TECO
MEDICAL INSTRUMENTS
PRODUCTION+TRADING GMBH
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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

Current issue date: 10 November 2022
Expiry date: 9 November 2025
Certificate identity number: 10479697

Original approval(s):
ISO 13485 - 10 November 2022

Certificate of Approval

This is to certify that the Management System of:

TECO Medical Instruments, Production + Trading GmbH

Dieselstr. 1, 84088 Neufahrn, Germany

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00038268

The scope of this approval is applicable to:

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

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA Limited

UKAS MANAGEMENT SYSTEMS 0001

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#008/02-2023

Hersteller / Manufacturer: **TECO Medical Instruments Production and Trading GmbH**

Anschrift / Address: **Dieselstrasse 1, 84088 Neufahrn, Germany**

Marktakteur / Actor ID SRN: **DE-MF-000022642** https://ec.europa.eu

Das hier benannte Produkte ist der generischen Produktgruppe Coatron® A zugehörig und erfüllt 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 426018278CAX809Z8 EMDN: W0202020102

IVD - automatisches Blutgerinnungsmessgerät - Handelsbezeichnung, Typ/Modell, Katalog-Nr., UDI-DI
IVD - automated Coagulometers - trade name, type/model, Catalog-No., UDI-DI

Coatron A6 80 920 00 UDI-DI 04260182780954

The mentioned product as part of the generic product group Coatron® A - Series 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 2023-02-03:

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 14971:2021
EN ISO 18113-3:2013
EN ISO 15223-1:2021
DIN EN 61326-1:2013
DIN EN 61326-2-6:2013
DIN EN 61000-3-2:2014
DIN EN 61000-3-3:2013
DIN EN 61000-4:2010
DIN EN 55011:2010
IEC 61010-1:2010
IEC 61010-2-101:2015
IEC 61010-1:2010
ISO/TR 20416
Richtlinie 2011/65/EU RoHS III
(incl. (EU) 2015/863) - DIN EN IEC 63000:2018

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 2023-02-03:

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 14971:2021
EN ISO 18113-3:2013
EN ISO 15223-1:2021
DIN EN 61326-1:2013
DIN EN 61326-2-6:2013
DIN EN 61000-3-2:2014
DIN EN 61000-3-3:2013
DIN EN 61000-4:2010
DIN EN 55011:2010
IEC 61010-1:2010
IEC 61010-2-101:2015
IEC 61010-1:2010
ISO/TR 20416
Directive 2011/65/EU RoHS III
(incl. (EU) 2015/863 - DIN EN IEC 63000:2018

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

Ort, Datum der Unterzeichnung:
Place and date of issue: Neufahrn, 2023-02-03

Gültigkeitsende:
Validity end Date: 2028-05-25

Matthias Dieckmann
General Manager

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

Certificate -Bescheinigung

TECO
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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

TECO

CE

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

Doc#200/12-2023

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 – 24 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 /- 24 IVD) 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: Neufahrn, 2023-12-20
Place and date of issue:

Medical Instruments TECO Production+Trading GmbH

Christian Hötzl
Verantwortliche Person / PRRC

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Doc#200/12-2023

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	A0230-010	TEClot PT-S (Quick)	5x2ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-010WW
2	A0230-040	TEClot PT-S (Quick)	10x4ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-040X7
3	A0230-100	TEClot PT-S (Quick)	10x10ml	Prothrombin time (quick test)	W0103020101 / 30539 B-PTS-A0230-100WY
4	A0260-050	TEClot PT-B (Owren)	5x10ml	Prothrombin time RT & POC	W0103020801 / 55986 B-PTB-A0260-050G2
5	A0320-050	TEClot APTT-S	10x5ml	Activated partial thromboplastin time	W0103020102 / 55982 B-APTTS-A0320-050AM
6	A0401-020	TEClot TT	10x2ml	Thrombin time / reptilase / batroxbin time	W0103020103 / 55988 B-TT-A0401-0207P
7	A0511-020	TEClot FIB	10x2ml	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-020N2
8	A0511-050	TEClot FIB	10x5ml	Fibrinogen assays (factor i)	W0103020201 / 55997 B-FIB-A0511-050NB
9	C1010-020	TEChrom AT	6x6ml reagent FXa 3x3 ml substrate	Antithrombin	W0103020602 / 56156 B-AT-C1010-020HL
10	D2010-012	Red D-Dimer	3x4ml latex 3x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2010-0126W
11	D2020-005	Blue D-Dimer LC	1x5ml latex LC 1x7ml reaction buffer	D-Dimer	W0103020503 / 47349 B-DD-D2020-0057E
12	P8001-005	TECal N	5x1ml	Calibration plasma for haemostasis	W0103020701 / 45786 B-CAL-P8001-005X8
13	P8200-005	TECal DD	5x1ml	Calibration plasma for haemostasis	W0103020701 / 47348 B-CAL-P8200-005XX
14	P6001-010	TEControl N	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6001-010H7
15	P6101-010	TEControl A	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6101-010HQ
16	P6201-010	TEControl A Plus	10x1ml	Control plasma for haemostasis	W0103020702 / 30590 B-CTRL-P6201-010J9
17	P5001-010	TEClot Factor II	10x1ml	Coagulation factor ii (prothrombin)	W0103020202 / 30542 B-FAC-II-P5001-010ML
18	P5101-010	TEClot Factor V	10x1ml	Coagulation factor v	W0103020204 / 30544 B-FAC-V-P5101-010AN
19	P5201-010	TEClot Factor VII	10x1ml	Coagulation factor vii	W0103020205 / 30545 B-FAC-VII-P5201-0107B
20	P5301-010	TEClot Factor VIII	10x1ml	Coagulation factor viii	W0103020207 / 30547 B-FAC-VIII-P5301-01097
21	P5401-010	TEClot Factor IX	10x1ml	Coagulation factor ix	W0103020208 / 30548 B-FAC-IX-P5401-0106C
22	P5501-010	TEClot Factor X	10x1ml	Coagulation factor x	W0103020209 / 30549 B-FAC-X-P5501-010EQ
23	P5601-010	TEClot Factor XI	10x1ml	Coagulation factor xi	W0103020210 / 30551 B-FAC-XI-P5601-010A8
24	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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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

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		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

TEClot FIB

CE 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

CE 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

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

21 500 01 / 21 500 00 / 21 500 09
Rinse Solution / Clean B

Information of Use
This solution is a general laboratory article for a wide range of uses in laboratories. It is also suitable for use in in vitro diagnostic tests.

The Solution is ready for use.
It can be applied with fully automated Coagulation analyser systems to operate the pump system.

The Solution in unopened tanks should not be applied to Coagulation Analysers beyond the expiry date indicated on the label. Avoid freezing, optimal storage temperature is (18 to 25°C). Opened tanks should be consumed within max. 3 years.

Units / consumption

Cat.No.	21 500 01	21 500 00	21 500 09
Content	1 x 1,25 L	3 x 1,25 L	9 x 1,25 L

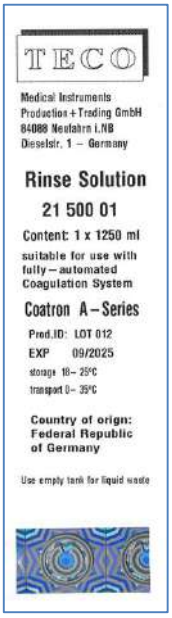
Precautions and Waste information
The Solution should be used once only.
Ingredients: Laboratory water pH 7.0 (± 1,0 at 37 °C ± 1 °C)
Collected used solution should be disposed as prescribed in local regulations. No further precautions.

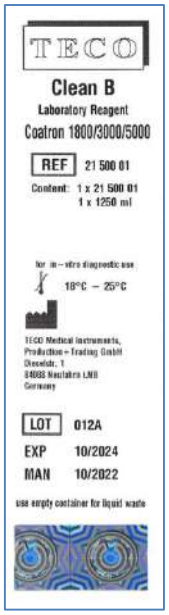
Warranty
This product is warranted to perform in accordance with its labelling and literature. TECO disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will TECO be liable for any consequential damages arising out of aforesaid express warranty.

Packaging Material, Dim.
Carton (3): (mm) L310 x W250 x H140
Carton (9): (mm) L310 x W250 x H330
PP (Tank): (mm) L110 x W300 x H80
Tank with Screwcap (PP) with inner PE Foil.
Tank additionally sealed with aluminium Foil.

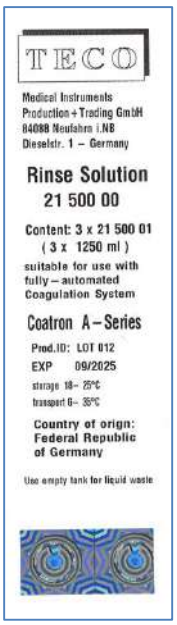
Product picture (exemplary)

Placement of Label





Label Artwork (with Hologram)



outer Packaging:

21 500 01 / 21 500 00 / 21 500 09
Rinse Solution / Clean B

Gebrauchsinformation
Die Lösung als allgemeiner Laborartikel für ein breites Spektrum von Anwendungen in Laboratorien eignet sich auch für den Einsatz bei in-vitro-diagnostischen Tests.

Die Lösung ist gebrauchsfertig. Sie kann mit voll-automatischen Gerinnungsanalysesystemen zum Betrieb des Pumpensystems verwendet werden.

Spüllösung in ungeöffneten Behältern sollte nach Ablauf des auf dem Etikett angegebenen Verfalls-datums nicht mehr in Gerinnungsanalysegeräten verwendet werden. Die Lagertemperatur sollte
(~18-25°C) betragen. Geöffnete Tanks sollten innerhalb von max. 3 Jahren verwendet werden.

Verkaufseinheiten

Kat.No.	21 500 01	21 500 00	21 500 09
Inhalt	1 x 1,25 L	3 x 1,25 L	9 x 1,25 L

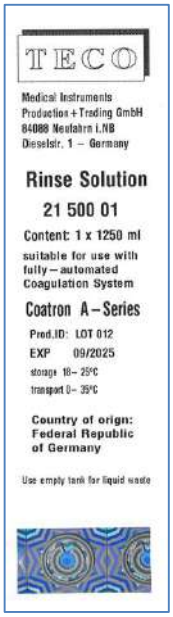
Vorsichtsmassnahmen und Entsorgungshinweise
Die Lösung sollte nur einmal verwendet werden.
Bestandteile: Laborwasser pH 7,0 (± 1,0 bei 37 °C ± 1 °C)
Aufgefangene gebrauchte Lösung sollte gemäß den örtlichen Vorschriften entsorgt werden. Keine weiteren Vorsichtsmaßnahmen.

Gewährleistung
Für dieses Produkt wird garantiert, dass es in Übereinstimmung mit den Angaben auf dem Etikett und in der Literatur funktioniert. TECO lehnt jede stillschweigende Garantie für die Marktgängigkeit oder die Eignung für einen anderen Zweck ab, und TECO haftet in keinem Fall für Folgeschäden, die sich aus der oben genannten ausdrücklichen Garantie ergeben.

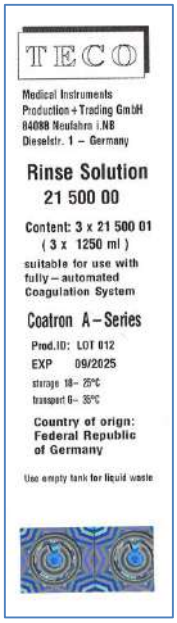
Verpackung
Karton (3): (mm) L310 x W250 x H140
Karton (9): (mm) L310 x W250 x H330
Tank (PP): (mm) L110 x W300 x H80
Tank mit Schraubdeckel PP Schaumfolie innen PE.
Tank zusätzlich versiegelt mit Aluminiumfolie

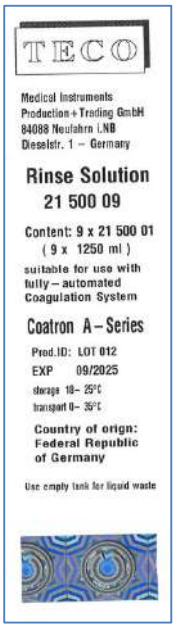
Produktbilder (exemplarisch)

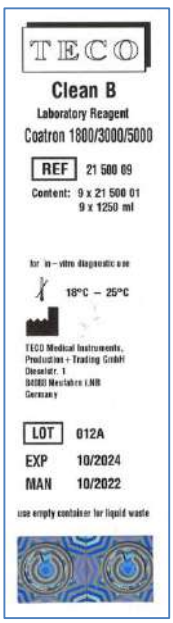
Platzierung



Label Layout (mit Hologramm)







Umverpackung

21 510 00
Clean Solution / Clean A

Information of Use
The Clean Solution (Clean A) is intended as a general laboratory article for a wide range of uses in laboratories. It is also suitable for use in automatically coagulation analysers which are used for in vitro diagnostics tests.

TECO recommend it to remove any residues from needle probe on following TECO instruments: **Coatron A4, Coatron A6, Coatron A6 Plus: Coatron 1800 / 3000 / 5000.**

Contents & Composition

Product	Clean Solution (Clean A)
Cat.No.	21 510 00
Content	1 x 500 ml

Ingredients: 99,6% acidic solution (pH 1.1±0.5) with detergent (slight foaming); generally no hazardous to water.

Preparation and waste information
Ready to use. The solution should be used once only.

Storage and
Avoid freezing, best storage temperature (~18 – 25°C)

Stability
See individual Expiry date on each box.

Precautions
General laboratory safety measures for use of chemical solutions. Avoid direct contact with eyes and skin.

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.

Product picture (example)

Clean Solution
(both with Hologram)

Clean A

Outer Package
no specific outer package of single unit
Shipping within total packaging

Safety data sheet: sds-id.com/100202-6

Symbols key (if applicable):

Temperature	Manufacturer	LOT	LOT Number	REF	Catalogue Number

80 560 00 Cuvette block, (6pos/ea)

Information of use

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

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

Content

Product	Cuvette block	1000 pcs
Cat.No.	80 560 00	
Content	50 bundles (=20 blocks 6 pcs.)	6000 det.

The Cuvettes can be used with Coatron A6 (3000) Analyzer.

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

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

Precautions and waste information

The Cuvette should only be used once in analyzers. To prevent contamination (sample/reagent), it is advised to avoid contact with skin and eyes. Suitable protective clothing and gloves are recommended. Please also note the disposal of components in accordance with local regulations for infectious material.

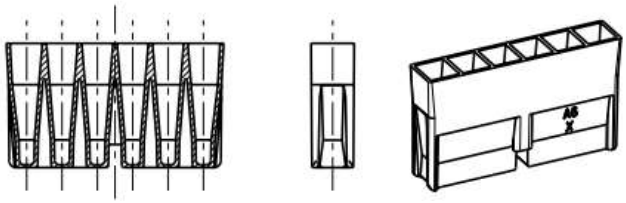
Material: pure, clear Polystyrol (PS)

Maximum volume per Single use Unit should be

less than ~ 1000µL

Minimum volume: 75 µL

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

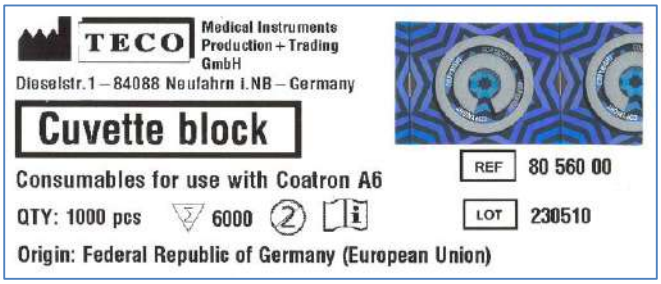


80 560 00

Example Picture of the package – 1000 Cuvettes blocks

Packaging:

1. Card Box, Dim.: (mm) 400 x 250 x 155
2. Labeling (see below)



Symbols key (if applicable):

Manufacturer	LOT Lot. Number	REF Catalogue Number	Consult accompanying documents	Determination	Single use

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

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

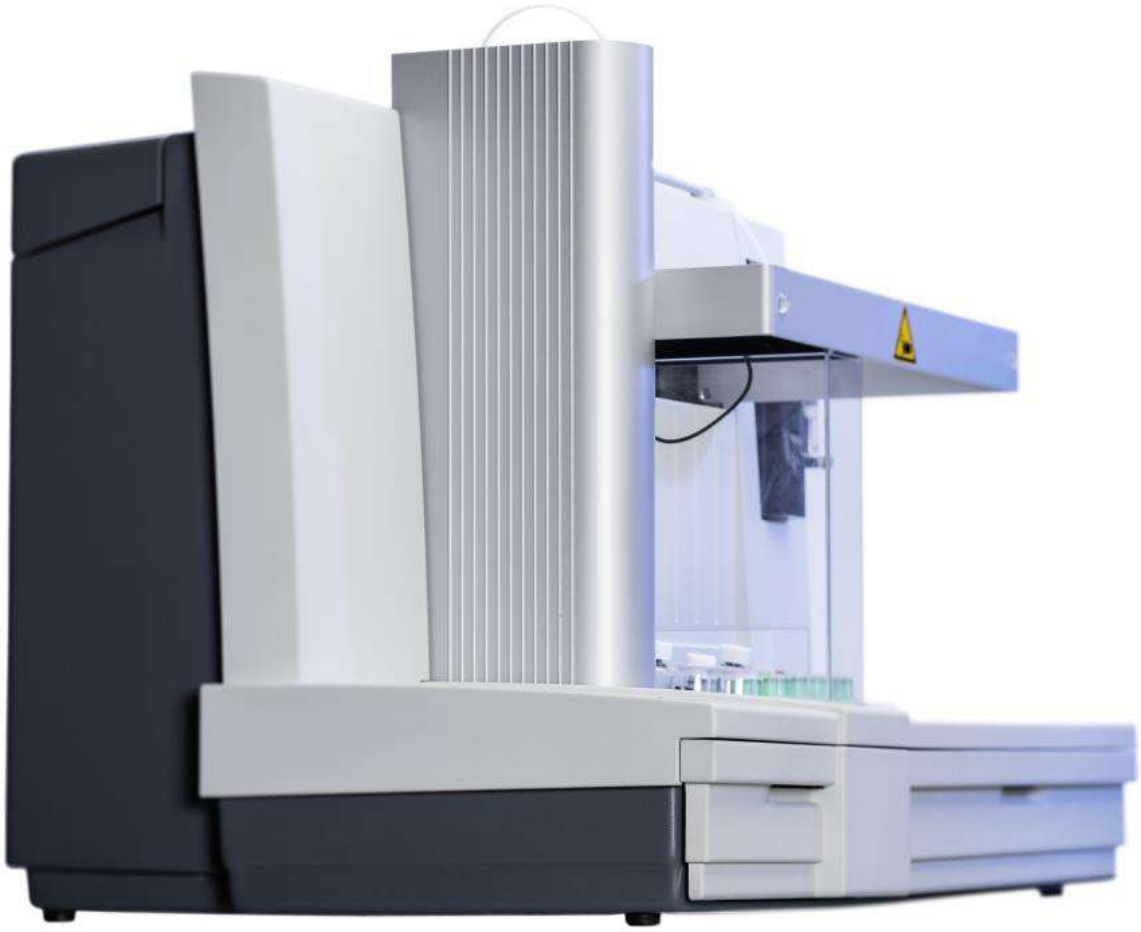
Garantie
Es wird garantiert, dass die Wirkungsweise dieses Produkts den Angaben auf der Packung und in der Produktliteratur entspricht. TECO haftet weder für die Verkäuflichkeit oder Eignung dieses Produktes für irgendwelche andere Zwecke noch für irgendwelche Folgeschäden, die sich aus der vorstehenden,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

Coatron A6

Operator's Manual



Teco Medical Instruments, Production + Trading GmbH
Operation Manual, Revision 10
Issued: Oct 2015
Document No:21 450 01

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Operator's Manual Version	Software Version	Date
6	1.02.06	2/2013
7	1.02.07	6/2013
8	1.03.01SW3	6/2014
9	1.03.01SW4	12/2014
10	1.03.02a	10/2015

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Trademarks

COATRON A6 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

Warranty

The Coatron A6 is warranted for a period of one year after first installation. It covers any defects in material, functionality or workmanship (see also the “General terms and conditions”)

The warranty expires in case of failures caused by

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

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1. INTRODUCTION

This device left the factory in fault-free condition regarding its safety and engineering functionality. To maintain this condition and ensure risk-free operation, the operator must comply with the safety warnings and information in this Operator's Manual.

> ***Use the COATRON A6 only in compliance with the instructions in this Operator's Manual. Otherwise the manufacture shall exclude the liability for any damages to the COATRON A6, patients or operators.***

1.1 SYMBOLS

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
Courier	**Info**	Key on keypad.
CAPS	**Info**	Screen message.
	Read	Indicates important information and tips.
	Info	Describes reaction of COATRON A6 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 A6** 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 50mg/dL Bilirubin (856µmol/l)
Do not use plasma with more than 2000mg/L Hemoglobin
Do not use plasma with more than 50 g/l Triglceride (57 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 A6.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 “9 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

1.2.7 EMC CONFORMITY

Coatron A6 complies with the requirements of emission and immunity, pursuant to GB/T 18268.1 (IEC 61326-1) and GB/T 18268.26 (IEC61326-2-6).

Coatron A6 has been designed, tested and found to comply with Class A device, pursuant to GB 4824 (IEC 61000-4). In domestic environment, this device may cause radio interference, in which case the user is required to take adequate measures.

Detecting electromagnetic environment is recommended before using this device.

To avoid operating this device nearby strong radiation source (for example, non-shielded RF source), which may interfere with the device working correctly.

1.3 LABORATORY REQUIREMENT

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

1.4 UNPACKING THE COATRON A6

Following receipt of the shipment, please inspect the packaging of the COATRON A6 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 A6 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

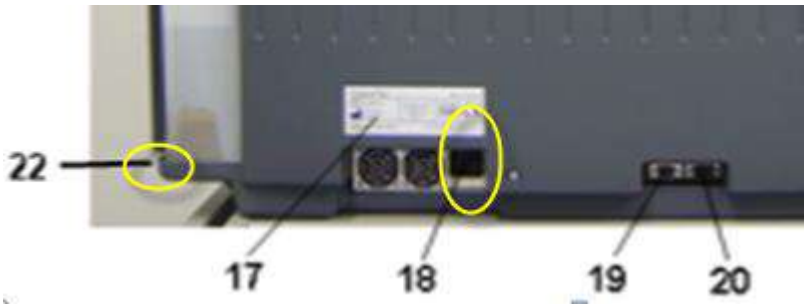
1.5 REMOVAL OF THE TRANSPORT RETAINER ELEMENTS

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

1.6 SWITCHING ON AND OFF THE COATRON A6

Switching on

1. Make sure the instrument 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



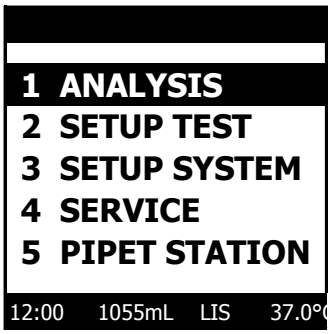
LOCATION OF POWER AND STANDYBY SWITCHMAIN SCREEN

The following screen appear in this order after the COATRON A6 is switched on.

Coatron A6	Name of instrument
V1.03.02	Version of firmware
SN-12345	Serialnumber
Service: 100000	Tests until next service
CUVETTES:1	Activated cuvettes
CLEAN-B: 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.

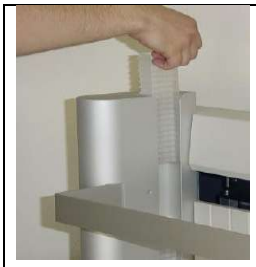
Switching off:

For normal shutdown at the end of the day and for changing the pipetting needle, rinsing solution tank and syringe, switch off the instrument with the standby switch on the right side of the housing. This will shut off all power-consuming components except of 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

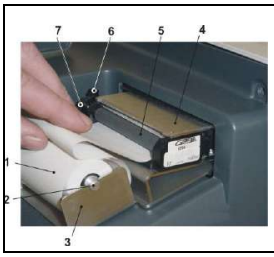
Never switch off the system while processing a worklist to avoid clogging the needle tip with coagulation residues.

1.7 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. Activate cuvettes by barcode if required

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



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

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

1.8 INSTALLATION OF TECAM SOFTWARE

TECAM software is a powerful enhancement of the Coatron A6 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
- 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:

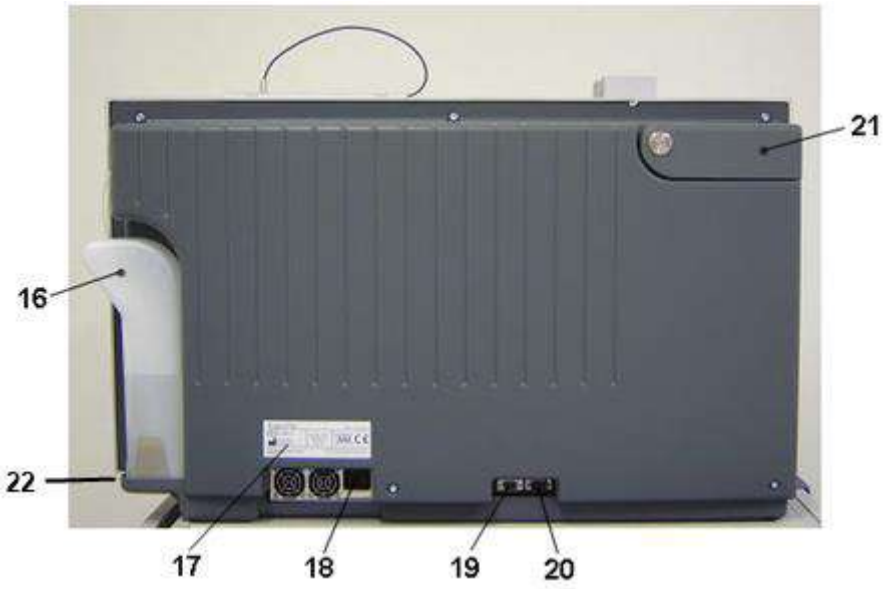
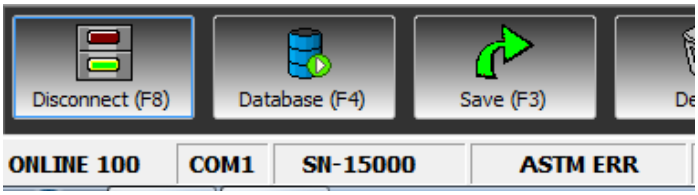


Figure 2: COATRON A6, rear view

1. Link instrument left RS232 port (location #19) to PC
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

2. DESCRIPTION OF THE COATRON A6

2.1 SHORT INTRODUCTION

The COATRON A6 is a fully automated laboratory analyzer for the fast and flexible coagulation diagnostic. It is equipped with six 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. 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

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) + free Proteion S (PSF)
- Lupus Anticoagulant (LA)
- Activated protein C resistance (APCR)
- Heparin (chromogenic)
- ATIII (chromogenic)
- D-dimers (immunoturbidimetric)
- Further tests on demand

2.2 VIEWS OF THE DEVICE

2.2.1 FRONT VIEW

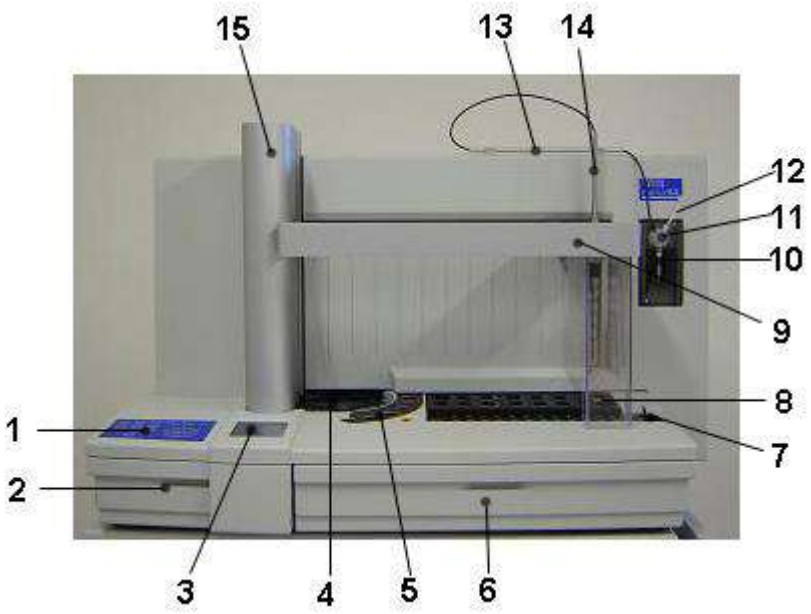


FIGURE 1: COATRON A6, FRONT VIEW

1	Keyboard
2	Cuvette waste drawer
3	Screen
4	Cuvette rotor
5	System block
6	Rinse solution waste drawer
7	Barcode ID Scanner and 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

*

2.2.2 REAR VIEW

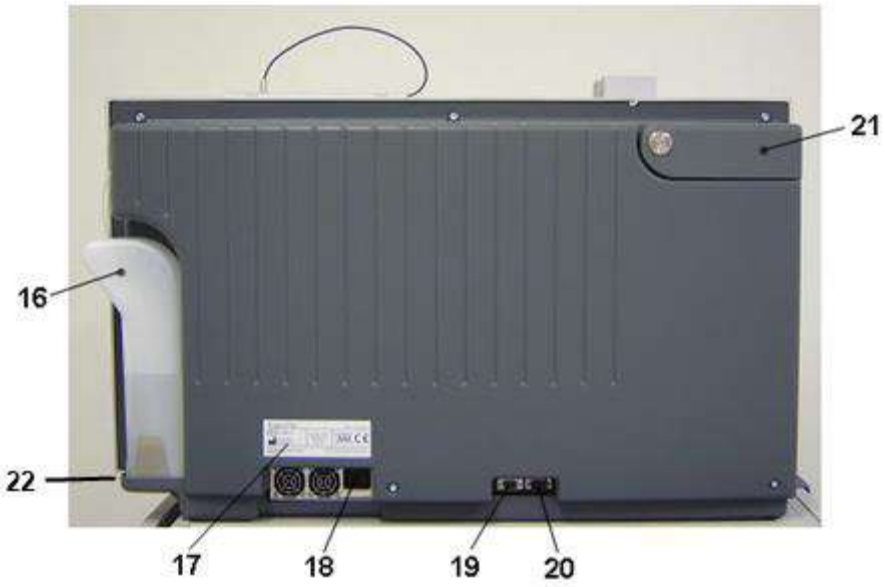


FIGURE 2: COATRON A6, REAR VIEW

16 Rinsing solution tank
17 Type plate
18 Power Main Switch
19 Comm1 (115200 baud, 8,1,N) for TECAM LIS software or firmware update (115K, 8,1,N)
20 Comm2 (115200 baud, 8, 1, N) for direct connection to third party LIS. Software solutions. Every result is automatically sent over this port. (reserved for manufacturer).
21 Printer cover
22 Power Standby Switch

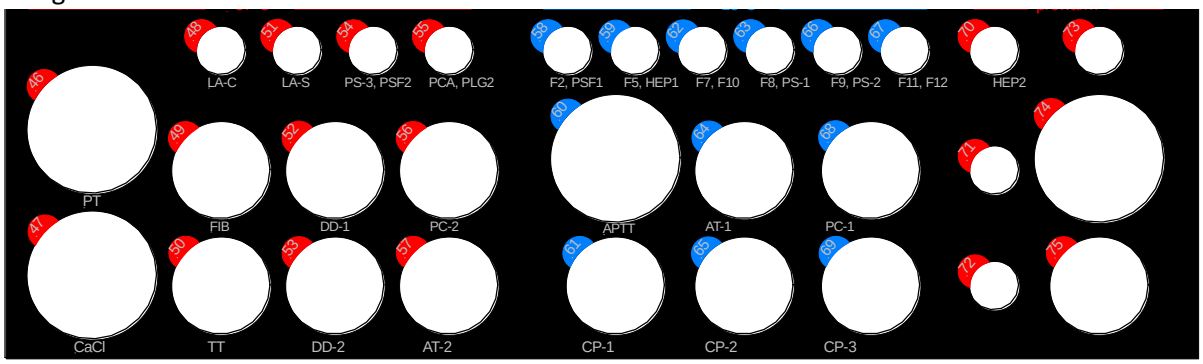
2.2.3 SIDE VIEW

FIGURE 3: SIDE VIEW

2.2.4 REAGENT POSITIONS

Pos. 1 - 45		Sample positions	Room temperature

Reagent block:



Pos. 46	PT	Position for PT, **magnetic stirring function**	36.5 - 37.5 °C
Pos. 47	CaCl	Position for $CaCl_2$ (Calcium Chloride)	36.5 - 37.5 °C
Pos. 48	LA-C	Position for LA-C (Lupus Anticoagulant - Confirmation)	36.5 - 37.5 °C
Pos. 49	FIB	Position for FIB (Fibrinogen)	36.5 - 37.5 °C
Pos. 50	TT	Position for TT (Thrombin Time)	36.5 - 37.5 °C
Pos. 51	LA-S	Position for LA-S (Lupus Anticoagulant – Screen)	36.5 - 37.5 °C
Pos. 52	DD-1	Position for DD-1 (D-Dimer Reaction buffer)	36.5 - 37.5 °C
Pos. 53	DD-2	Position for DD-2 (D-Dimer Latex)	36.5 - 37.5 °C
Pos. 54	PS-3, PSF2	Position forPS-3 (Protein-S)	36.5 - 37.5 °C
Pos. 55	PCA, PLG2	Position for PCA (Protein C activated) and Plasminogen	36.5 - 37.5 °C
Pos. 56	PC-2	Position for PC-2 (Protein C)	36.5 - 37.5 °C
Pos. 57	AT-2	Position for AT (Antithrombin)	36.5 - 37.5 °C
Pos. 58	F2, PSF1	Position for Deficient Plasma II,	<15 °C
Pos. 59	F5, HEP1	Position for Deficient Plasma V and Heparin	<15 °C
Pos. 60	APTT	Position for APTT	<15 °C
Pos. 61	CP-1	Position for Control plasma 1	<15 °C
Pos. 62	F7, F10	Position for Deficient Plasma VII and X	<15 °C
Pos. 63	F8, PS-1	Position for Deficient Plasma VIII and Protein-S	<15 °C
Pos. 64	AT-1	Position for AT (Antithrombin)	<15 °C
Pos. 65	CP-2	Position for Control plasma 2	<15 °C
Pos. 66	F9, PS-2	Position for Deficient Plasma IX and Protein-S	<15 °C
Pos. 67	F11, F12	Position for Deficient Plasma XI and XII	<15 °C
Pos. 68	PC-1	Position for PC-1 (Protein C)	<15 °C
Pos. 69	CP-3	Position for Control plasma 3	<15 °C
Pos. 70	HEP2	Position for HEP-2 (Heparin)	33 - 39 °C
Pos.71 - 75	Prewarm	5 x Position to prewarm reagents	33 - 39 °C

System block:

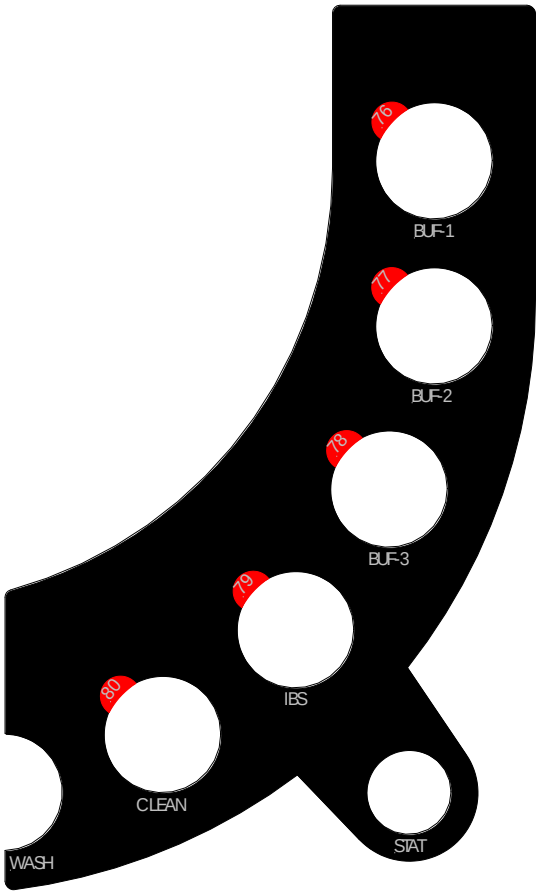


FIGURE 4: WORKING POSITIONS

Pos. 76	BUF-1	Position for Buffer	36.5 - 37.5 °C
Pos. 77	BUF-2	Position for Buffer	36.5 - 37.5 °C
Pos. 78	BUF-3	Position for Buffer	36.5 - 37.5 °C
Pos. 79	IBS	Position for Imidazole Buffered Saline	36.5 - 37.5 °C
Pos. 80	CLEAN	Position for Clean B Solution	36.5 - 37.5 °C
WASH	WASH	Position for liquid waste and cleaning of the needle (probe)	
STAT	STAT	Position for Emergency samples (STAT)	

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.

2.2.5 KEYPAD

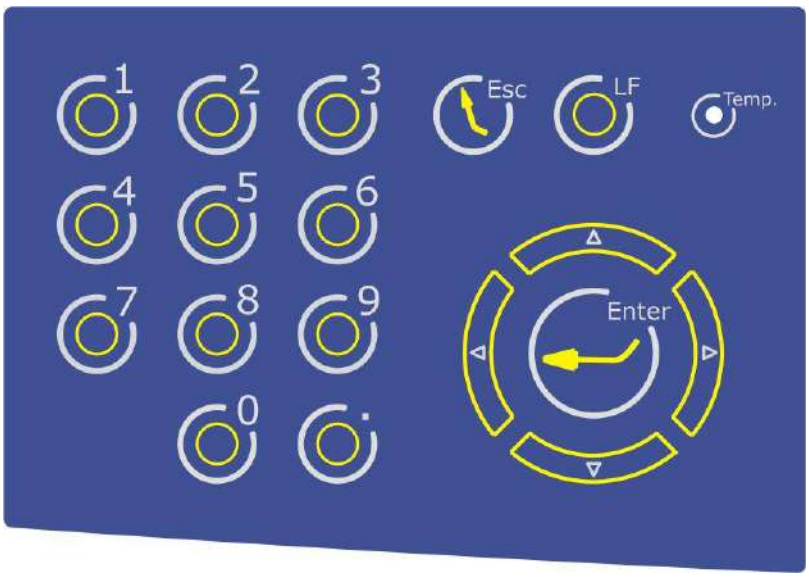


FIGURE 5: KEYPAD

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.

2.2.6 SCREEN SEGMENTS

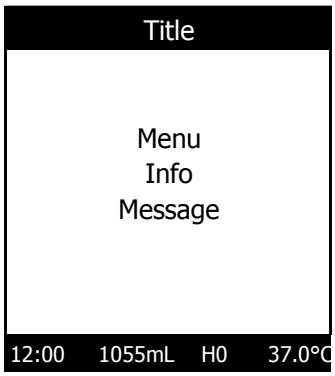


Figure 6: Screen segments

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.

2.3 MEASUREMENT PRINCIPLE

Blood plasma is filled into a cuvette. Special reagents are added, which initiate the blood coagulation. The cuvette is transmitted by ultra violet light during the coagulation process. When the sample starts to clot a change of light absorance is measured. The time from measurement start to change of light (turning point) is called clotting time and expressed in seconds [s].

2.3.1 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 " * ".

2.3.2 UNITS

Unit	Info	Decimal places	Maximum value	Unit Reflex
s	seconds	1	-	-
%	activity	1	180	<10%
U	units	0	999	>600
INR	int. ratio	2	30	-
R	ratio	2	30	-
PR	polish ratio	0	180	-
INR+	int. ratio	2	30	-
mg/dl		0	999	>600
g/l		2	9	>6
IE/ml	Int. Einheit	2	9	-
mg/l		2	9	-
µg/ml		1	999	-
ng/ml		0	9000	>5000
µg/l		0	9000	>5
IU/mL	Int. Units	2	9	-

R = clotting time / normal time
PR = 100 *(normal time/clotting time)
INR = Ratio ^{ISI} (International Normal Ratio)
INR+ = Like INR, except the ISI value is determined for a specific device.
This is done using a calibration curve with INR standards.
IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

Unit Reflex= System repeat testing if
Result < Unit Reflex : Repeat with half sample dilution
Result > Unit Reflex : Repeat with double sample dilution

2.3.3 CLOTTING METHOD

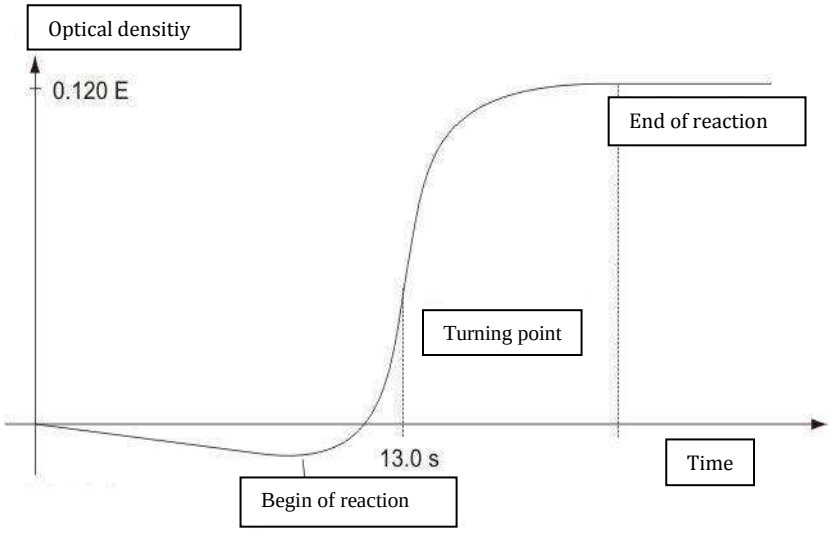


FIGURE 7: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

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).

2.3.4 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 results can give significant higher concentrations than compared to clauss method – especially for very high concentrations. Therefore 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.

2.3.5 CHROMOGENIC, ENDPOINT AND IMMUNOTURBIDIMETRIC METHOD

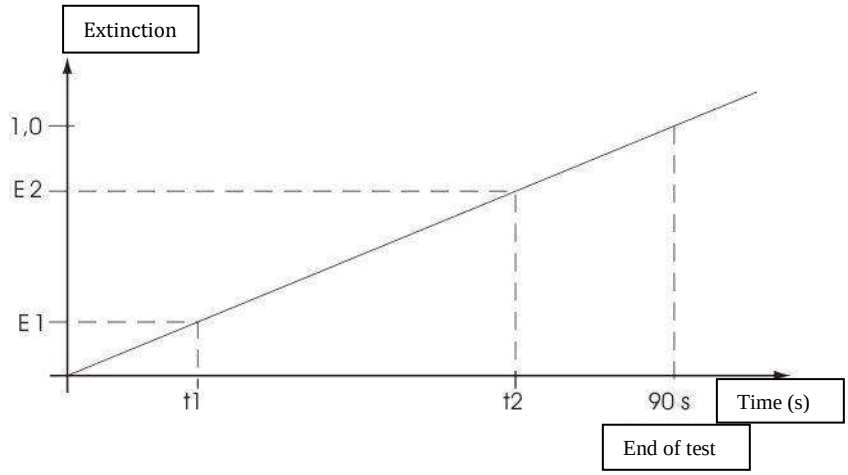


FIGURE 8: DETERMINATION OF RISE IN THE KINETIC TEST METHOD

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

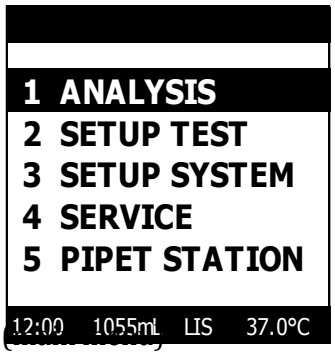
Result of method „POINT “= dE

2.4 TEST OVERVIEW

test ID	name of test	displayed as	Method
0	Prothrombin time	PT	clotting
1	Derived fibrinogen	DFIB	clotting
2	Activated partial prothrombin time	PTT	clotting
3	Fibrinogen	FIB	clotting
4	Antithrombin liquid (anti Xa)	AT	chrom
5	Thrombin Clotting Time	TT	clotting
6	D-dimers	DD	immun
7	Heparin	HEP	chrom
8	Protein-C	PC	chrom
9	Protein-S	PS	clotting
10	Factor II	F2	clotting
11	Factor V	F5	clotting
12	Factor VII	F7	clotting
13	Factor VIII	F8	clotting
14	Factor IX	F9	clotting
15	Factor X	F10	clotting
16	Factor XI	F11	clotting
17	Factor XII	F12	clotting
18	Plasminogen	PLG	chrom
19	Activated Protein-C resistance	APC	clotting
20		APC	clotting
21	Lupus anticoagulant	LA confirm	clotting
22		LA screen	clotting
23	free Protein-S	PSF	immun

3. OPERATION OF THE COATRON A6

Select menu item with cursors keys + ENTER or direct code (1, 2.,,)



Statusbar Information:
Time = 12:00
Rinse = 1150mL installed
LIS = Online
Temp = 37°C

Short descriptions of main menu

1. ANALYSIS: Define and run worklist
2. Setup Test Calibrate methods
3. Setup System Change system parameter like time, date
4. Service Run service like replenish rinse, needle
5. Pipet Station Menu to reconstitute reagent and controls

3.1 ROUTINE MEASUREMENT WITH TECAM

> This chapter is just a very quick overview of TECAM. Please read TECAM online manual for further informations

1. Switch on instrument
2. Run TECAM.
3. The worklist screen is automatically displayed

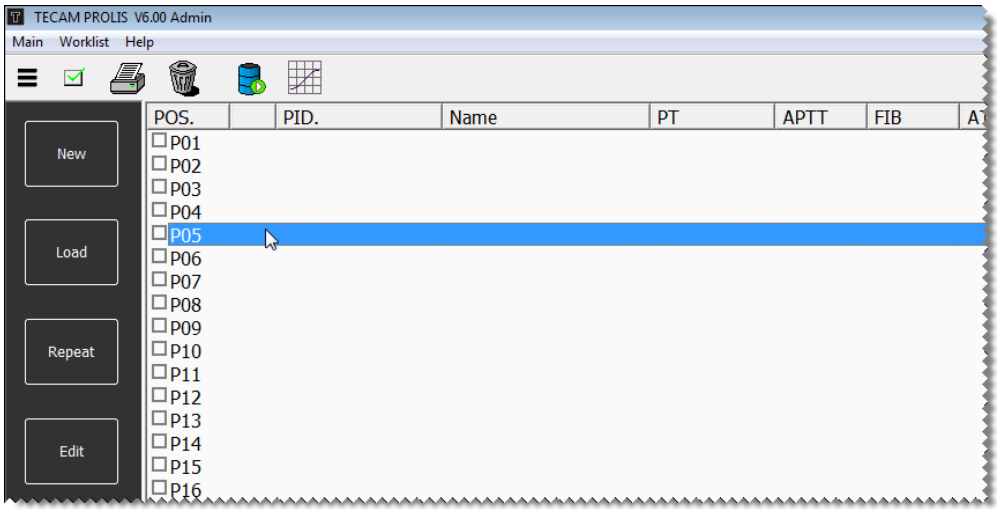


FIGURE 9: WORKLIST SCREEN OF TECAM

4. Import PID from analyser, if you work with patient barcode information.
   - Select menu "LOAD"
   - Goto analyser and scan the patient racks and press "ENTER"

5. Select rack position with cursor keys and press ENTER or click to EDIT. The Test order screen will popup.

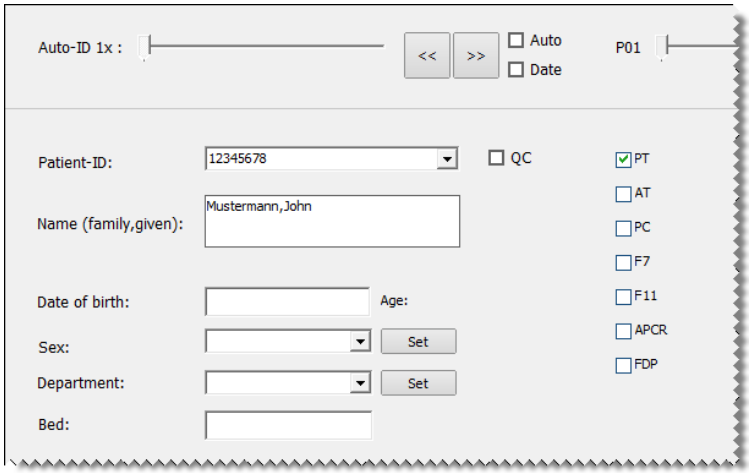


FIGURE 10: TEST ORDER SCREEN OF TECAM

Using Auto-IDNumber:

- Check “Auto” and enter start number into filed Patient-ID. Each new order will be increment automatically (e.g.1000, 1001,1002,..)
- Check “Date” to add date information. This is helpful to find the correct result later in the database.
- Slide Auto-ID 1x , if more then one order should be defined.
- Change Auto-Id number if required and select required tests
- Press OK

Using Patient-ID Number:

- Uncheck “Auto”
- Enter patient ID number (external barcode sanner can be used)
- Enter patient’s information + required tests
- Press “OK” to continue with the next sample
- Press “Exit” to return to worklist menu

6. Select menu Worklist\Send worklist

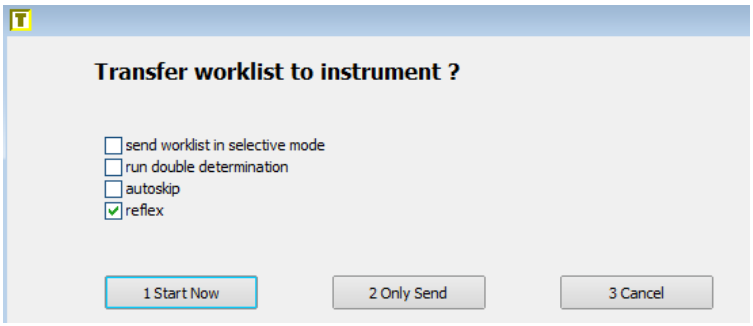
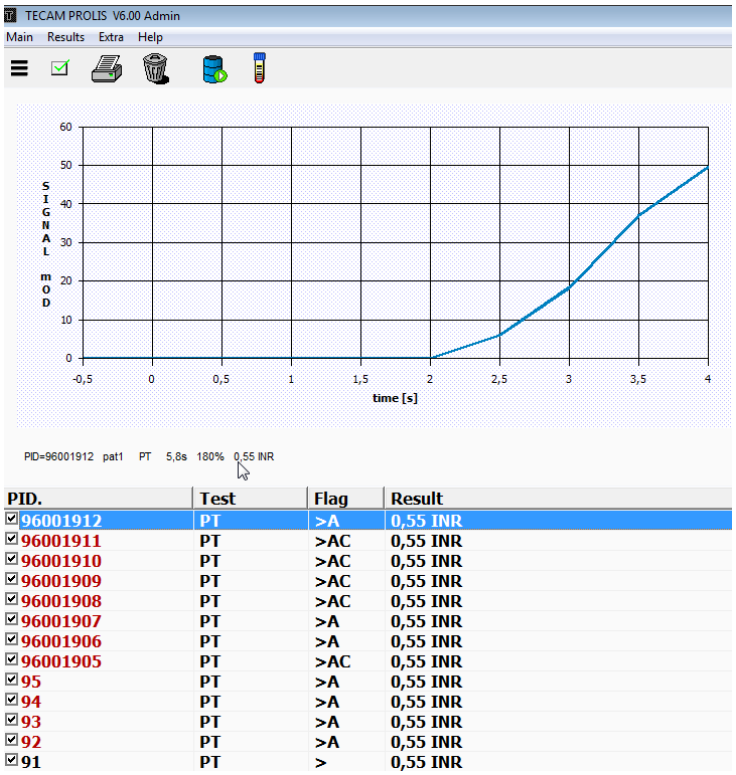


FIGURE 11: RUN WORKLIST SCREEN OF TECAM

- Selective mode
  If yes, then worklist is ordered by patient’s orders, otherwise by tests
- Run double determination
  If yes, then all orders are run in duplicate
- Autoskip
  If yes, then worklist is continued even some reagents are missing otherwise system stops worklist.
- Reflex
  If yes, then reflex testing is enabled
- Start Now
  Send worklist and start it immediately
- Only Send
  Send worklist. Goto analyser and press key “ENTER” to start the worklist.

7. Receiving results

- New incoming results will be automatically stored into database and displayed. Click on result to display reaction curve and report



PID.	Test	Flag	Result
96001912	PT	>A	0,55 INR
96001911	PT	>AC	0,55 INR
96001910	PT	>AC	0,55 INR
96001909	PT	>AC	0,55 INR
96001908	PT	>AC	0,55 INR
96001907	PT	>A	0,55 INR
96001906	PT	>A	0,55 INR
96001905	PT	>AC	0,55 INR
95	PT	>A	0,55 INR
94	PT	>A	0,55 INR
93	PT	>A	0,55 INR
92	PT	>A	0,55 INR
91	PT	>	0,55 INR

Coagulation Data-Report

Name:	pat1		
PID.:	96001912	SID.:	01165-27
Birth:		Age:	
Sex:		Bed:	

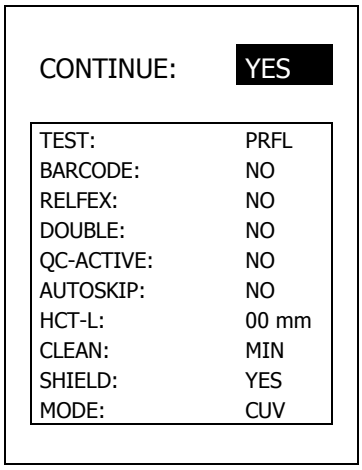
Test	Date	Flag	Result	Range	Grafic..
PT (%)	03.12.2014 10:26	A >	180 %	[70 - 120]	------->
PT (INR)	03.12.2014 10:26	A	0,55 INR	[0,9 - 1,15]	<--------

FIGURE 12: RECEIVE RESULT SCREEN OF TECAM

3.2 ROUTINE MEASUREMENT WITHOUT TECAM

This chapter however describes how to work without TECAM in very short words. For detailed information read chapter

Goto menu ANALYSIS and select NEW LIST and follow dialogue from screen1 to screen4.

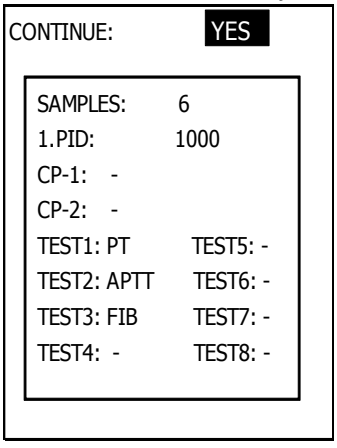


"New List" Screen 1

Select CONTINUE=YES to confirm and show the next screen

-A profile specification was defined.
-The samples identifications are input manually.
-Reflex testing is disabled
-Double testing of control samples is disabled
-Quality control is disabled
-Autoskipping is disabled
-The needle travels all the way to the bottom of the sample
-No sample to sample wash
-Shield detection is enabled
-The worklist is processed in batch mode (first all PT, then

Select CONTINUE=YES to confirm and show the next screen

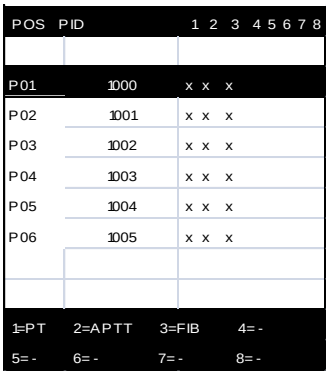


New List" Screen 2

- *6 samples were entered*
- *The sample ID begins at 1000, 1001,..*
- *No QC number was entered*
- *The profile PT+APTT+FIB was selected*

Select CONTINUE=YES to come to the next screen

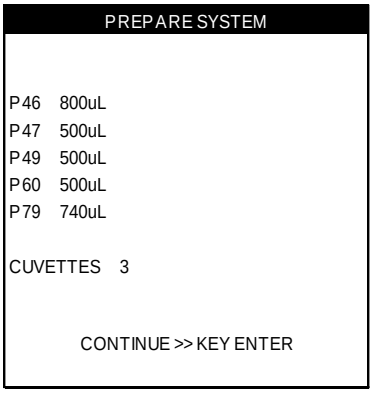
Press ENTER to confirm and show the next screen



- *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.*

"New List" Screen 3

Press ENTER to confirm and show the next screen



The COATRON A6 requires the following to process the active worklist:

- *800µl reagent in position 46=PT*
- *500µl reagent in position 47=CACL*
- *500µl reagent in position 49=Fibrinogen*
- *500µl reagent in position 60=PTT*
- *740µL reagent in position 79=FIB buffer*
- *3 cuvettes*

"New List" Screen 4

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

3.3 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:

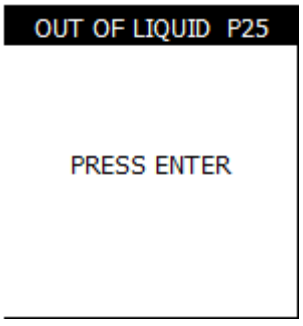
Moves robotic to left or right home position.

Contine worklist: Press key ENTER:

Continuous measurement

3.4 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

3.5 CONTINOUS LOADING OF SAMPLES

This feature requires TECAM software.

(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

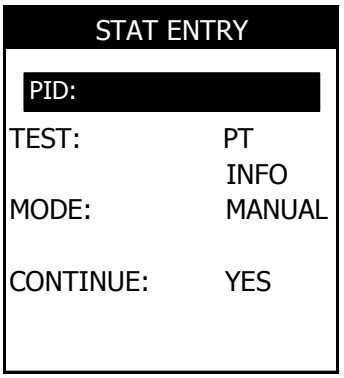
(2) Samples with patient barcode

- 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 !

3.6 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. above*).
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.
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.

3.7 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”. 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.

The analyser identifies a sample as a control if its position is CP1/CP2/CP3 or if its PID is equal to one of the two entered lot-numbers.

QC with positions CP1,CP2 or CP3 :

- 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 CP1,CP2 or CP2. The corresponding control position is printed with the test setup.

QC with position in patient racks (P01 ..):

- 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 in first rack position and then all samples
- Set the PID of the control equal to the lot-number

QC with TECAM software:

- Enter a new order at any rack position
- Define the order as quality control and update the QC rangecontrol range in the menu SETUP TEST
- Send the QC order to instrument
- After result is returned, open the database and set QC filter = Yes

Recommendation: Use TECAM PRO software for much easier and flexible QC-controlling including Levey-Jennings graphics and Westgard rules.

3.8 REFLEX TESTING

After worklist run, then instrument will validate results and repeat test under following circumstances:

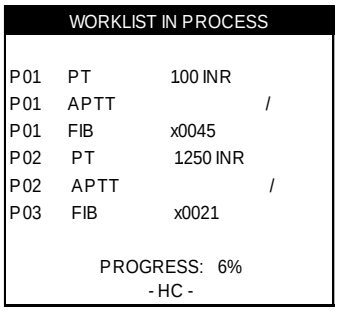
- Clot Reflex:
  Test is repeated with additionally 60s prolonged maximum reading time, if no clot was found (+++). This mode is only active for method “CLOT”.

- Unit Reflex
  Test is repeated with half or double plasma dilution, if result is above or below the unit reflex limits (see chapter 2.3.2 Units)2.3.2).

- Disable/Enable
  Reflex testing can be enabled globally in analyser menu “ANALYSIS”
  Unit reflex can be enabled for each test in analyser menu “SETUP TEST”.

Repeated results are flagged with “R”

3.9 DISPLAY DURING MEASUREMENT



PT result was found on measurement channel P01 and P02.
aPTT is waiting for incubation time
FIB is under process.

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

“HC” indicates that the analyser is linked to HOST.

A rotating bar at the right edge of the screen indicates 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!

While the message "CALIBRATE" is displayed, the COATRON A6 searches for the optimum amplification parameters for the measurement channel.

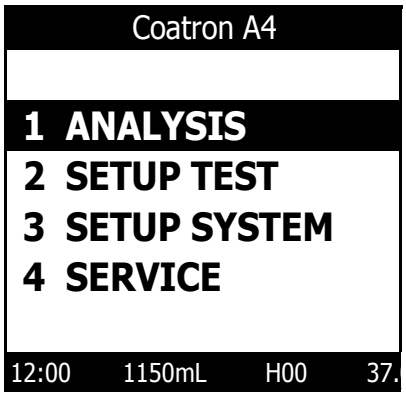
3.10 RESULT WARNING MESSAGES

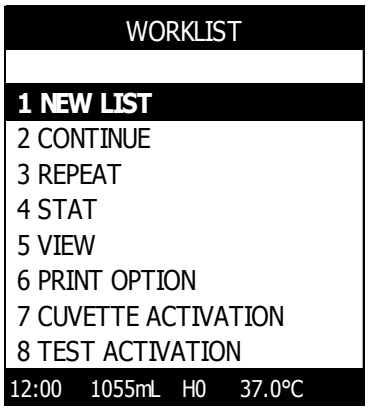
Results may also be displayed with various additional warning symbols:

- * 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.
- S External UV light too bright. Avoid sunlight or UV sources.
- 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
- RFX Job is repeated by reflex testing
- XXX No result was found
- SSS Signal transmission too low.
- +++ No coagulation determined within the measurement time
- ??? Result based on strange optical signals (e.g. air bubble, peaks)

4. MENU ANALYSIS

From main screen select “ANALYSIS”. Return to the previous screen with key ESC.



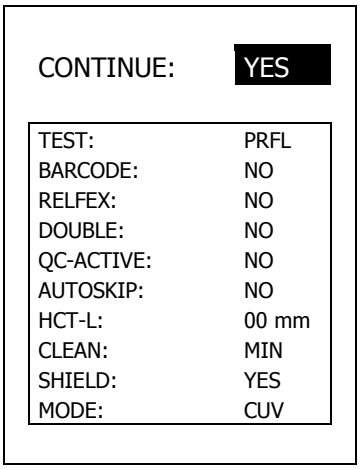


menu analysis

4.1 SUBMENU NEW LIST

With ESC one returns to the previous screen.
Select *CONTINUE = YES* and press ENTER to come to the next screen.

Screen: worklist setting



- **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.

- **Reflex** YES / NO**:**
  Activates reflex testing. The instrument can repeat automatically suspected results like +++ (no clot detected) or greater. smaller a certain limit (e.g. FIB > 600mg/dl).

- **Barcode** YES / NO**:**
  Primary tubes are provided with barcode label, which is used to input the patient identification number (PID)

- **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 are defined in the Test Setup printout. If the control measurement results are outside the QC, then 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 runs 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:

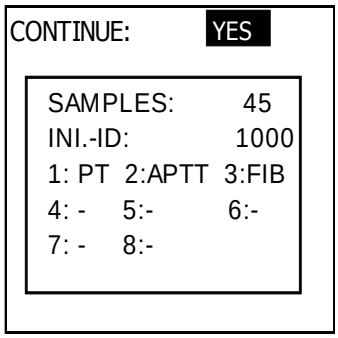
Deactivated shield function may lead to injury and infections cause by piercing needle.

➢ **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: This mode is used for quality issues during production of service.

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

Screen: Test Profil, Control plasma and Autoseries input:



Possible settings:

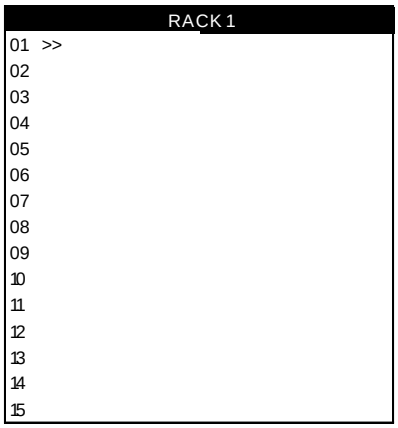
- **Samples:**
  (only visible of barcode is set to no)
  Manual input of number of samples.
- **INI.-ID**
  (only visible of barcode is set to no)
  Manual input of Identification Number for first sample. The other samples were automatically incremented by 1 (1000, 1001, 1002,…..)
- **Test 1 – 8:**
  When a profile is to be measured, you can define the individual tests here once again.

DFIB must be preformed together with PT, ACPR together with –APC and reverse;
LA-S together with 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:



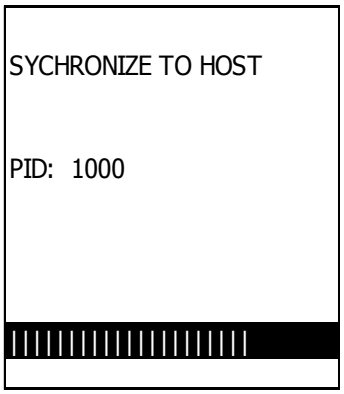
Shift the racks separately at an even and moderate speed in front of the barcode scanner. A signal tone is heard for each recognized barcode

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”

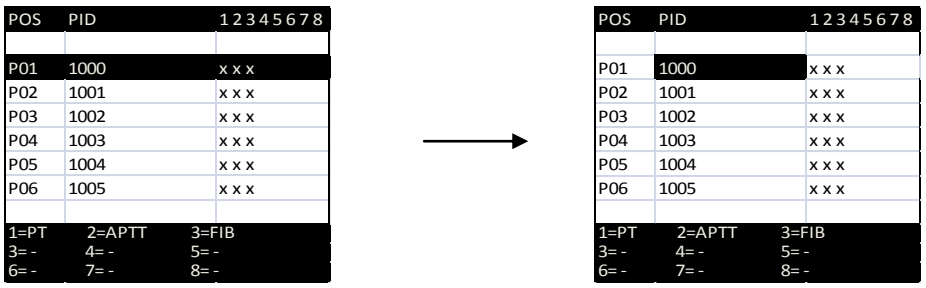
Press *ENTER* to come into the next screen.



All patient identification numbers will be send to host.

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

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

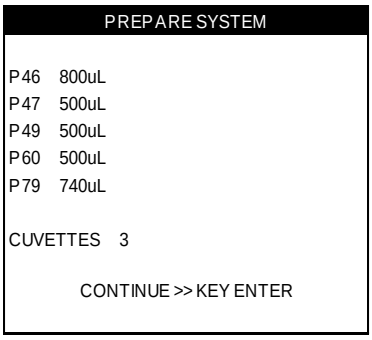


POS	PID	12345678
P01	1000	x x x
P02	1001	x x x
P03	1002	x x x
P04	1003	x x x
P05	1004	x x x
P06	1005	x x x
1=PT	2=APTT	3=FIB
3= -	4= -	5= -
6= -	7= -	8= -

POS	PID	12345678
P01	1000	x x x
P02	1001	x x x
P03	1002	x x x
P04	1003	x x x
P05	1004	x x x
P06	1005	x x x
1=PT	2=APTT	3=FIB
3= -	4= -	5= -
6= -	7= -	8= -

- *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.

Start worklist:
After worklist input is complete the requirement screen will appear. Check for enough reagent placed on correct positions , check enough cuvettes and key “ENTER” to start the measurement.



- 800µl reagent in position 46=PT
- 500µl reagent in position 47=CACL
- 500µl reagent in position 49=Fibrinogen
- 500µl reagent in position 60=APTT
- 740µl reagent in position 79=FIB buffer
- 3 cuvette trays

Use TECAM software to generate worklist in a much easier and flexible way

4.2 SUBMENU CONTINUE

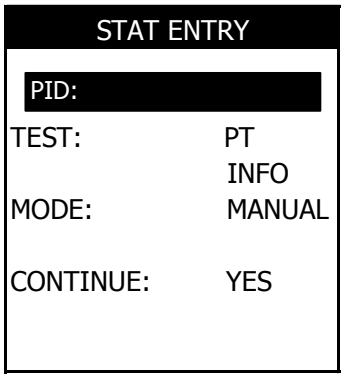
Following a test interruption (e.g. due to a STAT task or discontinuation due to a lack of liquid), routine measurement can be continued here.

4.3 SUBMENU REPEAT

Repeats the last worklist.

4.4 SUBMENU STAT

Interrupts the regular processing of the list with key “ESC” and select this menu.



- 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.

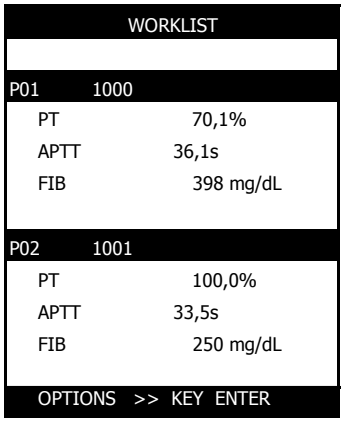
- Information on the test:
  Confirming the INFO field with Enter prints out the test setup just as in normal measurement.

- 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.

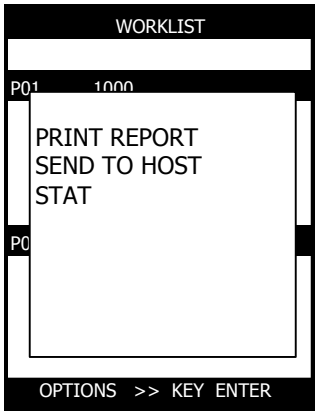
- Activation of emergency measurement:
  Go to the field CONTINUE and confirm with YES.
  The next screen SYSTEM PREPARATION displays the required position in the reagent block, the required amount of reagent and the number of cuvettes required.
  After checking the reagent position, the measurement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

4.5 SUBMENU OVERVIEW

Displays and prints lists according to given sorting criteria.



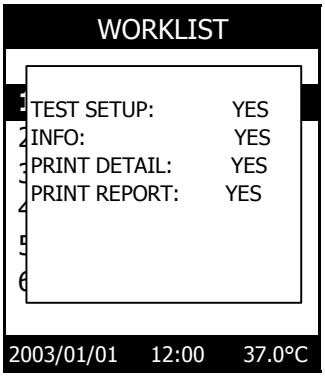
Enter calls up options, ARROW ↑ / ARROW ↓ pages through the options, Enter executes the operation:



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.
- STAT: Displays either the emergency list or the worklist.

4.6 SUBMENU PRINT OPTION

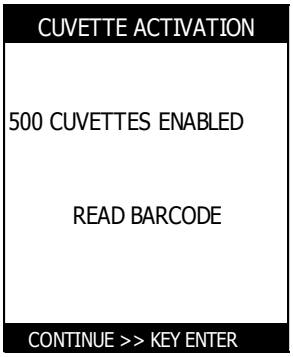


Determines what information is to be printed automatically:

- 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.

4.7 SUBMENU CUVETTE ACTIVATION

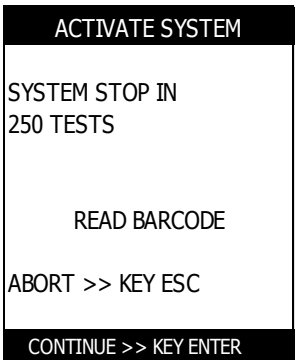
This menu is only shown, if instrument is configarated as “Closed to cuvette”.
Read the barcode, which is provided with the cuvette package.



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

4.8 SUBMENU SYSTEM ACTIVATION

This menu is only shown, if instrument is configarated as “Closed System”. Amount of determinations must be activated by barcode. Read the activation barcode, which is provided by the local distributor.

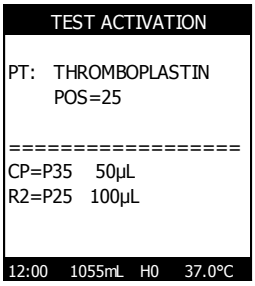


System will stop operation in 250 determinations.

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

4.9 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.

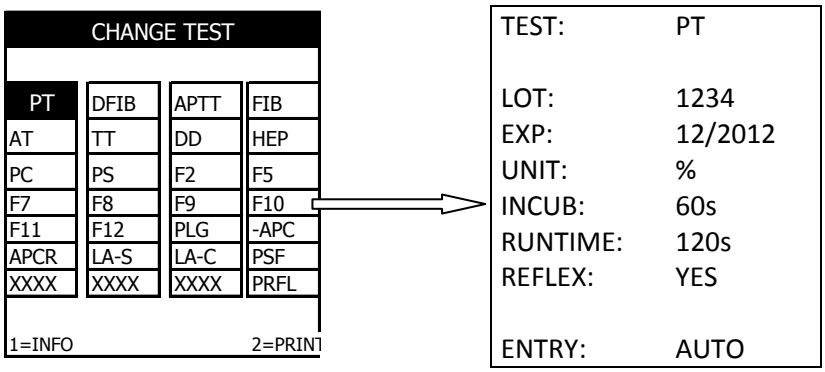
Reagent and test name is displayed as well as the test protocol (e.g. control plasma at P35 with 50µL and R2=Diaplastin-E at P25 with 100µL)

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 "TEST SETUP "

5. MENU SETUP TEST



- **1=INFO:**
  Show volumes and position of reagent
- **2=PRINT:**
  Print test setup
- **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 A6
- **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 2.3.2,* Units on the significance and calculation of the units.
- **Incubation time**
  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**
  Define the maximum reading time.
- **Reflex**
  Enable/disable. Reflex testing will be automatically disabled , if no CLOT and Unit reflex is possible. Unit limits can printed with “1:PRINT” during test selection. For more information see *chapter 3.8,* Reflex testing
- **Entry**

Select between manual input of calibration curve or automatical test calibration

5.1 CALIBRATION CURVE

The analyser gives the operator the option to calibrate a test manually (ENTRY=MANUAL) or automatically (ENTRY=AUTO).

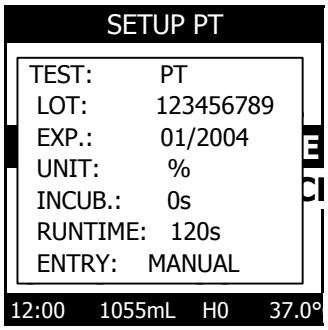
- Manual Calibration:
  The operator must prepare the standards and run them like normal samples. He must also enter the results manually

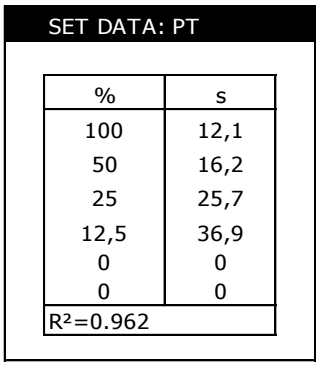
- Auto Calibration with dilutions:
  The operator must place the reference plasma into rack postion P01 and addionally empty vials in P02 – P06. The analyser will prepare all required plasma dilutions, run the standards and transfer the results into the calibration curve automatically.

- 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.

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.

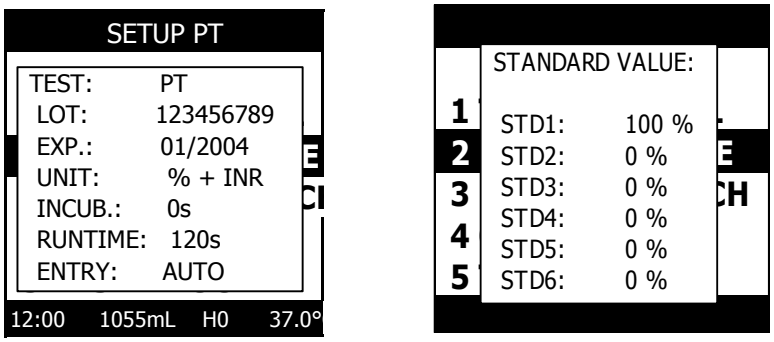
The calibration data are checked for plausibility when they are saved. The following rules must be complied with:

- ***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 A6 prepares and measures all of the required standard dilutions by itself and enters the mean values in the calibration curve.



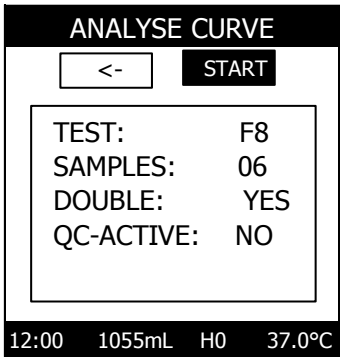
Select test and unit, set *ENTRY to Auto* and press ENTER.

- **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.

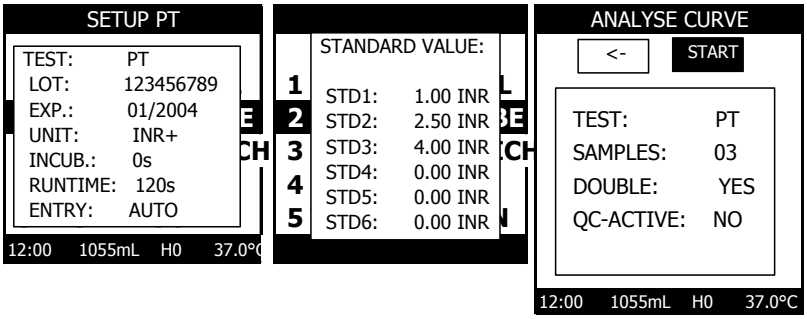


*6 standards are measured for factor VIII calibration. Therefore the calibrator must be placed in rack position 1and 5 other empty sample test tubes are required in rack positions 2-6, in which the **COATRON A6** then prepares the necessary dilutions.*

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 REAGENT BARCODE ENTRY

Scan barcode of reagent during menu “SETUP TEST”.

Test selection, lotnumber and expiry date will be input automatically by barcode information. Barcodes will be rejected if reagent is expired.

5.3 STORING OF TEST DATA

Press ESC to return to the main menu “TEST SETUP”. If any data was changed, the COATRON A6 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
- The expiry date must be valid

5.4 SUBMENU TEST PRINTOUT

During test selection press key “1”

SETUP FIB

LOT: 302501299
NAME: Fibronogen
EXP: 1/2015
LAST CHANGE: 03.04.2013

- lot number
- reagent name
- expiry date
- date of input

1: 80 mg/dl - 27.0 s
2: 120 mg/dl - 18.0 s
3: 240 mg/dl - 12.0 s
4: 480 mg/dl - 7.0 s

- calibration values

R^2 = 0,992

- Linearity of the calibration curve (1.000 for a straight line) (R^2 should be 0.850 – 1.000)

S-CORR: 0%
T-CORR: 0% 0s
START: 3s
INCUB.: 120s
RUNTIME: 120s
METHOD: COAG
CT-MECH: NO
SENS: 0
MIX: 0
CLEAN: 1
MULTI: 1
BARCODE: 1
REFLEX: >600mg/dL

-signal correction
-time correction
-deadtime
-incubation time
-max. runtime
-test method=coagulation
-clottingtime mechanical=no
-test sensitivity=low
-reagent mixing=no
-high cleaning cycle=yes
-multi dispensing=Yes
-barcode required=yes
-unit reflex=yes, if result>600mg/dL

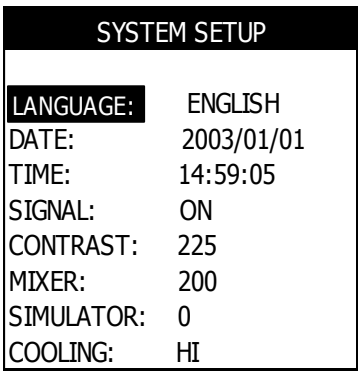
PAT: VOL= 10uL POS=62 (CP)
BUF: VOL= 90uL POS=78
CLR: VOL= 0uL
DEF: VOL= 90uL POS=0
R0 : VOL= 0uL POS=0
R1 : VOL= 0uL POS=0
R2 : VOL= 50uL POS=49

- 10µl Sample
- 90µL IBS from Pos=P78

- 50µL reagent from POS=P49

6. 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

6.1 LANGUAGE

Select between:English - Italian - Spanish - German

6.2 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).

6.3 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).

6.4 SIGNAL

Switches the acoustic signal on or off.
Possible settings:

- Signal on
- Signal off

6.5 CONTRAST

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

6.6 MIXER

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

6.7 SIMULATOR

Facilitates simulation of measurement operation without moving the pipetting arm.

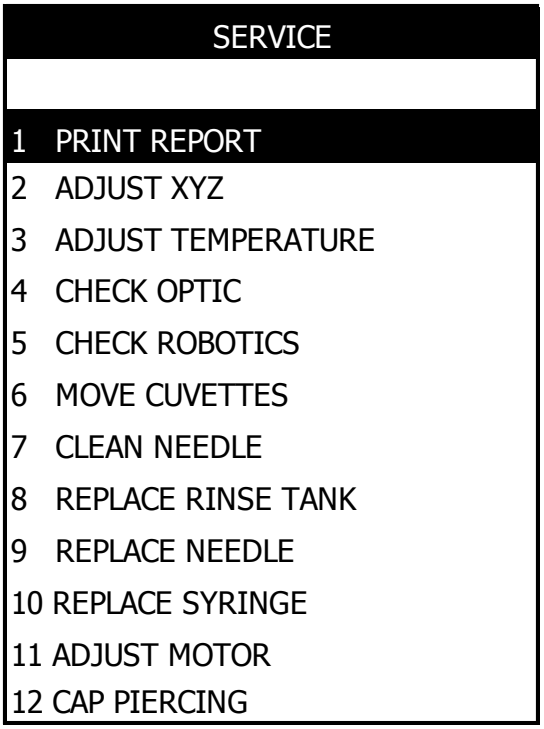
- Simulator = 0:
  Normal operation; simulator is not active
- Simulator = 1:
  Maintenance operation; commands issued to the XYZ robot are not executed. System functions as usual otherwise. This mode is very helpful for maintenance work or while familiarizing oneself with the system.
- Simulator = 2:
  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.

6.8 COOLING

Select between high (~12°C) and low. (~16°).

Mode “low” should be set, if high condensation is observed on the cooling block or if reagent block-2 (POS 70 – 75) will heat up over 40°C.

7. MENU SERVICE



ARROW ↑/↓	the desired menu item is selected
Enter	initiates the operation directly.
1-9	select item directly

7.1 REFILL CUVETTES

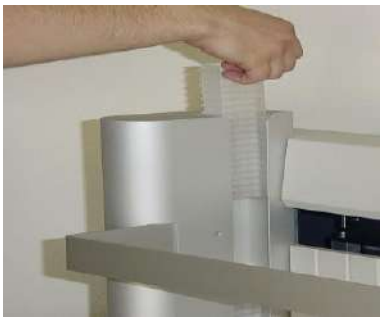


FIGURE 13: INSTALLATION OF CUVETTES

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.

Cuvettes are disposable items. Washing and re-use is not permitted for reasons related to hygiene and accuracy

7.2 INSERT PRINTER PAPER

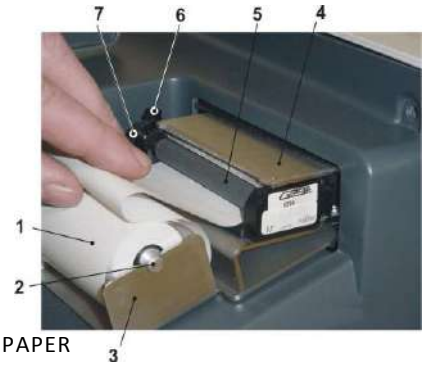


FIGURE 14: INSTALLATION OF PRINTER PAPER

1. Open the printer cover as shown at the back of the housing.
2. Feed paper (5). Device has autofeed function. Alternative you can feed manually with wheel (7)
3. Set printer to online by shift on arresting lever (6) in the direction of the front of the housing.

7.3 SYSTEM REPORT

Printout of important system data

SYSTEM - REPORT

DATE: 2012/25/10 13:59

SYSTEM: COATRON A6
SERIAL NO.: 1234567
SOFTWARE: 01.00.02

OPTIC 1: 80 30005 (162)
OPTIC 2: 62 29984 (169)
OPTIC 3: 85 29766 (153)
OPTIC 4: 50 29793 (165)
OPTIC 5: 50 29722 (135)
OPTIC 6: 50 29768 (144)

OPTICS : 80 30005 (162)

80 = Digital value when LED is off
30005 = Digital value when LED is on
162 = Amplification factor

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

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

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

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

CONTRAST: 225
MIXER: 200

Display contrast
Reagent mixing speed

----------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			

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

RINSE INSTALLED: 108 ml
NEEDLE TIMER: 9212 Tests
SYRINGE TIMER: 33421
STOP-STOP IN: 905 TESTS
SERVICE IN 58001 TESTS

Remaining system liquid
Age of needle: number of performed tests
Age of syringe: number of up/down cycles
Remaining determination before system stop
Next service required in

PT COUNTER: 344
PTT COUNTER: 6
FIB COUNTER: 302
ANALYSIS COUNTER: 1079

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

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

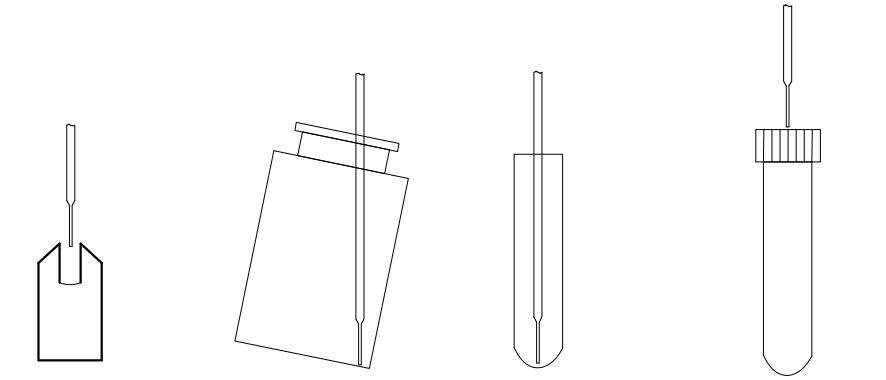
System requires a barcode to run tests
System requires a barcode to reset service interval
System requires a barcode before use of reagent

7.5 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

Five positions must be adjusted

- Wash postion
- Clean position
- Cuvette position
- Patient position
- Cap piercing height



1. Ensure yourself, that the needle is straight and correct mounted 115mm in length. For correct z-offset adjustment following tubes or vials must be placed

POS		Container
P01	Patient-1	empty primary tube
P02	Patient-2	empty primary tube
P76	Buffer-1	empty PT vial

P76 is used to adjust the all reagent positions. It is important that the same vial for adjustment is used than later during measurement. Otherwise the z-offset might be different, which may cause very high dead volume or even needle crashing.

2. 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.

3. Second the needle will go to buffer-1 position (P76). 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.

4. 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.

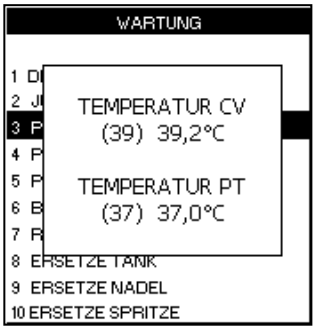
5. Forth the needle will go to sample position P01. Center the needle.The needle tip should be short before touching the vial buttom. Lift vial to determine the distance. Press “ENTER” to come to next postionen or press “ESC” to quit.

6. Fifth the needle will go to sample position P02. 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

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

7.6 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 6 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. The temperature should be in the range of +-0.5°C of target temperature. Use ARROW ↓ / ↑ to change.
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

○

7.7 CHECK OPTICS

Remove the cuvette in the measurement optics.

CHECK OPTIK

	OFF	ON	AMP
1=	78	29851	185
2=	105	29624	192
3=	56	29799	171
4=	78	29851	185
5=	98	29245	155
6=	110	29967	145

T1=34302 (34310)
T2=34081 (34081)
T3=31707 (31800)
CV-STATUS: 0
SHIELD: 0

X=	Measurement channel 1-6	
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 heat area, Target range 33000 - 36000	
T2	Digital value cuvette area, Target range 33500 – 36000	
T3	Digital value cool area	
CV-STAT	0= no cuvette	1 = cuvette is detected
SHIELD	0 = closed	1=open

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

7.8 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.

7.9 MOVE CUVETTES

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

7.10 CLEAN NEEDLE

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

7.11 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. The message can be ignored with key “ENTER”, but latest at zero value new rinse tanks must be activated by barcode.

1. Remove the full waste tank (located in the drawer or trolley) 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.

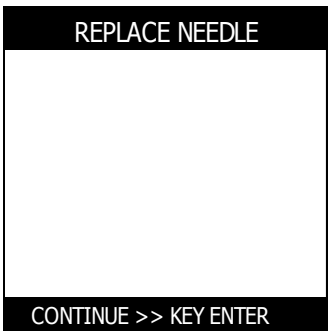
☝	The rinse tank activation barcode can be used only 1x time.

☝	Make sure a full tank is really installed, since otherwise the COATRON A6 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®.

7.12 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”

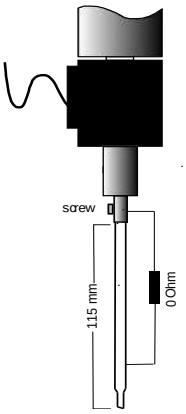


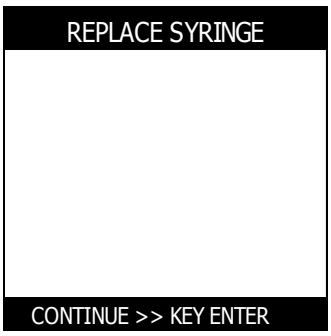
FIGURE 15: REPLACE NEEDLE

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.

7.13 REPLACE SYRINGE

Resets the operating time counter of the syringe to zero. This operation must be carried out when the COATRON A6 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”

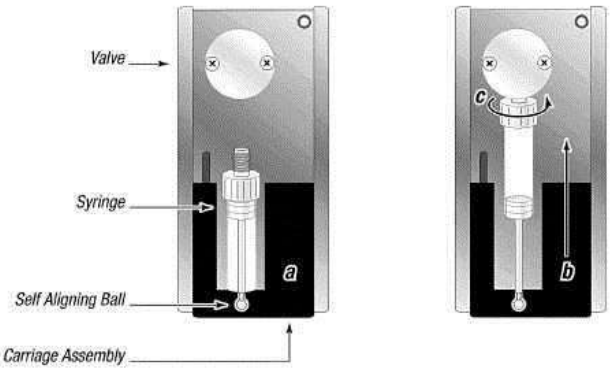


FIGURE 16: INSTALLATION OF SYRINGE

7.14 ADJUST MOTOR

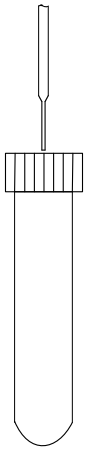
Changes the assignment of the cuvette to the measuring position. The cuvette must be positioned exactly centered to the optic, to ensure accurate results. Fill some water into a container and color the water with a green lightning pen. Remove all cuvettes onboard. Add 150µL green colored water into every 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 „8“ . An increase of the offset will shift the cuvette to the left.

False adjustment will cause errorneous results.

7.15 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

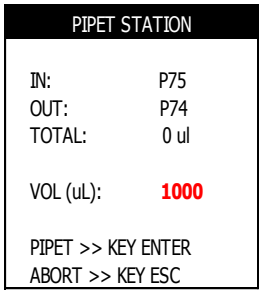
☝	Cap piercing function is deactivated , if height P-Offset is set to 0

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

⚠	Activated cap piercing function will shorten the lifetime of needle from 60.000 down to 15.000 dterminations.

8. MENU PIPET STATION

Menu to reconstitute reagent and controls



Fill enough diluent into container and place it to position P75. Open reagent vial and place it to position P74. 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.

9. 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.

9.1 GENERAL INFORMATIN

- 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.

9.2 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.

9.3 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

9.1 DAILY ACTIVITIES

- Clean system with detergent and bleach as described above
- Inspect level of rinse and waste container
- Empty cuvette drawer and fill tower
- Inspect tube system for any leaks and correct immediately

9.2 WEEKLY ACTIVITIES

- Decontaminate system with bleach and ethanol as described above

9.3 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

9.4 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)

9.5 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.

10. ELIMINATION OF MALFUNCTIONS

10.1 ERROR MESSAGES

Error message	Possible cause	Action
Service	Service interval is expired after 100.000 tests	Service instrument and reset interval with barcode certificate.
Activate System	System interval is expired	Scan barcode “Test Activation Key”
Activate Reagent	Reagent mut be validated	Refill cuvettes
Error pump	Needle clogged	Check needle and tube system
	Diluter valve defective	Replace valve
Error robot (system error 2-28)	No connection to robotic	Consult the customer service of your dealer
	Needle crash	Reboot the system
Fill cuvette tower	Cuvette tower empty	Refill cuvettes
Adjust XYZ	Replacement of needle	XYZ adjustment of pipetting arm
Adjust Motor	Replacement of main-board or software update	adjustment of cuvette
No liquid	No liquid in current position of pipetting needle	Refill liquid at current needle position.
	Z-offset false	XYZ adjustment of pipetting arm
Check printer	No printer paper	Replenish printer paper
	Arresting lever in offline position	Change arresting lever position
	No printer connected	Consult customer service
Check temperature	Temperature in system block too high or too low	Check temperature and adjust
Clean needle	Pipetting needle was replaced	Carry out needle cleaning cycle
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.

10.2 DEVICE MALFUNCTIONS

Malfunction / Error	Possible cause	Measures
No print on printout	Paper installed in wrong position	Turn paper roll around
Needle does not pipette correct volume	Tube system leaky	Replace the tube system
	Level sensor defective	Replace insulationblock
	Needle clogged	Place the needle in COATRON A6 Cleaner for 30 min, then run the wash cycle.
Poor reproducibility	Needle-tube system	Replace the needle, tube system ,syringe or valve.
	Motor is not adjusted	Check the adjustment of the cuvette to the optic
Cuvette assumes false position	Wrong cuvette	Use only original COATRON A6 cuvettes
	Motor is not adjusted	Check the adjustment of the cuvette to the optic
	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

10.3 MEASUREMENT MALFUNCTIONS

Malfunction / Error	Possible cause	Measures
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
Flagged "K"	Sample, Test is skipped because out of reagent.	

10.4 PACKING THE COATRON A6 FOR SHIPMENT

If the COATRON A6 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.

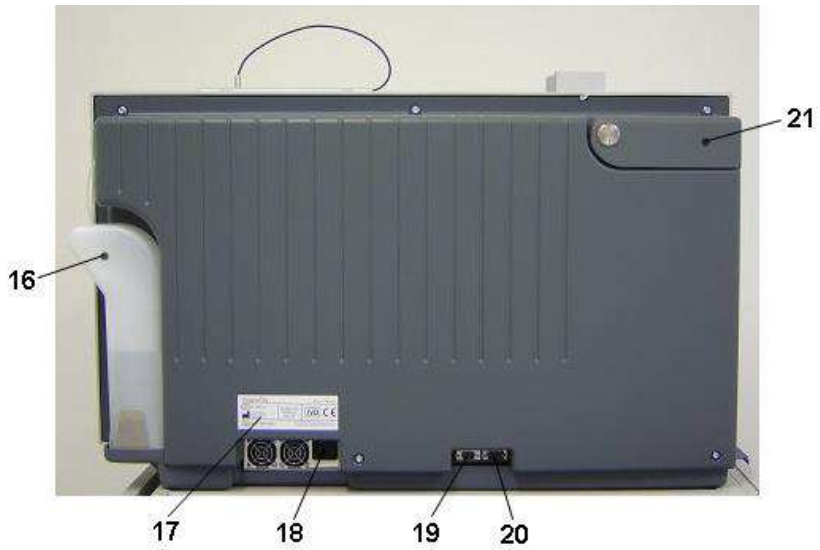
Preparation of the Analyzer for transport:

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.

11. APPENDIX

11.1 SERIAL INTERFACE

The instrument support two serial RS232 ports to connect. The left port (location 19) is used for bidirectional communication with TECAM software or firmware update. The right port (location 20) is used for unidirectional communication with alternative LIS software solutions.



Interface:	115200 Baud , no parity , 8 bit . 1 stop bit
Instrument port:	right RS232 (location “20” – 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
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

11.2 TECHNICAL DATA

Analyzer	
Measurement system	6 independent measurement channels wavelength of LED 400 nm
Measurement timer	Max. 600 s, error < 0.1 s
Cuvette	6 channel cuvette for optical detection capacity: 75 – 750 µl
Calibration	Automatic calibration or manual input of up to a max. of 6 calibration curve points for each test method
Positions	18 reagent positions at 36.5 – 37.5 °C 12 reagent positions at 12.0 – 16.0°C 6 park positions, preheating (33-38°C) 3x15 sampe primary tubes 1 emergency STAT positions
Reaction volumes	Minimum total volume is 75 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	2500 µl syringe with 300 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 at 45 – 60 Hz
Power consumption	Max. 250 VA
Class	1
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 to 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	50 mg/dL
max. hemoglobin concentration	2000 mg/L
max. triglyceride concentration	5000 mg/dL

Typical performance data		
Test	CV.	Range
PT	<3%	0-30INR
APTT	<3%	15 – 420s
FIB	<7%	50-999mg/dL

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

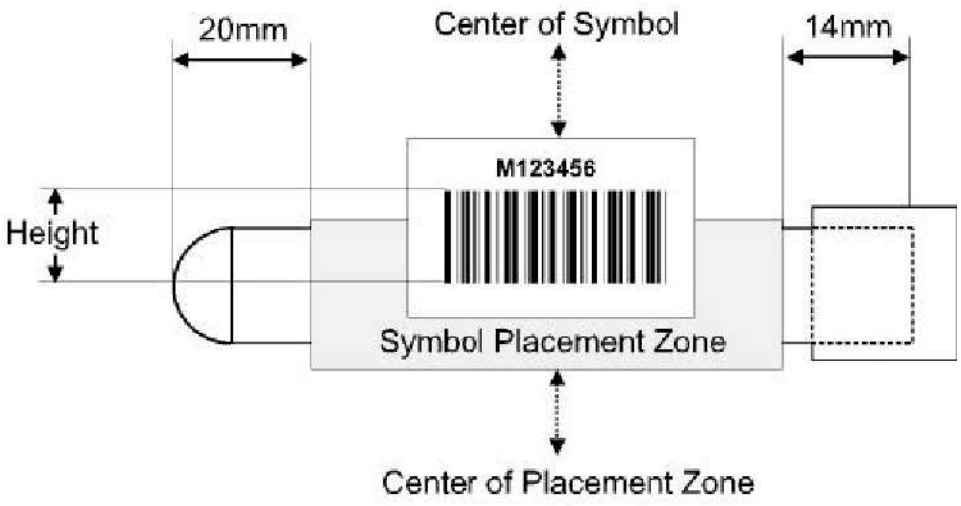
11.3 DISPOSAL AND RECYCLING

Please comply with the following points when disposing of the COATRON A6:

- 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 A6 prior to disposal to prevent cases of infection at the disposal company!

11.4 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 – 16 characters, use checksum without show
- EAN 128	3 – 13 characters, use checksum without show
- Code 39	4 – 13 characters, no checksum
- Code 93	4 – 13 characters, no checksum
- 2/5 interleaved	8 - 12 characters, no checksum

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