p> <p>The Coatron X is suitable for use in domestic and industrial establishments. It was tested according to standards IEC 61326-1:2013 and IEC 61326-2-6:2013, It is in compliance with the requirements</p> <p>Emission: EN 55011, Class B, Group1</p> <p>Immunity: EN 6100-4 -2,3,4,5,6,8</p> |
|  | <p>The maximum length of cables to external devices like printer, barcode or LIS must be less than 3m to keep compliance with EMC</p> |

1.5.6 RECYCLING OF THE INSTRUMENT

| | |
|---|---|
|  | <p>The system must be decontaminated before being transported to an authorized disposer for electrical waste.</p> |
|  | <p>The instrument must be recycled as required by guideline WEEE (2002/96/EG).</p> |

2. INSTALLATION OF THE COATRON X

2.1 SCOPE OF DELIVERY

Contents of standard delivery package:

- 1 Pc **Coatron X**
- 1 Pc Power Supply
- 25 Pcs Single cuvettes
- 5 Pcs Reagent tubes
- 1 Pc Protection foil with Clean tissue and Pick-off
- 1 Pc Operation Manual (not on picture below)



FIGURE 5: STANDARD DELIVERY PACKAGE

Optional available:

- External Thermal Printer
- External Barcode scanner
- Printer cable

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: Touchseinsitive 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)

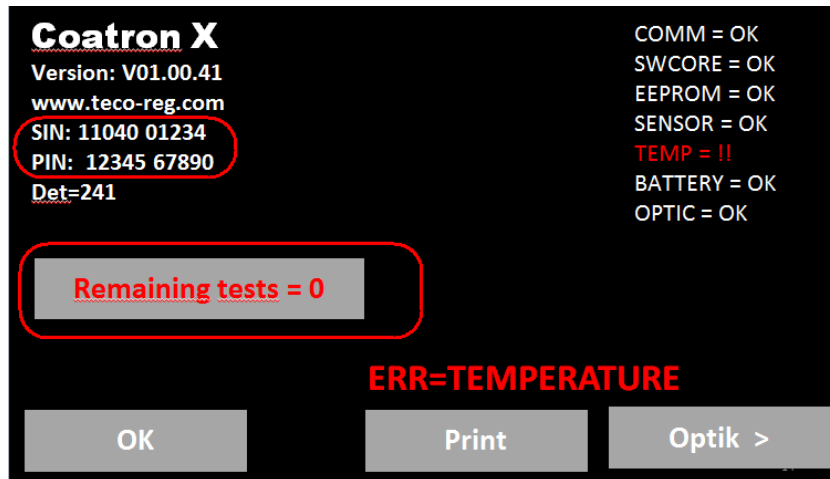


FIGURE 6: SYSTEM INFORMATION

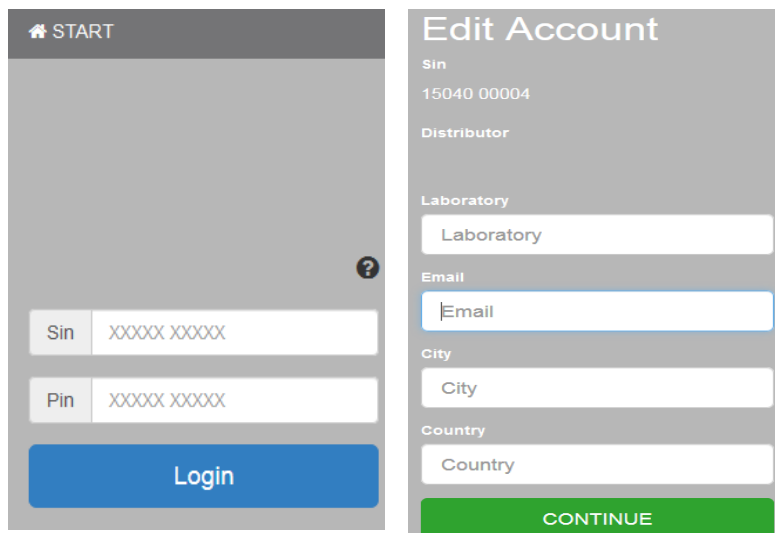


FIGURE 7: REGISTRATION OF COATRON-X

3. OPERATION OF THE COATRON X

3.1 HOMESCREEN

After boot or home button following screen is displayed

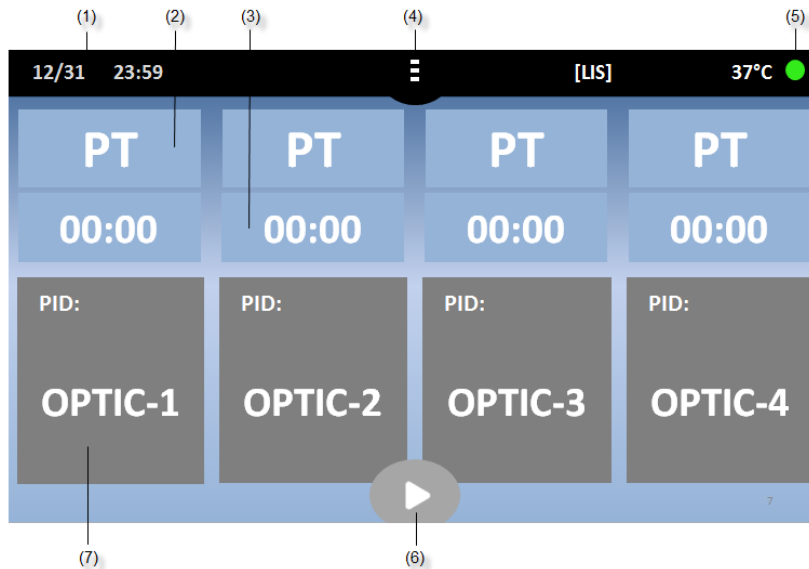


FIGURE 8: HOMESCREEN COATRON X TOP

| 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 orange | Ongoing measurement. Touch 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

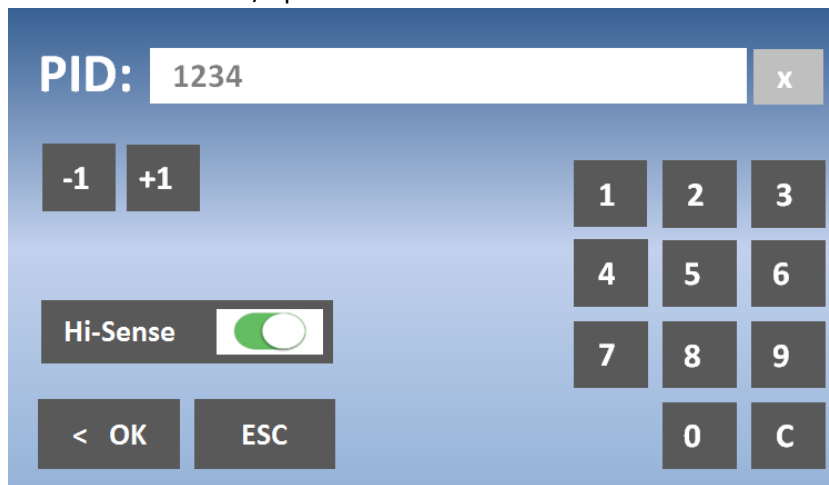


FIGURE 9: INPUT PATIETN ID

| 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

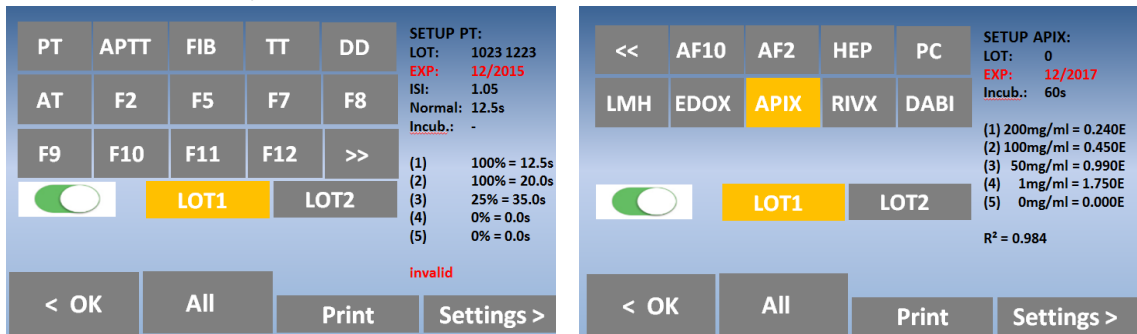


FIGURE 10: TEST SELECTION COATRON X PRO/TOP

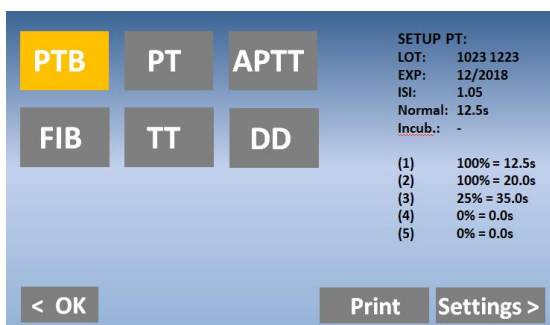


FIGURE 11: TEST SELECTION COATRON X ECO

| 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 | 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 testup. |
| 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. +++ = no clot reaction detected within runtime. |
| 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 = temperatue not 36 - 38°C. E = reagent expired. S = light intensity too low. |
| mOD | Current optical absorbance. A change of value > 50mOD indicates an ongoing clot reaction. |
| Timer | Current time of measurement. |

3.5 SYSTEM SETTINGS



Menu and functions depend on instrument version ECO or PRO/TOP !

Call: Homescreen/Menu button

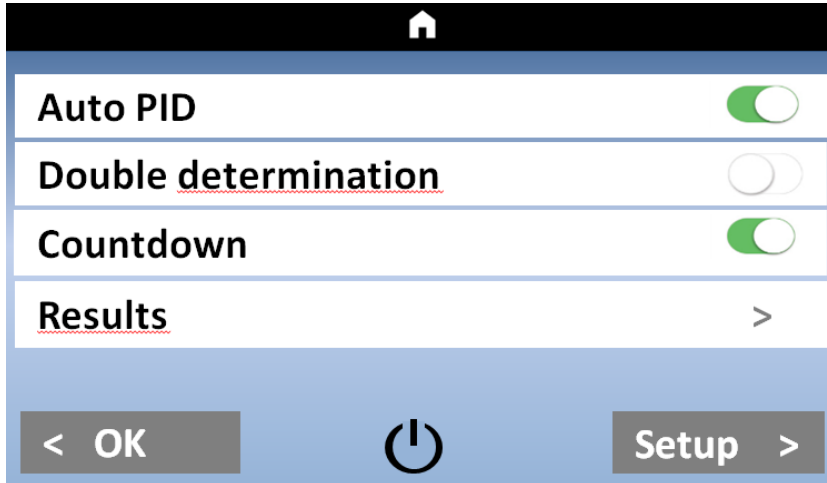


FIGURE 13: QUICKMENU COATRON X PRO/TOP

| Button | UI Element | Use Function |
|----------------------|-----------------------------|--|
| Auto PID | Toggle Auto PID | Enable/Disable the Auto PID feature. |
| Double determination | Toggle Double determination | Enable/Disable Double determination. |
| Countdown | Toggle Countdown | Switch between Stopwatch and Countdown mode. |
| Results | Results Button | Open the result history. |
| Setup | Setup Button | Open the system setup. |
| ⏻ | StandBy | Put the device into sleep mode. |
| OK / 🏠 | OK / Home Button | 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 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 | UI Element | Use Function |
|-----------------|----------------------|--|
| Date | 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 | Time < > | Set the system clock. Long Touch the time to reset to default. |
| Language | < > | Select the system language DE/EN/ESP/ITA/FR. |
| Mixer | < > | 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 | < > Temperature | 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 / | OK / Home | Return to the home screen. |
| Info | Info | Open system information. |

Call: Homescreen/Menu button

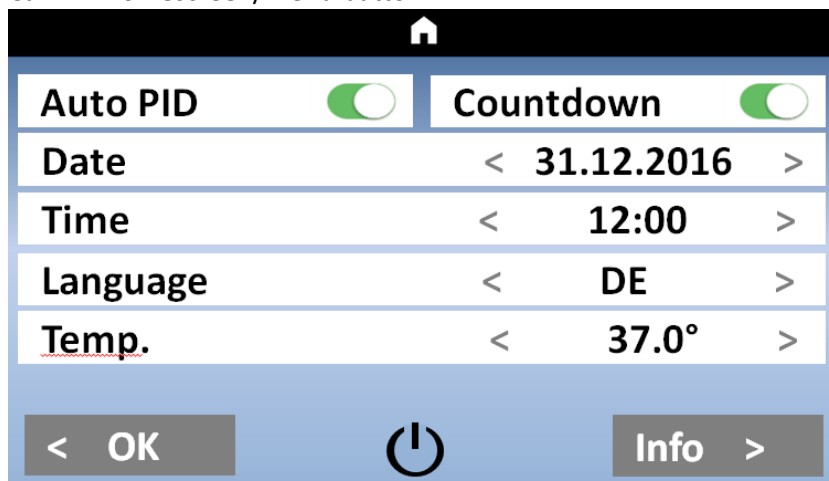


FIGURE 15: MENU / SYSTEM SETTINGS COATRON X ECO

| Setting/Buttons | UI Element | Use Function |
|----------------------|-----------------------------|--|
| Auto PID | Toggle Auto PID | Enable/Disable the Auto PID feature. |
| Double determination | Toggle Double determination | Enable/Disable Double determination. |
| Date | Date < > | Set system date, use long touch to scroll through the values faster. Touch the date to change between mm/dd/yyyy and dd.mm.yyyy mode. Long touch the date to reset to default. |
| Time | Time < > | Set the system clock. Long Touch the time to reset to default. |
| Language | < > | Select the system language DE/EN/ESP/ITA/FR. |
| Temp | < > Temperature | Correct the actual current temperature of the reagent block. Long touch the temperature value to reset to default. Detailed information can be read in chapter "Adjust temperature". |
| OK / | OK / Home | Return to the home screen. |
| | Sleep Button | Put the device into sleep mode. |
| Info | Info | Open system information. |

The functionality of the options on the setup screen for the **Coatron X Eco** are the same as for the **Coatron X Pro** and **Coatron X Top**. For detailed information about the available functions see the setup screen for the **Coatron X Pro** and **Coatron X Top**.

3.6 TEST SETTINGS

Call: Homescreen / Test button / Settings

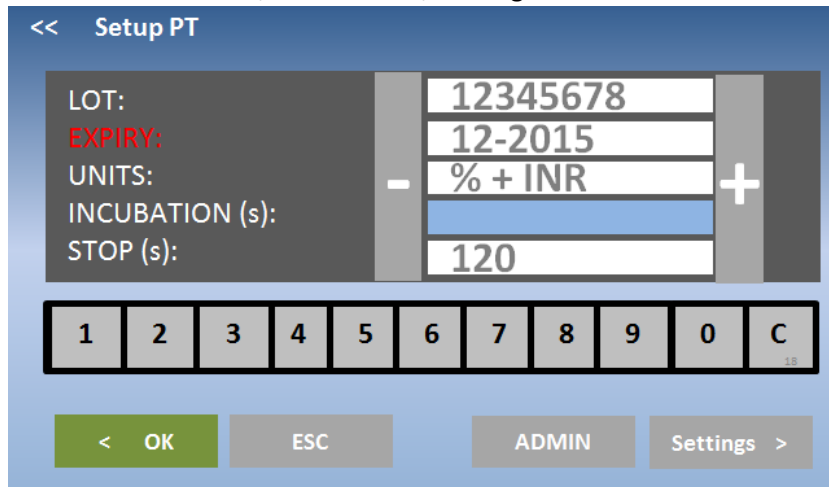


FIGURE 16: TEST SETTING 1

| 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 | Result Units field | Press the unit values to select the field. |
| 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:

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

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 break measurement and report “+++” (no clot detect)

Call: Homescreen / Test button / Settings / Settings

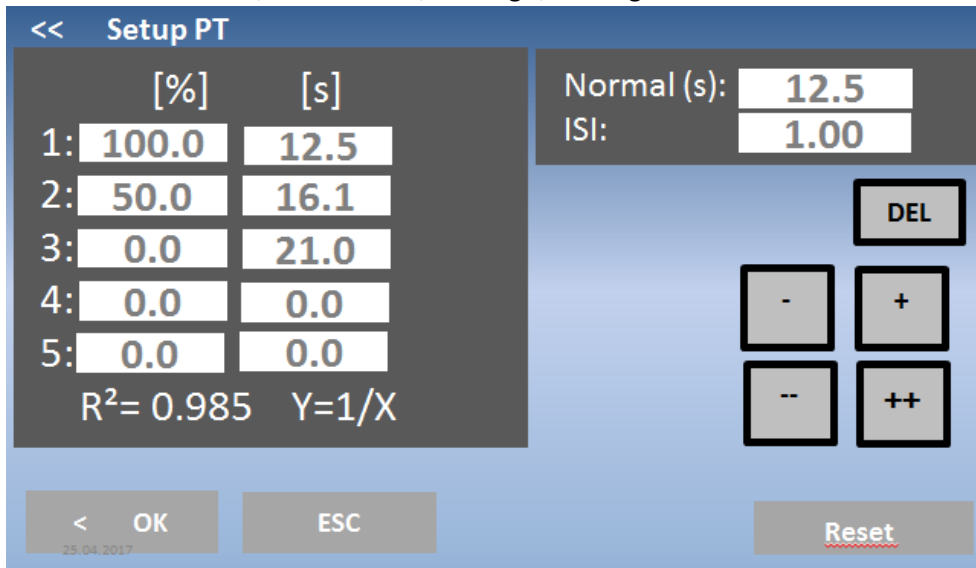


FIGURE 17: TEST SETTING 2

| 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 |
| Delete | DEL | Delete the selected value. |
| Reset | Reset | Reset all values to default. |
| 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



Menu not available for version ECO

Call: Homescreen / Menu / Results

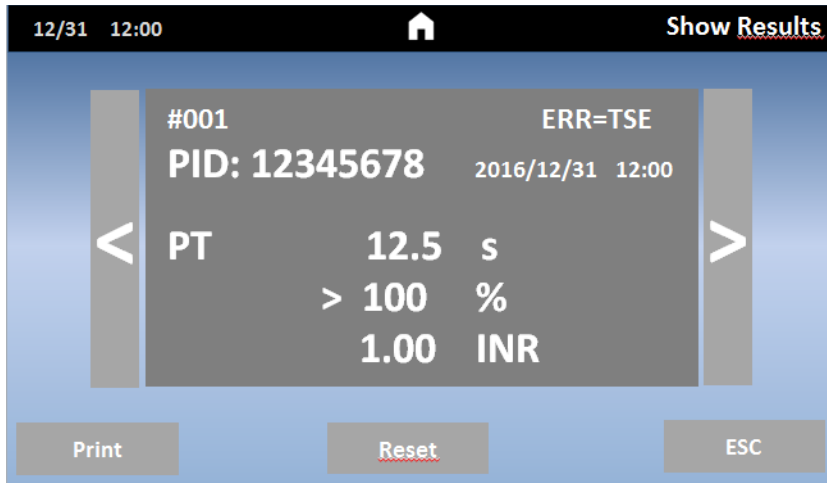


FIGURE 18: REVIEW RESULTS COATRON X PRO/TOP

| Setting/Buttons | UI Element | Use Function |
|------------------|------------|--|
| Result selection | <, > | Navigate the results. |
| Print result | Print | Print the shown result. |
| Reset view | Reset | Reset the result view to most recent result. |
| ESC | ESC | Exit screen. |

The result review screen shows the last 200 measurements made with the device. The most recent result is shown first. If the result history exceeds 200 values, the oldest measurement result is overwritten.

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 "OPTIC-1" 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.

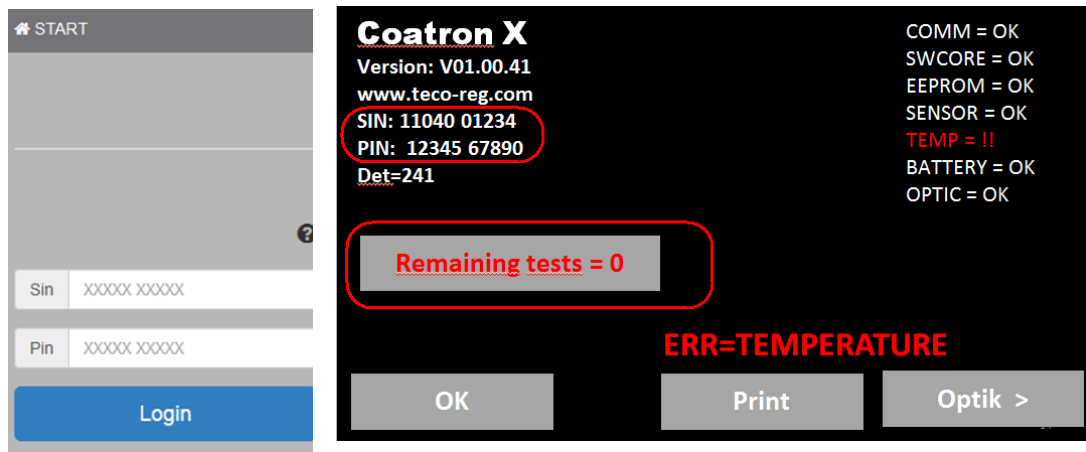
How to calibrate a FIB

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

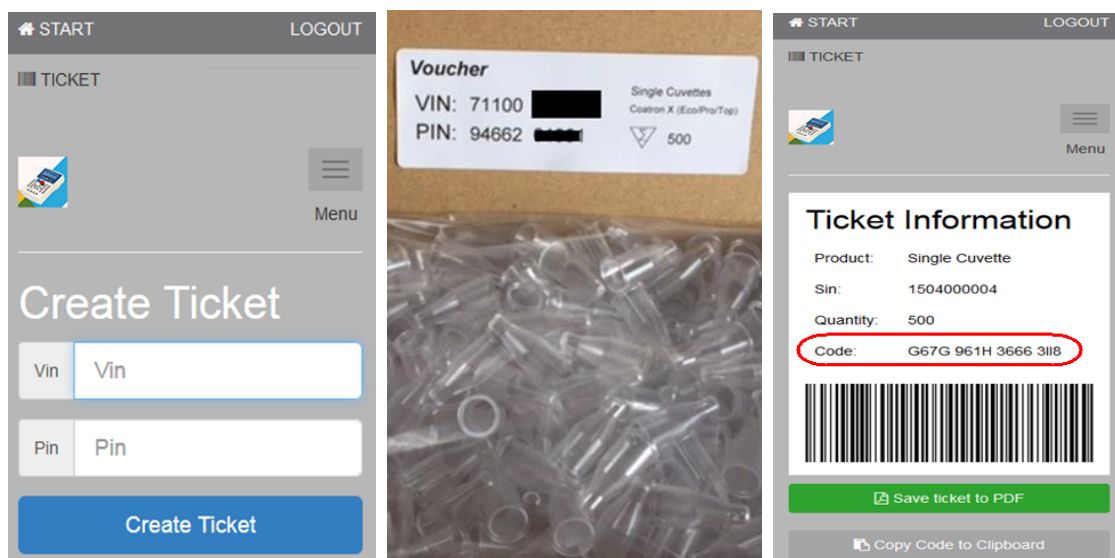
webpage: www.teco-reg.com



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



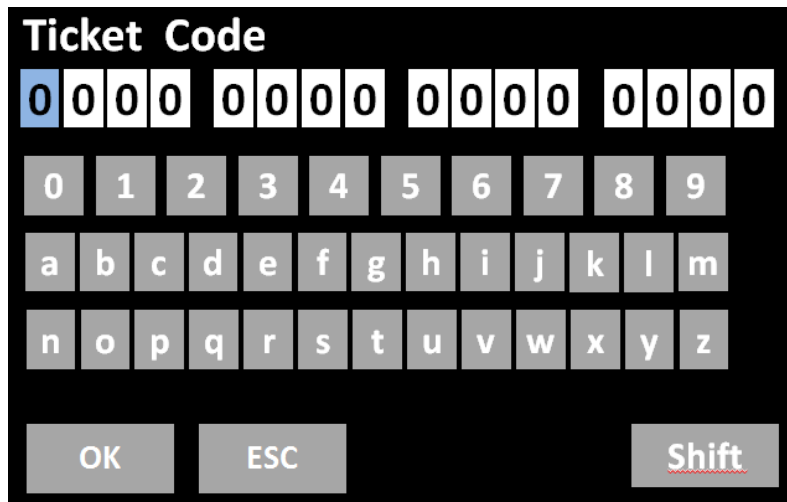
Enter VIN and PIN
of voucher

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

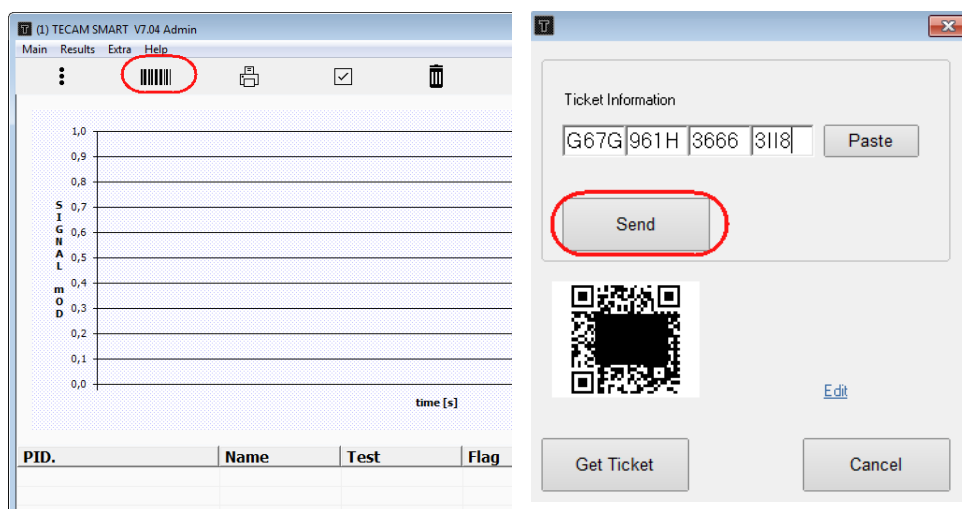


FIGURE 22: TICKET SYSTEM, TECAM SMART

- 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

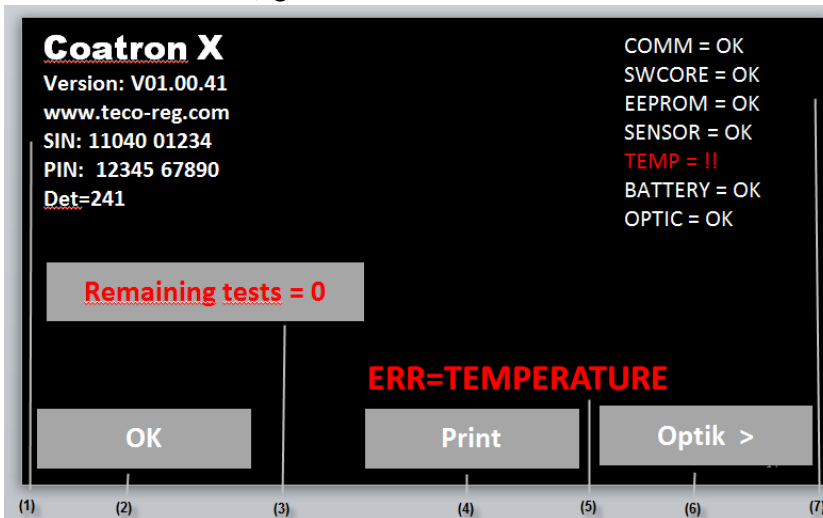


FIGURE 23: SYSTEM INFORMATION

| 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. How to do – see next chapter.

ERR messages:

| | |
|---|--|
| COMM= communication to LIS | SWCORE = software memory overflow |
| EEPROM= EEPROM/memory error | SENSOR = temperature sensor |
| TEMP= temperature not 36-38°C | BATTERY = CR2023 on mainboard below 3V |
| OPTIC= optical system out of range | RED =system not ready to measure |
| YELLOW =system ready to measure, minor problems | |

6.2 OPTIC CHECK

Call: Homescreen / green or red LED / Optic

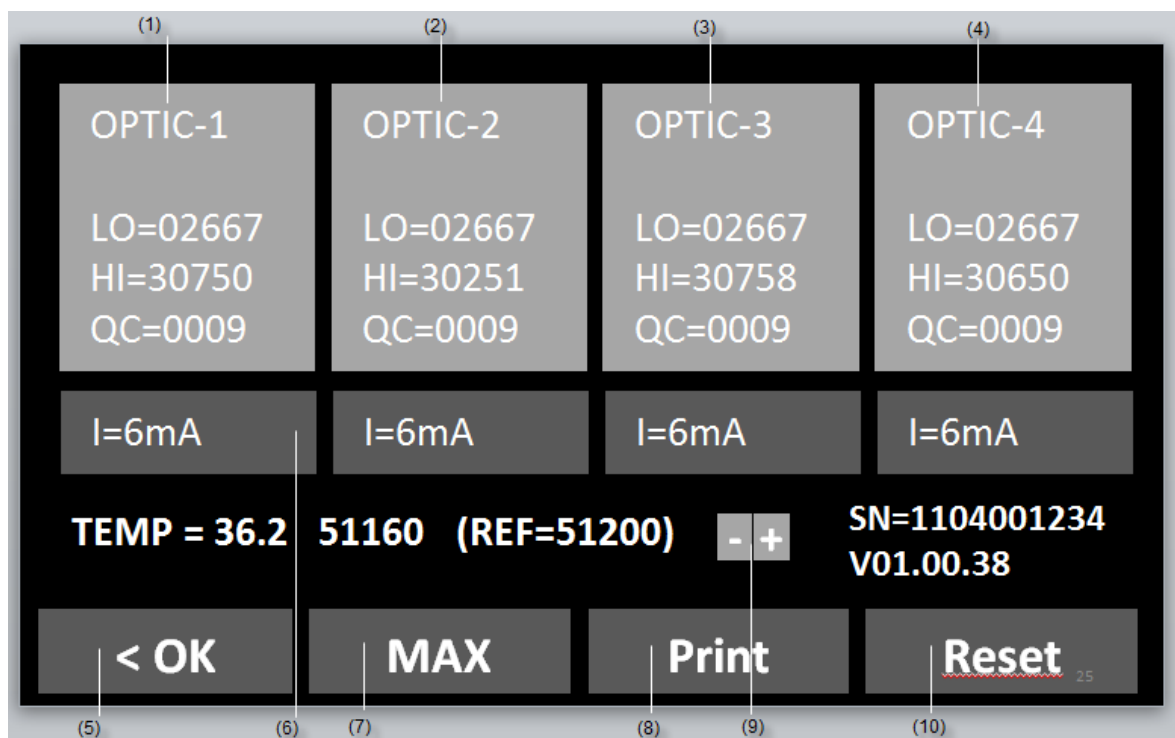


FIGURE 24: OPTIC CHECK

| 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 | not [28000 – 30900] | 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 |

*further troubleshooting can be read in chapter "Elimination of malfunctions"

6.3 SYSTEM REPORT

Call: Homescreen / green or red LED / Print

| SYSTEM REPORT | | | | |
|---------------|--------------------------------|----|----|----|
| 22.08.2017 | | | | |
| System: | Coatron X | | | |
| Version: | V1.01.42 | | | |
| SIN : | 01040 01234 | | | |
| PIN: | 12345 67890 | | | |
| TEMP: | 37.0°C 50981 (target=50992) | | | |
| Optic: | | | | |
| Lo | Hi | mA | Qc | |
| ----- | | | | |
| 1:2698 | 28822 | 5 | 6 | OK |
| 2:2698 | 29822 | 6 | 3 | OK |
| 3:2698 | 30822 | 7 | 1 | OK |
| 4:2698 | 29822 | 6 | 0 | OK |
| PT= | 26 | | | |
| aPTT= | 8 | | | |
| FIB= | 17 | | | |
| DD= | 0 | | | |
| AT= | 0 | | | |
| TOTAL | 101 | | | |

Date of report

name of system

software version

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 OVERVIEW OF MAINBOARD

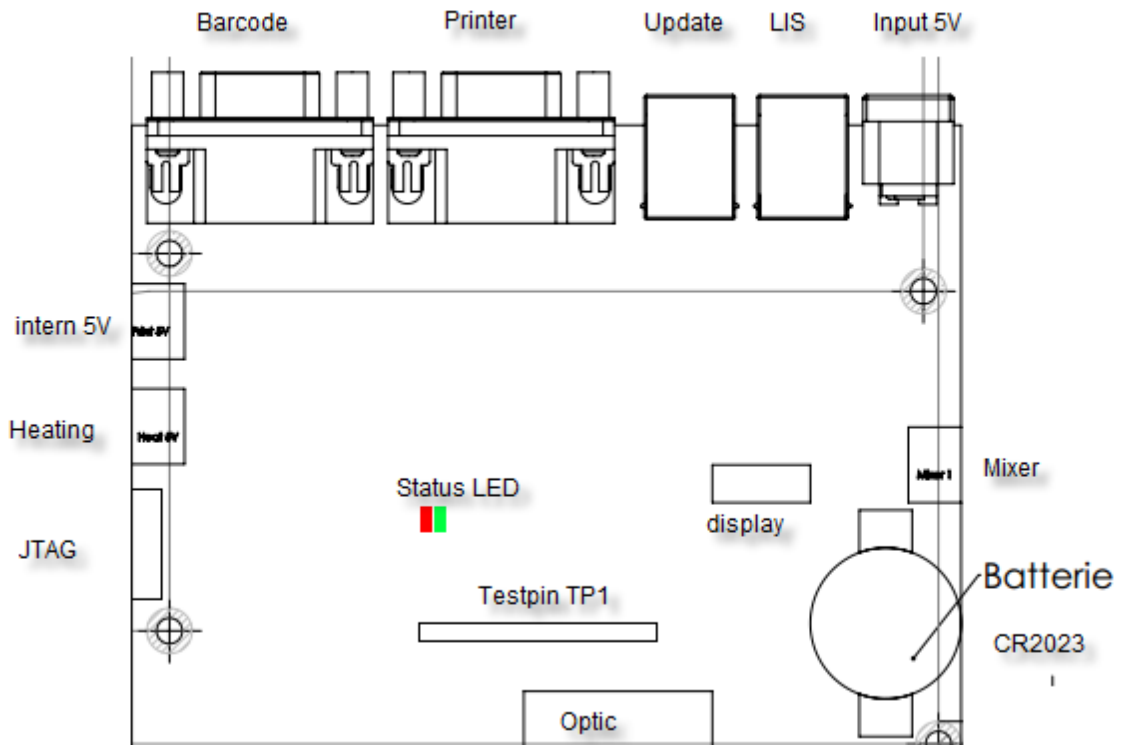


FIGURE 25: MAINBOARD

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

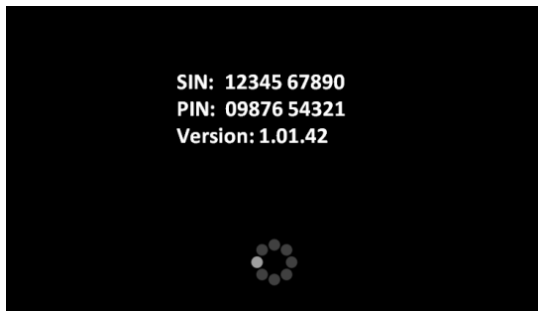
Status LED:

- | | |
|------------------|-----------------------------------|
| green, permanent | = everything OK |
| red, permanent | = EEPROM error |
| green, blink | = Battery error |
| red, blink | = Temp sensor/Optic not connected |

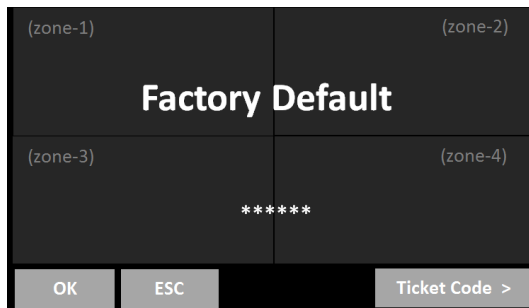
7. HIDDEN FUNCTIONS

7.1 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"

7.2 LOGIN AS ADMIN

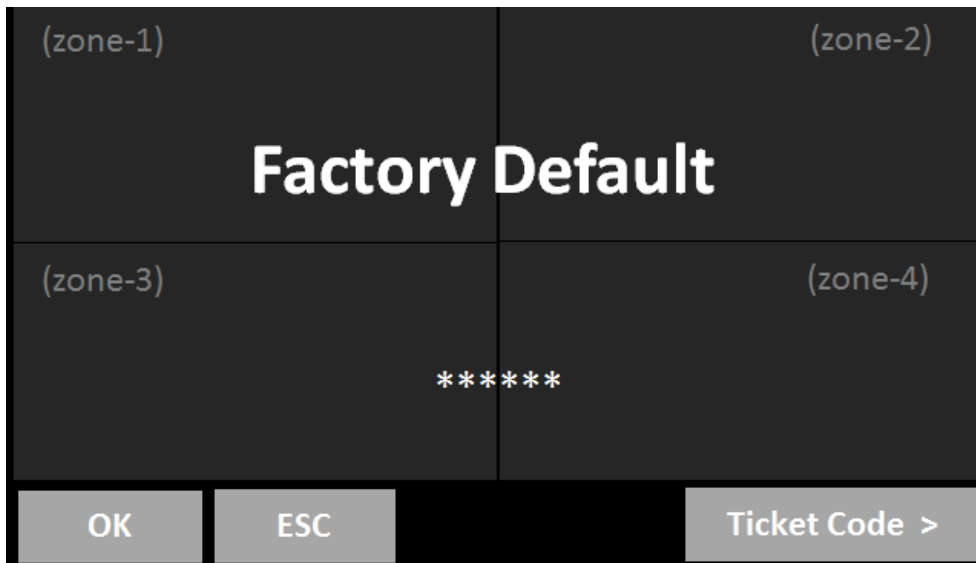


FIGURE 26: ADMIN LOGIN

1. Break welcome screen: Long press on spinner icon
2. Touch alternative: zone 1, 2, 1, 2, 1, 2

As admin following functions are enabled:

- Change test protocol (see next chapter)

7.3 CHANGE TEST PROTOCOL

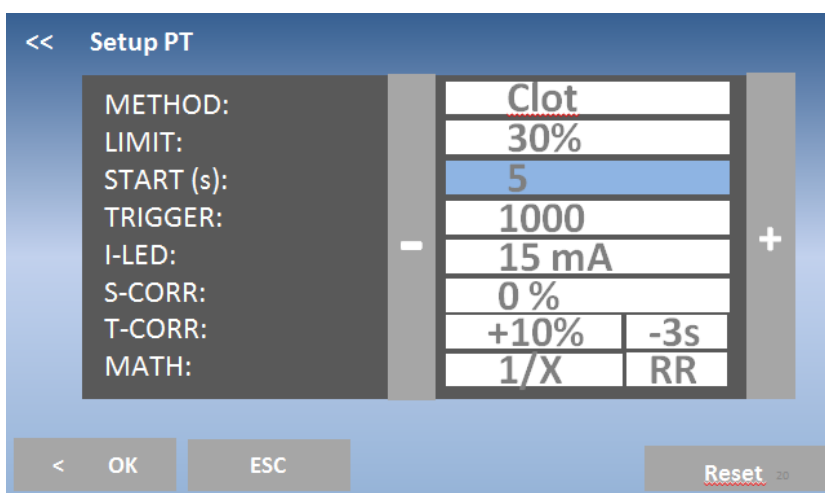


FIGURE 27: TEST PROTOCOL

| Setting | Select | Function |
|-----------------------|-------------------------------|--|
| METHOD | CLOT/CHROM | Clot = clotting assay Chrom = chromogenic or immunturbimetric test |
| Limit | CLOT method: 30-70% | Definition of clotting time 30% =shorter results, close to start of reaction 70% =longer results, close to end of reaction |
| | CHROM method: 25mE – 500mE | Definition of signal inlinearity or high dose Example: Signals more then 50mE of endpoint are D-Dimer positives. |
| Start (s) | 3-255s | Deadtime = First point of detection. |
| Autostart/ Trigger | 100 – 5000 | Sensitivity of autostart 100 = very sensitive. Risk of self start 5000 = very insensitive. Risk of no start |
| I-LED | 3-42 mA | Initial LED power during start of test. Very clear tests like FIB require just 5-10mA Very turbid tests like DD require 15-25mA The best LED power is set automatically during measurement. The initial signal isrequired to avoid adjustments. |
| S-Corr | + -200% | Mathematically correction of signal 0% = no correction 100%= signal doubled Can be helpful, if systems measure false short or prolonged clotting time. |
| T-Corr | + -70% + - 15s | Clotting time correction Eg. T-Corr=+20% - 3s, Result = 10s is corrected to 12s - 3s= 9s. Can be helpful to improve correlation to competitors or golden standard |
| Math | LIN, 1/X, logX,LogXY | interpolation between calibration points |
| | POINT/LINE | point to point interpolation or regression line, |

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 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 nee 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 |

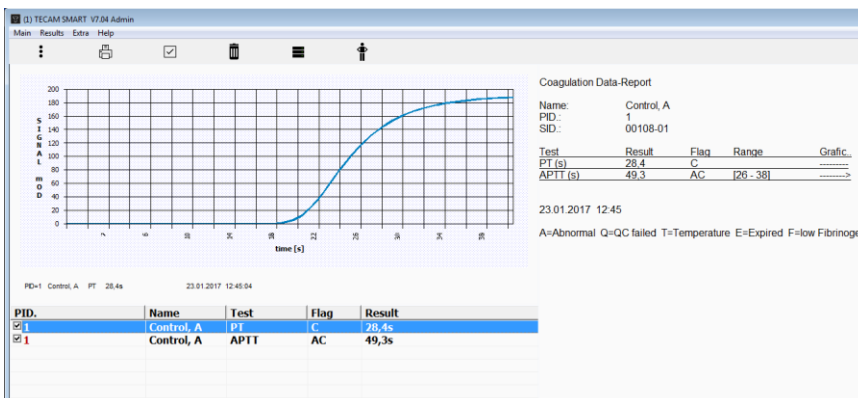


FIGURE 28: TECAM SMART

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. Bacillol®AF)
- Decontaminate working area. Don't apply liquid on display.

9.3 REGULAR MAINTENANCE

- No maintenance required

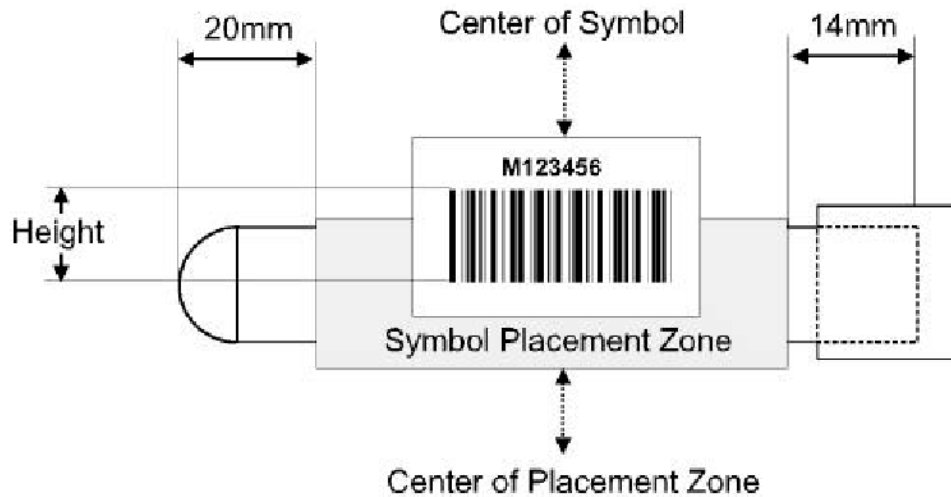
10. ELIMINATION OF MALFUNCTIONS

| 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 |

11. APPENDIX

11.1 BARCODE GUIDELINE



Specification of label:

| | |
|----------------------|---|
| - Label length: | 50 – 70 mm |
| - Label height: | 20 - 30 mm |
| - Barcode length: | 40 – 60 mm |
| - Barcode height: | 10 - 20 mm |
| - Quiet zone: | >5mm |
| - Resolution/module: | 5 -20mils (0.2 – 0.5mm) |
| - Ratio: | min. 1:2,5 to 1:3 (two dimensional codes) |
| - Quality | Level A or B according to ANSI X3.192 -1990 |

Accepted codes:

| | |
|-------------------|--|
| - Code 128 | 3 – 16 characters, use checksum without show |
| - EAN 128 | 3 – 13 characters, use checksum without show |
| - Code 39 | 4 – 13 characters, no checksum |
| - Code 93 | 4 – 13 characters, no checksum |
| - 2/5 interleaved | 8 - 12 characters, no checksum |

11.2 TECHNICAL DATA

| Analyzer | | |
|---|-----|---|
| Display | | capacitive touch sensitive TFT 4.3" 480x272 |
| Measurement system | | 1-4 independent measurement channels wavelength of LED 405 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 |
| Barcode scanner | | |
| CCD Scanner | | max. power = 120mA pulse period = 330/s wavelength = 617 nm best distance = 80 -120mm |
| Class B EN 55022:2010, EN 62471:2008 | | |
| Accepted codec | | EAN (8,13, 128), Code (39,93,128), Codabar, Interleaved 2 of 5 |
| Power supply | | |
| Nominal Input Voltage | | 100 – 240VAC, 47-63Hz |
| Maximal Input Current | | 0.7A rms |
| Output Power | | 5V DC, 3.3A |
| Batterie (maionboard) | | 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 |

12. INDEX

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