Operation Manual

Coatron M2

For *In-Vitro* Diagnostic use

Instrumentation and reagents for human coagulation and hemostasis

Revision 12
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Warning

This manual is valid for firmware **M2 1.17b**. 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 safety information must be followed.

Copyright

Trademarks

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Software

The software for TECO GmbH products is the intellectual property of TECO GmbH, which company retains all rights to usage of the software. The purchaser of a ***Coatron M2*** 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.

Manufacturer

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The Instrument is made in Germany.

Firmware History Coatron M2

1.09 - First Release

1.10 - 6 dialogue languages introduced
- Autosensitivity for clotting method
- New Fib algorithm
- Result Flag R & S introduced
- OD & coag correction introduced

1.11 – Chromogenic method introduced (requires UV-LED optic upgrade)
- New tests D-Dimer , Eccarin ECAH & ECAT

1.12 – Minor changes and fixes

1.13 – Tecam Smart interface implemented (LIS connection)
- Improved optic check for hi lipemic,bilirubin or other disturbance
- Autostart sensitivity can be adjusted for every test individually
- General improvements of measurements
- D-Dimer can be adjust with time & od correction for any reagent

1.14c – Profile can be set free
– Bugfix Tecam Interface & Print-Out
– Quick test change with keys up/down key
- Results (s,%,INR,..) are scrolled
- Result Flag 'B' (Biphasic aPTT) introduced
- Result Flag 'F' (low fibrinogen) introduced
- new test LA (DRVVT) with automatic ratio calculation
- new test APCR with automatic ratio calculation
- statistic counter for PT,aPTT,FIB,AT,DD and all introduced
- bugfix for high bilirubin samples
- Autostart sensitivity can be set now within SETUP TEST menu

1.15 – D_Dimer adapted to new TECO Blue D-dimer reagent 2008
- Bugfix DD: For zero D-Dimer curves the former system could reboot sometimes

1.16 - Results in units (eg. FIB mg/dL) are displayed
(before it was reported only as "U").
- FIB mg/dL with no decimal point anymore.
- All factors are reported in IU/mL to display, printout and host.
- Sensitivity of clotting algorithm slightly increased - especially
at begin of reaction.
- A press to key MENU during analysis will return to main menu,
if no measurement is running. With former firmware even just
activated channels had blocked the menu.
- Optic amplification is now doubled for extreme turbid samples.
- LED is switched off outside of measurement.
- PS default setup optimized for clotting method.
- Maximum reading time depending method.
For PT based test Maxtime=300s. For aPTT based test Maxtime=450s.
- A press on key "UNIT" after measurement will:
  - stop unit autoscrolling in display
  - restore old result
- Limits for units
  new: %=0-199 U=0-999 (DD=0-5000) I=0.3–15 R=0.3-15
  old: %=3-199 U=0-750 (DD=0-5000) I=0.5–12 R=0.5-9

- Kinetic algorithm can now be adjusted to required time scale by hidden value "COAG Correction".

0% (Default)	means: Endtime=100s	Starttime=Endtime/10 = 10s
100%	means: Endtime=200s	Starttime=Endtime/10 = 20s
-20%	means: Endtime=80s	Starttime=Endtime/10 = 8s

1.16b - Method 100mOD replaced by method "MECHANIK",which defines the clotting time not at the turnpoint but on the begin of the clot reaction. Therefore the results are shorter and more likely to mechanic instruments.
- Method "MECHANIC" is enabled for all clotting tests

1.17 - Barcode scanner improvement:
x Depending on barcode scanner, sometimes the label was read falsely.
x Coatron can now be operated with TECAM(LIS)+Scanner at same time. Before it was either barcode or LIS.
x Barcode label is limited to max. 9 characters
x Barcode can now be input either by scanner or manually at same time.
x A barcode reading event will now activate the next optic channel.

- New method "MECHANIC":
This method is replacing the older method "100mOD".
In principle both method are identical, only the stop limit was changed from 100mOD to 25mOD.Clotting tests (PT,PTT,..) run with method "MECHANIC" (instead of CLOT) will give shorter second results and can be better correlate to mechanical instrument

- TECAM/LIS improvement:
Zero results (eg. D-Dimer= 0ng/mL) were treated before always as no result. Now the Coatron M4 will send differently. As zero without any units,if the result is invalid, otherwise as "<1" with units.
(Example valid zero for DD: 0mE 0ng/mL-> transmission= 0mE <1ng/mL)
(Example invalid zero for PT: sec=+++ 0%-> transmission= 0 0)

- Measurement improvement:
x Better mixing: With old version, the optic was calibrated immediately after start.During this procedure it is not allowed to touch or mix the cuvette.For D-Dimer testing mixing is explicitely required. Now the system calibrate short before end of deadtime.This gives operator much better time window for mixing. Additionally a countdown gives information about time to mix.

x Optic Autosense Calibration
Amplification range is doubled to allow extreme turbid samples

x Calibration mode with key "5"
All channels can now be activated in duplicate mode with key "5". The difference to key "0" or key "." activation is, that the optic is switched to high sensitive mode. This will allow to measure also highest dilutions,like used during calibration.
High sensitive mode is displayed with blinking "CALIBRATE".

1.17b - Key Up/Down during manual input of PID will reset to zero
- Bugfix: Key 5 was read two times during manual input of PID

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Symbols

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.

1.0 Safety Information

Recommend materials
Use only origin disposables.
Use only manufacturer-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.

Environmental condition
Ambient 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.

Electrical 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.

2.0 General

The ***Coatron M2*** is a manual 2 channel photo-optical instrument that offers clotting & chromogenic & immunturbidimetric testing capabilities. The ***Coatron M2*** can be used for a wide variety of coagulation and fibrinolysis tests such as:

• Prothrombin Time (PT) • Activated Prothrombin Time (APTT) • Thrombin Time (TT) • Venom Time (VT) • Fibrinogen (FIB) • Factors (FII - FXII) • Antithrombin (AT3) • Heparin (HEP) • Activated PC resistance (APCR) • Lupus Anticoagulant (Screen, Confirm)	• Protein-C (PC) • Protein-S (PS) • D-Dimer (DD) • von Willebrand Factor (VWF) • Ecarin Chromogenic Assay Thrombin (ECAT) • Ecarin Chromogenic Assay Hirudin (ECAH) • Plasminogen (PLG) • a2-Antiplasmin (A2AP)

FEATURES:

- Coagulation analyser for turbidimetric, chromogenic and immunturbidimetric assays.
- Highly reliable, long life and nearly service free system
- Autosense optics to eliminate interferences like Bilirubin, Haemoglobin
- Approved clotting algorithm for all kind of samples and reagents. If there is a clot - it will be detected.
- Biphasic aPTT waveform curve detection to DIC indication
- Low fibrinogen curve detection
- Fibrinogen concentration can be derived from a PT result additionally. For sure the standard CLAUSS method is also available.
- Calculation in Activity %, INR, Ratio, g/L or mg/dL
- Every test is programmable up to 5 calibration points
- Correlation analyse of calibration curve
- 2 Stop-watch functions which can be used independently
- Multi-language software
  (German, English, Spanish, French, Italian, Portuguese)
- Patient identification (No PID, manual input, autoseries, barcode)
- Test-Duplicate Modus
- Free Profile testing (PT,APTT, FIB)
- APC-R with automatic ratio calculation
- DRVVT with automatic ratio calculation
- Micro volume testing (60 - 75µL)
- Reagent stirring with magnetic bars
- Routines for selftest (trouble-shooting)
- Routines for print outs (result, calibration, service, system)
- Optional autopipette for electronic triggered start
- Automatic Start triggered by adding reagent
- Optional data management and research software
- Optional printer
- Optional barcode scanner for patient identification
- Easy software update
- Interface for Laboratory Information & Management Systems (LIMS)
- CE marked
- Small dimension and weight - fits on every desktop

2.1. Intended purpose

The ***Coatron M2*** 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.).

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 Haemoglobin concentration

The **COATRON M2** must be operated by a specialist, trained in clinical laboratory techniques. The operator needs also training and instruction in operation and must read and understood this Operator's Manual.

2.2. Installation

No special precautions are necessary when starting up the ***Coatron M2***. 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.

2.3. Technical data

Instrument:

Boards	SMD (Small Mounted Devices) based
Microprocessor	NEC V25
Flash-EPROM	128 KByte
RAM	128 KByte
EEPROM	2 KByte
AD-Converter	18 Bit (16 bit used)
Optics	2 LED's ultra bright, pulse modulation control
RS 232	9600 Bauds, 8 Data, 1 Stop, no parity

Power Supply:

external,	
Input voltages	100 Vac to 240 Vac / 47 to 63 Hz
Output voltages	+5Vdc/5A; +15Vdc/2A; -15Vdc/0,8A
approvals	CE EN 60601-1, IEC60601-1, TÜV, UL, RoHS

Keyboard:
3x8 matrix, foil keyboard, with Test, Function and numerical keys

Display:
4 lines x 20 characters Liquid Crystal Display

Incubation block:
6x2 double-cuvette prewarming positions, 2 measuring and 3 reagent positions

Autopipette (optional):
25 / 50 / 100 / 200 µL volume with electronic triggered start

2.4. CE marking

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

TECO

CE

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

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Wir / *We*

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

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

Coatron M2
Bezeichnung, Typ oder Modellname / *name, type or model*

den Anforderungen der folgenden Richtlinien entspricht:	*corresponds to the requirements of:*
1. Richtlinie 98/79/EG über In-vitro Diagnostika klassifiziert gemäß Artikel 9 als: "alle anderen Produkte" 2. Richtlinie 2004/108/EG über Elektromagnetische Verträglichkeit	*1. Directive 98/79/EC on In-vitro diagnostic medical devices classified according to article 9 as: "all other products"* *2. Directive 2004/108/EC on electromagnetic Compatibility*
Zur Beurteilung der Konformität wurden u.a. folgende harmonisierte Normen herangezogen:	The following harmonized standards have been used amongst others:
1. Sicherheit: EN 61010-2-101:2002 Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte	*1. Safety:* *EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for in-vitro diagnostic (IVD)*
2. EMV: EN 61326-2-6:2006 Elektromagnetische Verträglichkeit – Anforderungen	*2. EMC:* *EN* 61326-2-6:2006 *Electromagnetic compatibility – Requirements*
3. Risikomanagement: DIN EN ISO 14971:2012: Medizinprodukte – Anwendung des Risikomanagement auf Medizinprodukte	*3. Risk management:* *DIN EN ISO 14971:2012: Medical devices – Application of risk management to medical devices*
4. Informationen: EN ISO 18113-3:2011: Bereitstellung von Informationen durch den Hersteller – Teil 3: Geräte für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal	*4. Information:* *EN ISO 18113-3:2011: In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 3: In vitro diagnostic instruments for professional use*
Das QM-System des Herstellers ist zertifiziert durch DEKRA Certification, Stuttgart, nach: **EN ISO 9001:2008** **EN ISO 13485:2003+AC:2009**	*The QM-system of the manufacturer is certified from DEKRA Certification, Stuttgart, for:* ***EN ISO 9001:2008*** ***EN ISO 13485:2003+AC:2009***
Diese Erklärung bescheinigt die Übereinstimmung mit den genannten Harmonisierungsrechtsvorschriften, beinhaltet jedoch keine Zusicherung von Eigenschaften.	*This declaration attests the accordance with the mentioned harmonization rule but does not include a warranty of quality.*

Ort und Datum der Unterzeichnung: Neufahrn, 25.03.2013
Place and date of issue: Neufahrn, March 25th, 2013

Christian Hötzl
General Manager

3.0 ***Instrument Components***

3.1. Incubator Block

The incubator block is made from aluminum, which ensures equal distribution of heat. The temperature of the incubator block is regulated to 36.5°C - 37.5°C

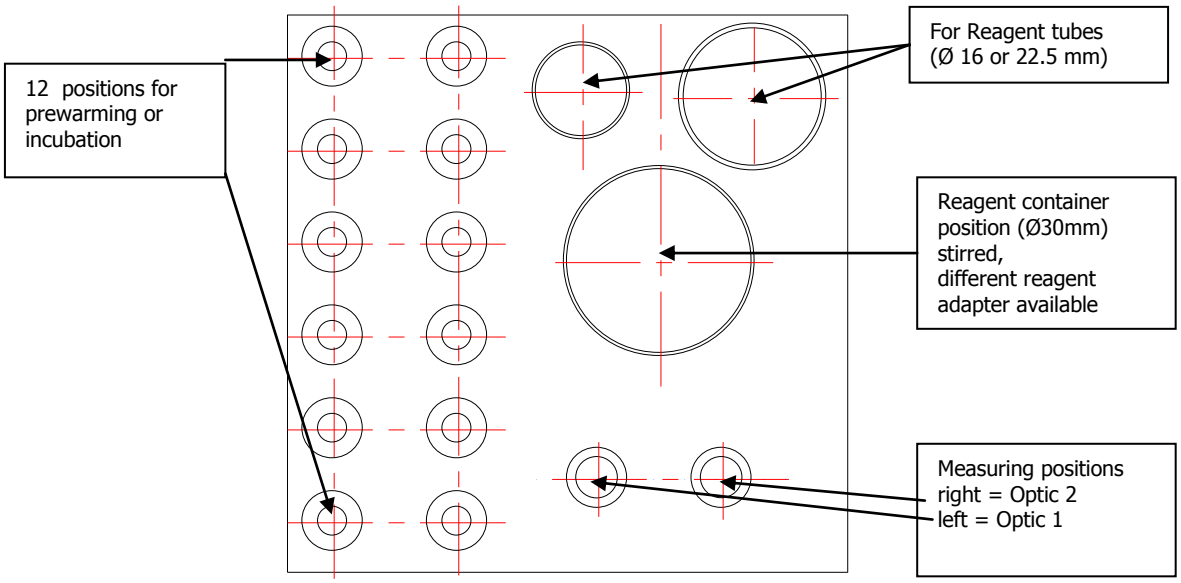
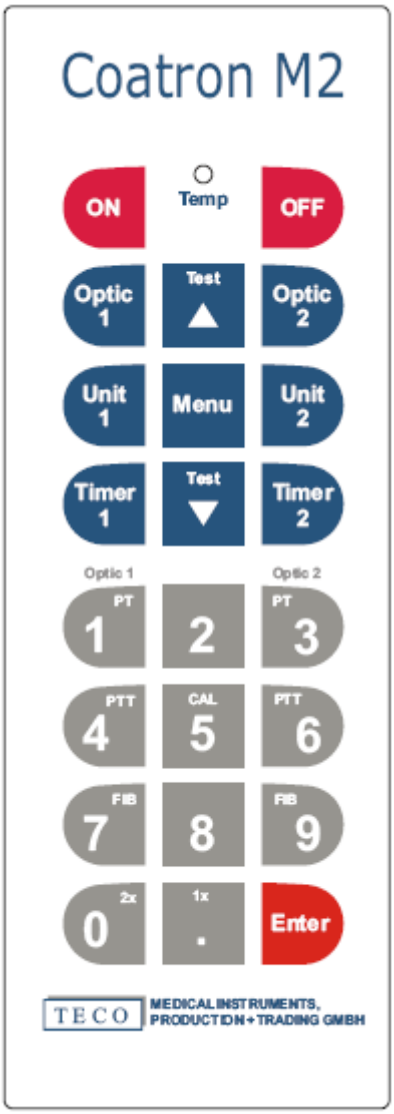


Figure 1- Incubator Block

3.2. Control panel



Temp.	indicates Temperature is in the allowed range of 37°C +/- 0,2°C
ON / OFF	switches on and off the unit
Optic 1 / 2	activate/start/stop channel 1+2
Unit 1 / 2	convert result into other dimensions
Timer 1 / 2	activate Timer function 1 and/or 2
Cursor up/down	Scroll up/down during - Test selection - Parameter selection - Patient-ID increment
Menu	Go back to Main Menu or next Entry or exit menu
Numeric keys	for input of any numbers or direct test code for test selection press - Optic-1: 1(PT), 4(PTT), 7(FIB) - Optic-2: 3(PT), 6(PTT), 9(FIB) for optic activation - "." (1x): Single mode - "0" (2x): Duplicate mode - "5" (CAL): Calibration mode
Enter	confirm entry or jump to next entry

Figure 2 - Control Panel

3.3. Rear of equipment

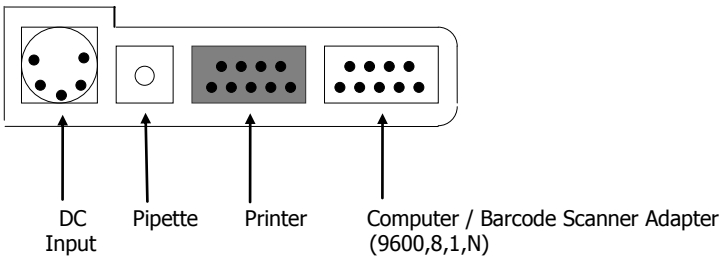


Figure 3 - Rear of Equipment

DC Input: For connector to Power Supply

Pipette: For connector to Autopipette (Cat.No. 19 029 00)

Printer: For connector to Thermal Printer (Cat.No. 80 535 00)

Computer For connector to PC (Firmware upgrading, TECMONI, LIMS) or connector to barcode scanner

3.4. Autopipette (optional)

Optional accessory tool for automatic test start. The pipette supports four different volumes (25, 50, 100 and 200 µL)

3.5. Thermal-Printer (optional)

Optional accessory tool for automatic printout. When the Thermal printer is connected with printer-port of the ***Coatron M2***, following data will be printed automatically:

- Result Print-Out
- Test Parameter Print-Out
- Service-Report Print-Out
- System-Identification Print-Out

3.6. Barcode Scanner (optional)

Optional accessory tool for easy handling of patient identification. Up to 20 characters can be read.

Barcodes with more information will cut off at the maximum length. The barcode-scanner must support a serial interface, set to 9600 Baud, 8 Data, 1 Stop, No parity.

▪ ⇨ **Warning: The barcode-scanner is powered with 5V over PIN 9 of the RS232 Interface of the analyzer. Do only use scanners with that feature.**

4.0 THEORY OF OPERATION

The ***Coatron M2*** is a highly sensitive 2-channel-photometer. A very bright LED-Optic 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, therefore it will support a wide range of different reagents (i.e. very turbid thromboplastins or very clear reagents). Additionally the software is based on optical density (extinction), which absorbs outside light effects.

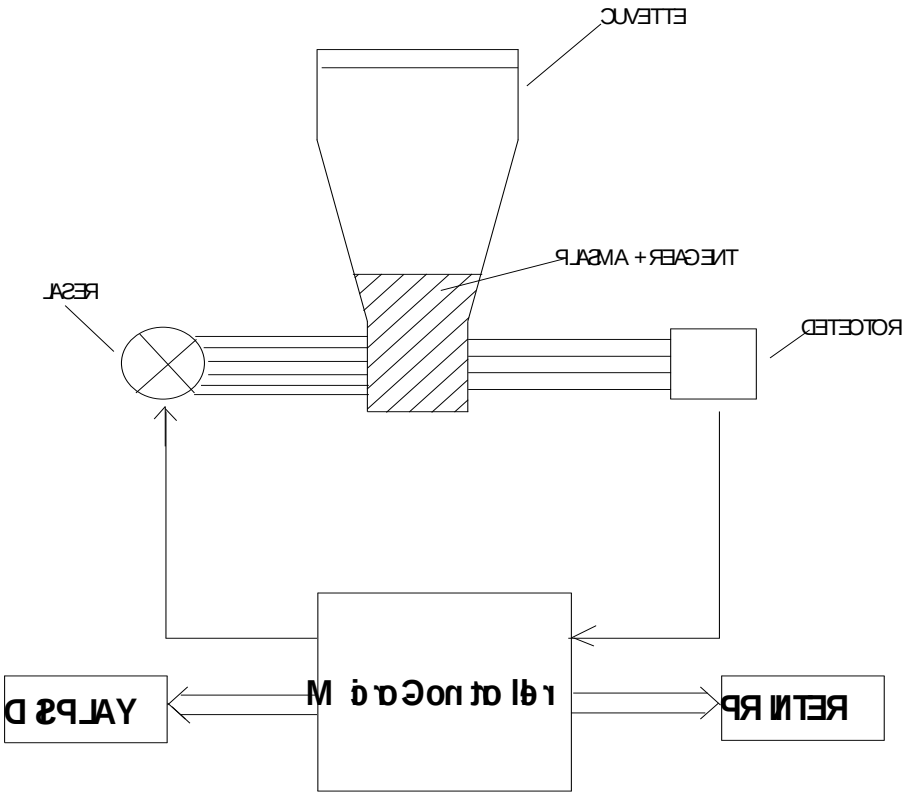


Figure 4 - The detection principle

4.1. Clotting Assay (CLOT)

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 manually by pressing the "Optic" key with simultaneous addition of the test reagent. Alternatively, the reaction is started by the addition of the test reagent using the Autopipette. The time between the start of the photometric detection, and the turning point of the reaction curve is the result. The result is displayed in seconds on the Liquid Crystal Display (and printed automatically to the optional Thermal Printer.)

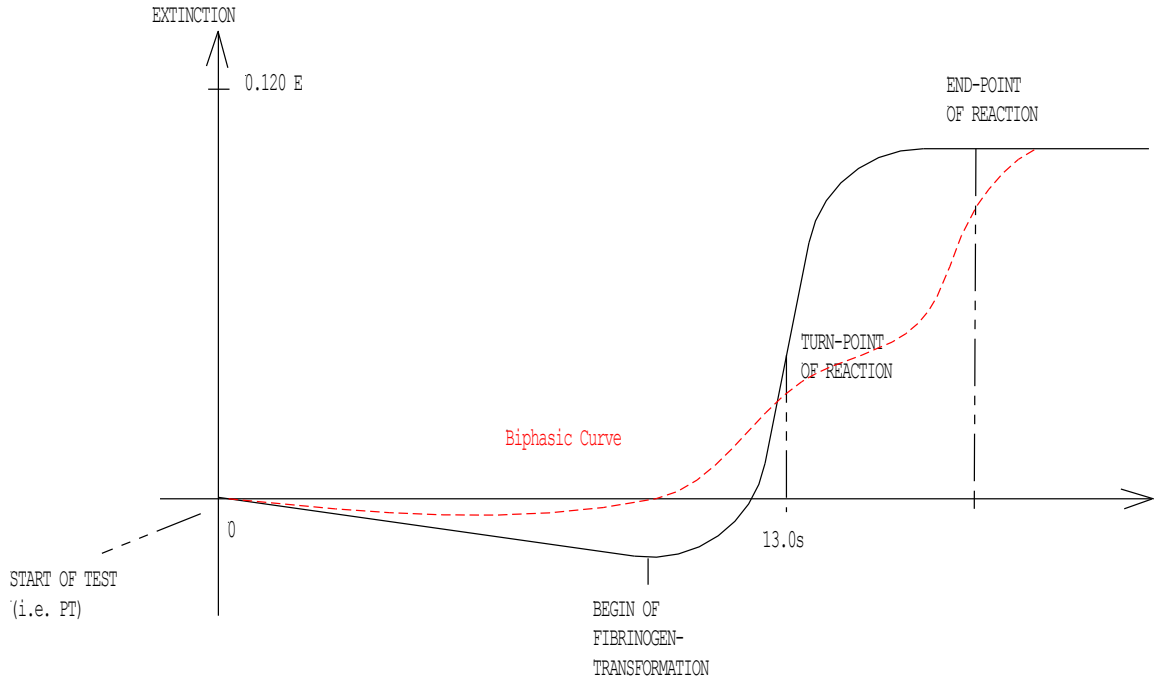


Figure 5 - The Turbidity Method

The diagram is representative of a typical PT curve with normal control plasma and a curve with biphasic reaction. Biphasic APTT reaction are highly indicators of disseminated intravascular coagulation (DIC)

4.2. Mechanical clotting time (MECHANIC)

Clotting event is not defined at turn-point of reaction, but at the begin of fibrin formation (see Figure **5**). Therefore the results are around 20% shorter than with method "CLOT"

4.3. Derived Fibrinogen (CLOT + FIB)

The derived fibrinogen is determined using the clotting method described in section above. The fibrinogen concentration in the sample is proportional to the change in optical density in the cuvette that accompanies the conversion of fibrinogen to fibrin at the end of the reaction. The result is expressed as "E", which represents the optical density at the end-point.

4.4. Chromogenic Assay (KINETIC)

In this method, the end result is determined from the rate of optical density change. Test plasma is pre-incubated with an enzyme (i.e. - Thrombin for determination of AT-III) and residual enzymatic activity is detected by the addition of a chromogenic substrate. The concentration of the analyte in the test plasma is directly or indirectly proportional (depending on the reagent system) to the rate of substrate hydrolysis, and is reported as the mean slope of optical density per minute (delta OD(E)/min).

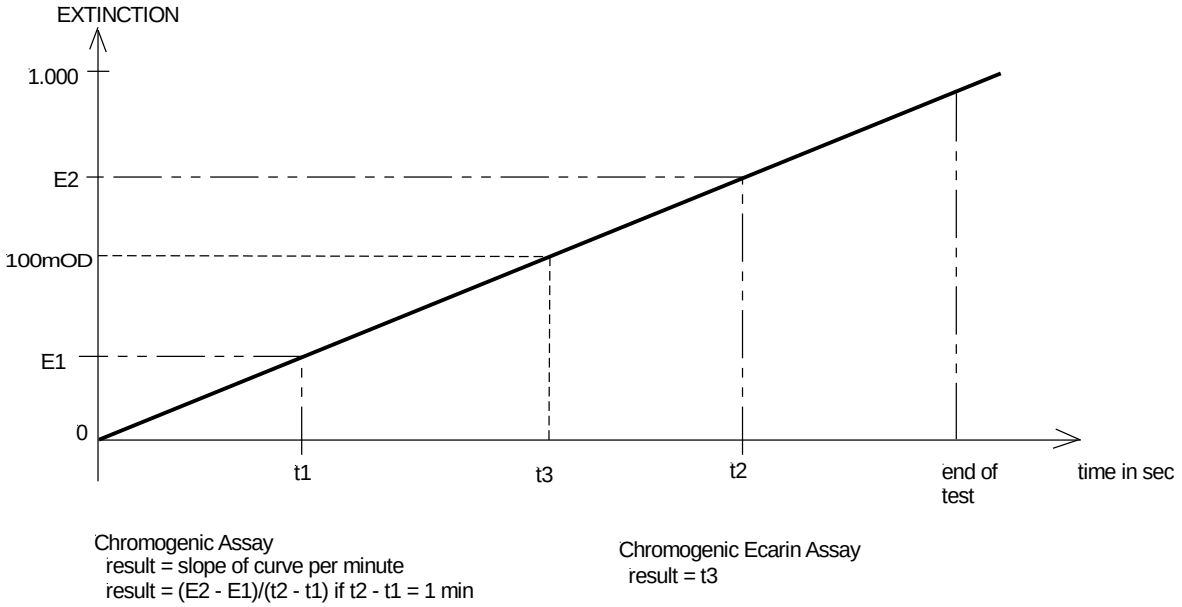


Figure 6 - The chromogenic method

4.5. Chromogenic time (MECHANIC)

The measurement principle is similar to a regular chromogenic assays. But the result is not the signal or slope of reaction,but instead the time between start of test and when signal brake through 25mOD.

4.6. Immunturbidimetric Assay (IMMUNO)

Intensive light is able to penetrate turbid solutions, such as latex suspensions used for the determination of D-dimer concentration. Latex particles, designed specifically for automated Dimex testing, are coated with a monoclonal antibody specific for D-dimer. If D-dimer antigen is present in the sample, an antigen-antibody reaction occurs, with a simultaneously change in light transmission. The concentration of D-dimer in the sample is directly proportional to the rate of the antigen-antibody reaction. The result is reported as the mean slope of optical density per minute (ΔOD (E)/min, E = Extinction, a unit of light-absorbance). The following diagram illustrates the measurement principle of the Dimex Jr.

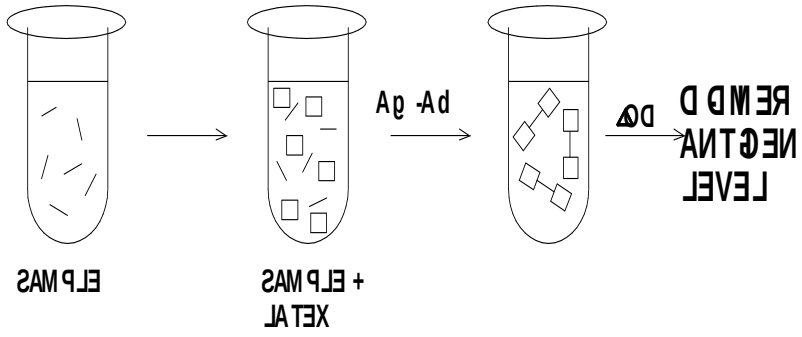


Figure 7 - Latex agglutination

The D-dimer concentration is proportional to the rate of change in optical density. The instrument calculates the average slope of reaction, using the linear portion of the curve only.

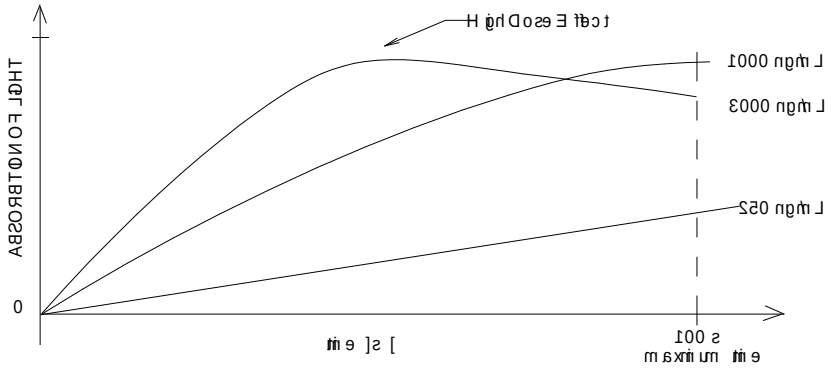


Figure 8 - Relationship of light absorbance and concentration of D-dimer

The kinetic algorithm for D-dimer testing is illustrated with three typical reaction curves. At high doses the linear relationship between signal and concentration is not valid. This is called "High Dose Hook Effect".

5.0 Operating Instructions

This section provides general instructions necessary for the user to achieve maximal use and benefit from the ***Coatron M2***. Please refer to section 9.0 for specific test applications.

The On/Off switch is located on the rear panel of the instrument. ***For optimal results, do not operate until the temperature indicator light is on***. It takes approximately 10-15 minutes for the instrument to equilibrate to 37°C. The general sequence of operation for test analysis is:
1.) Enter the "SETUP SYSTEM" submenu to confirm/change system settings
2.) Enter "SETUP TEST" to select test parameters and enter calibration data if desired; and
3.) Enter the "ANALYSIS" submenu for sample testing.

From the **Main Menu**, the following options are available:

1. ANALYSIS
2. SETUP TEST
3. SETUP SYSTEM
4. SERVICE

At each screen, selections are made using the Up/Down cursors. To proceed to the next menu item, press either the "Menu" or "Enter" key. If a mistake is made, press the "Menu" key until the main menu appears and start over.

⇨ ***To return the system to default values,***
Press simultaneously "Optic 1"+ "." + "Enter" keys.

5.1. Setup System

To enter this submenu, press #3 from the main menu. The default values for the system parameters are:

LANGUAGE:	ENGLISH
FIBRINOGEN:	mg/dL
TEMP.CONTROL:	ON
SIGNAL:	ON; VALUE 325
AUTOSTART	ON
CONTRAST OF LCD:	VALUE: 25
SPEED OF MIXER:	VALUE: 215
PAT.IDENT.:	NO PAT.ID.

5.1.1. Language

English, German, French, Italian, Spanish, Portuguese
Use the cursor keys to select, press "Enter" or "Menu" to advance

5.1.2. Fibrinogen Concentration Units

Use the cursor keys to select mg/dL or g/L, press "Enter" or "Menu" to advance

5.1.3. Temperature Control

On/Off - use the cursor keys to select, press "Enter" or "Menu" to advance. For temperature adjustment, refer to section 8.2 Temperature Adjustment

5.1.4. Signal

ON/OFF - (A beep at the start and end of testing) - use the cursor keys to select, press "Enter" or "Menu" to advance.

Higher/lower - use the cursor keys to change and "Enter" to advance.

5.1.5. Autostart

Change with cursor keys to change and continue with "*ENTER*"

ON Measurement starts with adding of reagent automatically.
No need for use of the Autopipette or extra pressing of the relevant Optic channel key.

Off regular mode for start with optional available Autopipette or manual start
by pressing relevant Optic channel key

■ ⇨ ***Activate optic channel just before adding of reagent. Movements of the cuvette can pre-start measurement – Do not touch cuvette, if optic channel is active!***

■ ⇨ ***The sensitivity of the autostart can set for every test individually within the menu "SETUP TEST".***

5.1.6. Contrast of the LCD (Liquid Crystal Display)

Higher/lower - use the cursor keys to change and "Enter" to advance.

5.1.7. Speed of the Mixer

Higher/lower - use the cursor keys to change and "Enter" to advance.

5.1.8. Patient Identification

Four choices are available:

- No Patient ID
- Autoseries
- Extra Input / Barcode
- Autoseries

Use the cursor keys to select, press "Enter" or "Menu" to advance.

No Patient ID: Results will be printed out without a patient identification number.

Autoseries *S*ample-id is automatically incremented by one.
Series will start at entered value (e.g. 1000, 1001, 1002, …)

Extra Input/Barcode: Patient-Id can be entered manually or by barcode (max. 9 characters)

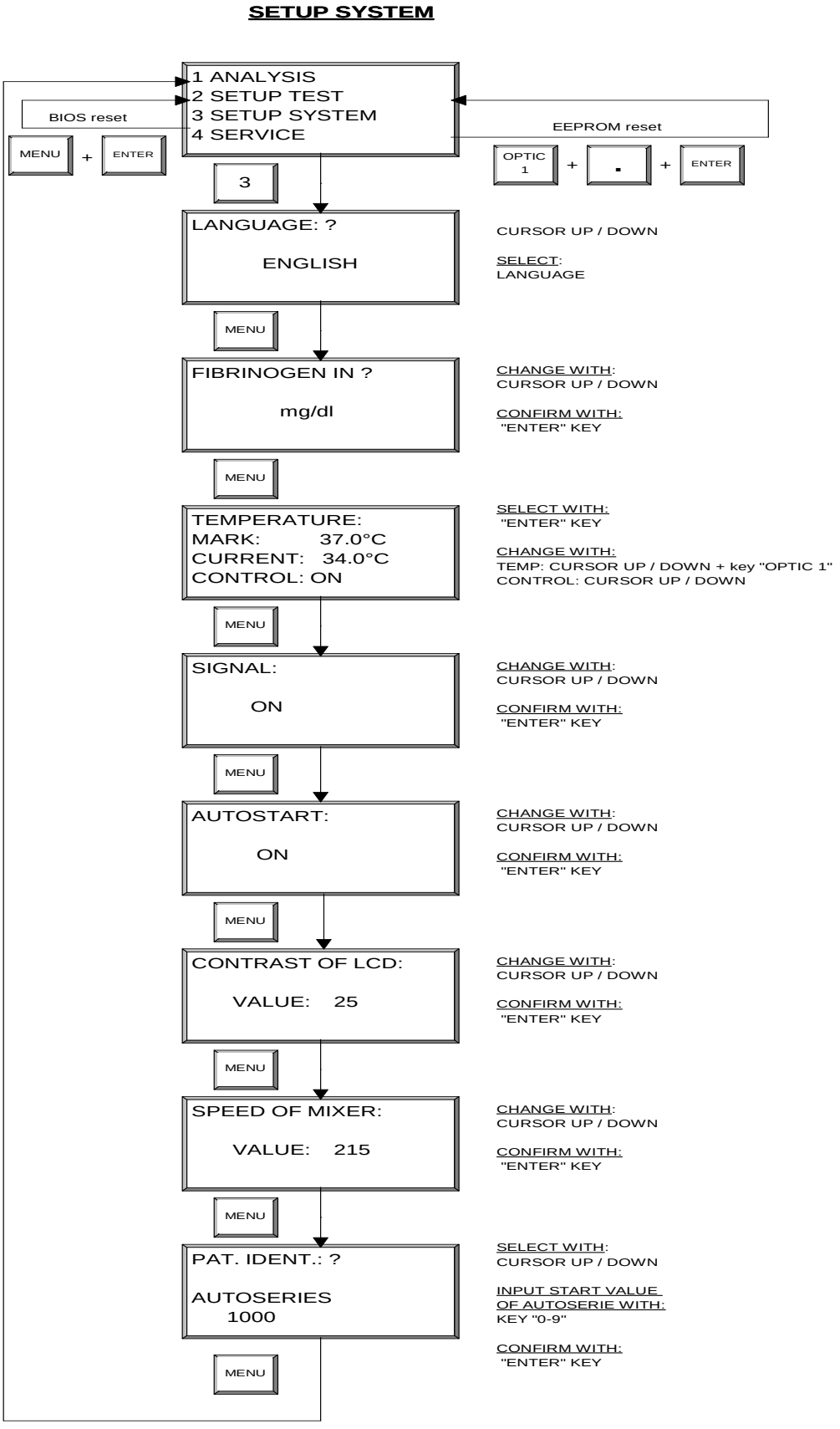


Figure 9 - Flow diagram for the "Setup" System" Submenu

5.2. Setup Test

The specific parameters for each test are entered in this menu. Once the initial data is entered and saved it is not necessary to go into this menu for routine testing. The submenu of "**SETUP TEST"** is illustrated in Figure **10**Figure **10** - Flow Diagram for the "Setup Test" Submenu. To enter this submenu, press #2 from the main menu. The default values for **"SETUP TEST"** are:

METHOD:	CLOTTING (or Clauss for FIB)
UNITS:	seconds
CALIBRATION CURVE:	Reset to zero
AUTOSTART:	500 (250 for FIB)

5.2.1. Setup Test

To select a test by enter the numeric code of the designated test. Alternatively, the Up/Down arrow keys can be used to scroll through the entire test menu. For example, key in #1 to select PT. Press "Enter" to confirm selection. The "METHOD" can also changed when blinking.

TEST:	PT
METHOD:	CLOT
AUTOSTART:	500

Depending which test is active, following methods can be selected:

- CLOT Clotting assays
- CLOT+FIB Fibrinogen will be derived from PT
- CLAUSS Fibrinogen according to CLAUSS
- KINETIC Chromogenic Assay
- MECHANIC Mechanical clotting time or chromogenic time
- IMMUNO Immunturbidimetric Assays

5.2.2. Units

Every result is displayed in seconds [s]. However, the user can also choose to display PT results in % (% activity), R (ratio) and I (INR). Calibration data, the mean normal PT value, and/or the ISI of the thromboplastin reagent must be entered to obtain results in %, R and I. Refer to next section for information on calibration data entry. Use the Up/Down cursor keys to select the desired units, "Enter" to confirm and "Menu" to advance.

UNITS:	PT
(s-%-R-I):	s-%-I- -
NORMALVALUE:	12.2s
ISI-VALUE:	1,05

The ***Coatron M2*** reports results using the following units (which are test dependent):

E = Extinction (optical density)	precision X.XXX
s = seconds	precision XXX.X
R = ratio	precision XX.XX
I = INR	precision XX.XX
% = percent activity	precision XXX.XX
U = mg/L (except FIB: mg/dL or g/L)	precision XXX.X

5.2.3. Standard Curve

To obtain results in units of concentration (mg/dL, IU/mL...) or % activity, a calibration curve is needed. A minimum of **two** points is required, with a maximum of five. Calibration data is obtained by testing plasma [in duplicate (2) or quadruplicate (4)] in the "Analysis" mode. An example of calibration data entry is shown below.

Example: A PT calibration curve with derived fibrinogen. Two different calibration curves are required. The order of entry is not critical, the instrument will automatically sort calibration points.

3-point Calibration Curve for PT	4-point Calibration Curve for Derived Fib.
100% = 12.2s	591 mg/dL = 0.413E
50% = 18.0s	377 mg/dL = 0.246E
25% = 27.2s	267 mg/dL = 0.140E
0% = 0.0s	95 mg/dL = 0.042E
0% = 0.0s	0 mg/dL = 0.0E

■ ⇨ **A correct calibration curve is required to obtain results in units of concentration or % activity. Those points remaining with no data entry are not used in the calibration curve calculation. For those tests that require a zero calibration point a value greater than zero must be entered (i.e. 0,1 % and 0.1s). All calibration points can be reset to zero by simultaneously pressing the "0" and "Enter" keys. A full parameter reset will eliminate calibration data for all assays**.

5.2.4. Correlation Factor (linearity index for calibration data)

Insert correct calibration data and confirm storing and printing. All test-parameters and in addition a correlation factor will be printed. The correlation factor (R^2) indicates the linearity of the calibration curve.
It is 1.000 if the points are exactly on one line.

If R^2 is less than 0.980, a calibration curve with more than 3 calibration points is recommend.

5.2.5. Store Data

Yes/No. Use the cursor key to select.

5.2.6. Print Test

Yes/No. Use the cursor key to select.

5.2.7. Autostart

The sensitivity of the autostart feature can be adjusted for every test individually.
The value represents the required optical change before the instrument triggers the measurement start.

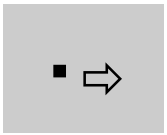
Range of sensitivity:

- Very sensitive: 250 – 500
- Normal: 500 – 1000
- Insensitive >1000

- The default value is 500 or 250 for test FIB.
- 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

Some tips:

- Pipetting clear in clear suspension will produce only low optical change and require a sensitive setup. (example: FIB or chromogenic tests)
- Try to pipet direct into the suspension instead of cuvette walls.
- Try to pipet with high pressure



Do not use autostart below 250 !

The optic could be triggered just by touching the instrument.

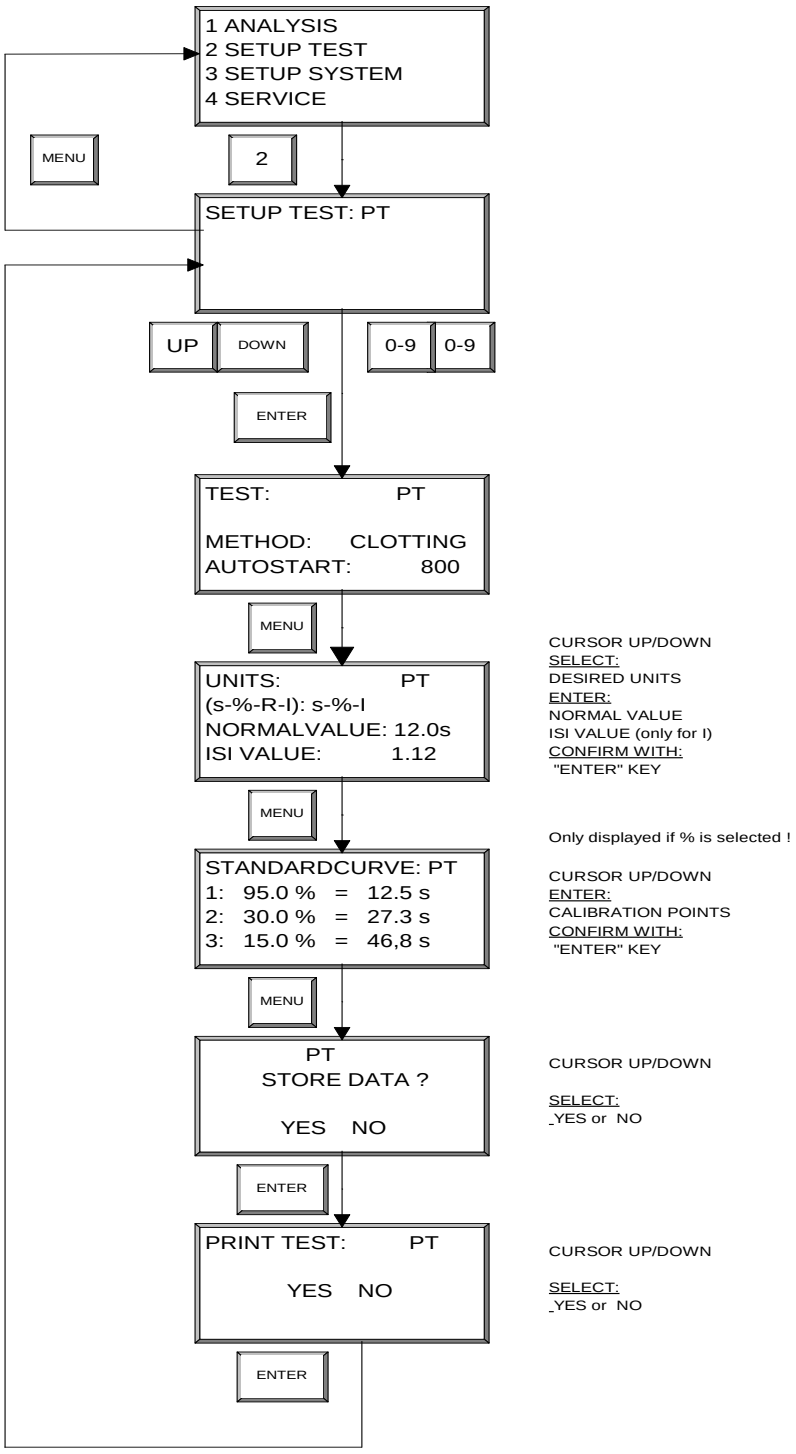


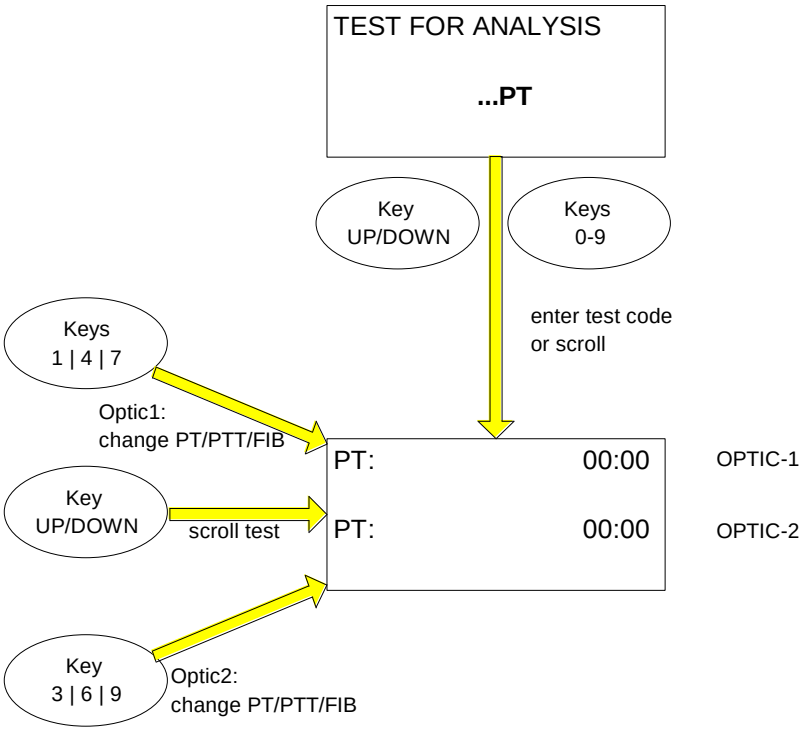
Figure 10 - Flow Diagram for the "Setup Test" Submenu

5.3. Test Analysis

To enter the submenu "Analysis", press #1 from the main menu.

5.3.1. Test Selection

The first screen in the "Analysis" submenu will ask the user to make a test selection. This can be done two ways: by scrolling through the test menu with the cursor Up/Down keys; or by entering a numeric test code (i.e. - "01" for PT test). The test selection is confirmed with the **"Enter"** key.



Once a test is chosen, the system will prompt the user to remove any remaining cuvette. Once "Enter" is pressed, the instrument performs a self-check. If any warnings or errors are identified, a message will appear. The user is given the option to ignore the error message or warnings by pressing the **"Enter"** key. ***However, all results will be printed with an error code and the results may be invalid***. It is recommended that if an error occurs, the test should be interrupted. Return to the Main Menu and enter the **"Service"** menu. Please refer to to section 6.0 for more specific instructions and information on error codes and warnings.

⇨

Within the analysis menu the actual test can switched if no measurement is ongoing.

Change test optic-1 with Key "1" (PT), Key "4" (PTT), Key "7" (FIB)
Change test optic-2 with Key "3" (PT), Key "6" (PTT), Key "9" (FIB)
Change test optic-1+2 with Key "UP" , Key "DOWN"

5.3.2. Optic Activation

FIB:	ACTIVE	00:00
FIB:	ACTIVE	00:00

The blinking message "ACTIVE" will indicate a ready channel.

The optic can be activate in four different ways.

Single activation :

- Press optic key
- Enter / Change PID
- Press optic key again → PID is confirmed and channel active

Repeat procedure for each desired optic channel

Multi activation with single PID

- Press key "." (dot)
- All four channels will activated

All patient ID number will set logical if autoseries is active (PID = 100,101,102,103)

Multi activation with double PID

- Press key "0"
- All four channels will activated in duplicate mode

Multi activation for test calibration

- Press key "5"
- All four channels will activated in duplicate mode with highest clotting sensitivity. This is especially required for running very high diluted samples like during calibration.

5.3.3. Entering Patient Identification Numbers

The entry of a PID will be always entered in following ways

- Press key "OPTIC" to select channel
- Enter or change PID
- Press key "OPTIC" again to confirm PID. Optic is now active and ready for start.

The different patient-id entry mode can be set within menu SETUP SYSTEM.

"No Pat Id" will disable PID. Result will be printed without any PID. Press Optic 1 to confirm and activate channel. Repeat for remaining channels.

"**Autoseries"** will be automatically incremented PID by one for each new measurement. Press the "Optic" key and PID will be displayed. Change number optional with cursor keys. Press "Optic" again to confirm PID and repeat procedure for remaining channels.

"**Manual Input/Barcode"** enables individual input of PID. Press the "Optic" key and last entered number will be shown. Change PID with cursor keys or overwrite with numeric keys or read barcode. Press "Optic" again to confirm PID and repeat procedure for remaining channels. A barcode scanner event will automatically activate the next channel.

5.3.4. Duplicate testing

If duplicate testing is desired, enter the same patient identification twice. The mean result will automatically be printed along with the individual channel data.

■ ⇨ **If the duplicates differ more than 7.5% from the mean value, the mean result will be flagged with 'X'!**

■ ⇨ **If autoseries is selected a press on key "0" during optic activation, will activate all channels in duplicate mode**

5.3.5. Starting the Analysis

The analysis can be started, if optic is "ACTIVE" (see chapter above) by one of following events

- Press on key **"OPTIC"**
- Optical Autostart (pipetting reagent with normal pipet)
- Autopipette (using a pipet with an electronic trigger signal)

Step by step procedure for PT measurement

Place the required number of cuvettes in the cuvette pre-warming positions and pipet 50µL plasma in each cuvette. Press the "Timer 1" button to start the stopwatch and wait 1-10min before continue with next step. Transfer cuvette to the measurement position. Press key "OPTIC" until channel is active.

PT: *ACTIVE*	01:30
PT: ACTIVE	00:00

Now 100 µL of prewarmed Thromboplastin reagent into the first left cuvette position. If autostart is enabled, the optic will start automatically. A beeping noise will indicate the start of the reaction. Repeat for the remaining cuvettes. The reaction can also be started either by pressing the optic key or by using the Autopipette, which electronically triggers the optic channel.

In summary, press the optic key once for patient identification data entry, press again to activate the channel, and a third time to manually initiate the reaction. (Do not press a third time if using the Autopipette to start the reaction!)

⇨ **If using the Autopipette,**
- **pipet always from left to right (channel 1 to 2)!**
- **disable the autostart function in the SETUP SYSTEM**

5.3.6. Display during measuring

Once started, a short beeping noise is followed by a blinking screen **"-------"**. After the test dead time the actual optical density will be displayed. Avoid contact with the cuvette while this message is shown. A beeping noise will sound when the reaction is complete and the result will be displayed on the screen. If the thermal printer is attached, results will automatically be printed.

PT:	050	00:00
PT:		00:00

Countdown after test start.
(Touching or mixing cuvette is allowed.)

PT:	S	31 mOD	00:00
PT:			00:00

Countdown finished.
(Don't touch cuvette anymore)

PT:	29 mOD	01:48
PT:	185 mOD	01:09

channels are in measurement
actual optical signal is displayed

PT:	S	31 mOD	01:52
PT:	R	188 mOD	01:13

a result is found on channel 2, but it wait until channel 1 is ready.
Channel 1 is running in high sensitivity

The flag "S" indicates, that the analyzer had switched to the high sensitivity
The flag "R" indicates, that a result was found, but it need more investigation.

The instrument will display and results sorted. If the instrument finds a result on optic channel x, it will not display as long as lower numbered channels are in measurement. In this case the actual optical density is flagged with "R" (result found).

5.3.7. Manual break of measurement

To cancel the measurement, press **"Optic"** keys. This will stop the reaction. All optic channels must be not in measurement in order to return to the main menu.

5.3.8. Return to main menu

Press key **"Menu"** . All optic channels must be not in measurement in order to return to the main menu. Stop any measurements (refer section above.)

5.3.9. Unit Key Functions

Once the measurement is complete, results can be converted to units other than s, E, E/min, if this option had been selected in **"Test Setup"**. For each optic channel, press the corresponding **"Unit"** key to convert.

5.3.10. Stopwatch Functions

To start each stopwatch, press the **"Timer"** keys. To stop and reset, press the Timer key again.

5.3.11. Result Warning Messages

Additionally to the result the instrument may inform the operator at critical samples by attaching status characters or error messages

DISPLAY	PRINTER	MEANING
*	*	Out of calibration (i.e. *167 %)
> | <	>	Out of scale (i.e. >999.9 mg/dL)
++++	NO CLOT DETECTED	No clot detected within 300 seconds
- - - -	NO CLOT DETECTED	Clot detected before dead time
???.?	COAGULATION ERROR	Detected reaction was not valid for coagulation
OPTIC	LOW SIGNAL	Light transmission was not enough.
"S"		High sensitivity mode
"R"		result found
"B"		Biphasic APTT found (maybe DIC disease)
"F"		Low fibrinogen found (maybe liver disease)

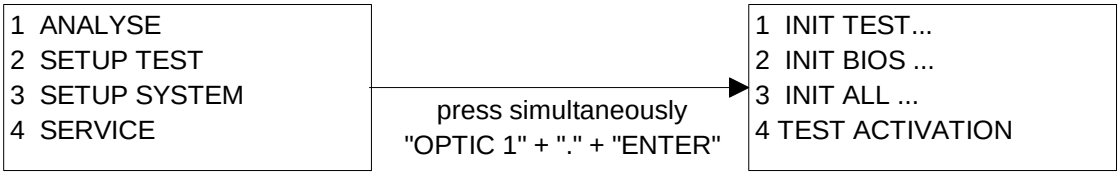
Read section troubleshooting for further details.

5.4. Hidden Functions

To protect the instrument from improper use, critical routines can be called by pressing special key combinations.

5.4.1. Set system to default

Within the "main menu" press key **"OPTIC 1"** and **" . "** and **"ENTER"** simultaneously.



INIT TEST:

- all tests will be correct initiate into the memory. This means in detail that all calibration points will be reset to zero, the method to clotting and the dimensions to seconds.
- The language is set to English
- The format of fibrinogen concentration is mg/dL

⇨ ***This routine is only recommend when a new software will be updated on the instrument***

INIT BIOS:

- Integration-time of the receiver to 100 µs
- Temperature Basis Value
- LCD-Contrast to 33
- Speed of Mixer to 215
- Frequency of beep to 325
- The serial interface is configured to 9600 Baud, Stop 1,Data 8, Parity Off

⇨ ***This routine is only recommend when the System pcb (Main board) will be exchanged. The procedure must be followed by a temperature adjustment (see section 5.4.2)!***

INIT ALL:

- INIT TEST
- INIT BIOS

TEST ACTIVATION:

Allows to fade in/out tests. Use keys *"UP" "DOWN"* to change, *"ENTER"* to proceed and *"MENU"* to escape. Deactivated test cannot be selected later in the operator's menu.

5.4.2. Change temperature adjustment

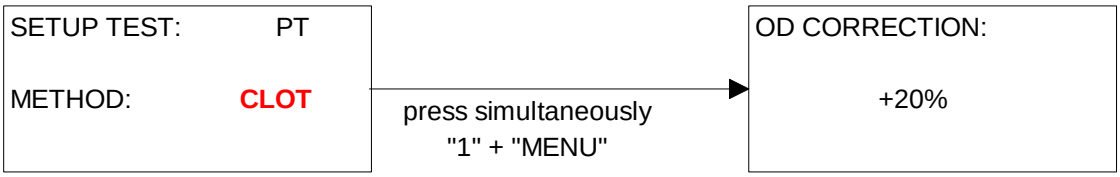
When entering the position "TEMPERATURE" in the submenu "SETUP SYSTEM" the current temperature can be changed by pressing the keys "OPTIC 1" and "UP or DOWN" simultaneously. The temperature will be in- or decrement by 0.1°C. When pressing the keys "OPTIC 1" and "UP or DOWN" and "1" simultaneously, the temperature will be in- or decrement by 1°C.
For more information, refer to section (8.2 Temperature Adjustment)

5.4.3. Set all test calibration points to zero

When entering the position "STANDARD CURVE" in the submenu "SETUP TEST" all calibration points can be set to zero by pressing the keys "0" and "ENTER" simultaneously.

5.4.4. Set OD correction

Change to "TEST SETUP" and select test, which you want to correct.
When method is blinking, press key **"1"** and **"MENU"** simultaneously.



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 = 0 no effect (default):

OD-CORRECTION > 0
will reduce sensitivity of method. This should be used, if the reagent gives a too high signal response, which can cause false early result (eg. PTT is 18s instead of 35s). A too less sensitive setting of the method can cause more "+++" result (no clot found).

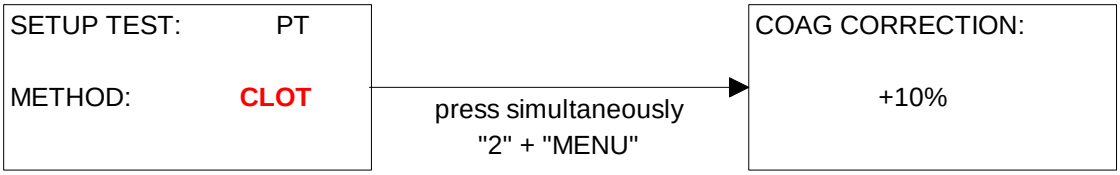
Positive OD-CORRECTION < 0
will increase sensitivity of method. This should be used, if the reagent gives a too low signal response and therefore no clot is detected (+++ results). A much sensitive setting of the method can cause more false early results (eg. PTT is 18s instead of 35s).

OD-CORRECTION = -100%
will invert the signal by -1. This is used for reagents which negative signal response, like a D-dimer assay for red light measured with blue light.

▪ ⇨ ***Improper setting can cause false result. Consult your local distributor or Manufacturer before changing the OD correction***

5.4.5. Set COAG correction

Change to "TEST SETUP" and select test, which you want to correct.
When method is blinking, press key **"2** and **"MENU"** simultaneously.



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

New result = factor x result

Factor = 1.00 (COAG CORRECTION = 0%)
Factor = 0.90 (COAG CORRECTION = -10%)
Factor = 1.10 (COAG CORRECTION = +10%)

Example: measured normal time of PT-S = 15s.

By setting COAG-CORRECTION=-20% the instrument will display 12s.
(New result = 0.80 * 15s = 12s)

Negative COAG-CORRECTION will cause shorter clotting times.

Positive COAG-CORRECTION will cause longer clotting times.

▪ ⇨ ***An new calibration run must be followed after every change COAG correction***

6.0 Service Menu

```
1 SYSTEM ANALYSIS
2 OPTIC VALUES
3 PRINT SYS-ID
```

6.1. System Analysis

Press #1 from the Service submenu to enter. Perform a **"SYSTEM ANALYSIS"** to check instrument operational status. In **"SYSTEM ANALYSIS"**, the ***Coatron M2*** check the optic, temperature, Memory values and Analog to Digital Conversion. The Error Level for each channel is determined and displayed if a system error or warning is identified.

```
ERROR IN SYSTEM
OPTIC 1:  00001000
OPTIC 2:  00000000
PRESS ANY KEY
```

An example of a **"SYSTEM ANALYSIS"** screen is:
The number after CH1-2 is the errorcode (see below). In this screen example the LED light of channel-1 is not working correctly, while channel-2 is without troubles.

After the self-check is complete, a **"SERVICE REPORT"** is automatically printed.

```
      SERVICE REPORT

SYSTEM:      TECO COATRON M2
SN:          1000
SOFTWARE:  C1.17b    400nm

TEMP.FACTOR:  15418
CONTRAST:     30
MIXER:        200
TEMPERATURE: 37,0°C

OPTIC              1         2
SIGNAL:         32753     32679
                (20000 - 35000)

NOISE:            153       166
                  (0 - 500)

SERVICE:          184       202
                  (110 - 300)

SYSTEM-ANALYSIS

OPTIC1 = 00000000   OK
OPTIC2 = 00000000   OK

STATISTIC

PT:  1000
PTT:1000
TT:  1000
FIB: 1000
AT:  1000
```

System name
Serial number
Software revision

Digital target temperature value
LCD contract value
Speed of reagent mixer
Current temperature at reagent position

Current optic values
Allowed range of values

Current noise values
Allowed range of values

Current service values
Allowed range of values

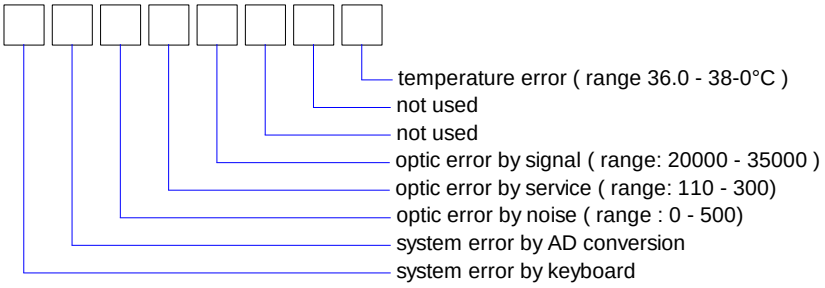
Errorcode Optic 1
Errorcode Optic 2

Counters for different tests

1000 PTs performed on instrument

Errorcode

When the self-check is followed by an error message, a 8 BIT long number in binary code can be seen. Each BIT is indicative of a specific error or warning:



Example: The Error Level "00000001" indicates that the temperature is out of range.

Refer to the troubleshooting guide for information on corrective actions.

6.2. Optic-Values

From the **"SERVICE"** submenu, remove cuvettes and press #2 to enter **"OPTIC VALUES"**. The values of signal, noise and service is displayed for each channel.

An example of a **"OPTIC VALUES"** screen is:

CH1:	32432	(202)
	152	
CH2:	32169	(213)
	168	

Recommended values:

SIGNAL :	20000 – 35000
NOISE:	0 - 500
SERVICE:	100 – 300

6.3. Print Sys-ID

press #3 from the Service menu.

MAINBOARD: 955.000
SYSTEM: 1000
BIOS: 1.00
FLASH: 2.00
SOFTWARE: 1.17b

SYSTEM IDENTIFICATION

MAINBOARD REVISION	955
MAINBOARD INDEX	0
MAINBOARD SER.NO.:	1000
BIOS REVISION:	1
BIOS INDEX:	0
FLASH REVISION:	2
FLASH INDEX:	0
SOFTWARE REVISION:	1
SOFTWARE INDEX:	17b

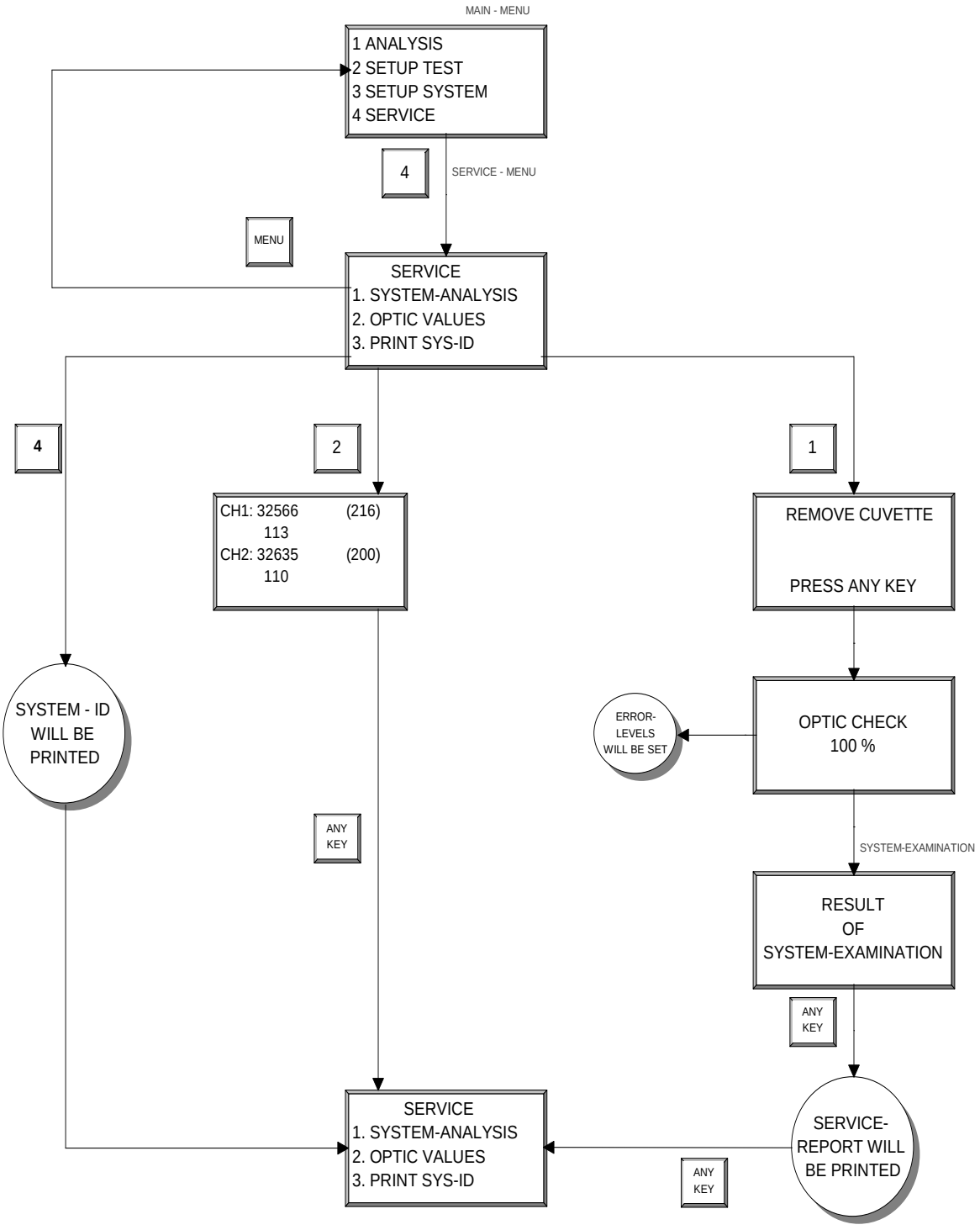


Figure 11 - Flow Diagram of "SERVICE" Submenu

7.0 Troubleshooting

TEMPERATURE ERROR	
DESCRIPTION	Temperature is not between 36.0 – 38°C
PROBABLY CAUSE	1. temperature draft environment (window) 2. electronic error 3. temperature is not adjusted correctly
CORRECTIVE ACTION	1. place instrument in a draft free environment without direct sun lighting 2. allow instrument to heat up at least 15 min after temp. adjustment or boot-up 3. adjust temperature (refer sections 8.1 & 8.2) Contact technical services at local distributor if error persists.

OPTIC ERROR : SIGNAL	
DESCRIPTION	This error occurs if not enough light is flashing onto the receiver. The optical signal must be between 20000 - 35000
PROBABLY CAUSE	1. Temperature is out of range 2. dirt in optics 3. LED's on optic block defective 4. chip errors on boards
CORRECTIVE ACTION	1. wait until instrument is heated up to 37°C 2. clean optics (refer section 8.3) 3. replace optic block 4. Contact technical services at local distributor if error persists

OPTIC ERROR : NOISE	
DESCRIPTION	Noise is produced by IC chips and external light sources (sun, lab-lighting) The digital value of the noise must be below 500.
PROBABLY CAUSE	1. The instrument is lighted by intensive external light sources, such as sun or halogen beamer 2. electronic errors
CORRECTIVE ACTION	1. Protect instrument against sun or UV – light 2. Contact technical services at local distributor if error persists

OPTIC ERROR : SERVICE	
DESCRIPTION	This error occurs if the required signal amplification is not between 110 - 300
PROBABLY CAUSE	1. Temperature is out of range 2. dirt in optics 3. LED's on optic block defective 4. chip errors on boards
CORRECTIVE ACTION	1. wait until instrument is heated up to 37°C 2. clean optics (refer section 8.3) 3. replace optic block 4. Contact technical services at local distributor if error persists

OPTIC ERROR : AD-Conversion	
DESCRIPTION	The photo receiver convert light intensity to analog direct current. This current Is converted to a digital signal. Every digital value has his own signature. If there is lost a value, the system error occurs.
PROBABLY CAUSE	1. CPU defect 2. ADC defect
CORRECTIVE ACTION	Contact technical services at local distributor

ANALYSIS ERROR : ++++	
DESCRIPTION	No clotting reaction is detected within 300s
PROBABLY CAUSE	1. There is really no clot 2. The fibrinogen concentration in the sample is below 50 mg/dL 3. started channel and pipetted channel are not equal
CORRECTIVE ACTION	1. confirm correct handling 2. Determine clotting time with research software "TECMONI" or observe the optical values on the display during screen. The time until a change in signal can be observed is the clotting time 3. change to recommended reagent provider

ANALYSIS ERROR : ----	
DESCRIPTION	Clotting reaction start and end before dead time
PROBABLY CAUSE	1. PT based test clot before 7 sec 2. PTT based tests clot before 15 sec
CORRECTIVE ACTION	change to recommended reagent provider

ANALYSIS ERROR :????	
DESCRIPTION	The instrument detected a reaction, but was not able to verify as a clot reaction.
PROBABLY CAUSE	1. air bubbles 2. touching of cuvette 3. clot reaction starts before dead time
CORRECTIVE ACTION	1. avoid air bubbles – pipet against cuvette wall 2. avoid touching the cuvette during measurement start 3. change to recommended reagent provider

ANALYSIS ERROR : OPTIC	
DESCRIPTION	The received signal is below 400 digits
PROBABLY CAUSE	1. very turbid samples or reagents 2. dirt in optics 3. optic is defective
CORRECTIVE ACTION	1. clean optics 2. check optic value (refer section 6.2) 3. change to recommended reagent provider

ANALYSIS ERROR : >, <	
DESCRIPTION	Assay range limitation
PROBABLY CAUSE	1. calculated units are not within 0-999 2. calculated activity is not within 3 – 180% 3. calculated ratio is not within 0-9 4. calculated INR is or within 0-12
CORRECTIVE ACTION	Check test setup and recalibrate test if necessary

ANALYSIS ERROR : *	
DESCRIPTION	Calculated result is extrapolated. Extrapolated results can vary to intrapolated results.
PROBABLY CAUSE	The obtained result is outside of calibration
CORRECTIVE ACTION	Extend the calibration curve. High and low standards are helpful.

ANALYSIS ERROR : B	
DESCRIPTION	The APTT is obtained from a biphasic reaction curve. The "B" is no error flag, but more an DIC indicator
PROBABLY CAUSE	Biphasic APTT correlate with disseminated intravascular coagulation (DIC)
CORRECTIVE ACTION	Confirm DIC. FIB, CRP and VLDL concentration may also helpful.

ANALYSIS ERROR : F	
DESCRIPTION	The PT is obtained from a very flat reaction curve. The "F" – Flag is no error flag, but more a low fibrinogen indicator.
PROBABLY CAUSE	Fibrinogen concentration of sample is below 75mg/dL. Low fibrinogen levels can be caused by liver-disease or DIC.
CORRECTIVE ACTION	Confirm low fibrinogen with a FIB determination according to CLAUSS method.

8.0 MAINTENANCE

8.1. Recommended Maintenance

Daily: Check that the optic unit and the filters are free from dirt. Clean with lint-free tissue paper if necessary.

Monthly: Check the temperature of the incubator block. When the green LED is on, place water in a reagent bottle and place in one of the reagent positions. Insert a thermometer and record temperature after 10 minutes. The temperature should be in the range of 36.5°C and 37.5°C. Proceed to next section if the temperature is incorrect.

Yearly: Service check by authorized technical person.
(total cleaning of instrument, function tests, quality-control routines)

8.2. Temperature Adjustment

1. When the green LED is on, fill a reagent container (bottle) with water and place in a reagent position on the incubator block. Place a thermometer in the water.

2. Allow to warm for 10 minutes.

3. Enter the submenu "Setup System" and advance to the temperature screen. The current temperature of the ***Coatron M2*** is displayed.

4. Compare the temperature displayed by the system and the thermometer. If the temperature is different, adjust the temperature on the ***Coatron M2*** by simultaneously pressing the Up/Down cursor keys *and* the "OPTIC 1" key. (To increase or decrease using larger increments, press additionally the numeric "1" key.)

5. Wait until a stable temperature of 37.0°C is displayed on the ***Coatron M2***. Check and correct the system temperature if not equivalent to the external thermometer.

6. If both the thermometer and instrument display the same temperature, press the "Enter"-key and exit back to the main menu.

8.3. Cleaning procedures

The casing should be cleaned with a light alcoholic solution or with a light soap solution, using a soft foam only. The optical filter should be cleaned with just light alcoholic solution. Dry well with clean, fat-free wipes

Warning:

- ***Do not use aggressive cleaning solutions!***
- ***Do not use hard foam material or metallic foams.***

9.0 APPLICATIONS

A summary of the current test applications supported by the ***Coatron M2***, the choice of medical dimensions and the numeric test codes are shown below:

Test	Method	Unit	#Code
STAT			00
PT +/- FIB	CLOT + FIB	s-%-R-I-E-U	01
PTT	CLOT	s - R	02
TT	CLOT	s - R	03
FIB(CLAUSS)	CLAUSS	s - U	04
VT	CLOT	s – R	05
PC	CLOT + KIN	s - % - U	06
PS	CLOT + KIN	s - % - U	07
F2	CLOT + KIN	s - %	08
F5	CLOT + KIN	s - %	09
F7	CLOT + KIN	s - %	10
F8	CLOT + KIN	s - %	11
F9	CLOT + KIN	s - %	12
F10	CLOT + KIN	s - %	13
F11	CLOT + KIN	s - %	14
F12	CLOT + KIN	s - %	15
F15 (Fletcher)	CLOT + KIN	s - %	16
HEP	CLOT + KIN	s – U	17
AT3	CLOT + KIN	s - % - U	18
APCR	CLOT	s - % - R	19
LA-S	CLOT	s - % - R	26
LA-C	CLOT	s - % - R	27
DD	IMMUNO	E - U	20
VWF	IMMUNO	E - U	21
ECAH*	100mOD	E - % - U	22
ECAT*	100mOD	E - % - U	23
PLG*	KIN	E - % - U	24
a2AP*	KIN	E - % - U	25

* ECAH and higher only for 400nm version

GLOSSARY

Method
- CLOT, clotting assay
- KIN, chromogenic assay
- IMMUNO, immunturbidimetric assay
- 100mOD, chromogenic Ecarin assay

Unit
- E, result in optical density (Extinction); precision XXXX
- s, result in seconds; precision XXX.X
- %, result in activity; precision XXX.X
- U, result in mg/dl, mg/l, µg/ml, g/l; precision XXX (except HEP: X.XXX)
- R, result in ratio; precision XX.XX
- I, result in INR; precision XX.XX

#Code
- Direct code for test selection

All application should carried out with a minimum volume of 75 µL, but in some cases, it is recommend using higher volume levels to keep the precision in a high accuracy. The next pages suggest test procedures, which are tested on the instrument and which guaranty a Coefficient Variation (CV) of below 5 % (depend on test, pipette).

9.1. Prothrombin Time

REAGENT PREPARATION

Reconstitute Thromboplastin reagents according to the package insert.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check setup system if necessary.
5. Check setup test if necessary . Enter new calibration curve data to obtain results in % activity; enter ISI of thromboplastin reagent and in-house determined mean normal PT if INR results are desired. Enter in-house determined mean normal value if results in R are required.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #01. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

Clotting Method:

1. Pipette ***25 µL plasma*** to cuvette(s).
2. Prewarm plasma for 2 min, or the time indicated in the reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Place Thromboplastin reagent with stir bar in large central reagent position.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add ***50 µL prewarmed Thromboplastin reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
7. The instrument will read for 300 secs. If no clot is detected, the display will read "***".
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results.

ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5. **It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Normal Coagulation Reference Plasma I in 0.9% $NaCl_2$ (saline). Refer to the table below for preparation of standards
2. Determine PT with undiluted normal plasma in duplicate.
3. Determine PT with diluted plasmas in duplicate.
4. If no clot time is detected for the diluted plasma samples (<25%), change the sensitivity in "Setup Test" to "High" and repeat.
5. Enter calibration data, % activity and seconds.
6. Check calibration curve with different controls, Controls Level I, II & III.

% Activity	Dilution	Preparation
100	none	
50	1:2	200 µL plasma + 200 µL saline
25	1:4	100 µL plasma + 300 µL saline
12.5	1:8	50 µL plasma + 350 µL saline

9.2. Derived Fibrinogen

REAGENT PREPARATION

Reconstitute Thromboplastin reagents according to the package insert.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

Clotting method with fibrinogen:

1. Pipette ***25 µL plasma*** to cuvette.
2. Prewarm plasma for 2 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Place Thromboplastin reagent with stir bar in large central reagent position.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add ***50 µL prewarmed Thromboplastin reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
7. The instrument will read for 300 secs. If no clot is detected, the display will read "***".
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results.

ASSAY CALIBRATION

For the derived fibrinogen test a calibration curve must be entered. **It is highly recommended that more than two calibration points be used.**

1. Test fibrinogen reference plasmas in duplicate. For example, test fibrinogen reference plasmas with low (~100 mg/dL), normal (~250 mg/dL) and high (>350 mg/dL) fibrinogen concentration. Record the Extinction (OD) values for all samples.
2. Enter the fibrinogen data for the calibration curve, Extinction & fibrinogen values.
3. Check the calibration curve with controls.
4. Note - If % PT *and* derived fibrinogen values are required, two calibration curves must be entered.

9.3. Clauss Fibrinogen Assay

REAGENT PREPARATION

Reconstitute Thrombin reagent 100 NIH U/mL according to the package insert.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary.
5. Check test setup if necessary and enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select Fib with the Up/Down arrow keys or enter the numeric test code, #6. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

All quality control and patient samples are diluted 1:10 in Imidazole Buffered Saline (IBS) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed.

1. Pipette ***50 µL of diluted sample*** to cuvette.
2. Prewarm sample for 5 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Transfer cuvette to measuring position.
4. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
5. Add ***25 µL 100 NIH U/mL Thrombin reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test).
6. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
7. The result is displayed in seconds, and both this result and the fibrinogen concentration are automatically printed. press the corresponding "Unit" key for fibrinogen concentration if a printer is not attached.
8. For samples diluted 1:10, this is the final result. For other dilutions, the result must be corrected. For example, if the sample was diluted 1:5, divide the result by 2; if the sample was diluted 1:20 or 1:40, multiply the result by 2 or 4, respectively.

ASSAY CALIBRATION

1. Prepare standards using Normal Coagulation Reference Plasma. A *suggested* standard curve is shown in the following chart:

Dilution	Preparation
1:5	200 µL plasma + 800 µL IBS
1:10	100 µL plasma + 900 µL IBS
1:20	50 µL plasma + 950 µL IBS
1:35	100 µL plasma + 3.4 mL IBS

2. Mix the standards and assay each in quadruplicate.
3. Enter the calibration data in the "Setup Test" submenu. For example: the assigned fibrinogen value for the plasma used to prepare the standard curve is 250 mg/dL. The 1:10 dilution corresponds to 100% activity, therefore it is equal to 250 mg/dL. The 1:5 dilution is twice as concentrated, it is equal to 500 mg/dL. (The 1:20 dilution = 125 mg/dL and the 1:35 = 71.4 mg/dL.)
4. Verify the calibration curve with different Control Plasmas Level I, II, III.

9.4. Thrombin Time Assay

REAGENT PREPARATION

Reconstitute Thrombin Reagent 10NIH/vial according to the package insert. (use "europe" procedure with concentration of 5NIH/ml)

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

Clotting Method:

1. Pipette ***50 µL of undiluted plasma*** to cuvette.
2. Prewarm sample for 3 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Transfer cuvette to measuring position.
4. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
5. Add ***50 µL Thrombin Time Reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test).
6. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
7. The result is displayed in seconds and is automatically printed.

9.5. APTT

REAGENT PREPARATION

Refer to package insert for APTT and $CaCL_2$ reagents.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

Clotting Method:

1. Pipette ***25 µL plasma*** to cuvette.
2. Prewarm plasma for 2 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
3. Place $CaCl_2$ in large central reagent position.
4. Add ***25 uL of the APTT reagent***. Incubate for 3 or 5 minutes (refer to package insert).
5. Transfer cuvette to measuring position.
6. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
7. Add ***25 µL prewarmed $CaCl_2$ reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test).
8. The instrument will read for 300 secs. If no clot is detected, the display will read "***".
9. The result is displayed in seconds. To obtain results in R, press the "Unit 1" key.

9.6. PT-Based Factor Assays (II, V, VII & X)

REAGENT PREPARATION

Reconstitute Factor Deficient Plasma and Thromboplastin reagent according to package insert.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0.

TEST PROCEDURE

All quality control and patient samples are diluted 1:10 in Imidazole Buffered Saline (IBS) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed. It is recommended to test 2 dilutions (1:10 & 1:20) for each sample. Refer to the reagent package insert for more information.

Clotting Method

1. Place Thromboplastin reagent with stir bar in large central reagent position.
2. Pipette ***25 µL of diluted plasma and 25 ul of deficient plasma*** to each cuvette. Refer to chart for sample preparation.
3. Incubate for 2 min, or the time indicated in reagent package insert. Press the "TIMER 1" key to start stop-watch 1.
4. Transfer cuvette to measuring position.
5. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
6. Add ***50 µL prewarmed Thromboplastin reagent*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
7. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
8. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results if a printer is not attached.
9. For patient and control samples diluted 1:10, this is the final result. If other dilutions are tested, the calculated value should be multiplied by the appropriate dilution correction factor. (i.e., samples diluted 1:20, multiply result by 2; for 1:40 dilutions, multiply by 4, etc.)

ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5. **It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Normal Coagulation Reference Plasma in Imidazole Buffered Saline (IBS). A *suggested* standard curve is shown below.
2. Assay standards in quadruplicate as described.
3. Enter calibration data (% activity and seconds) in "Setup Test". Check calibration curve with different controls.

Sample	Dilution	Preparation
100% Standard	1:10	100 µL reference plasma + 900 µL IBS
50% Standard	1:20	50 µL of reference plasma + 950 µL IBS
25% Standard	1:40	25 µL of reference plasma + 975 µL IBS
12.5% Standard	1:80	500 µL of 25% standard + 500 µL IBS
Patient or Control	1:10	100 µL sample + 900 µL IBS

9.7. APTT-Based Factor Assays (VIII, IX, XI & XII)

REAGENT PREPARATION

Reconstitute Factor Deficient Plasma and APTT reagents according to package insert.

SYSTEM PREPARATION

1. Turn on instrument and wait for green LED light to come on.
2. Turn on printer if connected.
3. Connect optional Autopipette to system.
4. Check system setup if necessary
5. Check test setup if necessary. Select method clotting+fibrinogen, enter new calibration curve data.
6. Return to main menu and enter "Analysis" by pressing #1. Select PT with the Up/Down arrow keys or enter the numeric test code, #1. If any warning or error message appears, refer to section 7.0..

TEST PROCEDURE

All quality control and patient samples are diluted 1:10 in Imidazole Buffered Saline (IBS) for testing. If the clotting times fall outside of the linear curve, prepare and test 1:5 or 1:20 dilutions as needed. It is recommended to test 2 dilutions (1:10 & 1:20) for each sample. Refer to the reagent package insert for more information.

Clotting Method

1. Place $CaCl_2$ in large central reagent position.
2. Pipette ***25 µL of diluted plasma and 25 µL of deficient plasma*** to each cuvette. Refer to chart for sample preparation.
3. Incubate for 2 min, or the time indicated in reagent package insert.
4. Add ***25 µL of APTT reagent***. Refer to package insert for appropriate activation times. Press the "TIMER 1" key to start stopwatch 1.
5. Transfer cuvette to measuring position.
6. While incubating, press "OPTIC 1". If selected, enter PAT-ID with numeric keys or Up/Down keys. Confirm by pressing "OPTIC 1" again. The message "ACTIVE" is displayed and channel 1 is ready to start the reaction. Repeat for the remaining channels.
7. Add ***25 µL prewarmed $CaCl_2$*** and simultaneously press the "OPTIC 1" key. The test will automatically start if using the Autopipette. (CAUTION: When the test procedure is running, pressing the "OPTIC 1" and the "Enter" keys will interrupt the test). Repeat for remaining channels.
8. The instrument will read for 300 secs. If no clot is detected, the display will read "+++" and "No Clot Detected" will print.
9. The result is displayed in seconds. Press the corresponding "Unit" key for conversion of results if a printer is not attached.
10. For patient and control samples diluted 1:10, this is the final result. If other dilutions are tested, the calculated value should be multiplied by the appropriate dilution correction factor. (i.e., samples diluted 1:20, multiply result by 2; for 1:40 dilutions, multiply by 4, etc.)

ASSAY CALIBRATION

For calibration curves, a minimum of two values is required, with a maximum of 5. **It is highly recommended that more than two calibration points be used.**

1. Make dilutions of Normal Coagulation Reference Plasma in Imidazole Buffered Saline (IBS). A *suggested* standard curve is shown below.
2. Assay standards in quadruplicate as described.
3. Enter calibration data (% activity and seconds) in "Setup Test". Check calibration curve with different controls.

Sample	Dilution	Preparation
100% Standard	1:10	100 µL reference plasma + 900 µL IBS
50% Standard	1:20	50 µL of reference plasma + 950 µL IBS
25% Standard	1:40	25 µL of reference plasma + 975 µL IBS
12.5% Standard	1:80	500 µL of 25% standard + 500 µL IBS
Patient or Control	1:10	100 µL sample + 900 µL IBS

10.0 SPECIAL FUNCTIONS

10.1. Software Upgrading

The process of evolution never stops. This is also valid for technical systems. Complaints or ideas from the customers and their direct solution or realization force an instrument to more and more functionality and stability. The ***Coatron M2*** supports a very easy procedure to use a new revision of software. For more information about latest software revision, ask your local distributor .

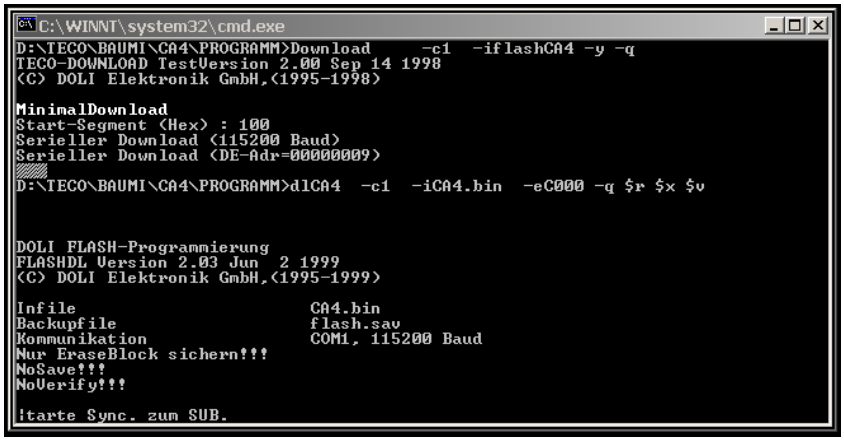
Requirements :

- Windows PC ,
- download cable ,
- update files - flash.bat , download.exe , flashdl.exe , flashv25.exe and the analyser firmware xxxxx.img (i.e. cm2114c.img → COATRON M2 V1.14c)

1. Save any important test setups of the instrument to paper
2. Reboot your PC. This will reset your comm ports !
3. Extract „Flash Disk to any local folder on your PC.
4. Connect Coatron to PC with 0 Modem cable (PIN 2-3-5 to PIN 3-2-5)
5. Double click to "upgrade.bat" and follow dialogue.
6. After a few minutes the Coatron will reboot.
7. Re-Initialisize the memory
   a. Power off/on instrument
   b. Press key **"Optic 1" +"." +"ENTER" simultaneously** -> message "INIT SYSTEM…" should appear and afterwards instrument should reboot automatically
8. Restore test setup parameter manually

Problems during updates:

-Update stays at following screen



➔ Reboot PC and try again
➔ If transfer still failed, boot PC with MS DOS floppy disk and perform MS DOS update

- Nothing happened after click to upgrade.bat
  ➔ perform update with MS DOS commands

- MS DOS update (for Windows 2000 / XP)

  - open data explorer and extract all files maybe to drive "C" , folder TECO
  - goto MS Windows "START/RUN" and enter "cmd" -> DOS command window will open
  - change to directory with command "cd c:\teco"
  - enter command "dir" -> all files including upgrade.bat should be listed
  - enter command "upgrade.bat" -> a dialog should open.
  - Follow dialog. Update will start and when finished the instrument will reboot.

11.0 TECAM SMART the LIMS solution

11.1. General

TECAM SMART is a user friendly software with LIMS functionality (Laboratory Information Management. It allows to sample all instrument results and manage it in a database application. The software can be downloaded from TECO homepage www.teco-gmbh.com . The trial version allows only saving 5 results each start but has no other limits. With a purchased license it can be switch to a registered version.

Requirements:
- Pentium III , 128MB Ram
- Microsoft Windows 2000 or XP

DataBase:
- Microsoft Access Jet Engine 4.0
- Max. 2GB (200.000 results)

Supported instruments:
- Teco Coatron M1 V1.18 or higher
- Teco Coatron M2 V1.13 or higher
- Teco Coatron M4 V1.08 or higher
- Teco Techrom IV V1.20 or higher

Key features:
- Account Management: operator can loggin as Administrator or user in order to control and manage the database with different access rights
- DataBase Management: operator can create, backup, import or export database
- Reaction Curve: can be displayed in fix or autoscale mode
- Patient DataBase: PID can be linked to patient names
- Filter functions: Every record field can be filtered (e.g. last 30 days all PT)
- Report Generator: Day report , patient report , or last x days report can created just by filter the fields
- Statistical analysis: includes mean, SD,CV for filtered data
- Online Update: software be updated by internet

11.2. Interface Protocol

Protocol:	TECAM = TECO Coatron Monitoring
Instruments:	Coatron M2 V1.13b or higher
	Coatron M4 V1.08b or higher
	TEChrom IV V1.20 or higher
Interface:	9600 Baud, no parity, 8 bit. 1 stop bit
Transmission:	result data = yes
	Reaction curve data = yes

ASCII command characters:

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)
DLE	idle	asc(16)

Overview of records and principle:

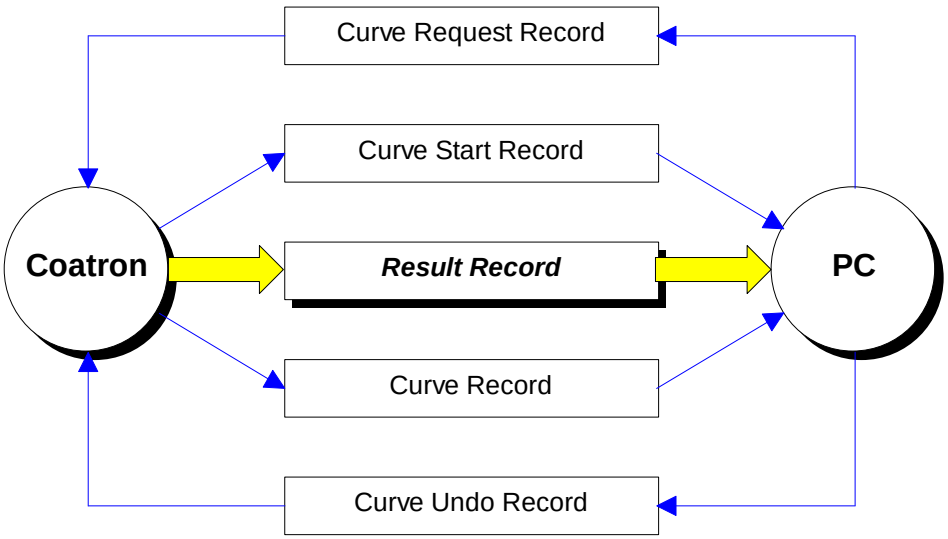


Figure 12 – LIMS communication

The result record is always transmitted from the Coatron.
The curve record transmission must be activated from PC with a request record.

The curve request record:

Function: enables curve transmission !
Definition: <DLE &"4" CR>

The curve undo record:

Function: disables curve transmission !
Definition: <DLE &"3" CR>

The curve start record

Function: Indicates that a new measurement had been started.
The transmission need to be enabled by the "Curve Request Record".

Definition: <STX &"P"><Optic><LF & ETX>

Fields:	Delimiter:	asc(9) = tabulator
	<STX & "P">	Record header; STX=asc(2)
	<Optic>	optic cannel 1-4 (channel 1 = 0)
	<LF & ETX>	Record end; LF=asc(10) , ETX=asc(3)

The curve record

Function: Send actual optical density every second
The transmission need to be enabled by the "Curve Request Record".

Definition: <STX &"O"><Optic><mOD ><LF & ETX>

Fields:	Delimiter:	asc(9) = tabulator
	<STX & "O">	Record header; STX=asc(2)
	<Optic>	optic cannel 1-4 (channel 1 = 0)
	<mOD>	milli optical density
	<LF & ETX>	Record end; LF=asc(10) , ETX=asc(3)

Example: Signal = 0,999 E in channel 1--> <STX "O"><0><999><LF & ETX>

The result record

Function: send after every result

Definition: <STX &"R"><Optic><SID><Error><Datel><Flags><PID><Test>
<sec><mOD><%><R><INR> <Unit><Scale><LF & ETX>

Fields:	Delimiter:	asc(9) = tabulator
	<STX & "R">	Record header; STX=asc(2)
	<Optic>	optic cannel 1-4 (channel 1 = 0)
	<SID>	system identifier
	<Error>	ystem error, hexadecimal
	<Date>	ddmmyy or 000000 if not used
	<Flags>	Result flags: + , - , * , >
	<PID>	Result or patient ID number
	<Test>	name of test ("PT","APTT",…)
	<sec>	125 (no decimal point. Divide by 10 -> 12.5s)
	<mOD>	000 (no decimal point)
	<%>	100.0 (with decimal point)
	<R>	1.00 (with decimal point)
	<INR>	1.00 (with decimal point)
	<Unit>	300. (with decimal point)
	<Scale>	mg/dL, ng/mL, ……
	<LF & ETX>	Record end; LF=asc(10) , ETX=asc(3)

Examples:

Test PT with 12.5s 1.02INR 98.5% PID=1000 ERR=0 Kanal=1
<STX R><0><1011000><0><311204><0><1000><PT>
<125><0><98.5><1.02><0><><LF ETX>

Test FIB with 10.0s 200 mg/dL PID=1000 ERR=0 Kanal=1
<STX R><0><1011000><0><311204><0><1000><FIB>
<100><0><0><0><200><mg/dL><LF TX>

Test AT3with 0.651E 78% PID=1000 ERR=0 Kanal=1 (chromogen)
<STX R><0><1011000><0><311204><0><1000><AT3>
<0><651><78><0><0><><LF ETX>

12.0 PRODUCT CATALOGUE

Coatron M2 **(with Standard Package)**
Cat. Number: 80 700 00

including:
1 pc Power supply
1 pc Power cord, Europe
25 pcs Double cuvettes (2 wells/each)
5 pcs Reagent container
1 pc Stirring magnet
1 pc Reagent adaptor (∅22.5mm)
1 Pc Printer cable
1 pc Operation manual
1 Pc Warranty card
1 Pc Installation report
1 Pc Service report

Consumables and Accessories

Cat.No.	Description	Content	Qty
19 000 02	Double-cuvette (2 pos/ea)	250	1 Pac
19 029 00	4-stage-Autopipette 25/50/100/200 µl	1	1 Pc
19 030 01	Reagent adaptor ∅i=22,5mm	1	1 Pc
19 030 02	Reagent adaptor ∅i=22,8mm	1	1 Pc
19 030 03	Reagent adaptor ∅i=24,2mm	1	1 Pc
19 030 04	Reagent adaptor ∅i=27,8mm	1	1 Pc
19 030 05	Reagent adaptor ∅i=25,2mm	1	1 Pc
19 030 06	Reagent adaptor ∅i=18,0mm	1	1 Pc
19 070 00	CCD- Barcodescanner	1	1 Pc
80 050 06	Stirring magnets	4	1 Pac
80 050 09E	Power cord Europe	1	1 Pc
80 050 09U	Power cord US	1	1 Pc
80 525 00	Reagent container ∅ 22,5mm	100	1 Pac
80 530 00	Reagent tubes ∅ 16mm	100	1 Pac
80 535 00	Thermal printer (EU)	1	1 Pc
80 920 07	Pipette tips 25/50/100/200 µl	1.000	1 Pac
80 920 12	Thermal paper for printer	5	1 Pac
80 920 14	Printer cable for printer, long	1	1 Pc
80 997 00	TECAM Smart Software Patient management, Monitoring Research CD and RS232 cable	1	1 Set

Coagulation Reagents

CAT. Number	Product	Size	Determinations
PT (Prothrombin Time)			
A0220-010	TEClot PT, ISI~1,5	5x2ml	200
A0220-010	TEClot PT, ISI~1,5	10x4ml	800
A0220-010	TEClot PT, ISI~1,5	10x10ml	2000
A0230-010	TEClot PT-S, ISI~1,0	5x2ml	200
A0230-010	TEClot PT-S, ISI~1,0	10x4ml	800
A0230-010	TEClot PT-S, ISI~1,0	10x10ml	2000
APTT (Activated Partial Thrombin Time)			
A0300-025	TEClot APTT-S Kit-25	Kit	1000
A0300-050	TEClot APTT-S Kit-50	Kit	1000
A0320-050	TEClot APTT-S	10x5ml	2000
A0320-100	TEClot APTT-S	10x10ml	4000
A0350-050	$CaCl_2$, 25mM	10x5ml	2000
A0350-100	$CaCl_2$, 25mM	10x10ml	4000
TT (Thrombin Time)			
A0401-020	TEClot TT	10x2ml	800
FIB (Fibrinogen)			
A0501-010	TEClot FIB Kit-10	Kit	400
A0501-025	TEClot FIB Kit-25	Kit	1000
A0511-020	TEClot FIB	10x2ml	800
A0511-050	TEClot FIB	10x5ml	2000
A0520-004	TEClot FIB liquid	2x2ml	1600
A0591-090	FIB Buffer (IBS)	1x90ml	
AT (Antithrombin, chromogenic assays)			
C1000-010	TEChrom AT (anti-Xa) Kit-10	Kit	50
C1010-020	TEChrom AT (anti-Xa) liquid	Kit	360
DD (D-Dimer, immunturbidimetric assays for 405nm)			
D2020-005	Blue D-Dimer LC Kit-65	Kit	66
D2020-010	Blue D-Dimer LC Kit-130	Kit	133

Special tests

C1100-012	TEChrom PC (Protein-C chromogen)	Kit	480
A0600-002	TEClot PS (Protein-S clotting)	Kit	80
A0700-020	TEClot LA Screen (DRVVT)	10x2mL	400
A0800-010	TEClot LA Confirm (DRVVT)	10x1mL	200
A0900-004	TEClot PCA Ratio (Factor Leiden)	Kit	160

Factor Assays (immundepleted)

P5001-010	Deficient Plasma, FII	10x1mL	400
P5101-010	Deficient Plasma, FV	10x1mL	400
P5201-010	Deficient Plasma, FVII	10x1mL	400
P5301-010	Deficient Plasma, FVIII	10x1mL	400
P5401-010	Deficient Plasma, FIX	10x1mL	400
P5501-010	Deficient Plasma, FX	10x1mL	400
P5601-010	Deficient Plasma, FXI	10x1mL	400
P5701-010	Deficient Plasma, FXII	10x1mL	400

Control plasma

P6001-010	TEControl N for PT,PTT,TT,FIB,DD	10x1mL
P6101-010	TEControl A for PT,PTT,TT,FIB,DD	10x1mL
P6201-010	TEControl A Plus (Factors,PC,PS,AT etc.)	10x1mL
P7100-005	TEClot LA positive	5x1mL

Reference plasma

P8001-010	TECAL N	10x1mL
P8200-005	TECAL DD	5x1mL