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1 General Information

1.0 Introduction

This manual contains the procedures to operate, maintain and troubleshoot the ACL System.

Personnel responsible for operating and maintaining the instrument should read and understand the included material prior to use. This manual should be kept near the instrument or in a suitable location for reference as required.

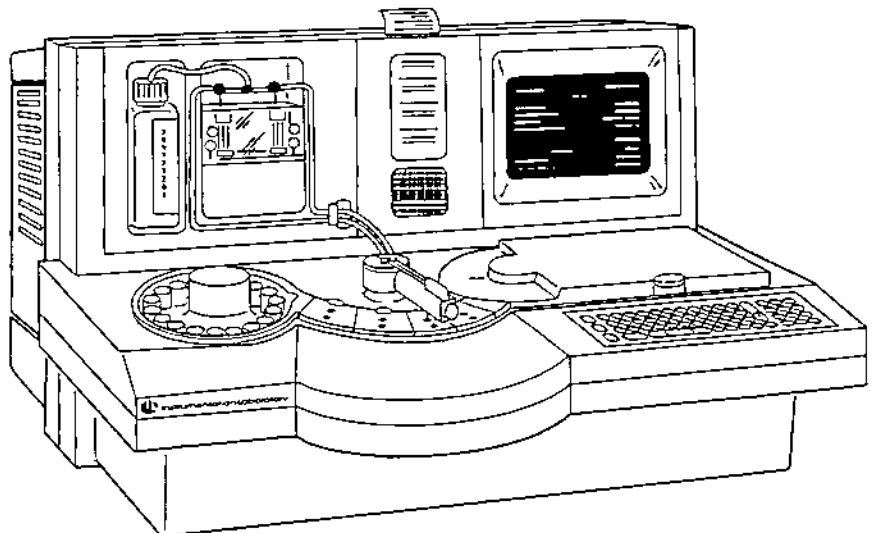
This section includes a general description of the Instrumentation Laboratory ACL. Covered material includes product use, methodology, additional features and procedural limitations.

1.1 Product Use

Instrumentation Laboratory's ACL System is a fully automated, high productivity analyzer for specific clinical use in coagulation and/or fibrinolysis testing.

Results include both direct hemostatic measurements and calculated parameters.

ACL System: Front View



1.2 Measured Parameters

The ACL system is capable of performing the following tests:

Note: An asterix () indicates that a test is not currently available in the United States.*

Coagulimetric Tests

- PT-FIB (Prothrombin Time and Fibrinogen Level)
- APTT (Activated Partial Thromboplastin Time)
- PT-FIB/APTT (three tests run simultaneously)
- TT (Thrombin Time)
- TT/APTT (two tests run simultaneously)
- Single Factors (VII, X, V, II, XII, XI, IX, VIII: high curve and low curve factor assays: simultaneous calibration and sample analysis).

Double Tests

A double test facility for PT-FIB, APTT, TT and PT-FIB/APTT is also provided.

Absorbance Tests

- Antithrombin III
- Heparin Xa
- Heparin (high curve and low curve)
- α -2-Antiplasmin
- Plasminogen
- Fibrinogen - C
- Pro - Chrom
- D-Dimer

Special Tests

- Pro - IL - Complex*
- Hepatocomplex*
- ProClot
- Protein - S
- APCR-V

Profiles

It is also possible to run the following profiles on a random access basis:

- PT-FIB/APTT
- PT-FIB/APTT/TT
- PT-FIB/FIB-C

- APTT/FIB-C
- TT/FIB-C
- HPX*/PCX*
- PCX*/APTT/TT*
- HPX*/APTT/TT*
- PCX*/FIB-C*
- HPX*/FIB-C*

* Not available in the US.

1.3 Expression of Results

The ACL system displays and prints results in:

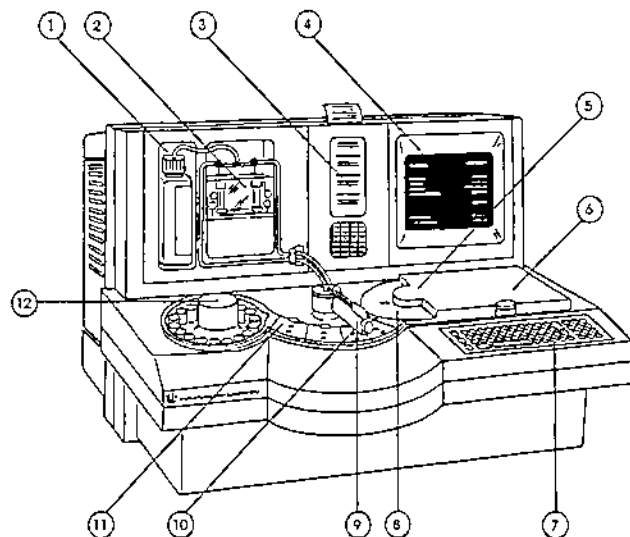
- s (seconds)
- R (ratio)
- INR (International Normalized Ratio)
- % (percent activity)
- U/mL (units/mL)
- mg/dL or g/L (Fibrinogen level)
- ng/mL (D-Dimer)

The ACL measures the parameters at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ ($98.6^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$) at an ambient temperature from 15°C to 32°C (59°F to 89°F).

At a constant ambient temperature, the ACL measures the parameters at $37^{\circ}\text{C} \pm 0.25^{\circ}\text{C}$.

ACL System: Components Description

1. Reference Emulsion
2. Dilutor
3. Internal Printer
4. VDU
5. Cover
6. Rotor Compartment
7. Keyboard
8. Rotor Housing
9. Sampling Arm
10. Rinse Reservoir
11. Reagent Reservoirs
12. Sample Tray



1.4 Instrument Description

The ACL is a fully automatic microcomputer-controlled, microcentrifugal analyzer. The ACL™ system incorporates a video display unit (VDU) that continually displays the status of the instrument and gives instructions on how to proceed. Instructions are entered into the ACL system via a membrane keyboard. When a sampling cycle is initiated, the samples and reagents are sequentially pipetted into a 20 polystyrene (loading). Sample and reagents are mixed via centrifugal force (rapid acceleration and braking to blend reaction mixture). Measurements are made while the rotor is spinning (acquisition). In batch mode the results are displayed on the VDU and printed by the thermal printer. The ACL performs an automatic calibration, offers a series of utility programs for the operator and is capable of carrying out a system precision quality assurance program.

1.4.1 Principal Components

The instrument is composed of the following functional parts:

- body structure
- sample tray (for cups and primary tubes)
- reagent reservoir group (macro and micro reservoirs)
- waste system
- sampling/dispensing system
- needle carrying arm assembly
- sensors
- rotor housing/measuring chamber
- rotor compartment
- optical measuring system (clotting and chromogenic)
- microprocessor and electronics
- thermal printer
- video display unit (VDU)
- keyboard
- RS232C interface
- internal cooling system
- bar code reader

Sample Tray

The autosampler uses a rotating sample tray with 20 positions each of 14.2 mm diameter (for sample cups of 14 mm and primary tubes of 13 x 75 mm).

Optical sensors confirm that the plate is positioned and centralized correctly. The optical sensor also detects the presence of cups/primary tubes.

Empty position (no cup/primary tube) will stop the loading operation of the instrument to maximize saving of rotor cuvettes.

The ACL is provided with two sample trays (type 1 and 2) according to the different kind of primary tube used.

1. Sample tray for cups (0.5, 2 or 4 mL) and primary tubes (13 mm x 75 mm) with a total filling volume of **5 mL**.
2. Sample tray for cups (0.5, 2 or 4 mL) and primary tubes (13 mm x 75 mm) with a total filling volume of **3.5 mL**.

Glass Volume	Anticoagulant Volume	Drawn Blood Volume	Total
13 x 75 mm	0.5 mL	4.5 mL	5 mL
13 x 75 mm	0.35 mL	3.15 mL	3.5 mL

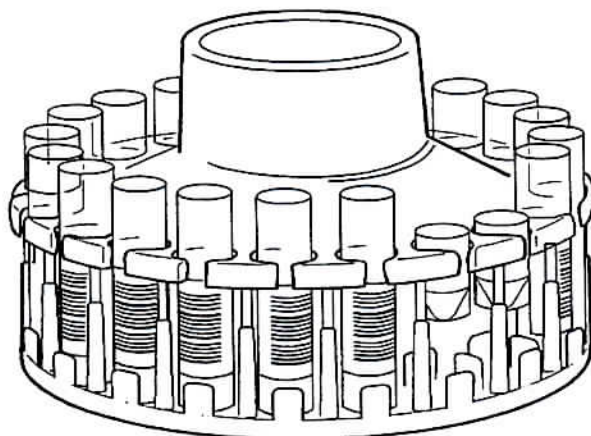
Dimensions and volumes indicated above have to be considered nominal values.

In general, a sample cup is loaded with calibration plasma (normal pool) in the pool position. In addition to the pool, IL diluent (sample or factor) is loaded in the DIL position to perform calibration procedures.

Reagent Reservoirs

This group consists of three reservoirs marked by their respective numbers of which two (Positions 1 and 2) are cooled to about 15°C by means of a Peltier effect regulator and agitated by magnetic stir bars (macro only).

Sample Tray



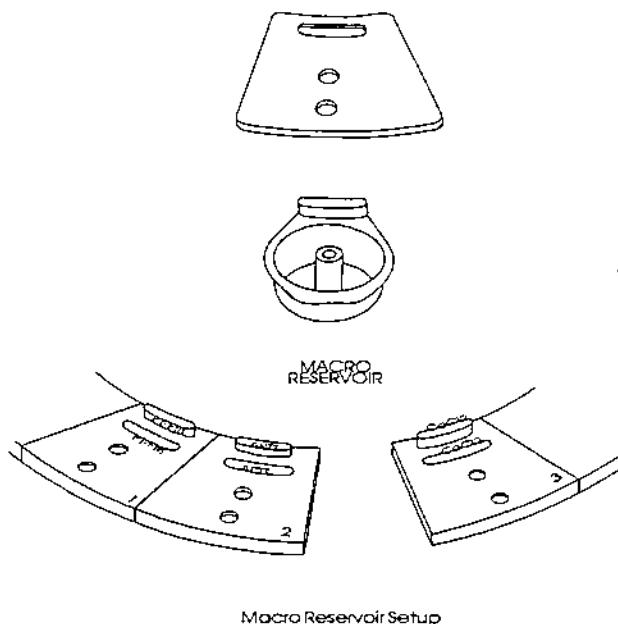
The reagent cups are of two types:

Macro, with a capacity of 10 mL

Reservoir #	Reservoir Name	Test
1	PT/FIB	PT/FIB Single Factors Extrinsic Pathway
1	PCX-HPX *	Pro-IL-Complex / Hepatocomplex
2	APTT	APTT Single Factors Intrinsic Pathway ProClot
3	CaCl ₂	APTT Single Factors Intrinsic Pathway ProClot
3	TT/CLEAN	TT or CLEAN (alternative reservoirs for Profiles)

* Not currently available in the US.

Macro Reservoir



Micro 1 with a capacity of 2.5 mL; 2 and 3 with a capacity of 2 mL

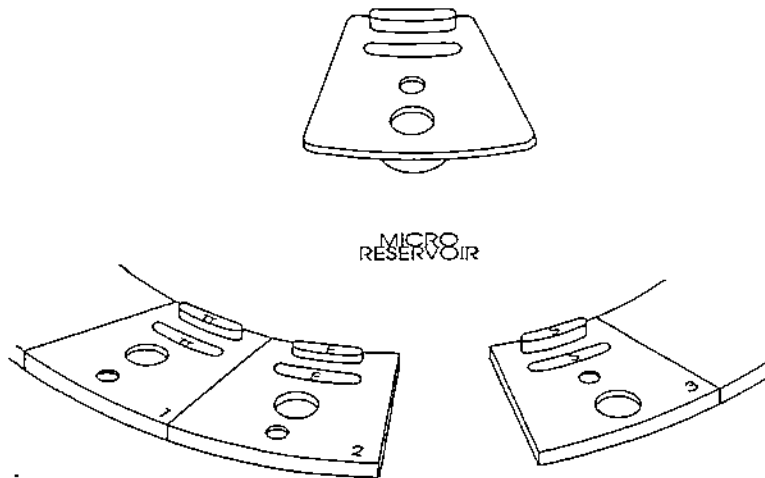
Reservoir #	Reservoir Name	Test
1	TT / PT - FIB	Thrombin Time / PT-FIB
2	E / APTT	Enzyme for Chromogenic Tests APTT
3	S / CaCl ₂	Substrate for Chromogenic Tests CaCl ₂

The waste/rinse cup is positioned between reservoirs 2 and 3. This cup is removable for cleaning.

Waste/Rinse System

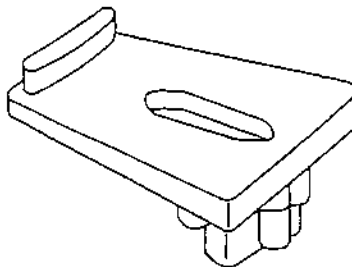
The ACL™ is provided with a waste/rinse system which internally connects the housing of the waste/rinse cup with an exit on the right side of the instrument by means of a plastic tube.

Micro Reservoir



Micro Reservoir Setup

Waste/Rinse System



Sampling / Dispensing System

The system consists of the following parts:

a. Reference Emulsion bottle

This is a plastic bottle containing 500 mL of silicon emulsion which is employed as a rinse solution and as the optical reference for the nephelometric channel.

b. Piston block

This is an acrylic block with two cylinders each of which has a stainless steel piston.

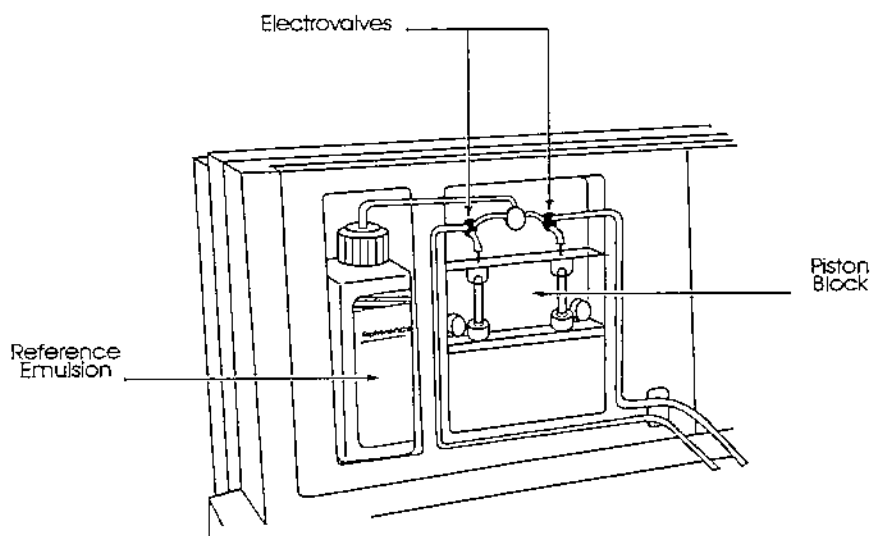
c. Electrovalve

Two electrovalves are housed above the acrylic block, one for each piston. They are controlled electronically and connect the pistons to the reference emulsion bottle and the two needles mounted on the autosampling arm.

Needle Carrying Arm Assembly

The two needles, one for the sample (S) and one for the reagent (R), are mounted on the distal end of an arm which moves radially by means of a stepping motor. The needle arm also moves in the vertical plane by means of a worm screw, driven by another stepping motor. The combination of these two movements permits the execution of the following operations:

Sampling / Dispensing System



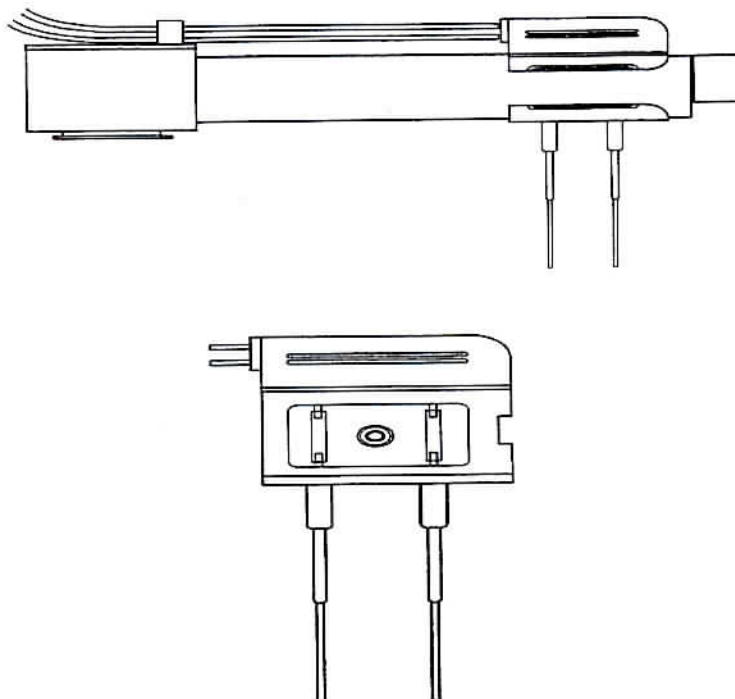
1. Aspiration of the sample (S) and/or reagent (R) from their respective positions.
2. Filling of the rotor with sample and reagent in the internal and external holes in the rotor cuvette.
3. Washing of the needles in the constant level waste/rinse station between reagent cups 2 and 3.

Two fluidic sensors are contained in the needle block to detect sample/s and reagent/s presence.

Sensors

The liquid sensors are integrated in the ACL by operating them in the analytical cycles without reducing throughput of the system. The fluid sensing cycle is executed during incubation and before the acquisition cycles. For some analytical cycles (i.e. PT, APTT, TT, FIB-C, PCX, HPX), the control is done in-line during the loading phase.

Sampling Arm with Sensor



The liquid sensors control the presence of:

- flush (reference emulsion)
- samples in the sample tray (pool, patient samples, deficient plasma, diluent)
- reagents (in reagent reservoirs)

The philosophy is to provide results with a general warning in case of sensor failure and absence of liquid (no reagent) in the reservoirs (reagents, flush) and to indicate "no sample" for a specific cup in the sample tray without liquid.

If all cuvettes in the sample tray are empty, the cycle will be aborted (after the final self check). No other warnings appear on the video nor on the printer.

The sequence performed during a cycle is as follows:

- a. self check
- b. liquid test
- c. flushing (450 μ L)
- d. final sensor self check
- e. indications about lack of reagents on the VDU

The liquid sensors are checked each time an analytical cycle is entered. Any warning of **SENSOR FAIL** or **NO REAGENT** will:

- disappear at the beginning of the loading phase
- appear during incubation/acquisition in case of selfcheck error or absence of reagents
- remain up to the next loading phase in the following cycle.

An error during the initial self check terminates the sensor test, but the analytical cycle continues. Test results will be presented along with a warning in the status line indicating the sensor failure. No indications will be given about the absence of samples and/or reagents.

The operator can view the warning condition by pressing the PROG key and selecting the WARNING option. An equivalent message will be printed out with the results.

Note:

Liquid quantity aspirated for sensor check on samples and reagents is 14 μ L.

Measuring Chamber

The measuring chamber is located under the cover on the right top side of the instrument. It consists of the following sections:

a. Rotor holder

The rotor holder in the measuring chamber is an aluminium disk thermostatically controlled to a temperature of $38.5 \pm 0.5^\circ\text{C}$ to guarantee 37°C inside the cuvette.

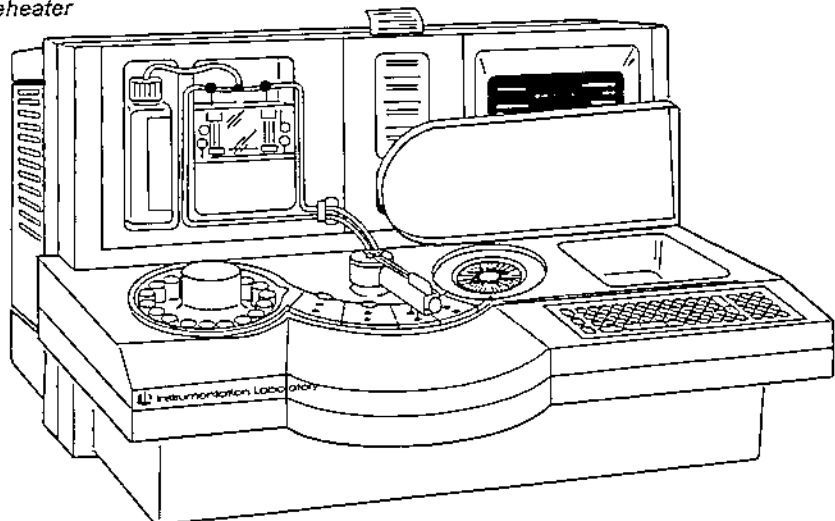
The 20 (position) cuvette rotors are mounted on the shaft of a stepping motor which is piloted by a bipolar-chopper circuit. The system, with the associated decoding disk, turns the rotor and controls positioning during the filling and measuring stages.

- The normal pool or calibration plasma is dispensed into cuvette 20 of the rotor when a clean rotor is used.
- The flush/optic reference emulsion taken from the 500 mL bottle housed in the instrument is usually dispensed into cuvette 19 of the rotor.
- The remaining 18 rotor cuvettes (1-18) are filled with samples and reagents.
- Therefore, 18 is the maximum number of samples that can be analyzed simultaneously for each rotor and cycle (PT/FIB or APTT) in single test mode.

b. Rotor preheater

The preheater holds up to ten rotors. The preheated rotor compartment is molded into the working surface and permits easy removal of the disposable rotor for analyses. The rotor preheater is thermostatically controlled at $36\text{--}39^\circ\text{C}$. The rotor support and the preheater are covered to maintain thermoregulation.

Rotor Holder and Rotor Preheater



c. Optical Measuring System

The measuring chamber also contains the optical paths for the two channels: (1) nephelometric and (2) chromogenic.

1. Nephelometric Channel

The light source is a light emitting diode (LED) with a life longer than 100000 hours.

The light is directed to the measuring cuvettes of the rotor by means of an optic fiber system ($\lambda = 660 \text{ nm}$). The scattered light is read at 90° with respect to the incident source by means of a solid state detector located below the rotor holder.

2. Chromogenic Channel

The light source is a halogen lamp, from which the radiation is directed to the cuvettes of the rotor via a quartz optic fiber and a focusing system.

The selection of the wavelength for analysis is effected by a narrow band interference filter centered at $\lambda = 405 \text{ nm}$. The optical detector is mounted in the cover of the measuring chamber. Therefore, readings are made at a 180° angle from the light source.

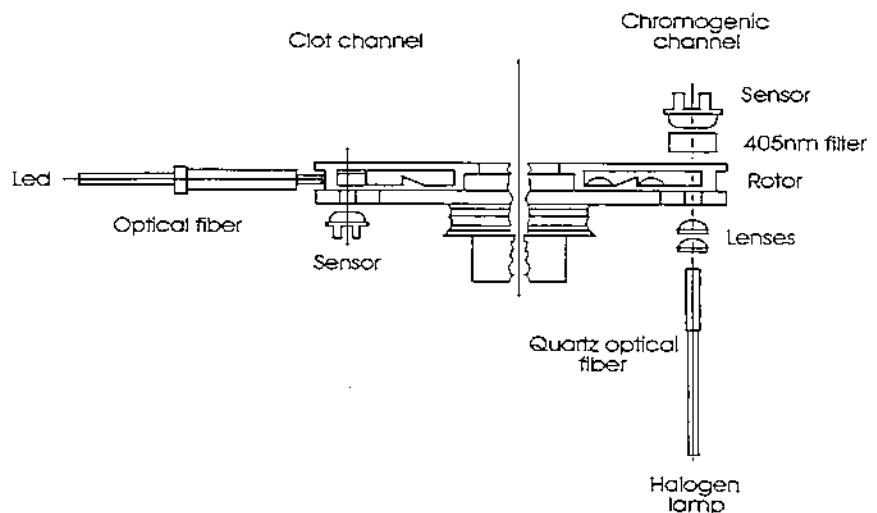
The optical path width for the chromogenic channel is 0,5 cm.

A removable cover on the right side of the instrument allows the operator to easily substitute the halogen lamp.

Microprocessor and Electronics

This section of the instrument is built around three Intel microprocessors. These microprocessors drive all events in the equipment, mechanical movements, aspiration and dispensing of samples and fluids, acquisition and processing of data and operator interface with input (keyboard) and output (video/printer) devices.

Clot and Chromogenic Detection System



The electronics consist of six printed circuit boards contained in a frame mounted on the rear of the front panel. Three boards are assigned to the microprocessor and logic sections while the other three are used for the interface modules and the various activation controls. These circuits and the subassemblies of the instruments are supplied by a switch mode power supply directly connected to the main power.

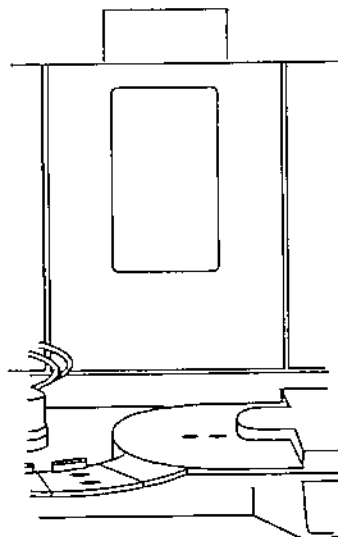
Internal Printer

This is a thermal printer with 150 print dots on a 72 mm wide strip. A maximum of 21 characters per line is allowed in either the graphic or column mode.

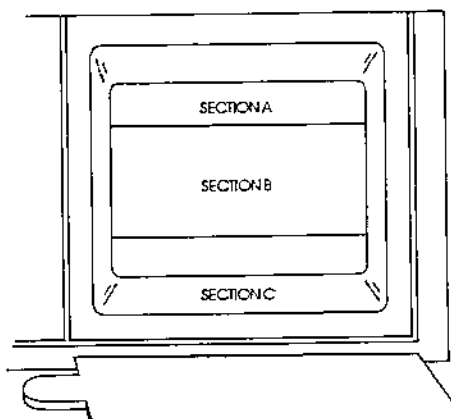
Video Display Unit (VDU)

This module consists of a command circuit and a 9 inch cathode ray tube (CRT). It guides the operator during the analytical cycle procedures and displays calibration data and patient results. It can also be used to display calibration curves.

Thermal Printer



Video Display Unit (VDU)



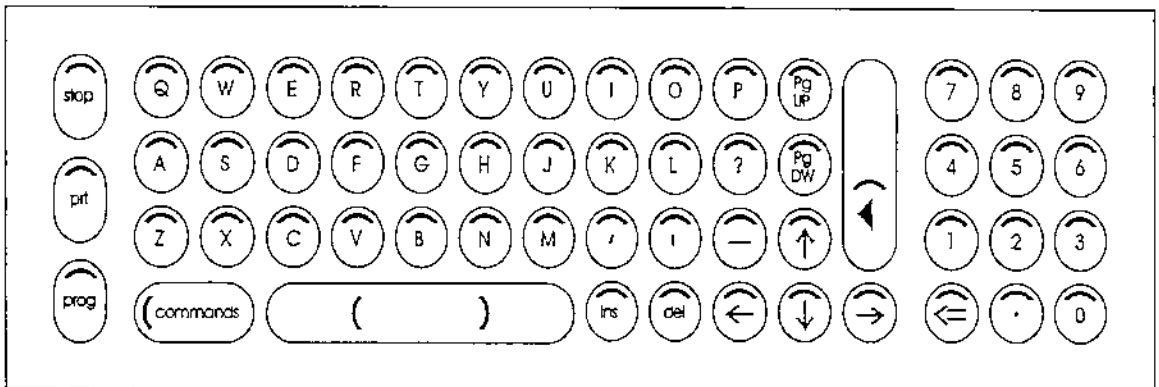
It is a split screen system that produces both white on black (normal format) and black on white (reverse format) alphanumeric displays. The upper section (A) displays the status of the instrument and each alarm. The central section (B) displays menus, results, graph plots and instructional guidelines. The lower section (C) displays the operational instructions.

Keyboard

The keyboard with 56 membrane keys makes it possible to enter the various operating modes of the instrument. The panel is spill proof. The keys are divided into four principal groups:

1. Operative (7 keys)
2. Decisional (7 keys)
3. Numerical (11 keys)
4. alpha-numeric (31 keys)

Keyboard



Operative Keys

STOP Will abort all cycles immediately, if confirmed by pressing the **ENTER** key within 5 seconds.

If **STOP** is activated when the instrument is in the PROG menu (PROG), it will return to the main menu or to a cycle in progress.

DO NOT OPEN COVER	24.JULY.92
PT-FIB [E]	12:00
LOADING	
PLEASE WAIT	
↑ to return ENTER to confirm STOP	

If the **STOP** key is activated and confirmed with **ENTER**, it will cause the cycle to abort. The messages "remove rotor" and "ENTER to continue" appear on the VDU.

PT-FIB [E]	24.JULY96
	12:00
CYCLE ABORTED STOP REQUESTED	
↓ to continue	

Upon pressing **ENTER**, the test menu will be presented.

If the operator does not confirm the stop command within 5 seconds by pressing **ENTER**, the instrument will proceed normally.

PRT This key is used to print out via the internal printer under the following conditions:

- When the VDU displays PRT, the operator may print calibration (CAL) and Q.C. data if available, or sample data if automatic printout has not been selected.
- A copy of the last data generated can be reprinted while the information is still in the instrument memory, in the results screen or in the "ready" state.

Notes:

PRT can always be used except during test cycles.

The grey paper advance key is located on the lower right side of the printer cover and it is accessible from the printer cover.

PROG This key is used to select the special programs (PROG) or to exit from the utility menu back to the test menu.

This special program menu (PROG) can be activated at any time except while the system is in the acquisition phase of the cycle. However some individual programs cannot be entered during an analytical cycle.

COMMANDS It is used to select specific menus.

INS To create a new sample record.

DEL To delete a sample record.

Decisional Keys

←, ↑, →, ↓

These keys are used to move the cursor ↑ or ↓ in a menu display. This enables selection of the desired cycle or program or to make choices requested on the video display.

ENTER To confirm numerical data or a decision.

←

To return to a previous frame and to save calibration results.

Page up/Page Down To move faster within the sample data base.

Numeric Keys

Numeric Keys To input all numerical data (also sample ID).

alpha-numeric Keys To input patient demographics and/or sample IDs.

RS 232C Interface

The ACL 6000 and ACL 7000 are provided with two RS 232C interfaces (DTE standard) for the output of data to a central computer or a personal computer. Communication to a host computer is via ASTM protocol.

External Bar Code Reader Interface

The ACL 6000 and the ACL 7000 are provided with an interface for a bar code scanner which allows sample ID reading (the external bar code scanner is optional on the ACL 7000).

External Printer Output

The ACL 6000 and ACL 7000 are provided with an output for an optional external printer.

Internal Cooling System

Two ventilators, with an air filter to prevent dust from entering the unit, are mounted on the left side of the instrument.

A safety element prevents the internal temperature from rising to temperatures which could damage the function of the instrument by means of a two level alarm to the operator. The first level alerts the operator to the condition allowing testing to continue although a warning will be displayed. The second level switches off the instrument.

1.5 Additional Features

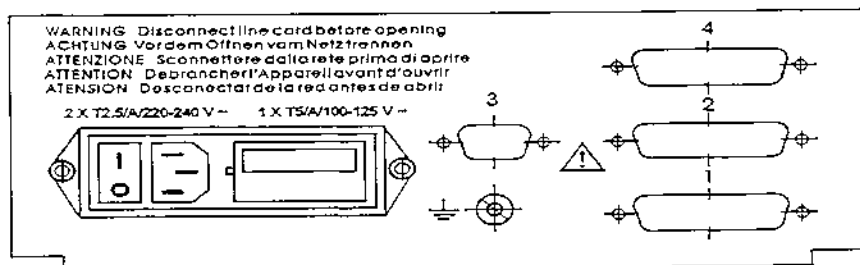
Standby Status

If the instrument is left on for a period of more than 30 minutes without operator action, the instrument moves into the standby status.

The VDU screen is dimmed (low light) and a standby display is presented.

Furthermore all motors are deactivated to reduce power consumption and the LED source is switched off.

Rear Panel



	See Operator's Manual	1	RS 232 C
	Functional Earth Terminal	2	RS 232 C
	ON (Supply)	3	Bar Code Scanner
	OFF (Supply)	~	Alternative current
		4	External Printer

An automatic priming cycle is performed every 30 minutes when the instrument is in the standby mode.

By pressing the ↓ key as indicated on the VDU, the display returns to normal brightness (the LED light source is switched on) and shows the last screen before entering the standby.

Note:

If the instrument was in the special programs menu (PROG) or in a results frame at the time the standby status started, activation of the analyzer will cause the display of the condition (menu or results) present before pressing the PROG key.

End of the Cycle

At the end of each analytical cycle, a 6-beep signal will notify the operator of the completion of the cycle.

Power Loss

The ACL contains a non-volatile memory to retain the data base in the event of a power interruption. The retained data is listed in the following table unless customizations have been made by the operator.

	Default Values at Initial Power On or after NV RAM Initialization
Date and Time	Date and Time of the last programmed date.
Calibration	Not calibrated
ISI	1.000
Ref. Values	PT=12.0 seconds APTT = 30.0 seconds TT = 12.0 seconds
INR	Off
Autocal	On
Units	Temp = °C FIB = mg/dL
Printer Status	On - 1 Copy
Printout Format	Fib ON
Interface Status Host	Automatic data transmission: Disabled Baud rate: 9600 Delete automatically trasmitted data: Disabled
Interface Status Research	Data trasmission: Automatic Baud rate: 9600

When power returns after an interruption, the instrument performs self checks including the temperature of the rotor holder (measuring chamber) and presents the "power on" display.

The instrument contains an internal clock that keeps track of the date and time.

1. The rotor holder temperature was in range during the checks.
The VDU presents the main menu.

Note:

The "Warning" indication may be given if the Peltier for the reagent reservoir and/ or preheater temperatures are out of range at this instant.

2. The rotor holder temperature was out of range.
The instrument display presents the alarm "INCUBATION TEMP OUT OF RANGE" in the upper section (A) of the VDU.

Special Programs (Utility Menu)

The instrument incorporates several special programs that allow certain functions of the instrument to be changed or set according to the individual needs.

These programs also aid troubleshooting.

Fault Detection

The system automatically monitors faults to ensure accuracy of sample data and proper system performance. Fault monitoring includes display of alarms and warnings.

1.6 Procedural Limitations

When "?" appears next to the title on the VDU, results data should be interpreted with great caution. An evaluation of the cause should be determined before accepting the data.

The operating range for the ACL is 15-32°C (59-89°F) at a relative humidity up to 85%. No safety hazards occur in the temperature range 10-40°C (50-104°F) and functional performance characteristics are resumed when the instrument re-enters the range of 15-32°C (59-89°F).

1.7 Reverse Video Display

Certain situations concerning results and calibration parameters will be displayed in reverse video.

More specific details are provided in the Operations (3) and in the Specifications sections (7).

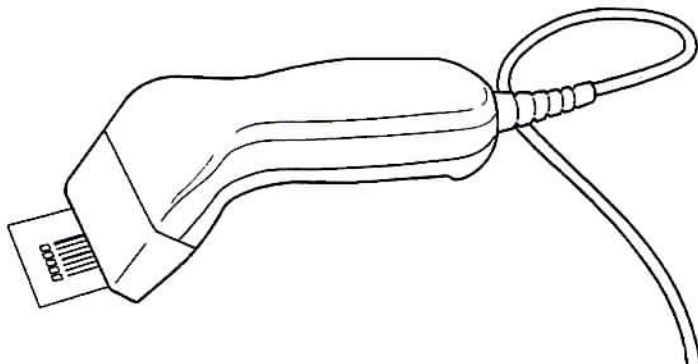
1.8 External Bar Code Scanner

The ACL 6000 is provided with a Bar Code Scanner which allows sample ID's reading. For the ACL 7000 the external bar code scanner is an option. The bar code scanner can read numeric and or alpha-numeric sample IDs up to a maximum of 12 digits. The maximum bar code label length readable is 6 cm with a resolution of 0.2 mm.

Numerical and alpha-numerical readable codes are:

1. Code 39
2. Code 128
3. Code 93
4. Codabar
5. Interleaved 2 of 5
6. MSI/Plessey

Bar Code Scanner



The scanner is provided with an on/off trigger. The scanner has a time out of 10 seconds. If no reading is performed in this period, the scanner will be switched off.

1.9 On-board Bar Code Reader (only on the ACL 7000)

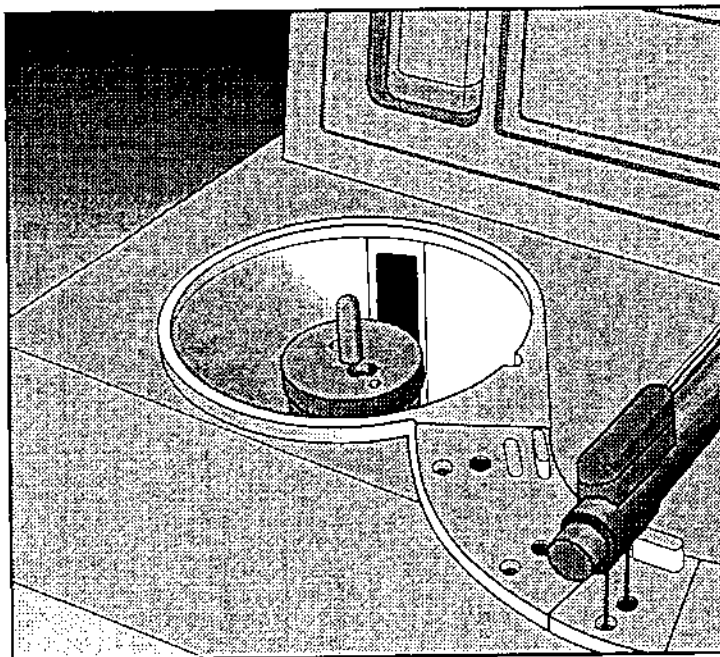
The on-board bar code reader is a standard feature on the ACL 7000. It is not present in the ACL 6000. The on-board bar code reader on the ACL 7000 is located inside the sample tray area. For additional information on the use of the on-board bar code reader please refer to the chapter 4.

Numerical and alpha-numerical readable codes are:

1. Codabar
2. Code 39
3. Code 128
4. Interleaved 2 of 5

Here below the position of the internal barcode reader (small window) inside the sampling area of the ACL 7000.

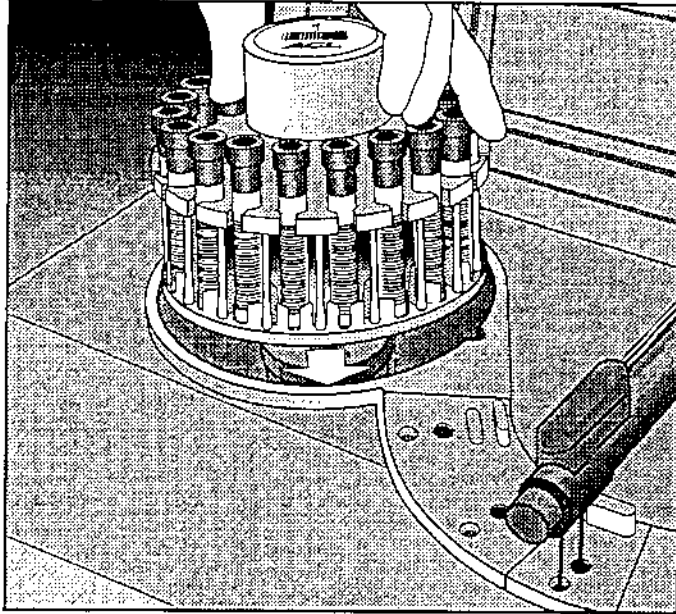
Internal barcode reader



When barcode labels are used it is recommended that the tubes are positioned with the labels to the outside of the sample tray.

This will allow a correct reading of the labels by the internal barcode scanner.

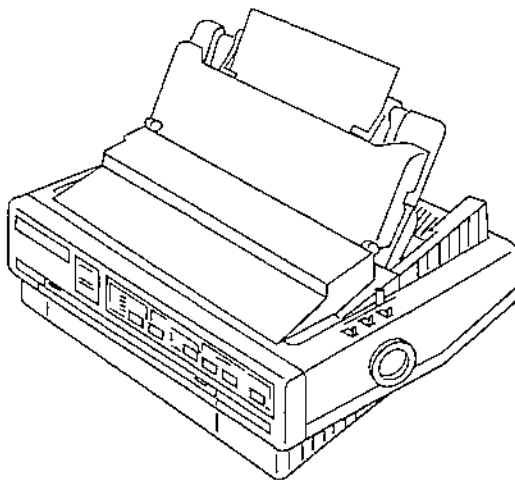
Barcode labels position



1.10 External Printer (optional)

An external 80 column printer can be interfaced to the ACL 6000 and ACL 7000 through port 4.

External printer



2 Installation

2.0 Inspection

This section describes all the information necessary for installation and control of the instrument.

The instrument must only be installed by IL personnel or other people authorized by IL.

Note:

Before starting installation confirm that, all the material identified in the shipping list is present.

2.1 Installation requirements

2.1.1 Ambient Conditions

The instrument will function correctly in an ambient temperature of 15-32°C with relative humidity up to 85% (non condensing).

The instrument should be positioned in an area free from dust, fumes, vibrations and excessive variations of temperature.

2.1.2 Space Requirements

The maximum external dimensions are:

- Height	45 cm	17.7 inches
- Height of analysis surface	21 cm	8.3 inches
- Width	75 cm	29.5 inches
- Depth	69 cm	27.2 inches
- Weight	52 Kg	114 lbs.

During operation the heat generated by the instrument is expelled via the base and front of the instrument.

It is important that sufficient space is allowed around the instrument and particularly on the left hand side to permit circulation of air for cooling. The instrument must be positioned so that a waste tube can be easily connected to the right hand side.

If the operator wishes to work seated in front of the instrument, empty space should be left under the front of the instrument.

2.1.3 Electrical Requirements

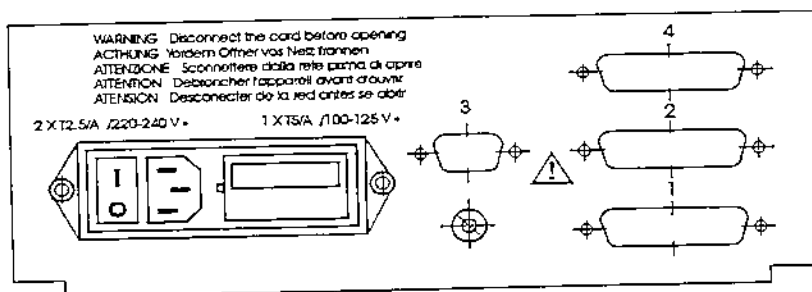
The instrument has been designed to operate correctly with variations of $\pm 10\%$ on the nominal line voltage and with line frequencies between 50-60 Hz.

Note:

Check that the nominal line voltage present in the laboratory is compatible with the label on the rear of the instrument as shown in the following table.

Value as shown on the label	Values of line voltage for normal function
220-240 V	220,230,240 Vac $\pm 10\%$
100-125 V	100,110,115,120,125 Vac $\pm 10\%$

Rear Panel



- See Operator's Manual
- Functional Earth Terminal
- ON (Supply)
- OFF (Supply)
- 1 RS 232 C
- 2 RS 232 C
- 3 Bar Code Scanner
- Alternative current
- 4 External Printer

Power Consumption

Check that the line is capable of supplying 2.5 A as required at 220-240 V or 5.0 A at 100-125 V.

Note:

The average power dissipation is about 300 W but peak loads or current surge when turning the instrument on can exceed this value.

Line Frequency

The instrument will function at any frequency between 50-60 Hz. The power cord is dedicated to the ACL analyzer; substitution cannot be made.

2.2 Instrument Unpacking

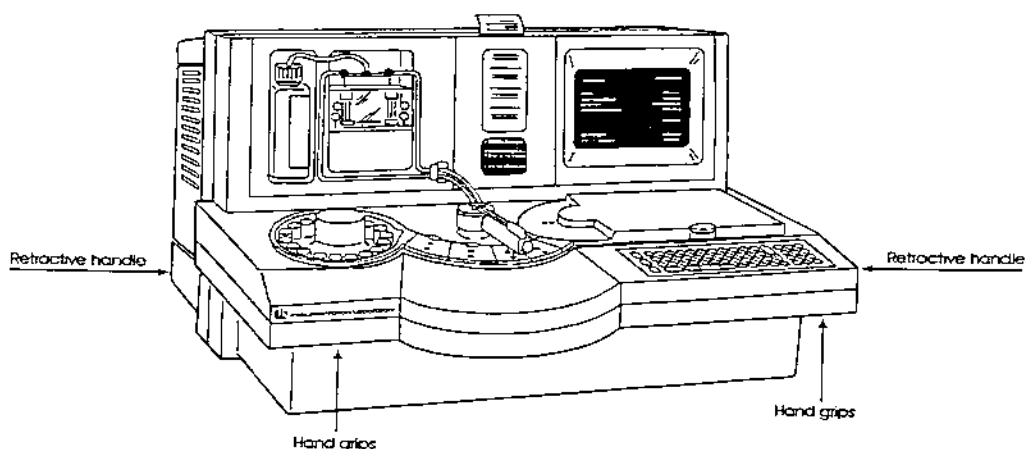
Remove the box containing rotors and the shipping list. Remove the instrument and place it on the working surface.

Note:

Two people should lift the instrument using the retractable handles and the front carrying points as shown in the next figure.

Using the shipping list included check that all parts are present. In case of damage notify the courier and your IL representative immediately.

Instrument Carrying Points



2.3 Instrument Parts Mounting

Waste tube

Connect the waste tube to the attachment on the bottom right hand side of the instrument.

Cut the tube to a suitable length to fit into a waste container which must be situated at a level below the instrument waste attachment.

Note:

The horizontal section of the tube should be kept as short as possible and the free end should not enter the waste liquid.

CAUTION

The liquid waste of the instrument is to be considered contaminated and should be discarded according to the waste management procedures of the laboratory and in compliance with the local regulations (see also NCCLS GP25-A Vol. 13 No.22: Clinical Laboratory Waste Management, Dec. 1993).

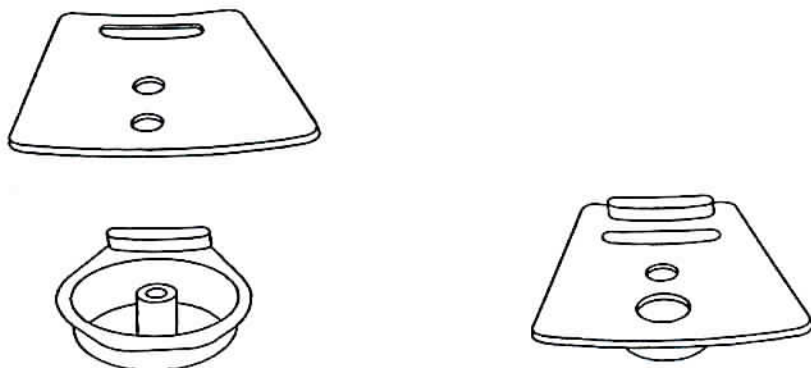
Reference Emulsion

Place a bottle of reference emulsion in the appropriate position to the left of the dilutor fitting and insert the aspiration tube.

Accessories

- Fit the appropriate sample tray on its relative support.
- Connect the Bar Code Scanner, if provided, to interface 3 on the rear panel.
- Fit the reagent reservoirs in their appropriate positions as follows:
 - MACRO PT/FIB in position 1
 - MACRO APTT in position 2
 - MACRO CaCl₂ in position 3

Reagent Reservoirs



Note:

MACRO APTT and MACRO CaCl₂ are contained in the same kit.

- Place the magnetic stirrer in the reagent reservoirs of position 1 and 2. Do not place a magnetic stirrer bar in reservoir 3.
- Place the relative covers, labelled numerically, in position.
- Insert the rinse reservoir in its appropriate position.
- Remove the adhesive tape used for transport from the various parts (printer cover, fan cover, etc.).
- Connect the two tubes from the dilutor/electrovalve assembly to the needle assembly and place the needle assembly in a beaker to collect any liquids.

Note:

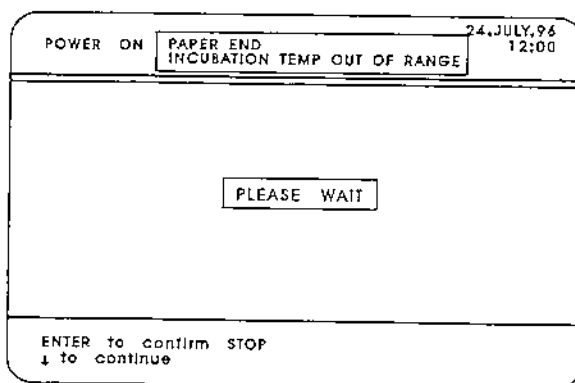
The tube from the left hand electrovalve fits into the lower needle (when mounted on the arm) and the right hand tube fits into the upper needle.

2.4 Switch On

Before switching the instrument on, check that the voltage setting of the laboratory is in accordance with the instrument label.

Connect the instrument to the supply and switch on using the power switch on the back panel.

Check that the indications "PAPER END" and "INCUBATION TEMP OUT OF RANGE" appear on the video as shown in the next figure.



Check that the magnetic stirrer in reagent reservoirs 1 and 2 are rotating.

Date/Time

Press the PROG key, select SET-UP and then select the DATE/TIME option. Enter the day, month, year, hour, minute and seconds; press the ENTER key after each entry (please refer to SPECIAL PROGRAMS, section 4.7.6 DATE/TIME Program).

Note:

The message "INCUBATION TEMPERATURE OUT OF RANGE" is presented for approximately 15 minutes until the rotor holder has reached operating temperature.

Printer Paper

Following the "POWER ON" cycle, open the printer cover and place a roll of paper in its seat above the printer. Insert the paper into the upper slot of the printer with the paper roll end coming from the bottom of the seat. Press the grey button on the right of the printer as shown in the next figure.

As the paper is advanced from the lower printer slot, feed it into the printer cover guide and close the cover pulling the paper gently to avoid blocking.

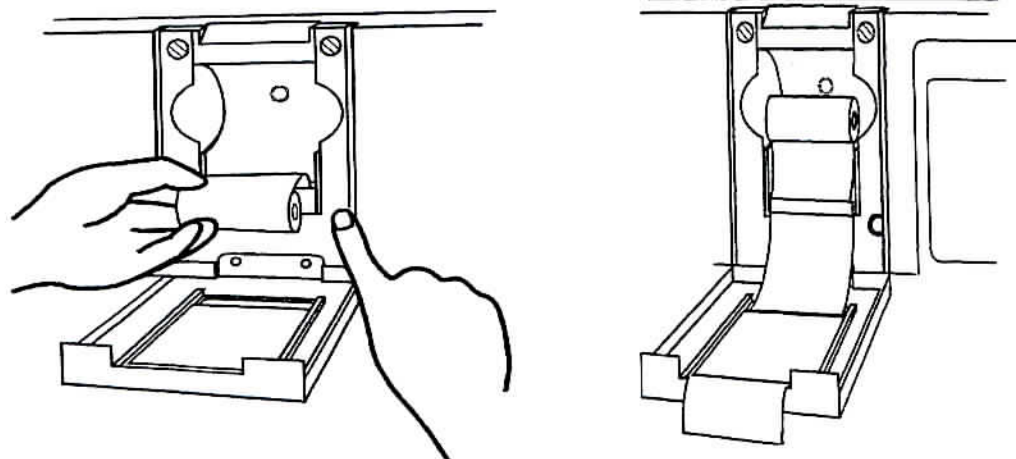
Check that the VDU warning "PAPER END" disappears.

Switch the instrument off and on again. Check that the print out shows no missing dots.

Note:

The paper advance key button is also accessible from the printer cover slot.

Loading the Printer Paper



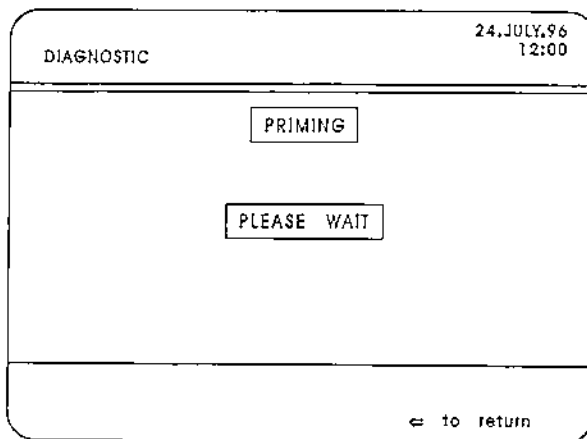
Needle Arm Assembly

Please refer to MAINTENANCE, section 5.5 Needles Position Procedure (as needed).

Priming

Press the PROG key. Select DIAGNOSTICS and select PRIMING option.

The display shown will appear during the priming cycle.



During priming check that the number of bubbles in the dilutor chambers is reduced to a minimum. If necessary pinch the chamber outlet tubes while the piston is descending and release them before the piston reaches bottom dead center. Repeat the priming cycle if necessary.

Check that there are no blockages or leaks in the fluidic path and that the liquid is flowing smoothly from the bottle to dilutors and dilutors to needles.

Check that the discharge of liquid from washing chamber to instrument outlet and then to the waste container is not impeded.

Note:

If the message "SENSOR FAIL" is displayed, the priming cycle must be repeated.

Video Intensity

Press the PROG key, select DIAGNOSTIC and select the VDU BRIGHTNESS option. Set the desired intensity by pressing arrow UP to increase or arrow DOWN to decrease as shown in the next figure.

Refer to SPECIAL PROGRAMS, section 4.6.5 VDU Brightness.

DIAGNOSTIC	24.JULY.96 12:00
VDU BRIGHTNESS	
↑ to increase brightness ↓ to decrease brightness	PROG (return) <= (previous)

Air Cooling System Check

Open the ventilation cover door on the left of the instrument.

Check for the presence and cleanliness of the filter and that the two fans are operating correctly.

Temperature Check

Wait until the INCUBATION TEMPERATURE OUT OF RANGE frame has disappeared and the main menu is displayed.

Press the PROG key. Select DIAGNOSTIC and select the TEMPERATURE CONTROL option. The frame shown in the next figure will appear.

Refer to SPECIAL PROGRAMS, section 4.6.3 Temperature Control.

DIAGNOSTIC	24.JULY.96 12:00
TEMPERATURE CONTROL	
ROTOR HOLDER [incubation: 37 ± 1°C]	: 38.5°C
PELTIER	: 13.2°C
PRE-HEATER	: 37.5°C
PRT to print	PROG (return) <= (previous)

The temperature should be within the following limits:

- Rotor Holder 38 to 39 °C
- Peltier 12 to 15 °C
- Preheater 36 to 39 °C

External Bar Code Scanner

It is a standard feature on the ACL 6000 but it is optional for the ACL 7000. Set up the Bar Code Scanner according to the procedure contained in Appendix C, CCD Barcode Scanner Setting.

On-board Bar Code Reader (only on the ACL 7000)

It is a standard feature on the ACL 7000 but is not present on the ACL 6000. Set up the On-board Bar Code Reader according to the procedure contained in the Chapter 4 of the Operator's Manual.

For additional information on the on-board barcode reader please refer to Appendix D.

Responsibility of the manufacturer

The manufacturer is responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustment, modifications or repairs are carried out by manufacturer-authorized personnel,
- the electrical installation complies with national requirements,
- the equipment is used in accordance with these operating instructions.

2.5 ACL - Host Interconnect Cable

The following table provides information regarding the wiring of the interconnection cable between the ACL and a PC (Host).

ACL Side		PC Side	
Interface Type: DTE		Interface Type: DTE	
25 Pin Connector		25/9 Pin Connector	
PIN	DESCRIPTION	PIN	DESCRIPTION
1	Protective GND	1/1	Protective GND
2	TXD	3/2	RXD
3	RXD	2/3	TXD
4	RTS	5/8	CTS
5	CTS	20/4	DTR
6	DSR	N.R.	
7	Signal GND	7/5	Signal GND
20	DTR	6/6	DSR

3 Operation

3.0 Preparation of the Instrument

Power on

When turned on, the instrument performs a series of self checks on the memory and the sampling arm movement.

If any check is not executed properly, an "alarm" frame appears. The various alarms and their definitions are listed in the chapter 6 (Troubleshooting).

The instrument is now in the warm up phase. The "incubation temperature out of range" message will remain for 15 minutes until the temperature of the rotor holder reaches 38.5°C.

Notes:

1. *It is inadvisable to open the rotor cover during the warm up period particularly if the ambient temperature is below about 18°C as this may cool the rotor holder and cause the warm up period to be extended.*
2. *If a printer paper roll has not been inserted into the appropriate housing, the message "PAPER END" (in the upper part of the video) is displayed.*

At the end of the "please wait" period, the presence of additional conditions which still allow the operator to use the instrument with limited actions (WARNINGS) is indicated by the message, in reverse video, "WARNING see PROG" adjacent to the date.

The ACL is a precision electronic instrument. We strongly recommend not switching it off except for extended periods of non-use (longer than 72 hours). The introduction of a standby condition minimizes power and reference solution consumption and ensures that the instrument is always ready for use, thus avoiding the 15 to 30 minutes warm up period.

Low Light or Standby Screen

If no operation is carried out for a period of time greater than 30 minutes the screen goes into low light and the LED light source is switched off.

Status Standby.

Action Press any key to resume.

Status The frame returns to normal and the LED light source is switched on.

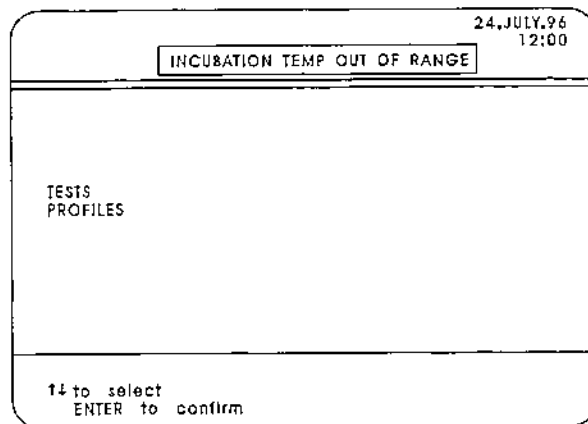
If the rotor holder temperature is out of range ($38.5 \pm 0.5^{\circ}\text{C}$), the message "INCUBATION TEMP OUT OF RANGE" is displayed in reverse video.

Note:

This means that the measuring chamber temperature is outside the range $37.0 \pm 1.0^{\circ}\text{C}$.

Date/Time

The instrument is equipped with an internal clock that keeps track of date and time. If date and time need to be modified please refer to chapter 4 Set-up Date/Time.



Warning Before selecting and running any type of tests, please check that:

- Proper sample level is present in sample cups. Dead volume for 0.5 mL cups is 100 μL and for 2 mL cups is 500 μL .
- For primary tubes, make sure that the quantity of blood collected allows a fill volume within the specifications stated by the manufacturer.
- There is adequate reagent level. Dead volume for PT/FIB, APTT, Pro-IL-Complex, Hepatocomplex and CaCl_2 reagent cups is 2 mL; for TT, enzyme and chromogenic substrate is 0.5 mL.

Sensors

The fluidic sensors work either during the loading or the incubation phase of each cycle according to the test selected.

The sampling arm moves to samples and reagents to check the effective presence of all liquids.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.

For flags and alarms regarding sensors, refer to section 6, Troubleshooting.

Note:

For additional information on the Setup of the analyzer please refer to chapter 4.

3.1.0 Introduction

From the main menu (presented after the switch on of the instrument and the temperature is in range) it is possible to select either TEST (Single test by batch) or PROFILES (Profile on a random basis).

READY	24 JULY 96 12:00
TESTS PROFILES	
↑↓ to select ENTER to confirm	

Select TESTS to access the single tests submenu.

READY	24. JUL, 96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑,↓,←,→ to select ENTER to confirm	⇐ to exit

Select DOUBLE TESTS to access the submenu "DOUBLE TESTS".

DOUBLE TESTS	24. JUL, 96 12:00
PT-FIB APTT TT PT-FIB/APTT	
↑,↓ to select ENTER to confirm	⇐ to exit

Select ABS. TESTS to access the submenu "ABS. TESTS".

ABS. TESTS	24.JUL.96 12.00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑,↓ to select ENTER to confirm	<= to exit

Select SPECIAL TESTS to access the submenu "SPECIAL TESTS".

SPECIAL TESTS	24.JUL.96 12:00
PRO-IL-COMPLEX HEPATOCOMPLEX PROCLOT PROTEIN S APCR-V	
↑↓ to select ENTER to confirm	<= to exit

Select SINGLE FACTOR to access the FACTORS submenu.

SINGLE FACTOR	24.JUL.96 12:00										
<table border="0"> <tr> <td>EXTR. PATHWAY</td> <td>INTR. PATHWAY</td> </tr> <tr> <td>FACTOR II</td> <td>FACTOR VIII</td> </tr> <tr> <td>FACTOR V</td> <td>FACTOR IX</td> </tr> <tr> <td>FACTOR X</td> <td>FACTOR XI</td> </tr> <tr> <td>FACTOR VII</td> <td>FACTOR XII</td> </tr> </table>		EXTR. PATHWAY	INTR. PATHWAY	FACTOR II	FACTOR VIII	FACTOR V	FACTOR IX	FACTOR X	FACTOR XI	FACTOR VII	FACTOR XII
EXTR. PATHWAY	INTR. PATHWAY										
FACTOR II	FACTOR VIII										
FACTOR V	FACTOR IX										
FACTOR X	FACTOR XI										
FACTOR VII	FACTOR XII										
↑,↓,←,→ to select ENTER to confirm	<= to exit										

From each of the above mentioned menus and submenus, it is possible to access the PROG menu by pressing PROG key.

PROG	24.JUL.96 12:00
DMS LOADLIST QC CALIBRATION DATA WARNING DIAGNOSTIC SETUP	
↑,↓ to select ENTER to confirm	PROG (return)

Select PROFILES to select the PROFILES menu.

PROFILES	24.JUL.96 12:00
PT-FIB/APTT PT-FIB / APTT / TT PT-FIB / FIB-C APTT / FIB-C TT / FIB-C PCX / APTT / TT HPX / APTT / TT PCX / FIB-C HPX / FIB-C	
↑,↓ to select ENTER to confirm	← to exit

3.1.0.1 Tests

Note:

An asterisk (*) indicates that a test or profile is not currently available in the United States.

Test name	Calibration	Undiluted samples detection	In run liquids check	In profiles
PT-FIB	dedicated, stored	--	yes	yes
APTT	--	--	yes	yes
TT	--	--	yes	yes
ATIII	dedicated, stored	yes, in cup	no	no
HPX *	dedicated, stored	--	yes (modified head volumes)	yes
PCX *	dedicated, stored	--	yes (modified head volumes)	yes
FIB-C	dedicated, stored	--	yes (modified head volumes)	yes
FACTORS (Intr./Extr.)	in run, storable (high curve)	yes, in line	no	no
HEPARIN Xa	dedicated, stored	yes, in cup	no	no
HEPARIN	in run, storable (high curve)	no	no	no
PROCHROM	in run, storable	no	no	no
PLASMINOGEN	in run, storable	no	no	no
ANTIPLASMIN	in run, storable	no	no	no
D-DIMER	dedicated, stored	no	no	no
PROTEIN-S	in run	no	no	no
PROCLOT	in run storable	no	no	no
APCR V	no	no	no	no

3.1.1 PT-Fibrinogen

For Calibration Plasma, Controls Plasma and reagent preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY. From the main screen, Select TESTS and press ENTER. The Ready state is displayed with the main menu listed. The last test executed is displayed in reverse video (in this description this is referred to as the cursor).

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
SINGLE FACTOR	
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor, by means of the ↑ and ↓, ←, → keys, to select PT-FIB and press ENTER. The "check" frame is displayed.

Status Usable rotor presence.

PT-FIB	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBOPLASTIN LEVEL	POS. 1
REFERENCE SOLUTION LEVEL	
CAL DATA (see PROG)	
↑ to calibrate ↓ to start analysis	← to exit

Action Check that a usable rotor is present in the rotor holder.

Status Thromboplastin level.

Action Empty the thromboplastin bottle content into reservoir No.1 (MACRO) of the instrument, marked PT-FIB.

Status Reference emulsion level.

Action Ensure that the reference emulsion level is adequate. A level of 1.5-2 cm is enough to run 1 or 2 rotors, considering the dead volume. Replace the bottle if necessary.

Status Indication for the status of the calibration data if the tests requires calibration. The message "CAL DATA (see PROG) is displayed if the PT-FIB has been previously calibrated. The message "NOT CALIBRATED" is displayed in reverse if the PT-FIB is not calibrated.

PT-FIB CAL	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE THROMBOPLASTIN LEVEL POS. 1 REFERENCE SOLUTION LEVEL	
NOT CALIBRATED	
↑ to calibrate ↓ to start analysis	← to exit

Action Press the PROG key to display the last calibration condition and relative data.

By pressing the PROG key again, the "check" frame is displayed.

PT -Fibrinogen Calibration (PT-FIB)

Note:

When the lot numbers of Calibration Plasma and/or thromboplastin and/or Reference Emulsion and/or rotor lot is/are changed and/or controls are out of range, the calibration must be repeated.

Action Press ↑ in the "check" frame to initiate a calibration cycle.

Status If the instrument is calibrated, the last accepted PT-FIB calibration conditions are displayed.

PT-FIB CAL	24.JUL.96 12:00
PT-FIB ANALYTICAL CALIBRATION CONDITIONS	
N.P. LOT No.
FIB REFERENCE VALUE [mg/dL]	0
REF. EMULSION LOT No.
THROMSOPLASTIN LOT No.
ISI	1.000
CALIBRATION DATE: 24.JUL.96	
Key in new value ENTER to confirm	<= to exit

- Status** If the instrument is not calibrated, this frame with the first parameter in reverse video is displayed.
- It is possible to change or confirm the following parameters:
- Normal Plasma Lot Identification Number (Calibration Plasma or Plasma Pool)
 - Normal Plasma Fibrinogen value (mg/dL or g/L)
 - Reference Emulsion Lot Number
 - Thromboplastin Lot Number
 - Thromboplastin ISI value

If a Fibrinogen value of 0 is introduced, the instrument will not calibrate the Fibrinogen.

For IL Calibration Plasma, insert the value written on relative insert sheet. The Fibrinogen value entered for the Plasma Pool must be defined using a separate method. The acceptable range for Fibrinogen is from 200 to 450 mg/dL.

Note:

The acceptable range for ISI is 0.100 to 9.999 (refer to the insert sheet included in the Thromboplastin kit).

- Action** The operator can confirm any parameter by pressing ENTER . If a parameter has to be changed, ENTER must be pressed after the new data has been entered.

The parameter to be confirmed or changed is displayed in reverse.

- Status** After keying all the data in, the instrument prompts the operator to place the Normal Plasma and Diluent in position on the sample tray (use 2 mL cups for calibration in the POOL and DIL positions).

PT-FIB CAL	24, JULY, 96 12:00
PLACE: N.P. IN 'POOL' POSITION DILUENT IN 'DIL' POSITION	
↓ to start analysis	< = to exit

- Action** The operator has to place the Calibration Plasma (2 mL) in position "POOL" and the Sample Diluent (2 mL) in position "DIL" on the sample tray. Press ↓ to start calibration.

Status The instrument checks for the correct positioning of the Normal Plasma and Sample Diluent and for the presence of a new rotor.

PT-FIB CAL PRE-ANALYSIS	24.JUL.96 12:00
<div style="border: 1px solid black; display: inline-block; padding: 2px;">CHECK SAMPLE TRAY</div>	
POS: 19 POS: 20	
← to abort cycle ↓ to continue	

PT-FIB CAL PRE-ANALYSIS	24.JULY.96 12:00
ROTOR NOT PRESENT	
← to abort cycle ↓ to continue	

Action Check sample tray. Load new rotor.

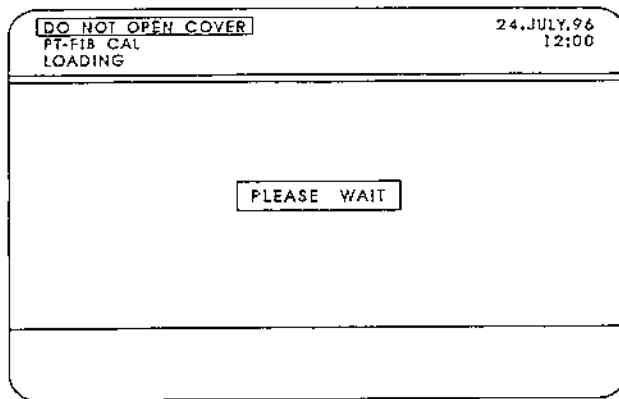
Status The "check" frame is displayed if the samples are not placed correctly in the sample tray.

The "load" frame is displayed if the rotor is missing or it has been completely or partially used.

The instrument starts to load. The instrument dispenses undiluted Normal Plasma (100%) and reagent in the first six cuvettes. In the following six positions, the instruments dispenses diluted Normal Plasma (50%) and reagent and in the last six positions diluted Normal Plasma (25%) and reagent.

The instrument automatically carries out the dilutions.

The message "DO NOT OPEN COVER" is displayed on the first line of the VDU.



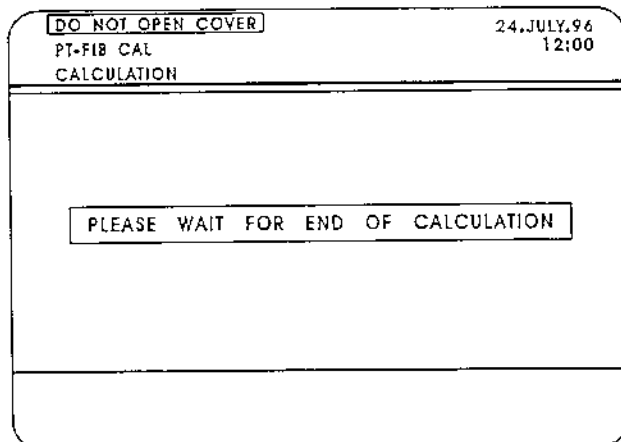
On the third line of the VDU, the following messages are displayed in sequence:

- "LOADING"
- "INCUBATION"
- "ACQUISITION"

During incubation, the sampling arm checks the presence of samples and reagent with fluidic sensors.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms related to this matter, refer to section 6 (Troubleshooting).

Status In the center of the video the message "PLEASE WAIT" is displayed the calibration results appear. At the end of the acquisition and before the appearance of the results, the message "PLEASE WAIT FOR END OF CALCULATION" is displayed.



At the end of the calculation phase, the "calibration results" frame is displayed.

By pressing **PRT**, the calibration data is printed.

PT FIB CAL		24.JUL.96	
RESULTS		12:00	
% S			
PT 100	12.9	CV=0.66	
50	18.0	CV=0.24	
25	29.5	CV=0.48	
m = 0.027 q = 0.017 r2 = 0.999			
mg/dL Δ			
FIB 300	68.21	CV=1.59	
150	29.44	CV=5.67	
75	16.12	CV=5.27	
m = 287.7 q = 15.01 r2 = 0.993			
↑ to see Cal Data and Graphics		PRT to print ← to save	

Action The operator can choose to accept the calibration or not.
Press **↑** to see cal data and graphics or press **←** to return and save.

Status The calibration results are expressed in the following way: the mean value, expressed in seconds, of the 6 cuvettes with Normal Plasma 100%, the mean of the 6 cuvettes with Normal Plasma 50% and the mean of the 6 cuvettes with Normal Plasma 25% and the CV corresponding to each dilution.

The coefficient of correlation (r^2) is also expressed. This gives an indication of the degree of alignment of the measured results to theoretical (a value of 1.000 represents perfect correlation).

Note:

If the "WARNING" display occurs during calibration refer to section 6 (Troubleshooting).

If, the operator decides to accept the calibration, in spite of the warnings, the appropriate error codes are printed on the respective calibration print-out and all subsequent PT-FIB analyses.

Calibration for PT-FIB is always carried out on the mean values of the 6 determinations for each level (100%, 50% and 25%).

The following calibration errors may occur:

- a) *If the average is calculated on less than 4 samples (the other two being excessively out of range e.g. Not coagulated or Coag Error), the message "NOT CALIBRATED" is displayed.*

PT-FIB CAL READY	24.JULY.96 12:00
PT not calibrated FIB not calibrated no liquid in "POOL" position	
← to return	

- b) If the coefficient of variation (CV) of a mean value is outside the pre-established range, that CV is presented in reverse.
The predetermined ranges for the values of CV for PT and FIB are:

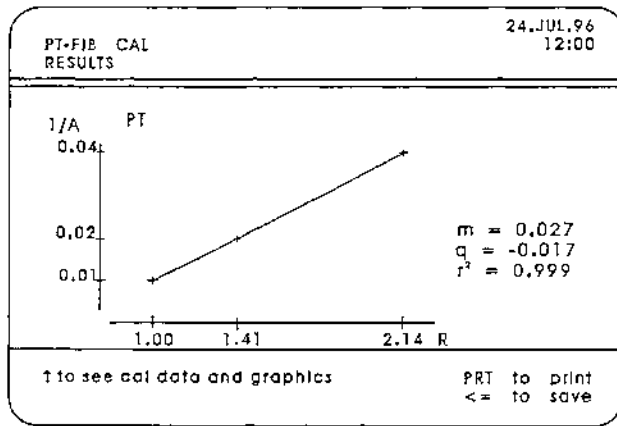
	PT	Fibrinogen
NP (100%)	CV < 1.5%	CV < 8.0%
NP (50%)	CV < 2.0%	CV < 12.0%
NP (25%)	CV < 2.0%	CV < 12.0%

- c) If the value of the coefficient of correlation (r^2) is outside the pre-established range (< 0.980), the value is presented in reverse video.
d) If both CV and r^2 are out of range, both are displayed in reverse video.
e) The results of calibration are not stored until accepted by the operator.

PT and Fibrinogen calibrations may be accepted if the flagged CVs are less than or equal to 1.0% greater than the specifications as stated above and the r^2 of the calibration curve is within acceptable limits. If the r^2 is flagged, calibration should be repeated.

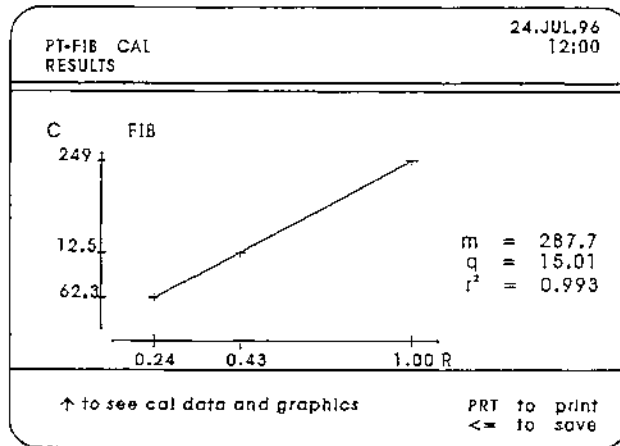
Should a power failure occur before acceptance by the operator, the results are lost and the instrument presents the previous calibration results. The results of a previous calibration are not substituted with the new values until accepted by the operator.

Status Press ↑ to see cal data and graphics in the "calibration results" frame. The instrument displays the PT graph with relative slope (m), intercept (q) and r^2 .

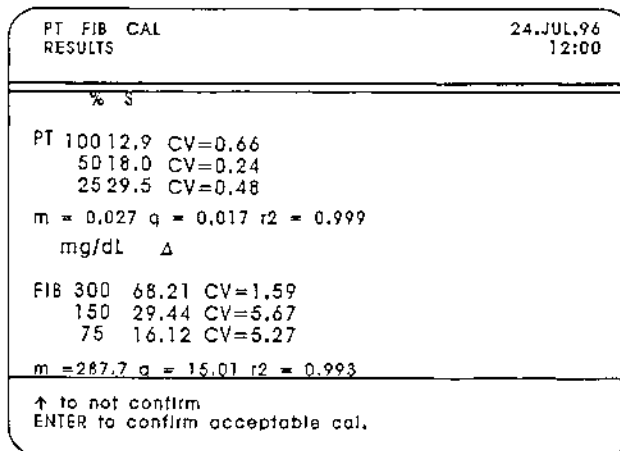


Action Press PRT to print the PT graph and m, q and r².
The operator must press ↑ key.

Status The instrument displays the Fibrinogen graph with relative slope (m), intercept (q) and r².



Action Press PRT to print the Fib graph and m, q and r².
After pressing <= to save the operator is asked to confirm or not the calibration.



- Action** Press <= to save the calibration.
Press PRT to print the calibration data.
- Status** The operator is asked to confirm the acceptable calibration.
- Action** Press ENTER to confirm.
- Action** In the calibration acceptance frame, press ↑ not to confirm, if the calibration is not acceptable.

Note:

After calibration acceptance, the last calibration is replaced by the new one.

Note:

Choosing ↑ not to confirm, the previous calibration is maintained in the memory.

PT-Fibrinogen (PT-FIB) Analysis

Action To carry out the analysis the operator has to press ↓ to start analysis in the "check" frame of the PT-FIB cycle.

PT-FIB	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE THROMBOPLASTIN LEVEL POS. 1 REFERENCE SOLUTION LEVEL CAL DATA [see PROG]	
↑ to calibrate ↓ to start analysis	<= to exit

Before ↓ to start analysis, the operator has to load the sample tray: Calibration Plasma in "POOL" position and max. 18 samples.

Note:

Prior to starting analysis make sure that the Calibration Plasma is present in the POOL position and that the samples are in positions from 1 to 18 (maximum) of the sample tray.

Make sure that there are no empty positions between samples, since the instrument does not detect sample cups/primary tubes which follow an empty position.

For example, cuvettes/primary tubes are placed in position 1 to 6 and then positions 8 to 18 (position 7 is empty), the instrument only aspirates sample from positions 1 to 6; it ignores the samples positioned after the empty space.

Action Load the rotor in the proper housing.

Note:

By pressing STOP and confirmed by ENTER (within 5 seconds) in any situation, the operator can go back to READY.

If the instrument was not in temperature the message "incubation temperature out of range" is displayed.

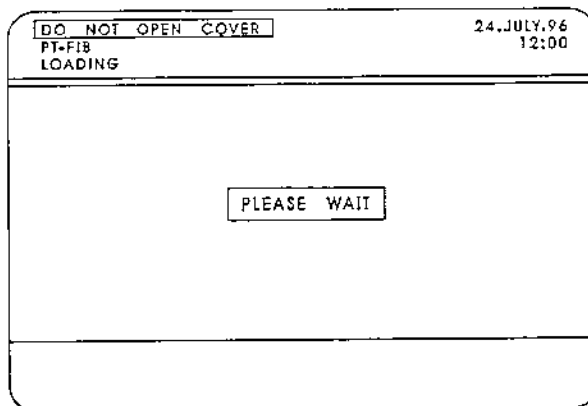
After the STOP key is pressed, during a cycle, the message "CYCLE ABORTED STOP REQUESTED" is displayed.

Action Check sample tray.

Status The "check" frame is displayed if the samples are not positioned correctly.

Action Load new rotor.

Status The "load" frame is displayed if the rotor is missing or it has been fully used.



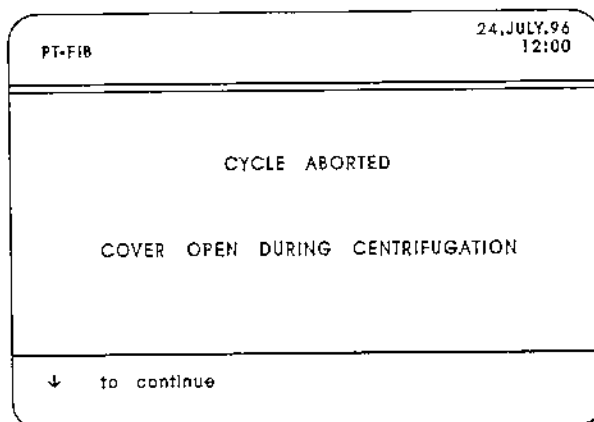
The sampling phase begins: the instrument dispenses the Calibration Plasma, the samples, the thromboplastin and the reference emulsion into the rotor. This is automatically followed by the incubation and the acquisition phases.

Note:

During the whole cycle the message "DO NOT OPEN COVER" is displayed.

If the cover is opened during incubation, an intermittent audible alarm and a message on the results printout will signal this situation. The message "DO NOT OPEN COVER" changes to "CLOSE COVER" until the operator closes the cover. On the VDU a question mark is displayed after the word RESULTS.

Warning If the cover is opened during acquisition, the cycle is aborted.



Status At the end of the acquisition phase, the calculation frame is followed by "results".

PT results are expressed in seconds, activity and ratio (compared to the Calibration Plasma); Fibrinogen results are expressed in mg/dL or g/L (refer to the SPECIAL PROGRAMS in chapter 4).

PT-FIB RESULTS					10.AUG.92 12:00
	PT			FIB	
	s	%	R	mg/dl	
1	11.7	92	1.03	271	
2	11.9	86	1.05	272	
3	11.9	86	1.05	281	
4	30.1	449	0.78	415	
5	not coag.				
6	7.35		0.64		
7	12.1	82	1.06	254	
8	13.3	63	1.17	166	
NP	11.4			244	

PRT to print
<= to exit

Note CAL:

If the instrument is calibrated:

- with the Calibration Plasma (N.P.) on the sample tray, the results for PT are expressed in seconds, activity and ratio/INR and mg/dL or g/L for Fibrinogen.
- without the Calibration Plasma (N.P.) on the sample tray, the results for PT are only expressed in seconds and no value is displayed for Fibrinogen.

If the instrument is not calibrated:

- with the Calibration Plasma (N.P.) on the sample tray, the results for PT are expressed in seconds and ratio/INR (if Autocal PT is on) and no value displayed for Fibrinogen.
- without the Calibration Plasma (N.P.) on the sample tray the results, for PT, are only expressed in seconds and no value is displayed for Fibrinogen.

Note AUTOCAL PT:

In the PT results calculation two options are available:

- 1) ON - Calibration Plasma (N.P.) value in seconds on each run is used for calculation of all patients samples (see chapter 4 and 7).
- 2) OFF - Calibration Plasma value in seconds of the first point of the calibration curve stored in the memory is used for the calculation of all patient samples (see chapter 4 and 7).

Note INR:

If PROG, SETUP, CALCULATION, INR ON has been selected and the thromboplastin ISI value has been keyed into the "calibration" frame, the results are expressed in INR instead of sample Ratio (according to the previously described conditions).

Note Flags:

If a sample coagulates in less than the blank time or the fibrinogen is very low (<60 mg/dL for PT/TT/APTT) the message "COAG ERROR" is displayed. If the sample does not coagulate within the maximum end time, the message "NOT COAG" is displayed (See PROG, SETUP, ACQUISITION TIME in chapter 4).

Note Calibration Plasma:

The Calibration Plasma (N.P.) PT value expressed in seconds and its defined Fibrinogen content expressed in mg/dL or g/L are displayed with the analysis results.

Note % - R - INR - PT Calculation:

The Calibration Plasma (N.P.) PT value in seconds (on each run if AUTOCAL PT is ON, or that of the first point of the calibration curve if AUTOCAL PT is OFF) is used as the denominator to calculate the Ratio/INR. The ratio between the patient values (in seconds) and the Calibration Plasma (N.P.) value in seconds (according to the PROG, SETUP, CALCULATION, AUTOCAL PT choice) is used to read the corresponding % activity on the basis of the calibration curve.

For more details on ratio calculation refer to chapter 4 (Ratio Adjustment).

Note FIB Calculation:

The ratio between the patient values (in delta) for fibrinogen and the Calibration Plasma value of the first point of the calibration curve (in delta) is used to obtain the correspondent value in mg/dL (or g/L) on the basis of the calibration curve.

Note Flags PT:

The PT value (N.P.) in seconds and the FIB value in mg/dL or g/L are printed in normal format when they are in range.

If the PT value of the Calibration Plasma (N.P.) is not within $\pm 9\%$ of the value in seconds of the calibration plasma (100%) of the calibration curve, the value is displayed and printed in reverse. Patient results are only expressed in seconds; % and R/INR are not given (instrument calibrated).

Note Flags FIB:

If the fibrinogen value of the Calibration Plasma (N.P.) is not within $\pm 20\%$ of the value in delta of the Calibration Plasma (100%) of the calibration curve, the result is displayed and printed in reverse.

Fibrinogen results of the patients are not given (instrument calibrated).

Note RESULTS ?:

If a warning situation occurs or the Calibration Plasma (N.P.) value is flagged, the message "RESULTS" in the upper sector of the video is followed by a question mark ("RESULTS?").

- Status** If in PROG, AUTOMATIC TRANSMISSION (QC and Patient Data, only Patient Data) has been selected, all data are transmitted to the central computer from the enabled interface.
If in PROG, MANUAL TRANSMISSION has been selected the results can be transmitted from the patient database (DMS).
- Action** Pressing <- the instrument returns to the main menu.
If the operator presses STOP in the "results" frame and ENTER within five seconds, the instrument does not store the Calibration Plasma value for the Q.C. when it is in range.

If the Calibration Plasma value is out of range (with respect to the Reference Data value), it is displayed in reverse.

Note:

Data transmission can also be activated from the internal DMS; please refer to chapter 4 for additional information.

PT-FIB		PT		FIB		24.JULY.96	
RESULTS						12:00	
	s	%	R	mg/dl			
1	11.7	92	1.03	271			
2	11.9	86	1.05	272			
3	11.9	86	1.05	281			
4	30.1	449	0.78	415			
5	not coag.						
6	7.35		0.64				
7	12.1	82	1.06	254			
8	13.3	63	1.17	166			
NP	11.4			244			

- to return
4 to validate Q.C. PT

If the cover is opened during the acquisition phase, the cycle is aborted.

- Action** Press ↓ to continue to return to the main menu.

It is not possible to start a new analysis during the results printout.

It is necessary to wait for the end of the printout before carrying out the new analysis.

Note:

The ACL™ Fibrinogen methodology is based on the total change in light scatter associated with the formation of a fibrin clot (Delta LS). Since inhibitors of fibrin (FDPs, etc.) generally affect the rate of formation and not the final clot size or opacity, methodologies using rate measurements (e.g. Clauss) may be markedly altered by the presence of these inhibitors. Procedures of this type will produce significantly longer clotting times and therefore apparently lower fibrinogen concentrations. The ACL™ fibrinogen method, as described, is not influenced by these inhibitors and will reflect the true fibrinogen concentration of the plasma. This value will correlate better with the antigenic fibrinogen value than with a Clauss procedure in those situations where large concentrations of inhibitors are present in the sample.

3.1.2 APTT

For Calibration Plasma, Control Plasma, reagent preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse video.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	⇐ to exit

Action Move the cursor, by means of the ↑↓←→ keys, to select APTT and press ENTER.
The "check" frame is displayed.

APTT	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE CEPHALIN LEVEL CALCIUM CHLORIDE LEVEL REFERENCE SOLUTION LEVEL	POS. 2 POS. 3
↓ to start analysis	⇐ to exit

Status Usable rotor presence.

Action Check that a usable rotor is present in the rotor holder.

Status Cephalin level control.

Action Pour the cephalin bottle contents into reservoir 2 (MACRO) of the instrument, marked APTT.

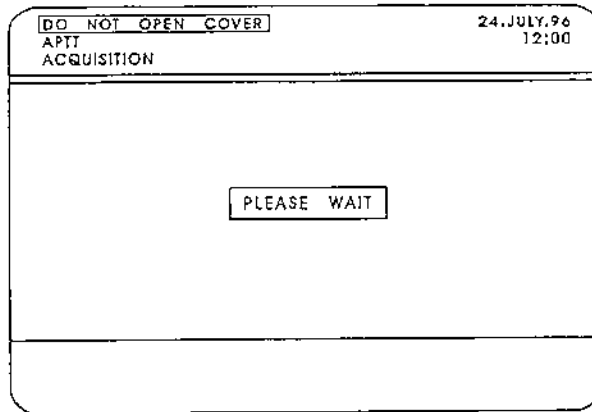
Status Calcium Chloride level.

Action Pour the Calcium Chloride bottle contents into reservoir 3 (MACRO) marked CaCl₂ of the instrument.

Status Reference emulsion level.

Action Ensure that the reference emulsion level is adequate; a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume, otherwise replace the bottle.

Load the sample tray, the Calibration Plasma in "POOL" position, the samples (18 maximum) and press ↓ to start analysis.



Status If the rotor and/or samples are missing during instrumental checks, or the rotor has been used, the same indications described for the PT-FIB cycle apply. The sampling phase begins and a sensor test is performed. The instrument dispenses the Calibration Plasma and cephalin into the rotor. This is followed by activation, loading of CaCl₂, incubation and acquisition phases.

Action The operator can enter the Sample ID using the numerical keyboard and confirming the number.

Status During the loading the liquid checks occurred.

Warning For flags and alarms related to this matter, refer to section 6, troubleshooting.

Status At the end of the acquisition phase, the "results" frame follows the calculation frame. APTT results are expressed in seconds and ratio (if the Normal Plasma is loaded on the sample tray and not in reverse).

APTT RESULTS						24.JULY.96 12:00
	s	R		s	R	
1	30.5	1.16	11	33.5	1.26	
2	46.3	1.75	12	42.0	1.58	
3	32.5	1.23	13	26.8	1.01	
4	41.0	1.55	14	60.8	2.29	
5	26.7	1.01	15	27.5	1.04	
6	60.3	2.28	16	58.3	2.20	
7	27.3	1.03	17	27.0	1.02	
8	58.1	2.19	18	42.0	1.59	
9	32.4	1.22				
10	48.3	1.82	NP	26.5		

PRT to print
<= to exit

For more details on Ratio calculation please refer to chapter 4 (Ratio Adjustment).

If a sample coagulates in less than the blank time or the fibrinogen is very low (< 60 mg/dL) the message "COAG ERROR" is displayed instead of the result. If, on the contrary, the sample does not coagulate within the maximum end time, the message "NOT COAG" is displayed instead of the result (refer to SPECIAL PROGRAMS - ACQUISITION TIME - Chapter 4). If the Calibration Plasma of the analysis rotor is in range, the patients results are given in seconds and ratio.

If the Calibration Plasma of the analysis rotor is not within $\pm 15\%$ of the value in seconds of the Calibration Plasma Reference value, the value is displayed and printed in reverse and the patient results are given only in seconds.

The message "RESULTS" in the upper section of the video is followed by a question mark ("RESULTS ?").

If the Calibration Plasma is not loaded into the analysis rotor, the results are expressed in seconds only.

Action Pressing "**<=** to exit" the display returns to the main menu.

If the operator presses **STOP** in the "results" frame and within five seconds press **ENTER**, the instrument does not store the Calibration Plasma value for the S.P. (when it is in range).

If the Calibration Plasma value is out of range (with respect to the Reference Data value), it is displayed in reverse video.

3.1.3 TT

For Calibration Plasma, Control Plasma, reagent preparation and handling, please refer to the manufacturer's instructions included with the kit.

Status Instrument **READY**. The last test executed is displayed in reverse.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	
=< to exit	

Action Move the cursor by means of the ↑↓←→ keys to select **TT** and press **ENTER**.

The "check" frame is displayed.

TT	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBIN LEVEL	POS.1
REFERENCE SOLUTION LEVEL	
↓ to start analysis	⇐ to exit

Status Usable rotor presence control.

Action Check that a usable rotor is present in the rotor holder.

Status Thrombin level.

Action Empty the thrombin bottle contents into reservoir 1 (MICRO) of the instrument, marked TT.

Status Reference solution level.

Action Make sure that the reference emulsion level is adequate; a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume, otherwise replace the bottle.

Load the sample tray, the Calibration Plasma in "POOL" position, the samples (18 maximum) and press ↓ to start analysis.

Status If during instrumental checks the rotor and/or samples are missing or used, the same conditions as described for the PT-Fibrinogen (PT-FIB) analysis.

DO NOT OPEN COVER	24.JULY.96 12:00
TT LOADING	
PLEASE WAIT	

The sampling phase begins (including the sensor test).

The instrument dispenses thrombin reagent, Calibration Plasma and samples into the rotor.

This is followed by the incubation and acquisition phases.

Note:

For flags and alarms related to the sampling/loading phase, refer to chapter 6, troubleshooting.

Action The operator is able to enter the Sample ID using the numerical keyboard and confirming the numbers with ENTER.

Status At the end of the acquisition phase after the calculation frame, the "results" frame is displayed.
TT results are expressed in seconds and ratio (if the Calibration Plasma is loaded on the sample tray and not in reverse).

TT RESULTS			24.JULY.96 12:00		
	s	R		s	R
1	12.4	1.09	11	12.4	1.09
2	12.7	1.11			
3	12.6	1.11	NP	11.4	
4	12.3	1.08			
5	12.2	1.07			
6	12.5	1.10			
7	12.4	1.09			
8	12.7	1.11			
9	12.4	1.09			
10	13.0	1.14			

PRT to print
<= to exit

It is possible to correct the Ratio calculation. For more details please refer to chapter 4 (Ratio Adjustment).

If a sample coagulates in less than the blank time or the fibrinogen is very low <60 mg/dL (for PT/TT/APTT), the message "COAG ERROR" is displayed instead of the result. If the sample does not coagulate within the maximum end time, the message "NOT COAG" is displayed instead of the result (refer to SPECIAL PROGRAMS - ACQUISITION TIME - Chapter 4).

If the Calibration Plasma of the analysis rotor is in range, the patient results are given in seconds and ratio.

If the Calibration Plasma of the analysis rotor is not within $\pm 20\%$ of the value in seconds of the Calibration Plasma Reference value, it is displayed and printed in reverse and the patient results are only given in seconds.

The message "RESULTS" in the "A" section of the video is followed by a question mark ("RESULTS ?").

If the Calibration Plasma is not loaded into the analysis rotor, the results are only expressed in seconds.

Action Pressing "<= to return" the instrument returns to the test menu. If the operator presses STOP in the "results" frame and within five seconds press ENTER, the instrument does not store the Calibration Plasma value for the S.P. (when it is in range).
If the Calibration Plasma value is out of range (with respect to the Reference Data value), it is displayed in reverse video.

3.1.4 PT-FIB/APTT

For Calibration Plasma, Control Plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kits.

Status Instrument READY.

The last test executed is displayed in reverse video.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
SINGLE FACTOR	
↑↓←→ to select ENTER to confirm	⇐ to exit

Action Move the cursor, by means of the ↑↓←→ keys to select PT-FIB/APTT and press ENTER.

The "check" frame is displayed.

PT-FIB/APTT	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBOPLASTIN LEVEL	POS.1
CEPHALIN LEVEL	POS.2
CALCIUM CHLORIDE LEVEL	POS.3
REFERENCE SOLUTION LEVEL	
CAL DATA (see PROG)	
↑ to calibrate ↓ to start analysts	⇐ to exit

Status Usable rotor presence.

Action Check that the usable rotor is present in the rotor holder.

Status Thromboplastin level.

Action Pour the thromboplastin bottle contents into reservoir 1 marked PT-FIB (MACRO) of the instrument.

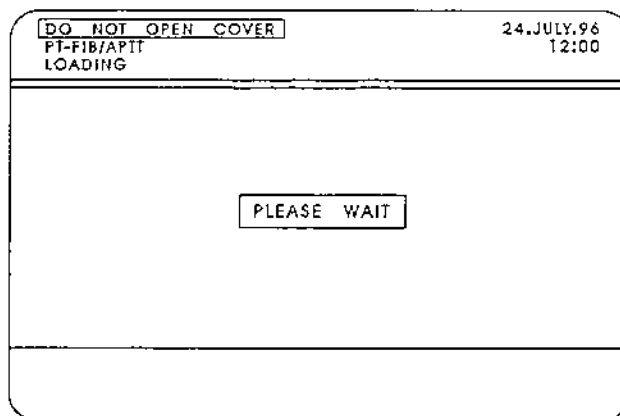
Status Cephalin level control.

Action Pour the cephalin bottle contents into reservoir 2 marked APTT (MACRO) of the instrument.

Status Calcium Chloride level control.

Action Pour the Calcium Chloride bottle content in reservoir 3 marked CaCl₂ (MACRO) of the instrument.

- Status** Reference solution level control.
- Action** Ensure that the reference solution level is adequate; a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume, otherwise replace the bottle.
 If the operator chooses ↑ to calibrate, the calibration is performed as described for the PT-FIB cycle.
 If the operator proceeds with the analysis, the sample tray must be loaded with the Calibration Plasma in "POOL" position, the samples (8 maximum) and press ↓ to start analysis.



- Status** If during instrumental checks the rotor and/or samples are missing or the rotor is used, the same conditions described for the PT-FIB cycle apply. The sampling phase for APTT begins (including the sensor test). The instrument dispenses Calibration Plasma, samples and reagent number 2 into the rotor. This is followed by the activation. Repositioning of the sample tray and the sampling phase for PT begins. The instrument dispenses Calibration Plasma, samples and reagent number 1 into the rotor. The rotor is again repositioned. Calcium chloride is dispensed, incubation and the acquisition phases follow.

Note:

For more details on Sample ID, please refer to chapter 4.

- Action** The operator is able to enter the Sample ID using the numerical keyboard and confirming the number.
- Status** At the end of the calculation and the acquisition phases, the "results" frame is displayed.
 PT results are expressed in seconds, activity and ratio (compared to the Calibration Plasma).
 Fibrinogen results are expressed in mg/dL or g/L, APTT results in seconds and ratio (compared to the Calibration Plasma).
 For more details on correction of the Ratio calculation refer to chapter 4 (Ratio Adjustment).
 The same conditions as described for the PT-FIB and APTT cycles apply.

PT-FIB/APTT RESULTS						24.JULY.96 12:00	
	PT			FIB	APTT		
	s	%	R	mg/dl	s	R	
1	11.7	92	1.03	271	27.8		
2	11.9	86	1.05	272	28.0		
3	11.9	86	1.05	281	27.7		
4	50.1	150	0.78	415	28.4		
5	not coag.				29.0		
6	7.35		0.64		27.7		
7	12.1	82	1.06	254	28.6		
8	13.3	63	1.17	166	39.6		
NP	11.4			244	NP	26.3	

PRT to print
=< to exit

Action Pressing =< the display returns to the main menu.
 If the operator presses STOP in the "results" frame and within five seconds ENTER, the instrument does not store the N.P. value for the Q.C. when it is in range.
 If the Calibration Plasma value is out of range (with respect to the Reference Data value), it is displayed in reverse.

3.1.5 TT/APTT

For Calibration Plasma, Control Plasma, reagents preparation and handling, please refer to the manufacturer's instructions included with the kit.

Status Instrument READY. The last test executed is displayed in reverse.

READY		24.JUL.96 12:00	
PT-FIB	DOUBLE TESTS		
APTT	ABS. TESTS		
TT	SPECIAL TESTS		
PT-FIB/APTT			
TT/APTT			
SINGLE FACTOR			

↑↓←→ to select
ENTER to confirm

=< to exit

Action Move the cursor, by means of the ↑↓ and ←→ keys to select TT/APTT test and press ENTER.
 The "check" frame is displayed.

TT/APTT	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBIN LEVEL	POS.1
CEPHALIN LEVEL	POS.2
CALCIUM CHLORIDE LEVEL	POS.3
REFERENCE SOLUTION LEVEL	
↓ to start analysis	⇐ to exit

Status Usable rotor presence.

Action Check that a usable rotor is present in the rotor holder.

Status Thrombin level.

Action Empty the thrombin bottle contents into reservoir 1 marked TT (MICRO) of the instrument.

Status Cephalin level.

Action Empty the cephalin bottle contents into reservoir 2 marked APTT (MACRO) of the instrument.

Status Indication for the Calcium Chloride level.

Action Empty the Calcium Chloride bottle contents in reservoir 3 marked CaCl₂ (MACRO) of the instrument.

Status Reference solution level.

Action Make sure that the reference emulsion level is adequate; a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume, otherwise replace the bottle.
Load the sample tray, the Calibration Plasma in "POOL" position, the samples (8 maximum) and press ↓ to start analysis.

DO NOT OPEN COVER	24.JULY.96
TT·APTT LOADING	12:00
PLEASE WAIT	

Status If during instrument checks the rotor and/or samples are missing or the rotor is used, the same conditions as described for the PT-FIB cycle apply. The sampling phase for APTT begins (including the sensor test). The instrument dispenses Calibration Plasma, samples and reagent number 2 into the rotor.

This is followed by the activation phase.

Repositioning of the sample tray and the sampling phase for TT begin. The instrument dispenses the Calibration Plasma, samples and reagent number 1 into the rotor.

Calcium chloride is dispensed, incubation and acquisition phases follow.

Note:

For more details on Sample ID, please refer to chapter 4.

Action The operator is able to enter the Sample ID using the numerical keyboard and confirming the number.

Status

For flags and alarms refer to chapter 6, troubleshooting.

At the end of the calculation and the acquisition phases, the "results" frame is displayed.

TT-APTT RESULTS		10.AUG.92 12:00		
— TT —		— APTT —		
	s	R	s	R
1	13.5	1.14	27.6	
2	12.7	1.07	28.5	
3	13.1	1.11	27.9	
4	13.0	1.10	28.8	
5	13.0	1.10	29.2	
6	13.0	1.10	28.1	
7	12.8	1.08	28.7	
8	18.8	1.59	38.5	
NP	11.8		NP	26.8

PRT to print
<= to exit

TT and APTT results are expressed in seconds and ratio compared to the Calibration Plasma.

For more details on correction of the Ratio calculation refer to chapter 4, Ratio Adjustment.

The same conditions as described for the TT and APTT cycles apply.

Action Pressing "<=" the display returns to the main menu.
If the operator presses STOP in the "results" frame and within 5 seconds, ENTER, the instrument does not store the N.P. APTT value for the Q.C. when it is in range.
If the Calibration Plasma value is out of range (with respect to the Reference Data value), it is displayed in reverse.

3.1.6 Factors

Pre-analytical phase

Factors are part of a group of tests that offer the possibility to store a calibration for the high curve, and use it for the subsequent runs.

SINGLE FACTOR		24,JUL,96 12:00
<u>EXTR. PATHWAY</u>	<u>INTR. PATHWAY</u>	
FACTOR II	FACTOR VIII	
FACTOR V	FACTOR IX	
FACTOR X	FACTOR XI	
FACTOR VII	FACTOR XII	
↑↓←→ to select ENTER to confirm		⇐ to exit

Selecting the Single Factor menu it is possible to decide starting from the specific factor the type of calibration curve to be executed.

EXTRINSIC FACTOR	24,JULY,96 12:00	
HIGH CURVE		
LOW CURVE		
↑ ↓ to select ENTER to confirm		⇐ to exit

According to the Extrinsic or Intrinsic factor being selected the indication on the screen will vary.

Extrinsic Factor

Factors of this pathway are : II, V, X and VII.

The CHECK frame will be shown.

If HIGH CURVE has been selected and no calibration has been stored, the message "NOT CALIBRATED" will be displayed.

If a calibration has been accepted then the message "CAL DATA (see PROG)" is displayed.

For LOW CURVE, the calibration is must be done every run and cannot be stored in memory. If the calibration curve selected is HIGH, the commands line will be the following:

FACTOR II	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBOPLASTIN LEVEL	POS.1
REFERENCE SOLUTION LEVEL	
↑ to start analysis and calibration ↓ to start analysis	⇐ to exit

If "↓" to start analysis option is selected without a stored calibration only the results in seconds will be presented.

If a LOW CURVE is selected, the commands line will be the following:

FACTOR II LOW	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
THROMBOPLASTIN LEVEL	POS.1
REFERENCE SOLUTION LEVEL	
↓ to start analysis	⇐ to exit

In both cases (HIGH or LOW CURVE) when calibration is required, the analytical condition frame is presented.

FACTOR II HIGH	24.JUL.96 12:00
FACTOR II HIGH ANALYTICAL CALIBRATION CONDITION	
N.P. LOT No.
THROMBOPLASTIN LOT. No.
DEFICIENT PLASMA LOT. No.
Key In new value ENTER to confirm	⇐ to exit

The PLACE frame for the calibration option in the HIGH CURVE is the following:

FACTOR II HIGH	24.JUL.96 12:00
PLACE	
N.P. IN *POOL* POSITION	100.0
EMPTY CUPS IN POS. No. 17 and No. 16	
FACTOR DILUENT IN *DIL* POSITION (2 mL CUP)	
DEFICIENT PLASMA IN POS. No. 18 (2mL CUP)	
SAMPLES (max. 15) STARTING FROM POS. No. 1	
Key In new value ENTER to confirm	← to exit

For the LOW CURVE the calibration frame is the following.

FACTOR II LOW	24.JUL.96 12:00
PLACE	
N.P. DILUTED 1 + 15 WITH FACTOR DILUENT IN *POOL* POSITION	6.25
EMPTY CUPS IN POS. No. 17 and 16	
FACTOR DILUENT IN *DIL* POSITION (2 mL CUP)	
DEFICIENT PLASMA IN POS. No. 18 (2mL CUP)	
SAMPLES (max. 15) STARTING FROM POS. No. 1	
Key In new value ENTER to confirm	← to exit

The instrument accepts input values for the calibration standard as follows:

- 70 - 130 % for the HIGH CURVE
- 4.3 - 8.2 % for the LOW CURVE

Any input can be corrected using the "DEL" key.

In the PLACE frame the instrument will display the default value.

In cases where it is not necessary to recalibrate (HIGH CURVE only with analysis), the following PLACE frame is presented.

FACTOR-II HIGH	24.JUL.96 12:00
PLACE:	
FACTOR DILUENT IN *DIL* POSITION (2 mL CUP)	
DEFICIENT PLASMA IN POS. No. 18 (2 mL CUP)	
SAMPLES (MAX 15) STARTING FROM POSITION No. 1	
↓ to continue	← to exit

Pressing the "↓" key triggers verification of the sample tray and rotor. If the calibration is executed, the following materials must be positioned on the sample tray.

- At least one sample (from position 1 to 15)
- Diluent in pos. DIL
- NP in pos. POOL
- Empty cups in pos. 17 and in pos. 16
- Deficient Plasma in pos. 18

After the analytical checks, the other phases begin (loading/incubation/acquisition). In the phase field the following status will be indicated (Loading, Activation, Incubation, Acquisition). During the analytical phase the message "PLEASE WAIT" will be indicated.

Intrinsic Factor

Factors of this pathway are: VIII, IX, XI, XII.

The CHECK frame will be shown.

If HIGH CURVE has been selected and no calibration has been stored, the message "NOT CALIBRATED" will be reported.

If a calibration has been accepted, the message "CAL DATA (see PROG)" will be indicated.

If the LOW CURVE has been selected no information will be given (low curve calibrations are always executed within the run).

If HIGH CURVE has been selected, the following command lines will be shown.

FACTOR-VIII HIGH	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE	
CEPHALIN LEVEL	POS. 2
CALCIUM CHLORIDE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
NOT CALIBRATED	
↑ to start analysis and calibration ↓ to start analysis	← to exit

If "↓" to start analysis option has been selected and no calibration has been stored, only results in seconds will be presented.

If the LOW CURVE has been selected, the commands line will be the following:

FACTOR VIII LOW	24.JUL.96 12:00
CHECK:	
USABLE ROTOR PRESENCE	
CEPHALIN LEVEL	POS. 2
CALCIUM CHLORIDE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
↓ to start analysis	⇐ to exit

In both cases (HIGH or LOW CURVE) when calibration is required the analytical condition frame is presented.

FACTOR VIII LOW	24.JUL.96 12:00
FACTOR-VIII LOW ANALYTICAL CALIBRATION CONDITION	
N.P. LOT No.
CEPHALIN LOT, No.
CALCIUM CHLORIDE LOT. No.
DEFICIENT PLASMA LOT, No.
Key in new value ENTER to confirm	⇐ to exit

The instrument accept input values for the calibration standard as follows:

- 70 - 130 % for the HIGH CURVE
- 4.3 - 8.2 % for the LOW CURVE

Any input can be corrected using the "DEL" key.

In the PLACE frame, the instrument will display the value assigned in the previous calibration.

In cases where it is not necessary to recalibrate (HIGH CURVE only with analysis), the following PLACE frame is presented.

FACTOR VIII HIGH	24.JULY.96 12:00
PLACE:	
FACTOR DILUENT IN 'DIL' POSITION [2 ml CUP]	
DEFICIENT PLASMA IN POS. No. 18 [2 ml CUP]	
SAMPLES (MAX 15) STARTING FROM POSITION No. 1	
NOT CALIBRATED	
↓ to continue	⇐ to exit

Pressing the "↓" key triggers verification of the sample tray and rotor. If calibration is executed, the following materials must be positioned on the sample tray.

- At least one sample (from position 1 to 15)
- Diluent in pos. DIL
- NP in pos. POOL
- Empty cups in pos. 17 and in pos. 16
- Deficient Plasma in pos. 18

After the analytical checks the other phases will begin (loading/incubation/acquisition). In the phase field the following status will be indicated:

- LOADING
- ACTIVATION
- INCUBATION
- ACQUISITION

During the analytical phases the message PLEASE WAIT is displayed.

Analytical results presentation

At the end of the analytical phase the results are presented.

Calibration results

The calibration is not shown but can be seen by pressing the PROG key for SPECIAL PROGRAMS menu, selecting the CAL DATA option and selecting the appropriate factor assay.

If the run has been completed, both "calibration and patients analysis" results will be shown. It is possible to see relative calibration data and curve by pressing "↑".

In the calibration frame using the "↓" key patient results will be shown. If the run was only analysis and no calibration was stored or the calibration in the run is not valid, the results of the patients are given only in seconds and the relative error message is shown.

- a) If the calibration standard or the diluent is missing from the sample tray positions, POOL, 17, 16, DIL respectively, the following messages are displayed:

NOT CALIBRATED
NO LIQUID "xx"

where xx is the position of the missing material.

- b) If a reagent is missing in pos. 18 and/or in the reagent reservoir 1 (extrinsic factor) or a reagent is missing in position 18 and/or in the reagent reservoirs 2 and/or 3 (intrinsic factor), the error message indicated is presented as follows:

WARNING see PROG and results will be flagged as "RESULTS ?"

FACTOR VIII HIGH RESULTS		24.JULY.96 12:00
F VIII h		
%	S	
100	47.7	
50	54.3	
25	60.6	
m = - 5.778 q = 2.008 r ² = 0.998		
↑ to see cal data and graphics ↓ to see analysis data		PRT to print = to save

Results are expressed in % activity and time in seconds.

The activity of the first standard point is represented by the value entered in the PLACE frame and the second and third point of the calibration is calculated according to the dilution ratio (1:2, 1:4).

- a) If an error occurs on the first standard, no results in % will be given and the following message appear:

NOT CALIBRATED
no first point

- b) If the error is both on the second and the third point of the calibration, the following message appear:

NOT CALIBRATED
insufficient data

- c) If the slope is out of range, the following message appear:

NOT CALIBRATED
slope out of range

In all these case the only patient results given will be in seconds.

- d) If there is an error on the second or the third point of the calibration, the message "2 Pnt Cal." will be shown in place of the correlation coefficient. Relative curve will be drawn using the 100 and 50%, or the 100 and 25%.

It is possible to print the calibration results and the calibration curve on request by pressing the PRT key.

Patient Results

Any errors will appear in the warning list with the message "RESULTS ?".

FACTOR VIII HIGH						24.JULY.96 12:00
	%	S	%	S		
1	29	70.2	11	27	70.9	
2	51	62.8	12	29	70.2	
3	99	55.2	13	51	62.8	
4	27	70.9	14	99	55.2	
5	29	70.2	15	27	70.9	
6	51	62.8				
7	99	55.2				
8		-0-			r ² = 0.995	
9	coag. error					
10	no sample					

↑ to see cal data and graphics PRT to print
↓ to see analysis data <= to save

If calibration has been executed, the command line will be as follow:

↑ to see cal data and graphics	PRT to print
↓ to see analysis data	<= to save

In the case of patient analysis only the command line will be:

	PRT to print
	<= to exit

Patient results will show :

- response expressed in seconds
- activity in % calculated on the base of the calibration curve
- correlation coefficient of the calibration or the message "2 Pnt Cal".

A non detectable curve will display an appropriate message (i.e. coag. error).

Activity out of range will be shown in reverse as underflow (—) or overflow (***)).

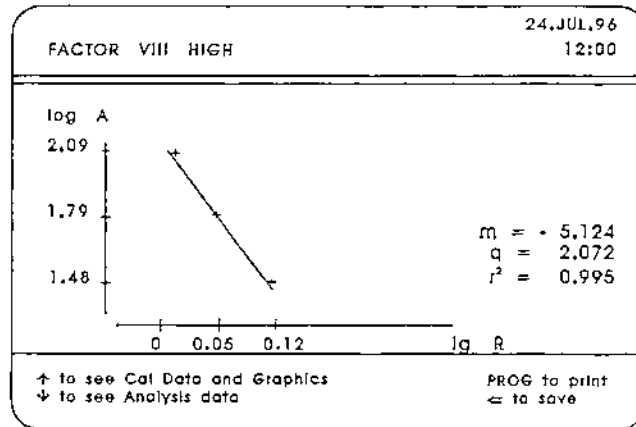
If the sample is missing or not sufficient, the message "no sample" appears.

If the printer is set on the automatic option, results are printed automatically.

Results associated with sample IDs will be memorized in the patient database.

If a calibration run only has been executed, return to the previous menu by pressing "<=". Use the key "↑" to see the data and the calibration graph.

Calibration curve graph



The calibration points (2 or 3), the associated curve and relative coefficients are presented.

PRT can be used to print the relative calibration.

If an error occurs in the graph construction, the following message is displayed:

"CALCULATION ERROR"

In this case the graph cannot be printed.

If a HIGH CURVE has been accepted with the calibration, pressing "<=" will require the user to accept the calibration curve or not.

In all other cases nothing is required when exiting this screen.
The command line will be changed:

↑ to not confirm
ENTER to confirm acceptable cal

Pressing ENTER will store the new calibration replacing any previous calibration existing.

3.1.7 Double Tests

For Calibration Plasma, Controls plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kits. Double test allows the instrument to test each sample in duplicate for PT-FIB, APTT, TT and PT-FIB/APTT. Results will be averaged on the printout only.

Status The last test executed is displayed in reverse video.

```
READY 24.JUL.96
12:00

PT-FIB
APTT
TT
PT-FIB/APTT
TT/APTT
SINGLE FACTOR
DOUBLE TESTS
ABS. TESTS
SPECIAL TESTS

↑↓←→ to select
ENTER to confirm           ⇐ to exit
```

Action Move the cursor by means of the ↑ and ↓ keys to select **DOUBLE TESTS** and press **ENTER**. The **DOUBLE TESTS** menu, which shows the sub-menu of the available double tests, is displayed.

```
DOUBLE TESTS 24.JULY.96
12:00

PT-FIB
APTT
TT
PT-FIB/APTT

↑ ↓ to select
ENTER to confirm           <= to exit
```

Move the cursor, by means of the ↑ and ↓ keys, to the double test desired and press **ENTER** to confirm.

Status The **DOUBLE TEST** is available for PT-FIB, APTT, TT and PT-FIB/APTT and differs from the normal cycles only in the number of samples which may be positioned on the sample tray and their dispensing into the rotor. It is possible to run a maximum of 9 samples + Calibration Plasma for PT-FIB, APTT and TT; a maximum of 4 samples for PT-FIB/APTT. The same sample is dispensed into two subsequent microcuvettes of the rotor. After having selected the type of double test to be carried out, everything proceeds as for a normal cycle (check, loading, calculation, acquisition).

Status The only difference from single tests appears in the "results" frame: two results are given for each sample.

TT DOUBLE RESULTS						24.JULY.96 12:00
	s	R		s	R	
1	12.3	1.07	6	12.5	1.09	
	12.3	1.08		12.5	1.10	
2	12.5	1.09	7	12.3	1.07	
	12.5	1.09		12.4	1.08	
3	12.4	1.08	8	12.5	1.10	
	12.6	1.09		12.5	1.09	
4	12.3	1.07	9	12.6	1.10	
	12.5	1.10		12.4	1.09	
5	12.2	1.07	NP	11.4		
	12.0	1.05				

PRT to print
← to exit

Only the mean of the two results of the sample is given on the printout.

Action In the "results" frame press ← to return to the Double Test menu. If the operator presses STOP in the "results" frame and ENTER within five seconds, the instrument will not store in the Q.C. (PT-FIB-APTT) the N.P. value, even if it is in range.

Note:

When the difference between the mean and the two results is higher than $\pm 5\%$ (mean $\pm 5\%$), or if at least one result is displayed in reverse video (but numerical), the mean value is printed in reverse (e.g. mean = 10 seconds - Control $\pm 5\%$ Limits; first value 9.5, second value 10.5. Outside these two values the mean is printed in the reverse format).

The flagging conditions valid for PT, APTT and TT are also valid for FIB when the difference between the mean and the two results is higher than $\pm 10\%$ (mean $\pm 10\%$).

When at least one value is in underflow/overflow formats the mean is not printed.

3.1.8.1 Heparin Xa

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse video.

Action Move the cursor by means of the ↑↓ and ←→ keys to select ABS. TESTS and press ENTER.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ keys to select HEPARIN Xa and press ENTER.

Status High curve is available.

ABS. TESTS	24.JULY,96 12:00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑↓ to select ENTER to confirm	

Action The operator must prepare the calibrator.

Heparin Calibrator

To prepare the heparin calibrators at 0.8 U/mL proceed as follows: using the same heparin utilized in your hospital for patient treatment, prepare a solution of 40 U/mL of this heparin.

Calibrator 0.8 U/mL: add 20 µL of heparin solution of 40 U/mL to one mL of fresh normal plasma pool.

Note:

Preparation of the 40 U/mL Heparin solution

For example: having heparin at the concentration of 25,000 U/mL, add 80 µL of this heparin to 50 mL of distilled water.

For example: having heparin at the concentration of 5,000 U/mL, add 80 µL of this heparin to 10 mL of distilled water.

Working diluent: to 11.5 mL of diluted diluent add 1 mL of dissolved AT-III.

Status After ENTER has been pressed, the "check" frame is displayed.
Usable rotor presence.

HEPARIN Xa	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE CLEANING SOLUTION LEVEL POS, 1 ENZYME LEVEL POS, 2 SUBSTRATE LEVEL POS, 3 REFERENCE SOLUTION LEVEL	
↑ to calibrate ↓ to start analysis	⇐ to exit

Action Check that a usable rotor is present in the rotor holder.

Status Cleaning solution level.

Action Empty the cleaning solution bottle contents into reservoir 1 (MICRO) of the instrument.

Status Enzyme level.

Action Empty the enzyme bottle contents into reservoir 2 marked E (MICRO) of the instrument.

Status Substrate level.

Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.

Note:

Label the reservoirs (micro E and S) with the appropriate stickers (marked HEP) included in the reservoir box.

Status Reference emulsion level.

Action Check that the reference solution level is adequate, a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume, otherwise replace the bottle.

Once the operator has carried out the necessary checks, press ↑ to calibrate.

HEPARIN Xa CAL	24.JULY.96 12:00
HEPARIN Xa ANALYTICAL CALIBRATION CONDITION N. P. LOT No. ENZYME LOT No. SUBSTRATE LOT No.	
Key In new value ENTER to confirm	= to exit

Status The instrument ask to enter the Lot Numbers of the material used.

Action Enter Calibrator, Enzyme and Substrate Lot Numbers. At the last ENTER the following frame appear.

HEPARIN HIGH	24.JULY.96 12:00
PLACE: CALIBRATOR IN "POOL" POSITION <input type="text" value="0.8"/> N.P. IN POSITION 18 WORKING DILUENT IN "DIL" POSITION (4 mL BIG CUP) EMPTY CUPS FROM POS. 1 TO POS. 12 AND IN POS. 17	
Key In new value ENTER to confirm	= to exit

Status The instrument indicates the positioning of the Calibrator, the normal plasma pool (0.00 U/mL), the working diluent and the empty cups. In this frame the operator is also requested to key in the heparin concentration of the Calibrator. This value is displayed in reverse.

HEPARIN Xa CAL	24.JULY.96 12:00
PLACE: CALIBRATOR IN "POOL" POSITION 0.8 N.P. IN POSITION 18 WORKING DILUENT IN "DIL" POSITION (4 mL BIG CUP) EMPTY CUPS FROM POS. 1 TO POS. 12 AND IN POS. 17	
↓ to start analysis	= to exit

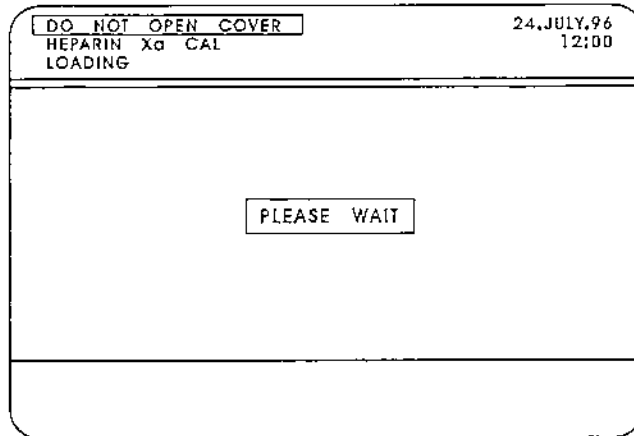
Note:

The value should be within the following range:

- High Curve: 0.64-0.96 U/mL

The calibration curve and relative dilutions are calculated according to the inserted value.

- Action** Key in the value of the Calibration Plasma and press ENTER.
The displayed values can be modified or confirmed by pressing ENTER.
Place the Calibrator in "POOL" position, the normal plasma pool in position 18, the working diluent and the empty cups into the correct positions.
Press "↓ to start analysis".



- Status** If during the instrumental checks the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.
- Action** The operator may key in the Sample ID using the numerical keyboard and confirming the number.
- Status** During incubation, the sampling arm with fluidic sensors checks the liquids presence.
- Warning** It is recommended not to remove the sample tray and the reagent reservoirs until the sensor check is ended.
For flags and alarms, please refer to section 6, Troubleshooting.
- Status** At the end of the acquisition the results are displayed.

Note:

If more than one calibration point or the first point (0.8 U/mL) is out of range the "not calibrated" frame is displayed instead of the "results" frame.

- Status** For HEPARIN the results are expressed in U/mL with respect to the calibration curve:

HIGH CURVE

0.8 U/mL

0.4 U/mL

0.0 U/mL

In addition, r^2 is reported which gives an indication of the acceptability of the correlation between the three points read.

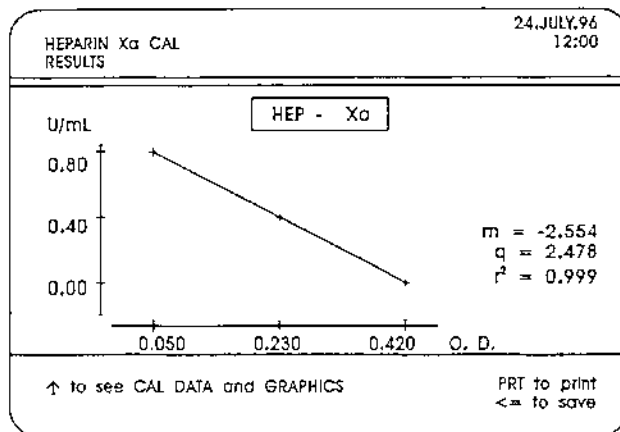
HEPARIN X ₀ CAL		24.JULY.96	
RESULTS		12:00	
U/ml	ΔOD		
0.80	0.352		
0.40	0.459		
0.00	0.571		
m = - 1.234 q = 0.445 r ² = 0.995			
↑ to see Cal Data and Graphics		PRT to print	
		⇐ to save	

Status In addition to the three point calibration, the r^2 , the slope (m) and the intercept are presented.
If one of the points (0.4 and 0.0 U/mL) is out of range, the curve is outlined on two points.
The out of range data are not presented and the message "2 POINT CAL" is displayed.
In cases where the first calibration point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Action Press "PRT" to print the calibration data.
Press "⇐" the operator is asked to accept or not the calibration.
If "↓" is pressed, the calibration curve graph is displayed.

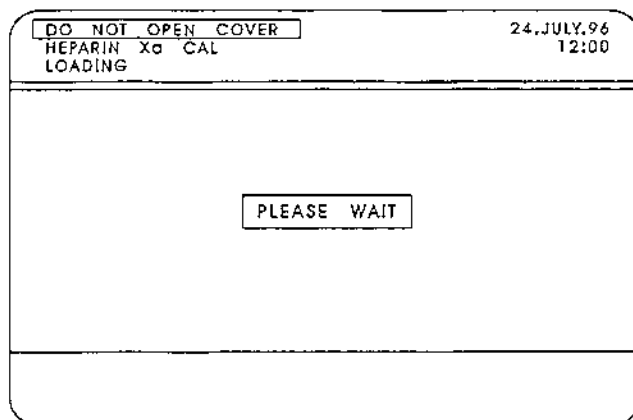
Status The calibration curve with its relative parameters (m, q, and r^2) is displayed.



Action Press "PRT" to print the calibration curve.
Press "←" and the operator is asked to accept or reject the calibration.

Heparin Xa Analysis

Status If analysis is selected the following frame appears.



Action Place the working diluent and the empty cups as indicated and press "↓" to start analysis.

Status At the end of the cycle (Loading, Incubation, Acquisition) the "results" frame is presented again. In the "results" frame and printout, the optical density of the samples is displayed close to the heparin concentration.

HEPARIN Xa RESULTS 10.AUG.92 12:00

	U/ml	ΔOD
1	0.59	0.259
2	0.94	0.065
3	1.00	0.046
4	0.32	0.359
5	0.17	0.423
6	0.15	0.445
7	0.26	0.347
8	0.32	0.359
9	0.32	0.359

PRT to print
← to exit

3.1.8.2 Heparin

For reagents preparation and handling, please refer to the manufacturer's instructions included with the kit (only Heparin Xa is currently available in the U.S.; Heparin IIa kit is not currently available in the U.S.).

Status Instrument READY.
The last test executed is displayed in reverse video.

Action Move the cursor by means of the $\uparrow\downarrow$ and $\leftarrow\rightarrow$ keys to select ABS. TESTS and press ENTER.

READY	24,JUL,96 12:00
PT-FIB	DOUBLE TESTS
APTT	ABS. TESTS
TT	SPECIAL TESTS
PT-FIB/APTT	
TT/APTT	
SINGLE FACTOR	
$\uparrow\downarrow\leftarrow\rightarrow$ to select ENTER to confirm	\leftarrow to exit

Action Move the cursor by means of the $\uparrow\downarrow$ keys to select HEPARIN and press ENTER.

Status High and Low curves are displayed.

ABS. TESTS	24,JULY,96 12:00
HEPARIN Xa	
HEPARIN	
AT-III	
PLASMINOGEN	
ANTIPLASMIN	
FIBRINOGEN-C	
PROCHROM	
D-DIMER	
$\uparrow\downarrow$ to select ENTER to confirm	\leftarrow to exit

Action The operator must prepare the calibrator.
Two different procedures must be followed according to the kind of heparin therapy (low or high doses) required.

Heparin Calibrators

To prepare the heparin calibrators at 0.8 U/mL and 0.2 U/mL proceed as follows: using the same heparin utilized in your hospital for patient treatment, prepare a solution of 40 U/mL of this heparin.

Calibrator 0.8 U/mL: add 20 μ L of heparin solution of 40 U/mL to one mL of fresh normal plasma pool.

Calibrator 0.2 U/mL: dilute calibrator 0.8 U/mL 1:4 with fresh normal plasma pool (1+3).

Note:

Preparation of the 40 U/mL Heparin solution

For example: having heparin at the concentration of 25,000U/mL, add 80 μ L of this heparin to 50 mL of distilled water.

For example: having heparin at the concentration of 5,000 U/mL, add 80 μ L of this heparin to 10 mL of distilled water.

HEPARIN (IIa) assay high doses: dilute calibrator 0.8 U/mL, samples and fresh normal plasma pool 1:30 (1+29) with working diluent.

HEPARIN (IIa) assay low doses: dilute calibrator 0.2 U/mL, samples and fresh normal plasma pool 1:15 (1+14) with working diluent.

Working diluent: to 5.6 mL of diluted buffer add 0.4 mL of dissolved AT-III.

Action Move the cursor by means of the \uparrow and \downarrow keys to the tests to the type of curve to be outlined and press ENTER to confirm the choice. The check frame is displayed.

Note:

The high or low choice is displayed adjacent to the selected test in the upper left hand corner of the screen.

In case of HIGH CURVE, the calibration can be stored and used for subsequent runs. For the LOW CURVE, the calibration is executed every run.

Status Usable rotor presence.

HEPARIN HIGH		24.JULY.96
		12:00
CHECK: USABLE ROTOR PRESENCE		
CLEANING SOLUTION LEVEL		POS. 1
ENZYME LEVEL		POS. 2
SUBSTRATE LEVEL		POS. 3
REFERENCE SOLUTION LEVEL		
NOT CALIBRATED		
\uparrow to start analysis and calibration		\leftarrow to exit
\downarrow to start analysis		

Action Check that a usable rotor is present in the rotor holder.

Status Enzyme level.

Action Empty the enzyme bottle contents into reservoir 2 marked E (MICRO) of the instrument.

Status Substrate level.
 Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.

Note:

Label the reservoirs (micro E and S) with the appropriate stickers (marked HEP) included in the reservoirs box.

Status Reference emulsion level.
 Action Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

Once the operator has carried out the necessary checks, he has to press ↑ to start analysis and calibration.

Before placing the Calibrator, the fresh normal plasma pool and the samples on the tray, the operator must carry out predilutions according to the curve selected as previously described.

Status The instrument indicates the positioning of the prediluted Calibrator, the prediluted fresh normal plasma pool and samples (15 maximum). In this frame the operator is also requested to key in the heparin concentration of the Calibration Plasma. This value is displayed in reverse video.

HEPARIN HIGH	24.JUL.96 12:00
PLACE:	
CALIBRATOR IN 'POOL' POSITION (DIL. WITH WORKING DILUENT)	0.80
N.P. IN 'DIL.' POSITION (DIL. WITH WORKING DILUENT)	
SAMPLES DILUTED WITH WORKING DILUENT (max 15) STARTING FROM POS. No. 1	
Key in new value ENTER to confirm	⇐ to exit

HEPARIN HIGH	24.JUL.96 12:00
PLACE:	
CALIBRATOR IN 'POOL' POSITION (DIL. WITH WORKING DILUENT)	0.80
N.P. IN 'DIL.' POSITION (DIL. WITH WORKING DILUENT)	
SAMPLES DILUTED WITH WORKING DILUENT (max 15) STARTING FROM POS. No. 1	
↓ to start analysis	⇐ to exit

Note:

The value should be within the following range:

- High Curve: 0.64-0.96 U/mL

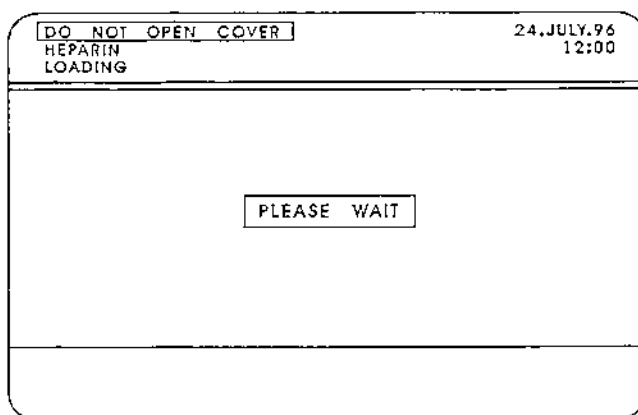
- Low Curve: 0.16-0.24 U/mL

The calibration curve and relative dilutions are calculated according to the inserted value.

Action Key in the value of the Calibration Plasma and then press ENTER. The displayed values can be modified or confirmed by pressing ENTER.

Place the prediluted Calibrator in "POOL" position, the prediluted fresh normal plasma pool in "DIL" position and the prediluted samples into the correct positions.

Press "↓ to start analysis".



Status If during the instrumental checks the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.

HEPARIN HIGH RESULTS						10.AUG.92 12:06
	U/ml	ΔOD		U/ml	ΔOD	
1	0.19	0.259	11	0.11	0.333	
2	0.24	0.265	12	0.17	0.347	
3	0.30	0.246	13	0.30	0.257	
4	0.22	0.259	14	0.25	0.261	
5	0.17	0.123	15	0.24	0.281	
6	0.15	0.345				
7	0.26	0.347				
8	0.22	0.259				
9	0.22	0.259				
10	0.19	0.262				
					r ² = 0.995	

↑ to see Cal Data and Graphics PRT to print
 ↓ to see Analysis Data ← to save

Action The operator may key in the Sample ID using the numerical keyboard and confirming the number.

- Status During incubation, the sampling arm with fluidic sensors checks the liquids presence.
- Warning It is recommended not to remove the sample tray and the reagent reservoirs until the sensor check is ended.
For flags and alarms, please refer to section 6, Troubleshooting.
- Status At the end of the acquisition the results are displayed.

Note:

If more than one calibration point or the first point (0.8 U/mL or 0.2 U/mL) is out of range, the "not calibrated" frame is displayed instead of the "results" frame.

- Status For HEPARIN the results are expressed in U/mL with respect to the calibration curve effected with the values from the first three cuvettes of the rotor:

HIGH CURVE	LOW CURVE
0.8 U/mL	0.2 U/mL
0.4 U/mL	0.1 U/mL
0.0 U/mL	0.0 U/mL

In addition, r^2 is reported which gives an indication of the acceptability of the regression line among the three points read.

HEPARIN LOW RESULTS		24.JULY.96 12:00
HEP	1	U/ml ΔOD
		0.20 0.352
		0.10 0.359
		0.00 0.371
$m = -1.234$ $a = 0.445$ $r^2 = 0.995$		
↑ to see Cal Data and Graphics		PRT to print ⇐ to exit

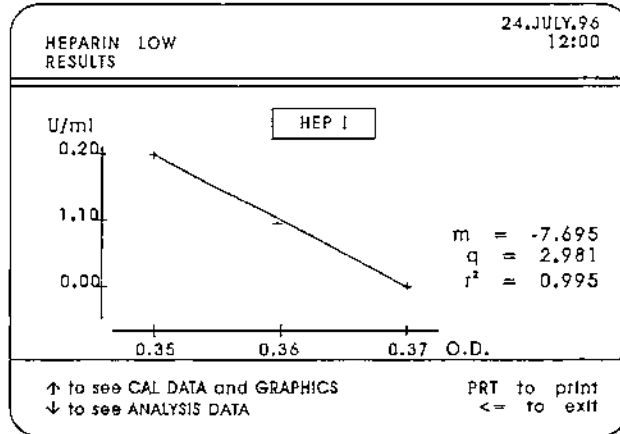
- Action By pressing "⇐" the operator is asked to save or not the calibration data.
By pressing "↑" it is possible to see the calibration data.

- Status In addition to the three point calibration, the r^2 , the slope (m) are presented.
If one of the points (0.4 and 0.0 for high curve or 0.1 and 0.0 for low curve) is out of range the curve is outlined on two points.
The out of range data are not presented the message "2 POINT CAL" is displayed.
In cases where the first calibration point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Action Press "PRT" to print the calibration data.
 Press "←" to return to the main menu.
 If "↑" to see cal data and graphics is pressed, the calibration curve graph is displayed.

Status The calibration curve with its relative parameters (m , q , and r^2) is displayed.



Action Press "PRT" to print the calibration curve.
 Press "←" the Operator is asked to accept or reject the calibration.
 Press ENTER to confirm acceptable Cal or Press ↑ to not confirm the calibration.
 Press "↓" to see Analysis Data.

HEPARIN HIGH RESULTS 10.AUG.92 12:00

	U/ml	ΔOD		U/ml	ΔOD
1	0.59	0.159	11	0.21	0.433
2	0.74	0.165	12	0.37	0.347
3	0.30	0.346	13	0.30	0.357
4	0.32	0.359	14	0.35	0.361
5	0.27	0.423	15	0.44	0.181
6	0.25	0.445			
7	0.26	0.447			
8	0.32	0.359			
9	0.32	0.359			
10	0.39	0.362			

$r^2 = 0.995$

↑ to see Cal Data and Graphics PRT to print
 ↓ to see Analysis Data ← to save

Status The "results" frame is presented again.

Note:

In the "results" frame and printout, the optical density of the samples is displayed close to the heparin concentration.

3.1.9 Antithrombin III

For Calibration Plasma, Control Plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select ABS. TESTS.

ABS. TESTS	24.JULY,96 12:00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑↓ to select ENTER to confirm	←= to exit

Action Move the cursor by means of the ↑ and ↓ keys to select AT-III and press ENTER.
The "check" frame appears.

AT-III	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE CLEANING SOLUTION LEVEL ENZYME LEVEL SUBSTRATE LEVEL REFERENCE SOLUTION LEVEL	POS. 1 POS. 2 POS. 3
CAL DATA see PROG	
↑ to calibrate ↓ to start analysis	← to exit

If the instrument is not calibrated, the Not Calibrated message will appear in reverse video. If the instrument is calibrated, the message CAL DATA (see PROG) will appear.

- Status Usable rotor presence.
 Action Check that a usable rotor is present in the rotor holder.
- Status Cleaning solution level.
 Action Place the cleaning solution in position 1.
- Status Thrombin level.
 Action Empty the thrombin bottle contents into reservoir 2 marked E (MICRO) of the instrument.
- Status Substrate level.
 Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.
- Note:*
 Label the reservoirs (micro E and S) with the appropriate stickers (market AT-III) included in the reservoirs box.
- Status Reference emulsion level.
 Action Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

3.1.9.1 AT-III Calibration

When the lot/s number of Calibration Plasma and/or reagents are changed and/or controls are out of range the calibration must be repeated.

- Action If “↑” is pressed in the “CHECK” frame , a calibration cycle is initiated.

AT-III CAL	24.JUL.96 12:00
AT-III ANALYTICAL CALIBRATION CONDITION	
N.P. LOT No.
ENZYME/SUBSTRATE LOT. No.
Key In new value ENTER to confirm	← to exit

Action The operator can key in new values or to continue by pressing ENTER.

AT-III CAL	24.JULY.96 12:00
PLACE	
N.P. IN 'POOL' POSITION	100,0
BUFFER IN 'DIL' POSITION (4 mL BIG CUP)	
BUFFER IN POS. 16	
EMPTY CUPS FROM POS. No. 1 TO POS. No. 12 AND IN POS. No. 18 and 17	
Key in new value ENTER to confirm	← to exit

In this frame the operator is also requested to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse.

Note:

The value should be within the range: 70-130%.

The Calibration curve and relative dilutions are calculated according to the inserted value.

AT-III CAL	24.JULY.96 12:00
PLACE	
N.P. IN 'POOL' POSITION	100,0
BUFFER IN 'DIL' POSITION (4 mL BIG CUP)	
BUFFER IN POS. 16	
EMPTY CUPS FROM POS. No. 1 TO POS. No. 12 AND IN POS. No. 18 and 17	
↓ to start analysis	← to exit

Action Key in the value of the Calibration Plasma and press ENTER. The displayed values can be modified or confirmed by pressing ENTER.

The operator places:

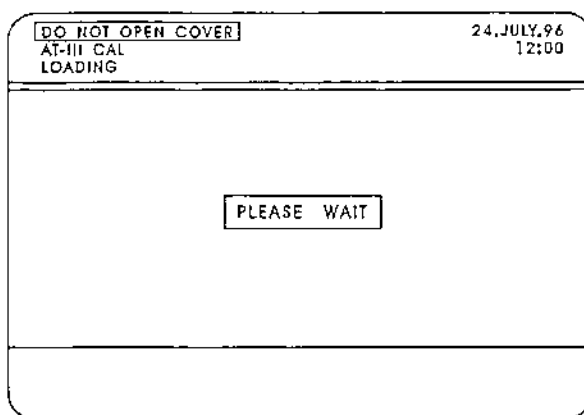
- the Calibration Plasma in "POOL" position,
- the diluted buffer in position "DIL" (using 4 mL cup),
- the diluted buffer in position 16,
- 12 empty cups from position 1 to 12 of the sample tray,
- empty cups in position 18 to 17.

Press "↓" to start analysis.

Notes:

- To avoid possible cross contamination problems due to the presence of polybrene (heparin inhibitor) in the AT-III substrate, the instrument performs an extra needle washing cycle (external needle) using position "DIL" of the sample tray where the diluted buffer of the kit is positioned.
- To avoid possible cross contamination problems due to the presence of thrombin (enzyme in position 2), the instrument performs an extra needle washing cycle (internal needle) using position 1 of the reagent reservoir where the cleaning solution is placed.

Status If during the instrumental check the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.



Afterwards the instrument loads 4 times the 100%, 4 times the 50% and 4 times the 25%. The instrument automatically carries out calibration dilutions.

Status During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.
For flags and alarms regarding sensors refer to section 6, Troubleshooting.

Status At the end of acquisition, the calibration data are displayed in terms of value expressed in activity and optical density corresponding to the 3 points (100% - 50% - 25%) and CV %.

AT-III CAL RESULTS		24.JULY.96 12:00	
	%	D OD	
AT-III	100	0.193	CV = 1.5
	50	0.421	CV = 2.0
	25	0.536	CV = 2.5
m = 273.2 q = 156.5 r ² = 1.000			
↑ to see Cal Data and Graphics		PRT to print ⇐ to save	

If relative CV % is outside the pre-established range values, the value is presented in reverse. Ranges are the following:

NP	(100%)	CV % =	8
NP	(50%)	CV % =	6
NP	(25%)	CV % =	4

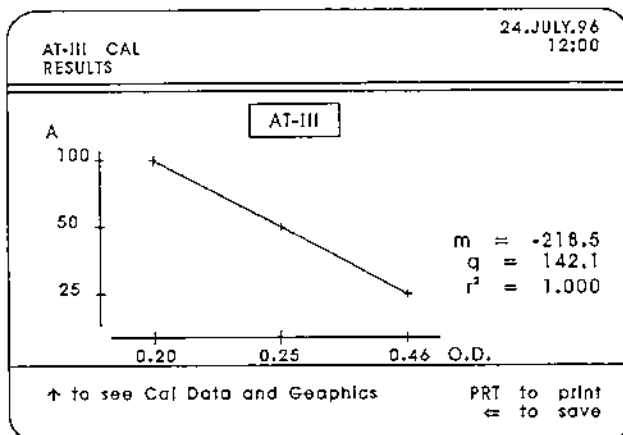
In cases where more than one point or the 100% point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Action Press PRT to print the calibration data.

If ↑ to continue is pressed, the calibration curve graph is displayed.

Status The calibration curve with relative parameters (m, q, and r²) is displayed.



Action By pressing PRT to print, the calibration data are printed.

Status Here it is possible to accept or reject the calibration.

Action Press ⇐ to return.

AT-III CAL RESULTS		24.JULY.96 12:00	
	%	D OD	
AT-III	100	0.193	CV = 1.5
	50	0.421	CV = 2.0
	25	0.536	CV = 2.5
m = 273.2 q = 156.6 r2 = 1.000			
↑ to see Cal Data and Graphics		PRT to print ← to save	

Status The operator is asked to confirm the acceptable calibration.

Action Press ENTER to confirm the choice.

Action In the calibration acceptance frame, press ↑ if the calibration is not acceptable.

3.1.9.2 AT-III Analysis

AT-III		24.JULY.96 12:00	
CHECK: USABLE ROTOR PRESENCE			
	CLEANING SOLUTION LEVEL	POS. 1	
	ENZYME LEVEL	POS. 2	
	SUBSTRATE LEVEL	POS. 3	
REFERENCE SOLUTION LEVEL			
CAL DATA (see PROG)			
↑ to calibrate		← to exit	
↓ to start analysis			

Action To carry out the analysis, the operator must press ↓ to start analysis in the "check" frame after having completed the required actions.

Status Before pressing ↓ to start analysis, the operator must load the sample tray as follows:

- Diluted buffer in "DIL" position (using 4 mL Big Cup)
- Samples (maximum 9) starting from position number 1
- Empty cups (maximum 9) starting from position number 10

Action Press ↓ to start analysis.

Status The sampling phase begins.

Note:

Additional needle washing is carried out as in AT-III CAL

Status If during the instrumental checks the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.

AT-III	24.JUL.96 12:00
PLACE: BUFFER IN 'DIL' POSITION (4 mL BIG CUP) SAMPLES (max 9) STARTING FROM POS. No. 1 EMPTY CUPS (max 9) STARTING FROM POS. No. 10	
↓ to start analysis	← to exit

DO NOT OPEN COVER	24.JULY.96 12:00
AT-III CAL LOADING	
PLEASE WAIT	

Status During the incubation phase, the sampling arm with fluidic sensors checks for liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms regarding sensors refer to section 6, Troubleshooting.

Status After acquisition, the results frame appears.

AT-III RESULTS			24.JULY,96 12:00
	%	Δ OD	
1	98	0.189	
2	51	0.174	
3	104	0.199	
4	92	0.186	
5	102	0.170	
6	47	0.199	
7	104	0.189	
8	98	0.173	
9	103	0.170	

PRT to print
<= to exit

Note:

For AT - III the results are expressed in activity with respect to the calibration curve stored in the memory.

- Action** Press <= to return to the ABS. menu.
Press PRT to print the results.

Note:

In the "results" frame and printout, the optical density of the samples is displayed near the activity.

- Status** If during sensors check the diluted buffer (DIL position of the sample tray) or the cleaning solution is missing (position 1 of the reagent reservoir), a "warning" frame is displayed before the main menu.

AT-III		24.JULY,96 12:00
ATTENTION:	ERROR CODE 25	
	BEFORE PROCEEDING REFER	
	TO THE OPERATOR'S MANUAL	
↓ to continue		

- Action** If extra washing has not been performed (because of the lack of diluted buffer or cleaning solution) or the cycle has been stopped by pressing STOP-ENTER, the operator must carry out a normal cleaning before starting a new cycle (refer to section 5, Maintenance). Press ↓ to continue and follow the directions for the normal cleaning procedure.

3.1.10 Plasminogen

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse video.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select ABS. TESTS and press ENTER.

ABS. TESTS	24.JULY.96 12:00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑↓ to select ENTER to confirm	←= to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select PLASMINOGEN and press ENTER.
The "check" frame is displayed.

PLASMINOGEN	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
STREPTOKINASE LEVEL	POS. 2
SUBSTRATE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
CAL DATA (see PROG)	
↑ to start analysis and calibration ↓ to start analysis	← to exit

- Status Usable rotor presence.
- Action Check that a usable rotor is present in the rotor holder.
- Status Streptokinase level control.
- Action Empty the streptokinase bottle contents into reservoir 2 marked E (MICRO) of the instrument.
- Status Substrate level control.
- Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.

Note:

Label the reservoirs (micro E and S) with the appropriate stickers (marked PLG) included in the reservoirs box.

- Status Reference Emulsion level .
- Action Make sure that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume). Press \downarrow to continue.
- Status Before placing the Calibration Plasma and the samples on the tray, the operator must carry out predilutions: 1 part of Calibration Plasma + 20 parts of diluted buffer, 1 part of sample + 20 parts of diluted buffer (1:21 Dilution).
- Action Press " \uparrow " to start analysis and calibration.
- Status The instrument indicates the positioning of the prediluted Calibration Plasma, diluted buffer and prediluted samples (15 maximum). In this frame the operator is also requested to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse.

Note:

The value should be within the range: 70-130%.

The calibration curve and relative dilutions are calculated according to the inserted value.

The calibration curve can be stored and used for subsequent runs.

PLASMINOGEN	24.JUL.96 12:00
<p>PLACE:</p> <p>N.P. IN "POOL" POSITION (PREDILUTED WITH BUFFER) 100.0</p> <p>BUFFER IN "DIL" POSITION</p> <p>SAMPLES (max 15) DILUTED WITH DILUENT STARTING FROM POS. NO.1</p>	
<p>Key in new value ENTER to confirm ⇐ to exit</p>	

Action Key in the value of the Calibration Plasma and press ENTER.

The displayed values can be modified or confirmed by pressing ENTER.

Place the prediluted Calibration Plasma in "POOL" position, the diluted buffer in "DIL" position and the prediluted samples into the correct positions.

Press ↓ to start analysis.

PLASMINOGEN	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL" POSITION (PREDILUTED WITH BUFFER)	90
BUFFER IN "DIL" POSITION	
SAMPLES (max 15) DILUTED WITH DILUENT STARTING FROM POS. NO.1	
↓ to start analysis	← to exit

Status If, during the instrumental checks, the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply.

DO NOT OPEN COVER	24.JULY.96
PLASMINOGEN	12:00
LOADING	
PLEASE WAIT	

The sampling phase begins and is followed by activation, loading, incubation and acquisition.

Action The operator may key in the Sample IDs using the numerical keyboard and confirming the number.

Status During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms related to this matter, refer to section 6, Troubleshooting.

Status At the end of the acquisition and calculation, the "results" frame appears.

Note:

If more than one calibration point or the 100% point is out of range the "not calibrated" frame is displayed instead of the results frame.

For Plasminogen the results are expressed in activity with respect to the calibration curve defined by the values from the first three cuvettes of the rotor (100% - 50% - 25%). In addition, r^2 is reported which gives an indication of the acceptability of the correlation between the three points.

PLASMINOGEN RESULTS						24.JULY.96 12:00
1	%	Δ OD	11	%	Δ OD	
2	88	0.320	12	110	0.362	
3	171	0.512	13	85	0.318	
4	104	0.357	14	83	0.316	
5	93	0.347	15	83	0.316	
6	89	0.340				
7	113	0.365				
8	93	0.357				
9	93	0.357				
10	126	0.380				$r^2 = 0.999$
	131	0.383				
↑ to see Cal Data and Graphics			PRT to print			
↓ to see Analysis data			← to save			

Action Press "←" the operator is asked to accept or reject the calibration.
Press "↑" to see the calibration data.

Status The values expressed in activity and optical density corresponding to the 3 points (100% - 50% - 25%) are displayed.

PLASMINOGEN RESULTS		24.JULY.96 12:00
%	Δ OD	
100	0.355	
50	0.159	
25	0.073	
$m = 1,234$ $q = 0,876$ $r^2 = 0,999$		
↑ to see CAL DATA and GRAPHICS		PRT to print
↓ to see analysis data		← to save

If one of the points 50% or 25% is out of range, the curve is outlined on two points.

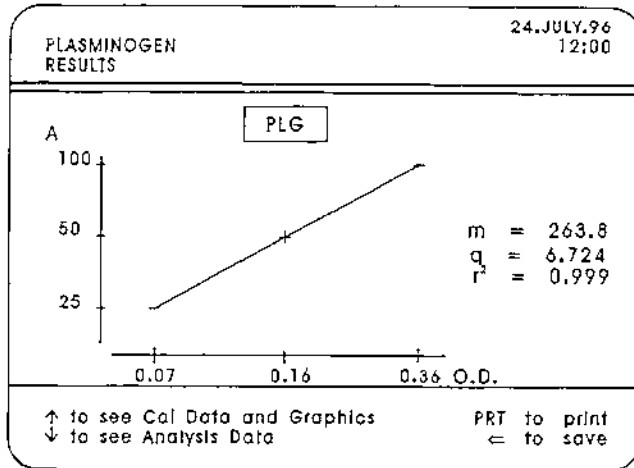
The data beyond the limits are not presented and, the message "2 POINT CAL" is displayed.

In cases where more than one point or the 100% point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Action Press "PRT" to print the calibration data.
 If "↑" to see Cal Data and Graphics is pressed, the calibration curve graph is displayed.

Status The calibration curve with relative parameters (m , q , and r^2) is displayed.



Action Press "PRT" to print the calibration graph.
 Press "↓ to see analysis data" the "results" frame appears.

Status The "results" frame is presented.

PLASMINOGEN RESULTS			24.JULY.96 12:00		
1	88	0.320	11	110	0.362
2	171	0.512	12	85	0.318
3	104	0.357	13	83	0.316
4	93	0.347	14	83	0.316
5	89	0.340	15	89	0.340
6	113	0.365			
7	93	0.357			
8	93	0.357			
9	126	0.380			$r^2 = 0.999$
10	131	0.383			

↑ to see Cal Data and Graphics PRT to print
 ↓ to see Analysis data ← to return

Action Press "PRT" to reprint the results.
 Press "←" to save or not the calibration data and return to the main menu.

Note:

In the "results" frame and printout, the optical density of the sample is displayed near the activity.

3.1.11 Alpha-2-Antiplasmin

For calibration Plasma, Controls plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse video.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select ABS. TESTS and press ENTER.

ABS. TESTS	24.JULY.96 12:00
HEPARIN Xo HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑↓ to select ENTER to confirm	

Action Move the cursor by means of the ↑↓ keys to select ANTIPLASMIN and press ENTER.
The "check" frame is displayed.

ANTIPLASMIN	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
PLASMIN LEVEL	POS. 2
SUBSTRATE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
CAL DATA (see PROG)	
↑ to start analysis and calibration ↓ to start analysis	← to exit

- Status Usable rotor presence.
- Action Check that a usable rotor is present in the rotor holder.
- Status Plasmin level.
- Action Empty the plasmin bottle contents into reservoir 2 marked E (MICRO) of the instrument.
- Status Substrate level.
- Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.

Note:

Label the reservoirs (micro E and S) with the appropriate stickers (marked AT-PL) included in the reservoirs box.

- Status Reference emulsion level.
- Action Make sure that the Reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.
- Action Press "↑" to start analysis,
- Status The instrument indicates the positioning of the prediluted Calibration Plasma, diluted buffer and prediluted samples (15 maximum).

ANTIPLASMIN		24.JUL.96 12:00
PLACE:	N.P. IN 'POOL' POSITION (PREDILUTED WITH BUFFER)	100.0
	BUFFER IN 'DIL' POSITION	
	SAMPLES [max 15] DILUTED WITH DILUENT STARTING FROM POS. NO.1	
Key In new value ENTER to confirm		= to exit

In this frame the operator is also requested to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse video.

Note:

The value should be within the range: 70-130%.

The calibration curve and relative dilutions are calculated according to the inserted value.

The calibration can be stored and used for subsequent runs.

- Action Key in the value of the Calibration Plasma and press ENTER. The displayed values can be modified or confirmed by pressing ENTER.

Before placing the Calibration Plasma and the samples on the tray, the operator must carry out predilutions: 1 part of Calibration Plasma + 10 parts of diluted buffer (1:11 Dilution).

Place the prediluted Calibration Plasma in "POOL" position, the diluted buffer in "DIL" position and the prediluted samples into the assigned positions.

Press ↓ to start analysis.

ANTIPLASMIN		24.JUL.96 12:00
PLACE:		
N.P. IN "POOL" POSITION (PREDILUTED WITH BUFFER)		100.0
BUFFER IN "DIL" POSITION		
SAMPLES (max 16) DILUTED WITH DILUENT STARTING FROM POS. NO.1		
↓ to start analysis		← to exit

Status If, during the instrument checks, the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins; it is followed by activation, loading, incubation and acquisition.

DO NOT OPEN COVER	24.JUL.96 12:00
ANTIPLASMIN LOADING	
PLEASE WAIT	

Action The operator may key in the Sample IDs using the numerical keyboard and confirming the number.

Status During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms, refer to section 6, Troubleshooting.

Status At the end of the acquisition and the calculation phases, the results frame is displayed.

ANTIPLASMIN RESULTS						24.JULY.96 12:00
	%	Δ OD		%	Δ OD	
1	123	0.462	11	117	0.480	
2	54	0.583	12	98	0.510	
3	118	0.474	13	111	0.484	
4	63	0.584	14	108	0.490	
5	117	0.321	15	184	0.270	
6	174	0.576				
7	63	0.474				
8	118	0.470				
9	120	0.460				$r^2 = 0.998$
10	127	0.484				

↑ to see Cal Data and Graphics PRT to print
 ↓ to see Analysis Data ← to save

Note:

If more than one calibration point or the 100% point is out of range, the "not calibrated" frame is displayed instead of the "results" frame.

For ANTIPLASMIN, the results are expressed in activity with respect to the calibration curve obtained from the values from the first three cuvettes of the rotor (100% - 50% - 25%). In addition r^2 is reported which gives an indication of the acceptability of the regression line between the three points.

Action Press "↑" to see the calibration data.

Status In addition to the three points of the calibration, the r^2 , the slope (m) and the intercept (q) are presented.

ANTIPLASMIN RESULTS			24.JULY.96 12:00
	%	Δ OD	
	100	0.500	
	50	0.585	
	25	0.636	
$n = 233.9$ $q = 167.9$ $r^2 = 0.998$			

↑ to see Cal Data and Graphics PRT to print
 ↓ to see Analysis Data ← to save

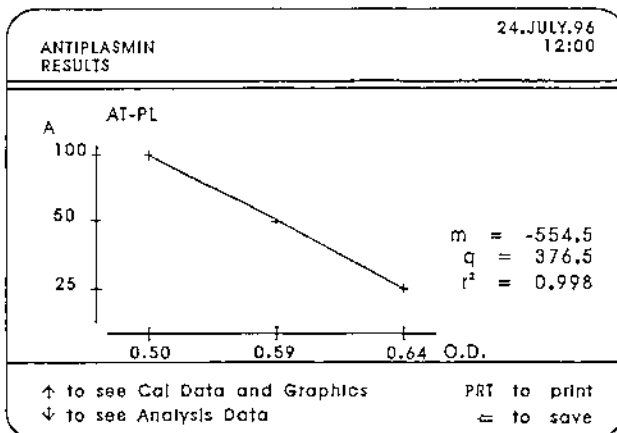
If one of the points 50% or 25% is out of range, the curve is outlined on two points.

Out of range data are not presented and the message "2 POINT CAL" is displayed.

In cases where more than one point or the 100% point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1* POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

- Action** Press "PRT" to print the calibration data.
 If "↑" is pressed, the calibration curve graph is displayed.
- Status** The calibration curve with relative parameters (m, q, and r²) is displayed.



- Action** Press "PRT" to print the calibration curve.
 Pressing "←" the operator is asked to confirm or reject the calibration.
- Pressing "↓ to see Analysis Data" to return to the "results" frame.
- Status** The "results" frame returns.

24.JULY.96
12:00

ANTIPLASMIN RESULTS

	%	ΔOD		%	ΔOD
1	123	0.462	11	117	0.480
2	54	0.583	12	98	0.510
3	118	0.474	13	111	0.484
4	53	0.584	14	108	0.490
5	117	0.321	15	184	0.270
6	174	0.576			
7	63	0.474			
8	118	0.470			
9	120	0.460			r ² = 0.998
10	127	0.484			

↑ to see Cal Data and Graphics PRT to print
↓ to see Analysis Data ← to save

- Action** Press "PRT" to reprint the results.

Note:

In the "results" frame and printout, the optical density of the samples is displayed near the activity.

3.1.12 Fibrinogen-C

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instruction included with the kit.

Status Instrument READY.

The last test executed is displayed in reverse video.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓↔ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ and ↔ keys to select ABS. TESTS and press ENTER.

ABS. TESTS	24.JULY.96 12:00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM D-DIMER	
↑↓ to select ENTER to confirm	←= to exit

Status The last test executed is displayed in reverse.

Action Move the cursor by means of the ↑↓ and ↔ keys to select FIBRINOGEN-C and press ENTER.

FIBRINOGEN-C	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE CLEANING SOLUTION POS. 1 THROMBIN LEVEL POS. 2 REFERENCE SOLUTION LEVEL	
CAL DATA [see PROG]	
↑ to calibrate ↓ to start analysis	← to exit

The "check" frame appears.

It is possible to select ↑ to calibrate or ↓ to start the analysis.

- Status Usable rotor presence.
- Action Check that a usable rotor is present in the rotor holder.
- Status Cleaning Solution level.
- Action Fill the reservoir Micro 1 (CLEAN) with the appropriate quantity of Cleaning Solution. Magnetic stir bar is not needed.
- Status Thrombin level.
- Action Empty the Thrombin vial content into the reservoir Micro 2 (FIB-C). Magnetic stir bar is not needed.
- Status Reference emulsion level.
- Action Make sure that the Reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

In case the instrument does not have a stored calibration, the check frame will show "NOT CALIBRATED".

If the instrument has a calibration in the memory, than the check frame will show "CAL DATA (see PROG)".

3.1.12.1 FIB-C Calibration

If in the check frame "↑" is pressed to calibrate the analytical conditions frame appears.

FIB-C CAL		24.JULY.96 12:00
FIBRINOGEN-C ANALYTICAL CALIBRATION CONDITIONS		
N. P. Lot, No.	
THROMBIN LOT, No.	
key in new value ENTER to confirm		<= to exit

In this frame the operator is asked to key in the Calibration Plasma Lot number (N,P. ID) and the reagent Lot No. (Thrombin Lot No.).

- Action Press ENTER to display the "place" frame.

FIB-C CAL	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL" POSITION	300
FACTOR DILUENT IN "DIL" POSITION (2 mL CUP)	
Key in new value ENTER to confirm	← to exit

In this frame the operator is asked to key in the Fibrinogen-C value of the Calibration Plasma in mg/dL or g/L (according to the selection done in PROG-UNITS). The value is displayed in reverse.

Note:

The value must be within the range 200-350 mg/dL (2.0 - 3.5 g/L), or the value will not be accepted and the cursor remains in place.

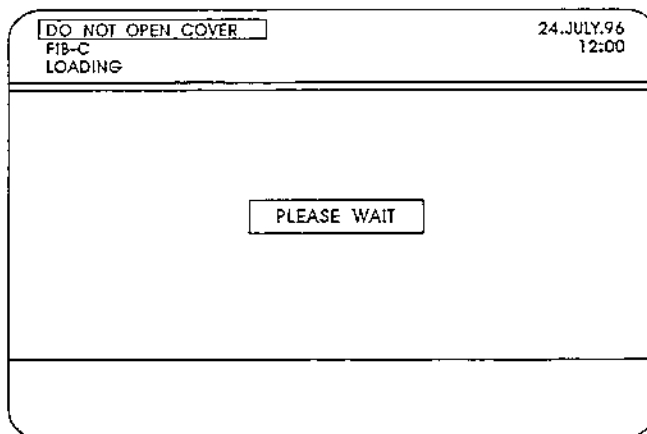
The calibration curve and relative dilutions are calculated according to the inserted value.

FIB-C CAL	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL" POSITION	300
FACTOR DILUENT IN "DIL" POSITION (2 mL CUP)	
↓ to start analysis	← to exit

Action Key in the Fibrinogen-C value of the Calibration Plasma indicated in the insert sheet and press ENTER. The displayed values can be modified or confirmed by pressing ENTER.

Place the Calibration Plasma in "POOL" position, the Factor diluent in "DIL" position (use 2 mL cups).

Press ↓ to start analysis.



Status The sampling phase begins and is followed by loading, incubation and acquisition.
During the incubation phase the sampling arm checks the liquids presence.
The instrument loads each standard point of the calibration four times.

Warning Do not remove the sample tray or the reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.

Status At the end of acquisition and calculation the calibration data are displayed in terms of values expressed in mg/dL (or g/L) and in seconds corresponding to the three points of the calibration curve (mean value + CV + curve parameters).
For example, if the Calibration Plasma is assigned to be 300 mg/dL, the calibration curve will be as follows:

- 450 mg/dL (150% of the Calibration Plasma - CV limits 1.5)
- 300 mg/dl (100% of the Calibration Plasma - CV limits 2.0)
- 150 mg/dL (50% of the Calibration Plasma - CV limits 2.5).

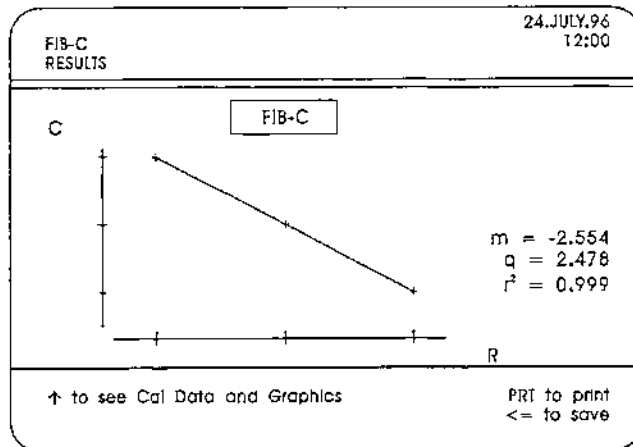
FIBRINOGEN-C RESULTS		24.JULY.96 12:00	
mg/dL	s		
450	7.2	CV = 0.90	
300	9.9	CV = 0.62	
150	20.7	CV = 2.17	
m = 2.538 q = 2.506 r2 = 0.999			
↑ to see Cal Data and Graphics		PRT to print	
↓ to see Analysis Data		← to save	

Action Press "↑" to see the calibration graph.
Press "←" to accept or reject the calibration.

Status In cases where one more points are out of range, a message is displayed, in place of the "results" frame, as follows:

- NOT CALIBRATED: NO 1st POINT
- NOT CALIBRATED: INSUFFICIENT DATA
- NOT CALIBRATED: SLOPE OUT OF RANGE.

Action Press "PRT" to print the calibration data.
If "↑" is pressed, the calibration curve graph is displayed.



Action Press "PRT" to print the calibration graph.
Press "←" to accept or reject the calibration.
By pressing ENTER the calibration is accepted and saved.
By pressing "↑", not to confirm, the calibration is not accepted.

3.1.12.2 FIB-C Analysis

Press "↓" to start analysis in the check frame to begin analysis.
The "place" frame will appear.

FIB-C 24.JULY.96 12:00

PLACE:

FACTOR DILUENT IN "DIL" POSITION [4 mL BIG CUP]

SAMPLES [max. 18] STARTING FROM POS. No. 1

↓ to start analysis <=> to exit

The operator must place the Factor diluent in "DIL" position (please use 4 mL BIG CUP) and samples (maximum 18) starting from position number 1. The loading, incubation and acquisition phases will follow.
At the end, the RESULTS frame will appear.

FIB-C RESULTS		24.JULY.96 12:00			
	mg/dL	s	mg/dL	s	
1	285	10.5	11	308	9.8
2	291	10.3	12	294	10.2
3	311	9.7	13	311	9.7
4	288	10.4	14	315	9.6
5	308	9.8	15	285	10.5
6	315	9.6			
7	294	10.2			
8	291	10.3			
9	288	10.4			
10	285	10.5			

PRT to Print
<= to exit

Action Press "PRT" to print the results.
Press "<" to return to the ABS. menu.

Status If extra washing has not been performed because of the lack of the Cleaning solution, or the cycle has been stopped by pressing STOP-ENTER, a "Warning" frame appears and the operator must carry out a manual cleaning procedure before starting a new cycle.

The extra washing cycle is needed to eliminate the thrombin residual from the needle and to avoid potential carry-over.

Press "↓" to continue and follow the indications described in the ACL Operator's Manual.

FIB-C		24.JULY.96 12:00	
ATTENTION:	ERROR CODE 25		
	BEFORE PROCEEDING REFER		
	TO THE OPERATOR'S MANUAL		
↓ to continue			

3.1.13 Pro-Chrom

For Calibration Plasma, Control plasma, reagents preparation and handling, refer manufacturer's instruction included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse video.

```
READY 24.JUL.96 12:00
-----
PT-FIB
APTT
TT
PT-FIB/APTT
TT/APTT
SINGLE FACTOR

DOUBLE TESTS
ABS. TESTS
SPECIAL TESTS

↑↓↔ to select
ENTER to confirm          ← to exit
```

Action Move the cursor by means of the ↑↓ and ↔ keys to select ABS. TESTS and press ENTER.

```
ABS. TESTS 24.JULY.96 12:00
-----
HEPARIN Xo
HEPARIN
AT-III
PLASMINOGEN
ANTIPLASMIN
FIBRINOGEN-C
PROCHROM
D-DIMER

↑↓ to select
ENTER to confirm          ← to exit
```

Action Move the cursor by means of the ↑↓ keys to select PROCHROM and press ENTER. The check frame is displayed.

```
PROCHROM 24.JUL.96 12:00
-----
CHECK: USABLE ROTOR PRESENCE

ENZYME LEVEL POS. 2
SUBSTRATE LEVEL POS. 3
REFERENCE SOLUTION LEVEL

NOT CALIBRATED

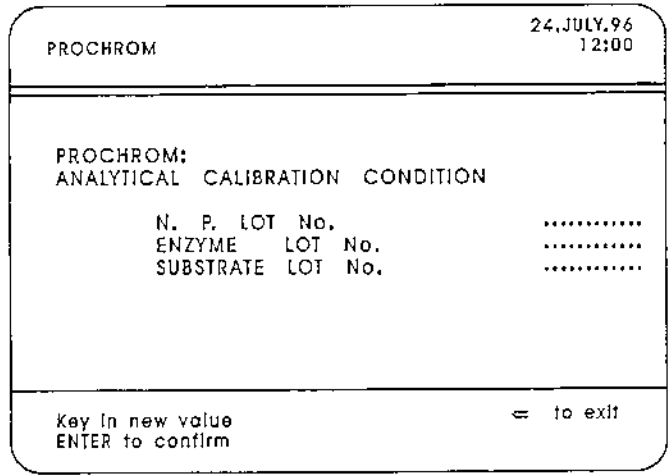
↑ to start analysis and calibration
↓ to start analysis          ← to exit
```

- Status Usable rotor presence.
- Action Check that a usable rotor is present in the rotor holder.
- Status Enzyme level.
- Action Empty the enzyme bottle contents into reservoir 2 marked E (MICRO) of the instrument.
- Status Substrate level.
- Action Empty the substrate bottle contents into reservoir 3 marked S (MICRO) of the instrument.

Note:

Label the reservoirs (micro E and S) with the appropriate sticker included in the reservoirs box.

- Status Reference Emulsion level.
- Action Make sure that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.
Press ↑ to start analysis and calibration.
- Status The analytical calibration conditions appear.



- Action Key in the required Lot Numbers.
- Status The instrument indicates the positioning of the Calibration Plasma, diluents and samples (15 maximum).
In this frame the operator is also asked to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse.

Note:

*The value should be within the range: 70-130%.
The calibration curve and relative dilutions are calculated according to the inserted value.*

PROCHROM	24.JUL.96 12:00
PLACE: N.P. IN "POOL" POSITION 100.0 PROCHROM DILUENT IN "DIL" POSITION PROCHROM DILUENT IN POS.No.18 (2 mL CUP) SAMPLES (MAX 15) STARTING FROM POS. No. 1	
Key in new value ENTER to confirm	← to exit

Action Key in the value of the Calibration Plasma and press ENTER. The displayed values can be modified or confirmed by pressing ENTER. The operator places the Calibration Plasma in "POOL" position, the diluent in "DIL" position and in position 18, and the samples into the correct positions. Press ↓ to start analysis.

PROCHROM	24.JUL.96 12:00
PLACE: N.P. IN "POOL" POSITION 100.0 PROCHROM DILUENT IN "DIL" POSITION PROCHROM DILUENT IN POS.No.18 (2 mL CUP) SAMPLES (MAX 15) STARTING FROM POS. No. 1	
↓ to start analysis	← to exit

Status If, during the instrument check, the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply.

DO NOT OPEN COVER	24.JULY.96 12:00
PROCHROM LOADING	
<div style="border: 1px solid black; padding: 5px; display: inline-block;">PLEASE WAIT</div>	

The sampling phase begins and is followed by loading, activation, incubation, acquisition.

- Action** The operator may key in the Sample ID using the numerical keyboard and confirm the number.
- Status** During the incubation phase the sampling arm with fluidic sensors checks the liquid presence.
- Warning** Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms related to this matter, refer to section 6, Troubleshooting.

Note:

If more than one calibration point or the 100% point is out of range, the "not calibrated" frame is displayed instead of the results one.

For ProChrom the results are expressed in activity with respect to the calibration curve defined by the values from the first three cuvettes of the rotor (100% - 50% - 25%). In addition, r^2 which gives an indication of the acceptability of the regression line between the three points read is reported.

PROCHROM RESULTS			24.JULY,96 12:00		
	%	ΔOD		%	ΔOD
1	88	0.320	11	110	0.362
2	104	0.512	12	86	0.318
3	104	0.357	13	83	0.316
4	93	0.347	14	83	0.316
5	89	0.340	15	89	0.340
6	113	0.365			
7	93	0.357			
8	93	0.357			
9	126	0.380			
10	131	0.383			
					$r^2 = 0.999$
↑ to see Cal Data and Graphics			PRT to print		
↓ to see Analysis Data			← to save		

- Action** Press "←" to save calibration and the screen returns to the main menu.
Press "↑" to see the calibration data.

Status The value expressed in activity and optical density corresponding to the 3 points (100% - 50% - 0%) are displayed.

PROCHROM RESULTS		24.JULY,96 12:00	
%	ΔOD		
0	0.000		
50	0.128		
100	0.238		
 m = 420.3 q = -1.376 r2 = 0.998 			
↑ to see Cal Data and Graphics		PRT to print	
↓ to see Analysis Data		← to save	

If one of the points 50% or 0% is out of range, the curve is outlined on two points.

The data beyond the limits are not presented and the message "2 POINT CAL" is displayed.

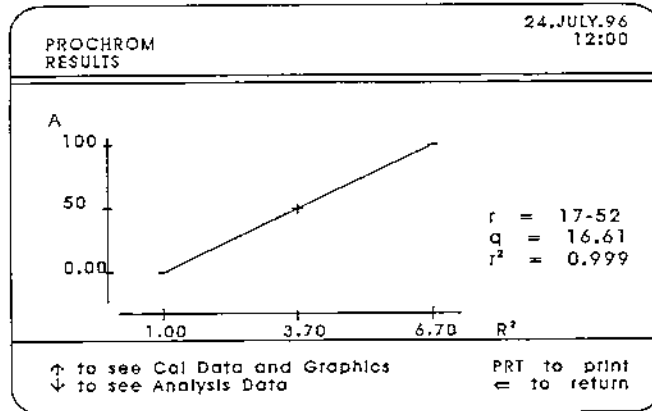
In cases where more than one point or the 100% point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED; NO 1st POINT"
- "NOT CALIBRATED; INSUFFICIENT DATA"
- "NOT CALIBRATED; SLOPE OUT OF RANGE"

Action Press "PRT" to print the calibration data.

If "↑" is pressed, the calibration curve graph is displayed.

Status The calibration curve with relative parameters (m, q, and r²) is displayed.



Action Press "PRT" to print the calibration graph.

Press "↓" to present again the "results Analysis Data" frame.

Status The "results" frame returns.

PROCHROM RESULTS						24.JULY.96 12:00	
	%	ΔOD		%	ΔOD		
1	88	0.320	11	110	0.362		
2	104	0.512	12	85	0.318		
3	104	0.357	13	83	0.316		
4	93	0.347	14	83	0.316		
5	89	0.340	15	89	0.340		
6	113	0.365					
7	93	0.357					
8	93	0.357					
9	126	0.380					
10	131	0.383					r ² = 0.999

↑ to see Cal Data and Graphics PRT to print
↓ to see Analysis Data ← to save

Action Press "PRT" to print the results.

Pressing "←" the operator is asked to accept or reject the calibration.

Note:

In the "results" frame and printout, the optical density of the sample is displayed near the activity.

Status If only analysis is selected.

PROCHROM	24.JUL.96 12:00
PLACE: PROCHROM DILUENT IN POS.No.18 (2 mL CUP) SAMPLES (MAX 15) STARTING FROM POS. No. 1	
↓ to start analysis	← to exit

Action Press ↓ to start analysis.

Status If, during the instrument checks, the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply.

DO NOT OPEN COVER	24.JULY.96
PROCHROM LOADING	12:00
PLEASE WAIT	

The sampling phase begins and is followed by activation, loading, incubation, acquisition.

Action The operator may key in the Sample ID using the numerical keyboard and confirm the number.

Status During the incubation phase the sampling arm with fluidic sensors checks the liquid presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms related to this matter, refer to section 6, Troubleshooting.

Note:

In the "results" frame and printout, the optical density of the sample is displayed near the activity.

PROCHROM RESULTS			24.JULY.96 12:00		
	%	ΔOD		%	ΔOD
1	88	0.320	11	110	0.362
2	121	0.372	12	85	0.318
3	104	0.357	13	83	0.316
4	93	0.347	14	83	0.316
5	89	0.340	15	89	0.340
6	113	0.365			
7	93	0.357			
8	93	0.357			
9	126	0.380			
10	131	0.383			

PRT to print
← to exit

3.1.14 D-Dimer

For Calibrator, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse.

READY	24.JUL.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS <u>ABS. TESTS</u> SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select ABS. TESTS.

ABS. TESTS	24.JULY,96 12:00
HEPARIN Xa HEPARIN AT-III PLASMINOGEN ANTIPLASMIN FIBRINOGEN-C PROCHROM <u>D-DIMER</u>	
↑↓ to select ENTER to confirm	←= to exit

Action Move the cursor by means of the ↑ and ↓ keys to select D-Dimer and press ENTER.
The "check" frame appears.

D-DIMER	24.JULY,96 12:00
CHECK: USABLE ROTOR PRESENCE LATEX REAGENT LEVEL REFERENCE SOLUTION LEVEL NOT CALIBRATED	POS. 1
↑ to calibrate ↓ to start analysis	= to exit

If the instrument is not calibrated relative message will appear. If the instrument is calibrated the message CAL DATA (see PROG) will appear.

- Status Usable rotor presence.
- Action Check that a usable rotor is present in the rotor holder.
- Status Latex reagent level in position 1.
- Action Place the latex reagent in position 1.
- Status Reference solution level.
- Action Check that the reference solution level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

3.1.14.1 D-Dimer Calibration

When the lot/s number of Calibration Plasma and/or reagents are changed and/or controls are out of range the calibration must be repeated.

- Action If in the "CHECK" frame "↑" is pressed, a calibration cycle is initiated.
- Status If the instrument is calibrated, the D-Dimer calibration analytical conditions are displayed.

D-DIMER CAL	24.JULY.96 12:00
D-DIMER:	
ANALYTICAL CALIBRATION CONDITION	
N.P. LOT. No.
LATEX REAGENT LOT. No.
DD BUFFER LOT. No.
Key In new value ENTER to confirm	⇐ to exit

- Action The operator is either able to key in new values or to continue by pressing ENTER.

D-DIMER CAL	10.AUG.92 12:00
PLACE:	
CALIBRATOR IN "POOL" POSITION	1000
D-DIMER BUFFER IN "DIL" POSITION	
EMPTY CUPS IN POSITION 18 AND 17	
FACTOR DILUENT IN POSITION 16	
Key in new value ENTER to confirm	<= to exit

In this frame the operator is also requested to key in the value in ng/mL of the Calibration Plasma. This value is displayed in reverse (default is 1000).

Note:

The value should be within the range: 950-1050 ng/mL.

The Calibration curve and relative dilutions are calculated according to the inserted value.

D-DIMER CAL	10.AUG.92 12:00
PLACE:	
CALIBRATOR IN "POOL" POSITION	1000
D-DIMER BUFFER IN "DIL" POSITION	
EMPTY CUPS IN POSITION 18 AND 17	
FACTOR DILUENT IN POSITION 16	
↓ to start analysis	<= to exit

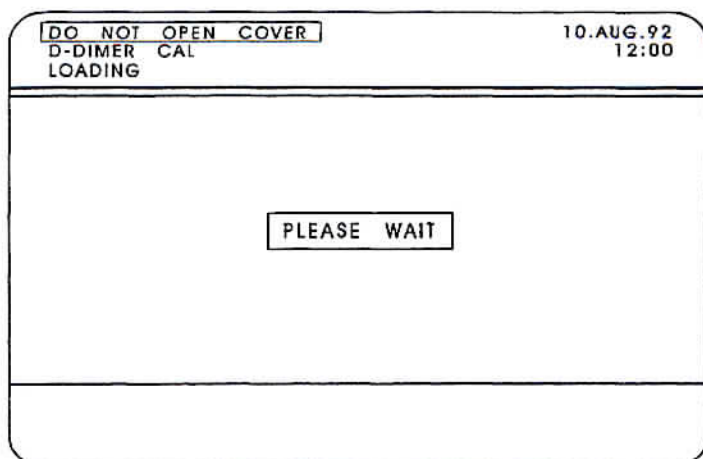
Action Key in the value of the Calibration Plasma and then press ENTER. The displayed values can be modified or confirmed by pressing ENTER.

The operator places:

- the Calibration Plasma in "POOL" position,
- empty cups in position 18 and 17,
- the D-Dimer buffer in position "DIL" (using 4 mL cup),
- the factor diluent in position 16,

Action Press "↓" to start analysis.

Status If, during the instrument checks, the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.



Afterwards the instrument loads 4 times the 100%, 4 times the 50% and 4 times the 25%. The instrument automatically carries out calibration dilutions.

Status During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms regarding sensors please refer to section 6, Troubleshooting.

Status At the end of acquisition the calibration data, in terms of value expressed in activity and optical density corresponding to the 3 points (1000 - 500 - 250 ng/mL) and CVs % are displayed.

D-DIMER CAL		RESULTS		10.AUG.92 12:00	
D-DIMER					
ng/mL	D	O.D.			
1000	0.180		CV =	1.5	
500	0.090		CV =	2.0	
250	0.045		CV =	2.5	
m = 273.2 q = 156.5 r2 = 1.000					
↑ to see Cal Data and Graphic			PRT to print ⇐ to save		

If relative CV % is outside the pre-established range values, the value is presented in reverse. Ranges are the following:

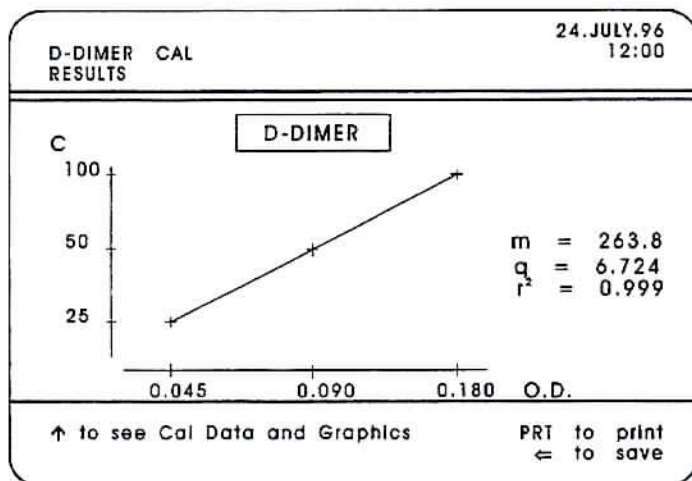
NP	(100%)	CV % =	4
NP	(50%)	CV % =	6
NP	(25%)	CV % =	10

In cases where more than one point, or the 1st point is out of range a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Action Pressing PRT to print it is possible to print the calibration data. If \uparrow to see cal data and graphics is pressed, the calibration curve graph is displayed.

Status The calibration curve with relative parameters (m, q, and r^2) is displayed.



Action By pressing PRT, the calibration data are printed.

Action By press \leftarrow to save the operator is asked to accept or not the calibration.

D-DIMER CAL RESULTS		10.AUG.92 12:00	
D-DIMER			
ng/mL	D	O.D.	
1000	0.180		CV = 1.5
500	0.090		CV = 2.0
250	0.045		CV = 2.5
m = 273.2 q = 156.5 r2 = 1.000			
↑ to see Cal Data and Graphs		PRT to print ⇐ to save	

Status The operator is asked to confirm the acceptable calibration.

Action By pressing ENTER the choice is confirmed.

Action In the calibration acceptance frame press ↑ if the calibration is not acceptable.

3.1.14.2 D-Dimer Analysis

D-DIMER		24.JULY.96 12:00	
CHECK: USABLE ROTOR PRESENCE			
LATEX REAGENT LEVEL		POS. 1	
REFERENCE SOLUTION LEVEL			
CAL DATA [see PROG]			
↑ to calibrate ↓ to start analysis		<= to exit	

Action To carry out the analysis, the operator has to press ↓ to start analysis in the "check" frame after having completed the required actions.

Status Before pressing ↓ to start analysis, the operator has to load the sample tray as follows:

- Latex reagent in position 1
- D-Dimer buffer in position "DIL"
- Samples starting from position 1 of the sample tray

Action Press ↓ to start analysis.

Status The sampling phase begins.

Status If during the instrumental checks the rotor and/or some samples are missing or the rotor is used, the conditions described for PT-FIB apply. The sampling phase begins and is followed by activation, loading, incubation and acquisition.

D-DIMER	10.AUG.92 12:00
PLACE: D-DIMER BUFFER IN "DIL" POSITION SAMPLES(max18) STARTING FROM POS.No.1	
↓ to start analysis	<= to exit

DO NOT OPEN COVER	10.AUG.92
D-DIMER CAL	12:00
LOADING	
PLEASE WAIT	

Status During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.

For flags and alarms regarding sensors please refer to section 6.

Status After the acquisition the results frame appears.

D-DIMER RESULTS							10.AUG.92 12:00	
	ng/mL	Δ OD	offset		ng/mL	Δ OD	offset	
1	988	0.189	0.689	11	480	0.171	0.671	
2	510	0.174	0.674	12	1010	0.187	0.687	
3	1040	0.199	0.699	13	490	0.172	0.672	
4	920	0.186	0.686	14	1010	0.184	0.684	
5	1020	0.170	0.670	15	1020	0.186	0.686	
6	470	0.199	0.699	16	990	0.170	0.670	
7	1040	0.189	0.689	17	970	0.165	0.665	
8	980	0.173	0.673	18	920	0.155	0.655	
9	1030	0.170	0.670					
10	470	0.204	0.654					

PRT to print
← to exit

Note:

For D-Dimer the results are expressed in activity with respect to the calibration curve stored in the memory.

Action By pressing ← the display returns to the ABS. menu.
Pressing PRT to print it is possible to print the results.

Note:

In the "results" frame and printout the optical density of the samples is displayed near the ng/mL together with the offset.

3.1.15 Pro-IL-Complex

NOTE:

This test is NOT currently cleared for use in the United States.

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit (IL kit currently not available in U.S.A.).

Status Instrument READY.
The last test executed is displayed in reverse video.

READY	24.JULY.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	← to exit

Action Move the cursor by means of the ↑ and ↓ keys to select **SPECIAL TESTS** and press **ENTER**.
The **SPECIAL TESTS** menu is displayed.

SPECIAL TESTS	24.JULY.96 12:00
PRO-IL-COMPLEX HEPATOCOMPLEX PROCLOT PROTEIN S APCR V	
↑↓ to select ENTER to confirm	← to exit

Select **PRO-IL-COMPLEX** and press **ENTER**.
The "check" frame is displayed.

Status Usable rotor presence.

PRO-IL-COMPLEX	24.JULY.96 12:00
<p>CHECK: USABLE ROTOR PRESENCE</p> <p>BOVINE THROMBOPLASTIN LEVEL POS. 1</p> <p>REFERENCE SOLUTION LEVEL</p> <p style="text-align: center;">NOT CALIBRATED</p>	
<p>↑ to calibrate ↓ to start analysis</p>	<p><= to exit</p>

Action Check that a usable rotor is present in the rotor holder.

Status Bovine thromboplastin level.

Action Empty the thromboplastin bottle contents into reservoir 1 of the instrument.

Note:

Label reservoir No. 1 with the appropriate sticker (marked PCX) included in the reservoirs box.

Status Reference emulsion level.

Action Check that the Reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

If the instrument is not calibrated, an appropriate message will appear.

3.1.15.1 Pro-IL Complex Calibration

When the lot/s number of Calibration Plasma and/or reagents are changed, the calibration must be repeated,

Action If ↑ is pressed in the check frame, a calibration cycle is initiated.

Status If the instrument is calibrated, the PCX last accepted calibration analytical conditions are displayed.

It is possible to change the following parameters:

- N.P. ID
- Bovine Thromboplastin Lot No.
- ISI value

PRO-IL-COMPLEX CAL	24.JULY.96 12:00
PRO-IL-COMPLEX ANALYTICAL CALIBRATION CONDITIONS	
N.P. LOT, No.
BOVINE THROMBOPLASTIN LOT No.
ISI	1.000
Key in new value ENTER to confirm	← to exit

Note:

Acceptable range for ISI is 0.100 to 9.999 (see the insert sheet included in the Pro-IL-Complex kit).

If an ISI of 1.000 is entered and the Calibration Plasma (100%) is present on the sample tray in position 17, the sample results are given in ratio. If an ISI different from 1.000 is entered and the Calibration Plasma (100%) is present on the sample tray in position 17, the sample results are given in INR.

Action The operator can confirm any parameter by pressing ENTER. If a parameter has to be changed, ENTER must be pressed after the new data has been entered.
The parameter to be confirmed or changed is displayed in reverse.

Status After keying in all data, the instrument displays the "place" frame. Position in for the prediluted Calibration Plasma (25%), Factor Diluent, Calibration Plasma (100%) and bovine deficient plasma are shown. In this frame the operator is also asked to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse.

PRO-IL-COMPLEX CAL	24.JUL.96 12:00
PLACE:	
N.P. DILUTED 1+3 WITH FACTOR DILUENT IN 'POOL' POSITION	
N.P. IN POSITION NO. 17	100
FACTOR DILUENT IN 'DIL' POSITION	
BOVINE DEFICIENT PLASMA IN POS. NO. 18 (2 mL CUP)	
Key in new value ENTER to confirm	← to exit

Note:

The value should be within the range: 70-130%.

The calibration curve and relative dilutions are calculated according to the inserted value.

Action Key in the value of the Calibration Plasma and press ENTER.
 The displayed values can be modified or confirmed by pressing ENTER.
 Place the prediluted Calibration Plasma 25% (1 part of Calibration Plasma + 3 parts of Factor Diluent) in "POOL" position.
 Place the Factor Diluent in "DIL" position.
 Place the Calibration Plasma 100% in position number 17 for R/INR calculation and cal curve between 100% and 25%.
 Place the bovine deficient plasma in position number 18 (use 2 mL cups).
 Press ↓ to start analysis.

PRO-IL-COMPLEX CAL	24, JULY, 96 12:00
PLACE:	
N.P. DILUTED 1+3 WITH FACTOR DILUENT IN "POOL" POSITION	
N.P. IN POSITION NO. 17	
FACTOR DILUENT IN "DIL" POSITION	100
BOVINE DEFICIENT PLASMA IN POS. NO. 18 [2 mL CUP]	
↓ to start analysis	← to exit

Status If, during instrument checks, the rotor and/or the sample/s are missing, the conditions described for PT-FIB apply.

On the third line of the video the following messages are displayed in sequence:

- "LOADING"
- "INCUBATION"
- "ACQUISITION"

DO NOT OPEN COVER	24, JULY, 96 12:00
PRO-IL-COMPLEX LOADING	
PLEASE WAIT	

The instrument loads the 25 %, the 12.5 %, the 6.25 % and (if present) the 100 %, 4 times each level.

Instrument automatically carries out calibration dilutions.

During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.
For flags and alarms, refer to section 6, Troubleshooting.

Status At the end of the acquisition phase the calibration data are displayed.

PRO-IL-COMPLEX CAL		24.JUL.96	
RESULTS		12:00	
PCX	%	s	CV
	25.0	41.0	0.5
	12.5	53.2	1.0
	6.3	71.0	1.5
m = 1.234 a = 0.567 r2 = 0.999			
	100	30.0	0.5
↑ to see CAL DATA and GRAPHICS		PRT to print ← to save	

Note:

In cases where more than one point or the first calibration point is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Status The results of the calibration are expressed in Activity (%) and seconds. If relative CV% is outside the pre-established range, the value is presented in reverse.

Ranges are the following:

- N.P. (25 %) 3 CV %
- N.P. (12.5 %) 4 CV %
- N.P. (6.25 %) 6 CV %
- N.P. (100 %) 2 CV %

The r^2 , which provides an indication of the regression line between the calibration points, is also expressed.

Error conditions are signalled on the VDU.

If a sample coagulates in less than the blank time, the message "COAG ERROR" (instead of the result) is displayed.

If a sample does not coagulate, the message "-0-" is displayed.

Status Pro-IL-Complex percentage (100% - 25% - 12.5% - 6.25%) and relative seconds are displayed.

If one of the points 12.5% or 6.25% of the calibration curve is out of range, the calibration curve is defined on two points.

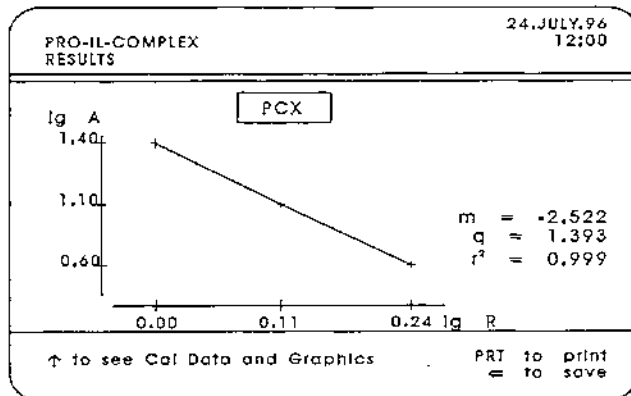
The out of range data is not displayed and the message "2 POINT CAL" appears.

Note:

In calculation of the results in activity two situations are possible:

- a) If the Calibration Plasma (100%) is not present in position number 17, the curve outlined (25% - 12.5% - 6.25%) gives a linearity from 25% to 4%. When the sample values are not in range, they are displayed in reverse.
- b) If the Calibration Plasma (100%) is present in position number 17, a second curve (outlined between 25% and 100%) gives a linearity from 4% to 150%. The reverse format appears when the sample result is higher than 150% or lower than 4%.

Action Press "PRT" to print the calibration data.
Press "↑" to see Cal Data and graphics" to display the calibration curve graph.



Action Press "PRT" to print the calibration graph.
Press "↑" to display the calibration curve from 25% to 100%.
Press again "↑" to display the calibration data are shown.

Status The "calibration" frame is displayed again.

PRO-IL-COMPLEX RESULTS 24.JULY.96 12:00

%	s	CV
25.0	41.0	0.5
12.5	53.2	1.0
6.3	71.0	1.5
m = 1.234 q = 0.456 r2 = 0.999		
100	30.0	0.5

↑ to not confirm
ENTER to confirm acceptable Cal

Action Press "←" to accept or reject the calibration.

3.1.14.2 Pro-IL Complex Analysis

PRO-IL-COMPLEX	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE BOVINE THROMBOPLASTIN LEVEL POS. 1 REFERENCE SOLUTION LEVEL CAL DATA (see PROG)	
↑ to calibrate ↓ to Start Analysis	← to exit

Action To carry out the analysis, the operator must press "↓ to start analysis" after having completed the required actions.

PRO-IL-COMPLEX	24.JULY.96 12:00
PLACE: BOVINE DEFICIENT PLASMA IN POSITION No. 18 SAMPLES (max 17) STARTING FROM POSITION No. 1	
↓ to start analysis	← to exit

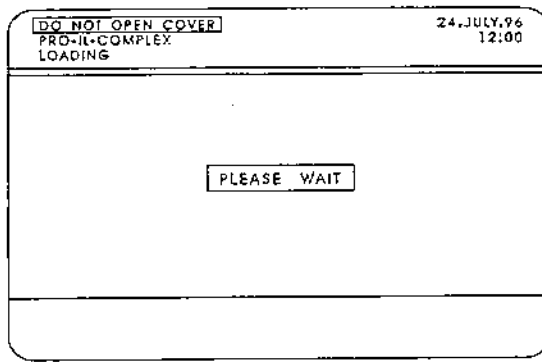
Status Before pressing "↓ to start analysis", the operator must load the sample tray as follows:

- Bovine deficient plasma in position 18
- Samples starting from position number 1 (maximum 17).

Action Press "↓ to start analysis".

Status The sampling phase begins and is followed by the following phases:

- "LOADING"
- "INCUBATION"
- "ACQUISITION"



Status After the acquisition, the results frame appears.

PRO-IL-COMPLEX
RESULTS

24, JULY, 96
12:00

	%	INR	s		%	INR	s
1	23.0	1.37	42.4	11	23.0	1.37	42.4
2	23.2	1.37	42.2	12	23.2	1.37	42.2
3	23.2	1.37	42.3	13	23.2	1.37	42.3
4	23.0	1.37	42.4	14	23.1	1.37	42.4
5	23.1	1.37	42.3	15	23.0	1.37	42.3
6	23.0	1.37	42.2	16	23.1	1.37	42.3
7	23.0	1.37	42.3	17	23.0	1.37	42.3
8	23.2	1.37	42.2				
9	23.0	1.37	42.4				
10	23.0	1.37	42.4				

PRT to print
⇐ to save

If the instrument was calibrated without using the 100%, results will be expressed in % and seconds.

Results above 25% will be in reverse because the linearity will be guaranteed from 4 to 25%.

If the instrument was calibrated using the 100%, results will be expressed in %, seconds and R/INR.

Linearity range will be guaranteed from 4 to 150%.

Action Press "PRT" to re-print the results.
Press "⇐" to display the Special Tests menu.

3.1.16 Hepatocomplex

NOTE:

This test is not currently cleared for use in the United States.

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit (IL kit currently not available in U.S.A.)

Status Instrument READY.
The last test executed is displayed in reverse video.

READY	24.JULY.96 12:00
PT-FIB APTT TT PT-FIB/APTT TT/APTT SINGLE FACTOR	DOUBLE TESTS ABS, TESTS SPECIAL TESTS
↑↓←→ to select ENTER to confirm	
⇐ to exit	

Action Move the cursor by means of the ↑ and ↓ keys to select SPECIAL TESTS and press ENTER.
The SPECIAL TESTS menu is displayed.

SPECIAL TESTS	24.JULY.96 12:00
PRO-IL-COMPLEX HEPATOCOMPLEX PROCLOT PROTEIN S APCR V	
↑↓ to select ENTER to confirm	
⇐ to exit	

Select HEPATOCOMPLEX and press ENTER.
The "check" frame is displayed.

Status Usable rotor presence.

HEPATOCOMPLEX	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE RABBIT THROMBOPLASTIN LEVEL POS. 1 REFERENCE SOLUTION LEVEL NOT CALIBRATED	
↑ to calibrate ↓ to start analysis	
⇐ to exit	

Action Check that a usable rotor is present in the rotor holder.

Status Rabbit Thromboplastin level.

Action Empty the thromboplastin bottle contents into reservoir 1 of the instrument.

Note:

Label reservoir number 1 with the appropriate sticker (marked HPX) included in the reservoirs box.

Status Reference emulsion level.

Action Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

If the instrument is not calibrated, an appropriate message will appear.

3.1.16.1 Hepatocomplex Calibration

When the lot/s number of Calibration Plasma and/or reagents are changed, the calibration must be repeated.

Action If \uparrow is pressed in the check frame the calibration cycle is initiated.

Status If the instrument is calibrated, the HPX last accepted calibration analytical conditions are displayed.

It is possible to change the following parameters:

- N.P. ID
- Rabbit Thromboplastin Lot No.
- ISI value

HEPATOCOMPLEX CAL		24.JULY.96 12:00
HEPATOCOMPLEX ANALYTICAL CALIBRATION CONDITIONS		
N.P. LOT. No.	
RABBIT THROMBOPLASTIN LOT No.	
ISI		1,000
Key in new value ENTER to confirm		← to exit

Note:

Acceptable range for ISI is 0.100 to 9.999 (see the insert sheet included in the Hepatocomplex kit).

If an ISI of 1.000 is entered, the sample results are given in ratio. If an ISI different from 1.000 is entered, the sample results are given in INR.

Action The operator can confirm any parameter by pressing ENTER. If a parameter has to be changed, ENTER must be pressed after the new information has been entered.

The parameter to be confirmed or changed is displayed in reverse.

- Status** After keying all data in, the instrument displays the "place" frame. Directions for the positioning of Calibration Plasma, Factor Diluent and bovine deficient plasma are displayed. In this frame the operator is also asked to key in the percentage of activity of the Calibration Plasma. This value is displayed in reverse.

HEPATOCOMPLEX CAL	24.JULY.96 12:00
PLACE:	
N.P. IN "POOL" POSITION	100
DILUENT IN "DIL" POSITION	
BOVINE DEFICIENT PLASMA IN POS. No. 18 [2 mL CUP]	
Key in new value ENTER to confirm	← to exit

Note:

The value should be within the range: 70-130%.

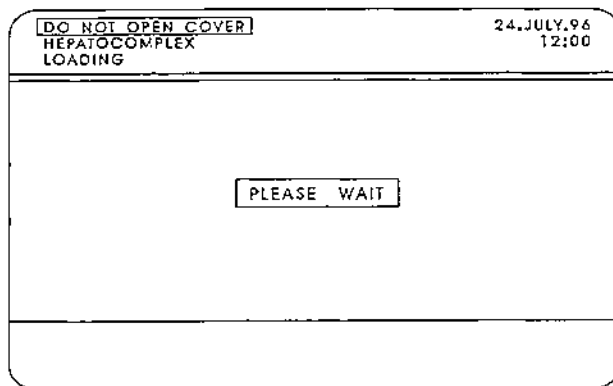
The calibration curve and relative dilutions are calculated according to the inserted value.

- Action** Key in the value of the Calibration Plasma and press ENTER. The displayed values can be modified or confirmed by pressing ENTER.
- Place the Calibration Plasma in "POOL" position.
Place the Factor Diluent in "DIL" position.
Place the bovine deficient plasma in position number 18 (use 2 mL cups). Press ↓ to start analysis.

HEPATOCOMPLEX CAL	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL" POSITION	100
DILUENT IN "DIL" POSITION	
BOVINE DEFICIENT PLASMA IN POS. No. 18 [2 mL CUP]	
↓ to start analysis	← to exit

- Status** If, during instrument checks, the rotor and/or the sample/s are missing, the conditions previously described are valid. On the third line of the video the following messages are displayed in sequence:

- "LOADING"
- "INCUBATION"
- "ACQUISITION"



The instrument loads the 100 %, the 50 %, and the 25 %, four times each level.

The instrument automatically carries out the dilutions.

Warning Do not remove the sample tray or the reagent reservoirs until the fluidic check has been completed or the cycle will be aborted. For flags and alarms, refer to section 6, Troubleshooting.

Status At the end of the acquisition phase the calibration data are displayed.

HEPATOCOMPLEX RESULTS		24.JULY.96 12:00	
%	s		
100	18.6	CV = 0.5	
50	27.5	CV = 1.0	
25	38.6	CV = 1.5	
m = 0.029 q = - 0.000 r2 = 0.986			
↑ to see CAL DATA and GRAPHICS		PRT to print <= to save	

Note:

In cases where more than one point, or the point 100% is out of range, a message is displayed in place of the "results" frame as follows:

- "NOT CALIBRATED: NO 1st POINT"
- "NOT CALIBRATED: INSUFFICIENT DATA"
- "NOT CALIBRATED: SLOPE OUT OF RANGE"

Status On the VDU the results are expressed in Activity (%) and seconds. If relative CV% is outside the pre-established range, the value is presented in reverse. Range are the following:

- N.P. (100%) 1.5 CV%
- N.P. (50%) 2.0 CV%
- N.P. (25%) 6.0 CV%

The r^2 , which provides an indication of the regression line between the calibration points, is also expressed.

Final conditions are signalled on the VDU.

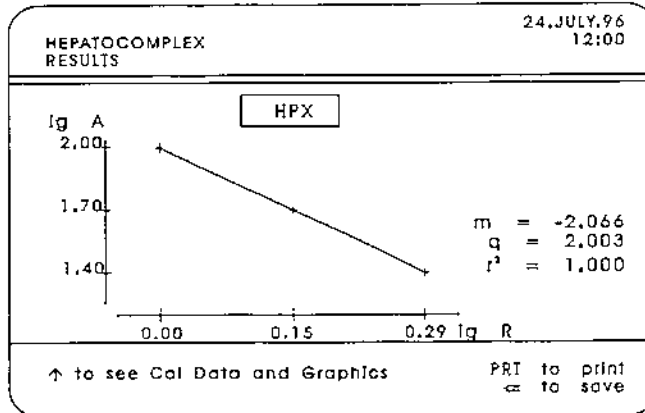
If a sample coagulates in less than the blank time, the message "COAG ERROR" (instead of the result) is displayed.

If a sample does not coagulate, the message "-0-" is displayed.

Status Hepatocomplex percentage (100% - 50% - 25%) and relative seconds are displayed.
 If one of the points 50% or 25% of the calibration curve is out of range, the calibration curve is outlined on two points.
 The out of range data is not displayed and the message "2 POINT CAL" appears.

Action Press "PRT" to print the calibration data.
 Press " \uparrow to see Cal Data and graphics" to display the calibration graph.

Status The calibration curve (100% - 50% - 25%) and relative parameters (m, q and r^2) are displayed.
 This curve gives a linearity between 8% and 150%. When a sample is not in this range, it is displayed in reverse.



Action Press PRT to print the calibration graph.
 Press " \uparrow to see Cal Data and Graphics" to display the calibration frame again.

Status The calibration frame is displayed again.

HEPATOCOMPLEX RESULTS			24.JULY.96 12:00	
PCX	%	s		
	100	18.5	CV = 0.5	
	50	27.5	CV = 1.0	
	25	38.6	CV = 1.5	
m = 0.029			q = - 0.000	r2 = 0.986
\uparrow to see CAL DATA and GRAPHICS			PRT to print <= to save	

Status It is possible to accept or reject the calibration.

Action Press \Leftarrow to save the following screen is displayed.

HEPATOCOMPLEX CAL			24.JULY.96	
RESULTS			12:00	
HPX	%	s		
	100	18.8	CV =	0.5
	50	27.5	CV =	1.0
	2.5	38.6	CV =	1.5
m = 0.029 q = -0.000 r2 = 0.986				
↑ to not confirm ENTER to confirm acceptable cal				

Status The operator is asked to confirm the acceptable calibration.

3.1.16.2 Hepatocomplex Analysis

HEPATOCOMPLEX		24.JULY.96	
		12:00	
CHECK: USABLE ROTOR PRESENCE			
RABBIT THROMBOPLASTIN LEVEL POS. 1			
REFERENCE SOLUTION LEVEL			
CAL DATA (see PROG)			
↑ to calibrate			
↓ to start analysis		⇐ to exit	

Action To carry out the analysis, the operator must press "↓" in the check frame after completing the required actions.

HEPATOCOMPLEX	24.JULY.96 12:00
PLACE: BOVINE DEFICIENT PLASMA IN POSITION No. 18 (2 mL CUP) SAMPLES (max 17) STARTING FROM POS. No. 1	
↓ to start analysis	⇐ to exit

Status Before pressing "↓ to start analysis" the operator must load the sample tray as follows:

- Bovine deficient plasma in position number 18
- Samples starting from position number 1 (maximum 17).

Action Press "↓ to start analysis".

Status The loading phase begins and is followed by the incubation and the acquisition phases.

DO NOT OPEN COVER HEPATOCOMPLEX LOADING	24.JULY.96 12:00
PLEASE WAIT	

During the incubation phase, the sampling arm with fluidic sensor checks the liquids presence.

Status After the acquisition, the results frame appears.

HEPATOCOMPLEX RESULTS		24.JULY.96 12:00					
	%	INR	s		%	INR	s
1	92.8	1.04	21.1	11	92.8	1.04	21.1
2	92.8	1.04	21.1	12	92.8	1.04	21.1
3	92.8	1.04	21.1	13	92.8	1.04	21.1
4	92.8	1.04	21.1	14	92.8	1.04	21.1
5	92.8	1.04	21.1	15	92.8	1.04	21.1
6	92.8	1.04	21.1	16	92.8	1.04	21.1
7	92.8	1.04	21.1	17	92.8	1.04	21.1
8	92.8	1.04	21.1				
9	92.8	1.04	21.1				
10	92.8	1.04	21.1				
				PRT to print ⇐ to exit			

Results are expressed in %, seconds and R/INR.
Linearity range in % is guaranteed from 8 to 150%

Action Press "PRT" to re-print the results.
Pressing "<=" to exit the instrument will show the main menu.

3.1.17 ProClot

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse.

READY	24.JULY,96 12:00
PT-FIB	DOUBLE TESTS
APTT	ABS. TESTS
TT	SPECIAL TESTS
PT-FIB/APTT	
TT/APTT	
SINGLE FACTOR	
↑↓←→ to select ENTER to confirm	= to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select **SPECIAL TESTS** and press ENTER to confirm.
The **SPECIAL TESTS** menu is displayed.

SPECIAL TESTS	24.JULY,96 12:00
PRO-IL-COMPLEX	
HEPATOCOMPLEX	
PROCLOT	
PROTEIN S	
APCR V	
↑↓ to select ENTER to confirm	= to exit

Select **PROCLOT** and press ENTER.
The "check" frame is displayed.

Status Usable rotor presence.

PROCLOT	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE	
CEPHALINE LEVEL	POS, 2
CALCIUM CHLORIDE LEVEL	POS, 3
REFERENCE SOLUTION LEVEL	
NOT CALIBRATED	
↑ to start analysis and calibration ↓ to start analysis	← to exit

Action Check that a usable rotor is present in the rotor holder.

Status Directions for positioning of cephalin, CaCl_2 and reference emulsion are displayed.

Action Empty the cephalin bottle contents into reservoir 2 marked APTT (MACRO) of the instrument.
Empty the Calcium Chloride bottle into reservoir 3 marked CaCl_2 of the instrument.
Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.
Press "↑ to start analysis and calibration". The "Analytical conditions" frame is displayed.

PROCLOT	24.JULY.96 12:00
PROCLOT ANALYTICAL CALIBRATION CONDITION	
N.P. LOT. No.
PROCLOT LOT. No.
CEPHALIN LOT. No.
CALCIUM CHLORIDE LOT. No.
Key In new value ENTER to confirm	← to exit

Action The operator must enter the Calibration Lot Number, the ProClot Lot Number, the Cephalin Lot Number and the Calcium Chloride Lot Number.

The "PLACE" frame appears.

PROCLOT	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL" POSITION	100.0
WORKING DILUENT IN "DIL" POSITION (2 mL CUP)	
PROTEIN C DEF. PLASMA [0% STD] IN POS. 18 (2 mL CUP)	
EMPTY CUP IN POS. 17	
SAMPLES (MAX 16) STARTING FROM POS.No.1	
key in new value ENTER to confirm	← to exit

Status Direction for positioning of the Calibration Plasma, of the working diluent, of the samples, of the empty cups and of the Protein C deficient plasma are displayed.

In this frame the operator is also asked to key in the percentage of the activity of the Calibration Plasma. This value is displayed in reverse.

Note:

The Cal Plasma value should be within the range 70%-130%.

The calibration curve can be stored and used for subsequent runs.

Action The value can be modified or confirmed by pressing ENTER. Calibration Plasma must be placed in "POOL" position, diluent in "DIL" position and the samples (maximum 16) from position number 1 of the sample tray onwards. An empty cup has to be placed in position 17.

Protein C deficient plasma must be placed in position number 18 of the sample tray.

If a calibration is already stored in the memory and only the analysis has to be performed the following "PLACE" frame appears.

PROCLOT	24.JUL.96 12:00
PLACE:	
WORKING DILUENT IN "DIL" POSITION (2 mL CUP)	
PROTEIN C DEFICIENT PLASMA [0% STD] IN POS. No. 18 (2 mL CUP)	
SAMPLES (max 16) STARTING FROM POS. No. 1	
↓ to start analysis	← = to exit

Press ↓ to start analysis.

Status If, during instrument checks, the rotor and/or the sample tray are missing or the rotor is used, the conditions described for PT-FIB apply. In the ProClot test, analysis and calibration are carried out simultaneously.

The loading phase begins. The instrument aspirates and dispenses Protein C deficient plasma and cephalin. Protein C deficient plasma activation starts. The instrument then aspirates and dispenses the Calibration Plasma (if no calibration has been stored) and the samples. Appropriate dilutions are made.

Calibration Plasma and sample activation starts.

The instrument aspirates and dispenses the CaCl_2 .

This is followed by the incubation and acquisition phases.

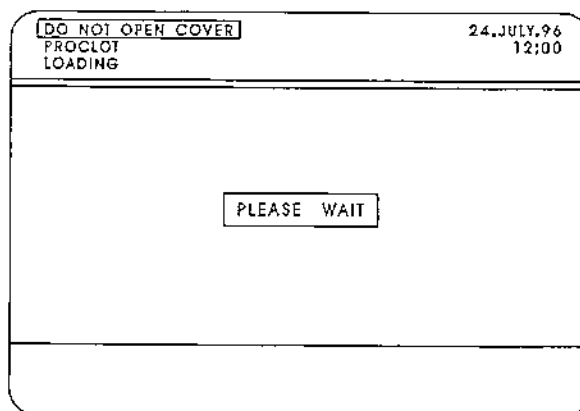
Note:

During the first incubation phase, the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.
For flags and alarms, refer to section 6, Troubleshooting.

Status The message "DO NOT OPEN COVER" is displayed on the first line of the video. On the third line of the video the following messages are displayed in sequence:

- "LOADING"
- "ACTIVATION"
- "LOADING"
- "INCUBATION"
- "ACTIVATION"
- "LOADING"
- "INCUBATION"
- "ACQUISITION"



PROCLOT RESULTS								24.JULY.96 12:00
	%	R	S		%	R	S	
1	105	2.65	165	11	99	2.58	161	
2	105	2.65	165	12	99	2.58	161	
3	105	2.65	165	13	99	2.58	161	
4	105	2.65	165	14	99	2.58	161	
5	105	2.65	165					
6	105	2.65	165					
7	105	2.65	165					
8	105	2.65	165					
9	99	2.58	161					
10	99	2.58	161					
↑ to see Cal Data and Graphics					PRT to print			
↓ to see Analysis Data					← to save			

Note:

Not calibrated conditions:

- NOT CALIBRATED: NO 1st POINT (the 0% point is out of range)
- NOT CALIBRATED: INSUFFICIENT DATA (1 point instead of 3)
- NOT CALIBRATED: SLOPE OUT OF RANGE.

Results are expressed in activity (%), ratio and seconds; the r^2 , which provides an indication of the regression line between the points, is also expressed.

On the printout, only activity (%) and ratio are reported.

Error indications are signalled on the video.

If a sample coagulates in less than the blank time, the message "COAG ERROR" (instead of the result expressed in activity) is displayed.

If a sample does not coagulate, the message "-0-" in reverse is displayed.

Action Press PRT to print the results.
Press "<=" to return to the main menu.

Press ↑ to see Cal Data and Graphics frame

Status Protein C percentage values (100% - 50% - 0%) and the corresponding values in seconds are displayed together with the r^2 .

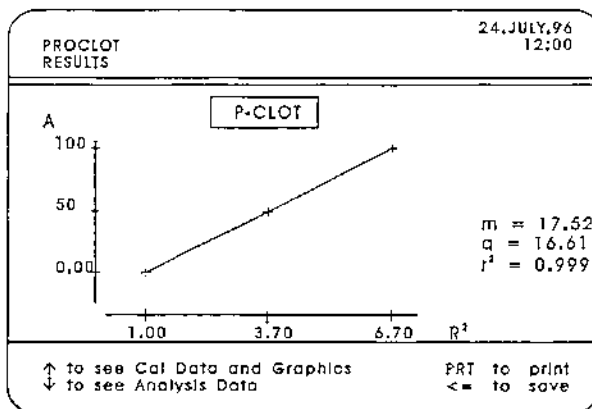
PROCLOT RESULTS		24.JULY.96 12:00
%	S	
0	62.3	
50	120	
100	120	
m = 13.48 q = 14.52 r2 = 0.999		
↑ to see Cal Data and Graphics		PRT to print
↓ to see Analysis Data		← to save

If one of the points 50% or 0% of the calibration curve is out of range, the calibration curve is defined on two points.

The data out of range is not displayed, and the message "2 POINT CAL" is displayed.

Action Press "↑ to see Cal Data and Graphics" to display the graph frame.

Status The calibration curve and relative parameters (m - q - r²) are shown.



Action Press "<=" to return to the main menu.

Press ↓ to return to the results frame.

Status The "results" frame is displayed again.

		PROCLOT RESULTS			24.JULY.96 12:00		
	%	R	s		%	R	s
1	105	2.65	165	11	99	2.58	161
2	105	2.65	165	12	99	2.58	161
3	105	2.65	165	13	99	2.58	161
4	105	2.65	165	14	99	2.58	161
5	105	2.65	165				
6	105	2.65	165				
7	105	2.65	165		r ² =	0.999	
8	105	2.65	165				
9	99	2.58	161				
10	99	2.58	161				

↑ to see Cal Data and Graphics PRT to print
↓ to see Analysis Data <= to save

Action Press "<=" to store the calibration.

Note:

In the "results" frame and printout, the sample value expressed in activity are presented the values in ratio and in seconds.

Limitations:

ProClot assay may be affected by LAC (Lupus Anticoagulant) or high concentrations of Factor VIII:C (> 250%) in the plasma assayed.

We suggest repeating the test performing additional dilutions of the plasma assayed (1:20, 1:40 with deficient plasma).

3.1.18 Protein-S

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instruction included in the kit.

Status Instrument READY.

The last test executed is displayed in reverse video.

READY	24.JULY,96 12:00
PT-FIB APTT IT PT-FIB/APTT IT/APTT SINGLE FACTOR	DOUBLE TESTS ABS. TESTS <input type="checkbox"/> SPECIAL TESTS
↑↓←→ to select ENTER to confirm	⇐ to exit

Action Move the cursor by means of the ↑↓ and ←→ keys to select SPECIAL TESTS and press ENTER.

The SPECIAL TESTS menu is displayed.

SPECIAL TESTS	24.JULY,96 12:00
PRO-IL-COMPLEX HEPATOCOMPLEX PROCLOT <input type="checkbox"/> PROTEIN S APCR V	
↑↓ to select ENTER to confirm	⇐ to exit

Select Protein S and press ENTER.

The "check" frame is displayed.

Status Usable rotor presence.

PROTEIN-S	24.JULY,96 12:00
CHECK: USABLE ROTOR PRESENCE BOVINE THROMBOPLASTIN LEVEL POS, 1 REFERENCE SOLUTION LEVEL	
↓ to continue	⇐ to exit

- Action** Check that a usable rotor is present in the rotor holder.
- Status** Directions for the bovine thromboplastin and the reference emulsion levels control are displayed.
- Action** Empty the thromboplastin bottle contents into reservoir 1 (MICRO) of the instrument.
 Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.
 Press "â to continue". The "PLACE" frame is displayed.
- Status** Indications concerning the positioning of the Calibration Plasma, of the Protein S deficient plasma (0%), of the 50% standard (optional), of the prediluted activated Protein S deficient plasma and of the samples are shown.
 In this frame the operator is also requested to key in the percentage of the activity of the Calibration Plasma. This value is displayed in reverse.

PROTEIN-S	24.JUL.96 12:00
PLACE:	
N.P. IN "POOL POSITION"	110
N.P. DILUTED 1+1 WITH 0% STD IN POS.N.17 (OPT.)	
PROTEIN-S DEF. PLASMA (0% STD) IN "DIL" POS.	
ACTIVATED PROTEIN-S DEF. PLASMA IN POS.18	
(2 mL CUP) PREDIL. 1+1 WITH FACTOR DIL.	
SAMPLES (MAX 16) STARTING FROM POS. No. 1	
Key in new value ENTER to confirm	← to exit

Note:

This value should be within the range 70%-130%.

- Action** The value can be modified or confirmed by pressing ENTER.
 Calibration Plasma has to be placed in "POOL" position, 0% (Protein S deficient plasma) in "DIL" position, 50% standard (optional) in position 17, activated Protein-S Deficient Plasma (prediluted 1:2 with Factor diluent) in position number 18 and the samples (maximum 16) from position number 1 of the sample tray onwards.
 Press â to start analysis.
- Status** If, during instrument checks, the rotor and/or the sample tray are missing or the rotor is used, the same indications described for the PT-Fib cycle apply. In the Protein-S test, analysis and calibration are carried out simultaneously.
 The loading phase begins. This is followed by the incubation and the acquisition phases.

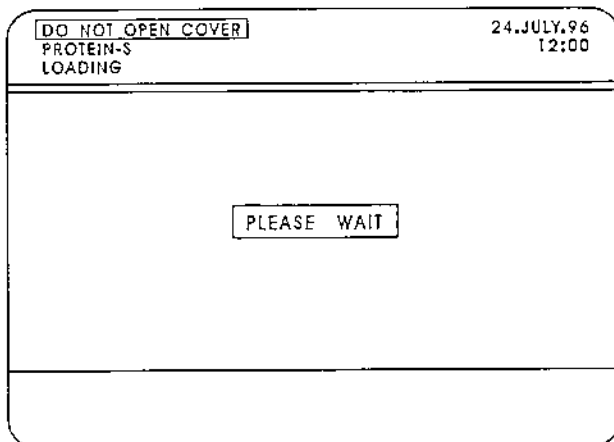
Note:

During the incubation phase the sampling arm with fluidic sensors checks the liquids presence.

Warning Do not remove the sample tray or reagent reservoirs until the fluidic check has been completed or the cycle will be aborted.
For flags and alarms, please refer to section 6.

Status The message "DO NOT OPEN COVER" is displayed on the first line of the video. On the third line of the video the following messages are displayed in sequence:

- "LOADING"
- "INCUBATION"
- "ACQUISITION"



Status At the end of the acquisition and calculation phases, the "results" frame is displayed.

PROTEIN-S RESULTS			24.JULY.96 12:00		
1	105	165	11	99	161
2	105	165	12	99	161
3	105	165	13	99	161
4	105	165	14	99	161
5	105	165			
6	105	165			
7	106	165			$r^2 = 0,999$
8	105	165			
9	99	161			
10	99	161			

↑ to see Cal Data and Graphics PRI to print
 ↓ to see Analysis Data ← to exit

Note:

Not calibrated conditions:

- NOT CALIBRATED: NO 1st POINT (the 0% point is out of range)
- NOT CALIBRATED: INSUFFICIENT DATA (1 point instead of 3)
- NOT CALIBRATED: SLOPE OUT OF RANGE.

Results are expressed in activity (%), ratio and seconds; the r^2 is also expressed which provides an indication of the regression line between the points.

On the printout, only activity (%) and seconds are reported.

Error indications are signalled on the video.

If a sample coagulates in less than the blank time, the message "COAG ERROR" (instead of the result expressed in activity) is displayed.

If a sample does not coagulate, the message "-0-" in reverse is displayed.

Action Press "PRT" to print the results.

Press "↑" to see Cal Data and Graphics to display the calibration data.

Status Protein S percentage values (100% - 50% - 0%) and the corresponding values in seconds are displayed together with the r^2 .

PROTEIN-S RESULTS			24.JULY.96 12:00
P-S	%	s	
	0	62.3	
	50	120	
	100	160	
m = 1.234 q = 0.876 r2 = 0.999			
↑ to see Cal Data and Graphics	PRT to print		
↓ to see Analysis Data	<= to exit		

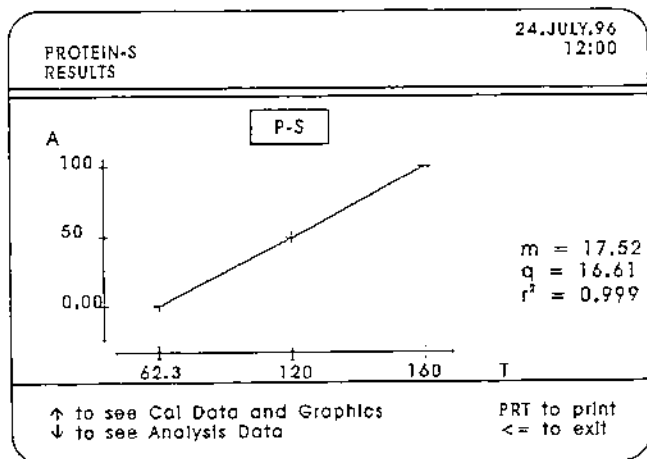
If one of the points 50% or 0% of the calibration curve is out of range, the calibration curve is defined on two points.

The data out of range is not displayed, and the message "2 POINT CAL" is displayed.

Action Press "←" to return" to the main menu.

Press "↑" to see Cal data and Graphics" to display the graph frame.

Status Presentation of the calibration curve and of the relative parameters (m-q-r²) are displayed.



Action Press "↓ to see Analysis Data " the display returns to the "results" frame.

Status The "results" frame is displayed.

PROTEIN-S RESULTS						24.JULY.96 12:00
	%	s		%	s	
1	105	165		11	99	161
2	105	165		12	99	161
3	105	165		13	99	161
4	105	165		14	99	161
5	105	165				
6	105	165				
7	105	165			$r^2 = 0.999$	
8	105	165				
9	99	161				
10	99	161				

↑ to see Cal Data and Graphics PRT to print
↓ to see Analysis Data ← to exit

Action Press "<- to exit" to return to the Special Tests menu.

Note:

In the "results" frame and printout, the sample value expressed in activity and are presented with the values in seconds.

Limitations:

Protein S assay may be affected by high concentrations of Factor VIIa and APCr in the plasma assayed.

We suggest repeating the test performing additional dilutions of the plasma assayed (1:2 or 1:4 with PS deficient plasma).

3.1.19 APCR-V

For Calibration Plasma, Control plasma, reagents preparation and handling, refer to the manufacturer's instructions included with the kit.

Status Instrument READY.
The last test executed is displayed in reverse.

READY	24.JULY.96 12:00
PT-FIB	DOUBLE TESTS
APTT	ABS. TESTS
TT	SPECIAL TESTS
PT-FIB/APTT	
TT/APTT	
SINGLE FACTOR	
↑↓↔ to select ENTER to confirm	⇐ to exit

Action Move the cursor by means of the ↑↓ and ↔ keys to select SPECIAL TESTS and press ENTER.
The SPECIAL TESTS menu is displayed.

SPECIAL TESTS	24.JULY.96 12:00
PRO-IL-COMPLEX	
HEPATOCOMPLEX	
PROCLOT	
PROTEIN S	
APCR V	
↑↓ to select ENTER to confirm	⇐ to exit

Select APCR-V and press ENTER.
The "check" frame is displayed.

Status Usable rotor presence.

APCR V	24.JUL.96 12:00
CHECK:	
USABLE ROTOR PRESENCE	
APTT REAGENT LEVEL	POS. 2
ACTIVATED CALCIUM CHLORIDE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
↓ to continue	⇐ to exit

Action Check that a usable rotor is present in the rotor holder.

Status Indications concerning the APTT reagent, the activated calcium chloride and the reference emulsion levels control are displayed.

Action Empty the cephalin bottle contents into reservoir 2 marked APTT (MACRO) of the instrument.

Empty the activated calcium chloride bottle contents into reservoir 3 marked CaCl₂ (MACRO) of the instrument.

Status Indications concerning the reference emulsion level.

Action Check that the reference emulsion level is adequate (a level of 1.5 - 2 cm is enough to run 1 or 2 rotors, considering the dead volume), otherwise replace the bottle.

Press "↓ to continue". The "PLACE" frame is displayed.

APCR V	24.JUL.96 12:00
CHECK:	
N.P. IN 'POOL' POSITION DEFICIENT PLASMA IN 'DIL' POSITION (4 mL CUP) CALCIUM CHLORIDE IN POS. No. 18 (2 mL CUP) SAMPLES STARTING FROM POSITION No. 1 (max 16)	
↓ to start analysis	← to exit

Status Indications concerning the positioning of the Calibration Plasma, of the Factor V deficient plasma, calcium chloride and of the samples are shown.

Action Place the indicated materials in accordance to the screen indications. Press ↓ to start analysis.

DO NOT OPEN COVER	24.JULY.96 12:00
APCR V ACQUISITION	
PLEASE WAIT	

3.1.20 Re-Use of Partially Used Rotors

3.1.20.1 Introduction

Rotors which have been previously used but still show free positions, may be re-used for all tests, provided that the number of samples to be analyzed does not require more free positions than those available. In the presence of very diluted samples (for example single factors or chromogenic tests) or dried out rotors, the instrument is not capable of absolutely defining all used positions. It is extremely important that the operator checks the actual status of the used rotor relative to the test to be performed and introduces the first free position to be used prior to starting analysis.

Minimum Number of Free Positions

The minimum number of consecutive free rotor cuvettes (positions) necessary for re-use of a rotor depends on the type of test to be carried out. Certain positions are "reserved" independently of the number of samples to be analyzed as follows:

Screening tests

PT-FIB, APTT, TT (standard or extended).

Number of reserved positions = 2 (1 for reference emulsion, 1 for sample tray N.P. position).

Thus, for n samples, $2 + n$ free positions are necessary.

Double tests

PT-FIB, APTT, TT (standard or extended).

Number of reserved positions = 2 (1 for reference emulsion, 1 for sample tray N.P. position).

In double tests each sample is loaded twice, the number of free positions necessary for n samples is $2 + 2n$.

Mixed tests

PT-FIB/APTT, TT/APTT

Number of reserved positions = 4 (2 for reference emulsion, 2 for sample tray N.P. position).

The number of free positions necessary for n samples is $4 + 2n$.

Note:

Half this number of positions must be in each of two sectors separated by 10 positions.

Single Factors

Number of reserved positions = 4 (1 for reference emulsion, 1 for calibration plasma 100%, 1 for calibration plasma 50%, 1 for calibration plasma 25%).

The number of free positions necessary for n samples is $4 + n$.

Absorbance Tests

HEPARIN, α -2-ANTIPLASMIN, PLASMINOGEN, PROCHROM, FIB-C
Number of reserved positions = 5 [1 for reference emulsion, 1 for the optical reference (buffer+enzyme), 1 for calibration plasma 100%, 1 for calibration plasma 50%, 1 for calibration plasma 25%].

The number of free positions necessary for n samples is $5 + n$.

AT-III analysis

Number of reserved positions = 2 (1 for reference emulsion, 1 for optical reference).

The number of free positions necessary for n samples is $2 + n$.

Pro-IL-Complex analysis

Number of reserved positions = 1 (for reference emulsion).

The number of free positions necessary for n samples is $1 + n$.

Hepatocomplex analysis

Number of reserved positions = 1 (for reference emulsion).

The number of free positions necessary for n samples is $1 + n$.

ProClot

Number of reserved positions = 4 (1 for reference emulsion, 1 for calibration plasma 100%, 1 for calibration plasma 50%, 1 for calibration plasma 0%).

The number of free positions necessary for n sample is $4 + n$.

Protein-S

Number of reserved positions = 4 (1 for reference emulsion, 1 for calibration plasma 100%, 1 for calibration plasma 50%, 1 for calibration plasma 25%).

The number of free positions necessary for n sample is $4 + n$.

3.1.20.2 Operator Actions

If, the instrument identifies a used rotor with sufficient free positions to enable the test to be carried out correctly, when the operator initiates a test, the frame shown below is displayed.

The information (N pos) indicates the number of positions necessary to carry out the test requested by the operator based on the number of samples in the sample tray, including the "reserved" positions.

PT-FIB	24.JULY.96 12:00
NUMBER OF NEEDED CUVETTE 3	
ENTER STARTING CUVETTE NUMBER	<input type="text"/>
Key In starting cuvette ENTER to confirm	← to load new rotor

The operator must check the rotor carefully, identifying the free sector/s and confirming there are sufficient truly free positions to enable the test to be completed correctly.

The first free cuvette position of the sector to be used must be entered via the keyboard.

If the instrument, during the rotor check, establishes that there are more samples than available free positions for the test requested, the message "INSUFFICIENT ROTOR POSITIONS" is presented.

PT-FIB PRE-ANALYSIS	24.JUL.96 12:00
INSUFFICIENT ROTOR POSITIONS LOAD NEW ROTOR	
← to abort cycle ↓ to continue	

Following a visual check of the rotor, the operator may choose to reduce the number of samples to be analyzed or insert a new rotor and start again. If a test has been requested or the instrument establishes that there are less free positions than those necessary to carry out a minimal test (1 sample or 1 Quality Control with just Calibration Plasma), the message "LOAD NEW ROTOR" is displayed.

Warning In particular cases the instrument is not capable of defining all used positions (i.e. last 6 positions in PT calibration, dilution 25%, chromogenic cycles, dried rotor). Please check the rotor carefully. If the used cuvettes are completely dried before starting the cycle, the operator is advised to introduce in one used position 200 µL of reference emulsion using a manual pipette to allow the use of the re-used rotor program.

3.1.20.3 Rotor Loading Characteristics

The following tables and diagrams show how the rotor cuvettes are loaded when tests are requested involving new or used rotors.

Cycle	Samples	New Rotor	Used Rotor	
PT FIB CAL	ref. emuls. 100 % 50 % 25 %	20 1 - 6 7 - 12 13 - 18	not re-usable	
PT-FIB	ref. emuls.	19	n	
APTT	N.P.	20	n + 1	
TT	sample 1	1	n + 2	
	sample 2	2	n + 3	
	.	.	.	
DOUBLE PT-FIB	ref. emuls.	19	n	
DOUBLE APTT	N.P.	20	n + 1	
DOUBLE TT	sample 1	1 and 2	n + 2	
	sample 2	3 and 4	n + 4	
	.	.	.	
PT-FIB/APTT	ref. emuls.	19 and 9	n+10	
TT/APTT	N.P.	20 and 10	n+1	
D-DIMER	sample 1	1 and 11	n+2	
	sample 2	2 and 12	n+3	
	.	.	.	
Single Factor	ref. emuls.	17	n	
	100%	18		
	50%	19		
	25%	20		
	sample 1	1	n + 4	
	sample 2	2	n + 5	
	.	.	.	
Plasminogen	ref. emuls.	16		
Heparin	optical reference	17		
α-2-Antiplasmin	100 %	18		
ProChrom	50 %	19		
	25%	20		
	sample 1	1	n + 5	
	sample 2	2	n + 6	
	.	.	.	

Cycle	Samples	New Rotor	Used Rotor
AT-III	ref, emuls.	19	
Heparin Xa	optical reference	20	
D-Dimer	sample 1	1	n + 1
analysis	sample 2	2	n + 2
.	.	.	.
Pro-IL-Complex	ref, emuls.	20	
analysis	sample 1	1	n + 1
	sample 2	2	n + 2
.	.	.	.
Hepatocomplex	ref, emuls.	20	
analysis	sample 1	1	n + 1
	sample 2	2	n + 2
.	.	.	.
ProClot	ref, emuls.	17	
	100%	18	
	50%	19	
	0%	20	
	sample 1	1	n + 1
	sample 2	2	n + 2
.	.	.	.
Fib-C	ref, emuls.	19	
analysis	optical ref.	20	
	sample 1	1	n + 2
	sample 2	2	n + 3
.	.	.	.
Protein S	ref, emuls.	17	
	100%	20	
	50%	19	
	0%	18	
	sample 1	1	n + 4
	sample 2	2	n + 5
.	.	.	.
AT-III	ref, emuls.	19	not re-usable
Heparin Xa	optical ref.	20	
D-Dimer	100%	1-4	
calibration	50%	5-8	
	25%	9-12	
PCX	ref, emuls.	20	not re-usable
calibration	25%	1-4	
	12.5%	5-8	
	6.25%	9-12	
	100% (optional)	13-16	
HPX	ref, emuls.	20	not re-usable
calibration	100%	1-4	
	50%	5-8	
	25%	9-12	

FIB-C	ref,emuls.	19	not re-usable
calibration	optical ref.	20	
	150%	1-4	
	100%	5-8	
	150%	9-12	

n: cuvette number keyed in by the operator corresponding to the first free position.

s: sample

3.1.21 Reference Values

As with many other clinical analyses, coagulation analysis requires accurate results to effect accurate and precise diagnoses. Even very small divergencies in measured variables can be significant. Furthermore, it is important to remember that PT, FIB and APTT are often necessary parameters to decide the therapy for patients in anticoagulant and heparin therapy.

We believe that this is a sufficient reason to insist on the necessity of precise results.

The ranges of the Reference values are:

- for PT xx.x seconds $\pm 9 \%$
- for FIB xxx mg/dL $\pm 20 \%$
- for APTT xx.x seconds $\pm 15 \%$

Note:

If the instrument is not calibrated, the Quality Control for FIB is not performed and the operator can insert the PT value of Calibration Plasma (100% activity) in the PROG Setup "Reference material".

If the instrument is calibrated for PT and FIB, the values (PT 100% in seconds and FIB in mg/dL) go directly into the PROG "Reference Values".

For APTT the operator inserts the value of the Calibration Plasma in the PROG "Reference material" according to the range of the laboratory and of the reagent.

For more details see section 4.

3.2 Profiles

Profiles allow the Operator to execute a combination of tests (profile) on samples placed on the sample tray.

The tests to be run are determined by the database. If no information is available in the database, the complete profile is executed.

The materials (reagents and rotor) must be placed during the preanalytical phase.

If more than one rotor is required to run the profile, the instrument will flag the operator when the rotor needs to be changed.

The available profiles are listed in the next table which also shows the correct positioning of the material (reagents, diluents and calibrators) needed for each single profile.

If the material must be positioned in the sample tray area, the table indicates if specific containers have to be used (i. e. 4 mL cup).

In order to increase the number of reagents on-board, the instrument will use a specific reservoir for position 3 (alternative reservoir).

Different profiles may have different positions for the materials to optimize the positions available.

The number of samples can be either 17 or 18 depending on the profile selected.

If the operator loads 18 samples for a profile allowing just 17 samples, a message will appear flagging the operator.

If a profile that allows only 17 samples is launched with 18 samples in the sample tray, a specific warning is given to the operator.

The execution of the tests in the profile is sequential according to the order indicated in the profile.

Profiles	Sample Tray				Reagents Reservoir		
	Pos. 17	Pos. 18	Pos. 19	Pos. 20	Reag. 1	Reag. 2	Reag. 3
PT-FIB APTT				Cal. Plasma (PT, APTT)	Calcium Thrombo- plastin (PT)	Cephalin (APTT)	Calcium Chloride (APTT)
PT-FIB APTT TT			Calcium Chloride (APTT)	Cal. Plasma (PT, APTT, TT)	Calcium Thrombo- plastin (PT)	Cephalin (APTT)	Thrombin (TT)
PT-FIB FIB-C			Factor Diluent (FIB-C)	Cal. Plasma (PT)	Calcium Thrombo- plastin (PT)	Thrombin (FIB-C)	Cleaning (FIB-C)
APTT FIB-C		Factor Diluent (FIB-C)	Calcium Chloride (APTT)	Cal. Plasma (APTT)	Thrombin (FIB-C)	Cephalin (APTT)	Cleaning (FIB-C)
TT FIB-C			Factor Diluent (FIB-C)	Cal. Plasma (TT)	Thrombin (TT)	Thrombin (FIB-C)	Cleaning (FIB-C)
HPX PCX			Deficient Plasma (PCX)	Deficient Plasma (HPX)	Bovine Thrombo- plastin (PCX)	Rabbit Thrombo- plastin (HPX)	
HPX APTT TT		Deficient Plasma (HPX)	Calcium Chloride (APTT)	Cal. Plasma (APTT, TT)	Rabbit Thrombo- plastin (HPX)	Cephalin (APTT)	Thrombin (TT)
PCX APTT TT		Deficient Plasma (PCX)	Calcium Chloride (APTT)	Cal. Plasma (APTT, TT)	Bovine Thrombo- plastin (PCX)	Cephalin (APTT)	Thrombin (TT)
HPX FIB-C			Factor Diluent (FIB-C)	Deficient Plasma (HPX)	Rabbit Thrombo- plastin (HPX) 2700 µl	Thrombin (FIB-C)	Cleaning (FIB-C)
PCX FIB-C			Factor Diluent (FIB-C)	Deficient Plasma (PCX)	Rabbit Thrombo- plastin (PCX)	Thrombin (FIB-C)	Cleaning (FIB-C)

3.2.1 Profiles selection

READY	24.JULY.96 12:00
TESTS PROFILE	
↑↓ to select ENTER to confirm	

From the main menu, select the profiles submenu.

PROFILES	24.JULY.96 12:00
PT-FIB/APTT PT-FIB/APTT/TT PT-FIB/FIB-C APTT/FIB-C TT/FIB-C HPX/PCX PCX/APTT/TT HPX/APTT/TT PCX/FIB-C HPX/FIB-C	
↑↓ to select ENTER to confirm	<= to exit

3.2.2 Preanalytical phase

The selection of a profile will open the preanalytical phase.

If a profile is selected where the calibration is expected to be, a message will flag the operator.

The operator may decide to continue or go back, interrupting the procedure.

If the FIB is derived from the PT and the Fib is not calibrated, the Fib result will not be given.

PT-FIB/APTT/TT	24.JULY.96 12:00
UNCALIBRATED TEST: PT, FIB FIB WILL NOT BE PERFORMED	
ENTER to confirm	PROG to return

According to the profile selected a specific check frame will indicate the materials needed to execute it.

PT-FIB/APTT	24.JULY.96 12:00
CHECK: USABLE ROTOR PRESENCE THROMBOPLASTIN LEVEL IN POS.1 CEPHALIN LEVEL IN POS. 2 CALCIUM CHLORIDE IN POS. 3 NORMAL POOL IN *POOL* POSITION SAMPLES (max 18) REFERENCE SOLUTION LEVEL	
↓ to start analysis	<= to exit

Check frames presented are those reported in the following table.

PT-FIB/APTT	Check: Usable rotor presence Thromboplastin level in Pos. 1 Cephalin level in Pos. 2 Calcium Chloride in Pos. 3 Normal Pool in Pool Position Samples (maximum 18) Reference emulsion level
PT-FIB/APTT/TT	Check: Usable rotor presence Thromboplastin level in Pos. 1 Cephalin level in Pos. 2 Thrombin level in Pos. 3 (alternative Reservoir) Calcium Chloride in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 18) Reference emulsion level

PT-FIB/FIB-C	Check: Usable rotor presence Thromboplastin level in Pos. 1 Thrombin Clauss level in Pos. 2 Cleaning level in Pos. 3 (alternative Reservoir) Factor Diluent in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 18) Reference emulsion level
APTT/FIB-.C	Check. Usable rotor presence Thrombin Clauss level in Pos. 1 Cephalin level in Pos. 2 Cleaning level in Pos. 3 (alternative Reservoir) Factor Diluent in Pos. 18 (4 mL big cup) Calcium Chloride in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 17) Reference emulsion level
TT/FIB-C	Check: Usable rotor presence Thrombin TT level in Pos. 1 Thrombin Clauss level in Pos. 2 Cleaning level in Pos. 3 (alternative Reservoir) Factor Diluent in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 18) Reference emulsion level
HPX/PCX	Check: Usable rotor presence Bovine Thromboplastin level in Pos. 1 Rabbit Thromboplastin level in Pos. 2 Deficient Plasma in Pos. 20 (HPX) Deficient Plasma in Pos. 19 (PCX) Samples (maximum 18) Reference emulsion level
HPX/APTT/TT	Check: Usable rotor presence Rabbit Thromboplastin level in Pos. 1 Cephalin level in Pos. 2 Thrombin TT level in Pos. 3 (alternative Reservoir) Deficient Plasma in Pos. 18 Calcium Chloride in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 17) Reference emulsion level

PCX/APTT/TT	Check: Usable rotor presence Bovine Thromboplastin level in Pos. 1 Cephalin level in Pos. 2 Thrombin TT level in Pos. 3 (alternative Reservoir) Deficient Plasma in Pos. 18 Calcium Chloride in Dil Position (4 mL big cup) Normal Pool in Pool Position Samples (maximum 17) Reference emulsion level
HPX/FIB-C	Check: Usable rotor presence Rabbit Thromboplastin level in Pos. 1 Thrombin Clauss level in Pos. 2 Cleaning level in Pos. 3 (alternative Reservoir) Factor Diluent in Dil Position (4 mL big cup) Deficient Plasma in Pool Position Samples (maximum 18) Reference emulsion level
PCX/FIB-C	Check: Usable rotor presence Bovine Thromboplastin level in Pos. 1 Thrombin Clauss level in Pos. 2 Cleaning level in Pos. 3 (alternative Reservoir) Factor Diluent in Dil Position (4 mL big cup) Deficient Plasma in N.P. Position Samples (maximum 18) Reference emulsion level

Before running a profile, the samples must be identified by sample IDs. The Loadlist option can be used (one of the nine available). The loadlist can be prepared independently or by selecting the analytical cycle just before starting.

It is important to identify the samples using their sample IDs. The following checks are carried out: IDs

1. The sample ID must be unique on the loadlist. A repeated sample ID is not accepted and a message is displayed
2. If the sample ID is the number 301 (greater than the 300 maximum) for the database, a message appears and the ID is cancelled automatically

A sample ID, which is not yet present in the database, will be created in the database.

In the preanalytical phase, it is possible to access the DMS through the INS function key to the loadlist (excluding the one already in use).

When the COMMANDS key is pressed to start the analysis, the following checks are carried out:

1. Sample IDs should not have more than 8 tests in the database. This calculation is done based on the following rules:

- for the samples already in the Database and with the tests already programmed (also if received through the RS232 interface), only the requested tests are considered if part of the selected profile. If the result is already present in the database for a given test the test is not executed. This is different from the single test, where the test is executed even if the result is present in the database and in this case the result is added into the database together with the others already present.
 - for the samples already in the database and with no tests being programmed, all requested tests present in the profile will be considered. If the requested tests exceed the 8 results (including the results already in the database), a message is given and the analysis cannot start.
 - for the samples not in the database, all tests included in the profile will be executed.
2. Sample IDs which identify QC materials will be executed if at least one sample is requested at the same time having the same test or the QC material being programmed.

If one or more samples have one of the above conditions, the message list is presented and the loadlist is represented.

If the loadlist contains more IDs than allowed, the IDs that exceed the maximum number are ignored.

The request is included in the database when the result is received (if STOP is pressed, the test is not left pending).

After initiating the COMMANDS to start, the material verification on the sample tray is carried out and the rotor presence is verified.

The following checks are done:

- At least one sample should exist.
- At least one executable test should be programmed for the samples to be run.
- All samples must be identified through the loadlist. If samples are present in the loadlist but not on the sample tray, they are ignored.
- All material needed for the requested tests should be present in assigned positions.
- The rotor should have at least 3 consecutive positions free.

If anyone of these checks is not correct the analysis cannot continue and the following actions must be taken.

- If samples or tests are not executable, a message appears.
- If a sample is not identified, a message appears.
- If the material is not available (required cup on the sample tray), a message will be displayed and it will be possible to stop the analysis or add the missing materials and then continue.
- If the rotor has less than 3 free cuvettes, a message appears and the operator must change the rotor and restart.

- If the rotor has 3 or more free cuvettes, a message relative to the sector being used is displayed.

The optional materials (i.e. Normal Pool) can be missing. However, this prevents the calculation of some results in the same way it does for the single tests.

Tests requiring calibration can be executed with the exception of Fib-derived and Fib-C. In this case only the measured result will be given.

3.2.3 Execution of a test run

When the analysis starts, the instrument schedules according to a predefined scheme with a specific sequence of tests.

Tests can be divided in more than one rotor (if necessary) according to the number of cuvettes available.

Execution is divided into a sequence of mini-batches which will contain loading, incubation and acquisition in accordance with the tests required.

When results are available, they are stored in the database.

Printing (internal printer) can be selected as ON or OFF.

The external printer can only be activated from the database while in the READY state.

During execution of the profile, the loadlist remains on the screen but it cannot be modified.

In the status area of the instrument, the test name and the phase in process are displayed.

Operations that can be done in this moment are:

- interrupt the execution of the profile
- access the PROG menu (excluding the DMS, QC and editing of the loadlist in use).

If the rotor is full (or it has less than 3 cuvettes available), the operator is informed via a specific message on the screen and a sound alarm (7 consecutive beeps).

The profile will continue only when the rotor has been changed and restart has been given.

When passing from one test to another, there are still sufficient positions to be used on the rotor, the instrument proceeds automatically.

At the end of each run, results are transferred to the database and printed on the internal printer (if activated).

Between one run and the other the same check on the materials present on the sample tray is carried out.

The execution of a profile can be blocked by pressing STOP-ENTER.

If the STOP-ENTER is used during the transfer of the results, results are still transferred into the database.

3.2.4 Loading phase

The loading phase is executed according to the positions of each material relative to the tests to be run and it is dependent on the selected profile.

Each loading phase is preceded by the same checks.

This allows changes (rearranging of cups) that may occur between one phase and another.

It is possible that rearranging of some of the material needed for the profile will cause testing to be stopped.

Additional washes (to minimize carry-over effects) are automatically handled by the scheduling.

3.2.5 Data Acquisition

Acquisition and data reduction are done in the same way as the single tests (independently from the profile).

If the tests have been programmed to be in standard or extended acquisition time, the single tests as well the profiles perform the same.

Results are stored in the database as soon as they are completed and are printed (automatically on the internal printer if ON) but are not shown on the screen.

The screen will show the loadlist being selected for all runs in process.

Results can be seen at the end in the database.

4 Special Programs

4.0 Special Programs (PROG)

Press the PROG key to display a secondary menu which allows the verification or the modification of various functions and information. These PROGRAMS are disabled in certain situations: during the introduction of data in a cycle, in the date/time screen at power on, and during acquisition.

Printout in Program Mode is possible when the instrument is in the READY state.

Prog	Submenu	Ready	Analysis	Acquisition
DMS		*		
LOADLIST		*	*	
QC		*		
CAL DATA		*	*	
WARNING		*	*	
DIAGNOSTIC	PRIMING	*		
	MAINTENANCE	*	*	
	TEMPERATURE CONTROL	*	*	
	NEEDLES POSITION	*		
	VDU BRIGHTNESS	*		
	SERVICE	*		
SET-UP	REFERENCE MATERIAL	*		
	CALCULATION	*		
	RATIO ADJUSTMENT	*		
	ACQUISITION TIME	*		
	UNITS	*		
	DATE/TIME	*		
	PRINTER STATUS	*		
	INTERFACE STATUS	*		
	SYSTEM CONFIGURATION	*		
	INTERNAL BCR #	*		

* Enabled

This option is not present on the ACL 6000

Status Any status prior to acquisition or following insertion of data or print out.

Action **Press PROG.**

Move the cursor using the ↑ and ↓ keys to the desired program
Press **ENTER.**

Status The program selected is presented in reverse. If the program is enabled, the following frame appears automatically.

If the program is disabled, the program list is presented for a second choice.

PROG	24.JULY,96 12:00
DMS LOADLIST QC CALIBRATION DATA WARNING DIAGNOSTIC SETUP	
↑↓ to select ENTER to confirm	PROG [return]

Note:

- If **PROG** is pressed a second time, the display returns to the cycle in progress. If information is entered during an operative cycle, the new conditions are only operative for the following cycle.

4.1 Patient Database

The patient database contains all patient results being stored including flags. The database also offers the ability to print results (according to different criteria) and to download and upload from/to the host computer (also according to specific criteria).

4.1.1 Sample List screen

From the PROG menu, selecting the DMS option it is possible to access the sample contained in the database.

Samples are presented from the last introduced. Use "Pg DW" to access subsequent pages and use "Pg UP" to return to the previous page.

This screen allows 12 patients lines for each page.

DMS xxx/300 SAMPLES	24.JULY,96 12:00
24-07-96-001 BONGIOVANNI PAOLO P E 24-07-96-002 PETRARCA FRANCESCO C E 24-07-96-003 DI GIOVANNI MARIO C - E 24-07-96-004 EPIS ERNESTO P - E 24-07-96-005 MANTOVANI MADDALENA P - E 24-07-96-006 P - E 24-07-96-007 P - E 24-07-96-008 FRANCESCHINI MAURO N - E 24-07-96-009 P - E 24-07-96-010	
PgUP/DW [move] INS [create] PRT [print] ENTER [select] DEL [remove] COMMANDS [more]	PROG [return] ⇐ [previous]

This list contains patient identification, name of the patient (if inserted), status of the tests associated to it (Completed, Pending, No test), and any flag which indicate the presence of a warning or an error.

Available keys:

Key	Associated action
Arrow UP Arrow DOWN	Position the selection bar from one sample to another; on the first/last sample shown it acts as scroll of the entire page.
Arrow LEFT	Disabled
Arrow RIGHT	Disabled
Page UP Page DOWN	Display the previous/next page.
BackSpace	Moves back to the previous menu (this case will be the PROG menu).
STOP	Disabled
PRT	Print the selected sample/samples according to the "Selection Criteria".
PROG	Close the display of the database going back to the Test menu.
COMMANDS	This key activates a secondary commands menu which includes several options: <i>Transmit</i> , <i>Receive</i> . Selecting <i>Transmit</i> the operator can access the "Selection Criteria" menu, while <i>Receive</i> selection activates the reception of the data from the Host. During the data reception, the of "Test download enquiry transmitting" message is presented.
INS	Opens a new window for the insertion of the data of a new sample ("New Patient Data" screen).
DEL	Allows deletion of a selected sample/samples using the "Selection Criteria" menu.
ENTER	Shows the data of the patient in details ("Patient Data" screen).

Error messages:

Action	Possible error
INS	DATABASE FULL
ENTER	SAMPLE ID NOT FOUND
ENTER	INVALID RANGE SPECIFICATION
During execution	PRINTER ERROR
During execution	TRANSMISSION ERROR
Operation completed	Indication of the number of samples processed.

During the execution of a print command or transmission/reception of data, errors are shown on the screen, offering the possibility to interrupt the execution of the same action.

4.1.2 Selection Criteria screen

DMS XXX/300 SAMPLES	24.JULY.96 12:00
SAMPLE ID..... ALL SAMPLES TRANSMITTED NOT TRANSMITTED COMPLETED PENDING FLAGGED NOT FLAGGED FROM TO BY LOADLIST No.	
↑↓←→ to select ENTER to confirm	PROG (return) ← (previous)

This submenu can be activated using the commands PRINT, DELETE, TRANSMIT which allow the selection of the samples.

The first option (presented as default with the cursor on the first character of the sample ID and the field in reverse) contains the sample identification currently selected at the moment of the request of the command. The user can confirm this option using the ENTER key to select on the single sample ID or to use the Arrow UP and DOWN to select different items.

The option FROM - TO allows specification of a sample ID interval.

The option BY LOADLIST allows selection all the samples present in a specific loadlist.

If printing, the operator can select the kind of report to be printed.

The selection is done using the help messages (last two lines) with the following information:

DMS XXX/300 SAMPLES	24.JULY.96 12:00
SAMPLE ID..... ALL SAMPLES TRANSMITTED NOT TRANSMITTED COMPLETED PENDING FLAGGED NOT FLAGGED FROM TO BY LOADLIST No.	
↑ to select Sample Report ↓ to select Cumulative Report	

During execution of this command, a message is displayed the number of samples to which this action applies.

In case of cancellation, of samples a message is presented to display the number of samples on which the action is done.

The messages are the following:

- "PROCESSED XXX SAMPLES"
- "TRANSMISSION IN PROGRESS FOR x SAMPLES"
- "PROCESSED XXX SAMPLES"

Available keys:

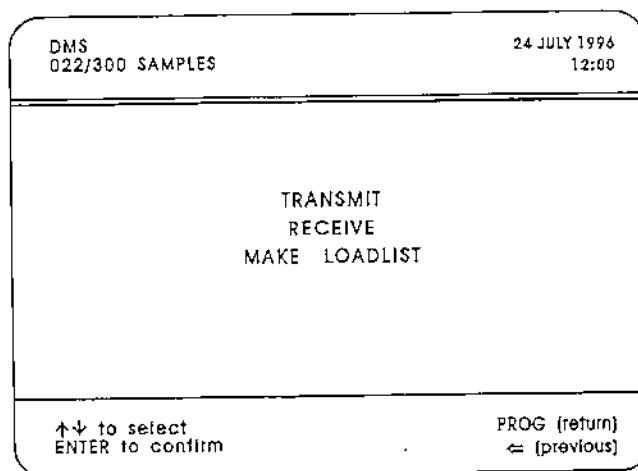
Key	Associated action
Arrow UP	The UP and DOWN keys allows selection of display.
Arrow DOWN	The selected option is represented in reverse. Default is by sample ID. If there are editable field, the cursor is positioned on the first character to be edited.
Arrow LEFT Arrow RIGHT	When the option selected is <i>FROM-TO</i> , the LEFT and RIGHT keys allow movement of the cursor on the first or on the second editable field. No defaults are presented in these cases.
Page UP Page DOWN	Disabled
Back Space	Back to the previous menu (in this case to the SAMPLE LIST).
STOP	Disabled
PRT	Disabled
PROG	Back to the test menu selection.

COMMANDS	Disabled
INS	Disabled
DEL	On the Sample_id, From, To, By_loadlist_no, fields allow cancellation of the last inserted character.
ENTER	Ends sample selection and activates the command. If the parameters are confirmed to be valid and in the command is not activated due to errors the cursor remains in the position to be corrected.

Error messages:

Action	Possible errors
ENTER	SAMPLE ID NOT FOUND
ENTER	INVALID RANGE SELECTION

4.1.3 Commands Menu screen



The COMMANDS key is associated with all the selected options using a submenu.

The COMMANDS content depends on the different actions.

The reported example is relative to the COMMANDS selection from the Sample List screen.

This menu allows activation of RECEIVE from the host and TRANSMIT to the host and Make Loadlist.

DMS XXX/300 SAMPLES	24, JULY, 96 12:00
<p>Test Upload In progress</p> <p>Transmitting message: 0000X</p>	
↑ ↓ → ← to select ENTER to confirm	PROG [return] <= [previous]

When this action is completed, the SAMPLE LIST screen is presented.

In TRANSMISSION to host, the selection criteria submenu is presented and it is possible to define how many samples need to be transmitted.

After the selection, a transmission of data begins (as described for the reception phase).

Available keys:

Key	Associated action
Arrow UP Arrow DOWN	Move the selection bar from one command to another.
Arrow LEFT Arrow RIGHT	Disabled
Page UP Page DOWN	Disabled
BackSpace	Back to the previous menu (in this case to the SAMPLE LIST menu).
STOP	Disabled
PRT	Disabled
PROG	Back to the tests selection menu
COMMANDS	Disabled
INS	Disabled
DEL	Disabled
ENTER	Close the section and activate the command.

Error messages:

Action	Possible errors
COMMAND. RECEIVE	DATABASE FULL
COMMAND. RECEIVE	DUPLICATED SAMPLE_ID
COMMAND. RECEIVE	MORE THAN 8 TESTS PER SAMPLE
COMMAND. RECEIVE	TRANSMISSION ERROR
COMMAND. RECEIVE	HOST NOT RESPONDING

If the make loadlist option is selected three possibilities are available:

- All samples
- Pending samples
- Mark samples

MAKE LOADLIST
XXX\300 SAMPLES
24 JULY 1996
12:00

SELECT ONE OF THE CRITERIA TO
MAKE LOADLIST:

ALL SAMPLES: FROM TO

PENDING SAMPLES: FROM TO

MARK SAMPLES

↑↓ to select
ENTER to confirm
PROG (return)
← (previous)

4.1.4 Patient Data screen

12 lines are available to display the data.

SAMPLE DATA
XXX\300 SAMPLES
24.JUL.96
12:00

sample ID	30-01-95-001	name	BONGIOVANNI MARIO		
TEST SELECTION		sex	M	birth	20.01.80
status	tions dept				
PI-d	12.6 s	0.73 INR	121 %	24.07.96	E
	12.6 s	0.71 INR	120 %		
APIT	32.6 s	0.84 R	97 %	24.07.96	E
FIB	12345 ^00			24.07.96	
P-S	coag.error 1			24.07.96	
HPX	-0-			24.07.96	
PCX	12.6 s	0.73 INR	141 %	24.07.96	
TI	-----s	**** INR	121 %	24.07.96	

PgUP (prev)
PgDW (next)
INS (create)
DEL (remove)
PRT(print) PROG(return)
ENTER (select) ←(previous)

The first three lines contains the patient demographics of the selected sample with the completion status of associated tests and host status (transmitted or not transmitted).

Status of the sample is one of the following:

C = completed (all results associated are available)

P = pending (associated tests are not completed)

N = no tests associated

For transmission, two status are available:

T = data being transmitted to host.

L = (Local) item not yet transmitted.

The ID field is only for reading.

The "TEST SELECTION" field is selectable and allows selection of the test programming screen.

The NAME, SEX, BIRTH, DEPARTMENT fields and the content can be modified.

The "E" field indicates the presence of warning messages.

It is possible to select the lines containing the text messages (with or without results). Use the ENTER key to display the complete warning message associated with the tests.

Using the DEL key to cancel the selected test. If the test has results pending, confirmation is required.

Each unusual event is shown through the warning list and on the internal printer through the error messages.

These messages are also stored in the database and shown using the field errors ("E").

Out of range results are shown in reverse using the "—" (underflow) and "****" (overflow) symbols.

Other error messages relating to the tests will be shown with a specific message using the entire result space as follows:

"calc. error"

"not coag."

"coag. error x"

"-0-"

For double tests the same considerations are valid.

The name of the test is presented on the first line of the sample.

Closing this screen using the PgUP, PgDW, INS, <=, PROG keys, and confirmation of the data introduced is required.

The operator can perform the following actions:

ENTER: confirm and save the data

DEL: do not confirm the changes

BACK: to cancel the command

Available keys:

Key	Associated action
Arrow UP Arrow DOWN Arrow LEFT Arrow RIGHT	Allows moving the cursor from one field to another; the selectable fields are: NAME, TEST SELECTION, SEX, BIRTH, DEPARTM.
Page UP Page DOWN	Display the previous / subsequent sample.
BackSpace	Back to the previous menu (sample list).
STOP	Disabled
PRT	Prints the displayed sample.
PROG	Close the display and returns to the Selection Test menu.
COMMANDS	Disabled
INS	Opens a new screen to insert new sample data (New Patient Data).
DEL	When the cursor is on an editable field, allows cancellation of the last editable field. When it is on one of the 8 tests, it permits the cancellation of the test selected. No effect on the other fields.
ENTER	Ends the editing of a single field and moves to go to the next field (as the Arrow-DOWN key). When the cursor is on an expandable field, it opens a detailed screen that displays or updates the correspondent data. In particular: - When the cursor is on the "TEST SELECTION" field, ENTER opens the programming test screen (Test Programming screen). - When the cursor is on one of the 8 tests, it opens a screen with the error messages and /or warnings associated with the selected tests.

4.1.5 New Patient Data Screen

SAMPLE DATA XXX/300 SAMPLES		24.JUL.96 12:00
SAMPLE ID TEST SELECTION Status	Trans	NAME sex birth dept
INS [create] ENTER(select)	PRT[print]	PROG (return) ← [previous]

The screen is similar to the one used for the display of sample data with the following differences:

The Sample ID field is editable and can accept numeric and alpha-numeric characters (space excluded).

Unique ID in the patient database level as well as the QC database is verified.

When closing the screen using PROG and STOP keys, the confirmation will be required to save the data introduced.

The operator can perform the following actions:

ENTER: to confirm and save the data

DEL: to remove a new sample

BACK: to cancel the command

Available keys:

Key	Associated action
Arrow UP	Allows movement of the cursor from one field to another, selectable fields are: SAMPLE ID, NAME, TEST SELECTION, SEX, BIRTH, DEPARTM
Arrow DOWN	
Arrow LEFT	
Arrow RIGHT	
Page UP	Disabled
Page DOWN	
Back Space	Returns to the previous menu (sample list)
STOP	Closes the display and returns to the main menu
PRT	Allows print of the displayed sample
PROG	Closes the display and returns to the Test Selection menu

COMMANDS	Disabled
INS	Opens a screen to insert a new patient record (New Patient Data).
DEL	When the cursor is on an editable field, allows cancellation of the last character being inserted. On the other fields it has no effect.
ENTER	Closes the editing on a single sample and passes to the next field (as the Arrow-DOWN key). When the cursor is on the "TEST SELECTION" field, ENTER opens the programming test screen (Test Programming screen).

Errors messages:

Actions	Possible errors
Request to insert a new sample record	DATABASE FULL
Confirm of an insertion	DUPLICATED SAMPLE ID

4.1.6 Test Selection Screen

TEST SELECTION		24,JUL,96		
017/300 SAMPLES		12:00		
PT	* AT-III	F-VIII h *	F-VIII I	pt-f/aptt
*FIB	HEP h	F-IX h	F-IX I	pt-f/aptt/tt
*APTT	HEP I	F-XI h	F-XI I	pt-f/fib-c
TT	PLG	F-XII h	F-XII I	aptt/fib-c
FIB-C	AT-PL	F-VII h	F-VII I	tt/fib-c
PCX	P-Chrom	F-X h	F-X I	hpx/pcx
HPX	PT-d	F-V h	F-V I	pcx/aptt/tt
P-Clot	FIB-d	F-II h	F-II I	hpx/aptt/tt
P-S	APTT-d			pcx/fib-c
APCR V	TT-d			hpx/fib-c
D-DIMER				

↑↓←→ to move	PROG{return]
COMMANDS to select/deselect	← (previous)

This screen shows the tests associated with the sample and allows selection and/or addition of new tests or cancel previous selection. Selection through a profile is considered a shorter way to select a group of tests.

The analyzer does not memorize if a test is selected directly or through a profile.

Up to 8 tests can be selected.

Tests already executed cannot be deselected.

Here are the rules for test programming.

1. A test cannot be reprogrammed if already in the database. This is independent of having results or coming from a profile.
2. It is not possible to deselect a test if it already has already results.
3. The PT and FIB tests can be selected individually.
4. The profile selection adds missing tests to those already present in the database, independently from the tests already executed.
5. The profile selection including the PT-Fib must *selected both PT and Fib*.

Available keys:

Key	Associated action
Arrow UP Arrow DOWN Arrow LEFT Arrow RIGHT	Moves the cursor on the tests and profiles selection.
Page UP Page DOWN	Disabled
Back Space	Ends with the programming of the tests and return to the previous screen (Patient Data screen).
STOP	Disabled
PRT	Enabled
PROG	Ends the insertion or the modification of the sample and returns to the menu of the TEST selection.
COMMANDS	Tests Selection
INS	Disabled
DEL	Disabled
ENTER	Selects or deselects the current test or the profile. The selection of a profile automatically selects the tests of the same profile. It is not possible to deselect a profile. The tests associated with a profile can be selected / deselected independently from the profile itself.

Error messages:

Action	Possible errors
TEST SELECTION	MORE THAN 8 TESTS PER SAMPLE

Notes:

- Use of the PROG key:

From the TEST menu it is possible to access the PROG functions only if the editing is not in process.

During an active cycle, some PROG functions can be disabled.

Accessing PROG, the principal menu is shown with the cursor on the DMS selection independently from the operation being done.

From the PROG screen it is possible to return to the TEST previously displayed; the PROG key is always interpreted as an end of an operation (similar to Previous Menu). If editing is in process, a confirmation message is shown.

- LIMITS:

Maximum number of samples = 300

Maximum number of tests = 8 (Double tests occupy two positions)

Number of digits on the Sample Data screen:

sampleID = 12 characters

name = 20 characters

department = 16 characters

sex = 1 characters

birth date = 10 characters (fixed format DD/MM/YYYY)

test-date = 10 characters (fixed format DD/MM/YYYY)

4.1.7 Test execution

1. The single test execution verifies the ability to store the results obtained in the database.

At the start the samples which have more than 8 tests are presented with a notification of too many tests.

2. For execution of a single test on identified samples, the following rules are valid:
 - the test to be executed is programmed, the result obtained is associated to the test programmed; and the sample status will be updated.
 - if the test to be executed is not programmed, the test is added to those already associated and the sample status is updated.
 - For PT and FIB the following rules are valid:

Test Programmed (not executed)	Test executed	Handling
PT	PT-FIB	The PT result is connected to the test being programmed. If the sample has already 8 test requests, the sample cannot be executed.
-	PT-FIB	Both are added
PT-d	PT-FIB	Both are added
PT FIB	PT-FIB/APTT	The PT and Fib results are associated with the tests being programmed and the APTT is added.
PT FIB-d	PT-FIB	The PT result is connected to the test being programmed and the Fib is added.
PT FIB	PT-FIB-d	The PT and Fib results executed in double are added while the PT and Fib in single remain pending.

3. For execution of the profile the following rules are valid:

- In particular for PT and FIB, these are the rules:

PT FIB-d	PT-FIB/APTT/TT profile	The PT result is connected to the test already programmed. The Fib is not archived and APTT and TT are not executed.
FIB	PT-FIB/APTT/TT profile	The Fib result is connected to the test being programmed. The PT is not archived; APTT and TT are not executed.

4.1.8 Results presentation

The presentation order of results (on the screen and on the printer) is fixed and is the same used for the test programming. Each test uses a single line for the results presentation and a time order is done. Each test can be cancelled singularly (valid for PT and Fib).

PT	AT-III	F-VIII h	F-VIII I
FIB	HEP h	F-IX h	F-IX I
APTT	HEP I	F-XI h	F-XI I
TT	PLG	F-XII h	F-XII I
FIB-C	AT-PL	F-VII h	F-VII I
PCX	P-Chrom	F-X h	F-X I
HPX	PT-d	F-V h	F-V I
P-Clot	FIB-d	F-II h	F-II I
P-S	APTT-d		
APCR-V	TT-d		
D-Dimer			

4.2 Loadlist Program

This program is used to store sample ID numbers through the loadlists. Sample IDs can be entered by using either the keyboard or the bar code scanner. The sample ID can be numerical or alpha-numerical and with a maximum of 12 digits for each sample.

The stored loadlist can be recalled during a cycle when required.

Status Ready state.

Action Move the cursor by means of the ↑ and ↓ keys to select LOADLIST and press ENTER.

Status A frame in which it is possible to clear all the loadlists stored in memory is displayed.

We suggest performing this operation at the beginning of each working day.

LOADLIST	24, JULY, 96 12:00
SELECT LOADLIST:	
1	19 JULY 96 11:58
2
3
4
5
6
7
8
9
↑ to clear all loadlists	← to exit
↓ to continue	

Note:

In order to identify the used / not used lists, a list of nine loadlists is displayed.

The date/time of the last change recorded will be indicated when the loadlist is used.

Action Press ↑ to clear all stored loadlists.

Status The instrument asks for a confirmation.

LOADLIST	24, JUL, 96 12:00
LOADLIST	
1	19 JULY 96 11:58
2
3
4
5
6
7
8
9
↑ to return without deletion	
ENTER to confirm deletion	

Action Press ENTER to confirm.

Status The memory will be cleared of all previously stored loadlists and the "select loadlist" frame will be displayed.

Action Press ↑ to return without deletion if it is not necessary to clear all loadlists.

Status The instrument will display the "select loadlist" frame.

LOADLIST		24, JULY, 96 12:00
SELECT LOADLIST:		
1	19 JULY 96 11:58	
2	*****	*****
3	*****	*****
4	*****	*****
5	*****	*****
6	*****	*****
7	*****	*****
8	*****	*****
9	*****	*****
Key in new value ENTER to confirm		PROG to return ← (previous)

Action Key in a number of a loadlist (from 1 to 9) and press ENTER to confirm.

Status The "sample ID insertion" frame will be displayed.

LOADLIST		24, JULY, 96 12:00
LOADLIST: 1		
1	10	
2	11	
3	12	
4	13	
5	14	
6	15	
7	16	
8	17	
9	18	
Key in new value ↑↓←→ to select ENTER to confirm COMMANDS to clear		PROG (return) ← (previous)

Action If it is necessary to clear the single loadlists press Commands.

Status The instrument asks for a confirmation.

Action Press ENTER to confirm.

Status Memory of the single loadlist will be cleared and the insert frame of the same loadlist will be displayed.

Note:

If UP is pressed to return without deletion, the loadlist will not be cleared from the memory.

Status If "↑" is pressed, the cursor will be displayed on the first sample ID number to allow editing of sample IDs.

LOADLIST		24.JULY,96 12:00
LOADLIST: 1		
1		10
2		11
3		12
4		13
5		14
6		15
7		16
8		17
9		18
Key in new value ↑↓←→ to select PROG to return ENTER to confirm COMMANDS to clear ← [previous]		

Action Use the numerical keyboard or the bar code scanner to enter the sample ID number and press **ENTER** to confirm.

Status The cursor will move to the next position.

Action Repeat this operation for the number of positions required by that loadlist.

Notes:

1. If the number of samples is less than 18, press **ENTER** the number of times required to complete the loadlist or press **PROG** to return after the last number.
2. When the operator selects **PROG/LOADLIST** from a cycle, the instrument goes directly to the "select loadlist" frame. When a cycle is running, it is possible to edit other loadlists as required.
3. *Warning: during the acquisition phase it is not possible to edit sample IDs.*
If the operator is editing sample IDs and the acquisition cycle starts, only the sample IDs entered before the beginning of the acquisition cycle will be stored in memory. Once the acquisition cycle is ended restart sample ID editing.

4.2.1 Use of the External Bar Code Scanner

On the ACL 6000 the Bar Code Scanner is a standard feature. On the ACL 7000 it is an option. The external bar code scanner it is mounted on the right side of the instrument. For additional information see Appendix C. The following codes may be read with the use of the bar code scanner:

1. Code 128
2. Code 39
3. Code 93
4. Codabar
5. Interleaved 2 of 5
6. MSI/Plessey

The bar code scanner can read numerical and alpha-numerical sample IDs up to a maximum of 12 digits. The maximum bar code label length readable is 6 cm with a resolution of 0.2 mm.

To enter the Patient ID number using the scanner, proceed as follows:

Primary tubes have to be loaded with the bar code label oriented towards the outside of the sample tray.

Once the loadlist number has been selected, the cursor is positioned on the first sample ID.

Switch on the bar code scanner.

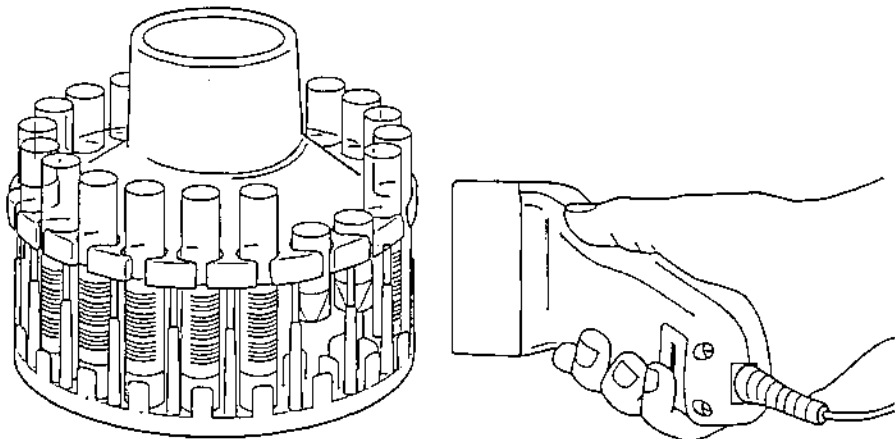
Position the scanner so that it can read the bar code label on the first primary tube and press the trigger.

LOADLIST		24.JULY.96 12:00
LOADLIST: 1		
1		10
2		11
3		12
4		13
5		14
6		15
7		16
8		17
9		18
Key in new value ↑↓←→ to select PROG to return ENTER to confirm COMMANDS to clear = (previous)		

Check that label number 1 has been read correctly; a beep emitted from the scanner will advise you that the reading has been performed. The Sample ID number will be displayed on the screen and the scanner LED will be switched off.

Repeat for all remaining bar code labels.

Reading the Bar Code Label



When all bar code labels have been read, two situations are possible:

- a. 18 primary tubes have been loaded on the sample tray.
The instrument displays the complete loadlist; the operator can check or go back to the main menu by pressing **PROG**.
- b. Less than 18 primary tubes have been loaded on the sample tray.
The instrument displays the loadlist. The operator should press **ENTER** to complete the loadlist and then proceed as for case a.

Notes:

- *If cups are used along with primary tubes, Sample ID numbers corresponding to these positions can be entered using the numerical keyboard and pressing **ENTER** to confirm.*
- *If a code with more than 12 digits or an alpha numeric code is used, the scanner will emit a long beep and the cursor will remain on the position corresponding to the non recognized label.*
- *If a bar code label is damaged and the bar code scanner cannot read it, the scanner will not emit any signal and the cursor will remain on the vacant position.*

*In this case, we suggest using the numerical keyboard to insert the Sample ID number and confirm it with **ENTER**. **ENTER** must be pressed to move the cursor to the next position.*
- *The operator should check the loadlist for correctness i.e. no duplicated or missed IDs.*

4.2.2 Use of the On-board Bar Code Reader (only on the ACL 7000)

On the ACL 7000 it is a standard feature. On the ACL 6000 the on-board barcode reader is not present and it is an option. For additional information see Chapter 4.

The following codes may be read with the use of the on-board bar code scanner:

1. Codabar
2. Code 39
3. Code 128
4. Interleaved 2 of 5

The bar code scanner can read numerical and alpha-numerical sample IDs up to a maximum of 12 digits. The maximum bar code label length readable is 6 cm with a resolution of 0.2 mm.

In order to enter the Patient ID number using the scanner, proceed as follow.

Primary tubes have to be loaded with the bar code label oriented towards the outside of the sample tray.

After selecting a cycle or a profile, once the loadlist number has been selected, press ↓ to start analysis.

The instrument will scan the tubes and report the readings on the screen.

If all readings are OK, the operator can confirm the loadlist and star the cycle.

If some readings are not present (cup, bad quality label, etc.) the operator can edit the loadlist before starting the cycle.

For additional information on the setup of the different barcode label please refer to Chapter 4.7.10.

READY	24, JULY, 96 12:00
LOADLIST: 1	
101	110
102	111
103	112
104	113
105	114
106	115
107	116
108	117
109	118
Key in new value ENTER to confirm	PROG to return = (previous)

4.3 Q.C. Data Base

4.3.1 Introduction

QC database can be accessed through the PROG menu.

PROG	24, JULY, 96 12:00
DMS LOADLIST QC CALIBRATION DATA WARNING DIAGNOSTIC SETUP	
↑↓ to select ENTER to confirm	PROG{return}

Within the QC program it is possible

- to access the stored data (QC Review)
- to define new control materials or new tests to be added to the materials already configured (QC Set Up).

QC	24.JULY.96 12:00
REVIEW QC DATA BASE SETUP QC	
↑↓ to select ENTER to confirm	PROG{return} <= {previous}

4.3.2 Set-up Q.C.

The QC Set-up is organized by material. It is possible to configure a maximum of 10 control materials.

Each material can be configured for 10 tests maximum.

QC SET-UP	24.JULY.96 12:00
Q.C. CONTROLS LIST NP LOW FIB PAT 1 PAT 2	
↑↓ to select ENTER to confirm	INS{create} PROG{return} DEL{remove} <= {previous}

NP (normal pool) is a QC material always present in the database as a default material.

The NP material is already set for a certain number of tests (PT, Fib, APTT and TT).

It is possible to add other tests for this material but it is not possible to deselect the 4 tests already configured from the set up.

The INS key allows a new material to be configured.

This function is available only if less than 10 materials are in the database.

The DEL key allows the material to be removed from the database.

The operation must be confirmed and in this case all information relative to the specific material is removed.

Select one material with ENTER and the following frame appears.

QC SET-UP		24.JUL.96 12:00	
Control ID		LOT No.	
Note			
*PT	*AT-III	*F-VIII h	*F-VIII I
FIB	HEP Xd	F-IX h	F-IX I
APTT	HEP h	F-XI h	F-XI I
TT	HEP I	F-XII h	F-XII I
FIB-C	PLG	F-VII h	F-VII I
PCX	AT-PL	F-X h	F-X I
HPX	P-Chrom	F-V h	F-V I
APCR	P-Clot	F-II h	F-II I
D-DIMER	P-S		
ENTER (select)		PRT to print	PROG(return)
DEL (deselect)			← (previous)

This frame outlines all tests effectively configured for the QC materials (marked with an asterisk).

If the selection is done for the PT, all variables of the tests are used for the QC material including all PT cycles (they can come from PT, PT-FIB, double PT, double PT-FIB, PT/APTT, and profiles such as PT-FIB/APTT/TT, PT-FIB/FIB-C, etc.).

Data are stored independently of the acquisition time selected (standard, extended). Tests configured for the specific material are marked with '*'. The material ID is not modified for the existing material. If it is a new material, it must be inserted using "INS". The lot number (6 digits) is optional.

If a lot of a material is modified, all QC data acquired up to that moment are lost; this operation is executed with confirmation.

The lot number is unique and is also valid for the NP material.

Positioning the cursor on a test, the ENTER key will select/deselect the test of the specific material. If the test has been already selected, it is possible to view the set-up data and eventually modify parameters.

When a test is selected and ENTER is pressed a frame describing the set-up conditions (default for target mean and SD set to 0, SD range is blank and range for QC range and patient checking set to off) is shown.

If the material has already 10 tests selected, it is not possible to add additional tests and the operator is alerted.

If a test is deselected, all data are removed from the database (this operation requires confirmation).

Pressing ENTER on select/review the following frame appears.

QC SET-UP		24.JUL.96 12:00	
Control ID		LOT No.	
Note		Test PT	
Unit		S	
Target Mean		XXX.X	
Target SD		XXX.X	
SD Range [1,2,3]		X	
QC Range check		ON	
Patient results flagging for range check		OFF	
↑↓←→ to select		PROG (return)	
ENTER to confirm		← (previous)	

When exiting from this screen modifications must be saved and confirmed. If modifications are made on an existing test, the new parameters become active without losing data already contained in the database. The unit field is predefined and cannot be modified. Units and target mean and target SD are reported for all tests in the following table:

TEST	UNIT	FORMAT (Target Mean and SD)
PT	sec.	xxx.x
FIB (PT derived)	mg/dL o g/L (as selected)	xxxx or x.xxx
APTT	sec.	xxx.x
FIB-C	mg/dL o g/L (as selected)	xxxx or x.xxx
AT-III	%	xxx.x
TT	sec.	xxx.x
HPX	%	xxx.x
PCX	%	xxx.x
Factors	%	xxx.x
P-Clot	%	xxx.x
Hep-Xa	U/mL	x.xx
Heparin	U/mL	x.xx
PLG	%	xxx.x
AT-PL	%	xxx.x
P-Chrom	%	xxx.x
P-S	%	xxx.x
D-Dimer	ng/mL	xxxx
APCR-V	seconds	xxx.x

When the QC check is ON, each result obtained on a specific control material is compared to the range selected.

The result is considered not valid if it is out of range.

If the QC check is OFF, no comparison is done (default is OFF).

When the patient results flagging is ON, all sample results related to the control material that was not valid are flagged for the specific test.

The flag remains for the entire analytical session (single test or profile).

If the patient results flagging is OFF, no flag is activated (default value is OFF).

SD range +/- max. deviation * target SD.

Note:

Refer to the Addendum page at the end of section 4 for expected SD for IL Reagents and Controls.

4.3.3 Review Q.C. Data Base

Review of the data present in the database is organized by material and then by test.

Each QC material (10 maximum) can be programmed for 10 tests maximum.

This organization shows the material selection, then the test selection screen.

Materials can be selected through their ID number.

QC REVIEW		24.JUL.96 12:00
Q.C. CONTROL LIST		
NP		
QC_MATERIAL 1		
QC_MATERIAL 2		
.....		
.....		
.....		
.....		
.....		
.....		
123456789012		
↑↓ to select		PROG(return)
ENTER to confirm		← (previous)

The material selection permits review of the general information and indications of which test is using a material being selected.

The test list includes from 0 to 10 elements.

Q.C. REVIEW		24.JUL.96 12:00
Control ID	NP	LOT No.
Note.....		
PT		AT-III
FIB	
APTT	
TT	
.....		12345678
↑↓↔ to select		PROG(return)
ENTER (select)	COMMANDS (transmit)	← (previous)

The test selection allows access of the detailed information of the material in respect to the test being selected (view only).

The first level of information contains the cumulative statistics.

Pressing Commands the Q.C. data can be transmitted to the Host as "All QC Data" or "By Interval Time".

Q.C. REVIEW		24.JUL.96 12:00	
Control ID	NP	LOT No.	
Note.....		Test PT	
Unit		S	
Actual Mean		xxx,x	
Target Mean		xxx,x	
Actual SD		xxx,x	
Target SD		xxx,x	
No. of results in statistics		xxxx	
No. of results currently in DB		xxx	
↑ to see plot		PROG(return)	
↓ single results		COMMANDS (transmit) ← (previous)	

Press UP to see the Plot and ENTER to confirm the date displays the Levey-Jennings plot and allows definition of a different time interval.

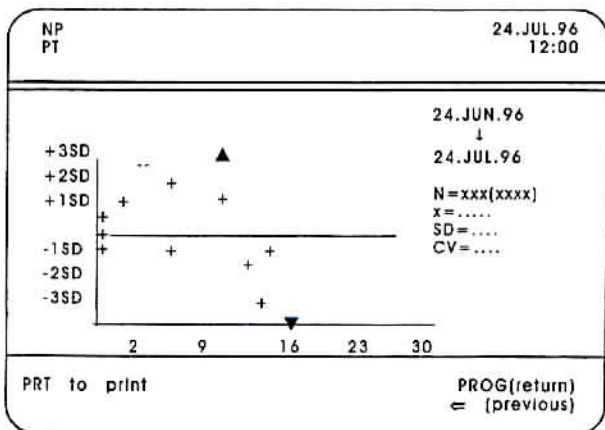
Q.C. REVIEW		24.JUL.96 12:00	
Material ID	NP	LOT No.	
Note.....		Test PT	
Unit		S	
Actual Mean		xxx,x	
Target Mean		xxx,x	
Actual SD		xxx,x	
Target SD		xxx,x	
No. of results in statistics		xxxx	
No. of results currently in DB		xxx	
End of time interval: 24.Jul.96			
↑ to modify date		PROG (return)	
ENTER to confirm		← (previous)	

The default date is the current one. The operator can introduce a desired date as the final period of time.

The date can be entered in the sequence day, month, year. If there is no data available in the requested period, an error message appears.

Q.C. REVIEW		24.JUL.96 12:00	
NO DATA IN THE SPECIFIED TIME INTERVAL			
↓ to continue			

If there is data available, the graph is displayed with the following characteristics.



The graph on the Y axis is centered on the target mean value with a fixed window of +/- 3SD.

On the X axis, the period being selected is represented.

The symbol '+' represents one or more valid result/s, the symbol '-' represents one or more invalid result/s (out of range), the symbol '*' represents an omitted result and the symbols '▽' and '△' indicate values out of the graphical representation.

If cumulative statistics are required, the following information is shown.

RESULTS	UNIT	DATE	TIME	FLAGS	OMITTED
xx.x	s	23.07.96	11:00	E	yes
xx.x	s	23.07.96	18:00		
.....	\$			
.....	\$			
.....	\$			
.....	\$			
.....	\$			
.....	\$			

PgUp/PgDw to move PRT to print PROG(return)
 ENTER to select DEL to omit result = (previous)

The results are presented with the oldest first.

Use PgDw/PgUp to move within the entire database for the material/test selection.

The Flags column is defined with 'E' and indicates that a sample has associated Flags.

Press ENTER to access the page containing all flags associated with a specific sample.

The column OMITTED indicates omitted results.

Omission can be done using the DEL key.

The result is flagged with omitted and excluded from the statistics (omission is done with confirmation).

The omitted result (and confirmed) cannot be retrieved into the statistics (a specific symbol is used on the graph to indicate an omitted result).

The added flag for the QC results is:

- invalid (for range checking)

4.3.4 Q.C. in Analysis

The number of QC samples in the analysis is defined by the operator. In single tests selection and with identified samples, the system can recognize (depending on the ID numbers) which samples are controls and/or patients.

If the QC material is not programmed for the requested test/s, the message "QC MATERIAL NOT PROGRAMMED" appears.

When the analysis starts, the QC materials are treated as the other samples (loading, incubation, acquisition).

Data obtained on the QC materials are stored in the QC database.

The N.P. material is considered as a QC material in a fixed position but is also connected to same tests (PT, Fib-derived, APTT and TT) to confirm the output of some results.

The NP must be positioned in position POOL for PT, FIB, APTT and TT.

For other tests this material must be placed on the sample tray.

If the QC material is used in a profile selection, the tests executed will be those set for the QC material if also requested in the profile. Considerations done for the single tests are also valid for profiles. QC materials cannot be added if the profile is already started. If a material is programmed into the Loadlist, its position should be verified. If the material in the cup for the QC is not sufficient, messages for insufficient sample will be displayed.

Note:

For any additional information concerning the QC refer to NCCLS C24-A vol. 11 No. 6, Internal Quality Control Testing: Principles and Definitions.

4.3.5 Elaboration Data

QC elaboration data is done on the specific units defined and fixed for each test. If the QC range check is ON, each result is compared with

$$\text{target mean} \pm \text{maximum deviation} * \text{target SD}$$

If the result is out of range it is considered invalid.

If the patient result flagging for the range check is ON, all results of the patients for the same tests obtained in the same analytical session with the QC material are flagged.

All non numeric values (not coag., coag. error, +++, ...) obtained on the QC plasma are stored in the database but they are not used to update the statistics. However, they are used to flag patients results.

Invalid numeric results influence the total statistics as well as the flag on the patients results.

Notes:

1. Reference values for the tests TT and APTT can be defined in relative PROG. The use is selectable in the PROG-Calculation (Ratio versus the value of the sample tray or versus the value of the Reference Data).
2. The ISI for PT is definable in the PROG-Reference data.
3. If the instrument is not calibrated, the Ratio/INR calculation can be done only if the NP is placed on the sample tray and the user has selected Autocal ON (value must be in range).
4. In the double or mixed cycles, QC results will be stored according to the tests but independent the cycle in which the QC is present.
For example: if the test is the PT, the QC results may derive from material placed in one of the following combinations:

- PT	- PT-FIB
- d-PT	- d-PT-FIB
- PT/APTT	- PT-Fib/APTT/TT
- PT-F/FIB-C	

 The results are stored independently of the acquisition selected (short-Standard, short-Extended, long-Standard, long-Extended).

WARNING IDs used for QC materials cannot be used for patient identification. QC samples obtained with Animal Option are stored and handled as for the other cycles (flagging, cumulative statistics, etc.). If necessary, they can be removed from the QC database.

4.4 Cal Data Program

This program is not accessible during:

- the Analysis cycle, from the start of the acquisition phase to the presentation of the results,
- the Calibration cycle, (PT-FIB, SINGLE FACTORS of the EXTR PATH, SINGLE FACTORS of the INTR PATH, PCX, HPX, AT-III, FIB-C, HEPARIN Xa) from the start of the acquisition phase until the operator has accepted or rejected the results of the calibration.

This program is used to verify the calibration analytical conditions (data, graphs, etc.). Press **PROG**.

Action Using the **↑** and **↓** keys, select the **CALIBRATION DATA** to be displayed and press **ENTER**.

PROG	24.JUL.96 12:00
DMS LOADLIST Q.C. CALIBRATION DATA WARNING DIAGNOSTIC SETUP	
↑,↓ to select ENTER to confirm	PROG to return

4.4.1 PT-FIB Cal Data

Action Using the ↑ and ↓ keys select PT-FIB and press ENTER.

CALIBRATION DATA		24.JUL.96 12:00	
PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997
FIB-C	24.MAY.1997	F-IX h	21.OCT.1997
PCX	15.JUN.1997	F-XI h	12.NOV.1997
HPX	18.JUL.1997	F-XII h	23.DEC.1997
AT-III	22.AUG.1997	F-VII h	11.SEP.1997
Hep Xa		F-X h	13.OCT.1997
Hep h		F-V h	24.NOV.1997
P-Chrom		F-II h	16.DEC.1997
PLG			
AT-PL		APCR	
P-Clot			
D-Dimer			
↑, ↓ ← → to select		PROG (return)	
ENTER to confirm		<= (previous)	

This screen indicates the date of the last saved calibration (if present) for each test.

Status The "ANALYTICAL CALIBRATION CONDITION" frame will be displayed.

Note:

In this program it is not possible to change the conditions, only display them. The conditions can be changed only when a new calibration takes place.

CALIBRATION DATA		24.JUL.96 12:00	
PT-FIB CAL ANALYTICAL CALIBRATION CONDITION			
N.P. ID.			357067
FIB REFERENCE VALUE [mg/dL]			249
REF. EMULSION LOT			380060
THROMBOPLASTIN LOT			270011
ISI			2,240
CALIBRATION DATE			24.JUL.96
↑ to see Cal Data and Graphics		PROG (return)	
		<= (previous)	

Action Press ↑ to see CAL DATA and GRAPHICS.

Status The PT-FIB Cal Data are displayed.

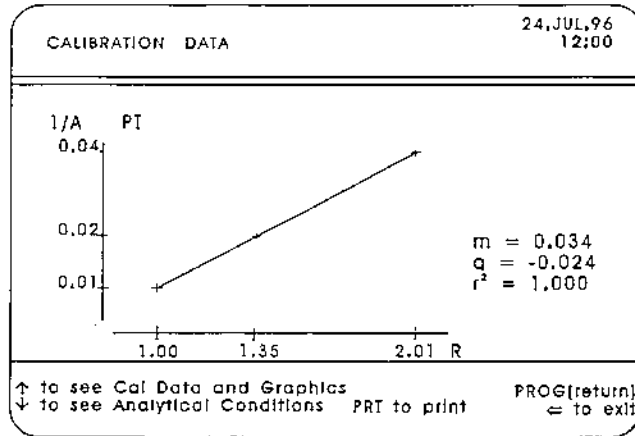
CALIBRATION DATA		24.JUL.96 12:00	
% s			
PT 100	12,9	CV =	0,65
50	18,0	CV =	0,31
25	29,5	CV =	0,83
m = 0,027 q = 0,017 r2 = 1,000			
mg/dl Δ			
Fib 298	60,53	CV =	2,35
149	26,26	CV =	6,62
60	13,5	CV =	5,25
m=275,7 q=23,91 r2=0,998			
↑ to see Cal Data and Graphics		PRT to print	
↓ to see Analytical Conditions		PROG(return) = to exit	

Action Press PRT to print.

Status The instrument prints the information contained on the display if in Ready state.

Action Press \uparrow .

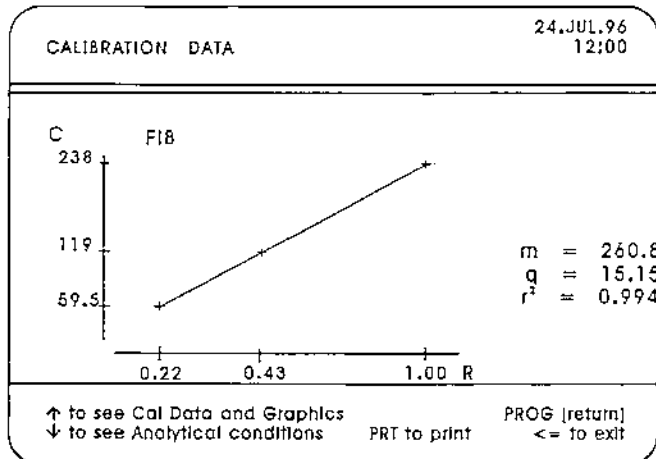
Status The instrument displays the PT graph and relative parameters.



Action Press PRT to print the calibration curve if in ready state.

Action Press " \uparrow ".

Status The instrument displays the FIB graph and relative parameters.



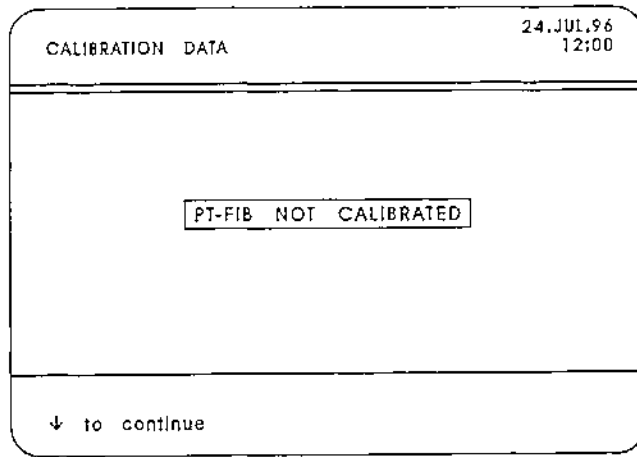
Action Press PRT to print the calibration curve if in ready state.

Action Press " \leftarrow ".

Status The instrument returns to the CALIBRATION DATA frame.

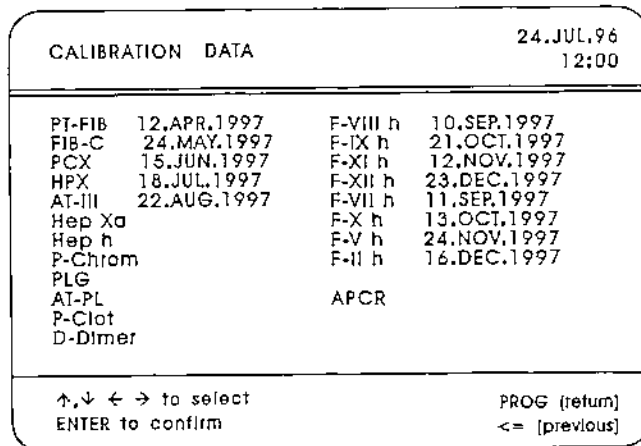
Note:

If the instrument is not calibrated for PT-FIB, when the PT-FIB CAL DATA program is entered, the "PT-FIB not calibrated" frame appears.



4.4.2 Single Factors of the Extrinsic Pathway (Cal Data)

Action Using the ↑ and ↓ keys, select the Single Factor of the EXTRINSIC PATHWAY (between the four available: II, V, X and VII) and press ENTER.



Status In case Factor II has been selected, the last accepted analytical conditions are displayed.

Note:

As for PT-FIB data, this information cannot be modified in the PROG menu, only during a calibration procedure.

CALIBRATION DATA	24.JUL.96 12:00
FACTOR - II HIGH ANALYTICAL CALIBRATION CONDITION	
N.P. LOT No. THROMBOPLASTIN LOT No. DEFICIENT PLASMA LOT No.	
CALIBRATION DATE: 21.JUL.96	
↑ to see Cal Data and Graphics	PROG [return] ← [previous]

Action Press ↑ to see CAL DATA and GRAPHICS.

Status The instrument presents the results of the calibration (high curve only) of the Factor II.

CALIBRATION DATA	24.JUL.96 12:00								
<table style="margin: auto;"> <thead> <tr> <th style="text-align: left;">%</th> <th style="text-align: left;">s</th> </tr> </thead> <tbody> <tr> <td>II 100</td> <td>12.9</td> </tr> <tr> <td>50</td> <td>18.0</td> </tr> <tr> <td>25</td> <td>29.5</td> </tr> </tbody> </table>		%	s	II 100	12.9	50	18.0	25	29.5
%	s								
II 100	12.9								
50	18.0								
25	29.5								
$m = 0.027$ $q = 0.017$ $r^2 = 1.000$									
↑ to see Cal Data and Graphics ↓ to see Analytical Conditions	PRT to print PROG[return] ← to exit								

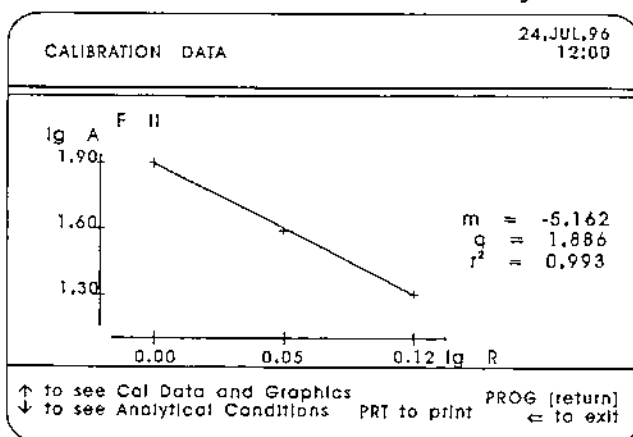
Action Press PRT to print.

Status The instrument prints out the information contained on the display.

Action Press ↑ to see CAL DATA and GRAPHICS.

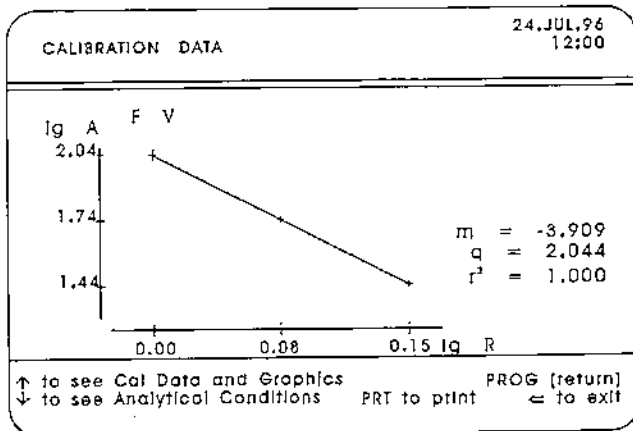
Status The instrument displays the calibration graph and parameters related to Factor II.

Action Pressing PRT to print the calibration curve if in ready state. Press "←" to return to the PROG CAL DATA entry screen.

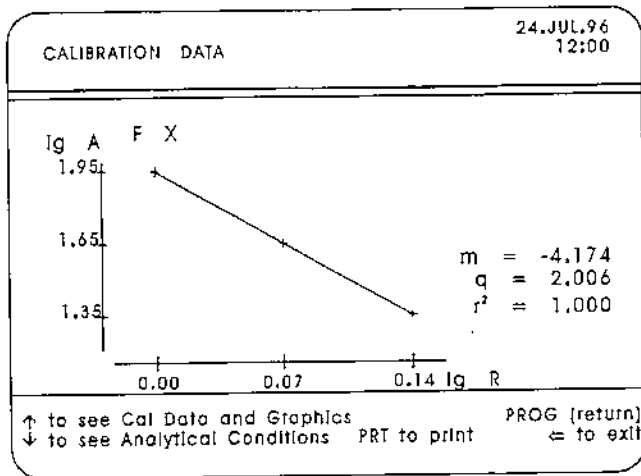


Status In case Factor V is selected in the CALIBRATION DATA frame, the instrument displays the calibration graph and parameters related to it.

Action Press PRT to print the calibration curve if in ready state.
Press "↓ to continue".

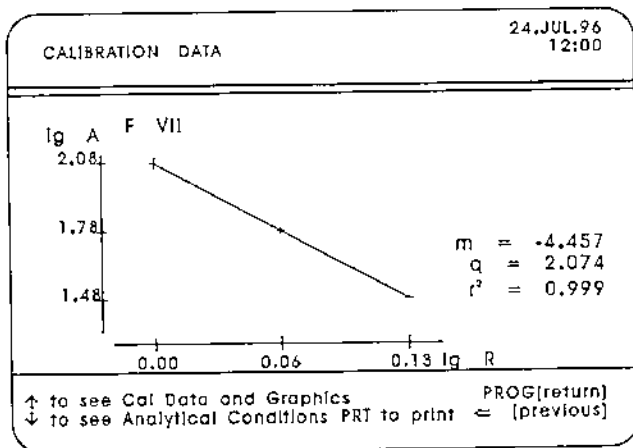


Status In case Factor X is selected in the CALIBRATION DATA frame, the instrument displays the calibration graph and parameters related to it.



Action Press PRT to print the calibration curve if in ready state.
Press "←" to go back to the CAL DATA entry screen.

Status In case Factor VII is selected in the CALIBRATION DATA frame, the instrument displays the calibration graph and parameters related to it.



Action Press PRT to print the calibration curve if in ready state.
Press "←".

Status If the selected Factor is not calibrated the following frame appears.

CALIBRATION DATA	24.JUL.96 12:00
<div style="border: 1px solid black; padding: 5px; display: inline-block;">F VII h NOT CALIBRATED</div>	
↓ to continue	

Action Press ↓ to return to the "PROG" frame.

Note:

Only the calibrated factor is presented. A non-calibrated factor is indicated as NOT CALIBRATED.

4.4.3 Single Factor of the Intrinsic Pathway (Cal Data)

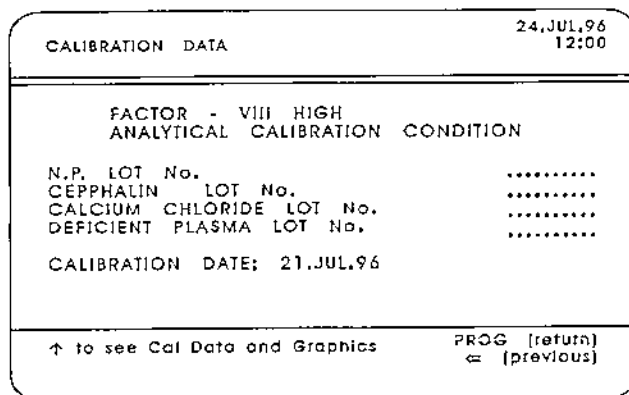
Action Using the ↑ and ↓ keys, select the Single Factor of the INTRINSIC PATHWAY (between the four available: VIII, IX, XI and XII) and press ENTER.

CALIBRATION DATA	24.JUL.96 12:00
PT-FIB 12.APR.1997	F-VIII h 10.SEP.1997
FIB-C 24.MAY.1997	F-IX h 21.OCT.1997
PCX 15.JUN.1997	F-XI h 12.NOV.1997
HPX 18.JUL.1997	F-XII h 23.DEC.1997
AT-III 22.AUG.1997	F-VII h 11.SEP.1997
Hep Xa	F-X h 13.OCT.1997
Hep h	F-V h 24.NOV.1997
P-Chrom	F-II h 16.DEC.1997
PLG	
AT-PL	APCR
P-Clot	
D-Dimer	
↑,↓ ← → to select ENTER to confirm	
PROG (return) <= (previous)	

Status In case Factor VIII has been selected, the last accepted analytical conditions for this factor are presented.

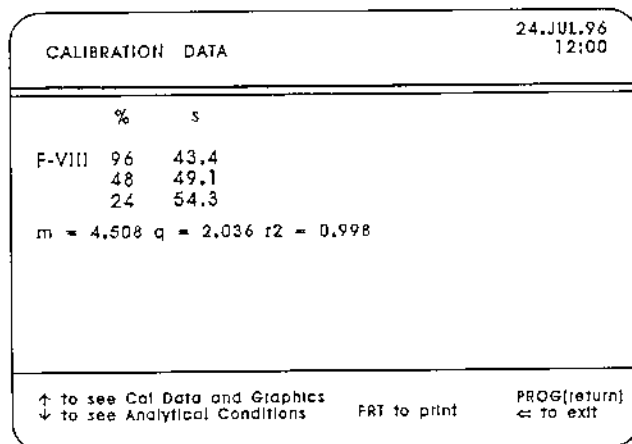
Note:

As for PT-FIB data, this information cannot be modified in the PROG menu, only during a calibration procedure.



Action Press ↑ to see CAL DATA and GRAPHICS.

Status The instrument presents the results of calibration for the selected factor.

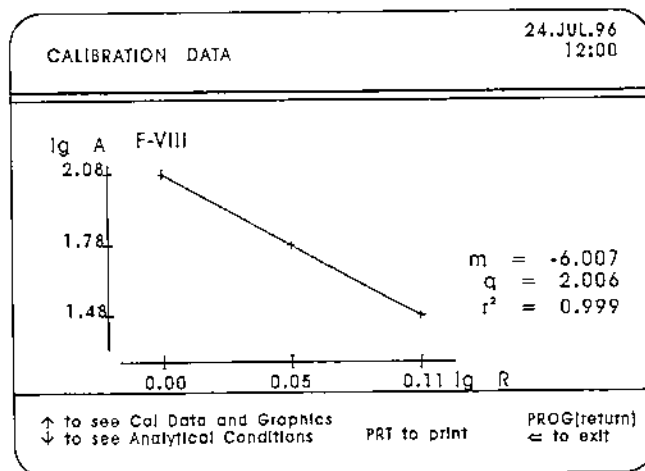


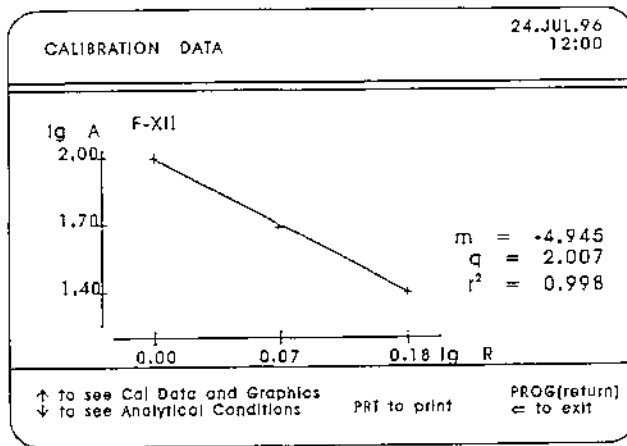
Action Press PRT to print.

Status The instrument prints out the information screen,

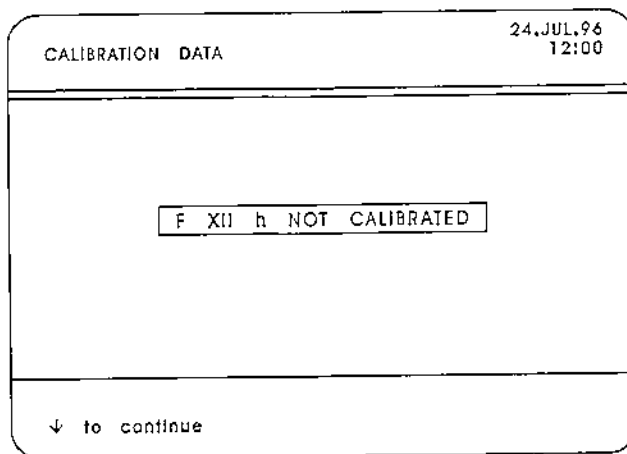
Action Press ↑ to see CAL DATA and GRAPHICS.

Status The instrument shows the calibration graph and relative parameters.





Status If the selected Factor is not calibrated the following frame appear.



Action Press ↓ to return to the "PROG" frame.

Note:

Only the calibrated factor is presented. A non-calibrated factor is indicated as NOT CALIBRATED.

4.4.4 Pro-IL-Complex Cal Data

Action Using the ↑ and ↓ keys, select PRO-IL-COMPLEX and press ENTER.

Status The "LAST ACCEPTED ANALYTICAL CALIBRATION CONDITIONS" frame will be displayed.

Note:

In this program it is not possible to change the conditions, only display them. The conditions themselves can be changed each time a new calibration takes place.

CALIBRATION DATA		24.JUL.96 12:00	
PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997
FIB-C	24.MAY.1997	F-IX h	21.OCT.1997
PCX	15.JUN.1997	F-XI h	12.NOV.1997
HPX	18.JUL.1997	F-XII h	23.DEC.1997
AT-III	22.AUG.1997	F-VII h	11.SEP.1997
Hep Xa		F-X h	13.OCT.1997
Hep h		F-V h	24.NOV.1997
P-Chrom		F-II h	16.DEC.1997
PLG			
AT-PL		APCR	
P-Clot			
D-Dimer			

↑ ↓ ← → to select
 ENTER to confirm

PROG (return)
 <= (previous)

Status The PRO-IL-COMPLEX analytical conditions are presented.

PRO-IL-COMPLEX CAL		24.JUL.96 12:00	
PRO-IL-COMPLEX ANALYTICAL CALIBRATION CONDITIONS			
N. P. LOT No.		918273	
BOVINE THROMBOPLASTIN LOT NO.		645546	
ISI		1.000	
CALIBRATION DATE : 12.SEP.1997			

↑ to see Cal Data and Graphics

PROG (return)
 <= (previous)

Action Press ↑ to see cal data and graphic.

PRO-IL-COMPLEX CAL		24.JUL.96 12:00	
PRO-IL-COMPLEX LAST ACCEPTED ANALYTICAL CALIBRATION CONDITIONS			
N. P. LOT No.		918273	
BOVINE THROMBOPLASTIN LOT NO.		645546	
ISI		1.000	

↑ to see Cal Data and Graphics

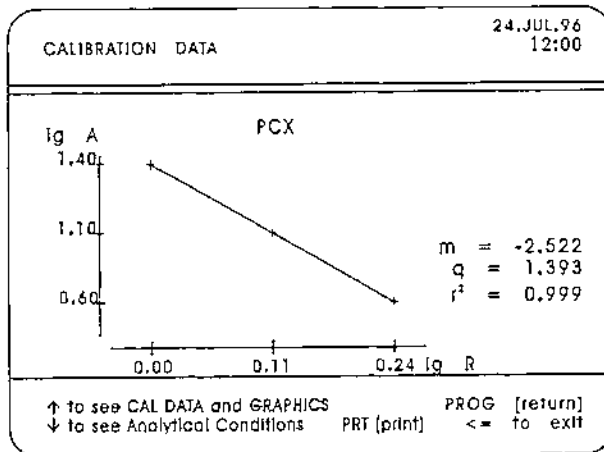
= to return

Status The instrument presents the PRO-IL-COMPLEX graph and the parameters.

Action Press **PRT** to print the calibration curve if in the ready state.
Press **<=** to return to PROG.

Status The instrument returns to the PROG CAL DATA frame.

CALIBRATION DATA			24.JUL.96 12:00
	%	s	
PCX	25.0	41.0	CV = 0.5
	12.5	53.2	CV = 1.0
	6.3	71.0	CV = 1.5
	100	30.0	CV = 0.5
m = 9.432 q = 1.289 r2 = 0.999			
↑ to see cal data and graphics			PROG [return]
↓ to see analytical conditions			PRT to print <= to exit



Note:

If the instrument is not calibrated for Pro-IL-COMPLEX, when the PRO-IL-COMPLEX CAL DATA program is entered, the "PRO-IL-COMPLEX not calibrated" frame appears.

CALIBRATION DATA		24.JUL.96 12:00
<div style="border: 1px solid black; padding: 5px; display: inline-block;">PCX NOT CALIBRATED</div>		
↓ to continue		

Action Press ↓ to return to the "PROG" frame.

4.4.5 Hepatocomplex Cal Data

Action Using the ↑ and ↓ keys, select the HEPATOCOMPLEX and press ENTER.

CALIBRATION DATA		24.JUL.96 12:00	
PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997
FIB-C	24.MAY.1997	F-IX h	21.OCT.1997
PCX	15.JUN.1997	F-XI h	12.NOV.1997
HPX	18.JUL.1997	F-XII h	23.DEC.1997
AT-III	22.AUG.1997	F-VII h	11.SEP.1997
Hep Xa		F-X h	13.OCT.1997
Hep h		F-V h	24.NOV.1997
P-Chrom		F-II h	16.DEC.1997
PLG			
AT-PL		APCR	
P-Clot			
D-Dimer			
↑,↓ ← → to select		PROG (return)	
ENTER to confirm		← (previous)	

CALIBRATION DATA		24.JUL.96 12:00	
HEPATOCOMPLEX ANALYTICAL CALIBRATION CONDITIONS			
N. P. LOT No.			918273
RABBIT THROMBOPLASTIN LOT NO.			645546
ISI			1.000
↑ to see cal data and graphics		PROG (return)	
		← (previous)	

Status The "LAST ACCEPTED ANALYTICAL CALIBRATION CONDITIONS" frame will be displayed.

Note:

In this program it is not possible to change the conditions, only display them. The conditions themselves can be changed each time a new calibration takes place.

Action Press ↑ to continue.

Status The HEPATOCOMPLEX Cal Data screen is presented.

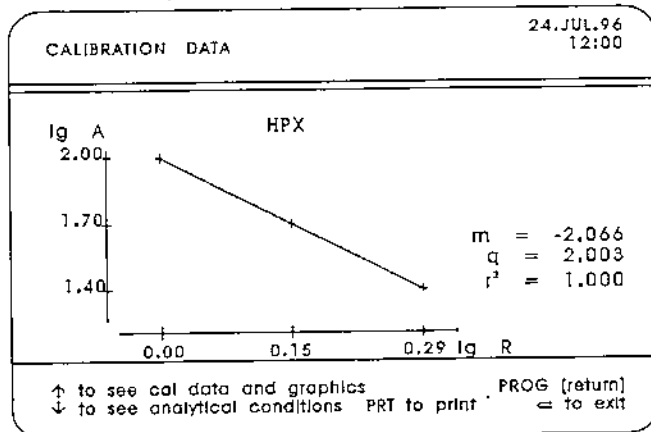
CALIBRATION DATA			24.JUL.96 12:00	
	%	s		
HPX	100	20.4	CV =	0.5
	50	28.8	CV =	1.0
	25	39.9	CV =	1.5
m = 0,975 q = - 1,234 r2 = 0,999				
↑ to see cal data and graphics			PROG (return)	
↓ to see analytical conditions			PRT to print ⇐ to exit	

Action Press PRT to print.

Status The instrument prints the information contained on the display (if in the ready state).

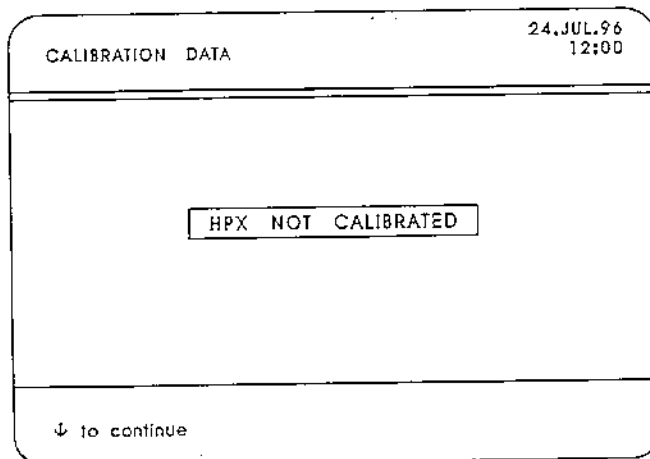
Action Press ↑ to see the Hepatocomplex graph.

Status The instrument presents the HPX graph and relative parameters.



Action Press PRT to print the calibration curve if in the ready state.
Press ⇐ to return to the Cal Data entry screen.

Status The instrument returns to the PROG frame.



Note:

If the instrument is not calibrated for HEPATOCOMPLEX, when the HETACOMPLEX CAL DATA program is entered the "HEPATOCOMPLEX NOT CALIBRATED" frame appears.

4.4.6 AT-III Cal Data

Action Using the ↑ and ↓ keys, select AT-III and press ENTER.

CALIBRATION DATA		24.JUL.96 12:00	
PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997
FIB-C	24.MAY.1997	F-IX h	21.OCT.1997
PCX	15.JUN.1997	F-XI h	12.NOV.1997
HPX	18.JUL.1997	F-XII h	23.DEC.1997
AT-III	22.AUG.1997	F-VII h	11.SEP.1997
Hep Xa		F-X h	13.OCT.1997
Hep h		F-V h	24.NOV.1997
P-Chrom		F-II h	16.DEC.1997
PLG			
AT-PL		APCR	
P-Clot			
D-Dimer			
↑,↓ ← → to select		PROG (return)	
ENTER to confirm		← (previous)	

Status The "LAST ACCEPTED ANALYTICAL CALIBRATION CONDITIONS" frame will be displayed.

Note:

In this program it is not possible to change the conditions, only display them. The conditions themselves can be changed each time a new calibration takes place.

CALIBRATION DATA		24.JUL.96 12:00	
ANTITHROMBIN-III ANALYTICAL CALIBRATION CONDITIONS			
N.P. LOT No.			918273
ENZYME/SUBSTRATE LOT NO.			645546
CALIBRATION DATE			8.JUN.92
↑ to see cal data and graphics		PROG (return)	
		← (previous)	

Action Press ↑ to see CAL DATA and GRAPHICS.

Status The AT-III Cal Data is presented.

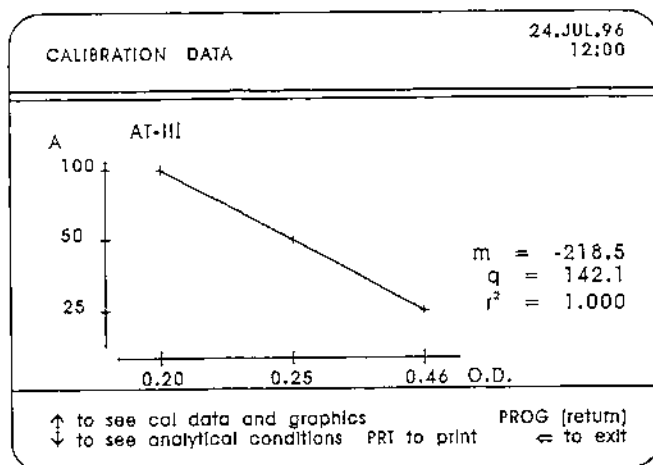
CALIBRATION DATA				24.JUL.96 12:00	
	%	D OD			
AT-III	100	0.204	CV =	0.5	
	50	0.488	CV =	1.0	
	25	0.609	CV =	1.5	
m = 0.975			q = - 1,234	r2 = 0,999	
↑ to see cal data and graphics ↓ to see analytical conditions				PRT to print	PROG [return] ⇐ to exit

Action Press PRT to print.

Status The instrument prints the information contained on the display if in the ready state.

Action Press again ↑ to see CAL data and GRAPHICS.

Status The instrument presents the AT-III graph and relative parameters.



Action Press PRT to print the calibration curve if in the ready state.
Press ⇐ to return to the Cal Data entry screen.

Status The instrument returns to the CALIBRATION DATA frame.

Note:

If the instrument is not calibrated for AT-III, when the AT-III CAL DATA program is entered, the "AT-III NOT CALIBRATED" frame appears.

CALIBRATION DATA	24.JUL.96 12:00
<div style="border: 1px solid black; padding: 5px; display: inline-block;">AT-III NOT CALIBRATED</div>	
↓ to continue	

4.4.7 Other Cal Data

For all the other remaining tests, the same approach as the tests described previously is followed.

CALIBRATION DATA	24.JUL.96 12:00																																																
<table border="0"> <tr> <td>PT-FIB</td> <td>12.APR.1997</td> <td>F-VIII h</td> <td>10.SEP.1997</td> </tr> <tr> <td>FIB-C</td> <td>24.MAY.1997</td> <td>F-IX h</td> <td>21.OCT.1997</td> </tr> <tr> <td>PCX</td> <td>15.JUN.1997</td> <td>F-XI h</td> <td>12.NOV.1997</td> </tr> <tr> <td>HPX</td> <td>18.JUL.1997</td> <td>F-XII h</td> <td>23.DEC.1997</td> </tr> <tr> <td>AT-III</td> <td>22.AUG.1997</td> <td>F-VII h</td> <td>11.SEP.1997</td> </tr> <tr> <td>Hep Xa</td> <td></td> <td>F-X h</td> <td>13.OCT.1997</td> </tr> <tr> <td>Hep h</td> <td></td> <td>F-V h</td> <td>24.NOV.1997</td> </tr> <tr> <td>P-Chrom</td> <td></td> <td>F-II h</td> <td>16.DEC.1997</td> </tr> <tr> <td>PLG</td> <td></td> <td></td> <td></td> </tr> <tr> <td>AT-PL</td> <td></td> <td>APCR</td> <td></td> </tr> <tr> <td>P-Clot</td> <td></td> <td></td> <td></td> </tr> <tr> <td>D-Dimer</td> <td></td> <td></td> <td></td> </tr> </table>	PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997	FIB-C	24.MAY.1997	F-IX h	21.OCT.1997	PCX	15.JUN.1997	F-XI h	12.NOV.1997	HPX	18.JUL.1997	F-XII h	23.DEC.1997	AT-III	22.AUG.1997	F-VII h	11.SEP.1997	Hep Xa		F-X h	13.OCT.1997	Hep h		F-V h	24.NOV.1997	P-Chrom		F-II h	16.DEC.1997	PLG				AT-PL		APCR		P-Clot				D-Dimer				
PT-FIB	12.APR.1997	F-VIII h	10.SEP.1997																																														
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PLG																																																	
AT-PL		APCR																																															
P-Clot																																																	
D-Dimer																																																	
↑,↓ ← → to select ENTER to confirm	PROG (return) <= [previous]																																																

4.5 Warnings

This program is used for troubleshooting procedures.

PROG	24.JULY,96 12:00
DMS LOADLIST QC CALIBRATION DATA WARNING DIAGNOSTIC SETUP	
↑↓ to select ENTER to confirm	PROG (return)

APTT RESULTS	24.JUL.96 12:00
<div style="border: 1px solid black; display: inline-block; padding: 2px;">WARNING LIST</div>	
DATA TRANSMISSION ERROR 2	
PRT to print	← to return

Note:

This program is only accessible when the upper part of the VDU indicates "WARNING see PROG".

Action Select the appropriate program and press ENTER. The "warning" frame appears. Press PROG to return.

Status The instrument returns to the frame displayed before entering PROG. The following indications can appear on the "warning" frame:

- Magnetic stirrer fail
- Flush/optic channel error
- Halogen lamp fail
- Printer fail
- Thermal fail
- Preheater temperature out of range
- Peltier temperature out of range
- Master storage battery
- Slave storage (battery or write error)
- Data transmission error
- Sensor OFF
- Sensor Fail (6-7-8-9)

If a warning occurs during analysis, an error code is printed. For explanation of the individual warnings, see Section 6.

4.6 Diagnostics

4.6.1 Priming

This program is used to rinse dilutors, tubes and needles with Reference emulsion.

Note:

This program is only enabled when the instrument is in the READY state (i.e. no cycle in progress).

DIAGNOSTIC	24.JUL.96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION VDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Action When this program is selected, the PRIMING frame appears.

Status The instrument carries out a dilutor priming cycle, flushing out the aspiration/dispensing tubes and needles.

DIAGNOSTIC	24.JUL.96 12:00
PRIMING PLEASE WAIT	
← to return	

Notes:

1. It is recommended that a priming cycle be carried out before starting the daily routine and at the end of the shift, whenever a new bottle of Reference Emulsion is fitted, or when the instrument has not been used for some days.
2. Check that during priming all large bubbles are removed from the dilutor chambers. See also *Troubleshooting*, section 6.
3. We recommend priming the instrument changing from a chromogenic test to a coagulimetric one or vice versa.

4.6.2 Maintenance

This program allows the operator to key in the date on which certain maintenance tasks were performed. This is memorized and serves as a record of the time elapsed from the last maintenance operations.

The frequency of procedure is fixed and is recommended to prevent problems with the instrument. Refer to section 5, Maintenance.

In laboratories where the work load is particularly heavy, it is possible to increase the maintenance frequency.

DIAGNOSTIC	24.JUL.96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION VDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG [return] ← [previous]

Action Select **MAINTENANCE**.

Status The **MAINTENANCE** frame appears.

A maintenance schedule for the following items is displayed:

- WASTE RESERVOIR
- OPTICAL SENSORS AND WINDOWS
- AIR FILTER
- REAGENT RESERVOIRS
- CLEANING CYCLE

DIAGNOSTIC	24.JUL.96 12:00
MAINTENANCE	
	LAST DATE DAYS
- RINSE WASTE RESERVOIR	20.JUN.96 7
- CLEAN OPTICAL SENSORS AND WINDOWS	20.JUN.96 15
- CLEAN AIR FILTER	20.JUN.96 28
- EMPTY AND WASH REAGENT RESERVOIRS	20.JUN.96 3
- CLEANING CYCLE	20.JUN.96 7
Key in new value PRT to print	PROG (return) ← (previous)
ENTER to confirm	

Status The cursor appears on the date next to the first parameter to be updated.

DIAGNOSTIC		24.JUL.96 12:00
MAINTENANCE		
	LAST DATE	DAYS
- RINSE WASTE RESERVOIR	20.JUN.96	7
- CLEAN OPTICAL SENSORS AND WINDOWS	20.JUN.96	15
- CLEAN AIR FILTER	20.JUN.96	28
- EMPTY AND WASH REAGENT RESERVOIRS	20.JUN.96	3
- CLEANING CYCLE	20.JUN.96	7
Key In new value ENTER to confirm	PRT to print	PROG (return) ← (previous)

Action Each parameter must be keyed in using the numerical keyboard and confirmed with ENTER.

DIAGNOSTIC		24.JUL.96 12:00
MAINTENANCE		
	LAST DATE	DAYS
- RINSE WASTE RESERVOIR	20.JUN.96	7
- CLEAN OPTICAL SENSORS AND WINDOWS	20.JUN.96	15
- CLEAN AIR FILTER	20.JUN.96	28
- EMPTY AND WASH REAGENT RESERVOIRS	20.JUN.96	3
- CLEANING CYCLE	20.JUN.96	7
Key In new value ENTER to confirm	PRT to print	PROG (return) ← (previous)

Action Repeat this operation for all five items presented on the video. Press ↓ to return to the Diagnostic entry frame.

DIAGNOSTIC		24.JUL.96 12:00
MAINTENANCE		
	LAST DATE	DAYS
- RINSE WASTE RESERVOIR	20.JUN.96	7
- CLEAN OPTICAL SENSORS AND WINDOWS	20.JUN.96	15
- CLEAN AIR FILTER	20.JUN.96	28
- EMPTY AND WASH REAGENT RESERVOIRS	20.JUN.96	3
- CLEANING CYCLE	20.JUN.96	7
Key In new value ENTER to confirm	PRT to print	PROG (return) ← (previous)

Action Press PRT to print.

Status The MAINTENANCE program is printed.

- Action Press <= (previous) to save data and return to DIAGNOSTIC menu.
- Status The instrument goes back to the DIAGNOSTIC menu.
- Action Press PROG to return.
- Status The instrument goes back to the main menu or to the last frame entered.

4.6.3 Temperature Control

This program is used to monitor the temperatures.

DIAGNOSTIC	24.JUL.96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION VDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG (return) <= (previous)

- Action Select Temperature Control.
Press PRT to print the temperature values.

DIAGNOSTIC	24.JUL.96 12:00
TEMPERATURE CONTROL	
ROTOR HOLDER (Incubation: 37 ± 1°C)	: 38.5°C
PELTIER	: 13.2°C
PRE-HEATER	: 37.5°C
PRT to print	PROG (return) <= (previous)

DIAGNOSTIC	24.JUL.96 12:00
TEMPERATURE CONTROL	
ROTOR HOLDER (Incubation: 98.6 ± 1.8°F)	101.2°F
PELTIER	56.7°F
PREHEATER	98.5°F
PRI to print	PROG [return] = [previous]

Notes:

- In this frame the following temperatures are displayed:
 - the measuring chamber area (rotor holder)
 - the reagent refrigeration area (peltier)
 - the rotor preheater area (preheater).
- The temperature of the rotor holder (38.5 ± 0.5 °C or 101.3 ± 0.9 °F) is always higher than the actual measuring chamber temperature in order to guarantee that under all normal ambient conditions (from 15 °C to 32 °C - from 59 °F to 89.6 °F) the temperature in the measuring chamber of the rotor itself remains within the range 37 ± 1 °C (98.6 ± 1.8 °F).
- The temperatures shown on the video have specific limits. If the actual temperature is outside these limits, the value is indicated as — or ****. The respective limits are:

Preheater : from 20 to 54 °C (from 68 to 129.2 °F)
 Peltier : from 4 to 22 °C (from 39.2 to 71.6 °F)
 Rotor holder : from 35 to 42 °C (from 95 to 107.6 °F)

During operation the normal temperature ranges are:

Preheater : from 36 to 39 °C (from 96.8 to 102.2 °F)
 Peltier : from 12 to 15 °C (from 53.6 to 59 °F)
 Rotor holder : 38.5 ± 0.5 °C (101.3 ± 0.9 °F)

If preheater and/or rotor holder temperatures are out of range this is indicated by "WARNING-INCUBATION TEMP OUT OF RANGE" in the upper part of the VDU.

The messages "WARNING" and "INCUBATION TEMP OUT OF RANGE" are shown in reverse.

If a temperature persists in remaining out of range, call your IL Representative.

- If the rotor holder temperature is out of range, the measuring chamber rotor cuvette temperature cannot be guaranteed to remain within the specified range with consequent effects on the analytical results.

4.6.4 Needles Position

This program allows alignment of the sample arm needles.

A check of the alignment of the sample arm needles should be done once a week or whenever a new lot of rotors is used.

See Maintenance; Section 5.

DIAGNOSTIC	24,JUL,96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION VDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

4.6.5 V.D.U. Brightness

This program is used to adjust VDU BRIGHTNESS.

DIAGNOSTIC	24,JUL,96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION VDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG (return) ← [previous]

Action Select VDU BRIGHTNESS and press ENTER.

DIAGNOSTIC	24,JUL,96 12:00
VDU BRIGHTNESS	
↑ to increase brightness ↓ to decrease brightness	PROG (return) ← (previous)

Action Using the key ↑ to increase or ↓ to decrease, select the brightness required and press ← (previous) to save.

Status All further normal frames will be at the brightness selected.

Note:

If the brightness cannot be increased to the level desired call your IL Representative.

4.6.6 Service

This program is only accessible by an authorized I.L. Service Technician.

DIAGNOSTIC	24.JUL.96 12:00
PRIMING MAINTENANCE TEMPERATURE CONTROL NEEDLES POSITION YDU BRIGHTNESS SERVICE	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

4.7 Set-up Menu

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

4.7.1 Reference Material

This program is used to verify and/or change the reference values of PT, FIB, APTT and TT of the Calibration Plasma used.

The data stored enables the operator to control variations in the above mentioned parameters and to be warned by the system whenever the N.P. data goes out of the reference range. In this latter case the N.P. data is displayed and printed in reverse and sample results are expressed in seconds only.

For PT and FIB, new calibration data corresponding to new reference values are automatically stored in the "Reference Data" program, deleting previously stored value.

For APTT and TT, the laboratory Reference values must be entered by the operator.

The same program enables the operator to verify and/or change the ISI of Thromboplastin.

Warning Since changing some parameters can cause loss of some data (e.g. calibration, etc.), read this paragraph carefully before operating.

SETUP	24.JUL.96 12:00
ATTENTION: BEFORE PROCEEDING REFER TO THE OPERATOR'S MANUAL	
↓ to continue	

Status When this program is selected, the appropriate frame warns the operator before proceeding.

Action Press "↓ to continue".

SETUP	24.JUL.96 12:00
REFERENCE DATA	
PT REFERENCE VALUE (sec.)	12.0
ISI (PT)	1.00
APTT REFERENCE VALUE (sec.)	30.0
TT REFERENCE VALUE (sec.)	12.0
Key in new value ENTER to confirm	PROG (return) ← (previous)

Status The instrument displays the reference data.

The cursor appears on the first parameter.

Action The operator can leave the values or change them.
Press ← to return to the Set Up entry screen.

Status The instrument returns to the SET UP menu.

Action Numerical data can be entered and confirmed with ENTER.
Once all parameters have been entered, ← saves all data entered.

SETUP	24.JUL.96 12:00
REFERENCE DATA	
PT REFERENCE VALUE (sec.)	12.0
ISI (PT)	1.00
APTT REFERENCE VALUE (sec.)	30.0
TT REFERENCE VALUE (sec.)	12.0
Key in new value ENTER to confirm	PROG (return) ← (previous)

Notes:

- Insertion of new reference values for PT, APTT and TT will not cancel old QC data and calibration data stored.
- No Fib values will be reported until PT-FIB is recalibrated.

4.7.2 Calculation

This program is used to select units representation.

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

SETUP	24.JUL.96 12:00
ATTENTION: BEFORE PROCEEDING REFER TO THE OPERATOR'S MANUAL	
↓ to continue	

Warning Changes in this program affect the calculation of some results, please read the following instructions carefully before making any modification. Make sure that settings are correct for your intended use.

First option

This is used for the selection of RATIO and INR in the PT results.

Action By means of the ← and → keys select INR ON or INR OFF and press ENTER to confirm.

Notes:

- If INR ON is selected, the PT results will be presented in INR as well as seconds and activity; the INR results are presented in place of R (Ratio).
- If the operator wishes to have the results in INR, the operator must enter during the PT-FIB calibration or in the Reference Data frame, the ISI value of the thromboplastin.

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	<input type="checkbox"/> OFF
PT AUTOCAL	<input type="checkbox"/> ON
N.P. RATIO APTT	<input type="checkbox"/> ON
N.P. RATIO TT	<input type="checkbox"/> ON
NORMALIZED RATIO APCR V	<input type="checkbox"/> ON
ANIMAL OPTION	<input type="checkbox"/> OFF
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Second option

Action By means of the ← and → keys, select AUTOCAL ON or AUTOCAL OFF and press ENTER to confirm.

Notes:

- If AUTOCAL ON is selected, the "POOL" position is used to adjust the PT results of each run with reference to the actual Normal Pool value.
- If AUTOCAL OFF is selected, PT results are expressed referring directly to the calibration stored in memory.

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	<input type="checkbox"/> OFF
PT AUTOCAL	<input checked="" type="checkbox"/> ON
N.P. RATIO APTT	<input type="checkbox"/> ON
N.P. RATIO TT	<input type="checkbox"/> ON
NORMALIZED RATIO APCR V	<input type="checkbox"/> ON
ANIMAL OPTION	<input type="checkbox"/> OFF
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Third option

Action By means of the ← and → keys, select APTT Ratio OFF or APTT Ratio ON and press ENTER to confirm.

Notes:

- If APTT Ratio ON is selected, the Ratio is calculated versus the Pool position on the sample tray in respect to the reference data range.
- If APTT Ratio OFF is selected, the Ratio is calculated versus the value inserted in the "Reference Data" frame.

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	OFF
PT AUTOCAL	ON
N.P. RATIO APTT	<input type="checkbox"/> ON
N.P. RATIO TT	ON
NORMALIZED RATIO APCR V	ON
ANIMAL OPTION	OFF
↑, ↓, ←, → to select ENTER to confirm	PROG [return] ⇐ (previous)

Fourth option

Action By means of the ← and → keys, select TT Ratio ON or TT Ratio OFF and press ENTER to confirm.

Notes:

- If TT Ratio ON is selected, the Ratio is calculated versus the Pool position on the sample tray in respect to the reference data range.
- If TT Ratio OFF is selected, the Ratio is calculated versus the value inserted in the "Reference Data" frame.

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	OFF
PT AUTOCAL	ON
N.P. RATIO APTT	ON
N.P. RATIO TT	<input type="checkbox"/> ON
NORMALIZED RATIO APCR V	ON
ANIMAL OPTION	OFF
↑, ↓, ←, → to select ENTER to confirm	PROG [return] ⇐ (previous)

Fifth option

Action By means of the ← and → keys, select NORMALIZED RATIO APCR-V ON or OFF and press ENTER to confirm

RATIO calculation for the samples is as follow:

Ratio = TA in seconds / T0 in seconds

TA is the activated time and T0 the basal time.

NR (= Normalized Ratio) is calculated as follow:

NR = Patient Ratio / Normal Pool Ratio

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	OFF
PT AUTOCAL	ON
N.P. RATIO APTT	ON
N.P. RATIO TT	ON
NORMALIZED RATIO APCR V	<input type="checkbox"/> ON
ANIMAL OPTION	<input type="checkbox"/> OFF
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Sixth option

Action By means of the ← and → keys, select ANIMAL APPLICATION ON or ANIMAL APPLICATION OFF and press ENTER to confirm.

Notes:

- If ANIMAL APPLICATION OFF is selected, the instrument uses all the algorithms for PT, APTT and TT including certain checks optimized for unusual coagulation curves (Human application).
- If ANIMAL APPLICATION ON is selected, one set of checks (slope check) for PT, APTT and TT is not used (in this way, the algorithm allows detection of short clotting curves which are sometimes present in animal plasma - Animal application).

Warning The message "ANIMAL APPLICATION" is shown on the printout. This indication does not appear on the screen or in the data transmitted via RS 232 interface.

SETUP	24.JUL.96 12:00
CALCULATION	
PT INR	OFF
PT AUTOCAL	ON
N.P. RATIO APTT	ON
N.P. RATIO TT	ON
NORMALIZED RATIO APCR V	<input type="checkbox"/> ON
ANIMAL OPTION	<input type="checkbox"/> OFF
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

4.7.3 Ratio Adjustment

Due to population variations the laboratory pool value relative to the Calibration Plasma may vary from area to area.

The operator has the option of using of the actual calculation or the adjusted one.

This program (available for PT, APTT and TT) offers the user the ability to correct the expression of the results according to the laboratory pool value when a lyophilized calibrator is used.

Normally the results for PT, APTT and TT are expressed as follows:

$$R = \frac{\text{Sample (seconds)}}{\text{Calibration Plasma (seconds)}}$$

- PT cycle: R is used to read the activity (%) on the calibration curve, the Ratio as it is and to calculate the INR.
- APTT and TT cycles: R is used for the Ratio as it is.

So, the actual R which is:

$$\frac{\text{Sample (seconds)}}{\text{Calibration Plasma (seconds)}}$$

can be adjusted in the following way:

$$R \text{ adjusted} = \frac{\text{Sample (seconds)}}{\text{Calibration Plasma (seconds)}} \times \frac{\text{Calibration Plasma (seconds)}}{\text{Laboratory Pool (seconds)}}$$

The Ratio Adjustment coefficient is the Ratio between the lyophilized calibrator (Calibration Plasma in seconds) and the laboratory pool (in seconds).

Warning Before keying in the Ratio adjusted values for PT, APTT and TT, the laboratory must determine carefully these coefficients.

When the lot of calibration plasma and/or the thromboplastin is changed, we suggest running the laboratory pool and the calibration plasma on the ACL for a significant number of determinations (minimum six for each parameter) and consider the mean values for the calculation of the Ratio Adjustment according to what is previously described. The value of the first point of the calibration curve in seconds can be considered as the mean value for the calibration plasma.

Action If this Program is selected, the RATIO ADJUSTMENT frame is displayed.

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Status The cursor appears on the first parameter (relative to PT) and allows the operator to input a new value. Limits for the insertion are from 0,800 to 1,200.

Action After entering in the value, the operator must press ENTER to pass to the second parameter.

Status The insertion proceeds in the same way for the other parameters.

Notes:

- If a coefficient out of the limits is keyed in, the cursor will stay on the same position for a new data input.
- The insertion of 1,000 causes no change in the expression of the results.
- If using the Ratio Adjustment program, we recommend that the system is run with Autocal OFF when reporting Ratios or INRs for PT.

Warning No indication to the coefficients inserted in RATIO ADJUSTMENT is given on the printout.
The operator is advised to check the values in the relative PROG before operating.

SETUP	24.JULY,96 12:00
RATIO ADJUSTMENT	
PT:	1,000
APT:	1,000
TT:	1,000
Key in new values ENTER to confirm	PROG (return) ← (previous)

4.7.4 Acquisition Time

This program is used to increase the acquisition time for PT-FIB, APTT and TT (single and double tests).

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ⇐ (previous)

SETUP	24.JUL.96 12:00
ACQUISITION TIME	
PT-FIB	STANDARD
APTT	EXTENDED
TT	STANDARD
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ⇐ (previous)

Action Using the ← and → keys, select STANDARD or EXTENDED and press ENTER for each test.

Status If the operator selects extended, the instrument will use an extended acquisition time. For more details see Section 7.

SETUP	24.JUL.96 12:00
ACQUISITION TIME	
PT-FIB	STANDARD
APTT	EXTENDED
TT	STANDARD
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ⇐ (previous)

Notes:

1. After testing in the extended mode, the operator should switch the instrument back to the standard mode, thus avoiding increasing the analysis time in the daily routine.
2. If the "extended mode" is selected, the letter (E) appears in the upper part of the video adjacent to the title of the analysis selected. The message "Extended Acq.Time" is also given in the results printout.
3. This program does not affect the acquisition time in the "Mixed tests" mode (see Section 7).

SETUP	24.JUL.96 12:00
ACQUISITION TIME	
PT-FIB	STANDARD
APTT	EXTENDED
TT	<input type="text" value="EXTENDED"/>
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ⇐ (previous)

APTT [E]	24.JUL.96 12:00
CHECK: USABLE ROTOR PRESENCE	
CEPHALIN LEVEL	POS. 2
CALCIUM CHLORIDE LEVEL	POS. 3
REFERENCE SOLUTION LEVEL	
↓ to start analysis	⇐ to exit

4.7.5 Units Program

This program is used to verify or change the units of measurement with which data are displayed.

It is available for the temperature unit (°C or °F) and Fibrinogen (mg/dL or g/L).

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Action When this program is selected and entered, the "units" frame appears.

Select the units (for temperature) required using the ← and → keys.

Status The instrument presents the system of units currently in use in reverse video.

SETUP	24.JUL.96 12:00
UNITS	
TEMP = °C	
FIB = mg/dL	
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Action Press ENTER.

Status The instrument memorizes the unit requested and moves to the Fibrinogen selection.

Action Select the units for the Fibrinogen using the ← and → keys.

Status The instrument displays in reverse the system of units currently in use.

SETUP	24.JUL.96 12:00
UNITS	
TEMP = °C	
FIB = mg/dL	
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Action Press <= (previous).

Status The instrument memorizes the units requested.

SETUP	24.JUL,96 12:00
UNITS	
TEMP = °C	
FIB =	<input type="text" value="g/L"/>
↑, ↓, ←, → to select ENTER to confirm	PROG (return) <= (previous)

Note:

The temperature unit system is defined by this program for all displays and printouts where temperature is indicated.

4.7.6 Date/Time Program

This program is used to change the date and/or time.

Following selection of this program the "DATE/TIME" frame appears.

SETUP	24.JUL,96 12:00
REFERENCE MATERIAL	
CALCULATION	
RATIO ADJUSTMENT	
ACQUISITION TIME	
UNITS	
DATE/TIME	
PRINTER STATUS	
INTERFACE STATUS	
SYSTEM CONFIGURATION	
INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) <= (previous)

SETUP	24.JUL,96 12:00
DATE AND TIME SETUP	
ENTER NEW VALUE FOR:	
DAY	<input type="text" value="06"/>
MONTH	MAY
YEAR	1997
HOUR	14
MINUTE	26
SECONDS	55
↑, ↓, ←, → to select ENTER to confirm	PROG (return) <= (previous)

SETUP	24.JUL.96 12:00
DATE AND TIME SETUP ENTER NEW VALUE FOR:	
DAY	06
MONTH	05
YEAR	1997
HOUR	14
MINUTE	26
SECONDS	55
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Action Key in the day followed by ENTER.

Status The instrument memorizes the day selected and the cursor moves to the month.

SETUP	24.JUL.96 12:00
DATE AND TIME SETUP ENTER NEW VALUE FOR:	
DAY	06
MONTH	MAY
YEAR	1997
HOUR	14
MINUTE	26
SECONDS	55
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Action Key in the month followed by ENTER.

Status The instrument memorizes the month selected and the cursor moves to the year.

Action Key in the year (four digits) followed by ENTER.

Status The instrument records the date, checking for invalid combinations and the cursor moves to the hour.

Action Key in the hour (24 hr clock) followed by ENTER.

Status The instrument records the hours and the cursor moves to the minutes.

Action Key in the minutes followed by ENTER.

Status The instruments records the minutes and the cursor vanishes.

Notes:

1. In the case of invalid entry (e.g. 31 of February), the information is not accepted and the cursor returns to the necessary point to permit a correct entry.
2. The DEL key operates as a "back space" to correct invalid information in the area identified by the cursor.

Notes:

- If the instrument receives a date not included between 1.1.1984 and 31.12.2083 and a time between 00.00 and 23.59 the entered values are displayed in reverse until the value is correctly entered and thus accepted.
- Any error in keying in the data may be corrected by pressing **DEL** as many times as there are numbers to be corrected. This must be done before **ENTER** is pressed.
- If no operation is carried out for a period of time longer than 30', the frame goes into low light, the LED light source is switched off and on the video displays the last parameter entered and confirmed.
- The year has to be entered in four digits. The representation in this manual will be indicated always as two digits.

4.7.7 Printer status

This program contains a submenu with the following options:- INTERNAL PRINTER and EXTERNAL PRINTER.

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Action Using the ↑ and ↓ keys, select the desired PRINTER (internal or external) and press ENTER to confirm.

Status The relative submenu is displayed.

4.7.7.1 Internal Printer

This program controls the status of the internal printer.

PRINTER STATUS	24.JUL.96 12:00
PRINTERS	
INTERNAL PRINTER	
EXTERNAL PRINTER	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

4.7.7.2 Automatic Printout (Internal Printer)

Action When this program is selected, the PRINTER SET UP frame appears identifying the current state of the instrument. Using the ← and → keys, select the status required and press ENTER.

Status The instrument memorizes the status selected and moves to the Fibrinogen selection. Results will be printed as defined.

PRINTER STATUS	24.JUL.96 12:00
INTERNAL PRINTER	
AUTOMATIC PRINT OUT:	<input type="text" value="1 COPY"/>
FIB:	ON
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

Action Press ← to save and exit.

Status The instrument returns to the frame displayed before pressing PROG.

Notes:

1. When the printer paper ends, the message "PAPER END" is displayed in the upper part of the VDU; in this situation the printer is protected by various internal circuits.
2. When PRT is pressed in other screens, only one copy is provided even if the automatic printout is set on 2 or 3 copies.

4.7.7.3 Fibrinogen Selection ON/OFF (Internal Printer)

This program is used to change the printout format of the PT-FIB results (single, mixed and double test).

Action When this program is selected, the following frame appears.

Status The cursor is placed to indicate the current status of the instrument.

PRINTER STATUS	24.JUL.96 12:00
INTERNAL PRINTER	
AUTOMATIC PRINT OUT: 1 COPY	
FIB:	ON
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← {previous}

Action Using ← and → keys, select the format required and press ⇐ (previous).

Status The instrument memorizes the format selected and prints out results appropriately.

4.7.7.4 External Printer (optional)

SETUP	24.JUL.96 12:00
EXTERNAL PRINTER	
PAPER FORMAT:	A4
PAPER LOADING:	SINGLE-SHEET
AUTOMATIC PRINTOUT:	NONE
CUSTOMIZED HEADER:	DISABLED
HOSPITAL	
DOCTOR	
DEPARTMENT	
ADDRESS	
CITY	
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← {previous}

Action By using ← and → keys, select the Paper Format between the A4 and the US Letter type, then press ENTER.

Action Also by using ← and → keys, select the Paper Loading between single sheet and fanfold formats.

Automatic printout is selectable: none, cumulative report or sample report.

Customized header can be enable/disable with 5 lines to be used as hospital and laboratory identification.

4.7.8 Interface Status Program

This program is used to control the status of the two RS 232 interfaces (port 1 = Host and port 2 = Research Program when available).

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Action Press ENTER.

Status The instrument shows the INTERFACE submenu.

SETUP	24.JUL.96 12:00
HOST RESEARCH	
↑, ↓ to select ENTER to confirm	PROG (return) ← (previous)

Action Using the ↑ and ↓ keys, select HOST or RESEARCH and press ENTER.

4.7.8.1 HOST Interface

When HOST is selected, the following frame appears.

SETUP	24.JUL.96 12:00
HOST	
AUTOMATIC DATA TRANSMISSION: DISABLED	
BAUD RATE:	9600
DELETE AUTOMATICALLY TRANSMITTED DATA:	DISABLED
INSTRUMENT ID (00 = DISABLED) XX	
←, → to select new value	PROG (return) = to exit

It is possible to select the automatic transmission of patient data and QC or of patient data only.

It is possible to select the following baud rate characteristics:

Baudrate : 2400
4800
9600
19200

It is possible to select the automatic deletion of a transmitted data from the internal DMS when successfully received from the Host.

4.7.8.2 Research Program Interface

When selecting RESEARCH, the following frame appears.

This allows to select manual or automatic transmission of the raw data from the ACL Research Program (configurable cycles) to the Research Program (optional) on an external PC (optional) at the end of the cycle.

SETUP	24.JUL.96 12:00
RESEARCH	
DATA TRANSMISSION:	AUTOMATIC
BAUD RATE:	9600
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

It is possible to select the following baudrate configurations.

Baudrate : 2400
4800
9600
19200

4.7.9 System Configuration

SETUP	24.JUL.96 12:00
REFERENCE MATERIAL CALCULATION RATIO ADJUSTMENT ACQUISITION TIME UNITS DATE/TIME PRINTER STATUS INTERFACE STATUS SYSTEM CONFIGURATION INTERNAL BCR	
↑, ↓ to select ENTER to confirm	PROG [return] ← [previous]

Selecting this PROG it is possible to define the system configuration according to the following options for test performing:

RANDOM ACCESS WITH HOST QUERY

Only programmed tests either present in the database or received from Host will be executed.

Sample ID with no requests will not be executed.

RANDOM ACCESS WITHOUT HOST QUERY

Only programmed tests present in the database will be executed.

Sample ID with no requests will not be executed.

TEST COMPLETION LOADLIST PROFILE ONLY

If a sample ID has no requests all tests contained in the profile will be executed. If a sample ID has only one test programmed for the requested profile no other test of the profile will be executed.

In single test the ID will not be requested and the instrument will operate as a batch analyzer executing all samples present on the sample tray.

TEST COMPLETION LOADLIST PROFILE/TEST.

If a sample ID has no requests all tests contained in the profile will be executed. If a sample has only one test programmed for the requested profile no other test of the profile will be executed.

In single test only the programmed tests will be executed.

SETUP	24.JUL.96 12:00
TEST PERFORMING : RANDOM ACCESS WITH HOST QUERY REMOVE SAMPLE ID FROM LOADLIST WHEN DELETED : ENABLED	
↑, ↓, ←, → to select new value	PROG (return) ← (previous)

Warning When using the option TEST COMPLETION LOADLIST PROFILE ONLY the Loadlist in the Single Tests is not required (sample processed in the single tests will only be printed in the internal printer but they will not be stored in the sample database: DMS).

If the selection is PROFILE-TEST, the Loadlist is always required both in single test profile. In this case the patient results are always stored in the sample database: internal DMS.

4.7.10 Internal Barcode Reader (only on the ACL 7000)

This program allows to setup the internal barcode reader and the supported codes.

SETUP	24.JUL.96 12:00
INTERNAL BCR : W.A.	
ENABLED BCR :	DISABLED
CODE 39 :	DISABLED
CODE 128 :	DISABLED
CODABAR :	DISABLED
I 2 OF 5 :	DISABLED
↑, ↓, ←, → to select ENTER to confirm	PROG (return) ← (previous)

The following selections are possible:

ENABLE BCR :	ENABLED, DISABLED
CODABAR :	DISABLED, AIM Mod. 16, NW7 Mod. 11, NW7 Mod. 16, No CKS (No Checksum)
CODE 39 :	DISABLED, Module 43, No CKS (No Checksum)
CODE 128 :	DISABLED, AIM CKS (Checksum)
I (Interleaved) 2 of 5 :	DISABLED, USS Mod. 10, OPCC Mod. 10, No CKS (No Checksum).

Addendum : Q.C. Expected SD with IL Reagents and Controls

Parameter	Reagent	Units	Normal C.P.	ABN level I	ABN level II	ABN Chrom/II	Controls Abnormal
PT	PT/FIB	sec	0.4	0.7	1.3		
	PT/FIB HS		0.5	1.5	3.0		
	PT/FIB HS PLUS		0.5	1.5	3.0		
APTT	APTT Ellagic Acid	sec	1.0	1.5	2.0		
	APTT Liquid silica		1.5	2.0	3.0		
	APTT LYO Silica		1.5	2.0	3.0		
	APTT-C		1.5				
TT	3.0 U/mL	sec	1.0				
	1.9 U/mL		1.5				
Fibrinogen PT derived	PT/FIB	mg/dL	30				
	PT/FIB HS		30				
	PT/FIB HS PLUS		30				
Fibrinogen Clauss		mg/dL	20				8
Factors		%	10				8 (F VIII)
Pro-IL Complex		%	6	1.5	1.5		
Hepatocomplex		%	10	2.0	2.0		
Antithrombin III		%	6			6	
Plasminogen		%	6			4	
Alpha 2- Antiplasmin		%	8			6	
Protein C	Pro-Chrom	%	6			4	
Protein C	ProClot	%	12	4			8
Protein S		%	10	2			6

5 Maintenance

5.0 Maintenance

The ACL™ System is a precision instrument. In order to maintain it in perfect functional condition we recommend that the following operations be carried out by a trained operator at the frequency specified.

CAUTION

The instrument should be decontaminated before preventive maintenance and service. For all decontamination procedures see section 10. During maintenance procedures personnel should wear gloves and other appropriate body clothing and protections to prevent contact with items potentially contaminated with blood. Wash hands immediately after gloves are removed and before leaving the laboratory (see also NCCLS GP25-A Vol. 13 No. 22: Clinical Laboratory Waste Management, Dec. 1993).

5.1 Daily Preventive Maintenance

Instrument Status

For the best possible results the instrument should be left on continually. The complex electronic circuitry is most reliable if the number of "switch-offs" and "ons" is reduced to a minimum. The standby condition (see section 1) guarantees minimum power consumption and maximum readiness for operation at any time.

Reference Emulsion

Check that there is at least 1.5 to 2 cm of liquid in the container. If there is less, replace with a new bottle of 1L Reference Emulsion and perform the priming procedure (see below).

Note:

A level of 2 cm is enough for 1 or 2 rotors, considering the dead volume.

Waste Liquid Container

Check the level and empty if necessary. Verify that the waste flows freely into the container.

CAUTION

The liquid waste of the instrument is to be considered contaminated and should be discarded according to the waste procedures of the laboratory and in compliance with the local regulations (see also NCCLS GP25-A Vol. 13 No. 22: Clinical Laboratory Waste Management, Dec. 1993).

Printer Paper

Check that there is sufficient paper for the printer; a colored line appears when the roll is almost finished.

Note:

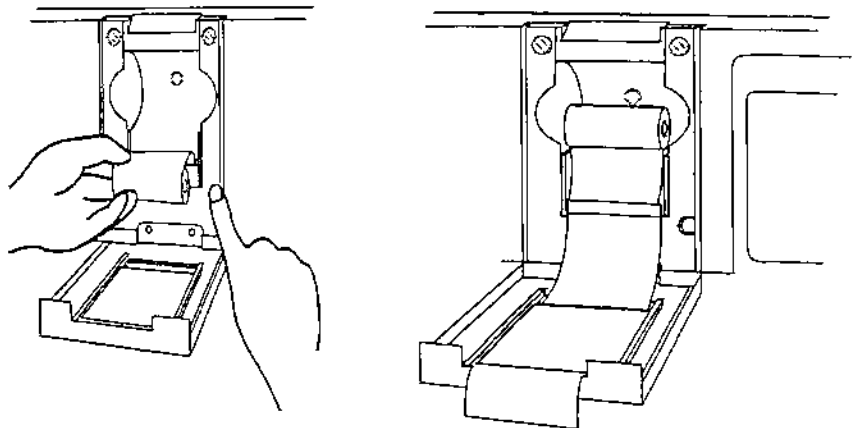
If the paper runs out completely, the message "PAPER END" appears in the upper right hand area of the VDU and the printer is disabled.

Printer Paper Replacement

To replace the printer paper proceed as follows:

- Pull the printer cover forward from the top.
- Remove the old roll and tear off the paper (if any) which passes into the printer mechanism.
- Press the grey button at the lower right of printer to eject any remaining paper.
- Cut the leading edge of the new paper roll and insert into the upper printer slot pushing it forward until it comes into contact with the paper advance roller as shown in the figure below.
- Press the grey button until paper exits from the lower slot. Place the roll into its housing.
- Continue to let paper advance and insert it into the printer cover guide as shown in the figure.
- When paper appears at the top of the cover, stop the paper advance and close the cover by pulling lightly upwards on the paper.

Printer Paper Replacement



- Check that the "PAPER END" warning has disappeared.

Note:

The paper advance (grey button) is also accessible externally without opening the printer cover.

Reagent Reservoir

For IL PT-FIB and APTT the reagent reservoirs may be topped off with fresh reagent, within the on-line stability of the reagent at 15°C. This is allowed only if the ratio between fresh and old reagent is 2 parts (fresh) to 1 part (old).

If the instrument is left on at the end of a working day, the reagent vessels should be emptied and washed out with distilled water.

We recommend storing any unused reagents in their original bottles, in a refrigerator at 2-8 °C.

Waste Line Cleaning Procedure

To avoid possible blockages in the waste line due to clot formation, we recommend the following daily procedure (at the end of each working day or more frequently if the number of samples makes it necessary).

1. Materials required:
 - Plastic syringe 20 mL
 - 20 cm PVC tube
 - 20 mL deionized water

Note:

The PVC tube should be selected (i.e. 4 mm internal - 6 mm external diameter) so that it fits correctly onto the syringe one end and, into the waste line at the other end.

2. Preparation

Remove the needle from the plastic syringe. Fit the PVC tube, of the correct diameter, in place of the needle.

Fill the syringe with deionized water.

3. Select PROG, DIAGNOSTIC and press ENTER.

Using the ↓ key select NEEDLES POSITION and press ENTER. Open the cover and press ↓ to continue.

The arm will be positioned on the rotor holder.

Remove the rinse reservoir (clean the rinse reservoir if necessary, see section 5.2).

Insert the PVC tube into the waste line of the ACL.

Carefully inject carefully the deionized water into the waste line and check that the liquid flows out from the external waste line of the instrument.

Repeat the procedure if any blockage is not completely removed.

Replace the rinse reservoir and return to the ready state by pressing ← (previous).

Priming Procedure

At the beginning and at the end of each working day, flush the fluidic path to ensure complete removal of all sample or reagent residues.

To flush, select PROG to display the DIAGNOSTIC menu. Using the ↑ and ↓, select the mode PRIMING; press ENTER to confirm.

The "please wait" display is presented during the priming cycle while the dispenser system flushes out both sample and reagent needles.

At the end of priming, pressing PROG returns the instrument to the main menu.

Check that during priming the number of bubbles in the dilutor chambers is reduced to a minimum. If necessary, pinch the chamber outlet tubes while the piston is descending and release them before the piston reaches the bottom dead center. Repeat the priming cycle if necessary.

Check that there are no blockages or leaks in the fluidic path and that the liquid is flowing smoothly from reservoir to dilutors and dilutors to needles. Check that the discharge of liquid from washing chamber to instrument outlet and then to waste container is not impeded.

Note:

We recommend priming the instrument when passing from a chromogenic test to a coagulimetric one, or vice versa.

Rotors

Discard any fully used rotors. A partially used rotor may be left in the rotor housing if it is intended to use it during the following working shift, otherwise we recommend discarding the rotor to avoid possible contamination problems. Do not return a partially used rotor to the rotor preheater.

When removing the rotor, do it carefully keeping the rotor orizzontally paying attention to the possible spillage phenomena.

Discard and incinerate the used rotor according to the proper local regulations.

5.2 Weekly Maintenance

Cleaning Procedure

The instrument parts which normally come into contact with the samples are:

- a. the instrument
- b. needles assembly
- c. autosampler and rotor holder area
- d. rinse reservoir
- e. internal and external waste tubing

The priming procedure, see section 5.1, is recommended at the end of each working day. It will normally maintain the needle assembly and the rinse reservoir in a clean condition.

Instrument Cleaning Procedure

In addition we recommend, on a weekly basis, a more extensive cleaning, wiping down all exposed surfaces and the inside of the autosampler and rotor compartment (excluding the rotor holder) using a cloth soaked in a diluted solution of Hydrochloric Acid (HCl 0.1 N) and rinsing with deionized water.

For the rotor holder please refer to the rotor holder cleaning section in this chapter and also to section 10 (decontamination procedure).

Cleaning Procedure for Needles

The following cleaning procedure will guarantee the removal of protein and other deposits from the inside and outside of the needles.

1. Materials required:
 - 3 x 0,5 mL sample cups
 - Reagent reservoir 1 (PT-FIB), 2 (APTT) and 3 (CaCl₂)
 - 10 mL (approximately) HCl 0.1N
 - 20 mL (approximately) Factor Diluent
2. Preparation
 - Load the sample tray as follows:
 - Position NP - HCl (0.1N), 0,5 mL
 - Position 1 - Factor Diluent, 0,5 mL
 - Position 2 - HCl (0.1N), 0,5 mL
 - Position 3 - Factor Diluent, 0,5 mL
 - Load reagent reservoirs as follows:
 - Reagent 1 - Factor Diluent, 9 mL
 - Reagent 2 - HCl (0.1N), 10 mL
 - Reagent 3 - Factor Diluent, 10 mL
 - Place a clean rotor on the rotor holder.
3. Cleaning Cycle
 - Enter **DOUBLE TESTS**.
 - Select the PT-FIB/APTT cycle; press **ENTER** and ↓ to start analysis.
 - At the end of the loading phase (including CaCl₂), press **STOP** and **ENTER**.
4. Remove the rotor from the rotor holder and discard it.
Remove the sample tray and the reagent reservoirs.
5. Execute a Priming cycle.

Autosampler and Rotor Holder Cleaning Procedure

In the case of sample spillage in the autosampler or rotor compartments, it may be necessary to clean the autosampler cuvette sensor and the two optic paths of the measuring chamber.

a. Cuvette sensor

Using a clean cloth or cotton tip applicator soaked in **diluted HCl 0.1 N solution**, wipe the two vertical faces of the cuvette sensor.

Wash with **deionized water** and dry with a clean cloth or cotton tip applicator.

b. Measuring chamber optic paths

Coagulometric Channel

Using a cotton tip applicator moistened with **deionized water** clean all the holes in the rotor holder and the surface of the channel sensor.

Use a dry cotton tip applicator to dry off after cleaning.

To clean the face of the LED optic fiber, use only a dry cotton tip applicator.

Chromogenic Channel

The halogen lamp fiber outlet below the rotor holder and the sensor mounted in the cover can be cleaned using a cotton tip applicator in **deionized water** and then dried using a clean bud.

Rinse Reservoir Cleaning Procedure

If there is evidence of dirt in the washing chamber set the instrument into the "Needles Position" program by selecting PROG, DIAGNOSTIC, ENTER, NEEDLES POSITION, ENTER, ↓ to continue (see section 5.5). Remove the washing chamber and wash it out with the diluted HCl 0.1N solution.

Wash thoroughly with deionized water.

Replace the washing chamber and return the instrument to the ready state by pressing ← (previous).

Internal and External Waste Tubing Cleaning Procedure

For the internal and external waste tubing cleaning procedure please refer to the Waste Line Cleaning Procedure in the daily maintenance (section 5.1).

5.3 Bi-Weekly Maintenance

Optic Paths

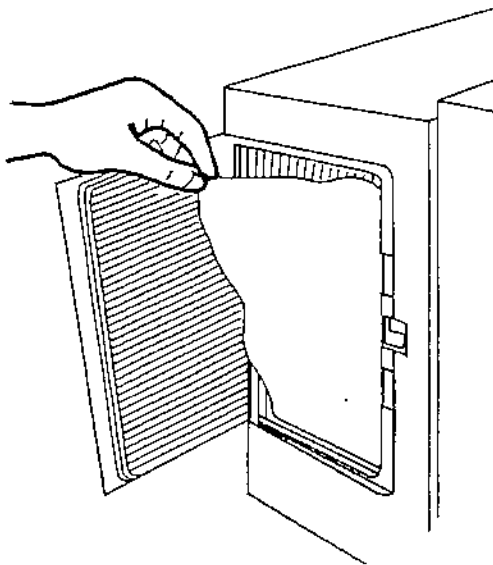
Using a cotton tip applicator moistened with deionized water, clean the chromogenic channel sensor filter surface (in the rotor cover) and the halogen lamp optic fiber (under the rotor holder). Also clean the LED sensor surface (under the rotor holder) and the LED fiber optic surface. Clean the surface and the 20 holes of the rotor holder in the same manner.

5.4 Monthly Maintenance

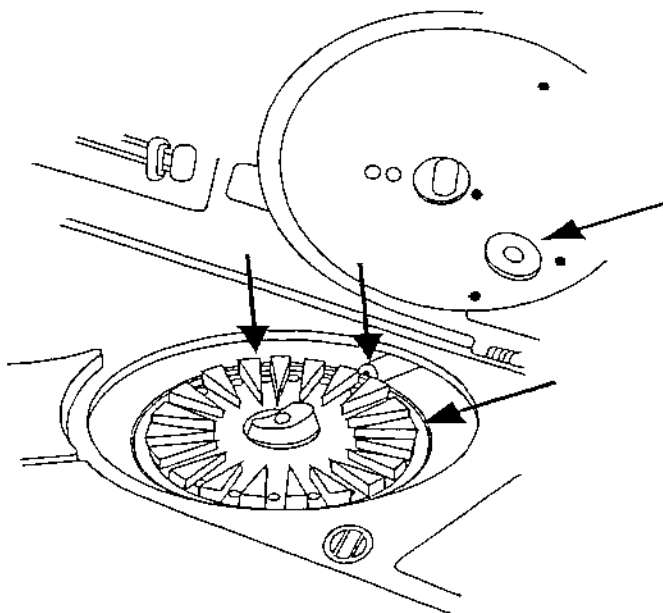
Instrument Fans (Ventilation)

Open the door on the left-hand side of the instrument and check the cleanliness of the filter. If it appears dirty or blocked, remove it (see figure) and clean it using compressed air or wash it in water and dry off in an air stream before replacing it.

Removing the Fan Filter



Cleaning the Optic Path



5.5 Needle Position Procedure (as needed)

If a cleaning procedure (see section 10) or dismantling of the needles block has been performed or a new lot of rotors is used, the needles position adjustment should be carried out as follows:

- Select PROG - DIAGNOSTIC - NEEDLES POSITION.

DIAGNOSTIC 24.JUL.96
12:00

NEEDLES POSITION

OPEN COVER

↓ to continue ← to exit

DIAGNOSTIC 24.JUL.96
12:00

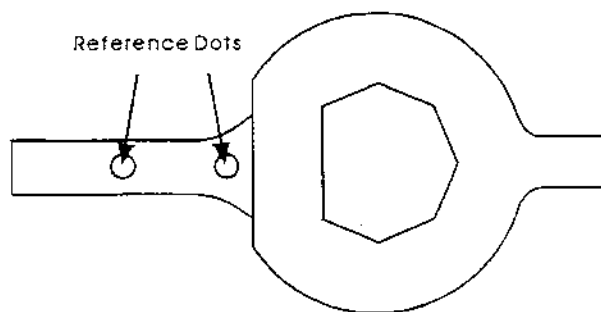
NEEDLES POSITION

↑ UP/DOWN
↓ ROTATE ← (previous)

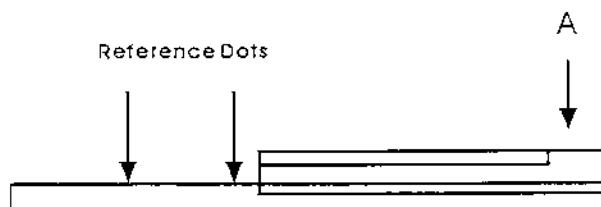
- Open the rotor cover. Press ↓ to continue. The arm moves onto the rotor holder.
- Loosen the orange knob on the needles arm and insert the new needles block leaving its upper surface higher than the arm upper surface.
- Insert the special tool (Needles position shim), contained in the shipping kit, into the rotor holder position 1 with the side A (see figure) facing up.
- Press ↑ : the arm lowers onto the rotor holder.
- Adjust the height of the needles block so that the needles touch the upper surface of the tool and confirm that the two needles match the two reference dots present on the tool surface.
- Tighten the needles by screwing the orange arm knob and make sure that after tightening it the position is not changed.
- Press ↑ to raise the arm.
- Remove the shim and insert a plastic rotor.

- Press ↑ to lower the arm and verify that the needles enter the rotor holes without touching the edges of the holes.
- Press ↑ to raise the arm.
- Press ↓ (rotate) to move the rotor to cuvette position 6 and repeat the same procedure as for position 1.
- Repeat as above for cuvettes 11, 16 and 1 of the plastic rotor.
- If needles centering is appropriate (both needles entered the tested cuvette ports and the visual check matches with the examples A and B reported on the "Needle Alignment" figure), proceed to next step.
- If necessary, center the sample needle to achieve proper alignment (see the example B on the "Needle Alignment" figure).
- Using the system keyboard, bring the rotor cuvette 1 into dispensing position, then repeat rotor procedure making sure that proper alignment has been achieved in all tested cuvettes.
- Select ← to (previous) and return to the DIAGNOSTICS menu.

Needles Position Shim: Top view



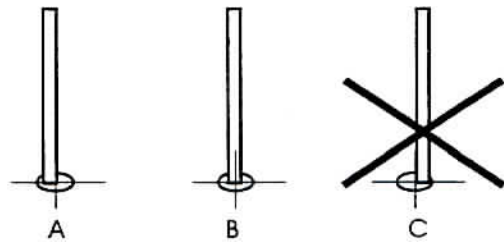
Needles Position Shim: Side view



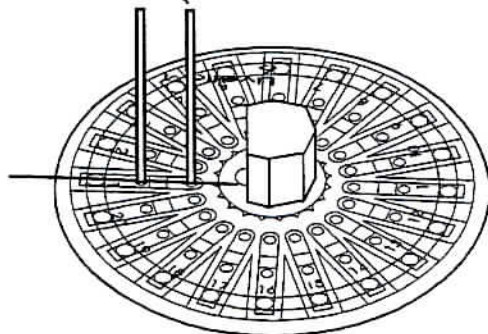
Note:

The needles alignment may not be identical in the four rotor cuvettes. If, while carrying out previous steps, needle/s did not enter port/s of the rotor or if the sample needle was found to the right of center in any one cuvette (see example C on figure below), it must be readjusted in the cuvette where it is furthest to right, repeating the entire procedure.

Needles Alignment



Sample probe centered
or biased left



5.6 Maintenance Table

Maintenance Procedure	
Daily	<ul style="list-style-type: none"> - Check Reference Emulsion level - Empty, if necessary, the liquid waste container - Check thermal printer paper supply - At the beginning and at the end of each working day, carry out a priming cycle - Empty and wash with distilled water the reagent reservoirs - At the end of each working day, or more frequently if the number of samples makes it necessary, perform a waste line cleaning procedure
Weekly	<ul style="list-style-type: none"> - Clean all exposed surfaces and the inside of the autosampler and rotor compartments, with exception of the rotor holder, with a cloth soaked in a diluted solution of Hydrochloric Acid (HCl 0.1N) and rinse with deionized water (clean the rotor holder with Sodium Hypochlorite with a concentration of available chlorine less than 0.625 %) - Remove the wash chamber and wash/rinse as described above - Carry out a cleaning cycle
Bi-Weekly	<ul style="list-style-type: none"> - Clean with a cotton tip applicator: <ul style="list-style-type: none"> ● the halogen lamp optic fibre surface ● the LED sensor ● the LED fiber optic surface ● the 20 holes of the rotor holder
Monthly	<ul style="list-style-type: none"> - Check the cleanliness of the filter
Annual	<ul style="list-style-type: none"> - Replace the air filter - Replace the sample and reagent tubes - Replace the waste tube - Replace the needle block - Replace the waste reservoir

6 Troubleshooting

6.0 Introduction

Though scrupulous maintenance, as described in the previous section, reduces the possibility of instrument failure, malfunctions may still occur. A system of warnings, alarms and checks helps the user to resolve most simple problems connected with operating the ACL systems. Complex defects regarding the mechanical or electronic functions are rare so that only a small percentage of defects cannot be resolved by the user.

6.1 Warnings

If a warning is displayed, it is possible to continue using the instrument with limitations.

The warning signal appears in the upper part of the video with the message "WARNING SEE PROG".

To display the actual warning, or warnings, the operator has to press PROG, select WARNING using ↑ and ↓ and press ENTER.

The frame displays one or more of the following warnings:

- Magnetic stirrer fail
- Flush/optic channel error
- Halogen lamp fail ✓
- Printer fail
- Thermal fail
- Preheater temperature out of range
- Peltier temperature out of range
- Master storage battery
- Slave storage (battery or write error)
- Data transmission error
- Sensor fail (xx)
 - xx = 6 electronic fail
 - xx = 7 reference out of range
 - xx = 8 air out of range
 - xx = 9 sensor leakage
 - xx = 11 no reagent (reservoir) 1

xx = 12 no reagent (reservoir) 2
xx = 13 no reagent (reservoir) 3
xx = 14 no reagents
xx = 18 no deficient plasma or diluent
xx = 19 no diluent
xx = 20 no NP

- Sensor off
- No sample

Two particular warnings are not shown in this display, but appear directly on the upper part of the video display.

1. "PAPER END" which indicates lack of printer paper;
2. "INCUBATION TEMP OUT OF RANGE" which indicates that the rotor holder temperature is not in range.

6.1.1 Magnetic Stirrer Fail

One or both of the magnetic stirrers placed under in the reagent reservoirs (positions 1 and/or 2) are not working.

The operator may continue, stirring the reagents properly before starting an analysis.

Call The IL Service Representative for additional instructions.

6.1.2 Flush/Optic Channel Error

- Check the level of the Reference Emulsion in the bottle. If less than 1 cm of liquid exists, replace the bottle with a new one. Mix gently by inversion before placing on the instrument.
- Check that Reference Emulsion was correctly dispensed into the rotor during analysis (if the rotor is new: rotor position 20 for calibration cycle; position 19 for PT-FIB, APTT, TT, DOUBLE TESTS, SINGLE FACTOR of the EXTRINSIC PATHWAY, SINGLE FACTOR of the INTRINSIC PATHWAY; rotor positions 19 and 9 for PT-FIB/APTT and TT/APTT cycles; rotor position 17 for SINGLE FACTORS and rotor position 16 for CHROMOGENIC cycles; rotor position 16 for PROCOMPLEX; rotor position 17 for HEPATOCOMPLEX; for further details see section 7.0). If Reference Emulsion is not present and the Reference Emulsion bottle contains sufficient liquid, check that the fluidic path is free of obstructions.

Note:

A quick method to check the fluidic path is to remove the needle assembly from the sample arm. Using a beaker to collect the liquid, carry out a PRIMING cycle to check that liquid comes from both needles. Remember to carry out the NEEDLES POSITION ADJUSTMENT after this check - see section 5. At the end of this cycle, the WARNING "Sensor Fail" appears. Ignore this WARNING.

- Check that the Light Emitting Diode is ON.

Note:

The red light ray can be seen in the rotor cuvettes. If the LED is off, call the IL service representative as the instrument cannot be used.

- If the LED is on, carry out the optic path cleaning as described in the Maintenance Section 5.3.
- If none of the above procedures correct the problem, call The IL Service Representative .

6.1.3 Halogen Lamp Fail

Enter the main menu and set the cursor on a chromogenic test. Open the rotor cover. Press ENTER.

- If the light comes on for a brief period only, repeat the test.
- If the fault persists, call The IL Service Representative .

TEST MENU
ABS TEST
| AM III | → ENTER

Halogen Lamp Replacement Procedure

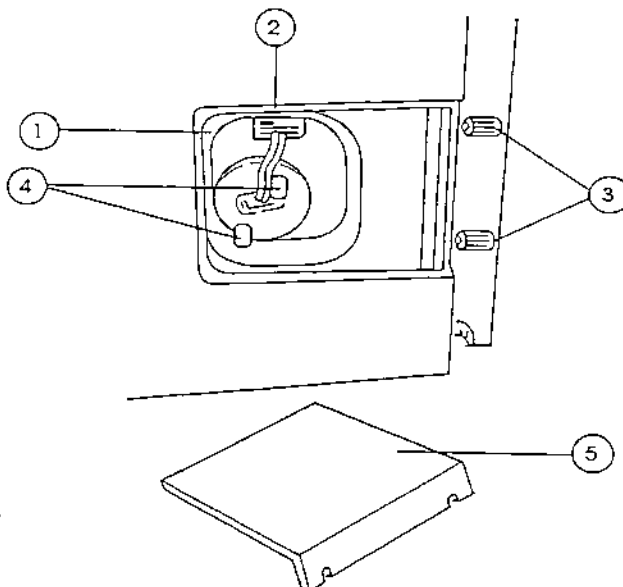
Should the instrument display the message "CYCLE ABORTED HALOGEN LAMP FAIL", the operator can check or replace the halogen lamp by following these steps:

1. If the above message is present on the video, open the rotor cover and check that the halogen lamp light is present in the vicinity of cuvette # 9. If the light is absent, turn off the instrument.
2. Loosen the knobs (3) located on the right side of the rear cover and remove the lamp cover plate (5) as shown in "The Halogen Lamp" figure.
3. Pull out the lamp connector (2) of the first figure. Unscrew and remove the knobs (4) shown in "The Halogen Lamp" figure and pull out the lamp assembly (see the "Replacing the Halogen Lamp" figure).
4. Remove the lamp cover ("The Halogen Lamp" figure) and install it on the new lamp assembly ("Replacing the Halogen Lamp" figure) P/N 181021-81.
Do not touch the lamp bulb with your fingers.
5. Insert the new lamp assembly into position, keeping the socket slot ("Replacing the Halogen Lamp" figure) in the up position so that it matches the corresponding pin in the lamp housing.
6. Fix the lamp cover by tightening the knobs.
7. Insert the lamp connector into its plug ("Replacing the Halogen Lamp" figure). The connector can be inserted in either one of its two positions.
8. Mount the lamp cover plate and fix it by tightening the two knobs on the right side rear cover.

9. Turn on the instrument.
10. After the "PLEASE WAIT" time, select a chromogenic test and check that the halogen lamp is on and can be seen through the rotor holder. If the halogen lamp still does not come on when entering a chromogenic test, call The IL Service Representative.

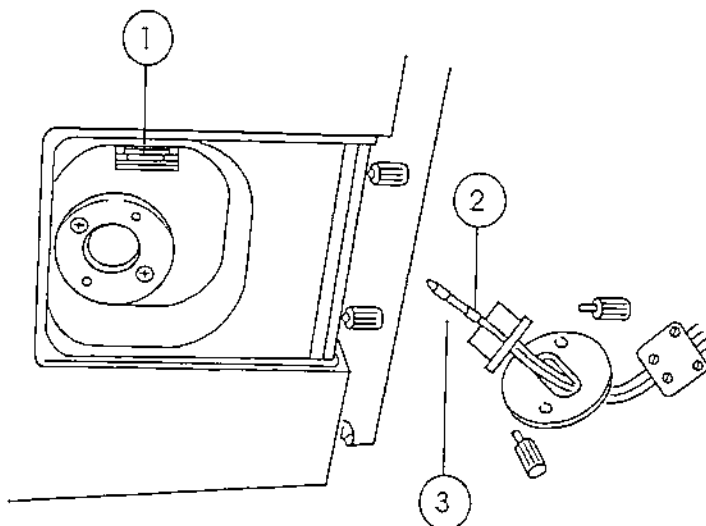
The Halogen Lamp

1. Lamp Cover
2. Lamp Connector
3. Orange Thumb Screws (External)
4. Internal Thumb Screws
5. Cover Plate



Replacing the Halogen Lamp

1. Lamp Connector Plug
2. Socket Slot
3. Lamp Assembly



6.1.4 Printer Fail

If no printout is produced, results must be transcribed from the video. The instrument continues to function correctly with results displayed on the video or transmitted via the RS 232 C data link, if connected and enabled. The printer will not function if there is a "write" failure in the slave memory. Verify that the paper is loaded correctly.

Call The IL Service Representative.

6.1.5 Thermal Fail

This warning indicates that the inside of the instrument is overheating and may affect the measuring chamber temperature.

Check the condition of the air filter on the left hand side of the instrument; clean or replace if necessary.

Check that the ambient air at filter entry can flow freely, without obstruction, and that its temperature is less than 35°C.

Note:

The instrument works correctly in an ambient temperature from 15 to 32°C and without failure in the range 10 to 40°C.

If cleaning the air filter does not resolve the warning and the ambient conditions are acceptable, call The IL Service Representative .

6.1.6 Preheater Temperature Out of Range

This warning appears when the temperature is outside the range 36 to 39°C.

Enter PROG, DIAGNOSTIC, TEMPERATURE CONTROL.

- If the video shows — or **** for the preheater temperature and the instrument is properly warmed up, call The IL Service Representative.
- If the video shows a high value (from 39° to 50°C), check the air filter and ambient conditions as indicated above (section 6.1.5). If there is no correction of the fault, call The IL Service Representative.
- If the video shows a low value (from 20° to 36°C) check that the instrument is properly warmed up and that the ambient temperature is greater than 15°C. If the fault persists call The IL Service Representative.

Note:

The instrument is fully operational even when the preheater temperature is out of range. However, care should be taken to ensure that there is no indication of INCUBATION TEMP OUT OF RANGE at the start of analysis.

6.1.7 Peltier Temperature Out of Range

This warning appears when the temperature is outside the range 12 to 15°C.

Enter PROG, DIAGNOSTIC, TEMPERATURE CONTROL.

- If the video shows the peltier temperature from 4° to 12°C the instrument is fully operational and no precautions need to be taken. However, The IL Service Representative should be called to rectify the situation.
- If the video shows — or ****, the temperature may be very low or too high. In this case the operator may continue to use the instrument taking care to leave the reagents in the reservoirs for the period of analysis only, after which they should be stored in a refrigerator (see also reagent kit instructions).

Call the IL Service Representative.

Note:

As described in section 6.1.5 high temperatures may be caused by dirty fans or ambient temperatures outside the normal range.

6.1.8 Master Storage Battery

The instrument continues to function correctly provided that it is not switched off and that there is no main power failure.

- When the instrument is switched on, it will indicate NVR INITIALIZED and the default parameters are as follows.

Date and Time	Date and Time of the latest software rev.	
Calibration	Not calibrated	
ISI	1.000	
Ref. Values (seconds)	PT = 12.0 APTT = 30.0 TT = 12.0	
INR	Off	
Autocal	On	
Units	Temp = °C FIB = mg/dL	
Printer Status	On - 1 Copy	
Printout Format	Fib ON	
Host	Baud rate	9600
Research	Baud rate	9600
Ratio Adjustment	PT = 1	
	APTT = 1	
	TT = 1	

- Call The IL Service Representative to repair the defect, bearing in mind that once the instrument is repaired, the default parameters will be in place.

6.1.9 Slave Storage Battery

This warning appears if there is a WRITE failure in the slave memory or if the battery is defective.

- If the problem is due to a WRITE failure, the instrument remains functional but the printer does not operate (see warning 6.1.4).
- If the problem is due to a battery failure, the instrument continues to function including printout. Following a lack of power, the last recorded print out information will be lost.
- Call the IL Service Representative to repair the defect.

6.1.10 Data Transmission

This warning appears when there has been an error in data transmission over the RS 232 C interface.

Check the following items:

- PROG, SET UP, INTERFACE STATUS (Data transmission characteristics to the Host computer)
- Data transmission connection (ACL - computer)
- Repeat the transmission from the Database
- If the fault persists call the IL Service Representative.

6.1.11 Sensor Fail

Sensor fail 6	Electronic fail	The instrument can be used.
Sensor fail 7	Reference out of range	Repeat Priming.
Sensor fail 8	Air out of range	Perform a cleaning procedure.
Sensor fail 9	Sensor leakage	The needle assembly must be replaced. See section 5.4 Needle Assembly.
Sensor fail 11	No reagent R1	Check if the reagent is present in reservoir 1.
Sensor fail 12	No reagent R2	Check if the reagent is present in reservoir 2.
Sensor fail 13	No reagent R3	Check if the reagent is present in reservoir 3.
Sensor fail 18	No def. plasma/diluent	Check if the reagent is present.
Sensor fail 19	No liquid in pos. 19	Check if the reagent is present.
Sensor fail 20	No liquid in pos. 20	Check if the reagent is present.
Sensor off	Sensors are disconnected.	Call The IL Service Representative.

6.2 Other Warnings and Alarms

6.2.1 Results"?"

If one or more of the following warnings are present during analysis, the results frame is presented with a question mark as shown above. The warning conditions which generate this situation are as follows:

- Magnetic stirrer fail
- Preheater temperature out of range
- Peltier temperature out of range
- Cover open during analysis (excluding the acquisition phase)
- Incubation temperature out of range at start of acquisition phase
- Sensor off/fail (xx) or no reagents.

Note:

Any system error (e. g. Error Code 5 - Incubation temperature out of range) occurring during the cycle (loading and/or incubation phases) will be remembered and flagged on the screen and on the internal printer (results?) and it will be tracked in the results record (E).

Note:

In the specific case of "Incubation temperature out of range" during the cycle the error will be remembered and flagged on the screen and on the internal printer (results?) and it will be tracked in the results record (E) only if occurring for more than 15 seconds.

6.2.2 Printer Error Codes

When the "?" is displayed on the RESULTS frame, the printout indicates the warning by means of an error code as follows:

Error Code 1	Magnetic stirrer fail
Error Code 2	Peltier temperature out of range
Error Code 3	Preheater temperature out of range
Error Code 4	Cover open during analysis (except acquisition phase)
Error Code 5	Incubation temperature out of range at start of acquisition phase
Error Code 6	Electronic fail
Error Code 7	Reference out of range
Error Code 8	Air out of range
Error Code 9	Sensor leakage
Error Code R1	No reagent in position 1
Error Code R2	No reagent in position 2
Error Code R3	No reagent in position 3
Error Code 18	No deficient plasma /diluent
Error Code 19	No liquid in position 19
Error Code 20	No liquid in position 20
Sensor off	

6.2.3 Cycle Abort Situations

If one of the following alarms occurs during analysis, the cycle will be aborted with an appropriate indication on the video:

- No sample(s) detected on sample tray during sensor check
- No N.P. (in cycles with on-run calibration)
- Optical reference out of range (see section 6.1.2)

- Halogen lamp fail (see section 6.1.3)
- Cover open during acquisition
- Motor Error + *device name*

In this frame, the *device name* can be one of the following condition:

- rotor motor
- autosampler motor
- horizontal arm motor
- vertical arm motor
- dilutor reagent motor
- dilutor sample motor

In this case the specific motor will be indicated together with the general Motor Error message.

In case more than one error occurs only the first error will be displayed.

6.2.4 Error Codes on VDU

Error Code 25

If during the AT-III test (See Section 3) the extra wash cycle has not been performed because of the lack of the diluted buffer in position DIL or the test has been stopped by pressing STOP-ENTER, the error code 25 will occur and the operator must carry out a normal cleaning procedure (see section 5) before starting a new test.

If during the AT-III and/or Fibrinogen-C tests (See Section 3) the extra wash cycle has not been performed because of the lack of the cleaning solution in the reagent reservoir number 1 or the test has been stopped by pressing STOP-ENTER, the error code 25 will occur and the operator must carry out a normal cleaning procedure (see section 5) before starting a new test.

6.2.5 Error in DMS

Error message	Possible explanation
Data base full	More than 300 sample IDs in the DMS. Delete sample IDs to allow space for programming
More than 8 tests programmed per sample	Trying to program the test number 9 for a sample ID. Delete tests to allow space for programming.
Duplicated sample ID	When editing a loadlist a duplicated sample ID has been entered. Delete the duplicate sample ID.
Control ID already used	ID already used in the QC. Change sample ID.
Control ID already used for patient	ID already used for patient sample. Change ID.
Invalid range selection	One of the two IDs in the selected range does not exist.
Sample ID not found	ID requested does not exist in the database.

6.2.6 Other errors

Error message	Possible explanation
Not identified sample in position X	Sample does not have a sample ID associated in the loadlist
Check sample tray	Material is missing from the sample tray
No sample	Sample is not present during aspiration or liquid level detection check
Test X is not calibrated	The test does not have a calibration associated to it
Added sample in position X	During the sample tray check one sample has been added to the previous loadlist

Error message	Possible explanation
Used rotor	Rotor is partially used. Enter the available positions
Load new rotor	Rotor has no sufficient positions. Place a new rotor
Used rotor More samples than available positions	Remove samples or place a new rotor
Remove rotor	After a Stop-Enter during an active cycle the operator is asked to remove the rotor
NP out of range	NP out of range ($\pm 9\%$ for PT, $\pm 15\%$ for APTT or $\pm 20\%$ for FIB-PT based)
QC out of range	QC material out of range according to the SD selected in the QC set up

6.2.7 Results flags (E, Q and I classes)

The system handles three flags type:

- E = system errors
- Q = QC errors
- I = Informative messages

The E flag will be used if one or more of the following error condition were verified:

- Magnetic stirrer fail
- Preheater temperature out of range
- Peltier temperature out of range
- Cover open during analysis
- Incubation temperature out of range at start of acquisition phase
- Sensor fail
- Sensor off
- No liquid (xx)

The Q flag will be used if one or more of the following error condition were verified:

- 2 points cal
- No cal verification
- NP out of range
- QC out of range

The I flag will be used if one or more of the following error condition were verified:

- Acquisition extended
- Animal application

The three flags will be presented with priority: E will be the highest one and I the lowest.

If a test has associated error conditions belonging to the three classes E, Q and I then the E flag will be presented. The specific error screen will still present the complete errors list.

If a test has associated error conditions belonging to the two classes Q and I then the Q flag will be presented. The specific error screen will still present the complete errors list.

If a test has associated error conditions belonging to the class I only then the I flag will be presented. The specific error screen will still present the complete errors list.

Note:

Any system error (e. g. Error Code 5 - Incubation temperature out of range) occurring during the cycle (loading and/or incubation phases) will be remembered and flagged on the screen and on the internal printer (results?) and it will be tracked in the results record (E).

Note:

In the specific case of "Incubation temperature out of range" during the cycle the error will be remembered and flagged on the screen and on the internal printer (results?) and it will be tracked in the results record (E) only if occurring for more than 15 seconds.

6.3 Alarms

Alarm situations completely block the instrument with an indication of an Alarm Number on the VDU display except in the case of video fail.

Some situations can be rectified by the operator by switching the instrument off and waiting for 2 or 3 seconds prior to switching it on. If the alarm condition persists, call The IL Service Representative.

The following list shows the alarm number, the cause and the possible remedial action to be taken by the operator.

No.	Cause	Remedial Action
128	Software fail	None
129	Arithmetic processor fail	None
130	Non-volatile RAM write error	None
132	NVRAM paging unit error	None
133	Software fail	None
135	Synchronization error during acquisition	None
136	Calculation error during acq.	None
138	Rotor temp out of range for more than 30 min.	<p>Check that ambient temp is not outside the range 10-40°C.</p> <p>Check that rotor cover is closed.</p> <p>Check that air filter is not obstructed. Switch the instrument off, wait 2 or 3 seconds and switch it on again. The instrument should exit from the PLEASE WAIT within 30 minutes.</p> <p>If the alarm condition persists, call The IL Service Representative.</p>
140	A/D Converter fail	None
144	Keyboard fail (key pressed)	<p>Check that there is no object (for more than 2 minutes) on the keyboard holding the key down. Switch the instrument off, wait 2 or 3 seconds and switch it on again.</p> <p>If the alarm persists, call The IL Service Representative.</p>
192	Slave not responding	None
213	Rotor logic fail	None
214	Slave error	None
216	Slave EPROM 1	None
217	Slave CPU-RAM error	None
218	Rotor motor fail	<p>Check that there are no objects obstructing relative motor.</p> <p>Switch the instrument off, wait 2 or 3 seconds and switch it on again.</p> <p>If the alarm condition persists, call The IL Service Representative.</p>

No.	Cause	Remedial Action
219	Autosampler fail	Check that there are no objects obstructing relative motor. Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm condition persists, call The IL Service Representative.
220	Horizontal arm motor	Check that there are no objects obstructing relative motor. Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm condition persists, call The IL Service Representative.
221	Vertical arm motor	Check that there are no objects obstructing relative motor. Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm condition persists, call The IL Service Representative.
222	Reagent dilutor motor	Check that there are no obstructions in relative fluidic path. Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm persists, call The IL Service Representative.
223	Sample dilutor motor	Check that there are no obstructions in relative fluidic path. Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm persists, call The IL Service Representative.
224	Slave receiver time out	None
228	Slave RAM	None
229	NVRAM write error	None
230	Power fail	None
240	Receiver time out	None
241	Receiver buffer fail	None
255	RAM failure at start up	Switch the instrument off, wait 2 or 3 seconds and switch it on again. If the alarm persists, call The IL Service Representative.

Note:

"None" means there is no action the operator can take to remedy the relative software/electronic failure and The IL Service Representative should be called immediately.

6.4 Coag Errors (1, 2 and 3)

To better identify from which algorithm the Coag Errors are generated, the errors are now identified by a number.

This number helps in obtaining information related to the limit that caused the specific error.

Coag Error 1

The clotting curve passes the first threshold, but not the second, before the end of the acquisition time.

Coag Error 2

When the initial slope of the curve is too high, the Maximum of the Second Derivative criterion is used.

This error is displayed if the Maximum of the Second Derivative limit is not passed because the acceleration of the reaction curve is not sufficient to be significant. If the reaction curve is not a real clotting curve (biphasic curves), this Coag error is shown.

Coag Error 3

The Third Criterion algorithm is not passed. This means that the difference in time between the two intersection points (curve/first threshold and curve/second threshold) is exceeded (non-phasic curves).

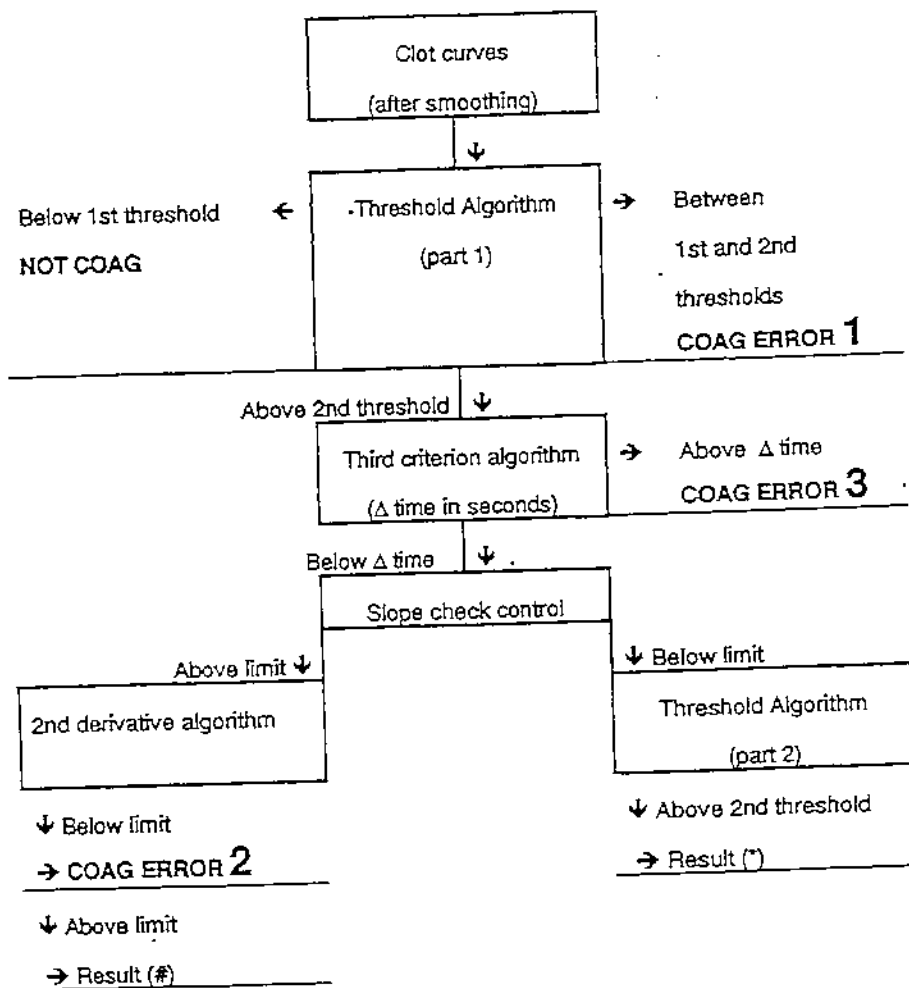
6.4.1 Errors on sample ID using the internal barcode reader

When the internal barcode reader is used the following errors on the sample ID may appear in one of the following conditions:

- No_R = sample ID missing
- Dpl = duplicated sample ID
- No_C = truncated sample ID
- Inv = invalid sample ID

The possibility to manually edit the sample ID is still possible in case these errors occur.

6.5 Data Redaction Diagram for PT, APTT and TT



(#) Time is calculated at the correspondence of the Max 2nd Der of the clotting curve

(*) Time is calculated at the intersection between the clotting curve and the first threshold

7 Specifications

7.0 Introduction

This section includes specification tables and technical descriptions.

7.0.1 Legenda

In some cases, the following abbreviations are used:

- AT-III = Antithrombin III
- PLG = Plasminogen
- PCX = Pro-IL-Complex *
- HPX = Hepatocomplex *
- PCL = ProClot
- PCH = ProChrom
- PS = Protein S
- FIB-C = Fibrinogen Clauss
- HEP = Heparin
- ATPL = alpha-2-antiplasmin
- DP = Deficient Plasma

* Not currently available in U.S.A.

7.1.1 Sample Tray Positions

Test	Pool	Dil.	Samples	Def. Plasma
PT-FIB CAL	Normal Pool	Sample Diluent	--	--
PT-FIB	Normal Pool	--	1 - 18	--
APTT	Normal Pool	--	1 - 18	--
TT	Normal Pool	--	1 - 18	--
PT-FIB/APTT	Normal Pool	--	1 - 8	--
TT/APTT	Normal Pool	--	1 - 8	--
SINGLE FACTORS (Cal. + Analysis)	Normal Pool	Factor Diluent	1 - 15	18

Test	Pool Position	Dil. Position	Sample Positions	Sample Tray Position 18	SampleTray Position 17
DOUBLE TEST (PT-FIB, APTT, TT)	Normal Pool	--	1 - 9	--	--
DOUBLE TEST (PT-FIB/APTT)	Normal Pool	--	1 - 4	--	--

Test	Pool Position	Dil. Position	Sample Positions	Sample Tray Position 18	SampleTray Position 17
AT-III CAL	Normal Pool	Diluted Buffer (& pos. 16)	1 - 12 Empty cups	Empty cup	Empty cup
AT-III Analysis	--	Diluted Buffer	1 - 9	Empty cups from 10 to 18	--
Heparin Xa CAL	Calibrator	Working Diluent	1 - 12 Empty cups	Normal Pool	Empty cup
Heparin Xa Analysis	--	Working Diluent	1 - 9	Empty cups from 10 to 18	--
HEPARIN	Diluted* Calibr.	Diluted* N.P.	1 - 15*	--	--
ATPL	Normal* Pool	Diluted Buffer	1 - 15*	--	--
PLG	Normal* Pool	Diluted Buffer	1 - 15*	--	--
PCX CAL	Normal* Pool	Factor Diluent	--	Deficient Plasma	Normal # Pool
PCX ANALYSIS	--	--	1 - 17	Deficient Plasma	--
HPX CAL	Normal Pool	Factor Diluent	--	Deficient Plasma	--
HPX ANALYSIS	--	--	1 - 17	Deficient Plasma	--
PROCLOT	Normal Pool	Working Diluent	1 - 16	Protein C Def. Plasma	Empty cup
FIB-C CAL	Normal Pool	Factor Diluent	--	--	--
FIB-C ANALYSIS	--	Factor Diluent	1 - 18	--	--
PS	Normal Pool	P.S. Def. Plasma	1 - 16	Activated P-S Def. Plasma	50 % Standard
PCH	Normal Pool	Diluted Diluent	1 - 15	Diluted Diluent	--
D-Dimer CAL	Calibrator Pool	Buffer (& pos. 16)	--	Empty cup	Empty cup
D-Dimer Analysis	--	Buffer	1 - 18	--	--
APCR-V	Normal Pool	Factor V D. Plasma	1 - 16	Calcium Chloride	

* These fluids require predilutions according to the procedure

Optional

Note:

The Normal Pool can either be the IL Calibration Plasma or a laboratory pooled plasma.

7.1.2 Rotor Positions for Samples and Reagent ("Unused Rotor" case)

Test	Cal Curve (high/low)	N.P.	Samples	Reference Emulsion	Diluted Buffer
PT-FIB CAL	100% 1-6 50% 7-12 25% 13-18	--	--	20	--
PT-FIB	--	20	1 - 18	19	--
APTT	--	20	1 - 18	19	--
TT	--	20	1 - 18	19	--
PT-FIB/ APTT	--	20 and 10	1 - 8 PT 11-18 APTT	19	-- --
TT/APTT	--	20 and 10	1 - 8 TT 11-18 APTT	19	-- --
SINGLE FACTOR CAL+ANALYSIS	100 % 18 50 % 19 25 % 20	--	1-15	17	--
SINGLE FACTOR ANALYSIS	--	--	1-15	17	--
DOUBLE TEST (PT-FIB, APTT, TT)	--	20	1 - 18	19	--
DOUBLE TEST (PT-FIB/APTT)	--	20 10	1 - 8 11 - 18	19	--
AT-III CAL	100% 1-4 50% 5-8 25% 9-12	--	--	19	20
AT-III (ANALYSIS)	--	--	1 - 9	19	20
Heparin Xa CAL	0.8 1-4 0.4 5-8 0.0 9-12	--	--	19	20
Heparin Xa (ANALYSIS)	--	--	1 - 9	19	20
HEPARIN	18-19-20	--	1 - 15	16	17
ATPL	18-19-20	--	1 - 15	16	17
PLG	18-19-20	--	1 - 15	16	17

Test	Cal Curve (high/low)	N.P.	Samples	Reference Emulsion	Diluted Buffer
PCX CAL	25% 1-4 12.5% 5-8 6.25% 9-12 100% (13-16)	--	--	20	--
PCX ANALYSIS	--	--	1 - 17	20	--
HPX CAL	100% 1-4 50% 5-8 25% 9-12	--	--	20	--
HPX ANALYSIS	--	--	1 - 17	20	--
PROCLOT	100 % 18 50 % 19 25 % 20	--	1 - 16	17	--
FIB-C CAL	1-4 150% 5-8 100% 9-12 50%	--	--	19	20
FIB-C ANALYSIS	--	--	1 - 18	19	20
PROTEIN S	18 100% 19 50% 20 0%	--	1 - 16	17	--
PROCHROM	100 % 18 50 % 19 25 % 20	--	1 - 15	17	16
D-Dimer CAL	1000 1-4 500 5-8 250 9-12	--	--	19	20
D-Dimer (ANALYSIS)	--	--	1 - 18	19	20
APCR-V	--	1 and 10	2 - 9 (TO) 11-18 (TA)	20	--

* These fluids require predilutions according to the procedure

Optional

Note:

The reference emulsion in the chromogenic cycle is dispensed to check for correct washing between samples and rotor presence.

7.1.3 Coagulometric Analytical Cycles (Volumes)

	PT-FIB Cal a) 100% b) 50% c) 25%	PT-FIB Analysis <i>PT-FIB (10µL)</i>	APTT	TT
Sample Head	a) 10µL per sample b) 0 c) 0	10µL per sample	10µL per sample	10µL per sample
Sample Dispensed	a) 50µL b) 25µL c) 12.5µL	50µL	53µL	75µL
Diluent Head	a) – b) 10µL per sample c) 10µL per sample	–	–	–
Diluent Dispensed	a) – b) 25µL c) 37.5µL	–	–	–
Reagent Head	a) 10µL b) 10µL c) 10µL	10µL per sample	10µL cephalin per sample 50µL CaCl ₂ per rotor	50µL per rotor
Reagent Dispensed	a) 100µL b) 100µL c) 100µL	100µL	53µL Cephalin 50µL CaCl ₂	75µL

Note (needles conditioning):

When the APTT test (in any combination) is preceded by a cycle with thromboplastin (PT, Extrinsic Pathway, Single Factor of the Extrinsic Pathway, Pro-IL-Complex and Hepatocomplex), the internal needle aspirates 30 µL of cephalin from the reagent reservoir 2 followed by 80 µL of air bubble.

The aspirated reagent is immediately dispensed into the waste reservoir. This step is repeated three times to prepare the needle ("needle conditioning") for the cephalin.

	Single Factors Extrinsic Pathway		Single Factors Intrinsic Pathway		
Sample Head	N.P. 1 st ST	10µL	N.P. 1 st ST	10µL	
	N.P. 2 nd ST	10µL	N.P. 2 nd ST	10µL	
	N.P. 3 rd ST	10µL	N.P. 3 rd ST	10µL	
	Samples	10µL	Samples	10µL	
Sample Dispensed	N.P. 1 st ST	8µL	N.P. 1 st ST	8µL	
	N.P. 2 nd ST	8µL	N.P. 2 nd ST	8µL	
	N.P. 3 rd ST	8µL	N.P. 3 rd ST	8µL	
	Samples	8µL	Samples	8µL	
Diluent Head	1 st ST	10µL	1 st ST	10µL	
	2 nd ST	10µL	2 nd ST	10µL	
	3 rd ST	10µL	3 rd ST	10µL	
Diluent Dispensed	1 st ST	32µL	1 st ST	32µL	
	2 nd ST	32µL	2 nd ST	32µL	
	3 rd ST	32µL	3 rd ST	32µL	
Reagent Head	10µL	50µL	10µL	50µL	50µL
	Standards and samples	Def. Plasma per each factor	Standards and samples	CaCl ₂ per rotor	Def plasma per each factor
Reagent Dispensed	80µL	40µL	40µL	40µL	40µL
	Thrombopl.	Def Plasma per each sample	Cephalin	CaCl ₂	Def Plasma per each sample

Standard positions will be as follow:

	HIGH CURVE	LOW CURVE
1 st STANDARD	100%	6.25%
2 nd STANDARD	50%	3.12%
3 rd STANDARD	25%	1.56%

Dilution of the standard /2 and /4.

For the preparation of the two additional standard using empty cups the following materials are used:

	First loading	Second Loading
STANDARD/2	110 µL (DIL)	120 µL (N.P.) + 10 µL (DIL)
STANDARD/4	110 µL (DIL)	60 µL (N.P.) + 70 µL (DIL)

7.1.4 Absorbance Analytical Cycles (Volumes)

	Pro-Chrom α -2-Antiplasmin Plasminogen			Heparin		
Sample* Head	Standard	100%	50 μ L	1 st Standard	10 μ L	
	Standard	50%	--	2 nd Standard	--	
	Standard	25%	--	3 rd Standard	--	
	Samples		10 μ L	Samples	10 μ L	
Sample Dispensed	Standard	100%	50 μ L	1 st Standard	50 μ L	
	Standard	50%	25 μ L	2 nd Standard	25 μ L	
	Standard	25%	12.5 μ L	3 rd Standard	0 μ L	
	Samples		50 μ L	Samples	50 μ L	
Position* DIL Head		100%	--	1 st Standard	--	
		50%	10 μ L	2 nd Standard	10 μ L	
		25%	10 μ L	3 rd Standard	10 μ L	
Position DIL Dispensed		100%	--	High Curve	Low Curve	--
		50%	25 μ L	0.8 U/mL	0.2 U/mL	25 μ L
		25%	37.5 μ L	0.4 U/mL	0.1 U/mL	50 μ L
			75 μ L	0.0 U/mL	0.0 U/mL	75 μ L
		blank sample			blank sample	
Enzyme Head		100%	10 μ L	High Curve	Low Curve	10 μ L
		50%	10 μ L	0.8 U/mL	0.2 U/mL	10 μ L
		25%	10 μ L	0.4 U/mL	0.1 U/mL	10 μ L
		Sample	10 μ L	0.0 U/mL	0.0 U/mL	10 μ L
Enzyme Dispensed	50 μ L per sample/Std			50 μ L per sample/Std		
	75 μ L blank sample			75 μ L blank sample		
Substrate Head	50 μ L per rotor			50 μ L per rotor		
Substrate Dispensed	50 μ L			50 μ L		

* In case of Heparin cycle the standard is the Calibrator and the position DIL is normal pooled plasma.

Note:

Blank sample (reference for the chromogenic) is 75 μ L of diluted buffer + 75 μ L of enzyme.

	Antithrombin III Calibration	Antithrombin III Analysis
Sample Head	10 μ L	10 μ L
Sample Dispensed	50 μ L	50 μ L
Enzyme Head	10 μ L	10 μ L
Enzyme Dispensed	50 μ L	50 μ L
Substrate Head	50 μ L per rotor	50 μ L per rotor
Substrate Dispensed	50 μ L	50 μ L

	Heparin Xa Calibration	Heparin Xa Analysis
Sample Head	10 μ L	10 μ L
Sample Dispensed	50 μ L	50 μ L
Enzyme Head	10 μ L	10 μ L
Enzyme Dispensed	50 μ L	50 μ L
Substrate Head	50 μ L per rotor	50 μ L per rotor
Substrate Dispensed	50 μ L	50 μ L

	Fibrinogen-C Calibration a) 150 % b) 100 % c) 50 %	Fibrinogen-C Analysis
Sample Head	10 μ L	10 μ L
Sample Dispensed	a) 15 μ L b) 10 μ L c) 5 μ L	10 μ L
Diluent Head	50 μ L	50 μ L
Diluent Dispensed	a) 85 μ L b) 90 μ L c) 95 μ L	90 μ L
Reagent Head	10 μ L	10 μ L
Reagent Dispensed	50 μ L	50 μ L

	D-Dimer Calibration a) 1000 b) 500 c) 250	D-Dimer Analysis
Sample Head	10 μ L	10 μ L
Sample Dispensed	a) 20 μ L b) 20 μ L c) 20 μ L	20 μ L
Buffer Head	50 μ L	50 μ L
Buffer Dispensed	70 μ L	70 μ L
Latex Head	10 μ L	10 μ L
Latex Dispensed	90 μ L	90 μ L

7.1.5 Special Tests

	Pro-IL-complex			Hepatocomplex			Proclot		
Sample	St.	25%	10 μ L	St.	100%	10 μ L	St.	100%	50 μ L
Head	St.	12.5%	--	St.	50%	--	St.	50%	--
	St.	6.25%	--	St.	25%	--	St.	0%	--
	Samples		10 μ L	Samples		10 μ L	Samples		10 μ L
Sample	St.	25%	10 μ L	St.	100%	10 μ L	St.	100%	32 μ L
Dispensed	St.	12.5%	5 μ L	St.	50%	5 μ L	St.	50%	16 μ L
	St.	6.25%	2.5 μ L	St.	25%	2.5 μ L	St.	0%	--
	Samples		10 μ L	Samples		10 μ L	Samples		32 μ L
Position		25%	--		100%	--		100%	--
DIL		12.5%	10 μ L		50%	10 μ L		50%	10 μ L
Head		6.25%	10 μ L		25%	10 μ L		0%	10 μ L
Position		25%	--		100%	--		100%	--
DIL		12.5%	5 μ L		50%	5 μ L		50%	16 μ L
Dispensed		6.25%	7.5 μ L		25%	7.5 μ L		0%	32 μ L
Position 17 Head			10 μ L			--			--
Position 17 Dispensed			10 μ L			--			--
Position 18 Head			50 μ L*			50 μ L*			50 μ L*
Position 18 Dispensed		50 μ L (For each sample)			50 μ L (For each sample)			32 μ L (For each sample)	
Reagent Head		10 μ L (For each sample)			10 μ L (For each sample)			10 μ L (For each sample)	
Reagent Dispensed		140 μ L			140 μ L			64 μ L Cephalin 64 μ L CaCl ₂	
* Head aspirated only the first time.									
Protein S									
Sample	St.	100%			50 μ L				
Head	St.	50%			--				
	St.	0%			--				
	Samples				10 μ L				
Sample	St.	100%			4 μ L				
Dispensed	St.	50%			4 μ L				
	St.	0%			4 μ L				
	Samples				4 μ L				
Position		100%			--				
DIL		50%			--				
Head		0%			10 μ L				
Position		100%			--				
DIL		50%			--				
Dispensed		0%			4 μ L				

Protein S		
Pos. 17 Head	50%	10 μ L
Pos. 17 Dispensed	50%	4 μ L
Pos. 18 Head		10 μ L
Pos. 18 Dispensed		76 μ L
Reagent Head		10 μ L
Reagent Dispensed		80 μ L

APCR-V		
	Head	Dispensed
Def, Plasma F. V	50 μ L	40 μ L
Plasma	10 μ L	10 μ L
APTT Cephalin	10 μ L	53 μ L
Calcium chloride	50 μ L	53 μ L
APC / CaCl ₂	50 μ L	53 μ L

7.2 Volume of Cups and Reagent Reservoirs

Cup

Two kinds of cups are available: 0.5 mL cups and 2 mL cups.

Reagent reservoir

Two kinds of reagent reservoirs are available: MACRO (total volume 10 mL), MICRO 1 (total volume 2.5 mL) and MICRO 2-3 (total volume 2 mL). In general a MACRO CUP is enough to run four rotors for PT and eight rotors for APTT.

The reagent reservoirs may be topped off with fresh reagent under the following conditions: for PT-FIB and APTT (IL reagents) if within the on-line stability of the reagent at 15°C, the ratio between fresh and old reagent must be 2 parts (fresh) to 1 part (old) may not be exceeded (for additional information see kit instructions).

	Total Volume	Usable Volume
Cup 0,5 mL	0,5 mL	0,4 mL
Cup 2 mL	2 mL	1,5 mL
Cup 4 mL	4 mL	3,5 mL
Macro Reservoir 1, 2 and 3	10 mL	8 mL
Micro Reservoir 1	2,5 mL	2 mL
Micro Reservoirs 2-3	2 mL	1,5 mL
Macro Alternative Reservoir 3	10 mL	8 mL

7.3 Calibration Plasma and Sample Predilutions

In some analytical cycles the Normal Pool and the samples have to be prediluted manually with Factor Diluent, Diluted Buffer or Working Diluent. The following table lists the volumes and the dilution ratio for the sampling and calibration cycles when IL Test reagent kits are used.

Calibration Plasma Predilutions	Predilution Ratio	N.P. or Calibrator Volume	Factor Diluent Volume	Diluted Buffer Volume
Single Factor Low Curve	6,25% 1+15	20 µL	300 µL	--
Hep. High Curve (0.8 U/mL)	1 + 29	25µL	--	725µL *
Hep. Low Curve (0.2 U/mL)	1 + 14	25µL	--	350µL *
α-2-Antiplasmin	1 + 10	50µL	--	500µL
Plasminogen	1 + 20	25µL	--	500µL
Pro-IL-complex (25%)	1 + 3	100µL	300µL	--

* Working diluent

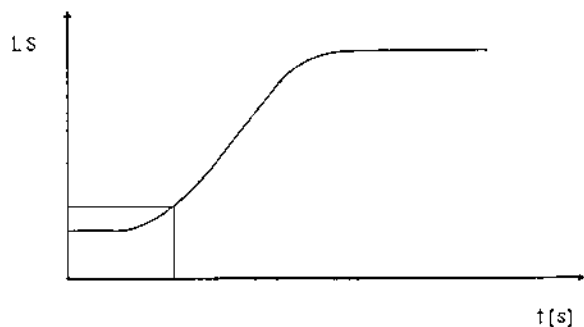
7.4 Measured Parameters

The ACL measures the following parameters at a temperature of $37 \pm 1^\circ\text{C}$ at ambient temperature from 15° to 32°C .

Coagulometric

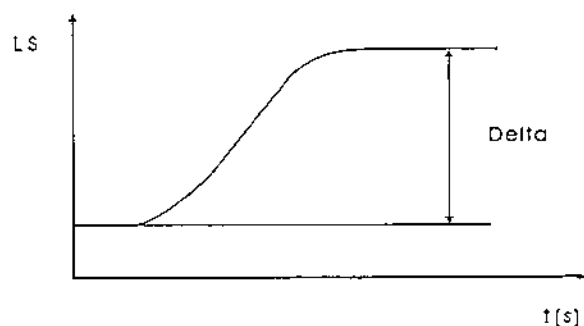
PT, APTT, TT, Factors, Pro-IL-Complex, Hepatocomplex, Proclot and Protein S.

The ACL measures a time (t), expressed in seconds, which represents the flexus point of the clot formation curve (LS = light scattered).



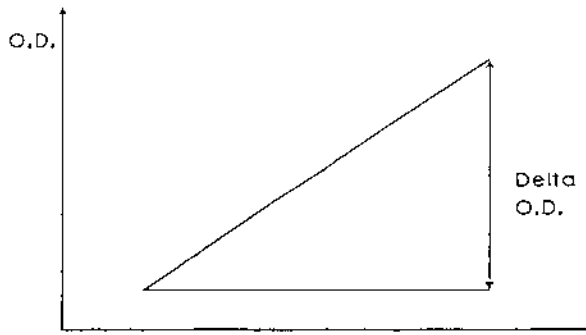
Fibrinogen (PT-derived)

The ACL measures a delta (Δ) which represents the difference between the light scattered before and after the clot formation.



Absorbance: Antithrombin III, Heparin, α -2-Antiplasmin, Plasminogen, Prochrom and D-Dimer

The ACL measures an absorbance which represents the difference between the light absorbed (O.D.) at the beginning and after a defined time of the reaction.



Fibrinogen-C

Fibrinogen-C is measured in seconds as a change in absorbance versus a predefined threshold.

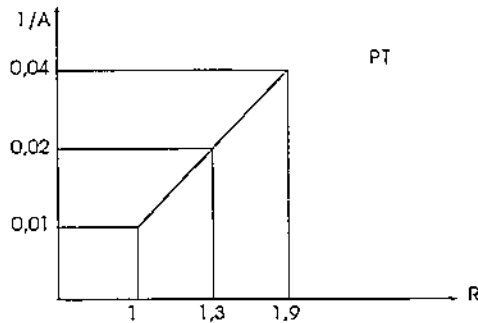
7.5 Calculated Units

- Coagulometric cycles

PT

The ACL calculates:

- The prothrombinic activity, expressed as percentage of activity (%), on the basis of the calibration curve.



* For example: Calibration Curve

$$100\% \quad 11s \quad \longrightarrow \quad \frac{11}{11} = 1 R$$

$$50\% \quad 15s \quad \longrightarrow \quad \frac{15}{11} = 1.3 R$$

$$25\% \quad 21s \quad \longrightarrow \quad \frac{21}{11} = 1.9 R$$

The Calibration Plasma (N.P.) value of each analysis run (if PT AUTO CAL ON has been selected) or the Calibration Plasma value (100%) of the calibration curve (if PT Autocal OFF has been selected) in seconds is used as denominator to calculate the Ratio/INR. The ratio between the patient values (in seconds) and the Calibration Plasma value (in seconds) of each run is also used to obtain the corresponding activity (%) on the basis of the calibration curve.

Note:

For more details see PT Calculation - Chapter 4.

- b. The ratio (R), with respect to the Calibration Plasma (N.P.) value (on each analysis run if PT Autocal ON has been selected) or the Calibration Plasma (100%) value of the first point of the calibration curve (if PT AUTO CAL OFF has been selected).

$$\text{Ratio} = \frac{\text{Sample Time expressed in seconds}}{\text{Cal. Plasma Time expressed in seconds}}$$

Note:

See Ratio Adjustment - Chapter 4.

- c. The International Normalized Ratio (INR), if the ISI value (International Sensitivity Index) has been keyed in during the calibration procedure or in the Reference Data.

$$\text{INR} = R^{\text{ISI}}$$

APTT, TT

The ACL calculates the ratio (R) with respect to the NORMAL PLASMA (on each analysis run) or versus a stored value (Prog Reference Data)

$$\text{Ratio} = \frac{\text{Sample Time expressed in seconds}}{\text{Cal. Plasma Time expressed in seconds}}$$

Note:

See Ratio Adjustment and Calculation - Chapter 4

APCR-V

The ACL calculates the ratio (R) for the samples as follow:

$$\text{Ratio} = \frac{\text{Activated Time (TA) expressed in seconds}}{\text{Basal Time (T0) expressed in seconds}}$$

TA is the activated time and T0 is the basal time.

NR (Normalized Ratio) is calculated as follow:

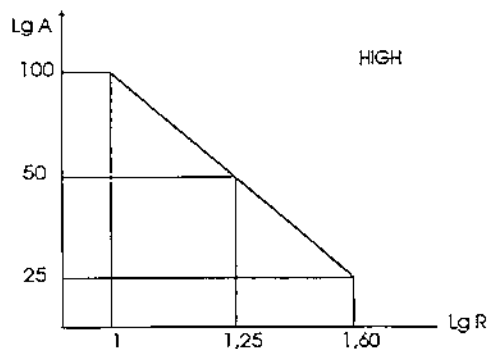
$$\text{NR} = \frac{\text{Patient Ratio}}{\text{N.P. Ratio}}$$

Note:

See Calculation - Chapter 4

FACTORS

The ACL calculates the factor activity (%), expressed as percentage of activity, on the basis of the calibration curve.



For example:

- High Curve Calibration

- 100% 40s $\rightarrow \frac{40}{40} = 1 \text{ R}$
- 50% 50s $\rightarrow \frac{50}{40} = 1.25 \text{ R}$
- 25% 60s $\rightarrow \frac{60}{40} = 1.50 \text{ R}$

The curve is expressed in ratio on the x axis (seconds) and activity on the y axis, on a log-log scale.

- Low Calibration Curve



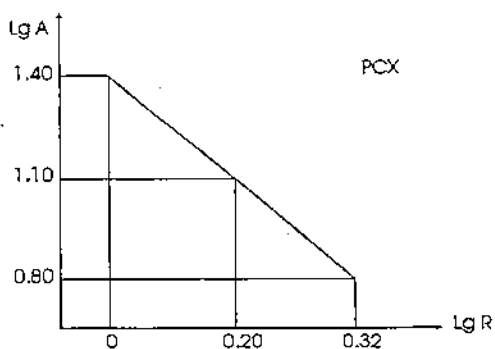
- 6.25% (log = 0.80) 70 s $\rightarrow \frac{70}{70} = 1 R$ (log = 0)
- 3.12% (log = 0.50) 80 s $\rightarrow \frac{80}{70} = 1.14 R$ (log = 0.05)
- 1.56% (log = 0.20) 90 s $\rightarrow \frac{90}{70} = 1.29 R$ (log = 0.11)

Sample activity is obtained in the following way:

- the ratio between the patient value (in seconds) and Calibration Plasma 6.25% (in seconds) is used to read the value of activity on the basis of the calibration curve.

Pro-IL-Complex

The ACL calculates the Pro-IL-Complex activity (%), expressed as percentage of activity, on the basis of the calibration curve
For example: Calibration curve



- 25% (log = 1.40) 40 s $\rightarrow \frac{40}{40} = 1 R$ (log = 0)
- 12.5% (log = 1.10) 64 s $\rightarrow \frac{64}{40} = 1.6 R$ (log = 0.20)
- 6.25% (log = 0.80) 96 s $\rightarrow \frac{84}{40} = 2.1 R$ (log = 0.32)

The curve is expressed as ratio (of seconds) on the x axis and activity on the y axis on a log-log scale. If the Calibration Plasma 100% is present on the sample tray a second curve (calculated using the same philosophy) is outlined between the 100% and the 25%.

The function used in the upper range (100%-25%), when the 100% is present, is $Y=1/A$ (activity expressed in %), $X=R$.

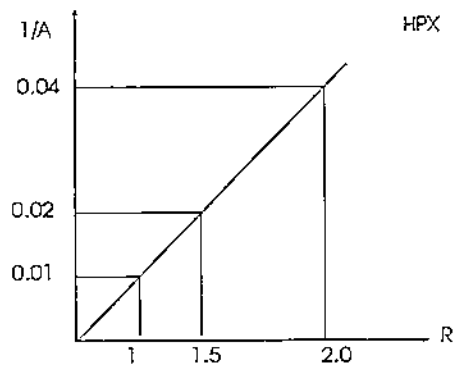
This curve provides linearity in the upper range (25% - 150%).

The sample activity is obtained in the following way: the ratio between the patient value (in seconds) and Calibration Plasma 25% value (in seconds) is used to read the value of activity on the basis of the calibration curve.

Hepatocomplex

The ACL calculates the Hepatocomplex activity (%), expressed as percentage of activity, on the basis of the calibration curve.

* For example: Calibration curve



- 100% 18 $\rightarrow \frac{18}{18} = 1 R$
- 50% 27 $\rightarrow \frac{27}{18} = 1.5 R$
- 25% 36 $\rightarrow \frac{36}{18} = 2 R$

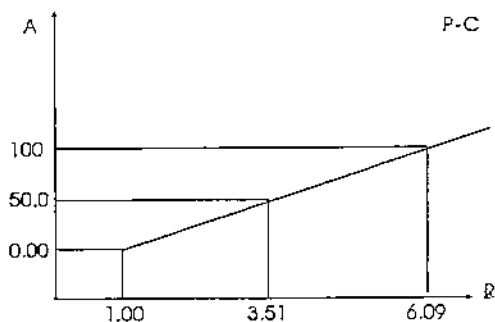
The curve is expressed in ratio (of seconds) on the x axis and the activity on the y axis on a linear scale.

The sample activity is obtained in the following way: the ratio between patient value (in seconds) and Calibration Plasma 100% value (in seconds) is used to read the value of activity on the basis of the calibration curve.

ProClot

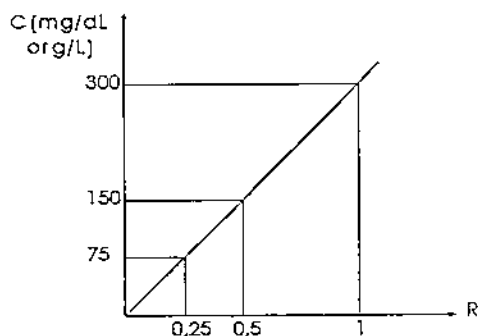
The ACL calculates the ProClot activity (%), expressed as percentage on the basis of the calibration curve.

The curve is expressed in R² (R = Ratio) on the x axis and in activity on the y axis.

**PT-Based Fibrinogen**

The ACL calculates the Fibrinogen value, expressed in mg/dl on the basis of a calibration curve which correlates in linear fashion the concentration of Fibrinogen with R of Delta (as shown below).

* For example: Calibration curve



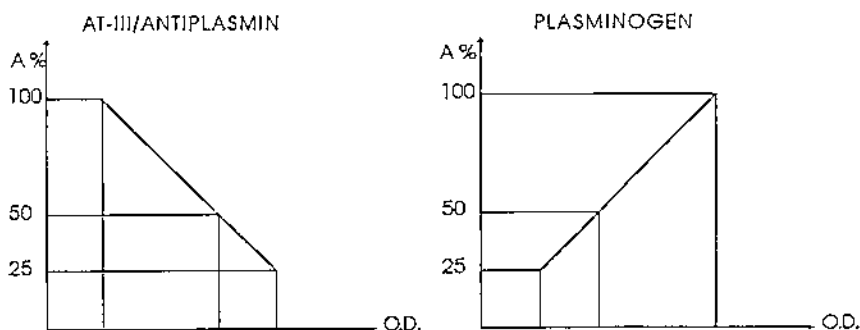
mg/dl	Delta	R
300	60	$\frac{60}{60} = 1$
150	30	$\frac{30}{60} = 0.5$
75	15	$\frac{15}{60} = 0.25$

The ratio between the patient values (in delta) for Fibrinogen and the first point of Calibration Plasma (in delta) is used to obtain the correspondent value in mg/dL on the basis of the calibration curve (for example: N.P. 55 of Delta, patient 66 of Delta; $66/55 = 1.2$; this value is used as Delta Ratio to calculate the Fibrinogen concentration in mg/dL on the calibration curve).

- **Chromogenics**

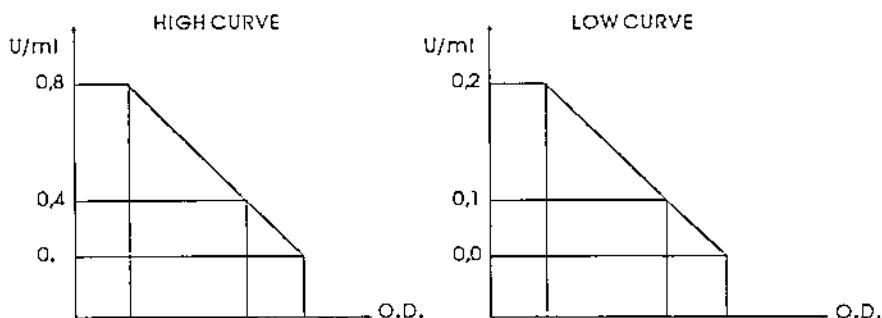
Antithrombin III, α -2-Antiplasmin, Plasminogen. ProChrom

The ACL calculates the activity of the listed parameters on the basis of the relative calibration curve (Δ of Optical Density and Activity).



Heparin

The ACL calculates the Heparin concentration on the basis of the calibration curve (Δ of Optical Density and U/mL).



The sample activity is obtained as a Δ difference between the last 10 reading points (mean) and the first 10 reading points (mean).

Note:

For AT-III and Heparin the Delta is calculated after 30 seconds; for α -2-Antiplasmin, Plasminogen and ProChrom after 60 seconds.

For the D-Dimer the ng/mL is calculated using the calibration curve done in delta absorbance.

The following table summarizes the tests described above.

Parameters	Measured Units	Calculated Units
PT	Seconds	%; R or INR
FIB	Delta Light Scattering	mg/dL or g/L
APTT	Seconds	R
TT	Seconds	R
Single Factor	Seconds	%
Antithrombin III	Delta Optical Density	%
Heparin	Delta Optical Density	U/mL
Plasminogen	Delta Optical Density	%
α -2-Antiplasmin	Delta Optical Density	%
Pro-IL-complex	Seconds	%; R or INR
Hepatocomplex	Seconds	%; R or INR
ProClot	Seconds	%; R
FIB-C	Seconds	mg/dL or g/L
PROCHROM	Delta Optical Density	%
PROTEIN S	Seconds	%
D-Dimer	Delta Optical Density	ng/mL
APCR-V	Seconds (TA and T0)	Ratio or NR

The display and printout of the calculated units depend on the instrumental and analytical conditions, summarized in the following table:

		Calibrated	Not Calibrated
PT Autocal on	with NP without NP	s % R/INR # seconds	s R/INR # seconds
PT Autocal off	with NP without NP	s % R/INR # seconds	seconds seconds
Fibrinogen	with NP without NP	mg/dL - g/L —	— —
APTT*	with NP without NP		seconds Ratio seconds
TT*	with NP without NP		seconds Ratio seconds
Antithrombin III		% ΔO.D.	ΔO.D.
Heparin Xa		U/mL	ΔO.D.
D-Dimer		ng/mL ΔO.D.	ΔO.D.
Factors High	If Calibrated	s %	—
Heparin High		U/mL ΔO.D.	—
α-2-Antiplasmin		% ΔO.D.	—
Plasminogen		% ΔO.D.	—
ProClot		s % R	—
FIB-C		s mg/dL - g/L	—
Factors High	If Not Calibrated	s	—
Heparin High		ΔO.D.	—
α-2-Antiplasmin		ΔO.D.	—
Plasminogen		ΔO.D.	—
ProClot		s	—
FIB-C		s	—
Prochrom	Calibration	% ΔO.D.	—
Heparin Low	compulsory	% ΔO.D.	—
Protein S	(Analysis cycles	s %	—
Factors Low	are rejected if the instrument is not calibrated)	s %	—
Pro-IL-complex	with N.P. without N.P.	s % INR s % R	s s
Hepatocomplex	with N.P. without N.P.	s % INR s % R	s s
APCR-V §	with NP without NP		seconds NR seconds Ratio

* APTT and TT do not require calibration.

INR ON and ISI have been keyed in during PT calibration procedure of the Reference Data Program.

§ NP is required for NR calculation

7.6 Flagging Limits

The flagging limits below represent the machine electro/mechanical capability and not necessarily the range of the assay listed. Please check the package insert for each assay to obtain the range and the limitations of the assay and procedures to follow outside linear ranges given in the insert sheets.

Note:

In the table below, the column titles "reverse" and "normal" indicate the display appearance. If the result is within the flagging range listed, then the display message is "normal" (black background/white words); however, if the result is above/below the flagging limits, then the display message is "reverse" (white background/black words).

Display	Reverse	Normal	Reverse	***
PT	< 15%	15-150%	> 150%	> 999%
Fibrinogen	< 40 mg/dL < 0.4 g/L	40-800 mg/dL 0.4-8.0 g/L	> 800 mg/dL > 8 g/L	> 999 mg/dL > 9.9 g/L
Factors High Curve	< 15%	15-150%	> 150%	> 999%
Factors Low Curve	< 1%	1-15%	> 15%	> 99.9%
Antithrombin III α -2-Antiplasmin Plasminogen Prochrom	< 15%	15-150%	> 150%	> 999%
Heparin Xa and Heparin High Curve	< 0.1 U/mL	0.1-1 U/mL	> 1 U/mL	> 9.99 U/mL
Heparin Low Curve	< 0.02 U/mL	0.02-0.3 U/mL	> 0.3 U/mL	> 9.99 U/mL
Pro-IL-complex	< 4%	4- 25% 4-150% *	> 25% > 150%	> 999%
Hepatocomplex	< 8%	8-150%	> 150%	> 999%
ProClot	< 10%	10-150%	> 150%	> 999%
Protein S	< 10%	10-150%	> 150%	> 999
FIB-C	< 60 < 0.6	60-550 mg/dL 0.6-5.5 g/L	> 550 > 5.5	>999 mg/dL > 9.9 g/L
D-Dimer	< 150 ng/mL	150-1050 ng/mL	> 1050 ng/mL	>9999 ng/mL
D-Dimer offset	-	0 - 0.85	> 0.85 indicated as >>>	
*** represents the higher operating limit of the system				
— represents the lower operating limit of the system				
* If Calibration Plasma 100% is present on the sample tray				
r ²	Reverse format < 0.980	Normal Format 0.980 - 1.000		

The ACL provides indications concerning the linearity of the calibration curves.

Best results are obtained when the r^2 is within the range 0.980 and 1.000.

When the r^2 value is lower than 0.980, it is displayed in reverse.

If r^2 appears in reverse, it is advisable to verify the appropriate graphs to determine the acceptability of the values read.

CV and r^2 in Calibration Cycles

The range of the CV values for PT and FIB calibration are:

	PT	FIB
NP (100%)	CV < 1.5%	CV < 8.0%
NP (50%)	CV < 2.0%	CV < 12.0%
NP (25%)	CV < 2.0%	CV < 12.0%

If the relative coefficient of variation (CV) of a mean is outside the range, the CV is presented in reverse.

PT and Fibrinogen calibrations may be accepted if the flagged CVs are less than or equal to 1.0% greater than the specifications as stated above and the r^2 is within the acceptable limits.

	AT III	HPX
NP (100%)	CV < 8.0%	CV < 1.5%
NP (50%)	CV < 6.0%	CV < 2.0%
NP (25%)	CV < 4.0%	CV < 6.0%

PCX	
NP (100%)	CV < 2.0%
NP (25%)	CV < 3.0%
NP (12.5%)	CV < 4.0%
NP (6.25%)	CV < 6.0%

FIB-C	
NP (150%)	CV < 1.5%
NP (100%)	CV < 2.0%
NP (50%)	CV < 2.5%

D-Dimer	
NP (1000)	CV < 4.0%
NP (500)	CV < 6.0%
NP (250)	CV < 10.0%

7.7 Output VDU and Printer

Test	Unit	Dimension
PT (single and double)	Seconds % R/INR	xxxx with floating point xxx fixed xxxx with floating point
FIB (single and double)	mg/dL g/L	xxx fixed x.xx fixed
APTT/TT (single and double)	Seconds Ratio	xxxx with floating point xxxx with floating point
Factors (Extrinsic and Intrinsic Pathways)	Seconds %	xxxx no decimal point xxx high curve (fixed) xx.x low curve (fixed)
AT III - Plasminogen α -2-Antiplasmin Prochrom	O.D. %	x.xxx fixed xxx fixed
Heparin Xa Heparin	O.D. U/mL	x.xxx fixed x.xx fixed
Pro-IL-Complex	Seconds % R/INR	xxxx with floating point xxx fixed xxxx with floating point
Hepatocomplex	Seconds % R/INR	xxxx with floating point xxx fixed xxxx with floating point
ProClot	Seconds/R %	xxxx with floating point xxxx fixed
FIB-C	Seconds mg/dL g/L	xx.x fixed xxx fixed x.xx fixed
Protein S	Seconds %	xxxx with floating point xxx fixed
D-Dimer	O.D, ng/mL offset	x.xxx fixed x.xx fixed x.xx fixed
APCR-V	Seconds Ratio	xxxx with floating point xxxx with floating point

Note:

Floating point means that the point in the decimal format can be in any of the x positions.

7.8 Particular Indications

Test	Indication	Possible Explanation
PT	<i>No Coag</i>	The sample does not coagulate within the programmed acquisition time. Read the sample in Extended time (See PROG - ACQUISITION TIME).
	<i>Coag Error</i>	- Fibrinogen < 60 mg/dL - Already coagulated sample
	<i>Normal plasma value displayed in reverse</i>	Normal Plasma out of range with respect to the reference data. (Range \pm 9% of the reference value). Results expressed in % and R/INR are not given.
FIB	<i>*** on the sample</i>	The Fib value is > 999 mg/dL. Dilute the sample 1:2 with sample DIL to enter the operating range of the instrument.
	<i>Value > 800 mg/dL on the sample, in reverse</i>	Dilute sample 1:2 to enter the operating range of the instrument.
	<i>Normal plasma value displayed in reverse</i>	Normal Plasma out of Q.C. range. (Range \pm 20 % of the reference value). The fibrinogen values of the samples are not reported.
	<i>Sample value in the range 40-800 mg/dL displayed in reverse</i>	If the PT time is prolonged, the clot may not be completely stabilized. Read the sample in the Extended time (See PROG-ACQUISITION TIME).
	<i>No Fib is given on the sample. Normal Plasma is in range.</i>	If the PT time of the sample is extremely prolonged (in seconds) the clot may not be completely stabilized.
	<i>PT of the patient are given in seconds, %, R/INR.</i>	Read the sample in Extended time. (See PROG - ACQUISITION TIME)
	<i>No Fib is given on the sample. Normal plasma is in range. PT of the patients are given in seconds, %, R/INR.</i>	Light scatter exceeds the maximum readable limit of the amplifier. a) Analysis mixture is very turbid and initially exceeds the readable limit. b) During clot formation the curve exceeds the readable limit. Dilute the sample 1:2 to enter the operating range of the instrument and multiply results by 2.

APTT	<i>No Coag</i>	The sample does not coagulate within the maximum end time. Read the sample in Extended time (See PROG-ACQUISITION TIME).
	<i>Coag Error</i>	- Fibrinogen < 60 mg/dL - Already coagulated sample
	<i>Normal plasma value displayed in reverse</i>	Normal Plasma out of range with respect to the reference data. (Range $\pm 15\%$ of the reference value). Results expressed in Ratio are not given.
TT	<i>No Coag</i>	The sample does not coagulate within the acquisition time. Read the sample in "Extended time". (See PROG-ACQUISITION TIME).
	<i>Coag Error</i>	- Fibrinogen < 60 mg/dL - Already coagulated sample
	<i>Normal Plasma value displayed in reverse</i>	Normal Plasma out of range with respect to the reference data. (Range $\pm 20\%$ of the reference value). Results expressed in Ratio are not given.
Factors	<i>0%</i>	Value $\leq 0.5\%$ (since no decimal points are displayed the number is rounded off).
	<i>-0-</i>	This message is displayed when no coagulation occurs.
	<i>Coag Error</i>	Already coagulated sample
Double Test	<i>All indications for PT-FIB, APTT and TT in single are valid.</i>	See relative explanations.
	<i>Mean in reverse</i>	- Difference of the two values with reference to the mean is higher than $\pm 5\%$. - One or two values are flagged but numerical. - For FIB only If the PT mean is printed in reverse, the FIB mean will be printed in reverse too. - If the difference of the two values with reference to the mean is higher than $\pm 10\%$, the mean will be printed in reverse.
	<i>No Mean</i>	- One or two values are: Not Coag, Coag Error, Overflow or Underflow.

PCX	0%	Value < 0.5% (since no decimal points are displayed the number is rounded off).
	-0-	This message is displayed when no coagulation occurs.
	Coag Error	Already coagulated sample
HPX	0%	Value < 0.5 (since no decimal points are displayed the number is rounded off).
	-0-	This message is displayed when no coagulation occurs.
	Coag Error	Already coagulated sample
ProClot	-0-	This message is displayed when no coagulation occurs.
	Coag Error	Already coagulated sample
	Not Coag	Sample with high activity. Perform additional dilutions.
D-Dimer	Value in ng/mL lower than 150 in reverse	The sample is below 150 ng/mL and it is below the cutoff value and in the normal range. Refer to the insert sheet of the kit for additional information.
	Value in ng/mL higher than 1050 in reverse	The sample is higher than 1050 ng/mL and needs to be diluted according to the indications reported in the insert sheet. Values need to be multiplied according to the insert sheet declaration.
	Offset reported as ">>>"	Sample may have a D-Dimer higher than 1050 ng/mL and needs to be diluted according to the indications reported in the insert sheet as for the previous case. Values need to be multiplied according to the insert sheet declaration.

Fibrinogen value

The Fibrinogen value displayed depends on the PT value in seconds. If the PT time is very long, the clot may not completely stabilized. The Fibrinogen value is displayed according to the following table.

ACQUISITION TIME: 55 SECONDS			
FIB sample value	Normal Format	Reverse Format	No value Presented
PT sample value N.P.=100% in sec	< 2.2 times N.P. value in seconds	2.2 to 2.8 times N.P. value in seconds	> 2.8 times N.P. value in seconds
For example: N.P. = 12 sec	< 26.4 sec	26.4 sec to 33.6 sec	> 33.6 sec

ACQUISITION TIME : 110 SECONDS			
FIB sample value	Normal Format	Reverse Format	No value Presented
PT sample value	< 2.8 times	2.8 to 5 times	> 5 times
N.P.=100% in sec	N.P. value in seconds	N.P. value in seconds	N.P. value in seconds
For example: N.P. = 12 sec	< 33.6 sec	33.6 sec to 60 sec	> 60 sec
ACQUISITION TIME: 165 SECONDS			
FIB sample value	Normal Format	Reverse Format	No value Presented
PT sample value	< 5 times	5 to 9 times N.P.	> 9 times
N.P.=100% in sec	N.P. value in seconds	value in seconds	N.P. value in seconds
For example: N.P. = 12 sec	< 60.0 sec	60.0 sec to 108 sec	> 108 sec

7.9 VDU Indications for not Calibrated Situations

- No liquid in POOL position
- No liquid in DIL position
- 1st standard out of range (Not Coag or Coag Error)
- Insufficient data:
 - In PT or FIB when there are less than 4 valid determinations for each dilution (Not Coag or Coag Error)
 - In Single Factors, Chromogenics and Special Tests when the second and third standards are both out of range (Not Coag or Coag Error)
- Calculation error
- Slope out of range.

7.10 Slope Curve (m) for Calibrated/Not Calibrated Situations

Test Name	Calibrated	Not Calibrated	
PT	$0 < m < 0.2$	$m \geq 0.2$	$m \leq 0$
FIB (mg/dL) (g/L)	$0 < m < 1000$ $0 < m < 10$	$m \geq 1000$ $m \geq 10$	$m \leq 0$ $m \leq 0$
Factors (Ext. and Int.) High Curve	$-20 < m < 0$	$m \leq -20$	$m \geq 0$
Factors (Ext. and Int.) Low Curve	$-30 < m < 0$	$m \leq -30$	$m \geq 0$
AT III; α -2-Antiplasmin	$-2000 < m < 0$	$m \leq -2000$	$m \geq 0$

Heparin	$-200 < m < 0$	$m \leq -200$	$m \geq 0$
Plasminogen	$0 < m < 1000$	$m \geq 1000$	$m \leq 0$
Pro-IL-Complex (Cal. Curve 25%-12.5%-6.25%)	$-12 < m < 0$	$m \leq -12$	$m \geq 0$
Pro-IL-Complex (Cal Curve 100%-25%)	$0 < m < 0.17$	$m \geq 0.17$	$m \leq 0$
Hepatocomplex	$0 < m < 0.35$	$m \geq 0.35$	$m \leq 0$
ProClot	$0 < m < 200$	$m \leq 0$	$m \geq 200$
FIB-C	$-10 < m < 0$	$m \leq -10$	$m \geq 0$
Prochrom	$0 < m < 1000$	$m \leq 0$	$m \geq 1000$
Protein S	$0 < m < 10$	$m \leq 0$	$m \geq 10$
D-Dimer	$3000 < m < 8000$	$m \leq 3000$	$m \geq 8000$

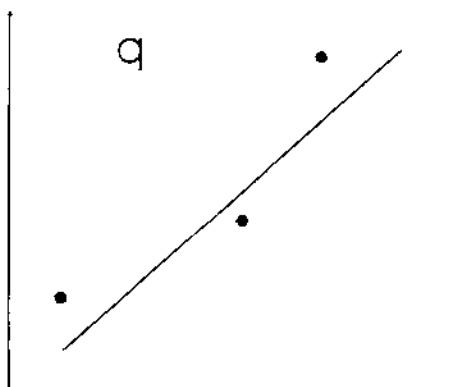
Note:

For factors and chromogenics cycles, the curve can be outlined on the basis of two points (100% and 50% or 100% and 25%); the graph will have a variable scale.

7.11 Intercept in Calibration Curves

In all tests which require a calibration curve (PT-FIB, Factors, Chromogenic Tests and Special Tests) an optimization of the curve is done so that the first point (intended as first dilution) lay on the calibration curve.

The relation between x and y can be summarised as follows:



- $Y = mX + q$
where:

- $q = Y - mX$

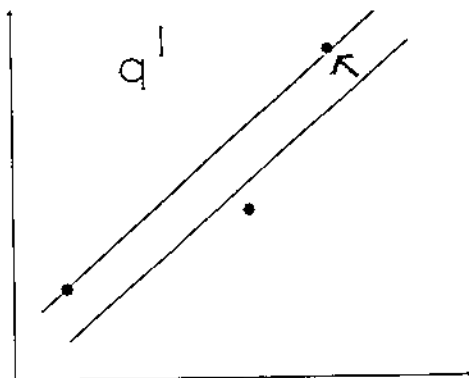
This function is used to display the graph on the video.

When the curve is translated on the first point a new q is calculated as follows:

- $q' = Y' - mX'$

In cases of cycles that require calibration all sample results are calculated on the new calibration curve.

This means that the curve passing through the first calibration point has the same slope (m) but a different intercept from the original calibration curve.



7.12 Ranges for Calibration Plasma Value Insertion

Cycle	Default	Range
Factors High Curve	100%	70%-130%
Factors Low Curve	6.25%	4.3%-8.2%
Heparin High Curve	0.8 U/mL	0.64-0.96 U/mL
Heparin Low Curve	0.2 U/mL	0.16-0.24 U/mL
Antithrombin III	100%	70%-130%
alpha-2-Antiplasmin	100%	70%-130%
Plasminogen	100%	70%-130%
Prochrom	100%	70%-130%
Pro-IL-Complex	100%	70%-130%
Hepatocomplex	100%	70%-130%
Proclot	100%	70%-130%
Protein-S	100%	70%-130%
Fib PT-based	0 0	200-450 mg/dL 2.0-4.5 g/L
Fibrinogen-C	0 0	200-350 mg/dL 2.0-3.5 g/L
D-Dimer	1000	950-1050 ng/mL

7.13 Measuring Ranges of all the Coagulometric and Chromogenic Parameters

Measuring Ranges of all the Coagulometric Parameters

Coagulometric Tests	Acquisition time for each data point (mseconds)	Maximum end time with 18 samples (seconds)	Total cycle time (seconds)
PT/FIB Cal	100	62	332
PT/FIB Analysis	100	62	332
APTT	100	70	424
TT	100	60	300
PT-FIB/APTT	100	62	502
TT/APTT	100	60	440
Single Factors Extrinsic Pathway Cal + Analysis	150	169	500
Single Factors Intrinsic Pathway Cal + Analysis	150	169	563
Factors Extrinsic Pathway High Analysis	150	169	510
Factors Extrinsic Pathway Low Cal + Analysis	150	169	510
Factors Intrinsic Pathway High Analysis	150	169	690
Factors Intrinsic Pathway Low Cal + Analysis	150	169	690

Coagulometric Tests	Acquisition time for each data point (mseconds)	Maximum end time with 18 samples (seconds)	Total cycle time (seconds)
Extended			
PT/FIB	150	169	440
APTT	100	119	524
TT	150	167	407

Notes:

- *Maximum end time = blank time + reading time.*
- *The extended time is available for PT-FIB, APTT and TT in single and in double.*
- *It is not available for combined tests (PT-FIB/APTT and TT/APTT).*

During the installation of the ACL, it is possible to select the long APTT acquisition time if required.

The measuring ranges are:

Coagulimetric Tests	Acquisition time for each data point (mseconds)	Maximum end time with 18 samples (seconds)	Total cycle time (seconds)
APTT Long Standard	100	119	568
APTT Long Extended	250	249	698
PT-FIB / APTT	150	169	609
TT / APTT	150	169	547

Measuring Ranges of all Absorbance Parameters

Absorbance Tests	Acquisition time for each data point (mseconds)	Maximum end time with 18 samples (seconds)	Total cycle time (seconds)
Antithrombin III *	100	30	360
Heparin Xa	100	30	360
Heparin	100	High 30 Low 30	360
Plasminogen	100	60	390
α -2-Antiplasmin	100	60	390
Pro-Chrom	100	90	420
Fibrinogen-C	100	90	330
D-Dimer	250	300	520

* Calibration and analysis

Note:

Total time does not include printing time.

Measuring Range of all Special Tests

Special Tests	Acquisition time for each data point (mseconds)	Maximum end time with 18 samples (seconds)	Total cycle time (seconds)
Pro-IL-Complex *	250	299	660
Hepatocomplex *	200	224	580
Proclot	250	244	468
Protein-S	200	220	550
APCR-V	200	220	750

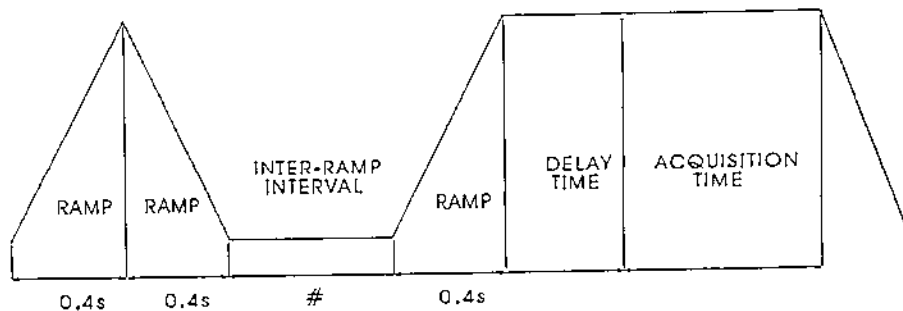
* Calibration and analysis

Note:

Total time does not include printing time.

7.14 Maximum End Time for Coagulometric and Chromogenic Tests

The coagulometric reading is represented in the following diagram:



Delay time is 1 second for TT, 3 seconds for all others coagulometric cycles

The ramps and the interval between ramps are present in all coagulometric cycles.

The delay time before the acquisition is present only in some cycles.

See the following table.

Tests	Blank Time (seconds)	Ramps + Delay Interval Time	Acquisition Time (seconds)	Maximum End Time (seconds)
PT (single and double)	4 - 4 -	- -	58 standard 165 extended	62 169
APTT - Short (single and double)	4 - 4 -	- -	66 standard 110 extended	70 114
TT (single and double)	2 - 2 -	- -	58 standard 165 extended	60 167
PT-FIB/APTT (single and double)	4	-	165	169
TT/APTT	2	-	165	167
Single Factors Extr./Intr.Pathways (High and Low curve)	4	-	165	169
Pro-IL-Complex *	4	20	275	299
Hepatocomplex *	4	-	220	224
ProClot	4	20	275	299
Protein-S	4	-	220	224
APCR-V	4	-	220	224

* Calibration and analysis

Note:

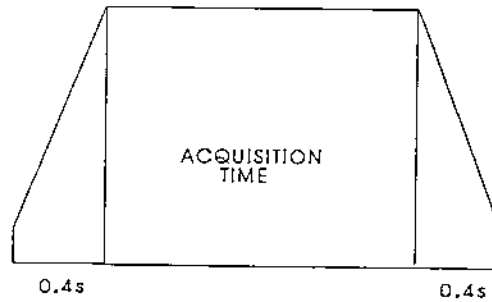
The numbers in the blank time and maximum end time columns are rounded-off to the nearest whole numbers.

Tests	Blank Time (seconds) Ramps + Delay Interval Time	Acquisition Time (seconds)	Maximum End Time (seconds)
APTT - Long (single and double)	4 - 4 -	115 standard 245 extended	119 249

Note:

The APTT ACQUISITION TIME (short or long) can be selected from Service Menu during the installation.

The absorbance reading is represented in the following diagram:



Acquisition time is 30 seconds for Antithrombin-III and Heparin, 60 seconds for alpha-2-Antiplasmin and Plasminogen, 90 seconds for ProChrom and 90 seconds for Fibrinogen-C.

7.15 Parameter Correlation

	Correlation	Y	X
PT	Linear	1/Activity	Ratio (cal. sec.)
Fibrinogen	Linear	C (mg/dL or g/L)	Ratio (Δ L.S.)
Factors	Log	Activity	Ratio (cal. sec.)
AT-III Plasminogen ProChrom α -2-Antiplasmin	Linear	Activity	Δ O.D.
Heparin	Linear	C (U/mL)	Δ O.D.
Pro-IL-Complex 25%-12.5%-6.25%	Log/Log	Activity	R
Pro-IL-Complex 100%-25%	Linear	1/Activity	R
Hepatocomplex	Linear	1/Activity	R
Proclot	Quadratic	Activity	R ²
Fibrinogen-C	Log-Log/Log	C (mg/dL or g/L)	seconds
Protein-S	Linear	Activity	seconds
D-Dimer	Linear	1/C (ng/mL)	Δ O.D.

7.16 Analytical Characteristics

Imprecision in Calibration Cycles

Within rotor

- CV (PT) = 100% \leq 1.5%
50% \leq 2%
25% \leq 2%
- CV (Fib) = 300 mg/dL \leq 8%
150 mg/dL \leq 12%
75 mg/dL \leq 12%

Imprecision in analysis using a pool of fresh plasma

- CV (PT) \leq 1% (within rotor) \leq 1.5% (between rotors)
- CV (FIB) \leq 6% (within rotor) \leq 8% (between rotors)
- CV (APTT) \leq 2% (within rotor) \leq 2% (between rotors)
- CV (TT) \leq 2% (within rotor)

7.17 Limitations

7.17.1 Carry-over

Sample carryover on the ACL Family has been determined to be less than 0.5 % by volume.

In most situations the inaccuracy attributed to this carryover is well within the normal imprecision of the method and therefore not statistically or clinically significant.

The following exceptions have been found to be statistically but not clinically significant:

When testing a plasma sample (PT or APTT) from a patient with a severe factor deficiency (< 10 %) immediately after a normal sample, statistically significant contamination can be observed.

Normal samples assayed immediately following unusually high heparinized samples (> 10 U/mL) or samples from patients undergoing aggressive factor replacement therapy may exhibit statistically significant contamination.

Note:

The amount of contamination will not shift an abnormal sample result into the normal range (i.e. not clinically significant).

7.17.2 Contaminating sample (Factors or Heparin)

For a sample suspected of containing high levels of Factors or Heparin, the following method is recommended:

In the duplicate mode for APTT or PT/FIB place the suspected deficient or heparin sample in cup # 1.

Place reference emulsion or factor diluent in the pool position.

Place HCl (Hydrochloric Acid) in positions 2 and 4.

Place deionized water in positions 3 and 5.

The remaining sample workload can be placed in the remaining cup positions (6 - 9).

WARNING No calculated results (i.e. ratio, INR, % activity and fibrinogen) will be reported.

7.17.3 Contaminated sample (Factors or Heparin)

For samples suspected of having been contaminated in a previous run by the sample preceding them in the run (because the contaminating sample had high levels of Heparin or Factors), the following method is recommended for rerunning the sample remaining in the cup.

Note:

Carry-over contamination would only occur in the aspirated sample. Contamination in the sample cup should be minimal.

In the duplicate mode for APTT or PT/FIB, place the non-deficient or non-heparinized recipient sample suspected of contamination in cup # 1. The remaining sample workload can be placed in the remaining cup positions (2 - 9).

7.17.4 Cephalin needles conditioning

When a test with cephalin (in any combination) is preceded by a cycle with thromboplastin (PT, Extrinsic Pathway, Single Factor of the Extrinsic Pathway, Pro-IL-Complex, Hepatocomplex or Protein-S), the internal needle aspirates 30 μ L of cephalin from reagent reservoir 2, followed by 80 μ L of an air bubble.

The aspirated reagent is immediately discarded into the waste reservoir. This step is repeated three times to prepare the needle ("needle conditioning") for the cephalin.

7.18 Lipemic Samples

Lipemic specimens may be cleared and retested on the ACL system. If a lipemic sample is tested on the ACL analyzer, the turbidity can mask the actual quantity of fibrinogen present by interfering with detected light scatter. However, a linear relationship between turbidity and expected fibrinogen values has been found and a correction has been introduced on the basis of the initial offset calculation of the sample.

7.19 Primary Tube Characteristics

The ACL can accept two kinds of primary tubes:

Glass	Anticoagulant Volume	Drawn Blood Volume	Total Volume
a) 13 x 75	0.5 mL	4.5 mL	5 mL
b) 13 x 75	0.35 mL	3.15 mL	3.5 mL

Tests performed on the above mentioned tubes have demonstrated the following:

Primary Tubes Type a

Considering a drawn blood volume of 4.5 mL (nominal value), the ACL can aspirate plasma within a tolerance of + 10 - 20 %.

In the case of maximum sample collection (4.5 mL + 10 %), plasma can be correctly aspirated if the hematocrit is \leq 70 %.

Primary Tubes Type b

Considering a drawn blood volume of 3.15 mL (nominal value), the ACL can aspirate plasma within a tolerance of + 10 - 20 %.

In the case of maximum sample collection (3.15 mL + 10 %), plasma can be correctly aspirated if the hematocrit is ≤ 70 %.

Values indicated in the above specifications may be slightly influenced by the following variables:

- internal diameter of primary tubes (this can vary from producer to producer and from lot to lot)
- production date of primary tubes (the level of vacuum decreases close to the expiration date).

7.20 Instrument Characteristics

- Cooling temperature of reagent reservoirs: $13.5 \pm 1.5^\circ\text{C}$
- Measuring chamber temperature : $37 \pm 1^\circ\text{C}$ at ambient temp
from 15 to 32°C
- Stirrer magnet for reservoirs 1 and 2 : (10x5 mm dia)
magnet 250 rpm
- Number of rotors in rotor compartment : maximum 10
- 21 column thermal printer
- Fuses (2) : 2.5A (for 220-240 Vac nom.)
5 A (for 100-125 Vac nom.)
- Impermeable keyboard
- Coagulometric channel light source : Light emitting diode = λ 660 nm
- Chromogenic channel light source : Halogen Lamp
(with filter = 405 nm) *
- Data transmission: the ACL is provided with an output for interface with two RS 232C: one for the HOST and one for the RESEARCH PROGRAM.
- One output is available for the hand-held Bar Code Scanner.
- One output is available for the external printer.
- Structure of expanded polyurethane, structural forming type for direct mounting of all internal elements.
- Dispensing with pistons (of stainless steel, contained in an acrylic structure).
- Diameter of waste tube on left side of the instrument: 12 mm.

- Two different sample trays:
 - sample tray for cups and primary tubes (13 mm x 75 mm) with a total filling volume of 5 mL
 - sample tray for cups and primary tubes (13 mm x 75 mm) with a total filling volume of 3.5 mL
- Reagent reservoir: 3 Macro with covers and 3 Micro.
- Two five blade cooling fans with dust filter.
- 9" video with white phosphors.

Note:

* Optic path for chromogenic channel is 0.5 cm.

7.21 Ambient Conditions

The instrument has been built for inside use.

Category

- Category II

Pollution degree

- Pollution degree 2

Ambient Conditions for transport and storage

- T °C = + 4 to + 45 °C
- RH = up to 95% (non-condensing)
- BP = 500 to 1060 mbar.
- Altitude = up to 3300 meters.

Functional ambient conditions

- T °C = + 15 to + 32 °C
- RH = up to 85% (non-condensing)
- BP = 500 - 1060 mbar.
- Altitude = up to 3000 meters.

Safety limit ambient conditions

- T °C = + 5 °C to + 40 °C
- RH = up to 95% (non-condensing)
- BP = 500 - 1060 mbar.
- Altitude = up to 3000 meters.

7.22 Electrical Characteristics

Frequency (Nominal)	Voltages (Nominal)
50, 60 Hz.	100V, 110-125V, 220-240V

- Voltage Tolerance : ± 10%
- Frequency Range : 50 - 60
- Power Consumption : 300 Watt

7.23 Dimensions

Maximum dimensions

The ACL can be installed with ease in any standard laboratory. The dimensions are as follows:

- Total height : 45 cm
- Height of analysis surface : 21 cm
- Width : 75 cm
- Depth : 69 cm
- Weight : 52 Kg

7.24 Performance Characteristics

With-in run precision

A precision run was performed on an ACL 6000 and ACL 7000 using 3 control levels (4 for the PTs):

IL Test PT-Fibrinogen, IL Test PT-Fibrinogen HS, IL Test PT-Fibrinogen HS PLUS, IL Test APTT-C, IL Test Pro-Chrom and IL Test Protein S. Three levels of controls were analyzed (four levels in the case of the PTs). The data were collected during in-house studies.

Reagent	level	n	mean	SD	%CV
PT (seconds)	Normal	18	12.0	0.11	0.88
	Abn I	18	16.9	0.12	0.71
	Abn II	18	28.1	0.28	1.00
	Low Fib	18	14.4	0.15	1.05
PT HS (seconds)	Normal	18	12.5	0.08	0.67
	Abn I	18	20.7	0.20	0.95
	Abn II	18	41.0	0.98	2.39
	Low Fib	18	15.8	0.12	0.77
PT HS+ (seconds)	Normal	18	13.7	0.13	0.92
	Abn I	18	27.3	0.40	1.45
	Abn II	18	54.2	1.22	2.25
	Low Fib	18	17.1	0.27	1.59
PT-Fib (mg/dL)	Normal	18	275	8.9	3.26
	Abn I	18	287	14.6	5.09
	Abn II	18	270	12.7	4.71
	Low Fib	18	108	8.0	7.40
PT-Fib HS (mg/dL)	Normal	18	265	7.8	2.95
	Abn I	18	298	11.1	3.72
	Abn II	18	281	14.1	5.00
	Low Fib	18	94	9.7	10.4
PT-Fib HS+ (mg/dL)	Normal	18	269	19.3	7.16
	Abn I	18	307	19.7	6.43
	Abn II	18	277	14.8	5.33
	Low Fib	18	103	7.4	7.19
APTT-C (seconds)	Normal	18	24.6	0.16	0.64
	Abn I	18	44.2	0.41	0.93
	Abn II	18	58.4	0.69	1.18
Pro-Chrom (%)	Normal	15	78	1.41	1.81
	Abn I	15	53	0.99	1.87
	Abn II	15	22	0.74	3.29
Protein S (%)	Normal	16	107	2.41	2.25
	Abn I	16	56	1.41	2.50
	Abn II	16	26	0.77	2.96

Precision % Activity

IL Test ATIII

Three levels of controls were tested in triplicate twice a day for 5 days (10 runs; n=30) on an ACL 6000 System.

ACL 6000									
Sample	Overall Mean	Within Run		Run to Run		Day to Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
NCP	81.6	1.69	2.07	2.52	3.09	1.88	2.3	3.42	4.19
ABN I	50.9	2.61	5.14	1.53	3.02	1.67	3.28	3.37	6.61
ABN II	24.6	2.71	11.01	3.91	15.88	0	0	4.1	16.66

IL Test ProClot

Three levels of controls were tested in triplicate twice a day for 5 days (10 runs; n=30) on an ACL 6000 System.

ACL 6000									
Sample	Overall Mean	Within Run		Run to Run		Day to Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
NCP	88.6	2.84	3.21	4.66	5.25	0	0	4.83	5.46
ABN I	57.05	2.83	4.95	0	0	1.72	3.02	3.21	5.63
ABN II	18.825	1.15	6.11	1.24	6.61	0.51	2.71	1.72	9.15

Factors

Fifteen replicates of normal control plasma were used for one run on the ACL 6000.

Extrinsic Pathway - high curve, PT-Fib reagent					
Deficient Plasma	Instrument	Mean	SD	%CV	Ref. range (%)
Factor II	ACL 6000	105	4.22	4.04	78-118
Factor V	ACL 6000	99	1.95	1.98	82-122
Factor VII	ACL 6000	90	2.99	3.31	75-115
Factor X	ACL 6000	103	1.55	1.50	84-124

Intrinsic Pathway - high curve, APTT-C reagent*					
Deficient Plasma	Instrument	Mean	SD	%CV	Ref. range (%)
Factor VIII	ACL 6000	101	2.37	2.35	91-131
Factor IX	ACL 6000	96	2.54	2.77	79-119
Factor XI	ACL 6000	81	2.47	3.04	68-108
Factor XII	ACL 6000	77	1.91	2.47	62-102

NOTE:

APTT-C is only distributed in U.S. and Canada.

Stored Calibration Stability

The ACL 6000 and ACL 7000 stored calibration cycle was tested for the Factor Deficient Plasma, IL Test Fibrinogen-C, IL Test AT III, IL Test Heparin (Xa), IL Test Plasminogen, and IL Test α -2-Antiplasmin. The stability results of the testing are shown in the table below.

Description	Stability
Factor II Deficient Plasma	5 days
Factor V Deficient Plasma	5 days
Factor VII Deficient Plasma	5 days
Factor VIII Deficient Plasma	5 days
Factor IX Deficient Plasma	5 days
Factor X Deficient Plasma	5 days
Factor XI Deficient Plasma	5 days
Factor XII Deficient Plasma	5 days
IL Test Fibrinogen-C	1 day
IL Test AT-III	5 days
IL Test Heparin (Xa)	1 day
IL Test Plasminogen	30 days
IL Test α -2-Antiplasmin	7 days

7.25 Hazards

7.25.1 Warning

Do not connect the analyzer to power before verifying correct voltage setting. The analyzer can be used with a power (mains) voltage of 90-137 VAC or 198-264 VAC (50/60Hz). Verify the voltage of the local power (mains) to be used. Check the voltage select label, located on the backplate on the analyzer. Listed are the nominal ranges of 100-125 (for 90-137 VAC input) and 220-240 (for 198-264 VAC input). Be sure the analyzer is correctly set for the power (mains) being applied. Always plug the analyzer into a grounded outlet.

Allow at least 6" (15.24 cm) of clearance on the sides, back, and top of the analyzer to ensure proper cooling.

This equipment has been tested and found to comply with national and international EMC and RFI requirements. These requirements are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at his own expense.

7.25.2 Personnel Shock Hazard

Operating technicians and maintenance personnel are urged to follow sound electrical safety practices at all times. Although all exposed metal parts of the analyzer are at ground potential (zero volts), never touch them with one hand while also touching a plumbing fixture, radiator, AC-operated device or other grounded object with the other hand.

7.25.3 Danger

Before opening the analyzer, remove the power cable from the power outlet. Do not replace components or attempt any repair with the analyzer switched "on". Do not operate the analyzer in an atmosphere containing explosive gases; components of the analyzer could possibly generate sparks.

7.25.4 Cautions to protect workers from biohazard

When working with human serum, all accessible parts of the analyzer must be considered biohazardous.

Gloves and protective body clothing should be worn during operations.

The surface of the analyzer should be examined frequently for visible contamination and decontaminated if necessary according to the procedure described in chapter 10 (Decontamination Procedure).

Sample tray which contains sample cups or tubes should be handled with caution to prevent spillage of specimens.

Avoid spilling fluid on or into the analyzer at any time.

Spills should be wiped up promptly.

The pipette tip trays, sample tray and the waste drawer should be routinely disinfected (Refer to Chapter 5 Maintenance and Chapter 10 Decontamination Procedure).

See also NCCLS I17-P vol. 11 No. 15: Protection of Laboratory Workers from Instruments Biohazard, 1991.

8 Sample Collection and Storage

8.0 Introduction

A detailed procedure for collection, transport and preparation of plasma for coagulation tests is necessary because important diagnostic and therapeutic decisions are based on the results of these tests. Many variables, e.g. the type of anticoagulant, the storage of the sample and the type of container for the blood, are all important because they affect the analytical results. The following procedure is a standard for any coagulation test.

This description gives general procedures for the collection of blood samples from the patient, for their transport from the collection site to the laboratory, for their handling and their storage in the laboratory.

8.1 Plasma Collection

Venous blood must be withdrawn with minimum stasis using a plastic syringe or in a test tube as recommended by NCCLS Document H21-A3.

For all tests concerning control of haemostasis with the exception of the platelet count, the preferred anticoagulant is trisodium citrate at the concentration recommended in the NCCLS Document H21-A3 in proportion of 1 volume of citrate to 9 volumes of blood.

The correct concentration of the anticoagulant is fundamentally important to the precision of the results. References to the NCCLS Document H21-A3 may be followed when adjustments to the Citrate concentration are required.

8.2.1 Plasma Separation

During collection and centrifugation of the sample, hemolysis must be avoided. The passage of red cells, whose phospholipid surfaces have thromboplastin activity, causes a change in coagulation times. For these reasons the samples should be centrifuged as soon as possible as recommended by NCCLS Document H21-A3.

For plasma storage please refer to the NCCLS document indicated in the Reference at the end of this chapter.

8.3 Calibration Plasma

ACL operative conditions require the utilization of a pool of normal plasma (calibration plasma), the main purpose of which is to check the whole system (instrument + reagents).

IL Test Calibration plasma consists of a lyophilized pool of normal human plasma, the characteristics of which are exactly the same of those of a pool of fresh normal human plasma.

A lyophilized product is more stable and can be more easily used and stored.

The Calibration plasma is used on the ACL in the following way:

- 1) To construct a calibration curve where needed.
- 2) To check and monitor assay conditions within the entire system during analysis.

For PT, PT-based Fibrinogen, APTT and TT, the Calibration plasma value should be within the reference range stored in the ACL memory. If it is out of range or missing, message flags will be given to the operator.

Preparation

Please refer to the package insert sheet.

Assignment

The Calibration plasma differs from a normal control plasma because it is used to construct the calibration curve and to monitor precision and accuracy of the system (instrument + reagents).

That means that the Calibration plasma has a target value which is the reference value of all tests.

The Normal control plasma will have an acceptability range centered on the mean value, not a target value, for all tests.

Calibration plasma should have an activity close to 100%, while the Normal control plasma should only be within the assigned reference range.

The Normal and Abnormal control plasmas can be used randomly as part of an internal quality control program to verify the analytical performance of the system (instrument + reagents).

The target value of the Calibration plasma, indicated on the insert sheet, is determined using a number of analyses, carried out on different instruments.

In order to counterbalance any possible laboratory-to-laboratory variation, it is advisable to calculate PT, APTT and TT times (seconds) for each lot of Calibration plasma, and use them as reference values under your own conditions.

We suggest the following procedure:

- Carry out, a minimum of 5 to a maximum of 10 APTT and TT determinations.
Calculate the mean value and key it in the Reference Data frame.
- For PT, the titre will correspond to the value, in seconds, of 100%.
Once the calibration has been accepted, it is automatically memorized in the "Reference Data" frame.

Fibrinogen: Key in the value reported on the insert sheet of the Calibration plasma. This value, once the calibration has been accepted, is automatically stored in the "Reference Data" frame.

Important: The above procedure must be carried out whenever the lot of the Calibration plasma or other variables (reagents lot, rotors lot letter, etc.) which require a new calibration of the instrument change.

References

NCCLS document H21-A3
Collection, Transport and Processing of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays - Second Edition - Vol.18 No. 20 - December 1998

ECCLS Vol. No. 1
Standard for Specimen Collection

NCCLS document H3-A3
Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture - Third Edition - Vol. 11 No. 10 - July 1991

9 P&E

9.0 Expendable Material

The ACL coagulometer is shipped with some expendable items.

9.1 Reagent Reservoirs

There are different types of reagent reservoirs:

Macro	: usable volume 8 mL, total volume 10 mL
--------------	--

Micro 1 (TT)	: usable volume 2 mL, total volume 2.5 mL
---------------------	---

Micro 2-3 (E, S)	: usable volume 1.5 mL, total volume 2 mL
-------------------------	---

Each reservoir has an indication describing the test for which it should be used.

		Position on ACL
Macro	PT-FIB, HPX, PCX with cover	1
Macro	APTT with cover	2
Macro	CaCl ₂ with cover	3
Micro	TT	1
Micro	E	2
Micro	S	3
Macro	TT and CLEAN with cover	3

For the micro types E and S there are five alternative uses:

AT III, Heparin, Plasminogen, alpha-2-Antiplasmin and Pro-Chrom

Packs for sales:

1. MACRO PT	2 pcs
2. MACRO APTT/CaCl ₂	1+1 pcs
3. MICRO TT	2 pcs
4. MICRO E + S	1+1 pcs
5. MACRO PCX/HPX	2 pcs
6. MICRO CLEAN + FIB-C	1+1 pcs
7. MACRO TT + CLEAN	2 pcs
8. MICRO PT	2 pcs
9. MICRO APTT/CaCl ₂	1+1 pcs

9.2 Block Probes Assy

The block probes assembly contains the sample and reagent needles and the associated liquid sensors.

9.3 Sample and Reagent Cups

0.5 mL and 2 mL cups are available in packages of 1000.

4 mL cups are available in packages of 100.

9.4 Sample Tray

Two types of sample tray are available:

- | | |
|----|--|
| 1. | Primary tube 5 mL total volume (13 x 75 mm) |
| 2. | Primary tube 3.5 mL total volume (13 x 75 mm). |

9.5 Rotors

Available in package of 100.

9.6 Magnetic Stirrer

Available in package of 6.

9.7 Waste Tube (1 meter)

9.8 Printer Paper

Available in package of 4 rolls.

9.9 Sample and Reagent Tubing (1 meter)

9.10 Waste Bottle

5 liter plastic bottle is available.

9.11 Startup - kit

	P/N	Description	Q.ty
1)	80075-04	Thermal printer paper (4 pcs.)	1
2a) *	68920-00	Fuse 2.2 AT (2 pcs.)	1
2b) *	68914-00	Fuse 4.5 AT (2 pcs.)	1
3)	181022-86	Air Filter	1
4)	181038-22	Needle Block	1
5)	181039-41	Needles Alignment Tool	1
6)	73289-01	Sample /Reagent Tubing	1.5 m
7)	99095-03	Waste Drain Tube	1.5 m
8)	65930-10	Sample Cups 0.5 mL (1000 pcs.)	1
9)	55751-00	Sample Cups 2.0 mL (1000 pcs.)	1
10)	181021-69	Anti-evaporation Cover "A"	1
11)	181038-90	Anti-evaporation Cover "B"	1
12)	181038-96	Sample Tray 3.5 mL (A)	2
12)	181038-97	Sample Tray 5.0 mL (B)	2
13)	97466-06	Magnetic Stirrer (6 pcs.)	1
14)	181024-91	Reagent Reservoir PT-FIB	1
15)	181024-92	Reagent Reservoir APTT + CaCl ₂	1
16)	181024-93	Reagent Reservoir TT	1
17)	181024-95	Reagent Reservoir Chromogenics	1
18)	181024-94	Reagent Reservoir PCX/HPX	1
19)	181038-06	Rinse/Waste Reservoir	1
20)	181057-69	Liquid Waste Container	1
20)	80960-61	Operator's Manual	1
21)	80960-7X	Application Manual	1

* = 2a is shipped when the ACL requires 220-240 V.

* = 2b is shipped when the ACL requires 115-125 and 100 V.

= either 12 (A) or 12 (B) are supplied according to the instrument Part No.

D = not currently available in the U.S.

X = according to the required software language: 1 = English
 2 = Italian
 3 = French
 4 = German
 5 = Spanish

10 Decontamination Procedure

10.0 Introduction

This section covers normal cleaning procedures, cleaning procedures following sample spillage, and a disinfection procedure to be adopted following analysis of samples contaminated with highly infectious pathogens (e.g. plasma from known or suspected Australia Antigen positive and AIDS patients).

10.1 Decontamination Procedure Following the Analysis of Highly Infectious Samples

Following the analysis of known or suspected highly infectious plasma, careful disinfection of the instrument surfaces and the parts (including the rotor holder) which came into contact with the affected sample must be undertaken by washing with Sodium Hypochlorite with a concentration of available chlorine less than 0.625 % [IL Cleaning Agent P/N 98327-00 diluted 1:8 (1+7) with distilled water].

Warning No other solution must be used instead of IL Cleaning Agent (P/N 98327-00) diluted 1:8 (1+7) with distilled water.

Caution The use of undiluted IL Cleaning Agent (P/N 98327-00) may potentially cause metal corrosion.

After the analysis of an affected sample use, the following procedure:

1. Materials required

- 3 x 0.5 mL ACL Sample Cups
- Reagent Reservoir 1 (PT-Fib), 2 (APTT) and 3 (Calcium Chloride)
- 10 mL (approximately) of IL Cleaning Agent diluted 1:8 (1+7)
- 20 mL (approximately) of Factor Diluent

2. Preparation

Load sample tray as follows:

- Position POOL - IL Cleaning Agent diluted 1:8 (0.5 mL)
- Position 1 - Factor Diluent (0.5 mL)
- Position 2 - IL Cleaning Agent diluted 1:8 (0.5 mL)
- Position 3 - Factor Diluent (0.5 mL)

Load reagent reservoirs as follows:

- Reservoir 1 - Factor Diluent (9 mL)
- Reservoir 2 - IL Cleaning Agent diluted 1:8 (9 mL)
- Reservoir 3 - Factor Diluent (9 mL)

Place a clean rotor on the rotor holder.

3. Cleaning Cycle

- Select Double Tests mode
- Select PT-FIB/APTT cycle
- Press \downarrow to start analysis

At the end of the loading phase (including Calcium Chloride), press STOP and ENTER.

4. Remove the used rotor from the rotor holder and discard it.

Remove the sample tray and the reagent reservoirs.

5. Execute a Priming cycle.

6. Replace the external waste tube and the waste container.

Notes:

- *These items must be placed in the appropriate container for material to be incinerated (using proper local regulations).*
- *In the case of suspected severe contamination, replace the tubings and discard the old ones in the appropriate container for material to be incinerated (using proper local regulations).*

WASTE LINE CLEANING PROCEDURE

Before the customer performs this procedure make sure they are performing the daily/weekly maintenance. If the customer is not routinely performing the daily/weekly maintenance direct the customer to the Operator's Manual and go over the maintenance with them.

This is not a "Routine" maintenance procedure and should be documented in the customers history when performed. Review the customers history and if there is a high frequency of bleaching the waste line troubleshoot why this occurring (water quality, lack of maintenance, tubing needing to be changed etc.).

Materials needed:

- .1N HCL
- 20cc syringe with tubing attached
- Tubing
- 20mL of .625% Bleach solution (1L Cleaning Agent PN 9832700 diluted 1:8)
- Approx. 2 liters of deionized water
- Clamp

1. Press PROG Key to display the specialty program screen.
2. Enter CHECKLIST.
3. Enter NEEDLES POSITION to move the sample arm out of the way.
4. Remove the Rinse/Waste Reservoir.
5. Clean the Reservoir with .1N HCL solution then rinse with deionized water.
6. Empty Reagent Reservoirs and clean with deionized water.
7. Place all reservoirs aside until cleaning is complete.
8. Clamp off the External Waste Tubing from the side of the ACL.
9. Fill the 20cc syringe with a fresh .625% Bleach solution (1L Cleaning Agent PN 98732700 diluted 1:8).
10. With the Waste/Rinse reservoir still out of the instrument, insert the syringe into the hole at the bottom of the reservoir and slowly push the .625% bleach solution through the waste line being careful that the bleach solution does not overflow into the well.
11. Let bleach solution sit in waste line for 15 minutes.
12. Unclasp the waste line.
13. Flush with approx. 1 liter of deionized water.
14. Perform the Needle cleaning procedure in the maintenance section of the Operator's Manual.
15. Place fresh reagents on the instrument and process controls.

If the customer actually sees green growth in the line make the Primary CSS aware so he/she can schedule a date and time for replacement of the waste line. If massive bacterial growth is present the customers should replace the reagent reservoirs.

Problems that may be resolved by bleaching waste line:

1. Waste not flowing properly due to clot stuck in line that will not dislodge by flushing with deionized water.
2. High or low control recovery. There may be a blockage in the waste line therefore causing the insufficient cleaning of needles due to a backup in the rinse/waste reservoir.

11 Warranty

11.0 General Warranty Conditions

IL declares to the original Purchaser that each instrument manufactured and/or sold by IL shall be free from defects in material workmanship and, under normal and proper use conditions, warrants it for a period of one year from installation and no more than 13 months from the shipping date.

IL's obligation is limited to repairing, replacing or modifying (at IL's undisputed judgment) at IL's factory - Paderno Dugnano or elsewhere the material whose defects have been verified, on condition that the Purchaser has informed IL of any defects found within 8 days from receipt or from discovery in case of defects which may not be identified in the normal inspection.

Damages caused by or connected to transport are excluded. Transport to and from IL Paderno Factory will be at Purchaser's charge and risk and shall be paid also for reshipment.

These replacements, repairs or alterations will in no case determine extension to the above specified warranty period.

This warranty does not cover those parts which deteriorate or which are considered consumables or those parts or items which by their nature are normally required to be replaced periodically consistent with normal maintenance (including without limitation lamps, and tubes).

Those instruments or accessories which are supplied by IL but are not of IL manufacturer will only benefit from the warranty conditions offered by the manufacturer.

It's also understood that, following the purchase and delivery of the instrument, the Purchaser shall be deemed liable for any losses, damages or complaints concerning persons or things incurred by the use or misuse of the instrument on behalf of the Purchaser, his employees, co-operators or others.

IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements as well as for any damage to the instrument directly or indirectly resulting from the use of reagents and/or consumables different from those produced by IL specifically for its own instruments on the same properly tested.

Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

- a. insufficient or negligent care by the Purchaser.
- b. insufficient or negligent maintenance by the Purchaser in relation to the instructions contained in the Manuals prepared by IL for this purpose, tampering or alterations of the instruments or in any case intervention or repairs made by any person not duly authorized by IL.
- c. misuse due to carelessness, negligence, inexperience.
- d. employment of materials under heavier conditions than those for which they had been designed and manufactured and use of the same in combination with incompatible or dangerous products.
- e. non-observance of regulations relative to installation, power supply and operation of the instruments (with particular regard to the regulations for accident prevention).

11.1 Disclaimer regarding non-IL brand product

IL brand reagents, consumable and expendable supplies (including, for example, rotors) were developed specifically for the ACL's centrifugal, nephelometric clot detection system. IL's ACL system products are tested to assure proper performance when using plasma samples in accordance with the protocol described in Section 8. Each lot of IL brand ACL reagents is tested against these criteria. Verification of other brands of reagent or supplies to ascertain their suitability for the ACL's methodology or their level of performance on the IL ACL instruments is not performed. The use of non-IL brand reagents or supplies for testing which is not done in accordance with IL protocols may cause a clinically significant degradation of performance and results.

IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements as for any damage to the instrument directly or indirectly resulting from the use of reagents, consumables and expendable supplies different from those produced by IL.

THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OR MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OR WARRANTIES, EXPRESSED OR IMPLIED, WHICH EXTEND BEYOND THE CONTENTS OF THIS AGREEMENT.

No agent or employee of IL is authorized to extend any other warranty or to assume for IL any liability except as above set forth.

IL does not test other manufacturer reagents to ascertain their suitability for the ACL's methodology or their level of performance on the IL ACL instruments.

ACL Warranty

The following items are considered as consumables:

-
- Fluidic tubing

 - Sampling probe

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Revision History

Rev.	Modifications
1.0	First edition
2.0	<ul style="list-style-type: none">• QC data transmission added• Added codes for new tests: APCR V, Heparin Xa• Host query mechanism• Automatic upload added
2.1	<ul style="list-style-type: none">• Text Corrections• Unique instrument identification added

1. Introduction

This document is a guide to integrate a Laboratory Information Management system with the Instrumentation Laboratory ACL 6000/7000 rev. 2.1 instrument using the ASTM (American Society for Testing and Materials) specification to transfer information between clinical instruments and computer systems.

ASTM specification E-1394-91 *Standard Specification for Transferring Information between Clinical instruments and Computer Systems* and E-1381-91 *Standard Specification for the Low-Level Protocol to transfer Messages between Clinical Laboratory Instruments and Computer Systems* have been used as standard to develop ACL6000/7000 Host Communication Protocol.

Specification E-1394 defines the logical layer of ASTM standard; all significant information for ACL 6000 and 7000 rev. 2.1 application can be found in chapters 2 to 7.

Specification E-1381 refers to the low level protocol; significant information for ACL 6000/7000 rev. 2.1 application can be found in chapter 2.

2. General Characteristics

ACL 6000 and ACL 7000 communication sessions with host computer can be started on operator request or automatically at session completion.

The operator can request the start of a download session, the host computer will transmit the test orders.

To start an *upload session*, the instrument will transmit a subset of sample results stored in the instrument patient data base or QC data base.

If the instrument is properly configured also automatic downloading or uploading session can be started by ACL 6000 or ACL 7000.

The first condition will happen at session starting if host query is configured. In this condition the instrument will require test orders for specific sample IDs.

The second condition will happen, if automatic uploading has been required, at session completion.

If a communication session is not explicitly opened by the instrument any host computer message is ignored.

All information received by the host computer must be associated with a Sample ID that is the primary key of the data base. In addition to programmed tests a certain amount of information can be associated to a Sample ID (patient data) and stored in ACL 6000/7000 data base, this information is optional.

The sample ID is the primary key to access information in the data base.

If the checks fail, any downloading operations will be aborted. See "*4. Test Order Downloading*".

At most 300 samples can be stored in ACL 6000/7000 data base; each sample can have a maximum of 8 tests associated. The system behavior when these limits are exceeded is explained in paragraph "*4. Test Order Downloading*".

The test ordering operation, to identify the type of ordered test, by host computer must refer, to a computer code that is instrument specific. Refer to "*4. Test Order Downloading*" for further details and to the Appendix at the end of this document for the test codes table.

3. Protocol Specification

3.1. Low Level Interface

The low level interface conforms to ASTM specification E-1381-91. The following characteristics are supported and are configurable by Operator Interface:

Baud Rate	2400, 4800, 9600, 19200
Character Length	8 bit
Parity	No parity
Stop Bits	1

3.2. Data Link and Logical Layer

For the Data Link and Logical Layer the ASTM specification E-1381-91 has been maintained as a reference. Protocol limits and constraints are those declared by the standard.

To mention some of them, the data part of the frames exchanged between the instrument and the host computer cannot exceed 240 bytes. As a consequence during transmission sessions specific routines provide the ability to divide large records into multiple frames and during a reception session they rebuild partial frames in a single record. The application level has no evidence of this mechanism.

According to ASTM standard the following characters cannot be part of data records: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, <DC4>.

Timeout and retry logic are those specified by the standard; the Low-Level Clinical Message State Diagram representing the implemented automatic is the reference.

In interrupt request state the instrument accept remote EOT.

3.3. Sessions

There are two types of sessions that the instrument handles with the ASTM interface: the test orders download and the test results upload. These sessions can be initiated by the operator or automatically activated by the instrument.

When the user/operator requests a download operation (Receive Command), the instrument will send a request to the host for available test orders (all) or for test orders requested for specific samples, and the host will answer with the test orders available for the instrument.

Test results upload (Transmit Command) is initiated by the user or automatically by the instrument at the same way. The host is not allowed to transmit unsolicited messages, any type of inquiries or test orders not explicitly required by the instrument.

3.3.1. Message Header and Message Terminator Records

Following ASTM specification, each type of transaction between the instrument (DTE) and the host computer (DCE) has two common records that are the *Message Header* record and the *Message Terminator* record. These records open and close data transmission between ACL 6000/7000 and host computer.

Their fields are described in the following:

Message Header Record:

Record Type ID	always set to 'H'
Delimiter Definition	the 5 ASCII characters composing this field define the type of delimiters will be used in the following records. See Appendix B for supported delimiters.
Message Control ID	not provided
Access Password	not provided
Sender Name or ID	set to 'ACL6000' or 'ACL7000' when transmitting to host or receiving. It is also supported, as an optional, the possibility to identify univocally the instrument by means of an extension to the instrument name: the name syntax becomes 'ACL6000-xx' or 'ACL7000-xx' where xx is a two digits code in the range 01-99. The extension to the instrument name is user configurable in the set-up environment.
Sender Street Address	not provided
Reserved Fields	not provided
Sender Telephone Number	not provided
Characteristics of Sender	not provided
Receiver ID	must be set to 'ACL6000' or 'ACL7000' when receiving from host. Also in this case is supported, depending on the instrument set-up, the possibility to identify univocally the instrument by means of the extension to the instrument name: the name syntax becomes 'ACL6000-xx' or 'ACL7000-xx' where xx is a two digits code in the range 01-99. If the ID is different from the expected one the session is interrupted.
Comment or special Instructions	not provided
Processing ID	always set to 'P' meaning Production
Version No.	set to the current ASTM standard version = '1'
Date and Time of Message	format is YYYYMMDDHHMMSS

Message Terminator Record:

Record Type ID	always set to 'L'
Sequence Number	always set to '1'
Termination Code	set to 'N' for normal termination and to 'E' for abnormal termination while transmitting to host; not considered for received data

4. Test Order Downloading

Test order downloading is used to request test orders available on the host and to have them on the instrument. This operation can be obtained in two way: opening manually a downloading session from the DMS environment or enabling on the instrument the host query function.

In the first case the host will provide to transmit to the instruments all pending test requests, in the second case the instrument will require automatically specific information for the samples placed on the sample tray and without any test requests.

Details for both modalities are explained in *4.1. Receive Session from DMS* and *4.2. Host Query* paragraphs.

4.1. Receive Session from DMS

The operator initiates manually the test order downloading from the DMS environment.

The host will provide to the instrument all available test requests. The host can send zero or more test orders in one or more messages, but all messages will be part of the same transmission session.

During a transmission session more test orders can be required for the same sample.

The host sends usually all test orders for which it has not yet received results even if they have been previously transmitted.

ACL 6000/7000 will process each received test order validating the fields that ACL 6000/7000 needs; some information will be extracted from the received record while other information will be ignored.

Only test orders related to patient sample will be considered, if the required sample ID does not exist already in the patient data base and the required sample ID is not used in the QC data base a new record is created. If the data base is full the transmission session will be aborted.

If the test orders are for a sample already existing in the sample data base the new orders will be added to the existing tests but all tests already ordered or performed will remain unchanged.

If a test order with more than 8 tests is sent the request is rejected.

If the test order is not recognized as one of those supported by ACL 6000/7000 it is rejected. The instrument will inform the host computer using a record containing the list of rejected test orders.

During a downloading session the listed error conditions can be detected, the associated ACL 6000/7000 action is listed as well:

Error Condition	Action	User Message
Sample ID used in the QC data base	Abort	Sample ID already used in the QC data base
Bad Sample ID (long, unsupported characters)	Abort	Invalid Sample ID
Data base full	Abort	Patient data Base is full
Patient record has no associated test order record	Abort	Not identified sample ID for patient data
Test order has no associated patient record	Abort	No patient record for ordered tests
Instrument Identifier different from ACL6000 or ACL 7000	Abort	Invalid instrument identifier
More than 8 test request for the same sample ID	Rejected	-
Unknown test request	Rejected	-
Bad Test	Rejected	-
Illegal record format	Abort	Incorrect record format in host messages

All abort conditions imply that ACL 6000/7000 will send to the host computer a message with the reason of transmission interruption (see 4.3. Rejected Test Order) while a message is presented to the user on the instrument. When transmission abort is not implied at transmission completion, one or more records will follow (see 4.3. Rejected Test Order) with an indication of rejected test orders. Information rejected are typically unknown test requests or test requests exceeding the sample record size in ACL 6000/7000 Data Management System. It must be observed that if any of this information is rejected, it does not imply that the sample data at all are rejected. The first eight legal test requests will be stored; the other requests for the same sample ID will be rejected.

It also must be underscored that ACL 6000/7000 limits the size of handled records (independently from the record type supported by ASTM) to 1024 byte during downloading session.

4.1.1. Test Request Message

The *Test Request Message* is used by ACL 6000/7000 to start the test order download session. It is composed by a *Message Header* record, a *Request Information* record and a *Message Terminator* record.

The *Request Information* record requests ALL test orders that the host has for the ACL 6000/7000 .

Following the ASTM specification the fields composing the *Request Information* are described in the following.

Request Information Record:

Record Type ID	always set to 'Q'
Sequence Number	as defined by the standard set to '1' when query is sent
Starting Range ID Number	set to the string 'ALL'
Ending Range ID Number	not provided
Universal Test ID	not provided
Nature of Request Time Limit	not provided
Beginning request Results Date and Time	not provided
Requesting Physician Name	not provided
User Field #1	not provided
User Field #2	not provided
Request Information Status Code	always set to 'O' (requesting test orders and demographics only)

An example for the complete message (composed by header message, request information record and message terminator record) is given by:

```
H|\^&|||ACL6000|1|1|1|P|1|19960210103227<CR>
  Q|1|ALL|1|1|1|1|1|O<CR>
L|1|N<CR>
```

4.1.2. Test Order Message

As an answer to the ACL 6000/7000 *Test Request Message* the host computer sends the *Test Order Message*. It contains the records specifying which tests are being requested. The host computer may answer with one or more messages each of which contains one or more test order specifications. The test order specification consists of a *Patient Information* record followed by one or more *Test Order* records.

The host can send for the same sample ID a Patient Information record followed by many Test Order records or, for each test to be ordered, a pair composed by the Patient Information record followed the Test Order record.

Comment Record messages during downloading operations are ignored by ACL 6000/7000 .

4.1.2.1. Patient Information Record

The fields characterizing this record are specified in the following:

Patient Information Record:

Record Type ID	must be 'P'
Sequence Number	must begin with '1' and then must increment by one for each new Patient Information record
Practice Assigned Patient ID	ignored
Laboratory Assigned Patient ID	ignored
Patient ID #3	ignored
Patient Name	stored, if available, as a unique string in the 'name' field of sample record considering only the first two subfields in this data field (second and first name). The string will be truncated to 20 characters. If a character not supported is found (see Appendix B for supported characters) the patient name and all the other strings in the same patient record will be ignored.
Mother's maiden Name	ignored
Birthdate	stored, if available. The data will be converted in according to ACL6000 supported format. Expected format, conforming to ASTM standard, is YYYYMMDD
Patient Sex	used if available. Allowed characters are 'M', 'm', 'F', 'f', 'U', 'u'; any other char is interpreted as 'U'.
Patient Race-Ethnic Origin	ignored
Patient Address	ignored
Reserved Field	ignored
Patient Telephone Number	ignored
Attending Physician ID	ignored
Special Field #1	ignored
Special Field #2	ignored
Patient Height	ignored
Patient Weight	ignored
Patient's Known or Suspected Diagnosis	ignored
Patient Active Medications	ignored
Patient's Diet	ignored

Practice Field #1	ignored
Practice Field #2	ignored
Admission and Discharged Dates	ignored
Admission Status	ignored
Location	used if available as a free string in the 'department' field of sample record. The string will be truncated to 16 characters. See Appendix B for supported characters.
Nature of Alternative Diagnostic Code and Classifiers	ignored
Alternative Diagnostic Code and Classifiers	ignored
Patient Religion	ignored
Marital Status	ignored
Isolation Status	ignored
Language	ignored
Hospital Service	ignored
Hospital Institution	ignored
Dosage Category	ignored

4.1.2.2. Test Order Record

The fields characterizing this record are specified in the following:

Test Order Record:

Record Type ID	must be 'O' (letter)
Sequence Number	must begin with '1' and then must increment by one for each new test order record for the same patient
Specimen ID	this is the ACL 6000/7000 sample ID; the field must be less than or equal to 12 characters and must be consistent with rules on sample ID (equality between patient and QC data bases, legal characters). Non conforming sample IDs will cause an abort of the download process. See Appendix B for ACL 6000/7000 supported characters.
Instrument Specimen ID	ignored
Universal Test ID	the field is composed of 4 parts; only the Manufacturer's Code component is used as a 3 character code (see table in Appendix A); unknown test ID will be rejected
Priority	ignored
Requested/Ordered Date and Time	ignored
Specimen Collection Date and Time	ignored
Collection End Time	ignored
Collection Volume	ignored
Collector ID	ignored
Action Code	ignored
Danger Code	ignored
Relevant Clinical Information	ignored
Date and Time Specimen Received	ignored

Specimen Descriptor

ignored both fields

Ordering Physician

ignored

Physician's Telephone Number

ignored

User Field #1

ignored

User Field #2

ignored

Laboratory Field #1

ignored

Laboratory Field #2

ignored

Laboratory Field #3

ignored

Date/time Results Reported or Last

ignored

Modified

Instrument Charge to Computer

ignored

System

Instrument Section

ignored

Report Type

set to O (letter); other codes will cause records rejection

Reserved Field

ignored

Location of Ward of specimen

ignored

Collection

Nosocomial Information Flag

ignored

Specimen Service

ignored

Specimen Institution

ignored

An example for a complete test ordering is given by:

```

H[\^&|||||]ACL6000||P|1|19960206134700<CR>
P|1|||ROSSI^MARIO^^^|19391127|M|||||||DEP 1|||||||<CR>
  O|1|SMP01|^000001|||||||O|||||<CR>
  O|2|SMP01|^000005|||||||O|||||<CR>
  O|3|SMP01|^000009|||||||O|||||<CR>
  O|4|SMP01|^000022|||||||O|||||<CR>
  O|5|SMP02|^000001|||||||O|||||<CR>
  O|6|SMP03|^000001|||||||O|||||<CR>
  O|7|SMP04|^000001|||||||O|||||<CR>
  O|8|SMP05|^000001|||||||O|||||<CR>
P|2|||GIALLI^GIANLUCA^^^|19551028|F|||||||DEP 2|||||||<CR>
  O|1|SMP10|^000001|||||||O|||||<CR>
  O|2|SMP10|^000005|||||||O|||||<CR>
  O|3|SMP10|^000009|||||||O|||||<CR>
  O|4|SMP10|^000022|||||||O|||||<CR>
P|3|||VERDI^P.^^^|19580821|U|||||||DEP 3|||||||<CR>
  O|1|SMP11|^000001|||||||O|||||<CR>

```

L|1|N<CR>

4.2. Host Query

The host query is automatically activated by the instrument each time the system is properly configured and starting the pre-analysis phase of a single test or profile one or more samples have not any type of test requests associated.

The instrument will send, using the request information record, the sample IDs requiring test programming and will accept only test orders for those sample IDs.

The mechanism supported by ASTM requires the request of a single sample Id for each Request Information record or a range selection (but this is related with the sample IDs sorting criteria). As a consequence the instrument will wait for the host information before sending a new request information record for a new sample.

Because the instrument is asking information for a specific sample Id it will reject any type of information associated to different sample IDs.

The host will provide to the instrument all available test requests. The host can send zero or more test orders in one or more messages, but all messages will be part of the same transmission session. During a transmission session more test orders can be required for the same sample.

ACL 6000/7000 will process each received test order validating the fields that ACL 6000/7000 needs; some information will be extracted from the received record while other information will be ignored.

If the test order is not recognized as one of those supported by ACL 6000/7000 it is rejected. The instrument will inform the host computer using a record containing the list of rejected test orders.

During a downloading session the listed error conditions can be detected, the associate ACL 6000/7000 action is listed as well:

Error Condition	Action	User Message
Sample ID different from the requested	Rejected	-
Bad Sample ID (long, unsupported characters)	Abort	Invalid Sample ID
Patient record has not an associated test order record	Abort	Not identified sample ID for patient data
Test order has not associated patient record	Abort	No patient record for ordered tests
Instrument Identifier different from ACL6000 or ACL 7000	Abort	Invalid instrument identifier
More than 8 test request for the same sample ID	Rejected	More than 8 tests for the same sample
Unknown test request	Rejected	-
Bad Test	Rejected	-
Illegal record format	Abort	Incorrect record format in host messages

All abort conditions imply that ACL 6000/7000 will send to the host computer a message with the reason of transmission interruption (see 4.3. Rejected Test Order) while a message is presented to the user on the instrument. When transmission abort is not implied at transmission completion one or more records will follow (see 4.3. Rejected Test Order) with indication of rejected test orders. Information can be rejected are typically unknown test requests or test requests exceeding the sample record size in ACL 6000/7000 Data Management System. It has to be observed that if any of these information is rejected it does not imply that the sample data at all are rejected; the first eight legal test requests will be stored also if the other requests for the same sample ID will be rejected.

It has also to be underlined that ACL 6000/7000 limits during downloading session the size of handled records (independently from the record type supported by ASTM) to 1024 byte.

4.2.1. Test Request Message

The *Test Request Message* is used by ACL 6000/7000 to require information for each specific sample that has not test orders into the instrument data base. It is composed by a *Message Header* record, a *Request Information* record and a *Message Terminator* record.

The *Request Information* record requests in this case information for a specific ID at time. The ASTM protocol limits the number of *Request Information* record to one. As a consequence the instrument will wait the *host answer* before sending a second *Request Information* record for a second sample.

Following the ASTM specification the fields composing the *Request Information* are described in the following.

Request Information Record:

Record Type ID	always set to 'Q'
Sequence Number	as defined by the standard set to '1' when query is sent
Starting Range ID Number	set to the specific sample ID to require information on; the meaningful component is the second one
Ending Range ID Number	not provided
Universal Test ID	not provided
Nature of Request Time Limit	not provided
Beginning request Results Date and Time	not provided
Requesting Physician Name	not provided
User Field #1	not provided
User Field #2	not provided
Request Information Status Code	always set to 'O' (requesting test orders and demographics only)

An example for the complete message (composed by header message, request information record and message terminator record) is given by:

```
H|\^&|||ACL6000|||||P|1|19960210103227<CR>
  Q|1|^S001^|||||O<CR>
L|1|N<CR>
```

4.2.2. Test Order Message

As an answer to the ACL 6000/7000 *Test Request Message* the host computer sends the *Test Order Message*. It contains the records specifying which tests are being requested to be run for the requested sample Ids.

See 4.1.2. Test Order Message for details.

4.3. Rejected Test Order

At completion of downloading operations ACL 6000/7000 can transmit a message to inform host computer about rejected test order and sample or about the reason of transmission interrupt.

The *Rejected Test Order Message* consists of a *Message Header* record followed by one or more *Comment records* and completed by the *Message Terminator Record*. A comment record will be transmitted for each rejected information.

It must be observed that if a non legal information has been received, the download process is interrupted and the rejected test order message will signal the reason for the interruption. If the download process has been normally completed, the possible following rejected test order message will report non legal test orders.

Comment Record structure is described in the following table:

Record Type ID	always set to 'C'
Sequence Number	must begin with '1' and then it will increment by one for each new comment record
Comment Source	always set to 'I'
Comment Text	this field indicates the reason of the test order rejection. It is a string with two components, each one can assume the reported values: <u>Rejection Reason:</u> BAD_TEST: the transmitted test code is invalid QC_MA_ID: the specified ID is already used as a material in the QC data base BAD_S_ID: the specified ID is invalid WRONG_ID: the host is sending information for a sample ID different from the expected one PDB_FULL: patient data base is full M_TEST_E: more tests than expected UNKNOWN_T: unknown test requested INSTR_ID: invalid instrument identifier NO_TESTS: no test ordered for patient record NO_PATIE: no patient record for ordered test BAD_RECO: incorrect record format <u>Identification:</u> this string contains the identification of the sample causing the problem; if a test order caused the problem the sample ID and test ID are transmitted sequentially. The character used to separate the rejection reason, and the two strings used for the identification field is ' '. Lacking information will be signaled as "UNKNOWN".

If BAD_RECO is the reason of the rejection the field will contain the record number and the field number caused the failure.

Comment Type always set to 'I'

To summarize the possible values for the rejection reason and identification fields are reported in the following table:

Rejection Reason	Transmission Interrupted	Identification: first sub_field	Identification: second sub_field
QC_MA_ID	yes	sample ID (causing the problem)	UNKNOWN
BAD_S_ID	yes	sample ID (causing the problem)	UNKNOWN
PDB_FULL	yes	sample ID (causing the problem)	test_ID
NO_TESTS	yes	UNKNOWN	UNKNOWN
NO_PATIE	yes	sample ID (causing the problem)	test_ID
INSTR_ID	yes	UNKNOWN	UNKNOWN
M_TEST_E	no	sample ID	test ID (causing the problem)
UNKWOWN_T	no	sample ID	test ID (causing the problem)
BAD_TEST	no	sample ID	test ID (causing the problem)
BAD_RECO	yes	Record No. (debug purpose)	Field No. (debug purpose)

An example for a complete rejection phase is given by:

```
H|\^&|||ACL6000|P|1|19960210103227<CR>
  C|1|1|M_TEST_E|SMP01      ^010|I<CR>
  C|2|1|BAD_TEST|SMP01      ^000|I<CR>
L|1|I|N<CR>
```

4.4. Downloading Session Volumes

Approximate data volumes for downloading sessions are provided as a guide for estimating the time required to complete typical sessions. Obviously, system latencies (both ACL 6000/7000 and host computer) are not considered.

The minimal session would occur if the host has no test orders available for ACL 6000/7000 . In this condition ACL 6000/7000 sends the test request message, the host would respond with a message containing no test orders (only message header and message terminator record).

In conditions in which the host has test orders for the instrument, the estimated data volume is:

Test Request Message = Message Header(41) + 17 + Message Terminator Record(6) = 64

Test Order Message = Message Header(41) +
 number of patient records (82 + 55 * number of ordered test)
 + Message Terminator Record(6)

Test Order Rejected = Message Header(41) +
 + 41 * number of rejected records
 + Message Terminator Record(6)

So considering the following situation: the host has 50 sample ID to be downloaded each one with 4 tests and considering 10 rejected records the data volume can be estimated in:

Test Request Message = 64

Test Order Message = $41 + 50 (82 + 55 * 4) + 6 = 15147$

Test Order Rejected = $41 + (41 * 10) + 6 = 457$

Total = 15668 characters

At 9600 baud rate and with no system overhead it would take approximately 17 seconds and considering a system efficiency of 60% it becomes about 27 seconds.

Going to the maximum limit of the instrument, that is 300 sample IDs to be downloaded each one with 8 tests and considering 300 rejected records the data volume can be estimated in:

Test Request Message = 64

Test Order Message = $41 + 300 (82 + 55 * 8) + 6 = 156647$

Test Order Rejected = $41 + (41 * 300) + 6 = 12347$

Total = 169058 characters

At 9600 baud rate and with no system overhead it would take approximately less than 3 minutes and considering an efficiency of 60% it becomes about 5 minutes.

All estimations have been done using for string fields the maximum expected length.

5. Test Results Uploading

Test Result Uploading allows transmission of results of the tests performed on ACL 6000/7000 to the host computer. Results, related to patient and QC samples, are transmitted on explicit user request or automatically at session completion.

In the first case the user must require the transmission command in the DMS environment or in the QC environment, select the patient samples or QC samples to be transmitted (in according with one of the supported selection criteria) and start operations.

In the second case the transmission will happen automatically at session completion and the instrument will provide to upload patient and/or QC samples data.

The type of data to be transferred during an automatic uploading are depending upon the instrument set-up (the automatic data transmission can be set to “patient samples only” or “QC and patient samples”).

If uploading is manually requested all data are transmitted independently from the transmission flag. Otherwise if transmission is performed automatically at session completion the instrument will upload for patient samples all the data available for the sample IDs just analyzed and will upload, for QC data, the results just obtained.

From a general point of view the automatic data transmission of the patient samples is equivalent to the manual data transmission, requested in DMS, of patient samples belonging to a specific loadlist. While the automatic data transmission of the QC data is equivalent to the manual data transmission, requested in QC data base, of the data in a specified interval for the QC material present in the loadlist.

Considering that ACL 6000/7000 fills the strings used for Sample ID, department and patient name with space characters (to align data), the host computer must ignore space characters on the right of these fields.

For both patient and QC samples if uploading is completed successfully the transmission flag associated to the single record will be updated from ‘L’ to ‘T’ (transmitted).

It must also be underscored that on ACL 6000/7000 modifications to sample data already transmitted (such as adding of a new test result or modifications of sample data) cause the transmission flag to change from ‘T’ to ‘L’.

It does not apply to QC data because the only modification the user can request on these data is to omit them. The effect is to exclude the data from the statistic but the data is not modified.

Modifications in the set-up values and note field do not modify the transmission status of QC data.

While transmission is in progress the user will be updated on the number of the sample being transmitted.

ACL 6000/7000 does not accept inquiries for test results.

5.1. Test Result Message

The *Test Result Message* is used by ACL 6000/7000 to transmit any available test results for a sample. All available test results will be transmitted for patient samples even if data have been already transmitted partially.

The message is composed by a *Message Header* record, a *Patient Information* record, one or more pair *Test Order* records followed by one or more *Results* records (depending upon the number of available test results and the number of results for each specific test).

The *Result* record can be completed by a *Comment* record containing flags associated to the executed test. An indication of the sequence used for test results transmission is reported in Appendix D. It is important to observe that, depending upon instrument status (i.e. calibrated, not calibrated, user options), not all listed type of results are necessarily calculated. Therefore, in some conditions only a subset of the listed results will be transmitted to the host computer.
The *Message Terminator* record complete the transmitted data.

The same structure is used also to upload QC data. In the following paragraphs any differences in the way to treat patient and QC samples will be underlined.

5.1.1. Patient Information Record

This information is transmitted to the host only if available on the instrument. The Patient Information structure is:

Patient Information Record:

File Type	Patient Sample	QC Sample
Record Type ID	must be 'P'	must be 'P'
Sequence Number	must begin with '1' and then must increment by one for each new Patient Information record	must begin with '1' and then must increment by one for each new Patient Information record
Practice Assigned Patient ID	not provided	not provided
Laboratory Assigned Patient ID	not provided	not provided
Patient ID #3	not provided	not provided
Patient Name	provided if known as a single string	not provided
Mother's maiden Name	not provided	not provided
Birthdate	provided if known as a single string without any checks	not provided
Patient Sex	provided if known as a single character	not provided
Patient Race-Ethnic Origin	not provided	not provided
Patient Address	not provided	not provided
Reserved Field	not provided	not provided
Patient Telephone Number	not provided	not provided
Attending Physician ID	not provided	not provided
Special Field #1	not provided	not provided
Special Field #2	not provided	not provided
Patient Height	not provided	not provided
Patient Weight	not provided	not provided
Patient's Known or Suspected Diagnosis	not provided	not provided
Patient Active Medications	not provided	not provided
Patient's Diet	not provided	not provided

Practice Field #1	not provided	not provided
Practice Field #2	not provided	not provided
Admission and Discharged Dates	not provided	not provided
Admission Status	not provided	not provided
Location	provided if known as a 16 characters free string ('department' field in sample record)	not provided
Nature of Alternative Diagnostic Code and Classifiers	not provided	not provided
Alternative Diagnostic Code and Classifiers	not provided	not provided
Patient Religion	not provided	not provided
Marital Status	not provided	not provided
Isolation Status	not provided	not provided
Language	not provided	not provided
Hospital Service	not provided	not provided
Hospital Institution	not provided	not provided
Dosage Category	not provided	not provided

5.1.2. Test Order Record

The fields characterizing this record are specified in the following:

Test Order Record:

File Type	Patient Sample	QC Sample
Record Type ID	must be 'O'	must be 'O'
Sequence Number	must begin with '1' and then must increment by one for each new test order record for the same patient	must begin with '1' and then must increment by one for each new test order record for the same patient
Specimen ID	provided, is the ACL 6000/7000 sample ID. See Appendix B for ACL 6000/7000 supported characters.	provided, is the ACL 6000/7000 QC material ID. See Appendix B for ACL 6000/7000 supported characters.
Instrument Specimen ID	not provided	not provided
Universal Test ID	the field is composed by 4 parts, only the Manufacturer's Code component is used as a 3 character code (see table in Appendix A).	the field is composed by 4 parts, only the Manufacturer's Code component is used as a 3 characters code (see table in Appendix A).
Priority	not provided	not provided
Requested/Ordered Date and Time	not provided	not provided
Specimen Collection Date and Time	not provided	not provided
Collection End Time	not provided	not provided

Collection Volume	not provided	not provided
Collector ID	not provided	not provided
Action Code	not provided	set to 'Q'
Danger Code	not provided	not provided
Relevant Clinical Information	not provided	not provided
Date and Time Specimen Received	not provided	not provided
Specimen Descriptor	not provided both fields	not provided both fields
Ordering Physician	not provided	not provided
Physician's Telephone Number	not provided	not provided
User Field #1	not provided	not provided
User Field #2	not provided	not provided
Laboratory Field #1	not provided	not provided
Laboratory Field #2	not provided	not provided
Laboratory Field #3	not provided	not provided
Date/time Results Reported or Last Modified	not provided	not provided
Instrument Charge to Computer System	not provided	not provided
Instrument Section	not provided	not provided
Report Type	set to F	set to F
Reserved Field	not provided	not provided
Location of Ward of specimen Collection	not provided	not provided
Nosocomial Information Flag	not provided	not provided
Specimen Service	not provided	not provided
Specimen Institution	not provided	not provided

5.1.3. Result Record

The fields characterizing this record are specified in the following table.

A result record is send to the host computer for each available test result. For double tests all available single values will be transmitted to the host computer (no mean values). Each result record will contain one of available test results.

Result Record:

File Type	Patient Sample	QC Sample
Record Type ID	set to 'R'	set to 'R'
Sequence Number	must begin with '1' and then must increment by one for each result record for the same patient test record for the same patient record	must begin with '1' and then must increment by one for each result record for the same patient test record for the same patient record
Universal Test ID	the field is composed by 4 parts, only the Manufacturer's	the field is composed by 4 parts, only the Manufacturer's

Data or Measurement Value	Code component is used as a 3 character code (see table in Appendix A), the obtained numeric value or qualitative message (coag. error X, not coag, ***, ---, > ..., calc. Error). If the sample was short, the information is transmitted in the following comment record and this field is empty.	Code component is used as a 3 characters code (see table in Appendix A). the obtained numeric value or qualitative message (coag. error X, not coag, ***, ---, > ..., calc. error). If the sample was short the information is transmitted in the following comment record and this field is empty.
Units	provided if the previous field is a numeric value; is a free string see Appendix C for supported units (maximum number of characters is 10). If the sample was short, this field is empty.	provided if the previous field is a numeric value; is a free string see Appendix C for supported units (max. number of chars is 10). If the sample was short this field is empty.
Reference range	not provided	not provided
Result Abnormal Flag	not provided	not provided
Nature of Abnormality Flag	not provided	not provided
Result Status	set to 'F'	set to 'F'
Data of Change in Instrument Normative Values or Units	not provided	not provided
Operator Identification	not provided	not provided
Date/Time Test Started	not provided	not provided
Date/Time Test Completed	execution time, string of the type YYYYMMDDHHMMSS	execution time, string of the type YYYYMMDDHHMMSS
Instrument Identification	not provided	not provided

5.1.4. Comment Record

The Comment record allows integration of the transmitted test results with possible error messages. One or more comment records can follow the result records. Fields characterizing this record are specified in the following.

Comment Record:

Record Type ID	set to 'C'
Sequence Number	must begin with '1' and then must increment by one for each comment record
Comment Source	set to 'I'
Comment Text	this field specifies the instrument errors (see table) as a numeric code (2 characters) plus the associated message
Comment Type	set to 'I'

01	no sample
10	2 point cal
11	Animal Application
12	No cal Verification
13	NP out of range
20	Acquisition Extended
25	QC Out of Range
26	Invalid for QC
30	Magnetic Stirrer fail
35	Peltier Temperature Out of Range
36	Pre-heater Temperature Out of Range
37	Incubation Temperature
40	Cover Open
50	Sensor Fail
51	Sensor Off
52	No liquid (XX)

N.B. Out of range indications are not transmitted to the host computer.

5.2. Uploading Session Volumes

Approximate data volumes for uploading sessions are provided as a guide for estimating the time required to complete typical sessions. Obviously, system latencies (both ACL 6000/7000 and host computer) are not considered.

The *minimal session* would occur if ACL 6000/7000 has no test results to be transmitted; no data is sent and the data volume is zero.

In conditions in which the ACL 6000/7000 has results to be transmitted, the data volume can be estimated on the Test Order and Test Result record size base.

Test Order Message = Message Header(41) +
number of patient records (82 + Results) + Message Terminator Record(6)

Results = number of ordered test(55 + 60*number of test result + 56* number of error messages))

Consider the following situation: ACL 6000/7000 has 50 sample IDs to be uploaded each with 4 tests, each test with 3 results and each test with 2 flags, the data volume can be estimated in:

Test Result Message = 41+ 50 (82 + 4(55 + 60*3 + 56*2)) + 6
Total = 69547 characters

At 9600 baud rate and with no system overhead it would take approximately 73 seconds and considering a system efficiency of 60% it becomes about 116 seconds.

Going to the maximum limit of the instrument, that is 300 sample IDs to be uploaded each one with 8 tests, 3 results for test and 5 flags for test the data volume can be estimated in:

Test Result Message = 41+ 300 (82 + 8(55 +60*3 +56*5)) + 6
Total = 1260647 characters

At 9600 baud rate and with no system overhead it would take approximately less than 22 minutes and considering an efficiency of 60% it becomes about 35 minutes.

Note that for all the strings the the maximum expected length has been considered.

6. Not Supported Records

The *Scientific* record and the *Manufacturer Information* record are not supported by ACL 6000/7000 protocol.

As a consequence the instrument ignores any type of information they contain.

1

7. Transmission Abort

The download or upload transmission session can be interrupted for an explicit user request detected on the instrument, because the host computer is not responding or because the host computer required interruption of the transmission process.

Further, as reported above, the download process can be interrupted because an illegal sample Identifier has been received. Instrument behavior in this particular condition was defined in section 4.3. Rejected Test Order.

ACL 6000/7000 behavior in each of the listed conditions is described in the following:

Condition	Action
<p>ACL 6000/7000 's operator requested stop download process</p>	<p>ACL 6000/7000 will signal the end of transmission to the host and will discard any following messages. The host must consider the interrupt request.</p> <p>It must be emphasized that ACL 6000/7000 will signal the transmission interruption with a message that is a rejected test order message if any information has been rejected or with a message header plus a message terminator record if no information has been rejected.</p>
<p>ACL 6000/7000 's operator requested stop upload process</p>	<p>ACL 6000/7000 will complete the message in progress with the message terminator and will not transmit any further test results.</p>
<p>Host computer is not responding</p>	<p>During downloading and uploading session transmission operation by ACL 6000/7000 is stopped. If downloading was in progress, no rejected test messages will be transmitted.</p> <p>A message will inform the user that the transmission has been interrupted: "Host Computer not responding"</p>
<p>Host computer required EOT</p>	<p>Both during downloading and uploading session operation by ACL 6000/7000 are stopped. If downloading was in progress no rejected test messages will be transmitted.</p> <p>It must be emphasized that the host computer must request the transmission interruption with a message composed by a message header plus a message terminator record.</p> <p>A message will inform the user that the transmission has been interrupted: "Host Computer required to interrupt transmission"</p>
<p>Incorrect record format</p>	<p>Transmission/reception is aborted and the user is informed: "Incorrect format in host messages"</p>

Appendix A - ACL 6000/7000 Test Codes

000	no test
001	PT
002	PT-double
003	FIB (PT derived)
004	FIB-double (PT derived)
005	APTT
006	APTT-double
007	APTT -3 min
008	APTT -3 min- double
009	TT
010	TT-double
020	Pro-IL-Complex
021	Hepatocomplex
022	Pro-Clot
023	Protein S
024	APCR V
030	AT-III
031	Fibrinogen Clauss
032	Heparin (high curve)
033	Heparin (low curve)
034	Plasminogen
035	Antiplasmin
036	Pro-Chrom
037	D-Dimer
038	Heparin Xa
040	F-VIII (high curve)
041	F-IX (high curve)
042	F-XI (high curve)
043	F-XII (high curve)
044	F-VII (high curve)
045	F-X (high curve)
046	F-V (high curve)
047	F-II (high curve)
050	F-VIII (low curve)
051	F-IX (low curve)
052	F-XI (low curve)
053	F-XII (low curve)
054	F-VII (low curve)
055	F-X (low curve)
056	F-V (low curve)
057	F-II (low curve)
100	PT-FIB/APTT/TT
101	PT-FIB/FIB-C
102	APTT/FIB-C
103	TT/FIB-C
104	PCX/APTT/TT
105	HPX/APTT/TT
106	PCX/FIB-C
107	HPX/FIB-C

Appendix B

ACL 6000/7000 Supported Characters for Sample ID

A÷Z

0÷9

Special characters:

space , ‘ - ? .

Also if ‘space’ and ‘.’ are allowed characters, a string containing only these two characters will be rejected.

ACL 6000/7000 Supported Characters for Patient name and Department

A÷Z

0÷9

Special characters:

! % ‘ ()
* + , - .
/ : ; < =
> ?

ACL 6000/7000 Supported Characters for delimiters

! “ # \$ %
& ‘ () *
+ / : ; =
@ [\] ^
_ { | } ~

ASCII character 127 is not allowed as delimiter.

Appendix C - ACL 6000/7000 Supported Units

Unit	Abbreviation
Time	s
Activity	%
Ratio	R
International Normalized Ratio	INR
Concentration	mg/dL
	g/L
	ng/mL
	U/mL
Delta Optical Absorbance	Delta Abs.
Normalized Ratio	NR

Appendix D - ACL 6000/7000 Test Results Sequence

Test	Results Sequence
PT	Time Activity Ratio/INR
PT-double	Time 1 Activity 1 Ratio/INR 1 Time 2 Activity 2 Ratio/INR 2
FIB (PT derived)	Concentration
FIB-double (PT derived)	Concentration 1 Concentration 2
APTT	Time Ratio
APTT-double	Time 1 Ratio 1 Time 2 Ratio 2
APTT -3 min	Time Ratio
APTT -3 min- double	Time 1 Ratio 1 Time 2 Ratio 2
TT	Time Ratio
TT-double	Time 1 Ratio 1 Time 2 Ratio 2
Pro-IL-Complex	Activity Ratio/INR Time

Test	Results Sequence
Hepatocomplex	Activity Ratio/TNR Time
Pro-Clot	Activity Ratio Time
Protein S	Activity Time
AT-III	Activity Delta Absorbance
Fibrinogen Clauss	Concentration Time
Heparin Xa (high curve)	Concentration Delta Absorbance
Heparin (high curve)	Concentration Delta Absorbance
Heparin (low curve)	Concentration Delta Absorbance
Plasminogen	Activity Delta Absorbance
Antiplasmin	Activity Delta Absorbance
Pro-Chrom	Activity Delta Absorbance
D-Dimer	Concentration Delta Absorbance Offset
Factors (high or low curve)	Activity Time
APCR V	Time (basal) Time (activated) Ratio (or Normalized Ratio)

APPENDIX B

APPLICATION HANDBOOK

ACL 6000

Revision 2.1 - December 1997

HEPARIN Xa CALIBRATION

Sample tray positions	Materials
POOL	Calibrator 0.8 U/mL (1st Standard)
DIL	Working Diluent (use 4 mL cup)
18	Calibrator 0.0 U/mL (3rd Standard)
17	Empty cup (0.5 mL)
1 - 12	Empty cups (0.5 mL)

Reagent area positions	Materials
1	Cleaning solution
2	Enzyme
3	Substrate

Material	Reconstitution
Calibrator	Refer to insert sheet for preparation
Working Diluent	Refer to insert sheet for preparation
Cleaning Solution	As it is
Enzyme	2.5 mL of distilled water
Substrate	4 mL of distilled water

HEPARIN Xa ANALYSIS

Sample tray positions	Materials
DIL	Working Diluent (use 4 mL cup)
1 to 9	Samples
10 to 18	Empty cups (0.5 mL)

Reagent area positions	Materials
1	Cleaning solution
2	Enzyme
3	Substrate

Material	Reconstitution
Working Diluent	Refer to insert sheet for preparation
Cleaning Solution	As it is
Enzyme	2.5 mL of distilled water
Substrate	4 mL of distilled water

AT - III CALIBRATION

Sample tray positions	Materials
POOL	Calibration Plasma (100% - 1st Standard)
DIL	Diluted buffer (use 4 mL cup)
16	Diluted buffer (use 2 mL cup)
18	Empty cup (0.5 mL)
17	Empty cup (0.5 mL)
1 - 12	Empty cups (0.5 mL)

Reagent area positions	Materials
1	Cleaning solution
2	Enzyme
3	Substrate

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
Diluted Buffer	Concentrated buffer diluted 1:10 (1+9) with distilled water
Cleaning Solution	As it is
Enzyme	2.5 mL of distilled water
Substrate	2 mL of distilled water

AT - III ANALYSIS

Sample tray positions	Materials
DIL	Diluted buffer (use 4 mL cup)
1 to 9	Samples
10 to 18	Empty (0.5 mL) cups

Reagent area positions	Materials
1	Cleaning solution
2	Enzyme
3	Substrate

Material	Reconstitution
Diluted Buffer	Concentrated buffer diluted 1:10 (1+9) with distilled water
Cleaning Solution	As it is
Enzyme	2.5 mL of distilled water
Substrate	2 mL of distilled water

PROCHROM CALIBRATION + ANALYSIS

Sample tray positions	Materials
POOL	Calibration Plasma (100%)
DIL	ProChrom Diluent (2 mL cup)
18	ProChrom Diluent (2 mL cup)
1 - 15	Samples

Reagent area positions	Materials
2	Enzyme
3	Substrate

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
ProChrom Diluent	Concentrated diluent diluted 1:10 (1+9) with distilled water
Enzyme	2.5 mL of distilled water
Substrate	2 mL of distilled water

PROCHROM ANALYSIS ONLY

Sample tray positions	Materials
18	ProChrom Diluent (2 mL cup)
1 - 15	Samples

Reagent area positions	Materials
2	Enzyme
3	Substrate

Material	Reconstitution
ProChrom Diluent	Concentrated diluent diluted 1:10 (1+9) with distilled water
Enzyme	2.5 mL of distilled water
Substrate	2 mL of distilled water

FIBRINOGEN - C CALIBRATION

Sample tray positions	Materials
POOL	Calibration Plasma
DIL	Factor Diluent (2 mL cup)

Reagent area positions	Materials
1	Cleaning solution
2	Thrombin

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
Factor Diluent	As it is
Cleaning Solution	As it is
Thrombin	2 mL of distilled water

FIBRINOGEN - C ANALYSIS

Sample tray positions	Materials
DIL	Factor Diluent (4 mL cup)
1 - 18	Samples

Reagent area positions	Materials
1	Cleaning solution
2	Thrombin

Material	Reconstitution
Factor Diluent	As it is
Cleaning Solution	As it is
Thrombin	2 mL of distilled water

PROCLLOT CALIBRATION + ANALYSIS

Sample tray positions	Materials
POOL	Calibration Plasma (100%)
DIL	Working Diluent (2 mL cup)
18	Protein-C Deficient Plasma (0%) in 2 mL cup
17	Empty cup (0.5 mL)
1 - 16	Samples

Reagent area positions	Materials
2	APTT Cephalin
3	APTT CaCl ₂

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
ProClot Diluent	As it is
Protein-C Activator	1.5 mL of distilled water
P-C Def. Plasma	1 mL of distilled water
Working Diluent	6.5 mL of ProClot Diluent + 1.5 mL of Protac (for one rotor only use 1.3 mL of ProClot Diluent + 0.3 mL of Protein-C Activator)
Cephalin	Refer to insert sheet
CaCl ₂	As it is

PROCLLOT ANALYSIS ONLY

Sample tray positions	Materials
DIL	Working Diluent (2 mL cup)
18	Protein-C Deficient Plasma (2 mL cup)
1 - 16	Samples

Reagent area positions	Materials
2	APTT Cephalin
3	APTT CaCl ₂

Material	Reconstitution
ProClot Diluent	As it is
Protein-C Activator	1.5 mL of distilled water
P-C Def. Plasma	1 mL of distilled water
Working Diluent	6.5 mL of ProClot Diluent + 1.5 mL of Protac (for one rotor only use 1.3 mL of ProClot Diluent + 0.3 mL of Protein-C Activator)
Cephalin	Refer to insert sheet
CaCl ₂	As it is

SINGLE FACTORS OF THE EXTRINSIC PATHWAY CALIBRATION + ANALYSIS

Sample tray positions	Materials
POOL	Calibration Plasma (1st Standard)
DIL	Factor Diluent (2 mL cup)
18	Deficient Plasma (VII or X or V or II) in 2 mL cup
17	Empty cup (0.5 mL)
16	Empty cup (0.5 mL)
1 - 15	Samples

	High Curve	Low Curve
1st Standard	100 % (as it is)	6.25 % (dilute 1 + 15 the 100% with Factor Diluent)

Reagent area positions	Materials
1	Thromboplastin

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
Factor Diluent	As it is
Deficient Plasma	1 mL of distilled water
Thromboplastin	Refer to insert sheet

SINGLE FACTORS OF THE EXTRINSIC PATHWAY ANALYSIS ONLY

Sample tray positions	Materials
DIL	Factor Diluent (2 mL cup)
18	Deficient Plasma (VII or X or V or II) in 2 mL cup
1 - 15	Samples

Reagent area positions	Materials
1	Thromboplastin

Material	Reconstitution
Factor Diluent	As it is
Deficient Plasma	1 mL of distilled water
Thromboplastin	Refer to insert sheet

SINGLE FACTORS OF THE INTRINSIC PATHWAY CALIBRATION + ANALYSIS

Sample tray positions	Materials
POOL	Calibration Plasma (1st Standard)
DIL	Factor Diluent (2 mL cup)
18	Deficient Plasma (VIII or IX or XI or XII) in 2 mL cup
17	Empty cup (0.5 mL)
16	Empty cup (0.5 mL)
1 - 15	Samples

1st Standard **High Curve**
100 % (as it is)

Low Curve
6.25 % (dilute 1 + 15 the
100% with Factor Diluent)

Reagent area positions	Materials
2	APTT Cephalin
3	APTT CaCl ₂

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
Factor Diluent	As it is
Deficient Plasma	1 mL of distilled water
Cephalin	Refer to insert sheet
CaCl ₂	As it is

SINGLE FACTORS OF THE INTRINSIC PATHWAY ANALYSIS ONLY

Sample tray positions	Materials
DIL	Factor Diluent (2 mL cup)
18	Deficient Plasma (VIII or IX or XI or XII) in 2 mL cup
1 - 15	Samples

Reagent area positions	Materials
2	Cephalin
3	CaCl ₂

Material	Reconstitution
Factor Diluent	As it is
Deficient Plasma	1 mL of distilled water
Cephalin	Refer to insert sheet
CaCl ₂	As it is

D-DIMER CALIBRATION

Sample tray positions	Materials
POOL	D-Dimer Calibrator
DIL	D-Dimer Buffer (use 4 mL cup)
18	Empty cup (0.5 mL)
17	Empty cup (0.5 mL)
16	Factor Diluent

Reagent area positions	Materials
1	Latex reagent

Material	Reconstitution
D-Dimer Calibrator	1 mL of distilled water
D-Dimer Buffer	As it is
Factor Diluent	As it is
Latex reagent	3 mL of distilled water

D-DIMER ANALYSIS

Sample tray positions	Materials
DIL	D-Dimer Buffer (4 mL cup)
1 - 18	Samples

Reagent area positions	Materials
1	Latex reagent

Material	Reconstitution
D-Dimer Buffer	As it is
Latex reagent	3 mL of distilled water

APCR-V ANALYSIS

Sample tray positions	Materials
POOL	Calibration Plasma
DIL	Deficient Plasma Factor V (2 mL cup)
18	Calcium Chloride (4 mL cup)
1 - 16	Samples

Reagent area positions	Materials
2	APTT Reagent
3	Activated Calcium Chloride

Material	Reconstitution
Calibration Plasma	1 mL of distilled water
Def. Plasma F V	4 mL of distilled water
APTT reagent	As it is
CaCl ₂	As it is
APC CaCl ₂	2 mL of distilled water

Appendix C

Warning We recommend that setting of the barcode scanner should be carried out by IL authorized personnel.

In any case the enclosed instructions must be strictly followed when setting the barcode scanner.

CCD BARCODE SCANNER SETTING

1. INTRODUCTION

Appendix A provides information related to the programming and checking of the CCD Barcode Scanner P/N 67221.03. The Scanner is standard provided with ACL 3000/3000+, and optional on ACL 2000/1000.

Appendix A is composed by the following subsections:

2. General information
3. Determining the CCD Barcode Scanner type
4. Enabling barcodes into the CCD Barcode Scanner "type A"
5. Enabling barcodes into the CCD Barcode Scanner "type B"
6. Checking the CCD Barcode Scanner
7. Setting of barcodes options
8. Resetting the CCD Barcode Scanner to default configuration

2. GENERAL INFORMATION

The following barcodes can be enabled into the ACL CCD Barcode Scanner P/N 62221.03:

- CODE 128
- CODE 39
- CODE 93
- CODABAR
- CODABAR ABC
- INTERLEAVED 2 OF 5
- MSI
- PLESSEY

The scanner is default programmed to read CODE 128 only. Enabling of different barcodes is achieved following the procedures hereafter reported.

Programming of the CCD Barcode Scanner is carried out by reading special labels, provided in this subsection.

Actually, two types of CCD Barcode Scanners are available, which require different programming procedures. Therefore, before starting with the programming procedure, the scanner type has to be determined, in order to use the proper programming procedure (see subsection 3).

Once the scanner type has been determined, proper programming is achieved by performing as per subsection 4 (scanner "type A"), or subsection 5 (scanner "type B").

After programming the Scanner, check its setting and correct functioning by reading the labels provided in subsection 6.

Disabling of enabled barcodes is described in subsections 4 and 5.

Subsection 7 contains the programming labels to set special options for some of the available barcodes.

Subsection 8 of this document contains the procedures (one for each of the two scanner types) to re-set the scanner to the default configuration. It includes setting of:

- RS 232 interface parameters
- Scanner operator's interface (e.g. buzzer, good reading led)
- Decoding options (e.g. single/multiple reading)

This setting procedures can be used to re-program scanners when initial setting conditions has to be re-established.

*** WARNING ***

As the ability of the Scanner to read labels correctly depends on the quality of the labels themselves, we recommend that further copies of this document are not made. Bad quality of the copies can lead to misreading or, in the worst case, to the inability of the Scanner to read the label.

2.1 Recommendations

This subsection provides some information on known existing limitations for some of the barcode types which can be enabled into the Scanner, and some general recommendations in order to operate the Scanner in the correct way.

- A. The ability of the Scanner to read correctly a barcode depends not only on the self-checking nature of the barcode type itself, but also on the quality of the printed label.
- B. CODABAR has no internal self-checking and is also susceptible to reflected ambient light.
- C. INTERLEAVED 2 of 5 has an internal parity bit but is susceptible to printing errors such as white or black lines at right angles to the "bars".
- D. We recommend enabling only those codes which are in use in the laboratory, in addition to CODE 128, used to decode the labels of the ACL Sample Tray.

3. DETERMINING THE CCD BARCODE SCANNER TYPE

Two different types of CCD Barcode Scanners can be used in conjunction with the ACL; we will identify them as:

- CCD Scanner "type A"
- CCD Scanner "type B"

Due to their different technical characteristics, different setting procedures must be adopted in order to enable the requested barcodes.

This subsection allows you to determine the type of CCD Barcode Scanner that you have to program, and indicates which setting procedure has to be followed.

To determine the type of CCD Barcode Scanner, act as follows:

A. Switch the ACL ON, then activate the Scanner by pushing the relevant button.

B. Read in sequence the two labels provided below; two different conditions can be met:

- The Scanner reads the labels (scanner beeper beeps):
indicates that it is a "type A" Scanner.
Enable the barcodes needed by referring to subsection 4.
- The Scanner does not read the labels:
indicates that it is a "type B" Scanner.
Enable the barcodes needed by referring to subsection 5.

C. After determining the scanner type, proceed with subsection 4 or 5 for the enabling of the requested barcode(s).

SET



END



4. ENABLING BARCODES INTO THE CCD BARCODE SCANNER "TYPE A"

This subsection contains the programming procedure for CCD Barcode Scanner "type A" (scanners which read the labels provided in subsection 3).

The programming session is divided in two phases:

- The first one, called "CHANGING OF BARCODE SETTING" (see subsection 4.1), allows the enabling of one barcode only. Enabling of this barcode, will automatically disable all other barcodes previously enabled into the scanner.
- The second phase, called "ENABLING OF ADDITIONAL BARCODES" (see subsection 4.2), allows the enabling of further barcodes. Enabling of additional barcodes must be carried out after performing phase one.

A maximum of 5 barcode types can be contemporaneously enabled into the scanner.


4.1 Changing of barcode setting

As the labels of the Sample tray are coded with CODE 128, this barcode must always be enabled into the Scanner.

To enable one barcode type perform as per the following procedure:

- A. Switch the ACL ON, then trigger the Scanner ON.
- B. Among the various sets of labels reported here below, locate the one corresponding to the barcode to be enabled.
- C. Read the SET CODE of the barcode to be enabled to get the Scanner into the program mode. The Scanner beeps intermittently to indicate that it is ready to be programmed.
- D. Read the PROG CODE of the Barcode type to be enabled. The scanner beeps once to indicate that it has been done.
- E. Read the END CODE to complete the whole operation. The selected barcode is now enabled; previous settings have been cancelled.

CODE 128 only

SET 

PROG 

END 


CODE 39 only

SET 

PROG 

END 

CODE 93 only

SET 


PROG 

END 

CODABAR only


SET 

PROG 

END 

INTERLEAVED 2 of 5 only

SET 

PROG 

END 

MSI/PLESSEY only

SET 

PROG 

END 

4.2 Enabling of additional barcodes

Up to 5 different barcodes can be contemporaneously enabled into the scanner.

In general terms, the more barcode options enabled on a Scanner, the more likelihood of misreading exists.

We therefore strongly recommend that, at installation, only the code used by the customer be enabled, in addition to the CODE 128, as it is used for the labels of the sample tray.

To enable additional barcodes proceed as follows:

- A. Switch the ACL ON, then trigger the Scanner ON.
- B. Read the SET CODE of the table reported below, to get the Scanner into the program mode.
- C. Read the PROG CODE(s) of the barcode type(s) to be added. The Scanner beeps once each time a PROGRAM CODE is read.
- D. Read the END code to complete the operation. The additional code(s) is(are) now enabled.

SET



Enable Code 39



Enable Codabar



Enable interleaved
2 of 5



Enable Code 93



Enable Code 128



Enable MSI/Plessey



END



5. ENABLING BARCODES INTO THE CCD BARCODE SCANNER "TYPE B"

This subsection contains the programming procedure for CCD Barcode Scanner "type B" (scanners which do not read the label provided in subsection 3).

The programming session consists of two phases:

- The first one, called "DISABLING ALL BARCODES" (see subsection 5.1), allows the disabling of all barcodes previously enabled into the scanner.
- The second phase, called "ENABLING OF BARCODES" (see subsection 5.2), allows the enabling of the needed barcode(s).

A maximum of 5 barcode types can be contemporaneously enabled into the scanner.

5.1 Disabling all barcodes

This subsection provides the procedure to disable all barcodes actually enabled into the scanner "type B" (refer to subsection 3 of this document to determine the scanner type).

To disable all barcodes, proceed as follows:

- A. Switch the ACL ON, then activate the scanner by pushing the relevant button.
- B. Referring to the labels here below, read the SET label to get the scanner into the program mode; once read the scanner beeps four times loudly to indicate that it is ready to be programmed, and switches the LED array OFF.
- C. Press the scanner button. Read the ERASE label; the scanner beeps once softly to acknowledge the reading, and switches the LED array OFF.
- D. Press the scanner button. Read the END label to terminate the programming session; the scanner beeps once softly, four times loudly, and switches the LED array OFF. All barcodes are now disabled.

SET



ERASE



END



5.2 Enabling of barcodes

This subsection provides the procedure to enable barcodes into the scanner "type B" (see subsection 3 to determine the barcode type).

Up to 5 different barcodes can be contemporaneously enabled into the scanner.

In general term, the more barcodes enabled, the more likelihood of misreading exists.

We therefore strongly recommend that, at installation, only the code(s) used by the customer be enabled, in addition to the CODE 128, which is used for the labels of the ACL sample tray.

Disabling of previously enabled barcodes can be achieved by performing the procedure provided in subsection 5.1 of this document.

To enable barcodes, read the labels provided here after.

Usually, the procedure to enable a barcode consists of a SET label, to get the scanner into the program mode, a ENABLE CODE "X" label, to enable the specific code, and a END label, to terminate the programming session. In the case of the scanners "type B", some of the barcodes require the reading of additional labels called 2° label; 3° label. Read these labels in sequence to properly enable the specific code into the scanner.

To enable barcodes, proceed as follows:

- A. Switch the ACL ON, then activate the scanner by pushing the relevant button.
- B. Referring to the tables in next 2 pages, read the SET label to get the scanner into the program mode; the scanner beeps four times loudly to indicate that it is ready to be programmed, and switches the LED array OFF.
- C. Press the scanner button.
Read the ENABLE CODE "X" label(s) of the desired code(s); the scanner beeps once softly for each label read, and switches the LED array OFF.
- D. Press the scanner button.
Read the END label to terminate the programming session; the scanner beeps once softly, four times loudly, and switches the LED array OFF.

SET



ENABLE CODE 128



ENABLE CODABAR
(1° label)



ENABLE CODABAR
(2° label)



ENABLE CODABAR ABC
(1° label)



ENABLE CODABAR ABC
(2° label)



ENABLE INTERLEAVED
2 OF 5
(1° label)



ENABLE INTERLEAVED
2 OF 5
(2° label)



ENABLE INTERLEAVED
2 OF 5
(3° label)



END



SET



ENABLE CODE 93



ENABLE CODE 39



ENABLE MSI
(1° label)



ENABLE MSI
(2° label)



ENABLE MSI
(3° label)



ENABLE PLESSEY
(1° label)



ENABLE PLESSEY
(2° label)



ENABLE PLESSEY
(3° label)



END



6. CHECKING THE SCANNER

Check the functioning of the programmed Scanner by performing the steps reported below.

6.1 Checking of enabled code(s)

A. Switch the ACL ON, access the PROG menu and activate the LOADLIST option.

B. Press DOWN to continue.

Enter a loadlist number (from 1 to 9), then press UP to edit; the first row on the left column of the screen will be shown in reverse.

C. Take the Scanner, press the trigger button and check that the red LED array is activated.

D. Using the labels shown here below, scan the label(s) of the code(s) previously enabled into the Scanner (the labels of the most used codes are provided). Check that:

- The Scanner beeper beeps.
- The red LED array is de-activated.
- The code of the label scanned is shown on the ACL screen.

Repeat steps C and D several times.



CODE 128



CODE 39



INTERLEAVED 2 of 5



CODABAR

6.2. Checking not enabled codes

A. Perform as per previous point 6.1, step A and B, to get into the LOADLIST mode.

B. Take the Scanner, press the trigger button and check that the red LED array is activated.

C. Using the labels shown in previous page, scan those codes not enabled into the Scanner (e.g. if into the Scanner CODE 39 has been enabled then read all labels except the one of CODE 39).
Check that:

- The multitone buzzer of the Scanner does not sound.
- The red LED array remains ON.
- The code of the label scanned is not shown on the ACL screen.

Repeat steps B and C several times.

6.3. Scanning alphanumeric or "long" codes

This test allows the checking of the Scanner when reading labels carrying alphanumeric codes (only for CODE 39; CODE 128) or labels carrying codes longer than 12 bits (for CODABAR; INTERLEAVED 2 of 5). As the system can only manage numeric codes with a maximum code length of 12 bits, scanning the labels reported below has to trigger an internal alarm.

Perform as follows:

- A. Perform as per previous point 6.1, steps A and B, to get into the LOADLIST mode.
- B. Take the Scanner, press the trigger button and check that the red LED array is activated.
- C. Using the labels below reported, scan the label(s) of the code(s) previously enabled into the Scanner (the labels of the most used codes are provided). Check that:
 - The Scanner beeper beeps.
 - The ACL emits a long (750 ms) beep.
 - The red LED array of the Scanner is de-activated.
 - The code of the label scanned is not shown on the ACL screen.

Repeat steps B and C several times.



CODE 128



CODE 39



INTERLEAVED 2 of 5



CODABAR

6.4 Checking of the Scanner time out

- A. Holding the Scanner with the hand, press its trigger button.
- B. Check that the red LED array of the Scanner is activated.
- C. Check that 10 seconds after the activation, the red LED array of the Scanner is de-activated.

7. SETTING OF BARCODES OPTIONS

This subsection allows you to "personalize" the following barcode types:

- INTERLEAVED 2 OF 5
- CODABAR
- CODE 39

Two separate procedures exist for setting barcode options, depending the CCD Barcode Scanner type (CCD Barcode Scanner "type A"; CCD Barcode Scanner "type B"; refer to subsection 3 of this document to determine the scanner type).

7.1 Setting of Barcodes options for CCD Barcode "type A"

*** NOTE ***

The labels provided in this subsection can be read by CCD Barcode Scanners "type A" having date codes higher than FC91800131. The date code digits, located on the cable of the scanners, have the following meaning:

- 91: year
- 8: month (August in this case); from 1 to 9, means from January to September. October is X, November is Y, December is Z.
- 00131: production number.

To set the available options for the CCD Barcode Scanner "type A", perform as per the following procedure:

- A. Switch the ACL ON, then trigger the Scanner ON.
- B. Choose the family of barcodes to be personalized (codes INTERLEAVED 2 OF 5; CODABAR; CODE 39).
- C. Among the various labels here after provided, locate the ones corresponding to the option(s) to be enabled.
- D. Read the SET CODE get the Scanner into the program mode. The Scanner beeps intermittently to indicate that it is ready to be programmed.
- E. Read the PROG CODE(s) of the option(s) to be enabled. The Scanner beeps once to indicate that it has been done.
- F. Read the END CODE to complete the whole operation. The new setting is now set in memory.

7.1.a Options for INTERLEAVED 2 OF 5

set



Disable check digit calculation



Enable check digit calculation



Not transmit check digit



end



7.1.b Options for CODABAR

set 

Not transmit start/stop characters



Enable check sum calculation



Disable check sum calculation



Not transmit check character



Normal + ABC + CX codes



Only ABC code pair reading



Only CX code pair reading



Only normal code reading



end 

7.1.c Option for CODE 39

set



Disable check sum calculation



Enable check sum calculation



Not transmit check character



Not transmit start/stop characters



Normal code 39 mode



end



7.2 Setting of Barcodes options for CCD Barcode "type B"

To set the available options for the CCD Barcode Scanner "type B", perform as per the following procedure:

- A. Switch the ACL ON, then trigger the Scanner ON.
- B. Choose the family of barcodes to be personalized (codes INTERLEAVED 2 OF 5; CODABAR; CODE 39).
- C. Among the various labels here after provided, locate the ones corresponding to the option(s) to be enabled.
- D. Read the SET CODE to get the Scanner into the program mode; the Scanner beeps four times to indicate that it is ready to be programmed, and switches the LED array OFF.
- E. Push the Scanner button.
Read the PROG CODE(s) of the option(s) to be enabled.
The Scanner beeps once for each label read, and switches the LED array OFF.
- F. Push the Scanner button.
Read the END CODE to complete the whole operation; the scanner beeps four times, and switches the LED array OFF.
The new setting is now set in memory.

7.2.a Options for INTERLEAVED 2 OF-5

Set



Disable check digit
calculation (1st label)



Disable check digit
calculation (2nd label)



Disable check digit
calculation (3rd label)



Not transmit check
digits



End



7.2.b Options for CODABAR

Set



Not transmit start/stop
characters (1° label)



Not transmit start/stop
characters (2° label)



Read Codabar without
check sum



Disable checksum
transmission (1° label)



Disable checksum
transmission (2° label)



Disable checksum
transmission (3° label)



Disable checksum
transmission (4° label)



End



Set



Read Codabar ABC without
transmitting checksum (1° label)



Read Codabar ABC without
transmitting checksum (2° label)



Read Codabar ABC without
transmitting checksum (3° label)



Read Codabar ABC without
transmitting checksum (4° label)



Read Codabar ABC without
transmitting checksum (5° label)



Read Codabar ABC without
transmitting checksum (6° label)



End



7.2.c Option for CODE 39

Set



Disable check sum
calculation



Not transmit check
character



End



8. RESETTING THE CCD BARCODE SCANNER TO DEFAULT CONFIGURATION

This subsection contains the complete scanners re-programming procedures (one for each of the two scanner types which can used with the ACL), which allow the re-setting to the default conditions of the following parameters:

- Enabled barcode (CODE 128 only)
- RS 232 interface setting
- Scanner operator's interface (e.g. buzzer, good reading led)
- Decoding options (e.g. single/multiple reading)

This setting procedure can be used to re-program a scanner when initial setting conditions has to be re-enstabilished.

The two mentioned setting procedures are hereafter provided.

8.1 Resetting the CCD Barcode Scanner "type A"

This procedure allows you to re-program into the "type A" scanner (see subsection 3 to determine the scanner type) all default setting parameters; after performing this procedure, only CODE 128 will be enabled into the scanner.

To re-program the scanner, read in sequence all labels provided with this subsection (after reading the SET label, the scanner beeps intermittently to indicate that it is in program mode; for each further label read, the scanner beeps once to acknowledge the reading; after reading the END label the LED array is de-activated).



SET



RS232c default



Only Code 128



Code39, disable checksum calculation



Code39, disable Start/Stop characters



Codabar, disable Start/Stop characters



Disable check sum calculation



Disable fixed length



9600 Baud



8 Data bits



No parity bits



1 Stop bit



No handshaking



Enable buzzer of 3kHz, 2.5kHz interval



Duration of buzzer: 0.2 sec



Buzzer loudness maximum



Synchronize goodread led with buzzer



Positive bar code only



Single read



Leds on for 10 seconds



Trigger enable



Four times redundant reading



Output for low and high density labels



END

8.2 Resetting the CCD Barcode Scanner "type B"

This procedure allows you to re-program into the "type B" scanner (see subsection 3 to determine the scanner type) all default setting parameters; after performing this procedure, only CODE 128 will be enabled into the scanner.

To re-program the scanner, read in sequence all labels provided with this subsection.



The scanner beeps 4 times loudly and deactivates the LEDs.



The scanner beeps once softly, 4 times loudly and deactivates the LEDs.



The scanner beeps 4 times loudly and deactivates the LEDs.



The scanner beeps once softly and deactivates the LEDs.



The scanner beeps once softly and deactivates the LEDs.



The scanner beeps
once softly and de-
activates the LEDs.



The scanner beeps
once softly, 4 times
loudly and de-
activates the LEDs.

APPENDIX C1

"Type C" Barcode Scanner Setting

1. INTRODUCTION

Appendix C1 explain the programming mode for a new type of barcode scanner.

The two previous model called "Type A" and "Type B" still remain in use and all the information in Appendix C are still reliable, in particular, see Appendix C. for General Information (par.2.) and to Check the CCD Barcode Scanner functionality (par.6.).

The Scanner is standard provided with ACL 3000/3000+/6000, and optional on ACL 2000/1000/7000.

For an easy comprehension starting from now we call the third type "Type C".

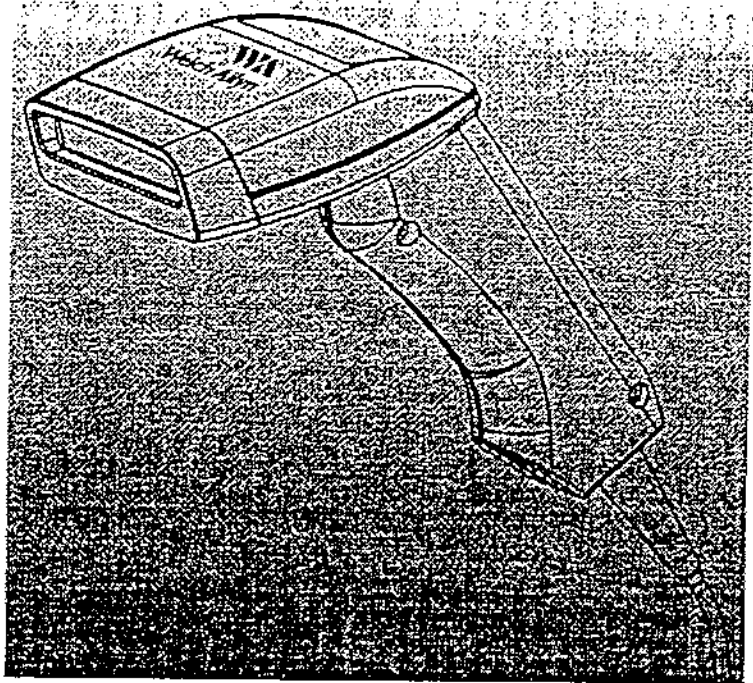
Appendix C1 is composed by the following subsections:

2. Determining the CCD Barcode Scanner type
3. Enabling barcodes into the CCD Barcode Scanner "type C"
4. Setting of barcodes options
5. Resetting the CCD Barcode Scanner to default configuration.

2. DETERMINING THE CCD BARCODE SCANNER TYPE

With the three type of barcode available the procedure for determining the type you have to program is a little more complex but if you look at figure A. you can probably see immediately if you have the barcode scanner "Type C".

Figure A.
Barcode Scanner "Type C"



To be sure, proceed as follows:

- A. Switch the ACL ON, then activate the Scanner by pushing the relevant button.
- B. Read in sequence the two labels provided below:

SET



END



Two different conditions can be met:

- The Scanner reads the labels (scanner beeper beeps):

indicates that it is a "type C" Scanner. Enable the barcodes needed by referring to this **Appendix C1**.

- The Scanner does not read the labels:

indicates that it is a "type A" or "type B" Scanner. Enable the barcodes needed by referring to **Appendix C**.

C. After determining the scanner type, proceed with section 3 for the enabling of the requested barcode(s).

After programming the Scanner, check its setting and correct functioning by reading the labels provided in **Appendix C section 6**.

3. ENABLING BARCODES INTO THE CCD BARCODE SCANNER "TYPE C"

This subsection contains the programming procedure for CCD Barcode Scanner "type C".

The programming session consists of two phases:

- The first one, called "DISABLING ALL BARCODES" (see subsection 3.1), allows the disabling of all barcodes previously enabled into the scanner.
- The second phase, called "ENABLING OF BARCODES" (see subsection 3.2).

<p>A maximum of 5 barcode types can be contemporaneously enabled into the scanner.</p>

3.1. Disabling all barcodes

This subsection provides the procedure to disable all barcodes actually enabled into the scanner "type C".

To disable all barcodes, proceed as follows:

- A. Switch the ACL ON, then activate the scanner by pushing the relevant button.
- B. Referring to the labels here below, read the SET label to get the scanner into the program mode;
once read the scanner beeps loudly to indicate that it is ready to be programmed, and switches the LED array OFF.
- C. Press the scanner button.
Read the ERASE label; the scanner beeps once softly to acknowledge the reading, and switches the LED array OFF.
- D. Press the scanner button.
Read the Exit label to terminate the programming session; the scanner beeps once softly, four times loudly, and switches the LED array OFF. All barcodes are now disabled.

SET



ERASE



END



3.2 Enabling of barcodes

This subsection provides the procedure to enable barcodes into the scanner "type C".

In general term, the more barcodes enabled, the more likelihood of misreading exist.

We therefore strongly recommend that, at installation, only the code(s) used by the customer be enabled, in addition to the CODE 128, which is used for the labels of the ACL sample tray.

Usually, the procedure to enable a barcode consists of a SET label, to get the scanner into the program mode, read ENABLE CODE "X" label, to enable the specific code, and read END label, to terminate the programming session.

To enable barcodes, proceed as follows:

- A. Switch the ACL ON, then activate the scanner by pushing the relevant button.
- B. Referring to the two tables in next page, read the SET label to get the scanner into the program mode; the scanner beeps loudly to indicate that it is ready to be programmed, and switches the LED array OFF.
- C. Press the scanner button.
Read the ENABLE CODE "X" label(s) of the desired code(s); the scanner beeps softly for each label read, and switches the LED array OFF.
- D. Press the scanner button.
Read the END label to terminate the programming session; the scanner beeps, and switches the LED array OFF.

CODE 128

SET



ENABLE CODE 128
(LABEL 1)



ENABLE CODE 128
(LABEL 2)



EXIT



CODE PLESSEY

SET



ENABLE PLESSEY
(LABEL 1)



ENABLE PLESSEY
(LABEL 2)



EXIT



CODE MSI

SET



ENABLE CODE MSI
(LABEL 1)



ENABLE CODE MSI
(LABEL 2)



EXIT



CODE 39

SET



ENABLE CODE 39
(LABEL 1)



ENABLE CODE 39
(LABEL 1)



EXIT



CODE INTERLEAVED 2/5

SET



ENABLE INTERLEAVED 2/5
(LABEL 1)



ENABLE INTERLEAVED 2/5
(LABEL 2)



EXIT



CODE CODABAR

SET



ENABLE CODABAR
(LABEL 1)



ENABLE CODABAR
(LABEL 2)



EXIT



CODE 93

SET



ENABLE CODE 93
(LABEL 1)



ENABLE CODE 93
(LABEL 2)



EXIT



4. SETTING OF BARCODES OPTIONS TYPE C

This subsection allows you to "personalize" the following barcode types:

- INTERLEAVED 2 OF 5
- CODABAR
- CODE 39

To set the available options for the CCD Barcode Scanner "Type C", perform the following procedure:

- A. Switch the ACL ON, then trigger the Scanner ON.
- B. Choose the family of barcodes to be personalized (codes INTERLEAVED 2 OF 5; CODABAR; CODE 39).
- C. Among the various labels here after provided, locate the ones corresponding to the option(s) to be enabled.
- D. Read the SET CODE to get the Scanner into the program mode; the Scanner beeps to indicate that it is ready to be programmed, and switches the LED array OFF.
- E. Push the Scanner button.
Read the PROG CODE(s) of the option(s) to be enabled.
The Scanner beeps once for each label read, and switches the LED array OFF.
- F. Push the Scanner button.
Read the END CODE to complete the whole operation; the scanner beeps, and switches the LED array OFF.
The new setting is now set in memory.

Options for INTERLEAVED 2 OF 5

SET



CHECK DIGIT REQUIRED
DISABLE



CHECK DIGIT TRANSMIT
DISABLE



END



Options for CODABAR

SET



START STOP TRANSMIT
DISABLE



CHECK CHARACTER REQUIRED
DISABLE



CHECK CHARACTER TRANSMIT
DISABLE



EXIT



Option for CODE 39

SET



CHECK CHARACTER
DISABLE



START/STOP TRANSMIT
DISABLE



CHECK CHARACTER TRANSMIT
DISABLE



EXIT



5. RESETTING THE CCD BARCODE SCANNER TO DEFAULT CONFIGURATION

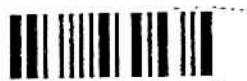
This subsection contains the complete scanners re-programming procedures, which allow the re-setting to the default conditions of the following parameters:

- Enabled barcode (CODE 128 only)
- RS 232 interface setting

This setting procedure can be used to re-program a scanner when initial setting conditions has to be re-established.

RESETTING BARCODE TYPE C

SET



DISABLE ALL BARCODE



CODE SELECTION 128



ENABLE



EXIT












CARRIAGE RETURN



ENTER RS232 PROGRAM



BAUD RATE SELECTION	
9600	
PARITY SELECTION	
NONE	
DATA FORMAT	
8 BIT	
CTS HANDSHAKE SELECTION	
DISABLE	
EXIT	

Introduction

In the following are described the characteristics of the Welch Allyn scanner installed in ACL 7000 instruments.

Purpose of this document is to give indication of the scanner characteristics in terms of readable codes, identify requirements the barcode labels have to satisfy and define constraints in terms of label positioning within ACL 7000 instrument.

Supported Codes and Checksum type

Code Type	Checksum Type	Data Digits
Code 128	AIM Procedure	up to 12
Code 39	Modulus 43	up to 12
	No Checksum	up to 12
Interleaved 2 of 5	USS - Modulus 10	up to 12
	OPCC - Modulus 10	up to 12
Codabar	AIM - Modulus 16 with start/stop digits	up to 12
	NW7 - Modulus 11	up to 12
	NW7 - Modulus 16 with start/stop digits	up to 12
	No Checksum	up to 12

All bar code symbols have to satisfy the appropriate AIM Uniform Symbology Specification.

In addition the following characteristics have to be considered:

- **Background substrate:** the barcode symbol should be printed on material which is reflective and has a matte (not glossy) finish. A background diffuse reflectance of at least 70% to 80% is suggested for optimum contrast.
- **Ink color and type:** the ink type has to be compatible with 660 nm LEDs used in the scanner. The barcode symbols inked bars should not exceed 10% reflectance at 660 nm which is being used for reading, whether printed with black ink or colored ink.
- **Voids and Specks:** the code has to be printed clearly, free of voids, specks, blemishes and lines which could "fool" the scanner.
- **Definition:** the bars in the barcode symbols should be well defined. Their edges should not be rough or fuzzy, so that bar and spaces have the proper widths intended for the used barcode symbol. Definition should be sharp and consistent.
- **Tolerance:** the ratio of the widths and spaces in a barcode symbol must conform to the appropriate AIM barcode specifications and can cause problems if not correct throughout the barcode. Problems can occur if bar edges are smeared or rough, or when they exhibit voids.

Barcode Label Positioning

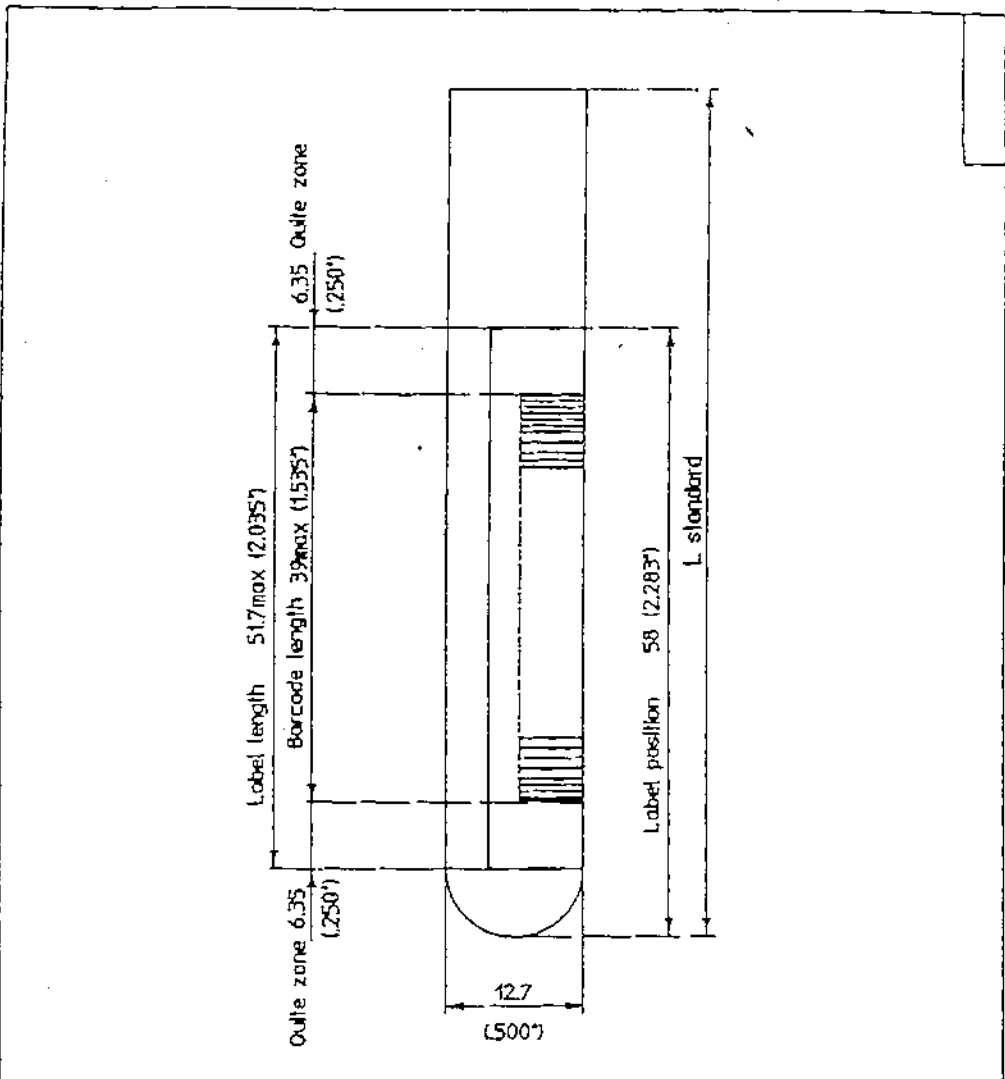
The attached drawing defines barcode labels dimensions and identify constraints in positioning labels on vacutainers.

The 13x75 vacutainers have been considered.

The proposed barcode labels dimension and positioning apply both to high and low sample tray models.

The following measurements are reported:

- Maximum label length (global label size) : 51.7 mm (2.035")
- Maximum barcode length (printed area): 39 mm (1.535")
- Quiet zone (white area before and after the printed area): 6.35 mm (.250")
- Label position (it is identified as the label edge measured starting from the vacutainer lower part): 51.7 mm (2.035")



REV.	DATE	DESCRIPTION	BY	APPO	NEXT ASST	Qty	USED ON
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