Operation Manual
for
Coatron M1

For *In-Vitro* Diagnostic use

Instrumentation and Reagents for Coagulation / Hemostasis

Revision 13
Firmware C1.20
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Warning

This manual is valid for firmware **Coatron M1 C1.20**. The manual may differ slightly from the actual product as a result of product improvements.

Please read the Operation manual in its entirety prior to operate. In order to ensure a high level of performance, all warnings and references to technical safety in this Operation Manual must be followed. Repairs to the instrument may only be carried out by trained personal, and replacement parts must comply with instrument specifications.

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Trademarks

Coatron is a trademark of **TECO GmbH**, Germany. Other product names used in this Operator's Manual are trademarks of the respective companies.

Software

The software for **TECO GmbH** products is the intellectual property of Teco GmbH AG, which company retains all rights to usage of the software. The purchaser of a Coatron M1. acquires rights of use for this software.

Warranty

Teco GmbH guarantees that the instrument will delivered in a fault free condition. Any damages resulted by accidents , improper use, using not recommended material or negligence of maintenance are excluded from warranty. Warranty will expire if not authorized persons perform any service on the instrument

Service

Repairs to the instrument may only be carried out by trained personnel, and replacement parts must comply with instrument specifications. Please contact the local distributor of **Teco GmbH** if service is required.

Symbols

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
⇨	**Advice**	Indicates important information and tips.
	**Warning!**	Risk of possible health damage or considerable damage to equipment if warning is not heeded.
	**Biohazard !**	Equipment can be potentially infectious due to the samples and reagents used .
	**Danger!**	Potential risk to operating personnel or equipment due to electric shock.

Manufacturer

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made in Germany

Authorized Distributor:

Distributor's stamp / address / label

Software History

1.04 - first release

1.08 - dead time for PT/TT/FaE = 5sec (former 7sec)
- dead time for PTT/FaI = 10sec (former 7sec)
- dead time FIB = 4.5sec (former 5sec)

1.09 - auto-amplification of optic improved to avoid optic-failure messages

1.10 - measurement control system complete new implemented. The basic timer interrupt is now controlled by the crystal clock instead of the controller clock to isolate the measurement from temperature.
- Optic check in the service menu added. By pressing key "menu" the optic will start to calibrate. The value should be between 10000 – 14000 (empty channel required). By pressing key "UP/DOWN" the amplification can be changed manually.
- Automatic start of optic. After the optic is set to "active" the measurement will start automatically when the optic signal change (i.e. adding reagent). At very clear reagents (f.e. Fibrinogen) the "Autostart" requires a very quick pipeting technique.
- COAC-correction introduced for each test.
- New test D-Dimer adapted

1.11 - Input of calibration data improved. The value is change by 10er increments firstly. By changing the direction the value is changed by 1er increments.
- Algorithms for all tests equalized to Coatron M2
- Change of auto-amplification of optic improved to avoid optic-failure messages

1.12 - Special Software, only for 400nm optic block.
- Test FA-I and FA-E reduced to one test FAC (to safe memory)
- Implementation of 2 new test ECAH and ECAT

1.13 - Tests on board: PT, PTT, TT, FAC, DD
- Implementation of 3 point calibration curve for PT (100%, 50%; 25%), if 50% and 25% are set to 0 (zero) – no calculation of %-activity is done
- Data transmission protocol changed ("M1 NR TEST SEC mOD % INR Unit"), separated with "TAB" and finished with "LF" (example: "M1 5 PT 12.5 0 100 1.00 0")

1.18 (requires 400nm optic block)
- Introduction of chromogenic methods
- New Tests on board: AT3, PC (or ECAH , ECAT for some countries)
- Double determination including meanvalue display and print
- PT-% will be calculated with double log mathematic to enhance linearity
- Instruments reboots on last used test
- Automatic optic start can be adjusted or switched off
- D-Dimer test can be adapted to different reagent providers
- Interface supports TECAM SMART protocol to use LIS features

1.19 - Improved analog digital conversion to reduce signal noise ratiost
- Autostart deactivated if optic signal is below 350 digits
- DD default: 3200-150mE, 1600-80mE, 200-20mE, OD_corr=180 , COAG_corr=240

1.20 - Optic check during Power Up.
- Service pack for AD conversion , especially required for D-Dimer testing

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1 Safety information

Recommend materials
Use only origin disposables.
Use only manufactorer approved material.

Avoid contact
Never touch moving parts such as the measurement rotor or pipetting arm during device operation.

Do quality control
Carry out control measurement runs at regular intervals to ensure that the Analyzer continues to function faultlessly.

Waste cuvettes
The cuvette blocks are intended as single-use items only.

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 work 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.

Enviromental condition
temperature must be 18 – 25°C
humidity must be below 80%
avoid any vibrations or impacts to analyzer
do not use analyser if explosive or inflammable gas is around.

Elektrical Safety
Make sure the operating voltage setting is correct before connecting the device to the power mains.
Use only shockproof (grounded) electrical sockets.
Use only shockproof extension leads in perfect condition. Defective leads must be replaced without delay.
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.

2 GENERAL DESCRIPTION

Hemostasis is the biochemical process to protect the body from loss of blood after vascular damages. The Hemostasis happens in three phases:

Vessel contraction and **Platelets Aggregation** stop immediately bleeding (within seconds) and trigger the coagulation cascade.

The **coagulation cascade** is a chain reaction in which inactive enzymes are converted to their active form. The cascade ends at fibrinogen to fibrin conversion catalyzed by activated Thrombin. In presence of activated factor XIIIa the fibrin is cross-linked and clotted to an insolutable thrombus (fibrin-clot). The bleeding is stopped finally.

To prevent the body from thrombotic events the coagulation has to be controlled very sensitive. This is done by the **fibrinolytic system**. Inhibitors are able to invert the activation of factors and regulate so the coagulation. The basic inhibitors are Antithrombin and Protein C. The fibrinolytic system is also responsible to lyse the fibrin-clot. After clot-lyse the vessel injury is completely healed.

All factors and inhibitors are balanced very carefully. In case of imbalance or any dysfunction, heavy vascular diseases can and will appear. Dysfunction of the complex Hemostasis is one of the most common disease, which ends very often deadly (~ 1 by 1000). Examples are deep veins thrombosis (DVT) or pulmonary embolism (PE).

The **Coatron M1** is a single-channel optical coagulometer to determine the basic parameters of the second stage of Hemostasis (coagulation cascade) in human citrated plasma. It is designed for in-vitro coagulation testing in the clinical laboratory. Clotting assays with fibrin formation as the endpoint may be run on the instrument, as well as immunturbidimetric test (like quantitative D-Dimer) or chromogenic test (eg. Antithrombin , ProteinC , Ecarin Chromogenic Assay).

Following tests and features are available on the instrument:

PT (Prothrombin Time).

The PT is expressed in seconds (100 ms sampling rate) and automatically normalized into INR (International Normalized Ratio). A normal PT-value (100%) and the Thromboplastin ISI - value (International Sensitivity Index) can be stored on board. Additionally the result can be converted into %-Activity, when the 100% value and the 25% value are stored in the memory.

APTT (Activated Partial Prothrombin Time).

The APTT is expressed in seconds and automatically normalized into Ratio. The normal APTT-value can be stored on board.

TT (Thrombin Time).

The TT is expressed in seconds and automatically normalized into Ratio. The normal TT-value can be stored on board.

FIB (Fibrinogen).

The FIB is expressed in seconds and automatically converted into mg/dL concentration in plasma. A calibration is necessary to obtain the results in mg/dL. Three calibration points can be stored on board.

FAC (Factors)

The coagulation factors are expressed in seconds and automatically converted into activity % in plasma. A calibration is necessary to obtain the results in %. Three calibration points can be stored on board.

DD (D-Dimer)

The D-Dimer is measured immunturbidimetric and expressed in milli optical density per minutes (mOD/min) and converted into ng/mL concentration in plasma. A calibration is necessary to obtain the results in ng/mL. Three calibration points can be stored on board.

AT3 (Antithrombin)
PC (Protein C)

The tests are measured chromogenic and expressed in milli optical density per minutes (mOD) and converted into % plasma activity. Upto three calibration points can be stored on board.
to % plasma activity.

ECAT (Ecarin Chromogenic Assay for Thrombin)*
ECAH (Ecarin Chromogenic Assay for Hirudin)*

ECA tests are used to monitor the direct thromin inhibitors (such as Hirudin). ECA tests are equivalent to Ecarin Clotting Time, but the performance is much advanced by chromonic method. The result is expressed in milli optical density (mOD) and converted into % plasma activity. Upto three calibration points can be stored on board.

* reserved for OEM partner. Not insalled on standard configuration.

FEATURES:

All tests are performed with a quarter of the regular volumes. The micro cuvette can be run with a minimum of 75 µl → i.e. 25 µl sample + 50 µl Thromboplastin for PT.

The **Coatron M1** supports an unidirectional RS232 interface (fixed setting at 2400, 8, 1, No). All results are printed automatically, if the interface is set to print mode. The RS 232 can also set to LIS mode. Then the results including their reaction curves are sent in TECAM SMART format to the PC. TECAM SMART is a easy using coagulation data management system which fulfills LIS demands (labaratory information system).

Incubation area for 6 sample and 2 reagent positions. The **Coatron M1** needs 3-5 min to warm up to 37.0°. A green signal light indicates the correct temperature.

- Coagulation analyser for turbidimetric, chromogenic and immunturbidimetric assays.
- Highly reliable, longlifing and nearly service free system
- Autosense optics to eliminate interferences like Bilirubin, Hemoglobin
- Approved clotting algorithm for all kind of samples and reagents. If there is a clot - it will be detected.
- Automatic start at reagent addition
- Cost-effective determination by micro volumes(total 75 µL)
- Every test is programmable up to 3 calibration points
- calculation of activity %, INR, Ratio, g/L , ng/mL
- Stop-watch function onboard
- Support of double determination (mean result)
- Print-outs for result, calibration, service and system
- Optional external thermal printer
- Optional RS232 communication for data research
- Linking to Laboratory Information Systems such as TECO TECAM
- Small dimension and weight - fits on every desktop

3 Intended purpose

The **COATRON M1** is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immunturbidimetric tests (for instance Antithrombin-III, D-dimer etc.).

The COATRON M1 must be operated by a specialist trained in clinical laboratory techniques who has also received instruction and training in operation and has read and understood this Operator's Manual

Use only citrate plasma for test analysis runs: Mix 9 parts venous blood with 1 part 3.2% (0.105M) sodium citrate and centrifuge the mixture at 1500g for approx. 10 minutes. Plasma must be used within 4h.

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

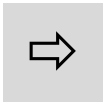
As there is no known test that can offer complete assurance that product derived from human blood will not transmit Hepatitis, AIDS, or other infectious diseases, appropriate precautions should be taken by the instrument operator. In case of plasma spill on the instrument, clean with a paper towel soaked in 10% bleach.

4 INSTALLATION

No special precautions are necessary when starting up the ***Coatron M1***.
However, the following is recommended:

- Place on a level surface in an area free from excessive temperature fluctuations
- Avoid vibration during measurement
- Protect the instrument from direct sunlight, moisture and dust
- Check that the voltage and frequency data on the identification plate on the instrument agree with the local power rating before starting the instrument for the first time

The instrument is connected to the power supply by the main cable supplied. If obvious damage has occurred during shipping, ***do not use***. Contact your local distributor for replacement or repair.



Note: When the printer is connected to the *Coatron M1.*, both the printer and the instrument must be turned on. The printer interface must set to serial, 2400 Baud, 8 Databit, 1 Stopbit, no parity.

4.1 Equipment

Standard delivery package

- 1 Pc **Coatron M1**
- 1 Pc Power Supply
- 25 Pcs Single cuvettes
- 5 Pcs Reagent tubes
- 2 Pcs Reagent adaptors
- 1 Pc Operation Manual
- 1 Pc Warranty card

Figure 1 standard equipment

Optional available:

- Thermal Printer
- Printer cable
- Adjustable Pipette 10 -100 µl, non-electronic
- Micropipettes 15µl, 25µl, 50µl

4.2 Overview

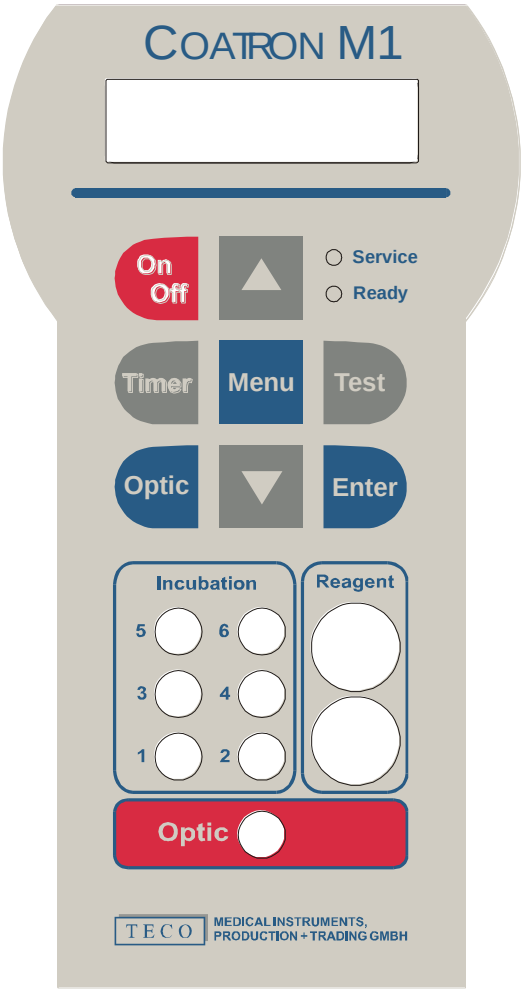


Figure 2 Front panel

Display
2x16 characters

Service
Red LED to indicates system failure and temperature not in correct range (36° to 39° C)

Ready
Green LED for system ready to operate

Cursor keys
change active parameter

Menu
Calibration of active test

Enter
confirm active parameter

Timer
start, stop, reset

Optic key
Activates start, stop measurement

Incubation
37°C warmed positions for 6 cuvettes

Reagent
37°C warmed positions for 2 reagent tubes
∅ 11mm

Optic Position
Measurement position 37°C warm.

4.3 Technical Data

Dimension (LxBxH):	245 x 130 x 60 cm
Weight:	0,51 kg (without power supply)
Ambient Temperature:	18 - 23°C
Power Supply	Input : 90-264 V~ Output : 12 V, 1.0 A
Device:	Micro controller Board 14 Bit ADC ; On-chip controlling of LCD, RS232, Keyboard, Charging, Temperature, Optic.
Interface:	Serial - 2400 Baud, 8 Bits, 1 Stop, No parity used in print or debug mode.
Optic Cell:	Photometer with pulsed 400 nm LED's Variable pulse modulation. Variable detector amplification. Linear Range 0.001 - 1.000 OD
Keyboard:	Foil keyboard with 8 keys and 2 LED's
Display:	2 lines x 16 Characters, Liquid Crystal
Incubation block:	1 measuring, 6 sample, 2 reagent wells; warmed at 37°C.

4.4 Declaration of conformity

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 das Produkt – IVD-Blutgerinnungsmessgerät,
declare under our own responsibility, that the product – IVD Coagulation analyzer

Coatron M1

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

allen anwendbaren Anforderungen der folgenden Richtlinien entspricht:	*meets all applicable requirements of:*
1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte"	*1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"*
2. Richtlinie 2004/108/EG über Elektromagnetische Verträglichkeit	*2. Directive 2004/108/EC on electromagnetic Compatibility*
Das QM-System des Herstellers ist zertifiziert nach:	*The QM-system of the manufacturer is certified for:*
EN ISO 9001:2008 **EN ISO 13485:2003+AC:2009**	***EN ISO 9001:2008*** ***EN ISO 13485:2003+AC:2009***
Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.	*This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of properties.*
Konformitätsbewertungsverfahren:	*Conformity assessment procedure:*
Gemäß Anhang III der Richtlinie 98/79/EG	*According to Annex III of Directive 98/79/EC*

Ort und Datum der Unterzeichnung: Neufahrn, 10.02.2016
Place and date of issue: Neufahrn, February 10, 2016

Gültig bis 01.04.2017
Valid until April 1st, 2017

Christian Hötzl
General Manager

5 Theory of operation

The ***Coatron M1*** is a highly sensitive single channel photometer. A very intensive laser LED-Optic at 400 nm ensures accurate and precise results, even when icteric or lipemic samples are used. The receiver signal is detected and converted to an electrical current. During the actual test the system is searching for the best signal amplification. The software algorithms are based on optical density (extinction), which absorbs outside light effects.

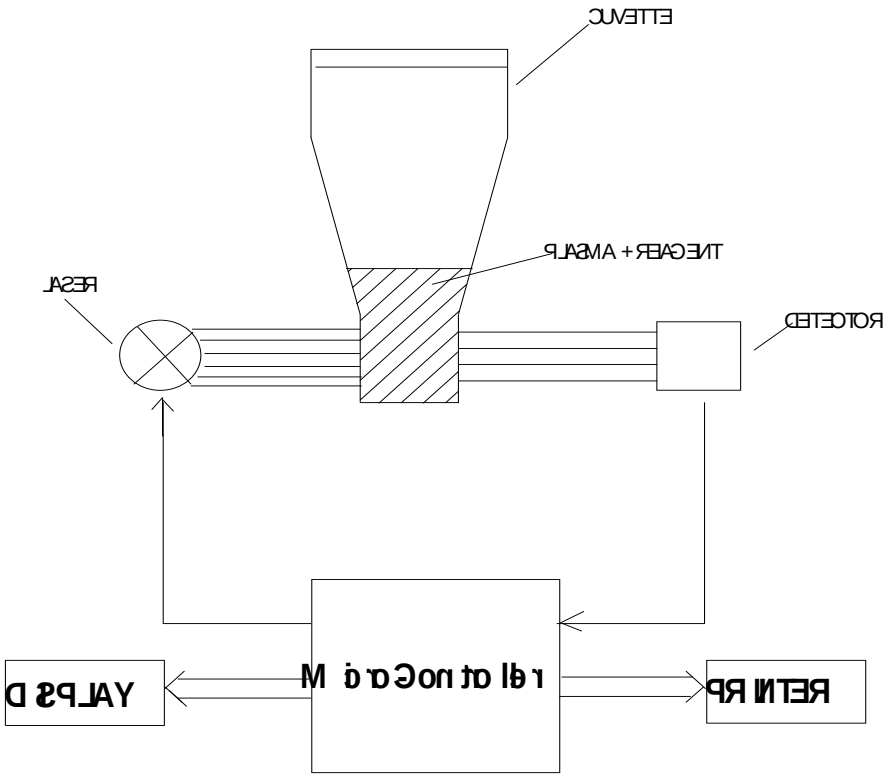


Figure 3 detection principle

Plasma/blood and reagent absorb the transmitted laser light. The rate of absorbency is obtained by the detector and sent to the micro controller. Here a program analyses the signal and send the result to the display and printer (optional).

5.1 Turbidity Method (Clotting Method)

The thrombin catalyzed conversion of Fibrinogen to fibrin is the final reaction in the 'coagulation cascade'. Fibrin formation results in an increase in sample turbidity which is detected by the photometer. Photometric detection is started automatically by adding the start reagent. The time between the start of the photometric detection, and the turning point of the reaction curve (see Figure) is the result. The result is displayed in seconds on the Liquid Crystal Display (and printed automatically to the optional printer.)

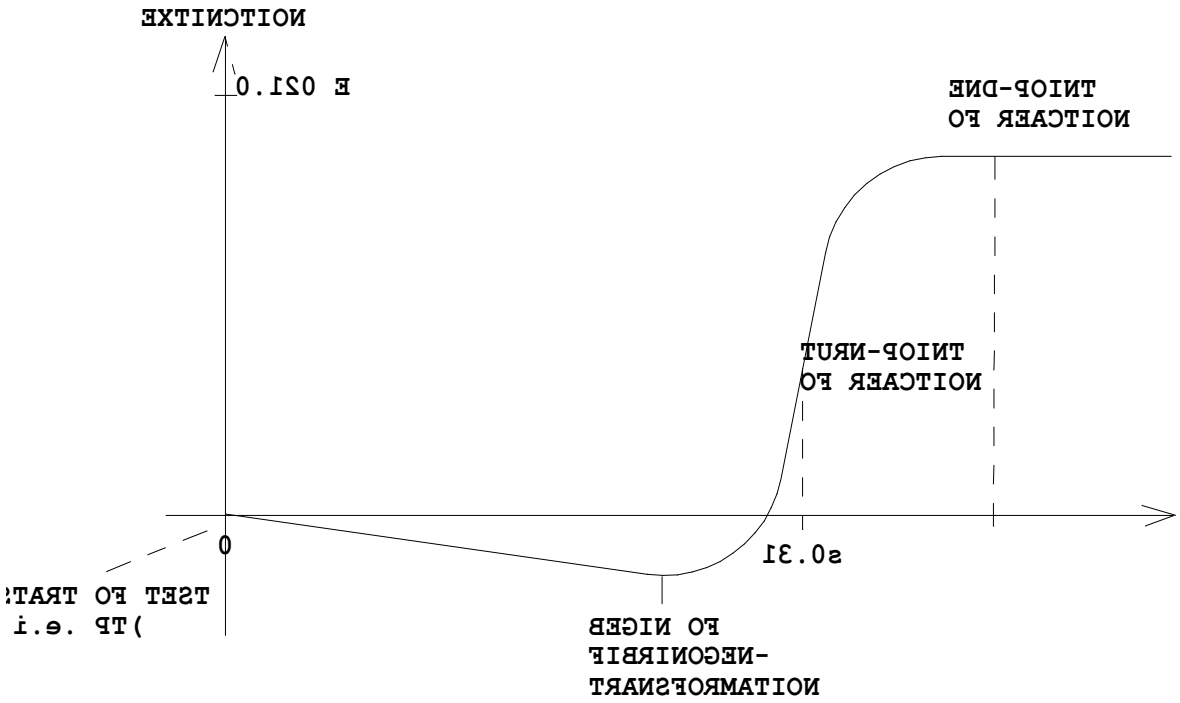


Figure 4 Clotting curve

The diagram is representative of a typical PT curve with normal control plasma. At ~10 sec the liquid plasma starts to clot. This process ends at the „end-point". The plasma is agglutinated by fibrin-monomers. The maximum kinetic of the reaction (turn-point) is defined as clotting time and displayed. INR and/or %-activity will be displayed and printed if calibration data are entered.

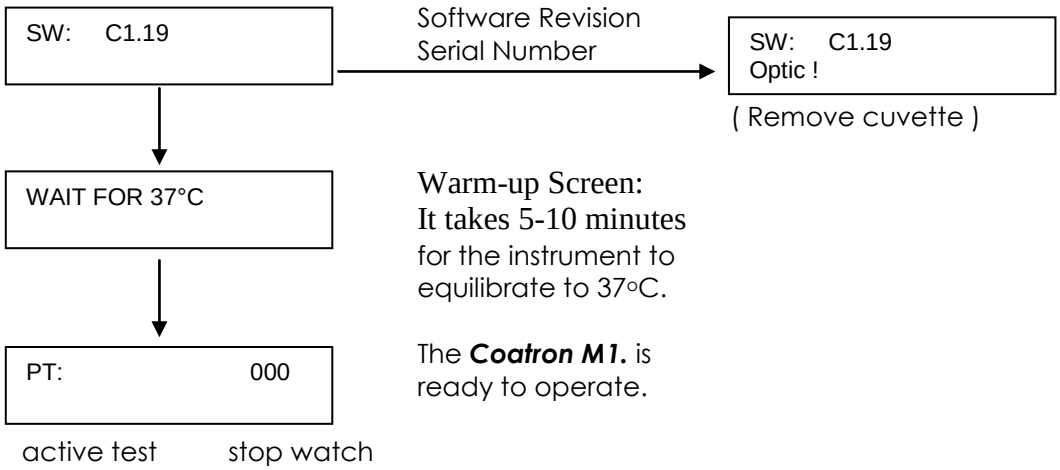
6 Operation Instruction

This section provides general instructions necessary for the user to achieve maximal use and benefit from the ***Coatron M1***.

⇨ For specific test applications refer to sections 7.

6.1 WARM UP

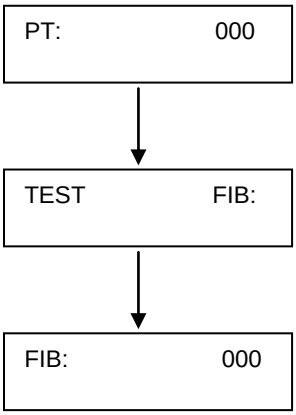
Remove cuvette from optic and power on the instrument.
The first visible screen give the operator the information of the installed software before change to the warm-up screen. If low optic values are encountered during bootup, then the message 'OPTIC" is display for two seconds before restarting the device. Check if no cuvette is in the optics.



Remove cuvette before power up !

Do not operate on the instrument until the red LED light is on.

6.2 TEST SELECTION



Enter test selection with ***key „Test“.***

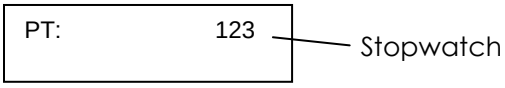
Change active test with ***cursor keys***.

Confirm active test with ***key „Enter“***.

To alternate between the tests, press key „***Test“*** to activate test selection, ***cursor keys*** to change and key ***Enter*** to confirm**.**

6.3 STOPWATCH

A stop watch function helps the operator to control the correct incubation times. The timer stops after 999s automatically.



To start the stopwatch press ***key „Timer“.***
To stop and reset press ***key „Timer“*** again.

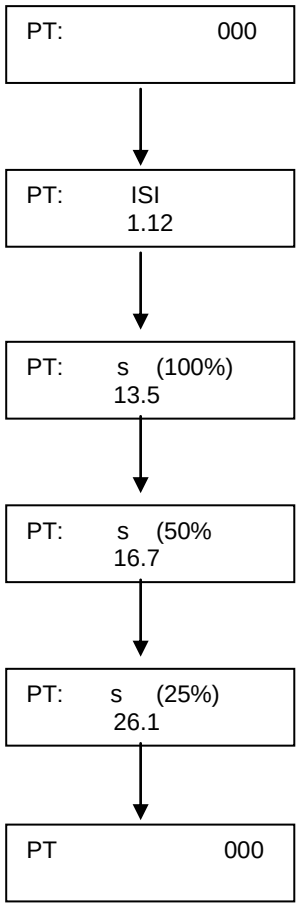
6.4 CALIBRATION

Calibration data are required if the instrument should display the result in % , INR or units.
The specific parameters for the tests can be entered and stored into the ***Coatron M1.***.
Upto 3 calibration points can be entered. Set calibration point zero if not used.

Change of values:

The initial change of value will in- or decrease the number firstly by 10. A change in direction will then change the number by 1.
Example: The change of ISI from 1.12 to 1.40:

- Press "key UP" 3xtime. The ISI will change to 1.22 , 1.32 and 1.42
- Press "key DOWN" 2xtime. The ISI will change to 1.41 , 1.40



Enter calibration with ***key „Menu".***

Change ISI with ***cursor keys***. Confirm with „***Enter"***

Change normal time with ***cursor keys***. Confirm with „***Enter"***

Change with ***cursor keys***. If value=0 → no activity Confirm with „***Enter"***

Change with ***cursor keys***. If value=0 → no activity Confirm with „***Enter"***

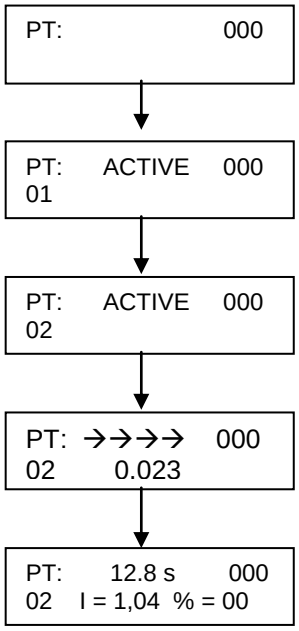
active test is calibrated.

Default values of tests:

PT:	ISI = 1.10	(1) 100% (Normal) = 13.5 s	(2) 50% = 16,7 s (3) 25% = 26.1 s
PTT:	Normal = 30.0 s		
TT:	Normal = 15.0 s		
FIB:	(1) 300 mg/dL = 12.0 s	(2) 150 mg/dL = 23.0 s	(3) 75 mg/dL = 36.0 s
FAC:	(1) 100 % = 32.5 s	(2) 10 % = 60.0 s	(3) 5 % = 70.0 s
DD:	(1) 1600 ng/ml = 150 mOD	(2) 200 ng/ml = 30 mOD	(3) 0 ng/ml = 0 mOD

6.5 MEASUREMENT

Prepare and place the cuvette in the measurement position.



Activate the optic with
key „Optic“.

change test ID number with keys **UP** or **DOWN**

the measurement starts automatically with the addition of reagent. In case of troubles: press key „Optic“ to start

the measurement is running.
Don't touch the cuvette during a run !
Value in the second line show the Optical density in [OD]

If a clot is found, the result is displayed and printed (if printer is connected)
(% = 00, if 25% value is set as zero !!!)

Before activating the channel the cuvette must be inserted into the measuring position and ready to add the start reagent. Press key "OPTIC" to activate the channel. Message "WAIT" indicates, that the instrument calibrates the optic to the actual optical value.

If "ACTIVE" is displayed on the screen, the measurement is ready to start. The actual result ID is also displayed. The ID value can be changed with the cursor keys.

If the optical value changes from the "trigger" value (e.g. by adding reagent), the measurement will start. The start can be also triggered by pressing the key "OPTIC".

Once started a small beeping noise is followed by a scrolling arrow. The current light absorbance (OD) can be read on the display. Avoid contact with the cuvette while this message is shown. A beeping noise will sound again when a clot-reaction was detect and the result will be displayed. If a printer is attached, the result will be also printed. If the clot reaction needs more than the maximum reading time of 300 s, the optic will stop and display „+++.+“, which means „no clot detected“

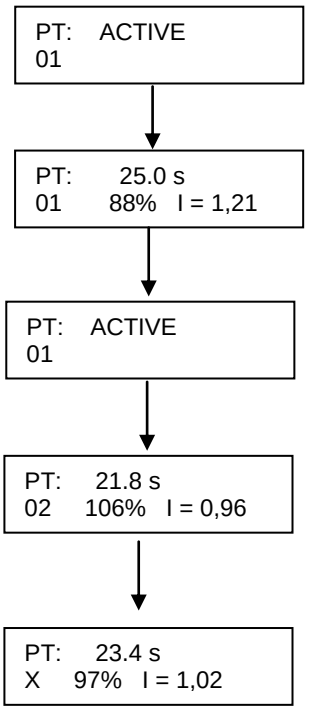
⇨ **The measurement can be canceled by pressing key „Optic“ again**

⇨ **Autostart:**
The measurement will start automatically by adding of reagent, when the optic is set to active. For the some tests (i.e. Fibrinogen, Thrombin) this feature is not working properly because the change of signal is too small. In this case pipet strong and quick or press key "optic" in addition.

The sensitivity of autostart can be adjusted for each test within the service menu. Refer to section service for more information.

6.6 DOUBLE DETERMINATION

Activate the optic and start the measurement. When the result is displayed, activate the optic again and duplicate the result ID number with the cursor keys. Start the measurement. The following result will be displayed for 3 seconds. Then the instrument will display the mean value.



activate optic

result 1

activate optic and duplicate result ID number

result 2

Three seconds later the mean result is displayed. The flag "X" indicates that the double values differ miore than 15%

⇨ The mean value of units, % or INR is derived from the mean-result (s,E)

7 PT – Determination

SUMMARY
The Prothrombin Time test, as originally devised by Quick, has been widely used for a number of years as a pre-surgical screen for assessing certain coagulation factors and in monitoring oral anticoagulant therapy. All Stage II and III factors are necessary for normal results when performing the Prothrombin Time Test, so it is sensitive to reduced levels or deficiencies in Factors I, II, V, VII and X. Dicumerol and related drugs reduce the activity of the so-called "Prothrombin complex" Factors, II, VII, IX and X. Since the Prothrombin Time test is sensitive to deficiencies of all these Factors, except IX, it has proven useful in monitoring oral anticoagulant therapy. The Prothrombin Time test is also used in the quantitative determination (Factor Assays) of Factors II, V, VII and X.

PRINCIPLE
The one stage Prothrombin Time measures the clotting time of test plasma after the addition of Thromboplastin reagent containing Calcium chloride. The reagent supplies a source of "tissue thromboplastin", activating Factor VII, and is therefore sensitive to all Stage II and III Factors. Deficiencies of Stage I Factors (VIII, IX, XI, and XII) are not detected by the test.

INTERNATIONAL SENSITIVITY INDEX (ISI)
International Committee for Standardization in Hematology and the International Committee on Thrombosis and Hemostasis have agreed on recommendations for the reporting of Prothrombin Time results based upon an International Sensitivity Index (ISI) of Thromboplastin reagents and an International Normalized Ratio (INR). Thromboplastin reagents are assigned an ISI value by calibration against an International Reference Preparation, (IRP, 67/40) which by definition has an ISI = 1.0. The ISI value assigned to commercial Thromboplastin reagents therefore defines a comparative slope, or relative sensitivity, in comparison to the Reference Thromboplastin. The lower the ISI value, the more "sensitive" the reagent. By knowing the ISI of a particular Thromboplastin reagent, the ratio can be calculated which would have been found if the IRP 67/40 had been used as the reagent.

This is termed the International Normalized Ratio (INR), and is determined by:

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

Each PT Reagent of TECO is assigned an ISI value in relationship to the WHO Standardized Thromboplastin.

PREPARATION

A. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Plasma Collection

1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min. using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hr, otherwise store frozen and thaw just prior to use.

C. Reagent Reconstitution

Reconstitute with high purity water at the volume stated on the vial label. Let stand at room temperature with occasional swirling until solution is complete. Stable for 7 days after reconstitution when stored at 2-8°C, avoid prolonged heating.

D. Coatron M1 Preparation

1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "PT" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

PROCEDURE ON Coatron M1

1. Pipette **25µl plasma** finto cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press **key „Optic"**)
5. Add **50 µl prewarmed Thromboplastin** and simultaneously start the optic. (press **key „Optic" again**)
6. The instrument will read maximal 300 secs. If no clot is detected, the display will read **„+++.+ s"**
7. The result is displayed in seconds and INR.

ASSAY CALIBRATION

For INR-calibration of PT two parameter are required.

The **normal value** (determine PT normal value with Calibrator Normal.- expected range is between 11 to 14 s)

The **ISI value** (read ISI value on the label of the reagent vial)

Enter both values into the **Coatron M1**.

QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determines the allowable variation in day to day performance of each Control Plasma.

EXPECTED RESULTS OF CONTROLS:

Control Normal	0.8 - 1,3 INR
Control A1	2,0 - 3,5 INR
Control A2	5.0 - 8,0 INR

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

8 PTT – Determination

SUMMARY
From its origins through the work of Langdell and coworkers, and later modified by others, the Activated Partial Thromboplastin Time test has been widely used for a number of years as a pre-surgical screen for assessing certain coagulation factors and in monitoring Heparin therapy. All Factors of the Intrinsic Pathway are necessary for normal results when performing the APTT test. It is used principally, however, to detect deficiencies in the Stage I Factors, namely Factors VIII, IX, XI and XII, as well as Fletcher Factor. The APTT test is also used to monitor Heparin therapy, showing prolonged test results at approximately 0.1 units and above. The test is also used in the quantitative determination (Factor Assays) of Factors VIII, IX, XI, XII and Fletcher Factor.

PRINCIPLE
The APTT test measures the clotting time of test plasma after the addition of APTT reagent, then allowing an "activation time", followed by the addition of calcium chloride. Deficiencies of approximately 40% and lower of Factors VIII, IX, XI and XII will result in a prolonged APTT. Heparin, in the presence of adequate amounts of AT-III will also result in a prolonged APTT.

REAGENT
APTT Reagent
Calcium Chloride

PREPARATION
A. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Specimen Collection (See, for example, Ref. 7)
1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hours, otherwise store frozen and thaw just prior to use.

C. Reagent reconstitution
Bring to room temperature prior to use. Mix well by swirling or inversion and maintain a stir bar in reagent container during use to avoid the particle activator from settling out. Avoid prolonged heating.

D. Coatron M1 Preparation
1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "PTT" as active test
4. Allow $CaCl_2$ to prewarm at least 5 min.

ASSAY CALIBRATION
PTT results should normalized against a normal value, which is obtained from a PTT of Calibrator Normal.- expected range: see box insert of Calibrator.

Enter the normal value into the **Coatron M1**. The PTT is then displayed in seconds and normalized into Ratio.

PROCEDURE ON Coatron M1

1. Pipette **25µl plasma** into cuvette
2. Add **25 µl APTT** to plasma
3. Incubate exactly for ***5 minutes***
4. Transfer cuvette to measuring position
5. Activate optic (press **key „Optic"**)
6. Add **25 µl prewarmed Calcium Chloride** and simultaneously start the optic. (press **key „Optic" again**)
7. The instrument will read maximal 300 secs. If no clot is detected, the display will read **„+++.+ s"**
8. The result is displayed in seconds and Ratio

QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control Plasma.

EXPECTED RESULTS OF CONTROLS:

Control Normal	0.8 - 1,2 Ratio
Control A1	1,5 - 2,0 Ratio
Control A2	2,0 - 3,0 Ratio

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

9 FIB – Determination

SUMMARY

The enzyme, Thrombin, is the penultimate protein in the clotting sequence, acting upon soluble Fibrinogen and converting it to insoluble Fibrin. Normal plasma Fibrinogen levels range from 200-400 mg/dl, although levels as low as 10-20 mg/dl may occur in acquired or congenital hypofibrinogenemia. The determination of plasma Fibrinogen levels has proven to be a useful test in the diagnosis of hemorrhagic disorders relating to plasma Fibrinogen content. These include hyperfibrinogenemia, hypofibrinogenemia, dysfibrinogenemia and a fibrinogenemia.

PRINCIPLE

The FIB reagent utilizes the Clauss clotting time method for the determination of plasma Fibrinogen levels, wherein excess Bovine Thrombin is used to clot diluted plasma. First, a standard curve is prepared using a reference plasma of known Fibrinogen content (Calibrator Normal). When Thrombin is added, the clotting time obtained is inversely proportional to the Fibrinogen content. Next, patient plasma, at a dilution of 1/10, is clotted with Thrombin and the resultant clotting time used to interpolate Fibrinogen level from the standard curve.

REAGENT

Fibrinogen Reagent
Dilution Buffer (IBS) or Owrens buffer

PREPARATION

B. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Plasma Collection

1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min. using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hr, otherwise store frozen and thaw just prior to use.

D. Reagent Reconstitution

Reconstitute with high purity water at the volume stated on the vial label. Let stand at room temperature with occasional swirling until solution is complete. Stable for 5 days after reconstitution when stored at 2-8°C, avoid prolonged heating.

D. Sample Preparation

Dilute sample 1:10 with IBS
(1 part sample + 9 part of dilution buffer)

E. Coatron M1 Preparation

1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "FIB" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

ASSAY CALIBRATION

For the calibration of Fibrinogen, two (max three) parameters are required.
The clotting time of Calibrator Normal in the dilutions 1:10, 1:20, 1:40
Read the fibrinogen concentration on the label of the reagent vial

A typical calibration would be 300 mg/dL = 9.2 s
150 mg/dL = 25.0 s
75 mg/dL = 38.0

Enter all values into the **Coatron M1**.

PROCEDURE ON Coatron M1

1. Pipette **50µl plasma dilution (1:10 with IBS)** into cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press **key „Optic"**)
5. Add **25 µl Thrombin** and simultaneously start the optic.
   (press **key „Optic" again**)
6. The instrument will read maximal 60 secs.
7. The result is displayed in seconds and mg/dL.

QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples.

EXPECTED RESULTS OF CONTROLS:

See individual values of the used Control plasma in the box insert

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

10 TT – Determination

SUMMARY
The enzyme Thrombin is the penultimate protein in the clotting sequence, acting upon soluble fibrinogen and converting it to insoluble fibrin. As a reagent, Thrombin has proven useful in the laboratory evaluation of may fibrinogen disorders, including hypofibrinogenemia and dysfibrinogenemia. A prolonged Thrombin clotting time will result at Fibrinogen levels of about 100 mg/dL and below. Nonfunctional fibrinogen molecules (dysfibrinogenemia) will also result in a prolonged Thrombin Time. Heparin, in the presence of adequate amounts of AT-III, will also produce a prolonged Thrombin Time.

REAGENT
Bovine Thrombin Reagent

PREPARATION

A. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Plasma Collection
1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min. using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hr, otherwise store frozen and thaw just prior to use.

C. Reagent Reconstitution
Reconstitute with high purity water at the volume stated on the vial label. Let stand at room temperature with occasional swirling until solution is complete. Avoid prolonged heating.

D. Coatron M1 Preparation
1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "TT" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

PROCEDURE ON Coatron M1

1. Pipette **50µl plasma sample** into cuvette
2. Prewarm plasma for 1 min
3. Transfer cuvette to measuring position
4. Activate optic (press **key „Optic“**)
5. Add **50 µl Bovine Thrombin** and simultaneously start the optic. (press **key „Optic“ again**)
6. The instrument will read maximal 300 secs.
7. The result is displayed in seconds and Ratio.

ASSAY CALIBRATION

TT results should normalized against a normal value, which is obtained from a TT of Calibrator Normal.- expected range 13-17s.

Enter the normal value into the **Coatron M1**. The TT is then displayed in seconds and normalized into Ratio.

QUALITY CONTROL

Control plasma should be tested in conjunction with patient samples. It is recommended that at least one Normal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determine the allowable variation in day to day performance of each Control plasma.

EXPECTED RESULTS OF CONTROL:

Control Normal 0,8 - 1,2 Ratio

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5% repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

11 Factor Extrinsic Determination

(Factors II,.V, VII, X)

SUMMARY:
Disfunctions of the extrinsic coagulation pathway are indicated by prolonged Prothrombin Time (PT). The activity of an extrinsic pathway factor (Factors II, V, VII, X) is determined with a PT of the test plasma mixed with factor deficient plasma.

REAGENT
Thromboplastin Reagent

DEFICIENT PLASMA
Deficient Plasma F II
Deficient Plasma F V
Deficient Plasma F VII
Deficient Plasma F X

PREPARATION

A. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Plasma Collection

1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min. using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hr, otherwise store frozen and thaw just prior to use.

C. Reagent Reconstitution

Reconstitute with high purity water at the volume stated on the vial label. Let stand at room temperature with occasional swirling until solution is complete. Avoid prolonged heating.

D. Sample Preparation

Dilute sample 1:10 with IBS
(1 part sample + 9 part of dilution buffer)

E. Coatron M1 Preparation

1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "FAC" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

PROCEDURE ON Coatron M1

1. Pipette **25µl 1:10 plasma dilution** into cuvette
2. Pipette **25µl deficient plasma** into cuvette
3. Incubate for 1 min
4. Transfer cuvette to measuring position and Activate optic (press **key „Optic"**)
5. Add **50 µl prewarmed Thromboplastin** and simultaneously start the optic (press **key „Optic"**)
6. The instrument will read maximal 300 secs. If no clot is detected, the display will read **„+++.+ s"**
7. The result is displayed in seconds and activity %.

ASSAY CALIBRATION

For Activity %-calibration of a factor two (max three) calibration points are required.

Prepare standards according to recommendation:
- **1:10 plasma dilution** (~ 100 % activity)
  Mix 1 part Calibrator Normal with 9 parts IBS
- **1:100 plasma dilution** (~ 10 % activity)
  Mix 1 part Calibrator Normal with 99 parts IBS
- **1:200 plasma dilution** (~ 5 % activity)
  Mix 1 part Calibrator Normal with 199 parts IBS

Determine the clotting time for both samples and enter the values into the **Coatron M1**.

QUALITY CONTROL

Calibrator Abnormal should be tested in conjunction with patient samples. It is recommended that at least one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determines the allowable variation in day to day performance of each Control Plasma.

EXPECTED RESULTS OF CONTROL :

Calibrator Abnormal 40 - 60 % factor activity

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

12 Factor Intrinsic Determination

Factors VIII, IX, XI, XII

SUMMARY:
Disfunctions of the intrinsic coagulation pathway are indicated by prolonged PTT. The activity of an intrinsic pathway factor (Factors VIII, XI, XI, XII) is determined with a PTT of the test plasma mixed with factor deficient plasma.

REAGENT
APTT-Reagent
Calcium Chloride

DEFICIENT PLASMA
Deficient Plasma F VIII
Deficient Plasma F IX
Deficient Plasma F XI
Deficient Plasma F XII

PREPARATION

A. Anticoagulant. Use buffered sodium citrate, 3.8% or 3.2%.

B. Plasma Collection
1. Obtain venous blood by clean venipuncture.
2. Immediately mix 9 parts blood with 1 part anticoagulant, mix well by inversion of tube against the stopper.
3. Centrifuge the specimen at 1000 rcf for 15 min.
4. Remove plasma from the tube within 60 min. using a plastic pipette and store in a plastic tube.
5. Test plasma sample within 2 hr, otherwise store frozen and thaw just prior to use.

C. Reagent Reconstitution
Reconstitute with high purity water at the volume stated on the vial label. Let stand at room temperature with occasional swirling until solution is complete. Avoid prolonged heating.

D. Sample Preparation
Dilute sample 1:10 with IBS
(1 part sample + 9 part of dilution buffer)

E. Coatron M1 Preparation
1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
3. Select "FAC" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

PROCEDURE ON Coatron M1

1. Pipette **25µl 1:10 plasma dilution** into cuvette
2. Pipette **25µl deficient plasma** into cuvette
3. Pipette **50µl APTT reagent** into cuvette
4. Incubate exactly 5 min
5. Transfer cuvette to measuring position and Activate optic (press **key „Optic"**)
6. Add **50 µl prewarmed $CaCl_2$** and simultaneously start the optic (press **key „Optic" again**)
6. The instrument will read maximal 300 secs. If no clot is detected, the display will read **„+++.+ s"**
7. The result is displayed in seconds and activity %.

ASSAY CALIBRATION

For Activity %-calibration of a factor two calibration points are required.

Prepare standards according to recommendation:
- **1:10 plasma dilution** (~ 100 % activity)
  Mix 1 part Calibrator Normal with 9 parts LBS
- **1:100 plasma dilution** (~ 10 % activity)
  Mix 1 part Calibrator Normal with 99 parts LBS
- **1:200 plasma dilution** (~ 5 % activity)
  Mix 1 part Calibrator Normal with 199 parts IBS

Determine the PTT clotting time for both samples and enter the values into the **Coatron M1**.

QUALITY CONTROL

Calibrator Normal and Calibrator Abnormal should be tested in conjunction with patient samples. It is recommended that at least one Normal and one Abnormal be run at least each shift and a minimum of once per 20 patient samples. A Control Range should be established by the laboratory to determines the allowable variation in day to day performance of each Control Plasma.

EXPECTED RESULTS OF CONTROL :

Calibrator Abnormal 40 - 60 % factor activity

APPLICATION RECOMMENDATIONS

1. Don't use glass. Use only plastic.
2. Don't delay mixing of blood with anticoagulant.
3. Avoid extreme hemolysis or lipemic samples.
4. Avoid plasma contamination with tissue thromboplastin.
5. Avoid improper ratio of anticoagulant with blood.
6. Run patient samples in duplicate. At differences greater than 5 % repeat testing.
7. Run quality controls regularly to confirm reagent + instrument functionality.
8. Don't run a test if the green LED is off.

13 D-dimer determination

REAGENT
Blue D-Dimer LC Kit, liquid reagent, ready to use

Intended Use
Blue D-dimer LC reagent is a micro-particle enhanced immunoassay for quantitative determination of D-dimer in human blood plasma. Blue D-dimer is intended for automated coagulation and clinical laboratory instruments, using either turbidimetric or nephelometric detection in the 350 – 550 nm wavelength range.

Specimen collection
- Obtain venous blood by clean vein puncture.
- Immediately mix 9 parts blood with 1 part 3.2% sodium citrate (0.105M) and mix well
- Centrifuge the specimen at 1500g for 10 min. (platelet < 10000/µL)
- Separate plasma after centrifugation and store in plastic or siliconised glass tube.
- Use plasma within 8 hours, otherwise store frozen and thaw just prior to use.

Coatron M1 Preparation
1. Turn on instrument and wait until the ready LED is lighting.
2. Turn on printer if connected
2. Place Latex reagent into prewarm position
3. Select "DD" as active test
4. Check calibration
5. Allow reagent to prewarm at least 5 min.

Quality control
To maintain consistent assay results, it is recommended that control plasmas are assayed at regular intervals.

Procedure on Coatron M1

1. Pipette **25µl plasma** into cuvette
2. Pipette **50µl rection buffer** into cuvette
3. Incubate for 2-10min
4. Transfer cuvette to measuring position and activate optic (press **key „Optic"**)
5. Add **75µl prewarmed Latex reagent.** Insert yellow tip into cuvette and mix cuvette by pumping up & down for at least 5.10times. Avoid air bubbles. Stop mixing latest after 15sec.

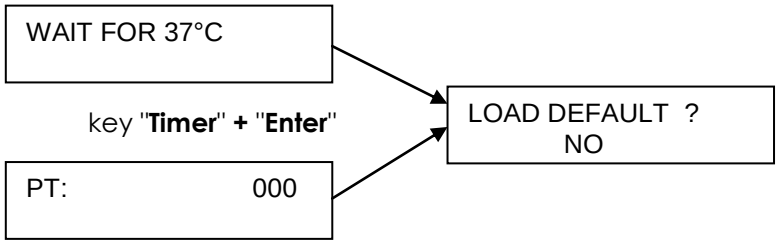
Results
Results below CUT-OFF value can be regarded as D-dimer negative and are typical for normal healthy normal subjects. Elevated levels are observed in causes of PE, DVT (deep venous thrombosis) or DIC or trauma. D-Dimer results can be reported in D-dimer units (DDU) or Fibrinogen Equivalent Units (FEU). 1 FEU is equal to 1.74 DDU. Teco is using DDU in certificates.

CUT-OFF: 200 ng/mL (DDU) Tecontrol N: 150 – 350 ng/mL Tecontrols A: 750- 1250ng/ml

Service

Please read this section in its entirety prior to operating the *Coatron M1*.. In order to ensure accurate and reliable performance of the instrument, only authorized personnel, should perform any service functions on the analyser

To enter the hidden submenu service, press **key "Timer"** and **key "Enter"** simultaneously.



Following service can be performed on the **Coatron M1**

Reset to default values
Temperature Adjustment
OD-Correction
Coag.-Correction
Optic Check
Set Trigger
Set RS232

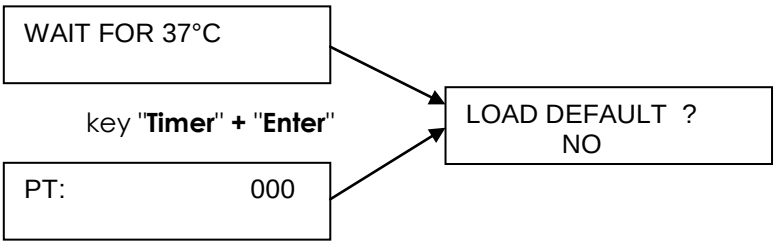
Use the **cursor keys** to change and **key "Enter"** to confirm !

Wrong adjustments will influence the measurement decisively ! Before change anything, be aware of the consequence !

14 Service

Please read this section in its entirety prior to operating the *Coatron M1*.. In order to ensure accurate and reliable performance of the instrument, only authorized personnel, should perform any service functions on the analyser

To enter the hidden submenu service, press **key "Timer"** and **key "Enter"** simultaneously.



Following service can be performed on the **Coatron M1**

Reset to default values
Temperature Adjustment
OD-Correction
Coag.-Correction
Optic Check
Set Trigger
Set RS232

Use the **cursor keys** to change and **key "Enter"** to confirm !

Wrong adjustments will influence the measurement decisively ! Before change anything, be aware of the consequence !

14.1 Default values

The **Coatron M1** can store test and system parameter permanent on board.

Calibration PT:	ISI = 1.10 (1) 100% (Normal) = 12.8 s (2) 50% = 16,7 s (3) 25% = 25.0 s
Calibration PTT:	Normal = 30.0 s
Calibration PT:	Normal = 15.0 s
Calibration FIB:	(1) 300 mg/dL = 12.0 s (2) 150 mg/dL = 23.0s (3) 75 mg/dL = 36.0 s
Calibration FAC:	(1) 100 % = 32.0 s (2) 10 % = 60.0 s (3) 5 % = 70.0 s
Calibration DD:	(1) 1600 ng/ml = 150 mOD (2) 200 ng/ml = 30 mOD (3) 0 ng/ml = 0 mOD
Temperature	°C=370 (9085)
OD Correction PT:	100
OD Correction PTT:	100
OD Correction TT:	100
OD Correction FIB:	100
OD Correction PT:	100
OD Correction FAC:	100
OD Correction DD:	100
Coag Correction PT:	100
Coag Correction PTT:	100
Coag Correction TT:	100
Coag Correction FIB:	100
Coag Correction PT:	100
Coag Correction FAC:	100
Coag Correction DD:	100
Optic check (mw):	approx. 11000 (± 2000)
Autostart Trigger:	300
RS 232 Print Results	(Data->RS232 = NO)

14.2 Temperature Adjustment

The incubation block of the **Coatron M1** have a temperature of 37°C.
When the green LED is on, fill a reagent tube with 1 ml water and place it in a reagent position. Place a (digital thermometer in the reagent tube and let warm-up for approx. 10 min.

Allow to warm for 10 min and read the temperature.

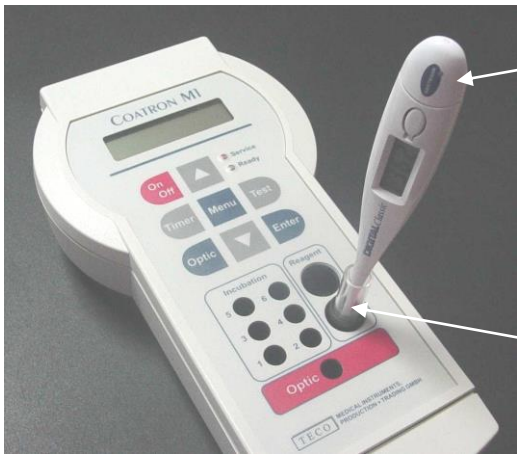
SET TEMPERATURE °C=371 (9000- 9085)

Example: The actual temperature is 37,1°C. The current AD-value is 9000 and the digital target value is 9085.

Compare the temperature displayed by the system and the thermometer. If the temperature is different, adjust the temperature on the **Coatron M1** by pressing the Up/Down cursor keys

Wait until a stable temperature of 37.0°C is displayed on the **Coatron M1**. Check and correct the system temperature if not equivalent to the external thermometer.

Up / Down keys for increase or decrease of temperature



Digital Thermometer
Precision ± 0,1 °C

Reagent tube, prefilled with approx 1ml water

Figure 5 Temperature adjustment

14.3 Result correction

A. OD CORRECTION

OD-CORRECTION
PT = **100**

The measured optical density of the instrument can be corrected by a factor for each test. Therefore it is possible to adapt other reagents.

(OD-Correction = 100 → optical density * 1.00 -> no effect)
(OD-Correction = 120 → optical density * 1.20)

OD-CORRECTION **below 100** will cause:
- longer clotting times
- reduce sensitivity of method (more results as +++.+ s)

OD-CORRECTION **above 100** will cause:
- shorter clotting times
- increase sensitivity of method, which can cause wrong results (short time results !!!!)

B. COAG CORRECTION

COAG-CORRECTION
PT = **100**

With the Coag Correction the instrument can correct the result for better correlation to other systems or reagents.

Example: On other instrument a plasma is measured with PT = 12,1 seconds, on the Coatron M1 result is 11,0 seconds. To get equal results, the result have to be corrected by factor 1,10 (+10%).
This can be done by entering COAG CORRECTION = 110 (Factor 1,10).

OD-CORRECTION for fibrinogen test

Run a 300 mg/dL calibrator. The result should be close to 10 sec. If it is above/below 10sec, in-/decrease the OD-Correction slightly.

CORRECTION for D-Dimer test

OD CORRECTION is used for sensitivity limit. (100 = 100mOD)
COAG CORRECTION is used to set the maximum reading time (100 = 120s)

14.4 Optic Check

The Optic-check is recommend, if problems with measurements arise. Remove cuvette from optic. Ensure that no cuvette is placed in the optic.

mw=11301 81	004

signals high=11301 digital value when optic LED is on

low=81 digital value when optic LED is off

amp=004 actual amplification

Optic calibration: press key "MENU" to recalibrate the optic.
Empty optic before !

- target range high: 10.000 – 15.000
- target range low: 0 - 250
- target range amp: 3-20

Manual change: press key "UP" or "DOWN" to change the amplification

The Optic-check is recommend, if problems with measurements arise. Remove cuvette from optic.

Optic check will fail, if
- optic path is blocked or spilt
- LED is burnt (exchange optic block)
- Controller malfunction (exchange)

14.5 Autostart Trigger

The sensitivity of the autostart feature can be adjusted.
The value is the required optical change before the instrument triggers the measurement start.

SET TRIGGER 300

- The default value is 300.
- Increase value if test does start before adding the reagent
- Decrease value if test does not start at all.
- Set to 0 will disable the autostart for the test

14.6 Interface RS 232

CONNECTED WITH PRINTER

The interface port is set to 2400 Baud, 8 Bits, 1 Stop, No parity

```
DATA → RS232
       NO
```

Example of a result print:

```
01      PT:
  12.6 s
  %=95
  I = 1.03

01      PT:
  13.2 s
  %=85
  I = 1.35

MEAN:
  12.9 s
  %=90
  I = 1.19
```

run #01

run#02

mean

CONNECTED WITH LIS (TECAM SMART SOFTWARE

YES → result will be send to host with following syntax

```
DATA → RS232
       YES
```

CURVE DATA: every 500ms the value of the optical density (eg. "123" = 123mOD)

RESULT DATA: [SYS][SN][TYP][NR][TEST][RES1][SCALE1][RES2][SCALE2][RES3][SCALE3][LF]

Delimiter:	TAB	(for each data field)
SYS:	"D1"	(system id)
SN:	"1234"	(serial number of instrument)
TYP:	"S"/"M"	(Single result or Mean result)
NR:	"12"	(Result ID number)
TEST:	"PTB:"	(name of test)
RES1:	"12.5"	(result 1)
SCALE1:	"s"	(unit 1)
RES2:	"100"	(result 2)
SCALE2:	"%"	(unit 2)
RES3:	"1.00"	(result 3)
SCALE3:	"I"	(unit 3)
LF:	Line feed	

Example: "D1 1234 S 1 PTB: 12.5 s 100 % 1.00 I"

15 Troubleshooting Guide

Note : Always verify instrument performance by testing appropriate control samples.

System Error Message	Interpretation and corrective action
Optic Failure !	During bootup: Low signal detected. Remove cuvette and reboot. If error remain, clean optics or replace LED or replace microcontroller. During service menu: The ***Coatron M1.*** is not operating in its optical specification. This can happen, if: • there is not sufficient light (i.e. with very turbid reagents or lipemic samples). Change to TECO reagent. Avoid extreme samples. • light is too intense (i.e. direct sunlight). Protect against sunlight. Laser LED is burned out. Replace device.
Red Service LED is on	Electrical power is not sufficient. use original power supply load battery-pack, if used
Green Ready LED is off	Temperature is out of range. Wait a few minutes. If error remains contact technical services
Temperature not correct	Adjust the temperature

Test-specific errors	Interpretation and corrective action
+++.+ s **"No Clot Detect"**	Always repeat the sample to verify result Possible reasons include the following: Clotting time is longer than 300 secs Clotting time is shorter than 8 secs Incorrect reagent Fibrinogen level of sample is below 100 mg/dL (i.e. sample dilutions) Air bubbles Debris in cuvette Sample improperly collected OD-Correction is set to zero
Clotting time too short	Always repeat the sample to verify result Possible reasons include the following: Incorrect reagent Air bubbles Debris in cuvette Sample improperly collected Optic is wrong adjusted Action: Use recommended materials Decrease slightly OD-Correction Increase OD-Range
Clotting time too long	Always repeat the sample to verify result Possible reasons include the following: Incorrect reagent Air bubbles Debris in cuvette Low fibrinogen level Sample improperly collected Optic is wrong adjusted Action: Use recommended materials Increase slightly OD-Correction Decrease OD-Range

16 Spare parts & technical drawings

Cat.No.	Product	content	no. on drawing
20 001 02	Casing cpl.	1	1; 2; 3
20 004 01	Power Supply 90-264Vac EU	1	not on drawing
20 004 03	Power Supply 90-264 Vac USA	1	not on drawing
20 005 00	Keyboard	1	4
20 010 01	Display cpl.	1	12
20 006 01	System board	1	11
20 007 01	Transmitter board	1	10
20 008 01	Receiver board	1	9
20 011 00	Mounting plate	1	5
20 012 00	Distance M3x16	1	29
20 013 00	Distance D6xH3	1	18
20 015 01	Optic block (w/o boards)	1	8
20 016 00	Heating foil	1	13
20 017 00	Temperature sensor	1	17
20 018 00	Cable RS232	1	14
20 019 00	Cable DC input	1	15
20 020 00	Heating block	1	6

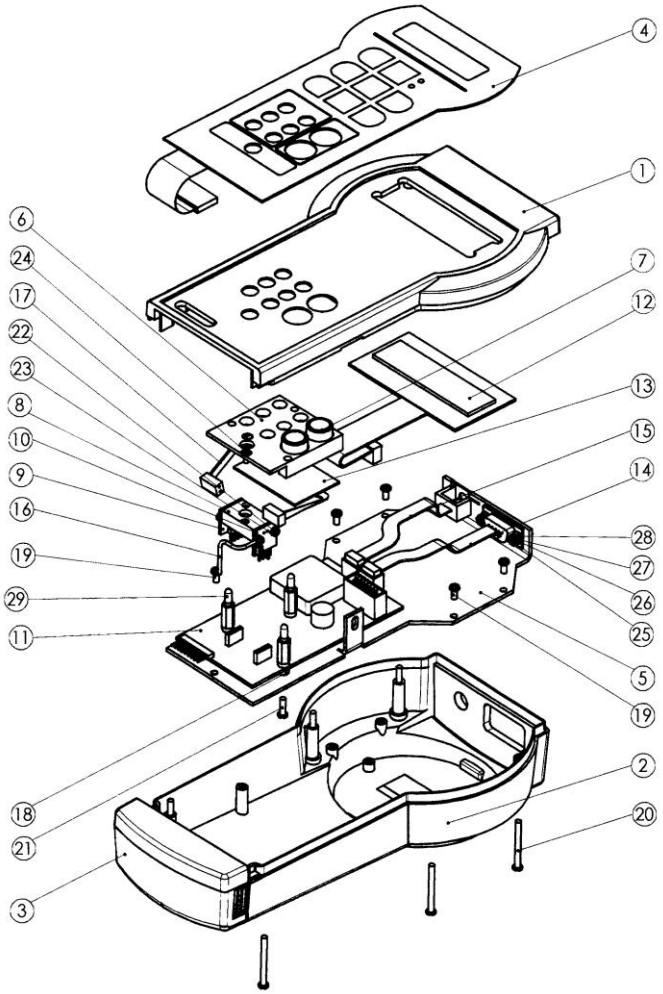


Figure 6 3D explosion drawing