

TO WHOM IT MAY CONCERN

To any governmental departments,
registration and/or trade offices in MOLDOVA

Distribution Authorisation Letter

This letter confirms that **Sanmedico**
Mun. Chisinau
Str. Petricani 88/1 of. 10
Republica MOLDOVA

is the **legal, exclusive and sole** representative of **TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn NB, Germany**, for the territory of **MOLDOVA** only for all TECO products listed below. **Sanmedico** may participate in public and private tenders, providing sales to all TECO customers in the territory. We as manufacturer certify that our warranty is duly passed to the purchaser through **Sanmedico** for the price, delivery schedules and the specifications of the published literature, catalogues and fully covering the commodities offered.

Sanmedico will provide the following information to TECO GmbH when so required in relation to its market surveillance activities:

Reporting of incidents to TECO must take place within 3 working days
Serial number of the device, exact location of the device and the user.

Validity: January 1st, 2023 to December 31st, 2024


Termination: Confirmation ends automatically on Dec. 31st of 2024
and must be then renewed.

Products:

- Coatron M1 Semi-automated 1-channel Coagulometer (out of production)
 - Coatron M2 Semi-automated 2-channel Coagulometer (out of production)
 - Coatron X Eco Semi-automated 1-channel Coagulometer
 - Coatron X Pro Semi-automated 2-channel Coagulometer
 - Coatron X Top Semi-automated 4-channel Coagulometer
 - Coatron A4 Fully automated Coagulometer, 4 optic channels
 - Coatron A6 Fully automated Coagulometer, 6 optic channels
 - Coatron A6 plus Fully automated Coagulometer, 6 optic channels
 - Hemostasis Reagents Complete product line
- all instruments with complete accessory, consumables and spare parts

This document is signed in Neufahrn, Germany, on January 18th, 2023

TECO Medical Instruments Production+Trading GmbH


Christian Hoetzel



Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

Design, development, manufacturing, storage and sales of coagulation instruments and in-vitro-diagnostic reagents used in the hemostaseology and coagulation.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited



0001





KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#007/11-2021

Wir / We **TECO Medical Instruments Production and Trading GmbH**

Name des Herstellers / Manufacturer's *name*
Dieselstrasse 1, 84088 Neufahrn, Germany
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass die Produkte – IVD-Blutgerinnungsmessgeräte,
declare under our own responsibility, that the products – IVD Coagulation analyzers

Coatron A4

Bezeichnung, Typ oder Modellname / *name, type or model*

Alle anwendbaren Anforderungen der folgenden Richtlinien entsprechen:

1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 –"alle anderen Produkte"
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit
3. Richtlinie 2011/65/EU RoHS III

Weitere angewandte Normen:

4. Sicherheit: EN 61010-2-101:2002
5. Risikomanagement: DIN EN ISO 14971:2019
6. Informationen: EN ISO 18113-3:2011
7. Medizingeräte-Software
- Lebenszyklus-Prozesse: DIN EN 62304:2016

Standards and regulations applied:

1. *Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. *Directive 2014/30/EU on electromagnetic Compatibility*
3. *Directive 2011/65/EU RoHS III*

Further related standards:

4. *Safety: EN 61010-2-101:2002*
5. *Risikomanagement: DIN EN ISO 14971:2019*
6. *Information: EN ISO 18113-3:2011*
7. *Medical device software
- life-cycle processes: DIN EN 62304:2016*

Das QM-System des Herstellers ist zertifiziert nach:

EN ISO 13485:2016

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

Konformitätsbewertungsverfahren:

Gemäß Anhang III der Richtlinie 98/79/EG

Conformity assessment procedure:

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 11.11.2021
Neufahrn, November 11, 2021

Matthias Dieckmann
General Manager





**Medical Instruments
Production+Trading GmbH**
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CERTIFICATE OF TRAINING

Vitalie Goreacii

General manager of
Sanmedico
Chisinau
Republic of Moldava

have participated with success at the training session supervised
by TECO GmbH, Germany for following instruments:

Coatron A series

- **Installation**
- **Application**
- **General use, also in combination with TECAM**
- **Maintenance**
- **Troubleshooting**
- **After Sales Service**

Training details:

Supervisor: Chr. Baumgartner, Director RD of TECO
Device: Coatron A4 + A6, Inhouse Master Device
Place: Laboratories of TECO
Date: May 5th 2023



Dipl.-Ing. Univ. (TUM)
Christian Baumgartner
Director R&D

CERTIFICATE OF PERFORMANCE

Coatron A4	Coatron A6	Coatron A6 Plus
1.07.04a	1.03.04a	1.03.05a

Throughput samples/h ^{(1), (2)}			
PT	156	194	320
aPTT (INC=120s)	90	125	160
TT	110	182	320
FIB	100	148	250
DD	88	108	210
FDP	66	108	148
PT+aPTT+Fib	35	50	80
Clean=MIN Mode=BAT	28	35	60
Clean=MAX Mode=BAT	23	30	45
Clean=MAX Mode=ECO			
PT+aPTT+Fib+TT	27	39	61
PT+aPTT+Fib+TT+DD	21	29	47
PT+aPTT+Fib+TT+DD+FDP	16	23	38
Consumption of rinse tank 1.25l ⁽¹⁾			
best case ⁽²⁾	1800 tests	2200 tests	3000 tests
Mode=BAT ⁽³⁾	1100 tests	1300 tests	1800 tests
Mode=ECO ⁽³⁾	1600 tests	1800 tests	2200 tests
total volume in cuvette	150µL	75µL	72µL
Performance	precision C.V.	linearity of calibration	linear range
PT (s)	0,83%	-	5 – 600
aPTT (s)	2,76%	-	5 – 600
FIB (mg/dl)	2,73%	0,995	50 – 600
DD (ng/mL)	5,00%	0,99	50 – 3000
AT (%)	3,20%	0,998	15 – 125
interfering substances			
Hemoglobin	9.00 g/l	9.00 g/l	9.00 g/l
Bilirubin	40 mg/dl	40 mg/dl	40 mg/dl
Triglyceride	2500 mg/dl	2500 mg/dl	2500 mg/dl

⁽¹⁾ real clinical data depending strongly on the workflow and samples per run and can be 50% lower as assigned or even more

⁽²⁾ running fully loaded patient racks with test PT only in mode BAT and Clean=MIN

⁽³⁾ running 10samples with PT+aPTT+FIB in random access in CLEAN=MAX

13th March 2018



Christian Baumgartner

Research department of TECO GmbH

Coatron® A4

Fully automated Hemostasis Analyzer

Made in Germany
REF: 80 900 00



- ▶ Easy operation
- ▶ Multi languages
- ▶ Highly reliable
- ▶ Four channels
- ▶ Fully optical detection
- ▶ Clotting, chromogenic and immunturbidimetric methods
- ▶ Autosense optics to reduce interferences of Bilirubin and Hemoglobin
- ▶ Approved clotting algorithm with biphasic waveform analysis
- ▶ Batch and Random Access
- ▶ High throughput
- ▶ Emergency (STAT) mode
- ▶ Laser Barcode reader for samples and reagents
- ▶ Liquid Level sense
- ▶ Cap piercing
- ▶ Compact construction
- ▶ Operation as open or closed system

TECO

Innovation in Coagulation

Coatron® A4

Fully automated Hemostasis Analyzer



1 Keyboard

Numerical and function keys for easy controlling of the instrument, as well quick setup of all individual tests.

2 Graphic display

128 x 128 dot matrix
Blue backlight

3 Cuvette waste drawer

Removable waste drawer for fast removing of used cuvettes

4 Cuvette tower

For load of 45 cuvettes: enough for 180 tests, continuous loadable

5 Printer (back side)

Thermal printer for quick printout of results, system analysis, test setups etc.

6 Liquid handling

x-y-z robotic system with special Cap Piercing probe, Level sense. Autoskip function for empty reagent vials. Special clean solution and software program to avoid carry over from sample to sample, sample to reagent and reagent to reagent to.


TECAM PROLIS

For Microsoft Windows™ XP/Vista

Software for TECO Coatron® A4 Analyzer

- ▶ New features for Coatron® A4
- ▶ Intuitive and easy one click operation
- ▶ Database up to 1 Mio results
- ▶ Worklist management
- ▶ Bidirectional ASTM interface to LIMS
- ▶ Multi-lingual (Chinese+ Russian included)
- ▶ Reaction curve display
- ▶ Powerful filter and patient report engine
- ▶ QC with Levey-Jennings and Westgard rules

TECAM PROLIS is a perfect and user friendly tool to combine laboratory data management, quality control and research purpose in one. The Worklist management allows defining orders much faster and flexible then on the instrument itself. Powerful filter functions will help to create any report. Levey-Jennings graph and Westgard analysis are used for quality control monitoring. An ASTM interface is included, which allows to link over LAN network with the laboratory information system.

Coagulation Data-Report
 Thrombosis & Haemostasis Research Center
 Dieselstr.1, D-84088 Neufahrn, Germany
 tel: +49 8773 910010
 email: info@teco-medical.de

Test	Warning	Result	Range
APTT	08.05.2007 14:31:39 A	38,4s	[26-38s]
PT	08.05.2007 14:30:31 A	* 27,7s 11,6% 2,22 INR	[10-15s] [70-120%] [0,8-1,2INR]
TCT	08.05.2007 14:33:19 A	26,5s	[16-24s]

Create reports with a click. Powerful filter functions will help to select just specific results. (e.g. day report, report the last 30 days of patient xyz, report all D-Dimer results of last year which are positive)

PID	Name	Test	Result	Time	Date	Flag
001	PI Calibration	PT	15,6sec 74,3%	11.25.09	16.01.2005	*
002	PI Calibration	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
003	PI Calibration	PT	70,8sec 75,1%	11.25.09	16.01.2005	* (3)
004	PI Calibration	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
005	Normalised data	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
006	Abnormal	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
007	Abnormal	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
008	Abnormal	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	* (3)
009	SAC	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*
010	SAC	APTT	83,0sec 93,8mg/dL	11.25.09	16.01.2005	*

Receive results from instrument including the reaction curve which will help to validate before saving them into the database.

POS.	PID.	Name	PT	DFIB	APTT	FIB	AT	TT11	VT	DD	HEP
<input type="checkbox"/>	35	QC									
<input checked="" type="checkbox"/>	01	0002 Control-2	PT		APTT	FIB					
<input checked="" type="checkbox"/>	02	00602004 Akratou,John	PT		APTT						
<input checked="" type="checkbox"/>	03	00702004 Terzides	PT		APTT	FIB					
<input checked="" type="checkbox"/>	04	00732004 Triadafiou	PT		APTT	FIB					DD
<input checked="" type="checkbox"/>	05	00742004 Mourtzou	PT		APTT	FIB					
<input checked="" type="checkbox"/>	06	00752004 Xanthous	PT		APTT	FIB	AT				HEP
<input type="checkbox"/>	07										
<input type="checkbox"/>	08										
<input type="checkbox"/>	09										
<input type="checkbox"/>	10										
<input type="checkbox"/>	11										
<input type="checkbox"/>	12										
<input type="checkbox"/>	13										
<input type="checkbox"/>	14										
<input type="checkbox"/>	15										
<input type="checkbox"/>	16										
<input type="checkbox"/>	17										
<input type="checkbox"/>	18										
<input type="checkbox"/>	19										
<input type="checkbox"/>	20										
<input type="checkbox"/>	21										

Create or receive orders from LIMS and send them to instrument.

Statistical analysis

UCL: 14,4100
 Mean: 11,072000 - 10.05.2005
 LCL: 7,734000

Wetgard Rules
 1-2s OK
 1-3s OK
 2-2s OK
 2-3s OK
 R-4s OK
 R-5s OK
 R-6s OK
 R-7s OK
 R-8s OK
 R-9s OK
 R-10s OK
 R-11s OK
 R-12s OK
 R-13s OK
 R-14s OK
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 R-92s OK
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 R-95s OK
 R-96s OK
 R-97s OK
 R-98s OK
 R-99s OK
 R-100s OK

Results can be displayed in a Levey-Jennings graph and analysed with Westgard rules. This tool can be used for QC but also for powerful patient monitoring (e.g. last 30 PT of patient)

TECAM PROLIS

For Microsoft Windows™ XP/Vista

▶ Recommended system requirements:

Microsoft XP, CPU 1.5 GHZ, 1GB RAM, Graphic 1280x1024

▶ Support instruments

Coatron® A4 and OEM's

▶ Instrument Interface

Serial RS232, 115000 Baud, 8,1,N

Bidirectional for results, including reaction curve and orders.

▶ ASTM Interface

Protocol: ASTM E1381-94; E1394-97

Communication: TCP/IP (network, LAN)

Bidirectional for results, including reaction curve and orders.

▶ Intuitive handling

One click principle for data collection, filtering, reporting or QC

▶ Multi lingual

English, Spanish, Italian, Portuguese, Russian, Greek, Chinese, further languages possible.

▶ Database

Manage over 1 Mio results and patient information in one database.

▶ Data fields for:

Date, patient (Id, name, sex, birth, bed, station), test, results (s, %, INR), reaction curve, Flags, error, comment, reagent-LOT, patient-memo, analyser SN., ranges (QC + normal)

▶ Database functions:

Create, Switch, Backup, Compress, Import, Export, Replace or fill data

▶ Complete Traceability by one click

Review for Date, PID, Test, and QC by one click

▶ Reporting

Make reports by one click. Use multi-filter or presets to generate specific reports (e.g. show results of specific patient of all PT within the last 30 days)

▶ Worklist management

Create, load, save, repeat, receive and send. Positive patient identification by barcode validation. USB barcode scanner supported. Up to 3 different profiles. Max 8 tests per profile. Preset for up to 6 different QC samples.

▶ Flexible multi filter

Combine every data field:

PID=1234+ Date=today + Test=FIB + Result< 200mg/gL + Reagent LOT = 1234 + etc)

▶ Filter Presets:

Today; last 7, 15, 30, 180, 360 days; morning, afternoon; only QC etc.

▶ Statistical analyse for QC or patients

Filter any data (e.g. Patient XYZ, only PT, last 30days), and visualize them with Levey Jenning diagram with one click.

Analyse data with Westgard Multirules. Define QC or Patient ranges.

▶ Research

Curve analysis, Tecmoni transmission, Export data, grids, charts, curves to PDF, XLS, TXT or HTML file

▶ Tecmoni transmission

This tools allows to visualize all optic channels in real-time. It is perfect for enhanced curve analysis and used in many research laboratories. With Tecmoni the reaction curves can also sent back to instrument. Especially for developing new test application and instrument firmware, this will save a lot of reagent and time.

▶ Security

Operator can login as Administrator or user in order to control and manage the database with different access rights

▶ Online update



Innovation in Coagulation

Coatron® A4

Fully automated Hemostasis Analyzer

7 Pump/syringe

Maximum volume: 1000 µl
Minimum volume: 3 µL
Long life syringe
Easy to replace and maintain

8 Rinse container (back side)

Containing 1,25 Liter high quality rinse solution for flushing the probe after each pipette circle.

9 Reagent block

4 positions heated at 37°C
2 positions at room temp.
6 positions cooled
3 positions for prewarm

10 System block

5 positions heated at 37°C for Buffers, Clean solution and Flush position for the probe, inside and outside
Separate STAT position for immediate Emergency

11 Sample racks

2 racks with 12 positions each, suitable for most common primary tubes.
Every position have individual bar code for positive sample identification

12 Barcode

Laser Barcode Scanner for quick and accurate identification of all Common Barcodes

13 Liquid waste drawer

Contain container for collection liquid waste
Volume: 1,25 Liter max.

14 Trolley (Option)

For mobile usage and enlarged waste management (big box for used cuvettes and large container for liquid waste)
Lift-up plate for sample preparation (more work area)
Moveable plate for easy replacement of box and container
Additional drawer for accessories and spare parts

Special features of the Coatron® A4:

System

- ▶ Ultraviolet light (400 nm). The measurement amplification is adapted Photometric measurement principle with high-resolution 4-channel optics, automatically to the methods used. Extraneous and scattered light energy is absorbed.
- ▶ High-precision XYZ pipetting system with liquid level sensor
- ▶ Long living and flexible Cap Piercing needle for primary tubes such as BD Vacutainer® or Sarstedt Monovette®.
- ▶ Integrated ID-barcode reader
- ▶ Bi-directional Interface for PC-Link to LIS.
- ▶ Optional trolley to enlarge the waste management
- ▶ **Integrated graphical thermal printer**
- ▶ Heated and cooled positions for reagents
- ▶ Integrated drawers for consumables

Software

- ▶ Approved and highly accurate detection algorithm based on optical density. The clotting time is defined at the turning point of reaction.
- ▶ An intuitive TECO familiar graphical user interface with „Plug and Go“ feeling.
- ▶ Multi language dialogue. (English, German and other)
- ▶ Random access scheduler. Profiles can be performed as batch or selective.
- ▶ Positive sample identification (ID and rack position) either manual or with barcode scanner
- ▶ Fast and easy processing of STAT samples

- ▶ Free programmable test protocols to change or adapt new tests
- ▶ Calculation of activity %, INR, Ratio, g/L, mg/dL and more.
- ▶ Calibration curve can be identified with up to 6 points per test. The results can be calculated with regression line analysis or linear interpolation.
- ▶ Single or double determinations
- ▶ Simple firmware update

Special Functions

- ▶ Automatic plasma dilutions up to 1:100
- ▶ Automatic cleaning cycles
- ▶ Automatic test calibration routines
- ▶ Automatic quality control
- ▶ Automatic or manual printout
- ▶ Automatic test skip, if reagent run out.
- ▶ Quality control according to Westgard rules *
- ▶ Result traceability *
- ▶ Patient monitoring for long time periods *
- ▶ Reaction curve monitoring *

Economic

- ▶ Half volume procedures resulting in 50% cost savings.
- ▶ Reagent dead volume is below 300 µL
- ▶ Very economic consumption of rinse and cleaning solution.
- ▶ Cuvette with no mixing bars, etc.
- ▶ All critical system parameters are monitored and make the instrument nearly free of service.

Coatron® A4

Fully automated Hemostasis Analyzer



Tests on board:

PT
APTT
TT
Fibrinogen Clauss
Fibrinogen derived
Factor II
Factor V
Factor VII
Factor VIII
Factor IX
Factor X
Factor XI
Factor XII
Protein C
Protein S
LA Screen (DRVVT)
LA Confirm (DRVVT)
Activated Protein C resistance
Heparin
Antithrombin
D-Dimer

Calculated units

%, R, INR, mg/dl, µg/L

Technical specification

Dimension
85 x 60 x 70 cm

Weight
50 kg

Power input
90-240 Vac / 50-60 Hz

Ambient conditions
18°C – 30°C
20 to 80% RH.
no direct sunlight



Optional available

- ▶ Trolley (for enlarged waste management)
- ▶ Complete Cover protection
- ▶ TECAM PRO – Research, QC, and Patient management software
- ▶ TECAM PRO LIS - Research, QC and Patient management software with LIS Module

Delivery package

- 1 Coatron® A4
- 1 Power cord
- 100 Cuvettes, 4 pos/ea
- 10 Reagent container Ø 22,5
- 10 Reagent tubes Ø 13
- 10 Plasma tubes Ø 16
- 4 Magnetic stirrer
- 1 Rinse Solution, 1,25 L
- 1 Clean solution, 50 mL
- 1 Thermal paper roll
- 1 Waste container
- 1 Reagent adapter Ø 22,5
- 2 Plasma adapter Ø 16
- 1 Operation manual
- 1 CE Conformity declaration
- 1 Service CD
- 1 Download cable
- 1 Screw driver, small
- 1 Flat wrench, size 8



Innovation in Coagulation

TECO Medical Instruments,
Production + Trading GmbH

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Germany

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Email: info@teco-gmbh.com
Web: www.teco-gmbh.com

80 521 10 Cuvette block, (4pos/ea)

Information of use

The Cuvette block as general laboratory article is suitable to hold a reaction mixture for use in optical analyzers which are used in laboratories for in vitro diagnostic tests.

The cuvettes are ready for immediate use. They have unlimited shelf life if stored at 0 - 50°C.

Content

Product	Cuvette block	1000 pcs
Cat.No.	80 521 10	
Content	50 bundles (= 20 blocks 4 pcs.)	4000 det.

The Cuvettes can be used with Coatron A (1800) Analyzers.

Depending on configuration of IVD analyser instrument a cuvette "activation"-code could be necessary. In this case the box contains an appropriate Voucher with a VIN and PIN code to generate a ticket on the web-based registration page (www.teco-reg.com).

The ticket information (VIN/PIN) must be entered for the respective device to release the number of tests for this device only. The (VIN/PIN) can only be used once per unit.

Precautions and waste information

The Cuvette should only be used once in analyzers. To prevent contamination (sample/reagent), it is advised to avoid contact with skin and eyes. Suitable protective clothing and gloves are recommended.

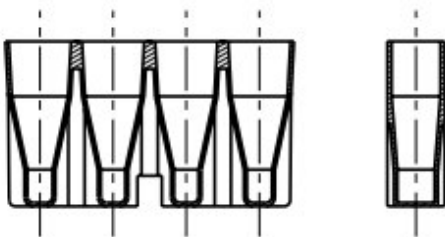
Please also note the disposal of components in accordance with local regulations for infectious material.

Material: pure, clear Polystyrol (PS)

Maximum volume per Single use Unit should be less than ~ 1000µL

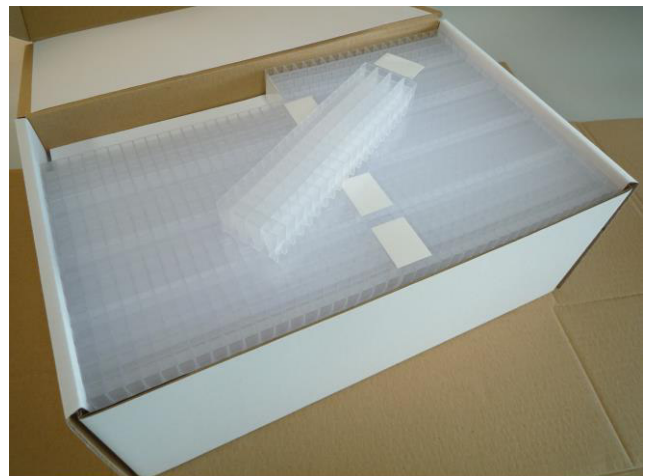
Minimum volume: 150 µL

Dimensions max.: (mm) L48 x H27 x W9,5



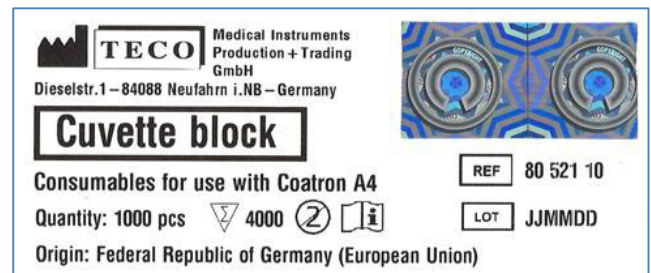
80 521 10

Example Picture of the package – 1000 Cuvettes blocks



Packaging:

1. Card Box, Dim.: (mm) 410 x 260 x 145
2. Labeling (see below)



Symbols key (if applicable):

Manufacturer	Lot. Number	Catalogue Number	Consult accompanying documents	Determination	Single use
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80 521 10 Cuvette block, (4pos/ea)

Gebrauchsinformation

Die Küvette als allgemeiner Laborartikel eignet sich zur Aufnahme eines Reaktionsgemisches zur Verwendung in optischen Analysegeräten, welche in Laboren für in-vitro-diagnostische Tests verwendet werden.

Die Küvetten sind sofort einsatzbereit. Sie sind unbegrenzt haltbar, wenn sie bei 0 - 50°C gelagert werden.

Inhalt

Product	Küvetten Block	1000 Stck.
Kat.Nr.	80 521 10	
Inhalt	50 Bündel (=20 Blöcke/ 4Stck.)	4000 Best.

Die Küvetten können mit dem voll-automatischen Koagulations System Coatron A4 (1800) verwendet werden.

Je nach Konfiguration des IVD-Analysegerätes kann ein Küvetten-"Aktivierungs"-Code erforderlich sein. In diesem Fall enthält die Box einen entsprechenden Voucher mit einem VIN- und PIN-Code, um ein Ticket auf der webbasierten Registrierungsseite (www.teco-reg.com) zu generieren.

Die Ticketinformationen (VIN/PIN) müssen für das jeweilige Gerät eingegeben werden, um die Anzahl der Tests nur für dieses Gerät freizugeben. Die (VIN/PIN) kann nur einmal pro Gerät verwendet werden.

Vorsichtsmaßnahmen und Entsorgungshinweise

Die Küvette sollte nur einmal im Analysegerät verwendet werden. Um eine Kontamination (Probe/Reagenz) zu vermeiden, ist es ratsam, den Kontakt mit Haut und Augen zu vermeiden. Es werden geeignete Schutzkleidung und Handschuhe empfohlen.

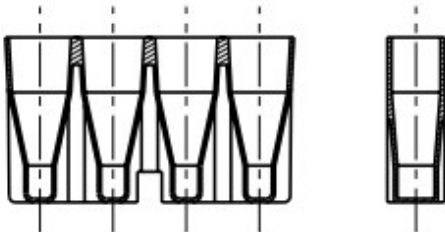
Bitte beachten Sie auch die Entsorgung der Komponenten in Übereinstimmung mit den örtlichen Vorschriften für infektiöses Material.

Material: pure, clear Polystyrol (PS)

Maximum volume per Single use Unit should be less than ~ 1000µL

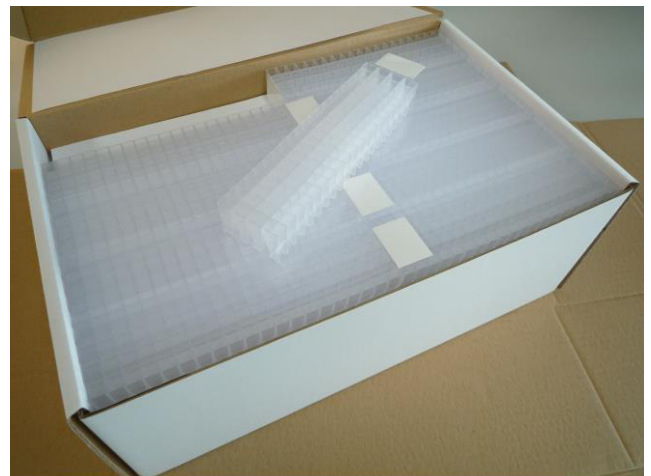
Minimum volume: 150 µL

Dimensions max.: (mm) L48 x H27 x W9,5



80 521 10

Beispielbild – Packung mit 1000 Küvetten Blöcken



Verpackung:

1. Karton, Maße: (mm) 410 x 260 x 145
2. Etikett – siehe unten

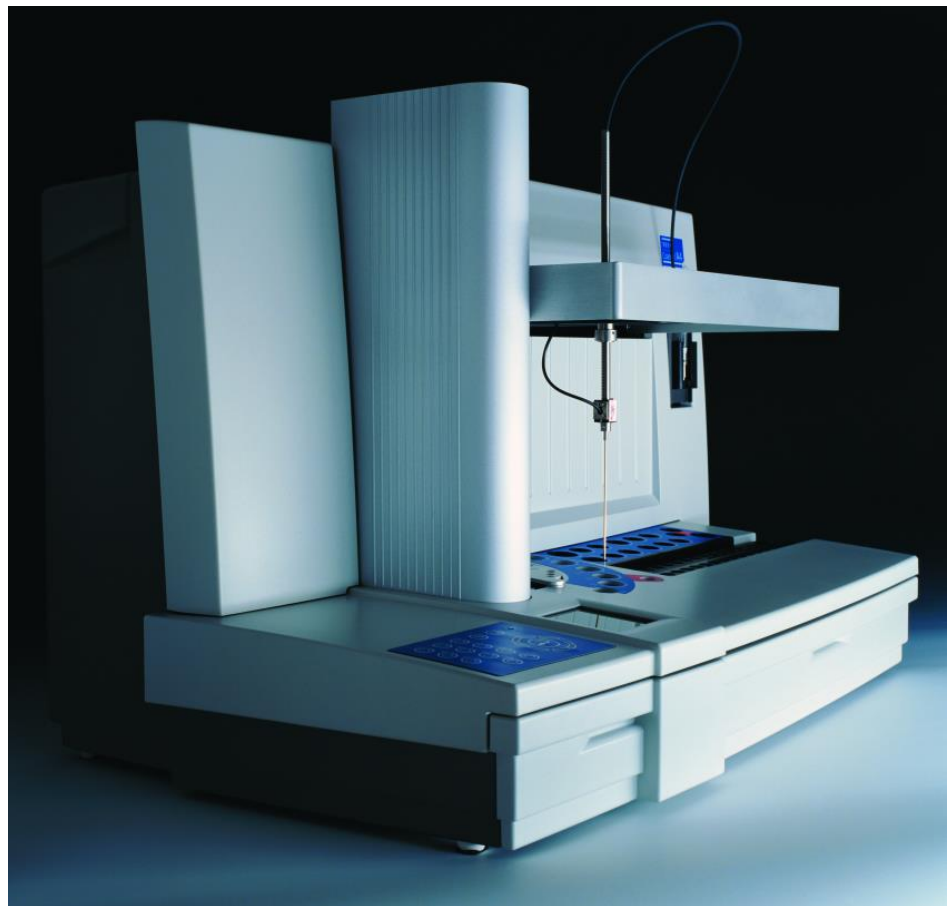
TECO Medical Instruments Production + Trading GmbH Dieselstr.1 – 84088 Neufahrn i.NB – Germany	
Consumables for use with Coatron A4	REF 80 521 10
Quantity: 1000 pcs	LOT JJMDD
Origin: Federal Republic of Germany (European Union)	

Symbole (wenn zutreffend):

Hersteller	LOT Chargen Nr.	REF Katalog Nummer	Begleitdokumente beachten	Anzahl Bestimmungen	Einmalgebrauch
------------	------------------------	---------------------------	---------------------------	---------------------	----------------

Coatron A4

Operator's Manual



Instrumentation and Reagents for *In-Vitro* Diagnostic use

Revision 22

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17	1.06.04 SW3	3/2012
18	1.06.06	2/2013
19	1.06.08SW2	12/2013
20	1.07.01SW3	6/2014
21	1.07.01SW4	12/2014
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The software for Teco GmbH products is the intellectual property of Teco GmbH, which company retains all rights to usage of the software. The purchaser of a COATRON A4 acquires rights of use for this software

Trademarks

COATRON A4 is a trademark of Teco GmbH. Other product names used in this Operator's Manual are trademarks of the respective companies.

Manufacturer

Instrument is produced by

TECO GmbH
 Dieselstrasse. 1
 D-84088 Neufahrn
 Germany

Phone: +49 (0)8773 70780-0
 Fax: +49 (0)8773 70780-29
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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.

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 important information and tips.
	Info	Describes reaction of COATRON A4 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 Safety information

1.2.1 Intended use

IVD

The **COATRON A4** 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.). The instrument has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the SAFETY WARNINGS. This manual contains instructions for professional qualified operators.



Do not use plasma with more than 25mg/dL Bilirubin (428µmol/l)
Do not use plasma with more than 1000mg/L Hemoglobin
Do not use plasma with more than 25 g/l Triglyceride (28.5 mmol/l)



Use only citrated plasma for sample analysis. Mix 9 parts of venous blood with 1 part 3.2% (0.105M) sodium citrate and centrifuge the mixture at 1500g x 15min. Use plasma within 4 hours.

1.2.2 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 A4. Prevent reagents from leaking into the Analyzer. Failure to do so may make expensive maintenance work necessary!



Never touch moving parts such as the measurement rotor or pipetting arm during device operation. Never try to pull a cuvette block out of the measurement rotor during test processing operation. Carry out control measurement runs at regular intervals to ensure that the Analyzer continues to function faultlessly.



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

1.2.3 Safety information for MATERIALS

**Important!**

Use only organic solvents where specified. The cuvettes are intended as single-use items only. Repeated use may result in false results due to contamination. Follow the instructions in the reagent package circulars. Incorrect handling may result in falsified results.

1.2.4 Safety information regarding risk of health

**Infectious Material**

Avoid direct contact with samples and sample residues in the used cuvettes.

Infectious material such as cuvette waste and liquid waste must be disposed in compliance with local regulations governing for infectious materials.

Wear medical infection grade protective gloves for all cleaning and maintenance works involving potential contact with infectious liquids and use each pair of gloves once only. Use a hand disinfectant product, e.g. Sterilium[®], to disinfect your hands after completion of the work.

NOTICE

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective

instrument which may have come into contact with such samples must equally be considered as potentially infectious. The

„BIOHAZARD“ warning label must be affixed to instrument prior to first use with biological material!

**Laser Radiation**

The internal barcode scanner is assigned to laserclass 2 – EN60825-1:2007.

Avoid direct eye exposure

max. power = 1.7 mW pulse period = 420 μs wavelength = 655 nm

1.2.5 Safety information for cleaning, maintenance and servicing

**About authorized service !**

Carry out only the maintenance, repair and replacement measures listed in this Operator's Manual. Improper manipulation of the device will void the manufacturer's liability obligations and may make service calls necessary, payment of which is 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

**About 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 "7 Cleaning and maintenance" and should be performed by authorised well-trained personnel only, observing all necessary safety precautions

**Cleaning certificate required !**

Instruments to be returned have to be accompanied by a decontamination certificate completed 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 servicing centre, or from authority's interventions.






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.

1.2.6 Electrical safety

	<p>Precautions:</p> <ul style="list-style-type: none"> ▪ Avoid spilled liquids into system. But in case disconnect system from power and clean and dry all contaminated parts. ▪ Remove power cord before open 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 so doing could expose parts carrying electric current. ▪ Make sure surfaces such as the floor and workbench are not moist while work is being done on the device. ▪ Check electrical equipment regularly. Defective leads or socket must be replaced without delay.
	<p>Connect to power:</p> <p>Instrument is classified to Class-1 (IEC) and must therefore be reliably earthed and professionally installed in accordance with the prevailing electrical wiring regulations and the safety standards covered herein.</p> <ul style="list-style-type: none"> ▪ Use only three wire power cord. ▪ Make sure the operating voltage setting is correct before connecting the device to the power mains. ▪ Ensure at least 20cm space to power socket and instrument power ON/OFF switch for easy and quick access to power cord during operation.
	<p>Disconnect from power:</p> <ul style="list-style-type: none"> ▪ Unplug power cord from wall socket/UPS or from instrument power-in

2. Installation of the COATRON A4



Initial startup of the COATRON A4 is carried out by the authorized Customer Service of the dealer. A protocol is kept of the first installation which is then sent in to the manufacturer as a basis for processing guarantee claims.

Procedures of first installation:

- Unbox and place instrument in conformity with the laboratory requirements (see below)
- Remove transport retainer
- Switch on
- Install Rinse tank + Rinse waste container
- Install print paper
- Install cuvette + cuvette waste drawer

2.1 Scope of delivery

The scope of delivery can be different from customer to customer and must be read in the document "List of accessories", which is separately included to the operation manual on the first page.

2.2 Laboratory Requirement

- Power Input: 85 – 264VAC; 45-60Hz ; Class-1 socket (connected to earth)
- Ambient temperature must be 15-30°C
- Rel. humidity < 70%
- Altitude 0 - 3000m
- A stable, flat surface free of vibrations. Recommended workspace 80x150cm. On rearside a minimum space of 20cm is required.
- No direct sunlight
- Avoid ionizing air conditioner or circulating air
- Surroundings free of moisture and dust

2.3 Unpacking the COATRON A4

Following receipt of the shipment, please inspect the packaging of the COATRON A4 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. Inspect the COATRON A4 and accessories for any damage. Report any damage found to the dealer without delay. Even if the packaging appears undamaged, check the analyzer and accessories for any transport damage, caused for example by impact, dropping, etc. during transport.



Keep the original packaging material for purposes of later transport

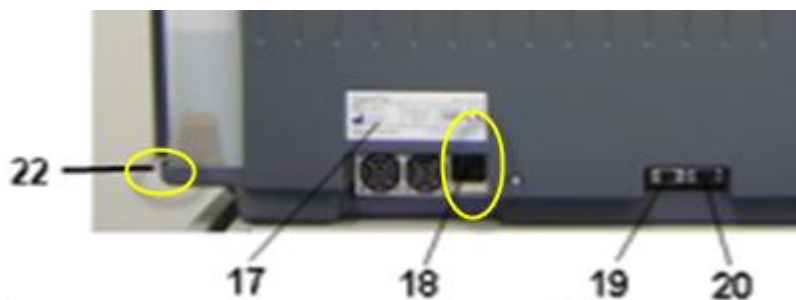
2.4 Removal of the transport retainer elements

1. Remove the tape strips on the printer shaft.
2. Remove the 3 cable binders on the pipetting arm.
3. Remove the foam element between the pipetting arm and protective bar

2.5 Switching ON and off the COATRON A4

Switching the COATRON A4 on

1. Make sure the COATRON A4 is connected to the power mains.
2. Check for sufficient rinsing and cleaning fluid levels.
3. Set main switch to on. See rear side, location #18
4. Set standby switch to on. See right side, location #22



Location of power and standby switch Main screen

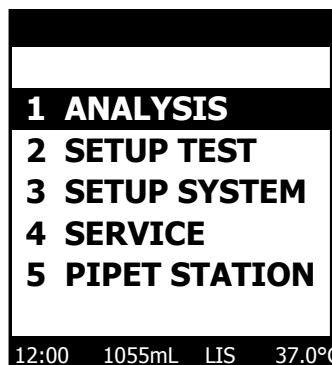
The following screen appear in this order after the COATRON A4 is switched on.

Coatron A4	Name of instrument
V6.07.02	Version of firmware
SN-12345	Serialnumber
Service: 100000	Tests until next service
CUVETTES:1	Activated cuvettes
RINSE: 0	Activated rinse tank
REAGENT: CLOSE	Reagent system is closed



There is no information about cuvette or Rinse or reagent , if system is configured as "OPEN DEVICE". Please contact local distributor for more information about open or closed system.

At the end of the initialization phase, the main screen appears:



Main screen

Time= 12:00
Rinse installed = 1055mL
LIS = online
Temperature at cuvette= 37°C

After about 15 min. of warm-up time (depending on the ambient temperature), the lighting up of the LED (Temp.) on the keypad indicates the system is ready to make measurements.

Switching the COATRON A4 off:

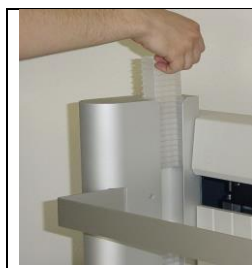
For normal shutdown at the end of the day and for changing the pipetting needle, rinsing solution tank and syringe, switch off the COATRON A4 with the standby switch on the right side of the housing. This will shut off all power-consuming components of the COATRON A4 except the ventilator. For longer interruptions in operation such as weekends, holiday periods and service activities such as cleaning and maintenance, switch off the mains power switch as well.



Switching off the device deletes all measurement data. Backup the data as required by means of manual printout or manual transmission to the host

Never switch off the system while processing a worklist to avoid clogging the needle tip with coagulation residues.

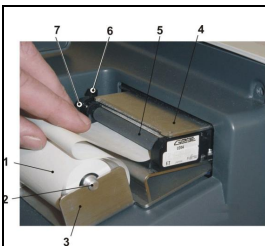
2.6 Installation of Components



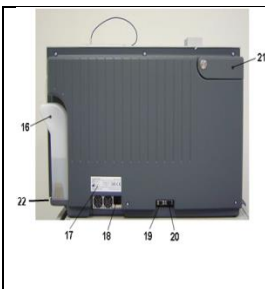
1. Remove a strip of cuvettes from the package.
2. Shift the cuvettes as shown from above in the guide groove back into the cuvette tower.
3. Remove the tape off the cuvettes.



4. Place a new Rinse tank as shown
5. Insert the tube completely
6. Fill a reagent container (15 ml) with cleaning solution and place it into position CLEAN



7. Open the print cover
8. Feed paper. Device has autofeed function.
9. Set printer to online by shift on arresting lever in the direction of the front of the housing.



10. Plug download cable into left port (19)
11. Plug in power cord (18)
12. Connect download cable with PC computer
13. Move power switch to ON. (right of 18)
14. Move standby switch to ON (22).
15. After Bootup start TECAM software

2.7 Installation of TECAM software

TECAM software is a powerful enhancement of the Coatron A4 and allows very easy and flexible to generate orders (including sample continuous loading). Results can be reported including the reaction curve and administrate in a database. For further information read the online manual of TECAM software

System requirement

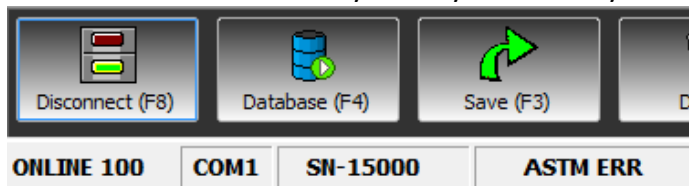
- Operating system: Microsoft Windows XP or 7 32Bit
- 100 MB free hard-disk space
- Grafik: 1280x1024 Pixel
- **Interface: RS232** Sub-D9 (if not supported , use USB convertor, commport must be set between com1 - com15)
- Cable: 2x Female Sub D9, crosslink. Pin 2 to 3; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected.

Install:

1. Link instrument left RS232 port to
2. Check PC comport number (it must be between 1 to 15)
3. Start "SETUP.EXE" from the CD. The Setup will install Smart ,PRO or PROLIS and all required driver for database access.
4. Enter fingerprint and activation code

Run TECAM:

1. Switch on and bootup instrument
2. Start TECAM and enter administrator password (default = blank) or enter "Blank" to login as a restricted user
3. Tecam search automatically for any available system and connects.



TECAM is linked to system "15000" over com port 1. No ASTM is active

4. Enter administrator password (default = blank) or enter "Blank" to login as a restricted user



TECAM license can be installed on any PC, but is locked to the serial number of instrument

3. Description of the COATRON A4

3.1 Short introduction

The Coatron A4 is a fully automated, stand alone “State of Art” analyzer for the fast and flexible coagulation diagnostic. It is equipped with four optical channels and offers clotting, chromogenic and immunological testing in random access mode as well as fast processing of STAT samples. All sample dilutions and assay calibration are performed automatically. ID-barcode scanner is on board. CAP Piercing is supported for any primary tube system. The analyzer is also focused on a minimum consumption of consumables and reagents, which makes the analyzer very cost effective. The nearly zero service requirements will ensure a long living device by a minimum of service costs.

Optional the analyser can be linked to powerful LIMS software to give exceptional features like unlimited result traceability by an one click report engine or a unique quality control system with Levey Jennings chart and Westgard rules



Use only citrate plasma for sample analysis. Mix 9 parts of venous blood with 1 part 3.2% (0.105M) sodium citrate and centrifuge the mixture at 1500g x 15min. Use plasma within 4 hours.



Do not use plasma with more than 25mg/dL Bilirubin concentration.
Do not use plasma with more than 1000mg/L Hemoglobin concentration.

Based on the optical measurement principle used by this device (transmitted light turbidimetry) with ultraviolet light, a number of coagulation and fibrinolysis parameters can be determined, for example

- Prothrombin time (Quick or Owrens)
- Activated partial thromboplastin time (APTT)
- Fibrinogen (FIB) (Clauss) & derived PT (DFIB)
- Thrombin time (TT)
- Single factor measurements
- Protein C (PC)
- Protein S (PS)
- Lupus Anticoagulant (LA)
- Activated protein C resistance (APCR)
- Heparin (chromogenic)
- ATIII (chromogenic)
- D-dimers (immunoturbidimetric)

Special features:

System

- Ultraviolet light (400 nm). The measurement amplification is adapted to photometric measurement principle with high-resolution 4-channel optics and automatic amplification to any method. Extraneous and scattered light energy is absorbed.
- High-precision XYZ pipetting system with liquid level sensor
- Long living and flexible Cap Piercing needle for primary tubes such as BD Vacutainer® or Sarstedt Monovette®.
- Integrated ID-barcode reader
- Bi-directional ASTM Interface for PC-Link to LIS.*
- Optional trolley to enlarge the waste management
- Integrated graphical thermal printer
- Heated and cooled positions for reagents
- Integrated drawers for consumables

Software

- Approved and highly accurate detection algorithm based on optical density. The clotting time is defined at the turning point of reaction.
- An intuitive TECO GMBH familiar graphical user interface with “Plug And Go” feeling.
- Multi language dialogue. (english , german, spanish, italian)
- Random access scheduler. Profiles can be performed as batch or selective.
- Positive sample identification (ID and rack position) either manual or with barcode scanner
- Fast and easy processing of STAT samples
- Free programmable test protocols to change or adapt new tests
- Calculation of activity %, INR, ratio, g/L , mg/dL , and more.
- Calibration curve can be identified with up to 6 points per test. The results can be calculated with regression line analysis or linear interpolation.
- Single or double determinations
- Simple firmware update
- ASTM interface to link to any LIS *

Special Functions

- Automatic plasma dilutions upto 1:100
- Automatic cleaning cycles
- Automatic test calibration routines
- Automatic quality control
- Automatic or manual printout
- Automatic test skip, if reagent run out.
- Automatic reflex testing for “+++2 results
- Unlimited result management including also reaction curve *
- Quality control according to Westgard rules *
- Result traceability *
- Patient monitoring for long time periods *

Economic

- Half volume procedures resulting in 50% cost savings.
- Reagent dead volume is below 300 µL
- Very economic consumption of Rinse and cleaning solution.
(1L Rinse ~ 1000 det. ; 15mL cleaner is enough for a day work)
- Cuvette with no mixing bars, etc.
- All critical system parameters are monitored and make the instrument nearly free of service.

* only the TECAM PRO software

3.2 Views of the device

3.2.1 Front view

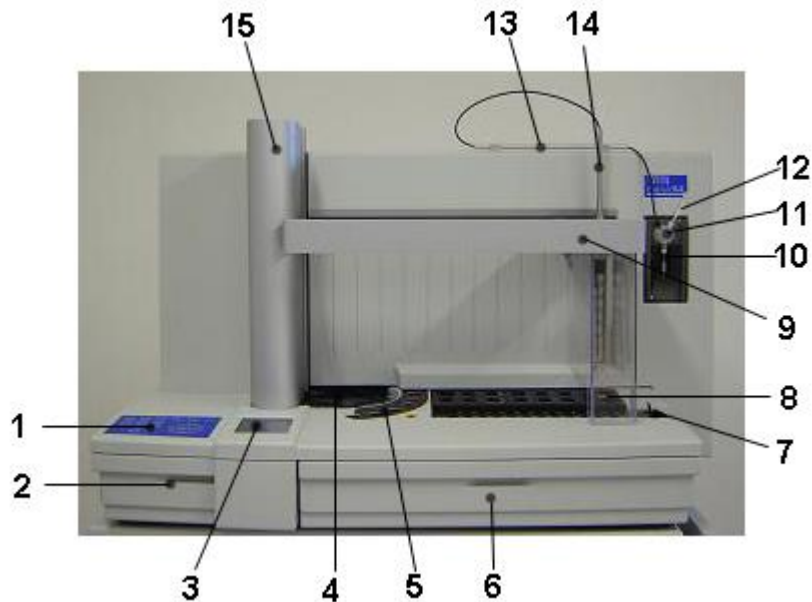


Figure 1: COATRON A4, front view

- | | |
|----|--------------------------------------|
| 1 | Keyboard |
| 2 | Cuvette waste drawer |
| 3 | Screen |
| 4 | Cuvette rotor |
| 5 | System block |
| 6 | Rinse solution waste drawer |
| 7 | Sample racks |
| 8 | Reagent block |
| 9 | Protective bar |
| 10 | Syringe |
| 11 | Pump unit |
| 12 | Tube to Rinsing solution tank |
| 13 | Tube guide for Pipetting needle tube |
| 14 | Pipetting arm |
| 15 | Cuvette tower |

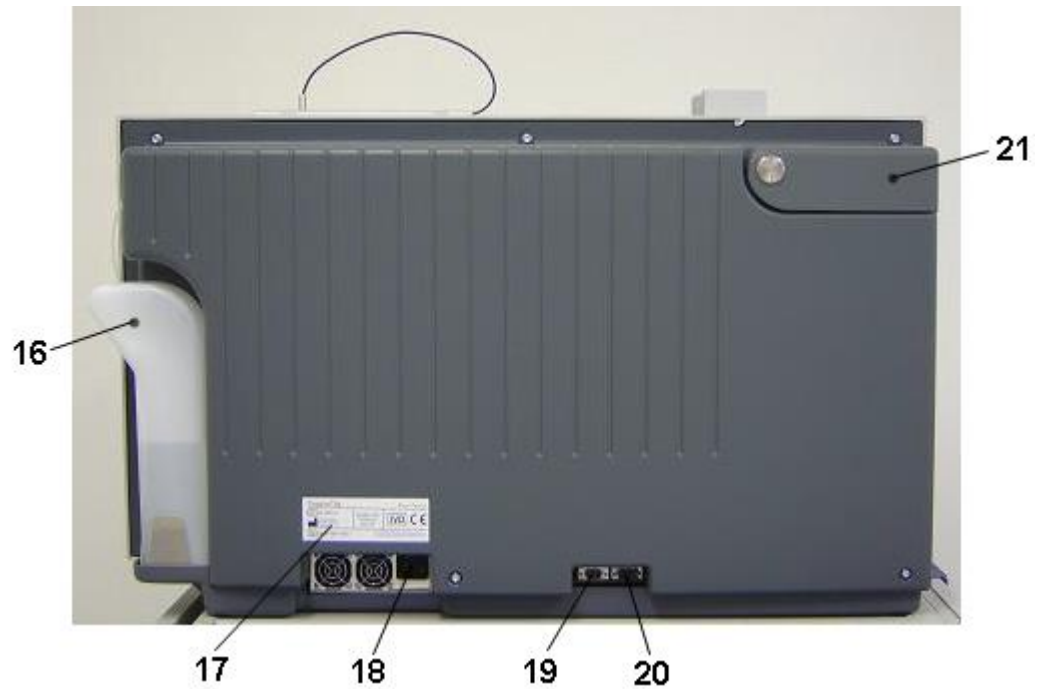
3.2.2 Rear view

Figure 2: COATRON A4, rear view

- 16 Rinsing solution tank
- 17 Type plate
- 18 Mains switch and power input
- 19 RS232 service interface for updating and data transmission (115K, 8,1,N)
- 20 RS232 debug interface for error analysis (reserved for manufacturer)
- 21 Printer cover

3.2.3 Side view

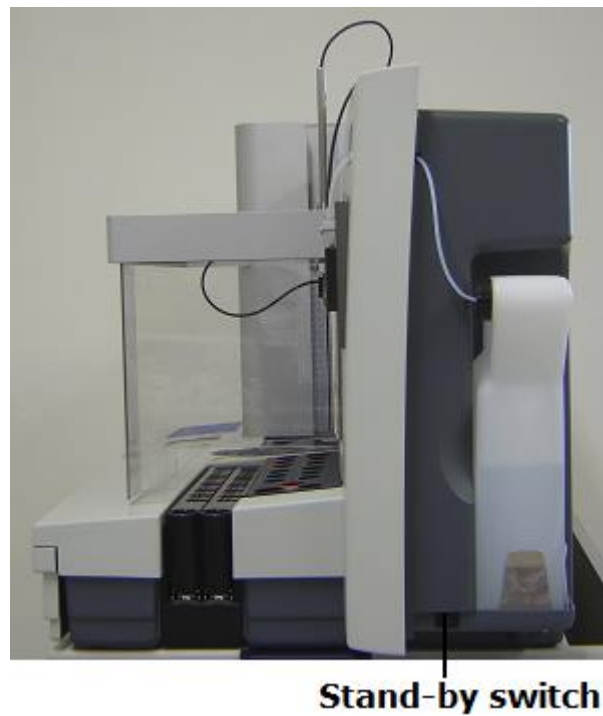


Figure 3: Side view

3.2.4 Sample rack

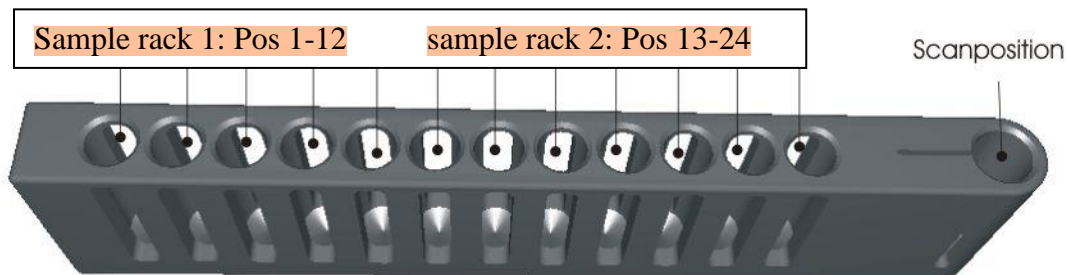


Figure 4: Sample rack

All commercially available sampling systems with a diameter of 11-13 mm can be used as sample tubes (eg. Sarstedt Monovette® or BD Vacutainer®).

3.2.5 Working Positions

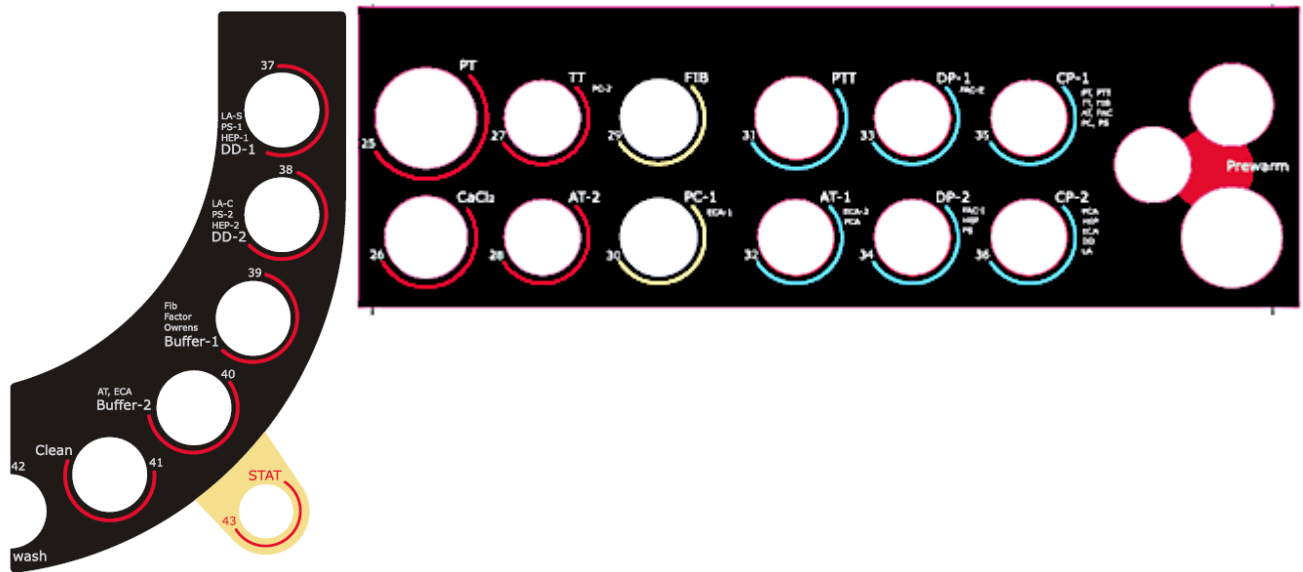


Figure 5: Working Positions

Pos. 1 - 24		Sample positions	Room temperature
Pos. 25	PT	Reagent position for PT, magnetic stirring function	37.0 °C
Pos. 26	CaCl ₂	Reagent position for CaCl ₂	37.0 °C
Pos. 27	TCT	Reagent position for TCT and PC-2 , APC	37.0 °C
Pos. 28	AT-2	Reagent position for AT-2 (substrate)	37.0 °C
Pos. 29	FIB	Reagent position for FIB	Room temperature
Pos. 30	PC-1	Reagent position for PC-1 (activator)	Room temperature
Pos. 31	PTT	Reagent position for PTT	15.0 °C
Pos. 32	AT-1	Reagent position for AT-1 (thrombin/factor Xa reagent)	15.0 °C
Pos. 33	DP-1	Deficient Plasma 1: for FII,FV ,FIIIV, FX ,	15.0 °C
Pos. 34	DP-2	Deficient Plasma 2 : for FVIII, FIX, FXI,FXII,PS,APCR, PK,HMWK	15.0 °C
Pos. 35	CP-1	Control plasma 1: for PT, PTT, TCT, FIB, Factors, PC, AT	15.0 °C
Pos. 36	CP-2	Control plasma 2 : for DD, HEP, APCR, LA	15.0 °C
Pos. 37	DD-1	used for DD-1, HEP-1, LA Screen	37.0 °C
Pos. 38	DD-2	used for DD-2, HEP-2, LA Confirm	37.0 °C
Pos. 39	Buffer-1	Owren's Buffer for plasma dilution (FIB , factors)	37.0 °C
Pos. 40	Buffer-2	Working Buffer for chromogenic tests (AT)	37.0 °C
Pos. 41	Clean	Position for cleaning solution	37.0 °C
Pos. 42	Wash	Wash and waste position	37.0 °C
Pos. 43	STAT	Emergency sample position	Room temperature
Pre-heat	Prewarm	3 prewarm positions	~37.0 °C

Reagent adapters are found in the right-hand device drawer for various reagent container or vials.



The above test reagent allocations are only valid for the factory default protocols.

3.2.6 Keypad

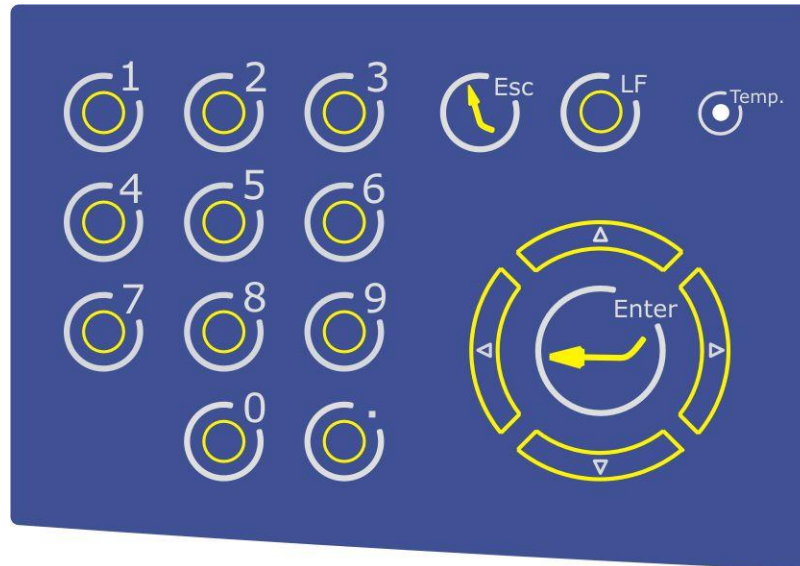


Figure 6: Keypad

0-9	Numeric value input	ARROW ↑	Navigation key
Esc	Leave screen	ARROW ↓	Navigation key
LF	Line up, printer paper	ARROW ←	Navigation key
Temp	Display of standby to measure status	ARROW →	Navigation key
Enter	Input / selection confirmation		

Use the arrow keys to change to the screens up, down, right or left. See chap. 5 for an accurate description of software operations.

3.2.7 Screen segments

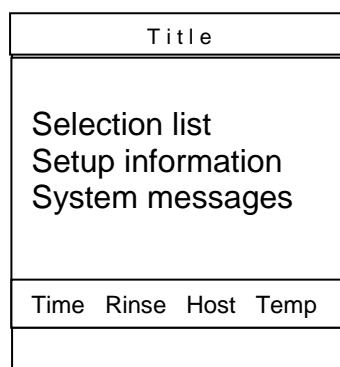


Figure 7: Screen segments

There are 3 screen segments:

- The current menu item appears in the title line.
- The main segment displays the selection lists, information and system messages.
- The bottom line contains the current time, volume of Rinse solution, status of host connection and the temperature in the Optic block.

3.3 Measurement principle

The COATRON A4 is equipped with highly sensitive 4-channel LED optics at a wavelength of 400 nm, making precise and reliable measurements possible even with icteric or lipaemic plasmas.

Once a reaction charge has been prepared, the optimum transillumination settings are found using an amplifier that facilitates measurement of both clear and cloudy samples.

Recording of measurement process data is started automatically when the start reagent is added. When coagulation begins, transmission is reduced, which changes the form of the measurement curve. The time from measurement start to this change (turning point) in seconds [s] is the result. The software then converts this datum into other units.

3.3.1 Mathematical principles

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 " * ".

3.3.2 Units

Unit	Decimal places	Maximum value
s	1	-
%	1	180
U	0	999
INR	2	12
Ratio	2	9
INR+	2	12
mg/dl	0	900
g/l	2	9
U/ml	2	1
mg/l	2	5
µg/ml	1	999
ng/ml	0	5,000
µg/l	0	5,000

Ratio = clotting time / normal time

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

ISI = International Sensitivity Index (sensitivity of the PT reagent).
(The ISI value is listed on the reagent information sheet)

INR+ = Like INR, except the ISI value is determined for a specific device. This is done using a calibration curve with INR standards.

3.3.3 Clotting method

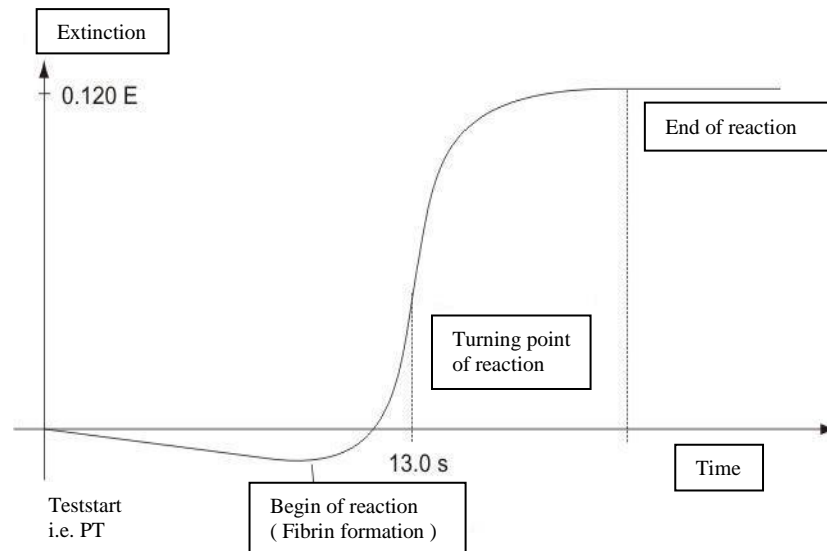


Figure 8: Determination of turning point in clotting method

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 greatest extinction increase (reaction turning point).

3.3.4 Derived fibrinogen

The photometric measurement method facilitates measurement of the prothrombin time (PT) as well as, at the same time, derivation of the relevant fibrinogen concentration.

The optical reaction rise (see figure above) between the start and end of the fibrinogen transformation reaction is linearly proportional to the fibrinogen concentration.



The DFIB method should only be used to select samples. Samples with a fibrinogen concentration outside the normal range must be confirmed using the FIB Clauss method.

3.3.5 Chromogenic, endpoint and immunoturbidimetric method

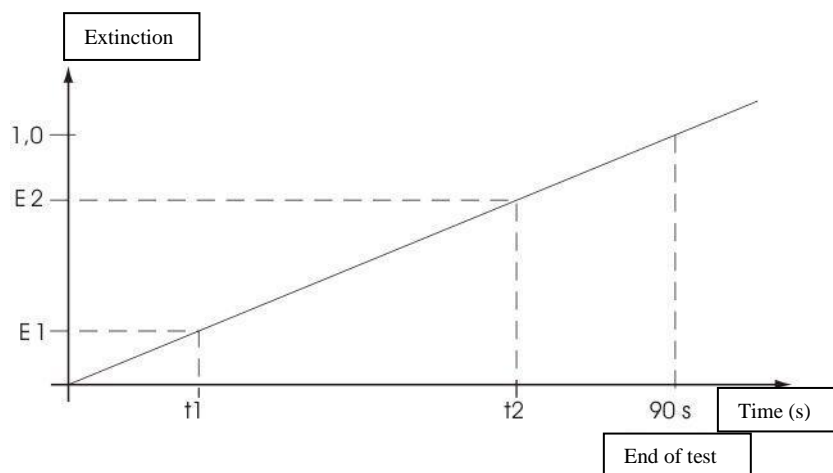


Figure 9: Determination of rise in the kinetic test method

t1 = deadtime in s

t2 = endtime in s

Delta signal $dE = E2 - E1$

Delta time $dT = t2 - t1$

Result of method „CHROM“ = $60 * (dE/dT)$ [dE/min]

Result of method „IMMUN“ = dE/dT

Result of method „POINT“ = dE

3.4 Test overview

Test	Name
PT	Prothrombin Time
DFIB	Fibrinogen, derived
aPTT	Activated Partial Clotting Time
FIB	Fibrinogen, Clauss
AT	Antithrombin
TT	Thrombin Time
DD	D-Dimer
HEP	Heparin
PC	Protein-C
PS	Protein-S
F2	Factor II
F5	Factor V
F7	Factor VII
F8	Factor VIII
F9	Factor IX
F10	Factor X
F11	Factor XI
F12	Factor XII
PLG	Plasminogen
-APC	Activated PC resistance Step1
APCR	Activated PC resistance Step2
LA-S	Lupus Anticoagulants Screen
La-C	Lupus Anticoagulants Confirm
PSF	free Protein S
FDP	Fibrin Degradation Product



Setup off test protocol is described in 5.2.10



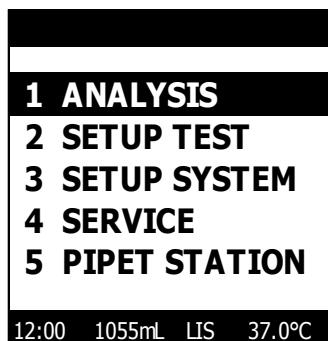
Ask local distributor for more information about specific test protocol setup

4. Routine measurement (Typical use case)

- Run 24 patients with PT + aPTT + FIB
- Scan the barcode of the samples
- Instrument should carry out all measurements in single
- Instrument should skip test, if system is out of reagent
- Instrument should not repeat results automatically
- Instrument should report first samples as soon as possible

4.1 Preparation

1. Wait until the COATRON A4 has reached operating temperature.
2. Make sure sufficient cuvettes, rinsing liquid and cleaning liquid are available for the testing procedure.
3. Supply the reagent positions with the required reagents and buffer solutions.
4. Re-enter the calibration curve for the planned tests when new reagents with new lot numbers are used.
See chap. 5.2.2 Submenu Data input for input of a calibration curve
5. Wait about 15 min. after supplying the reagent positions before test processing until the reagents have reached the right temperature (37°C in positions 25 – 28 and room temperature in positions 29 and 30).
6. Change to menu ANALYSIS



Select ANALYSIS and confirm with ENTER.

4.2 New list input

1. Fill the sample racks with the sample test tubes.
2. Remove the sample test tube cover
3. Make sure barcode labels are visible in the barcode window of the sample rack.
4. In the menu ANALYSIS, go to NEW LIST

CONTINUE:		YES
TEST:	PRFL	
BARCODE:	YES	
RELFE:	NO	
DOUBLE:	NO	
QC-ACTIVE:	NO	
AUTOSKIP:	NO	
HCT-L:	00 mm	
CLEAN:	MIN	
SHIELD:	YES	
MODE:	CUV	

Select YES and press ENTER to continue

- Select PRFL. Later define profile as PT+aPTT+FIB
- The samples identifications input by barcode
- No automatic test repeat
- Single determination
- No quality control
- Skip test, if out of reagent
- Search for plasma until bottom of tube
- Standard cleaning procedure
- Activate shield protection
- Run worklist in cuvette

CONTINUE:		YES
TEST1: PT	TEST5: -	
TEST2: APTT	TEST6: -	
TEST3: FIB	TEST7: -	
TEST4: -	TEST8: -	

Select YES and press ENTER to continue

Set profile to PT + APTT + FIB

5. Input patient-ID by barcode reader:

BARCODE ENTRY	
RACK1	RACK2
01	13
02	14
03	15
04	16
05	17
06	18
07	19
08	20
09	21
10	22
11	23
12	24

Shift the racks separately at an even and moderate speed in front of the barcode scanner. A signal tone is heard for each recognized barcode

In case of reading errors, check correct position of barcode, shift out rack and repeat scanning..

Press ENTER to continue

6. Start measurement

By select START and press ENTER

PREPARE SYSTEM	
P25	800uL
P26	500uL
P29	500uL
P31	500uL
P39	740uL
CUVETTES 5	
CONTINUE >> KEY ENTER	

Check, if all required reagents are on board and in correct position.

Press ENTER to start measurement
Star measurement

7. After completion of the measurement, the results and other information on the test are printed out and send to LIS automatically.

4.3 Interrupt or exit measurement

Automatic interrupt of worklist:

Instrument will interrupt worklist automatically, if it runs out of reagent or cuvette during measurement.

Manual interrupt worklist: Press key ESC:

Robotic will finish current command and moves to home and set measurement to pause and an alarm will be activated. Following actions can be performed during interrupt:

Exit worklist: Press key ESC again:

Measurement and worklist will be aborted.

Move robotic: Press key LEFT/RIGHT:

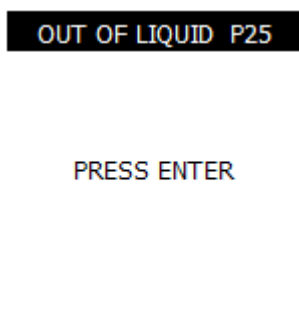
Moves robotic to left or right home position.

Continue worklist: Press key ENTER:

Continuous measurement

4.4 Out of liquid or cuvette during measurement

System will interrupt worklist automatically, if



Out of liquid:

Replace vial at indicated position within 30sec after alarm and press ENTER to continue worklist. After 30sec system will exit worklist or skip order according to setup of autoskip function.

Out of cuvette:

Reload cuvettes and press ENTER to continue worklist

4.5 Continuous loading of samples

This feature requires the host software TECAM PRO. The system must be set to "HC", which means host communication is online.

Samples can be loaded during measurement.

(1) Samples without patient barcode

- Define new orders with TECAM software and send to instrument
- Goto instruments and press ESC and wait until robotic is idle
- Place patient samples into rack according to TECAM order sequence

(2) Samples with patient barcode

- Scan patient barcode. System will display rack position and barcode number and interrupt current worklist.
- Wait until measurement is interrupted. Then place the tube into the required rack position.
- Scan and place further samples
- press ENTER to continue worklist
- New PID are now visible at TECAM software. Add methods and send order to instrument.



Do not access or move patient racks during operation of robotic. Always interrupt measurement before loading reagent, cuvette or samples during measurement. Otherwise system can be damaged !

4.6 Measuring the emergency samples

The emergency sample position (STAT position) makes it possible to interrupt regular test processing without losing the worklist settings or the measurement results up to that point. All current tests are terminated and the current worklist is saved so that the worklist can be continued after the emergency measurement. The STAT position is only designed for individual samples. If several emergency samples are to be measured, either repeat the following steps or start with a new list.

STAT ENTRY	
PID:	
TEST:	PT
	INFO
MODE:	MANUAL
CONTINUE:	YES

1. Interrupt the current worklist with Esc (*see chap. 4.4*).
2. Go to the submenu STAT in the main menu ANALYSIS.
3. Either input the PID manually via the numeric keypad or with the barcode scanner as described in chap. 5.1.4.
4. Place the emergency sample in the STAT position (position 43).
5. Select the test.
6. Under INFO you can print out the test SETUP.
7. Set the mode. If it is set to Manual, the interrupted worklist must be continued manually after the emergency sample has been measured. In Auto mode this is done automatically.
8. Leave the screen with Enter.
9. Check the reagents according to the information in the following screen, SYSTEM PREPARATION.
10. Start the emergency measurement with Enter.
11. After the measurement is completed, the test results are printed out analogously to normal test processing.
12. With CONTINUE in the main menu ANALYSIS, processing of the interrupted worklist recommences.



The software "TECAM PRO" features STAT orders, which can be run in regular patient rack and loaded during during operation.



4.7 Quality control measurement

The analyser allows to run one control plasma for each test. The specific control range must be entered in the menu "TEST SETUP". No warning flag "Q" is generated, if the control range is defined equal to zero.

There are two internal position for control plasma (CP-1 , CP-2). But also rack positions can be used for control plasma. The internal positions CP1/CP2 for each test can be found in the printout of the test setup

The analyser identifies a sample as a control if its position is CP1/CP2 or if its PID is equal to one of the two entered lot-numbers A control result is always marked with flag "C" and in case that it is out of range also with flag "Q". All further results will be flagged with "Q" until a new control result is successfully or the instrument is rebooted.

QC with positions CP-1 and CP-2:

- Define control range in the menu SETUP TEST
- Activate QC-ACTIVE within worklist menu
- Optional: Enter lot-number of control plasma within the worklist menu
- Place control plasma to position CP-1 or CP-2. The corresponding control position is printed with the test setup.

QC with rack position P01 and P02:

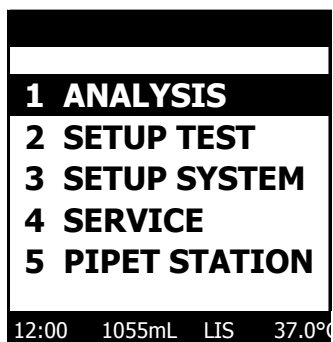
- Define control range in the menu SETUP TEST
- Set QC-ACTIVE=NO within worklist menu
- Set BARCODE=YES within worklist menu
- Enter the lot-number of control plasma within the worklist menu
- Place control plasma to position P01 and/or P02 and then all samples
- Enter the PID of the samples manually or by barcode. It is important that the PID number of sample P01 is equal to lot-number.



The terminal program "TECAM PRO" features quality control processing according to Levey-Jennings graphics and Westgard rules.

5. Software description

Following menu is displayed after start of instrument



- **ANALYSIS**
Menu to define orders and run patient samples
- **SETUP TEST**
Menu to calibrate methods
- **SETUP SYSTEM**
Menu to change system parameters
- **SERVICE**
Menu to service system
- **PIPET STATION**
Menu to reconstitute reagent and controls

The statusbar shows current information about time, installed RINSE solution, LIS connection and onboard temperature.

5.1 Main menu Analysis

WORKLIST	
1 NEW LIST	
2	CONTINUE
3	REPEAT
4	STAT
5	VIEW
6	PRINT OPTION
7	SYSTEM ACTIVATION
8	REAGENT ACTIVATION
12:00	1055mL LIS 37.0°C

5.1.1 Submenu New List

Creation and processing of a new list is achieved in 3 consecutive screens, each reached from the previous screen by way of Enter on CONTINUE: YES.

ARROW ↑ / ARROW ↓ selects the desired menu item, ARROW ← / ARROW → pages through the options.

With ESC one returns to the previous screen.

Select *CONTINUE = YES* to come to the next screen.

Screen: worklist settings

CONTINUE:	YES
TEST:	PRFL
BARCODE:	NO
RELFEY:	NO
DOUBLE:	NO
QC-ACTIVE:	NO
AUTOSKIP:	NO
HCT-L:	00 mm
CLEAN:	MIN
SHIELD:	YES
MODE:	CUV

Possible settings:

- **Test:**
With ARROW → one proceeds to the list of all available tests in which one navigates with the arrow keys, Enter selects the test from the worklist. With Enter on the field INFO an overview of the test settings is printed out (identical with *chap. 5.2.5, Test printout*).
- **Barcode YES / NO:**
Primary tubes are provided with barcode label, which is used to input the patient identification number (PID)
- **Reflex YES / NO:**
Activates reflex testing. The instrument can repeat automatically suspected results like +++ (no clot detected).
- **Double: YES / NO**
Activates the double test. The mean value is automatically used in the results report. If the two individual results differ by 15%, the result is labelled Flag "%."
- **QC Active: YES / NO**
Carries out control measurements with control plasma before each worklist is started; for this purpose, positions P35 (CP-1) or P36 (CP-2) must be filled with control plasma. The control positions for each test is defined in the Test Setup printout. If the control measurement results are outside the QC range (*see chap. 5.2.4, Submenu QC range*), the results printouts for the worklist will bear the remark "Q."
- **Autoskip YES / NO:**
The instrument will skip current job or test, if plasma or reagent run out and continue with the next order. Skipped jobs are printed as "SKP". Select "CONTINUE" in the analysis menu to re-run only skipped jobs.
- **HCT-L: 0 – 63 mm**
Determines the height of the coagulum (haematocrit level) measured from bottom of tube. The needle will search for plasma only upto this level. HCT-L must be set to 0 ,if only plasma is used

- **CLEAN:** Min - Max
Defines how to clean needle after pipetting samples
 - MIN: Don't perform a clean cycle from sample to sample. The risk of sample to sample carryover was evaluated with extreme high levels of Heparin and concerned low.
 - MAX: Always perform a clean cycle from sample to sample. It required much more Rinse solution and time to carry out a worklis
- **SHIELD:** Yes - No
This setting is only display, if a protection shield is installed.
 - YES: System stop immediately operation, if protection shield is opened during worklist.
 - No: Deactivate shield detection

**Important:**

Deactivated shield function may lead to injury and infections cause by piercing needle.

- **Mode:** BAT / SEL / CUV / EV1 / QC
Determines the mode of test processing:
 - Test Batch (BAT): Processes all similar tests in sequence (eg. all PT , than all APTT, ..) Well-suited to time-optimized test processing in routine operation, but complete patient reports are available after end of worklist.
 - Patient selective (SEL): Processes patients in sequence (eg. Patient 1, PT+APTT then next patient). Important: Complete patient reports are available during run, but worklist need more time and Rinse.
 - Cuvette Batch (CUV): This is a combination of BAT and SEL and combines the best of both. (eg. First cuvette PT, second cuvette aPTT,...).
 - Evaluation 1 (EV1): Regardless of how many samples were entered, plasma is only taken from sample position 1. Well-suited for determination of precision, consumption and throughput volume.
 - QC (QC): This mode is used for quality issues during production of service.



EV1, QC are not suitable for routine processing and should used only for research issues.

Screen: Test Profil, Control plasma and Autoseries input:

CONTINUE:	YES																
<table border="1"> <tr> <td>SAMPLES:</td> <td>24</td> </tr> <tr> <td>1.PID:</td> <td>1000</td> </tr> <tr> <td>CP-1:</td> <td>N12345678</td> </tr> <tr> <td>CP-2:</td> <td>P23456789</td> </tr> <tr> <td>TEST 1:PT</td> <td>5: AT</td> </tr> <tr> <td>2:APTT</td> <td>6: -</td> </tr> <tr> <td>3:FIB</td> <td>7: -</td> </tr> <tr> <td>4:TT</td> <td>8: -</td> </tr> </table>		SAMPLES:	24	1.PID:	1000	CP-1:	N12345678	CP-2:	P23456789	TEST 1:PT	5: AT	2:APTT	6: -	3:FIB	7: -	4:TT	8: -
SAMPLES:	24																
1.PID:	1000																
CP-1:	N12345678																
CP-2:	P23456789																
TEST 1:PT	5: AT																
2:APTT	6: -																
3:FIB	7: -																
4:TT	8: -																

Possible settings:

- **Samples:**
(only visible of barcode is set to no)
Manual input of number of samples.
- **1. ID**
(only visible of barcode is set to no)
Manual input of Identification Number for first sample. The other samples were automatically incremented by 1 (1000, 1001, 1002,.....)
- **CP-1 , CP-2:**
Input of lot.-numbers for two control plasma manually or by barcode. If the analyser identify a PID number as a control lot. , the result will flagged with "C" and checked if within control range.
- **Test 1 – 8:**
When a profile is to be measured, you can define the individual tests here once again.



-DFIB requires also PT
-ACPR requires also –APC and reverse
-LA requires also LA-C and reverse



Ensure yourself that all reagents for profile can be placed on board.
Otherwise the profile will not operate correctly and lead to erratic results.

Input of PID by barcode or manual entry:

(set BARCODE=YES , see screen 1 above)

In this screen you can enter the patient ident numbers by 3 ways:

BARCODE ENTRY	
RACK 1	RACK 2
01	13
02	14
03	15
04	16
05	17
06	18
07	19
08	20
09	21
10	22
11	23
12	24

- Shift the racks separately at an even and moderate speed in front of the barcode scanner. A signal tone is heard for each recognized barcode

- Use cursor keys to mark the current sample position and scan the sample. Place the sample into current rack position.

- Use cursor keys to mark the current sample position and enter manually the ID number and place the sample into the rack.



If a barcode was not recognized, check alignment and rescan. Read detailed information in chapter "Barcode Guideline"

Press *ENTER* to come into the next screen.

SYNCHRONIZE TO HOST


If PID: 1000

All patient identification numbers will be send to host.

the instrument is linked to host, it will receive corresponding job orders.

In the next screen you can still revise the PID numbers and active tests, which are counted upwards from the PID number of the first sample

POS	PID	1	2	3	4	5	6	7	8
P01	1001	X	X	X	X	X	X	X	X
P02	1001	X	X	X	X	X	X	X	X
P03	1002	X	X	X	X	X	X	X	X
P04	1003	X	X	X	X	X	X	X	X
P05	1004	X	X	X	X	X	X	X	X
P06	1005	X	X	X	X	X	X	X	X
1=PT	2=APTT	3=FIB							
4=TT	5=AT	6=DD							
7=F5	8=F5								



POS	PID	1	2	3	4	5	6	7	8
P01	1000	X	X	X	X	X	X	X	X
P02	1001	X	X	X	X	X	X	X	X
P03	1002	X	X	X	X	X	X	X	X
P04	1003	X	X	X	X	X	X	X	X
P05	1004	X	X	X	X	X	X	X	X
P06	1005	X	X	X	X	X	X	X	X
1=PT	2=APTT	3=FIB							
4=TT	5=AT	6=DD							
7=F5	8=F5								

- Select the order record with cursor keys UP/DOWN.
- Select the order items PID or TESTS with cursor keys RIGHT.
- If a PID is highlighted , use numeric keys to change the number and confirm with Enter.
- If a TEST is highlighted , use Enter to (de)activate. Use dot key "." to (de)activate the tests in all orders.
- To come to the next screen , use key RIGHT until the current order is completely highlighted and press Enter.

When worklist input is complete a further input overview appears.

WORKLIST	
<-	START
TEST:	PRFL
SAMPLES:	06
DOUBLE:	NO
QC-ACTIVE:	NO
AUTOSKIP:	NO
12:00 1055mL H0 37.0°C	

The COATRON A4 requires the following to process the active worklist:

PREPARE SYSTEM	
P25	800uL
P26	500uL
P29	500uL
P31	500uL
P39	740uL
CUVETTES	5
CONTINUE >> KEY ENTER	

- 800µl reagent in position 25=PT
- 500µl reagent in position 26=CACL
- 500µl reagent in position 29=Fibrinogen
- 500µl reagent in position 31=APTT
- 740µl reagent in position 38=FIB buffer
- 5 cuvette trays

Check once again to make sure all reagents and cuvettes on the device are filled. The worklist is started with Enter.

5.1.2 Submenu Continue

Following a test interruption (e.g. due to a STAT task or discontinuation due to a lack of liquid), routine measurement can be continued here.

5.1.3 Submenu Repeat

Repeats the last worklist.

5.1.4 Submenu Stat

Interrupts the regular processing of the list and selects the emergency sample at position 43 in the system block.

STAT ENTRY	
PID:	
TEST:	PT INFO
MODE:	MANUAL
CONTINUE:	YES

- Input of PID:
Enter the Patient Identification Number (PID) manually or just scan it with the barcode scanner. Enter terminates input of the PID. Then place the emergency sample in the STAT position.
- Selection of the test:
With ARROW ↓ one gets to test selection, ARROW → opens the list of available tests; then use the navigation keys to select the test and return to STAT INPUT with Enter.
- Information on the test:
Confirming the INFO field with Enter prints out the test setup just as in normal measurement.
- Setting the mode:
If the mode is set to manual, the interrupted worklist must be continued manually after the emergency sample has been measured. In the Auto mode this is done automatically.
- Activation of emergency measurement:
Go to the field CONTINUE and confirm with YES.
The next screen SYSTEM PREPARATION displays the required position in the reagent block, the required amount of reagent and the number of cuvettes required.
After checking the reagent position, the measurement procedure can be initiated with Enter.

5.1.5 Submenu Overview

Displays and prints lists according to given sorting criteria.

WORKLIST	
P01	1000
PT	70,1%
APTT	36,1s
FIB	398 mg/dL
P02	1001
PT	100,0%
APTT	33,5s
FIB	250 mg/dL
OPTIONS >> KEY ENTER	

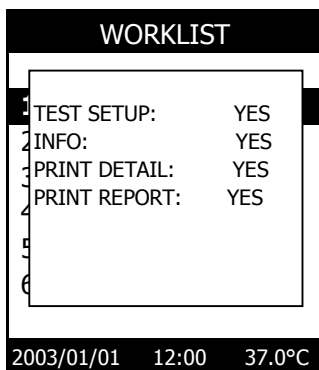
Enter calls up options, ARROW ↑ / ARROW ↓ pages through the options, Enter executes the operation:

WORKLIST	
P01	1000
PRINT REPORT SEND TO HOST STAT	
PC	
OPTIONS >> KEY ENTER	

The following options can be selected:

- Prints report
- Sends to host. Transmit the results from the processed worklist to a PC for further processing. For this function you require the optional software package "TECAM" or similar.
- Displays either the emergency list or the worklist.

5.1.6 Submenu Print Option

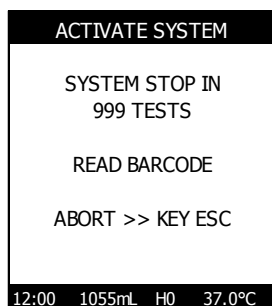


Determines what information is to be printed automatically:

- Test Setup: YES / NO
The Test Setups are printed at the beginning
- Info: YES / NO
Information on worklist is printed at the beginning
- Print details: YES / NO
Detailed results are printed during the measurements
- Print report: YES / NO
A report is printed after the worklist is processed.

5.1.7 Submenu System Activation

This menu is only visible, if instrument is configured as closed system



System will stop operating after 999 determinations.

- Skip message with key ESC.
- Scan "Test Activation Key" to activate system.

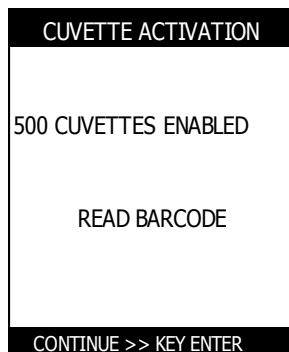
Barcode will be rejected in case of invalid syntax or if barcode was already scanned before.



Contact your local distributor, if you require a valid barcode.

5.1.8 Submenu Cuvette Activation

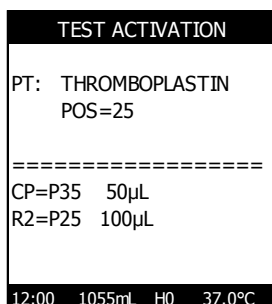
This menu is only shown, if instrument is configured as “Closed to cuvette”.
Read the barcode, which is provided with the cuvette package.



Activation barcode can be read only one time and is checked by serial number of instrument.

5.1.9 Submenu Reagent Activation

A test must be activated by barcode, if the instrument is configured as closed to specific reagent. The barcode is normally printed on the label of the vial. The activation can be done in this separate menu or short before starting the worklist.



Activate reagent by scanning the barcodes of certain reagents. The activation is valid until next system reboot.

Reagent and test name is displayed as well as the test protocol (e.g. control plasma at P35 with 50µL and R2=Thromboplastin at P25 with 100µL)

Barcodes will be rejected in case of

- invalid syntax of barcode
- date expired
- barcode differs to data stored in the SETUP test



A new LOT must be first calibrated before it can be used within the Worklist. Refer to chapter 5.2 “TEST SETUP”

5.1.10 Reflex testing

This feature is always enabled. After worklist run, then instrument will validate results and repeat test under following circumstances:

- For clotting tests like PT,aPTT,Factors: If result is “+++”, then test is repeated 1x with 60s prolonged maximum reading time.
- For chromogenic tests like AT: If result is “0.000E, then test is repeated 1x.

Repeated results are flagged with “R”

5.1.11 Display during measurement

WORKLIST IN PROCESS		
ID1:	1000	
PT		70,1%
ID2:	1001	
PT		x178
ID3:	1002	
PT		x026
ID4:	1003	
PT		x003
		- HC -
		PROGRESS
		5%

A PT result for sample ID 1000 has already been found in measurement channel 1. On channel 2-4 is a measurement ongoing.

Progress in the worklist is displayed in %. 100% means the worklist has been completely processed.

"HC" indicates that the analyser is linked to HOST.

The above screen appears during measurement.

A rotating bar at the right edge of the screen indicates an incubation (e.g. PTT) in the next cuvette.

A rotating bar in front of a number indicates an ongoing measurement. The number is the current light absorbance in mOD (milli optical density). A pronounced increase in light absorption indicates a coagulation event!

5.1.12 Result warning messages

Results may also be displayed with various additional warning symbols:

- * Result outside calibrated range
- A Result outside normal range
- T Temperature outside 36 – 38°C range
- Q Quality control outside control range
- C Result is identified as a quality control
- E Reagent is expired
- F Low Fibrinogen level found
- R Result repeated (reflex testing)
- ! Result not trustful and should be repeated.
- X Double values deviate by more than 15%
- K Measurement skipped, because out of reagent
- SKP Job was skipped due to missing reagent or plasma
- XXX No result was found
- SSS Signal transmission too low.
- +++ No coagulation determined within measurement time
- ??? Result based on strange optical signals (e.g. air bubble, peaks)

5.1.13 Printout of results

Depending on how the print options are set (see chap. 5.1.6, Submenu *Print Options*), the results are automatically printed out as follows. Each report can be identified with a unique worklist-id number.

TASKLIST 18.04.2003 00:34 TEST: PRFL SAMPLES: 06 BARCODE: NO DOUBLE: NO QC ACTIVE: NO P01 1000 PT 16.1 s 70.1 % P02 1001 PT 16.1 s 70.1 % P03 1002 PT 16.1 s 70.1 % P04 1003 PT 16.1 s 70.1 % P05 1004 PT 16.1 s 70.1 % P05 1004 FIB 8.1 s 398 mg/dl P06 1005 FIB 8.1 s 398 mg/dl	<table border="1"> <thead> <tr> <th colspan="3">REPORT OF RESULTS</th> </tr> </thead> <tbody> <tr> <td colspan="3">Worklist-ID: 1000</td> </tr> <tr> <td colspan="3">TIME: 18.04.2003 00:36</td> </tr> <tr> <td colspan="3">P01 1000</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> <tr> <td colspan="3">P02 1001</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> <tr> <td colspan="3">P03 1002</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> <tr> <td colspan="3">P04 1003</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> <tr> <td colspan="3">P05 1004</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> <tr> <td colspan="3">P06 1005</td> </tr> <tr> <td>PT</td> <td>70.1%</td> <td>16.1s</td> </tr> <tr> <td>PTT</td> <td></td> <td>36.1s</td> </tr> <tr> <td>FIB</td> <td>398 mg/dl</td> <td>8.1s</td> </tr> </tbody> </table>	REPORT OF RESULTS			Worklist-ID: 1000			TIME: 18.04.2003 00:36			P01 1000			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s	P02 1001			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s	P03 1002			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s	P04 1003			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s	P05 1004			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s	P06 1005			PT	70.1%	16.1s	PTT		36.1s	FIB	398 mg/dl	8.1s
REPORT OF RESULTS																																																																																		
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PTT		36.1s																																																																																
FIB	398 mg/dl	8.1s																																																																																

Individual results

Report

5.1.14 Host communication

The COATRON A4 has a serial bi-directional interface for data transmission. The terminal program "TECAM PRO" allows to define jobs on the PC surface and send them to the analyser. Once the program has started, all results are automatically sent to the HOST, where they can be graphically presented, including the coagulation curves, and managed in a database. A demo version of TECAM can be downloaded from the distributor's homepage. An active host connection is indicated with "H1" in the screen statusbar and with "HC" in the measurement screen

5.2 Main menu Test Setup

WORKLIST			
1 CHANGE TEST			
2 SET DATA			
3 NORMAL RANGE			
4 CONTROL RANGE			
5 PRINT TEST			
6 PRINT OVERVIEW			
12:00	1055mL	H0	37.0°C

CHANGE TEST			
PT	DFIB	APTT	FIB
AT	TT	DD	HEP
PC	PS	F2	F5
F7	F8	F9	F10
F11	F12	PLG	-APC
APCR	LA-S	LA-C	PSF

1=INFO

5.2.1 Using of reagent barcode

The internal barcode scanner will be activated by entering the submenu SET DATA. After every barcode event, the Coatron A4 will enter the LOT number and expiry date of the barcode.

SETUP F8	
TEST:	F8
LOT:	123456789
EXP.:	01/2004
UNIT:	%
INCUB.:	180s
RUNTIME:	180s
ENTRY:	MANUAL
12:00	1055mL H0 37.0°C

5.2.2 Test Selection

All of the available tests are listed in a table. Navigation within the table is realized with ARROW \uparrow / ARROW \downarrow / ARROW \leftarrow / ARROW \rightarrow . Enter selects a test and returns to the main menu Test Setup. The selected test is displayed in the headline. The following menu items always refer to the current test setting. To carry out several tests on each sample, select the last item, PRFL (profile). In this case, the next menu item DATA INPUT differs from data input in single tests.

5.2.3 Submenu "Set Data"

SETUP F8	
TEST:	F8
LOT:	123456789
EXP.:	01/2004
UNIT:	%
INCUB.:	180s
RUNTIME:	180s
ENTRY:	MANUAL
12:00 1055mL H0 37.0°C	

Single tests:

After replacing the reagents, the lot number (LOT) and expiry date (EXP.) must be re-entered. With ARROW ↑ / ARROW ↓ one selects the value to be changed.

➤ **New lot number (LOT):**

If the LOT number is inverted, ARROW → is used to get to selection of individual digits, numbers and letters and ARROW ↑ / ARROW ↓ are used to page through them; numbers can also be entered directly using the numeric keypad.

➤ **Input of expiry date (EXP.):**

With ARROW ← / ARROW → the month can be changed, with ARROW ↓ the year is changed analogously to the month.



Expired dates will not be accepted by the COATRON A4

➤ **Selection of unit:**

With ARROW ← / ARROW → the units are changed in which the results are displayed with the exception of the basic unit (which depends on the measurement principle). The available units are %, INR, Ratio, INR+ and no further unit (-). Calibration curves can only be entered when a unit has been selected. See *chapter 3.3.2, Units* on the significance and calculation of the units.

➤ **Incubation time setting**

Define the delay time before start reagent (R2) is added.

With ARROW ← / ARROW → the incubation time is changed in 30-second increments from **60 to 450 seconds**.

➤ **Runtime setting**

Define the maximum reading time.

➤ **Mode of calibration**

Select between Manual = manual input
 Auto = automatical test calibration

5.2.4 Test Calibration

The analyser gives the operator the option to calibrate a test manually or automatically.

- **Manual Calibration:**
The operator must prepare the standards and run them like normal samples. He must also enter the results manually
- **Auto Calibration with dilutions:**
The operator must place the reference plasma into rack position P01 and additionally empty vials in P02 – P06. The analyser will prepare all required plasma dilutions, run the standards and transfer the results into the calibration curve automatically.
- **Auto Calibration with fix standards:**
The operator can place up to 6 plasma standards into rack. The analyser will run the standards and transfer the results into the calibration curve automatically.
- **Manual calibration**

The operator must prepare the standards and run them like normal samples. He must also enter the results manually

SETUP PT	
TEST:	PT
LOT:	123456789
EXP.:	01/2004
UNIT:	%
INCUB.:	0s
RUNTIME:	120s
ENTRY:	MANUAL
12:00 1055mL H0 37.0°	

SET DATA: PT	
%	s
100	12,1
50	16,2
25	25,7
12,5	36,9
0	0
0	0
R ² =0.962	

Select test and unit, set *ENTRY* to *MANUAL* and press ENTER.

The calibration curve can be entered or changed now manually. At least 2 value pairs are required up to a maximum of 6 value pairs. List navigation is with the arrow keys and the values are confirmed with Enter. A value pair can be added, deleted or changed at any position. Subsequent data saving automatically sorts the calibration data.

INR Calibration:

The operator can select the unit between

- INR = Ratio^{ISI} (International Normal Ratio)
- INR+= INR calculated from a INR/sec reference curve

For UNIT=INR the operator must enter a normal value and the reagent ISI value manually. If a PT % calibration is entered, the instrument will calculate and display the 100% value. This value can be used as normal value if there is no laboratory inhouse normal value.

Linearity of calibration:

The curve linearity is indicated with the regression factor R^2 .

*$R^2 > 0.998$: the curve is linear. Two points are enough.
 $R^2 < 0.950$: the curve is inlinear. Use more than 2 points.
 $R^2 < 0.900$: change math. model and use more than 5 points.
Results outside of calibration are not trustful.*

Invalid calibration data

The calibration data are checked for plausibility when they are saved.

The following rules must be complied with:

- *At least 2 value pairs must be entered*
- *None of the value pairs may be entered double*
- *The values must be $\neq 0$.*
- *The expiry date must be valid*

An invalid "TEST SETUP" will be indicated with a long beep and rejected.

➤ Auto calibration

The COATRON A4 prepares and measures all of the required standard dilutions by itself and enters the mean values in the calibration curve.

SETUP PT

TEST: PT
 LOT: 123456789
 EXP.: 01/2004
 UNIT: % + INR
 INCUB.: 0s
 RUNTIME: 120s
 ENTRY: AUTO

12:00 1055mL H0 37.0°

STANDARD VALUE:

1 STD1: 100 %
 2 STD2: 0 %
 3 STD3: 0 %
 4 STD4: 0 %
 5 STD5: 0 %
 STD6: 0 %

12:00 1055mL H0 37.0°

Select test and unit, set *ENTRY* to *Auto* and press ENTER.

• Autocalibration with serial dilutions

The dilutions are always prepared in following way:

1	2	3	4	5	6
1:1	1:2	1:4	1:8	1:16	1:96

1. Enter the calibrator target value in the field "STD1," e.g. 100% for PT calibration, and confirm with Enter.
2. Enter the calibrator in position 1 of the sample rack.

ANALYSE CURVE

<- START

TEST: F8
 SAMPLES: 06
 DOUBLE: YES
 QC-ACTIVE: NO

12:00 1055mL H0 37.0°C

6 standards are measured for factor VIII calibration. Therefore the calibrator must be placed in rack position 1 and 5 other empty sample test tubes are required in rack positions 2-6, in which the COATRON A4 then prepares the necessary dilutions.

3. Additional empty sample test tubes are required in rack positions 2-6. The number of samples corresponds to the

number of sample test tubes and depends on the particular test.

4. Select START, check the reagents and numbers of cuvettes required in the screen SYSTEM PREPARATION and initiate the measurement procedure with Enter.

- **Autocalibration with fixed levels**

Enter more than one standard value in the fields STD1 – STD6. Enter a reference value. Confirm with ENTER. Select next standard field with key DOWN or press ENTER again to proceed with calibration.

SETUP PT		STANDARD VALUE:		ANALYSE CURVE	
TEST:	PT	1	STD1: 1.00 INR	<-	START
LOT:	123456789	2	STD2: 2.50 INR	TEST:	PT
EXP.:	01/2004	3	STD3: 4.00 INR	SAMPLES:	03
UNIT:	INR+	4	STD4: 0.00 INR	DOUBLE:	YES
INCUB.:	0s	5	STD5: 0.00 INR	QC-ACTIVE:	NO
RUNTIME:	120s		STD6: 0.00 INR		
ENTRY:	AUTO				
12:00 1055mL H0 37.0°C				12:00 1055mL H0 37.0°C	

3 fixed standard levels are measured for PT INR calibration. Place INR calibration plasma STD1,2,3 into rack position P01,02 and 03.

5.2.5 Submenu Normal Range

During a routine, a measurement result is flagged "A" (abnormal) if it is outside the normal range. If the normal range is min=max=0, the results are not checked.

Selection of the upper and lower limits of the normal range for the selected tests is with ARROW ↑ / ARROW ↓. If the value is inverted, use the numeric keypad to enter the new limit directly.

Leave the screen with Esc after all of the parameters to be changed have been entered.

In response to the query SAVE DATA? use ARROW ← / ARROW → to select either YES or NO and confirm with Enter.

5.2.6 Submenu QC Range

Indicates the measurement result range expected in a control measurement. The range depends on the particular control plasma and test. See the reagent sheet for the control range. If the measurement result for a control is outside the QC range it will be flagged "Q." If the QC range is min=max=0, the results are not checked.

5.2.7 Storing of test data

Press ESC to return to the main menu "TEST SETUP". If any data was changed, the COATRON A4 will ask for confirmation before storing.

The test data are checked for plausibility when they are saved.

The following rules must be complied with:

- ***The calibration curve must be valid***
- ***The LOT-Number must be in conformity with TECO GMBH***
- ***The expiry date must be valid***

5.2.8 Submenu Test Printout

Prints out the selected parameters for this test

SETUP FIB	
LOT: 302501299	
EXP: 1/2004	- expiry date
LAST CHANGE: 03.04.2003	- date of input
<hr/>	
1: 80 mg/dl - 27.0 s	
2: 120 mg/dl - 18.0 s	
3: 240 mg/dl - 12.0 s	
4: 480 mg/dl - 7.0 s	- calibration values
<hr/>	
R ² = 0,992	- Linearity of the calibration curve (1.000 for a straight line) (R ² should be 0.850 – 1.000)
NORMAL RANGE: 0 - 0 mg/dl	ranges
QC RANGE : 0 - 0 mg/dl	
S-CORR: 0%	signal correction
T-CORR: 0% 0s	time correction
START: 4s	deadtime
INCUB.: 60s	incubation time
RUNTIME: 120s	max. runtime
METHOD: COAG	test method
CT-MECH: NO	clottingtime mechanical
SENS: 0	test sensitivity
MIX: 0	reagent mixing
CLEAN: 0	high cleaning cycle
DIL.: 1:10	plasma dilution
PAT: VOL= 10uL	- Sample volume in µl
CP : VOL= 10uL POS=35	- Control plasma, amount and position
BUF: VOL= 90uL	- Buffer, amount and position
R2 : VOL= 50uL POS=29	- Start reagent, amount and position (here 10 µl sample + 90 Owren's buffer + 50 µl fibrinogen reagent)

5.2.9 Submenu Test Overview

Prints out the current protocols of all tests.

TEST	PAT	BUF	CLR	DEF	R1	R2
PT uL	50	0	0	0	0	100
POS	P35	P38	P00	P00	P00	P25
DFIB uL	50	0	0	0	0	100
POS	P35	P38	P00	P00	P00	P25
APTT uL	50	0	0	0	50	50
POS	P35	P38	P00	P00	P31	P26
...
...

example test protocol APTT:

- add 50µL sample (the control plasma position is P35)
- add 50µL aPTT reagent from P31
- add 50µL CaCl from P26

5.2.10 Setup of test protocol

This feature allows you to change or adapt new reagents or tests.

The test protocols are protected. They can be activated or modified by trained and authorized personel only.

Important:

Improper changing can lead to false results.

Please contact your local authorized distributor/agent, if there is a need to change the parameters.

TEST:	F8
UNIT:	3
METHOD:	COAG
MATH:	logXY
CT-MECH:	NO
START:	15s
POINTS:	6
SENS:	1
MIX:	0
CLEAN:	0
VALIDATE:	YES
S-CORR:	0%
T-CORR:	0%
	0s
MULTI	NO

Screen 1 : test protocols

PAT:	10uL
	P35
BUF:	40uL
	P38
CLR:	0uL
DP:	50uL
	P34
R0:	0uL
	P00
R1:	50uL
	P31
R2:	50uL
	P26

Screen 2 : test protocols

- NAME 4 Characters for test
- UNITS selectable units, decimal code of every bit.
(i.e. units=11-> s,%,INR
 - Bit 0 = always (sec or E)
 - Bit 1 = %
 - Bit 2 = U
 - Bit 3 = INR
 - Bit 4 = RATIO
 - Bit 5 = INR+
 - Bit 6 = INR+%
 - Bit 7 = -
 - Bit 8 = mg/dL
 - Bit 9 = g/L
 - Bit 10 = IE/mL
 - Bit 11 = mg/L
 - Bit 12 = ug/mL
 - Bit 13 = ng/mL
 - Bit 14 = ug/L
 - Bit 15 = IU/mL
- METHODE COAG,FIB,CHROM,IMMUN
- MATH XY-calibration relationship (lin,1/X,logY,logXY)
- CT-MECH Clotting Time Mechanical. Define clot point at 50% of endpoint
 - YES: Clot at 50% signal
 - NO: Clot at turnpoint of reaction (default)
- START Time when measurements start (deadtime)
- POINTS data points for auto calibration
- SENS sensitivity of clotting test (Max=3 -> very sensitive)
- MIX After adding of start reagent the robot will mix in the cuvette
- CLEAN needle will be flushed with double Rinse solution
- VALIDATE reagent must will be validated by barcode (eg. lot, expiry).
- S-CORR signal correction (eg. Calculate FIB signal 10% higher)
- T-CORR % time correction (eg. Calculate PT 10% shorter)
- T-CORR s time correction (eg. Calculate PT 2s shorter)
- Multi allow sample multi dispensing to increase throughput.
- Vol Pat Volume of patient in μL
- Pos CP Position of Control plasma
- Vol Buffer Volume of buffer
- Pos Buffer Position of buffer
- Vol Clr Clear Volume
- Vol DP Volume of deficient plasma in μL
- Pos DP Position of deficient plasma
- Vol R0 Volume of reagent 0
- Pos R0 Position of reagent 0
- Vol R1 Volume of reagent 1
- Pos R1 Position of reagent 1
- Vol R2 Volume of reagent 2 = Start reagent
- Pos R2 Position of reagent 2

Set volume and position to "0" if not required

Set volume and position to "0" if not required

Regard the impression of dispenser:



- Below 4 μ L: >15%
- At 5 μ L: 5%
- Above 10 μ L: <1%

Concern the clear volume:



A minimum of 75 μ L must be left in the cuvette. Example instrument pipet 5 μ L sample and 195 μ L buffer into cuvette. Then a maximum of 125 μ L plasmadilution can be cleared.

5.3 Main menu System Setup

System Setup is used to for basic device settings that are normally only rarely changed.

SYSTEM SETUP	
LANGUAGE:	ENGLISH
DATE:	2003/01/01
TIME:	14:59:05
SIGNAL:	ON
CONTRAST:	225
MIXER:	200
SIMULATOR:	0

General operation:

ARROW ↑/↓ left column Change item

ARROW → change to right column

ARROW ↑/↓ right column: Change value

Enter to confirm the value.

ESC exit menu

5.3.1 Language

Select between: English - Italian - Spanish - German

5.3.2 Date

The date format is changed in change mode with ARROW ↑ / ARROW ↓:

- European date format (DD.MM.YYYY)
- American date format (YYYY/MM/DD)

Use Enter to get into change mode for day, month and year, use ARROW ↑ / ARROW ↓ to change the date elements (day, month, year).

5.3.3 Time

Use Enter to get into change mode for hours, minutes and seconds, use ARROW ↑ / ARROW ↓ to change the time elements (hours, minutes and seconds).

5.3.4 Signal

Switches the acoustic signal on or off.

Possible settings:

- Signal on
- Signal off

5.3.5 Contrast

Changes screen image contrast.

Continuous settings from 214 to 255; the result can be checked on the screen without delay.

5.3.6 Mixer

Changes the magnetic stirrer speed at position 25 in the reagent block. Continuous settings from 0 to 255, standard setting 200.

5.3.7 Simulator

Facilitates simulation of measurement operation without moving the pipetting arm.

- Simulator = 0:
Normal operation; simulator is not active
- Simulator = 1:
Maintenance operation; commands issued to the XYZ robot are not executed. System functions as usual otherwise. This mode is very helpful for maintenance work or while familiarizing oneself with the system.
- Simulator = 2:
Demonstration operation; remove the syringe from the pump. Fill all required test and plasma positions with water-filled vessels. Cuvettes are not required. Now start a worklist. This mode is intended for system demonstration.

5.4 Main Menu SERVICE

SERVICE	
1	PRINT REPORT
2	ADJUST XYZ
3	ADJUST TEMPERATURE
4	CHECK OPTIC
5	CHECK ROBOTICS
6	MOVE CUVETTES
7	CLEAN NEEDLE
8	REPLACE RINSE TANK
9	REPLACE NEEDLE
10	REPLACE SYRINGE
11	ADJUST MOTOR
12	CAP PIERCING

ARROW ↑/↓
Enter
1-9

the desired menu item is selected
initiates the operation directly.
select item directly

5.4.1 System report

Printout of important system data

```

SYSTEM - REPORT

DATE: 2010/25/10 13:59

SYSTEM: COATRON A4
SERIAL NO.: 1234567
SOFTWARE: 01.06.01

OPTIC 1: 80 30005 (162)
OPTIC 2: 62 29984 (169)
OPTIC 3: 85 29766 (153)
OPTIC 4: 50 29793 (155)

TEMPERATURE CV:39.2 °C (39.0)
                34968 (34970)

TEMPERATURE PT:37.1 °C (37.0)
                34395 (34398)

CONTRAST: 225
MIXER: 200

-----WASH  REAG  CUV   PAT
OFFSET X: 1  -2    0     0
OFFSET Y: 3   1    0    -5
OFFSET Z: 0  13    0    850
OFFSET M: 4
OFFSET P: 0

RINSE INSTALLED: 108 ml
NEEDLE TIMER: 2300
SYRINGE TIMER: 32023
STOP-STOP IN: 905 TESTS
SERVICE IN 58001 TESTS

PT COUNTER: 10000
PTT COUNTER: 10000
FIB COUNTER:5000
TT COUNTER: 1000
DD COUNTER: 1000
ANALYSIS COUNTER: 27000

---- SYSTEM STATUS ----
SYSTEM = OPEN
SERVICE = CLOSE
REAGENT = OPEN

```

OPTICS : 80 30005 (162)
 80 = Digital value when LED is off
 30005 = Digital value when LED is on
 162 = Amplification factor

Temperature cuvette:current celsius (target)
 Current digits (target)

Temperature reagent PT:current celsius (target)
 Current digits (target)

Display contrast
 Reagent mixing speed

Needle Position for Wash , Reagent,Cuvette & Patient
 X-Offset = left/right
 Y-Offset = forward/backward
 Z-Offset = up/down
 Motor Adjustment: Offset=4
 CAP PIERCING height

Remaining system liquid
 Age of needle: number of performed tests
 Age of syringe: number of up/down cycles
 Remaining determination before system stop operation.

Number of carried out tests for counted PT,PTT,FIB or
 all tests

System do not require a barcode to run tests
 System requires a barcode to reset service interval
 System do not require a barcode before use of reagent

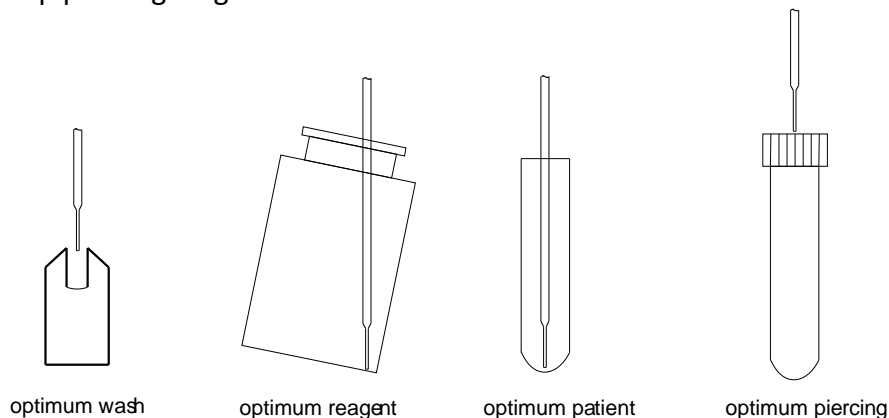
5.4.2 Adjust XYZ

Key 4/6	move needle left/right (X-offset)
Key 2/8	move needle backward/forward (Y-offset)
ARROW ↑/↓	move needle up/down (Z-offset)
ENTER	goto next position
ESC	exit adjustment

Ensure yourself, that the needle is straight and correct mounted 115mm in length. Place an empty reagent container to position P27, two empty cuvettes in the tower, an empty plasma tube to position P01 and an unused Sarstedt Monovette® or BD Vacutainer® in position P02. (only if CAP PIERCING option is required)

Five position must be adjusted

- Wash position
- Reagent position
- Cuvette position
- Patient position
- Cap piercing height



1. First the needle will go to wash position. Center the needle exactly. The needle tip must be at same level with top of wash position. Press "ENTER" to come to next position or press "ESC" to quit.
2. Second the needle will go to P27 position. Center the needle. The needle tip should be short before touching the vial bottom. Lift vial to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.
3. Third the needle will go to cuvette position. Center the needle and afterwards lower the needle until it is short before touching the cuvette. Lift the cuvette to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.

4. Forth the needle will go to P01 position. Center the needle. The needle tip should be short before touching the vial bottom. Lift vial to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.
5. Fifth the needle will go to P02 position. Center the needle. The needle tip should be short before touching the cap membrane. Press "ENTER" to test cap piercing or press "ESC" to quit.



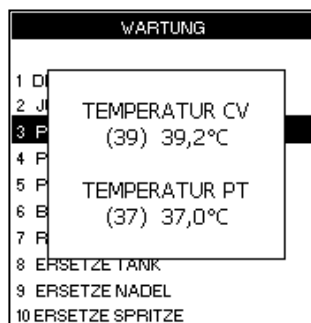
skip cap piercing if not required. The value P-OFFSET must be 0 to deactivate cap piercing.



Important:

To avoid needle crash the z-offset is set to default, before the needle drives to this position. So even if you didn't change the offset, the z-position must be re-adjusted anytime

5.4.3 Check Temperature



Temperature CV	Temperature around measurement cuvette.
Temperature PT	Temperature at reagent position PT (P25)
(xx)	Target temperature in degrees Celsius
xx,x	Current temperature

Setting the temperature:

With ARROW ↓ / ↑ the current temperature is changed in 0.1°C increments. Enter selects the temperature ESC returns to the service menu.

1. Place an empty cuvette in the measuring cell and fill 300 µl water into all of the 4 measurement positions. Place a standard commercial fever thermometer in one of the cuvette wells. Make sure the cuvette is standing upright.

2. Place also an empty reagent container in position "PT" (P25) and fill with 6 - 7 ml water. Place a standard commercial digital fever thermometer in the water.
3. On the keyboard the green Temp. LED should light up.
4. Wait for at least 15 minutes. Now read off the temperature on the Thermometer.
5. In the cuvette position the temperature should be in the range of $\pm 0.5^{\circ}\text{C}$ from target value. Temperature can be increased or decrease by pressing ARROW \downarrow / \uparrow .
6. Adjust temperature so often until the temperature shown on display matches the temperature in the cuvette or PT position.
7. For "PT" also the target temperature can be adjusted. Lower storage temperature of reagents will significantly increase stability, while results will be nearly unchanged.



Please ask local distributor about change of reagent target temperature.

5.4.4 Check Optics

Remove the cuvette in the measurement optics.

CHECK OPTIK			
	OFF	ON	AMP
1=	78	29851	185
2=	105	29624	192
3=	56	29799	171
4=	78	29851	185
T1=	34302		
T2=	34429		
CV-STATUS:	0		
SHIELD:	0		

X=	Measurement channel 1-4	
OFF	Digital value when LED is off. Target range <500	
ON	Digital value when LED is on. Target range 28000 - 32000	
AMP	Signal amplification, Target range 150 - 300	
T1	Digital value temperature CV, Target range 33000 - 36000	
T2	Digital value temperature PT, Target range 33500 - 36000	
CV-STAT	0=no cuvette	1=if cuvette is detected.
Shield	0=closed	1 = open



Please contact customer service if the values deviated from the target values.

5.4.5 Check Robot

To check, if XYZ, pump and level sensor is working. Press ESC to abort this test. It is used for service and quality issues. Remove all vials and tubes before continue. Print "FALSE LEVEL" indicates that level detector stops false in air. In this case the insulation block must be replaced.

5.4.6 Move Cuvettes

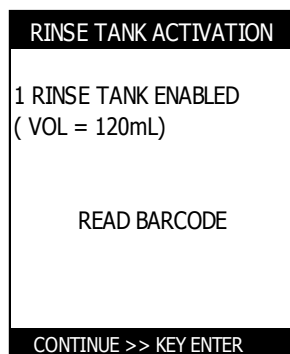
Turns cuvette rotor for transport of cuvettes until Enter is pressed. It is used to empty the cuvette tower.

5.4.7 Clean Needle

Carries out an intensive needle cleaning cycle. It is used after needle is complete and partial clogged during measurement.

5.4.8 Replace Rinse tank

Barcode activation is only shown if instrument is closed to Rinse solution. Read the barcode, which is provided with the cuvette package.



The current numbers of remaining Rinse tanks and installed volume of Rinse solution is displayed.

1. Remove the waste tank r and dispose it according to regulations for infectious material
2. Replace the empty rinsing tank with a full one. Ensure that the tube is insert completely into the tank.
3. Use the empty Rinse tank as new waste tank !
4. Run menu "SERVICE\REPLACE RINSE TANK"to reset the Rinse counter
5. If zero tanks are enabled, scan the barcode of the certificate, which is included to each new box of Rinse tanks.



Make sure a full tank is really installed, since otherwise the COATRON A4 will calculate the consumption incorrectly.



The full liquid waste tank may contain infectious substances and must be handled and disposed of as infectious waste. Always wear gloves for infection protection when replacing the liquid waste tank! After this procedure, disinfect your hands with a hand disinfectant, e.g. Sterilium®.

5.4.9 Replace Needle

Resets the operating time counter of the pipetting needle to zero. This operation must be carried out when the needle is replaced.

1. Switch off instrument
2. Drive needle manually into wash position and open the tube fitting on valve.
3. Wait until needle is complete empty from Rinse solution. Clean and dry needle outside, to avoid any liquid contamination with the insulation block.
4. Loosen the screw (see figure below)and remove the needle
5. Insert new needle until 115mm is visible and tighten the screw
6. Screw the tube fittings to the left valve channel and tighten only by finger
7. Switch on instrument and run menu "SERVICE\REPLACE NEEDLE"

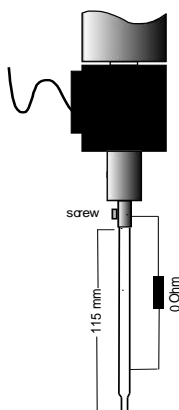


Figure 10: Replace Needle



Any liquid contamination of the insulation block with the needle may malfunction the level sensing.



The used pipetting needle may contain infectious substances and must be handled and disposed of as infectious waste.

5.4.10 Replace Syringe

Resets the operating time counter of the syringe to zero. This operation must be carried out when the COATRON A4 is when the syringe is replaced.

1. Switch off instrument
2. Lower the plunger drive manually by pushing down on the carriage assembly until it reaches the bottom of travel.
3. Now open the syringe and remove it.
4. Insert the new syringe and tighten just with your fingers
5. Switch on instrument and run menu "SERVICE\REPLACE SYRINGE"

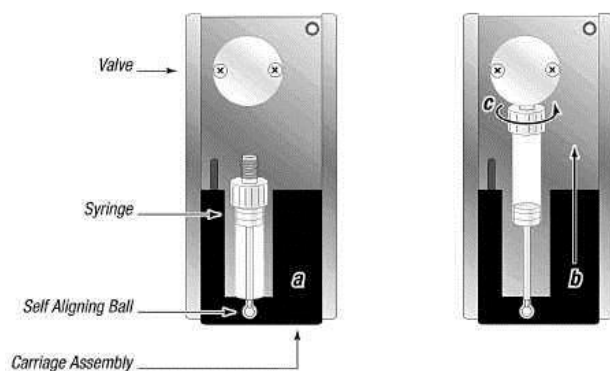


Figure 11: Installation of syringe

5.4.11 Adjust Motor

Changes the assignment of the cuvette to the measuring position. The cuvette must be positioned exactly centered to the optic, to ensure accurate results. Fill some water into a container and color the water with a green lightning pen. Remove all cuvettes onboard. Add 150 μ L green colored water into every cuvette position and place it into position prewarm. Run menu "ADJUST MOTOR". The system moves now cuvette into optics. If the light beams are not centered, change the offset value, move cuvette back and repeat the procedure until correct adjustment of the cuvette position. The factory default value is „4“ . An increase of the offset will shift the cuvette to the left.

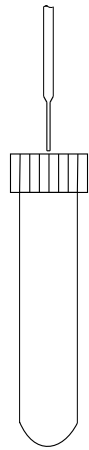


Important:

False adjustment will reduce the measuring precision.

5.4.12 Cap Piercing

Fill a Sarstedt Monovette® or BD Vacutainer® or a similar system with 2mL water. Close the cap and place it into rack position P02. Lower the needle until it is just before touching the cap. Then center the needle to the cap.



optimum piercing

- ⇒ use keys 4/6 or 2/8 or Up/Down to move needle
- ⇒ confirm with Enter to check cap piercing
- ⇒ confirm with ESC to exit adjustment



Cap piercing function is deactivated , if height P-Offset is set to 0



Activated cap piercing function allows to operate with open or closed tubes. The throughput gets a little lower.



Warning!

The system may be damaged, if no needle protection is mounted.

Cap piercing requires also a special needle, which is designed for it. Ask your local distributor for further information.

5.5 Main menu PIPET STATION

Menu to reconstitute reagent and controls

PIPET STATION	
IN:	P26
OUT:	P25
TOTAL:	0 ul
VOL (uL):	1000
PIPET >> KEY ENTER	
ABORT >> KEY ESC	

Fill enough diluent into container and place it to position P26. Open reagent vial and place it to position P25. Change volume with keys UP/DOWN and press ENTER to dispense diluent into reagent vial. Press ENTER again if more diluent is required. The total volume will be updated with each pipeting step. Press ESC to reset total counter and press ESC again to exit menu.

6. Replacement of consumables

6.1 Disposal



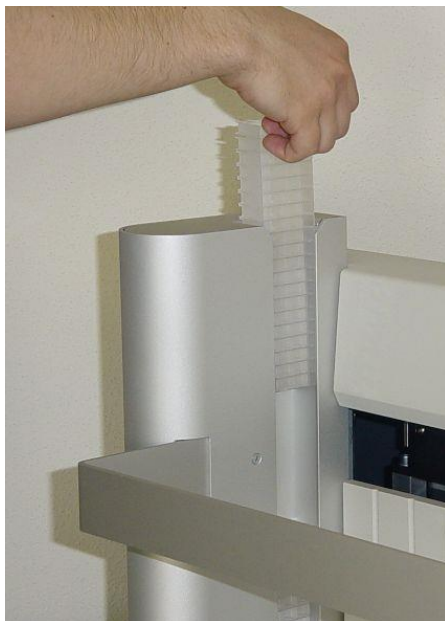
Warning!

The full liquid waste tank and used cuvette may contain infectious substances and must be handled and disposed of as infectious waste. Always wear gloves for infection protection when replacing the liquid waste tank! After this procedure, disinfect your hands with a hand disinfectant, e.g. Sterilium®.

6.2 Refill cuvettes



Cuvette trays are disposable articles, reuse is not permissible for reasons related to hygiene and measurement technology!



1. Remove a row of cuvettes from the package
2. Hold the row by the tape and insert the cuvettes as shown, from above and with the guide groove to the rear, into the cuvette tower.
3. Pull the tape off the cuvettes

Figure 12: Refill cuvettes

6.3 Replace Rinse tank

Follow instruction from chapter 5.4.8

6.4 Replenishing the printer paper



Figure 13: Printer cover

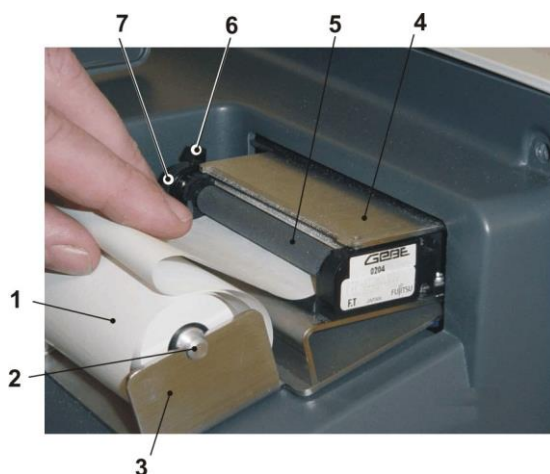


Figure 14: Replenishing the printer paper

1. Open the printer cover as shown at the back of the housing.
2. Remove the printer shaft from the mount (3).
3. Pull the empty printer paper roll off the printer shaft
4. Insert the printer shaft 2) through the new printing paper roll (1) and place the printer shaft on the mounts as shown (3), so that the paper is pulled into the rubber roller (5) from below.
5. Move the arresting lever (6) in the direction of the back wall of the housing to release it.
6. As shown, insert the printer paper under the rubber roller and turn the transport wheel (7) to the left until the printer paper sticks out of the gap between the rubber roller and the metal cover (6) by about 5 cm.
7. Secure the arresting lever 6) by moving it towards the front of the housing.
8. Hold the printer paper towards the front of the housing and close the cover.

7. Cleaning and maintenance

Maintenance must be performed on a regular basis in order to maintain accuracy and precision. The schedule below outlines the proper intervals to check or replace components of the instrument.

7.1 General cleaning information

- Use detergent and water and 10% diluted bleach or commercial decontaminant for daily cleaning
- Use 30% diluted bleach and commercial disinfectant (e.g. Bacillol®AF) for weekly decontamination
- Clean with a lint free cotton cloth or stick
- Never pure any liquid into optic or working area
- 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 it immediately with a pipette and clean the measurement channel with 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.

7.2 Cleaning

- Use detergent and water and 10% diluted bleach or commercial decontaminant
- Clean and wipe up all spills around the working area or needle pump system with detergent and water.

7.3 Decontamination

- Use 30% diluted bleach and commercial disinfectant (e.g. Bacillol®AF)
- Decontaminate working area, needle area, patient racks, keyboard, LCD screen, front casings, printer and waste drawers

7.4 Daily activities

- Clean and wipe up all spills around the working area or needle pump system

with a 10% diluted bleach.

- Inspect level of Rinse and waste container
- Empty cuvette drawer and fill tower
- Inspect tube system for any leaks and correct immediately

7.5 Weekly activities

- Decontaminate system with bleach and ethanol as described above

7.6 Yearly activities

- Clean and decontaminate equipment
- A yearly service check according to TECO test specification QMV-07-10 must be carried out by the authorized and qualified technician
-

7.7 Regular Replacements

Every 100.000 tests following parts must be replaced

1. Replace needle
2. Replace syringe seal
3. Replace tubing
4. Replace insulation block
5. Replace cleaning position
6. After 5 year replace battery of the mainboard (Li-Mn CR 2430)

7.8 Reset Service Interval

- After 100.000 tests the message "SERVICE" will be shown. The reset of the service interval is protected by barcode. Contact local distributor for more information.

7.9 Error messages

Error message	Possible cause	Action
Service	Service interval is expired after 100.000 tests	Service instrument and reset interval with barcode certificate.
Replace Rinse tank	Rinsing solution tank empty	Replace rinsing solution tank (<i>chap. 6.1</i>)
Error pump	Needle clogged	Check needle and tube system
Error robot (system error 2-28)	No connection to pipetting arm	Consult the customer service of your dealer
	Needle crash	Reboot the system
Activate System	System interval is expired	Scan barcode "Test Activation Key"
Activate Reagent	Reagent must be validated	Refill cuvettes (<i>chap. 6.3</i>)
Adjust XYZ	Replacement of needle	XYZ adjustment of pipetting arm (<i>chap. 5.4.2</i>)
Adjust Motor	Replacement of main-board or software update	adjustment of cuvette (<i>chap. 5.4.11</i>)
No liquid	No liquid in current position of pipetting needle	Refill liquid at current needle position.
	Z-offset false	XYZ adjustment of pipetting arm (<i>chap. 5.4.2</i>)
Check printer	No printer paper	Replenish printer paper (<i>chap. 6.7</i>)
	Arresting lever in offline position	Change arresting lever position (<i>chap. 6.7</i>)
	No printer connected	Consult customer service
Check temperature	Temperature in system block too high or too low	Check temperature and adjust (<i>chap. 5.4.2</i>)
Clean needle	Pipetting needle was replaced	Carry out needle cleaning cycle (<i>chap. 5.4.7</i>)
Check waste	Every 80 cuvette or every new Rinse tank the instrument do a reminder to check also the waste.	Check cuvette waste drawer and also Rinse waste tank. Then just confirm message.

8. Elimination of malfunctions

8.1 Device malfunctions

Malfunction / Error	Possible cause	Measures
No print on printout	Paper installed in wrong position	Turn paper roll around (<i>chap. 6.7</i>)
Needle does not pipette	Tube system leaky	Replace the tube system
	Needle clogged	Place the needle in COATRON A4 Cleaner for 30 min, then run the wash cycle.
Poor reproducibility	Needle-tube system	Replace the needle, tube system and syringe.
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (<i>chap. 5.4.11</i>)
Cuvette assumes false position	Wrong cuvette	Use only original COATRON A4 cuvettes
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (<i>chap. 5.4.11</i>)
	Defective cuvette motor or microswitch for cuvette recognition	Consult customer service of your dealer
Optics not within target value range	Cuvette is in measurement position during optics check	Remove the cuvette and repeat the optics check
	Soiling or liquid in measurement channel	Optics must be cleaned. Consult customer service
	LED does not light up.	Customer service will replace optics

8.2 Measurement malfunctions

Malfunction / Error	Possible cause	Measures
Control measurements do not supply expected results	False calibration data	Consult customer service of your dealer
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (<i>chap. 5.4.11</i>)
False measurement results	Reagent	Check TEST SETUP
	Temperature	Check temperature (<i>chap. 5.4.3</i>)
	Optics	Check optics (<i>chap. 5.4.4.</i>)
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (<i>chap. 5.4.11</i>)
Results flagged "*"	Result outside calibration range	
Flagged "A"	Result outside normal range	
Flagged "T"	Temperature outside 36 – 38°C range	
Flagged "E"	Reagent is expired	
Flagged "Q"	Quality control outside control range	
Flagged "S"	Environment light too bright (low >750digits)	Avoid direct sunlight or other UV sources
Flagged "F" (only test PT)	Low fibrinogen.	Run test FIB to confirm.
Flagged "R"	Result repeated. Max. Runtime too short or problems with level sensor	
Flagged "!" (only test DD)	Result not trustful.	Dilute sample and repeat.
Flagged "X"	Double values deviate by more than 15%	
Flagged "+++"	No coagulation seen with measurement time	
Flagged "???"	Coagulation time indeterminate; course of reaction does not correspond to the criteria of the evaluation algorithm (e.g. turbidity due to air bubbles or coagulation begins before dead time)	
Flagged "SSS"	Low signal. Light transmission is not enough.	Check optics (<i>chap. 5.4.4</i>)
Flagged "K"	Sample, Test is skipped because out of reagent.	

8.3 Packing the COATRON A4 for shipment

If the COATRON A4 is to be shipped, e.g. to the Technical Service, please include the following information in an accompanying letter:

- Complete address of owner.
- Name of dealer from whom the Analyzer was purchased.
- Exact designation of the Analyzer and serial number (on type plate).
- A useful description of the reason why the equipment is being sent in (error / malfunction description).

You should use the original packaging material to avoid transport damage. If the original packaging is no longer available, contact your dealer.

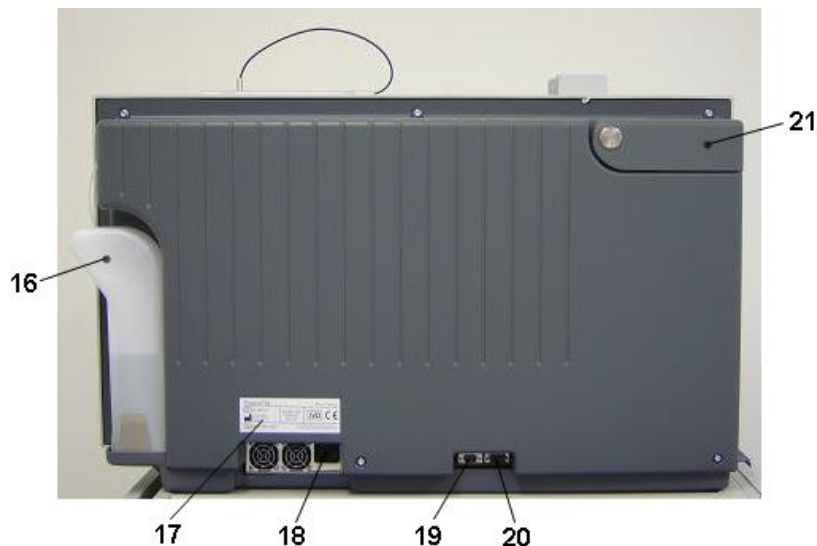
Preparation of the Analyzer for transport:

1. Remove the power cord from the socket and from the Analyzer.
2. Immobilize all moving parts such as sample racks printer shaft, etc. with tape.
3. Remove the needles place them in the drawer for the waste tank.
4. Fix the robot in the resting position (seen from the front—right, rear) with tape or cable binders to the protective bar.
5. Push the Analyzer to the edge of the table; then two persons must lift it by the short sides.
6. Life the Analyzer carefully into the packaging.

9. Appendix

9.1 Interface to LIS

The instrument support two serial RS232 ports to connect with laboratory information system (LIS).



9.1.1 Bidirectional communication with TECAM software

TECAM software is a perfect and user friendly tool to combine laboratory data management, quality control and research purpose in one. The worklist management allows defining orders much faster and flexible then on the instrument itself. Powerful filter functions will help to create any report. Levey-Jennings graph and Westgard analysis are used for quality control monitoring. An ASTM interface is included, which allows to link with the laboratory information system (LIMS) over LAN network or RS232. The TECAM database can be saved central on a server and accessed simultaneously. This will allow to unify different Coatron analyser into one database.

Interface: 115200 Baud , no parity , 8 bit . 1 stop bit

Instrument port: location "19" – see picture above

Cable: 2x Female Sub D9, crosslink. Pin 2 to 3 ; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected



Contact your local distributor for further information about TECAM software.

9.1.2 Unidirectional communication

Interface: 115200 Baud , no parity , 8 bit . 1 stop bit
 Instrument port: location "20" – see page 7
 Cable: 2x Female Sub D9, crosslink. Pin 2 to 3 ; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected
 Handshake: No
 Establishing: Not required. The instrument sends results information automatically

Protocol & syntax: TECAM V5.30

STX	start of transmission	asc(2)	ETX	end of transmission	asc(3)
TAB	vertical tabulator	asc(9)	LF	line feed	asc(10)
CR	carriage return	asc(13)			

STX+TYPE | RID | STYP | SN | Kanal | Position | PID | LOT | Test-ID | Test-Name | Date | Time | status | result1 | scale1 | flag | result2 | scale2 | result3 | scale3 | progress|worklist-id|ETX

All fields are separated with vertical tabulator. No TAB is placed after STX or ETX !

STX: Start of Transmission
 Type: Always "R" = Result Record
 RID: Record ID. Unique record number
 SID: Analyser ID . Here always "1800"
 SN: Serial number of the analyzer
 Channel: optic channel 1-4. Here always "0".
 Position : Rack position of the sample tube (1 – 24). Here always "0".
 PID: Patient ID (max 13 characters)
 LOT: Lotnumber of the Reagent
 TEST-ID : ID Number of the Test (for ex. Test PT = 0 -> look at analyser's manual)
 TEST-Name: Name of the test, for example „PT“
 Date: Date of result. Always in format "yyyy/mm/dd".
 Date Time: Time of result. Always in format "hh:mm:ss"
 Status: Status of measuring „T“ = temperature error , „Q“ = Quality Control out of range, „%“ = big difference by double-measuring ; „A“ = abnormal ; „C“ = Control plasma; example: „TAQ%“ is possible
 Result1: Result of the standard scale (mostly sec);always in format „12.5“ ;
 Scale1: Scale of result1 ;ie. „s“ for second
 Flag: Information about the result2;
 „>“ „<“ Value smaller, bigger than ...
 „*“ result out of calibration
 „+“ no clotting detected
 „-“ clotting before dead time
 Result2: Result in the second scale ; f ex: in % : „100“
 Scale2: Scale of Result2 , ie. „%“
 Result3: Result in the third scale ; ie. INR : „1.23“
 Scale3: Scale of Result3 , ie. „INR“
 Progress: Progress of worklist. 0% = Start, 100%=End
 Worklist-ID Unique ID-number of current worklist
 ETX: End of Transmission
 CRLF: Carriage Return , LineFeed

9.2 Technical data

Analyzer	
Measurement system	4 independent measurement channels wavelength of LED 400 nm
Measurement timer	Max. 600 s, error < 0.1 s
Cuvette	4 channel cuvette for optical detection capacity: 150 – 1000 µl
Calibration	Automatic calibration or manual input of up to a max. of 6 calibration curve points for each test method
Positions	4 reagent positions at 36.5 – 37.5 °C 2 reagent positions at RT (~25°C) 6 reagent positions at 12.0 – 16.0°C 3 park positions, preheating (33-38°C) 2x12 sampe primary tubes 1 emergency STAT positions
Reaction volumes	Minimum total volume is 150 µl
Approvals	CE
XYZ Robotics	
Movement	X = 383mm, 1714 steps, v = 894mm/s Y = 150mm, 1054 steps, v = 569mm/s Z = 167mm, 3400 steps, v = 181mm/s
Level Sensor	Yes , capacity change detection with Aldium sensor
Neddle	-Capacity for 4880 µL -Inner hydrophob cermamic coating -Lifetime for 50000 determination
pump	1000 µl syringe with 1000 step resolution Lifetime of syringe is 250.000 cycles
imprecision	15% at 3µL 5% at 5µL 1% > 10µl

Barcode scanner

Laserclass 2 – EN60825-1:2007

max. power = 1.7 mW

pulse period = 420 µs

wavelength = 655 nm

Accepted codec

Code 39, Codabar, Interleaved 2 of 5,
Code 128 , EAN 128 and Code 93**Power supply**

Power input

85 – 264 VAC , Class-1 socket
at 45 – 60 Hz

Power consumption

Max. 250 VA

Approvals

EN 60950-1

UL 60950-1

IEC 60950-1

CSA 22.2 No. 60950-1

Dimensions

Size (W x D x H)

650 x 102 x 630 mm

Weight

approx. 55 kg (incl. packaging)

Size (W X D x H) on palette

650 x 1065 x 765 mm

Weight (with palette)

approx. 62 kg

Ambient conditions

Operating Temperature

15 – 30 °C, no direct sunlight

Storage and transport temperature

-20 to 60 °C

Humidity

Max. <70% rel. humidity, not
condensing

Elevation above NN sea level

0 – 3,000 m

Impact resistance

according to IEC/EN 61010-1, 8.2.2

Noise output

Operating noise

max. 65 dBA

Graphic user interface / software

Interface

RS 232 (serial interface) for commu-
nication with PC for software updates,
service functions, PC evaluation**LCD display**

128 x 128 items, 70 x 70 mm

backlit, adjustable contrast

Language

German,English,Italian,Spanish

Specimen Collection

analyte	Fresh or frozen human plasma; Use within 4 hours
centrifugation	1500g x 10-15 min
anticoagulant	Sodium citrate 3.2% (0.105M)
	Mix 1 part citrate with 9 part venous blood
max. bilirubin concentration	25 mg/dL
max. hemoglobin concentration	1000 mg/L
max. triglyceride concentration	25 g/L



Typical performance data at system speed = high

Test	CV.	Range	Throughput
PT	<3%	0-30INR	108/h
APTT	<3%	15 – 420s	59/h
FIB	<7%	50-999mg/dL	65/h



Contact local distributor or manufacturer for detailed performance data (throughput, consumption, precision and accuracy).

9.3 Declaration of Conformity

			
<h2 style="margin: 0;">KONFORMITÄTSERKLÄRUNG</h2> <h2 style="margin: 0;">DECLARATION OF CONFORMITY</h2>			
<p>Wir / We</p> <p style="text-align: center;">TECO Medical Instruments Production and Trading GmbH Name des Anbieters / Supplier's name Dieselstrasse 1, D-84088 Neufahrn NB Anschrift / Address</p>			
<p>erklären in alleiniger Verantwortung, dass das Produkt, <i>declare under our own responsibility, that the product,</i></p> <p style="text-align: center;">Coatron A4</p> <hr/> <p style="text-align: center;">Bezeichnung, Typ oder Modellname / name, type or model</p>			
<p>den Anforderungen der folgenden Richtlinien entspricht:</p> <ol style="list-style-type: none"> 1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte" 2. Richtlinie 2004/108/EG über Elektromagnetische Verträglichkeit 		<p><i>corresponds to the requirements of:</i></p> <ol style="list-style-type: none"> 1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products" 2. Directive 2004/108/EC on electromagnetic Compatibility 	
<p>Zur Beurteilung der Konformität wurden u.a. folgende harmonisierte Normen herangezogen:</p> <ol style="list-style-type: none"> 1. Sicherheit: EN 61010-2-101:2002 Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte 2. EMV: EN 61326-2-6:2006 Elektromagnetische Verträglichkeit – Anforderungen 3. Risikomanagement: DIN EN ISO 14971:2012: Medizinprodukte – Anwendung des Risikomanagement auf Medizinprodukte 4. Informationen: EN ISO 18113-3:2011: Bereitstellung von Informationen durch den Hersteller – Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal 		<p>The following harmonized standards have been used amongst others:</p> <ol style="list-style-type: none"> 1. Safety: EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for in-vitro diagnostic (IVD) 2. EMC: EN 61326-2-6:2006 Electromagnetic compatibility – Requirements 3. Risk management: DIN EN ISO 14971:2012: Medical devices – Application of risk management to medical devices 4. Information: EN ISO 18113-3:2011: In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use 	
<p>Das QM-System des Herstellers ist zertifiziert durch DEKRA Certification, Stuttgart, nach: EN ISO 9001:2008 EN ISO 13485:2003+AC:2009</p>		<p><i>The QM-system of the manufacturer is certified from DEKRA Certification, Stuttgart, for:</i> EN ISO 9001:2008 EN ISO 13485:2003+AC:2009</p>	
<p>Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.</p>		<p><i>This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of quality.</i></p>	
<p>Ort und Datum der Unterzeichnung: Place and date of issue:</p>		<p>Gültig bis 01.04.2015 Valid until April 1st, 2015</p>	
<p>Neufahrn, 25.03.2014 Neufahrn, March 25th, 2014</p>  <p>Christian Högl General Manager</p>			

9.4 Disposal and recycling

Please comply with the following points when disposing of the COATRON A4:

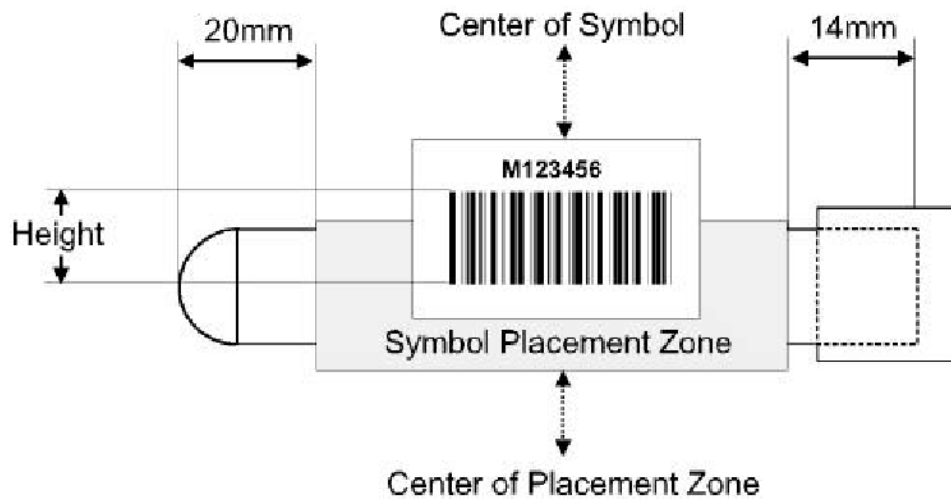
- The housing is made of polystyrene.
- The mechanical parts are mainly aluminium.
- Electronic parts must be disposed of in accordance with currently valid regulations for their disposal.



Important!

You must disinfect the COATRON A4 prior to disposal to prevent cases of infection at the disposal company!

9.5 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: 8 -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 – 13 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

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KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY

Doc#001-01/06-2022

Hersteller / Manufacturer: **TECO Medical Instruments
Production and Trading GmbH**
Adresse / Address: **Dieselstrasse 1, 84088 Neufahrn, Germany**
Marktakteur / Actor ID SRN: **DE-MF-000022642 <https://ec.europa.eu>**

Die hier benannten Produkte der generischen Produktgruppe erfüllen die Anforderungen der aufgeführten Verordnungen, Richtlinien und Normen. Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers ausgestellt.

BASIS UDI-DI 426018278CMX81152

IVD - halb-automatische Blutgerinnungsmessgeräte - Handelsbezeichnung, Typ, Kat.-Nr.
IVD - semi-automated Coagulation Systems - trade name, type, model, Cat.-No.

Coatron X Eco / Coatron X Pro / Coatron X Top

81 101 10

81 101 20

81 101 40

The products of the generic product group named here fulfil the requirements of listed regulations, directives and standards. In the case of unauthorised modifications to the product or use not in accordance with the intended purpose, this declaration becomes invalid.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Verordnung (EU) 2017/746

für in-vitro Diagnostika-IVDR
und dem harmonisierten Standard am 2022-05-12:
Risikoklassifizierung gemäß Artikel 47–Anhang VIII
Regel 5 b – „Klasse A“

Konformitätsbewertungsverfahren gemäß:
(EU) 2017/746 Artikel 17 (Anhang II+III)

Angewandte Normen zur Sicherstellung der
grundlegenden Anforderungen an Leistung und
Sicherheit:

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Richtlinie 2011/65/EU RoHS III
(incl. (EU) 2015/863) - DIN EN IEC 63000

QM-System gemäß (EU) 2017/746 Art.10(8)
angewandter Standard: EN ISO 13485:2021

Regulation (EU) 2017/746

for In-vitro diagnostic medical devices
and it's harmonized standard at 2022-05-12:
Risk classified according to article 47 annex VIII
Rule 5 b – "Class A"

Conformity assessment procedure in accordance with:
(EU) 2017/746 Article 17 (annex II+III)

Standards applied to ensure the essential requirements
for performance and safety:

EN ISO 18113-3:2011
DIN EN 62304:2018
DIN EN 62366-1
DIN EN 62366-1:2017
DIN EN 61326-1:2013
DIN EN 55011:2009 + A1:2010
IEC 61010-1:2010, AMD1:2016
IEC 61010-2-101:2015
IEC 61010-1:2010

Directive 2011/65/EU RoHS III
(incl. (EU) 2015/863 - DIN EN IEC 63000

QM-Systems in accordance with (EU) 2017/746 art.10(8)
Applied standard procedure: EN ISO 13485:2021

Ort und Datum der Unterzeichnung: Neufahrn, 2022-06-21
Place and date of issue:

Matthias Dieckmann
General Manager



Christian Hötzel
Verantwortliche Person / PRRC



KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#100/07-2021

Wir / We

TECO Medical Instruments Production and Trading GmbH

Name des Herstellers / Manufacturer's name

Dieselstrasse 1, 84088 Neufahrn, Germany

Anschrift / Address

erklären in alleiniger Verantwortung, dass die unten gelisteten IVD Zubehör Produkte:
declare under our own responsibility, that the IVD accessories products, listed below:

Doppelküvette / <i>Double cuvette</i>	Ref. 19 000 02
Einzelküvette / <i>Single cuvette</i>	Ref. 20 000 02, 24 100 00
4-fach Küvette / <i>Cuvette 4 pos/ea</i>	Ref. 80 521 10
6-fach Küvette / <i>Cuvette 6 pos/ea</i>	Ref. 80 560 00
6-fach Küvette (micro) / <i>Cuvette 6 pos/ea (micro)</i>	Ref. 80 570 00

allen anwendbaren Anforderungen folgender Richtlinien entsprechen: *meet all applicable requirements of:*

1. Richtlinie 98/79/EG über In-vitro Diagnostika und ihrem Zubehör, klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"- im Sinne von Zubehör zu In vitro Diagnostika gemäß Artikel 1.

1. Directive 98/79/EC on In-vitro diagnostic medical devices and their accessories, classified according to article 9 as: "all other products" – and in term of accessories for in vitro diagnostics according to article 1.

2. Richtlinie 2011/65/EU (RoHS III)

2. Directive 2011/65/EU (RoHS III)

Das QM-System des Herstellers ist zertifiziert nach:

The QM-system of the manufacturer is certified for:

EN ISO 13485:2016

EN ISO 13485:2016

Konformitätsbewertungsverfahren gemäß:

Conformity assessment procedure according to:

Gemäß Anhang III der Richtlinie 98/79/EG

According to Annex III of Directive 98/79/EC

Ort und Datum der Unterzeichnung:
Place and date of issue:

Neufahrn, 27.07.2021
Neufahrn, July 27, 2021

Matthias Dieckmann
General Manager



TECO

MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH

Dieselstraße 1
D-84088 Neufahrn N.B.
fon: +49-8773/707 80-0
fax: +49-8773/707 80-29

Neufahrn, 26/04/2018

TO WHOM IT MAY CONCERN

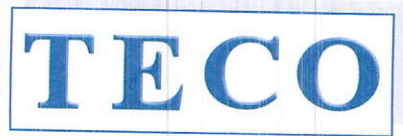
We confirm that the instruments Coatron X Eco, Coatron X Pro and Coatron X Top have a closed cuvette system. Cuvettes have to be purchased with voucher identification code from TECO GmbH.



Christian Hoetzl
General Manager
TECO Germany



Quality Management
We are certified
Voluntary participation in regular
monitoring according to ISO 9001:2008



MEDICAL INSTRUMENTS
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CERTIFICATE

for: **Mr. Vitalie Goreacii**

Company: **Sanmedico SRL**
Str. Petricani 88/1, oficiul 10
Chisinau - Rep. Moldava MD-2059
MOLDOVA

have participated with success at the intensive training session:

Application and technical training for following instruments:

- **Coatron X series**
 - **Installation**
 - **Application**
 - **General use, also in combination with TECAM Software**
 - **Technical and After Sales Service**

Supervisors: **Mr. Chr. Hoetzi and Mrs. Wendy Guo**

Place of Training: **TECO – Germany**

Date: **November 18th, 2019**



Christian Hoetzi
General Manager



TOP
INNOVATION
2017 - 2018

Clotting
Chromogenic
Immunturbidimetric

Coatron

Semi-automated
Coagulation Analyzer Series

With 1, 2 or 4 optical channels



TECO

Innovation in Coagulation

A new area of manual and semi-automated Coagulation Analyser rise up

The Coatron X instrument line is a consequent continuation in the development of the Coatron product line. Over 25 years in experience and innovation is the reference for our new Coatron X instrumentation line.

The unique detection principle in combination with the high-level analytical algorithm calculates exact, precise and reproducible results.

Easy in operation – self instructing user dialogue - reliable

Highest optical resolution, enlarged optic range, smallest sample and reagent volume

0.1 mOD, 0 - 3800 mOD, just with 75 µL sample and reagent volume

Complete optical analysis

No further parts required, like balls, stirrers etc.

Adaptation of the light level

Automatic light level adjustment of the optic channels to each sample

Exclusion of disturbance

Stray light reduction, exact temperature control, all parameter are preset

“Complete range of Coagulation Analysis with the highest standard and reliability. The new generation of Coagulation instruments with optical detection are here.”

Coatron X - product family



With 1, 2 or 4 optical channels.

www.teco-medical.com

Prepared for the daily routine and the upcoming requirements

One instrument – many possibilities

The Coatron X family is prepared to work with one, two or four channels. The built-up and functionality is specifically designed to each instrument version and requirements. The operation with the intuitive user dialogue and handling of the detection results are easy and effective. The possibility to connect the instrument to the **TECO Cloud** offers new perspective of instrument, reagent and consumables verification and handling. The precise and correct patient result is what we want to secure.



Quality is our basic demand

TECO develop and produce with qualified and specialized companies, located in Germany. High reliability, nearly maintenance free instruments are our benefit. Our reference is 25 years, in worldwide laboratories, with satisfied users.



TECO Cloud Services – A strong data bank and application service behind

All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.



Coatron	Eco	Pro	Top
General			
Dimensions	230 x 148 x 94 mm (l, b, h)		
Display	Colored touch display 4.3"		
Pre-warm temperature	37°C		
Pre-warm cuvettes (pcs.)	10	20	20
Pre-warm reagent 24mm (pcs.)	1	1	1
Pre-warm reagent 22mm (pcs.)	2	2	2
Pre-warm reagent 11mm (pcs.)	2	2	2
Reagent mixing position	-	1	1
Power values	110-240Vac, 50-60Hz / 5Vdc, 3.3A		
Interfaces			
RS232 (2x)	Printer, Barcode reader		
USB (2x)	Network, Firmware update		
Bluetooth	TECO Cloud, App		
Optic / tests			
Optic channels	1	2	4
Wavelength (nm)	620 (red)	405 (UV)	405 (UV)
Global Coag. tests	PT, APTT, TT, FIB		
Specific Coag. tests	-	individual factors	
Chromogenic Coag. tests	-	AT, PC	
Latex based tests	D-Dimer		
Whole blood tests	PT-B		-



The details make the difference

Coatron X

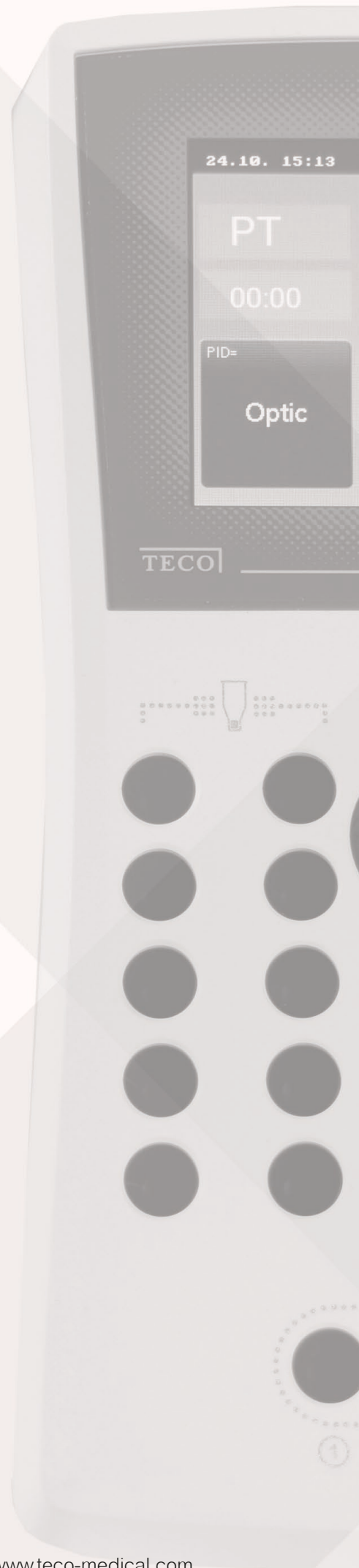
The remarkable details in every single component is achieved by selecting of premium suppliers.

The performance of a high level instrument is strongly depending on the concept in general and the perfect usability to reach the requirements of a modern laboratory analyser.

Priority No. 1 was to get a daily routine reliability and easy-to-use operation.

Software and connection possibilities

With the Coatron X product family starts a new time line in analysis management and service maintenance. Operation via intuitive, colored touchscreen, as well patient result management are perfectly optimized.



Operation details

Coatron	Eco	Pro	Top
Operation			
Touchscreen 4.3"	✓	✓	✓
Real time clock	✓	✓	✓
Stopwatch	✓	✓	✓
Language selection	✓	✓	✓
Interfaces			
USB to LIS	✓	✓	✓
Network to LIS (TECAM software required)	✓	✓	✓
Management			
Test calibration	✓	✓	✓
Tracking to Pat.ID, Patient ID, Sample ID or Auto ID	✓	✓	✓
Automatic optic start (no Starterpipette required)	✓	✓	✓
Double determination	✗	✓	✓
Sample management (ID)	✗	✓	✓
Reagent management (ID) (lot und expiry)	✗	✓	✓
Internal result databank	✗	✓	✓
Patient identification with barcode		optional	



Intuitive operation and control

Clear and easy to operate user dialogue with a high quality colored touchscreen

- Direct usable
- Short learning phase
- Logic, intuitive operation
- Reliable touchscreen surface
- Quick touch response



For small and mediate laboratory requirements

Concept is suitable for daily routine work in Coagulation laboratories and hospitals

- Three different versions available, depending on number of samples per day
- In maximum up to 4 optic channels available

Interfaces

RS232 (2x)

- For external serial printer and external barcodereader

LIS/USB

Bluetooth



Integrated barcode scan for reagents.





TECO Cloud Services

A strong data bank and application service behind

All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.



For trading partners worldwide, please visit our web-page

TECO Medical Instruments Production + Trading GmbH
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TECO
Innovation in Coagulation

TECO

Manual de operare

Seria X Coatron

Eco / Pro / Top



IVD

CE

REP

Doar pentru diagnosticul in-vitro

Dispozitive și reagenți pentru coagulare și hemostază

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OPM Revizuirea 1

Program V01.00.39

Document No: 26 900 01

Reprezentant autorizat în Republica Moldova:

SANMEDICO SRL

mun. Chișinău, str. Petricani 88/1, of.10

tel: (022) 623 032; 060 155 788

Actualizări

VERSIUNEA INSTRUCȚIUNII UTILIZATORULUI	VERSIUNEA PROGRAMULUI
1	1.00.39 (prima ediție)

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Mărcile comerciale

Coatron este marcă comercială a TECO GmbH. Alte denumiri de produse utilizate în acest manual al operatorului sunt mărci comerciale ale companiilor respective.

Producătorul

Dispozitivul este produs de
TECO GmbH
Dieselstrasse. 1
D-84088 Neufahrn, Germania

Telefon: +49 (0) 8773 70780-0
 Fax: +49 (0) 8773 70780-29
 Internet: <http://www.teco-gmbh.com>

Garanție

Coatron X are o garanție de un an după livrare sau după prima instalare. Garanția acoperă orice defecte de material, funcționalitate sau manoperă (a se vedea, de asemenea, „Termenii și condițiile generale”). Prima instalare trebuie înregistrată în „Registrul de instalare”.

Garanția expiră în caz de defecțiuni cauzate de:

- Accident, neglijență în întreținere și înșelăciune, abuz sau utilizarea necorespunzătoare.
- Folosirea de reactivi, materiale consumabile sau piese de schimb neautorizate.
- Deservirea neautorizată. Orice reparație sau deservire trebuie efectuată de persoane autorizate.

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1. INTRODUCERE

Acest dispozitiv a fost fabricat în condiții de maximă eficiență în ceea ce privește siguranța și funcționalitatea sa de inginerie. Pentru a menține această condiție și a asigura o operare fără riscuri, operatorul trebuie să respecte avertismentele și informațiile de siguranță din acest manual de utilizare.



Folosiți Coatron X numai în conformitate cu instrucțiunile din acest manual de utilizare. În caz contrar, producătorul exclude răspunderea pentru daunele aduse dispozitivului Coatron X, pacienților sau operatorilor.

1.1 SIMBOLURI

Următoarele simboluri standard sunt utilizate în acest manual:

SIMBOL	Semnificația	Explicația
Courier	Informație	Buton pe tastatură
CAPS	Informație	Mesaj pe ecran
	Citare	Indică <u>informație importantă</u> și sfaturi
	Informație	Descrie reacția Coatron X la intrarea făcută de operator.
	Atenție	Risc de posibile daune de sănătate sau daune considerabile echipamentului dacă nu se ține cont de avertisment.
	Pericol	Risc potențial pentru personalul care operează cu echipament sau pentru dispozitiv din cauza șocului electric.
	Pericol biologic	Echipamentul poate fi potențial infecțios datorită probelor și reactivilor folosiți.
	Radiație laser	Evitați expunerea directă a ochilor

1.2 IMAGINI CU DISPOZITIVUL



Ecranul principal

Ecran tactil color

Zona completată este preîncălzită până la 37°C

1 x poziția reagentului Ø24mm

1 x poziția reagentului Ø22mm

1 x poziția reagentului Ø22mm, amestecat

2 x pozițiile reagentului Ø13mm

20 x pozițiile de incubare ale cuvetelor

4 x pozițiile de măsurare a cuvetelor

(depinde de versiunea ECO/PRO/TOP)

Imaginea 1: Vedere de sus



5V: Cablul de energie

PC: LIS sau PC

DESERVIRE: Actualizarea programului

IMPRIMANTĂ: Impriantă în serie

CODUL DE BARE: Scanner de mână a codurilor de bare

Imaginea 2: Vedere din spate



5V: Cablul de energie

PC: LIS sau PC

DESERVIRE: Actualizarea programului

IMPRIMANTĂ: Impriantă în serie

CODUL DE BARE: Scanner de mână a codurilor de bare

Imaginea 3 : Vederea laterală cu slotul pentru codul

de bare




1.3 UTILIZAREA PROPUȘĂ



Familia COATRON-X este proiectată pentru a efectua teste coagulometrice, cum ar fi PT, PTT, TT, fibrinogen, teste cu un singur factor, teste cromogene și imunoturbidimetrice (de exemplu, antitrombină, D-dimer etc.) pe plasmă citrată umană. Aparatul trebuie utilizat în scopurile preconizate și în condiții tehnice perfecte, de către personal calificat, în condiții de muncă și operațiuni de întreținere, așa cum este descris în acest document. Este conceput pentru mediu de laborator sau clinic și pentru a fi operat de un utilizator instruit. Nu este destinat uzului casnic.

1.3.1 COMPARAȚIA DISPOZITIVELOR COATRON X

Coatron-X este disponibil în trei versiuni diferite numite Eco, Pro sau Top.

Coatron-X	Eco	Pro	Top
			
Canalele optice	1	2	4
Lungimea de undă optică	620nm	405nm	405nm
Cuvete, volum total	Singular, 75μL	Singular, 75μL	Singular, 75μL
Analize totale de coagulare	PT+aPTT+Fib+TT		
Analize speciale de coagulare	-	Toți factorii	Toți factorii
Analize cromogene	-	AT, PC	AT, PC
Analize avansate latex	D-Dimer		
Testarea sângelui integru	Da (PT INR+%)	Nu	Nu
Ecran	TFT 4.3" , 480x272 , 18bit color, multi-touch		
Parametrii fizici	Forma X 225x150x90mm (LxlxÎ) cu imprimeu tampon		
Blocarea reagenților și optică	Preîncălzit la 37°C		
Preîncălzirea cuvetelor	10x	20x	20x
Preîncălzirea reagenților, 24mm	1x		
Preîncălzirea reagenților, 22mm	2x		
Preîncălzirea reagenților, microtuburi	2x		
Agitator de reagenți	nu	1x	1x
Interfața pentru imprimanta din serie	Da		
Interfață pentru scannerul de coduri de bare portabil	Da		
Modulul scannerului de coduri integrat	opțional		
LIS, USB	Da		

Actualizarea programului, USB	Da
Bluetooth V4.0	Urmează

Funcțiile utilizatorului	Eco	Pro	Top
Utilizare intuitivă prin Touchscreen		Da	
nu este necesară experiență sau pregătire			
Algoritmul de coagulare TECO avansat		Da	
Cel mai bun din experiența de 25 de ani			
Lotul de reagent dublu	Nu	Da	Da
gestionați două loturi diferite pentru fiecare test			
Barcodul de reagenți		Da	
LOT de intrare + Detectare LOT de expirare sau LOT pozitiv			
Calibrarea testului		Da	
LOT, expirare și maximum 5 puncte pentru fiecare test			
Codul de bare a pacientului		Da	
Introduceți ID-ul pacientului prin scenerul de coduri de bare până la 16 caractere			
Baza de date a rezultatelor	Nu	Da	Da
Salvați rezultatele în dispozitiv			
Determinarea dublă	Nu	Da	Da
Rulați pacientul de două ori și afișați valoarea medie			
Funcția cronometru	1x	2x	4x
Cronometrați timpul de incubare			
Identificarea rezultatelor		Da	
Numărul de identificare al pacientului, a mostrei sau autoidentificare			
Ceas în timp real		Da	
Funcția dată și timp			
Modificarea limbii		Da	
EN,ESP, ITA, FR,DE – în continuare ca opțiune			
Începeți testarea la adăugarea reagentului		Da	
Nu este necesară o pipetă de start scumpă			
Vizualizați curba de reacție		Da	
Este necesar programul Tecmoni			
Link către LIS prin USB		Da	
Protocolul programului TECAM SMART			
Link către LIS prin rețea / ASTM		Da	
Este necesar programul TECAM SMART			

1.3.2 METODE DE TESTARE

Următoarele teste sunt furnizate pentru a detecta afecțiunile sistemului de coagulare uman, care pot fi sângerare sau tromboză și monitorizarea medicamentelor anti-coagulare precum Heparin sau Marcumar.

Testul	Denumirea	Specimen	Coatron X		
			Eco	Pro	Top
PTB	Timpul de protrombină	Sînge	Da	Nu	Nu
PT	Timpul de protrombină	Plasmă	Da	Da	Da
aPTT	Timpul protrombinic parțial activat	Plasmă	Da	Da	Da
FIB	Fibrinogenul	Plasmă	Da	Da	Da
TT	Timpul trombinei	Plasmă	Da	Da	Da
AT	Antitrombina	Plasmă	Nu	Da	Da
DD	D-Dimer	Plasmă	Da	Da	Da
PC	Proteina C	Plasmă	Nu	Da	Da
Factors	Factorii II, V, VII, VIII, IX, X, XI, XII	Plasmă	Nu	Da	Da

1.3.3 COLECTAREA MOSTRELOR

Tipul: Plasmă citrată umană
 Colectarea: puncția venei, 1:10 citrat de sodiu mixt 3.2% (0.105M)
 Centrifugarea: 10 min la 1500g
 Păstrarea: Max 4h după colectare, la temperatura camerei

Bilirubina: < 50mg/dl
 Hemoglobina: < 2000mg/l
 Trigliceridele: < 50g/l

Specimen destinat pentru PTB (Coatron X Eco)

Tipul: sânge capilar din puncția degetului, sânge integru citrat



În cazul în care există diferențe față de elementele de siguranță ale reactivului, urmați întotdeauna instrucțiunea din cutie.

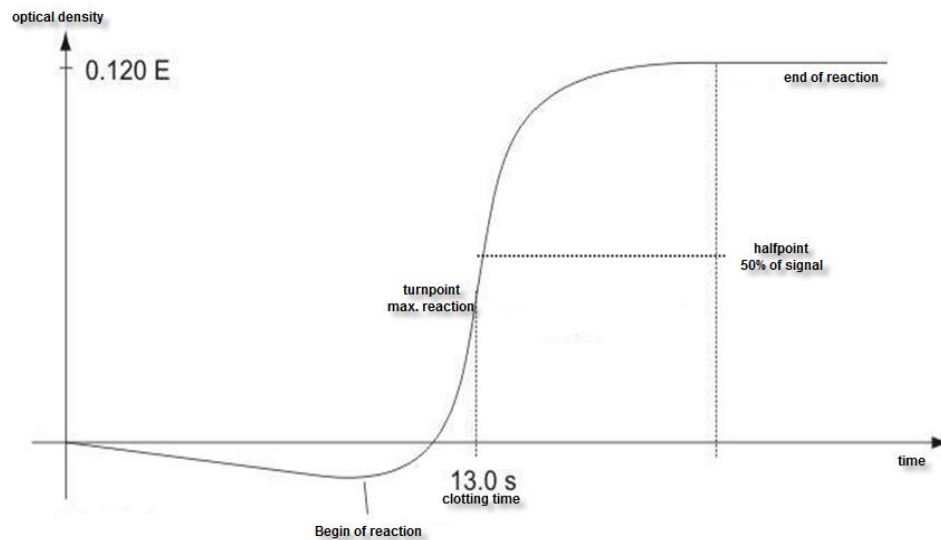
1.3.4 PRINCIPIUL DE MĂSURARE

Detectarea coagulării plasmatică se bazează pe principiul fotometric. Nu sunt necesare accesorii mecanice precum bilele de amestecare. Plasma de sânge este turnată într-o cuvă. Se adaugă reactivi speciali, care inițiază coagularea sângelui. Cuvă este expusă prin lumină ultravioletă în timpul procesului de coagulare. Când proba începe să coaguleze, se măsoară o schimbare a absorbției luminii. Timpul de la începerea măsurării până la schimbarea luminii (punct de cotitură) se numește timp de coagulare și se exprimă în secunde [s]. Conversia timpului de coagulare într-o unitate de test specifică este una folosind o interpolare liniară, hiperbolică, semi-logaritmică sau dublu-logaritmică a punctelor de calibrare stocate. Modelul matematic actual este tipărit în „SETUP TEST”. Valorile în afara domeniului de calibrare sunt calculate prin extrapolare și marcate ca " * ".

Unitate	Informație	Locurile decimale	Valoare maximă
s	secunde	1	-
%	activitate	1	180.0
U	unități	0	999
INR	Raport int.	2	30.00
R	raport	2	30.00
NR	raport polonez	0	180
mg/dl		0	900
g/l		2	10.00
IE/ml	Unități int.	2	10.00
mg/l		2	10.00
μg/ml		3	7.000
ng/ml		0	7500
μg/l		0	7500
IU/mL	Unități int.	2	10.00

R = timpul de coagulare / timpul normal
 NR = 100 * (timpul normal / timpul de coagulare)
 INR = Ratio^{ISI} (Raport normal internațional)
 IU/mL = IE/mL = Unități internaționale (1.00 IU/mL = 100 % activitate)

1.3.5 METODA DE COAGULARE (PT, APTT,..)



IMAGINEA 4: DETERMINAREA PUNCTULUI DE ÎNTOARCERE ÎN METODA DE COAGULARE

Reacția finală în cascada de coagulare este transformarea fibrinogenului în fibrină catalizată de trombină. Formarea fibrinei are ca rezultat oglindirea (nivel turbidimetric mai mare) în probă, care este măsurată de fotometru și stocată ca dispariție. Rezultatul în câteva secunde este timpul de la începutul reacției până la momentul vitezei maxime de schimbare (punctul de cotitură al reacției). Dispozitivul poate fi comutat și pentru a defini coagularea la jumătatea punctului de reacție.

1.3.6 METODA CROMOGENĂ (ANTITROMBINA):

Schimbarea semnalului optic nu este cauzată de reacția de cheag, ci de eliberarea de particule de culoare (pNA), care provoacă o culoare galbenă. Schimbarea culorii este măsurată la 405 nm și exprimată ca „dE/60sec” și proporțională cu concentrația sau activitatea analitului.

1.3.7 METODA IMUNOTURBIDIMETRICĂ (D-DIMER):

Schimbarea luminii este cauzată de reacțiile Antigen - anticorp, care au dispersat lumina. Anticorpul se leagă de particulele de latex la amplitudinea reacției optice. Schimbarea luminii este proporțională cu concentrația de antigen precum D-Dimer și exprimată ca dE/120 sec.

1.4 INFORMAȚIA CU PRIVIRE LA SIGURANȚĂ

1.4.1 INFORMAȚII DE SIGURANȚĂ PENTRU FUNCȚIONARE



Folosiți numai lichidele de curățare și clătire aprobate de producător. Nerespectarea acestui lucru poate duce la măsurări defectuoase sau defecțiuni ale reactivilor Coatron X. Preveniți scurgerile în analizator. În caz contrar, este necesar ca lucrările de întreținere costisitoare să fie necesare!



Efectuați măsurări de control la intervale regulate pentru a vă asigura că analizorul continuă să funcționeze impecabil .



Dacă dispozitivul este utilizat într-o manieră, care nu este specificată de producător, garanția ar putea fi afectată!



Vă rugăm să citiți manualul de utilizare în întregime înainte de operare. Pentru a asigura un nivel ridicat de performanță și pentru a evita erorile utilizatorului.

1.4.2 INFORMAȚII DE SIGURANȚĂ PENTRU MATERIALE



Folosiți numai materiale aprobate și etichetate TECO, cum ar fi cuvete, piese de schimb sau reactivi pentru care dispozitivul este destinat și validat.



Consumabile precum cuvete sau vârfuri galbene sunt destinate obiectelor de unică folosință. Utilizarea repetată poate duce la rezultate false din cauza contaminării. Urmați instrucțiunile din circularele pachetului de reactivi. Utilizarea incorectă poate duce la rezultate false.



Nu folosiți materialele după data de expirare. Reactivii IVD în special expirați pot provoca rezultate false.



Controlați funcția corectă a pipetei manuale în fiecare an pentru a asigura rezultate precise.

1.4.3 INFORMAȚII DE SIGURANȚĂ PRIVIND RISCUL PENTRU SĂNĂTATE

Sângerare sau tromboză

Diagnosticul și medicația sistemului de coagulare uman bazat pe rezultate false poate duce la sângerare critică sau tromboză. Pentru reducerea riscurilor, este esențial să urmăriți indicațiile de mai jos.

Provocată din cauza stării de eroare a dispozitivului, a reactivului sau a datelor de calibrare:

Efectuați un control al calității înainte de a rula o serie de probe de pacient sau după reconstituirea unui flacon sau după calibrarea testului pentru a exclude erorile de date ale dispozitivului, reactivului sau calibrării.



Provocată de o pipetă imprecisă:

Validați pipeta în fiecare an și etichetați ultima dată de validare.

Provocat de alocarea falsă a valorilor țintă

Executați standardele interoperaționale de control al calității.

Provocat de apa purificată

Folosiți doar apă purificată pentru a reconstitui controale sau reactivi. Verificați vizual ca apa să nu conțină impurități.

Provocat de reactivul expirat

Nu folosiți reagentul *in vitro* sau materialele după data lor de expirare.

Material contaminant

Aveți în vedere toate suprafețele și materialele, care ar putea intra în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.

Evitați contactul

Purtați mănuși de protecție contra infecțiilor medicale pentru toate lucrările, care implică un contact potențial cu materiale infecțioase și utilizați fiecare pereche de mănuși o singură dată. Folosiți un produs dezinfectant pentru mâini, de ex. Sterilium®, pentru a dezinfecta mâinile după finalizarea lucrărilor.



Aruncați

Materialele infecțioase, cum ar fi deșeurile de cuvă și deșeurile lichide, în conformitate cu legile locale, care reglementează materialele infecțioase.

Condițiile de igienă

Validează sistemul de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, servirii sau curățării.



Radiație cu lumină LED

Evitați expunerea directă a ochilor.
Scannerul intern de coduri de bare CCD este atribuit
EN 55022:2010 clasa B, EN 62471:2008

1.4.4 INFORMAȚII DE SIGURANȚĂ PENTRU CURĂȚARE, ÎNTREȚINERE ȘI DESERVIRE



Despre deservirea autorizată!

Efectuați numai măsurile de întreținere, reparație și înlocuire enumerate în acest manual de utilizare. O manipulare necorespunzătoare a dispozitivului va anula obligațiile de răspundere ale producătorului și poate face necesară efectuarea apelurilor de servicii, a căror plată nu este acoperită de garanție. Numai Serviciul Clienți autorizat poate efectua reparațiile. Se pot folosi numai piese de schimb originale. Înainte de a efectua orice reparație pe dispozitiv, este foarte important să dezinfecțați complet toate piesele posibil contaminate.



Despre curățire și decontaminare!

Înainte ca dispozitivul să fie scos din laborator pentru eliminare sau întreținere, acesta trebuie decontaminat. Procedura este descrisă în capitolul „Curățare și întreținere” și trebuie efectuată doar de personal autorizat bine instruit, respectând toate măsurile de siguranță necesare.



Certificatul de decontaminare este necesar!

Dispozitivele, care trebuie returnate trebuie să fie însoțite de un certificat de decontaminare completat de responsabilul de laborator. Dacă nu este furnizat un certificat de decontaminare, laboratorul de returnare va fi responsabil pentru taxele rezultate din neacceptarea dispozitivului de către centrul de deservire.






Aveți în vedere toate suprafețele și materialele care ar putea fi în contact cu plasmă sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.



Evitați orice contact direct cu decontaminanți sau dezinfecțanți.

1.4.5 SIGURANȚA ELECTRICĂ

	<p>Precauții:</p> <ul style="list-style-type: none"> ▪ Evitați lichidele vărsate în sistem. Dar în cazul în care acest lucru se întâmplă, deconectați dispozitivul de la sursa de energie și curățați și uscați toate părțile contaminate. ▪ Scoateți cablul de alimentare înainte de a deschide dispozitivul. ▪ Nu atingeți piesele electronice în timpul funcționării. ▪ Nu folosiți sistemul fără o conexiune adecvată la împământare. ▪ Nu întrerupeți niciodată intenționat contactele de protecție la sol. ▪ Nu îndepărtați niciodată elementele carcasei, capacele de protecție sau elementele structurale securizate, deoarece acest lucru ar putea expune piese, care transportă curent electric. ▪ Asigurați-vă că suprafețele precum podeaua și masa de lucru nu sunt umede în timp ce se lucrează pe dispozitiv. ▪ Verificați regulamentul echipamentelor electrice. Conducele sau soclurile defecte trebuie înlocuite fără întârziere.
	<p>Conectați la energie:</p> <ul style="list-style-type: none"> ▪ Dispozitivul este clasificat în clasa 1 (IEC) și, prin urmare, trebuie să fie legat în mod fiabil și instalat profesional, în conformitate cu reglementările în vigoare privind cablurile electrice și cu standardele de siguranță prevăzute aici. ▪ Asigurați-vă că setarea tensiunii de funcționare este corectă înainte de a conecta dispozitivul la rețeaua de alimentare. Citiți capitolul „Instalare” despre condițiile electrice.
	<p>Deconectați de la energie:</p> <ul style="list-style-type: none"> ▪ Deconectați cablul de alimentare de la priza de perete sau de la sursa de alimentare a dispozitivului.

1.4.6 DECLARAȚIA EMC



Coatron X respectă cerințele privind emisiile și protecția, în conformitate cu GB/T 18268.1 (IEC 61326-1: 2012) și GB/T 18268.26 (IEC61326-2-6: 2012).



Coatron X a fost proiectat, testat și găsit în conformitate cu dispozitivul Clasa A, în conformitate cu GB 4824 (IEC 61000-4). În mediul intern, acest dispozitiv poate provoca interferențe radio, caz în care utilizatorul este obligat să ia măsuri adecvate.



Detectarea mediului electromagnetic este recomandată înainte de a utiliza acest dispozitiv.



Evitați să acționați acest dispozitiv în apropierea unei surse de radiație puternică (de exemplu, o sursă RF ne-ecranată), care poate interfera cu funcționarea corectă a dispozitivului.



Lungimea maximă a cablurilor către dispozitivele externe precum imprimanta, codul de bare sau LIS trebuie să fie mai mică de 3 m pentru a păstra conformitatea cu EMC. (IEC 61326-1:2012)



Nu instalați pe masa metalică de 3m.

1.4.7 RECICLAREA DISPOZITIVULUI



Sistemul trebuie decontaminat de deșeurile electrice înainte de transportare către un dispozitiv autorizat.



Dispozitivul trebuie reciclat, așa cum este indicat de DEEE (2002/96/EG).

2. INSTALAREA DISPOZITIVULUI COATRON X

2.1 OBIECTUL LIVRĂRII

Pachet de livrare standard

- 1 buc. **Coatron X**
- 1 buc. Sursa de energie
- 25 buc. Cuvete de unică folosință
- 5 buc. Tuburi pentru reagenți
- 1 buc Manualul utilizatorului



Imaginea 5: Setul standard la livrare

Opțional sunt disponibile:

- Imprimantă termică
- Cablul imprimantei
- Rulouri de hîrtie pentru imprimantă (5/ea)
- Pipetă cu volum variabil 10 -100 μ l, simplă
- Programul TECAM Smart

2.2 CONDIȚII DE LUCRU

Condițiile de mediu:

Temperatura de operare	15 - 30 °C
Umiditatea	< 70%
Ridicarea deasupra nivelului mării	< 3.000m
Protecție de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu este permis	Vibrații, lumină directă a soarelui; expunerea directă la condițiile de aer.

Condițiile electrice:

100-240 VAC, 47 - 63Hz, Clasa-1 (61010)

Condițiile de păstrare:

0°C to +40°C, maxim 12 luni în ambalajul original

Condițiile de transportare:

0°C - +40°C, < 70% umiditate relativă

Nu este definit special. Regulamentul general pentru transport poate fi utilizat.

Condițiile de igienă:

Validat conform sistemului de management igienic în conformitate cu biroul federal german GLP pentru bune practici de laborator sau standarde de calitate similare. Orice deșeuri trebuie considerate potențial infecțioase. Trebuie evitat contactul direct. Sunt necesare mănuși de protecție în timpul funcționării, deservirii sau curățării.

2.3 DESPACHETAREA DISPOZITIVULUI COATRON X

Verificați ambalajul Coatron X și al accesoriilor pentru eventuale deteriorări vizibile. Dacă ambalajul este deteriorat, contactați compania de transport pentru a putea fi evaluată orice deteriorare a dispozitivului sau a accesoriilor.

Procedurile la prima instalare:

1. Despachetați și așezați dispozitivul în conformitate cu condițiile de funcționare (a se vedea cu un capitol înainte).
2. Conectați la sursa de energie.
3. Porniți și așteptați până la regimul verde.
4. Atingeți Green Status și selectați „print”.
5. Atașați raportul de sistem în „Înregistrare protocol de instalare” sau casetă.
6. Confirmați funcția corectă a sistemului printr-o măsurare de control al calității cu PT și plasmă de control.

Instalarea programului TECAM Smart

1. Deconectați dispozitivul de la calculator.
2. Rulați TECAM setup.exe.
3. Confirmați, atunci când vi se cere să instalați driver-ul Coatron X.
4. Conectați dispozitivul la calculator. PC-ul ar trebui să mesajeze, că a fost găsit un dispozitiv nou.
5. Reporniți TECAM.

Informații suplimentare pot fi citite în capitolul „7” sau ajutorul online TECAM.



Păstrați materialul de ambalare original pentru transportul ulterior.

2.4 PORNIREA ȘI OPRIREA

Pornirea

Conectați la sursa de energie.

Dispozitivul necesită aproximativ 15 min pentru încălzirea blocului optic la 37 ° C. După aceea este gata pentru măsurare, care este indicat cu un LED verde pe afișaj.

Oprire

Aparatul nu acceptă întrerupător de alimentare. Trebuie să se deconecteze de la energie.

Regim de așteptare

Comutarea sistemului în standby după 2 min de funcționare inactivă. În standby, luminozitatea afișajului este redusă pentru a economisi durata de viață a afișajului și pentru a reduce consumul de energie.

Regimul "somn"

Deschideți meniul și atingeți butonul „Sleep”.

Meniul este afișat în partea de sus a ecranului și este disponibil numai dacă nu există nici măsurare. Consumul de energie în timpul somnului este de 0,2W.

"Trezirea"

Ecranul tactil.



Nu există niciun risc de deteriorare a sistemului sau de pierdere de date. Sistemul poate fi (de) conectat în orice situații de operare.

2.5 ÎNREGISTRAREA

Producătorul trebuie informat despre data primei instalări. Pentru aceasta, navigați pe site-ul web TECO GmbH www.teco-gmbh.com și conectați-vă cu datele contului dispozitivului, care sunt afișate în timpul pornirii sau a ecranului cu informații despre sistem sau pe placa de dispozitive.

User= S/N Numărul de serie, de exemplu 0104000005

Pass= PIN Numărul de identificare al produsului, de exemplu 1234 5678 90

2.6 GARANȚIA

Termenul de garanție va începe din data livrării sau înregistrării (prima instalare).

3. OPERAREA CU DISPOZITIVUL COATRON X

Coatron X este controlat în totalitate prin ecran tactil.

- Atingere scurtă: Funcția este executată la atingere
- Atingerea lungă: Funcția este repetată de 10 ori
- Textul butonului gri: Funcția este oprită

În timpul măsurării active, unele funcții din meniu nu sunt vizibile sau afișate cu text gri. Opriți măsurarea pe toate canalele pentru a reactiva butoanele.

3.1 GHIDUL RAPID

Cum se execută o măsurare PT:

1. Porniți dispozitivul și așteptați starea verde (~ 15min până la 37 ° C).
2. Puneți flaconul PT în blocul de reactiv și lăsați să se incubeze timp de cel puțin 5 min.
3. Schimbați testul canalului 1 în „PT”.
4. Plasați cuva în optică.
5. Introduceți 25 ul de probă în cuvă.
6. Apăsați pe „00:00” și așteptați 30 sec.
7. Apăsați „OPTIC-1” și introduceți un PID sau scanați un cod de bare de probă.
8. Adăugați 50 uL reactiv PT, când „Activ” clipește. Măsurarea va fi începută.
9. Așteptați să se rupă rezultatul sau atingeți butonul optic.

Activarea multiplă (cu excepția Coatron ECO)

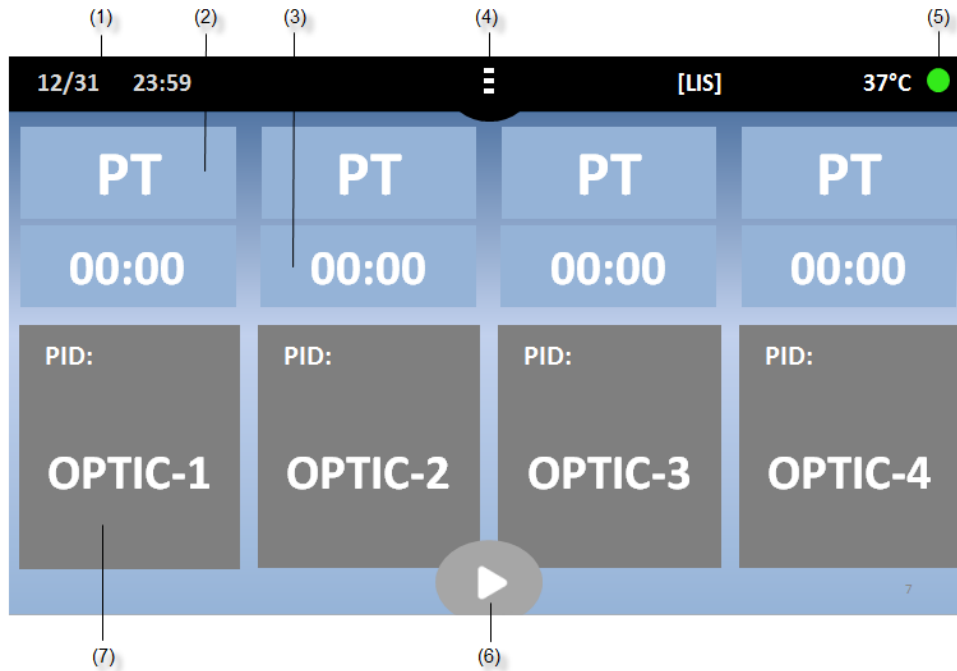
1. Deschideți meniul și setați Auto PID = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul mutlistart.
4. Adăugați 50 ui PT la fiecare cuvă.

Cum se introduce o calibrare PT:

1. Porniți dispozitivul și treceți la ecranul de pornire.
2. Atingeți orice buton de testare.
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT.
4. Introduceți LOT, data de expirare și selectați Unități în „% + INR”.
5. Apăsați din nou butonul „Configurare”.
6. Selectați câmpul de date și schimbați cu butoanele incrementale (- / +). Utilizați funcția de atingere lungă pentru o introducere ușoară.
7. Confirmați cu „OK”.

3.2 MĂSURAREA

Primul ecran după pornire



IMAGINEA 6: ECRANUL DE BAZĂ COATRON X TOP

Butonul	Titlul	Utilizarea funcției
(1)	Data și timpul Testarea	Redactarea datei
(2)	curentă	Modificarea testului
(3)	Taimer Meniu sau	Start/Resetarea taimerului sau alarmei
(4)	Acasă	Deschideți meniul sau reveniți la principal
(5)	Verde sau Roșu	Deschideți informațiile despre sistem
(6)	Multistart	Activați toate canalele Channel-1 este inactiv. Atingeți pentru a introduce un
(7)	Optic-1	nou PID și activați Canalul este activ. Atingeți sau adăugați reactiv pentru a începe
(7)	Activ Portocaliu	
(7)	intermitent Rezultatul	Măsurarea continuă. Atingeți pentru a opri măsurarea
(7)	curent	Atingeți pentru a introduce un nou PID

Altele

eșantion cod de bare	Citiți ID-ul pacientului și urmăriți activarea gratuită
[LIS]	Vizibil, dacă este conectat cu LIS
LED Verde	Sistemul este gata pentru măsurare
LED Roșu	Indică problemele sistemului. Nu este posibilă nicio măsurare.
37.0°C	Temperatura pe blocul de reactiv.
Butoane gri Contrast	Funcția de utilizare nu este posibilă în timpul măsurării.
Întunecat	Modul de salvare. Atingeți pentru a reactiva.

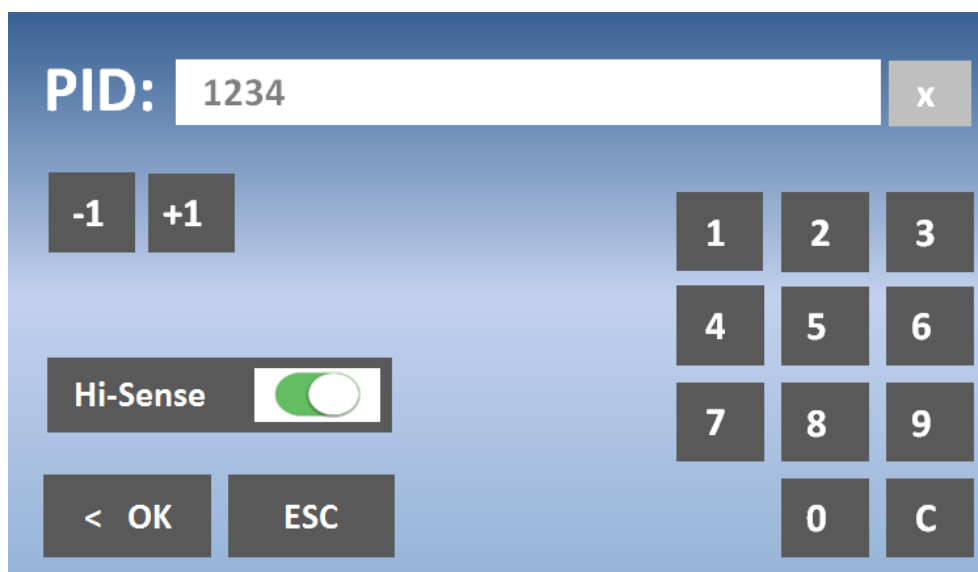


IMAGINEA 7: ECRANUL ÎN TIMPUL MĂSURĂRII

Butonul (7) în timpul măsurării

PID	Numărul de identificare al pacientului (maxim 16 cifre)
Rezultat	PT = 12.5s, 115% 0,91 INR +++ nici o reacție de cheag nu a fost detectată în timp de execuție
Indicator	f = fibrinogen foarte scăzut (cheag slab) F = fibrinogen foarte mare (cheag puternic) * = Rezultatul nu corespunde cu calibrarea X = valoarea dublă deviază mai mult decât 15%
Err	T = temperatura nu este la 36 - 38°C E = reagent expirat S = intensitatea luminii este prea joasă
mOD	absorbție optică curentă. O schimbare a valoare > 50mOD indică o reacție de cheag în curs.
Taimer	Ora curentă de măsurare

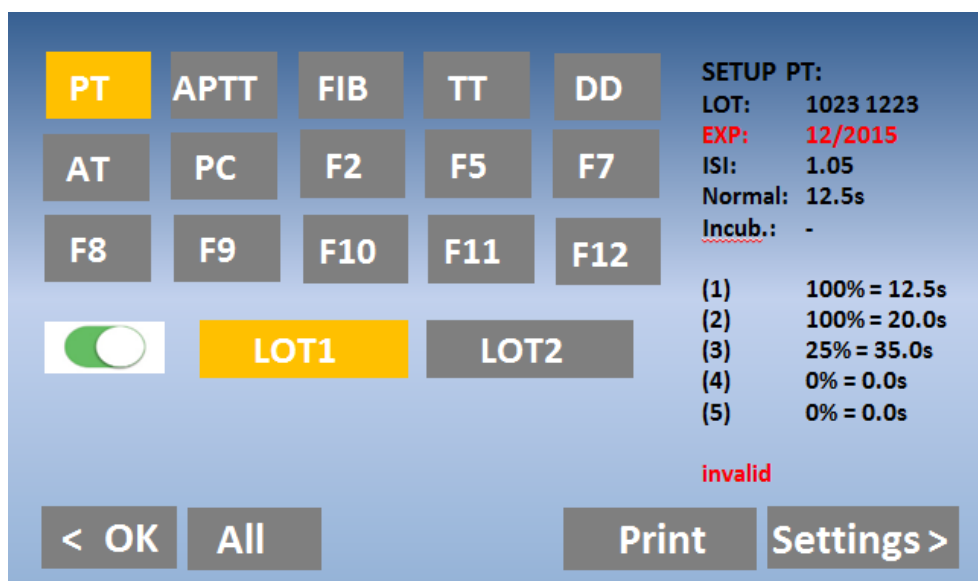
3.3 INTRODUCEREA INFORMAȚIEI DESPRE PACIENT



IMAGINEA 8: INTRODUCEREA NUMĂRULUI DE IDENTIFICARE AL PACIENTULUI

Buton	Titlu	Funcția utilizată
Taste numerice	0-9, C, X	Modificați sau ștergeți NIP
Incrementa	-1 / +1	Măriți NIP. Utilizați posibilitatea de atingere lungă pentru modificarea ușoară.
Hi-Sense	Hi-Sense	Pornește sensibilitatea foarte înaltă de detecție. Util pentru mostre sau rezultate "+++".
Apăsarea lungă	-	Apăsați butonul > 2 sec
Codul de bare mostră	-	Setați numărul de identificare la codul de bare

3.4 ALEGEREA TESTULUI



IMAGINEA 9: ALEGEREA TESTULUI LA COATRON X PRO/TOP

Butonul	Titlul	Utilizarea funcției
Butoanele de testare	PT – F12	Alegeți testul
On / Off	On / Off	Activați două LOT-uri pe test (nu sunt disponibile) pentru Coatron X Eco)
LOT 1/2	LOT 1/2	Încărcați datele LOT 1 sau 2 de la EEPROM
OK	OK	Confirmați testul pentru canalul curent
Toate	Toate	Confirmați testul pentru toate canalele
Setările	Setările	Schimbați calibrarea testului
Print	Print	Tipăriți setarea testului curent

Codul de bare al reagentului

-

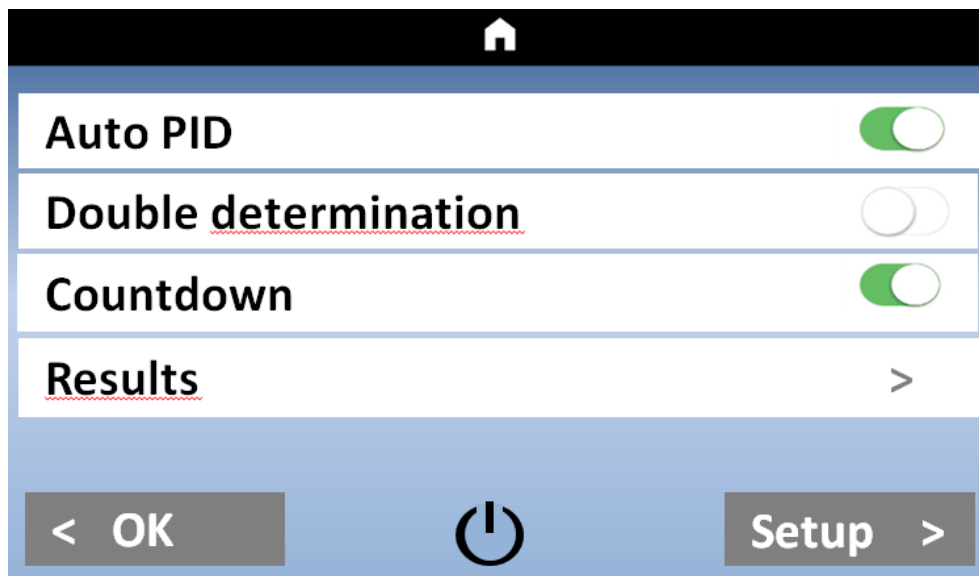
Selectați testul curent și lotul.
Un semnal sonor lung indică codul de bare sau LOT-ul nevalide.

SETAREA PT

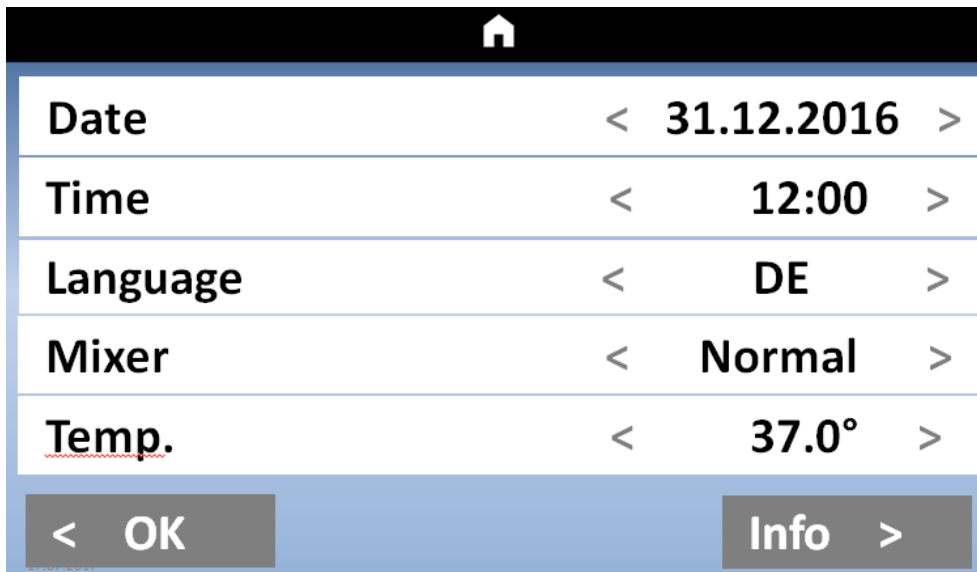
-

Date de calibrare a lotului și testului curent.
Valorile roșii indică date nevalide.

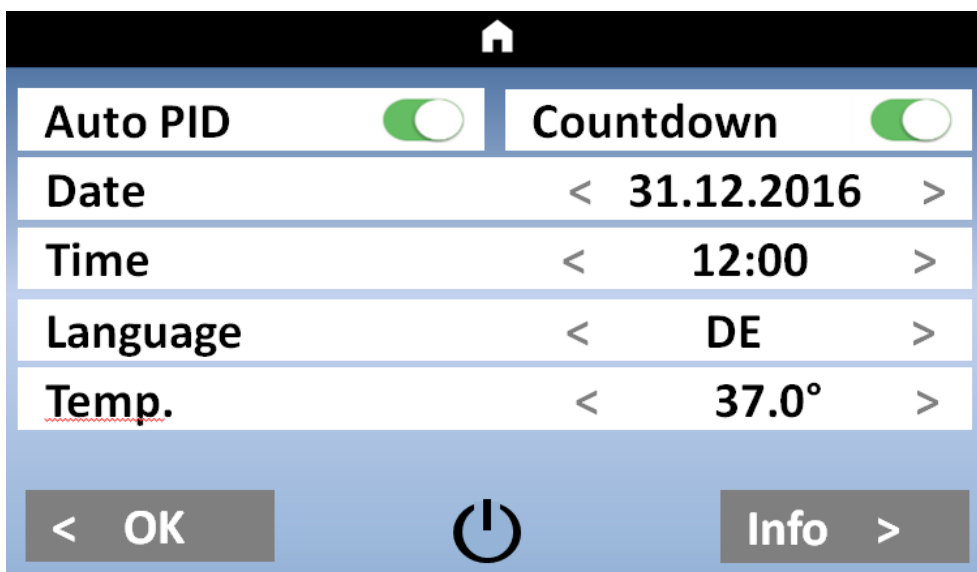
3.5 SETĂRILE DE SISTEM



IMAGINEA 10: MENIUL RAPID COATRON X PRO/TOP

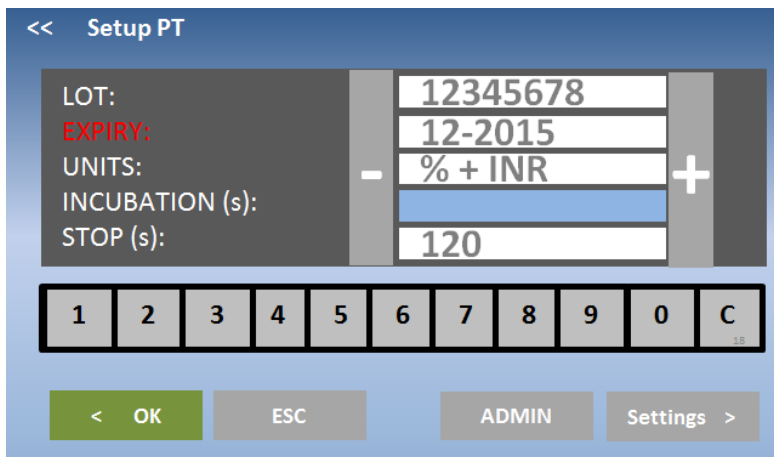


IMAGINEA 11: SETĂRILE DE SISTEM COATRON X PRO/TOP

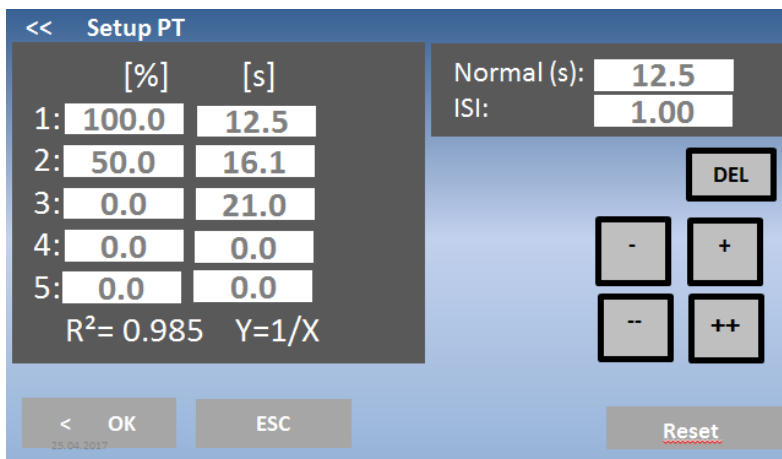


IMAGINEA 12: SETĂRILE DE SISTEM COATRON X ECO

3.6 SETĂRILE TESTULUI

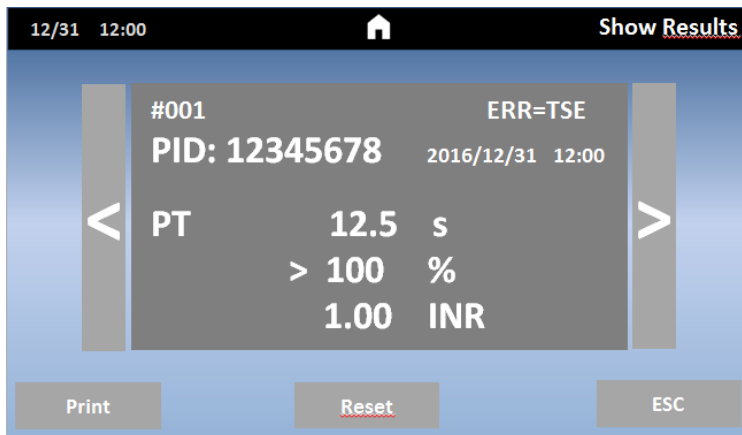


IMAGINEA 13: SETĂRILE TESTULUI 1



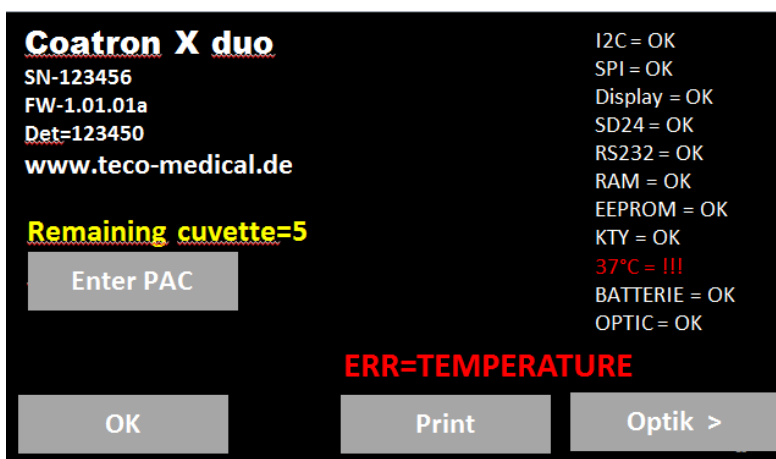
IMAGINEA 2: SETĂRILE TESTULUI 2

3.7 ANALIZAREA REZULTATELOR



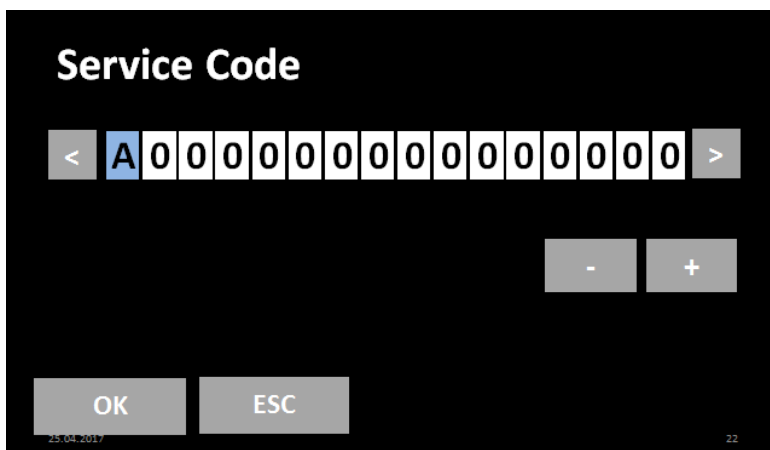
IMAGINEA 15: ANALIZAREA REZULTATELOR COATRON X PRO/TOP

3.8 INFORMAȚIA CU PRIVIRE LA SISTEM



IMAGINEA 16: INFORMAȚIA DESPRE SISTEM

3.9 INFORMAȚIA PRIVIND INTRODUCEREA TICHETELOR



IMAGINEA 17: INFORMAȚIA PRIVIND INTRODUCEREA TICHETULUI

4. TESTE DE COAGULARE DE BAZĂ

4.1 DETERMINAREA PT DIN PLASMĂ

Cum se execută o măsurare PT:

1. Porniți dispozitivul și așteptați aprinderea stării verzi (~ 15 min până la 37 ° C).
2. Reconstituiți reactivul PT și așteptați 30-60 min înainte de pasul următor.
3. Introduceți flaconul PT în blocul de reactiv + bara de agitare și lăsați să incubeze timp de cel puțin 5 min.
4. Schimbați testul canalului 1 în „PT” apăsând pe testul curent.
5. Puneți cuva goală în optică.
6. Introduceți 25 ul de probă în cuvă.
7. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
8. Apăsați „OPTIC-1” și introduceți un numărul de identificare al pacientului sau scanați un cod de bare de probă.
9. Adăugați 50 uL reactiv PT, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Activarea multiplă (cu excepția dispozitivului Coatron ECO)

1. Deschideți meniul și setați Auto NIP = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul multistart.
4. Adăugați 50 ul PT în fiecare cuvă de la stânga la dreapta.

Cum se calibrează:

1. Reconstituiți calibratorul și așteptați 15-30 min înainte de a continua cu pasul următor
2. Calibratoare.
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu
Soluția IBS, Owrens sau NaCl2 pot fi utilizate ca diluant pentru probă
 - a. 100%: Pipetați calibrul 100 μl în tubul gol
 - b. 50%: Pipetați 100 uL 100% calibrator + 100 ul diluant în tubul gol
 - c. 25%: Pipetați 100 uL 50% calibrator + 100 ul diluant în tubul gol
 - d. 12,5%: Pipetați 100 uL 25% calibrator + 100 ul diluant în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare
(se recomandă efectuarea determinării duble)
4. Introduceți setările PT și introduceți
 - a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
 - b. setați UNITATE la „INR +%”
 - c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
 - d. % Calibrare de intrare

4.2 DETERMINAREA PT DIN SÎNGE CAPILAR

Cum se execută o măsurare PT-B din sângele capilar:

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „PTB” apăsând pe testul curent.
3. Reconstituiți PT-B cu componenta-1 (diluant) și așteptați 30-60 min înainte de pasul următor.
4. Adăugați componenta-2 (CaCl₂) în PT-B și așteptați din nou timp de 30-60 min înainte de pasul următor.
5. Puneți cuva goală în optică sau în pre-incubare.
6. Introduceți 150 ul de PT-B în cuvă. Cuva trebuie folosită în următorii 10 minute.
7. Închideți flaconul PT-B și păstrați-l în frigider până la următoarea utilizare. Reactivul este stabil timp de 30 de zile.
8. Apăsați „OPTIC-1” și introduceți un NIP (număr de identificare al pacientului) sau scanați un cod de bare de probă.
9. Când „activ” clipește, străpungeți degetul și pipetați 15μL de sânge capilar în cuvă.
10. Măsurarea ar trebui să înceapă. Este important să amestecați în cuvă. Pentru aceasta coborâți pipeta în cuvă și pompați 10-15x în sus și în jos. Terminați amestecarea celei mai recente probe atunci când numărătoarea inversă ajunge la zero.

Cum se calibrează PTB

1. Reconstituie calibratorul cu 1,7mL și așteaptă 15-30min
2. Calibratoare.
Valoarea țintă a calibratorului este starea la certificat. Îmi asum 100% ca exemplu
Soluția IBS, Owrens sau NaCl₂ pot fi utilizate ca diluant pentru probă
 - a. 100%: Pipetați calibrul 100 μl în tubul gol
 - b. 25%: pipetați 100ul 100% calibrator + diluant 500 ul în tubul gol
3. Rulați toate cele 4 calibrate ca pacienții și notați timpul de coagulare
4. Introduceți setările PTB și introduceți
 - a. LOT corect, Exp (citiți codul de bare al etichetei flaconului)
 - b. setați UNITATE la „INR +%”
 - c. Timp normal de intrare (= 100% rezultat) + ISI (a se vedea flaconul)
 - d. % Calibrare de intrare

4.3 DETERMINAREA APTT

Cum să executați o măsurare aPTT:

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 ° C).
2. Schimbați testul în „APTT” apăsând pe testul curent.
3. Puneți CaCl în dispozitiv, lăsați să se incubeze timp de cel puțin 5 min.
4. Puneți cuva goală în optică sau în pre-incubare.
5. Introduceți 25 ul de probă în cuvă.
6. Introduceți 25 uL de reactiv aPTT rece în cuvă.
7. Apăsați „00:00” pentru a porni cronometrul și așteptați 180 de secunde.
8. Cu puțin înainte de sfârșitul incubării, apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare.
9. Adăugați 25 ul de CaCl, când „Active” clipește. Măsurarea va începe automat.
10. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

4.4 DETERMINAREA FIB

Cum să executați o măsurare FIB:

Metoda nr.1

1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Puneți cuva goală în optică.
6. Introduceți 10 uL de probă în cuvă.
7. Introduceți 90 uL de tampon IBS în cuvă.
8. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
9. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
10. Adăugați 50 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
11. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Metoda nr.2

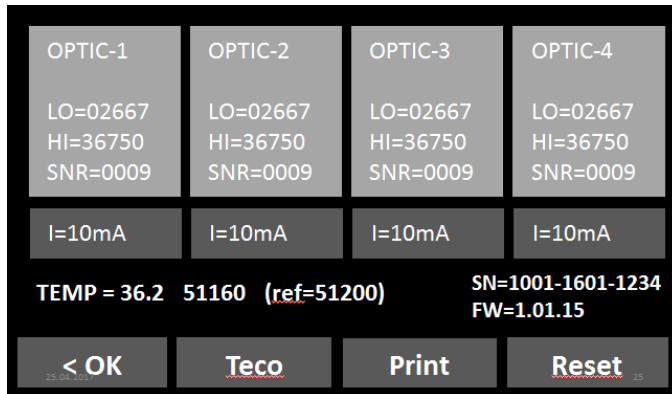
1. Porniți dispozitivul și așteptați starea verde (~ 15 min până la 37 °C).
2. Schimbați testul în „FIB” apăsând pe testul curent.
3. Reconstituiți reactivul FIB și așteptați 30-60 min înainte de pasul următor.
4. Puneți flaconul FIB nu în blocul de reactiv. Temperatura camerei este potrivită.
5. Pipetați 50 uL de probă prediluată 1: 10 în cuvă (prediluarea se face cu sol. IBS).
6. Apăsați „00:00” pentru a porni cronometrul și așteptați 30 de secunde.
7. Apăsați „OPTIC-1” și introduceți un NIP sau scanați un cod de bare de probă.
8. Adăugați 25 µL de reactiv FIB, când „Active” clipește. Măsurarea va începe automat la adăugarea reactivului.
9. Așteptați rezultatul sau atingeți butonul optic pentru a anula.

Cum să calibrezi FIB

1. Reconstituiți calibratorul și așteaptă 15-30min înainte de a continua cu pasul următor
2. Calibratoare.
Valoarea țintă a calibrаторului este starea la certificat. Se presupune ca exemplu 300mg / dL
 - a. 600 mg / dL: Pipetați 50 pi calibrator + 200 uL tampon IBS în tubul gol
 - b. 300 mg / dL: Pipetați 50 pi calibrator + 4500 pL tampon IBS în tubul gol
 - c. 150 mg / dL: Pipetați 50 pi calibrator + 950 uL tampon IBS în tubul gol
 - d. 75 mg / dL: Pipetați 50 pi calibrator + 1950 uL tampon IBS în tubul gol
3. Rulați totți 4 calibratori
 - a. Adăugați 50 uL de calibrator în cuvă
 - b. Adăugați 25 uL de reactiv FIB pentru a începe măsurarea. Scrieți timpii de coagulare pe hârtie sau imprimați
4. Introduceți setările FIB și introduceți
 - a. LOT corect, Exp
 - b. setați unitățile la “mg/dL”
- c. Introduceți calibrarea mg/dl

5. FUNCȚIILE DE DESERVIRE

5.1 VERIFICAREA OPTICĂ



IMAGINEA 18: VERIFICAREA OPTICĂ

5.2 RAPORTUL DE SISTEM

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			

Data raportului
denumirea sistemului
versiunea programului
numărul de identificare al sistemului
numărul de identificare al produsului
temperatura opticii și valoarea digitală al sensorului
temperaturii
Valorile optice
Lo= LED stins
Hi= LED pornit
mA= energia LED
Qc= zgomotul opticii
OK= nu există eroare
!!= condiție de eroare

Numărarea testelor efectuate

5.3 AJUSTAREA TEMPERATURII

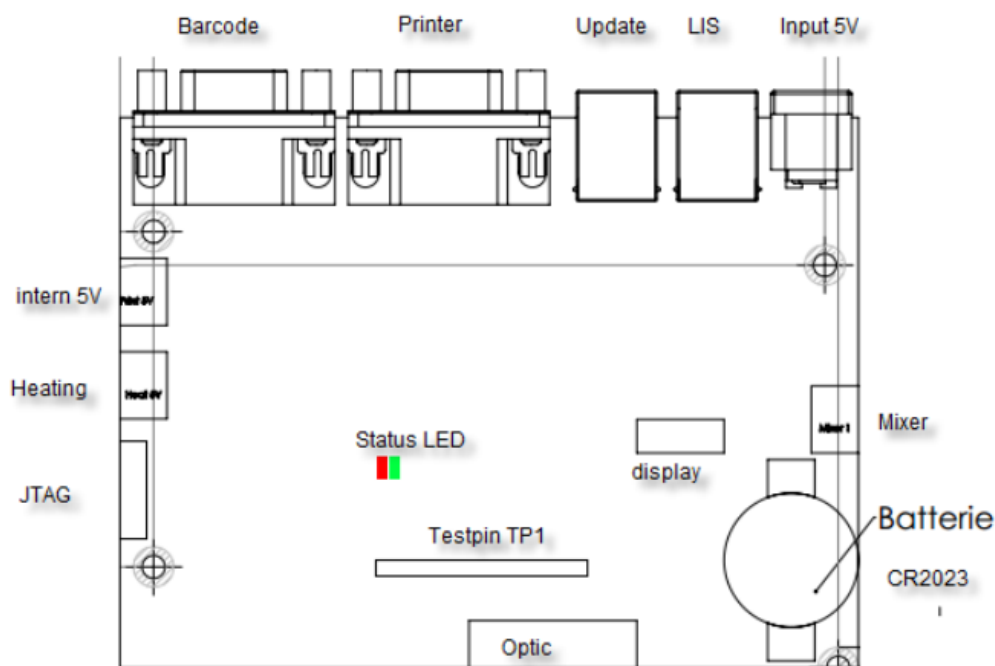
1. Porniți dispozitivul și așteptați aprox. 15min până când sistemul afișează 37 ° C pe ecran.
2. Umpleți un tub / flacon de reactiv cu 2 ml de apă și așezați-l într-o poziție de reactiv. Plasați un termometru digital în tubul de reactiv și lăsați să se încălzească timp de aproximativ 10 minute.
3. Apăsați meniul

Schimbați temperatura sistemului curent la valoarea termometrului. Așteptați 10 min și repetați procedura.

Problemele tipice:

Defecțiunea/Eroarea	Cauza posibilă	Măsurări
Încălzirea sistemului nu a ajuns la 37°C	Calibrarea senzorului este dincolo de spectrul stabilit	Resetați la implicit din fabrică ca descris în capitolul „Funcție ascunsă”
Sistemul arată 0.00°C	Senzorul a ieșit din diapazon	Temperatura mediului trebuie să fie de 0 – 45°C.
Placa cu senzor sau cu LED optic este defectă	Înlocuiți placa LED	

5.4 PREZENTAREA GENERALĂ AL PLĂCII PRICIPALE



Statutul după becul LED:

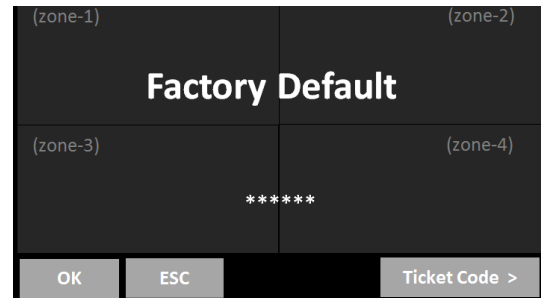
verde permanent	= totul este bine
roșu, permanent	= EEPROM eroare
verde, intermitent	= eroarea bateriei
roșu, intermitent	= senzor de temperatură/optica nu este conectată

6. FUNCȚIILE ASCUNSE

6.1 RESETAREA LA STAREA DIN FABRICĂ



IMAGINEA 19: ECRANUL DE START



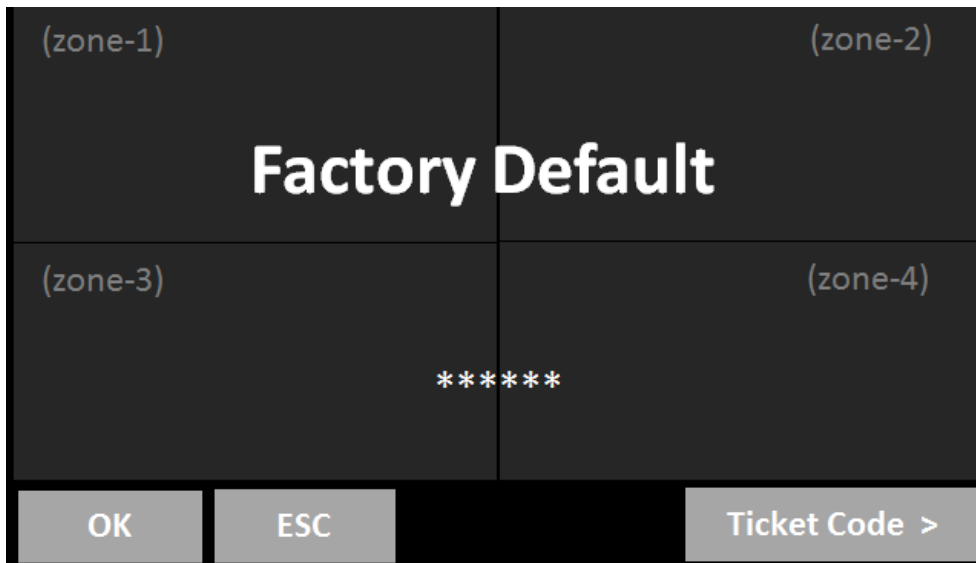
IMAGINEA 20: SETĂRILE IMPLICITE

Apăsați
spinerul timp
de 3 sec

Cum se resetează calibrarea PT la setările implicite de fabrică:

1. Porniți dispozitivul și treceți la ecranul de pornire
2. Atingeți orice buton de testare
3. Schimbați testul în „PT” și atingeți „Configurare” sau scanați codul de bare al flaconului PT
4. Introduceți LOT, data expirării și selectați Unități în „% + INR”

6.2 LOGAREA ÎN CALITATE DE ADMINISTRATOR



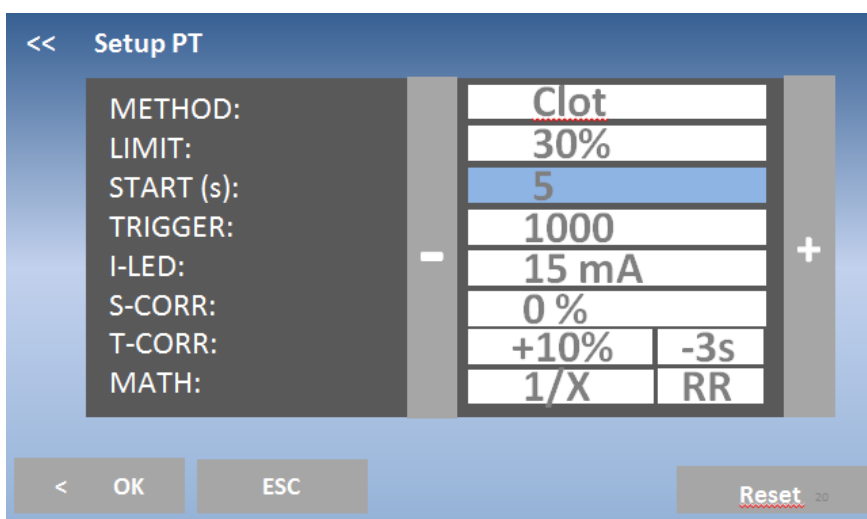
IMAGINEA21 : LOGAREA ÎN CALITATE DE ADMINISTRATOR

1. Ecran de întâmpinare: Apăsați lung pe pictograma filetelui
2. Alternativa tactilă: zona 1, 2, 1, 2, 1, 2

Ca admin funcțiile următoare sunt activate:

- Schimbă protocolul de testare (vezi următorul capitol)

6.3 MODIFICAREA PROTOCOLULUI DE TESTARE



IMAGINEA 22: PROTOCOLUL DE TESTARE

7. CURĂȚIREA ȘI MENTENANȚA

7.1 INFORMAȚIA GENERALĂ CU PRIVIRE LA CURĂȚIRE

- Curățați cu o cârpă sau un stick de bumbac fără scame.
- Nu purificați niciodată lichidul în zona optică sau de lucru.
- Păstrați dispozitivul fără praf și umezeală.
- Dacă dispozitivul este murdar cu lichide, îndepărtați murdăria cu o cârpă absorbantă.
- Dacă un lichid a fost vărsat sau pipetat accidental într-un canal de măsurare, deconectați imediat de la sursa de alimentare și curățați canalul de măsurare cu pipeta și o cârpă fără scame. Verificați funcția opticii din meniul DESERVIRE.



Aveți în vedere toate suprafețele și materialele, care ar putea fi în contact cu plasma sau cu alt lichid biologic, deoarece ar putea fi contaminate cu materiale infecțioase.



Evitați orice contact direct cu decontaminanți sau dezinfectanți.

7.1 CURĂȚIREA

- Folosiți detergent, apă și înălbitor diluat 10% sau decontaminant comercial.
- Curățați și ștergeți toate deversările din jurul zonei de lucru sau ale sistemului de pompare cu ac cu detergent și apă.

7.2 DECONTAMINAREA

- Utilizați înălbitor diluat cu 30% și dezinfectant comercial (de exemplu, Bacillo[®]AF)
- Decontaminați zona de lucru, zona acului, rafturile pentru pacienți, tastatura, ecranul LCD, carcasa față, imprimanta și sertarele pentru deșeuri

7.3 MENTENANȚA REGULATĂ

- Curățați dispozitivul după fiecare utilizare
- Decontaminați dispozitivul în fiecare săptămână sau înainte de expediere pentru reparare / aruncare
- După 5 ani înlocuiți bateria plăcii de bază (CR2032)

8. ELIMINAREA ERORILOR

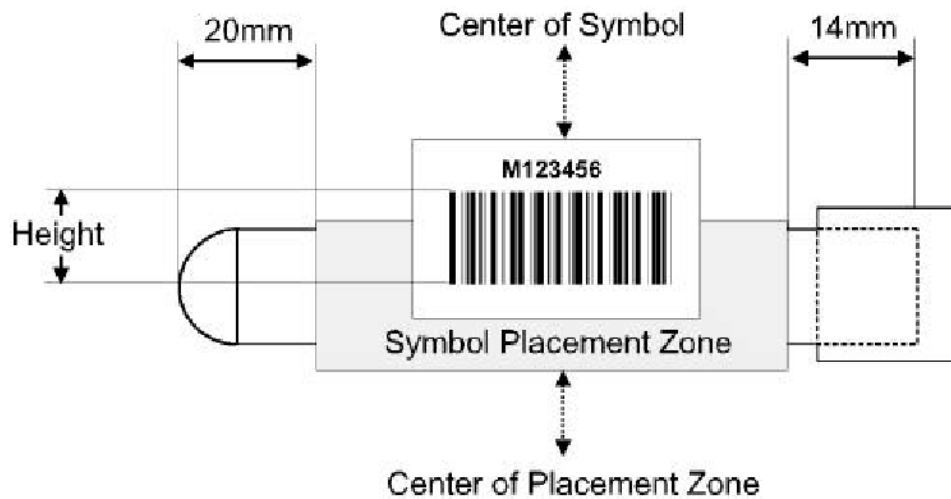
8.1 ERORILE DE MĂSURARE

Eroarea	Cauza posibilă	Măsurarea
Rezultatele marcate "*"	Rezultate ce trec peste limita de calibrare	
Marcă "T"	Temperatura dincolo de 36 – 38°C	
Marcă "E"	Reagentul este expirat	
Marcă "S"	Semnalul optic este foarte scăzut, din cauza turbidității extreme.	Verificați optica Evitați interferențele optice probe lipemice.
Marcă "f" sau "F" (doar testul PT)	Fibrinogen ridicat sau scăzut	Executați testul FIB pentru confirmare
Marcă "X"	Valorile duble deviază cu mai mult de 15%	
Marcă "+++"	Nu a fost observată nici o coagulare cu timpul de măsurare	

- Problemă cu pornirea automată ! (Pipetați spre centru, reduceți sau măriți declanșarea autostartului).

9. ANEXĂ

9.1 GHIDUL CODULUI DE BARE



Specificația etichetei:

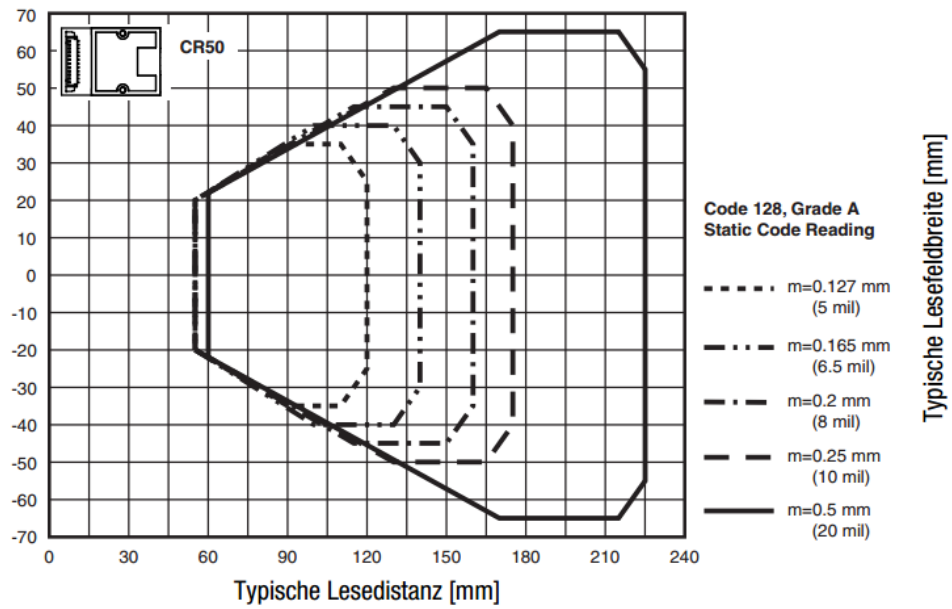
- Lungimea: 50 – 70 mm
- Lățimea: 20 - 30 mm
- Lungimea codului de bare: 40 – 60 mm
- Lățimea codului de bare: 10 - 20 mm
- Zona goală: > 5mm
- Rezoluția/modul: 5 -20mils (0.2 – 0.5mm)
- Diapazon: minim 1:2,5 to 1:3 (coduri bidimensionale)
- Calitate: Nivelul A sau B în conformitate cu ANSI X3.192 -1990

Coduri acceptate:

- Code 128 3 – 16 caractere
- EAN 128 3 – 13 caractere
- Code 39 4 – 13 caractere
- Code 93 4 – 13 caractere
- 2/5 intercalat 8 - 12 caractere

Câmpul de detecție:

Cea mai bună distanță de etichetă și scanner este de 80 - 120mm



9.2 SPECIFICAȚIILE TEHNICE

Analizator

Ecran	Ecran tactil TFT 4.3" 480x272
Sistemul de măsurare	1-4 canale de măsurare independente lungimea de undă a LED-ului 405 nm
Cuvete	Cuva cu un singur canal pentru detectarea optică
Poziții (pre-încălzite)	5 poziții ale reagentului la 36.5 – 37.5 °C 20 poziții ale cuvetelor la 36.5 – 37.5°C
Volumele de reacție	Volumul minim total 75 µl
Aprobări	Analizatorul corespunde cu 98/79/EC (IVDD)

Scannerul codului de bare

Scanner CCD	Energie maximă = 120mA Perioada de pulsație = 330/s
Clasa B EN 55022:2010 , EN 62471:2008	Lungimea de undă = 617 nm Cea mai bună distanță = 80 -120mm
Codec-ul acceptat	EAN (8,13, 128), Codul (39,93,128), Codabar, Intercalat 2 din 5

Sursa de energie

Voltajul nominal de intrare	100 – 240VAC , 47-63Hz
Curentul maxim de intrare	0.7A rms
Energia de ieșire	5Vdc , 3.3A
Bateria (placa de bază)	Lithium CR2032 3V
Consumul de energie	max. = 14W așteptare < 0.5W

Dimensiuni

Dimensiuni (W x D x H)	225 x 150 x 90 mm
Greutatea	1.04 kg (fără sursa de energie)

Condițiile de mediu

Temperatura de operare	15 - 30 °C
Umiditatea	< 70% umiditate relativă
Ridicarea deasupra nivelului mării	< 3.000m
Liber de praf	Gradul 2
Rezistența la impact	În conformitate cu IEC/EN 61010-1, 8.2.2
Nu sunt permise	Vibrațiile, expunerea la razele directe ale soarelui sau condițiile de aer.
Condițiile de păstrare	0°C - +40°C maxim 12 luni în ambalajul original
Condițiile de transport	0°C - +40°C

Zgomot

Zgomotul de operare	Maxim 50 dBA
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Interfețe

RS232 (Codul de bare)	Sub-D9, feminin; 9600 Baud/8/1/N; Pin-9 alimentat cu 5V DC. Pentru scanere externe de coduri de bare portabile, imprimante în serie
RS232 (Printer)	Sub-D9 feminin; 9600 Baud/8/1/N; pentru imprimante în serie
USB (Service, Firmware Update)	Tip-B, feminin, 115200 Baud/8/1/N
USB (LIS)	Tip-B, feminin, 115200 Baud/8/1/N; Pentru comunicarea LIS

Date tipice de performanță

Testul	CV.	Spectrul
PT	<3%	0-30 INR
APTT	<3%	15 – 420 s
FIB	<7%	50-999 mg/dL