Coatron A4

Operator's Manual
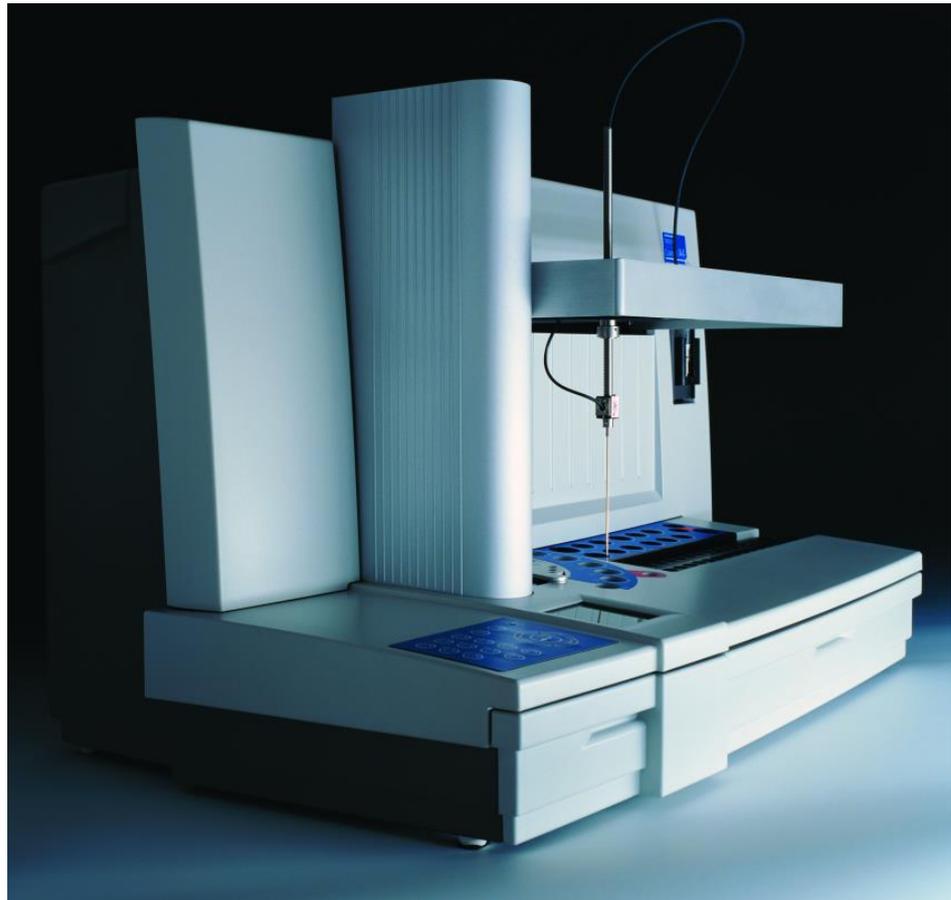
Instrumentation and Reagents for *In-Vitro* Diagnostic use

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Manufacturer

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1.   Introduction

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

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 A4 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 A4** 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 25mg/dL Bilirubin (428µmol/l)*
> *Do not use plasma with more than 1000mg/L Hemoglobin*
> *Do not use plasma with more than 25 g/l Triglceride (28.5 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 A4.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 "7 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

2.   Installation of the COATRON A4

> Initial startup of the COATRON A4 is carried out by the authorized Customer Service of the dealer. A protocol is kept of the first installation which is then sent in to the manufacturer as a basis for processing guarantee claims.

Procedures of first installation:
- Unbox and place instrument in conformity with the laboratory requirements (see below)
- Remove transport retainer
- Switch on
- Install Rinse tank + Rinse waste container
- Install print paper
- Install cuvette + cuvette waste drawer

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

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

2.3   Unpacking the COATRON A4

Following receipt of the shipment, please inspect the packaging of the COATRON A4 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 A4 and accessories for any damage. Report any damage found to the dealer without delay.Even if the packaging appears undamaged, check the analyzer and accessories for any transport damage, caused for example by impact, dropping, etc. during transport.

Keep the original packaging material for purposes of later transport

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2.4   Removal of the transport retainer elements

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

2.5Switching ON and off the COATRON A4

Switching the COATRON A4 on

1. Make sure the COATRON A4 is connected to the power mains.
2. Check for sufficient rinsing and cleaning fluid levels.
3. Set main switch to on. See rear side, location #18
4. Set standby switch to on. See right side, location #22
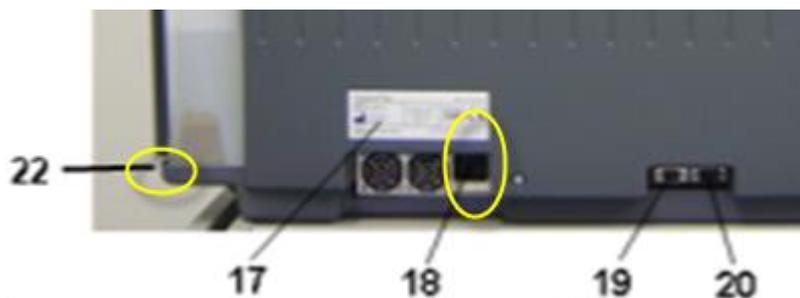
Location of power and standyby switchMain screen

The following screen appear in this order after the COATRON A4 is switched on.

Coatron A4	Name of instrument
V6.07.02	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 configured as "OPEN DEVICE". Please contact local distributor for more information about open or closed system.

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

```
┌─────────────────────┐
│                     │
│                     │
│ 1  ANALYSIS         │
│ 2  SETUP TEST       │
│ 3  SETUP SYSTEM     │
│ 4  SERVICE          │
│ 5  PIPET STATION    │
│                     │
│ 12:00   1055mL  LIS   37.0°C │
└─────────────────────┘
```
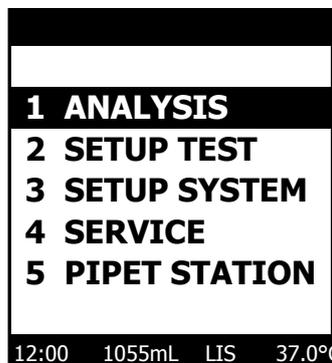
Main screen

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 the COATRON A4 off:

For normal shutdown at the end of the day and for changing the pipetting needle, rinsing solution tank and syringe, switch off the COATRON A4 with the standby switch on the right side of the housing. This will shut off all power-consuming components of the COATRON A4 except 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.

2.6   Installation of Components

	1. Remove a strip of cuvettes from the package. 2. Shift the cuvettes as shown from above in the guide groove back into the cuvette tower. 3. Remove the tape off the cuvettes.
	4. Place a new Rinse tank as shown 5. Insert the tube completely 6. Fill a reagent container (15 ml) with cleaning solution and place it into position CLEAN
	7. Open the print cover 8. Feed paper. Device has autofeed function. 9. Set printer to online by shift on arresting lever in the direction of the front of the housing.
	10. Plug download cable into left port (19) 11. Plug in power cord (18) 12. Connect download cable with PC computer 13. Move power switch to ON. (right of 18) 14. Move standby switch to ON (22). 15. After Bootup start TECAM software
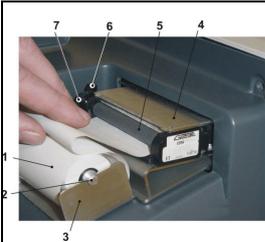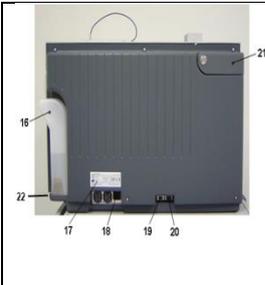
2.7   Installation of TECAM software

TECAM software is a powerful enhancement of the Coatron A4 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 32Bit
- 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:
1. Link instrument left RS232 port to
2. Check PC comport number (it must be between 1 to 15)
3. Start "SETUP.EXE" from the CD. The Setup will install Smart ,PRO or PROLIS and all required driver for database access.
4. Enter fingerprint and activation code

Run TECAM:

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

| ONLINE 100 | COM1 | SN-15000 | ASTM ERR |

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

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

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3.   Description of the COATRON A4

3.1   Short introduction

The Coatron A4 is a fully automated, stand alone "State of Art" analyzer for the fast and flexible coagulation diagnostic. It is equipped with four 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.

Optional 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

☞	Use only citrate 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.

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

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)
- Lupus Anticoagulant (LA)
- Activated protein C resistance (APCR)
- Heparin (chromogenic)
- ATIII (chromogenic)
- D-dimers (immunoturbidimetric)

Special features:

System
- Ultraviolet light (400 nm). The measurement amplification is adapted to photometric measurement principle with high-resolution 4-channel optics and automatic amplification to any method. Extraneous and scattered light energy is absorbed.
- High-precision XYZ pipetting system with liquid level sensor
- Long living and flexible Cap Piercing needle for primary tubes such as BD Vaccutainer® or Sarstedt Monovette®.
- Integrated ID-barcode reader
- Bi-directional ASTM Interface for PC-Link to LIS.*
- Optional trolley to enlarge the waste management
- Integrated graphical thermal printer
- Heated and cooled positions for reagents
- Integrated drawers for consumables

Software
- Approved and highly accurate detection algorithm based on optical density. The clotting time is defined at the turning point of reaction.
- An intuitive TECO GMBH familiar grafical user interface with "Plug And Go" feeling.
- Multi language dialogue. (english , german, spanish, italian)
- Random access scheduler. Profiles can be performed as batch or selective.
- Positive sample identification (ID and rack position) either manual or with barcode scanner
- Fast and easy processing of STAT samples
- Free programmable test protocols to change or adapt new tests
- Calculation of activity %, INR, ratio, g/L , mg/dL , and more.
- Calibration curve can be identified with up to 6 points per test. The results can be calculated with regression line analysis or linear interpolation.
- Single or double determinations
- Simple firmware update
- ASTM interface to link to any LIS *

Special Functions
- Automatic plasma dilutions upto 1:100
- Automatic cleaning cycles
- Automatic test calibration routines
- Automatic quality control
- Automatic or manual printout
- Automatic test skip, if reagent run out.
- Automatic reflex testing for "+++2 results
- Unlimited result management including also reaction curve *
- Quality control according to Westgard rules *
- Result traceability *
- Patient monitoring for long time periods *

Economic
- Half volume procedures resulting in 50% cost savings.
- Reagent dead volume is below 300 µL
- Very economic consumption of Rinse and cleaning solution.
  (1L Rinse ~ 1000 det. ; 15mL cleaner is enough for a day work)
- Cuvette with no mixing bars, etc.
- All critical system parameters are monitored and make the instrument nearly free of service.

* only the TECAM PRO software

3.2 Views of the device

3.2.1   Front view
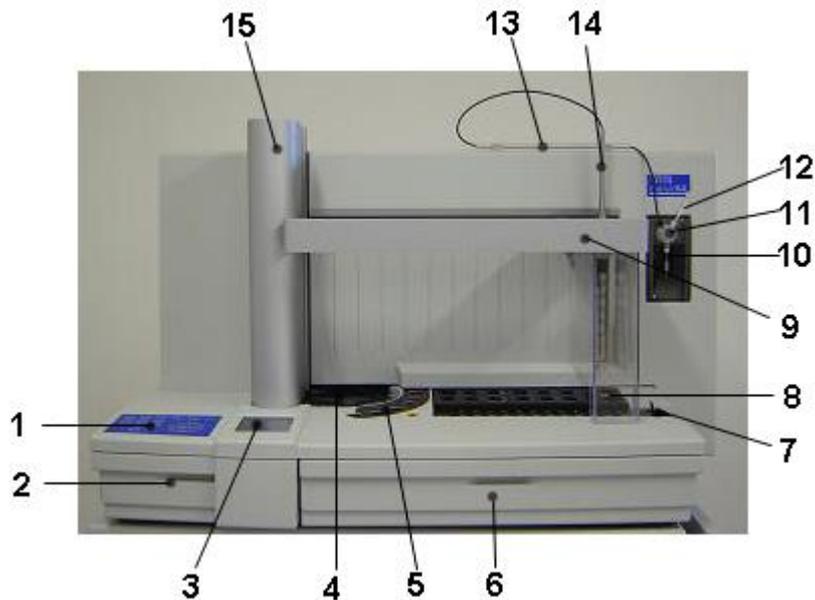
Figure 1: COATRON A4, front view

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

3.2.2 Rear view
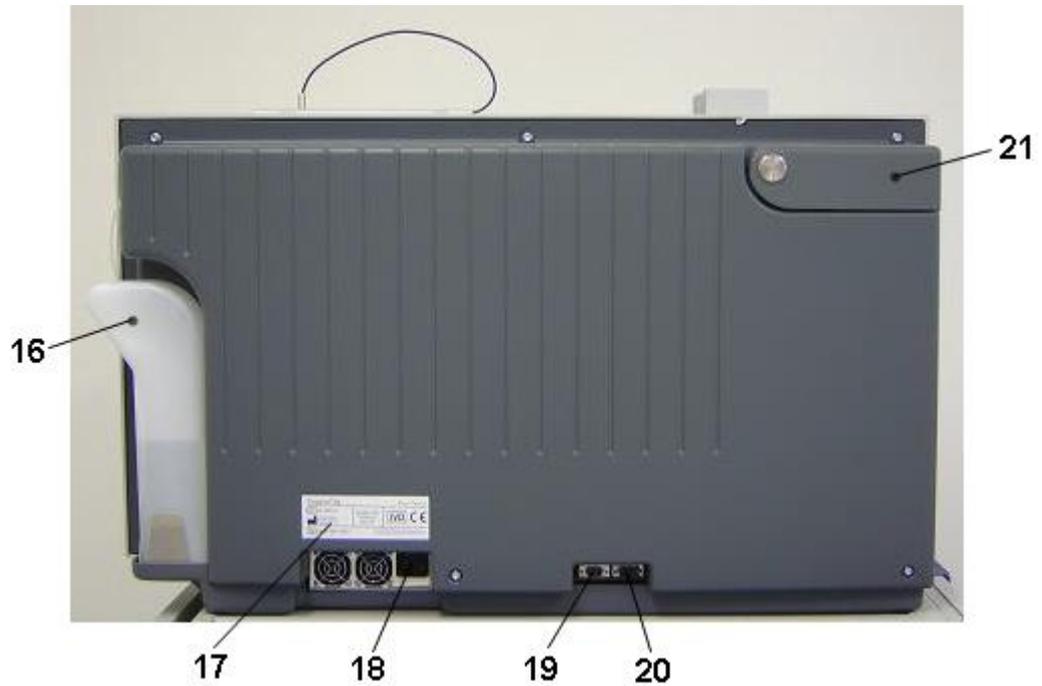
Figure 2: COATRON A4, rear view

16   Rinsing solution tank
17   Type plate
18   Mains switch and power input
19   RS232 service interface for updating and data transmission
       (115K, 8,1,N)
20   RS232 debug interface for error analysis
       (reserved for manufacturer)
21   Printer cover

3.2.3   Side view
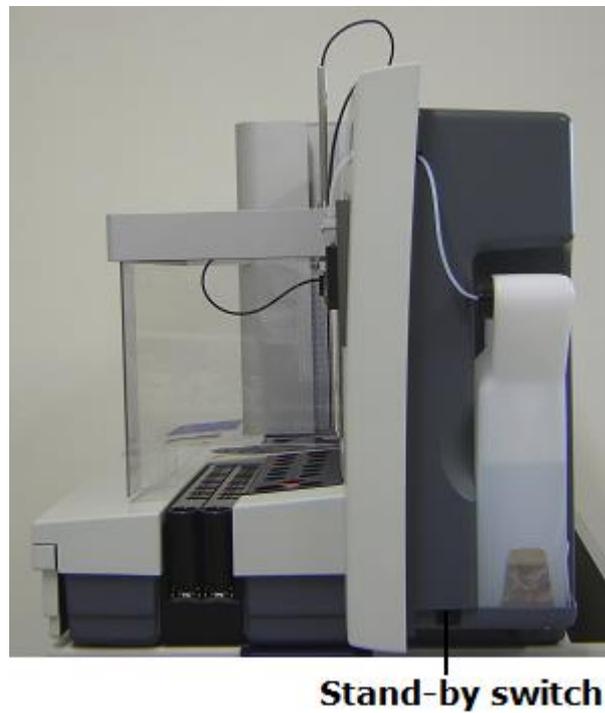
Figure 3: Side view

3.2.4   Sample rack
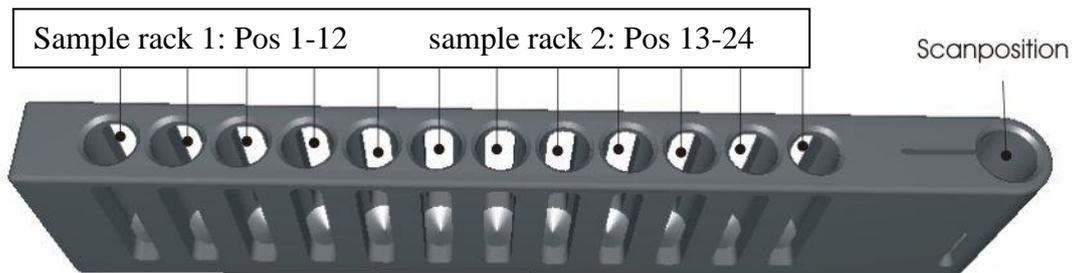
Figure 4: Sample rack

All commercially available sampling systems with a diameter of 11-13 mm can be used as sample tubes (eg. Sarstedt Monovette® or BD Vacutainer®).

3.2.5   Working Positions
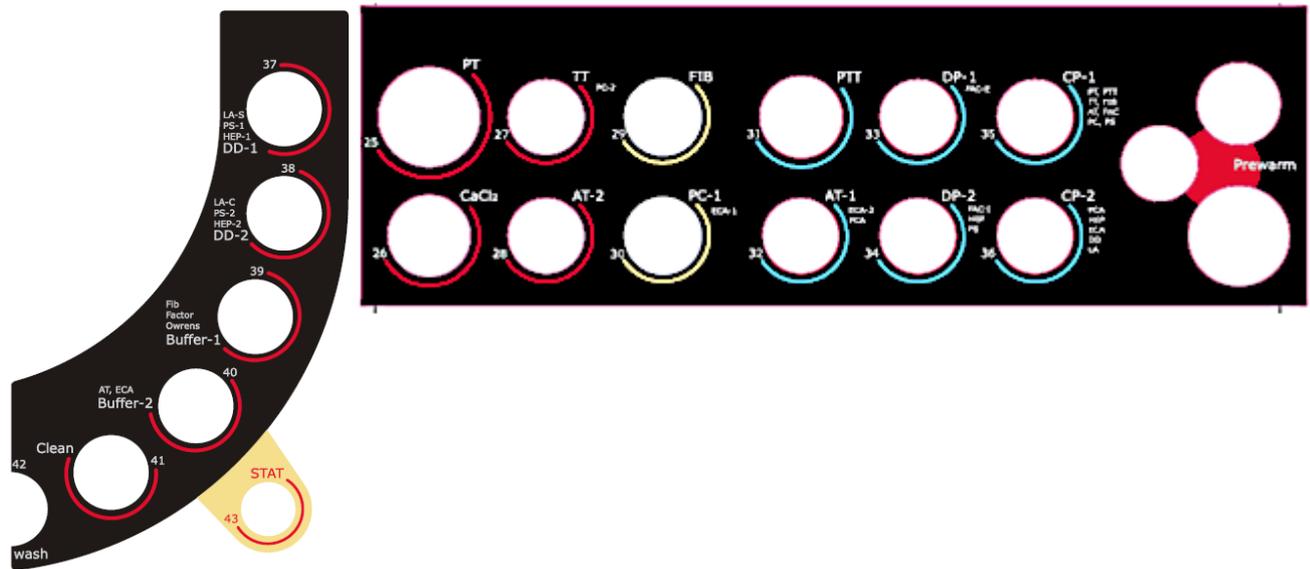
Figure 5: Working Positions

Pos. 1 - 24		Sample positions	Room temperature
Pos. 25	PT	Reagent position for PT, **magnetic stirring function**	37.0 °C
Pos. 26	CaCl	Reagent position for CaCl$_2$	37.0 °C
Pos. 27	TCT	Reagent position for TCT and PC-2 , APC	37.0 °C
Pos. 28	AT-2	Reagent position for AT-2 (substrate)	37.0 °C
Pos. 29	FIB	Reagent position for FIB	Room temperature
Pos. 30	PC-1	Reagent position for PC-1 (activator)	Room temperature
Pos. 31	PTT	Reagent position for PTT	15.0 °C
Pos. 32	AT-1	Reagent position for AT-1 (thrombin/factor Xa reagent)	15.0 °C
Pos. 33	DP-1	Deficient Plasma 1: for FII,FV ,FIIV, FX ,	15.0 °C
Pos. 34	DP-2	Deficient Plasma 2 : for FVIII, FIX, FXI,FXII,PS,APCR, PK,HMWK	15.0 °C
Pos. 35	CP-1	Control plasma 1: for PT, PTT, TCT, FIB, Factors, PC, AT	15.0 °C
Pos. 36	CP-2	Control plasma 2 : for DD, HEP, APCR, LA	15.0 °C
Pos. 37	DD-1	used for DD-1, HEP-1, LA Screen	37.0 °C
Pos. 38	DD-2	used for DD-2, HEP-2, LA Confirm	37.0 °C
Pos. 39	Buffer-1	Owren's Buffer for plasma dilution (FIB , factors)	37.0 °C
Pos. 40	Buffer-2	Working Buffer for chromogenic tests (AT)	37.0 °C
Pos. 41	Clean	Position for cleaning solution	37.0 °C
Pos. 42	Wash	Wash and waste position	37.0 °C
Pos. 43	STAT	Emergency sample position	Room temperature
Pre-heat	Prewarm	3 prewarm positions	~37.0 °C

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.

3.2.6   Keypad
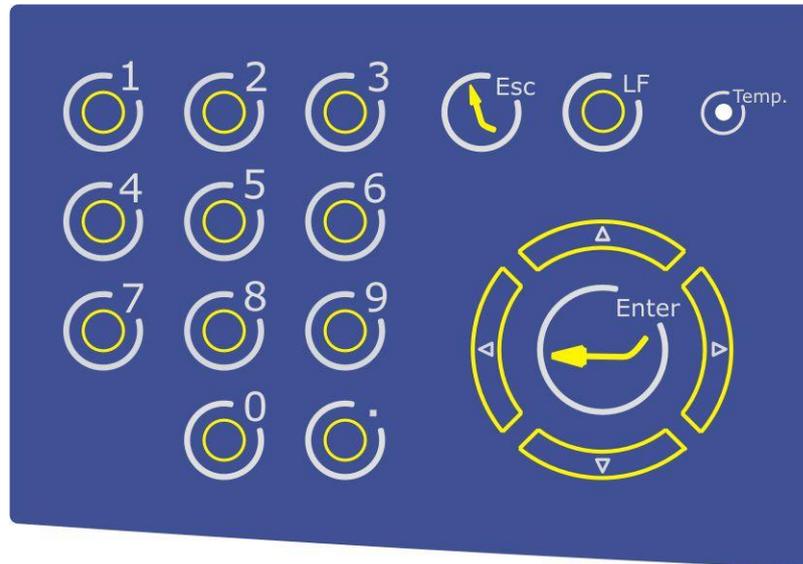
Figure 6: Keypad

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.

3.2.7   Screen segments
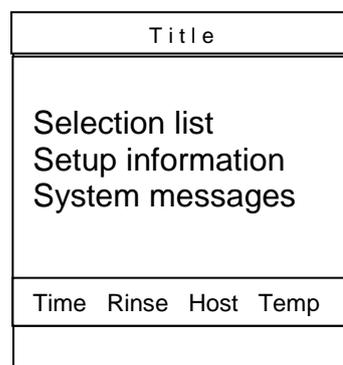
Figure 7: Screen segments

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

The COATRON A4 is equipped with highly sensitive 4-channel LED optics at a wavelength of 400 nm, making precise and reliable measurements possible even with icteric or lipaemic plasmas.

Once a reaction charge has been prepared, the optimum transillumination settings are found using an amplifier that facilitates measurement of both clear and cloudy samples.

Recording of measurement process data is started automatically when the start reagent is added. When coagulation begins, transmission is reduced, which changes the form of the measurement curve. The time from measurement start to this change (turning point) in seconds [s] is the result. The software then converts this datum into other units.

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	Decimal places	Maximum value
s	1	-
%	1	180
U	0	999
INR	2	12
Ratio	2	9
INR+	2	12
mg/dl	0	900
g/l	2	9
U/ml	2	1
mg/l	2	5
µg/ml	1	999
ng/ml	0	5,000
µg/l	0	5,000

Ratio = clotting time / normal time

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

ISI   = International Sensitivity Index (sensitivity of the PT reagent).
               (The ISI value is listed on the reagent information sheet)

INR+   = Like INR, except the ISI value is determined for a specific device. This is done using a calibration curve with INR standards.

3.3.3   Clotting method
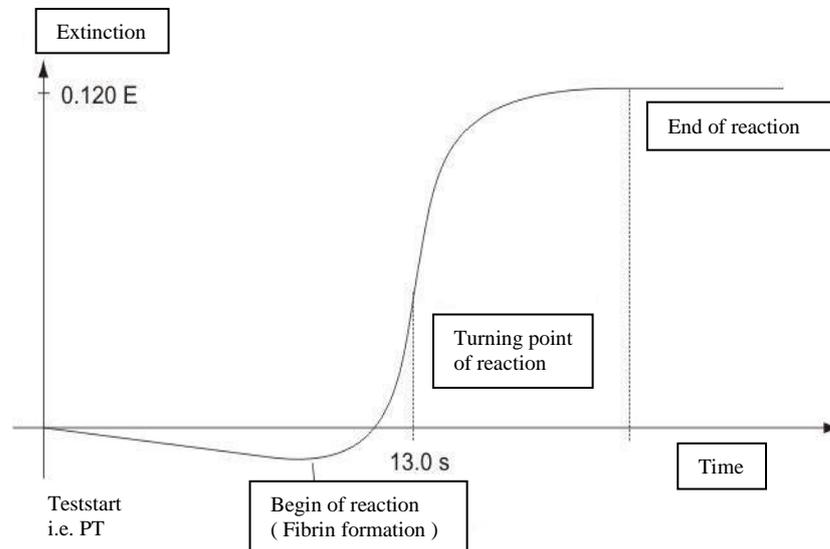
Figure 8: Determination of turning point in clotting method

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

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 method should only be used to select samples. Samples with a fibrinogen concentration outside the normal range must be confirmed using the FIB Clauss method.

3.3.5   Chromogenic, endpoint and immunoturbidimetric method
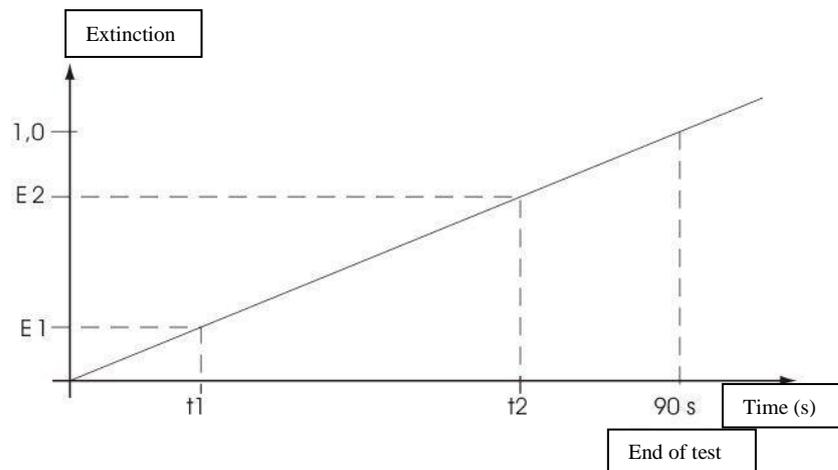
Figure 9: Determination of rise in the kinetic test method

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	Name
PT	Prothrombin Time
DFIB	Fibrinogen, derived
aPTT	Activated Partial Clotting Time
FIB	Fibrinogen, Clauss
AT	Antithrombin
TT	Thrombin Time
DD	D-Dimer
HEP	Heparin
PC	Protein-C
PS	Protein-S
F2	Factor II
F5	Factor V
F7	Factor VII
F8	Factor VIII
F9	Factor IX
F10	Factor X
F11	Factor XI
F12	Factor XII
PLG	Plasminogen
-APC	Activated PC resistance Step1
APCR	Activated PC resistance Step2
LA-S	Lupus Anticoagulants Screen
La-C	Lupus Anticoagulants Confirm
PSF	free Protein S
FDP	Fibrin Degradation Product

☞   Setup off test protocol is described in 5.2.10

☞   Ask local distributor for more information about specific test protocol
         setup

4. Routine measurement (Typical use case)

- Run 24 patients with PT + aPTT + FIB
- Scan the barcode of the samples
- Instrument should carry out all measurements in single
- Instrument should skip test, if system is out of reagent
- Instrument should not repeat results automatically
- Instrument should report first samples as soon as possible

4.1 Preparation

1. Wait until the COATRON A4 has reached operating temperature.
2. Make sure sufficient cuvettes, rinsing liquid and cleaning liquid are available for the testing procedure.
3. Supply the reagent positions with the required reagents and buffer solutions.
4. Re-enter the calibration curve for the planned tests when new reagents with new lot numbers are used.

   See *chap. 5.2.2 Submenu Data input* for input of a calibration curve
5. Wait about 15 min. after supplying the reagent positions before test processing until the reagents have reached the right temperature (37°C in positions 25 – 28 and room temperature in positions 29 and 30).
6. Change to menu ANALYSIS

```
1 ANALYSIS
2 SETUP TEST
3 SETUP SYSTEM
4 SERVICE
5 PIPET STATION

12:00   1055mL   LIS   37.0°C
```
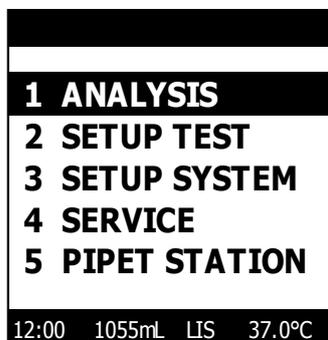
Select ANALYSIS and confirm with ENTER.

4.2 New list input

1. Fill the sample racks with the sample test tubes.
2. Remove the sample test tube cover
3. Make sure barcode labels are visible in the barcode window of the sample rack.
4. In the menu ANALYSIS, go to NEW LIST

CONTINUE: **YES**	Select YES and press ENTER to continue

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

-Select PRFL. Later define profile as PT+aPTT+FIB
-The samples identifications input by barcode
-No automatic test repeat
-Single determination
-No quality control
-Skip test, if out of reagent
-Search for plasma until buttom of tube
-Standard cleaning procedure
-Activate shield protection
-Run worklist in cuvette

CONTINUE: **YES**

Select YES and press ENTER to continue

TEST1: PT	TEST5: -
TEST2: APTT	TEST6: -
TEST3: FIB	TEST7: -
TEST4: -	TEST8: -

Set profile to PT + APTT + FIB

5. Input patient-ID by barcode reader:

BARCODE ENTRY	
RACK 1	**RACK 2**
01▷	13
02	14
03	15
04	16
05	17
06	18
07	19
08	20
09	21
10	22
11	23
12	24

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

In case of reading errors, check correct position of barcode, shift out rack and repeat scanning..

Press ENTER to continue

6. Start measurement
   By select START and press ENTER

PREPARE SYSTEM
P25 800uL
P26 500uL
P29 500uL
P31 500uL
P39 740uL
CUVETTES 5
CONTINUE >> KEY ENTER

Check, if all required reagents are on board and in correct position.

*Press ENTER to start measurement*Star measurement

7. After completion of the measurement, the results and other information on the test are printed out and send to LIS automatically.

4.3 Interrupt or exit measurement

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

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

> Exit worklist: Press key ESC again:
> Measurement and worklist will be aborted.

> Move robotic: Press key LEFT/RIGHT:
> Moves robotic to left or right home position.

> Contine worklist: Press key ENTER:
> Continuous measurement

4.4 Out of liquid or cuvette during measurement

System will interrupt worklist automatically, if

```
OUT OF LIQUID  P25



     PRESS ENTER


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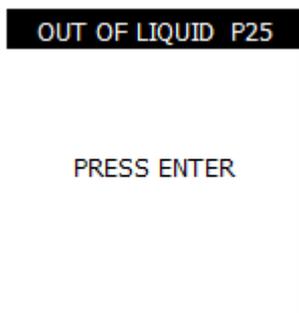
Out of liquid:
Replace vial at indicated position within 30sec after alarm and press ENTER to continue worklist. After 30sec system will exit worklist or skip order according to setup of autoskip function.

Out of cuvette:
Reload cuvettes and press ENTER to continue worklist

4.5 Continous loading of samples

This feature requires the host software TECAM PRO. The system must be set to "HC", which means host communication is online.

Samples can be loaded during measurement.

 (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

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

```
┌──────────────────────────────┐
│         STAT ENTRY           │
├──────────────────────────────┤
│ PID:                         │
│                              │
│ TEST:          PT            │
│                INFO          │
│ MODE:          MANUAL        │
│                              │
│ CONTINUE:      YES           │
│                              │
│                              │
└──────────────────────────────┘
```

1. Interrupt the current worklist with Esc (*see chap. 4.4*).
2. Go to the submenu STAT in the main menu ANALYSIS.
3. Either input the PID manually via the numeric keypad or with the barcode scanner as described in chap. 5.1.4.
4. Place the emergency sample in the STAT position (position 43).
5. Select the test.
6. Under INFO you can print out the test SETUP.
7. Set the mode. If it is set to Manual, the interrupted worklist must be continued manually after the emergency sample has been measured. In Auto mode this is done automatically.
8. Leave the screen with Enter.
9. Check the reagents according to the information in the following screen, SYSTEM PREPARATION.
10. Start the emergency measurement with Enter.
11. After the measurement is completed, the test results are printed out analogously to normal test processing.
12. With CONTINUE in the main menu ANALYSIS, processing of the interrupted worklist recommences.

> ☞ *The software "TECAM PRO"features STAT orders, which can be run in regular patient rack and loaded during during operation.*
>
>   •

4.7 Quality control measurement

The analyser allows to run one control plasma for each test. The specific control range must be entered in the menu "TEST SETUP". No warning flag "Q" is generated, if the control range is defined equal to zero.

There are two internal position for control plasma (CP-1 , CP-2). But also rack positions can be used for control plasma. The internal positions CP1/CP2 for each test can be found in the printout of the test setup

The analyser identifies a sample as a control if its position is CP1/CP2 or if its PID is equal to one of the two entered lot-numbers A control result is always marked with flag "C" and in case that it is out of range also with flag "Q". All further results will be flagged with "Q" until a new control result is successfully or the instrument is rebooted.

QC with positions CP-1 and CP-2:
- Define control range in the menu SETUP TEST
- Activate QC-ACTIVE within worklist menu
- Optional: Enter lot-number of control plasma within the worklist menu
- Place control plasma to position CP-1 or CP-2. The corresponding control position is printed with the test setup.

QC with rack position P01 and P02:
- Define control range in the menu SETUP TEST
- Set QC-ACTIVE=NO within worklist menu
- Set BARCODE=YES within worklist menu
- Enter the lot-number of control plasma within the worklist menu
- Place control plasma to position P01 and/or P02 and then all samples
- Enter the PID of the samples manually or by barcode. It is important that the PID number of sample P01 is equal to lot-number.

> *The terminal program "TECAM PRO"features quality control processing according to Levey-Jennings graphics and Westgard rules.*

5.   Software description

Following menu is displayed after start of instrument

```
┌─────────────────────────┐
│ █████████████████       │
│ 1 ANALYSIS              │
│ 2 SETUP TEST            │
│ 3 SETUP SYSTEM          │
│ 4 SERVICE               │
│ 5 PIPET STATION         │
│                         │
│ 12:00  1055mL  LIS  37.0°C│
└─────────────────────────┘
```
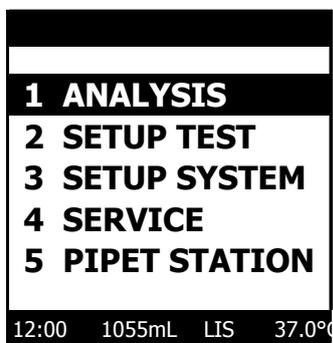
> **ANALYSIS**
  Menu to define orders and run patient samples

> **SETUP TEST**
  Menu to calibrate methods

> **SETUP SYSTEM**
  Menu to change system parameters

> **SERVICE**
  Menu to service system

> **PIPET STATION**
  Menu to reconstitute reagent and controls

The statusbar shows current information about time, installed RINSE solution, LIS connection and onboard temperature.

5.1   Main menu Analysis

```
        WORKLIST

1 NEW LIST
2 CONTINUE
3 REPEAT
4 STAT
5 VIEW
6 PRINT OPTION
7 SYSTEM ACTIVATION
8 REAGENT ACTIVATION
12:00   1055mL  LIS    37.0°C
```

5.1.1   Submenu New List

Creation and processing of a new list is achieved in 3 consecutive screens, each reached from the previous screen by way of Enter on CONTINUE: YES.
ARROW ↑ / ARROW ↓ selects the desired menu item, ARROW ← / ARROW → pages through the options.
With ESC one returns to the previous screen.
Select *CONTINUE = YES* to come to the next screen.

Screen: worklist settings

```
CONTINUE:        YES

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

Possible settings:

> **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 (identical with *chap. 5.2.5, Test printout*).

> **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).

> **Double:**   YES / NO
> Activates the double test. The mean value is automatically used in the results report. If the two individual results differ by 15%, the result is labelled Flag "%."

> **QC Active:**YES / NO
> Carries out control measurements with control plasma before each worklist is started; for this purpose, positions P35 (CP-1) or P36 (CP-2) must be filled with control plasma. The control positions for each test is defined in the Test Setup printout. If the control measurement results are outside the QC range (*see chap. 5.2.4, Submenu QC range*), the results printouts for the worklist will bear the remark "Q."

> **Autoskip**   YES / NO**:**
> The instrument will skip current job or test, if plasma or reagent run out and continue with the next order. Skipped jobs are printed as "SKP". Select "CONTINUE" in the analysis menu to re-run only skipped jobs.

> **HCT-L:**   0 – 63 mm
> Determines the height of the coagulum (haematocrit level) measured from buttom of tube.The needle will search for plasma only upto this level. HCT-L must be set to 0 ,if only plasma is used

- ➢ **CLEAN:** Min - Max
  Defines how to clean needle after pipetting samples
  - MIN: Don't perform a clean cycle from sample to sample. The risk of sample to sample carryover was evaluated with extreme high levels of Heparin and concerned low.

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

- ➢ **SHIELD:** Yes - No
  This setting is only display, if a protection shield is installed.
  - YES: System stop immediately operation, if protection shield is opened during worklist.
  - No: Deactivate shield detection

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

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

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

Screen: Test Profil, Control plasma and Autoseries input:

```
CONTINUE:           YES

  SAMPLES:       24
  1.PID:          1000
  CP-1:   N12345678
  CP-2:   P23456789
  TEST   1:PT    5: AT
         2:APTT 6: -
         3:FIB   7: -
         4:TT     8: -
```

Possible settings:
  ➢ **Samples:**
    (only visible of barcode is set to no)
    Manual input of number of samples.
  ➢ **1. 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,…..)
  ➢ **CP-1 , CP-2:**
    Input of lot.-numbers for two control plasma manually or by barcode. If the analyser identify a PID number as a control lot. , the result will flagged with "C" and checked if within control range.
  ➢ **Test 1 – 8:**
    When a profile is to be measured, you can define the individual tests here once again.

-DFIB requires also PT
-ACPR requires also –APC and reverse
-LA requires also 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:

BARCODE ENTRY	
RACK 1	**RACK 2**
01▷	13
02	14
03	15
04	16
05	17
06	18
07	19
08	20
09	21
10	22
11	23
12	24

- *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.

SYCHRONIZE TO HOST

All patient identification numbers will be send to host.

If   PID: 1000   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.*

When worklist input is complete a further input overview appears.

```
          WORKLIST
     ┌──────────┐ ┌───────────┐
     │    <-    │ │   START   │
     └──────────┘ └───────────┘
     ┌────────────────────────┐
     │ TEST:          PRFL    │
     │ SAMPLES:       06      │
     │ DOUBLE:         NO     │
     │ QC-ACTIVE:      NO     │
     │ AUTOSKIP:       NO     │
     └────────────────────────┘

  12:00    1055mL   H0      37.0°C
```

The COATRON A4 requires the following to process the active worklist:

```
        PREPARE SYSTEM

   P25   800uL
   P26   500uL
   P29   500uL
   P31   500uL
   P39   740uL

   CUVETTES   5

        CONTINUE >> KEY ENTER
```

- 800μl reagent in position 25=PT
- 500μl reagent in position 26=CACL
- 500μl reagent in position 29=Fibrinogen
- 500μl reagent in position 31=APTT
- 740μl reagent in position 38=FIB buffer
- 5 cuvette trays

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

5.1.2   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.

5.1.3   Submenu Repeat

Repeats the last worklist.

5.1.4   Submenu Stat

Interrupts the regular processing of the list and selects the emergency sample at position 43 in the system block.

```
┌─────────────────────────────┐
│        STAT ENTRY           │
│ ┌─────────────────────────┐ │
│ │ PID:                    │ │
│ └─────────────────────────┘ │
│ TEST:          PT           │
│                INFO         │
│ MODE:          MANUAL       │
│                             │
│ CONTINUE:      YES          │
│                             │
│                             │
└─────────────────────────────┘
```

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

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

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

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

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

5.1.5   Submenu Overview

Displays and prints lists according to given sorting criteria.

```
              WORKLIST


  P01      1000
       PT              70,1%
       APTT            36,1s
       FIB             398 mg/dL


  P02      1001
       PT              100,0%
       APTT            33,5s
       FIB             250 mg/dL


    OPTIONS   >>  KEY  ENTER
```

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

```
              WORKLIST


  P01      1000
   ┌──────────────────────┐ ▓
   │ PRINT REPORT         │ ▓
   │ SEND TO HOST         │ ▓
   │ STAT                 │ ▓
  P0│                     │ ▓
   │                      │
   │                      │
   │                      │
   └──────────────────────┘
    OPTIONS   >>  KEY  ENTER
```

The following options can be selected:
➢   Prints report
➢   Sends to host. Transmit the results from the processed worklist
        to a PC for further processing. For this function you require the
        optional software package "TECAM" or similar.
➢   Displays either the emergency list or the worklist.

5.1.6   Submenu Print Option

```
┌─────────────────────────────┐
│         WORKLIST            │
│ ┌─────────────────────────┐ │
│ │TEST SETUP:      YES     │ │
│ │INFO:            YES     │ │
│ │PRINT DETAIL:    YES     │ │
│ │PRINT REPORT:    YES     │ │
│ │                         │ │
│ │                         │ │
│ │                         │ │
│ └─────────────────────────┘ │
│ 2003/01/01   12:00   37.0°C │
└─────────────────────────────┘
```
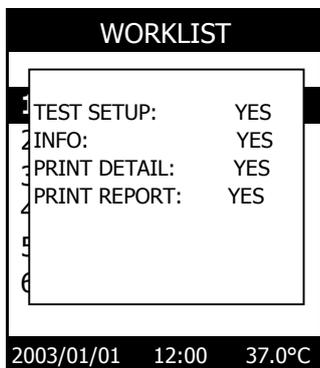
Determines what information is to be printed automatically:
- ➢ Test Setup: YES / NO
     The Test Setups are printed at the beginning
- ➢ Info: YES / NO
     Information on worklist is printed at the beginning
- ➢ Print details: YES / NO
     Detailed results are printed during the measurements
- ➢ Print report: YES / NO
     A report is printed after the worklist is processed.

5.1.7   Submenu System Activation

This menu is only visible, if instrument is configurated as closed system

```
┌─────────────────────────────┐
│       ACTIVATE SYSTEM       │
│                             │
│        SYSTEM STOP IN       │
│          999 TESTS          │
│                             │
│        READ BARCODE         │
│                             │
│        ABORT >> KEY ESC     │
│                             │
│ 12:00  1055mL  H0   37.0°C  │
└─────────────────────────────┘
```
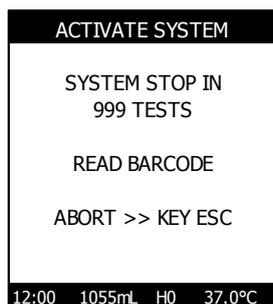
System will stop operating after 999 determinations.
- ➢ Skip message with key ESC.
- ➢ Scan "Test Activation Key" to activate system.

Barcode will be rejected in case of invalid syntax or if barcode was already scanned before.

⇨   ***Contact your local distributor, if you require a valid barcode.***

5.1.8   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.

```
┌─────────────────────────┐
│   CUVETTE ACTIVATION     │
│                          │
│                          │
│  500 CUVETTES ENABLED    │
│                          │
│                          │
│      READ BARCODE        │
│                          │
│                          │
│                          │
│                          │
│  CONTINUE >> KEY ENTER   │
└─────────────────────────┘
```
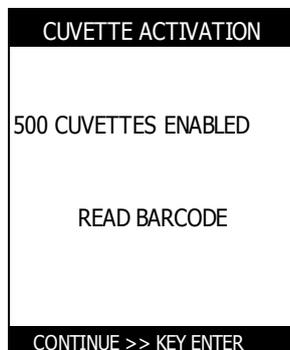
> ✍ *Activation barcode can be read only one time and is be checked by serialnumber of instrument.*

5.1.9   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.

```
┌─────────────────────────┐
│     TEST ACTIVATION      │
│                          │
│ PT:  THROMBOPLASTIN      │
│       POS=25             │
│                          │
│ ==================       │
│ CP=P35   50µL            │
│ R2=P25   100µL           │
│                          │
│ 12:00  1055mL  H0  37.0°C│
└─────────────────────────┘
```
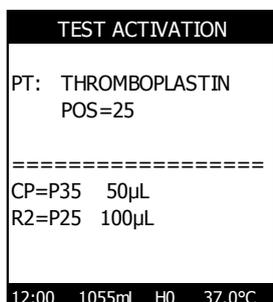
Activate reagent by scanning the barcodes of certain reagents. The activation is valid until next system reboot.

Reagent and test name is displayed as well as the test protocol (e.g. control plasma at P35 with 50µL and R2=Thromboplastin 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 5.2 "TEST SETUP"***

5.1.10   Reflex testing

This feature is always enabled. After worklist run, then instrument will validate results and repeat test under following circumstances:

➢ For clotting tests like PT,aPTT,Factors: If result is "+++", then test is repeated 1x with 60s prolonged maximum reading time.
➢ For chromogenic tests like AT: If result is "0.000E, then test is repeated 1x.

Repeated results are flagged with "R"

5.1.11   Display during measurement

```
 *    WORKLIST IN PROCESS

ID1:   1000
   PT                  70,1%
ID2:   1001
   PT                  x178
ID3:   1002
   PT                  x026
ID4:   1003
   PT                  x003
              - HC -
           PROGRESS
              5%
```

A PT result for sample ID 1000 has already been found in measurement channel 1. On channel 2-4 is a measurement ongoing.

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

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

The above screen appears during measurement.

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

5.1.12   Result warning messages

Results may also be displayed with various additional warning symbols:
- ➢ *   Result outside calibrated range
- ➢ A   Result outside normal range
- ➢ T   Temperature outside 36 – 38°C range
- ➢ Q   Quality control outside control range
- ➢ C   Result is identified as a quality control
- ➢ E   Reagent is expired
- ➢ F   Low Fibrinogen level found
- ➢ R   Result repeated (reflex testing)
- ➢ !   Result not trustful and should be repeated.
- ➢ 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
- ➢ XXX   No result was found
- ➢ SSS   Signal transmission too low.
- ➢ +++   No coagulation determined within measurement time
- ➢ ???   Result based on strange optical signals (e.g. air bubble, peaks)

5.1.13 Printout of results

Depending on how the print options are set (*see chap. 5.1.6, Submenu Print Options*), the results are automatically printed out as follows. Each report can be identified with a unique worklist-id number.

```
TASKLIST   18.04.2003 00:34

TEST: PRFL
SAMPLES: 06
BARCODE: NO
DOUBLE: NO
QC ACTIVE: NO


P01 1000
   PT   16.1 s    70.1 %

P02 1001
   PT   16.1 s    70.1 %

P03 1002
   PT   16.1 s    70.1 %

P04 1003
   PT   16.1 s    70.1 %

P05 1004
   PT   16.1 s    70.1 %
.
.
.
.
.
P05 1004
   FIB  8.1 s     398 mg/dl

P06 1005
   FIB  8.1 s     398 mg/dl
```

```
        REPORT OF RESULTS

Worklist-ID: 1000
TIME: 18.04.2003 00:36


P01  1000
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s

P02  1001
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s

P03  1002
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s

P04  1003
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s

P05  1004
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s

P06  1005
PT        70.1%          16.1s
PTT       36.1s
FIB       398 mg/dl      8.1s
```

Individual results   Report

5.1.14 Host communication

The COATRON A4 has a serial bi-directional interface for data transmission.The terminal program "TECAM PRO" allows to define jobs on the PC surface and send them to the analyser. Once the program has started, all results are automatically sent to the HOST, where they can be graphically presented, including the coagulation curves, and managed in a database. A demo version of TECAM can be downloaded from the distributor's homepage.An active host connection is indicated with "H1" in the screen statusbar and with "HC" in the measurement screen

5.2 Main menu Test Setup

WORKLIST
1 CHANGE TEST
2 SET DATA
3 NORMAL RANGE
4 CONTROL RANGE
5 PRINT TEST
6 PRINT OVERVIEW
12:00   1055mL   H0   37.0°C

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

1=INFO

5.2.1   Using of reagent barcode

The internal barcode scanner will be activated by entering the submenu SET DATA. After every barcode event, the Coatron A4 will enter the LOT number and expiry date of the barcode.

SETUP F8
TEST: F8
LOT: 123456789
EXP.:   01/2004
UNIT: %
INCUB.:   180s
RUNTIME: 180s
ENTRY: MANUAL
12:00   1055mL   H0   37.0°C

5.2.2   Test Selection

All of the available tests are listed in a table. Navigation within the table is realized with ARROW $\uparrow$ / ARROW $\downarrow$ / ARROW $\leftarrow$ / ARROW $\rightarrow$. Enter selects a test and returns to the main menu Test Setup. The selected test is displayed in the headline. The following menu items always refer to the current test setting. To carry out several tests on each sample, select the last item, PRFL (profile). In this case, the next menu item DATA INPUT differs from data input in single tests.

5.2.3   Submenu "Set Data"

```
┌─────────────────────────────┐
│          SETUP F8           │
│ ┌─────────────────────────┐ │
│ │ TEST:     F8            │ │
│ │ LOT:      123456789     │ │
│ │ EXP.:     01/2004       │ │
│ │ UNIT:     %            ██│H
│ │ INCUB.:   180s          │ │
│ │ RUNTIME:  180s          │ │
│ │ ENTRY:   MANUAL         │ │
│ └─────────────────────────┘ │
│ 12:00   1055mL   H0    37.0°C│
└─────────────────────────────┘
```

Single tests:

After replacing the reagents, the lot number (LOT) and expiry date (EXP.) must be re-entered. With ARROW ↑ / ARROW ↓ one selects the value to be changed.

➢ **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 A4

➢ **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 setting**
   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 setting**
   Define the maximum reading time.

➢ **Mode of calibration**
   Select between   Manual = manual input
                         Auto = automatical test calibration

5.2.4   Test Calibration

The analyser gives the operator the option to calibrate a test manually or automatically.

➢ 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

```
        SETUP PT
 ┌──────────────────────┐
 │ TEST:      PT         │
 │ LOT:       123456789  │
 │ EXP.:      01/2004    │ E
 │ UNIT:      %          │
 │ INCUB.:    0s         │ CI
 │ RUNTIME:   120s       │
 │ ENTRY:     MANUAL     │
 └──────────────────────┘
 12:00    1055mL   H0    37.0°
```

```
     SET DATA: PT
 ┌──────────────────┐
 │  ┌────────┬─────┐ │
 │  │   %    │  s  │ │
 │  ├────────┼─────┤ │
 │  │  100   │12,1 │ │
 │  │   50   │16,2 │ │
 │  │   25   │25,7 │ │
 │  │  12,5  │36,9 │ │
 │  │   0    │  0  │ │
 │  │   0    │  0  │ │
 │  ├────────┴─────┤ │
 │  │ R²=0.962     │ │
 │  └──────────────┘ │
 └──────────────────┘
```

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

The calibration curve can be entered or changed now manually. At least 2 value pairs are required 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.

Linearity of calibration:

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.

Invalid calibration data
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 A4 prepares and measures all of the required standard dilutions by itself and enters the mean values in the calibration curve.

```
        SETUP PT                         STANDARD VALUE:

 TEST:      PT                  1
 LOT:       123456789               STD1:      100 %
 EXP.:      01/2004             2   STD2:      0 %
 UNIT:      % + INR                 STD3:      0 %
 INCUB.:    0s                  3   STD4:      0 %
 RUNTIME:   120s                4   STD5:      0 %
 ENTRY:     AUTO                5   STD6:      0 %

 12:00   1055mL   H0     37.0°
```
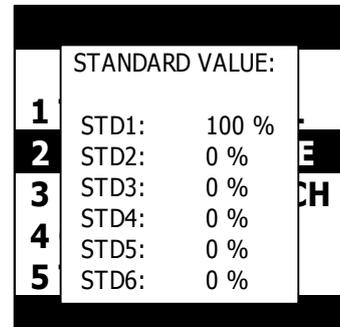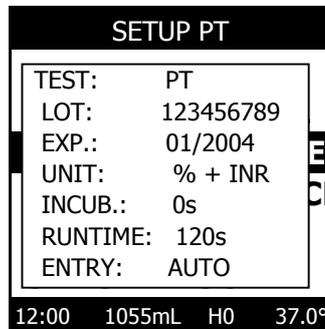
Select test and unit, set *ENTRY to Auto* and press ENTER.

• **Autocalibration with serial dilutions**

The dilutions are always prepared in following way:

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

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

```
        ANALYSE CURVE

      [  <-  ]    [ START ]

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


 12:00   1055mL   H0     37.0°C
```
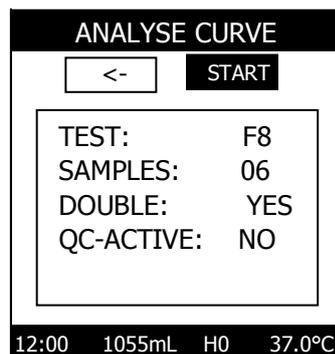
*6 standards are measured for factor VIII calibration. Therefore the calibrator must be placed in rack position 1and 5 other empty sample test tubes are required in rack positions 2-6, in which the **COATRON A4** then prepares the necessary dilutions.*

3. Additional empty sample test tubes are required in rack positions 2-6. The number of samples corresponds to the

number of sample test tubes and depends on the
particular test.
4. Select START, check the reagents and numbers of
cuvettes required in the screen SYSTEM PREPARATION
and initiate the measurement procedure with Enter.

- **Autocalibration with fixed levels**

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

SETUP PT				ANALYSE CURVE

	STANDARD VALUE:			<-	START
TEST: PT	1				
LOT: 123456789		STD1: 1.00 INR			
EXP.: 01/2004	2	STD2: 2.50 INR		TEST: PT	
UNIT: INR+	3	STD3: 4.00 INR		SAMPLES: 03	
INCUB.: 0s		STD4: 0.00 INR		DOUBLE: YES	
RUNTIME: 120s	4	STD5: 0.00 INR		QC-ACTIVE: NO	
ENTRY: AUTO	5	STD6: 0.00 INR			
12:00 1055mL H0 37.0°C				12:00 1055mL H0 37.0°C	
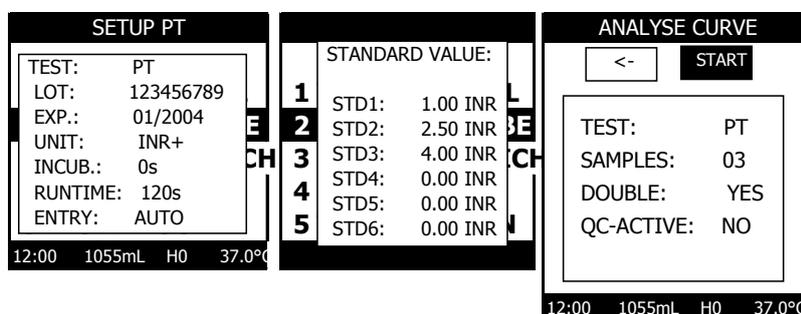
*3 fixed standard levels are measured for PT INR calibration. Place INR calibration
plasma STD1,2,3 into rack position P01,02 and 03.*

5.2.5   Submenu Normal Range

During a routine, a measurement result is flagged "A" (abnormal) if it is
outside the normal range. If the normal range is min=max=0, the results
are not checked.

Selection of the upper and lower limits of the normal range for the
selected tests is with ARROW ↑ / ARROW ↓. If the value is inverted, use
the numeric keypad to enter the new limit directly.
Leave the screen with Esc after all of the parameters to be changed have
been entered.
In response to the query SAVE DATA? use ARROW ← / ARROW → to
select either YES or NO and confirm with Enter.

5.2.6   Submenu QC Range

Indicates the measurement result range expected in a control
measurement. The range depends on the particular control plasma and
test. See the reagent sheet for the control range. If the measurement
result for a control is outside the QC range it will be flagged "Q." If the
QC range is min=max=0, the results are not checked.

5.2.7   Storing of test data

Press ESC to return to the main menu "TEST SETUP". If any data was changed, the COATRON A4 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 GMBH*
> - *The expiry date must be valid*

5.2.8   **Submenu Test Printout**

Prints out the selected parameters for this test

SETUP FIB **LOT: 302501299** **EXP: 1/2004** **LAST CHANGE: 03.04.2003** ――――――――――――――――― **1: 80 mg/dl - 27.0 s** **2: 120 mg/dl - 18.0 s** **3: 240 mg/dl - 12.0 s** **4: 480 mg/dl - 7.0 s** ――――――――――――――――― **R² = 0,992** **NORMAL RANGE: 0 - 0 mg/dl** **QC RANGE : 0 - 0 mg/dl** **S-CORR: 0%** **T-CORR: 0% 0s** **START: 4s** **INCUB.: 60s** **RUNTIME: 120s** **METHOD: COAG** **CT-MECH: NO** **SENS: 0** **MIX: 0** **CLEAN: 0** **DIL.: 1:10** **PAT: VOL= 10uL** **CP : VOL= 10uL POS=35** **BUF: VOL= 90uL** **R2 : VOL= 50uL POS=29**	 - expiry date - date of input - calibration values - Linearity of the calibration curve (1.000 for a straight line) (R² should be 0.850 – 1.000) ranges signal correction time correction deadtime incubation time max. runtime test method clottingtime mechanical test sensitivity reagent mixing high cleaning cycle plasma dilution - Sample volume in µl - Control plasma, amount and position - Buffer, amount and position - Start reagent, amount and position (here 10 µl sample + 90 Owren's buffer + 50 µl fibrinogen reagent)

5.2.9   **Submenu Test Overview**

Prints out the current protocols of all tests.

TEST	PAT	BUF	CLR	DEF	R1	R2
PT uL	50	0	0	0	0	100
POS	P35	P38	P00	P00	P00	P25
DFIB uL	50	0	0	0	0	100
POS	P35	P38	P00	P00	P00	P25
APTT uL	50	0	0	0	50	50
POS	P35	P38	P00	P00	P31	P26
…	…	…	…	…	…	…
…	…	…	…	…	…	…

example test protocol APTT:

> ➢ add 50µL sample (the control plasma position is P35)
> ➢ add 50µL aPTT reagent from P31
> ➢ add 50µL CaCl from P26

5.2.10   **Setup of test protocol**

This feature allows you to change or adapt new reagents or tests.

The test protocols are protected. They can be activated or modified by trained and authorized personel only.

Important:
Improper changing can lead to false results.
Please contact your local authorized distributor/agent, if there is a need to change the parameters.

TEST:	F8
UNIT:	3
METHOD:	COAG
MATH:	logXY
CT-MECH:	NO
START:	15s
POINTS:	6
SENS:	1
MIX:	0
CLEAN:	0
VALIDATE:	YES
S-CORR:	0%
T-CORR:	0%
	0s
MULTI	NO

PAT:	10uL
	P35
BUF:	40uL
	P38
CLR:	0uL
DP:	50uL
	P34
R0:	0uL
	P00
R1:	50uL
	P31
R2:	50uL
	P26

Screen 1 : test protocols   *Screen 2 : test protocols*

- ➢ NAME   4 Charakters for test
- ➢ UNITS   selectable units, decimal code of every bit.
                     (i.e. units=11-> s,%,INR
    - • Bit 0 = always (sec or E)
    - • Bit 1 = %
    - • Bit 2 = U
    - • Bit 3 = INR
    - • Bit 4 = RATIO
    - • Bit 5 = INR+
    - • Bit 6 = INR+%
    - • Bit 7 = -
    - • Bit 8 = mg/dL
    - • Bit 9 = g/L
    - • Bit 10 = IE/mL
    - • Bit 11 = mg/L
    - • Bit 12 = ug/mL
    - • Bit 13 = ng/mL
    - • Bit 14 = ug/L
    - • Bit 15 = IU/mL
- ➢ METHODE   COAG,FIB,CHROM,IMMUN
- ➢ MATH   XY-calibration relationship (lin,1/X,logY,logXY)
- ➢ CT-MECH Clotting Time Mechanical. Define clot point at 50% of endpoint
    - • YES: Clot at 50% signal
    - • NO: Clot at turnpoint of reaction (default)
- ➢ START   Time when measurements start (deadtime)
- ➢ POINTS   data points for auto calibration
- ➢ SENS   sensitivity of clotting test (Max=3 -> very sensitive)
- ➢ MIX   After adding of start reagent the robot will mix in the cuvette
- ➢ CLEAN   needle will be flushed with double Rinse solution
- ➢ VALIDATE   reagent must will be validated by barcode (eg. lot, expiry).
- ➢ S-CORR   signal correction (eg. Caculate FIB signal 10% higher)
- ➢ T-CORR %   time correction (eg. Calculate PT 10% shorter)
- ➢ T-CORR s time correction (eg. Calculate PT 2s shorter)
- ➢ Multi   allow sample multi dispensing to increase throughput.
- ➢ Vol Pat   Volume of patient in µL
- ➢ Pos CP   Position of Control plasma
- ➢ Vol Buffer   Volume of buffer
- ➢ Pos Buffer   Position of buffer
- ➢ Vol Clr   Clear Volume
- ➢ Vol DP   Volume of deficient plasma in µL
- ➢ Pos DP   Position of deficient plasma
- ➢ Vol R0   Volume of reagent 0
- ➢ Pos R0   Position of reagent 0
- ➢ Vol R1   Volume of reagent 1
- ➢ Pos R1   Position of reagent 1
- ➢ Vol R2   Volume of reagent 2 = Start reagent
- ➢ Pos R2   Position of reagent 2

Set volume and position to "0" if not required
Set volume and position to "0" if not required

Regard the impression of dispensor:
- Below 4µL: >15%
- At 5µL: 5%
- Above 10 µL: <1%

Concern the clear volume:

A minimum of 75µL must be left in the cuvette. Example instrument pipet 5µL sample and 195µL buffer into cuvette. Then a maximum of 125 µL plasmadilution can be cleared.

5.3 Main menu System Setup

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

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

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

5.3.1   Language

Select between:English - Italian - Spanish - German

5.3.2   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).

5.3.3   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).

5.3.4   Signal

Switches the acoustic signal on or off.
Possible settings:
  ➢ Signal on
  ➢ Signal off

5.3.5   Contrast

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

5.3.6   Mixer

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

5.3.7   Simulator

Facilitates simulation of measurement operation without moving the pipetting arm.

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

5.4 Main Menu SERVICE

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

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

5.4.1   System report

Printout of important system data

```
SYSTEM - REPORT


DATE: 2010/25/10  13:59

SYSTEM: COATRON A4
SERIAL NO.: 1234567
SOFTWARE: 01.06.01


OPTIC 1:  80 30005 (162)
OPTIC 2:  62 29984 (169)
OPTIC 3:  85 29766 (153)
OPTIC 4:  50 29793 (155)


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


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


CONTRAST: 225
MIXER: 200


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


RINSE INSTALLED: 108 ml
NEEDLE TIMER: 2300
SYRINGE TIMER: 32023
STOP-STOP IN: 905 TESTS
SERVICE IN 58001 TESTS


PT COUNTER: 10000
PTT COUNTER: 10000
FIB COUNTER:5000
TT COUNTER: 1000
DD COUNTER: 1000
ANALYSIS COUNTER: 27000


---- SYSTEM STATUS ---
SYSTEM = OPEN
SERVICE = CLOSE
REAGENT = OPEN
```

OPTICS : 80   30005 (162)
  80 = Digital value when LED is off
  30005 = Digital value when LED is on
  162 = Amplification factor

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

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

Display contrast
Reagent mixing speed

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

Remaining system liquid
Age of needle: number of performed tests
Age of syringe: number of up/down cycles
Remaining determination before system stop operation.

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

System do not require a barcode to run tests
System requires a barcode to reset service interval
System do not require a barcode before use of reagent

5.4.2   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

Ensure yourself, that the needle is straight and correct mounted 115mm in length. Place an empty reagent container to position P27, two empty cuvettes in the tower,an empty plasma tube to position P01 and an unused Sarstedt Monovette*®* or BD Vacutainer*®* in position P02. (only if CAP PIERCING option is required)

Five position must be adjusted
- Wash postion
- Reagent position
- Cuvette position
- Patient position
- Cap piercing height

optimum wash   optimum reagent   optimum patient   optimum piercing
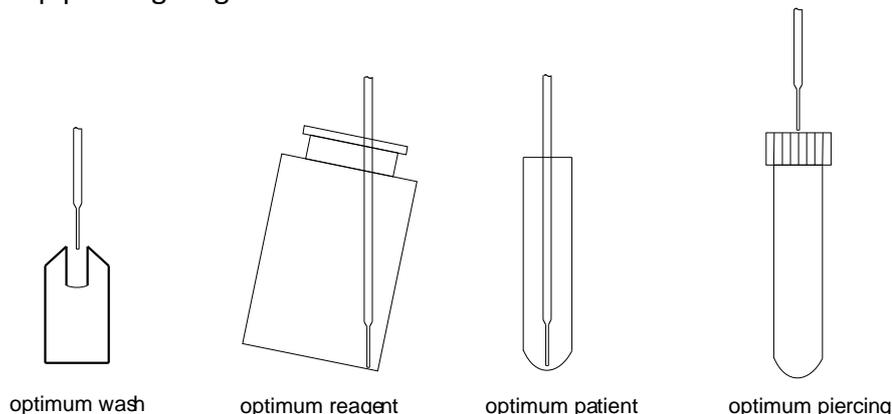
1. First the needle will go to wash position. Center the needle exaktly. The needle tip must be at same level with top of wash position. Press "ENTER" to come to next postion or press "ESC" to quit.

2. Second the needle will go to P27 position. 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. Third the needle will go to cuvette position. Center the needle and afterwards lower the needle until it is short before touching the cuvette. Lift the cuvette to determine the distance. Press "ENTER" to come to next postionen or press "ESC" to quit.

4. Forth the needle will go to P01 position. 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.

5. Fifth the needle will go to P02 position. Center the needle.The needle tip should be short before touching the cap membrane. Press "ENTER" to test cap piercing or press "ESC" to quit.

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

⚠️   **Important:**
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

5.4.3   Check Temperature

```
               WARTUNG
 1 DI┌─────────────────────┐
 2 J │                     │
 3 P │    TEMPERATUR CV     │■
 4 P │     (39) 39,2°C      │
 5 P │                     │
 6 B │    TEMPERATUR PT     │
 7 R │     (37) 37,0°C      │
 8 ERSETZE TANK────────────┘
 9 ERSETZE NADEL
10 ERSETZE SPRITZE
```
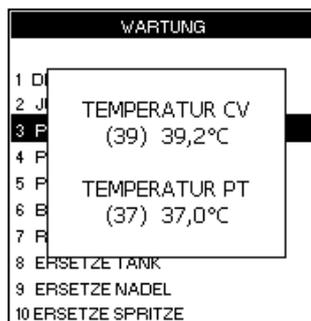
Temperature CV	Temperature around measurement cuvette.
Temperature PT	Temperature at reagent position PT (P25)
(xx)	Target temperature in degrees Celsius
xx,x	Current temperature

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 4 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. In the cuvette position the temperature should be in the range of +- 0.5°C from target value. Temperature can be increased or decrease by pressing ARROW ↓ / ↑ .
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.

5.4.4   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
T1=34302
T2=34429
CV-STATUS:  0
SHIELD:  0
```

X=	Measurement channel 1-4
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 temperature CV, Target range 33000 - 36000
T2	Digital value temperature PT, Target range 33500 – 36000
CV-STAT	0=no cuvette 1=if cuvette is detected.
Shield	0=closed 1 = open

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

5.4.5 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.

5.4.6 Move Cuvettes

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

5.4.7 Clean Needle

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

5.4.8 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.
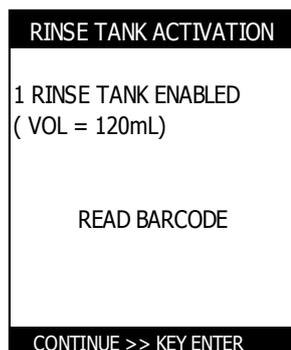
The current numbers of remaining Rinse tanks and installed volume of Rinse solution is displayed.
1. Remove the waste tank r and dispose it according to regulations for infectious material
2. Replace the empty rinsing tank with a full one. Ensure that the tube is insert completely into the tank.
3. Use 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.

☞	Make sure a full tank is really installed, since otherwise the COATRON A4 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®.

5.4.9   Replace Needle

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

1. Switch off instrument
2. Drive needle manually into wash position and open the tube fitting on valve.
3. Wait until needle is complete empty from Rinse solution. Clean and dry needle outside, to avoid any liquid contamination with the insulation block.
4. Loosen the screw (see figure below)and remove the needle
5. Insert new needle until 115mm is visible and tighten the screw
6. Screw thetube fittings to the left valve channel and tighten only by finger
7. Switch on instrument and and run menu "SERVICE\REPLACE NEEDLE"
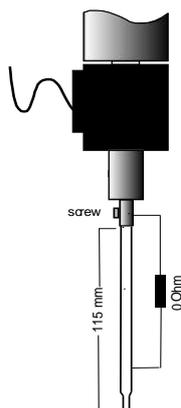
Figure 10: Replace Needle

| ☝ | *Any liquid contamination of the insulation block with the needle may malfunction the level sensoring.* |

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

5.4.10   Replace Syringe

Resets the operating time counter of the syringe to zero. This operation must be carried out when the COATRON A4 is when the syringe is replaced.

1. Switch off instrument

2. Lower the plunger drive manually by pushing down on the carriage assembly until it reaches the bottom of travel.

3. Now open the syringe and remove it.

4. Insert the new syringe and tighten just with your fingers

5. Switch on instrument and and run menu "SERVICE\REPLACE SYRINGE"
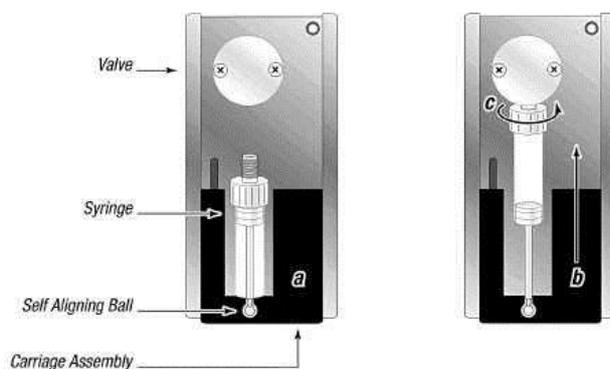
Figure 11: Installation of syringe

5.4.11   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 „4" . An increase of the offset will shift the cuvette to the left.

Important:
False adjustment will reduce the measuring precision.

5.4.12   Cap Piercing

Fill a Sarstedt Monovette® or BD Vacutainer® or a simular system with 2mL water. Close the cap and place it into rack position P02.
Lower the needle until it is just before touching the cap. Then center the needle to the cap.
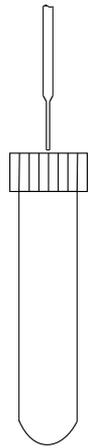
⇨ use keys 4/6 or 2/8 or Up/Down to move needle
⇨ confirm with Enter to check cap piercing
⇨ confirm with ESC to exit adjustment

optimum piercing

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

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

Warning!
The system may damaged, if no needle protection is mounted.

Cap piercing requires also a special needle, which is designed for it. Asked your local distributor for further information.

5.5   **Main menu PIPET STATION**

Menu to reconstitute reagent and controls

```
┌─────────────────────────────┐
│        PIPET STATION        │
├─────────────────────────────┤
│                             │
│  IN:            P26         │
│  OUT:           P25         │
│  TOTAL:         0 ul        │
│                             │
│  VOL (uL):      1000        │
│                             │
│  PIPET >> KEY ENTER         │
│  ABORT >> KEY ESC           │
└─────────────────────────────┘
```

Fill enough diluent into container and place it to position P26. Open reagent vial and place it to position P25. 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.

6. Replacement of consumables

6.1 Disposal

⚠️ **Warning!**
The full liquid waste tank and used cuvette 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®.

6.2 Refill cuvettes

☞ **Cuvette trays are disposable articles, reuse is not permissible for reasons related to hygiene and measurement technology!**
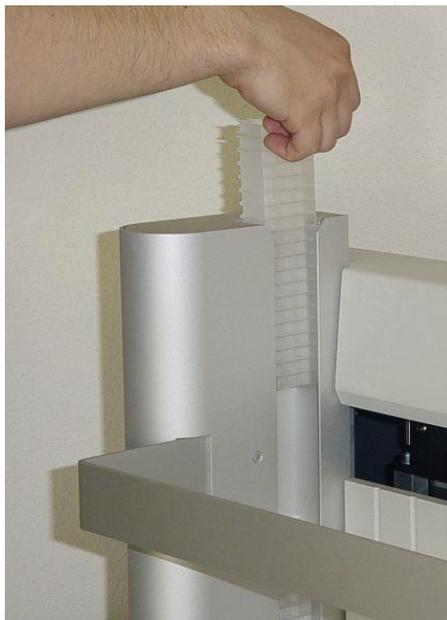
1. Remove a row of cuvettes from the package

2. Hold the row by the tape and insert the cuvettes as shown, from above and with the guide groove to the rear, into the cuvette tower.

3. Pull the tape off the cuvettes

Figure 12: Refill cuvettes

6.3 Replace Rinse tank

Follow instruction from chapter 5.4.8

6.4 Replenishing the printer paper

Figure 13: Printer cover
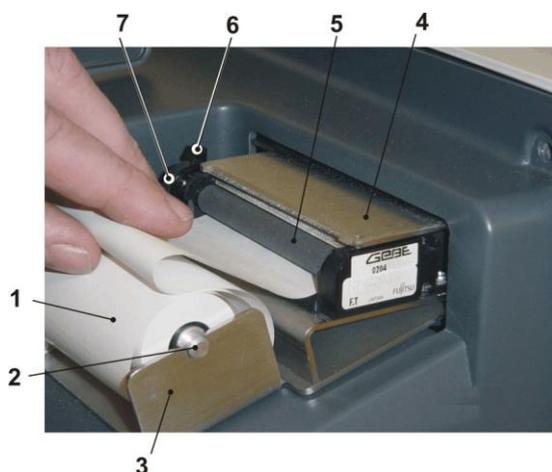
Figure 14: Replenishing the printer paper

1. Open the printer cover as shown at the back of the housing.
2. Remove the printer shaft from the mount (3).
3. Pull the empty printer paper roll off the printer shaft
4. Insert the printer shaft 2) through the new printing paper roll (1) and place the printer shaft on the mounts as shown (3), so that the paper is pulled into the rubber roller (5) from below.
5. Move the arresting lever (6) in the direction of the back wall of the housing to release it.
6. As shown, insert the printer paper under the rubber roller and turn the transport wheel (7) to the left until the printer paper sticks out of the gap between the rubber roller and the metal cover (6) by about 5 cm.
7. Secure the arresting lever 6) by moving it towards the front of the housing.
8. Hold the printer paper towards the front of the housing and close the cover.

7.   Cleaning and maintenance

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

7.1   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.

7.2   Cleaning

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

7.3   Decontamination

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

7.4   Daily activities

- Clean and wipe up all spills around the working area or needle pump system

with a 10% diluted bleach.
- Inspect level of Rinse and waste container
- Empty cuvette drawer and fill tower
- Inspect tube system for any leaks and correct immediately

7.5   Weekly activities

- Decontaminate system with bleach and ethanol as described above

7.6   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
  -

7.7   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)

7.8   Reset Service Interval

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

7.9   Error messages

Error message	Possible cause	Action
Service	Service interval is expired after 100.000 tests	Service instrument and reset interval with barcode certificate.
Replace Rinse tank	Rinsing solution tank empty	Replace rinsing solution tank (*chap. 6.1*)
Error pump	Needle clogged	Check needle and tube system
Error robot (system error 2-28)	No connection to pipetting arm	Consult the customer service of your dealer
	Needle crash	Reboot the system
Activate System	System interval is expired	Scan barcode "Test Activation Key"
Activate Reagent	Reagent mut be validated	Refill cuvettes (*chap. 6.3*)
Adjust XYZ	Replacement of needle	XYZ adjustment of pipetting arm (*chap. 5.4.2*)
Adjust Motor	Replacement of main-board or software update	adjustment of cuvette (*chap. 5.4.11*)
No liquid	No liquid in current position of pipetting needle	Refill liquid at current needle position.
	Z-offset false	XYZ adjustment of pipetting arm (*chap. 5.4.2*)
Check printer	No printer paper	Replenish printer paper (*chap. 6.7*)
	Arresting lever in offline position	Change arresting lever position (*chap. 6.7*)
	No printer connected	Consult customer service
Check temperature	Temperature in system block too high or too low	Check temperature and adjust (*chap. 5.4.2*)
Clean needle	Pipetting needle was replaced	Carry out needle cleaning cycle (*chap. 5.4.7*)
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.

8.   Elimination of malfunctions

8.1   Device malfunctions

Malfunction / Error	Possible cause	Measures
No print on printout	Paper installed in wrong position	Turn paper roll around (*chap. 6.7*)
Needle does not pipette	Tube system leaky	Replace the tube system
	Needle clogged	Place the needle in COATRON A4 Cleaner for 30 min, then run the wash cycle.
Poor reproducibility	Needle-tube system	Replace the needle, tube system and syringe.
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (*chap. 5.4.11*)
Cuvette assumes false position	Wrong cuvette	Use only original COATRON A4 cuvettes
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (*chap. 5.4.11*)
	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

8.2   Measurement malfunctions

Malfunction / Error	Possible cause	Measures
Control measurements do not supply expected results	False calibration data	Consult customer service of your dealer
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (*chap. 5.4.11*)
False measurement results	Reagent	Check TEST SETUP
	Temperature	Check temperature (chap. 5.4.3)
	Optics	Check optics (chap. 5.4.4.)
	Motor is not adjusted	Check the adjustment of the cuvette to the optic (*chap. 5.4.11*)
Results flagged "*"	Result outside calibration range	
Flagged "A"	Result outside normal range	
Flagged "T"	Temperature outside 36 – 38°C range	
Flagged "E"	Reagent is expired	
Flagged "Q"	Quality control outside control range	
Flagged "S"	Enviremont light too bright (low >750digits)	Avoid direct sunlight or other UV sources
Flagged "F" (only test PT)	Low fibrinogen.	Run test FIB to confirm.
Flagged "R"	Result repeated. Max. Runtime too short or problems with level sensor	
Flagged "!" (only test DD)	Result not trustful.	Dilute sample and repeat.
Flagged "X"	Double values deviate by more than 15%	
Flagged "+++"	No coagulation seen with measurement time	
Flagged "???"	Coagulation time indeterminate; course of reaction does not correspond to the criteria of the evaluation algorithm (e.g. turbidity due to air bubbles or coagulation begins before dead time)	
Flagged "SSS"	Low signal. Light transmission is not enough.	Check optics (chap. 5.4.4)
Flagged "K"	Sample, Test is skipped because out of reagent.	

8.3   Packing the COATRON A4 for shipment

If the COATRON A4 is to be shipped, e.g. to the Technical Service, please include the following information in an accompanying letter:

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

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

Preparation of the Analyzer for transport:

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

9.   Appendix

9.1   Interface to LIS

The instrument support two serial RS232 ports to connect with laboratory information system (LIS) .
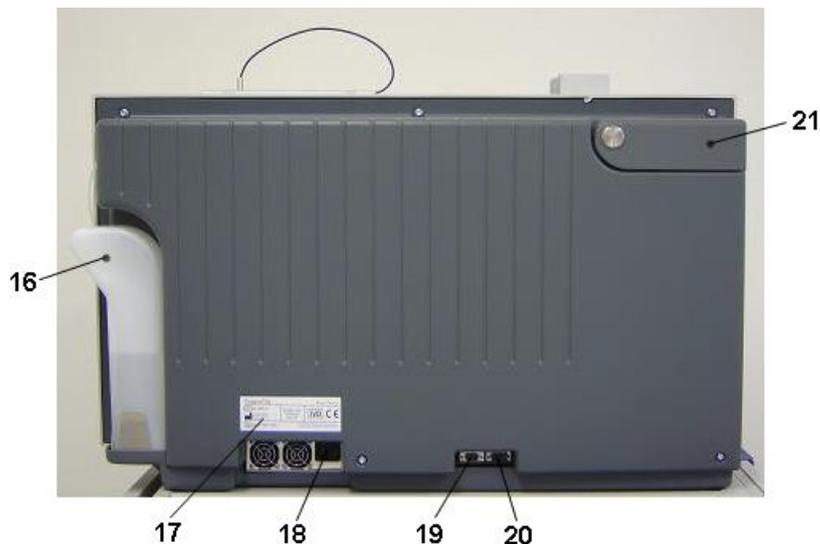
9.1.1   Bidirectional communication with TECAM software

TECAM software is a perfect and user friendly tool to combine laboratory data management, quality control and research purpose in one. The worklist management allows defining orders much faster and flexible then on the instrument itself. Powerful filter functions will help to create any report. Levey-Jennings graph and Westgard analysis are used for quality control monitoring. An ASTM interface is included, which allows to link with the laboratory information system (LIMS) over LAN network or RS232. The TECAM database can be saved central on a server and accessed simultanously. This will allow to unify different Coatron analyser into one database.

Interface: 115200 Baud , no parity , 8 bit . 1 stop bit

Instrument port: location "19" – see picture above

Cable: 2x Female Sub D9, crosslink. Pin 2 to 3 ; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected

⇨   *Contact your local distributor for further information about TECAM software.*

9.1.2   Unidirectional communication

Interface:	115200 Baud , no parity , 8 bit . 1 stop bit
Instrument port:	location "20" – see page 7
Cable:	2x Female Sub D9, crosslink. Pin 2 to 3 ; Pin 3 to 2 and Pin 5 to 5. All other wires should be disconnected
Handshake:	No
Establishing:	Not required. The instrument sends results information automatically
Protocol & syntax:	TECAM V5.30

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

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

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

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

9.2   Technical data

Analyzer	
Measurement system	4 independent measurement channels wavelength of LED 400 nm
Measurement timer	Max. 600 s, error < 0.1 s
Cuvette	4 channel cuvette for optical detection capacity: 150 – 1000 µl
Calibration	Automatic calibration or manual input of up to a max. of 6 calibration curve points for each test method
Positions	4 reagent positions at 36.5 – 37.5 °C 2 reagent positions at RT (~25°C) 6 reagent positions at 12.0 – 16.0°C 3 park positions, preheating (33-38°C) 2x12 sampe primary tubes 1 emergency STAT positions
Reaction volumes	Minimum total volume is 150 µl
Approvals	CE

XYZ Robotics	
Movement	X = 383mm, 1714 steps, v = 894mm/s Y = 150mm, 1054 steps, v = 569mm/s Z = 167mm, 3400 steps, v = 181mm/s
Level Sensor	Yes , capacity change detection with Aldium sensor
Neddle	-Capacity for 4880 µL -Inner hydrophob cermamic coating -Livetime for 50000 determination
pump	1000 µl syringe with 1000 step resolution Lifetime of syringe is 250.000 cycles
imprecision	15% at 3µL 5% at 5µL 1% > 10µl

Barcode scanner	
	Laserclass 2 – EN60825-1:2007
	max. power = 1.7 mW
	pulse period = 420 µs
	wavelength = 655 nm
Accepted codec	Code 39, Codabar, Interleaved 2 of 5, Code 128 , EAN 128 and Code 93

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

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

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

Noise output	
Operating noise	max. 65 dBA

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

Specimen Collection

analyte	Fresh or frozen human plasma; Use within 4 hours
centrifugation	1500g x 10-15 min
anticoagulant	Sodium citrate 3.2% (0.105M)
	Mix 1 part citrate with 9 part venous blood
max. bilirubin concentration	25 mg/dL
max. hemoglobin concentration	1000 mg/L
max. triglyceride concentration	25 g/L

Typical performance data at system speed = high

Test	CV.	Range	Throughput
PT	<3%	0-30INR	108/h
APTT	<3%	15 – 420s	59/h
FIB	<7%	50-999mg/dL	65/h

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

9.3 Declaration of Conformity

TECO $C\epsilon$

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Wir / We

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

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

Coatron A4

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

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

Ort und Datum der Unterzeichnung: Place and date of issue:	Neufahrn, 25.03.2014 Neufahrn, March 25th, 2014	Gültig bis 01.04.2015 Valid until April 1st, 2015

Christian Hötzl
General Manager

9.4 Disposal and recycling

Please comply with the following points when disposing of the COATRON A4:
- The housing is made of polystyrene.
- The mechanical parts are mainly aluminium.
- Electronic parts must be disposed of in accordance with currently valid regulations for their disposal.

Important!
You must disinfect the COATRON A4 prior to disposal to prevent cases of infection at the disposal company!

9.5 Barcode Guideline
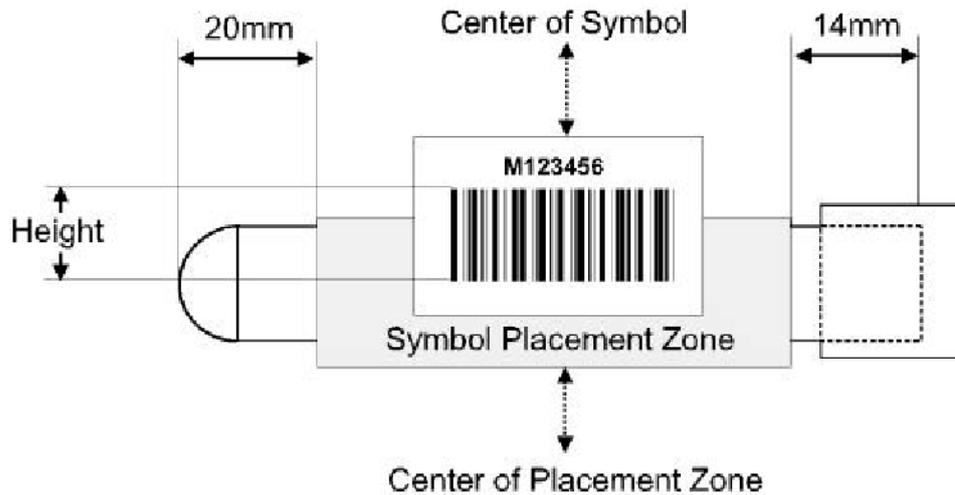
Specification of label:

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

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