User Manual

Clinical Chemistry System

SAT450

User Manual - Rev. 06

Analyzer
Medical
System

CHAPTER 01

– CONFIGURATION SHEET –

CHAPTER	DESCRIPTION	REVISION
01	***CONFIGURATION SHEET***	***06***
02	SYSTEM DESCRIPTION	01
03	SOFTWARE DESCRIPTION	07
04	USER INSTALLATION	03
	❑ Appendix A: *Software Installation Procedure*	03
05	DIAGNOSTIC PROGRAM	08
06	FORMULAS AND CALCULATION MODELS	03
07	USER MAINTENANCE	01
08	DAILY ROUTINE	01
09	ERROR SIGNALLING AND TROUBLESHOOTING	08

CHAPTER 02

– SYSTEM DESCRIPTION –

INDEX

2 DESCRIPTION OF THE SYSTEM…….....2

2.1 Introduction……2

2.2 Sampling Arm……2

2.3 Diluter…….…2

2.4 Reactions Plate……...3

2.5 Samples Plate…….…3

2.6 Reagents Plate……3

2.7 Photometer…….…4

2.8 Washing Station…….…4

2.9 Reagents and Samples Barcode Readers…….5

2.10 ISE Module…….5

2 DESCRIPTION OF THE SYSTEM

2.1 INTRODUCTION

The *SAT 450* is a benchtop, fully automatic, random access, open analyzer for clinical and immunoturbidimetric assays.

It communicates with a computer through a USB and/or RS 232 port.

The *SAT450* instrument is composed of the following main parts:

- Sampling Arm;
- Diluter;
- Reactions Plate;
- Samples Plate;
- Reagents Plate;
- Photometer;
- Washing Station;
- Electronic Boards;
- Barcode Readers (*optional*);
- ISE Module (*optional*).

2.2 SAMPLING ARM

One mechanical Arm performs all sampling operations. It is able to reach the aspiration point of the Reagents Plate, the aspiration point of the Samples Plate, the delivery point of the Reactions Plate and the two Washing Wells.

A specific sampling Probe is connected on its head. The Sampling Arm can move vertically and horizontally with respect to the Raising Top of the instrument by means of two stepper motors, respectively. The horizontally movement take place along a arch of circumference.

A Pre-Heater Assy allows a reagent pre-warming at 37.0 °C. Moreover, one Level Sensor Assy - opportunely connected to the Sampling Probe - allows a liquid level (capacitive) sensing.

2.3 DILUTER

The Diluter allows to perform all the operations of aspiration and delivery of the liquid up till the capacity of 1000 µl. It is connected to the Sampling Arm and to its electrovalve and micropump. It is able to sample volumes of 0.25 µl, with a CV less than 1%.

The device is actuated through the movement of a unique central piston for the operations of aspiration and delivery of the liquid. The piston is moved through a stepper motor without use of step-down gears to minimize the backlash. Moreover, in this device are implemented some solutions to avoid the presence of air microbubble inside it and inside the hydraulic circuit.

2.4 REACTIONS PLATE

The Reactions Plate of the instrument contains 4 disposable racks with 20 reaction cuvettes each, for a total of 80 cuvettes. Each of them has a optical path of 6 mm. The reactions racks can be removed individually. The plate is covered by a specific plate cover.

The plate can rotate through a stepper motor. This motor assures a high precision of positioning, superior to ±0.1°.

The basic operating cycle includes: aspiration and dispensing of the reagents and the samples by the Sampling Arm in the reaction cuvettes, optic reading of the cuvettes in incubation by the Photometer - along with the relative positioning of the Reactions Plate -, washing of the filled cuvettes by a Washing Station.

The incubation temperature in the reactions cuvettes is controlled at 37° C ± 0.3 by a controlled heating unit (Reactions Plate Resistor) placed inside the Reactions Plate .

2.5 SAMPLES PLATE

The Samples Plate is composed from a main plate that revolves around its axis and from the four Satellite Racks (“A”, “B”, “C” and “D”) which, each of them, revolve at the same time around to own axis. Therefore, the Samples Plate is apt to describe a substantially hypocycloidal motion.

The main plate can rotate through a stepper motor, whereas the four Satellite Racks can rotate through another stepper motor. This two motors assure a high precision of positioning. The two different rotations are controlled through the respective Home Sensors.

The four separate Satellite Racks (“A”, “B”, “C” and “D”) are universal racks for continuous loading of samples, calibrators and controls. Each Satellite Rack contains up to 15 AMS cups (3,7 ml) and/or tubes with 10÷16 mm of diameter and 40÷100 mm of height. Moreover, 8 extra positions - for the same AMS cups and/or tubes - are positioned on the main plate for urgent samples, calibrators and controls.

The Samples Plate is covered by means of two covers: Samples Plate cover and Samples Plate safety protection. Removing only the Samples Plate safety protection allows the replacement of the Satellite Racks for continuous loading. A urgent sample execution is allowed at any time.

2.6 REAGENTS PLATE

The Reagents Plate is composed from a main plate that revolves around its axis and from the four Satellite Racks (“A”, “B”, “C” and “D”) which, each of them, revolve at the same time around to own axis. Therefore, the Reagents Plate is apt to describe a substantially hypocycloidal motion.

The main plate can rotate through a stepper motor, whereas the four Satellite Racks can rotate through another stepper motor. This two motors assure a high precision of positioning. The two different rotations are controlled through the respective Home Sensors.

Each of four removable universal racks (“A”, “B”, “C” and “D”) contains 8 positions for triangular bottles of 50 ml. Each of eight triangular bottles of 50 ml can be substituted with two triangular bottles of 20 ml or, by a adaptor, with two micro-cup of 5 ml. Moreover, 8 extra positions for rounded bottles of 10/20 ml are positioned on the main plate. Over each of four peripheral racks (“rA”, “rB”, “rC” and “rD”) can be positioned, by a adaptor, two AMS cups of 3,7 ml.

All the bottles inside the Reagents Plate are cooled by four Cooler Modules positioned on its border. Each module is composed from two Peltier cells and two fans opportunely powered. One of them has a Cooler Temperature Sensor in order to control the refrigeration temperature.

The plate is covered by a specific plate cover.

2.7 PHOTOMETER

The Photometer allows the direct reading of the Optic Density (O.D.) of the reaction that take place in any cuvette of the Reactions Plate.

The device is composed from two reading channels: Sample Channel for the direct reading of the O.D. value and Reference Channel for its reference value. Each of them is provided of a Pre-Ampl./ADC board for the conversion in a digital signal of the light beam that pass through the cuvette.

The light source is a halogen lamp (6V/10W). It is powered by a Photometer Lamp Board.

The device contains a Filters Wheel for the reading of the reaction at different wavelengths. The wavelengths of the 9 narrow band interferential filters placed on the wheel are the following: 340 nm, 380 nm, 405 nm, 492 nm, 510 nm, 546 nm, 577 nm, 620 nm and 690 nm. Moreover, the Filters Wheel has a dark position.

The Filters Wheel can rotate through a stepper motor. The selection of the exact reading filter is controlled by means of the Filters Wheel Home Sensor and its reference on the wheel.

2.8 WASHING STATION

The Washing Station allows the washing operations of the Reactions Plate cuvettes.

The Washing Station is made up of a series of five small probes. It is situated on a part of the Reactions Plate and each probe can goes down into a single cuvette.

This said five probes are opportunely connected to the washing station electrovalves and micropumps for the emptying, washing and drying operations of the cuvettes. In particular, the last probe has a pad for the drying operations.

The vertical movement of the Washing Station on the Reactions Plate is allowed by its leadscrew connected to a stepper motor.

2.9 REAGENTS AND SAMPLES BARCODE READERS

Two barcode readers can be installed (*optional*) for reagents and samples on the *SAT 450* instrument.

The bar codes families expected on the Samples Plate to be read from the *Samples Barcode Reader* are only the following:

Code 2/5, Code 39, CODABAR, Code 128 and MSI.

The features of this families are reported in the following table:

Code Family	Family Members	General Options	Options	Code Length	
				Min	Max
Code 2/5	Interleaved 2/5	[No check digit control] / [Check digit control (without Transmission)]	NA	4	16
Code 39	Standard Code 39	[No check digit control] / [Check digit control (without Transmission)]	NA	1	16
CODABAR	Standard	Start/Stop control	No transmission start/stop	1	16
Code 128	Standard	No check digit control	NA	1	16
MSI	Standard	[Check digit control (without Transmission)]	NA	1	1

2.10 ISE MODULE

An ISE Module can be installed (*optional*) on the *SAT 450* instrument.

The ISE Module measures the concentration of Na+, K+ and Cl- in serum and urine. It contains an integral sample entry port, positioned at the top. This compact design allows for small sample size and fast operation.

CHAPTER 03

– SOFTWARE DESCRIPTION –

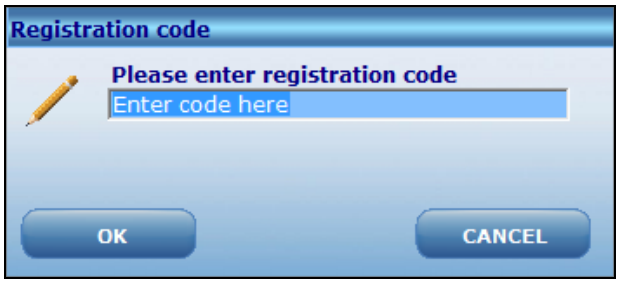
INDEX

3.1 SYSTEM MONITOR 2
3.1.1 START 11
3.2 CHECKS 17
3.2.1 WATER BLANK LEVEL 17
3.2.2 REAGENTS CONFIGURATION 19
3.2.3 REAGENTS MAP 25
3.3 ROUTINE 26
3.3.1 WORK LIST SETUP 26
3.3.2 RESULTS BY PATIENT 33
3.3.3 RESULTS BY TEST 41
3.3.4 CALIBRATION & Q. C. SETUP 46
3.3.5 CALIBRATION RESULTS 50
3.3.6 QUALITY CONTROL 54
3.4 ARCHIVE 61
3.4.1 PATIENTS 61
3.4.2 CALIBRATIONS 66
3.4.3 BACKUP 68
3.4.4 RESTORE 70
3.4.5 TEST COUNTER 72
3.4.6 EVENT LOG 73
3.4.7 ADMISSION LOG 74
3.4.8 QUALITY CONTROL 75
3.5 PARAMETERS 75
3.5.1 METHODS 76
3.5.2 PROFILES 81
3.5.3 RATIO 82
3.5.4 STANDARD 83
3.5.5 CONTROLS 86
3.5.6 OPTIONS 89
3.5.7 PRINT/SAMPLING ORDER 91
3.5.8 REPORT OPTIONS 92
3.5.9 ACCOUNTS 93
3.5.10 ISE 97
3.5.11 PROBE WASH RULES 98
3.6 HELP 100
3.6.1 GUIDE F1 100
3.6.2 INFO 100
3.6.3 ASK FOR SUPPORT 100
3.7 SHUT DOWN 102
3.8 KEYBOARD SHORTCUTS 102

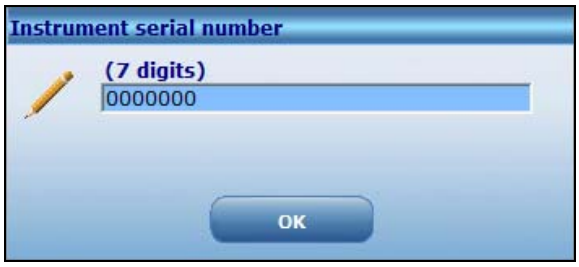
3.1 SYSTEM MONITOR

To access the software double click on the dedicated "**SAT 450**" icon (located on the computer's Desk Top) and then enter User name and Password in the "Login" window.

In case of the Registration Code has never been set, the Admin (or the Producer) user must enter the eight alphanumeric digits provided by the Producer.



In case of the Instrument Serial Number has never been set, the Admin user must enter seven numeric digit.



The user interface is subdivided into two main areas:

- a Desktop area
- a Data Visualization area

The Desk Top area is a graphic illustration of the instrument and appears as described below:

Reagents Plate made up of:

- four removable satellite Rotors. Each satellite Rotor is identified by a letter (respectively A, B, C and D). Each removable sector can house 8 positions for 50 ml trapezoidal bottles. Each of the 50 ml bottle positions can be divided either into two 20 ml positions (trapezoidal bottles) or into two 5 ml positions (cylindrical bottles) through a specific adapter.
- four peripheral Rotors, each containing two positions. Each of the peripheral Rotors is identified as either rA, rB, rC or rD followed by a number. Each Rotor can house 5 ml cylindrical bottles.

***Note 1**: in "Stand-By, Search or Pause" status, by right – clicking on a reagent position a "Refill" context menu opens (see the below figure). It informs the software that a reagent has been refilled. This operation is available only for reagents that are associated to Open Methods. In presence of Reagents Barcode reader, a read barcode menu item will be visible too in order to perform a single reagent barcode read (software will accept only the previous reagent id with the same bottle type).*

***Note 2**: following reagent levels indicators are used to inform the operator about the related status:*

Low Level Reagent Bottle

Empty Reagent Bottle

Abnormal Measured Level Bottle

Illegally refilled liquid: usage not allowed

***Note 3**: a zoom of a satellite removable rotor opens by left-clicking over its identifier letter (A, B, C, D) (see the below picture):*

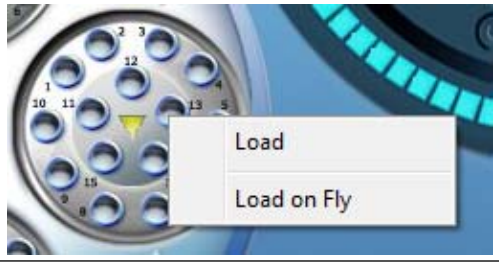
Position	Test	Rgt Code	Bottle Type	Res. Tests	Lot N°
A-1	AC-URI	A-URI1	50 ml	0	LOT01
A-3	AZOU	AZOU	20 ml	Unknown	LOT7
A-4a	BID	BID	20 ml	Unknown	LOT09
A-4b	AC-URI	A-URI2	20 ml	Unknown	LOT02
A-5a	ALB	ALB	5 ml	Unknown	LOT03
A-5b	AMIL.U	AMIL.U	5 ml	Unknown	LOT6
A-6	BID BIT	NITR	5 ml	1766 1766	
A-7	AMI	AMI	50 ml	245	LOT04
A-8	BIT	BIT	20 ml	32	

Samples Plate made up of:

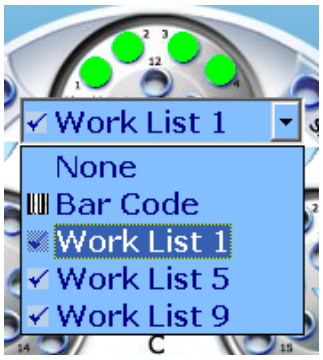
- 4 satellite Rotors each having 15 positions. Each satellite Rotor is identified by a letter (respectively A, B, C and D). Each Rotor can house 2.7 ml cups as well as primary sample tubes (diameter: 12÷16; length: 75÷100mm)
- 4 peripheral Racks (each having two positions), identified as either sA, sB, sC or sD.

***Note 1**: in "Stand-by, Running, RUN CMD, Pause or Pausing" status, it is possible to open a "Load" context menu (by right-clicking on the Sample Plate). It is used in order to load physically the rack.*

***Note 2**: by right-clicking on any Sample Plate free position, a "Load on fly" context menu opens. It is used to set sample on the free selected position.*



***Note 3**: by left-clicking on the "yellow triangle" located in the middle of each rotor, a foreground combo box (see the below picture) opens. It allows to select an available work list.*



Bar Code item will be available in the foreground combo box only if the "Sample Bar Code" option has been set in the "Options" mask.

Sample Bar Code reading is only allowed when Instrument is in "Stand-by, Pause or Pausing (with the Sample Plate Ready)" status.

***Note 4**: zoom of a satellite rotor opens by left-clicking over its identifier letter (A, B, C, D) (see the below picture):*

Reaction Plate made up of:

- four Rotors, each holding 20 reaction cuvettes.

Data Visualization Area

Located in the lower portion of the "**Sys. Mon**." mask, this area contains more detailed information regarding that particular item selected (reagent/diluent, standard/control, sample, reaction cuvette).

This detailed information can be accessed by using the mouse to select the item required.

- If a Reagent/Diluent present in the reagents plate is selected:
  information regarding that single reagent/diluent will be visualized.

- If Water for RBL/Standard/Control is selected:
  information regarding the selected material will be visualized in the same way used in the Details Area of the Calibration Results mask.

- If a Sample is selected:
  information regarding that single sample will be visualized.

- If a Reaction Cuvette is selected:
  a table containing information regarding that single cuvette for each wavelength of both the sample channel and the reference channel will be visualized.

Log Out/Log In

allows the user to Log Out and Log In.

Alarms

There are two types of alarms:

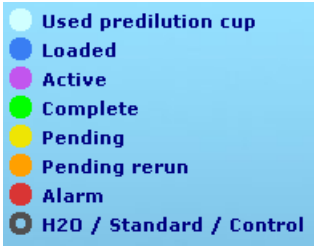
- one is a brief text message and alerts (for example: Status - Stand By);
- the second are **Process indicators** (upper right).

Warning – this triangle lights up yellow when activated. When lit, the user can click on this button to view which data visualization area has generated the alarm; i.e.: the cause of the warning (for example: Reagent Cover Open).

Emergency Stop - this button lights up red when activated. In the event of an Emergency Stop, only those readings that have been completed will be saved, while those still running will be interrupted (e.g.: incubation). Cuvette washing is mandatory after any interruption due to an Emergency Stop. When this button lights up, the user can click on it to view the data visualization area that has generated the error (for example: Temperature error).

Legend

It shows colors and symbols used for reagents, standards, controls and samples status.



- Light Grey (used predilution cup): it is visible if at least a predilution rack has been set;
- Blue (Loaded);
- Purple (Active);
- Green (Complete);
- Yellow (Pending);
- Orange (Pending rerun);
- Red (Alarm);
- Ring (H2O / Standard /Control).

Operative Buttons

Start (green triangle): allows the user to access the **"**Start**"** mask.

Pause: allows the user to temporarily interrupt the sampling process without interrupting either incubation or the reading of already dispensed samples. As soon as the instrument will not use the sample plate, the user will be notified by the SW; in this state the user can load the sample plate.

Stop: stops the instrument.

System Status

When operating, the instrument lid is lit in one of three colors, as illustrated below, indicating instrument status:

Blue: Instrument in Stand-by status

Yellow: Instrument in Pause status or in Pausing status with sample plate ready

Red: Instrument in Running, RUN CMD, Init Analyzer status or in Pausing status with sample plate not ready

Available Menus:

- Sys. Mon.
- Checks
- Routine
- Archive
- Parameters
- Help
- Shutdown

Command Buttons

I command buttons are visualized as needed and correspond to the following functions:

"Validate" Button

used to check results regarding an executed test. In the event of rerun tests, after the user has selected the results to be assigned to the test in question, s/he must click on this button in order to definitively assign those results to that test.

Whenever the results of a test are assigned in this manner, they will be viewed printed in bold.

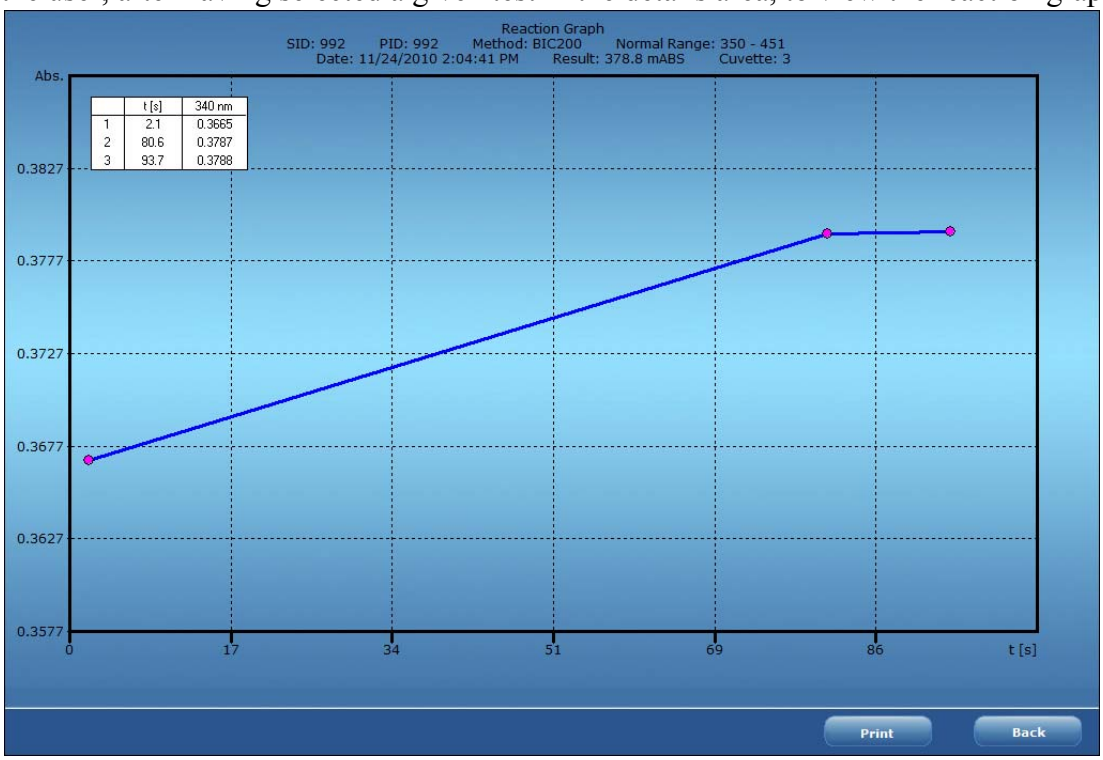
Test	PreDilution	Post Dil.	Manual Dil.	Result	Unit	Normal Values	Flags	Date
BIC202 (1)	1/1	1/1	1/1	395.8	mAbs	370 - 430		03/07/2009 12.28.55
BIC202 (2)	1/1	1/1	1/1	407.1	mAbs	370 - 430		03/07/2009 12.29.22
BIC202 (3)	1/1	1/1	1/1	407.7	mAbs	370 - 430		03/07/2009 12.29.49
BIC202 (4)	1/1	1/1	1/1	407.5	mAbs	370 - 430		03/07/2009 12.30.15
BIC202 (5)	1/1	1/1	1/1	404.8	mAbs	370 - 430		03/07/2009 12.30.42
BIC202 (6)	1/1	1/1	1/1	405.7	mAbs	370 - 430		03/07/2009 12.31.08

"Print" Button

- allows the user, after having selected a given sample of a loaded Work List, to have a print-out either in report format or in work list format.
- allows the user, after having selected a given sample of a loaded Work List and a number of lines of the Data Visualization Area, to have a print-out of the selected items.

"Graph" Button

allows the user, after having selected a given test in the details area, to view the reaction graph.



"Print" Button

allows the user to print the graph.

"Exit" Button

allows the user to close the graph page.

"Rerun" Button

allows the user to rerun methods already executed.

Select a sample present in the samples plate;

select one or more tests from the Details Area and then click on the rerun button.

Please note: *only tests that have already been executed can be rerun.*

Select dilution ratio: allows the user to use a pull-down menu to select the dilution ratio for the test. This operation can be carried out only for a single Test – provided sample volume is sufficient – and not when programming involves more than one test at a time.

The **OK** button allows the user to confirm the rerun request.

The **Exit** button cancels the rerun request.

Please note: *right clicking on a specific test or ratio shown in the Details Area that is not scheduled or running it shall be possible to request the deletion of the selected element. If a test is an element of the formula of a ratio associated to the sample, in order to delete the test, user should delete the ratio before.*

"Edit" Button

allows the user to manually modify the results of a test.

Select a test present in the samples plate;
Select a test from the Details Area and then click on the edit button.

The below-illustrated window will automatically appear.

Whenever a result is **Edited** manually, that result will appear having an "**E**" in the Flags field.

Note*: the edited value could also produce the following flags: Low/High, Pathologic Low/High, Alert Low/High.*

The "**OK"** button allows the user to confirm the edit request.

The "**Exit"** button cancels the request.

3.1.1 START

The "**Start"** button, located in the "Sys. Mon." mask, accesses the **"**Start**"** mask. Here, the user can carry out the following operations:

- **Washing Cuvettes**

  This operation allows the user to select the Reaction Plate Rack/s that are to be washed.

  The oldest date and time of the wash event of a cuvette per rack is shown at the right of the single rack only if all the usable cuvettes have been washed at least once.

- **Water Base Line**

  This option allows the user to select which Reaction Plate rack is to be used for the Water Base Line. If the user asks for a WBL execution on a unwashed Rack, software will execute a wash on that rack.

  The Water Base Line values thus obtained are used by the instrument to calculate the concentration of the required analyte.

  The reading system (photometer) detects and measures light intensity via photodiodes as it exits the cuvettes, expressing the results in "Counts".

  "Counts" are the digital transformation of the analogical data (millivolt) detected by the photometer.

The absorbance data detected during reaction reading (see reaction graph) includes offset (about 100 counts).

Any signal variations due to the lamp and/or interferential filters (Thermic Drift) are automatically compensated for by the reference channel reading.

- **Replace Predilution Racks**

This operation allows the user to request substitution of the predilution racks.

Whenever no predilution rack is set up in the reaction plate in use, the relative check is not visualized.

- **Calibration & Q.C.**

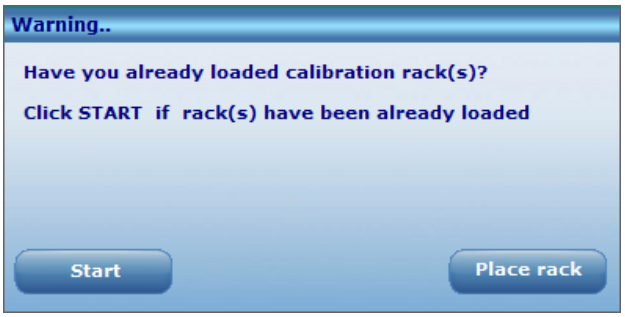
This option allows the user to execute method calibration.

The "**Details**" button allows the user to open the "Calibration & Q. C. Setup" mask.

Request for calibration and quality control execution must proceed as follows:

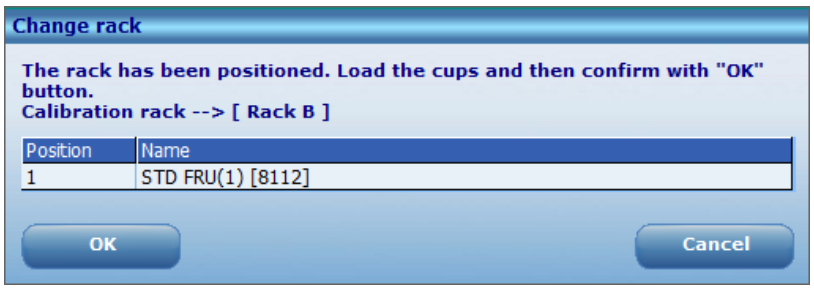
- Select the "**Calibration & Q.C.**" option under the "Start" mask;
- Press **OK** under the "Start" mask to begin execution.

A Warning message appears.



Select "Place Rack" in order to physically load the calibration rack/s (wait for the rotor to position itself properly), otherwise, select "Start" if the rack/s have already been physically loaded onto (are already onboard) the instrument.

***Note**: as the rack has been positioned, the following window appears.*



"**OK**" Button

allows the user to start execution of the options selected.

"**Cancel**" Button

allows the user to close this mask in order to return to the "Start" mask.

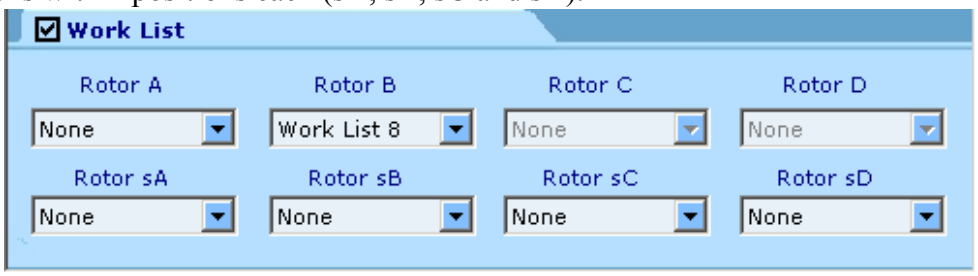
***Note**: the user could decide - through the Pause state - the following:*

- *to continue with the previous scheduled calibration or*
- *to start with a new calibration (eventually comprehensive of RBL).*

- **Work List**

This option allows the user to activate previously programmed work lists.

There are four Racks, each having 15 positions (Rotor A, Rotor B, Rotor C and Rotor D), plus four Racks with 2 positions each (sA, sB, sC and sD).



The selected Work List is automatically visualized under the "Sys. Mon." mask.

*<u>Please note</u> that **<u>before a Test can be processed, the Reagent Blank (RBL) must be executed</u>** – Calibration must also be executed if the calculation model is not Factor. This condition must be satisfied before the instrument is activated for the execution of the test.*

Request for execution of one or more Work Lists must proceed as follows:

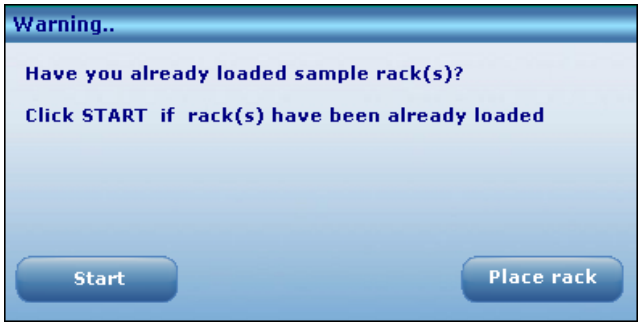
Mode A

- Starting under the "Sys. Mon**."** mask, press "**Start"** button;
- Select the "**Work List"** option form under the "Start**"** mask**;**
- Select the required Work List/s using the Rotor A,B,C,D - Rotor sA, sB, sC, sD combo boxes;
- Press **OK** to begin execution.

Mode B

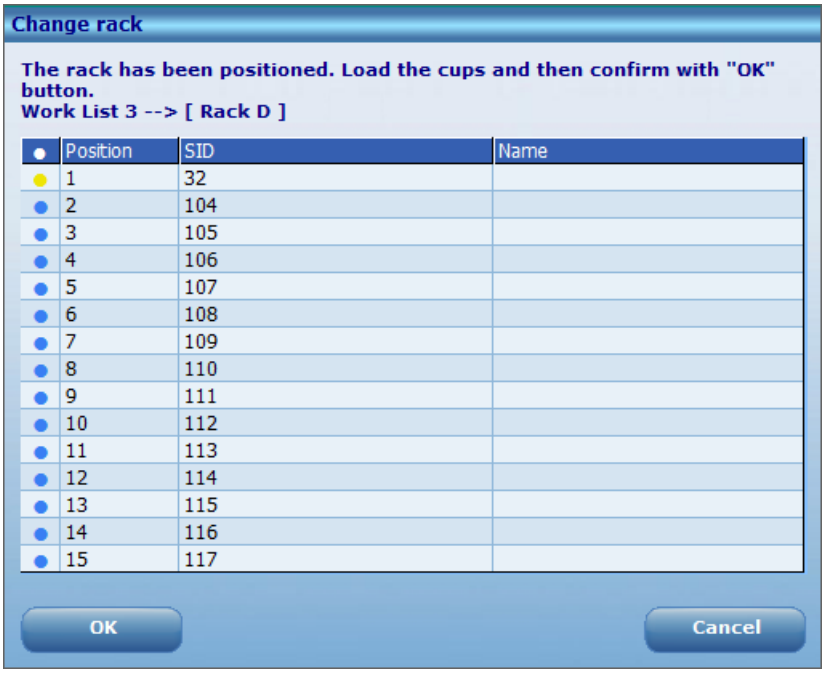
- Starting under the "Sys. Mon.**"** mask, select the required Work List on each peripheral/satellite plate and then press "**Start**" button;
- At the bottom of the "Start**"** screen, select the "**Work List"** option and then press **OK.**

A Warning message appears.



Select "**Place Rack**" in order to physically load the work list/s (wait for the rotor to position itself properly), otherwise, select "**Start**" if the list/s have already been physically loaded onto (are already onboard) the instrument.

***Note**: as the rack has been positioned, the following window appears.*



	Position	SID	Name
	1	32	
	2	104	
	3	105	
	4	106	
	5	107	
	6	108	
	7	109	
	8	110	
	9	111	
	10	112	
	11	113	
	12	114	
	13	115	
	14	116	
	15	117	

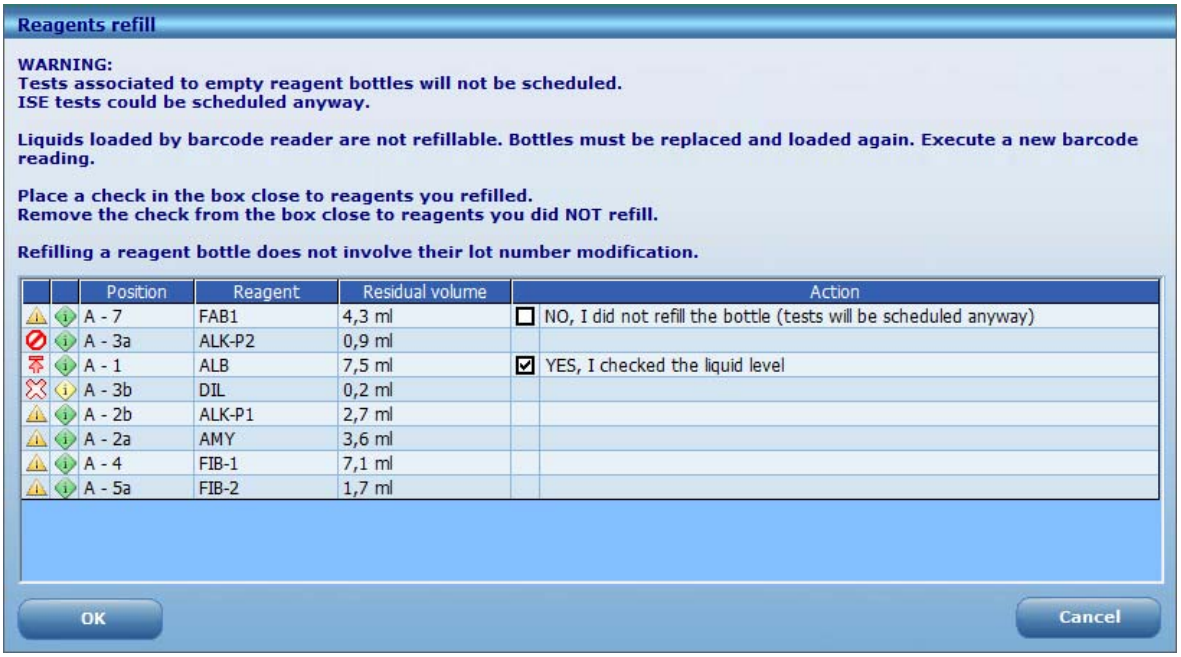
"**OK**" Button

allows the user to start execution of the options selected.

"**Cancel**" Button

allows the user to close this mask in order to return to the "Start" mask.

***Note**: the following window appears to set Reagents Status either as "Refilled" (option available only with liquids used by Open Methods) or as checked (option available only with abnormally measured liquids). This windows appears if "Calibration & Q.C. and/or Work List" options have been selected and if almost a reagent is low, over, abnormally measured or illegally refilled.*



***Note**: if during calibration "missing reagent" occurs, the user could decide - through the Pause state - the following:*

- *to continue with the scheduled calibration or*
- *to start with a new calibration (eventually comprehensive of RBL).*

The "Start" mask is showed as below in case of:

A **B** **C**

CASE A: after a stop command or a fatal error with dirty cuvettes

CASE B: no valid WBL for any cuvette

CASE C: Probe Wash rules need liquid(s) to be set on plate.

The following Status Bar is always showed.

It contains the following:

- Actual date and time.
- Remove device button (): to disconnect removable device.
- Task Manager button (): allows to access either to a previously opened application for 30 sec (ie: printer error window) or to the Windows ® calculator.
- Diagnostic button (Diagnostic): to open "Diagnostic" program.

3.2 CHECKS

The term **Checks** indicates that set of masks which visualize a series of data and/or activate those functions necessary for correct routine preparation.

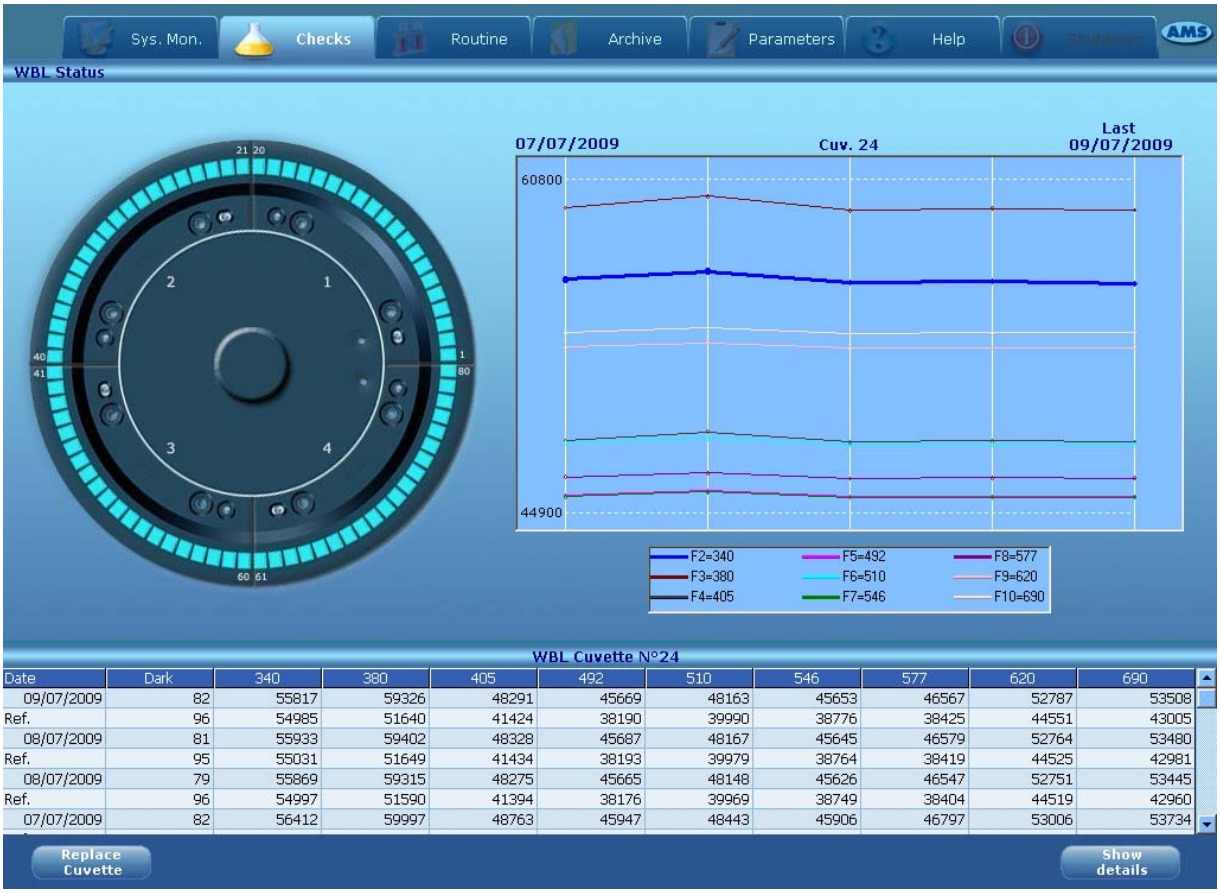
Following is a list of these masks:

Water Blank Level: this mask makes it possible to check WBL results (quality control for the 80 reaction cuvettes).

Reagents Configuration: this mask makes it possible to configure the reagents plates as well as the samples plate, with specific reference to the controls.

Reagent Map: this mask makes it possible to view information regarding the reagent/diluents present in the active Reagents Plate Configuration.

3.2.1 WATER BLANK LEVEL



This mask allows the user to check WBL results.

Clicking on any single position (reaction cuvette) allows the user to view the graph of that cuvette as well as the results obtained (expressed in counts) visualized in the details area.

The graph reports the last 5 WBLs executed (color-coded according to the filter used) over time. The mask also includes a legend for filter colors.

"**Replace Cuvette**" Button

Replacement of the reaction plate Racks can be carried out only when the instrument is in Stand By.

The reaction plate cuvettes can turn red, meaning that the cuvette is out-of-range regarding transparency and is therefore unacceptable for use.

Any time there is a request for reaction plate cuvette replacement, it is necessary to perform a **WBL** (cuvette auto-zeroing).

Details Area

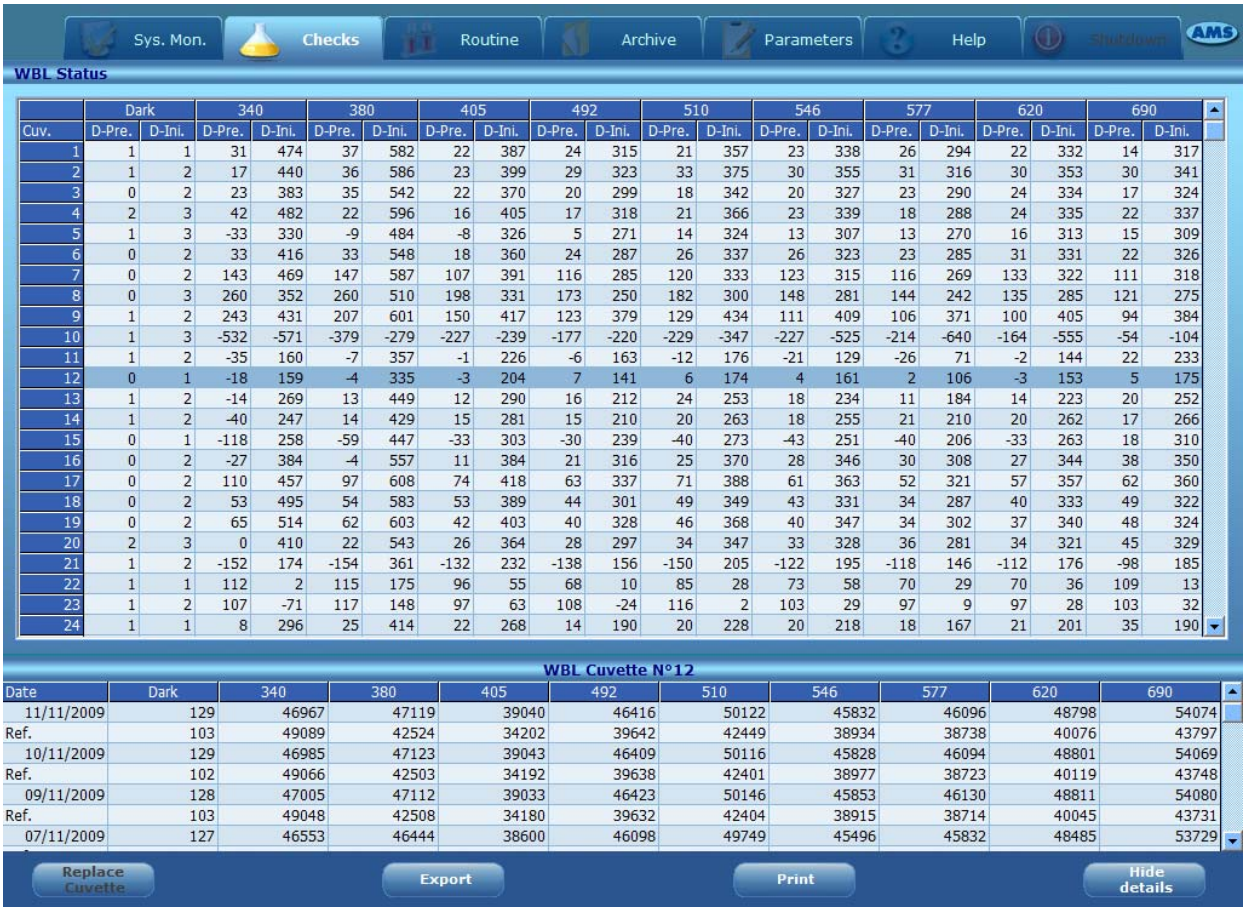
For each cuvette selected in the Main Area, the Details Area reports the date on which the WBL was executed along with the following information for each of the wavelengths:

- WBL results in counts for the sample channel;
- WBL results in counts for the reference channel (Ref.).

Date	Dark	340	380	405	492	510	546	577	620	690
09/07/2009	82	55817	59326	48291	45669	48163	45653	46567	52787	53508
Ref.	96	54985	51640	41424	38190	39990	38776	38425	44551	43005
08/07/2009	81	55933	59402	48328	45687	48167	45645	46579	52764	53480
Ref.	95	55031	51649	41434	38193	39979	38764	38419	44525	42981
08/07/2009	79	55869	59315	48275	45665	48148	45626	46547	52751	53445
Ref.	96	54997	51590	41394	38176	39969	38749	38404	44519	42960
07/07/2009	82	56412	59997	48763	45947	48443	45906	46797	53006	53734

"**Show Details**" Button (visible only if Show WBL Details option has been set - see section Options)

Whenever this button is pressed, a table containing WBL results for all the reaction cuvettes is visualized.



	Dark		340		380		405		492		510		546		577		620		690	
Cuv.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.
1	1	1	31	474	37	582	22	387	24	315	21	357	23	338	26	294	22	332	14	317
2	1	2	17	440	36	586	23	399	29	323	33	375	30	355	31	316	30	353	30	341
3	0	2	23	383	35	542	22	370	20	299	18	342	20	327	23	290	24	334	17	324
4	2	3	42	482	22	596	16	405	17	318	21	366	23	339	18	288	24	335	22	337
5	1	3	-33	330	-9	484	-8	326	5	271	14	324	13	307	13	270	16	313	15	309
6	0	2	33	416	33	548	18	360	24	287	26	337	26	323	23	285	31	331	22	326
7	0	2	143	469	147	587	107	391	116	285	120	333	123	315	116	269	133	322	111	318
8	0	3	260	352	260	510	198	331	173	250	182	300	148	281	144	242	135	285	121	275
9	1	2	243	431	207	601	150	417	123	379	129	434	111	409	106	371	100	405	94	384
10	1	3	-532	-571	-379	-279	-227	-239	-177	-220	-229	-347	-227	-525	-214	-640	-164	-555	-54	-104
11	1	2	-35	160	-7	357	-1	226	-6	163	-12	176	-21	129	-26	71	-2	144	22	233
12	0	1	-18	159	-4	335	-3	204	7	141	6	174	4	161	2	106	-3	153	5	175
13	1	2	-14	269	13	449	12	290	16	212	24	253	18	234	11	184	14	223	20	252
14	1	2	-40	247	14	429	15	281	15	210	20	263	18	255	21	210	20	262	17	266
15	0	1	-118	258	-59	447	-33	303	-30	239	-40	273	-43	251	-40	206	-33	263	18	310
16	0	2	-27	384	-4	557	11	384	21	316	25	370	28	346	30	308	27	344	38	350
17	0	2	110	457	97	608	74	418	63	337	71	388	61	363	52	321	57	357	62	360
18	0	2	53	495	54	583	53	389	44	301	49	349	43	331	34	287	40	333	49	322
19	0	2	65	514	62	603	42	403	40	328	46	368	40	347	34	302	37	340	48	324
20	2	3	0	410	22	543	26	364	28	297	34	347	33	328	36	281	34	321	45	329
21	1	2	-152	174	-154	361	-132	232	-138	156	-150	205	-122	195	-118	146	-112	176	-98	185
22	1	1	112	2	115	175	96	55	68	10	85	28	73	58	70	29	70	36	109	13
23	1	2	107	-71	117	148	97	63	108	-24	116	2	103	29	97	9	97	28	103	32
24	1	1	8	296	25	414	22	268	14	190	20	228	20	218	18	167	21	201	35	190

Date	Dark	340	380	405	492	510	546	577	620	690
11/11/2009	129	46967	47119	39040	46416	50122	45832	46096	48798	54074
Ref.	103	49089	42524	34202	39642	42449	38934	38738	40076	43797
10/11/2009	129	46985	47123	39043	46409	50116	45828	46094	48801	54069
Ref.	102	49066	42503	34192	39638	42401	38977	38723	40119	43748
09/11/2009	128	47005	47112	39033	46423	50146	45853	46130	48811	54080
Ref.	103	49048	42508	34180	39632	42404	38915	38714	40045	43731
07/11/2009	127	46553	46444	38600	46098	49749	45496	45832	48485	53729

This mask is divided into a Main Area and a Details Area (see previous picture).

Main Area

	Dark		340		380		405		492		510		546		577		620		690	
Cuv.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.	D-Pre.	D-Ini.
1	1	1	-157	-593	-112	-713	-45	-498	-27	-290	-19	-290	5	-263	-37	-238	20	-226	34	-233
2	1	0	-109	-721	-70	-795	-22	-549	0	-331	14	-332	27	-295	6	-272	38	-258	64	-255
3	1	0	-127	-775	-80	-831	-36	-580	-15	-354	0	-355	14	-318	-4	-292	29	-278	43	-275
4	1	0	-116	-619	-101	-716	-51	-498	-26	-296	-10	-297	4	-270	-20	-247	17	-238	30	-245
5	2	1	-120	-578	-74	-661	-32	-459	-13	-267	3	-270	17	-244	-6	-217	30	-211	44	-212
6	2	1	-133	-615	-86	-700	-39	-489	-22	-292	-10	-294	11	-265	-16	-236	25	-230	32	-233
7	0	0	-140	-612	-99	-677	-43	-474	-27	-276	-17	-280	10	-252	-28	-226	23	-218	26	-228
8	1	1	-144	-602	-98	-680	-46	-481	-26	-282	-15	-282	10	-254	-23	-229	20	-224	29	-233
9	2	1	-135	-608	-90	-674	-39	-472	-19	-276	-7	-277	13	-253	-20	-228	24	-221	34	-231
10	2	1	-121	-594	-79	-671	-36	-467	-11	-276	3	-277	20	-248	-4	-228	31	-220	40	-230
11	1	1	-133	-601	-93	-682	-43	-473	-23	-282	-9	-282	10	-258	-23	-237	24	-225	33	-235
12	2	1	-113	-569	-91	-672	-42	-466	-20	-276	-9	-281	12	-252	-20	-235	26	-219	37	-225
13	1	0	-112	-564	-73	-635	-22	-433	-6	-252	2	-257	27	-226	-13	-214	43	-192	57	-196
14	1	0	-115	-576	-80	-659	-22	-448	-17	-270	-12	-279	14	-246	-34	-240	24	-216	31	-226
15	1	0	-121	-573	-88	-663	-28	-452	-18	-268	-11	-275	17	-243	-33	-237	27	-215	36	-219
16	1	0	-105	-552	-82	-655	-30	-449	-23	-267	-15	-270	11	-243	-39	-230	22	-212	31	-219
17	1	0	-126	-581	-89	-658	-27	-453	-24	-270	-16	-270	13	-244	-38	-224	25	-213	40	-220
18	1	0	-100	-588	-68	-679	-19	-479	-16	-292	-7	-295	19	-273	-28	-250	28	-249	42	-243
19	1	0	-134	-578	-102	-671	-44	-463	-43	-283	-35	-287	-2	-253	-54	-242	7	-225	13	-232
20	1	0	-160	-627	-128	-722	-67	-497	-63	-319	-55	-326	-27	-288	-74	-282	-26	-269	-10	-261
21	1	0	-103	-229	-78	-145	-25	-73	-13	-89	-3	-69	18	-37	-16	-79	27	-36	46	8
22	2	1	-117	-225	-83	-123	-36	-67	-18	-76	-10	-53	7	-23	-19	-54	15	-18	31	27
23	2	1	-109	-238	-75	-143	-35	-76	-15	-78	0	-56	11	-29	-11	-64	22	-24	35	24
24	1	1	-116	-217	-76	-120	-37	-61	-18	-69	-4	-48	8	-20	-12	-54	23	-13	28	26

This area reports, for each of the 80 reaction cuvettes, the following information:

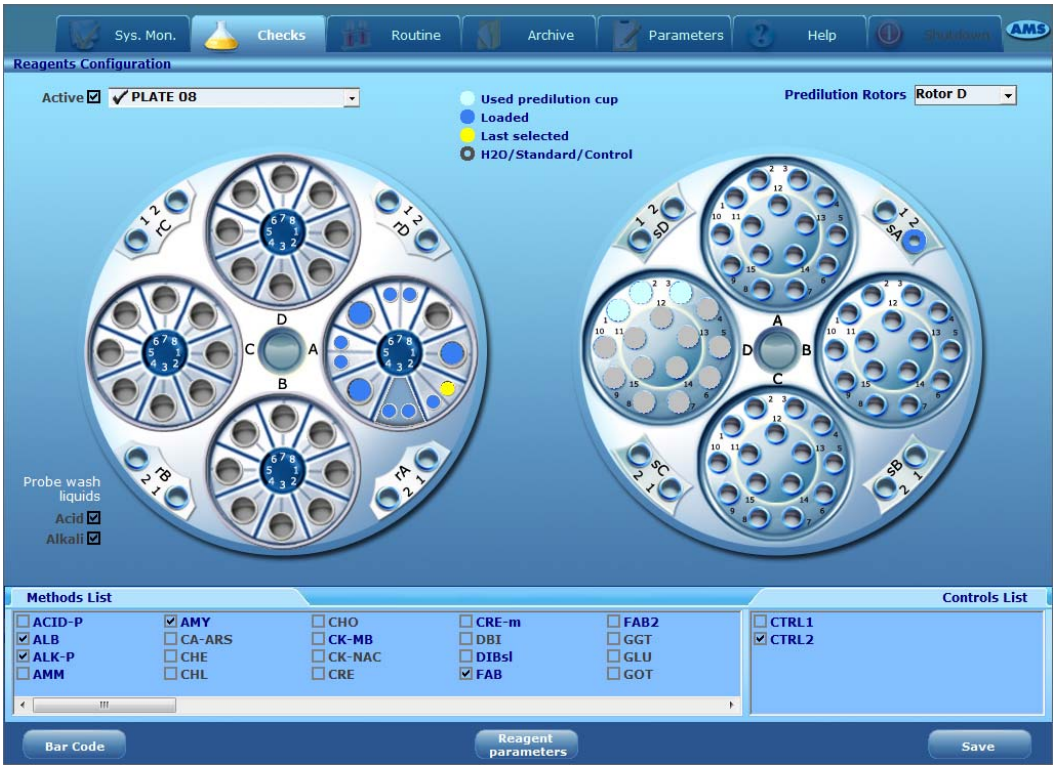
- variance in counts with respect to the previous WBL (**D-Pre**.);
- variance in counts with respect to the WBL executed during installation (**D-Ini.).**

"Export" Button (visible only in "Details" visualization)
allows the user to generate a csv file that includes the Main area data.

"Print" Button (visible only in "Details" visualization)
allows the user to print the Main area

"**Hide Details**" Button
allows the user to close this mask and return to the previous mask.

3.2.2 REAGENTS CONFIGURATION



This mask makes it possible to configure the reagents plates as well as the samples plate with specific reference to controls and predilution.

The upper, left-hand corner lists the various plate configurations. This configurations list is a combo box where the user can select the name of a plate configuration.

Selecting a name makes it possible to set up a specific configuration (up to 10 different configuration).

It is possible to change the name of the plate configurations directly within this combo box.

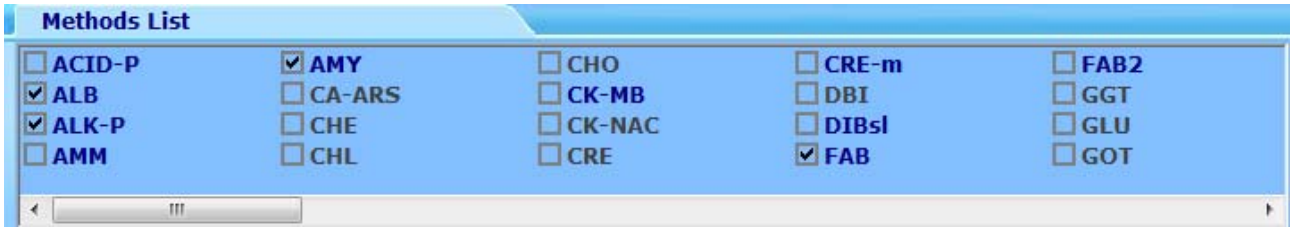
The selected plate is made active by selecting "**Active**".

***Please note**: this mask allows the user to change, with the exception of the active configuration, the setup of any previously inserted configuration at any time and under any instrument status. In the case of the active configuration, setup can be modified only when the instrument is in "Stand By" or in "Search" status and when there are no Calibrations Pending.*

There is a "**Predilution Rotors**" field located in the upper, right-hand corner where the user can choose the Rotor/s that is/are to be dedicated to predilution.

The lower area is dedicated to a visualization of previously defined methods: the "Methods List". This area is made up of a list of checkboxes tagged with the short name of the method.

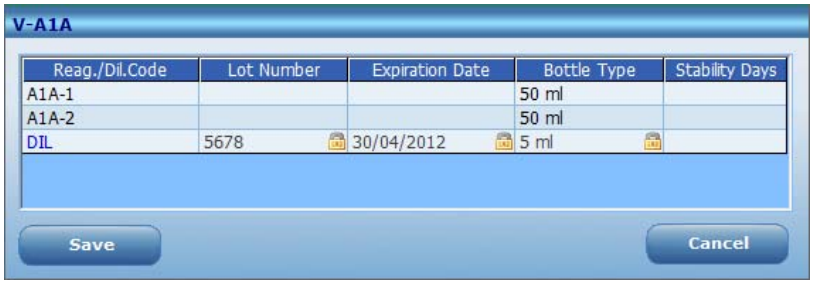
Whenever the number of Rotors dedicated to predilution is zero ("None") for that selected plate configuration, all prediluted methods will be visualized in grey in the methods area. Furthermore *Closed methods* will be visualized in gray if at least one of their liquids has not been read through the barcode reader. Grey methods cannot be added to the current reagent configuration.



***Note**: if ISE Option has been set (see section Options), the following items will be available too:*

- *ISE check ("Calibrant A" position)*
- *ISEu check (only if, ISE urine methods are prediluted → "Calibrant A" and "Diluent" position)*

Every time the user ticks a blu method checkbox in the methods area, a data entry window opens allowing the user to set up the lot number of the reagent/diluent, the expiration date of that lot and the type of bottle to be used (50, 20 and 5 ml). The "Stability Day" field visualizes for how many days the reagent is to be considered stable.



"**Save**" Button

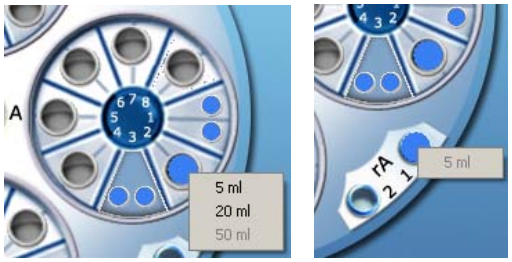
Pressing Save positions the reagents/diluents in suitable free positions according to the type of bottle/cup chosen.

"**Cancel**" Button

allows the user to close the data entry window.

"**Drag & Drop**" can be used to move a reagent/diluent from one position to another in the reagents plate (option available only with liquids used by *Open Methods*).

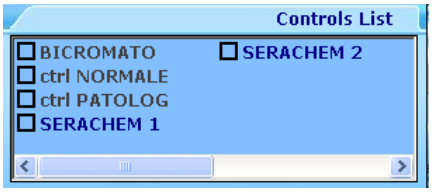
Instrument Software will check that the new position requested by the user is able to accept that type of reagent/diluent bottle. It is possible to change the type of reagent/diluent bottle from 50 ml to 20 ml or to 5 ml and vice versa by right clicking on the reagents plate visualization area (option available only with liquids used by *Open Methods*).



Whenever the mouse pointer is positioned on a "reagent/diluent", a tool tip will appear reporting the name and the lot number of the reagent/diluent.

One other lists is located next to the "Methods List".

Controls List



The Controls List is a list of checkboxes each tagged with the name of the individual control. Whenever a control is selected, it is positioned according to availability respecting the following order of priority: samples plate peripheral rotor, samples plate satellite rotor, reagents Rotor peripheral rotor.

Drag & Drop can be used to move a control from one position to another.

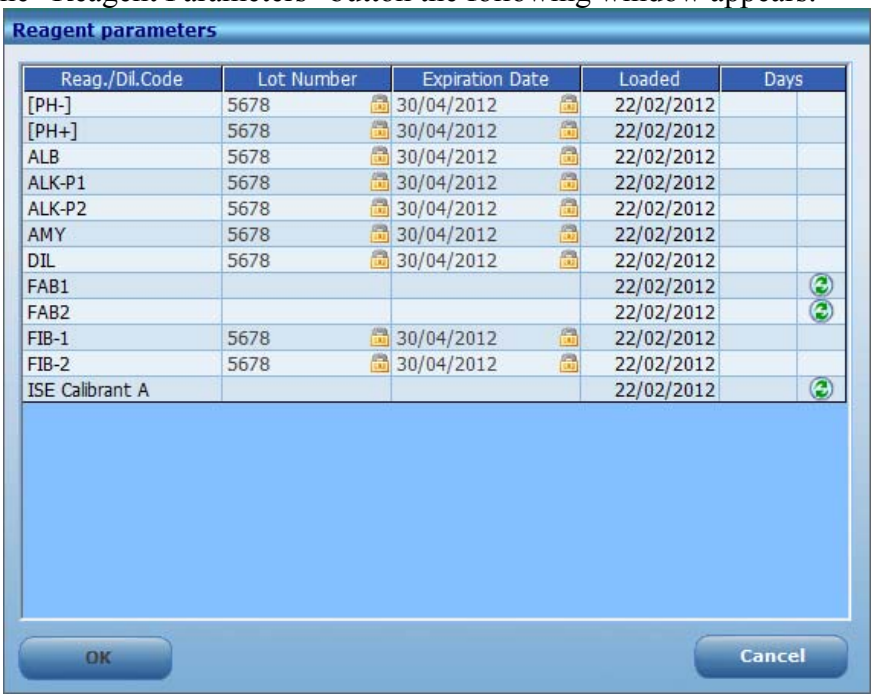
Whenever the mouse pointer is positioned over a control, a tool tip will appear reporting the name and the lot number of the control.

Please note: *it is not possible to position a control in the samples plate satellite rotor if it is associated with a method that requires a dynamic control.*

Check boxes dedicated to Acid and Alkali liquid positioning will be available if "Probe Wash Rules" option has been set (see section Options). These two check boxes could manually be used only if the related liquid is considered as an *Open Liquid*.

"**Reagent Parameters**" Button

By clicking on the "Reagent Parameters" button the following window appears:



Reag./Dil.Code	Lot Number	Expiration Date	Loaded	Days
[PH-]	5678	30/04/2012	22/02/2012	
[PH+]	5678	30/04/2012	22/02/2012	
ALB	5678	30/04/2012	22/02/2012	
ALK-P1	5678	30/04/2012	22/02/2012	
ALK-P2	5678	30/04/2012	22/02/2012	
AMY	5678	30/04/2012	22/02/2012	
DIL	5678	30/04/2012	22/02/2012	
FAB1			22/02/2012	
FAB2			22/02/2012	
FIB-1	5678	30/04/2012	22/02/2012	
FIB-2	5678	30/04/2012	22/02/2012	
ISE Calibrant A			22/02/2012	

It allows the user to change the "Lot Number, Expiration Date and Loaded Date" of the reagents set present on the selected plate (option available only with liquids used by *Open Methods*)

Lot Number and Expiration Date are settable by input box (option available only with liquids used by *Open Methods*)

Click on "reload circle" picture to set Loaded Date (option available only with liquids used by *Open Methods*)

***Note**: in order to save the new reagent parameters, select "Save" button ("Reagent Configuration" mask).*

"**Bar Code**" Button

Whenever this button is selected the below-illustrated window is visualized:

This window allows the user to start reading using the BarCode Reader.

To activate the "Read from Barcode" button, it is necessary to select the checkboxes relative to the Rotors/rotors to be used for reading.

Status: reading status for each position (Void, "Wrong BC Format", "Unknown Reagent ID", "Moved from position", "Duplicated", "Wrong Bottle Type", "Uncompliant BC Label");

Position: position occupied by the reagent;

Reagent ID: code("ID") used to identify the reagent. The reagent ID is automatically read by the Bar Code reader and compared to that entered under the "Reagent ID Configuration" (Parameters – Methods) window;

Bottle Type: type of reagent container (50 ml, 20 ml, 5 ml);

Reagent Code: the reagent code is the code used to define each reagent bottle (see "Volumes and Time" table – Chemistry Definition mask);

Lot Number: lot number of the reagent bottle;

Loaded: date the reagent container was loaded onto the instrument;

Stability Days: how many days the reagent onboard is to be considered stable;

Expiration Date: expiration date of the reagent bottle. The date is automatically entered via the barcode; it can also be entered manually.

Note: in case of barcode reading error the system will automatically retry to read the same barcode for a maximum of three times; in case of a Read error, user shall manually type the Barcode through a dedicated mask; from the same mask the user can also ask for a new single barcode read attempt.

"**Exit**" Button

Allows the user to close the window.

Saving the Reagents Plate Configuration

The

button under the "**Reagents Configuration**" mask makes it possible to save the changes made to previously defined configurations.

3.2.3 REAGENTS MAP

Position	Reagent ID	Test	Rgt Code	Bottle Type	Residual Volume	Res. Tests	Loaded	Stable	Days	Lot N°	Expiration Date
A-1	ALB1	ALB	ALB	50 ml	7,5 ml	26	22/02/2012			5678	30/04/2012
A-2a	AMY1	AMY	AMY	20 ml	3,6 ml	18	22/02/2012			5678	30/04/2012
A-2b	ALP1	ALK-P	ALK-P1	20 ml	2,7 ml	16	22/02/2012			5678	30/04/2012
A-3a	ALP2	ALK-P	ALK-P2	5 ml	0,9 ml	22	22/02/2012			5678	30/04/2012
A-3b	DIL1	V-FIB	DIL	5 ml	0,2 ml	0	22/02/2012			5678	30/04/2012
A-4	FIB1	V-FIB	FIB-1	50 ml	7,1 ml	26	22/02/2012			5678	30/04/2012
A-5a	FIB2	V-FIB	FIB-2	20 ml	1,7 ml	94	22/02/2012			5678	30/04/2012
A-5b	ALKA		Alkali	20 ml	Unknown	Unknown	22/02/2012			5678	30/04/2012
A-6	ACID		Acid	50 ml	Unknown	Unknown	22/02/2012			5678	30/04/2012
A-7		FAB	FAB1	50 ml	4,3 ml	1433	22/02/2012				
A-8		FAB	FAB2	50 ml	7,6 ml	38	22/02/2012				
Internal		ISECl ISEK ISENa	ISE Calibrant A	100 ml	98,6 ml		22/02/2012				

The Reagent Map by Tray Position displays the reagent status information arranged by its reagent tray position.

Position: indicates the reagent tray position;

Reagent ID: indicates the code ("ID") used to identify the reagent (see "Reagent ID Configuration" window – Chemistry Definition mask). If reagent barcodes are being used, this number corresponds to the barcode number;

Test: short name of the method;

RGT. Code: indicates the code used to define each reagent bottle (see "Volumes and Time" table – Chemistry Definition mask);

Bottle Type: indicates type of reagent container (50 ml, 20 ml, 5 ml);

Residual Volume: indicates the quantity of reagents left in the container and available for use in other analyses (this information is automatically update as each test is carried out). The amount is expressed in ml; this field reports the liquid status too;

Res. Tests: indicates the test cycles remaining based on the residual volume in the reagent bottle and the volume used for each test;

Loaded: date the reagent bottle was loaded on the analyzer;

Stable : date the reagent bottle is stable until, based on the Stability Day defined in the "Reagent ID Configuration" window – Chemistry Definition mask);

Days: how many days the reagent onboard is to be considered stable;

Lot N°: lot number of the reagent bottle;

Expiration Date: expiration date of the reagent bottle (month/year) declared by the producer;

Void: this field shows if a liquid has been manually positioned.

Note: *Low reagents volumes are yellow-highlighted. Exhausted reagents volumes are red-highlighted. Abnormal Measured Level reagents volumes are arrow-highlighted.*

3.3 ROUTINE

The term **Routine** comprises all those masks used for programming Patients and Calibration regarding relative Tests. This topic also includes a simple and intuitive guide aimed at assisting the user in best verifying the results of the various operations.

Work List Setup: makes it possible to program the work lists;

Results by Patient: visualizes patient data, results of the tests executed, as well as indications to execute other operations (Checks, Archive, Edit, Print Results or Print Work List, etc.);

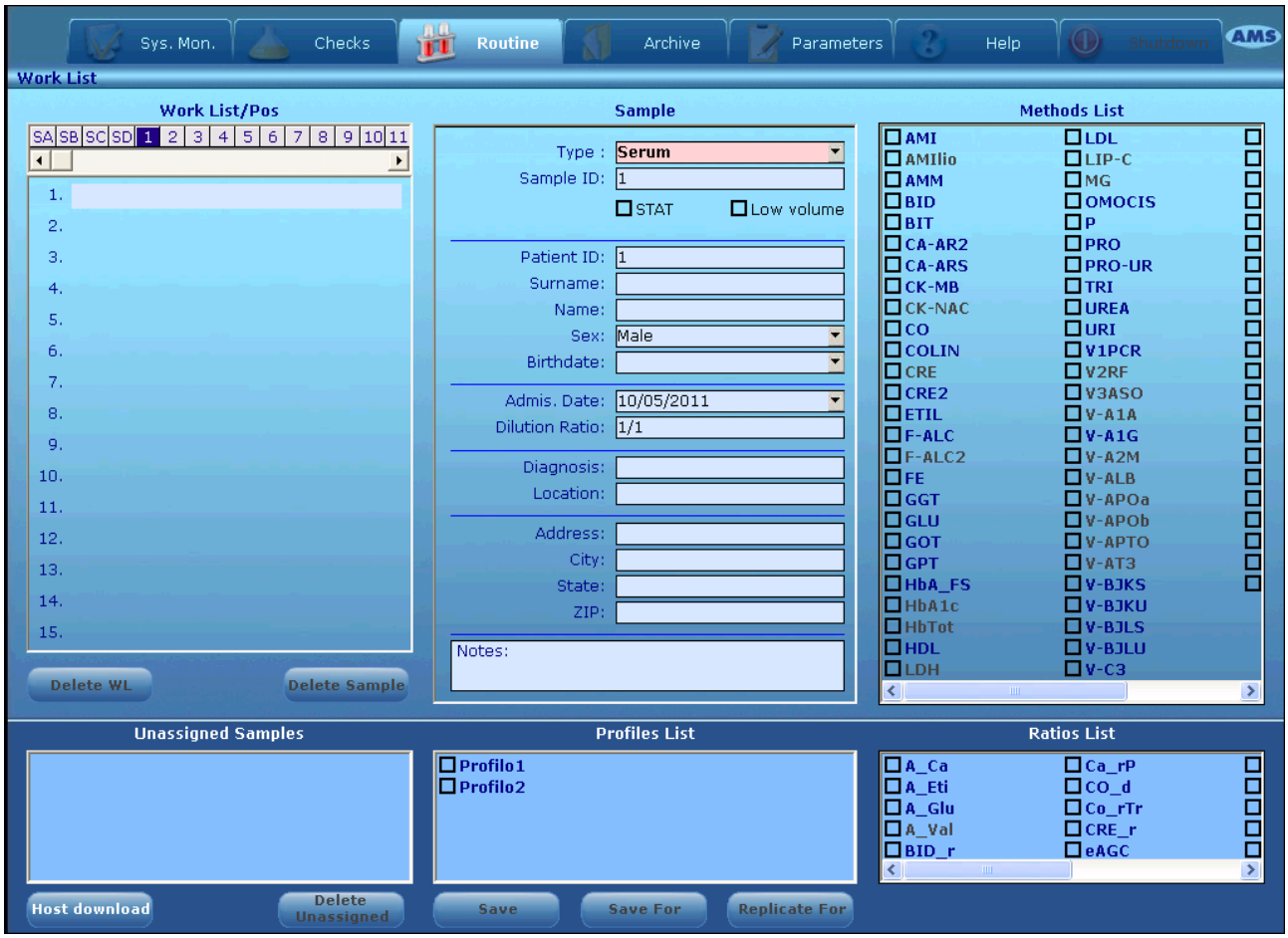
Results by Test: visualizes certain patient data, results of the tests executed and indications to execute certain operations (Checks, Edit, Print, etc.);

Calibration & Q. C. Setup: makes it possible to assign calibration operations (necessary preparatory phase in which the user requests execution of the reagent blank, calibration and controls for each individual method in configuration);

Calibration Results: visualizes the results of the various calibration operations;

Quality Control: visualizes data relative to quality control.

3.3.1 WORK LIST SETUP



This mask allows the user to set up patient data.

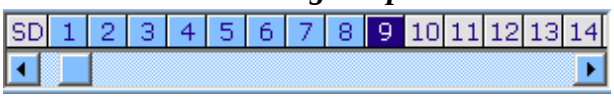
The user can access this mask in two ways:

- directly from the Routine menu (Routine – Work List Setup);
- indirectly, after **Load on Fly** from the "Sys. Mon." mask.

The mask is divided as follows:

- the left-hand portion of the screen is dedicated to **Work List** selection and Sample positioning;
- an area dedicated to patient data regarding the Sample, to the Methods, to the Profiles and to the Ratios;
- an area in the lower portion containing buttons needed for mask management.

Positioning samples



The Work List/Pos. area is made up of two elements:

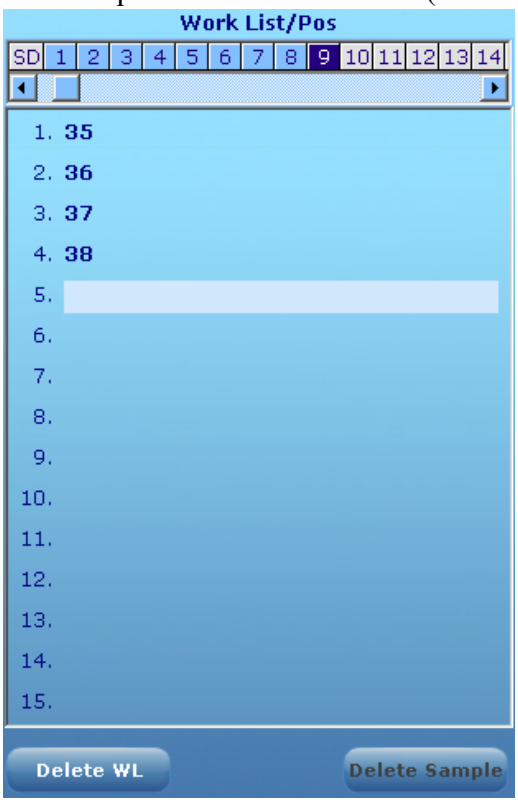
- 4 peripheral samples plate racks (sA, sB, sC, sD); each racks can house at most two samples.
- 99 work lists (from 1 to 99) that can be configured in the samples plate satellite rotors. Each list can be made up of a maximum of 15 samples.

The work lists can be selected in the event that the user has accessed the mask from the Routine menu (instead of via Load on Fly from System Monitor).

The rotors can turn the following colors:

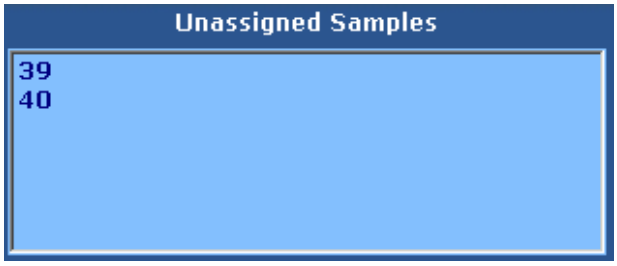
- Grey: Rotor not configured
- Light Blue: Rotor having at least one programmed sample
- Dark Blue: Rotor selected by the user

Upon Rotor selection, the 15 available positions are visualized (from 1 to 15).



An individual, univocal code is associated with each sample (**S**ample **ID**).

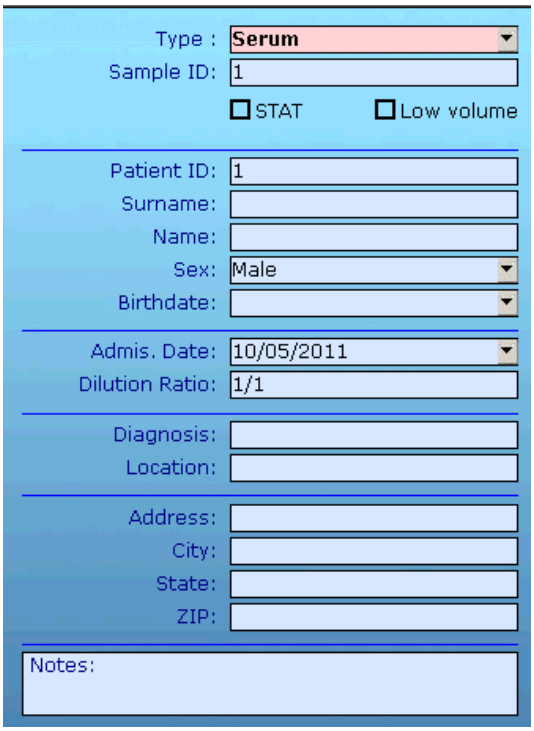
Unassigned Samples



The **"Unassigned Samples"** box reports those samples, using their Sample **IDs,** which have been programmed and sent via the **Host** connection.

The user can use **Drag & Drop** in this area to move a Sample **ID** within a Work List or from Work List/Pos. to Unassigned Samples and vice versa.

Patient data regarding the Sample



Type: allows the user to choose from among the following:

- Serum
- Urine
- Control

Stat: allows the user to set the execution up as urgent.

Low Vol: allows the user to set up a sample having only a small quantity (valid only for primary tubes).

Sample ID: (mandatory field) indicates the **Sample Identification Code;**

Patient ID: indicates the Patient Identification Code;

Name: allows the user to set up the patient's last name;

First Name: allows the user to set up the patient's first name:

Sex: allows the user to select from among the following:

- Male
- Female
- Other (stands for Child)

Birth date: allows the user to enter the patient's date of birth. The date can also be entered using the electronic calendar;

Admis. Date: allows the user to enter the date the sample was accepted. The date can also be entered using the electronic calendar;

Dilution Ratio: allows the user to manually set up sample dilution. All the final results of the tests associated with that sample will automatically be adjusted and corrected in relation to the dilution ratio set up (for example: multiplied by 2 if the dilution ratio has been manually set at 1/2);

Diagnosis: allows the user to enter (if s/he so desires) the medical diagnosis;

Location: allows the user to enter information regarding patient location;

Address: allows the user to enter the patient's address;

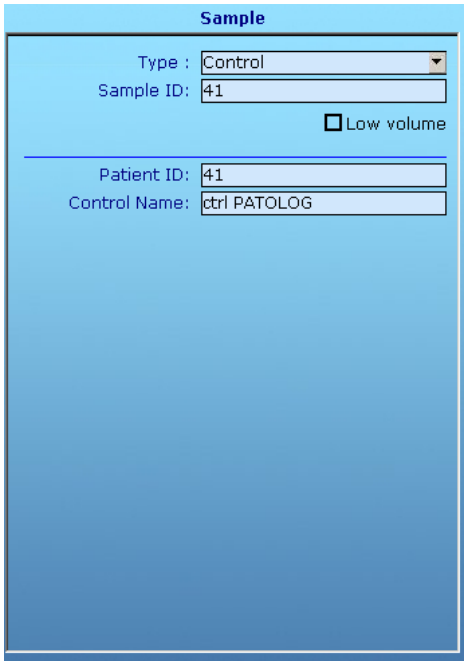
City: allows the user to enter the name of the city where the patient resides;

State: allows the user to enter the name of the state where the patient resides;

Zip: allows the user to enter the patient's postal ZIP code;

Notes: allows the user to enter any information deemed useful regarding the patient.

Please note: *if the user has selected "Control" under the "Type" field, the patient data table will be visualized as illustrated below:*



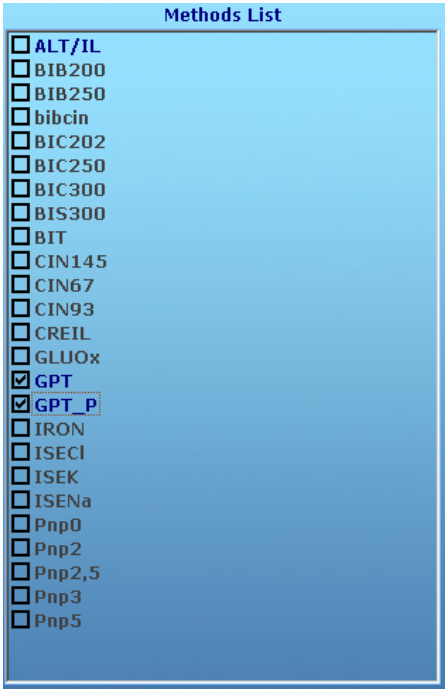
Low Vol: allows the user to set up a sample having only a small quantity (valid only for primary tubes);

Sample ID: (mandatory field) indicates the **Sample Identification Code;**

Patient ID: indicates the Patient Identification Code;

Control Name: allows the user to select the name of the control to be used from among those previously defined.

Methods List



Reports the list (ordered alphabetically) of those methods programmed in the "Chemistry Definition" mask.

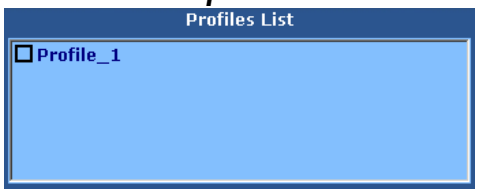
The list is a set of checkboxes each tagged with an acronym of a method.

The methods selected here will be applied to the sample in question.

The acronym of any method present in the Reagents Plate Configuration currently in use is visualized using white characters – otherwise it is written in grey.

Please note: *ISE methods are showed only if the "ISE Module" option has been set (see: "Options" mask).*

Profiles List



Reports the list (ordered alphabetically) of the previously programmed profiles ("Profiles Configuration" mask).

Whenever a profile is selected, the methods associated with that profile are automatically selected in the methods list.

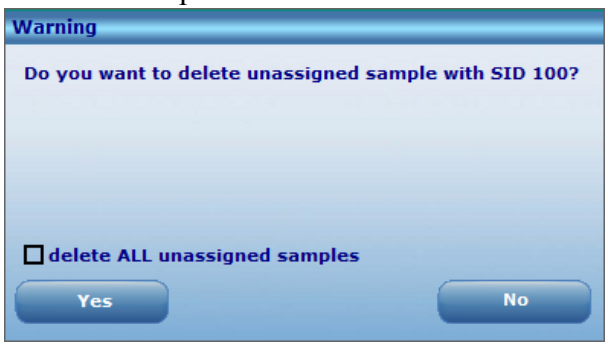
Ratios List

Reports the list, ordered alphabetically, of previously programmed Ratios.

Whenever a Ratio is selected, the methods associated with that ratio are automatically selected in the methods list.

"**Delete Unassigned**" Button

allows the user to delete the selected sample from the Unassigned Area. Whenever this button is selected, the below-illustrated window opens:



If the user wants to delete all the samples in the Unassigned Area, he or she has to flag the "delete ALL unassigned samples" check.

Select "**Yes**" to confirm the deletion of the sample(s).

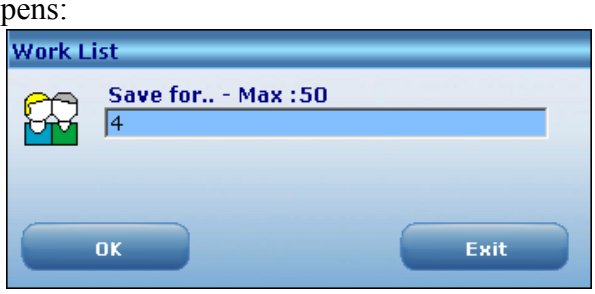
Select "**No**" to cancel the operation and close the window.

"**Save**" Button

allows the user to save the programming of a sample.

"**Save For**" Button

allows the user to save data common to more than one sample. Whenever this button is selected, the below-illustrated window opens:



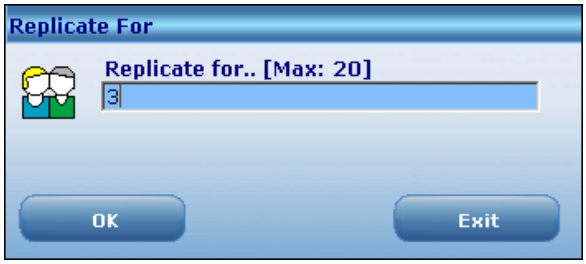
At most 50 samples having common data can be entered.

Select **OK** to confirm the number entered.

Select **Exit** to cancel the operation and close the window.

"**Replicate For**" Button

allows the user to request multiple test repetition for a given sample. The below-illustrated window will appear whenever this button is pressed. A maximum number of 20 replicates is allowed.



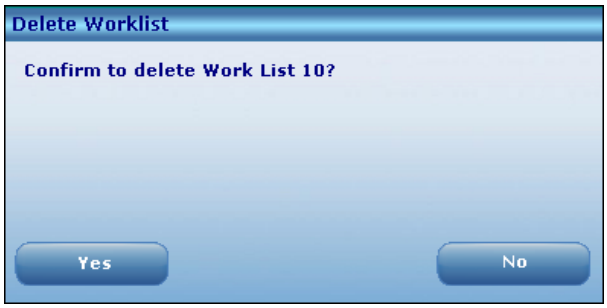
Select **OK** to confirm the number of replicates requested.

Select **Exit** to cancel the request and close the window.

"**Delete WL**" Button

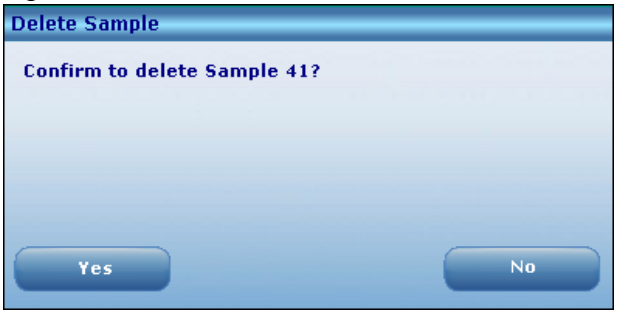
Pressing this button allows the user – after having confirmed the request – to physically cancel a previously programmed Rotor (or rather, it allows the user to cancel the entire work list).

Please note: *in order for a work list to be cancelled it* ***cannot*** *be in running status.*



"**Delete Sample**" Button

Pressing this button allows the user – after having confirmed the request – to physically cancel a previously programmed sample.



"**Host Download**" Button

This button is active only if the "**Host Connection**" option has been selected under the "**Options**" mask.

Pressing this button allows the user to query the Host in order to receive data.

The Host responds providing a list of patients and all relative analysis.

Upon reception of each individual patient, the software automatically checks the Patient ID (PID). If the PID is already in the instrument Database the software then checks congruency regarding that patient's personal data. In the event that any of the personal data does not match up, the below-listed choices will be offered to the user.

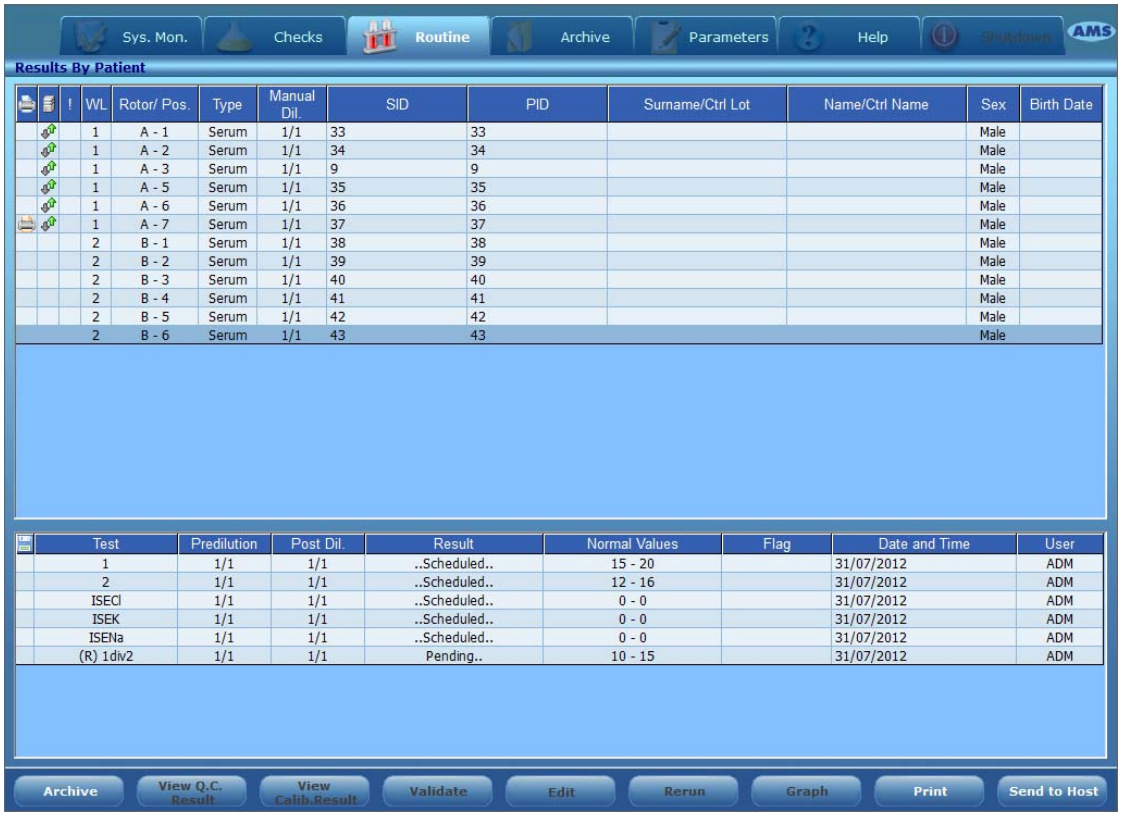
- Maintain the data as is in the instrument database (or rather, do not replace the instrument database data with that received from the Host);
- Replace the data in the instrument Database with that received from the Host;
- Cancel the Query request.

All patients received from the Host are entered:

- in the "**Unassigned Samples**" area (if "Sample Barcode" is configured);
- in a full free "**Work List"** (if "Sample Barcode" is not configured).

3.3.2 RESULTS BY PATIENT

This mask makes it possible to visualize data regarding already programmed patients.



This mask is divided into two areas:

- Main Area
- Details Area

Main Area

This area contains all the fields that the user needs for positive identification of the sample.

		!	WL	Rotor/ Pos.	Type	Manual Dil.	SID	PID	Surname/Ctrl Lot	Name/Ctrl Name	Sex	Birth Date
			1	A - 1	Serum	1/1	33	33			Male	
			1	A - 2	Serum	1/1	34	34			Male	
			1	A - 3	Serum	1/1	9	9			Male	
			1	A - 5	Serum	1/1	35	35			Male	
			1	A - 6	Serum	1/1	36	36			Male	
			1	A - 7	Serum	1/1	37	37			Male	
			2	B - 1	Serum	1/1	38	38			Male	
			2	B - 2	Serum	1/1	39	39			Male	
			2	B - 3	Serum	1/1	40	40			Male	
			2	B - 4	Serum	1/1	41	41			Male	
			2	B - 5	Serum	1/1	42	42			Male	
			2	B - 6	Serum	1/1	43	43			Male	

Description of the fields contained in the Main Area:

Printer Picture: indicates if the sample report has ever been printed and if some data related to the sample have been changed after the report printing (*No Picture*: the report has never been printed; *Green Picture*: no data related to the sample has been changed after the report printing; *Red Picture*: some data related to the sample have been changed after the report printing);

Host Picture: indicates the synchronization status between the instrument and the host; next table shows possible status:

	Sample not received by the host; no test sent to the host
	Sample with at least one test received by the host; no test sent to the host
	Sample with at least one test received by the host; at least one test sent to the host
	Sample with at least one test received by the host; all the tests sent to the host
	Sample not received by the host; at least one test sent to the host
	Sample not received by the host; all the tests sent to the host

!: indicates that the sample has been programmed as urgent (Stat);

Rotor/Pos: indicates the Rotor and the position occupied by the sample;

Type: indicates the type of sample set up (Serum/Urine/Control);

Manual Dil: indicates the Manual Dilution Ratio set up for the sample ("Work List" mask);

SID: indicates the sample identification code (Sample ID);

PID: indicates the patient identification code (Patient ID);

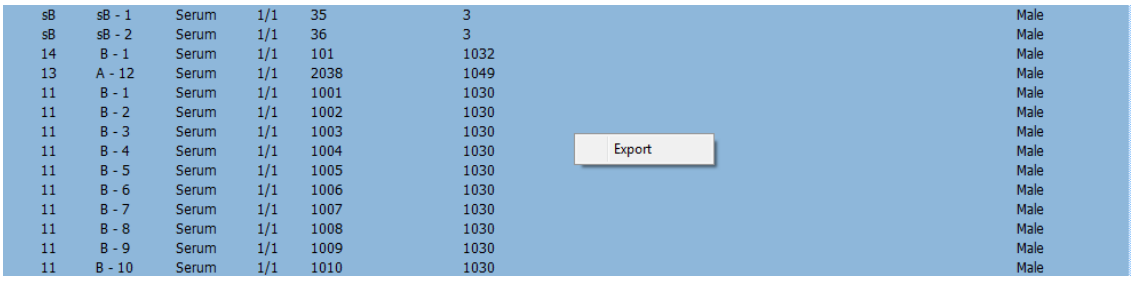
Surname/Ctrl Lot: indicates the last name of the donor of the sample if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the lot number of the control;

Name/Ctrl Name: indicates the first name of the donor of the sample if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the name of the control;

Sex: indicates the sex of the patient;

Birth Date: indicates the patient's date of birth.

After selecting any given number of rows from the Main Area, it is possible to request a **csv export of the selected data**.



Data exported in the csv file will have the following format.

!
WL
Rotor/Pos.
Type
Manual Dil
SID
PID
Name/CTRL Name
Surname /CTRL Lot
Sex
Birthdate
Test
Replicate
Predilution
Post Dil
Validated
Result
Unit
Normal Values
Flag
Flag Description
Date and Time
User

Whenever a row in the main area is selected, all detailed information regarding that selected row is visualized in the Details Area.

Details Area

Test	Predilution	Post Dil.	Result	Normal Values	Flag	Date and Time	User
BIC202 (1)	1/1	1/1	405.5 [mAbs]	370 - 430	C	03/07/2009 11.28.45	ADM
BIC250 (1)	1/1	1/1	415.3 [mAbs]	370 - 430	C	03/07/2009 11.28.58	ADM
BIC202 (2)	1/1	1/1	402.0 [mAbs]	370 - 430	C	03/07/2009 11.57.10	ADM
BIC250 (2)	1/1	1/1	423.2 [mAbs]	370 - 430	C	03/07/2009 11.57.23	ADM
BIC202 (3)	1/1	1/1	406.9 [mAbs]	370 - 430	C	03/07/2009 11.57.37	ADM
BIC250 (3)	1/1	1/1	417.1 [mAbs]	370 - 430	C	03/07/2009 11.57.50	ADM
BIC202 (4)	1/1	1/1	406.7 [mAbs]	370 - 430	C	03/07/2009 11.58.03	ADM
BIC250 (4)	1/1	1/1	423.8 [mAbs]	370 - 430	C	03/07/2009 11.58.16	ADM
BIC202 (5)	1/1	1/1	404.6 [mAbs]	370 - 430	C	03/07/2009 11.58.30	ADM
BIC250 (5)	1/1	1/1	420.2 [mAbs]	370 - 430	C	03/07/2009 11.58.43	ADM
BIC202 (6)	1/1	1/1	405.0 [mAbs]	370 - 430	C	03/07/2009 11.58.56	ADM

The fields included in the Details Area are the following:

Test: reports the acronym of the test;

Predilution: indicates the predilution ratio set up for the test ("Chemistry Definition" mask);

Post Dil: indicates the dilution ratio of the test;

Result: reports the results of the test (pending if the test has not yet been executed);

Unit: indicates the unit of measurement set up for the test;

Normal Values: reports the normal reference values set up for the test**;**

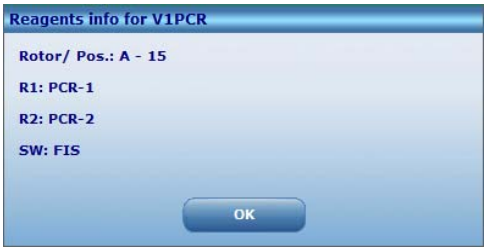
Flags: indicates what type of error, if any, occurred during test execution;

Please note*: whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error.*

Data and Time: indicates the exact date and time the test was executed (if already run), or if not yet executed, it reports the date the sample was accepted;

User: reports the acronym of the user logged in.

***Please note**: whenever the mouse is positioned over the "i" symbol (to the left of the "**Test**" field), information regarding the sample position and the reagents used for the test is visualized. The same information can be obtained by clicking on the abovementioned symbol.*



***Please note:** right clicking on a specific test or ratio shown in the Details Area that is not scheduled or running it shall be possible to request the deletion of the selected element. If a test is an element of the formula of a ratio associated to the sample, in order to delete the test, user should delete the ratio before.*

Commands Area

The Commands Area is made up of a series of buttons, as described below:

"**Archive**" Button

Makes it possible to transfer the results obtained and patient personal data to a historical archive.

Whenever this button is pressed, the user will view a window reporting the number of samples selected.

"**View Q. C. Result**" Button

Pressing this button allows the user to view the results of quality control run on the required method for a specific sample. The user must first select a sample from the Main Area, then select a method in the Details Area, and then press the "View Q. C. Result" button.

View Calib. Result" Button

Pressing this button allows the user to view the data and results regarding calibration as associated with the methods run on the selected sample. The user must first select a sample in the Main Area and then press the "View Calib. Result" button.

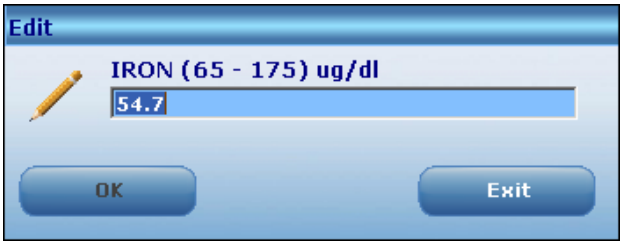
"**Validate**" Button

Necessary in order to be able to validate the results of any already run test. In the case of rerun tests and after having selected the chosen results, this button is activated by the user in order to definitively assign these results to the test in question.

"Validated" results will be viewed in bold print.

"**Edit**" Button

Makes it possible to manually modify the results of a run test. After having selected a test regarding a sample in the Details Area, the user then presses this button causing a data entry window to open where s/he can manually modify the results of that test.



Whenever a result is **Edited** manually, that result will appear having an "**E**" in the Flags field.

***Note**: the edited value could also produce the following flags: Low/High, Pathologic Low/High, Alert Low/High.*

"OK" allows the user to confirm the request for Editing.

"**Exit"** allows the user to cancel the request.

"**Rerun**" Button

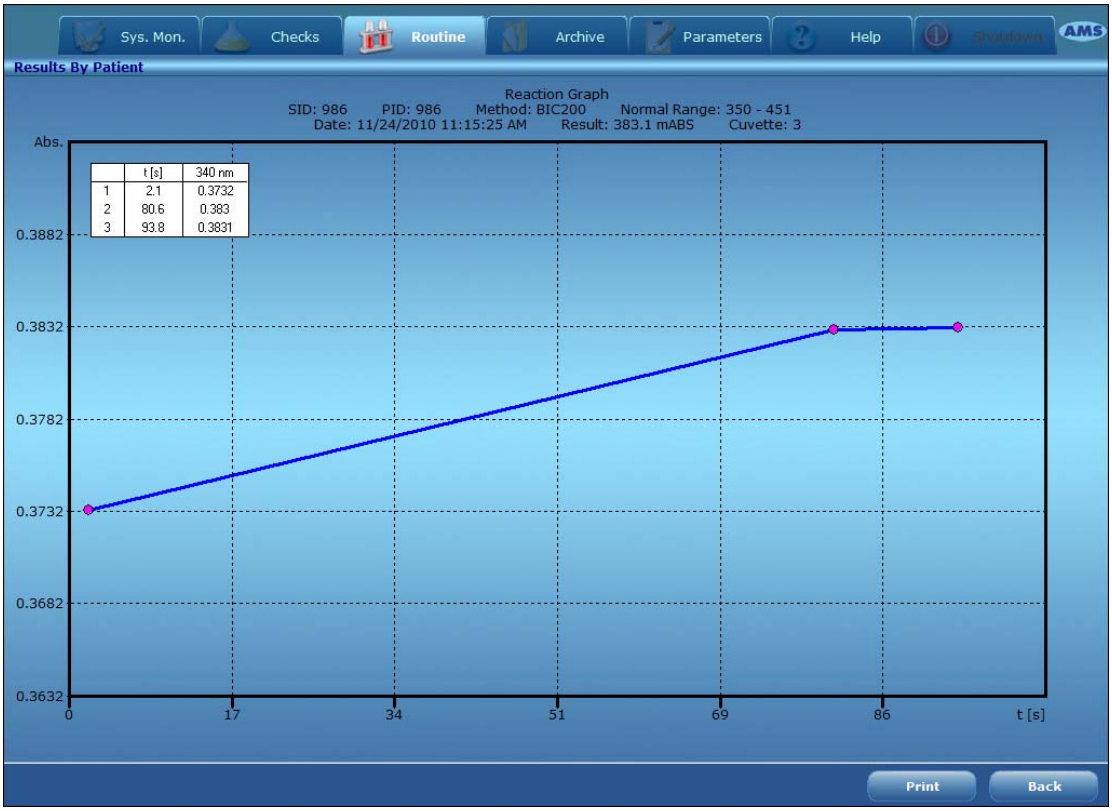
allows the user to request a rerunning of the method/s selected in the Details Area.

***Please note:** only tests that have already been executed can be rerun.*

Select dilution ratio: allows the user to select – from a pull-down menu – the dilution ratio for the test. It is possible to select a dilution ratio only for a single test (provided that sample volume as set up in the method is sufficient).

"**Graph**" Button

Pressing this button allows the user to view the graph of any method selected from the Details Area.



Press **Print** to have a print-out of the graph.

Press **Back** to close the graph.

"**Print**" Button

After selecting a row in the Main Area and pressing the Print button, the user can then request:

- a print-out of the results regarding the patient/s (sample/s) selected;
- a print-out of the Sample List regarding the patient/s (samples) selected;
- a print-out of the Work List regarding the patient/s (samples) selected;
- to cancel the Print request.

By selecting any number of rows from the Details Area and then pressing Print, the user can request a print-out of the selected data.

"**Send to Host**" Button

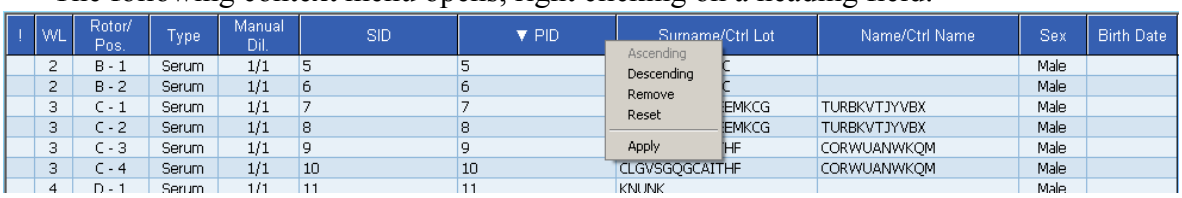
This button is active only if the "**Host Connection**" option has been selected under the "Options" mask.

The user must first select the required samples from the Main Area and then press "**Send to Host**".

Sort

Click on the data headings field (of the Main or Details Area) to make a sort.

- Left clicking on a heading field to sort in ascending/descending way;
- The following context menu opens, right clicking on a heading field:



Ascending: to define an ascending order of the data related to the selected field;
Descending: to define a descending order of the data related to the selected field;
Remove: to delete the selected field from the sorting logic;
Reset: to set the default sorting logic (*);
Apply: to apply the sorting logic.

Through the right clicking, the user can define a multiple field order.

Select "**Apply**" to store a sorting logic. Any time the user re-opens the mask, will be showed the stored sorting.

***** The default order logic is the following: "WL" and "Rotor/Pos." (both ascending).

Precision Check

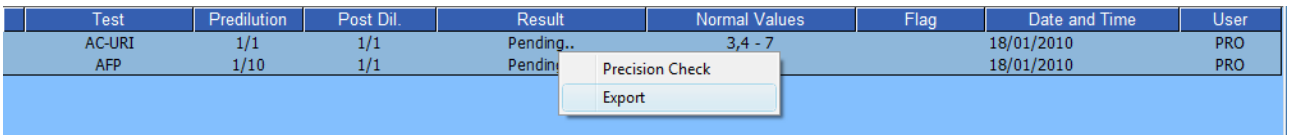
After selecting any given number of rows from the Details Area, it is possible to request a **precision check**. After having selected the required rows, right click on the highlighted area; the below-illustrated window will open:

Test	Total	Mean	SD	CV%
CA-AR2 (mg/dl)	1	8,5	---	---
CA-ARS (mg/dl)	1	10,38	---	---
CO (mg/dl)	1	210	---	---
CRE2 (mg/dl)	2	1,59	0,01	0,45
GLU (g/l)	1	1,55	---	---
GOT (U/l)	1	19,2	---	---
GPT (U/l)	1	19,0	---	---
HDL (mg/dl)	1	72,2	---	---
ISEK (mEq/L)	2	5,67	0,02	0,37
ISENa (mEq/L)	1	144,5	---	---
LDH (mg/dl)	1	219	---	---
TRI (mg/dl)	1	81	---	---
UREA (mg/dl)	1	0,82	---	---
URI (mg/dl)	1	2,60	---	---
A_Glu (mg/dl)	1	1,55	---	---
A_K (mEq/L)	1	5,65	---	---
A_Na (-)	1	145	---	---

This window contains the following fields:
Test: acronym of the method;
Total: indicates the total number of rows selected;
Mean: reports the mean value of the results obtained corresponding to the rows selected;
SD: reports the standard deviation with reference to the test indicated;
CV %: reports the coefficient of variation percentage with reference to the test indicated.

Press **Print** to have a print-out of the table.
Press **Exit** to close the precision check.

After selecting any given number of rows from the Details Area, it is possible to request a **csv export of the selected data**.



Data exported in the csv file will have the following format.

!
WL
Rotor/Pos.
Type
Manual Dil
SID
PID
Name/CTRL Name
Surname /CTRL Lot
Sex
Birthdate
Test
Replicate
Predilution
Post Dil
Validated
Result
Unit
Normal Values
Flag
Flag Description
Date and Time
User

3.3.3 RESULTS BY TEST

This mask allows the viewer to view all data regarding the patients: more precisely, data relative to tests already executed or to be executed.

!	WL	Rotor/ Pos.	Type	Manual Dil.	SID	PID	Surname/Ctrl Lot	Name/Ctrl Name	Test	Post Dil.	Result	Flag
	10	B - 1	Serum	1/1	41	41			GPT	1/1	14 []	ER
									GPT_P	1/1	45 []	ER
									IRON	1/1	54.7 [ug/dl]	ER
	9	A - 4	Serum	1/1	38	38	PKYCXPIDLFYDAI		ALT/IL (1)	1/1	123.2 [U/L]	R
									ALT/IL (2)	1/1	124.2 [U/L]	R
									ALT/IL (3)	1/1	124.1 [U/L]	R
									ALT/IL (4)	1/1	123.1 [U/L]	R
									ALT/IL (5)	1/1	122.8 [U/L]	R
									ALT/IL (6)	1/1	123.1 [U/L]	R
									ALT/IL (7)	1/1	124.0 [U/L]	R
									ALT/IL (8)	1/1	122.4 [U/L]	R
									ALT/IL (9)	1/1	123.6 [U/L]	R
									ALT/IL (10)	1/1	121.7 [U/L]	R
									CREIL (1)	1/1	3.6 [mg/dl]	
									CREIL (2)	1/1	3.6 [mg/dl]	
									CREIL (3)	1/1	3.3 [mg/dl]	
									CREIL (4)	1/1	3.3 [mg/dl]	
									CREIL (5)	1/1	3.5 [mg/dl]	
									CREIL (6)	1/1	3.6 [mg/dl]	
									CREIL (7)	1/1	3.5 [mg/dl]	
									CREIL (8)	1/1	3.6 [mg/dl]	
									CREIL (9)	1/1	3.6 [mg/dl]	
									CREIL (10)	1/1	3.5 [mg/dl]	
									GLUOx (1)	1/1	234.3 [mg/dl]	RC
									GLUOx (2)	1/1	239.2 [mg/dl]	RC
									GLUOx (3)	1/1	237.0 [mg/dl]	RC
									GLUOx (4)	1/1	230.7 [mg/dl]	RC
									GLUOx (5)	1/1	234.8 [mg/dl]	RC
									GLUOx (6)	1/1	236.1 [mg/dl]	RC
									GLUOx (7)	1/1	242.8 [mg/dl]	RC
									GLUOx (8)	1/1	232.6 [mg/dl]	RC
									GLUOx (9)	1/1	230.1 [mg/dl]	RC
									GLUOx (10)	1/1	231.9 [mg/dl]	RC
									IRON (1)	1/1	159.8 [ug/dl]	C
									IRON (2)	1/1	158.2 [ug/dl]	C
									IRON (3)	1/1	158.3 [ug/dl]	C

Description of the fields contained in this mask:

!: indicates that the sample has been programmed as urgent (Stat);

WL: indicates the Work List number;

Rotor/Pos: indicates the Rotor and the position occupied by the sample;

Type: indicates the type of sample set up (Serum/Urine/Control);

Manual Dil: indicates the Manual Dilution Ratio set up for the sample ("Work List" mask);

SID: indicates the sample identification code (Sample ID);

PID: indicates the patient identification code (Patient ID);

Surname/Ctrl Lot: indicates the last name of the donor of the sample if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the lot number of the control;

Name/Ctrl Lot: indicates the first name of the donor of the sample if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the lot number of the control;

Test: indicates the acronym used for the test;

Post Dil: indicates the dilution ratio of the test;

Result: reports the results of the test (pending if the test has not yet been executed);

Flag: indicates what type of error, if any, occurred during test execution.

Commands Area

The Commands Area is made up of a series of buttons, as described below:

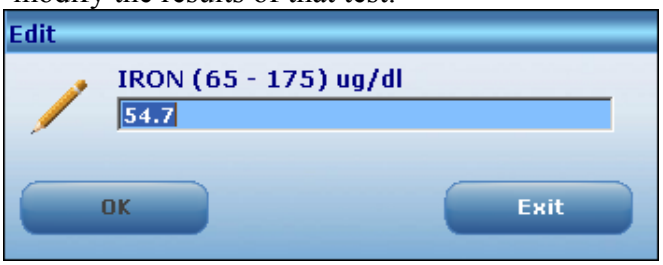
"**Validate**" Button

Necessary in order to be able to validate the results of any already run test. In the case of rerun tests and after having selected the chosen results, this button is activated by the user in order to definitively assign these results to the test in question

*"**Validated**"* results will be viewed in bold print.

"**Edit**" Button

Makes it possible to manually modify the results of a test. After having selected a test regarding a sample in the Main Area, the user then presses this button causing a data entry window to open where s/he can manually modify the results of that test.



Whenever a result is **Edited** manually, that result will appear having an "**E**" in the Flags field.

***Note**: the edited value could also produce the following flags: Low/High, Pathologic Low/High, Alert Low/High.*

"OK" allows the user to confirm the request for Editing.

"**Exit"** allows the user to cancel the request.

Rerun" Button

allows the user to request the rerunning of methods selected in the Main Area.

***Please note:** only tests that have already been executed can be rerun.*

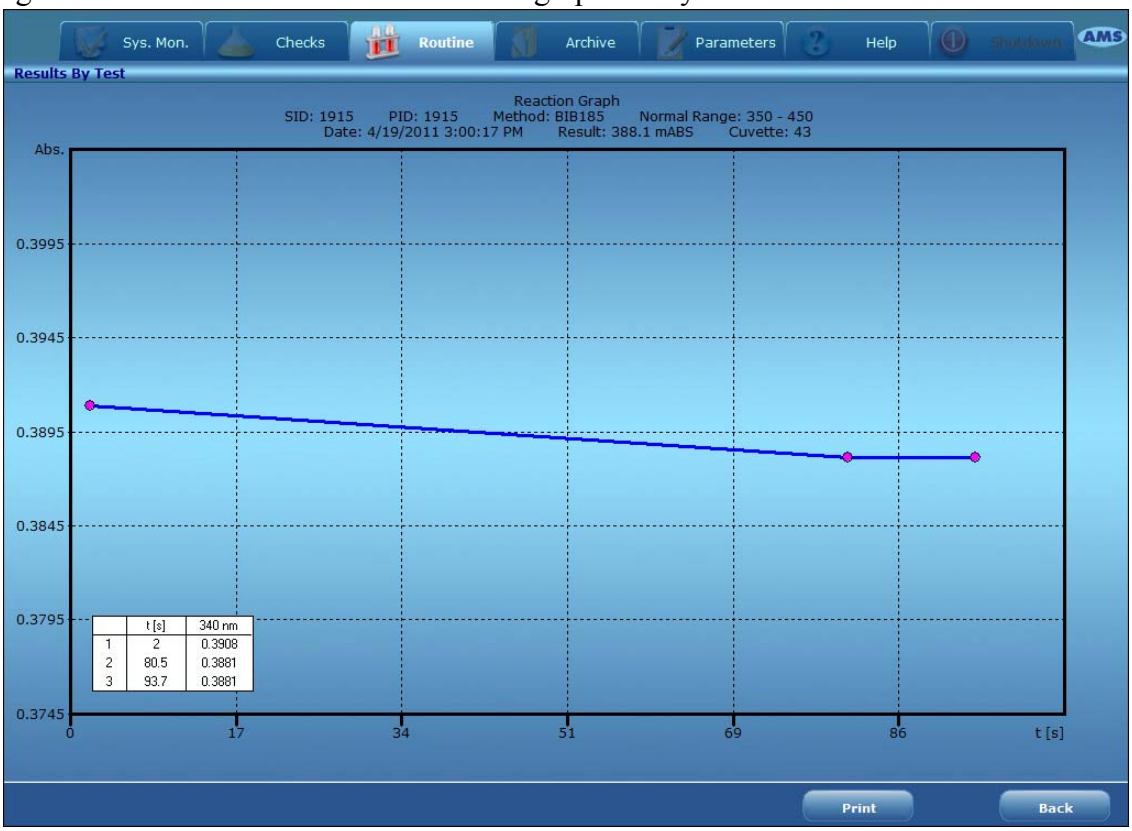
Select dilution ratio: allows the user to select – from a pull-down menu – the dilution ratio for the test. It is possible to select a dilution ratio only for a single test (provided that sample volume as set up in the method is sufficient).

"OK" allows the user to confirm the request.

"**Exit"** allows the user to cancel the request.

"**Graph**" Button

Pressing this button allows the user to view the graph of any method selected from the Main Area.



Press **Print** to have a print-out of the graph.

Press **Back** to close the graph.

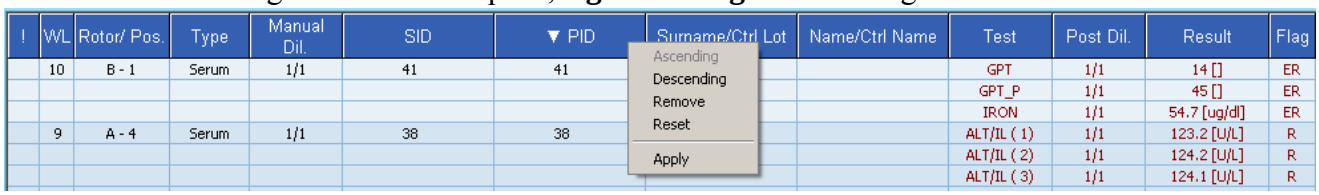
"**Print**" Button

allows the user to have a print-out of the selected data.

Sort

Click on the data headings field (of the Main) to make a sort.

- **Left clicking** on a heading field to sort in ascending/descending way;
- The following context menu opens, **right clicking** on a heading field:



Ascending: to define an ascending order of the data related to the selected field;
Descending: to define a descending order of the data related to the selected field;
Remove: to delete the selected field from the sorting logic;
Reset: to set the default sorting logic (*);
Apply: to apply the sorting logic.

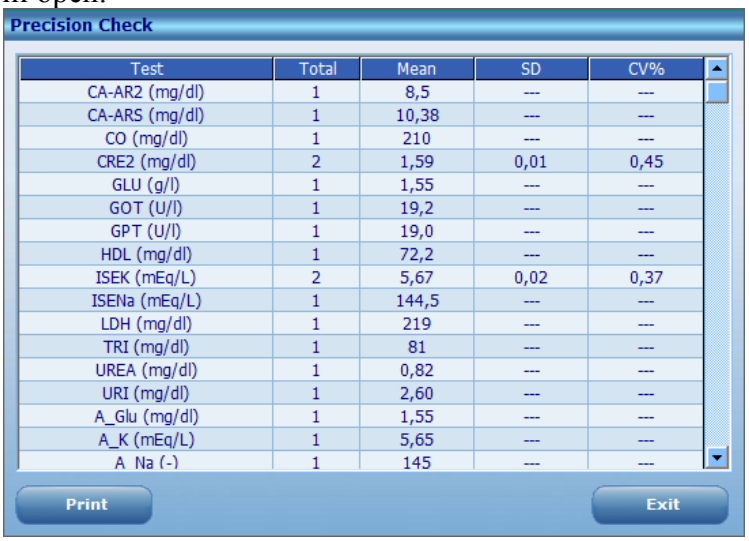
Through the right clicking, the user can define a multiple field order.

Select "**Apply**" to store a sorting logic. Any time the user re-opens the mask, will be showed the stored sorting.

***** The default order logic is the following: "**WL**" descending, "**Stat**" and "**Rotor/Pos**." descending, "**SID**" and "**Test**" ascending.

Precision Check

After selecting any given number of rows from the Main Area, it is possible to request a **precision check**. After having selected the required rows, right click on the highlighted area; the below-illustrated window will open:



Precision Check

Test	Total	Mean	SD	CV%
CA-AR2 (mg/dl)	1	8,5	---	---
CA-ARS (mg/dl)	1	10,38	---	---
CO (mg/dl)	1	210	---	---
CRE2 (mg/dl)	2	1,59	0,01	0,45
GLU (g/l)	1	1,55	---	---
GOT (U/l)	1	19,2	---	---
GPT (U/l)	1	19,0	---	---
HDL (mg/dl)	1	72,2	---	---
ISEK (mEq/L)	2	5,67	0,02	0,37
ISENa (mEq/L)	1	144,5	---	---
LDH (mg/dl)	1	219	---	---
TRI (mg/dl)	1	81	---	---
UREA (mg/dl)	1	0,82	---	---
URI (mg/dl)	1	2,60	---	---
A_Glu (mg/dl)	1	1,55	---	---
A_K (mEq/L)	1	5,65	---	---
A_Na (-)	1	145	---	---

Print Exit

This window contains the following fields:

Test: acronym of the method;

Total: indicates the total number of rows selected;

Mean: reports the mean value of the results obtained corresponding to the rows selected;

SD: reports the standard deviation with reference to the test indicated;

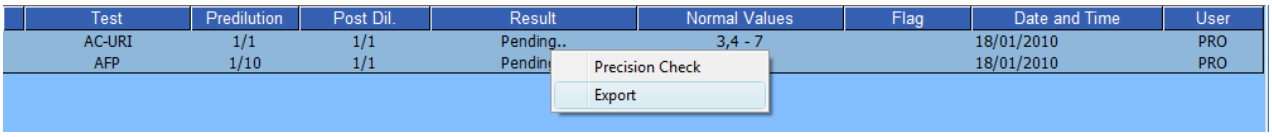
CV %: reports the coefficient of variation percentage with reference to the test indicated.

Press **Print** to have a print-out of the table.

Press **Exit** to close the precision check.

Please note: *right clicking on a specific test or ratio shown in the Main Area that is not scheduled or running it shall be possible to request the deletion of the selected element. If a test is an element of the formula of a ratio associated to the sample, in order to delete the test, user should delete the ratio before.*

After selecting any given number of rows from the Main Area, it is possible to request a **csv export of the selected data**.



Test	Predilution	Post Dil.	Result	Normal Values	Flag	Date and Time	User
AC-URI	1/1	1/1	Pending..	3,4 - 7		18/01/2010	PRO
AFP	1/10	1/1	Pendin			18/01/2010	PRO

Precision Check
Export

Data exported in the csv file will have the following format.

!
WL
Rotor/Pos.
Type
Manual Dil
SID
PID
Name/CTRL Name
Surname /CTRL Lot
Sex
Birthdate
Test
Replicate
Predilution
Post Dil
Validated
Result
Unit
Normal Values
Flag
Flag Description
Date and Time
User

3.3.4 CALIBRATION & Q. C. SETUP

This mask makes it possible to program calibration. Calibration must be executed by the user upon initial installation of the instrument. It must also be verified daily via a reading of known serums (controls).

The above-illustrated mask includes:

- Legend Area;
- a visualization area regarding the reagents plate;
- a visualization area regarding the samples plate;
- a calibrations area (Methods List – Controls List - Materials);
- a Last Standard placed Area;
- a commands area.

Legend Area

The legend area explains the various colors and symbols used for representing reagents, standards, controls and samples status.

- Blue (Loaded)
- Yellow (Just Placed)
- Ring (H2O / Standard /Control)

Reagents Plate Area

This area allows the user to view positions to be occupied by reagents or diluents, standards and/or controls and/or H2O for RBL.

Whenever the user places the mouse over a position occupied by a Reagent or Diluent, Standard and Control, a tool tip will appear reporting the following information:

- reagent/diluent acronym;
- name of the standard/control and its relative lot number;
- H2O for RBL.

***Note**: Standards and H_2O can be moved in the samples plate peripheral/satellite and in the reagents plate peripheral sectors.*

"**Drag & Drop**" can be used to move a Standard Master Diluent and/or a Standard and/or H2O from a position to another one in the reagents plate.

"**Drag & Drop**" can be used to move a Standard and/or H2O from a position to another one (from the reagents plate to the samples plate and vice-versa).

Moreover, it is possible to change the type of a Standard Master Diluent bottle - by right clicking on the reagents plate visualization area.

Samples Plate Area

This area allows the user to view the positions occupied by "Predilution Racks, Standards and/or Controls and/or H2O".

Whenever the user places the mouse over a position occupied by a Standard or a Control or H2O, a tool tip opens - showing the following information:

- Standard/Control name & Lot Number.
- H2O.

***Note:** Standards can be moved in the samples plate peripheral/satellite sectors and in the reagents plate peripheral sectors. H_2O can be moved in the samples/reagents plate peripheral sectors.*

"**Drag & Drop**" can be used to move a Standard and/or H2O from a position to another one in the Samples Plate.

"**Drag & Drop**" can be used to move a Standard and/or H2O from a position to another one from the samples plate to the reagents plate and vice-versa.

The following table

Std_GPT

N	Pos.	Lot	Vol
1	sB - 2	GGG	612
2	sC - 1	GGG	612
3	sC - 2	GGG	612
4	sD - 1	GGG	612

shows the details of the last positioned Standard (D stands for diluents *)

* Diluent of the Master Standard

Calibrations Area

The central portion of the above-illustrated window is dedicated to the selection of the tests for execution of reagent blank (RBL), calibration and controls.

In this area there are three tabs:

- Methods List - Controls List (simultaneously active);
- Materials.

The tabs Methods and Controls List contains the following elements:

Run: if selected, indicates that RBL, Standard and/or Control must be executed, where requested, for the test considered;

Method: reports the short name of the Method/Ratio;

RBL Expiration: reports for how many more days the reagent blank is to be considered valid. If the number is negative (RBL expired), it will be printed in red. Whenever the mouse is placed over this field, the user can view the exact date and time the last RBL was executed;

RBL On/Off: if selected, indicates a request for RBL execution regarding that method being considered. Whenever this checkbox is ticked, water is placed in an unoccupied position of the reagents/samples plate peripheral Rotors or in the reagents plate satellite Rotors;

Calibration Expiration: reports for how many more days the calibration is to be considered valid. If the number is negative (Calibration expired), it will be printed in red. Whenever the mouse is placed over this field, the user can view the date and exact time the last calibration was executed;

Note: *for the ISE methods the "Calibration Expiration" is expressed in hours and minutes.*

Calibration On/Off: if selected, indicates a request for Calibration execution regarding that method being considered. Whenever this checkbox is ticked, the Standard is placed in an unoccupied position of the reagents/samples plate peripheral Rotors or in the reagents plate satellite Rotors;

Note: *in case of Standard Master, whenever the previous checkbox is ticked, appears the following mask that allows the user to place the diluent of the Master Standard.*

Standard diluents positioning

Reag./Dil.Code	Lot Number	Expiration Date	Bottle Type	Stability Days
STDDIL	444	18/07/2009	50 ml	

Save Cancel

After pushing the "**Save**" button the diluent of the Master will be placed in a free position of the reagents plate.

Calibration Material: reports the list of the Standards associated with that method. Please note: a row of question marks will be visualized in the field is that method is not associated with any standard;

Control: if selected, indicates a request to execute controls for that method. No checkbox will be viewed unless the active configuration for the plate includes at least one control for that method (Checks - Reagents Configuration).

The tab Materials shows the details related to the materials requested for the execution of the operations defined by the user through the tabs Methods and Controls List.

Methods List | Materials | Controls List

Position	Type	Name	Lot	Point	Test count	Needed vol (µl)
sB - 1	RBL	[H2O]			4	78.5
sB - 2	Standard	Std_GPT	GGG	1	1	600
sC - 1	Standard	Std_GPT	GGG	2	1	600
sC - 2	Standard	Std_GPT	GGG	3	1	600
sD - 1	Standard	Std_GPT	GGG	4	1	600

***Note**: Methods with a running, scheduled or partially executed calibration are shown by a locker. It is possible to make a modification in Stand By or in Search status – by selecting "Delete Pending" button.*

Commands Area

Delete Pending

allows the user to cancel a previously assigned calibration.

Assign Check

activates the procedure for assigning calibrations, RBL and controls.

Whenever this button is pressed, a visual text message will appear telling the user how many operations have been requested.

Summary

3 RBL
3 Calibrations

Name	Test
RBL	AC-URI
RBL	AFP
CAL PRT S	
RBL	ALB
CAL PRT S	V-C3
CAL PRT S	V-C4

OK

Print

allows the user to have a print-out of the occupation status of the samples plate and of the reagents plate.

3.3.5 CALIBRATION RESULTS

This mask visualizes calibration results.

The mask is divided into the following areas:

- a "Main Area" located in the upper portion of the mask contains all those fields regarding calibration results – explained below;
- a "Details Area" placed in the lower portion of the mask dedicated to calibration data regarding a single test.

Main Area

Test Name	RBL					Calibration						Controls			
	Days	Flags	D	Abs.	Rate	Days	Flags	Conc.	Abs.	CV%	Factor	Name	Flags	Result	Range (Mean)
CO	9		1	0,0336	0,0000	336		153	0,6786		225,46	CT N 158033		102	82 - 122 (102,0)
COLIN	-5		1	1,5767	-0,0050						-65800,00	CT N 158033		5620	4754 - 6842 (5798,0)
CRE2	-5		1	0,2697	0,0070	-18	C	3,80	0,1586	0,40	23,96	CT N 158033	C	1,09	0,91 - 1,37 (1,140)
F-ALC	-4		1	0,4819	0,0034						2750,00	CT N 158033		160	141 - 211 (176,0)
FE	15		1	0,0107	0,0100	16		184,0	0,1906		965,46	CT N 158033		98,3	94,0 - 110,0 (102,00)
GGT	-2		1	0,7684	0,0030						1158,00	CT N 158033		39,4	34,0 - 50,0 (42,00)
GLU	10		1	0,0135	0,0000	335	C	1,90	0,4441		4,28	CT N 158033		0,93	0,82 - 1,10 (0,960)
			2	0,0043	0,0000										
GOT	9		1	1,4512	-0,0007						-1746,00	CT N 158033		42,7	34,0 - 52,0 (43,00)
GPT	9		1	1,4607	-0,0010						-1746,00	CT N 158033		43,4	34,0 - 52,0 (43,00)
HbA_FS	-9		1	0,3559	0,0000	308	C	0	0,0036	55,00	0,00	CT14354HbFS1	C	40	33 - 49 (41,0)
								3	0,1496	1,09	19,79				
								6	0,3766	3,30	15,61				
								10	0,8236	2,27	12,63				
								16	1,3214	0,14	11,96				
HDL	4		1	0,0073	0,0000	287		59,0	0,1294		455,95	CT N 158033		32,9	29,0 - 39,0 (34,00)
LDH	-1		1	1,3768	-0,0008						-8888,00	CT N 158033		253	213 - 319 (266,0)
LDL	5		1	0,0096	0,0000	336		63,0	0,1118		563,76	CT N 158033		63,9	48,0 - 64,0 (56,00)
LIP-C	-3	A	1	0,3364	0,0072	337		89	0,2003		444,44	CT N 158033	C	48	42 - 64 (53,0)
MG	-5		1	0,4974	0,0000	350		2,96	0,3321		8,91	CT N 158033		2,42	1,80 - 2,70 (2,250)
P	-5		1	0,0688	0,0000	310		5,39	0,5856		9,20	CT N 158033		4,63	3,25 - 4,87 (4,060)

Test Name: reports the short name of the method.

RBL Section

Days: reports how many days have gone by since last RBL execution. Whenever the mouse cursor is placed over the field, a tool tip opens informing the user of the exact date of RBL execution;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

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

Abs: reports the optical density values obtained for the **RBL.** In the event of more than one replicate (from 2 to 4), the program will calculate the average of the readings executed and in the case of 3 or 4 replicates, it will ignore the reading furthest from the mean. The mean value thus obtained will be reported in this field; the absorbance values of the replicates are given in the Details Area, where it is also possible to view the graph.

Rate: reports reagent mobility over reaction time expressed in absorbance;

Calibration Section

Days: reports how many days have gone by since the last calibration. Whenever the mouse cursor is placed over the field, a tool tip opens informing the user of the exact date the Standard was executed;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

Conc.: reports the concentration value of the standard;

Abs.: reports the absorbance value;

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

Factor: for linear and standard model methods reports the calibration factor; for the other calculation models reports the concentration-absorbance ratio of the single calibration point.

Controls Section

Name: reports the name of the control;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

Result.: indicates the results obtained for the control;

Range: indicates the normal range regarding the control.

Details Area

AMP2ft

Type	Position	Name	Lot	Expiration	Abs.	Ref./Result	Flags	Date	User
STD	sB - 1	Amph (1) [1/3]	11111	25/04/2011	0,0860	0 ng/mL	A	09/03/2011 06:01:03 PM	ADM
STD	sB - 1	Amph (1) [2/3]	11111	25/04/2011	-0,0657	0 ng/mL		09/03/2011 06:01:16 PM	ADM
STD	sB - 1	Amph (1) [3/3]	11111	25/04/2011	-0,1526	0 ng/mL		09/03/2011 06:01:29 PM	ADM
STD	sB - 2	Amph (2) [1/3]	222222	25/04/2011	-0,0439	500 ng/mL		09/03/2011 06:01:42 PM	ADM
STD	sB - 2	Amph (2) [2/3]	222222	25/04/2011	0,0486	500 ng/mL		09/03/2011 06:01:55 PM	ADM
STD	sB - 2	Amph (2) [3/3]	222222	25/04/2011	-0,0648	500 ng/mL		09/03/2011 06:02:08 PM	ADM

Once calibration has been executed, this section will visualize detailed information regarding the method selected in the upper portion ("Main Area")**.** The fields included are:

Type: reports the type of operation requested (RBL, STD or CTRL);

Rotor-Pos: reports the rotor and the position occupied by that item (H_2O, STD, CTRL);

Name: reports the name of the standard or the control;

Lot: reports the lot number of the standard or the control;

Expiration: reports the Expiration Date of the standard or the control;

Abs: reports the optical density value calculated;

Ref./Result.: reports the results calculated for controls or the reference value for standards;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

Date: reports the date and exact time of "RBL/STD/CTR" execution;

User: reports the acronym of the user who executed the operations on the instrument.

Commands Area

"**View Q. C. Result**" Button

Pressing this button allows the user to view the results of quality control run on the required method. The user must first select a method from the Main Area, and then press the "**View Q. C. Result**" button.

"Rerun" Button

Pressing this button allows the user to request a rerunning of any already executed RBL, Standard or Control. The user must first select the rows from the Details Area and then press the "**Rerun**" button.

"Graph" and "Calib. Graph" Buttons

This button is active only after a method has been selected in the Main Area or a row has been selected in the Details Area.

After a method has been selected in the Main Area and the

button has been pressed, a window will open presenting the calibration results in graph form (see: "Calibration Curve").

After a row has been selected in the Details Area and the

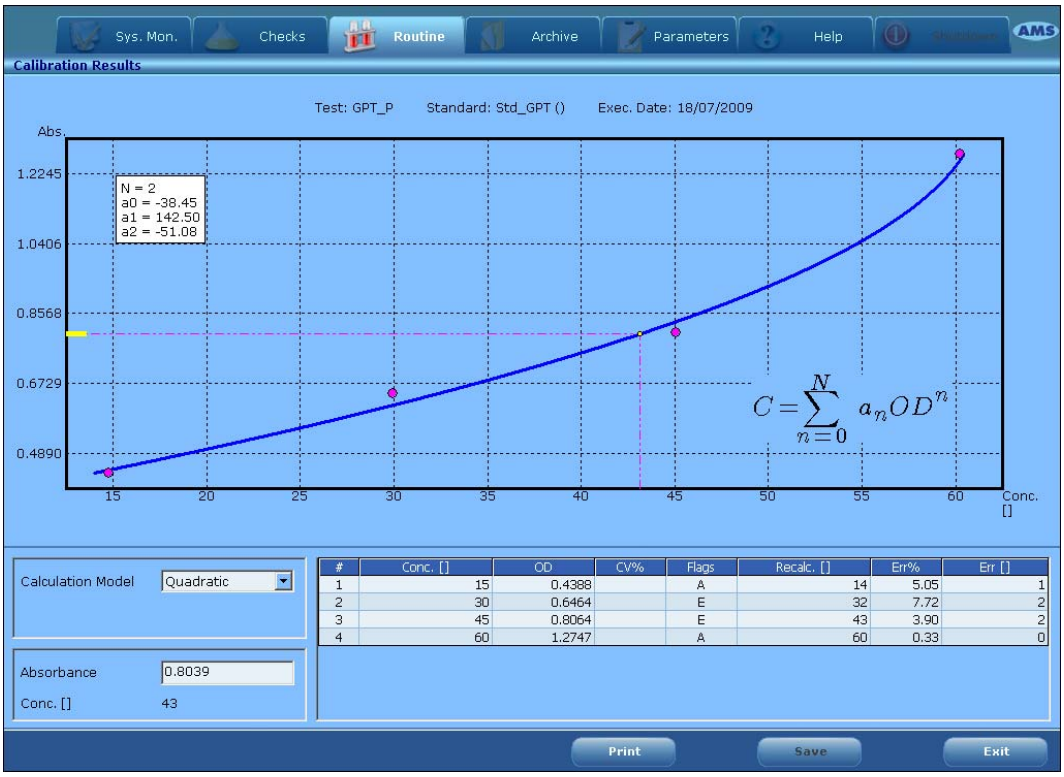
button has been pressed, a window will open presenting the reaction in graph form of the item selected.

"Print" Button

allows the user to print the data selected in the Main Area or in another area of the mask.

Calibration Curve

This mask reports Calibration results in graph form.



This mask contains a Main Area and a Buttons Area.

Main Area

This area visualizes the graph of the standard. It reports in graph form the Curve and all its reading points. Left/Right clicking on any point of the graph allows the user to disable/enable that calibration point. Disabling a point is only possible if the calculation model allows it (or rather, number of parameters fewer than the actual number of calibration points).

Details Area

Reports for each of the points of the standard the following information:

#: reports the ordinal regarding the calibration point (interval from 1 to 8);

Conc. [ ]: reports the reference value (concentration) of the standard;

OD.: reports the optical density of the standard. The user can modify the optical density of one or more calibration points;

CV%: reports the Coefficient of Variation percentage between the replicates of the standard;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

Recalc [ ]: reports the new concentration value obtained in relation to the type of calculation algorithm selected (see: "Calculation Model" field);

Err%: reports the percentage error determined between the value reported in the "Conc [ ]" field and that in the "Recalc [ ]" field;

Err [ ]: reports the absolute error determined between the value reported in the "Conc [ ]" field and that in the "Recalc [ ]" field;

Calculation Model: reports calculation models compatible with the number of points for that standard;

Absorbance: allows the user to set an absorbance value to determine the concentration that would be obtained according to the calculation model selected;

Concentration [ ]: reports the results obtained that correspond to the value entered in the "Absorbance" field.

Buttons Area

"Print" Button

allows the user to print the data visualized in the mask.

"**Save**" Button

allows the user to save the new setup (e.g.: change of calculation model).

This button is activated only if the graph has in some way been modified by the user.

"**Exit**" Button

allows the user to close the "Calibration Curve" mask and return to "Calibration Results".

3.3.6 QUALITY CONTROL

The **Quality Control** mask shows the results of the controls currently defined in the Control mask. It is divided into two areas in order to facilitate comprehension and use.

Test	Reference Data Mean	Reference Data SD	Statistic Data Tot.	Min	Max	Range	Mean	SD	CV%
AC-URI (mg/dl)	4,37	0,33	12	4,3	4,7	0,4	4,4	0,1	2,62
ALB (g/dl)	4,65	0,35	12	4,4	4,6	0,2	4,5	0,1	1,46
AMI (U/l)	80	8	6	73	81	8	78	3	4,02
BID (mg/dl)	0,76	0,075	11	0,77	0,84	0,07	0,80	0,02	2,40
BIT (mg/dl)	1,18	0,12	11	1,19	1,26	0,07	1,23	0,02	2,03
CA (mg/dl)	8,57	0,515	13	8,0	9,0	1,0	8,5	0,3	3,50
CK-NAC (U/l)	148	13,5	8	130,6	138,8	8,2	135,0	2,4	1,75
CL (mg/dl)	94	4,7	2	99,1	101,5	2,4	100,3	1,7	1,69
COL (mg/dl)	100	10	12	100,3	108,4	8,1	104,0	2,0	1,96
COLIN2 (U/l)	4973	447,5	6	4347	4935	588	4762	217	4,55
CRE2 (mg/dl)	1,065	0,108	13	1,00	1,10	0,10	1,04	0,03	2,84
F-ALC (U/l)	141,5	14,25	6	135	140	5	137	2	1,42
FEcab (ug/dl)	99	12,5	13	81	89	8	85	2	2,83
FOS (mg/dl)	4,015	0,403	3	4,0	4,2	0,2	4,1	0,1	2,84
GGT (U/l)	41,5	4,15	13	38,7	42,8	4,1	41,0	1,2	2,84
GLU (mg/dl)	94	7	13	90	99	9	95	3	3,10

Control: CRT NORM (Lot: 181943 - Exp. Date: 31/05/2010) Method: AMI

Position	Cuv.	Pred. Lot #	R.1 Lot #	R.2 Lot #	R.3 Lot #	Abs	Result	Flags	Date	Time	User
sA - 1	45					0,0203	76		03/08/2009	09.33	ann
sA - 1	43					0,0193	73		04/08/2009	09.47	isa
~~sA - 1~~	~~43~~					~~0,0184~~	~~69~~		~~05/08/2009~~	~~09.59~~	~~isa~~
~~sA - 1~~	~~43~~					~~0,0175~~	~~66~~		~~06/08/2009~~	~~09.40~~	~~isa~~
~~sA - 1~~	~~43~~					~~0,0146~~	~~55~~	~~R~~	~~07/08/2009~~	~~08.29~~	~~eli~~
~~sA - 1~~	~~1~~					~~0,0137~~	~~51~~	~~R~~	~~07/08/2009~~	~~08.58~~	~~eli~~
sA - 1	44					0,0216	81		11/08/2009	09.13	mon
sA - 1	48					0,0214	81		25/08/2009	09.26	mon
sA - 1	42					0,0204	77		27/08/2009	09.15	mon
sA - 1	48					0,0211	79		31/08/2009	09.00	isa

- a **Main Area** located in the upper portion
- a **Details Area** located in the lower portion

Main Area

This area contains the following fields:

Control: drop-down menu that reports all the controls that have been executed. The user can select either a single control or the option "**All**" (if the user selects "All", s/he must then select a test in the "Methods" field).

Method: drop-down menu listing all the tests that have been executed. The user can select either a single test or the option "**All**" (if the user selects the latter, s/he must then select a control in the "Controls" field).

Filter By: drop-down menu listing the options "Day", "Month" and "Date Range";

From - To: "Date" selection field.

The Main Area visualizes all results relative to control/s corresponding to the type of filter applied (or rather: "Control", "Method", "Filter by" and "From – To").

The field contained herein are:

Test Name (measurement unit): reports the short name of the test.

Reference Data

Mean: reports the mean as calculated in function of the "minimum and maximum" values set up for the control;

SD: reports th standard deviation in function of the "minimum and maximum" values set up for the control;

Statistic Data

Tot.: reports the number of controls executed for the test in question;

Min: reports the minimum value of the results of the controls executed for the test in question;

Max: reports the maximum values of the results of the controls executed for the test in question;

Range: reports the difference between the maximum value and the minimum value of the results of the controls executed for the test in question;

Mean: reports the mean value calculated regarding the results of the controls executed for the test in question;

SD: reports the standard deviation of the results of the controls executed for the test in question;

CV%: reports the coefficient of variation percentage of the results of the controls executed for the test in question;

After selecting any given number of rows from the Main Area, it is possible to request a **csv export of the selected data**.

Control: CRT NORM (Lot: 181943 - Exp. Date: 31/05/2010) From: 01/09/2009 To: 30/09/2009

	Reference Data		Statistic Data						
Test	Mean	SD	Tot.	Min	Max	Range	Mean	SD	CV%
AC-URI (mg/dl)	4.37	0.33	22	4.0	4.7	0.7	4.3	0.2	4.18
ALB (g/dl)	4.65	0.35	22	4.3	4.6	0.3	4.4	0.1	2.04
AMI (U/l)	80	8	9	73	81	8	77	2	3.10
BID (mg/dl)	0.76	0.075	15	0.72	0.83	0.11	0.77	0.04	4.57
BIT (mg/dl)	1.18	0.12	18	1.09	1.23	0.14	1.16	0.04	3.35
CA (mg/dl)	8.57	0.515	20	8.4	9.2	Export	8.8	0.2	2.30
CK-NAC (U/l)	148	13.5	22	123.6	152.4	28.8	134.1	8.3	6.17
CL (mg/dl)	94	4.7	19	93.5	99.2	5.7	96.2	1.8	1.90
COL (mg/dl)	100	10	17	96.7	114.2	17.5	103.5	4.8	4.61
COLIN2 (U/l)	4973	447.5	22	4460	5304	844	4800	192	4.00
CRE2 (mg/dl)	1.065	0.108	21	0.98	1.10	0.12	1.04	0.03	3.06

Data exported in the csv file will have the following format:

Method
Control Name
Lot Exp. Date
From
To
Ref. Data Mean
Ref. Data SD
Stat. Data Tot
Stat. Data Min
Stat. Data Max
Stat. Data Range
Stat. Data Mean
Stat. Data SD
Stat. Data CV%
Pos.
Status
Cuv.
Pred. Lot
R1 Lot
R2 Lot
R3 Lot
Abs
Result
Unformatted Result
Unit
Flags
Flags Descr.
Date
Time
User

After the user has selected a row in the Main Area (independently by number of selected rows of the Detail Area) and then pressed the "**Levy Jennings**" button, a window will automatically open containing the following information:

Name of the control that the graph represents, the lot number, relative expiration date and the time frame that the graph refers to;

Monthly/daily or by range graph;

***Please note**: if the graph is monthly, the abscissa shows the days; while for the daily graph or the by range graph, it reports the number of controls executed **(from 1 to N)**;*

The left ordinate of the graph reports the values of the results of the control executed in that time frame; in particular:

- ✓ Monthly – the points on the graph represent the calculated mean value of the results of the control for that single day; in this case it is possible to visualize the graph relative to the results of the point selected;
- ✓ time frame equal to one or more days – the points on the graph represent the value of the results of the control;

The right ordinate of the graph reports the standard deviation values (as ±1, ±2, ±3 with 1 equal to the reference standard deviation relative to the control) centered around the value 0 equal to the mean reference value for the control in question;

Horizontal row colored red: represents the mean value of the results of the control relative to the time frame;

Tag: reports the total number of controls executed in that time frame (tag: Total), the mean value of the results of the control in that time frame (Mean), the standard deviation of the results of the control in that time frame (SD), and the coefficient of variation percentage of the control in that time frame (CV%).

It is possible to exclude (right clicking) the points on the graph; once excluded, they are represented on the graph by an "x" and will not contribute to determining the mean or the standard deviation. The excluded points can however be re-included (right clicking).

Monthly Graph: if a given point on the graph is the mean of the daily results, it is possible to request a graphic visualization of the points that contributed to this mean.

- Right click on the point of the monthly graph to open the "Details" tool tip;
- Right click inside the tool tip.

Please note: *if only one control has been executed for a row selected in the Main Area of the "**Quality Control**" mask, Levy Jennings button appears as disabled.*

"<<" Button - Allows the user to view the Levy Jennings graph of the previous filtered control.

">>" Button - Allows the user to view the Levy Jennings graph of the next filtered control.

"**Print**" Button - Allows the user to print either the graph viewed or all the filtered graphs.

"**Close Graph**" Button - Allows the user to return to the "Quality Control" mask.

Please note the red symbol under the 16th position, that indicates a control reference range change. The reference range applied to the graph is the defined once during the last control execution inside the graph.

Details Area

Upon selection of any given row in the Main Area, the Details Area will visualize the below-described fields:

Position: reports the position occupied by the control;

Cuv.: reports the number of the cuvette being used;

Pred. Lot#: reports the lot number of the diluent;

R1 Lot#: reports the lot number of Reagent 1;

R2 Lot#: reports the lot number of Reagent 2;

R3 Lot#: reports the lot number of Reagent 3;

Abs: reports the value of the optical density for the control;

Result: reports the results for the control;

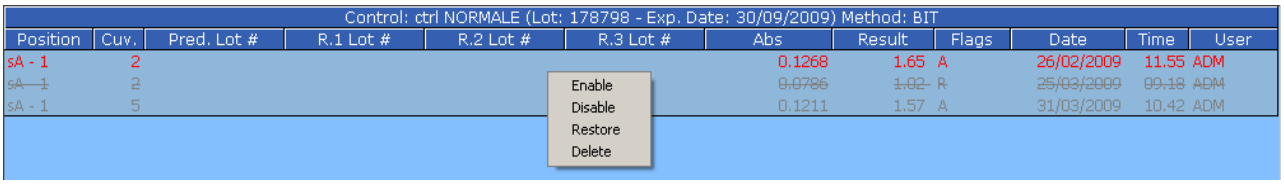
Flags: contains characters standing for the type of error, if any, detected;

Date: reports the date the control was executed;

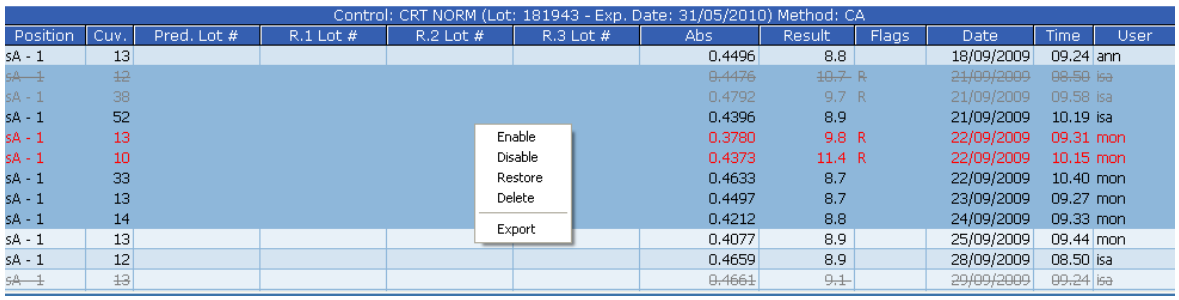
Time: reports the exact time the control was executed;

User: reports the acronym of the user logged on at the time the control was executed.

After having selected one or more rows in the Details Area, the user can right click and the disable/enable or delete/restore the row/s selected (after explicit SW confirmation).



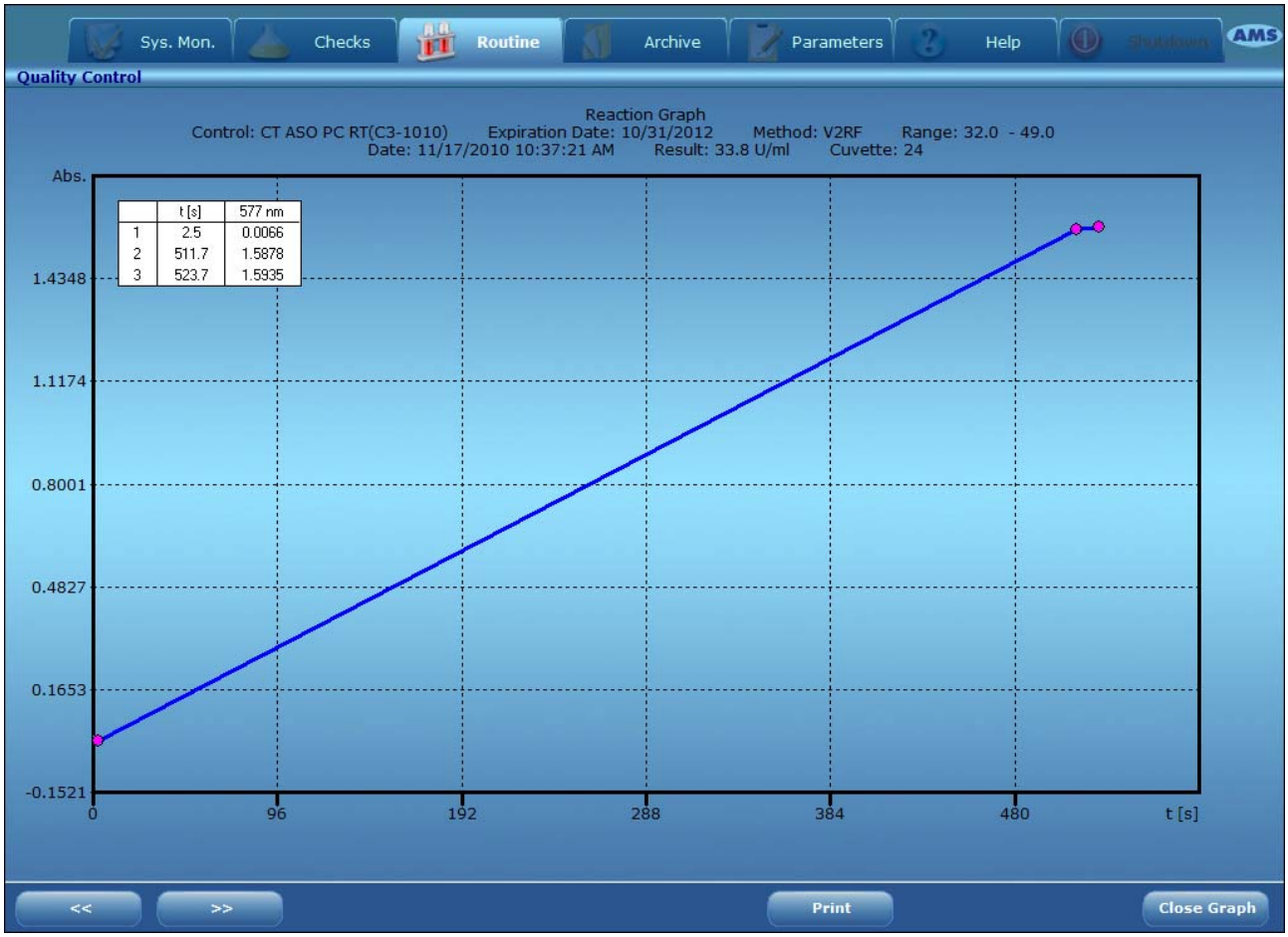
After selecting any given number of rows from the Details Area, it is possible to request a **csv export of the selected data**.



Data exported in the csv file will have the following format:

Method
Control Name
Lot Exp. Date
From
To
Ref. Data Mean
Ref. Data SD
Stat. Data Tot
Stat. Data Min
Stat. Data Max
Stat. Data Range
Stat. Data Mean
Stat. Data SD
Stat. Data CV%
Pos.
Status
Cuv.
Pred. Lot
R1 Lot
R2 Lot
R3 Lot
Abs
Result
Unformatted Result
Unit
Flags
Flags Descr.
Date
Time
User

After selecting one row from the Details Area, it is possible to request, thanks to the "**Graph"** Button, the visualization of the graph of the "run" selected from the Details Area.



Press "<<" to view the graph of the previous run.

Press ">>" to view the graph of the next run.

Press "**Print**" to have a print-out either of the graph viewed or of all the filtered graphs.

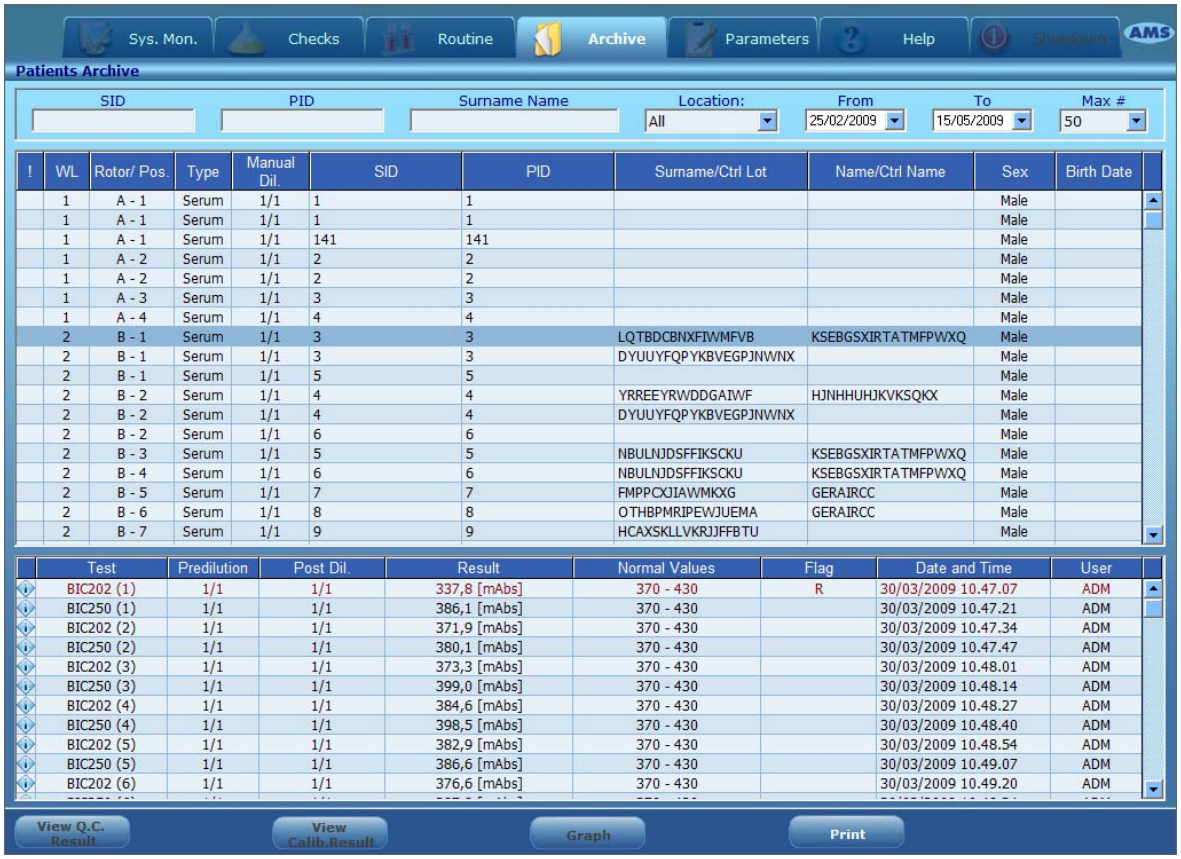
Press **"Close Graph"** to close the graph.

3.4 ARCHIVE

This menu includes the entire set of masks needed to have a complete visualization for managing tests and their results. The pages visualize recorded data and describe in a user-friendly manner how to execute both Backup and Restore.

3.4.1 PATIENTS

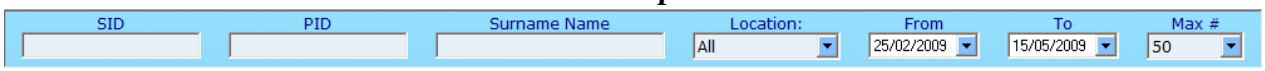
This page allows the user to view data and results regarding archived samples.



The "Patients" mask includes the following areas:

- Filter Setup Area
- Main Area
- Details Area
- Commands Area

Filter Setup Area



This area includes the below-listed fields:

SID (Sample ID): Input Box where the user can enter an SID and request search results;

PID (Patient ID): Input Box where the user can enter an PID and request search results;

Name: Input Box that allows the user to enter the name or last name to be searched for;

Location: Input Box where the user can enter a location and request search results;

From: data entry box used to set beginning of search period;

To: data entry box used to set end of search period;

Max #: drop-down menu where the user can choose how many rows (patients) are to be visualized.

Main Area

!	WL	Rotor/ Pos.	Type	Manual Dil.	SID	PID	Surname/Ctrl Lot	Name/Ctrl Name	Sex	Birth Date
	1	A - 1	Serum	1/1	1	1			Male	
	1	A - 1	Serum	1/1	1	1			Male	
	1	A - 1	Serum	1/1	141	141			Male	
	1	A - 2	Serum	1/1	2	2			Male	
	1	A - 2	Serum	1/1	2	2			Male	
	1	A - 3	Serum	1/1	3	3			Male	
	1	A - 4	Serum	1/1	4	4			Male	
	2	B - 1	Serum	1/1	3	3	LQTBDCBNXFIWMFVB	KSEBGSXIRTATMFPWXQ	Male	
	2	B - 1	Serum	1/1	3	3	DYUUYFQPYKBVEGPJNWNX		Male	
	2	B - 1	Serum	1/1	5	5			Male	
	2	B - 2	Serum	1/1	4	4	YRREEYRWDDGAIWF	HJNHHUHJKVKSQKX	Male	
	2	B - 2	Serum	1/1	4	4	DYUUYFQPYKBVEGPJNWNX		Male	
	2	B - 2	Serum	1/1	6	6			Male	
	2	B - 3	Serum	1/1	5	5	NBULNJDSFFIKSCKU	KSEBGSXIRTATMFPWXQ	Male	
	2	B - 4	Serum	1/1	6	6	NBULNJDSFFIKSCKU	KSEBGSXIRTATMFPWXQ	Male	
	2	B - 5	Serum	1/1	7	7	FMPPCXJIAWMKXG	GERAIRCC	Male	
	2	B - 6	Serum	1/1	8	8	OTHBPMRIPEWJUEMA	GERAIRCC	Male	
	2	B - 7	Serum	1/1	9	9	HCAXSKLLVKRJJFFBTU		Male	

Description of those fields included in the Main Area.

!: indicates that the sample has been programmed as urgent (Stat);

WL: indicates the Work List number;

Rotor/Pos: indicates the Rotor and position occupied by the sample;

Type: indicates the type of sample set up (Serum/Urine/Control);

Manual Dil: indicates the Manual Dilution Ratio set up for the sample ("Work List" mask);

SID: indicates the sample identification code (Sample ID);

PID: indicates the patient identification code (Patient ID);

Surname/Ctrl Lot: indicates the last name of the sample donor if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the lot number of the control;

Name/Ctrl Name: indicates the name of the sample donor if the "Type" field is different from the "Control" field. If the two fields are the same, it reports the name of the control;

Sex: indicates the sex of the patient;

Birth Date: indicates the patient's date of birth.

After selecting any given number of rows from the Main Area, it is possible to request a **csv export of the selected data**. Data exported in the csv file will have the following format:

!
WL
Rotor/Pos.
Type
Manual Dil
SID
PID
Name/CTRL Name
Surname /CTRL Lot
Sex
Birthdate
Test
Replicate
Predilution
Post Dil
Validated
Result
Unit
Normal Values
Flag
Flag Description
Date and Time
User

Whenever a row in the Main Area is selected, detailed information regarding that selected row is visualized in the Details Area.

Details Area

Test	Predilution	Post Dil.	Result	Normal Values	Flag	Date and Time	User
BIC202 (1)	1/1	1/1	337,8 [mAbs]	370 - 430	R	30/03/2009 10.47.07	ADM
BIC250 (1)	1/1	1/1	386,1 [mAbs]	370 - 430		30/03/2009 10.47.21	ADM
BIC202 (2)	1/1	1/1	371,9 [mAbs]	370 - 430		30/03/2009 10.47.34	ADM
BIC250 (2)	1/1	1/1	380,1 [mAbs]	370 - 430		30/03/2009 10.47.47	ADM
BIC202 (3)	1/1	1/1	373,3 [mAbs]	370 - 430		30/03/2009 10.48.01	ADM
BIC250 (3)	1/1	1/1	399,0 [mAbs]	370 - 430		30/03/2009 10.48.14	ADM
BIC202 (4)	1/1	1/1	384,6 [mAbs]	370 - 430		30/03/2009 10.48.27	ADM
BIC250 (4)	1/1	1/1	398,5 [mAbs]	370 - 430		30/03/2009 10.48.40	ADM
BIC202 (5)	1/1	1/1	382,9 [mAbs]	370 - 430		30/03/2009 10.48.54	ADM
BIC250 (5)	1/1	1/1	386,6 [mAbs]	370 - 430		30/03/2009 10.49.07	ADM
BIC202 (6)	1/1	1/1	376,6 [mAbs]	370 - 430		30/03/2009 10.49.20	ADM

The fields included in the Details Area are the following:

Test: reports the acronym of the test;

Predilution: indicates the predilution ratio set up for the test ("Chemistry Definition" mask);

Post Dil: indicates the dilution ratio of the test;

Result: reports the results of the test (Never Executed, if the test has not yet been executed);

Normal Values: reports the normal reference values set up for the test**;**

Flag: indicates what type of error, if any, occurred during test execution;

Data and Time: indicates the exact date and time the test was executed (if already run);

User: reports the acronym of the user logged on.

Please note: *whenever the mouse is positioned over the "i" symbol (to the left of the "**Test**" field), information regarding the reagent used for the test is visualized. The same information can be obtained by clicking on the abovementioned symbol.*

After selecting any given number of rows from the Details Area, it is possible to request a **csv export of the selected data**. Data exported in the csv file will have the following format:

!
WL
Rotor/Pos.
Type
Manual Dil
SID
PID
Name/CTRL Name
Surname /CTRL Lot
Sex
Birthdate
Test
Replicate
Predilution
Post Dil
Validated
Result
Unit
Normal Values
Flag
Flag Description
Date and Time
User

Commands Area

The Commands Area is made up of a series of buttons, described below.

"**View Q.C. Result**" Button

Whenever the user presses this button, s/he can view the quality control results regarding the test for a specific sample. The user must first select a sample from the Main Area, then select a method in the Details Area and then press this button.

"**View Calib. Result**" Button

This button allows the user to visualize data and calibration results associated with the methods executed on the selected sample. The user must first select a sample from the Main Area, then select a method in the Details Area and then press this button.

"**Graph**" Button

Allows the user to view the graph of a method selected in the Details Area.

Press **Print** to have a print-out of the graph.

Press **Back** to close the graph.

"**Print**" Button

After selecting a row/s in the Main Area and pressing the Print button, the user can then request:

- a print-out of the results regarding the patient/s (sample/s) selected;
- a print-out of the Work List regarding the patient/s (samples) selected;
- to cancel the Print request.

By selecting any number of rows from the Details Area and then pressing "**Print**", the user can request a print-out of the selected data.

Sort

Clicking on the various headings regarding data reported in the Main Area causes the data contained in the selected field to be ordered.

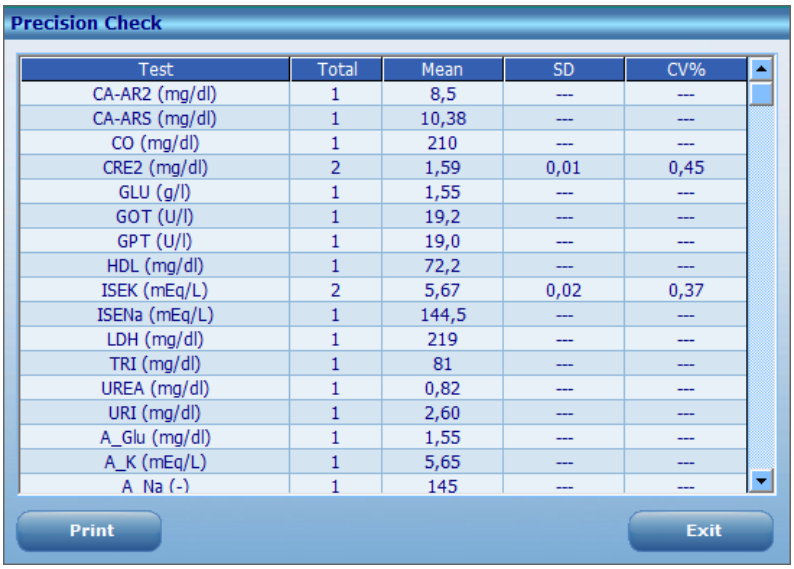
- Left click on the required field to define an increasing/decreasing order;
- Right click to request the "Sort" required.

Please note: *by default the order for "WL" and "Rotor/Pos." is increasing.*

Precision Check

After selecting a given number of rows (n) from the Details Area, (n>1), it is possible to request a **precision check**.

- Select the required rows;
- Right click to open the below-illustrated window.



Test	Total	Mean	SD	CV%
CA-AR2 (mg/dl)	1	8,5	---	---
CA-ARS (mg/dl)	1	10,38	---	---
CO (mg/dl)	1	210	---	---
CRE2 (mg/dl)	2	1,59	0,01	0,45
GLU (g/l)	1	1,55	---	---
GOT (U/l)	1	19,2	---	---
GPT (U/l)	1	19,0	---	---
HDL (mg/dl)	1	72,2	---	---
ISEK (mEq/L)	2	5,67	0,02	0,37
ISENa (mEq/L)	1	144,5	---	---
LDH (mg/dl)	1	219	---	---
TRI (mg/dl)	1	81	---	---
UREA (mg/dl)	1	0,82	---	---
URI (mg/dl)	1	2,60	---	---
A_Glu (mg/dl)	1	1,55	---	---
A_K (mEq/L)	1	5,65	---	---
A_Na (-)	1	145	---	---

This window contains the following fields:

Test: acronym of the method;

Total: indicates the total number of rows selected;

Mean: reports the mean value of the results obtained corresponding to the rows selected;

SD: reports the standard deviation with reference to the test indicated;

CV %: reports the coefficient of variation percentage with reference to the test indicated.

Press **Print** to have a print-out of the table.
Press **Exit** to close the precision check.

3.4.2 CALIBRATIONS

This mask visualizes the results of calibrations executed (automatically archived).

Test Name	RBL Exec. Date	Flags	Abs. 1	Rate 1	Abs. 2	Rate 2	Replicates	Calibration Exec. Date	Flags	Name	Control Count
ALT/IL	09/07/2009 10.25.28		1,5347	0,0000			3				2
BIC202	03/07/2009 12.23.04		-0,0002	0,0000			1				1
	03/07/2009 12.23.04	C	-0,0002	0,0000			1				
BIC250	03/07/2009 12.23.34		-0,0003	0,0000			1				1
	03/07/2009 12.23.34	C	-0,0003	0,0000			1				
CREIL	09/07/2009 10.25.55		0,0613	0,0014			3	09/07/2009 10.27.41		REFERIL G	2
GLUOx	09/07/2009 10.27.28		0,0527	-0,0001			3	09/07/2009 10.28.07		REFERIL G	2
	09/07/2009 10.27.28	C	0,0527	-0,0001			3				
IRON	09/07/2009 10.35.40		0,0404	0,0431			3	09/07/2009 10.36.22		REFERIL G	2
	09/07/2009 10.35.40	C	0,0404	0,0431			3				

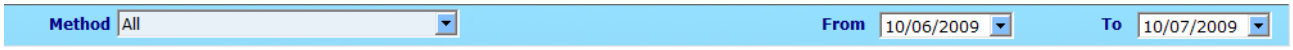
GLUOx

Type	Position	Name	Lot	Expiration	Abs.	Ref./Conc.	Factor	Flags	Date	User
RBL	sB - 1	(1/3)			0,0529				09/07/2009 10.26.20	ADM
RBL	sB - 1	(2/3)			0,0529				09/07/2009 10.26.33	ADM
RBL	sB - 1	(3/3)			0,0526				09/07/2009 10.27.27	ADM
STD	sC - 1	REFERIL G 1 (1/3)	18257000	30/09/2010	0,3117	190,0 mg/dl	609,56		09/07/2009 10.27.40	ADM
STD	sC - 1	REFERIL G 1 (2/3)	18257000	30/09/2010	0,3153	190,0 mg/dl	602,60		09/07/2009 10.27.53	ADM
STD	sC - 1	REFERIL G 1 (3/3)	18257000	30/09/2010	0,3219	190,0 mg/dl	590,25		09/07/2009 10.28.07	ADM
CTRL	sA - 1	SERACHEM 1	IO109001		0,1579	95,7 mg/dl			09/07/2009 10.28.20	ADM
CTRL	sA - 2	SERACHEM 2	I1008196		0,3976	241,0 mg/dl			09/07/2009 10.28.33	ADM

The "Calibration Archive" mask includes the following areas:

- Filter Setup Area
- Main Area
- Details Area
- Commands Area

Filter Setup Area



This area contains the following fields:

Method: drop down menu where the user can select the required test;

From: data entry box used to set beginning of search period;

To: data entry box used to set end of search period.

Main Area

Test Name	RBL Exec. Date	Flags	Abs. 1	Rate 1	Abs. 2	Rate 2	Replicates	Calibration Exec. Date	Flags	Name	Control Count
ALT/IL	09/07/2009 10.25.28		1,5347	0,0000			3				2
BIC202	03/07/2009 12.23.04		-0,0002	0,0000			1				1
	03/07/2009 12.23.04	C	-0,0002	0,0000			1				
BIC250	03/07/2009 12.23.34		-0,0003	0,0000			1				1
	03/07/2009 12.23.34	C	-0,0003	0,0000			1				
CREIL	09/07/2009 10.25.55		0,0613	0,0014			3	09/07/2009 10.27.41		REFERIL G	2
GLUOx	09/07/2009 10.27.28		0,0527	-0,0001			3	09/07/2009 10.28.07		REFERIL G	2
	09/07/2009 10.27.28	C	0,0527	-0,0001			3				
IRON	09/07/2009 10.35.40		0,0404	0,0431			3	09/07/2009 10.36.22		REFERIL G	2
	09/07/2009 10.35.40	C	0,0404	0,0431			3				

Test Name: indicates the short name of the method.

RBL Section

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

Flags: contains characters that stand for the type of error, if any, detected. Whenever the mouse is placed on this field, a tool tip opens describing the error encountered;

Abs 1: reports the optical density value obtained for the **RBL.** In the event of more than one replicate (from 2 to 4), the program will calculate the average of the readings executed and in the case of 3 or 4 replicates, it will ignore the reading furthest from the mean. The mean value thus obtained will be reported in this field; the absorbance values of the replicates are given in the Details Area, where it is also possible to view the graph;

Rate 1: reports reagent mobility, expressed in absorbance, during reaction;

*** Abs 2:** reports the optical density value obtained for the **RBL.**

*** Rate 2:** reports reagent mobility, expressed in absorbance, during reaction.

***** For Bicromatic (second wavelength) or Differential Methods.

Replicates: reports the number of replicates;

Calibration Section

Exec. Date: reports the date in which the operation was carried out;

Flags: contains characters that stand for the type of error, if any, detected. Whenever the mouse is placed on this field, a tool tip opens describing the error encountered;

Name: reports the name of the calibrator (standard);

Lot: reports the lot number of the calibrator (standard);

Control Count: reports the number of controls executed.

Details Area

GLUOx										
Type	Position	Name	Lot	Expiration	Abs.	Ref./Conc.	Factor	Flags	Date	User
RBL	sB - 1	(1/3)			0,0529				09/07/2009 10.26.20	ADM
RBL	sB - 1	(2/3)			0,0529				09/07/2009 10.26.33	ADM
RBL	sB - 1	(3/3)			0,0526				09/07/2009 10.27.27	ADM
STD	sC - 1	REFERIL G 1 (1/3)	18257000	30/09/2010	0,3117	190,0 mg/dl	609,56		09/07/2009 10.27.40	ADM
STD	sC - 1	REFERIL G 1 (2/3)	18257000	30/09/2010	0,3153	190,0 mg/dl	602,60		09/07/2009 10.27.53	ADM
STD	sC - 1	REFERIL G 1 (3/3)	18257000	30/09/2010	0,3219	190,0 mg/dl	590,25		09/07/2009 10.28.07	ADM
CTRL	sA - 1	SERACHEM 1	IO109001		0,1579	95,7 mg/dl			09/07/2009 10.28.20	ADM
CTRL	sA - 2	SERACHEM 2	I1008196		0,3976	241,0 mg/dl			09/07/2009 10.28.33	ADM

Type: reports the type of operation requested (RBL, STD or CTRL);

Rotor-Pos: reports the rotor and the position occupied by that item (H_2O, STD, CTRL);

Name: reports the name of the standard or the control;

Lot: reports the lot number of the standard or the control;

Abs: reports the optical density value calculated;

Ref./Conc.: reports the result calculated for the controls or the reference value for the standards;

Factor: reports calibration factor;

Flags: contains characters standing for the type of error, if any, detected. Whenever the mouse cursor is placed over the field, a tool tip opens containing a description of the error;

Date: reports the exact date and time of "RBL/STD/CTR" execution;

User: reports the acronym of the user who has executed the operations.

***Please note**: whenever the mouse is positioned over the "i" symbol (to the left of the "**Test**" field), a window containing information regarding the reagents associated with the test will be visualized.*

Buttons Area

"Graph" and **"Calib. Graph"** Buttons

This button is active only after a method has been selected in the Main Area or a row has been selected in the Details Area.

After a method has been selected in the Main Area and the

button has been pressed, a window will open presenting the calibration results in graph form (see: "Calibration Curve").

After a row has been selected in the Details Area and the

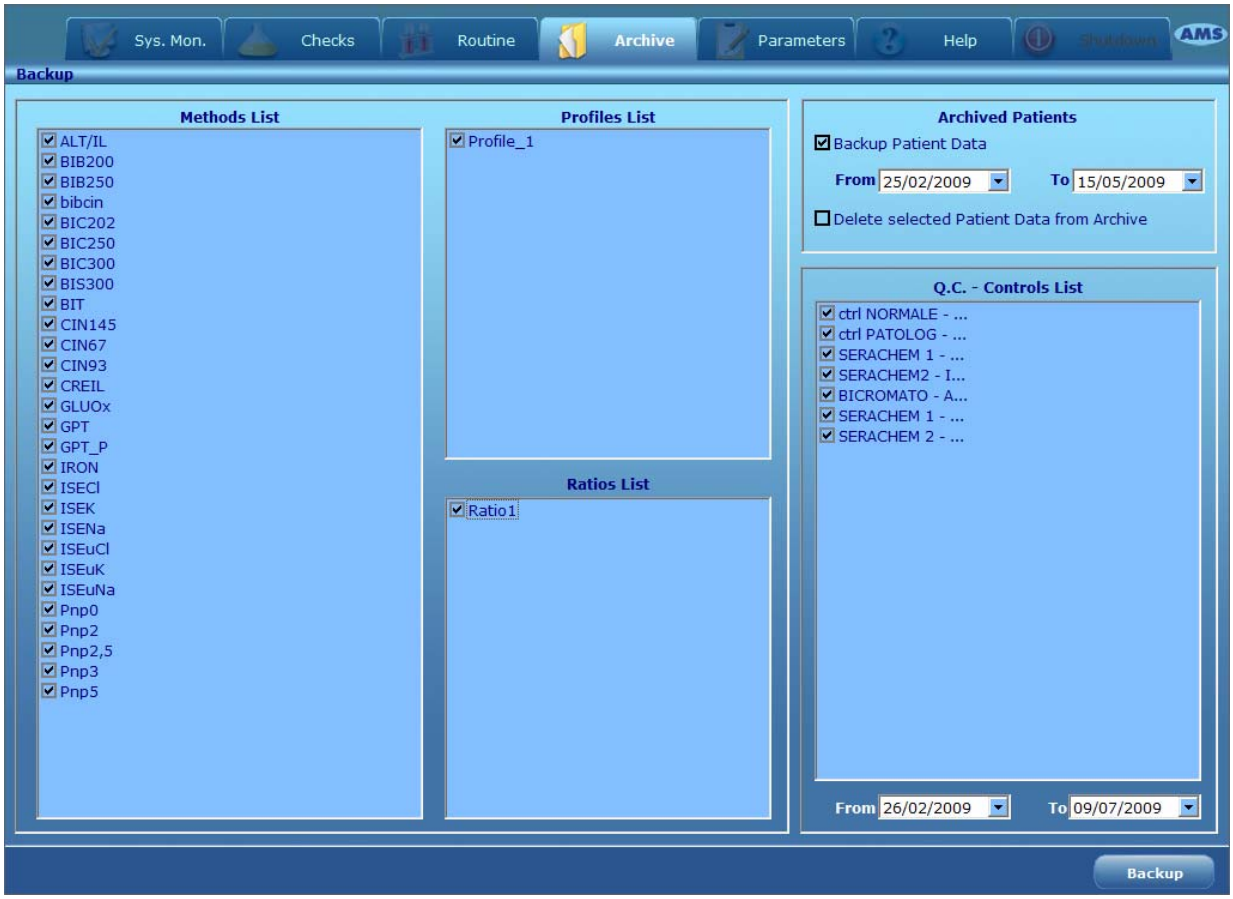
button has been pressed, a window will open presenting the reaction of the item selected in graph form.

"Print" Button

allows the user to print the data selected in the Main Area or in another area of the mask.

3.4.3 BACKUP

This mask allows the user to save data contained in the database used by the software to any internal support (Hard Disk) or to an external support (e.g.: floppy/ USB key, etc.), with the exclusion of a CD writer.



This mask includes the following areas:

- Test Area
- Quality Control Data Area
- Patient Data Area
- Commands Area

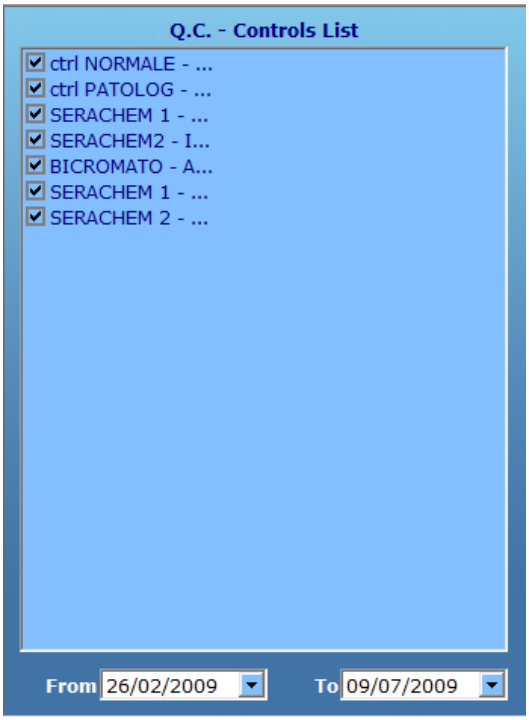
Test Area

This area is made up of three lists (Methods, Profiles, Ratios). Each list contains checkboxes where the user can select the Methods, Profiles and Ratios to be included in a partial backup. Right click to select/deselect the required checkbox/es.

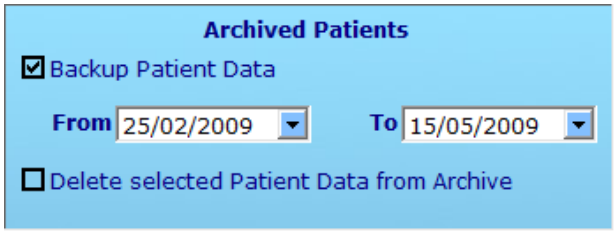
Whenever a Profile or a Ratio is selected and the Backup button is then pressed, all those methods that make up that Profile or Ratio will be automatically saved.

Quality Control Data Area

This area contains:



- two input boxes (**From** and **To**) that allow the user to define the time interval of the results that are to be included in the backup.
- a list of checkboxes (**Q.C. – Controls List**) where the user can select the Controls to be included in the backup. Right click to select/deselect the required checkbox/es.



- a check box (Backup Patient Data) that allow the user to backup patient data. The user can define the interval time (two input boxes "From and To") of the data that are to be included in the backup.

- two input boxes (**From** and **To**) that allow the user to define the time interval of the patient data that are to be included in the backup.

- a check box (Delete selected Patient Data from the Archive) that allow the user to delete patient data from the archive.

Commands Area

"Backup" Button

allows the user to save the requested data. After pressing this button, the user can then interact with the navigation mask to choose where (on which support) to save the data.

3.4.4 RESTORE

This mask allows the user to recover and restore data previously saved onto external and/or internal support systems.

This mask includes the following areas:

- Commands Area
- Test Area
- Quality Control Data Area

Commands Area

"**Select Cab**" Button

This button allows the user to recover and restore data previously saved into any support. After having pressed this button, the user must interact with the navigation mask in order to select which previously saved databases are to be restored.

After the user has selected the database/s to be restored, the Software will automatically place said data in its proper position (Methods List, Profiles List, Ratios List, Standards List and Controls List).

If after having pressed the "**Restore**" button, it turns out that there are Methods, Ratios, and/or Profiles that have the same name in the database that the user has requested be restored and that in use, a visual text message will appear requiring that the user confirm the overwrite/replacement of said data.

If after having pressed the "**Restore**" button it turns out that there are Standards and/or Controls to be restored, a summary report of the actions will appear at the end of the procedure.

"**View Q.C. Result**" Button

This button is active only if the restored file (.CAB) contains controls. Whenever the user presses this button, s/he can view the quality control results.

"**View Patients**" Button

This button is active only if the restored file (.CAB) contains patient data. Whenever the user presses this button, s/he can view patient results.

Test Area

This area is made up of three sections (Methods, Profiles, Ratios). Each section contains a list of checkboxes where the user can select the Methods, Profiles and Ratios that s/he wishes to Restore. Right clicking allows the user to select/deselect any or all of the checkbox/es here-present.

Any time a Profile or Ratio is selected and the Restore button is pressed, all associated methods are automatically saved.

Quality Control Data Area

It contains the controls included in the backup.

3.4.5 TEST COUNTER

This mask visualizes statistics relative to the executed tests.

Test	Samples	RBLs	Controls	Standards
A1C-E	0	0	0	5
AC-URI	8956	708	724	329
ALB	0	3	0	3
AMI	1008	745	834	0
AMM	0	0	0	0
ASO	0	1	0	10
BID	430	717	740	344
BIT	9745	710	693	344
CA-ARS	4926	751	821	375
CK-MB	0	0	0	0
CK-NAC	2462	706	763	0
CL	404	410	420	243
COL	17455	721	740	341
COLIN	405	722	730	0
COLIN2	0	2	0	0
CRE2	20122	753	812	365
F-ALC	5272	726	803	0
FE	10405	723	695	333
FOS	1655	712	757	336
GGT	12651	703	710	0
GLU	25553	724	748	342
GOT	22000	732	839	0
GPT	22191	709	777	0
HbA1c	0	0	0	0
HbTot	0	0	0	0
HDL	11217	771	862	407
ISECl	2143	0	546	1130
ISEK	2156	0	580	1126
ISENa	2156	0	573	1126
ISEuCl	0	0	0	0
ISEuK	0	0	0	0

The below-listed and described fields are included:

Test: reports the executed test's acronym;

Samples Number: reports the number of samples executed for that test;

RBLs Number: reports the number of RBLs (Reagent Blank) executed for that test;

Controls Number: reports the number of controls executed for that test;

Standards Number: reports the number of standards executed for that test.

Commands Area

This area contains:

- two input boxes (**From** and **To**) that allow the user to define the time interval that is to be included in the search.

"**Export**" Button

Allows the user to generate a csv file with the selected data.

"**Print**" Button

Allows the user to print the data included in the mask.

"**Exit**" Button

Allows the user to close the mask and return to System Monitor.

"**Clear test counter**" Button

Allows the user to reset the test count.

3.4.6 EVENT LOG

Type	Description	Date
	Time Out	07/07/2009 11.31.50
	Reagent Cover Open	07/07/2009 11.03.48
	Sample Cover Open	07/07/2009 9.40.59
	Cover Lock	07/07/2009 9.40.59
	Sample Cover Open	07/07/2009 8.54.09
	Cover Lock	07/07/2009 8.54.09
	Sample Cover Open	07/07/2009 8.38.49
	Cover Lock	06/07/2009 17.35.44
	Low Liquid Level I (Probe Rinse Solution)	06/07/2009 17.05.28
	Cover Lock	06/07/2009 16.31.48
	Reagent Cover Open	06/07/2009 15.56.15
	Reagent Cover Open	06/07/2009 15.56.01
	Sample Cover Open	06/07/2009 15.55.56
	Cover Lock	06/07/2009 15.55.56
	Reagent Cover Open	06/07/2009 12.49.08
	Low Liquid Level I (Probe Rinse Solution)	06/07/2009 12.16.26
	Low Liquid Level I (Probe Rinse Solution)	06/07/2009 12.10.05
	Reagent Cover Open	06/07/2009 11.46.03
	Reagent Cover Open	06/07/2009 11.45.47
	Reagent Cover Open	06/07/2009 11.17.34
	Reagent Cover Open	06/07/2009 10.01.23
	Reagent Cover Open	06/07/2009 9.48.55
	Reagent Cover Open	06/07/2009 9.32.07
	Reagent Cover Open	06/07/2009 9.20.04
	Reagent Cover Open	06/07/2009 9.19.29
	Reagent Cover Open	06/07/2009 9.18.44
	Reagent Cover Open	06/07/2009 9.04.13
	Sample Cover Open	06/07/2009 8.57.35
	Cover Lock	06/07/2009 8.57.35
	Reagent Cover Open	06/07/2009 8.52.49
	Cover Lock	06/07/2009 8.52.49
	Reagent Cover Open	06/07/2009 8.52.48
	Reagent Cover Open	06/07/2009 8.52.47
	Cover Lock	06/07/2009 8.52.47

This mask reports all the events that have occurred during instrument functioning. These anomalies can be grouped as follows:

- **Warning** (identified by a yellow triangle)
- **Fatal Error** (identified by a red "X")

"**Export**" Button

Allows the user to export data included in the mask . The user can set up the name of the CVS file as well as where the file itself is to be saved (including external devices, excluding CD writers).

"**Print**" Button

Allows the user to print the data included in the mask.

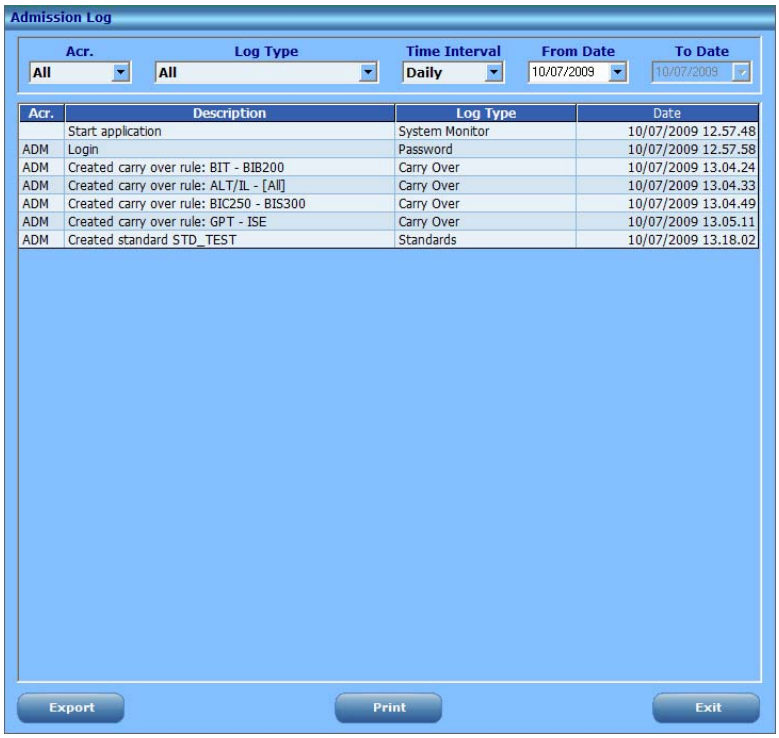
"**Exit**" Button

Allows the user to close the mask and return to System Monitor.

3.4.7 ADMISSION LOG

This mask visualizes any and all actions carried out by the various users regarding the SW.

This menu can be accessed only by the "Producer" and the "Administrator" (the instrument must be in Stand-By or in Search status).



This mask includes the following areas:

- Filter Set Up Area.
- Main Area.
- Commands Area.

Filter Set Up Area

This area contains the following fields:

Acr.: drop-down menu that lists all previously created users along with the option "**All**"; the user can therefore choose to visualize either a single user or all the users;

Log Type: drop-down menu that reports the various modules along with the option "**All**".

Time Interval: drop-down menu listing the options "**Daily**", "**Monthly**" and "**Range**".

From Date: data entry box that is visible only if "Time Interval" is different from "Monthly"; allowed values are all dates after the date of machine installation;

To Date: data entry box that is visible only if "Time Interval" is different from "Range"; allowed values are all the dates after the date set up by the user in the From Date field;

Month: drop-down menu, visible only if the user selects the option "**Monthly**", that lists all the possible year/month combination options, from the most recent to the year/month of machine installation.

Main Area

The Main Area reports information regarding each event that corresponds to the search criteria set up in the Filters Set Up area.

After the user has selected a setup (see Filters Set Up area), an area reporting the following fields is visualized:

Acr.: visualizes the acronym of the user selected;

Description: describes the actions taken by the user;

Log type: visualizes the log type;

Date: visualizes the event data.

Commands Area

"**Print**" Button

Allows the user to print the data included in the mask.

"**Export**" Button

Allows the user to export data included in the mask. The user can set up the name of the CVS file as well as where the file itself is to be saved (including external devices, excluding CD writers).

"**Exit**" Button

Allows the user to close the mask.

3.4.8 QUALITY CONTROL

The **Quality Control** mask shows the results of all the executed controls.
It is possible to find a description of this mask in the section 3.3.6.

3.5 PARAMETERS

The Parameters module allows access to the following masks:

- Methods
- Profiles
- Ratio
- Standards
- Controls
- Options
- Print/Sampling Order
- Report Options
- Accounts
- Probe Wash Rules (this item will be viewed only if the "Probe Wash Rules" option has been activated under the "Options" mask)
- ISE (this item will be viewed only if the "ISE Module" option has been activated under the "Options" mask).

3.5.1 METHODS

This function allows the user to define the parameters of the methods to be used for executing analysis. Any number of methods can be memorized.

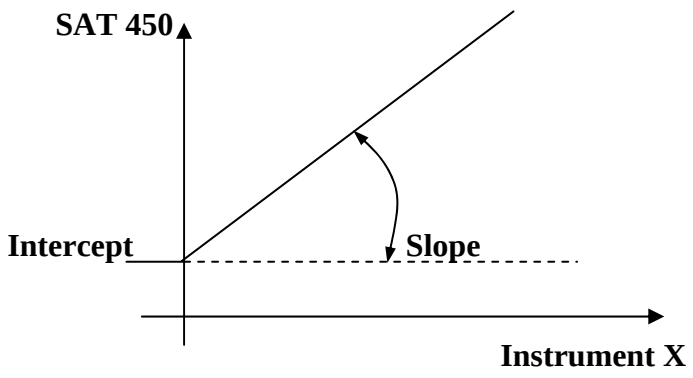
This screen shows a series of parameters divided into areas as listed below:

(upper left)

- **Description** = allows the user to enter a description of the test;
- **Unit** = allows the user to define the measurement unit employed (mg/dl, U/l, …);
- **Decimals** = allows the user to define the number of decimal places (from 0 to 3);
- **LIS Code** = Laboratory Information System; code used during communication between the instrument and the Host Computer, in those cases in which the instrument is part of a computerized laboratory system;
- **Unit Factor** = allows the user to define the conversion factor for the measurement unit;
- **Slope** = allows the user to define the slope (default value is set at 1);
- **Intercept** = allows the user to define the intercept value (default value is set at 0).

The above fields can be set by the user for *Closed Methods* too.

Please note: *Slope and Intercept values make it possible to correlate various methods and/or instruments. In order to correlate different instruments it is necessary to calculate the regression line.*



Reference Range *(upper right) [Serum – Urine]*

- **Low Values** = allows the user to define "Low Alert, Very Low and Low" values for male, female, child categories;
- **Normal Values** = allows the user to define normal reference values for male, female, child categories;
- **High Values** = allows the user to define "High, Very High and High Alert" reference values for male, female, child categories;
- **Rerun** = option that allows automatic rerunning of a test, indicating allowed dilutions possible.

The above fields can be set by the user for *Closed Methods* too.

Reaction Parameters *(center left)*

- **Reaction Type** = allows the user to define the type of calculation (End Point, Fixed Time, Kinetic, Differential);
- **Direction** = allows the user to define reaction direction (increase in absorbance = **direct**, or a decrease in absorbance = **inverse**. The value **none** is selected whenever the other options are not applicable;
- **E.P. Limit (abs) =** the value entered in this field indicates the limit, expressed in absorbance, within which the reaction is judged stable (see Chapter 06). This field is active only for End Point methods;
- **Depl. Limit (abs) =** the value entered in this field represents the absorbance limit – no reaction should go either above or below (depending on its direction) this limit (substrate exhaustion). This field is active only for Kinetic and Fixed Time methods;
- **First Limit (abs) =** expresses a reaction stability control (see Chapter 06). This field is active only for Fixed Time methods;
- **Linear Factor =** the value entered in this field expressed the linearization factor used for reaction stability control (see Chapter 06). This field is active only for Fixed Time methods;
- **Fit** = the values entered in this field indicates how closely the read points respect the calculated regression line and within which the reaction is judged linear. This field is active only for Kinetic methods;
- **Rerun When Over** = allows the user to request an automatic rerunning in the event that results are outside linearity limits (in those cases in which the results are outside alert limits);

- **Calculation Model** = allows the user to define the mathematical calculation for the test in execution (Factor, Standard, Point-to-Point, Quadratic, Cubic, Quartic, Inverse Cubic, Linear Log Logit, Cubic Log Logit, Linear);
- **Factor** = expresses the calibration factor;
- **Sample Blank** = allows the user to request a subtraction of the absorbance due to the sample (matrix effect). This field is active only for End Point methods.
- **Min Cal. Factor =** allows the user to define the minimum acceptable calibration factor. This field is active only for Standard and Linear Calculation Model.
- **Max Cal. Factor =** allows the user to define the maximum acceptable calibration factor. This field is active only for Standard and Linear Calculation Model.

Volumes and Time *(center right)*

- **Predilution** = this column of the table indicates the diluent used (name and lot number) and the predilution ratio requested;
- **S+R1** = this column allows the user to define the code for Reagent 1 as well as volumes for the reagent, the sample and the rinse (amount of Reagent 1 used to minimize any possible negative contamination – not used for the reaction);
- **Reag.2** = this column allows the user to define timing for Reagent 2, the code for Reagent 2, and the volumes for the reagent and the rinse (amount of Reagent 2 used to minimize any possible negative contamination – not used for the reaction);
- **Reag.3** = same as Reagent 2 (see above);
- **Incubation** = allows the user to define incubation time (expressed in seconds) starting from when the last reagent is added (1st, 2nd or 3rd reagent);
- **Read** = allows the user to define the time within which reading is to be executed (how long before reading);
- **"Special Wash"** = allows the user to define the code of the diluent/reagent that is to be used for the special wash (extra wash for the sampling probe) and the amount to be used (minimum: 2 µl – max: 200 µl);
- **Filter 1 (nm)** = allows the user to define the primary filter (available filters: 340 – 380 – 405 – 492 – 510 – 546 – 577 – 620 – 690);
- **Filter 2 (nm)** = allows the user to define the secondary filter;
- **Bichr. Factor:** = allows the user to define the dichromatic factor (correlates the absorbance value of the sample read with the secondary filter (Filter 2) to the primary filter (Filter 1)];
- **RBL Min – Max (abs)** = allows the user to define the minimum and maximum values for the reagent blank;
- **RBL Replicates** = allows the user to define the number of reagent blank replicates (1,2,3,4).
- **RBL Stab. (Days)** = allows the user to define reagent stability regarding the instrument (expressed in number of days); or rather, how long the RBL is to be considered valid. After this number of days has gone by, the instrument will automatically inform the user that a new RBL must be executed by visualizing the expired RBL date in red under the calibration program;
- **Calib. Stab. (Days)** = allows the user to define how long (number of days) calibration is to be considered valid; after which the instrument will inform the user that a new calibration must be executed;
- **RBL Max CV%** = allows the user to define the maximum coefficient of variation percentage value among the RBL replicates.

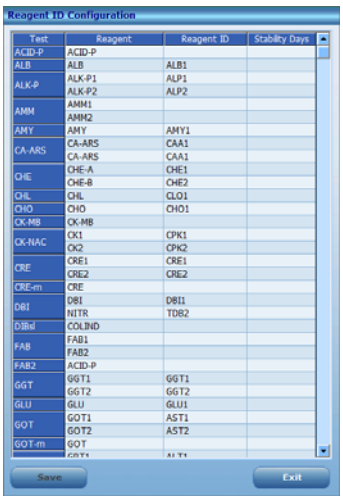
Calculation Model, Factor, Min Cal. Factor, Max Cal. Factor, Calibration Stability, RBL Replicates, RBL Min, RBL Max, RBL Max CV% and RBL Stability fields can be also modified by the user with reference to closed Kinetic Methods with either Factor or Standard Calculation Model.

Methods List

- **Methods List** = list of configured methods. Whenever a test is selected, its corresponding parameters will be visualized.

Buttons

- **Save** = allows the user to save method parameters;
- **Add** = allows the user to add a new method;
- **Copy as New** = allows the user to generate a new method using a current method as a template;
- **Delete** = allows the user to delete a method;
- **Reagent ID** = shows the identification code for the on-board reagent and the number of days for which it is to be considered valid; the pressure of this button will show the following mask.



- **Print** = allows the user to have a print-out of the method/s selected in the methods list.

***Note**: whenever the user modifies a method, it will be visualized in yellow in the "Methods List".*

READ TIMES FOR KINETIC ("Read" field in the "Volumes and Times" table)

39	52	65	78	91	104	117	130	143	156	169	182	195
208	221	234	247	260	273	286	299	312	325	338	351	364
377	390	403	416	429	442	455						

READ TIMES FOR FIXED TIME ("Read" field in the "Volumes and Times" table)

	52	65	78	91	104	117	130	143	156	169	182	195
208	221	234	247	260	273	286	299	312	325	338	351	364
377	390	403	416	429	442	455	468	481	494	507	520	533
546	559	572	585	598	611	624	637	650	663	676	689	702

READ TIMES FOR KINETIC

Read time (sec)	Read Interval (sec.) (between one reading and the next)	Number of readings
39	13	4
52	13	5
65	13	6
78	13	7
91	13	8
104	26	5
130	26	6
156	26	7
182	26	8
195	39	6
234	39	7
260	52	6
273	39	8
312	52	7
325	65	6
364	52	8
390	65	7
455	65	8

INCUBATION TIME (“Incubation” field in the “Volumes and Times” table)

15	28	41	54	67	80	93	106	119	132	145	158	171
184	197	210	223	236	249	262	275	288	301	314	327	340
353	366	379	392	405	418	431	444	457	470	483	496	509
522	535	548	561	574	587	600	613	626	639	653	665	678
691	704	717										

Minimum incubation time for End Point = 28”

MINIMUM AND MAXIMUM VOLUMES

	Sample Blank	No Sample Blank
Monoreagent Methods	S+R1>=200 µl	S+R1>=200 µl
	S+R1<=350 µl	S+R1<=350 µl
Multireagent Methods	S+R1>=200 µl	S+R1+R2+R3>=200 µl
	S+R1+R2+R3<=450 µl	S+R1+R2+R3<=450 µl

3.5.2 PROFILES

This mask allows the user to program test profiles (predetermined groups of tests/analyses that are executed together).

Profiles List

A list of the Profiles that have been programmed and saved.

Methods List

A list of all the methods programmed under the "Chemistry Definition" mask. This list does not report ISE methods unless the "**ISE Module"** option has been activated under the "Options" mask.

Ratios List

A list of all the Ratios programmed under the "Ratio Definition" mask.

Buttons

Add: allows the user to add a new profile.

Delete: allows the user to delete a profile.

Save: allows the user to save a profile.

3.5.3 RATIO

This mask is dedicated to programming Ratios.

The fields included in this mask are described below:

LIS Code: indicates the **acronym (max. 6** characters) of the Ratio used for serial data transmission;

Description: allows the user to define the entire name of the ratio programmed;

Unit: allows the user to define the measurement unit of the ratio;

Decimals: allows the user to define the number of decimal places (0÷3).

Ratio List

A list of the programmed Ratios.

Methods List

A list of all the methods programmed under the "Chemistry Definition" mask.

Reference Range: tables that allows the user to define "Very low, Low, Normal Value, High and Very High values for Male, Female and Child categories.

"**Print**" Button

allows the user to have a print-out of the Ratio selected.

"**Delete**" Button

allows the user to delete a Ratio (after having selected the Ratio from the Ratio List).

"**Add**" Button

allows the user to create a new Ratio. Whenever this button is pressed, a data entry window will open where the user can define the short name of the Ratio. After assigning a name, it is possible to configure all the parameters of the new Ratio.

"**Save**" Button

allows the user to save the parameters entered.

Programming a new formula

Programming a new formula includes declaring the name of the formula (using an acronym) and then defining said formula by setting up all component data.

To define a mathematical relationship:

- select a single method and then use Drag & Drop to move it to the field positioned to the right of the calculator icon; (or simply double-click on the required method);
- use the operators of the calculator positioned to the right of the "Methods List".

3.5.4 STANDARD

This mask allows both configuration and visualization of parameters relative to the Standards to be associated to the various preciously defined methods. It is organized into the below-described areas:

- an area located in the left-hand portion of the screen, containing an alphabetical list of the programmed standards (name of the standard). Whenever any standard is selected from the list, the **methods** associated to that standard and relative parameters are automatically visualized.
- an area dedicated to setting up the standards and to the values of the individual methods is situated in the central portion of the screen: the upper section (Details) reports the following information:

Expiration Date: equals to the minimum expiration date set up for the **Std**.

Prediluted: if selected, indicates that the calibration curve is ready and diluted according to the method's dilution ratio. If the field is **not enabled,** it means that the calibration curve is ready and undiluted; the system will apply the same dilution ratio to the standard as to the method, if required.

Diluent*:* visible only for Master Standard Master. It allows the user to define the diluent name.

Lot1…Lot8: allows to setup the Lot Number for each point of the standard (Note that for a Standard Master the Lot Number of all points is the same).

Expiration Date1…Expiration Date8: allows to setup the Expiration Date for each point of the standard (Note that for a Standard Master the Expiration Date of all points is the same).

The below-listed fields are associated with each method for a Standard:

Replicates: allows to setup the number of replicates (1..4);

CV%: allows to setup the CV% if "Replicates" is different by 1;

Ref1...Ref8: allows to setup the reference value for each point of the standard;

Note: for ISE methods Ref1 cannot be modified.

The below-listed fields are associated with each method for a Standard Master.

Replicates: allows to setup the number of replicates (1..4);

CV%: allows to setup the CV% if replicates is different by 1;

Conc: allows to setup the Concentration;

Ref1%...Ref8%: allows to setup the reference percentage for each point of the standard.

"**Add TEST**" Button

Allows the user to add methods to a preciously created standard. Adding one or more methods to a standard can be done only after having selected the standard from the List Area. After having pressed this button, a multiple selection window will open containing all the methods previously saved that correspond to the characteristics presented in the following table, based on the calculation model associated with the individual method. Once one or more methods have been selected, the user must fill in the fields contained in the Parameters Visualization and Configuration Area.

Calculation Models applied to the methods	Points required for the calculation models
Factor	None
Standard	1
Point to point	≥2
Linear	≥2
Quadratic	≥3
Cubic	≥4
Quartic	≥5
Inverse Cubic	≥4
Linear LogLogit	≥4
Cubic LogLogit	≥6

"**Delete TEST**" Button

Allows the user to delete a method from a standard previously selected from the list of standards.

"**Copy As New**" Button

Allows the user to create a copy of a standard previously selected from the list of standards.

All the parameters of the copied standard will be presented to the user as identical to their original, with the exception of the fields regarding concentration values which will be presented as nil.

"**Add STD**" Button

Allows the user to create a new standard.

Whenever this button is pressed, a data entry window will appear containing the fields listed in the following table along with the **OK** and **Exit** buttons which allow the user to save or cancel the operation.

Name: allows the user to set up the name of the Standard;

Lot Number: allows the user to set up the lot number of the Standard;

Expiration Date: allows the user to set up the expiration date of the Standard;

Points: allows the user to select the number of points to be used for the calibration curve (from 1 to 8 points);

Master: allows the user to specify if the calibration points are to be produced automatically by the system based on the Master Standard; in this case the check button must be ticked (✓).

It is possible (see the below picture) to setup the expiration date for each standard points:

	Replicates	CV%	Ref.1	Ref.2	Ref.3	Ref.4
Lots			11111111	1234567	123455	98765432
Exp.			10/07/2010	10/07/2011	10/08/2010	10/09/2010

"**Delete STD**" Button

Allows the user to delete a Standard from the list of standards.

"**Print**" Button

Allows the user to request a print-out of one or all the standards included in the list.

"**Save**" Button

Allows the user to save all the data relative to the Standards or to modifications concerning existing Standards.

Note 1: *"Prediluted" option, diluent name, lot number and expiration date of a standard can be modified only if it is not Pending or Running (for any of its associated methods).*

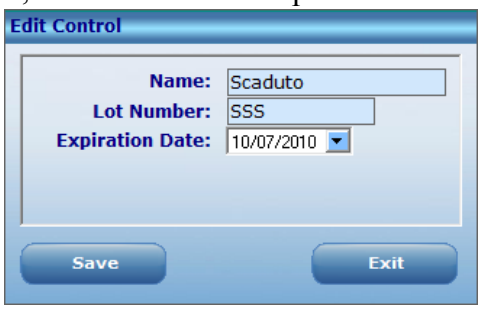
Note 2*: data related to the specific method can be modified only if the standard is not Pending or Running (for that specific method).*

3.5.5 CONTROLS

This mask allows both configuration and visualization of parameters relative to Controls and is divided into the following areas:

- an area located in the left-hand portion of the screen, containing an alphabetical list of the programmed controls (name of the control and lot number). Whenever any control is selected from the list, the associated **methods** and relative parameters are automatically visualized.

  Double clicking with the left button of the mouse on a single control (never executed), it is possible to modify its "Name, Lot Number and Expiration Date" (see the below window).



- an area dedicated to setting up the controls and to the values of the individual methods is situated in the central portion of the screen – the upper section (Details) reports the following information:

  Prediluted: checkbox that indicates that the control is already prediluted;

  Lot Number: lot number of the control;

  Expiration Date: expiration date set up for the control**.**

The below-listed fields are associated with each method:

Mean: indicates the mean value calculated based on the minimum and maximum values of that method; or is a field that allows the user to enter the Mean value that, in relation to the Standard Deviation, will determine the Minimum and Maximum values;

SD: indicates the standard deviation calculated on the basis of the minimum and maximum values of that method; or is a field that allows the user to enter the Standard Deviation value that, in relation to the Mean Value, will determine the Minimum and Maximum values;

Min. Value: allows the user to either set up the minimum value that the Control can accept for the selected method, or to view the Minimum Value relative to the data entered in the Mean Value and Standard Deviation fields;

Max. Value: allows the user to either set up the maximum value that the Control can accept for the selected method, or to view the Maximum Value relative to the data entered in the Mean Value and Standard Deviation fields.

"**Add TEST**" Button

Allows the user to add methods to a preciously created control.

Delete TEST" Button

Allows the user to delete a method from a control previously selected from the list of controls.

"**Copy As New**" Button

Allows the user to create a copy of a control previously selected from the list of controls .

All the parameters of the copied control will be presented to the user identical to their original with the exception, if not explicitly requested by the user (check in the Copy As New mask), of the fields regarding "Mean, SD, Min and Max Value" which will be presented as nil.

"**Add CTRL**" Button

Allows the user to create a new control.

Whenever this button is pressed, a data entry window will appear containing the fields listed in the following table, along with **OK** and **Exit** buttons which allow the user to save or cancel the operation.

Name: allows the user to set up the name of the Control;

Lot Number: allows the user to set up the lot number of the Control;

Expiration Date: allows the user to set up the expiration date of that lot.

"Delete CTRL" Button

Allows the user to delete a Control from the list of controls.

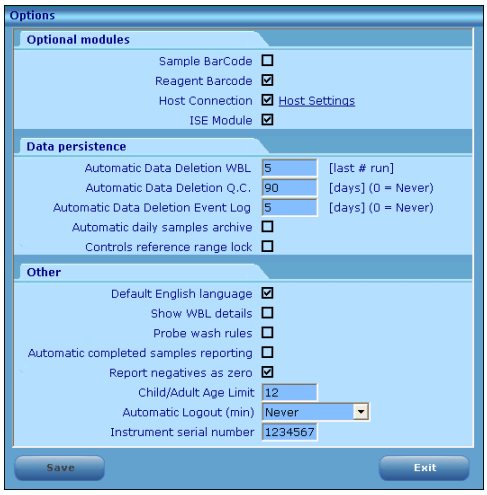
"**Print**" Button

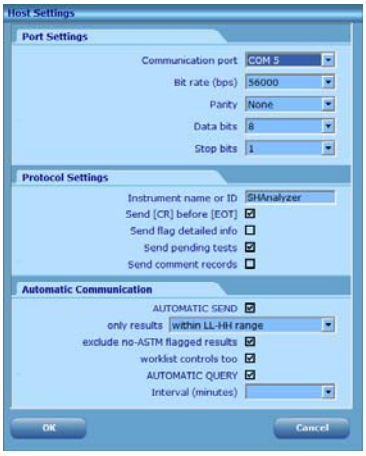
Allows the user to request a print-out of one or all the controls included in the list.

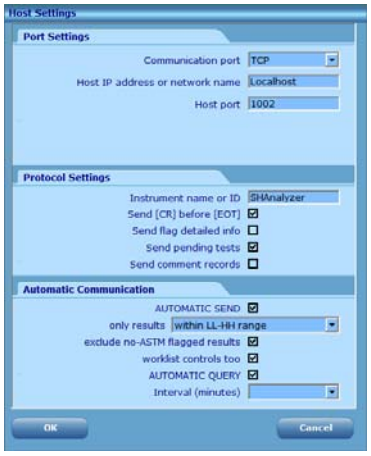
"**Save**" Button

Allows the user to save all the data relative to the controls or to modifications concerning existing controls .

3.5.6 OPTIONS







The **Options** mask allows the user to define a series of default parameters for the analyzer, as illustrated below.

Sample Barcode: option that the user selects whenever s/he wishes to read samples using the Bar Code;

Reagents Barcode: option that the user selects whenever s/he wishes to read reagents using the Bar Code;

Host Connection: option that the user selects whenever s/he wishes to connect to the Host. Clicking on **Host Settings**, software shall open a specific window dedicated to the host parameter settings; following parameters can be set:

- **Communication Port**: could be either any serial port or Ethernet port; for serial port:
  Bit Rate (bps): 110, 300, 600, 1200, 2400, **9600**, 14400, 19200, 28800, 38400, 56000, 128000, 256000
  Parity: E (even), O (odd), **N (none)**, M (mark), S (space)
  Data bits: 4, 5, 6, 7, **8**
  Stop bits: **1**, 1.5, 2
  OR for Ethernet port
  Host IP address or network name: any IP address associated to the host (default localhost)
  Host port: any port associated to the host (default 1002)
- **Instrument name or ID**: Sender name or ID used by the instrument during the communication with host;
- **Send [CR] before [EOT]**: user can decide either to add, or not, <CR> character (ASCII 13) at the end of each record;
- **Send Flag detailed info**: user can decide to send the complete map of the flags as present in the instrument; this bit mask will be sent as a second component of the field *Result Abnormal Flags* of the *Results Record*;
- **Send Pending Tests**: user can decide either to send to the host or not info related to pending tests;
- **Send Comment records**: user can decide either to send to the host or not the *Comment Records;*
- **Automatic Send:** user can decide to send automatically the results to the Host; checking this flag, user can decide also to send all the results, only the validated results, only the results within normal range, only the results within the Low – High Range, only the results within the Very Low – Very High range; furthermore user can decide either to send to the host only the results characterized by ASTM flags or all the results. Finally user can decide to send to the host the work list control results or not.

- **Automatic Query:** user can decide to query the host automatically every n minutes.

ISE Module: option that the user selects whenever s/he wishes to activate the instrument's ISE Module. It will not be possible to view the ISEs in those masks involved in the programming of the tests, nor the term ISE under the Parameters menu, unless this option has previously been selected;

Automatic Data Deletion (WBL, Q.C./Calib., Event Log) : allows the user to set up in each of these fields how long (in terms of number of days) the data is to be kept in memory/saved. After this time frame has elapsed, the data will be automatically deleted.

Automatic daily samples archive: check box that allows the user to request the automatic samples archiving at the change of date or at the next start of the software.

Control reference range lock: check box that allows the user to change the control reference range for a specific method even after having previously executed the same control on that method.

Default English language: check box that allows the user to change the language.

Show WBL Details: check box that allows the user to view the "**Show Detail**s" button in the WBL mask.

Probe Wash Rules: check box that allows the user to setup the probe wash rules function.

Automatic completed samples reporting: check box that allows the user to request the automatic samples reporting; automatic printing of the report will be made by the software once the instrument has completed all the tests, without any flag that causes the red color of the sample, associated with the sample.

Report negatives as zero: if this option is checked the negative result will be shown as zero.

Child/Adult Age Limit: text box where the user can enter the age cut-off for distinguishing a Child from an Adult, to be used when assigning normal values.

Automatic Logoff (min): combo box that allows the user to setup the number (expressed in minutes) of inactivity. After that time, the user will be logout

Instrument Serial Number: text box that allows the "Admin" to modify the Instrument Serial Number.

3.5.7 PRINT/SAMPLING ORDER

This mask allows the user to define:

the print-out order for test results, independently of the order in which the tests were executed;

a sampling order, to avoid unwanted analysis sequence.

The "**Print Order**" area contains a list of the Short Names of the methods and of the ratios that the user can put in whatever order s/he requires. Next to each test is a data entry box ("Order") where the user can assign the required positioning to that test regarding print-out. Initially all tests are assigned position "0" which tells the software that the print-out is to be executed in alphabetical order. The user can modify this print order by assigning a number to the various tests. In the event that the same number is assigned to more than one test, those tests will be printed out in alphabetical order. Print Order can also be modified by the following bottoms: push to top, push up, alphabetical order, push down, push to bottom.

The same is true for the "**Sampling Order**" Area.

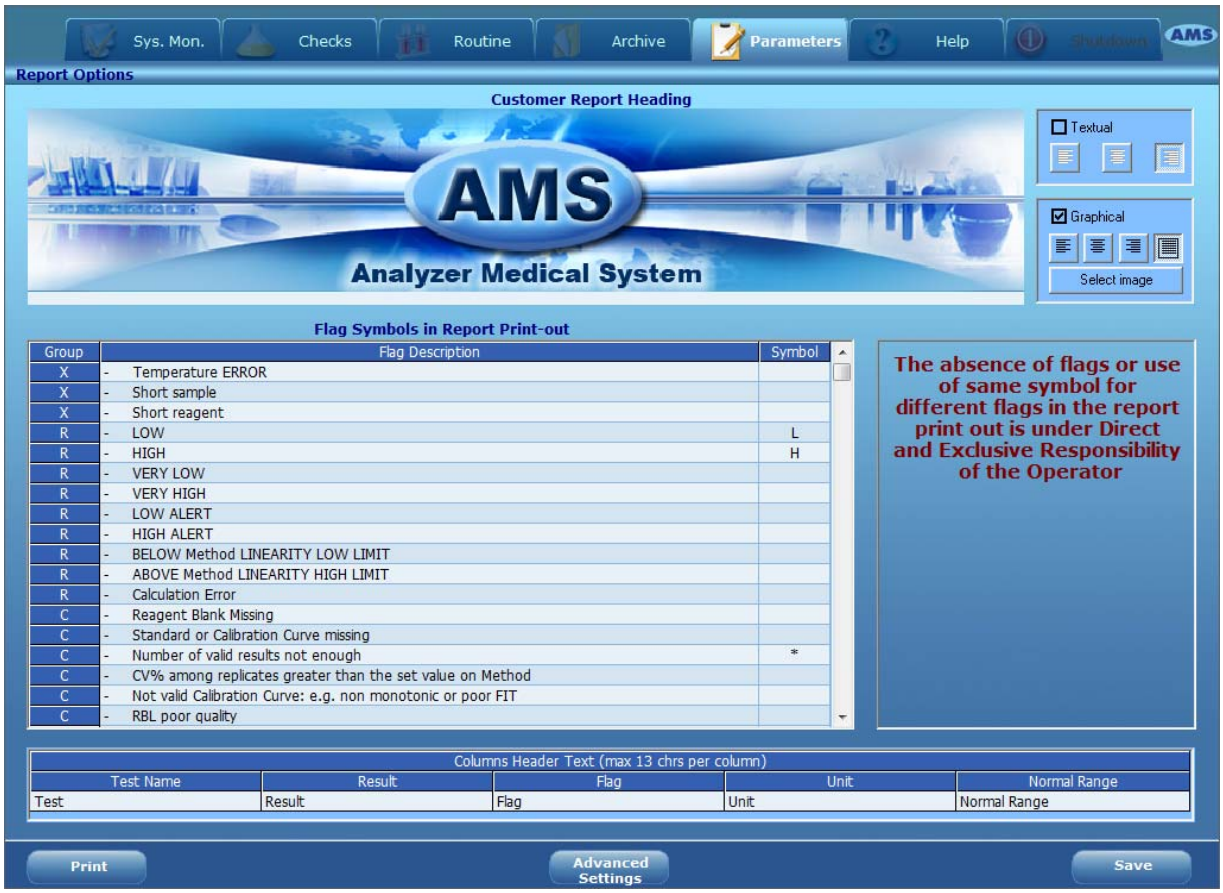
"**Print**" Button

Allows the user to print the list of tests as ordered;

"**Save**" Button

Allows the user to save the new print-out order.

3.5.8 REPORT OPTIONS



The Report Options mask allows the user to define the heading for the medical report concerning: page orientation; font type and size for exam results and the report itself; characters to be associated with the different error groups.

Customer Report Heading

Customer Report Heading: allows the user to define the textual heading of the medical report (max: 800 characters) or to select the image (*.bmp, *.jpg, *.jpeg, *.gif) to use as header of the medical report.

Flag Symbols in report Print-out

Group: reports the symbol of the group that the Flag refers to;

Flag Description: provides a brief description of the Flag;

Symbol: indicates the character that will be printed in the report in the event of an error (can be modified by the user).

Columns Header Text *(Max: 13 characters per column)*

Area dedicated to modify the heading of the following fields in the report: Test Name, Result, Flag, Unit and Normal Range.

"**Save**" Button

Allows the user to save the options selected and the changes made.

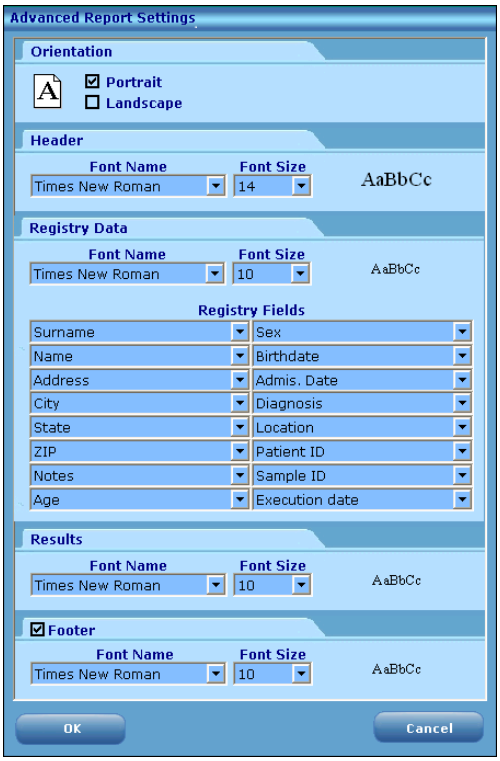
"**Print**" Button

Allows the user to have a print-out of the "Flag Symbols in report Print-out" table.

"**Advanced Settings**" Button

The mask that appears, allows the user to:

- set the page orientation of the report print-out;
- set the font name and size for the different sections of the report;
- decide which fields, and in which order, have to inserted in the Registry Data section of the Report;
- decide either to print or not the footer of the report print-out.



3.5.9 ACCOUNTS

This page allows to define a profile configuration for the different users of the analyzer.

"**Change Password"** Button.

Allows to change the old password.

Whenever this button is pressed, a data window will appear containing the fields listed in the following table, along with **OK** and **Exit** buttons which allow the user to save or cancel the operation.

User name: reports the acronym of the user logged;

Old Password: allows to enter the old password (mandatory);

New Password: allows to enter the new password (mandatory);

Confirm Password: allows to enter (to confirm) the new password.

"**OK"** Button

Allows to confirm the operation.

"**Exit**" Button

Allows the user to cancel the request.

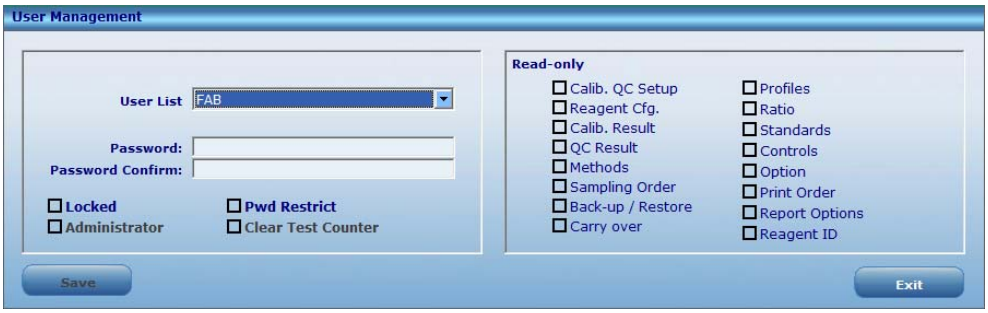
"**User Management"** Button.

This button is active for the Producer or Administrator User.

Whenever this button is pressed, a data windows will appear containing the exit button and three other buttons:

- Modify User;
- Delete User;
- Add User.

"Modify User" Button.



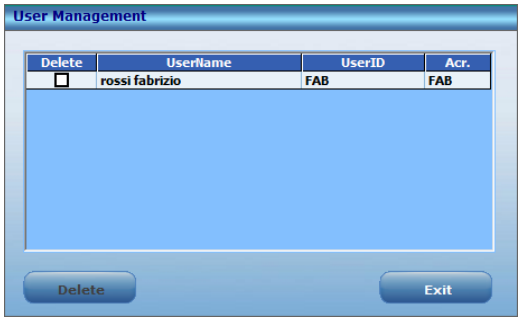
Whenever this button is pressed, a data window will appear containing the following fields listed:

- **User list**: indicates all the user previously created;
- **Password** and **Confirm password**: allows the user to create a password and confirm it;
- **Locked**: indicates whether the user is blocked or not (a user who inserts the wrong password more than three times will be blocked);
- **PWD Restrict**: allows the user to deactivate the password control (e.g. expired and length);
- A list of checkbox (Reagent Cfg, Calib. QC setup, QC results, etc....): if selected indicates user can just read the respective module, s/he cannot modify it;
- **Test counter**: if selected, allows the administrator to reset the test counter.

"Exit" Button

Allows the user to close the mask and return to Accounts windows.

"Delete User" Button.



Whenever this button is pressed, a data window will appear containing the following fields listed:

- **Username**: reports user name;
- **UserID**: report user ID;
- **Acr.**: reports user acronym;
- **Delete**: checkbox that indicate the user elimination request.

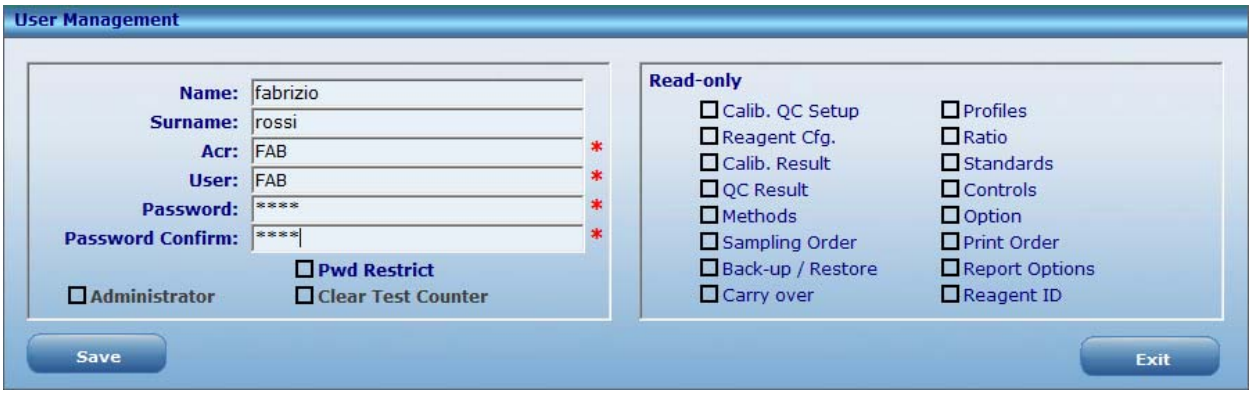
"Delete" Button

Allows to delete the user previously indicated.

"Exit" Button

Allows the user to close the mask and return to Accounts windows.

"Add user" Button



Allows to add a user.

Whenever this button is pressed, a data window will appear containing the following fields listed:

- **Name**: reports user name;
- **Surname**: reports user surname;
- **Acr.**: reports user acronym (max 3 characters);
- **User:** user name that the instrument recognize;
- **Password**: allows to enter the password;
- **Password restrict**: check box, allows the user to deactivate the password control (e.g. expired and length);
- **Clear test counter**: checkbox, allows the new user the ability to reset the test counter;
- **Administrator**: allows to select the user as administrator (it allowed just one administrator)

(*): Indicates mandatory fields

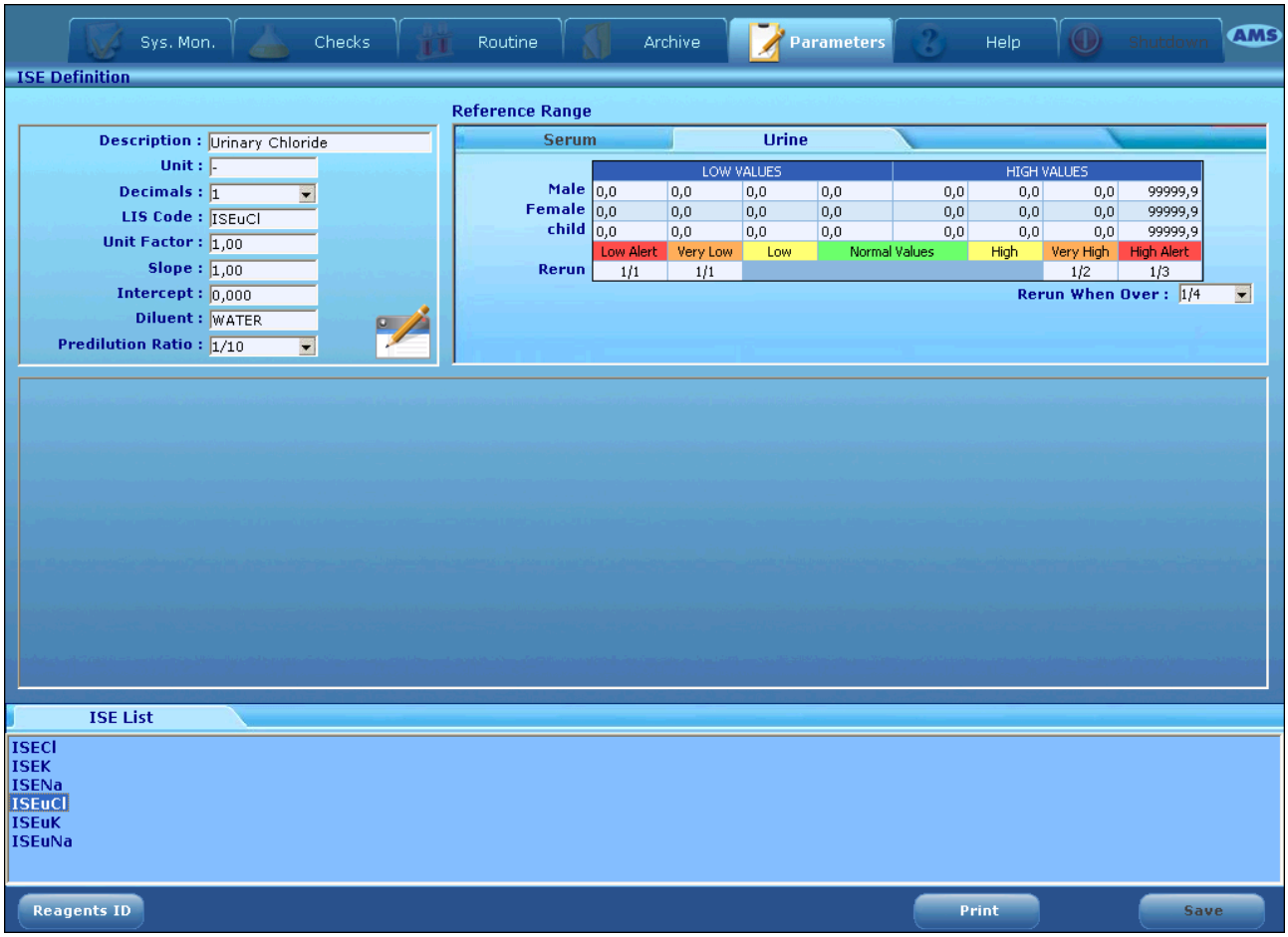
"**Save**" Button

Allows the user to save the changes made.

"Exit" Button

Allows the user to close the mask and return to Accounts windows.

3.5.10 ISE



This mask allows the user to define the ISE methods parameters. The database of the SW contains 3 ISE methods for serum (ISECl, ISEK, ISENa) and 3 ISE Methods for urine (ISEuCl, ISEuK, ISEuNa).

- **Description** = allows the user to enter a description of the test;
- **Unit** = allows the user to define the measurement unit employed;
- **Decimals** = allows the user to define the number of decimal places (from 0 to 3);
- **Lis Code** = Laboratory Information System; code used during communication between the instrument and the Host Computer;
- **Unit Factor** = allows the user to define the conversion factor for the measurement unit;
- **Slope** = allows the user to define the slope (default value is set at 1);
- **Intercept** = allows the user to define the intercept value (default value is set at 0);
- **Diluent** = allows the user to setup the diluents (for Urine ISE Methods)
- **Predilution Ratio** = allows the user to setup the predilution ratio to be used (for Urine ISE Methods); this field is visible only if the user has set the diluent field

Reference Range (upper right) [Serum – Urine]

- **Low Values** = allows the user to define "Low Alert, Very Low and Low" values for male, female, child categories;
- **Normal Values** = allows the user to define normal reference values for male, female, child categories;

- **High Values** = allows the user to define "High, Very High and High Alert" reference values for male, female, child categories.

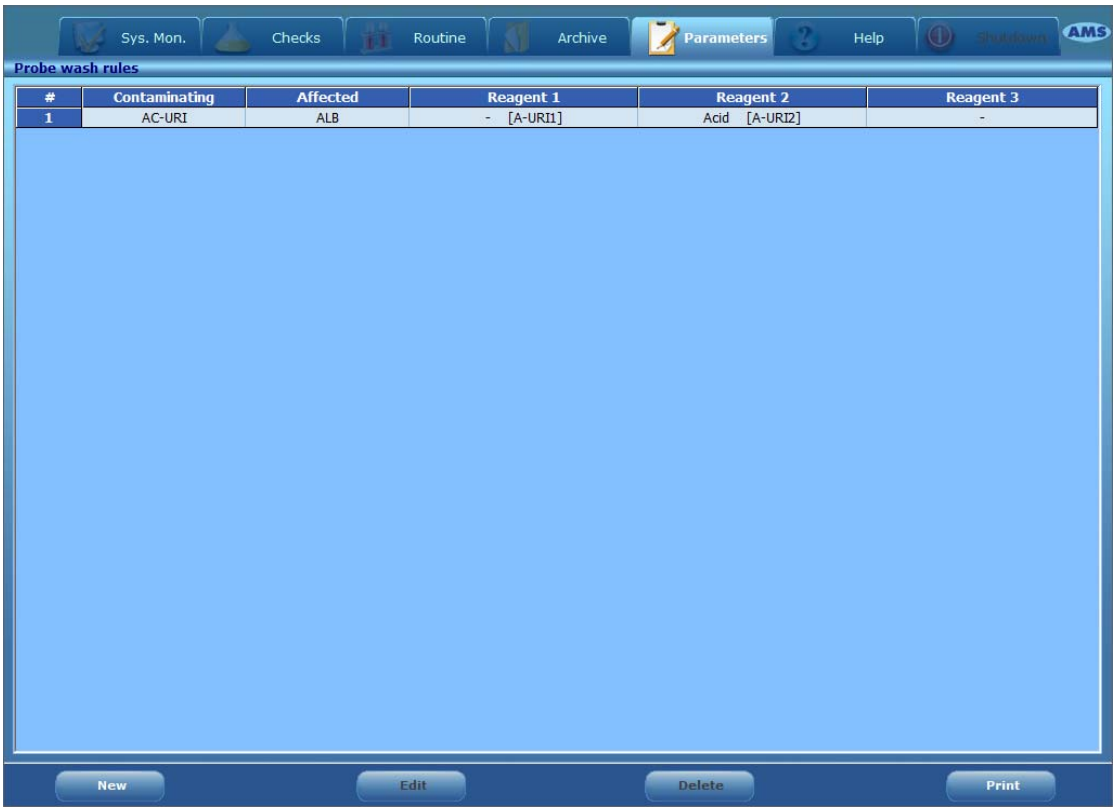
Rerun = option that allows automatic rerunning of a test, indicating allowed dilutions possible.

Rerun When Over = allows the user to request an automatic rerunning in the event that results are outside linearity limits (in those cases in which the results are outside alert limits).

Buttons

- **Save** = allows the user to save ISE method parameters;
- **Reagent ID =** allows the user to define the identification code for the on-board reagent and the number of days for which it is to be considered valid.
- **Print** = allows the user to have a print-out of the ISE method/s selected in the methods list.

3.5.11 PROBE WASH RULES



This mask allows the user to view / define the probe wash rules to be applied between different methods.

The "**Probe Wash rules**" mask includes the following areas:

- Main Area
- Commands Area

Main Area

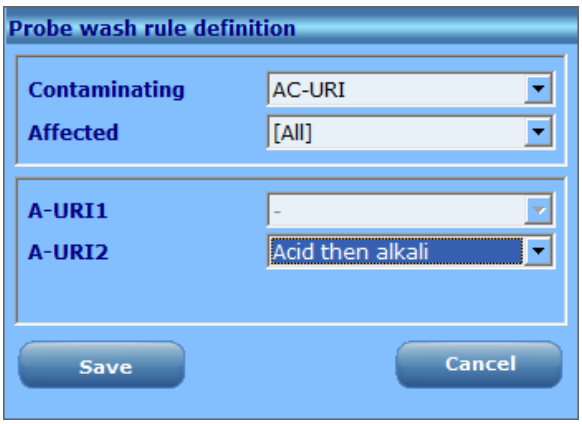
The Main Area reports information regarding each probe wash rule defined by user. For each rule, this area shows following data:

- **Contaminating**: reports the short name of the method that can act as contaminating towards another method;
- **Affected**: reports the short name of the method that can be affected by a contaminating method; select "ALL" choice if the contaminating method affects all methods.
- **Reagent 1, Reagent 2 and Reagent 3**: reports the requested wash after the ith reagent of the contaminating method.

Commands Area

"**New**" Button

Allows the user to define a new probe wash rule.



The types of wash that can be defined by user are the following: Acid, Alkali, Acid then Alkali, Alkali then Acid.

For multi-reagent methods the wash can be requested after the first reagent only if

- the first reagent incubation time is greater than 39 seconds and
- after the second reagent only if the second reagent incubation time is greater than 39 seconds.

"**Edit**" Button

Allows the user to modify a previous defined probe wash rule.

"**Delete**" Button

Allows the user to delete a previous defined probe wash rule.

"**Print**" Button

Allows the user to print the data included in the mask.

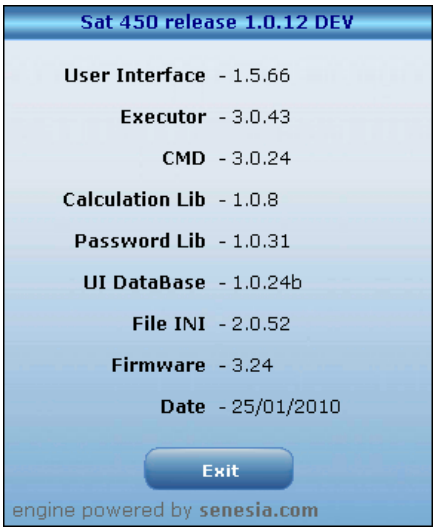
3.6 HELP

This function allows the user to access the system's on-line help guide and to view the list of installed software components revisions.

3.6.1 GUIDE F1

Allows to open User Guide file.

3.6.2 INFO

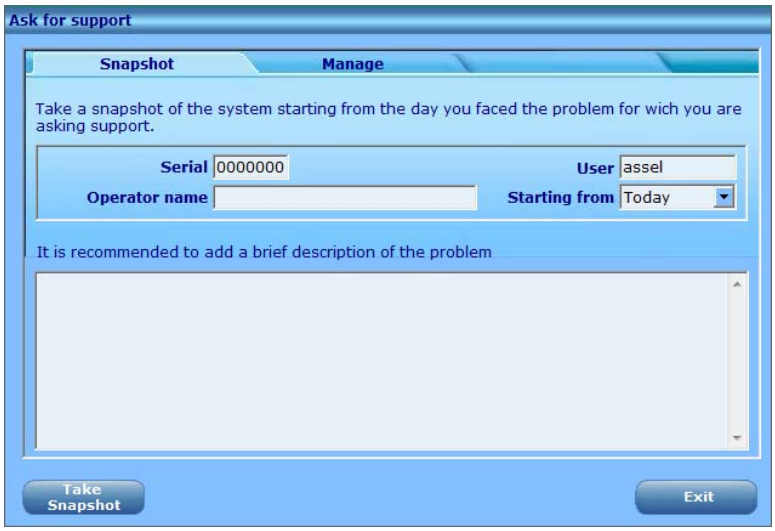


This windows lists the revisions regarding all in-use system software components.

"Exit" Button

Allows the user to close the window and return to "Sys. Mon." mask.

3.6.3 ASK FOR SUPPORT



This mask allows the user to generate/manage "Log files and Database" useful to the producer to analyze the problems occurred during software execution.

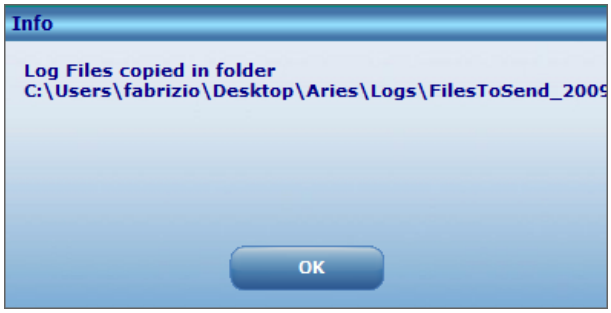
The "Ask for support" mask includes two tabs:

- Generate Tab
- Manage Tab

Generate Tab

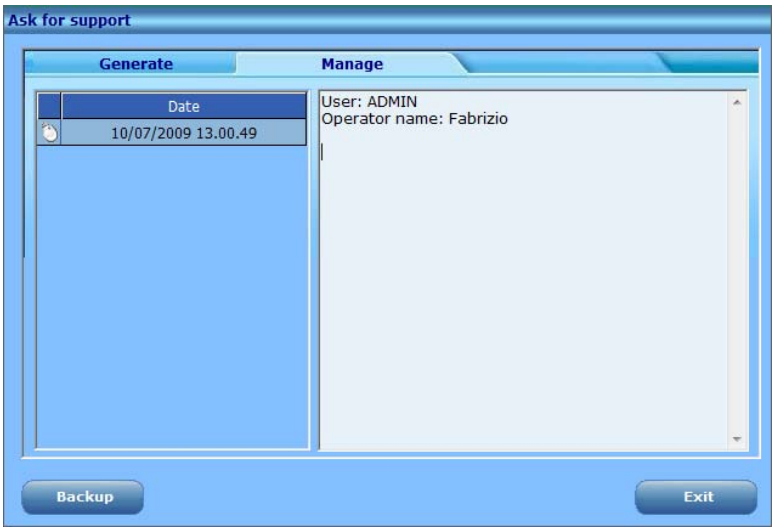
This tab includes following elements:

- **Serial Number**: show the Serial Number (not editable by the user);
- **User**: reports the logged User acronym (not editable by the user);
- **Operator Name:** allows to insert the name of the operator that is generating the log file;
- **Starting From:** allows the user to select how many days of logs file to add to the log file he is generating;
- **Text box**: allows to write a description of the occurred problem;
- **Generate button**: allows to generate the Log Files.



- **Exit button**: allows to close the window and return to Sys. Mon.

Manage Tab



This tab includes following elements:

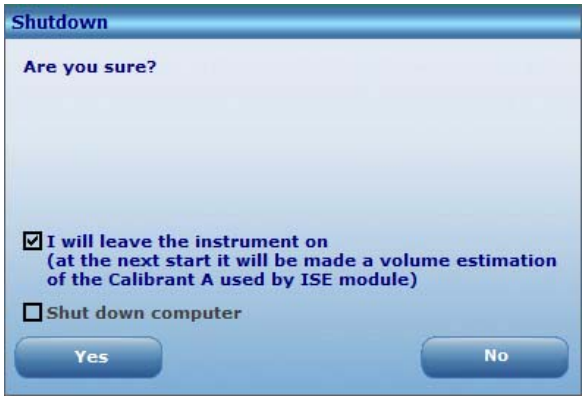
- **A list of the generated file ordered by date**: each element is selectable by the user. It is possible to identify the files generated by the user from the files automatically generated by the software (after a Run Time). The mouse image stand for Files generated by the user. The triangle image stands for Files generated by the software;
- **Text box**: after the selection of each item of the list this text box reports the description of the problem;
- **Backup button**: allows to save the selected item of the list on another support (i.e. USB pen drive) or directory.
- **Exit button**: allows to close the window and return to “Sys. Mon.” mask.

3.7 SHUT DOWN

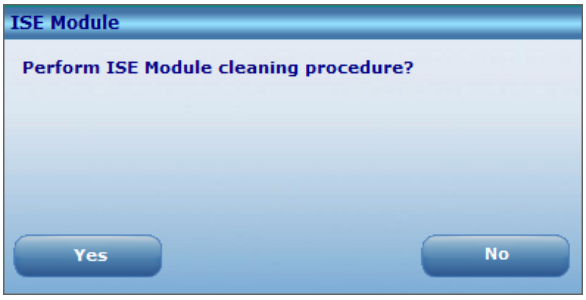
Software Shut Down can be requested only from the "Sys. Mon." (System Monitor) mask.

The user must confirm the request for software shut down, thanks to the following mask.

***Note**: if the ISE Module has been configured, the confirmation mask includes one more checkbox that can be flagged by the user in order to have a more detailed estimation of the Calibrant A volume if the instrument will be left on.*



After the user confirmation, if the ISE Module has been used during the last session and the Instrument at the moment of the shutdown request was in Stand-by Status, user will be prompted with the following request.



If the user will choose to proceed with the cleaning procedure, the Instrument will follow the cleaning procedure and only at the end, it will close itself.

3.8 KEYBOARD SHORTCUTS

Following keyboard shortcuts and combinations can be used instead of mouse:

- **F1**: opens the help file;
- **ALT+F4**: closes the opened window;
- **TAB**: shifts to the next input box;
- **SHIFT+TAB**: shifts to the previous input box.

CHAPTER 04

- USER INSTALLATION -

INDEX

4 USER INSTALLATION…….2

4.1 UNPACKING..... 2

4.2 INSTRUMENT INSTALLATION 4

4.2.1 ENVIRONMENT OF THE INSTALLING SITE……..... 4

4.2.2 ELECTRICAL POWER SUPPLY 5

4.2.3 ACCESSORIES: CONNECTIONS 5

4.2.3.1 Power Supply..... 5

4.2.3.2 Instrument-Computer: connections 5

4.2.3.3 Liquid Reservoir Bottles Container: installation……6

4.2.3.4 Liquid Reservoir Bottles: connections……8

4.2.3.5 Waste Tanks: connections……...9

4.2.4 LABLES AND SYMBOLS..... 10

4.2.5 LEGEND AND SYMBOLS……11

4.2.6 WARRANTY...……..……..……..12

4.2.7 APPLICABLE REGULATIONS……...……..……..……..……13

4.2.8 USAGE LIMITATIONS.....…...13

- **APPENDIX A** (Rev. 03): **Software Installation Procedure**……..14

4 USER INSTALLATION

4.1 UNPACKING

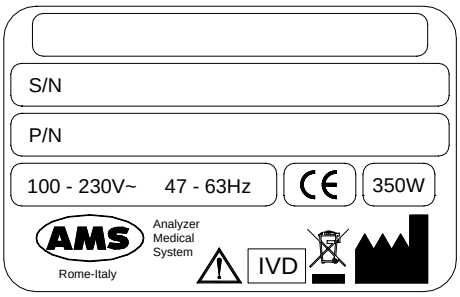
The *SAT 450* is packed and delivered in two separate wooden crates: one containing the analyzer and the other the computer along with its accessories. In the event that the order not include the PC, packing and delivery will involve one wooden crate plus a corrugated cardboard box.

This packing modality has been expressly studied and designed to insure maximum protection of the contents during shipping and handling. It is therefore extremely important that the crates or crate/box combo be carefully inspected upon delivery in order to ascertain their integrity.

Special attention should be dedicated to examining the color of the ShockWatch ® glued to the crates: it must be white. A 'red' ShockWatch ® indicates that the crate(s) have experienced some sort of mishandling (shock) during transport and/or delivery. This fact must be recorded by the courier on the delivery note, as must any and all visible external damage to the packing crates/box (e.g.: holes, dents, rips or tears, water marks, etc.) evident at the moment of consignment. This serves to simplify matters in the event of any future claims for damages.

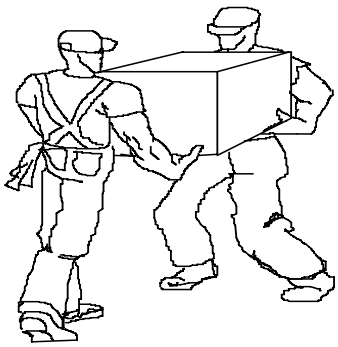
PLEASE NOTE: THE SHIPPER ASSUMES TOTAL RESPONSIBILITY FOR THE CRATES AND/OR BOX AND THEIR CONTENTS ONCE THE GOODS HAVE LEFT THE FACTORY UNTIL THE MOMENT THEY ARE CONSIGNED AT DESTINATION. FURTHERMORE, THE SHIPPER IS RESPONSIBLE FOR ANY AND ALL DAMAGES ARISING DURING HANDLING, STORAGE AND/OR TRANSPORT. ANY AND ALL DAMAGE CLAIMS MUST BE TAKEN UP WITH THE SHIPPER IMMEDIATELY UPON DISCOVERY.

Upon consignment 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/box and that they are undamaged. Check that the serial number on the delivery note/packing list corresponds to that impressed on the plate on the right side of the instrument.



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

- the instrument;
- the computer and other accessories.



MAKE SURE THAT 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.

Remove the adhesive tape from the cover of the samples and reagents housings, from the front panels, and from the samples and reagents racks.

Before connecting the *SAT 450* instrument, remove the protective packing material placed under the Sampling Arm and under the Washing Station group.

Warning: in the event that it is necessary to repack any or all of the delivered items, the below-listed procedure must be carefully followed:

⇒ Reposition the protective packing material under the Sampling Arm and under the Washing Station group.

⇒ Tape down (using masking tape is possible) the cover of the samples and reagents housings.

⇒ Remove the Probe from the Sampling Arm and place it inside a cuvette, cap the cuvette and tape the cap in place.

⇒ Be very careful to not bend the Washing Station probes when repositioning the packing material.

⇒ Fill all the empty spaces around the accessories packed in the crate using pluriballs or other suitable packing material.

In the event that the repacking is carried out after clinical diagnostic use of the instrument, it is necessary to first perform the decontamination procedure as outlined in Chapter 7 of this same manual.

Ambient-climatic conditions for transportation, warehousing and storing the instrument inside its packing crate:

- Temperature: between –20°C and +70°C
- Humidity: 10% ÷ 90%
- Warehoused: INDOOR
- Maximum length of warehousing: 6 months (after which length of time, preventive maintenance regarding certain components is required - e.g.: membranes)

4.2 INSTRUMENT INSTALLATION

The *SAT450* instrument must be installed only by authorized, specialized technical personnel.

During instrument installation, the system will be checked once again to make sure that it functions correctly. The *SAT450* is for professional use only; therefore, the operators who use the instrument (in addition to the academic qualifications and state certification required to meet government regulations) must be trained in its proper use and this training must also regard ordinary instrument maintenance practices. Maintenance activities are described in Chapter 7 of this same manual.

In order to preclude risks of potential biological hazards, it is absolutely necessary that good practices regarding the handling of biological samples, consumables and waste/refluents be scrupulously adhered to.

The *SAT450* is a complex system and, as such, it is of utmost importance that the installation procedure be executed correctly in order to guarantee optimum levels of performance. In the event that the indications reported herein (in this manual) and/or relevant safety norms are not followed, AMS cannot and does not guarantee proper instrument functioning. Furthermore, user safety may be placed at risk.

4.2.1 ENVIRONMENT OF THE INSTALLING SITE

Make sure that the *SAT450* instrument is not installed where it is in direct sunlight, subject to drafts, dust or strong magnetic fields. Observe the conditions outlined in the below-illustrated table regarding the installing site:

USE	Indoors and dry
POLLUTION DEGREE	2
ISOLATION CLASS	I
INSTALLATION CATEGORY	II
USAGE: TEMPERATURE	between 18°C and 30°C
HUMIDITY	20% ÷ 85%
ALTITUDE	Maximum: 3000 m
PLACEMENT	Counter-top or table: minimum surface area 110 x 70 cm. Stable surface with no vibrations. Position the instrument in such a manner that it can be easily disconnected. Position the instrument in plane.
VENTILATION	Leave a space of at least 10 cm around the instrument in order to allow air circulation. Make sure that the fans (located under the reagents housing) are not obstructed.

4.2.2 ELECTRICAL POWER SUPPLY

The electrical power tension/voltage for the instrument is indicated on the right-hand side of the instrument (see the label in Page 2). This same information is also reported on the label located above the input line socket. Make sure that power supply used conforms to that here-indicated and that it is properly grounded:

VOLTAGE	100 ÷ 230Vac 47/63Hz ±10%

PLEASE NOTE: IT IS IMPORTANT THAT THE LABORATORY'S ELECTRICAL POWER SOURCE BE EXTREMELY STABLE. IF SAID STABILITY CANNOT BE GUARANTEED, THE USE OF THE FOLLOWING DEVICES IS STRONGLY SUGGESTED:

⇒ **ELECTRONIC STABILIZER**

Used to stabilize the power source voltage in the laboratory. Any stabilizer available on the market can be used (power not less than 0.5 kW).

⇒ **NO-BREAK MODULE (UPS - Uninterrupted Power Supply)**

This module offers two important functions:

- stabilizes the power voltage;
- powers the instrument in the event of a power failure.

4.2.3 ACCESSORIES: CONNECTIONS

4.2.3.1 Power supply

Use the power supply cable that is provided to connect the instrument to the power source.

4.2.3.2 Instrument-Computer: connections

The *SAT450* instrument and the Personal Computer are connected via a RS232 standard serial cable and/or USB standard cable, which constitutes the hardware for the exchange protocol. The respective connectors (Serial and USB connectors) are shown in **Fig. 4(a)**.

4.2.3.3 Liquid Reservoir Bottles Container: installation

Install the container of the four liquid reservoir bottles on the *SAT 450* instrument in the following way:

1. Make sure that the instrument is turned off.
2. Unscrew the two captive screws on the front underside of the instrument and lift up the Raising Top.
3. Take the container, unscrew the four screw nuts from the respective threaded pins (**Fig. 1**) and take off the four washers.

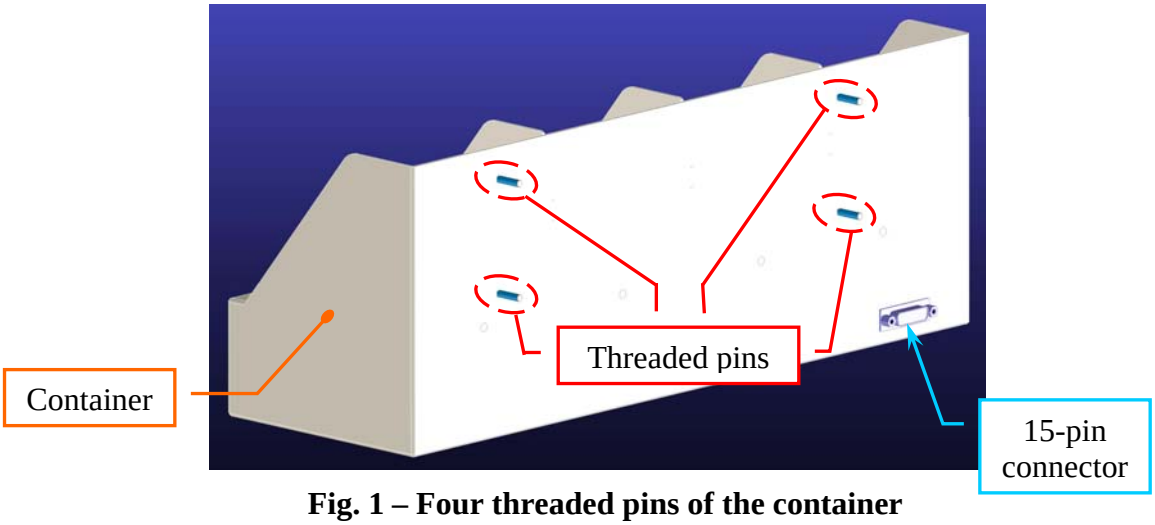


Fig. 1 – Four threaded pins of the container

4. Draw up the container to the left-hand side of the instrument and put on completely the four threaded pins in the four through holes located on the chassis (**Fig. 2**).

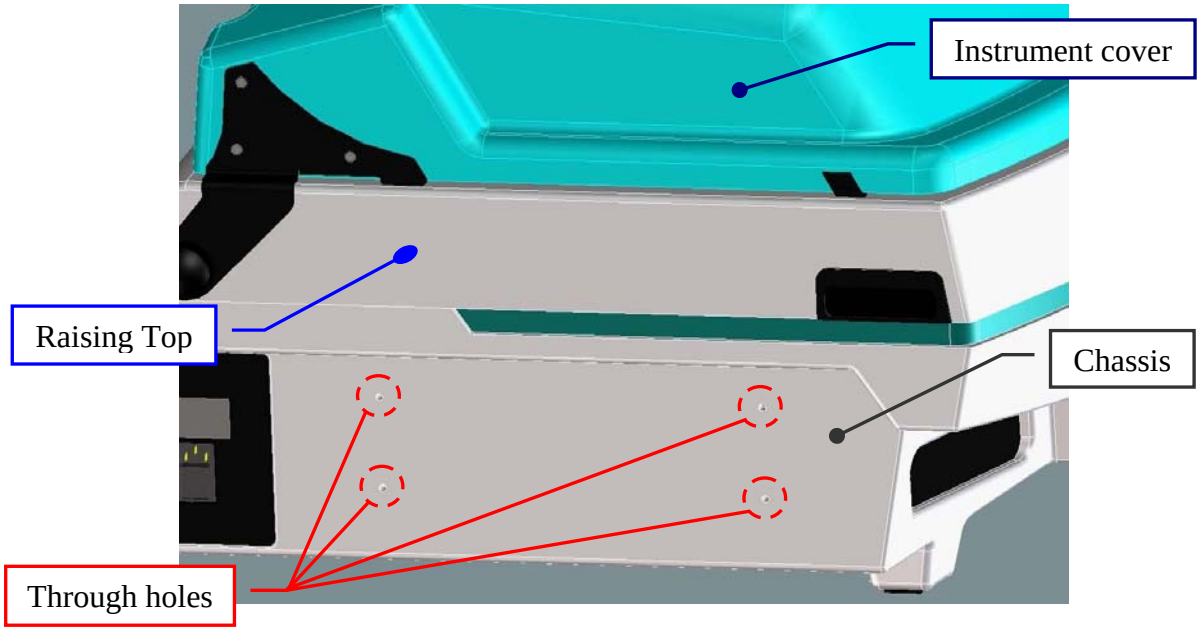


Fig. 2 – Four through holes located on the chassis

5. Put the four washers on the threaded pins from the left-hand interior side of the instrument (**Fig. 3**).
6. Screw completely the four screw nuts on the threaded pins from the left-hand interior side of the instrument (**Fig. 3**).

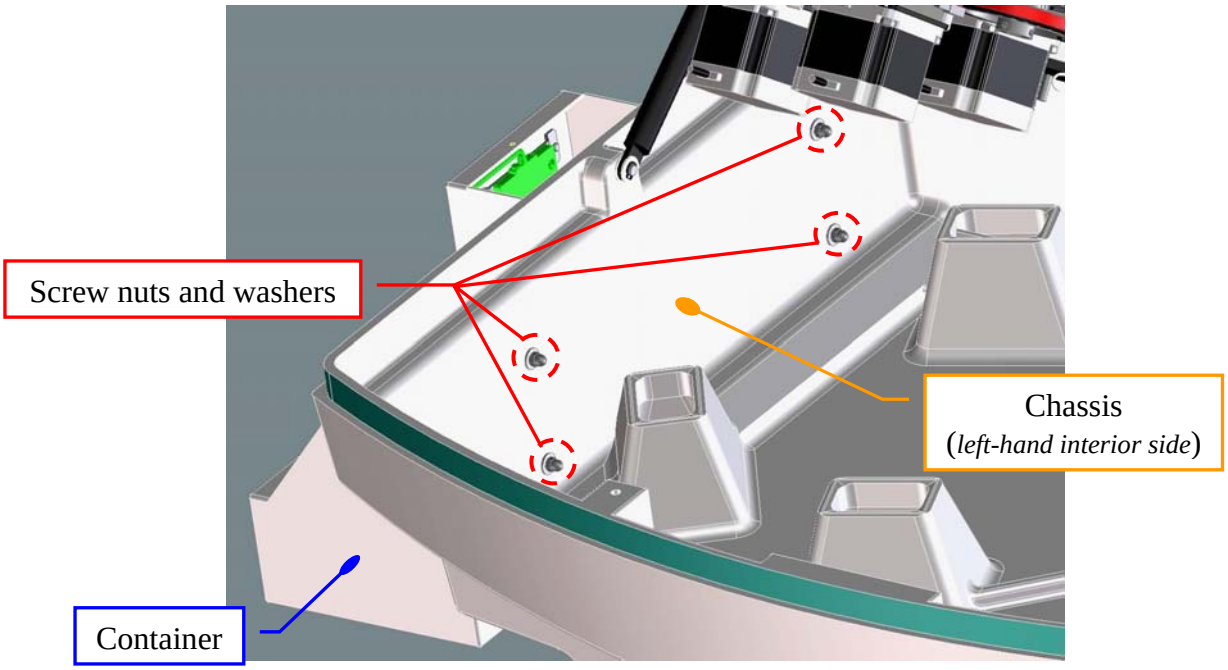
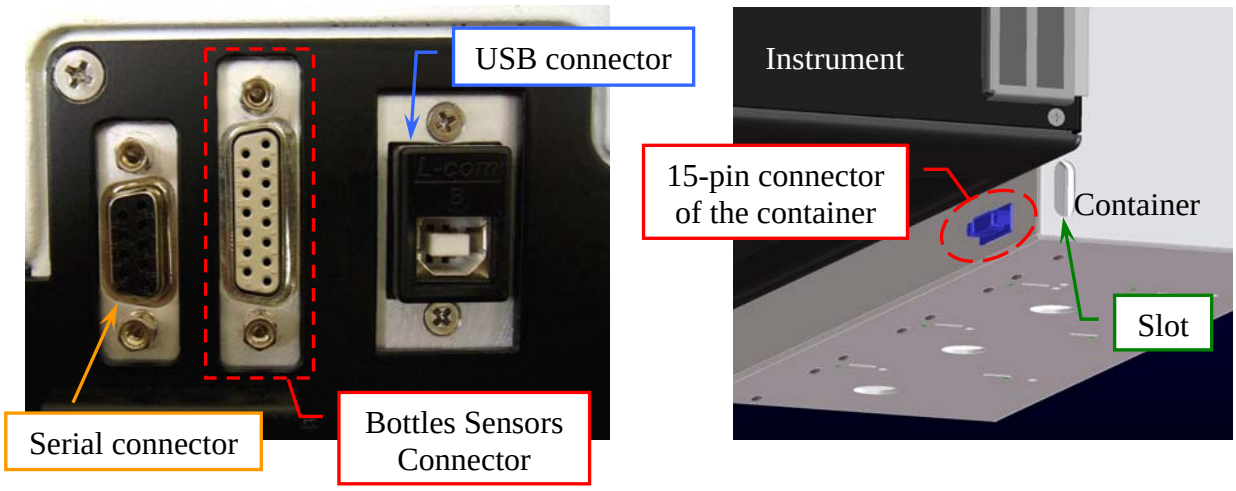


Fig. 3 – Container installed on the instrument

7. Bring down the Raising Top and screw the two captive screws on the front underside of the instrument.
8. Take the "Bottles Connection Cable" (P/N: 50-02684-00) and plug its 15-pin male connector in the 15-pin connector (shown in the **Fig. 4-a**) located on the back side of the instrument (*Bottles Sensors Connector*).
9. Plug the 15-pin female connector of the "Bottles Connection Cable" in the 15-pin connector of the container (shown in the **Fig. 4-b**) located on its back side.



(a) **(b)**

Fig. 4 [(a), (b)] – Connectors to plug the "Bottles Connection Cable"

4.2.3.4 Liquid Reservoir Bottles: connections

Carry out the following steps:

1. Position the four bottles on the container in the order indicated and illustrated here-below (**Fig. 5**):

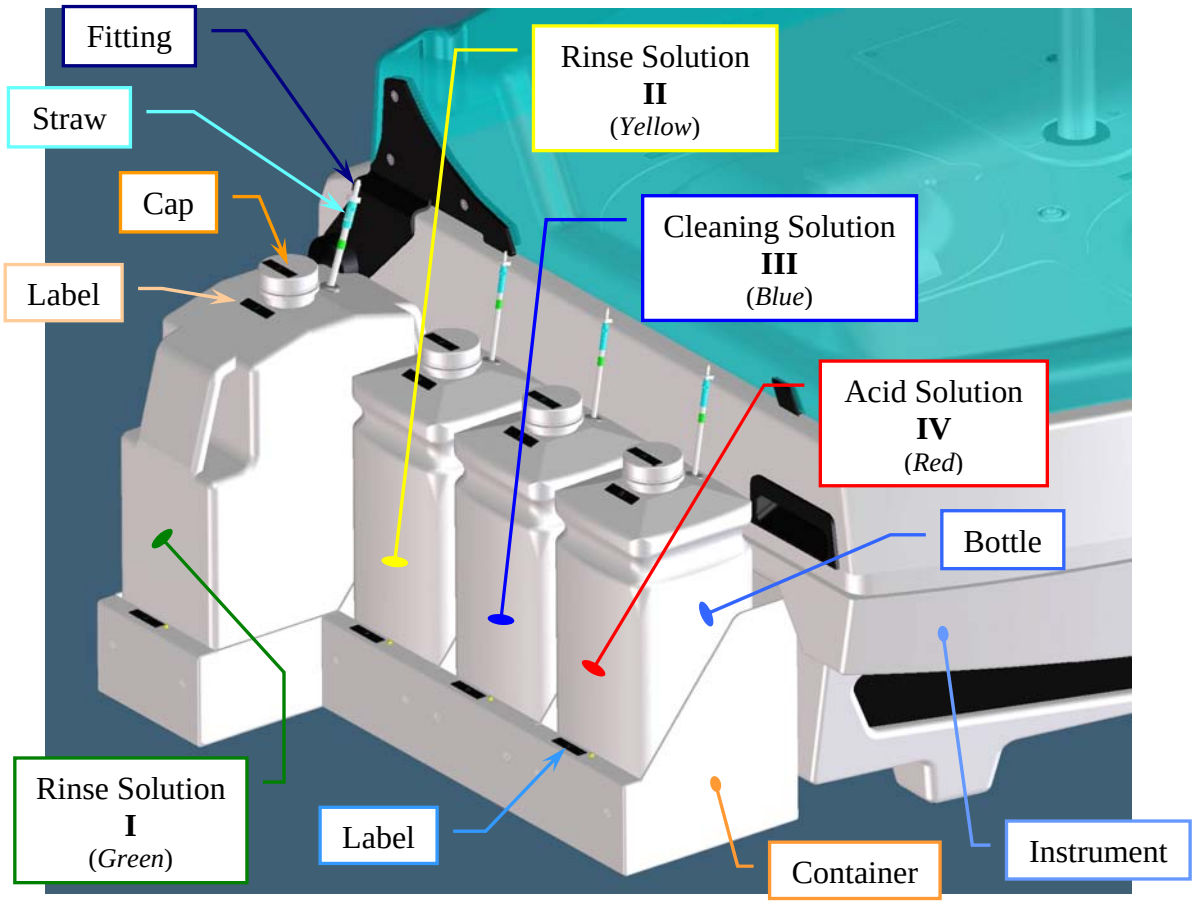


Fig. 5 – Four Liquid Reservoir Bottles

2. Connect the fittings of the four loading tubes on their respective fittings located on the back of the instrument (*Loading connections*). The *loading connections* on the back of the instrument are clearly labeled (**Fig. 6**). *Note: the fittings of the connections dedicated to **loading** are numbered accordingly with the labels of the bottles.*

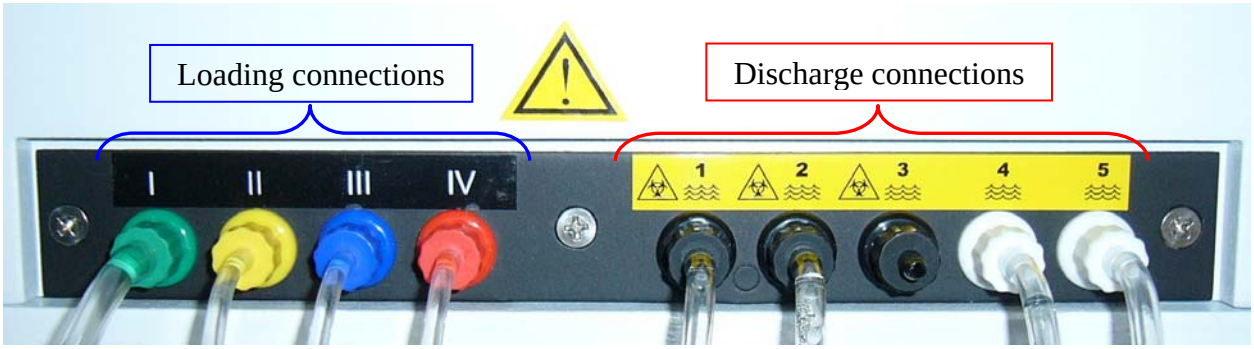


Fig. 6 – Loading and discharge connections

3. Push the four loading tubes through the slot of the container (**Fig. 4 (b)**) and pull them into the container.
4. Connect the other extremities of the four loading tubes at the fittings of the straws (**Fig. 5**).
5. Insert the four aspiration straws in their respective bottles according to the indications dictated by **Figures 5** and **6**.

4.2.3.5 Waste Tanks: connections

Carry out the following steps:

1. Connect the fittings of the discharge tubes on their respective fittings located on the back of the instrument (*Discharge connections*). The *discharge* (*Waste*) *connections* on the back of the instrument are clearly labeled. They are numbered (**Fig. 6**) and must be connected as specified following:
   - ⇒ tubes having black fitting on discharges 1 and 2 from Washing Wells, and on discharge 3 from the ISE module (if installed as *optional device*);
   - ⇒ tubes having white fitting on discharges 4 and 5 coming from the Washing Station for those liquids which do not constitute a biological hazard.

2. Insert the other extremities of the discharge tubes in the two waste tanks as specified following:
   - ❖ tubes having black fitting – discharges 1, 2 (and 3) – in the *biohazard waste tank*;
   - ❖ tubes having white fitting – discharges 4 and 5 – in the waste tank.

Note	The instrument does not come with the waste tanks. Laboratory personnel must see to acquiring the appropriately sized containers suited to their needs. The *biohazard waste tank* should be properly identified and labeled using the biological hazard symbol (please see the following paragraph).

4.2.4 LABELS AND SYMBOLS

CAUTION

The below-illustrated label can be found on the back of the instrument:

⚠CAUTION
TO PREVENT ELECTRIC SHOCK
DO NOT REMOVE BACK PANEL.
NO USER-SERVICEABLE PARTS INSIDE.
REFER SERVING TO QUALIFIED
SERVICE PERSONNEL

PLEASE NOTE: NEVER OPEN THE INSTRUMENT WITHOUT HAVING FIRST TURNED IT OFF AND DISCONNECTED IT FROM ITS POWER SOURCE (UNPLUG THE POWER SUPPLY CABLE).

CAREFULLY FOLLOW THE CLEANING AND MAINTENANCE PROCEDURES AS OUTLINED IN CHAPTER 7 OF THIS SAME MANUAL.

4.2.5 LEGEND AND SYMBOLS

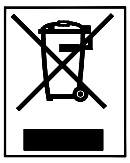
CAUTION! READ INSTRUCTIONS IN USER MANUAL

EARTH GROUND

BIOLOGICAL HAZARD

(Placed next to the Samples Plate and the waste discharge black fittings)
Wear proper protective clothing/equipment and handle all biological samples, consumables and waste liquids produced during analysis with extreme care. The disposal of the used consumables and the waste liquids produced must conform to all applicable government laws and regulations. Furthermore, to prevent overflow of the discharge tanks, make sure to periodically check the level of the waste liquids collected.

MANUFACTURING COMPANY
This symbol is placed next to the name of the company that has produced/manufactured the item.



This “crossed-out wheelie bin/trash can symbol” can be found on the label and reports information indicating that the instrument and parts are not to be disposed of with ordinary household waste/garbage. They must be disposed of according to applicable government regulations regarding electrical and electronic equipment (Directive 2002/96/EC WEEE).

4.2.6 WARRANTY

AMS guarantees the replacement of all defective components and/or materials for a period up to 14 (fourteen) months from the date of invoice.

This warranty, as for all Technical Assistance in general, is intended as provided ex works, Rome, Italy.

This warranty does not cover consumables or those parts of the instrument in direct contact with liquids. A detailed list of the individual components excluded from and not covered by this warranty is provided in the table below.

Moreover, this warranty is not valid in those cases in which damage/s to the *SAT 450* arise from or are the result of:

- improper use of the instrument (or use in any manner not in conformance with instructions provided by the Manufacturer or the Seller);
- mishandling and/or transportation errors;
- insufficient (or lack of) ordinary maintenance on the part of the User.

More in detail, any and all damages arising from mishandling or caused during transport must be immediately reported to the Shipping Company upon delivery of the goods.

LIST OF CONSUMABLES AND ACCESSORIES EXCLUDED FROM WARRANTY:

Description
Reagents bottles
Samples cups
Reaction Racks
Loading bottles
Tubes
Sampling Probe
Drying Pad
Photometer Lamp (6V – 10 W)
Washing Station Probes
Micropumps
Electrovalves
ISE Electrodes

4.2.7 APPLICABLE REGULATIONS

The *SAT450* conforms to the following government regulations:

- **Directive 98/79/CE** relative to In-Vitro Diagnostic Devices

This compliance is certified by the here-illustrated symbols placed on the instrument:

4.2.8 USAGE LIMITATIONS

The *SAT450* cannot be used by the blind as the user must interact with the instrument by reading/writing on the monitor.

Furthermore, the *SAT450* must be used with extreme care by color-blind users as the user interface graphics employs and associates different colors to provide the user with important information.

MINIMUM SYSTEM REQUIREMENTS FOR *SAT 450* SW

- **OPERATING SYSTEM**
  - Windows XP Professional (SP2 or higher)
  - Windows Vista
  - Windows 7
- **HARDWARE**
  - CPU: Intel or AMD - 2.0 GHz
  - RAM: 512 MB (1024 MB recommended for Windows Vista)
  - Hard Disk: 80 GByte
  - Monitor: 17'' color
  - 1 CD-ROM for installation purposes
  - I/O Ports: 1 Serial Port for the connection to the instrument, 1 parallel port or 1 USB for local printer, 1 Serial Port for the connection to the Host computer (*optional*)

→ **Warning**: the Hard Disk must have the volume C:\

WINDOWS SETTINGS

SAT 450 SW needs the following Windows settings:

- Display Resolution : "1024 x 768"
- Screen Saver: Disable
- Power Options: Disable

Operational Instruction to change the setting by using Windows 7, Vista and XP:

1. Display Resolution Settings

Windows 7

Select **Start** Button → Select **Control Panel** → Select **Adjust screen resolution** under the **Appearance and Personalization** menu → Set the resolution to **1024 x 768 pixels** → Select **OK** Button

Select **Start** Button → Select **Control Panel** → Select **Appearance and Personalization** → Select **Display** → Set **Smaller – 100%** → Select **Apply** Button

Windows Vista

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Personalization** → Select **Display Settings** → Set the resolution to **1024 x 768 pixels** → Select **OK** Button

Windows XP

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Display** → Select **Setting tab** → Set the resolution to **1024 x 768 pixels** → Select **OK** Button

2. Screen Saver Settings

Windows 7

Use the **Start** Button → Select **Control Panel** → Select **Appearance and Personalization** → Select **Change screen resolution** under the **Personalization** menu → Set the screen saver combo box to **None** → Select **OK** Button

Windows Vista

Use the **Start** Button → Select **Settings** → Select **Control Panel** → Select **Personalization** → Select **Screen Saver** → Set the screen saver combo box to **None** → Select **OK** Button

Windows XP

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Display** → Select **Screen Saver** tab → Set the screen saver combo box to **None** → Select **OK** Button

3. Power Options

Windows 7

Select **Start** Button → Select **Control Panel** → Select **System and Security** → Select **Power Options** → Choose **Balanced** as Preferred Plans → Click on "**Change Plan Settings**" under Balanced → Click on "**Change advanced power settings**" and:

1. Click on "+" of Hard Disk Option → Click on "+" of Turn off Hard Disk After → Put Setting to **Never**
2. Click on "+" of Sleep → Click on "+" of Hibernate After → Put Setting to **Never**
3. Click on "+" of Display → Click on "+" of Turn off Display After → Put Setting to **Never** → Select **OK** button

Windows Vista

Select **Start** Button → Select **Control Panel** → Select **System and Security** → Select **Power Options** → Choose **Balanced** as Preferred Plans → Click on "**Change Plan Settings**" under Balanced → Click on "**Change advanced power settings**" and:

1. Click on "+" of Hard Disk Option → Click on "+" of Turn off Hard Disk After → Put Setting to **Never**
2. Click on "+" of Sleep → Click on "+" of Hibernate After → Put Setting to **Never**
3. Click on "+" of Display → Click on "+" of Turn off Display After → Put Setting to **Never** → Select **OK** button

Windows XP

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Power Options** → Select **Power Schemes** tab → Set all combos in Settings for Home/Office Desk power scheme to **Never** → Select **OK** Button

4. Localization Options

Windows 7

Select **Start** Button → Select **Control Panel** → Select **Clock, Language and Region** → Select **Regional and Language** → Select **Administrative** tab → Click **Change system locale** ... button → Select from the list the language version of non-Unicode programs that will be used → Select **OK** Button

Windows Vista

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Regional and Language Options** → Select **Administrative** tab → Click **Change system locale** ... button → Select from the list the language version of non-Unicode programs that will be used → Select **OK** Button

Windows XP

Select **Start** Button → Select **Settings** → Select **Control Panel** → Select **Regional and Language Options** → Select **Advanced** tab → Under Language for non-Unicode programs, click the language version of non-Unicode programs that will be used → Select **OK** Button

SAT 450 software installation procedure

a. Close all the applications in use on your PC.

b. Insert the CD into the CD-Rom drive.
SAT 450 Setup starts automatically.
If it not be so:

- open the CD-Rom drive;
- click twice on "Autorun.exe" file.

Note (only related to Windows Vista): in case of the User Account Control Window appears select **Allow** option.

c. The "Welcome to Sat450 Installation CD" window appears:

- Click on "**Software**" button to install the *SAT 450 software*.
- Click on "**Firmware**" button to install the *Firmware DownLoad Manager*.
- Click on "**Adobe**" button to install the *Adobe Reader*.
- Click on "**Exit**" button to exit.

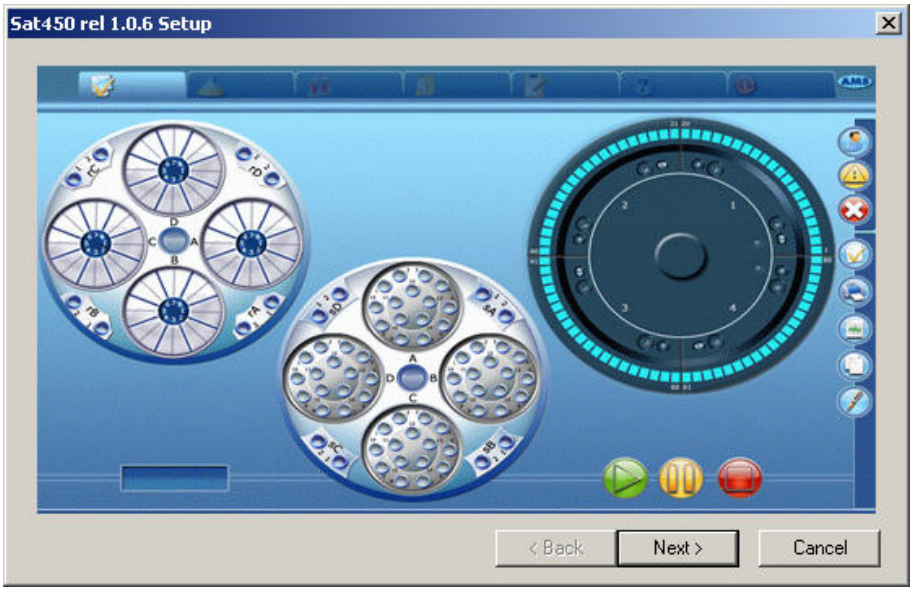
SAT 450 Software - COMPLETE installation procedure

Warning: the complete software installation procedure deletes all the previous data.

Note 1 (only related to Windows Vista): in case of the User Account Control Window appears select **Allow** option.

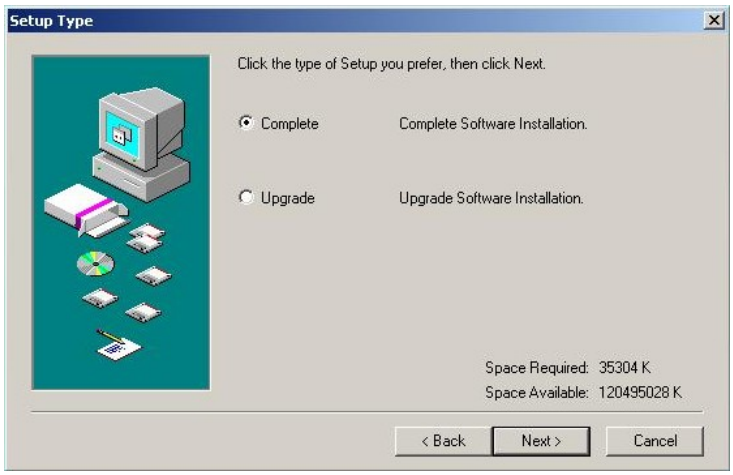
1. Click on "**Software**" button in the "Welcome to Sat450 Installation CD" window:

2. After that the "Sat450 rel x.y.z Setup" window appears



click on **"Next"** button.

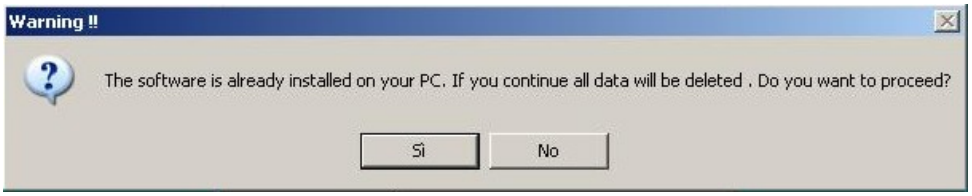
3. In the “Setup Type” window:



choose the **Complete** option, then click on **“Next”** button.

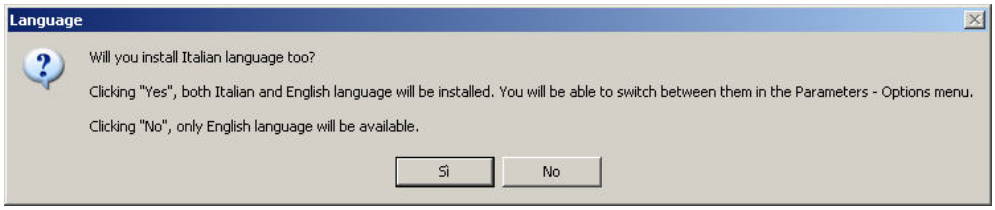
4. If in your PC will be found a previous SAT 450 SW installation, the following “Warning” message appears:

   “*The software is already installed on your PC. If you continue all data will be deleted. Do you want to proceed?*”



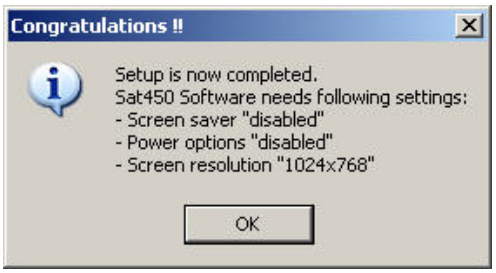
- Select “**Yes**” button to continue the SAT 450 installation.
- Select “**No**” button to abort the SAT 450 installation. The following message appears: Setup was unsuccessful. Installation program will be closed.

5. After few seconds, the user will be prompted with the following message (Language selection):



- Select “**Yes**” button to install both Italian and English Language.
- Select “**No**” button to install the English Language only.

6. After few seconds, the message “Congratulations !!” appears to warning the user about Windows Settings (that SAT 450 needs to work properly):



7. Click on **“OK”** button to finish the Setup.

SAT 450 installation program creates:

- a shortcut to SAT 450 program on desktop;
- an SAT 450 folder (with shortcut to SAT 450 program and with a shortcut to the uninstaller) inside Program Groups.

Note: at the end of the SAT 450 SW installation, the system could require a reboot of the system.

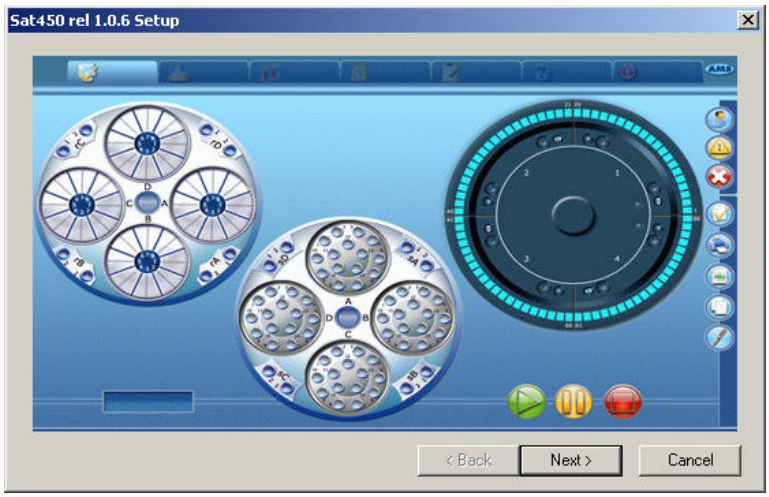
SAT 450 Software - UPGRADE installation procedure

1. Click on "**Software**" button in the "Welcome to Sat450 Installation CD" window:

Note 1: it is strongly suggested to perform a copy of the Analyzer.mdb and Archive.mdb (located in the directory C:\Sat450\Db) before to perform the Upgrading Procedure.

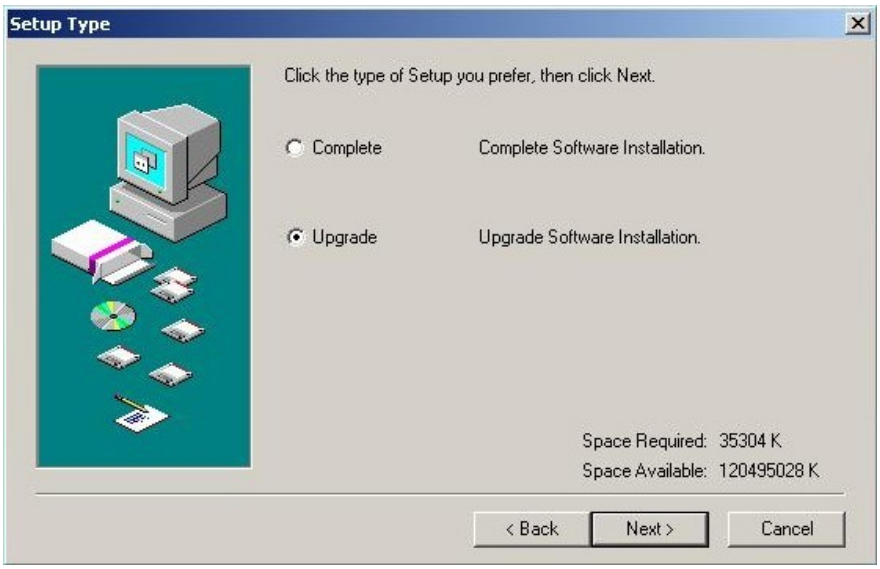
Note 2: if you are installing SAT 450 SW on Windows Vista, after SAT 450 Setup has started, it will probably appears the window User Account Control; click on **Allow**.

2. After that the "Sat450 rel x.y.z Setup" window appears:



click on "Next" button.

3. In the “Setup Type” window:

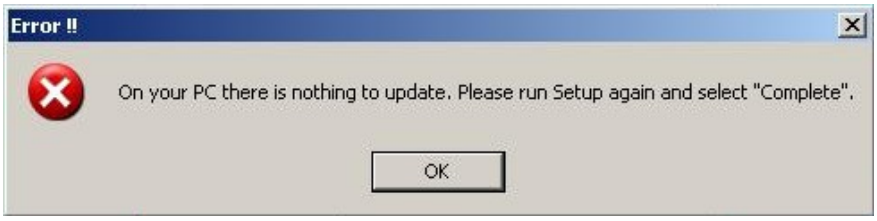


choose the **Upgrade** option, then click on **“Next”** button.

4. If on your PC will be found a previous installation of SAT 450 SW, after few seconds appears a message “Upgrade is now completed”:

- click on **“OK”** button and the installation program will be closed.

5. If on your PC will not be found a previous installation of SAT 450 SW, the following message appears: *“On your PC there is nothing to update. Please run Setup again and select “Complete”*:



- click on **“OK”** button to close the “Error !!” window.

Note 3: at the end of the SAT 450 SW installation, system could require reboot of the system.

Database upgrade note

During the SAT 450 software upgrading procedure, the software checks the Analyzer.mdb and Archive.mdb in order to update the two databases. During the checking some choices will be shown to the installer. You can find below a description of the possible choices.

CASE 1 – Analyzer.mdb and Archive.mdb not found in C:\Sat450\Db and a security backup does not exist

1. The upgrading software shows a form with two buttons (OK, Cancel): *DB not found. Make a copy of an Empty Database*? If the operator selects **OK** button, an empty database (Analyzer.mdb) will be installed - otherwise - the installation program will be closed.

CASE 2 – Analyzer.mdb and Archive.mdb not found in C:\Sat450\Db and a security backup exists

2. The upgrading software shows a form with three buttons (Yes, No, Cancel): *DB not found. Restore the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed. If the operator selects **No** button - see point 1. If the operator selects **Cancel** button, the installation program will be closed.

CASE 3 – Analyzer.mdb and Archive.mdb corrupted in C:\Sat450\Db and a security backup does not exist

3. The upgrading software shows a form with two buttons (OK, Cancel): *Analyzer.mdb and Archive.mdb corrupted. Replace them with an Empty Analyzer.mdb Database*? If the operator selects **OK** button, an empty database (Analyzer.mdb) will be installed – otherwise – the installation program will be closed.

CASE 4 – Analyzer.mdb and Archive.mdb corrupted in C:\Sat450\Db and a security backup exists

4. The upgrading software shows a form with three buttons (Yes, No, Cancel): *Analyzer and Archive.mdb corrupted. Make a restore of the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed. If the operator selects **No** button - see point 3. If the operator selects **Cancel** button, the installation program will be closed.

CASE 5 – Analyzer.mdb corrupted in C:\Sat450\Db and a security backup does not exist

5. The upgrading software shows a form with two buttons (OK, Cancel): *Analyzer.mdb corrupted. Replace it with an Empty Database*? If the operator selects **OK** button, an empty database (Analyzer.mdb) will be installed. In case of - a previous Archive.mdb exists - a backup will be created in C:\Sat450\Db to be read from the "Restore" form (Archive – Restore – menu). If the operator selects **Cancel** button the installation program will be closed.

CASE 6 – Analyzer.mdb corrupted in C:\Sat450\Db and a security backup exists

6. The upgrading software shows a form with three buttons (Yes, No, Cancel): *Analyzer.mdb corrupted. Make a restore of the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed. In case of a previous Archive.mdb exists a backup will be created in C:\Sat450\Db to be read from the "Restore" form (Archive – Restore – menu). If the operator selects **No** button see point 5. If the operator selects **Cancel** button, the installation program will be closed.

CASE 7 – Archive.mdb corrupted in C:\Sat450\Db and a security backup does not exist

7. The upgrading software shows a form with two buttons (OK, Cancel): *Archive.mdb corrupted. Delete it*? If the operator selects **OK** button, Archive.mdb will be deleted - otherwise - the installation program will be closed.

CASE 8 – Archive.mdb corrupted in C:\Sat450\Db and a security backup exists

8. The upgrading software shows a form with three buttons (Yes, No, Cancel): *Archive.mdb corrupted. Make restore of the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed. If the operator selects **No** button see point 7. If the operator selects **Cancel** button, the installation program will be closed.

CASE 9 – Analyzer.mdb not found in C:\Sat450\Db and a security backup does not exist

9. The upgrading software shows a form with two buttons (OK, Cancel): *Analyzer.mdb not found. Make a copy of an Empty Database*? If the operator selects **OK** button, an empty database (Analyzer.mdb) will be installed and a backup of Archive.mdb will be created in C:\Sat450\Db to be read from the "Restore" form (Archive – Restore – menu). If the operator selects **Cancel** button the installation program will be closed.

CASE 10 – Analyzer.mdb not found in C:\Sat450\DB and a security backup exists

10. The upgrading software shows a form with three buttons (Yes, No, Cancel): *Analyzer.mdb not found. Make a restore of the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed and a backup of Archive.mdb will be created in C:\Sat450\Db to be read from the "Restore" form (Archive – Restore – menu). If the operator selects **No** button see point 9. If the operator selects **Cancel** button, the installation program will be closed.

CASE 11 – Analyzer.mdb and Archive.mdb not compatible in C:\Sat450\DB and a security backup does not exist

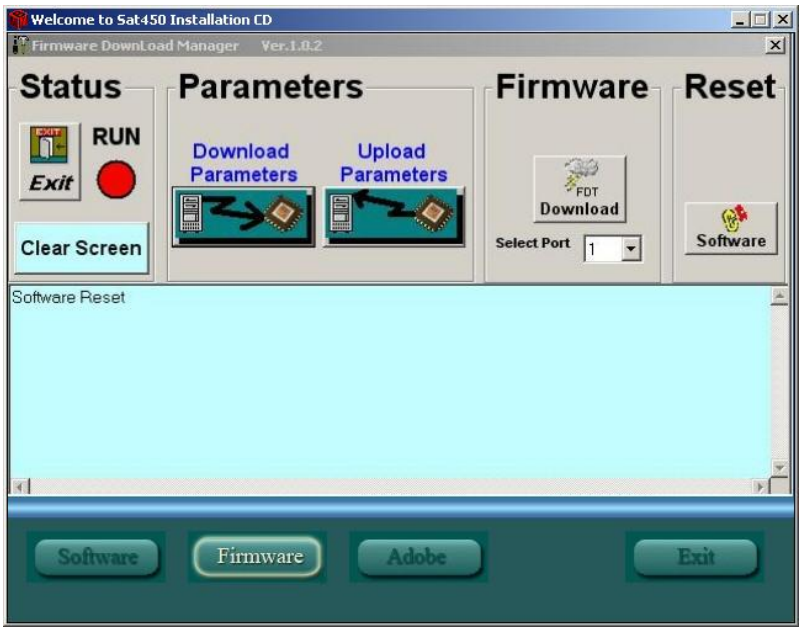
11. The upgrading software shows a form with two buttons (OK, Cancel): *Analyzer and Archive.mdb not compatible. The Archive.mdb will be deleted and a backup that can be read from the Restore form (Archive – Restore – menu) will be created. Confirm to proceed*? If the operator selects **OK** button, the upgrading of the Analyzer.mdb version will be made; further a backup of Archive.mdb will be created in C:\Sat450\Db to be read from the "Restore" form (Archive – Restore – menu). If the operator selects **Cancel** button the installation program will be closed.

CASE 12 – Analyzer.mdb and Archive.mdb not compatible in C:\Sat450\Db and a security backup exists

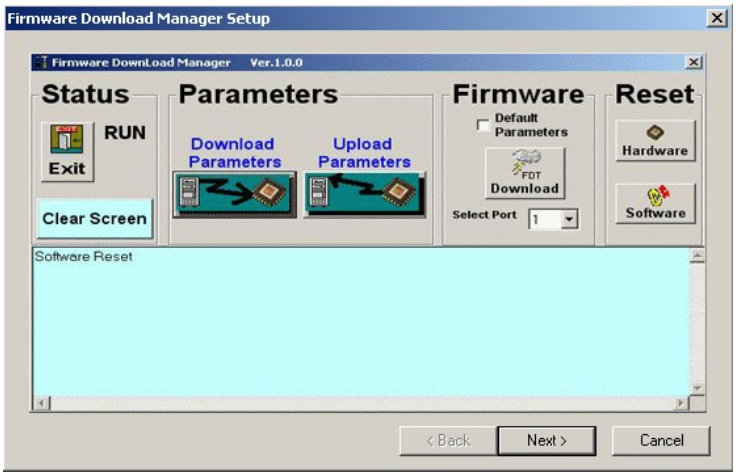
12. The upgrading software shows a form with three buttons (Yes, No, Cancel): *Analyzer and Archive.mdb not compatible. Make a restore of the last Security Backup*? If the operator selects **Yes** button, a copy of the last security backup will be installed. If the operator selects **No** button see point 11. If the operator selects **Cancel** button, the installation program will be closed.

Firmware DownLoad Manager installation procedure

1. Click on "**Firmware**" button in the "Welcome to Sat450 Installation CD" window:



2. After that the "Firmware DownLoad Manager" window appears:



click on **"Next"** button.

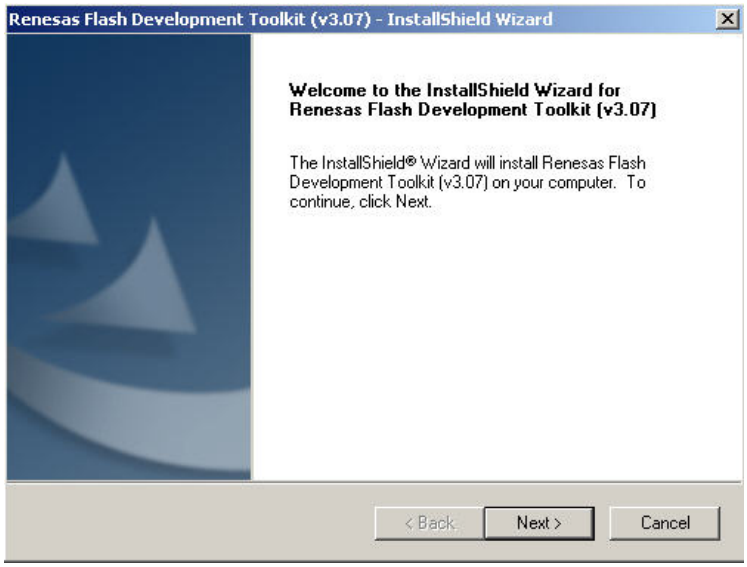
3. If the following window appear:

click on **"OK"** button.

4. On the following message box (“FDT 3.07 Release 01 Installation”):

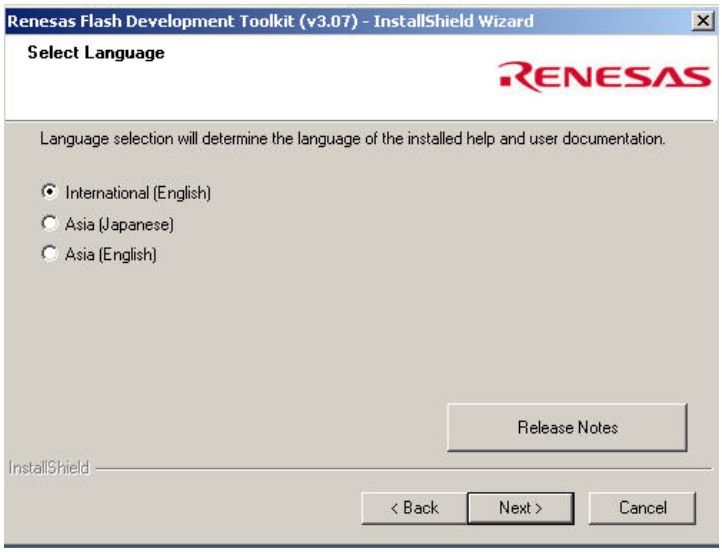
click on **“OK”** button.

5. Wait until the following window appears:



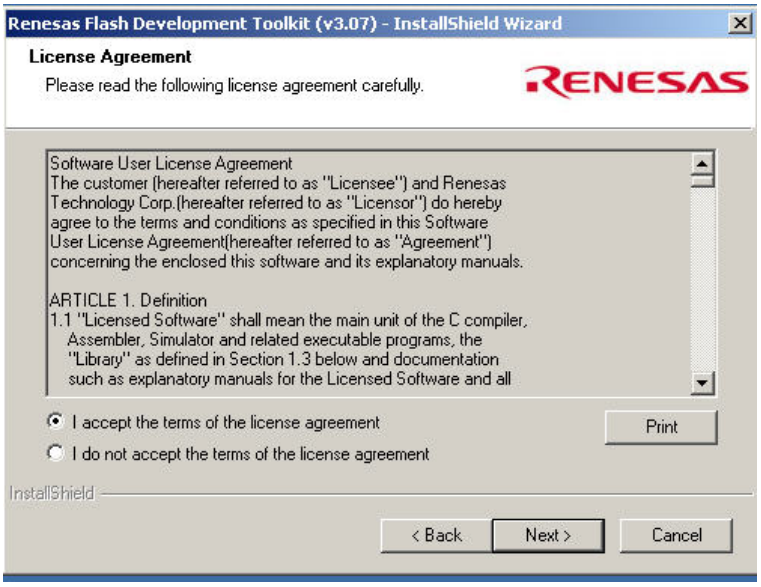
and click on **“Next”** button.

6. On the following windows (**Warning**: do not modify the “International English” language option):



click on **“Next”** button.

7. On the following window ("Renesas Flash Development Toolkit (v3.07) – InstallShield Wizard"):

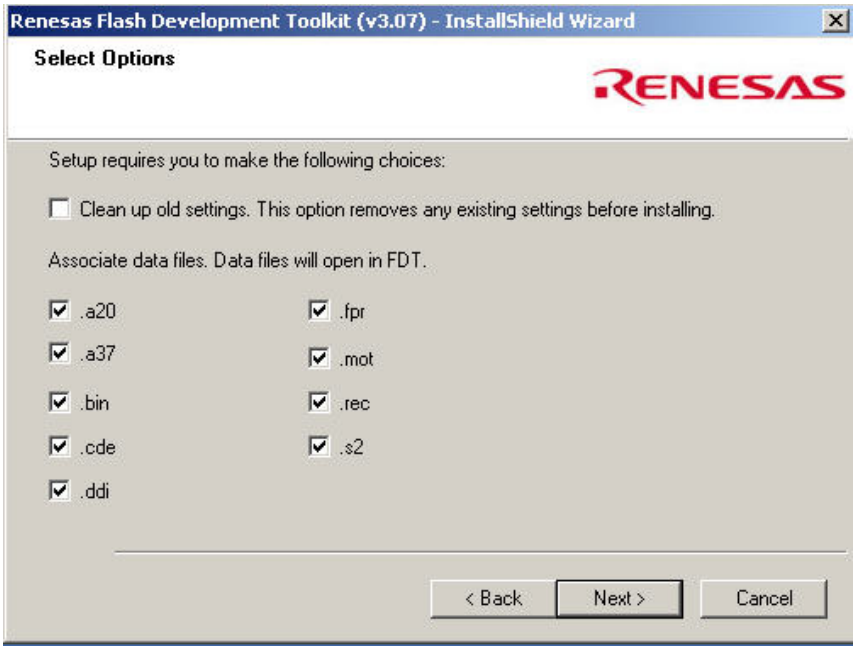


- select the **"I accept the terms of the license agreement"** option;
- click on **"Next"** button.

8. On the following window:

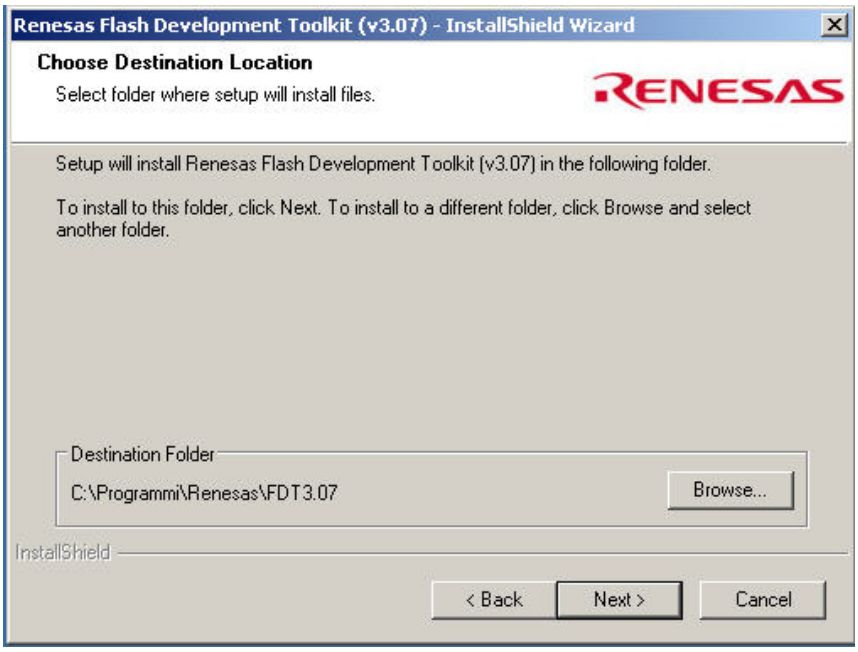
click on "Next" button.

9. On the following window:



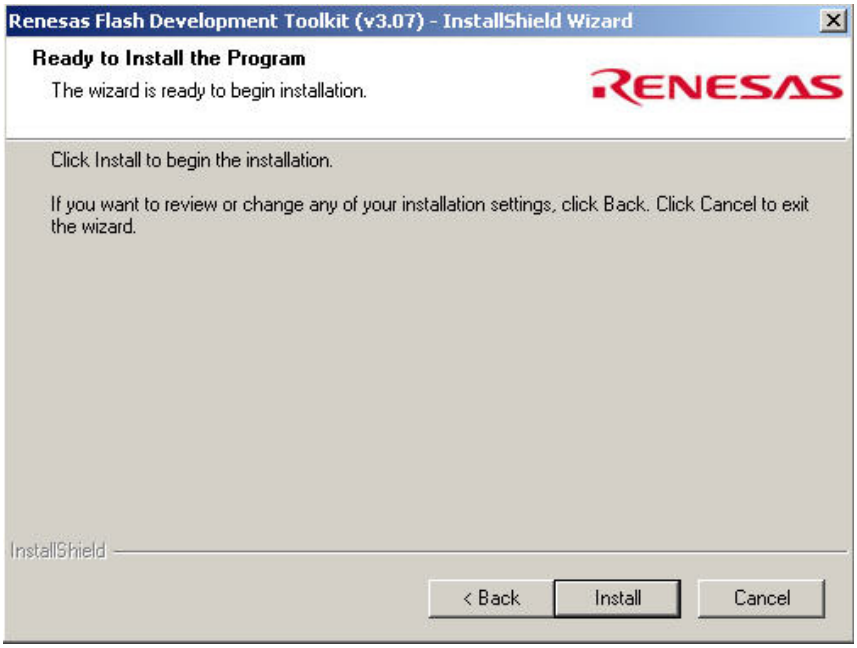
click on **"Next"** button.

10. On the following window:



click on **"Next"** button.

11. On the following window:

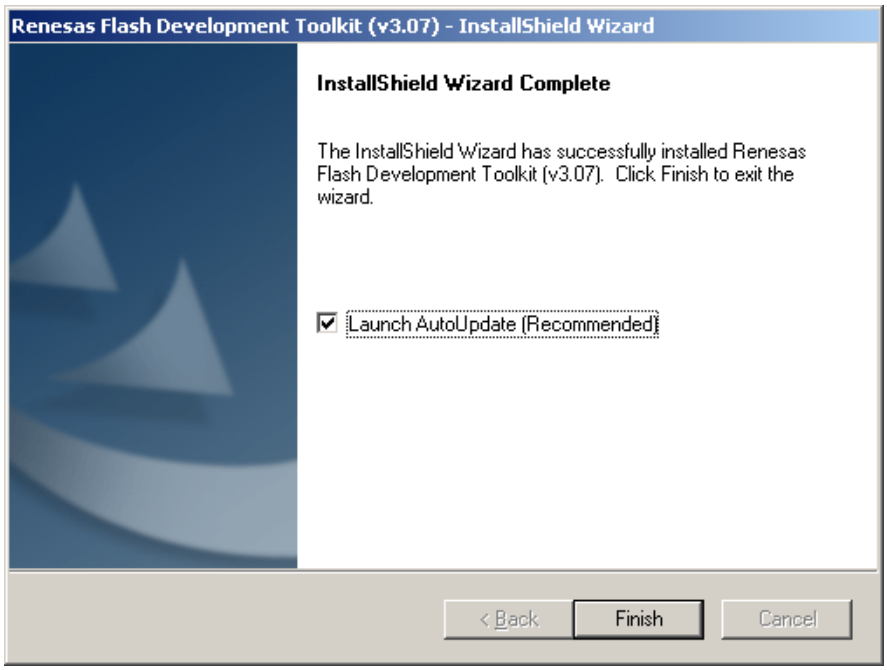


click on **"Install"** button.

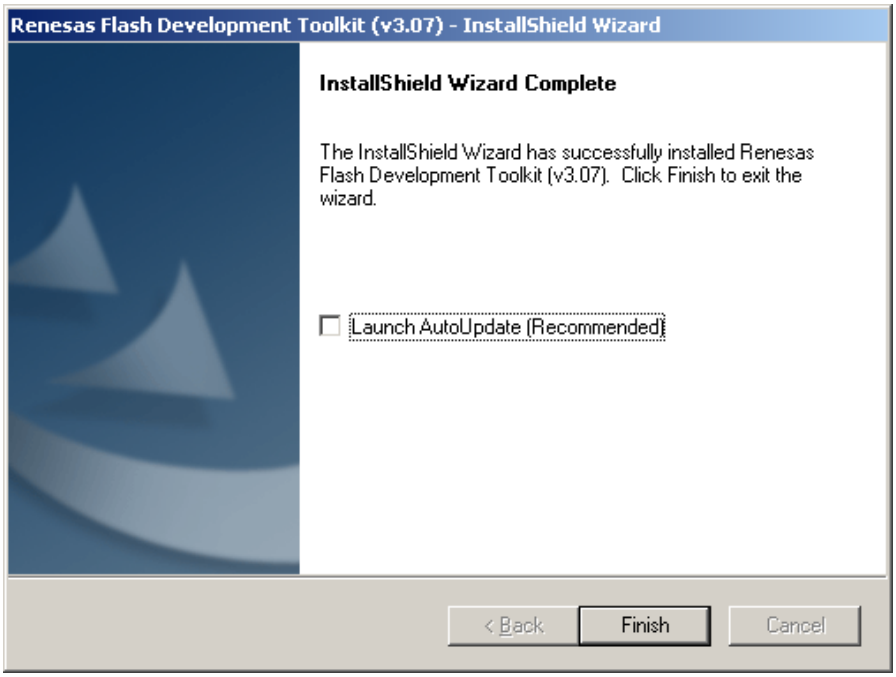
< The first installation phase of the "FDT 3.07" program begins >

<<< Wait … >>>

12. **If** the following window appears:

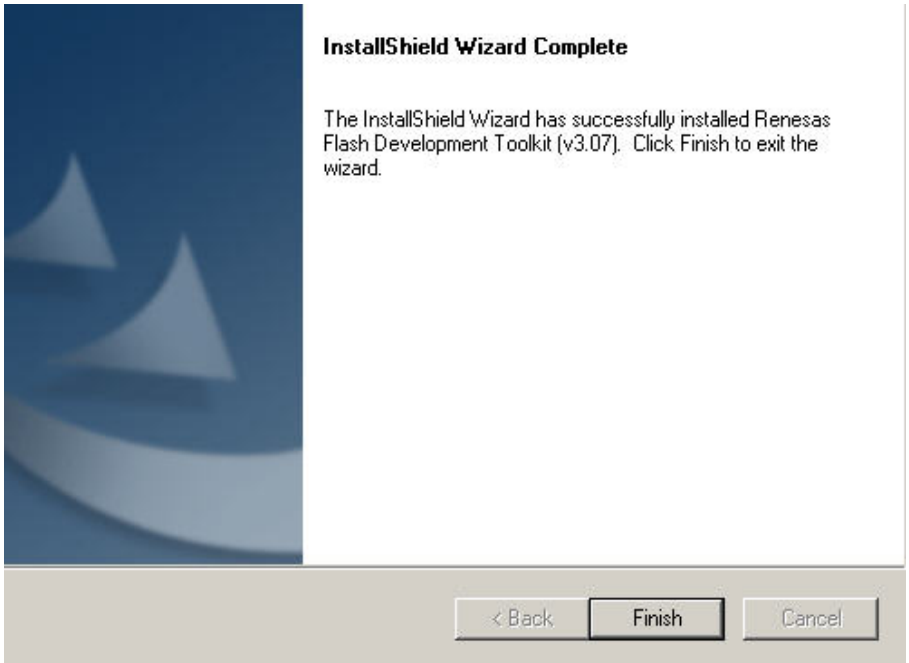


remove the flag into the "Launch AutoUpdate (Recommended)" check box as shown below:



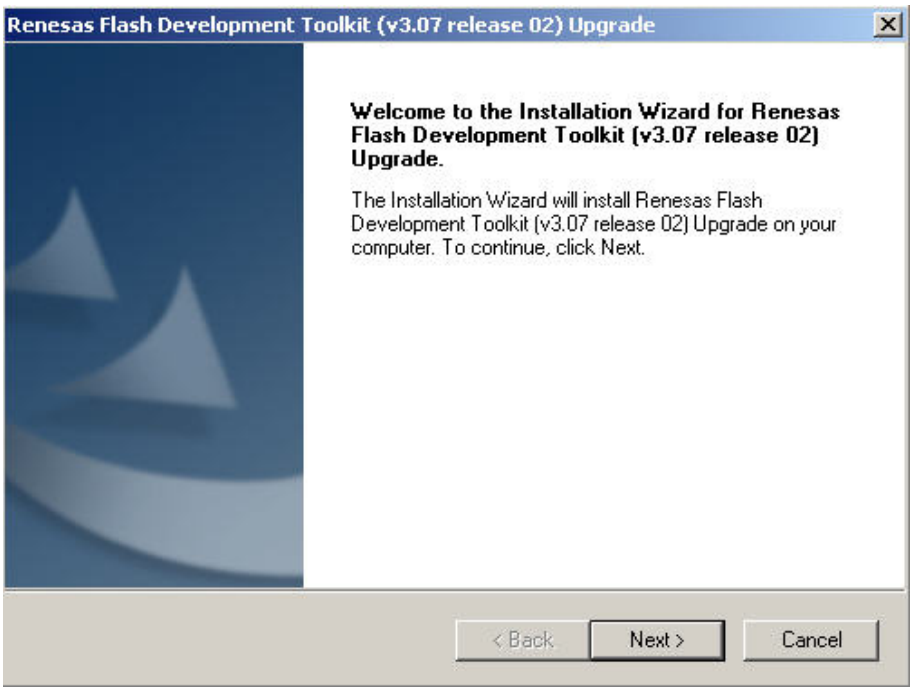
and then click on **"Finish"** button.

Otherwise, on the following window:



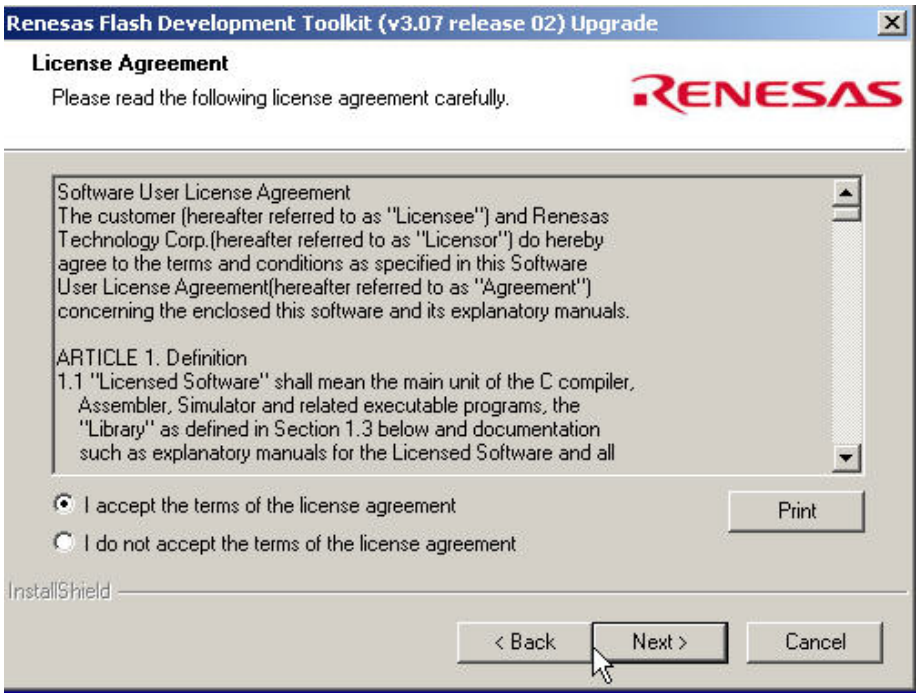
click on **"Finish"** button.

13. Wait until the following window appears:



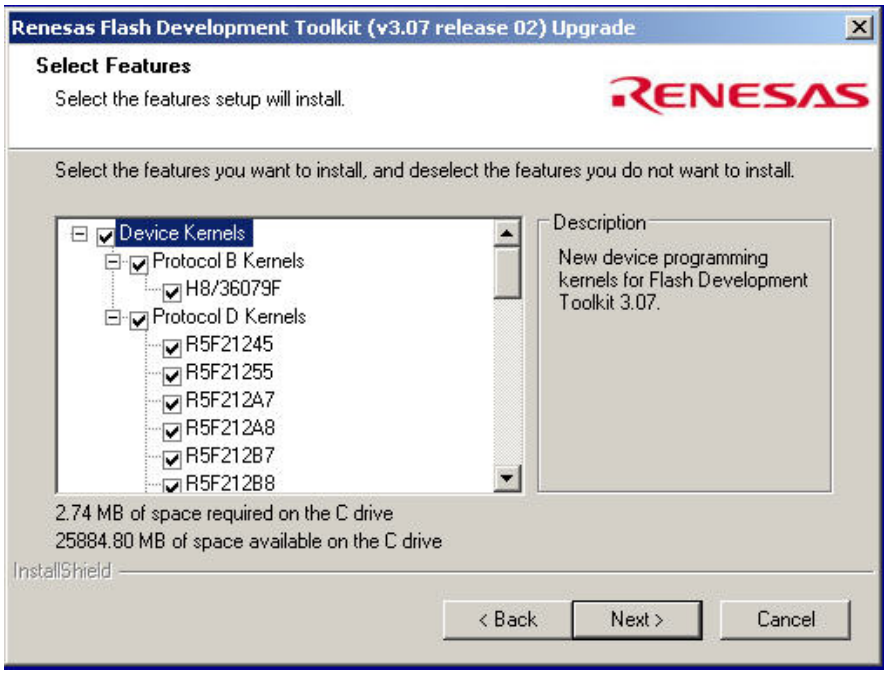
and then click on **"Next"** button.

14. On the following window:



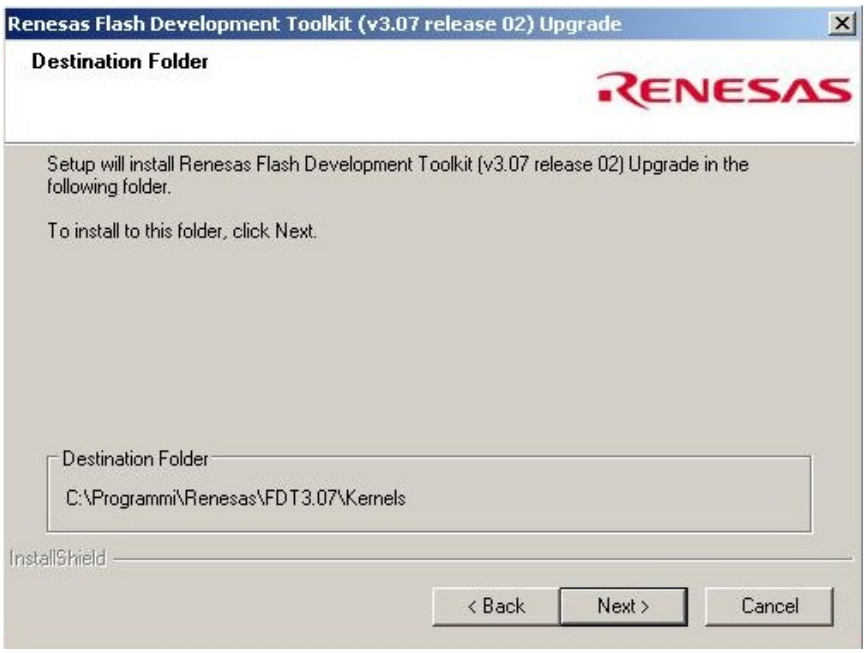
- select the **"I accept the terms of the license agreement"** option;
- click on **"Next"** button.

15. On the following window:



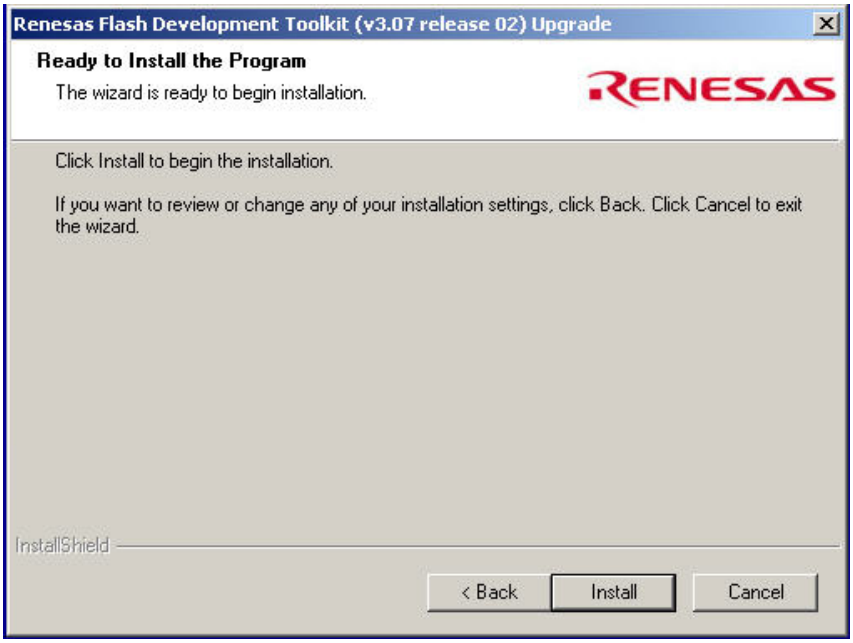
click on **"Next"** button.

16. On the following window:



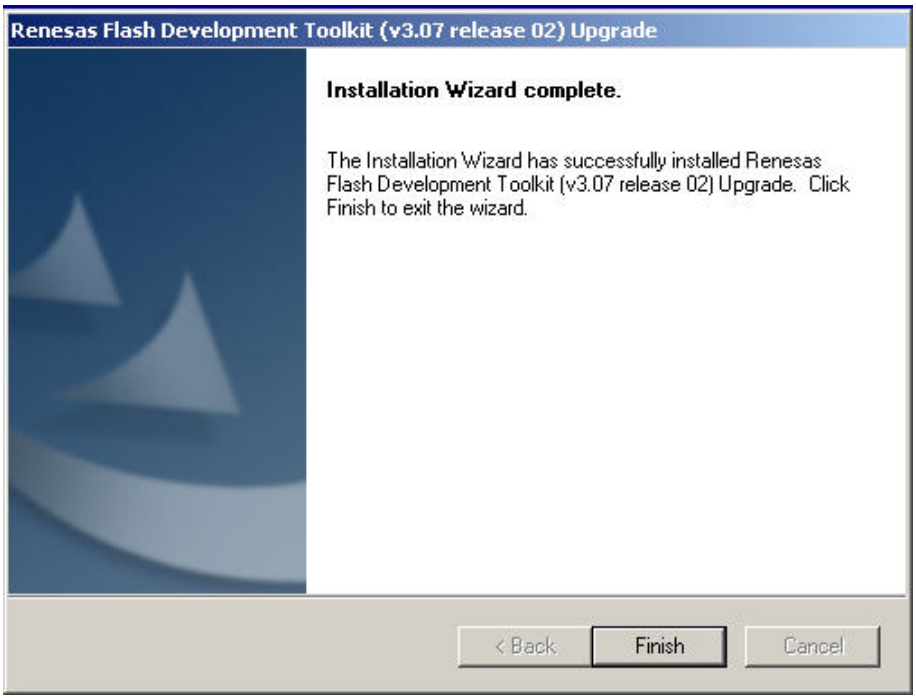
click on **"Next"** button.

17. On the following window:



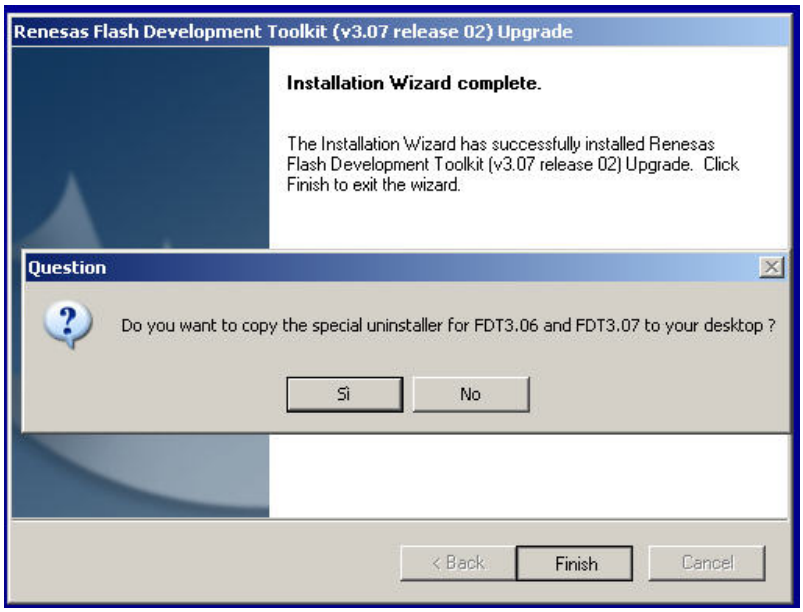
click on **"Install"** button.

18. Wait until the following window appears:



and then click on **"Finish"** button.

19. On the following "Question" message box ("Do you want to copy the special uninstaller for FDT3.06 and FDT3.07 to your desktop ?"):



click on **"NO"** button.

20. Wait for the next message box.

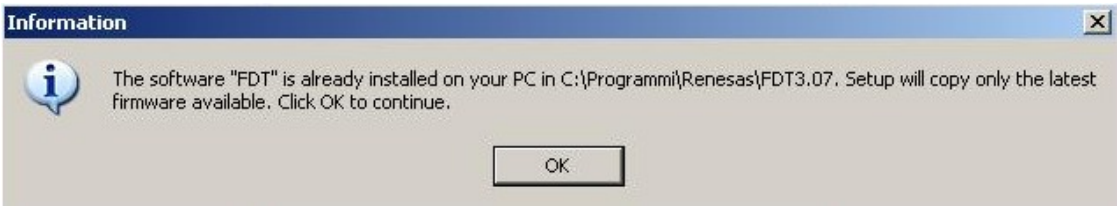
21. On the following message box:

click on **"OK"** button.

< *The* Firmware DownLoad Manager *installation has been completed* >

Note: if it has already been installed a version of the *Firmware DownLoad Manager* on the P.C. in use, then the "Firmware DownLoad Manager installation procedure" is composed of the above mentioned step 1 and 2 and – successively – of the following step:

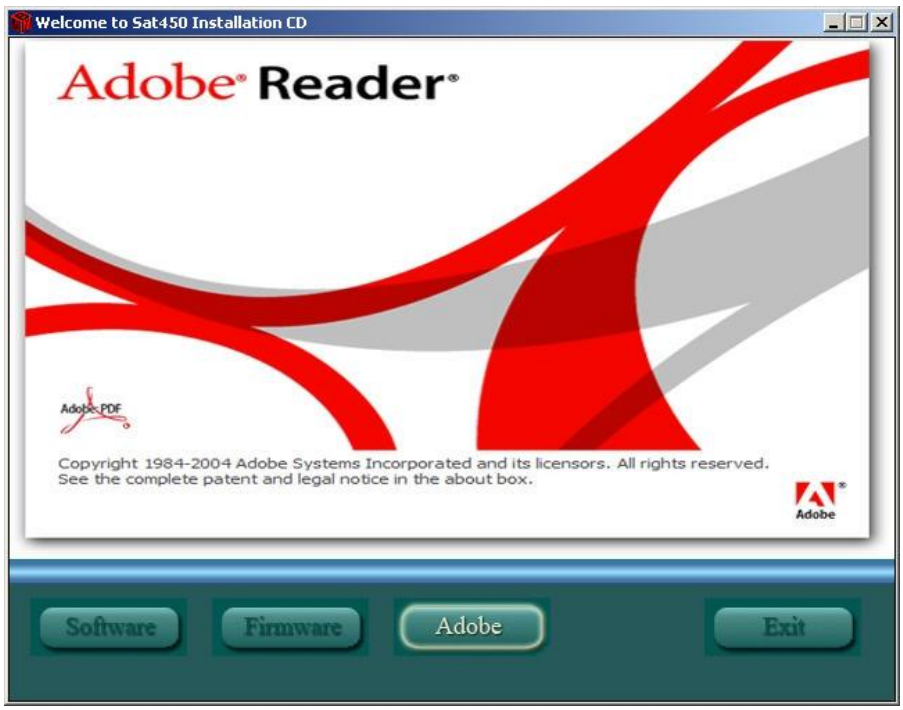
⇒ On the following message box:



click on **"OK"** button to return to the above mentioned step 21.

Adobe Reader installation procedure

1. Click on "**Adobe**" button in the "Welcome to Sat450 Installation CD" window:



2. Carry out the steps requested to the following Adobe forms (for more information contact the web site www.adobe.com).

< Firmware Upgrading Procedure >

1. INITIAL CONDITIONS

This document explains how to upgrade the firmware in the SAT 450 Equipment.

The microcontroller that handles all the low-level functions of the SAT 450 Equipment (H8SX/1663) is supplied by RENESAS. RENESAS also supplies the Programming Software for downloading the firmware. The firmware upgrading procedure is a generic tool; it means that allows the firmware to be loaded on different micro-controllers.

There are two different cases to be considered:

- First Upgrading on a specific computer.
  In this case it is important that specific guidelines pertaining to the kind of microcontroller are followed.

- The specific computer has been already used for the upgrading.
  Further downloading of the Firmware can be performed automatically since the necessary information has already been acquired and recorded in the specific computer with the first upgrading procedure.

1. From the desktop of Windows, select "My Computer → C".
2. Check the presence of the following folder:
   - "**RENESAS**" Folder
3. In the "**RENESAS**" Folder, check the presence of the "**FDT3.07**" Folder.
4. From the desktop of Windows, select "My Computer → C → Sat450".
5. In the "**Sat450**" Folder, check the presence of the following folder:
   - "**FW**" Folder
6. In the "**FW**" Folder, check the presence of the following files:
   - "**L3001663 rev .mot**"
   - **"FDM.exe"**

In case of one of the above mentioned items ("**Renesas**", "**FDT3.07**", "**Sat450**", "**FW**" Folders or "**L3001663 rev .mot**", "**FDM.exe**" files) are missing, **<u>it is mandatory</u>** to perform the "Firmware DownLoad Manager installation procedure" before proceeding with the "Firmware Upgrading Procedure".

2. FIRMWARE UPGRADING PROCEDURE

1. Connect the P.C. to the *SAT 450* instrument through the "COMX" port ("X" stands for one of the available COM Port of the PC).

2. Switch on the SAT 450 Equipment.

3. Select **Start** Button → Select **Programs** → Select **Sat 450** → Select **Firmware DownLoad Manager** .

4. The following "Firmware DownLoad Manager" window appears:

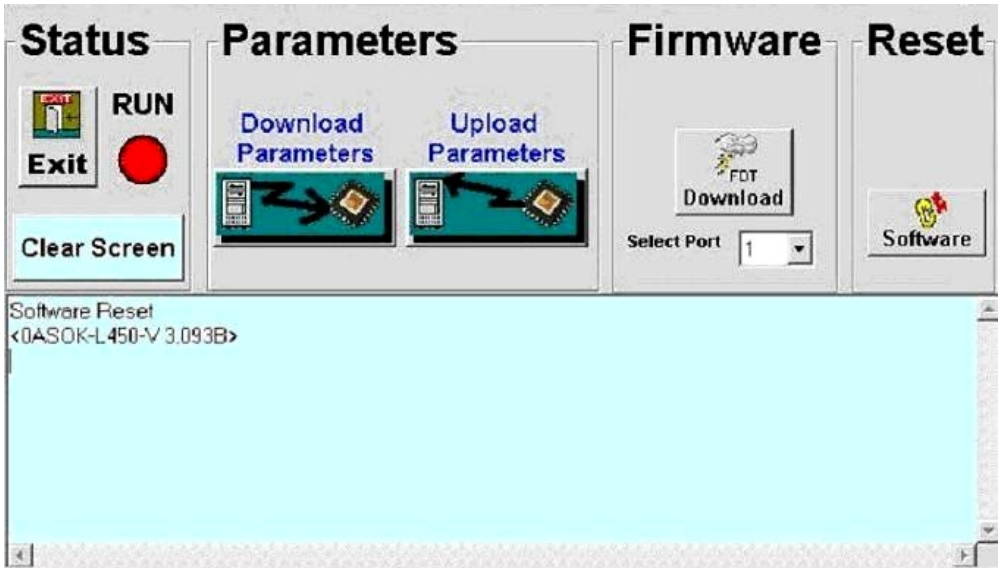


Fig. 1

Note: for the description and explanation of the all functions shown in **Fig. 1** see the Section 3 of the "Firmware Upgrading Procedure".

5. The program automatically proceed to scan available ports and selects that is physically connected to the equipment. Therefore, you wait the acoustic beep from Sat 450 and the version message on the Screen (in the example of **Fig.1** the version message is <0ASOK-L450-V 3.093B>).
   If the version does not appear on the screen, select the port and click on "Software" button in the "Reset" area.
   Also in the case of no response, if you are sure that the selected port is that correct, anyway go to the next step.

6. In the "Parameters" area, select "Upload Parameters" key.

7. Click on the **"FDT Download"** button:
   - if it was the first time the upgrading procedure is performed then automatically step 8 (**Fig. 2**) is shown;
   - else the procedure jumps to step 23 (**Fig. 14**).

8. The following form appears:

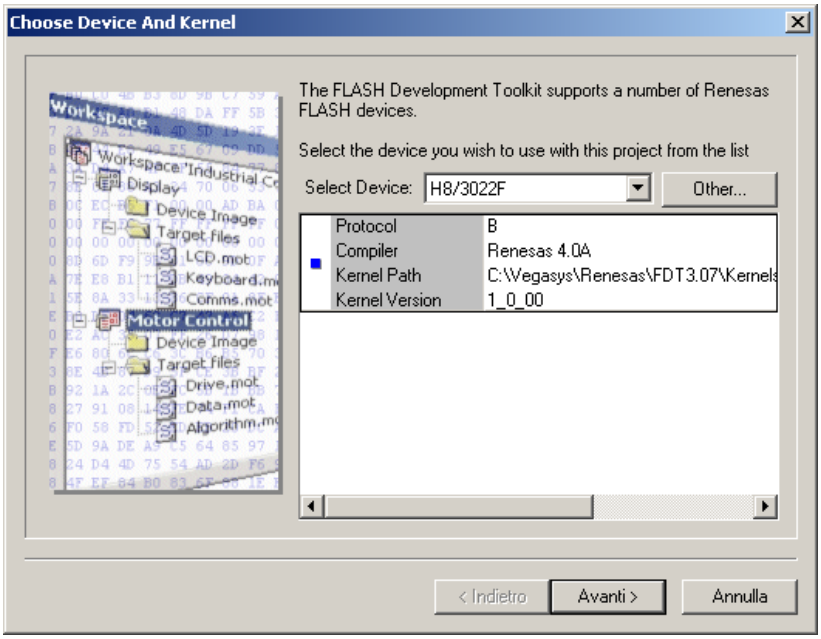


Fig. 2

9. Through the vertical scroll of the "Select Device" field, select the "Generic BOOT Device" option:

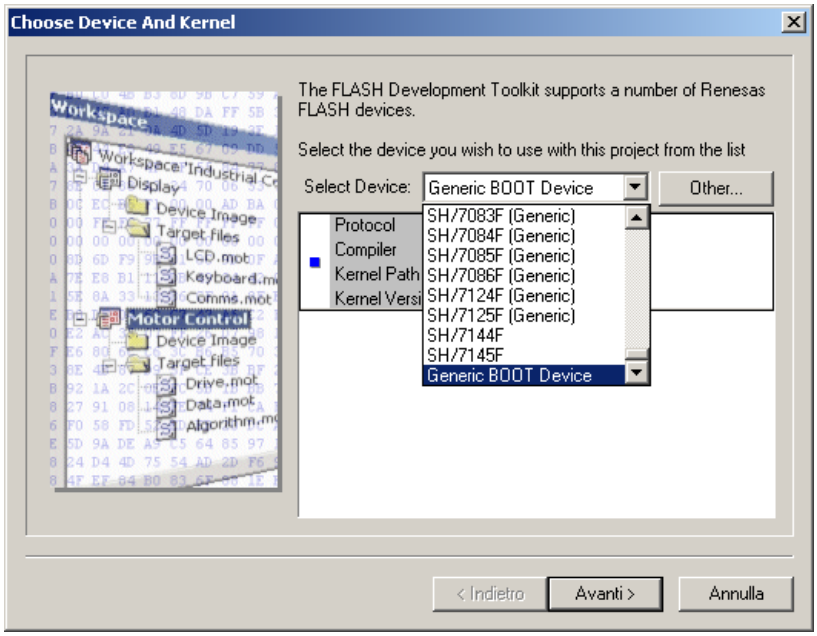


Fig. 3

and click on **"Avanti"** button.

10. The following window appears:

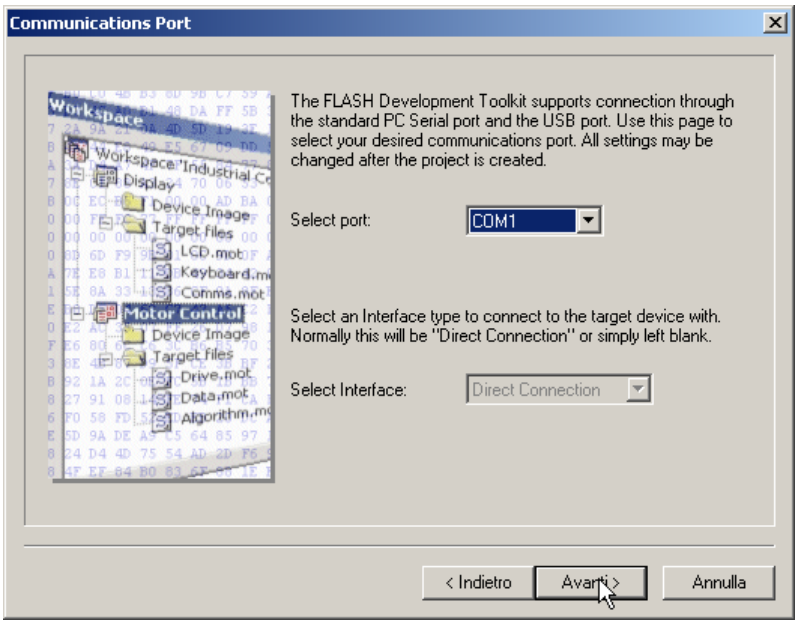


Fig. 4

11. Through the vertical cursor of the "Select port" field, select the port physically used for the connection (PC – *SAT 450* instrument).

Warning: on the above window, "COM1" is just an example; it is mandatory to select the port physically used for the connection between the PC and the *SAT 450* instrument.

12. Click on **"Avanti"** button.

13. The following "FLASH Development Toolkit" dialog box appears:

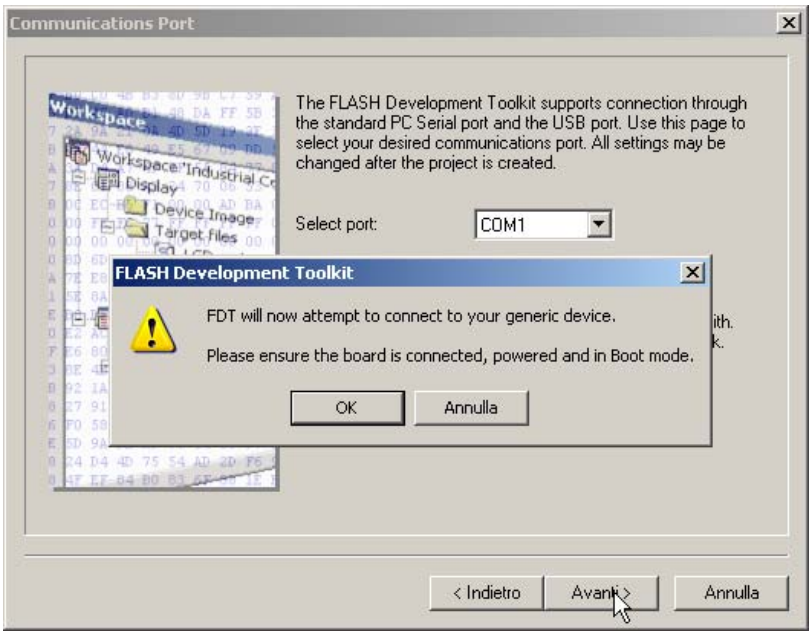


Fig. 5

14. Click on **"OK"** button, then wait.

15. The following "Select Clock Mode" dialog box appears:

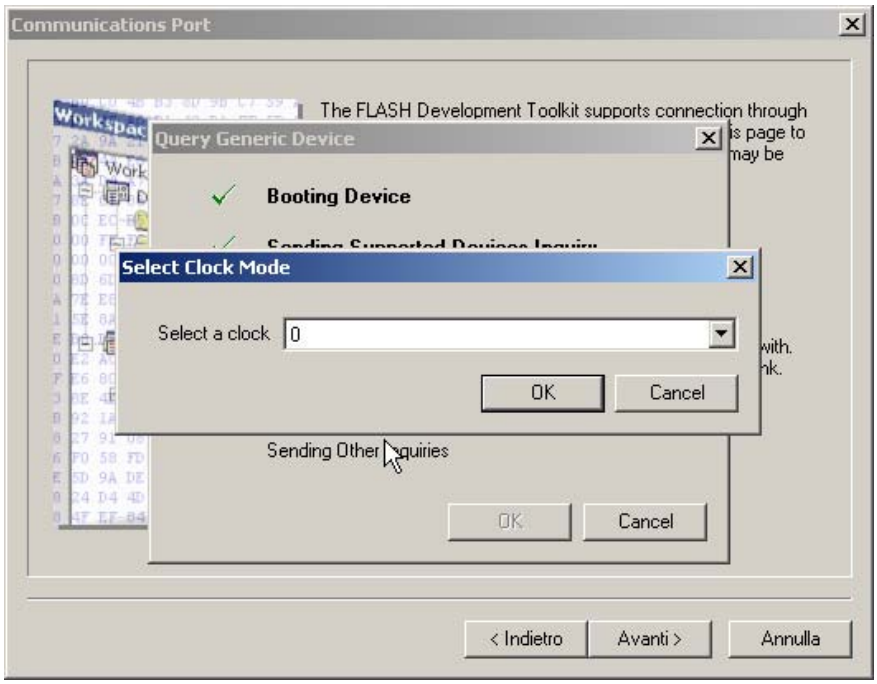


Fig. 6

and click on **"OK"** button.

16. The following window appears:

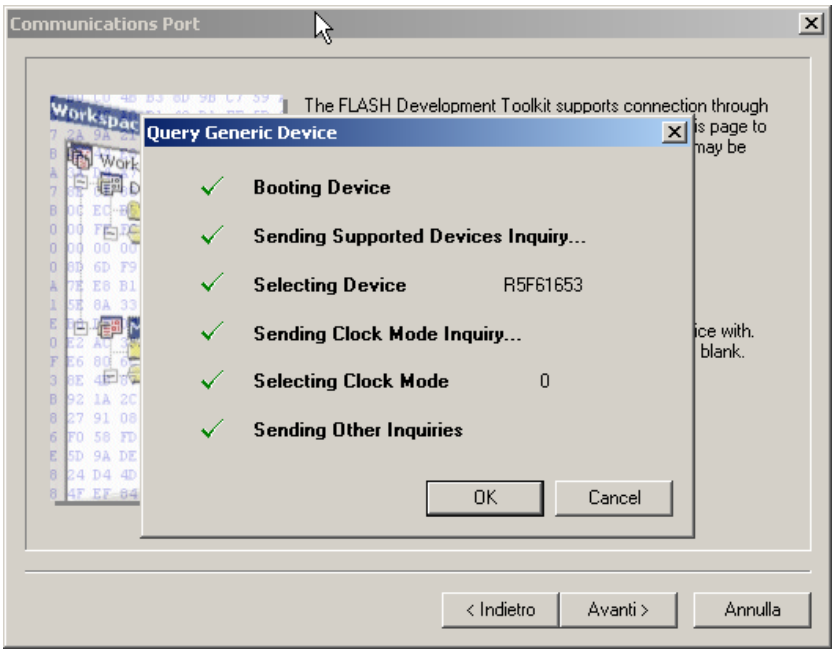


Fig. 7

and click on **"OK"** button.

17. The following window appears:

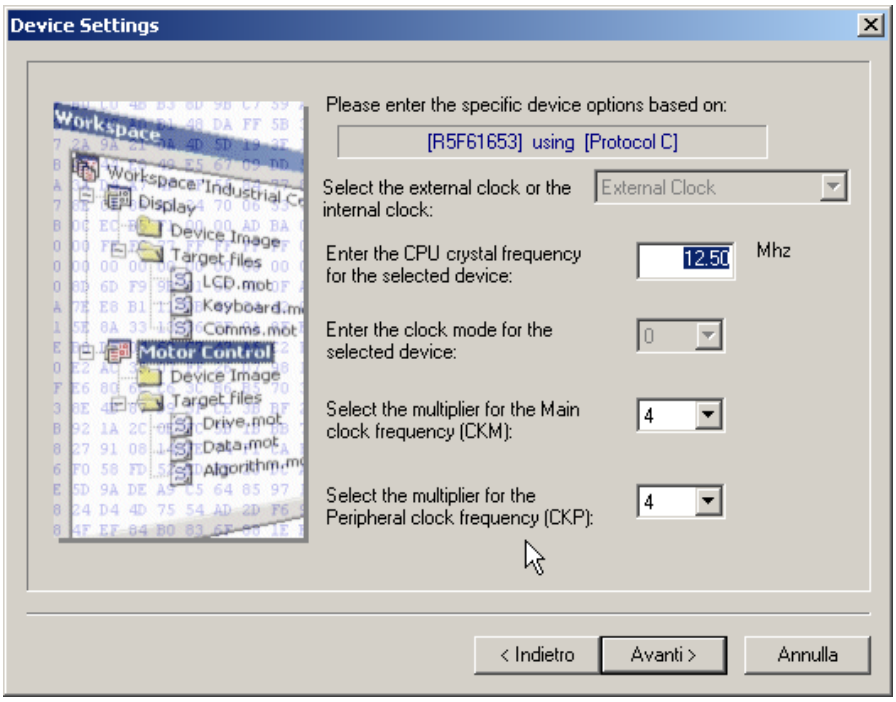


Fig. 8

18. In the above window (shown in **Fig. 8**):

- <u>enter</u> the new values as shown below (**Fig. 9**):

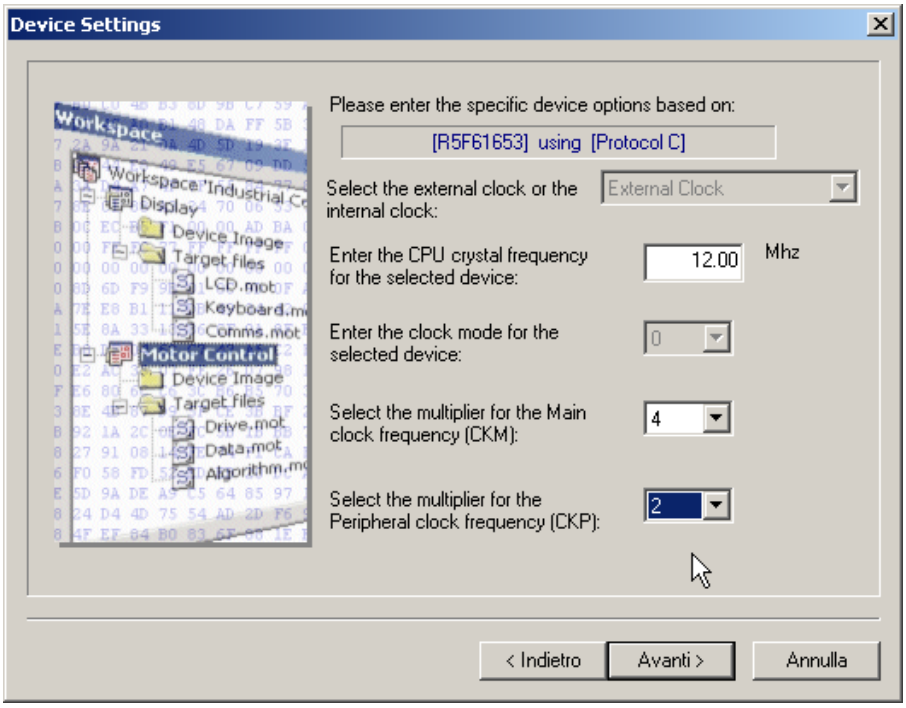


Fig. 9

- <u>click</u> on **"Avanti"** button.

19. The following window appears:

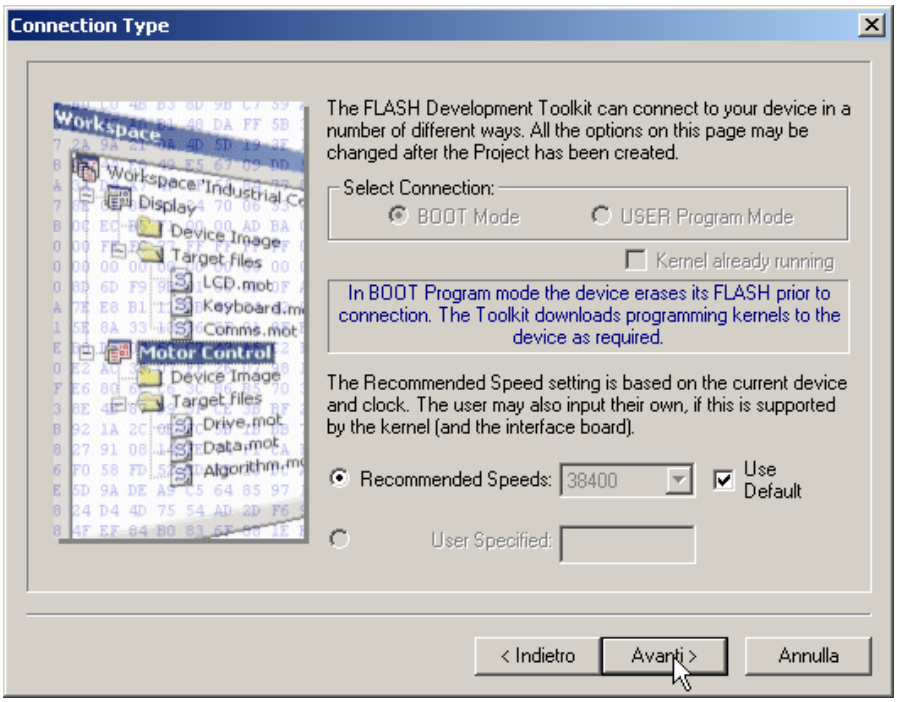


Fig. 10

and <u>click</u> on **"Avanti"** button.

20. The following window appears:

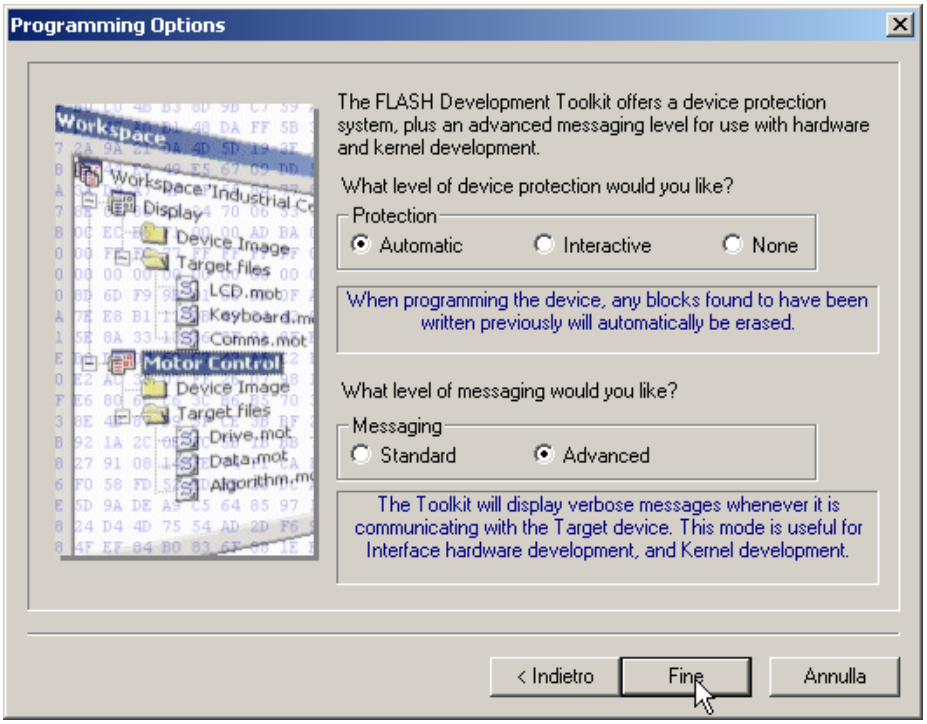


Fig. 11

and <u>click</u> on **"Fine"** button.

21. Wait until the following window appears:

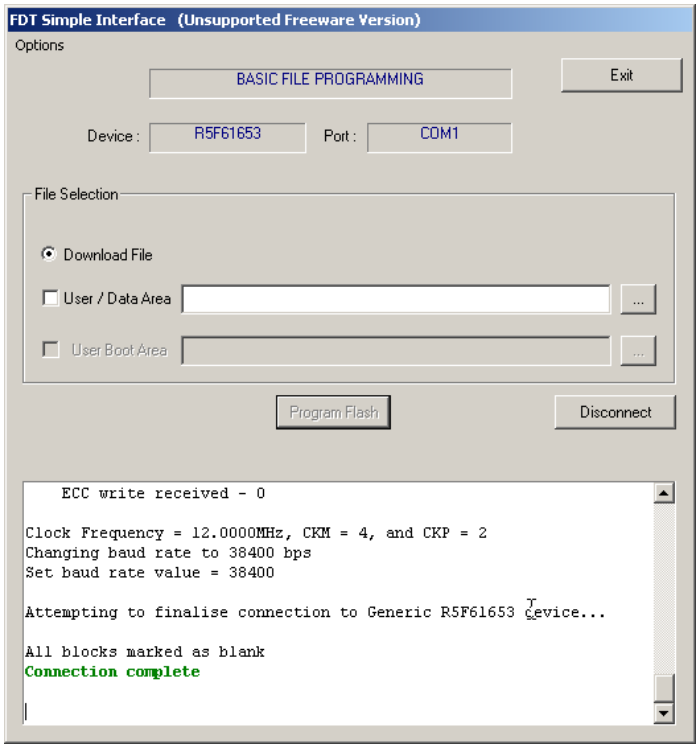


Fig. 12

22. Click on the "User/Data Area" check box (as shown in **Fig. 13**):

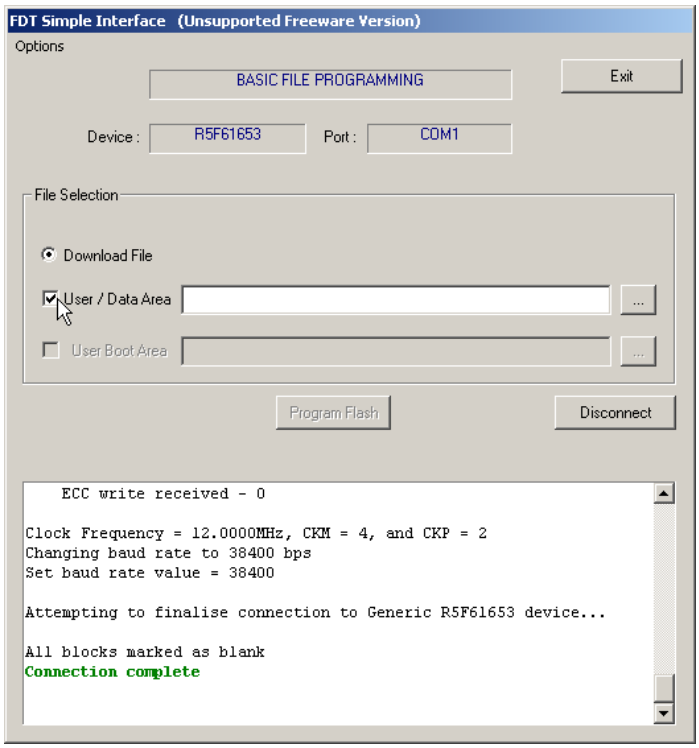


Fig. 13

23. In the "User/Data Area" field text, enter or select the last available firmware file (e.g. C:\Sat450\FW\L3001663 rev .mot) as shown in **Fig. 14**:

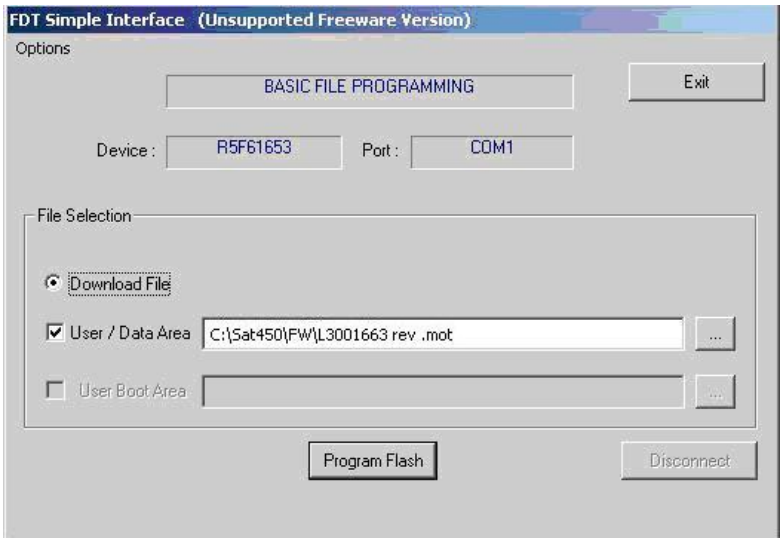


Fig. 14

and click on the **"Program Flash"** button.

24. Wait until the following window appears:

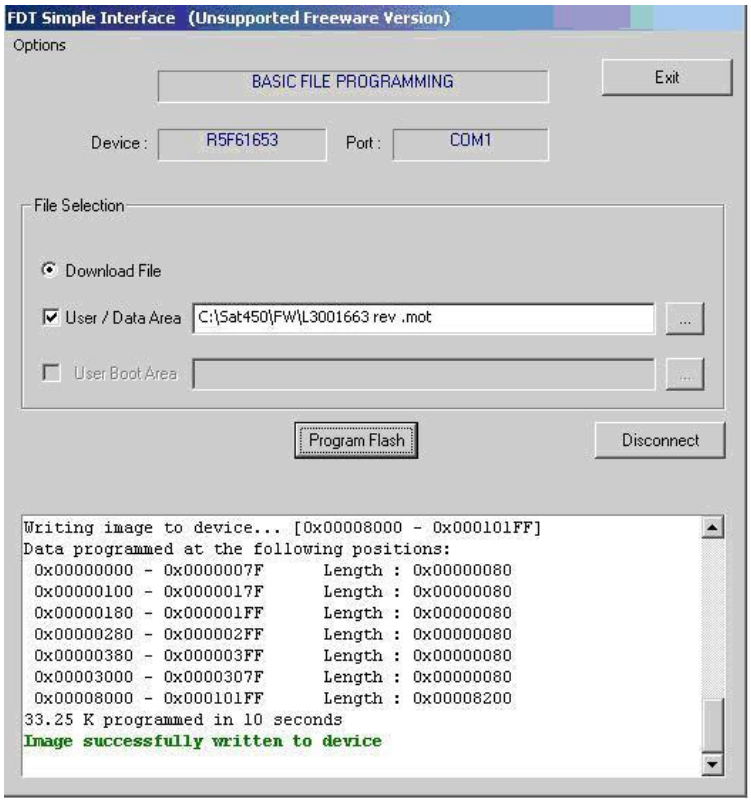


Fig. 15

25. Click on the **"Exit"** button of the "FDT Simple Interface" program.

26. In the “Parameters” area, select “Download Parameters” key. Then, check on the Log monitor the presence of the two following strings: **<0WROK33>** and **<0WFOK27>**.

27. In the “Status” area, click on the **“Clear Screen”** button.

28. In the “Reset” area, click on the **“Software”** button. Make sure that the New Firmware Version is shown on the Log monitor (see **Fig. 16**):

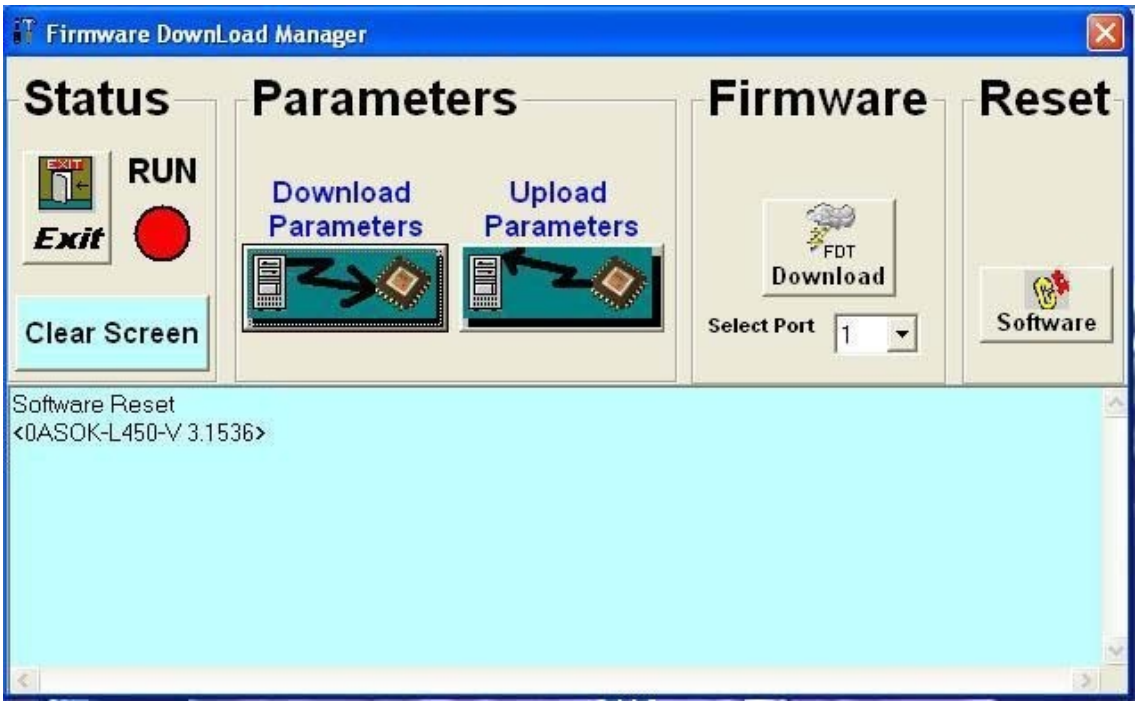


Fig. 16

In the example of the **Fig. 16**, the New Firmware Version is the 3.15 .

29. In the “Status” area, click on **“Exit”** button to exit from the “Firmware DownLoad Manager” program.

3. DESCRIPTION OF ALL FUNCTIONS OF THE PROGRAM

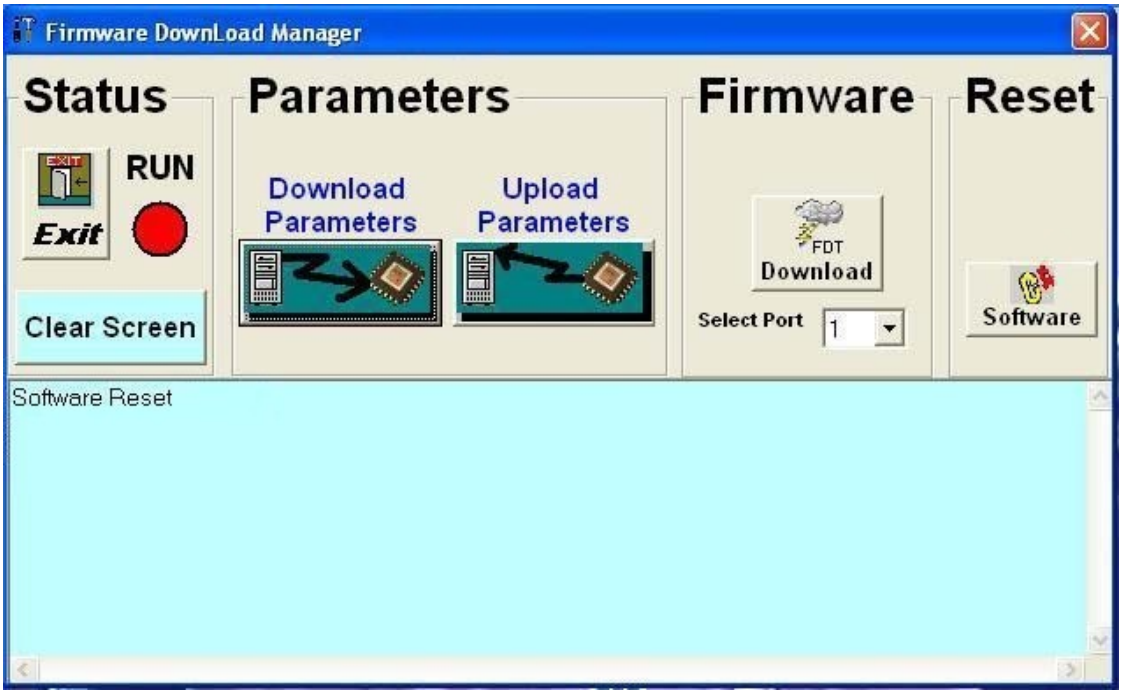


Fig. 17

- **Exit** Button - click on this button to exit from the program.
- **SCREEN** (cyan) - all commands and answers are displayed on the screen.
- **Clear Screen** Button - click on this button to clear the screen.
- **RUN –** a Red Led blinks with 1 second interval.
- **Software** Button - generates a reset.
- **FDT Download** Button - executes the Firmware download (as explained in Section 2).
- **Select Port** Combo - allows to select the serial port for the communication between the *SAT 450* and the Host computer, among those serial ports available on that specific computer that you are using.
- **Upload Parameters** Button - a click on this button generates a Read Parameters Command:
  - the previous data contained in "firmware.par" file (which, if exists, is in the directory C:\SAT450\FW where is present the "Firmware DownLoad Manager" program) are copied to "firmware.bkp";
  - the new read values are stored in the file "firmware.par".
- **Download Parameters** Button - a click on this button generates a Write Parameters Command:
  - the data contained in "firmware.par" are copied in the flash.

CHAPTER 05

- DIAGNOSTIC PROGRAM -

INDEX

5 DIAGNOSTIC PROGRAM **3**

5.1 DIAGNOSTIC FOLDERS **6**

5.2 "ARM" FOLDER **6**
5.2.1 "VERTICAL" COMMAND AREA **7**
5.2.2 "HORIZONTAL" COMMAND AREA **7**
5.2.3 "STATUS COMMAND" AREA 8
5.2.4 "ARM SETTING" COMMAND AREA 8
5.2.5 RESET BUTTON AREA 8
5.2.6 "SENSOR STATUS" AREA 8

5.3 "DILUTER" FOLDER **9**
5.3.1 "OPERATIONS" AREA 9
5.3.2 "SENSOR STATUS" AREA 9
5.3.3 "USER" AREA 10
5.3.4 "STATUS COMMAND" AREA 10
5.3.5 RESET BUTTON AREA 10

5.4 "OPTIC" FOLDER **10**
5.4.1 "LAMP" AREA 11
5.4.2 "SENSOR STATUS" AREA 11
5.4.3 "FILTERS" AREA 11
5.4.4 "DIGITAL CONVERSION" AREA 11
5.4.5 "STATUS COMMAND" AREA 11
5.4.6 RESET BUTTON AREA 11

5.5 "PLATE" FOLDER **12**
5.5.1 "REACTION PLATE" AREA 12
5.5.2 "SAMPLE PLATE" AREA 13
5.5.3 "REAGENT PLATE" AREA 13
5.5.4 ALL MOTORS ON/OFF AREA 13
5.5.5 "STATUS COMMAND" AREA 13

5.6 "TEMPERATURES" FOLDER 14
5.6.1 BUTTONS AREA 14
5.6.1.1 "Temperature Test" form 14
5.6.1.2 "Calibration Temperature Sensor" form 15
5.6.2 TEMPERATURES AREA 15
5.6.3 SERVICE PROBE AREA 15
5.6.4 "STATUS COMMAND" AREA 15

5.7 "WASH" FOLDER 16
5.7.1 "OPERATIONS" AREA 16
5.7.2 "TEST" AREA 17
5.7.3 WASHING CYCLES AREA 17
5.7.4 "STATUS COMMAND" AREA 17

5.8 "MISCELLANEOUS" FOLDER 17
5.8.1 "GENERAL RESET" AREA 18
5.8.2 "CONTINUOUS TEST RUN" AREA 18
5.8.3 "COVER LOCK" AREA 18
5.8.4 "BARCODE" AREA 18
5.8.4.1 "Sample plate barcode offset" form 19
5.8.5 "STATUS COMMAND" AREA 19

5.9 "CONFIGURATION" FOLDER 19
5.9.1 GAP AND BACKLASH DIL. AREA 20
5.9.2 "ARM HEATER" AREA 21
5.9.3 "PLATE HEATER" AREA 21
5.9.4 "REFRIGERATOR" AREA 21
5.9.5 "BARCODE SETTINGS" AREA 22
5.9.6 "EXT. LIQUID SENSORS" AREA 22
5.9.7 "WASTE SENSORS" AREA 22
5.9.8 "COVER ALARMS" AREA 22

5.10 "ISE" FOLDER 23
5.10.1 "SOFTWARE RELEASE" BUTTON 23
5.10.2 "PURGE" BUTTON 23
5.10.3 "MAINTENANCE" BUTTON 24
5.10.4 "ST.BY CYCLE" BUTTON 24
5.10.5 "BUBBLE DETECTOR READ" BUTTON 24
5.10.6 "mV TRANSMISSION" BUTTON 24
5.10.7 "CLEANING CYCLE" BUTTON 25
5.10.8 "CLEANING POSITION" PULL DOWN MENU 25

5 DIAGNOSTIC PROGRAM

The *Diagnostic* program enables the operator to perform a complete check of each of the modules of the *SAT 450* instrument.

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" button located on the lower right side of the screen of the *System Monitor* (**Fig. 1**).

The *SAT 450* instrument must be in the stand-by state to access this area.

Fig. 1 – System Monitor

Once the *Diagnostic* program starts, the following folder appears (**Fig. 2**):

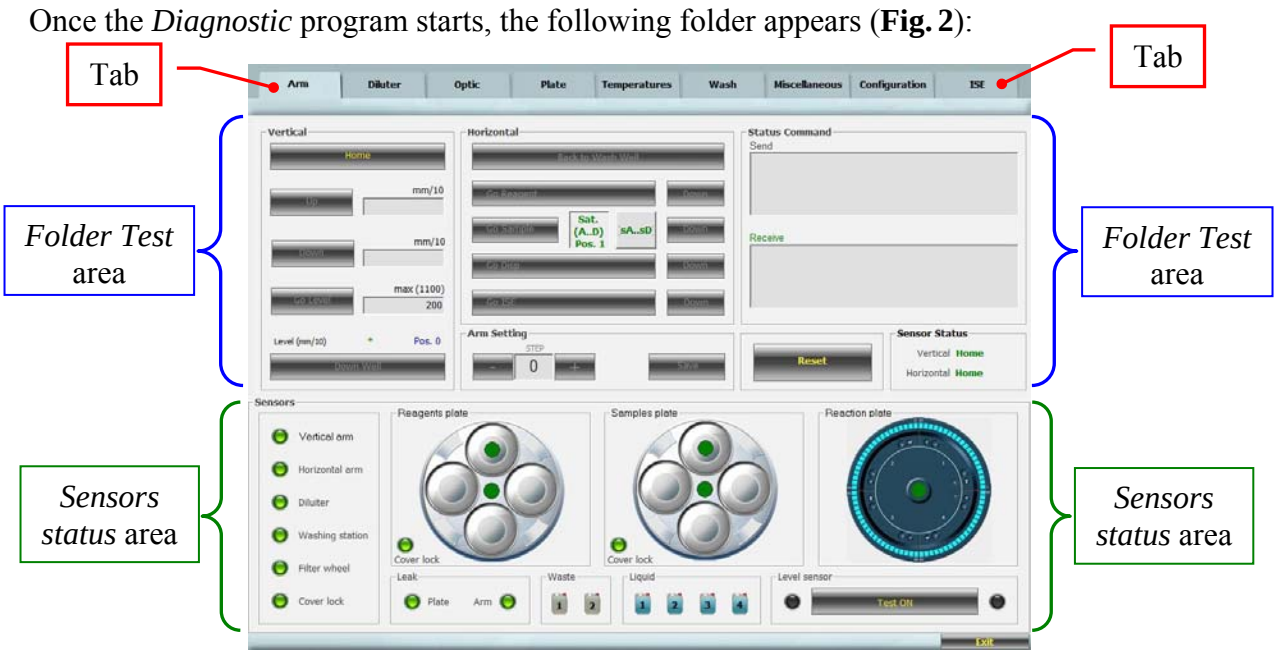


Fig. 2 – Diagnostic program

The *Diagnostic* program is subdivided into two distinct areas: *Folder Test* and *Sensors status*. This two areas are present on every Diagnostic window and enable the operator to verify multiple functions as specified below:

Folder Test: checks the functionality of the various sub-systems. The individual functions are illustrated later on;

Sensors status: visualizes the status of the home sensors that control the Sampling Arm, the Diluter, the Washing Station, the Filters Wheel, the Reactions Plate, the Samples Plate, the Reagents Plate and the two Cover Locks, as well as the Liquid Reservoire Alarms (Waste and Liquid) and the Level Sensor test (**Fig. 3**).

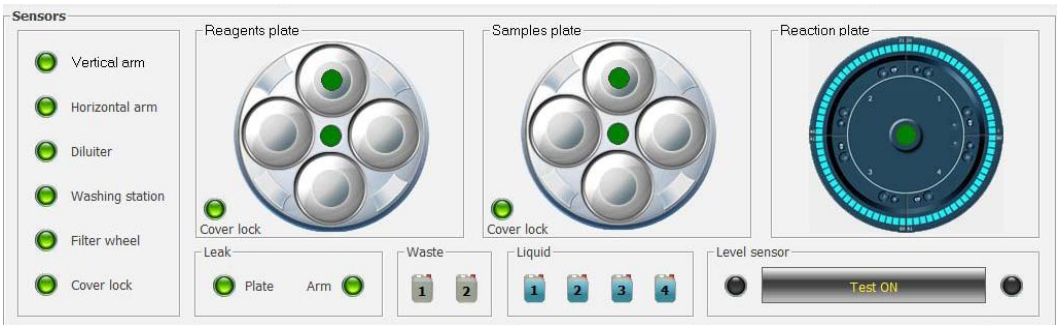


Fig. 3 – Sensors status area in the Diagnostic program

The Home Sensors:

- **Vertical Arm Home Sensor**
- **Horizontal Arm Home Sensor**
- **Diluter Home Sensor**
- **Washing Station Home Sensor**
- **Filters Wheel Home Sensor**
- **Reagents Plate Home Sensor**
- **Satellites Mov. Reagents Plate Home Sensor**
- **Samples Plate Home Sensor**
- **Satellites Mov. Samples Plate Home Sensor**
- **Reactions Plate Home Sensor**

turn green when the specific device is in the home position.

The **Cover Lock** Home Sensor is green when the Instrument Cover is closed.

The Home Sensors:

- **Reagents Plate Cover Lock**
- **Samples Plate Cover Lock**

turn green when the specific cover is positioned on its plate.

The following six fields signal the alarms for the two waste tanks and the four liquid bottles:

- **Waste1 (*Liquid Reservoire Alarm*)**
- **Waste2 (*Liquid Reservoire Alarm*)**

turn blue when the correspondent waste tank is full;

- **Liquid 1 (*Liquid Reservoire Alarm*)**
- **Liquid 2 (*Liquid Reservoire Alarm*)**
- **Liquid 3 (*Liquid Reservoire Alarm*)**
- **Liquid 4 (*Liquid Reservoire Alarm*)**

disappear the blue if the liquid quantity is below the predetermined minimum level (the bottle is almost empty).

Button **Test ON**: if pushed, the sensor on its right side turn red.
Moreover, the sensor on its left side becomes temporarily green when the liquid is detected with the Sampling Probe (*Level Sensor test*).

The "Exit**"** button (**Fig. 4**) allows to exit from the *Diagnostic* program.

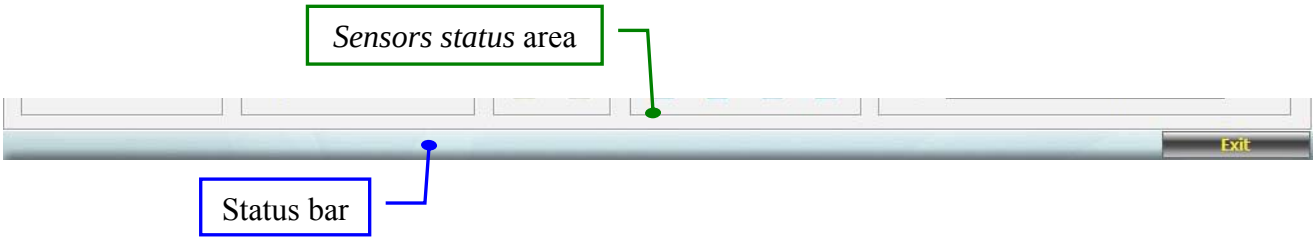


Fig. 4 – "Exit" button in the Diagnostic program

5.1 DIAGNOSTIC FOLDERS

The Diagnostic program is subdivided into 9 folders:

- **Arm**: allows to perform and check the adjustments of the Sampling Arm;
- **Diluter**: checks the accurate functioning of the Diluter;
- **Optic**: checks the accurate functioning of the Photometer;
- **Plate**: checks the accurate functioning of the Reactions Plate, Samples Plate and Reagents Plate;
- **Temperatures**: checks the temperature of the Pre-Heater and Reactions Plate;
- **Wash**: checks the accurate functioning of the Washing Station;
- **Miscellaneous**: checks the accurate functioning of the Barcode Readers and allows to perform the General Reset of the instrument;
- **Configuration**: allows to adjust specific parameters of the instrument (*the access in this folder is restricted by password*);
- **ISE**: allows to perform necessary operations for the ISE Module.

5.2 "ARM" FOLDER

Fig. 5 – "Arm" folder

The wrong use of the functions described in this folder can damage the Sampling Probe.

The "Arm" folder is subdivided into six areas:

- **VERTICAL**
- **HORIZONTAL**
- **STATUS COMMAND**
- **ARM SETTING**
- ***RESET BUTTON***
- **SENSOR STATUS**

5.2.1 "VERTICAL" COMMAND AREA

(*5 commands*)

Home: brings the Sampling Arm vertically to a home position.

Down Well: brings the Arm's axis "z" to the height of the Washing Well.

Up: raises the Sampling 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 Sampling Arm is positioned on a sample, a reagent, a standard or a cuvette.

Down: lowers the Sampling Arm tenths of a millimeter as pre-determined by the square found immediately on the right; the box becomes active when the Sampling Arm is positioned on a sample, a reagent, a standard or a cuvette.

Go Level: brings the Sampling 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*).

5.2.2 "HORIZONTAL" COMMAND AREA

(*5 commands*)

Back to Wash Well: brings the Sampling Arm back to the home position.

Go Reagent: brings the Sampling Arm to the reagent position.

Go Sample: brings the Sampling Arm to the sample position; moreover, it's possible choose between two different positions: the first [Sat (A..D) Pos.1] allows to bring the Sampling Probe in correspondence of the position #1 of one of four Satellite Racks, instead the second [(sA..sD)] allows to bring the Sampling Probe in correspondence of the Peripheral Racks.

Go Disp.: brings the Sampling Arm to the dispense position.

Go ISE: brings the Sampling Arm to the Sample Cup of the ISE Module.

The "Down" button allows to the Sampling Probe go down at the right height.

5.2.3 "STATUS COMMAND" AREA

Send: visualizes the commands sent from the program to the instrument's hardware.

Receive: visualizes the answers of the instrument's hardware to the commands sent by the program.

5.2.4 "ARM SETTING" COMMAND AREA

(*4 commands*)

Step: visualizes the number of steps.

+ : performs the counter-clockwise rotation of the Sampling Arm (to adjust the position).

- : performs the clockwise rotation of the Sampling Arm (to adjust the position).

Save: saves the adjustment data.

In this area the boxes can be activated when the Sampling Arm is positioned on a sample, a reagent, a standard, a control or a reaction cuvette.

5.2.5 RESET BUTTON AREA

(*1 command*)

Reset: completely resets the Sampling Arm.

5.2.6 "SENSOR STATUS" AREA

Sensor Status: indicates the home sensors status relative to the Sampling Arm's vertical axis (*Vertical*) and the Sampling Arm's latitudinal motion (*Horizontal*).

5.3 "DILUTER" FOLDER

Fig. 6 – "Diluter" folder

The "Diluter" folder is subdivided into five areas:

- **OPERATIONS**
- **SENSOR STATUS**
- **USER**
- **STATUS COMMAND**
- ***RESET BUTTON***

5.3.1 "OPERATIONS" AREA

(*2 commands*)

Asp: aspirates the micro-litres as predetermined in the "µl." box (may be set manually through + and – or by using the cursor located immediately above).

Disp.: dispenses the micro-litres as predetermined in the "µl." box (may be set manually through + and – or by using the cursor located immediately above).

5.3.2 "SENSOR STATUS" AREA

In the Sensor Status area the Diluter home sensor status is indicated.

5.3.3 "USER" AREA

(*1 command*)

Probe Wash Test: activates/deactivates the Probe Wash Test. The number of the cycles for this test can be chosen with the field "Cycles #".

5.3.4 "STATUS COMMAND" AREA

Send: visualizes the commands sent by the program to the instrument's hardware.
Receive: visualizes the instrument hardware's response to the commands sent by the program.

5.3.5 RESET BUTTON AREA

(*1 command*)

Reset: brings the Diluter to the home position.

5.4 "OPTIC" FOLDER

Fig. 7 - "Optic" folder

The "Optic" folder is subdivided into six areas:

- **LAMP**
- **SENSOR STATUS**
- **FILTERS**
- **DIGITAL CONVERSION**
- **STATUS COMMAND**
- ***RESET BUTTON***

5.4.1 "LAMP" AREA

(*2 commands*)

ON: turns on the Photometer Halogen Lamp.

OFF: turns off the Photometer Halogen Lamp.

5.4.2 "SENSOR STATUS" AREA

This area indicates the status of the Filters Wheel home sensor.

5.4.3 "FILTERS" AREA

(*10 commands*)

Dark: positions the Filters Wheel in dark position;
340 nm: positions the int. filter n° 1 (*340 nm*) in front of the reading sensor;
380 nm: positions the int. filter n° 2 (*380 nm*) in front of the reading sensor;
405 nm: positions the int. filter n° 3 (*405 nm*) in front of the reading sensor;
492 nm: positions the int. filter n° 4 (*492 nm*) in front of the reading sensor;
510 nm: positions the int. filter n° 5 (*510 nm*) in front of the reading sensor;
546 nm: positions the int. filter n° 6 (*546 nm*) in front of the reading sensor;
577 nm: positions the int. filter n° 7 (*577 nm*) in front of the reading sensor;
620 nm: positions the int. filter n° 8 (*620 nm*) in front of the reading sensor;
690 nm: positions the int. filter n° 9 (*690 nm*) in front of the reading sensor.

5.4.4 "DIGITAL CONVERSION" AREA

(*2 commands*)

START/STOP Sample Channel Conversion: performs an analogical/digital conversion of the Sample Channel (*counts*).

START/STOP Reference Channel Conversion: performs an analogical/digital conversion of the Reference Channel (*counts*).

Moreover, a Output Box is present that shows the selected interferential filter.

5.4.5 "STATUS COMMAND" AREA

Send: visualizes the commands sent by the program to the instrument's hardware.

Receive: visualizes the instrument hardware's response to the commands sent by the program.

5.4.6 RESET BUTTON AREA

(*1 command*)

Reset: brings the Filters Wheel of the Photometer to the home position.

5.5 "PLATE" FOLDER

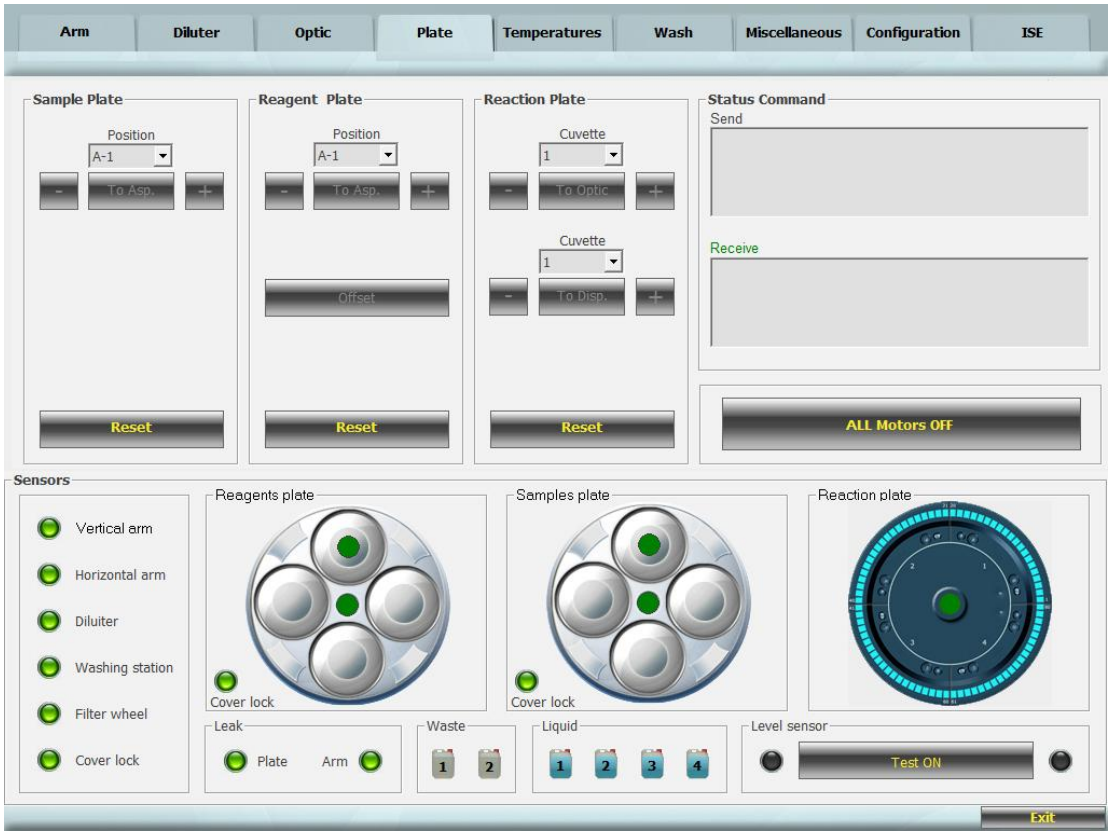


Fig. 8 – "Plate" folder

The "Plate" folder is subdivided into five areas:

- **REACTION PLATE**
- **SAMPLE PLATE**
- **REAGENT PLATE**
- ***ALL MOTORS ON/OFF***
- **STATUS COMMAND**

5.5.1 "REACTION PLATE" AREA

(*3 commands*)

To Optic: automatically positions the reaction cuvette, selected on the Pull Down Menu above, (*) in front of the Photometer.

To Disp.: automatically positions the reaction cuvette, selected on the Pull Down Menu above, (*) under the dispensing position.

Reset: performs the reset of the Reactions Plate by positioning the reaction cuvette #1 in the reading position (in front of the Photometer).

(*) { **+ :** automatically positions the next reaction cuvette;
- : automatically positions the previous reaction cuvette. }

5.5.2 "SAMPLE PLATE" AREA

(*2 commands*)

To Asp.: automatically brings the sample cup, selected on the Pull Down Menu above, under the aspiration position.

→ **+ / - :** automatically positions the next / previous position.

Reset: performs the reset of the Samples Plate by positioning the position #(A-1) (position #1 of the Satellite Rack A) under the aspiration position.

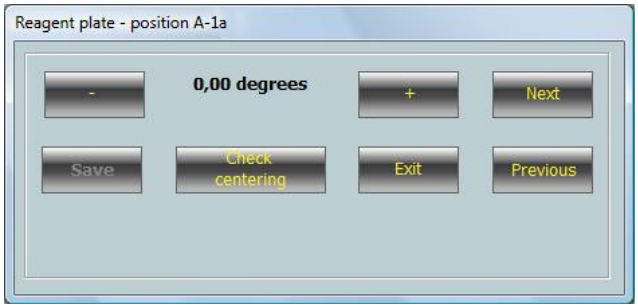
5.5.3 "REAGENT PLATE" AREA

(*3 commands*)

To Asp.: automatically brings the reagent bottle, selected on the Pull Down Menu above, under the aspiration position.

→ **+ / - :** automatically positions the next / previous position.

Offset: allows to get in the following form



to perform a more accurate centering of the A-1a and A-1b positions of the four Satellite Racks A, B, C, D of the Reagents Plate (for a total of 8 positions).

(*7 buttons*)

+ / - : increase / decrease the angle of rotation - visualized between them - of the Sampling Arm (to adjust the centering).

Next / Previous: automatically positions the next / previous position of the 8 above-mentioned positions.

Check centering: brings the Sampling Arm to the right height for a correct centering.

Save: saves the adjustment data.

Exit: allows to exit from the form.

Reset: performs the reset of the Reagents Plate by positioning the position #(A-1) (position #1 of the Satellite Rack A) under the aspiration position.

5.5.4 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, Reactions Plate, Reagents Plate, Samples Plate, Washing Station, Photometer Filters Wheel).

5.5.5 "STATUS COMMAND" AREA

Send: visualizes the commands sent by the program to the instrument's hardware.

Receive: visualizes the instrument hardware's response to the commands sent by the program.

5.6 "TEMPERATURES" FOLDER

Fig. 9 – "Temperatures" folder

The "Temperatures" folder is subdivided into four areas:

- ***BUTTONS***
- ***TEMPERATURES***
- ***SERVICE PROBE***
- **STATUS COMMAND**

5.6.1 BUTTONS AREA

(*2 commands*)

Temp. Test Run: allows to get in the "Temperature Test" form (**Fig. 10**) and performs the Temperature Test (*see Section 5.6.1.1*).

Calib. Sensor: allows to perform (*see Section 5.6.1.2*) the Calibration Procedure of the Service Probe included in the kit having P/N: 55-01204-00 and described in the "Calibration Temperature Sensor" form (**Fig. 11**).

5.6.1.1 "Temperature Test" form

(*4 commands*)

Move reaction plate: automatically positions the Reaction Cuvette, selected on the "Cuvette" Pull Down Menu, under the dispensing position.

Start: allows to start the Temperature Test.

Wash: allows to empty the five reaction cuvettes used in the Temperature Test.

Exit: allows to exit from the "Temperature Test" form.

Cuvette: allows to select the Reaction Cuvette #10, #30, #50 and #70.

 # Cycles = 5: number of reaction cuvettes used in the Temperature Test.

Cuvette Sector: allows to select the cuvette sector for the Temperature Test.

Reagent=A-1: indicates the position **(**position #1 of the Satellite Rack A of the Reagents Plate) where take place the aspiration of the Sampling Arm.

Sample=A-1: indicates the position **(**position #1 of the Satellite Rack A of the Samples Plate) where take place the aspiration of the Sampling Arm.

Service Probe: text box that shows the temperature reading (°C) with the Service Probe.

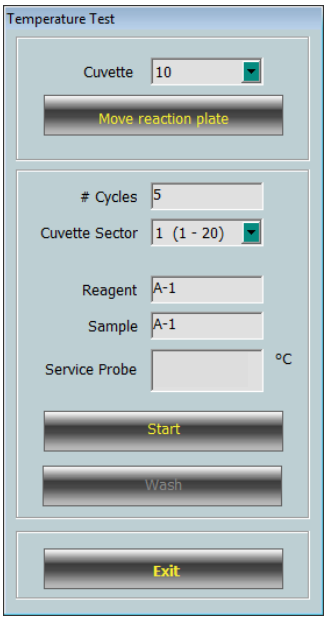


Fig. 10 – "Temperature Test" form

5.6.1.2 "Calibration Temperature Sensor" form
(*2 commands type*)

The "Calibration Temperature Sensor" form describes (step-by-step) the Calibration Procedure of the Service Probe.

Read *val*K: allows to read the resistor value.

Exit: allows to exit from the "Calibration Temperature Sensor" form.

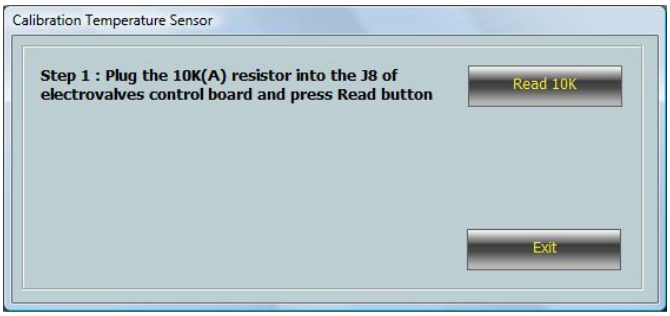


Fig. 11 – "Calibration Temperature Sensor" form

5.6.2 TEMPERATURES AREA
(*4 commands*)

Plate: performs a temperature reading (°C and mV) in the Reactions Plate compartment.

Arm: performs a temperature reading (°C and mV) in the Pre-Heater of the Sampling Arm.

External: performs a temperature reading (°C and mV) in the instrument.

Refrigerator: performs a temperature reading (mV) in the Reagents Plate refrigeration system.

5.6.3 SERVICE PROBE AREA
(*1 command*)

Service Pb.: performs a temperature reading (°C and mV) with the Service Probe.

Offset: allows to enter (using the slide located immediately to the right) the temperature offset value (°C) between the reference thermometer reading and the Service Probe reading (*note*: the offset value resets to zero when exit to the Diagnostic program).

5.6.4 "STATUS COMMAND" AREA

Send: visualizes the commands sent by the program to the instrument's hardware.
Receive: visualizes the instrument hardware's response to the commands sent by the program.

5.7 "WASH" FOLDER

Fig. 12 – "Wash" folder

The "Wash" folder is subdivided into four areas:

- **OPERATIONS**
- **TEST**
- ***WASHING CYCLES***
- **STATUS COMMAND**

5.7.1 "OPERATIONS" AREA

(*3 commands*)

Home: brings the washing device of the Washing Station to the home position.

Down to Adjust: makes the washing device go down to the position for adjusting operations.

Down (Full): makes the washing device go down to the washing position.

5.7.2 "TEST" AREA

(*5 commands*)

P5: actives the P5 µ-pump and automatically turns it off after a period of 0,5 seconds.

P6: actives the P6 µ-pump and automatically turns it off after a period of 0,5 seconds.

P8: actives the P8 µ-pump and automatically turns it off after a period of 0,5 seconds.

P9: actives the P9 µ-pump and automatically turns it off after a period of 0,5 seconds.

EV5-EV7-EV8: actives the EV5, EV7 and EV8 electrovalves and automatically turns them off after a period of 0,5 seconds.

5.7.3 WASHING CYCLES AREA

(*1 command*)

Washing Cycles: allows to perform the Functional Check of the Washing Station. The number of cycles is selectable on the Pull Down Menu "Cycles #".

5.7.4 "STATUS COMMAND" AREA

Send: visualizes the commands sent by the program to the instrument's hardware.

Receive: visualizes the instrument hardware's response to the commands sent by the program.

5.8 "MISCELLANEOUS" FOLDER

Fig. 13 – "Miscellaneous" folder

The "Miscellaneous" folder is subdivided into five areas:

- **GENERAL RESET**
- **CONTINUOUS TEST RUN**
- **COVER LOCK**
- **BARCODE**
- **STATUS COMMAND**

5.8.1 "GENERAL RESET" AREA

(*1 command*)

Reset: performs the reset procedure of the general system.

5.8.2 "CONTINUOUS TEST RUN" AREA

(*1 command*)

Start Test: allows to start an automatic test during which the modules of the system are moved to all the different positions.

5.8.3 "COVER LOCK" AREA

(*1 command*)

ON: allows to active the Cover Lock of the analyzer (if selected, its caption turns into **OFF)**.

OFF: allows to deactivate the Cover Lock of the analyzer (if selected, its caption turns into **ON)**.

5.8.4 "BARCODE" AREA

(*2 commands*)

Read: allows to read the *barcode* (visualized in its text box) present on the bottle/cup in a specific position of the Samples Plate or Reagents Plate.

Offset: allows to perform (*see Section 5.8.4.1*) the Sample barcode reader setting procedure opening the "Sample plate barcode offset" form.

(2 options)

Sample: option to select the Samples Plate upon which read the barcode in the position chosen in the near Pull Down Menu.

Reagent: option to select the Reagents Plate upon which read the barcode in the position chosen in the near Pull Down Menu.

(*2 check boxes*)

Continuous reading: if selected, allows to read in continuous mode the *barcode* present on the bottle/cup in a specific position selected on the Samples Plate or Reagents Plate.

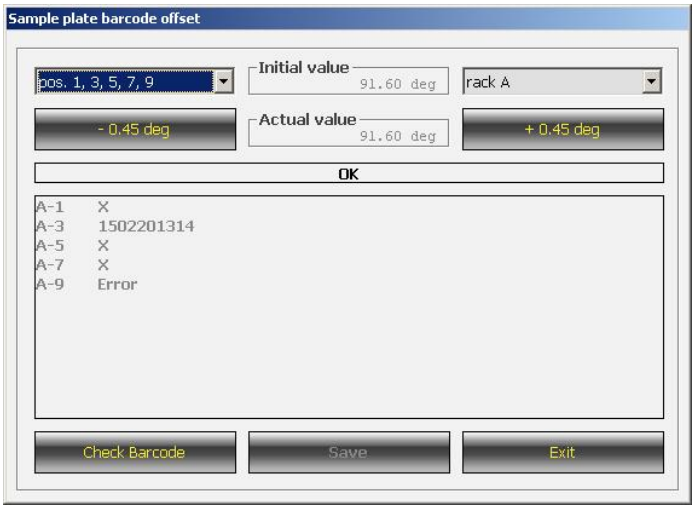
Barcode tuning: if selected, allows only to activate the beam of light of the chosen Barcode Reader.

5.8.4.1 "Sample plate barcode offset" form

This form allows the user to define a specific offset that will be applied to the sample plate barcode reader with reference to 4 different positions (left top combo box):

- sA..sD
- Pos. 1, 3, 5, 7, 9
- Pos. 2, 4, 6, 8, 10
- Pos. 11, 12, 13, 14, 15

Having selected a position, the user could modify the offset through the "-0.45 deg" and the "+0.45 deg" commands. Furthermore user can verify the correct setting through the "Check Barcode" command that activate the barcode reading on the selected positions. With reference to the three numeric positions, user must choose one of the four racks of the sample plate (right top combo box).



5.8.5 "STATUS COMMAND" AREA

This area visualizes the commands sent by the program to the instrument's hardware.

5.9 "CONFIGURATION" FOLDER

This folder must be accessible only by qualified technical operators.

It is necessary insert a password in the "Password" form (**Fig. 14**) to access in this folder.

Fig. 14 – "Password" form

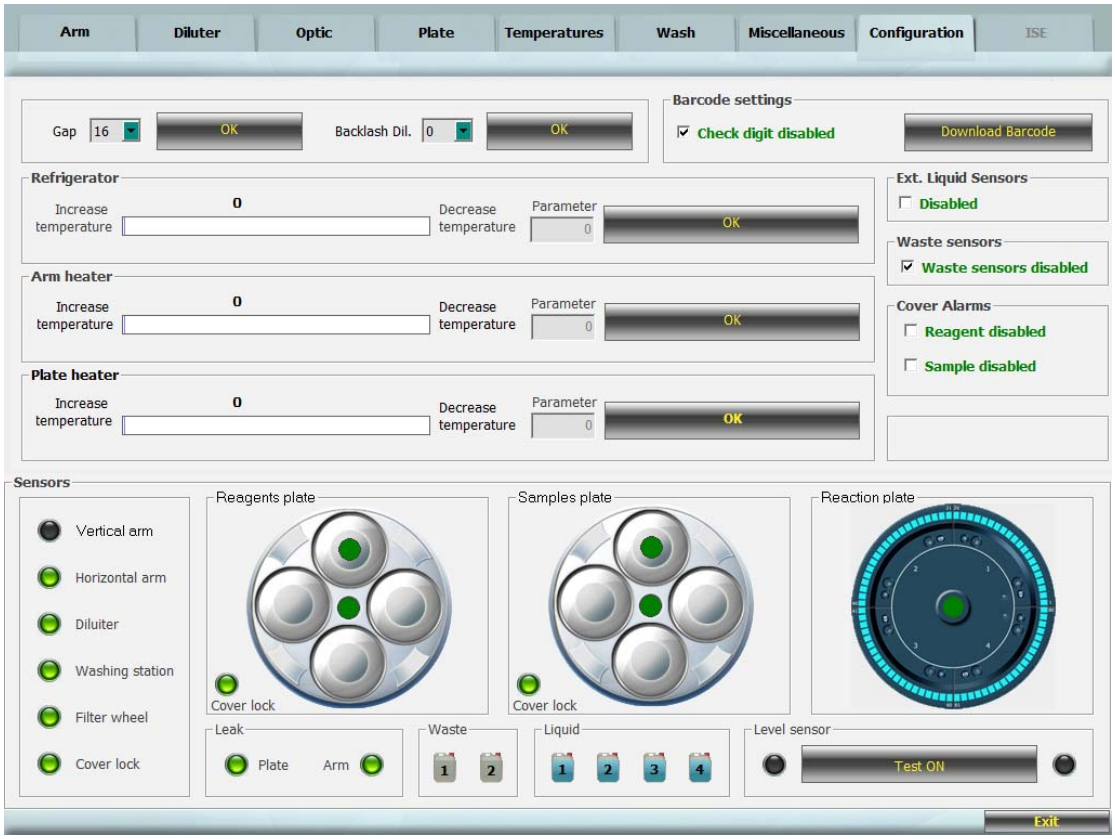


Fig. 15 – "Configuration" folder

The "Configuration" folder is subdivided into eight areas:

- ***GAP AND BACKLASH DIL.***
- **ARM HEATER**
- **PLATE HEATER**
- **REFRIGERATOR**
- **BARCODE SETTINGS**
- **EXT. LIQUID SENSORS**
- **WASTE SENSORS**
- **COVER ALARMS**

5.9.1 GAP AND BACKLASH DIL. AREA

(*2 commands*)

- *GAP*

  OK: allows to save the volume (in µL), selected in the relative Pull Down Menu, of the air bubble that separates the Rinse (the liquid column into the Sampling Arm tube) from the sampled Reagent. The default value is 18.

- *BACKLASH DIL.*

  OK: allows to save the redress value for the sampling imprecision generated by the Diluter motor when it inverts the rotation of its shaft. The setting value in the relative Pull Down Menu is expressed in µL. It is obtained by using the following procedure:

1. Select "Arm" folder and request an Sampling Arm reset. Wait until the reset Sampling Arm procedure has been completed.
2. Select "Diluter" folder and request an Diluter reset. Wait until the reset Diluter procedure has been completed.
3. Select the number "4" in the Pull Down Menu "Cycles #" and push "Probe Wash Test" in order to fill the hydraulic sampling line. Wait until the requested cycles have been completed.
4. Select "Arm" folder and push "Go Sample" button in order to move the Sampling Probe to sample position #(A-1).
5. Put a sample cup containing distilled water (about 1ml) under the Sampling Probe.
6. Select **"**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 "Disp." button consecutively until water appears on the tip of the Sampling Probe.
9. Substract 1 from the number of times that you pressed the "Disp" button. The obtained number has to be introduced in the relative Pull Down Menu as BACKLASH value.
10. Push "OK" button in the "Backlash Dil." area to save the inserted value.
11. Select "Arm" folder and request an Sampling Arm reset. Wait until the reset Sampling Arm procedure has been completed.

5.9.2 "ARM HEATER" AREA

(*1 command*)

OK: allows to save the parameter to adjust the heating temperature of the Sampling Arm's Pre-Heater. This parameter is selectable in the relative slide and the value is visualized both above the slide and into the relative text box.

5.9.3 "PLATE HEATER" AREA

(*1 command*)

OK: allows to save the parameter to adjust the heating temperature of the Reactions Plate resistor. This parameter is selectable in the relative slide and the value is visualized both above the slide and into the relative text box.

5.9.4 "REFRIGERATOR" AREA

(*1 command*)

OK: allows to save the parameter to adjust the cooling temperature of the Reagents Plate refrigerator. This parameter is selectable in the relative slide and the value is visualized both above the slide and into the relative text box.

5.9.5 "BARCODE SETTINGS" AREA

(*1 check box, 1 command*)

Check box | **Check digit disabled:** if selected, allows to disable the check digit control of the two BarCode Readers.

Command | **Download Barcode:** performs the download in the instrument's hardware of the firmware for the two BarCode Readers activating the selectioned function by check box.

5.9.6 "EXT. LIQUID SENSORS" AREA

(*1 check box*)

Disabled: if selected, allows to disable the control of the sensors of the four Liquid Reservoir Bottles (Liquid: 1, 2, 3 and 4).

5.9.7 "WASTE SENSORS" AREA

(*1 check box*)

Waste sensors disabled: if selected, allows to disable the control of the sensors of the two waste tanks.

5.9.8 "COVER ALARMS" AREA

(*2 check box*)

Reagent disabled: if selected, allows to disable the control of the presence sensor of the Reagents Plate cover.

Sample disabled: if selected, allows to disable the control of the presence sensor of the Samples Plate cover.

5.10 "ISE" FOLDER

Fig. 16 – "ISE" folder

The "ISE" folder has seven buttons:

- **SOFTWARE RELEASE**
- **PURGE**
- **MAINTENANCE**
- **ST.BY CYCLE**
- **BUBBLE DETECTOR READ**
- **mV TRANSMISSION**
- **CLEANING CYCLE**

and the "Cleaning position" Pull Down Menu.

5.10.1 "SOFTWARE RELEASE" BUTTON

(*1 command*)

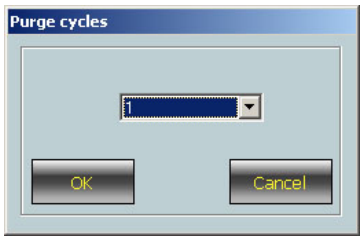
Software Release: allows to visualize into the text box of the folder the software release of the ISE Module.

5.10.2 "PURGE" BUTTON

(*1 command*)

Purge: allows to fill the hydraulic circuit of the ISE Module.

The "Purge cycles" form appears by clicking the **Purge** button; in this form it's possible to select the number of the *Purge cycles* by its Combo Box. The "OK" button allows to confirm, whereas the "Cancel" button annuls the operation.



5.10.3 "MAINTENANCE" BUTTON

(*1 command*)

Maintenance: allows to empty the electrodes (in order to replace them) of the ISE Module.

5.10.4 "ST.BY CYCLE" BUTTON

(*1 command*)

St.By Cycle: allows to perform a priming cycle in order to renew the "Calibrant A" solution into the electrodes of the ISE Module.

5.10.5 "BUBBLE DETECTOR READ" BUTTON

(*1 command*)

Bubble Detector Read: allows to read the values of the two Bubble Detectors of the ISE Module.

Answer to the command: <4ISOK*num1* *num2* *num3* *num4* CS>

where:

- *num1*, *num2*: number couple relative at the Bubble Detector placed on the top;
- *num3*, *num4*: number couple relative at the Bubble Detector placed at bottom;
- CS: CheckSum;
- *num1*, *num3*: number couple relative at the air;
- *num2*, *num4*: number couple relative at the fluid.

The values must be:

- $num1 \approx 160$ and $num3 \approx 160$
- $num2 \geq 40$ and $num4 \geq 40$
- $(num1 - num2) > 50$ and $(num3 - num4) > 50$

[**Note**: more informations in the *Chapter 9 - Error Signalling and Troubleshooting*]

5.10.6 "mV TRANSMISSION" BUTTON

(*1 command*)

mV Transmission: allows to get in the following "ISE Voltages" form

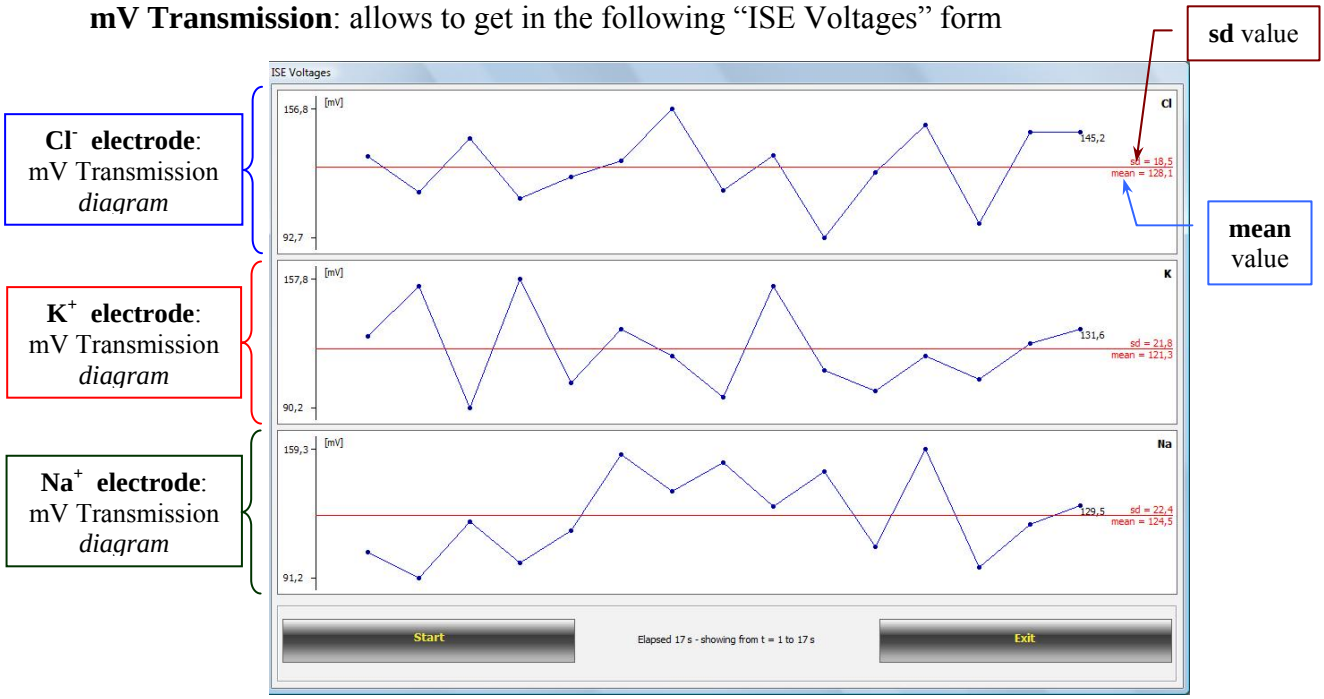


Fig. 17 – "ISE Voltages" form

The "ISE Voltages" form (**Fig. 17**) shows the *mV Transmission diagrams* of the Cl^-, K^+ and Na^+ electrodes – respectively – of the ISE Module.

Start [/Stop]: command that allows to activate [/deactivate] the voltages reading on the electrodes and - therefore - the evolution of the *mV diagrams*.

Exit: command that allows to exit from the "ISE Voltages" form.

[**Note**: more informations in the *Chapter 9 - Error Signalling and Troubleshooting*]

5.10.7 "CLEANING CYCLE" BUTTON

(*1 command*)

Cleaning Cycle: allows to perform the "Cleaning Cycle" procedure of the electrodes of the ISE Module.

5.10.8 "CLEANING POSITION" PULL DOWN MENU

(*1 Pull Down Menu*)

Cleaning position: allows to select the position of the Samples Plate for the Cleaning solution.

CHAPTER 06

- FORMULAS AND CALCULATION MODELS -

INDEX

6.1 END POINT METHODOLOGY - Single reagent (without Sample Blank).....3
6.2 END POINT METHODOLOGY - Single reagent (with Sample Blank).....6
6.3 "END POINT LIMIT" CONCEPT.....9
6.4 "RGT RATE" CONCEPT 10
6.5 END POINT METHODOLOGY - Two or three reagents (without Sample Blank).....11
6.6 END POINT METHODOLOGY – Two or three reagents (with Sample Blank) 14
6.7 SAMPLE BLANK CORRECTION 18
6.8 FIXED TIME OR INITIAL RATE METHODOLOGY – Single reagent 24
6.9 FIRST LIMIT CONCEPT 30
6.10 FIXED TIME OR INITIAL RATE METHODOLOGY – Two or three reagents 32
6.11 DEPLETION LIMIT CONCEPT (Fixed Threshold) 35
6.12 DEPLETION LIMIT CONCEPT (Variable Threshold).....37
6.13 KINETICS METHODOLOGY 40
6.14 USE OF REPLICATES IN STANDARD AND RBL CALCULATION 43

This chapter describes the mathematical models and the formulas used to define the results of the analyses carried out with the *SAT 450* 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 = [(1 / Dilution Ratio) x Analytical Result x Unit Factor] x Slope + Intercept

where:

- Dilution Ratio is the dilution ratio of the sample prepared by the user.
- Unit Factor can be used in order to obtain the result in a different measurement unit.
- The Slope and Intercept parameters refer to the conventional formula $Y = aX + b$ where:

  Y = results of the reference instrument;

  X = results of the *SAT 450* instrument;

  a = slope;

  b = intercept.

  reporting the Y values (reference instrument) in ordinate and X (*SAT 450* system) in abscissa.

The Dilution Ratio can be set by the user through the Work List Setup Mask where one finds a field with the same name whose default value is 1/1 (in order to obtain more information, please refer to *Chapter 03 – Software description [Section "Work List Setup"]* of the present manual).

In order to obtain more information on how to set the Unit Factor, Slope and Intercept fields, please refer to *Chapter 03 – Software description [Section "Methods"]* of the present manual.

6.1 END POINT METHODOLOGY - Single reagent (without Sample Blank) Monochromatic

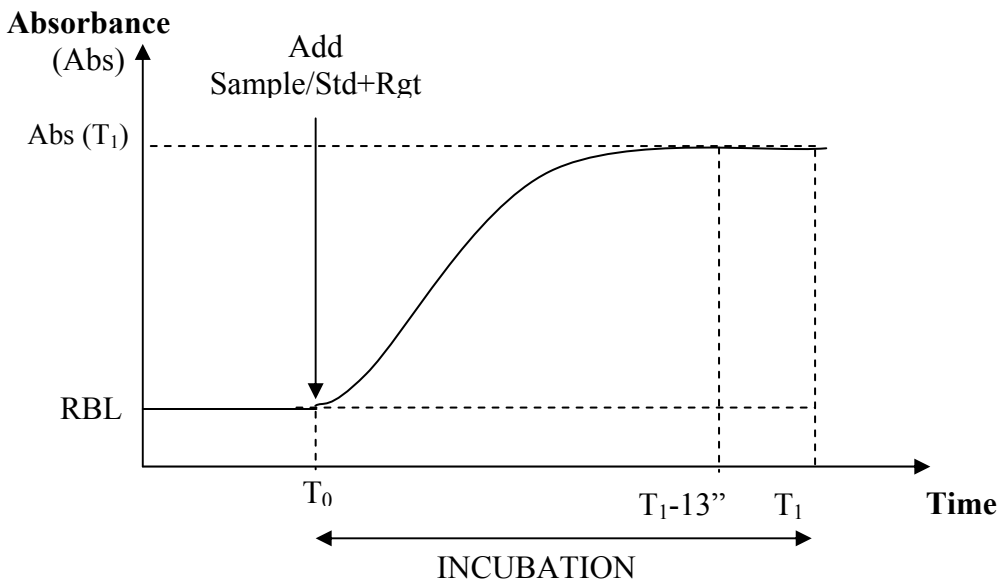
For each "End Point" test, the system carries out three readings expressed in optical density, respectively at times T_0, T_1-13" and T_1.

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 following discussion refers specifically to End Point Methods, Single reagent, Monochromatic, without Sample Blank, with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model).

The Analytical Result is obtained using the Abs (T_1) RBL value, that is taken during the calibration phase as the first reading point, and Abs (T_1) taken during the analysis phase as the second reading point.

The T_0 reading is not used for this method type.



Analytical Result = CF x [Abs (T_1) - RBL] x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{\text{Abs}_{STD}(T_1) - \text{RBL}}$$

where:

$T_1 - T_0$ = Incubation time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

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.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation Time can be set by the user choosing the correct value of the Incubation field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).
Furthermore, an absorbance reading is also carried out at time T_1 - 13". It is used to check the reaction stability - End Point Limit (see *Section End Point Limit Concept*).

Note
For End Point Methods, Single reagent, Monochromatic, without Sample Blank, with at least one RBL replicate and <u>with a Factor Calculation Model</u>, the Analytical Result is evaluated according to the previous formula without considering the CF element.
In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

RBL = Reagent Base Line

Example:

GLU	
Res	91
Abs	**Time**
0.236	(T_0)
0.3319	(T_1 -13")
0.3336	(T_1)

CF = 295
RBL = 0.0251
Method Multiplier Factor = 1

Analytical Result = CF x [Abs (T_1) - RBL]

Analytical Result = 295 x (0.3336 - 0.0251) = 91

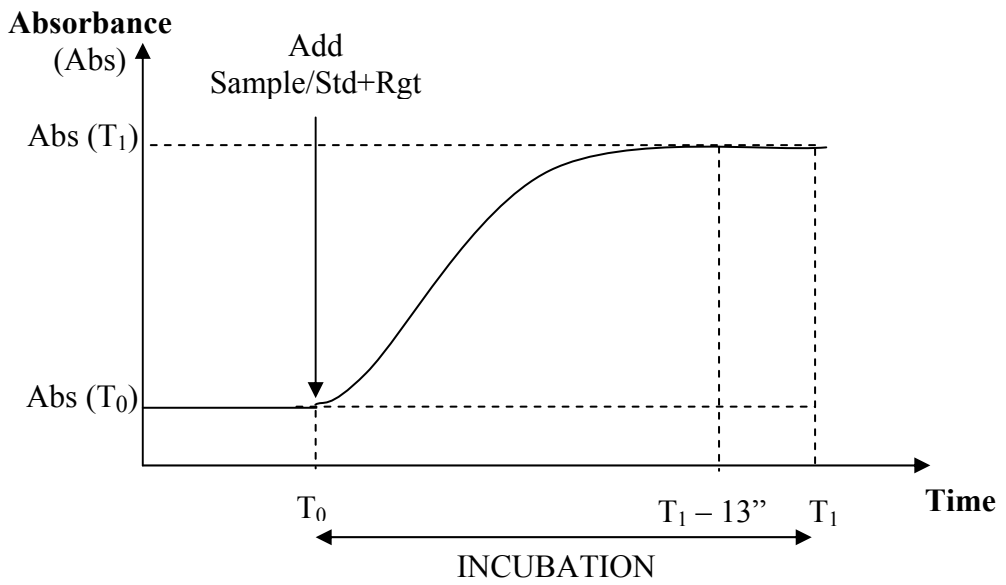
6.2 END POINT METHODOLOGY - Single reagent (with Sample Blank) Monochromatic

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 following discussion refers specifically to End Point Methods, Single reagent, Monochromatic, with Sample Blank, <u>without RBL and with a Single Standard Calibration (Standard Calculation Model)</u>.
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 than RBL value detected during the calibration phase, it is not possible to use this type of methodology.



Analytical Result = CF x [Abs (T_1) - Abs (T_0)] x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{\text{Abs}_{STD}(T_1) - \text{Abs}_{STD}(T_0)}$$

where:

T_1 - T_0 = Incubation time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

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.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation Time can be set by the user choosing the correct value of the Incubation field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Furthermore, an absorbance reading is also carried out at time T_1 - 13". It is used to check the reaction stability - End Point Limit (see *Section End Point Limit Concept*).

Note

For End Point Methods, Single reagent, Monochromatic, with Sample Blank, without RBL and <u>with a Factor Calculation Model</u>, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

RBL = Reagent Base Line

Example:

GLU	
Res	91
Abs	**Time**
0.237	(T_0)
0.5442	(T_1 -13")
0.5454	(T_1)

CF = 295
Method Multiplier Factor = 1

Analytical Result = CF x [Abs (T_1) - Abs (T_0)]

Analytical Result = 295 x (0.5454 - 0.237) = 91

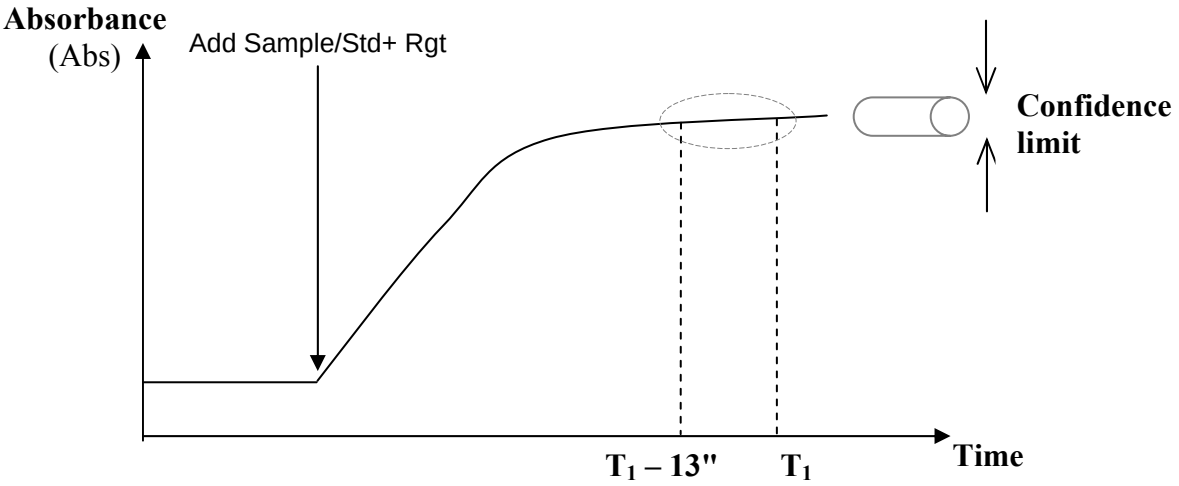
6.3 "END POINT LIMIT" CONCEPT

The end point limit is a check performed by the analyzer to verify the reaction stability and determine the validity of the result obtained.

The End Point Limit is the acceptability value (expressed in absorbance) that has to be inserted by the operator into the E.P. Limit (abs) field in the method parameters mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Result's acceptability conditions:

$$\mathbf{Abs\ (T_1) - Abs\ (T_1 - 13") < End\ Point\ Limit}$$



$$\mathbf{\Delta Abs = Abs\ (T_1) - Abs\ (T_1 - 13") = 0.3336 - 0.3319 = 0.0017 < End\ Point\ Limit}$$

The following example shows how the end point limit value is calculated:

Calibration factor obtained = 300 mg/l

By maintaining an uncertainty of 1 mg/l as acceptable, it follows:

$$\frac{\mathbf{1\ mg}}{\mathbf{300}} = \mathbf{0.003}$$

The value to be inserted in the End Point Limit box, represents in absorbance, the uncertainty that may exist between Abs (T_1) and Abs (T_1 - 13")

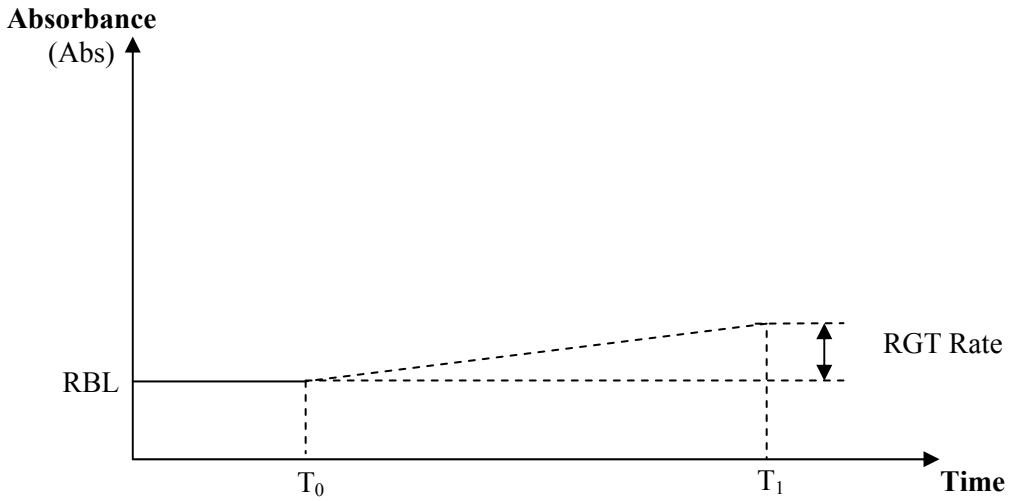
In the analysis phase, tests in which the following inequality is verified:

Abs (T_1) - Abs (T_1 - 13") > 0.003 (End Point Limit)

When End Point Limit check fails, the result will be flagged with **"A".**

6.4 "RGT RATE" CONCEPT

The Reagent Rate represents, in terms of absorbance, the reagent's mobility during the reaction.



The Reagent Rate is automatically evaluated by the software

With reference to a monoreagent method, the Reagent Rate can be expressed as Abs (T_1) RBL - Abs (T_0) RBL.

The Reagent Rate is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual).

The Reagent Rate value is not displayed in monoreagent End Point methods because it is already enclosed in the RBL value.

In the End Point Methods with two reagents, the Reagent Rate measured value is used for the analytical result calculation only when the Sample Blank correction is actively selected. The Reagent Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

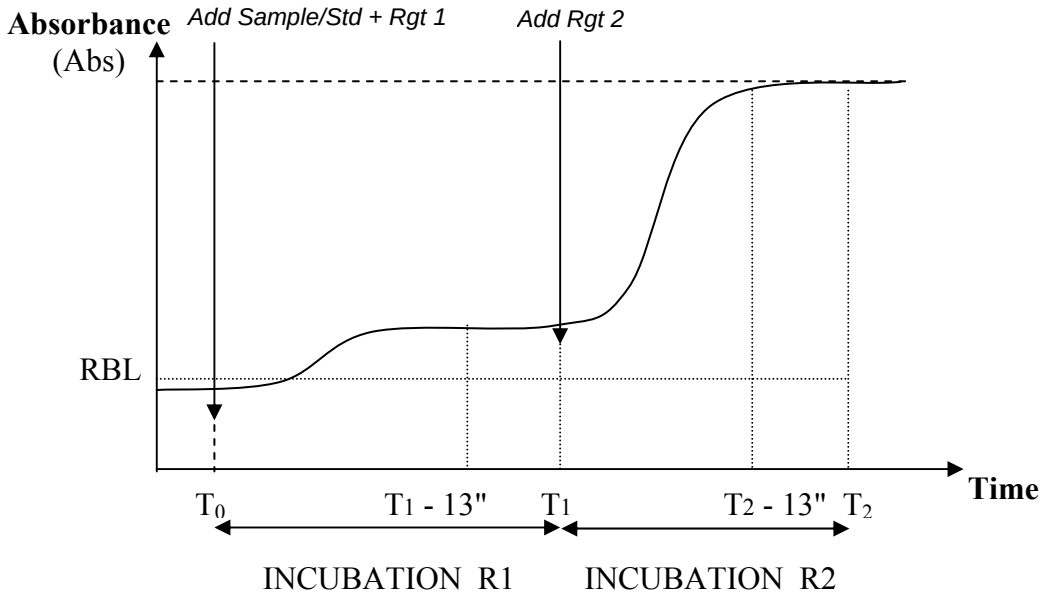
6.5 END POINT METHODOLOGY - Two or three reagents (without Sample Blank) Monochromatic

For each "End Point" test that uses two/three reagents, the system carries out three readings expressed in optical density, respectively at time T_1-13", 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 following discussion refers specifically to End Point Methods, Two reagents, Monochromatic, without Sample Blank, <u>with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model)</u>. There is no significant difference for the three-reagent case.

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.



Analytical Result = CF x [Abs (T_2) – RBL] x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{[\text{Abs}_{STD}(T2) - RBL]}$$

where:

T_1 - T_0 = Incubation time Reagent 1 = INCUBATION R1

T_2 - T_1 = Incubation time Reagent 2 = INCUBATION R2

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

RBL = Reagent Base Line value taken at time T_2 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_2) = reading expressed in absorbance carried out at the end of the INCUBATION R2 (time T_2) and used to produce the Analytical Result.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation R1 can be set by the user choosing the correct value of the Reag. 2 Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Incubation R2 can be set by the user choosing the correct value of the Incubation field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Furthermore an absorbance reading is also carried out at time T_2 - 13". It is used to check the reaction stability "End Point Limit" (please refer to *Section End Point Limit Concept*).

Note

For End Point Methods, Two reagents, Monochromatic, without Sample Blank, with at least one RBL replicate and with a Factor Calculation Model, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

RBL = Reagent Base Line

Example:

CA2	
Res	11.9
Abs	**Time**
0.3133	(T_1)
0.7711	(T_2 - 13")
0.7700	(T_2)

CF = 27.78
RBL = 0.3416
Method Multiplier Factor = 1

Analytical Result = CF x [Abs (T_2) - RBL]

Analytical Result = 27.78 x (0.770-0.3416) = 11.9

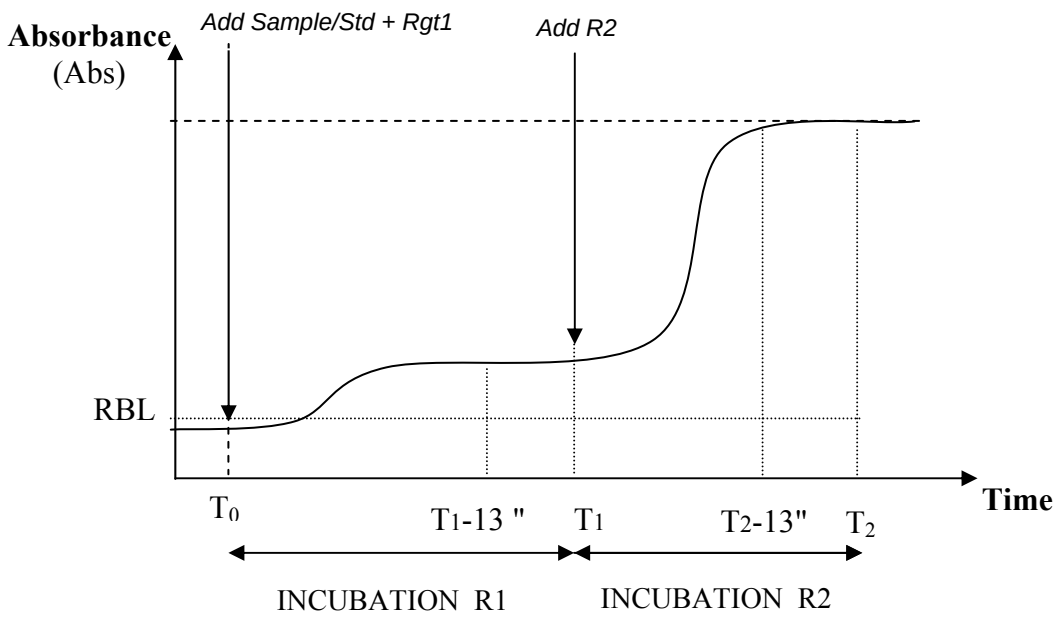
6.6 END POINT METHODOLOGY – Two or three reagents (with Sample Blank) Monochromatic

For each "End Point" test that uses two/three reagents, the system carries out three readings expressed in optical density, respectively at the time T_1-13", 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 following discussion refers specifically to End Point Methods, Two reagents, Monochromatic, with Sample Blank, with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model). There is no significant difference for the three-reagent case.

The Analytical Result is obtained by the system using the Abs (T_1-13") value as the first reading point and Abs (T_2) value as the second reading point, described in the chart below.



Analytical Result = CF x {[Abs (T_2)– (Abs (T_1-13") x VCF)] - RGT Rate} x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{[\text{Abs}_{STD}(T_2) - (\text{Abs}_{STD}(T_1 - 13'') \times VCF)] - \text{RGT Rate}}$$

where:

T_1 - T_0 = Incubation time R1
T_2 - T_1 = Incubation time R2

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

Abs (T_1-13") = reading, expressed in absorbance, taken 13 seconds before the end of the Incubation time R1. This reading is used as the first reading point to produce the Analytical Result.

Abs (T_2) = reading, expressed in absorbance, taken at the end of the incubation time R2 and used to produce the Analytical Result.

VCF = Volume Correction Factor. This factor is automatically calculated by the system and is introduced to compensate for the addition of the second reagent.

$$VCF = \frac{V1}{V2} = \frac{R1 + \text{Sample}}{R1 + \text{Sample} + R2}$$

RGT RATE = reading, expressed in absorbance, of the reagent's mobility during the reaction. This value is automatically calculated during the phase of calibration; the value is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). The RGT RATE is calculated in the as follows: Abs (T_2) RBL – [(Abs (T_1-13") RBL x VCF]

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation R1 can be set by the user choosing the correct value of the Reag. 2 Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Incubation R2 can be set by the user choosing the correct value of the Incubation field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Furthermore an absorbance reading is also carried out at time T_2 - 13". It is used to check the reaction stability "End Point Limit" (please refer to *Section End Point Limit Concept*).

Note

For End Point Methods, Two reagents, Monochromatic, with Sample Blank, with at least one RBL replicate and with a Factor Calculation Model, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

VCF = Volume correction factor

RGT Rate = Reagent rate

V1 = Total volume of reagent1 + sample.

V2 = Total volume of reagent1, plus sample, plus reagent 2

Example:

	DBIL
Res	3.0
Abs	**Time**
0.1336	(T_1)
0.1662	(T1 - 11")
0.1681	(T2)

CF = 85.47
RGT Rate = 0.0036
Method Multiplier Factor = 1

$$VCF = \frac{V1}{V2} = \frac{R1 + Sample}{R1 + Sample + R2}$$

$$VCF = \frac{300 + 12}{300 + 12 + 10} = 0.9689$$

Analytical Result = CF x { [Abs (T_2)- (Abs (T_1-13") x VCF)] - RGT Rate }

Analytical Result = 85.47 x { [0.1681 - (0.1336 x 0.9689)] - 0.0036 } = 3.0

6.7 SAMPLE BLANK CORRECTION

In the End Point 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 (on line correction)

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 in the method parameters (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual), is active.

This kind of correction must be considered valid only for slow developing reactions.

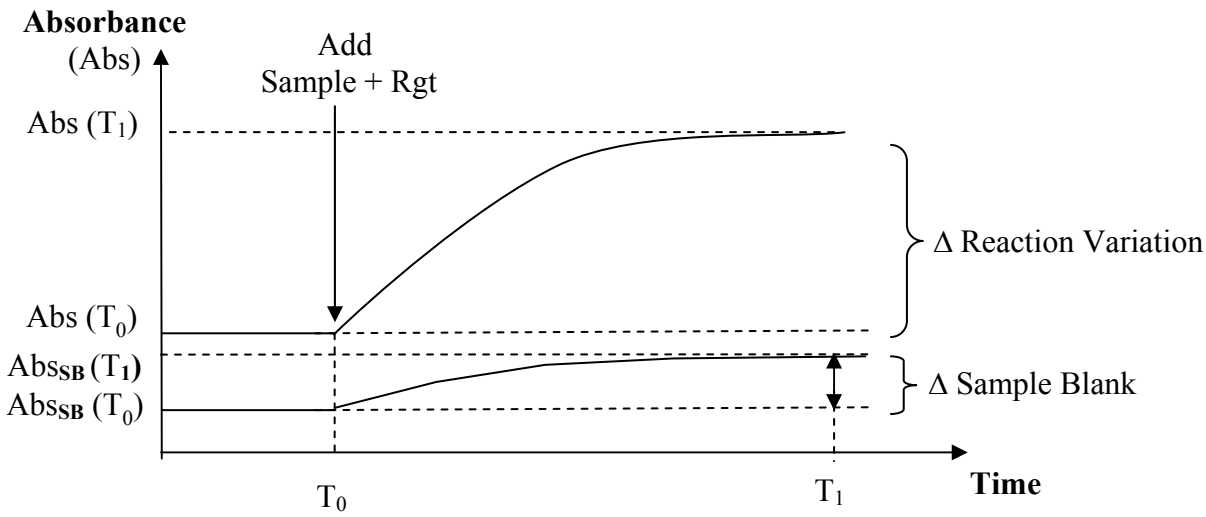
In monoreagent reactions, a reading is taken at time T_0, immediately after the dispensing of the sample in the reagent, neglecting the value of the RBL (the value of the RBL is not taken into consideration for the calculation of the final result).

In two-reagent reactions, a reading is taken at time T_1 – 13” and it is used as the basis for the calculation of the final result.

DIFFERENTIAL

This type of methodological approach, applicable only with monoreagent methods, is used for the resolution of the problems posed by the "Sample Blank". 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)] } x Method Multiplier Factor

Analytical Result = CF x { [Abs (T_1) - RBL] - [Abs_{SB} (T_1) - RBL] } x Method Multiplier Factor

where:

$$\mathbf{CF} = \frac{\textbf{STD Concentration}}{\{ [Abs\ (T_1) - RBL\ ] - [Abs_{SB}\ (T_1) - RBL\ ] \}}$$

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

RBL = Reagent Base Line value taken at time T1 during the calibration phase and displayed in the calibration results window.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

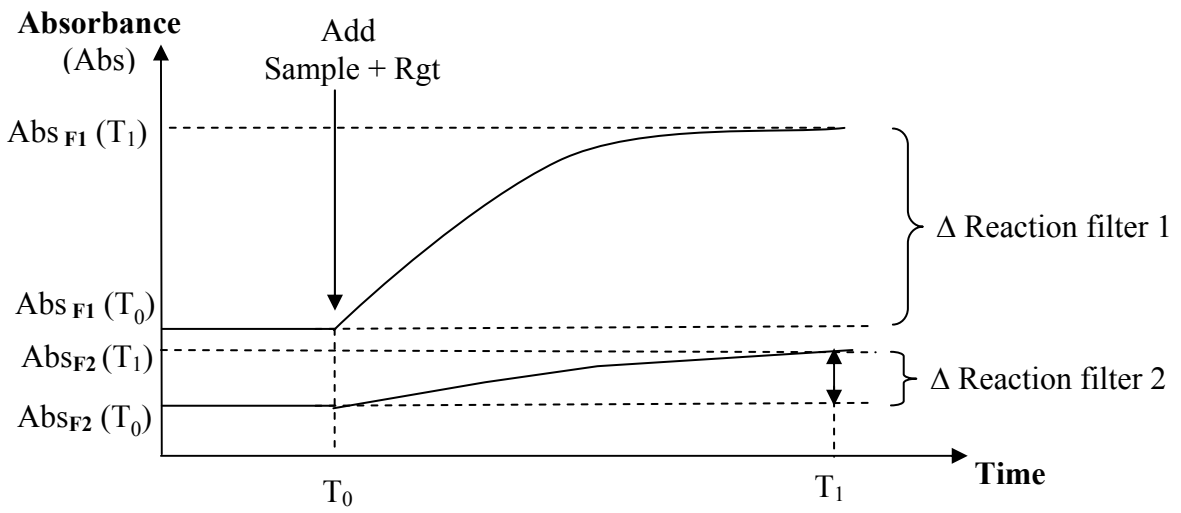
BICHROMATIC

This type of methodology is applicable to the End Point reactions, which require a reading of the "Sample Blank".

The following discussion refers specifically to End Point Methods, monoreagent with at least one RBL replicate and with a Single Standard Calibration. There is no significant difference for the two or three-reagent case.

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, ittera, hemolyses).
- A bichromatic correction factor (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).



Analytical Result =CF x {[Δ Abs(Reaction filter 1)]-[Bic.Fact. x Δ Abs(Reaction filter 2)]} x Method Multiplier Factor

Analytical Result =CF x {[Abs $_{F1}$ (T_1) - RBL $_{F1}$] - [Bic.Fact. x[Abs$_{F2}$ (T_1) - RBL$_{F2}$]]} x Method Multiplier Factor

where

$$CF = \frac{\text{STD Concentration}}{\{[Abs_{F1}(T_1) - RBL_{F1}] - [Bic.Fact. \times [Abs_{F2}(T_1) - RBL_{F2}]]\}}$$

RBL $_{F1}$ = Reagent Base Line value taken at time T1 on filter 1 during the calibration phase and displayed in the calibration results window

RBL $_{F2}$ = Reagent Base Line value taken at time T1 on filter 2 during the calibration phase and displayed in the calibration results window

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note: *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 into 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 <u>turbidity:</u>**

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 <u>ittera</u>** 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 = 577 (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
Absorbance/Time Chart

RBL			SAMPLE	
620 nm				
OPTICAL DENSITY	TIMES		OPTICAL DENSITY	TIMES
0.0015 B_{620}	0		**0.0495 A_{620}**	0
0.0015	171		0.267	171
0.0015	184		0.268	184
510 nm				
0.001 B^1_{510}	184		**0.174 A^1_{510}**	184

Increase of the absorbance due to the reaction (Rgt + Smp) at 620 nm equal to:

$$\mathbf{A_{620} - B_{620} = 0.0495 - 0.0015 = 0.048}$$

Increase of the absorbance due to the reaction (Rgt + Smp) at 510 nm equal to:

$$\mathbf{A^1_{510} - B^1_{510} = 0.174 - 0.001 = 0.173}$$

$$\textbf{BICHROMATIC FACTOR} = \frac{\textbf{0.048 (}\Delta\textbf{Abs 620 nm)}}{\textbf{0.173 (}\Delta\textbf{Abs 510 nm)}} = \mathbf{0.277}$$

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 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.

6.8 FIXED TIME OR INITIAL RATE METHODOLOGY – Single reagent Monochromatic and Bichromatic

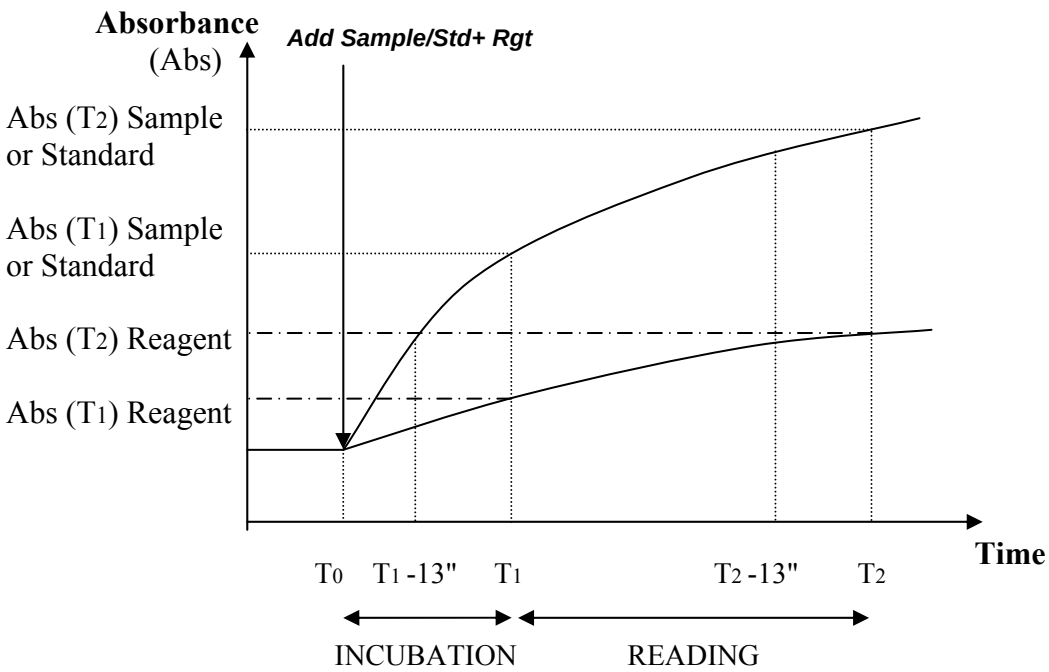
This methodology type does not need any correction referring to the possible interference due to the sample (matrix), since the results are calculated with variations of absorbance (Δ Abs), and not with absolute values of absorbance.

For each single reagent "Fixed Time" test, the system carries out four readings expressed in absorbance, respectively at the times 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 following discussion refers specifically to Fixed Time Methods, Single reagent, Monochromatic <u>with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model)</u>.

The Analytical result is obtained by the system using the ΔAbs obtained between Abs(T_1) value as first reading point and Abs (T_2) value as second reading point as described in the following formula:



Analytical Result = CF x (ΔAbs Sample x FT- RGT Rate) x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{\Delta\text{Abs Standard x FT - RGT Rate}}$$

where:

T_1 - T_0 = Incubation Time

T_2 - T_1 = Reading time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

ΔAbs Standard = the value expressed in absorbance variation detected between the end and the beginning of the reading time (Abs(T_2) - 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.

ΔAbs Sample = the value expressed in absorbance variation detected between the end and the beginning of the reading time (Abs(T_2) - 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 itself during the reaction expressed in Absorbance (Abs(T_2) Reagent - Abs(T_1) Reagent) This value is automatically calculated during the phase of calibration; the value is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

FT = Time Factor Correction, it is used to consider the possible difference between the actual reading time and the ideal Reading Time. The calculated value is Ideal Reading Time / Actual Reading Time.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation Time can be set by the user choosing the correct value of the Incubation Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Reading Time can be set by the user choosing the correct value of the Read Times (sec) field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

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" (please refer to *Section First Limit Concept*).

Note

For Fixed Time Methods, Single reagent, Monochromatic with at least one RBL replicate and <u>with a Factor Calculation Model</u>, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard

CF = Calibration Factor

Example:

CREAT

Res	1.457
Abs	**Time**
0.2451	(T_1 - 13")
0.3732	(T_1)
0.6047	(T_2 - 13")
0.6796	(T_2)

CF = 5.00
RGT Rate = 0.015
FT = 1
Method Multiplier Factor = 1

Analytical Result = CF x (Abs (T_2)- Abs (T_1) – RGT Rate)

Analytical Result = 5.0 x (0.6796 - 0.3732 – 0.015) = 1.457

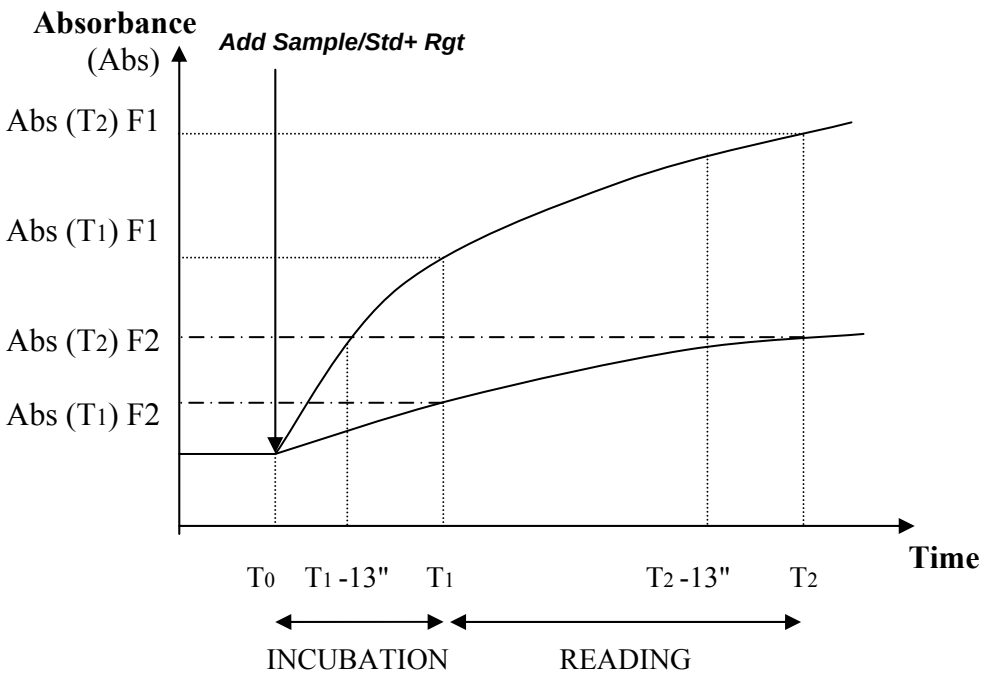
FIXED TIME OR INITIAL RATE METHODOLOGY – Single reagent - Bichromatic.

For each single reagent "Fixed Time" test, bichromatic, the system carries out eight readings (four at the first wavelength and four at the second wavelength) expressed in absorbance, respectively at the times 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 following discussion refers specifically to Fixed Time Methods, Single reagent, Bichromatic <u>with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model)</u>.

The Analytical result is obtained by the system using the ΔAbs obtained between Abs(T_1) value as first reading point and Abs (T_2) value as second reading point for each wavelength as described in the following formula:



Analytical Result = CF x {[Abs $_{F1}$ (T2) – Abs $_{F1}$ (T1)] x FT – RGT Rate} x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{\{[\text{Abs}_{F1\,STD}\ (T2) - \text{Abs}_{F1\,STD}\ (T1)] \times FT - \text{RGT Rate}}$$

where:

T_1 - T_0 = Incubation Time

T_2 - T_1 = Reading time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

RGT RATE = the reagent rate is the mobility of the reagent itself during the reaction expressed in Absorbance [Abs $_{F1\ RBL}$ (T2) – Abs $_{F1\ RBL}$ (T1)] x FT. This value is automatically calculated during the phase of calibration; the value is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

FT = Time Factor Correction, it is used to consider the possible difference between the actual reading time and the ideal Reading Time. The calculated value is Ideal Reading Time / Actual Reading Time.

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation Time can be set by the user choosing the correct value of the Incubation Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Reading Time can be set by the user choosing the correct value of the Read Times (sec) field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

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" (please refer to *Section First Limit Concept*).

Note

For Fixed Time Methods, Single reagent, Bichromatic with at least one RBL replicate and with a Factor Calculation Model, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

Note

For Bichromatic Fixed Time Methods, the Analytical Result is evaluated according to the same Monochromatic Fixed Time Methods formula

6.9 FIRST LIMIT CONCEPT

This is a control of the reaction stability, where:

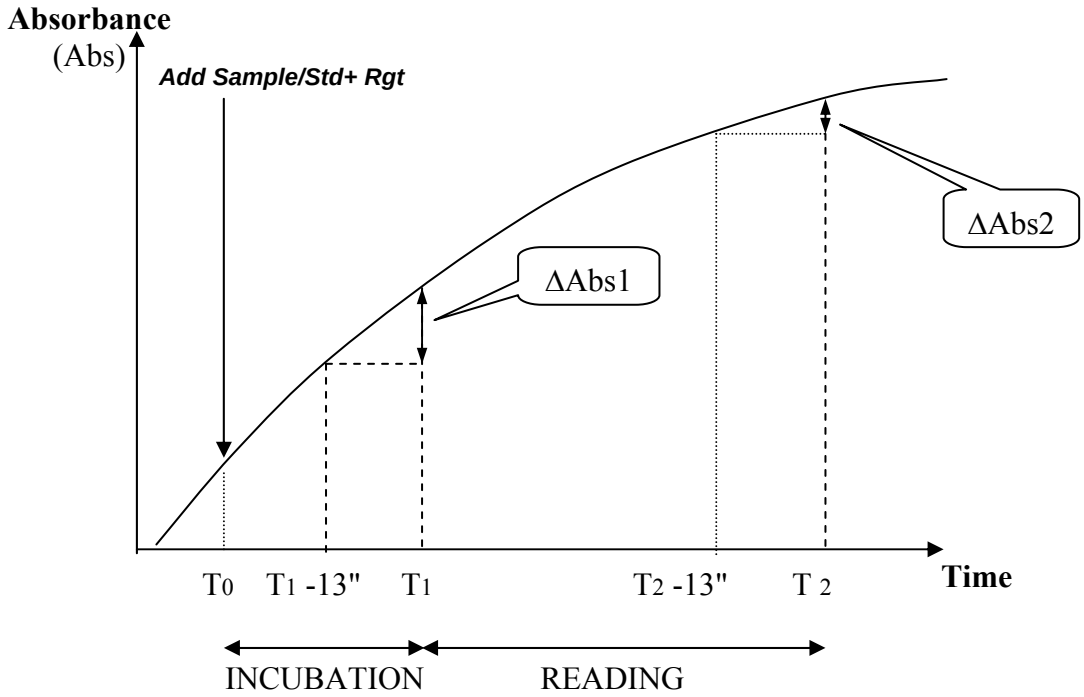
$\Delta Abs1 = | Abs (T_1) - Abs (T_1 -13") |$

$\Delta Abs2 = | Abs (T_2) - Abs (T_2 - 13") |$

In case the following formula is not satisfied

$| \Delta Abs1 - Lin\ Fact \times \Delta Abs2 | < First\ Limit$

the result of the test carried out will be accompanied by the "**A**" flag.



HOW TO 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 milli absobance or 1 absorbance, 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.

Calculate the average for the three sample series for the ΔAbs1 and ΔAbs2 values.

$$\text{The ratio } \frac{\Delta Abs1}{\Delta Abs2} = \text{Linear Factor}$$

This factor permits the correlation of the two absorbances 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 of the severity of the desired control.

6.10 FIXED TIME OR INITIAL RATE METHODOLOGY – Two or three reagents Monochromatic

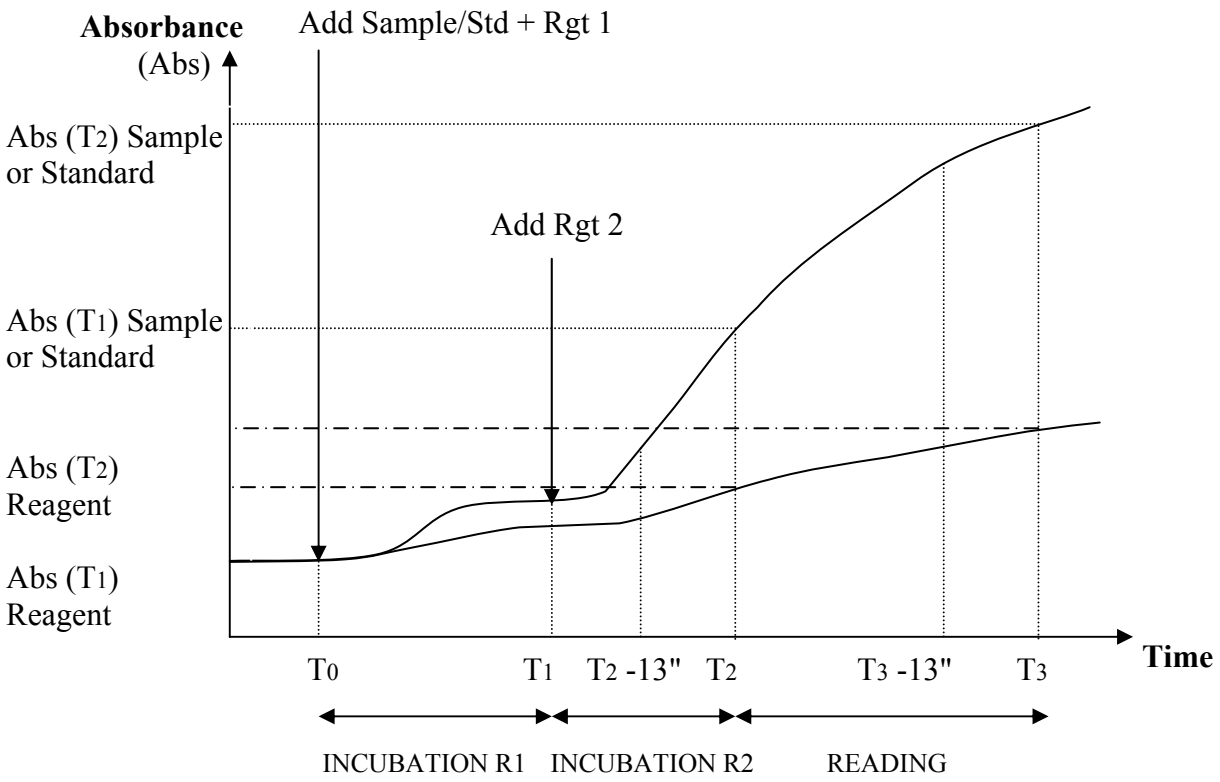
This methodology type does not need any correction with reference to the possible interference due to the sample (matrix), since the results are calculated with variations of absorbance (Δ Abs), and not with absolute values of absorbance.

For each "Fixed Time" test two/three reagents, the system carries out five readings expressed in optical density, respectively at times 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 the button "Graph".

The following discussion refers specifically to Fixed Time Methods, Two reagents, Monochromatic, <u>with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model)</u>. There is no significant difference for the three-reagent case.

The system gets the Analytical result by using the ΔAbs obtained between the Abs(T_2) value as the first reading point and the Abs (T_3) value as the second reading point as described in the following formula:



Analytical Result = CF x (ΔAbs Sample x FT - RGT Rate) x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{\Delta\text{Abs Standard x FT - RGT Rate}}$$

where:

T_1 - T_0 = Incubation Time R1

T_2 - T_1 = Incubation Time R2

T_3 - T_2 = Reading time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

ΔAbs Standard = the value expressed in absorbance variation detected between the end and the beginning of the reading time (Abs(T_3) - 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.

ΔAbs Sample = the value expressed in absorbance variation detected between the end and the beginning of the reading time (Abs(T_3) - 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 expressed in Absorbance (Abs(T_3) Reagent - Abs(T_2) Reagent) This value is automatically calculated during the phase of calibration; the value is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

FT = Time Factor Correction, it is used to consider the possible difference between the actual reading time and the ideal Reading Time. The calculated value is Ideal Reading Time / Actual Reading Time .

Method Multiplier Factor = this value can be set through the Factor Field that appears in the Parameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

Note that the Incubation R1 can be set by the user choosing the correct value of the Reag. 2 Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Incubation R2 can be set by the user choosing the correct value of the Incubation field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Reading Time can be set by the user choosing the correct value of the Read Times (sec) field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

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" (please refer to *Section First Limit Concept*).

Note

For Fixed Time Methods, Two reagents, Monochromatic, with at least one RBL replicate and with a Factor Calculation Model, the Analytical Result is evaluated according to the previous formula without considering the CF element.
In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

ABBREVIATIONS:

STD = Standard
CF = Calibration Factor
FT = Time Factor Correction

Example:

CRE AT 2RGT

Res	0.90
Abs	**Time**
0.2868	(T_1)
0.5577	(T_2 - 13")
0.5738	(T_2)
0.5991	(T_3 - 13")
0.6100	(T_3)

CF = 33
RGT Rate = 0.0089
FT = 1
Method Multiplier Factor = 1

Analytical Result = CF x [(Abs (T_3)- Abs (T_2)) - RGT Rate]

Analytical Result = 33 x [(0.6100 - 0.5738) - 0.0089] = 0.90

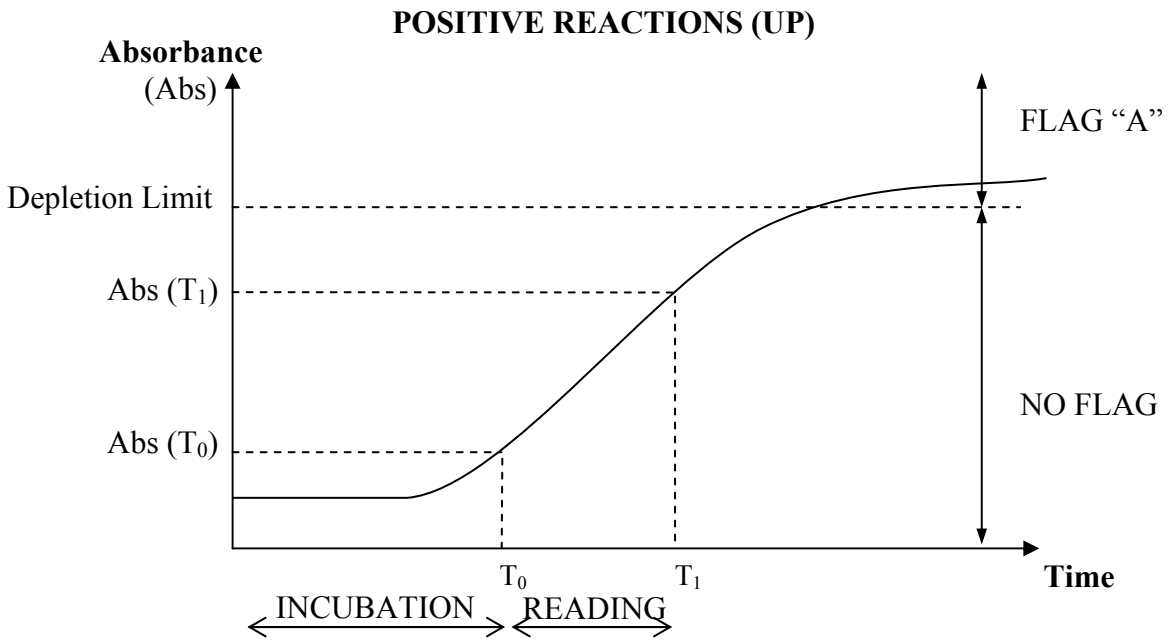
6.11 DEPLETION LIMIT CONCEPT (Fixed Threshold)

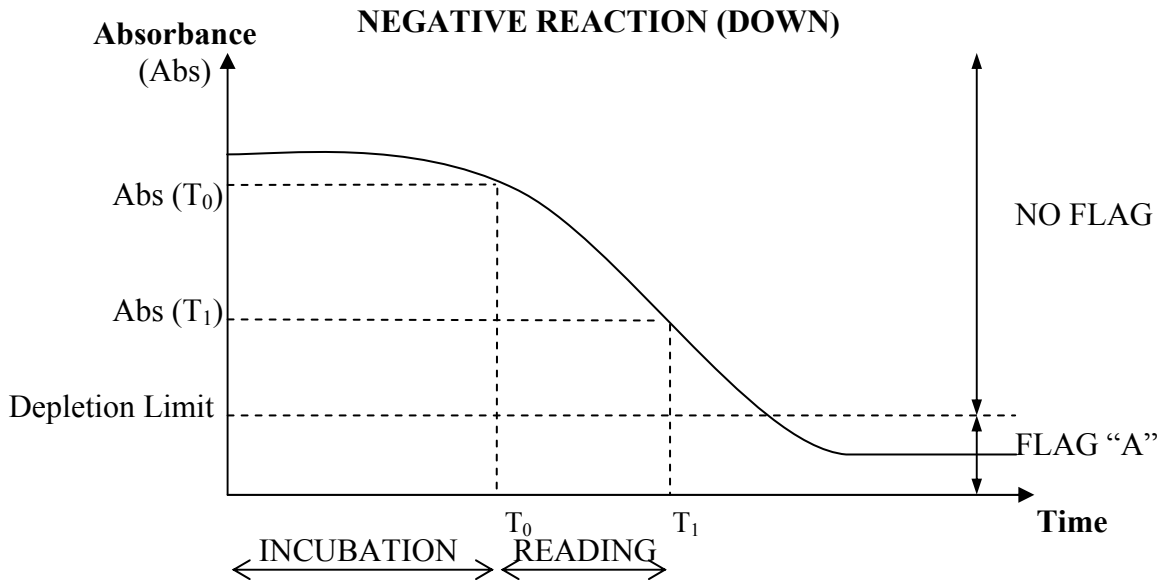
This is a control parameter for the reaction. If the initial reaction happens quickly, it can exhaust the substrate, and needs to be checked to avoid errors. This parameter refers to absolute values of absorbance, meaning that it can be applied on Initial Rate and Kinetic methods only.

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 (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual), the results will be 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 (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual), the results will be accompanied by a flag **"A"**.

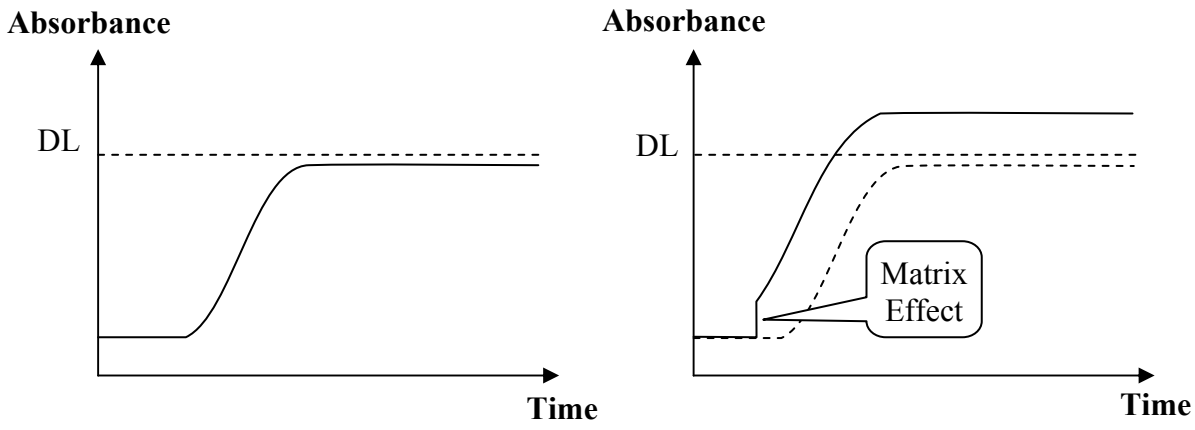

POSITIVE REACTIONS (UP)
Absorbance
(Abs)
FLAG "A"
Depletion Limit
Abs (T1)
NO FLAG
Abs (T0)
T0
T1
Time
INCUBATION
READING


NEGATIVE REACTION (DOWN)
Absorbance
(Abs)
Abs (T0)
NO FLAG
Abs (T1)
Depletion Limit
FLAG "A"
T0
T1
Time
INCUBATION
READING

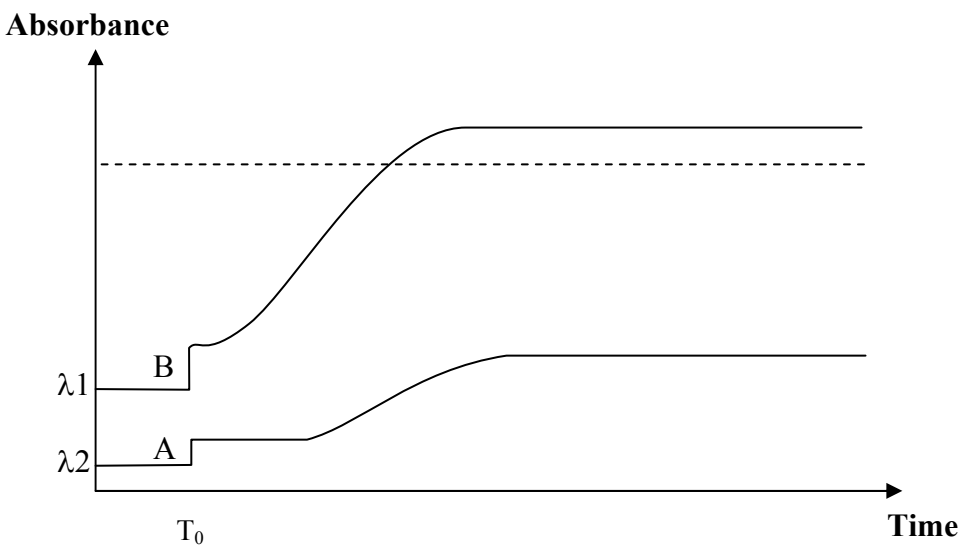
6.12 DEPLETION LIMIT CONCEPT (Variable Threshold) With Bichromatic Correction Factor

Bichromatic readings have several advantages amongst which surely the most interesting is the possibility to consider the matrix effect in kinetic reactions, with the aim of compensating for the value of the "Depletion Limit" (see previous page).

Take 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. Consequently, the Analytical results will be erroneously flagged. 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:

$$\mathbf{DL\ (corrected) = DL(in\ method) + BCF \times Abs_{\lambda 2}(T_0)}$$

Where:

Segment A = represents the absorbance value of the matrix wave-length λ2.

Segment B = represents the absorbance value of the matrix wave-length λ1.

BCF = represents the Bichromatic Correction Factor.

$Abs_{\lambda 2}(T_0)$ = represents the absorbance of the sample at time T_0 taken at the wave-length λ2.

The Bichromatic Correction Factor (BCF) is a numerical factor which permits evaluation of the matrix value at the wave-length λ1 by means of a reading taken at the wave-length λ2. The BCF is given by the ratio between the reading on λ1 and the reading on λ2 (please refer to the following section):

$$BCF = \frac{\text{Segment B}}{\text{Segment A}}$$

Corrections to the Depletion Limit (DL) are carried out automatically by the *SAT450* software program 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:

- activate in the method parameters (see *Chapter 03 – Software description [Section Methods]* 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 statistic mean 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)	
		$\lambda 1 = 340\mu m$		
Abs	Times		Abs	Times
1.2931 RBL_{340}	0		**1.7251 Smp_{340}**	0
1.2981	69.9		1.5445	69.9
1.2984	95		1.5152	95
1.2979	121		1.4867	121
1.2982	148.2		1.4600	148.2
1.2987	172.8		1.4317	172.8
1.2985	198.8		1.4032	198.8
1.2993	226.8		1.3763	226.8
1.2998	250.6		1.3488	250.6
		$\lambda 2 = 380\mu m$		
0.1988 RBL_{380}			**0.5719 Smp_{380}**	

Increase of absorbance due to the Sample reaction (Rgt + Smp) at 340 nm equal to:

$$\textbf{Smp Blk}_{340} - \textbf{RBL}_{340} = 1.7251 - 1.2931 = 0.432$$

Increase of absorbance due to the reaction (Rgt + Smp) at 380 nm equal to:

$$\textbf{Smp Blk}_{380} - \textbf{RBL}_{380} = 0.5719 - 0.1988 = 0.3731$$

$$\textbf{BICHROMATIC CORRECTION FACTOR} = \frac{0.432 \quad (\Delta Abs\ 340\ nm)}{0.3731\ (\Delta Abs\ 380\ nm)} = 1.1578$$

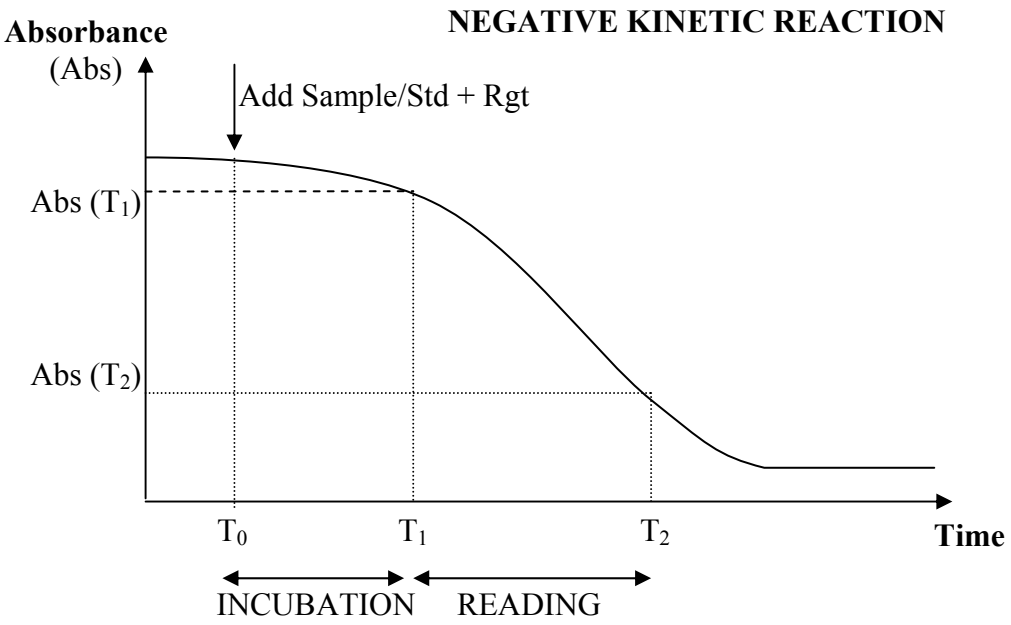
Note: the absorbance values used in the calculation are representative of the absorbance mean of 30 samples.

6.13 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 (ΔAbs/min), and not with absolute absorbance values.

For each "Kinetic" test, the system carries out a number of readings expressed in optical density, respectively at time T_0, and "n" readings between T_1 to T_2 according to the incubation and reading time defined in the method parameters (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

The following discussion refers specifically to Kinetics Methods, Monoreagent, Monochromatic, <u>with at least one RBL replicate and with a Single Standard Calibration (Standard Calculation Model)</u>.
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 (ΔAbs/min) is used to produce the Analytical result.



Analytical Result = CF x (SLOPE – RGT Rate) x Method Multiplier Factor

$$CF = \frac{\text{STD Concentration}}{(\text{SLOPE}_{STD} - \text{RGT Rate})}$$

where:

T_1 - T_0 = Incubation Time

T_2 - T_1 = Reading time

CF = Calibration Factor, is automatically evaluated by the software according to the specified formula. This value is displayed in the calibration results window (Factor field of the Main area).

SLOPE = (ΔAbs/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 criterion of least squares. With reference to bichromatic reactions, for the calculation of ΔAbs/min. instead of the absorbance at the F1 wavelength, the difference between the absorbances at F1 and F2 wavelengths is considered.

RGT RATE = the reagent rate is the mobility of the reagent itself during the reaction expressed in Absorbance (Abs(T_2) Reagent - Abs(T_1) Reagent) This value is automatically calculated during the phase of calibration; the value is displayed in the Calibration Results mask (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). The RGT Rate correction could be positive or negative according to the direction of the reaction (Up or Down).

Method Multiplier Factor = The Method Multiplier Factor for calculating the enzyme activity is directly correlated to the following parameters:

- temperature
- optical path length
- reagent-serum dilution ratio
- coefficient of the molar extinction of the co-enzyme detector
- reading time

The Method Multiplier Factor can be set through the Factor Field that appears in the Patameter Methods Mask of the software (please refer to *Chapter 03 – Software description [Section Calibration Results]* of the present manual). Default value for this field is set to 1.

The general formula for the determination of the calibration factor for enzyme activity calculation is the following:

$$\text{Method Multiplier Factor} = \frac{Vt}{Vs \times O.T. \times \varepsilon}$$

where:

Vt = Sample volume + Reagent volume

Vs = Sample volume

For Vt and Vs it is necessary to use an identical unit of measure (i.e. µl)

O.T. = Optical path length (cm)

ε = Molar extinction coefficient at the specified wave-length λ

Note that the Incubation Time can be set by the user choosing the correct value of the Incubation Times (sec) of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Note that the Reading Time can be set by the user choosing the correct value of the Read Times (sec) field of the Method mask (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual).

Furthermore in Kinetic Methods it is used a control parameter: the Linear correlation coefficient. 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 (please refer to *Chapter 03 – Software description [Section Methods]* of the present manual), the result is flagged "**A**".

Note

For Kinetics Methods, Monoreagent, Monochromatic, with at least one RBL replicate and <u>with a Factor Calculation Model</u>, the Analytical Result is evaluated according to the previous formula without considering the CF element.

In this case, the Method Multiplier Factor is displayed in the calibration results window (Factor field of the Main area).

Note

For Bichromatic Kinetics Methods, the Analytical Result is evaluated according to the same Monochromatic Kinetics Methods formula

6.14 USE OF REPLICATES IN STANDARD AND RBL CALCULATION

Whenever either the RBL or the Standard Replicates is set to a value greater than 2, the following criterium is used in order to obtain the RBL or Standard value needed to calculate the concentration. The final RBL/STD value is the average of the measured replicates, once the replicate which lies furthest from the average based on all the replicates is discarded.

Let $\{x_i\}$, with i=1, …, N, be the set of all the replicates. First, the average X_N=(x1 + … + xN)/N is calculated. The replicate to be excluded, say i*, is such that $|x_{i*} - X_N| = \max_{i=1,\ldots,N} (|x_i - X_N|)$. The final RBL/STD value X* is the average calculated from the reduced set of replicates, i.e., $X^* = (x_1 + \ldots + x_N - x_{i*})/(N-1)$.

Those replicates for which the “low reagent level”, “low sample level”, i.e., low H_2O level, “generic error”, or “calculation error” flag has been raised are excluded from the calculation. For the STD replicates, also the “missing RBL” flag causes the exclusion. This means that if, for instance, the RBL Replicates is 3, but the third replicate shows the “low reagent level” flag, the effective replicate number is 2 and the above criterium is not applied.

CHAPTER 07

- USER MAINTENANCE -

INDEX

7 USER MAINTENANCE…….2
7.1 PREVENTIVE MAINTENANCE…….2
7.2 SAMPLING PROBE – Cleaning procedure…….3
7.3 WASHING STATION PROBES – Cleaning procedure……..……..……...3
7.4 FOUR LIQUID RESERVOIR BOTTLES – Cleaning procedure….……..……..……3
7.5 DRYING PAD – Cleaning procedure ……...……4
7.6 PROCEDURE FOR REPLACING THE DRYING PAD……..5
7.7 HYDRAULIC CIRCUIT – Washing procedure..……...6
7.8 REPLACEMENT OF THE PHOTOMETER HALOGEN LAMP……..……..6
7.9 REPLACEMENT OF THE REACTION CUVETTES…….……..…7
7.10 USER MAINTENANCE PROCEDURES...……..8
7.11 REPLACEMENT OF THE SAMPLING PROBE…….9
7.12 ISE MODULE……...10

7 USER MAINTENANCE

This chapter contains all those routine operations, which concern *SAT450* instrument maintenance. Said procedures for the user/operator, listed and described below, should be carefully and scrupulously followed in order to guarantee the specifications and the perfect working order of the instrument over time.

7.1 PREVENTIVE MAINTENANCE

The 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 *SAT450* instrument.

FREQUENCY	PROCEDURE	NOTES
DAILY – Before launching "Start Work"	Check the levels of the four liquid reservoir bottles I, II, III and IV and, if necessary, fill their bottles	
DAILY – Before launching "Start Work"	Check the levels of the Reagents, Standards and Controls	
DAILY – Before launching "Start Work"	Check the levels of the two waste tanks and, if necessary, empty them	
DAILY – Before to start with daily routine	Carry out a WBL cycle	
DAILY – After Shutdown	Clean the Sampling Probe using either paper towel or gauze	See Section 7.2

Table A – Maintenance Schedule (*Daily*)

FREQUENCY	PROCEDURE	NOTES
EVERY TWO WEEKS	Clean the (four) Washing Station probes	See Section 7.3
EVERY TWO WEEKS	Clean the four liquid reservoir bottles	See Section 7.4
ONCE A MONTH	Clean the Pad	See Section 7.5
ONCE A MONTH	Clean the Hydraulic Circuit	See Section 7.7
EVERY THREE MONTHS	Change the Reaction Cuvettes	See Section 7.9
EVERY SIX MONTHS	Change the Pad	See Section 7.6
EVERY 2000 HOURS	Change the Photometer Halogen Lamp	See Section 7.8

Table B – User Maintenance Schedule

7.2 SAMPLING PROBE – Cleaning procedure

Use only lint free paper towel or gauze.

1. Make sure that the *SAT450* instrument is turned off.
2. Dampen the gauze or the paper towel with distilled water and clean the outside of the Sampling Probe. ***Note:*** *wipe the Probe from the top downwards only! This is to avoid that any bits of cloth, paper or lint fibres accidentally enter inside the Probe.*

It is suggested that once weekly the above described cleaning procedure must be performed using a 5% sodium hypochlorite solution instead of distilled water to dampen the gauze or the paper towel. Then, repeat the procedure using distilled water.

7.3 WASHING STATION PROBES – Cleaning procedure

Use only lint free paper towel or gauze.

1. Make sure that the *SAT450* instrument is turned off.
2. Place a sheet of paper under the Washing Station probes in order to keep any extraneous material from accidentally downfall into the reaction cuvettes.
3. Dampen the gauze or the paper towel with distilled water and clean the outside of the probes (with the exception of the last probe). ***Note:*** *wipe the probes from the top downwards only! This is to avoid that any bits of cloth, paper or lint fibres accidentally enter inside the probes.*
4. Remove the sheet of paper from under the Washing Station probes.

It is suggested that once monthly the above described cleaning procedure must be performed using a 5% sodium hypochlorite solution instead of distilled water to dampen the gauze or the paper towel. Then, repeat the procedure using distilled water.

7.4 FOUR LIQUID RESERVOIR BOTTLES – Cleaning procedure

During a normal use and over time, mold and dust can build up inside the four liquid reservoir bottles. For this reason, it is extremely important that they be periodically washed. The 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, it is recommended to make 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 four liquid reservoir bottles are located on the side of the instrument inside their container.

- **Cleaning procedure for the four liquid reservoir bottles:**

1. Make sure that the *SAT450* instrument is turned off.
2. Take the caps and the straws off from the bottles and empty them.
3. Fill each bottle with a 5% sodium hypochlorite solution.
4. Clean the inside of each bottle using a bottle-brush in order to remove all traces of mold and/or residue.
5. Leave the sodium hypochlorite solution stand in the bottles for at least ten minutes.
6. Empty the bottles, rinse them repeatedly and well with tap water, then twice more using distilled water.
7. Dry the bottles.
8. Fill the bottles with their proper solutions.
9. Replace the bottles in their respective positions inside the container.
10. Close the bottles with their caps, insert the straws in them and turn on the instrument.
11. Carry out two 'Washing Cuvettes' cycles and two 'WBL' cycles. Check the system efficiency by comparing the WBL values and the test results obtained against the laboratory's quality control values.

7.5 DRYING PAD – Cleaning procedure

The Pad is used to dry the cuvettes after they have been washed. This drying process is carried out via aspiration and therefore, over time, the Pad will necessarily absorb various contaminating particles.

It is suggested that the Pad 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 Pad must be washed regularly in order to guarantee proper functioning and must be replaced - if necessary - with a new Pad.

- **Cleaning procedure for the Pad:**

1. Make sure that the *SAT450* instrument is turned off.
2. Unscrew the fastening screw of the Washing Station cover and remove the cover from its place on the Raising Top.
3. Unscrew the four fastening screws of the Washing Station tubes cover and remove the cover from the Washing Station.
4. Remove the probe that contains the Pad (the *Probe 5*) and its spring.
5. Disconnect the aspiration tube.
6. Once the probe has been removed, immerge it in a 5% solution of sodium hypochlorite for at least 15 minutes.

7. Attach a 10 ml syringe to the probe, then aspirate and dispense the hypochlorite solution through the probe (and the Pad) until the latter is completely clean. This aspirating and dispensing forces the liquid through the Pad fibers in both directions.
8. Once the Pad is clean, repeat the aspirating and dispensing cycle 10 more times using distilled water, then disconnect the syringe.
9. Reconnect the aspiration tube to the probe.
10. Re-position the probe in its housing being careful to not kink the aspiration tube.
11. Re-position the spring on the probe.
12. Re-position the tubes cover of the Washing Station – making sure that the cylindrical tops of the probes fit into the corresponding holes on it – and screw its four fastening screw.
13. Manually move the Washing Station downwards and centre the pad with the reaction cuvette turning it.
14. Re-position the Washing Station cover and screw its fastening screw.

7.6 PROCEDURE FOR REPLACING THE DRYING PAD

1. Make sure that the *SAT 450* instrument is turned off.
2. Unscrew the fastening screw of the Washing Station cover and remove the cover from its place on the Raising Top.
3. Unscrew the four fastening screws of the Washing Station tubes cover and remove the cover from the Washing Station.
4. Remove the probe that contains the Pad (the *Probe 5*) and its spring.
5. Disconnect the aspiration tube.
6. Remove the used Pad and replace it with a new one.
   Note: *press lightly to push the new Pad into place – be careful to not press too hard as this could deform the Pad.*
7. Insert the probe containing the new Pad into a reaction cuvette, pushing it down inside until it takes on the shape of the inside of the cuvette.
8. Remove the cuvette, connect the aspiration tube to the probe and reposition the probe back into its proper housing in the Washing Station. ***Note:*** *be careful to not kink the aspiration tube while doing so.*
9. Re-position the spring on the probe.
10. Re-position the tubes cover of the Washing Station – making sure that the cylindrical tops of the probes fit into the corresponding holes on it – and screw its four fastening screw.
11. Manually move the Washing Station downwards and centre the pad with the reaction cuvette turning it.
12. Re-position the Washing Station cover and screw its fastening screw.

7.7 HYDRAULIC CIRCUIT – Washing procedure

During normal use and over time, mold and dust can build up inside the bottles and can have a negative effect on the hydraulic circuit, compromising the correct functioning of the micropumps and electrovalves. 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. It is recommended to make 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 straws are located inside the liquid reservoir bottles on the side of the instrument.

- **Washing procedure for the Hydraulic Circuit:**

1. Make sure that the *SAT450* instrument is turned on.
2. Prepare a bottle containing 500 ml of a 5% sodium hypochlorite solution.
3. Insert the four aspiration straws, located inside the liquid reservoir bottles, into the bottle containing the sodium hypochlorite solution.
4. Carry out a ‘WBL’ cycle and then a ‘Washing cuvettes’ cycle.
5. Wait for fifteen minutes. Clean and dry the four straws and then insert them into a bottle containing distilled water.
6. Carry out a ‘WBL’ cycle and then a ‘Washing cuvettes’ cycle.
7. Insert the four aspiration straws back into their respective bottles. In the meantime, said bottles should have been cleaned and filled with a fresh supply of the required solution.
8. Carry out a ‘Washing cuvettes’ cycle and then a ‘WBL’ cycle. Check the system efficiency by comparing the WBL values and the test results obtained against the laboratory’s quality control values.

7.8 REPLACEMENT OF THE PHOTOMETER HALOGEN LAMP

It is suggested that the halogen lamp be replaced after approximately 2000 hours of use.

The halogen lamp is mounted on the Photometer, which is located on the side of the Reactions Plate.

- **Replacement procedure**:

1. Make sure that the *SAT450* instrument is turned off.
2. Unscrew the two captive screws on the front underside of the instrument and lift up the Raising Top.
3. Unscrew the two screws of the J2 connector of the “Photometer Halogen Lamp” and take out the two lamp wires from the connector.

Fig. 1 – Photometer Halogen Lamp [P/N: 09-35-0016-00]

4. Unscrew the lamp fastening screw and remove the lamp keep plate from the Photometer.
5. Take out the Photometer Halogen Lamp from its emplacement on the Photometer.

To replace the new Photometer Halogen Lamp **(Fig. 1)** perform the following steps:

Do not touch glass portion of Photometer Halogen Lamp with your hands.

6. Repeat the above steps in inverse order: from 5 to 3.
7. Bring down the Raising Top and screw the two captive screws on the front underside of the instrument.
8. Turn on the *SAT 450* instrument and wait until the instrument has reached its proper operating temperature.
9. Carry out a 'Washing cuvettes' cycle and then a 'WBL' cycle. Check the WBL results: if the cuvettes are acceptable to use then the instrument is ready to start again immediately, otherwise **contact Technical Service Support**.

7.9 REPLACEMENT OF THE REACTION CUVETTES

Over time and through normal use the perfect transparency of the cuvettes diminishes. This has a negative impact on the quality of the optical readings. It is suggested that the cuvettes be replaced after three months of use. The four Reactions Plate Racks are located inside the Reactions Plate.

❑ Replacement procedure of one Reactions Plate Rack:

1. Remove the Reactions Plate cover from its housing.
2. Unscrew the two fastening pommels of the Rack.
3. Remove the Rack from its housing and replace it with a new one.

   Note: make sure to reinsert the new Rack in the Reactions Plate vertically.

4. Screw the two fastening pommels in order to fix the Rack.

Be especially careful to not touch the external surface of the reaction cuvettes dedicated to photometric reading.

5. Replace the Reactions Plate cover on the Reactions Plate.
6. Carry out a 'Washing cuvettes' cycle and then a 'WBL' cycle. Check the system efficiency by comparing the WBL values and the test results obtained against the laboratory's quality control values.

7.10 USER MAINTENANCE PROCEDURES

The following table is a list of the maintenance procedures that can be performed by the operator.

Note: *the frequency indicated in the table may vary according to the individual instrument's daily workload.*

PROCEDURE	FREQUENCY	EFFECTUATED BY
CLEANING THE SAMPLING PROBE	DAILY	OPERATOR
CLEANING THE FOUR WASHING STATION PROBES	EVERY TWO WEEKS	OPERATOR
CLEANING THE FOUR LIQUID RESERVOIR BOTTLES	EVERY TWO WEEKS	OPERATOR
REPLACING THE REACTION CUVETTES	EVERY THREE MONTHS	OPERATOR
CLEANING THE PAD	ONCE A MONTH	OPERATOR
REPLACING THE PAD	EVERY SIX MONTHS	OPERATOR
REPLACING THE PHOTOMETER HALOGEN LAMP	AFTER 2000 HOURS OF USE	OPERATOR
REPLACING THE SAMPLING PROBE	AS NEEDED	OPERATOR
CLEANING THE HYDRAULIC CIRCUIT	ONCE A MONTH	OPERATOR

7.11 REPLACEMENT OF THE SAMPLING PROBE

- **Removing of the Sampling Probe**:

1. Turn on the *SAT 450* system (instrument and computer) and launch the "Diagnostic" program.
2. Select "Miscellaneous" folder and request an Instrument General reset. Wait until the reset instrument procedure has been completed.
3. Turn off the *SAT 450* instrument and lift up the instrument cover.
4. Remove the Sampling Probe from its housing by unscrewing (clockwise) its ring nut (**Fig. 2**).

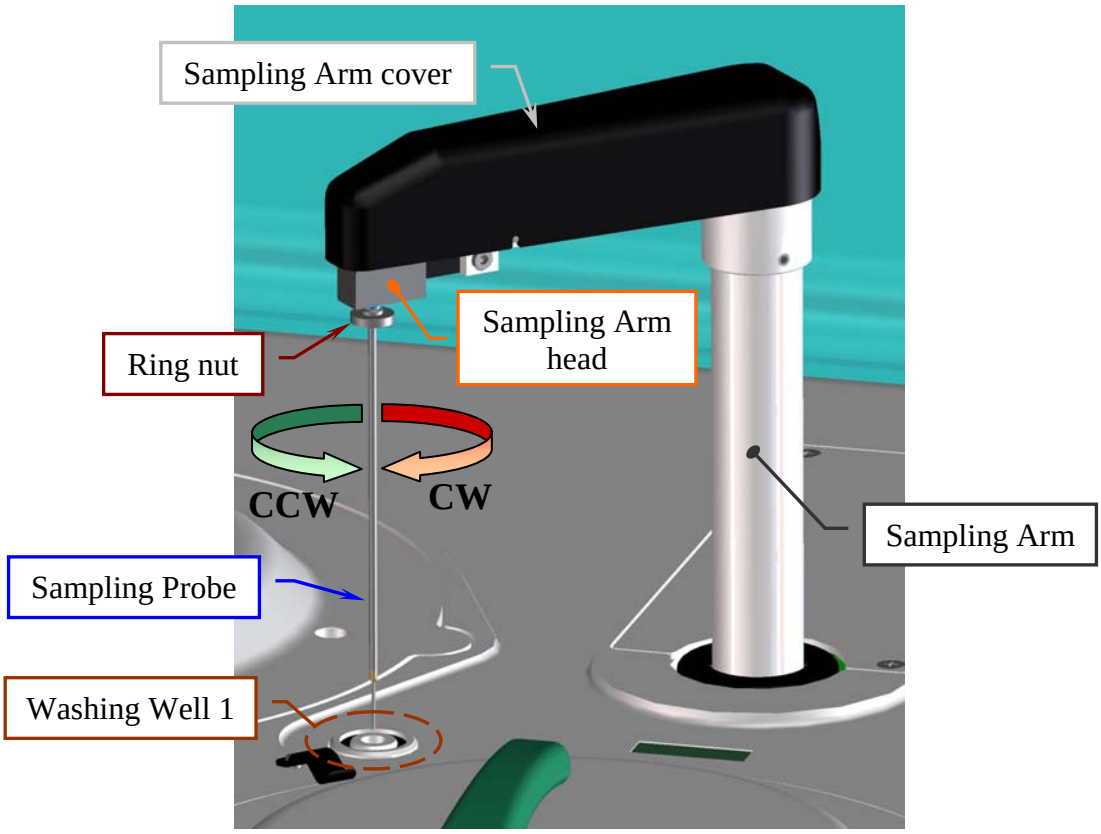


Fig. 2 – Sampling Probe

- **Replacement of the Sampling Probe**:

5. Turn on the *SAT 450* system (instrument and computer) and launch the "Diagnostic" program.
6. Select "Miscellaneous" folder and request an Instrument General reset. Wait until the reset instrument procedure has been completed.
7. Turn off the *SAT 450* instrument and lift up the instrument cover.
8. Attach the (straight) Sampling Probe to the Sampling Arm head (**Fig. 2**).
9. Rotate slowly (counter clockwise) the Sampling Probe ring nut in its thread hold until you feel the stop (**Fig. 2**), then screw tight.
10. Make sure that the Sampling Probe is vertically aligned and centered with respect to the Washing Well 1.

7.12 ISE MODULE

⇒ Maintenance Schedule

The Electrolyte Measurement System has been designed to require very little operator maintenance. The only daily maintenance required is to run the Cleaning Solution after the last sample of the day. All other parts and expendables are replacement items (see schedule below).

- **Recommended Component Maintenance/Replacement Schedule (low volume user):**
  - Pump Cassette 9 months
  - Na^+ Electrode 6 months
  - K^+ Electrode 6 months
  - Cl^- Electrode 6 months
  - Reference Electrode 6 months
- **Recommended Maintenance/Replacement Schedule (greater than 100 samples/day):**
  - Pump Cassette 6 months
  - Na^+ Electrode 10,000 samples
  - K^+ Electrode 10,000 samples
  - Cl^- Electrode 10,000 samples
  - Reference Electrode 10,000 samples
- **Electrode Shelf Life:**
  - Na^+ Electrode 9 months
  - K^+ Electrode 9 months
  - Cl^- Electrode 12 months
  - Reference Electrode 12 months

⇒ Shutdown Procedure: preparing the ISE Module for storage

If the laboratory plans to store the ISE Module for a period greater than one week, during which the analyzer will not be connected to power, the following steps should be performed: before removing the electrodes, they should be cleaned using the Cleaning Solution and then running 3 <PURGE> cycles. Enter the Maintenance Cycle of the analyzer which purges all fluid from the analyzer fluid path.

- **Reference, Na^+, Cl^- electrodes:**
  - Depress the compression plate and remove all electrodes, including the reference electrode from the sensor module.
  - Place the Reference, Na^+ and Cl^- electrodes into individual sealed bags.
- **K^+ electrode:**
  - Aspirate a small volume of Calibrant A from the top port of the reagent module into a syringe fitted with a blunt needle.
  - Inject sufficient Calibrant A into the lumen of the K^+ electrode until fluid fills the lumen.
  - Cover both ends of the lumen (both sides of the K^+ electrode) with cellophane tape to hold the Calibrant A in place.
  - Insert the K^+ electrode into a sealed bag.

- **Calibrant A:**
  - Remove the Calibrant A from the analyzer and discard it.

- **Analyzer re-activation:**
  - Remove all electrodes from sealed bags.
  - Remove cellophane tape from K^+ electrode.
  - If necessary, soak the reference electrode in warm water until the lumen of the electrode has been cleared of salt build-up.
  - Place electrodes into the sensor module (mounting before the Reference electrode, then – in order – the Cl^-**,** K^+ and Na^+ electrodes).
  - Place new Calibrant on analyzer.
  - Calibrate analyzer.

The electrodes are sensible to electric charge, electric shock, dirt and handling.

It's important avoid in any way electric shocks and keep them tidy.

Make sure the absence of air bubbles in the hydraulic circuit of the analyzer during the Purge cycles.

CHAPTER 08

- DAILY ROUTINE -

INDEX

8.1 DAILY ROUTINE 2
8.2 STAND-BY FUNCTION 3

In this chapter the main operations are resumed for the correct execution of the analytical routine on the *SAT 450* instrument.

8.1 DAILY ROUTINE

The operation listed below have to be carried out in sequential order:

⇒ Switch on the analytical module of the *SAT 450*, the computer and the peripheral equipment (e.g. the printer).

⇒ Launch the *SAT 450* program.

⇒ Wait until the work-temperature has been reached (wait for the activation of the Power On signal in the System Monitor).

⇒ Control the liquid level in the four liquid reservoir bottles and in the two waste tanks.

⇒ If the *SAT 450* has remained unused for more than 24 hours (e.g. during the weekend), execute a cuvette washing cycle.

⇒ Execute the "Autozero" of the cuvettes (WBL *Water Base Line* or *Water Blank Level*) by pressing the designated key in "Start" mask.

⇒ Evaluate the "Autozero" results.

⇒ Verify the reagents configuration in the "System Monitor".

⇒ Verify reagent supply levels (see "Reagent Map by Tray Position" mask under the "Checks" menù).

⇒ Verify the validity of the current calibration by running the controls. If necessary, carry out a new calibration.

⇒ Program the routine by introducing the patients data and the requested analysis manually or by receiving the requests from the Host Computer, if the *SAT 450* is integrated into the information system of the laboratory ("Work List" mask).

⇒ Prepare the sample cups/tubes in the dedicated rotors.

⇒ Run the routine.

⇒ Examine the results (shown on the video); evaluate them and decide (when necessary) to request the re-run of a specific analysis.

⇒ Transmit the results to the Host Computer (if the *SAT 450* is integrated into the information system of the laboratory).

⇒ Print out the analysis results.

⇒ Archive the analysis results.

⇒ When the work has finished, close the *SAT 450* program and switch off the Peripheral Equipment.

⇒ Switch off the analytical module or leave it in "Stand-By".

⇒ Clean the sampling probe using either paper towel or gauze.

NOTE: ALWAYS REMOVE ALL THE CUPS/TUBES USED.

8.2 STAND-BY FUNCTION

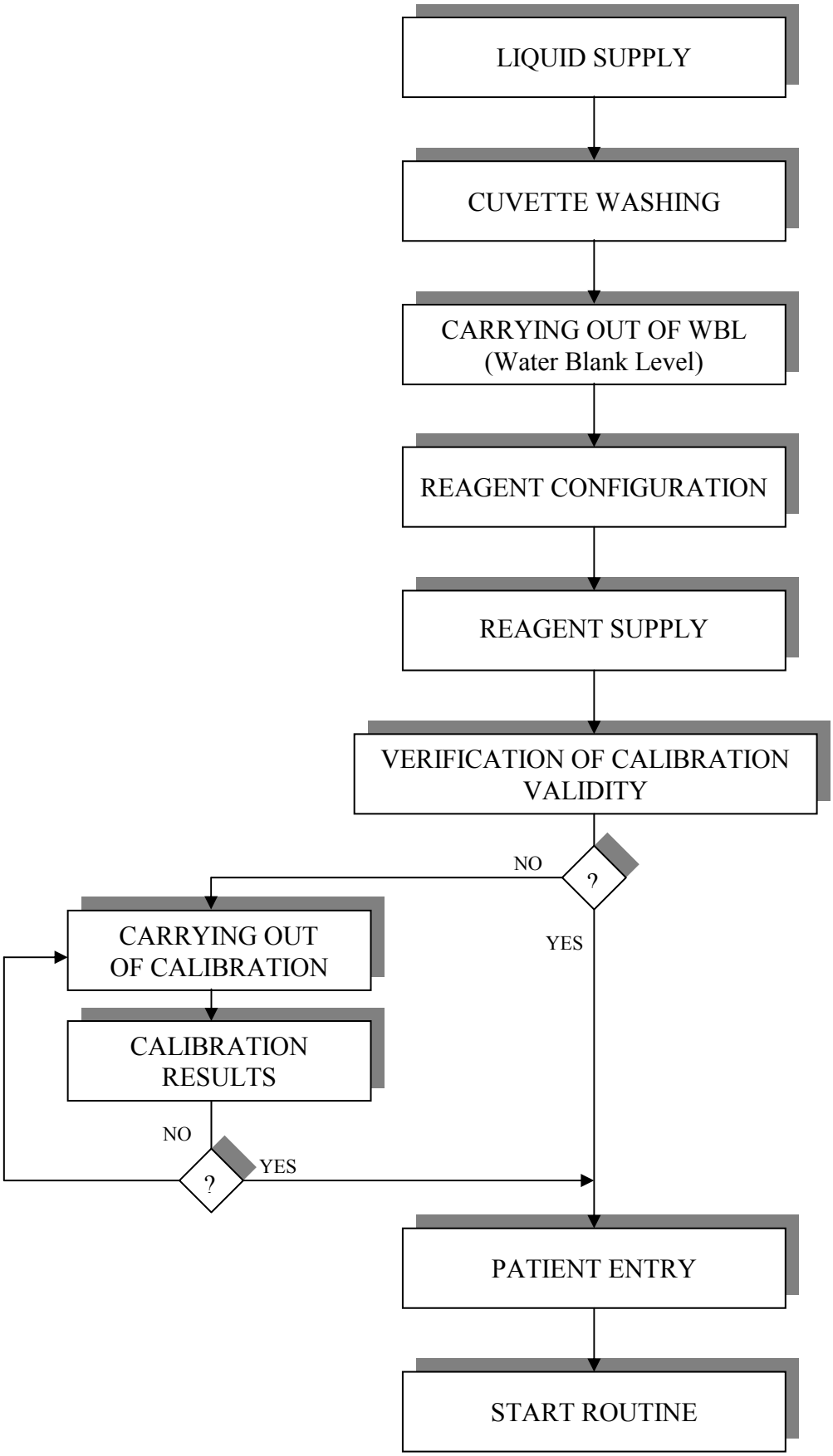
In the eventuality that the laboratory needs to process the samples throughout the span of the entire day (small batches taken outside of the normal routine, Stat, etc.), it is appropriate to keep the instrument in the "Stand-by" condition. This condition reduces the time required for the reaction plate temperature stabilization.

During “Stand-By”, the principal functions of the instrument are kept active (reagents cooler, temperature of reaction plate, low voltage supply of the photometric lamp). Thus immediate execution of the samples that have arrived unexpectedly, is possible.

The instrument enters in 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 *SAT 450* program is closed.

DAILY ANALYTICAL ROUTINE OPERATIONS



CHAPTER 09

- ERROR SIGNALLING AND TROUBLESHOOTING -

INDEX

9.1 ERROR SIGNALLING 2
9.1.1 SYSTEM ERRORS 2
9.1.2 RESULT FLAGS 3
9.1.2.1 Description of the Result Flags 4
9.1.2.2 Special cases for the result visualization 6
9.1.2.3 Liquid alarms visualization 8
9.1.2.4 Synopsis of the result errors 10
9.2 TROUBLESHOOTING GUIDE 13
9.3 ISE MODULE - TROUBLESHOOTING GUIDE 14
9.4 SYSTEM ERRORS MANAGEMENT 20
9.4.1 REAGENTS PLATE SATELLITE RACKS (PY Error) 27
9.4.2 REAGENTS PLATE (PR Error) 29
9.4.3 SAMPLES PLATE SATELLITE RACKS (CB Error) 30
9.4.4 SAMPLES PLATE (PX Error) 30
9.4.5 HORIZONTAL MOVEMENT ARM (BA, BH, BB, BS Error) 31

9 ERROR SIGNALLING AND TROUBLESHOOTING

9.1 ERROR SIGNALLING

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 System Monitor screen. It lights up yellow when activated.

If this yellow triangle lights up, the operator needs simply to 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:

- Low Liquid Level I (Probe Rinse Solution)
- Low Liquid Level II (Distilled Water)
- Low Liquid Level III (Basic Wash Cleaning Solution)
- Low Liquid Level IV (Acid Wash Cleaning Solution)
- System in pause due to liquid alarm
- Plate temperature above maximum (incubation temperature)
- Plate temperature below minimum (incubation temperature)
- Arm Heater Time Out
- Waste I alarm
- Waste II alarm
- System in pause due to waste alarm
- Sample cover open
- Reagent cover open
- Cover lock
- Host communication error
- ISE Module not responding
- ISE module: establishing connection
- ISE module: Calibrant A empty
- ISE module: Calibrant A low volume

Please note that a special message box over System Monitor will appear to the user if the instrument is in running operation and occurs at least one of the following warnings: Low Liquid Level I, Low Liquid Level II, Low Liquid Level III, Low Liquid Level IV, Waste I alarm, Waste II alarm.

- **Emergency Stop** Light: an "X"-shape located in the System Monitor mask. It lights up red when activated.

If this red "X" lights up, the operator needs simply to click on it to access the relative visual text message explaining the cause of the Emergency Stop (said window will open in that area dedicated to viewing data).

Following is a list of possible Emergency Stop visual text messages:

- Horizontal movement Arm (BA Error) – position sensor not found over Reagents Plate
- Horizontal movement Arm (BB Error) – home sensor not found
- Horizontal movement Arm (BH Error) – position sensor not found
- Horizontal movement Arm (BS Error) – wrong steps number in home position
- Vertical movement Arm (AZ Error)
- Filter (FI Error)
- Drum Filter (FE Error)
- Data ADC Conversion (CD Error)
- Reference ADC Conversion (CR Error)
- Reagents Plate (PR Error)
- Reagents Plate Satellite Racks (PY Error)
- Samples Plate (PX Error)
- Samples Plate Satellite Racks (CB Error)
- Reactions Plate (RP Error)
- Wash Station (WH Error)
- Diluter (DO Error)
- Time Out
- Time Out (SW Error)
- Instrument not responding

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 **OPTICAL DENSITY ERRORS**

E **RESULTS EDITED MANUALLY**

I **ISE MODULE ERRORS**

? **GENERIC ERROR**

Every Result Flag, signalling an error, is accompanied by a symbol representing the pertinent group. The operator needs simply to move the mouse on 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 encountered, as used in the print-out of the final report. These symbols can be modified by the operator in the "Print Options" form of the "Parameters" section.

Note	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.

9.1.2.1 DESCRIPTION OF THE RESULT FLAGS

X Physical *Errors*		
Plate Temperature Error	**T**	Reaction temperature (of the Reactions Plate) is out-of-range.
Arm Temperature Error	**T**	Arm temperature reading failed (either no measure obtained or arm heater time out)
Short Sample	**S**	Either no sample or sample serum quantity below minimum for the declared container.
Sample Level Detection Error	**S**	Sample serum quantity above maximum level for the declared container.
Short Reagent	**R**	Either no reagent (diluent) or reagent (diluent) level below minimum for the declared container.
Reagent Level Detection Error	**R**	Reagent (diluent) level above maximum level for the declared container.
Short auxiliary liquid	**R**	Either no special wash (acid or basic) or reagent (acid or basic) level below minimum for the declared container.
Auxiliary liquid level detection error	**R**	Special wash (acid or basic) level above maximum level for the declared container.
Optical density outside photometer linearity range	**P**	Optical density outside photometer linearity range.

R Concentration *Errors*		
Low and High	**L-H**	Flags determined by test results out-of-range as setup in the Methods.
Very Low and Very High	**P**	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.
Below Method Linearity Low Limit **Above Method Linearity High Limit**	**G**	Flags determined by test results out-of-range as setup in the Methods.
Calculation Error	**C**	Concentration calculation error due to foreseeable causes (asymptote).

C Calibration *Errors*

Reagent Blank Missing	*	No Reagent Blank Level.
Standard or Calibration Curve missing	*	No Standard or no Calibration curve.
Number of valid results not enough	*	The obtained standard or RBL results are not enough to get a significant value to be used for calculating sample concentration.
CV% among replicates greater than the set value on method	*	Percentage Coefficient of Variation in the Standard Replicates over the set value.
Edited or not valid Calibration Curve: e.g., non monotonic or poor FIT	*	The calibration curve is either edited or not monotonic, or the resulting Fit value is out of range, or at least one of the calibration point does not satisfy the constraints set in the method definition.
RBL: reagent changed	*	The RBL values used has been run with reagents different from those on the current plate.
RBL poor quality	*	The RBL values used for the sample or the control do not fulfil all the chosen constraints.
Calibration and/or RBL expired	*	The RBL and/or calibration used for the sample or the control is expired.
Calibration Factor Out of range	*	Calibration factor outside the defined range.

A Optical Density *Errors*

Inversion of reaction direction	**I**	Reaction direction not in line with that set-up.
End Point Limit: **EP Limit > than method set value**	**P**	Values over the limits setup in the Methods Parameters.
KI and FT: **Depletion Limit > than method set value**	**D**	Values over the limits setup in the Methods Parameters.
Fixed Time: **First Limit > than method set value**	*	Values over the limits setup in the Methods Parameters.
Kinetic: **FIT > than method set value**	**F**	Values over the limits setup in the Methods Parameters.
RBL out of method set value	*	Reagent Blank Levels outside the range defined.
Optical Density **> than last standard point**[1]	#	Sample/control absorbance lies outside the Optical Density range determined by the related standard.

[1] This flag does not apply to following Calculation Models: Linear and Point to Point.

Optical Density < than first standard point[1]	**#**	Sample/control absorbance lies outside the Optical Density range determined by the related standard.
Reagent Expired	**!**	The Reagent Lot has expired.
Reagents stability days on board expired	**-**	The Reagent on Board stability has expired.

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 except for the concentration errors excluded the calculation error.

I ISE Module Errors

Air in ISE Module	*****	Air in ISE Module
Noise in ISE Module	*****	Noise in ISE Module
Air in ISE Calibrant B	*****	Air for Calibrant B
Noise in ISE Calibrant A	*****	Noise for Calibrant A
Air in ISE Calibrant A	*****	Air for Calibrant A
Drift in ISE Calibrant A	*****	Drift in Calibrant A
Result Out Range in ISE Module	*****	Result out of Range as set for the ISE Module
Na Error in ISE Module	*****	Na urine error
ISE Module not properly calibrated	*****	Related to the calibration, this flag rises up after an ISE module restart or if during a calibration the result obtained for at least one electrode (K, Na, Cl) is 0. This flag is added to the ISE calibration only after the execution of a control or sample following one of the previous cases.

? Generic Error

All those software errors - which are deemed unforeseeable - are indicated using this symbol.

9.1.2.2 SPECIAL CASES FOR THE RESULT VISUALIZATION

Result Asterisk

In the event that the following situations and/or error conditions occur, the system will notify the user via a visualization of one asterisk (*****) in the Results field:

- PHYSICAL ERRORS
  1. Short sample
  2. Sample Level Detection Error
  3. Short reagent
  4. Reagent Level Detection Error
  5. Short auxiliary liquid
  6. Auxiliary liquid level detection error
  7. Optical density outside photometer linearity range
- CONCENTRATION ERRORS
  8. Calculation error
- CALIBRATION ERRORS
  9. Reagent blank missing
  10. Standard or Calibration curve missing
  11. Number of valid results not enough (RBL and/or Calibrations)
  12. Edited or not valid Calibration Curve: e.g., non monotonic or poor FIT[2]
- GENERIC ERROR
  13. All cases
- ISE ERRORS
  14. Air in ISE Module
  15. Noise in ISE module
  16. Drift in ISE Calibrant A
  17. Noise in ISE Calibrant A
  18. Air in ISE Calibrant A
  19. Air in ISE Calibrant B

[2] The Result field shows an asterisk only when the calibration curve or the calibration points are not monotonic.

< First Standard Concentration Value or > Last Standard Concentration Value

If the Optical Density of the sample/control lies outside the Optical Density range determined by the related standard and the curve fitting has an asymptote before the sample Optical Density, the Results field will contain the symbol "< First Standard Concentration Value" or "> Last Standard Concentration Value".

Less than or equal to zero Result

If the option "Report Negatives as zero" is activated any negative result will be rounded to zero if:

- either the sample or control absorbance lies outside the absorbance range obtained from the calibration process and the curve fitting has not any asymptote before the sample Optical Density (see the next special case for the result visualization);
- or the concentration is below the linearity minimum for those methods that require a single standard or no standard at all.

9.1.2.3 LIQUID ALARMS VISUALIZATION

A **sample/control** is represented by the software, in the System Monitor mask, using the red colour when at least one of the associated analysis is characterized by at least one of the following flags:

- PHYSICAL ERRORS
  1. Plate Temperature Error
  2. Arm Temperature Error
  3. Short Sample
  4. Sample Level Detection Error
  5. Short Reagent
  6. Reagent Level Detection Error
  7. Short auxiliary liquid
  8. Auxiliary liquid level detection error
  9. Optical density outside photometer linearity range
- CONCENTRATION ERRORS
  10. Below Method Linearity Low Limit
  11. Above Method Linearity High Limit
  12. Calculation Error
- CALIBRATION ERRORS
  13. Reagent Blank Missing
  14. Standard or Calibration Curve missing
- OPTICAL DENSITY ERRORS
  15. Inversion of reaction direction
  16. End Point Limit: EP Limit > than method set value
  17. KI and FT: Depletion Limit > than method set value
  18. Fixed Time: First Limit > than method set value
  19. Kinetic: FIT > than method set value

- GENERIC ERROR
  20. All Cases
- ISE ERRORS
  21. Air in ISE Module
  22. Noise in ISE Module
  23. Air in ISE Calibrant B
  24. Noise in ISE Calibrant A
  25. Air in ISE Calibrant A
  26. Drift in ISE Calibrant A
  27. Result Out Range in ISE Module
  28. Na Error in ISE Module

***Note**: with reference to a control it is considered the reference range too; if the control result lies outside the reference range, the control is represented by the software, in the System Monitor Mask, using the red colour.*

Water for RBL and standards are represented by the software, in the System Monitor mask, using the red colour when at least one of the associated analysis is characterized by at least one of the following flags:

- CONCENTRATION ERRORS
  1. Calculation Error
- OPTICAL DENSITY ERRORS
  2. Inversion of reaction direction
  3. End Point Limit: EP Limit > than method set value
  4. KI and FT: Depletion Limit > than method set value
  5. Fixed Time: First Limit > than method set value
  6. Kinetic: FIT > than method set value
  7. RBL out of method set value
- GENERIC ERROR
  8. All Cases
- CALIBRATION ERRORS
  9. Reagent Blank Missing
  10. Number of valid results not enough
  11. Calibration Factor Out of range
- ISE ERRORS
  12. Air in ISE Module
  13. Noise in ISE Module
  14. Air in ISE Calibrant B
  15. Noise in ISE Calibrant A
  16. Air in ISE Calibrant A
  17. Drift in ISE Calibrant A
  18. Result Out Range in ISE Module

9.1.2.4 SYNOPSIS OF THE RESULT ERRORS

Group Flag	Group Flag Symbol	Flag	Flag Symbol	Result Visualization	System Monitor Red Displayed (Liquid Type)
Physical Errors	X	Plate Temperature Error	T		SAMPLE / CONTROL
		Arm Temperature Error	T		SAMPLE / CONTROL
		Short Sample	S	*	SAMPLE / CONTROL
		Sample Level Detection Error	S	*	SAMPLE / CONTROL
		Short Reagent	R	*	SAMPLE / CONTROL
		Reagent Level Detection Error	R	*	SAMPLE / CONTROL
		Short auxiliary liquid	R	*	SAMPLE / CONTROL
		Auxiliary liquid level detection error	R	*	SAMPLE / CONTROL
		Optical density outside photometer linearity range	P	*	SAMPLE / CONTROL
Concentration Errors	R	Low and High	L-H		CONTROL
		Very Low and Very High	P		
		Low Alert and High Alert	A		
		Below Method Linearity Low Limit Above Method Linearity High Limit	G		SAMPLE / CONTROL
		Calculation Error	C	*	SAMPLE / CONTROL
Calibration Errors	C	Reagent Blank Missing	*	*	SAMPLE / CONTROL / STANDARD
		Standard or Calibration Curve Missing	*	*	SAMPLE / CONTROL
		Number of valid results not enough	*	*	RBL / STANDARD

Group Flag	Group Flag Symbol	Flag	Flag Symbol	Result Visualization	System Monitor Red Displayed (Liquid Type)
Calibration Errors	C	CV% among replicates greater than the set value on method	*		
		Edited or not valid Calibration Curve: e.g. non monotonic or poor FIT	*	*[2]	
		RBL: reagent changed	*		
		RBL poor quality	*		
		Calibration and/or RBL expired	*		
		Calibration Factor Out of range	*		STANDARD
Optical Density Errors	A	Inversion of reaction direction	I		SAMPLE / CONTROL / RBL / STANDARD
		End Point Limit: EP Limit > than method set value	P		SAMPLE / CONTROL / RBL / STANDARD
		KI and FT: Depletion Limit > than method set value	D		SAMPLE / CONTROL / RBL / STANDARD
		Fixed Time: First Limit > than method set value	*		SAMPLE / CONTROL / RBL / STANDARD
		Kinetic: FIT > than method set value	F		SAMPLE / CONTROL / RBL / STANDARD
		RBL out of method set value	*		RBL
		Optical Density > than last standard point[1] Optical Density < than first standard point[1]	#	< First Standard Concentration Value > Last Standard Concentration Value	
		Reagent Expired	!		
		Reagent stability days on board expired	-		

Group Flag	Group Flag Symbol	Flag	Flag Symbol	Result Visualization	System Monitor Red Displayed (Liquid Type)
Results Edited Manually	E	Results Edited	E		
Generic Error	?	Generic Error	?	*	SAMPLE / CONTROL / RBL / STANDARD
ISE Module Errors	I	Air in ISE Module	*	*	SAMPLE / CONTROL / STANDARD
		Noise in ISE Module	*	*	SAMPLE / CONTROL / STANDARD
		Air in ISE Calibrant B	*	*	SAMPLE / CONTROL / STANDARD
		Noise in ISE Calibrant A	*	*	SAMPLE / CONTROL / STANDARD
		Air in ISE Calibrant A	*	*	SAMPLE / CONTROL / STANDARD
		Drift in ISE Calibrant A	*	*	SAMPLE / CONTROL / STANDARD
		Result Out Range in ISE Module	*		SAMPLE / CONTROL / STANDARD
		Na Error in ISE Module	*		SAMPLE / CONTROL
		ISE Module not properly calibrated	*		

9.2 TROUBLESHOOTING GUIDE

PROBLEM	➢ POSSIBLE CAUSE ❖ SOLUTION
Insufficient repeatability of results	➢ Sampling Probe dirty. ❖ Clean the Sampling Probe. – ➢ Hydraulic leak and/or air bubbles in the hydraulic circuit. ❖ Check the Sampling 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. ❖ Change the wash solution. ❖ Clean the liquid reservoir bottle(s) and carry out the Hydraulic Circuit washing procedure. – ➢ Deterioration of the Reagent(s). ❖ Substitute the bad Reagent(s). – ➢ Reaction cuvettes not dried correctly after being washed. ❖ Check the Pad used to dry the cuvettes after washing to make sure it is in good working condition. If necessary, clean the Pad or change it, following the relative procedure. – ➢ Halogen lamp not stable. ❖ Halogen lamp nearing the end of its life cycle (2000 hours), or premature deterioration. In both cases, change the Halogen Lamp following the replacement procedure.
Insufficient volume/quantity of the various solutions	➢ This type of problem can be present either when there is a lack of liquid in one/more bottle(s) or - during the test running - when the involved liquid is finished. ❖ Refill the involved bottle(s). If the instrument is running tests, it will go automatically in “Pause”. Wait until sampling is suspended, then refill the involved bottle(s) with the required liquid(s). Press *Start* to run the rest of the programmed tests.

9.3 ISE MODULE - TROUBLESHOOTING GUIDE

SYMPTOM	PROBLEM	CORRECTION
System does not respond	1. RS232 cable is disconnected or damaged.	Reconnect or replace cable.
	2. Module connector has been damaged.	Replace board.
	3. Component failure on board.	Replace board.
Low Slope Na or K < 45 mV/decade Cl < 35 mV/decade *or* *High Slope* Na or K > 63 mV/decade Cl > 60 mV/decade	1. Misalignment of sensors.	Remove and replace sensors to re-seat.
	2. Deterioration of calibrator solutions.	Replace Cal B first and retest. If still low, replace Cal A and retest.
	3. Deterioration of sensing electrode.	Replace problem sensor and test.
	4. Air bubble on Reference electrode membrane.	Remove electrode, tap to dislodge bubble, replace, and recalibrate.
	5. Deterioration of Reference electrode.	Replace Reference electrode and retest.
	6. Interaction between sensing electrodes.	Replace Cl electrode only and retest.
	7. Module or fluid temperatures exceed 37 ºC.	Monitor temperature. Change instrument location if ambient is too great.
Noise Error Flag Single electrode	1. Deterioration of sensing electrode.	Replace problem sensor and test.
	2. Electrical noise spike from environmental source.	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace board.
Noise Error Flag Multiple electrodes	1. Deterioration of Reference electrode.	Replace Reference electrode and retest.
	2. Electrical noise spike from environmental source.	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace board.
Drift Error Flag Single electrode	1. Deterioration of sensing electrode.	Replace problem sensor and test.
	2. May occur when new sensor or new bottle of Cal A is installed on system.	Purge the Cal A and recalibrate the module. If the sensor is new it may initially drift as it rehydrates over the course of 15 minutes.

SYMPTOM	PROBLEM	CORRECTION
Drift Error Flag Multiple electrodes	1. Deterioration of Reference electrode.	Replace Reference electrode and retest.
	2. Electrical spike from environmental source.	a) Check for electrical noise coincident with activation. b) Component failure on module board. Replace the board.
	3. May occur when new sensor or new bottle of Cal A is installed on system.	Purge Cal A and recalibrate the module.
Air in Sample	1. Sample not positioned properly.	a) Pumps not connected properly. b) Pump tubing obstructed or tubing length is excessive.
Air in Sample *and* Cal A	1. Sample and Cal A are segmented with air.	a) Sensors are not properly compressed. Check Compression Plate, spring and seal. b) Ensure that all sensors and o-rings are in place.
	2. Fibrin or salt is plugging the sensor flow path.	a) Use Cleaning procedure <CLEN> for module. b) Disassemble module and clean or replace sensor with plugged flow path.
	3. Bubble Detector is malfunctioning	Replace Bubble Detector.
	4. Waste Pump is malfunctioning.	Replace Waste Pump.
Air in Cal B *and* Air in Cal A	1. Cal B and Cal A are segmented with air.	a) Sensors are not properly compressed. Check Compression Plate, spring and seal. b) Ensure that all sensors and o-rings are in place.
	2. Fibrin or salt is plugging the sensor flow path.	a) Use Cleaning procedure <CLEN> for module. b) Disassemble module and clean or replace sensor with plugged flow path.
	3. Waste Pump malfunction.	Replace Waste Pump.
	4. Bubble Detector malfunction.	Replace Bubble Detector.

SYMPTOM	PROBLEM	CORRECTION
Air in Cal B	1. Sample not positioned properly.	a) Pumps not connected properly. b) Pump tubing obstructed or tubing length is excessive.
Air in Cal A (no "Air" errors reported for Sample or Cal B)	1. Cal A bottle is empty.	Replace Cal A bottle with a new one, purge and recalibrate.
	2. Tubing is disconnected.	Reconnect or replace tubing.
	3. Cal A pump is not working properly.	a) Check electrical connections. b) Replace pump cassette. c) Replace motor.
	4. Tubing is plugged, split or crimped.	Replace tubing.

- **BBCL (command)**

The bubble calibration (BBCL) is a command that ensures the bubble detector is correctly identifying liquid and air. Below, you will see four measurements displayed – 2 sets (one set is the upper and one set is the lower sensor). The first and third reads are the "air" values, the second and fourth values are the "liquid" values. Values should be approximately 160 for air and at least 40 for liquid. Several bubble calibrations in a row should result in measurements that are close in proximity. Typically bubble calibration results are around the values below, however there are no specific ranges, the key is to get consistent readings – if they are not consistent then the bubble detector may need to be replaced. Each bubble detector can have slightly different calibration values.

The Bubble detector readings are very reproducible. The suggested range is < 5%.

- Examples of good bubble detector calibrations (***Bubble Calibrations***) are:

Note: bold numbers is the check digit. Consider only the first three.

<BBCL><113 061 183 100**07**>
<BBCL><115 062 182 100**03**>
<BBCL><114 062 183 100**12**>

<BUBD><171 095 165 091**09**>
<BUBD><172 096 167 092**08**>
<BUBD><171 095 165 091**09**>

The values must be:

- $num1 \approx 160$ and $num3 \approx 160$
- $num2 \geq 40$ and $num4 \geq 40$
- $(num1 - num2) > 50$ and $(num3 - num4) > 50$

▪ mV diagnostic tool

The mV diagnostic tool is designed to evaluate electrode stability. The mV output range is not critical. The important aspect to be monitored is the consistency (repeatability) of the mV output in a short time. mV readings will tend to drift slowly over time, and drifting does not indicating a direct problem (the lower the mV output value the smaller is the drift). For instance the Na mV read below is 129.6, you might see a drift of 1mV from read to read, and however in the Cl which has lower value you may only see a 0.5mV drift. Drift is acceptable if it trends slightly over time (1-1.5 mV dec). If the drift is large or the reads are up and down, the electrode may have stability issues.

⇒ **Which is the best way to check the ISE voltage readings?**
If you want to observe the stability of an electrode over time, then multiple readings over time would be acceptable (ex. every sixty minutes). If you are looking for stability at a certain time first run a Ise two points calibration then read the voltage for 60 seconds and check if stable.

- Examples of good mV reads are:

  <RDMV><Na 129.6 K 129.5 Cl 78.0>

  <RDMV><Na 129.6 K 129.5 Cl 78.0>

  <RDMV><Na 129.6 K 129.5 Cl 78.0>

  <RDMV><Na 129.6 K 129.5 Cl 78.0>

  <RDMV><Na 129.6 K 129.6 Cl 78.0>

- Examples of Stability Issues are:

  <RDMV><Na 129.6 K 129.5 Cl 78.0>

  <RDMV><Na 129.6 K 130.5 Cl 76.0>

  <RDMV><Na 125.6 K 131.5 Cl 76.0>

  <RDMV><Na 132.6 K 132.5 Cl 78.0>

  <RDMV><Na 123.6 K 133.6 Cl 78.0>

  Na is up an down and change in between reads is too great (reads are assumed to be taken in succession). **K** is increasing consistently, but it is a really large change for such a small amount of time. This may be acceptable if reads are taken hours apart, but close in succession this is too great. **Cl** jumps after one read and then recovers, may indicate bubble or instability.

▪ Calibration results specification are:

Na^+ = 50 – 63 mV/decade

K^+ = 50 – 63 mV/decade

Cl^- = 40 – 59 mV/decade

Typical calibration results for Na^+/K^+ electrodes are approximately 55 mV/decade, while Cl^- results are approximately 42 mV/decade. Additionally mV readings must not vary by more than 7 mV/decade; if mV's vary more than 7 mV per decade then a drift error will be recorded.

- **Blocked Flow Path**

Blockage in the flow path is usually due to sample issues, environmental contamination issues or inadequate cleaning of the electrodes. Care must be taken in sample preparation to make sure solids such as fibrin or gels from the sample tube are not introduced to the ISE Module. It is also possible that materials from the environment such as dust is accruing in the Sample Cup and resulting in blockages. Careful monitoring and cleaning of the Sample Cup will help reduce problems from this source. In regards to this problem, clean the ISE hole on the Raising Top of the instrument and the Sample Cup of the ISE module with a cotton swab and the ISE cleaning, after that with a clean cotton swab rinse with Calibrant A; run 6 Purge Cycles by using the "Purge" button of the Diagnostic program, then run 3 ISE Calibration Replicates. Moreover, check if the Sampling Probe is well centered over the ISE hole and - if necessary - replace (don't refill) the Calibrant A bottle (*note*: both Calibrant A and Calibrant B must be stored at room temperature never refrigerated). It is also possible that the daily cleaner is not being used properly or often enough.

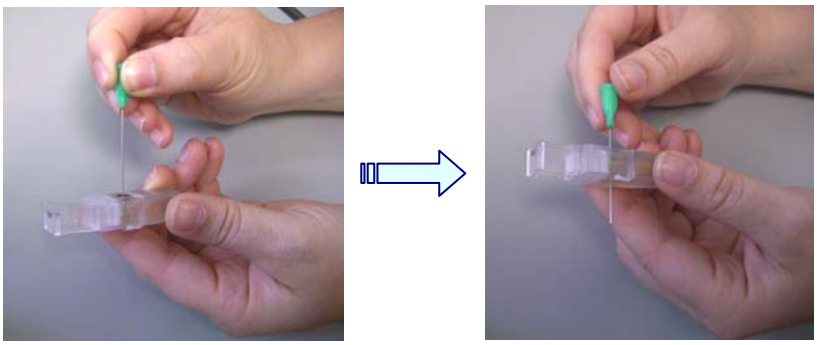
Proper cleaning of the flow path will also help keep the outlet of the ISE and the waste line clear of obstructions which can lead to other issues such as movement of fluids after the pump has stopped rotating. See also if tubing are not kinked, including the one from the exit nipple, under the module, to the waste.

If however you do have a blockage in the flow path, gently push a blunt tip 22 gauge needle through the flow path to remove any obstructions that may be present.

The flow path of the electrodes may become plugged. Remove them the Module after first using the appropriate Maintenance command to flush the flow path of fluids. Use the blunt tip 22 gauge needle to gently remove any obstructions in the flow path of the electrodes.

A plug or restriction in the flow path of the Reference Electrode is usually due to dried salts. Again follow the proper Maintenance command to purge the flow path of liquids and remove the Reference Electrode. Place it in warm water for fifteen minutes to loosen the salts and then carefully clear out the flow path with the 22 gauge blunt tip needle.

If you are finding blockages are reoccurring, it is recommended that the daily cleaning be performed more frequently to prevent this situation.



In particular, if you see any sign of microcrystal formation somewhere (internal of tubes, external of the electrodes, sites of the electrodes), run 3 Maintenance cycles by using the "Maintenance" button of the Diagnostic program, remove the electrodes, remove the microcrystal formation and clean with distilled water. Replace and align the electrodes performing the relative procedure described in the **Appendix C** of this Manual. Then, run 8 Purge Cycles by using the "Purge" button of the Diagnostic program and run 2 ISE calibrations.

Some examples

- **Example 1: unstable Na (up and down)**

  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 125.6 K 129.5 Cl 78.0>
  <RDMV><Na 132.6 K 129.5 Cl 78.0>
  <RDMV><Na 123.6 K 129.5 Cl 78.0>

  ⇒ ***Action depends on the age of the electrode:***
  - **old electrode**: there could be too much protein on the membrane. Perform a cleaning cycle. In the case the electrode will not get stable, use tip needle through fluidic path (see above).
  - **new electrode**: lack of proteins or dry membrane. Perform a cleaning cycle.
  - Only if the above will not work, substitute the electrode.

- **Example 2: unstable Na (up and down)**

  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 127.5 K 129.5 Cl 78.0>
  <RDMV><Na 130.6 K 129.5 Cl 78.0>
  <RDMV><Na 127.0 K 129.5 Cl 78.0>

  ⇒ ***Action: change Na electrode?***
  No. The above values could be due to air bubbles. Perform a cleaning cycle.

- **Example 3: unstable Na (large increasing)**

  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 130.5 K 129.5 Cl 78.0>
  <RDMV><Na 131.6 K 129.5 Cl 78.0>
  <RDMV><Na 133.0 K 129.5 Cl 78.0>

  ⇒ ***Action: change Na electrode?***
  If 1 electrode only has this behaviour, change it. If all 3 electrodes have the below behaviour, change the Reference or check the reagent (Cal A).

- **Example 4: unstable Cl (up and down)**

  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 129.6 K 129.5 Cl 78.0>
  <RDMV><Na 129.6 K 129.5 Cl 77.3>
  <RDMV><Na 129.6 K 129.5 Cl 78.5>
  <RDMV><Na 129.6 K 129.5 Cl 77.2>

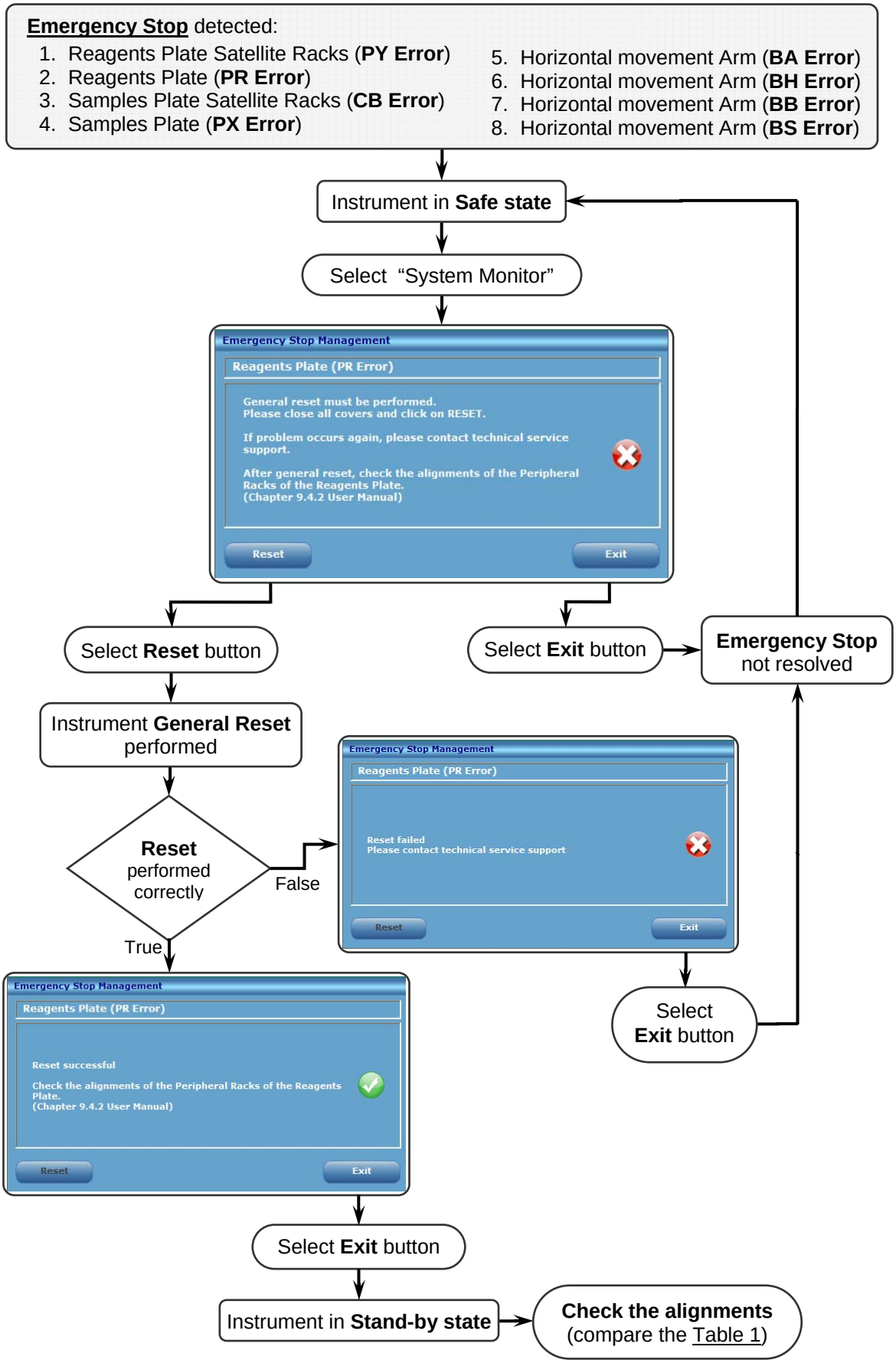
  ⇒ ***Action: change Cl electrode?***
  Same as Example 1 and Example 2.

When the Reference Electrode should be changed?

1. All 3 electrodes show the same trend behaviour.
2. Noisy Cl^- .

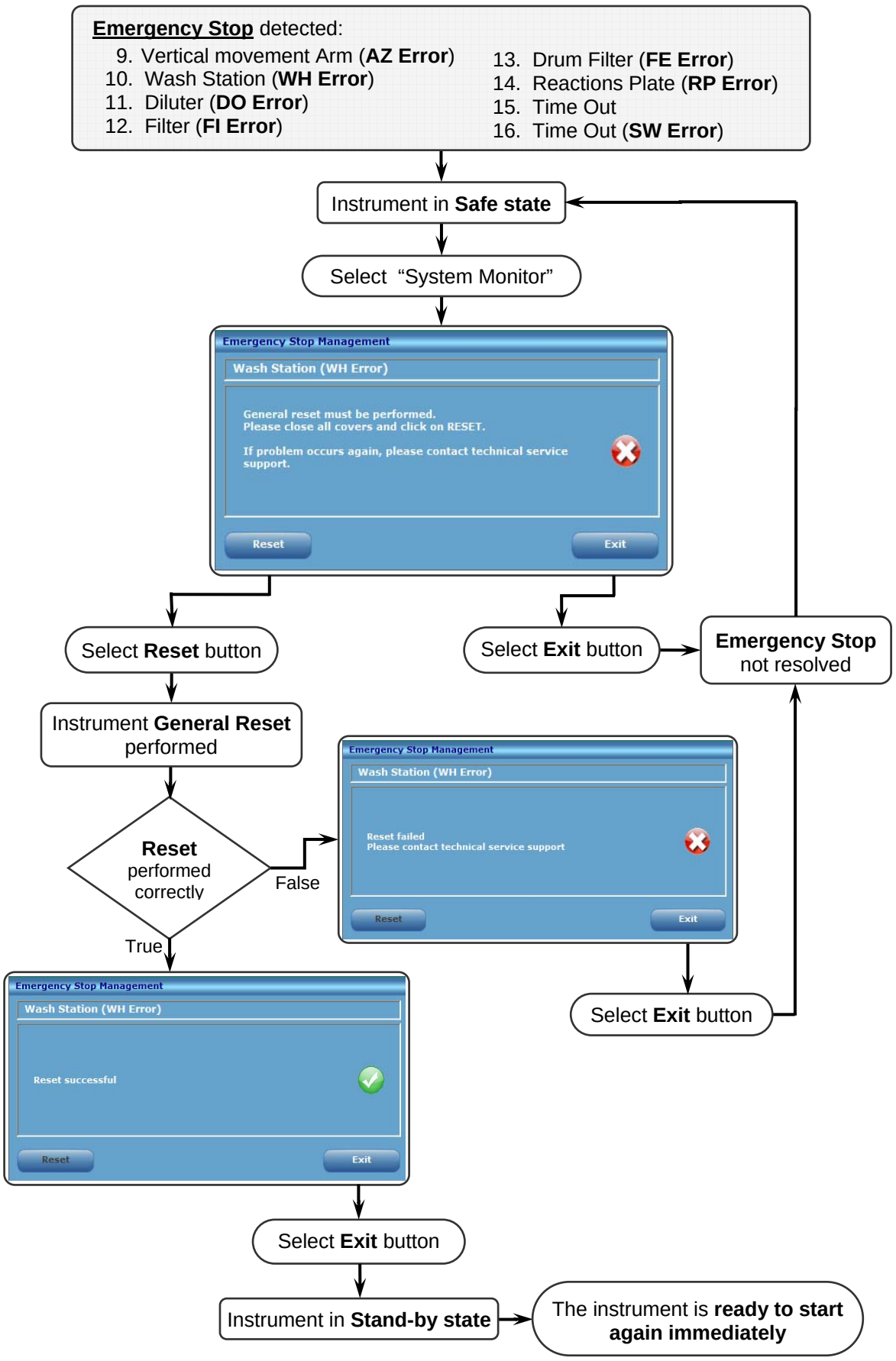
9.4 SYSTEM ERRORS MANAGEMENT

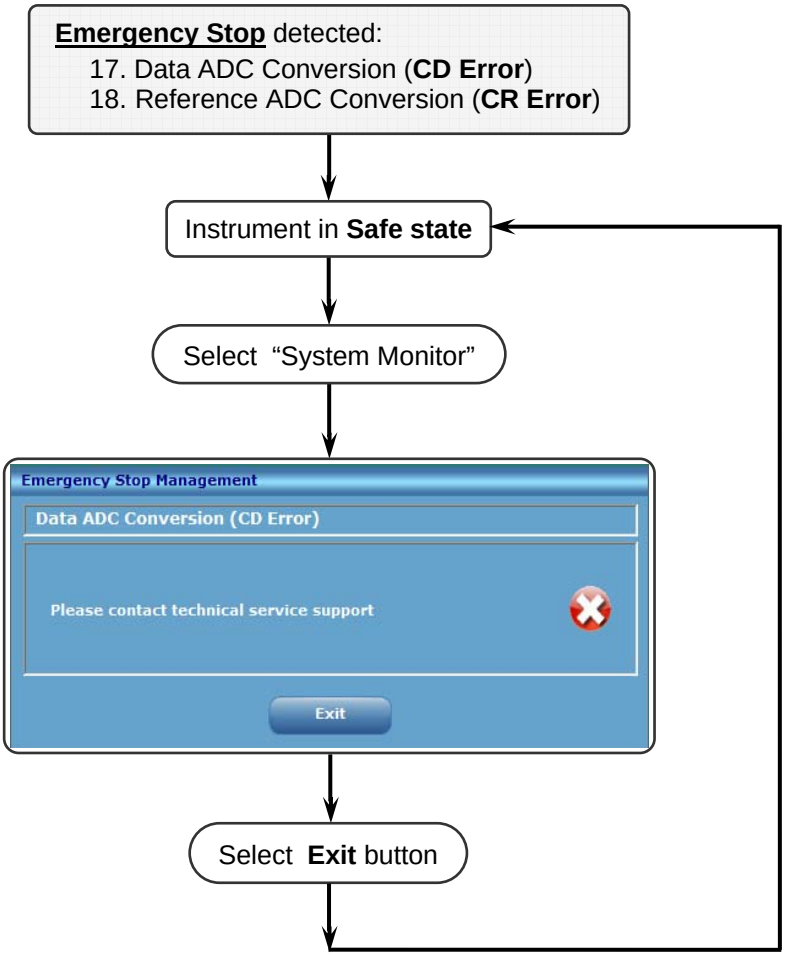
Flow charts for the management of the Emergency Stops (and a Warning) detected:

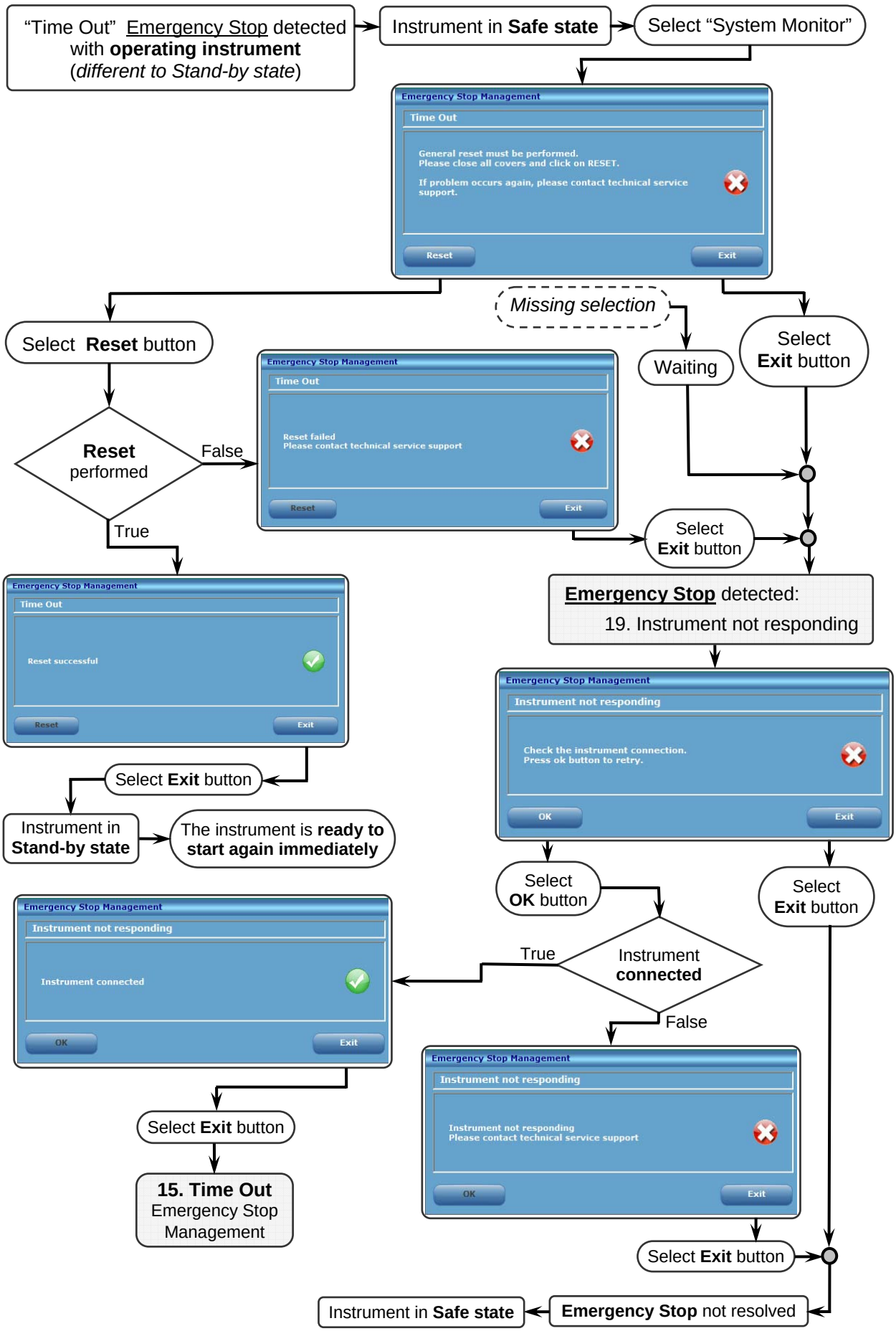


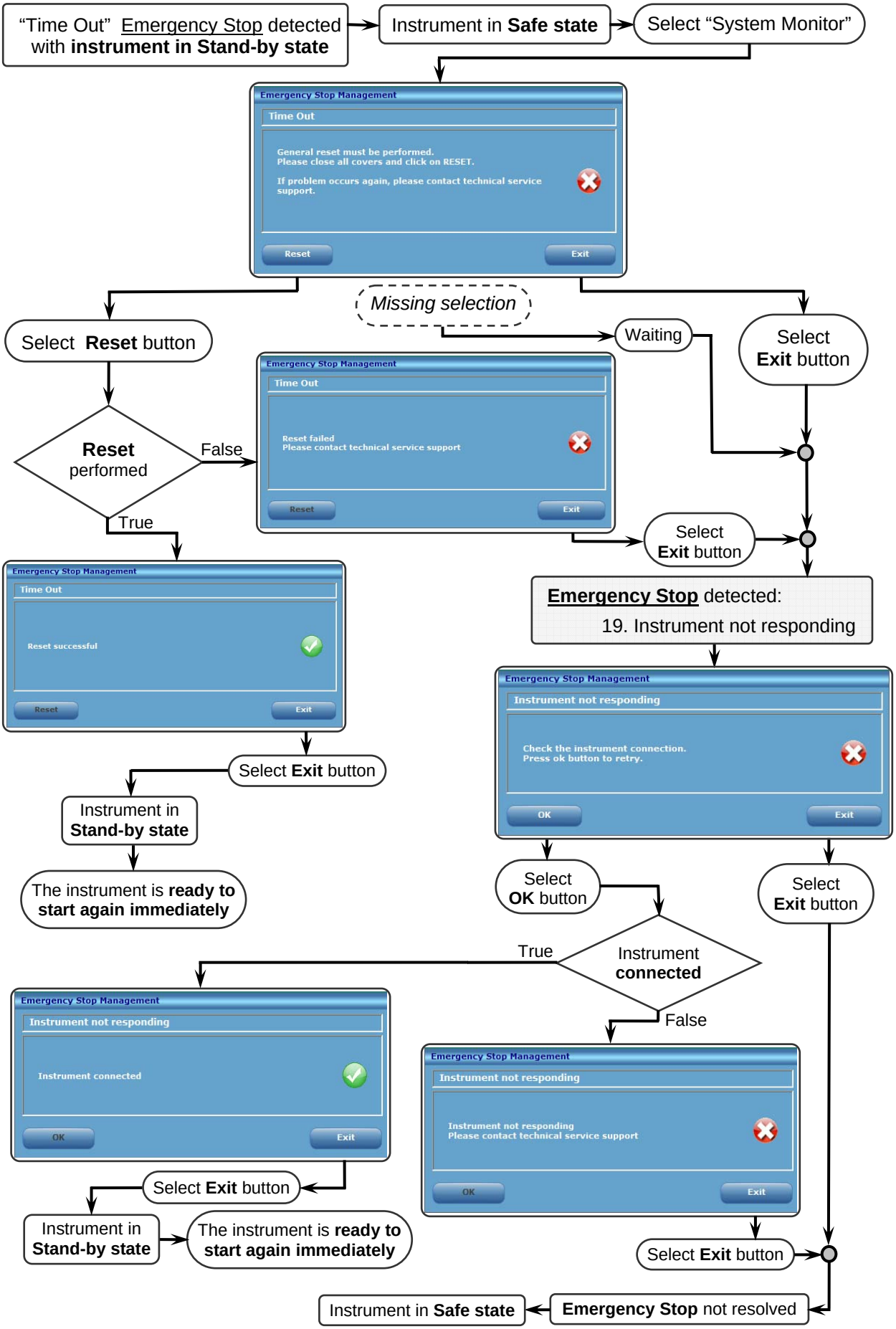
Emergency Stop	**Operations**
Reagents Plate Satellite Racks (**PY Error**)	Check the alignments of the Satellite Racks of the Reagents Plate performing the procedure described into the **Section 9.4.1** .
Reagents Plate (**PR Error**)	Check the alignments of the Peripheral Racks of the Reagents Plate performing the procedure described into the **Section 9.4.2** .
Samples Plate Satellite Racks (**CB Error**)	Check the alignments of the Satellite Racks of the Sample Plate performing the procedure described into the **Section 9.4.3** .
Samples Plate (**PX Error**)	Check the alignments of the Peripheral Racks of the Sample Plate performing the procedure described into the **Section 9.4.4** .
Horizontal movement Arm (**BA Error**)	Check the centering of the Sampling Probe with respect to the Washing Well 1 performing the procedure described into the **Section 9.4.5** .
Horizontal movement Arm (**BH Error**)	Check the centering of the Sampling Probe with respect to the Washing Well 1 performing the procedure described into the **Section 9.4.5** .
Horizontal movement Arm (**BB Error**)	Check the centering of the Sampling Probe with respect to the Washing Well 1 performing the procedure described into the **Section 9.4.5** .
Horizontal movement Arm (**BS Error**)	Check the centering of the Sampling Probe with respect to the Washing Well 1 performing the procedure described into the **Section 9.4.5** .

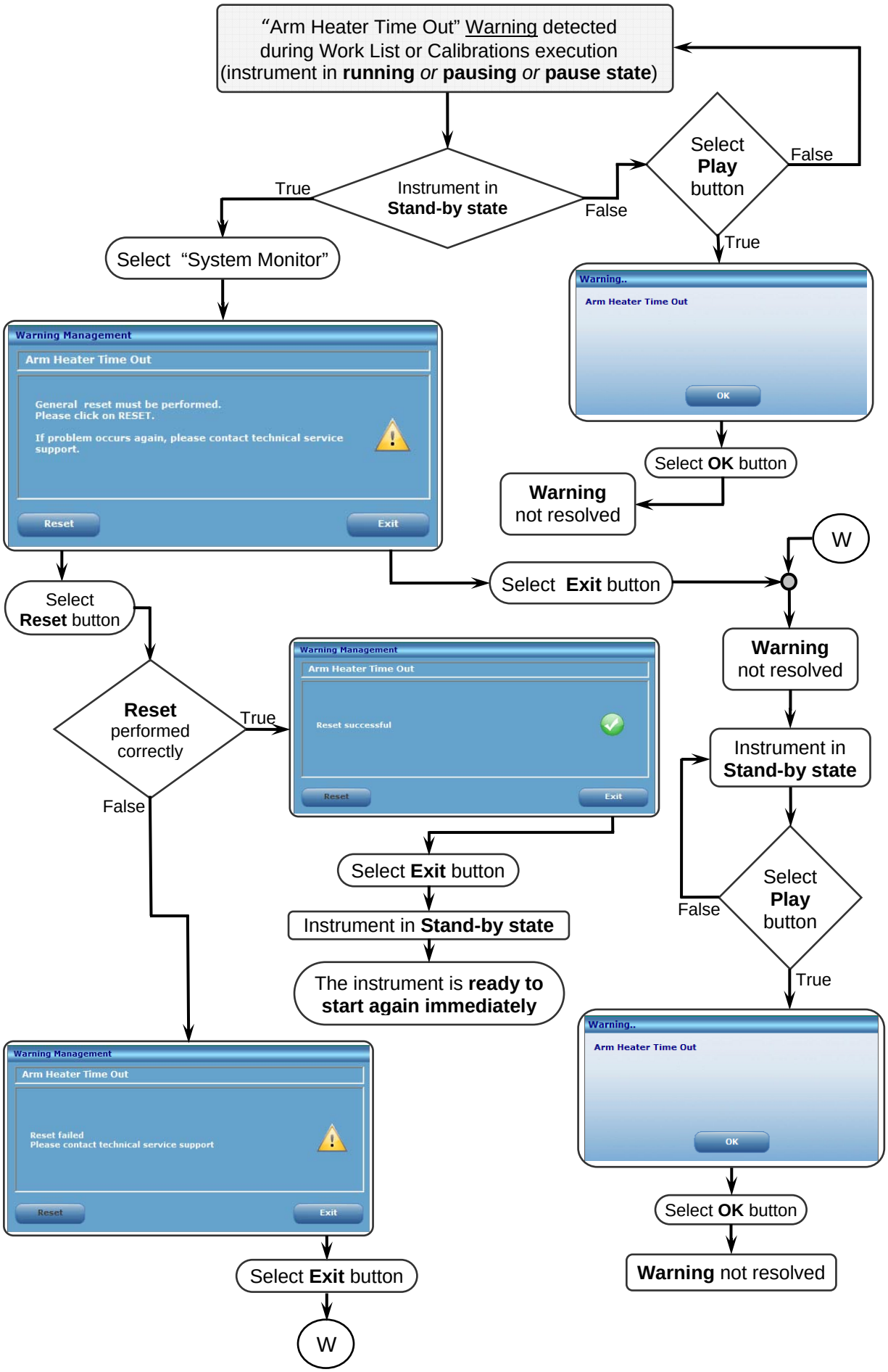
Table 1 – Checking procedures


Emergency Stop detected:
9. Vertical movement Arm (AZ Error)
10. Wash Station (WH Error)
11. Diluter (DO Error)
12. Filter (FI Error)
13. Drum Filter (FE Error)
14. Reactions Plate (RP Error)
15. Time Out
16. Time Out (SW Error)
Instrument in Safe state
Select "System Monitor"
Emergency Stop Management
Wash Station (WH Error)
General reset must be performed.
Please close all covers and click on RESET.
If problem occurs again, please contact technical service support.
Reset
Exit
Select Reset button
Select Exit button
Emergency Stop not resolved
Instrument General Reset performed
Reset performed correctly
False
True
Emergency Stop Management
Wash Station (WH Error)
Reset failed
Please contact technical service support
Reset
Exit
Select Exit button
Emergency Stop Management
Wash Station (WH Error)
Reset successful
Reset
Exit
Select Exit button
Instrument in Stand-by state
The instrument is ready to start again immediately


Emergency Stop detected:
17. Data ADC Conversion (CD Error)
18. Reference ADC Conversion (CR Error)
Instrument in Safe state
Select "System Monitor"
Emergency Stop Management
Data ADC Conversion (CD Error)
Please contact technical service support
Exit
Select Exit button


"Time Out" Emergency Stop detected with operating instrument (different to Stand-by state)
Instrument in Safe state
Select "System Monitor"
Emergency Stop Management
Time Out
General reset must be performed.
Please close all covers and click on RESET.
If problem occurs again, please contact technical service support.
Reset
Exit
Missing selection
Waiting
Select Exit button
Select Reset button
Reset performed
False
True
Reset failed
Please contact technical service support
Select Exit button
Emergency Stop detected:
19. Instrument not responding
Reset successful
Select Exit button
Instrument in Stand-by state
The instrument is ready to start again immediately
Instrument not responding
Check the instrument connection.
Press ok button to retry.
OK
Select OK button
Select Exit button
Instrument connected
True
Instrument connected
False
Instrument not responding
Please contact technical service support
Select Exit button
15. Time Out
Emergency Stop Management
Select Exit button
Instrument in Safe state
Emergency Stop not resolved


"Time Out" Emergency Stop detected with instrument in Stand-by state
Instrument in Safe state
Select "System Monitor"
Emergency Stop Management
Time Out
General reset must be performed.
Please close all covers and click on RESET.
If problem occurs again, please contact technical service support.
Reset
Exit
Missing selection
Waiting
Select Exit button
Select Reset button
Reset performed
False
True
Reset failed
Please contact technical service support
Select Exit button
Reset successful
Emergency Stop detected:
19. Instrument not responding
Instrument not responding
Check the instrument connection.
Press ok button to retry.
OK
Select Exit button
Instrument in Stand-by state
The instrument is ready to start again immediately
Select OK button
Select Exit button
Instrument connected
True
False
Instrument connected
Instrument not responding
Please contact technical service support
Select Exit button
Instrument in Stand-by state
The instrument is ready to start again immediately
Select Exit button
Instrument in Safe state
Emergency Stop not resolved


"Arm Heater Time Out" Warning detected during Work List or Calibrations execution (instrument in **running** *or* **pausing** *or* **pause state**)
Instrument in **Stand-by state**
True
False
Select **Play** button
False
True
Select "System Monitor"
Warning..
Arm Heater Time Out
OK
Warning Management
Arm Heater Time Out
General reset must be performed.
Please click on RESET.
If problem occurs again, please contact technical service support.
Reset
Exit
Select **OK** button
Warning not resolved
W
Select **Exit** button
Select **Reset** button
Reset performed correctly
True
False
Warning Management
Arm Heater Time Out
Reset successful
Reset
Exit
Warning not resolved
Instrument in **Stand-by state**
Select **Exit** button
Instrument in **Stand-by state**
The instrument is **ready to start again immediately**
Select **Play** button
False
True
Warning..
Arm Heater Time Out
OK
Select **OK** button
Warning not resolved
Warning Management
Arm Heater Time Out
Reset failed
Please contact technical service support
Reset
Exit
Select **Exit** button
W

9.4.1 REAGENTS PLATE SATELLITE RACKS (PY ERROR)

Check the alignments of the Satellite Racks of the Reagents Plate in the following way:

1. Launch the "Diagnostic" program clicking on the "Diagnostic" button located on the lower right side of the screen of the System Monitor (**Fig. 1**).

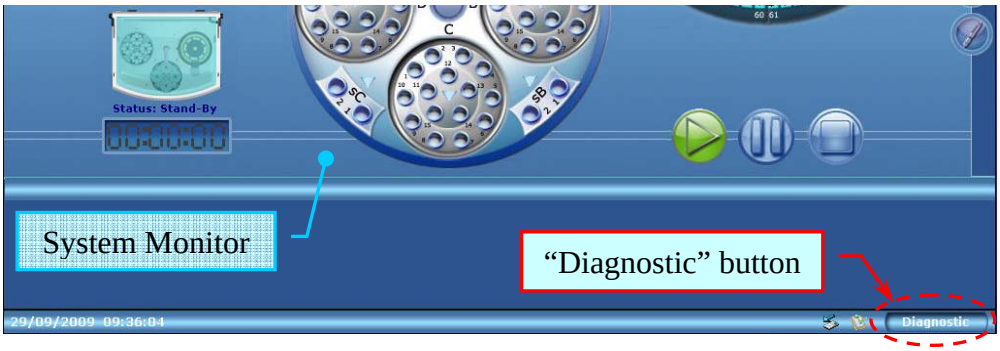


Fig. 1 – "Diagnostic" button

2. Make sure that all the Home Sensors of the Sampling Arm, Reactions Plate, Reagents Plate and Samples Plate light up in green (**Fig. 2**).

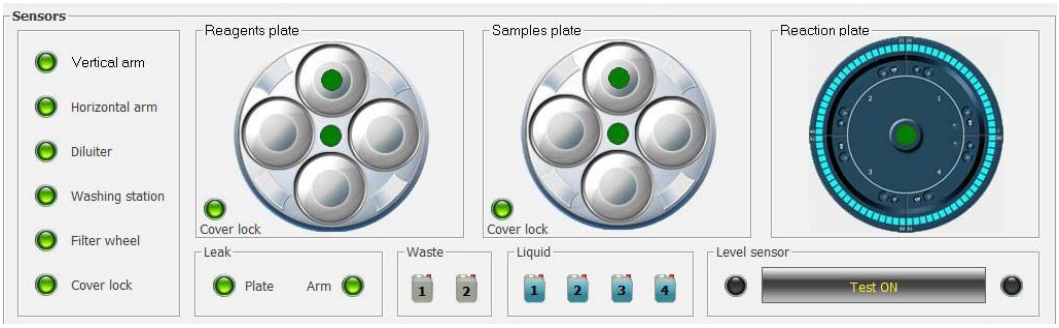


Fig. 2 – Sensors status area in the Diagnostic program

3. <u>Make sure that the Sampling Probe is centered</u> (as shown in **Fig. 4**) <u>with respect to the Washing Well 1</u> (well places between Reagents Plate and Samples Plate indicated in the **Fig. 3**).

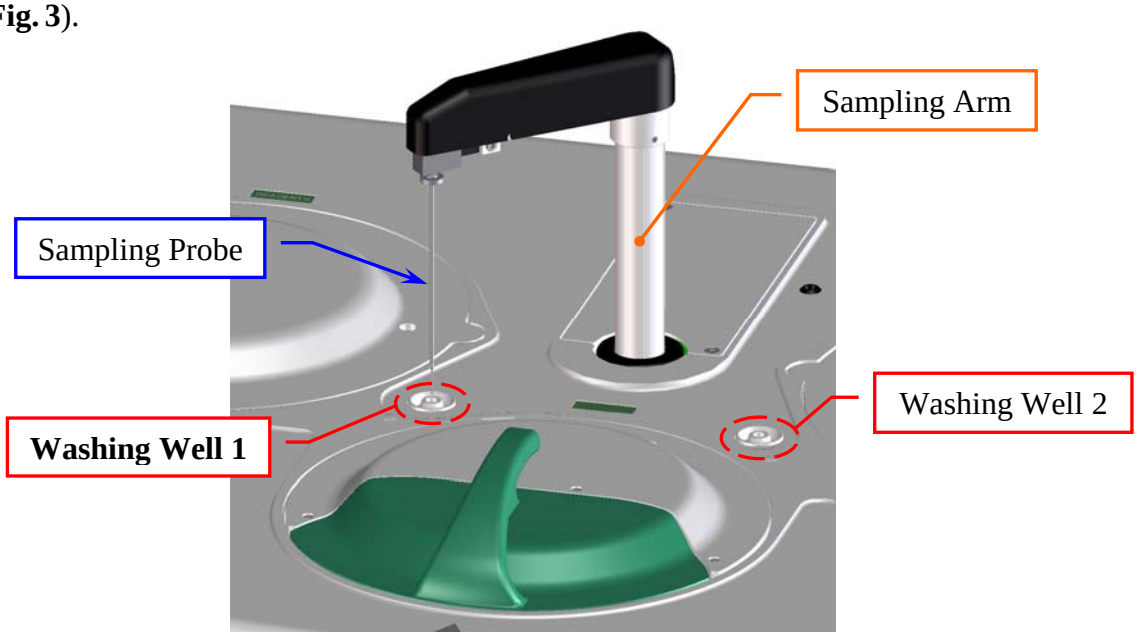


Fig. 3 – Sampling Probe and Washing Well 1

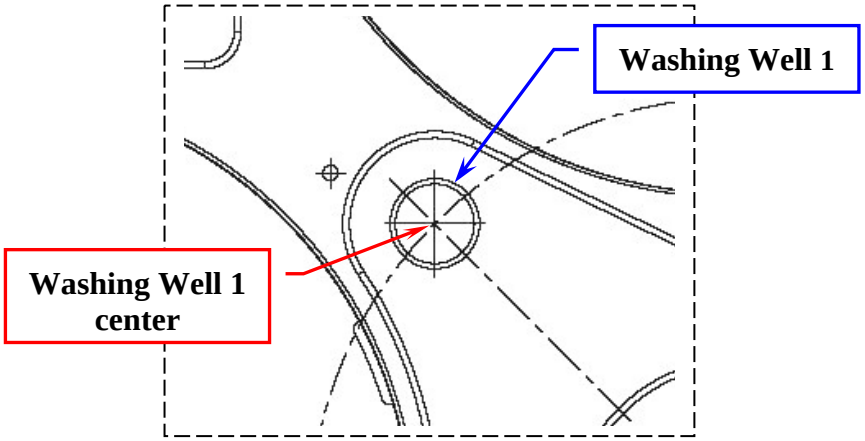


Fig. 4 – Center of the Washing Well 1

4. If it not be so, **contact Technical Service Support**.

5. Remove the Reagents Plate cover from the Reagents Plate and position a Reagent bottle (of 50 ml) in the position #1 of the Satellite Rack "A".

6. Select "Plate" folder (**Fig. 5**), choose the **Position #(A-1)** in the "Position" Combo Box of the "Reagent Plate" area, then click the correspondent "To Asp." button. *Wait until the requested operation has been completed.*

7. Select "Arm" folder (**Fig. 6**), click the "Go Reagent" button in the "Horizontal" area, then click the correspondent "Down" button. *The Sampling Arm will move to aspiration position of the Reagents Plate, then it will go down until to reach the right height.*

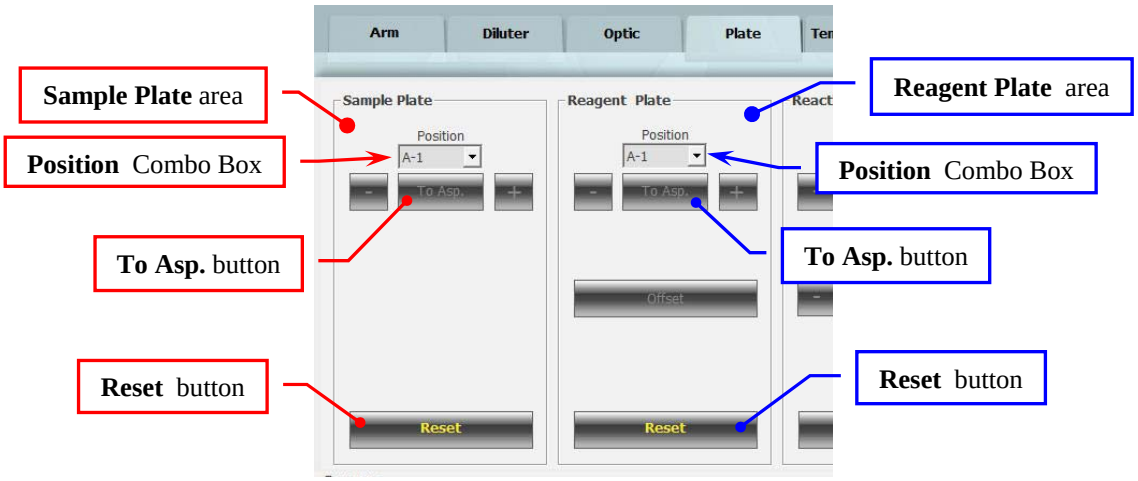


Fig. 5 – "Plate" folder

8. Make sure that the Sampling Probe is centered with respect to the Position #(A-1) of the Reagents Plate. If it not be so, **contact Technical Service Support**.

9. Click the "Reset" button in the "Arm" folder (**Fig. 6**). *Wait until the reset Sampling Arm procedure has been completed.*

10. Click the "Reset" button in the "Reagent Plate" area of the "Plate" folder (**Fig. 5**). *Wait until the reset Reagents Plate procedure has been completed.*

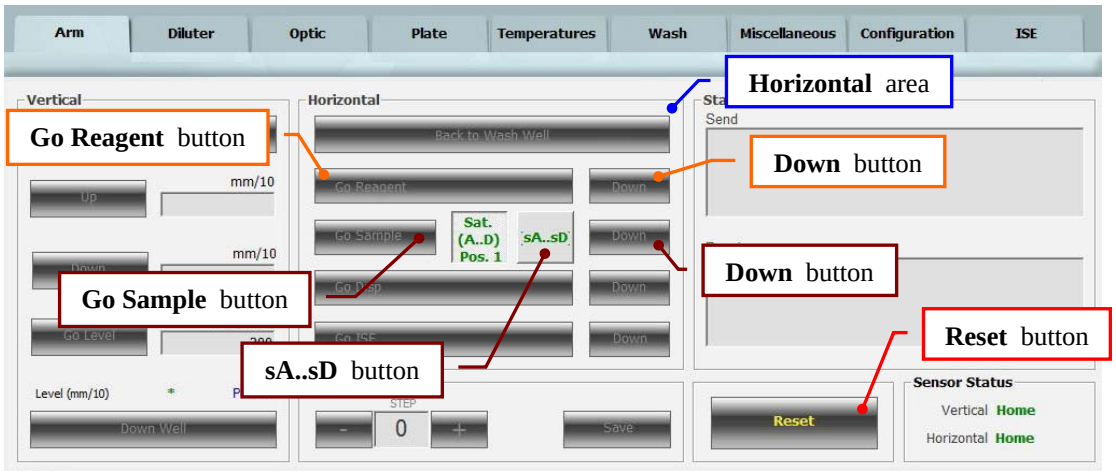


Fig. 6 – "Arm" folder

11. Remove the Reagent bottle from the Position #(A-1) of the Reagents Plate and replace the Reagents Plate cover.

12. Click the "Exit" button (**Fig. 7**) to exit from the *Diagnostic* program.

Fig. 7 – "Exit" button in the Diagnostic program

→ The instrument is **ready to start again immediately**.

9.4.2 REAGENTS PLATE (PR ERROR)

Check the alignments of the Peripheral Racks of the Reagents Plate in the following way:

1. Perform the procedure described into the previous Section 9.4.1, from step 1 to step 4.
2. Remove the Reagents Plate cover from the Reagents Plate and position a cup in the position #1 of the Peripheral Rack "rA".
3. Select "Plate" folder (**Fig. 5**), choose the **Position #(rA-1)** in the "Position" Combo Box of the "Reagent Plate" area, then click the correspondent "To Asp." button. *Wait until the requested operation has been completed.*
4. Select "Arm" folder (**Fig. 6**), click the "Go Reagent" button in the "Horizontal" area, then click the correspondent "Down" button. *The Sampling Arm will move to aspiration position of the Reagents Plate, then it will go down until to reach the right height.*
5. Make sure that the Sampling Probe is centered with respect to the Position #(rA-1) of the Reagents Plate. If it not be so, **contact Technical Service Support**.
6. Click the "Reset" button in the "Arm" folder (**Fig. 6**). *Wait until the reset Sampling Arm procedure has been completed.*

7. Click the "Reset" button in the "Reagent Plate" area of the "Plate" folder (**Fig. 5**). *Wait until the reset Reagents Plate procedure has been completed.*
8. Remove the cup from the Position #(rA-1) of the Reagents Plate and replace the Reagents Plate cover.
9. Click the "Exit" button (**Fig. 7**) to exit from the *Diagnostic* program.

→ The instrument is **ready to start again immediately**.

9.4.3 SAMPLES PLATE SATELLITE RACKS (CB ERROR)

Check the alignments of the Satellite Racks of the Samples Plate in the following way:

1. Perform the procedure described into the previous Section 9.4.1, from step 1 to step 4.
2. Remove the two Samples Plate covers from the Samples Plate and position a cup in the position #1 of the Satellite Rack "A".
3. Select "Plate" folder (**Fig. 5**), choose the **Position #(A-1)** in the "Position" Combo Box of the "Sample Plate" area, then click the correspondent "To Asp." button. *Wait until the requested operation has been completed.*
4. Select "Arm" folder (**Fig. 6**), click the "Go Sample" button in the "Horizontal" area, then click the correspondent "Down" button. *The Sampling Arm will move to aspiration position of the Samples Plate, then it will go down until to reach the right height.*
5. Make sure that the Sampling Probe is centered with respect to the Position #(A-1) of the Samples Plate. If it not be so, **contact Technical Service Support**.
6. Click the "Reset" button in the "Arm" folder (**Fig. 6**). *Wait until the reset Sampling Arm procedure has been completed.*
7. Click the "Reset" button in the "Sample Plate" area of the "Plate" folder (**Fig. 5**). *Wait until the reset Samples Plate procedure has been completed.*
8. Remove the cup from the Position #(A-1) of the Samples Plate and replace the two Samples Plate covers.
9. Click the "Exit" button (**Fig. 7**) to exit from the *Diagnostic* program.

→ The instrument is **ready to start again immediately**.

9.4.4 SAMPLES PLATE (PX ERROR)

Check the alignments of the Peripherals Racks of the Samples Plate in the following way:

1. Perform the procedure described into the previous Section 9.4.1, from step 1 to step 4.
2. Remove the two Samples Plate covers from the Samples Plate and position a cup in the position #1 of the Peripheral Rack "sA".
3. Select "Plate" folder (**Fig. 5**), choose the **Position #(sA-1)** in the "Position" Combo Box of the "Sample Plate" area, then click the correspondent "To Asp." button. *Wait until the requested operation has been completed.*

4. Select "Arm" folder (**Fig. 6**), click the "sA..sD" button in the "Horizontal" area, click the "Go Sample" button, then click the correspondent "Down" button. *The Sampling Arm will move to aspiration position of the Samples Plate, then it will go down until to reach the right height.*
5. Make sure that the Sampling Probe is centered with respect to the Position #(sA-1) of the Samples Plate. If it not be so, **contact Technical Service Support**.
6. Click the "Reset" button in the "Arm" folder (**Fig. 6**). *Wait until the reset Sampling Arm procedure has been completed.*
7. Click the "Reset" button in the "Sample Plate" area of the "Plate" folder (**Fig. 5**). *Wait until the reset Samples Plate procedure has been completed.*
8. Remove the cup from the Position #(sA-1) of the Samples Plate and replace the two Samples Plate covers.
9. Click the "Exit" button (**Fig. 7**) to exit from the *Diagnostic* program.

→ The instrument is **ready to start again immediately**.

9.4.5 HORIZONTAL MOVEMENT ARM (BA, BH, BB, BS ERROR)

Check the centering of the Sampling Probe with respect to the Washing Well 1 in the following way:

1. Perform the procedure described into the previous Section 9.4.1, from step 1 to step 4.
2. Click the "Exit" button (**Fig. 7**) to exit from the *Diagnostic* program.

→ The instrument is **ready to start again immediately**.