Coatron A6 Plus

Operator's Manual

Teco Medical Instruments, Production + Trading GmbH
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Updates

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Warranty

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

The warranty expires in case of failures caused by

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

1. Introduction 8
1.1 Symbols 8
1.2 Safety information 9
1.2.1 Intended use 9
1.2.2 Safety information for operation 9
1.2.3 Safety information for MATERIALS 9
1.2.4 Safety information regarding risk of health 10
1.2.5 Safety information for cleaning, maintenance and servicing 11
1.2.6 Electrical safety 12
1.2.7 Emc sTATEMENT 14
2. Installation of the COATRON A6 PLUS 15
2.1 Scope of delivery 15
2.2 Laboratory Requirement 16
2.3 Unpacking the COATRON A6 PLUS 16
2.4 Switching ON and off 17
2.5 Installation of Components 19
2.6 Installation of TECAM software 20
2.7 installation Record & Warranty 21
3. Description of the COATRON A6 PLUS 22
3.1 Short introduction 22
3.2 Views of the device 23
3.2.1 Overview 23
3.2.2 Rear view 24
3.2.3 REAGENT Positions 24
3.2.4 Keypad 27
3.2.5 Screen segments 28
3.3 Measurement principle 28
3.3.1 Mathematical principles 28
3.3.2 Units 29

3.3.3 Clotting method 30
3.3.4 Derived fibrinogen 30
3.3.5 Chromogenic, endpoint and immunoturbidimetric method 31
3.4 Test overview 32
4. Operation of the COATRON A6 PLUS 33
4.1 Routine measurement with TECAM 34
4.2 Routine measurement without TECAM 37
4.3 Interrupt or exit measurement 39
4.4 Out of liquid or cuvette during measurement 39
4.5 Continous loading of samples 40
4.6 Measuring the emergency samples 41
4.7 Measuring the samples in micro tubes 42
4.8 Quality control measurement 43
4.9 Reflex testing 44
4.10 Display during measurement 44
4.11 Result warning messages 45
5. Menu Analysis 46
5.1 Submenu New List 46
5.2 Submenu Continue 51
5.3 Submenu Repeat 51
5.4 Submenu Stat 52
5.5 Submenu Overview 53
5.6 Submenu Print Option 54
5.7 Submenu Cuvette Activation 55
5.8 Submenu System Activation 55
5.9 Submenu Reagent Activation 56
6. Menu Setup Test 57
6.1 Calibration Curve 58
6.2 Reagent barcode ENTRY 61

6.3 Storing of test data 61
6.4 Submenu Test Printout 62
7. Menu System Setup 63
7.1 Language 63
7.2 Date 63
7.3 Time 63
7.4 Signal 63
7.5 Contrast 64
7.6 Mixer 64
7.7 Simulator 64
7.8 SHIELD 64
7.9 COOLING 64
8. Menu SERVICE 65
8.1 Refill Cuvettes 66
8.2 Insert printer paper 66
8.3 System report 67
8.4 Adjust XYZ 68
8.5 Check Temperature 70
8.6 Check Optics 71
8.7 Check Robot 71
8.8 Move Cuvettes 71
8.9 Clean Needle 71
8.10 Replace Rinse tank 71
8.11 Adjust Motor 73
8.12 Microtube 73
8.13 INIT SYSTEM 74
8.14 Reset service Interval 74
9. Menu PIPET STATION 75
10. Cleaning and maintenance 76

10.1 General cleaning information 76
10.1 Cleaning 76
10.2 Decontamination 76
10.3 Daily activities 77
10.4 Weekly activities 77
10.5 Yearly activities 77
10.6 Regular Replacements 77
11. Elimination of malfunctions 78
11.1 Error messages 78
11.2 Device malfunctions 79
11.3 Measurement malfunctions 80
12. Appendix 81
12.1 Technical data 81
12.2 Transport and Storage 84
12.3 Disposal and recycling 84
12.4 Barcode Guideline 85
13. Index 86

List of figures

Figure 1: COATRON A6 PLUS, Overview 23
Figure 2: COATRON A6 PLUS, Rear view 24
Figure 3: Working Positions 26
Figure 4: Keypad 27
Figure 5: Screen segments 28
Figure 6: Determination of turning point in clotting method 30
Figure 7: Determination of rise in the kinetic test method 31
Figure 8: Worklist Screen of Tecam 34
Figure 9: Test Order Screen of Tecam 34
Figure 10: RUN WORKLIST Screen of Tecam 35
Figure 11: Receive Result Screen of Tecam 36
Figure 12: Emergency Samples 41
Figure 12: Emergency Samples 42
Figure 14: QC sample 43
Figure 15: QC sample 43
Figure 14: Installation of cuvettes 66
Figure 15: Installation of printer paper 66

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

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

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

1.2.2 SAFETY INFORMATION FOR OPERATION

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

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

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

1.2.3 SAFETY INFORMATION FOR MATERIALS

Important!
Use only organic solvents where specified.The cuvettes are intended as single-use items only. Repeated use may result in false results due to contamination.Follow the instructions in the reagent package circulars. Incorrect handling may result in falsified results.

1.2.4 SAFETY INFORMATION REGARDING RISK OF HEALTH

Infectious Material

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

NOTICE

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

Laser Radiation

The internal barcode scanner is assigned to laserclass 2 – EN60825-1:2007.
Avoid direct eye exposure
max. power = 1.7 mW pulse period = 420 µs wavelength = 655 nm

1.2.5 SAFETY INFORMATION FOR CLEANING, MAINTENANCE AND SERVICING

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

Abount cleaning and decontamination !
Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. The procedure is described in chapter “10 Cleaning and maintenance” and should be performed by authorised well-trained personnel only, observing all necessary safety precautions

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

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

Avoid any direct contact with decontaminants or disinfections.

1.2.6 ELECTRICAL SAFETY

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

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

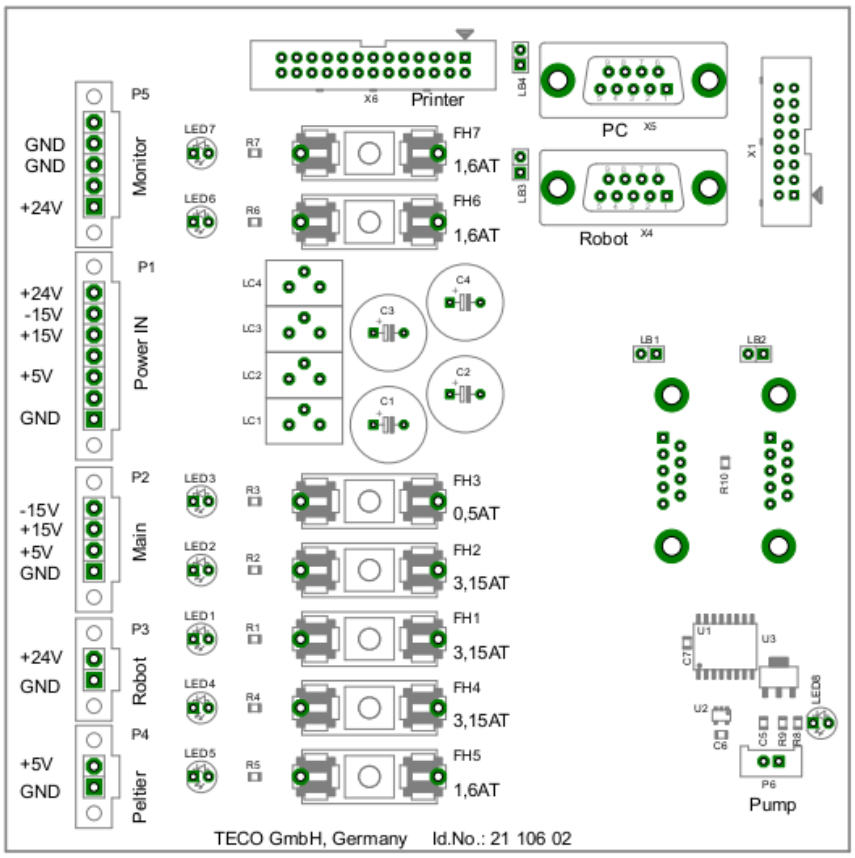
	**Disconnect from power:** ▪ Unplug power cord from wall socket/UPS or from instrument power–in

Fuse replacement:
Unplug power cord and remove back casing. All fuses are located on the power board and identified as FH1 – FH7. Use only following fuses:

Glas micro fuse 5x20mm
Time Delay = T (100-300ms)
Nominal Voltage 250V

Nominal Current:

FH1=3.15A FH2=3.15A FH3=0.50A FH4=3.15A
FH5=1.60A FH6=1.60A FH7=1.60A



Further fuses are located inside of power supply and inside of robotics.
Power supply internal fuse (FS1): 6.3AH, 250V, 5x20mm
Robotic internal fuse (FS1): 4.0AH, 250V, 5x20mm

1.2.7 EMC STATEMENT

Coatron A6 Plus 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 Plus 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.

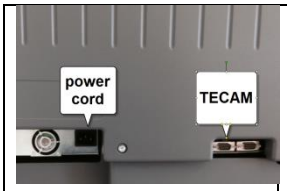
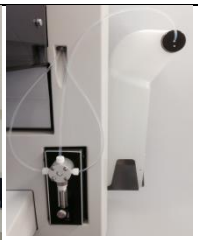
To avoid operating this device nearby strong radiation source (for example, non-shielded RF source), which may interfere with the device working correctly.

2. INSTALLATION OF THE COATRON A6 PLUS

> Initial startup of the COATRON A6 PLUS should be carried out by the authorized Customer Service. After first installation print out a system report (see chapter 8.3) and sent to the manufacturer as a basis for processing guarantee claims**.**

Procedures of first installation:

1. Unpack and place instrument in conformity with the laboratory requirements
2. Connect Power
3. Connec TECAM interface to PC
4. Install consumables (Rinse tank, waste tank, paper, cuvettes)

			
Connect power Connect TECAM			

5. Switch on
6. Goto menu service and perform “Replace Rinse Tank”
7. Goto menu service and print system report and sent to manufacturer to enable warranty period.
8. Install TECAM software

2.1 SCOPE OF DELIVERY

The scope of delivery can be different from customer to customer and must be read in the document “List of accessories”, which is separately included to the operation manual on the first page.

2.2 LABORATORY REQUIREMENT

1. Power Input: 100 – 240VAC; 45-63Hz ; 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

2.3 UNPACKING THE COATRON A6 PLUS

Inspect the packaging of the COATRON A6 PLUS 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 PLUS 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.

1. Lift instrument on the 4 notches on the side out of packaging. Two persons are required and placed it on a stable table.
2. Remove the cable binders on the pipetting arm.
3. Remove the foam element between the pipetting arm and protective bar

Keep the original packaging material for purposes of later transport

2.4 SWITCHING ON AND OFF

Switching on

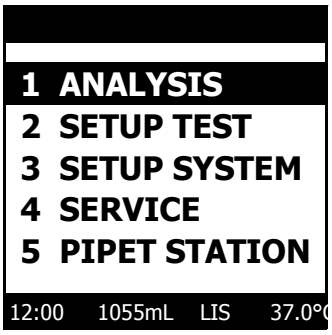
1. Make sure the instrument is connected to the power mains.
2. Check for sufficient rinsing and cleaning fluid levels.
3. Set power switch to on. See right side of instrument

The following screen appear after switch on.

Coatron A6 Pluss	Name of instrument
V6.03.02	Version of firmware
SN-12345	Serialnumber
Service: 100000	Tests until next service
CUVETTES:1	Activated cuvettes
RINSE: 0	Activated Rinse tank
REAGENT: CLOSE	Reagent system is closed

There is no information about cuvette or Rinse or reagent , if system is configurated as “OPEN DEVICE”. Please contact local distributor for more information about open or closed system.

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



MAIN SCREEN:

Time= 12:00
Rinse installed = 1055mL
LIS = online
Temperature at cuvette= 37°C

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

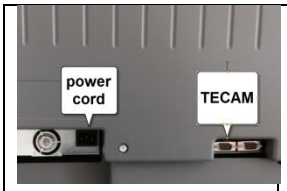
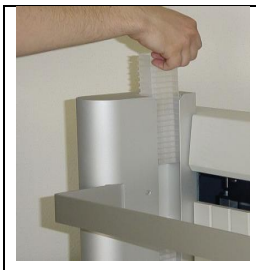
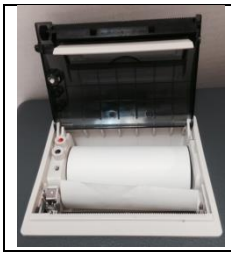
Switching off:

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.

2.5 INSTALLATION OF COMPONENTS

	• Plug in power cord • Plug download cable into left port and connect with PC
	• Remove a strip of cuvettes from the package. • Shift the cuvettes as shown from above in the guide groove back into the cuvette tower. • Remove the tape off the cuvettes. • Activate cuvettes by barcode if required
	• Place a new Rinse tank as shown
	• Load thermo paper as shown

2.6 INSTALLATION OF TECAM SOFTWARE

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

System requirement

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

Install:

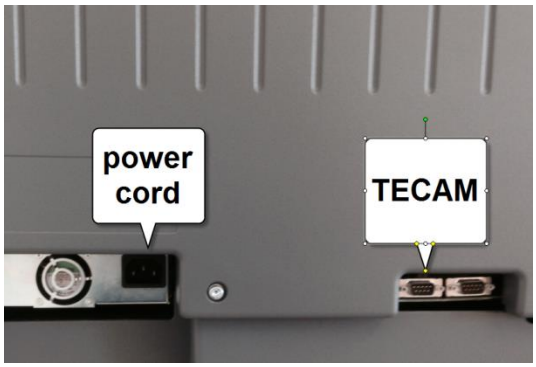


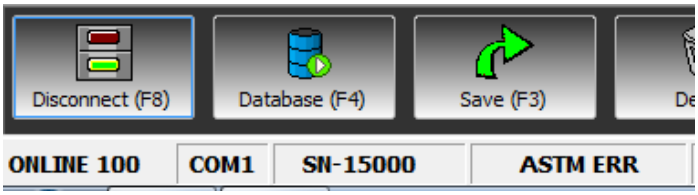
Figure 2: COATRON A6 PLUS, Rear view

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

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

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

2.7 INSTALLATION RECORD & WARRANTY

The manufacturer must be informed about date and correct procedure of installation. For this the “Installation Record” is attached to the delivery.

Fill out the record completely and send it to manufacturer by email or telefax.

The term of warranty will begin with the date of delivery or first installation

3. DESCRIPTION OF THE COATRON A6 PLUS

3.1 SHORT INTRODUCTION

The COATRON A6 PLUS 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

3.2 VIEWS OF THE DEVICE

3.2.1 OVERVIEW

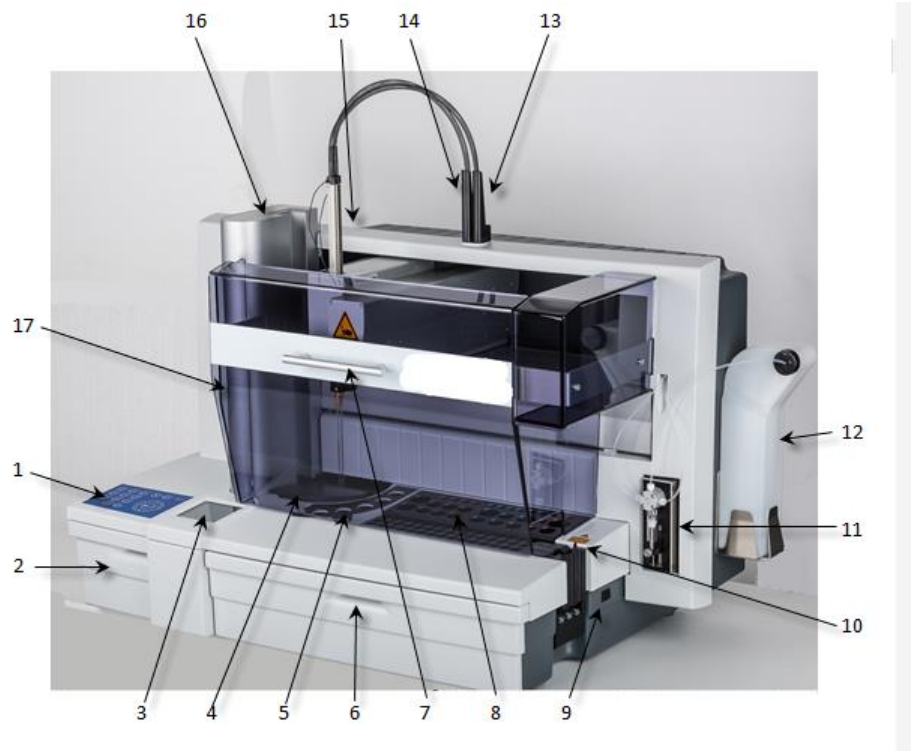


FIGURE 1: COATRON A6 PLUS, OVERVIEW

1	Keyboard
2	Cuvette waste drawer
3	LCD Screen
4	Cuvette rotor
5	System block
6	Rinse solution waste drawer
7	Shield handle. Move to right to open.
8	Reagent and sample positions
9	Power switch ON/OFF
10	Barcode ID Scanner
11	Pump unit. Left=reagent, Up=Rinse, Right=sample probe,
12	Rinse solution tank 1.25mL (RINSE)
13	Sample probe tubing
14	Reagent probe tubingt
15	Integrated thermo printer
16	Cuvette tower
17	Shield, removeable

3.2.2 REAR VIEW

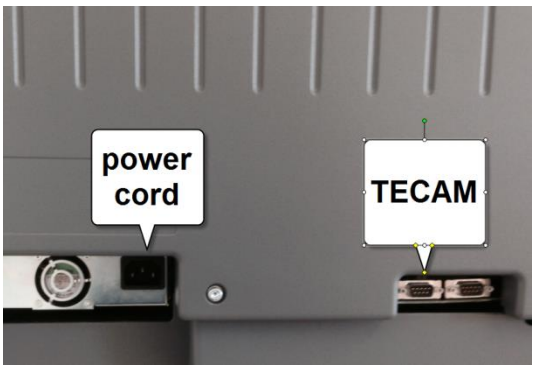


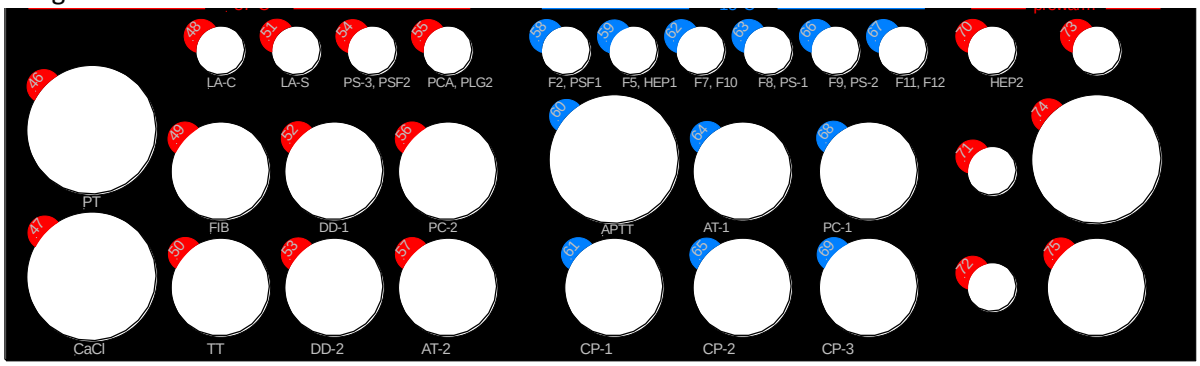
FIGURE 2: COATRON A6 PLUS, REAR VIEW

Power Cord	Power Input 85 – 264 VAC @ 45 – 60 Hz.
TECAM	Interface to TECAM software,(115200 baud, 8,1,N
Free RS2322	Reserved for debugging

3.2.3 REAGENT POSITIONS

Pos. 1 - 45		Sample positions	Room temperature

Reagent block:



Pos. 46	PT	Position for PT, **magnetic stirring function**	36.5 - 37.5 °C
Pos. 47	CaCl	Position for $CaCl_2$ (Calcium Chloride)	36.5 - 37.5 °C
Pos. 48	LA-C	Position for LA-C (Lupus Anticoagulant - Confirmation)	36.5 - 37.5 °C
Pos. 49	FIB	Position for FIB (Fibrinogen)	36.5 - 37.5 °C
Pos. 50	TT	Position for TT (Thrombin Time)	36.5 - 37.5 °C
Pos. 51	LA-S	Position for LA-S (Lupus Anticoagulant – Screen)	36.5 - 37.5 °C
Pos. 52	DD-1	Position for DD-1 (D-Dimer Reaction buffer)	36.5 - 37.5 °C
Pos. 53	DD-2	Position for DD-2 (D-Dimer Latex)	36.5 - 37.5 °C
Pos. 54	PS-3, PSF2	Position forPS-3 (Protein-S)	36.5 - 37.5 °C
Pos. 55	PCA, PLG2	Position for PCA (Protein C activated) and Plasminogen	36.5 - 37.5 °C
Pos. 56	PC-2	Position for PC-2 (Protein C)	36.5 - 37.5 °C
Pos. 57	AT-2	Position for AT (Antithrombin)	36.5 - 37.5 °C
Pos. 58	F2, PSF1	Position for Deficient Plasma II,	<15 °C

Pos. 59	F5, HEP1	Position for Deficient Plasma V and Heparin	<15 °C
Pos. 60	APTT	Position for APTT	<15 °C
Pos. 61	CP-1	Position for Control plasma 1	<15 °C
Pos. 62	F7, F10	Position for Deficient Plasma VII and X	<15 °C
Pos. 63	F8, PS-1	Position for Deficient Plasma VIII and Protein-S	<15 °C
Pos. 64	AT-1	Position for AT (Antithrombin)	<15 °C
Pos. 65	CP-2	Position for Control plasma 2	<15 °C
Pos. 66	F9, PS-2	Position for Deficient Plasma IX and Protein-S	<15 °C
Pos. 67	F11, F12	Position for Deficient Plasma XI and XII	<15 °C
Pos. 68	PC-1	Position for PC-1 (Protein C)	<15 °C
Pos. 69	CP-3	Position for Control plasma 3	<15 °C
Pos. 70	HEP2	Position for HEP-2 (Heparin)	33 - 39 °C
Pos.71 - 75	Prewarm	5 x Position to prewarm reagents	33 - 39 °C

System block:

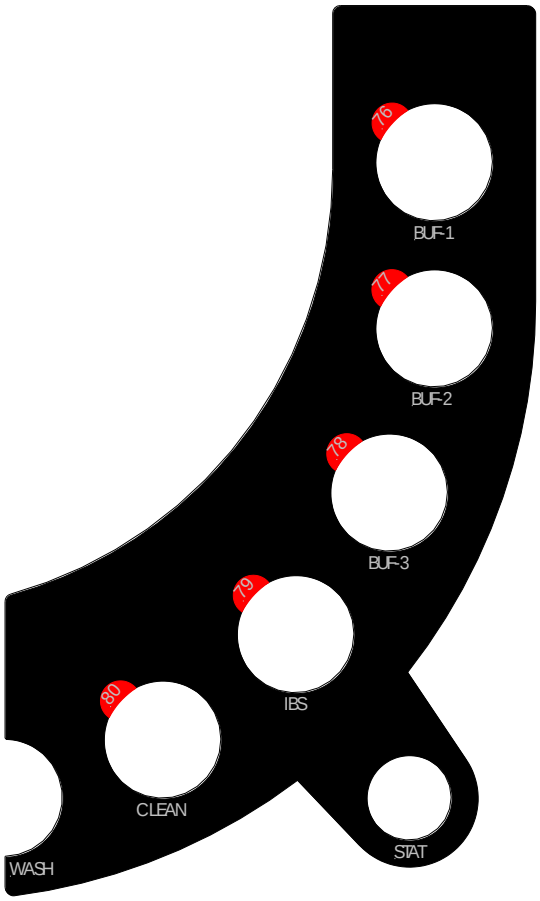


FIGURE 3: WORKING POSITIONS

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 A Solution	36.5 - 37.5 °C
WASH	WASH	Position for liquid waste and cleaning of the needle (probe)	
STAT	STAT	Not used	

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

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

3.2.4 KEYPAD

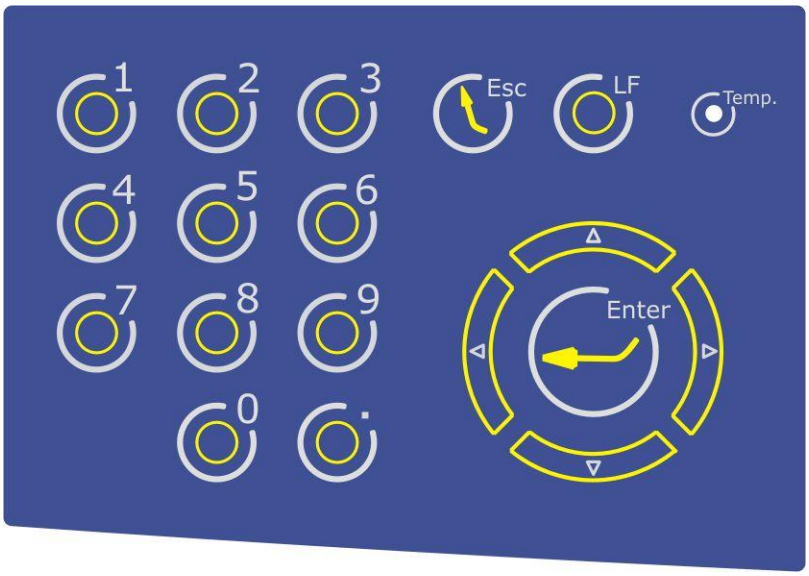


FIGURE 4: KEYPAD

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

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

3.2.5 SCREEN SEGMENTS

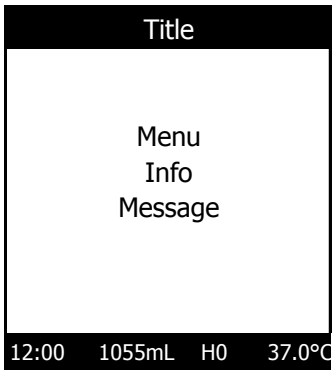


Figure 5: Screen segments

There are 3 screen segments:

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

3.3 MEASUREMENT PRINCIPLE

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

3.3.1 MATHEMATICAL PRINCIPLES

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

3.3.2 UNITS

Unit	Info	Decimal places	Maximum value	Unit Reflex
s	seconds	1	-	-
%	activity	1	180.0	<10%
U	units	0	999	>600
INR	int. ratio	2	30.00	-
R	ratio	2	30.00	-
PR	polish ratio	0	180	-
INR+	int. ratio	2	30.00	-
mg/dl		0	999	>600
g/l		2	9.00	>6
IE/ml	Int. Einheit	2	9.00	-
mg/l		2	9.00	-
µg/ml		1	999.9	-
ng/ml		0	9000	>5000
µg/l		0	9000	>5
IU/mL	Int. Units	3	9.000	-

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

3.3.3 CLOTTING METHOD

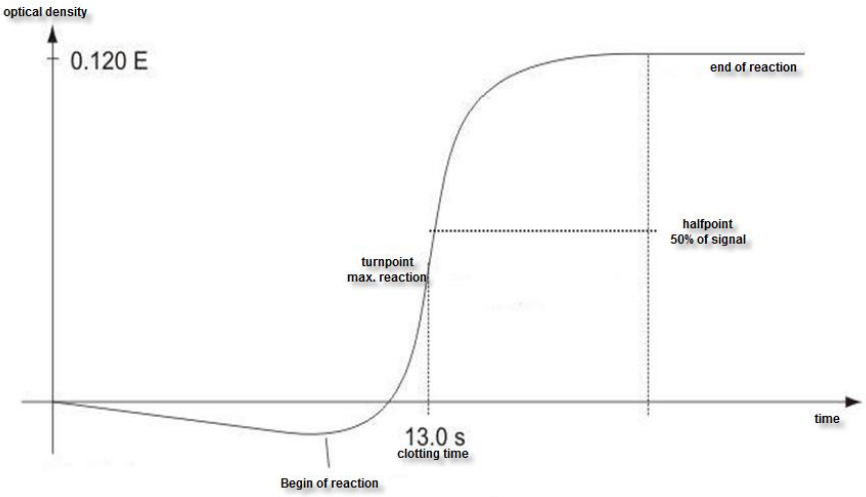


FIGURE 6: DETERMINATION OF TURNING POINT IN CLOTTING METHOD

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 maximum rate of change (reaction turning point). The instrument can be switched also to define the clotting at the halfpoint of reaction.

3.3.4 DERIVED FIBRINOGEN

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

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

☝ The DFIB results can give significant higher concentrations than compared to clauss method – especially for very high concentrations. Therefore method should only be used to screen for abnormal levels and confirm these samples with FIB Clauss method.

3.3.5 CHROMOGENIC, ENDPOINT AND IMMUNOTURBIDIMETRIC METHOD

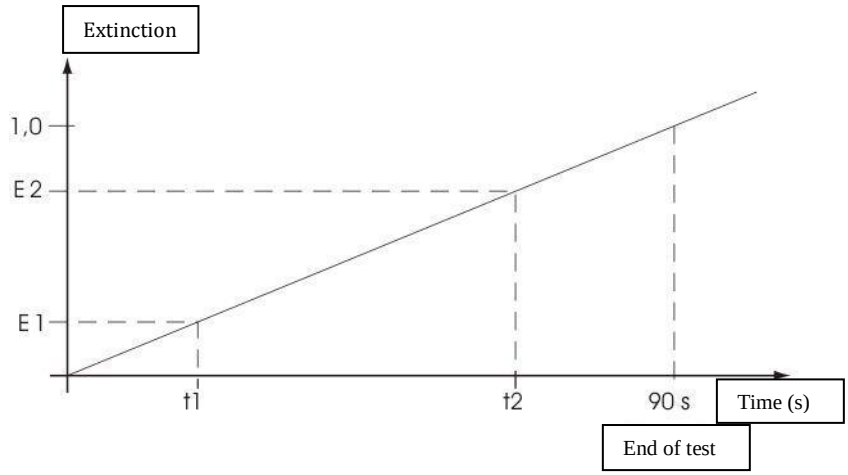


FIGURE 7: DETERMINATION OF RISE IN THE KINETIC TEST METHOD

t1 = deadtime in s
t2 = endtime in s

Delta signal dE =E2 – E1
Delta time dT =t2 – t1

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

Result of method „IMMUN = dE/dT

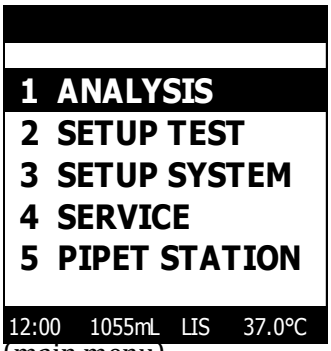
Result of method „POINT “= dE

3.4 TEST OVERVIEW

test 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
24	Fibrin Degradiation Product	FDP	immun

4. OPERATION OF THE COATRON A6 PLUS

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



(main menu)

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

4.1 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

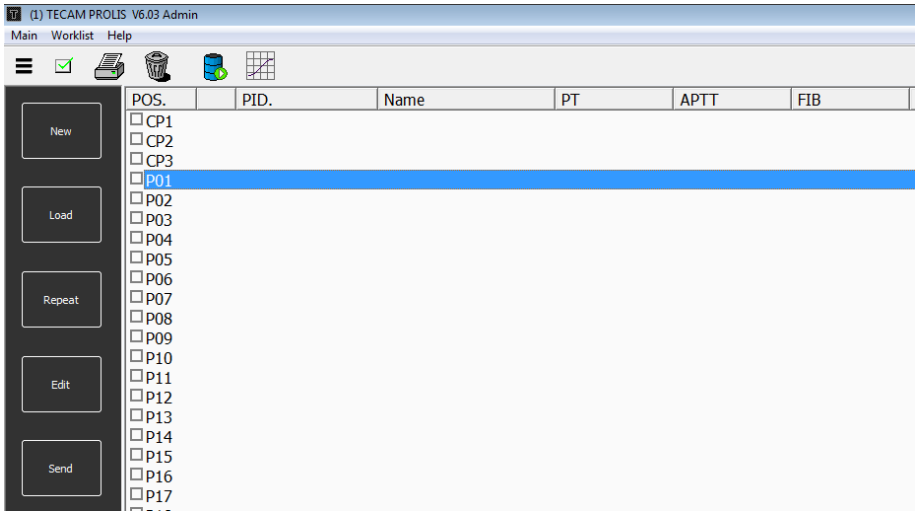


FIGURE 8: WORKLIST SCREEN OF TECAM

4. Import PID from analyser, if you work with patient barcode information.
   - Click on command “LOAD”
   - Goto analyser and scan the patient racks and press “ENTER”

5. Select position with cursor keys and click on command “EDIT” or press ENTER.

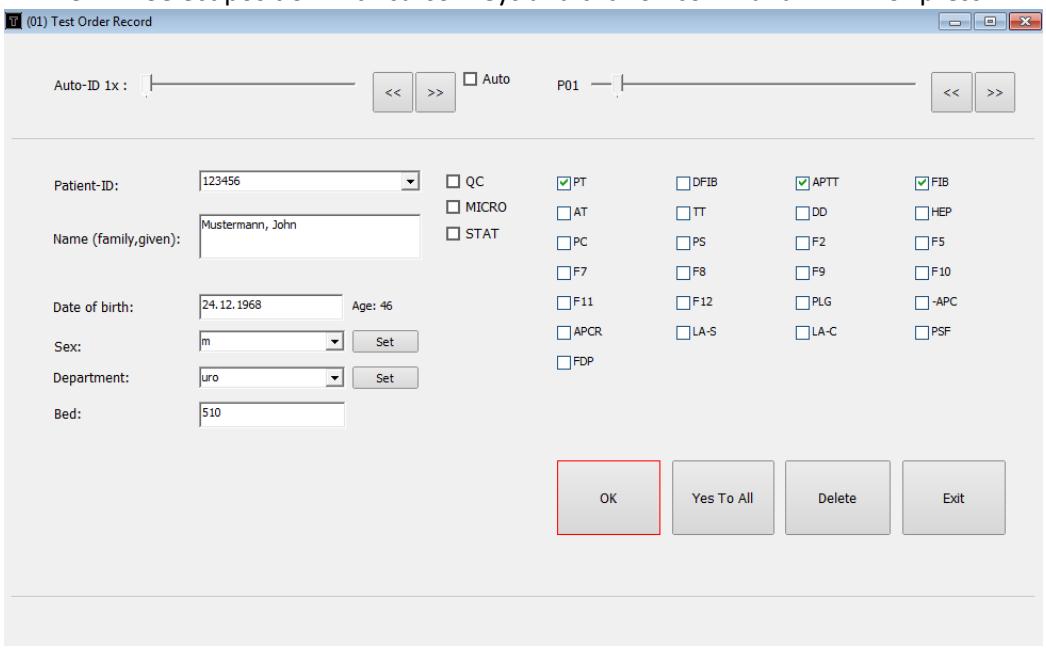


FIGURE 9: TEST ORDER SCREEN OF TECAM

- 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
- QC: Sample is a quality control
- MICRO: Sample is filled into micro tube
- STAT: Sample is urgent
- AUTO: Use Auto-ID number instead of patient-ID

6. Select menu Worklist\Send worklist

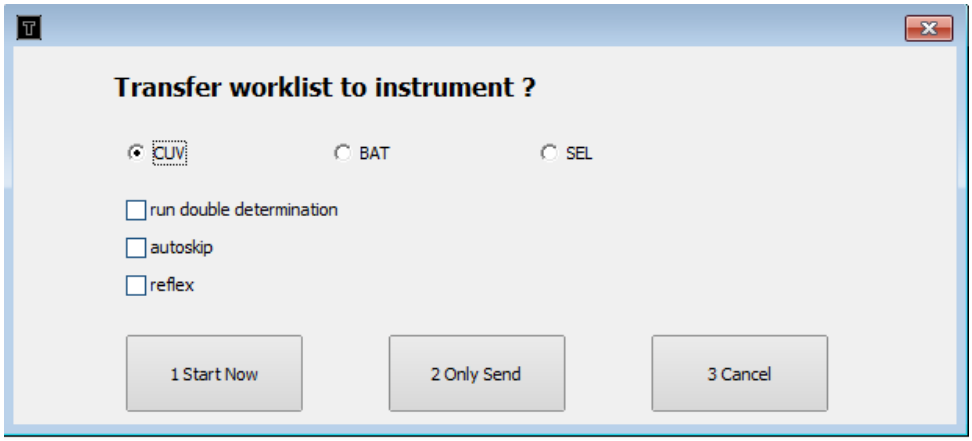


FIGURE 10: RUN WORKLIST SCREEN OF TECAM

- Mode CUV, BAT, SEL
  Run worklist cuvette or test or patient wise
- 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

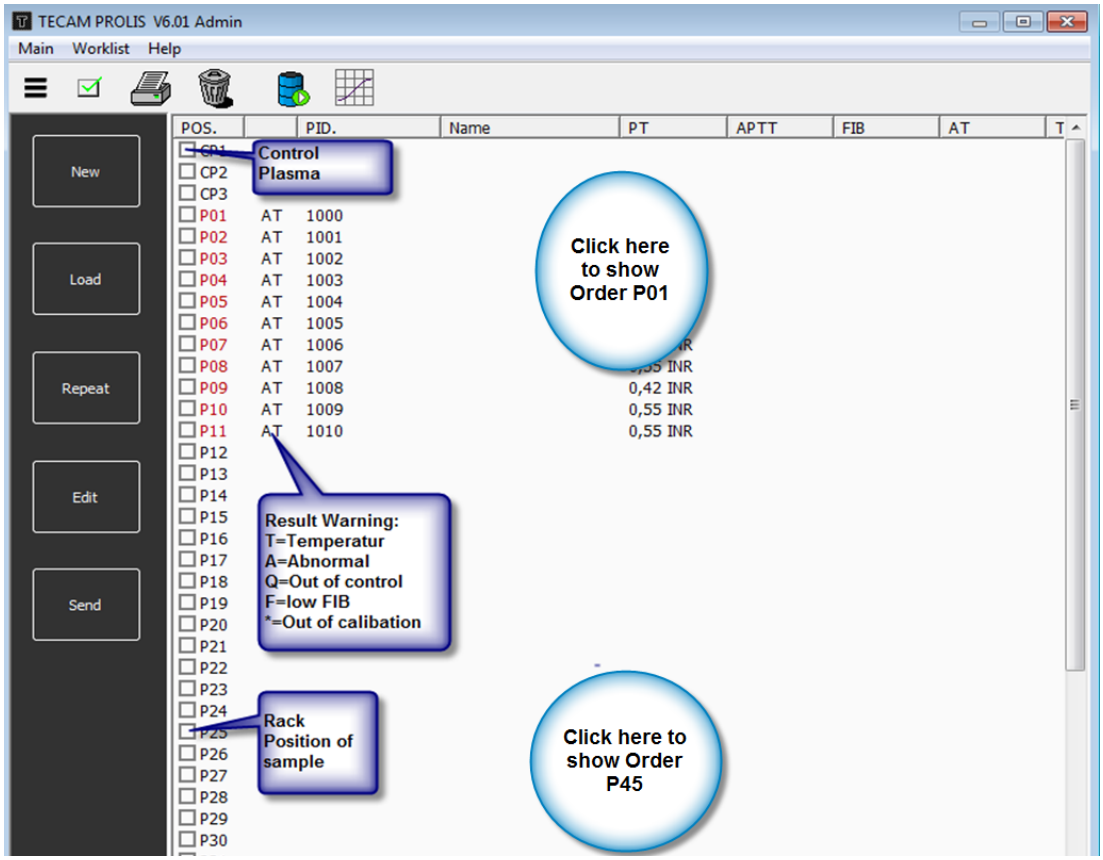


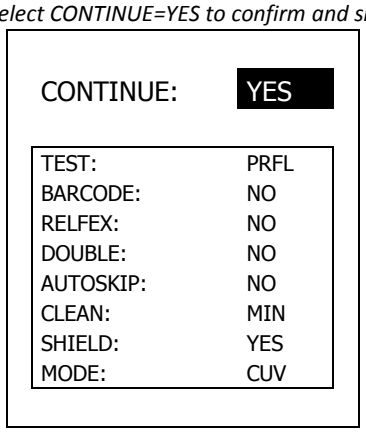
FIGURE 11: RECEIVE RESULT SCREEN OF TECAM

4.2 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.

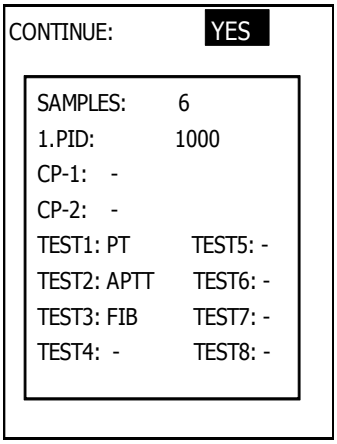
Select CONTINUE=YES to confirm and show the next screen



"New List" Screen 1

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

Select CONTINUE=YES to confirm and show the next screen

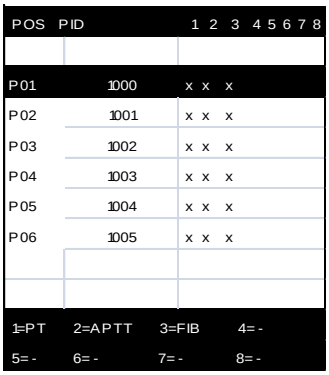


New List" Screen 2

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

Select CONTINUE=YES to come to the next screen

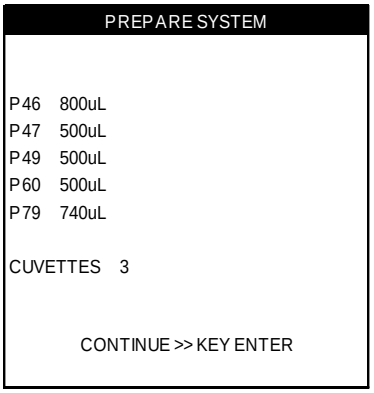
Press ENTER to confirm and show the next screen



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

"New List" Screen 3

Press ENTER to confirm and show the next screen



The COATRON A6 PLUS 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.

4.3 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:

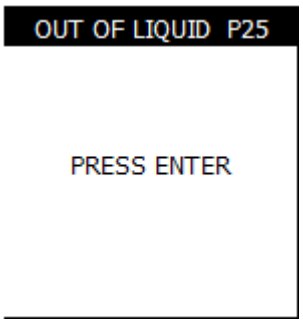
Moves robotic to left or right home position, which allows access to reagent rack or cuvette tower for reloading.

Contine worklist: Press key ENTER:

Continuous measurement

4.4 OUT OF LIQUID OR CUVETTE DURING MEASUREMENT

System will interrupt worklist automatically, if



Out of liquid:

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

Out of cuvette:

Reload cuvettes and press ENTER to continue worklist

4.5 CONTINOUS LOADING OF SAMPLES

This feature requires 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 !

4.6 MEASURING THE EMERGENCY SAMPLES

(1) Load new sample like descriped in chapter 4.5 .

(2) Define new order with TECAM and mark sample as “STAT” and send to instrument.

(3) The instrument will process all STAT orders as soon as possible.

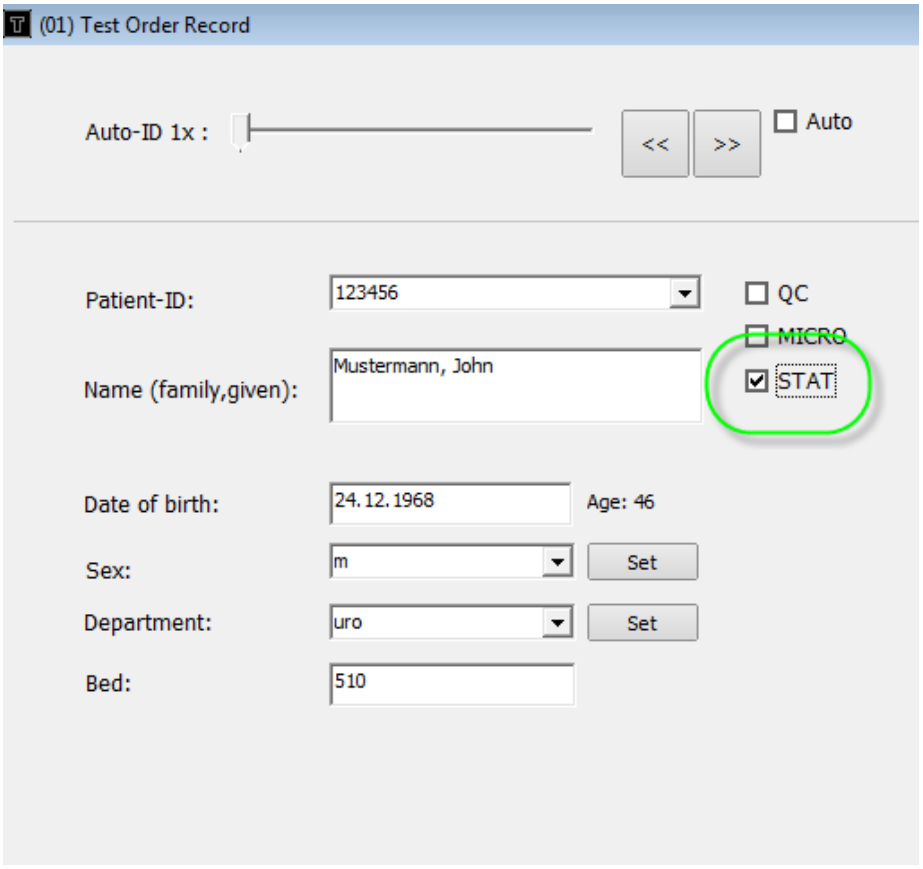


FIGURE 12: EMERGENCY SAMPLES

4.7 MEASURING THE SAMPLES IN MICRO TUBES

(1) Load new sample like descriped in chapter 4.5 .

(2) Define new order with TECAM and mark sample as “MICRO” and send to instrument.

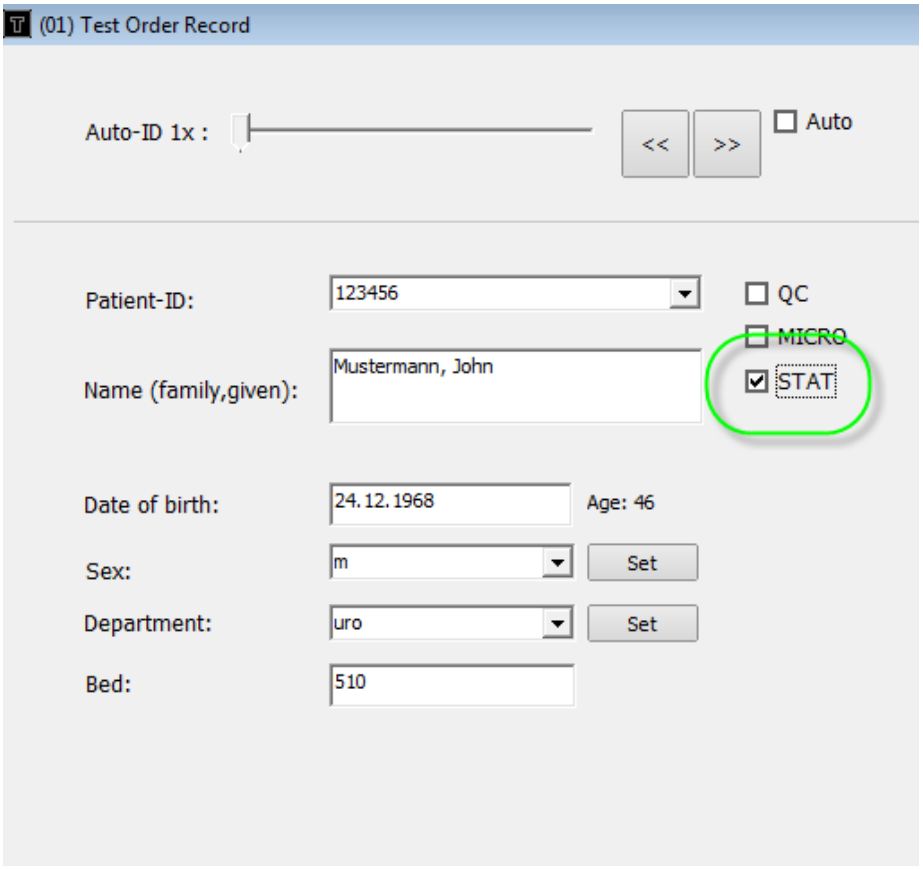


FIGURE 13: EMERGENCY SAMPLES

(3) The instrument will process the sample as micro volume

- Smallest possible tubes are 2mL Safe lock tubes (see figure)
- At least 100µL of sample is required
- Z-Offset of micro tube must be adjust within service menu

4.8 QUALITY CONTROL MEASUREMENT

TECAM PRO software is required for flexible QC-controlling including Levey-Jennings graphics and Westgard rules.

QC with TECAM software: :

- Place quality control into cooled position CP1, CP2 or CP3 or use regular rack position. Select correct position and click on “Edit”

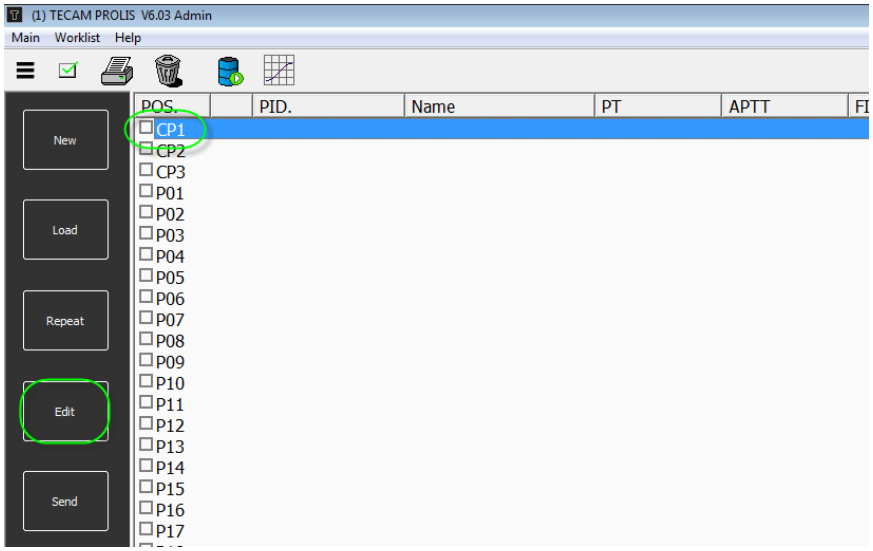


FIGURE 14: QC SAMPLE

- Define the order as quality control and update the QC rangecontrol range in the menu SETUP TEST

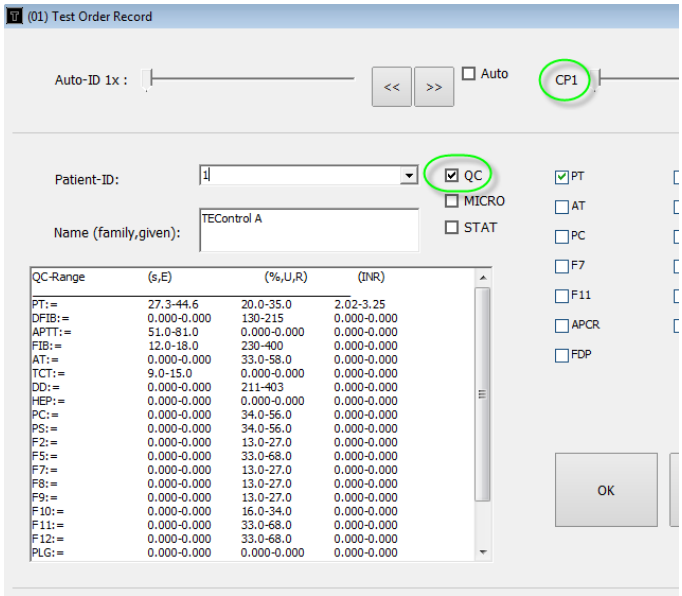


FIGURE 15: QC SAMPLE

- Send the QC order to instrument

4.9 REFLEX TESTING

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

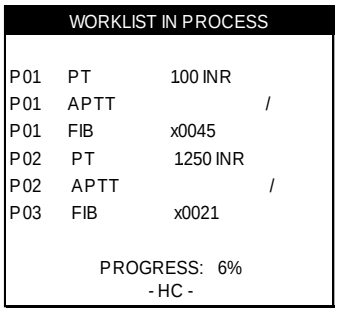
- Clot Reflex:
  Test is repeated with additionally 60s prolonged maximum reading time, if no clot was found (+++). This mode is only active for method “CLOT”.

- Unit Reflex
  Test is repeated with half or double plasma dilution, if result is above or below the unit reflex limits (see chapter 3.3.2 Units)3.3.2).

- 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”

4.10 DISPLAY DURING MEASUREMENT



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

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

“LIS” 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 PLUS searches for the optimum amplification parameters for the measurement channel.

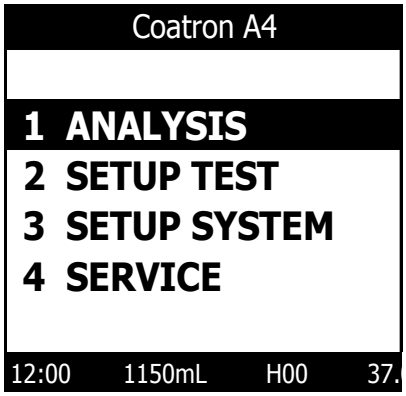
4.11 RESULT WARNING MESSAGES

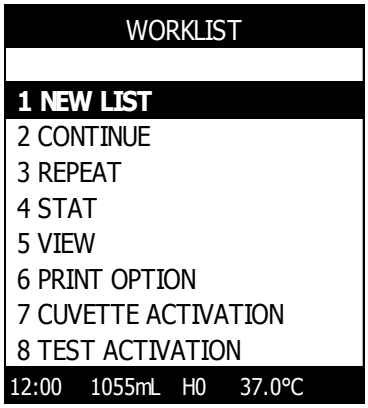
Results may also be displayed with various additional warning symbols:

- * 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. Endsignal of PT is <75mE
- F High Fibrinogen level found. Endsignal of PT is >800mE
- 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)

5. MENU ANALYSIS

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



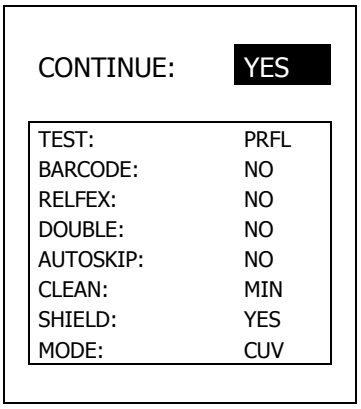


menu analysis

5.1 SUBMENU NEW LIST

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

Screen: worklist



- **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.

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

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

- **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 "%."

- **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.

- **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.

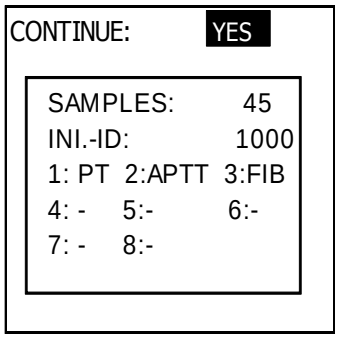
- **Mode:** BAT / SEL / CUV / HS-1 / HS-2 / EV1 / QC
  Determines the mode of test processing:

  - 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.
- HS-1: Allows the maximum throughput for PT testing
- HS-2: Allows the maximum throughput for 45 repeatition

Mode EV1, QC, HS-2 are not suitable for routine processing and should used only for research issues.

Screen: Test Profil, Control plasma and Autoseries input:



Possible settings:

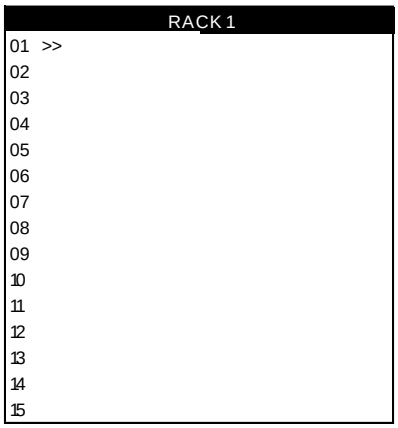
- **Samples:**
  (only visible of barcode is set to no)
  Manual input of number of samples.
- **INI.-ID**
  (only visible of barcode is set to no)
  Manual input of Identification Number for first sample. The other samples were automatically incremented by 1 (1000, 1001, 1002,…..)
- **Test 1 – 8:**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

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

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

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

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



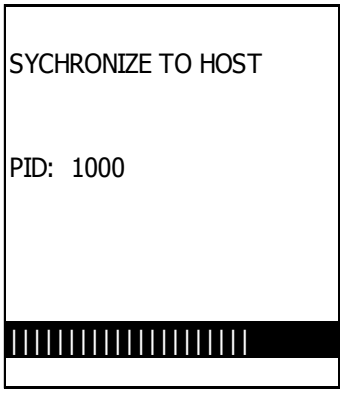
Shift the racks separately at an even and moderate speed in front of the barcode scanner. A signal tone is heard for each recognized barcode

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

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

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

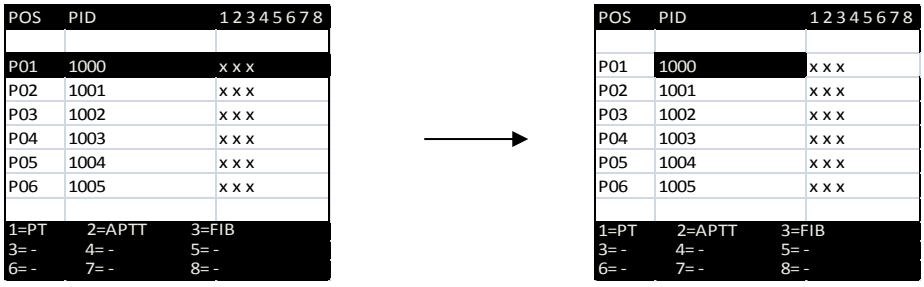
Press *ENTER* to come into the next screen.



All patient identification numbers will be send to host.

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

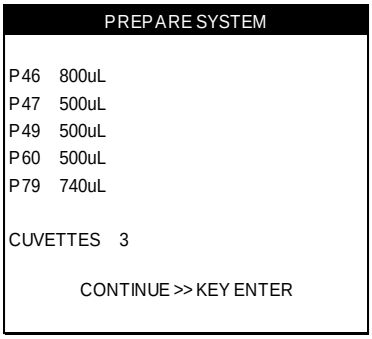
In the next screen you can still revise the PID numbers and active tests, which are counted upwards from the PID number of the first sample



- *Select the order record with cursor keys UP/DOWN.*

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

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



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

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

5.2 SUBMENU CONTINUE

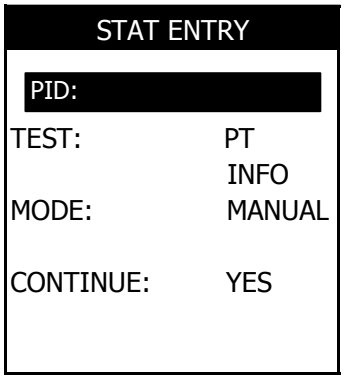
Following a test interruption (e.g. due to a STAT task or discontinuation due to a lack of liquid), routine measurement can be continued here.

5.3 SUBMENU REPEAT

Repeats the last worklist.

5.4 SUBMENU STAT

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



- Input of PID:
  Enter the Patient Identification Number (PID) manually or just scan it with the barcode scanner. Enter terminates input of the PID.
  Then place the emergency sample in the STAT position.

- Selection of the test:
  With ARROW ↓ one gets to test selection, ARROW → opens the list of available tests; then use the navigation keys to select the test and return to STAT INPUT with Enter.

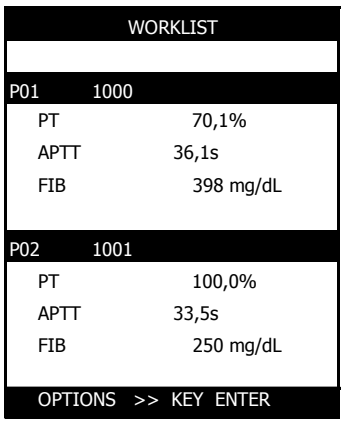
- Information on the test:
  Confirming the INFO field with Enter prints out the test setup just as in normal measurement.

- Setting the mode:
  If the mode is set to manual, the interrupted worklist must be continued manually after the emergency sample has been measured. In the Auto mode this is done automatically.

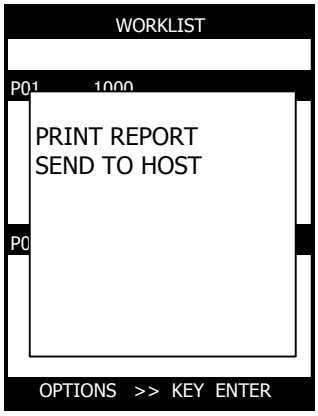
- Activation of emergency measurement:
  Go to the field CONTINUE and confirm with YES.
  The next screen SYSTEM PREPARATION displays the required position in the reagent block, the required amount of reagent and the number of cuvettes required.
  After checking the reagent position, the measurement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

5.5 SUBMENU OVERVIEW

Displays and prints lists according to given sorting criteria.



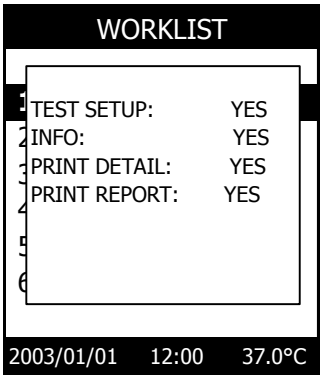
Enter calls up options, ARROW ↑ / ARROW ↓ pages through the options, Enter executes the operation:



The following options can be selected:

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

5.6 SUBMENU PRINT OPTION

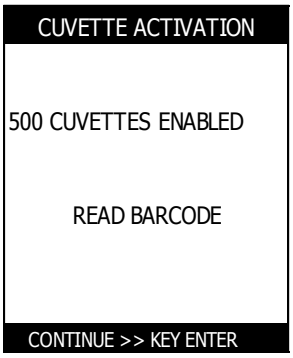


Determines what information is to be printed automatically:

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

5.7 SUBMENU CUVETTE ACTIVATION

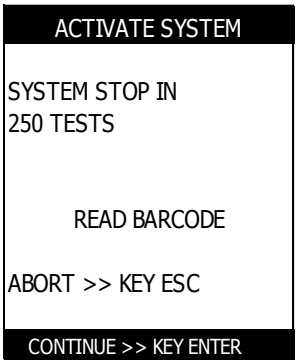
This menu is only shown, if instrument is configarated as “Closed to cuvette”.
Read the barcode, which is provided with the cuvette package.



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

5.8 SUBMENU SYSTEM ACTIVATION

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



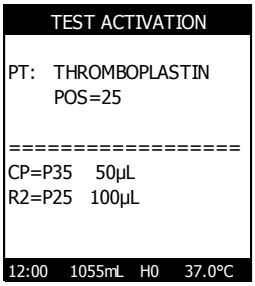
System will stop operation in 250 determinations.

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

In case of barcode reading problems, press key “0” to activate manual input

5.9 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)

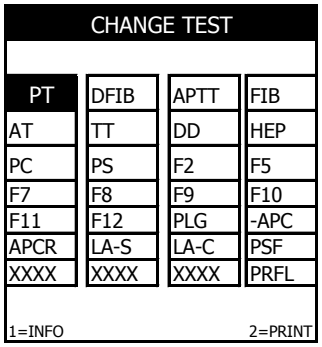
Barcodes will be rejected in case of

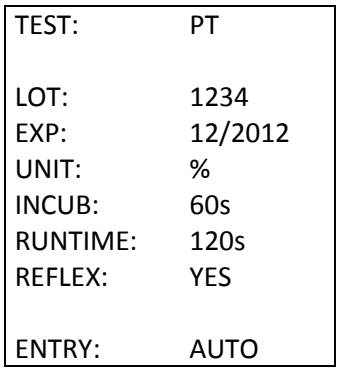
- invalid syntax of barcode
- date expired
- barcode differs to data stored in the SETUP test

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

In case of barcode reading problems, press key "0" to activate manual input

6. MENU SETUP TEST





- **1=INFO:**
  Show volumes and position of reagent
- **2=PRINT:**
  Print test setup
- **New lot number (LOT):**
  If the LOT number is inverted, ARROW → is used to get to selection of individual digits, numbers and letters and ARROW ↑ / ARROW ↓ are used to page through them; numbers can also be entered directly using the numeric keypad.
- **Input of expiry date (EXP.):**
  With ARROW ← / ARROW → the month can be changed, with ARROW ↓ the year is changed analogously to the month. Expired dates will not be accepted by the COATRON A6 PLUS
- **Selection of unit:**
  With ARROW ← / ARROW → the units are changed in which the results are displayed with the exception of the basic unit (which depends on the measurement principle). The available units are %, INR, Ratio, INR+ and no further unit (-). Calibration curves can only be entered when a unit has been selected. See *chapter 3.3.2,* Units on the significance and calculation of the units.
- **Incubation time**
  Define the delay time before start reagent (R2) is added.With ARROW ← / ARROW → the incubation time is changed in 30-second increments from 60 to 450 seconds.
- **Runtime**
  Define the maximum reading time.
- **Reflex**
  Enable/disable. Reflex testing will be automatically disabled , if no CLOT and Unit reflex is possible. Unit limits can printed with “1:PRINT” during test selection. For more information see *chapter 4.9,* Reflex testing
- **Entry**
  Select between manual input of calibration curve or automatical test calibration

6.1 CALIBRATION CURVE

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

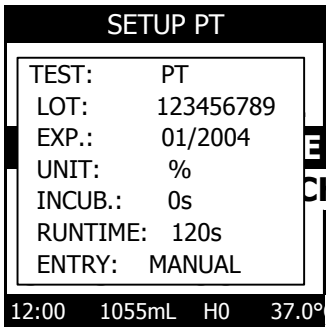
- Manual Calibration:
  The operator must prepare the standards and run them like normal samples. He must also enter the results manually

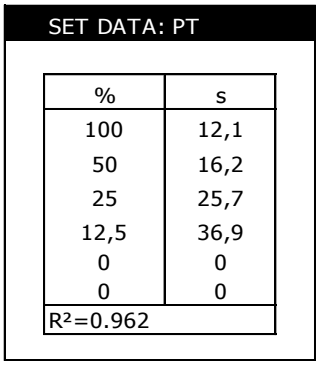
- Auto Calibration with dilutions:
  The operator must place the reference plasma into rack postion P01 and addionally empty vials in P02 – P06. The analyser will prepare all required plasma dilutions, run the standards and transfer the results into the calibration curve automatically.

- Auto Calibration with fix standards:
  The operator can place upto 6 plasma standards into rack. The analyser will run the standards and transfer the results into the calibration curve automatically.

- **Manual calibration**

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





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

The calibration curve can be entered or changed now manually. At least 2 value pairs are required upto a maximum of 6 value pairs. List navigation is with the arrow keys and the values are confirmed with Enter. A value pair can be added, deleted or changed at any position. Subsequent data saving automatically sorts the calibration data.

INR Calibration:

The operator can select the unit between

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

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

The curve linearity is indicated with the regression factor R^2.
$R^2 > 0.998$: the curve is linear.Two points are enough.
$R^2 < 0.950$: the curve is inlinear. Use more than 2 points.
$R^2 < 0.900$: change math. model and use more than 5 points. Results outside of calibration are not trustful.

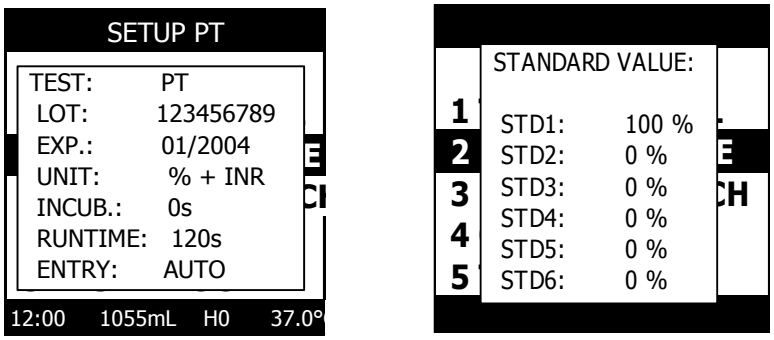
The calibration data are checked for plausibility when they are saved. The following rules must be complied with:

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

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

➢ **Auto calibration**

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



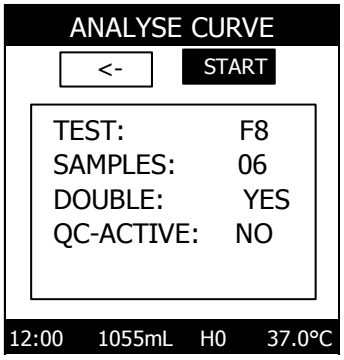
Select test and unit, set *ENTRY to Auto* and press ENTER.

- **Autocalibration with serial dilutions**

The dilutions are always prepared in following way:

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

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

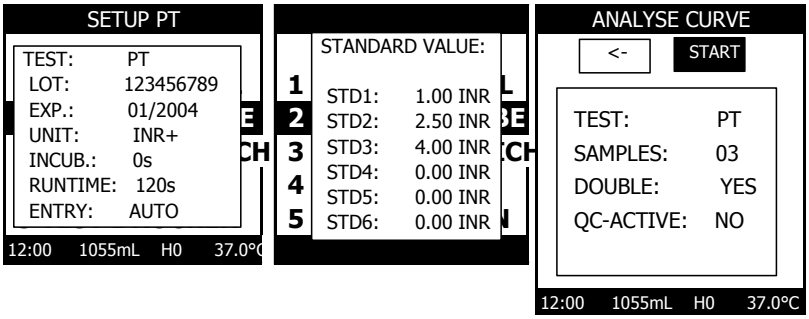


6 standards are measured for factor VIII calibration. Therefore the calibrator must be placed in rack position 1and 5 other empty sample test tubes are required in rack positions 2-6, in which the ***COATRON A6 PLUS*** *then prepares the necessary dilutions.*

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

- **Autocalibration with fixed levels**

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



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

6.2 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.

6.3 STORING OF TEST DATA

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

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

The following rules must be complied with:

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

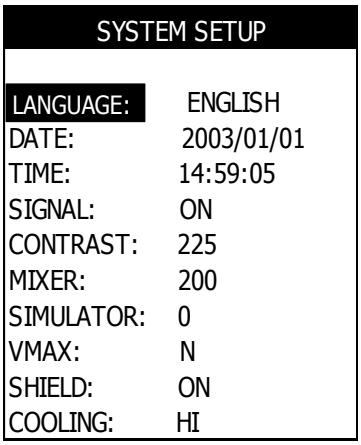
6.4 SUBMENU TEST PRINTOUT

During test selection press key “1”

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

7. MENU SYSTEM SETUP

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



General operation:

ARROW ↑/↓ left column Change item

ARROW → change to right column

ARROW ↑/↓ right column: Change value

Enter to confirm the value.

ESC exit menu

7.1 LANGUAGE

Select between:English - Italian - Spanish - German

7.2 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).

7.3 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).

7.4 SIGNAL

Switches the acoustic signal on or off.
Possible settings:

- Signal on
- Signal off

7.5 CONTRAST

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

7.6 MIXER

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

7.7 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 all vials and containers. Add oje cuvette into system and run any worklist. Instrument will simulate levelsensing and reaction curve.

7.8 SHIELD

The robotics will not move, if shield is opened.You can deactivate this protection.

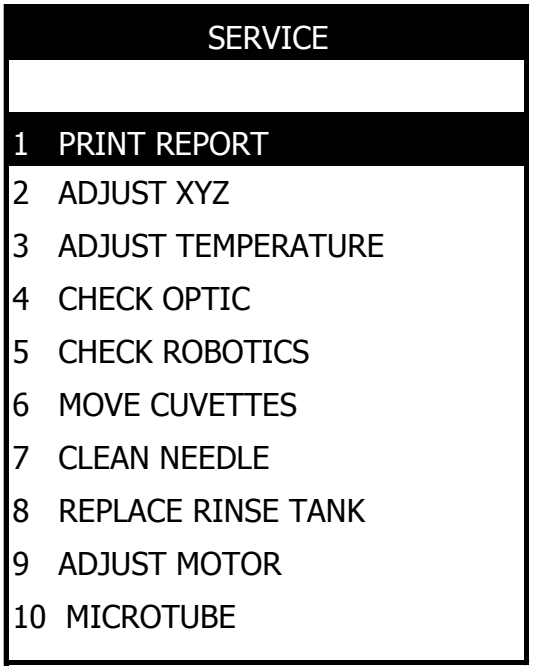
Deactivated shield function may lead to injury and infections cause by piercing needle.

7.9 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.

8. MENU SERVICE



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

8.1 REFILL CUVETTES

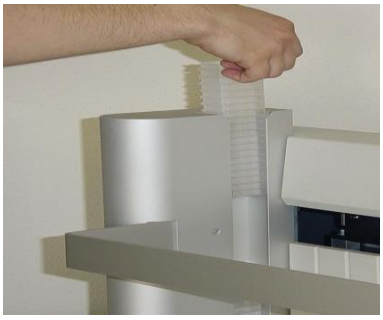


FIGURE 16: INSTALLATION OF CUVETTES

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

8.2 INSERT PRINTER PAPER

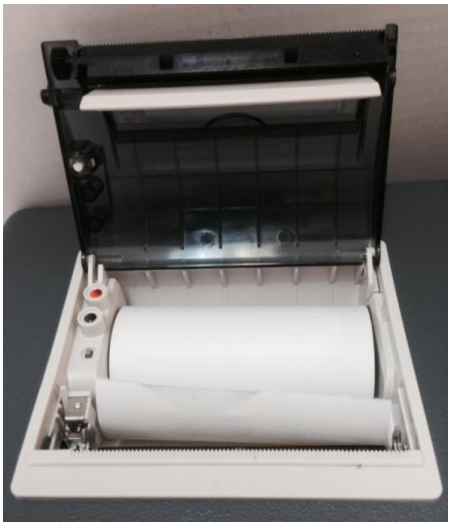


FIGURE 17: INSTALLATION OF PRINTER PAPER

1. Open the printer cover as shown.
2. Input new paper and close cover.

8.3 SYSTEM REPORT

Printout of important system data

```
SYSTEM - REPORT


DATE: 2012/25/10  13:59

SYSTEM: COATRON A6 PLUS
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      1      0      1020
OFFSET M:  4

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

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

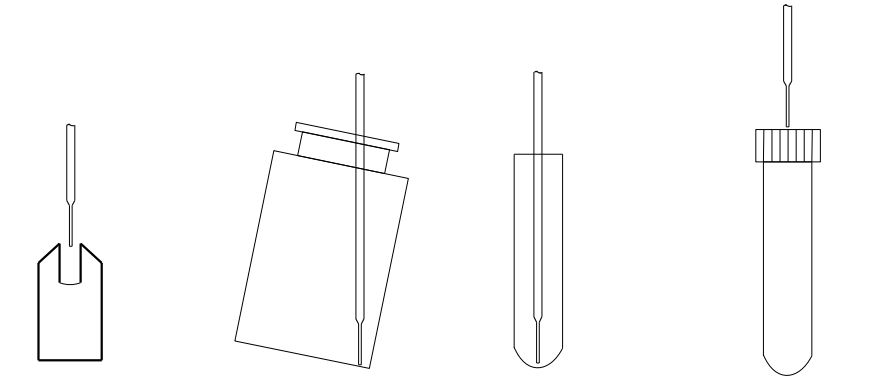
System requires a barcode to run tests
System requires a barcode to reset service interval
System requires a barcode before use of reagent

8.4 ADJUST XYZ

Key 4/6 move needle left/right (X-offset)
Key 2/8 move needle backward/forward (Y-offset)
ARROW ↑/↓ move needle up/down (Z-offset)
ENTER goto next position
ESC exit adjustment

Five positions must be adjusted

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



Preparation:

Ensure yourself, that the needle is straight and correct mounted 105mm in length. For correct z-offset adjustment following tubes or vials must be placed

POS		Container
P01	Patient-1	primary tube
P80	CLEAN-A	CLEAN-A solution
-	Cuvette1	empty cuvette

Confirm with “YES” to start adjustment

1. 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 postion or press “ESC” to quit.

2. Needle will go to P80. Center the needle.The needle tip should be short before touching the vial buttom. Lift vial to determine the distance. Press “ENTER” to come to next postionen or press “ESC” to quit.

3. Needle will go to cuvette position. Center the needle exactly to cuvette and press “ENTER” to forward or “ESC” to quit.

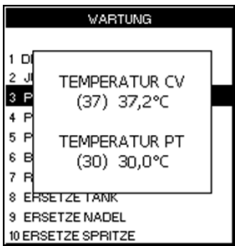
4. Needle will go into air. Remove the optical protection shield, if installed and press “ENTER” to adjust z-offset of cuvette position.

5. Needle will go down into cuvette position. Adjust z-offset until needle is short before touching the cuvette buttom. Press “ENTER” to come to next position or press “ESC” to quit.

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

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

8.5 CHECK TEMPERATURE



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

Setting the temperature:

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

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

Please ask local distributor about change of reagent target temperature

8.6 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)
SENS: 1-1-0-0

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			
Sensor:	cuvette-	shield	rinsetank	wastetank
	0=empty	0=opened	0=full	0=empty

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

8.7 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.

8.8 MOVE CUVETTES

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

8.9 CLEAN NEEDLE

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

8.10 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 PLUS will calculate the consumption incorrectly.

BIOHAZARD	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®.

8.11 ADJUST MOTOR

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

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

False adjustment will cause errorneous results.

8.12 MICROTUBE

Adjust the height of micro tubes.

- Pipet 100µL water into an empty micro tube
- place the tube into rack P02.
- Press ENTER to continue.
- Z-axis drives to default 500
- Lower needle with key DOWN until tip get in contact with micro tube
- Press ENTER to check level sensor
- Press ESC to save and exit

How to use micro tubes in routine measurement is explained in chapter 4.7

8.13 INIT SYSTEM

- Switch off instrument.
- Presse key “0” and keep it pressed
- Switch on instrument.

Following screen is displayed

0 EXIT
1 INIT TESTS
2 INIT ALL
3 RESET SERVICE

- EXIT
  Return to system bootup
- INIT TESTS
  Reset all calibration data (lot,exp,calibration curve,,) to zero
  Reset all protocol data (regent volumes,position) to default
- INIT ALL
  Include init tests and additional
  Reset all system parameter (contrast, language,…) to default
- RESET SERVICE
  Clear service warning and set interval to next 50.000 tests

8.14 RESET SERVICE INTERVAL

After 50.000 tests the message “SERVICE” will be shown.

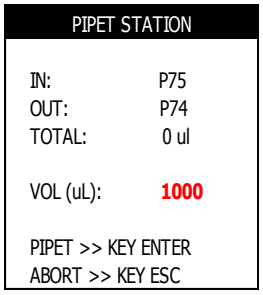
To reset service interval:

- Switch off instrument.
- Press key “0” and keep it pressed
- Switch on instrument.
- Wait until init screen is displayed
- Select “RESET SERVICE”

Form more information see chapter 8.13 I

9. MENU PIPET STATION

Menu to reconstitute reagent and controls



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

10. CLEANING AND MAINTENANCE

Cleanung and 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.

10.1 GENERAL CLEANING INFORMATION

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

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

Avoid any direct contact with decontaminants or disinfections.

10.1 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.

10.2 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

10.3 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

10.4 WEEKLY ACTIVITIES

- Decontaminate system with bleach and ethanol as described above

10.5 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

10.6 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)

11. ELIMINATION OF MALFUNCTIONS

11.1 ERROR MESSAGES

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

11.2 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 PLUS 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 PLUS 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

11.3 MEASUREMENT MALFUNCTIONS

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

12. APPENDIX

12.1 TECHNICAL DATA

Analyzer	
Measurement system	6 independent measurement channels wavelength of LED 400 nm
Measurement timer	Max. 540 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	The analyzer is conform to 98/79/EC (IVDD)

XYZ Robotics	
Movement	XY + Dual-Z
Level Sensor	Yes. Detection limit is 100µL or 5% of vial.
Needle	-Capacity for 450 µL -Inner nanoskin coating -Livetime for 100000 determination
Pump	2500 µl syringe with 300 step resolution Lifetime of syringe is 100000 determination
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	
Nominal Input Voltage	100 – 240VAC at 45 – 63Hz
Maximal Input Current	5A rms
Output Power	Max. 300 W
Socket	Class-1
Approvals	EN 60950-1, UL 60950-1 IEC 60950-1, EN 60601-1 CSA 22.2 No. 60950-1 2006/95/EC & 2011/65/EU

Dimensions	
Size (W x D x H)	900 x 520 x 700 mm
Weight	approx. 65 kg
Required space on table	1200 x 800 x 1000mm
Distance rear to wall	200mm

Ambient conditions	
Operating Temperature	15 to 30 °C
Humidity	< 70% rel. humidity
Elevation above NN sea level	< 3,000m
Free of dust	Grade 2
Impact resistance	according to IEC/EN 61010-1, 8.2.2
Not allowed	Vibrations, direct sun light; direct exposure of air condition.

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.

12.2 TRANSPORT AND STORAGE

Storage and transport temperature:	0 to 50°C
Size on palette (W x D x H)	1000 x 630 x 920 mm
Weight with palette	approx. 80 kg

Box the device always into original packaging prior transport or longtime storage.If the original packaging is no longer available, contact your dealer.

1. Remove the power cord from the socket and from the analyzer.
2. Decontaminate the complete equipment and confirm with a decontamination certificate
3. Immobilize all moving parts such as sample racks printer shaft, etc. with tape.
4. Remove the needles and place them in the drawer for the waste tank.
5. Fix the robot in the resting position (seen from the front—right, rear) with tape or cable binders to the protective bar.
6. Wrap plastic foil around analyzer
7. Push the analyzer to the edge of the table; then two persons must lift it by the short sides.
8. Lift the analyzer carefully into the packaging.
9. Add accessory and required information and close box.
   - Complete address of owner.
   - Name of dealer from whom the Analyzer was purchased.
   - Exact designation of the Analyzer and serial number (on type plate).
   - Decontamination certificate
   - A useful description of the reason why the equipment is being sent in (error / malfunction description).

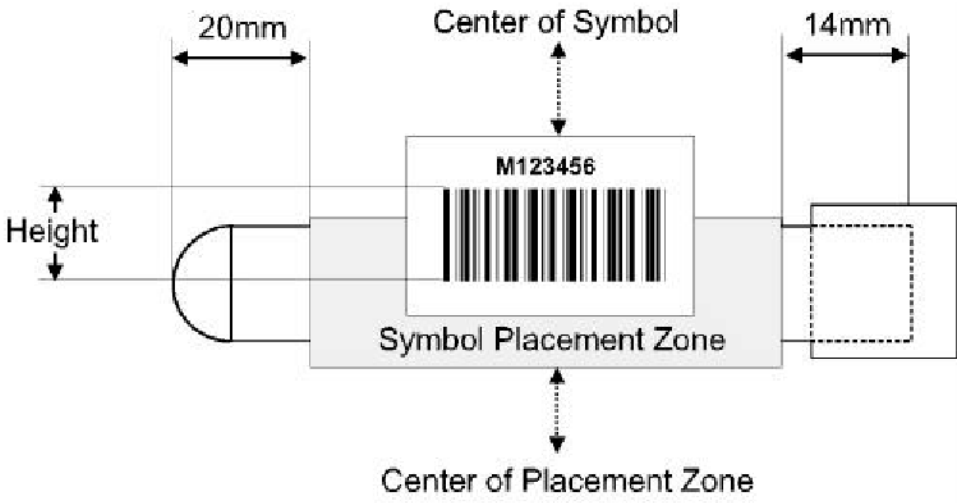
12.3 DISPOSAL AND RECYCLING

The instrument is be subject to European Directive 2002/96/EC (WEEE). Contact your local distributor the assistance

- 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.

Warning! The equipment must be decontamination prior any disposal or transport to an authorized electronic waste processing site.

12.4 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

13. INDEX

ACTIVATE REAGENT 56
ACTIVATE SYSTEM 55
Adjust Motor 73, 78, 79
Adjust XYZ 68
Ambient conditions 82
Analysis 46
Anticoagulant 83
Approvals 81
Autoskip 39, 47
Barcode 46, 50, 61
Barcode for Rinse tank 72
Barcode Scanner 23, 82
BAT 47
Bilirubin 9, 83
Calibration 57, 58, 59, 60, 81
Calibration curve 58
Centrifugation 83
Clean 47
CLEAN-A 26
CLEANING 76
Clotting 30
Contrast 64
Control measurement 9
COOLING 64
CP1 43
CP2 43
CP3 43
CUV 47
Cuvette 66, 71, 81
CUVETTE activation 55
Cuvette rotor 23
Cuvette tower 23, 66
Date 63
Decontamination 11, 76
DFIB 30
Disposal 84
Error messages 78
EV1 47
Exp. 57
Factroy reset 74
Fibrinogen 22
flag '!' 80
flag '*' 45, 80
flag '???' 80
flag '+++' 45, 80
flag 'A' 45, 80
flag 'C' 45
flag 'E' 45, 80
flag 'f' 80
flag 'F' 45, 80
flag 'I' 45
flag 'K' 45, 47, 80
flag 'Q' 45, 80
flag 'R' 44, 45, 80
flag 'RFX' 45
flag 'S' 45, 80
flag 'SSS' 45, 80
flag 'T' 45, 80
flag 'X' 45, 80
flag 'XXX' 45
Flag , summary 45
Hemoglobin 9, 83
Host 28, 50
HS-1 47
HS-2 47
Immunoturbidimetric 31
Imprecision 81, 83
Incubation time 57
Infection 10
Infectious Material 10
Info 57
INIT 74
INR 29
INR+ 29
Installation 21, 66
Intended Use 9
Interrupt worklist 39
Interruption 40
ISI 29
Keypad 8, 18, 27
Kinetic 31
Language 63
Laser 10
Laserclass 82
LIS 44
Lot No. 57
Main Menu 33
Maintenance 76
Mean 47
Measurement principle 28
measurement screen 44
Measurement start 38
Microtube 42, 73
Mixer 64
mOD 44
Needle 71
Optic 71
ORDER 50
Out of cuvette 39
Out of liquid 39
OVER view 23
Package 66
PID 46, 49, 50
Pipet Station 33
PIPET STATION 75
Pipetting arm 9
Precision 48
PRFL 49
Print out 62, 67
Print test 57
Printer 23
Pump 23
QC 47
Quality control 43
Range 83
reagent probe 23
REAGENTS Positions 24
Rear view 23, 24
Recycling 84
Reflex Testing 29, 44, 47, 57
Regulatorys 81
Report of system 67
Report of test 62
reproducibility 79
Requirement screen 51
RESET SERVICE 74
RINSE 23
Robot 71
Runtime 57
Safety information 9, 10, 11
sample probe 23
Scope of delivery 15
Screen 23, 28
SEL 47
Serial-No. 84
Setup System 63
SETUP TEST 57
Shield 23, 47, 64
Signal 63
Simulator 64
Single factor measurements 22
SKP 45, 47, 80
Start worklist 51
STAT 41, 51
Storage 84
switchin on/off 17
Symbols 8
SYNCHRONIZE 50
System block 23
System status 28
Tank 71
Tecam 24, 40, 43
TECAM 20, 51
Test Activation 56
Test overview 32
Thrombin 30
Thrombin Time 22
Throughput 48, 83
Time 63
Transport 84
Triglyceride 9, 83
Type plate 84
Units 29
Warm-up time 18
Warranty 21
Wavelength 81
Work list 46