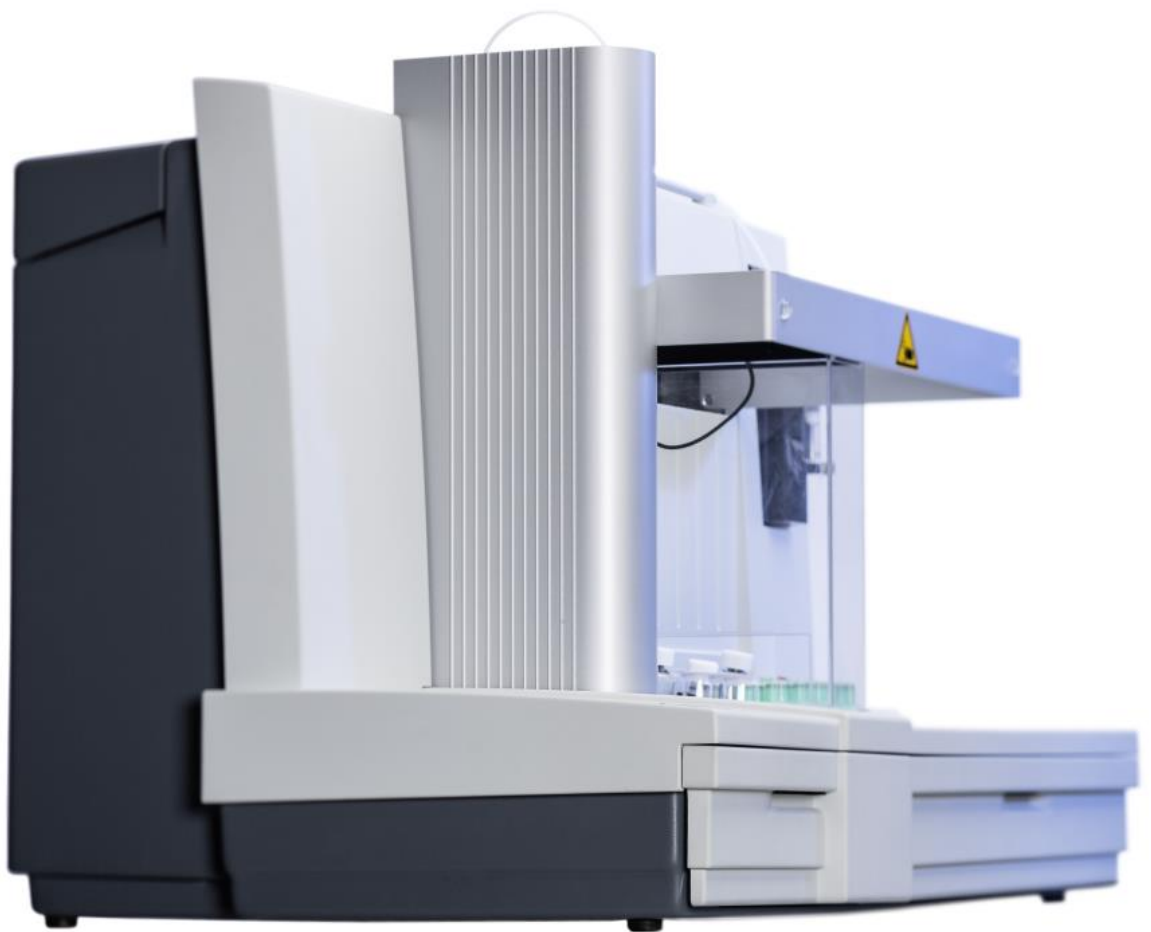


Coatron A6

Operator's Manual



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

Updates

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

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Warranty

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

The warranty expires in case of failures caused by

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

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1. INTRODUCTION

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



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

1.1 SYMBOLS

The following standard symbols are used in this manual:

Symbol	Meaning	Explanation
Courier	Info	Key on keypad.
CAPS	Info	Screen message.
	Read	Indicates important information and tips.
	Info	Describes reaction of COATRON A6 to operator input.
	Warning	Risk of possible health damage or considerable damage to equipment if warning is not heeded.
	Danger	Potential risk to operating personnel or equipment due to electric shock.
	Biohazard	Equipment can be potentially infectious due to the samples and reagents used .
	Laser Radiation	Avoid direct eye exposure

1.2 SAFETY INFORMATION

1.2.1 INTENDED USE

IVD

The **COATRON A6** is designed to carry out coagulometric tests such as PT, PTT, TT, fibrinogen, single factor tests, chromogenic and immunoturbidimetric tests (for instance Antithrombin, D-dimer etc.). The instrument has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the SAFETY WARNINGS. This manual contains instructions for professional qualified operators.



Do not use plasma with more than 50mg/dL Bilirubin (856µmol/l)
Do not use plasma with more than 2000mg/L Hemoglobin
Do not use plasma with more than 50 g/l Triglyceride (57 mmol/l)



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

1.2.2 SAFETY INFORMATION FOR OPERATION



Use only the cleaning and rinsing liquids approved by the manufacturer. Failure to do so could result in faulty measurements or malfunctions of the COATRON A6. Prevent reagents from leaking into the Analyzer. Failure to do so may make expensive maintenance work necessary!



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



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

1.2.3 SAFETY INFORMATION FOR MATERIALS

**Important!**

Use only organic solvents where specified. The cuvettes are intended as

single-use items only. Repeated use may result in false results due to contamination. Follow the instructions in the reagent package circulars. Incorrect handling may result in falsified results.

1.2.4 SAFETY INFORMATION REGARDING RISK OF HEALTH



Infectious Material

Avoid direct contact with samples and sample residues in the used cuvettes. Infectious material such as cuvette waste and liquid waste must be disposed in compliance with local regulations governing for infectious materials. Wear medical infection grade protective gloves for all cleaning and maintenance works involving potential contact with infectious liquids and use each pair of gloves once only. Use a hand disinfectant product, e.g. Sterilium®, to disinfect your hands after completion of the work.

NOTICE

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious. The „BIOHAZARD“ warning label must be affixed to instrument prior to first use with biological material!



Laser Radiation

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

Avoid direct eye exposure

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

1.2.5 SAFETY INFORMATION FOR CLEANING, MAINTENANCE AND SERVICING

**About authorized service !**

Carry out only the maintenance, repair and replacement measures listed in this Operator's Manual. Improper manipulation of the device will void the manufacturer's liability obligations and may make service calls necessary, payment of which is not covered by warranty. Only the authorized Customer Service may carry out servicing. Only original replacement parts may be used. Before doing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts

**About cleaning and decontamination !**

Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. The procedure is described in chapter "9 Cleaning and maintenance" and should be performed by authorised well-trained personnel only, observing all necessary safety precautions

**Cleaning certificate required !**

Instruments to be returned have to be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre, or from authority's interventions.



Regard all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.



Avoid any direct contact with decontaminants or disinfections.

1.2.6 ELECTRICAL SAFETY

	Precautions: ▪ Avoid spilled liquids into system. But in case disconnect system from power and clean and dry all contaminated parts. ▪ Remove power cord before open the instrument ▪ Do not touch any electronic parts during operation. ▪ Do not operate system without proper connection to grounding ▪ Never intentionally interrupt protective ground contacts. ▪ Never remove housing elements, protective covers or secured structural elements, since so doing could expose parts carrying electric current. ▪ Make sure surfaces such as the floor and workbench are not moist while work is being done on the device. ▪ Check electrical equipment regularly. Defective leads or socket must be replaced without delay.
---	---

	Connect to power: Instrument is classified to Class-1 (IEC) and must therefore be reliably earthed and professionally installed in accordance with the prevailing electrical wiring regulations and the safety standards covered herein. ▪ Use only three wire power cord. ▪ Make sure the operating voltage setting is correct before connecting the device to the power mains. ▪ Ensure at least 20cm space to power socket and instrument power ON/OFF switch for easy and quick access to power cord during operation.
---	--

	Disconnect from power: ▪ Unplug power cord from wall socket/UPS or from instrument power-in
---	---

1.2.7 EMC CONFORMITY



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



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



Detecting electromagnetic environment is recommended before using this device.



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

1.3 LABORATORY REQUIREMENT

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

1.4 UNPACKING THE COATRON A6

Following receipt of the shipment, please inspect the packaging of the COATRON A6 for any visible external damage. If the packaging is damaged, contact the transport company so that any damage to the device or accessories can be assessed. Inspect the COATRON A6 and accessories for any damage. Report any damage found to the dealer without delay. Even if the packaging appears undamaged, check the analyzer and accessories for any transport damage, caused for example by impact, dropping, etc. during transport.



Keep the original packaging material for purposes of later transport

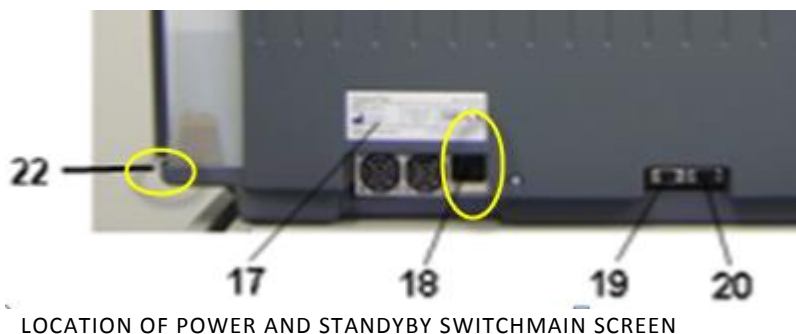
1.5 REMOVAL OF THE TRANSPORT RETAINER ELEMENTS

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

1.6 SWITCHING ON AND OFF THE COATRON A6

Switching on

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



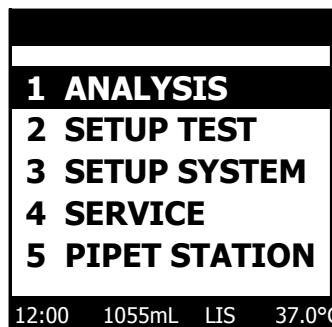
The following screen appear in this order after the COATRON A6 is switched on.

Coatron A6	Name of instrument
V1.03.02	Version of firmware
SN-12345	Serialnumber
Service: 100000	Tests until next service
CUVETTES:1	Activated cuvettes
CLEAN-B: 0	Activated rinse tank
REAGENT: CLOSE	Reagent system is closed



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

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



MAIN SCREEN:

Time= 12:00

Rinse installed = 1055mL

LIS = online

Temperature at cuvette= 37°C

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

Switching off:

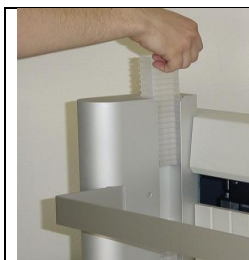
For normal shutdown at the end of the day and for changing the pipetting needle, rinsing solution tank and syringe, switch off the instrument with the standby switch on the right side of the housing. This will shut off all power-consuming components except of the ventilator. For longer interruptions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



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

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

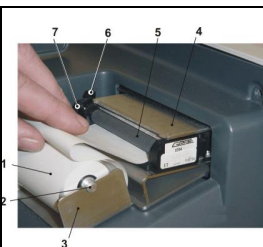
1.7 INSTALLATION OF COMPONENTS



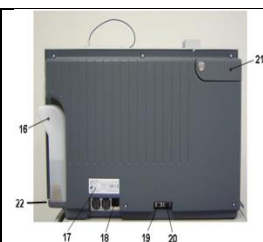
1. Remove a strip of cuvettes from the package.
2. Shift the cuvettes as shown from above in the guide groove back into the cuvette tower.
3. Remove the tape off the cuvettes.
4. Activate cuvettes by barcode if required



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



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



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

1.8 INSTALLATION OF TECAM SOFTWARE

TECAM software is a powerful enhancement of the Coatron A6 and allows very easy and flexible to generate orders (including sample continuous loading). Results can be reported including the reaction curve and administrate in a database. For further information read the online manual of TECAM software

System requirement

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

Install:

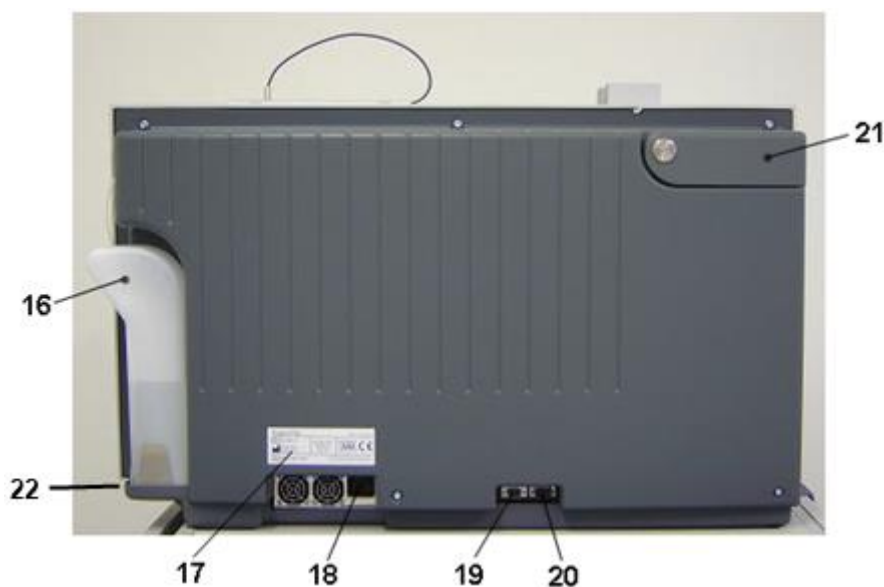
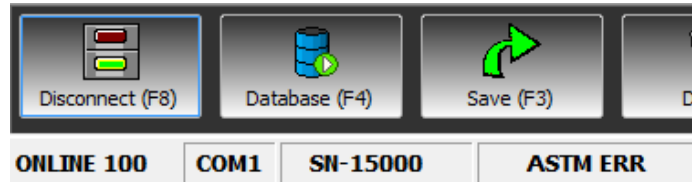


Figure 2: COATRON A6, rear view

1. Link instrument left RS232 port (location #19) to PC
2. Check PC comport number (it must be between 1 to 15)
3. Start "SETUP.EXE" from the CD. The Setup will install Smart ,PRO or PROLIS and all required driver for database access.
4. Enter fingerprint and activation code

Run TECAM:

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



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

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



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

2. DESCRIPTION OF THE COATRON A6

2.1 SHORT INTRODUCTION

The COATRON A6 is a fully automated laboratory analyzer for the fast and flexible coagulation diagnostic. It is equipped with six optical channels and offers clotting, chromogenic and immunological testing in random acces mode as well as fast processing of STAT samples. All sample dilutions and assay calibration are performed automatically. ID-barcode scanner is on board. CAP Piercing is supported for any primary tube system. The analyzer is also focused on a minimum consumption of consumables and reagents, which makes the analyzer very cost effective. The nearly zero service requirements will ensure a long living device by a minimum of service costs. The analyser can be linked to powerful LIMS software to give exceptional features like unlimited result traceability by an one click report engine or a unique quality control system with Levey Jennings chart and Westgard rules

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

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

2.2 VIEWS OF THE DEVICE

2.2.1 FRONT VIEW

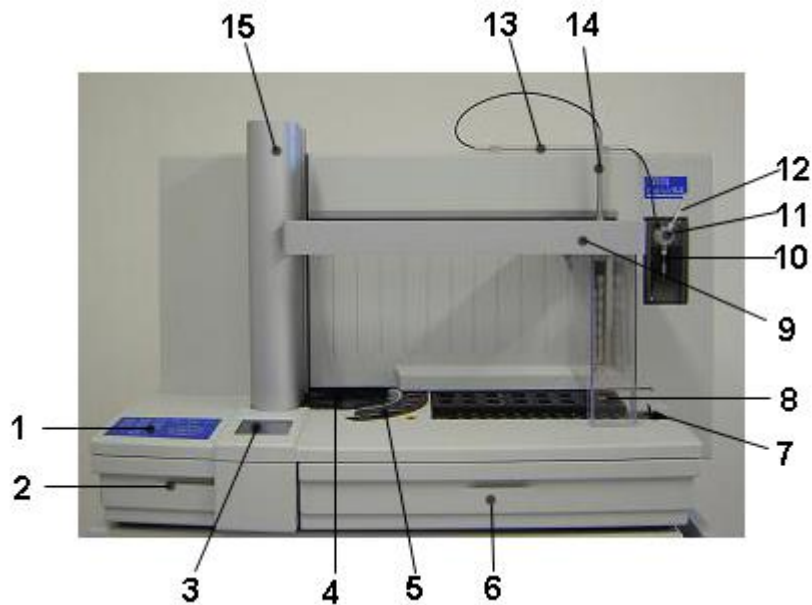


FIGURE 1: COATRON A6, FRONT VIEW

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

*

2.2.2 REAR VIEW

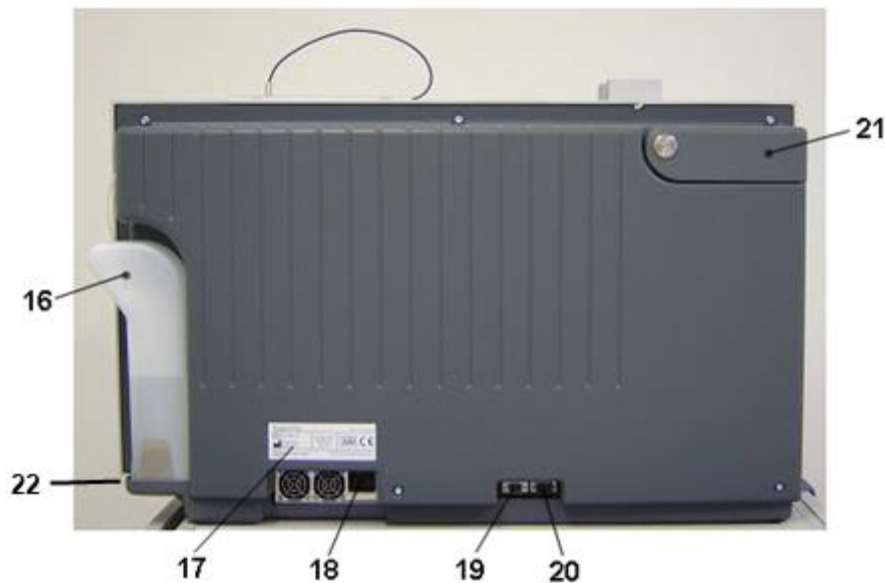


FIGURE 2: COATRON A6, REAR VIEW

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

2.2.3 SIDE VIEW

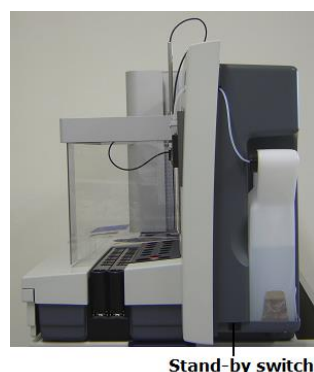
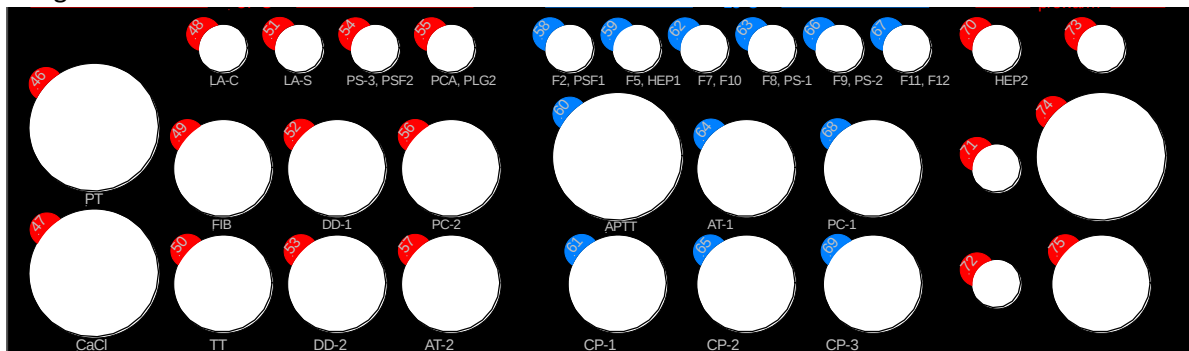


FIGURE 3: SIDE VIEW

2.2.4 REAGENT POSITIONS

Pos. 1 - 45		Sample positions	Room temperature
-------------	--	------------------	------------------

Reagent block:



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

System block:

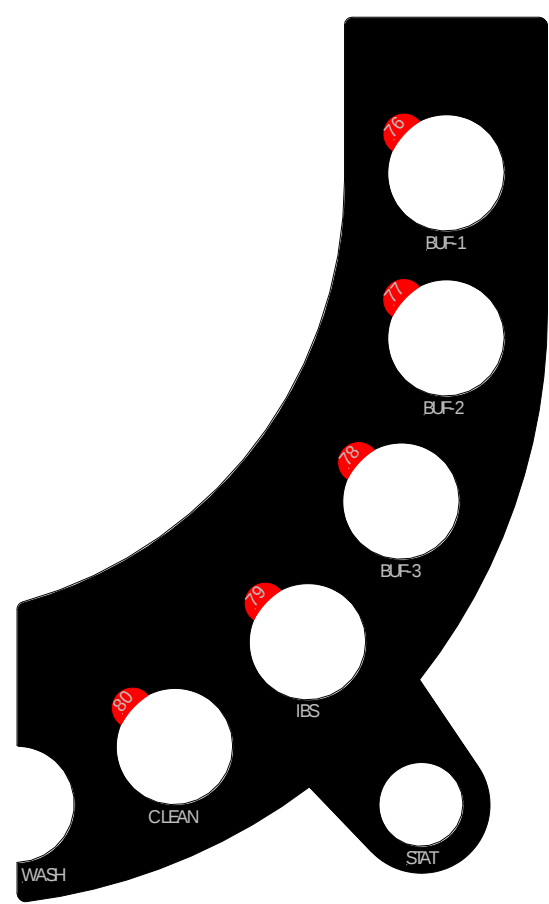


FIGURE 4: WORKING POSITIONS

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

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



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

2.2.5 KEYPAD

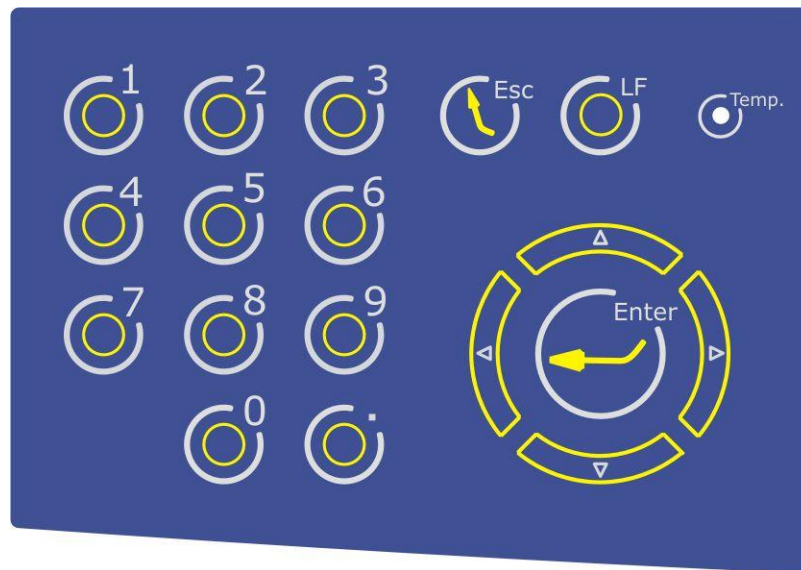


FIGURE 5: KEYPAD

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

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

2.2.6 SCREEN SEGMENTS



Figure 6: Screen segments

There are 3 screen segments:

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

2.3 MEASUREMENT PRINCIPLE

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

2.3.1 MATHEMATICAL PRINCIPLES

The conversion of coagulation time into a specific test unit is one using a linear, hyperbolic, semi-logarithmic or double-logarithmic interpolation of the stored calibration points. The current mathematical model is printed out in "TEST SETUP." Values outside the calibration range are calculated by extrapolation and flagged as " * ".

2.3.2 UNITS

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

R = clotting time / normal time

PR = 100 * (normal time / clotting time)

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

INR+ = Like INR, except the ISI value is determined for a specific device.

This is done using a calibration curve with INR standards.

IU/mL = IE/mL = International Units (1.00 IU/mL = 100 % activity)

Unit Reflex= System repeat testing if

Result < Unit Reflex : Repeat with half sample dilution

Result > Unit Reflex : Repeat with double sample dilution

2.3.3 CLOTTING METHOD

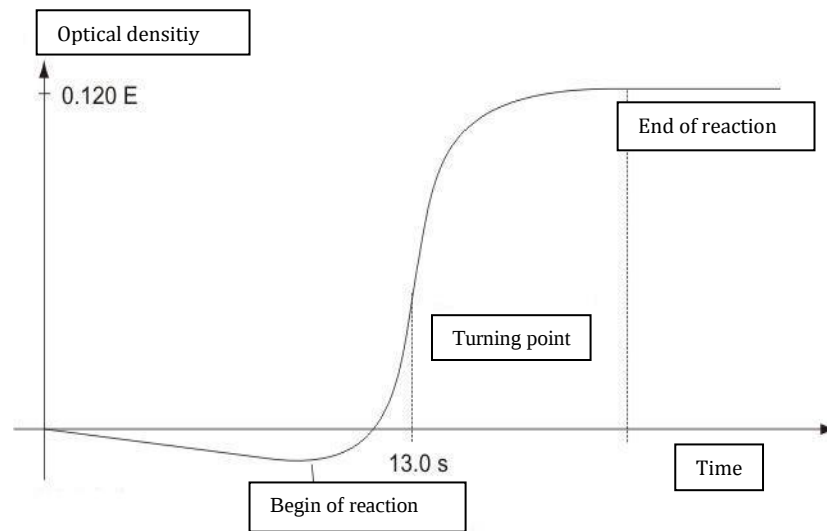


FIGURE 7: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

The final reaction in the coagulation cascade is the transformation of fibrinogen into fibrin catalyzed by thrombin. Fibrin formation results in clouding (higher turbidimetric level) in the sample, which is measured by the photometer and stored as the extinction. The result in seconds is the time from the start of the reaction to the time of greatest extinction increase (reaction turning point).

2.3.4 DERIVED FIBRINOGEN

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

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



The DFIB results can give significant higher concentrations than compared to clauss method – especially for very high concentrations. Therefore method should only be used to select samples. Samples with a fibrinogen concentration outside the normal range must be confirmed using the FIB Clauss method.

2.3.5 CHROMOGENIC, ENDPOINT AND IMMUNOTURBIDIMETRIC METHOD

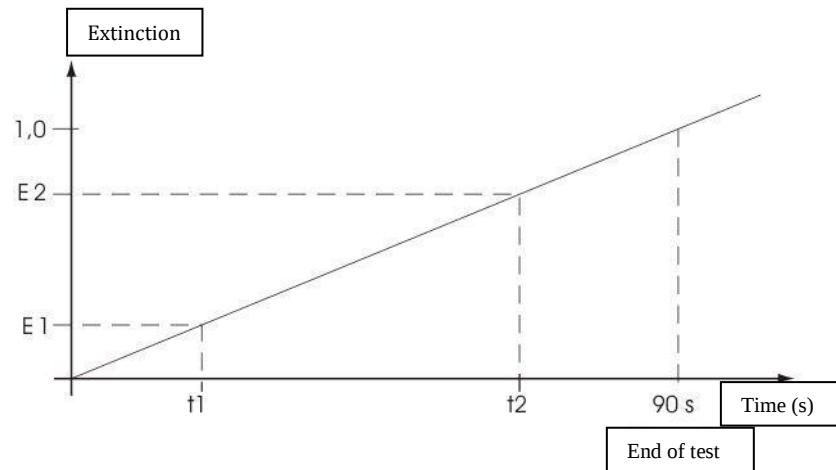


FIGURE 8: DETERMINATION OF RISE IN THE KINETIC TEST METHOD

t_1 = deadtime in s

t_2 = endtime in s

Delta signal $dE = E_2 - E_1$

Delta time $dT = t_2 - t_1$

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

Result of method „IMMUN“ = dE/dT

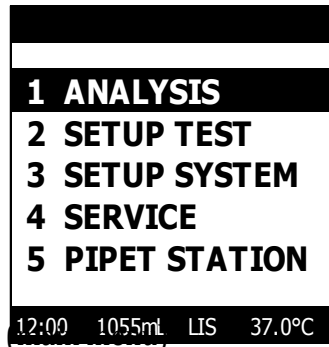
Result of method „POINT“ = dE

2.4 TEST OVERVIEW

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

3. OPERATION OF THE COATRON A6

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



Statusbar Information:

Time = 12:00

Rinse = 1150mL installed

LIS = Online

Temp = 37°C

Short descriptions of main menu

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

3.1 ROUTINE MEASUREMENT WITH TECAM



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

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

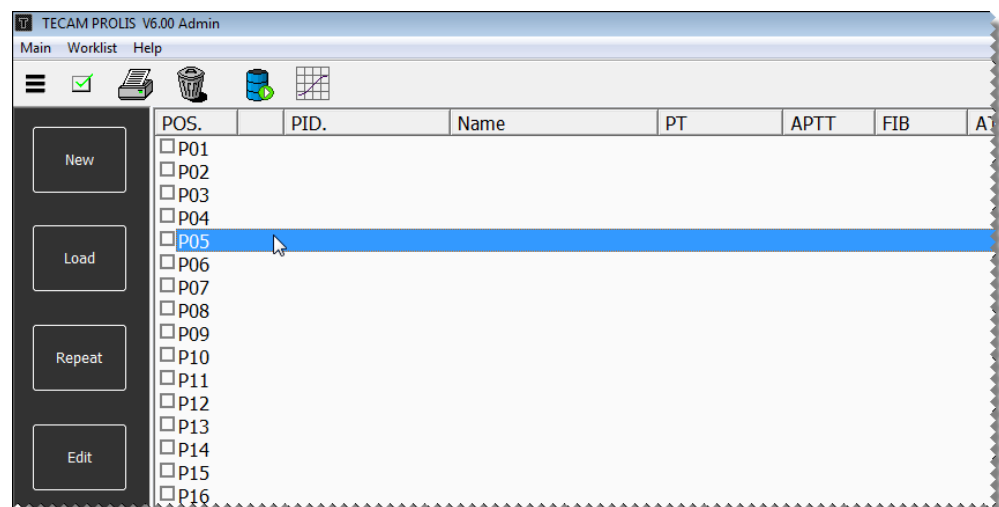


FIGURE 9: WORKLIST SCREEN OF TECAM

4. Import PID from analyser, if you work with patient barcode information.
 - Select menu “LOAD”
 - Goto analyser and scan the patient racks and press “ENTER”
5. Select rack position with cursor keys and press ENTER or click to EDIT. The Test order screen will popup.

FIGURE 10: TEST ORDER SCREEN OF TECAM

Using Auto-IDNumber:

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

Using Patient-ID Number:

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

6. Select menu Worklist\Send worklist

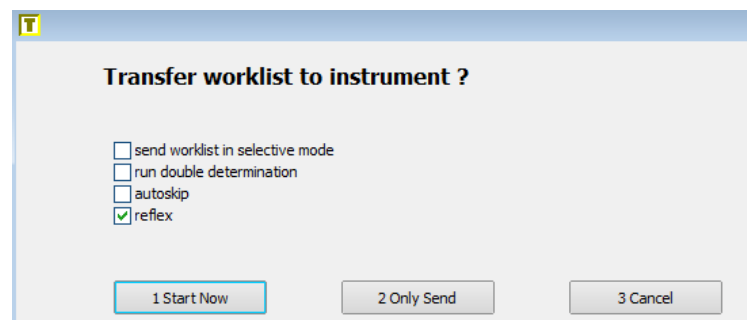


FIGURE 11: RUN WORKLIST SCREEN OF TECAM

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

7. Receiving results

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

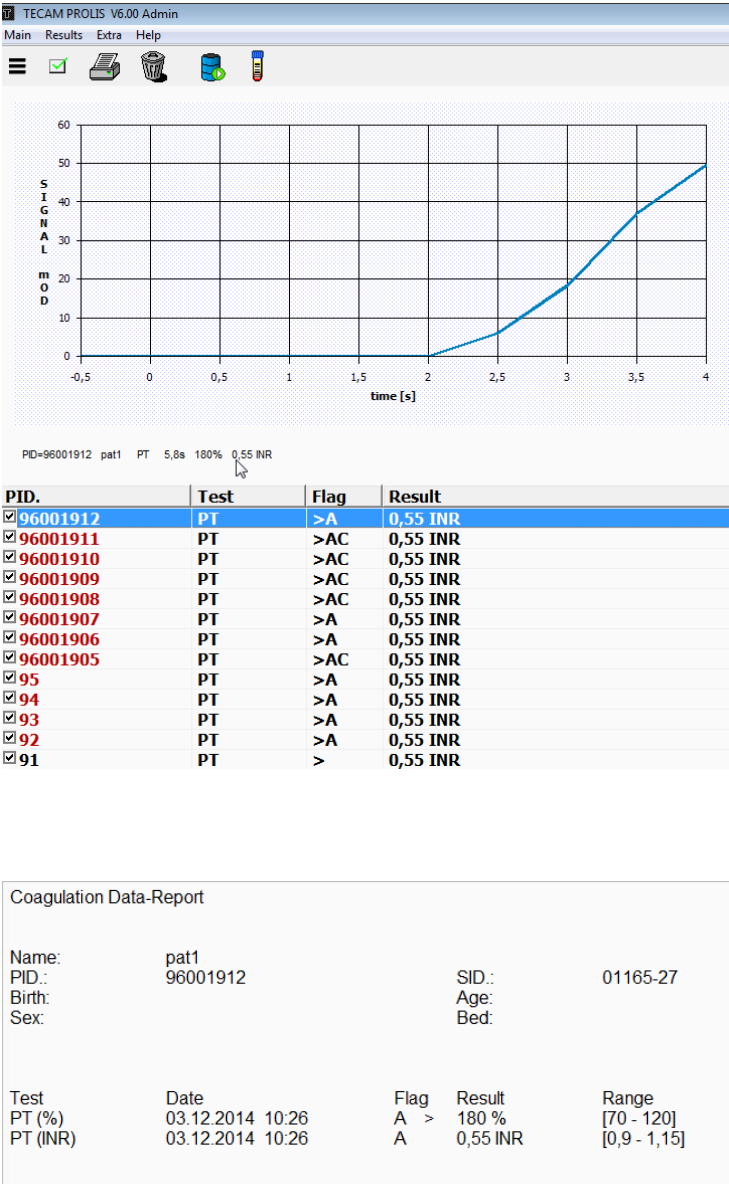


FIGURE 12: RECEIVE RESULT SCREEN OF TECAM

3.2 ROUTINE MEASUREMENT WITHOUT TECAM



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

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

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

"New List" Screen 1

Select CONTINUE=YES to confirm and show the next screen

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

Select CONTINUE=YES to confirm and show the next screen

CONTINUE:		YES
SAMPLES:	6	
1.PID:	1000	
CP-1:	-	
CP-2:	-	
TEST1: PT	TEST5: -	
TEST2: APTT	TEST6: -	
TEST3: FIB	TEST7: -	
TEST4: -	TEST8: -	

New List" Screen 2

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

Select CONTINUE=YES to come to the next screen

Press ENTER to confirm and show the next screen

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

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

"New List" Screen 3

Press ENTER to confirm and show the next screen

PREPARE SYSTEM	
P46	800uL
P47	500uL
P49	500uL
P60	500uL
P79	740uL
CUVETTES 3	
CONTINUE >> KEY ENTER	

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

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

"New List" Screen 4

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

3.3 INTERRUPT OR EXIT MEASUREMENT

Automatic interrupt of worklist:

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

Manual interrupt worklist: Press key **ESC**:

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

Exit worklist: Press key **ESC** again :

Measurement and worklist will be aborted.

Move robotic: Press key **LEFT/RIGHT** :

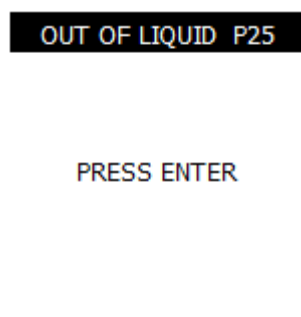
Moves robotic to left or right home position.

Continue worklist: Press key **ENTER** :

Continuous measurement

3.4 OUT OF LIQUID OR CUVETTE DURING MEASUREMENT

System will interrupt worklist automatically, if



Out of liquid:

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

Out of cuvette:

Reload cuvettes and press **ENTER** to continue worklist

3.5 CONTINUOUS LOADING OF SAMPLES



This feature requires TECAM software.

(1) Samples without patient barcode

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

(2) Samples with patient barcode

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



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

3.6 MEASURING THE EMERGENCY SAMPLES

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

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

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

3.7 QUALITY CONTROL MEASUREMENT

The analyser allows to run one control plasma for each test. The specific control range must be entered in the menu "TEST SETUP". A control result is always marked with flag "C" and in case that it is out of range also with flag "Q". All further results will be flagged with "Q" until a new control result is successfully or the instrument is rebooted.

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

QC with positions CP1,CP2 or CP3 :

- Define control range in the menu SETUP TEST
- Activate QC-ACTIVE within worklist menu
- Optional: Enter lot-number of control plasma within the worklist menu
- Place control plasma to position CP1,CP2 or CP3. The corresponding control position is printed with the test setup.

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

- Define control range in the menu SETUP TEST
- Set QC-ACTIVE=NO within worklist menu
- Set BARCODE=YES within worklist menu
- Enter the lot-number of control plasma within the worklist menu
- Place control plasma in first rack position and then all samples
- Set the PID of the control equal to the lot-number

QC with TECAM software:

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



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

3.8 REFLEX TESTING

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

- **Clot Reflex:**
Test is repeated with additionally 60s prolonged maximum reading time, if no clot was found (+++). This mode is only active for method "CLOT".
- **Unit Reflex**
Test is repeated with half or double plasma dilution, if result is above or below the unit reflex limits (see chapter 2.3.2 Units)2.3.2).
- **Disable/Enable**
Reflex testing can be enabled globally in analyser menu "ANALYSIS"
Unit reflex can be enabled for each test in analyser menu "SETUP TEST".

Repeated results are flagged with "R"

3.9 DISPLAY DURING MEASUREMENT

WORKLIST IN PROCESS		
P01	PT	100 INR
P01	APTT	/
P01	FIB	x0045
P02	PT	1250 INR
P02	APTT	/
P03	FIB	x0021
PROGRESS: 6% - HC -		

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

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

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

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

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

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

3.10 RESULT WARNING MESSAGES

Results may also be displayed with various additional warning symbols:

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

4. MENU ANALYSIS

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

Coatron A4

1 ANALYSIS

2 SETUP TEST

3 SETUP SYSTEM

4 SERVICE

12:00 1150mL H00 37.

WORKLIST

1 NEW LIST

2 CONTINUE

3 REPEAT

4 STAT

5 VIEW

6 PRINT OPTION

7 CUVETTE ACTIVATION

8 TEST ACTIVATION

12:00 1055mL H0 37.0°C

menu analysis

4.1 SUBMENU NEW LIST

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

Screen: worklist setting

CONTINUE: YES

TEST: PRFL

BARCODE: NO

RELFE: NO

DOUBLE: NO

QC-ACTIVE: NO

AUTOSKIP: NO

HCT-L: 00 mm

CLEAN: MIN

SHIELD: YES

MODE: CUV

- **Test:**
With ARROW → one proceeds to the list of all available tests in which one navigates with the arrow keys, Enter selects the test from the worklist. With Enter on the field INFO an overview of the test settings is printed out.
- **Reflex** YES / NO:
Activates reflex testing. The instrument can repeat automatically suspected results like +++ (no clot detected) or greater. smaller a certain limit (e.g. FIB > 600mg/dl).
- **Barcode** YES / NO:
Primary tubes are provided with barcode label, which is used to input the patient identification number (PID)
- **Double:** YES / NO
Activates the double test. The mean value is automatically used in the results report. If the two individual results differ by 15%, the result is labelled Flag "%."
- **QC Active:**YES / NO
Carries out control measurements with control plasma before each worklist is started; for this purpose, positions P35 (CP-1) or P36 (CP-2) must be filled with control plasma. The control positions for each test are defined in the Test Setup printout. If the control measurement results are outside the QC, then the results printouts for the worklist will bear the remark "Q."
- **Autoskip** YES / NO:
The instrument will skip current job or test, if plasma or reagent runs out and continue with the next order. Skipped jobs are printed as "SKP". Select "CONTINUE" in the analysis menu to re-run only skipped jobs.
- **HCT-L:** 0 – 63 mm
Determines the height of the coagulum (haematocrit level) measured from bottom of tube. The needle will search for plasma only upto this level. HCT-L must be set to 0, if only plasma is used
- **CLEAN:** Min - Max
Defines how to clean needle after pipetting samples
 - **MIN:** Don't perform a clean cycle from sample to sample. The risk of sample to sample carryover was evaluated with extreme high levels of Heparin and concerned low.

- **MAX:** Always perform a clean cycle from sample to sample. It required much more rinse solution and time to carry out a worklis

➤ **SHIELD:** Yes - No

This setting is only display, if a protection shield is installed.

- **YES:** System stop immediately operation, if protection shield is opened during worklist.
- **No:** Deactivate shield detection



Important:

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

➤ **Mode:** BAT / SEL / CUV / EV1 / QC

Determines the mode of test processing:

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



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

Screen: Test Profil, Control plasma and Autoseries input:

CONTINUE:	YES										
<table border="1"><tr><td>SAMPLES:</td><td>45</td></tr><tr><td>INI.-ID:</td><td>1000</td></tr><tr><td>1: PT 2:APTT 3:FIB</td><td></td></tr><tr><td>4: - 5:- 6:-</td><td></td></tr><tr><td>7: - 8:-</td><td></td></tr></table>		SAMPLES:	45	INI.-ID:	1000	1: PT 2:APTT 3:FIB		4: - 5:- 6:-		7: - 8:-	
SAMPLES:	45										
INI.-ID:	1000										
1: PT 2:APTT 3:FIB											
4: - 5:- 6:-											
7: - 8:-											

Possible settings:

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



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



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

Input of PID by barcode or manual entry:
(set BARCODE=YES , see screen 1 above)

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

RACK 1

01 >>

02

03

04

05

06

07

08

09

10

11

12

13

14

15

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

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

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



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

Press *ENTER* to come into the next screen.

SYNCHRONIZE TO HOST

PID: 1000



All patient identification numbers will be send to host.

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

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

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



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

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

Start worklist:

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

PREPARE SYSTEM	
P46	800uL
P47	500uL
P49	500uL
P60	500uL
P79	740uL
CUVETTES 3	
CONTINUE >> KEY ENTER	

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



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

4.2 SUBMENU CONTINUE

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

4.3 SUBMENU REPEAT

Repeats the last worklist.

4.4 SUBMENU STAT

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

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

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

4.5 SUBMENU OVERVIEW

Displays and prints lists according to given sorting criteria.

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

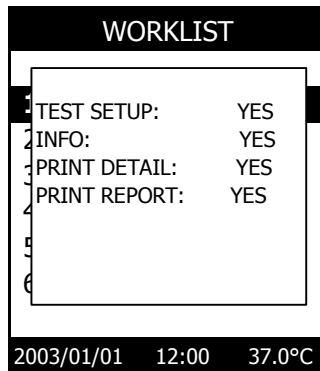
Enter calls up options, ARROW ↑ / ARROW ↓ pages through the options, Enter executes the operation:

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

The following options can be selected:

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

4.6 SUBMENU PRINT OPTION

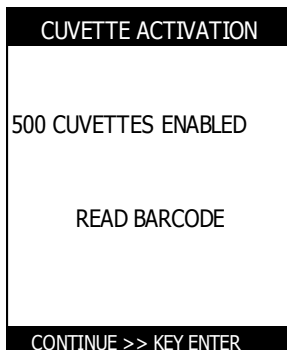


Determines what information is to be printed automatically:

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

4.7 SUBMENU CUVETTE ACTIVATION

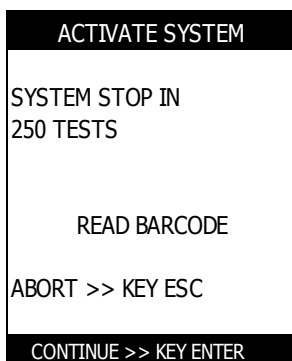
This menu is only shown, if instrument is configurated as “Closed to cuvette”.
Read the barcode, which is provided with the cuvette package.



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

4.8 SUBMENU SYSTEM ACTIVATION

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



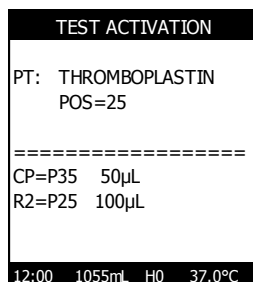
System will stop operation in 250 determinations.



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

4.9 SUBMENU REAGENT ACTIVATION

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



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

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

Barcodes will be rejected in case of

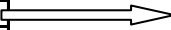
- invalid syntax of barcode
- date expired
- barcode differs to data stored in the SETUP test



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

5. MENU SETUP TEST

CHANGE TEST			
PT	DFIB	APTT	FIB
AT	TT	DD	HEP
PC	PS	F2	F5
F7	F8	F9	F10
F11	F12	PLG	-APC
APCR	LA-S	LA-C	PSF
XXXX	XXXX	XXXX	PRFL
1=INFO		2=PRINT	



TEST:	PT
LOT:	1234
EXP:	12/2012
UNIT:	%
INCUB:	60s
RUNTIME:	120s
REFLEX:	YES
ENTRY:	AUTO

- **1=INFO:**
Show volumes and position of reagent
- **2=PRINT:**
Print test setup
- **New lot number (LOT):**
If the LOT number is inverted, ARROW → is used to get to selection of individual digits, numbers and letters and ARROW ↑ / ARROW ↓ are used to page through them; numbers can also be entered directly using the numeric keypad.
- **Input of expiry date (EXP.):**
With ARROW ← / ARROW → the month can be changed, with ARROW ↓ the year is changed analogously to the month. Expired dates will not be accepted by the COATRON A6
- **Selection of unit:**
With ARROW ← / ARROW → the units are changed in which the results are displayed with the exception of the basic unit (which depends on the measurement principle). The available units are %, INR, Ratio, INR+ and no further unit (-). Calibration curves can only be entered when a unit has been selected. See *chapter 2.3.2, Units* on the significance and calculation of the units.
- **Incubation time**
Define the delay time before start reagent (R2) is added. With ARROW ← / ARROW → the incubation time is changed in 30-second increments from 60 to 450 seconds.
- **Runtime**
Define the maximum reading time.
- **Reflex**
Enable/disable. Reflex testing will be automatically disabled, if no CLOT and Unit reflex is possible. Unit limits can be printed with "1:PRINT" during test selection. For more information see *chapter 3.8, Reflex testing*
- **Entry**

Select between manual input of calibration curve or automatical test calibration

5.1 CALIBRATION CURVE

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

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

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

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

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

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

The calibration curve can be entered or changed now manually. At least 2 value pairs are required up to a maximum of 6 value pairs. List navigation is with the arrow keys and the values are confirmed with Enter. A value

pair can be added, deleted or changed at any position. Subsequent data saving automatically sorts the calibration data.

INR Calibration:

The operator can select the unit between

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

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



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

$R^2 > 0.998$: the curve is linear. Two points are enough.

$R^2 < 0.950$: the curve is inlinear. Use more than 2 points.

$R^2 < 0.900$: change math. model and use more than 5 points. Results outside of calibration are not trustful.



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

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

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

➤ Auto calibration

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

SETUP PT

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

12:00 1055mL H0 37.0°

STANDARD VALUE:

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

12:00 1055mL H0 37.0°

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

• Autocalibration with serial dilutions

The dilutions are always prepared in following way:

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

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

ANALYSE CURVE

<-
START

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

12:00 1055mL H0 37.0°C

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

3. Additional empty sample test tubes are required in rack positions 2-6. The number of samples corresponds to the number of sample test tubes and depends on the particular test.
4. Select START, check the reagents and numbers of cuvettes required in the screen SYSTEM PREPARATION and initiate the measurement procedure with Enter.

- **Autocalibration with fixed levels**

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

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

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

5.2 REAGENT BARCODE ENTRY

Scan barcode of reagent during menu “SETUP TEST”.

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

5.3 STORING OF TEST DATA

Press ESC to return to the main menu “TEST SETUP”. If any data was changed, the COATRON A6 will ask for confirmation before storing.

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

The following rules must be complied with:

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

5.4 SUBMENU TEST PRINTOUT

During test selection press key "1"

SETUP FIB LOT: 302501299 NAME: Fibrinogen EXP: 1/2015 LAST CHANGE: 03.04.2013 1: 80 mg/dl - 27.0 s 2: 120 mg/dl - 18.0 s 3: 240 mg/dl - 12.0 s 4: 480 mg/dl - 7.0 s R² = 0,992 S-CORR: 0% T-CORR: 0% 0s START: 3s INCUB.: 120s RUNTIME: 120s METHOD: COAG CT-MECH: NO SENS: 0 MIX: 0 CLEAN: 1 MULTI: 1 BARCODE: 1 REFLEX: >600mg/dL PAT: VOL= 10uL POS=62 (CP) BUF: VOL= 90uL POS=78 CLR: VOL= 0uL DEF: VOL= 90uL POS=0 R0 : VOL= 0uL POS=0 R1 : VOL= 0uL POS=0 R2 : VOL= 50uL POS=49	
- lot number - reagent name - expiry date - date of input	
- calibration values	
- Linearity of the calibration curve (1.000 for a straight line) (R² should be 0.850 – 1.000)	
-signal correction -time correction -deadtime -incubation time -max. runtime -test method=coagulation -clottingtime mechanical=no -test sensitivity=low -reagent mixing=no -high cleaning cycle=yes -multi dispensing=Yes -barcode required=yes -unit reflex=yes, if result>600mg/dL	
- 10µl Sample - 90µL IBS from Pos=P78	
- 50µL reagent from POS=P49	

6. MENU SYSTEM SETUP

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

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

General operation:

ARROW ↑/↓ left column Change item

ARROW → change to right column

ARROW ↑/↓ right column: Change value

Enter to confirm the value.

ESC exit menu

6.1 LANGUAGE

Select between: English - Italian - Spanish - German

6.2 DATE

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

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

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

6.3 TIME

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

6.4 SIGNAL

Switches the acoustic signal on or off.

Possible settings:

- Signal on
- Signal off

6.5 CONTRAST

Changes screen image contrast.

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

6.6 MIXER

Changes the magnetic stirrer speed at position 25 in the reagent block.

Continuous settings from 0 to 255, standard setting 200.

6.7 SIMULATOR

Facilitates simulation of measurement operation without moving the pipetting arm.

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

6.8 COOLING

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

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

7. MENU SERVICE

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

ARROW ↑/↓
Enter
1-9

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

7.1 REFILL CUVETTES

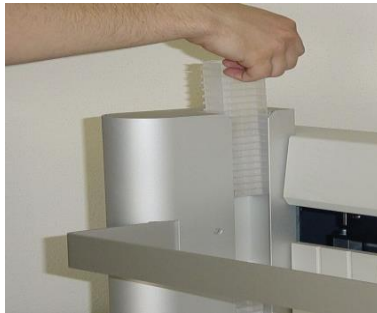


FIGURE 13: INSTALLATION OF CUVETTES

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



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

7.2 INSERT PRINTER PAPER

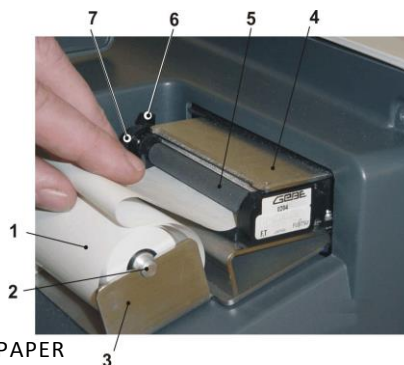


FIGURE 14: INSTALLATION OF PRINTER PAPER

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

7.3 SYSTEM REPORT

Printout of important system data

SYSTEM - REPORT

DATE: 2012/25/10 13:59

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

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

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

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

CONTRAST: 225
MIXER: 200

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

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

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

---- SYSTEM STATUS ---

SYSTEM = CLOSE
SERVICE = CLOSE
REAGENT = CLOSE

OPTICS : 80 30005 (162)

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

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

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

Display contrast
Reagent mixing speed

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

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

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

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

7.5 ADJUST XYZ

Key 4/6 move needle left/right (X-offset)

Key 2/8 move needle backward/forward (Y-offset)

ARROW ↑/↓ move needle up/down (Z-offset)

ENTER goto next position

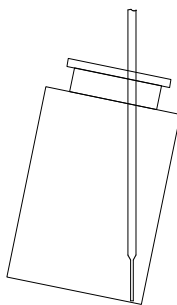
ESC exit adjustment

Five positions must be adjusted

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



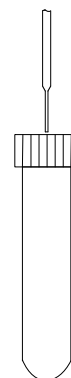
optimum wash



optimum reagent



optimum patient



optimum piercing

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

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



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

2. First the needle will go to wash position. Center the needle exactly. The needle tip must be at same level with top of wash position. Press "ENTER" to come to next position or press "ESC" to quit.
3. Second the needle will go to buffer-1 position (P76). Center the needle. The needle tip should be short before touching the vial bottom. Lift vial to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.
4. Third the needle will go to cuvette position. Center the needle and afterwards lower the needle until it is short before touching the cuvette. Lift the cuvette to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.
5. Fourth the needle will go to sample position P01. Center the needle. The needle tip should be short before touching the vial bottom. Lift vial to determine the distance. Press "ENTER" to come to next position or press "ESC" to quit.
6. Fifth the needle will go to sample position P02. Center the needle. The needle tip should be short before touching the cap membrane. Press "ENTER" to test cap piercing or press "ESC" to quit.

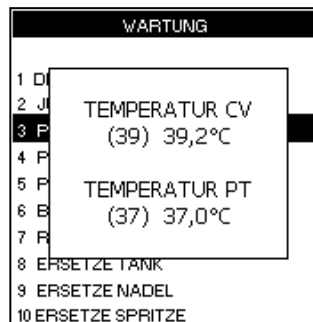


Skip cap piercing if not required. The value P-OFFSET must be 0 to deactivate cap piercing



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

7.6 CHECK TEMPERATURE



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

Setting the temperature:

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

1. Place an empty cuvette in the measuring cell and fill 300 µl water into all of the 6 measurement positions. Place a standard commercial fever thermometer in one of the cuvette wells. Make sure the cuvette is standing upright.
2. Place also an empty reagent container in position "PT" (P25) and fill with 6 - 7 ml water. Place a standard commercial digital fever thermometer in the water.
3. On the keyboard the green Temp. LED should light up.
4. Wait for at least 15 minutes. Now read off the temperature on the Thermometer.
5. The temperature should be in the range of $\pm 0.5^{\circ}\text{C}$ of target temperature. Use ARROW ↓ / ↑ to change.
6. Adjust temperature so often until the temperature shown on display matches the temperature in the cuvette or PT position.
7. For "PT" also the target temperature can be adjusted. Lower storage temperature of reagents will significantly increase stability, while results will be nearly unchanged.



Please ask local distributor about change of reagent target temperature

○

7.7 CHECK OPTICS

Remove the cuvette in the measurement optics.

CHECK OPTIK		
	OFF	ON AMP
1=	78	29851 185
2=	105	29624 192
3=	56	29799 171
4=	78	29851 185
5=	98	29245 155
6=	110	29967 145
T1=	34302	(34310)
T2=	34081	(34081)
T3=	31707	(31800)
CV-STATUS: 0		
SHIELD: 0		

X=	Measurement channel 1-6	
OFF	Digital value when LED is off. Target range <500	
ON	Digital value when LED is on. Target range 28000 - 32000	
AMP	Signal amplification, Target range 150 - 300	
T1	Digital value heat area, Target range 33000 - 36000	
T2	Digital value cuvette area, Target range 33500 – 36000	
T3	Digital value cool area	
CV-STAT	0= no cuvette	1 = cuvette is detected
SHIELD	0 = closed	1=open



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

7.8 CHECK ROBOT

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

7.9 MOVE CUVETTES

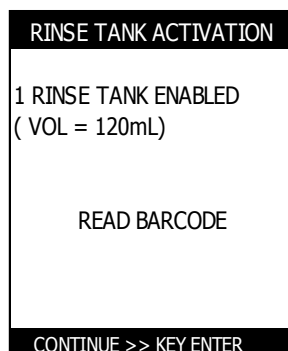
Turns cuvette rotor for transport of cuvettes until Enter is pressed. It is used to empty the cuvette tower.

7.10 CLEAN NEEDLE

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

7.11 REPLACE RINSE TANK

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



The current numbers of remaining rinse tanks and installed volume of rinse solution is displayed. The message can be ignored with key "ENTER", but latest at zero value new rinse tanks must be activated by barcode.

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



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



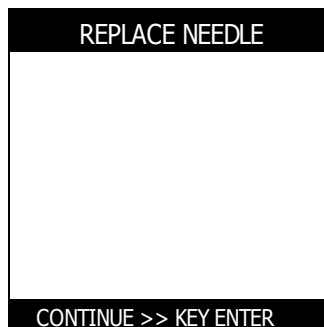
Make sure a full tank is really installed, since otherwise the COATRON A6 will calculate the consumption incorrectly.



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

7.12 REPLACE NEEDLE

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



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

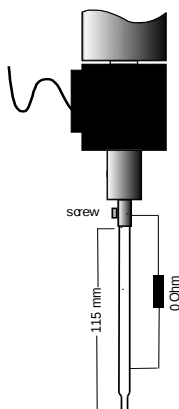


FIGURE 15: REPLACE NEEDLE



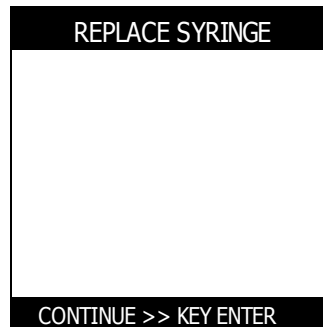
Any liquid contamination of the insulation block with the needle may malfunction the level sensing.



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

7.13 REPLACE SYRINGE

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



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

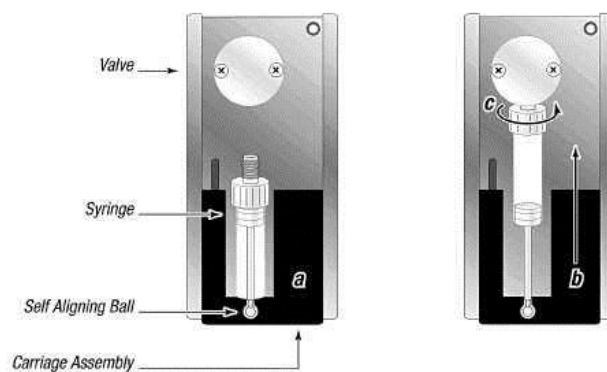


FIGURE 16: INSTALLATION OF SYRINGE

7.14 ADJUST MOTOR

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

The factory default value is „8“ . An increase of the offset will shift the cuvette to the left.

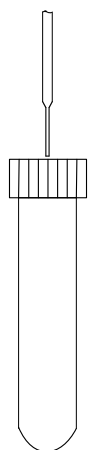


False adjustment will cause erroneous results.

7.15 CAP PIERCING

Fill a Sarstedt Monovette® or BD Vacutainer® or a similar system with 2mL water. Close the cap and place it into rack position P02.

Lower the needle until it is just before touching the cap. Then center the needle to the cap.



optimum piercing

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



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



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



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

8. MENU PIPET STATION

Menu to reconstitute reagent and controls

PIPET STATION	
IN:	P75
OUT:	P74
TOTAL:	0 ul
VOL (uL):	1000
PIPET >> KEY ENTER	
ABORT >> KEY ESC	

Fill enough diluent into container and place it to position P75. Open reagent vial and place it to position P74. Change volume with keys UP/DOWN and press ENTER to dispense diluent into reagent vial. Press ENTER again if more diluent is required. The total volume will be updated with each pipeting step. Press ESC to reset total counter and press ESC again to exit menu.

9. CLEANING AND MAINTENANCE

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

9.1 GENERAL INFORMATIN

- Use detergent and water and 10% diluted bleach or commercial decontaminant for daily cleaning
- Use 30% diluted bleach and commercial disinfectant (e.g. Bacillol®AF) for weekly decontamination
- Clean with a lint free cotton cloth or stick
- Never pure any liquid into optic or working area
- Keep the device free of dust and moisture.
- If the device is soiled with liquids, remove the soiling with an absorbent cloth.
- If a liquid has accidentally been spilt or pipetted into a measurement channel, remove it immediately with a pipette and clean the measurement channel with a lint-free cloth. Check the function of the optics in the menu SERVICE



Regard all surfaces and materials which might be in contact with plasma or other biological liquid as potentially contaminated with infectious material.



Avoid any direct contact with decontaminants or disinfections.

9.2 CLEANING

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

9.3 DECONTAMINATION

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

9.1 DAILY ACTIVITIES

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

9.2 WEEKLY ACTIVITIES

- Decontaminate system with bleach and ethanol as described above

9.3 YEARLY ACTIVITIES

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

9.4 REGULAR REPLACEMENTS

Every 100.000 tests following parts must be replaced

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

9.5 RESET SERVICE INTERVAL

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

10. ELIMINATION OF MALFUNCTIONS

10.1 ERROR MESSAGES

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

10.2 DEVICE MALFUNCTIONS

Malfunction / Error	Possible cause	Measures
No print on printout	Paper installed in wrong position	Turn paper roll around
Needle does not pipette correct volume	Tube system leaky	Replace the tube system
	Level sensor defective	Replace insulationblock
	Needle clogged	Place the needle in COATRON A6 Cleaner for 30 min, then run the wash cycle.
Poor reproducibility	Needle-tube system	Replace the needle, tube system ,syringe or valve.
	Motor is not adjusted	Check the adjustment of the cuvette to the optic
Cuvette assumes false position	Wrong cuvette	Use only original COATRON A6 cuvettes
	Motor is not adjusted	Check the adjustment of the cuvette to the optic
	Defective cuvette motor or microswitch for cuvette recognition	Consult customer service of your dealer
Optics not within target value range	Cuvette is in measurement position during optics check	Remove the cuvette and repeat the optics check
	Soiling or liquid in measurement channel	Optics must be cleaned. Consult customer service
	LED does not light up.	Customer service will replace optics

10.3 MEASUREMENT MALFUNCTIONS

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

10.4 PACKING THE COATRON A6 FOR SHIPMENT

If the COATRON A6 is to be shipped, e.g. to the Technical Service, please include the following information in an accompanying letter:

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

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

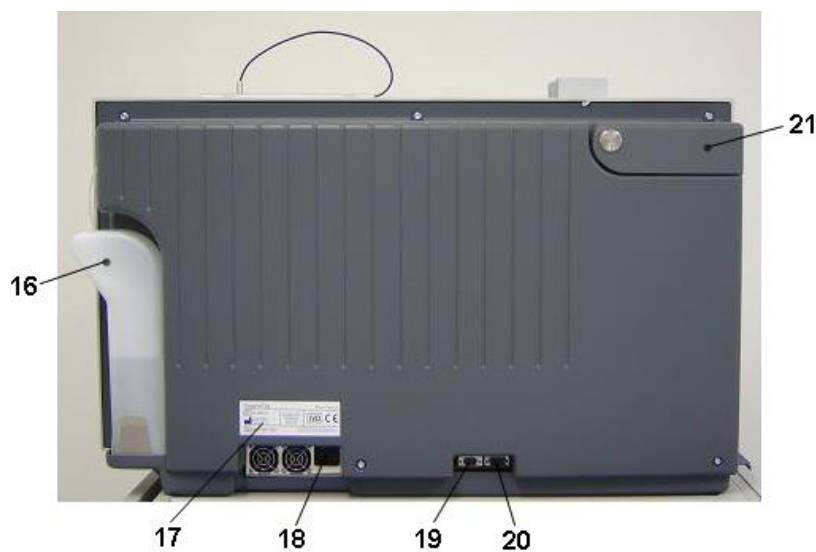
Preparation of the Analyzer for transport:

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

11. APPENDIX

11.1 SERIAL INTERFACE

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



Interface:	115200 Baud , no parity , 8 bit . 1 stop bit
Instrument port:	right RS232 (location "20" – see picture above)
Cable:	2x Female Sub D9, crosslink. Pin 2 to 3 ; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected
Handshake:	No
Establishing:	Not required. The instrument sends results information automatically

Protocol & syntax: TECAM V5.30

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

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

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

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

11.2 TECHNICAL DATA

Analyzer

Measurement system	6 independent measurement channels wavelength of LED 400 nm
Measurement timer	Max. 600 s, error < 0.1 s
Cuvette	6 channel cuvette for optical detection capacity: 75 – 750 µl
Calibration	Automatic calibration or manual input of up to a max. of 6 calibration curve points for each test method
Positions	18 reagent positions at 36.5 – 37.5 °C 12 reagent positions at 12.0 – 16.0°C 6 park positions, preheating (33-38°C) 3x15 sampe primary tubes 1 emergency STAT positions
Reaction volumes	Minimum total volume is 75 µl
Approvals	CE

XYZ Robotics

Movement	X = 383mm, 1714 steps, v = 894mm/s Y = 150mm, 1054 steps, v = 569mm/s Z = 167mm, 3400 steps, v = 181mm/s
Level Sensor	Yes , capacity change detection with Aldium sensor
Neddle	-Capacity for 4880 µL -Inner hydrophob cermamic coating -Livetime for 50000 determination
pump	2500 µl syringe with 300 step resolution Lifetime of syringe is 250.000 cycles
imprecision	15% at 3µL 5% at 5µL 1% > 10µl

Barcode scanner

Laserclass 2 – EN60825-1:2007

max. power = 1.7 mW

pulse period = 420 µs

wavelength = 655 nm

Accepted codec

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

Power supply

Power input	85 – 264 VAC at 45 – 60 Hz
Power consumption	Max. 250 VA
Class	1
Approvals	EN 60950-1 UL 60950-1 IEC 60950-1 CSA 22.2 No. 60950-1

Dimensions

Size (W x D x H)	650 x 102 x 630 mm
Weight	approx. 55 kg (incl. packaging)
Size (W X D x H) on palette	650 x 1065 x 765 mm
Weight (with palette)	approx. 62 kg

Ambient conditions

Operating Temperature	15 to 30 °C, no direct sunlight
Storage and transport temperature	-20 to 60 °C
Humidity	Max. <70% rel. humidity, not condensing
Elevation above NN sea level	0 – 3,000 m
Impact resistance	according to IEC/EN 61010-1, 8.2.2

Noise output

Operating noise	max. 65 dBA
-----------------	-------------

Graphic user interface / software

Interface	RS 232 (serial interface) for communication with PC for software updates, service functions, PC evaluation
LCD display	128 x 128 items, 70 x 70 mm backlit, adjustable contrast
Language	German, English, Italian, Spanish

Specimen Collection

analyte	Fresh or frozen human plasma; Use within 4 hours
centrifugation	1500g x 10-15 min
anticoagulant	Sodium citrate 3.2% (0.105M)
	Mix 1 part citrate with 9 part venous blood
max. bilirubin concentration	50 mg/dL
max. hemoglobin concentration	2000 mg/L
max. triglyceride concentration	5000 mg/dL

Typical performance data

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



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

11.3 DISPOSAL AND RECYCLING

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

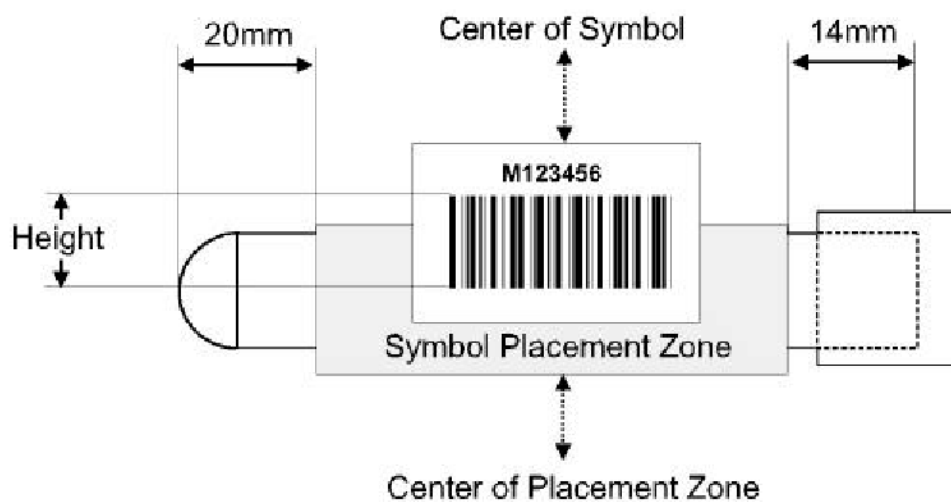
- The housing is made of polystyrene.
- The mechanical parts are mainly aluminium.
- Electronic parts must be disposed of in accordance with currently valid regulations for their disposal.



Important!

You must disinfect the COATRON A6 prior to disposal to prevent cases of infection at the disposal company!

11.4 BARCODE GUIDELINE



Specification of label:

- Label length: 50 – 70 mm
- Label height: 20 - 30 mm
- Barcode length: 40 – 60 mm
- Barcode height: 10 - 20 mm
- Quiet zone: >5mm
- Resolution/module: 8 -20mils (0.2 – 0.5mm)
- Ratio: min. 1:2,5 to 1:3 (two dimensional codes)
- Quality: Level A or B according to ANSI X3.192 -1990

Accepted codes:

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

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