CE

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Doc#001/12-2020

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 X Eco, Pro, Top

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" Anhang II – Liste A
2. Richtlinie 2014/30/EU über Elektromagnetische Verträglichkeit
3. Richtlinie 2011/65/EU RoHS II

Standards and regulations applied:

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

Weitere angewandte Normen:

4. Sicherheit:	EN 61010-2-101:2015
5. Risikomanagement:	DIN EN ISO 14971:2013-04
6. Informationen:	EN ISO 18113-3:2011
7. Medizingeräte-Software - Lebenszyklus-Prozesse:	DIN EN 62304:2016

Further related standards:

4. Safety:	*EN 61010-2-101:2015*
5. Risikmanagement:	*DIN EN ISO 14971:2013-04*
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: Neufahrn, 08.12.2020
Place and date of issue: Neufahrn, December 8, 2020

Digitally signed by Monastîrschii Viorica
Date: 2024.01.31 08:48:06 EET
Reason: MoldSign Signature
Location: Moldova

Matthias Dieckmann
General Manager

Medical Instruments
TECO
Production+Trading GmbH

CE

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. Risikmanagement: 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: Neufahrn, 11.11.2021
Place and date of issue: Neufahrn, November 11, 2021

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

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:
Place and date of issue: Neufahrn, 2022-06-21

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
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 / *Double cuvette*	Ref. 19 000 02
Einzelküvette / *Single cuvette*	Ref. 20 000 02, 24 100 00
4-fach Küvette / *Cuvette 4 pos/ea*	Ref. 80 521 10
6-fach Küvette / *Cuvette 6 pos/ea*	Ref. 80 560 00
6-fach Küvette (micro) / *Cuvette 6 pos/ea (micro)*	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 artivel 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

Medical Instruments TECO Production+Trading GmbH

Matthias Dieckmann
General Manager

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#200/08-2022

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

Wir erklären hier für die im Anhang A (Seite 2 – 23 IVD Produkte) spezifizierten Produkte dass sie gemäß der Richtlinie für In-vitro-Diagnostika Medizinprodukte 98/79/EC klassifiziert sind als allgemeine IVD.

Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers i.V.m. Artikel 110 Abs.3 und Abs.4 der Verordnung (EU) 2017/746 und des § 8 Abs.1 des Medizinprodukte-Durchführungsgesetzes, in der jeweils geltenden Fassung, ausgestellt.

Im Falle eigenmächtiger Veränderungen am Produkt oder der nicht bestimmungsgemäßen Verwendung verliert diese Erklärung ihre Gültigkeit.

We declare herewith for the products specified in Annex A (page 2 - 23 IVD products) that they are classified as general IVD according to the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of the manufacturer in according to article 110 para.3 and para.4 of Regulation (EU) 217/746 and section 8 para.1 of the Medical Device Law Implementing Act.

In case of unauthorised modifications to the products or un-intended use, this declaration loses its validity.

Sie entsprechen den anwendbaren Anforderungen der Richtlinie:	They meet applicable requirements of:
Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert gemäß Artikel 9 als "alle anderen Produkte"	Directive 98/79/EC on in-vitro-diagnostic medical devices classified according to article 9 as „all other products"
Die Qualitätssicherung entspricht den Anforderungen der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The Quality Assurance is in accordance with the requirements of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.
Der implementierte QM-Prozess entspricht der EN ISO 13485:2021	The implemented QM Process complies with EN ISO 13485:2021
Die vorstehende Konformitätserklärung ist gültig für alle Chargen dieser Produkte, die nach dem Datum der Unterzeichnung in Verkehr gebracht wurden.	The above mentioned declaration of conformity is valid for all lots of this product, which are distributed after the date of signature.
Das Konformitätsbewertungsverfahren entspricht Anhang III der Richtlinie 98/79/EG über In-vitro-Diagnostika für diese Art von Produkten.	The conformity assessment procedure complies with Annex III of Directive 98/79/EC on in-vitro-diagnostic medical devices for those kind of products.

Ort und Datum der Unterzeichnung:
Place and date of issue: Neufahrn, 2022-08-31

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

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Doc#200/08-2022

KONFORMITÄTSERKLÄRUNG – DECLARATION OF CONFORMITY

Directive 98/79/EC Annex A
Übrige Produkte – Reagenzien für In-vitro-Diagnostika
Other products – Reagents for in vitro diagnostic – general IVD

Pos.	Article No	Tradename	Unit	Generic Device Term	EMDN / GMDN Code EUDAMED DI
1	A0230-040	TEClot PT-S (Quick)	10x4ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-040X7
2	A0230-100	TEClot PT-S (Quick)	10x10ml PT-S	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-100WY
3	A0260-050	TEClot PT-B (Owren)	5x10ml PT-B	Prothrombin time (quick test)	W0103020199 / 55986 B-PTB-A0260-050G2
4	A0320-050	TEClot APTT-S	10x5ml APTT-S	Activated partial thromboplastin time	W0103020102 / 55982 B-APTTS-A0320-050AM
5	A0401-020	TEClot TT	10x2ml TT	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
6	A0511-020	TEClot FIB	10x2ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
7	A0511-050	TEClot FIB	10x5ml FIB	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
8	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
9	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
10	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
11	P8001-010	TECal N	10x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
12	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
13	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
14	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
15	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
16	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
17	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
18	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
19	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
20	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
21	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
22	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
23	P5701-010	TEClot Factor XII	10x1ml	Coagulation factor xii	W0103020211 / 30552 B-FAC-XII-P5701-010CJ

(Recital 23 of Directive 98/79/EC on In Vitro Diagnostics Medical Devices) - Annex A - general IVD

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TECO
MEDICAL INSTRUMENTS
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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.

Medical Instruments
TECO
Production+Trading GmbH

Christian Hoetzl
General Manager
TECO Germany

TECO
MEDICAL INSTRUMENTS
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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

all instruments with complete accessory, consumables and spare parts

- Hemostasis Reagents — Complete product line

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

TECO Medical Instruments Production+Trading GmbH

Christian Hoetzl

Medical Instruments TECO Production+Trading GmbH

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Important Customer Information regarding the introduction of the IVDR

Due to coming regulation 2017/746 (IVDR), which will apply from May 26th, Teco has classified their products new.

1. Sales of consumables from 2022/05/26

Cuvettes (for Coatron M, X, A Family) REF: 2410000|2420000I 2000002|1900002|8052110|8056000|8057000 **Rinse and Clean solution** (for Coatron A Family) REF: 2150001|2150000|2150009|2151009	Classified as: **Generic laboratory product** (IVDR, Art. 1, Para 3a)

On May 2022, Teco had withdrawn cuvettes, rinses and cleaners from EU registration for IVD and offer these products as general laboratory products without CE mark! Of course, the premium quality, safety and performance remains unchanged.

2. Sales of auxiliary reagents from 2022/05/26

Buffers and solutions REF: A0350-050 Calcium Chloride 0.025M REF: A0590-125 IBS Buffer REF:A0592-100 Owren's Buffer REF:A0593-035 Dilution Buffer	Classified as: **Generic laboratory product, chemical solution** (IVDR, Art. 1, Para 3a)

On May 2022, Teco had withdrawn these auxiliary reagents from EU registration for IVD and offer these products only in conformity to REACH regulation EG/1907/2006.

3. Sales of Coatron X family from 2022/05/26

Coatron X Family REF:8110110|8110120|8110140|85001|85002|85004|8080000| 8070000|8042000|9830021|9830022|9830024|8111510|8111520| 8111540|8090000|8090008|8092000|8092040|8092060|8092061	Classified as: **Class A (IVDR)** (IVDR, Annex VIII, rules 5b)

Since May 2022, TECO offers the Coatron X family in conformity to IVDR, Class A.

TECO
MEDICAL INSTRUMENTS,
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DIESELSTRASSE 1
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fax: #49 8773 70780 29

4. Sales of Coatron A family from 2022/05/26

On May 2022, Teco had withdrawn the Coatron A family from EU registration for IVD, but we will still distribute the instruments as 'old device'* in Europe. Consumables, spare parts and service will be available beyond May 26, 2022 for at least 10 years.

*Old devices are those devices that were placed on the market or put into service before 26 May 2022 in accordance with the IVDD or the applicable national rules before the IVDD had become applicable and which are still on the market or in use after 26 May 2022." (guidance MDCG 2022-8)

5. Sales of reagents/plasma intended for clotting, chromogenic or immunological test

Due to postponement of IVDR (EU) 2017/746 for Class B/C devices to 26 May 2026/2027 , Teco will offer these IVD-products only in conformity with old IVDD 98/79/EC.

6. New prices

In March 15 2022 we adjusted our prices, because of increased production costs in consequence of Covid-19 pandemic. Now the ongoing war in Ukraine worsened the market situation again. Disrupted supply chains and hyperinflation on energy forces as again to plan further price increase of 10-15% planned for 2023. In addition, we recommend very early forecasts. Orders without forecasts may take 6 months or longer, due to extreme delay time for some components or raw material.

Best regards

Neufahrn, September 28th 2022

Matthias Dieckmann,
General Manager

Bestehendes Zertifikat:	10 November 2022	Erstmalige Zulassung:
Dieses Zertifikat ist gültig bis:	9 November 2025	ISO 13485 - 10 November 2022
Zertifikat-Nr.:	10479696	

Zertifikat

Hiermit wird bescheinigt, dass das Managementsystem von:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Deutschland

durch LRQA geprüft und bewertet wurde und den folgenden Normen entspricht:

ISO 13485:2016

Gültigkeits-Nr.: ISO 13485 – 00038268

Das Managementsystem ist anwendbar für:

Konstruktion, Entwicklung, Herstellung, Lagerung und Vertrieb von Gerinnungsmessgerätenund in-vitro Diagnostik Reagenzien aus den Bereichen der Hämostaseologie und Koagulation.

Paul Graaf

Area Operations Manager, Europe

Ausgestellt von: LRQA Limited

UKAS MANAGEMENT SYSTEMS
0001

Certificate -Bescheinigung

TECO
Medical Instruments
Production+Trading GmbH
web: www.teco-gmbh.com
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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

TECO
Dipl.-Ing. Univ.
Christian Baumgartner

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

Certificate -Bescheinigung

TECO **Medical Instruments Production+Trading GmbH**
web: www.teco-gmbh.com
mail: info@teco-gmbh.com

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D-84088 Neufahrn/NB
fon: +49 8773 70780 00
fax: +49 8773 70780 29

CERTIFICATE OF TRAINING

Luminita Padurar
Bioengineer
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

TECO
Dipl.-Ing. Univ.
Christian Baumgartner

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

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

2 Grafic 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.

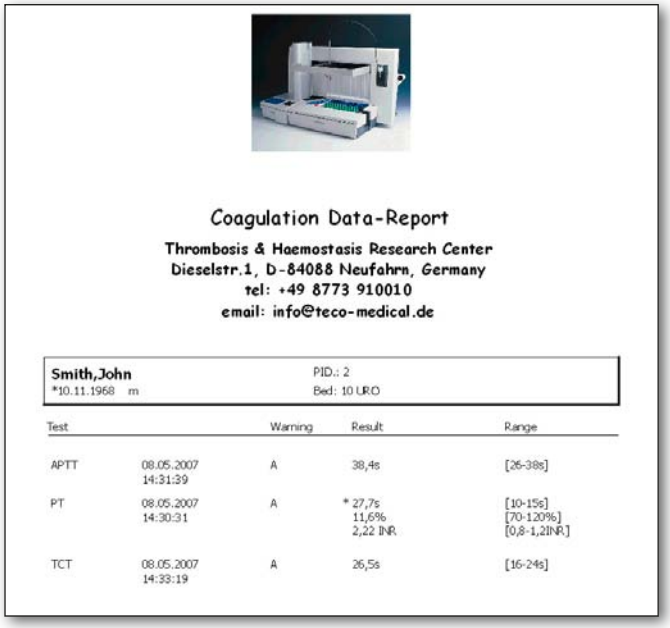
TECAM PROLIS

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 West gard analysis are used for quality control monitoring. An ASTM interface is included, which allows to link over LAN network with the laboratory information system.



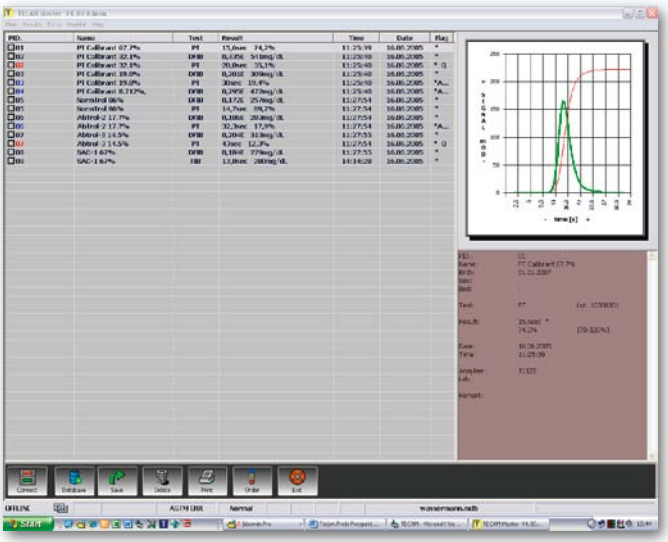
Coagulation Data-Report

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

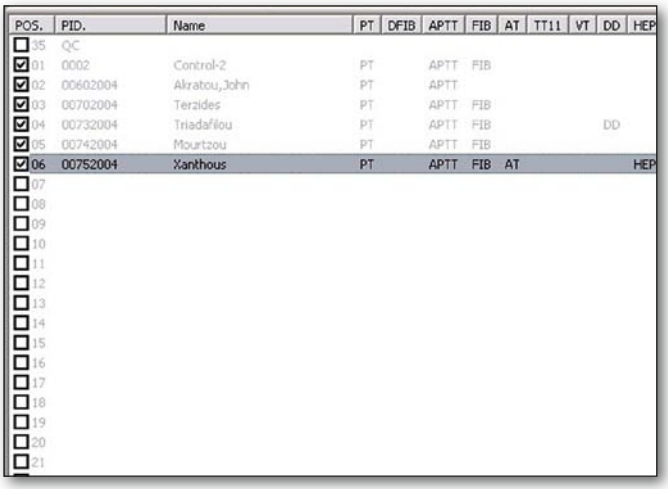
Smith,John PID.: 2
*10.11.1968 m Bed: 10 URO

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)



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
35	QC										
01	0002	Control-2	PT		APTT	FIB					
02	00602004	Akratou,John	PT		APTT						
03	00702004	Terzides	PT		APTT	FIB					
04	00732004	Triadafilou	PT		APTT	FIB				DD	
05	00742004	Mourtzou	PT		APTT	FIB					
06	00752004	Xanthous	PT		APTT	FIB	AT				HEP
07											
08											
09											
10											
11											
12											
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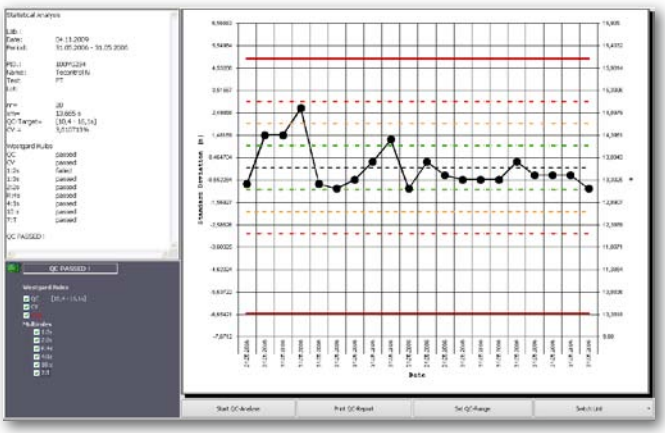
20											
21											

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



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

TECO

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 Vaccutainer® 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

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

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

CE

Quality Management EN ISO 13485:2003 + AC:2007
Voluntary participation in regular monitoring
DEKRA Certification
DEKRA certified

Quality Management ISO 9001:2008
Voluntary participation in regular monitoring
DEKRA Certification
DEKRA certified

TECO

Innovation in Coagulation

TECO Medical Instruments,
Production + Trading GmbH

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D-84088 Neufahrn NB.
Germany

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Web: www.teco-gmbh.com

www.md-miethke.de · 11/09

TOP
INNOVATION
2017 - 2018

Clotting
Chromogenic
Immunturbidimetric

Coatron X

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

TECO

Innovation in Coagulation

“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

Coatron X

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.

MADE IN GERMANY

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

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

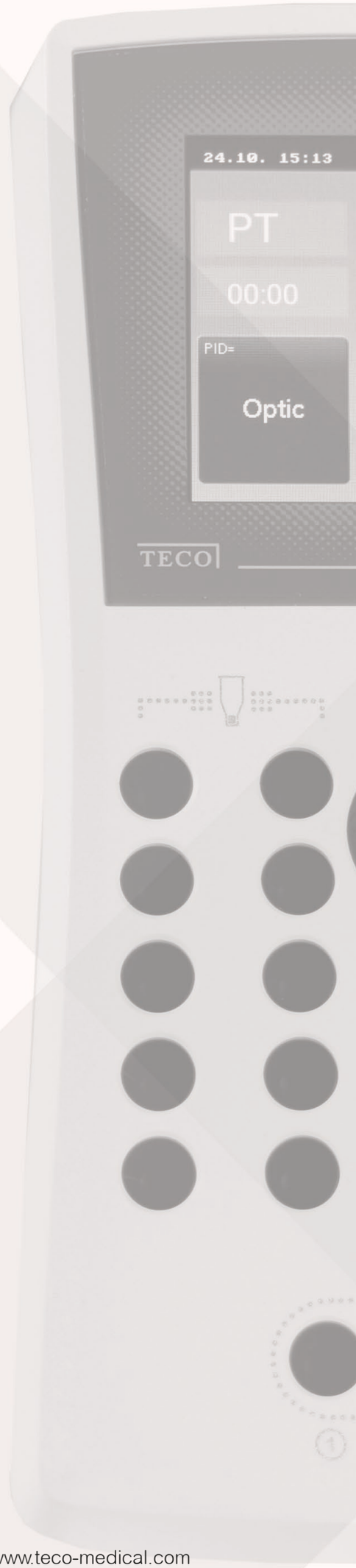
All instrument versions of the Coatron X family are connectable via Bluetooth to Smart-devices, like mobile devices, tablets, etc. with a specific APP or direct access to the TECO Cloud Services.

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	-	

CE IVD

Coatron X

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

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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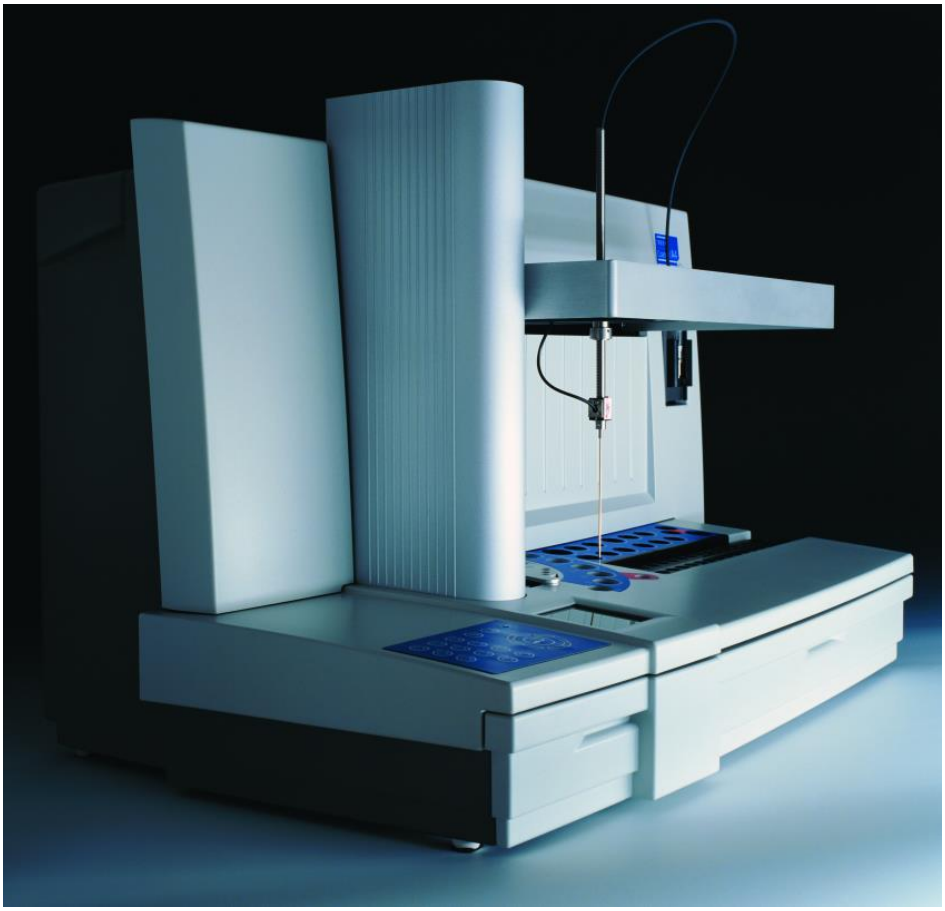
TECO
Innovation in Coagulation

CoatronX-E-v0E

Coatron A4

Operator's Manual



CE Instrumentation and Reagents for *In-Vitro* Diagnostic use

Revision 22
Issue Oct-2015
Document No:21 440 01

Updates

Operator's Manual Version	Software Version	Date
10	1.03.30	05/2006
11	1.05.00	02/2009
12	1.05.02	05/2009
14	1.06.01	10/2010
15	1.06.02	05/2011
16	1.06.04	10/2011
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
22	1.07.02	10/2015

Copyright

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
Internet: http://www.teco-gmbh.com

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 Triglceride (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 potentiallyinfectious. 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

Abount 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

	**Precautions:** ▪ Avoid spilled iquids 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 equipement regulary. Defective leads or socket must be replaced without delay.
	**Connect to power:** 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. ▪ 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.
	**Disconnect from power:** ▪ 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

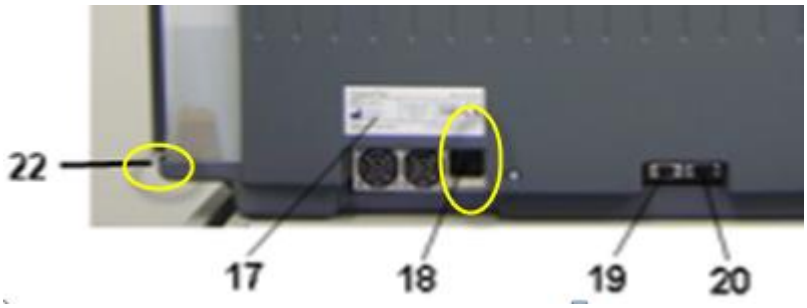
2.4 Removal of the transport retainer elements

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

2.5Switching 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



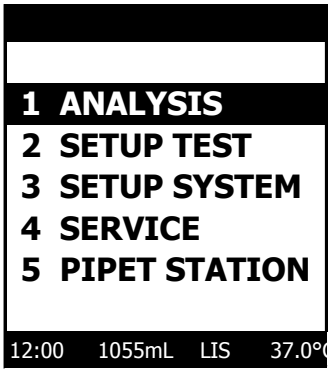
Location of power and standyby switchMain screen

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 configurated 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.

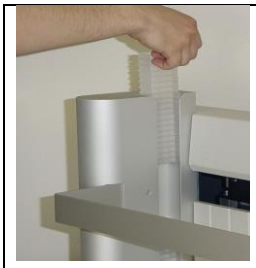
Switching the COATRON A4 off:

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

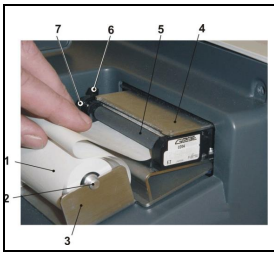
Never switch off the system while processing a worklist to avoid clogging the needle tip with coagulation residues.

2.6 Installation of Components

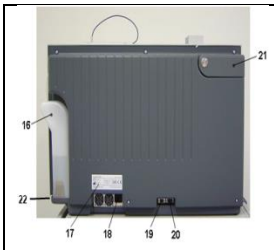


1. Remove a strip of cuvettes from the package.
2. Shift the cuvettes as shown from above in the guide groove back into the cuvette tower.
3. Remove the tape off the cuvettes.

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 continous 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

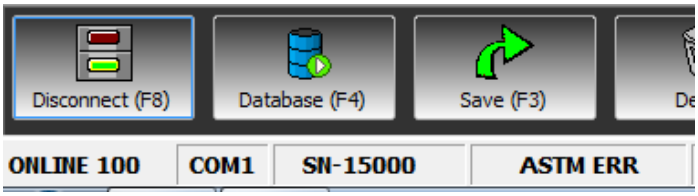
- Operating system: Microsoft Windows XP or 7 32Bit
- 100 MB free hard-disk space
- Grafik: 1280x1024 Pixel
- Interface: RS232 Sub-D9 (if not supported , use USB convertor, commport must be set between com1 - com15)
- Cable: 2x Female Sub D9, crosslink. Pin 2 to 3; Pin 3 to 2 and Pin 5 to 5. All other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

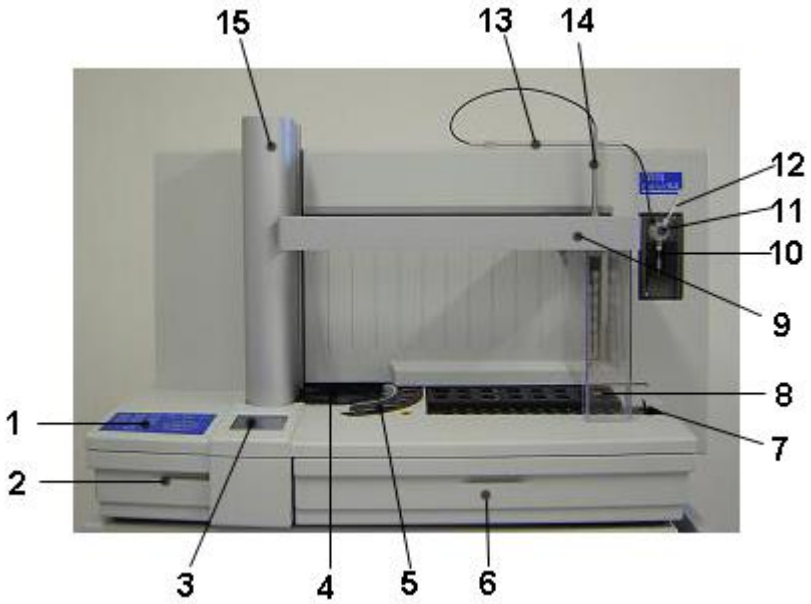


Figure 1: COATRON A4, front view

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

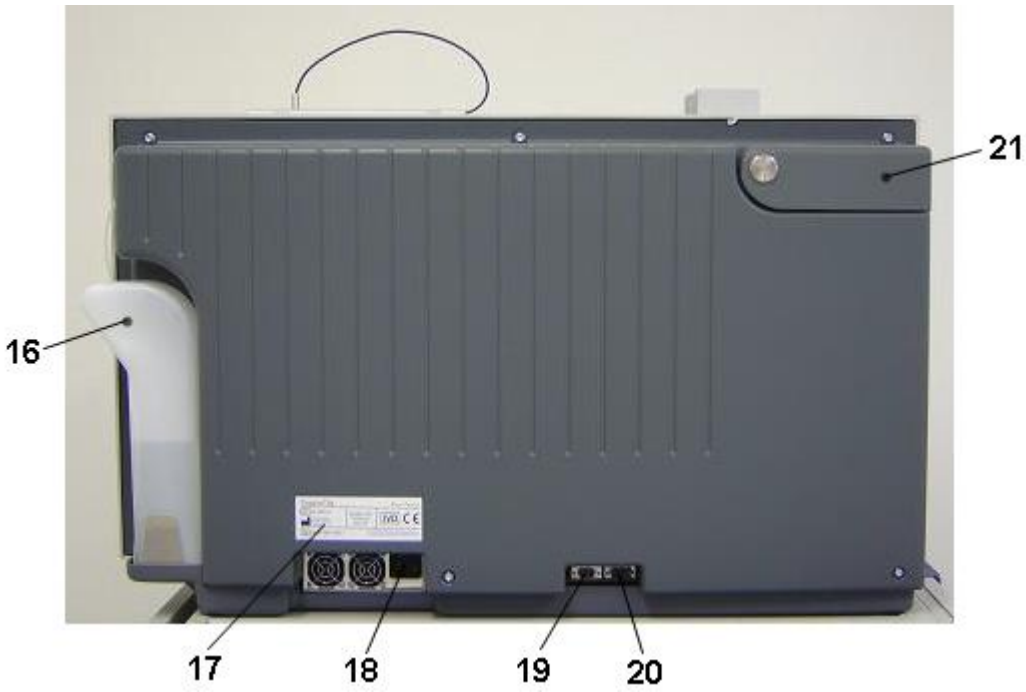


Figure 2: COATRON A4, rear view

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

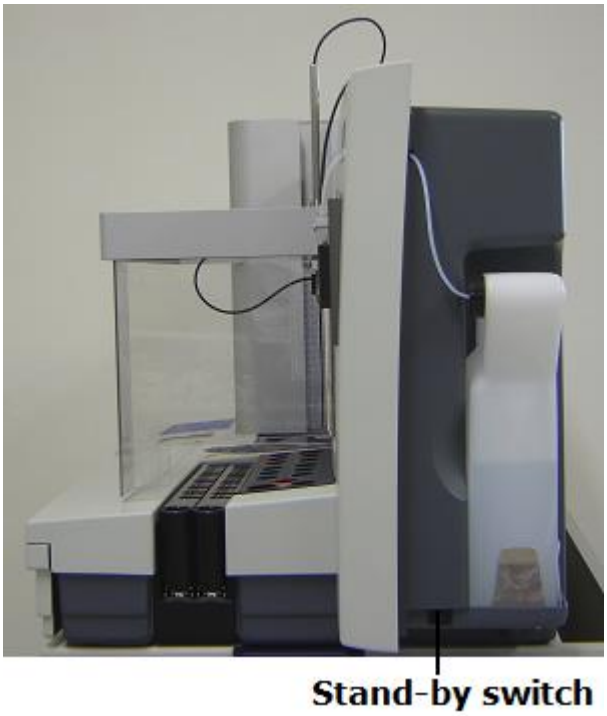


Figure 3: Side view

3.2.4 Sample rack

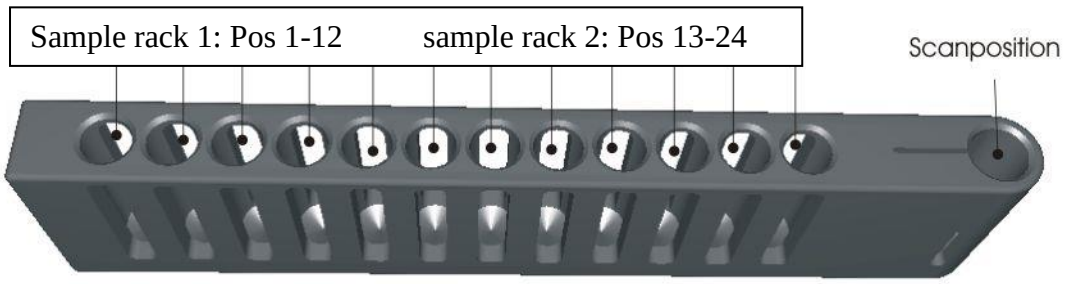


Figure 4: Sample rack

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

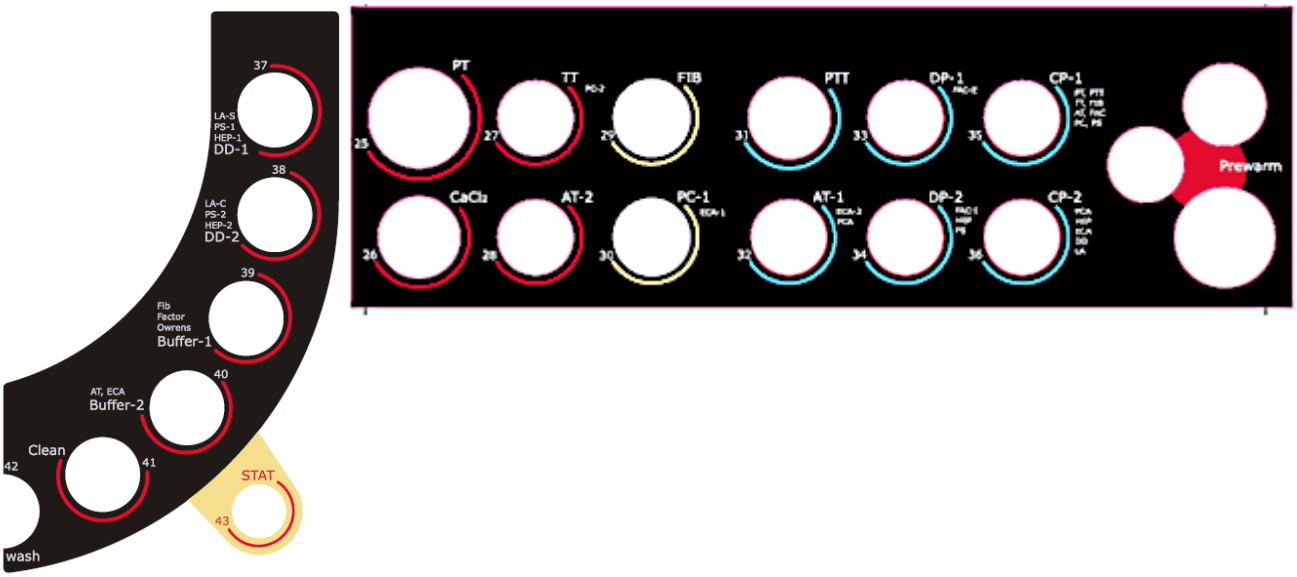


Figure 5: Working Positions

Pos. 1 - 24		Sample positions	Room temperature
Pos. 25	PT	Reagent position for PT, **magnetic stirring function**	37.0 °C
Pos. 26	CaCl	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 ,FIIV, 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

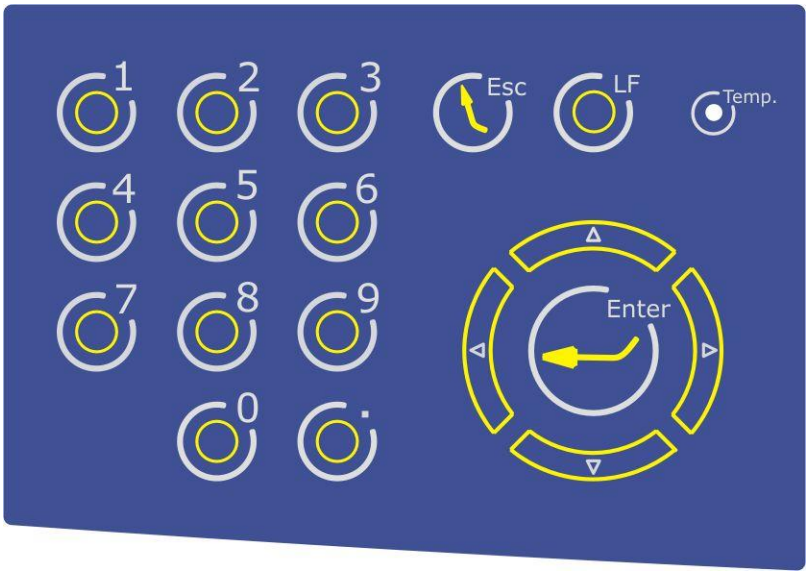


Figure 6: Keypad

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

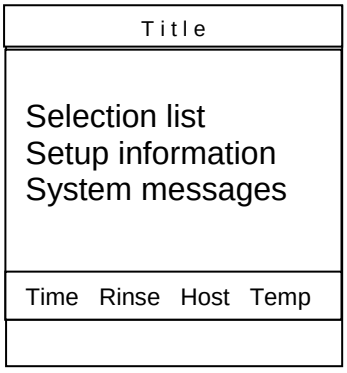


Figure 7: Screen segments

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

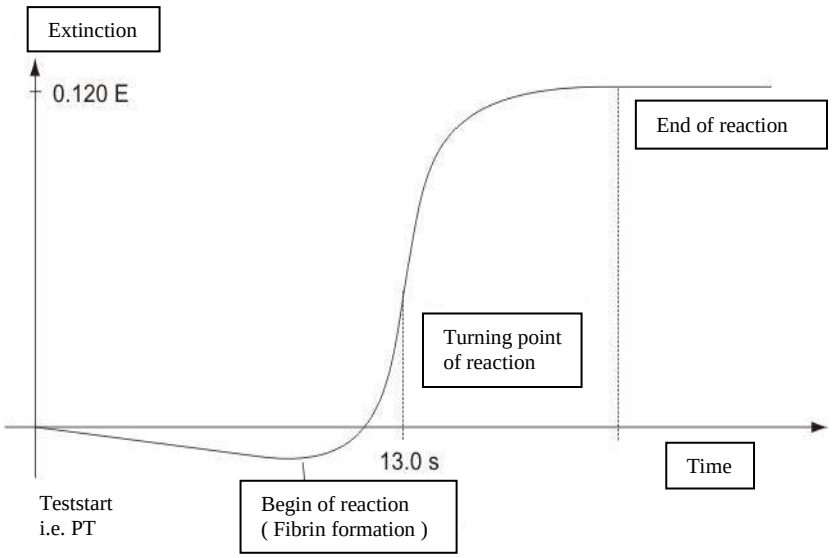


Figure 8: Determination of turning point in clotting method

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

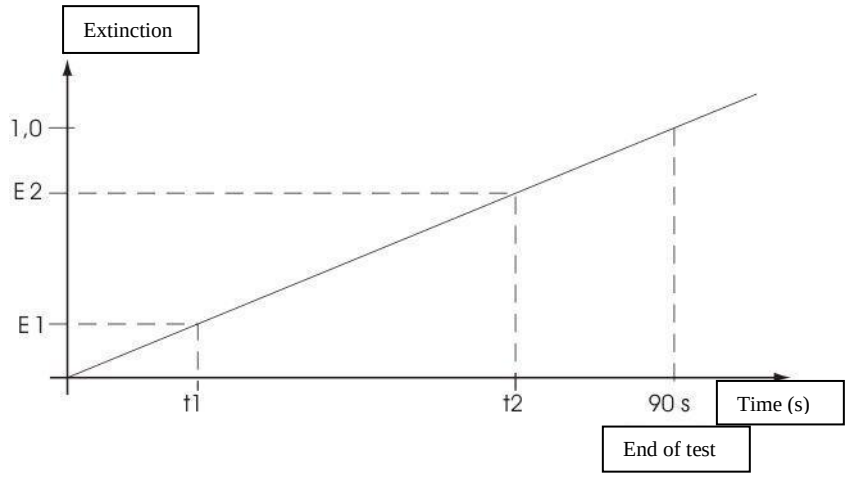


Figure 9: Determination of rise in the kinetic test method

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

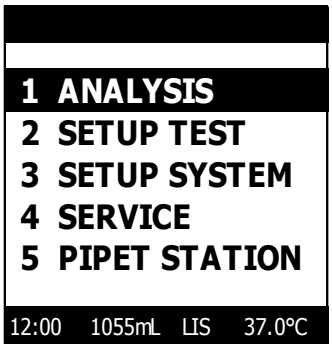
4. Routine measurement (Typical use case)

- 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.

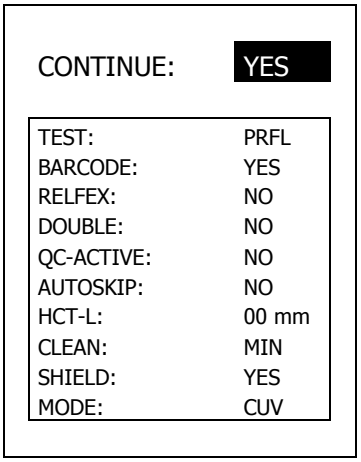
   See *chap. 5.2.2 Submenu Data input* for input of a calibration curve
5. Wait about 15 min. after supplying the reagent positions before test processing until the reagents have reached the right temperature (37°C in positions 25 – 28 and room temperature in positions 29 and 30).
6. Change to menu ANALYSIS



Select ANALYSIS and confirm with ENTER.

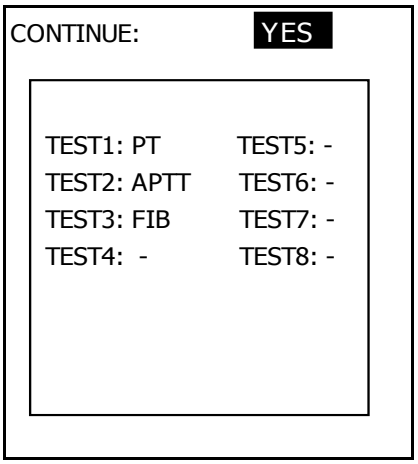
4.2 New list input

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



Select YES and press ENTER to continue

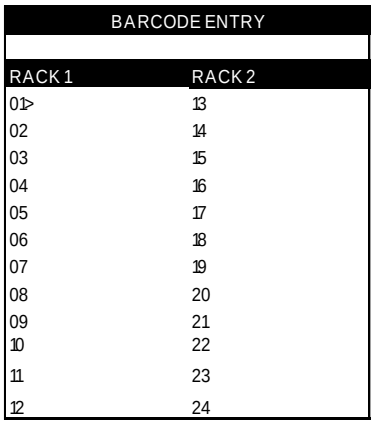
-Select PRFL. Later define profile as PT+aPTT+FIB
-The samples identifications input by barcode
-No automatic test repeat
-Single determination
-No quality control
-Skip test, if out of reagent
-Search for plasma until buttom of tube
-Standard cleaning procedure
-Activate shield protection
-Run worklist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



Select YES and press ENTER to continue

Set profile to PT + APTT + FIB

5. Input patient-ID by barcode reader:

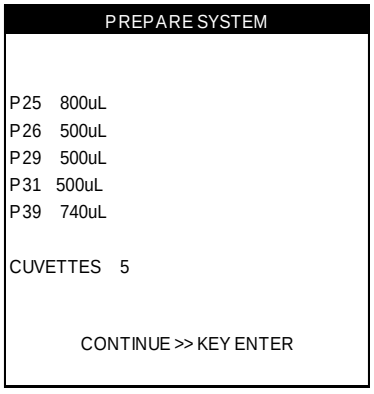


Shift the racks separately at an even and moderate speed in front of the barcode scanner. A signal tone is heard for each recognized barcode

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



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 sautomatically, 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:

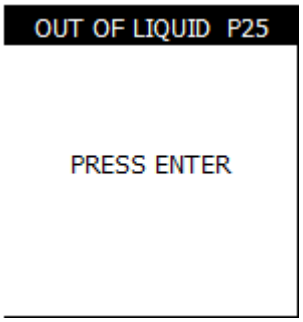
Exit worklist: Press key ESC again:
Measurement and worklist will be aborted.

Move robotic: Press key LEFT/RIGHT:
Moves robotic to left or right home position.

Contine 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 Continous 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.

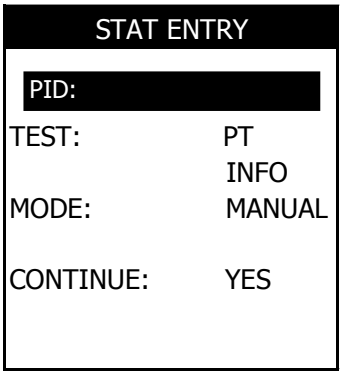
(1) Samples without patient barcode
- Define new orders with TECAM software and send to instrument
- Goto instruments and press ESC and wait until robotic is idle
- Place patient samples into rack according to TECAM order sequence

(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.



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.

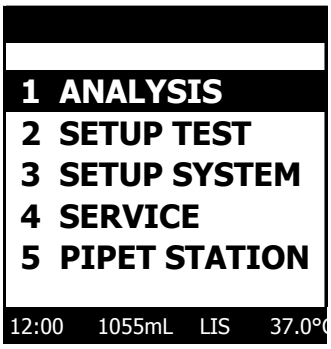
QC with rack position P01 and P02:

- 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

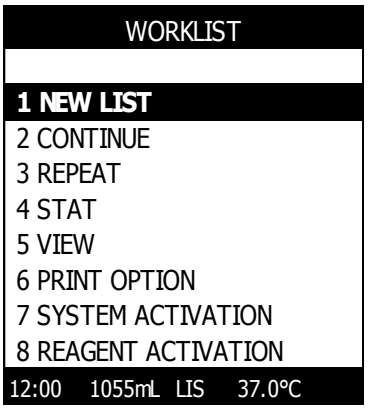
- **SETUP SYSTEM**
  Menu to change system parameters

- **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.

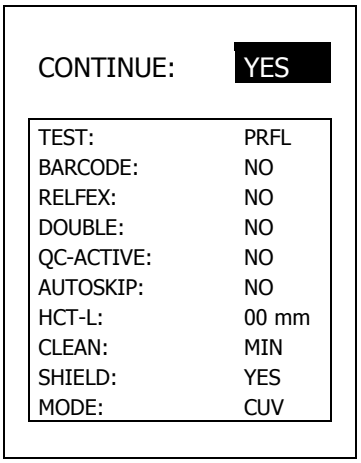
5.1 Main menu Analysis



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



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 buttom 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

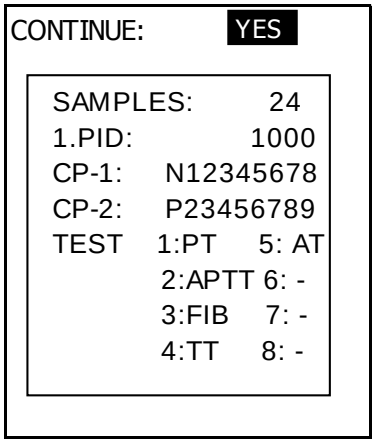
- **SHIELD:** Yes - No
  This setting is only display, if a protection shield is installed.
  - YES: System stop immediately operation, if protection shield is opened during worklist.
  - No: Deactivate shield detection

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:



Possible settings:

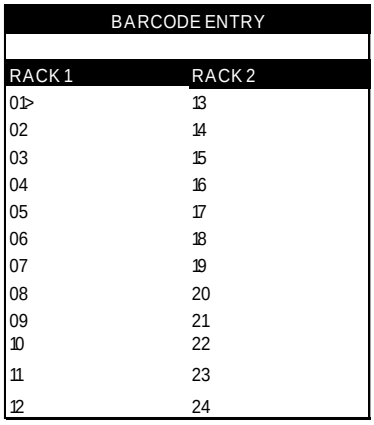
- **Samples:**
  (only visible of barcode is set to no)
  Manual input of number of samples.
- **1. ID**
  (only visible of barcode is set to no)
  Manual input of Identification Number for first sample. The other samples were automatically incremented by 1 (1000, 1001, 1002,…..)
- **CP-1 , CP-2:**
  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:



- *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*

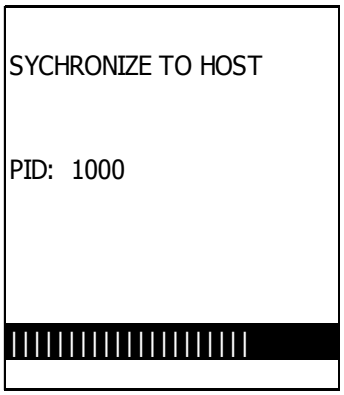
- *Use cursor keys to mark the current sample position and scan the sample. Place the sample into current rack position.*

- *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.

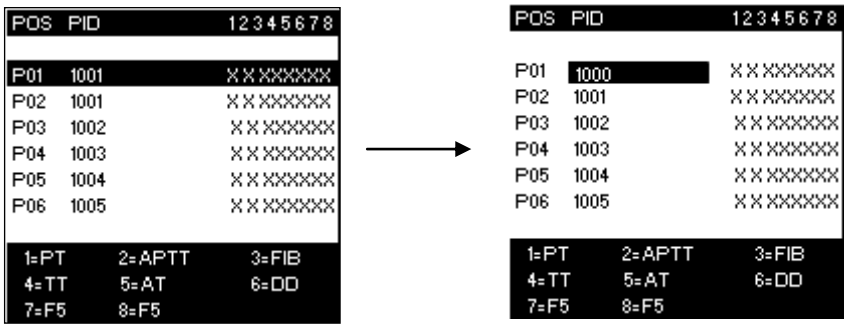
If



All patient identification numbers will be send to host.

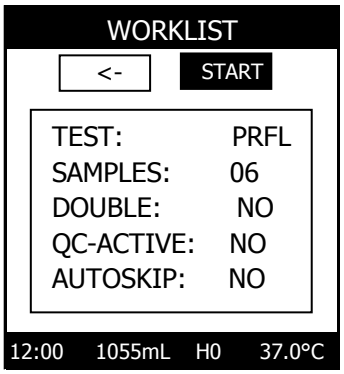
the instrument is linked to host, it will receive corresponding job orders.

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

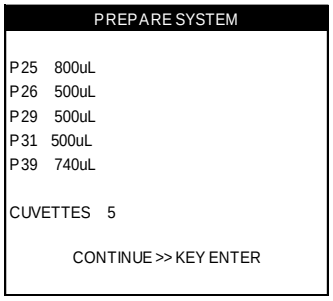


- *Select the order record with cursor keys UP/DOWN.*
- *Select the order items PID or TESTS with cursor keys RIGHT.*
- *If a PID is highlighted , use numeric keys to change the number and confirm with* Enter.
- *If a TEST is highlighted , use* Enter *to (de)activate. Use dot key "." to (de)activate 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.



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



- 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

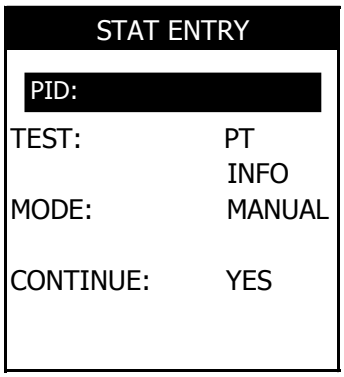
Following a test interruption (e.g. due to a STAT task or discontinuation due to a lack of liquid), routine measurement can be continued here.

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.



- 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.

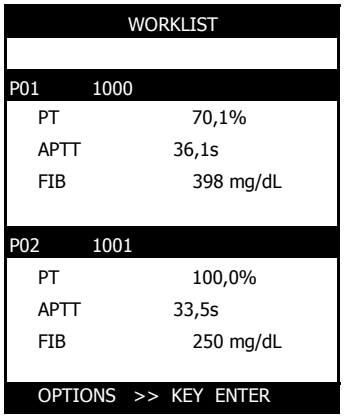
- Information on the test:
  Confirming the INFO field with Enter prints out the test setup just as in normal measurement.

- 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.

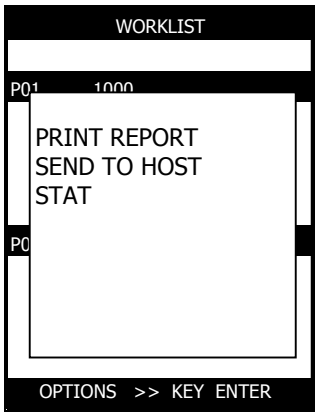
- Activation of emergency measurement:
  Go to the field CONTINUE and confirm with YES.
  The next screen SYSTEM PREPARATION displays the required position in the reagent block, the required amount of reagent and the number of cuvettes required.
  After checking the reagent position, the measurement procedure can be initiated with Enter.

5.1.5 Submenu Overview

Displays and prints lists according to given sorting criteria.



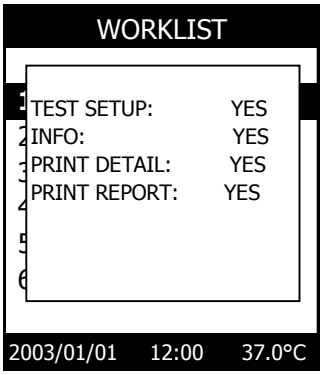
Enter calls up options, ARROW ↑ / ARROW ↓ pages through the options, Enter executes the operation:



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

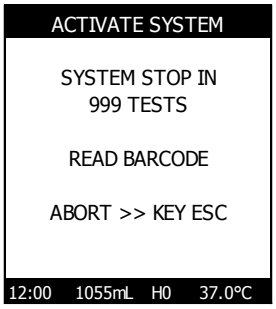


Determines what information is to be printed automatically:

- 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 configurated as closed system



System will stop operating after 999 determinations.

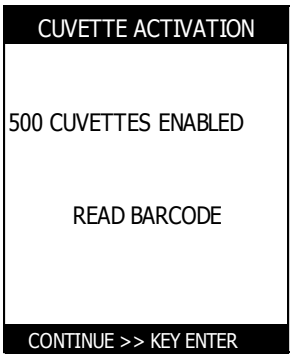
- Skip message with key ESC.
- Scan “Test Activation Key” to activate system.

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

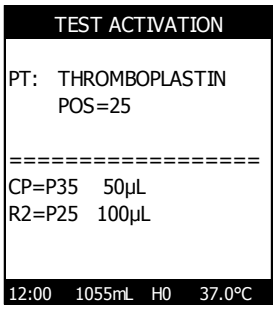
This menu is only shown, if instrument is configarated as “Closed to cuvette”. Read the barcode, which is provided with the cuvette package.



Activation barcode can be read only one time and is be checked by serialnumber 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”

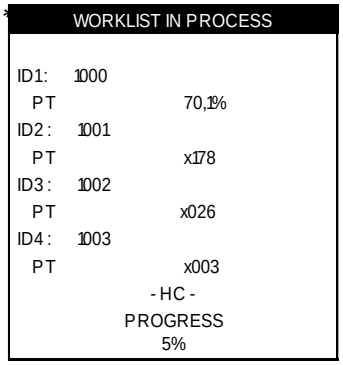
5.1.10 Reflex testing

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



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!

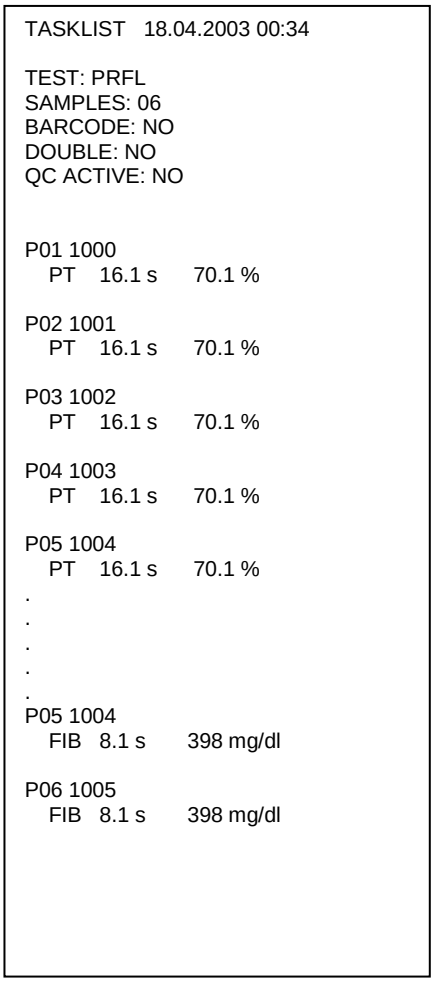
5.1.12 Result warning messages

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 %

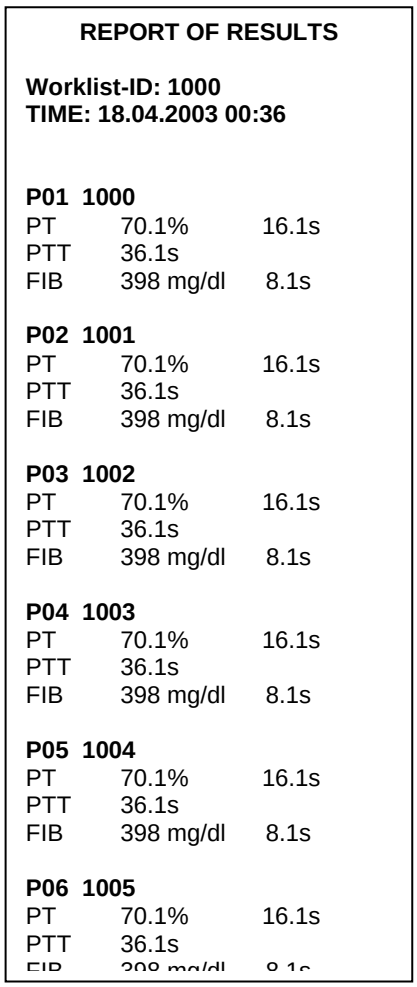
P03 1002
PT 16.1 s 70.1 %

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

Individual results



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

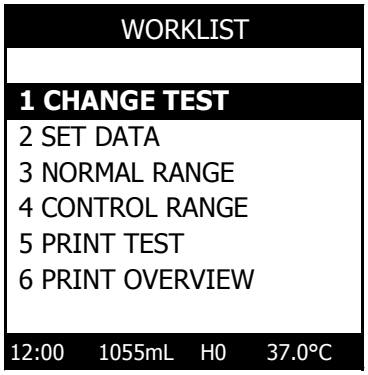
P06 1005
PT 70.1% 16.1s
PTT 36.1s
FIB 398 mg/dl 8.1s

Report

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



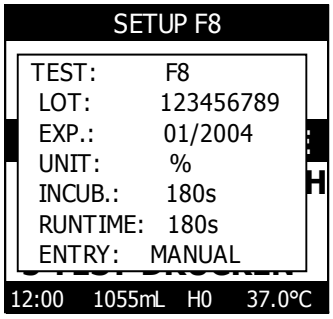
CHANGE TEST

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

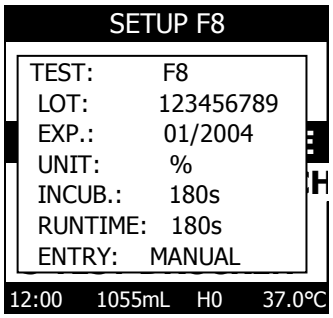
The internal barcode scanner will be activated by entering the submenu SET DATA. After every barcode event, the Coatron A4 will enter the LOT number and expiry date of the barcode.



5.2.2 Test Selection

All of the available tests are listed in a table. Navigation within the table is realized with ARROW ↑ / ARROW ↓ / ARROW ← / ARROW →. 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”



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.

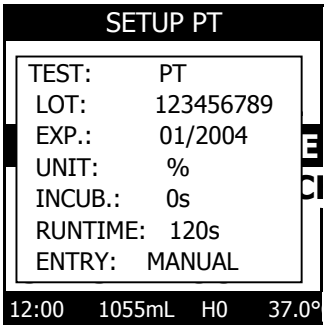
- Manual Calibration:
  The operator must prepare the standards and run them like normal samples. He must also enter the results manually

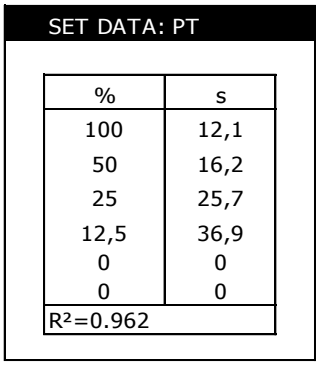
- Auto Calibration with dilutions:
  The operator must place the reference plasma into rack postion P01 and addionally empty vials in P02 – P06. The analyser will prepare all required plasma dilutions, run the standards and transfer the results into the calibration curve automatically.

- Auto Calibration with fix standards:
  The operator can place upto 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





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 upto 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.

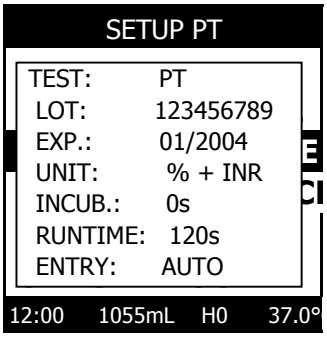
The following rules must be complied with:

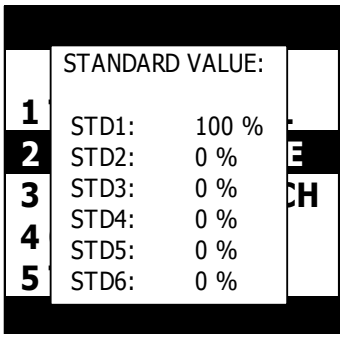
- ***At least 2 value pairs must be entered***
- ***None of the value pairs may be entered double***
- ***The values must be $\neq 0$.***
- ***The expiry date must be valid***

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.





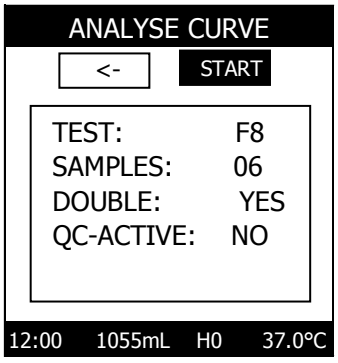
Select test and unit, set *ENTRY to Auto* and press ENTER.

- **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.



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

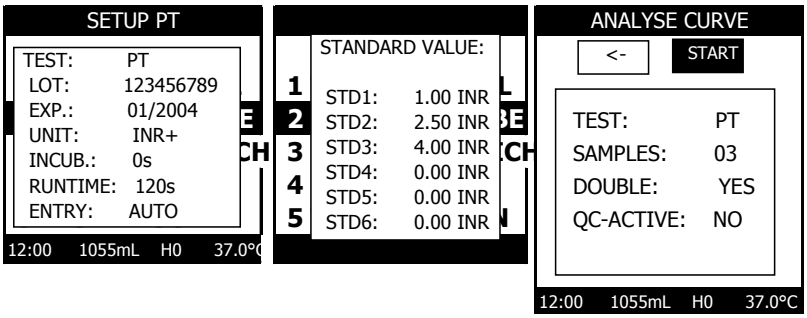
3. Additional empty sample test tubes are required in rack positions 2-6. The number of samples corresponds to the

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.



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 conformitity 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
_____	
1: 80 mg/dl - 27.0 s	
2: 120 mg/dl - 18.0 s	- calibration values
3: 240 mg/dl - 12.0 s	
4: 480 mg/dl - 7.0 s	
_____	
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 Charakters 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. Caculate 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 dispensor:

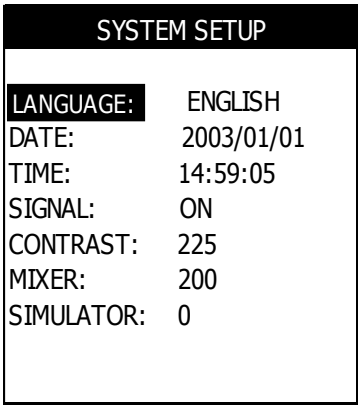
- Below 4µL: >15%
- At 5µL: 5%
- Above 10 µL: <1%

Concern the clear volume:

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



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

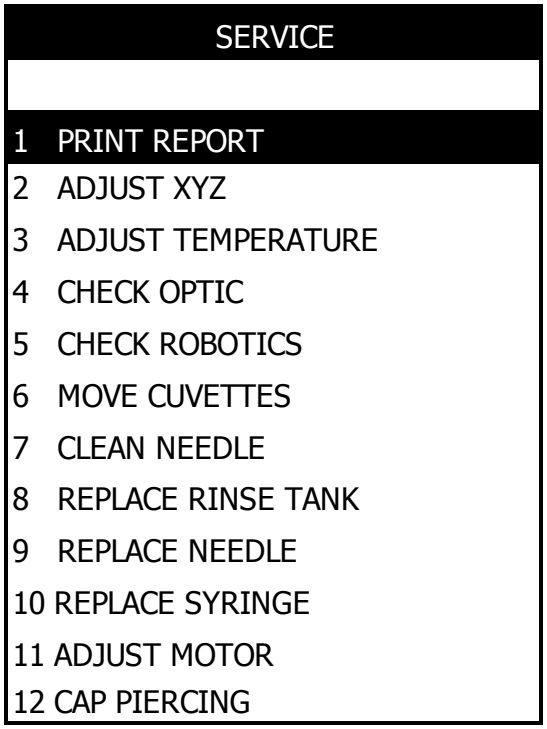
Changes the magnetic stirrer speed at position 25 in the reagent block. Continuous settings from 0 to 255, standard setting 200.

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



ARROW ↑/↓	the desired menu item is selected
Enter	initiates the operation directly.
1-9	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 celsisus (target)
Current digits (target)

Temperature reagent PT:current celsisus (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

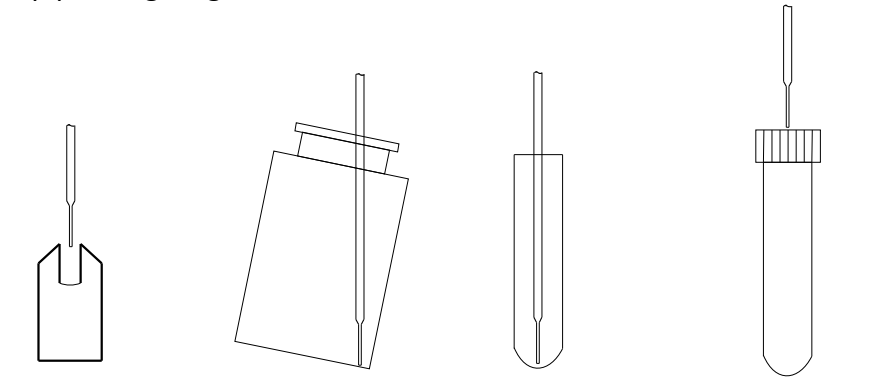
5.4.2 Adjust XYZ

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



1. First the needle will go to wash position. Center the needle exaktly. The needle tip must be at same level with top of wash position. Press “ENTER” to come to next postion 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 buttom. Lift vial to determine the distance. Press “ENTER” to come to next postionen 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 postionen or press “ESC” to quit.

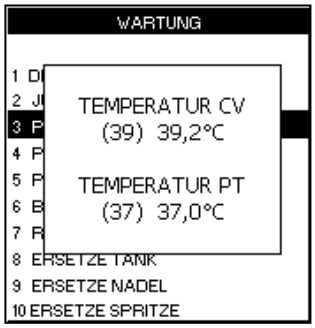
4. Forth the needle will go to P01 position. Center the needle.The needle tip should be short before touching the vial buttom. Lift vial to determine the distance. Press “ENTER” to come to next postionen or press “ESC” to quit.

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.

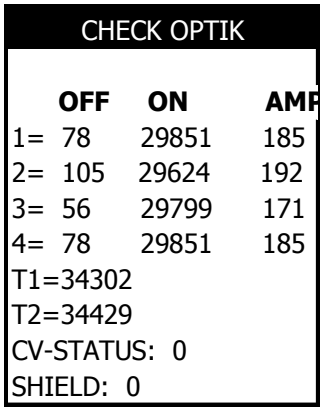
1. Place an empty cuvette in the measuring cell and fill 300 µl water into all of the 4 measurement positions. Place a standard commercial fever thermometer in one of the cuvette wells. Make sure the cuvette is standing upright.

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 +- 0.5°C from target value. Temperature can be increased or decrease by pressing ARROW ↓ / ↑ .
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.



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 thetube fittings to the left valve channel and tighten only by finger
7. Switch on instrument and and run menu “SERVICE\REPLACE NEEDLE”

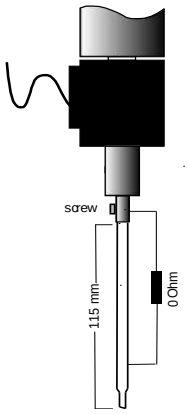


Figure 10: Replace Needle

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

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 and run menu “SERVICE\REPLACE SYRINGE”

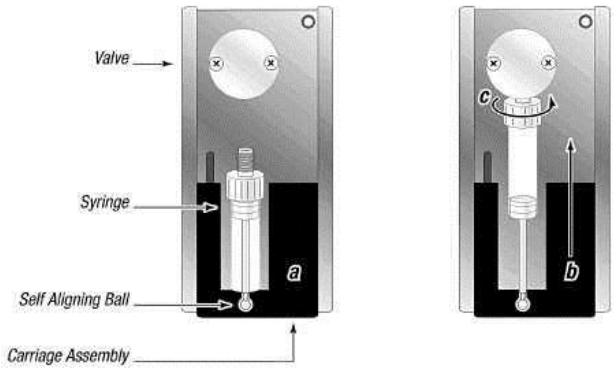


Figure 11: Installation of syringe

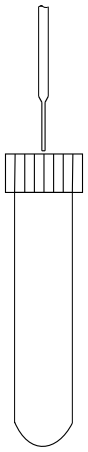
5.4.11 Adjust Motor

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 150µL 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 simular 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

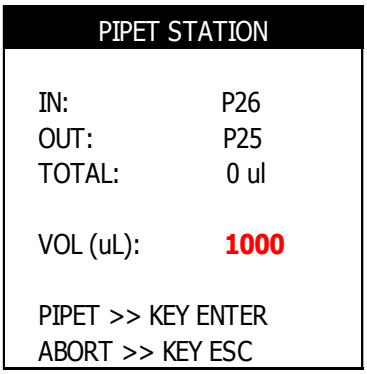
Activated cap piercing function allows to operate with open or closed tubes. The throuphput gets a little lower.

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

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

5.5 Main menu PIPET STATION

Menu to reconstitute reagent and controls



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 perss ESC again to exit menu.

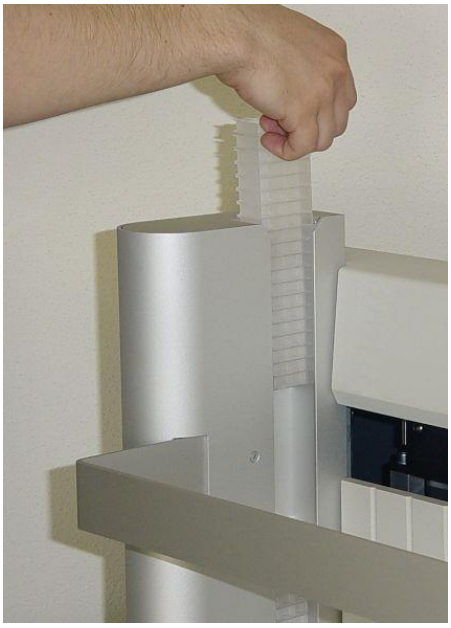
6. Replacement of consumables

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

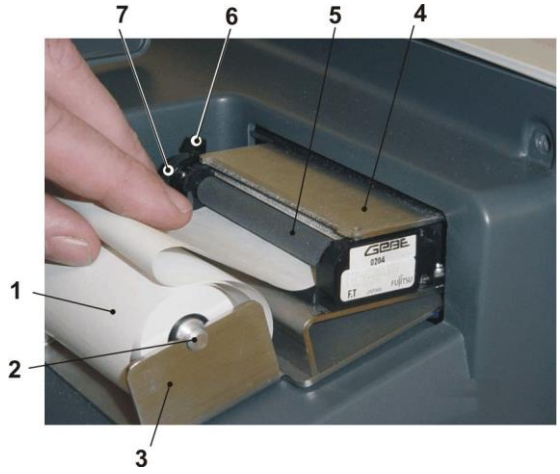


Figure 14: Replenishing the printer paper

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 (*chap. 6.1*)
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 mut be validated	Refill cuvettes (*chap. 6.3*)
Adjust XYZ	Replacement of needle	XYZ adjustment of pipetting arm (*chap. 5.4.2*)
Adjust Motor	Replacement of main-board or software update	adjustment of cuvette (*chap. 5.4.11*)
No liquid	No liquid in current position of pipetting needle	Refill liquid at current needle position.
	Z-offset false	XYZ adjustment of pipetting arm (*chap. 5.4.2*)
Check printer	No printer paper	Replenish printer paper (*chap. 6.7*)
	Arresting lever in offline position	Change arresting lever position (*chap. 6.7*)
	No printer connected	Consult customer service
Check temperature	Temperature in system block too high or too low	Check temperature and adjust (*chap. 5.4.2)*
Clean needle	Pipetting needle was replaced	Carry out needle cleaning cycle (*chap. 5.4.7*)
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 (*chap. 6.7*)
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 (*chap. 5.4.11*)
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 (*chap. 5.4.11*)
	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 (*chap. 5.4.11*)
False measurement results	Reagent	Check TEST SETUP
	Temperature	Check temperature (chap. 5.4.3)
	Optics	Check optics (chap. 5.4.4.)
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (*chap. 5.4.11*)
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"	Enviremont 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 (chap. 5.4.4)
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.

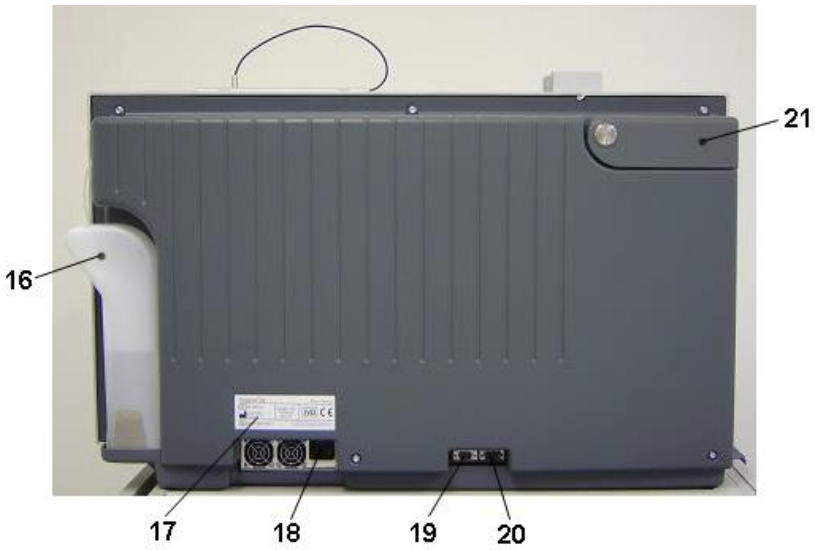
Preparation of the Analyzer for transport:

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 simultanously. 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:	Anaylser 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:	Timee 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 -Livetime 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 communication 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 (throuput, consumption, precision and accuracy.

9.3 Declaration of Conformity

TECO CE

Quality Management ISO 9001:2008 ▸ Voluntary participation in regular monitoring DEKRA Certification DEKRA certified

Quality Management EN ISO 13485:2003 + AC:2009 ▸ Voluntary participation in regular monitoring DEKRA Certification DEKRA certified

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Wir / *We*

TECO Medical Instruments Production and Trading GmbH
Name des Anbieters / *Supplier's name*
Dieselstrasse 1, D-84088 Neufahrn NB
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass das Produkt,
declare under our own responsibility, that the product,

Coatron A4
Bezeichnung, Typ oder Modellname / *name, type or model*

den Anforderungen der folgenden Richtlinien entspricht:	*corresponds to the requirements of:*
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	*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*

Zur Beurteilung der Konformität wurden u.a. folgende harmonisierte Normen herangezogen:	The following harmonized standards have been used amongst others:
1. Sicherheit: EN 61010-2-101:2002 Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte	*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. EMV: EN 61326-2-6:2006 Elektromagnetische Verträglichkeit – Anforderungen	*2. EMC:* *EN* 61326-2-6:2006 *Electromagnetic compatibility – Requirements*
3. Risikomanagement: DIN EN ISO 14971:2012: Medizinprodukte – Anwendung des Risikomanagement auf Medizinprodukte	*3. Risk management:* *DIN EN ISO 14971:2012: Medical devices – Application of risk management to medical devices*
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	*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*

Das QM-System des Herstellers ist zertifiziert durch DEKRA Certification, Stuttgart, nach: **EN ISO 9001:2008** **EN ISO 13485:2003+AC:2009**	*The QM-system of the manufacturer is certified from DEKRA Certification, Stuttgart, for:* ***EN ISO 9001:2008*** ***EN ISO 13485:2003+AC:2009***

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.

This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of quality.

Ort und Datum der Unterzeichnung: Neufahrn, 25.03.2014
Place and date of issue: Neufahrn, March 25th, 2014

Gültig bis 01.04.2015
Valid until April 1st, 2015

Christian Hotar
General Manager

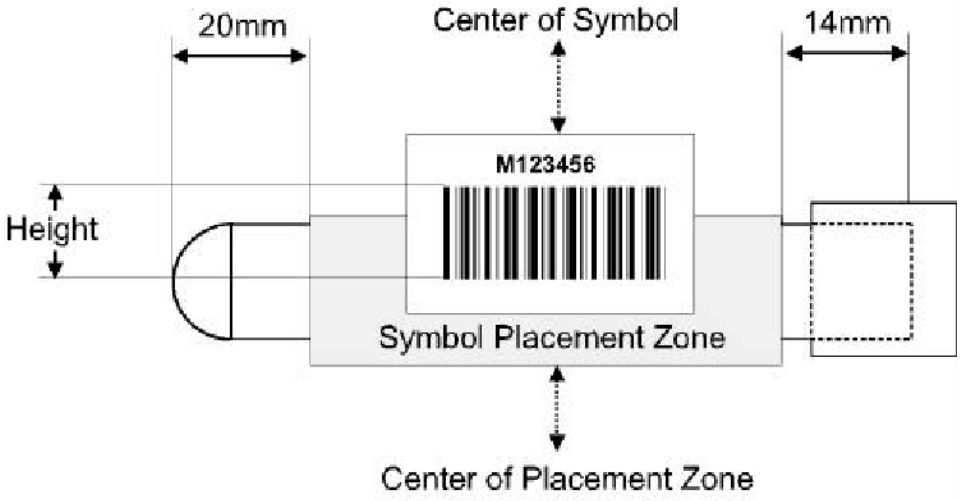
9.4 Disposal and recycling

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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Manual de operare

Seria X Coatron

Eco / Pro / Top

Doar pentru diagnosticul in-vitro

Dispozitive și reagenți pentru coagulare și hemostază

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)

Drepturi de autor

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.

Lista imaginilor din manual:

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
	**Citire**	Indică informație importantă 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: Scaner de mînă 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: Scaner de mînă a codurilor de bare

Imaginea 3 : Vederea laterală cu slotul pentru codul de bare

1.3 UTILIZAREA PROPUSĂ

IVD

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 scanerul de coduri de bare portabil	Da		
Modulul scanerului de coduri integrat	opțional		
LIS, USB	Da		

Actualizarea programului, USB	Da
Bluetooth V4.0	Urmează

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

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, sînge integru citrat

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

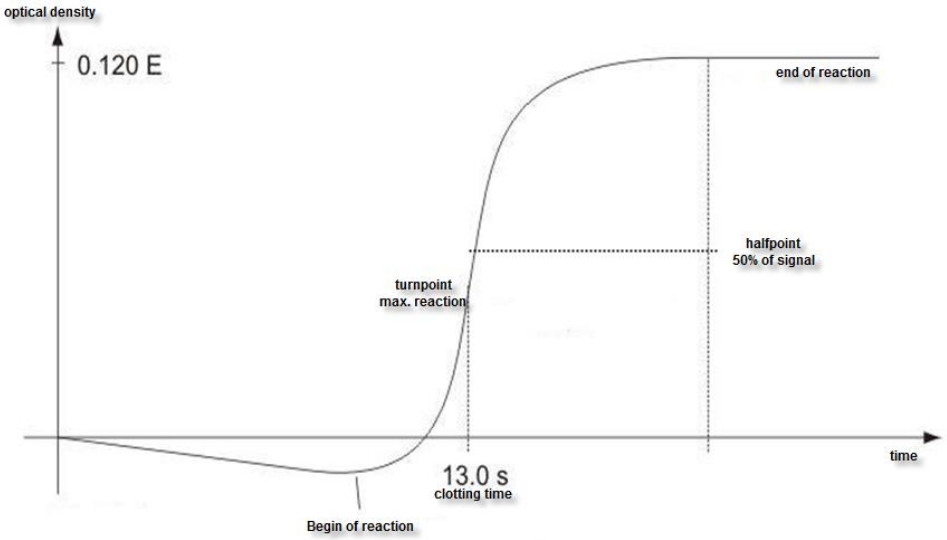
1.3.4 PRINCIPIUL DE MĂSURARE

Detectarea coagulării plasmatice 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. Cuva 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. Anticorpii 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, deservirii sau curățării.

Radiație cu lumină LED
Evitați expunerea directă a ochilor.
Scanerul 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 dezinfectați 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 dezinfectanți.

1.4.5 SIGURANȚA ELECTRICĂ

	**Precauții:** ▪ 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. Conductele sau soclurile defecte trebuie înlocuite fără întârziere.

	**Conectați la energie:** ▪ 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.

	**Deconectați de la energie:** ▪ 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 µl, 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)

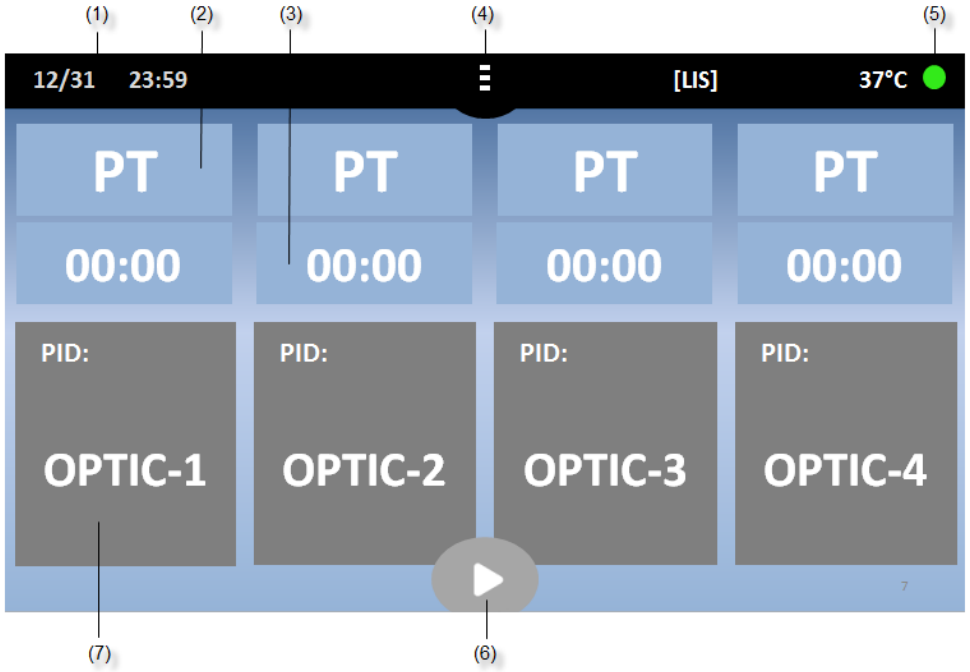
1. Deschideți meniul și setați Auto PID = Pornit.
2. Puneți cuve goale în fiecare canal și pipetați 25 ul de probă pe fiecare cuvă.
3. Apăsați butonul mutlistart.
4. Adăugați 50 ui PT la fiecare cuvă.

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

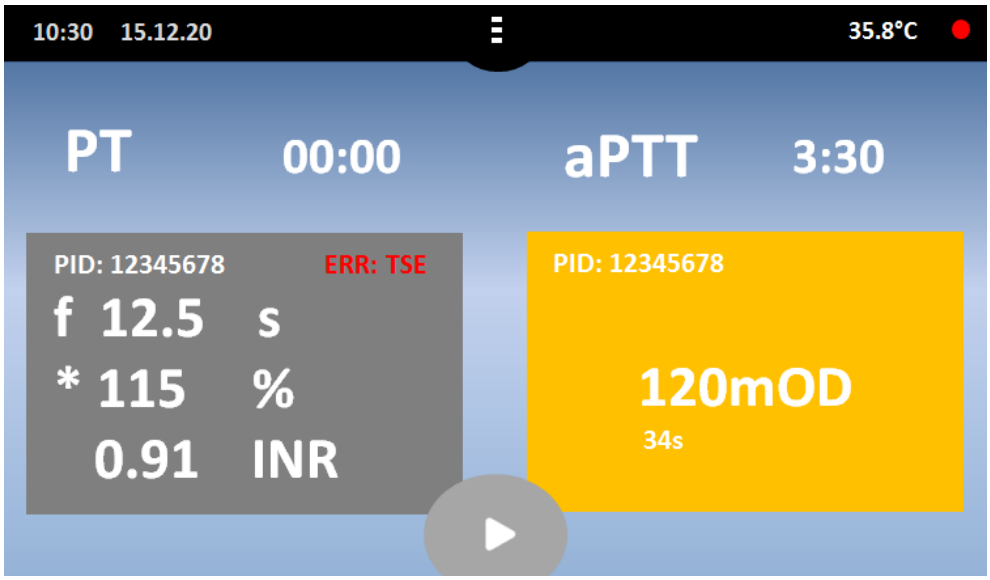
Primul ecran după pornire



IMAGINEA 6: ECRANUL DE BAZĂ COATRON X TOP

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

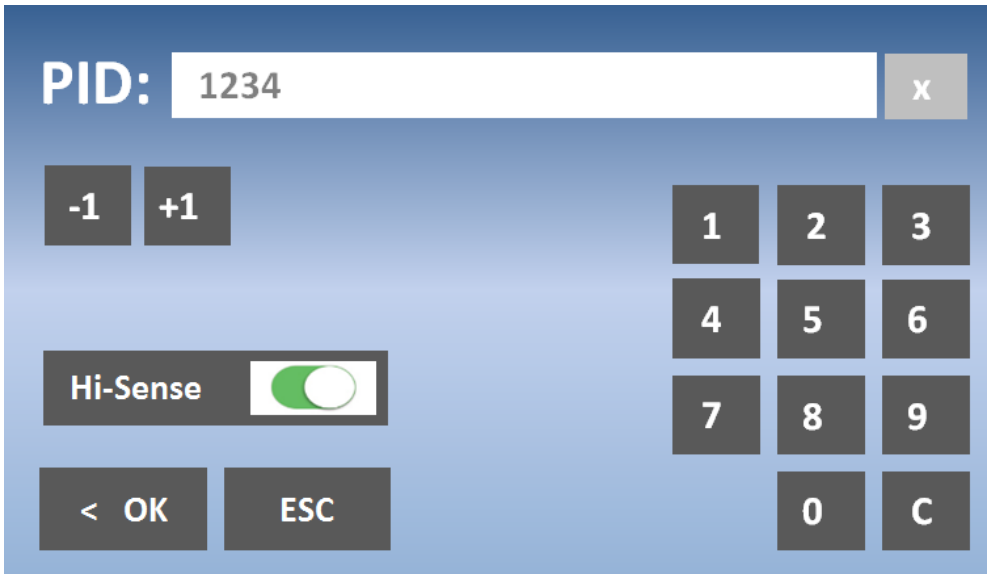
Altele	
eșantion cod de bare	Citiți ID-ul pacientului și urmăriți activarea gratuită
[LIS]	Vizibil, dacă este conectat cu LIS
LED Verde	Sistemul este gata pentru măsurare
LED Roșu	Indică problemele sistemului. Nu este posibilă nicio măsurare.
37.0°C	Temperatura pe blocul de reactiv.
Butoane gri	Funcția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

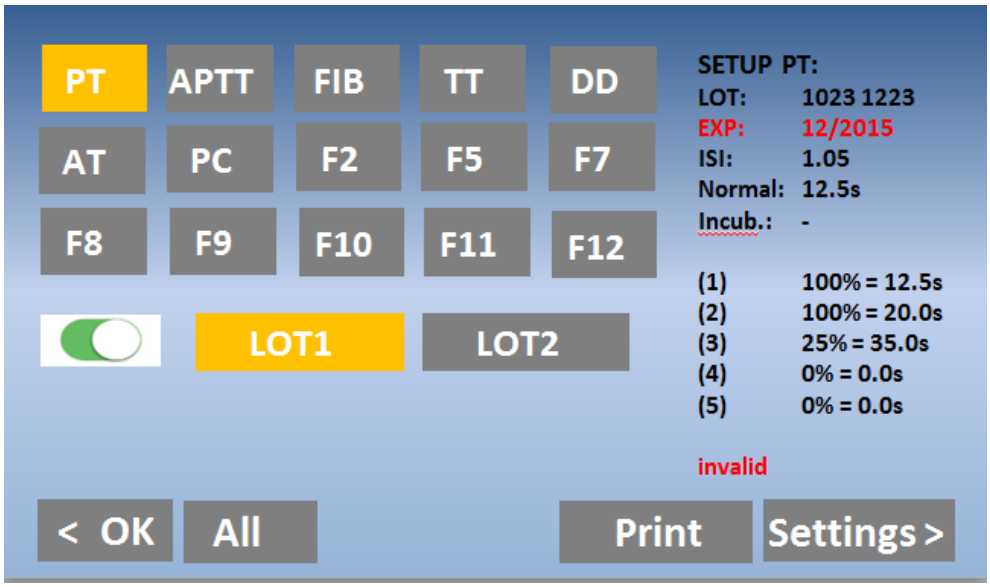
3.3 INTRODUCEREA INFORMAȚIEI DESPRE PACIENT



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

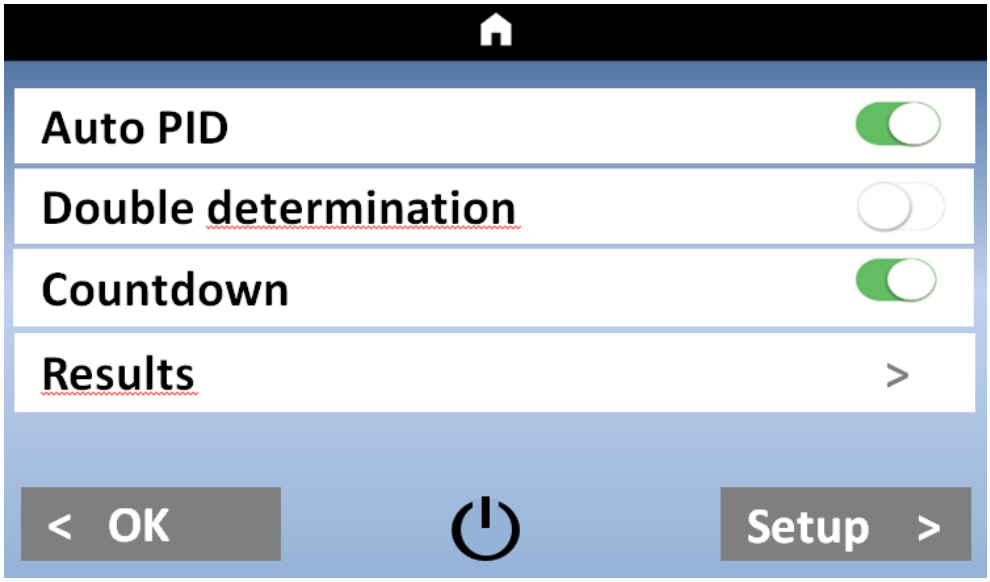


IMAGINEA 9: ALEGEREA TESTULUI LA COATRON X PRO/TOP

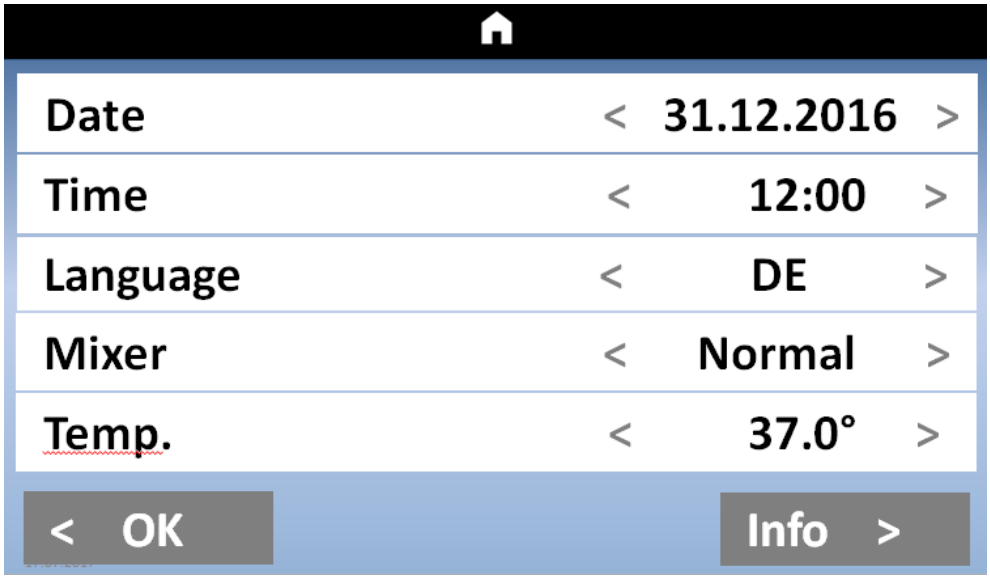
Butonul	Titlul	Utilizarea funcției
Butoanele de testare	PT – F12	Alegeți testul
On / Off	On / Off	Activați două LOT-uri pe test (nu sunt disponibile pentru Coatron X Eco)
LOT 1/2	LOT 1/2	Încărcați datele LOT 1 sau 2 de la EEPROM
OK	OK	Confirmați testul pentru canalul curent
Toate	Toate	Confirmați testul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

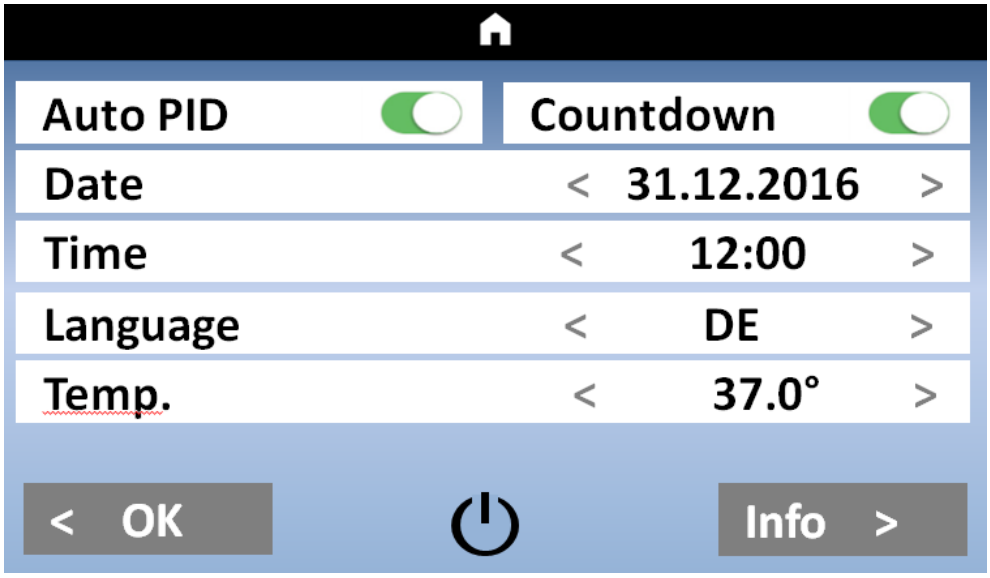
3.5 SETĂRILE DE SISTEM



IMAGINEA 10: MENIUL RAPID COATRON X PRO/TOP

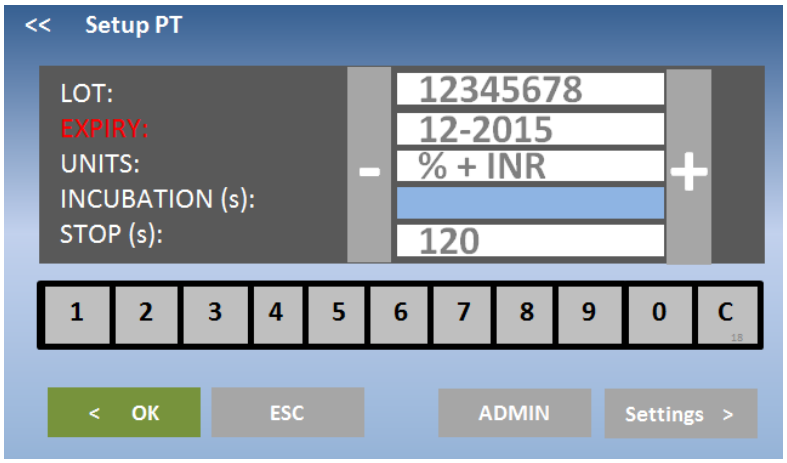


IMAGINEA 11: SETĂRILE DE SISTEM COATRON X PRO/TOP

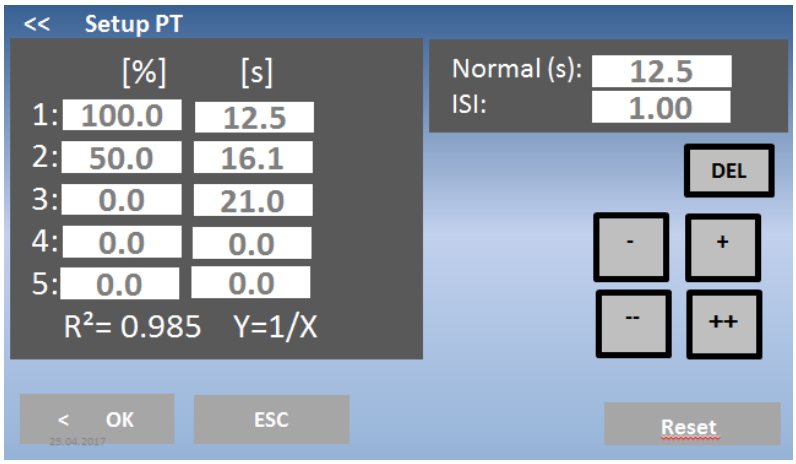


IMAGINEA 12: SETĂRILE DE SISTEM COATRON X ECO

3.6 SETĂRILE TESTULUI

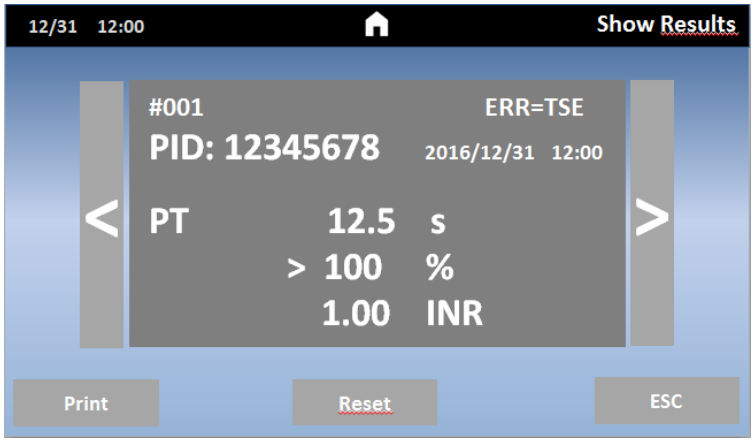


IMAGINEA 13: SETĂRILE TESTULUI 1



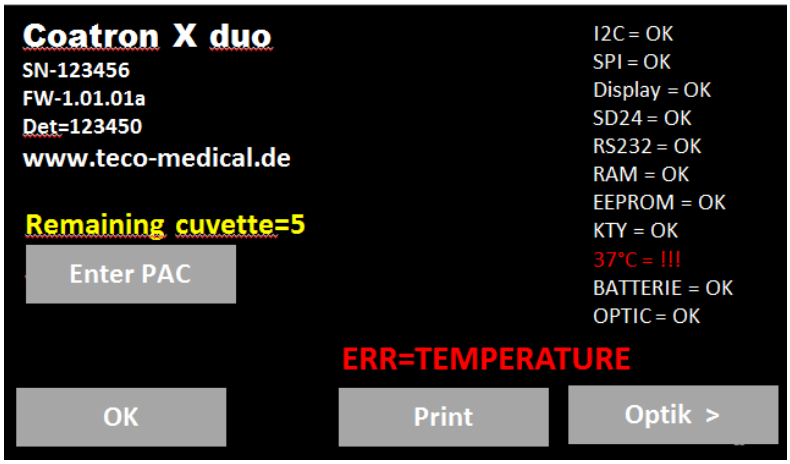
IMAGINEA 2: SETĂRILE TESTULUI 2

3.7 ANALIZAREA REZULTATELOR



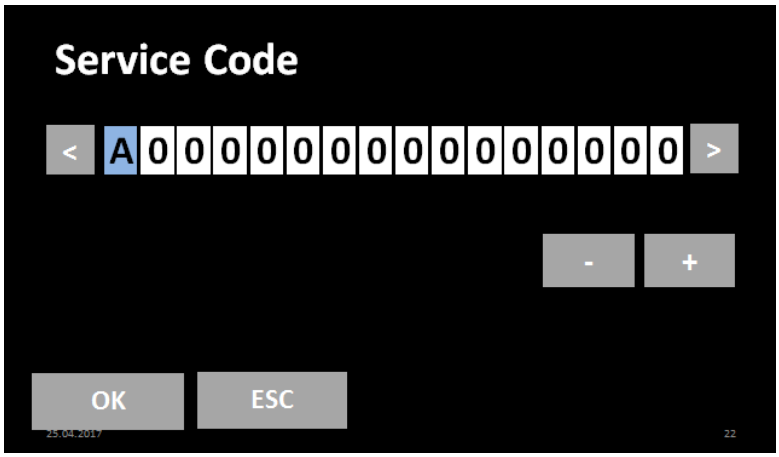
IMAGINEA 15: ANALIZAREA REZULTATELOR COATRON X PRO/TOP

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 așteaptați 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 mpsurare 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. Adaugați 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. Adaugați 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 calibratorului 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 toți 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 senzorului 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

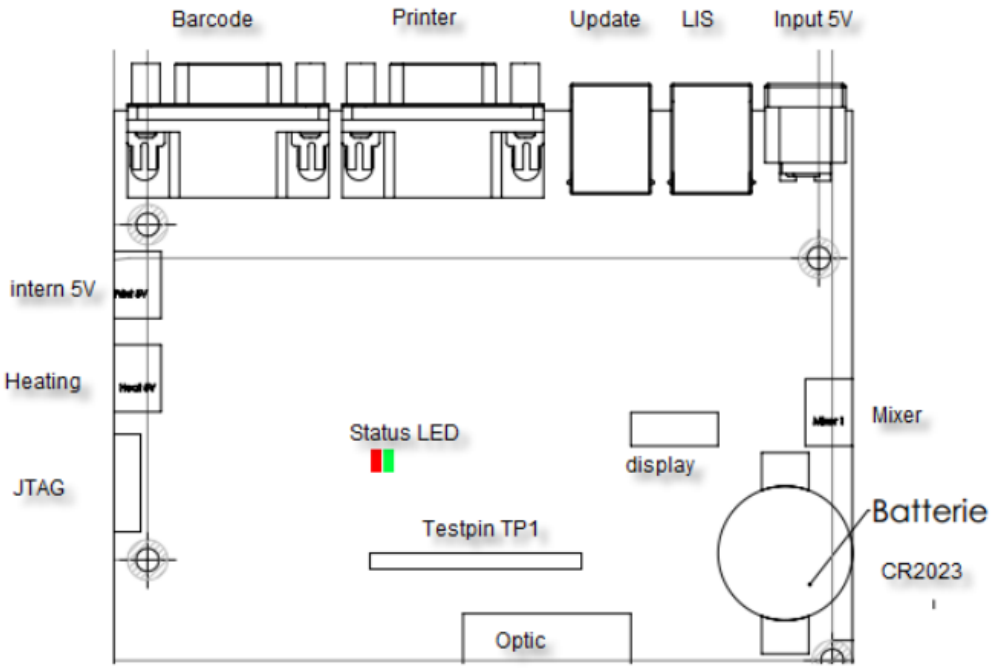
1. Porniți dispozitivul și așteptați aprox. 15min până când sistemul afișează 37 ° C pe ecran.
2. Umpleți un tub / flacon de reactiv cu 2 ml de apă și așezați-l într-o poziție de reactiv. Plasați un termometru digital în tubul de reactiv și lăsați să se încălzească timp de aproximativ 10 minute.
3. Apăsați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

5.4 PREZENTAREA GENERALĂ AL PLĂCII PRICIPALE



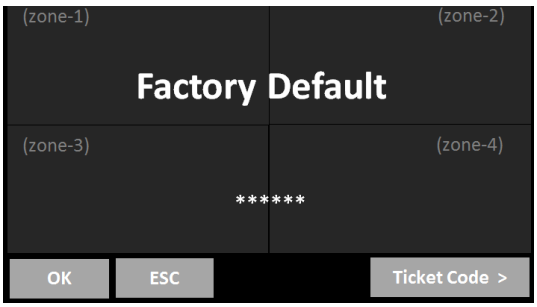
Statutul după becul LED:

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

6. FUNCȚIILE ASCUNSE

6.1 RESETAREA LA STAREA DIN FABRICĂ

IMAGINEA 19: ECRANUL DE START



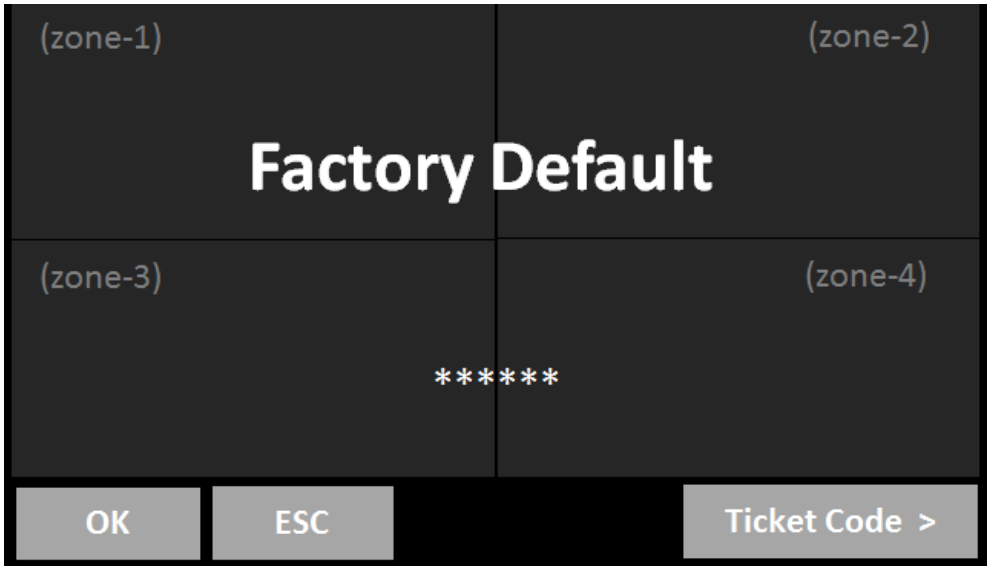
IMAGINEA 20: SETĂRILE IMPLICITE

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



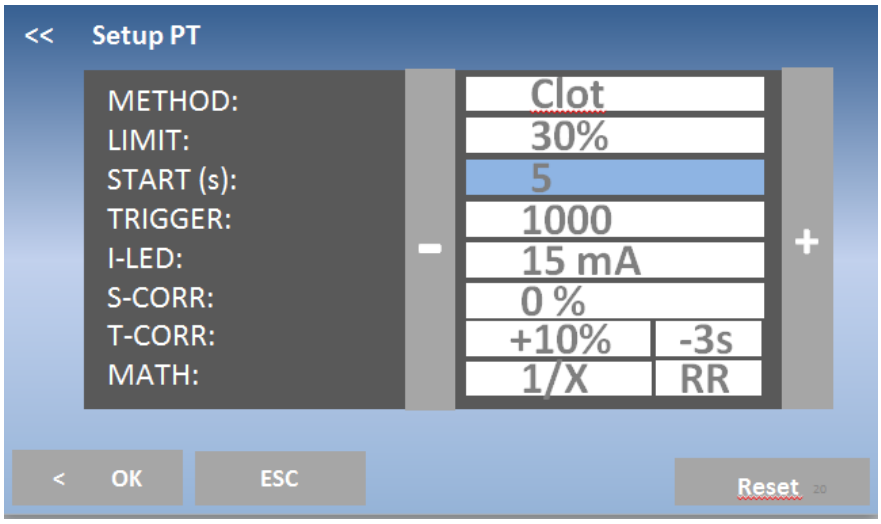
IMAGINEA21 : LOGAREA ÎN CALITATE DE ADMINISTRATOR

1. Ecran de întâmpinare: Apăsați lung pe pictograma filetului
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, Bacillol®AF)
- Decontaminați zona de lucru, zona acului, rafturile pentru pacienți, tastatura, ecranul LCD, carcasele 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

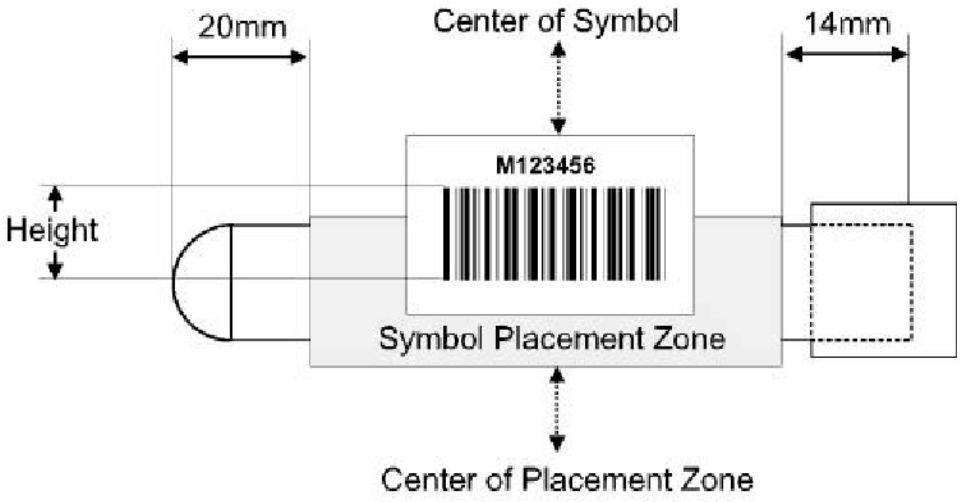
8.1 ERORILE DE MĂSURARE

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

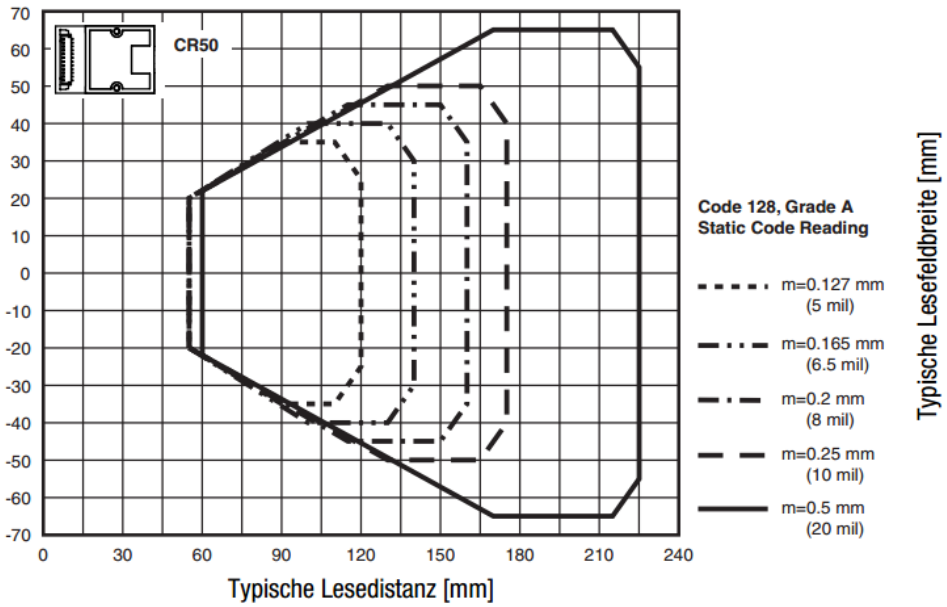
- Lungimea:	50 – 70 mm
- Lățimea:	20 - 30 mm
- Lungimea codului de bare:	40 – 60 mm
- Lățimea codului de bare:	10 - 20 mm
- Zona goală:	> 5mm
- Rezoluția/modul:	5 -20mils (0.2 – 0.5mm)
- Diapazon:	minim 1:2,5 to 1:3 (coduri bidimensionale)
- Calitate	Nivelul A sau B în cpnformitate cu ANSI X3.192 -1990

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 scaner 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)
Scanerul codului de bare	
Scaner 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

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

TEClot PT-S

CE IVD REF **A0230-010, A0230-040, A0230-100,**

Intended Use
This product is used for the determination of prothrombin time (PT) in plasma according to Quick[1,2]. The test is sensitive to the extrinsic pathway coagulation factors II,V,VII,X and fibrinogen and therefore used for oral anticoagulant therapy with Vitamin-K inhibitors like Warfarin or Marcumar and also for the quantitative determination of extrinsic coagulation factors. The PT measures the extrinsic clotting time (factor VII activation) of test plasma after the addition PT reagent.

Contents & Determinations

Product	TEClot PT-S	TEClot PT-S	TEClot PT-S
Cat.No.	A0230-010	A0230-040	A0230-100
PT-S Reagent*	5x2 mL	10x4 mL	10x10 mL

Determinations

Coatron M**	200 Det.	800 Det.	2000 Det.
Coatron A4	100 Det.	400 Det.	1000 Det.
Coatron A6	200 Det.	800 Det.	2000 Det.

*contains an extract of Rabbit brain with buffer, stabilizers and Calcium chloride.
**Micro method (75µL in total)

Preparation
Reconstitute with high purity water with the volume stated on the vial label.

A0230-010	A0230-040	A0230-100
2 mL	4 mL	10 mL

Let stand at room temperature with occasional swirling for at least 15 min. Then place reagent into instrument and let incubate for further 15 min. The reagent sediments and must be swirled before each testing. On Coatron instruments, you can use a mixing bar for this.

Storage & Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37°C
PT Reagent	5 days	36 hours	8 hours

Precautions
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

Specimen collection and storage[4]
1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 30d at -20°C 6m at -70°C

Procedure
A. Automated Method: Coatron A

Prothrombin Time		A4		A6	
PAT	Patient	50µl	CP1	25µl	CP1
BUF	IBS Buffer	0µl	P39	0µl	P79
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	-	0µl	P00	0µl	P00
R2	PT Reagent	100µl	P25	50µl	P46

	A4	A6
Incubation	0s	
Maxtime	120s	
Unit	251	
Method	Coag	
Math	log XY	
CT-Mech	No	
Deadtime	7s	

	A4	A6
SENS	2	
POINTS	4	
MIX	No	
Clean	0	0
Multi	1	3
S-Corr	0%	
T-Corr	30% - 4s	

B. Manual Method: Coatron M system
1. Incubate PT reagent at 37°C for at least 10 minutes
2. Pipette **25 µl of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
3. Add **50 µl of PT reagent** (37°C) and simultaneously start test.
4. Record the clotting time in seconds.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

Expected Results
Typical seconds: 11 – 18 sec
Normal range: 70 - 130% 0.85 – 1.15 INR

However results are influenced by instruments, technique, calibration etc. Each laboratory is recommended to establish its own range on the specific instrument used.

Standardisation and Calibration
The PT result is expressed as seconds or activity (% Quick) or INR (International Normalised Ratio).

INR results:
were calculated from normal time and ISI value (international sensitivity index). First is obtained by running fresh plasma from a pool of healthy individuals. The ISI value is stated in the LOT specific certificate of analysis.

$$INR = \left(\frac{Patient\ PT}{Normal\ PT}\right)^{ISI}$$

Activity % (Quick) result:
were calcaluted from a calibration curve, which is prepared from reference plasma (e.g. TECAL N) and dilutions in saline solution like 0.9% $NaCl_2$ or TECLOT IBS buffer. At least three or more calibration points are recommended. The calibration curve must be confirmed with control plasma in normal and abnormal range.

% of normal	100%*	50%	25%	12,5%**
diluted in saline	not dil.	1+1	1+3	1+7

* The median of at least 21 healthy individuals is defined as 100%.[5]
**12.5% dilution may cause "+++" results in same cases, because the level of fibrinogen is too high diluted for optical detection.

Quality Control
TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations
Great care must be taken to minimize variations which may occur by seemingly insignificant factors.
A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.
4. ISI value is not constant within the first 30 min after reconstitution.
5. Reagent sediments and must be swirled before each testing.

Performance Characteristics
Typical performance on instrument Coatron M4

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 3,0	< 5,0
Abnormal control	< 3,0	< 5,0

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Quick, A.J., The Hemorrhagic Diseases and the Physiology of Hemostasis. Charles C. Thomas: Springfield, IL. 1942.
2. Quick, A.J., Hemorrhagic Diseases. Lea and Febiger: Philadelphia. 1957.
3. Miale, J.B., Laboratory Medicine-Hematology, 4th Edition. C.V. Mosby: St. Louis. 1972.
4. National Committee for Clinical Laboratory Standards: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays.
5. Besselaar A M H P van den, Lewis SM, Mannucci P n Poller L. 1993. Status of present and candidate International Reference Preparations (IRP) of thromboplastin for prothrombin time. Thromb Hemostas 69; 85
6. Besselaar A M H P van den. 1991. The significance of the International Normalized Ratio (INR) for oral anticoagulant therapy. H17CC 3; 146153.

Symbol keys

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number	AQUA DEST.	Reconstitute with dest. water		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number		Ready to use	EC REP	Authorized Representative

TECO GmbH, Dieselstr. 1, 84088 Neufahrn NB Germany

Calcium Chloride 0,025M

CE IVD REF ***A0350-050, A0350-100***

Intended Use
This product is used in combination with reagent TEClot APTT-S (Cat.No. A0320) to determine the APTT or also for other 25mM $CaCl_2$ requiring coagulation tests.

Contents & Determinations

Product	Calcium Chloride	Calcium Chloride
Cat.No.	A0350-050	A0350-100
$CaCl_2$ 0.025M	10x5 mL	10x10 mL

Determinations

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

Preparation
Ready to use.

Storage and Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2-8°C.

Opened reagent is stable for 30 days at 2-8°C in the original vial.

Precautions
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

Calcium Chloride Solution contains sodium azide. Sodium azide under acid conditions yields Hydrazoic acid, an extremely toxic compound. Azide compounds should be diluted with running water before being discarded. Upon disposal, azide compounds should be flushed with large volumes of water. These precautions are recommended to avoid deposits in metal pipes in which explosive conditions may develop.

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

Calcium Chloride 0,025M

IVD REF ***A0350-050, A0350-100***

Verwendungszweck
Wird zusammen mit dem Reagenz TEClot APTT-S (Kat. Nr. A0320) zur Bestimmung von der APTT verwendet oder auch für andere Gerinnungstests, für die 25mM CaCl2 benötigt wird.

Inhalt und Bestimmungen

Produkt	Kalzium Chlorid	Kalzium Chlorid
Kat. Nr.	A0350-050	A0350-100
$CaCl_2$ 0.025M	10x5 mL	10x10 mL

Bestimmungen

Coatron M	2000 Det.	4000 Det.
Coatron A	1000 Det.	2000 Det.

Vorbereitung
Das Reagenz ist gebrauchsfertig

Lagerung und Stabilität
Ungeöffnete Reagenzien sind bei einer Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar.

Geöffnete Reagenzien sind bei Lagerung zwischen 2-8°C im Originalfläschchen 30 Tage haltbar.

Vorsichtsmaßnahmen
Haut- und Augenkontakt vermeiden. Schutzkleidung tragen. Abfälle unter Beachtung der vorgeschriebenen internationalen, nationalen und lokalen Bestimmungen entsorgen.

Die Calcium Chlorid Lösung enthält Natriumazid. Unter sauren Bedingungen setzt Natriumazid Hyrogenazid frei, ein höchst giftiger Wirkstoff. Azidverbindungen sollten unter laufendem Wasser gelöst werden bevor sie entsorgt werden. Diese Vorsichtsmaßnahmen werden empfohlen, um Ablagerungen in Metallrohren zu verhindern, die explosive Bedingungen entwickeln könnten.

Garantie
Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

	Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern	CE	EU Konformität		Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter

TEClot TT

CE IVD REF **A0401-020**

Intended Use
TEClot TT reagent can be used manually or on semi-automated and automated instruments. The test is commonly applied to detect various sources of interference with normal blood coagulation. Prolongation of the thrombin clotting time can be taken as a qualitative indication of abnormal fibrinogen levels (high or low), or the presence of interfering substances such as FDP's or heparin. Quantitative evaluation of the possible causes of prolonged thrombin clotting time should be performed as follow-up studies, such as APTT or chromogenic assay for heparin, Clauss fibrinogen, FDP determinations, heparin neutralization by protamine sulphate or polybrene[1] , normal plasma mixing studies[2] or reptilase assay[3] to distinguish between hypofibrinogenaemia and FDP effects.

Contents & Determinations

Product	TEClot TT
Cat.No.	A0401-020
TT Reagent*	10 x 2mL

Determinations

Coatron M	Coatron A4	Coatron A6
800	400	800

*Each vial contains a lyophilized preparation of 26 units bovine thrombin with buffers and stabilizers. The final thrombin concentration in test application for Coatron systems is 4.33 E/mL.

Preparation
Reconstitute the reagent with 2 mL purified water. Allow to stand for 5 minutes then mix gently by inversion.

Storage & Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Reconstituted reagent:

	-20 °C	12 °C	20-25 °C
TT Reagent	1 month	24 hours	8 hours

The vials can be only frozen once.

Precautions
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Specimen collection and storage[4]
1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

Procedure
A. Automated Method: Coatron A

TT A0401-020		A4		A6	
PAT	Patient	100µl	CP1	50µl	CP1
BUF	-	0µl	P00	0µl	P00
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	-	0µl	P00	0µl	P00
R2	TT Reagent	50µl	P27	25µl	P50

	A4	A6
Incubation	0s	
Maxtime	120s	
Unit	3	
Method	Coag	
Math	-	
CT-Mech	No	
Deadtime	5s	

	A4	A6
SENS	2	
POINTS	-	
MIX	No	
Clean	0	2
Multi	1	3
S-Corr	0%	
T-Corr	20% - 3s	

(Refer to instrument operation manual for detailed instructions)

B. Manual Method: Coatron M system

1. Pipette **50 µl of sample** into a test cuvette. Incubate at 37°C for 1-2 minutes.
2. Add **25 µl of TEClot TT** reagent and simultaneously start test.
3. Record the clotting time in seconds.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

Expected Results
Typical normal results are 12 – 24 s [6]. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control
TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations
A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems
6. Heparin below 1U/mL will not interfere results.

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.

As well as the cause of elongated Thrombin Clotting Times indicated above, a recent report has suggested that many systemic amyloidosis patients with bleeding complications may have a circulating inhibitor which prolongs the Thrombin Clotting Time[5]. Also therapeutic levels of heparin may entirely abolish clotting in the Thrombin Clotting Time test, although neutralization with protamine sulphate or polybrene should correct the Thrombin Clotting Time[1].

Performance Characteristics

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 3.0	< 5.0
Abnormal control	< 3.0	< 5.0

(Typical performance on instrument Coatron M4)

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Laposata et al. The Clinical Haemostasis Handbook, Yearbook Medical Publishers Inc., p219, 1989.
2. Thompson, A.R. and Harker, L.A. Manual of Haemostasis and Thrombosis. 3rd Ed., F.A. Davis Co., p62,1983.
3. DeMott, W.R., in: Laboratory Test Handbook, 2nd Ed., Jacobs D.S. et al Eds., Lexi.Comp Inc., p432-433, 1990.
4. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays
5. Gastineau, D.A. et al. Inhibitor of the Thrombin Time in Systemic Amyloidosis: A Common Coagulation Abnormality Blood, 1991, 77: 2637-2640.
6. Lothar Thomas, Labor und Diagnose, 6.Auflage,2005, Page846

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

TEClot FIB

IVD REF **A0501-010, A0501-025, A0511-020, A0511-050**

Intended Use

The TEClot FIB is intended for the quantitative determination of fibrinogen in human plasma according to method developed by Clauss.[1] Levels of fibrinogen can increase as a result of inflammation, pregnancy or oral contraceptive use[2]. Decreased levels can be found in certain states such as liver disease and DIC. Congenital deficiencies include afibrinogenaemia (no detectable fibrinogen), hypofibrinogenaemia (<1 mg/ml) and dysfibrinogenaemia (abnormal fibrinogen molecule).

Contents & Preparation

Product	TEClot FIB Kit-10	TEClot FIB Kit-25	TEClot FIB	TEClot FIB
Cat.No.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagent	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Buffer	1x125 mL	1x125 mL	-	-
TECal Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

Determinations

Coatron M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatron A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatron A6	200 Det.	500 Det.	400 Det.	1000 Det.

*Micro method (75µL in total)

1. Thrombin Reagent:
   Contains bovine thrombin (~80NIH) with stabilizers
   REF: A0501-010/A0511-020: Reconstitute with 2mL purified water
   REF: A0501-025/A0511-050: Reconstitute with 5mL purified water
2. IBS Buffer: Ready to use. Contains Imidazole buffered saline
3. TECal Normal: Reconstitute with 1 mL purified water. Contains citrated human plasma.
4. TEControl A: Reconstitute with 1 mL purified water. Contains citrated human plasma.

Swirl gently after reconstitution and allow standing for 15 minutes at room temperature. Mix well before use. Do not shake.

Storage & Stability

Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

Thrombin Reagent*	2-8 °C	15-25 °C	37 °C
	12 days	5 days	24 hours
TEControl or Plasma	2-8 °C	15-25 °C	-20 °C
	8 hours	4 hours	30 days

* Reagent must be protected from UV-light and evaporation

Precautions

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.
All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

Specimen collection and storage[3]

1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Procedure

A. Automated Method. Coatron A

Fibrinogen		A4		A6	
PAT	Patient	10µl	CP1	10µl	CP1
BUF	IBS Buffer	90µl	P39	90µl	P79
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	-	0µl	P00	0µl	P00
R2	Fibrinogen	50µl	P29	50µl	P49

	A4	A6
Incubation	0s	
Maxtime	120s	
Unit	769	
Method	Coag	
Math	log XY	
CT-Mech	Yes	
Deadtime	3s	

	A4	A6
SENS	0	
POINTS	4	
MIX	No	
Clean	1	3
Multi	1	1
S-Corr	0%	
T-Corr	0%	

B. Manual Method: Coatron M

1. Preparation of Standard, Control and Patient Dilutions

Standard Dilution	Plasma	IBS Buffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient or Control	100µL Plasma	900µL

2. Pipette **50 µl diluted standard or patient plasma** (1:10) into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µl Thrombin reagent** and simultaneously start test.

For other instrument, please refer to your instrument manual for more detailed instrument specific instructions.

Calibration

TECal Normal or other commercially prepared plasma standard in which Fibrinogen has been determined should be used as reference (200-300mg/dL).
Plot the clotting time obtained with each of the FIB standard dilutions on the y-axis against the concentration of FIB (mg/dL) on the x-axis using log-log graph paper. The line of best fit should be determined by linear regression analysis. The fibrinogen in plasma samples can be determined by interpolation from the calibration curve.

Expected Results

Typical normal results are 180-450 mg/dL[4,5]. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control

TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP).). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations

A. Specimen Collection. AVOID:
   1. Use only plastic tubes or siliconised glass.
   2. Delayed mixing of blood with anticoagulant.
   3. Contamination with tissue thromboplastin.
   4. Improper ratio of anticoagulant with blood.
   5. Hemolyzed, icteric or lipemic samples may interfer optical systems

B. Laboratory Techniques
   1. Perform tests at 37°C.
   2. Use only high purity water.
   3. Optimum pH is 7.0-7.5.

Performance Characteristics

Precision:	CV% (within run)	CV% (inter-runs)
Normal control	< 5.0	< 5.0
Abnormal control	< 5.0	< 10.0

(Typical performance on instrument Coatron M4)

Warranty

This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
2. Shaw, T.S.,Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
3. National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
4. Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
5. Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

TEClot FIB

IVD REF **A0501-010, A0501-025, A0511-020, A0511-050**

Verwendungszweck

TEClot FIB wird zur quantitativen Bestimmung von Fibrinogen im menschlichen Plasma nach einer von Clauss[1] entwickelten Methode verwendet. Der Fibrinogenpegel kann auf Grund von Entzündungen, Schwangerschaft und dem Gebrauch von Ovulationshemmern ansteigen[2]. Geringere Konzentrationen können bei verschiedenen Krankheiten wie Leberversagen und DIC auftreten. Angeborene Defizite beinhalten Afibrinogenämie (kein auffindbares Fibrinogen), Hypofibrigonämie (<1mg/ml) und Dysfibrinogenämie (abnormale Fibrinogenmoleküle).

Inhalte und Vorbereitungen

Produkt	TEClot FIB Kit-10	TEClot FIB Kit-25	TEClot FIB	TEClot FIB
Kat. Nr.	A0501-010	A0501-025	A0511-020	A0511-050
Thrombin Reagenz	5x2 mL	5x5 mL	10x2 mL	10x5 mL
IBS Puffer	1x125 mL	1x125 mL	-	-
TECal Normal	1x1 mL	1x1 mL	-	-
TEControl A	1x1 mL	1x1 mL	-	-

Bestimmungen

Coatron M*	400 Det.	1000 Det.	800 Det.	2000 Det.
Coatron A4	200 Det.	500 Det.	400 Det.	1000 Det.
Coatron A6	200 Det.	500 Det.	400 Det.	1000 Det.

*Mikromethode (75µL insgesamt)

1. Thrombin Reagenz:
   Enthält Rinderthrombin (~80 NIH) mit Stabilisatoren.
   REF: A0501-010/A0511-020: mit 2ml hochreinem Wasser anlösen
   REF: A0501-025/A0511-050: mit 5ml hochreinem Wasser anlösen
2. IBS Puffer: gebrauchsfertig, 125ml
   Enthält gepufferte Natriumchlorid Lösung, pH 7,3-7,4
3. TECal Normal: Mit 1ml hochreinem Wasser anlösen
   Enthält mit Zitrat versetztes menschliches Plasma.
4. TEControl A: Mit 1ml hochreinem Wasser anlösen
   Enthält mit Zitrat versetztes menschliches Plasma.

Nach der Anlösung vorsichtig leicht schwenken und bei Raumtemperatur 15 Minuten stehen lassen. Vor Gebrauch gut mischen. Nicht schütteln.

Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar. **Geöffnete Reagenzien:**

Thrombin Reagenz*	2-8 °C	15-25 °C	37 °C
	12 days	5 days	24 Std
TEControl oder Plasma	2-8 °C	15-25 °C	-20 °C
	8 Std	4 Std	30 Std

* Reagenz muss vor UV-Licht und Verdunstung geschützt werden.

Vorsichtsmaßnahme

Haut- & Augenkontakt vermeiden. Abfälle gemäß lokaler Richtlinien für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös behandelt werden.

Probenentnahme und Lagerung [3]

1. Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
2. Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
3. Probe bei 1500g 10 Minuten lang zentrifugieren (Thrombozyten <10000µl)
4. Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisierten Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

Verfahren

A. Automatenmethode: Coatron A

Fibrinogen		A4		A6	
PAT	Patient	10µl	CP1	10µl	CP1
BUF	IBS Buffer	90µl	P39	90µl	P79
CLR	-	0µl	-	0µl	-
DP	-	0µl	P00	0µl	P00
R0	-	0µl	P00	0µl	P00
R1	-	0µl	P00	0µl	P00
R2	Fibrinogen	50µl	P29	50µl	P49

	A4	A6
Incubation	0s	
Maxtime	120s	
Unit	769	
Method	Coag	
Math	log XY	
CT-Mech	Yes	
Deadtime	3s	

	A4	A6
SENS	0	
POINTS	4	
MIX	No	
Clean	1	3
Multi	1	1
S-Corr	0%	
T-Corr	0%	

B. Manuelle Methode: Coatron M

1. Vorbereitung von Standard-, Kontroll- und Patientenlösungen

Standardlösung	Plasma	IBS Puffer
1:5	200µL Standard	800µL
1:10	500µL 1:5 STD	500µL
1:20	500µL 1:10 STD	500µL
1:40	500µL 1:20 STD	500µL
Patient oder Kontrolle	100µL Plasma	900µL

2. 50µl verdünntes Standard- oder Patientenplasma (1:10) in eine Küvette pipettieren. Bei 37°C für 1-2 Minuten erwärmen
3. 25µl Thrombinreagenz hinzufügen und gleichzeitig Test starten.

Wenn Sie ein anderes Gerät verwenden, lesen Sie bitte für genauere Informationen die entsprechende Geräteanleitung.

Kalibrierung

TECal Normal oder anderes kommerzielles Standardplasma, mit bekanntem Fibrinogengehalt, sollte als Referenz (200-300 mg/dl) verwendet werden. Geben Sie die Gerinnungszeit jeder FIB Standard Lösung auf der Y- Achse gegen die FIB Konzentration (mg/dl) auf der X- Achse an. Verwenden Sie Millimeterpapier. Die Reihe der besten Ergebnisse sollte durch lineare Regressionsanalyse bestimmt werden. Fibrinogen in den Plasmaproben kann durch Interpolation der Kalibrierungskurve bestimmt werden.

Erwartete Ergebnisse

Typische normale Ergebnisse sind 180-450mg/dl[4,5]. Die Ergebnisse sind jedoch von der Methode, wie die Gerinnungszeit bestimmt wird, abhängig und können von Labor zu Labor variieren. Jedem Labor wird empfohlen, seinen
eigenen normalen Ergebnisbereich auf dem verwendeten Instrument zu erstellen.

Qualitätskontrolle

TEControl oder anderes kommerzielles Kontrollplasma sollte, um eine gute Qualität sicherzustellen, in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. TEControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden.

Beschränkungen

A. Probenvorbereitung. Achten Sie auf:
1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit Antikoagulanz vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulanz und Blut vermeiden
5. Hämolytische,lipämische oder ikterische Proben können optische Systeme stören

B. Labortechniken
1. Tests bei 37°C durchführen
2. nur hochreines Wasser verwenden
3. der optimale pH Wert ist 7,0-7,5

Leistungsdaten

Präzision:	VK% (Einzellauf)	VK% (Mehrfachlauf)
Normale Kontrolle	< 5.0	< 5.0
Abnormale Kontrolle	< 5.0	< 10.0

(Typische Leistung beim Gerät Coatron M4)

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Referenzen

1. Clauss, A., Gerinnungsphysiologische Schnellmethode zur bestimmung des Fibrinogens. Acta Haematol., 1957, 17: 237-246.
2. Shaw, T.S.,Assays for Fibrinogen and its Derivatives, CRC Crit. Rev. Clin. Lab. Sci., 1977, 8: 145-192.
3. National Committee for the National Laboratory (NCCLS) Standards: Collection transport and preparation of blood specimens for coagulation testing and performance of coagulation assays. Document H21-A2, vol. 11, No. 23, 1991.
4. Scully, R.E. et al., Normal Reference Laboratory Values, N. Eng. J. Med., 1980, 302(37) : 37-48.
5. Okuno, T. and Selenko, V., Amer. J. Med. Tech., 1972, 38(6) : 196-201.

Erklärung der Symbole:

	Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern	CE	EU Konformität		Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter

Revisions-Übersicht:

Rev.	am	Änderung durch	Gültig für	Freigabe am	Freigabe durch
1	5.4.11	WG	Technoclone FIB		
	Beschreibung:	New box insert for Technoclone FIB.			
2	21.12.11	CB	Technoclone FIB	21.12.11	CH
	Beschreibung:	Neue Stabilitätsangaben. Die Vorgaben wurden dem Technoclone Stability Test Report „TC6E0C.01“ vom 5.5.2010 entnommen.			
3	11.11.13	CB	Technoclone FIB		
	Beschreibung:	- Protokoll für A4+A6 - Stabilitätsdaten neu			
4	16.10.17	AR	Technoclone FIB	16.10.17	CH
	Beschreibung:	Technoclone Puffer (A0591-090) wird ersetzt durch IBS (A0590-125) (wegen deutlicher Messunterschiede bei Coatron A und X Serie) Werteermittlung für das CoA erfolgt ebenso mit IBS (A0590-125)			
5	23.01.18	VG	Technoclone FIB	23.01.18	VG
	Beschreibung:	Neue Stabilitätsangaben von Technoclone vom Thrombin Reagent.			

IBS Buffer

CE IVD REF ***A0590-125***

Intended Use
The IBS Buffer solution is optimally formulated for use on Coagulation Analyzers. Use in accordance with the recommended Operators Manuals for installing and replacing Owrens Veronal Buffer (OVB). The IBS can be used as the diluent for preparing plasma dilutions in the performance of Fibrinogen determinations and Coagulation Factor Assays with all manual, mechanical, or photo-optical means of clot detection. Follow Reagent manufacturer's recommended procedures for preparation of plasma dilutions using Imidazole Buffered Saline.

Contents & Determinations

Product	IBS Buffer
Cat.No.	A0590-125
IBS Buffer	1x125 mL

Preparation
IBS: pH 7.3 - 7.4, liquid
Ready to use.

Storage and Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2-8°C.

Precautions
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

IBS Buffer

IVD REF *A0590-125*

Verwendungszweck

Die IBS Pufferlösung (Imidazole Buffered Saline) wird für die Verdünnung von Plasma verwendet werden, wie es z.B. bei der koagulometrischen Bestimmung von Fibrinogen, Einzelfaktoren oder auch Verdünnungsreihen für die Methoden Kalibrierung notwendig ist.

Inhalte und Bestimmungen

Produkt	IBS Puffer
Kat.Nr.	A0590-125
IBS Buffer	1x125 mL

Vorbereitung

IBS: pH 7.3 - 7.4, flüssig
Gebrauchsfertig

Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar.

Vorsichtsmaßnahmen

Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Bestandteile gemäß lokaler Vorschriften für infektiöse Materialien entsorgen.

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

	Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern	CE	EU Konformität		Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter

TEClot APTT-S

CE IVD REF **A0320-050**

Intended Use
Clotting test for quantitative determination of the Activated Partial Thromboplastin Time (APTT) in citrated human plasma using silicate as contact activator for factor XII. Intended to be used by professional laboratory personnel using coagulation analysers. The determination of the APTT is used for the global evaluation of the intrinsic pathway and detecting deficiencies of the intrinsic coagulation factors VIII, IX, XI, XII, and Fletcher Factor or other coagulation methods where an APTT reagent is required[1,2].

The APTT reagent in the kit contains phospholipids and silica to ensure a highly consistent and stable product[3]. The APTT reagent is lupus anticoagulant insensitive. Lupus anticoagulant insensitive reagents yield more reliable factor assay results than reagents, which are sensitive to lupus inhibitors[4].

Prolonged clotting times maybe observed in the following situations: deficiency of intrinsic coagulation factors, presence of heparin or other anticoagulants, which affect the intrinsic pathway and in liver diseases.

Contents

Product	TEClot aPTT-S
REF	A0320-050
aPTT-S reagent	10x5 mL
Determinations*	2000

*Micro method (75µL in total)

APTT-S reagent contains colloidal silicate with phospholipids, buffer and preservatives.

Recommended additional material (not included in package)

Auxilary reagents	A0350-050 Calcium Chloride 0.025M, 10 x 5mL
Calibration	not required
Quality Control	P6001-010 TEControl N, 10 x 1mL P6101-010 TEControl A, 10 x 1mL

Preparation
Ready to use. Swirl APTT reagent gently prior usage

Storage & Stability
Unopened reagents are stable until the expiration date shown on the label stored at 2°-8°C. Opened reagent:

	2-8 °C	20-25 °C	37 °C
APTT-S Reagent	30 days	8 days	8 hours

Precautions
The reagent contains sodium azide (less than 0.1%) to prevent microbial growth. Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material.

Specimen collection and storage[5]
1. Obtain venous blood by clean vein puncture.
2. Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
3. Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
4. Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5. Use plasma within 4 hours, otherwise store frozen and thaw just prior to use.

Stability of plasma: 4h at 18-26°C 8h at 2-8° 14d at -20°C 6m at -70°C

Procedure
A. Automated Method: Coatron A
See application book of device

B. Manual Method: Coatron X
1. Prewarm **$CaCl_2$** (0.025M) at 37°C for at least 10 min
2. Pipette **25 µl of sample** into a test cuvette. Prewarm at 37°C for 1-2 minutes.
3. Add **25 µl APTT-S reagent** and incubate exactly for **3 min** at 37°C.
4. Add **25 µl of $CaCl_2$** (0.025M) and simultaneously start test.
5. Record the clotting time in seconds.

Expected Results
Typical normal results are 27-42 sec. However results are influenced by the method of clot detection and can vary from laboratory to laboratory. Each laboratory is recommended to establish its own normal range on the specific instrument used.

Quality Control
TEControl or other commercial control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). TEControl can be frozen one time after reconstitution. 120-150 µl stored in closed polypropylen tubes at -20°C is stable for 30 days

Limitations
A. Specimen Collection. AVOID:
1. Use only plastic tubes or siliconised glass.
2. Delayed mixing of blood with anticoagulant.
3. Contamination with tissue thromboplastin.
4. Improper ratio of anticoagulant with blood.
5. Hemolyzed, icteric or lipemic samples may interfere optical systems

B. Laboratory Techniques
1. Perform tests at 37°C.
2. Use only high purity water.
3. Optimum pH is 7.0-7.5.

C. Interfering substances
1. Bilirubin 40mg/dL
2. Haemoglobin 1000 mg/dL

Performance Characteristics
Typical performance on instrument Coatron X

Precision:	CV% (within run)	CV% (inter-runs)
QC control	< 3,0	< 5,0

Factor & Heparin sensitivity:

	APTT Clotting time (s)		
Factor (%)	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT clotting time (s)	35	70	180

These values should be used as guidelines only. Each laboratory should establish factor or heparin sensitivity using its own instruments and techniques.

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

References

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol 36, 212-219 (1961).*
2. Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol 70, 556-569 (1978).*
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost 55, 250-258 (1986).*
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis 25, 98-105 (1995).*
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Symbols key:

	Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
	Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1 - 84088 Neufahrn i.NB - Germany

TEClot APTT-S

CE | IVD | REF A0320-050

Verwendungszweck

Dieses Produkt ist bestimmt für die quantitative Bestimmung der aktivierten partiellen Thromboplastinzeit (APTT) in humanen Citratplasma mit Hilfe von Silikat als Kontaktaktivator für Faktor XII. Die Anwendung ist bestimmt für medizinisches Fachpersonal und benötigt einen Gerinnungsanalyser.

Die Bestimmung der APTT dient der globalen Auswertung des intrinsischen Gerinnungssystems, sowohl zum Nachweis von Mängeln bei den intrinsischen Koagulationsfaktoren VIII, IX, XI, XII und Fletcher Faktor oder anderer Koagulationsmethoden, bei denen ein APTT - Reagenz benötigt wird.[1,2]

Das APTT Reagenz in diesem Kit enthält Phospholipide und Silizium, um ein sehr widerstandsfähiges und stabiles Produkt zu gewährleisten[3]. Das Reagenz reagiert nicht auf Lupus Antikoagulanz und liefert daher verlässlichere Ergebnisse bei Faktorbestimmungen[4]. Verlängerte Gerinnungszeiten können bei den folgenden Situationen beobachtet werden: Mangel an intrinsischen Koagulationsfaktoren, Vorhandensein von Heparin oder andere Antikoagulantien, die das intrinsische System beeinflussen und bei Lebererkrankungen.

Inhalt

Produkt	TEClot aPTT-S
REF	A0320-050
aPTT-S Reagenz	10x5 mL
Bestimmungen*	2000

*Micro Methode (75µL insgesamt)

Das APTT-S Reagenz enthält kolloidales Silikat mit Phospholipiden, Puffer und Konservierungsstoffe.

Zusätzlich notwendige Reagenzien (nicht in der Packung vorhanden)

Hilfsreagenzien	A0350-050 Calcium Chloride 0.025M, 10 x 5mL
Kalibration	Nicht notwendig
Qualitätskontrolle	P6001-010 TEControl N, 10 x 1mL P6101-010 TEControl A, 10 x 1mL

Vorbereitung

Das Reagenz ist gebrauchsfertig und muss vor dem Gebrauch leicht aufgemischt werden.

Lagerung und Stabilität

Ungeöffnete Reagenzien sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum stabil. Geöffnetes Reagenz:

	2-8 °C	20-25 °C	37°C
APTT-S Reagenz	30 Tage	8 Tage	8 Stunden

Vorsichtsmaßnahmen

Das Reagenz beinhaltet Natriumazid (< 0.1%). Augen und Hautkontakt vermeiden. Geeignete Schutzkleidung tragen. Abfall gemäß lokaler Bestimmungen für infektiöse Materialien entsorgen.

Probenentnahme und Lagerung [5]

1. Venöses Blut mittels Venenpunktur unter sauberen Bedingungen entnehmen.
2. Sofort 9 Teile Blut mit einem Teil 3,2% Natriumzitrat (0,105M) gut mischen.
3. Probe bei 1500g 10Minuten lang zentrifugieren (Thrombozyten <10000µl)
4. Plasma nach der Zentrifugierung entfernen und in einem Röhrchen aus Plastik oder silikonisierten Glas aufbewahren.
5. Plasma innerhalb von 4 Stunden verwenden, andernfalls gefroren lagern und kurz vor Gebrauch auftauen.

Stabilität von Plasma: 4h bei 18-26°C 8h bei 2-8° 14d bei -20°C 6m bei -70°C

Verfahren

A. Automatenmethode: Coatron A
Siehe Applikationsbuch des Gerätes

B. Manuelle Methode: Coatron X

1. Kalciumchlorid (0,025M) mind. 10 Minuten lang bei 37°C erwärmen.
2. **25µl Probe** in eine Küvette pipettieren. Bei 37°C für 1-2 min vorwärmen.
3. **25µl APTT-S** Reagenz hinzufügen und für genau **3 min bei 37°C inkubieren**
4. **25µl $CaCl_2$** (0,025M) hinzufügen und gleichzeitig Test starten.
5. Gerinnungszeit in Sekunden notieren.

Erwartete Ergebnisse

Typische normale Ergebnisse liegen bei 27-42 Sekunden. Jedoch sind die Ergebnisse von der verwendeten Methode der Gerinnungsbestimmung abhängig und können in verschiedenen Labors unterschiedlich ausfallen. Jedem Labor wird empfohlen, eine eigene Ergebnisreihe und den Normalbereich mit dem verwendeten Gerät zu erstellen.

Qualitätskontrolle

TEControl oder anderes kommerzielles Kontrollplasma sollte in regelmäßigen Abständen entsprechend Laborrichtlinien gemessen werden. TEControl kann einmalig wieder eingefroren werden. Hierfür 120-150µL in einem verschließbaren polypropylen Gefäß bei -20°C aufbewahren und innerhalb der nächsten 30 Tage verwenden.

Vorschriften

A. Probenvorbereitung. Achten Sie auf:
1. nur Plastikröhrchen oder silikonisiertes Glas verwenden
2. verzögertes Mischen von Blut mit Antikoagulanz vermeiden
3. Kontaminierung mit Gewebethromboplastin vermeiden
4. falsches Verhältnis von Antikoagulanz und Blut vermeiden
5. Hämolytische,lipämische oder ikterische Proben können optische Systeme stören

B. Labortechniken
1. Tests bei 37°C durchführen
2. nur hochreines Wasser verwenden
3. der optimale pH Wert ist 7,0-7,5

C. Interferenzen
1. Bilirubin: kein Effekt unter 40mg/dL
2. Hämoglobin: kein Effekt unter 1000mg/dL

Leistungsdaten

Typische Leistungsdaten beim Gerät Coatron X

Präzision:	VK% (Einzellauf)	CV% (Mehrfachlauf)
QC control	< 3,0	< 5,0

Faktor & Heparin Empfindlichkeit:

	APTT Gerinnungszeit (s)		
Faktor (%)	F VIII	F IX	F XI
< 1%	100	80	103
10%	53	52	58
40%	40	39	41
100%	35	35	358

Heparin (U/mL)	0 U/mL	0,2 U/mL	0,4 U/mL
APTT Gerinnungszeit	35	70	180

Diese Werte sollen nur als Richtlinien verwendet werden. Jedes Labor sollte mit eigenen Instrumenten und Techniken Sensitivitätswerte erstellen.

Garantie

Es wird garantiert, dass die Wirkungsweise dieses Produktes den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Referenzen

1. Proctor RR, Rapaport SI. The partial thromboplastin time with kaolin. A simple screening test for first stage plasma clotting factor deficiencies. *Am J Clin Pathol 36, 212-219 (1961).*
2. Triplett DA, Harms CS, Koepke JA. The effect of heparin on the activated partial thromboplastin time. *Am J Clin Pathol 70, 556-569 (1978).*
3. Stevenson KJ, Easton AC, Thomson JM, Poller L. The reliability of activated partial thromboplastin time methods and the relationship to lipid composition and ultrastructure. *Thromb Haemost 55, 250-258 (1986).*
4. Denis-Magdelaine A, Flahault A, Verdy E. Sensitivity of sixteen APTT reagents for the presence of lupus anticoagulants. *Haemostasis 25, 98-105 (1995).*
5. NCCLS: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays

Erklärung der Symbole:

Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer	Begleitpapiere beachten

TECO Medical Instruments Production + Trading GmbH, Dieselstr. 1 - 84088 Neufahrn i.NB - Germany

TEControl N

CE IVD REF **P6001-010**

Intended Use
Use as a normal control for following coagulation tests:

PT, APTT, Thrombintime, Fibrinogen, Antithrombin and D-Dimer

Contents
10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation
Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability
Unopened vials are stable until the expiration date shown on the label stored at 2°-8°C.

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions
This product contains substance from human origin!
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Expected Results
Refer to "Certificate of Analysis".

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date		IVD	In Vitro Diagnostica		Biological hazard		REF	Catalogue Number	Consult accompanying documents
Store at 2-8°C		CE	EU conformity		Manufacturer		LOT	Lot. Number	EC REP	Authorized Representative

TECO Medical Instruents Production + Trading GmbH, Dieselstr. 1, 84088 Neufahrn i.NB Germany

TEControl N

CE IVD REF P6001-010

Verwendungszweck
Als normale Kontrolle für folgende Gerinnungstests verwenden:

PT, APTT, Thrombinzeit , Fibrinogen, Antithrombin und D-Dimer

Inhalt
10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung
Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität
Ungeöffnete Fläschchen sind bei Lagerung zwischen 2-8°C zum bis auf dem Etikett angegebenen Verfallsdatum haltbar.

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C
1 Monat	8 Stunden	4 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen
Dieses Produkt enthält Substanzen humanen Ursprungs!
Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

Garantie
Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

	Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern	CE	EU Konformität		Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter

TEControl A

CE IVD REF P6101-010

Intended Use
Use as an abnormal control for following coagulation tests:

PT, APTT, Thrombintime, Fibrinogen, Antithrombin and D-Dimer

Contents
10 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation
Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability
Unopened vials are stable until the expiration date shown on the label stored at 2°-8°C.

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C
1 month	8 hours	4 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions
This product contains substance from human origin!
Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Expected Results
Refer to "Certificate of Analysis".

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

TEControl A

CE IVD REF P6101-010

Verwendungszweck
Als abnormale Kontrolle für folgende Gerinnungstests verwenden:

PT, APTT, Thrombinzeit, Fibrinogen,
Antithrombin und D-Dimer

Inhalt
10 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung
Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität
Ungeöffnete Fläschchen sind bei Lagerung zwischen 2-8°C zum bis auf dem Etikett angegebenen Verfallsdatum haltbar.

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C
1 Monat	8 Stunden	4 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen
Dieses Produkt enthält Substanzen humanen Ursprungs!
Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

Garantie
Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

	Verfallsdatum	IVD	In-Vitro Diagnostik		Biologische Gefahr	REF	Katalog-Nummer		Begleitpapiere beachten
	Bei 2-8°C lagern	CE	EU Konformität		Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter

TECal N

IVD | REF P8001-005

Intended Use
Use as a calibrator or normal control for following coagulation tests:

PT, APTT, Thrombintime, Fibrinogen,
Factors: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, free Protein-S,
D-Dimer

Contents
5 x 1mL freeze dried citrate-anticoagulated human plasma

Preparation
Reconstitute individual vials with **1,0 ml** distilled water. Allow to stand at room temperature, with occasional swirling, for 15 min before use. Be certain all particulate matter is well dissolved.

PT whole blood (TEClot PT-B CAT=A0260 xxx): Reconstitute individual vials with **1,7 ml** distilled water.

Storage & Stability
Unopened vials are stable until the expiration date shown on the label stored at 2°-8°C.

Dissolved plasma change analytic levels below 10% if stored as following:

-20 °C	2-8 °C	20-25 °C	37°C
30 days	24h	8h	2 hours

Dissolved plasma can be refrozen only one time in aliquots (120-150µL). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

Precautions: Potential Biohazardous material
This product contains substance from human origin! Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV and HCV. However products from human blood should be considered as potentially infectious.

Performance Characteristics:
Refer to "Certificate of Analysis".

Limitations:
The control plasma is subject to the limitations of the assay system (reagent + instrument). Results out of expected range may indicate deterioration, false test calibration or problems with one or more components of the test system

Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Symbols key:

Expiry date	IVD	In Vitro Diagnostica		Biological hazard	REF	Catalogue Number		Consult accompanying documents
Store at 2-8°C	CE	EU conformity		Manufacturer	LOT	Lot. Number	EC REP	Authorized Representative

TECal N

CE | IVD | REF P8001-005

Verwendungszweck
Als Kalibrator oder Normalkontrolle für folgende Gerinnungstests verwenden:

PT, APTT, Thrombinzeit, Fibrinogen,
Faktoren: II, V, VII, VIII, IX, X, XI, XII,
Antithrombin, Protein-C, freies Protein-S,
D-Dimer

Inhalt
5 x 1mL gefriergetrocknetes mit Zitrat versetztes gerinnungshemmendes Humanplasma

Vorbereitung
Die einzelnen Fläschchen mit 1,0ml destilliertem Wasser anlösen. Fläschchen bei Raumtemperatur bis zur Anwendung unter gelegentlichen Verwirbeln 15 Minuten lang stehen lassen. Stellen Sie sicher, dass alle Partikel gut aufgelöst sind.

Vollblut PT (TEClot PT-B CAT=A0260 xxx): einzelne Fläschchen mit 1,7ml destilliertem Wasser anlösen.

Lagerung und Stabilität
Ungeöffnete Fläschchen sind bei Lagerung zwischen 2-8°C zum bis auf dem Etikett angegebenen Verfallsdatum haltbar.

Gelöstes Plasma verändern die analytischen Levels unter 10% wenn wie folgt gelagert:

-20 °C	2-8 °C	20-25 °C	37°C
30 Tage	24 Stunden	8 Stunden	2 Stunden

Gelöstes Plasma kann einmalig wiedereingefroren werden. Die Aliquots (120-150µL) sind 30 Tage haltbar, wenn sie in polypropylen Gefäßen bei -20°C aufbewahrt werden.

Vorsichtsmaßnahmen: Potentiell infektiöses Material
Dieses Produkt enthält Substanzen humanen Ursprungs!
Haut- und Augenkontakt vermeiden. Angemessene Schutzkleidung tragen. Abfälle laut lokaler Regelungen für infektiöse Materialien entsorgen. Alle Bestandteile wurden auf HIV, HBV und HCV getestet. Trotzdem müssen Produkte aus menschlichem Blut immer als potentiell infektiös angesehen werden.

Erwartete Ergebnisse
Lesen Sie das Analysenzertifikat

Einschränkungen:
Das Kontrollplasma unterliegt den Einschränkungen der verwendeten Reagenzien und Geräte. Ergebnisse außerhalb des Sollbereichs können verursacht werden durch abgelaufene Materiale, ungültige Methodenkalibration oder Problemen an Reagenz, Gerät oder Zubehör.

Garantie
Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden, expliziten Garantie ergeben.

Erklärung der Symbole:

Verfallsdatum	IVD	In-Vitro Diagnostik	Biologische Gefahr	REF	Katalog-Nummer	Begleitpapiere beachten
Bei 2-8°C lagern	CE	EU Konformität	Hersteller	LOT	Lot. – Nummer	EC REP	Bevollmächtigter