

ELLIPSE

User Manual



**Analyzer
Medical
System**

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CONFIGURATION SHEET

CHAPTER	DESCRIPTION	REVISION
INDEX	TABLE OF CONTENTS	02
01	INSTALLATION	02
02	GENERAL DESCRIPTION	02
03	SOFTWARE DESCRIPTION	02
04	DAILY ROUTINE	01
05	METHODOLOGY	01
06	CALIBRATION CURVES	01
07	MAINTENANCE	02
08	FORMULAS AND CALCULATION MODELS	01
09	ERROR SIGNALING AND TROUBLESHOOTING	02
10	HOST COMMUNICATION	01
11	PACKING LIST	01
12	DIAGNOSTIC PROGRAM	03

TABLE OF CONTENTS

Chapter 01	INSTALLATION
Chapter 02	GENERAL DESCRIPTION
Chapter 03	SOFTWARE DESCRIPTION
Chapter 04	DAILY ROUTINE
Chapter 05	METHODOLOGY
Chapter 06	CALIBRATION CURVES
Chapter 07	MAINTENANCE
Chapter 08	FORMULAS AND CALCULATION MODELS
Chapter 09	ERROR SIGNALING AND TROUBLESHOOTING
Chapter 10	HOST COMMUNICATION
Chapter 11	PACKING LIST
Chapter 12	DIAGNOSTIC PROGRAM

CHAPTER 01 - INSTALLATION

INDEX

1.1	UNPACKING	2
1.2	INSTALLATION	4
1.2.1	INSTALLATION SITE SPECIFICATIONS	4
1.2.2	ELECTRIC CURRENT REQUIREMENTS	4
1.2.3	CONNECTION OF THE ACCESSORIES	5
1.2.3.1	POWER SUPPLY	5
1.2.3.2	COMPUTER - INSTRUMENT CONNECTION	6
1.2.3.3	HYDRAULIC CONNECTIONS	6
1.2.4	ATTENTION	6
1.2.5	SYMBOLS	7
1.2.6	REGULATORY COMPLIANCE	8
1.2.7	LIMITATION OF USE	8
1.2.8	BARCODE READER	8
1.2.9	WARRANTY	8
1.2.10	CONSUMABLES AND ACCESSORIES PARTS LIST OUT OF WARRANTY	9

1.1 UNPACKING

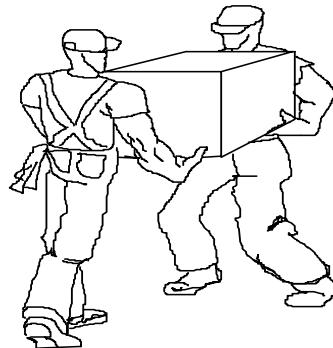
The **ELLIPSE** is packed and delivered in two separate wooden crates: one contains the analyzer itself and the other the computer, along with its accessories. In the event that the order does not include the PC component, the packing and delivery will involve one wooden crate plus a corrugated cardboard box. The packing has been expressly studied and designed to insure maximum protection of the contents during shipping and handling. It is therefore extremely important that the crate(s)/box be carefully examined upon delivery in order to ascertain their integrity. Special attention should be dedicated to examining the color of the "Shock Watch" glued to the crates, which must show the color 'white'. A 'red' "Shock Watch" indicates that the crate(s) have experienced some sort of 'shock' during handling, transport and/or delivery. This fact must be noted by the courier on the delivery note, as must any and all visible external damage (for example: holes, dents, rips or tears, water marks, etc.) evident at the moment of delivery. This will simplify matters in the event of any future claims for damages.

Upon arrival of the crate(s)/box, take out the delivery note and make sure that all the items on the packing list are included in the crates and are undamaged. Make sure the series number on the delivery note/packing list corresponds to that impressed on the plate on the left side of the instrument.



Open the crate(s)/box from the top and very carefully take out:

- the instrument;
- the computer and accessories.



MAKE SURE THAT THE UNPACKING IS CARRIED OUT BY TWO PEOPLE.

Do not discard the delivery crate(s)/box or the packing material until the correct functioning of the instrument has been ascertained.

Remove all the items from the crate(s)/box very carefully.

Before connecting the "*Ellipse*", remove the protective packing material placed under the sampling arm and under the wash station group.

Warning: in the event that it is necessary to repack any or all of the delivered item(s), the following procedures must be carefully followed:

- Reposition the protective packing material under the sampling arm and under the wash station group.
- Tape down (using masking tape if possible) the cover of the samples and reagents housing, the front panels, and the samples and reagents racks.
- Remove the probe from the sampling arm and place it inside a primary tube. Then cap the tube and tape the cap down.
- Be very careful to not bend the wash station cannulas when repositioning the protective packing material.
- Fill the empty spaces around the accessories packed in the crate using "pluriballs" or other suitable packing material.

1.2 INSTALLATION

The ELLIPSE must only be installed by a qualified technician who has been authorised and trained to do so. During its installation the system will be checked once again to ensure correct functioning. The persons who are required to operate the ELLIPSE system must have received the adequate training. This should also include the "know-how" of the normal maintenance for the instrument. A description of the maintenance will be found in Chapter 7 of this manual.

ELLIPSE is a complex system, and it is therefore extremely important that it is correctly installed in order to fully guarantee fine performance. If the installation and use directions, given in this manual, are not correctly followed and/or safety indications are not respected, AMS cannot guarantee correct functioning of the instrument. Apart from this, the safety of the operator could be placed at risk.

1.2.1 INSTALLATION SITE SPECIFICATIONS

Ascertain that the ELLIPSE system is not exposed to direct sunlight, draughts, dust or strong magnetic fields. In addition, please take note of the following conditions required for the location of the installation:

USE	In covered and dry place
DEGREE OF POLLUTION	2
INSULATION CLASS	I
INSTALLATION CATEGORY	II
TEMPERATURE	Between 18°- 30°C
HUMIDITY	20% ÷ 85%
ALTITUDE	Max 3000 m
LOCATION	Shelf or table with a minimum surface of 75 x 60 cm stable and free of vibration
VENTILATION	Leave a minimum distance of 10 cm around the instrument to permit air circulation. Make sure that the front and rear holes are not blocked by any object

1.2.2 ELECTRIC CURRENT REQUIREMENTS

The power voltages to which the instrument is adapted are indicated on the left-hand side (see fig. 1). It must be plugged into a plug of the correct voltage.

VOLTAGE	100÷ 230 Vac 47/63 Hz ± 10%
FUSES	6.3 A /T - 5 x 20

NOTE: IT IS ADVISABLE TO MAINTAIN THE MAXIMUM STABILITY OF THE ELECTRICAL CURRENT IN THE LABORATORY. WHERE THIS IS NOT POSSIBLE OR ASCERTAINABLE, USE OF THE FOLLOWING SUPPLEMENTARY DEVICES IS RECOMMENDED:

ELECTRONIC STABILIZER

Used to stabilise the electric voltage in the laboratory. Any stabiliser with a power potential greater than 0.5 KW, currently available on the market, can be used.

NO-BREAK MODULE UPS - (Uninterrupted Power Supply)

This module provides two important functions:

- stabilises the main-line power
- supplies current to the instrument in case of a main-line power failure.

1.2.3 CONNECTION OF THE ACCESSORIES

1.2.3.1 POWER SUPPLY



Warning. Fire hazard. For continued protection
replace with the same type and rating of fuses.
Warning. Disconnect line cord before opening.
Fuses 6,3 Asb / T - 5x20 ~ 100 - 230 V

Fig. 1 – Plug (use the feeder cable supplied with the instrument).

The sticker below the plug in indicates the power supply voltage and the values of the fuses.

1.2.3.2 COMPUTER - INSTRUMENT CONNECTION

The instrument and the Personal Computer are connected by one serial RS232 standard cable (Cod. 9-35-0055-01), which provides the hardware support for the communication.

1.2.3.3 HYDRAULIC CONNECTIONS

The instrument uses Cleaning solution and distilled water for reaction cuvettes cleaning; it uses Rinse solution for sampling probe cleaning and cuvette blank determination (WBL). A second Rinse hydraulic line is used for cuvettes quality control checking after washing.

For connecting said solution there are four inlet on the instrument left side identified by roman numbers as here below specified:

- I Rinse solution (green color)
- II Rinse solution (yellow color)
- III Distilled water (blue color)
- IV Cleaning solution (red color)

The waste hydraulic lines are located on the instrument right side

Further information can be taken on the Hydraulic diagram (SI 16 00571 01 Service manual -chapter 04).

1.2.4 ATTENTION

The following label is found at the rear of the instrument.



NOTE: THE REAR PANELS OF THE INSTRUMENT MUST NEVER BE OPENED WITHOUT HAVING FIRST SWITCHED THE INSTRUMENT OFF AND DISCONNECTED THE ELECTRICITY CABLE.

THE MAINTENANCE AND CLEANING PROCEDURES FOUND IN CHAPTER 07 OF THIS MANUAL MUST BE RESPECTED AT ALL TIMES. REMEMBER TO FOLLOW THE DECONTAMINATION PROCEDURE WHEN REQUIRED BEFORE INSTRUMENT MAINTENANCE OPERATION (SEE CHAPTER 07).

1.2.5 SYMBOLS



ATTENTION: READ THE INSTRUCTIONS IN THE USER MANUAL



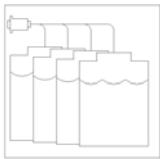
TERMINAL OF TOTAL MASS PROTECTION (CONDUCTOR)



BIOLOGICAL HAZARD

(LOCATED NEAR THE REACTION PLATE AREA)

Carefully manipulate all the consumables and the wastes produced during the analysis routines. Use appropriate protective garment. Disposal of wastes must be done in compliance with applicable regulation. It is recommended to periodically check the level in the waste container, in order to avoid overflow.



INDICATES THE BOTTLES CONNECTION

- | | |
|------------|--------------------------|
| I | RINSE SOLUTION |
| II | RINSE SOLUTION |
| III | DISTILLED WATER |
| IV | CLEANING SOLUTION |



STAND-BY BUTTON



BUZZER FORCE OFF BUTTON

**BARCODE READER BUTTON**

1.2.6 REGULATORY COMPLIANCE

The ELLIPSE instrument complies with:

- European Directive 98/79/CE for In Vitro Diagnostic Devices

1.2.7 LIMITATION OF USE

The ELLIPSE can not be used by blind operators because the user interface with the system requires a monitor.

Furthermore the ELLIPSE must be used with particular caution by color blind operators because the graphic interface displays different colors with different meaning.

1.2.8 BARCODE READER

A bar code reader can be optionally installed on the ELLIPSE. The barcode reader has a laser micro-scanner classified as Class II laser device. It is compliant with applicable safety regulations.

WARNING TURN OFF ALWAYS THE INSTRUMENT before removal of those panels and covers that protect from any interference and/or exposure to the laser beam active during sample identification.

1.2.9 WARRANTY

AMS guarantees the substitution of all defective components and/or materials for a period of time not above of fourteen months starting from the date of invoicing. Saying warranty, as well as Technical Assistance, generally is intended furnished as net ex factory Rome.

This warranty does not include consumable and instrument parts in contact with liquids. All components not covered by the warranty are reported in the table on the next page.

Besides warranty does not cover damage caused by:

- improper use of the ELLIPSE instrument (or however not according to the Producer or Seller instructions)
- bad transport
- insufficient (or missing) preventive maintenance by the User

In particular any damages due to the transport must be immediately reported to the carrier when he delivers.

1.2.10 CONSUMABLES AND ACCESSORIES PARTS LIST OUT OF WARRANTY

Description	Type	Quantity (Pieces)	Code
Reagents containers	35 ml	12	C101-00190-00
Reagents containers	6 ml	12	C101-00191-00
Samples cups	0.8 ml	1000	AS650002
Short samples cups	1 ml	1000	AS650100
Adapter for short samples cups		1	9-01-0609-00
Reaction sectors		6	C101-00217-00
Washing solution bottle	2 lt	1	9-35-0041-00
Bottle level sensor		1	9-05-0078-00
Tubing Kit for peristaltic pump		2	65-01835-00
Tubing Kit – complete		1	65-01836-00
Cleaning solution	250 ml	2	ASRN0020
Rinse solution	50 ml	1	ASRN0021
Sampling probe (internal needle)		1	05-00707-00
Complete Sampling probe		1	10-00703-00
Drying Pad		1	01-01920-00
Halogen Lamp (6 V - 10 W)		1	9-35-0016-00
Interferential filters Kit (Stablife)		1	65-02017-00
Fuse 6,3 A-T	5x20	10	C132-01238-08
Inlet/outlet fitting for Rinse & Clean conts		1	01-01224-00
Cuvettes protection cover		1	05-01249-00
Reagent protection cover		1	10-00584-00
Reagent plate		1	10-00585-00
Samples rack		1	05-01829-00
Washing station, first or second cannulas (A)		1	05-01633-00
Washing station, third cannula (B)		1	05-01633-01
Washing station, fourth cannula (C)		1	05-01638-00
Washing station, fifth cannula without pad (D)		1	05-01919-00
Diluter Micro-Pump		1	05-01710-40
Air Micro-Pump (μ P 6)		1	05-02454-20
Micro-Pump (μ P 2 ÷5)		1	05-01826-16
Predilution rack		1	05-01735-00
Solenoid Valve –2 way		1	9-35-0035-00
Solenoid Valve –3 way		1	9-35-0036-00

CHAPTER 02 – GENERAL DESCRIPTION

INDEX

2.1	INTENDED USE AND SYSTEM DESCRIPTION	2
2.2	ANALYSES CYCLE	3
2.2.1	REACTION PLATE	3
2.2.2	REACTION PLATE CYCLE	3
2.2.3	SAMPLING ARM - OPERATIONAL SEQUENCE	4
2.2.4	SAMPLING SYSTEM	5
2.2.5	WASH STATION	6
2.2.6	WASH STATION CYCLE	6
2.3	TECHNICAL-OPERATIVE SPECIFICATIONS	7
2.3.1	SOFTWARE AND COMPUTER SPECIFICATIONS	8
2.3.2	OPTIONAL MODULES	9
2.3.3	DIMENSIONS, WEIGHT AND OPERATING ENVIRONMENT	9
2.3.4	INSTALLATION SPECIFICATIONS	9

2.1 INTENDED USE AND SYSTEM DESCRIPTION

The “*Ellipse*” is a random access, computer controlled, counter-top, clinical analysis instrument. The system can perform 138 tests per hour and has a machine cycle of 26 seconds. Its execution time ranges from a minimum of 18 seconds to a maximum of 1040, depending on the analysis method chosen.

The first time the system is used for laboratory analyses, the operator must configure the system based on the specific needs of that laboratory; i.e.: the chemistry parameters and the reagents racks, along with the normal, calibrated and control values, must all be defined.

The “*Ellipse*” is an “OPEN” system that allows configuration with different reagents selected by the customer in order to fit his needs.

NOTE:

In order to assure the analytical performances of the system “instrument + reagents”, it is responsibility of the laboratory staff to use reagents, controls and calibrators validated on the “*Ellipse*”, or in alternative, to qualify other reagents, controls and calibrators in compliance with the applicable regulations.

The daily routine analyses will be carried out according to patient sample arrival in a sequential and continuous, non-stop manner.

The work list is organized using a loading rack holding up to 8 patient samples. Rack loading is non-stop.

The racks can accommodate test tubes or micro caps. The bar code for primary tubes and reagent containers is an optional feature.

When the system, the analytical unit and the computer, is turned on the color-meter lamp is supplied with low voltage power (1.2 volts), the sampling arm pre-heater remains turned off, while instead the reaction plate heater, the reagents refrigerating unit (optional module) and the electronic components are turned on.

In this phase, the "Stand-by" light, placed on the front panel, will flash until the reaction plate reaches a temperature of 36° C. When this temperature is reached, the "Stand-by" light will stop flashing and will remain constantly lit.

In the case of system failure or malfunction, the "Ready" light, situated on the front panel of the instrument, will light up red.

In order to access the main program, double click on the "*Analyzer*" icon on the computer desktop.

The main menu - "System Monitor" - will appear.

Whenever any system function is launched, the color-meter lamp and the sampling arm pre-heater will receive regular power.

2.2 ANALYSES CYCLE

2.2.1 REACTION PLATE

The reaction plate of the "*Ellipse*" system contains 6 disposable racks with 20 reaction cuvettes each.

The racks can be removed individually.

The basic operating cycle of the reaction plate takes 26 seconds. This cycle includes: optic reading of the cuvettes in incubation, aspiration and dispensing of the reagents and the samples by the arm, along with the relative positioning of the plate.

The reactions take place at 37° C. This temperature is maintained constant by a controlled heating unit placed under the reaction plate.

2.2.2 REACTION PLATE CYCLE

After reagents and samples have been placed in cuvette #1, the reaction plate will rotate 40 positions counter-clockwise, so as to bring the first cuvette to be analyzed in front of the color-meter for reading with either one or two wavelengths, if required.

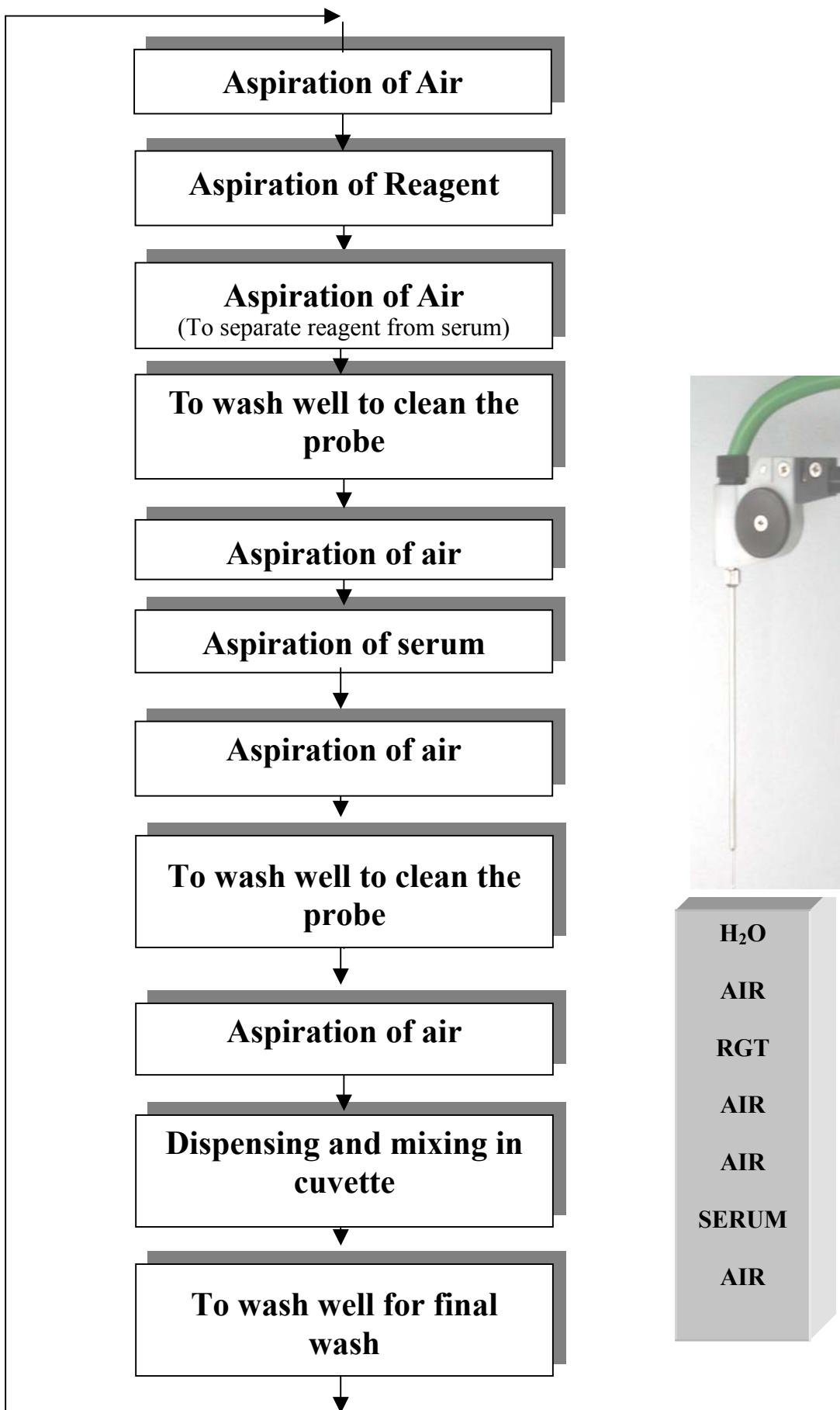
The plate will then, moving clockwise, carry out all the readings of any other prepared cuvettes. After having effectuated all the readings, the plate will move counter-clockwise to its initial position minus one cuvette, ready for a new dispensing.

In this manner, the reaction cuvettes move clockwise 1 - 2 - 3 - 4 for dispensing, washing and the relative readings.

2.2.3 SAMPLING ARM - OPERATIONAL SEQUENCE

1. The sampling arm lifts up from the wash well and carries out a wash cycle;
2. The arm moves toward the specific reagent container, while the diluter aspirates an air bubble to separate the rinse column from the reagent;
3. The arm lowers itself into the reagent, below the level indicated by the sensor, and aspirates the required quantity of reagent. If the method requires a Rinse (used in order to reduce the possibility of negative contamination between the water column and the reagent) an extra amount of reagent (not used in the analysis) will be aspirated before the quantity of reagent necessary for the analysis, along with another air bubble for their separation;
4. While the diluter aspirates a second air bubble, the arm rises and then lowers into the wash well so that it can be washed externally, to minimize cross contamination;
5. The arm moves to the specified sample and aspirates a third air bubble;
6. Once the level sensor has indicated the presence of the liquid, the arm stops and aspirates the sample;
7. The arm once again is raised, while the diluter aspirates a fourth air bubble to prevent sample loss;
8. At this point, the arm returns to the wash well in order to clean the outside of the probe and aspirates a fifth air bubble;
9. The arm moves to the reaction plate, dispenses, and mixes the reagent and sample in the reaction cuvette for incubation and reading;
10. The arm returns to the wash well and carries out a probe wash cycle.

2.2.4 SAMPLING SYSTEM



2.2.5 WASH STATION

The reaction plate wash station is made up of a series of five small needles situated on one side of the reaction plate. Said needles are opportunely connected to the valve and pump system for emptying, washing and drying operations (please see the hydraulic diagram).

2.2.6 WASH STATION CYCLE

The wash station carries out its operations alternating upward and downward movement. In its downward movement phase the needles are guided in such a manner as to carry out the following operations:

- The first needle, using the central cannula, removes the reaction mix while the external cannula dispenses, shower-like fashion, the wash solution; after that the external cannula dispenses wash solution and then the liquid is aspirated from the central cannula;
- The second needle operates exactly like the first but uses distilled water instead;
- The third needle operates exactly like the first but dispenses rinse solution into the cuvette so that an optics check can be performed (if the results are negative, the cuvette is discarded);
- The fourth needle aspirates the Rinse solution used for the optic check.
- The fifth needles dries the sides.

All these operations are part of the routine operation of the instrument. Every reaction cuvette is washed at the end of each round of analysis.

The reusability (optical integrity) of each reaction cuvette is always tested before the next round of analysis.

2.3 TECHNICAL-OPERATIVE SPECIFICATIONS

DESCRIPTION	◆ Completely automatic, random access, computer controlled, counter-top, non-stop loading clinical chemistry and immunoturbidimetric analysis instrument
REACTION TYPES	◆ End Point, Fixed Time, Kinetic, Bichromatic, Differential
TEST SELECTION MODES	◆ Selective, Batch, Profile, STAT
PRODUCTIVITY	◆ 138 tests per hour
OPERATING TEMPERATURE	◆ 37° C
IN LINE REAGENTS	◆ 24 removable containers (capacity 35 and 6 ml) ◆ Reagent plate cooling unit (Optional) ◆ 12 positions for Controls and Standards ◆ Positive Bar Code Reader (Optional)
SAMPLE CONTAINERS	◆ Primary tubes (diameter from 8 to 16 mm; height up to 100 mm) cups from 1 to 4 ml
SAMPLE LOADING	◆ 4 racks, each having 8 positions for non-stop sample loading ◆ Positive Bar Code Reader (Optional)
MINIMUM REACTION VOLUME	◆ 220 µl
MAXIMUM REACTION VOLUME	◆ 550 µl
SAMPLING ARM	◆ A single mechanical arm performs all the sampling operations and is equipped with: <ul style="list-style-type: none">• A volume level sensor• Pre-heating of the reagent(s) to 37 °C• Automatic probe washing
DILUTER	◆ Integrated syringe-free module having the following specifications: <ul style="list-style-type: none">• Sample volume: 2 µl ÷ 99 µl (1 µl incr.)• Reagent 1 volume: 3 µl ÷ 500 µl (1 µl incr.)• Reagent 2 volume: 3 µl ÷ 330 µl (1 µl incr.)• Reagent 3 volume: 3 µl ÷ 330 µl (1 µl incr.)

PRECISION	◆ CV < 1 % at 2 µl
READING SYSTEM	◆ Direct reading
OPTIC SYSTEM	<ul style="list-style-type: none"> ◆ Photometer: double ray, interferential filters ◆ Wavelength: 8 narrow band – from 340 nm to 620 nm – interferential filters plus one available optional filter position ◆ Light source: 6V/10W halogen bulb ◆ Linearity range: up to 3,500 Abs ◆ Resolution: 0.0005 Abs
CUVETTE OPTIC LENGTH	◆ 6 mm
WASHING STATION	<ul style="list-style-type: none"> ◆ Composed of five probes that empty, wash and dry the reaction cuvettes.
REACTION PLATE	<ul style="list-style-type: none"> ◆ 6 individually replaceable racks with 20 cuvettes each ◆ Incubation temperature: 37°C

2.3.1 SOFTWARE AND COMPUTER SPECIFICATIONS

TYPE	◆ IBM Compatible
CPU	◆ Pentium IV 500 MHz, 512 Kb Cache or plus
MEMORY	<ul style="list-style-type: none"> ◆ RAM 256 Mb or plus ◆ Hard Disk 20 Gb or plus ◆ Floppy Disk 3 1/2" 1.44 Mb
MONITOR	Colour SVGA 15" low radiation Resolution 800 x 600 pixels; max number of colors 65536 (16 bit)
PRINTER	◆ 80 Columns impact graphic (EPSON LX 300)
KEYBOARD AND MOUSE	◆ PS2
INTERFACE	◆ One Bi-directional RS 232C serial ports and one parallel (one second serial port for the Host link)
SOFTWARE AVAILABLE LANGUAGES	<ul style="list-style-type: none"> ◆ Multitasking WINDOWS XP Home edition ◆ Italian, English, Chinese, Czech. Software to be released soon in these languages: Russian, Portuguese, French, Polish. Upon request it is possible to release the software in other languages.

SETTINGS	<ul style="list-style-type: none"> ◆ Disable all the energy saving options ◆ Disable the screen saver ◆ Select English “USA” as language, dot as decimal symbol and date and time in Regional setting
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NOTE: Even though the computers demonstrate the same technical and operative characteristics, some of these could have different hardware installed.

This could cause problems for the Ellipse software when running tests (A message appears indicating “Random” error or blocks the program).

Therefore, if the PC is bought separately/locally, it is highly recommended to test the system before proceeding with the installation at customer laboratories.

Consequently, AMS denies any responsibility for software problems that are due to buying the computer separately from the instrument.

2.3.2 OPTIONAL MODULES

- | |
|---|
| <ul style="list-style-type: none"> ◆ POSITIVE BAR CODE READER |
|---|

2.3.3 DIMENSIONS, WEIGHT AND OPERATING ENVIRONMENT

DIMENSIONS	<ul style="list-style-type: none"> ◆ Height: 53 cm ◆ Width: 57 cm ◆ Length: 75 cm
WEIGHT	<ul style="list-style-type: none"> ◆ 35 kilos
OPERATING ENVIRONMENT	<ul style="list-style-type: none"> ◆ Temperature: 18 °C ÷ 30 °C ◆ Relative Humidity: 20% ÷ 85%

2.3.4 INSTALLATION SPECIFICATIONS

POWER SUPPLY	<ul style="list-style-type: none"> ◆ Input voltage: 100 ÷ 230 Vac ◆ Input frequency: 47 ÷ 63 Hz ◆ Power consumption: <ul style="list-style-type: none"> ◆ 300 W for the analysis unit ◆ 400 W for the work station
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Warning: in order to assure proper instrument functioning, the manufacturer strongly advises the use of a stable tension supply outlet (+/-10%). If it is not possible to guarantee said stability, the manufacturer suggests the use of:

- ◆ **UPS (Uninterrupted Power Supply)**
- ◆ **ELECTRONIC STABILIZER**

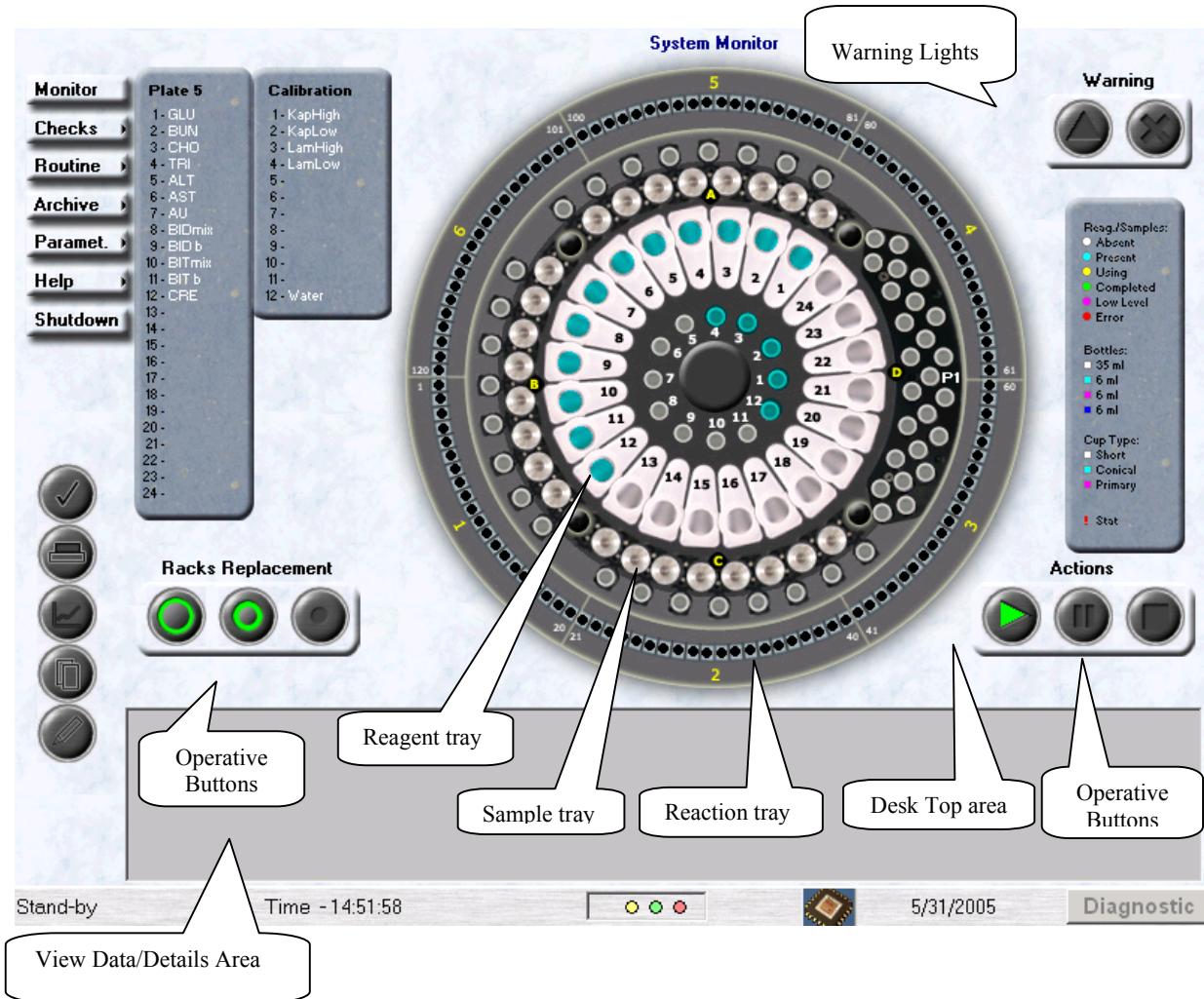
CHAPTER 03 - DESCRIPTION OF INSTRUMENT SOFTWARE

INDEX

3.1 SYSTEM MONITOR.....	3
Warning Lights.....	5
Legends	7
Status Line.....	8
Menus available under System Monitor:	9
Command Buttons.....	10
Check button	11
Order button	11
Print button.....	13
Graph button.....	13
Rerun button.....	14
Edit Results button	15
Move to Archive button	16
Unload button.....	16
3.1.1 START WORK.....	17
Wash all cuvettes.....	17
Water Blank Level	18
Calibration & Quality Control.....	18
Work List	19
Start Running	19
3.2 CHECKS.....	20
WBL.....	21
Main Area.....	21
Reagent Volume.....	23
Main Area.....	23
Details Area.....	24
Reagent Configuration	25
Predilution Rack.....	27
3.3 ROUTINE	31
Work List Setup	32
Unassigned Sample	33
Saving data for more than one patient.....	37
Deleting a Patient.....	37

Deleting a rack.....	38
Result by Patient	40
Printing Data	43
Main Area.....	44
Precision check.....	46
Calibration & Quality Control Setup	47
Calibration Programming.....	49
Editing Calibration.....	50
Calibration Results	51
Quality Control Results.....	58
Quality Control Graphs	60
Receive from Host.....	61
3.4 ARCHIVE	62
Patients	63
Main Area.....	63
Details Area.....	64
Calibration.....	65
Main Area.....	66
Details Area.....	68
Backup.....	69
Restore.....	70
Tests Counter	71
Event Log.....	72
3.5 PARAMETERS	73
Inserting the Password	74
Profiles	75
Ratio	77
Standards.....	82
Controls	87
Options	91
Print Order.....	92
Report Options	93
Password Setting	94
3.6 HELP	96
Guide F1.....	97
Software versions	98
3.7 SHUT DOWN	99

3.1 SYSTEM MONITOR



The system's management software is extremely user-friendly and, moreover, allows maximum flexibility in its use.

The operator can access the management software by simply turning on the instrument. If the last instrument Shut Down was due to a Fatal Error or if the *Analyzer* is at the time turned off, the user must double click on the *Analyzer* icon located on the computer Desk Top.

The user interface screen is subdivided into two main areas:

- the Desk Top area
- the View Data/Details Area

The Desk Top area is a graphic illustration of the instrument that allows the operator to easily identify each single item and its status. It includes:

- ✓ A reagent tray with twenty-four reagents and twelve Standards and Controls positions;
- ✓ A Samples tray composed by four racks with eight positions each.

- ✓ A reaction tray composed by six racks with twenty cuvettes each.

View Data/Details Area

Located in the lower section of the System Monitor mask, the View Data/Details Area contains precise, detailed information concerning the item selected (Cuvette, Samples, Reagents, Standards and Controls).

It is possible to view data details regarding single items by clicking on them whenever the mouse pointer turns into a question mark as it passes over that particular element.

- If the operator selects a given position on the Reaction Plate, by placing the mouse pointer over the required item:
a table containing the WBL values of the cuvette selected (both the main channel and the reference channel values) will be viewed. The Print button will also be activated.

WBL. Cuvette No. 14.										
Date	F0	F1	F2	F3	F4	F5	F6	F7	F8	F9
2/24/2005	23	43917	40884	31745	39875	41486	48435	30712	45069	65535
Ref.	118	41258	33559	26061	30862	31177	36968	22600	33715	65535

- If the operator selects a given position on the Samples Rack, by placing the mouse pointer over the required item:
a table listing the tests programmed to be run on that sample will appear in the lower portion of the window and information regarding the sample itself (patient name, sample ID, rack and position) will appear in the upper portion of the window.

Name: SID: 1 (Rack/Pos.: 1/1).							
Test	PreDil.	Test Dil.	Result	Unit	Normal Values	Flags	Date
bib	1/1	1/1	363	-	(0-0)	R	02/06/2003 14:57:26

- If the operator selects a given position on the Reagents Rack, by placing the mouse pointer over the required item, the below-illustrated table will appear allowing the user to view information regarding the selected Reagent.

Reagent Rack. Position No. 1.					
Type	Name	Ratio/Volume [ul]	Rinse [ul]	Residual Volume [ml]	
Reag./Dil.	GPT	300	0	33.2	

- If the operator selects a given position on the Controls or Standards, by placing the mouse pointer over the required item, the below-illustrated table will appear allowing the user to view information regarding the selected Control or Standard.

Calibration Rack. Position No. 1.			
Type	Name	Lot	Exp. Date
Control	CTR1	123456	30-Nov-04

WARNING LIGHTS

There are two types of alarms:

- The first type is a brief visual text message, which appears in the lower, left-hand portion of the screen, up to the operative buttons. It can inform the operator that either there is “no instrument connection”, or the “cover is open”, or that a “remote link” is in operation.
- The second are **Warning Buttons** (located in the upper, right portion of the mask) and they can be:
 - either a “**Warning**” represented by a triangle that lights up yellow. If the operator clicks on this button, it is possible to view in the Details Area those events which caused the warning (e.g.: liquid(s) finished).
 - or a “**Fatal Error**” represented by an X that lights up red. Whenever a fatal error is signalled, only those readings that have already been carried out will be saved; those operations being carried out at the time are interrupted (e.g.: incubation). After every “Fatal Error”, the user must have the instrument carry out a Wash cuvette cycle. If the operator clicks on this button, it is possible to view in the Details Area those events that caused the warning (e.g.: temperature error).

At this point, it can be useful for the operator to consult **Event Log**, listed under the **Archive** menu, where all instrument status information is memorized, in order to have more information regarding the occurrence.

Operative Buttons “Actions”:



START (green triangle): allows the operator to access the Start Work mask where it is possible to start the running of the various tests and of any other operation regarding the instrument.



PAUSE: temporarily interrupts only the sampling process. It does not interrupt incubation, nor the reading of already dispensed samples. To restart, press START.



STOP: halts instrument functioning - the sampled tests are lost.

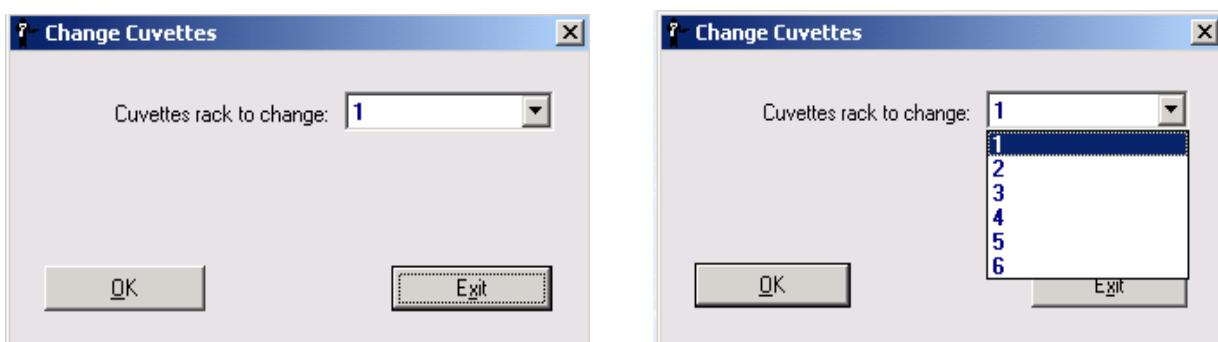
Operative Buttons “Racks Replacement”:



Change cuvettes: allows the operator to change cuvettes rack. Clicking on it, the following dialog box will automatically open and rack selection to be replaced can be done clicking on the pull-down menu from 1 to 6.

Clicking on “OK” the instrument pass to the **Priming** and then in **Stand-By** condition while the reaction plate turns up to bring the selected position in front of the operator to allow the cuvette rack replacement.

Click on “OK” into the message that appears after reaction plate positioning to confirm the happened replacement.



Cuvettes rack can be changed only when the instrument is not performing any operation or procedure. In such condition, the button is made disable.

Whenever one or more cuvettes illustrated in the Reaction Plate are coloured Red, it is because the instrument cannot perform the required readings on them due to the fact that they are not perfectly transparent, or rather; their transparency is below the minimum or above the maximum limit acceptable to the instrument program. If the operator wishes to view the filter readings, he/she can do so from within the Details Area.

Whenever a cuvettes rack is inserted for the first time in the Reaction Plate, it is indicated in red under System Monitor because the instrument does not have that data necessary for the mathematical equations needed to calculate test results. Therefore, it is necessary to carry out a **WBL** for that cuvettes rack (auto-zeroing) in order to be able to use it.



Load Sample/s: allows the operator to load samples rack. Clicking on it, the following dialog box will automatically open and rack selection to be replaced can be done on the pull-down menu, among those programmed, in the reported position A, or B, or C or D, defined by the instrument.

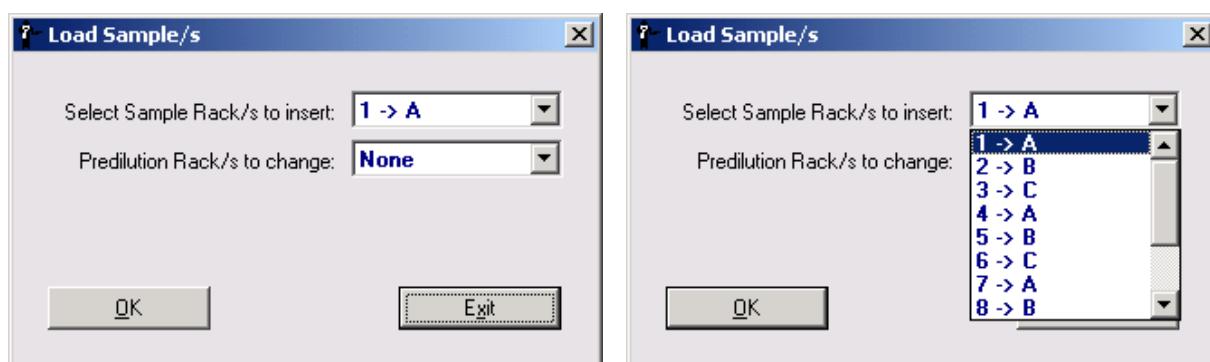
Clicking on “OK”, the sample plate turns up to bring the selected position in front of the operator, to allow the sample rack loading.

Click on “OK” into the message that appears after sample plate positioning to confirm the happened loading.

Samples rack can be loaded at any time, even if the instrument is in running condition.

In this case, pushing the loading operative button, the instrument pass from the **Running** to the **Pausing** and then to the **Pause** condition, to allow the selected rack loading.

Click on “OK” into the message that appears after sample plate positioning to confirm the happened loading; click on the **START** button and confirm pushing **OK** in order to restart the running.



Load Reagents: allows the operator to load reagents. The button is able in Running condition only. Clicking on it, the following dialog box will automatically open and **ALL** selection to load reagents can be done on the pull-down menu.

Clicking on “OK” the instrument pass from the **Running** to the **Pausing** and then to the **Pause** condition the allow the refill of one or more then one used reagents, or one new reagent configuration loading.

Click on “OK” into the message that appears after reagent plate positioning to confirm the happened loading; click on the **START** button and confirm pushing **OK** in order to restart the running.

LEGENDS

There are three legends and one symbol to be found under System Monitor and they are the following:

- **A Legend regarding the colours associated with certain visual text messages concerning reagent and sample status:** (upper right)

Reag./Samples:

- White (absent)
- Sky blue (present)
- Yellow (in use)
- Green (completed)

- Magenta (low level)
 - Red (error - no sample or reagent)
- A legend regarding the various types of reagent bottles having different volume capacities, that can be selected for use by the operator (medium right)
 - white 35 ml
 - sky blue 6 ml
 - magenta 6 ml
 - blu 6 ml
- A legend regarding the various types of test-tubes having different volume capacities, that can be selected for use by the operator (lower right)
 - white (short – approximately 1 ml)
 - sky blue (conic– approximately 2 ml)
 - magenta (primary tube)

By clicking on “Options” under the “Parameters” menu, the operator can select the reagent bottle to be used by default. The reagent code will be written in the colour of the bottle that contains that reagent.

- A symbol regarding STAT



Samples having this symbol will be processed first of all the other programmed and loaded samples.

STATUS LINE

The Status Line, lower left, contains information regarding the functioning condition of the instrument. Said information allows the operator to follow and check the status of instrument operation.

- ➔ Stand By
- ➔ Stop
- ➔ Washing
- ➔ Running WBL

➔ Running

➔ Pause

➔ Pausing

➔ Safe

➔ Priming

Moreover, in the Status Line, are reported the following information:



Icon indicating a fault sample reading executed by the Bar Code reader.



If the operator places the mouse pointer on this icon, it is possible to view the *Firmware* version.

MENUS AVAILABLE UNDER SYSTEM MONITOR:

- ⇒ Monitor
- ⇒ Checks
- ⇒ Routine
- ⇒ Archive
- ⇒ Parameters
- ⇒ Help
- ⇒ Shut Down

COMMAND BUTTONS

The Command Buttons are automatically activated as needed and have the following functions:



Make validated the results of a given Test (**Check** button);



Reorder the viewed data (**Order** button);



Print the viewed data (**Print** button);



View an absorbance graph (**Graph** button);



Repeat an already run test (**Rerun** button);



Modify the results of a test (**Edit** button)



Save and File results in the Archive (**Move to Database** button);



Send the data to the remote computer (**Unload** button)

The various icons are activated in accordance with the mask being used. It is possible to recognize an inactive button by its opaque colouring or by the fact that it cannot be viewed. If the user places the mouse pointer over an icon, a visual text message will appear describing the corresponding function.

CHECK BUTTON



Working within the Patient Results window and within the Test Results window (even under System Monitor), the operator has the possibility to verify, select and confirm the results of the tests by using the **Check** button located on the Desk Top. By selecting, from the offered list, a row containing a result deemed correct (e.g.: the same test repeated for the same patient), the operator can, by clicking on this command, make the selected test “valid”. The system will automatically show the examined data in **bold** print, in order to make it more readily visible to the user.

ORDER BUTTON



Whenever the operator looks over the results of any one of the various operations carried out, he/she may find it necessary to **Re-order** that list in a manner judged by him/her to be simpler and more useful. This procedure is described in the following paragraph. The **Order** command can be applied to the visualization of the various results listed here below:

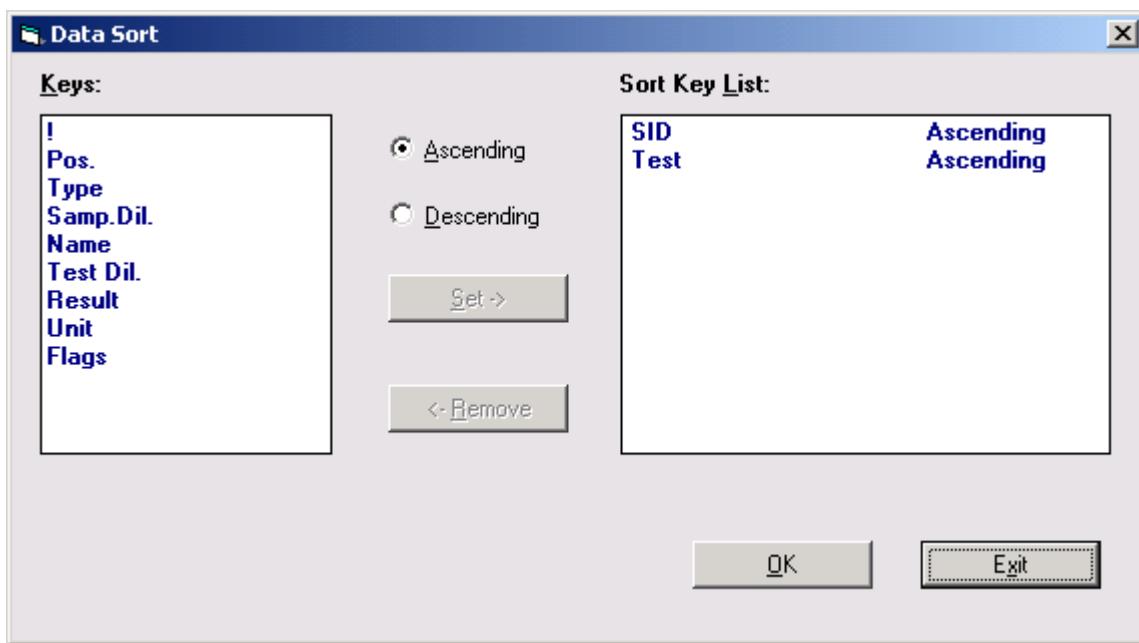
Patients Results;
Test Results;
Quality Control Results;
Archive – Patients;
Archive – Calibration;
Tests Counter.

This re-ordering can be requested via the **Order** button located on the **Desk Top**, and can be viewed (or rather, is activated) only during the visualization of those lists whose contents can be re-ordered.

Re-ordering can also be requested directly from the area involved, by clicking on the small triangle symbol that appears in the field heading. After clicking on the symbol, the user need only select to have an alphanumerical order either ascending or descending.

➤ How to Re-order

In order to carry out a re-ordering of viewed data, the operator must first select a row from the required list and then click on the above-described Order button. The below-illustrated mask will automatically open, allowing the user to select from the offered options and perform the operation.



The **Order Data** mask contains: a “**Keys**” area where the operator can select which field(s) in the List he/she wants to re-order; options concerning which type of Order is to be effectuated; another ”**Sort Key List**” area where those field(s) to be re-ordered, selected from the Key area, are listed; plus the various buttons necessary for carrying out the procedures.

Set ->

The operator must first click on the name of that field, within the “**Keys**” area, which is to be re-ordered and then click on “**Set**”. The selected field will automatically be listed in the “**Sort Key List**” area, ready to be re-ordered.

<- Remove

Once a given field (or fields) has been selected from the “**Key**” area and is listed in the “Re-order List” area, the operator can change his/her mind and decide to delete one or more fields from this list to be re-ordered. He/she need only click on the required field and then click on “**Remove**”. The Remove button is activated only after at least one field has been selected from the “**Key**” area.

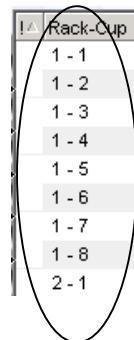
For each individual field that is to be re-ordered the operator can choose from two Order options, **Ascending or Descending**, located between the “**Key**” area and the “**Re-order List**” area.

OK

After all the above-described selections have been made, the operator need simply click on “**OK**” to have the instrument carry out the Order procedure. The **Order Data** mask will automatically close and the List will now be viewed according to the order requested by the user. To annul the operation and exit the **Order Data** mask, click on “**Exit**”.

Following are two examples, which could be useful for a better understanding of the above-described procedure and also helpful in carrying out the Re-order operation.

The two illustrations provided below are ordered according to two different criteria. The “Position” (Pos) has been selected in the first illustration and an “Ascending” order has been designated.



Rack-Cup	Type	Samp.Dil.	SID	PID	Name	Sex	Birthdate
1 - 1	Serum	1/1	435	435		Male	
1 - 2	Serum	1/1	436	436		Male	
1 - 3	Serum	1/1	437	437		Male	
1 - 4	Serum	1/1	438	438		Male	
1 - 5	Serum	1/1	439	439		Male	
1 - 6	Serum	1/1	440	440		Male	
1 - 7	Serum	1/1	441	441		Male	
1 - 8	Serum	1/1	442	442		Male	
2 - 1	Serum	1/1	368	KXSA1	KXSA1	Male	

The second illustration, instead, exemplifies the selection of the “Sample ID” and the designation of a “Descending” order.



Rack-Cup	Type	Samp.Dil.	SID	PID	Name	Sex	Birthdate
12 - 1	Serum	1/1	434	434	Enzo Zattini	Male	
11 - 8	Serum	1/1	433	433	III Run SOLO ALT	Male	
11 - 7	Serum	1/1	432	432	III Run SOLO ALT	Male	
11 - 6	Serum	1/1	431	431	III Run SOLO ALT	Male	
11 - 5	Serum	1/1	430	430	III Run SOLO ALT	Male	
11 - 4	Serum	1/1	429	429	III Run SOLO ALT	Male	
11 - 3	Serum	1/1	428	428	III Run SOLO ALT	Male	
11 - 2	Serum	1/1	427	427	III Run SOLO ALT	Male	
11 - 1	Serum	1/1	426	426	III Run SOLO ALT	Male	



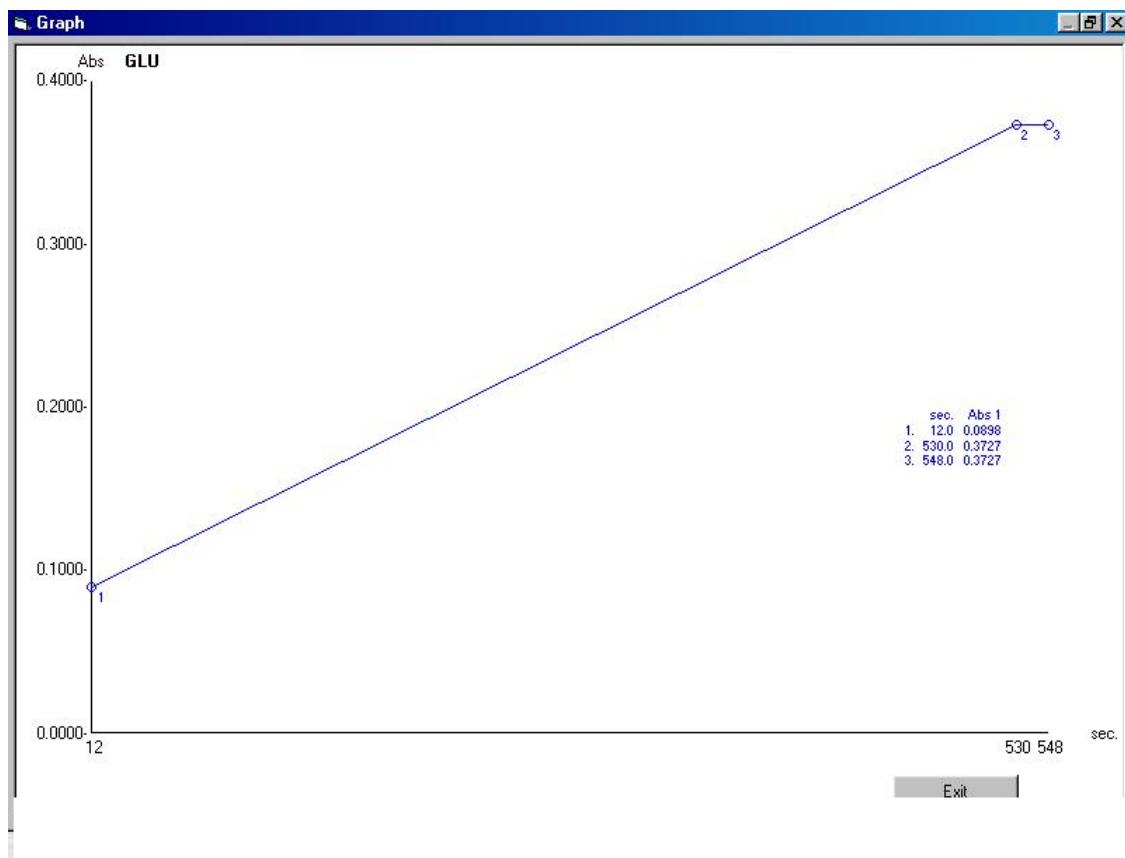
PRINT BUTTON

In order to print the data viewed in a given mask, the operator must first select those rows that are to be printed and then click on the “Print” button, located on the Desk Top.

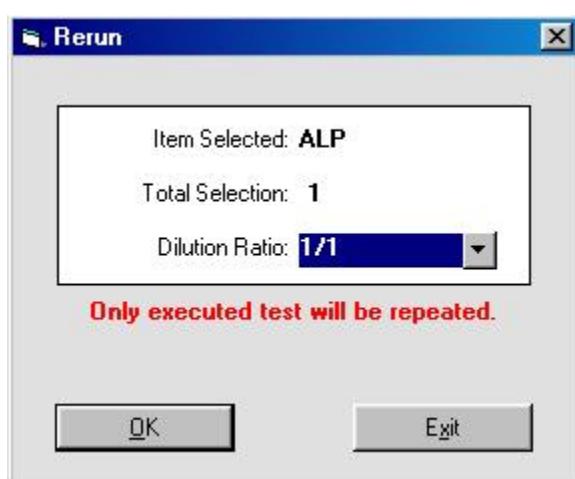


GRAPH BUTTON

In order to view the reaction graph, or rather, the Graph of the Optical Densities obtained and the reading times expected (as given under Methods) for the result selected, the user need simply select the row in the Details Area containing the results he/she is interested in and then either double click on it with the mouse or click on the “Graph” button located on the Desk Top. This Graph button is activated only when the Details Area contains at least one row of data.

**Exit**

To exit the Graph mask, click on "Exit".

**RERUN BUTTON**

Whenever it is deemed necessary to rerun a test (e.g.: the sample appears too concentrated, the quantity of reagent seems insufficient, etc.), the operator can do so by using this "**Rerun**" procedure – the relative button is located on the **Desk Top**.

Select the required row and then click on "**Rerun**". The previously illustrated window will automatically appear within which the operator can reprogram the required test. In order to carry out the operation, the relative command, under the **Start Work** mask must be activated. All those

fields, which may be of help to the user in the reprogramming of the test, can be viewed in this mask. Among them:

Item Selected: indicates the name of the Test the operator has selected to be rerun, if only one type of test has been selected. If more than one type of test has been selected, the window will show “**Multiple Selection**”;

Total Selection: allows the operator to view the total number of reruns requested for the required Test(s);

Dilution Ratio: allows the operator to decide, using a pull-down menu, the dilution ratio for that test. This is possible only when one single type of test has been selected to be rerun, and not when the operator has requested a Multiple Selection rerunning or when the sample volume permits to do so (Sample volume more than four microliters).

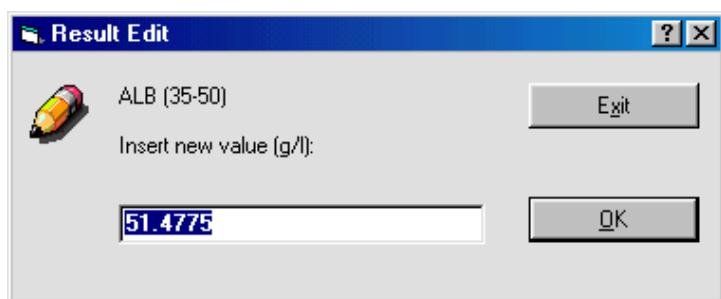


By clicking on “**OK**”, the operator confirms the operation. Clicking on **Exit**, instead, annuls the selection, as well as the operation.



EDIT RESULTS BUTTON

This button allows the operator to edit the results of the tests performed. To perform this operation, first select the required row from the Details Area and click on the **Edit** button located on the Desk Top. The below-illustrated window will open, containing two buttons: “**OK**” and “**Exit**”.



Insert the new value for the test result and click on **OK**. The new value will automatically be registered and will appear in the **Results** field of the relative test. At the same time, the **Flags** column will show an **E** in the relative field (see the illustration below), indicating an Edit (see Result Flags).

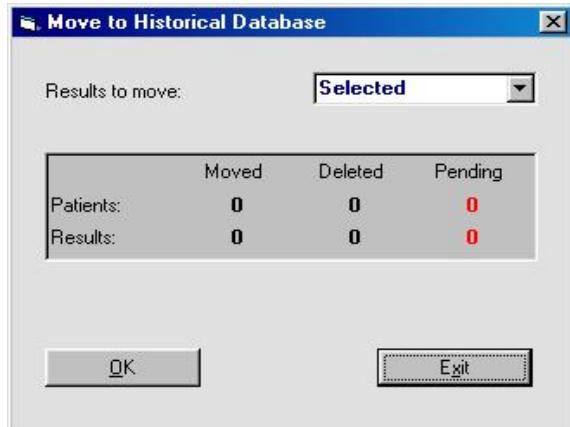
Name: ROSS MARY SID: 1 (Rack/Pos.: 1/1)							
Test	PreDil.	Test Dil.	Result	Unit	Normal Values	Flags	Date
ALP	1/1	1/1	1.28	ukatU	(0.1-2.7)	E	04/08/2003 10:09:21

The window’s **Exit** button allows the operator to annul the editing operation.



MOVE TO ARCHIVE BUTTON

The results of all those operations carried out under Start Work can be recorded and saved, along with the patient data contained in the “Work List”, in a Archive. First, select the record to be saved in the Archive from the Main Area and then click on “**Move**”, located on the Desk Top. The following window will automatically come up:



This window contains a pull-down menu in the field labeled “**Results to move**” where the operator can choose to save either the individual records selected from the **Main Area** or an entire Rack. To confirm the move, click on “**OK**” and the selected data will automatically be moved and thereby recorded in the Archive.

The **Exit** button annuls the move and the operation.

Data can be moved to the Archive only if the patient has been assigned tests and the tests have been performed (and therefore have results). If the operator tries to confirm, “**OK**”, the movement of data to the Archive when no results or tests are available for that patient, the program will automatically annul the operation and the user will be informed via a visual text information message to that effect.

The centred portion of this window contains the number of records moved, deleted or pending for both Patients and Results. All this saved and filed data (“moved” data) can be consulted under **Archive – Patients**.



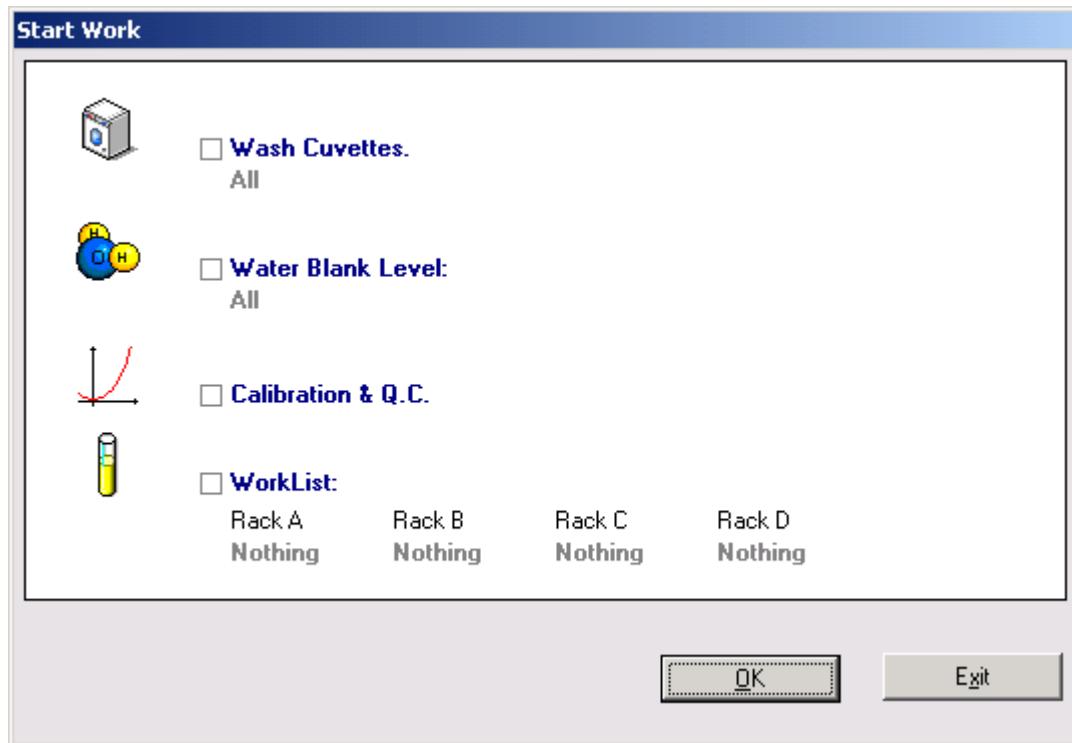
UNLOAD BUTTON

This command makes it possible to activate data transmission to the Host. To carry out this Transmission, select one or more rows from the Main Area of the **Result by Patient** window in the **Routine** menu and then click on “**Unload** button” (located on the Desk Top only if **Host Connection** selection has been made active in the Option Menu). In order to view this command (not automatically shown on the Desk Top), the operator must have selected at least one record under Patient Results.

The program will guide the operator during the data transmission, via a series of visual text messages.

3.1.1 START WORK

The **START WORK** button (green triangle) allows the operator to open the **Start Work** window where he/she can select, as needed, the below-illustrated operations:



Wash all cuvettes

“Wash all Cuvettes” is the first option offered. Here, the user can select which cuvettes rack contained in the Reaction Plate is to be washed. To do so, the operator must select, from the field’s pull-down menu, one of the following: **All, Rack 1, Rack 2, Rack 3, Rack 4, rack 5, Rack 6**. If he/she selects **All**, the programme will automatically wash all the cuvettes in the Reaction Plate, while remain selections permit washing of the selected rack only.

Whenever this option is highlighted in red and is accompanied by a visual text information message, viewed at the bottom of the **Start Work** mask, it means that the instrument is in the condition to warrant cuvette washing. Therefore, the programme notifies the user to this effect and suggests that said operation (“Wash all Cuvettes”) be carried out before performing any other operation.

WATER BLANK LEVEL

The second option, “**WBL**”, allows the user to activate a pull-down menu where he/she can choose those cuvettes racks to be subjected to a water blank level reading, auto-zeroing. The options offered are the following: **All, Rack 1, Rack 2, Rack 3, Rack 4, rack 5, Rack 6**.

All carry out WBL readings on all the cuvettes racks contained in the Reaction Plate, while remain selections permit WBL readings on the selected rack only.

The **WBL** operation (auto-zeroing of the cuvettes) **must be carried out daily**, before running the Work List tests. Each cuvette is filled with approximately 400 micro-liters of Rinse solution and read for all the wavelengths of the eight filters. These readings are fundamental to determining cuvette quality and for instrument auto-zeroing, necessary for subsequent numeric calculations. The user can view the obtained WBL readings in the “**Water Blank Level**” mask.

The resulting WBL values will be used by the system to calculate the concentration of the tested analita.

The reading system (Photometer) reads light intensity that passes through photodiodes. The analogical values expressed in millivolt read by the photodiodes are then digitally transformed into logical data expressed in “Counts” from 0 to 6553.

As we know from Lambert/Beer law, the relationship between transmittance (Ratio between incident light I_0 and transmitted light I) and absorbance is an inverse logarithmic type. In order to obtain a linear data, proportional to the concentration of the Analita tested, the following mathematic algorithmic is used:

$$-\text{Log}(\text{I} / \text{I}_0) = -\text{Log}[\text{counts}(1) / \text{counts}(2)] = \text{Abs} = \Sigma * \text{C} * \text{r}$$

Where:

counts(1) = reaction reading (I)

counts(2) = cuvette containing water reading (WBL = I₀)

Abs = Absorbance (optical density)

Σ = absorbivity or Coefficient of molar extinction

C = concentration

r = Optical path length

The absorbance data given in the reaction reading (see reaction graph) contains the offset value (about 100 counts).

Possible signal variation due to the lamp or to the filters (Thermal drift) are automatically compensated by the readings taken from the reference channel.

CALIBRATION & QUALITY CONTROL

This third option makes it possible to calibrate the methods. In order to activate this option, it is not only necessary to select the relative field, but also to request at least one Sample Blank (RBL) execution in the **Calibration & Quality Control** function under the **Routine** menu.

WORK LIST

The fourth option allows the operator to activate the work lists previously programmed. There are four **positions** available for the **Samples racks**, identified by the “A”, “B”, “C” e “D” characters.

By selecting the Work List option, the positions containing the previously programmed and loaded samples rack are activate. After selection, samples racks are shown in the System Monitor in the dedicated area. Here, the rack number is also available by assuming the colour corresponding to the size of the liquid container. The samples are shown in sky blue colour if they are still to be run; in yellow if they are in process and in green if they have been completed.

Note: A sample position will remain yellow coloured until all its programmed tests are completed.

Clicking on the rack number of each active position, a pull-down menu will be shown, where the user can disable the selected rack by clicking on **Nothing** (when the machine is not in running). So that, by pushing the start button, the samples will not be sampled, even if still shown on the System Monitor.

While tests are in process, the reaction mixture in the reading will be shown on the System monitor by changing the concerned cuvettes colour: from black to grey.

START RUNNING

To activate the carrying out of the option selected, click on “**OK**”. Note that the “**Parameters**” menu is blocked (inactivated by the instrument itself) during the carrying out of any and all operations. This is done in order to protect those masks that contain fields where, if the contents were edited, the results of the operations could be compromised. When said operations have been completed, the Parameters menu will automatically be reactivated. This reactivation can also be obtained by clicking on “**Stop**” or “**Pause**”.

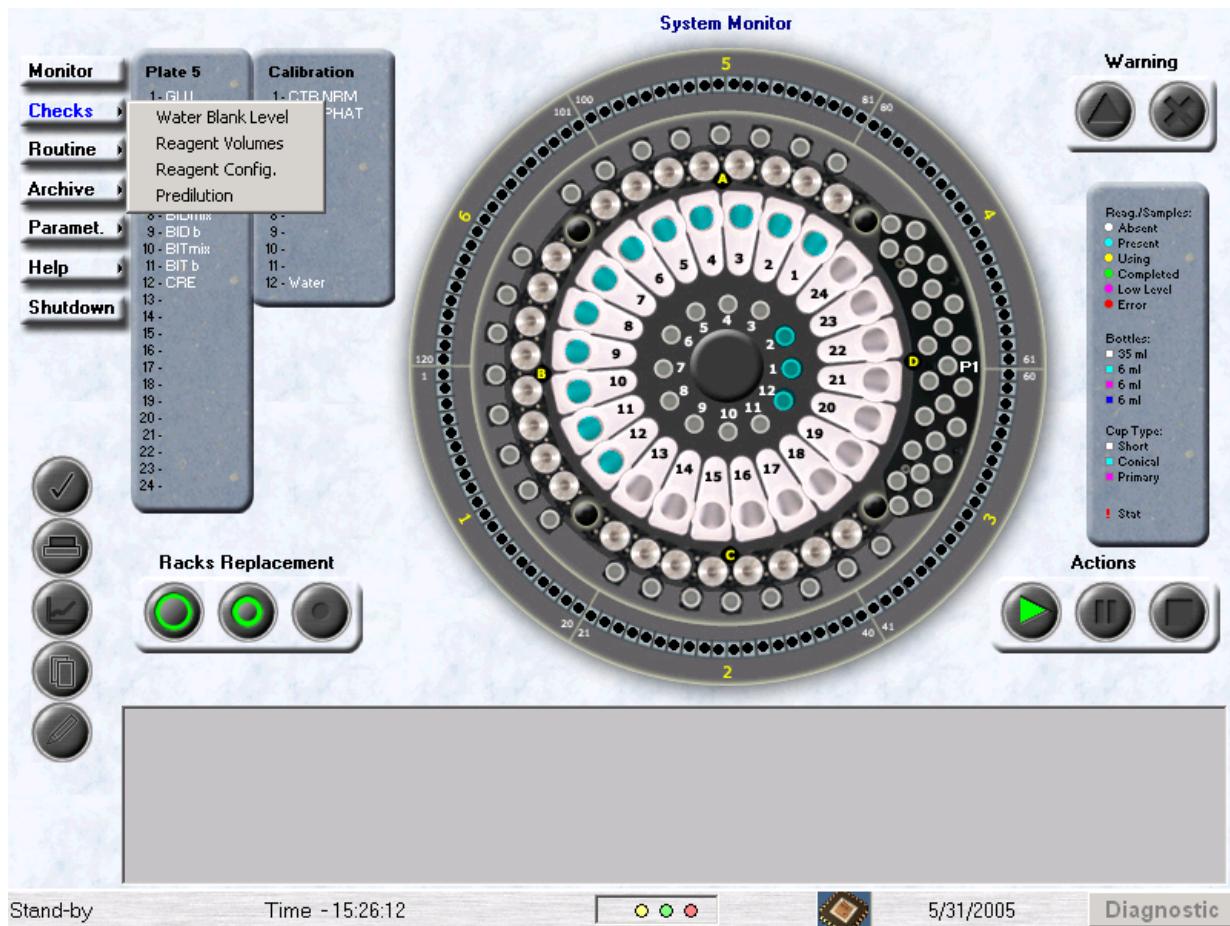
By clicking on “**Exit**”, the operator can exit the Start Work menu without carrying out any operation.

N. B.:

The instrument program will carry out any automatic rerunning of the tests without the need for the operator to intervene.

Further rerunning can be requested only after testing has been completed and preferably before rack replacement.

3.2 CHECKS



Checks ▶ “Checks” includes the entire set of masks which allow the operator to access and activate functions, as well as view a series of data, both useful and necessary for correctly preparing the instrument for routine operation.

Each set of data, grouped according to information category, has its own dedicated mask. Following is a list of these masks:

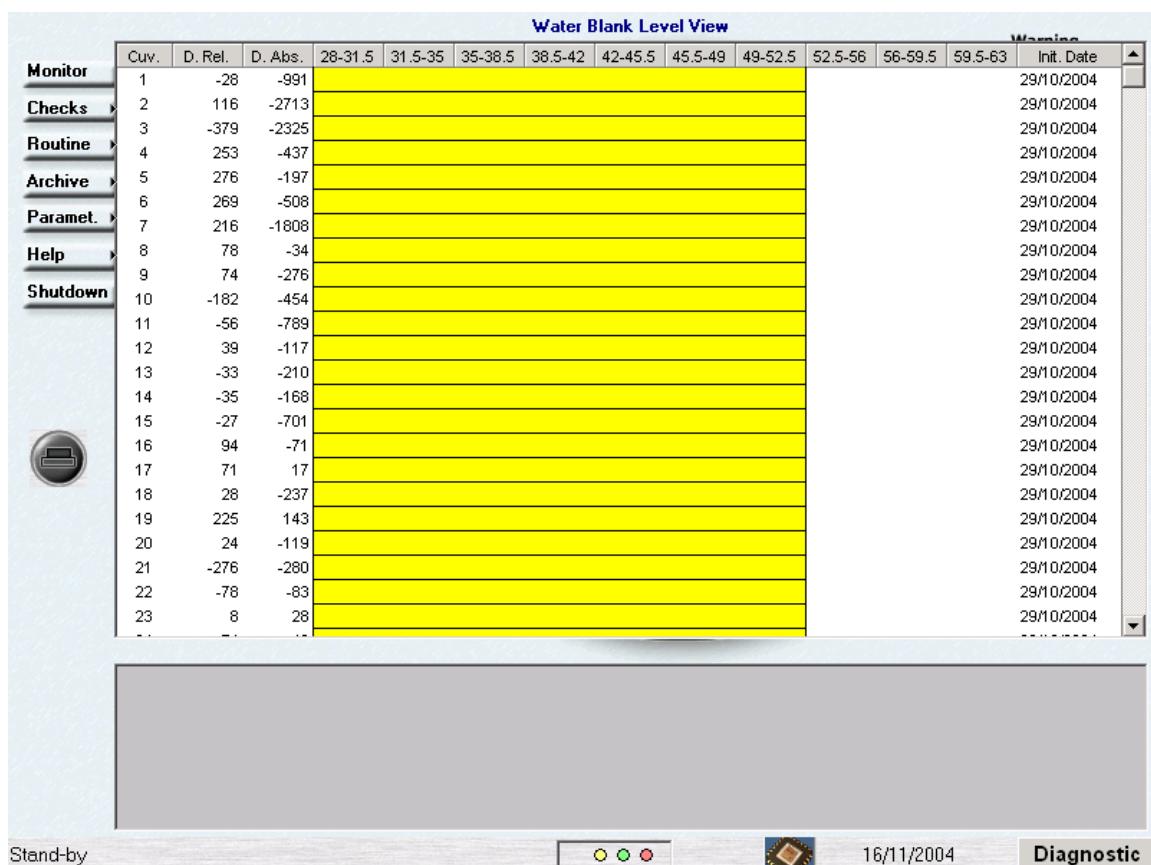
Water Blank Level: contains a graphic illustration of the results of all the WBLs run as quality control on each of the 120 cuvettes.

Reagent Volume: contains an organized view of all that data set-up in the “Reagent Configuration” mask, along with the calibration programming data (CTRL and STD).

Reagent Configuration: a necessary preliminary step before performing any analytical testing. In this mask, the operator can assign the positions of the reagent liquids and also, if desired, that of the controls, from among those set aside within the instrument specifically for this purpose.

Predilution: this mask contains all that data regarding the positions dedicated to sample predilution as set-up in the “Reagent Configuration” mask.

WBL



To access the **Water Blank Level mask**, first select the **Checks Menu** and then, from the options listed, click on **Water Blank Level**.

The window that opens graphically illustrates the results of the operations carried out when the **WBL** option is selected under the **Start Work** mask.

The values of the WBL are used in the mathematical operations for calculating test results and for performing quality control checks on the 120 cuvettes (e.g. when checking transparency).

This window is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension.

The mask also contains buttons, which allow the operator to move on to other applications or procedures.

MAIN AREA

The main area of the **WBL** mask contains a histogram of the **WBL** results on a scale ranging between 28,000 and 63,000 counts.

By consulting this chart, the operator can immediately evaluate the status of the cuvettes within this reference interval.

The histogram indicates the WBL values as explained below:

- The initial WBL measurement value is indicated in grey line;
- The penultimate WBL measurement value is indicated in matt yellow;
- The last WBL measurement value obtained is indicated in bright yellow.

PLEASE NOTE 1: the difference between the penultimate and the last WBL readings are illustrated by the different colouring of the histogram bar (a reduction in the counts value), or by the presence of a vertical line on the bar coloured bright yellow (an increase in the counts value).

PLEASE NOTE 2: the bar is coloured yellow for WBL values falling within the tolerance range (28,000 – 63,000 counts). If one or more of the reported values is out-of-range, a red line will appear next to the number of the cuvette whose reading(s) is/are out-of-range.

In the **Details Area**, the operator can view the Archive information regarding readings for all eight wavelengths and for each cuvette. The **Main Area** will, therefore, contain only that information regarding the reading with the Optical filter set at **340 nm**, while the **Details Area** will show the values relative to all the positions of the photometer filter wheel.

The Main Area's heading contains the following fields:

Cuv.: in addition to identifying the row, this heading also indicates the number of the Cuvette to which the thereafter-reported values (in the following fields) refer. Whenever the cuvette is judged to be “bad”, this number will be shown in red.

D. Rel.: refers to the difference between the value of the last WBL carried out and that of the previous one.

D. Abs.: refers to the difference between the value of the last WBL carried out and that of the first carried out.

Initial Date: indicates the date the first WBL was carried out.

The obtained values, subdivided according to filter (fields F0 to F9), are reported in the **Details Area**.

Whenever the operator selects a given row from the Main Area, the **Details Area** will automatically show more specific itemized data, in chronological order, regarding the values obtained for the cuvette indicated by that selected row.

In the column regarding the “**Date**” field, the row containing “**Ref**” values report the values obtained using the Optical reference channel.

All the data in the various fields will be shown in red in the Details Area, whenever the cuvette(s) selected from the Main Area is/are judged “bad”.

Details Area

WBL. Cuvette No. 10.										
Date	F0	F1	F2	F3	F4	F5	F6	F7	F8	F9
13-Dec-02	118	51384	42890	47130	51329	52997	51139	49320	55752	65535
Ref.	102	40248	29660	31919	32584	33378	31971	30237	34614	65535
03-Dec-02	171	52833	47936	48784	53073	54008	52151	49892	56531	65535
Ref.	150	41015	32981	32850	33443	33780	32310	30376	34781	65535

This mask allows the operator to print the information herein contained. This is made possible via the use of the **command buttons** located under System Monitor (please see the section regarding the Command Buttons).



REAGENT VOLUME

To access the **Reagent Volume** mask, first select the **Checks Menu** and then, from the options listed, click on "**Reagent Volume**".

This mask gathers and suitably organizes all that data set-up in the Reagent Configuration mask and in the **Calibration Programming** mask. In addition to the reagents contained in the reagent housing, this mask also allows the operator to view data regarding standards and controls assigned to the calibration procedure. This window is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension.

The **Main Area** is located in the upper portion of the screen and contains generalized information.

The **Details Area** is located in the lower portion of the screen and contains more specific, itemized information.

MAIN AREA

Following is an illustration of the Main Area window as seen by the operator. This window contains, in addition to those fields to be described in this paragraph, buttons that allow the user to move on to other applications or carry out other procedures.

Reagents View

Position	Type	Name	Cup/Bottle Type	Residual Volume (ml)
Std/Ctrl 1	Control	CTR NRM	Short	
Std/Ctrl 2	Control	CRT PHAT	Short	
Std/Ctrl 12	Water	Water	Short	
Reag. 1	Reag./Dil.	GLU	35 ml	0.0
Reag. 2	Reag./Dil.	BUN	35 ml	0.0
Reag. 3	Reag./Dil.	CHO	35 ml	0.0
Reag. 4	Reag./Dil.	TRI	35 ml	0.0
Reag. 5	Reag./Dil.	ALT	35 ml	0.0
Reag. 6	Reag./Dil.	AST	35 ml	0.0
Reag. 7	Reag./Dil.	AU	35 ml	0.0
Reag. 8	Reag./Dil.	BIDmix	35 ml	0.0
Reag. 9	Reag./Dil.	BID b	35 ml	0.0
Reag. 10	Reag./Dil.	BITmix	35 ml	0.0
Reag. 11	Reag./Dil.	BIT b	35 ml	0.0
Reag. 12	Reag./Dil.	CRE	35 ml	0.0

Stand-by Time - 15:28:02 [Color Status] 5/31/2005 Diagnostic

The fields, that will be herein described, are the following:

Position: allows the operator to view the position occupied in the reagents rack; there are 24 positions available;

Type: indicates the type of liquid tested;

Name: indicates the reference acronym for that liquid;

Cup/Bottle Type: allows the operator to view the format of the container to be used for the liquid indicated. There are two bottle types configurable on the instrument, which can be chosen according to user needs. They are:

- 35 ml;
- 6 ml;

Residual Volume (ml): quantity of reagent left in the container and available for use in other analyses (this information is automatically updated as each test is carried out). The amount is expressed in millilitres and is a decimal figure.

DETAILS AREA

Reagent Rack. Position No. 1.				
Type	Name	Ratio/Volume (ul)	Rinse (ul)	Residual Volume (ml)
Reag./Dil.	GLUCOSE	220	0	0.0

The Details Area is located in the lower portion of the screen – above is an illustration as seen by the user. This area allows the operator to view the specific details regarding the particular liquid selected in the upper portion of the window (i.e. in the Main Area). A description of the more important fields follows:

Type: indicates the type of liquid tested;

Name: indicates the full name of the liquid being tested;

Predil. Ratio/Volume (ul): if the indicated liquid is a diluent, this field expresses the predilution ratio set-up. Otherwise, it allows the operator to view the volume of reagent necessary for each reaction;

Rinse (ul): quantity of liquid used to avoid an intermixing (i.e. cross-contamination) of the reagents;

Residual Volume (ml): quantity of reagent left in the container and available for use in other analyses (this information is automatically updated as each test is carried out). The amount is expressed in milliliters and is a decimal figure.

Whenever the operator selects a **Control** from the Main Area, the Details Area will show the **Name**, **Lot Number**, and **Expiration Date** of said Control.

If, instead, the operator selects a **Standard** from the Main Area window, the Details Area will view the **Type of STD**, the **Name**, the **Lot Number**, the **Expiration Date**, the **number of Points**, and the relative **Diluent**.

Whenever the level of any Reagent drops below its “reserve level”:

- the position of that reagent under System Monitor will be shown coloured magenta;

The “reserve levels” are as follow:

- 5,7 ml for the 35 ml capacity container;
- 1,8 ml for the 6 ml capacity container;

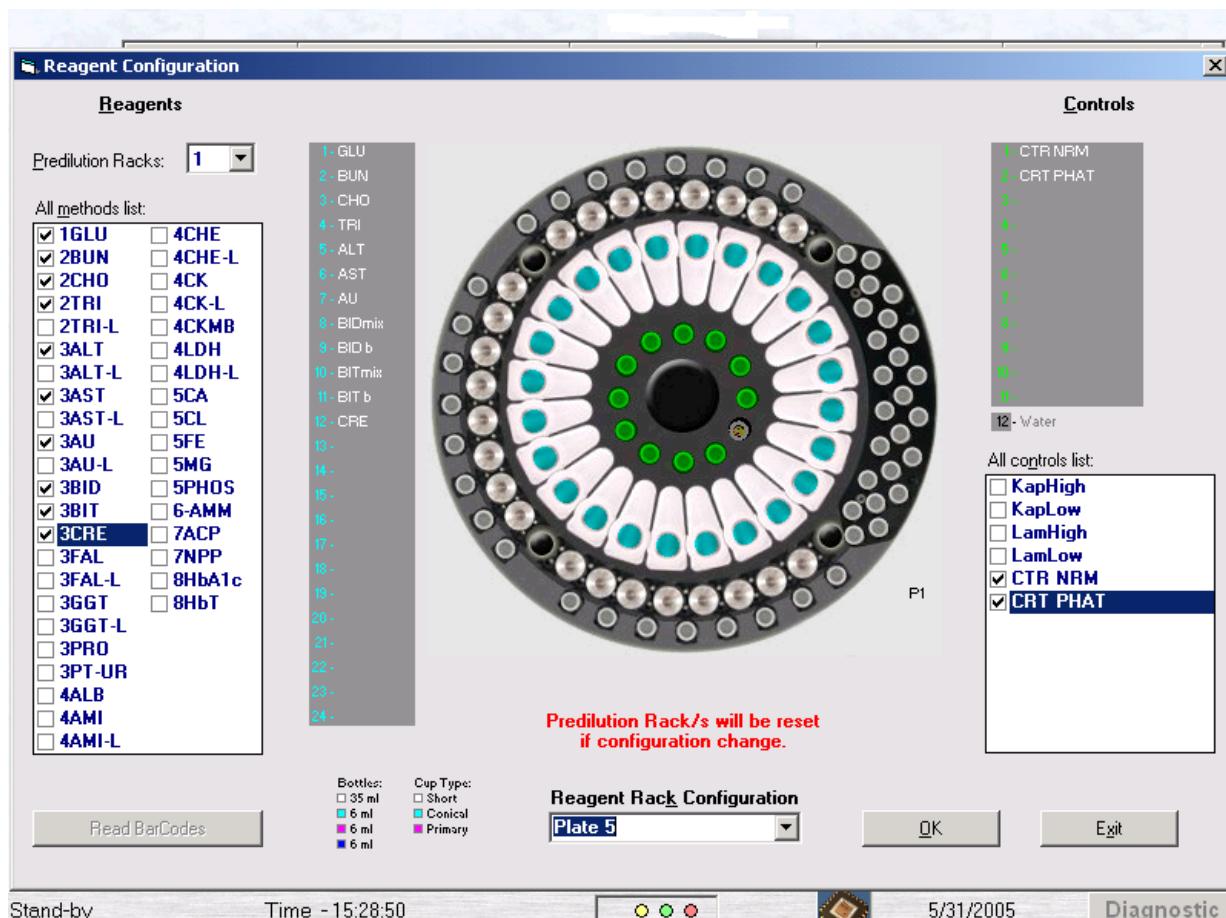
Whenever the Reagent ends:

- the position of that reagent under System Monitor will be shown coloured red;
- it will be given an hearing warning message;

The operator can print the data visualized in this mask by using the **command button** located under System Monitor (please see the section regarding the Command Buttons).



REAGENT CONFIGURATION



To access the **Reagent Configuration** mask, first select the **Checks Menu** and then, from the options listed, click on **Reagent Configuration**.

This function allows the operator to configure the reagents on the instrument.

The central area of the screen illustrates the reagent tray (including standards and controls), the samples and predilution racks.

The lower left area of this mask dedicated to the reagents, the operator can view the legend of those colours corresponding to the various sizes (capacities) of the reagent containers.

The right-hand area of the mask contains an enlarged illustration of the positioning of the standards and controls. Those controls already configured on the instrument are listed below this enlargement (please see the following paragraph dedicated to programming the controls).

A control can be activated or deactivated by simply clicking on its corresponding "box". The instrument will automatically assign an activated control to the first available, free, position in the STD/CTRL rack. The operator can also, if he/she so desires, change the position of a given control, moving it to another free position in the same standards and controls rack, or to one in the reagents positions. Using the mouse – "Drag & Drop", carries out this move.

PREDILUTION RACK

In the left-hand portion of the screen, below “**Reagents**”, the operator can view the following:



by clicking on the pull-down menu, the user can select a number from 0 to 2.

These numbers indicate the racks dedicated to the predilution of the samples and are as follows:

- 0** no predilution rack will be set-up;
- 1** the sample plate position **D** will be dedicated to the predilution rack **P1**;
- 2** the sample plate position **D** and **C** will be dedicated to the predilution rack **P2** and **P1** respectively;

Methods List



This frame allows the user to view all the **tests** without predilution if no predilution rack will be set-up or all the tests with and without predilution if predilution rack will be set-up.

These tests are listed in alphabetical order.

The selection of a given test immediately determines the automatic placement, in that area reserved for reagents, of the diluents and the reagents necessary for correctly carrying out that specific test. The reagents are placed in the first position available within the reagents tray. However the operator can change their position, if he/she so wishes, by using the mouse to move them via the **Drag & Drop** function.

The reagents are placed in the first position available within the reagents tray. However the operator can change their position, if he/she so wishes, by using the mouse to move them via the **Drag & Drop** function.

The name of the Reagent positioned in the rack will be shown in the colour that indicates its container format. The relative legend can be viewed in a chart located below the Reagents Racks. In order to change the format of the reagent container, the operator must first point the mouse towards the name of that particular reagent and then right click. This will automatically open a dialog box where the operator can select the type of container desired

In the lower portion of the screen, the user can view:

- **Reagent Tray(s) Configuration**

This section allows the operator to select from a pull-down menu, one of the eight programmed reagents plates. The user can program up to 8 (eight) different reagent configurations. Moreover, it is also possible to rename a given configuration, substituting its current name with a new one, using the keyboard and then confirming the change by clicking on **OK**. The user can at any time view the reagent configuration the instrument is using under System Monitor.

OK

The “**OK**” button allows the operator to save the change(s) made and confirm the configuration of the selected reagent(s).

Warning: if the operator enters the Reagents Configuration window once the **Calibration** has been programmed, he/she will view the following message:

CALIBRATION PENDING!

It's not possible to change the Reagent Configuration.

Retry later or delete Calibration.

In order to make any changes, the operator must first wait until the calibration has been either carried out or eliminated from the programming.

If the name of the reagent has been changed in the Methods window, it will also be eliminated from within the reagents configurations. **System Monitor** will therefore no longer show the name of the configuration in use, but will instead indicate “**INVALID**”.

If the operator enters the Reagents window, he/she will view the following message:

CONFIGURATION NOT VALID!

Methods definition has been changed.

Select a new Reagent Tray Configuration and

Check its methods.

It is the operator’s responsibility at this point to either insert the modified test in the reagents configurations and confirm the change by clicking on “**OK**”, or to not do so.

Exit

The “**Exit**” button allows the operator to close the Reagents Configuration mask and to return to the main mask – **System Monitor** – without saving any operated changes or modifications.

Predilution

Predilutions View				
	Position	Sample Type	Sample ID Name	Predilution Ratio
Monitor	101	-		1/1
Checks	102	-		1/1
Routine	103	-		1/1
Archive	104	-		1/1
Paramet.	105	-		1/1
Help	106	-		1/1
Shutdown	107	-		1/1
	108	-		1/1
	109	-		1/1
	110	-		1/1
	111	-		1/1
	112	-		1/1
	113	-		1/1
	114	-		1/1
	115	-		1/1
	116	-		1/1
	117	-		1/1
	118	-		1/1
	119	-		1/1
	120	-		1/1
	121	-		1/1
	122	-		1/1
	123	-		1/1
	124	-		1/1
	226	-		1/1
	227	-		1/1
	228	-		1/1
	229	-		1/1
	230	-		1/1
	231	-		1/1
	232	-		1/1

Stand-by Time - 15:30:33 [LED Status] 5/31/2005 Diagnostic

In order to access the **Predilution** mask, first select the **Checks Menu** and then, from the options listed, click on **Predilution View**.

This window contains all that data regarding the pre-diluted samples carried out in their appointed positions and activated under reagents configuration.

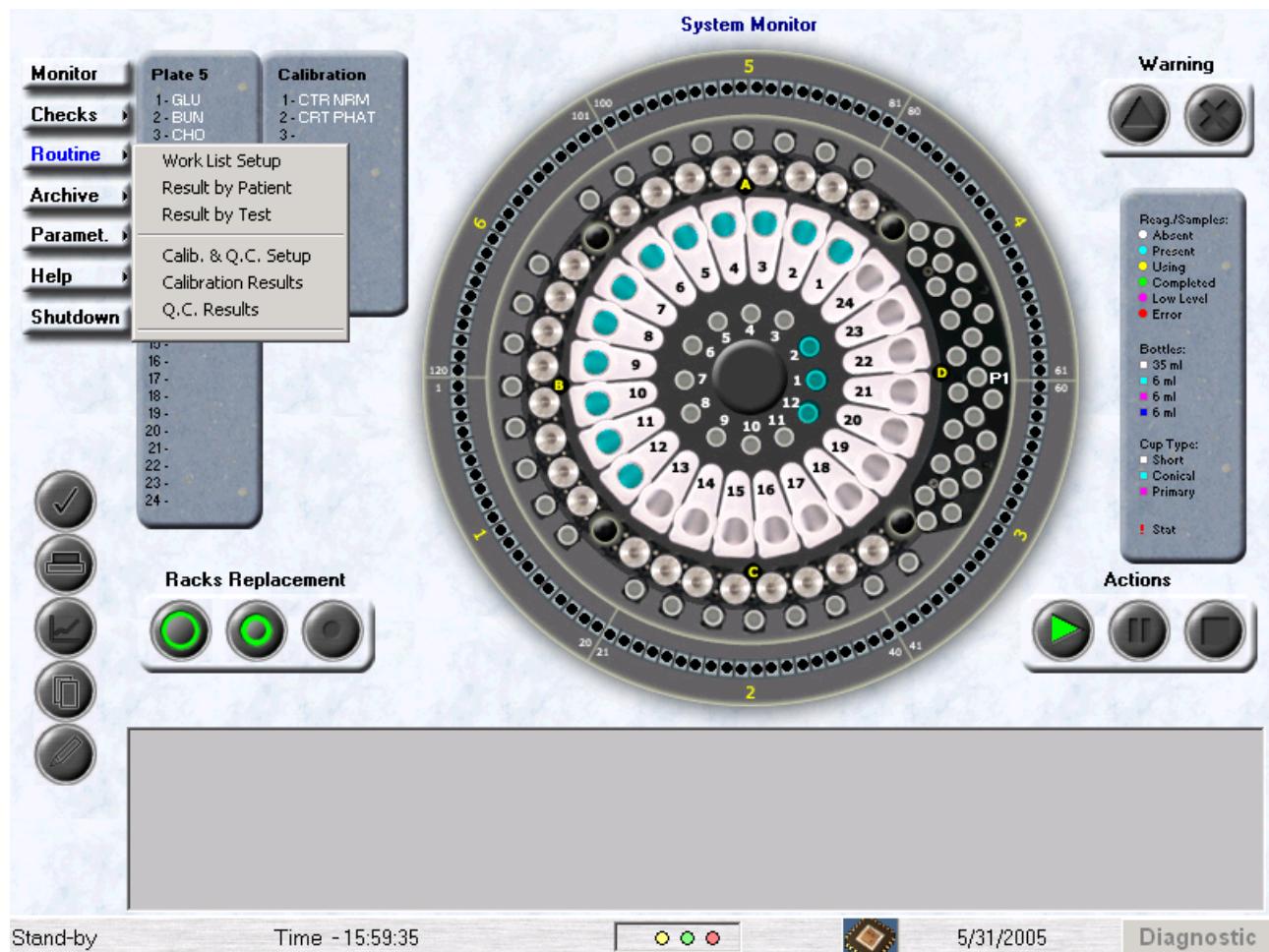
The fields to be considered are the following:

- Position** = position assigned to the diluted sample in the samples rack and in the predilution rack.
The numbering goes by 101 to 132 for the samples rack and by 201 to 250 for the predilution rack positions.
- Sample Type** = allows the operator to view the type of diluted sample (Serum / Urine)
- Sample ID name** = indicates ID code of the sample and patient name
- Predilution Ratio** = indicates the predilution ratio of the sample as set-up in the corresponding method



This mask allows the operator to print the information herein contained.
This can be done by using the **command button** located in System Monitor (please see the section regarding the Command Buttons).

3.3 ROUTINE



Routine ▶ The term **Routine** includes all those masks which are used both for programming the Patients and for the Calibration of the relative Tests. This heading also includes all those paragraphs which can help the operator better and more easily check the results of the performed operations.

Work List Setup: this mask is necessary for programming all those operations involving the patients and their respective tests;

Result by Patient: here the operator can view the personal data of the patients as set-up in the **Work List** programming mask and, if so desired, also the results of the programmed tests. The user can also request a print-out of the report(s) and of the work list(s);

Result by Test: here the operator can view, in addition to the patient data as set in the **Work List** programming mask, all that data specifically regarding the tests carried out;

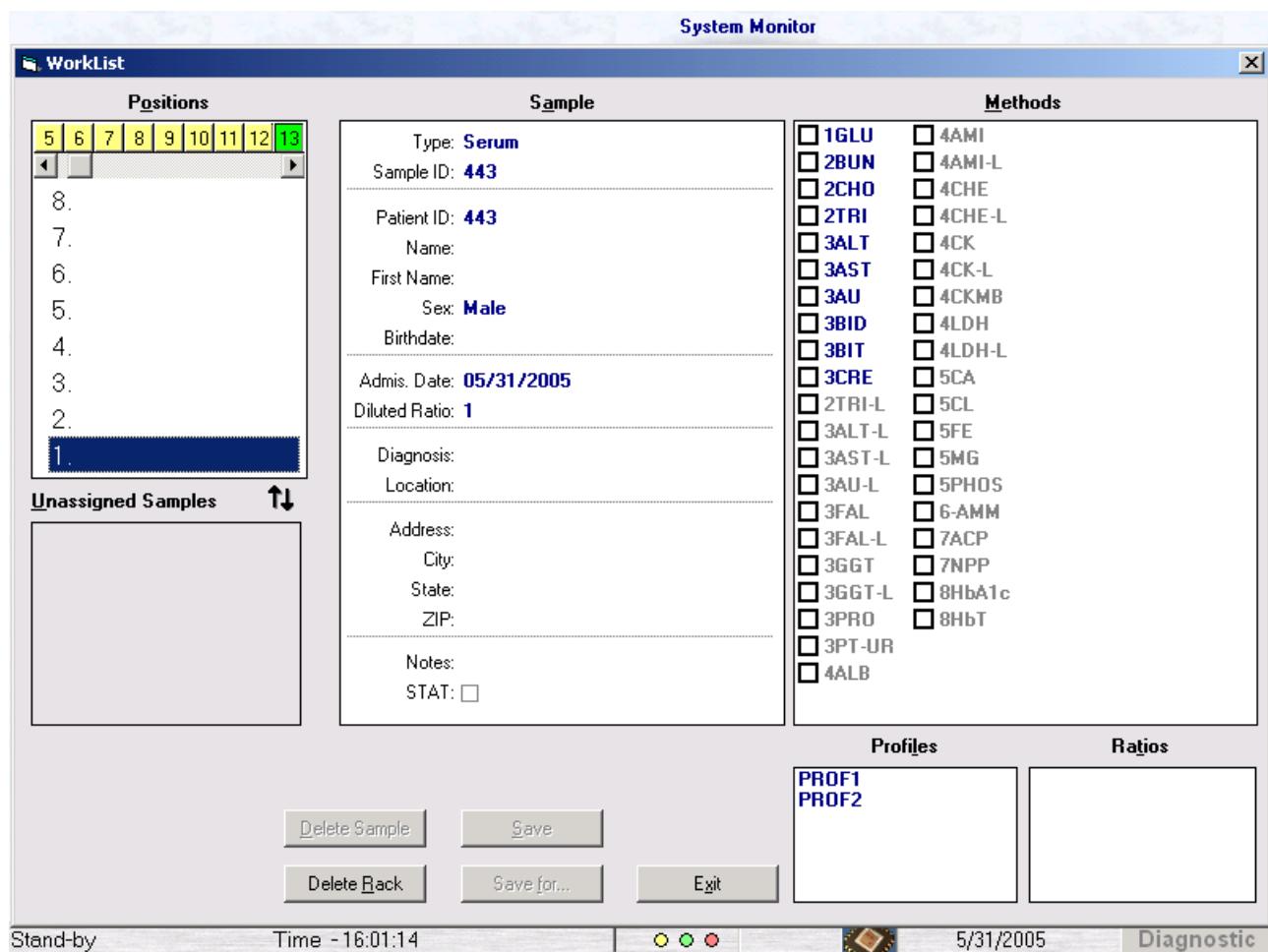
Calibration and Q. C. Setup: this is a necessary and preliminary first step to be carried out before any calibration. Here, the operator requests that the instrument carry out the RBL, the calibration and the controls for each individual method in the configuration;

Calibration Results: here the user can view the results obtained regarding the “Calibration” and all other related data;

Quality Control Results: here the operator can view all the data regarding the controls carried out on the tests;

Receive from Host: this command makes it possible to receive data from the Host regarding the Patients and the Tests to be carried out (only if **Host Connection** selection has been made active in the Option Menu).

WORK LIST SETUP



To access the **Work List** mask, the operator must first select **Routine** from the Menu and then, from the options offered, click on **Work List**. The Work List window, illustrated above, allows the operator to insert data regarding the patients and their respective **Tests**.

This programming phase is necessary before being able to load samples rack and to go on to the “**Start Work**” window.

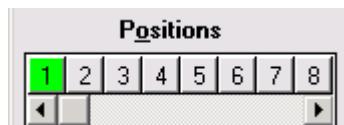
The Work List mask is organized in the following manner:

- An area located on the left-hand side of the screen, dedicated to the selection of the Racks and to the **positioning** of the Samples in these Racks;
- An area located in the central, right-hand part of the screen, dedicated to **personal data** regarding the patient, to the Methods, to the Profiles, and to the relative Ratios;

- An area located in the lower portion of the screen that contains those buttons necessary for the various **management** operations regarding the mask.

Positioning of the samples in the racks

Positions



The “**Positions**” field is located in the area dedicated to **Rack** selection, as illustrated here to the left. There is a scroll bar which allows the user to view all the available Racks, numbered from 1 to 99.

Within this area, those Racks which are available for sample assignment will be coloured grey, while those that have already been assigned at least one programmed sample are coloured yellow. The number of that particular Rack taken into consideration by the operator is highlighted in green, as illustrated here above. If the rack number is coloured red, it means that testing is being run on the sample therein contained. In this case, it is not possible to cancel the samples or the rack itself. However, the operator can add samples to be run if there are still positions left free.

Cup Set-up

8.	321331
7.	
6.	
2.	321325
1.	3217

Once the Rack has been selected, the operator can view in the “**Positions**” area (as seen here to the left) the **CUPS** for each of the Rack’s 8 positions, represented by the first column of numbers. Each cup has its own **SID** (Sample IDentification number) as set-up in the **Samples** card (in the central area) and this SID can be viewed in the second column of numbers.

For each position selected, the operator can view the Sample’s corresponding personal data in the central area of the **Samples** card; and the relative associated **Methods**, in the right area of the **Methods** card.

UNASSIGNED SAMPLE

?	000323
?	23232
?	212121
?	424
?	4313134

The **SIDS** of samples which have been programmed and sent to the **Work List via the Host Link**, but have not, as of yet, been physically assigned to a specific Rack, will be viewed in the “**Unassigned Samples**” field, illustrated here to the left. Within this field, the operator can move a SID from here in the Rack and viceversa, via the mouse using the **Drag & Drop** function.

Furthermore, this area allows the operator to use the Bar Code Module (please see the section: Options) to manually program the samples without worrying about assigning them to a certain position, as position assignment will be carried out by the instrument via a reading of the Bar Code. The operator will automatically be notified through a visual text information message whenever this function is active. The user can view this message in the that part of the screen located above the command buttons in the System Monitor screen.

Patient Personal Data

Sample

Personal data regarding the Patient and data regarding the corresponding sample are included in this card. The following information can be viewed:

Type: a pull down menu containing a list of sample type options - Serum, Urine, Control – from which the operator can choose. (**Please see the ‘Controls in the Racks’ paragraph for information regarding the choice of Control.**) Once the sample type has been set-up, i.e. said selection saved, it can no longer be changed. At this point it will appear coloured dark grey.



Sample ID: required field – the **Sample Identification Code** can be made up of a **Maximum of 15** letters or digits and will be assigned to only one of the accepted samples. If the SID is numerical, it is set-up by the instrument program and is progressive. The operator can change the SID, but should pay special attention as duplicate SIDs are not allowed. Said SID can be modified by the operator up until the moment in which it is saved, at which point it can no longer be changed and will appear coloured dark grey.

Patient ID; required field – **Patient Identification Code.** It is an unequivocal reference code, unique to that individual patient. PIDs can be modified by the user up until the moment in which they are saved, at which point they can no longer be changed and will appear coloured dark grey. Seeing as how a given Patient can be tested more than once, different **SIDs** can be assigned to the same **PID.** (Glycemic Curve):

Last Name: the patient’s last name (family name/surname);

First Name: the patient’s first name (given name);

Sex: this required field contains a pull-down menu offering two possible choices – male or female, for the sex of the patient. During sample running, it is not possible to modify this choice and the field will therefore appear coloured dark grey;



Birthdate: patient’s date of birth. This data can be inserted using the program’s calendar, accessible by pressing **F4** or by **double clicking** with the mouse. In case of patient’s date of birth absence, regarding the reference range, patient will be consider as **Adult.** During sample running, it is not possible to modify this choice and the field will therefore appear coloured dark grey;

Admis. Date: date of admission of the patient. This data can be inserted using the program calendar, accessible by first selecting **Admis. Date**, then **F4** or by **double clicking** with the mouse;

Diluted Ratio: indicates the dilution ratio of an already pre-diluted sample. Leaving he predefined value of “**1**” unaltered, means that the sample is undiluted.

Choosing “2” means that the sample is diluted manually by the operator in a 1 to 2 ratio. If “2” is selected, the final result of the test run on that sample will be automatically multiplied by 2. During sample running, it is not possible to modify this choice and the field will therefore appear coloured dark grey;

The following include more detailed information:

Diagnosis: description of a possible pathology;

Location: department or ward;

Address: patient's street address;

City: name of the city where the patient resides;

State: name of the state (or country) where the patient resides;

ZIP: Postal Zip Code

Notes: here the operator can insert any information deemed important or useful

STAT: indicates that the sample is urgent and will be executed as first before all other programmed and loaded samples. After STAT sampling the analyzer will continue with other samples without any further operation by the user.

Stat samples can be loaded on any of samples rack either on a free or busy position. In the latter case, the previously loaded sample must be removed and re-programmed.

Methods

Methods		
<input type="checkbox"/> 1-GLU	<input type="checkbox"/> 2-TRI	<input type="checkbox"/> FE-2
<input type="checkbox"/> 1-UREA	<input type="checkbox"/> ALB	<input type="checkbox"/> FE-PAP
<input type="checkbox"/> 2-CHO	<input type="checkbox"/> ALP-2	<input type="checkbox"/> FRU
<input checked="" type="checkbox"/> 3-ALT	<input type="checkbox"/> AMI	<input type="checkbox"/> HB1AC
<input checked="" type="checkbox"/> 3-AST	<input type="checkbox"/> AU	<input type="checkbox"/> HDL
<input checked="" type="checkbox"/> ALP	<input type="checkbox"/> bib	<input type="checkbox"/> H-LDL
<input type="checkbox"/> AMY	<input checked="" type="checkbox"/> BID	<input type="checkbox"/> LIP
<input type="checkbox"/> CA	<input checked="" type="checkbox"/> BIT	<input type="checkbox"/> LIP-C
<input checked="" type="checkbox"/> CHE	<input type="checkbox"/> CA-2	<input type="checkbox"/> P
<input type="checkbox"/> CL	<input type="checkbox"/> CA-ARS	<input type="checkbox"/> PRO-T
<input type="checkbox"/> CRE	<input type="checkbox"/> CHE-2	<input type="checkbox"/> PRO-UR
<input checked="" type="checkbox"/> GGT	<input type="checkbox"/> CK-MB	<input type="checkbox"/> ric1

The Methods window (central area of the window –illustrated here above) contains a list of the test acronyms that have been previously programmed under the Methods mask.

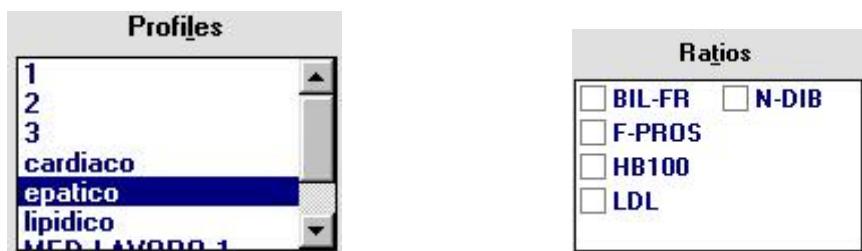
The tests in the Methods list are listed in alphabetical order and priority is given to those contained in the reagents configuration currently in use by the instrument.

The acronyms are coloured either blue or grey as an indication of whether their relative reagents have already been or not yet been programmed under the Reagents configuration currently in use. Blue indicates that the reagents have already been programmed; grey, that they have not yet been programmed. Click on the small boxes located beside the test acronyms to “check” the relative methods for that patient being programmed in the Sample card.

The methods written in blue will be run when the sample rack is loaded and the relative Work List is activated under the “Start Work” mask, while those highlighted in grey will remain set-up, but will not be run until their relative reagents have been configured.

These tests will appear coloured dark grey when the instrument is in the process of carrying them out or whenever they have already been run. It is not possible to modify or change the Test assignment regarding Tests already carried out or those being run.

Profiles / Ratios Areas



Located below the Methods List, this area includes the two, here-illustrated, frames. These frames contain those tests which have been previously memorized (saved) under the respective Profiles and Ratios programming masks.

Whenever a profile is selected in the Profiles Area, all those tests which are included in that Profile, as set-up in the Methods list and necessary for carrying out that particular Profile, will be automatically selected and a check mark (✓) will appear in the small adjacent box.

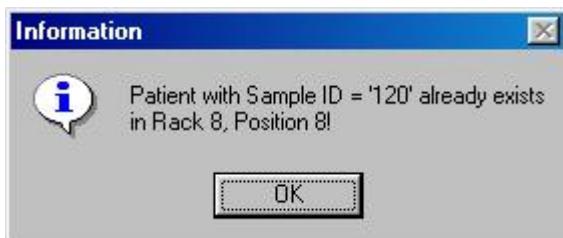
If the operator selects a Ratio which is listed under the Ratios area, a check mark (✓) will appear in the small adjacent box and all those tests which are included in that Ratio will be automatically selected and a check mark (✓) will appear in the small adjacent box of the methods window.

Already Assigned Sample ID

Save

Select the required Rack (“**Positions**” area) and a position within the Rack. Fill out the “**Sample**” card – the **Patient ID** is mandatory and therefore must be inserted – and mark (‘check’) the relative methods in the **Methods** card. If the operator selects an unassigned position, the instrument will propose the first available **Sample ID** to the user to be inserted in the “**Sample**” card. If an already assigned position is selected by the user, then the operator must be careful when choosing the SID, so as to not assign one already in use.

To confirm, click on “**Save**”, which will be activated only after a Sample ID and a Method have been selected. If, by mistake, an already assigned Sample ID is set-up, the following dialog box/visual text information message will appear:



Confirm by clicking on “**OK**”, change the SID and then click on “**Save**” once again.

If, instead, the operator tries to save data without having first selected at least one **Method**, then the following dialog box/visual text information message will appear:



Confirm by clicking on “OK”, select one or more Methods, and then click on “Save” once again.

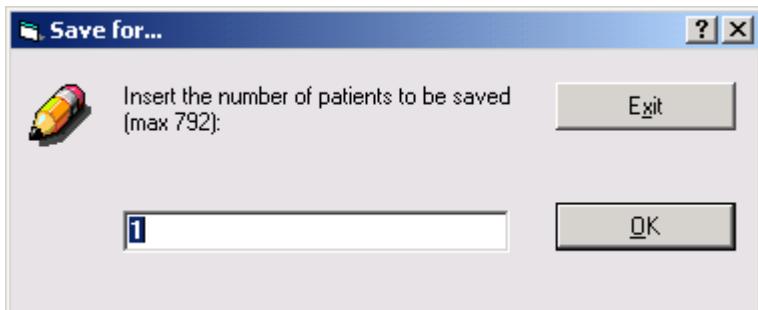
Once the operator has clicked on “Save”, the “Positions” card will automatically be updated and another, different **Sample ID**, available for a subsequent sample, will be proposed for the next sample.

SAVING DATA FOR MORE THAN ONE PATIENT

Save for...

To save data that is the same for more than one patient at a time, or rather, for more than one patient all having the same methods programmed, use the “Save for...” button. The selection process is the same as that used for a single patient. Click on “Save for...” instead of on “Save”.

The following dialog box will appear:



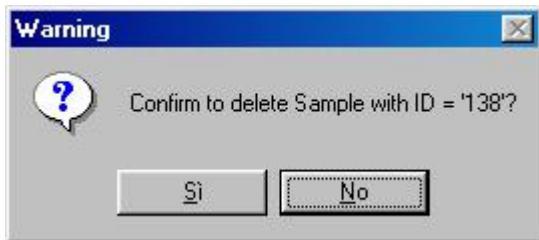
Insert the number of patients for whom data is to be recorded, remaining within the **Maximum** number position of the 99 samples racks. If the number inserted is greater than the number of positions left free in a Rack, the program will assign the patients to the next Rack. Click on “OK” to confirm and complete the operation. Click on “Exit” to cancel the operation

DELETING A PATIENT

Delete Sample

Select the **Rack** and the position of the **Sample ID** to be deleted in the “Positions” card. Then click on “Delete Sample” (this option is not activated if the operator chooses a sample contained in the rack that the instrument is running at the time).

The following visual text information message/dialog box will appear:

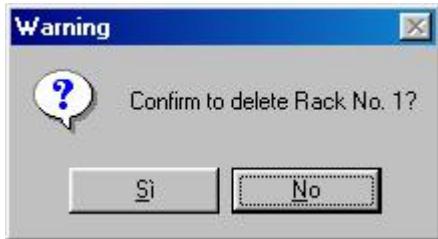


Click on “Yes” to confirm the deletion of the **Sample**; click on “No” to annul the request and exit.

DELETING A RACK

Delete Rack

To delete all the samples contained in a given rack, select the Rack from the **“Positions”** pull-down menu, then click on “**Delete Rack**” (this option is not activated if the operator chooses a rack that the instrument is running at the time). The following visual text information message/dialog box will appear:



Click on “Yes” to confirm the deletion of the **Rack**; click on “No” to annul the request and exit.

Exit

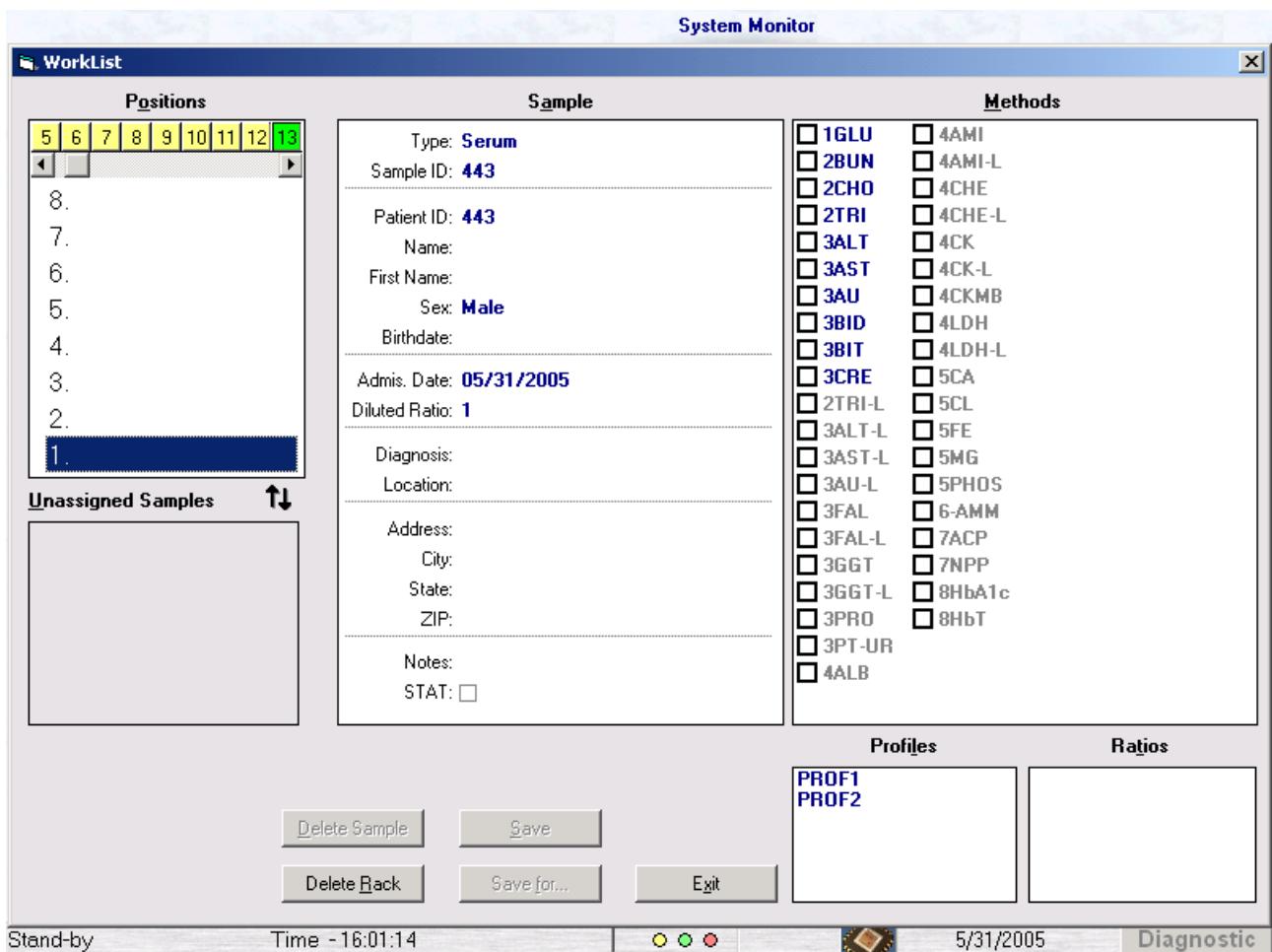
To Exit the **Work List** mask and return to the **System Monitor** main screen, click on “**Exit**”.

Controls in the Samples Racks

A Control in the Samples Rack can be programmed under the Work List mask. To access the Work List mask, the operator must first select Routine from the Menu and then, from the options offered, click on **Work List**.

This mask allows the operator not only to set-up the Controls, but also to program the patients and their respective Tests (as described in the section dedicated to the **Work List**). When opened, the mask will appear, structure-wise, as illustrated in the section dedicated to the **Work List**.

Whenever this mask is used for programming a Control, it will appear structurally identical to that illustrated under the Work List section but certain fields will be deactivated. Therefore, the mask will appear to the user as pictured below:



Following is a more detailed description of the sections of the mask necessary for programming Controls:

- An area in the left-hand portion of the mask dedicated to the selection of the Racks and the positioning of the Controls in the Racks;
- An area in the central, right-hand portion of the mask dedicated to setting-up the Control and the relative Methods;
- An area in the bottom portion of the mask containing those buttons necessary for the various management operations concerning the mask.

All the fields contained in the above-described areas maintain the same structure and function as reported in the Samples Programming description (Work List).

Programming a Control



Select the required Rack (“**Positions**” area) and a position in that Rack for the Control. From the Type field’s pull-down menu (central area of the mask, as illustrated here to the right), click on “**Control**” and the above-illustrated mask will automatically appear.

Fill out the “**Sample**” card – the Patient ID must be here-inserted as it is mandatory data – then click on “Name” (n. b.: in this particular case, the “Name” field allows the user to open a pull-down menu listing the various controls). Select the required Control.

The program will automatically view in the Methods card only those methods that in the programming of the Control were assigned to the selected control and are currently configured in the Reagents Plate.

The operator must, at this point, “Check” (✓), in the Methods card, all those Tests that he/she wishes to set-up the control on. It is not possible to select a Profile or insert a Ratio in the programming of a Control. In fact, the two areas dedicated to these tests are not activated.

If the operator selects an unassigned position, the program will automatically propose the first available Sample ID to the user to be inserted in the Sample Card. If an already assigned position is selected by the user, then the operator must be careful when choosing the Sample ID, so as to not assign one already in use.



Save

To confirm, click on “Save”, which will be activated only after a Method has been selected.

If the operator wishes to save the data inserted for carrying out Control(s), or delete an entire Rack or a single sample, he/she must use the buttons located in the lower portion of the mask. These operations are described in detail in the **Work List** section.

RESULT BY PATIENT

To access the **Result by Patient** mask, first select the **Routine Menu** and then, from the options listed, click on **Result by Patient**.

This mask allows to the operator the report(s) print-out and the Work List print-out for sample racks preparation.

Furthermore in this mask are showed all that data regarding the patients as inserted in the **Work List** Programming mask and also more specific data concerning the tests carried out or to be executed.

This is provided in two areas:

- a **Main Area** located in the upper portion of the mask - below is an illustration. This mask contains all the pertinent fields needed by the operator in order to correctly identify the sample.

Patient WorkList

	Rack-Pos	Type	Samp.Dil.	SID	PID	Name	Sex	Birthdate
Monitor	1 - 1	Serum	1/1	435	435		Male	
Checks	1 - 2	Serum	1/1	436	436		Male	
Routine	1 - 3	Serum	1/1	437	437		Male	
Archive	1 - 4	Serum	1/1	438	438		Male	
Paramet.	1 - 5	Serum	1/1	439	439		Male	
	1 - 6	Serum	1/1	440	440		Male	
	1 - 7	Serum	1/1	441	441		Male	
	1 - 8	Serum	1/1	442	442		Male	
Help	2 - 1	Serum	1/1	368	KXSA1	KXSA1	Male	
Shutdown	2 - 2	Serum	1/1	369	KXSA2	KXSA2	Male	
	2 - 3	Serum	1/1	370	KXSM	KXSM	Male	
	2 - 4	Serum	1/1	371	LXSG1	LXSG1	Male	
	2 - 5	Serum	1/1	372	LXSG2	LXSG2	Male	
	2 - 6	Serum	1/1	373	LXSG3	LXSG3	Male	
	2 - 7	Serum	1/1	374	LXSG4	LXSG4	Male	
	2 - 8	Serum	1/1	375	LXSA1	LXSA1	Male	
	3 - 1	Serum	1/1	376	LXSM	LXSM	Male	
	4 - 1	Serum	1/20	377	KAPPA	G1XS	Male	
	4 - 2	Serum	1/20	378	KAPPA	G2XS	Male	
	4 - 3	Serum	1/20	379	KAPPA	G3XS	Male	
	4 - 4	Serum	1/20	380	KAPPA	A1XS	Male	
	4 - 5	Serum	1/20	381	KAPPA	A2XS	Male	
	4 - 6	Serum	1/20	382	KAPPA	MXS	Male	



The window contains the following fields:

! : indicates STAT sample

Rack/Pos: indicates the Rack number and position in the rack used for that sample;

Type: indicated the type of sample used;

Sample Dilution: indicates the Dilution ratio used for the serum;

Sample ID: allows the operator to view the sample identification number;

Patient ID: allows the operator to view the patient identification number;

This section also contains specific personal data regarding the patient, such as that shown in the fields entitled: **Name, Sex, Birth date** (please see the section: Work List).

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



- Print the selected data – reports/work list (**Print** button);



- Repeat the selected samples (**Rerun** button);



- File the selected samples in the Archive (**Move** to Database button);



- Send the data to the remote computer (**Unload** button)

(Please see the section: Command Buttons)

- a **Details Area** located in the lower portion of the mask. Below is an illustration of this Details Area which contains specific, itemized information regarding each of the fields contained in the Main Area.

Name: De Niro Robert SID: 129 (Rack/Pos.: 9/1).

Test	PreDil.	Test Dil.	Result	Unit	Normal Values	Flags	Date
COLESTEROLO	1/1	1/1	Pending				04/04/2003 16:54:38
GLUCOSIO	1/1	1/1	Pending				04/04/2003 16:54:38
UREA	1/1	1/1	Pending				04/04/2003 16:54:38

Whenever a row in the Main Area is selected by the operator, the relative Details Area will automatically appear providing all that specific data concerning the row selected.

Herein will be shown: the **Tests** performed, the **Pre-dilution**, the **Dilution**, the **Result**, the **Unit of Measurement** used, and the **Normal Values** for that test.

Special attention should be paid to that column entitled **Flags**, as it lists any **errors** encountered during operation. Whenever an error occurs, all those fields regarding that test are automatically shown coloured **red**. In this case, a small red square (■) appears in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the name of the error encountered. In this window, as in many others, errors are signaled using letters which stand for the type of error encountered – as reported in Result Flags description.

The last column in this Details Area is the **Date** column which gives the date the test was either carried out or edited. If the test has not as of yet been carried out (pending), then this field will show the date and exact time that the sample was accepted.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Make validated the results of selected data (**Check** button);



- Reorder the viewed data (**Order** button);



- Print the selected data – reports/work list (**Print** button);



- Repeat the selected tests (**Rerun** button);



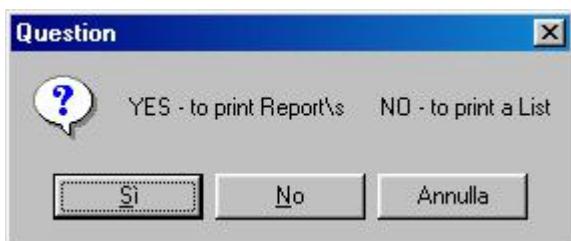
- Modify the results of the selected test (**Edit** button)

(Please see the section: Command Buttons)

PRINTING DATA



In order to print the data viewed in this mask, the operator must first select the row or rows to be printed and then click on the Print button located on the Desk Top. The below- illustrated dialog box will appear, asking if the operator wishes to print reports or work list. Work list print-out can be useful to the operator in order to prepare the sample racks.



If the operator clicks on “YES”, only the report of the selected row(s) will be printed; if instead he/she clicks on “NO”, the entire list of the selected patients will be printed for sample racks preparation. Clicking on “Cancel” will annul the Print request. Likewise, the “Cancel” button that appears during printing allows the operator to stop the printing process even while it is underway.

Result by Test

To access the **Result by test** mask, first select the **Routine Menu** and then, from the options listed, click on Result by Test. The above-cited List will automatically be opened for viewing.

This mask allows the operator to view all that data regarding the patients as inserted in the **Work List** Programming mask and more specific data concerning the tests carried out. Said information is provided in a single “**Main Area**” which contains all the pertinent fields.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Make validated the results of selected data (**Check** button);



- Reorder the viewed data (**Order** button);



- Print the selected data (**Print** button);



- View the absorbance graph of the selected test (**Graph** button);



- Repeat the selected tests (**Rerun** button);



- Modify the results of the selected test (**Edit** button).

(Please see the section: Command Buttons)

MAIN AREA

Located in the upper portion of the mask and illustrated below, this section contains all that data regarding the carrying out of the samples testing.

Test WorkList										
	Pos.	Type	Samp.Dil.	SID	Name	Test	Test Dil.	Result	Unit	Flags
Monitor	1 - 1	Serum	1/1	435		1GLU	1/1	96	mg/dl	E
Checks						2BUH	1/1	22	mg/dl	E
Routine						2CHO	1/1	158	mg/dl	E
Archive						2TRI	1/1	145	mg/dl	E
Paramet.						3ALT	1/1	33	mg/dl	E
Help	1 - 2	Serum	1/1	436		3AST	1/1	28	U/l	E
Shutdown						3AU	1/1	3.3	mg/dl	E
	1 - 3	Serum	1/1	437		1GLU	1/1	Pending		
						2BUH	1/1	Pending		
						2CHO	1/1	Pending		
						2TRI	1/1	Pending		
						3ALT	1/1	Pending		
						3AST	1/1	Pending		
						3AU	1/1	Pending		
	1 - 4	Serum	1/1	438		1GLU	1/1	Pending		
						2BUH	1/1	Pending		
						2CHO	1/1	Pending		
						2TRI	1/1	Pending		
						3ALT	1/1	Pending		
						3AST	1/1	Pending		
						3AU	1/1	Pending		
	1 - 5	Serum	1/1	439		1GLU	1/1	Pending		
						2BUH	1/1	Pending		
						2CHO	1/1	Pending		

The following fields of the above-illustrated window are worthy of mention:

! :indicates STAT sample

Pos.: indicates the **Rack** number and position in the rack used for that sample;

Type: indicated the type of sample used;

Sample Dilution: indicates the Dilution ratio of the sample;

Sample ID: indicates the Sample Identification number (please see the section: Work List);

Name: indicates the name of the patient whose sample is being tested;

Test: indicates the name of the method(s) applied;

Test Dil.: provides the operator with information regarding the dilution of the sample for that specific test (e.g.: 1:5 rerunning with dilution);

Results: indicates the obtained result(s);

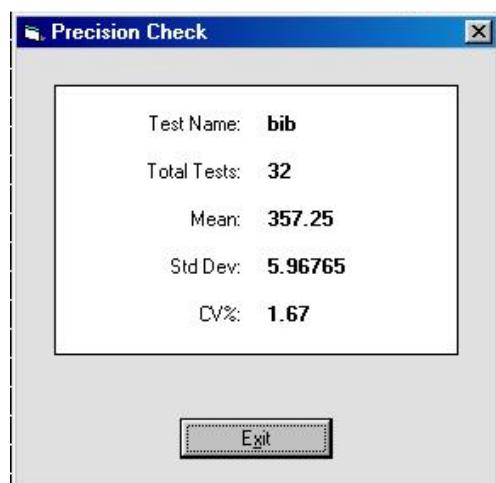
Unit: indicates the unit of measurement used;

Flags: this field allows the operator to view if any errors occurred during operation.

Whenever an error occurs, all those fields regarding that test are automatically shown **colored red**. In this case, a small red square (■) appears in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the full name of the error encountered. In this window, as in many others, errors are signaled using letters which stand for the type of error encountered – as reported in Result Flags description.

PRECISION CHECK

This mask allows the operator to check exactly how precise the results of a given test(s) are along with their level of precision. To carry out this check, the operator must first select, in the Main Area, the row(s) to be checked and right click with the mouse. (If the operator selects more than one row for the Precision Check and these rows contain different tests, the check will be performed only on the first test selected and any other of the same type test contained in the other rows selected; all dissimilar test types will be automatically ignored.) At this point, the system will automatically activate the visualization of the “**Precision**” command. Clicking on this button will open the below-illustrated “**Precision Check**” window.



The “**Precision Check**” window contains the following useful information:

Test Name: indicates the name of the test to be checked. In the example window, the name of the test is **bib**;

Total Tests: indicates how many tests of the indicated test-name are included in the rows the operator has selected to be checked. In this example window, there are **32 bib** tests to be checked;

Mean: indicates the mean value of the results of the **32 tests** checked;

STD Deviation and CV%: indicate the Standard Deviation and Coefficient of Variation of the checked tests.

Exit

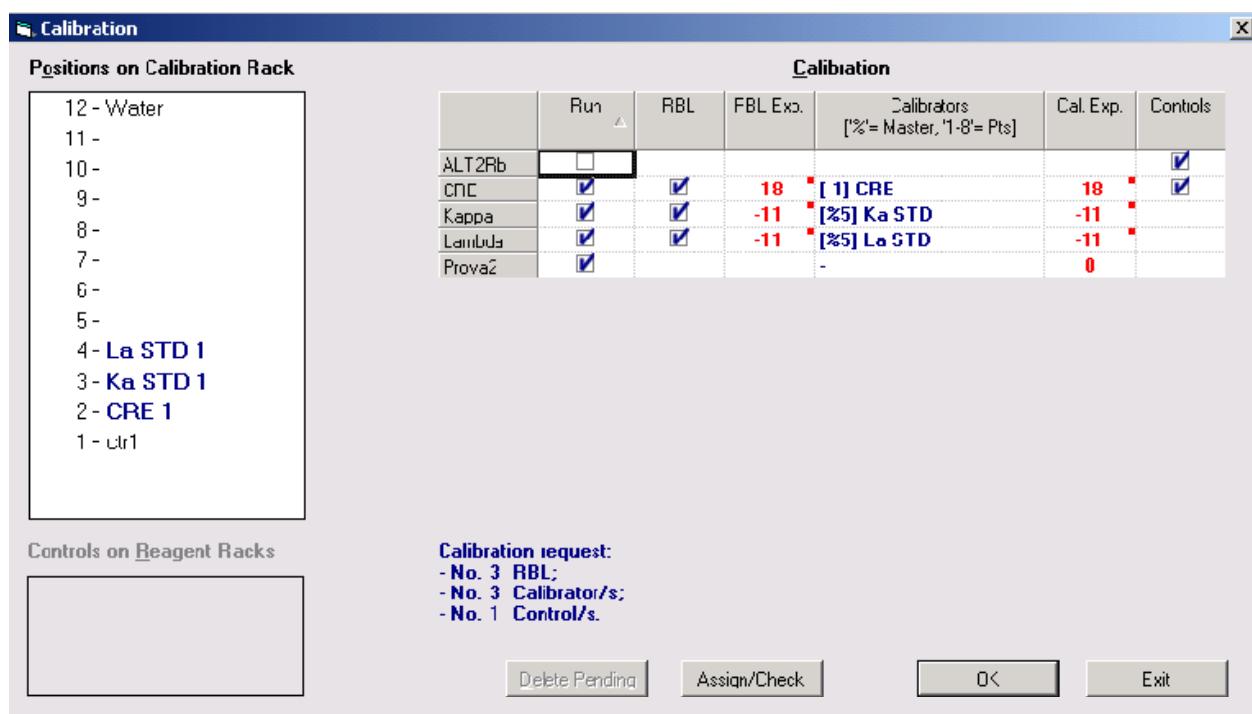
To exit the “Precision Check” window, click on **Exit**.

CALIBRATION & QUALITY CONTROL SETUP

In order to guarantee that the instrument provide reliable test results, correct and precise calibration must be performed. This operation is carried out, for those tests for which it is required, and it must necessarily be carried out by the operator whenever the instrument is first installed. Calibration can then be either periodic or whenever required by factors external to the instrument itself, such as reagent substitution. It may also be necessary to repeat calibration in the event that an instrument part, concerning the analytical module, is replaced (photometer lamp, dilutor module, etc.)

Prior to any calibration, it is mandatory that both **controls** and **standards** for the relative methods be correctly programmed.

To access the **Calibration & Quality Control Setup** mask, first select the **Routine Menu** and then, from the options listed, click on “**Calibration & Quality Control Setup**”.



The above-illustrated window includes a central area dedicated to the selection of those tests for which the operator can request an RBL, a calibration and/or a controls running.

The first column reports, in alphabetical order, the methods programmed in the currently-in-use reagents configuration. The other columns concern the following fields:

Run: automatically checked (“”) whenever either the RBL or the calibration is expired. This field can be activated or deactivated (checked “” or “un-checked”) by the operator;

RBL: automatically checked (“”) whenever the RBL must be run for the first time, or when it is expired;

RBL Expiration: number of days left before the RBL expires. For example: a “6” indicates that the RBL is valid for another six days. Furthermore, the RBL is automatically scheduled to be run at the end of said period. A “-3” indicates that the RBL expired three days ago. If the RBL has already expired (past its expiration date), this number will be a negative number and will be shown in red. A small, red square (■) will be viewed next to this negative number.

Placing the mouse pointer over this symbol will cause a visual text message to appear informing the user of the date that the RBL is programmed to be run. Please note that the operator can decide the RBL validity period by setting said value in the “**RBL stability (# of days)**” field in the “Methods” mask;

Calibrators: this column contains the name of the Standard preceded by a number in parenthesis indicating the relative number of points (in the case of a Master Standard, this number is preceded by a % symbol, as reported in Standard), or by the symbol “-” if there are no Standards to calibrate. Whenever a Standard is selected, both the Run and the RBL fields are automatically checked (“”). However, they can be “un-checked” by the operator if he/she does not wish to have the calibration run on these two fields. The number and the name of the Standard are shown in Blue, if they are still to be calibrated, or in Black if already assigned to calibration;

Warning: expired standard will not be shown.

Calibration Expiration: number of days left before the Calibration expires. For example: a “10” indicates that the calibration is valid for another ten days. Furthermore, the calibration is automatically scheduled to be run at the end of said period. A “-5” indicates that the calibration expired five days ago. If the calibration has already expired (past its expiration date), this number will be a negative number and will be shown in red. A small, red square (■) will be viewed next to this negative number. Placing the mouse pointer over this symbol will cause a visual text message to appear informing the user of the date that the calibration is programmed to be run;

Please note that the operator can decide, for each test, a calibration validity period by setting said value in the “**Calibration Stability (# of days)**” field in the “**Methods**” mask.

Controls: a check mark will automatically appear for those controls programmed in the currently-in-use reagents configuration. This field can be activated or deactivated (checked “” or “un-checked”) by the operator.

Warning: expired Controls will not be shown.

Assign/Check | An “**Assign/Check**” button is located in the lower portion of the mask. This allows the operator to assign positions to the Standards and the Controls in the **Calibration rack**.

Calibration Request

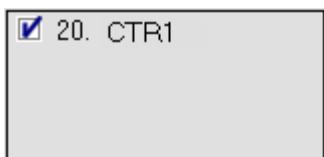
Calibration request:
 - No. 17 RBL;
 - No. 2 Calibrator/s;
 - No. 14 Control/s.

Whenever the operator clicks on **Assign/Check**, a **Calibration Request** visual text message will appear within this same area informing the user of the number of operations already assigned.

Positions on Calibration Rack

12 - Water
11 -
10 -
9 -
8 -
7 -
6 -
5 -
4 - La STD 1
3 - Ka STD 1
2 - CRE 1
1 - ctr1

In the left-hand portion of the calibration programming mask, the operator can view the rack containing the standards and controls, whose positions will be assigned using the Assign/Check button. The rack has 12 positions; the 12th is by instrument specifications reserved for distilled water to be used for carrying out the RBL. The running of the controls can be confirmed by the operator by either checking or not the relative boxes.

Controls in the Reagents Racks

Here reported to the left is an illustration of the area of the mask where the **Controls** inserted in the calibration and positioned in the reagents tray under reagents programming, can be viewed by the operator.

Automatic rerunning of the Controls

This paragraph is dedicated to those **Controls** which the user wishes to rerun after a given interval. A continuous rerunning of a Control can be useful whenever relatively unstable or extremely sensitive solutions are tested. In these cases the operator may find it useful to run a given control at determined intervals in order to verify the reliability of the results.

The automatic rerunning of the controls must be programmed in the **Methods Programming** mask under the **Parameters** menu.

The system automatically processes the Control whenever the latter has been calibrated, into the used Reagent Configuration, and the method being run requires that particular Control.

A rerunning of the Control will be automatic every time the system runs a test belonging to a control which is listed as expired.

CALIBRATION PROGRAMMING

To correctly carry out this procedure, first make sure that the automatic selection of the items in the **Calibration** table has been carried out correctly. Make any necessary changes and then click on "**Assign/Check**". This activates that procedure which assigns the position of the Standards and the Controls in the **Calibration rack**.

When the assign procedure is successful, the following visual text message will appear informing the user of the number of operations programmed.

Calibration request:
 - No. 17 RBL;
 - No. 2 Calibrator/s;
 - No. 14 Control/s.

Warning! It is not possible to carry out this “Assign” procedure for already assigned Standards or for expired calibrators. If Standards having dilutions are assigned to calibration, the operator must first make sure that there is enough liquid, in terms of volume, to carry out the operation set-up. He/she must also ascertain that the concentration percentage of the Master Standards is not too low with respect to the predilution volumes set-up in the Methods programming mask. If either of these two situations occurs, the program will inform the operator using a visual text message coloured red when he/she attempts to assign Standards to calibration. Moreover, no procedure will be carried out for that Standard.

The **Master Standards** occupy only a single position, regardless of the points contained, while the **Standards** occupy all those positions previously declared in the programming mask.

OK

To confirm calibration, click on “OK”. This button is activated only after positions have been assigned. Clicking on “OK” automatically closes the viewed window.

If the operator returns to the Calibration mask, after having confirmed the above-explained operation by clicking on “OK”, the following visual text information message will appear: **CALIBRATION PENDING!** – informing the user that a programmed calibration already exists.

At this point, the names of the **Standards** and of the **Controls** in the Calibration rack and in the Calibration table are no longer coloured blue, but rather they appear coloured black to attest to the fact that they have already been programmed.

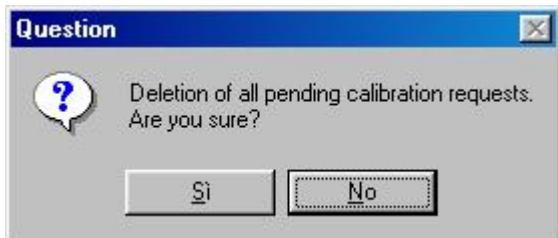
The operator can, if he/she so desires, print a list of those items assigned to calibration. To do so, first select those items to be printed from the **Reagents Volume** List in the **Checks** menu, and then proceed as for any other Print request.

EDITING CALIBRATION

Delete Pending

Even after having programmed a calibration, it is still possible to add **RBL**, **Standards** and **Controls** not previously requested – as long as there are still free positions left in the **STD/CTRL Positions** rack. However, it is not possible to remove elements from an already programmed calibration. It is only possible to completely cancel the entire already programmed calibration by using the “**Delete Pending**” button, which is activated only when there is a calibration pending

If the operator clicks on this button, the following visual text message will appear:



If the operator clicks on “**Yes**”, the cancellation of the pending calibration(s) is confirmed, and the calibration is no longer valid. By clicking on “**No**” the operator can annul his/her request to cancel any pending calibration.

 The “**Exit**” button allows the operator to close the **Calibration and Quality Control** programming mask and to return to the main mask: **System Monitor**.

CALIBRATION RESULTS

To access the **Calibration Results** mask, first select the **Routine Menu** and then, from the options listed, click on **Calibration Results**.

The operator can here – please see the Calibration Results mask illustrated below – view the results of the calibration and all the pertinent associated data. This window is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension.

- the **Main Area** is located in the upper portion of the screen and contains all the fields regarding calibration results;
- the **Details Area** is located in the lower portion of the screen and contains specific, itemized information regarding the calibration data of the individual test.

This mask also contains buttons which allow the user to move on to other applications or carry out other procedures.

Main Area

Calibration Results															
	TEST Name	RBL Days	Flags	Abs	Rate	STD Days	Flags	Refer.	Abs	CV%	Factor	CTRL Flags	Result	Mean	Reference
Monitor	ACPT												743.00		
Checks	ALB														
Routine	AMY												3953.00		
Archive	BILI-T	-642	■	1	-0.0021	0.0013	-648	■	4.7	0.3014	0.26	15.60		4.28	4.69 3.85-5.53
														1.33	1.34 1.1-1.58
Paramet.	CREM	-642	■	1	0.2922	0.0020	-648	■	0	-0.0003	43.60	0.00		4.13	3.83 3.14-4.52
														1.26	1.09 0.89-1.29
Help	GLU								0.625	0.0221	0.48	28.29			
Shutdown	GPT	-642	■	1	1.3098	0.0004			1	0.0333	0.38	30.03			
									2	0.0690	0.22	28.98			
	IGG	-692	■	X	1	0.1406	0.0094	-692	■ XAC	500	-0.0102	0.00 46862.58			
									750	-0.0095	0.00 79182.34				
									1000	-0.0106	0.00 94380.49				
									1500	-0.0093	0.00 60631.80				
									2000	-0.0095	0.00 09766.50				
									2500	-0.0092	0.00 71984.70				
	IGM	-713	■	1	0.2026	0.1824	-713	■	0	-0.0006	64.91	0.00		186.35	194 144-244
									50	0.0939	0.70	532.22			
									200	0.1162	0.44	620.00			

The following fields are included in this window:

Test Name: indicates the name of the method;

RBL Days: indicates the number of days since the last **RBL** was carried out. A small symbol - (■) – indicates the presence of a message to be read by the operator. This visual text message can be accessed by pointing the mouse at said symbol (please see the section: Calibration – **RBL Expiration**);

Flags: informs the operator if any **errors** occurred during the running of the **RBL**. In this section the Flags field is viewed twice more, indicating if the error has occurred during the running of the Standard and/or during the reading of the controls. Whenever an error occurs, all those fields regarding that item are automatically shown coloured red. In this case, errors are signalled using letters which stand for the type of error encountered – as reported in Result Flags description;

D: indicates, by using either the number 1 or 2, the first or second row of data referring to either differential or bichromatic methods;

Abs: here the user can view the optical density values obtained for the **RBL**. The **Abs** field is shown a second time in this mask in order to report the optical density values obtained from the standards. In the event of replicates (from 2 to 4) the program will automatically calculate the average of the valid readings and in case of 3 or 4 replicates will eliminate the reading furthest from the average. The mean value obtained will then be reported in this field. The absorbance values of the replicates can be viewed in the Details area where the operator can also consult the graph;

Rate: represents reagent mobility during the reaction time expressed in absorbance;

STD days: indicates the number of days since the last calibration was carried out. A small symbol - (■) – indicates calibration execution date, pointing the mouse at said symbol (please see the section: Calibration – **STD Expiration**);

Refer.: indicates the concentration of the Standard utilized (in the event of multi-point calibration, more than one reference value will appear);

CV %: indicates the coefficient of variation percentage among replicates of the standard considered valid with respect to the mean;

Factor: indicates the calibration factor;

Result: indicates the results obtained for the control;

Mean: indicates the mean value of the control;

Reference: indicates the range considered normal for that control.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures.



- Print the selected data (**Print** button);



- Modify the results of the Optical density of the standard (**Edit** button).

(Please see the section: Command Buttons).

Details Area

CHO Calibration										
Type	Pos.	Name	Lot	Abs	Ref./Res.	Unit	Factor	Flags	Date	Time
RBL	Std/Ctrl 14			0.0211	0 mmol/L				13-12-02	10:44
STD	Std/Ctrl 03	DIACAL 1	0850201	0.2197	4 mmol/L	18.21			13-12-02	10:44
STD	Std/Ctrl 03	DIACAL 1	0850201	0.2171	4 mmol/L	18.42			13-12-02	10:44
STD	Std/Ctrl 03	DIACAL 1	0850201	0.2206	4 mmol/L	18.13			13-12-02	10:45
CTRL	Std/Ctrl 01	DIACON N	0810202	0.1499	2.72 mmol/L				13-12-02	10:45
CTRL	Std/Ctrl 02	DIACON P	0820201	0.2530	4.6 mmol/L				13-12-02	10:45

Located in the lower portion of the mask, the Details Area can be viewed by the operator as illustrated above. If there are RBLs, Standards or Controls programmed for calibration and already being carried out, they can be viewed at the beginning of this area and are highlighted by a yellow background.

Once calibration has been carried out, this area allows the operator to view the details of the results regarding the method selected in the **Main Area**. The most important fields are the following:

Type: indicates the type of operation requested (RBL, STD or Control);

Pos.: indicates the position occupied within the STD/CTRL rack;

Name: indicates the name of the standard or control;

Lot: indicates the lot number assigned to that standard or control;

Abs: indicates the Optical density obtained;

Ref/Res.: indicates the results obtained for the control or the reference value for the standards;

Unit: indicates the measurement unit used for that method;

Factor: indicates the calibration factor;

Flags: this field allows the operator to view if any errors occurred during operation (please see the Result Flags description). Whenever an error occurs a character with a small red square (■) appear in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the full name of the error encountered;

Date: allows the operator to view the date in which the RBL/STD/CTR was carried out;

Time: allows the operator to view the exact time the RBL/STD/CTR was carried out.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Print the selected data (**Print** button);



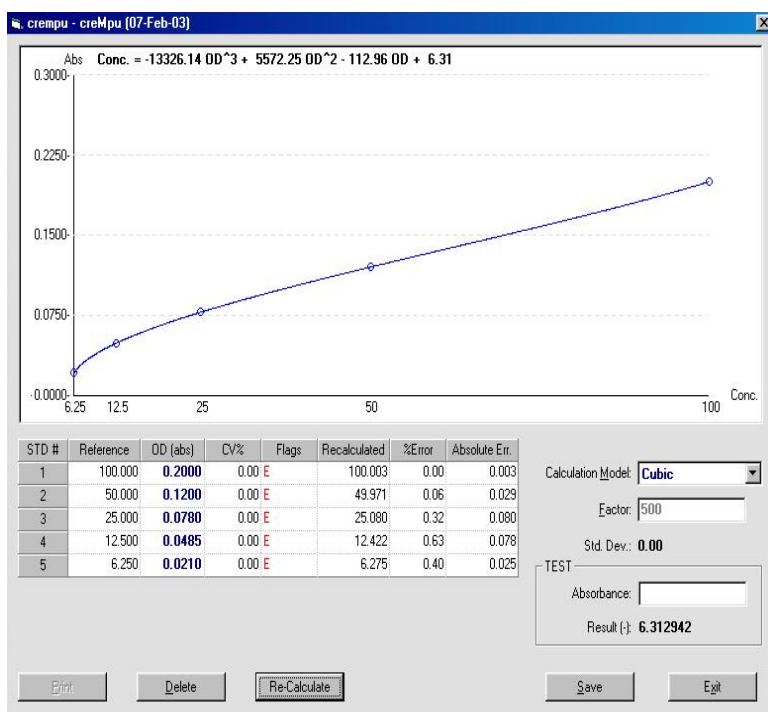
- View the absorbance graph of the selected test (**Graph** button);



- Repeat the selected tests (**Rerun** button).

(Please see the section: Command Buttons).

Calibration Curve



This window graphically illustrates the results of those operations carried out under the “Start Work” mask, after clicking on the “**Calibration**” option.



To access the **Edit Calibration Curve** mask, select the required Standard (containing results) from the Main Area of the **Calibration Results** list and click on the **Edit** button, located on the Desk Top.

This mask contains a graphic illustration of the results of the Calibration operations plus those fields that allow the user to view the mathematical procedure used for calculating the results of the calibration curve. The **Name of the Standard** and the **Date** in which the calibration was carried out can be viewed in the heading of the mask.

This window is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension. This mask also contains, in the lower portion of the window, buttons which allow the user to carry out the necessary procedures.

Main Area

The Main Area of this mask is dedicated to a **Graph** of the indicated standard. The information provided in this area is organized in such a manner as to be easily accessible and user friendly. Furthermore, it provides the operator with all that data necessary for a proper understanding of the calibration process underway. Here, the user can view a graphic representation of the **Curve**, including all its readings, regarding the Standard selected in the Calibration Results mask. The equation used for calculating the data is provided at the top-center of the Graph. The ordinate axis shows data regarding Optical Density; and the abscissa, data concerning Concentration.

Details Area

Located in the lower area of this same mask, the Details Area contains a table in the left-hand portion, reporting data necessary for viewing the graph in the Main Area. For each point declared for that given Standard, said table contains the values of the following items, organized in columns:

Reference: indicates the reference value of the concentration as set-up by the user for that Standard in the Standards mask;

O.D. (abs): provides the value of the read Optical Density;

CV %: indicates the coefficient of variation percentage among replicates of the standards considered valid with respect to the mean;

Flags: this field allows the operator to view if any errors occurred during calibration. Errors are signaled using letters which stand for the type of error encountered – as reported in Result Flags description;

Recalculated: indicates the new value obtained with relation to the type of calculation algorithm;

% Error: allows the user to view the % of error found. Or rather, it indicates, in percentage form, the gap between the value set-up by the operator in the **Reference** field and that given in the **Recalculated** field;

Absolute Error: indicates the absolute error obtained between the value set-up by the operator in the **Reference** field and that shown in the **Recalculated** field;

- The following fields are listed, to the right of the above-described table:

Calculation Model: this field contains a pull-down menu offering the various calculation types available for the Standard;

Factor: this field is activated only for test that have been declared against factor;

STD. Dev.: contains values that indicate the deviation of the curve with respect to the points of that Standard (lower values mean best Calculation Model);

Absorbance: the operator can insert in this field an Optical Density value in order to verify and check the concentration that would be obtained based on the curve had using the **Recalculate** button;

Recalculate: this button allows the operator to edit the calibration data obtained;

Result (mg/l): shows the result of a new recalculation. This value will be represented by a red circle in the graph illustrated in the Main Area.

Recalculating the concentration

Recalculate

If, after calibration, the operator believes that anomalies may have occurred or that the calculation model previously set-up in the Methods mask does not truly satisfy the reaction, he/she can have the instrument perform a new calculation on the concentration of the Standard.

The user can, in this mask, based on the points contained in the Standard, insert values in the **O. D. (abs)** field; select a calculation model deemed appropriate from the **Calculation Model** pull-down menu and insert, if the selected calculation so requires, values in the other fields of the Details Area. Please note that this will automatically cause the program to signal an **E** in the Flags field.

The **Factor** field is activated only for those methods defined **against-factor** in the Calculation Model field. Here, the user should insert those values needed for calculating the concentration.

Once the Factor calculation has been selected and the data saved, it is no longer possible to change the model. This is because when the data is saved, all the points the Standard curve not involved in the calculation operation are automatically zeroed. Click on **Recalculate**, located in the lower-left portion of the mask under the table, to run the concentration calculation.

If the data inserted in the fields are not correct, as can happen in the **O. D. (abs)** field, and the resulting curve is different from the considered Standard, the program will automatically allow the operator to view, in the graph illustrated in the Main Area, those points of the Standard which do not coincide with the entire curve. Moreover, the following visual text message will appear in the upper portion of the mask:

"CALCULATION ERROR"

Deleting a point from a Standard

Delete

To delete a point in a Standard curve, first select the required point from the table containing all the points of the Standards curve and then click on "**Delete**", located in the lower portion of the mask, in that area dedicated to the various buttons. The instrument will automatically open a visual text message dialog box requesting confirmation of the delete procedure. If the user clicks on "**Yes**", the point will be deleted from the Standard curve. If he/she clicks on "**No**", the delete procedure will be annulled.

Save

In order to memorize and, therefore, utilize the settings programmed in this mask, the user must click on "**Save**", located in the lower portion of the mask.

Printing Data

Print

The operator can print the graph and the data contained in the **Calibration Curve** mask by clicking on the "**Print**" button. This button is deactivated while editing is being carried out, but is automatically reactivated once the edited data has been memorized by clicking on "**Save**".

QUALITY CONTROL RESULTS

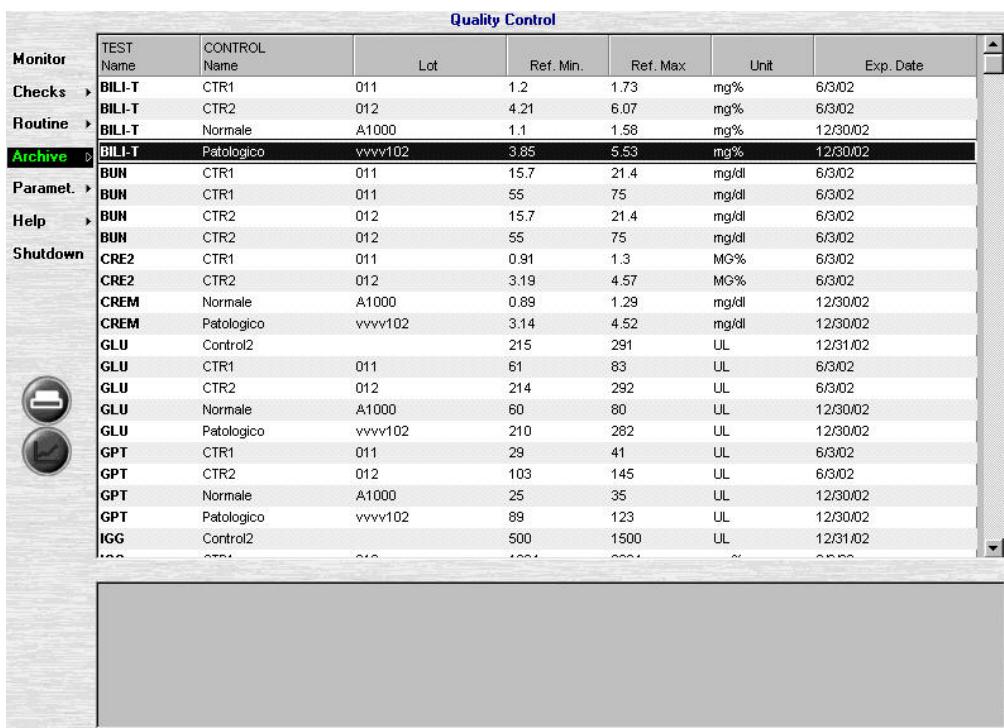
To access the **Quality Control Results** mask, first select the **Routine Menu** and then, from the options listed, click on “**Quality Control Results**”.

This mask allows the operator to view all that data regarding the methods and their relative controls in order to make sure that all relative constraints have been satisfied and necessary conditions met (e.g.: that each test have at least one control).

This **Quality Control Results** mask is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension:

- the **Main Area** is located in the upper portion of the screen;
- the **Details Area** is located in the lower portion of the screen.

Main Area



The screenshot shows a software interface titled "Quality Control". On the left, there is a vertical menu bar with icons for "Monitor", "Checks", "Routine", "Archive", "Paramet.", "Help", and "Shutdown". Below the menu is a toolbar with two icons: a square with a minus sign and a square with a plus sign. The main area contains a table with the following columns: TEST Name, CONTROL Name, Lot, Ref. Min., Ref. Max., Unit, and Exp. Date. The table lists various test and control entries, such as BILI-T, CTR1, 011, 1.2, 1.73, mg%, 6/3/02; BUN, CTR1, 011, 15.7, 21.4, mg/dl, 6/3/02; and CREM, Patologico, vvvv102, 3.85, 5.53, mg%, 12/30/02. The "Archive" option in the menu is highlighted.

Quality Control						
	TEST Name	CONTROL Name	Lot	Ref. Min.	Ref. Max.	Unit
Monitor	BILI-T	CTR1	011	1.2	1.73	mg%
Checks	BILI-T	CTR2	012	4.21	6.07	mg%
Routine	BILI-T	Normale	A1000	1.1	1.58	mg%
Archive	BILI-T	Patologico	vvvv102	3.85	5.53	mg%
	BUN	CTR1	011	15.7	21.4	mg/dl
	BUN	CTR1	011	55	75	mg/dl
	BUN	CTR2	012	15.7	21.4	mg/dl
	BUN	CTR2	012	55	75	mg/dl
	CRE2	CTR1	011	0.91	1.3	MG%
	CRE2	CTR2	012	3.19	4.57	MG%
	CREM	Normale	A1000	0.89	1.29	mg/dl
	CREM	Patologico	vvvv102	3.14	4.52	mg/dl
	GLU	Control2		215	291	UL
	GLU	CTR1	011	61	83	UL
	GLU	CTR2	012	214	292	UL
	GLU	Normale	A1000	60	80	UL
	GLU	Patologico	vvvv102	210	282	UL
	GPT	CTR1	011	29	41	UL
	GPT	CTR2	012	103	145	UL
	GPT	Normale	A1000	25	35	UL
	GPT	Patologico	vvvv102	89	123	UL
	IGG	Control2		500	1500	UL
	IGG	vvvv102		vvvv	vvvv	vvvv

The above-illustrated window contains, from left to right, the following fields:

Test Name: the name of the method (**its acronym**);

Control Name: the name of the control regarding that particular test;

Lot: indicates the Lot Number of the control;

Ref. Min.: indicates the minimum reference value;

Ref. Max.: indicates the maximum reference value;

Unit: indicates the unit of measurement used;

Exp. Date: indicates the expiration date of the control (please see the section: Controls – Programming).

The mask also contains buttons which allow the operator to move on to other applications.

Details Area

DIACON N: ALB Results.						
Type	Pos.	Flags	Abs	Concentration	Unit	Date
CTRL	Cal. 01		0.8297	34.2	g/l	13-Dec-02 09:24:13
CTRL	Cal. 01		0.8308	34.2	g/l	12-Dec-02 09:57:09
CTRL	Cal. 01		0.8572	35.2	g/l	11-Dec-02 16:29:30
CTRL	Cal. 01		0.8310	33.8	g/l	11-Dec-02 15:12:58

Whenever a row in the **Main Area** is selected by the operator, the relative Details Area will automatically appear, providing all that specific data concerning the row selected.

The following fields are contained herein:

Type: the acronym “CTRL” (control) is listed here;

Pos.: indicates the position occupied by that control;

Flags: this field allows the operator to view if any errors occurred during operation (please see the Result Flags description). Whenever an error occurs a character with a small red square (■) appear in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the full name of the error encountered;

Optical Density, Concentration, and Unit are also listed, followed by **Date** and **Time**: each column contains information relative to that heading selected.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Print the selected data (**Print** button);



- View the absorbance graph of the selected test (**Graph** button).

(Please see the section: Command Buttons)

Deleting (a) Control(s)

The operator can, if he/she so desires, delete the results of the Quality Control. First, select the result to be deleted and then right click with the mouse.

Delete Selected Controls

The menu, “**Delete the Selected Control(s)**”, here-illustrated to the left, will automatically appear. Clicking on this option will immediately cause the program to delete all those controls selected in the Details Area.

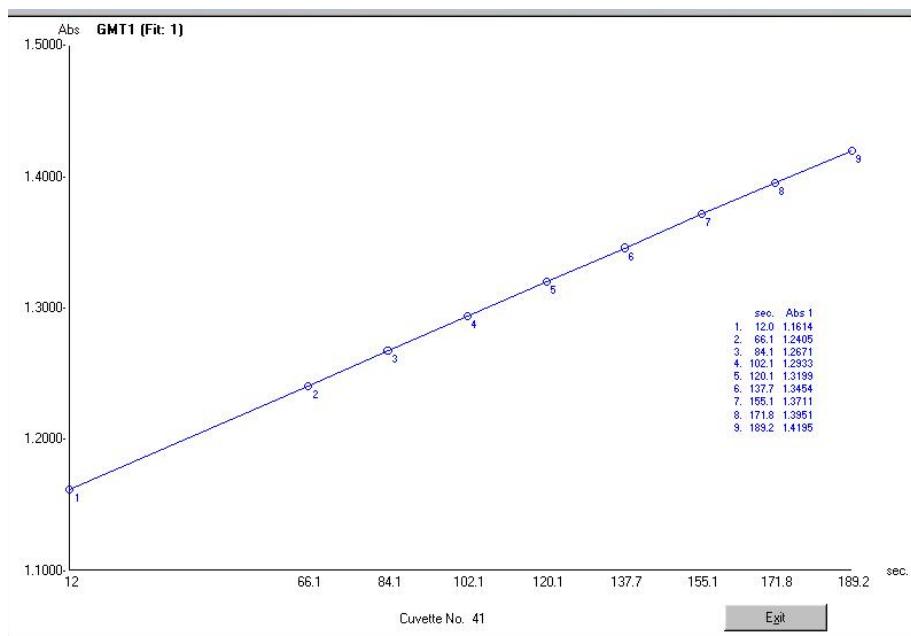
QUALITY CONTROL GRAPHS



The **Quality Control Graphs** mask allows the operator to view two graphs. Following is an illustration of the two:

The first concerns the Graph of the Optical Density relative to the reading times for results contained in the rows of the Details Area. The user need simply select the row in the Details Area containing the results he/she is interested in and then either double click with the mouse or click on the “**Graph**” button located on the Desk Top.

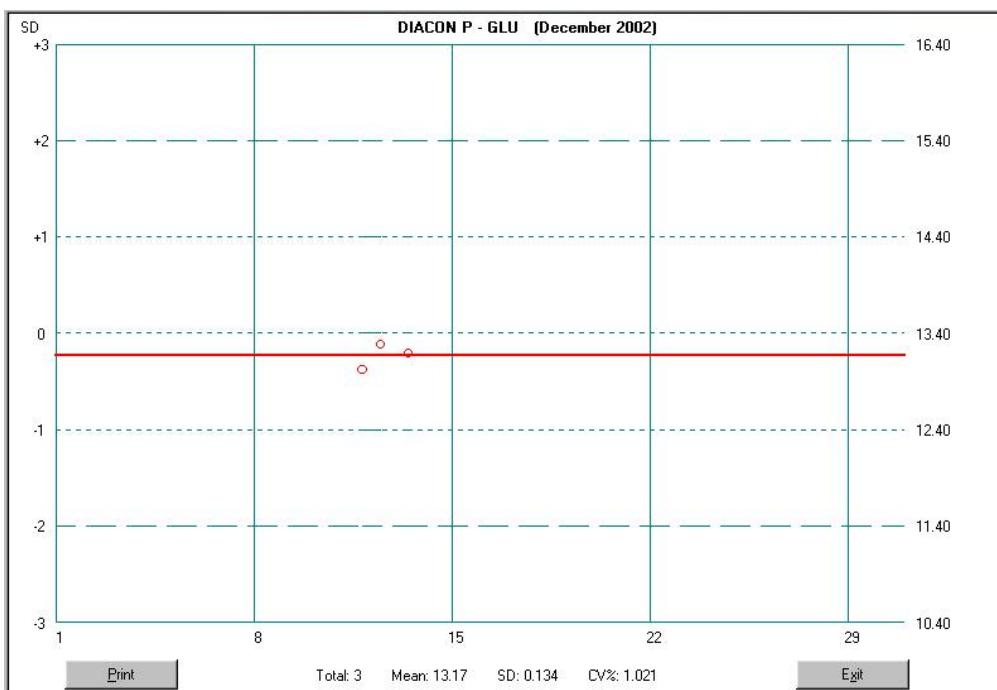
This Graph button is activated only when the **Details Area** contains at least one row of data.



To exit the graph and return to the **Quality Control Results** mask, click on “**Exit**”.

The second graph – following is an illustration – reports, in the uppermost area, the name of the Control, the name of the Test and the month in which it was carried out.

The operator must first select the required row in the **Main Area** and at least two rows in the **Details Area**, and then click on the “**Graph**” button located on the Desk Top.



On the left-hand side of the Graph, the operator can view the standard deviations (from $-3SD$ to $+3SD$) and on the right-hand side, their relative concentration value.

A red line represents the mean value obtained with respect to the expected mean value.

At the bottom of the Graph, the user can read the total number of controls viewed, the mean concentration value, the standard deviation and the coefficient of variation percentage obtained.

The operator can print the graph by clicking on the “Print” button located in the lower, left-hand corner of the mask.

Please note that the graph is monthly and therefore, the print-out will be month by month.

To close the graph mask, click on “Exit”, located in the lower, right-hand corner of the mask.

RECEIVE FROM HOST

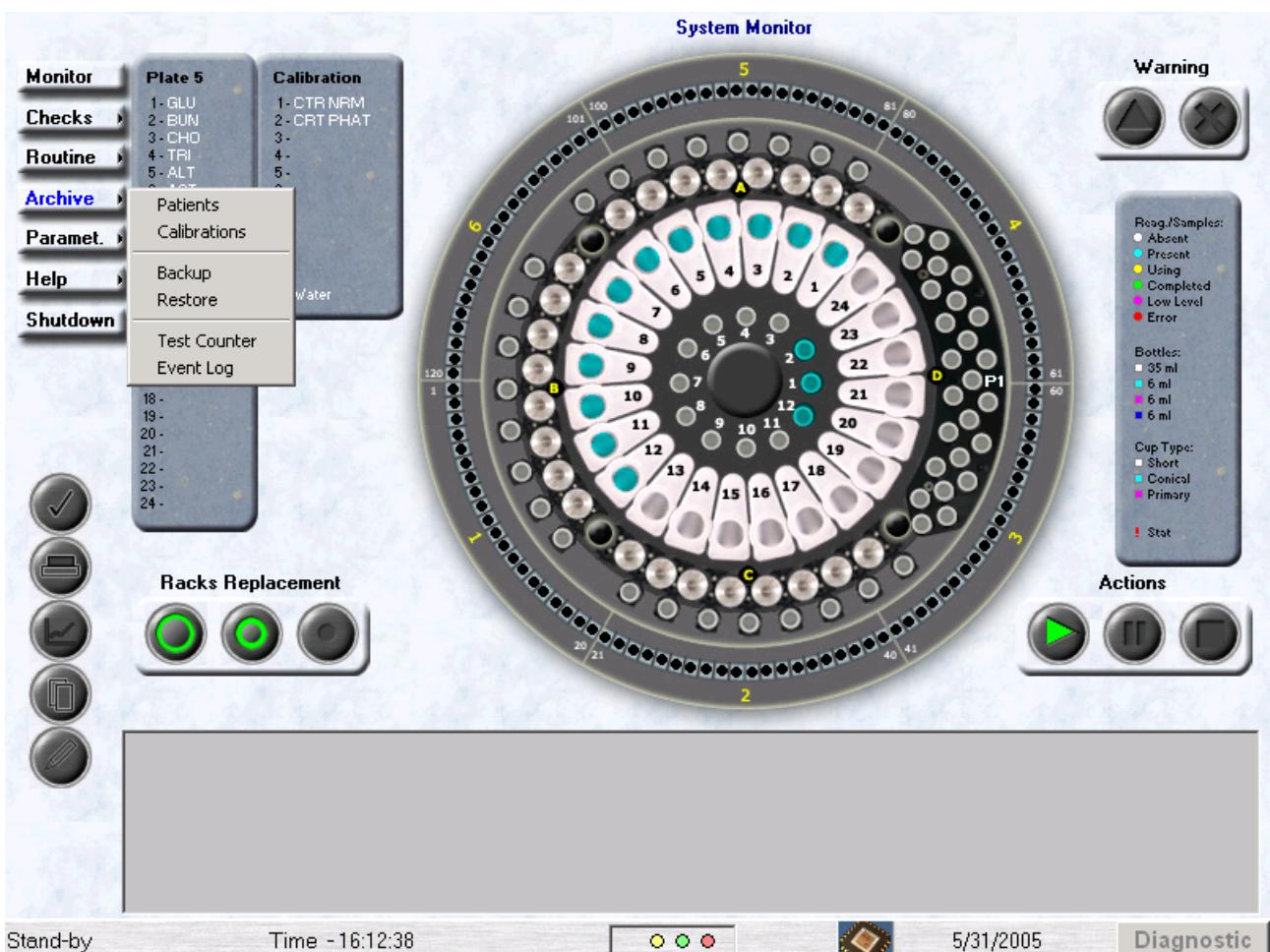
The last item on the **Routine Menu** is “Receive from Host”.

This command allows the operator to activate and receive data transmission from the Host. However, this item is not automatically viewed under this Menu. In order to view said item, the user must first select the “Host Connection” option inside the Options mask.

To activate data transmission, click on the above-cited command: the connection is automatic.

For further information regarding data transmission, see the paragraph entitled **Host – Communication**.

3.4 ARCHIVE



Archive The term Archive indicates the entire set of all those masks which provide the operator with a complete and total overview, necessary for managing both the exams and their results. These masks allow the user to view all the filed data and also describe simply, yet thoroughly, both the "Backup" and "Restore" operations. These two operations can be used only with this program – they are not compatible with any other analyzer.

Each set of data, specific to its own topic, has its own mask. Following is a list of the included masks:

Patients: this mask includes the results of those tests run on the patient samples as set-up in the programming mask **Work List** and contained in the Archive;

Calibration: here the operator can view all the calibrations run;

Backup: this mask is necessary in order to be able to make a copy of the Patients onto a floppy disk. Here, the user can select those results to be copied;

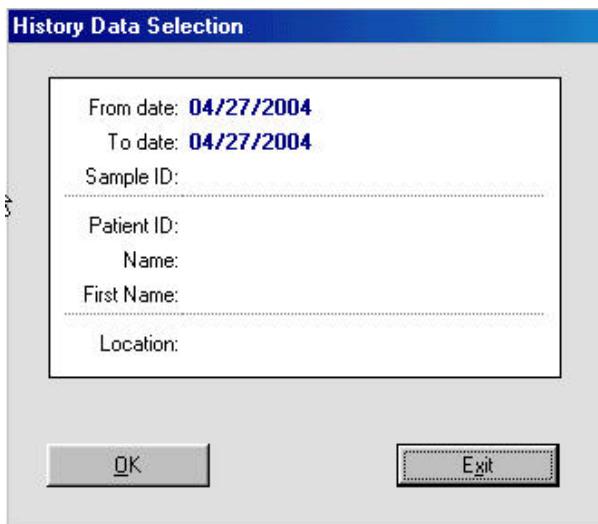
Restore: allows the user to replace data back into the Archive from a floppy disk;

Tests Counter: allows the operator to view the total number of tests carried out, subdivided into groups (RBL, STD, CTRL and Samples);

Event Log: this mask records any and all anomalous events involving instrument status.

PATIENTS

To access the **Patients** mask (illustrated below), select **Archive** from the **Menu** and then click on **“Patients”**. The following window will automatically open:



This mask allows the operator to search for Patients in the **“Archive – Patients”** mask by inserting the relevant search criteria data into the given fields.

For example: if the user inserts as the search criteria data in the **“from date”** and the **“to date”** fields, the program will pull up and view in the Work List, all those patients contained in the Archive and filed between those two dates.

To confirm a selection criterion, click on **OK**. To annul the selection and request that no operation be carried out, click on **Exit**.

This mask allows the operator to view the results of the tests run along with personal data regarding the patients as inserted in the **Work List** programming mask and contained in the Archive - Patients. The results of the operations, together with data regarding the **samples** of those patients inserted in the Work List are here-given into two sections, a Main Area and a Details Area, in order to facilitate user access and comprehension.

- the **Main Area** is located in the upper portion of the screen and contains all the fields regarding patient data and a description of the sample;
- the **Details Area** is located in the lower portion of the screen and is dedicated to more specific, itemized information, in particular to the results of the given operation.

MAIN AREA

Located in the upper portion of the mask, below is an illustration of the Main Area window as seen by the operator:

History WorkList							
Rack-Cup ▲	Type	Samp.Dil.	SID	PID	Name	Sex	Birthdate
1 - 1	Serum	1/1	1	1	ROSS MARY	Female	
1 - 1	Serum	1/1	01	01	Novák	Male	
1 - 2	Serum	1/1	2	2	ROSS MARY	Female	
1 - 2	Serum	1/1	11	11	Pokus1	Male	
1 - 3	Serum	1/1	12	12	Pokus2	Male	

Following is a list and relative description of those fields contained in this area of the mask:

Rack and Cup: indicates the number of the Rack and the position in that Rack of the given sample;

Type: indicates the type of sample used;

Sample Dilution: allows the operator to view the predilution ratio;

Sample ID: indicates the sample's identification number;

Patient ID: indicates the patient's identification number;

Name: allows the operator to view the name of the patient;

Sex and Birth date : indicates the sex and date of birth of the patient.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



- Print the selected data – reports/work list (**Print** button);

(Please see the section: Command Buttons)

DETAILS AREA

Located in the lower portion of the mask, the Details Area contains specific, itemized information regarding the row selected in the Main Area. Below is an illustration:

Name: ROSS MARY SID: 1 [Rack/Pos.: 1/1].							
Test ▲	PreDil.	Test Dil.	Result	Unit	Normal Values	Flags	Date
ALP	1/1	1/1	1.28	ukat/l	(0.1-2.7)	E	08-Apr-03 10:09:21
ALT	1/1	1/1	0.5	ukat/l	(0.1-0.7)	E	08-Apr-03 10:10:47
Amylaza	1/1	1/1	2.2	ukat/l	(1.25-3)	E	08-Apr-03 10:10:57
AST	1/1	1/1	0.6	ukat/l	(0.1-0.7)	E	08-Apr-03 10:11:05

Following is a list and relative description of those field contained in this area of the mask:

Test: indicates the name of the test carried out;

Predilution and Dilution: indicate the predilution and the dilution ratio of the involved sample;

Results: allows the operator to view the results obtained;

Unit: indicates the measurement unit used for that test, as set-up in the methods parameters;

Normal Values: allows the operator to view the normal range of values for the performed test;

Flags: this field allows the operator to view if any errors occurred during operation (please see the Result Flags description). Whenever an error occurs a character with a small red square (■) appear in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the full name of the error encountered;

Date: indicates the date and exact time of day in which the test was run.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



- Print the selected data (**Print** button);

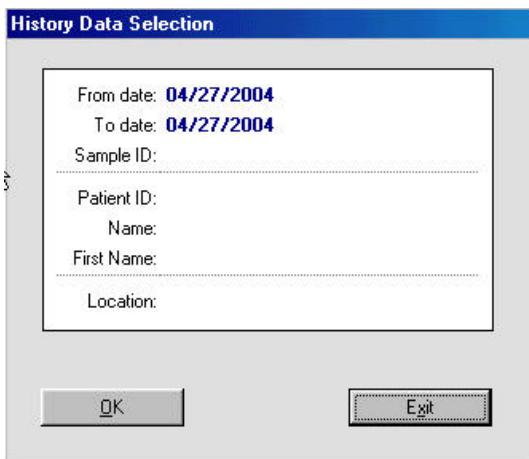


- View the absorbance graph of the selected test (**Graph** button);

(Please see the section: Command Buttons)

CALIBRATION

To access the **Calibration** mask (illustrated below), select **Archive** from the **Menu** and then click on **Calibration**. The following window will automatically open:



This mask allows the operator to insert date and then request that the program search for a Calibration previously carried out.

For example: if the user inserts as the search criteria data in the “**from date**” and the “**to date**” fields, the program will pull up and view all the calibrations contained in the **Archive – Calibration** List filed between those two dates.

To confirm a selection criterion, click on **OK**. To annul the selection and request that no operation be carried out, click on **Exit**.

This **Archive – Calibration** window allows the operator to view the results of the procedures previously carried out and programmed in the **Calibration** preparation mask.

The results of the operations and filed data are here given.

The **Calibration** window is divided into two sections, a **Main Area** and a **Details Area**, in order to facilitate user access and comprehension.

- the **Main Area** is located in the upper portion of the screen and contain all the fields regarding calibration.
- the **Details Area** is located in the lower portion of the screen and contains specific, itemized information.

MAIN AREA

Located in the upper portion of the mask, below is an illustration of the Main Area window as seen by the operator.

History Calibration							
	Test	Total	RBL	Std	Ctrl	First Date	Last Date
Monitor	3RCRE	1	0	1	0	10/11/2004	10/11/2004
Checks	ALT	13	13	0	0	10/20/2004	02/24/2005
Routine	BIB	47	47	0	0	07/09/2004	10/29/2004
	BIBstd	8	4	4	0	10/19/2004	10/27/2004
Archive	BIT	14	14	0	0	10/20/2004	02/24/2005
Paramet.	CRE	34	17	17	0	10/20/2004	02/24/2005
Help	GLU	27	14	13	0	10/20/2004	02/24/2005
	IGG2sb	7	1	6	0	07/09/2004	07/09/2004
Shutdown	Kappa	137	14	123	0	10/25/2004	02/11/2005
	Lambda	88	11	77	0	10/25/2004	02/11/2005
	Prova	60	9	51	0	09/26/2004	10/12/2004
	Prova2	3	0	3	0	10/11/2004	10/12/2004



Following is an explanation of the contained fields:

Test: indicates the name of the test carried out;

Total: indicates the total number of tests run for the Calibration procedure and for the Analyzer check, as filed in the Archive;

RBL: allows the user to view the number of RBLs carried out for each test and filed in the Archive;

Std: indicates the number of Standards run for each test and filed in the Archive;

Ctrl: allows the operator to view the number of Controls run for each test and filed in the Archive;

First Date and Last Date: indicates the time-window relative to the data contained in the database, for each test.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



- Print the selected data (**Print** button);

(Please see the section: Command Buttons.)

DETAILS AREA

Located in the lower portion of the mask, the Details Area contains specific, itemized information regarding each of the fields selected in the Main Area.

GLU History Calibration										
Type	Pos.	Name	Lot	Abs	Ref./Res.	Unit	Factor	Flags	Date	Time
RBL	Std/Ctrl 14			0.0280	0	mmol/L			03-12-02	10:21
STD	Std/Ctrl 02	DIACAL 1	0850201	0.4544	10.5	mmol/L	23.11		03-12-02	10:21
CTRL	Std/Ctrl 01	DIACON N	0810202	0.2682	6.2	mmol/L			03-12-02	10:22

Following is an explanation of the contained fields:

Type: indicates the type of item considered;

Pos: indicates the position occupied by that item within the rack dedicated to calibration;

Name: allows the operator to view the name of that item;

Lot: indicates the lot number assigned to that item;

Abs: indicates the Optical density measured;

Ref./Res.: gives the reference value for the standards and the result obtained for the controls;

Unit: indicates the measurement unit used;

Factor: indicates the factor resulting from the calibration procedure regarding that given test;

Flags: this field allows the operator to view if any errors occurred during operation (please see the Result Flags description). Whenever an error occurs a character with a small red square (■) appear in the Flags field. If the operator passes over this symbol with the mouse, a visual text message will appear indicating the full name of the error encountered;

Date: indicates the date in which the operation was carried out.

Time: indicates the time in which the operation was carried out.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



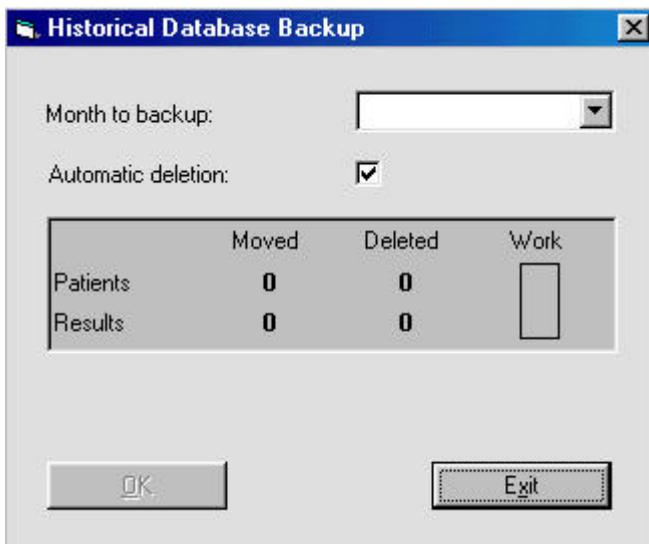
- Print the selected data (**Print** button);



- View the absorbance graph of the selected test (**Graph** button);

(Please see the section: Command Buttons)

BACKUP



To access the **Backup** mask, select **Archive** from the Menu, and then, from the options listed, click on **Backup**. This mask, as illustrated here above, allows the operator to make a copy of the data contained in the Archive. Said data is copied onto a floppy disk and can be saved for future reference or reinserted in (re-copied back into) the Archive at a later date (please see the **Archive – Restore** description).

The **Backup** mask is quite simple – a detailed description follows:

Month to backup: a pull-down menu containing a list of all the months of the year – data is organized by the program under monthly headings and is therefore filed, stored and shown, when requested, in this manner. By selecting a given month, the operator can view all that data pertaining to that requested time interval.

Automatic Deletion: this is a “check” () field. If the operator clicks on and therefore “checks” () this field, the program will automatically delete/cancel the data from the Archive at the same time it carries out the Backup procedure - i.e.: copies it onto the floppy.

The central area of this mask contains the fields that allow the operator to view the total number of patients and results which have been copied onto the floppy. If the **Auto Delete** field has been activated (“checked” – “”), this area will also indicate the total number of results eliminated.

The mask also contains two buttons for performing the following two operations.

Performing Backup

OK

Select the month containing those results to be copied from the pull-down menu:

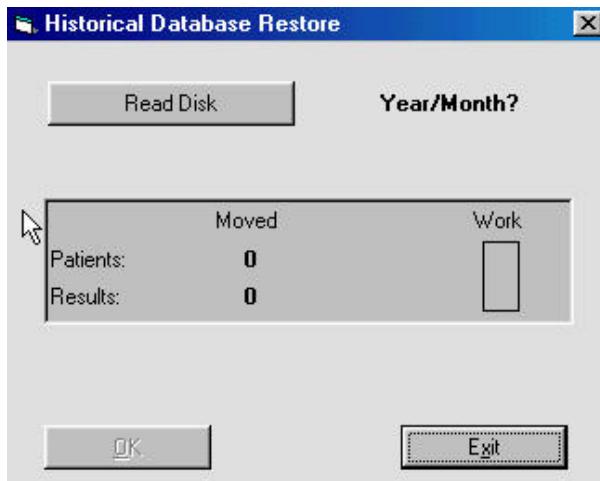
Month to backup. If the user wishes to eliminate these results from the Archive at the same time they are copied onto the floppy, he/she need only click on the **Automatic Delete** window thereby “checking” () the relative field. At this point, click on “**OK**”, located in the lower, left-hand corner of the window.

The user can monitor the Backup operation via a series of visual text messages provided by the program regarding the copying of the data onto the floppy. In addition, these messages also serve as a guide to the user.

EXIT

To exit the **Backup** mask and return to the **System Monitor** main screen, click on “**Exit**”.

RESTORE



To access the **Restore** mask, select **Archive** from the Menu, and then, from the options listed, click on **Restore**. This mask, as illustrated here above, allows the operator to recopy data back into the Archive. Said data are copied from the floppy, that

was previously used for performing a **Backup**, and are hereby reinserted into the program (under Work List - Setup) where they can be accessed for reference and/or for performing various other operations.

The **Restore** mask is quite similar to the **Backup** mask – a detailed description of the included fields follows:

Read Disk

The upper, right-hand corner of this mask has a field where the user can view the data contained on the floppy. This field is activated by clicking on **Read Disk**, located in the upper, left-hand corner of the mask. Doing so opens a pull-down menu where the operator can choose the required month. At this point the user can select the month and thereby view all the data contained in the floppy regarding that selected time frame.

The central area of this mask contains those fields that allow the operator to view the total number of patients and results which have been copied back from the floppy into the Archive - Patients. The mask also contains two buttons for performing the following two operations.

Performing Restore

Read Disk

Use the **Read Disk** command to view all the data contained within the floppy. The contents of the disk will automatically be viewed in the upper portion of the screen. Using the pull-down menu, select the month that contains the required data that the operator wishes to recopy back into the system's Archive.

OK

Clicking on “**OK**” will automatically cause the restore operation to be performed. This button is located in the lower, left-hand portion of the mask.

The user can monitor the **Restore** operation via a series of visual text messages provided by the program regarding the copying of the data from the floppy back into the Archive. In addition, these messages also serve as a guide to the user.

EXIT

To exit the **Restore** mask and return to the **System Monitor** main screen, click on “**Exit**”.

TESTS COUNTER

Tests Counter								
	Test	Total	RBL	Std	Ctrl	Sample	First Date	Last Date
Monitor	ALT	50	1	0	0	49	02/24/2005	03/10/2005
Checks	BIT	34	2	0	0	32	02/24/2005	02/24/2005
Routine	CRE	35	1	1	0	33	02/24/2005	03/10/2005
Archive	GLU	36	2	1	0	33	02/24/2005	03/10/2005
Paramet.	Kappa	96	4	33	0	59	01/19/2005	02/11/2005
	Lambda	127	3	30	0	94	01/18/2005	02/11/2005

To access the **Tests Counter** mask, select **Archive** from the Menu and then, from the options listed, click on **Tests Counter**.

The **Tests Counter** mask, as illustrated above, provides the user with information regarding all the various operations. It presents the sum of all those tests carried out in the various operations. Following is a description of the included fields.

Test: allows the operator to view the acronym used for the Test carried out;

Total: indicates how many times that particular test was carried out, in the various operations;

RBL: indicates how many RBLs (Reagent Blanks) were carried out for that specific test;

Std: allows the user to view the total number of Standards carried out for that particular test;

Ctrl: allows the user to view the total number of Controls carried out for that particular test;

Sample: indicates the number of unknown Samples carried out for that particular test;

First Date and **Last Date:** allow the operator to view the dates on which that particular test was first and last run.

This mask also contains buttons which allow the user to move on to other applications or carry out the following procedures:



- Reorder the viewed data (**Order** button);



- Print the selected data (**Print** button);

(Please see the section: Command Buttons).

EVENT LOG

Event Log		
	Description	Date
Monitor	Temperature over-range (34.8 °C)	13-Dec-02 08:03:37
Checks	Temperature over-range (34.8 °C)	13-Dec-02 08:03:35
Routine	Temperature over-range (34.8 °C)	13-Dec-02 08:03:33
Archive	Temperature over-range (34.8 °C)	13-Dec-02 08:03:23
Paramet.	Temperature over-range (34.2 °C)	13-Dec-02 08:03:08
Help	Temperature over-range (34.2 °C)	13-Dec-02 08:02:43
Shutdown	Temperature over-range (33.8 °C)	13-Dec-02 08:01:59
	Temperature over-range (33.2 °C)	13-Dec-02 08:01:17
	Temperature over-range (32.8 °C)	13-Dec-02 08:00:44
	Temperature over-range (32.8 °C)	13-Dec-02 08:00:38
	Temperature over-range (32.2 °C)	13-Dec-02 08:00:33
	Temperature over-range (32.2 °C)	13-Dec-02 08:00:19
	Temperature over-range (31.8 °C)	13-Dec-02 07:59:18
	Temperature over-range (31.2 °C)	13-Dec-02 07:59:04
	Temperature over-range (31.2 °C)	13-Dec-02 07:58:57
	Temperature over-range (30.8 °C)	13-Dec-02 07:58:53
	Temperature over-range (30.8 °C)	13-Dec-02 07:58:18
	Temperature over-range (30.2 °C)	13-Dec-02 07:57:38
	Temperature over-range (29.8 °C)	13-Dec-02 07:57:19
	Temperature over-range (29.2 °C)	13-Dec-02 07:56:33

To access the **Event Log** mask, select **Archive** from the Menu and then, from the options listed, click on “**Event Log**”.

This window logs all those events/occurrences judged to be anomalies which are encountered during instrument operation. Said anomalies can be either:

- **Warning!** – identified by a yellow triangle
- **Fatal Error!** – identified by a red ics (X) sign

This mask also contains the following fields:

A: allows the operator to view the type of anomaly encountered;

Description: provides the user with a brief description of the anomaly recorded;

Date: indicates date and exact time of the registered event.

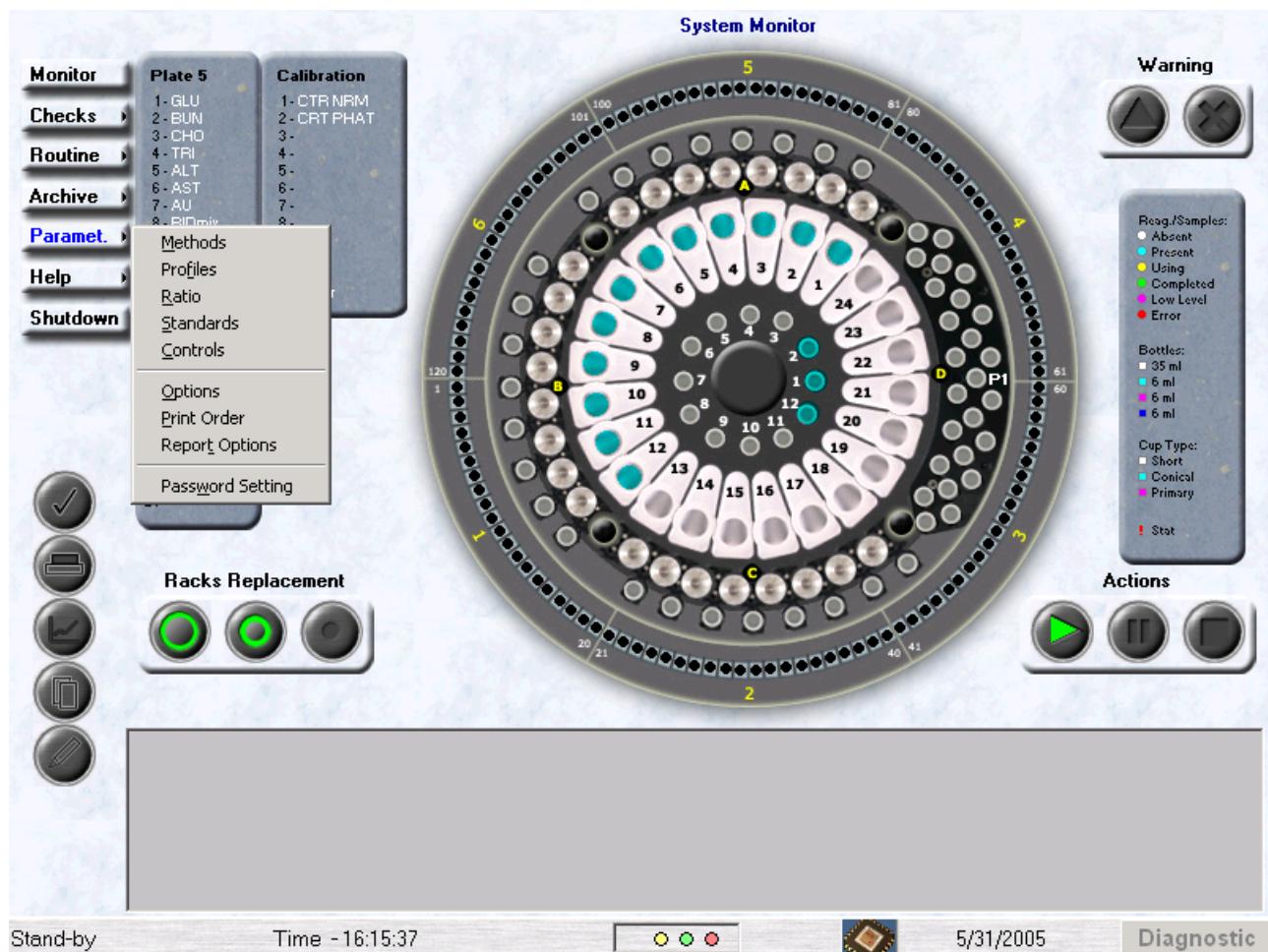
This mask also contains buttons which allow the user to move on to other applications or carry out the following procedure:



- Print the selected data (**Print** button)

(Please see the section: Command Buttons).

3.5 PARAMETERS



Paramet. The term **Parameters** indicates that mask in which system configuration is carried out. Each set of parameters regarding a specific operation to be performed will have its own programming mask where the operator can carry out a guided set-up. The Parameters Menu is protected by a Password and cannot be viewed without its insertion.

It is not possible to access the Parameters Menu masks while the instrument is in operation.

This is a self-protect mechanism aimed at avoiding any conflicts which may occur as a result of changes made regarding parameters involved in the on-going operation and/or its results. Therefore, the Parameters Menu is inactivated and effectively blocked during instrument test running. Instructions follow:

INSERTING THE PASSWORD

Whenever **Parameters** is selected, the below illustrated **Password** mask will open. This mask allows the operator to protect the programming masks from unauthorized viewing and/or manipulation which could risk the integrity of the work carried out.



In order to view the various elements contained under the **Parameters** Menu, the user must correctly digit the valid **Password** within the provided field (maximum 10 letters – no numbers or other symbols are allowed).

At this point, the user must click on “**OK**”. The system will automatically close the Password mask and open a pull-down menu containing the various included elements.

N. B.: the valid Password must be inserted in order to be able to access and/or insert programming data within the individual masks which make up the Parameters Menu.

This mask contains the following fields:

Methods: indicates the screen where the methods along with their relative parameters are defined. For further, more detailed information, please see Chapter 05 – Methods.

Profiles: this mask is dedicated to setting up the Profiles and the relative tests that they include;

Ratio: this mask concerns setting up the Ratios and their respective parameters;

Standards: the standards, along with the relative tests, are programmed in this screen;

Controls: this mask allows the user to program the controls and their relative tests;

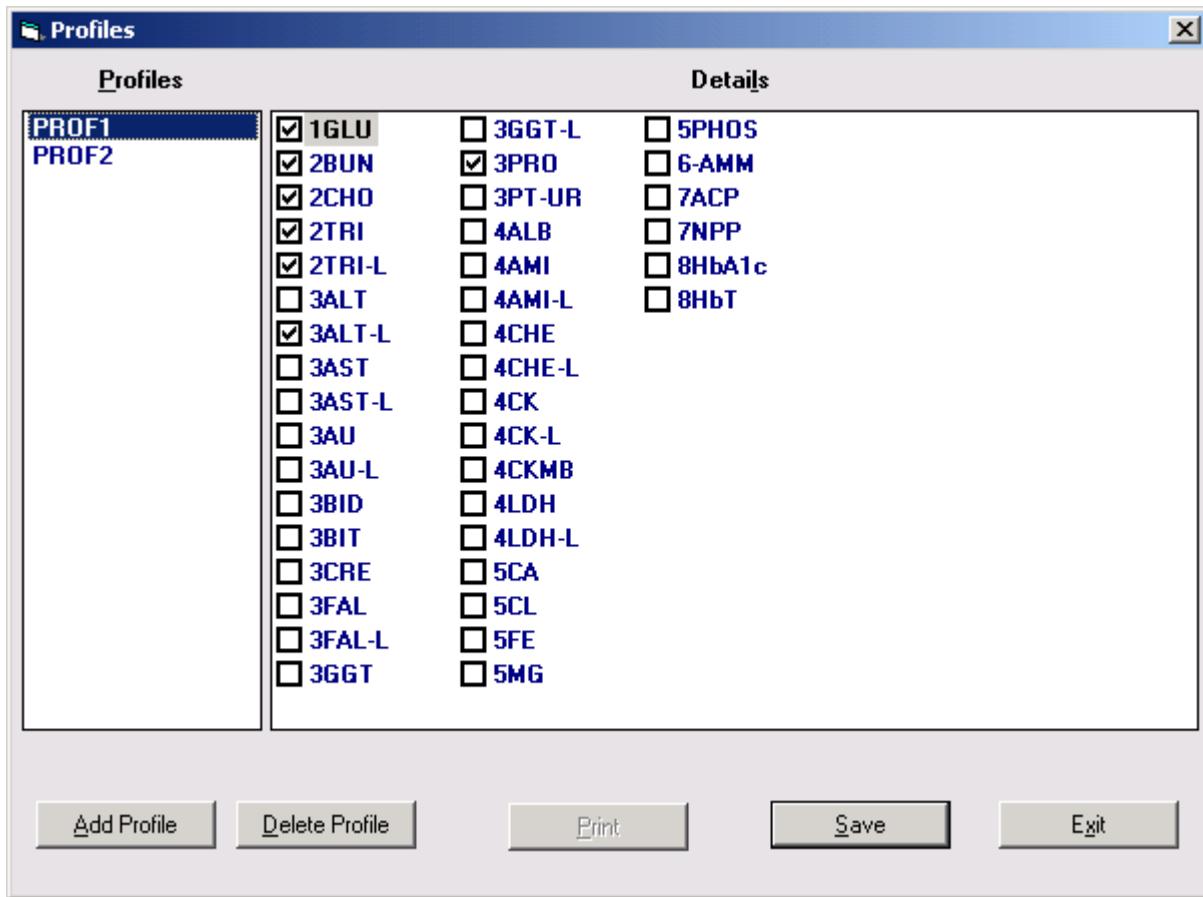
Options: this mask allows the operator to define the system's defaults options;

Print Order: this mask makes it possible for the user to decide the order in which the results of the various analyses will be printed out, regardless of the order in which the tests were carried out;

Report Options: this mask is where the user can define the Header Text of the Report Print-out and the error symbols that will be used therein;

Password Setting: this mask is necessary in order to be able to modify the current password.

PROFILES



To access the **Profiles** mask, select **Parameters** from the Menu, insert the current password, and then, from the options offered, click on “**Profiles**”.

This function makes it possible to program test profiles (predetermined groups of tests that are programmed to be carried out together). There is no numerical limit to the number of profiles that the user can define.

The left-hand area of this mask contains a list of all the already programmed and saved Profiles. Whenever a Profile is selected from this area, the operator will view, in the central portion of the window, the list of all the tests said Profile includes.

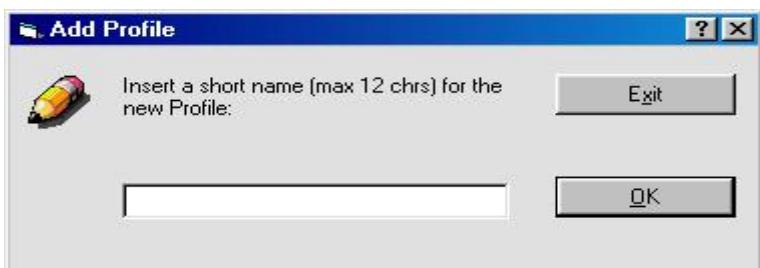
The central section of this mask is dedicated to the selection of the tests. Here, the operator can view, in alphabetical order, all programmed tests and checked (✓) that are already part of existing Profiles.

The lower portion of the screen includes those operative buttons necessary for carrying out the following operations:

Adding a New Profile

Add Profile

To create a new Profile, click on “**Add Profile**”. The following dialog box will automatically open.



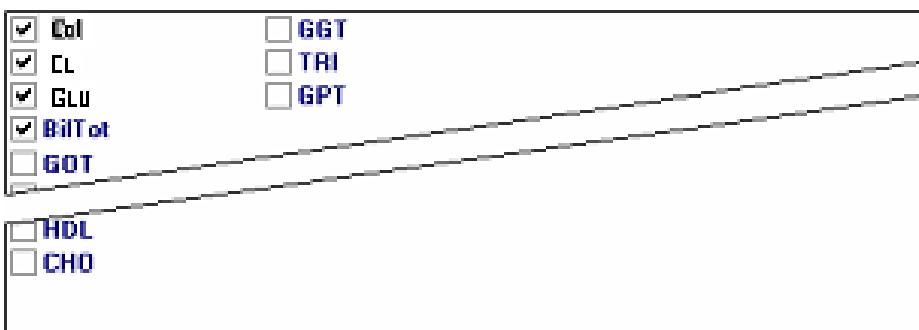
Save

Digit the name of the new **Profile** in the space provided for a **Maximum of 12** characters. Confirm the operation by clicking on **OK**. The new Profile will now be viewed listed along with the other pre-existing Profiles in the left-hand portion of the window. Select with check (✓) the tests to be included in the new profile and the click on “**Save**” to memorize the new data and complete the programming operation.

Adding or Removing test(s) from a Profile

Save

To edit the list of **Tests** which make up a **Profile**, select the required Profile from the “Profiles” List. At this point, the Tests List will appear, allowing the operator to view all those tests that are available; and among these, all those tests which currently make up the selected Profile will appear checked (✓). Please see the illustration below:



The user, at this stage, need simply click on a yet, unchecked Test to check (✓) it and thereby include it in the selected Profile, or click on an already checked Test, to uncheck it and thereby remove it from the selected Profile. Click on “**Save**” to memorize and save the changes made.

Eliminating a Profile

Delete Profile

Whenever the operator wishes to eliminate an entire **Profile**, he/she must first select the required Profile from the Profiles List in the left-hand portion of the window, and then click on “**Delete Profile**”. The following visual text warning message will appear:



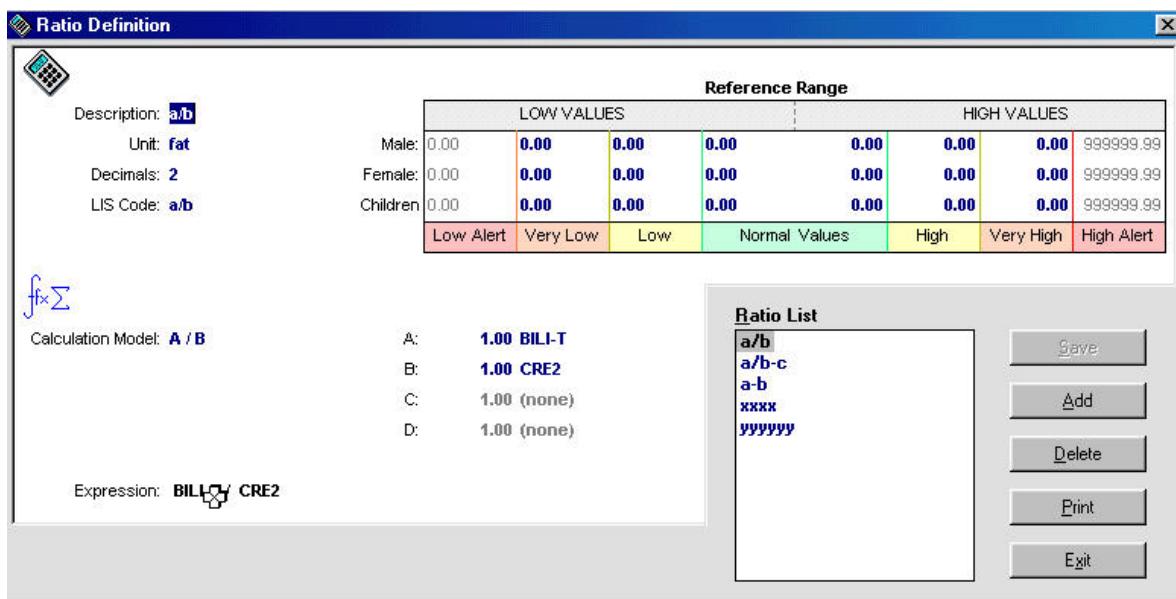
Click on “Yes” to confirm the elimination of the named Profile or on “No” to annul the request and the operation.

Exit

EXIT

To exit the **Profiles** mask and return to the main mask, **System Monitor**, click on “Exit”.

RATIO



To access the **Ratio Definition** mask, select **Parameters** from the **Menu**, insert the current password, and then, from the options offered, click on “Ratio”.

The mask that opens is dedicated to the programming of the Ratios and their respective parameters. This function makes it possible for the operator to obtain more detailed information regarding the mathematical calculations carried out, having available to him/her the results of the individual tests. Said mask is divided into three areas:

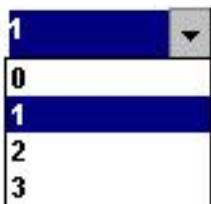
- the section located in the upper portion of the mask contains the following fields:

Description: indicates the full name of the programmed ratio. This field can contain a **Maximum of 20** characters.

Unit: indicates the unit used for representing the values of the ratio;

Decimals: indicates how many decimal places are to be included in the ratio values, as reported in the “Reference Values” Table and in the Print-out of the Patient’s Test Results. Said selection can

be effectuated from the field's pull-down menu (as illustrated here-below), by selecting from a **Minimum of 0** to a **Maximum of 3**;



LIS Code: indicates the **acronym (maximum 6 characters)** used for the serial data transmission of the test;

Reference Range: in this same area, to the right, there is also a “**Reference Range**” table where the reference values regarding the tests are given. They are divided into the following categories: Low, Normal, High, according to the sex and age of the subject. Following is an illustration:

Reference Range								
	LOW VALUES				HIGH VALUES			
Male:	0.0	0.0	0.0	4.0	6.0	8.0	20.0	1000000.0
Female:	0.0	0.0	0.0	4.0	6.0	8.0	20.0	1000000.0
Children	0.0	0.0	0.0	4.0	6.0	8.0	20.0	1000000.0
	Low Alert	Very Low	Low	Normal Values		High	Very High	High Alert

The values which are inserted for **Male** subjects are automatically entered into the **Female** and **Child** category areas as predefined values. However, the operator can choose other values for these two categories and insert them into the appropriate spaces provided by selecting that area and inserting the desired values.

- The section that is located in the lower, left-hand portion of the mask is dedicated to the calculation ratio and contains the following fields:

Calculation Model: indicates the operation set-up for test **calculation** as selected from the field's pull-down menu. This menu automatically appears whenever this field is selected and offers the user five options. The operator can choose an operation containing: **2** elements, identified by the letters **A** and **B**; **3** elements, identified by the letters **A**, **B** and **C**; or **4** elements, identified by the letters **A**, **B**, **C** and **D**.

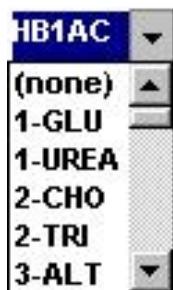
Expression: allows the user to view the programmed ratios. Please note that in this field the letters viewed in the **Calculation Model** field are not seen and in their place the operator will find the **LIS Code** of the selected **Tests**,

Other fields, regarding calculation of the tests, listed here-below, are indicated by the letters **A**, **B**, **C** and **D**.

- A: **100.00 HB1AC**
 B: **1.00 HB**
 C: **1.00 (none)**
 D: **1.00 (none)**

These letters in fact, refer to the elements selected in the **Calculation Model** and include multiplicative coefficient and the name of the test set-up for the calculation.

Whenever the user selects one of the four fields described in order to be able to set-up a test, upon clicking, a pull-down menu will automatically open containing the names of the tests which can be selected.



If no test has been selected for that field, this field is not activated and will appear coloured light grey – the other activated fields will appear coloured blue.

- the section located in the lower, right-hand portion of the mask contains a list of the programmed ratios and includes the operative buttons necessary for carrying out the following operations:

Programming a new Ratio

Programming a new ratio includes declaring its name, using an acronym, and also defining it by setting-up all the data relative to this new test.

Currently, there are five equations available for defining a mathematical relation between two or more analyses. They are:

1. $aX - bY$
2. aX / bY
3. $aX / (bY - cZ)$
4. $(aX + bY) - (cZ + dW)$
5. $aX - bY - (cZ / dW)$

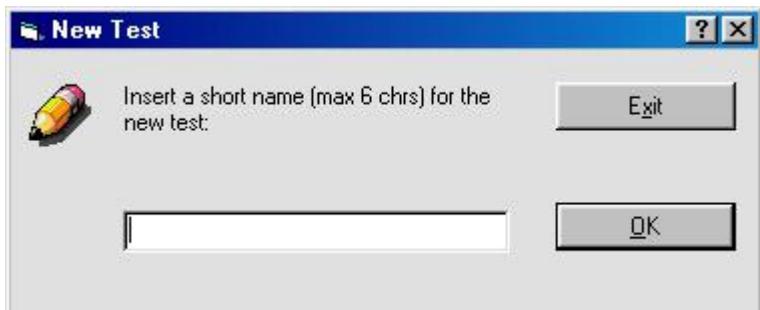
These equations can be applied to many analytical relations. Following are some examples:

➤ BUN/CRE RATIO	aX / bY	1xBUN / 1xCRE
➤ ALBUMIN/GLOBULIN RATIO	aX / (bY - cZ)	1xALB / (1xPRO - 1xALB)
➤ GLOBULIN	aX - bY	1xPRO - 1xALB
➤ INDIRECT BILIRUBIN	aX - bY	1xBIT - 1xBID
➤ LDL CHOLESTEROL	aX - bY - (cZ/dW)	1xCHO-[(1xHDL-(0.2TRI)]
➤ RISK INDEX	aX / bY	1xCHO / 1xHDL
➤ NON-PROSTATIC PHOSPHATASE	aX - bY	1xACP - ACP Inhibit
➤ AST/ALT RATIO	aX / bY	1xAST / 1xALT
➤ DIBUCAINE	aX - bY - (cZ/dW)	100-0-(100DIB/CHE)
➤ % HbA1C	aX / bY	100 HbA1C/ HB

Adding a new Ratio

Add

Click on “Add” in the **Ratio Definition** mask. The following **New Test** dialog box window will automatically open:



The operator must digit, in the space provided, the name (an acronym) of the new ratio making sure to use a **maximum of 6 characters**.

The user must be careful to not insert an acronym which is already in use, or rather, one which corresponds to another listed test. If the acronym is already in use, when the operator clicks on “OK”, the following visual text information message will appear:



At this point the user must: click on “OK”, change the name to be assigned to the new test and then click once again on “OK”. At this point the new name will be accepted.

Defining a Ratio

Save

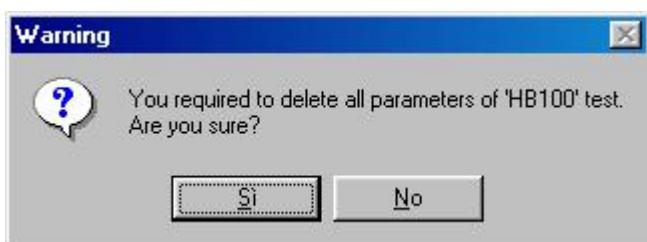
In order to correctly program a new test, the user must insert the settings for the parameters in the fields of the previously discussed sections of the **Ratio Definition** mask. These parameters can all be subsequently edited – with the exception of the acronym, which will remain as set-up here.

Insert settings into those fields necessary; both in the case of a new method and in the event of editing for already programmed tests. To memorize the data inserted, click on “**Save**”.

Deleting a Ratio

Delete

First select the required ratio from the list of **Ratio** in the Ratio Definition mask, and then click on “**Delete**”. The following warning message dialog box will appear:



Click on “**Yes**” to confirm the elimination, or on “**No**” to cancel the Delete procedure and exit this operation.

Printing Ratio

Print

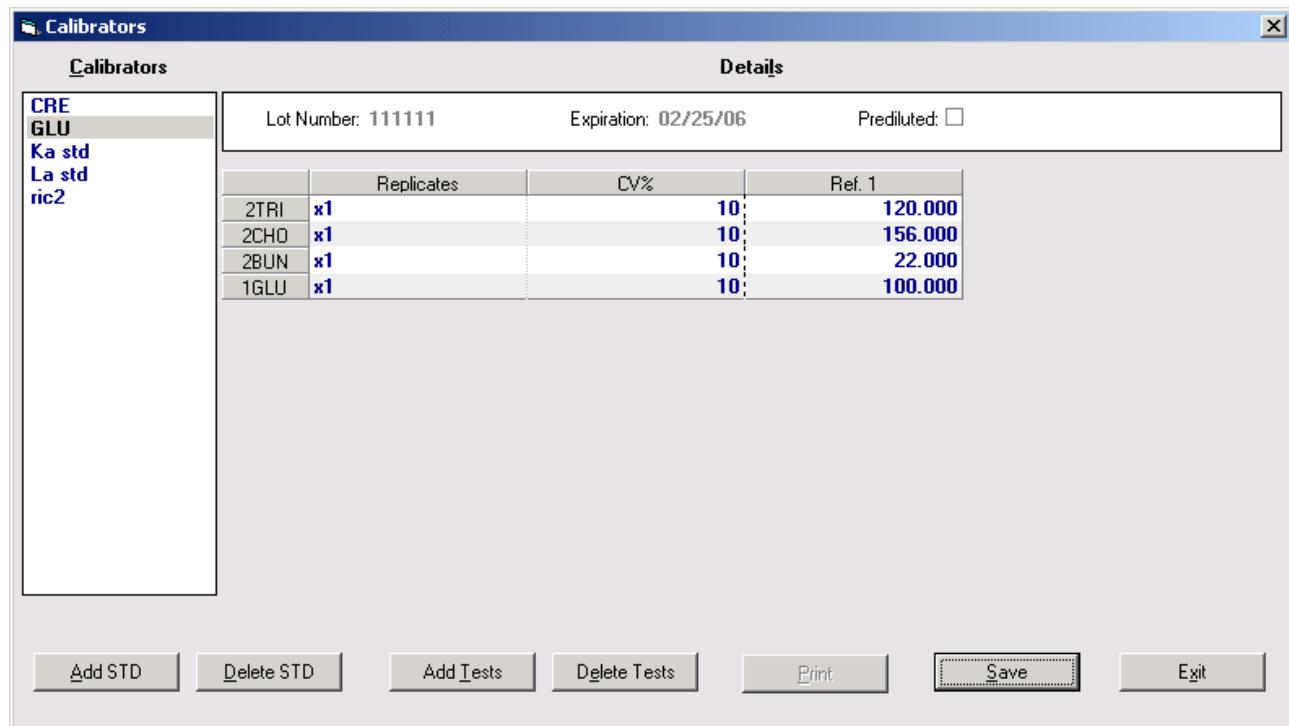
First select the required ratio from the list of **Ratio** in the Ratio Definition window, and then click on “**Print**”.

Exiting the Ratio Definition Mask

EXIT

To exit the **Ratio Definition** mask and return to the main mask, **System Monitor**, click on “**Exit**”.

STANDARDS



To access the **Calibrators** mask, first select **Parameters** from the **Menu**, insert the current password, and then, from the options offered, click on "**Standards**".

This window is used to program the standards and their relative tests. It is divided into the following three sections:

- an area located in the left-hand portion of the screen containing a list of the already programmed Standards, provided in alphabetical order. Whenever the operator selects a standard from the list, the tests therein contained along with their relative values will be viewed.
- an area located in the central portion of the screen, dedicated to setting-up the standards and to the values of the individual tests. The upper portion of this area contains the following required fields:

Lot Number: allows the user to view the **Lot** number of each individual standard;

Expiration Date: allows the user to view the expiration date set for the **Standard**.

Warning! Once the standard has expired, it will no longer be viewed.

Predilution: if this field **is not activated**, it means that the calibration curve is ready and diluted according to the dilution ratio of the method. If this field **is activated**, it means that the calibration curve is ready and undiluted – the instrument will apply to the standard the same dilution ratio as that of the method (if there is one). For Master Standard, please see Chapter 06 – Multipoint Calibration.

Diluent: Indicates the diluent type used

The lower-most area of this section is dedicated to a table of the tests contained in the standards. The rows in the table provide information regarding the various methods; while the columns indicate the reference values.

- The lower area of the screen is dedicated to mask management. It is made up of the operative buttons necessary for carrying out the required operations:

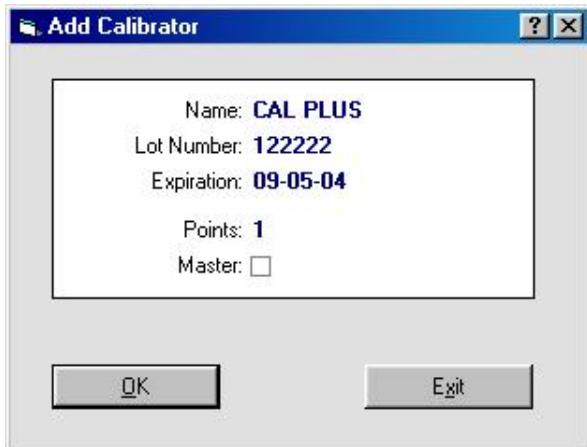
Inserting a new Standard

Inserting a standard includes both **Adding a New Standard** (declaring its name using an acronym) and **Defining the Standard** by setting-up all the data relative to this New Standard to be Added.

Adding a New Standard

Add STD

Click on “**Add STD**” in the **Calibrators** mask. The following **Add Calibration** dialog box window will automatically open



where the operator must digit, in the spaces provided, the following information:

Name: the name of the new Standard (maximum 12 characters);

Lot Number: the lot number of the Standard (maximum 8 characters);

Expiration Date: the expiration date for the new Standard. When this mask first opens, this field will contain the current date. However, the user can open a calendar by pressing **F4** or double clicking with the mouse, or can simply edit the date by digitizing a new date in the place of that one given. **Warning! Once the standard has expired (i.e. after its programmed expiration date), it will no longer be viewed.**

Points: here, operator must specify the number of calibration points of the Standard – a value between a **Minimum** of 1 and a **Maximum** of 8;

Master: the user must check (✓) this field in order to specify that the calibration points are automatically produced by the system itself based on the Master Standard.

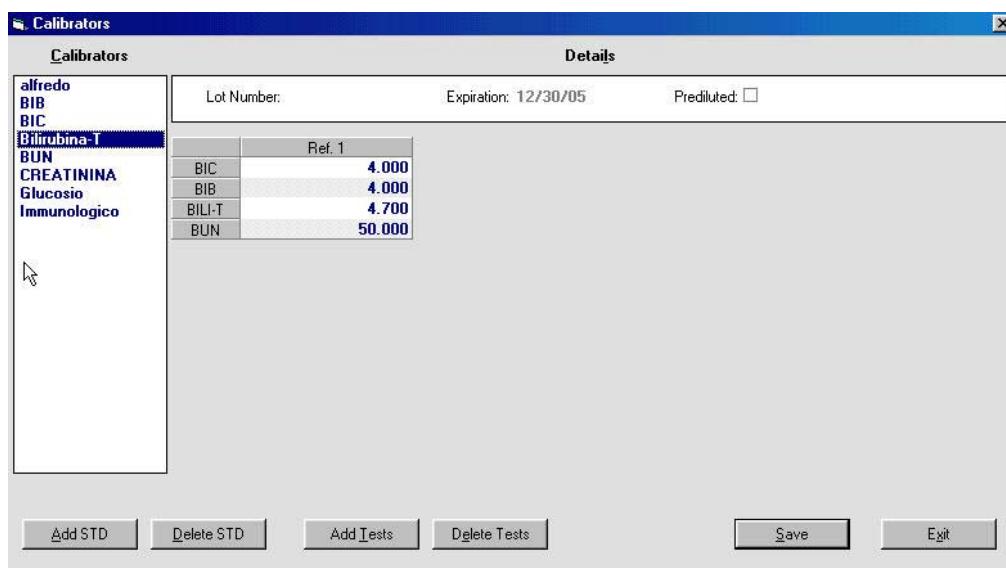
To confirm the data set-up and therefore the adding of the New Standard, the user must click on “OK” located in the **Add New Standard** mask. At this point, the new standard can be viewed along with all the other, already programmed standards, in the standards list. Clicking on “Exit” allows the operator to annul the entire operation.

Warning! The data set-up and inserted in this mask for the purpose of adding a new Standard cannot be edited or modified in any way. To change any data, the user must necessarily eliminate (delete) the required Standard.

Defining a Standard

Save

In order to correctly program a new **Standard**, the user must define both the tests (Please see the section “Adding a Test or Tests”, further along in this text), and the concentrations relative to each single point.



To memorize the data inserted regarding new Standards, or in the event of editing data for already programmed Standards, click on “Save”.

If the below-illustrated visual text information message appears, it means that the “Save” button has been clicked on without any editing of the already set-up data.



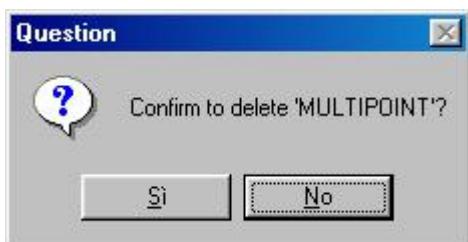
The user need only confirm, by clicking on “OK”.

Deleting a Standard

Delete STD

First select the required standard from the list of **Standards** in the left-hand part of the “**Calibrators**” mask, and then click on “**Delete STD**”.

The following warning message dialog box will appear:



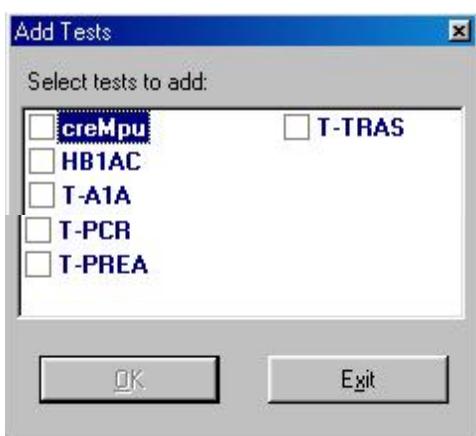
Click on “**Yes**” to confirm the elimination or on “**No**” to cancel the Delete procedure.

Adding a Test or Tests to a Standard

Add Tests

First select the name of the **Standard** from the List of Standards in the Calibrators mask. Then click on “**Add Test(s)**”. The below-illustrated Add Test(s) window will automatically open. This window contains all those tests available for that particular Standard and not defined **against-factor**. The methods shown are appropriate for the type of Standard selected; or rather: if the Standard is a 1 point standard, only those tests defined as **against-standard** will be listed. If the Standard required has 2 points, then the list will contain all those methods defined as **Cubic**, **PtP**, etc. – or rather; multipoint calculations. Select the required test, confirm the selection by clicking on **OK**, and the method will automatically be inserted in the Standard. Clicking on **Exit**, allows the user to annul the operation. At this point, the Calibrators mask will view the added test(s), and the operator must now insert the number of **Replicates**, the relevant **CV %** and in the **Ref. 1** column, (Ref.n for multipoint Standards), the known concentration value.

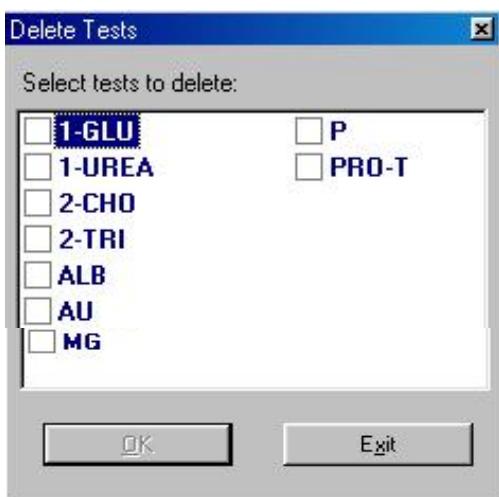
Whenever a test or tests are added to an existing Standard, this window will contain a list of only those tests which are not already included in that Standard.



Deleting a Test or Tests from a Standard

Delete Tests

First select the name(s) of the **Standard(s)** from the List of Standards in the Calibrators mask. Then click on “**Delete Test(s)**”. The following Delete Test(s) window will automatically open containing a list of all those tests included in that Standard:



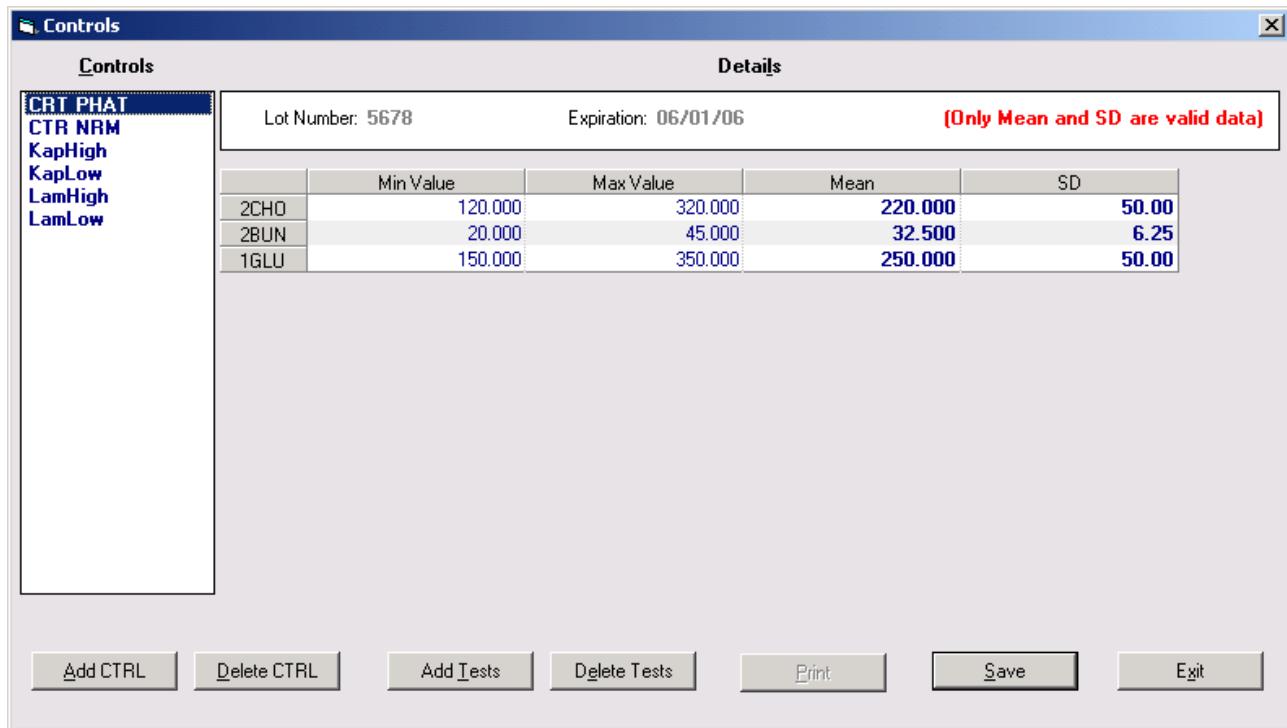
Select the test(s) (✓) to be eliminated and then confirm the operation by clicking on “**OK**”; or click on “**Exit**” to annul the Delete procedure.

Exit

EXIT

To exit the **Calibrators** mask and return to the main mask, **System Monitor**, click on “**Exit**”.

CONTROLS



To access the **Controls** mask, select **Parameters** from the **Menu**, insert the current password, and then, from the options offered, click on “**Controls**”.

This window allows the operator to program the controls along with their relative tests. It is made up of:

- an area located on the left-hand side of the mask where the user can view the list of programmed **Controls**, provided in alphabetical order.

Whenever the operator selects a control from the list, the tests therein contained will be viewed in the central area of this window;

- an area located in the central portion of the mask, whose upper section is dedicated to data that identifies the control, contained in the following required fields:

Lot Number – here the user can view the Lot Number of each individual control;

Expiration Date – here the operator can view the expiration date of the controls. **Warning!** Once the control has expired (i.e. after its programmed expiration date), it will no longer be viewed in the calibration programming mask

- an area located in the central portion of the mask, whose lower section provides the operator with a table of the tests contained in the selected control. Each row in the table refers to a given test; while the columns indicate the following data:

Minimum Value: the minimum value that is considered acceptable for that control;

Maximum Value: the maximum value that is considered acceptable for that control;

Mean and SD: the mean value and the Standard Deviation regarding the range of acceptable values, as defined by the Minimum and Maximum values inserted for that control.

- an area in the lower portion of the mask made up of those buttons necessary for mask management operations.

Adding a New Control or Controls

Add CTRL

To create a new Control(s), click on “Add CTRL”. The following dialog box will automatically open containing the below-listed fields in which the user must insert the required data.



Name: Digit, in the space provided, a short name for the New Control, having a maximum of 12 characters;

Lot Number: Specify the Control's lot number, using a maximum of 8 characters;

Expiration Date: Insert in the field the expiration date of the new Control. When this mask first opens, this field will contain the current date. However, the user can open a calendar by pressing F4 or double clicking with the mouse, or can simply edit the date by digitizing a new date in the place of that one given.

To confirm the data set-up and therefore the adding of the New Control, the user must click on “OK” located within the **Add Control** mask. At this point, the new control can be viewed along with all the other, already programmed ones, in the dedicated list. Clicking on “Exit” allows the operator to annul the operation.

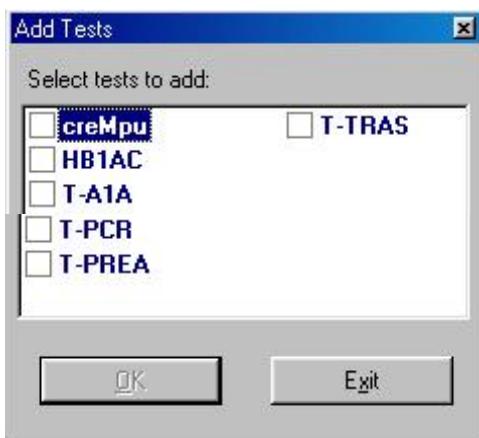
Warning! The data set-up and inserted in this mask for the purpose of adding a new Control cannot be edited or modified in any way. To change any data, the user must necessarily eliminate (delete) the required Control.

Adding a Test or Tests to a Control

Add Tests

First select the name of the **Control** from the List of Controls. Then click on “**Add Test(s)**”.

The below-illustrated “Add Test(s)” window will automatically open. This window contains all those tests not already contained in that Control. If the control is a **New Control**, then this window will contain a list of all the methods; seeing as how no test has, as of yet, been inserted in the new control.



OK

Select the required test (✓) and confirm the selection by clicking on “**OK**”. The method will automatically be inserted in the list of tests for that Control.

EXIT

The operator can annul the operation by clicking on **Exit**.

The Controls mask will now view the added test, along with the relative columns in which data regarding the acceptable range values of the control must be inserted.

To memorize the data inserted, or in the event of editing data for already programmed Controls, click on “**Save**”.

If the below-illustrated visual text information message appears, it means that the “Save” button has been clicked on without any editing of the already set-up data.



The user need only confirm, by clicking on “**OK**”.

Deleting a Control

Delete CTRL

First select the required control from the list of **Controls**, and then click on “**Delete CTRL**”. The following warning message dialog box will appear:



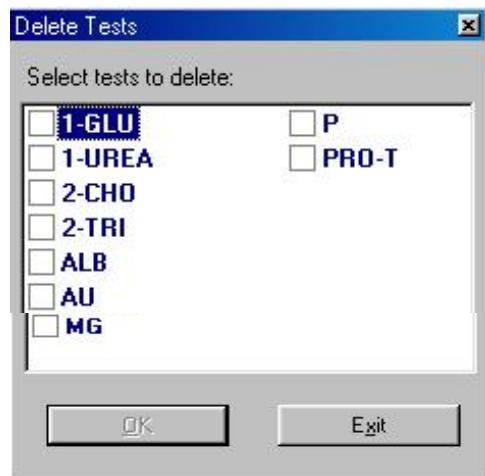
Click on “**Yes**” to confirm the elimination.
Click on “**No**” to annul the Delete procedure.

Deleting a Test or Tests from a Control

Delete Tests

To eliminate a test from a Control, first click on “**Delete Test(s)**”.

The following Delete Test(s) window will automatically open containing a list of all those tests included in that Control.



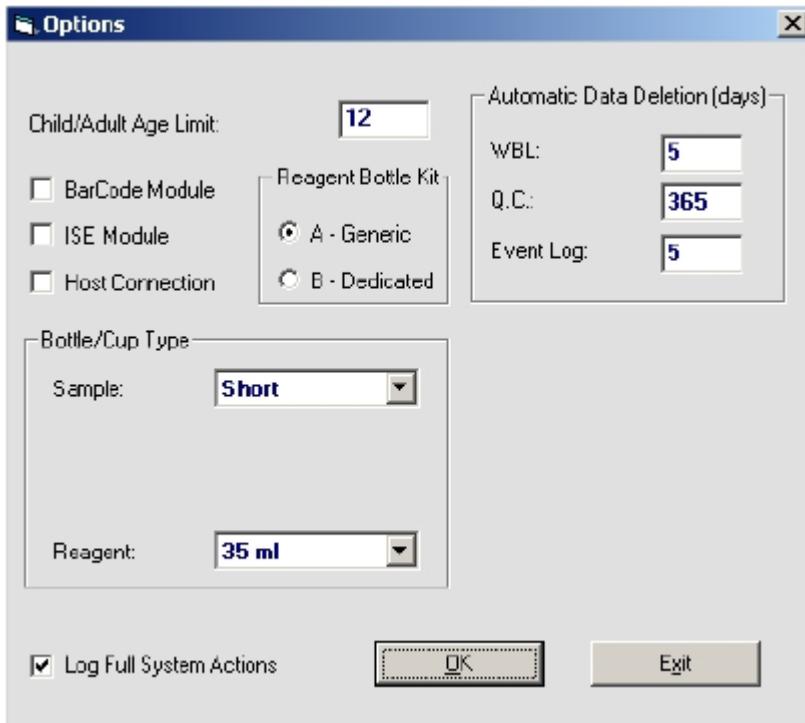
Select the test (✓) to be eliminated and then confirm the operation by clicking on “**OK**”. Clicking on **Exit** annuls the delete operation.

Exit

EXIT

To exit the **Controls** mask and return to the main mask, **System Monitor**, click on “**Exit**”.

OPTIONS



To access the **Options** mask, select **Parameters** from the **Menu**, insert the current password, and then, from the options offered, click on “**Options**”.

The **Options** mask allows the operator to define a series of default parameters for the analyzer, as described below:

Age Limit – Child/Adult: the operator can insert in this field an age limit for defining a patient as either an Adult or a Child. This age limit will be used by the program when the normal values range is assigned;

Bar Code Module: this field must be “checked” (✓), whenever the user wishes to insert samples using the **Bar Code**;

ISE Module: to be defined;

Host Connection: this option allows the operator to connect to the Host. Whenever the command is selected, the user can view on the System Monitor and in the Instrument Routine Menu those commands necessary for Receiving and Transmitting data;

Setting of the Reagent and sample containers

Configuration 1 - Select A – Generic into the Reagent Bottle kit field.

Sample: allows the user to set the type of samples containers. It contains a pull-down menu where the operator can choose either: Short, Conical or Primary;

Short = Short cup P/N 650100 must be loaded on sample cup Rack P/N 05-01829-00.

Conical = Conical cup P/N 01-01739-00 (next introduction) can be loaded on sample cup Rack P/N 05-01829 and on the Primary tube sample Rack (Universal) P/N 05-00586-00.

Primary = Primary tube can be loaded on the Primary tube sample Rack (Universal) P/N 05-00586-00 and in case of poor sample, Conical cup P/N 01-01739-00 can be loaded.

In this configuration, the needle aspiration course has been reduced in order to permit Conical cup P/N 01-01739-00 (next introduction) safe using. Needle aspirates up to 26 mm from the primary tube button.

Reagent: allows the operator to declare the de-fault type of container to be used for the reagents. This field contains a pull-down menu, offering the operator the choice of either 35 ml or 6 ml sizes;

Configuration 2 - Select B – Dedicated into the Reagent Bottle kit field.

Sample: allows the user to declare the type of container to be used for the samples. It contains a pull-down menu where the operator can choose either: Short, Conical or Primary;

Short = Short cup P/N 650100 must be loaded on the Primary tube sample Rack (Universal) P/N 05-00586-00 using adapter P/N 9-01-0609-00

Conical = Short cup P/N 650100 must be loaded on the Primary tube sample Rack (Universal) P/N 05-00586-00 using adapter P/N 9-01-0609-00

Primary = Primary tube can be loaded on the Primary tube sample Rack (Universal) P/N 05-00586-00.

With this configuration, the needle aspirates up to 12 mm from the primary tube button.

Reagent: allows the operator to declare the de-fault type of container to be used for the reagents. This field contains a pull-down menu, offering the operator the choice of either 35 ml or 6 ml sizes;

Each liquid container size corresponds to a different colour. For further information, please see the legend provided under System Monitor;

Log Full System Actions: it makes it possible to record, in dedicated files, all those system operations useful for identifying the cause of the problem, whenever unidentifiable instrument errors occur. This field is “checked” (✓) always, it can be made not active for one run only.

Automatic Data Deletion (days): this field makes it possible for the operator to define for how long the following data must be retained in memory: **Water Blank Levels, Quality Control** and the **Event Log** table. The user must simply insert, in the corresponding field, the number of days for which said data must be kept in the system memory – after which the data will be automatically deleted;

Memorizing the Operations Carried Out

OK

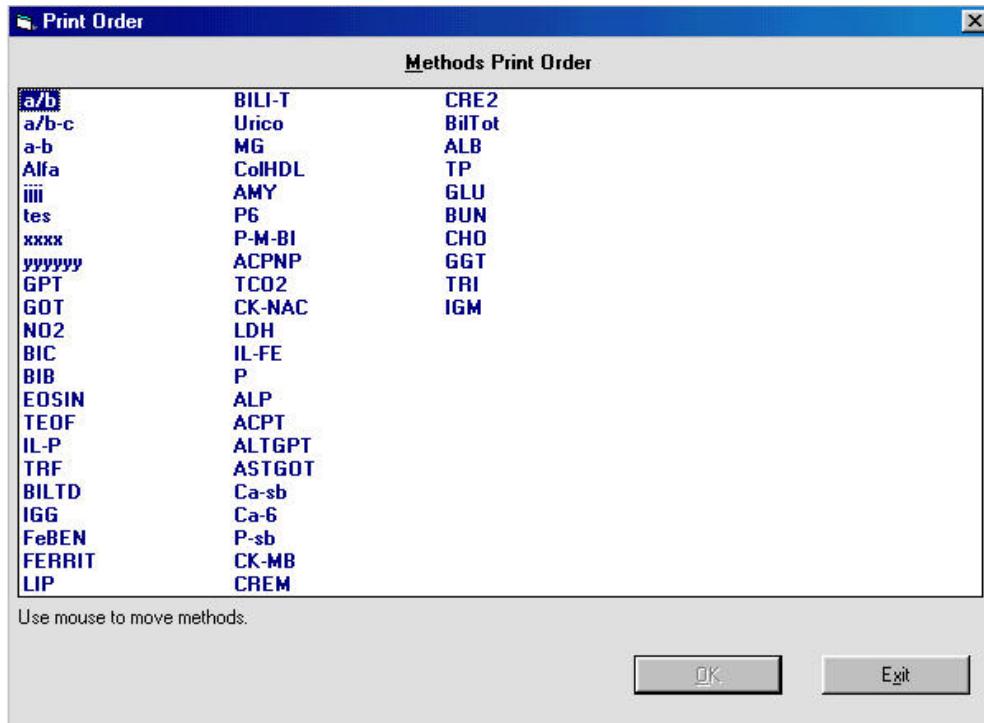
In order to memorize and, therefore, utilize the settings programmed in this mask, the user must click on “OK”, located in the lower portion of the mask.

Exit

EXIT

To exit the **Options** masks and return to System Monitor, click on “Exit”, located in the lower right-hand portion of the mask.

PRINT ORDER



To access the **Print Order** mask, select **Parameters** from the **Menu**, insert the current password, and then, from the options offered, click on “**Print Order**”.

This window allows the operator to decide in what order the tests are to be printed for the final report, regardless of the order in which they were carried out.

A **Methods (Test) Print Order** list is located in the central area of this window. Here the operator can view all those tests to be placed in whatever order is deemed appropriate. Those buttons useful for the various operations are located in the lower portion of the window.

The tests included in the list are given using the same acronym as that used in the “**Methods List**” field in the “**Methods**” mask, where they were previously set-up.

Setting-up the Test Print Order

OK

The operator can choose the criteria to be used when deciding the order in which to print the tests – selecting either to print them according to test type or functionality. To do so,

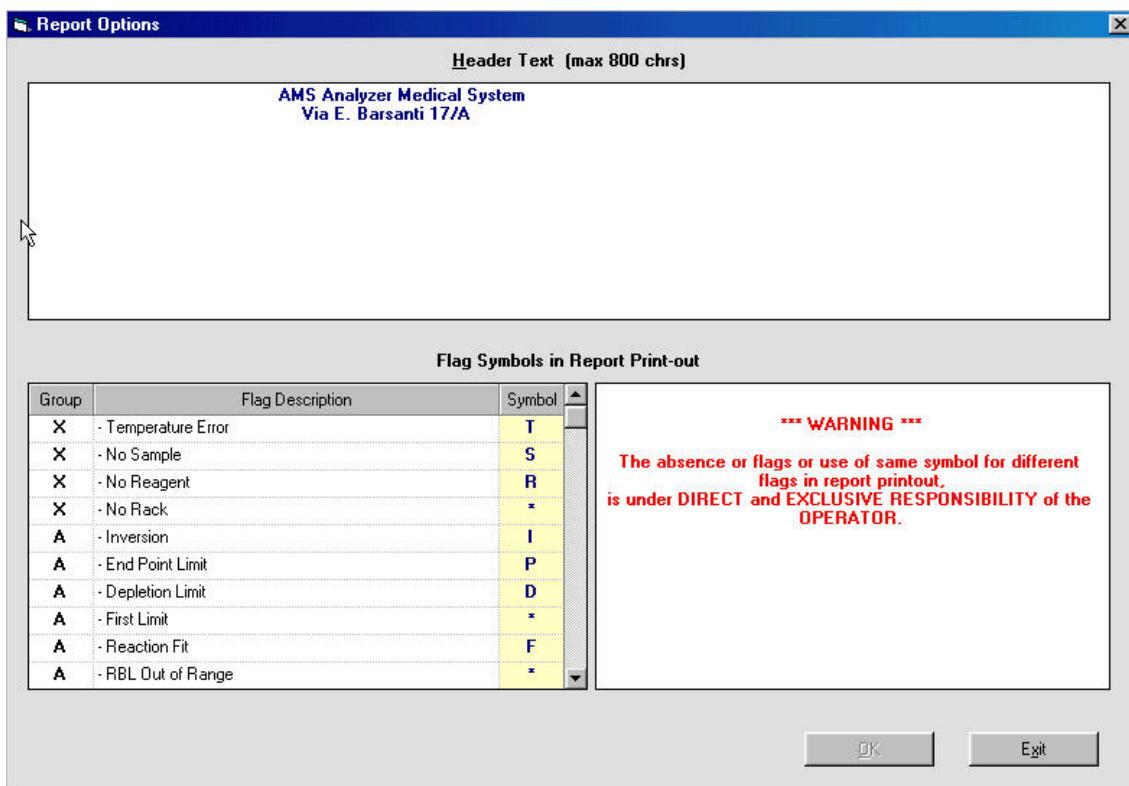
he/she must simply use the “Drag and Drop” function of the mouse to position the tests in the order he/she wishes them to be printed, and then click on “OK” to memorize the data.

Exit

EXIT

To exit the **Print Order** mask and return to System Monitor, click on “Exit”.

REPORT OPTIONS



To access the “Report Options” mask, select “Parameter” from the menu and then, from the options offered, click on “Report Options”. This mask allows the operator to define the header report and symbols that will indicate errors on the report print-out.

This mask contains:

- A **Header Text** area located in the upper portion of the mask, where up to 800 characters can be inserted;
- A lower area containing a **Warning message** on the right and on the left the flags list with the following fields:

Group: allows the operator to view the group to which that Flag belongs. Each group has its own symbol, which indicates the exact type of Flag (See Chapter 09 – TROUBLE SHOOTING GUIDE AND LIST OF ALARMS);

Flag Description: this field allows the user to see the name set-up for that type of error;

Symbol: this field contains either a character or a symbol indicating one or more errors. The characters or symbols set-up, have will be those used in the report print-out, or rather, they will substitute the character used to declare that error in the report print-out (See Chapter 09 – TROUBLE SHOOTING GUIDE AND LIST OF ALARMS);

The right-hand portion of this section contains an area dedicated to the visual text “**Warning!**” message. The operator should always consult this message before undertaking any further action that might compromise the reliability of the test result(s).

- Two **Operation** buttons located in the lower, right-hand portion of the mask.

Setting-up the Report

OK

To set-up the header text within the space provided – **Header Text** – click on this area and type in the desired text, making sure to not exceed the **800**-character **Maximum**.

If the user wishes to edit the character used to indicate a given Flag, he/she need only select the **Symbol** field of the relative Flag and insert the new character.

To make sure that both the text and any new symbols are memorized by the program and subsequently used for the print-out of the report, click on **OK**, located in the lower, right-hand corner of the mask. “OK” is activated only after the information contained in this mask has been edited in some way.

Exit

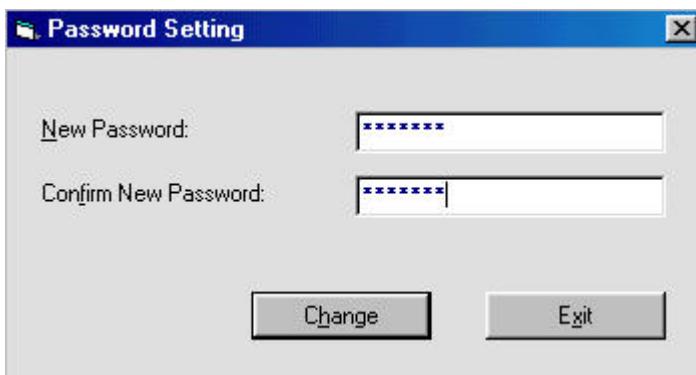
EXIT

To exit the **Report Options** mask and return to the main mask, System Monitor, click on “**Exit**”.

PASSWORD SETTING

To access the **Password Setting** mask, select **Parameters** from the **Menu**, insert the current password, and then, click on **Password Setting**.

The **Password Setting** mask, as illustrated below, allows the operator to change the Password currently in use.

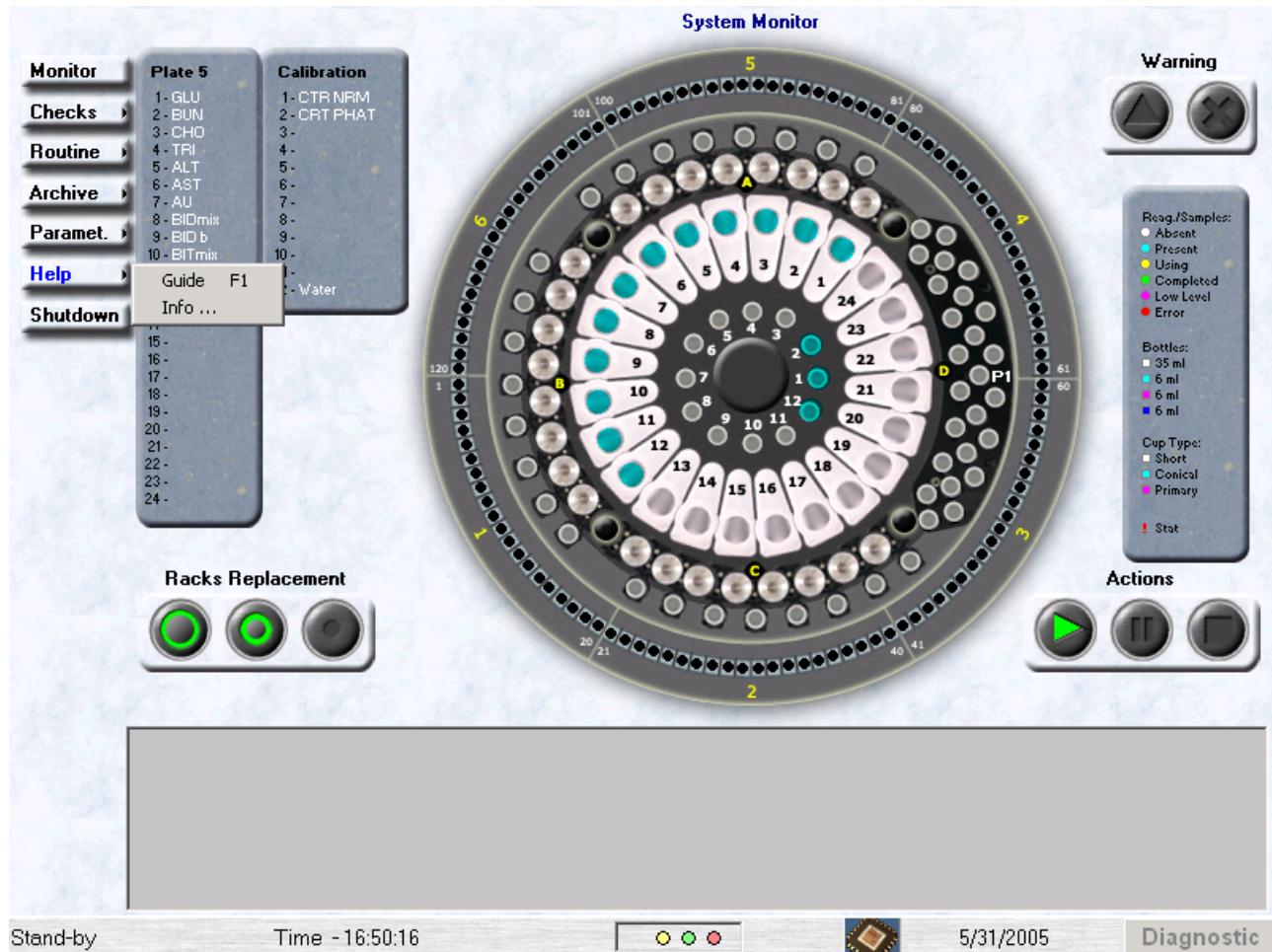


In order to edit the current Password, the user must insert, in the **New Password** field, a new code having a **Maximum** of 10 alphanumerical characters.

Change

Digit the new code (new Password) in the **Confirm New Password** field and then click on “**Change**”. This button is activated only when the exact same code has been inserted in both the New Password field and the Confirm New Password field. If the operation has been carried out correctly, and is therefore successful, the program will notify the user via a visual text information message. The **Exit** button can be used to annul the operation at any time.

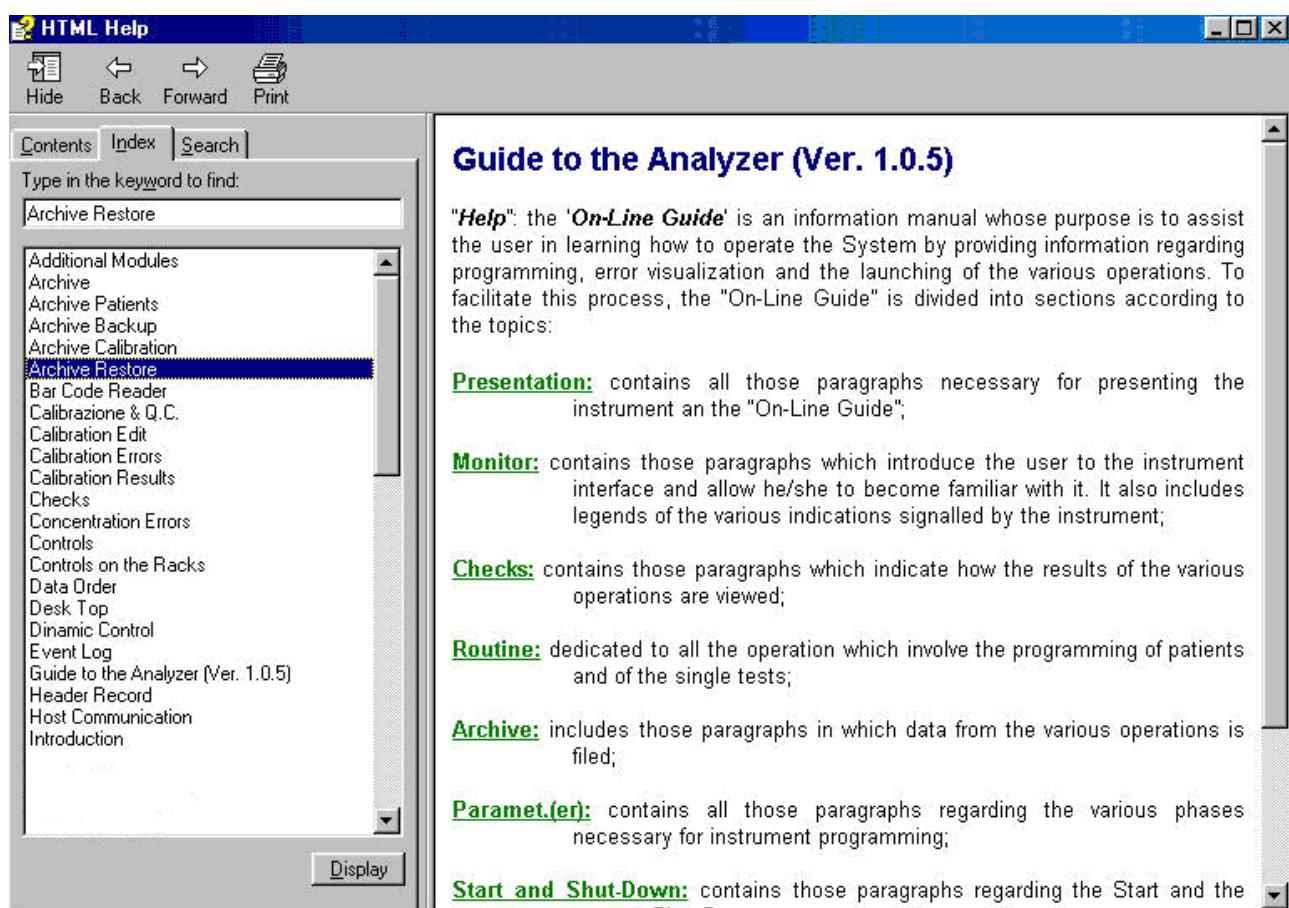
3.6 HELP



Help

This function allows the user to access the system's on-line Guide “*Help*”. Here, the operator can view the list of revisions regarding the installed software components.

GUIDE F1



To access the **Guide F1** mask, select "**Help**" from the Menu and then, from the options listed, click on **Guide F1**. The on-line "**Guide F1**" can also be accessed directly from any screen by pressing the F1 key on the keyboard.

This mask contains an information manual whose aim is to assist the user in learning how to operate the system. Individual topics can be selected by either clicking directly on the highlighted key words, or from the three tabs marked "**Contents**", "**Index**", "**Search**" – briefly explained as follows:

Contents: allows the user to view the contents of the guide;

Index: allows the user to view the index of the key words (please see the screen);

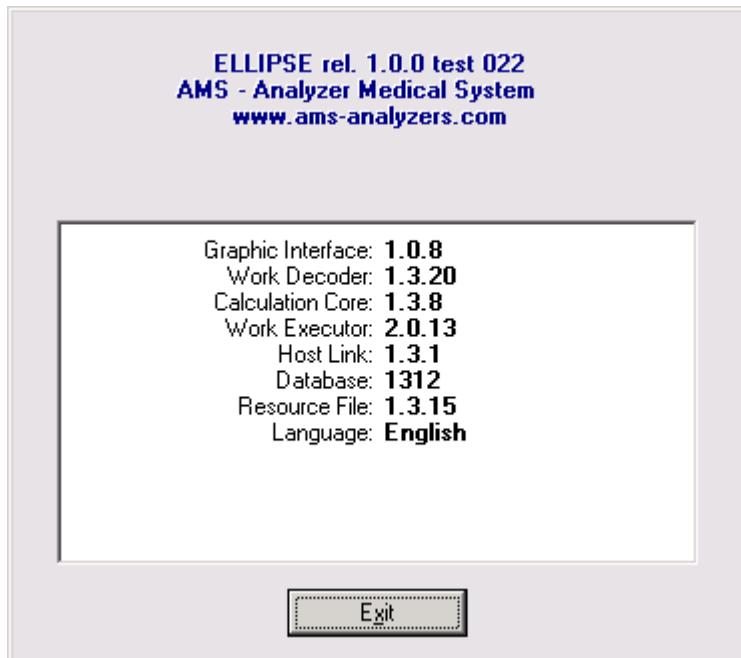
Search: presents another screen to be used for searching within the guide.

The window on the right-hand side of the screen allows the operator to view the text explaining the topic selected.

X

To exit the on-line **Guide F1** and return to the preceding screen, click on the "X" located in the upper, right-hand corner of the screen.

INFO SOFTWARE VERSIONS



To access the **Info** mask, select "**Help**" from the Menu and then, from the options listed, click on **Info**.

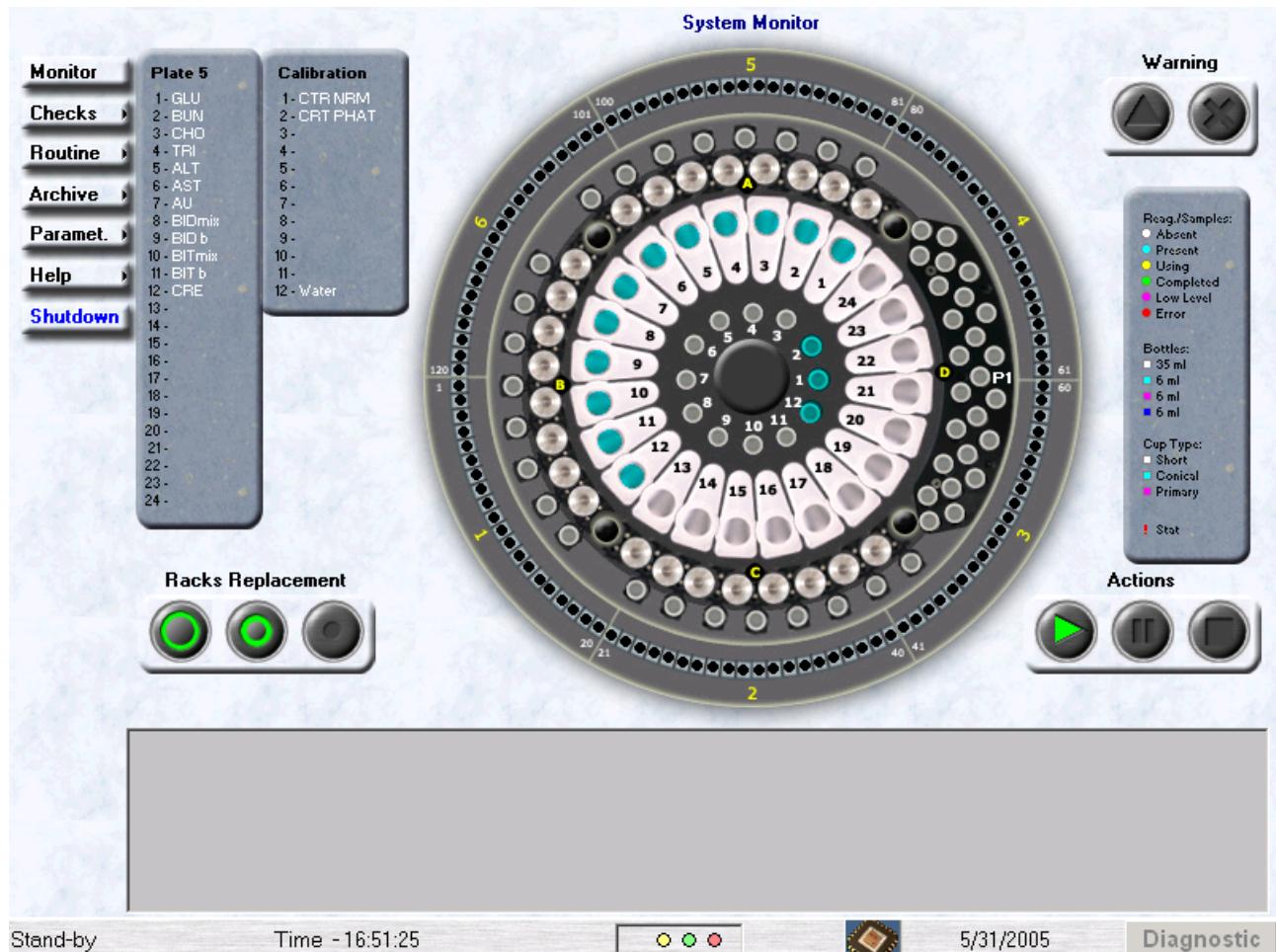
This window allows the user to view the list of the revisions of all the software components, that are installed in the system the operator is using.

Exit

EXIT

To close this window, exit the **Info** mask and return to the main mask, System Monitor, click on **Exit**.

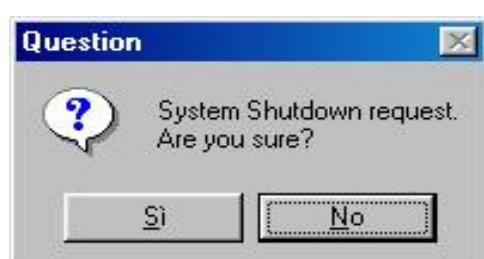
3.7 SHUT DOWN



Shutdown In order to exit the programme, the operator must first allow the instrument to complete all the still running operations (System in Stand By).

The “**Shut Down**” command that allows the user to close the programme and the software is located on the instrument **Desk Top**.

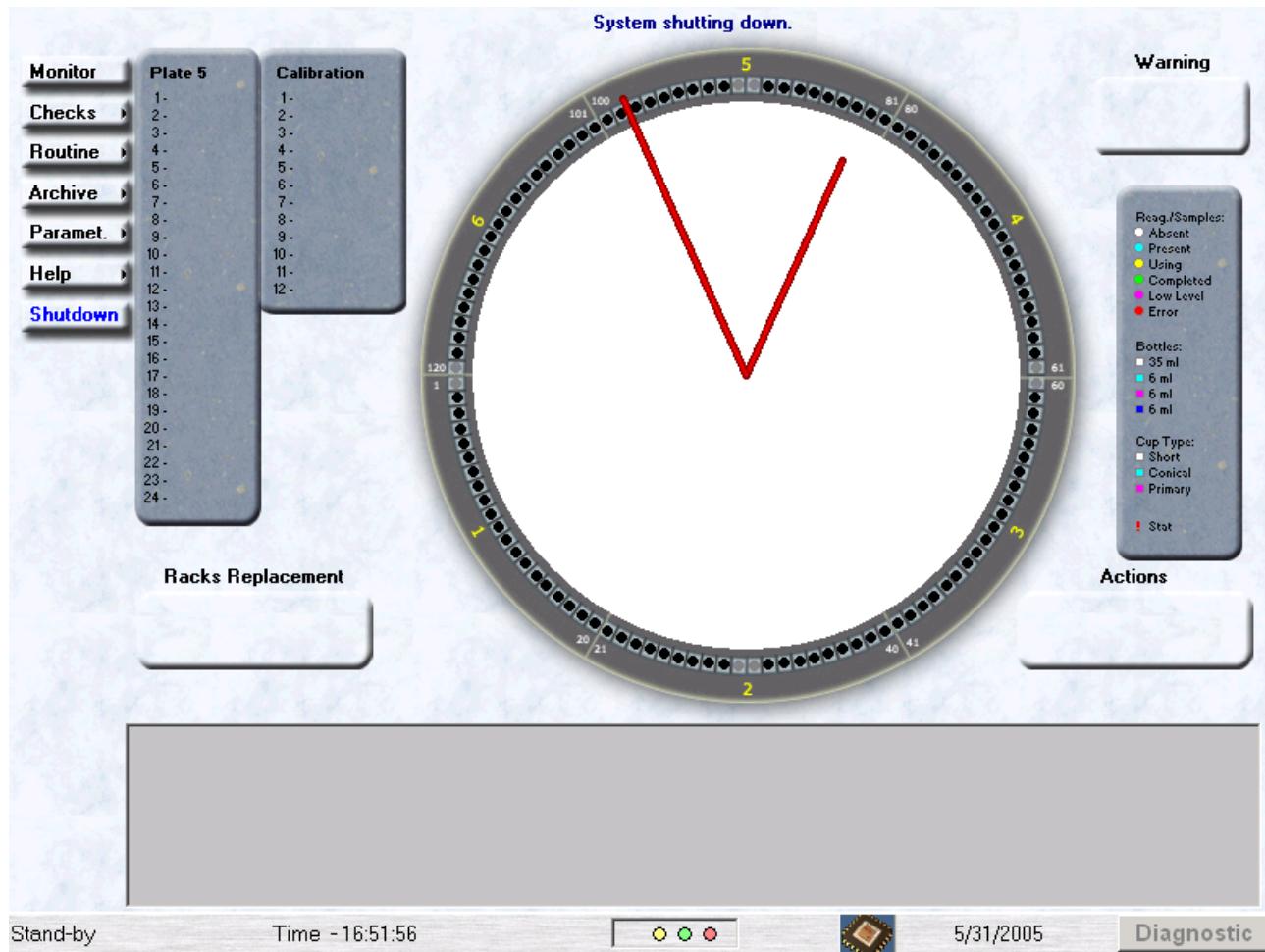
Clicking on this command causes the following visual text dialog box to appear after a few seconds:



Clicking on “**Yes**” will cause the programme to close and the system to shut down. The operation takes a few seconds. Conversely, clicking on “**No**”, will annul the request and no system shut down will occur.

Whenever the Shut Down procedure is launched, the Cuvette Plate normally viewed in the System Monitor window, will change into a **clock** figure (please see the illustration) whose hands move counter-clockwise, marking the closure of the programme.

Complete Shut Down will occur within a maximum of **four minutes**.



Once **Shut Down** is completed, the instrument can either be turned off or left on – in **stand-by** – ready to be reactivated for another work cycle.

During **Stand-by**, the instrument will maintain the following conditions:

- heating of the **Reaction Plate**;
- reduced power (voltage) to the photometer **Lamp**.

CHAPTER 04 – DAILY ROUTINE

INDICE

4.1	DAILY ROUTINE.....	2
4.2	STAND-BY FUNCTION.....	3

In this chapter the main operations are resumed for the correct execution of the analytical routine on the **Ellipse**.

4.1 DAILY ROUTINE

The operations listed below, have to be carried out in sequential order:

- ⇒ Switch on the analytical module of the ELLIPSE, the computer and the peripheral equipment (e.g. the printer)
- ⇒ Wait until the work-temperature has been reached and stabilized

In the mean time:

- ⇒ Control the liquid level in the bottles: H₂O distilled, Rinse and Cleaning Solutions
- ⇒ Control the liquid level in the waste bottles, empty them if necessary
- ⇒ If the ELLIPSE has remained unused for more than 24 hours (e.g. during the weekend), run a cuvette wash cycle by pressing the designated key in the "Start Work" mask
- ⇒ Run the "autozero" of the cuvette WBL(*Water Base Line*) by pressing the designated key in the "Start Work" mask
- ⇒ Verify the reagents configuration in the "System Monitor", if modifications need to be made, enter into the function, "Reagent Tray Configuration" (under the "Checks" menu)
- ⇒ Check reagent supply levels (See Reagent Volumes mask under the "Checks" menu)
- ⇒ Verify the correct positioning of the Standard and Controls
- ⇒ Verify the validity of the current calibration by running the controls. If necessary, carry out a new calibration in the program "Calibration & C.Q." (under the "Routine" menu).
- ⇒ Program the routine by introducing the patients data and the requested analysis (under the "WorkList" window)

OPERATIONAL:

- ⇒ Place the sample cup/tubes in the dedicated racks
- ⇒ Push the relevant button on the System monitor mask to loading the samples racks on the instrument
- ⇒ Click on **Start** key in the System Monitor screen (green arrow), then in the **Start Work mask**, active the "Work List" function by pressing the designated key
- ⇒ Run the routine by clicking the "OK" key in the "Start Work" window

- ⇒ Check the results (shown on the video); evaluate them and decide (if necessary), to request the re-run or edit of a specific analysis
- ⇒ Transmit the results to the Host Computer (if the ELLIPSE is integrated into the Laboratory Information System)
- ⇒ Print out the tests results
- ⇒ Transfer the completed samples into the archive
- ⇒ When the work has finished, click on the **Shutdown** key to exiting from the ELLIPSE program and switch off the Computer and Peripheral Equipment
- ⇒ Switch off the analytical module or leave it in Stand-by.
- ⇒ Always remove all the cups/tubes used and, if necessary, remove the reagent tray for refrigeration

On the following page the flow chart indicates the sequential operations that need to be done to insure that the daily routine will be carried out correctly.

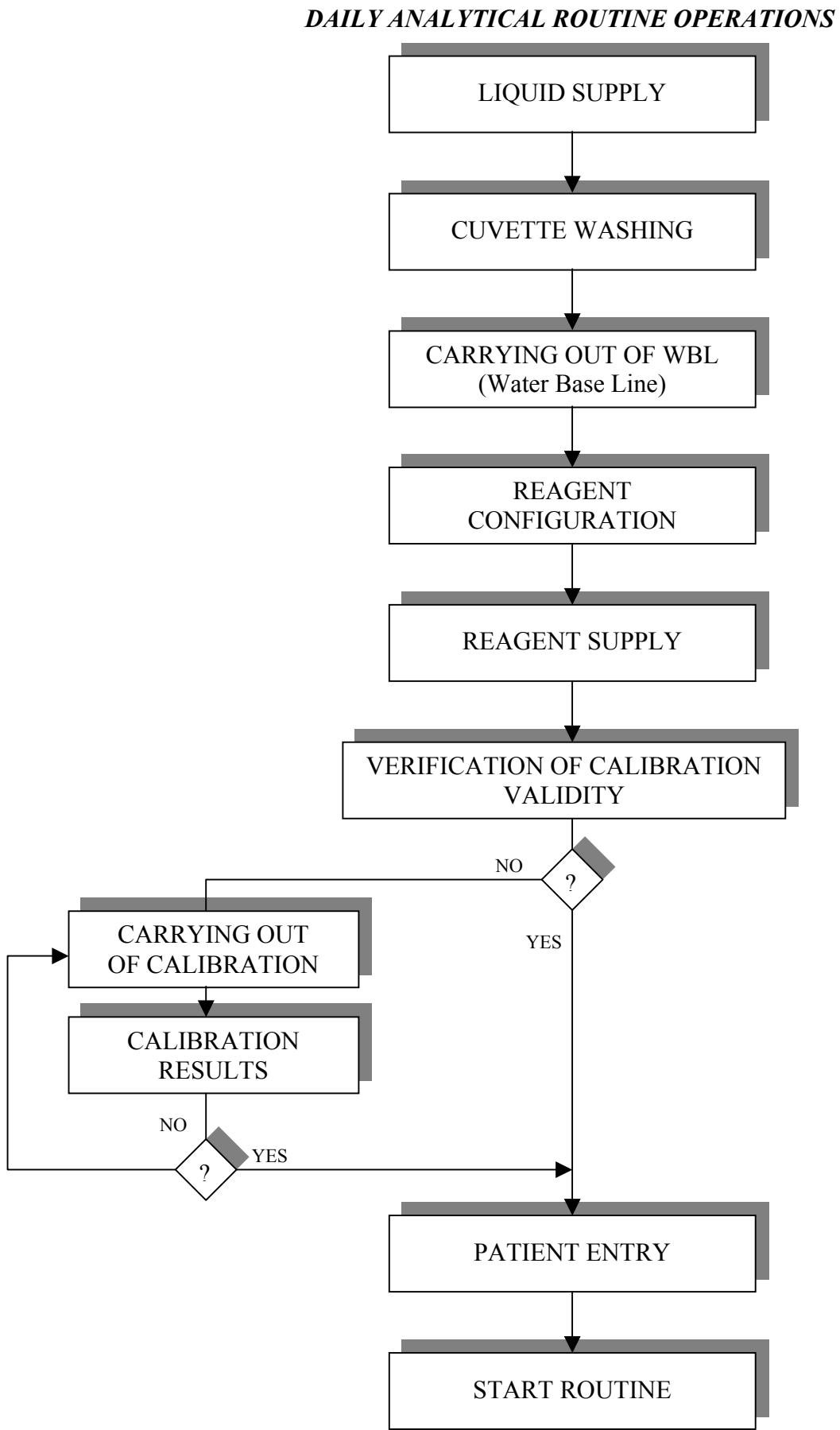
4.2 STAND-BY FUNCTION

In the eventuality that the laboratory needs to process the samples throughout the span of the entire day (small batches taken outside of the normal routine, Stat, etc.), it is opportune to keep the system in a "Stand-by" condition. This condition reduces the time required for the reaction plate temperature stabilisation after the switching off and the switching on of the Analyzer.

During Stand-by, the main functions of the instrument are kept active (temperature of reaction plate, low voltage supply of the photometric lamp). Thus, immediate process of samples that have arrived unexpectedly, is possible.

The instrument enters the Stand-by status when:

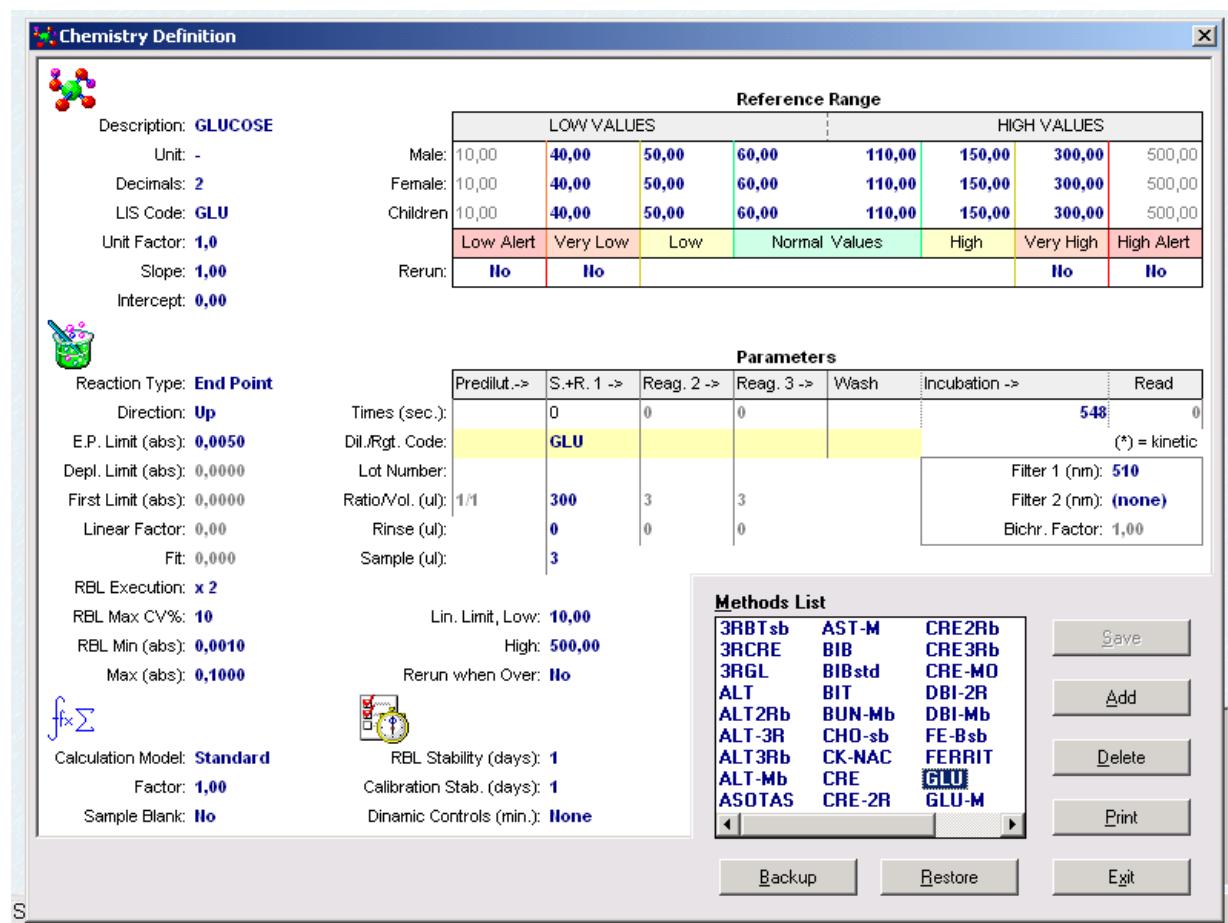
- the analytical module is switched on but the computer is switched off
- the analytical module and the computer are still switched on, but the ELLIPSE program is closed.



CHAPTER 05 - METHODOLOGY

INDICE

❖	REFERENCE RANGE.....	3
❖	REACTION PARAMETERS	4
❖	MEASURE PARAMETERS	6



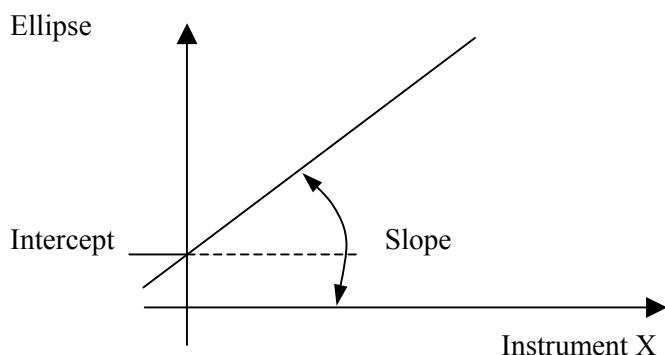
This function enables the user to define the methodology parameters to be used for test execution. It is possible to memorize an unlimited number of methods.

The window displays a series of parameters divided in the following three areas:

(top left side)

- **Description** = Test's long name
- **Unit** = Choose unit of measure (mg/dl, U/l, ...)
- **Decimals** = Number of decimal places expressed in the results and patient report. Selection can be done by positioning the mouse in the field and choosing from 0 to 3 inside the pull down menu showed
- **Lis Code** = Laboratory Information System; communication code used between the instrument and the Host Computer. (This code applies only if the instrument has been inserted in the Laboratory Information System).
- **Unit Factor** = conversion factor for the unit of measure
- **Slope** = default value imposed at 1
- **Intercept** = default value imposed at 0

NOTE: the values of Slope and Intercept permit the user to establish a correlation between instruments and/or different methods. To evaluate the correlation between different instruments, it is necessary to calculate the linear regression.



(top right)

REFERENCE RANGE

- **Low Values** = Lower range reference values differentiated for men, women and children. Each patient category gives three values defined according to the parameters set for the normal values: Low Alert, Very Low, Low.
- **Normal Values** = Normal range reference values differentiated for men, women and children.
- **High Values** = Upper range reference values differentiated for men, women and children. Each patient category gives three values defined according to the parameters set for the normal values: High, Very High, High Alert.
- **Rerun** = Option to repeat test automatically with indications given regarding any eventually requested sample dilutions or increase. The dilution or increase ratios are differentiated according to the value field for which the rerun was requested; Furthermore, any anomaly found regarding congruity between the imposed serum/urine volume and the separated part that is to be sampled (based upon the dilution ratio requested) will be flagged. (For example, 3 µl of the sample cannot be divided by five because there is not enough sample material).
The Rerun option requires the automatic repetition of the tests whose results are out of the Normal Values range.

(on the center left)

REACTION PARAMETERS

- **Reaction Type** = Defines the type of calculation (End Point, Fixed Time, Kinetic, Differentiated)
- **Direction** = Defines the direction of the reaction: (assorbancy increment = direction Up) or (absorbancy decrease = direction Down). If the user does not want this control, he should select the option “None”.
- **E.P. Limit (abs)** = The value placed in this field indicates the limit, expressed in absorbancy, within which the reaction is considered stable (See Chapter 08). If the value is equal to or higher than the limit, it will automatically be flagged. This specific parameter is applicable only when using the “End Point” methodologies.
- **Depl. Limit (abs)** = Absorbancy limit below or above which, (according to the direction of the reaction), no reaction must go. Indicates exhaustion of the substrate. Such situation will automatically be flagged. This specific parameter is applicable only when using the “Kinetics and Initial Rate” methodologies.
- **First Limit (abs)** = This function checks the reaction stability (see Chap. 08). If the check has a negative result, the test will be flagged. This specific parameter is applicable only when using the “Fixed Time” methodologies.
- **Linear Factor** = This value regards a check on the stability of the “First Limit” reactions. This specific parameter:
 - is applicable only when using the “Initial Rate” methodologies
 - depends on the reading time
 - is statistically calculated
- **Fit** = The value introduced into this field indicate the limit of variation of the reading points compared to the calculated regression line, and within which the reaction is considered stable. If the value is outside of this parameter, even by only one reading point, it will be flagged. This specific parameter is applicable only when using the “Kinetics” methodologies.
- **RBL Execution:** = This field permits to define RBL request, from 0 (never) to 4

- **RBL Max CV %:** = The value introduced into this field indicate the maximum acceptable coefficient of variation percentage (**CV%**) among the replicates.
- **RBL Min – Max (abs)** = Minimum and maximum values inserted for the RBL (central right)
- **Predilution** = This column of the chart indicates the diluent used, the Lot Number and the requested predilution ratio (The following ratios are possible: 1:1 – 1:2 – 1:3 – 1:4 – 1:5 – 1:10 – 1:15 – 1:20 – 1:25).
- **S+R1** = This column of the chart shows the reagent code that has been used, the batch number, the reagent, rinse and sample volumes expressed in μl .
The Rinse solution is aspirated in order to rinse the tube (see Chapter 02) before the reagent aspiration. The Rinse solution is not dispensed in the reaction cuvette.
- **Reag.2** = This column of the chart shows, for those methods that require a second reagent, the 2nd reagent's addition time, code, batch number, and the volume required expressed in μl .
- **Reag.3** = same conditions that apply to Reagent 2 (see above)
- **Wash** = This column of the chart shows the washing solution code that has been used. The Washing solution is aspirated in order to further rinse the probe before the reagent aspiration.
- **Incubation** = Incubation time given in seconds, starting from the moment of the last reagent's addition (1°, 2° or 3° reagent, depending on which method is used).
- **Read** = The total time needed to perform the reading; it is expressed in seconds. For kinetics methods, the reading time must be selected inside the pull-down menu from the timing reporting the symbol (*); the readings start from time T_0 that coincides with that of adding the reagent R1 and the sample in the reaction cuvette; the next readings are taken after the incubation period and are repeated every 13, 26, 39, 52 or 65 seconds with relation to the relevant selection (see table nr 1 in the chapter 08 – Formulas and calculation models). The End point methods reading coincides with the end of the Incubation period, and therefore a zero value appears in the Read field.

- **Filter 1 (nm)** = Primary filter; the following filters are available: 340 – 380 – 405 – 492 – 510 – 546 – 578 – 620
- **Filter 2 (nm)** = Secondary filters; The choices are the same as those given above.
- **Bichr. Factor** = Bichromatic Factor; allows the user to correlate the sample absorbancy read with the secondary filter (Filter 2) to the primary filter (Filter 1).

(on the lower left)

MEASURE PARAMETERS

- **Measure Model** = method's mathematic calculation model being executed (Factor, Standard, Point to Point, Quadratic, Cubic, Quadratic 5 Points, Reverse Cubic, Log Logit 2 parameters, Log Logit 3 parameters)
- **Factor** = Calibration factor
- **Sample blank** = This selection permits to the system to subtract the absorbance value of the sample (matrix effect).
This specific parameter is applicable only when using the "End Point" methodologies.
- **Lin. Limit low** = The lower limit for reagent linearity, expressed in concentration. This value is reported in the Low Alert field of the chart "Reference Range" (the table located at the top right).
- **High** = The upper limit for reagent linearity, expressed in concentration. This value is reported in the High Alert field of the chart "Reference Range" (the table located at the top right).
- **Rerun when Over** = Option to repeat the test if the results are out of the linearity limits (if the results are superior to the High value). The dilution ratio is selected by using the menu options available when the user places the mouse on the field; it is possible to choose one of the following ratios: 1:1 – 1:2 – 1:3 – 1:4 – 1:5 – 1:10 – 1:15.
- **RBL stability (days)** = Instrument's Reagent stability, expressed in days. In other words, it is the number of days that the RBL is considered valid. After this period of time, the instrument indicates that it is necessary to perform a new RBL, highlighting in red the date that the RBL has expired.

- **Calibr. stability (days)** = The number of days that the calibration is considered valid. After this period of time, the instrument indicates that it is necessary to perform a new calibration, highlighting in red the date that the calibration has expired.
- **Dynamic Controls (min)** = A request to perform quality control during the routine analysis, at specified time intervals (of 15 minutes and multiples of 15 minutes); It is possible to position the control bottle in a free position of the reagent rack because this operation requires a higher consumption of the controls compared to the normal calibration operations.

(on the bottom right)

- **Method List** = Lists the configurated methods; By choosing a method the corresponding parameters automatically appear.
- **Save** = Saves the method and visualized parameters; This button is pushed to either confirm the changes made, or after the initial programming has been done.
- **Add** = Used to insert a new method.
 ⇒ A new window “New Test” requests the user to insert the name of the new test (from 1 to 6 characters max)
 ⇒ push OK
 ⇒ insert the parameters
 ⇒ push Save
- **Delete** = deletes the visualized methods. The user is asked to confirm the execution of the Delete command before continuing.
- **Print** = Prints the page with the parameters of the selected method.
- **Backup** = Used to copy all the methods on the floppy disk
- **Restore** = Used to restore all the methods from the floppy disk
- **Exit** = Returns to System Monitor.

For each selected Method, the disabled fields are highlighted opaque gray. The values of the enabled fields are given in black figures.

CHAPTER 06 – CALIBRATION CURVES

INDICE

6.1	CALIBRATION CURVE	3
6.2	EXAMPLE OF HOW TO PREPARE A CURVE.....	5

Multipoint calibration is used for all non-linear type methods.

Multipoint calibration requires the carrying out of more than one standard; each standard is one point on the calibration curve (for a maximum of 8 points).

As far as the calibration curve itself is concerned, it is necessary to further distinguish whether or not the method, in addition to being non-linear, requires a predilution of the sample (please see Methods Parameters) and if the standard is a **Master Standard**.

➤ Method requiring Predilution

If the considered method does require predilution, then the following situations are possible:

Ready-to-Use Calibration curve (Calibrators), diluted-type.

Master Standard field not selected and Predilution field selected:

All of the points of the calibration curve are available in the calibration rack (or rather, the same number of cups of **diluted** standard are available and loaded as there are points on the calibration curve).

The instrument treats the standards differently from the samples. In fact, in order to carry out the standard, it does not dilute the standard, as setup in the method, as the standard is already diluted. The system then performs the calibration test on the available points.

Ready-to-Use Calibration curve (Calibrators), undiluted-type.

Master Standard and Predilution field not selected:

All of the points of the calibration curve are available in the calibration rack (or rather, the same number of cups of **undiluted** standard are available and loaded as there are points on the calibration curve). The instrument treats the standards as if they were samples and carries out the dilution of the standard in a predilution cup according to the dilution ratio of that method. It prepares as many cups of pre-diluted standard as there are calibration points setup in the programming of that standard and then goes on to carry out the calibration test on the points prepared.

Master Standard – Undiluted

Master Standard and Predilution field selected:

Only the cup containing the Master Standard is available in the calibration rack. The system prepares the individual points of the calibration curve, starting from the Master Standard.

The instrument itself does the preparation and, after having determined the single points of the calibration curve in the predilution rack, in accordance with the concentration percentage setup in the programming of the standard, with the exception of any eventual 0% and/or 100% concentration, and then goes on to carry out the calibration test on the points prepared.

The instrument treats the standards differently from the samples

Master Standard – Undiluted**Master Standard field selected and Predilution field not selected:**

Only the cup containing the Master Standard is available in the calibration rack. The system prepares the individual points of the calibration curve, starting from the Master Standard. The instrument itself does the preparation and, after having determined the single points of the calibration curve in the predilution rack, in accordance with the concentration percentage setup in the programming of the standard and with the dilution ratio of the method, it then goes on to carry out the calibration test on the prepared points.

The instrument treats the standards as if they were samples.

This type of preparation is defined as **OPTIMIZED**, in so far as it makes it possible to use a minimum quantity of the Master Standard.

6.1 CALIBRATION CURVE

Immunoturbidimetric methods require multiple-point type calibration because the reaction curves are not linear and do not respect “*Lambert and Beer’s*” law .

The types of reactions used are: END POINT, FIXED TIME and KINETIC (mono and bi-reagent).

The relationship between the concentrations of the standards and the optical density readings is not linear and, therefore, must be resolved using the following mathematical algorithms:

POINT TO POINT $Y = bX + a$

SQUARED $Y = cX^2 + bX + a$

SQUARED - HAVING
5 COEFFICIENTS $Y = eX^4 + dX^3 + cX^2 + bX + a$

CUBIC $Y = dX^3 + cX^2 + bX + a$

INVERSE CUBIC $1/Y = d(1/X)^3 + c(1/X)^2 + b(1/X) + a$

LINEAR LOG LOGIT $\log Y = b \log |X / (K - X)| + a$

CUBIC LOG LOGIT $\log Y = d \log^3 |X/(K - X)| + c \log^2 |X/(K - X)| + b \log |X/(K - X)| + a$

Where:

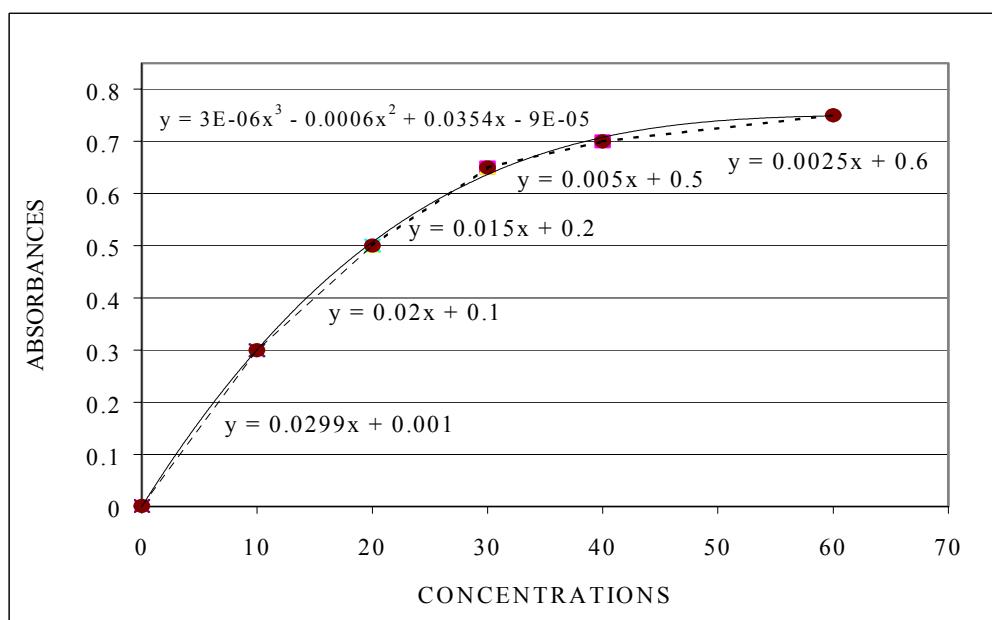
a, b, c, d, e	represent the coefficients of the curve
Y	represents the concentration of the standard
X	represents the optical density of the standard
K	represents the optical density of the standard at 0 concentration

➤ POINT TO POINT

$$(Y = bX + a)$$

This type of calculation algorithm does not make it possible to have a true calibration curve, but rather a series of straight lines which unite the various points representing the concentration of the standards. In fact, the above equation represents a straight line passing between two (standard) concentrations, having its own angular co-efficient (b) and intercept (a).

The example below clearly illustrates the differences between a Point to Point mathematical solution and a cubic calculation model.

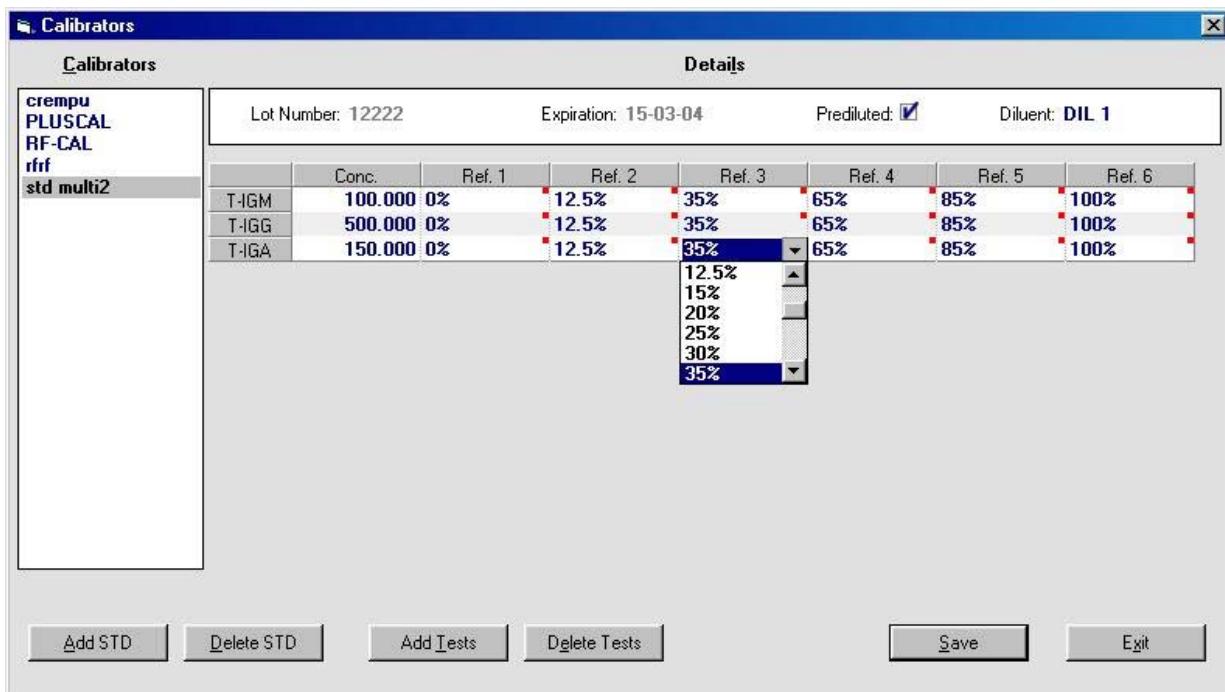


The equation to the third degree (here represented by the continuous line) makes it possible to create a true calibration curve, in so far as it is the most accurate interpolation among the calibration points.

The other equation (here represented by the dotted line) expresses the linearization of two adjacent standards. In fact, each straight line has its own angular co-efficient and intercept.

6.2 EXAMPLE OF HOW TO PREPARE A CURVE

In order to prepare a calibration curve, the operator must first select “Standard” from the “Parameters” menu.

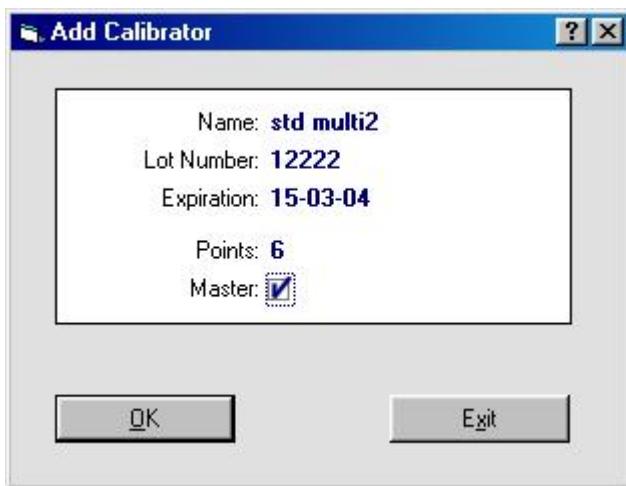


If the required standard is not included in the list of calibrators, proceed as follows in order to setup a new calibrator on the instrument:

⇒ press “**Add STD**”

⇒ insert in the window that opens (see below): the name of the calibrator to be added; the number of calibration points (maximum eight); and, where applicable, indicate whether or not it is a Master Standard.

IMPORTANT! The Lot Number and the expiration date are required data. They MUST necessarily be inserted in this window.

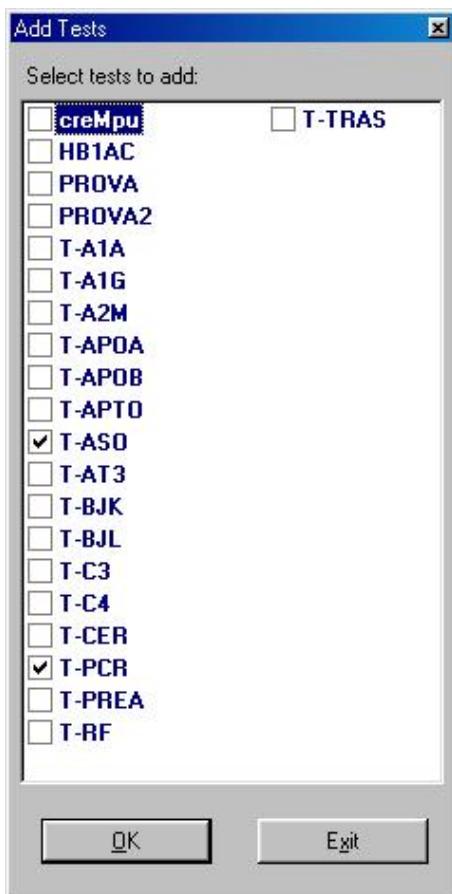


- ⇒ press OK to return to the previous screen
- ⇒ select the **Predilution** option, if needed (please see above-given indications)

IMPORTANT! The name of the diluent **must** be indicated always for Standard Master, whether the **Predilution** field is optioned, or not.

The diluent of the calibrator can either be the same one used to dilute the samples (i.e. coincides with that indicated in the method) or it can be a different one. If it is the same, the diluent will be assigned to a position in the reagents rack during the reagents configuration programming phase; if it is different, the instrument software will assign, the last free position available on the reagent rack and its name will appear in “**System Monitor**”, but only when calibration is requested.

- ⇒ press “**Add Tests**” to select those tests to be calibrated using that standard



- ⇒ select the tests to be added and press **OK**
- ⇒ insert the concentration value of the standard (reference value) in the “Conc.” field

Calibrators

Calibrators **Details**

crempu	Lot Number: 12222	Expiration: 15-03-04	Prediluted: <input checked="" type="checkbox"/>	Diluent: DIL 1			
PLUSCAL	Conc.	Ref. 1	Ref. 2	Ref. 3	Ref. 4	Ref. 5	Ref. 6
RF-CAL	100.000	0%	12.5%	35%	65%	85%	100%
rif	500.000	0%	12.5%	35%	65%	85%	100%
std multi2	150.000	0%	12.5%	35%	65%	85%	100%

12.5%
15%
20%
25%
30%
35%

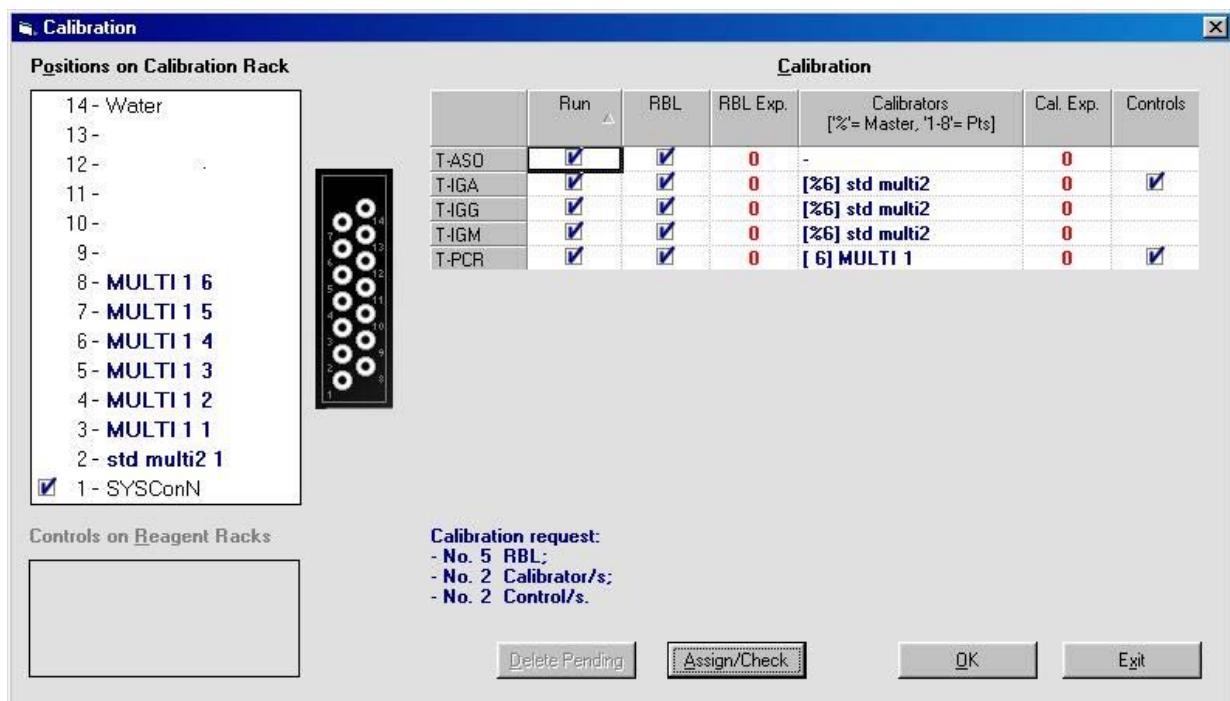
Add STD **Delete STD** **Add Tests** **Delete Tests** **Save** **Exit**

- ⇒ define the concentration percentages for each single point of the curve by selecting from among the available percentages listed in the **Ref.** field column. The values given in concentration and corresponding to the percentages defined can be viewed by positioning the mouse over the red dot inside the “**Ref**” field window.

N.B.: the percentages inserted must be in either increasing or decreasing order.

If the Calibration Curve is of the Ready-to-Use type (pre-prepared standards for the various points), the operator must insert in the “**Ref**” field, the concentration value of the standards.

- ⇒ Once the programming has been completed, press “**Save**” and then “**Exit**”



- ⇒ Access the “**Calibration and Q. C.**” function from the “**Routine**” menu
- ⇒ Request calibration and then press “**Assign/Check**”
- ⇒ Position the Standards and the Controls following the indications as shown on the screen (See the above-illustrated window. Please note that further, more detailed information is available under the **Reagents Volume** function which can be found in the **Preparation** menu)
- ⇒ Press “**OK**”
- ⇒ Press “**Start Work**” (green button) under “System Monitor”
- ⇒ After having placed the Reagent(s), Diluent(s), and the predilution cups in their respective positions, select calibration under the “**Start Work**” window and then press OK.

CHAPTER 07

- MAINTENANCE -

INDEX

7.	MAINTENANCE.....	2
7.1	PREVENTIVE MAINTENANCE.....	2
7.2	LIST OF PARTS SUBJECT TO WEAR AND USAGE.....	4
7.3	SAMPLING PROBE - CLEANING PROCEDURE.....	5
7.4	WASH STATION CANNULAS - CLEANING PROCEDURE.....	5
7.5	WASH SOLUTION BOTTLES - CLEANING.....	6
7.5.1	WASH SOLUTION BOTTLES - CLEANING PROCEDURE.....	6
7.6	TIP WASHING	7
7.6.1	TIP - CLEANING PROCEDURE.....	7
7.6.2	PROCEDURE FOR REPLACING THE TIP.....	9
7.7	HYDRAULIC CIRCUIT WASHING	10
7.7.1	HYDRAULIC CIRCUIT - CLEANING PROCEDURE.....	10
7.8	CHANGING THE PERISTALTIC PUMP TUBES.....	11
7.8.1	PROCEDURE FOR REPLACING THE PERISTALTIC PUMP TUBES.....	11
7.9	CHANGING THE PHOTOMETER LAMP.....	12
7.9.1	PROCEDURE FOR REPLACING THE PHOTOMETER LAMP.....	12
7.10	CHANGING THE REACTION CUVETTES.....	13
7.10.1	PROCEDURE FOR REPLACING THE REACTION CUVETTES.....	13
7.11	CHANGING THE TUBES KIT.....	15
7.11.1	PROCEDURE FOR REPLACING THE TUBES KIT.....	15
7.12	TABLE C – LIST OF THOSE MAINTENANCE PROCEDURES THAT CAN BE PERFORMED BY THE USER AND/OR BY THE MAINTENANCE TECHNICIAN.....	16
7.13	DECONTAMINATION PROCEDURE.....	18

7 MAINTENANCE

This chapter contains all those routine operations, which concern instrument maintenance. Said procedures, listed and described below, should be carefully and scrupulously followed in order to guarantee the manufacturer's specifications and the perfect working order of the instrument over time.

7.1 PREVENTIVE MAINTENANCE

MAINTENANCE SCHEDULE

Table A, illustrated below, lists all those procedures to be carried out by the user/operator and the relative frequency schedule. Strict adherence to said schedule will guarantee the optimal operative efficiency of the instrument.

TABLE A – MAINTENANCE SCHEDULE

FREQUENCY	PROCEDURE	NOTES
DAILY – Before launching “Start Work”	Check the levels of all the wash solutions (Rinse, Water and Cleaning)	See Table B
DAILY – Before launching “Start Work”	Check the levels of Reagents, Standards and Controls	See Table B
DAILY – Before launching “Start Work”	Check the levels of the Waste Bottles and, if necessary, empty them	
DAILY – Before launching “Start Work”	Carry out a WBL cycle	See the User’s Manual, Chapter 03– Description of Instrument Software
DAILY – After Shutdown	Clean the Sampling Probe using either paper towelling or gauze	See Procedure 7.3

TABLE B – MAINTENANCE SCHEDULE

FREQUENCY	PROCEDURE	NOTES
EVERY TWO WEEKS	Clean the Wash Station's four cannulas	See Procedure 7.4
EVERY TWO WEEKS	Clean the wash solution bottles (Rinse, Water and Cleaning)	See Procedure 7.5
ONCE A MONTH	Clean the Tip	See Procedure 7.6
ONCE A MONTH	Clean the Hydraulic Circuit	See Procedure 7.7
EVERY THREE MONTHS	Change the Reaction Cuvettes	See Procedure 7.10
EVERY SIX MONTHS	Change the Peristaltic Pump Tubes	See Procedure 7.8
EVERY SIX MONTHS	Change the Tip	See Procedure 7.6
ONCE A YEAR	Change all the tubes (Tube Kit)	See Procedure 7.11
EVERY 2000 HOURS	Change the Photometer lamp	See Procedure 7.9

- N. B.: the above-described maintenance schedule refers to that situation in which the workload of the *Analyzer* is approximately 500 tests per day. The interval frequency may vary according to the individual instrument's daily workload.

7.2 LIST OF PARTS SUBJECT TO WEAR AND USAGE

Description	Type	Quantity Pieces	Code
Reagents containers	35 ml	12	C101-00190-00
Reagents containers	6 ml	12	C101-00191-00
Samples cups	0.8 ml	1000	AS650002
Short samples cups	1 ml	1000	AS650100
Adapter for short samples cups		1	9-01-0609-00
Reaction sectors		6	C101-00217-00
Washing solution bottle	2 lt	1	9-35-0041-00
Bottle level sensor		1	9-05-0078-00
Tubing Kit for peristaltic pump		2	65-01835-00
Tubing Kit – complete		1	65-01836-00
Cleaning solution	250 ml	2	ASRN0020
Rinse solution	50 ml	1	ASRN0021
Sampling probe (internal needle)		1	05-00707-00
Complete Sampling probe		1	10-00703-00
Drying Pad		1	01-01920-00
Halogen Lamp (6 V - 10 W)		1	9-35-0016-00
Interferential filters Kit		1	9-65-0029-00
Fuse 6,3 A-T	5x20	10	C130-01238-08
Inlet/outlet fitting for Rinse & Clean conts		1	01-01224-00
Cuvettes protection cover		1	05-01249-00
Reagent protection cover		1	10-00584-00
Reagent plate		1	10-00585-00
Samples rack		1	05-01829-00
Washing station, first or second cannulas (A)		1	05-01633-00
Washing station, third cannula (B)		1	05-01633-01
Washing station, fourth cannula (C)		1	05-01638-00
Washing station, fifth cannula without pad (D)		1	05-01919-00
Diluter Micro-Pump		1	05-01710-40
Air Micro-Pump (μ P 6)		1	05-02454-20
Micro-Pump (μ P 2 ÷ 5)		1	05-01826-16
Solenoid Valve –2 way		1	9-35-0035-00
Solenoid Valve –3 way		1	9-35-0036-00

7.3 SAMPLING PROBE – CLEANING PROCEDURE

- 1) Turn off the *Analyzer*.
- 2) Use only lint-free paper towelling or gauze.
- 3) Dampen the gauze or paper towelling with distilled water and clean the outside of the sampling probe. Wipe the probe from the top downwards only! This is to avoid that any bits of cloth, paper or lint fibres accidentally enter the probe itself.
- 4) The manufacturer suggests that once weekly the above-described cleaning procedure be performed using, instead of only simple distilled water, a 5% sodium hypochlorite solution to dampen the gauze and then be repeated using distilled water.

7.4 WASH STATION CANNULAS – CLEANING PROCEDURE

- 1) Turn off the *Analyzer*.
- 2) Place a sheet of paper under the wash station cannulas in order to keep any extraneous material from accidentally falling into the cuvettes.
- 3) Use only lint-free paper towelling or gauze.
- 4) Dampen the gauze or paper towelling with distilled water and clean the outside of the cannulas. Wipe the cannulas from the top downwards only! This is to avoid that any bits of cloth, paper or lint fibres accidentally enter the cannulas themselves.
- 5) The manufacturer suggests that once weekly the above-described cleaning procedure be performed using, instead of only simple distilled water, a 5% sodium hypochlorite solution to dampen the gauze and then be repeated using distilled water.

7.5 WASH SOLUTION BOTTLES – CLEANING

During normal use and over time, mold and dust can build up inside the wash solution bottles. For this reason, it is extremely important that they be periodically washed. Said cleaning must be thorough and meticulous in order to insure that every trace of mold or residue be removed.

How often the bottles must be cleaned depends on their use and on the quality of the distilled water used in that particular laboratory. However, the manufacturer recommends thorough washing at least once every two weeks.

It is extremely important that the user not underestimate the risks associated with mold and dust particles. They are to be regarded as a serious hazard as they can be the cause of instrument malfunction.

The wash solution bottles are located on the right side of the analyzer.

7.5.1 WASH SOLUTION BOTTLES - CLEANING PROCEDURE

- 1) Turn off the *Analyzer*.
- 2) Pull the level sensor connectors out from the bottle caps.
- 3) Take the caps off the bottles and empty them.
- 4) Fill each bottle with a 5% sodium hypochlorite solution.
- 5) Clean the inside of each bottle using a bottlebrush in order to remove all traces of mold and/or residue.
- 6) Leave the sodium hypochlorite solution stand in the bottles for at least ten minutes.
- 7) Empty the bottles, rinse them repeatedly and well with tap water, and then twice more using distilled water.
- 8) Dry the bottles.
- 9) Fill the bottles with their proper solutions.
- 10) Replace the bottles in their respective housings.
- 11) Close the bottles and reconnect the level sensors.
- 12) Carry out two ‘Wash Cuvettes’ cycles and two ‘WBL’ cycles. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory’s quality control values.

7.6 TIP WASHING

The Tip is used to dry the cuvettes after they have been washed. This drying process is carried out via aspiration and therefore, over time, the Tip will necessarily absorb various contaminating particles. The manufacturer suggests that the Tip be replaced every six months. Said frequency may vary depending on the workload of the individual laboratory and the operating conditions/environment of the single instrument.

The Tip must be washed regularly in order to guarantee proper functioning and must be replaced with a new Tip as necessary.

7.6.1 TIP - CLEANING PROCEDURE

1. Turn off the *Analyzer*.
2. Unscrew the fastening screw and remove the Washing station protective cover (Fig. 1).
3. Remove the top cover of the washing station unscrewing the four fastening screws (Fig. 2).
4. Remove the cannula that contains the Tip (the 5th cannula) and the spring (Fig. 3).
5. Disconnect the aspiration tube (Fig. 4).
6. Once the cannula has been removed, immerse it in a 5% solution of sodium hypochlorite for at least 15 minutes (Fig. 5).
7. Attach a 10 ml syringe to the cannula and aspirate and dispense the hypochlorite solution through the cannula (and the Tip) until the latter is completely clean (Fig. 6). This aspirating and dispensing forces the liquid through the Tip fibers in both directions
8. Once the Tip is clean, repeat the aspirating and dispensing cycle 10 more times using distilled water, then disconnect the syringe.
9. Re-connect the aspiration tube to the cannula (Fig. 7).
10. Re-position the cannula in its housing being careful to not kink the aspiration tube
11. Re-position the spring on the cannula's cylindrical axel.
12. Re-position the top cover of the washing station, making sure that the cylindrical tops of the cannulas fit into the corresponding holes on it.
13. Manually move the wash station downwards and centre the tip with the cuvette turning it.
14. Remount the Washing station protective cover (Fig. 1).



Fig.1 Instrument Top view

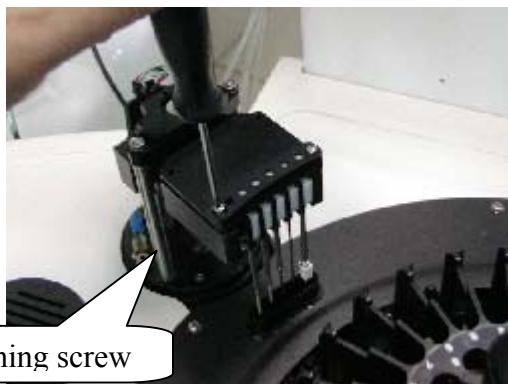


Fig. 2

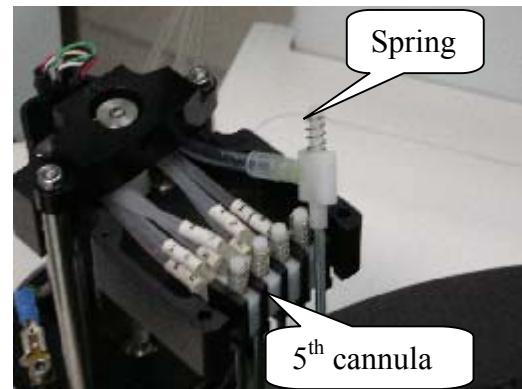


Fig. 3

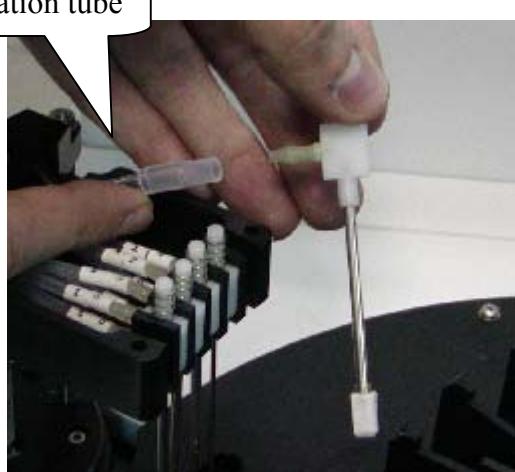


Fig. 4

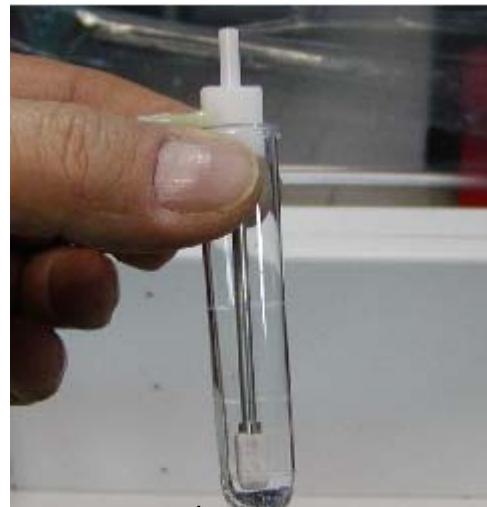


Fig. 5

Connect the syringe to the cannula

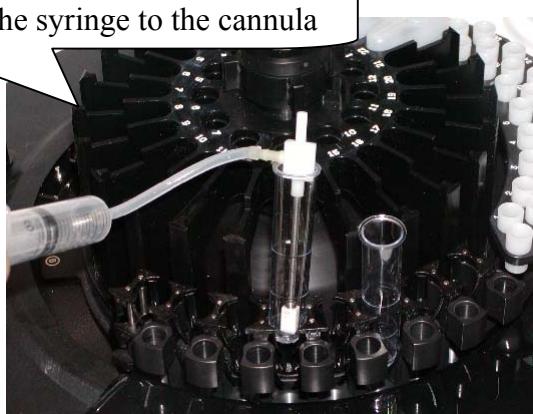


Fig. 6



Fig. 7

7.6.2 PROCEDURE FOR REPLACING THE TIP

1. Turn off the *Analyzer*.
2. Unscrew the fastening screw and remove the Washing station protective cover (Fig. 1).
3. Remove the top cover of the washing station unscrewing the four fastening screws (Fig. 2).
4. Remove the cannula that contains the Tip (the 5th cannula) and the spring (Fig. 3).
5. Disconnect the aspiration tube (Fig. 4), remove the used Tip and replace it with a new one. Press lightly to push the new Tip into place – be careful to not press too hard as this could deform the Tip (Fig. 8).
6. Insert the cannula containing the new Tip into a cuvette, pushing it down inside until it takes on the shape of the inside of the cuvette (Fig. 9).
7. Remove the cuvette, connect the aspiration tube to the cannula and reposition the cannula back into its proper housing in the wash station. Be careful to not kink the aspiration tube while doing so.
8. Reposition the spring in its proper housing. Remount the wash station coverlid making sure that the cylindrical tops of the cannulas fit into the corresponding holes on the wash station coverlid.
9. Manually move the wash station downwards and centre the tip with the cuvette turning it.
10. Remount the Washing station protective cover (Fig. 1).

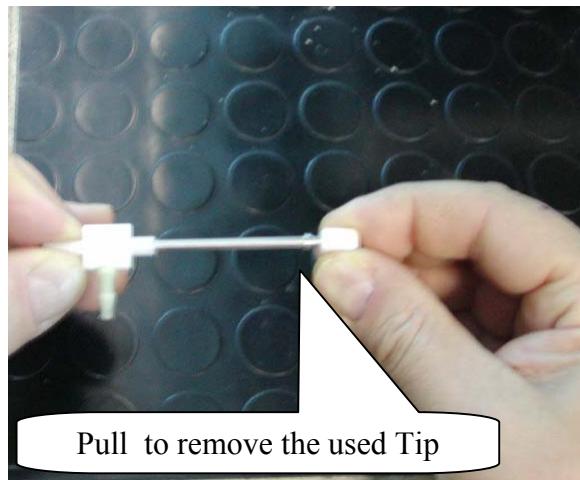


Fig. 8

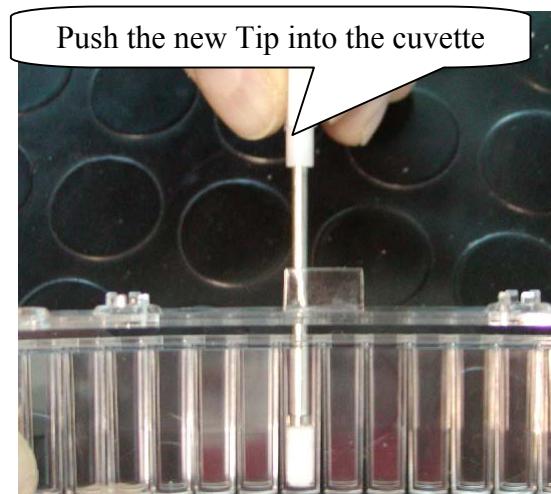


Fig. 9

7.7 HYDRAULIC CIRCUIT WASHING

During normal use and over time, mold and dust can build up inside the wash bottles and can have a negative effect on the hydraulic circuit, compromising the correct functioning of the micro-pump and valves. This, in turn, can lead to inefficiency in the sampling probe and cuvette washing system.

For this reason, it is extremely important that the hydraulic circuit be periodically washed. Said cleaning must be thorough and meticulous in order to assure that every trace of mold or residue be removed.

How often the hydraulic circuit must be washed depends on the operating conditions/environment of the single instrument and the quality of the distilled water used in that particular laboratory. The manufacturer recommends thorough washing at least once a month.

It is extremely important that the user not underestimate the risks associated with mold and dust particles. They are to be regarded as a serious hazard as they can be the cause of instrument malfunction.

The hydraulic circuit input cannulas are located inside the bottles on the left side of the *Analyzer*.

7.7.1 HYDRAULIC CIRCUIT - CLEANING PROCEDURE

- 1) Turn on the *Analyzer*.
- 2) Prepare a bottle containing 500 ml of a 5% sodium hypochlorite solution
- 3) Insert the four aspiration cannulas, located inside the liquids bottles, into the bottle containing the sodium hypochlorite solution.
- 4) Have the instrument carry out a 'WBL' cycle and then a 'Wash cuvettes' cycle.
- 5) Wait for fifteen minutes. Clean and dry the four cannulas and then insert them into a bottle containing distilled water.
- 6) Have the instrument carry out a 'WBL' cycle and then a 'Wash cuvettes' cycle.
- 7) Insert the four aspiration cannulas back into their respective bottles. Said bottles should have, in the meantime, been cleaned and filled with a fresh supply of the required solution.
- 8) Have the instrument carry out a 'WBL' cycle and then a 'Wash cuvettes' cycle. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory's quality control values.

7.8 CHANGING THE PERISTALTIC PUMP TUBES

The manufacturer recommends that the Peristaltic Pump tubes be replaced every six months. Said frequency may vary depending on the workload of the individual laboratory. The quality and reliability of these tubes is fundamental to a correct emptying of the cuvettes.

7.8.1 PROCEDURE FOR REPLACING THE PERISTALTIC PUMP TUBES

1. Open the panel located on the right side of the instrument pushing down the looking door (Fig. 1).
2. Unhook the hinged guide by pushing the pin toward to the left (Fig. 2).
3. Pull the tubes off their relative nipples and substitute with new ones (Fig. 2).
4. After having unhooked the hinged guide, disconnect the tubes from their nipples
5. Remount, repeating the above steps, 4 through 2, in reverse order. Turn clock wise the peristaltic pump rotor, in manual way, in order to be sure that tubes are right positioned inside the guide.

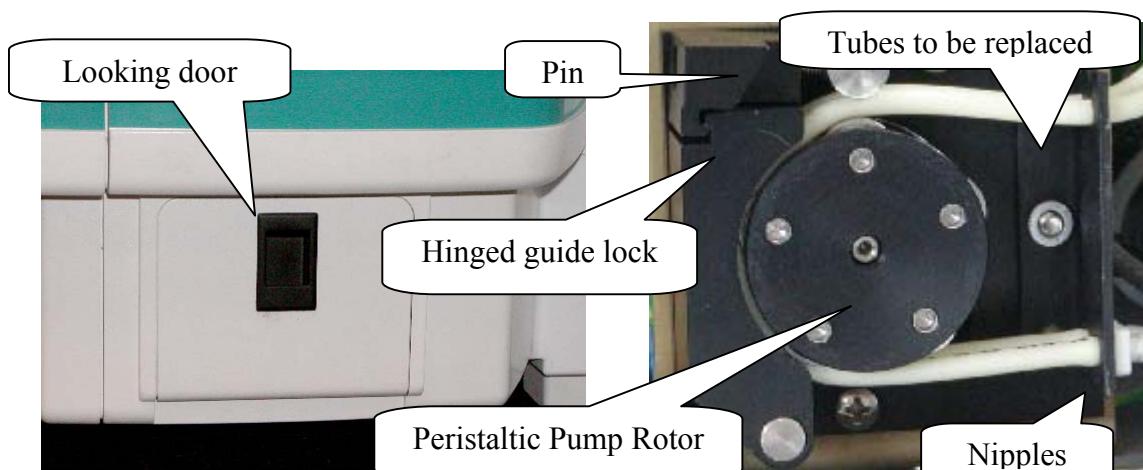


Fig. 1 Instrument right side

Fig. 2 Peristaltic Pump Assembly

6. Turn on the *Analyzer* and wait until the instrument has reached its proper operating temperature.
7. Have the instrument carry out a ‘Wash cuvettes’ cycle and then a ‘WBL’ cycle. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory’s quality control values.
8. Make sure that there is no leakage and then close back the panel.

- Always use original replacement parts; never lubricate the peristaltic pump roller bearings.
- After prolonged instrument inactivity: verify the efficiency of the peristaltic pump tubes.

Please note: if the instrument is not able to completely empty the washing well, check the condition of the tube and make sure that there are not obstruction into the hydraulic lines.

7.9 CHANGING THE PHOTOMETER LAMP

The manufacturer suggests that the lamp be replaced after approximately 2000 hours of use.

Figure 2 illustrates the photometer lamp, its support base and its power supply wires. There is a small hole on the lamp base useful for its mechanical alignment. The lamp is mounted on the photometer, which is located on the left-hand side of the reaction plate.

7.9.1 PROCEDURE FOR REPLACING THE PHOTOMETER LAMP

- 1) Turn off the *Analyzer*.
- 2) Remove the front panel unscrewing the four anchored screws (Fig. 1).
- 3) Disconnect the power supply wires from the Lamp Regulator Board by loosening the clamp screws on the M1 connector (Fig. 2).
- 4) Unscrew the lamp's fastening screw and remove the lamp from its housing (Fig. 2)
- 5) Replace the old lamp with a new one making sure that the pin is correctly inserted in the alignment hole (Fig. 2). Remount the assembly by repeating the above steps 4 through 1 in inverse order.
- 6) Turn the *Analyzer* on and wait until the instrument has reached its proper operating temperature.
- 7) Have the instrument carry out a 'WBL' cycle. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory's quality control values.

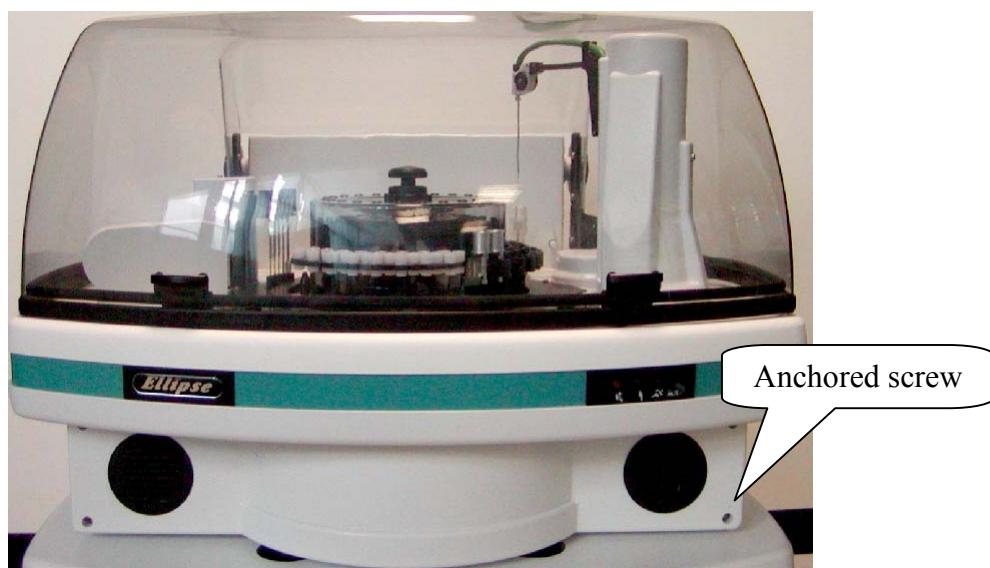


Fig. 1 Instrument front view

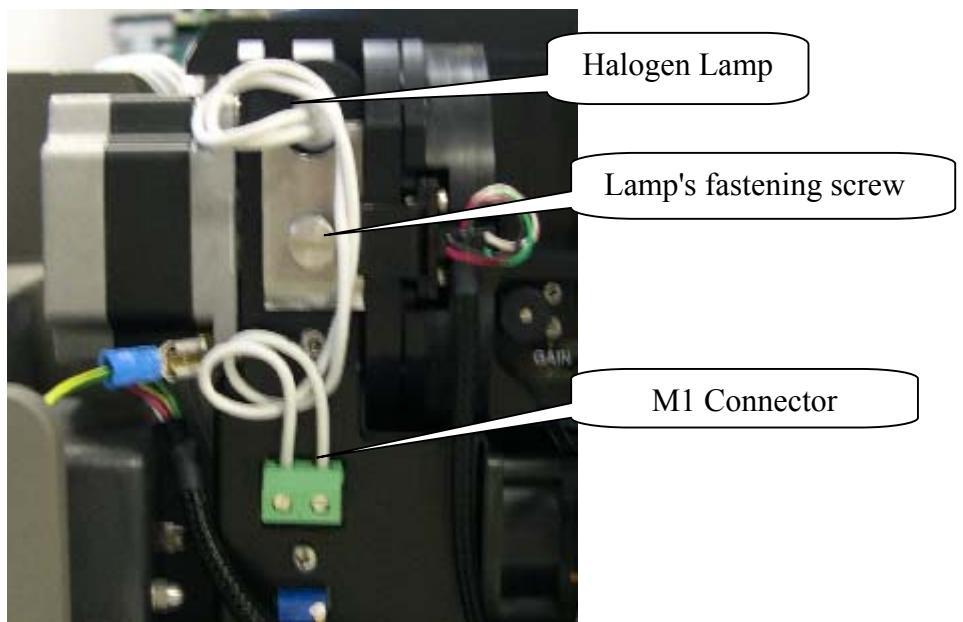


Fig. 2 Photometer

WARNING! DO NOT TOUCH THE GLASS PART OF THE LAMP WITH YOUR FINGERS!
 IF NECESSARY, USE A CLEAN CLOTH TO REMOVE DUST, OR ALCOHOL TO REMOVE MORE STUBBORN DIRT.

7.10 CHANGING THE REACTION CUVETTES

Over time and through normal use the perfect transparency of the cuvettes diminishes. This less-than-perfect transparency has a negative impact on the quality of the optical readings. The manufacturer suggests that the cuvettes be replaced after three months of use. The cuvettes racks are located inside the reaction plate.

7.10.1 PROCEDURE FOR REPLACING THE REACTION CUVETTES

1. Turn on the *Analyzer* and wait until the instrument has reached its proper operating temperature.
2. Click on the change cuvettes rack button , located under the work program (Please see Chapter 03 – Description of Instrument Software).
3. A pull-down menu will appear. Click on the rack number 1 and then on **OK**, in order to have the selected rack accessible (Fig. 1)

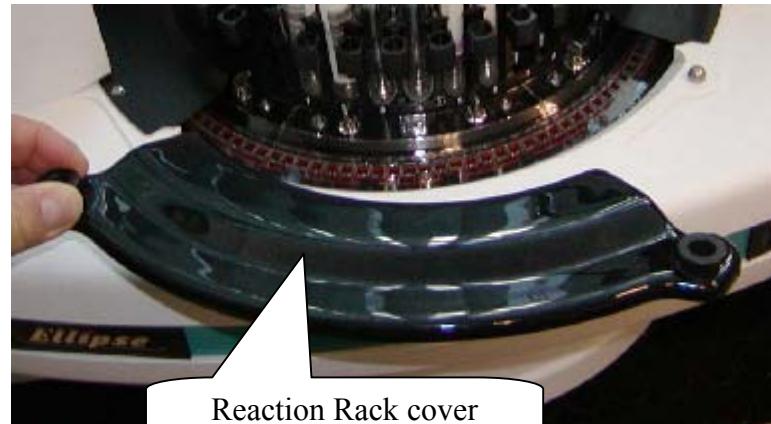


Fig. 1

4. Remove the reaction rack cover from its housing (Fig. 1).
5. Turn the two locking pins making free the reaction rack.
6. Remove the reaction rack from its housing and replace it with a new one (Fig. 2).
7. Make sure to reinsert the new rack **VERTICALLY**. Turn the two locking pins in order to fix the rack. **Be especially careful to not touch the external surface of the cuvettes dedicated to photometric reading.**
8. Repeat the procedure from point 2 to 7 in order to replace the reaction racks from 2 to 6.
9. Have the instrument carry out a 'WBL' cycle. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory's quality control values.

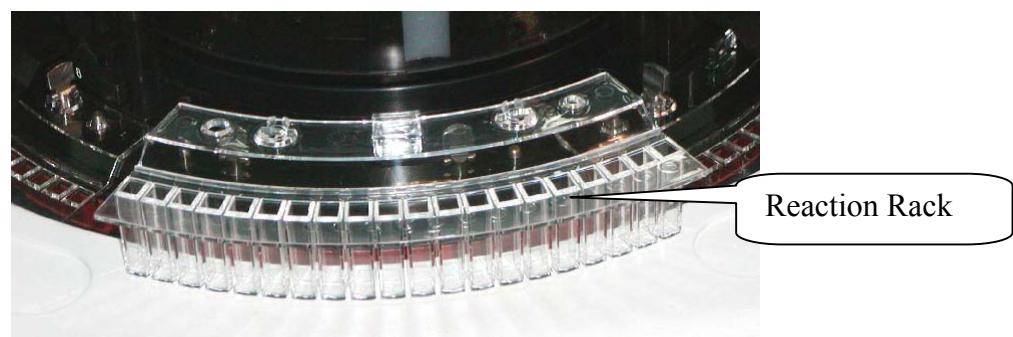


Fig. 2

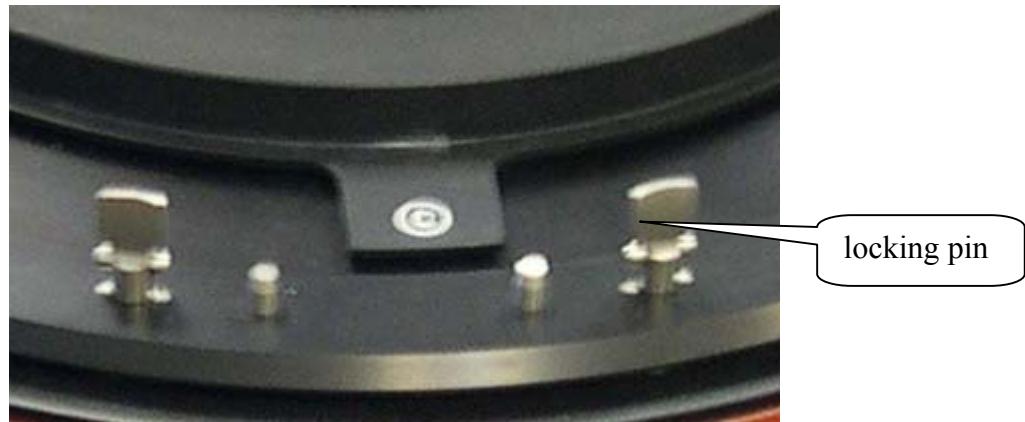


Fig. 3

7.11 CHANGING THE TUBES KIT

Over time and through normal use, the tubes become worn.

The manufacturer suggests that the tubes be replaced at least once a year. These tubes are located inside the instrument to link the Washing Station, the Peristaltic Pump and the Washing Well to the Washing Pump Assembly.

7.11.1 PROCEDURE FOR REPLACING THE TUBES KIT

1. Turn off the *Analyzer*.
2. Unscrew the four screws to remove the panel located on the rear side of the instrument to access the washing pump assembly (Fig. 1 and Fig 2).
3. Replace the tubes following the indications provided in the hydraulic diagram (SI-00571-01).
4. Turn on the *Analyzer* and wait until the instrument has reached its proper operating temperature.
5. Have the instrument carry out a ‘Wash cuvettes’ cycle and then a ‘WBL’ cycle. Make sure that there is no leakage.
6. Check system efficiency by comparing the WBL values and the test results obtained against the laboratory’s quality control values.

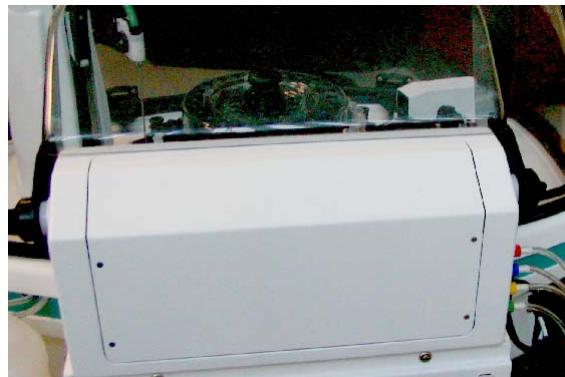


Fig. 1 Instrument rear view

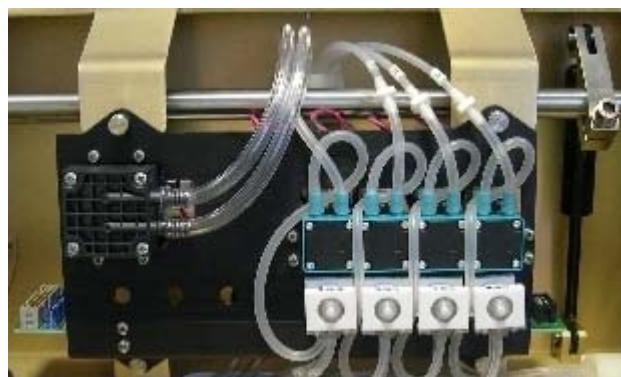


Fig.2 Pumps module

7.12 TABLE C – LIST OF THOSE MAINTENANCE PROCEDURES THAT CAN BE PERFORMED BY THE USER AND/OR BY THE MAINTENANCE TECHNICIAN

PROCEDURE	FREQUENCY (*)	EFFECTUATED BY
CLEANING THE SAMPLING PROBE	DAILY	OPERATOR
CLEANING THE FOUR WASH STATION CANNULAS	EVERY TWO WEEKS	OPERATOR
CLEANING THE WASH SOLUTION BOTTLES	EVERY TWO WEEKS	OPERATOR
REPLACING REACTION CUVETTES	EVERY THREE MONTHS	OPERATOR
CLEANING THE TIP	ONCE A MONTH	OPERATOR
REPLACING THE TIP	AS NEEDED	OPERATOR
ALIGNING AND ADJUSTMENT OF THE SAMPLING ARM (Std&Ctr/Reagents/Samples/Dispensing)	AS NEEDED (e.g.: after replacing any mechanical part)	OPERATOR

REPLACING THE PERISTALTIC PUMP TUBES	EVERY SIX MONTHS	OPERATOR
REPLACING THE PHOTOMETER BULB	AFTER 2000 HOURS OF USE	OPERATOR
REPLACING THE SAMPLING PROBE	AS NEEDED	OPERATOR
CLEANING THE HYDRAULIC CIRCUIT	AS NEEDED	OPERATOR
REPLACING THE TUBES (Tubes Kit)	ONCE A YEAR	MAINTENANCE TECH
REPLACING THE PRE-HEATER AND THE SENSOR LEVEL	AS NEEDED	MAINTENANCE TECH
MECHANICAL ALIGNMENT OF THE SAMPLING ARM	AS NEEDED	MAINTENANCE TECH
REPLACING OR ADJUSTING THE OPTIC SENSORS	AS NEEDED	MAINTENANCE TECH
REPLACING THE BELT	AS NEEDED	MAINTENANCE TECH
REPLACING A MOTOR	AS NEEDED	MAINTENANCE TECH
ALIGNING THE WASH STATION/REACTION PLATE	AS NEEDED	MAINTENANCE TECH
ALIGNING THE REACTION OR REAGENT OR SAMPLE PLATE	AS NEEDED	MAINTENANCE TECH
REPLACING THE PHOTOMETER	AS NEEDED	MAINTENANCE TECH
ADJUSTING THE PHOTOMETER	AS NEEDED	MAINTENANCE TECH
REPLACING THE ELECTRONIC BOARDS/CARDS AND THE MECHANICAL MODULES	AS NEEDED	MAINTENANCE TECH

N. B.: the above-indicated frequency intervals may vary according to the individual instrument's daily workload.

7.13 DECONTAMINATION PROCEDURE

Before replacing any instrument parts, repairing any defective items or performing any instrument maintenance procedure(s), the operator or maintenance technician must carry out the below-described decontamination procedure of the instrument part(s) involved in the operation(s).

This procedure can be performed on:

- the entire *Analyzer*
- those part(s) of the instrument subject to possible contamination

Material necessary

- an *ESOFENOL* solution diluted to 6% (60 cc in one liter of distilled water). *ESOFENOL* is an antibacterial and antiviral substance.
- Rubber gloves
- Mask
- Lab coat

External surfaces and individual parts

- ➔ Spray the solution all over the instrument, paying particular attention to wetting:
 - the sampling arm
 - the reaction plate (including the cuvettes)
 - the reagent and standard and control plate
 - the sample plate (including the racks)
 - the instrument chassis
- ➔ Allow the solution to stand for approximately 30 minutes
- ➔ Wipe the solution off the instrument and the various components using a sponge dampened with distilled water

Carry out a decontamination of the internal hydraulic circuit.

Hydraulic circuit (Entire Instrument)

- ➔ Fill a container with a 5% sodium hypochlorite solution.
- ➔ Disconnect the three silicon aspiration tubes from the nipples on the caps of their respective tanks.
- ➔ Immerge all three tubes into the container filled with the 5% sodium hypochlorite solution and have the instrument carry out two 'Wash cuvettes' cycles and then two 'WBL' cycles.
- ➔ Remove the three tubes from the 5% sodium hypochlorite solution and immerge them in another container containing the instrument Rinse Solution.
- ➔ Have the instrument carry out one 'Wash cuvettes' cycle and then one 'WBL' cycle.
- ➔ Reconnect the three aspiration tubes to the nipples on their respective tanks.

CHAPTER 08

FORMULAS AND CALCULATION MODELS

INDEX

8.1 END POINT METHODOLOGY - SINGLE REAGENT.....	2
8.2 END POINT METHODOLOGY - SINGLE REAGENT.....	4
8.3 “END POINT LIMIT” CONCEPT	5
8.4 “RGT RATE” CONCEPT.....	6
8.5 END POINT METHODOLOGY - TWO REAGENTS.....	7
8.6 END POINT METHODOLOGY - TWO REAGENTS.....	9
8.7 SAMPLE BLANK CORRECTION.....	11
8.8 FIXED TIME OR INITIAL RATE METHODOLOGY	15
8.9 FIRST LIMIT CONCEPT	17
8.10 FIXED TIME OR INITIAL RATE METHODOLOGY –.....	18
8.11 DEPLETION LIMIT CONCEPT WITH FIXED THRESHOLD.....	20
8.12 DEPLETION LIMIT CONCEPT.....	21
8.13 KINETICS METHODOLOGY.....	24
8.14 TIMING OF THE KINETIC REACTIONS	26

This chapter describes the mathematical models and the formulas used to define the results of the analyses carried out with the Ellipse instrument.

The three principal groups of analysis are:

- End Point Mono and Bi Reagent, Monochromatic and Bichromatic
- Fixed Time or Initial Rate Mono and Bi Reagent, Monochromatic and Bichromatic
- Kinetics Mono and Bi Reagent, Monochromatic and Bichromatic

The same "Final Result" formula is used for each analysis group:

Final Result = (Analytical Result x Unit Conversion Factor) x Slope + Intercept

The Slope and Intercept parameters refer to the conventional formula $Y = aX + b$ where:

Y = results of the reference instrument
 X = results of the Ellipse instrument
 a = slope
 b = intercept

reporting the Y values (reference instrument) in ordinate and X (Ellipse system) in abscissa.

8.1 END POINT METHODOLOGY - SINGLE REAGENT

Monochromatic, Without Sample Blank

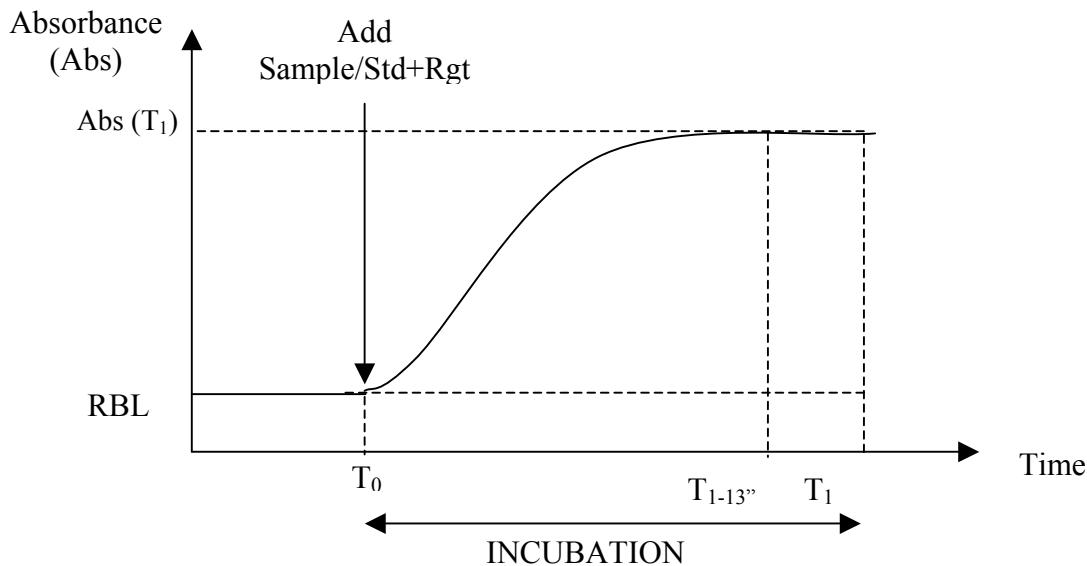
This methodology is used to determine the substrate concentrations.

For each "End Point" test, the system carries out three readings expressed in optical density, respectively at times T_0 , T_{1-13} and T_1 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button "Graph" (the graph also appears by clicking twice the selected test).

The Analytical Result is obtained using the $\text{Abs}(T_1)$ RBL value, that is taken during the calibration phase as the first reading point, and $\text{Abs}(T_1)$ taken during the analysis phase as the second reading point.

The T_0 reading is not used for this method type.



$$\text{Analytical Result} = \text{CF} \times [\text{Abs} (\text{T}_1) - \text{RBL}] \quad \text{CF} = \frac{\text{STD Concentration}}{\text{Abs STD} (\text{T}_1) - \text{RBL}}$$

Where:

$\text{T}_1 - \text{T}_0$ = Incubation time (1032" max)

RBL = Reagent Base Line value taken at time (T_1) during the calibration phase and displayed in the calibration results window. This value is used as the first reading point to produce the Analytical Result.

Abs (T_1) = Reading carried out at the end of the incubation period and used as the second reading point to produce the Analytical Result.

Furthermore, an absorbance reading is also carried out at time $\text{T}_1 - 13''$. It is used to check the reaction stability (End Point Limit).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

RBL = Reagent Base Line

Example:

GLU		
Res	91	
Abs	Time	
0.236	0	(T_0)
0.3319	317	($\text{T}_1 - 13''$)
0.3336	330	(T_1)

$$\text{CF} = 295$$

$$\text{RBL} = 0.0251$$

$$\text{Analytical Result} = \text{CF} \times [\text{Abs} (\text{T}_1) - \text{RBL}]$$

$$\text{Analytical Result} = 295 \times (0.3336 - 0.0251) = 91$$

8.2 END POINT METHODOLOGY - SINGLE REAGENT

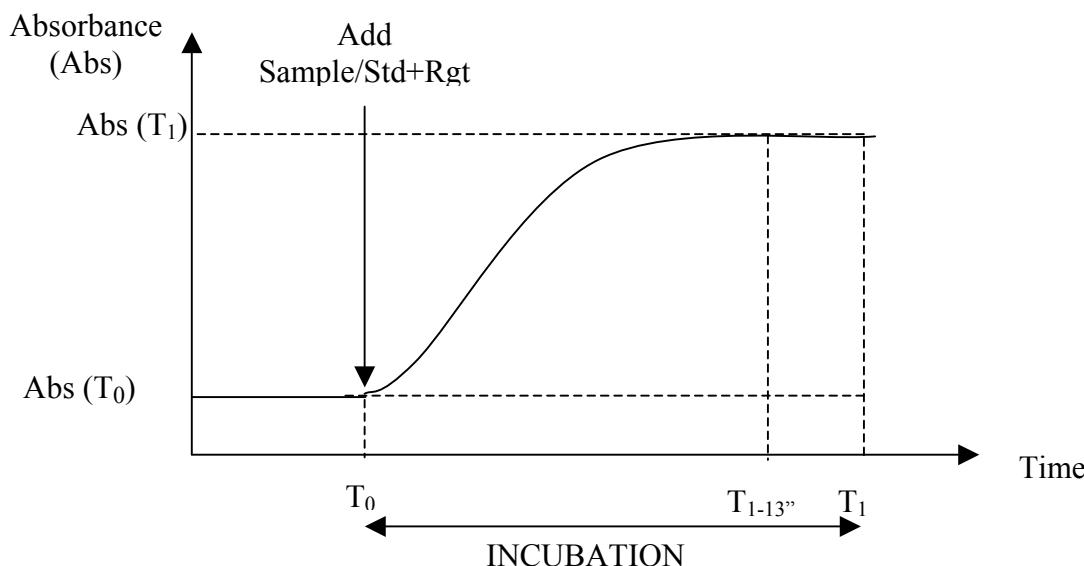
Monochromatic, With Sample Blank

For each "End Point" test, the system carries out three readings expressed in optical density, respectively at time T_0 , $T_{1-13''}$ and T_1 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button "Graph" (the graph also appears by clicking twice the selected test).

The Analytical Result is obtained using the optical density readings at times T_0 and T_1 respectively as the first and second reading points.

- **Attention:** In the event of a fast reaction where the first reading point value taken ($Abs(T_0)$) is significantly higher with respect to the RBL value detected during the calibration phase, it is not possible to use this type of methodology.



$$\text{Analytical Result} = CF \times [Abs(T_1) - Abs(T_0)]$$

$$CF = \frac{\text{STD Concentration}}{Abs(T_1)\text{STD} - Abs(T_0)}$$

Where:

$T_1 - T_0$ = Incubation time (1032" max)

$Abs(T_0)$ = the reading expressed in absorbance carried out immediately after the reagent and sample have been dispensed. This value is used as the first reading point to produce the Analytical Result.

$Abs(T_1)$ = the reading expressed in absorbance carried out at the end of the incubation time and used as the second reading point to produce the Analytical Result.

Furthermore, an absorbance reading is also carried out at time $T_1 - 13''$. It is used to check the reaction stability "End Point Limit".

ABBREVIATIONS:

STD	= Standard
CF	= Calibration Factor
RBL	= Reagent Base Line

Example:

$$CF = 295$$

GLU		
Res	91	
Abs	Time	
0.237	0	(T ₀)
0.5442	317	(T ₁ - 13'')
0.5454	330	(T ₁)

$$\text{Analytical Result} = CF \times [\text{Abs}(T_1) - \text{Abs}(T_0)]$$

$$\text{Analytical Result} = 295 \times (0.5454 - 0.237) = 91$$

8.3 "END POINT LIMIT" CONCEPT

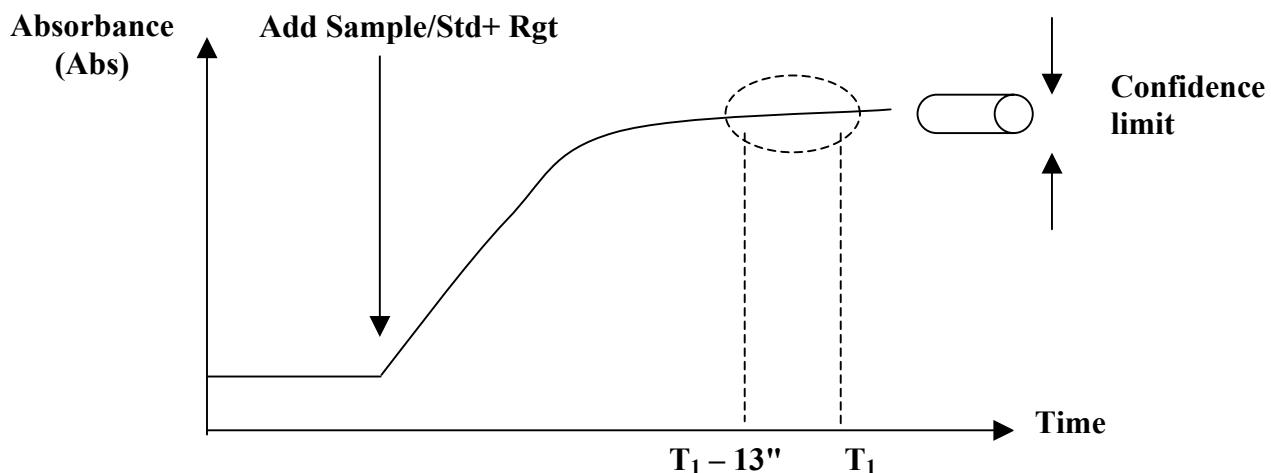
The end point limit is a check performed by the analyzer to verify the reaction stability and determine the validity of the result obtained.

An acceptability value (expressed in absorbance) is inserted by the operator into the End Point field in the method parameters (See Chapter 05 - Methodology in the present manual).

A low acceptability value increases the severity of the control, while a high value reduces the same.

Result's acceptability conditions:

$$\text{Abs}(T_1) - \text{Abs}(T_1 - 13'') < \text{End Point Limit}$$



$$\Delta \text{Abs} = \text{Abs}(T_1) - \text{Abs}(T_1 - 13'') = 0.3336 - 0.3319 = 0.0017 < \text{End Point Limit}$$

The following example shows how the end point limit value is calculated:

Calibration factor obtained = 300

By maintaining an uncertainty of 1 mg as acceptable, it follows:

$$\frac{1 \text{ mg}}{300} = 0.003$$

The value to be inserted in the End Point Limit box, represents in absorbance, the uncertainty that may exist between $\text{Abs}(T_1)$ and $\text{Abs}(T_1 - 13'')$

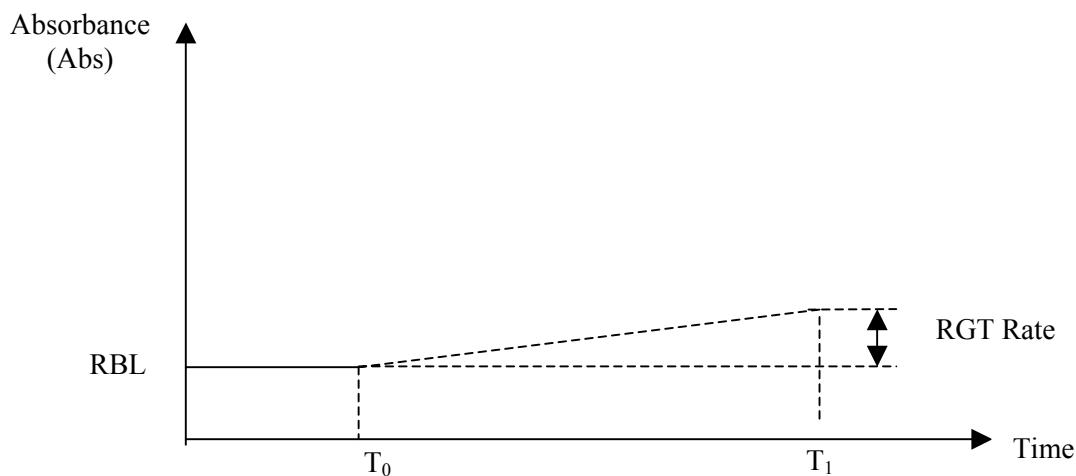
In the analysis phase, tests in which the following ratio is verified:

$$\text{Abs}(T_1) - \text{Abs}(T_1 - 13'') > 0.003 \text{ (End Point Limit)}$$

the results will be flagged "A".

8.4 "RGT RATE" CONCEPT

The Reagent Rate represents in terms of absorbance, the reagent's mobility during the reaction.



The RGT Rate value is automatically evaluated in the calibration phase and displayed in the Calibration results mask. The RGT Rate value is not displayed in End Point methods because it is already enclosed in the RBL value. In the End Point Methods with two reagents, the RGT Rate value measured is used for the analytical result calculation only when the Sample Blank correction is actively selected. The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

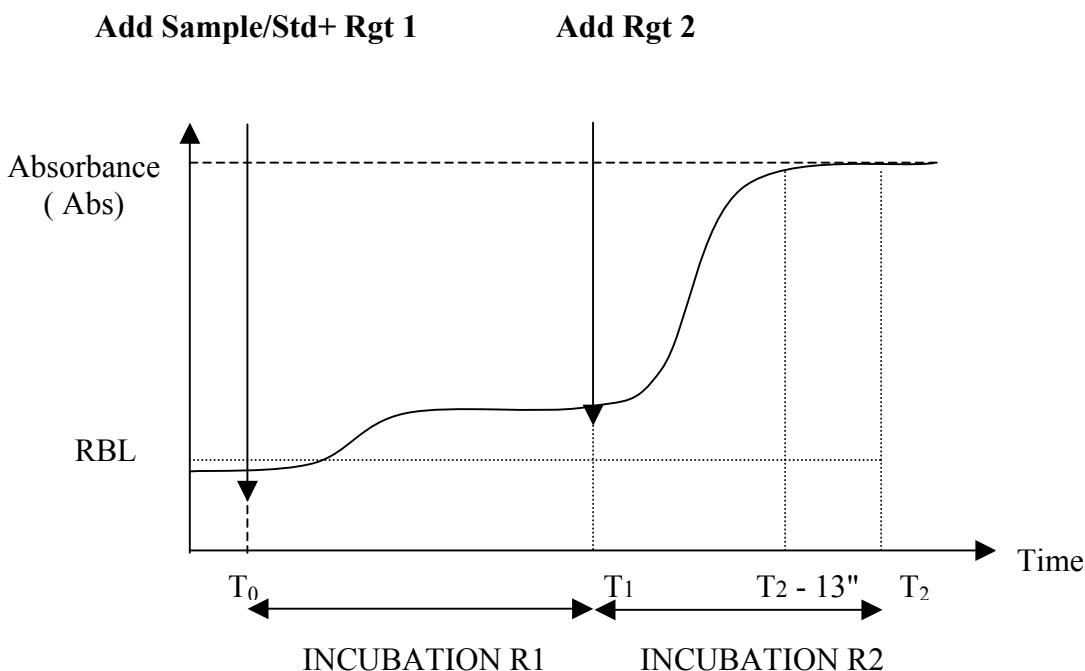
8.5 END POINT METHODOLOGY - TWO REAGENTS

Monochromatic, Without Sample Blank

For each "End Point" test that uses two reagents, the system carries out four readings expressed in optical density, respectively at time T_0 , $T_1 - 8''$, $T_2 - 13''$ and T_2 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button "Graph" (the graph also appears by clicking twice the selected test).

The T_0 reading is not used for this method type. The system obtains the Analytical result by using the Abs (T_2) RBL value, detected during the calibration phase, as the first reading point and Abs (T_2) value taken during the analysis phase as the second reading point.



$$\text{Analytical Result} = \text{CF} \times [\text{Abs} (T_2) - \text{RBL}]$$

$$\text{CF} = \frac{\text{STD Concentration}}{[\text{Abs STD} (T_2) - \text{RBL}]}$$

Where:

$T_1 - T_0$ = Incubation time Reagent 1

$T_2 - T_1$ = Incubation time Reagent 2

(The total time must be $\leq 1040''$)

- RBL = Reagent Base Line value taken at time (T₂) during the calibration phase and displayed in the calibration results window. This value is used as the first reading point to produce the Analytical Result.
- Abs (T₂) = reading expressed in absorbance carried out at the end of the incubation time R2 (T₂) and used to produce the Analytical Result.

Furthermore an absorbance reading is also carried out at time T₂ - 13". It is used to check the reaction stability "End Point Limit".

ABBREVIATIONS:

- STD = Standard
 CF = Calibration Factor
 RBL = Reagent Base Line

Example:

CA2		
Res	11.9	
Abs	Time	
0.3037	0	(T ₀)
0.3133	18	(T ₁ - 8")
0.7711	330	(T ₂ - 13")
0.7700	343	(T ₂)

$$\begin{aligned} \text{CF} &= 27.78 \\ \text{RBL} &= 0.3416 \end{aligned}$$

$$\text{Analytical Result} = \text{CF} \times [\text{Abs (T}_2\text{)} - \text{RBL}]$$

8.6 END POINT METHODOLOGY - TWO REAGENTS

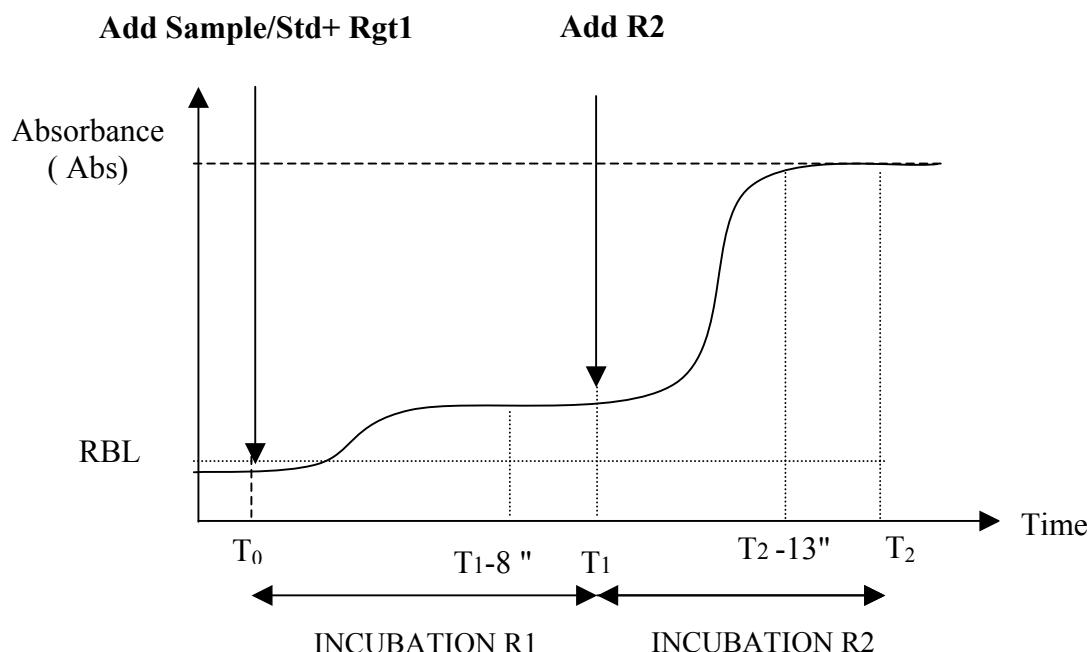
Monochromatic, With Sample Blank

For each "End Point" test that uses two reagents, the system carries out four readings expressed in optical density, respectively at the time T_0 , $T_1 - 8''$, $T_2 - 13''$ and T_2 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button "Graph" (the graph also appears by clicking twice the selected test).

The Analytical Result is obtained by the system using the $\text{Abs } T_1 - 8''$ value as the first reading point and $\text{Abs } (T_2)$ value as the second reading point, described in the chart below.

- **Attention:** This methodology type can be used as an automatic sample blank correction. In fact, the first reading point $T_1 - 8''$ corresponds to the absorbance value "Rgt1+Sample" in the reaction cuvette. In order to obtain a correct reading at the time $T_1 - 8''$, the minimum Rgt1+ Sample volume must be $\geq 220 \mu\text{L}$.



$$\text{Analytical Result} = \text{CF} \times \{[\text{Abs } T_2 - (\text{Abs } T_1 - 8'' \times \text{VCF})] \pm \text{RGT Rate}\}$$

STD Concentration

$$\text{CF} = \frac{\text{STD Concentration}}{[\text{Abs } T_2 - (\text{Abs } T_1 - 8'' \times \text{VCF})] \pm \text{RGT Rate}}$$

Where:

$$\begin{aligned} T_1 - T_0 &= \text{Incubation time R1} \\ T_2 - T_1 &= \text{Incubation time R2} \end{aligned}$$

Abs (T₁ - 8") = reading, expressed in absorbance, taken 8 seconds before the end of the Incubation time R1. This reading is used as the first reading point to produce the Analytical Result.

Abs (T₂) = reading, expressed in absorbance, taken at the end of the incubation time R2 and used to produce the Analytical Result.

VCF = Volume Correction Factors. This factor is automatically calculated by the system and is introduced to compensate for the dilution ratio introduced with the addition of the second reagent.

RGT RATE = reading, expressed in absorbance, of the reagents's mobility during the reaction. This value is automatically calculated during the phase of calibration and is reported in the "Calibration Results" window.

Furthermore an absorbance reading is also carried out at time T₂ - 13". It is used to check the reaction stability "End Point Limit".

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

VCF = Volumetric correction factor

RGT Rate = Reagent rate

V1 = Total volume of reagent1 + sample. It must be **≥ 220 ml**

V2 = Total volume of reagent1, plus sample, plus reagent 2

Example:

DBIL		
Res	3.0	
Abs	Time	
0.1187	0	(T ₀)
0.1336	18	(T ₁ - 8")
0.1662	330	(T ₂ - 13")
0.1681	343	(T ₂)

$$\begin{aligned} \text{CF} &= 85.47 \\ \text{RGT Rate} &= 0.0036 \end{aligned}$$

$$\text{VCF} = \frac{\text{V1}}{\text{V2}} = \frac{\text{R1} + \text{Sample}}{\text{R1} + \text{Sample} + \text{R2}}$$

$$\text{VCF} = \frac{300 + 12}{300 + 12 + 10} = 0.9689$$

$$\text{Analytical Result} = \text{CF} \times \{ [\text{Abs T}_2 - (\text{Abs T}_1 - 8" \times \text{VCF})] \pm \text{RGT Rate} \}$$

8.7 SAMPLE BLANK CORRECTION

In the End Point monoreagent methodology where the absorbance of the sample itself can affect the analytical result, it is necessary to evaluate the Sample Blank. This correction can be done by choosing one of the following according to the specific need:

- Sample blank (on line correction)
- Differential (absolute correction)
- Bichromatic (partial correction)

SAMPLE BLANK

This option performs the calculation of the "Sample Blank" on line, without using the differential or bichromatic type methodologies.

This correction will be considered in the Analytical Result only if the "Sample Blank" field located on the method parameters (See Chapter 05 - Methodology in the present manual).

This kind of correction must be considered valid only for slow developing reactions (monoreagent).

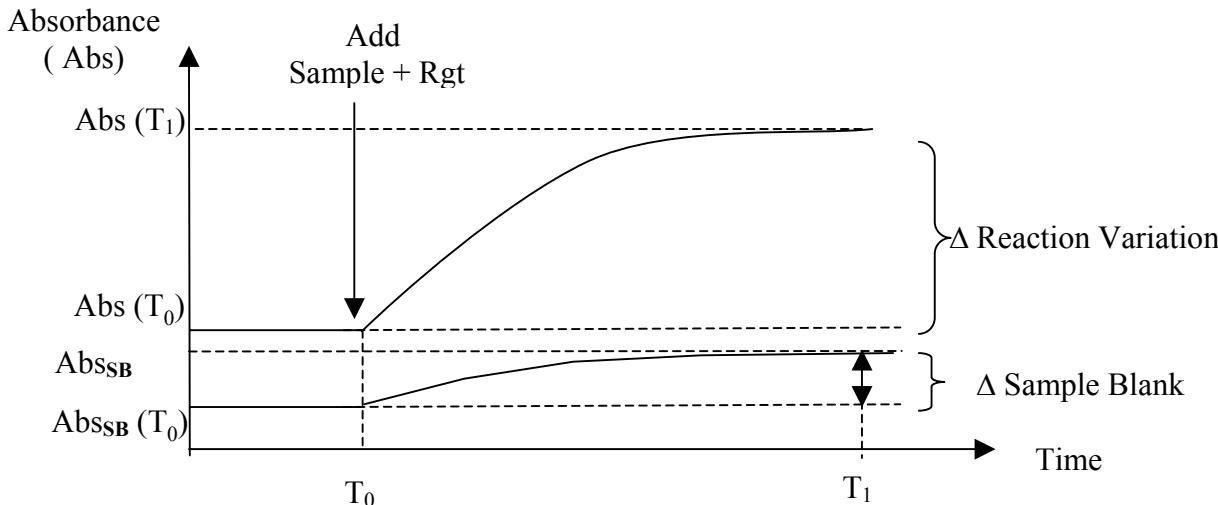
As the basis for the calculation, a reading is taken at time T_0 , immediately after the dispensing of the sample in the reagent, neglecting the value of the RBL (the value of the RBL is not taken in consideration for the calculation of the final result).

In two reagent reactions, a reading is taken at time $T_1 - 8''$ and used as the basis for the calculation of the final result.

DIFFERENTIAL

This type of methodological approach is used for the resolution of the problems posed by the "Sample Blank", and is always usable. Most importantly, it is decisively the most valid approach. The operative disadvantages due to this type of methodology are the following:

- A double system cycle (one for the "Sample Blank" and one for the reaction).
- Use of two cuvettes (one for the "Sample Blank" and one for the reaction which are read on the same wave-length.)
- Double Consumption of the sample volume.



Analytical Result = CF x { [Δ ABS (reaction) - Δ ABS(Sample blank)] }

Analytical Result = CF x { [Abs (T₁) - Abs (T₀)] - [Abs_{SB} (T₁) - Abs_{SB} (T₀)] }

STD Concentration

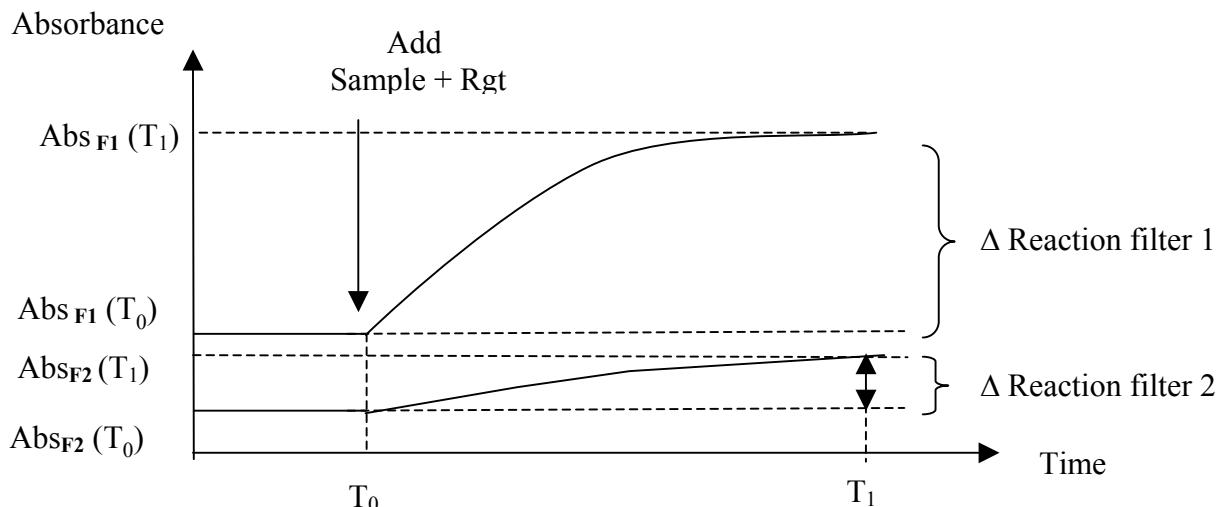
$$\text{CF} = \frac{\{ [\text{Abs} (\text{T}_1) - \text{Abs} (\text{T}_0)] - [\text{Abs}_{\text{SB}} (\text{T}_1) - \text{Abs}_{\text{SB}} (\text{T}_0)] \}}{\{ [\text{Abs} (\text{T}_1) - \text{Abs} (\text{T}_0)] - [\text{Abs}_{\text{SB}} (\text{T}_1) - \text{Abs}_{\text{SB}} (\text{T}_0)] \}}$$

BICHROMATIC

This type of methodology is applicable to the End Point reactions, which require a reading of the "Sample Blank". The correction that will carry onto the matrix, is not absolute, but relative.

The Bichromatism use requires the following selections:

- A secondary wavelength (filter 2) useful for the evaluation of the absorbance due only to the biological liquid's properties (turbidity, itteria, hemolyses).
- A bichromatic correction factor.



Analytical Result = CF x { [Δ Abs(Reaction filter 1)] - [Bic.Fact. x Δ Abs(Reaction filter 2)] }

Analytical Result = CF x { [Abs_{F1} (T₁) - Abs_{F1} (T₀)] - [Bic.Fact. x [Abs_{F2} (T₁) - Abs_{F2} (T₀)]] }

STD Concentration

$$\text{CF} = \frac{\{ [\text{Abs}_{\text{F1}} (\text{T}_1) - \text{Abs}_{\text{F1}} (\text{T}_0)] - [\text{Bic.Fact.} \times [\text{Abs}_{\text{F2}} (\text{T}_1) - \text{Abs}_{\text{F2}} (\text{T}_0)]] \}}{\{ [\text{Abs}_{\text{F1}} (\text{T}_1) - \text{Abs}_{\text{F1}} (\text{T}_0)] - [\text{Bic.Fact.} \times [\text{Abs}_{\text{F2}} (\text{T}_1) - \text{Abs}_{\text{F2}} (\text{T}_0)]] \}}$$

N.B. As the absorbance spectrum of the interferential substance is varied (turbidity, ittera or hemolyses), the choice of the second wavelength will be in function of the interferential substance that is meant to be corrected.

The secondary filter choice is made with the following criteria:

1. Significant indication of the interferent absorbance to be taken in consideration
2. Minimum evaluation in terms of chromogene absorbance

The possibility to make this choice is supplied by observation of the absorbance spectrum of the chromogene by the interferential substances, using a scansion spectrophotometer.

If it is not possible to use a spectrophotometer, an alternative can be found by coupling the following historical indications:

For all the **NADH dependent reactions** (End Point, Kinetics), ascendant or descendant, resort is made to a **prevailing correction of turbidity**:

$$F1 = 340$$

$$F2 = 380$$

For all the reactions read at **405 nm** with substrate equivalent to **Paranitrophenol, Paranitroaniline** etc. ascendant or descendant, a **prevailing correction of the ittera** is performed:

$$F1 = 405$$

$$F2 = 492 (460/500)$$

For all the reactions having **TRINDER** indicators, a prevailing correction of the emulsion (hemolyses) is performed:

$$F1 = 510$$

$$F2 = 578 (560/580)$$

For all the reactions, a prevailing correction of the turbidity with a filter is performed:

$$F2 = 620 (600/700)$$

Examples:

Prot. Tot	F1 = 546	F2 = 620
-----------	----------	----------

Calcium	F1 = 578	F2 = 620
---------	----------	----------

Bil. Tot.	F1 = 546	F2 = 620
-----------	----------	----------

Etc. etc.

For the calculation of the bichromatic correction factor, please refer to the example on the following page.

EXAMPLE OF THE CALCULATION OF THE BICHROMATIC CORRECTION FACTOR

The example illustrated below presupposes the use of a primary filter at 620 nm and a correction of the matrix with a filter at 510 nm.

END POINT
Absorbancies/Times Chart

RBL			SAMPLE	
620 nm				
OPTICAL DENSITY	TIMES		OPTICAL DENSITY	TIMES
0.0015 B₆₂₀	0		0.0495 A₆₂₀	0
0.0015	174		0.267	174
0.0015	187		0.268	187
510 nm				
0.001 B¹₅₁₀	187		0.174 A¹₅₁₀	187

Increase of the absorbance due to the reaction (Rgt + Smp) at 620 nm equal to:

$$A_{620} - B_{620} = 0.0495 - 0.0015 = 0.048$$

Increase of the absorbance due to the reaction (Rgt + Smp) at 510 nm equal to:

$$A_{510}^1 - B_{510}^1 = 0.174 - 0.001 = 0.173$$

$$\mathbf{0.048 \ (\Delta Abs \ 620 \ nm)}$$

$$\mathbf{BICHROMATIC \ FACTOR = \frac{0.048}{0.173 \ (\Delta Abs \ 510 \ nm)} = 0.277}$$

The combination of the Absorbance and Time are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button “Graph” (the graph also appears by clicking twice the selected test).

The Abs values of the samples, should have been taken from several different numbers “n” of matrixes, in order to obtain an average that is as representative as possible.

8.8 FIXED TIME OR INITIAL RATE METHODOLOGY

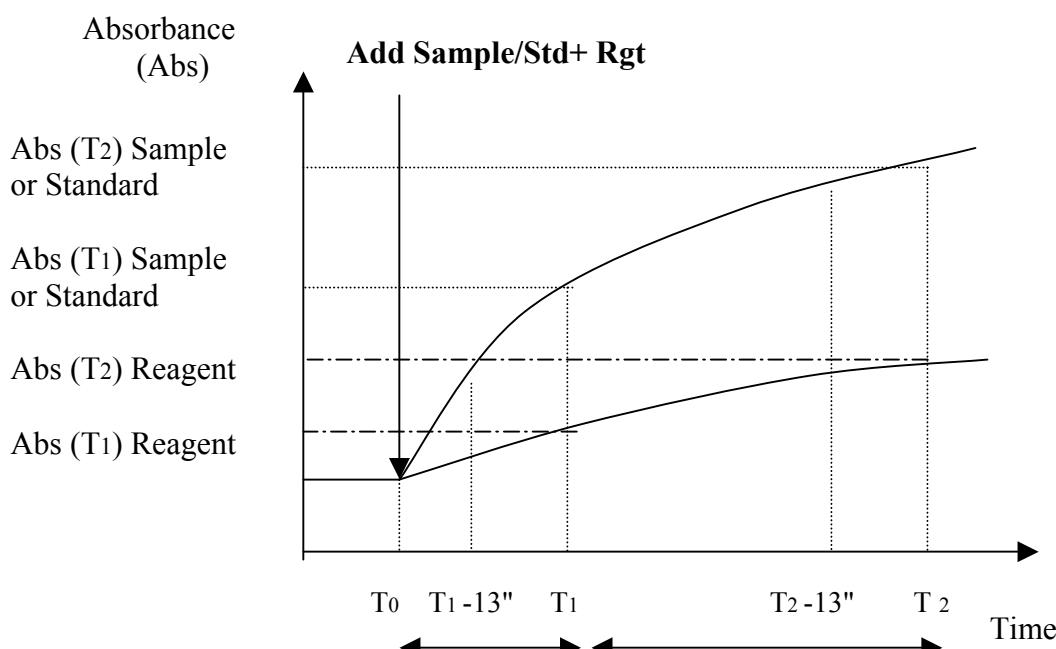
Single Reagent, Monochromatic

This methodology type does not need of any correction referring to the possible interference due to the sample (matrix), since the results are calculated with variations of absorbance (Δ Abs), and not with absolute values of absorbance.

For each "Fixed Time" test single reagent, the system carries out five readings expressed in optical density, respectively at the times T_0 , $T_{1-13''}$, T_1 , $T_{2-13''}$ and T_2 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button "Graph" (the graph also appears by clicking twice the selected test).

The Analytical result is obtained by the system using the Δ Abs obtained between $\text{Abs}(T_1)$ value as first reading point and $\text{Abs}(T_2)$ value as second reading point as described in the following formula:



$$\text{Analytical Result} = CF \times (\Delta\text{Abs Sample} \pm \text{RGT Rate}) \quad CF = \frac{\text{STD Concentration}}{\Delta\text{Abs Standard} \pm \text{RGT Rate}}$$

Where:

$T_1 - T_0$ = Incubation Time

$T_2 - T_1$ = Reading time

$\Delta\text{Abs Standard}$ = the value expressed in absorbance variation detected between the end and the beginning of the reading time ($\text{Abs T}_2 - \text{Abs T}_1$). This value is taken during the calibration phase and it is memorized in the calibration results screen. It is used to determine the calibration factor which will be used to produce the Analytical Result.

$\Delta\text{Abs Sample}$ = the value expressed in absorbance variation detected between the end and the beginning of the reading time ($\text{Abs T}_2 - \text{Abs T}_1$). This value is taken during the analysis phase and it is used to produce the Analytical Result.

RGT RATE = The reagent rate is the mobility of the reagent it self during the reaction express in Absorbance ($\text{Abs T}_2 \text{ Reagent} - \text{Abs T}_1 \text{ Reagent}$). This value is automatically calculated during the calibration phase and it is memorized in the calibration results window. The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

Furthermore, two absorbance variations are also carried out between time T_2 and $T_2 - 13''$ and between T_1 and $T_1 - 13''$. These absorbance variations are used to check the reaction stability "First Limit".

ABBREVIATIONS:

STD = Standard
CF = Calibration Factor

Example:

CREAT		
Ris	1.46	
Abs	Time	
0.2362	0	(T_0)
0.2451	5	($T_1 - 13''$)
0.3732	18	(T_1)
0.6047	83	($T_2 - 13''$)
0.6796	96	(T_2)

CF = 5.00
RGT Rate = 0.015

$$\text{Analytical Result} = \text{CF} \times [(\text{Abs SMP } T_2 - \text{Abs SMP } T_1) - (\text{Abs RGT } T_2 - \text{Abs RGT } T_1)]$$

8.9 FIRST LIMIT CONCEPT

This is a control of the reaction stability, where:

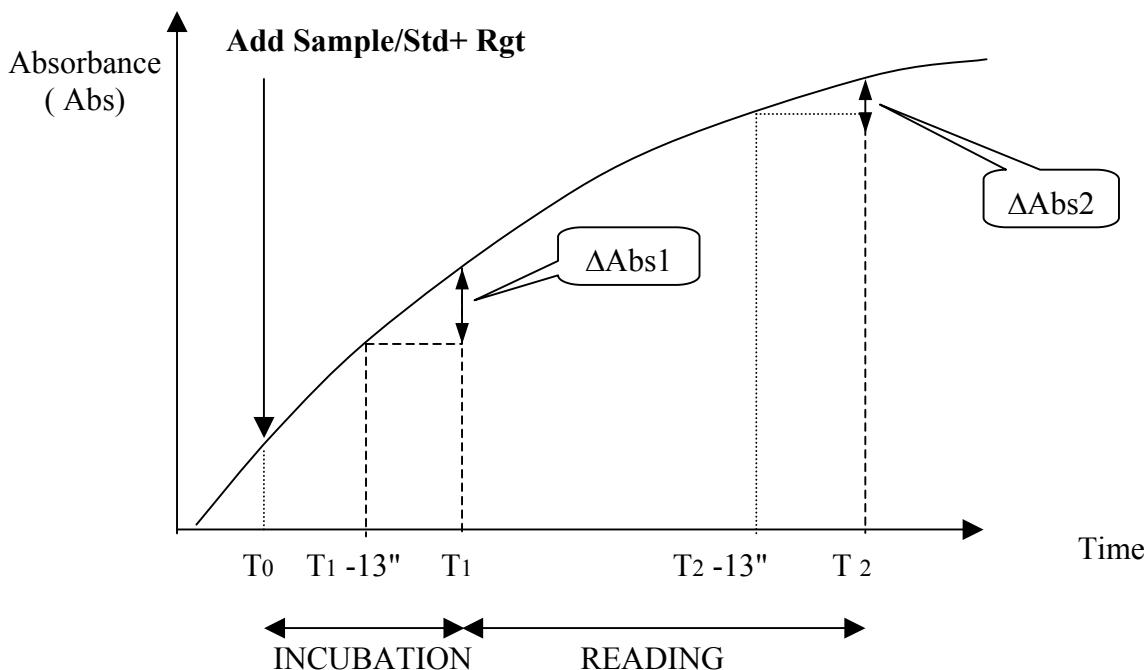
$$\Delta\text{Abs1} = \text{Abs}(\text{T}_1) - \text{Abs}(\text{T}_1 - 13'')$$

$$\Delta\text{Abs2} = \text{Abs}(\text{T}_2) - \text{Abs}(\text{T}_2 - 13'')$$

In case the following formula is not satisfied

$$\Delta\text{Abs1} - \text{Lin Fact} \times \Delta\text{Abs2} < \text{First Limit}$$

the result of the test carried out will be accompanied by the "A" flag.



HOW CALCULATE THE FIRST LIMIT AND THE LINEAR FACTOR

- 1) Initially increase the First Limit Value (e.g.: First Limit Value = 1 indicates absorbance differences equal to 1000, for which there will be no flag)
- 2) Launch routine
 - 5 samples low pathological level
 - 5 samples normal level
 - 5 samples high pathological level
- 3) Select the graph of the reactions, and evaluate the two partial deltas (ΔAbs1 , ΔAbs2) sample by sample.
- 4) Calculate the average for the three sample series for the ΔAbs1 and ΔAbs2 values.

$$\Delta\text{Abs1}$$

The ratio $\frac{\Delta\text{Abs1}}{\Delta\text{Abs2}}$ = Linear Factor

This factor permits the correlation of the two absorbancies for the "First Limit" control.

The effective value of the First Limit to be inserted into the methodology, will be established by the operator according to the same criteria followed for the End Point Limit, that is in function to the severity of the desired control. Elevated values of Abs reduce the efficiency of the control.

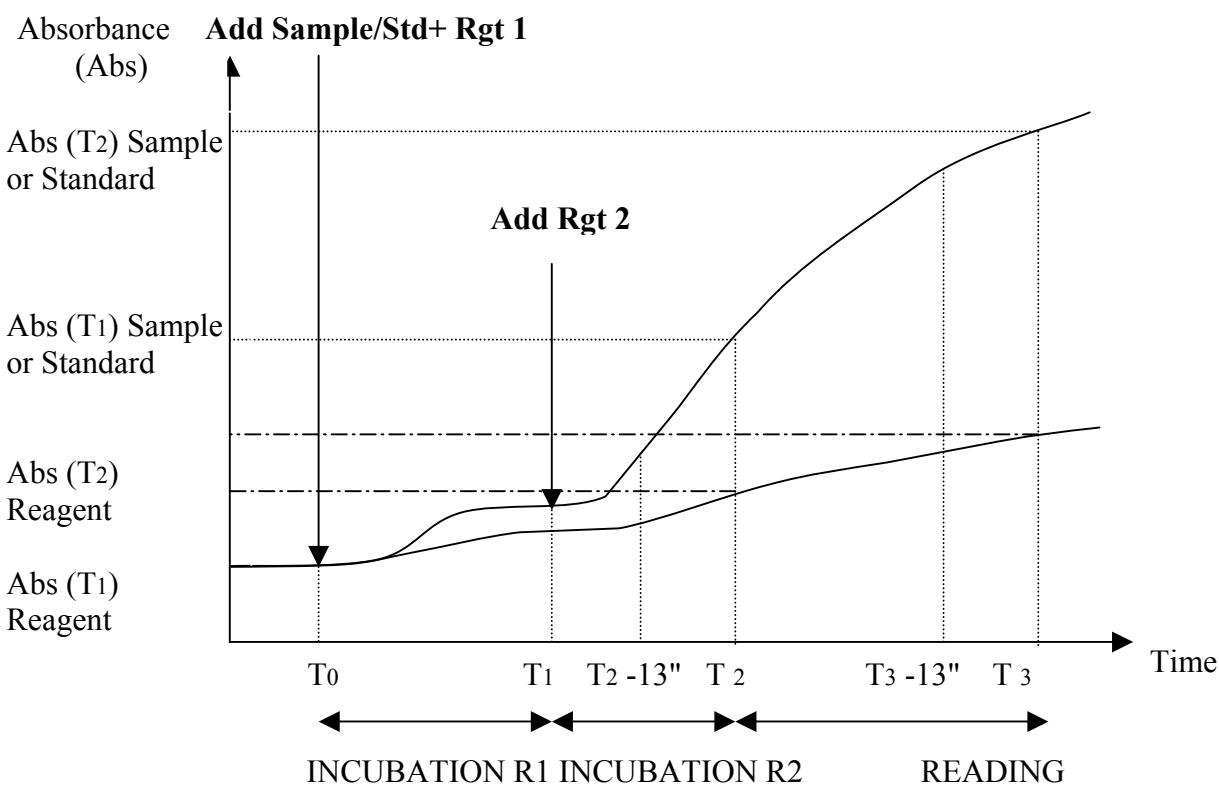
8.10 FIXED TIME OR INITIAL RATE METHODOLOGY – TWO REAGENTS Monochromatic

This methodology type does not need of any correction with reference to the possible interference due to the sample (matrix), since the results are calculated with variations of absorbance (ΔAbs), and not with absolute values of absorbance.

For each "Fixed Time" test two reagents, the system carries out six readings expressed in optical density, respectively at times T_0 , T_1 , T_2-13'' , T_2 , T_3-13'' and T_3 .

These readings and times are both displayed on the Reaction Graph. In order to visualize the graph, select the relevant test and then click on the button “Graph” (the graph also appears by clicking twice the selected test).

The system gets the Analytical result by using the ΔAbs obtained between $\text{Abs}(T_2)$ value as the first reading point and $\text{Abs}(T_3)$ value as the second reading point as described in the following formula:



$$\text{Analytical Result} = \text{FC} \times (\Delta \text{Abs Sample} \pm \text{RGT Rate}) \quad \text{CF} = \frac{\text{STD Concentration}}{\Delta \text{Abs Standard} \pm \text{RGT Rate}}$$

Where:

$T_1 - T_0$ = Incubation Time R1

$T_2 - T_1$ = Incubation Time R2

$T_3 - T_2$ = Reading time

$\Delta\text{Abs Standard}$ = the value expressed in absorbance variation detected between the end and the beginning of the reading time ($\text{Abs T}_3 - \text{Abs T}_2$). This value is taken during the calibration phase and it is memorized in the calibration results screen. It is used to determine the calibration factor which will be used to produce the Analytical Result.

$\Delta\text{Abs Sample}$ = the value expressed in absorbance variation detected between the end and the beginning of the reading time ($\text{Abs T}_3 - \text{Abs T}_2$). This value is taken during the analysis phase and it is used to produce the Analytical Result.

RGT RATE = the reagent rate is the mobility of the reagent itself during the reaction Absorbance ($\text{Abs T}_3 \text{ Reagent} - \text{Abs T}_2 \text{ Reagent}$). This value is automatically calculated during the calibration phase and it is displayed in the calibration results window. The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

Furthermore, two absorbance variations are also carried out between times T_3 and $T_3 - 13''$ and between T_2 and $T_2 - 13''$. These absorbance variations are used to check the reaction stability "First Limit".

ABBREVIATIONS:

STD = Standard
CF = Calibration Factor

Example:

CRE AT 2RGT		CF	= 33
Ris	Abs	RGT Rate	= 0.0089
	0.90		
	Abs	Time	
0.2852	0	(T ₀)	
0.2868	18	(T ₁)	
0.5577	31	(T ₂ - 13'')	
0.5738	44	(T ₂)	
0.5991	109	(T ₃ - 13'')	
0.6100	122	(T ₃)	

Analytical Result = CF x [(Abs T₃ - Abs T₂) ± RGT Rate]

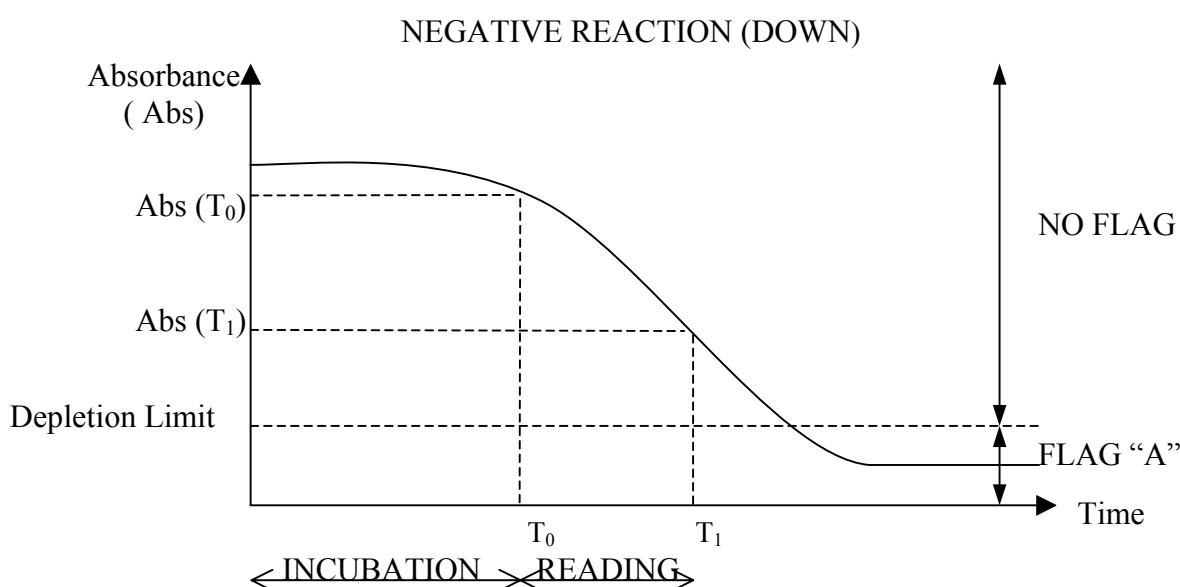
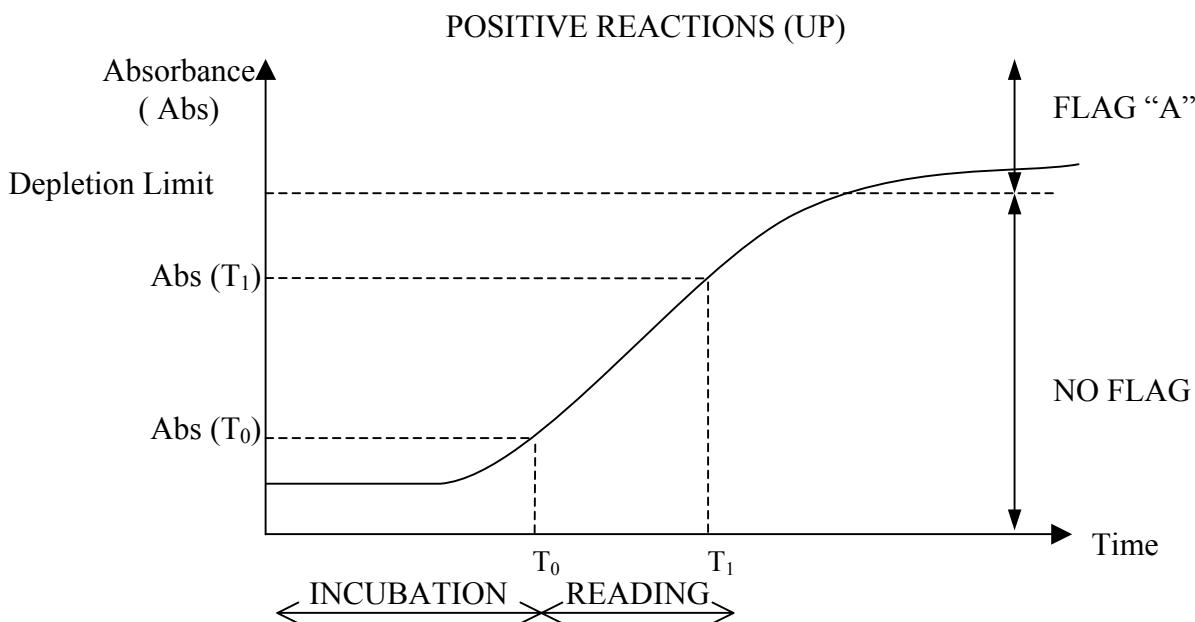
8.11 DEPLETION LIMIT CONCEPT WITH FIXED THRESHOLD

This is a control parameter for the reaction. If the initial reaction happens quickly, it can exhaust the substrate, and needs to be checked to avoid errors. This parameter refers to absolute values of absorbance, meaning that it can be applied on Initial Rate and Kinetic methods only.

These values must never be reached during the entire analytical process for either the positive reactions (UP) or the negative ones (Down) as specified in the method parameters.

When the direction of the reaction is positive (UP), and the absorbance values detected at the beginning and at the end of the reading time are greater than the value inserted into the field "Dep. Lim" in the method parameters (See Chapter 05 - Methodology in the present manual), the results will be two asterisks accompanied by a flag "A".

When the direction of the reaction is negative (DOWN), and the absorbance values detected at the beginning and at the end of the reading time are less than the value inserted into the field "Dep. Lim" in the method parameters (See Chapter 05 - Methodology in the present manual), the results will be two asterisks accompanied by a flag "A".

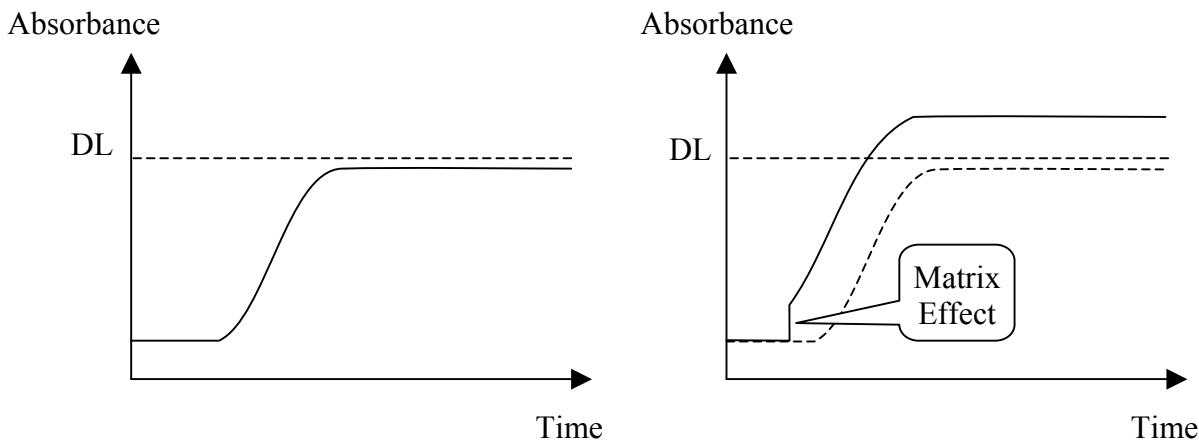


8.12 DEPLETION LIMIT CONCEPT

With Bichromatic Correction Factor (Variable Threshold)

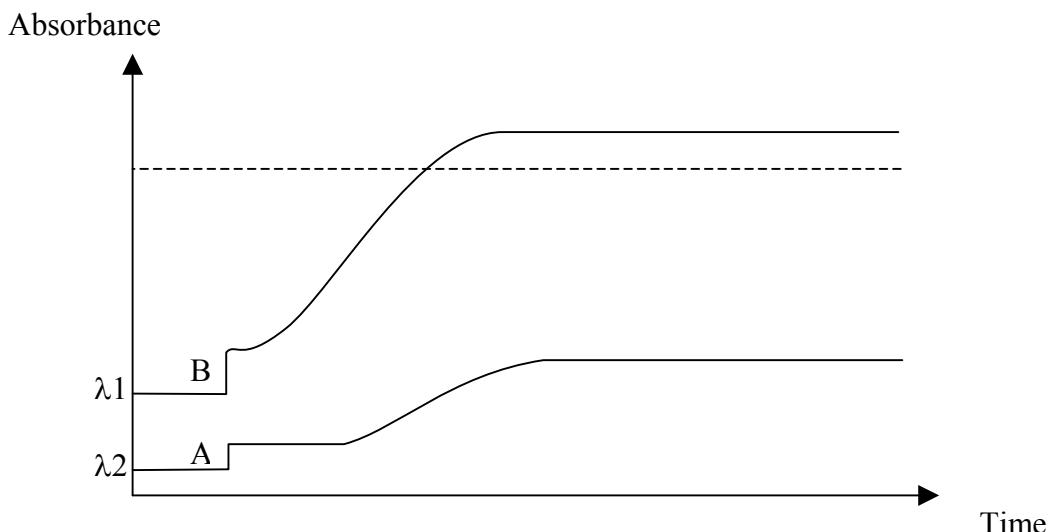
Bichromatic readings have several advantages amongst which surely the most interesting is the possibility to consider the matrix effect in the kinetic reactions, with the aim of compensating for the value of the "Depletion Limit" (see previous page).

Taking once again the graph on the previous page into consideration:



The value of the Depletion Limit (DL) is expressed in the absolute value. Considering the introduction of a sample with a particular matrix, which creates a rising of the reaction curve, (graph at right) one has a lower DL value, that is consequently erroneously flagged next to the Analytical results that will be two asterisks.

With the bichromatic correction it is possible to measure the amount of interference created by the matrix effect on the basic reaction. This amount will be taken into account for modifying the DL value, as illustrated below:



The correct Depletion Limit value is represented by the following formula:

$$\mathbf{DL \text{ (corrected)} = DL(in \text{ method}) + BCF}$$

Where:

Segment A = represents the absorbance value of the matrix wave-length λ_2 .

Segment B = represents the absorbance value of the matrix wave-length λ_1 .

BCF = represents the Bichromatic Correction Factor.

The Bichromatic Correction Factor (BCF) is a numerical factor which permits evaluation of the matrix value at the wave-length λ_1 by means of a reading taken at the wave-length λ_2 . The BCF is given by the ratio between the reading on λ_1 and the reading on λ_2 :

$$BCF = \frac{\text{Segment B}}{\text{Segment A}}$$

Corrections to the Depletion Limit (DL) are carried out automatically by the Ellipse software programme which controls both of the methods UP and DOWN, with their combinations.

In order to become active the automatic correction of the variable threshold for Depletion Limit control, the user needs to:

- to activate in the method parameters (See Chapter 05 - Methodology in the present manual) the option of correction by selecting the secondary filter
- calculate the Bichromatic Correction Factor (BCF) as illustrated on the following page.

Example of the Bichromatic Correction Factor (BCF) with Kinetic Reactions Calculation, in order to obtain the correction of the Depletion Limit (DL)

The BCF is calculated only once, per instrument, per method and per filter used. One proceeds for the mean statistic of the differences in absorbance provoked by a number "n" of samples (at least 30 with low activity), in comparison with the reagent blank in use, and read at two wave-lengths.

The following example expresses the type of calculation to be carried out with the absorbance values of the reaction graphs displayed on the screen.

KINETICS Absorbances/Times Chart			
REAGENT BLANK (RBL)		SAMPLE BLANK(Smp + Rgt)	
Abs	Times	Abs	Times
1.2991 RBL₃₄₀	0	1.7251 Smp₃₄₀	0
1.2981	174	1.5445	174
1.2984	187	1.5152	187
1.2979	200	1.4867	200
1.2982	213	1.4600	213
1.2987	226	1.4317	226
1.2985	239	1.4032	239
1.2993	252	1.3763	252
1.2991	265	1.3488	265
$\lambda_1 = 340\mu\text{m}$		$\lambda_2 = 380\mu\text{m}$	
0.1988 RBL₃₈₀		0.5719 Smp₃₈₀	

Increase of absorbance due to the Sample reaction (Rgt + Smp) at 340 nm equal to:

$$\text{Smp Blk}_{340} - \text{RBL}_{340} = 1.7251 - 1.2991 = 0.4260$$

Increase of absorbance due to the reaction (Rgt + Smp) at 380 nm equal to:

$$\text{Smp Blk}_{380} - \text{RBL}_{380} = 0.5719 - 0.1988 = 0.3731$$

$$0.426 (\Delta\text{Abs } 340 \text{ nm})$$

$$\text{BICHROMATIC CORRECTION FACTOR} = \frac{0.426}{0.3731 (\Delta\text{Abs } 380 \text{ nm})} = 1.1417$$

Note: The absorbance values used in the calculation are representative of the absorbance mean of 30 samples.

8.13 KINETICS METHODOLOGY

This methodology type is used to determine the enzyme activity. Its does not need any correction due to possible sample (matrix) interference, since the results are calculated with variations of absorbance per minute ($\Delta \text{Abs} \times \text{min}$), and not with absolute absorbance values. For that the analytical result is computed as follows:

$$\text{Analytical Result} = \text{CF} \times (\Delta \text{Abs Sample} \times \text{min} \pm \text{RGT Rate})$$

$$\text{Analytical Result} = \text{CF} \times (\text{Slope Sample} \pm \text{slope RGT Rate})$$

The calibration factor for calculate the enzyme activity is directly correlated to the following parameters:

- temperature
- optical path length
- ratio dilution reagent-serum
- co-efficient of the molar extinction of the co-enzyme detector
- reading time

Follows the general formula for the determination of the calibration factor for enzyme activity calculation:

$$\text{Calibration Factor} = \frac{V_t}{V_s \times \text{O.T.} \times \epsilon}$$

Where:

V_t = Sample volume + Reagent volume

V_s = Sample volume

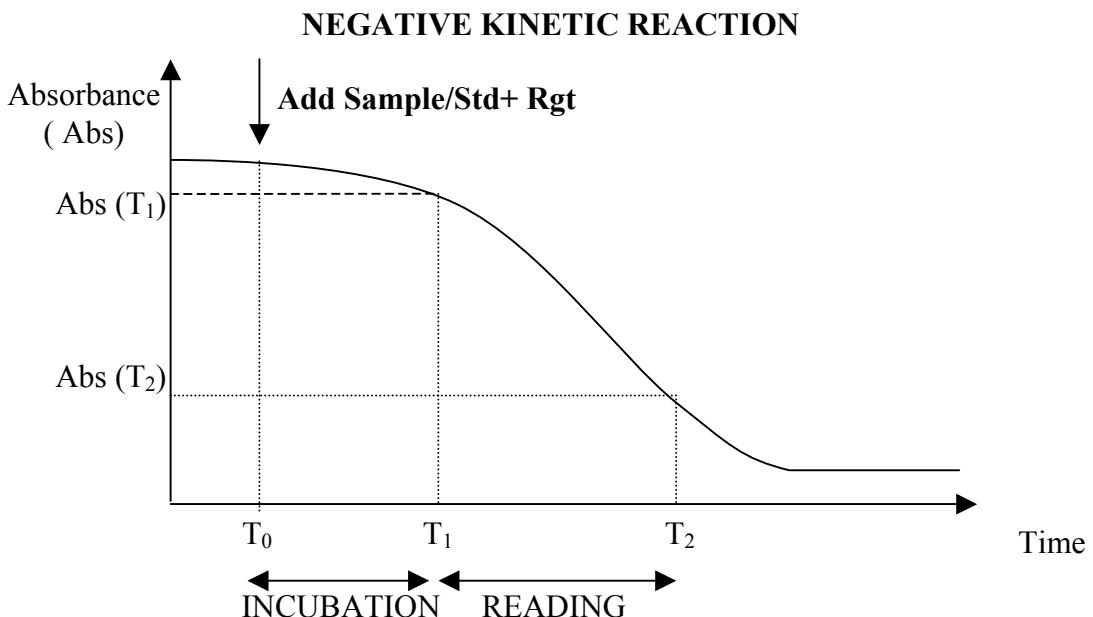
(*) For V_t and V_s it is necessary to use an identical unit of measure, for example: ml or $\square\text{l}$

O.T. = Optical path length (cm).

ϵ = Molar extinction coefficient at the specified wave-length λ

For each "Kinetic" test, the system carries out a number of readings expressed in optical density, respectively at time T_0 , and "n" reading between T_1 to T_2 (a number of readings from four to eight as indicated on the next table nr 1) according to the incubation and reading time defined in the method parameters (See Chapter 05 - Methodology in the present manual).

All the reading points taken during the reading time (from T_1 to T_2) are used by a linear regression algorithm to calculate the slope of a theoretical straight line. This slope ($\Delta \text{Abs} \times \text{min}$) is used to produce the Analytical result.



Analytical Result = CF x SLOPE $CF = \frac{\text{STD Concentration}}{\Delta \text{Abs STD} (T_2 - T_1)} \times 60$

Where:

$T_1 - T_0$ = Incubation Time

$T_2 - T_1$ = Reading time

SLOPE = ($\Delta \text{Abs} \times \text{min.}$) used to produce the Analytical Result. The slope that best approximates the reading points detected between the beginning and the end of the reading time, using a criteria of minimum squares.

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

FIT = Linear correlation coefficient. Represents a control parameter for Kinetic reactions. Indicates the addition of the mean square errors, normalized to the variance, related to all the reading points detected during the reading time. If the detected value is more than the number inserted into the specific field FIT on the method parameters (See Chapter 05 - Methodology in the present manual), the result is flagged "A".

GOT/AST		
Ris	35	
FIT	0.980	
Abs	Time	
1.5598	3	(T ₀)
1.5180	122	(T ₁)
1.5110	135	
1.5061	148	
1.4995	161	
1.4930	174	
1.4878	187	
1.4827	200	
1.4762	213	(T ₂)

Example:

CF = 1746

FIT = 1

Incubation time = 122"

Reading time = 91 "

Analytical Result = CF x SLOPE

Analytical Result = CF x (Abs T₁ - Abs T₂) x 60 / 91

8.14 TIMING OF THE KINETIC REACTIONS

Incub Max	RT	NrR	Incub Max	RT	NrR	Incub Max	RT	NrR	Incub Max	RT	NrR	Incub Max	RT	NrR
Reading every 13 "			Reading every 26 "			Reading every 39 "			Reading every 52 "			Reading every 65 "		
988	39	4												
975	52	5												
962	65	6												
949	78	7												
936	91	8												
			923	104	5									
			897	130	6									
			871	156	7									
			845	182	8									
						832	195	6						
						793	234	7						
									767	260	6			
						754	273	8				715	312	7
									663	364	8			
												637	390	7
													572	455
														8

TAB. N° 1

Where:

Inc Max = Maximum Incubation time (including eventual reagent incubation time)

RT = Reading time inserted in the method parameter

Nr R = Number of readings carried out by the Ellipse to calculate the slope

The above table shows the combinations of the maximum incubation time with the reading time programmed in the method parameters. The minimum incubation time is 5 seconds. The reading time is selected inside a pull down menu in the method programming mask (See Chapter 05 - Methodology in the present manual). Selectable reading times can be from 39 seconds minimum to 455 seconds maximum and they are accompanied by an asterisk.

With regards to the selected reading time, the system will carry out all the readings needed for slope calculation, from four to a maximum of eight, every 13, 26, 39, 52 or 65 seconds as showed in the above table.

CHAPTER 09 - ERROR SIGNALING AND TROUBLESHOOTING

INDEX

9.1	ERROR SIGNALING.....	2
9.1.1	SYSTEM ERRORS	2
9.1.2	RESULT FLAG.....	3
9.1.3	DESCRIPTION OF RESULT FLAGS.....	3
9.2	TROUBLESHOOTING GUIDE	6

9.1 ERROR SIGNALING

This chapter is dedicated to a description of the **error** signalling which may occur during the programming or carrying out of the various operations. Error signals can be divided into the following two groups:

- System Errors
- Result Flags

9.1.1 SYSTEM ERRORS

Whenever a system error is detected, it is signalled via the activation of the below-listed warning lights/buttons:

➤ **Warning Light:** a triangle-shape located in the upper, right-hand portion of the System Monitor screen. It lights up yellow when activated.

If this yellow triangle does light up, the operator need simply click on it to access the relative visual text warning message indicating the cause of the signalled anomaly (said window will open in that area dedicated to viewing data).

Following is a list of possible visual text “Warning!” messages:

- Liquid Alarm I (Rinse Solution)
- Liquid Alarm II (Distilled Water)
- Liquid Alarm III (Cleaning Solution)
- Liquid Alarm IV (Optional Solution)
- Temperature Out-of-Range
- Host Serial Port cannot be opened

➤ **Fatal Error:** an “X”-shape located in the upper, right-hand portion of the System Monitor mask. It lights up red when activated.

If this red “X” lights up, the operator need simply click on it to access the relative visual text message explaining the cause of the Fatal Error (said window will open in that area of the mask dedicated to viewing data).

Following is a list of possible Fatal Error visual text messages:

- Horizontal Arm Error
- Sample Tray Error
- Filter Error
- ADC Error – Sample Channel
- ADC Error – Reference Channel
- Reaction Tray Position Error
- Plate Error (Home sensor not found)
- Vertical Arm error
- Reagent Tray Error
- Wash System Error
- Diluter Error
- Interlock Open while Instrument is running
- Macro send Error
- Overflow Rx Buffer Micro
- Time out Error (Generic error)
- Invalid command error
- Invalid parameter error

- Check sum error

9.1.2 RESULT FLAGS

Result Flags are categorized under the following group headings, Each group is identified by a symbol, as listed here-below:

X	PHYSICAL ERRORS
R	CONCENTRATION ERRORS
C	CALIBRATION ERRORS
A	OPTIC DENSITY ERRORS
E	RESULTS EDITED MANUALLY
?	PROGRAMMING ERRORS

Every Result Flag, signalling an error, is accompanied by a symbol representing the group it is part of. The operator need only click on the small red square () next to the Result Flag symbol to access the visual text message explaining the cause(s) of the signalled error.

In the central column of the following tables, the user will find those symbols which signal the type of error encounter, as used in the print-out of the final report. These symbols can be modified by the operator, in the **Parameters** section, under **print options**.

WARNING! The use of the Error Symbols in the print-out of the results (inclusion and/or exclusion) **IS UNDER THE DIRECT AND SOLE RESPONSIBILITY OF THE USER**

9.1.3 DESCRIPTION OF RESULT FLAGS

➤ **X Physical Errors**

Temperature Error:	T	Reaction temperature (Reaction Plate) is out-of-range.
No Sample	S	Either no sample or sample serum quantity below minimum or above maximum level for the declared container.
No Reagent:	R	Either no reagent or reagent level below minimum or above maximum level for the declared container.
No Rack:	*	No Rack present during sampling.

➤ R Concentration Errors

Very Low and Very High:	L-H	Flags determined by test results out-of-range as setup in the Methods.
Low Alert and High Alert:	A	Flags determined by test results out-of-range as setup in the Methods.
Low and High Linearity Limit:	G	Flags determined by test results out-of-range as
Calculation Error:	C	Concentration calculation error due to foreseeable causes (Asymptote).

➤ C Calibration Errors

RBL missing:	*	No Reagent Blank Level.
Calibration missing:	*	No Standard or no Calibration curve.
STD Replicate insufficient:	*	Insufficient number of valid Standard Replicates.
STD Replicate outside CV%:	*	Coefficient of Variation Percentage in the Standard Replicates over the set value.
Invalid Calibration:	*	Calibration curve not valid – either because it is not monotonic or because the Fit is above the set value.

➤ A Optic Density Errors

Inversion:	I	Reaction direction not in line with that set-up.
End Point Limit:	P	Values over the limits setup in the Methods Parameters
Depletion Limit:	D	Values over the limits setup in the Methods Parameters.
First Limit:	*	Values over the limits setup in the Methods Parameters.
FIT:	F	Values over the limits setup in the Methods Parameters.

RBL out-of-range: * Reagent Blank Levels outside the range Setup.

Sample outside Standard: # Sample absorbance outside the calibration curve.

➤ E

Results Edited Manually

Results Edited: E This symbol automatically appears whenever the operator has manually modified the obtained results. This operation annuls all the symbols indicating errors which, in this case, will not be viewed.

➤ ?

Programming Errors

All those software errors which are deemed unforeseeable are indicated using this symbol.

➤ **Result Asterisks**

In the event that the following situations and/or error conditions occur, the system will notify the user via a visualization of two asterisks (**) in the Results field:

PHYSICAL ERRORS

- 1 – very little or no sample
- 2 – very little or no reagent
- 3 – no rack

CONCENTRATION ERRORS

- 4 – calculation error
- 5 – signalling depletion limit

PROGRAMMING ERROR

- 6 – all cases

In the following situations and/or error conditions, the results field will contain a “0”:

- 1 – if the result is less than zero
- 2 – if the result is equal to zero

OPTIC DENSITY ERRORS

- 3 – Flag signalling inversion

9.2 TROUBLESHOOTING GUIDE

PROBLEM	> POSSIBLE CAUSE	❖ SOLUTION
Repeatability of results insufficient	<ul style="list-style-type: none"> > Sample Probe dirty <ul style="list-style-type: none"> ❖ Clean the Sample Probe as described in Chapter 07 – Maintenance > Hydraulic leak and/or air bubble in the hydraulic circuit (sampling) <ul style="list-style-type: none"> ❖ Check Sample Probe fit ❖ Check the fit of the hydraulic tubes and their connection: if necessary, substitute the tubes and/or adjust their connections/fittings > Wash solution is contaminated. If the wash solution contains contaminating particles (e.g.: mold, dust, lint), these micro-particles can cause errors during the WBL running. <ul style="list-style-type: none"> ❖ Change the wash solution ❖ Clean the Wash Solution Bottle(s) and carry out the Hydraulic Circuit wash procedure as described in Chapter 07 – Maintenance > Deterioration of the Reagent(s) <ul style="list-style-type: none"> ❖ Substitute the bad reagent(s) > Reaction cuvettes not dried correctly after being washed <ul style="list-style-type: none"> ❖ Check the Tip used to dry the cuvettes after washing to make sure it is in good working condition. If necessary, clean the Tip or change it, following the procedure described in Chapter 07 – Maintenance > Light bulb not stable <ul style="list-style-type: none"> ❖ Light bulb nearing the end of its 2000-hour life cycle duration, or premature deterioration. In both cases, change the light bulb following the substitution procedure described in Chapter 07 – Maintenance. 	
Insufficient volume/quantity of the various Rinse, Cleaning and Distilled Water solutions.	<ul style="list-style-type: none"> > This type of problem could happen either when the instrument is first turned on due to a lack of liquid in one or more bottles, or during test running whenever the involved liquid has been finished <ul style="list-style-type: none"> ❖ Refill the required bottle. If the instrument is running tests, it will automatically Pause. Wait until sampling is suspended, then refill the involved bottle with the required liquid (Rinse/Cleaning/ Distilled Water). Press Start to continue running the rest of the programmed tests. This operation will not adversely affect the already run tests. 	

CHAPTER 10 – HOST COMMUNICATION

INDEX

10.1	COMMUNICATION WITH THE HOST COMPUTER	2
10.1.1	COMMUNICATION PARAMETERS	2
10.2	PROTOCOL SPECIFICATION	3
	HEADER RECORD (H).....	4
	PATIENT RECORD (P).....	5
	TEST ORDER RECORD (O).....	8
	RESULTS RECORD (R).....	10
	MESSAGE TERMINATOR RECORD (L)	12
	REQUEST INFORMATION RECORD (Q):.....	13

10.1 COMMUNICATION WITH THE HOST COMPUTER

The *Ellipse* can be connected to a host computer for the purpose of facilitating results print-out and patient management.

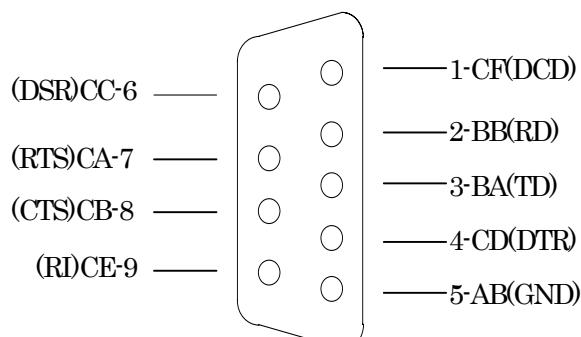
In order to enable communication between the *Ellipse* and the host computer, select the **Host Link** field under **Options** in the **Parameters** menu.

To activate communication between the *Ellipse* and the host computer, select **Host-Tx** (please see the software description in Chapter 03 of this User's Guide)

10.1.1 COMMUNICATION PARAMETERS

The *Ellipse* is linked to the managing computer using an RS-232C serial connector having the following specifications:

- Transmission method : Asynchronous, half duplex
- Baud Rate : 9600 Bit/sec.
- Data bits: : 8
- Parity : None
- Stop bit : 1
- Connector : 9 pin type D (male output from the Ellipse)



Serial connector

10.2 PROTOCOL SPECIFICATIONS

This part of Help (**Protocol Specifications**) contains information for the laboratory computer and analyzer. This exchange of data follows specific **ASTM** protocols:

E 1381-95 Standard Specification for Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems;

E 1394-97 Standard Specification for Transferring Information between Clinical Instruments and Computer Systems.

ASTM uses a number of different terms to indicate the way it groups data.

- **Field:** an individual piece of data often referred to as a data field or a data element.
- **Record:** a number of logically related data fields grouped together to form one part of a complete message.
- **Repeat field:** a data field of the same type as the one immediately preceding it. A delimiter separates one instance of a repeat field from the next.
- **Component field:** part of data field that might contain more than one piece of data.

The default communication configuration for the *Analyzer* is the following: "**9600,N,8,1**".

ASTM uses record types that are common and familiar to all laboratory personnel. It uses the following record types:

- **Header Record (H):** contains identifying information about the sending station, conventions that the device uses for field recognition, and the date and time of send station transmission.
- **Patient Record (P):** contains patient information and identification number.
- **Test Order Record (O):** contains information about the assay or requests themselves and includes other data.
- **Result Record (R):** contains information about the outcome of individual tests for an individual patient and follows a sample program record. The results contain the actual measurements derived from the test and a comparison of the individual result to certain ranges specified as norms for the laboratory.

- **Message Terminator Record (L)**: although the ASTM protocol supports three additional record types - a Request for Information Record, a Scientific Record and a Manufacturer's Information Record - the *Analyzer* is not implementing these in the first release and will ignore them.
- **Request Information Record (Q)**: is used by either clinical instruments or computer systems for a remote request for information from its reciprocal system.

The instrument does not send or accept comment records.

Header Record (H)

Field	Field Title	Down Load	Up Load	Max Len	Description and Valid Values																				
1	Record Type ID	R	A	1	This is a required field that contains an "H" identifying it as a header record.																				
2	Delimiters	I	A	4	<p>The <i>Analyzer</i> System uses only the four default values shown here. Delimiters may not be duplicated. The field delimiter follows the escape character to separate the delimiter specification from a subsequent field in the header record. Using default values, the first six characters of the header record will appear using the following characters:</p> <table> <tr> <td>H</td> <td>I</td> <td>\</td> <td>&</td> </tr> <tr> <td>Field Delimiter</td> <td>I</td> <td></td> <td></td> </tr> <tr> <td>Repeat Delimiter</td> <td>\</td> <td></td> <td></td> </tr> <tr> <td>Component Delimiter</td> <td>^</td> <td></td> <td></td> </tr> <tr> <td>Escape Delimiter</td> <td>&</td> <td></td> <td></td> </tr> </table>	H	I	\	&	Field Delimiter	I			Repeat Delimiter	\			Component Delimiter	^			Escape Delimiter	&		
H	I	\	&																						
Field Delimiter	I																								
Repeat Delimiter	\																								
Component Delimiter	^																								
Escape Delimiter	&																								
3	Message Control ID	I	N																						
4	Access Password	I	N																						
5	Sender Name or ID	I	A	10	'SHAnalyzer': This is the name of the device that is sending the data.																				
6	Sender Street Address	I	N																						
7	Reserved Field	I	N																						
8	Sender Tel. Number	I	N																						

9	Characteristics of Sender	I	N		
10	Receiver ID	I	N		
11	Comments or Special Instructions	I	N		
12	Processing	I	N		
13	ASTM Version No.	I	N		
14	Date and Time	I	A	14	Date and Time of transmission: formatted as YYYYMMDDHHMMSS. For example: 3:35 PM on March 1, 1995 would be represented using the following characters: 19950301153500.
Legend:		R Required	D Down Load		
		O Optional	U Up Load		
		I Ignored	N Never		
		A Always	S Sometimes		

Example Header Record Layouts (H)

Download	
Host	H I\^III HOST I I19950301153500<CR>
Upload	
Analyzer System	H \^ & SHAnalyzer 19950301154000<CR>

Patient Record (P)

Field	Field Title	Down Load	Up Load	Max Len	Description and Valid Values
1	Record Type ID	R	A	1	This is a required field that contains a “P” identifying it as a patient record.
2	Sequence Number	R	A	3	This field starts with a “1” for the patient and is incremented by 1 for each additional patient within the transmission.
3	Practice Assigned Patient ID	R	A	15	This field can be assigned by the instrument with no corresponding download.

4	Laboratory Assigned Patient ID	I	N		
5	Patient ID No. 3	I	N		
6	Patient Name	O	S	36	This field has two components: <ul style="list-style-type: none">• Last Name (up to 20 characters)• First Name (up to 15 characters).
7	Mother's Maiden Name	I	N		
8	Birth Date	O	S	8	Formatted as YYYYMMDD: For example, a birth date of December 1, 1980 would be represented as: 19801201
9	Patient Sex	R	A	1	The valid values are: <ul style="list-style-type: none">• M for Male• F for Female
10	Patient Race/Ethnic Origin	I	N		The <i>Analyzer</i> System will ignore this field at launch.
11	Patient Address	O	S	60	For <i>Analyzer</i> , this is a four-component field: <ul style="list-style-type: none">• Address (25 characters)• City (25 characters)• State (2 characters e.g.: NY, IT)• Zip (5 characters)
12	Reserved Field	I	N		
13	Patient Tel Number	I	N		
14	Attending Physician ID	I	N		
15	Special Field 1	I	N		
16	Special Field 2	I	N		
17	Patient Height	I	N		
18	Patient Weight	I	N		
19	Patient Known or Suspected Diagnosis	I	N		
20	Patient Active Medications	I	N		
21	Patient's Diet	I	N		

22	Practice Field No. 1	I	N		
23	Practice Field No. 2	I	N		
24	Admission Date and Discharge Date (if desired)	O	S	8	Admission date only. Formatted as YYYYMMDD.
25	Admission Status	I	N		
26	Location	O	S	20	
27	Nature of Alternative Diagnostic Code and classifiers	I	N		
28	Alternative Diagnostic Code and classification	I	N		
29	Patient Religion	I	N		
30	Marital Status	I	N		
31	Isolation Status	I	N		
32	Language	I	N		
33	Hospital Service	I	N		
34	Hospital Institution	I	N		
35	Dosage Category	I	N		
Legend:	R Required O Optional I Ignored A Always	D Down Load U Up Load N Never S Sometimes			

Example Patient Record (P)

	Download
Host	P 1 B108K MW5910^Smith 19861002 M Park Avenue^New York^NY^10002 20020923 Hematology
Analyzer System	P 1 B108K MW5910^Smith 19861002 M Park Avenue^New York^NY^10002 20020923 Hematology

Test Order Record (O)

Field	Field Title	Down Load	Up Load	Max Length	Description and Valid Values
1	Record Type ID	R	A	1	This is required field that contains an “O” identifying it as an order
2	Sequence Number	R	A	3	This field starts with “1” for the first Test Order Record and is incremented by 1 for each additional Test Order Record within the record. This will be reset to “1” whenever another patient record is transmitted.
3	Specimen ID	R	A	15	Although the operator can manually edit this field at any time, the value of this field is usually assigned by the laboratory computer before down loading. The <i>Analyzer</i> uses and reports its results based on the assigned specimen ID.
4	Instrument Specimen ID	I	N		
5	Universal Test ID	I I I R	N N N A	9	This is a four-component field: <ul style="list-style-type: none">• Universal Test ID Code (not used)• Universal Test ID Name (not used)• Universal Test ID Type (not used)• Manufacturer's or local code (6 characters): This is the code defined in the <i>Analyzer</i>.
6	Priority	I	N		
7	Request Ordered Date/Time	I	N		

8	Specimen Collected Date/Time	I	N		
9	Collection End Time	I	N		
10	Collection Volume/Units	I	N		
11	Collector ID	I	N		
12	Action Code	I	N		
13	Danger Code	I	N		
14	Relevant Clinical Info.	I	N		
15	Date/Time Specimen Received	I	N		
16	Specimen Type	R	A	1	This is a numeric field indicating the type of specimen: The Imm. System uses the following ASCII characters: 0 = Serum 1 = Urine
17	Ordering Physician	I	N		
18	Physician Tel. Number	I	N		
19	User Field No. 1	I	N		
20	User Field No. 2	I	N		
21	Lab Field No. 1	I	N		
22	Lab Field No. 2	I	N		
23	Date /Time Result Reported Last or Modified	I	N		

24	Instrument Charge	I	N		
25	Instrument Section ID	I	N		
26	Record Type	I	A	1	The field indicates the direction of the transmission: O - Down Loading F - Up Loading
27	Reserved Field	I	N		
28	Location or Ward of Specimen Collection	I	N		
29	Nosocomial Infection Flag	I	N		
30	Specimen Service	I	N		
31	Specimen Institution	I	N		
Legend:	R Required	D	Down Load		
	O Optional	U	Up Load		
	I Ignored	N	Never		
	A Always	S	Sometimes		

Example Test Order Record Layouts (O)**Download**

Host O | 1 | AR102 || ^^^GLU|||||0|||||O|||

Analyzer System O | 1 | AR102 || ^^^GLU|||||0|||||F|||

Results Record (R)

Field	Field Title	Down Load	Up Load	Max Len	
1	Record Type ID		A	1	This is a required field that contains an “R” identifying it as a Results Record.

2	Sequence Number		A	3	This field starts with “1” for the first result and is incremented by 1 for each additional result within the record. This will be reset to “1” when the results from another test order record are transmitted to the laboratory computer.
3	Universal Test ID	I I I R	N N N A	9	<p>This is a four-component field:</p> <ul style="list-style-type: none"> • Universal Test ID Code (not used) • Universal Test ID Name (not used) • Universal Test ID Type (not used) • Local Manufacturer's or local code (6 characters) this is the code defined in the <i>Analyzer</i>.
4	Data or Measurement value		A	10	‘Data’ is a 10-character, floating point field that includes the decimal point. The number of precision point digits will vary according to the test and is configurable on the <i>Analyzer</i> .
5	Units of Measure		A	6	This is a field for up to 6 characters that the operator defines for analytic measurement.
6	Reference Ranges		A	21	This field has two components; one giving the lower limit and the other the upper limit of the range. The format for this field is N^N.
7	Result Abnormal Flags		A	2	<p>This field indicates the normal status of the result. The following codes are valid values:</p> <p>L - Below Low normal H - Above High normal LL - Below Panic normal HH - Above Panic normal < - Below absolute low (under linearity) > - Above absolute high (over linearity) N - Normal A - Abnormal E – Edited</p>

8	Nature of Abnormality Testing		N		
9	Result Status		A	1	The Imm. System currently implements only two valid values: F - final results; V - operator verified/approved result.
10	Date of Change in Instrument Normative Values or Units		N		
11	Operator ID		N		
12	Date/Time Test Started		N		
13	Date/Time Test Completed		A	14	Date and Time of test completion: formatted as YYYYMMDDHHMMSS.
14	Instrument ID		N		
Legend:		R Required O Optional I Ignored A Always	D Down Load U Up Load N Never S Sometimes		

Example Result Record Layouts (R)

Upload	
Analyzer System	R 1 ^^^GLU 70.97 UL 70^105 N F 20020923114302

Message Terminator Record (L)

Field	Field Title	Down Load	Up Load	Max Len	Description and Valid Values
1	Record Type ID	R	A	1	This is a required field that contains an “L” identifying it as an Message Terminator Record.
2	Sequence Number	R	A	1	For a message terminator, this message should always be “1”.
3	Termination Code	R	A	1	This indicates the cause of termination. The following codes are valid values for

					the <i>Analyzer</i> : Null or N-normal termination
Legend:	R Required O Optional I Ignored A Always	D Down Load U Up Load N Never S Sometimes			

Example Message Terminator Record Layout (L)

Host	L I 1 I N
<i>Analyzer</i> System	L I 1 I N

Request Information Record (Q):

Field	Field Title	Down Load	Up Load	Max Len	Description and Valid Values
1	Record Type ID		A	1	This is a required field that contains a "Q" identifying it as a request.
2	Sequence Number		A	1	It is always "1".
3	Starting Range ID Number		A	31	This field can either be: "ALL" - to mean all demographics and tests being ordered should be sent to the instrument at this time, or can have two components: <ul style="list-style-type: none">• Computer system patient ID No. (up to 15 characters);• Computer system specimen ID No. (up to 15 characters).
4	Ending Range ID Number		N		
5	Universal Test ID		N		
6	Nature of Request Time Limits		N		
7	Beginning Request Results Date and Time		N		
8	Ending Request Results Date and Time		N		

9	Requesting Physician Name		N		
10	Requesting Physician Telephone Number		N		
11	User Field No. 1		N		
12	User Field No. 2		N		
13	Request Information Status Codes		A	1	It is always "O" (requesting test orders and demographics only).

Example Request Information Record Layouts (Q)

Download To

Analyzer System

```
H | \^& ||| SHAnalyzer||||||| 20020927100402
Q | 1 | ALL ||||||||| O
L | 1 | N
```

CHAPTER 11 – PACKING LIST

CUSTOMER - _____ **NATION -** _____ **DATE -** _____

Packing: Wooden Box N°1	Size: cm 65x80x77	Gross weight: 58 Kg	Net weight : 35 Kg
Carton Box N°2	: cm 60x40x25	: 5 Kg	: 4 Kg

INSTRUMENT

Ref.	Code	Description	Q.ty	Box N°	OK
01	16-00571-.....	CLINICAL CHEMISTRY ANALYZER ELLIPSE - S/N	1	1	
02	70-01832-00	ELLIPSE SOFTWARE – Rev.	1	2	

ACCESSORIES

Ref.	Code	Description	Q.ty	Box N°	
03	AS620005	POWER CORD	1	2	
04	32-01238-08	FUSE 6,3A-T 5x20	2	2	
05	9-35-0055-01	INTERCONNECTING CABLE (5 m)	1	2	
06	9-05-0078-00	RESERVOIR LEVEL SENSOR	4	2	
07	9-35-0041-00	BOTTLE 2 Lt.	4	2	
08	50-01831-00	BOTTLES INTERCONNECTING CABLE	1	2	
09	01-00217-00	REACTION RACKS	6	2	
10	AS650100/1	PACK OF 200 SAMPLE CUPS (1 mL)	1	2	
11	9-01-0609-00	ADAPTOR FOR SAMPLE CUPS	5	2	
12	650002/1	PACK OF 200 SAMPLE CUPS (0.8 mL)	1	2	
13	ASRN0020	CLEANING SOLUTION (2 x 250 ml)	1	2	
14	ASRN0021	RINSE SOLUTION (50 ml)	1	2	
15	01-00190-00	PACK REAGENT CONTAINER 35 ml	12	2	
16	01-00191-00	PACK REAGENT CONTAINER 6 ml	12	2	
17	90-01891-00	REAGENT CONTAINER SCREW CAP	24	2	
18	AS070096	SCREWDRIVER	1	2	
19	10-00586-00	PRIMARY TUBE SAMPLE RACK	4	2	
20	05-01829-00	SAMPLE CUP RACK	4	2	
21	55-01548-00	SPECIAL KEY FOR PROBE TIGHTENING	1	2	
22	90-01862-00	USER MANUAL	1	2	

List Rev. 02

CHAPTER 12

- DIAGNOSTIC PROGRAM -

INDEX

12 DIAGNOSTIC PROGRAM	3
12.1 STATUS BAR	6
12.2 TEST FOLDER	7
12.3 “ARM” FOLDER	8
12.3.1 VERTICAL COMMAND AREA	9
12.3.2 HORIZONTAL COMMAND AREA	9
12.3.3 STATUS COMMAND AREA	10
12.3.4 ARM SETTING COMMAND AREA	10
12.4 “DILUTER” FOLDER	11
12.4.1 OPERATIONS AREA	12
12.4.2 SENSOR STATE AREA	12
12.4.3 USER AREA	12
12.4.4 STATUS COMMAND AREA	12
12.5 “OPTIC” FOLDER	13
12.5.1 OPERATIONS AREA	13
12.5.2 SENSOR STATE AREA	14
12.5.3 FILTERS AREA	14
12.5.4 DIGITAL CONVERSION AREA	14
12.5.5 STATUS COMMAND AREA	14
12.6 “PLATE” FOLDER	15
12.6.1 OPERATIONS AREA	15
12.6.2 MOTOR ON/OFF AREA	16
12.6.3 STATUS COMMAND AREA	16

12.7 “TEMPERATURES” FOLDER	17
12.7.1 TEMPERATURES AREA	17
12.7.2 OFFSET AREA	18
12.7.3 TEMPERATURE TEST AREA	18
12.7.4 STATUS COMMAND AREA	19
12.8 “WASH” FOLDER	19
12.8.1 OPERATIONS AREA	20
12.8.2 TEST AREA	20
12.8.3 STATUS COMMAND AREA	20
12.9 “USER” FOLDER	21
12.9.1 USER TEST MICRO AREA	21
12.9.2 STATUS COMMAND AREA	22
12.10 “MISCELLANEOUS” FOLDER	22
12.10.1 GENERAL RESET AREA	23
12.10.2 LOG RAW DATA AREA	23
12.10.3 CONTINUOUS TEST RUN	23
12.10.4 STATUS COMMAND AREA	24
12.11 “GLOBAL SETTING” FOLDER	24
12.12 “MACRO SETTING” FOLDER	25
12.13 “CONFIGURATION” FOLDER	26

12 DIAGNOSTIC PROGRAM

The diagnostic program enables the operator to perform a complete check of each of the Ellipse module functions.

This program has a folder structure, with each folder containing functions pertaining to the specific module. To launch the program the operator has to click with the left side of the mouse, on the **Diagnostic** area located on the lower right side of the screen of the System Monitor (Fig.1).

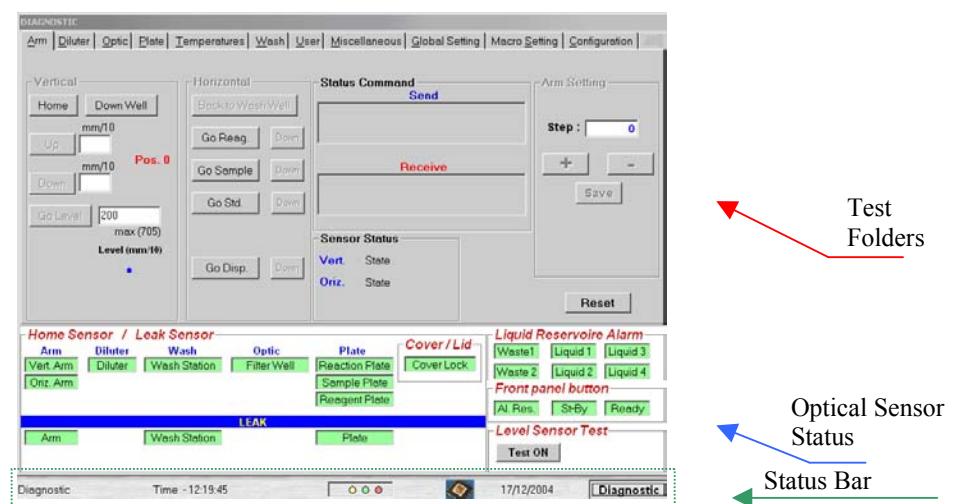
The Ellipse must be in the stand-by state to access this area.

Fig. 1



Once the program starts, the following screen appears (Fig. 2)

Fig. 2



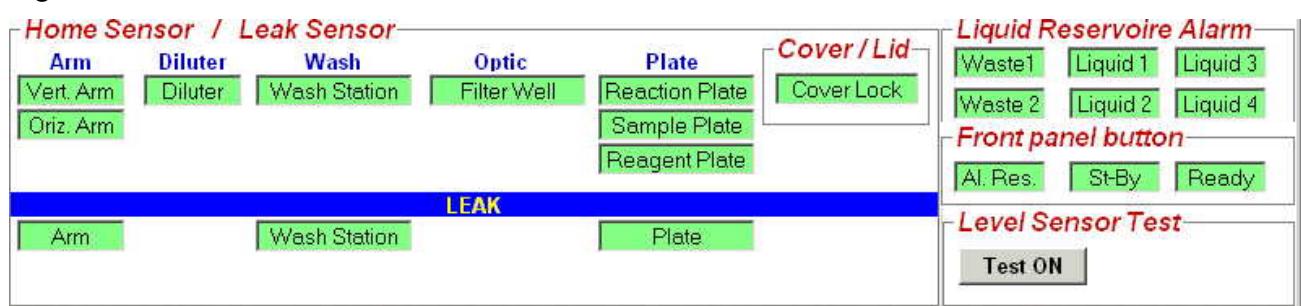
The diagnostic program is subdivided into three distinct areas: test folders, optical sensor status, status bar. The last two areas are present on every diagnostic window.

The three areas enable the operator to verify multiple functions as specified below:

Test Folders: checks the functionality of the Ellipse' various sub-systems; The individual functions are illustrated later on.

Optical Sensor Status: visualizes the sensor status that controls the Sampling Arm, the Diluter, the Washing Station, the Optical filter wheel, the Reaction plate, the Sample plate, the Reagent plate and the Cover Lock, as well as the Liquid Reservoir Alarm, the Front panel button and the Level Sensor Test (Fig. 3)

Fig. 3



Furthermore, there are three types of unused fields for future use: Leak for Arm, Washing Station and Plate. While the program is running, the fields given in the figure can be either of two distinct colors, red or green.

The fields:

- **Vertical Arm's Optical Switch (O.S.)**
- **Horizontal Arm's Optical Switch (O.S.)**
- **Diluter's Optical Switch (O.S.)**
- **Wash Station's Optical Switch (O.S.)**
- **Filter Wheel's Optical Switch (O.S.)**
- **Reaction Plate's Optical Switch (O.S.)**
- **Sample Plate's Optical Switch (O.S.)**

- **Reagent Plate's Optical Switch (O.S.)**

turn green when the specific device is in the home position, and turn red when not in the home position.

The field

- **Cover Lock**

turns green when the cover is closed, and turns red when open.

The fields:

- **Arm Leak Alarm** (Arm Leaking)
- **Wash Station Leak Alarm** (Wash Station Leaking)
- **Plate Leak Alarm** (Reaction Plate Leaking)

turn green when there is no leaking, and red when there is.

The following six fields signal the alarms for the bottles containing the washings liquids and waste materials:

- **Waste1 Liquid Reservoir Alarm**
- **Waste2 Liquid Reservoir Alarm**

turning green when the liquid level is not excessive, and red when the waste bottle indicated by the alarm is almost full.

- **Liquid 1 Liquid Reservoir Alarm**
- **Liquid 2 Liquid Reservoir Alarm**
- **Liquid 3 Liquid Reservoir Alarm**
- **Liquid 4 Liquid Reservoir Alarm**

turning green if the liquid level is above the predetermined minimum limit, and red if the liquid quantity is below the predetermined minimum level (the bottle is almost empty).

The following fields signal the state of the button on the Ellipse's operator panel:

- **AI.Res. Front Panel Button**
- **St-By Front Panel Button**
- **Ready Front Panel Button**

turning green when the button is not pushed in, and red if it is.

The field

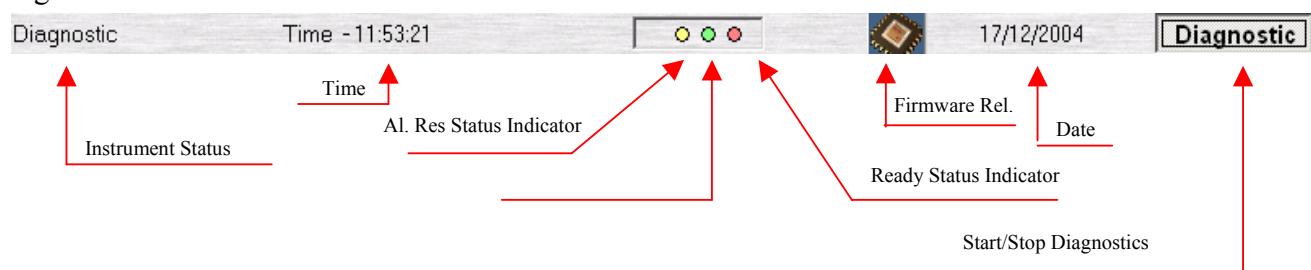
- **Test ON**

It is green fixed; if pushed, on the right of it will be showed a red drop that becomes temporarily green when the liquid is detected.

12.1 STATUS BAR

Monitors the instrument's status (Fig.4).

Fig. 4



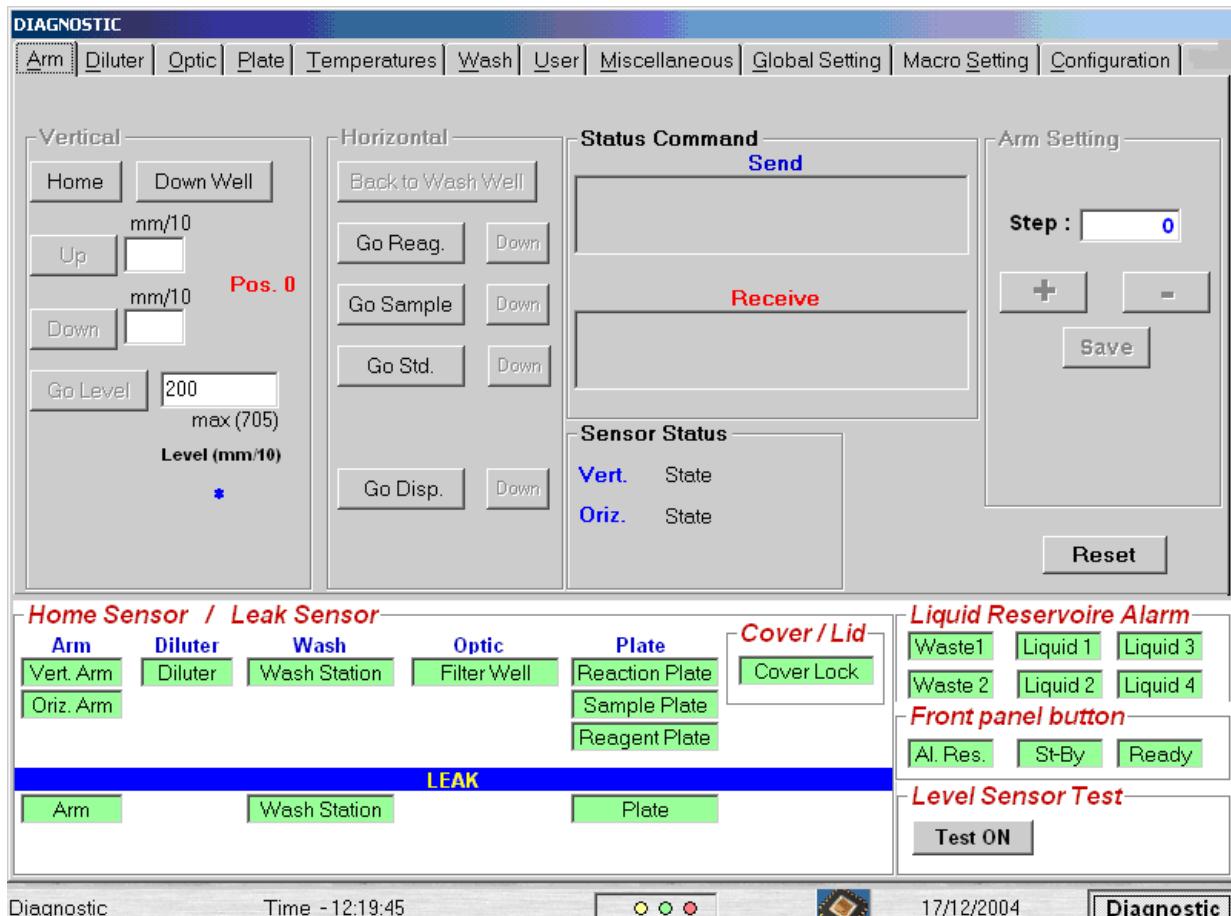
12.2 TEST FOLDER

The following is a summary of each individual test folder's function.

The Ellipse's diagnostic program is subdivided into 10 folders:

- Arm:** the adjustment of the arm position can be checked and carried out;
- Diluter:** checks if the diluter is functioning correctly;
- Optic:** checks if the optical block is functioning correctly;
- Plate:** checks if the reaction, samples and reagents plates are functioning correctly;
- Temperature:** checks the temperature of the pre-heater and reaction plate;
- Wash:** checks if the wash station is functioning correctly;
- User:** checks if the user functions are working properly;
- Miscellaneous:** performs general checks;
- Macro Setting:** the operator can identify which macros have been loaded;
- Configuration:** Through the use of a password, only qualified technical personal can adjust certain parameters (This file is not accessible to the Laboratory operator).

12.3 “ARM” FOLDER



Warning: the improper use of the functions described in this folder can damage the sampling probe.

The Arm File is subdivided into four areas:

- ◆ **VERTICAL**
- ◆ **HORIZONTAL**
- ◆ **STATUS COMMAND**
- ◆ **ARM SETTING**

12.3.1 VERTICAL COMMAND AREA

(5 commands)

- Home:** Brings the arm vertically to a home position;
- Down Well:** Brings the arm's axis "z" to the height of the well;
- Up:** Raises the arm tenths of a millimeter as preset in the square found immediately on the right, with relation to the previous Down movement; the box becomes active when the arm is positioned on a sample, a reagent, a standard or a cuvette.
- Down:** Lowers the arm tenths of a millimeter as pre-determined by the square found immediately on the right; the box becomes active when the arm is positioned on a sample, a reagent, a standard or a cuvette.
- Go Level:** Brings the probe to either the reagent level, the sample or the standard and reads the level. Before giving this command, it is necessary to set the parameter for the probe's maximum lowering level in the max area (mm);

12.3.2 HORIZONTAL COMMAND AREA

(5 commands)

- Back to wash well:** Brings the arm back to the home position;
- Go Reag.:** Brings the arm to the reagent position specified in the sheet menu next to the command;
- Go Sample:** Brings the arm to the sample position specified in the sheet menu next to the command;
- Go Std.:** Brings the arm to the standard/control position specified in the sheet menu next to the command;
- Go Disp.:** Brings the arm to the dispense position;

12.3.3 STATUS COMMAND AREA

- Send:** Visualizes the commands sent from the program to the instrument hardware;
- Receive:** Visualizes the answers of the instrument's hardware to the commands sent by the program;
- Sensor State:** Indicates the sensor status relative to the arm's vertical axis, the internal arm and the external arm.

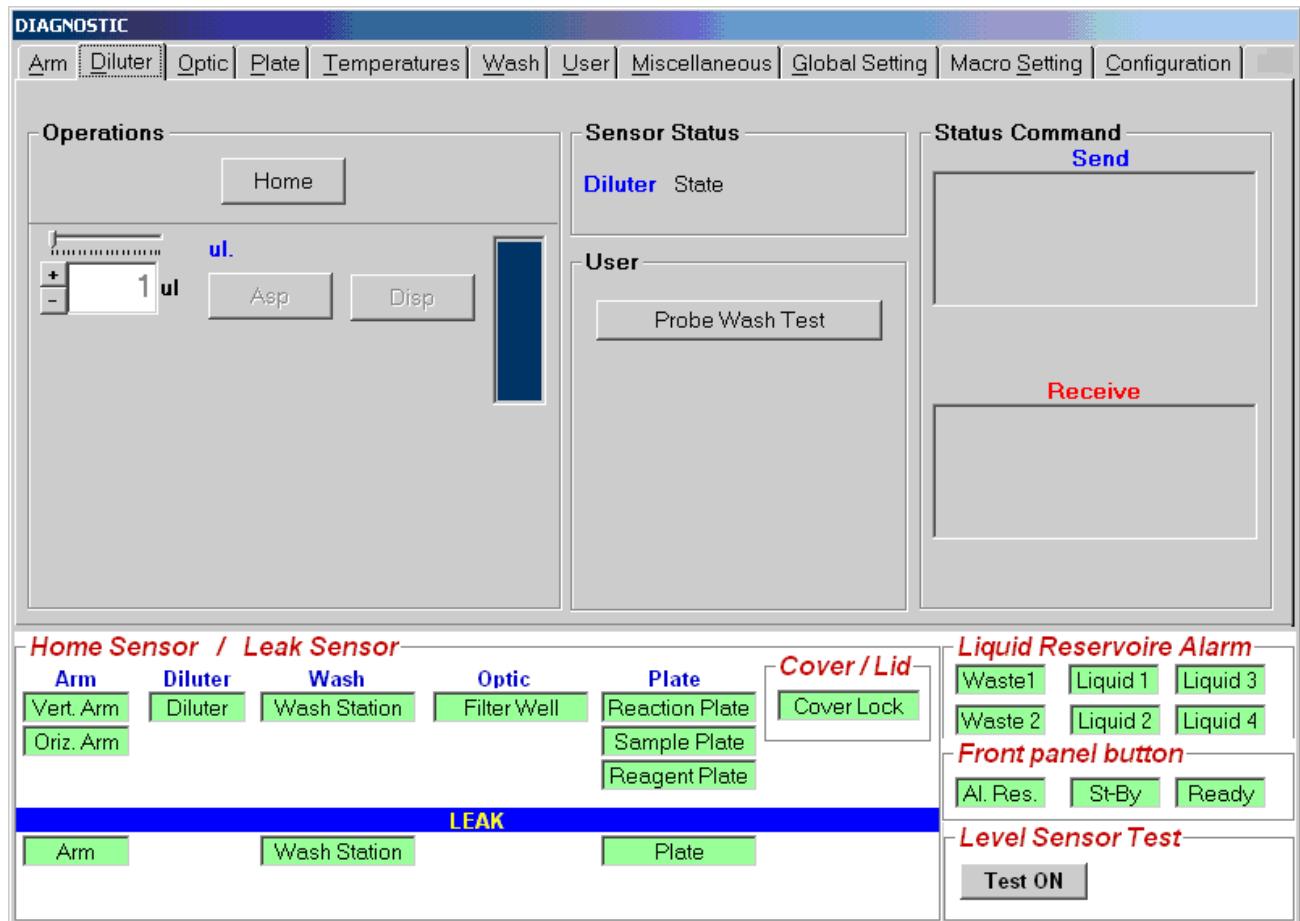
12.3.4 ARM SETTING COMMAND AREA

(5 commands)

- Step:** Visualizes the number of steps.
- + :** Performs the counter-clockwise rotation of the arm (to adjust the position);
- :** Performs the clockwise rotation of the arm (to adjust the position);
- Save:** Saves the adjustment data;
- Reset:** Completely resets the Arm

In this area the boxes can be activated when the arm is positioned on a sample, a reagent, a standard or a control or a cuvette.

12.4 “DILUTER” FOLDER



The Diluter Folder is subdivided into four areas:

- ◆ **OPERATIONS**
- ◆ **SENSOR STATE**
- ◆ **USER**
- ◆ **STATUS COMMAND**

12.4.1 OPERATIONS AREA

(3 commands)

- Home:** Brings the diluter to the Home position;
- Asp:** Aspirates the micro-litres as predetermined in the ul. box (may be set manually through + and – or by using the cursor located immediately above);
- Disp.:** Distributes the micro-litres as predetermined in the ul. box (may be set manually through + and – or by using the cursor located immediately above);

12.4.2 SENSOR STATE AREA

In the Sensor State area the diluter sensor status is indicated.

12.4.3 USER AREA

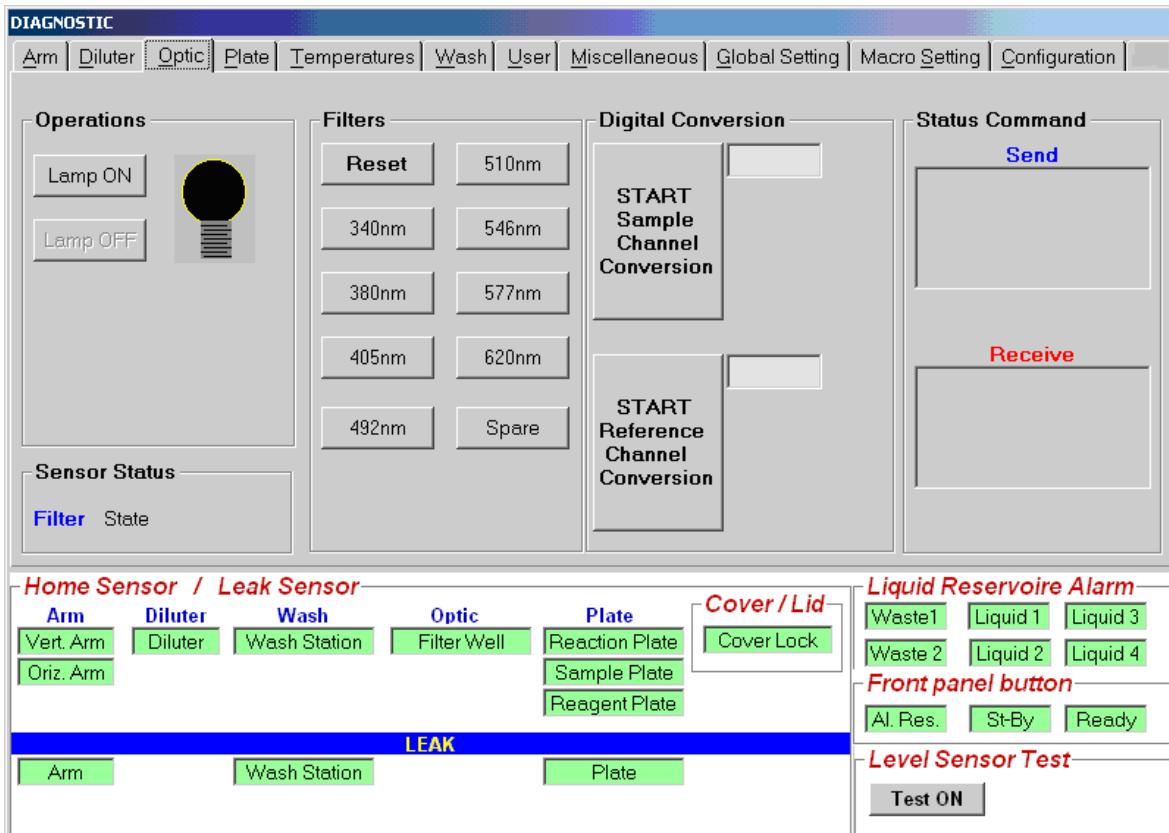
(1 command)

Probe Wash Test: Activates and deactivates the probe wash system

12.4.4 STATUS COMMAND AREA

- Send:** Visualizes the commands sent by the program to the instrument hardware;
- Receive:** Visualizes the instrument hardware's response to the commands sent by the program.

12.5 “OPTIC” FOLDER



The Optic folder is subdivided into five areas:

- ◆ **OPERATIONS**
- ◆ **SENSOR STATUS**
- ◆ **FILTERS**
- ◆ **DIGITAL CONVERSION**
- ◆ **STATUS COMMAND**

12.5.1 OPERATIONS AREA

(2 commands)

Lamp ON: Turns on the Optic Lamp;

Lamp OFF: Turns off the Optic Lamp;

12.5.2 SENSOR STATE AREA

This area indicates the status of the wheel filters.

12.5.3 FILTERS AREA

(10 commands)

- Reset :** Positions the wheel filters in home position (dark);
- 340 nm:** Positions filter n° 1 in front of the reading sensor;
- 380 nm:** Positions filter n° 2 in front of the reading sensor;
- 405 nm:** Positions filter n° 3 in front of the reading sensor;;
- 492 nm:** Positions filter n° 4 in front of the reading sensor;
- 510 nm:** Positions filter n° 5 in front of the reading sensor;
- 546 nm:** Positions filter n° 6 in front of the reading sensor;
- 577 nm:** Positions filter n° 7 in front of the reading sensor;
- 620 nm:** Positions filter n° 8 in front of the reading sensor;
- Spare:** Positions filter n° 9 in front of the reading sensor (Optional);

12.5.4 DIGITAL CONVERSION AREA

(2 commands)

START/STOP Sample Channel Conversion: Performs an analogical/digital conversion of the principal channel;

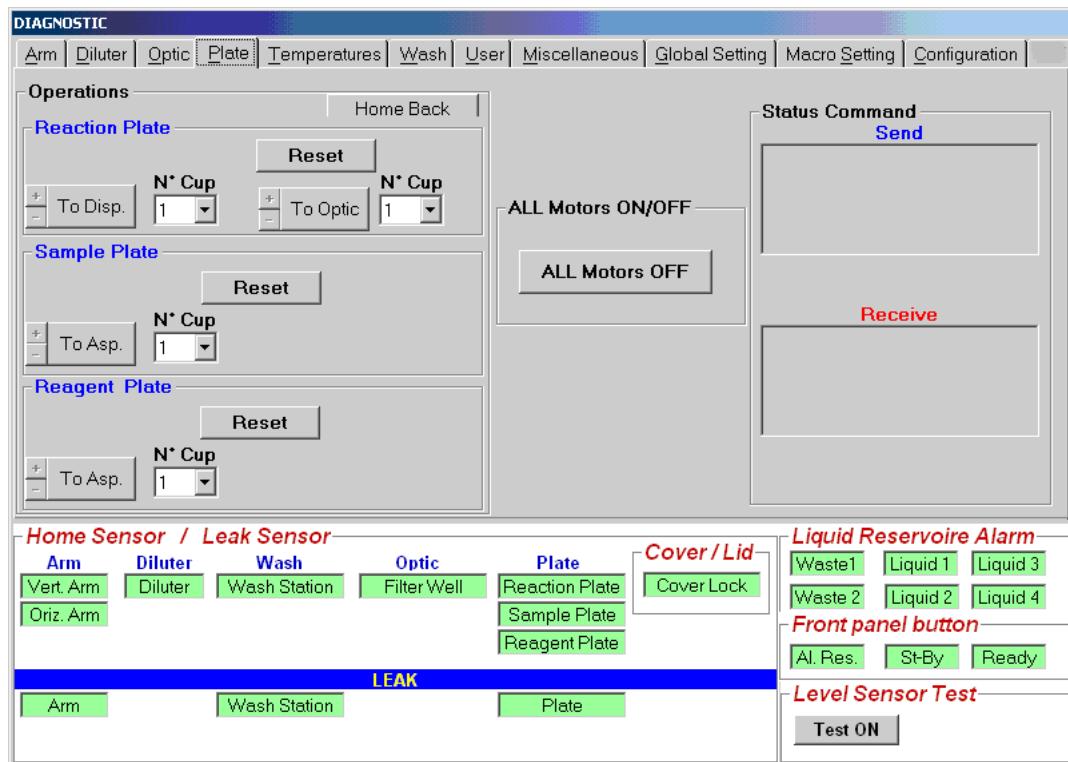
START/STOP Reference Channel Conversion: Performs an analogical/digital conversion of the reference channel;

12.5.5 STATUS COMMAND AREA

Send: Visualizes the commands sent by the program to the instrument hardware;

Receive: Visualizes the instrument hardware's response to the commands sent by the program.

12.6 “PLATE” FOLDER



The Plate Folder is subdivided into three areas:

- ◆ **OPERATIONS**
- ◆ **ALL MOTORS ON/OFF**
- ◆ **STATUS COMMAND**

12.6.1 OPERATIONS AREA

Reaction Plate area:

(3 commands)

To Disp.: Automatically positions the cuvette, indicated on the sheet menu aside, under the dispensing position

- To Optic:** Automatically positions the cuvette, indicated on the sheet menu aside, in front of the colorimeter
- Reset:** Performs the reset of the reaction plate by positioning the # 1 cuvette in the dispensing position

Sample Plate area:

(2 commands)

- To Asp.:** Automatically brings sample, indicated on the sheet menu aside, under the aspiration position
- Reset:** Performs the reset of the sample plate by positioning the # 1 sample in the aspiration position

Reagent Plate:

(2 commands)

- To Asp.:** Automatically brings reagent, indicated on the sheet menu aside, under the aspiration position
- Reset:** Performs the reset of the sample plate by positioning the # 1 reagent in the aspiration position

12.6.2 ALL MOTORS ON/OFF AREA

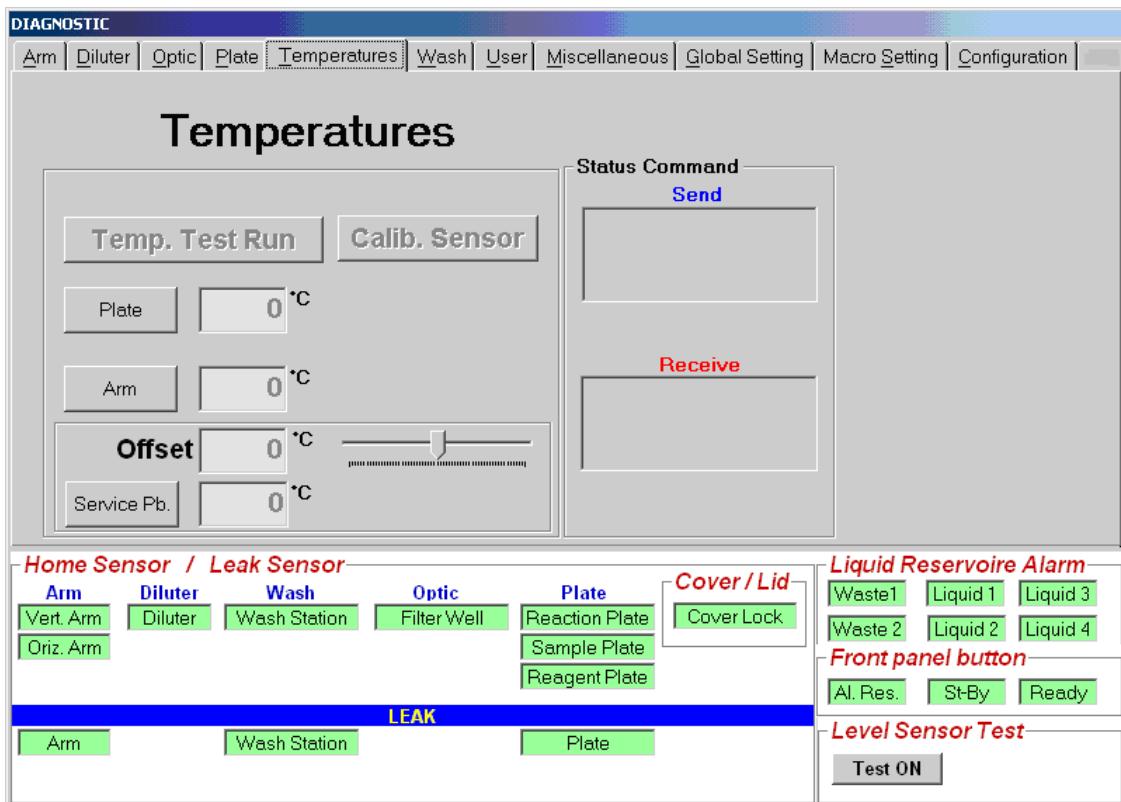
(1 command)

ALL Motors ON/OFF: Engages/Disengages the motors to allow a manual movement of the modules (Sampling Arm; Reaction, Reagents and samples Plates, Washing Station, Filter Wheel and Peristaltic Pump).

12.6.3 STATUS COMMAND AREA

- Send:** Visualizes the commands sent by the program to the instrument hardware;
- Receive:** Visualizes the instrument hardware's response to the commands received from the program.

12.7 “TEMPERATURES” FOLDER



The Temperature Folder is subdivided into three areas:

Temperatures

Offset

Status Command

12.7.1 TEMPERATURES AREA

(4 commands)

- Temp. Test Run:** To enter in the Temperature Test folder
- Plate:** Performs a temperature reading in the reaction plate compartment;
- Arm:** Performs a temperature reading in the arm's pre-heater.
- Calib. Sensor:** To carry out the calibration procedure of the thermometric probe included in the kit P/N 55-01204-00, as illustrated in Chapter Six “Settings and Adjustments”.

12.7.2 OFFSET AREA

(2 commands)

To correlate the thermometric probe included in the kit P/N 55-01204-00 with another reference thermometric probe.

Service probe: The offset value that has been previously inserted and the temperature value read by the thermometric probe appear in the closed fields.

Cursor: To enter the offset value $\pm 3 \text{ C}^\circ$. The offset value will be zero after exiting from the folder.

12.7.3 TEMPERATURE TEST AREA



(3 commands)

START: To perform the test check and to regulate the temperature of the preheater and of the reaction plate by using the kit P/N 55-01204-00, as illustrated in Chapter 6 “Setting and Adjustments”.

The number of sample cycles are predefined, whereas the reagent and sample positions for test execution can be selected by the operator.

Service Probe: the field in which the temperature of the service probe appears.

WASH: To run a wash cycle on the cuvettes used for testing.

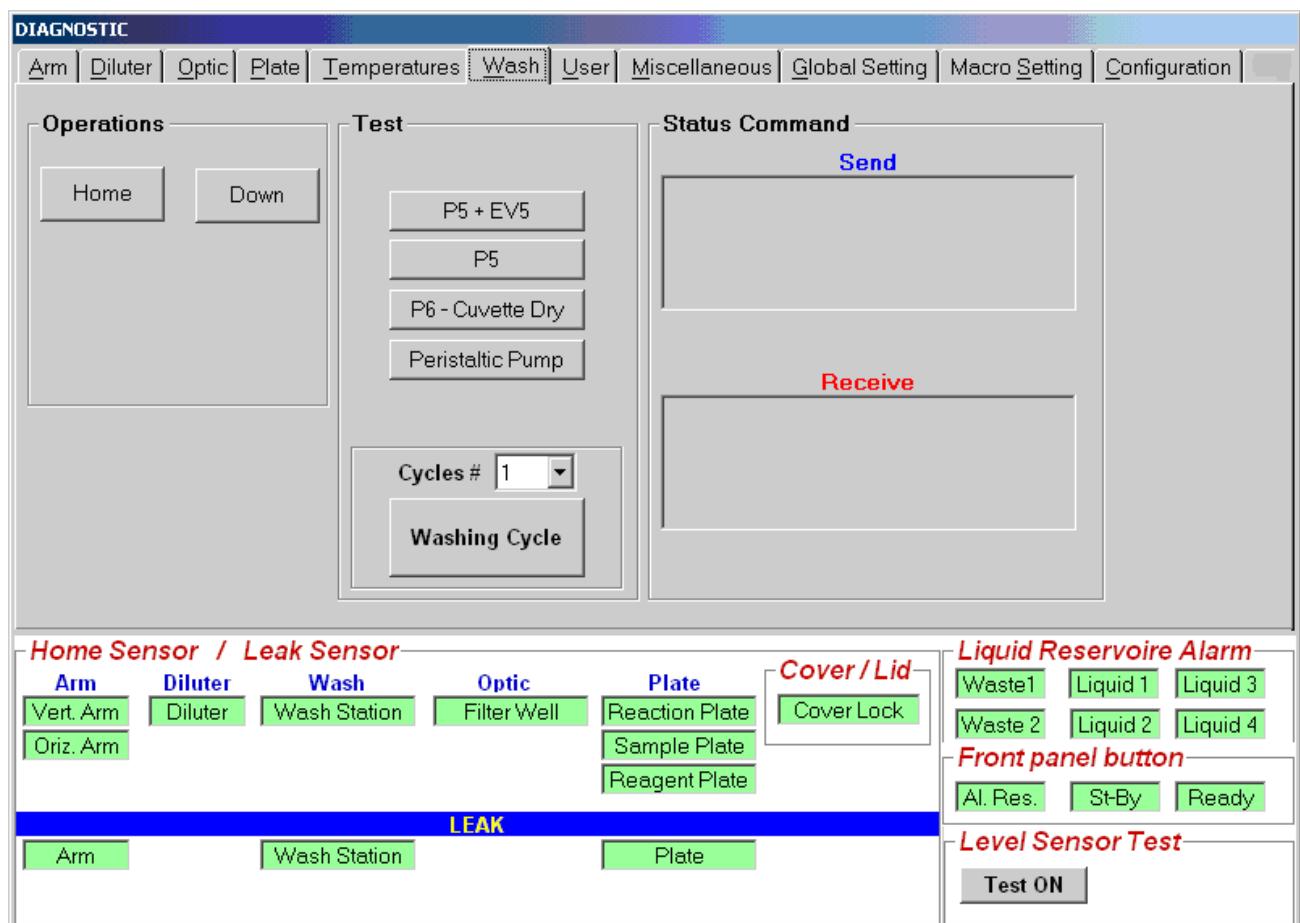
EXIT: To exit from the Temperature Test box and to run a wash cycle on the cuvettes if they have been used.

12.7.4 STATUS COMMAND AREA

Send: Visualizes the commands sent by the program to the instrument hardware;

Receive: Visualizes the instrument hardware's response to the commands sent by the program.

12.8 “WASH” FOLDER



The Wash folder is subdivided into three areas:

- ◆ **OPERATIONS**
- ◆ **TEST**
- ◆ **STATUS COMMAND**

12.8.1 OPERATIONS AREA

(2 commands)

Home: Brings the washing device to the Home position;

Down: Makes the washing device go down to the washing position.

12.8.2 TEST AREA

(5 commands)

Test P5 + E.V. 5: Performs switching on of the E.V. 5 solenoid valve and turns on the P5 pump and automatically switching off the E.V. 5 solenoid valve and turns off the P5 pump after a period of four seconds

Test P5: It turns on the μ P5 pump and automatically turns it off after a period of four seconds.

Test P6–Cuvette Dry: It turns on the μ P6 pump and automatically turns it off after a period of four seconds.

Peristaltic Pump: It turns on the peristaltic pump and automatically turns it off after one second.

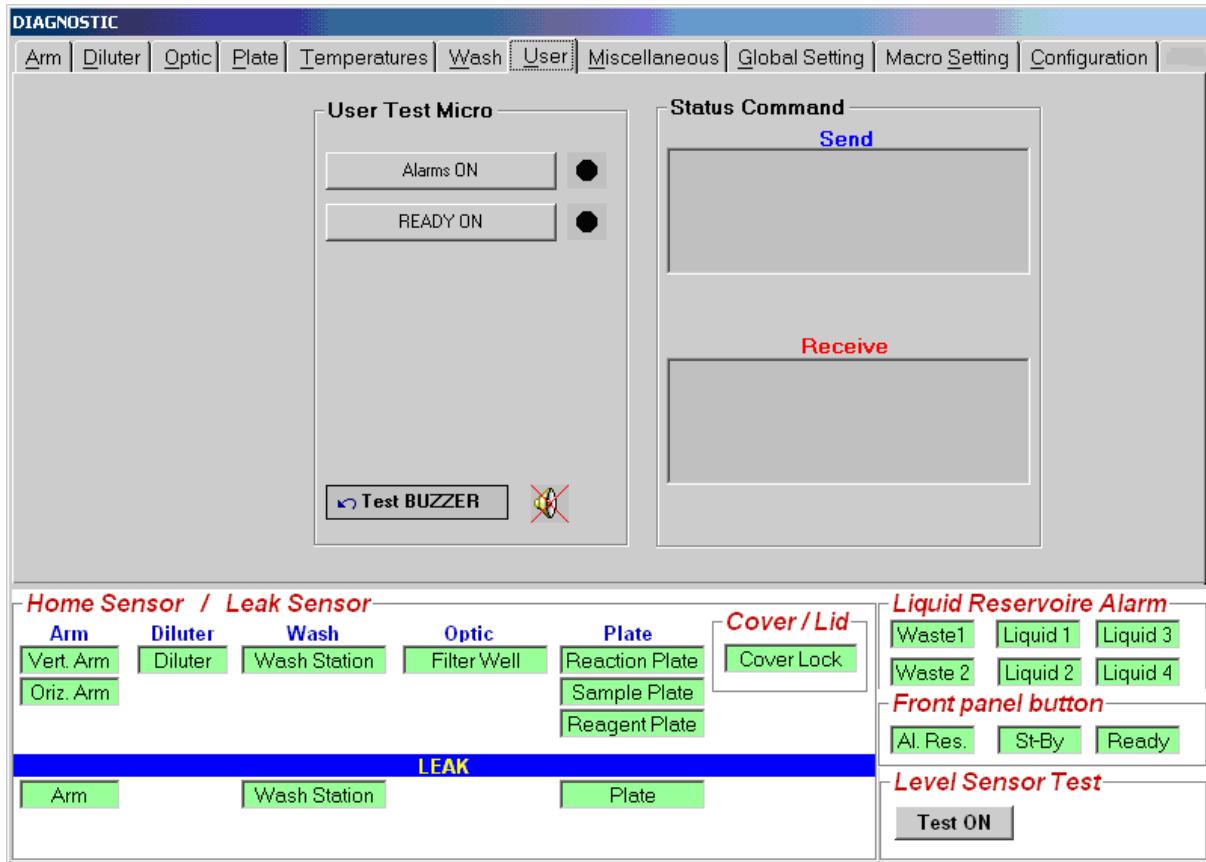
Washing Cycle: It performs the functional check of the Washing Station , as illustrated in Chapter Six “Settings and Adjustments”.

12.8.3 STATUS COMMAND AREA

Send: Visualizes the commands sent by the program to the instrument hardware;

Receive: Visualizes the instrument hardware’s response to the commands sent by the program.

12.9 “USER” FOLDER



The User Folder is subdivided into two areas:

- ◆ **USER TEST MICRO**
- ◆ **STATUS COMMAND**

12.9.1 USER TEST MICRO AREA

(3 commands)

Alarms ON: Turns on and off the Alarms indicator lamp;

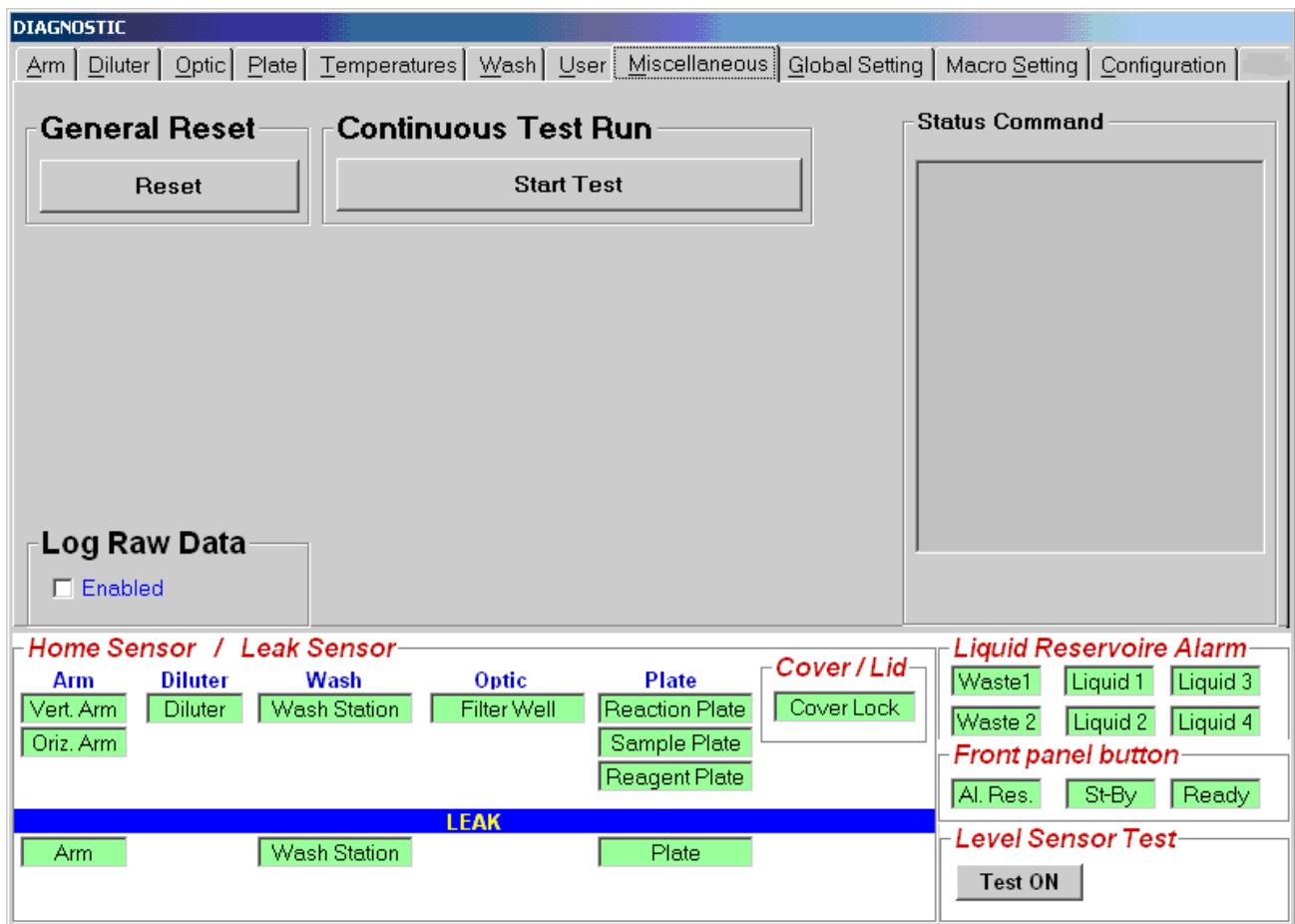
Ready ON: Turns on and off the READY indicator lamp;

Test BUZZER: Performs a complete operational test of the buzzer;

12.9.2 STATUS COMMAND AREA

- Send:** Visualizes the commands sent by the program to the instrument hardware;
- Receive:** Visualizes the instrument hardware's response to the commands sent by the program.

12.10 “MISCELLANEOUS” FOLDER



The Miscellaneous folder is subdivided into four areas:

- General Reset
- Log Raw data
- Continuous Test Run
- Status Command

12.10.1 GENERAL RESET AREA

(1 command)

Reset: Performs the resetting of the general system.

12.10.2 LOG RAW DATA AREA

(1 command)

Enable: To save a copy of the files for the technical diagnosis if the instrument malfunctions. The files are memorized in the folder “Log” inside the folder “Analyzer”.

12.10.3 CONTINUOUS TEST RUN

(1 command)

Start Test: Performs an automatic test during which the modules (Sampling Arm, Reaction plate, Washing Station and Photometer) are moved to all the different positions.

The correct modules positioning is also automatically verified and showed on the following table:

Mechanical Test		
Go Reagent	22	OK
Down 400 Step		OK
Vertical Home		OK
Go Home (Arm)		OK
Go Sample or Std/Ctrl	Std. 5	OK
Down 400 Step		OK
Vertical Home		OK
Go Home (Arm)		OK
Move Cuvette to Disp.	31	OK
Go Disp.		
Down 400 Step		
Vertical Home		
Go Home (Arm)		
Move Cuvette to Optic		
Down Wash		
Home Wash		
Exit Test		

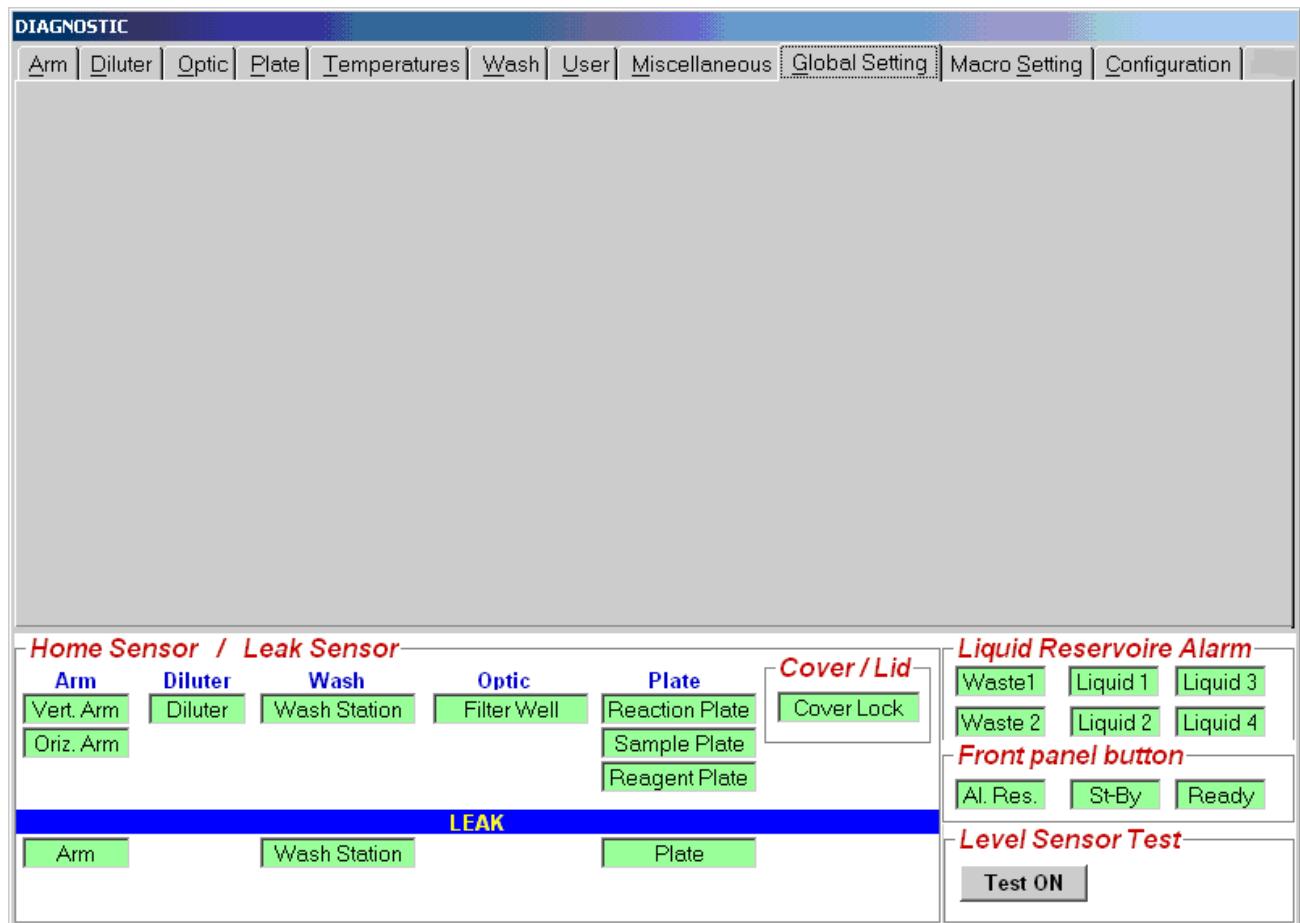
To stop the test push on the “Exit Test” key

12.10.4 STATUS COMMAND AREA

Send: Visualizes the commands sent by the program to the instrument hardware

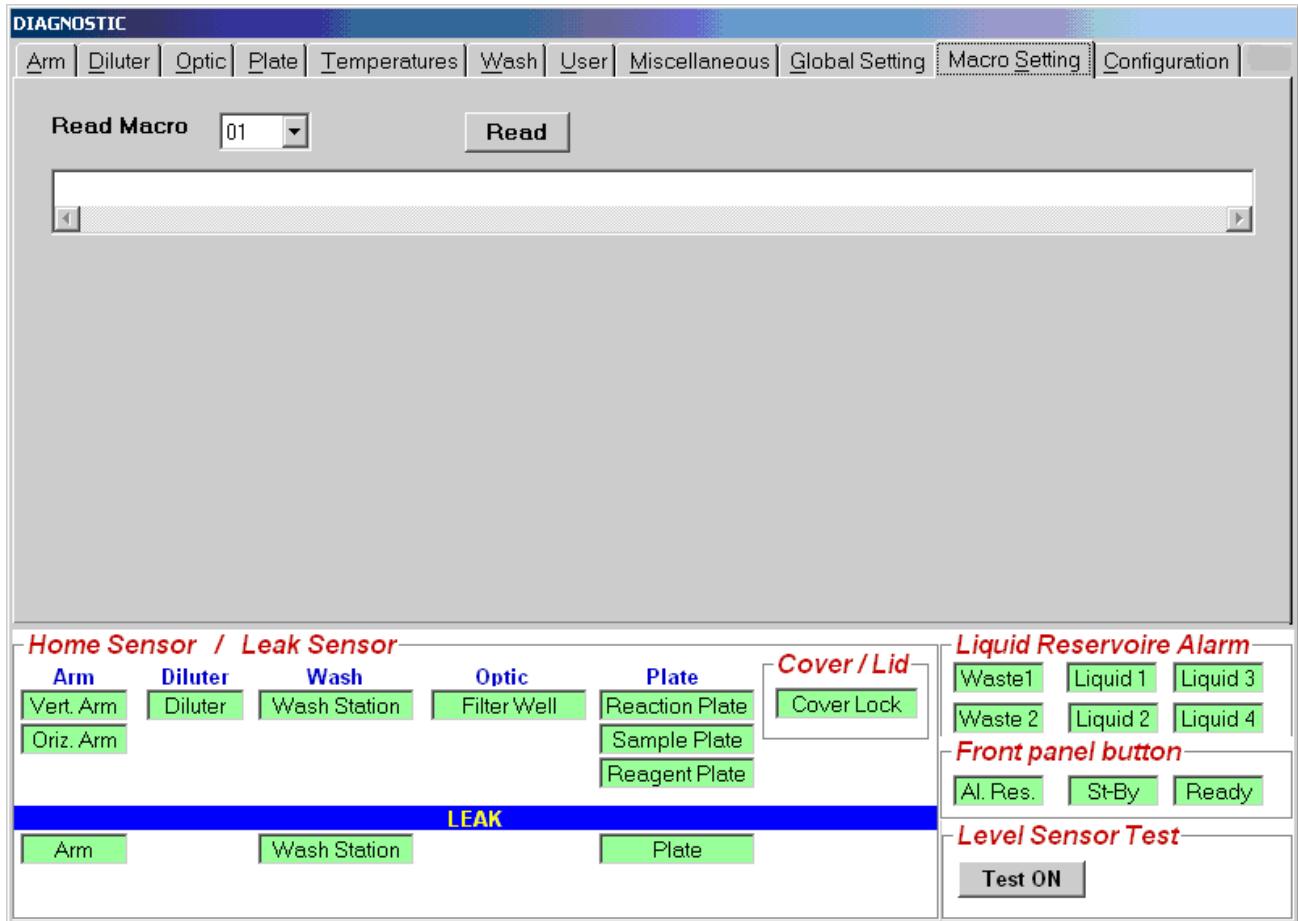
Receive: Visualizes the instrument hardware's response to the commands.

12.11 “GLOBAL SETTING” FOLDER



The Global Setting Folder is for next application.

12.12 “MACRO SETTING” FOLDER



This folder allows the user to read the macro present in the Ellipse.

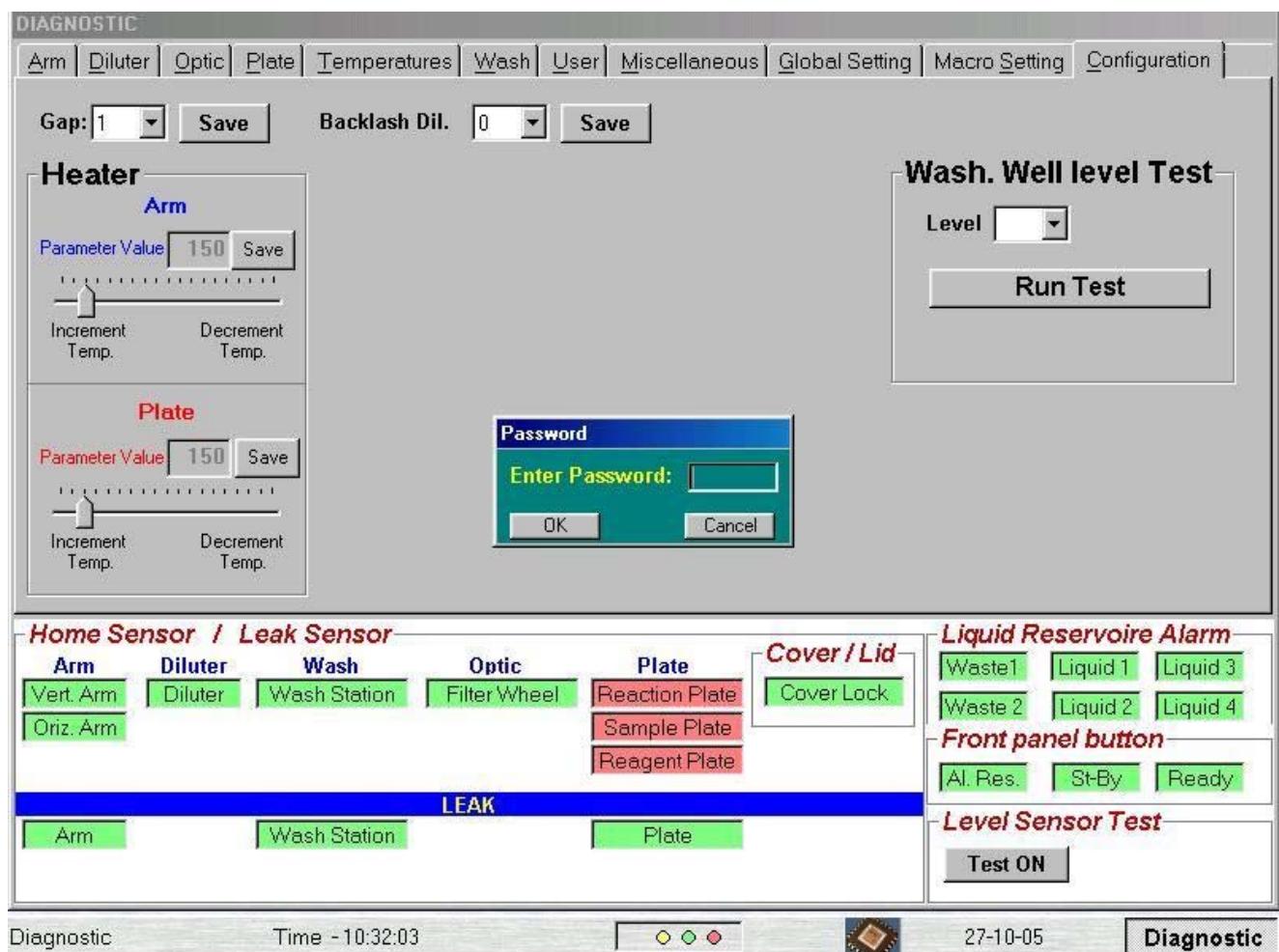
To read the macro follow the below procedure:

- ⇒ Select from the menu sheet “Read Macro” the number of relevant macro;
- ⇒ Click with the left side of the mouse on the Read area;
- ⇒ If the Macro requested exists, the information will appear in the designated area.

12.13 “CONFIGURATION” FOLDER

This folder may be accessed only by qualified technical assistant.

It is necessary for the technical assistant to insert a password to access this folder.



The Configuration Folder is subdivided into four areas:

- **Gap**
- **Backlash Dil.**
- **Heater**
- **Wash. Well level Test**

Gap: defines the volume, in μL , of the air bubble that separates the Rinse (the liquid column into the sampling arm tube) from the sampled reagent; this volume must be set in the range from 10 to 24 (Standard value 16).

For the correct setting of the gap volume it is necessary to apply the procedure of BIB (Precision check of the Analytical plate) and BIC (Volume precision check of the Sampling line).

If BIC's CV values should exceed the limit specified below, the GAP has to be increased by steps of 2 μL (starting from 10 μL) until obtaining the expected BIC's CV value

Precision check of the Analytical plate **BIB**

Prepare two series of 32 samples each by using a diluted solution of **K2Cr2O7** (obtained from 4 gr/l concentrated solution diluted 1:100 with Rinse solution (distilled water + 1000 $\mu\text{L}/\text{litre}$ of Brij))

Use the same solution as samples and reagent

Program a new method with the following parameters:

Method name: **BIB**

Type: **End Point**

Sample volume **K2Cr2O7 0,04 gr/l** 3 μL

Reagent volume **K2Cr2O7 0,04 gr/l** 300 μL

Rinse volume 20 μL

Filter: 340 nm

Incubation time: 116 sec

Calculation factor: 1000

BIB Procedure

1. Select conical cup in **Options**
2. Program the BIB method using the above parameters and configure a reagent rack containing it
3. Enter in the calibration screen and select RBL for BIB method.
4. Put the Rinse solution as reagent and standard (fourteenth position of the Crt/Std rack) and Start the Calibration

5. Program 64 BIB; fill 32 conical samples cup with **K2Cr2O7 0,04 gr/l**
6. Load the samples racks into the Analyzer at positions 1 and 2
7. Substitute the Rinse Solution with **K2Cr2O7 0,04 gr/l** in the reagent rack
8. Start the Analyzer. At the end of the last sampling, move the samples racks to positions 3 and 4.

The mean of the reading obtained from each of the 32 sample series must fall within **360 ÷ 400**.

The coefficient of variation (CV %) must be lower than **0.7 %** for each series of 32 samples.

Precision check of the Sampling volume **BIC**

Prepare two series of 32 samples each by using **K2Cr2O7 4 gr/l** (concentrated)

Put Rinse Solution as reagent and **K2Cr2O7** solution as sample.

Program a new method with the following parameters:

Method name: **BIC**

Type: **End Point**

Sample volume K2Cr2O7 4 gr/l	3 µL
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Reagent volume RINSE Solution (distilled water + 1000 µL/litre of Brij)	300 µL
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Filter:	340 nm
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Incubation time:	116 sec
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Calculation factor:	1000
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BIC Procedure

1. Program the BIC method using the above parameters and configure a reagent rack
2. Enter in the Calibration screen and select RBL for BIC method.
3. Put the Rinse Solution as reagent and Standard (fourteenth position of the Crt/Std rack) and Start the Calibration
4. Program 64 BIC ; fill 32 conical samples cup with **K2Cr2O7 4 gr/l** (concentrated)
5. Load the samples racks into the Analyzer at positions 1 and 2
6. Start the Analyzer. At the end of the last sampling, move the sample racks to positions 3 and 4.

The mean of the readings obtained from each of the 32 sample series must fall between **350 ÷ 450**.

The coefficient of variation (CV %) must be lower than **1.6 %** for each series of 32 samples

If BIC's CV values should exceed the limit specified above, the GAP has to be increased by steps of 2 µL (starting from 10 µL) until obtaining the expected BIC's CV value

Backlash Dil.: Allows to recover the sampling imprecision generated by the motor when it inverts its rotation; the setting is expressed in µL and obtained by using the following procedure:

1. Enter in the Diagnostic Arm folder menu and make the Sampling Arm “Reset”
2. Enter in the **Diluter** folder, press the “HOME” button and then Push “PROBE WASH TEST” button three times in order to fill the hydraulic sampling line
3. Remove the plastic cover of the sample racks vane and take out the samples racks
4. Enter in the **ARM** folder and push the “GO” button in order to move the probe to sample position # 1
5. Put a sample cup containing distilled water (about 1ml) under the sampling probe
6. Enter in the **DILUTER** folder and aspirate 300 µL of distilled water from the cup
7. Remove the sample cup containing distilled water
8. Select 1 µL to dispense and press the “Disp” key repeatedly until water appears on the tip of the probe.
9. Subtract 1 from the number of times you pressed the “Disp” key. The obtained number has to be introduced as BACKLASH value
10. Push the **Save** button to memorize the inserted data
11. Push the **Reset** button into the ARM folder
12. Close the Diagnostic program by clicking on the Diagnostic button

Heater: to adjust the preheater and reaction plate temperatures;

Wash. Well level Test: By clicking on the “Run Test” button the system performs an automatic verification and adjustment cycle for the liquid level in the washing well. A number appears in the box “Level” that corresponds to the rotation time of the rinse pump in milliseconds, that is necessary to maintain the correct liquid level in the washing well.
The functioning range is between 350 and 700 milliseconds. If the washing well is not sufficiently filled, a message appears to warn the user to check the hydraulic line.
If the value taken during the test is different from the previous one, it is necessary to click on “Save” in order to save the new data.