



KROMA Plus

Random Access Analyser
User Manual





INTRODUCTION

i.1 Identification Data

This document is the user manual of the instrument named KROMA PLUS, a random access automatic analyser.

It is available in two basic models: **SINGLE Sampling ARM (M1)** and **DOUBLE Sampling ARM (M2)**. Both of those models can be supplied in more sample tray configurations differing for the number of available sample positions on board. This document must be considered part of the instrument.

The user must read carefully every session of this manual before to undertake any operation. The producer doesn't take on any responsibility about partial and unauthorized copies of this document.

This manual has been written and produced with the utmost care; however errors cannot be fully excluded.

The producer doesn't take on any responsibility or due about every kind of incidents that may occur from mistakes in the manual.

The user can contact the distributor or the producer in case of doubts or necessity.

i.1.1 Document

• Document code:	MNU-10563-01-D
• Document revision:	D
• Revision date:	Apr 10, 2012
• Software version:	2.2.0.6
• Date of software version:	Mar 30, 2012

i.1.2 Instrument

- KROMA PLUS-Single sampling arm p/n 10674-xx-A (xx=version) (M1):
- KROMA PLUS-Double sampling arm p/n 10001-xx-A (xx=version) (M2):

Version 01: 79 available positions on the sample tray

Version 02: 59 available positions on the sample tray.

i.1.3 Producer

- LiNEAR



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i.2 Copyright

The content of this document, the pictures, the tables and the graphics included, is intellectual property of LiNEAR

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Permission for Kroma Plus Installation and Use

THIS EULA, when applied to this system and/or derived products, PERMITS INSTALLATION AND USE BY THE USER OF THE PROGRAM ON A SINGLE COMPUTER CONNECTED WITH A **KROMA PLUS family AUTOMATIC ANALYZERS**.

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Without prejudice to any other rights, LINEAR may terminate this EULA IF YOU FAIL to comply with the terms and conditions of this EULA. In such event, you must destroy all copies of the SOFTWARE PRODUCT and all of its component parts.

i.4 International and European Prescriptions

The present document has been written in conformity with following rules:

- UNI EN 591, 2nd Ed. Nov.2001,
- CEI EN 62079, 1st Ed. 2002-01,
- CEI EN 61010-1, 1st Ed. 1997-06,
- CEI EN 61010-2-101, 1st Ed. 2003-11.

The instrument complies the following directive:

- Directive IVD 98/79/CE - In-Vitro Diagnostic Medical Devices
- Directive 2002/96/EC – Waste Electrical and Electronic Equipment (WEEE)

i.5 End of Life Recycling and Disposal Information

Please observe the regulation applicable in your country.

Within the **European Community**, the Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC is intended to protect the quality of the environment and human health through the responsible use of natural resources and the adoption of waste management strategies that focus on recycling and reuse. This Directive requires producers / distributors of electrical and electronic products put on the market in European Union (EU) member countries after August 2005, to mark such products with the crossed-out wheeled waste-bin **symbol** shown in the picture aside.



At the end of its useful life, the product marked with the crossed out wheeled waste-bin symbol **must be disposed of separately from urban waste**.

Disposing of the product according to this Directive:

- avoids potentially negative consequences to the environment and human health which otherwise could be caused by incorrect disposal
- enables the recovery of materials to obtain a significant savings of energy and resources.



If you need more information on the collection, reuse, and recycling systems, please contact your local or regional waste administration.

You may also contact the manufacturer / distributor for disposing the equipment in case of replacing with a new one or for getting more information on the environmental performances of this product.

- The disposing of the instrument must be executed in conformity with the national rules, with reference to the local environment authority, considering that it is built with materials not dangerous for the environment and that it was treating fluids potentially infected.
- In case of illicit disposal, sanctions will be levied on transgressors.

i.6 Patents

Not applicable.

i.7 Purpose of This Document

This document is the user manual of the automatic "random access" analyser KROMA PLUS. It is addressed to personal staff expert of GLP.

NOTE: information included in this manual allows a correct use of the instrument just in the case the user has attended a specific training course hold by LiNEAR or by authorized LiNEAR representatives.

i.8 Use of Manual

The producer recommends the operators to read carefully all sections of the manual with particular consideration for notes, used for specifying or deepening a concept discussed before, and for warnings, used to highlight possible risks or dangers.

Every note and warning has been written in bold character and must be read carefully; particular care must be paid for the following sections:

- Section 1 – Safety
- Section 3 - Installation
- Section 8 - Maintenance.

Note: this document must be preserved and kept close to the system to be read, in case of necessity, during daily laboratory activity.



i.9 List of Contents

Section i INTRODUCTION	1
i.1 Identification Data	2
i.1.1 Document	2
i.1.2 Instrument	2
i.1.3 Producer	2
i.2 Copyright	3
i.3 End User Licence Agreement (EULA) for the Software	3
i.4 International and European Prescriptions	4
i.5 End of Life Recycling and Disposal Information	4
i.6 Patents	5
i.7 Purpose of This Document	5
i.8 Use of Manual	5
i.9 List of Contents	6
i.10 List of Figures	14
Section 1 SAFETY	17
1. Safety Prescriptions	17
1.1. General Instructions	17
1.2. Labelling	19
1.3. Safety Precautions	24
1.3.1. Installation	24
1.3.2. Operations	24
1.3.3. Maintenance	25
1.3.4. Transport and Storage	25
1.4. Risks During Use	26
1.4.1. Risks for the Operators	26
1.4.2. Safety Information for the Operators	26
1.4.3. Information on Liquids and Infected Parts	26
1.4.3.1. Treatment	27
1.4.3.2. Waste Materials	27
1.5. Advices for a Correct Use	28
Section 2 ICONS	29
2. Icons	29
Section 3 INSTALLATION	31
3. Description of the Instrument	31
3.1. Supplied Parts	33
3.1.1. List of the Supplied Parts	33
3.1.2. List of Optional Parts	35
3.2. Installation Requirements	36
3.2.1. Mechanical Constrains	36
3.2.2. Environment Constrains	36



3.2.3. Software	36
3.3. Storing the Instrument.....	38
3.4. Unpacking	38
3.4.1. Packing Characteristics	38
3.4.2. Inspection for Damages Caused by the Transportation	38
3.4.3. Unpacking the Instrument.....	39
3.4.4. Fixing PC Monitor on the support	41
3.4.5. Removal of Sampling ARMs' Clamps (for Double ARM only)	43
3.4.6. Unpacking the Floor-stand (Option)	43
3.5. Instrument Installation	48
3.5.1. Main Steps to Follow During Instrument Installation	48
3.5.2. Electrical Connections and Stabilizer	49
3.5.3. External Fuses.....	49
3.5.4. Fittings and Consumables	50
3.5.4.1. Liquid Solutions for the System	50
3.5.4.2. Liquid Tanks	51
3.6. Software and Firmware Installation	54
3.6.1. Requirements and Recommendations	54
3.7. 4-channel ISE Module (option)	55
3.7.1. Supplied Parts with ISE Module	56
3.7.2. ISE Module Installation.....	56
3.7.2.1. Connections.....	56
3.7.3. ISE Module Solutions and Consumables	57
Section 4 THEORY OF OPERATION.....	59
4. The Instrument	59
4.1. Generals	59
4.1.1. PC and Management Software.....	63
4.1.2. Barcode Reader (Option)	64
4.1.3. Refrigeration Unit for Reagents.....	65
4.2. Operating Principles	67
4.2.1. Operating Principle in Clinical Chemistry.....	67
4.2.1.1. Lambert-Beer Law	69
4.2.1.2. Types of Reactions	71
4.2.1.3. End-Point Methods	71
4.2.1.4. Kinetic Methods	73
4.2.1.5. Calibration in Clinical Chemistry	76
4.2.1.6. Calibration Curve	77
4.2.2. Operating Principle in Turbidimetry.....	78
4.2.3. Method Timings and Result Calculations	80
4.3. The ISE Module (option)	106
4.3.1. Generals	106
4.3.2. ISE Module, Operating Principles	107



4.3.3.	Electrodes	108
4.3.4.	Fluid Management	109
4.4.	Bibliography	111
Section 5	FUNCTIONS.....	112
5.	Functions	112
5.1.	Purpose of the Instrument	112
5.2.	Instruments Functions.....	112
5.3.	Functions.....	115
5.3.1.	Loading Trays.....	115
5.3.1.1.	Sample Tray.....	116
5.3.1.2.	Reagent Tray.....	117
5.3.2.	Sample and Reagent Dispensing Assemblies - ARMs	118
5.3.2.1.	Sampling Probe Sub-assembly.....	119
5.3.2.2.	Diluters	120
5.3.2.3.	Electrovalve	121
5.3.2.4.	Pump for Probe Washing	121
5.3.3.	Probe Washing Sink	122
5.3.4.	Incubation and Reading Assembly and Washing Station	123
5.3.4.1.	Incubation and Reading Assembly.....	124
5.3.4.2.	Optical Group.....	125
5.3.4.3.	Washing Station and Pumps.....	125
5.3.5.	Barcode Reader (option)	129
5.3.6.	Electronics.....	129
5.3.7.	Power Supply Unit	130
5.3.8.	Software and User Interface	133
5.3.8.1.	Management Software Structure	133
5.3.8.2.	Introduction to Main Menu.....	134
5.3.8.3.	Introduction to Work List Menu.....	134
5.3.8.4.	Introduction to Status Menu	135
5.3.8.5.	Introduction to Results Menu	135
5.3.8.6.	Introduction to Chemistry Menu	136
5.3.8.7.	Introduction to Memory Files Menu.....	136
5.3.8.8.	Introduction to System Config Menu	136
5.3.8.9.	ISE Module Config Menu.....	137
5.3.9.	ISE Module (option)	137
5.3.10.	L.I.S. Interface	137
Section 6	PERFORMANCES AND LIMIT OF USE.....	138
6.	Generalities.....	138
6.1.	General principles	138
6.2.	Formulas.....	138
6.3.	Testing the Performance	139
6.3.1.	Test of the Photometer: Accuracy and Imprecision	140



6.3.2. Test of Pipetting: Accuracy & Imprecision	143
6.3.3. Instrument Throughput	145

Section 7 OPERATING PROCEDURES AND MENUS.....146

7. Overview	146
7.1. Software Description.....	146
7.1.1. Main Menu.....	148
7.1.2. Work List Menu.....	150
7.1.2.1. Patient Private Data Window	157
7.1.2.2. Work List Display Window	159
7.1.3. Reagents Menu, During Work List programming	161
7.1.4. Work List Summary Menu	165
7.1.5. Status Menu	168
7.1.6. Methods Menu	176
7.1.6.1. Automatic Dilutions - Dilutions by Sample Submenu.....	197
7.1.6.2. Dispensable Volumes	199
7.1.6.3. Reading and Incubation Times	200
7.1.6.4. Extra Settings Submenu	201
7.1.6.5. Formula Builder Calculator Submenu	202
7.1.7. View Restriction Menu.....	204
7.1.8. Reagents Menu.....	207
7.1.9. Profiles Menu.....	210
7.1.10. Standards Menu.....	212
7.1.10.1. Calibration Curve	218
7.1.11. Quality Control Menu	219
7.1.11.1. QC and Levy-Jennings Graph	222
7.1.12. Results by Patient Menu	225
7.1.12.1. Kinetics and Fixed-Time Methods OD graph	229
7.1.12.2. Results and Methods Exported Files	230
7.1.13. Repetitions Menu	233
7.1.14. Results by Method Menu	235
7.1.15. Q.C./Std Results Menu	239
7.1.16. Memory Files Menu	243
7.1.16.1. Patient Results Auto-exporting for Back Up	246
7.1.16.2. Report Window	247
7.1.17. Std/Q.C. Archive Menu	250
7.1.17.1. QC and Standard Results Exported Files	253
7.1.17.2. QC and Standard results Auto-exporting for Back Up	256
7.1.18. System Config Menu	259
7.1.18.1. Action Logs Auto-exporting for Back Up	263
7.1.19. Cuvette Status Menu.....	264
7.1.20. Users Menu	266
7.1.21. ISE Module Menu	269



7.1.21.1. ISE Calibration Auto-exporting for Back Up	272
7.1.22. ISE Module Calibration History Menu	273
7.1.23. Show Alerts Window and Actions.....	275
7.1.24. Extra Procedures Pull-down Menu	276
7.1.24.1. Actual Statistics Window	279
7.2. Preparation for Operation	281
7.2.1. Safety Rules.....	281
7.2.1.1. Knowledge Level Required	281
7.2.2. Samples Handling	281
7.2.2.1. Samples.....	281
7.2.2.2. Sample Pre-treatment	282
7.2.2.3. Sample Storage	282
7.2.2.4. Sample Identification by Bar-code	282
7.2.2.5. Sample Tube Minimum Volume	283
7.2.2.6. Dead Volume	283
7.2.3. Reagents and Consumables	283
7.2.3.1. Use	284
7.2.3.2. Storage	284
7.2.3.3. Reagent identification	284
7.3. ISE Module Configuration and Use (if included as option)	286
7.3.1. Methods Menu, ISE Module Methods settings	287
7.3.2. Reagents Menu, Configuration of ISE Module Solutions	289
7.3.3. Work List Menu, Electrolytes Programming	289
7.3.4. Working Session, Status Menu	290
7.3.5. Working Session Results and Warning on Results	291
7.3.6. Troubleshooting Low Slope, Noise and Drift Error or other ISE Module Issues	293
7.3.7. ISE Electrodes Calibration.....	295
7.3.8. ISE Module, Working with Controls	296
7.3.9. ISE Module, Memory Files - Database	296
7.3.10. ISE Module, Shutdown Procedure	296
7.4. Procedures	298
7.4.1. Operating Flow Chart	298
7.4.2. Instrument Set-up and Power-On.....	299
7.4.3. Login, Main Menu Access and Auto-diagnosis	300
7.4.4. Warming Up Procedure	301
7.4.5. Working Session Programming and Run.....	302
7.4.5.1. Manual Work List Programming and Run	303
7.4.5.2. Automatic Work List Programming with L.I.S. Connection.....	309
7.4.5.3. Notes on Standards and Control	313
7.4.6. Set Reagents on Board During WL Programming	314
7.4.7. Running a Work List.....	316



7.4.8.	Working Session	318
7.4.8.1.	Pausing a Working Session	319
7.4.8.2.	Adding STAT Samples During a Run	320
7.4.8.3.	Adding One or More Samples During a Run	321
7.4.9.	Working Session Results	323
7.4.9.1.	Filing a Patient Completed.....	323
7.4.9.2.	Deleting Analysis Result	324
7.4.9.3.	Deleting a Sample and its Analyses' Result	324
7.4.9.4.	Repetition of One or More Analysis.....	325
7.4.9.5.	Printing Results.....	325
7.4.9.6.	Calculation of Statistic Parameters on Results.....	326
7.4.10.	Reagents Control System	327
7.4.10.1.	Reagent Panel: Manual Configuration	327
7.4.10.2.	Automatic Panel Configuration.....	328
7.4.10.3.	Reagents Barcode Scanning	328
7.4.10.4.	Reagent Lot Number Modification	329
7.4.10.5.	Programming Profiles.....	329
7.4.10.6.	Deleting Profiles	330
7.4.11.	Working with Standards and Controls	332
7.4.11.1.	Mono-standard Methods.....	332
7.4.11.2.	Multi-standard Methods	334
7.4.11.3.	Entering Values for Controls (QC)	335
7.4.11.4.	Viewing Levy-Jennings Graphs and Printing QC Values	336
7.4.12.	Memory Files - Database	339
7.4.12.1.	Searching and Handling Patient Results	339
7.4.12.2.	Searching and Handling QC Results.....	341
7.4.13.	Shutdown Procedure	343
Section 8	MAINTENANCE.....	344
8.	Generalities.....	344
8.1.	General Rules.....	344
8.1.1.	Competences	344
8.1.2.	Cleaning.....	344
8.1.3.	Disinfection.....	345
8.1.3.1.	Instrument Disinfection	345
8.1.3.2.	Metallic Sampling Probes Disinfection	345
8.1.3.3.	Waste Tubing Disinfection	346
8.1.3.4.	Charge Tubing Disinfection	346
8.1.3.5.	Washing Station Needles Disinfection.....	346
8.1.3.6.	Waste Tank Disinfection	346
8.1.3.7.	Systemic Solution and Cleaner Solution Tanks Cleaning	346
8.2.	Safety Precautions	347
8.3.	Periodic Maintenance Plan.....	348



8.3.1.	Daily Maintenance Scheduling	348
8.3.2.	Weekly Maintenance Scheduling.....	349
8.3.3.	20,000 tests Maintenance Scheduling.....	349
8.3.4.	Two Months Maintenance Scheduling.....	350
8.3.5.	One Year Maintenance Scheduling.....	350
8.3.6.	Other Maintenance Needs.....	351
8.3.7.	Maintenance Charts	351
8.4.	ISE Module Maintenance Scheduling.....	355
8.4.1.	Scheduling for LOW Volume Users	355
8.4.1.1.	Daily Maintenance Scheduling	355
8.4.1.2.	One Month Maintenance Scheduling.....	356
8.4.1.3.	Six Months Maintenance Scheduling.....	356
8.4.1.4.	One Year Maintenance Scheduling	356
8.4.2.	Scheduling for HIGH Volume Users.....	357
8.4.2.1.	Daily Maintenance Scheduling	357
8.4.2.2.	One Month Maintenance Scheduling.....	357
8.4.2.3.	Six Months Maintenance Scheduling.....	358
8.4.2.4.	At 3,000 samples Maintenance Scheduling	358
8.4.2.5.	At 10,000 samples Maintenance Scheduling	358
8.4.2.6.	One Year Maintenance Scheduling	358
8.5.	Maintenance Procedures.....	359
8.5.1.	Generalities	359
8.5.2.	Reading Cuvettes Replacement	359
8.5.2.1.	Single Cuvette Replacement.....	360
8.5.3.	Peristaltic Pump Heads Replacement.....	361
8.5.4.	Photometer Lamp Replacement	363
8.5.5.	Sampling Probes Replacement.....	365
8.6.	ISE Module Maintenance Procedures	367
8.6.1.	Reagent Pack Replacement	367
8.6.2.	Electrodes Replacement.....	369
8.6.3.	Electrodes Storage	370
Section 9	PROBLEM SOLVING	372
9.	Introduction	372
9.1.	Generalities	372
9.2.	Auto-diagnosis System.....	372
9.3.	Main Failures and Corrective Actions	373
9.4.	Instrument Status Messages.....	378
9.4.1.	Error Messages, Warnings and Troubleshooting.....	378
9.4.2.	Competences	390
Section 10	TECHNICAL SPECIFICATIONS	391
10.	Generalities	391
10.1.	Instrument Technical Specifications	391



10.1.1.	Sample Tray	391
10.1.2.	Barcode Sample Identification (Option)	391
10.1.3.	Barcode reader (Option)	392
10.1.4.	Reagent Tray	392
10.1.5.	Barcode Reagent Identification (Option)	392
10.1.6.	Smart Card Reader (Option)	392
10.1.7.	Sampling System	393
10.1.8.	Incubation and Reading Cuvette Tray	394
10.1.9.	Optical Group	394
10.1.10.	Washing Station.....	395
10.1.11.	ISE Module (option).....	395
10.1.12.	Control Electronics	396
10.1.13.	Productivity	396
10.1.14.	Liquid, Consumption and Waste Autonomy	396
10.2.	Control System Technical Specifications	397
10.3.	Mechanical Calibrations, Trimmings and Tunings	397
10.4.	Power Supply Requirements	398
10.5.	Operating Environment Requirements	398
10.6.	Storage Environment Requirements	398
10.7.	Dimensions and Weight.....	398
10.8.	Emissions	399
10.9.	Electromagnetic Compatibility	399
10.10.	Electrical Consumptions (with options)	399
Section 11	ADDITIONAL INFORMATION.....	400
11.	Generalities	400
11.1.	Quick Start Guide	400
11.2.	Warranty Limitations	400
11.3.	List of Spare Parts and Consumables	402
11.4.	Information for Orders.....	402
11.5.	System Expansions	402
11.6.	Service	402
11.6.1.	Training Courses	402
11.6.2.	Firmware and Software Upgrades	402
11.7.	Forms.....	403
11.7.1.	Training Course Evaluation	403
11.7.2.	Customer's Satisfaction Questionnaire	405
Section 12	GLOSSARY	408
12.	Glossary	408
12.1.	List of Acronym and Abbreviations.....	408
12.2.	List of Terms	409



i.10 List of Figures

Figure 1: Single ARM model, Instrument Label	19
Figure 2: Double ARM model, Instrument Label.....	19
Figure 3: Electrical Risk Label.....	20
Figure 4: Electrical Risk Icons	20
Figure 5: Laser Light Risk Label	21
Figure 6: Laser risk Icon	21
Figure 7: Moving Part Risk Label.....	21
Figure 8: Potentially Infected Area Label.....	22
Figure 9: Biological Risk Icon.....	22
Figure 10: Generic Risk Icon	23
Figure 11: Potentially Infected Tank Label	23
Figure 12: WEEE symbol	23
Figure 13: CE Mark	29
Figure 14: Generic Danger Icon	29
Figure 15: Electrical Danger Icon	30
Figure 16: Laser Light Danger Icon	30
Figure 17: Biological Danger Icon	30
Figure 18: WEEE Icon.....	30
Figure 19: Bench-top Version	31
Figure 20: ARMs' Clamp.....	43
Figure 21: Floor Stand outline	45
Figure 22: Shelves Assembling.....	47
Figure 23: Power Block, Main Line Protection Fuses	49
Figure 24: Charging and Waste Tanks	52
Figure 25: Charging/Waste Tanks Connections	53
Figure 26: ISE Module, location into the instrument (behind the front panel)	56
Figure 27: ISE Module, Reagent Pack connection	57
Figure 28: M2-79, double ARM with 79-sample positions, working area	60
Figure 29: M1-59, single ARM with 59-sample positions, working area	60
Figure 30: Barcode Reader (option)	65
Figure 31: Refrigeration Unit – ON/OFF Switch.....	66
Figure 32: Photometer, Functional Drawing	69
Figure 33: Generic End-Point Method	72
Figure 34: End Point Method	73
Figure 35: Kinetic Method	74
Figure 36: Calibration Curve	77
Figure 37: M2-79 Working area, entry to ISE Module	106
Figure 38: ISE Module, functional diagram	107
Figure 39: M2-79, Working Area	115



Figure 40: M2-59, Sample and Reagent Wheels	116
Figure 41: M2-79, Sample and Reagent Wheels	117
Figure 42: ON/OFF Front Switches.....	118
Figure 43: Dispensing Assembly, ARM1 and ARM2	118
Figure 44: Dispensing Assembly, ARM1	119
Figure 45: Diluter and Electrovalve	120
Figure 46: Probe Washing Pumps	122
Figure 47: Washing Sink	123
Figure 48: Incubation and Reading Assembly and Washing Station	124
Figure 49: Optical Group – Measurement Circuit.....	125
Figure 50: Washing Station.....	126
Figure 51: Washing Station Scheme.....	126
Figure 52: Washing Station Peristaltic Pumps.....	128
Figure 53: Washing Station, 2-Heads Diaphragm Pump for Aspiration Needles.	129
Figure 54: Main Switch Block	130
Figure 55: Side Panel.....	131
Figure 56: Internal Fuse Panel.....	131
Figure 57: Kroma Plus, User Interface	134
Figure 58: Software, SW Functional Drawing	147
Figure 59: Kroma Plus, Main Menu	148
Figure 60: Work List Menu.....	150
Figure 61: Patient Private Data Window.....	157
Figure 62: Show Work List Window	159
Figure 63: Reagents Menu during WL programming	161
Figure 64: Work List Summary Menu	165
Figure 65: Starting session with alerts.....	167
Figure 66: Status Menu - WL in run	168
Figure 67: Menu Status – System temporary in Pause during a run.....	169
Figure 68: Menu Status – Reagent text summary window.....	169
Figure 69: M2-59, Menu Status – Idle (for Double ARM system)	174
Figure 70: M1-59, Menu Status – Idle (for Single ARM system)	175
Figure 71: Methods Menu	176
Figure 72: Extra Settings Submenu	201
Figure 73: Formula Builder	202
Figure 74: Restriction Menu.....	204
Figure 75: Reagents Menu	207
Figure 76: Profiles Menu.....	210
Figure 77: Standards Menu – Mono-standard example	212
Figure 78: Standards Menu – Multi-standard example	213
Figure 79: Calibration Curve	218
Figure 80: Quality Control Menu	219
Figure 81: Levy-Jennings Graph	223



Figure 82: Results by Patient Menu	225
Figure 83: Kin/Fixd Time graph	229
Figure 84: Repetitions Menu	233
Figure 85: Results by Method Menu	235
Figure 86: Selection and Statistics Calculation.....	236
Figure 87: Q.C./Std Results Menu	239
Figure 88: Memory Files Menu	243
Figure 89: Report Window.....	247
Figure 90: Std/Q.C. Archive Menu.....	250
Figure 91: System Config Menu	259
Figure 92: Cvt status Menu	264
Figure 93: Users Menu	266
Figure 94: ISE Module Menu	269
Figure 95: Calibration history Menu.....	273
Figure 96: Show Alerts Window	275
Figure 97: Extra Procedure Pull-down Menu	276
Figure 98: Actual Statistics Window.....	279
Figure 99: Primary Tubes – Barcode labelling	283
Figure 100: 50ml Reagent Bottle – Barcode Labelling	285
Figure 101: 20ml Reagent Bottle – Barcode Labelling	285
Figure 102: Operating Flow Chart	299
Figure 103: Power-Up Switches	299
Figure 104: Software – Login User name and Password.....	300
Figure 105: Software, Work List Menu.....	302
Figure 106: Software, Patient Private Data Window.....	304
Figure 107: Software, Display Work List	306
Figure 108: Software, Work List programming	311
Figure 109: Software, Reagent Menu	314
Figure 110: Software, Work List Summary Menu	316
Figure 111: Software, Error Message on WL Start	317
Figure 112: Software, Status Menu	318
Figure 113: Software, Result by Patient Menu	323
Figure 114: Software, Reagent Menu	327
Figure 115: Software, Quality Control Menu	336
Figure 116: Software, Memory Files, Patients Archive Menu	339
Figure 117: Software, Std/Q.C. Archive Menu.....	342
Figure 118: Cuvette Replacement.....	360
Figure 119: Peristaltic Pump Heads Placement.....	361
Figure 120: Pumps/Loads Connections to the PWR Driver Boards	362
Figure 121: Photometer Lamp Replacement	363
Figure 122: Sampling Probe Replacement	365
Figure 123: ISE Module, Outline.....	367



Section 1 SAFETY

1. Safety Prescriptions

The user must strictly observe all prescriptions included in this section when using the instrument and its consumable/disposable materials.

Different use of the instrument, as described in the session 5 and following, automatically revoke the warranty.

This warranty applies exclusively to new products which have never been used and which have not, after shipment by the producer, been damaged, altered, repaired or modified in any manner, due to negligence or other reasons, by persons not authorised to represent the producer, even if they have sold/worked on the product. The producer is not liable for any Warranty obligations should any modifications (on hardware and software) or repairs have been made to the product without producer's express written consent nor for missing of periodic maintenance.

1.1. General Instructions

Every note and warning included in this manual, highlighted in bold and/or underlined characters, must be read carefully and special attention must be given to the following sections or sub-sections:

- Section 3 – Installation
- Section 8 – Paragraph on Disinfection

The user must not take off the sampling probe protection defence or by-pass the cover sensor of the instrument and he must be sure that it is correctly closed before starting every session of analysis.

The user must be sure that every technical intervention for installation, maintenance, calibration, inspection of services and reparation is carried out by qualified technical personnel.

The user must follow every precautions referring to good laboratory practice (GLP). The instrument indeed, even if executes diagnostic tests automatically, would not be able to operate what the operator could solve manually: this is the case of the preparation of samples and reagents; so read the proper and suitable instructions within Section 7.

During the use of consumables, the user must be sure about their integrity and lack of defects.

The user must be sure to follow the correct analysis procedures and monitor the following points:

- Aspiration, transfer and distribution of the liquids.



- Mixing of the liquids without the formation of bubbles, which could be cause of problems in the subsequent steps of the diagnostic process.
- Accuracy of calculations: he must be sure that the calculation carried out by the software give results which can be compared to those given by using the methods of the producer.

These processes are usually verified by the producer or by the distributing agent; if the specifications for a particular method of analysis aren't available, the user must validate this procedure by himself. Every alteration of a pre-validated procedure needs to be validated again.



1.2. Labelling

Marking of instrument

The following label is placed on the right-rear part of the instrument, close to main-switch, and shows: the producer's name, the instrument type, the instrument part number, the instrument serial number, the supply and consumption specifications, the type of protection fuses and the year of production. Moreover the label informs the user or the qualified technician that the fuses must be replaced by other ones of the same type and value in order to protect the instrument and avoid risk of fire.

The symbol CE indicates the conformity of the instrument, and of the parts where it is applied, to the essential safety requirements according to the corresponding European directives.

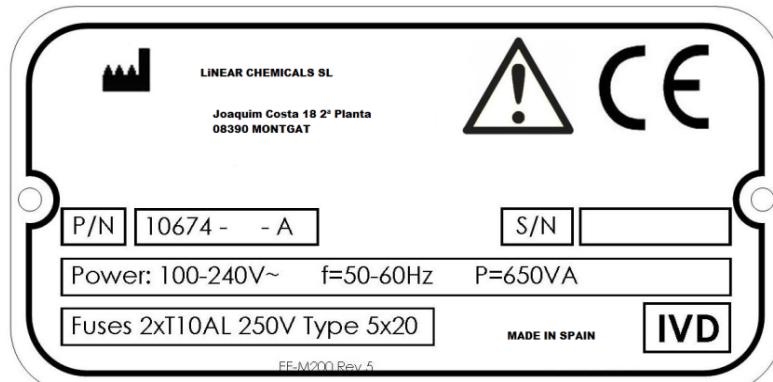


Figure 1: Single ARM model, Instrument Label

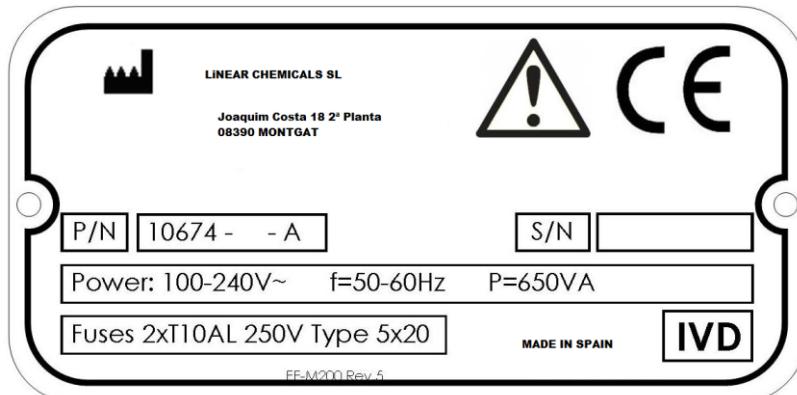


Figure 2: Double ARM model, Instrument Label

Electrical Hazard

The following label is placed on the instrument.



- a) two of the following labels are placed on the instrument, one on the removable back panel and the other one on the removable right side panel; they inform the user about the potential electrical risk associated with opening the panels and that such operations must be carried out by qualified technician for maintenance.



Figure 3: Electrical Risk Label

- b) the following label (icons) are placed inside the instrument, on the AC/DC power supplies area, to inform the qualified technician about the potential electrical risk.



Figure 4: Electrical Risk Icons

Laser Light Hazard

The following labels are placed on the instrument.

- a) This label is placed inside the instrument, on the barcode reader, to warn and advise the qualified technician about the laser source characteristics.



Figure 5: Laser Light Risk Label

- b) This label (icon) is placed near the reagents tray of the instrument and informs the user or the qualified technician about the presence of a laser source below, inside the instrument.



Figure 6: Laser risk Icon

Moving Parts Hazard

The label is placed on the front part of the instrument and it informs the user about the risk associated with certain moving parts within the working area of the instrument: sampling probes, washing station, sample tray and reagent tray.



Figure 7: Moving Part Risk Label

Bio-hazard Area

This label is placed on the working area. It informs the user of the potential risk of biological contamination from infected liquids in the area.



Figure 8: Potentially Infected Area Label

Bio-hazard liquids

Four of these labels (icons) are placed on the instrument: one is near the waste outlet of the instrument, one on the washing station cover and two on each of the sampling ARMs. The label informs the user of the possible contamination from infected liquids or probe.



Figure 9: Biological Risk Icon

Generic Hazard

Two similar symbols (icon) are placed on the instrument: one on the protection cover and one on the plexiglass protection of the step motor driver. It informs the user of the potential risk associated with opening the protection and with residual possible probe movements.

This icon informs that there is a risk associated to the operation, that the user is going to execute and, consequently, it is necessary to carefully follow the proper instructions mentioned in this manual.





Figure 10: Generic Risk Icon

Potentially infected tank label

This label is placed on the external waste tank. It informs the user of the possible biological contamination related to the waste tank.



Figure 11: Potentially Infected Tank Label

WEEE Compliance

This label is placed on the rear side of the instrument near power inlet. It informs users that this product must be disposed off in accordance with the European Union WEEE Directive 2002/96/EC.



Figure 12: WEEE symbol



1.3. Safety Precautions

The instrument does not constitute an electrocution hazard if installed without modification, and if connected to an electrical power supply having the required characteristics.

To reduce danger of shock stay away from the electrical circuits.

The instrument, which must be always and permanently grounded, is provided with a three conductor sheathed cable to be connected to single-phase sockets 110Vac/220Vac with frequency 50Hz/60Hz. Install the instrument and the PC under a 1kW - UPS.

See Section 3 - Installation, and Section 10 - Technical Specifications, for details regarding the electrical power supply.

The operator must not remove the protective cover.

Service must be carried out by qualified personnel, trained by the producer.

1.3.1. Installation

The installation, the check and the calibration of the instrument must be made by qualified technicians on buyer's request. He must be sure that the installation of the instrument is in conformity with environmental and electro-magnetic specifications for the instrument (see Section 10 – Technical Specifications). Every significant transfer of the instrument must be carried out by qualified personnel.

The instrument can be placed closer to a rear wall by leaving at least **15cm of free space** for the correct cooling-fan operation and for the opening of the cover. The space under the instrument must be free from objects and obstructions to allow air circulation and way out for the air that the fan extracts from the inside of the instrument itself.

1.3.2. Operations

The user must respect the following safety precautions not to get wrong results:

- Don't use reagents, solutions and consumables different from those suggested by the producer.
- Don't use the external PC for purposes different from those specified by the producer.
- Don't open the cover during the runs without reasons; its opening is controlled by the software managing the instrument (follow the proper procedure).
- Follow only working procedures pre-validated by producer or by delegated company.
- Don't change pre-validated procedures.



- Follow the instructions of the Producer to switch on and off the instrument (see Section 7 – Operational Procedures).

NOTE: The producer reminds the user that the unobserved procedures can cause risk of biological contamination, damages for the instrument, danger and damages for the operator.

NOTE: The producer recommends filling the samples tubes and the reagent bottles avoiding formation of bubbles or foam. Those can disturb the correct operation of the liquid sensor and cause wrong sampling, with consequent errors in the determination of the results.

1.3.3. Maintenance

During the life of the instrument the user must carry on daily, weekly and periodic procedures of maintenance referring to Section 8.

NOTE: the producer reminds the user that the periodic visual inspection of the instrument is the first and easier way to guarantee the best performance of the instrument itself.

The user, during the periodical maintenance must observe the following safety recommendations:

- Read carefully the instructions included in the section 8 before starting the maintenance.
- Clean every parts of the instrument using a soft cloth; use only not corrosive solutions.
- Remove possible splashes or liquid losses from the working area.
- Use only suggested disinfection solutions diluted with the correct ratio.
- Never introduce metallic objects into the sampling needles.

WARNING

The maintenance operations left to the user must be carried out with the instrument OFF and with the power supply cable disconnected from the socket of the main line.

1.3.4. Transport and Storage

To transport the instrument use always the original packing.

For preserving the instrument read carefully the paragraph 10.6 – Environment Storage Requirements.



1.4. Risks During Use

The producer reminds the user that the use of the instrument doesn't exclude the exposure to contamination risk, so it must be always considered as potentially infected.

The producer declares that the information included in this manual can be considered sufficient for the use without risks of the instrument **only** in case the user has attended a **specific training**, effectuated by the producer or by its representative.

In order to get the best performances and to fully use the instrument, the producer recommends that operators were educated about the basic use of the operative system MS Windows®.

The producer assumes that all precautions and recommendations, normally used in a laboratory, are followed (GLP – Good Laboratory Practice).

NOTE: To avoid risks during operation, don't make any change to the instrument.

1.4.1. Risks for the Operators

To avoid risks the operator must observe the following prescriptions:

- Don't eat, drink or smoke in laboratory.
- Wear the gown, especially when close to the instrument.
- Wear protection glasses and gloves to handle samples and reagents.

1.4.2. Safety Information for the Operators

The manufacturer declares that all internal parts of the instrument are designed and made so as to prevent all possible risks for the user, in accordance with established legislation and according to the rule EN 61010-1.

It is essential, for the safety of the operator, to install an emergency switch not beyond than 1m from the instrument.

1.4.3. Information on Liquids and Infected Parts

The use of the instrument doesn't assure the absence of exposures to biological risk.

The producer informs the user that each of the parts of the instrument that can get in touch with blood, serum or other biological liquids, controls and/or reagents included, must be always treated like potentially infected materials.

WARNING

The instrument must be always considered like potentially infected.



1.4.3.1. Treatment

Biological samples (serum, plasma, urine, CSF, ...) and reagents or controls, if not explicitly declared by their manufacturers, must be always considered potentially infected; consequently, in order to avoid any contact, the operator must treat them wearing the following protections:

- Gown.
- Mono-use Latex Gloves.
- Safety glasses.

The operator must be particularly careful when treating the following parts of the instrument:

- Washing station.
- Sampling probes.
- All needles and the tip of the washing station.
- Waste tank and waste tubing.
- Cuvettes tray.
- Washing sink for the sampling probes.

These parts are in contact with biological liquids and can be contaminated.

Refer to section 8 for correct disinfection procedure.

Every tool and instrument used for the technical service must be disinfected after use and before packing away.

1.4.3.2. Waste Materials

Every waste material, both liquid and solid, must be disposed of according to the local laws and rules.

WARNING

Every waste material must be always considered potentially infected.

The producer declares that the qualified personnel has been educated and trained about the infected materials treatment.

The parts of the instrument out of order and replaced by authorized technician must be treated like potentially infected.

WARNING

Discharges and replaced instrument's materials, that could be contaminated, must be sterilized, first to go out from the customer laboratory.



The disposing of the instrument must be executed in conformity with the national rules, with reference to the local environment authority, considering that it is built with materials not dangerous for the environment.

1.5. Advices for a Correct Use

The user must observe the following recommendations to have good instrument performances:

- pay attention to any leak of liquids (i.e.: fill the sample tubes out from the instrument).
- The user must be sure that bottles of reagent and sample tubes are correctly positioned.
- Do not install any software on the PC not required for the system. **During use of the instrument, other programs must not be used** (i.e.: Antivirus, Screen Savers, Power Managers, ...)
- The instrument isn't provided with a system for detecting the presence of reading cuvettes (or reaction cells). In case of total or partial substitution of them, the operator must carefully check that the cuvettes have been placed in **all** of the 80 positions.
- If the laboratory isn't equipped with an on-line emergency power supply, **the Producer strongly suggests to connect the system (instrument and PC) under an UPS (1kW power)** to overcome reasonable supply gaps. Short supply gaps can cause wrong results not traceable by the operator nor by the instrument itself.
- Prior to run the instrument, the user must be sure that all of the caps have been removed from all reagent bottles and samples.

WARNING

The use of the instrument for purposes different from those specified, indicated or approved by the producer allows the warranty terms to lapse automatically. The producer can act legally to protect his interests.



Section 2 ICONS

2. Icons

The following general icons are placed on the instrument to assure a correct and safe use. The user must know their means and positions.

- **Quality Mark**

CE Mark

This icon means that the instrument and its parts are in conformity with the European directives. It is placed on the back of the instrument near the main switch.



Figure 13: CE Mark

- **Safety Icons**

Warning of Moving Parts

This icon is placed on the protection cover of the instrument. It informs the user of the potential risk caused by moving mechanic parts when the cover is opened or the washing station protection is removed.



Figure 14: Generic Danger Icon

Electrical Risk Danger

This icon, placed on the AC/DC power supply and on the back of the instrument, near the main switch, informs the user of the electrical risk.



**Figure 15:** Electrical Danger Icon**Laser Light Danger**

This symbol (icon), placed near the reagent tray of the instrument and on the barcode reader inside the instrument, informs the user of the risk caused by the laser light emission.

**Figure 16:** Laser Light Danger Icon**Contamination by Infected Liquids**

This icon is placed: near the waste liquids discharge outlet of the instrument, on the washing station cover, on the back panel, on the waste tank and on the working area and it informs the user of the possible risk of biological contamination.

**Figure 17:** Biological Danger Icon

- **Indication Symbol**

WEEE

This icon informs users that this product must be disposed off in accordance with the European Union WEEE Directive 2002/96/EC.

**Figure 18:** WEEE Icon



Section 3 INSTALLATION

3. Description of the Instrument

This system, in each of its configurations, is a random access auto-analyzer designed to operate in safety mode and with the maximum productivity in accordance with the latest manufacturing standard and in conformity with the actual international normative.

The instrument is basically available in two models, **SINGLE Sampling ARM (M1)** and **DOUBLE Sampling ARM (M2)**, that differ substantially in throughput. Both of these models can be supplied in two configurations of the sample tray, **59-sample** and **79-sample** positions on board.

All of these systems can be supplied for **bench-top** installation and for **floor-standing** installation by ordering the optional stand. The second version provides the installation of the instrument on a specific **stand** that contains the tanks for fluids (charging and waste), the PC and to the A4-printer.

The basic versions are:

- **M1-59**, single-ARM, 59-sample positions
- **M1-79**, single-ARM, 79-sample positions
- **M2-59**, double-ARM, 59-sample positions
- **M2-79**, double -ARM, 79-sample positions

Configurations with 59-sample positions can accept tubes with diameter **12mm-16mm**. Configuration with 79-sample positions can accept tubes with diameter **12mm-13mm**. The tube height is between 75mm and 100mm in both cases.



Figure 19: Bench-top Version



The User Software application is installed on an external PC, provided with LCD monitor (assembled on the instrument cabinet), mouse and keyboard; it allows the complete control of the instrument through a RS-232 serial link.

The instrument working area is protected by a protection cover. It includes the samples and the reagents tray and the sampling ARMs; the reaction cuvettes wheel is on the right. Cuvette incubation temperature is constantly maintained at 37°C. Reagents can be refrigerated at about 12°C ±2°C.

On the instrument cabinet, right frontal side, are placed two switches, one for the electronic control of the instrument (green colour) and the other for the refrigeration unit (blue colour). The ON/OFF status of the refrigerator is completely separated and independent from the ON/OFF status of the electronic and from the ON/OFF status of the PC.

A built-in barcode reader (option) allows the positive identification of reagent bottles and of sample tubes, when barcoded.

The software controls also marginal events in order to operate in safety conditions within the working area.

Note: Installation must be carried out by authorized personnel only.



3.1. Supplied Parts

This section lists all of the parts actually supplied together with the instruments.

3.1.1. List of the Supplied Parts

The instrument shipment includes all the items listed in the packing list; at the actual date the following items have been included.

Model: M2-XX, Double sampling ARM

Item	Conf./Pack
External PC with mother board box	1 pcs
CD with SW licence	1 pcs
CD with drivers	1 pcs
Power cord for PC	1 pcs
PC Monitor	1 pcs
Support for monitor	1 pcs
Power cord for monitor	1 pcs
Serial cable for monitor	1 pcs
Keyboard with mouse	1 pcs
USB cable for printer	1 pcs
Printer	1 pcs
Operation program software	1 CD
Photometer lamp (20W)	1 pcs
Reagent bottle 20 ml	30 pcs
Reagent bottle 50 ml	50 pcs
Serial cable	1 pcs
Dilution and pediatric cups	250 pcs
Reading cuvettes	5 pcs
Waste tank 25 lt	1 pcs
Charge tank 20 lt for systemic sol.	1 pcs
Cleaner sol. tank 5 lt	1 pcs
Sistemic solution 6x50 ml	1 kit
Multiclean solution 2 lt	1 kit
Rinse solution (Cvt) 6x50 ml	1 kit
Rinse solution (Prb) 6x20 ml	1 kit
Cuvette's extraction tool	1 pcs
Plug for reagent bottle	80 pcs
Power cord	1 pcs
Kit tubes for waste tank (25 lt) red	1 pcs
Kit tubes for cahrge tank (20 lt) systemic sol. Green	1 pcs
Kit tubes for cleaner sol. tank (5 lt) blue	1 pcs
Serum cups 3 ml	250 pcs
Adaptors for serum cups 3 ml	50 pcs
Tank adaptor	1 pcs
User manual	1 pcs
Brief manual	1 pcs



Item	Conf./Pack
Conformity declarat.	1 pcs
Check list	1 pcs
ISE module manual (OPTION)	1 pcs
Smart card reader (OPTION)	1 pcs

Model: M1-XX, Single sampling ARM

Item	Conf./Pack
External PC with mother board box - OPTION	1 pcs
CD with SW licence - OPTION	1 pcs
CD with drivers - OPTION	1 pcs
Power cord for PC - OPTION	1 pcs
Monitor - OPTION	1 pcs
Support for monitor	1 pcs
Power cord for monitor - OPTION	1 pcs
Serial cable for monitor - OPTION	1 pcs
Keyboard with mouse - OPTION	1 pcs
USB cable for printer - OPTION	1 pcs
Printer - OPTION	1 pcs
Operation program software	1 CD
Photometer lamp 20 W	1 pcs
Reagent bottle 20 ml	30 pcs
Reagent bottle 50 ml	50 pcs
Serial cable	1 pcs
Dilution and pediatric cups	250 pcs
Reading cuvettes	5 pcs
Waste tank 25 lt	1 pcs
Charge tank 20 lt for sistemic sol.	1 pcs
Cleaner sol. tank 5 lt	1 pcs
Sistemic solution 6x50 ml	1 kit
Multiclean solution 2 lt	1 kit
Rinse solution (Cvt) 6x50 ml	1 kit
Rinse solution (Prb) 6x20 ml	1 kit
Cuvette's extraction tool	1 pcs
Plug for reagent bottle	80 pcs
Power cord	1 pcs
Kit tubes for waste tank (25 lt) red	1 pcs
Kit tubes for cahrge tank (20 lt) sistemic sol. Green	1 pcs
Kit tubes for cleaner sol. tank (5 lt) blue	1 pcs
Serum cups 3 ml	250 pcs
Adaptors for serum cups 3 ml	50 pcs
Tank adaptor	1 pcs
User manual	1 pcs
Brief manual	1 pcs
Conformity declarat.	1 pcs
Check list	1 pcs
ISE module manual (OPTION)	1 pcs



Item	Conf./Pack
Smart card reader (OPTION)	1 pcs

3.1.2. List of Optional Parts

The following items are considered as option and they are supplied by default with the system (unless otherwise specified):

- Bar code reader.
- Reagent refrigerator unit.
- Double door floor-stand (pedestal).
- Personal Computer, including: CPU, LCD monitor, keyboard, mouse and A4 printer.
- ISE Module (only on express request upon purchase order).



3.2. Installation Requirements

To achieve a correct installation of the instrument the operator must observe and respect each of the mechanical and environment constrains listed in the following of this document; only in this case the correct operation of the system is assured.

3.2.1. Mechanical Constrains

This instrument must be exclusively used indoor and not outdoor.

The bench-top version must be installed on a horizontal flat surface not subject to vibrations (i.e.: centrifuges, etc.). The workbench (min. 150cm long and 80cm deep) must be stable enough to avoid unwanted oscillations and auto-vibrations, indeed it must accept at least **100kg** nominal load on its surface.

The floor-standing version must be installed on a horizontal flat floor not subject to vibrations, as for bench-top version, and far away from vibration sources.

3.2.2. Environment Constrains

The room where the instrument is installed should have air conditioning system to get constant temperature and constant relative humidity for better performance. Avoid placing instrument to the direct sunlight.

The operating environment temperature is included in the range **+18°C÷+32°C**.

The maximum operating relative humidity is **80%** at +31°C with linear fall to 65% at 32°C (without condensation).

The instrument must be located far away from electromagnetic wave sources (such as big electric motors, lifts, therapeutic equipment, X-Ray machines).

The instrument can be situated next a wall, **not closer than 15cm** so to have enough free space at back to allow the correct fan cooling operation and the opening of the cover.

In order to give easy operations around the bench-top version, the user must provide enough space for the Personal Computer.

The instrument should be placed near to the discharge point to help the handling of the 25lt waste tank.

Note: before to unpack the instrument for installation, all of the mechanical and environment constrains must be verified.

3.2.3. Software

The user software is an application developed expressly for this instrument in order to run under MS Windows XP® operating system. This application must be used only for monitoring and controlling the instrument.



A special section of the software is available to the service operators only for service purposes (mechanical calibrations, controls, motion commands, etc.); it can be accessed using a special and “confidential” user ID and password only by authorized service personnel.



3.3. Storing the Instrument

Store the instrument in a dry environment and respect instructions described in the paragraph 10.6.

The instrument must be stored solely in its original packing box; the storing operations must be executed by qualified personnel authorized only and the instrument must be fixed on the base of the box.

For reagents preservation refer to the instructions for the use.

3.4. Unpacking

Before proceeding to unpack the instrument, all of the mechanical and environment constrains must be verified.

3.4.1. Packing Characteristics

The instrument is generally sent fixed and closed into a proper wooden box to give the maximum protection during transportation in normal conditions. In case the instrument must be moved or re-delivered always use the original package. The management PC is also packed separately from instrument and together with the accessories in another wooden box.

The double-door floor-stand pedestal, when part of the supply, is delivered in an additional wooden box.

3.4.2. Inspection for Damages Caused by the Transportation

At the receipt of the instrument and anyway before installation, the customer must check the goods for possible damages. The eventual damages caused during the transportation must be noted down and immediately notified to the shipping company.

After the delivery acceptance of the packages, the responsibility for their integrity is in charge of the recipient.

In case that damages have been noticed follow this procedures:

1. Don't reject the shipment;
2. Write a note describing the instance;
3. Don't remove the instrument from its packing and request the shipping agent to inspect the goods within 15 days from delivery. If the shipment is international you must ask for inspection within 3 days from delivery.
4. Immediately notify the instance to the distributing LiNEAR representatives.

NOTE: the above mentioned procedure can change in conformity with local rules and/or with particular agreements reached with the shipping agent.

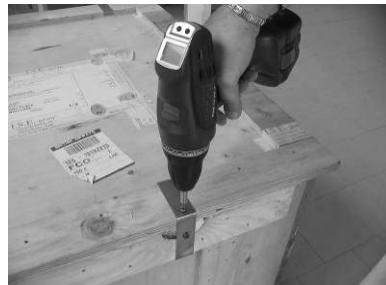


3.4.3. Unpacking the Instrument

A minimum of two people are required to unpack and to take out the instrument from the box.



1. Remove all screws that fix the clips of the box top cover by using a manual or an automatic phillips screwdriver. Remove that clips and save them for re-use.



2. Remove the box top cover.

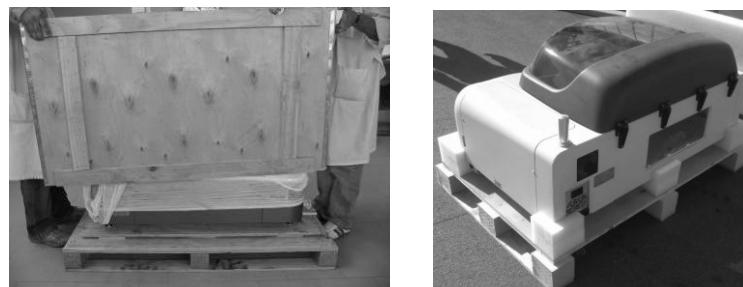




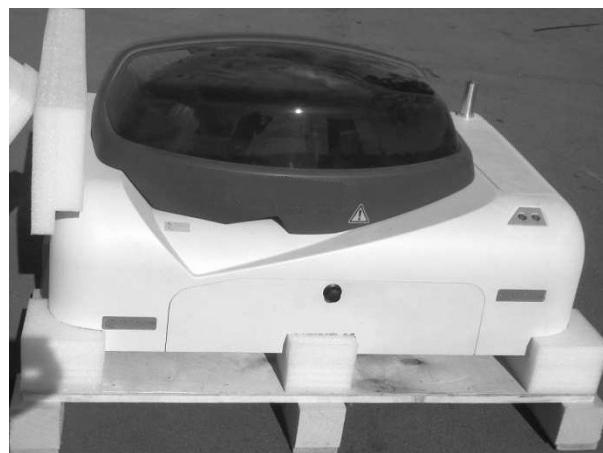
3. Unscrew all screws (if any) fixing the clips of the box walls to the box base. Remove the clips and save them for re-use.



4. Carefully lift up and remove the side walls of the box.



5. Take out any protective film from the instrument.
6. Extract the four hidden shifting handles, integrated in the base of the instrument, lift it up and place it on the working bench (if bench-top version) or on its stand (if floor-standing version).



7. Fix the monitor on the cabinet through the support (see details in the following), place keyboard and mouse on the workbench and the PC-CPU



close to the instrument (if bench-top version). In case of floor-stand version keyboard and mouse can be placed on the console-tables of the pedestal and the PC-CPU and printer, inside the pedestal.

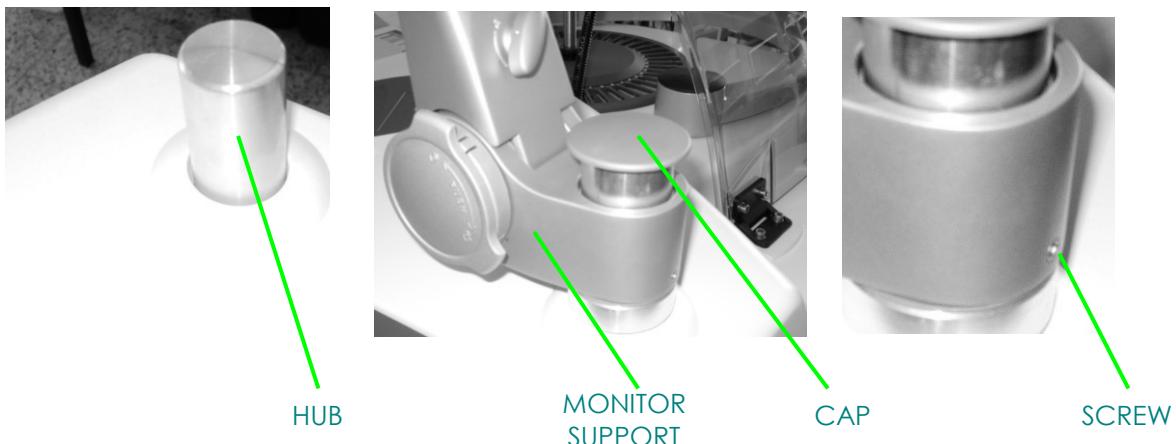
8. Control the presence of all parts listed in the packing list.
9. Control that the instrument serial number is the same reported "on the packing list"; if different, write a note about the problem.

NOTE: Store the original boxes in case you want to re-pack or to move the instrument.

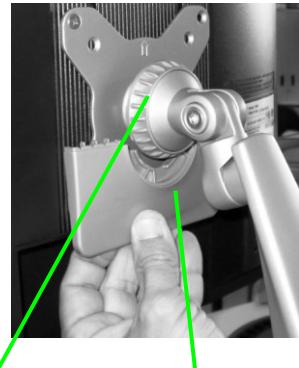
3.4.4. Fixing PC Monitor on the support

To fix the PC monitor on the cabinet, use the support supplied in the packing list by placing it on the hub:

1. Insert the monitor support on the anchor hub fixed to the instrument cabinet and put the cap on it. Tight the screw to regulate the support rotating friction.

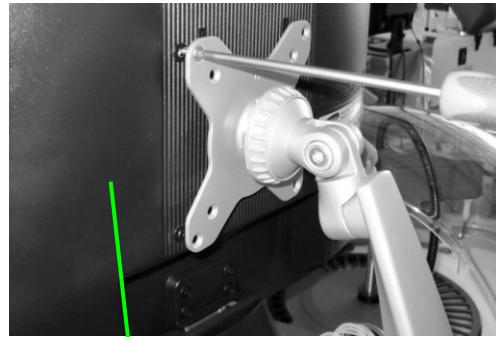


2. Unfasten the rear lock wheel the and take out both protecting covering. Fix the monitor to the support by the four screw on the standard VESA fixings using a phillips screwdriver.



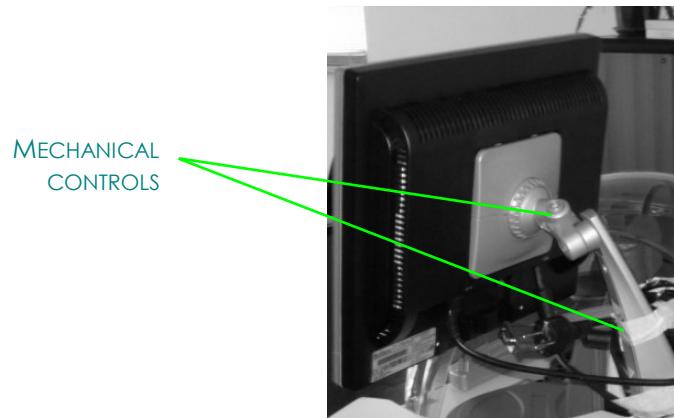
LOCK WHEEL

PROTECTIVE COVERING



MONITOR

3. Reassemble both protective covering and lock them by turning the wheel. Regulate the monitor positions by losing the mechanical controls and then fix it.



MECHANICAL CONTROLS





3.4.5. Removal of Sampling ARMs' Clamps (for Double ARM only)

Open the instrument cover and remove the clamps fixing together the sampling arms by using an Allen key measure 3mm (for M4 hexagonal screws).
Also remove the probe protection.

NOTE: Store the elements in case you will further re-pack or move the instrument again.



Figure 20: ARMs' Clamp

3.4.6. Unpacking the Floor-stand (Option)

A minimum of two people are required to unpack and to take out the double-door floor-stand from the box.



4. Remove all screws that fix the clips of the box top cover by using a manual or an automatic phillips screwdriver. Remove that clips and save them for re-use (refer to the instrument unpacking instructions).
5. Remove the box top cover. Unscrew all screws that fix the clips of the box walls to the base. Remove that clips and save them for re-use (refer to instrument unpacking instructions).
6. Remove the side foam protections.



7. Carefully lift up and remove the side walls of the box.
8. Take out the protective film enveloping the floor-stand.



9. Cut and take away the strapping that fix the floor-stand on the base of the box.



10. Provide box assembling on a flat floor.

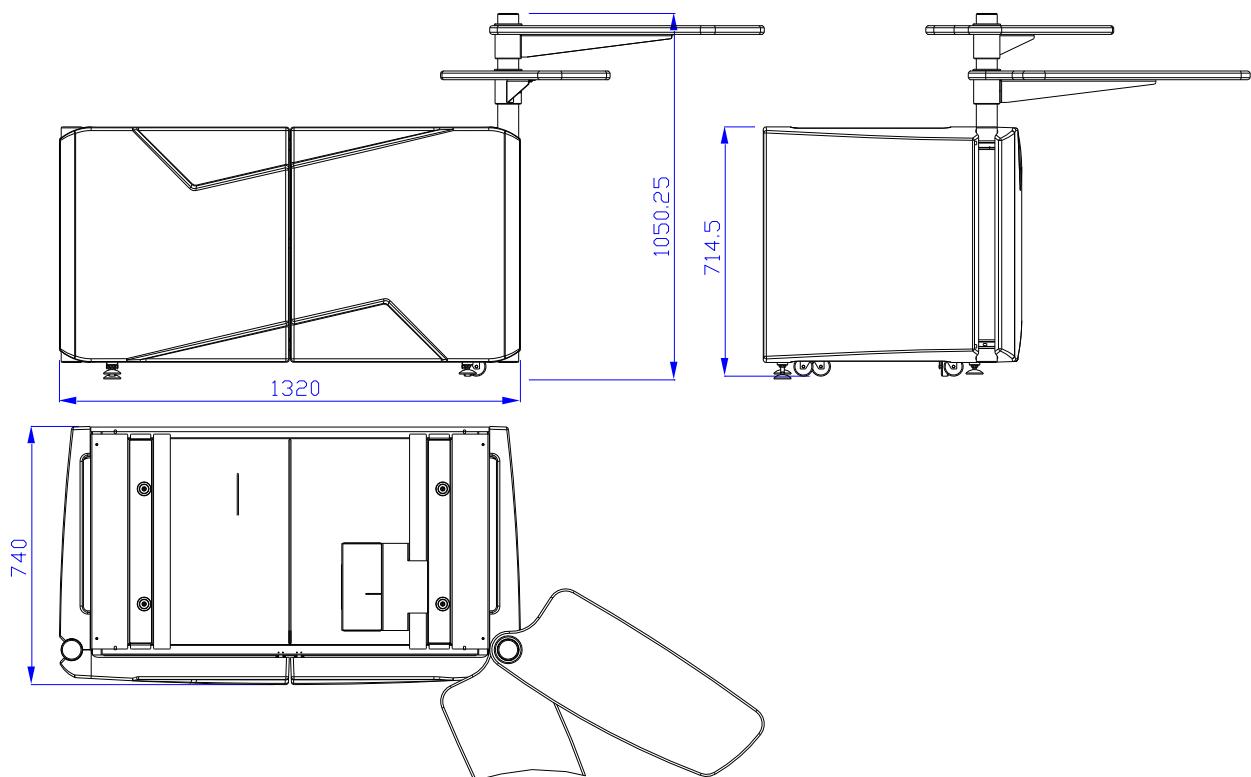




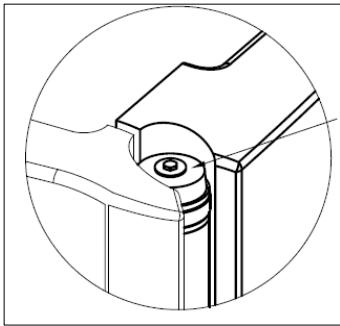
Figure 21: Floor Stand outline



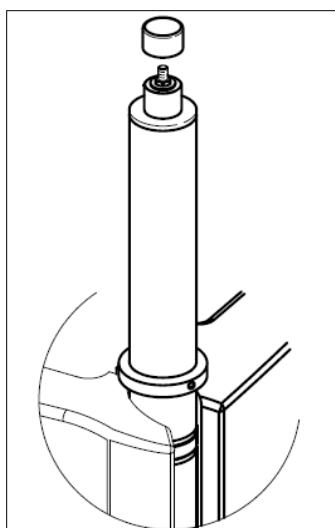
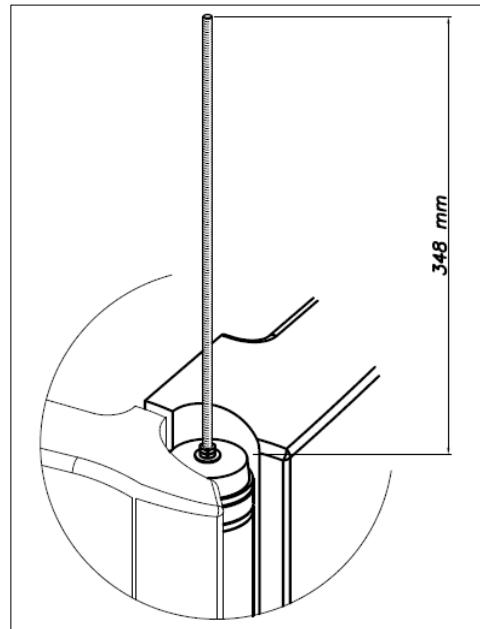
SHELF HOLDER BAR – Assembly procedure

Requested tools:

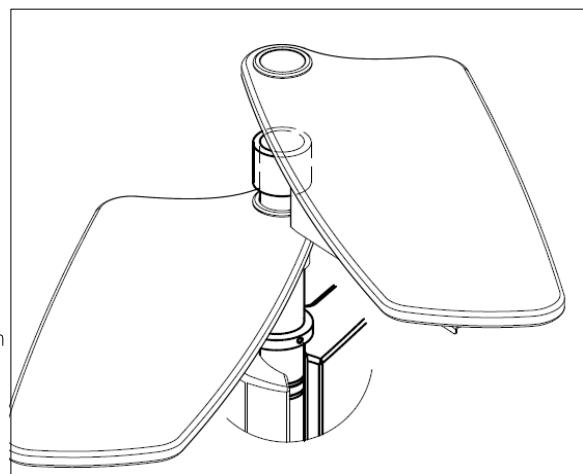
- Open end wrench Ch=13
- Measuring tape



- 1) – Remove the screw and the washer used for the shipment



- 2) – Screw in the Threaded Bar, insert a washer and lock at the suggested measurement by two M8 nuts.



- 3) – Insert the Black Holder Cylinder, insert the upper bushing and lock by using a washer and a M8 nut; then screw on and tight the top cap.
- 4) – Insert the first shelf, insert the diam.80mm spacer and then insert the second shelf. Position both shelves and then lock by the two knobs.



Figure 22: Shelves Assembling



3.5. Instrument Installation

The system is a sophisticated instrument for precision measurements. A proper installation assures the user the correct instrument operation. The Producer recommends that the installation has to be carried out by qualified personnel authorized and specifically trained by LiNEAR

For the instrument installation apply the procedure specified in the following paragraphs. For floor-stand version install first the pedestal (see previous paragraph).

Detailed instructions about safety have been already given in Section 2.

3.5.1. Main Steps to Follow During Instrument Installation

After having unpacked the instrument and prepared the work bench the authorized technician must refer to the steps of the "System First Installation Check List"; the **main** steps have been listed below:

Actions
1. Before to install the instrument, control that the site respects all environment requirements. Check the power outlet of the electrical system to have the earth leakage protection in order to properly ground the system.
2. Check the instrument and accessories integrity; remove the protections including eventual clamps blocking the sampling ARM.
3. Place the instrument on its proper floor-stand, after levelling off the pedestal by using its adjustable small wheels and locking them. In case of a bench-top analyser, install it on a flat surface able to withstand the load and if required regulate the supports to level the instrument.
4. Connect the Personal Computer (PC) parts.
5. Control the proper voltage selection on the rear selector of the Personal Computer. Specify if 220Vac _____ or 110Vac _____.
6. Install the system under UPS (universal power supply) - minimum power = 1kW.
7. Interconnect the PC to the instrument by mean of the RS232 serial cable.
8. Fill the Systemic tank, the 20-litres green one, with the Systemic Solution (composed by one 50ml vial of concentrated Systemic solution diluted into 20 litres of distilled water). Connect the tank to the instrument.
9. Fill the Cleaner tank; the 5-litres blue one, with the Cleaner Solution (5-litres of Multiclean solution not to be diluted). Connect the tank to the instrument.
10. Empty the Waste tank, the 25-litres red one, and connect it to the instrument.
11. Power on the instrument.



12. Power on the PC and enter the operating system by using the default "User" account → User Name: "**user**" without entering any password.
13. Close the cover and run the software by clicking on the green arrow icon in the desktop and log-in the software using the default Username "**admin**" and the default password "**12345678**": the instrument will perform a complete hardware reset and then will enter the warming-up time.
14. Wait for the end of the Warming Up (about 30 minutes) and check that the system will pass in the IDLE status waiting for commands.

3.5.2. Electrical Connections and Stabilizer

According to the safety prescriptions listed at the beginning of this manual the instrument must be grounded in order to reduce the electrical shock risk for the operator. Not only, full performance of the System is assured only in case of proper ground connection.

The instrument is provided with a 3-conductor sheathed power cable suitable for connection to 110Vac/230Vac supply inlets; selection of the operating voltage or frequency is not requested nor necessary on the instrument, it is required only on the PC. Plug one end of the power cable in the inlet placed in the rear side of the instrument, and the other end to 110/230Vac @ 50/60Hz wall socket equipped with safety ground connection.

NOTE: the system cannot manage temporary power supply gaps. Consequently it is strongly recommended to install an UPS, able to supply 1.0kW, to power both the instrument and the personal computer (PC).

3.5.3. External Fuses

Into the power supply block, placed in the left side of the instrument, there are two standard protection fuses 5x20mm, 10A/250V T-type (delayed).

In case of power failure, it is possible to replace them by pulling out the 2-pole fuse-drawer. In that case disconnect the power cord before to open the drawer.



Figure 23: Power Block, Main Line Protection Fuses



3.5.4. Fittings and Consumables

The standard accessories of the instrument are essential parts for a proper operation.

The instrument must be connected to the three external tanks:

- 20lt tank: for the systemic solution needed to fill up the hydraulic circuits devoted to cuvettes washing (washing station) and to probe rinsing;
- 5lt tank: for the multi-cleaner solution used from the first needle of the washing station for the washing of cuvettes;
- 25lt tank: for the waste liquids.

The connection between tanks and instrument will be discussed in the following paragraph.

The cuvette tray (for reactions and readings) must be always provided with *all of the 80 plastic cuvettes; no position must be ever left without its own cuvette.*

The table shown in paragraph 3.1.1 “List of the Supplied Parts” lists accessories and consumables supplied with the instrument (the instrument is furnished with the sampling probe/s and 80 cuvettes already assembled).

3.5.4.1. Liquid Solutions for the System

The Systems need the following solution for normal and reliable operation:

- **Systemic Solution:** filled into the 20 litres tank (“green” colour).
- **Multi-Cleaner Solution:** filled into the 5 litres tank (“blue” colour).
- **Rinse solution EW Cvt** filled into 50ml reagent bottle type 1.
(for Cuvette Extra-washing):
- **Rinse solution EW Prb** filled into 20ml reagent bottle type 2.
(for Probe Extra-washing):

The **Systemic Solution** is supplied as concentrated solution into kits of 6 x 50ml vials each. Each 50ml vial content must be mixed and diluted with 20 litres of distilled water (the dilution ratio is then **1:400**) in order to prepare the new 20 litres Systemic Solution to be poured into the apposite **20 litres tank** (Green connections).

The Systemic Solution must be purchased by LiNEAR

Avoid the contact with the skin and with eyes; in case of contact with skin, wash immediately with plenty of water. Handle vials and pour into tanks by using gloves for hand protection and glasses for eyes protection.

Note: refer to Systemic Solution Safety Data Sheet for correct handling and detailed complete information.

The **Cleaner Solution** is supplied into concentrated vials or 5 litres ready-to-use containers. It prepared into the apposite 5 litres tank (Blue connections).



The Cleaner Solution must be purchased by LiNEAR This alkaline solution contains sodium hydroxide, it's irritant to eyes and skin, and can cause burnings. Use the solution for diagnostic only on this System. Avoid the contact with the skin and with eyes; in case of contact with skin, wash immediately with plenty of water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Handle vials and pour into tanks by using gloves for hand protection and glasses for eyes protection.

Note: refer to Cleaner Solution Safety Data Sheet for correct handling and detailed complete information.

The **Rinse solution EW Cvt** is a special solution supplied into 6x50ml vials kit. It is ready to be used and it must be placed on the reagent tray. It is used by the system for the routine cuvette extra washing and, on-line, to avoid contaminations in case methods restrictions have been set.

Avoid the contact with the skin and with eyes; in case of contact with skin, wash immediately with plenty of water. Handle vials and pour into tanks by using gloves for hand protection and glasses for eyes protection.

Note: refer to Rinse solution EW Cvt Safety Data Sheet for correct handling and detailed complete information.

The **Rinse solution EW Prb** is a special solution supplied into 6x20ml vials kit. It is ready to be used and it must be placed on the reagent tray. It is used on-line by the system for probe extra washing procedure to avoid contaminations in case **methods restrictions** have been set.

Avoid the contact with the skin and with eyes; in case of contact with skin, wash immediately with plenty of water. Handle vials and pour into tanks by using gloves for hand protection and glasses for eyes protection.

Note: refer to Rinse solution EW Prb Safety Data Sheet for correct handling and detailed complete information.

3.5.4.2. Liquid Tanks

Place charge and waste tanks close to the instrument; it is possible to put them under the workbench (or into the floor-stand) on the left side and not lower than 1m from the flat bench.



20lt Systemic Solution Tank



5 lt Cleaner Solution Tank



25lt Waste Tank

Figure 24: Charging and Waste Tanks

The following table shows the electrical connections between instrument and tanks:

Tanks wiring	Instrument
Low level sensor of 20lt Systemic tank , one green male floating connector	→ to be plugged into left green panel socket connector (Systemic)
Low level sensor of 5lt Cleaner tank , one blue male floating connector	→ to be plugged into centre blue panel socket connector (Cleaner)
High level sensor of 25lt waste tank , one red male floating connector	→ to be plugged into right red panel socket connector (Waste)

The following table shows the hydraulic connections between instrument and tanks:

Tanks wiring	Instrument
20lt Systemic solution tank , one green floating fitting	→ to be plugged into the left panel fitting, (Systemic)
5lt Cleaner tank , one blue floating fitting	→ to be plugged into centre panel fitting, (Cleaner)
25lt Waste tank , two red floating fittings	→ both to be plugged into the two right panel fittings, (Waste)

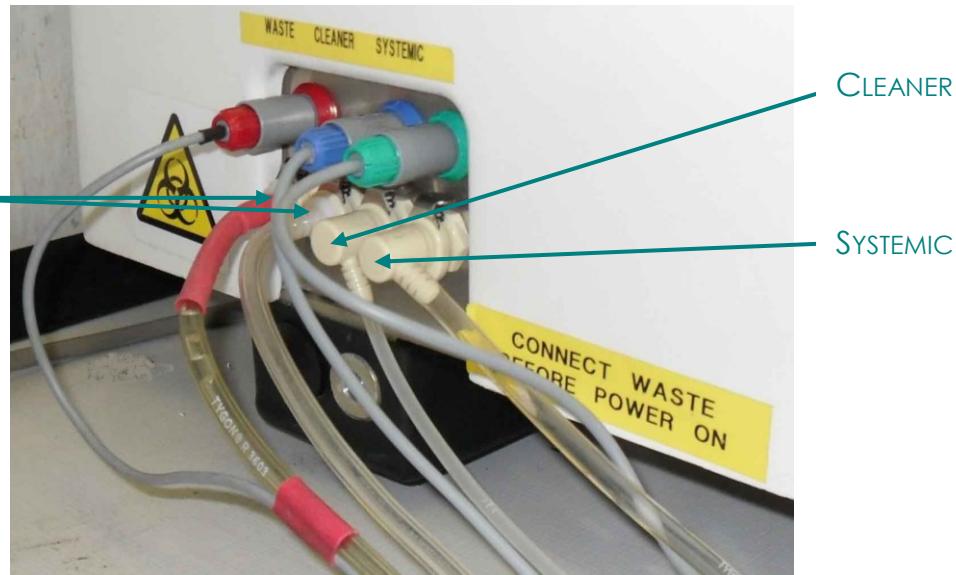


Figure 25: Charging/Waste Tanks Connections

In the floor-standing version, tanks are into the stand. Each tank is connected with the instrument. Wirings have been marked with different colours to facilitate connections; then, according to the picture above:

- **Red** colour: for Waste tank, electric connector and double tubing - two hydraulic fittings;
- **Green** colour: for Systemic solution tank, electric connector and single tubing – one hydraulic fitting;
- **Blue** colour: for Cleaner solution tank, electric connector and single tubing – one hydraulic fitting.



3.6. Software and Firmware Installation

The instrument has been updated at factory with the latest **firmware** versions. The user doesn't need to install any firmware. In case of firmware upgrades, updates will be released and sent with the proper documentation and instructions for installation; authorized personnel will take care of it.

The management PC, if supplied together with the instrument, has been updated at factory with the latest **software** versions. The user doesn't need to install any software program. In case of software upgrades, updates will be released and sent with the proper documentation and instructions for installation; authorized personnel will take care of it.

If the management PC is not part of the supply and it is arranged by the customer/distributor, provided the compliance with the minimal PC required characteristics, the management **software** application must be installed by authorized personnel only, following the instructions given in the proper technical Manufacturer's document.

3.6.1. Requirements and Recommendations

In case of software and/or firmware upgrades, updates will be released and sent with the proper documentation and instructions for installation.

If not otherwise stated, further software updates for this System must be installed by LiNEAR authorized personnel only or by local distributors to assure a correct operation of the system.



3.7. 4-channel ISE Module (option)

The ISE Module, when included in configuration as option, requires some operations for the proper start-up and initialization. It can be supplied with different configuration depending on the number of electrodes installed (from 1 to 4). The 4-channel ISE Module is assembled at factory and it is located on the front right side of the instrument, behind the front panel.

It is composed by:

- in its full configuration the ISE Module includes 4 measurement electrodes (Li⁺, Na⁺, K⁺, and Cl⁻), one reference electrode, one bubble detector and the conditioning electronics (if some electrodes hasn't been requested in its position must be used a special "Spacer electrode" to maintain the sample flow path);
- the ISE Module pump assembly with 3 peristaltic stepper pumps (Cal A, Cal B and Waste);
- the ISE Module electrical wiring (flat cable from ISE Module to pumps assembly, reagent pack connector and mother-board);
- the ISE Module reagent pack (containing Calibrant A, Calibrant B and Waste not used – it was used only in the older instrument models);
- the ISE Module reagent pack connector;
- ISE Module hydraulic tubing and fittings.

Electrodes must be installed before powering the instrument on and before using the ISE Module. If some electrodes have not been requested, replace the position with a special dummy electrode called "**spacer electrode**".

ISE Module waste is connected to the instrument main waste.

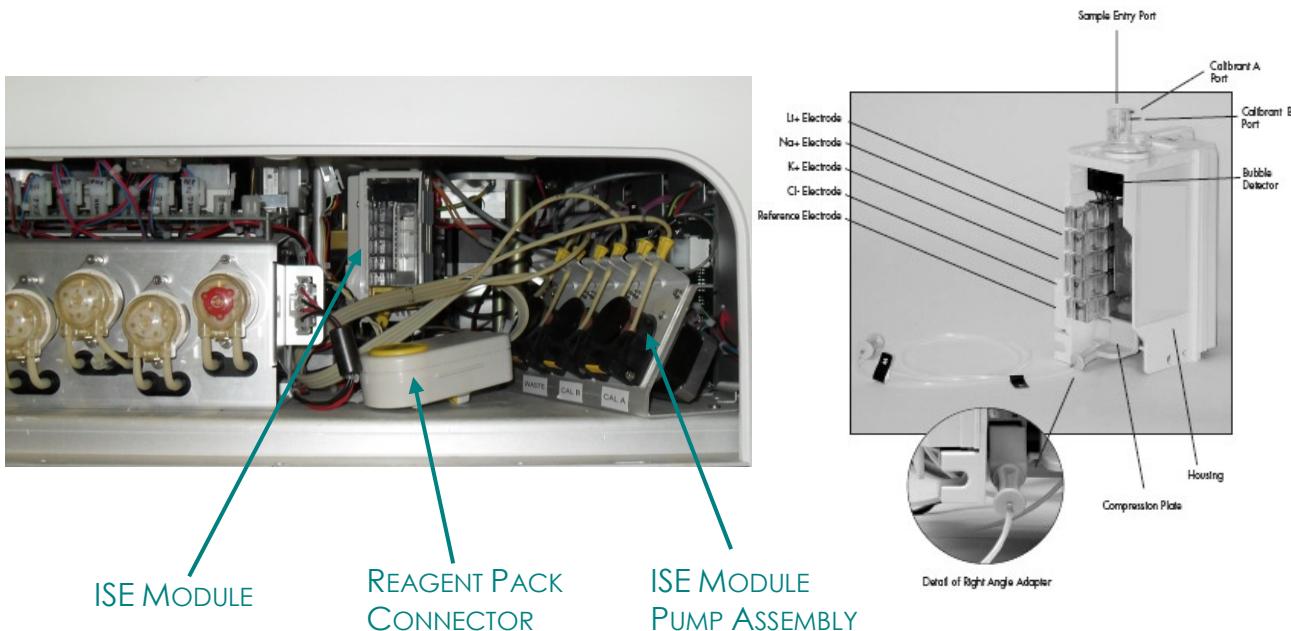




Figure 26: ISE Module, location into the instrument (behind the front panel)

Note: All Electrodes, Reagent Pack (CalA + CalB), Cleaning Solution and Urine Diluent are not included in the standard shipping; they are consumables to be ordered separately.

3.7.1. Supplied Parts with ISE Module

When the ISE Module is included in the system it is supplied complete of wiring, bubble detector, reagent pack connector and tubing.

On the other hand, the **following items are not included** in the instrument shipping; they are considered **consumables** and they must be ordered separately as they are needed and consumed for the normal operation:

Item to be ordered separately	Conf./Pack
Reagent pack (includes Cal A and Cal B)	1 kit
Na ⁺ electrode for ISE module	1 kit
K ⁺ electrode for ISE module	1 kit
Cl ⁻ electrode for ISE module	1 kit
Li ⁺ electrode for ISE module	1 kit
Reference electrode	1 kit
Cleaning solution 90 ml	1 kit
Spacer electrode (if needed)	1 kit
Urine diluent 500 ml (if needed)	1 kit

Electrodes must be installed **before** powering the instrument on and before using the ISE Module. If some electrodes have not been requested, it must be replaced by a special dummy electrode called "**spacer electrode**".

3.7.2. ISE Module Installation

The ISE Module has been previously installed into the instrument at factory by the producer. The user must only install the electrodes before installation and use. After having installed electrodes, they can be enabled or disabled by software (see *ISE Module Config* menu).

3.7.2.1. Connections

Following the picture below, the user has only to connect the Reagent Pack Connector on top of the Reagent Pack itself: press the yellow button and at the same time press it on the Reagent Pack, then release the yellow button and check it is fixed.



The instrument doesn't require the user to carry out any other connections, just check that the internal side walls of the peristaltic pump tubings are not glued together to obstruct the flow and that tubing aren't disconnected.

Hydraulic connections have been installed into the instrument by the Producer at factory. The user doesn't need to install any additional tubing.



Figure 27: ISE Module, Reagent Pack connection

NOTE: the user must properly connect and fix the Reagent Pack Connector on the Reagent Pack taking particular care in not bending tubes.

3.7.3. ISE Module Solutions and Consumables

The ISE Module proper operation requires the following solutions:

1. **Reagent Pack**, containing:

- **Calibrant A.** It is used in both the two-point and single-point calibrations **for sample analysis**.
- **Calibrant B.** It is used in two-points and single-point calibrations **for urine sample analysis**.

No preparation is required. Store reagent pack at 4°C÷25°C until expiration date on labels. When install new reagent pack: record the exact date.

**WARNING**

Biohazard Waste: waste material must be always considered potentially infected. Dispose off according to local laws and rules.

2. **Cleaning solution.** It is used once a day **to prevent protein build-up.** It must be used more frequently if the ISE Module performs greater than **50 samples per day.** It is composed by mixing the Pepsin powder and by the Cleaner Diluent. Pepsin/HCl cleaning solution must be prepared once per week and stored at 4°C. When ISE Module is in use, cleaning solution must be dropped into a 20ml reagent vial and placed on the instrument reagent tray; that position is chosen by the User in the Reagents menu.

Store unprepared components at 18÷25°C until expiration date on labels.

Preparation

- Add cleaner diluent into top of pepsin bottle and shake well.
- Record date.
- Spill the solution into a clean 20ml vial and place on the proper reagent tray position.
- Refrigerate at 2÷8°C when not in use.
- Discard 4 weeks after mixing.

WARNING

IRRITANT! This solution is irritating to eyes and skin.

Avoid contact with skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Contains ammonium bifluoride.

3. **Urine Diluent.** Urine samples are automatically diluted 1:10 by the instrument to perform urine measurement: 1 part urine sample plus 9 parts urine diluent. When the ISE Module is in use, the user has to fill with urine diluent a 20ml reagent vial and must place it on the instrument reagent tray; that position is chosen by the User in the Reagents menu.

No preparation is required. Store at 5°C÷25°C until expiration date marked on labels.



Section 4 THEORY OF OPERATION

4. The Instrument

This system is a pure Random Access Automatic Analyser for Clinical Chemistry and Turbidimetry, developed for being used in normal structures of laboratory.

4.1. Generals

The system is basically available in two models, **Single ARM** and **Double ARM**, that differ substantially in throughput and two configurations of the sample tray, **59-sample** and **79-sample** positions. The basic versions are:

- **M1-59**, single-ARM, 59-sample positions (see picture below)
- **M1-79**, single-ARM, 79-sample positions
- **M2-59**, double-ARM, 59-sample positions
- **M2-79**, double -ARM, 79-sample positions (see picture below)

The system single and double ARM with sample tray at **59 positions** can accept sample tubes with **diameter 12mm-16mm** and **height 75mm and 100mm**. Sample cups, "Hitachi® like" **3ml sample cups** with 12mm diameter, can be used only **with** a special adapter (both supplied by the Producer).

The system single and double ARM with sample tray at **79 positions** can accept sample tubes with **diameter 12mm-13mm** and **height 75mm and 100mm**. Sample cups, "Hitachi® like" **3ml sample cups** with 12mm diameter, can be used **without** any adapter.

All sample positions can accept Standard/Calibrators, Controls or Samples (normal, paediatric or STAT).





Figure 28: M2-79, double ARM with 79-sample positions, working area



Figure 29: M1-59, single ARM with 59-sample positions, working area

The system can work both in *Random Mode* and in *Batch Mode*, with standard procedure for urgency (**STAT**), reaching the maximum productivity with mono-reagent test types: up to 300test/hour (or up to 500test/hour with the integrated ISE Module version - option).

The *Random mode* runs the Work List by processing the programmed tests "sample by sample"; for each sample, the sequence of tests follows an optimized internal scheduling.

The *Batch mode* runs the Work List sorting the test by "type of analysis"; the sequence of tests follows an optimized internal scheduling.

In both modes it is possible to perform **STAT** sample at any moment; they are processed with the **highest priority** over all of the others non **STAT** samples.

The instrument has been designed for *in vitro* diagnostic (IVD) analysis of serum, plasma, urines and CSF.

The instrument automatically performs the following basic operations:

- sampling, dispensing and on-line volume control of the reagents;
- sampling and dispensing of the samples;
- reaction mixing;
- automatic dilution of calibration curves;
- automatic sample pre-dilution;
- incubation of the reactions at constant temperature;
- photometric direct reading of the reactions;



- processing of photometric readings and presentation of the analysis results;
- archiving and printing on operator request of results;
- processing of electrolytes (option);
- managing of calibrators and controls;
- on-line quality control;
- automatic repetition of results (with post-dilution);
- sample and reagent positive barcode identification.

All above mentioned phases are entirely automated and controlled by the software, reducing the run-time and the necessary human resources; in the meantime the lowered human intervention assures the final result free of accidental errors.

The **reagent tray** includes 49 positions for bottles of 50ml/20ml including one position for diluent (48 mono-reagents on-line); the position nr. 49 is reserved to the diluent solution (i.e.: distilled water or physiological solution) used for the sample dilutions. Two more reagent positions can be assigned to two additional bottles used for cuvette extra-washing and for probe extra-washing procedures (the second is skipped if no method incompatibilities at probe level have been set).

Two-reagents method needs 2 positions of the tray; at the same time three-reagents method needs 3 positions.

The reagent assembly includes an integrated **refrigeration unit** to preserve reagents on board.

In order to speed up the reagent tray loading operations and to avoid bottle placement errors, the instrument can integrate a **barcode reader** (option on request) for the positive identification of the reagent bottles; the arrangement of the reagents in the reagent tray can be manually done at any moment and can also be modified by the user through the proper User software menu.

The system can memorize up to 1,000 different methods. Each method can use on, two or three different reagents. For each sample it is possible to program up to 60 different methods (parameters) – obviously only reagents on the tray are on-line and then processed in the current run without further requests by the system.

It is possible to set a maximum of 100 different profiles of analysis.

Depending on the configurations, the sample tray includes 59 or 79 positions usable for normal samples, for paediatric samples, for standards/calibrators (max 8-position for each calibration curves) and for quality controls (3 levels). sample/standard dilutions are performed into the re-washable cuvette (no need of additional disposable cups).

The primary tubes can be labelled with barcodes for the positive identification of the patients and the automatic association in Work List.

The volume of reagent needed for each analysis is automatically sampled by the reagent arm and dispensed in the reading cell (cuvette). It is possible to dispense from a minimum of 180 μ l up to 450 μ l total reagent volume for R1, R2 and R3.



Provided the sum of reagent volumes greater or equal to 180 μ l, each of the reagents can be sampled anyway from 1 μ l to 450 μ l, with 1 μ l minimum increment. In case of dispensing of the reagent 2 or 3, the arm performs the automated mixing of the reagents into the cuvette.

Similarly, the sample arm handles the aspiration of the necessary quantity of sample and the dispensing and mixing of it with the reagent in the reading cuvettes. It is possible to dispense sample volumes from 1 μ l up to 300 μ l, with 1 μ l minimum increment.

The total volume of sample and reagents (reaction volume), dispensed for each reading cuvette, **must** be included between 200 μ l and 500 μ l: anyway note that the **typical reaction volume is between 220 μ l and 250 μ l**; in order to preserve a much longer life to the cuvettes it is suggested **not to overcome 300 μ l total reaction volume**. Sampling probes are washed, internally and externally, after every sampling cycle.

The incubation and the reading are performed in the cuvette tray containing 80 cuvettes in optic plastics (Bionex®). Each of the 80 cuvettes, being semi-disposable, can be individually replaced when requested by the system. The system washes, dries and automatically checks the cuvettes after the use.

The solution in the cuvettes is maintained at the constant temperature of 37°C to allow the incubation and the correct interpretation of the results of reading. **The maximum processing time for each cuvette is 720 seconds; that time is the sum of incubation and reading intervals.**

The duration of a machine cycle is fixed and managed by the system; in every cycle the machine performs the photometric readings related to the analyses, the cuvette auto-zero after washing and the reading of reagent blanks.

The optical group includes the photometer with 10-positions filter wheel: standard interferential filters are 8 (wavelengths between 340nm and 700nm), one position is for off-set calibration; one more position is free for one additional and optional wavelength (to be chosen in the range between 340nm and 800nm). The light source is constituted by a 12V/20W halogen lamp. The standard wavelengths are:

- 340nm
- 405nm
- 492nm
- 505nm
- 546nm
- 578nm
- 630nm
- 700nm

Anyway it is possible to customize the wavelengths on request.

For every sample the following method types can be selected: **End-point (mono- or bi-chromatic), Kinetic, Fixed Time, Differential two-reagents, Differential Sample**



Blank (mono- or bi-chromatic). The system can work in reaction **sample starting** mode or in reaction **substrate starting** mode.

Electrolytes processing (Na^+ , Cl^- , K^+ and Li^+) is possible through the optional ISE Module.

The final results are automatically processed by normalizing the actual optical-path (= 0,6cm) to 1cm.

The instrument, in case of results out of ranges, performs the test repetition (with or without dilution) automatically or on request.

As already mentioned the system gives the possibility of two different modes of operation for the execution of the protocol of analysis:

- Random mode: the system schedules and processes test by samples;
- Batch mode: the system schedules and processes test by method.

For each analysis the instrument performs the reagent blank measurements to verify that the value is included in the allowed range; in case of "sample starting" the blank is performed on each cuvette, whereas in case of "substrate starting" it is performed into a separate cuvette.

Through a selection in the method, it is possible to enable the subtraction of the value of the OD reagent blank from the OD final result.

Results of analyses are displayed as soon as they conclude.

It is possible to set and to process calibration curves up to 8 points with or without automatic dilution of the concentrated standard (mother); any of the points generating the curve can be excluded by the calculation.

Three level Quality Control sera (i.e.: "abnormal low", "normal" and "abnormal high") for each parameter can be placed on the sample tray. The presentation of the measurements is on a three level Levy-Jennings graph where the last 50 verifications can be visualized (if belonging on the same QC lot number).

The manual programming of the Work Lists is extremely simplified and it is possible to add samples at any moment (continuous loading). The graphical user software interface allows the real time verification of the proceeding **status** for each sample; at the same time it performs a constant monitoring of the reagent volumes, of the washing solutions and waste alarm levels.

Addition of urgent samples (**STAT**) can be done any time and they are processed with the maximum priority as soon as started.

The system provides a particular protocol for the data exchange with a **LIS** (Laboratory Information System) based on the ASTM standard.

4.1.1. PC and Management Software

An external personal computer (option) provides the control of the instrument through a bi-directional serial connection and constitutes the user interface.



The Software is based on the operating system MS Windows® XP; the contemporary run of more different software applications can affect the correct functionality of the System.

The Work List can be programmed manually, through mouse and keyboard, or can be introduced automatically with the help of the barcode reader integrated in the instruments; in the latter case the optional connection with a LIS must be present, then the data (Work List and results) are exchanged in automated way with the host computer.

Methods, results and computed data are stored in the external computer and can be printed with the possibility of customization of the report; a compact laboratory draft printing of results is available.

It's possible to export results in text file format; the export is generated by the system on request.

The personal computer must have the following minimal characteristics:

- CPU: Intel Pentium IV 2.8 GHz or more with Hyper threading technology, or Intel dual Core 2.8 GHz or more
- Ram: 512 Mb or more
- Monitor: 15"/17" 1024x768 resolution or better
- Graphic interface: 32Mb RAM minimum
- Hard-Disk: 40 GByte or more
- CD-Rom: 16X or more
- Serial COM port: 1 x RS-232 (DB-9pin)
- USB port: 2 x USB 2.0 or more
- LAN port: standard Ethernet (RJ-45 connector)
- Operating system: MS Windows XP.

4.1.2. Barcode Reader (Option)

As already mentioned, a barcode reader can be integrated into the instrument (option on request), internally placed in proximity of the sample and reagent tray.

The reader is a laser device, able to perform 650nm/600 scans for second, with integrated decoder that allows the decoding of barcodes of different types with recommended module $\geq 0,25\text{mm}$. For samples, the following **codes** can be read:

- Code 128 type B
- Code UPCA/UPCE
- Code 39
- Code EAN 8/13
- Code 2/5 Interleaved
- Code 93
- Codabar.



Figure 30: Barcode Reader (option)

Each of the reagent bottles is identified with an adhesive label showing manufacturer information for use, preservation and identification of the product. On the same label it is printed the barcode type “**Code 128 types B**” (9 characters, module = 0.25mm); it can be read and automatically identified by the instrument. To allow the instrument the automatic association among patients, the protocol of analysis and the real positions on the sample tray, also the primary tubes can be labelled with barcode.

In this way it is possible to create a “free of human errors” correspondence between the Work List and sample tray positions (with L.I.S. connection option).

4.1.3. Refrigeration Unit for Reagents

The instrument includes an internal cooler for the refrigeration of the reagent bottles. It can be powered independently from the rest of the electronics: this allows the operator to leave cooling ON overnight without the need of the PC controlling. The cooler preserves reagents at constant temperature of about $12^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (anyway not less than a maximum of 14°C below the ambient temperature). The command for turning ON/OFF the refrigeration unit is separate and independent from that dedicated to the power ON/OFF of the electronics; in this way, with the *main breaker* of the instrument in ON position, it is possible to turn ON or OFF the refrigeration unity independently from the rest of the instrument.

The Cooler assembly is composed by the following main parts:

- four **Peltier Cells**;
- one temperature sensor;
- four small fans, to cool down each of the four Peltier heatsinks.



Figure 31: Refrigeration Unit – ON/OFF Switch



4.2. Operating Principles

This system is an auto-analyser for Clinical Chemistry and Turbidimetry intended as integrated platform for the execution of the methods below mentioned.

4.2.1. Operating Principle in Clinical Chemistry

The Clinical Chemistry is a generic definition that commonly includes most of the quantitative analyses based on chemical or bio-chemical methods carried out on human fluid. It is one of the three greatest disciplines that are found within the medicine laboratories together with Haematology and Microbiology. In this paragraph only Biochemistry is treated, also called "General Chemistry" in the Anglo-Saxon countries; that includes the applications of the most frequent routine determinations. Measurements are usually carried out on biological fluids like: serum, plasma, urines, cerebrospinal fluid (CSF); uncommonly other fluids can also be used.

The main tests of Clinical Chemistry, currently used with the system, can be classified into the following main groups:

1. Substrates

- Uric Acid
- Direct Bilirubin
- Total Bilirubin
- Creatinine
- Fructosamine
- Glucose
- Urea UV

2. Electrolytes

- Calcium
- Chloride
- Iron
- Phosphorous UV
- Lipase
- Magnesium
- Potassium
- Sodium
- Lithium

3. Enzymes

- ALP_DEA
- ALT_GPT
- Amylase
- AST_GOT
- CK NAC
- CK MB
- Cholinesterase
- Gamma GT
- LDH-P

4. Proteins

- Albumin
- Total Proteins

5. Lipids

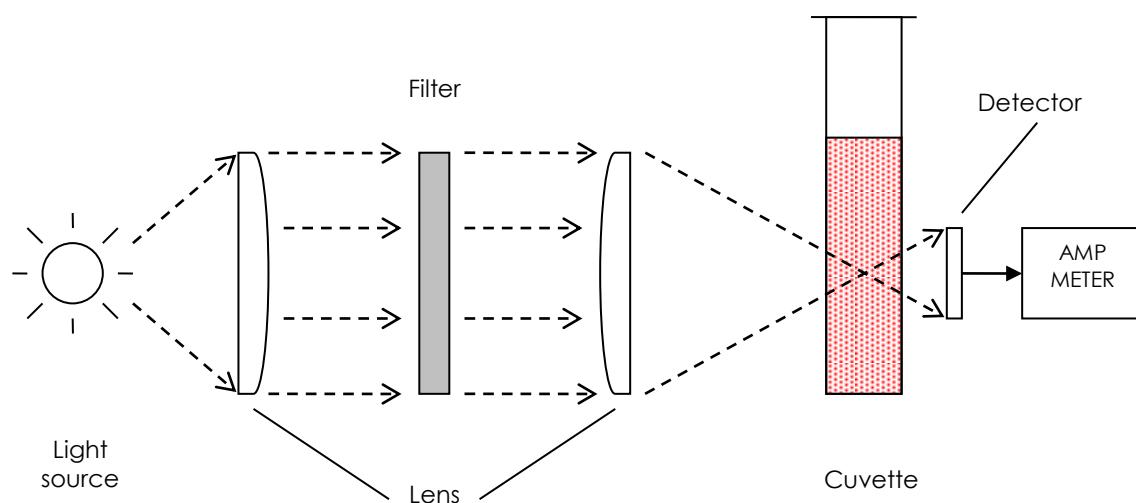


- Cholesterol
- HDL Cholesterol
- LDL Cholesterol
- Triglycerides

The most common way to perform these measurements is the spectrophotometer analysis. The spectrophotometry is the process that determines the quantity of light absorbed by chemical mixtures at determined wavelengths; it is used to estimate, at quantitative level, the unknown concentration of a substance into a reactions. For the measurement of a determined component in a sample solution, a chemical reaction must be generated in order to develop a colour generated by the union of that component, included in the sample, with the appropriate reagents (colorimetric reaction).

The photometry is therefore the process that determines the quantity of light absorbed by coloured mixtures; it is used for the quantitative evaluation of the colour of mixtures in order to measure the spectral properties of atoms and molecules. Electrons can be distributed on different energetic levels, but they mainly occupy the lowest levels, or fundamental state. To allow electrons passing from a lower energetic level to a higher one (excited status), energy must be supplied to the system; if this energy is given by an electromagnetic radiation (light), an absorption spectrum will be gotten. It is absorbed therefore the quantity of energy sufficient to jump to the higher energetic level, according to the rules of the quantum mechanics. When an electron returns from the excited state to the fundamental state, the system releases energy developing a spectral emission. Transitions of electrons are in the visible spectral region, covering a wavelength from 200nm up to 800 nm (mainly from 340nm up to 700nm).

The instrument's photometer is used for measuring the absorbance and works according to the scheme shown in the following figure.



**Figure 32:** Photometer, Functional Drawing

The polychromatic light, emitted by the light source (i.e. halogen lamp), is made practically monochromatic by crossing an appropriate interferential filter of a determinate wavelength. The monochromatic ray is partly absorbed by crossing the solution contained in the reading cuvette; the emergent ray (part not absorbed) hits the surface of the photo-detector that produces a signal linearly proportional to the intensity of the incident light.

As principle, before proceeding to estimate the unknown concentration of a substance into a solution, the reading cuvette (previously cleaned) is filled with clear distilled water (or similar washing solution) so that it is possible to measure the absorption of the same cell under conditions of "transparency"; with this operation the photometer performs the *auto-zero* (reference) of the single cuvette and "reads" the zero-value of "transparency" (needed for the Absorbance measurements).

It is useful to consider that some reagents already introduce a colour by itself and that it overlaps to the colour of the final reaction generating interference. For this reason it is often necessary the contemporary measurements of the absorption of the reagent only and of the concentration of the unknown solution to allow the exclusion of the interference. The first one is referred to as "*measurement of the reagent blank*", and it must be subtracted from the measurement of the concentration of the unknown solution.

The photometric measurement is based on the Lambert-Beer law that defines the quantity of light absorbed by a solution at a determined wavelength.

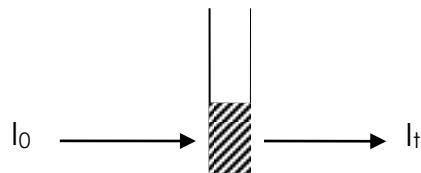
The light source is generally an incandescent halogen lamp.

4.2.1.1. Lambert-Beer Law

The Lambert-Beer law takes origin by the combination of two different laws; each of them relates the light absorption given by an *absorbent substance* with the optical path length, or liquid layer thickness crossed by the light (related to the absolute quantity of the absorbent substance).

The following definitions are valid:

- I_0 = intensity of the incident light
- I_t = intensity of the transmitted light through a transparent substance,
- Transmittance $T = I_t / I_0$.





Given $I_t \leq I_0$, we have that:

$$T \leq 1$$

hence, the Transmittance can be given by a positive number < 1 (it can be also shown in percentage).

The decimal logarithm of the inverse of Transmittance is given the name: Absorbance (A) or, indifferently, Optical Density (OD) or Extinction (E).

Hence:

$$A = OD = \log_{10} 1/T = \log_{10} (I_0 / I_t)$$

Since Transmittance ranges from 0 to 1, correspondently, the Absorbance (A) ranges from 0 to infinite (∞). The **Lambert-Beer** law is given by the formula:

$$A = \epsilon \cdot d \cdot C$$

where:

- d = thickness of the solution crossed by the light [in cm], or optical path; as rule it is assumed = 1cm;
- C = concentration of the coloured solution [in mole/lit];
- ϵ = molar extinction coefficient, or extinction of a solution containing 1mole/lit and examined along 1cm thickness at the considered wavelength.

The coefficient ϵ has been obtained by assessing $d=1$ and $C=1$, therefore

$$A = \epsilon$$

that means: constant ϵ is the measurement of the absorption of a solution having thickness and concentration =1. It changes from compound to compound.

Lambert-Beer law states the direct proportionality between the Absorbance (A) and the Concentration of the diluted substance (C).

Thus:

$$\epsilon \cdot C = (1/d) \cdot \log_{10} (I_0 / I_t)$$

The Absorbance is used then for determining the concentration of a solution to be examined. For this purpose, the following measures have to be carried out: the Absorbance of the unknown solution, the Absorbance of the other solution whose substance has a well known concentration (called "standard solution" or "calibrator") and then the following formula must be applied keeping in mind the linear relation between concentration and absorbance:

$$A_c / C_c = A_{st} / C_{st}$$

where:

- A_c = absorbance of the unknown sample



- C_c = concentration of the unknown sample
- A_{st} = absorbance of the standard
- C_{st} = concentration of the standard

so:

$$C_c = (A_c / A_{st}) \cdot C_{st}$$

the concentration of a substance is given by the ratio of the absorbance of the unknown sample by the absorbance of the standard multiplied by the concentration of the standard (given).

The calculation to determine the concentration is simplified if the value of the extinction coefficient ϵ of the substance under evaluation is known, provided that a linear relation between absorbance and concentration is present.

From the Lambert-Beer law can be deduced that, if $d = 1\text{cm}$:

$$C_c = A_c / \epsilon = A \cdot F = F \cdot (1/d) \cdot \log_{10} (I_0 / I_t)$$

with $\epsilon = A_{st} / C_{st}$.

That is: the concentration of the substance is equal to the absorbance multiplied the factor $F=1/\epsilon$.

4.2.1.2. Types of Reactions

The colorimetric reactions imply the development of colour during the reaction of an analytes with a specific set of reagents.

Two categories of reactions can be identified:

- simple particular reactions (complex generation, oxidation, reduction, ...);
- enzymatic reactions (when a substance acts as a substrate for a given enzyme or when that substance is an enzyme).

The colour developed during a reaction can be measured with two different techniques, depending on the type of reaction; both of them allow the classification of the methods in two main groups:

- END-POINT, or final point method,
- KINETIC, or multiple points method.

4.2.1.3. End-Point Methods

These are the classic reactions used for measuring the concentration of substrates and metabolites. They can be enzymatic reactions in equilibrium for the complete exhaustion of the analytes.

In order to correctly read these methods, the end of the reaction must be waited. After a determined time interval Δt , that mainly depends on the concentration of



the enzyme, on the temperature and on the type of reagent, the reaction reaches the equilibrium and the colour that has been produced remains stable in time from a few minutes up to hours.

This technique is used therefore for those reactions that end within a reasonable time (max 30') and whose products of reaction are sufficiently stable in time.

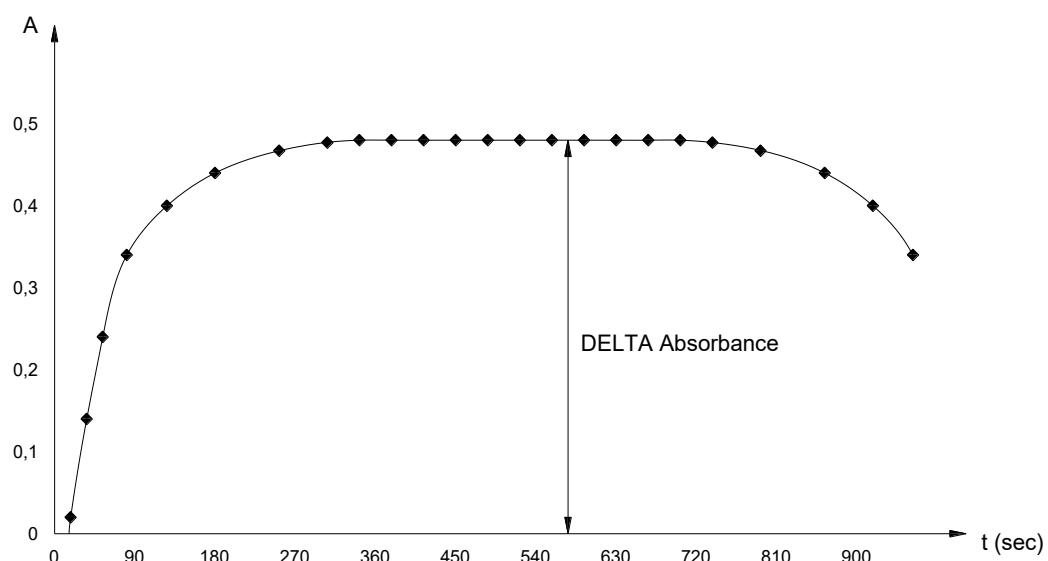


Figure 33: Generic End-Point Method

With this technique it is possible to find the unknown concentration of the solution (C_x) by using a “standard” (or calibrator),

$$A_x : A_{st} = C_x : C_{st}$$

therefore:

$$C_x = \frac{A_x \cdot C_{st}}{A_{st}} = A_x \cdot F$$

where F is the factor, that can be obtained from the instrument (standard measurement) or manually introduced, and A_x is the measured Absorbance of the solution.

Example:

The concentration of the standard to determine the Cholesterol is 200mg/100ml; the absorbance of the standard is generally equal to 0,800. Then, factor $F = C_{st} : A_{st}$ to be introduced in the system is:



$$F = \frac{C_{st}}{A_{st}} = \frac{200}{0,800} = 250$$

Two types of end-point reactions can be classified from the process point of view:

- end-point reaction with single reagent (mono-reagent),
- end-point reaction with two reagents (or more reagents).

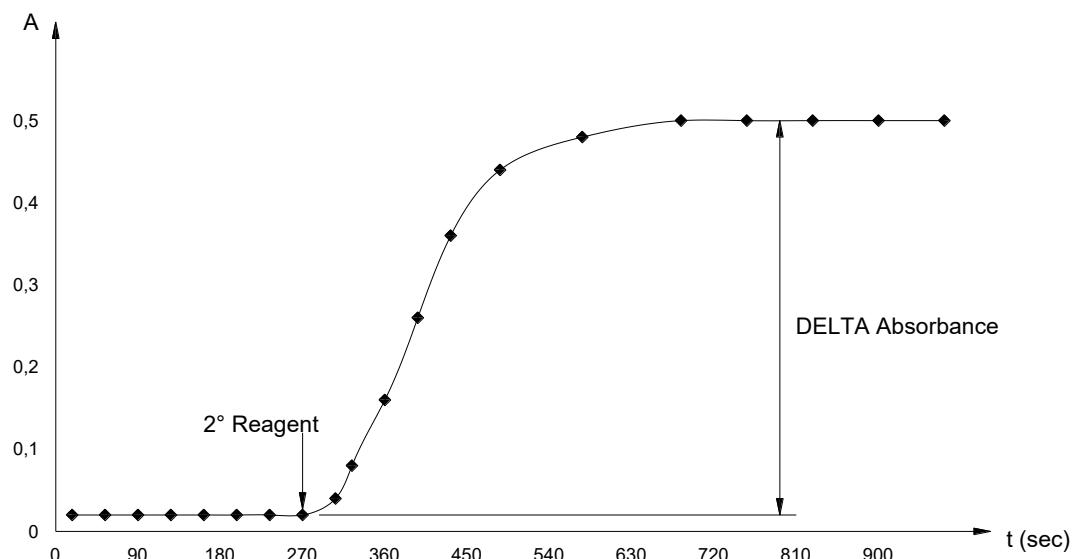


Figure 34: End Point Method

The following table shows benefits and limits of multi-reagent reactions:

MULTI-REAGENTS	
Benefits	Limits
Greater stability and preservation of the reagents on board	Longer reaction time
Exclusion of manual mixing of solution by the user	Multiple sampling
All marginal reactions can take place without waiting for measurement	Higher reagent bottle positions on the reagent tray

4.2.1.4. Kinetic Methods

These types of reaction are commonly used for measuring the catalytic activity of the enzymes. For these reactions, conditions are such that the absorbance



increases (or decreases) proportionally to the enzymatic activity in the linear area of the reaction.

Generally it is spoken about enzymatic activity and not about enzymatic concentration because what interests, both from the diagnostic point of view and from the quantitative point of view, is the catalytic capability of the enzyme, independently from the stoichiometric quantity of the enzyme (Stoichiometry is, in chemistry, the determination of the proportions in which elements or compounds react with one another; the rules followed in the determination of stoichiometric relationships are based on the laws of conservation of mass and energy and the law of combining weights or volumes).

The unit of measure of the activity is the speed of reaction, that is the quantity of substratum turned in the unit of time. The most used unit of measure is the International Unit (U.I.) defined as *the quantity of enzyme that transforms 1 µmole of substratum at a defined temperature*.

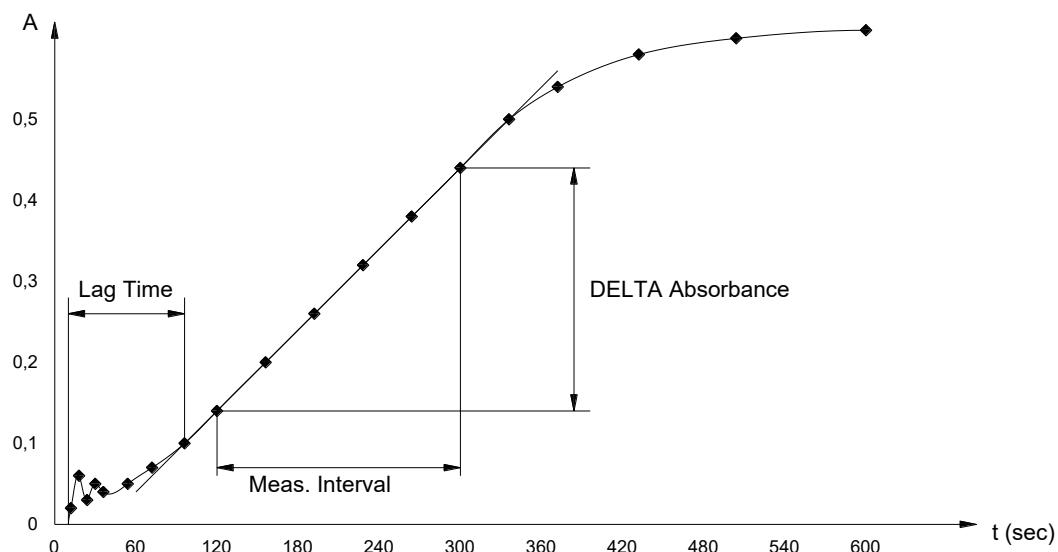


Figure 35: Kinetic Method

From the variation of Absorbance in a minute (as convention it's standardizes to 60 seconds) it is possible to find the enzymatic activity in U.I. in the following way:

$$\text{Activity: } \frac{\text{substrate variation}}{\text{minutes}} = \frac{\Delta C}{\text{min}}$$

from Lambert-Beer law:

$$C = \frac{A}{\varepsilon \cdot d} \Rightarrow \Delta C = \frac{\Delta A}{\varepsilon \cdot d}$$



$$\text{Activity} = \frac{\Delta A}{\text{min} \cdot \varepsilon \cdot d}$$

If the volume of the sample is v and it is diluted into a total volume V of solution, the dilution factor is given by:

$$\frac{V}{v}$$

where:

V = total volume of the reaction solution,

v = sample volume,

thus:

$$\frac{\text{Attività}}{\text{ml}} = \frac{\Delta A \cdot V}{\text{min} \cdot \varepsilon \cdot d \cdot v}$$

to obtain the Activity/l, or U/l, it must be multiplied by 1000:

$$U/l = \Delta A \cdot \frac{V \cdot 1000}{v \cdot \text{min} \cdot \varepsilon \cdot d}$$

since, by definition, $\text{min}=1$ and $d=1$:

$$U/l = \Delta A \cdot \frac{V \cdot 1000}{v \cdot \varepsilon}$$

That's the most important formula for calculating the enzymatic activity since it gives the recurrent factor transforming **ΔA/min** in activity, in fact:

$$U/l = \Delta A \cdot F$$

where:

$$F = \frac{1000 \cdot V}{\varepsilon \cdot v}.$$

Any variation of the ratio V/v determines a new factor.

The measure of the activity of a kinetic method (or better, of its enzymatic activity) it is performed by taking several OD measurements in different given instants on the linear slope of the reaction; each of the measured OD values is graphed corresponding to the instant of measurement and the final plot is the straight line that better interpolates the data given by a simple linear regression.

The method normally used for getting the “best fitting regression line” is the “least squares method” and the resultant straight line has called “least squares line”:

$$y = a + bx$$



where:

- $a \rightarrow$ "intercept",
- $b \rightarrow$ "slope".

To determine if the resultant straight line (*linear regression*) adequately describes the relationship among the variables, it is used an indicator that expresses the "fit" called "*Multiple squared correlation coefficient*"; it is a measure of the *linear association* between the variable x and y and it is obtained by the following formula:

$$R_{xy}^2 = \left(\frac{\sum (x_i - \bar{x}) \cdot (y_i - \bar{y})}{\sqrt{\sum (x_i - \bar{x})^2} \cdot \sqrt{\sum (y_i - \bar{y})^2}} \right)^2$$

R_{xy}^2 is included within 0 and +1 and it is =+1 only when all values (x_i, y_i) fall on the regression line. Generally it is given as a percentage value.

The method *fixed time* is a particular kind of kinetics measured over two points only. In this method it is no more necessary to follow the variation of absorbance $\Delta A/min$, but it is used to measure the jump of absorbance (ΔA) that better fit the determination in order to obtain sufficient sensibility and linearity.

To determine the result as variation of concentration is used the following formula:

$$\Delta C = \Delta A \cdot F$$

4.2.1.5. Calibration in Clinical Chemistry

Solutions having a known concentration, necessary for the determination of the factor F to be used for the determination of the results, are called "standard solutions" (or calibrators). All methods can be branched into: "single-standard methods" and "multi-standard methods".

Single standard methods:

The "single-standard" methods use a **single factor F** to multiply the optical density (OD) in order to determine the concentration. Such a factor is the result of an operation of calibration (and it is calculated therefore by measuring the OD of the standard or calibrator) or it can be manually introduced by the operator because extrapolated by the technical sheets of the standard. These methods use only one "standard" for the calibration.

Multi standard methods:

The "multi-standard" methods are those that, for the determination of the concentration, use more solutions of the same standard diluted to different



concentrations; these are generated from a single concentrated standard that is diluted with distilled water (or similar solution) in different ratios as required by the technical sheet of the methods. By measuring the OD of the solutions at different concentrations, it is possible to get the **Calibration Curve** by interpolation of the values.

4.2.1.6. Calibration Curve

Due to the variability of absorption of some standard solutions with their concentration, it is often necessary to determine the “calibration curve” that describes the range from the lower to the higher standard concentration. The **Calibration Curve** is given by the relationship between the optical density and the concentration. It is therefore necessary in the following cases:

- when one only reference solution cannot be used (for substances whose absorbance is not stable or not easily repeatable),
- when a measurement is taken out at a wavelength that is not that required by the method of a given reaction (i.e.: not enough wavelength filters).

In order to draw the Calibration Curve, the instrument automatically prepares a certain number of solutions by diluting the concentrated solution to be examined at known and increasing concentrations. The number of the solutions depends on the quantity of points at known concentration planned for the construction of the curve.

The instrument reads the absorbances of said solutions and the values of OD are drawn on the ordinates of a Cartesian graph; the concentrations corresponding to the diluted solutions are drawn on the abscissas.

If a straight line is drawing passing for the point that identifies a determined value of concentration (relative to one of the known concentration solutions) and perpendicular to the ordinates and another passing line for the corresponding value of the measured absorbance, the two lines intersect in a cross-point.

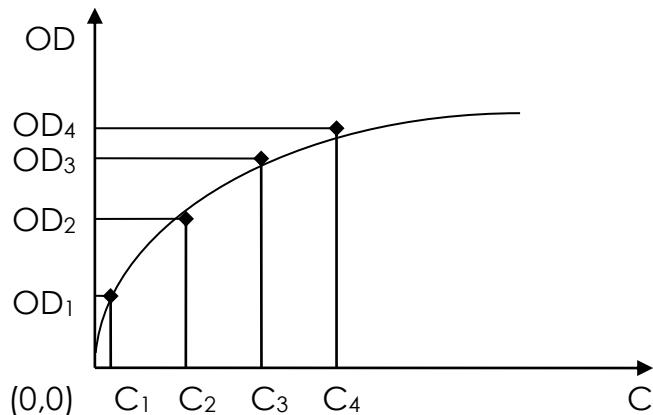


Figure 36: Calibration Curve



Proceeding similarly for the other values of concentration and absorbance of the solutions at higher concentration, more points on the chart are obtained; it is drawn therefore the curve that more approximates the data, using the more proper method of interpolation. The values of unknown concentration are read on the curve in correspondence of any measured OD. The following curves of interpolation can be used: linear regression, cubic spline, piecewise, polynomial 4 parameters (the most proper must be used).

The value of OD correspondent to C=0 is the value of absorbance of the "reagent blank" referring to the reagent only, without standard (zero concentration).

In case that the method provides the subtraction of the reagent blank in the calculations (calculation with "Blank Value") this means to subtract such value from the values of OD measured for every single concentration. The curve shifts down and it will cross the origin (0,0):

$$\text{concentration} = 0 \Rightarrow OD = 0$$

in this way, the effect of the colour of the reagent has been removed.

4.2.2. Operating Principle in Turbidimetry

With the term Turbidimetry has been intended the quantitative determination of the turbidity of a solution through the measure of the absorbed or not transmitted light. It must be specified that, in this case, the quantity of light not transmitted is not attributable to a mechanism of absorption of the light to molecular level, as for the clinical chemistry, but it occurs for the presence of lost solid particles that result opaque to radiations at whatever wavelength. Because of this, reflections and refractions of the radiation are produced.

Turbidimetry is based therefore on the photometric detection that measures the turbidity, or the concentration, of suspended small particles in a solution. The light crossing the solution is dispersed and refracted depending on the amount of turbidity reached by the solution and the photo-detector measures the reduction of intensity: the more turbidity the more light absorption.

Turbidimetry causes therefore the reduction of the light intensity crossing the solution and, likewise the spectral absorption, turbidity can be defined as:

$$t = (1/d) \cdot \log_{10} (I_0 / I_t)$$

where:

- t = turbidity
- d = thickness of the solution crossed by light (in cm) or optical path; it is assumed = 1cm;
- I_0 = intensity of incident light;



- I_t = intensity of the transmitted light through a transparent medium.

The process for measurement of the Turbidity and the necessary electro-optic components are the same used for the measurement of the Absorbance in a spectrophotometer; it can be then measured with the instrument and the same principles exposed for the analyses of Clinical Chemistry are valid. Thus the value of the measured turbidity is given as absorbance or percentage of transmission. The increasing of turbidity, or the reduction of Absorbance, is in relationship with the concentration of the antigen.

Turbidimetry is used for particular analysis as serum proteins and drugs of abuse.

Biological fluids generally used for measurements are: serum, plasma e urine.

Some of the Immuno-Turbidimetric tests actually provided on the system have been listed below:

- | | |
|---|---|
| <ul style="list-style-type: none">• Alfa-1 Acid Glycoprotein• Anti Streptolysin O• Antithrombin III• Beta 2 Microglobulin• C3 factor• C4 factor. | <ul style="list-style-type: none">• Rheumatoid Factor• Ferritin• Fibrinogen• Ig A• Ig G |
|---|---|



4.2.3. Method Timings and Result Calculations

This paragraph shows the timing diagrams valid for processing the different method types in the instrument.

Note that any operation during analysis routines is regulated by machine cycles. One machine cycle generally includes one or more of the following activities: reagent aspiration and dispensing, sample aspiration and dispensing, probes washing (after aspiration and dispensing), cuvettes washing, readings.

“Sample Start” and “Substrate Start” different cases have been taken into account. The Sample Start methods use the sample as reaction starter. On the other hand the Substrate Start methods use R2 or R3 as reaction starter.

Results are computed on the base of the absorbance readings performed by the system. In order to reduce noise and false result probability, any photometric measurement (reading) is taken as the average of packets of 50 single reading each, after digital filtering at the AtoD Converter output.

Results for “single standard” methods are calculated using the **factor F**. Results for “multi standard” methods are calculated performing an **interpolation** over “n” calibration curve positions; this procedure, in the following formula, has been identified by the acronym **Intpol(OD)**.

Incubation time, reading time (if any) and wavelength are characteristic of each single method.

In the following of this paragraph it is assumed that the **Optical Density “OD”** (or Absorbance “A”) is the result of the Lambert-Beer formula:

$$OD = \left(\frac{1}{d} \right) \cdot \log_{10} \left[\frac{(V_o - V_{os})}{(V_m - V_{os})} \right]$$

The abbreviations in the legend below have been used in the previous formula and in the following diagrams, calculations and comments:

- R1** : **Reagent 1** dispensing.
- R2** : **Reagent 2** dispensing.
- R3** : **Reagent 3** dispensing.
- S** : **Sample** dispensing.
- d** : **optical path** = 0,6cm, inner distance between the two side walls orthogonal to the optical light-path, into the cuvette containing the reaction.
- Res** : **result** (or Concentration **C**)
- V_m** : **measured value** – average value of the light passing the cuvette

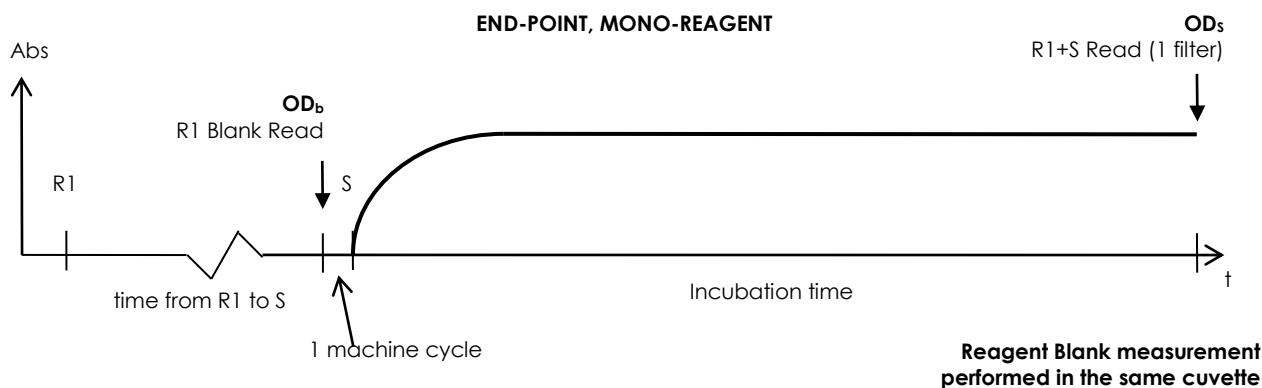


containing the *reaction* measured at the end of the incubation time and at the wavelength λ .

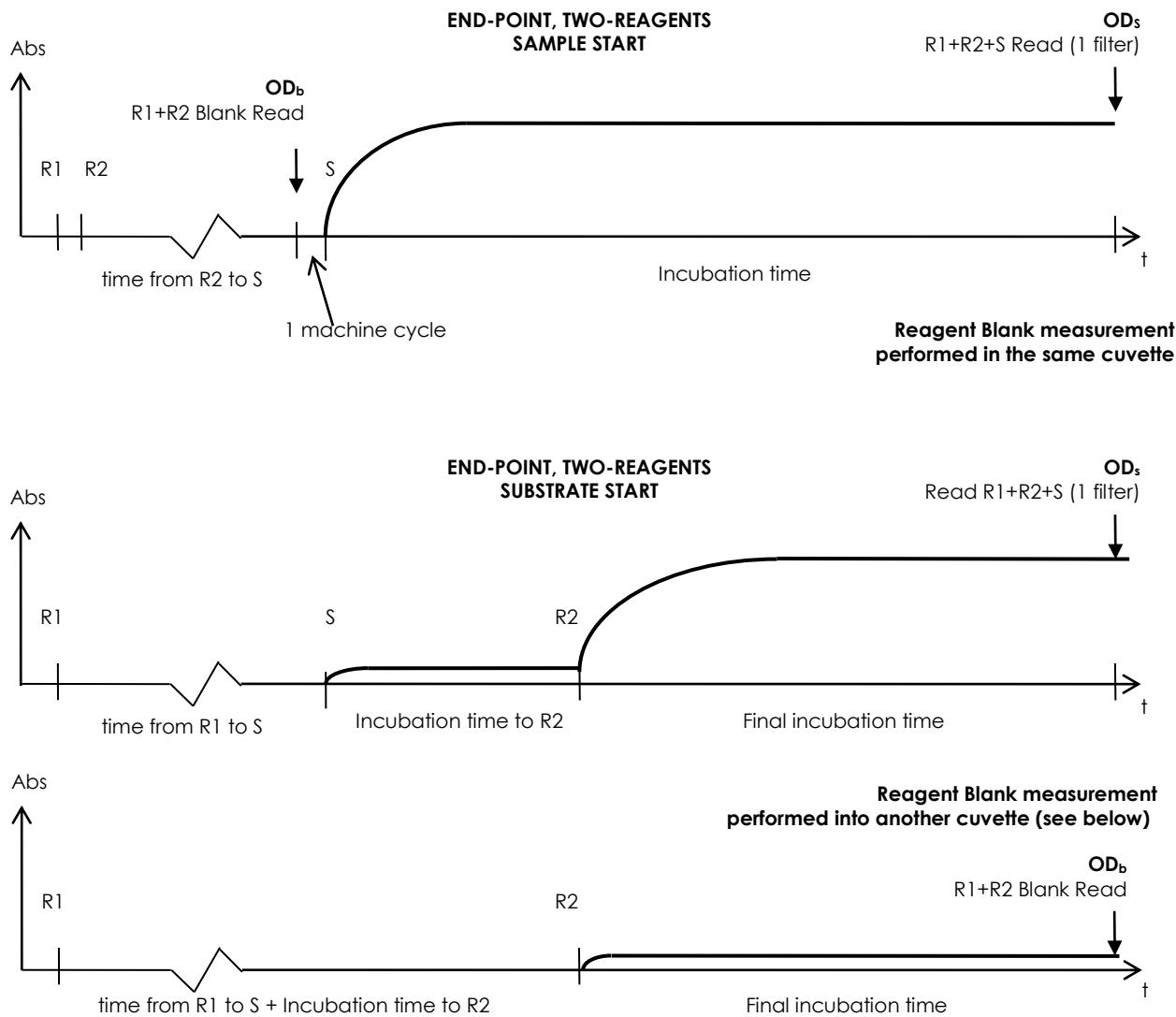
- V_o : **transparent value** – average value of the light passing the cuvette containing the *Systemic washing solution* measured at the end of the cuvette washing cycle at the wavelength λ .
- V_{os} : **Off-set value** – average value of the residual light passing the cuvette containing the *Systemic washing solution* measured in “dark” conditions when the light source is not enabled.
- OD** : **Optical Density** measured (Absorbance-Abs)
- OD_b** : **Optical Density** measured on the cuvette containing the reagent only (reagent blank).
- OD_{bc}** : **Optical Density** measured on the cuvette containing the reagent only (reagent blank); this value is corrected taking into account the ratio between reagent and the final volumes.
- C_s** : **Concentration** of the sample.
- OD_s** : **Optical density** measured on the cuvette containing the reaction with the sample.
- C_{st}** : **Concentration** of the standard (or calibrator).
- OD_{st}** : **Optical density** measured on the cuvette containing the reaction with the standard or calibrator.
- F** : **Factor**.
- V_s** : **Volume** of the Sample.
- V_{R1}** : **Volume** of the Reagent 1.
- V_{R2}** : **Volume** of the Reagent 2.
- V_{R3}** : **Volume** of the Reagent 3.

**Monochromatic ENDPOINT Method**

The result is related to the absorbance taken on the Sample S mixed with the R1 (or with R1+R2 or with R1+R2+R3) at the end of the incubation time at one fixed wavelength λ .



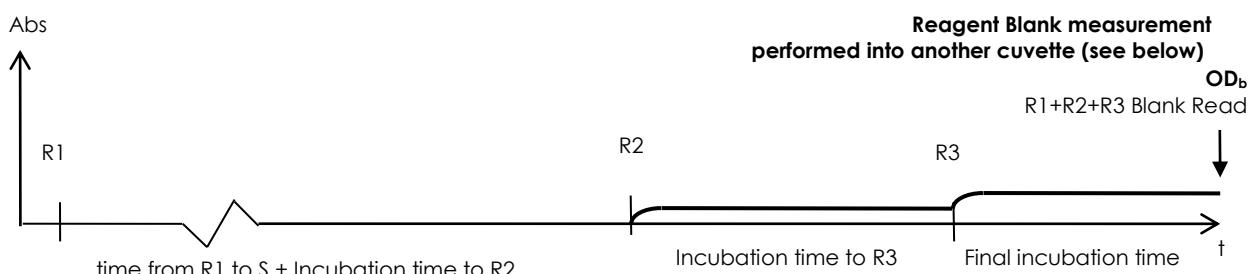
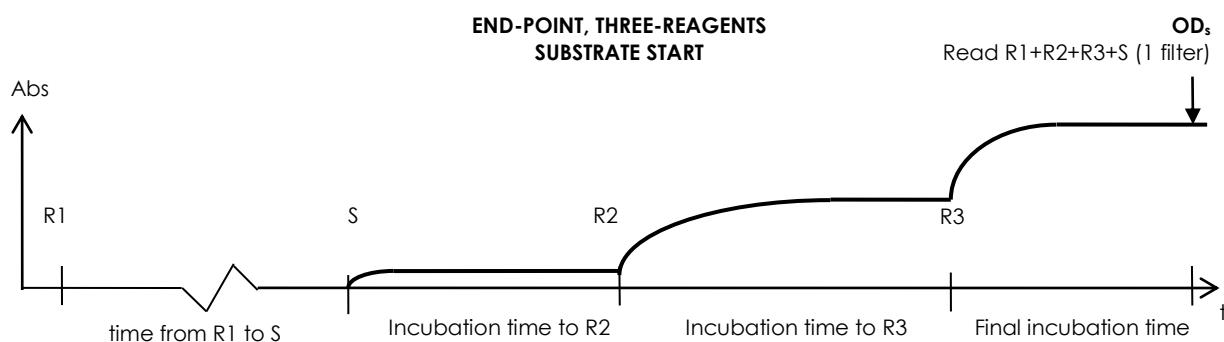
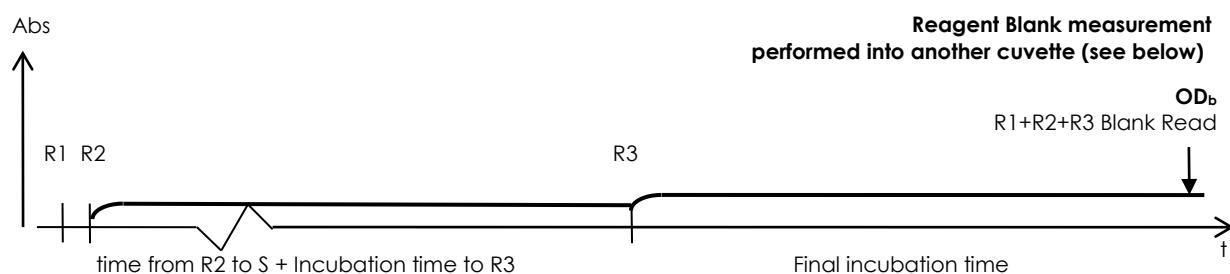
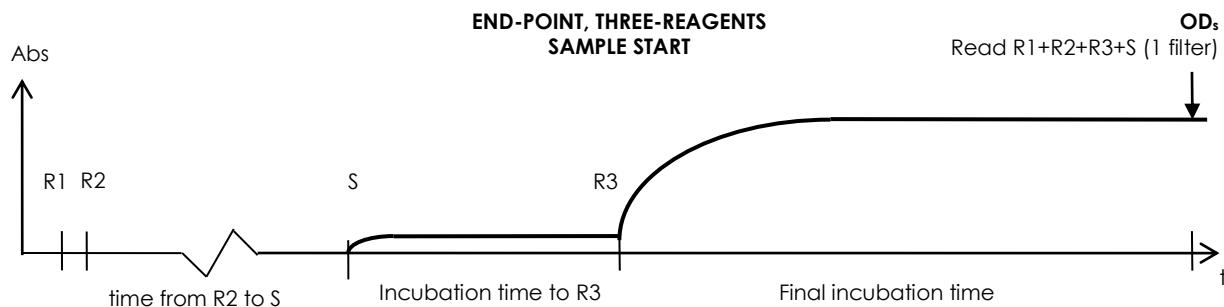
Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $ResEP = (OD_s \cdot F)$ calculation of Factor F: $F = \frac{C_{st}}{OD_{st}}$ OD _{st} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $OD_{bc} = OD_b \cdot \left(\frac{V_{R1}}{V_{R1} + V_s} \right)$ $ResEPb = [(OD_s - OD_{bc}) \cdot F]$ calculation of Factor F: $F = \frac{C_{st}}{(OD_{st} - OD_{bc})}$ OD _{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResEP = Intpol(OD_s)$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $ResEPb = Intpol(OD_s - OD_{bc})$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD _{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	



Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u>	<u>Single-Standard Concentration Result:</u>
$ResEP = (OD_S \cdot F)$	$OD_{bc} = OD_b \cdot \left(\frac{V_{R1} + V_{R2}}{V_{R1} + V_{R2} + V_S} \right)$
calculation of Factor F:	$ResEPb = [(OD_S - OD_{bc}) \cdot F]$
$F = \frac{C_{st}}{OD_{st}}$	calculation of Factor F:
	$F = \frac{C_{st}}{(OD_{st} - OD_{bc})}$



Calculation without Blank Value	Calculation with Blank Value
OD_{st} measured with the standard in place of the sample	OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResEP = \text{Intpol}(OD_s)$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $ResEPb = \text{Intpol}(OD_s - OD_{bc})$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD_{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	





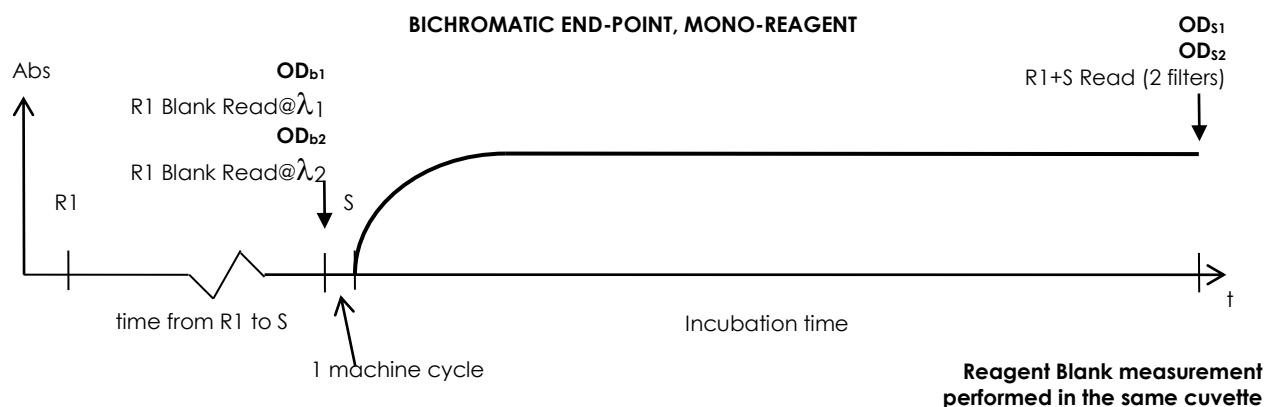
Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $ResEP = (OD_S \cdot F)$ calculation of Factor F : $F = \frac{C_{st}}{OD_{st}}$ OD_{st} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $OD_{bc} = OD_b \cdot \left(\frac{V_{R1} + V_{R2} + V_{R3}}{V_{R1} + V_{R2} + V_{R3} + V_s} \right)$ $ResEPb = [(OD_S - OD_{bc}) \cdot F]$ calculation of Factor F : $F = \frac{C_{st}}{(OD_{st} - OD_{bc})}$ OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResEP = Intpol(OD_S)$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $ResEPb = Intpol(OD_S - OD_{bc})$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (OD_{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	

**Bichromatic ENDPOINT Method**

The result is related to the difference between two absorbances taken on the Sample S mixed with the R1 (or with R1+R2 or with R1+R2+R3) at the end of the same incubation time on the same cuvette and at two fixed wavelength, λ_1 (filter F1) and with λ_2 (filter F2). F2 absorbance (secondary wavelength) is deducted from F1 absorbance (main wavelength).

OD_{_1} : F1 measured value – V_m at wavelength λ_1

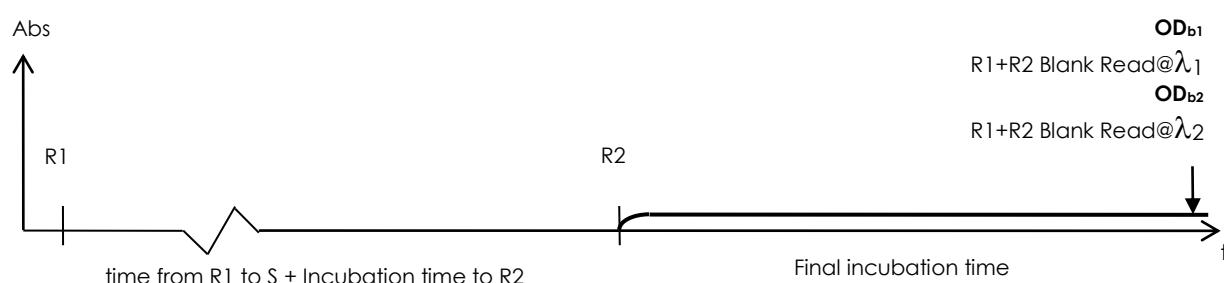
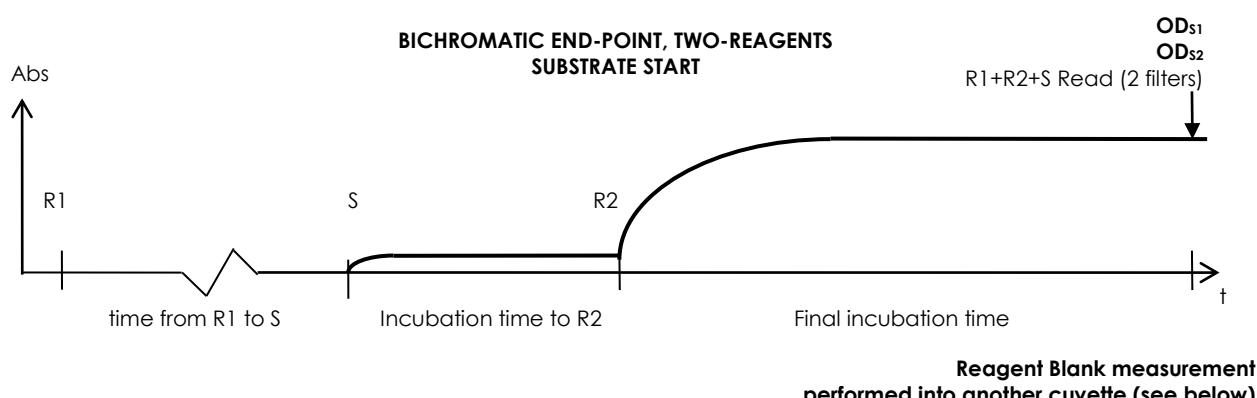
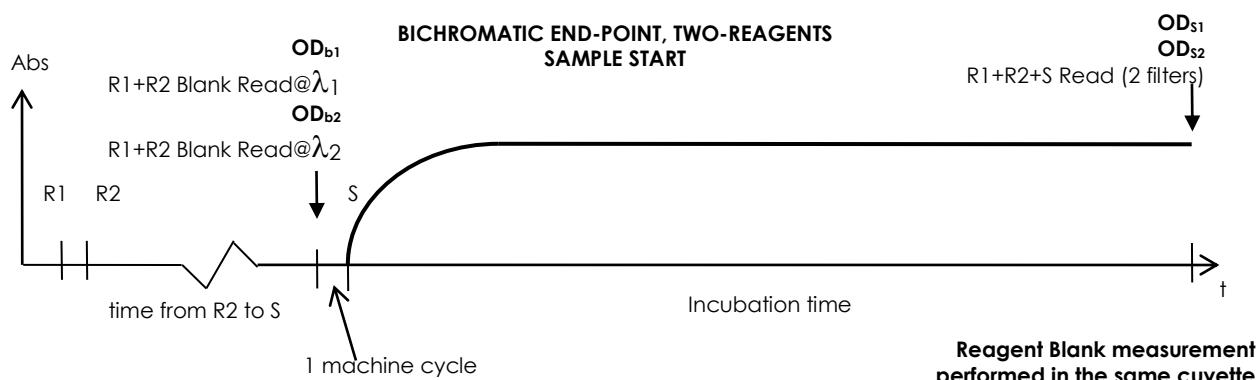
OD_{_2} : F2 measured value – V_m at wavelength λ_2



Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $\Delta OD_S = (OD_{S1} - OD_{S2})$ $ResBE = [\Delta OD_S \cdot F]$ <p>calculation of Factor F:</p> $\Delta OD_{st} = (OD_{st1} - OD_{st2})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$	<u>Single-Standard Concentration Result:</u> $\Delta OD_{bc} = (OD_{b1} - OD_{b2}) \cdot \left(\frac{V_{R1}}{V_{R1} + V_S} \right)$ $\Delta OD_S = (OD_{S1} - OD_{S2})$ $ResBEb = [(\Delta OD_S - \Delta OD_{bc}) \cdot F]$ <p>calculation of Factor F:</p> $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_{bc})}$

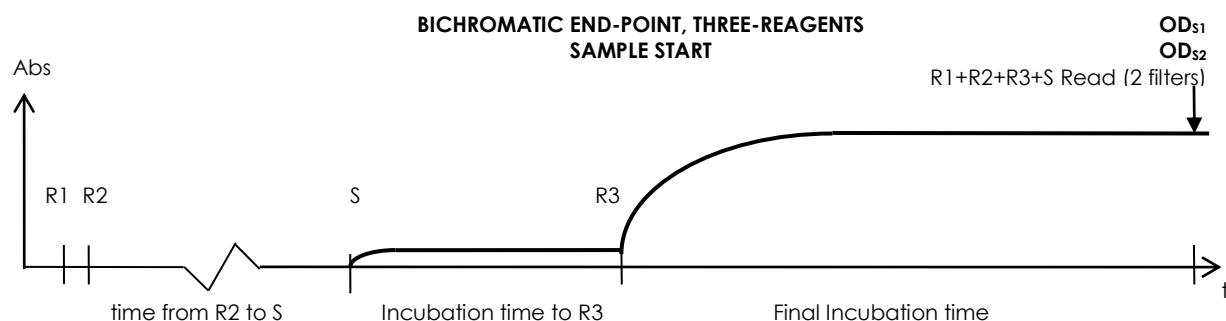


Calculation without Blank Value	Calculation with Blank Value
OD_{stx} measured with the standard in place of the sample	OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResBE = \text{Intpol}(\Delta OD_s)$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $ResBEb = \text{Intpol}(\Delta OD_s - \Delta OD_{bc})$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD_{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	

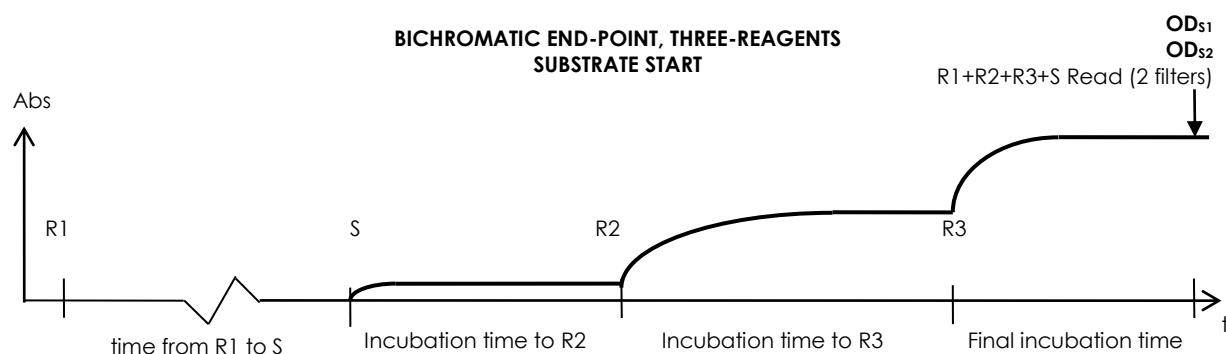
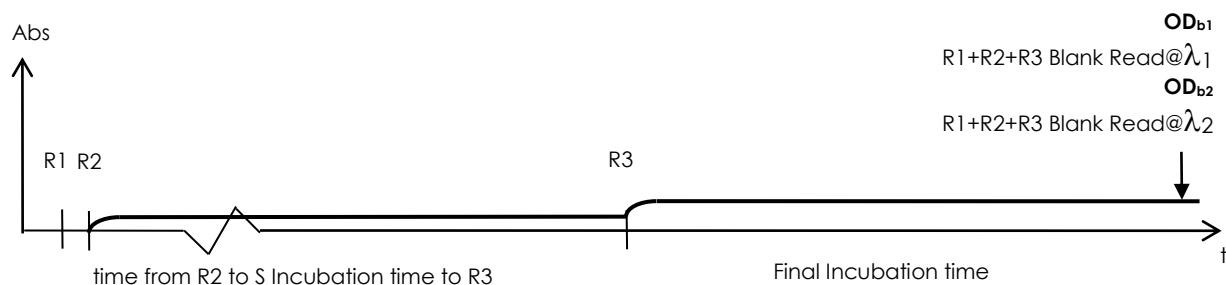




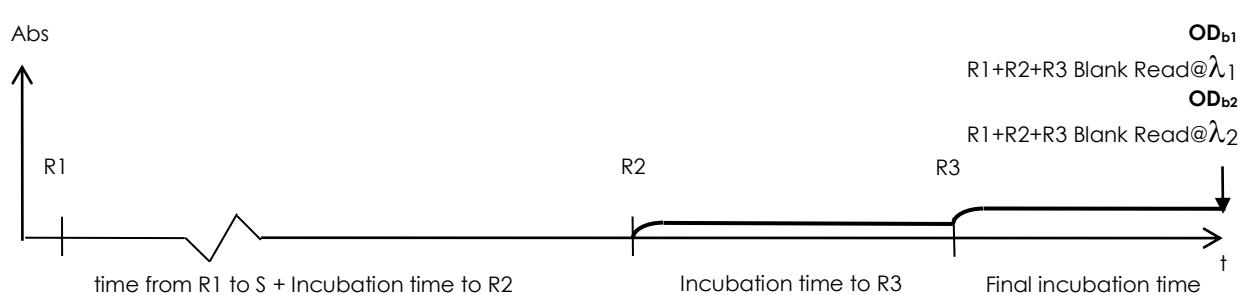
Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $\Delta OD_S = (OD_{S1} - OD_{S2})$ $ResBE = [\Delta OD_S \cdot F]$ calculation of Factor F : $\Delta OD_{st} = (OD_{st1} - OD_{st2})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ OD_{stx} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $\Delta OD_{bc} = (OD_{b1} - OD_{b2}) \cdot \left(\frac{V_{R1} + V_{R2}}{V_{R1} + V_{R2} + V_S} \right)$ $\Delta OD_S = (OD_{S1} - OD_{S2})$ $ResBEb = [(\Delta OD_S - \Delta OD_{bc}) \cdot F]$ calculation of Factor F : $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_{bc})}$ OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResBE = Intpol(\Delta OD_S)$	<u>Multi-Standard Concentration Result:</u> $ResBEb = Intpol(\Delta OD_S - \Delta OD_{bc})$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD_{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	



Reagent Blank measurement
performed into another cuvette (see below)



Reagent Blank measurement
performed into another cuvette (see below)





Calculation without Blank Value	Calculation with Blank Value
<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_S = (OD_{S1} - OD_{S2})$ <p>ResBE = [ΔOD_S · F]</p> <p>calculation of Factor F:</p> $\Delta OD_{st} = (OD_{st1} - OD_{st2})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ <p>OD_{stx} measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_{bc} = (OD_{b1} - OD_{b2}) \cdot \left(\frac{V_{R1} + V_{R2} + V_{R3}}{V_{R1} + V_{R2} + V_{R3} + V_S} \right)$ $\Delta OD_S = (OD_{S1} - OD_{S2})$ <p>ResBEB = [(ΔOD_S - ΔOD_{bc}) · F]</p> <p>calculation of Factor F:</p> $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_{bc})}$ <p>OD_{st} measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> <p>ResBE = Intpol(ΔOD_S)</p> <p>Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C.</p>	<p><u>Multi-Standard Concentration Result:</u></p> <p>ResBEB = Intpol(ΔOD_S - ΔOD_{bc})</p> <p>Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD_{bc}) is taken into account.</p>
Reagent blank taken for calculation purpose and for reagent quality check (its value must be included within the reagent blank admissible range).	

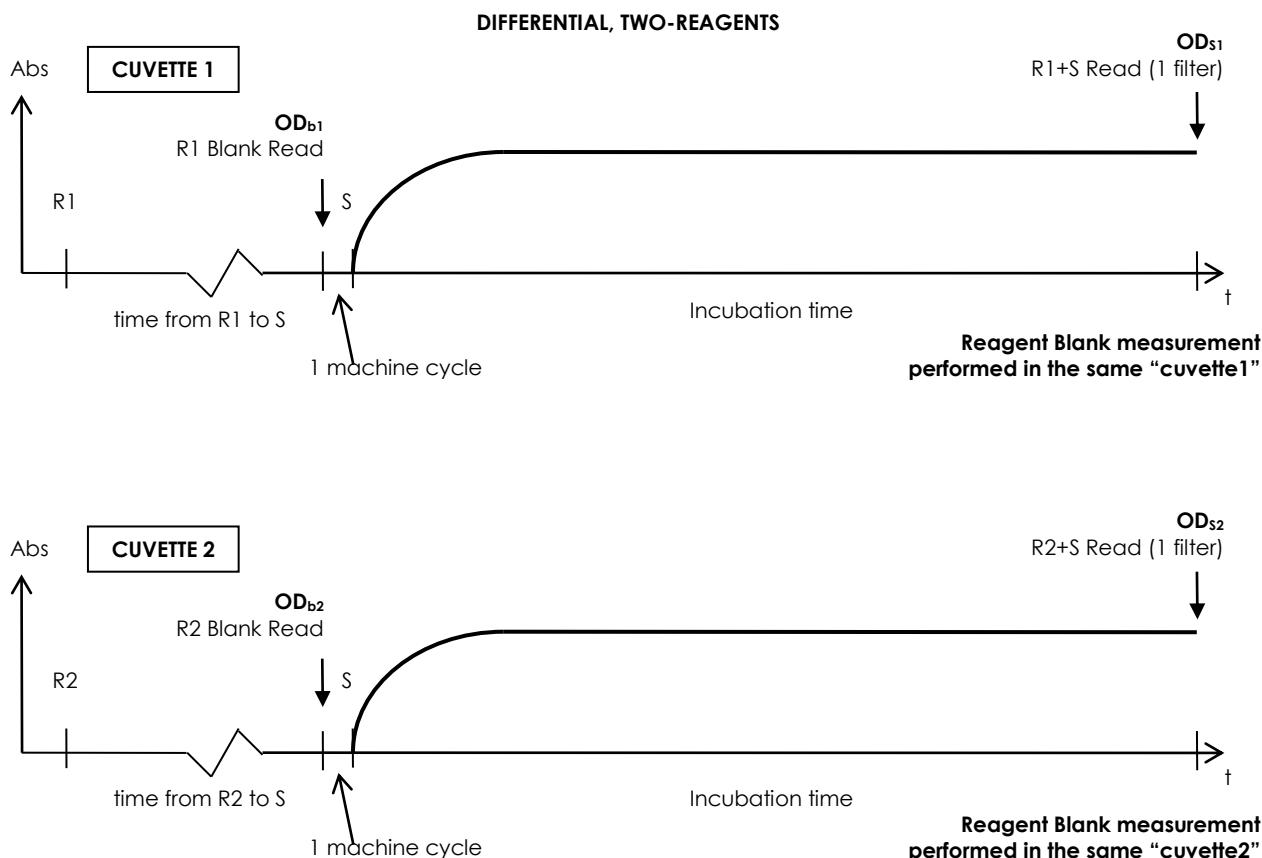
**Differential ENDPOINT – TWO REAGENTS Method**

The result is related to the difference between the two absorbances taken at the end of the same incubation time on two different cuvettes:

- the absorbance of the sample mixed with the reagent R1 at one fixed wavelength λ into a given cuvette, at the end of the incubation time t.
- the absorbance of the sample mixed with the reagent R2 at the same wavelength λ into another *different* cuvette, at the end of the same incubation time t.

OD₁ : **measured value** – Sample + R1 in cuvette #1

OD₂ : **measured value** – Sample + R2 in cuvette #2





Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $\Delta OD_S = (OD_{S2} - OD_{S1})$ $ResDD = \Delta OD_S \cdot F $ calculation of Factor F : $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ OD_{stx} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $\Delta OD_{S1} = OD_{S1} - \left(OD_{b1} \cdot \frac{V_{R1}}{V_{R1} + V_S} \right)$ $\Delta OD_{S2} = OD_{S2} - \left(OD_{b2} \cdot \frac{V_{R2}}{V_{R2} + V_S} \right)$ $ResDDb = (\Delta OD_{S2} - \Delta OD_{S1}) \cdot F $ calculation of Factor F : $F = \frac{C_{st}}{(\Delta OD_{st2} - \Delta OD_{st1})}$ OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResDD = \text{Intpol}(\Delta OD_S)$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $ResDDb = \text{Intpol}(\Delta OD_{S2} - \Delta OD_{S1})$ Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (OD_b) is taken into account.
Reagent blank taken for calculation purpose.	

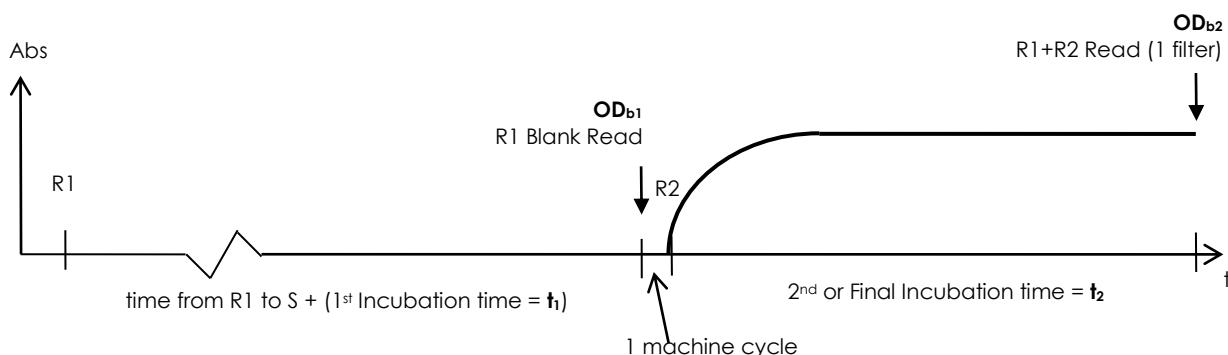
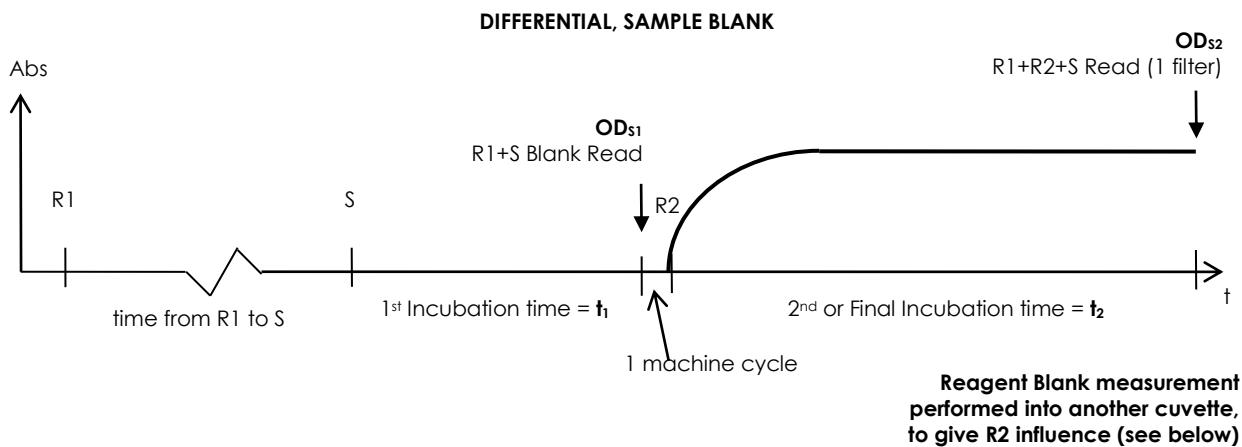
**Differential ENDPOINT – SAMPLE BLANK Method**

The result is related to the difference between the two absorbances taken on the **same** cuvette with S+R1 only and S+R1+R2 respectively:

- the absorbance of the sample mixed with the single reagent R1 at a fixed wavelength λ , at the end of the first incubation time t_1 .
- the absorbance of the sample mixed with both the reagents R1 + R2 at the same wavelength λ , at the end of the second incubation time t_2 (starting after R2 dispensing and mixing).

OD_{s1} : **measured value** – Sample + R1 after incubation time t_1 (sample blank)

OD_{s2} : **measured value** – Sample + R1 + R2 after incubation time t_2



Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $K_S = \left(\frac{V_{R1} + V_S}{V_{R1} + V_{R2} + V_S} \right)$	<u>Single-Standard Concentration Result:</u>

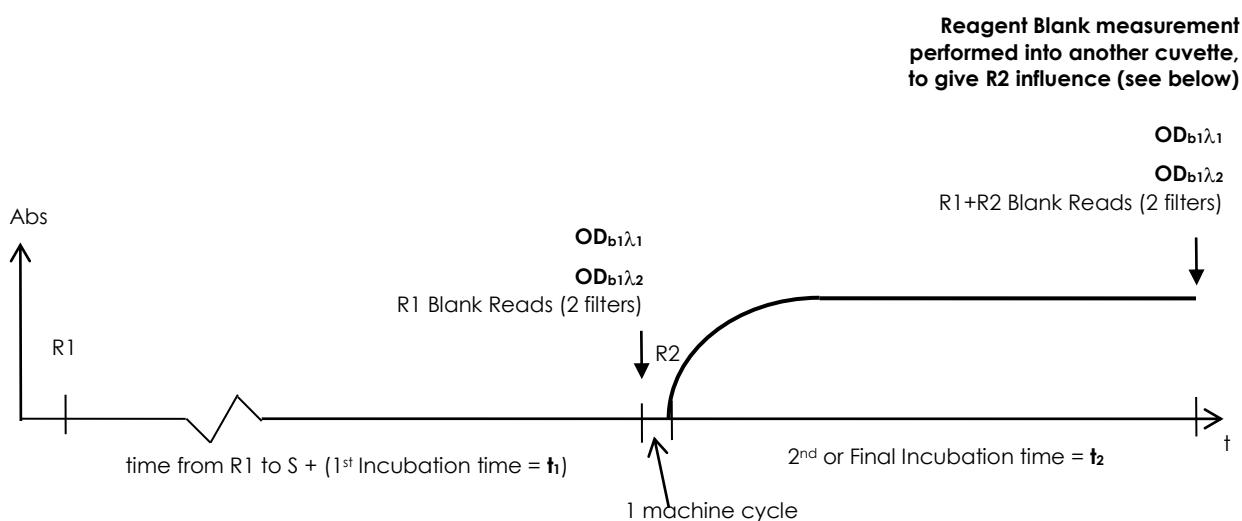
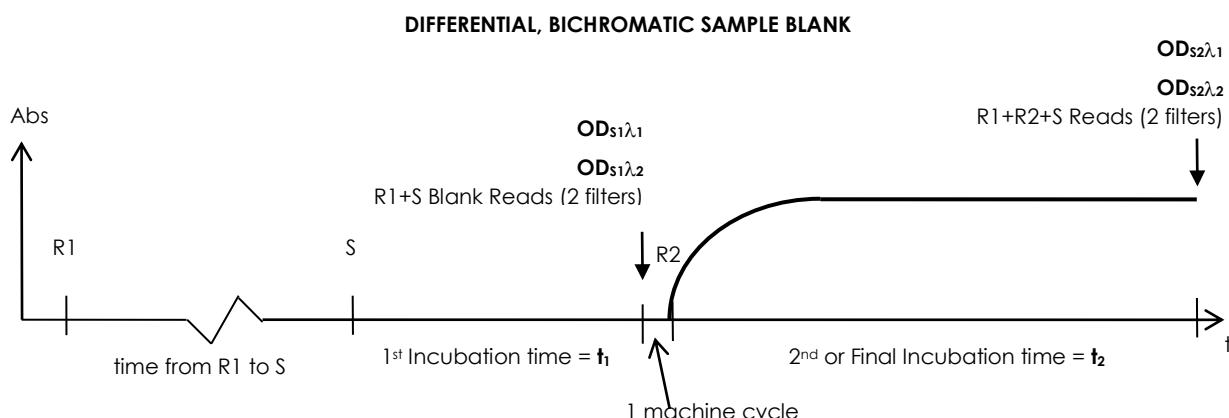


Calculation without Blank Value	Calculation with Blank Value
$\Delta OD_S = [OD_{S2} - (OD_{S1} \cdot K_S)]$ $ResDS = \Delta OD_S \cdot F$ calculation of Factor F : $F = \frac{C_{st}}{[OD_{st2} - (OD_{st1} \cdot K)]}$ OD_{stx} measured with the standard in place of the sample	$K_b = \left(\frac{V_{R1}}{V_{R1} + V_{R2}} \right)$ $\Delta OD_{bc} = [OD_{b2} - (OD_{b1} \cdot K_b)]$ $ResDSb = [(\Delta OD_S - \Delta OD_{bc}) \cdot F]$ calculation of Factor F : $F = \frac{C_{st}}{[OD_{st2} - (OD_{st1} \cdot K)] - [\Delta OD_{bc}]}$ OD_{stx} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $ResDS = Intpol(\Delta OD_S)$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solutions at different C.	<u>Multi-Standard Concentration Result:</u> $ResDSb = Intpol(OD_S - OD_{bc})$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (ΔOD_{bc}) is taken into account.
Reagent blank taken for calculation purpose and for reagent quality check (R_1+R_2 measurement must be included into the reagent blank admissible range).	

**Differential ENDPOINT – Bichromatic SAMPLE BLANK Method**

The result is related to the difference between the two Δ -absorbances taken on the **same** cuvette respectively with $[S+R1]$ after the first incubation time t_1 (starting after S dispensing and mixing) and with $[S+R1+R2]$ after the second incubation time t_2 (starting after R2 dispensing and mixing), both taken at two fixed wavelength: λ_1 (filter F1) and with λ_2 (filter F2). To obtain a Δ -absorbance, F2 absorbance (secondary wavelength) is deducted from F1 absorbance (main wavelength).

- $OD_{S1\lambda_1}$** : **F1 measured value** – V_m at wavelength λ_1 for $(S+R1)$
 $OD_{S1\lambda_2}$: **F2 measured value** – V_m at wavelength λ_2 for $(S+R1)$
 $OD_{S2\lambda_1}$: **F1 measured value** – V_m at wavelength λ_1 for $(S+R1+R2)$
 $OD_{S2\lambda_2}$: **F2 measured value** – V_m at wavelength λ_2 for $(S+R1+R2)$
 $OD_{b1\lambda_1}$: **F1 blank measured value** – V_m at wavelength λ_1 for $(R1)$
 $OD_{b1\lambda_2}$: **F2 blank measured value** – V_m at wavelength λ_2 for $(R1)$
 $OD_{b2\lambda_1}$: **F1 blank measured value** – V_m at wavelength λ_1 for $(R1+R2)$
 $OD_{b2\lambda_2}$: **F2 blank measured value** – V_m at wavelength λ_2 for $(R1+R2)$





Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $K_s = \left(\frac{V_{R1} + V_s}{V_{R1} + V_{R2} + V_s} \right)$ $\Delta OD_{S1} = (OD_{S1\lambda_1} - OD_{S1\lambda_2})$ $\Delta OD_{S2} = (OD_{S2\lambda_1} - OD_{S2\lambda_2})$ $\Delta OD_S = [\Delta OD_{S2} - (\Delta OD_{S1} \cdot K_s)]$ $ResDB = \Delta OD_S \cdot F$ <p>calculation of Factor F:</p> $F = \frac{C_{st}}{[\Delta OD_{st2} - (\Delta OD_{st1} \cdot K)]}$ <p>ΔOD_{stx} measured with the standard in place of the sample</p>	<u>Single-Standard Concentration Result:</u> $K_b = \left(\frac{V_{R1}}{V_{R1} + V_{R2}} \right)$ $\Delta OD_{b1} = (OD_{b1\lambda_1} - OD_{b1\lambda_2})$ $\Delta OD_{b2} = (OD_{b2\lambda_1} - OD_{b2\lambda_2})$ $\Delta OD_{bc} = [\Delta OD_{b2} - (\Delta OD_{b1} \cdot K_b)]$ $ResDBb = [(\Delta OD_S - \Delta OD_{bc}) \cdot F]$ <p>calculation of Factor F:</p> $F = \frac{C_{st}}{[\Delta OD_{st2} - (\Delta OD_{st1} \cdot K)] - [\Delta OD_{bc}]}$ <p>ΔOD_{stx} measured with the standard in place of the sample</p>
<u>Multi-Standard Concentration Result:</u> $ResDB = Intpol(\Delta OD_S)$ <p>Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solutions at different C.</p>	<u>Multi-Standard Concentration Result:</u> $ResDBb = Intpol(\Delta OD_S - \Delta OD_{bc})$ <p>Interpolation with the Calibration Curve determined on the "n" values read for the "n" standard solution at different C. The reagent blank (ΔOD_{bc}) is taken into account.</p>
(R1+R2) reagent blank taken on a separate cuvette for calculation purpose and for reagent quality check (R1+R2 measurement must be included into the reagent blank admissible range).	

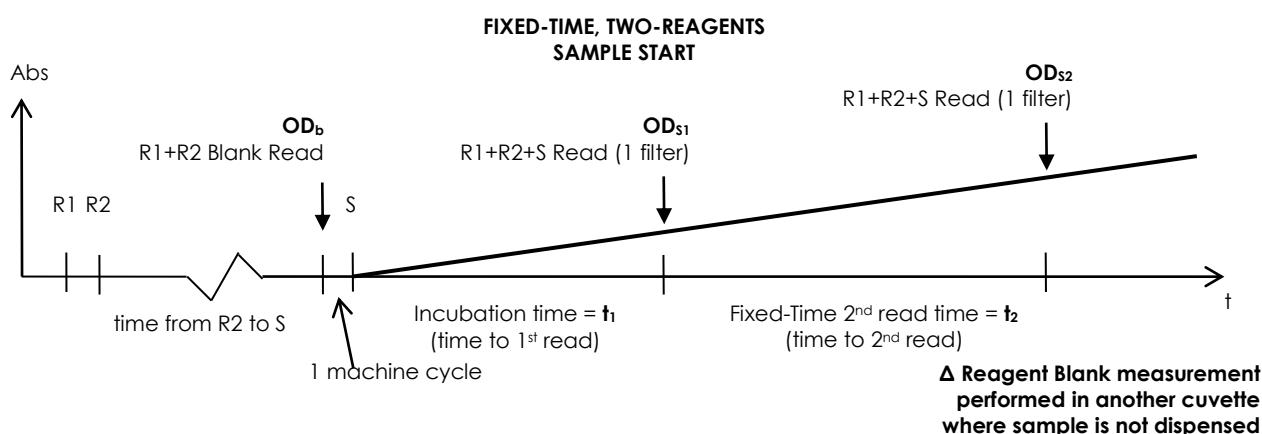
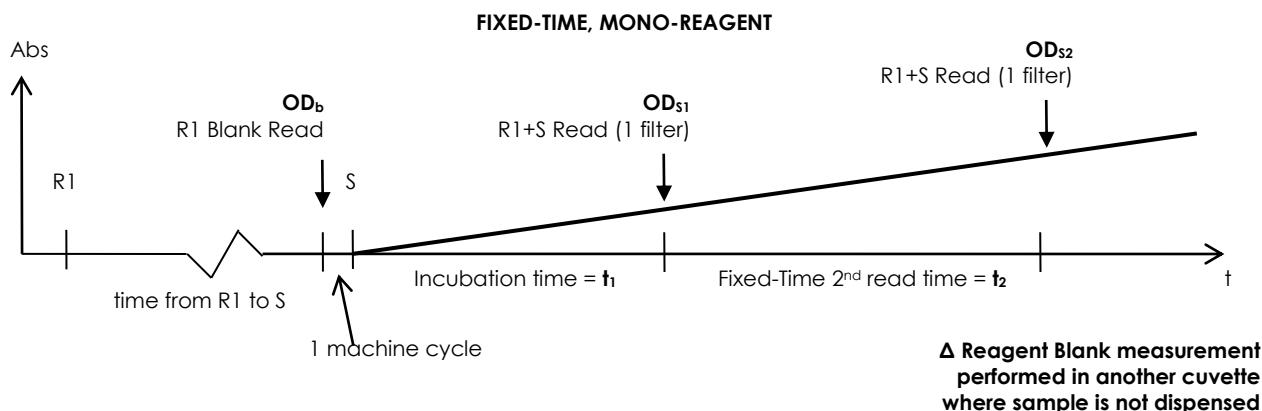
**FIXED TIME Method**

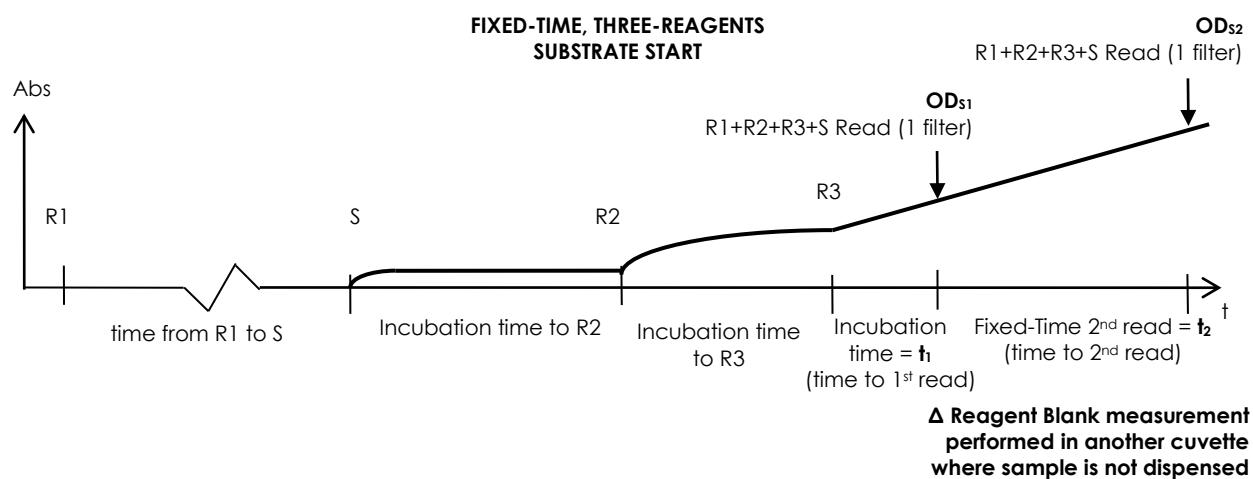
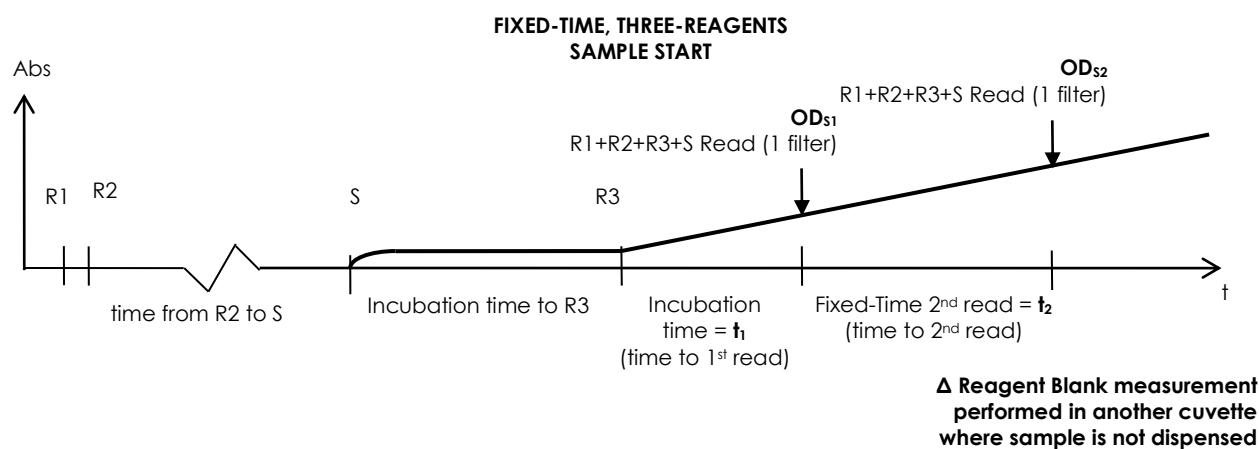
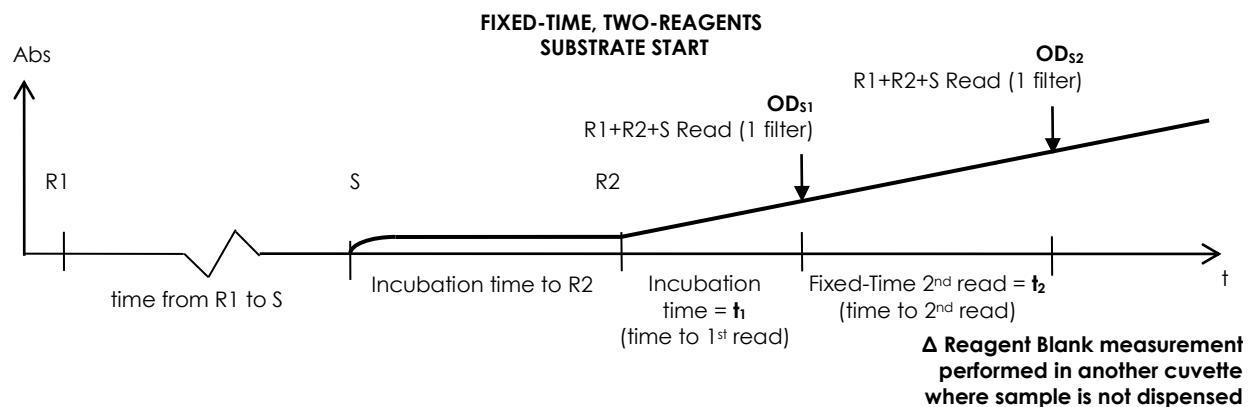
The result is related to the difference between the two absorbances taken on the **same** cuvette at two different time instants:

- the absorbance of the sample mixed with the reagent R1 (or with R1+R2 or with R1+R2+R3) at a fixed wavelength λ , at the end of the incubation time t_1 .
- the absorbance of the sample mixed with the reagent R1 (or with R1+R2 or with R1+R2+R3) at the same wavelength λ , measured after a fixed reading time t_2 (starting just after 1st measurement reading).

OD₁ : **measured value** – Reaction after incubation time t_1

OD₂ : **measured value** – Reaction after fixed 2nd read time t_2





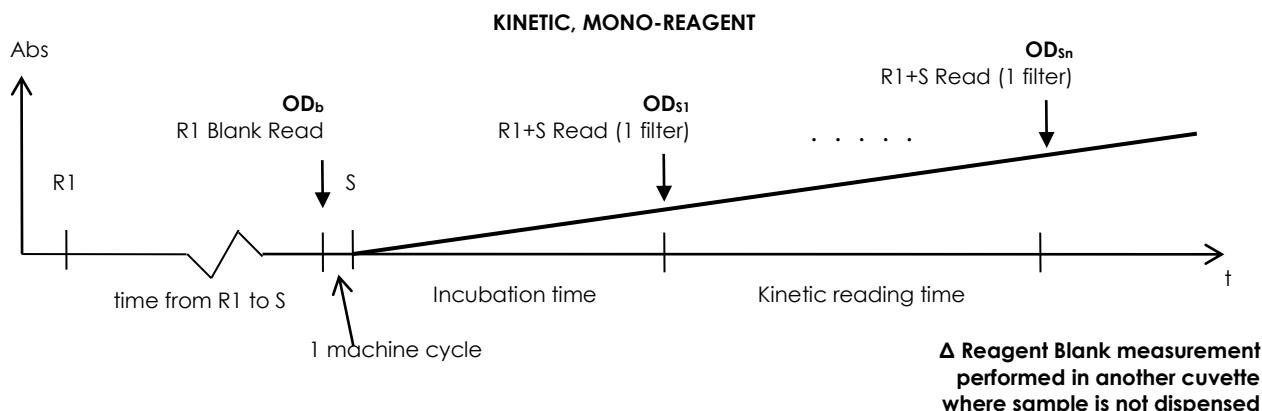


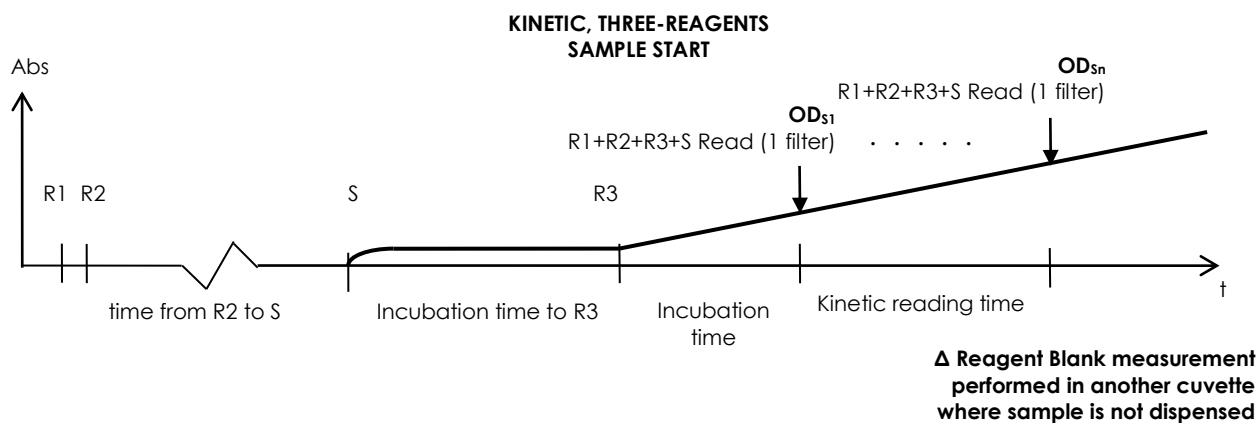
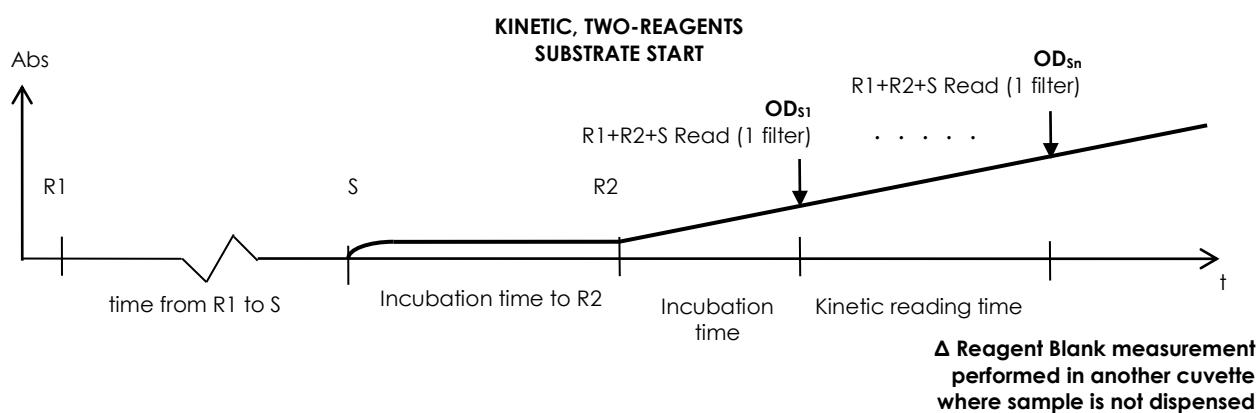
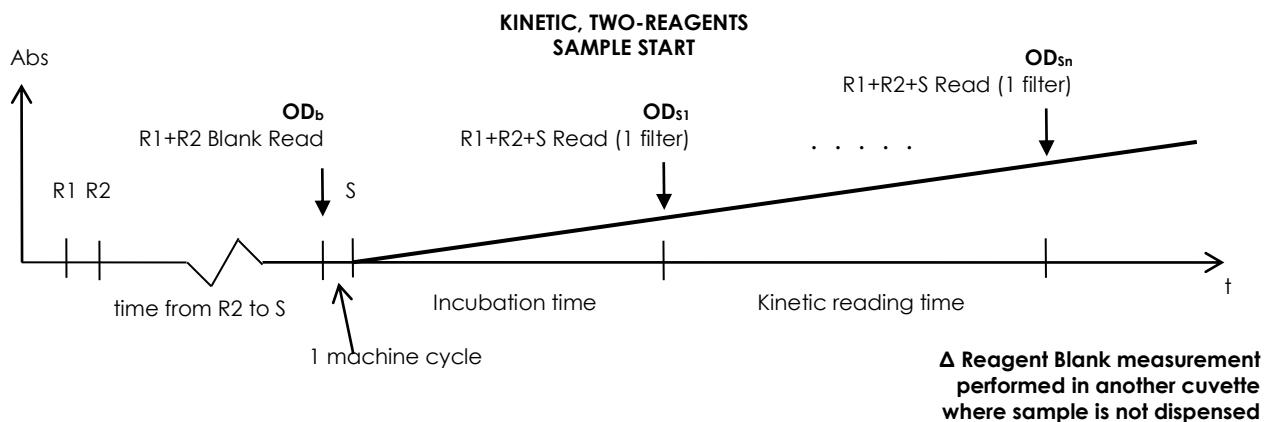
Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $\Delta OD_S = (OD_{S2} - OD_{S1})$ ResFT = (ΔOD_S) · F calculation of Factor F : $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ OD_{stx} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $\Delta OD_b = OD_{b2} - OD_{b1}$ $\Delta OD_S = OD_{S2} - OD_{S1}$ ResFTb = [$(\Delta OD_S - \Delta OD_b) \cdot F$] calculation of Factor F : $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_b)}$ OD_{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> ResFT = Intpol(ΔOD_S) Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solutions at different C.	<u>Multi-Standard Concentration Result:</u> ResFTb = Intpol($\Delta OD_S - \Delta OD_b$) Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (ΔOD) is taken into account.
ΔOD_b of the reagent blank taken for calculation purpose; for reagent quality check, R ₁ , or R ₁ +R ₂ , or R ₁ +R ₂ +R ₃ measurement must be included into the reagent blank admissible range.	

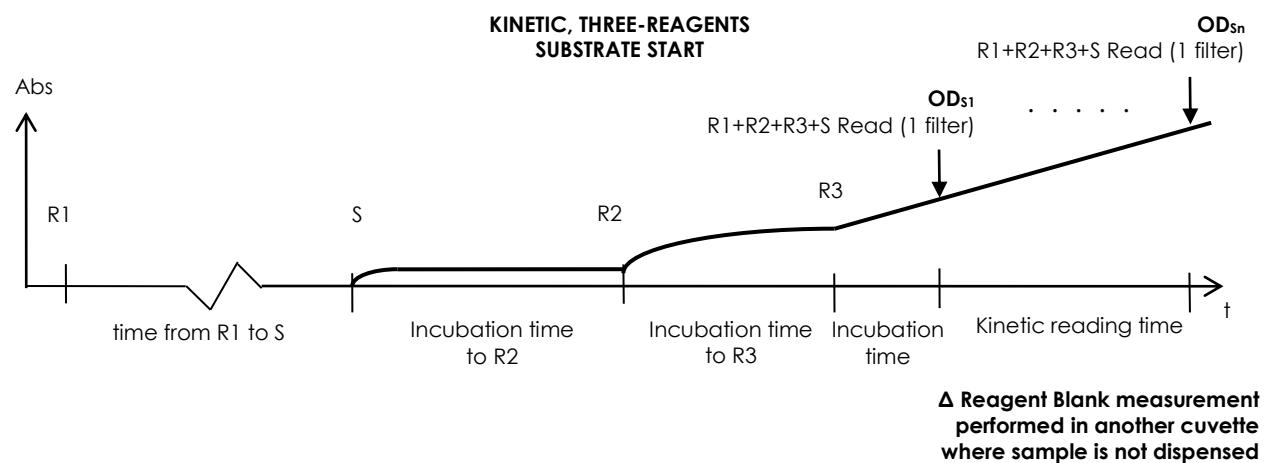
**KINETIC Method**

The result is related to the absorbances measured during a given reading time starting at the end of the incubation time. Absorbances are taken on the same cuvette where the reaction takes place: sample S mixed with the R1 (or with R1+R2 or with R1+R2+R3), at one fixed wavelength λ . The measurement is taken **n** times ($n=3\div9$) during the “reading time” interval ΔT .

Each of the **n** absorbances is stored together with the measurement instant (“real time” of the reading) so to build a **OD/time** bi-dimensional array. The system uses these couples of values to calculate, through a *linear regression*, a straight line that best fits and describes the relation between the couples of values using the method of the Minimized Least Squares. The “slope” of the straight line (the angle from the horizontal) determines: the *trend* of the reaction (if positive – the absorbance increases with time – or negative), the *activity* of the reaction and then the final result. The slope must be *normalized* to 60sec as worldwide convention. The “fit” gives a measure of how much the straight line is near to the scattered measured points; it ranges from 1 (“best fit”) down to 0.









Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> Calculation of the slope, intercept and <i>FIT</i> (squared correlation coefficient) over the OD _x /time array of the n measured values $\text{ResKT} = (\text{slopes}) \cdot F \cdot 60$ calculation of Factor F : $F = \frac{C_{st}}{(\text{slope}_{st}) \cdot 60}$ OD _{st} measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> Calculation of the slope, intercept and <i>FIT</i> (squared correlation coefficient) over the OD _x /time array of the n measured values for sample and reagent blank $\text{ResKTb} = [(\text{slopes}) - (\text{slope}_b)] \cdot F \cdot 60$ calculation of Factor F : $F = \frac{C_{st}}{[\text{slope}_{st} - \text{slope}_b] \cdot F \cdot 60}$ OD _{st} measured with the standard in place of the sample
<u>Multi-Standard Concentration Result:</u> $\text{ResKT} = \text{Intpol}(\text{slopes}) \cdot 60$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C.	<u>Multi-Standard Concentration Result:</u> $\text{ResKTb} = \text{Intpol}(\text{slopes} - \text{slope}_b) \cdot 60$ Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (slope_b) is taken into account.
Slope _b of the reagent blank taken for calculation purpose; for reagent quality check, R ₁ , or R ₁ +R ₂ , or R ₁ +R ₂ +R ₃ measurement must be included into the reagent blank admissible range.	



4.3. The ISE Module (option)

The system can include the optional **ISE Module** used as a component of the chemistry analyzer itself. Its purpose is to measure lithium, sodium, potassium, and chloride concentration in serum / plasma / urine and to transmit the results to the analyzer for integration into the final test results report.

4.3.1. Generals

The ISE Module includes up to four ion-selective electrodes and three peristaltic pumps to be mounted within the chemistry analyzer. The ISE Module measures the concentration of Li⁺, Na⁺, K⁺, and Cl⁻ in serum, plasma and diluted urine. An integral sample entry port is positioned on top of the ISE Module.

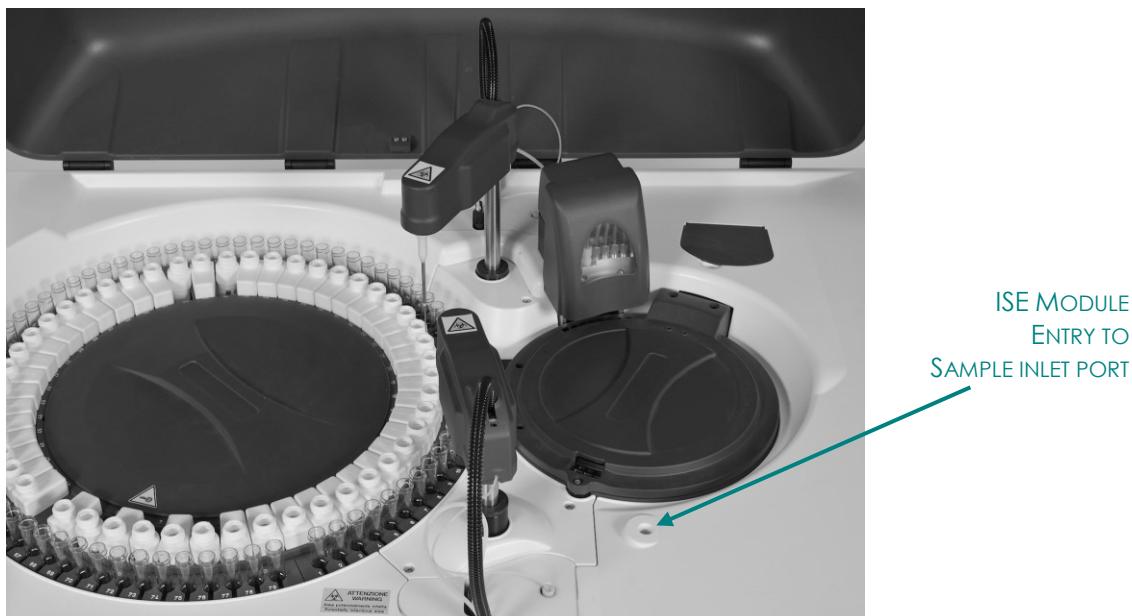


Figure 37: M2-79 Working area, entry to ISE Module

The Module requires a *minimum* sample size of 70µl (90µl is normally used for serum/plasma and 2x90µl for diluted urine).

The ISE Module houses snap-in, snap-out electrodes which connect directly to an electronic board within the ISE Module.

Samples and calibrators are positioned in front of the electrodes by three peristaltic pumps. Two separate pumps move Calibrant A and Calibrant B into the ISE Module's sample entry port and the waste pump positions samples and calibrants in front of the electrodes.



The sample is dosed by the analyzer ARM into the ISE Module sample entry port. After each sample measurement, calibrant is pumped in front of the electrodes for a single-point calibration.

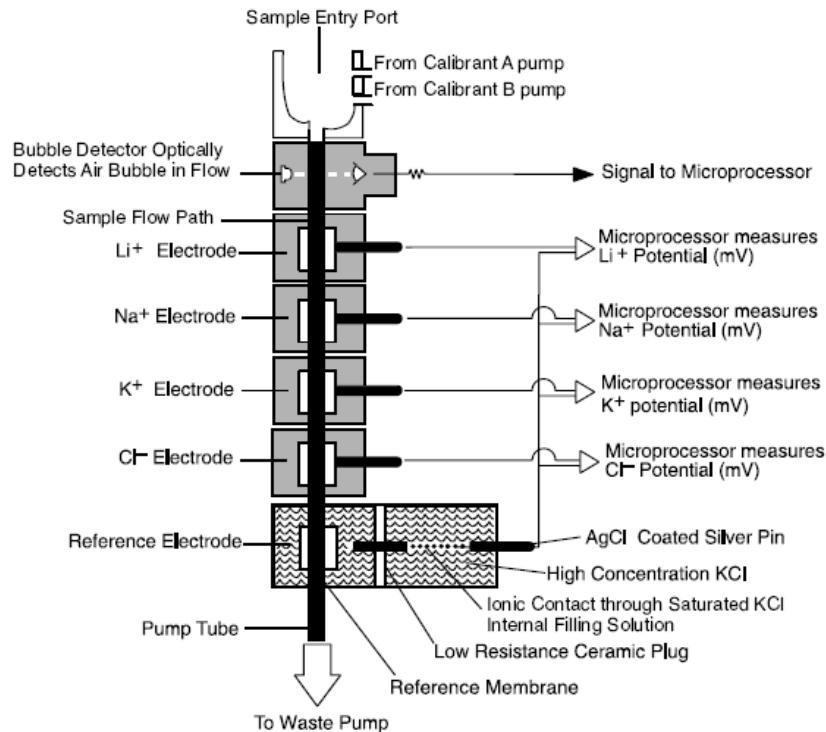


Figure 38: ISE Module, functional diagram

The removal of protein build-up is accomplished by the use of cleaning solution. Cleaning solution must previously placed in a 20ml reagent bottle on the reagent tray, aspirated, and deposited into the sample entry port by the instrument Sample ARM.

The ISE Module results are given in units of **mmol/L**.

4.3.2. ISE Module, Operating Principles

Electrolyte measurements in blood products were traditionally performed using flame photometry. Using this method, a sample that has been diluted with a known concentration of a reference ion (usually lithium or cesium) is aerosolized and passed through a flame which excites the cations. They re-emit the energy as light of different frequencies; the amplitude of this emission is proportional to the ion concentration in the sample. The development of selective organic compounds for sodium, potassium, chloride, and other electrolytes has permitted the development of sensors capable of directly measuring biological fluids



throughout the physiological range. These sensors are known as ion-selective electrodes.

The ISE Module measures lithium, sodium, potassium, and chloride in biological fluids, using ion-selective electrode technology. A diagram of the electrode measurement system has been shown above. The flow-through sodium electrode uses a selective membrane, specially formulated to be sensitive to sodium ions. The potassium, lithium, and chloride electrodes employ similar designs with appropriate selective membrane materials. The potential of each electrode is measured relative to a fixed, stable voltage established by the double-junction silver/silver chloride reference electrode. An ion-selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic (Nernst equation).

A comparative method of measurement is utilized. First the ISE Module measures the potentials developed when the sample is positioned in the electrodes. Next, Calibrant A is positioned in the electrodes. The difference in the two potentials is related logarithmically to the concentration of the measured ions in the sample divided by their respective concentrations in the calibrant solution. Since the difference in potentials and the concentration of the lithium, sodium, potassium, and chloride ions in the calibrant solution are known, the system can calculate the concentration of the ions in the sample.

When a two-point calibration is initiated, the slope is calculated from the difference between each Calibrant A and Calibrant B reading. Excessive drift or noisy readings will be flagged and the appropriate error message is shown.

The system checks these **slopes** and in case they are outside the acceptable slope limits appropriate flags are given or calibration is repeated. Typical slopes are approximately 55mV/decade for Li⁺, Na⁺ and K⁺ and 45mV/decade for Cl⁻.

Acceptable slope limits are:

Slope	(mV/decade)
Na ⁺	52–64
Cl ⁻	40–55
Li ⁺	47–64
K ⁺	52–64

The values of slopes between calibrations performed successively (one after the other) should not differ by more than 1.5 mV/decade for any of the channels, (Li⁺, Na⁺, K⁺, or Cl⁻).

4.3.3. **Electrodes**

ISE Module electrodes are maintenance-free and the following operation will be performed:



- Cleaning solution, aspirated from the proper reagent bottle, must be used at least once a day at the end of the day in order to minimize protein build-up in the fluid lines and in the electrodes. The instrument runs a cleaning cycle automatically after 50 samples.
Note: The Producer strongly recommends the User to run a Cleaning cycle (about 2 minutes) at the end of the working day before instrument shuts down.
- A pump calibration is automatically performed by the instrument during instrument warming up.
- A two-point calibration of the ISE module is automatically performed during instrument warming up and repeated every 8 hours when in use.
- After 50 samples run in a day, both cleaning and two-point calibration are performed after 50 samples.
- To ensure reliable operation, the ISE Module will perform automatic calibrant sipping every 30 minutes after the last sample is run. **Provide Reagent Pack always connected.**

The ISE Module utilizes a double-junction **reference electrode**. The reference electrode is filled with saturated KCl. If the concentration of the reference electrode reservoir drops below 3.0M KCl, serious errors will result in the measured electrolyte concentrations. The reference electrode contains a **small red sphere** in the reservoir which normally resides on top of the filling solution. If the sphere begins to sink, the reference electrode must be replaced.

If any electrode is not used replace it with the **spacer electrode**.

Note: check daily the red sphere on top of the reference electrode filling solution.

4.3.4. Fluid Management

When measuring **serum or plasma** samples, the instrument aspirates it from the proper tube (on the sample tray), dispenses it into the sample entry port and starts the measuring process returning back four results.

When measuring **urine** samples, the instrument automatically provides an accurate sample dilution of 1 part sample with 9 parts **urine diluent** (placed on the reagent tray) into one cuvette. The instrument then aspirates the diluted urine and dispenses it into the sample entry port starting the process and returning back four results.

After the sample is dispensed into the sample entry port on top of the ISE Module it is automatically positioned in front of the electrodes for the measurement by the ISE Module waste pump.

During the process the following solutions are required to operate the ISE Module:

1. **Calibrant A** is used in both the two-point and single-point calibrations **for sample analysis**. Calibrant A is pumped into the sample entry port by the



Calibrant A pump and then positioned in front of the electrodes by the waste pump. Calibrant A solution is also used for the pump calibration.

2. **Calibrant B** is used in two-point and single-point calibrations **for urine sample analysis**. Calibrant B is pumped into the sample entry port by the calibrant B pump and then positioned in front of the electrodes by the waste pump.
3. **Cleaning solution** is used once a day **to prevent protein build-up**. It must be used more frequently if the ISE Module performs greater than 50 samples per day. A precise volume of cleaning solution is aspirated by the instrument sample ARM and dispensed into the sample entry port. Cleaning solution is aspirated from the proper reagent bottle and then dispensed into the sample entry port. **The reagent bottle must be covered** to eliminate evaporation.
4. **Urine Diluent**. Urine samples are diluted to perform urine measurement: 1 part urine sample to 9 parts urine diluent. The diluted is thoroughly mixed before aspirating a sample. Urine Diluent is aspirated from the proper reagent bottle just before the sample of urine.

The instrument maintains internal record of Calibrant A and Calibrant B estimated consumptions.



4.4. Bibliography

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Section 5 FUNCTIONS

5. Functions

5.1. Purpose of the Instrument

This system is an automatic analyser designed for in-vitro diagnosis of clinical chemistry and turbidimetry tests to be used in laboratories and similar diagnostic facilities.

It has been designed to execute automatically every analysis phase with the exception of sample preparation. It assures precise results and repeatability, good productivity and safety for the operator.

WARNING

The use of this instrument for some analyses, which nevertheless have been validated, could require in some countries the approval or registration by the competent Government Agency.

5.2. Instruments Functions

This system can automatically process a great number of Clinical Chemistry and Turbidimetric tests. All of the following operations have been automated and are currently available as standard option or on request:

- Reagents sampling and dispensing (up to three reagents) with refrigeration.
- Samples, standards and controls sampling, dispensing, dilution and mixing.
- Reactions incubation at constant temperature.
- On-line sampling probes washing.
- Photometer readings with wavelength auto-gain control.
- Washing and optical control of reading cuvette integrity.
- On-line monitoring of the reaction liquids level.
- On-line control of the washing liquid level.
- On-line calibration curves.
- Bar-coding positive identification of reagents and samples (option).
- Work List compilation.
- Computing and printing of results.
- Continuous patients loading.
- On-line quality control.
- Results storing in archive.
- Export of results.
- L.I.S. bidirectional data exchange connection (option).
- Electrolytes tests management (ISE Module option).



The system can operate as “open system” or “closed system” depending on the particular customer’s agreement. In case of closed system a smart card reader will be supplied to allow loading of the tests purchased.

The system shows the following hardware and software characteristics:

Hardware

- Instrument easy to use.
- Positive identification of samples and reagents by Barcode reader (option) with possibility to use more coding for sample labelling.
- Precision system for sample and reagent aspiration and dispensing, reached by using high precision micro-metering stepping motor pump, that assure the best accuracy and reproducibility.
- Minimization of probe carry-over through an on-line special washing procedure of the sampling probes.
- Minimization of cuvette carry-over and contamination through an on-line special washing procedure and test restriction constrains.
- Capacitive liquid sensor able to detect the level of samples and reagents touched by the sampling probe.
- Shock sensor able to detect obstacles during the way down of the sampling arms.
- Separation between reaction fluids and systemic washing solution through air gap and an electrovalve.
- Thick walls Teflon® internal hydraulic charging tubing.
- Photometric optical group, with interferential filters, that assures precise, reliable and quick readings of absorbance.
- High reliability modular electronics; modularity gives low-cost, fast and targeted servicing.
- Easy loading by smart-card of the information related to the reagents used from the instrument (option).
- Four electrodes I.S.E. module with auto calibration and bubble detector (option).
- Minimization of the human risk factor.

Software

- Application based on MS Windows XP®.
- Easy to use User Interface – wizard style.
- Easy access to all menus.
- Interactive communication between instrument and user.
- Real-time control of the reaction fluids and washing solutions: management for easy replacement.



- Analyse routines easy to program and to run.
- Real-time control of test results.
- Quick and accurate printing of the results.
- 3-level Levy-Jennings graphs based on-line Quality Control.
- Graphic representation of the current working session status.
- Interactive management of alarm and warning states.
- Easy software and firmware updating procedures through automatic downloading.
- Reduction of risks due to human errors.



5.3. Functions

The instrument includes the following functional sub-assemblies:

- Loading trays: Sample tray and Reagent tray (within working area).
- Sampling ARM assembly, for patient reagents, samples, calibrators / standards and quality controls (within working area, two-assemblies in case of double ARM configuration).
- Sampling probes washing sink (within working area).
- Incubation and optical reading assembly and washing station (within working area).
- Barcode reader (internal - option).
- Command and control electronics (internal).
- Power supply unit (internal).
- Management software and user interface (on external management PC).
- ISE module (internal - optional).
- L.I.S. interface (option).

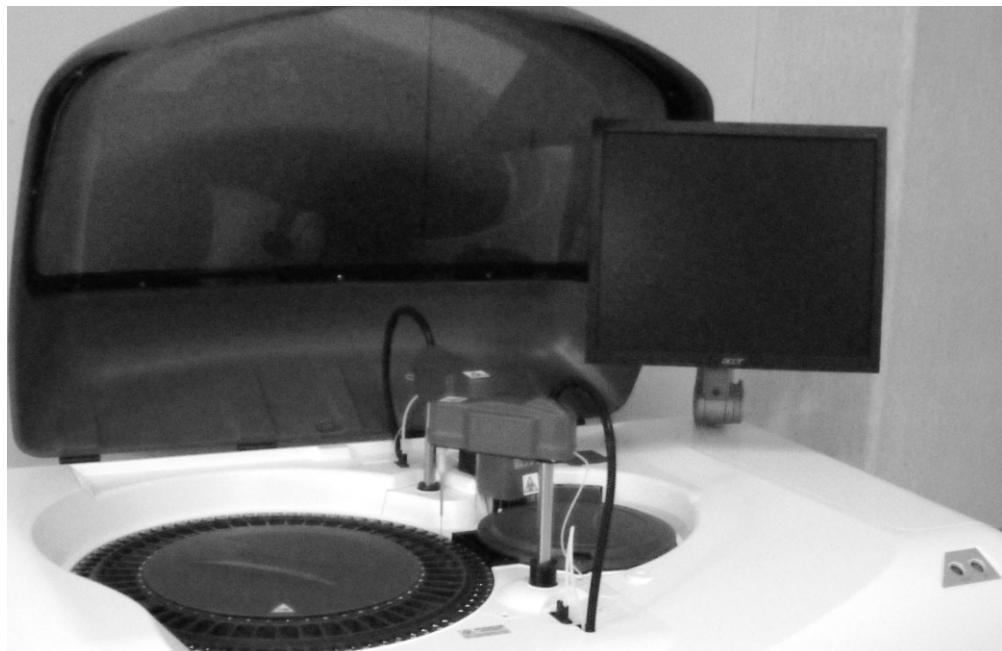


Figure 39: M2-79, Working Area

5.3.1. Loading Trays

The loading trays include:

- Sample tray.
- Reagent tray and reagent cooling unit (refrigeration as option).

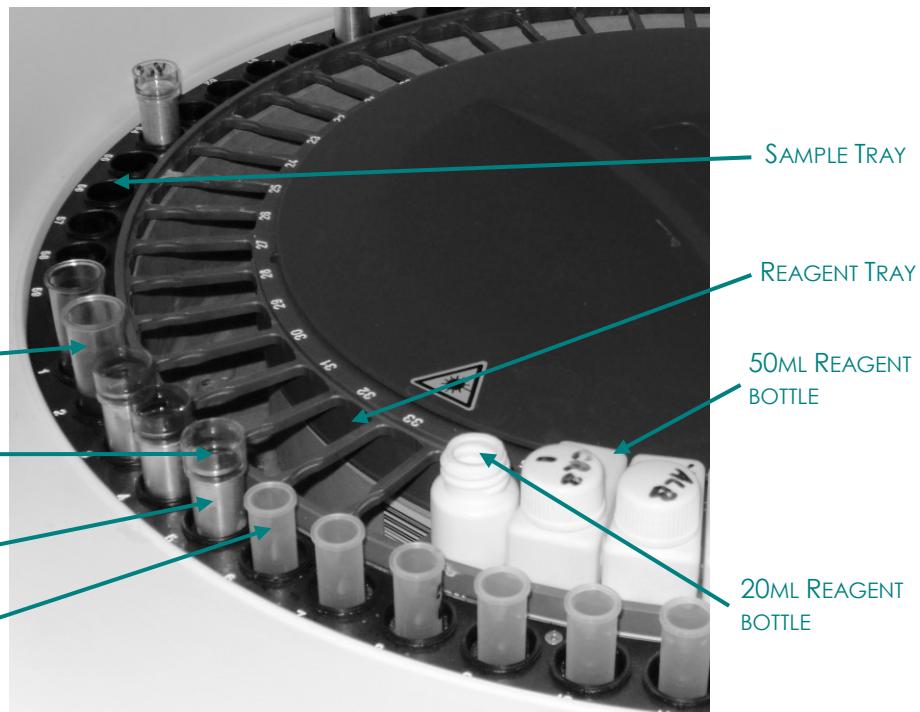


Figure 40: M2-59, Sample and Reagent Wheels

5.3.1.1. Sample Tray

This tray is located on left side of the working area; there are two concentric carousels, it is the external one.

It includes several positions depending on the instrument configuration,

- **Instruments with 59 sample positions:**

59 numbered positions (from 1 to 59) to place up to 59: normal samples, paediatric samples, standard / calibrators, QC's, that can be placed anywhere; also **STAT** samples can be placed anywhere. It is possible to use primary tubes **12mm-16mm diameter** and **75mm-100mm height**. Use Hitachi® like **3ml sample cups** (diameter 12mm) with special **adapter**.

- **Instruments with 79 sample positions:**

79 numbered positions (from 1 to 79) to place up to 79: normal samples, paediatric samples, standard / calibrators, QC's, that can be placed anywhere; also **STAT** samples can be placed anywhere. It is possible to use primary tubes **12mm-13mm diameter** and **75mm-100mm height**. Use Hitachi® like **3ml sample cups** (diameter 12mm) **without** any **adapter**.

All numbered positions are identified by pantographic numbers increasing in counter-clock wise direction.



Figure 41: M2-79, Sample and Reagent Wheels

5.3.1.2. Reagent Tray

This tray is positioned on left side of the working area; there are two concentric carousels, it is the internal one.

It includes **49** numbered positions; all of them are refrigerated. Only **50ml** reagent bottles or **20ml** reagent bottles can be placed there.

One of them - **position 49th** - is reserved for the diluent (i.e.: distilled water, physiologic solution or similar). In this way it is possible to load the tray with mono-reagent, 2-reagent or 3-reagents methods for clinical chemistry or turbidimetry analysis.

All numbered positions are identified by pantographic numbers, increasing in counter-clock wise direction.

A maximum of 48 different mono-reagent methods or 24 bi-reagent ones or any other combination of them can be placed on the tray, including methods using three reagents.



Figure 42: ON/OFF Front Switches

The refrigeration unit is located under reagent tray. The cooler preserves all reagent bottles at constant temperature of about $12^{\circ}\text{C} \pm 2^{\circ}\text{C}$; the refrigeration temperature cannot anyway decrease more than 14°C below the ambient temperature. The refrigerator includes four Peltier cells cooled by heatsink and fan each. The temperature on the reagent tray is monitored in real time when cooler is ON. Through a specific switch placed in front of the machine (blue colour) it is possible to turn ON/OFF the cooler only, separately from electronic.

5.3.2. Sample and Reagent Dispensing Assemblies - ARMs

Depending on the configuration of the system, the instrument can be supplied with one or with two sampling ARMs. The system with two sampling ARMs shows double throughput.

In case of double ARMs, the ARM next the cover is named **ARM2** and the ARM in front of the instrument is named **ARM1**.

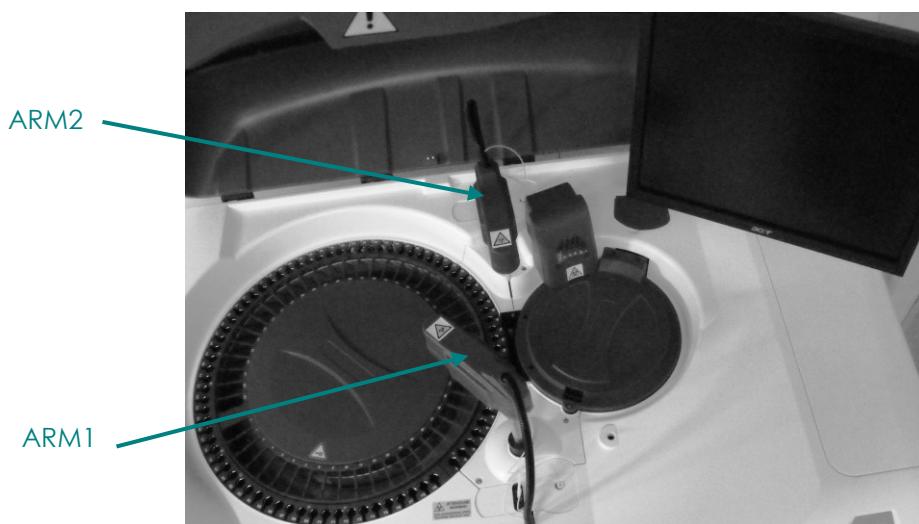


Figure 43: Dispensing Assembly, ARM1 and ARM2



ARM assemblies are used for aspiration and dispensing of samples and reagents; they are similar and each of them is composed by the following main parts:

- Sampling probe sub-assembly (including: one capacitive liquid detector and one obstacle sensor).
- Diluter – micro-metering pump.
- Electrovalve.
- Remote washing peristaltic pump.

After each dispensing operation in cuvette, within the same machine cycle, the instrument automatically performs a probe washing cycle in the washing sink before the next aspiration.

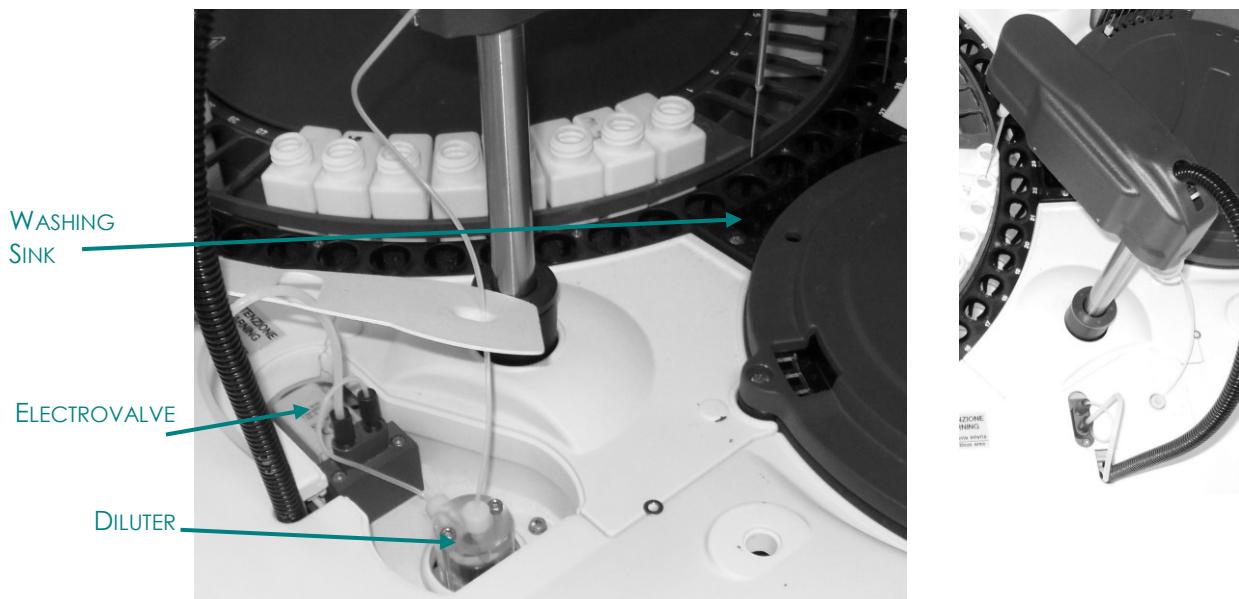


Figure 44: Dispensing Assembly, ARM1

5.3.2.1. Sampling Probe Sub-assembly

This sub-assembly (one for each sampling arm) is composed by the probe itself, by the liquid level sensor and by the shock sensor.

Sampling probe material is stainless steel; its shape and its surface treatment has been studied in order: to get high precisions, to maximize the fluid flow and to make easier and more efficient the automatic washing of the internal and external probe surfaces.

The carry-over is minimized by rinsing, in the “washing sink” using the systemic solution, the whole internal surface of the probe and its external surface that has been in touch with the reaction fluids.

Hence each probe sub-assembly, beyond the probe itself, includes:



- One capacitive liquid detector, that limits the depth of penetration into the liquid (and consequently the possible contamination) and allows the correct volume monitoring; this sensor has been coated with protective resin to assure the correct operation also in extremely humid conditions;
- One optical obstacle sensor (shock sensor), for detection of eventual obstacles when the probe is descending.

5.3.2.2. Diluters

The instrument is equipped with a diluter for each of the sampling ARMs. Diluter provides to aspirate and to dispense the correct volume of samples, reagents, standard / calibrators, quality controls and diluents, assuring great precision also for very small volumes.

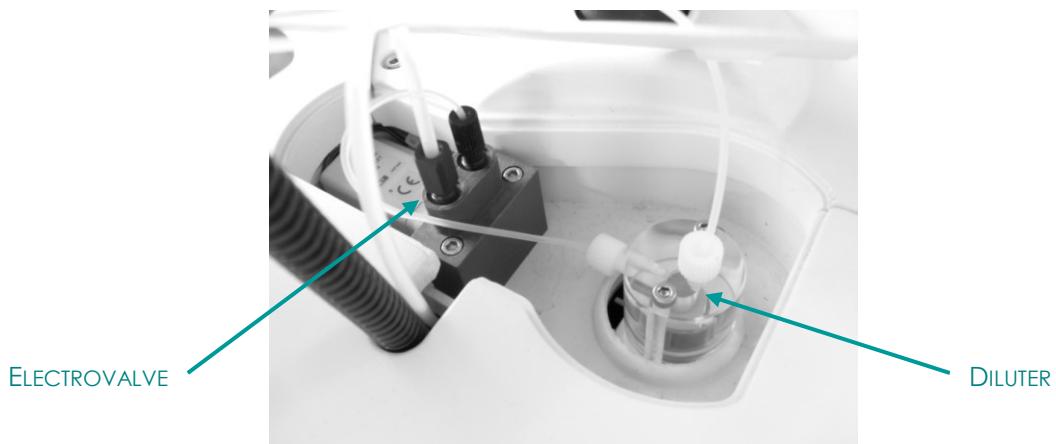
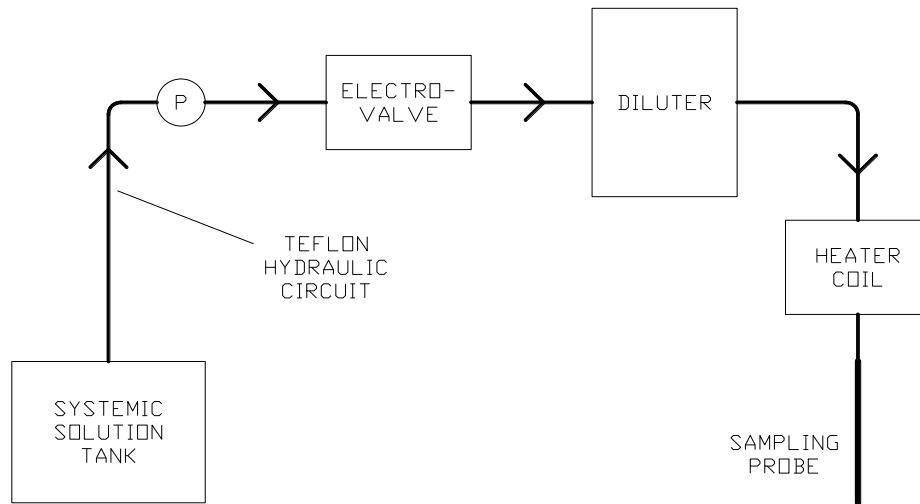


Figure 45: Diluter and Electrovalve

Each diluter has two fittings: one for hydraulic connection with the sampling probe, through the heater coil, the other for hydraulic connection with the electrovalve. The electrovalve itself is connected on the other side to the peristaltic washing pump. The hydraulic schematic diagram is the following:



The diluter has the following characteristics:

- Maximum sampling capacity 500µl, including air gaps.
- High Resolution.
- Minimized dead volume.
- High dimensional accuracy plunger.
- Long life plunger seal.

During sampling, the electrovalve closes the way out to systemic solution circuit; when washing, the electrovalve opens to the systemic solution circuit and the washing pump starts flushing.

5.3.2.3. Electrovalve

The electrovalve is used to cut off and separate into the tubing the systemic solution when inhaling or dispensing reaction fluids. It opens only during probe washing cycles.

5.3.2.4. Pump for Probe Washing

The pump is used to move the systemic solution into the probe hydraulic circuits that must be washed. All washing pumps have been placed on a support located just behind the front panel of the instrument; it make it easy the periodic maintenance operations and the integrity monitoring to the service personnel.

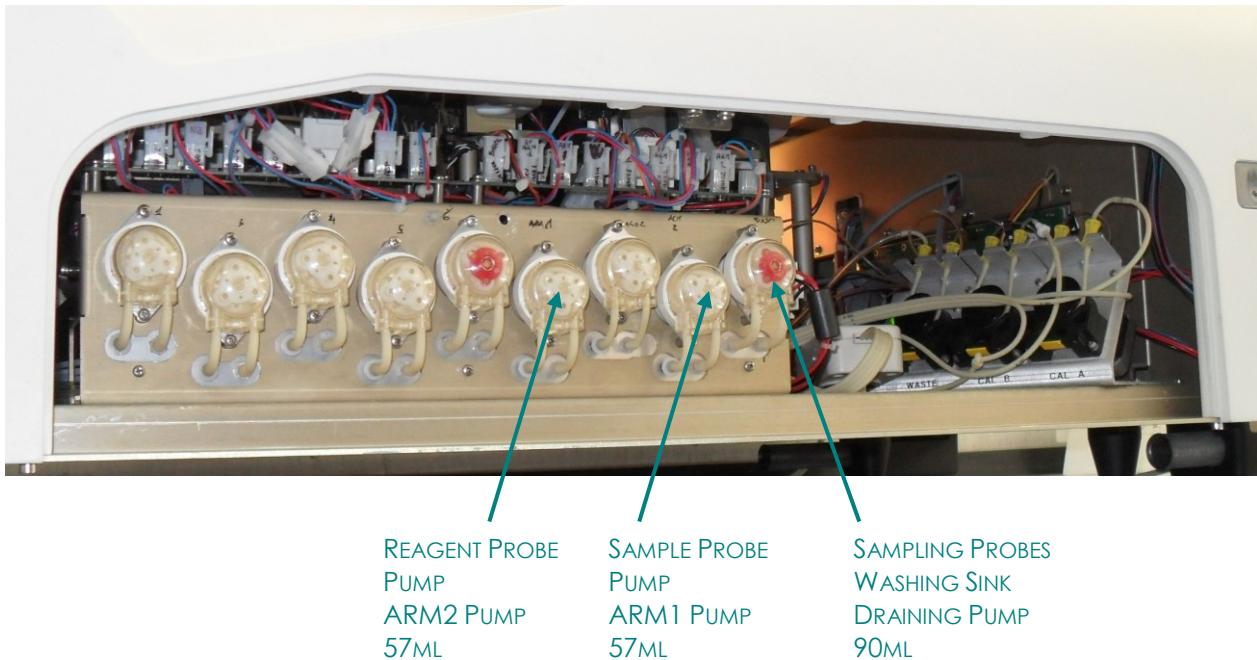


Figure 46: Probe Washing Pumps

The instrument performs a probe washing cycle by enabling the electrovalve and the washing pump for each sampling cycle.

Washing cycles have been tuned at factory to reach the lowest cross contamination.

5.3.3. Probe Washing Sink

The washing sink is situated in middle of the working area, between the reagent and sample wheels and the reading cuvette tray. After dispensing, each probe is rinsed into its proper white tip, within the washing sink, in order to wash both the inner and outer surfaces.

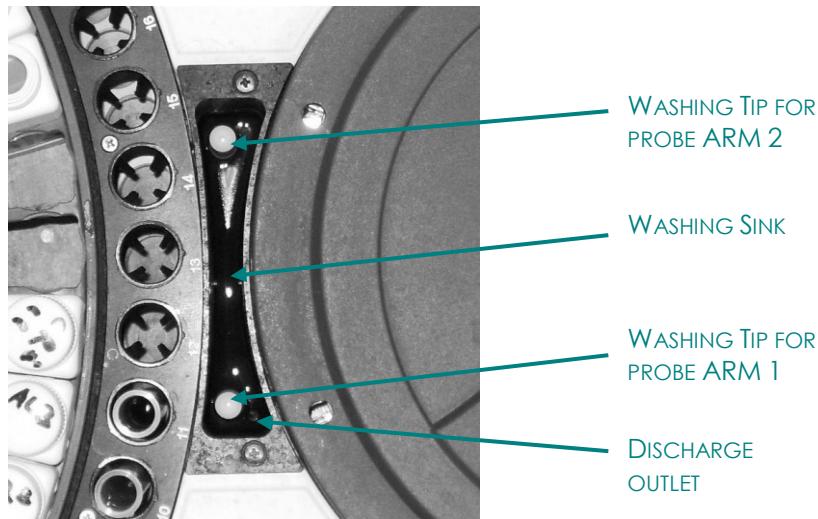


Figure 47: Washing Sink

To discharge the washing sink, the system automatically starts a specific pump during probe rinsing.

5.3.4. Incubation and Reading Assembly and Washing Station

This assembly is composed by the following main parts:

- Cuvette tray assembly for incubation of reactions and Absorbance reading.
- Optical group.
- Cuvette washing station.

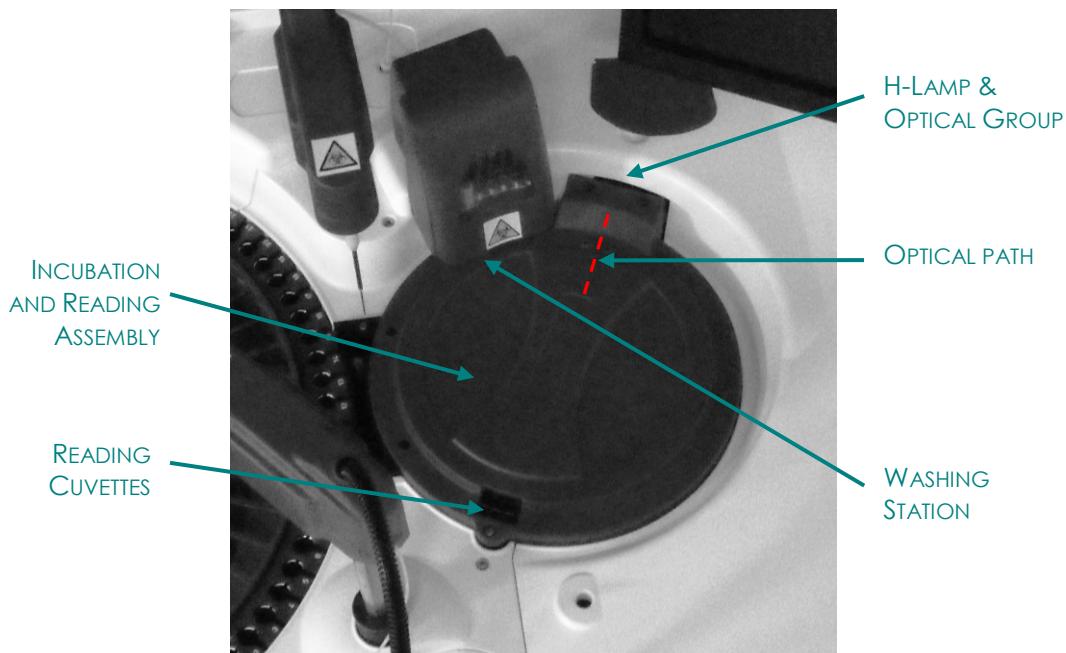




Figure 48: Incubation and Reading Assembly and Washing Station

The reaction solutions are dispensed by the ARM into the cuvette for incubation and reading according to the related method parameters.

Each cuvette, at the end of its incubation time, is positioned in front of the optical group to be read by the photometer. After the reading and according to the scheduling of the management system, the washing station provides the discharging of the products of reaction, the washing of the cuvette and its optical check.

The photometric reading is performed directly on the cuvette containing the reaction solution and it is carried out by positioning it in front of the optical group ("direct reading"); the centre of the cuvette smaller walls are crossed by the optical path. The reading group provides both the selection of the wave-length, by moving the filter wheel for setting the right filter, and the measurement of Absorbance.

5.3.4.1. Incubation and Reading Assembly

The incubation and reading assembly is based on a rotating tray that contains 80 cuvettes in Bionex® optical plastic. The cuvettes are reusable and, after washing, they are filled with the reaction to be incubated and read.

When requested during the machine cycle, the cuvette tray rotates for placing the right cuvettes under the sampling probes and it allows the contemporaneous sampling of the reagent and sample arms in two different cuvettes.

At the end of the incubation time, during which the system anyway is working on the other cuvettes, the particular cuvette to be read is moved in front of the optical group. After the reading operation the cuvette is discharged from liquids, washed and dried by the washing station. After being washed, the cuvette is optically checked in order to verify its neatness and for updating the auto-zero value with the new actual one; in case the value is out of the acceptable range, the system marks the cuvette as dirty and it will not be used but washed again. If, after three more washing cycles, the cuvette is detected as still dirty, the system will alert the operator for replacing it with a new one by marking it in red colour.

This assembly is kept at constant temperature in order to maintain the temperature of the solutions into the cuvettes at +37,0°C (if the ambient temperature doesn't overcome the specification limits). The assembly provides a thermal switch that operates a hardware protection in case of failure of the control system; it prevents the over-heating of the assembly.



5.3.4.2. Optical Group

Measurement of Absorbance is taken on each cuvette in direct mode. The measurement is made by a spectrophotometer through interferential filters. The light source is based on a 12V/20W halogen lamp. All of the filters are assembled on a filter tray that allows the selection of the particular wavelength required by the method. The following picture shows the measurement block diagram.

The measurement chain includes an automatic gain control circuit in order to assure always similar signal dynamic ranges over the different wavelength and even in case the boundary conditions change.

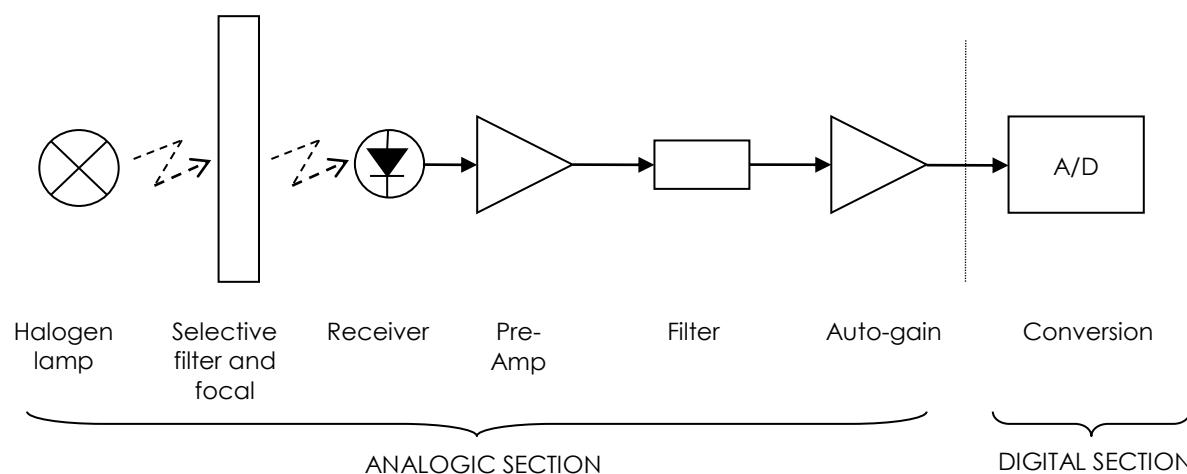


Figure 49: Optical Group – Measurement Circuit

An internal system controls 9 interferential filter positions (one of them is free for customization) and it measures the optical density for each test in mono- or bi-chromatic reading. Another position on the filter tray (black) is used for the automatic auto-zero of the circuit off-set. In the standard version the eight wavelengths implemented are the following:

- 340nm
- 405nm
- 492nm
- 505nm
- 546nm
- 578nm
- 630nm
- 700nm.

Readings are based on the Lambert-Beer's law (see paragraph 4.2.1 and following).

5.3.4.3. Washing Station and Pumps

The washing station washes all of the cuvettes using particular dedicated washing solutions and respecting an internal optimized scheduling. During the routine a



cuvette begins its washing cycle when it reaches the first washing station position (DIS1/ASP1 couple of needles).

The Washing Station needles configuration includes:

- 5 couples of needles, the bigger for aspiration the smaller for dispensing;
- 1 aspirating needle, big size;
- 1 drying tip (white Teflon).

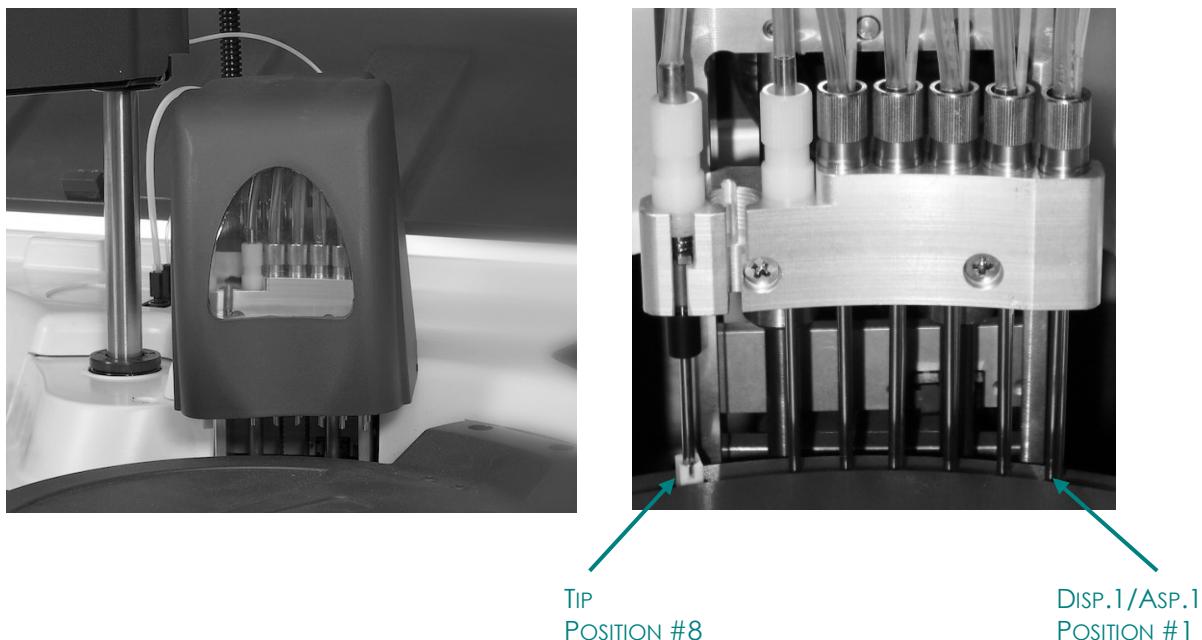


Figure 50: Washing Station

The washing station architecture is shown in the following picture:

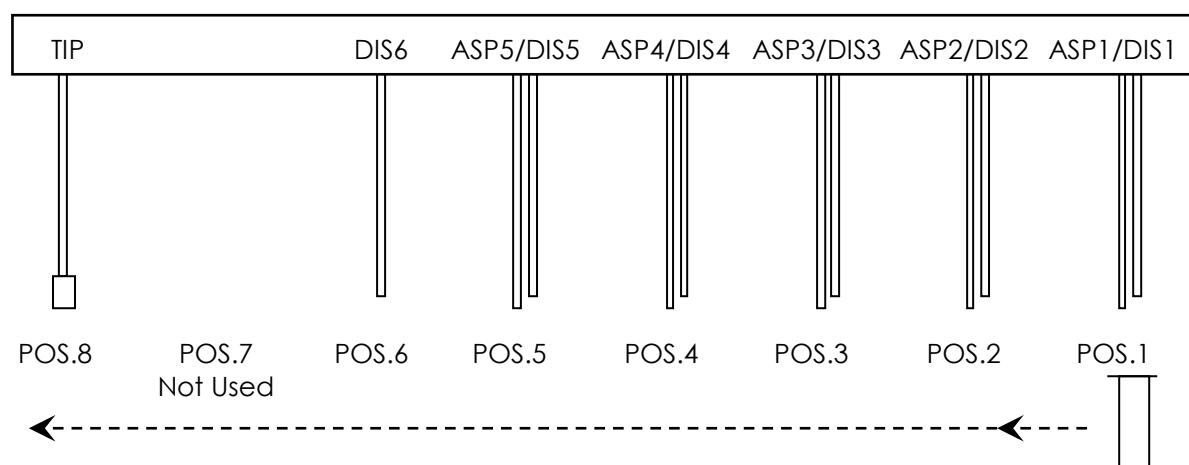


Figure 51: Washing Station Scheme



The washing station pumps configuration includes:

- 5 peristaltic pumps, for dispensing the washing solution (all peristaltic pumps are placed behind the front panel of the instrument);
- 1 peristaltic pump for aspiration of the reaction in position #1 (placed behind the front panel of the instrument);
- 2 diaphragm pumps, one single-head for the drying tip and one double-head for the aspiration needles (these pumps are placed behind the back panel of the instrument).

Each of the 5 dispensing peristaltic pumps is directly connected to only one **dispensing needle** (from position 1 to position 5 - short ones) of the washing station. One additional peristaltic pump is on the **aspiration needle** in position 1; it aspirates reaction fluids limiting the foam generation (and then the impedance) along the waste path to enhance the flow.

The double-heads (single motor) diaphragm pump is connected in parallel to 5 of the 6 **aspirating needles** (long and smaller ones): one head aspirates in parallel from needle 2 and 3, the other aspirates from needles 4, 5 and 6. The single-head diaphragm pump is dedicated to the **drying tip** only.

During the washing cycle all cuvettes progressively run under each of the needles from position 1 up to position 8, moving one position on at any machine cycle. During the washing cycle, composed from a descent phase, a waiting phase and a rising phase, the needles, placed in the different positions, behave as follow:

- Positions 1 (couple of needles): the cuvette is fully discharged of the reaction fluid and then filled with Systemic Solution; solution level left is about 450ul;
- Positions 2 (couple of needles): the cuvette is fully discharged and then filled with Cleaner Solution; solution level left is about 400ul;
- Positions 3÷4 (couple of needles): the cuvette is fully discharged and then filled with Systemic Solution; solution level left is about 450ul;
- Position 5 (couple of needles): the cuvette is fully discharged and then filled with Systemic Solution; solution level left is about 450ul. It is optically measured and checked (transparent or zero-value updating);
- Position 6 (single needle): the cuvette is fully discharged;
- Position 7 (no needle): no actions;
- Position 8 (tip): the cuvette is dried from residual liquid.

Dedicated Start Up cycle is automatically run by the system during the power-up of the instrument, or on operator request, to assure the cleaning and control of



each cuvette and the current updating of the auto-zero values. It includes washing and reading of all cuvettes.

Cuvette that is showing absorbance out of the admissible range is automatically “marked” by the system and skipped in subsequent sampling cycles. When that “marked” cuvette reaches once more the washing station, it is washed and read again; this up it is reaching an acceptable absorbance. In case that after three times the cuvette is still dirty, the instrument alerts the user to replace it by colouring it in **red**.

The instrument doesn't guarantee the declared performances, in terms of throughput, when more “marked” cuvette have been detected, and in any case dirty cuvettes must be substituted when their number exceeds 20 units or when there are more “marked” cuvettes following each other.

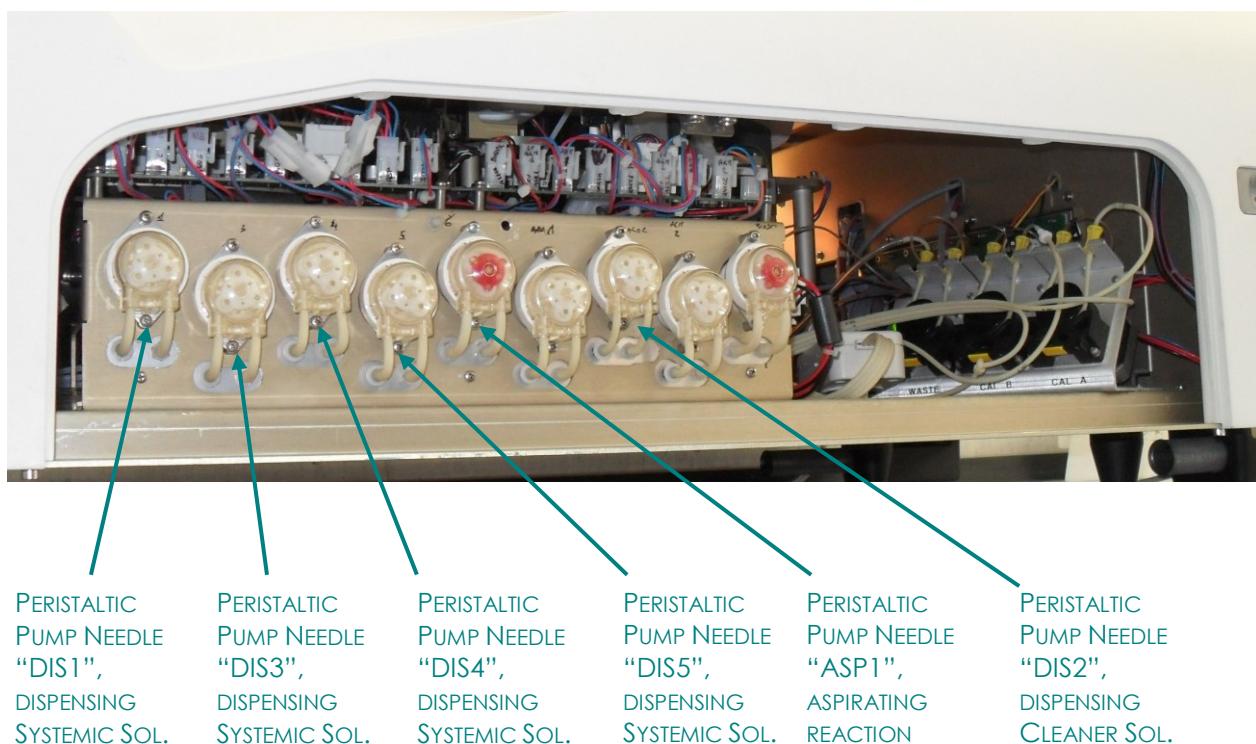


Figure 52: Washing Station Peristaltic Pumps

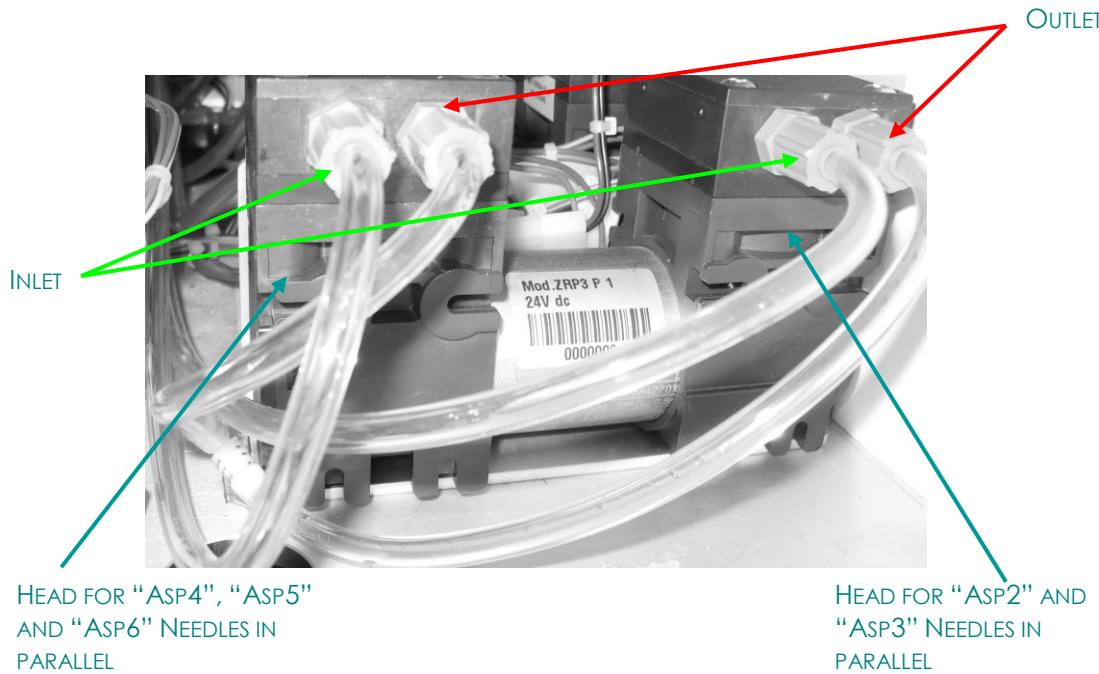


Figure 53: Washing Station, 2-Heads Diaphragm Pump for Aspiration Needles

5.3.5. Barcode Reader (option)

The system can be equipped on request with a barcode reader integrated into the instrument. Its purpose is to identify reagents and samples (see paragraph 4.1.2). It is fully integrated with the L.I.S. connection interface.

5.3.6. Electronics

The instrument includes a rack for the Controller boards. Each of the boards manages its own functional assembly and all of the related functions, controls, sensors and peripherals. The micro-controller boards are intra-connected by two buses, one for data and the other for synchronization respecting a master/slave architecture.



The flash memory device structure allows the upgrading of the firmware to be done by only downloading files by the external PC through the existing serial link. The power circuits for driving motors, pumps and all peripherals, have been designed to help the servicing (modularity) and to increase their lifetime.

The digital control circuit, the data acquisition and signal conditioning circuits have been shielded and placed far away by the power circuits. Thus electrical switching noise influence has been minimized.



The instrument provides several fans, automatically run by the system at the start-up (one is internal to the unit power supply); those allow the cooling of the active internal devices and the air exchange.

5.3.7. Power Supply Unit

The instrument includes an **universal main AC/DC power supply** to generate the continuous voltages necessary to the instrument operation. In this way the instrument accepts any alternate stable supply in the range from **100Vac up to 240Vac**, whose frequency ranges from **47Hz to 63Hz** without voltage selections required (on the other hand, the PC has a Vac selector).

The main switch block is placed on the back of the unit and it includes:

- The main breaker.
- Two line protection fuses.
- The EMI line filter.
- The supply cable inlet.



Figure 54: Main Switch Block

External main fuses on the main switch block:

- Fuse F1 and F2: size 5mmX20mm, rating 10A/250Vac, T-type (delayed).

WARNING

When replacing or controlling main fuses the instrument must be powered off and the power cable must be disconnected from the instrument.



Each of the internal low voltage DC supply lines is protected by a fuse placed inside of the instrument, on a support behind the right side panel.



SIDE PANEL
ACCESS TO
ELECTRONICS
AND
INTERNAL
PROTECTION
FUSES

Figure 55: Side Panel

The fuse panel includes the following 6 fuses:

- Fuse F3: size 6.3mmX32mm, rating 15A/250Vac, T-Type (delayed).
- Fuse F4, F5, F8: size 5mmX20mm, rating 6.3A/250Vac, T-Type (delayed).
- Fuse F6: size 5mmX20mm, rating 2A/250Vac, T-Type (delayed).
- Fuse F7: size 5mmX20mm, rating 1A/250Vac, T-Type (delayed).



Figure 56: Internal Fuse Panel

Internal filtered supplies have been provided for powering the photometer lamp and the control electronics.



The refrigeration unit is fed with a dedicated section of the main power supply, separate from the one for management and control electronics; it is protected by fuse F3.

Fuses F4 to F8 protect internal electronic with the exception of the refrigeration unit.

WARNING

When replacing or checking internal fuses, the instrument must be powered off and the power cable must be disconnected from the instrument. This operation must be carried on by qualified personnel only.



5.3.8. Software and User Interface

The user interface has been developed to run under MS Windows XP® operating system. The management software has been installed on an external Personal Computer (option) connected through a serial link with the instrument.

The multi-tasking structure allows the operator to surf through the different user menus during instrument operation.

A Status window shows the actual status of the machine during the working session and the PC monitor displays on request and in real time the progress status of any single sample.

In any menu currently displayed on the monitor, the operator will be alerted by the system in case any functional alarm rises up; the system activates the acoustic buzzer (beeper) and a window explaining the problem and the tentative resolution of it.

A proximity sensor controls if the upper instrument cover is closed; in case the operator opens it during the run, the sampling arms, the sample and the reagent wheels **stop at the end of the current sampling phase**, in order to avoid that the operator can get in touch with moving parts. The instrument doesn't reset with cover open.

Through a special selection it's possible to enable PC alert sounds.

WARNING

Before to open the cover, place the system in PAUSE from the Status menu and wait the software giving PAUSED status.

WARNING

The producer recommends not running on the PC any other software different from the User Interface; this could affect the operation and the communication between the PC and the instrument, and it could cause loss of data and of functionalities.

5.3.8.1. Management Software Structure

The software is organized in two main modules following a Client/Server architecture.

The BCServer, at lower level, is the PC front-end towards the instrument and it manages the scheduling of activities, commands and controls, the acquisitions and exchange of data.

The BCClient represents the User Interface, the User interacts with it. BCClient and BCServer exchange data, information and commands through a TCP/IP protocol.

All results are stored in the external PC memory and they can be sent to an external printer connected to the computer. The software allows the customization of the reports. Test, control and calibration results are registered in the PC too and



they can be recalled at any time or exported on request. It is possible to export results into special text files.

The software allows the connection with a Laboratory Information System (L.I.S.) for exchanging of data and work lists through a particular protocol.

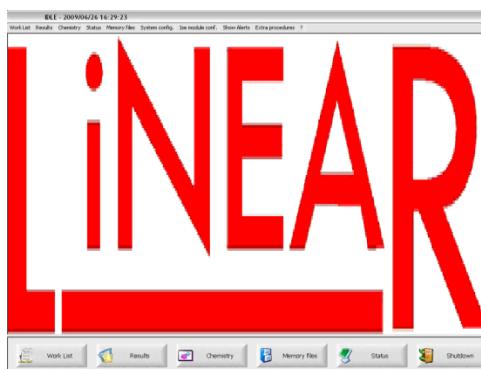


Figure 57: Kroma Plus, User Interface

The following paragraphs briefly describe the main menus and summarize the most important functions of the software that will be **discussed in detail later on through this document**.

5.3.8.2. Introduction to Main Menu

The Main Menu allows the user to enter one of the six main sections described in the following paragraphs.

The system, when started, requests the User ID and the password (there are three possible levels of login with different privileges and priorities) and automatically runs the start-up procedure; remember to close the instrument top cover before running the system to allow the initial reset.

From this menu it is also possible to exit the application by running the Shutdown procedure.

5.3.8.3. Introduction to Work List Menu

This menu allows the user to program the *Work List* for the next working session and to introduce the patient data for each sample.

Thus, it is possible:

- To choose the sample ID, the sample type, the patient type
- To change the default sample tube type.
- To select methods to be run for each patient or for patient groups (profiles).
- To fill patient data.
- To set eventual STAT conditions.
- To display and to modify the Work List.



- To archive previous results.
- To run sample bar-code scanning.
- To include standards and controls in the Work List.
- To control and summarize the Work List before running.
- To delete the Work List.
- To modify the reagent tray configuration.
- To print information.
- To run the working session in *Random* or *Batch* modes.
- To add on line more samples to a run.
- To add STAT samples to a run with immediate processing.

5.3.8.4. Introduction to Status Menu

This menu displays on line the status of the instrument during operation.

During the execution of the working session the PC visualizes:

- The instrument status (i.e.: warming up, idle, running, in alarm, etc.).
- The progress of the analysis for any single sample, standard/calibrator or quality control.
- The reagent tray configuration and the status of the bottles (volume/alarm).
- Any single cuvette status (in use, dirty, in washing, ...).
- A special window showing a sort of scheduling of the process.

Moreover, during the instrument *Idle* status it is possible:

- To run Start-Up cycles (includes tubing refilling, probe/cuvettes washing and cuvette auto-zeroing) through the *StartUp* command.
- To run sampling probe rinsing cycles (includes arm reset), through the *XXX ARM Rinsing* command.
- To run the optical group gain calibration cycles (includes cuvette washing and auto-zeroing procedures), through the *Gain Calibration Cycle* command.
- To run cuvette extra-washing procedure with a special solution on the reagent tray, through the *Extra wash* command.
- To move a single cuvette in the front aperture for replacing it.
- To move a sample position in the front of the instrument for loading/unloading purposes.
- To move a reagent position in the front of the instrument for loading/unloading purposes.

5.3.8.5. Introduction to Results Menu

This menu allows the operator to visualize the results of the analysis sorted by patient or by method and to print them out. It is also possible to delete or to archive concluded results and to export them into special text files.



Results for standard/calibrators and QC are in separates windows within the same section.

In a separate sub-menu it is possible to display results of standard (calibration) and controls (QC). Another sub-menu is for the managing of sample re-runs (repetitions on request).

5.3.8.6. Introduction to Chemistry Menu

This menu allows:

- To visualize the stored method parameters and to modify them (when required and allowed).
- To create/delete methods (when required and allowed).
- To create analysis profiles.
- To set restriction and method incompatibilities criteria.
- To set automatic sample re-run criteria with/without auto-dilution.
- To run reagent bar-code scanning (option).
- To configure the reagent tray with the desired parameters on board.
- To insert lot data and expiration date for each reagent.
- To manage quality controls data and to show the Levy-Jennings graphs.
- To manage and set standards, calibrator and calibration curves and to check their values (when required) and factors.
- To print reagent volumes on board.
- To request a reagent position to move to the front of the instrument for loading/unloading purposes.

5.3.8.7. Introduction to Memory Files Menu

In this menu it is possible to search, to visualize and to print the test results previously executed and stored; the sort can be carried out by any combination of many different keys (like name, date, parameter, ...). It is also possible to export the result of the research into special text files. That's valid for patients as for standards and quality controls.

5.3.8.8. Introduction to System Config Menu

This menu allows general system and user parameters setting.

The System Parameters menu includes common instrument settings related to the main functionalities.

Moreover, the menu provides a field to input the laboratory identification data to be printed on each result report.



The User menu visualizes the information related to the user that logged in as actual operator; it allows to set, to change and to save the passwords to run the instrument at the different priority levels.

The service section, on the other hand, isn't accessible to the operator and the access is allowed only to qualified and authorized personnel through special passwords.

5.3.8.9. ISE Module Config Menu

This menu manages the ISE Module (electrolytes) if provided as option. It gives evidence of the electrode calibrations results. It is possible to set electrodes data and to verify reagent pack calibrant volumes.

Semi-servicing commands have been included in order to facilitate module managing.

5.3.9. ISE Module (option)

The instrument can be equipped on request with the option **ISE Module**, used as a component for determining electrolyte concentrations of lithium, sodium, potassium, and chloride on serum, plasma and urine.

When not used, some of the electrodes can be avoided by replacing it with a proper "spacer".

5.3.10. L.I.S. Interface

The system can be equipped on request with the option **L.I.S. Interface**. It is a link used for patient data to be exchanged with a host computer through a network; it is possible in this way to manage patient work lists and results from a remote station.



Section 6 PERFORMANCES AND LIMIT OF USE

6. Generalities

The guideline procedures to be followed for testing the performance of the auto-analyzers (in any of its versions or configurations) have been given in the following sub-paragraphs.

6.1. General principles

The following concepts are valid:

- **Precision:** it is defined like the consistency between more measurements of the same quantity; it returns the instrument capability to reproduce the same value when performing more measurements of the same standard (it gives the test reproducibility).
- **Accuracy:** it is defined like the difference between the standard value, measured by instrument, and its real value (it gives the test accuracy).
- **Linearity:** let's assume that the values measured by an ideal instrument lies on a straight line; linearity is the gap between the measures performed by the real instrument and the ideal straight line.
- **Carry-over:** it is the quantity of liquids (serums, reagents, washing solutions, etc.) that, after the end of a sampling operation, it is transferred in the next cuvette.
- **Throughput:** it is the number of test, of the same type, that the instrument processes in a fixed time. It is normally given in number of test per hour (test/h) and measured from the **first** to the **last result** received (normalization to 60min).

6.2. Formulas

The following calculations have been integrated in the software for computing the statistical values to check.

Calculation of the Mean:

$$OD_m = \frac{\sum_{i=1}^n OD_i}{n}$$

where:

- OD_m = mean



- OD_i = measured value
- n = nr. of tests.

Standard Deviation Calculation:

$$DS = \sqrt{\frac{\sum_{i=1}^n (OD_m - OD_i)^2}{n-1}}$$

where:

- OD_m = mean
- OD_i = measured value
- n = nr. of tests.

Variation coefficient calculation:

$$CV = \frac{DS}{OD_m} \times 100$$

where:

- DS = standard deviation
- OD_m = mean

Accuracy calculation:

$$ACC = \frac{(OD_m - OD_r)}{OD_r} \times 100$$

where:

- OD_m = mean
- OD_r = reference value

6.3. Testing the Performance

The following paragraphs give the procedure for testing instrument performance.



6.3.1. Test of the Photometer: Accuracy and Imprecision

This test is intended for testing the photometer performance at different wavelengths. It validates the complete optical group (lamp, filter wheel, photodiode) and also the reading circuit on the R&W Controller board.

When testing the performance of an instrument, run this test before the following ones so to check the photometer as first and then to address it possible causes of malfunctioning.

Preparation

To run this test it is necessary to get the following materials (food colourings and distilled water – herein after named as H₂O) to prepare different solutions for checking each one of the wavelengths (actually 340nm, 405nm, 492nm, 505nm, 546nm, 578nm, 630nm, 700nm as standard configuration, change solutions accordingly to the new wavelength). They will be used as reagents.

Each solution can be generated by mixing special food colouring with distilled water and it's stable for about 48 hours; just remember to gently shake the solution before using. Use good distilled water as sample.

Solution	Components	Concentration
E102 for 340nm	• E102 – Giallo Limone N.32 by Chimival srl	0.90 g/l into H ₂ O
E102 for 405nm	• E102 – Giallo Limone N.32 by Chimival srl	0.08 g/l into H ₂ O
E102 for 492nm	• E102 – Giallo Limone N.32 by Chimival srl	0.90 g/l into H ₂ O
E124 for 505nm	• E124 – Rosso Vivo Brillante N.54 by Chimival srl	0.05 g/l into H ₂ O
E124 for 546nm	• E124 – Rosso Vivo Brillante N.54 by Chimival srl	0.05 g/l into H ₂ O
E131 for 578nm	• E131 – Azzurro Brillante N.13 by Chimival srl	0.25 g/l into H ₂ O
E131 for 630nm	• E131 – Azzurro Brillante N.13 by Chimival srl	0.10 g/l into H ₂ O
(E131+E102) for 700nm	• E131 E102 – Verde Brillante N.56 by Chimival srl	5.00 g/l into H ₂ O

When ready, pour each solution into a new and clean reagent bottle and, after some minutes of stabilization, place it on the **reagent tray**.

Programming

In the Chemistry Menu, create eights applications, one for each solution (or wavelength), using the following general parameters:

Reagent:	Specific food colouring
Sample:	H ₂ O
Test type:	Endpoint
Calibration model (Standard Menu):	Nr. of standard=0, Factor=1000
Wavelength:	xxx nm
Blank included in calculation:	No
Reagent volume:	200µl
Sample volume:	1µl
Reagent + sample incubation:	300 sec (to equilibrate to 37°C)
Unit:	Abs



Decimals: 1 [0.0]
Instrument Factor: a=1, b=0

Specialize each application with the following filters 340nm, 405nm, 492nm, 505nm, 546nm, 578nm, 630nm, 700nm, and parameters below:

Method Name	Method Code	Filter	Expected Values [10samples]	
			Mean [mAbs]	CV [%]
EP340	340	340nm	1300 ± 100	≤ 1.0
EP405	405	405nm	800 ± 100	≤ 1.3
EP492	492	492nm	750 ± 100	≤ 1.3
EP505	505	505nm	850 ± 100	≤ 1.3
EP546	546	546nm	500 ± 100	≤ 2.3
EP578	578	578nm	450 ± 100	≤ 2.3
EP630	630	630nm	600 ± 100	≤ 2.3
EP700	700	700nm	450 ± 100	≤ 2.3

Execution and performance

1. Run a Start-Up cycle from the *Status* menu.
2. In the *System Config Menu* lock the instrument on sample #1 and Save.
3. Program a Work-List of 10 samples running all of the eight methods (EPxxx) above, for an amount of 80 tests.
4. Start the run in *Batch* mode.
5. At run concluded, check that for each method the **Mean** and the **CV%** for all 10 tests are within the limits given in the table above (Expected Values columns).

Main troubleshooting

Accuracy

1. In case the results of one test present a different Absorbance for the Mean (i.e.: due to different food colouring producer or product), **crosscheck** the Mean value by testing the absorbance of the same solution on a different standalone photometer with equivalent light path to compare the values.
Note - Values read by different photometers may be slightly different due to the filters characteristics of each: to assess if the mean value read on the instrument is correct, the readings must be compared at different wavelength.

Precision

1. In case of a flyer repeat only that test.
2. In case the results of one test present a CV% out of range, run an extra-wash cycle and then repeat the test. If the problem persist check the following:



- a. Replace solution
 - b. Filter
 - c. Replace cuvettes
3. In case that the results for most (all) tests present the CV% out of range, run an extra-wash cycle and then repeat the test. If the problem persist check the following:
 - a. Cuvette #1 in the centre of the Optical Reading Path
 - b. Filter Wheel → mechanical filters calibration (steps)
 - c. Photodiode and its wiring
 - d. Replace R&W Controller board
 - e. Filter Wheel belt tension and its home sensor
 - f. Replace cuvettes
 - g. Order of filters (there positioning on the wheel)



6.3.2. Test of Pipetting: Accuracy & Imprecision

This test is intended for testing the pipetting performance. It validates the complete pipetting system (ARM1 and eventually ARM2 for double ARMs systems - dosing, mixing) including the Controller board.

When testing the performance of an instrument, run this test after the previous one, that assured good performance of the photometer.

Preparation

Pipetting accuracy and imprecision is tested through a standard sample dye solution ($K_2Cr_2O_7$ - Potassium Dichromat) at the fixed concentration of 100Abs to be used as sample.

To prepare that dye solution, it is necessary to get the following materials to prepare a valid sample to be checked at 340nm: pure potassium dichromat and sulphuric acid.

The solution can be generated by mixing the two ingredients above; it will remain stable for about 30 days when saved at controlled temperature [from +2°C to +18°C] and protected from the light. Just remember to gently shake the solution before using. Use good distilled water as reagent.

Solution	Components	Concentration
Potassium Dichromat Sample Dye	<ul style="list-style-type: none">• $K_2Cr_2O_7$ (purity 99%)• H_2SO_4 (Sulphuric Acid)	10 g/l $K_2Cr_2O_7$ into 0,0144mol/l H_2SO_4

Pour each solution into a new and clean sample tube and, after some minutes of stabilization, place it on the **sample tray** – position #1.

Programming

In the *Chemistry Menu*, create one application using the following general parameters:

Reagent:	H_2O
Sample:	Sample Dye
Test type:	Endpoint
Calibration model (Standard Menu):	Nr. of standard=0, Factor=1000
Wavelength:	340 nm
Blank included in calculation:	Yes
Reagent volume:	198 μ l
Sample volume:	2 μ l
Reagent + sample incubation:	300 sec (to equilibrate to 37°C)
Unit:	Abs
Decimals:	1 [0.0]



Instrument Factor: $a=1, b=0$

The parameters below are valid:

Method Name	Method Code	Filter	Expected Values [25samples]	
			Mean [mAbs]	CV [%]
340DYE	DYE	340nm	1000 ± 100	≤ 2.5

Execution and performance

1. Run a Start-Up cycle from the *Status* menu.
2. In the *System Config Menu* lock the instrument on sample #1 and Save.
3. Program a Work-List of 25 samples running all of the eight methods (340DYE).
4. Start the run in *Random* mode.
5. At run concluded, check that for each method the **Mean** and the **CV%** are within the limits given in the table above (Expected Values columns).

Main troubleshooting

Accuracy

1. In case the results present a different Absorbance for the Mean, **crosscheck** the Mean value by testing the absorbance of the same reaction solution (this time obtained by manually mixing 198µl of H₂O with 2µl of potassium dichromat) on a different standalone photometer and compare the values. If the values are far more than 3%:
 - a. Check the dosing circuit/s

Precision

1. In case of a flyer repeat the test.
2. In case the results of one test present a CV% out of range, run an extra-wash cycle and then repeat the test. If the problem persist check the following:
 - a. Replace solution
 - b. Replace cuvettes
 - c. Check the dosing circuit
 - d. Cuvette #1 in the centre of the Optical Reading Path



6.3.3. Instrument Throughput

This test is used to verify that the number of tests, belonging on the same method and carried out by the instrument in a fixed amount of time, is compliant with the specifications.

The measurement is performed measuring the **time interval between the first result out and the last result out that have been received** (or by counting how many results can be obtained in an hour starting from the first available).

It is expressed in **test/hour**.

Generally it can be measured by running 300 mono-reagent same tests (i.e.: 30 samples by 5 repetition each by two same mono-reagent endpoint methods) and counting the time elapsing between the first result out and the last one received. Times can be found in the archive just after storing results.



Section 7 OPERATING PROCEDURES AND MENUS

7. Overview

This Section gives the operator the needed information to correctly use the instrument; it follows the organization below:

- general description of the User Interface software through the detailed explanation of all menus;
- setting-up and preliminary operations;
- operating procedures' description;
- additional functionalities.

All information, instructions, procedures and details given in this section are fully compatible with the different system configurations:

- **M1-59**, single-ARM, 59-sample positions
- **M1-79**, single-ARM, 79-sample positions
- **M2-59**, double-ARM, 59-sample positions
- **M2-79**, double -ARM, 79-sample positions

and valid for all of them even if they refer to only one of the models.

7.1. Software Description

The User Interface is a “user friendly” application running under MS Windows® XP operating system.

Accounts protected by password allow the operator to login at one of three possible levels of operation; only the authorized personnel at highest priority can change it or create new accounts.

The following paragraphs show all menus and sub-menus of the software and include the detailed description for each field and command.

The menu's functional drawing is shown in the following page.

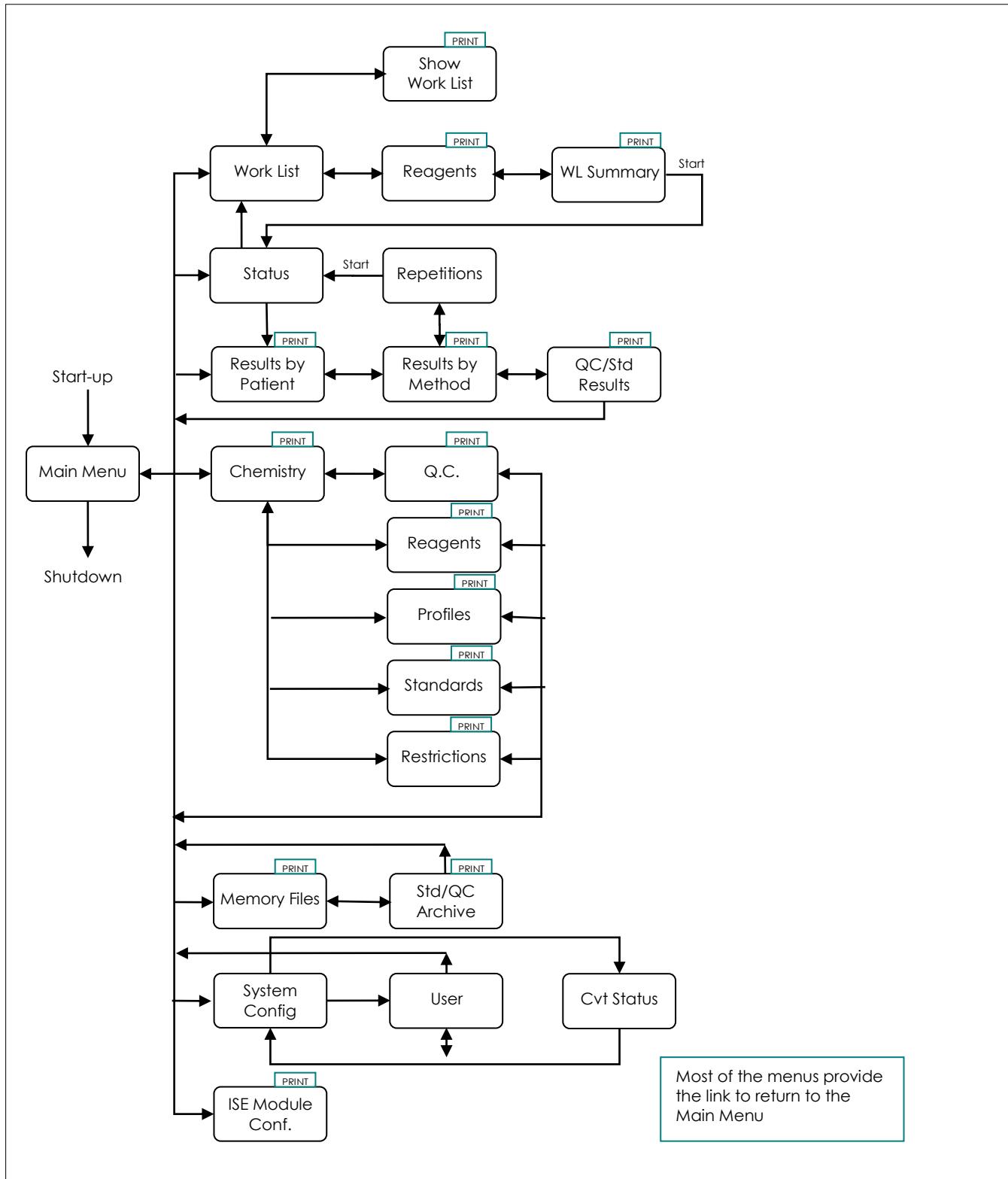


Figure 58: Software, SW Functional Drawing



7.1.1. Main Menu

The lower tool-bar includes the following sub-menus and commands:

- *Work List*, it allows Work Lists compilation and modification by programming and running working session of samples, standards/calibrators and quality controls.
- *Results*, it allows to display, to export, to archive and to print analysis results.
- *Chemistry*, it allows to create, to verify and to modify the method parameters, the standard/calibrators/factors, the quality control values and the configuration of on-board reagents.
- *Memory files*, this is the archive of the patient analysis results.
- *Status*, it shows the actual status of the instrument during a working session or when in stand-by; in the latter case it allows some semi-service auxiliary functions.
- *Shutdown*, this command runs the shut down procedure.

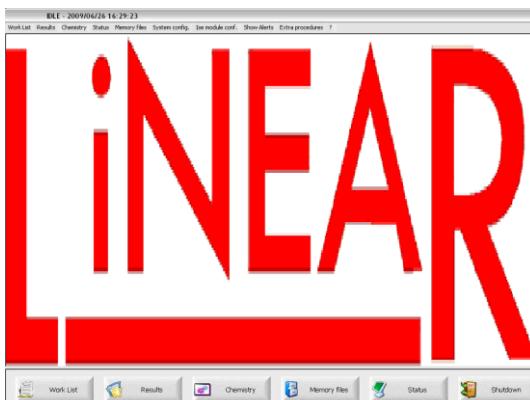


Figure 59: Kroma Plus, Main Menu

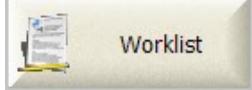
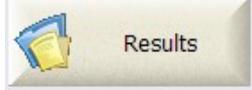
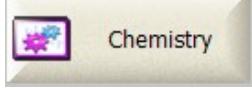
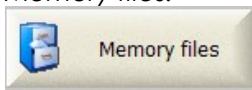
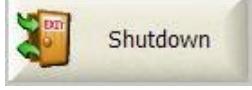
The upper menu-bar gives the operator the same possibilities of the lower bar and includes the additional function/menu:

- *System Config*, it allows the access to the user and system parameters setting pages.
- *ISE Module Conf.*, it allows management of the Ion Selective Electrode Module (Electrolyte measurement system as option).
- *Show alerts*, it displays alarms and warnings in the actual status.
- *Extra procedures*, it gives data administration extra utilities.



- About [?], it shows the actual release versions of any single software packet.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Work List:  Worklist	This command enters the <i>Work List</i> menu. It allows the operator to program working sessions of patients (samples) with associated analysis, standards, calibrators and controls. When connected to a L.I.S. (Laboratory Information System) it allows patients upload.
Results:  Results	This command enters the <i>Results</i> menu. It allows the visualization, the printing and the exporting of the analysis results (including standards and controls). It is possible to order the results by patient or by method.
Chemistry:  Chemistry	This command enters the <i>Chemistry</i> menu. It allows the managing of the method parameters and the setting of the standard and control values. Moreover, it is possible to generate analysis profiles, to set normal ranges for each method, to configure the reagent tray, to display the calibration curves and the Q.C. Levy-Jennings graphs, to set reagent restrictions and re-run criteria.
Memory files:  Memory files	This command enters the <i>Memory Files</i> menu. It gives access to the archive of patients and analysis results (standards and controls included). More research keys have been included.
Status:  Status	This command enters the <i>Status</i> menu displaying the actual running status. When the instrument is in stand-by (<i>Idle</i> status) this menu allows also the following main functions: <ul style="list-style-type: none">• reset of alarms;• sampling probes rinsing and arm reset;• cuvette extra-wash cycles;• optical gain calibration cycles (includes wavelength gain equalization, and cuvette auto-zeroing and washing);• start-up procedure, including: tubing refilling, cuvette washing and auto-zeroing;• replacing of cuvette;• visualization of reagent tray configuration and of cuvette status;• system hibernation and wake-up. During the instrument running of a working session, this menu allows the real time control of the analysis progress; the monitor displays: <ul style="list-style-type: none">• the real time analysis progress for each sample in work list;• the real time status for each reagent used in work list;• the real time status for each cuvette;• the status of each process step, in a special status window;• the operating status of the instrument.
Shutdown:  Shutdown	This command quits the system by running the shutdown procedure. This procedure gives the operator the chance to run a final extra-washing of all cuvettes before exit (the manufacturer - and the system - suggest to run daily this washing procedure). It also allows the change of user account by asking for a different login without quitting the system.



7.1.2. Work List Menu

The operator enters this menu by selecting the command *Work List* from the *Main Menu* or from the *Status* menu.

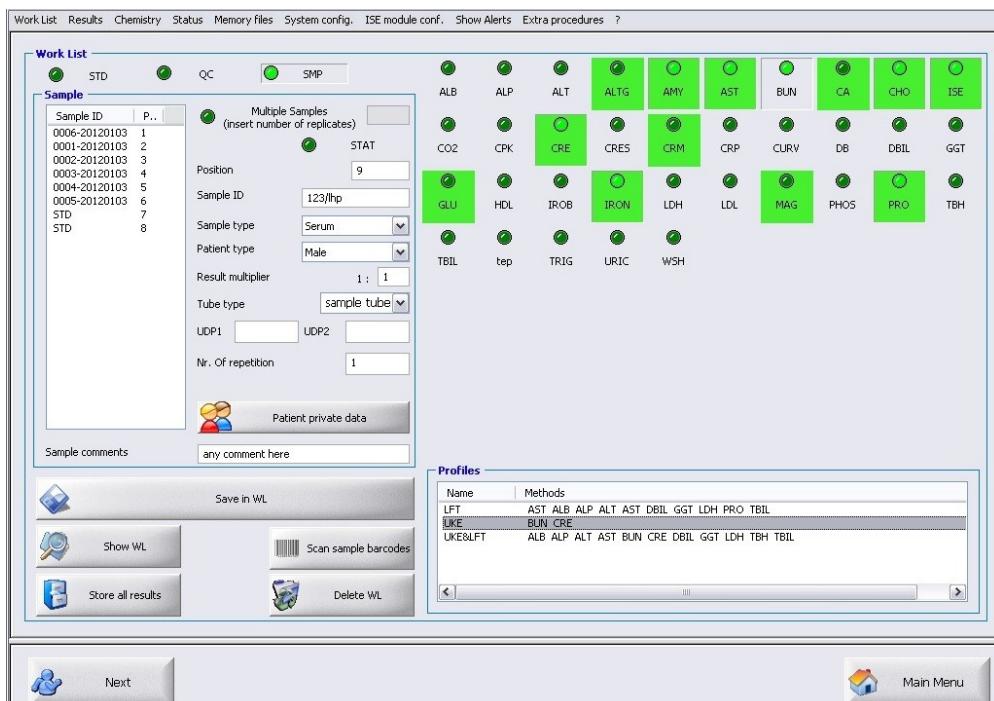


Figure 60: Work List Menu

This menu shows, constantly on the left, the actual Work List under programming, while methods are listed into the panel on the right. That panel can contain a maximum of **60 available methods** (visible). Methods can be already on board in assigned positions, in that case they are green back-lighted. If not green back-lighted they are non assigned. Any of them can be anyway chosen and programmed in the Work List; it will be run when a position will be assigned.

Programmed samples are added in the sample window on the left. By clicking on any single sample it is possible to visualize and modify the associated methods to be run and its position on the sample tray. Samples that have not been assigned are marked with position number “0” as well as the excess of patients in case the tray is full. Methods in run cannot be deleted.

Also, patients uploaded by L.I.S. are included in this list: the position on the sample tray can be assigned automatically, manually or by barcode scanning. In case of manual assigning, the operator must select the sample on the sample window and then he has to assign the position number coincident with real position on the sample tray.



The “sample window” lists all samples, standards/calibrators and controls to be processed; it also includes those concluded but not yet archived.

Patients whose results must be stored in the archive stay in that list and they will be removed only upon storing in archive; in this way the instrument manually clears sample tray positions that become immediately available for new samples.

The reagent panel lists all the methods that have been created and that have been set as “visible”. It gives evidence of the presence of any method in the reagent tray configuration: when a method is highlighted in light-green it means that method is on board, if not highlighted it must be positioned. Also: calculated methods (by formulas), if any, will be shown on the reagent panel as derived from basic ones.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
STD:	this flag must be activated when a standard/calibrator must be programmed in the Work List; in this case the system shows in the right panel the list of the methods that can be calibrated because a standard has been set.
QC:	this flag must be activated when a quality control must be programmed in the Work List; in this case the system shows in the right panel the list of the methods whose QC values have been set.
SMP:	this flag must be activated when a sample must be programmed in the Work List; in this case the system shows in the right panel the list of the methods set as visible.
Sample window:	this window shows all samples (patients, standards/calibrators and QCs) that have been programmed in the Work List or that have been loaded by L.I.S. or by barcode. Any sample is identified and listed by its IdCode number. The column aside, named Position, shows the position of the sample in the sample tray. If the sample has not been assigned, this number is “0” (zero).
Multiple Samples (insert number of samples):	when selected it gives the operator the possibility to program in a fast mode the Work List. This feature is useful in case of more samples running the same set of analysis. In that case, the field aside must be filled with the number of samples being programmed and included in the actual WL with the same set of analysis chosen in the panel on the right. This field must be edited by the operator and the value must be included, depending on the configuration, in the range from 1 to 59 or from 1 to 79.
STAT:	this flag must be activated when a sample is considered “urgent” (STAT); in this case the system gives the analysis associated to the STAT sample the highest priority over all of the other not STAT patients.
Position:	It identifies the position on the sample tray that has been assigned to the sample actually under programmed. In case of WL faster programming it is the first position that will be used to place samples. This field must be edited by the operator and the value must be included,

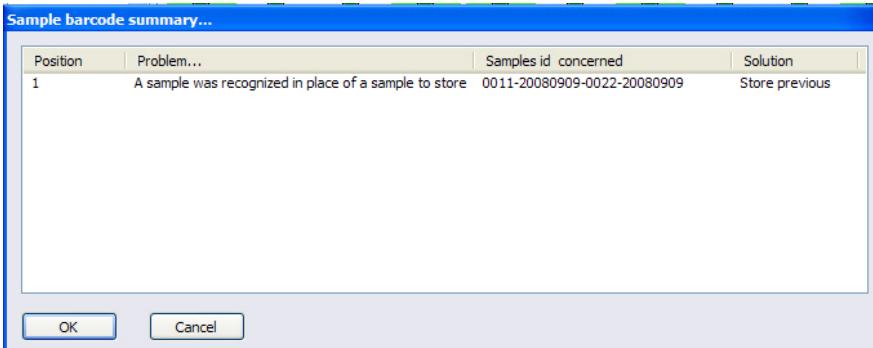


Field/Command	Function
	depending on the configuration, in the range from 1 to 59 or from 1 to 79. The software automatically shows the first free available position of the sample tray. Samples not assigned to a position on the tray have number "0".
Sample ID:	the operator can enter the sample identification code; this code can be composed by a maximum of 20 alphanumeric characters. If the operator doesn't fill this field, the system automatically assigns a code to samples whose format is the following: <ul style="list-style-type: none">• xxxx, it is the progressive number within the day;• -, dash• yyyy, it is the current year;• mm, it is the current month;• dd, it is the current day. In case the operator runs a sample barcode scanning (optional feature), this field will be automatically filled by the software with the id codes read on the tube.
	In case the operator uploads from L.I.S. , this field is automatically filled by the software with the IdCodes given by the host system and correspondent to the sample bar-code .
	The system checks for duplication of Sample ID codes in the same solar day and allows it only on operator request.
Sample type:	this pull down menu allows the selection of the type of sample; the following standard choices are: <ul style="list-style-type: none">• Serum;• Urine;• CSF;• Plasma other sample types can be created an "Extra procedures" menu.
Patient type:	this pull down menu allows the selection of the patient type; the following standard choices are: <ul style="list-style-type: none">• Male;• Female;• Paediatric other patient types can be created an "Extra procedures" menu.
Result multiplier:	This field allows the user to have a manual result multiplier in case of sample manual dilution made off-line. Each of the results obtained for the sample are automatically multiplied by the factor shown in this field ("1:1" doesn't imply any multiplication). This field is useful to show correct results for samples that have been diluted off-line.
Tube type:	this pull down menu allows the selection of the sample tube type; the following choices are allowed: <ul style="list-style-type: none">• Sample tube;• Sample Cup, when using 3ml sample cup. The system automatically gives as default what the selection set in the System Config. Menu: "Default sample tube type" field (one selection for each of Standard, QC or Sample); the operator can anyway chose a different tube type from default. In this way it is possible to use mixed type of tubes in the sample tray and within the same run.
UDP1:	UDP1 stands for User Defined Parameter #1, this field allows the user to



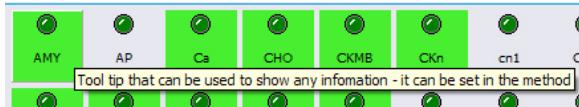
Field/Command	Function
	introduce, for each patient, a special value [value 1] to be computed in the formula of a "formula type" method whenever that field has been mentioned in that formula itself.
UDP2:	UDP2 stands for User Defined Parameter #2, this field allows the user to introduce, for each patient, a special value [value 2] to be computed in the formula of a "formula type" method whenever that field has been mentioned in that formula itself.
Nr. of repetitions:	By entering a number "n" between 1 and 10 in this field, it is possible to set a number of repetitions of the same sample – that means, all analysis for that sample will be replicated "n" times.
Patient Private Data:	this command opens a window whose fields can be filled with the personal and administrative patient data.
Sample comments:	this field allows the operator to enter a comment for each of the sample to run; those comments will be visible in the patient and in the lab reports and also on the result page (Result by Sample). The maximum length is 50 characters. The value is memorized in the archive too and it can be modified also from the archive page.
Save in WL:	this command allows the operator to add in the Work List the sample with the analysis that have been selected. When activating this command, the software controls if the Sample ID codes has been already introduced and used in the actual solar day: if yes, the program asks the operator if he wants to introduce and process a duplicate; if not, the system just adds the sample and the selected analysis.
Show WL:	this command opens a window showing the actual compiled Work List; in that window it is possible to edit or to delete samples, to move samples, to optimize the reagent tray for this particular WL, or to go back to the previous menu.
Scan sample barcodes:	with this command the systems runs the scanning of the sample barcodes labelling the tubes in the tray. The Sample tray turns to allow the reader to scan barcodes labelling the tubes and adds the samples in the Work List. Recognized samples will be associated to their physical position on the sample tray. In case of Work List downloaded from L.I.S. or anyway in case of a pre-existing Work List, the system associates any sample position tray position with its correct set of analysis, if the barcode has been recognized. When some problems is detected by the system, the software alerts the user by suggesting a possible solution through a special "message window"; the user can accept or not the suggestion given. The message window has been shown below; possible problems are the following: <ul style="list-style-type: none">- Case of a sample that have been processed but not yet validated and archived: in its position the reader has detected a new sample; the system stores the old sample results and it accepts the new sample to be processed in its position.- Case of a sample that have been processed but not yet validated and archived: its position has been detected as free (or anyway the barcode is not readable); the system stores the old sample results and it sets the position as free.- Case of a sample that have been partially processed and the system



Field/Command	Function
	<p>doesn't find it on the tray anymore; the system alerts the operator that the sample cannot be found, it leaves the sample in the WL without the position number and the operator has to take a decision (replacing the sample on the tray or deleting pending analyses).</p> <ul style="list-style-type: none">- Case of sample whose barcode is not readable: the system considers the position as free.- Case of barcode error: the system only alerts the operator.
	
	<p>By clicking on the button “OK” the operator accepts the suggestion (result storing) and the window closes.</p> <p>By clicking on the button “Cancel” the operator aborts the suggested operation (result storing) and the window closes. The situation has left like before the scanning.</p> <p>In case of unreadable barcodes the operator can anyway manually modify the WL data.</p>
Store all results:	This command runs the automatic storing in archive of all the results obtained for samples, standards/calibrators and QC's of the previous run. Consequently, those positions on the sample tray will be cleared and they become available for new WL programming (important to free position for “continuous sample loading” so to load new patients without to wait for the end of the run).
Delete WL:	This command deletes any current Work List currently under programming. Samples in process or concluded will not be deleted.
Profile window:	This window shows all analysis profiles previously created and stored by the user; in this window it is possible to select one or more profiles for each sample to be introduced in the Work List. By selecting one profile the system automatically adds and associates all the included methods with the sample itself.
Reagent panel:	The reagent panel includes all methods that have been memorized and set as “visible”. It can contain a maximum of 60 methods and it is customizable by the user whom can include or not any of the methods stored. It is possible to run a standard or a control by selecting the icons. Methods already present in the reagent tray have been highlighted with light green background. It is possible to include each of the standards or controls in the Work List by mouse selection.
	Derived methods by formula can be also included. By crossing on any method icon, a tool tip appears in case special notes have been set in

**Field/Command****Function**

the methods menu (in MS Windows® mode); it that can be used for user information.



After standard and control selection the operator **must** activate the command Save in Work List to add selections in the programmed Work List.

In case of “SMP” programming:

all methods set as “visible” will be displayed. The selection of one parameter is “cyclic” and sequential and, for each click with the left mouse button on the same icon, its status changes as follow:

- 1) Light green → that method has been selected and associated to the sample for the WL execution;
- 2) Dark green → that method has not been selected for the WL execution.

In case of “QC” programming:

Quality Controls are shown when they have been previously enabled in the method (see the Chemistry menu). For **QCs** this means that only methods with given value of controls and programmed in-method control position can be run; if not so, the control icon [QC(x)] is not present.

- Selection of Controls:

For each method the selection is cyclic and sequential and, for each click with the left mouse button on the QC icon, its status changes as follow:

- 1) Dark green → control not selected for WL execution;
- 2) Light green → control selected for WL.

Any icon show a number between brackets that gives evidence of the number of controls, associated with that method, that will be performed. Note that Controls having the same **lot number** will refer to the same position on the sample tray.

In case of “STD” programming:



Field/Command	Function

all methods whose standard values have been set by the operator will be displayed. The selection of one parameter is “cyclic” and sequential and, for each click with the left mouse button on the same icon, its status changes as follow:

- 1) Light green → the standard associated to that method has been selected for WL execution; ; in case of multi-standard method ($n>1$, calibration curve) the system doesn't provide automatic dilution and the operator needs to use previously diluted standards;
- 2) Blue → the standard associated to that method has been selected, it is a multi-standard that includes a calibration curve and implies the **automatic pre-dilution of the standard** (according to the fixed dilution ratios); the blue selection is active only in case of multi-standard method, $n>1$;
- 3) Dark green → method not selected.

The icons show a number between brackets that gives evidence of the number of standard associated with that method (number of the points of the calibration curve). The number can range between 1 and 8, depending on what it has been set in the Standard Menu. The condition $n>1$ (multi-standard), means that the system must generate a “calibration curve” and for it is possible to run the automatic dilution; in case the operator doesn't decide for the automatic dilution he has to place on the tray pre-diluted standards.

Note that Standards having the same **lot number** will refer to the same position on the sample tray only when they have similar **dilution ratio** (case of ready-to-use standard not to be automatically pre-diluted in cuvettes by the system).

Next:
this command allows the operator to enter the Reagents menu; that menu allows the operator to manage reagent bottles within the reagent tray positions.

Main Menu:
this command allows the operator to go back to the Main Menu.



7.1.2.1. Patient Private Data Window

The operator can enter this window selecting the *Patient Private Data* command from the *Work List* menu.

The screenshot shows the 'Patient private data' window with the following fields filled:

Field	Value
Sample ID	0001-20120103
Patient unique id	aaabbddfgert563gg
Last name	Mario
First name	Rossi
Date of birth	1980/03/27
Age	31
Address	Via dei Fiori, 987 - 0010 Rome - Italy
Email	m.rossi@provider.ff
Phone	+1234567890123
Bed	345
Dpt.	MXF
Clinic	KS78H
Request date	2011/12/12
Doctor	Bianchi
Notes	Cardiopathic

At the bottom are buttons for Close, Previous, Next, and Save.

Figure 61: Patient Private Data Window

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Sample ID:	this alphanumeric field shows the ID number given to the sample.
Patient unique id:	this alphanumeric field shows the ID number considered unique for that specific sample (patient). It can be a custom number or it can be coincident with the unique number given to anybody from the government or anyway it is a code considered as "unique" by the system for that patient. The system identifies a patient through this field.
Look up:	this command allows the system research into the data base of any eventual sample with that given Unique ID and overwrites patient data with what found or overwrites old data with the new ones by clicking on the Save button.
Last name:	this alphanumeric field allows the operator to introduce the name of the patient.
First name:	this alphanumeric field allows the operator to introduce the surname of the patient.



Field/Command	Function
Date of birth:	this alphanumeric field allows the operator to introduce the patient date of birth. Format of the field: yyyy/mm/dd, where <ul style="list-style-type: none">• yyyy → year, 4 digits• mm → month, 2 digits• dd → day, 2 digits.
Age:	this alphanumeric field allows the operator to introduce the patient age.
Address:	this alphanumeric field allows the operator to introduce the address of the patient.
Email:	this alphanumeric field allows the operator to introduce the patient e-mail address.
Phone:	this alphanumeric field allows the operator to introduce the patient telephone number.
Bed:	this alphanumeric field allows the operator to introduce the patient bed number (when in hospital structures).
Dpt:	this alphanumeric field allows the operator to introduce the department.
Clinic:	this alphanumeric field allows the operator to introduce the clinic ID.
Request date:	this alphanumeric field allows the operator to introduce the date of the analysis request. Format of the field: yyyy/mm/dd, where <ul style="list-style-type: none">• yyyy → year, 4 digits• mm → month, 2 digits• dd → day, 2 digits.
Doctor:	this alphanumeric field allows the operator to introduce the ID of the doctor.
Notes:	this alphanumeric field allows the operator to introduce eventual remarks.
Commands	
Save:	this command saves the patient data.
Close:	this command allows the operator to go back to the <i>Work List</i> menu without to save any modification.
Arrows:	Both of this commands allows the operator to surf easily among the patients of the <i>Work List</i> menu.

The compilation of the fields above is not strictly necessary to run the *Work List*; private data can be introduced at any moment during the run or, in the *Memory Files* archive menu, upon results storing at later time.



7.1.2.2. Work List Display Window

The operator can enter this window selecting the Show Work List command from Work List menu; it shows the actual programmed Work List.

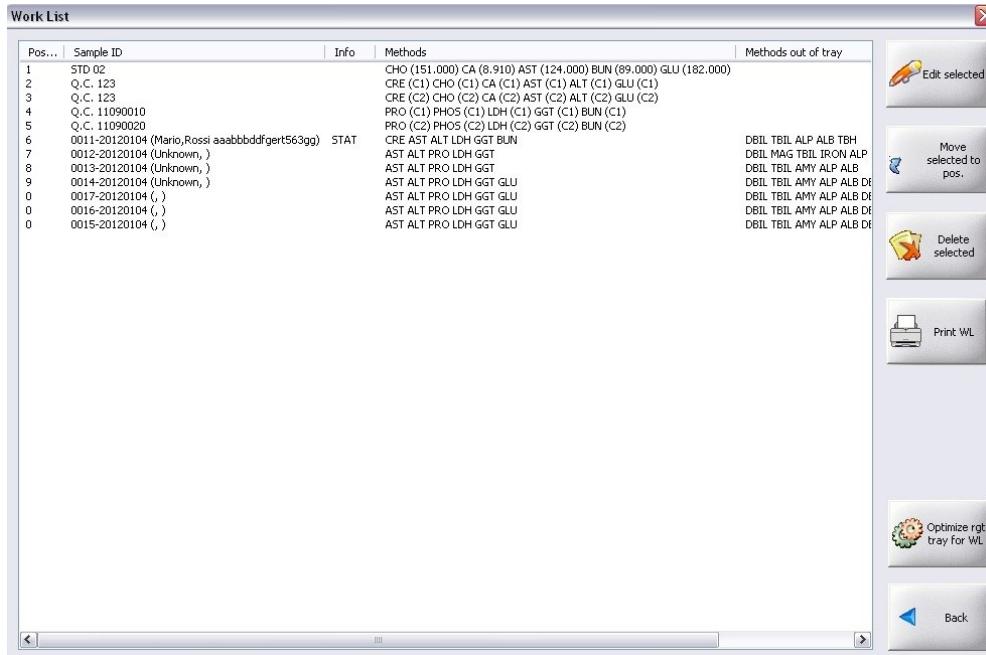


Figure 62: Show Work List Window

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Work List Display Window	
Position:	this column isn't editable and shows the number of the sample position on the tray.
Sample Id:	this column isn't editable and shows the ID code assigned to the sample (plus Last name, First name and Unique ID in brackets, if any).
Info:	this column isn't editable and shows eventual STAT conditions or eventual sample pre-dilutions.
Methods:	this column isn't editable and shows the method codes associated to each sample that are present on the reagent tray.
Methods out of tray:	this column isn't editable and shows the method codes associated to each sample that are not present on the reagent tray and must be placed.
Commands	
Edit selected:	if a sample has been selected with the left mouse button, this command allows the operator the modification of it; when this command is activated, the software returns the Work List menu and shows just the sample to be modified. To save modifications in Work List the operator must select the command Save in Work List.



Field/Command	Function
Move selected to pos.:	if a sample has been selected with the left mouse button, this command allows the operator to move that sample in another free position of the sample tray.
Delete selected:	if a sample has been selected with the left mouse button, this command allows the operator to delete it. It is also possible to multiple-select more samples, following the typical Windows® mode, and to delete all of them at the same time: <ul style="list-style-type: none">• Selecting a range of samples: click with the left mouse button on the first sample of the desired range and then, at the same time press the key SHIFT and click again on the last sample of the range ==> the range is then selected.• Selecting more discrete samples: press the key CTRL and at the same time click with the left mouse button on all sample to be selected.
Print WL:	this command allows the print out of the Work List to be run with the START command.
Optimize rgt tray for WL:	this command optimizes the reagent tray configuration in order to include in the tray positions only needed reagents clearing what is not needed.
Back:	this command allows the operator to go back to the Work List menu.



7.1.3. Reagents Menu, During Work List programming

By selecting the command *Next* in the menu *Work List* or the command *Reagents* in the menu *Methods*, the operator enters the menu *Reagents*; it allows the configuration of the reagent tray by fixing reagent positions on the tray.



Figure 63: Reagents Menu during WL programming

The right side of this menu shows the configuration of the on-board reagents; positions can be assigned in two different modes:

- manual: the operator must select a method, with the mouse, in the window Methods and then, again with the left mouse button, needs to click on one reagent of the window Reagents and drag it onto the desired position. If that position is free, the tray configuration is automatically updated; if the position is used, the software asks the operator if to replace the old reagent with the new one or ignore the operation.
 - automatic: the operator can automatically update the reagent tray configuration by running a barcode scanning or by using the command Selection in Tray (includes all selected parameters) or by clicking on the command Optimize rgt tray for WL (includes all parameters scheduled in the next work list).

To remove a single reagent from its position on the tray, the operator has to click, to drag and to release it out of the tray.



To remove all reagents loaded on board, the operator has to run the command *Empty rgt tray*.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function										
Methods window:	this window, not editable, shows the list of all methods stored in memory set as <i>visible</i> . The operator can select with the left mouse button one of the methods to display in the window <i>Reagents</i> the associated reagents to place on-board.										
Reagents window:	when the operator selects one method in <i>Methods</i> , this window shows the acronym (code) of the method, the related reagent bottles (R1, R2 and R3) and their lot number. <ul style="list-style-type: none">• For mono-reagents methods only R1 is visualized.• For bi-reagents methods R1 and R2 are visualized.• For three-reagents methods R1, R2 and R3 are visualized. To assign reagent positions on the tray the operator must select, click and drag any reagent bottle from this window onto the reagent tray desired position. It is possible to place more reagent bottles of the same type on the reagent tray only if they have the same <i>lot number</i> .										
Reagent data window:	this window allows the operator to enter or modify the lot number and the expiring date (format: YYYY/MM) for each reagent related to the previously selected method.										
Move rgt tray to:	this command allows the operator to move the desired position of the reagent tray to the front side of the instrument.										
Reagent text summary:	this command gives the situation of the reagents on-board. It displays a special window listing the volume left for any reagent on the tray based on the last sampling operation. This list can be printed out.										
Scan rgt barcodes:	this command, active only with Barcode option, allows the operator to run the automatic scanning of the reagents' barcode; this has meaning only in case the reagent bottles have been labelled with a barcode. By running this command, the system scans all reagent positions in order to read all barcodes: in case that some positions doesn't show a valid barcode, the instruments repeat the scanning two more times at lower speeds. At the end, each position of the reagent tray will be associated to a valid barcode, if any, or marked by the system. One of the following possibilities (colors) can be associated to each position: <table><thead><tr><th>Color</th><th>Description</th></tr></thead><tbody><tr><td>• White:</td><td>Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);</td></tr><tr><td>• Cyan blue:</td><td>Rgt R1 position used by an R1 position;</td></tr><tr><td>• Purple:</td><td>Rgt R2 position used by an R2 position;</td></tr><tr><td>• Blue:</td><td>Rgt R3 position used by an R3 position;</td></tr></tbody></table>	Color	Description	• White:	Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);	• Cyan blue:	Rgt R1 position used by an R1 position;	• Purple:	Rgt R2 position used by an R2 position;	• Blue:	Rgt R3 position used by an R3 position;
Color	Description										
• White:	Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);										
• Cyan blue:	Rgt R1 position used by an R1 position;										
• Purple:	Rgt R2 position used by an R2 position;										
• Blue:	Rgt R3 position used by an R3 position;										



Field/Command	Function
	<ul style="list-style-type: none">• Orange: <i>Unknown</i> position used by an unknown reagent (its barcode has been read and understood but the method is not included in memory);• Red: <i>Unreadable</i> position used by a reagent bottle with unreadable barcode or without barcode;• Yellow: <i>Lot mismatch</i> position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot number, that has to match with that provided on the reagent bottles);• Pink: <i>Diluent, or solution for processing</i> diluent solution (distilled water or physiologic solution) used for sample and standard dilutions. Solution for processing are: EW Cvt (Extra Washing for cuvette), EW Prb (Extra Washing for Probe), ISE Cs (ISE Module Cleaning Solution), ISE UD (ISE Module Urine Diluent).
Selection in tray:	At the end of the barcode scanning, the reagent tray configuration is updated with the new data (and can be anyway manually changed). this command allows the system to place automatically on to the reagent tray any group of reagents, previously selected , in the reagent window. The multiple selection of more samples is possible following the typical Windows® mode: <ul style="list-style-type: none">• Selecting a range of samples: click with the left mouse button on the first sample of the desired range and then, at the same time press the key SHIFT and click again on the last sample of the range ==> the range is then selected.• Selecting more discrete samples: press the key CTRL and at the same time click with the left mouse button on all sample to be selected. After selection, the operator presses the command and the system will assign positions to the reagent bottles starting from the first position free. In case of more bottles of the same type on the tray, the system asks for confirmation.
Optimize rgt tray for WL:	this command allows the system to automatically place on to the reagent tray all of the reagents scheduled for the Work List, and to clear positions from the other reagents not used.
Empty rgt tray:	this command allows the operator to clear all reagent tray positions.
Commands	
Next:	this command allows the operator to enter the Work List Summary menu; that menu summarizes samples, standards, controls, reagents and washing solutions included and needed in the next run to be started.
Back:	this command allows the operator to go back to the previous WL menu.
Main Menu:	this command allows the operator to go back to the Main Menu.





7.1.4. Work List Summary Menu

The operator enters this menu by selecting the command Next from the menu Reagents during the WL programming.

This menu summarizes, in the two windows named Samples and Reagents, what has been programmed and included in the current Work List to be run and allows the operator to check the presence in the correct positions of the reagents, of the samples, of the standards/calibrators and of the QCs to be processed.

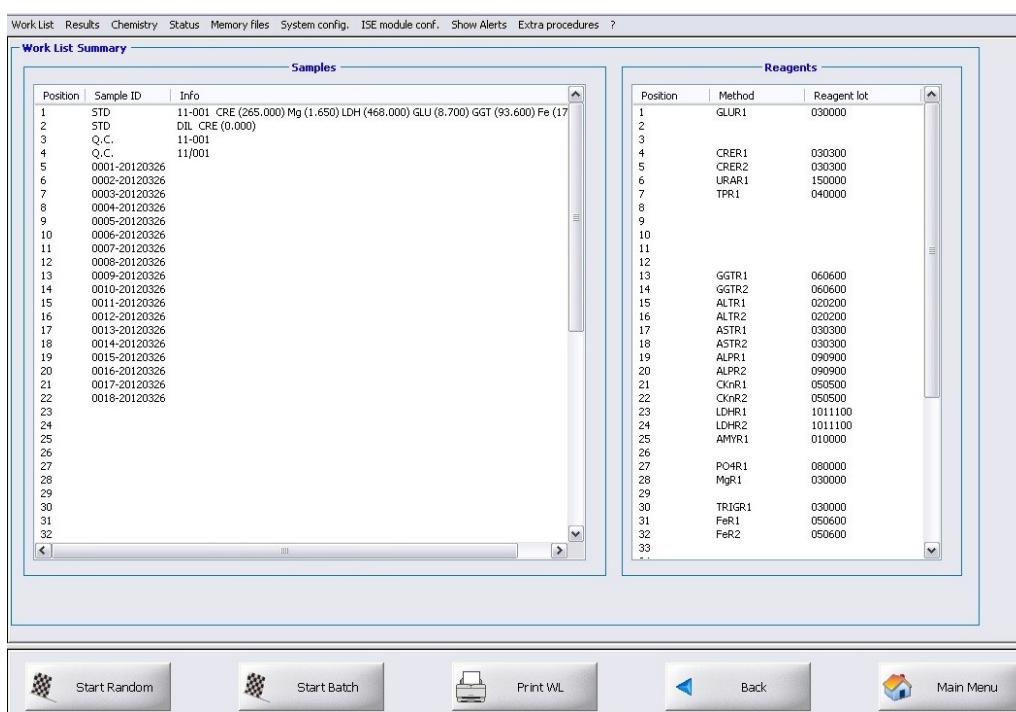


Figure 64: Work List Summary Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Samples Window	
Position:	this column, not editable, shows the tray positions of the samples to be placed to run the Work List.
Sample Id:	this column, not editable, shows the Sample ID code.
Info:	this column, not editable, shows the additional process information, if any, for each single sample (eventual dilution ratio and/or STAT condition).
Reagents Window	
Position:	this column, not editable, shows the tray positions of the reagents necessary to run the Work List.
Methods:	this column, not editable, shows the method code associated to the reagent number: R1, R2 or R3.
Reagent lot:	this column, not editable, shows the reagent lot code (the word "lot" is



Field/Command	Function
Commands	shown in case code is missing).
Start Random:	this command allows the operator to start the working session in Random mode . The Random mode causes the instrument to process tests sorted sample by sample, or rather: all tests of sample "n" will be run before those of sample "(n+1)". This mode has the advantage to issue all the results of any single sample as soon as completed. After the command START, the software handles the scheduling of the analyses, it automatically enters the Status menu and it starts the working session. When a WL is already running, further START commands can be used to add other samples or STAT. Standards and controls cannot be added to a running WL as they are processed only in the beginning.
Start Batch:	this command allows the operator to start the working session in Batch mode . The Batch mode causes the instrument to process tests sorted by methods, or rather: first are processed all tests of method "A", then all test of method "B" and so on until the end. This mode has the advantage to minimize the possible effects due to reagents cross-contaminations. After the command START, the software handles the scheduling of the analyses, it automatically enters the Status menu and it starts the working session. When a WL is already running, further START commands can be used to add other samples or STAT. Standards and controls cannot be added to a running WL as they are processed only in the beginning.
Print WL:	this command allows the print out of the Work List to be run with the START command.
Back:	this command allows the operator to go back to the previous Reagents menu.
Main Menu:	this command allows the operator to go back to the Main Menu.

In case some conditions necessary to the run execution is needed, an appropriate message will be displayed to alert the operator about the necessary operations to be carried out.

In the case shown in the following picture the system alerts the operator about action to be taken.

By cancelling the window, the operator can return back and carry on correct operation by taking the proper action.

By pressing START, the operator accept what proposed by the system.



Figure 65: Starting session with alerts



7.1.5. Status Menu

The Status menu shows the operator the actual instrument status under operating conditions. Basically this menu can show one of two different conditions: system *in running* or system *in stand-by* (or Idle). The software automatically turns on the Status menu after having started a working session (activation of the command *Start Random* or of the command *Start Batch* from the *Work List Summary* menu). The operator is free to surf through the different menus and this menu can however be entered any moment by selecting the command *Status*. Anytime this menu is entered, the information will be immediately refreshed and updated.

STATUS – For system in running

During the execution of a working session, the Status menu displays:

- the actual status of the instrument (running, in pause, in alarm, in warning, etc.);
- the status of any single analysis (sample, control and standard) that is in processing and not yet concluded; each position of the sample tray shows, in run-time, the progress through the use of different colours depending on the state of the analyses;
- the configuration of the reagent tray and the status of the reagent bottles or methods (residual volume and number of tests left, reagent finished, method in alarm because of control out of range, etc.);
- the status of the incubation and reading cuvettes (ready to use, in use, dirty, in washing, to be replaced);
- a window showing the detail of analyses progress.

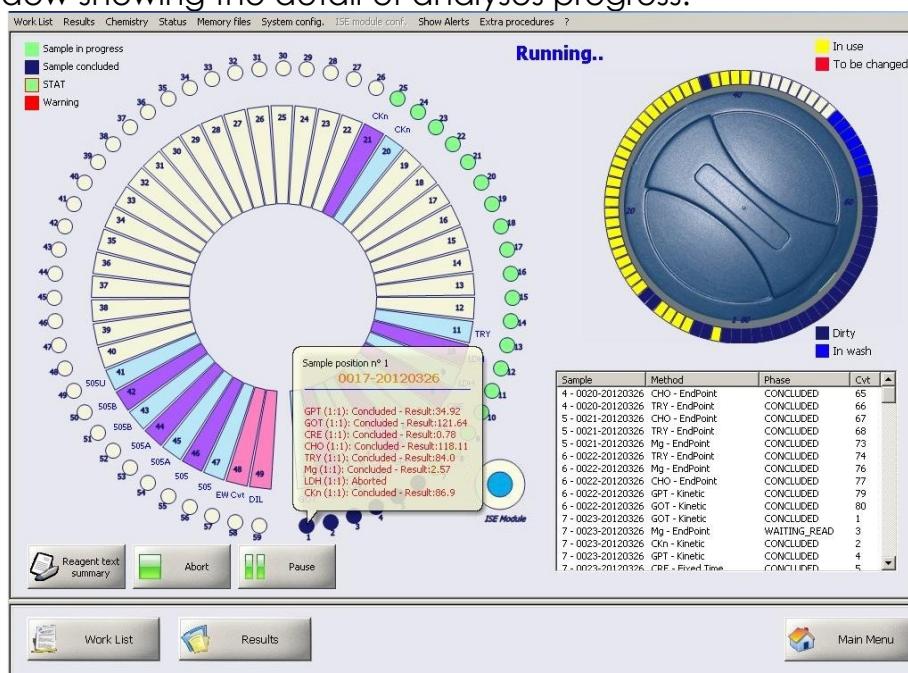


Figure 66: Status Menu - WL in run

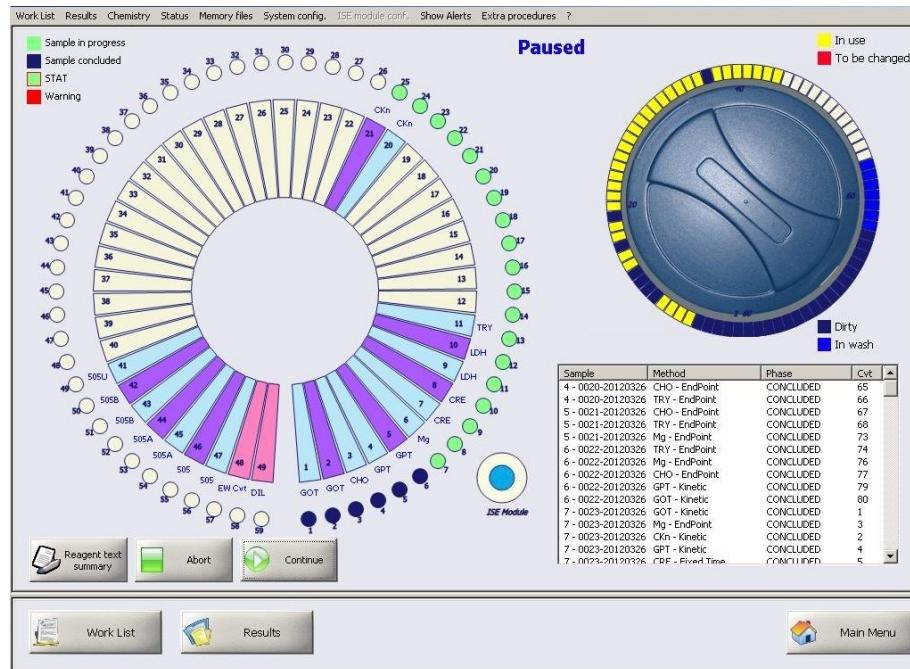


Figure 67: Menu Status – System temporary in Pause during a run

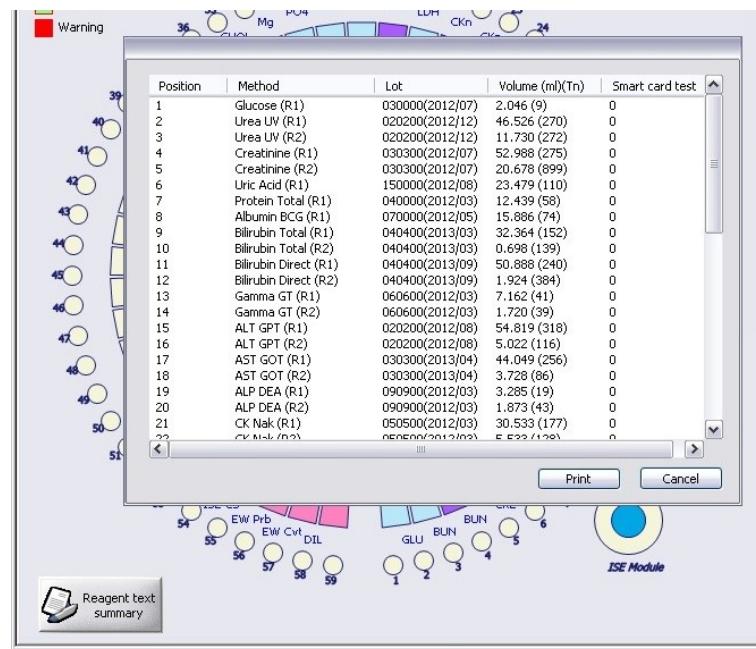
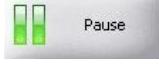


Figure 68: Menu Status – Reagent text summary window

The operative fields and the operational commands included have the following meaning:



Field/Command	Function
Sample tray positions	
White position:	it identifies a free position, or anyway a position not used in the current Work List.
Yellow position:	it identifies a sample included in the Work List but not yet processed.
Green position:	it identifies a sample in processing phase.
Dark blue position:	it identifies a sample completely processed (concluded) whose results can be validated and stored in archive.
Any-colour position with red border:	it identifies a sample included in the Work List as "urgent" (STAT).
Red position:	it alerts that one sample has finished. Clicking once with the left mouse button onto the sample, it is possible to display a special window that allows the operator to choose what to do: <ul style="list-style-type: none">• to definitely abort the residual analyses and to conclude the sample (Abort),• to refill the empty tube with more sample and to perform the rest of the analyses (Retry),• to exit, leaving the sample as it is by postponing the decision (Exit - the system doesn't consider the run of analysis as finished until the operator decision whether to abort or to continue). In case it is chosen to refill the sample, the operator needs: <ul style="list-style-type: none">• to click with the left mouse button the button <i>Pause</i> on the monitor,  Pause• to wait the arrest of both sampling arm phases,• to open the cover,• to refill the sample,• to close the cover,• to click with the left mouse button the button <i>Continue</i> on the monitor.  Continue
Notes:	
1-	To make the reading of the information easier, in correspondence of some positions of the sample tray as been displayed the numeration on the tray.
2-	By clicking on any sample position with the left mouse button it is possible to open an information window showing sample analyses results and their status.
Reagent tray positions	
White position:	it identifies a free position.
Cyan blue position:	it identifies a position used by a R1 type reagent.
Purple position:	it identifies a position used by a R2 type reagent.
Blue position:	it identifies a position used by a R3 type reagent.
Pink position:	it identifies a reagent position used by the system for special processing solutions as: <ul style="list-style-type: none">• Diluent - distilled water or physiological solution (pos. #49 has been permanently reserved as fixed position for diluent),• EWP – Extra Washing Probe solution (any position, this solution is used for probe extra-washing in case of restrictions between methods),• EWC – Extra Washing Cuvette solution (any position, this solution is used



Field/Command	Function
	for cuvette extra-washing in case of restrictions between methods or cuvette extra-washing cycles),
	• ISE CS – ISE Module Cleaning solution (any position, this solution is used by the ISE Module during operation against protein build-up),
	• ISE UD – ISE Module Urine Diluent solution (any position, this solution is used by the ISE Module during urine electrolyte analyses),
Red position:	it points out that the system has detected a problem on the reagent or on the related method. The software highlights in this way one of the following events: <ul style="list-style-type: none">• the reagent marked in red is finished; in this case the system suspends and skips the analyses associated to that method. Clicking once with the left mouse button on the reagent it is possible to visualize a special window that allows the operator to choose if:<ul style="list-style-type: none">❖ to definitely abort all the remaining analyses (Abort);❖ to replace the reagent bottle with a new one (Retry);❖ to go out leaving the reagent as it is and to postpone the decision (Exit - the system doesn't consider the run of analysis as finished until the operator decision whether to abort or to retry).• the measurement of the control, for the method whose reagent is marked in red, is out of range; in this case the system suspends only the analyses of that particular method and communicates the operator, with a special message, the followings possible choices:<ul style="list-style-type: none">❖ to abort all the analyses related to the method (Abort);❖ to repeat the measurement on the control (Retry);❖ to ignore the result of the control and to perform however the analyses related to the method (Ignore);❖ to go out leaving the reagent as it is and to postpone the decision (Exit - the system doesn't consider the run of analysis as finished until the operator decision whether to abort, to retry or to ignore).
Notes:	
1-	To make the reading of the information easier, in correspondence of some positions of the reagent tray as been printed the numeration on the tray.
2-	The reagent tray represents what's loaded on the panel used for the Work List. In correspondence of any reagents has been printed its own code.
3-	By clicking on any reagent position with the left mouse button it is possible to open an information window showing the actual reagent volume (or tests left).
Cuvette tray	
White position:	it identifies a clean cuvette, ready to be used by the system.
Yellow position:	it identifies a cuvette in use.
Cyan blue position:	it identifies a cuvette in washing.
Dark blue position:	it identifies a dirty cuvette, to be washed again by the system.
Red position:	it identifies a defective cuvette, to be replaced by the operator. The system will mark a cuvette as defective after having tried to recover it by three more washing cycles.
Scheduling window	
Sample:	this column, not editable, shows the ID code of the sample.
Method:	this column, not editable, shows the code and the type of the analysis (i.e.: GLU – EndPoint).



Field/Command	Function
Phase:	this column, not editable, shows a text explaining the process phase for each analysis (i.e.: planned, concluded, waiting_read, waiting_sample, aborted, etc).
Cvt:	this column, not editable, shows the cuvette position number used for any analysis execution.
Notes:	<p>1- Any time this menu is refreshed, by re-entering or by clicking on the "Status" button, the content of this scheduling window will be refreshed, and then cleaned out of the concluded analyses and samples. History will not be maintained up to the end of the run but only phases to be processed.</p> <p>2- Operations are not necessarily listed following a sequential descending or ascending time ordering.</p>
ISE Module icon	<p>It is present only in case the ISE Module is included and configured in the system. It shows the actual ISE Module status.</p> <p>When outer area colour is "white", the ISE Module doesn't show any problem during operation. It is working correctly.</p> <p>In case the outer area colour is "red" then the ISE Module is in alarm and it needs intervention by the operator.</p>
Commands	
Reagent text summary:	this command gives the situation of the reagents on-board. It displays a special window listing the volume left for any reagent on the tray based on the last sampling operation. This list can be printed out.
Key Pause: 	this command, visualized only when the system is not in Pause, allows the operator to pause instrument, that means: at the end of the current phase, the system arrests the movement of the sampling; meanwhile, the instruments doesn't arrest the ongoing incubation, the reading and the washing processes. The system remains anyway waiting for the command Continue to restart the sampling process. During the working session, the operator must place the instrument in Pause in case he needs: <ul style="list-style-type: none">• to replace a reagent which is over;• to replace, add or refill a sample in the tray;• to add a STAT in the tray;• to control the working area. The operator must open the cover only after having paused the system.
Key Continue: 	this command, visualized only when the system is in Pause, allows the operator to continue the working session previously paused. It also allow the operator to resume the system after a recoverable alarm.
Key Abort: 	this command allows the operator to permanently abort the working session: the system arrests sampling, incubations, readings, probe washing and definitely quit the actual Work List. When the Abort command is activated, the system runs an auto-zero cycle (and consequently washes all cuvettes).
Work List:	this command allows the operator to go back to the Work List menu.
Results:	this command allows the operator to enter the Results menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



The operator can control the residual reagent volume for each reagent bottle in the tool-tip that opens when clicking with the left mouse button any reagent on the display (this information is updated on-line after the first sampling of the reagent). In case of smart-card manager, this information will include also the number of residual tests.

The operator can control the progress of the analysis for each sample in the tool-tip that opens when clicking with the left mouse button on any sample.

STATUS – For system in Idle

When the instrument is in stand-by (*Idle* status), waiting for commands, the operator can:

- run a short rinsing and reset cycle for any single sampling probe (depending if “single arm” or “double arms” system);
- run a complete cuvette Extra-Washing cycle using the dedicated cuvette extra-wash solution (EWCvt) on the reagent tray;
- run a wavelength optical Gain Calibration cycle of the optical group (it includes tubing refill, cuvette washing cycle, gains equalization and the final updating of auto-zeros).
- run a read cycle for updating cuvette auto-zeros including a refilling of the tubing and a complete washing of the cuvettes;
- move the cuvette tray presenting a cuvette to replace in the centre of the aperture provided on the cover;
- move the sample tray presenting a sample position on the front of the instrument;
- move the reagent tray presenting a reagent position on the front of the instrument;
- query the system to show the residual volume for each reagent.

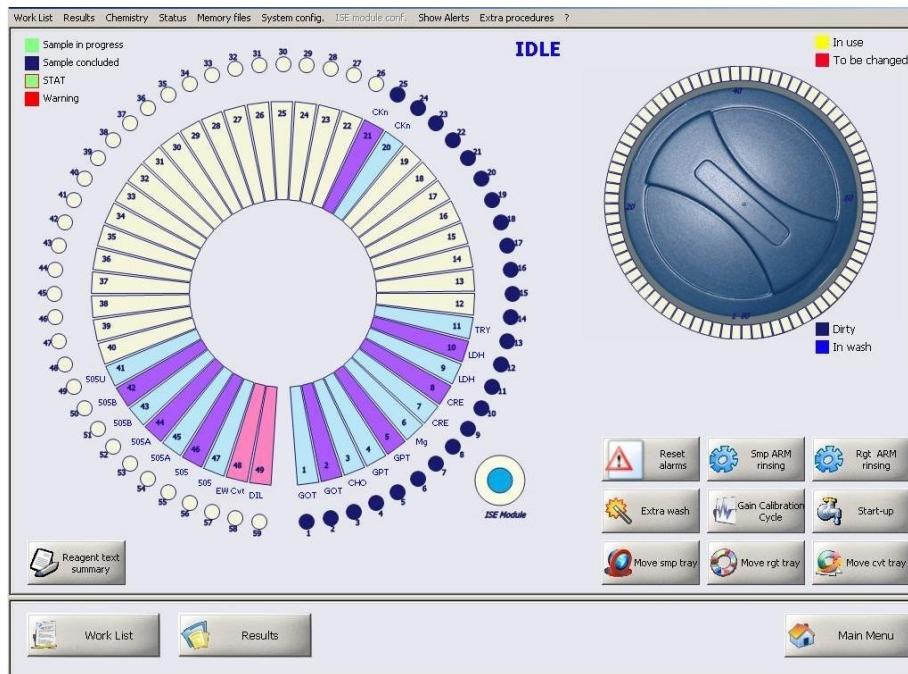


Figure 69: M2-59, Menu Status – Idle (for Double ARM system)

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Sample tray positions	As per Running status, previously described.
Reagent tray positions	As per Running status, previously described.
Cuvette tray	As per Running status, previously described.
ISE Module icon	As per Running status, previously described.
Commands	
Reset alarms:	this command allows the operator to reset the instrument in case of alarms to try to recover the system to Idle status (this in case the alarm can be cleared).
Smp ARM rinsing (or ARM rinsing):	this command allows the operator to run the rinsing of the sample probe and the reset of the sample ARM. In Single ARM System (M1-xx), this command has been called "ARM rinsing".
Rgt ARM rinsing:	this command allows the operator to run the rinsing of the reagent probe and the reset of the reagent ARM. In Single ARM System (M1-xx), this command does not exist.
Extra wash:	this command allows the operator to run a special washing cycle of the reading cuvettes. The system samples and dispenses in each cuvette a dedicated washing solution, named "EW Cvt", previously placed on the reagent tray. Probe washing is included. It is advisable to run an Extra wash cycle at the end of any working day .
Gain Calibration Cycle:	this command allows the operator to refill tubing, to wash all cuvettes, to

**Field/Command****Function**

Start-up:

update and equalize the wavelengths filter gains and to update the auto-zero value for each cuvette. In fact a calibration cycle is always followed by an auto-zero cycle that allows to read all cuvettes with the new updated gains (the new auto-zero values are used for ODs' calculation).

Move smp tray:

this command allows the operator to refill tubing, to wash all cuvettes, to update the auto-zero value for each cuvette (to be used in Ods' calculation).

Move rgt tray:

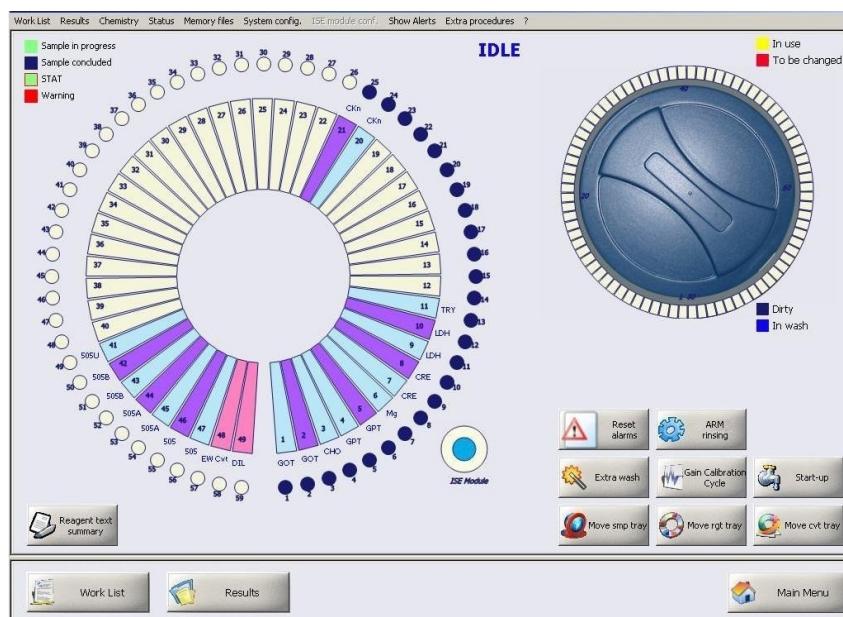
this command allows the operator to place a sample position in front of the instrument.

Move cvt tray:

this command allows the operator to place a reagent position in front of the instrument.

Work List:

this command allows the operator to enter the Work List menu.
this command allows the operator to enter the Results menu.
this command allows the operator to go back to the Main Menu.

Results:
Main Menu:**Figure 70:** M1-59, Menu Status – Idle (for Single ARM system)



7.1.6. Methods Menu

By selecting *Chemistry* from the *Main Menu* or from the upper menu bar the operator can enter the *Methods Menu*. This menu allows the setting, modification and management of the analysis methods.

Methods can be created, modified or deleted. To create a new method it is necessary to set **at the same time** a new name and a new code that must be different from the others that are already used. Any method can be modified by changing fields and parameters at any moment except when that method is not included in a work list to be run or whose results have not been archived yet. Pay attention during modifications: as stated before, the contemporary variation of name and code creates a new method.

Remember to set always “Instrument factor ($Y=ax+b$)” parameters to avoid results equal to zero; in case the operator doesn’t need the instrument factor influence, set $a=1$ and $b=0$.

Any method includes a special “Restriction” section in order to set special constrains to decrease, where needed, the possibility of cuvette and/or probe cross-contaminations. This is useful wherever it should exist significant incompatibilities.

The screenshot shows the 'Methods' screen of the KROMA PLUS software. On the left, a list of available methods is shown, with 'AST GOT' selected. The main area contains several panels:

- General Info:** Fields include Name (AST GOT), Type (Kinetic), Unit (U/L), and Decimal digits (0).
- Filters:** Set F1 to 340nm and F2 to 'not used'.
- Volumes [microlitres]:** Sample volume is 20 μL. R1 is 160 μL, R2 is 40 μL, and R3 is 0 μL. Bottles sizes are 50 mL, 20 mL, and 20 mL.
- Reagents:** Includes sections for Reagent linearity (Blank Abs min/max: 1, 3.5; 400, 2.4) and Detection limit.
- Incubation/Reading time [sec]:** Substrate/Sample Start, Kinetic reading time (336 sec), and Kinetic/Fixed Time data (Substrate depletion: 0.5, Fit limit: 0.95).
- Reference range:** Sample type (Serum) and reference ranges for Patient, Male, Female, and Paediatric groups.
- Instrument Factor ($Y = ax + b$):** Parameters a (1.000) and b (0.000).
- Controls:** Options for C1, C2, and C3, and a field for No. of SD for QC ref range (3).
- Printout customization:** Printout sort order (0), and options for Linearity instead of * and < Det. Limit instead of *.
- Buttons:** Formula Builder, Print, Delete, Dilutions by sample, Extra settings, and Save.

At the bottom, there are links to Reagents, Profiles, Controls, Standards, View Restrictions, and Main Menu.

Figure 71: Methods Menu

It is possible to create methods making use of one, two or three reagents.



Mono-reagents parameters dispense first the reagent and then the sample. Methods using two or three reagents can use "sample start" or "substrate start" philosophy for dispensing order:

- "Sample Start" with two reagents uses the sample as starter for the reaction, in this case the sample is always dispensed and mixed after reagents R1 and R2.
- "Sample Start" with three reagents uses the sample as starter for the reaction, in this case the sample is always dispensed and mixed after reagents R1 and R2 and then reagent R3 is added as reaction "stopper".
- "Substrate Start" with two reagents uses the reagent R2 as starter for the reaction, in this case the sample is always dispensed and mixed after reagents R1. Then R2 is added as reaction "starter".
- "Substrate Start" with three reagents uses the reagent R2 as starter for the reaction, in this case the sample is always dispensed and mixed after reagents R1. Then R2 is added as reaction "starter" and R3 is used as reaction "stopper".

After reagents and sample dispensing and mixing the system runs the incubation and the reading time.

Note: before to modify an existing method, all related Patient, Standard and QC results must be archived (stored in memory).

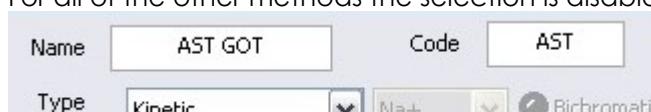
The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Methods section	
Method:	this column, not editable, shows the names of all method stored in memory. By selecting a particular method with the left mouse button, the software shows all of method characteristics' data and settings in the right side of the screen.
Code:	this column, not editable, shows method codes.
SC:	this column, not editable, is <u>active only in case of smart-card</u> ; it shows the number of available tests (not including those already programmed in Work List); in case of no residual tests the value is "0". In case smart card is not used the value is "UNLIMITED".
General Info section	
Name:	this field shows the name given to the method.
Code:	this field shows the code (acronym) given to the method, i.e.: name GLUCOSE → code GLU name AST GOT → code GOT name CREATININE, → code CRE, etc.
NOTE: to create a new method the operator must assign or must modify at the same time both Name field and Code field. If one only of the two fields have been changed the system doesn't create any new method and just records the modification.	
Barcode:	this field allows the operator to enter the two-digit code that will identifies



Field/Command	Function
	the method as part of the barcode printed on the bottle label (if used). This two-digit code can be customized after agreement with the producer.
Units:	this pull down menu allows the user to select the unit of measurement to be used for the results of the analyses related to that method. The following units are actually available: <ul style="list-style-type: none">• µg/ml• mg/ml• ng/ml• Abs• UI/ml• µmol/l• mg/l• g/l• %• U/l• mEq/l• mmol/l• µg/dl• mg/dl• g/dl• none• mL/min/m²• mL/min• mg/H• mg/min• g/24H Changing the Unit of Measurement doesn't affect results (no automatic conversion available).
Decimal digits:	this field allow the operator to fix the number of useful digits to be represented and printed in the results of that particular method. Allowed values are from 0 to 5.
Visible:	this selection give the operator the choice to hide/show the method throughout the software. When selected, that method is visible everywhere within the software (work list menu, standard menu, control menu, etc.). If not selected the method remains hidden in any other menu.
Type:	this pull down menu allows the user to select the method's type; it can be chosen one of the following types: <ul style="list-style-type: none">• End-Point• Differential – Two reagents• Differential – Sample Blank• Fixed Time• Kinetic• ISE Module (electrolytes: Na⁺, K⁺, Li⁺ and Cl⁻).• Formula (for calculated parameters, i.e. creatinine clearance). If ISE Module has been selected, the electrode selection pull down menu will be enabled.
ISE electrolytes selection:	this pull down menu allows the operator to select the desired electrolytes.



Field/Command	Function
	The following ISE methods are available: <ul style="list-style-type: none">• Na+• K+• Li+• Cl-
Bichromatic:	this selection give the operator the choice the mode mono-chromatic or bi-chromatic for ENPOINT and for DIFFERENTIAL SAMPLE BLANK method types. When selected, the method aside is performed in bichromatic way (reading at two wavelengths). This selection is possible only if EndPoint or Differential Sample Blank methods have been selected, then the flag is active
	
	For all of the other methods the selection is disabled:
	
	If not selected the method is run in monochromatic way (one wavelength).
Nr. Of Rgt:	this pull down menu allows the operator to fix the number of reagents used for that particular method: 1, 2 or 3 reagents. This selection is not available for the following methods: Differential sample blank (Mono- or Bi-chromatic), Differential two-reagents, Formula and ISE Module because meaningless. In case of 2 or 3 reagents, it is possible to further select "sample starting" or "substrate starting" method types.
Multiply diluted results/ Don't multiply diluted results:	this pull down menu allows the user to select whether to multiply or not the results obtained for a pre-diluted sample only by the dilution ratio set during WorkList programming: <ul style="list-style-type: none">• <i>Multiply diluted results</i>: the obtained result is multiplied by the sample pre-dilution ratio set in the method, section "dilutions by sample";• <i>Don't multiply diluted results</i>: the obtained result is NOT multiplied by the sample pre-dilution ratio. Then: in case of "Don't multiply pre-diluted results" the system gives the raw result for pre-diluted results, but it applies the dilution factor to the post-diluted results. This because a post-diluted result is assumed to be done to reduce the impact of the pathological sample in the reactions, on the other hand pre-dilution is assumed to be done to follow the method rules.
Notes:	this field allows the user to introduce some text comments or notes to be displayed on the work list as a tool tip when passing over the method to be selected with the mouse. Up to 100 characters can be introduced.
Filters section	
F1:	this pull down menu allows the user to select the wavelength used by this method for the photometric reading (or for the <i>first</i> photometric reading in case of <i>Bichromatic</i> type methods).

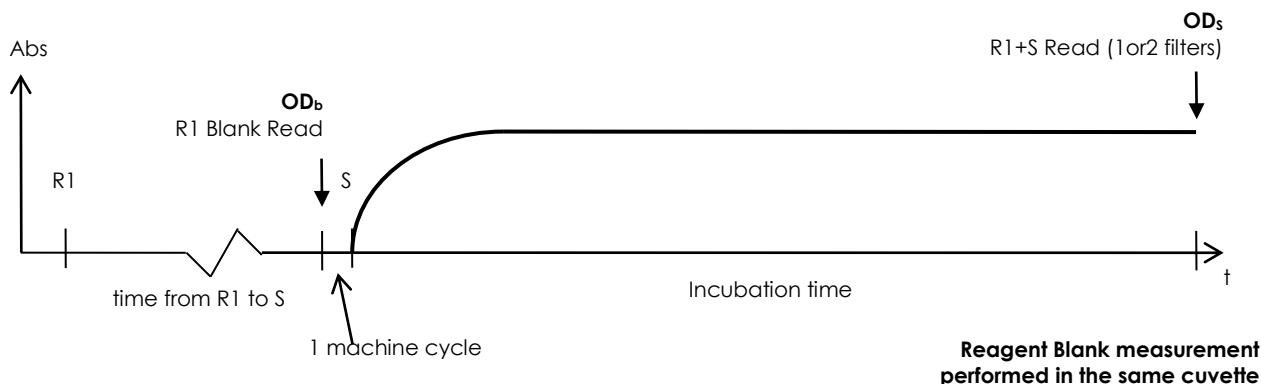


Field/Command	Function
F2:	this pull down menu, active only for <i>Bichromatic</i> methods, allows the user to select the second wavelength used for the second photometric reading. The instrument calculates the result by subtracting filter 2 (secondary) from filter 1 (main): [F1result – F2result] .
Volumes [microliters] section	
Samples:	this field allows the user to enter the sample reaction volume (in microlitres) that the instrument must dispense for the analysis execution (resolution = 1µl).
R1:	this field allows the user to enter the reagent R1 reaction volume (in microlitres) that the instrument must dispense for the analysis execution (resolution = 1µl).
R2:	this field allows the user to enter the reagent R2 reaction volume (in microlitres) that the instrument must dispense for the analysis execution (resolution = 1µl). The value = 0 (zero) means that the instrument doesn't use reagent R2 (mono-reagent method).
R3:	this field allows the user to enter the reagent R3 reaction volume (in microlitres) that the instrument must dispense for the analysis execution (resolution = 1µl). The value = 0 (zero) means that the instrument doesn't use reagent R3 (mono-reagent or bi-reagent method).
Bottle sizes sub-section	
R1:	this pull down menu allows the user to define the bottle size used for reagent R1.
R2:	this pull down menu allows the user to define the bottle size used for reagent R2 (if used).
R3:	this pull down menu allows the user to define the bottle size used for reagent R3 (if used).



Incubation/Reading Time [sec] section → BELOW DIFFERENT CASES
(see also Section 4)

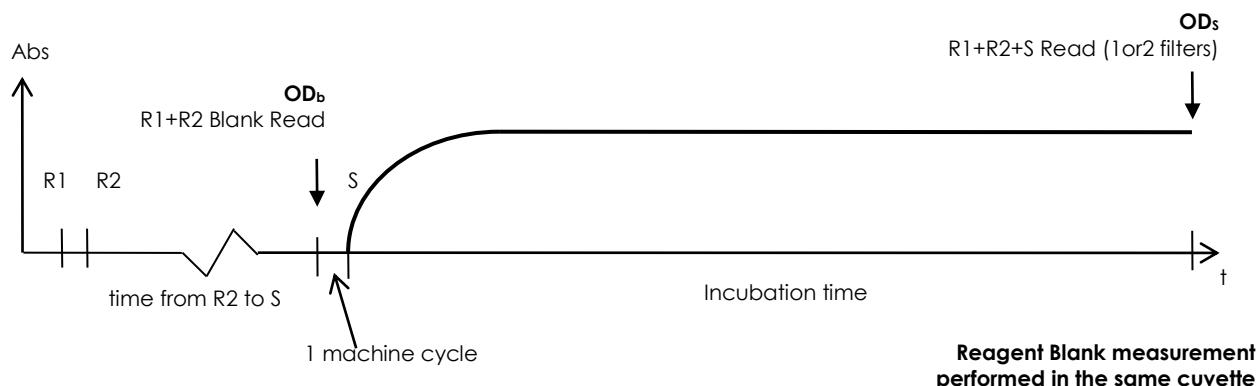
Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC END-POINT mono-reagent



- Substrate/Sample Start: this field is disabled in case of mono-reagent.
R1,S->R2: this field is disabled in this case.
R1,R2,S->R3: this field is disabled in this case.
Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette
(R1 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC END-POINT two-reagents sample start



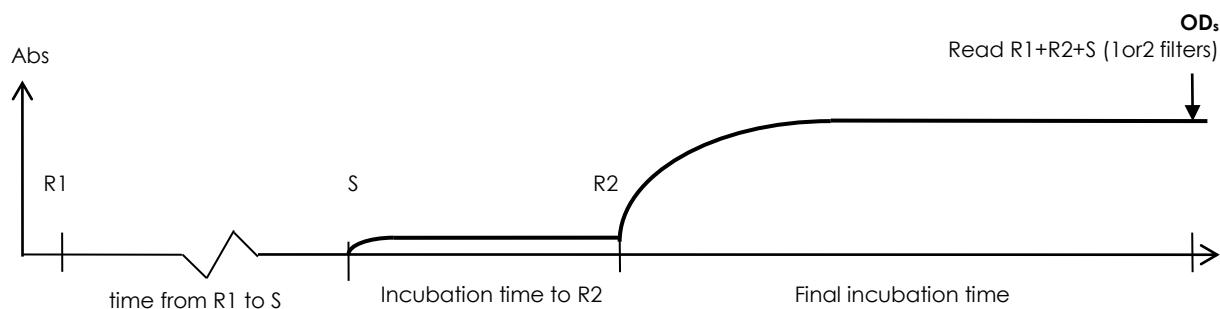
- Substrate/Sample Start: this field allows the operator to set "sample start" or "substrate start" method type; select the desired type from the pull down menu. In this case the selection is on "**sample start**".
R1,S->R2: this field is disabled in this case.
R1,R2,S->R3: this field is disabled in this case.
Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette



(R1 + R2 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC END-POINT two-reagents substrate start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**substrate start**”.

R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample)

before dispensing R2.

It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

R1,R2,S->R3:

Final incub.:

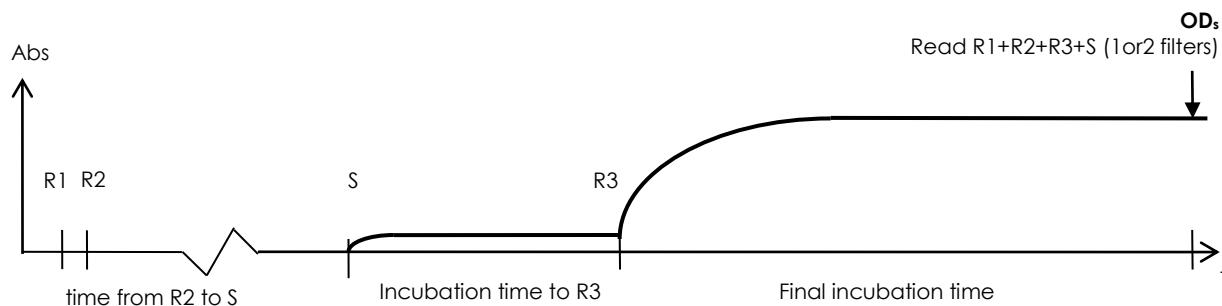
this field is disabled in this case.

this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC END-POINT three-reagents sample start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**sample start**”.

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample)

before dispensing R3.

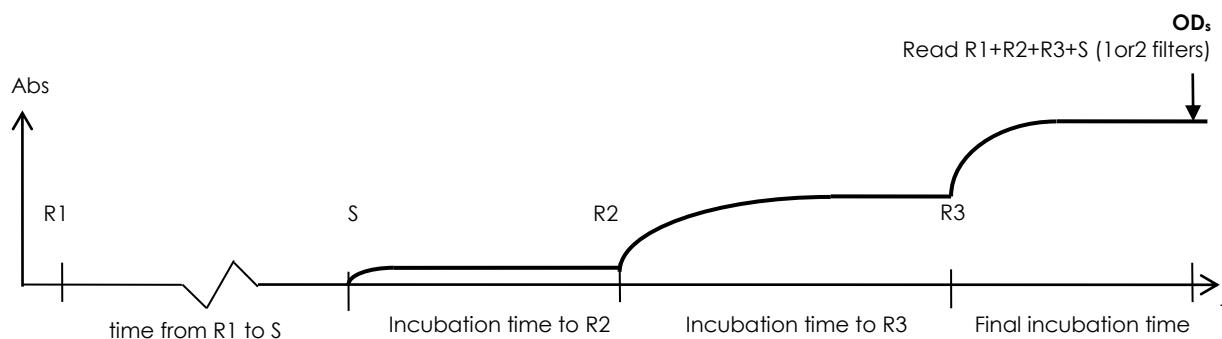
It is the time elapsing from the dispensing of the sample to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + R3 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC three-reagents substrate start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**substrate start**”.

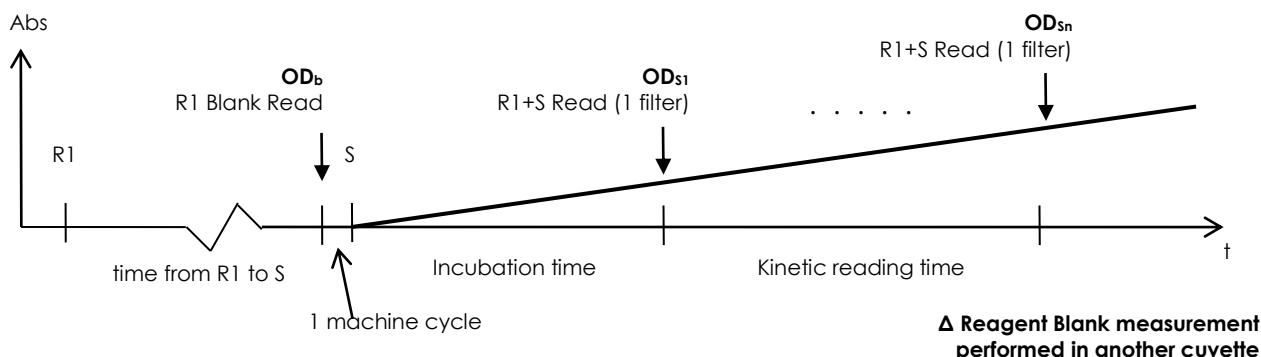
R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample)



- before dispensing R2.
It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.
- R1,R2,S->R3:
this field allows the user to enter the incubation time (in seconds) of the solution in cuvette
(R1 + sample + R2)
- before dispensing R3.
It is the time elapsing from the dispensing of reagent R2 to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.
- Final incub.:
this field allows the user to enter the incubation time (in seconds) of the solution in cuvette
(R1 + R2 + sample).

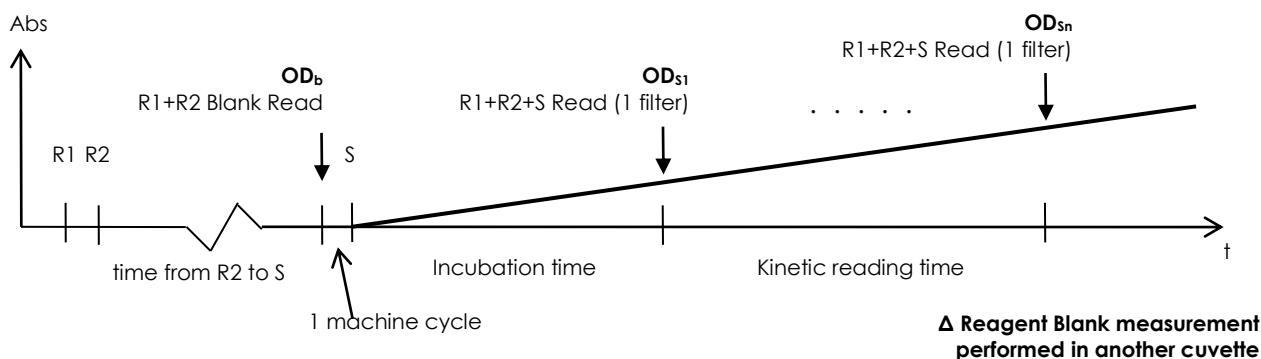
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Incubation/Reading Time [sec] section → valid in case of KINETIC mono-reagent

- Substrate/Sample Start: this field is disabled in case of mono-reagent.
- R1,S->R2: this field is disabled in this case.
- R1,R2,S->R3: this field is disabled in this case.
- Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette
(R1 + sample).
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.
- Kinetic reading time: this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.
It is the time elapsing from the first photometric reading (performed at the end of the incubation time) to the last reading.
A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.



Incubation/Reading Time [sec] section → valid in case of KINETIC two-reagents sample start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**sample start**”.

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field is disabled in this case.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample).

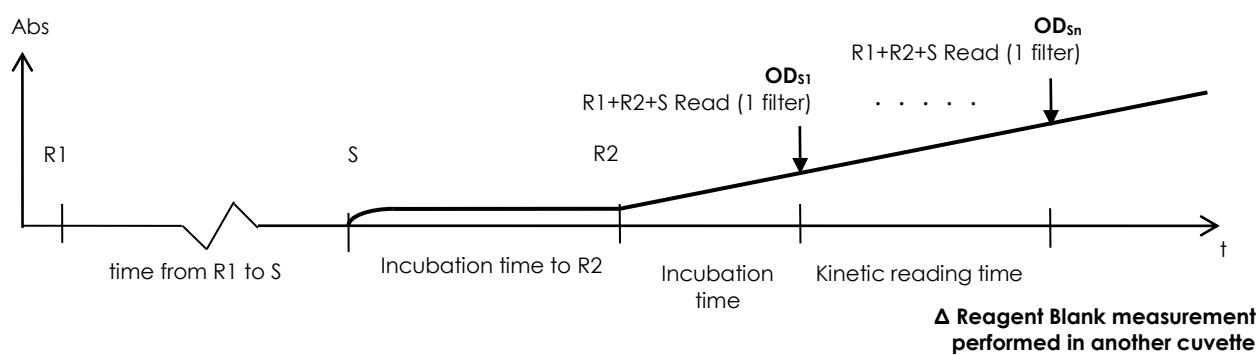
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Kinetic reading time: this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

It is the time elapsing from the first photometric reading (performed at the end of the incubation time) to the last reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.

Incubation/Reading Time [sec] section → valid in case of KINETIC two-reagents substrate start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**substrate start**”.

R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette



R1,R2,S->R3:
Final incub.:

Kinetic reading time:

(R1 + sample)

before dispensing R2.

It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

this field is disabled in this case.

this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample + R2).

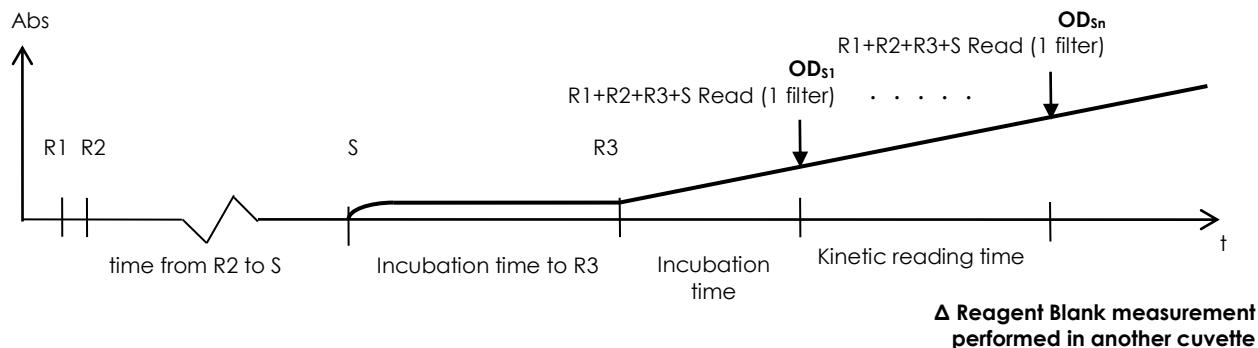
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

It is the time elapsing from the first photometric reading (performed at the end of the incubation time) to the last reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.

Incubation/Reading Time [sec] section → valid in case of KINETIC three-reagents sample start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**sample start**”.

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample)

before dispensing R3.

It is the time elapsing from the dispensing of the sample to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample + R3).

It is the time elapsing from the dispensing of the sample to the reading of



Kinetic reading time:

the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

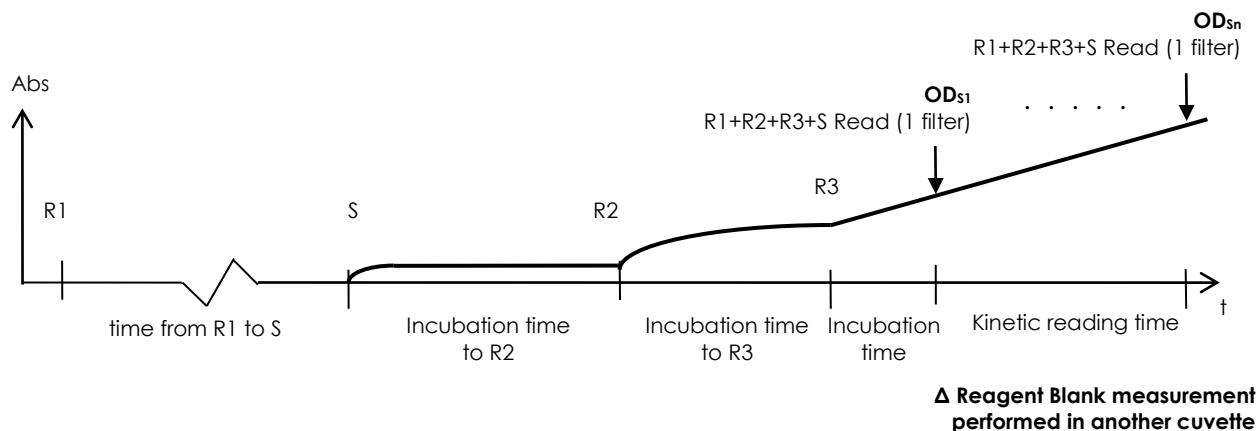
this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

It is the time elapsing from the first photometric reading (performed at the end of the incubation time) to the last reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.



Incubation/Reading Time [sec] section → valid in case of KINETIC three-reagents substrate start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**substrate start**”.

R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample)

before dispensing R2.

It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

R1,R2,S->R3: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample + R2)

before dispensing R3.

It is the time elapsing from the dispensing of reagent R2 to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

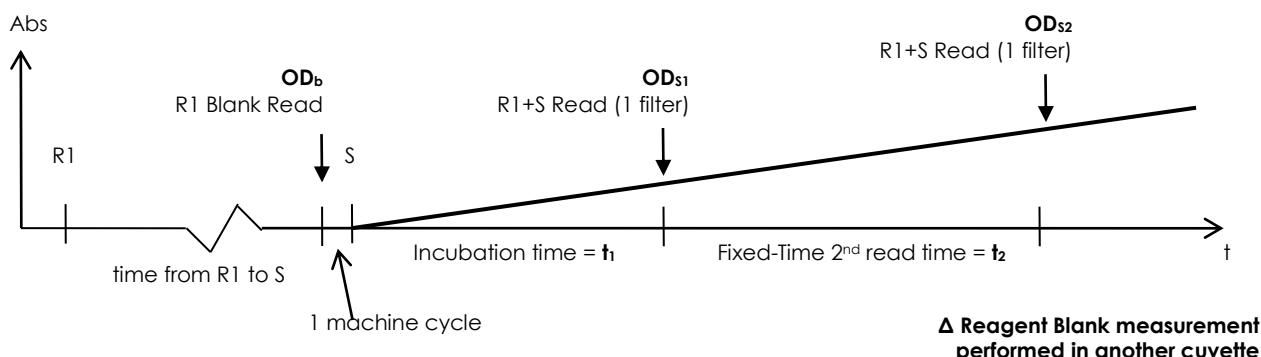
(R1 + R2 + sample + R3).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Kinetic reading time: this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

It is the time elapsing from the first photometric reading (performed at the end of the incubation time) to the last reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.

**Incubation/Reading Time [sec] section → valid in case of FIXED TIME mono-reagent**

Substrate/Sample Start: this field is disabled in case of mono-reagent.

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field is disabled in this case.

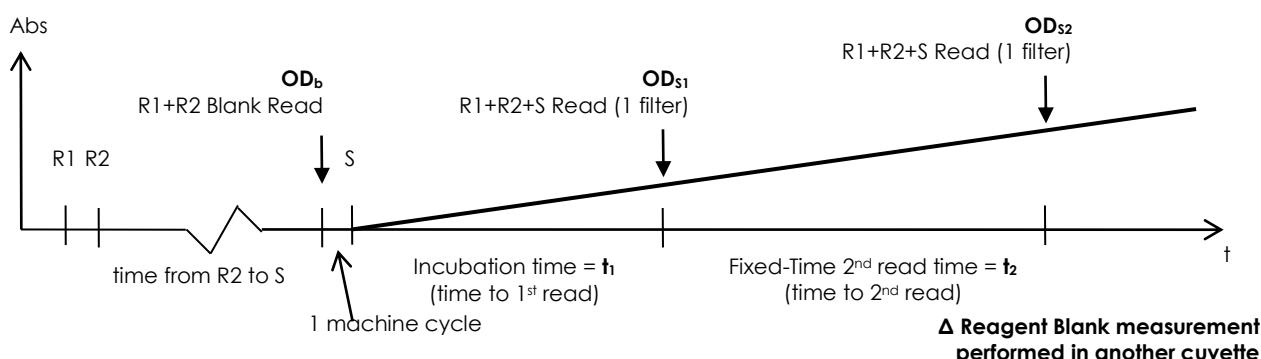
Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Fixed Time second read: this field allows the user to enter the time (in seconds) elapsing from the first photometric reading (performed at the expiring of the incubation time) to the second reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.

Incubation/Reading Time [sec] section → valid in case of FIXED TIME two-reagents sample start

Substrate/Sample Start: this field allows the operator to set "sample start" or "substrate start" method type; select the desired type from the pull down menu. In this case the selection is on "**sample start**".

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field is disabled in this case.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette



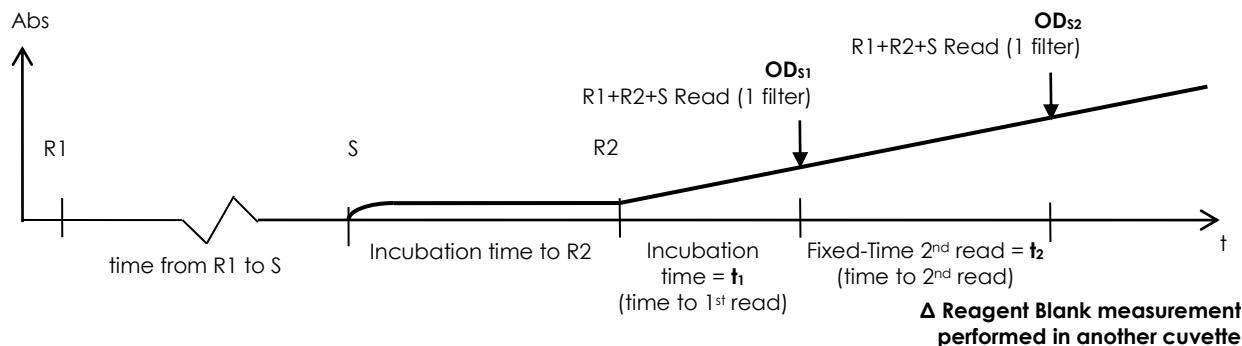
(R1 + R2 + sample).

It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Fixed Time second read: this field allows the user to enter the time (in seconds) elapsing from the first photometric reading (performed at the expiring of the incubation time) to the second reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.

Incubation/Reading Time [sec] section → valid in case of FIXED TIME two-reagents substrate start



Substrate/Sample Start: this field allows the operator to set "sample start" or "substrate start" method type; select the desired type from the pull down menu. In this case the selection is on "**substrate start**".

R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample)

before dispensing R2.

It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

R1,R2,S->R3:

Final incub.:

this field is disabled in this case.

this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample + R2).

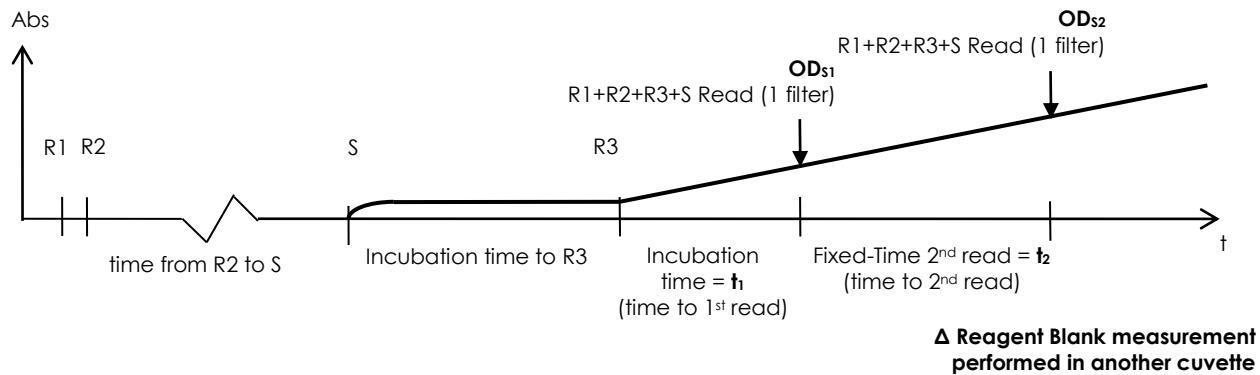
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Fixed Time second read: this field allows the user to enter the time (in seconds) elapsing from the first photometric reading (performed at the expiring of the incubation time) to the second reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.



Incubation/Reading Time [sec] section → valid in case of FIXED TIME three-reagents sample start



Substrate/Sample Start: this field allows the operator to set "sample start" or "substrate start" method type; select the desired type from the pull down menu. In this case the selection is on "**sample start**".

R1,S->R2: this field is disabled in this case.

R1,R2,S->R3: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample)

before dispensing R3.

It is the time elapsing from the dispensing of the sample to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.:

this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample + R3).

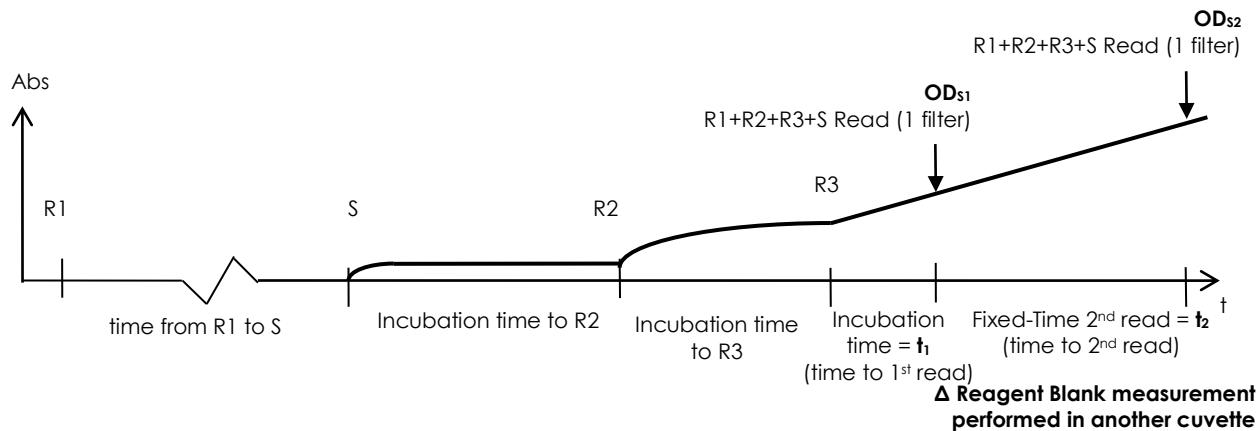
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Fixed Time second read: this field allows the user to enter the time (in seconds) elapsing from the first photometric reading (performed at the expiring of the incubation time) to the second reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.



Incubation/Reading Time [sec] section → valid in case of FIXED TIME three-reagents substrate start



Substrate/Sample Start: this field allows the operator to set “sample start” or “substrate start” method type; select the desired type from the pull down menu. In this case the selection is on “**substrate start**”.

R1,S->R2: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample)

before dispensing R2.

It is the time elapsing from the dispensing of the sample to the R2 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

R1,R2,S->R3: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + sample + R2)

before dispensing R3.

It is the time elapsing from the dispensing of reagent R2 to the R3 dispensing. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(R1 + R2 + sample + R3).

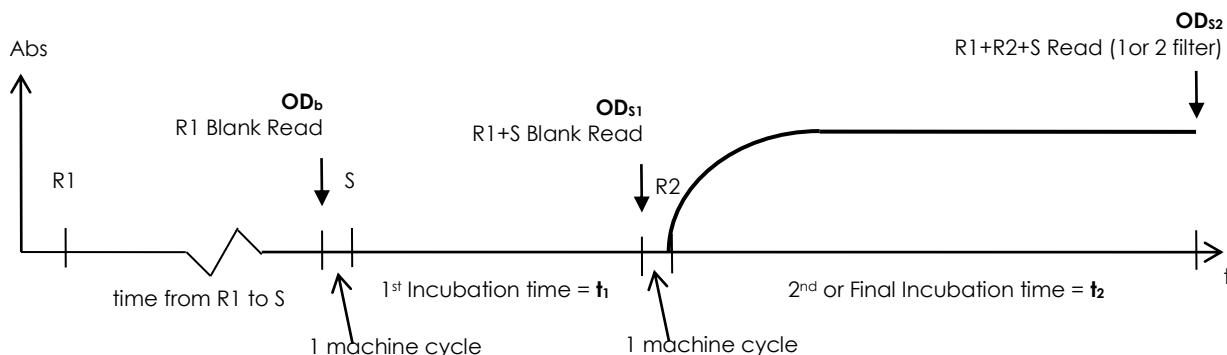
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Fixed Time second read: this field allows the user to enter the time (in seconds) elapsing from the first photometric reading (performed at the expiring of the incubation time) to the second reading.

A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 48, 72, 96, 120, 144, 168, 192, 216, 240, 264, 288, 312 and 336.



Incubation/Reading Time [sec] section → valid in case of DIFFERENTIAL SAMPLE BLANK mono- and bi-chromatic



Substrate/Sample Start: this field is disabled in this case.

$R1,S \rightarrow R2$: this field is disabled in this case.

$R1,R2,S \rightarrow R3$: this field is disabled in this case.

First incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

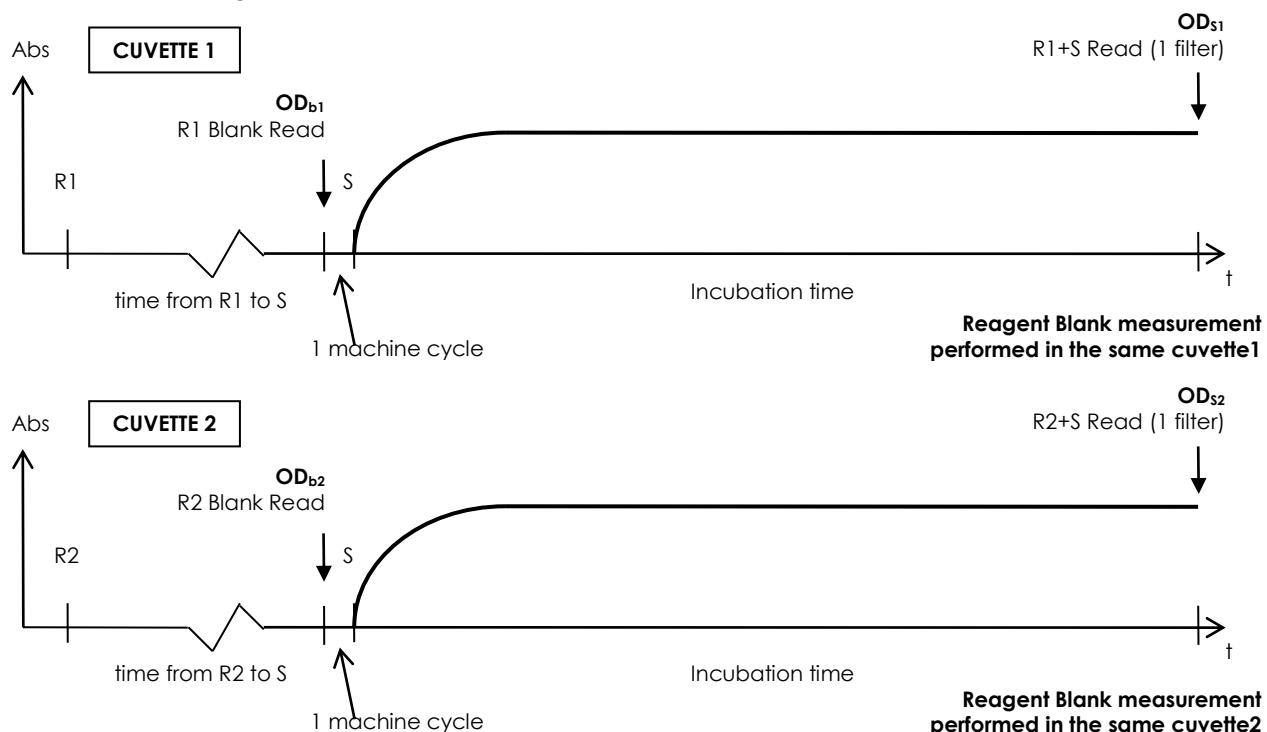
($R1 + \text{sample}$).

It is the time elapsing from the dispensing of the sample to the FIRST reading of the solution " $R1 + \text{sample}$ ". A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

[$(R1 + \text{sample}) + R2$].

It is the time elapsing from the dispensing of the reagent R2 to the second reading of the solution " $(R1 + \text{sample}) + R2$ ". A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**Incubation/Reading Time [sec] section → valid in case of DIFFERENTIAL TWO REAGENTS**

Substrate/Sample Start: this field is disabled in this case.
R1,S->R2: this field is disabled in this case.
R1,R2,S->R3: this field is disabled in this case.
Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in the two cuvettes
(R1 + sample) in cuvette1 and (R2 + sample) in cuvette2.
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

Kinetic/Fixed Time data section

Substrate depletion: this field allows the user to enter the Substrate Depletion value for Kinetic and Fixed Time methods. In the Results Menu the system highlights the result when the substrate depletion condition is detected.
This field is displayed only for Kinetic and Fixed Time methods and represents the maximum acceptable change of the first useful OD reading (in Abs) from the OD reagent blank value (in Abs). Values must be entered in Absorbance with format: Y.XXXXXX (6 X-digits maximum).

Fit limit: this field allows the user to enter the admissible limit for the FIT, calculated over the best fit linear regression slope for Kinetic methods. In the Results Menu the system highlights when the "out of FIT" condition is verified.
This field is displayed only for Kinetic methods and it represents the level of approximation of the linear regression to the measured points.
Values must be entered in percentage with format: Y.XXXXXX with values included in the range 0 to 1. The absolute "best fit" is obviously identified by 1.000000. Generally only 2 decimal are used.

**Reagents**

- Include blank in calc.: when this selection is active, the system subtracts the value measured for the reagent blank (or of its drift if kinetic or fixed time methods) from the final result.
Anyway the system always measures reagent blank in order to check if included in the admissible range (reagent integrity).
Reagent blank for mono-reagent or "sample start" methods is taken online on any single reaction cuvette; reagent blank for "substrate start" methods is taken once at the beginning of the run, on one separate cuvette. In case of mono-reagent or "sample start" the instrument performs the reading of the reagent blank just one machine cycle before dispensing the sample; if the reagent blank measured value is not included within the range defined by low and high absorbance, the instrument executes anyway the analysis but gives evidence of this condition in the Results Menu by highlighting the result.
- Abs range [min]: this field allows the user to enter the lowest value of the admissible range for reagent blank value; it must be expressed in **Absorbance**.
- Abs range [max]: this field allows the user to enter the highest value of the admissible range for reagent blank value; it must be expressed in **Absorbance**.
- Reagent linearity: this field allows the user to enter the maximum value related to reagent linearity; if the result of the analysis is above that value, the instrument gives evidence of this condition in the Results Menu by highlighting the results. It must be expressed in **Concentration**. This check is performed before the multiplication of the obtained concentration result by the eventual dilution ratio (if any).
- Detection limit: this field allows the user to enter the minimum value for valid result; if the result of the analysis is below that value, the instrument gives evidence of this condition in the Results Menu by highlighting the results. It must be expressed in **Concentration**. This check is performed before the multiplication of the obtained concentration result by the eventual dilution ratio (if any).

Printout customization

- Print sort order: this field accepts integers that define the analysis order of printing in the patient report by sorting them according to the number given. The lowest number the highest position (obviously "0" is = highest priority). "0" is given by default. In case of same priority, the alphabetic sort order is respected.
- > Linearity instead of *: this parameter, when enabled, gives the possibility to print the message "> than linearity value" for those results marked as out of linearity and masked by the "stars" [-> "*"]. Moreover, in case of the results out of calibration curve, this parameter is used also in the software result menus. On the monitor the results will be always shown except if out of the calibration curve, then you'll get the string above.
- < Det. Limit instead of *: this parameter, when enabled, gives the possibility to print the message "< than detection limit" for those results marked as below the detection limit and masked by the "stars" [-> "*"]. Moreover, in case of the results out of calibration curve, this parameter is used also in the software result menus. On the monitor the results will be always shown except if out of the calibration curve, then you'll get the string above.

Controls section

- C1: this selection allows the user to display the control C1 in the Std/Q.C. menu related to the Work List programming flow. In this way the user will



C2:

be able to include this control in the Work List.

This selection is active if in Q.C. Menu it has been previously programmed the values for control C1 and its lot number.

C3:

this selection allows the user to display the control C2 in the Std/Q.C. menu related to the Work List programming flow. In this way the user will be able to include this control in the Work List.

This selection is active if in Q.C. Menu it has been previously programmed the values for control C2 and its lot number.

Nr. of SD for QC ref range:

this selection allows the user to display the control C3 in the Std/Q.C. menu related to the Work List programming flow. In this way the user will be able to include this control in the Work List.

This selection is active if in Q.C. Menu it has been previously programmed the values for control C2 and its lot number.

this field accepts integers, between 1 and 3, that define the "standard deviation" associated to any of the QC range limits for that particular method: it allows the user to determinate which standard deviation is considered by the QC reference values (limits). The value must be set to 1, 2 or 3 depending on the instruction inserts of the QC manufacturer. This parameter doesn't affect the way to show the Levy-Jennings chart that it is drawn using 3 standard deviations, but applying the correct scale.

Instrument Factor ($Y = aX + b$) section

a:

this field allows the user to set the correlation factor (slope) for this test in order to convert results only for correlate them with alternative methods or other temperatures. If not used enter 1, zero causes all results = 0.

b:

this field allows the user to set the offset (intercept) for this test in order to convert results only for correlate them with alternative methods or other temperatures. If not used enter 0.

Reference Ranges (Results Normal Values) section

Sample type:

this pull down menu allows the user to select the sample type: serum, plasma, urine o CSF, whose normal values have to be set.

Patient type column:

this column, not editable, shows the patient type: male, female e paediatric; for each of them it is possible to set the normal range correspondent to the sample type.

Column "min":

following the selection of the sample type, the fields on this column allow the user to set the lower values of the normal range for each patient type.

Column "max":

following the selection of the sample type, the fields on this column allow the user to set the higher values of the normal range for each patient type.

Commands

Dilutions by sample:

this command allows the user to set the proper dilution ratios to be executed on the sample. It is possible to set fixed ratios for pre-dilutions and post-dilutions for several matrix of sample and for different conditions causing the post-dilution auto-request (see the next paragraph).

Extra Settings:

this command gives the possibility to ignore some of the alerts that can be generated with reference to the focused method (i.e.: ignore some alerts on the results). It allows the user to enter a submenu where to set some alert exclusions.

Formula Builder:

this command is enabled only if a "Formula" method type has been set. It allows the user to enter a formula builder calculator to fix the formula used to calculate the final result.

Print:

this command allows the user to print out the selected method.



Delete:	this command allows the user to delete the selected method.
Save:	this command allows the user to save the method modifications; it controls of the congruence of volume data and incubation/reading time.
Reagent:	this command allows the operator to enter the Reagents menu.
Profiles:	this command allows the operator to enter the Profiles menu.
Controls:	this command allows the operator to enter the Q.C. menu.
Standards:	this command allows the operator to enter the Standard menu.
View Restriction:	this command allows the user to set and solve reciprocal incompatibilities among different reagents (methods).
Main Menu:	this command allows the operator to go back to the Main Menu.

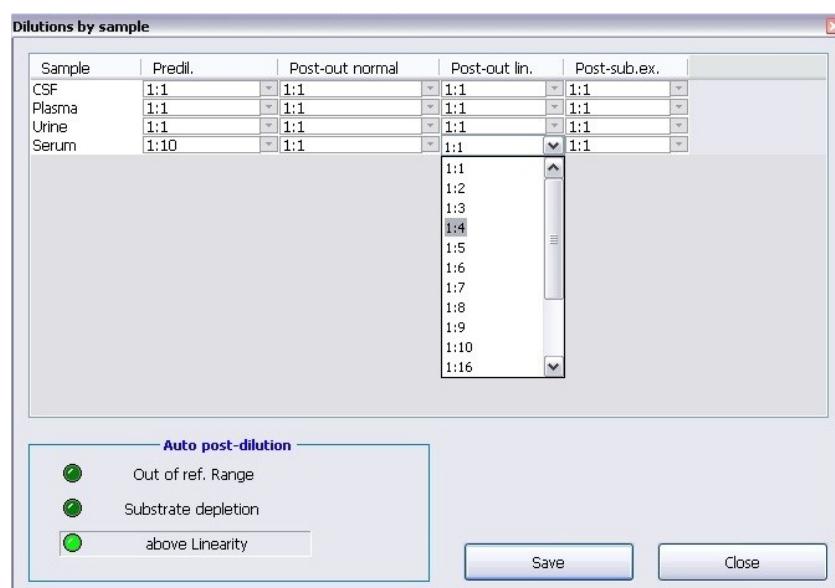
7.1.6.1. Automatic Dilutions - Dilutions by Sample Submenu

This submenu can be entered by the Method menu by clicking on the **Dilutions by Sample** button. It allows the operator to set, for each method, the dilution ratios for the sample on the base of its matrix and depending on the condition requesting the dilution.

The matrixes actually included are: Plasma, CSF, Urine and Serum.

The dilution can be made just before the analysis (**pre-dilution**) or consequently to an abnormal analysis result (**post-dilution**).

In case of post-dilution, it is possible to choose the possible cause triggering the request: out of normal range result, substrate depletion or out of linearity conditions or any combination of these three elements.



Dilution ratio are the following: 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:16, 1:20, 1:30, 1:40, 1:50 and 1:100. In case of ISE Module analysis it is not possible any further dilution for urine: in fact, in that case the system provides automatically the 1:10 necessary and unique dilution.



The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Sample dilution table	
Predil.:	this column allows the operator to choose the proper pre-dilution ratio for any sample matrix. If 1:1, the system will not perform any pre-dilution on the sample.
Post-out normal:	this column allows the operator to choose the proper post-dilution ratio for any sample matrix in case of <i>result out of normal range</i> . If 1:1, the system will not consider that post-dilution.
Post-out lin.:	this column allows the operator to choose the proper post-dilution ratio for any sample matrix in case of <i>result out of limit</i> . If 1:1, the system will not consider that post-dilution.
Post-sub. ex.:	this column allows the operator to choose the proper post-dilution ratio for any sample matrix in case of <i>substrate depletion detected</i> (exhaustion of the substrate). If 1:1, the system will not consider that post-dilution.
Selections	
Out of ref. Range:	this selection allows the operator to enable the auto post-dilution in case the result has been detected "out of reference range". The post-dilution will be automatically performed by the system without asking the operator for confirmation.
Substrate depletion:	this selection allows the operator to enable the auto post-dilution in case the condition "substrate depletion" has been detected. The post-dilution will be automatically performed by the system without asking the operator for confirmation.
Out of linearity:	this selection allows the operator to enable the auto post-dilution in case for the result has been detected the "out of linearity" condition. The post-dilution will be automatically performed by the system without asking the operator for confirmation.
Commands	
Save:	this command allows the operator to save the settings that have been made.
Close:	this command allows the operator to close this submenu and to go back to the method.



7.1.6.2. Dispensable Volumes

During programming of methods, when setting parameters, the sample and reagent reaction volumes to be dispensed in any single cuvette, must be always included within fixed limits.

The total reaction sample and reagent volumes, dispensed into each cuvette, must range between 200 μ l and 500 μ l: the typical suggested reaction volume is anyway from 200 μ l to 260 μ l; in order to preserve cuvettes longer life, it is suggested not to overcome 300 μ l of total reaction volume.

With reference to **reagents**, it is possible to dispense from a minimum of 180 μ l up to 450 μ l reagent volume of R1, R2 and R3 in total. Provided the sum of reagent volumes greater or equal to 180 μ l, each of the reagents can be sampled anyway from 1 μ l to 450 μ l, with 1 μ l minimum increment. In case of dispensing of the reagent R2 or R3, the system performs the automated mixing of the reagents into the cuvette.

With reference to **samples**, it is possible to dispense sample volumes from 1 μ l up to 300 μ l, with 1 μ l minimum increment. The system performs the automatic mixing of the sample with the reagent into the cuvette.

The **suggested** values (in μ l) to be programmed in the methods are included in the ranges shown in the following table:

Method type	Suggested Volumes (Sample/Substrate Starting)	
Kinetic	Sum of Reagent Volumes (R1 or R1 + R2 or R1 + R2 + R3) 200 μ l÷250 μ l	Total Reaction Volume (Reagents + Sample) 200 μ l÷260 μ l
Fixed Time		
End Point (mono- and bi-chromatic)		
Differential - 2 Reagents	R1 and R2 200 μ l÷250 μ l	R1 + Sample and R2 + Sample 200 μ l÷260 μ l
Differential - Sample Blank (mono- and bi-chromatic)	R1 + Sample 200 μ l÷250 μ l	R1 + Sample + R2 200 μ l÷260 μ l



7.1.6.3. Reading and Incubation Times

With reference to the incubation and reading times the following table is valid for the different typologies of test methods and gives the admissible ranges:

Type: SAMPLE STARTING Methods	1st incub.	Incub. to R2: R1,S=>R2	Incub. to R3: R1,R2,S =>R3	Final Incub.	Fixed Time 2nd read	Kinetic Reading Time	MAX Total Method Time
End Point 1-Reag. (Monochr./Bichrom.)				36-720			720
End Point 2-Reag. (Monochr./Bichrom.)				36-720			720
End Point 3Reag. (Monochr./Bichrom.)			36-720	36-720			720
Fixed Time 1-Reag.				36-720	48-336		720
Fixed Time 2-Reag.				36-720	48-336		720
Fixed Time 3-Reag.			36-720	36-720	48-336		720
Kinetic 1-Reag.				36-720		48-336	720
Kinetic 2-Reag.				36-720		48-336	720
Kinetic 3-Reag.			36-720	36-720		48-336	720
Differential Sample Blk (Monochr./Bichrom.)	36-720			36-720			720
Differential 2-Reagents				36-720			720

Type: SUBSTRATE STARTING Methods	1st incub.	Incub. to R2: R1,S=>R2	Incub. to R3: R1,R2,S =>R3	Final Incub.	Fixed Time 2nd read	Kinetic Reading Time	MAX Total Method Time
End Point 2-Reag. (Monochr./Bichrom.)		36-720		36-720			720
End Point 3Reag. (Monochr./Bichrom.)		36-720	36-720	36-720			720
Fixed Time 2-Reag.		36-720		36-720	48-336		720
Fixed Time 3-Reag.		36-720	36-720	36-720	48-336		720
Kinetic 2-Reag.		36-720		36-720		48-336	720
Kinetic 3-Reag.		36-720	36-720	36-720		48-336	720

Note: The maximum total method time is intended as the sum of the incubation times and of the reading time (if any), and it cannot overcome 720sec in order to avoid degradation in throughput performance.



7.1.6.4. Extra Settings Submenu

This submenu allows the user to set specific exclusions about alerts generated referring to the applications.

In example: for some applications, a result below the Detection Limit is not an error or a condition that must be alerted to the operator, it can be normal. Nevertheless the software marks that result in RED colour as “*below the detection limit*”. In this case it is possible to set a flag that overcomes this behaviour avoiding the result red backlighting. This must be set for each method the operator wishes such a feature as the system leaves that flags deselected by default.

NOTE: leave such settings to expert personnel dealing with application development as the exclusion of alerts must be done in a manner consistent with the technical characteristics of the application itself. It can be dangerous if done without the necessary competence.



Figure 72: Extra Settings Submenu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Don't mark in red results below the detection limit:	this field allows the user to enable/disable the alert generated by the system in case of result revealed below the <i>Detection Limit</i> . When the flag is ON (light green) the alert is excluded and the results will not be marked in red.



7.1.6.5. Formula Builder Calculator Submenu

The Formula Builder menu allows the user to set specific calculations for computing the final result. It is given as a facility and it is generally used when a specific test result is related to other tests or parameters by mathematical formula. In case that other test parameters are needed, those must be included in the work list and run to get the result.

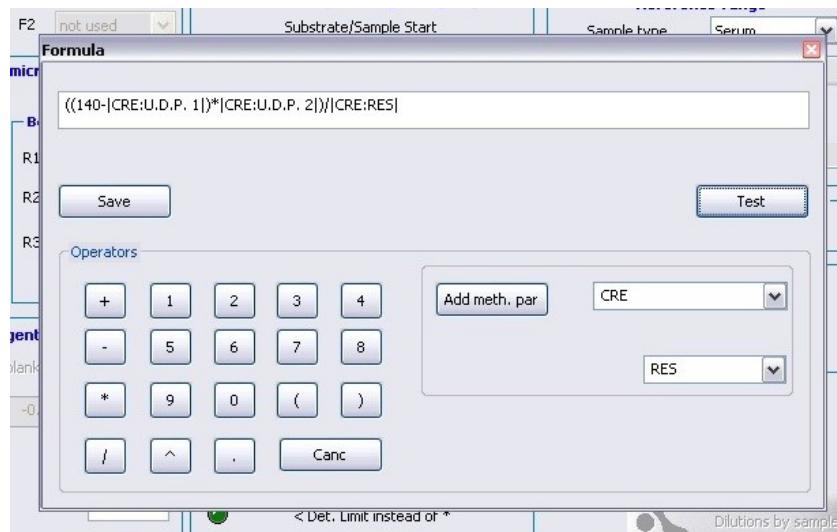


Figure 73: Formula Builder

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Formula bar display:	this field, non editable, shows the formula during implementing.
Save:	this command allows the operator to save new formula editing or modifications.
Test:	this command allows the operator to test the formula. Values obviously not available are set equal to zero just for calculation purpose.
Operators section:	the buttons within this section allow the operator to insert numbers and math operator in the formula or their deletion by clicking on Canc button.
Method pull down menu:	this pull down menu allows the operator to select a method, whose parameter must be further selected in the pull down menu below, to be introduced into the formula. This menu lists all methods that have been stored as visible.
Parameter pull down menu:	this pull down menu allows the operator to select a parameter related to a method, selected in the pull down menu above, to be introduced into the formula. The parameters included in the list are the following: <ul style="list-style-type: none">• AGE, age of the patient• FIN_INC, that is the final incubation time (in Conc.)• RES, that is the result of the test



Field/Command	Function
<ul style="list-style-type: none">• RGT_O.D.,• SMP_O.D.,• U.D.P.1, each patient• U.D.P.2, each patient• VOL_R1,• VOL_R2,• VOL_R3,• VOL_SMP,	that is the reagent blank O.D. result (in Abs) that is the final O.D. result (in Abs) that a user defined parameter value 1 specific of that a user defined parameter value 2 specific of that is the reagent R1 volume in μl that is the reagent R2 volume in μl that is the reagent R3 volume in μl . that is the sample volume in μl .
Add meth. par:	this command allows the operator to add the selected parameter method into the formula.



7.1.7. View Restriction Menu

The View Restriction menu allows the user to set specific restriction for the current method in order to avoid cross-contamination in reading cuvettes and on sampling arm and with the purpose to solve different reagents incompatibilities.

Note: in order to limit constrains to the software and to maintain a good efficiency, the operator must use restrictions only when and where really necessary, without overdoing.

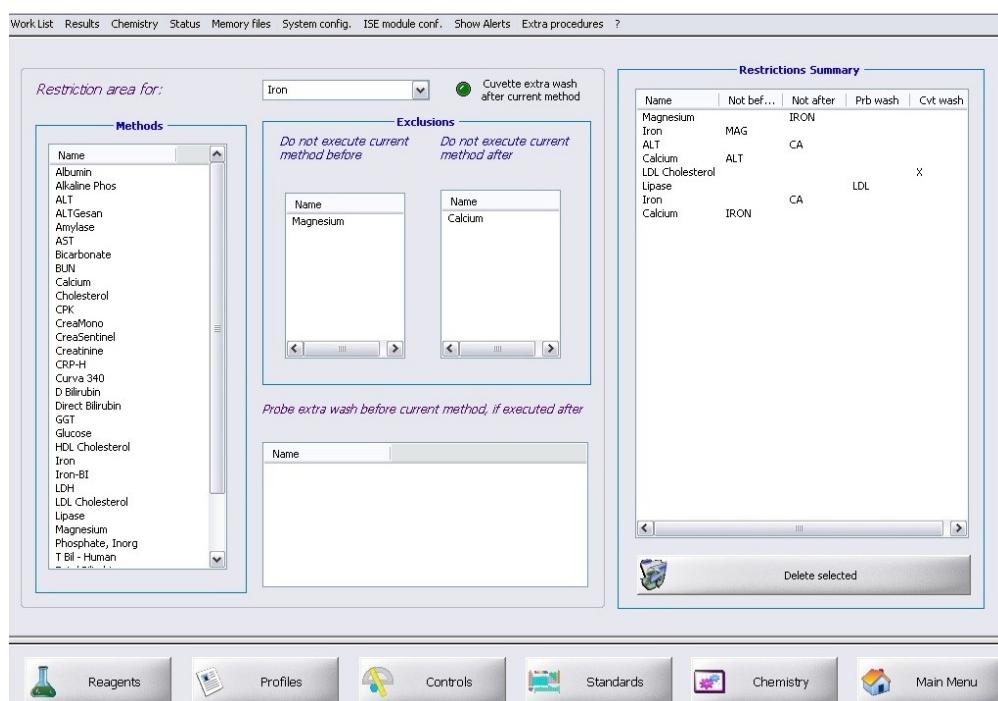


Figure 74: Restriction Menu

Restrictions can be given at three different levels:

- exclusions at scheduling level,
- constrains at cuvette level,
- constrains at probe level.

Exclusions at scheduling level

Those restrictions can be set by two windows named "Don't execute current method before" and "Don't execute current method after" and included in the section "Exclusion". They are valid both at probe level and at cuvette level.

The selected method, whose restrictions refer to, will never be executed *just one test* before the methods listed in the window on the left side: "Don't execute current method before". The selected method, whose restriction refer to, will never be executed *just one test* after methods listed in the window on the left side:



“Don’t execute current method after”. The system will schedule one different analysis in the between. If not possible, the system skips a sampling by running an additional probe washing (at probes level) or skip the cuvette that will be further washed once more (at cuvette level).

To set a new restriction for the current method, the operator must click on a test method in the left side list and must drag it into the wished window.

In the example shown in the previous picture, Iron will never be executed **just one test before** Magnesium and it also will never be executed **just one test after** Calcium.

To delete a restriction, the operator has to click and to drag it out of the window, back into the left side list.

Constrains at Cuvette level

When this selection “Cuvette extra wash after current method” is active, the system automatically skips the cuvette used for the focused method (*contaminant*) and dispenses into it a special cuvette extra washing solution (EW Cvt) placed in the reagent tray. That cuvette will be again available for all other test after washing.

The system saves memory of the previous runs about restrictions.

In the example shown in the previous picture, cuvette used for LDL will be skipped and extra washed.

Constrains at Probe level

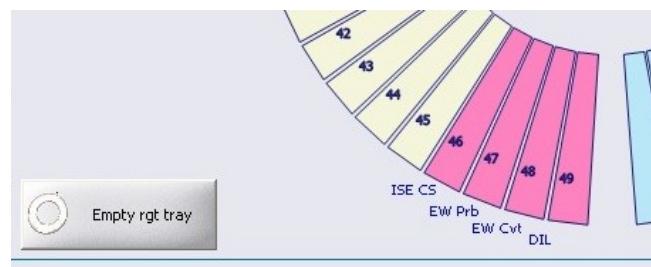
This restriction can be set by the window list named “Probe extra wash before current method, if executed after”. The system, before to run the current method (*contaminated*), will run a probe washing if previously it has been run one or more of the methods included in the window list (*contaminants*). Probe will be washed with a special probe extra washing solution (EW Prb) placed in the reagent tray.

To set a new restriction for the current method, the operator must click on a test method in the left side list and must drag it into the wished window.

In the example shown in the previous picture, probe will be washed if LDL will be sampled before Lipase.

To delete a restriction, the operator has to click and to drag it out of the window, back into the left side list.

Note: when running working session including restriction with constrains at probe level and at cuvette level, the system controls if the reagent tray includes the proper washing solutions (EW Prb – Probe extra washing solution and/or EW Cvt – Cuvette extra washing solution) and alerts the operator in case they are missing.





The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Restriction area for:	a pull-down menu allows the operator to choose the method whose restriction must apply to. Just click and select one of the list of all method previously set as visible.
Methods window:	this column, not editable, includes all methods stored in the system and set as visible.
Cuvette extra washing after current method:	this selection allows the user to set a cuvette extra washing for any cuvette that has been used for the selected method; the extra wash will be performed on-line or anyway at the end of the current run. The operator must provided the EWCvt (extra-washing cuvette) solution on board.
Exclusions section: “Do not execute current method before”:	this window lists the methods that will never be executed just one test before the one whose restrictions apply to. Methods can be added by clicking and dragging them from the left side list into this window. Methods can be deleted by clicking and dragging them from this window into the left side list. This restriction applies both at probe and cuvette level.
Exclusions section: “Do not execute current method after”:	this window lists the methods that will never be executed just one test after the one whose restrictions apply to. Methods can be added by clicking and dragging them from the left side list into this window. Methods can be deleted by clicking and dragging them from this window into the left side list. This restriction applies both at probe and cuvette level.
Probe extra wash before current method, if executed after:	this window lists all methods that, when run before the selected one, cause contamination and interference with it. In that case, the system runs a probe extra washing before to sample the selected method (contaminated) if before at least one method included in the list (contaminant) has run. Methods can be added by clicking and dragging them from the left side list into this window. Methods can be deleted by clicking and dragging them from this window into the left side list. In case of runs including contaminants, the system runs anyway a probe washing at the end of the run even if no contaminated have been programmed; this in order to prevent further interferences in the next runs.
Restriction summary:	this window lists all restrictions set for all of the visible methods.
Commands	
Delete selected:	this command allows the operator to delete a special restriction previously selected in the window Summary of the restrictions.
Reagents:	this command allows the operator to enter the Reagents menu.
Profiles:	this command allows the operator to enter the Profiles menu.
Controls:	this command allows the operator to enter the Quality Control menu.
Standards:	this command allows the operator to enter the Standard menu.
Chemistry:	this command allows the operator to enter the main page of the Chemistry menu, the Method menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



7.1.8. Reagents Menu

By selecting the command *Reagents* in the menu *Chemistry*, the operator enters the menu *Reagents*; it allows the setting up of the reagent tray by assigning methods to the different position on the reagent tray section.

In this menu it is also possible to set reagent bottle Lot number and its expiration date.



Figure 75: Reagents Menu

The right side of this menu shows the configuration of the on-board reagents; positions can be assigned in two different modes:

- manual: the operator must select a method, with the mouse, in the window *Methods* and then, again with the left mouse button, needs to click on one reagent of the window *Reagents* and drag it onto the desired position. If that position is free, the tray configuration is automatically updated; if the position is used, the software asks the operator if to replace the old reagent with the new one or ignore the operation.
- automatic: the operator can automatically update the reagent tray configuration by running a barcode scanning or by using the command *Selection in Tray* (includes all selected parameters) or by clicking on the command *Optimize rgt tray for WL* (includes all parameters scheduled in the next work list).



To remove all reagents loaded on board, the operator has to run the command *Empty rgt tray*.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function												
Methods window:	this window, not editable, shows the list of all methods stored in memory set as <i>visible</i> . The operator can select with the left mouse button one of the methods to display in the window <i>Reagents</i> the associated reagents to place on-board.												
Reagents window:	when the operator selects one method in <i>Methods</i> , this window shows the acronym (code) of the method, the related reagent bottles (R1, R2 and R3) and their lot number. <ul style="list-style-type: none">• For mono-reagents methods only R1 is visualized.• For bi-reagents methods R1 and R2 are visualized.• For three-reagents methods R1, R2 and R3 are visualized. To assign reagent positions on the tray the operator must select, click and drag any reagent bottle from this window onto the reagent tray desired position. It is possible to place more reagent bottles of the same type on the reagent tray only if they have the same <i>lot number</i> .												
Reagent data window:	this window allows the operator to enter or modify the lot number and the expiring date (format: YYYY/MM) for each reagent related to the previously selected method.												
Move rgt tray to:	this command allows the operator to move the desired position of the reagent tray to the front side of the instrument.												
Reagent text summary:	this command gives the situation of the reagents on-board. It displays a special window listing the volume left for any reagent on the tray based on the last sampling operation. This list can be printed out.												
Scan rgt barcodes:	this command, active only with Barcode option, allows the operator to run the automatic scanning of the reagents' barcode; this has meaning only in case the reagent bottles have been labelled with a barcode. By running this command, the system scans all reagent positions in order to read all barcodes. At the end, each position of the reagent tray will be associated to a valid barcode, if any, or marked by the system. One of the following possibilities (colors) can be associated to each position: <table><thead><tr><th>Color</th><th>Description</th></tr></thead><tbody><tr><td>• White:</td><td>Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);</td></tr><tr><td>• Cyan blue:</td><td>Rgt R1 position used by an R1 position;</td></tr><tr><td>• Purple:</td><td>Rgt R2 position used by an R2 position;</td></tr><tr><td>• Blue:</td><td>Rgt R3 position used by an R3 position;</td></tr><tr><td>• Orange:</td><td>Unknown position used by an unknown reagent (its barcode has</td></tr></tbody></table>	Color	Description	• White:	Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);	• Cyan blue:	Rgt R1 position used by an R1 position;	• Purple:	Rgt R2 position used by an R2 position;	• Blue:	Rgt R3 position used by an R3 position;	• Orange:	Unknown position used by an unknown reagent (its barcode has
Color	Description												
• White:	Free position free and ready to be used or position used by an unknown reagent bottle (barcode cannot be read because damaged or missing);												
• Cyan blue:	Rgt R1 position used by an R1 position;												
• Purple:	Rgt R2 position used by an R2 position;												
• Blue:	Rgt R3 position used by an R3 position;												
• Orange:	Unknown position used by an unknown reagent (its barcode has												



Field/Command	Function
	been read and understood but the method is not included in memory); <i>Unreadable</i> position used by a bottle without barcode or with unreadable barcode (i.e.: condensation, damaged, ...); <i>No lot</i> position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot number, that has to match with that provided on the reagent bottles); <i>Diluent, or solution for processing</i> diluent solution (distilled water or physiologic solution) used for sample and standard dilutions. Solution for processing are: EW Cvt (Extra Washing for cuvette), EW Prb (Extra Washing for Probe), ISE Cs (ISE Module Cleaning Solution), ISE UD (ISE Module Urine Diluent).
Selection in tray:	At the end of the barcode scanning, the reagent tray configuration is updated with the new data (and can be anyway manually changed). this command allows the system to place automatically on to the reagent tray any group of reagents, previously selected , in the reagent window. The multiple selection of more samples is possible following the typical Windows® mode: <ul style="list-style-type: none">• Selecting a range of samples: click with the left mouse button on the first sample of the desired range and then, at the same time press the key SHIFT and click again on the last sample of the range ==> the range is then selected.• Selecting more discrete samples: press the key CTRL and at the same time click with the left mouse button on all sample to be selected. After selection, the operator presses the command and the system will assign positions to the reagent bottles starting from the first position free. In case of more bottles of the same type on the tray, the system asks for confirmation.
Optimize rgt tray for WL:	this command allows the system to automatically place on to the reagent tray all of the reagents scheduled for the Work List, and to clear positions from the other reagents not used. this command allows the operator to clear all reagent tray positions.
Empty rgt tray: Commands	Methods: this command allows the operator to enter the Methods menu. Profiles: this command allows the operator to enter the Profiles menu. Controls: this command allows the operator to enter the Quality Control menu. Standards: this command allows the operator to enter the Standard menu. Main Menu: this command allows the operator to go back to the Main Menu.



7.1.9. Profiles Menu

By selecting the command *Profiles* from the menu *Chemistry*, the operator enters the menu *Profiles*; it allows to program new profiles of analysis and to modify the existing ones.

A profile is a set of tests or methods that the operator can group in order to speed Work List compilation; in fact a profile can be easily recalled and associated to a sample during with only one mouse click operation.

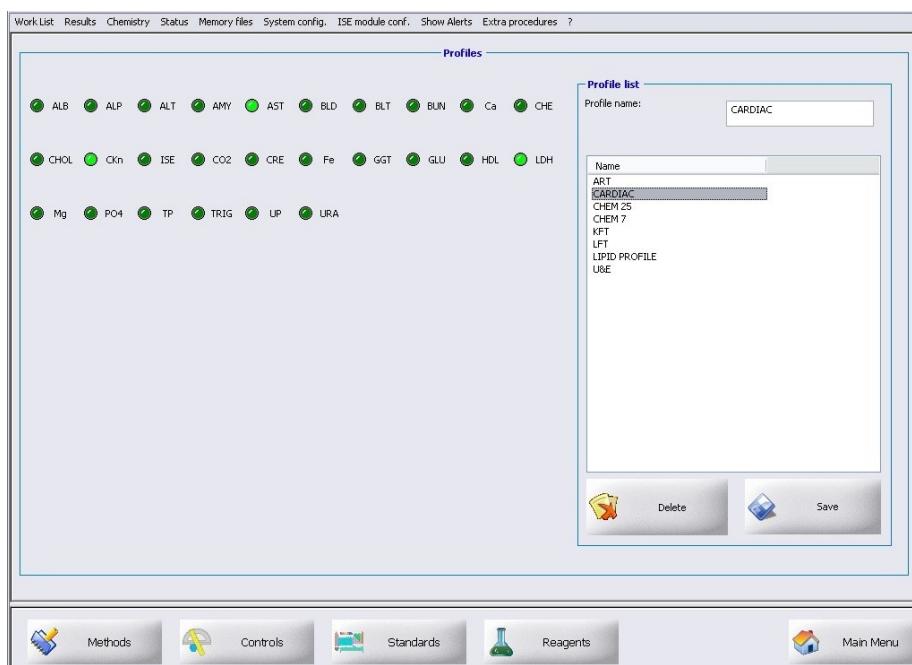


Figure 76: Profiles Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Profiles – Method selection:	in this menu it is possible to select the methods to include in a profile. The selection of the methods made by the operator it is evident by the followings colours: 1) Light green → the method is selected to be included into a profile; 2) Dark green → method is not selected.
Profile List section	
Profile name:	this alphanumeric field allows the operator to introduce the profile name.
Profile List window:	this field shows the list of profiles in memory related to the focused panel. When the operator selects a profile with the left mouse button, the panel shows the methods associated with that specific profile; it is possible to change a profile by modifying the selected methods and by saving it with the command Save.
Delete:	this command allows the operator to delete the selected profile.



Field/Command	Function
Save:	this command allows the operator to save a profile that has been created or modified.
Commands	
Methods:	this command allows the operator to enter the Methods menu.
Controls:	this command allows the operator to enter the Quality Control menu.
Standards:	this command allows the operator to enter the Standard menu.
Reagents:	this command allows the operator to enter the Reagents menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



7.1.10. Standards Menu

The operator can enter the *Standards* menu by selecting the command **Standards** in the menu *Chemistry*. This menu allows the operator to **manage calibrators and standards** for all stored methods that have been set as “visible”. In special fields included in this menu it is possible to load the values of the standards or the factors for each method, to fix the number of replicates (if one or three – for triplicate) for each standard and its stability on board. Standards and calibrators can be placed in any position within the sample tray section, so they do not have any fixed position.

For each method it is possible to choose if calibration has to be performed on a single standard (**mono-standard**) or on more standards (**multi-standard**); multi-standards can include successive auto-dilutions of the concentrated standard with the purpose to generate a Calibration Curve. Hence, dilutions of the standard can be automatically performed by the instrument; the operator can anyway use kits of ready-to-use (pre-diluted) standards without enabling, in this case, the auto-dilution in the instrument.

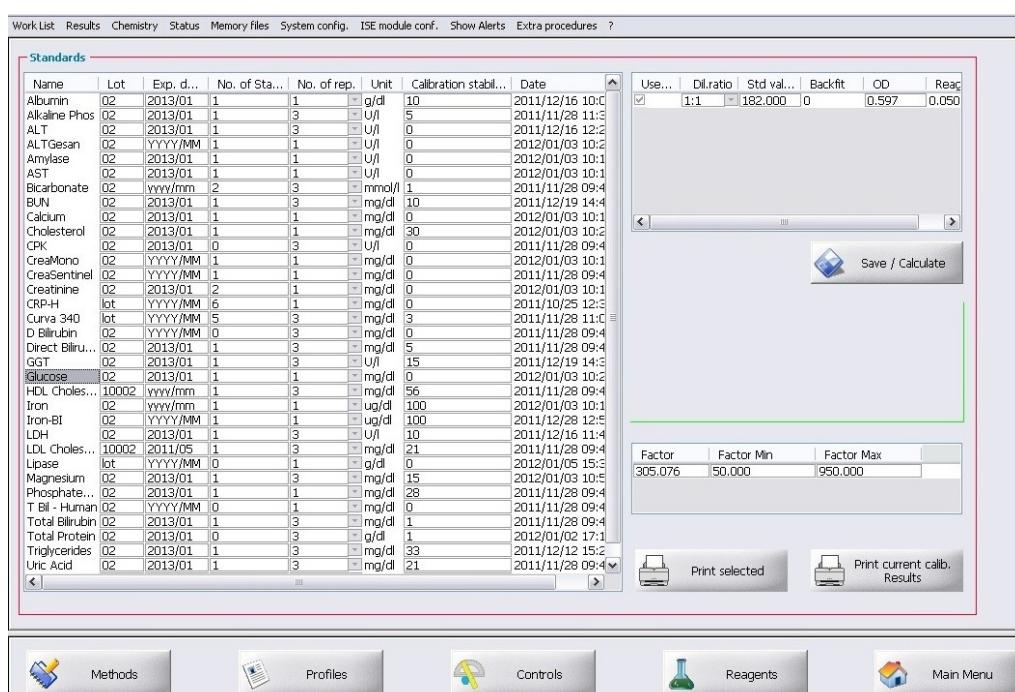


Figure 77: Standards Menu – Mono-standard example

The operator can choose if performing the calibration of the method or to assign it a fixed Factor [**F**]. In the first case the operator runs the standardization of some methods and the previous factor in memory will be overwritten by the new



measured value (the program gives evidence of actual standardization date and time). In the latter case that method works against factor.

To enable the calculation of the factor the operator must have previously introduced the value of the standard; when the operator runs a working session, the instrument informs about eventual lack of the factor in memory or about the lack of the value of the standard. Thus, before to run a working session, the operator must be sure that he has assigned the correct standard value or factor to each of the method to be used: at the Start **the system doesn't enable methods without factor or without standardization to be run**.

The system lets the operator choose if performing the standard just once (choose "1") or three times - triplicate (choose "3"); in the latter case, the final value is given as the average of the two nearest values with the exclusion of the farthest one.

Note: when the operator is setting calibration curves he has to introduce the standard values, and then dilution ratios, for each of the standard in "decreasing order" by descending (from top down): that means, the greatest value on the top (i.e.: concentrated) to the lowest on the bottom (i.e.: saline at zero concentration).

This menu allows the operator to show the calibration curves obtained and for some of them also the equation and R².

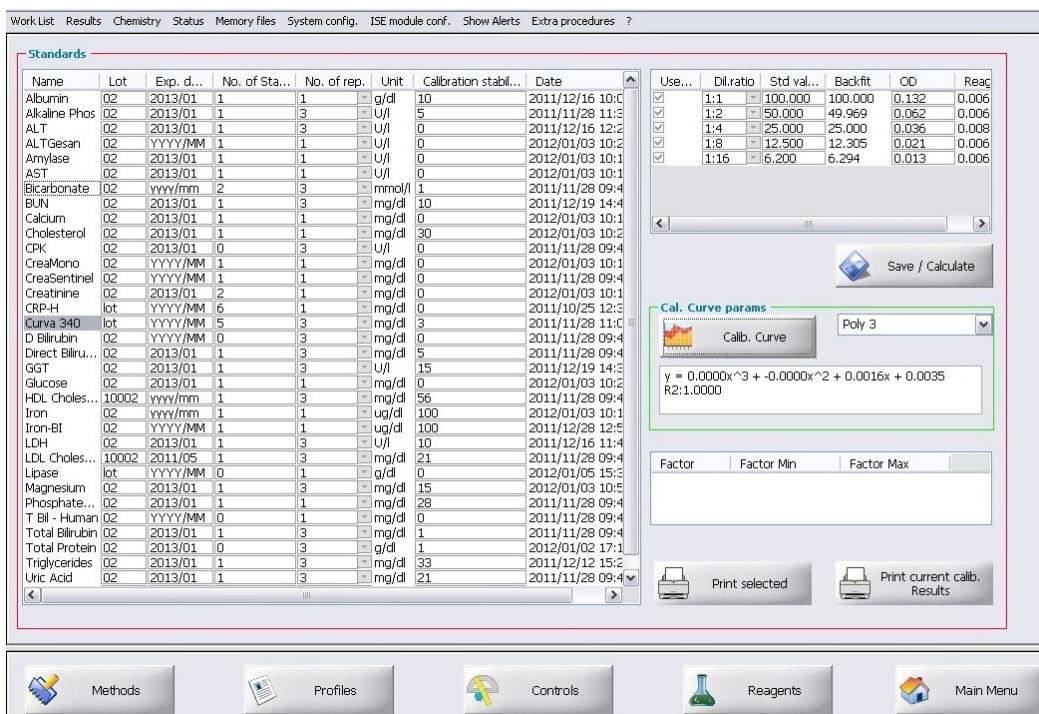


Figure 78: Standards Menu – Multi-standard example

The operative fields and the operational commands included have the following meaning:



Field/Command	Function
Name:	this field, not editable, shows all methods, set in memory as visible.
Lot:	this field allows the operator to set the Lot number of the standard/calibrator.
Exp. date (YYYY/MM):	this field allows the operator to set the expiration date of the standard/calibrator.
Nr. of Standards:	this numeric fields allows the operator to introduce the number "n" of the standard/calibrator to perform. "n" ranges between 0 and 8. Mono-standard=1. Calibration curves allowed from 2 to 8 points. No calibration =0 that means the method works only against factor.
Nr. of Rep.:	this field, by the pull down menu, can be set to 1 or to 3. It allows the operator to introduce the number of repetitions of the standard measurement: if equal to three, the final O.D. value is then calculated as the average of the nearest two measurements.
Unit:	this field, not editable, shows the unit of measurement assigned to the method.
Calibration Stability:	this numeric field allows the user to set the number of days of calibration stability. When starting a working station, the system checks these fields for the methods included in the work list and, in case some of these limits has been overcome, it alerts for calibration expired and it will not schedule that particular method. Then the user has to include the calibration in the work list to run the locked method. Introducing "0" in this field, the system will skip such a control by ignoring it.
Date:	this field, not editable, shows the date when the factor has changed (calibration performed) or has been manually modified.
Standard value section	
This section is active only in case of Nr. of Standards $n \geq 2$, multi-standard.	
It shows as many rows as the number set in the field Nr. of Standards. In case of Nr. of Standards $n=1$, mono-standard, the row is one only. Each row includes the following fields.	
Used in calc:	the check-boxes under the column "Used in Calculation" give the user the possibility to choose how many points of a calibration curve should be used in the evaluation of a patient result. Two main reasons could justify this choice: <ul style="list-style-type: none">- necessity to pre-dilute an highly concentrated calibrator without using the first point to compute the results (no higher concentration standard needed in the calculation);- opportunity to skip points showing large "backfit" difference. By default this field is automatically set (checked) to keep the compatibility with previous versions.
	This parameter doesn't affect the real execution of the standard curve. All of the points will be always read by the instrument. This flag defines only the points used in the "formula".
	The selection of the points can be done before the standard executions or after, when results have been measured.
Dil. ratio:	this pull down menu allows the operator to select the needed dilution ratio from the concentrated standard (mother). The operator can select a ratio for any row of the table associated with a position on the tray. The following dilution ratios are provided: 1:1, 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:16, 1:20, 1:30, 1:40, 1:50, and 1:100. In case of Master Curves or pre-diluted standards, that doesn't need



Field/Command	Function
	automatic dilution by the instrument, and whose dilution ratios aren't included in the default values (see pull down menu), the operator must leave the value 1:1 and the system calculates the proper value on its own. When the ratio is set to 1:1, the system expects to find a ready-to-use standard in some of the sample tray positions. For ratios else then 1:1 the system will perform the in-cuvette dilution based on the concentrated standard that must be placed in one position of the sample tray. When setting calibration curves the operator has always to write dilution ratios (if different from 1:1) and then standard values, in decreasing order by descending (from top down): that means, the greatest value on the top (i.e.: concentrated) to the lowest on the bottom (i.e.: saline at zero concentration).
Std value:	the numeric field of this column allow the operator to introduce the value for each standard of the calibration curve. The following consideration are valid: <ul style="list-style-type: none">• the operator must always introduce the value of the concentrated standard (1:1);• the values of the other diluted standards are automatically calculated and introduced by the system when the operator introduces the dilution ratio;• when the operator makes use of pre-diluted standard kits (whose calibration curve is already given), that means: kits having particular dilution ratios for which the instrument <i>isn't</i> requested to perform the automatic dilution, values of standards must be introduced manually from the operator and the dilution ratios (Dil. Ratio) must be left equal to 1:1.• in case of master-curves, the operator can set concentration values, O.D. values and without the need to run standardization (he needs anyway to set positions). When setting calibration curves the operator has always to write standard values, and then dilution ratios (if different from 1:1), in decreasing order by descending (from top down): that means, the greatest value on the top (i.e.: concentrated) to the lowest on the bottom (i.e.: saline @ zero concentration).
Backfit:	this field shows the concentration value corresponding to the point of the calibrator interpolated in the measured calibration curve. This is a read-only parameter and it can be evaluated for each curve model selecting the model and clicking on the button Save/Calculate.
O.D.:	the fields of this column, not editable, will be automatically updated by the instrument with the result values, given in absorbance (OD), and obtained from the last standard measurement. These fields can be anyway modified by the operator to build a calibration curve.
Reagent blank:	the fields of this column, not editable, will be automatically updated by the instrument with the absorbance value (O.D.) obtained as the reagent blank measurement on the cuvette with its reagent and without the sample (standard).
Save/Calculate button:	this button is required to save the information related to the standard

**Field/Command****Function**

values, dilution ratio or OD. Any modification will be discarded if this button is **not** pressed to validate inserted values. Furthermore the button evaluates backfit and equation for a new selected curve model.

Calculate Curve Parameters section

Calc. Curve params selection:

this pull down menu, active for "n" ≥ 2 (multi-standard), allows the user to select the algorithm to be used for the calibration curve generation; each selection becomes active upon saving the method. Actual calibration curves includes: Linear regression, Cubic spline, Piecewise linear, Logit/Log 4-parameters, Polynomial 2-parameters, Polynomial 3-parameters and Polynomial 4-parameters.

Calc. Curve params window:

this field shows the evaluated equation related to the chosen curve model. It is read-only and it is available only for Linear regression, Poly2, Poly3, Poly4 and Piecewise Linear.

Calib. Curve button:

this command gives the user the opportunity to display the calibration curve (only when already existing in memory).

Factor value section

This section is active only in case of Nr. of Standards n=0 or n=1, mono-standard.

Factor:

this field represents the factor of the methods only in case of mono-standard. It can be filled or modified by the operator or it comes out as result of a calibration (in the first case the reagent blank is 0 in the latter it has its real measured value). The factor is stored in memory until to the next measurement or modification. After standardization, the content of this field is overwritten and automatically updated by the system: the result is then calculated on the base of the measurement of the standard itself.

The following considerations are valid:

- when, for a method to be run in Work List, the factor is equal to 0 and its standardization has not been included in the Work List itself, the instrument alerts the operator about this condition: the operator must then introduce in the Work List the standard value (or the factor in case he will not run standardization).
- when needed, the value of the standard must be introduced **with its proper sign** (depending on the reaction trend) to allow the correct calculation of the final result: positive number for kinetic tests and for fixed time test stands for method with increasing trend (the sign "+" can be omitted), negative number (the sign "-" must be included) stands for a method with decreasing trend.

Factor min:

this field allows the user to introduce the minimum reference value for the factor admissible range (in case this control is enabled).

Factor Max:

this field allows the user to introduce the maximum reference value for the factor (in case this control is enabled). This limit, together with the Factor min, states the **factor acceptable range**. If the result of the standard is out of range, all the results of this method are back-light marked and noticed as Out of Calibration.

By writing a value in one in this field or in the previous one, this control is enabled.

If the Factor max or both of these values are **left equal to 0**, the control on the range is skipped and then **disabled**.

Commands



Field/Command	Function
Print Current Calib.	This command allows the operator to print all current calibrations and factors.
Results:	this command allows the operator to enter the <i>Methods</i> menu.
Methods:	this command allows the operator to enter the <i>Profiles</i> menu.
Profiles:	this command allows the operator to enter the <i>Quality Control</i> menu.
Controls:	this command allows the operator to enter the <i>Reagents</i> menu.
Reagents:	this command allows the operator to go back to the <i>Main Menu</i> .
Main Menu:	



7.1.10.1. Calibration Curve

Multi-standard methods make use of a calibration curve for extrapolation of results at different standard concentrations. The Methods menu includes the command Calibration Curve that allows the visualization of the Calibration Curve plot, OD values vs. Concentration. This graph is related to the concentrations, that have been set in the relevant section (when already existing in memory), and to the related ODs. For the determination of the curve interpolating the Concentration/OD couple of points, one of the following algorithms can be chosen: Linear regression, Cubic spline, Piecewise linear, Logit/Log 4-parameters, Polynomial 2-parameters, Polynomial 3-parameters and Polynomial 4-parameters.

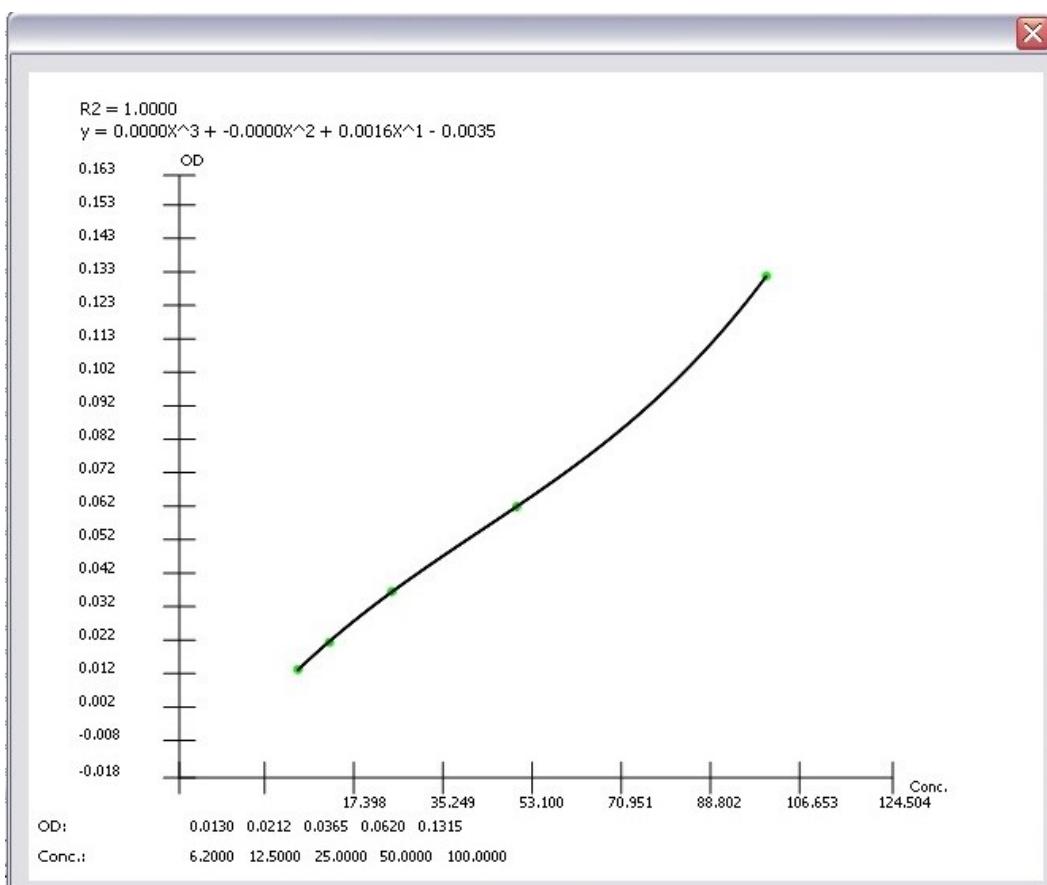


Figure 79: Calibration Curve



7.1.11. Quality Control Menu

The operator can enter the *Quality Control* menu by selecting the command *Controls* in the menu *Chemistry*. It allows the management of the Quality Control serum values and parameters.

In this menu it is possible to introduce the values of the control sera for each of the methods in memory and the related identification data; for each of the controls, the system provides the Levy-Jennings graph for visualization over three levels of the fifty last values (one for every solar day, the last one in case of more measurements in the same day).

The user can set one, two or three QCs depending on his needs (i.e.: Abnormal low, normal, abnormal high).

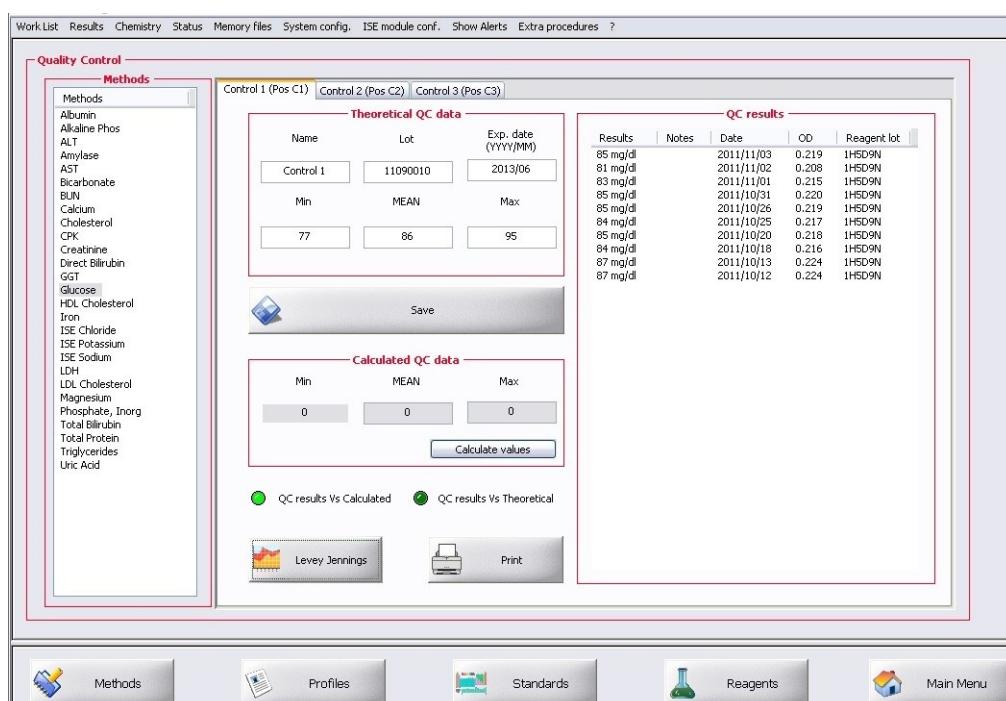
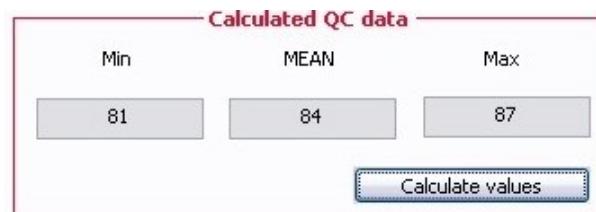


Figure 80: Quality Control Menu

The operator can switch between “QC vs. theoretical data” and “QC vs. real” calculated on the real data limits of the window QC results (standard deviations, means, etc.) to monitor the system performance trend with higher flexibility.

By clicking on the command *Calculate values* the system computes the Real QC data over the values displayed on the results shown into the side window.





The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Methods section	
Methods:	this column, not editable, lists all methods set in memory as "visible"; when the operator selects one of the listed methods, the system displays the data of its controls on the right of this menu.
Control 1 (Pos C1) section	
Theoretical QC data sub-section	
Name:	this alphanumeric field allows the operator to introduce the name of the control.
Lot:	this alphanumeric field allows the operator to introduce the lot number of the control. The operator must introduce always the lot number for each control otherwise the system does not consider that control as valid and it doesn't save it.
Exp. date (YYYY/MM):	this alphanumeric field allows the operator to introduce the expiring date of the control. The format of this field is YYYY/MM where, <ul style="list-style-type: none">• YYYY is the year (i.e.: 2012)• MM is the month (i.e.: 03 for March)
Min:	this numeric field allows the operator to introduce the <i>minimum</i> value of the control (to be deduced from the technical sheet following the kit). It corresponds to the <i>nth</i> standard deviation specified in the methods parameters. The operator must introduce always the minimum value for each control otherwise the system does not consider that control as a valid one; this value can be equal to 0.
MEAN:	this numeric field allows the operator to introduce the <i>mean</i> value (or the Theoretical Value) of the control (to be deduced from the technical sheet following the kit). The operator must introduce always the mean value for each control otherwise the system does not consider that control as a valid one; this value cannot be equal to 0.
Max:	this numeric field allows the operator to introduce the <i>maximum</i> value for the control (to be deduced from the technical sheet following the kit). It corresponds to the <i>nth</i> standard deviation specified in the methods parameters. The operator must introduce always the maximum value for each control otherwise the system does not consider that control as a valid one; this value cannot be equal to 0.
Calculated QC data sub-section	
Min:	this numeric field is automatically filled by the system and shows the operator the <i>minimum</i> value for the control (calculated over all of the QC results as the <i>nth</i> standard deviation fixed in the method). The calculation is performed by activating the command Calculate



Field/Command	Function
MEAN:	<p>values. The system can perform meaningful calculations only when the QC results are ≥ 2.</p> <p>this numeric field is automatically filled by the system and shows the operator the average value for the control (calculated as the mean over all of the QC results).</p> <p>The calculation is performed by activating the command Calculate values.</p> <p>The system can perform meaningful calculations only when the QC results are ≥ 2.</p>
Max:	<p>this numeric field is automatically filled by the system and shows the operator the maximum value for the control (calculated over all of the QC results as the n^{th} standard deviation fixed in the method).</p> <p>The calculation is performed by activating the command Calculate values.</p> <p>The system can perform meaningful calculations only when the QC results are ≥ 2.</p>
Calculate values:	<p>this command allows calculation of Min, Average and Max values over all of the QC results shown into the window aside. When activated the system shows the values.</p>
Selections	
QC Results vs. theoretical:	<p>this selection allows the operator to display in the Levy-Jennings graph the values given in the technical sheet of the QC serum used:</p> <ul style="list-style-type: none">• $\min (-n^{\text{th}} \text{ SD}, n=1 \div 3)$,• mean,• $\max (+n^{\text{th}} \text{ SD}, n=1 \div 3)$.
QC Results vs. real:	<p>this selection allows the operator to display in the Levy-Jennings graph the values calculated over the real results coming from the QC serum measurements of the instrument.</p> <ul style="list-style-type: none">• $\min (-n^{\text{th}} \text{ SD over all of the results}, n=1 \div 3)$,• average (mean value over all of the results),• $\max (+n^{\text{th}} \text{ SD over all of the results}, n=1 \div 3)$.
Commands	
Save:	<p>this command allows to save the QC values entered by the operator and deduced from the technical sheet following the QC serum kit.</p>
Print:	<p>this command allows the operator to print all of the QC results in Controls History. The program asks the operator to include or not the Levy-Jennings graph.</p>
Levey Jennings:	<p>Depending on the selection QC Results vs. theoretical or QC Results vs. real, the graph will show theoretical values or calculated values for the $\min (-n^{\text{th}} \text{ SD}, n=1 \div 3)$, theoretical and $\max (+n^{\text{th}} \text{ SD}, n=1 \div 3)$.</p> <p>this command allows the operator to display the Levy-Jennings graph. The graph includes the last 50 values, one for each day; if more measurement of the same quality control are carried out in one day, the system graphs only the last one of that day.</p> <p>Depending on the selection QC Results vs. theoretical or QC Results vs. real, the graph will show theoretical values or calculated values for the $\min (-n^{\text{th}} \text{ SD}, n=1 \div 3)$, theoretical and $\max (+n^{\text{th}} \text{ SD}, n=1 \div 3)$.</p>

Control 2 (Pos C2) section



Field/Command	Function
	as per Control 1 (Pos C1) section but for C2 control data.
Control 3 (Pos C3) section	as per Control 1 (Pos C1) section but for C3 control data.
QC Results section	This window shows results got from QC measurement and plotted on the Levy-Jennings graph; the results are automatically deleted any time that the lot number of the QC serum is changed. All results are anyway stored in the Memory Files menu under Std/QC Archive sub menu.
Results:	this column, not editable, shows the results of measurements carried out on QC sera.
Notes:	this column, not editable, shows the notes related to each result carried out on QC sera.
Date:	this column, not editable, shows the date of each result carried out on QC sera.
OD:	this column, not editable, shows the measured OD carried out on QC sera.
Reagent lot:	this column, not editable, shows the lot number related to the reagent used for QC measurement.
Other commands	
Methods:	this command allows the operator to enter the Methods menu.
Profiles:	this command allows the operator to enter the Profiles menu.
Standards:	this command allows the operator to enter the Standard menu.
Reagents:	this command allows the operator to enter the Reagents menu.
Main Menu:	this command allows the operator to go back to the Main Menu.

7.1.11.1. QC and Levy-Jennings Graph

For each of the three QCs that can be set and run for each method, the command View Levy-Jennings allows the visualization of the graph of Levy-Jennings on three levels.

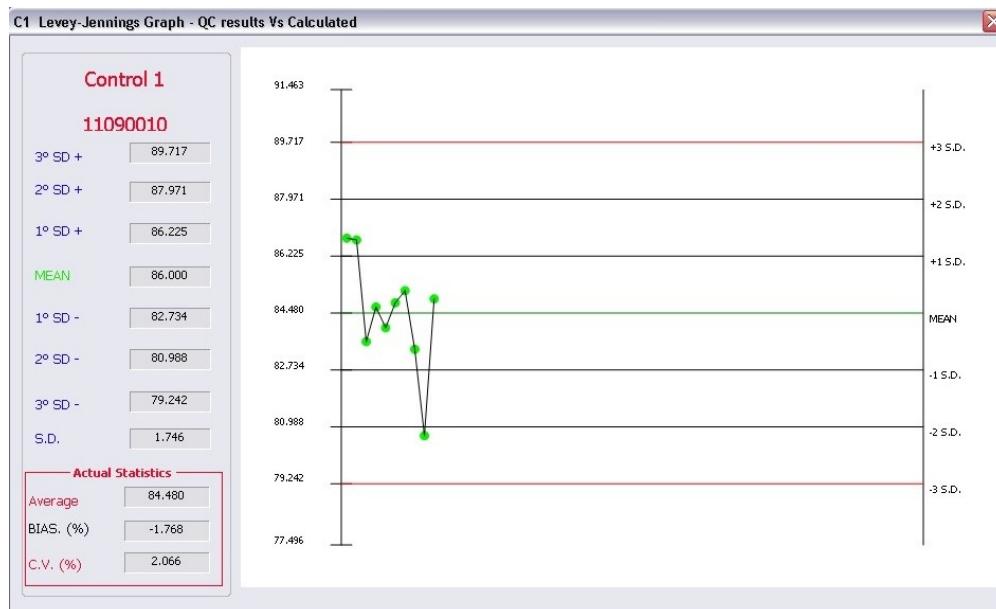


Figure 81: Levy-Jennings Graph

Within the graph, the system plots a straight line crossing the theoretical (or mean) value, and others correspondent to $\pm 1\text{SD}$, $\pm 2\text{SD}$ and $\pm 3\text{SD}$. The limits (*min* and *max*) given for each method will be correspondent to the standard deviation coincident with the parameter that have been set for that particular methods. The last 50 values depending on the same lot (one only for each day – the last one in case of more) are drawn on the graph; any new value introduced causes the exclusion of the oldest of the 50 values.

Depending on the selection QC Results vs. theoretical or QC Results vs. real, the graph will refer respectively to “theoretical values” or to “calculated values”.

	QC Results vs. theoretical	QC Results vs. real
min (-nth SD)		
average (mean)	deduced from technical sheet for QC serum	calculated over QC serum measurement results
max (+nth SD)		

When the result of a control falls within the range (*min* – *max*) given for that QC, the system is considered statistically under control and the results of the working session can be considered valid; that value is displayed in green colour on the graph.

When the result of a control exceeds the range or “limit of action”, the system is statistically out of control for that method and that value is displayed in red colour on the graph. The system then does not perform the analyses related to the method, in the Status menu the reagent of that method becomes red and it is given the operator the possibility of:



-
1. to abort and to quit all the analysis of that method;
 2. to repeat the control measurement;
 3. to perform however the analysis related to that method by ignoring the problem under his responsibility.

When for one given method the system becomes out of control, the software informs the operator about a "Reagent problem" by colouring with red, in the Status menu, the position of the related reagent/s.

WARNING

When the system informs the operator that a method is out of control, he must repeat the analysis related to that method after having identified and solved the cause of the problem.

WARNING

When the result of a control exceeds the 2nd standard deviation ($\pm 2SD$) or "limit of alarm", this means that in the system something is not correctly working or tends to go out of control and the operator has to inspect the system (reagents and/or instrument).



7.1.12. Results by Patient Menu

The operator can enter the *Results by Patient* menu by selecting the command **Results** in the **Main menu**. It shows the results for the analyses of each sample (patient). Results are related to the Work List in progress or also to the last one performed when not yet stored.

In this menu, by the upper left pull down menu, the operator can choose the patient whose results have to be displayed; the operator, after validation of results, can decide if:

- **to print results**, to store results in archive or to delete a patient with the related results;
- to delete only some results for any single sample;
- **to repeat** one or more analyses for any single sample;
- to print results, to file results in archive or to delete **all** patients and the related results;
- to export all results into a file;
- to print a compact laboratory report showing the displayed results.

Note: before to modify parameters of an existing method, patient results for that particular method must be previously archived (filed in memory) and Standard and QC results too.

The screenshot shows the 'Results by patient' screen. At the top, there's a dropdown menu showing '2 - 0002-20120110 Unknown (Serum Male)'. To the right is a 'Patient private data' icon. Below the menu is a table with columns: Method, Status, Result, Reference ..., Flags, O.D., Reagent bl..., Fit, and Single OD readings. The table lists various analytical methods with their results and status. At the bottom of the screen are several buttons: 'Store concluded', 'Print patient report', 'Delete', 'Send results to LIS', 'Repeat selected', 'Export concluded results', 'Print lab report', 'Results by methods', 'QC / Std Results', 'Repetitions', 'Status', and 'Main Menu'.

Figure 82: Results by Patient Menu



Note: results that are out of range or that have been detected as abnormal by the system or that are out of some internal automated controls (substrate depletion, linearity, detection limit, etc.) will be automatically highlighted in red or in orange to be easily recognized by the operator during the result validation. This automated feature doesn't dismiss the responsible of the final validation from his full duties and controls for results interpretation.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Patient/Sample field	
Pull down menu:	this not editable pull down menu, shows all patient in the sample tray and allows the selection of each of them in order to show its results.
Results window	
Method:	this column, not editable, shows the test methods for the selected sample that are in scheduling or that have been already processed. This field is printed in the result report. It also gives evidence of eventual dilution ratio for that analysis and about its order of repetition (if any).
Status:	this column, not editable, shows the progress of any single analysis for the selected sample. This field is not printed on the report. The following conditions are possible: <ul style="list-style-type: none">• concluded, test has been concluded;• in process, test is in progress;• to begin, test has to begin (repetitions);• aborted, test has been aborted;• in error, system in error – the results is not reliable;• to repeat, test has been chosen to be repeated.
Result:	this column, not editable, shows the final result and the unit of measurement for each analysis that has been completed. This field is printed on the report. Results that are not congruent (i.e.: negative) will be shown with a series of stars (*****). When entering this page results are updated related to the actual Factor.
Reference range:	this column, not editable, shows the lower and the higher limits of the normal result range set in the Methods Menu. This field is printed on the report.
Flags:	this column, not editable, shows eventual notes related to the result (i.e.: like when it is out of normal range). This field is printed on the report; in case of some annotations the method is printed in bold characters and the operator has to evaluate the result. This field shows: <ul style="list-style-type: none">• the capital letter "H", In case of result above the normal range (this flag is printed also on the patient report),• the capital letter "L" in case of result below the normal range (this flag is printed also on the patient report),• the capital letter "M", In case the result has been manually modified by the operator (this flag is not printed on the patient report),• the capital letter "T", In case the result has been transmitted by the L.I.S. (this flag is not printed on the patient report).
OD:	this column, not editable, shows the final raw value measured and

**Field/Command****Function**

Reagent blank:	expressed in absorbance (OD). This field is not printed on the report. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Fit:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD). This value is measured by the instrument on any single reading cuvette filled with reagent just before to dispense the sample in case of sample start tests. This field is not printed on the report. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Single OD readings:	this column, not editable, shows the value of the fit (squared correlation factor) calculated on the linear regression for kinetic methods. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
	This column, not editable, shows each single OD value read for Kinetics (during the reading time), for Fixed Time methods (first and second values) or for Differential Sample Blank mono and bi-chromatic (first and second values). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.

Pop-Up Menu - right mouse button on the selected test result

View Extended details:	in case one result is out of normal range or it has been highlighted in orange or red, select it with the left mouse button then click on the selection with the right mouse button and select View Extended details on the pop-up menu: detailed information about the results, if any, will be displayed.
Delete:	select one or more analyses to be deleted with the left mouse button, then click on the selection with the right mouse button and select Delete on the pop-up menu: results selected are deleted.
View Kin/Fixed Time graph:	in order to show the graph of Kinetic or Fixed Time methods, select one analysis with the left mouse button, then click on the selection with the right mouse button and select View graph on the pop-up menu: the single ODs will be plotted into a graph.
Repeat:	select with the left mouse button one or more analyses to be repeated, then click on the selection with the right mouse button and select Repeat on the pop-up menu: the selected analyses will be moved to the Repetitions menu. In that menu the operator can re-run, within the actual working session or later, that particular analysis by selecting a different and proper new dilution ratio (if needed). A different dilution ratio for each analysis of the same sample can be chosen. Dilutions are performed in cuvette.

Commands

Patient Private Data:	this command opens a window whose fields can be filled with the personal and administrative patient data at any moment.
Store concluded:	this command opens a special window that allows the operator to file in the archive a range of patients, whose analyses have been concluded.





Field/Command	Function
Print patient report:	this command opens a special window that allows the operator to print the results' report for a range of patients.
Delete:	this command opens a special window that allows the operator to delete a range of patients; deleted patient results will not be saved in archive.
Send results to LIS:	in case the L.I.S. connection (Laboratory Information System) has been enabled in the system, this command is active and when clicked it opens a special window that allows the operator to select a range of patients whose results will be send to the host computer.
Repeat selected:	select with the left mouse button one or more analyses to be repeated, then click on the command Repeat selected: the selected analyses will be moved to the Repetitions menu. It acts like the previous command Repeat in the pop-up menu.
Export concluded results:	this command allows the user to export results of all concluded analyses into files. See " Results and Methods Exported File " paragraph of this manual for format and location of exported files.
Print lab report:	This command opens a special window that allows the operator to print all results of a range of patients, sorted and grouped by IDcode, in a compact report.
Results by method:	this command allows the operator to enter the Results by method Menu.
Q.C./Std Results:	this command allows the operator to enter the Q.C./Std Results Menu.
Repetitions:	this command allows the operator to enter the Repetitions Menu.
Status:	this command allows the operator to go back to the Status Menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



Note: the "Export result concluded" command generates a file, on User request, that can be used by external software for data handling. The User can export results for treating data on his own under his responsibility (it can be used in case of L.I.S. connection is missing).

Note: the system, in order to limit the database dimension, automatically generates other files to be considered as back up of the oldest data there exported.



7.1.12.1. Kinetics and Fixed-Time Methods OD graph

This graph can be displayed by the pop-up menu (View Kin/Fixd Time graph) after selecting an analysis result in Result for Patient menu (w/mouse right click).

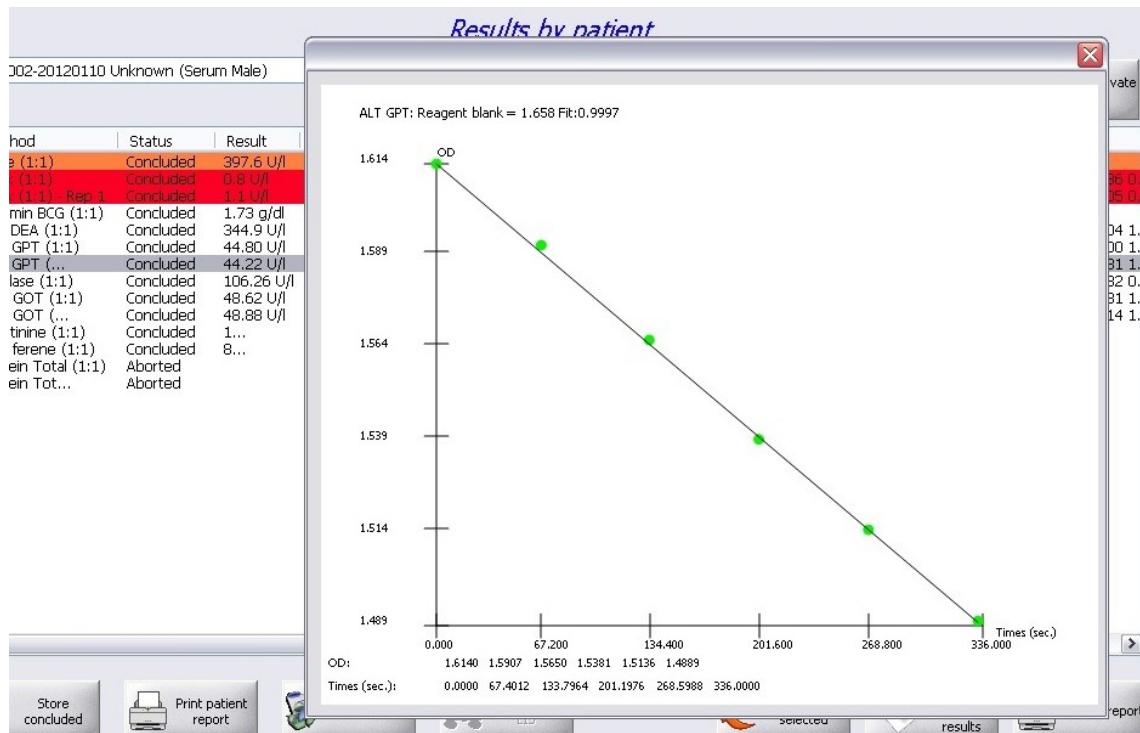


Figure 83: Kin/Fixd Time graph

This pop-up menu shows Kinetics or Fixed Time read ODs vs. time in graphical mode, by plotting them on 2-axes. On Y-axis OD readings are shown, on X axis reading time is plotted. On top of the window the correlation coefficient will be shown.



7.1.12.2. Results and Methods Exported Files

The command *Export concluded results* in Result for Patient menu gives the operator the possibility to export the results and the list of methods into files. In fact, the “Export Concluded Results” command automatically generates a file including the results of all concluded patient analysis of the actual or last working session.

As well, the Memory Files Menu provides the “Export” command, that allows exporting of the results given by the sorted research.

Moreover, any time that the operator saves or deletes a method, the system generates automatically a file listing all of the methods stored. This file over-writes the previous one.

These files are exported into a special folder (“exported results”) for user handling; they can be copied on a media or accessed by an host computer when, in example, the managing PC has been connected into a LAN.

In case that the Personal Computer has been included into a LAN, the “**ExportedResults**” folder can be “shared” in the network in order to allow an host computer to download and treat the file itself.

The exported files are *.csv type.

Program root folder

ProgramRoot = %ROOT% \BCA

Location and Format of the Result Export file

This file includes the working session concluded results, it is created for each export operation and it doesn't over-write the old one.

Its name allows the identification by the actual date and time.

The exported file is a *.csv type (with the semicolon “;” as values separator).

The export file is composed by a series of records, one for each analysis concluded.

Default location of the file:

%ProgramRoot% \ExportedResults

File name:

exp_YYYY_MM_DD hh_mm_LastName_Name.csv

(i.e.: exp_2006_10_17_17_23_Rossi_Paolo.csv)

where:

- YYYY = year
- MM = month
- DD = day
- hh = hour
- mm = minute
- LastName = logged user's last name



- Name = logged user's name.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**

Record Field delimiter: **ascii code 59 (';')**

Record fields:

Patient Last Name	Patient Name	Patient Id Code	Method Internal Index*	Method Acronym	Index repeat	Result	Unit of Measurement	Minimum Reference Value	Maximum Reference Value	Date
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* See Method export file format

Fields meaning:

- Patient Last name: patient family name
- Patient Name: patient first name
- Patient Identification Code: work list identification code of patient
- Method Internal Index: identification code of the analysis method. A list of the methods linked to the proper identification code is included in the file *methods.csv*; it is generated automatically and over-written by the instrument every time that a method has been saved (SAVE command in Methods Menu).
- Method Acronym: acronym given to the analysis method.
- Repetition Index: 0 based index to identify multiple execution of same analysis
- Result: result of the analysis
- Unit of measurement: unit of measurement of the result
- Minimum Reference Value: minimum normal value
- Maximum Reference value: maximum normal value.
- Date: date of the analysis; format YYYY_MM_DD_hh_mm where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.

Location and Format of the Methods exported file

This file gives the association between methods and their Id Code. This file is created every time a method is saved and over-writes the last one.

Location:

%ProgramRoot% \ MethodList

File name:

methods.csv

File Structure Format:



Record delimiter character: **ascii code 10 (Line Feed)**
Record Field delimiter: **ascii code 59 (';')**

Record fields:

Method Name	Method Acronym	Method barcode	Method Internal Index
-------------	----------------	----------------	-----------------------

Fields meaning:

- Method Name: name given to the analysis method
- Method Acronym: acronym given to the analysis method.
- Method Barcode: unique barcode for method.
- Method Internal Index: identification code of the analysis method.

Note: the field Barcode could be empty.



7.1.13. Repetitions Menu

The operator can enter the *Repetitions* menu by selecting the command *Repetitions* in any of the *Results* menu. This menu allows the repetition of samples, standards or controls by launching them within the Work List in progress or in that to be run.

Analysis will be repeated at the command Start and they will be rescheduled at the end of the run (or in a new one).

In this menu the operator can also delete analyses or samples that has been previously destined to the repetition.

For each analysis to repeat, the user can select by the pull-down menu the needed dilution ratio without any restriction.

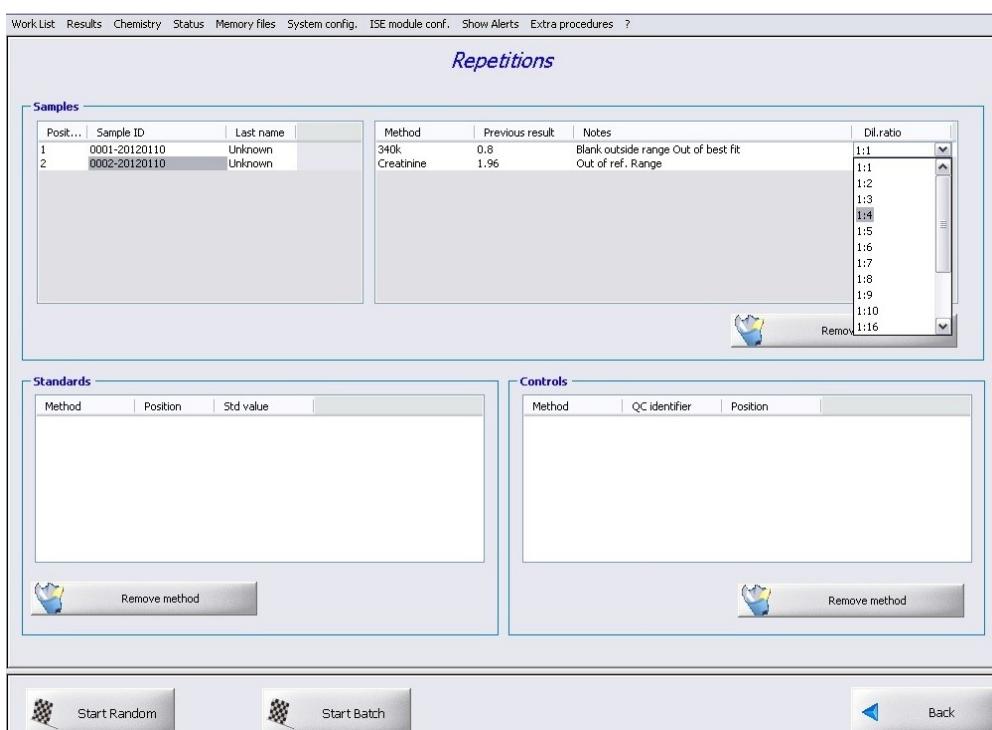


Figure 84: Repetitions Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Samples section - Patient window	
Position:	this column, not editable, shows the position of the sample to repeat.
Sample id:	this column, not editable, shows the ID code of the sample to repeat.
Last name:	this column, not editable, shows the surname of the patient to repeat.
Samples section - Method window	
Method:	this column, not editable, shows the analyses to repeat.



Field/Command	Function
Previous result:	this column, not editable, shows the result of the previous analysis to repeat.
Notes:	this column, not editable, shows eventual notes on the previous analysis.
Dil. ratio:	this field allows the operator to enter, by a pull-down menu, the dilution ratio for any single analysis to repeat. It is possible to choose one of the following ratios: 1:2, 1:3, 1:4, 1:5, 1:6, 1:7, 1:8, 1:9, 1:10, 1:16, 1:20, 1:30, 1:40, 1:50, 1:100. The ratio 1:n is intended as 1 part of “n” parts. Thus, the ratio 1:1 doesn’t provide any dilution.
Std/QC section - Standards/calibrators window	
Method:	this column, not editable, shows the method whose standard/calibrator has to be repeated.
Position:	this column, not editable, shows the position of the standard/calibrator to repeat.
Standard value:	this column, not editable, shows the value of the standard/calibrator to be repeated.
Std/QC section - Controls window	
Method:	this column, not editable, shows the method whose control has to be repeated.
QC identifier:	this column, not editable, shows the QC Identifier number (composed by position and lot number).
Position:	this column, not editable, shows the position of the QC to repeat.
Commands	
Remove method: (in any section)	this command allows the operator to delete a method selected from repetition.
Start Random:	this command allows the operator to run the repetitions in <i>Random</i> mode by adding the tests to the session in progress, if any, or by running a new session. After the command START, the software provides the scheduling of the analysis to repeat and automatically turns to the <i>Status Menu</i> and runs the session. The Start Random is not valid if a Batch Work List is already running, in that case samples will be anyway run in Batch mode.
Start Batch:	this command allows the operator to run the repetitions in <i>Batch</i> mode by adding the tests to the session in progress, if any, or by running a new session. After the command START, the software provides the scheduling of the analysis to repeat and automatically turns to the <i>Status Menu</i> and runs the session. The Start Batch is not valid if a Random Work List is already running, in that case samples will be anyway run in Random mode.
Back:	this command allows the operator to go back to the <i>Results by Patient</i> .



7.1.14. Results by Method Menu

The operator can enter the Results by Method menu by selecting the command *Results by Method* in the *Results by Patient* menu or in *QC/Std Result* menu. It allows the presentation of all results sorted by methods. The displayed results are those of the Work List in progress or, if a new working session has not been run, those of the last one performed if not yet stored. Within this menu the operator can choose the test method whose all samples' analysis results will be displayed; this menu is also useful when the user needs to verify periodically the instrument or when a global statistics results overview is needed.

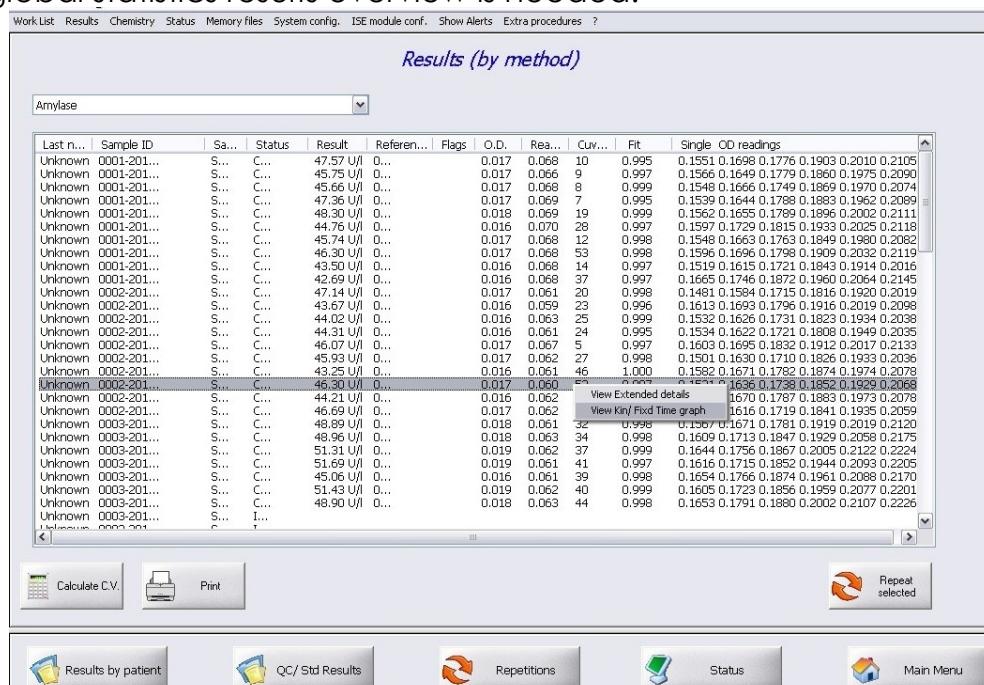


Figure 85: Results by Method Menu



Figure 86: Selection and Statistics Calculation

In this menu the operator can:

- select the methods whose results need to be displayed;
 - select one single test in order to view more details or to display the plot (valid for kinetics and fixed time);
 - calculate, only for the selected tests, the Coefficient of Variation (CV), the Mean and the Standard Deviation (SD).

Note: results that are out of range or that have been detected as abnormal by the system or that are out of some internal automated controls (substrate depletion, linearity, etc.) will be automatically highlighted in red or in orange to be easily recognized by the operator during the result validation. This automated feature doesn't dismiss the responsible of the final validation from his full duties and controls for results interpretation.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Method field	this not editable pull down menu, shows all methods that have been run, or that are running, and allows the selection of each of them in order to show results.
Results windows	
Last name:	this column, not editable, shows the last name of each patient.
Sample id:	this column, not editable, shows the sample ID code of the patient.
Samples are sorted and displayed by sample Id.	
Sample type:	this field, not editable, shows the sample type (if serum, plasma, urine, CSF, ...).
Patient type:	this field, not editable, shows the patient type (if male, female, paediatric,



Field/Command	Function
Status:	...). this column, not editable, shows the progress of any single analysis of the selected method. The following conditions are possible: <ul style="list-style-type: none">• concluded, method whose analysis has been concluded;• in process, method whose analysis is in progress;• to begin, methods whose analysis has to begin (repetitions);• aborted, method whose analysis has been aborted;• in error, system in error – the results is not reliable;• to repeat, method whose analysis has been chosen to be repeated.
Results:	this column, not editable, shows the final result and the unit of measurement for each analysis that has been completed. Results that are not congruent (i.e.: negative) will be shown with a series of stars (*****). When entering this page results are updated related to the actual Factor. This field can show "> of the <i>linearity value</i> " or "<of the <i>detection limit</i> " in place of the stars in case that the related selection has been checked in Methods menu for that application.
Reference values:	this column, not editable, shows the lower and the higher limits of the normal result range, as have been set in the Methods Menu.
Flags:	this column, not editable, shows any condition of results out of normal range. This field is printed on the report; in case of some annotations the method is printed in bold characters and the operator has to evaluate the result. In case of result above the normal range it shows the capital letter "H", in case of result below the normal range it shows the capital letter "L".
O.D.:	this column, not editable, shows the final measured value in terms of absorbance (OD). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Reagent blank:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD). This value is measured by the instrument on any single reading cuvette filled with reagent just before to dispense the sample in case of sample start tests. This field is not printed on the report. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Cuvette:	this column, not editable, shows the cuvette number where the analysis has been incubated and read. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated for the kinetic methods. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Single OD readings:	This column, not editable, shows each single OD value read for Kinetics (during the reading time), for Fixed Time methods (first and second values) or for Differential Sample Blank mono and bi-chromatic (first and second values). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.

Commands performed through the right mouse button on the selected test method

View Extended details: in case one result is out of normal range or it has been highlighted in orange or red, select it with the left mouse button then click on the



Field/Command	Function
View kinetics/F.Time graph:	selection with the right mouse button and select View Extended details on the pop-up menu: detailed information about the results, if any, will be displayed.
Commands	
Calc. C.V.:	in order to show the graph of Kinetic or Fixed Time methods, select one analysis with the left mouse button, then click on the selection with the right mouse button and select View graph on the pop-up menu: the single ODs will be plotted into a graph.
Print:	when activated, this command allows the system to calculate, over all of the previously selected tests, the following statistic parameter: <ul style="list-style-type: none">• Coefficient of Variation (CV);• Mean;• Standard Deviation (SD).
Repeat selected:	this command allows the operator to print the results for the selected method.
Results by patient:	select one or more analyses to delete with the left mouse button, then click Repeat: the selected analyses are then moved to the Repetitions menu. In that menu the operator can re-run that analysis in the actual working session and with different dilutions.
Q.C./Std Results:	this command allows the operator to go back to the Results by patient menu.
Repetitions:	this command allows the operator to enter the Q.C./Std Results Menu.
Status:	this command allows the operator to enter the Repetitions Menu.
Main Menu:	this command allows the operator to go back to the Status Menu.
Note: the selection of more results can be executed with the typical Windows® mode:	this command allows the operator to go back to the Main Menu.
<ul style="list-style-type: none">• Selecting a range of samples: click with the left mouse button on the first sample of the desired range and then, at the same time press the key SHIFT and click again on the last sample of the range → the range is then selected.• Selecting more discrete samples: press the key CTRL and at the same time click with the left mouse button on all samples to be selected.	



7.1.15. Q.C./Std Results Menu

The operator can enter the Q.C./Std Results menu by selecting the command Q.C./Std Results in the Results by Patient or in the Results by Methods menus. It allows the presentation of all results of the standards/calibrators and of QCs that have been processed.

The displayed results are those of the Work List in progress or, if no work list is running, those of the last one performed, if not yet stored.

In this menu the operator can do the following main operations:

- to store in archive (Memory files menu) the obtained QC and Standard results with separate commands;
- to print into a compact laboratory report both results of standards and QCs actually displayed.

Note: remember that to modify an existing “method”, all related Test results, Standard results and QC results must be previously archived (filed in memory).

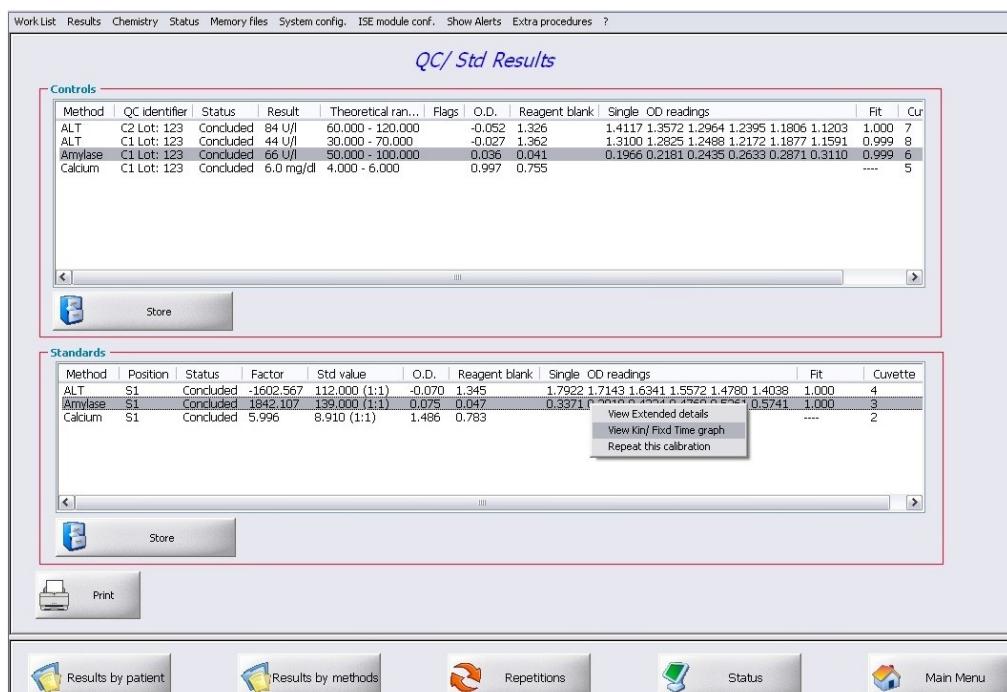


Figure 87: Q.C./Std Results Menu

Note: results that are out of range or that have been detected as abnormal by the system or that are out of some internal automated controls (substrate depletion, linearity, etc.) will be automatically highlighted in red or in orange to be easily recognized by the operator during the result validation. This automated feature doesn't dismiss the responsible of the final validation from his full duties and controls for results interpretation.



The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Controls section	
Method:	this column, not editable, shows the method whose control is related to.
QC Identifier:	this column, not editable, shows if control is C1 or C2 or C3 and the Lot number.
Status:	this column, not editable, shows the progress of any single control. The following conditions are possible: <ul style="list-style-type: none">• concluded, test has been concluded;• in process, test is in progress;• to begin, test has to begin (repetitions);• aborted, test has been aborted;• in error, system in error – the results is not reliable;• to repeat, test has been chosen to be repeated (at the end of the run).
Result:	this column, not editable, shows the final result and unit of measurement for each control completed.
Theoretical range:	this column, not editable, shows the lower and the higher limits of the range set for that control.
Flags:	this column, not editable, shows any condition of QC results out of limits. In case of result above the admissible range it shows the capital letter "H", in case of result below the admissible range it shows the capital letter "L".
O.D.:	this column, not editable, shows the final value measured in terms of absorbance (OD). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Reagent blank:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD). This value is measured by the instrument on any single reading cuvette filled with reagent just before to dispense the sample in case of sample start tests. This field is not printed on the report. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Single OD Readings:	this column, not editable, shows each single OD value read for Kinetics (during the reading time), for Fixed Time methods (first and second values) or for Differential Sample Blank mono and bi-chromatic (first and second values). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated for the kinetic methods. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Cuvette:	this column, not editable, shows the cuvette number where the specific reaction has been incubated and read. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Standards section	
Method:	this column, not editable, shows the method whose standard is related to.
Position:	this column, not editable, shows the position of the standard.
Status:	this column, not editable, shows the progress of any single standard.



Field/Command	Function
	The following conditions are possible: <ul style="list-style-type: none">• concluded, test has been concluded;• in process, test is in progress;• to begin, test has to begin (repetitions);• aborted, test has been aborted;• in error, system in error – the results is not reliable;• to repeat, test has been chosen to be repeated (at the end of the run).
Factor:	this column, not editable, shows the Factor calculated for each standard.
Std value:	this column, not editable, shows the value given to that standard.
O.D.:	this column, not editable, shows the final value in terms of absorbance (OD). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Reagent blank:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD). This value is measured by the instrument on any single reading cuvette filled with reagent just before to dispense the sample in case of sample start tests. This field is not printed on the report. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Single OD Readings:	this column, not editable, shows each single OD value read for Kinetics (during the reading time), for Fixed Time methods (first and second values) or for Differential Sample Blank mono and bi-chromatic (first and second values). This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated for the kinetic methods. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Cuvette:	this column, not editable, shows the cuvette number where the specific reaction has been incubated and read. This field is visible only if the flag "Show reaction details in result page" in System Config menu has been enabled.
Commands performed through the right mouse button on the selected test method	
View Extended details:	in case one QC result is out of admissible range or it has been highlighted in orange or red, select it with the left mouse button then click on the selection with the right mouse button and select View Extended details on the pop-up menu: detailed information about the results, if any, will be displayed.
View kinetics/F.Time graph:	in order to show the graph of Kinetic or Fixed Time methods, select one analysis with the left mouse button, then click on the selection with the right mouse button and select View graph on the pop-up menu: the single ODs will be plotted into a graph.
Repeat this QC: or Repeat this standard:	select with the left mouse button one analysis to be repeated, then click on the selection with the right mouse button and select Repeat on the pop-up menu: the selected analyses will be moved to the Repetitions menu. In that menu the operator can re-run, within the actual working session or later, that particular analysis by selecting a different and proper new dilution ratio (if needed). A different dilution ratio for each analysis of the same sample can be chosen. Dilutions are performed in cuvette.

Commands



Field/Command	Function
Print:	this command allows the printing of a compact laboratory report with all results displayed.
Store:	Each of this two commands allows the operator to store in archive (Memory Files menu) the displayed QC results or the displayed Standard results.
Results by patient:	this command allows the operator to go back to the <i>Results by patient</i> menu.
Results by method:	this command allows the operator to go back to the <i>Results by method</i> menu.
Repetitions:	this command allows the operator to go back to the <i>Repetitions</i> menu.
Status:	this command allows the operator to go back to the <i>Status Menu</i> .
Main Menu:	this command allows the operator to go back to the <i>Main Menu</i> .



7.1.16. Memory Files Menu

The operator can enter the *Memory Files* menu (archive of all results) by selecting the command *Memory files* in the *Main Menu*. This menu allows the operator to manage all standard, control and patient analysis results that have been filed. It is then possible to search for old results or patient reports for verification or printing purposes. The user can run researches using different keys and their full combinations. Searching keys are:

- *Last name,*
- *patient ID code,*
- *sample ID*
- *date,*
- *method*
- *calibration unique id number,*

it is possible whatever combination of those keys for creating different research criteria.

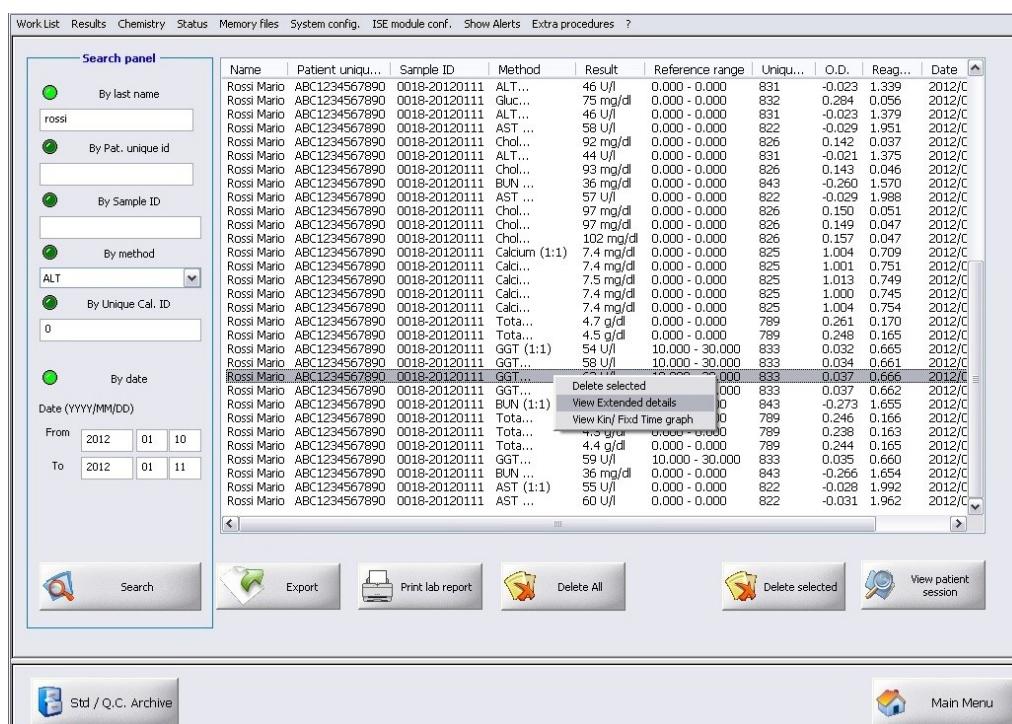


Figure 88: Memory Files Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Search Panel section By last name:	this field allows the operator to introduce the patient last name to search



Field/Command	Function
By Pat. unique id:	in archive. The system considers the content of this field only if this searching option has been flagged.
By Sample ID:	this field allows the operator to introduce the patient unique id-code to search in archive. Remember that this ID number is characteristic of the "Patient" and could be coincident with any ID number given by the government for example. The system considers the content of this field only if this searching option has been flagged.
By method:	this field allows the operator to introduce the analysis method to search in archive. From the pull down menu it is possible to select one method from the list in memory (set as visible). The system considers the content of this field only if this searching option has been flagged.
By Cal. Unique id:	this field allows the operator to introduce the Calibrator Unique id number to search in archive. The system considers the content of this field only if the searching option "by Cal. Unique id" has been flagged. This searching key is useful when the operator needs to track all results related to a specific calibration performed in the past. The system considers the content of this field only if this searching option has been flagged.
By Date (yyyy mm dd) from:	this field allows the operator to introduce the analysis range starting date to search in archive. The system considers the content of this field only if this searching option has been flagged.
to:	this field allows the operator to select the analysis range ending date to search in archive. The system considers the content of this field only if this searching option has been flagged.
Research results window	
Name:	this column, not editable, shows the name and surname of the patients found by the searching process.
By Pat. unique id:	this field, not editable, shows the Patient unique ID code of the patients found by the searching process.
Sample id:	this column, not editable, shows the Sample ID code of the patients found by the searching process.
Method:	this column, not editable, shows all methods executed for the patients found by the searching process and the sample dilution ratio that has been used.
Results:	this column, not editable, shows the results of the methods executed for the patients found by the searching process.
Reference range:	this column, not editable, shows the lower and the higher limits of the normal result range set in the Methods Menu.
Unique Cal. id:	this column, not editable, shows the Calibrator Unique ID number associated to a specific calibration performed in the past and related to the given result.
O.D.:	this column, not editable, shows the final measured value in terms of absorbance (OD).
Reagent blank:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD).



Field/Command	Function
Date:	this column, not editable, shows the date and the time (hh:mm:ss) of the analysis.
Commands performed through the right mouse button on the selected test method	
Delete:	This command is used to delete the result highlighted. Select with the left mouse button one test, then click on the selection with the right mouse button and click <i>Delete</i> on the pop-up menu: that particular test will be deleted.
View Extended details:	this command allows the operator to enter the Report window showing all details and analysis executed for the selected patient in that special working session.
View kinetics/F.Time graph:	in order to show the graph of Kinetic or Fixed Time methods, select one analysis with the left mouse button, then click on the selection with the right mouse button and select <i>View graph</i> on the pop-up menu: the single ODs will be plotted into a graph.
Commands	
Search:	this command allows the operator to start the research of patient results based on the chosen criteria (keys combination).
Export:	this command allows the user to export the research into files. See " Results and Methods Exported File " paragraph of this manual for format and location of exported files.
Print lab report:	This command allows user to print all result in a compact format laboratory report.
Delete All:	this command allows the operator to delete "all the records" that have been got as result of the research.
Delete selected:	this command allows the operator to delete the result that have been selected with the mouse.
View patient session:	this command allows the operator to enter the Report window showing all details and analysis executed for the selected patient in that special working session. Through this window the operator can modify any patient personal data or print the report of the results.
Std/QC Archive:	this command allows the operator to enter the Std/QC Archive menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



7.1.16.1. Patient Results Auto-exporting for Back Up

The Memory files menu allows the operator to handle and display all results previously filed.

The database can contain 150,000 records. When records approach 150,000 the program removes the oldest 50,000 records from database and **automatically** stores them into a special file ".csv", available for the User as **back up**; estimating an average of about ten analyses for each sample, the database will roughly include between 9,000 and 15,000 patients.

The exported file is a *.csv type (with the semicolon ";" as values separator).

The export file is composed by a series of records, one for each analysis concluded.

Location of the file:

%ProgramRoot% \Export

File name:

result_yyyy_mm_dd_LastName_Name.csv
(i.e.: result_2006_10_17_Rossi_Paolo.csv)

where:

- yyyy = year
- mm = month
- dd = day
- LastName = logged user's last name
- Name = logged user's name.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**
Record Field delimiter: **ascii code 59 (';')**

Record fields:

idArchive	idPatient	Barcode	Method name	results	Minimum Reference Value	Maximum Reference Value	Date

Fields meaning:

- idArchive: table index - reserved
- idPatient: patient pointer - reserved
- Barcode: barcode identification for method
- method name: name of the method
- Result: result of the analysis
- Minimum Reference Value: minimum normal value



- Maximum Reference value: maximum normal value.
- Date: date of the analysis; format YYYY_MM_DD hh_mm where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.

7.1.16.2. Report Window

The operator can enter the Report window by selecting the command *Show details from Memory files* menu. This window allows the operator to print the report of analysis or to modify the personal data of the patient.

Sample ID	Methods	Result	Reference range	Notes
Level 2	Calcium (1:1)	12.2 mg/dl	0.000 - 0.000	
Level 2	ALT (1:1)	92 U/l	0.000 - 0.000	Out of best fit
Level 2	Triglycerides (1:1)	228 mg/dl	0.000 - 0.000	
Level 2	Total Protein (1:1)	7.6 g/dl	0.000 - 0.000	
Level 2	Magnesium (1:1)	2.8 mg/dl	0.000 - 0.000	
Level 2	BUN (1:1)	48 mg/dl	0.000 - 0.000	
Level 2	Total Bilirubin (1:1)	3.1 mg/dl	0.000 - 0.000	
Level 2	Uric Acid (1:1)	9.1 mg/dl	0.000 - 0.000	
Level 2	LDL Cholesterol (1:1)	93 mg/dl	0.000 - 0.000	
Level 2	Alkaline Phos (1:1)	159 U/l	0.000 - 0.000	
Level 2	Albumin (1:1)	4.4 g/dl	0.000 - 0.000	
Level 2	Bicarbonate (1:1)	27 mmol/l	0.000 - 0.000	

Figure 89: Report Window

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Patient private data section	
Sample ID:	this alphanumeric field shows the ID number given to the sample.
Patient unique id:	this alphanumeric field shows the ID number considered unique for that specific sample (patient). It can be a custom number or it can be coincident with the unique number given to anybody from the government or anyway it is a code considered as "unique" by the system

**Field/Command****Function**

Look up:	for that patient. The system identifies a patient through this field. this command allows the system research into the data base of any eventual sample with that given Unique ID and overwrites patient data with what found or overwrites old data with the new ones by clicking on the Save button.
Last name:	this alphanumeric field allows the operator to introduce the name of the patient.
First name:	this alphanumeric field allows the operator to introduce the surname of the patient.
Date of birth:	this alphanumeric field allows the operator to introduce the patient date of birth. Format of the field: yyyy/mm/dd, where <ul style="list-style-type: none">• yyyy → year, 4 digits• mm → month, 2 digits• dd → day, 2 digits.
Age:	this alphanumeric field allows the operator to introduce the patient age.
Address:	this alphanumeric field allows the operator to introduce the address of the patient.
Email:	this alphanumeric field allows the operator to introduce the patient e-mail address.
Phone:	this alphanumeric field allows the operator to introduce the patient telephone number.
Bed:	this alphanumeric field allows the operator to introduce the patient bed number (when in hospital structures).
Dpt:	this alphanumeric field allows the operator to introduce the department.
Clinic:	this alphanumeric field allows the operator to introduce the clinic ID.
Request date:	this alphanumeric field allows the operator to introduce the date of the analysis request. Format of the field: yyyy/mm/dd, where <ul style="list-style-type: none">• yyyy → year, 4 digits• mm → month, 2 digits• dd → day, 2 digits.
Doctor:	this alphanumeric field allows the operator to introduce the ID of the doctor.
Notes:	this alphanumeric field allows the operator to introduce eventual remarks.
Daily Session	
Sample id:	this column, not editable, shows the Sample ID code of the patients found by the searching process.
Methods:	this column, not editable, shows all methods executed for the patients found by the searching process and the sample dilution ratio that has been used.
Results:	this column, not editable, shows the results of the methods executed for the patients found by the searching process.
Reference range:	this column, not editable, show the lower and the higher limits of the normal result range set in the Methods Menu.
Notes:	this column, not editable, shows the notes related to the side analysis result.
Commands	
Save:	this command allows the operator to save modifications of the patient data.



Field/Command	Function
<i>Print patient report:</i>	this command allows the operator to print the patient analysis report.



7.1.17. Std/Q.C. Archive Menu

The operator can enter the Std/Q.C. Archive menu by selecting the command Std/Q.C. Archive in the Memory Files menu. This menu allows the operator to manage all filed results related to standards and controls. It is possible to search old results for verification or printing purposes. The user can run researches using different keys and their full combinations. Searching keys are: by method, by lot number, by date and by unique calibration id; any combination of the keys is possible for creating a research criterion.

The screenshot shows the 'Std/Q.C. Archive' window. On the left is a 'Search panel' with four sections: 'By method' (dropdown: 340BicDiff), 'By lot' (text input: 12345), 'By date' (date range: From 2011/01/23 To 2012/01/23), and 'By Unique Cal. ID' (text input: 0). The main area contains two tables: 'Controls' and 'Standards'. The 'Controls' table lists various analytes (Total Bilirubin, Bicarbonate, LDL Cholesterol, etc.) with their corresponding QC id, QC Lot, Reagent lot, Result, Theoretical range, Unique Cal. ID, O.D., Rea., and Date. The 'Standards' table lists standards (AST, ALT) with Unique, Method, Lot, Dil., Factor, Std value, O.D., Rea., Date, Backfit, and Cal. Cu columns. At the bottom are buttons for 'Search' (with magnifying glass icon), 'Export' (with green floppy disk icon), 'Print' (with printer icon), 'Patients archive' (with folder icon), and 'Main Menu' (with house icon).

Figure 90: Std/Q.C. Archive Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Search Panel window	
By method:	this field allows the operator to introduce the analysis method whose standards/controls have to be searched in the archive. From the pull down menu it is possible to select one method from the list in memory (set as visible). The system considers the content of this field only if the searching option "by method" has been flagged.
By lot:	this field allows the operator to introduce the lot number of the standard/controls that must be searched in the archive. The system considers the content of this field only if the option search "by lot" is flagged.



Field/Command	Function
By date (yyyy mm dd) from:	this field allows the operator to select the starting date to search in archive. The system considers the content of this field only if the searching option "by date" has been flagged.
(yyyy mm dd)to:	this field allows the operator to select the ending date to search in archive. The system considers the content of this field only if the searching option "by date" has been flagged.
By Unique Cal. ID:	this field allows the operator to introduce the Calibrator Unique id number to search in archive. The system considers the content of this field only if the searching option "by Cal. Unique id" has been flagged.
Controls window	
Method:	this column, not editable, shows the methods whose control refers to.
QC identifier:	this column, not editable, shows the control considered if C1, C2 or C3.
QC lot:	this column, not editable, shows the lot number of the QC serum.
Reagent lot:	this column, not editable, shows the lot number of the reagent used for that QC analysis.
Result:	this column, not editable, shows the results of the control and the unit of measurement.
Theoretical range:	this column, not editable, show the lower and the higher limits of the normal range of the control.
Unique Cal. ID:	this column, not editable, shows the Calibrator Unique id number whose QC refers to.
O.D.:	this column, not editable, shows the final value in terms of absorbance (OD).
Reagent blank:	this column, not editable, shows the reagent blank measured value in terms of absorbance (OD).
Date:	this column, not editable, shows the date of the control test execution.
Flags:	this column, not editable, shows any flag related to the control's analysis result.
Standards window	
Unique Cal. ID:	this column, not editable, shows the Calibrator Unique id number whose standard/calibrator refers to.
Method:	this column, not editable, shows the methods whose standard/calibrator refers to.
Lot:	this column, not editable, shows the lot number of the standard/calibrator.
Dil. ratio:	this column, not editable, shows the dilution ratio of the standard/calibrator, if any.
Factor:	this column, not editable, shows the Factor (F) given as result of analysis, or manually entered by the operator, for the standard in question.
Std value:	this column, not editable, shows the value of the standard.
O.D.:	this column, not editable, shows the final value in terms of absorbance (OD).
Reagent blank:	this column, not editable, shows the reagent blank value in terms of absorbance (OD).
Date:	this column, not editable, shows the date and time (hh:mm:ss) related analysis of the standard.
Backfit:	this column shows the concentration values corresponding to the point of the calibrator interpolated in the measured calibration curve.
Cal. Curve params:	this column shows the evaluated equation related to the chosen curve



Field/Command	Function
Commands	
Search:	model. It is available only for Linear regression, Poly2, Poly3, Poly4 and Piecewise Linear.
Export:	this command allows the operator to start the research of standards and controls based on the chosen criteria.
Print:	this command allows the user to export the QC's and the Standards got as results of the search into two separate file. See " Std/QC Results Exported File " paragraph of this manual for format and location of exported files.
Patients Archive:	This command allows user to print all result in a compact format report.
Main Menu:	this command allows the operator to enter the Patient Archive menu.
	this command allows the operator to go back to the Main Menu.

Note: the system, in order to limit the database dimension, automatically generates and exports other files to be considered as back up of the oldest data.



7.1.17.1. QC and Standard Results Exported Files

The command *Export* in Std/Q.C. Archive menu gives the operator the opportunity to **export the results of Standard and Controls into two different files**. Those files include the result of the research carried out in the Std/QC Archive menu. The file are exported into a special folder ("exported results") that can be changed for user handling; it can be copied into a media or accessed by a host computer when i.e. the managing PC has been connected into a LAN. In case that the Personal Computer has been configured into a LAN, the "ExportedResults" folder must be "shared" in network in order to allow an host computer to download and treat the file itself. The exported files are *.csv type.

Program root folder

ProgramRoot = %ROOT% \BCA

Location and Format of the QC exported file

This file includes the results for **Controls** searched and found and also displayed in the Std/QC Archive (Controls section). Its name allows the identification by the actual date and time. The exported file is a *.csv type (with the semicolon ":" as values separator). The export file is composed by a series of records, one for each analysis concluded.

Default location of the files:

%ProgramRoot% \ExportedResults

File name:

expQC_YYYY_MM_DD_hh_mm_LastName_Name.csv

(i.e.: expQC_2011_10_18_55_43_Rossi_Paolo.csv)

where:

- YYYY = year
- MM = month
- DD = day
- hh = hour
- mm = minute
- LastName = logged user's last name
- Name = logged user's name.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**

Record Field delimiter: **ascii code 59 (';')**

Record fields:

Method	Method	QC	QC	Reagent	Result	Unit of	Minimum	Theoretical	Maximum	Date
--------	--------	----	----	---------	--------	---------	---------	-------------	---------	------



Internal Index *	Acronym	Identifier	lot	lot		Measur-ement	Referen-ce Value	Reference Value	Reference Value	
------------------	---------	------------	-----	-----	--	--------------	------------------	-----------------	-----------------	--

* See Method export file format

Fields meaning:

- Method Internal Index: identification code of the analysis method. A list of the methods linked to the proper identification code is included in the file *methods.csv*; it is generated automatically and over-written by the instrument every time that a method has been saved (SAVE command in Methods Menu).
- Method Acronym: acronym given to the analysis method.
- QC Identifier: identify if control C1, C2 or C3.
- QC lot: lot number of the QC serum.
- Reagent lot: lot number of the method.
- Result: result of the control.
- Unit of measurement: unit of measurement of the result.
- Minimum Reference Value: minimum normal value of the control.
- Theoretical Reference Value: theoretical value of the control.
- Maximum Reference value: maximum normal value of the control.
- Date: date of the analysis; format YYYY_MM_DD_hh_mm
where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.

Location and Format of the STD exported file

This file includes the results for **Standards** searched and found and also displayed in the Std/QC Archive (Standards section). Its name allows the identification by the actual date and time. The exported file is a *.csv type (with the semicolon ";" as values separator). The export file is composed by a series of records, one for each analysis concluded.

Default location of the files:

%ProgramRoot% \ ExportedResults

File name:

expSTD_YYYY_MM_DD_hh_mm_LastName_Name.csv
(i.e.: expSTD_2011_10_18_55_43_Rossi_Paolo.csv)

where:

- YYYY = year
- MM = month
- DD = day
- hh = hour



- mm = minute
- LastName = logged user's last name
- Name = logged user's name.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**
Record Field delimiter: **ascii code 59 (';')**

Record fields:

Method Internal Index *	Method Acronym	Unique Cal. ID	Calib Lot	Calib Exp Date	Numb. of Std	Factor	Std Dil Ratio 1	Std Value 1	Std OD 1	...
...	Std Dil Ratio 8	Std Value 8	Std OD 8	Date						

* See Method export file format

Fields meaning:

- Method Internal Index: identification code of the analysis method. A list of the methods linked to the proper identification code is included in the file *methods.csv*; it is generated automatically and over-written by the instrument every time that a method has been saved (SAVE command in Methods Menu).
- Method Acronym: acronym given to the analysis method.
- Unique Cal. ID: It is the Unique Calibration ID number given by the system at that standardization.
- Cal lot: lot number of the Standard/Calibrator.
- Calib Exp Date: Expiration date of the Standard / Calibrator.
- Number of Standard: it is the number of standard for that method.
- Factor: it is the factor got for that method.
- Std Dil Ratio1: it is the dilution ration for the standard number 1.
- Std Value1: it is the value of the standard number 1.
- Std OD1: it is the measured OD got for the standard number 1.
-:
- Std Dil Ratio8: it is the dilution ration for the standard number 8.
- Std Value8: it is the value of the standard number 8.
- Std OD8: it is the measured OD got for the standard number 8.
- Date: date of the analysis; format YYYY_MM_DD_hh_mm where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.



7.1.17.2. QC and Standard results Auto-exporting for Back Up

The system keeps in memory the results of Controls and Standards of the **last twelve months** (on-line QCs/STDs results); when reached that time, every day the system removes from database the results of the day before than one year ago and **automatically** stores those into special files ".csv", available for the User as **back up**. The files are ".csv" type (Comma Separated Value), generated one for each month and available to the user.

The exported file is *.csv type (with the semicolon ";" as values separator) and includes the results of the whole month – so the exporting routine will everyday update the same file for one month and then it will generate a new one on the next month. The export files are three: one file for QCs of the day (that means the QC results included in Levy-Jennings plot – one QC for each day, the last one), one file including all of the QCs (all QCs performed in the day) and one file for Standards/Calibrators.

Program root folder

ProgramRoot = %ROOT% \BCA

Location and Format of the Controls exported file

These two file includes the monthly results for **Controls** automatically exported by the system. Names allow the identification by the actual date and time. The exported file is a *.csv type (with the semicolon ";" as values separator). The export file is composed by a series of records, one for each analysis concluded.

Location of the files for QCs:

%ProgramRoot% \Export

File names:

ResultQCDaily_yyyy_mm.csv (→ one QC per day)
(i.e.: ResultQC_2011_10_18.csv)

ResultQC_yyyy_mm.csv (→ all QCs)
(i.e.: ResultQC_2011_10_18.csv)

where:

- yyyy = year
- mm = month.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**
Record Field delimiter: **ascii code 59 (';')**

Record fields:

Method	Method	Unique	QC	QC	UM	Date	Errors	QC Lot	Min	Max	Reagent
--------	--------	--------	----	----	----	------	--------	--------	-----	-----	---------



name	barcode	Cal ID	Identifier	Result							lot
------	---------	--------	------------	--------	--	--	--	--	--	--	-----

Fields meaning:

- Method name: analysis method. A list of the methods linked to the proper identification code is included in the file methods.csv; it is generated automatically and over-written by the instrument every time that a method has been saved (SAVE command in Methods Menu).
- Method barcode: barcode given to the analysis method.
- Unique Cal. ID: It is the Unique Calibration ID number given by the system at the standardization whose QC refers to.
- QC Identifier: identify if control C1, C2 or C3.
- Result: result of the QC.
- UM: unit of measurement of the result.
- Date: date of the analysis; format YYYY_MM_DD_hh_mm where
 - YYYY, year
 - MM, month
 - DD, day
 - hh, hour
 - mm, minute.
- Errors: list of the errors associated to the result.
- QC Lot: lot number of the QC serum.
- Min: minimum normal value of the control.
- Max: maximum normal value of the control.
- Reagent lot: lot number of the reagent.

Location and Format of the STD exported file

This file includes the monthly results for **Standards** automatically exported by the system. Its name allows the identification by the actual date and time. The exported file is a *.csv type (with the semicolon ";" as values separator).

The export file is composed by a series of records, one for each analysis concluded.

Location of the files for STDs:

%ProgramRoot% \Export

File name:

ResultSTD_yyyy_mm.csv
(i.e.: ResultQC_2011_10_18.csv)

where:

- yyyy = year
- mm = month.

*File Structure Format:*

Record delimiter character: **ascii code 10 (Line Feed)**
Record Field delimiter: **ascii code 59 (';')**

Record fields:

Method Internal Index *	Method Acronym	Unique Cal. ID	Calib Lot	Calib Exp Date	Numb. of Std	Factor	Std Dil Ratio 1	Std Value 1	Std OD 1	...
...	Std Dil Ratio 8	Std Value 8	Std OD 8	Date						

* See Method export file format

Fields meaning:

- Method Internal Index: identification code of the analysis method. A list of the methods linked to the proper identification code is included in the file *methods.csv*; it is generated automatically and over-written by the instrument every time that a method has been saved (SAVE command in Methods Menu).
- Method Acronym: acronym given to the analysis method.
- Unique Cal. ID: It is the Unique Calibration ID number given by the system at that standardization.
- Calib lot: lot number of the Standard/Calibrator.
- Calib Exp Date: Expiration date of the Standard / Calibrator.
- Number of Standard: it is the number of standard for that method.
- Factor: it is the factor got for that method.
- Std Dil Ratio1: it is the dilution ration for the standard number 1.
- Std Value1: it is the value of the standard number 1.
- Std OD1: it is the measured OD got for the standard number 1.
-:
- Std Dil Ratio8: it is the dilution ration for the standard number 8.
- Std Value8: it is the value of the standard number 8.
- Std OD8: it is the measured OD got for the standard number 8.
- Date: date of the analysis; format YYYY_MM_DD_hh_mm where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.



7.1.18. System Config Menu

The operator can enter the *System Configuration* menu by selecting the command *System Config* from any menu; it is located in the upper menu-bar only. This menu allows the user to set or to change general order system parameters like: PC serial COM port setting, Cuvette tray temperature setting, Sample tube types, L.I.S. functionalities, etc.

WARNING

**Never use sample cups different from those suggested by the producer.
It could cause sampling probe crashes and/or false sampling.**

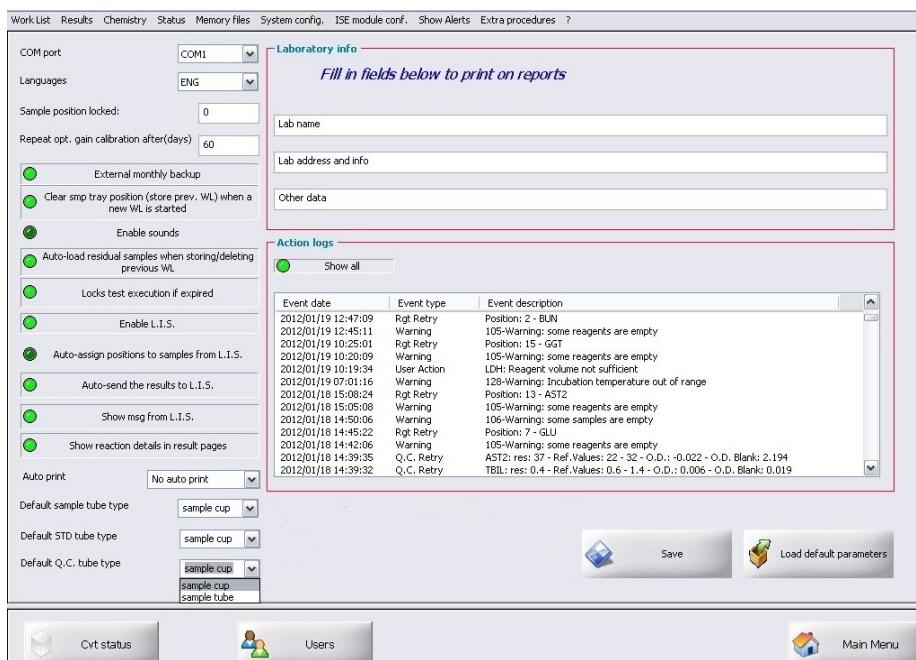


Figure 91: System Config Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Selections	
COM port:	this pull down menu allows the user to select the serial PC's COM port to be used for the serial link with the instrument. Only available ports will be displayed. Any modification must be saved by the command Save ; any modification will be operating on the next software start-up (after closing and restarting the system).
Languages:	this pull down menu allows the user to select the language for the User software interface. From the pull down menu it is possible to select one of the languages listed in memory. Any modification must be saved by the command Save ; most modifications will be active immediately even if full activation will be operating on the next start up.

**Field/Command****Function**

Sample position locked:	this field gives the operator the possibility to block and lock the system to aspirate the sample only from a given position on the tray even if other different positions have been programmed in the worklist. This feature must be used only for service purposes or for special needs because only one sample will be used and the other ignored. By entering the number of the desired sample position (in the range 1 to 9 or 1 to 15, depending on the instrument configuration) it is possible to fix the position to be used by the system. That means: the instrument, during sampling operations in the run, will not consider the real position of each sample given during Work List programming, but it will aspirate the sample always from the same locked position (the one that has been set). Again, this has meaning only for servicing or maintenance purposes in case it is requested to check repeatability with the same sample and without to waste sample. Any modification must be saved and it will be active with the next Start running. For normal operation enter "0". By introducing the position "0" (zero), the sample tray isn't blocked and then the instrument is enabled to draw from any position; this is the correct setting for normal operation. Leave this field = 0 during normal operation.
	WARNING Instrument operates in normal condition only with this field set to "0".
Repeat opt. gain calibration after (days):	this field allows the operator to introduce the number of days after while the system alerts the operator with a message requesting the optical group gain calibration. The counter starts on the last calibration done. Any modification must be saved. Optical gain calibration is periodically needed to optimize the quality of the readings during the life of the instrument. Typical values is 30 or 60 days.
External monthly back-up:	if this selection is active, every month the user software interface will alert the operator to run the back up of the database by generating a special encrypt file automatically, he will be asked to decide the path.
Clear smp tray position (store prev. WL) when a new WL is started:	if this selection is active, the system automatically archives all concluded results on the WL Start command only if it has been started by the <i>Idle</i> status (and not from a Running status). On results filing, the related sample positions will be cleared and then are available as free for new samples.
Enable sounds:	if this selection is active, the PC generates sounds in case it detects one of the following events: warnings, alarms, concluded results, start up and shut down (PC needs multimedia speakers/monitor).
Auto-load residual samples when storing/deleting previous WL:	if this selection is active, the system automatically looks for any new programmed sample that has no assigned position (coming from L.I.S. or from manual programming) and it assigns it to a free position on the sample tray (beginning from the lowest that is free). If the system is already running, in order to run the new samples in the actual Work List they have to be Started with standard procedure.
Lock tests execution in case of date expired:	if this selection is active, the system doesn't enable the operator to run tests whose reagent, standard/calibrators or control expiry date have been exceeded; they are locked and cannot be run . If this selection is not active, the system alerts anyway the operator when tests whose reagent, standard/calibrators or control exceeds expiry date; they are not locked and can be run.



Field/Command	Function
Enable L.I.S.:	this selection allows the operator to enable the instrument P.C. to the L.I.S. (Laboratory Information System) connection with the host computer through the dedicated LAN bidirectional serial link. This L.I.S. connection (option) allows the results and the Work List data bidirectional exchange.
Auto-assign positions to samples from L.I.S.:	if this selection is active, the system automatically assigns free positions on the sample tray to patients that have been received via the L.I.S. connection (if it is existing and enabled). If the system is already running, in order to run the new samples in the actual Work List they have to be Started with standard procedure.
Auto-send the results to L.I.S.:	if this selection is active, the system automatically sends results of concluded analyses to the host computer via the L.I.S. connection (if it is existing and enabled). Note: this feature meets the request of some customers that wish to receive and validate results on a remote workstation. Remember that the “automatic results sending” doesn’t dispense the operator from their validation.
Show msg from L.I.S.:	if this selection is active, the system automatically will display the message “New samples received from L.I.S.” anytime receiving new samples from the Laboratory Information System link. In case this features hasn't been selected, the software will not show any message on the screen even if new samples are received and accepted by the system.
Show reaction details in result page:	if this selection is active, the system automatically will display details over the results of analysis in the “result menu”: in theis case ODs, cuvette numbers and other info will be shown. To enable it save and restart the system.
Auto print:	by this selection the operator can enable/disable the automatic printing of the results on any patient conclusion; when enabled, just after all tests of a sample concludes the system prints out or a “lab report” or a “user report” depending on the selection done.
Default sample tube type:	this pull down menu allows the operator to select the type of tubes given for patient samples as default choice in the work list menu. It is possible to select: <ul style="list-style-type: none">• sample tube• (3ml) sample cups. Any modification must be saved and it will be active with the next Start running.
Default STD tube type:	this pull down menu allows the operator to select the type of tubes given for Standard/Calibrators as default choice in the work list menu. It is possible to select: <ul style="list-style-type: none">• sample tube;• (3ml) sample cups. Any modification must be saved and it will be active with the next Start running.
Default Q.C. tube type:	this pull down menu allows the operator to select the type of tubes given for Q.C. samples as default choice in the work list menu. It is possible to select: <ul style="list-style-type: none">• sample tube;• (3ml) sample cups.



Field/Command	Function
	Any modification must be saved and it will be active with the next Start running.
Laboratory Info window	
Upper field:	this field allows the operator to introduce any text information like the laboratory data of identification. The system prints these data on any results reports.
Middle field:	this field allows the operator to introduce any text information like the laboratory address and other data. The system prints these data on any results reports.
Lower field:	this field allows the operator to introduce any text information like the laboratory info or notes. The system prints these data on any results reports.
Action Logs window	
This section lists important events recorded by the system.	
Show all:	if this selection is not active, the window list all main events recorded during the last session since the last system start up. If this selection is active, the window list all main events recorded during the system life. The last 5,000 recorded main events are on line, the excess is exported in a special file.
Commands	
Save:	this command allows the operator to save any modification done within the menu.
Load default parameters:	this command allows the operator to reload the values of this menu as pre-defined at factory.
Cvt status:	This command allows the operator to enter the Cuvette menu.
Users:	This command allows the operator to enter the Users menu.
Main Menu:	this command allows the operator to go back to the Main Menu.



7.1.18.1. Action Logs Auto-exporting for Back Up

The system stores in memory and keeps on-line up to 3,000 main events; when reaching the 3,000th, the program removes the oldest 1,500 from the database and **automatically** stores them into a special file “.csv”, available for the User as **back up**. The file is a “.csv” type (Comma Separated Value) available to the user; the name given to the file has the following format: ExpLogs_yyyy_mm_dd.csv.

The exported file is a *.csv type (with the semicolon “;” as values separator).

The export file is composed by a series of records, one for each analysis concluded.

Program root folder

ProgramRoot = %ROOT% \BCA

Location of the file:

%ProgramRoot% \Export

File name:

ExpLogs_yyyy_mm_dd.csv

(i.e.: ExpLogs_2011_10_18.csv)

where:

- yyyy = year
- mm = month
- dd = day.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**

Record Field delimiter: **ascii code 59 (‘;’)**

Record fields:

idEvent	EventType	EventTime	EventDescription
----------------	------------------	------------------	-------------------------

Fields meaning:

- idEvent: progressive identification number of the particular event.
- EventType: identification code of the type of the event.
- EventTime: time of the event occurring.
- EventDescription: description of the particular event.



7.1.19. Cuvette Status Menu

The operator can enter the Cuvette Status menu by selecting the command Cvt Status from the System Config menu. This menu allows the operator to display the transparent values (autozeros) for each cuvette and for each wavelength; it also shows the cuvette life and the number of test performed.

This menu must be entered and used upon replacing a complete cuvette rotor in order to recalibrate optical gains.

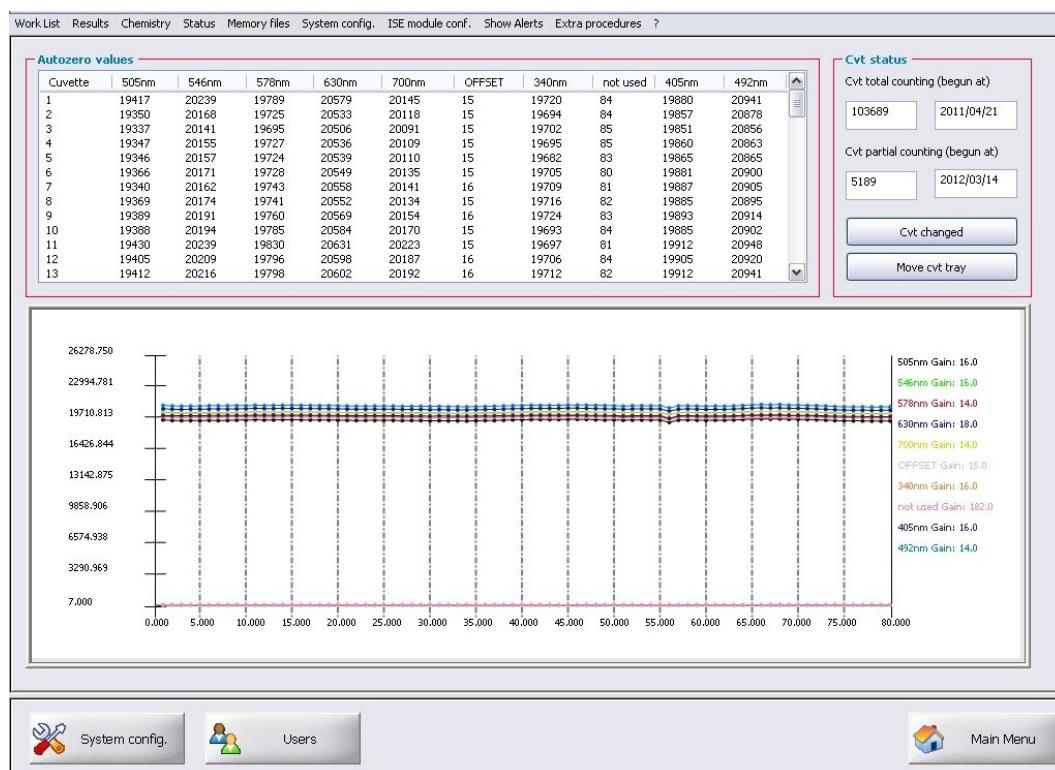


Figure 92: Cvt status Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Autozero values	this window shows all wavelength transparent values for each of the 80 cuvettes. Those values are used by the Levy-Jennings formula for absorbance calculation.
Autozero plot	this graph shows all wavelength transparent values for each of the 80 cuvettes by giving an immediate feedback on the actual cuvette status.
Cuvette status window Cuvette total counting (begun at):	The left field gives the total number of tests run on the system from the date shown on the field on the right. It cannot be reset.

**Field/Command****Function**

Cuvette partial counting The left field gives the partial number of tests run on the system from the (begun at): last cuvette replacement whose date is shown on the field on the right. This counter is reset when pressing the command Cvt changed.

Commands

Cvt changed:

this command must be pressed by the operator just after a cuvette replacement in order to run an automatic gain calibration /(including washing and autozero) and also a partial counter reset.

Move cvt tray:

this command allows the operator to place a cuvette to be changed in the centre of the aperture provided on the cover in front of the instrument.

System config.:

this command allows the operator to go back to System Parameters menu.

Users:

this command allows the operator to enter the Users Menu.

Main menu:

this command allows the operator to go back to Main Menu.



7.1.20. Users Menu

The operator can enter the *Users* menu by selecting the command *Users* from the *System Config* menu. This menu allows the operator to display the actual user logging data and to modify and save the password for accessing the different user levels. It is also used to create new accounts.

The screenshot shows the 'Users' menu interface. At the top, there's a navigation bar with links: Work List, Results, Chemistry, Status, Memory files, System config., ISE module conf., Show Alerts, Extra procedures, and a question mark icon. Below the navigation bar, the main area is divided into three sections:

- Logged user:** A section on the left containing fields for Name (Default), Last name (Default), Additional info, User name (Default), Password, and Confirm password. It includes a 'Save' button with a floppy disk icon.
- User description:** A box containing the text: "System administrator. This account has maximum privileges throughout system. Can modify methods, parameters and users data."
- Users:** A central section showing a table of existing users and a form for creating new users. The table has columns for User (SIGN OFF, admin) and User type (Administrator). The new user form includes fields for Name, Last name, Additional info, User name, Password, and Confirm password, along with a dropdown menu for User type (Administrator, Expert technical, Technical staff) and 'Add new' and 'Delete' buttons. It also has a 'Save' button with a floppy disk icon.

At the bottom of the interface are three buttons: 'System config.' (with wrench and screwdriver icon), 'Cvt status' (with document icon), and 'Main Menu' (with house icon).

Figure 93: Users Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Logged User section	
Name:	this field allows the user to introduce and modify the name of the logged-in user. Any modification must be saved by clicking the command Save.
Last name:	this field allows the user to introduce and modify the surname of the logged-in user. Any modification must be saved by clicking the command Save.
Additional info:	this field can be used for logging general information that will be printed below the operator name in the reports. Any modification must be saved by clicking the command Save.
User name:	this field allows the user to introduce and modify the username of the logged-in user. Any modification must be saved by clicking the command Save.
Password:	this field allows the user to introduce the new password of the logged-in user.



Field/Command	Function
Confirm password:	the user must introduce once more the new password in this field for confirmation. Any modification must be saved by clicking the command Save.
Users section	
Users column:	this window, not editable, shows all registered users with the different privileges. It is possible to add a new user by clicking on the command Add new.
Users type column:	this window, not editable, shows the level of login for the user aside.
Name:	this field allows the operator to introduce the name of the new user in course of registration (the one selected in the window). To save it the operator must click on the command Save.
Last name:	this field allows the operator to introduce the name of the new user in course of registration (the one selected in the window). To save it the operator must click on the command Save.
User name:	this field allows the operator to introduce the username of the new user in course of registration (the one selected in the window). To save it the operator must click on the command Save.
Additional info:	this field can be used for logging general information that will be printed below the operator name in the reports. Any modification must be saved by clicking the command Save.
Password:	this field allows the operator to introduce the password of the new user in course of registration (the one selected in the window).
Confirm password:	this field allows the operator to introduce once more for confirmation the password of the new user in course of registration (the one selected in the window). To save it the operator must click on the command Save.
Commands	
Save:	this command allows the operator to save the data that have been introduced or modified.
Add new:	this command allows the operator to create a new user; the level of the new user must be chosen in the above pull down menu before to activate this command.
Delete:	this command allows the operator to delete the selected user.
System config.:	this command allows the operator to go back to System Parameters menu.
Cvt status:	this command allows the operator to enter the Cuvette status menu.
Main menu:	this command allows the operator to go back to Main Menu.

Note: The system allows the operator to create and modify user data only if its level of login is adequate.

The system login provides three levels, protected by password, that can be set in the System Config menu, User section:

Administrator level, this user can use all operative functions of the instrument; he can create accounts and modify the parameter of menus System Config and Users;



Expert Technical level,

this user can use all operative functions of the instrument, he can modify methods parameters, but he cannot create new accounts;

Technical staff level,

this user can only operate on the instrument and he cannot save any modification (like: method parameters, config. parameters, accounts, ...).



7.1.21. ISE Module Menu

This window is active and can be entered only in case the system includes the **ISE Module** hardware device and if it has been configured at factory or from the service personnel. The operator can enter the *ISE Module* menu by selecting the command *ISE Module conf.* from any menu; it is located in the upper menu-bar only. This menu allows the user to enable and to manage ISE Module and to introduce electrodes data; it also shows the previous electrodes calibration values and in case the calibration is out of range its result is highlighted and automatically retried up to three more times.

Refer to the *ISE Module* paragraph for more detailed information.

WARNING

To use the **ISE Module** remember that it must be enabled in this menu.

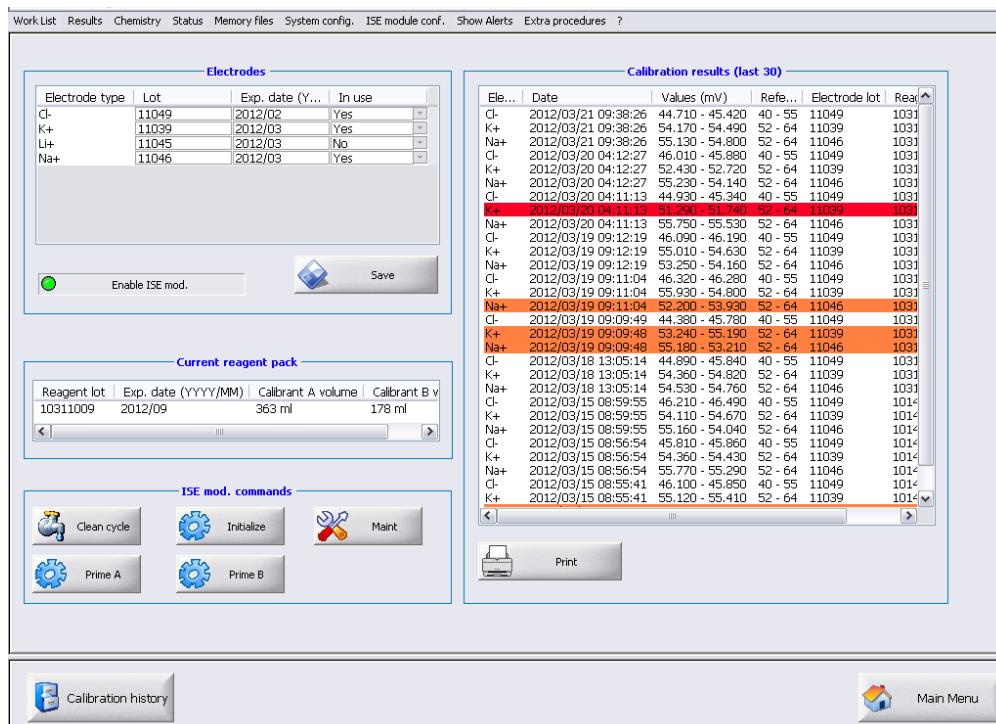


Figure 94: ISE Module Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Electrodes section	
Electrode table list	
Electrode type:	this field lists the electrodes included in the ISE Module: Na+, K+, Li+ and Cl-.

**Field/Command****Function**

Lot:	this field allows the user to introduce Lot number referred to the electrodes aside. Any modification must be saved by clicking the command Save.
Exp. date (YYYY/MM):	this field allows the user to introduce the expiration date of the electrodes. Any modification must be saved by clicking the command Save.
In use:	this field allows the user to set any single electrode as enabled or disabled . The system will not consider disabled electrodes that can be replaced with dummy ones (called " spacers ") and of course their meaningless results. That means that also calibration results and patient results associated with disabled electrodes will be ignored.
<i>Commands</i>	
Enable ISE mod.:	with this selection the operator enables the ISE Module to be used in the system. The ISE module hardware must be powered on and previously configured in the system. If the selection is active, the ISE Module is enabled and electrolytes methods can be programmed in the Work List. At the system start up the instrument runs the pumps and electrodes auto-calibration and the module will be available only in case the check and calibrations have been passed. If the selection is not active, the ISE Module is ignored and electrolytes methods cannot be programmed in the Work List. The ISE Module can be switched off to avoid auto-rinsing operation and then calibrant waste. Any modification must be saved by clicking the command Save.
Save:	this commands allows the operator to save any modification carried out in the electrodes section.

Current reagent pack section

Reagent lot:	this field cannot be edited and shows the lot number of the reagent pack actually installed.
Exp. date (YYYY/MM):	this field cannot be edited and shows the expiration date of the reagent pack actually installed.
Calibrant A volume:	this field cannot be edited and shows the left volume of Calibrant A [in ml] into the reagent pack actually installed; this quantity is an estimated value and could slightly differ from the real volume left.
Calibrant B volume:	this field cannot be edited and shows the left volume of Calibrant B [in ml] into the reagent pack actually installed; ; this quantity is an estimated value and could slightly differ from the real volume left.

Calibration results section (last 30)

A calibration result is highlighted in "red" colour if the result is out of the admissible range (reference values).

A calibration result is highlighted in "orange" colour if the difference between the first and the second calibration is greater than 1.5mV.

The last 30 results will be reported, older result are archived in *Calibration History*.

Electrode type:	this field cannot be edited and lists the electrode whose calibration result refers to.
Date:	this field cannot be edited and lists the date and the time (hh:mm) of the calibration.
Values (mV):	this field cannot be edited and shows the value [in mV] obtained as result of the electrode calibration.
Reference values:	this field cannot be edited and lists the reference range values [in mV] given for the calibration result of the electrode aside.



Field/Command	Function
Electrode lot:	this field cannot be edited and shows the lot number of the related electrode used for calibration.
Reagent lot:	this field cannot be edited and shows the reagent pack lot number used for calibration.
ISE Mod. commands	
Clean cycle:	this command allows the operator to run a clean cycle of the ISE Module inlet sample cup and of the path. This procedure makes use the ISE Module cleaning solution that must be placed into the reagent tray and kept on board.
Initialize:	this command allows the operator to reply the initialization cycle of the ISE Module once more. It is just the same that have been run at the system start up and includes: prime of calibrants A and B, bubble check, pumps calibration and electrodes calibration.
Maint:	this command allows the operator to empty the ISE Module path just before to change electrodes . It must be activated before to replace one or more electrodes. It suspend the 30' auto-rinsing. The command Initialize must be activated when new electrodes have been replaced.
Prime A:	this command allows the operator to prime one or more times Calibrant A rinsing into the ISE Module inlet sample cup.
Prime B:	this command allows the operator to prime one or more times Calibrant B rinsing into the ISE Module inlet sample cup. It should be always followed by a Prime A command.
Other commands	
Print:	this command allows the operator to print the list of the calibration results displayed in the Calibration result window.
Calibration history:	this command allows the operator to enter the Calibration history menu.
Main menu:	this command allows the operator to go back to Main Menu.



7.1.21.1. ISE Calibration Auto-exporting for Back Up

The *ISE* module config menu allows the operator to handle and display all the results previously filed.

The database can contain 10,000 records. When records approach 10,000 the program removes the oldest 3,000 records from database and **automatically** stores them into a special file “.csv”, available for the User as **back up**.

The exported file is a *.csv type (with the semicolon “;” as values separator).

The export file is composed by a series of records, one for each analysis concluded.

Program root folder

ProgramRoot = %ROOT% \BCA

Location of the file:

%ProgramRoot% \Export

File name:

expisecal_yyyy_mm_dd_LastName_Name.csv
(i.e.: expisecal_2006_10_17.csv)

where:

- yyyy = year
- mm = month
- dd = day
- LastName = logged user's last name
- Name = logged user's name.

File Structure Format:

Record delimiter character: **ascii code 10 (Line Feed)**

Record Field delimiter: **ascii code 59 (';')**

Record fields:

idISEcal	idMeth	CalRES1	CalRES2	Date
-----------------	---------------	----------------	----------------	-------------

Fields meaning:

- idISEcal: progressive identification number of that calibration
- idMeth: identification code of the ISE method whose calibration result refers to
- CalRES1: result of the first calibration
- CalRES2: result of the second calibration
- Date: date of calibration; format YYYY_MM_DD_hh_mm
where
YYYY, year
MM, month
DD, day
hh, hour
mm, minute.



7.1.22. ISE Module Calibration History Menu

This window is active and can be entered only in case the system includes the **ISE Module** hardware device. The operator can enter the *Calibration history* menu by selecting the command *Calibration history* from the ISE Module config Menu. This menu allows the user to show ISE Module calibration results older than the last 30 ones (that are visualized in ISE Module conf. menu).

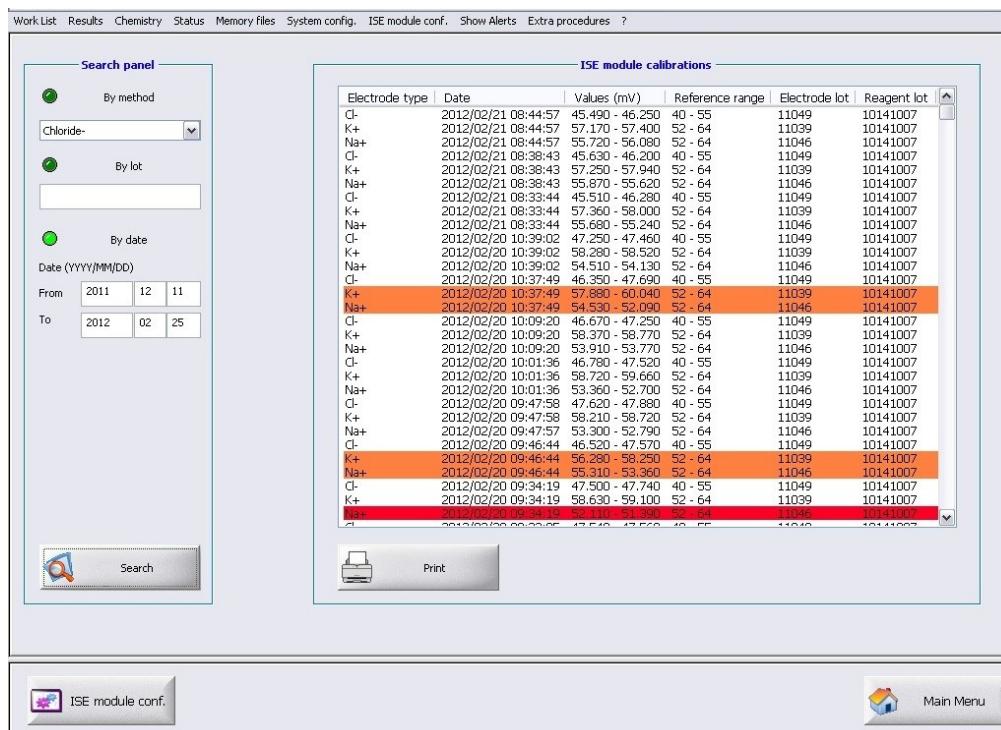


Figure 95: Calibration history Menu

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Search panel:	
By method:	this field allows the operator to introduce the electrode type to search in archive. From the pull down menu it is possible to select one of the electrodes installed. The system considers the content of this field only if this searching option has been flagged.
By lot:	this field allows the operator to introduce the electrode lot number to search in archive. The system considers the content of this field only if this searching option has been flagged.
By Date (yyyy mm dd)	this field allows the operator to introduce the ISE Module calibration range
From:	starting date to search in archive. The system considers the content of this field only if this searching option has been flagged.
To:	this field allows the operator to select the ISE Module calibration range



Field/Command	Function
Commands	
Search:	this commands allows the operator to start the research.
ISE Module Calibration section	
The results of the research will be listed in this section.	
Electrode type:	this field cannot be edited and lists the electrode whose calibration result refers to.
Date:	this field cannot be edited and lists the date and the time (hh:mm) of the calibration.
Values (mV):	this field cannot be edited and shows the value [in mV] obtained as result of the electrode calibration.
Reference values:	this field cannot be edited and lists the reference range values [in mV] given for the calibration result of the electrode aside.
Electrode lot:	this field cannot be edited and shows the lot number of the related electrode used for calibration.
Reagent lot:	this field cannot be edited and shows the reagent pack lot number used for calibration.
Commands	
Print:	this commands allows the operator to print the results of the research.
Other commands	
ISE Module conf.:	this command allows the operator to go back to ISE Module conf. menu.
Main menu:	this command allows the operator to go back to Main Menu.



7.1.23. Show Alerts Window and Actions

This window arises anytime an alarm or a warning condition is detected by the system. It can be closed by the “X” icon on the upper right corner. It can be recalled by selecting, from any menu, the command Show Alerts located in the upper menu-bar only.

This menu allows the user to view active alarms and warnings: alerts can be considered active when back-lighted in orange (warnings) or in red (alarms) colour. If not back-lighted, they are not active anymore and included in the list as solved until the system will be shut down. The list then keeps history from the last start-up. At the system shut-down the list is cleared. Old alerts can anyway be recalled by the System Config. Menu, Action logs window.

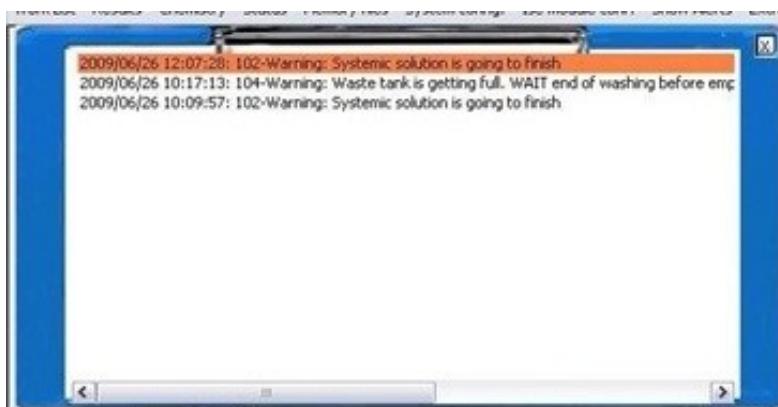


Figure 96: Show Alerts Window

Alerts in red are considered as **alarm**, which is the highest event to overcome for the system normal operation. Any alarm causes the system block that needs to be solved: follow instructions given in this window, most of the alarms can be automatically recovered by the system on operator decision (i.e.: by clicking on Continue when in running status, or by clicking on Reset alarms when in Idle).

Alerts in orange are considered as **warnings** that need the intervention of the operator on the base of the message given in this window and in order to solve or notice the problem (i.e.: *Systemic solution is going to finish*); warnings do not necessarily imply system block.

Alerts are listed with their identification number at the beginning of the message and the date and time of detection.

Alerts that need a decision to be taken by the operator and that are still pending, cause the run to hang until the intervention: all processes that can run will be ended up to the end but the run will finish only after user decisions (i.e.: in case some reagents are finished, the operator must decide if to abort the related analyses into that run or if to refill the bottles and continue the run itself).

Refer to the troubleshooting section of this manual for correct interpretation.



7.1.24. Extra Procedures Pull-down Menu

This pull-down menu can be opened from any menu by selecting the command **Extra Procedures** located in the upper menu-bar only.

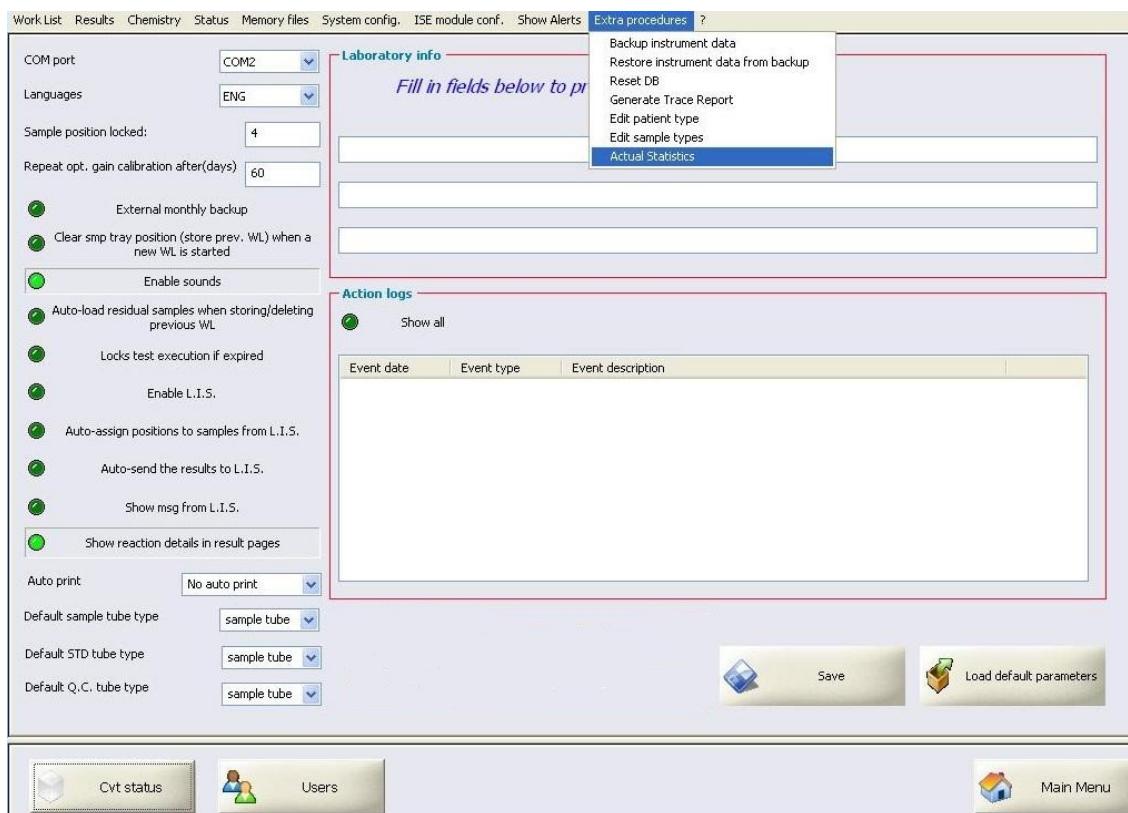


Figure 97: Extra Procedure Pull-down Menu

It allows the operator to choose one of the following utilities:

- **Backup instrument data**
This procedure generates a special file that is stored into a folder and support chosen by the operator. In this file the systems saves all data and information included in the database.
The file is created with the name YYYY-MM-DD.mbk, where
 - YYYY, is the year
 - MM, is the month
 - DD, is the dayof creation.
- **Restore instrument data from backup**



This procedure restores the data contained into a special file that has been previously stored by the operator with the command *Backup instrument data*. This procedure can be used to restore the original system data in case of system corruption or PC break down.

This command requires the system restart.

- **Reset DB**

This procedure helps in case of sudden and unwanted power down or in case of “unknown” run interruptions. It cleans the database from all hanging process. It should be run from the operator after a problem if some “in process” samples still remain active.

Pay attention when using this command as it also clears results that have been concluded but not yet stored. So, use it after memorization of the concluded results.

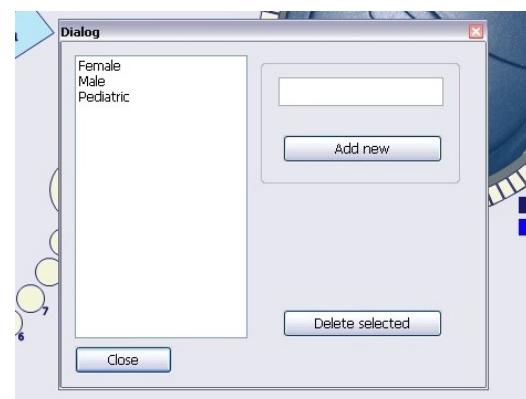
- **Generate Trace Report**

This procedure generates a compressed file that can be requested by the distributor or by producer in case of service or maintenance operations. This file is named: TR_YYYY_MM_DD_HH_MM.mtr and it is memorized into the folder C:\BCA\TraceReports.

The file can be copied and send to the service via email for any complain or to report a problem.

- **Edit patient type**

This command opens a window giving the possibility to create new patient types. Write a new type in the white field on the right and then click on the command *Add new*. To delete types just select it on the left window and click on the command *Delete selected*. Click on *Close* to shut down this window.



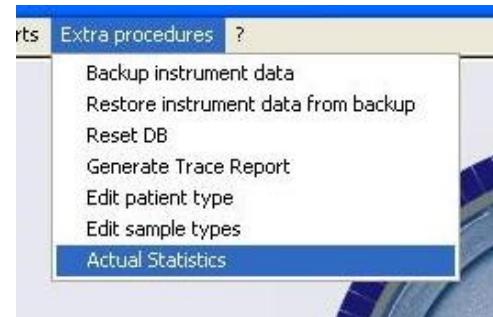
- **Edit sample types**

This command opens a window giving the possibility to create new sample types. Write a new type in the white field on the right and then click on the command *Add new*. To delete types just select it on the left window and click on the command *Delete*.





selected. Click on Close to shut down this window.



- *Actual Statistics*

It is possible to enter the Statistics window by clicking on *Actual Statistics* command.
It shows the number of tests run for methods, QC and Standards on a monthly base.



7.1.24.1. Actual Statistics Window

This window can be opened from any menu by selecting the command *Extra Procedures* located in the upper menu-bar only.

This feature allows the operator to have a better control over the instrument performance counting the total number of test run monthly. It gives also possibility to see the amount of the QCs and Standard/Calibrations run.

Actual Statistics			
Methods (Ref. Month)	Total (ref. month)	Qc (ref. month)	Std (ref. month)
Alkaline Phos	140 (140)	0 (0)	0 (0)
ALP	267 (267)	0 (0)	0 (0)
ALTGesan	286 (286)	0 (0)	0 (0)
AST	179 (179)	0 (0)	1 (1)
BUN	162 (162)	2 (2)	3 (3)
BUNSclavo	280 (280)	2 (2)	3 (3)
CPK	205 (205)	0 (0)	0 (0)
GGT	162 (162)	0 (0)	0 (0)
Glucose	231 (231)	0 (0)	0 (0)
Iron	179 (179)	0 (0)	0 (0)
LDH	143 (143)	0 (0)	0 (0)
	2234	4	7

Figure 98: Actual Statistics Window

This table is a list of the methods actually counted grouping the test by their total amount, by amount of QCs and by amount of Standards. Between the round brackets the software shows the amount of tests related to the reference month only. Changing the date (yyyy and mm format) and pressing the “Go to” button, the software shows the situation updated at the that time, going back to the past, if required.

The operative fields and the operational commands included have the following meaning:

Field/Command	Function
Methods (Ref. month) column:	this column lists all of the methods that have been run on the system.
Total (Ref. month) column:	this column lists the total amount of tests run for any single method on the system Including QCs and Stds); between brackets only tests in the



Field/Command	Function
QC (Ref. month) column:	reference month are shown.
Std (Ref. month) column:	this column lists the amount of Standards/Calibrations run for any single method on the system; between brackets only Std in the reference month are shown.
Other commands	
Go to:	this command allows the operator to show the statistics updated to the year and month introduced in the fields aside. Introduce the year (4-digits: yyyy) in the left field and the month (2-digits: mm) in the right one.
Close:	this command allows the operator to close this window.



7.2. Preparation for Operation

Information about reagents and consumables handling have general meaning. Thus, the Producer recommends the user to read with care the insert instructions following each product.

7.2.1. Safety Rules

In order to lower the risk connected with the use of the system, the user must read carefully Section 1 "Safety" and follow the instructions provided.

7.2.1.1. Knowledge Level Required

The user must be proficient and skilled in Good Laboratory Practice (GLP), and in the In Vitro Diagnostics analysis (IVD) in particular. It is necessary to take all of the precautions recommended in Section 1 and to adopt a good laboratory practice to reach a correct safety level.

The user must have a deep knowledge of this manual, and must have attended a specific training course to correctly operate on the system.

7.2.2. Samples Handling

Read carefully the following information for a correct use of the system and to achieve the most reliability results:

- the user makes sure, before usage, that samples are at ambient room temperature,
- the user must be sure that samples are free from lumps, fibres, froth or bubbles that could cause problems during samples dispensing.

NOTE: The information over samples provided by this manual has a general meaning. A careful reading of the reagent kit inserts is therefore recommended.

NOTE: This system is not equipped with a cloth sensor.

WARNING

The Manufacturer reminds that an incorrect use of the samples could affect the results accuracy and reliability.

7.2.2.1. Samples

The system can be used for an automatic In-Vitro analysis of the following samples types:

- serum,
- plasma,



• urine,
and other biological fluids resulting by the sample treatment (read the section on the documentation complementing the Reagent Kit).

- CSF,

7.2.2.2. Sample Pre-treatment

Follow the specifications in the reagent kit for the sample storage, in order to avoid In-Vitro alterations. The systems automatically pre-dilutes each Sample if requested in the method or in the repetition menu.

7.2.2.3. Sample Storage

General instructions for sample storage:

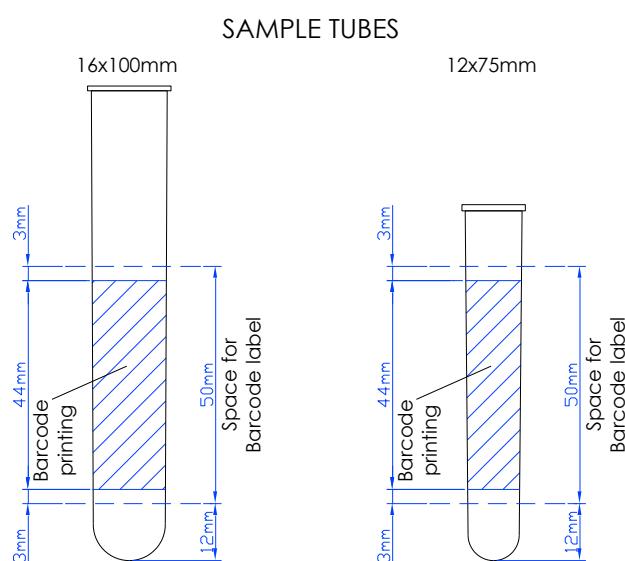
Blood: when the sample has been taken into the tube, store it in the refrigerator (+4°C) until it is analysed.

Serum or plasma: spin the sample tube containing blood (after coagulation, if serum); pour the plasma or serum in a sample tube and store it in a refrigerator (+4°C) until it is analysed. Make use of the proper anti-cloth if requested from methods.

Urine: put the samples in 10ml sample tubes and store in the refrigerator until they are analysed.

7.2.2.4. Sample Identification by Bar-code

The system can adopt a barcode reader (option) for positive sample identification and their relation to the Work-List.



**Figure 99:** Primary Tubes – Barcode labelling

When the barcode reader is used, the label (50mm high) must be stick on the primary tubes (diameter=12÷13mm or 16mm, height=75÷100mm), so that the printed barcode is placed within the hatched field in the picture above. The “barcode type” must be included in the list of paragraph 10.1.2.

7.2.2.5. Sample Tube Minimum Volume

The sample minimum volume is composed by the “dead volume” (volume that cannot be used) plus the sample biological liquid required for the analytic test programmed in the Work List.

In order to ensure a correct instrument performance the sample tubes must have the following features:

- sample tubes: diameter = 12÷13mm or 16mm,
height = 75÷100mm.

Note: Pay attention in not using primary tubes higher than 100mm as sampling probes can be damaged; in order to take primary tubes easily out don't use them if shorter than 75mm.

The sample tray includes 59 or 79 primary sample positions (depending on the configuration) for normal and paediatric samples, for standard and calibrators and for QC's.

When convenient it is possible to use 3ml sample cups **prior special selection** in the software (see Work List).

WARNING

The use of sample tubes that do not meet the conditions required could give problems in sample aspiration/dispensation and then may affect the final result.

7.2.2.6. Dead Volume

In case the sample volume is less or equivalent to the dead volume, it cannot be aspirated by the sampling probe. The dummy volumes are as follows:

Description	Dead Volume
Primary tube diam. 12/13mm	≤110µl
Primary tube diam. 16mm (only for 59 pos. configuration)	≤210µl
3ml sample cups	≤100µl

7.2.3. Reagents and Consumables

Reagents are filled in two kinds of high density polyethylene bottles (HDPE):



- 50ml bottles;
- 20ml bottles.

The 50ml bottles usually are used to contain the mono-reagent or the R1 reagent, while the 20ml bottles are generally used for the second and third reagent.

NOTE: The information provided by this manual on reagents and consumables have a general character. A careful reading of the product documentation is therefore recommended.

7.2.3.1. Use

Prepare reagents according to the reagent insert instructions included in each kit; prepare them in advance, according to their stability and put them on the refrigerated tray (option).

Specific reagents, standard and controls can be loaded on the refrigerated tray (option) directly from the fridge. All the containers used for any reagent preparation must be carefully cleaned, rinsed with distilled water and dried before use.

Reagents and controls must not have any froth or bubbles inside or on surface.

7.2.3.2. Storage

In order to store reagents and consumables properly, the user must follow the instruction provided by the product documentation following the kits.

NOTE: the Manufacturer recommends to store the consumables far away from heat sources, and not to expose them to direct sun light, as they could be damaged or the bottles could be deformed.

7.2.3.3. Reagent identification

The system can adopt a barcode reader (option) for the reagent identification and their association with the reagent tray position and the Work List.

When the barcode reader is used, the label must be stick on the bottles so that the printed barcode is respecting the following pictures.



The barcode type must be: **code 128 type-B**.

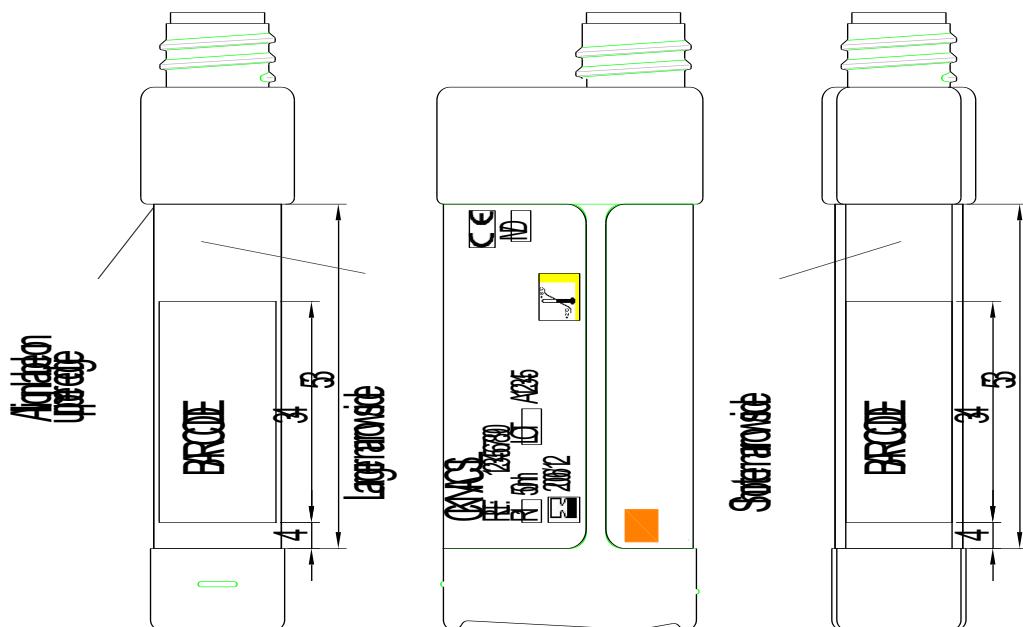


Figure 100: 50ml Reagent Bottle – Barcode Labelling

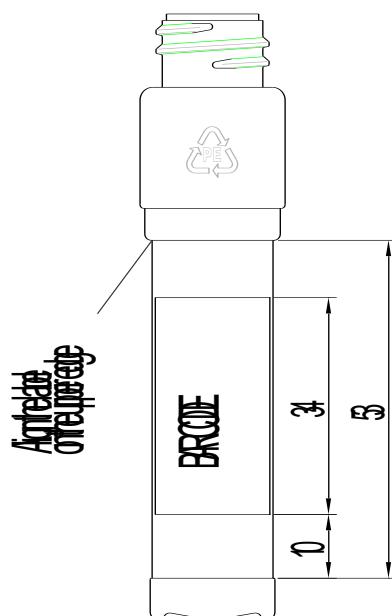


Figure 101: 20ml Reagent Bottle – Barcode Labelling



7.3. ISE Module Configuration and Use (if included as option)

When the ISE Module is included as option in the instrument, it must be powered on and configured as “enabled” in the user software interface before to use it for electrolyte analysis. This must be done once and the configuration will last until the next change.

A green internal lamp shows that the ISE Module is powered on; it must be lighting ON when instrument is in electronic ON status.

When the user plans not to use the ISE Module for more than one week, he can disable it by software and extract and save the electrodes. The following procedure must be followed when the User needs to enable or disable the ISE Module by software.

Enable the ISE Module:

1. Switch ON the instrument.
2. Run the user software and wait for the Warming Up
3. From the user interface software enter the ISE Module configuration menu by clicking “ISE module config” on the upper Menu bar.

Work List Results Chemistry Status Memory files System config. ISE module config. Show Alerts Extra procedures ?

The ISE module config menu allows the operator to enable or disable the ISE Module in the system

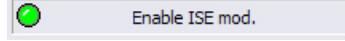
Electrodes			
Electrode type	Lot	Exp. date (Y...)	In use
Cl-	1234	2012/12	Yes
K+	5678	2012/12	Yes
Li+	lot	www/mm	No
Na+	abcd	2012/12	Yes

Enable ISE mod.

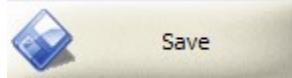
Electrodes

- Cl-
- K+
- Na+
- Cl-
- K+

4. Check *Enable ISE mod.*



5. Click on *Save* button



6. Click on *Initialize* button to start ISE Module initialization.



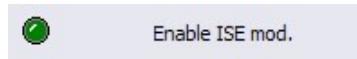


Initialization includes automatic priming of Calibrant A, priming of Calibrant B, Bubble check calibration, Pump Calibration Cycle and ISE electrode Calibration cycle. Results of ISE Calibration are stored in the ISE Calibration history table (right side) and, when not in range, it's automatically repeated until it's valid (maximum three times).

Any further system power on will include automatic ISE Module initialization only during Warming Up of the instrument.

Disable the ISE Module:

1. With the instrument in ON status enter the *ISE module config* menu



2. Un-check *Enable ISE*



3. Click on *Save* button

From this moment at any further system power on the ISE Module will be disabled.

7.3.1. Methods Menu, ISE Module Methods settings

Methods related to ISE Module (i.e. Ise Na+, Ise Cl-, Ise Li+, Ise K+) are included in the methods list. When the ISE Module processes a new sample, the system gets four results at the same time (one for each of the four electrodes that are assembled), one for each electrode. Results will be displayed only for ISE Module methods that have been included in the actual work list.

If not included in the list the user must set them. For each ISE Module method, the type field in the General Info section must show "**ISE Module**" and it must be selected the **kind of electrode** (if Na+, K+, Li+ or Cl-). Also, appropriate **Results Normal Values** have to be introduced and **Controls** must be chosen.



Work List Results Chemistry Status Memory files System config. ISE module conf. Show Alerts Extra procedures ?

Methods	
Method	Code
Albumin	ALB 0
Alkaline Phos	ALP 0
ALT	ALT 0
Amylase	AMY 0
AST	AST 0
AST2	AST2 0
B/C Ratio	B/C Unir
BUN	BUN 0
BUN2	BUN2 0
Calcium	CA 0
Cholesterol	GHO 0
CO2	CO2 0
CO2 WITH BLK	CO22 0
CPK	CPK 0
Creatinine	CRE 0
Creatinine2	CRE2 0
dichromate 2/200	dic 0
Direct Bilirubin	DBIL 0
eGFR Female	GFRF Unir
eGFR Male	GFRM Unir
Fix Time (blk)	FTblk 0
Fix Time (noblk)	FTno 0
fixed time test	FTT 0
GGT	GGT 0
GGT2	GGT2 0
Glucose	GLU 0
HDL Cholesterol	HDL 0
Iron	IRON 0
ISE Chloride	CL 0
ISE Potassium	K+ 0
ISE Sodium	Na+ 0
LDH	LDH 0

41/60 visible methods

Name: ISE Sodium Code: Na+ Barcode: c8 Unit: mmol/l Decimal digits: 0
Visible Type: ISE Module Na+: No. of rgt: 1 Multiply pre-diluted result
Notes:

F1: not used F2: not used
Filters

Volumes [microlitres]

Sample: 0	Bottle sizes:
R1: 0	R1: 0
R2: 0	R2: 0
R3: 0	R3: 0

Incubation/Reading time [sec]

Substrate/Sample Start: R1,5 > R2 Final incub.

36 36

Reference range

Sample type: Serum

Pati...	Min	Max
Female	136.00	146.00
Male	136.00	146.00
Pediatric	0.00	0.00

Instrument Factor (Y = aX + b)

a: 1.000 b: 0.000

Controls: C1, C2, C3
No. of SD for QC ref range: 3

Printout customization

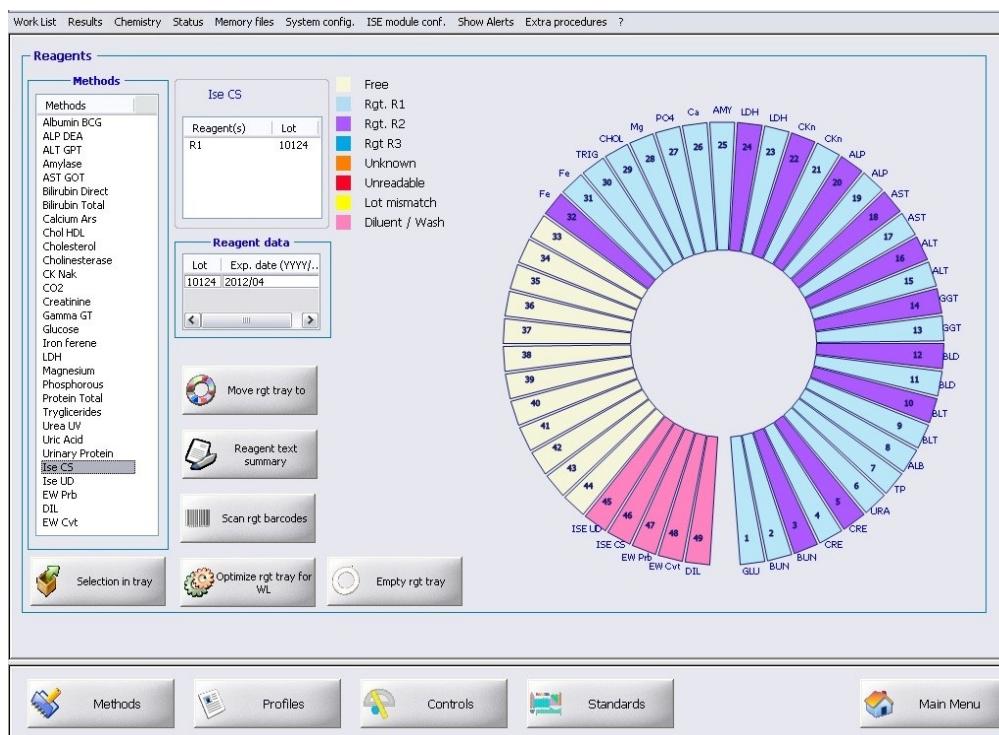
Printout sort order: 0
> Linearity instead of *
< Det. Limit instead of *

Printout icons: Formula Builder, Print, Delete, Save, Dilutions by sample



7.3.2. Reagents Menu, Configuration of ISE Module Solutions

When using ISE Module, the user must configure positions for the Cleaning Solution and for the Urine Diluent (only if some urine analyses have been requested) within the "Reagent" menu.

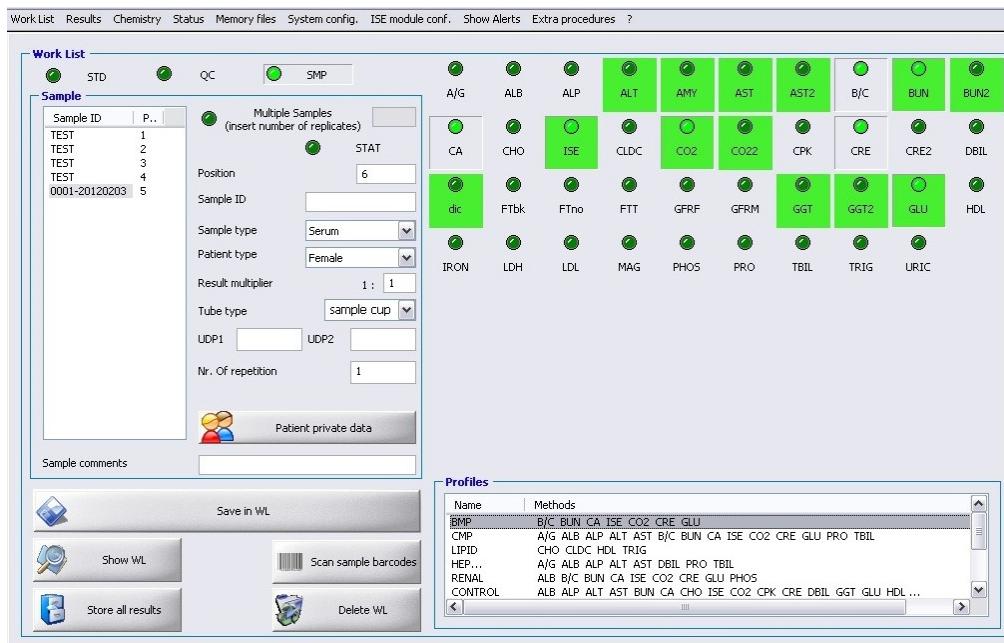


This can be achieved by placing **Ise CS** (ISE Cleaning Solution) and **Ise UD** (ISE Urine Diluent) in the reagent tray like for other methods (click and drag with mouse); remember that the cleaning solution and the urine diluent must be previously poured into 20ml reagent bottle. Of course this includes that the operator keeps such bottles always on board so that the instrument, when required, can use those solutions automatically.

7.3.3. Work List Menu, Electrolytes Programming

When the ISE Module is enabled, the user has the possibility to add Electrolytes tests to any sample in the *Work List* menu; just follow the standard procedure described in the User Manual:

1. simply select the sample type (serum, urine, ...) and then select *ISE* together with other methods;



2. after START, the Work List includes and processes the measurement for Li+, Na+, K+, and Cl- for the selected sample (or anyway the measurement for the used electrodes);
3. after processing, four results for each sample (if four electrodes have been enabled) will be displayed in the Result menu.

During a working session any sample including electrolytes measurement can be added as STAT at any time when ISE Module is currently enabled.

Sample Types:

SERUM/PLASMA

If the User has selected serum or plasma, the system processes the sample 1:1 or diluted, if a different dilution ratio has been chosen.

URINE

If the User has selected **urine**, the system automatically dilutes 1:10 the urine sample (without the need to select any dilution ratio) and works on it without any intervention or further possibility for the operator; it is not possible to select further pre- or post-dilutions.

7.3.4. Working Session, Status Menu

During the working session the **Status Menu** allows the user to control the instrument on-line. An ISE icon has been provided in the middle of the window to show the status of the ISE Module. When the border is in white colour, no problems are with



ISE Module. If the border is filled with red colour a warning is occurring for ISE Module (they can be shown by clicking Show Alerts on the upper menu bar).



During normal operation, by clicking with the left mouse button on the centre of the ISE icon (see picture below) it is possible to visualize the estimated volume in [ml] of Calibrant A and Calibrant B left in the Reagent Pack. Click into the pop up to close that small information window.

7.3.5. Working Session Results and Warning on Results

The *Results* menu allows the operator to handle and display all results obtained in the last working session, including ISE Module results.

In case a result is **out of normal range**, it is marked with the character **H** (if high) or **L** (if low) under the *Notes* column.

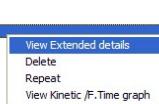
Results are back-lighted in **red** colour if a warning condition related to the result has been detected. In this case just click with the right mouse button and select *View Extended Details* to show a window describing the problem; then take the appropriate decision if to discard result, to repeat analysis, etc.

In case of warnings, results are automatically marked with the string “*Ise module error*” by the system on the printed patient report (if result hasn’t been deleted).

Note: when occurring one of the above mentioned instances analysis must be repeated.

Note: the user must check the congruence of all results and validate them before they are filed or delivered.

Method	Status	Result	Reference v...	Notes	O.D.	Reagent blank	Fit	Kn. / F.T. single OD readings
Urea UV (1:1)	Concluded	96.76 mg/dl	12.00 - 45.00	H	-0.2556	1.6616	---	1.47971 1.2108
Cholesterol (1:1)	Concluded	270.68 m...	0.00 - 0.00	H	0.6789	0.0263	---	
Creatinine (1:1)	Concluded	2.85 mg/dl	0.40 - 1.30	H	0.0300	0.0324	---	0.32580 0.3563
Glucose (1:1)	Concluded	220.62 m...	0.00 - 200.00	H	0.7446	0.0205	---	
AST GOT (1:1)	Concluded	59.07 U/l	5.00 - 50.00	H	-0.0589	1.3324	1.000	1.30711 1.21481 1.1110
ALT GPT (1:1)	Concluded	94.12 U/l	5.00 - 50.00	H	-0.0539	1.3514	1.000	1.34151 1.24791 1.1645
Ise K (1:1)	Concluded	4.44 mmol/l	0.00 - 0.00	H	---	---	---	
Ise CL (1:1)	Concluded	108.50 m...	0.00 - 0.00	H	---	---	---	
Ise Na (1:1)	Concluded	143.80 m...	0.00 - 0.00	H	---	---	---	
Uric Acid (1:1)	Concluded	7.71 mg/dl	0.00 - 0.00	H	0.1309	0.0493	---	





Deletion, repetition, filing and printing of results follow the same rules as per normal clinical chemistry analysis (see user manual).

Possible warnings over results that are shown in Extended Detail when result is back-lighted in red colour:

Warning	Description	Action
Ise air hard	Air in solutions or hardware malfunctioning.	Reinitialize ISE Module from the <i>ISE module config</i> menu, if the problem persists contact service. See also next <i>Troubleshooting</i> paragraph. Repeat analysis.
Ise Mv Out	mV reading out of admissible range (for Cal B or Sample).	Re-initialize the ISE Module from the <i>ISE module config</i> menu.
Ise Mv Out 2	mV reading out of admissible range (for Cal A during calibration or in Sample mode or for Cal B in Urine mode).	If the problem persists: <ol style="list-style-type: none">1. Check ambient temperature to be within 32°C.2. Inspect electrodes and o-rings.3. Replace reagent Pack.4. Replace electrodes or reference electrode. See also next <i>Troubleshooting</i> paragraph. Repeat analysis.
Ise Mv noise	mV noise out of admissible range (for Cal B or Sample).	Initialize the ISE Module from the <i>ISE module config</i> menu.
Ise Mv noise 2	mV noise out of admissible range (for Cal A during calibration or in Sample mode or for Cal B in Urine mode).	If the problem persists: <ol style="list-style-type: none">1. Check floating of red ball into the reference electrode.2. Check for electro-magnetic noise spike source near the instrument and remove it.3. Replace reference electrode. See also next <i>Troubleshooting</i> paragraph. Repeat analysis.
Ise Cal A Drift	Cal A drift in Sample or Slope drift in calibration.	Re-initialize the ISE Module from the <i>ISE module config</i> menu, wait 20 minutes if electrodes are new and repeat initialization.



Warning	Description	Action
Ise out of slope	Result Out of Slope or Out of Machine range.	If the problem persists: 1. Check floating of red ball into the reference electrode. See also next Troubleshooting paragraph. Repeat analysis, or dilute the sample. If the problem persists on all samples: 1. Check floating of red ball into the reference electrode. See also next Troubleshooting paragraph.

7.3.6. Troubleshooting Low Slope, Noise and Drift Error or other ISE Module Issues

Low slope is usually the result of an electrode losing its sensitivity over time although it could be due to other issues. The **noise error** indicates instability of the mV values for a given solution during successive measurement during one analysis. **Drift** indicates that the analyzer is not observing stable mV values between measurements of the calibration solutions.

The first level of troubleshooting is to run the appropriate daily ISE Module Cleaner solution a couple of times to remove any built up protein residues in the flow path. If that does not eliminate the observed problem, make sure the routine maintenance has been performed, such as replacing the reference electrode and pump tubing. If that does not work, replace the questionable electrode(s) and see if this cures the problem. If not, salt contamination may be the source of the problems.

In all types of Ion Specific Electrode (ISE) modules, the possibility of dried salt providing an electrical leakage path exists which can result in various errors including "Drift" or "Noise" or incorrect slope values.

Customers often do not go into the maintenance mode (Menu ISE Module Conf. → command "MAINT") to empty the flow path prior to removing electrodes. This causes the solution that is in the flow path to leak onto the electrode contacts or bubble detector contacts. These small amounts of the calibration solutions eventually dry out; leaving traces of salt residues that may not be visible to the naked eye. These "salt tracks" are conductive to electricity and may provide electrical leakage paths from the electrodes interfering with their function. The electrical signal coming from the ISE electrodes is extremely small and any



interference with those weak signals will result in errors. Customers must replace the electrodes properly. They should always wipe the ISE Module with a dry cloth whenever replacing electrodes, just in case solution has leaked. To eliminate this electrical leakage and resulting signal errors, the salt tracks need to be cleaned up. This is best done by removing all the electrodes from the analyzer and wiping down their contacts with a damp paper towel and allowing them to dry. The next step is to remove any traces of dried salt from the ISE module by taking another damp paper towel and wiping down the areas where the electrode contacts plug into the module. Follow this by removing the moisture with a dry paper towel and allow to dry. When assured everything is properly dry, reinstall all the electrodes and retest. Also check the electrode contacts. Make sure the contacts are clean. If they are dirty or corroded, clean them gently with a pencil eraser, (being careful not to remove the delicate gold coating). The contacts in the module are spring loaded. Make sure the springs are functioning properly and the contacts are moving in and out.

Another potential source of noise errors in particular is related to flow. When the pump stops, the flow is also supposed to stop. Noise occurs when the solution in the system keeps moving while the analyzer is measuring the sample or calibrant. A "noise in Cal A" error occurs when the ISE Module reads the mV's for the electrodes while Calibrant A is present. What actually occurs is that the ISE Module takes six mV readings in rapid succession. Then the ISE Module calculates the average of the six readings. If one of the readings is more than 0.7mV above or below the average, then you will receive a "noise" error. This can occur due if there is a small flow problem and the Calibrant A is moving when the reading is taking place. You must make sure that all of the electrodes are seated properly and the o-rings are present. A quick test of this is to dispense Cal A into the Sample Cup and observe if the solution stays inside the cup. If it slowly empties, then you have a small air leak. Also make sure the pump tubing has been replaced as per the routine maintenance schedule.

Assuring proper and continuous instrument grounding is also necessary. Sometimes moving an analyzer to a different location will help determine if improper grounding or fluctuating strong EMF fields are involved with inducing errors (i.e. big elevator motors, ...). Installation of an Uninterruptible Power Supply, which also corrects for out of specification local power, is also a possible solution to noise and drift problems.

Noise can also occur if the reference electrode is older than six months. Ensure that they perform maintenance when required.

Of course, if one electrode is continually giving noise errors, simply replace the electrode.

"Drift in Cal A" occurs after sample analysis. After every sample analysis, calibrant A is positioned in front of the electrodes and an mV reading is taken. It then compares the mV result to the previous Calibrant A reading. If the change is more



than 7 mV, you will get a "drift" error. Troubleshooting is similar to the procedure listed above for "noise" errors. However, in both cases, try running a cleaning cycle and re-calibrating as a first step.

If problems continue, it is probably due to external factors such as poor or intermittent electrical instrument grounding, improper supply voltage or Electro Magnetic Field, (EMF), effects from other instrumentation such as the electrical motors in refrigerators or centrifuges.

The 4-channel ISE Module calibration cycle is calibrant B-A-B-A. This enables the system to check for drift errors during calibration and not just for sample analysis. It also enables the system to check for drift in both Cal A and Cal B.

7.3.7. ISE Electrodes Calibration

When the system is powered up it goes through Warming Up cycle. During Warming Up the instrument automatically initializes the ISE Module; the initialization cycle includes the following steps and checks:

1. Priming of Calibrant A;
2. Priming of Calibrant B;
3. Bubble detector check and calibration;
4. ISE Pump calibration;
5. ISE electrodes calibration.

If one of these activities fails, the system automatically retries it three more times. In case the failure persists, the system gives a warning to the operator that has to decide if to repeat initialization or not. ISE calibration is then performed and saved by the system; the ISE module automatically performs two successive calibrations in order to control that slopes are within the admissible range (Reference values) and they are repeatable within 1.5mV/decade change.

Values obtained from Calibration are visualized in the *ISE Config* menu and they can be printed out on user command.

Calibration history is available upon dedicated command from *ISE Config* menu.



Calibration results (last 30)						
El..	Date	Values (mV)	Referenc...	Electro...	Reag.	
O-	2012/01/24 07:49:55	42.230 - 42.680	40 - 55	lot	1042	
K+	2012/01/24 07:49:55	57.430 - 57.230	52 - 64	lot	1042	
NH+	2012/01/24 07:49:55	56.570 - 56.840	52 - 64	lot	1042	
O-	2012/01/23 23:49:56	42.970 - 43.340	40 - 55	lot	1042	
K+	2012/01/23 23:49:56	57.590 - 57.240	52 - 64	lot	1042	
NH+	2012/01/23 23:49:56	57.050 - 57.530	52 - 64	lot	1042	
O-	2012/01/23 23:48:44	42.420 - 40.920	40 - 55	lot	1042	
K+	2012/01/23 23:48:44	57.700 - 60.690	52 - 64	lot	1042	
NH+	2012/01/23 23:48:44	57.200 - 52.990	52 - 64	lot	1042	
O-	2012/01/23 15:47:33	42.670 - 42.780	40 - 55	lot	1042	
K+	2012/01/23 15:47:33	57.510 - 57.820	52 - 64	lot	1042	
NH+	2012/01/23 15:47:33	57.590 - 57.300	52 - 64	lot	1042	
O-	2012/01/23 07:46:23	42.640 - 42.810	40 - 55	lot	1042	
K+	2012/01/23 07:46:23	57.520 - 57.600	52 - 64	lot	1042	
NH+	2012/01/23 07:46:23	57.130 - 57.080	52 - 64	lot	1042	
O-	2012/01/22 23:46:22	43.120 - 43.250	40 - 55	lot	1042	
K+	2012/01/22 23:46:22	57.220 - 57.080	52 - 64	lot	1042	
NH+	2012/01/22 23:46:22	57.300 - 57.360	52 - 64	lot	1042	
K+	2012/01/22 23:45:12	59.770 - 57.570	52 - 64	lot	1042	
NH+	2012/01/22 23:45:12	57.200 - 57.190	52 - 64	lot	1042	
O-	2012/01/22 15:45:12	42.700 - 42.800	40 - 55	lot	1042	
K+	2012/01/22 15:45:12	57.390 - 57.570	52 - 64	lot	1042	
NH+	2012/01/22 15:45:12	57.630 - 57.190	52 - 64	lot	1042	
O-	2012/01/22 07:45:11	43.070 - 43.260	40 - 55	lot	1042	
K+	2012/01/22 07:45:11	57.230 - 57.120	52 - 64	lot	1042	
NH+	2012/01/22 07:45:11	57.270 - 57.500	52 - 64	lot	1042	
O-	2012/01/22 07:44:01	42.540 - 41.970	40 - 55	lot	1042	
K+	2012/01/22 07:44:01	57.230 - 59.210	52 - 64	lot	1042	

For each electrode values from both calibrations (in mV) are shown. Calibration results will be back-lighted in **orange** in case the repeatability is out of the limit (>1.5mV/decade). Calibration results will be back-lighted in **red** in case values are out of the reference range (shown aside).

7.3.8. ISE Module, Working with Controls

Controls and data related to Controls used for electrolytes work in the same manner as for all of the other methods (see instrument User manual).

7.3.9. ISE Module, Memory Files - Database

In the Memory files menu, the process for searching electrolyte results works in the same manner as for all of the other methods (see proper paragraph "Memory Files").

7.3.10. ISE Module, Shutdown Procedure

Before shutting down the system or at the end of the working day, if some ISE analysis have been run, the operator **must** run a cleaning cycle from the ISE Config menu. The Shutdown commands the automatic system shutdown.

The program gives the operator the default option for the final cuvette washing.



As the procedure completes, the software exits and the Operating System can be closed. The instrument can then be powered down.

WARNING

The Manufacturer recommends the operator to enable cuvette washing at the end of any working day in order to preserve performances.

WARNING

The Manufacturer recommends the operator never switch off the *instrument* before completing the shutdown procedure.

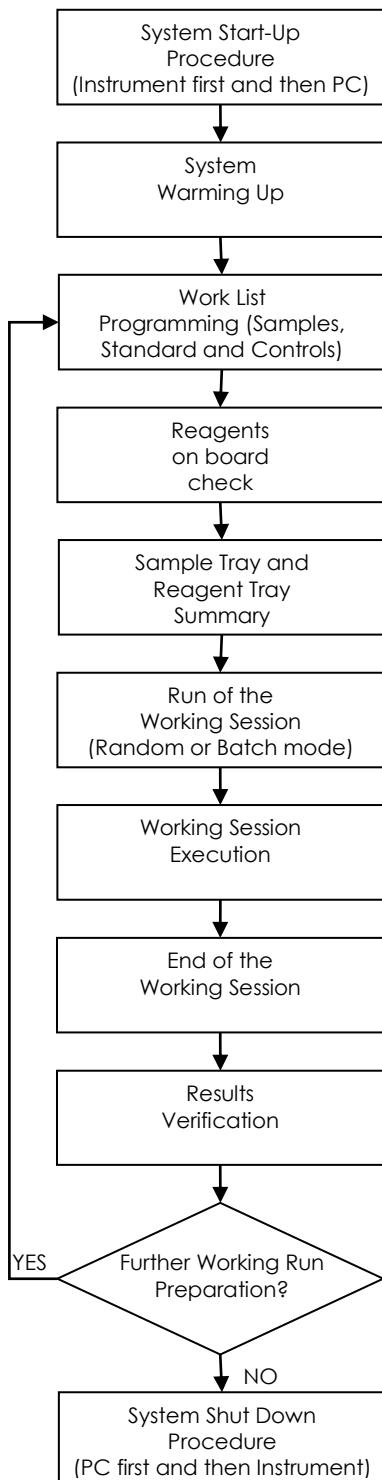
WARNING

The Manufacturer recommends the operator never switch off the *Personal Computer* during the shutdown procedure as database can corrupt.



7.4. Procedures

7.4.1. Operating Flow Chart



**Figure 102:** Operating Flow Chart

The operator, through the user interface, has the possibility to program and to execute Work Lists that include tests for each patient, standards, calibrators and quality controls. The details on the use of the user interface are traced in the following paragraphs.

The previous figure shows the operating flow chart.

7.4.2. Instrument Set-up and Power-On

The main switch is placed on the rear side of the instrument: the operator can power the instrument by switching it on; in this way it's powered by the line AC Voltage.

Two switches are placed on the right front of the instrument:

- **Green switch**, all electronic circuits are powered when this switch is ON;
- **Blue switch**, the refrigerator circuit is powered when this switch is ON; these two switches are totally independent from each other.

**Figure 103:** Power-Up Switches

Note: in case the reagents are kept on-board with the instrument shut down, the refrigerator switch should remain in ON position to preserve them.

Follow the instructions below to start up the instrument:

1. Empty the Waste Tank if full;
2. Prepare the Systemic solution and the Cleaner solution following the insert kit instructions for use;
3. Fill the washing liquids tanks: the 20lt tank with the Systemic solution and the 5lt tank with the Cleaner solution;
4. Turn on the switches in the system following the sequence below:
 - a. the main switch on the rear side of the instrument,
 - b. the Green switch (for electronic),
 - c. if wished, the Blue switch (for refrigeration),



5. Power ON the control PC and wait for the operating system loading,
6. Run the Software of the system on the PC.

7.4.3. Login, Main Menu Access and Auto-diagnosis

As soon as the software starts up, the instrument goes into motors reset and then it checks all main functions. The software also asks the user to login in order to gain access at the required operating level:

The program asks the user to introduce username and password: digit username and password and then press the key "**Enter**". The user name and password are alphanumeric and must have at least 4 digits (See System config Menu):

- the default user name is "**admin**"
- the default password is "**12345678**".

the user at *Administrator Level* **can change** these data as desired. The access is denied until the correct password is entered. As mentioned before, three password levels are provided. Any account must be set or modified in the *System config*. → User Menu:

- *Administrator level*, this kind of user can fully operate on the instrument.
- *Expert Technical level*, this kind of user can use all operative functions of the instrument and he can modify the parameter of menus *System Config*. He cannot create or delete other user accounts.
- *Technical staff level*, this kind of user can operate on the instrument without modifying anything (i.e.: methods, accounts, etc.).

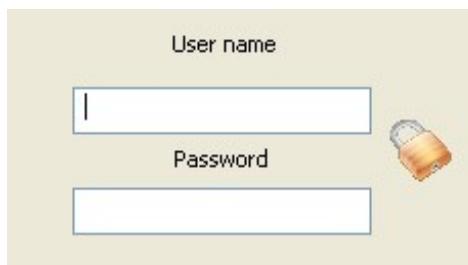


Figure 104: Software – Login User name and Password

After running the software, the system resets and checks the status of all instrument assemblies (Auto-diagnosis test), it starts the automatic warm-up procedure and, after a successful login, the software displays the *Main Menu*. If any problem occurs, an alert message will be displayed on the screen. In case the washing tanks are empty or the waste tank is full, a message is also displayed, asking for the user intervention and waiting for resetting.

Before running the software close the instrument cover.



7.4.4. Warming Up Procedure

During the start up, the system automatically measures and verifies the time from the last shut down:

- if this OFF time is longer than 120 minutes the system starts the full warming up procedure that includes: lamp stabilization, incubation temperature stabilization, tubing refilling, washing and auto-zero of all cuvettes.
- when this OFF time is included in the range between about 2 minutes and 120 minutes, the system starts the shorter warming up procedure above without tubing refilling, washing and auto-zero of all cuvettes (just wait for lamp stabilization and temperatures auto-setting).
- in case this OFF time is within about 2 minutes, the system ignores any warming up procedure and enters directly the Idle status ready to start.

The full Warming Up auto-procedure takes about 30 minutes; in this phase the system carries out the following operations:

- instrument Initialization, reset and auto-check;
- start, control and regulation of the cuvette incubation heater;
- photometer lamp power on and stabilization;
- tubing refilling;
- tank levels check;
- cuvette washing and auto-zeroing.

The User Interface program displays the Warming Up status on the monitor. During the Warming Up the user cannot select any functional command that can change the current instrument operative status.

The shorter Warming Up procedure lasts 20 minutes.

The user can program anyway the new Work List, he can enter and modify data, he can visualize results, check methods, update control data and surf within the software.

At the end of the Warming Up procedure the instrument enables an acoustic alarm (internal beeper) for a short time.

In case of emergency the system will display alerts asking for operations.



7.4.5. Working Session Programming and Run

By the command *Work List* the operator enters the *Work List* menu for working session programming.

The *Work List* menu shows on the right panel all tests that can be run for each sample. All of the analyses that have been programmed for samples, standard/calibrators, and controls constitutes the working session and they'll be run all together at the *START* command.

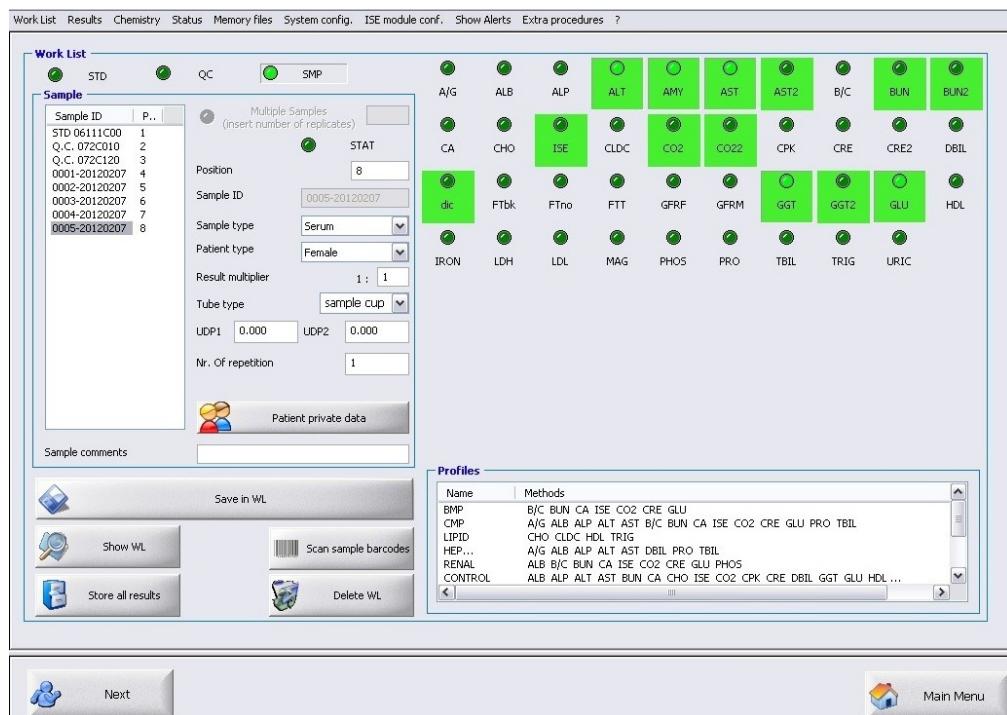


Figure 105: Software, Work List Menu

The *Work List* can be programmed by the operator in normal manual mode or in automatic mode if the L.I.S. (Laboratory Information System) connection has been fixed and enabled.

During the manual programming, the operator will set tests for each of the samples; patient data must be entered manually for each sample if wished and requested.

Depending on the actual instrument configuration, 59-samples or 79-samples tray, the system automatically assigns the available positions to STDs, CTRLs and Samples.

On the other hand, when the L.I.S. connection has been established, the patient list (list of sample IdCodes) and associated analyses will be uploaded from the host remote Personal Computer to the system that assigns them positions on the tray with the help of the bar-code reader.



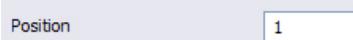
7.4.5.1. Manual Work List Programming and Run

The standard procedure for manual Work List programming, in case that no samples are already hanging for position assignment, is the following:

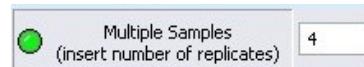
1. Select the "SMP" option in order to enter the patient Work List.



2. Enter the desired sample position (on the sample tray) in the Position field or accept the one proposed by the software (that is the first lower free position, automatically presented).



If case the **same** set of analyses must be programmed for more samples, a quick programming mode is available. Select the WL faster option to activate it:



in this case introduce the number of the samples to be programmed. Those samples will be automatically assigned to the first free positions on the sample tray. If desired, single positions can be moved by selecting a sample and giving it a new position number:

Sample ID	P..
0005-20120402	1
0006-20120402	2
0007-20120402	3
0008-20120402	4

Multiple Samples (insert number of replicates) Position
Sample ID
Sample type
Patient type
Result multiplier
Tube type
UDP1 UDP2
Nr. Of repetition

If you want to repeat analyses for a special sample two or more times fill the field "Nr. of repetitions" with that number (between 2 and 9 max).

3. Enter the sample identification code SampleID; in case the user does not enter a sample ID, the program gives it a code automatically.
Code format:

"xxxx-yyyymmdd"

where

xxxx=progressive number of the day,

yyyy=year,

mm=month,

dd=day.



Once given and saved, this IdCode number cannot be modified anymore: can be deleted but not changed.

4. Select the Sample type, from the pull down menu.

Sample type	Serum
Patient type	Serum
Result multiplier	Urine
Tube type	sample tube

5. Select Patient type, from the pull down menu.

Sample type	Serum
Patient type	Male
Result multiplier	Male
Tube type	Female

6. Select Patient Private Data and enter data in the fields of the displayed window (if desired).

Patient private data

Sample ID	0008-20120402		
Patient unique id	mrrfghgdbct12345	Look up	
Last name	Rossi	First name	Maria
Date of birth	1955/02/28	Age	57
Address	Via dei Fiori, 467 - 00199 Rome - Italy		
Email	m.r.example@prov.it		
Phone	123456789		
Bed	123	Dpt.	123
Clinic	Card	Request date	2012/01/31
Doctor	Bianchi		
Notes	Cardipatic		

Buttons: Close, < and >, Save

Figure 106: Software, Patient Private Data Window

This data can be entered before or during the working session or, at the end of the session from the archive menu, after the results have been saved in the Memory files. In the latter case any the single sample can be recalled. Arrows help to surf among patient in archive or in work list.



7. For any sample, select the parameters (analyses) and/or profiles to be executed (value for eventual pre-dilutions of the sample will be taken from method parameters).

Select STAT in the priority field in case the introduced sample is URGENT.

The screenshot shows the 'Work List' software interface. In the top menu, 'Work List', 'Results', 'Chemistry', 'Status', 'Memory files', 'System config.', 'ISE module conf.', 'Show Alerts', and 'Ex' are listed. Below the menu, there are tabs for 'STD', 'QC', and 'SMP'. The 'Sample' tab is active. On the left, a list of samples is shown with their IDs and positions: 0005-20120402 at position 1, 0006-20120402 at 2, 0007-20120402 at 3, 0008-20120402 at 4, and 0009-20120402 at 5. To the right of the sample list are fields for 'Multiple Samples' (with a 'STAT' radio button selected), 'Position' (set to 5), 'Sample ID' (0009-20120402), 'Sample type' (Serum), 'Patient type' (Male), 'Result multiplier' (1 : 1), and 'Tube type' (sample tube). On the far right, a grid of analysis icons is displayed: ALB, ALP, CHOL, CKn, Mg, and PO4.

8. If the sample has been pre-diluted off-line and it is desired the multiplication of the obtained results by the dilution ratio, select that ratio in *Result multiplier*.

Result multiplier 1 :

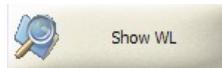
9. Select *Save in WL* to save the sample/s together with the programmed analyses in the current Work List that is under programming.



When a sample has been saved in the Work List, the program automatically shows the User, in the *Position* field, the first available position on the sample tray.

10. The sample can now be placed on the sample tray.

11. Repeat all the steps (from 1 to 10) for each sample to be entered in the Work List. The WL can be displayed and modified at any moment through the command *Show WL*.



When the *Show WL* command is selected, the program displays a window showing the actual Work List:

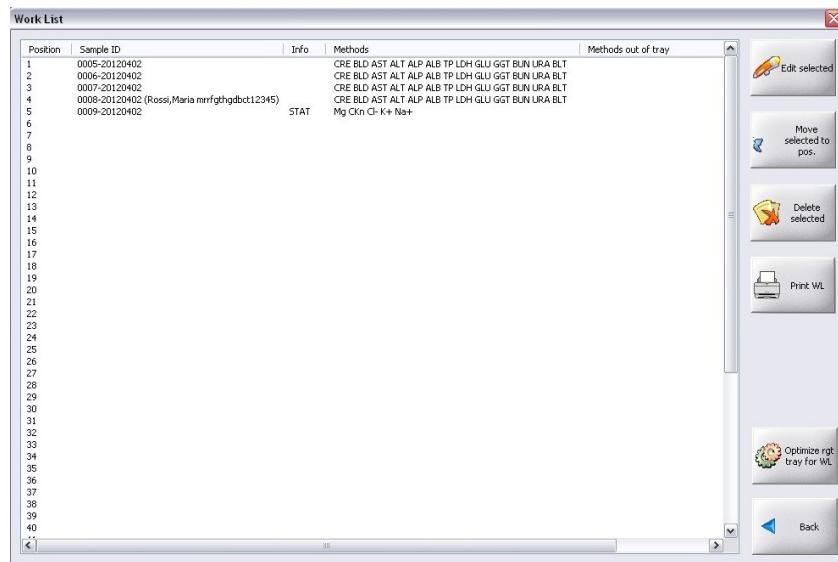


Figure 107: Software, Display Work List

any of the samples can be modified. Select the sample to modify and then click on the command *Edit selected*, the program focuses that sample in the Work List Menu, then execute modifications and save it again.

Samples can be deleted. Select the sample to be deleted and click on the command *Delete selected*.

Samples can also be moved to another position on the sample tray: click on the command *Move selected to pos.*

To go back to the Work List, select the command *Back*.

The column "Methods out of tray" shows the parameters whose bottles must be loaded on board.

12. When the patient work list compilation has been completed, select the "STD" option if some standards or calibrators must be included in the Work List (you can program Standard or controls before samples too).



13. Then proceed with the selection of the method/s to be calibrated (if any) by selecting each standard to run and assigning a new position to each of them. Remember that standard/calibrators with same lot number and the same dilution ratio (case of standard ready-to-use not to be diluted) have the same sample position on the tray. In case the standard dilution must be performed automatically by the instrument, click twice on the method until you get blue colour; then the dilution of the standard with ratio different from 1:1 will be performed in the cuvettes starting from the mother that must be placed in a sample tray position. In case of ready-to-use standards, that do not need dilutions, provide enough free positions on the sample tray to locate all standards (otherwise the system doesn't load them).

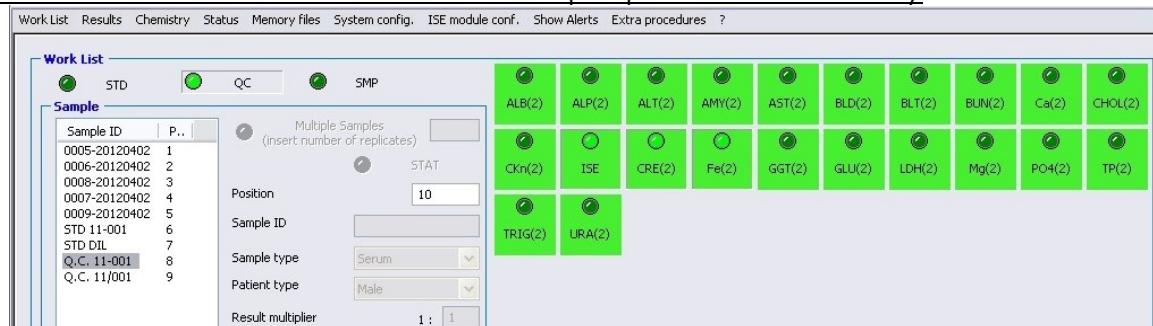


After selection, click on “Save in work list” to include the standard in the working session. The number between brackets stands for the number of standards to be performed.

14. In case that also controls must be run, select the “QC” (you can program Standard or controls before samples too).



15. Then proceed with the selection of the method/s to be controlled and assigning a new position to each of them. Remember that controls with same lot number have the same sample position on the tray.



After selection click on “Save in work list” to include the controls in the working session.

16. If the Show WL command is again selected, the program displays the actual Work List:



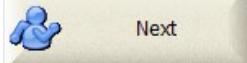
Work List

Position	Sample ID	Info	Methods	Methods out of tray
1	0005-20120402		CRE BLD AST ALT ALP ALB TP LDH GLU GGT BUN URA BLT	
2	0006-20120402		CRE BLD AST ALT ALP ALB TP LDH GLU GGT BUN URA BLT	
3	0008-20120402		CRE BLD AST ALT ALP ALB TP LDH GLU GGT BUN URA BLT	
4	0007-20120402...		CRE BLD AST ALT ALP ALB TP LDH GLU GGT BUN URA BLT	
5	0009-20120402	STAT	Mg CKn Cl- K+ Na+	IGA (100.000) IGA (0.000)
6	STD 11-001			
7	STD DIL			
8	Q.C. 11-001		CRE (C1) Fe (C1) Cl- (C1) K+ (C1) Na+ (C1)	
9	Q.C. 11/001		CRE (C2) Fe (C2) Cl- (C2) K+ (C2) Na+ (C2)	
10				
11				
12				
13				
14				
15				
16				
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40				

Buttons on the right:

- Edit selected
- Move selected to pos.
- Delete selected
- Print WL
- Optimize rgt tray for WL
- Back

When finished WL programming, select the command Next to proceed with the next page about Reagent tray configuration control,



In case the system includes the connection with the L.I.S. (Laboratory Information System) and this is active, established and working, the exchange of data (WL and results) with the remote host computer is possible and automatic.



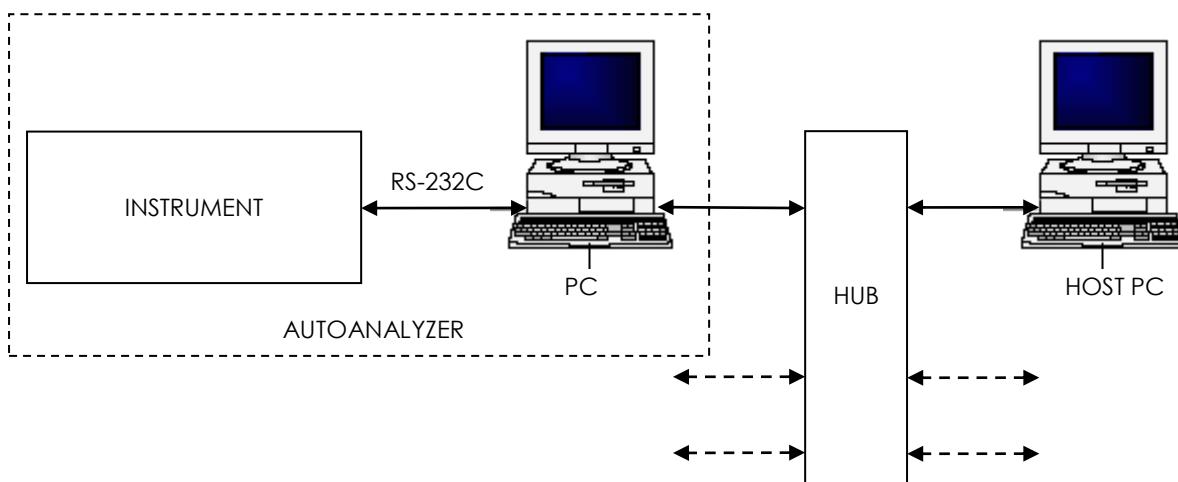
7.4.5.2. Automatic Work List Programming with L.I.S. Connection

When the L.I.S. connection has been enabled and it is operative, the host remote workstation in the laboratory can set a link with the system for data exchange. The link is based on an ASTM-like protocol described in the document cod. MNT-10910-01-x (last revision) addressed to IT technical personnel only. This document describes the electronic transmission of digital data information between a laboratory instrument and an information computer system. This kind of connection allows the “Auto-analyzer to/from Host” bi-directional communication to improve automation in data request transmission (i.e.: work-lists and patient data) and in patient final results data response. This document also defines the digital message structure allowing the data transfer between Auto-analyzer and Host.

The communication between the system and the external Host is compliant to the IEEE 802.3 standard, regulating the most common local area network (LAN) technology based on Ethernet standard. The system PC is supplied with an internal network Ethernet interface; it can be linked to the laboratory information local area network through a Hub or through a Switch Hub that connects several other stations for communication purposes. The Host Computer is obviously part of the same network and it is connected in the same manner.

Note: local area network L.I.S. architecture and realization, software drivers and interfaces to Systems, physical links, Hubs and Switches, and any other part or line or connection are considered part of the end user structure and must be fully carried out by the end user (if not otherwise stated with special different agreements) under its own responsibility.

The following picture shows the supposed functional diagram of connection.





When the system receives new data from the host computer, it displays the following message on the monitor:



The operator, in order to run a new WL or to add those new samples to a WL in running, has to click on OK and must enter the Work List menu.

All samples received from L.I.S. will be added into the sample window on the left side of this menu. Upon receipt, if the following selection in the System config. menu has been checked



the system auto-assigns the first free tray positions to the samples received.

In case all positions are busy, samples will be added with position number "0" to the list. The operator will move them when new free positions are available.

Position	Sample ID	Info	Methods	Methods out of tray
25	0016-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
26	0017-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
27	0018-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
28	0019-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
29	0020-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
30	0021-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
31	0022-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
32	0023-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
33	0024-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
34	0025-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
35	0026-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
36	0027-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
37	0028-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
38	0029-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
39	0030-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
40	0031-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
41	0032-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
42	0033-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
43	0034-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
44	0035-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
45	0036-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
46	0037-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
47	0038-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
48	0039-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
49	0040-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
50	0041-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
51	0042-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
52	0043-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
53	0044-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
54	0045-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
55	0046-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
56	0047-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
57	0048-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
58	0049-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
59	0050-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
0	0051-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
0	0052-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
0	0053-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
0	0054-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02
0	0055-20120405		CRE CHOL TRIG GLU BUN Cl-K+ Na+	IGA HDL C02

The operator will Start samples after having placed them on the sample tray. New free positions are cleared after validation and storing of concluded final results.

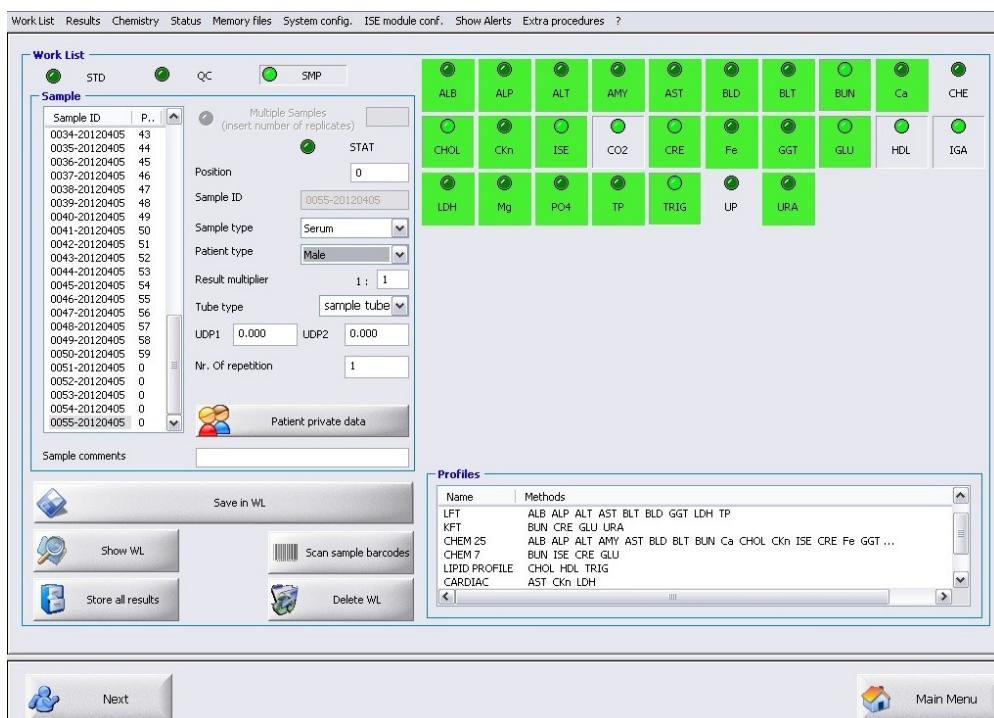


Figure 108: Software, Work List programming

If samples have been bar-coded for positive identification, the operator, after receiving the WL from L.I.S., places samples on board and runs the Scan sample barcode procedure. The system assigns the proper tests (uploaded by the L.I.S.) to any sample on the tray. If some samples are unknown the software alerts the user that can anyway modify the WL manually to include that sample.

By running the command Scan sample barcode the system runs the reader to scan barcodes attached on the tubes and adds the samples in the Work List. Recognized samples will be associated to their physical position on the sample tray. In case of Work List downloaded from L.I.S. or anyway pre-existing Work List, the system associates any sample tray position with its correct set of analysis, if the barcode has been recognized.

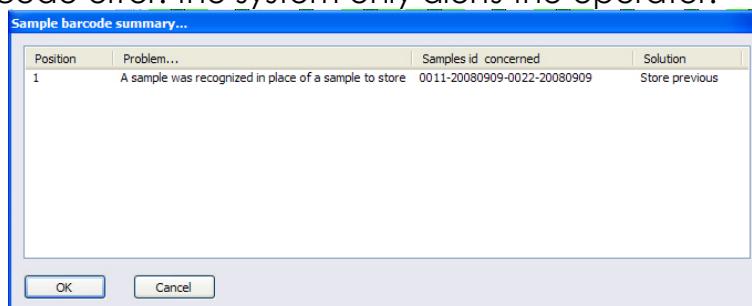
When some problems is detected by the system, the software alerts the user by suggesting a possible solution through a special “message window”; the user can accept or not the suggestion. The message window has been represented below; possible problems are the following:

- Case of a sample that have been processed but not yet validated and archived: in its position the reader has detected a **new sample**; the system stores the old sample results and it accepts the new sample to be processed in its position.
- Case of a sample that have been processed but not yet validated and archived: its position has been detected as **free** or in its position the reader has



not detected a valid sample; the system stores the old sample results and it sets the position as free.

- Case of a sample that have been partially processed and the system **doesn't find it** on the tray anymore; the system alerts the operator that the sample cannot be found, it leaves the sample in the WL without the position number and the operator has to take a decision (replacing the sample on the tray or deleting pending analyses).
- Case of barcode error: the system only alerts the operator.



By clicking on the button “**OK**” the operator accepts the suggestion (result storing) and the window closes.

By clicking on the button “**Cancel**” the operator aborts the suggested operation (result storing) and the window closes. The situation has left like before the scanning.

The operator can anyway and at any time modify WL data.



7.4.5.3. Notes on Standards and Control

The factor (F) or the calibration curve used for calculation of the final result is saved in the system for a proper result interpretation. The **F factor** can be the result of a standardization/calibration or it can be previously and manually set by the user. At the end of any standardization, the system automatically replaces the old factor with the new one by saving the date and time. Standard/Calibrations can be run one shot or in triplicate.

Also any **manual** off line modification of Factors or of Calibration Curve points carried out from the operator are logged with date and time.

The instrument can measure concentrated standards, or it can generate a calibration curve. In the latter case the user can decide whether the instrument has to process **pre-diluted** standards or if it must automatically generate all dilutions starting from the concentrated standard (**standard dilutions**).

The same considerations made for the factor are valid for the calibration curve. Once the patient Work List to be run has been programmed, the user can include in the Work List the execution of the Standards and of the Quality Controls by choosing the methods among those listed in the reagent panel. Standards values and characteristic parameters for controls must have been previously set in the Standards menu and in the Controls menu.

Note: The system can anyway process standards and controls in the current work list even if they have been scheduled after the first *Start* command. Standards and Calibrations can then be added and launched in the current run if the related method has not yet included in the current work list. Controls can be run at any moment.

Note: It is also possible to launch Work list running only Standards and/or only Controls (w/o samples).



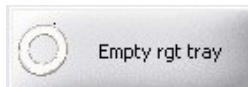
7.4.6. Set Reagents on Board During WL Programming

In the Reagent menu, the user can set reagents on board configuring manually or automatically by bar-code (when provided) the tray positions.

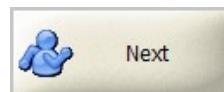


Figure 109: Software, Reagent Menu

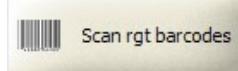
1. If necessary, reset all the tray positions by clicking on the button *Empty rgt tray*:



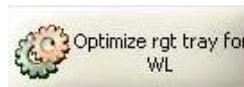
2. In the *Methods* window, click with the mouse on the method to be introduced in the tray.
3. In the *Reagents* window, click the mouse on the Reagent (R1, R2, etc.) and drag it to a position on the tray. The position is automatically allocated and saved in the configuration.
4. Enter the reagent lot and expiry date.
5. Place in the same manner the other reagents of the same method (if any).
6. Repeat the operations 2 to 5 for every method to be introduced in the tray.
7. To delete a method from the configuration, click and drag it out of the tray.
8. Select the command *Next* to exit the menu *Reagents*, and enter the menu *Work List Summary*.



In case that reagents have been provided with proper bar-coding and the system includes the reader, the operator can simply place the reagent bottles on the reagent tray positions and then by clicking the button:



the system will auto-configure the reagent tray positions on the screen.
If the bar-codes are missing, the system can optimize the reagent tray by clicking the button:



reagents needed for the work list ready to run will be positioned on the tray and the operator has only to fill the suggested positions.

The last reagent position is reserved for the diluent (**more positions** for the same reagent can be anyway used when needed).

More reagents, previously selected in the method window, can be automatically moved in the tray by clicking on the button:





7.4.7. Running a Work List

In the WL Summary menu, the user can control samples, reagents, standards and controls to be positioned on the different trays. In the reagents window the system solutions will be highlighted in blue. The Work List to be run can be modified in the previous menus going back by the Back command.

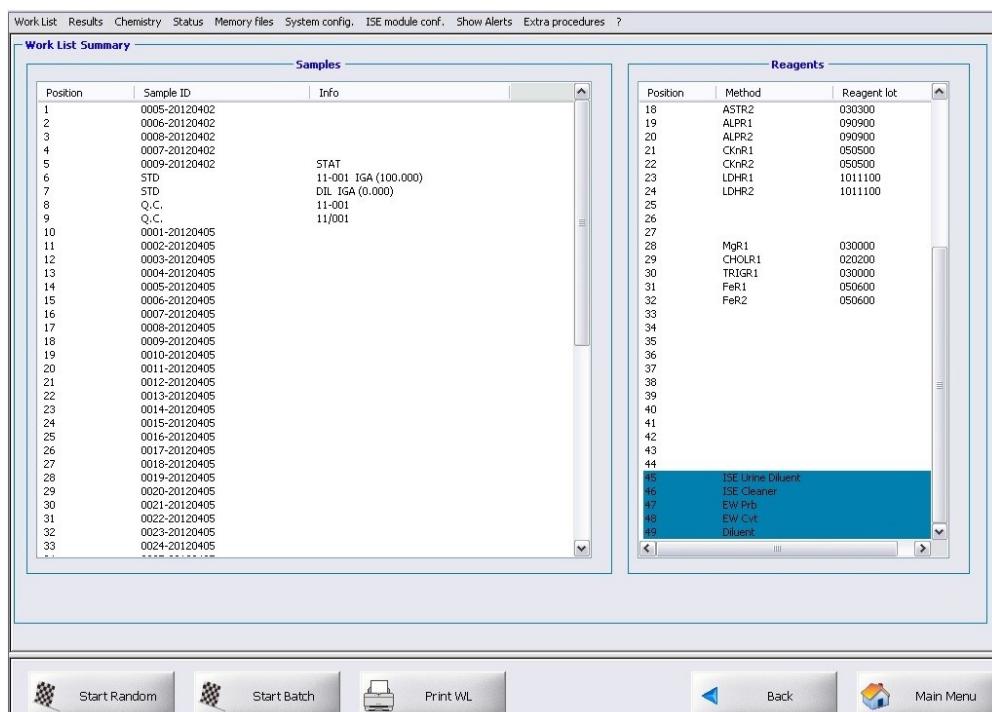


Figure 110: Software, Work List Summary Menu

1. In the Samples window check the congruence of sample tray positions for Sample, Standard and Controls and of values for eventual Calibration Curves.
2. In the Reagents window check the congruence with the tray of the reagent positions.
3. Select the command *Start Random* to run the working session in Random mode. In this case the program schedules the analysis sorted by sample,



in alternative, select the command *Start Batch* to run the working session in Batch mode. In this case the software schedules the analysis sorted by method.

4. In the absence of any error message, the program starts the working session: the system loads the data, schedules the analysis and turns automatically on the *Status* page.

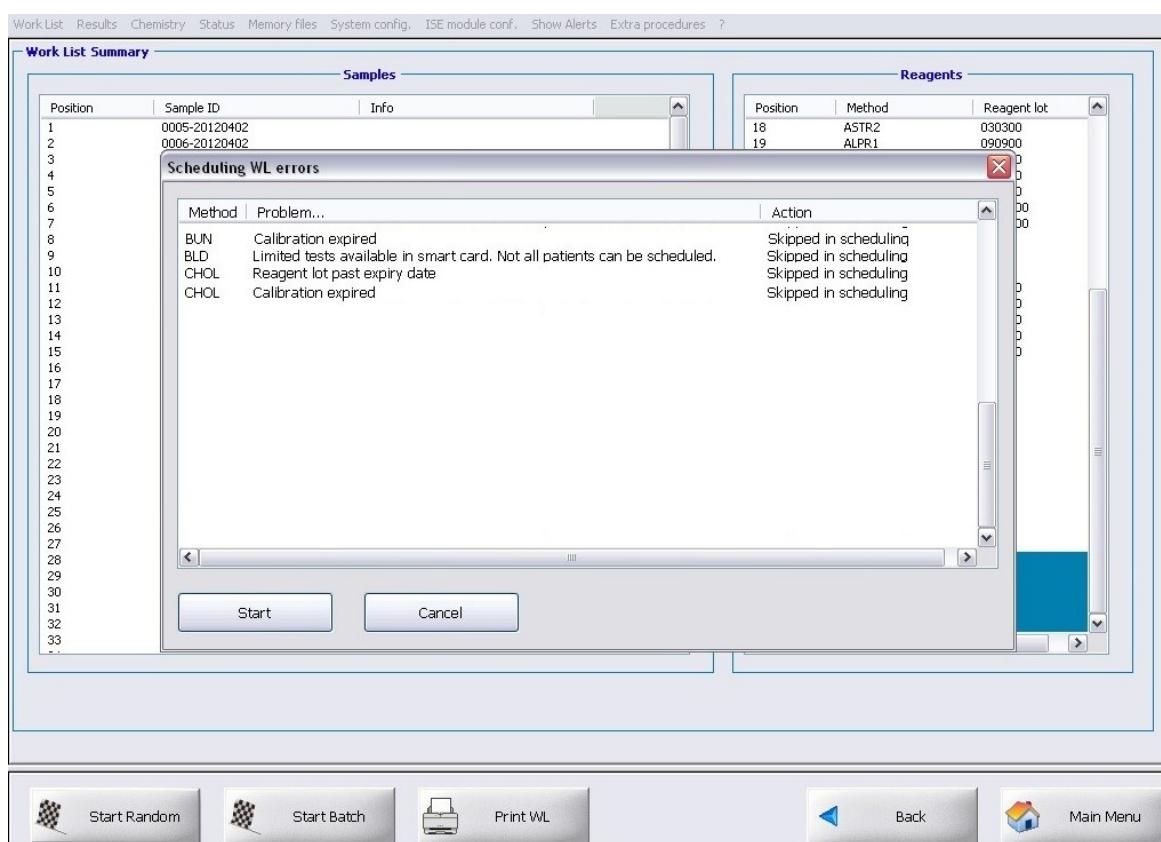


Figure 111: Software, Error Message on WL Start

5. In case of errors, the software open a special message window explaining any inconsistency on the work list to run, the eventual action to take and the possibility to Start anyway the session or to Quit (button Cancel) and to correct the errors.



7.4.8. Working Session

The Status Menu allows the user to control the instrument on-line during the working session. In the bottom-right of this window, the system displays the status of each scheduled analysis.

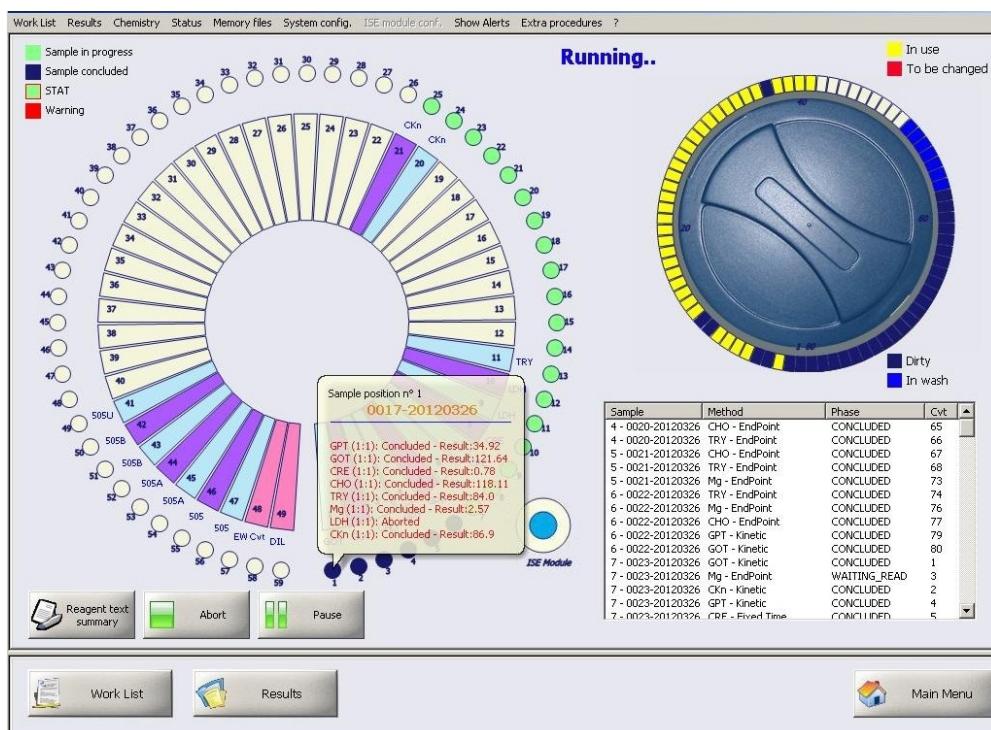


Figure 112: Software, Status Menu

The user can perform congruent operative actions or enter other menus in the software while the working session is in progress.

Operative actions allowed in this Menu:

- to pause the instrument (it pauses sampling operations);
- to add STAT sample in the Work List in process (by entering the Work List menu);
- to add of one or more samples in the Work List in process (by entering the Work List menu);
- to replace empty reagent bottles;
- to extract, change and refill samples;
- to refill handle external tanks, in case of system notification;
- to stop and abort the current working session.

Actions allowed in other menus:

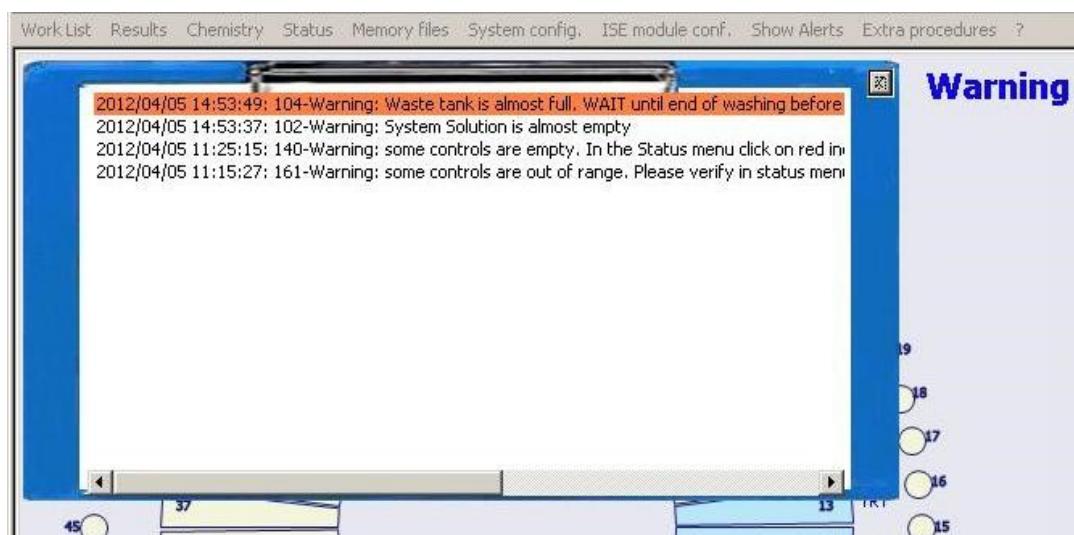
- to enter or to update data related to any patients;
- to add new samples in the current Work List;



- to display and to print results of concluded analyses;
- to operate in the Memory files Menu (Archive);

In the absence of system error messages, the user shall just wait until the working session is completed and then validate and print *all* the final Results from the Results Menu before running a new Work List.

During the operation eventual warning and/or alarms will be alerted by a proper window always in front of any menu. Warnings are highlighted in orange, alarms in red. Warnings/alarms highlighted are still active, the others have been overcame.



7.4.8.1. Pausing a Working Session

During a working session, the user can turn the system on **Pause** at any time (i.e.: to add samples or to refill bottles); of course this operation should be carried out only in case of needs because it slows the throughput.

The procedure to Pause the system has been described below:

1. Select the Command **Pause** to pause the instrument.



2. Wait the message on the screen indicating Sampling Arm to complete the phase and to stop above the Washing Sink.





3. Open the cover and do the needed operations within the working area – don't change position to reagents running in Work List.
4. Close the cover.
5. Select the command Continue to start again the working session.



6. The system restarts running in a few seconds giving evidence on the screen.



7.4.8.2. Adding STAT Samples During a Run

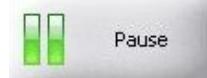
The user can add urgent samples (STAT) at any time. The STAT sample can be placed in a free position of the sample tray (save and discharge concluded samples if more free positions are requested).

The procedure is the following:

1. Check if the needed number of free positions are available on the sample tray;
2. If free positions are missing, open the *Results for patient* menu, validate the results of completed Samples and archive them.

Note: whenever possible, the user should leave some free positions on the sample tray for STAT urgency.

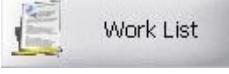
3. Select the Command Pause to pause the Instrument.



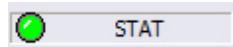
4. Wait Sampling Arm to complete their working phase and to stop above the Washing Sink.
5. Open the cover and introduce the STATS (urgent sample).
6. Close the cover.
7. Select the command Continue to start again the working session.



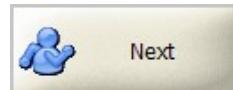
8. Select the command Work List to program the STAT.



9. Program the analyses for the STAT and activate the priority selection STAT.



10. Select the command Next.



11. In the Reagent page add the missing reagent bottles if needed then select Next again and enter the Work List Summary menu.

12. Select the command Start Random or Start Batch according to the previous one.



The system will process the Urgent Sample as soon as possible and with the highest priority. Add and run also standard/calibrators if needed.

7.4.8.3. Adding One or More Samples During a Run

The user can add one or more samples any time during a working session (continuous loading). Samples can be placed in free positions, or they can replace concluded samples that have already been archived.

The procedure is described below:

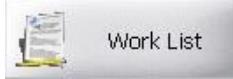
1. Check if the needed free positions are available on the sample tray.
2. If free positions are not enough, open the Results for patient menu, validate results and archive as many concluded samples as the positions required.
3. Select the Command Pause to pause the Instrument.



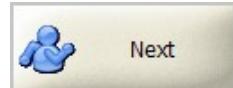
4. Wait for the sampling Arm to complete the phase and stop above Washing Sink.
5. Open the cover, take the completed samples out and replace them with the new samples.
6. Close the cover.
7. Select the command Continue to start again the working session.



13. Select the command Work List to program the new samples,



8. Program the analyses for the new samples.
9. Select the command Next,





14. In the Reagent page add the missing reagent bottles if needed then select Next again and enter the Work List Summary menu.
15. Select the command Start Random or Start Batch according to the previous one.



The system will process the new samples as soon as possible after completing the previous ones.



7.4.9. Working Session Results

The **Results** menu allows the operator to handle and display all results obtained in the last working session or in the current run (for analyses concluded).

This section provides two menus:

- the menu to display all results grouped by patient (*Results by Patient*);
- the menu to display all results grouped by method (*Results by Method*).

The information about patients, whose analyses have been completed, can be printed and archived.

Note: the user must check the congruence of all results and then must validate them before they are filed or sent by L.I.S.

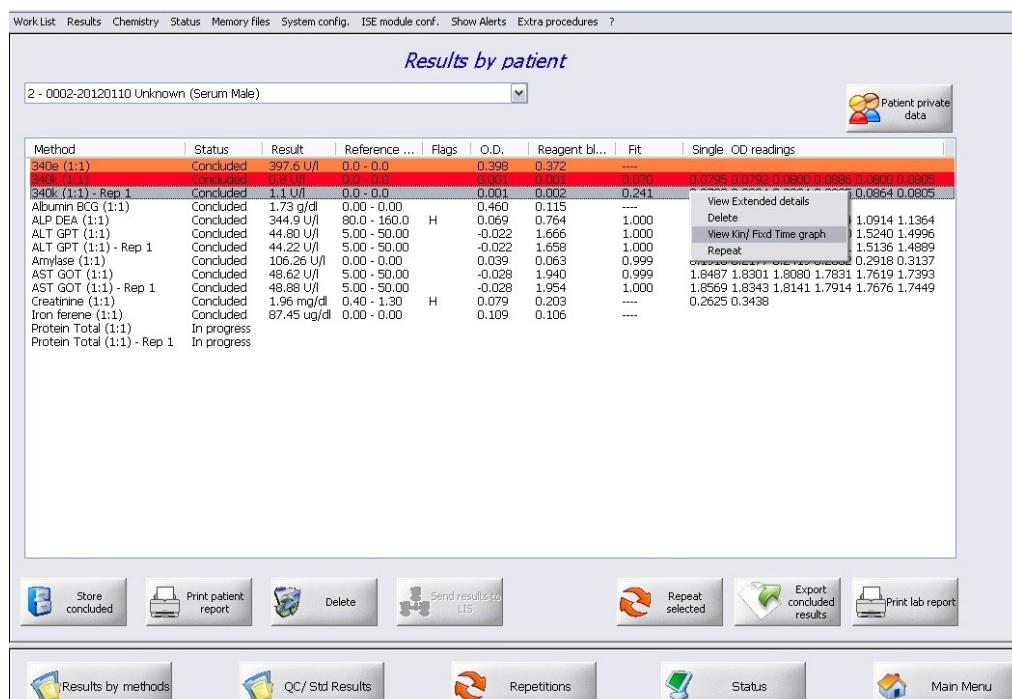


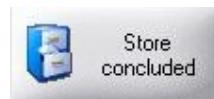
Figure 113: Software, Result by Patient Menu

7.4.9.1. Filing a Patient Completed

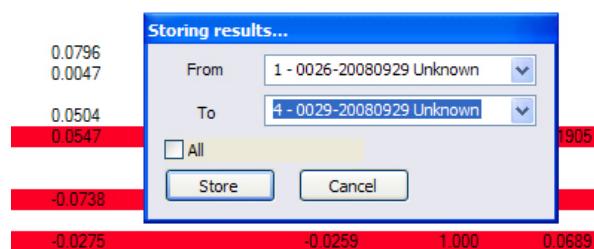
When *all* the analyses on a sample have been concluded, the patient data and results can be filed as "concluded". The procedure is described below:

1. In the patients' pull down menu select the sample to be focused.

2. Control the displayed results in order to validate them.
3. Select the command *Store selected patient*.



4. In the window that opens on the command above, choose the first and the last patient of the range whose results will be archived then click on the command Store. Also one patient at a time can be filed. On storing, the patient and its results disappear from the Result menu – its position on the sample tray is free for a new sample).



Note: only patients whose analyses have been entirely completed can be moved to the archive.

7.4.9.2. Deleting Analysis Result

When one or more analyses of a patient need to be deleted, the procedure is described below:

1. In the patients' pull down menu select the sample.
2. Select the result to delete (left mouse button).
3. Right click the selection with the mouse and choose Delete.

Method	Status	Result	Reference v...	Notes	O.D.
Amylase (1:1)	Concluded	View Extended details	0.0000		
Calcium Ars (1:1)	Concluded	Delete	H 0.0208		
Cholesterol (1:1)	Concluded	View Kinetic /F.Time graph	0.0093		
CK MB (1:1)	Concluded	Repeat	-0.0110		
CK Nak (1:1)	Concluded		0.0103		
Creatinine Jaffe (1:1)	Aborted				

4. Confirm (only that result is deleted).
5. Repeat the procedure above for all results to be deleted.

Note: a deleted result is not filed in the archive and goes lost.

7.4.9.3. Deleting a Sample and its Analyses' Result

When *all* analyses of a patient have to be deleted, the procedure is described below:

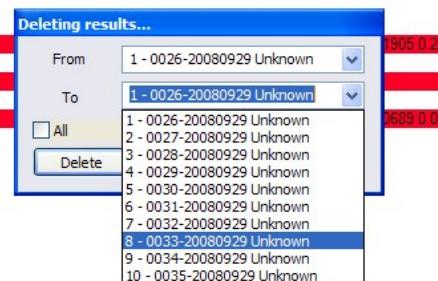
1. In the patients' pull down menu select the sample to be deleted.



2. Select the command Delete.



3. In the window that opens on the command above, choose the first and the last patient of the range whose results will be deleted then click on the command Delete. Also one patient at a time can be deleted. On deleting, the patient and its results disappear from the Result menu – its position on the sample tray is free for a new sample).



Note: a deleted sample is not filed in the archive and goes lost.

7.4.9.4. Repetition of One or More Analysis

When a patient is concluded, the operator can repeat some of the methods if requested. The procedure is described below:

1. In the patients' pull down menu select the sample.
2. Select the method to repeat (left mouse button).
3. Right click the selection with the mouse and choose Repeat.
4. Confirm.
5. Repeat the procedure above for all results to be repeated.
6. Enter the Repetitions menu and select the new dilution ratio (if any) and click on START (Random o Batch).

Note: The repetition can be run for concluded tests only.

7.4.9.5. Printing Results

The user can print Result reports for each Patient.

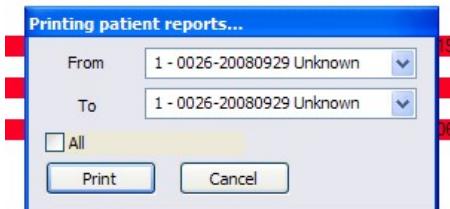
The procedure is described below:

1. From the Result by Patient menu select the command Print patient report.





2. In the window that opens on the command above, choose the first and the last patient to be printed out then click on the command *Print*. Also one patient at a time can be printed.



3. On the other hand, in order to print a quick compact report for laboratory purposes, select the command *Print lab report*;

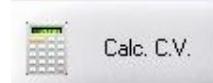


4. In the window that opens on the command above, choose the first and the last patient to be printed in the compact report then click on the command *Print*.

7.4.9.6. Calculation of Statistic Parameters on Results

The user can run the automatic calculation of the statistic parameters on a set of analyses, made on the same sample, in order to check the instrument precision. The procedure is described below:

1. Enter the *Results for Method* menu and select the methods for the calculation.
2. Select the patients whose results have to be included in the calculation.
3. Select the command *Calc. C.V.*, the statistic values are displayed below the results window.





7.4.10. Reagents Control System

Using the Chemistry Menu and all its sub-menus, the user can handle reagent, standard and controls' data.

7.4.10.1. Reagent Panel: Manual Configuration

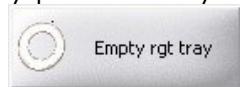
The following procedure allows the manual creation of a panel concerning a reagent tray configuration:

1. Enter the Reagent menu.



Figure 114: Software, Reagent Menu

2. If necessary, reset all the tray positions by the command *Empty rgt tray*.



3. In the Methods window, click with the mouse on the method to be introduced in the tray.
4. In the Reagents window, click the mouse on the Reagent (R1, R2 or R3) and drag it to the desired position on the tray aside. The position is registered and saved in the configuration.
5. Enter the reagent lot and expiry date.
6. Place in the same manner the other reagents of the same method (if any).
7. Repeat the operations 3 to 6 for every method to be introduced in the tray.



8. To delete a method from the configuration, click and drag it out of the tray.

More reagent bottles of the same method can be placed in the same panel: they must belong on the **same lot**.

The **last reagent position is reserved for the Diluent bottle** (more bottles can be anyway added if needed) that must always be on board.

Remember to place on the reagent tray also the following solutions:

- **EW Cvt**: extra wash solution for cuvettes (used for cuvettes extra washing or in case of method restrictions to prevent interferences);
- EW Prb: extra wash solution for sampling probe (used for probe extra washing in case of method restrictions to prevent interferences);
- **ISE CS**: ISE Module cleaning solution (if the ISE is included in the system and enabled);
- ISE UD: ISE Module urine diluent (if the ISE Module is enabled in the system and urine must be processed).

7.4.10.2. Automatic Panel Configuration

The following procedure applies for instrument with Barcode reader only and it allows the automatic creation of a reagent panel configuration. It can be activated when all of the reagent bottles have a proper barcode identification:

1. Enable the automatic barcode scanning activating the command `Scan rgt barcode`. The program will automatically update tray positions on the basis of the valid barcodes.



2. Reagent lot numbers and expiry date must be introduced for each reagent.



3. In case that some reagents have not been found, a manual loading or modification is always allowed.

Multiple reagent bottles of the same method can be placed in the same panel: they must belong on the **same lot**.

The Diluent bottle must occupy the last reagent position (reserved).

7.4.10.3. Reagents Barcode Scanning

The command `Scan rgt barcode` allows the operator to run the automatic identification of the reagents loaded. The procedure has been described in the previous paragraph and is available with Barcode reader instrument option.



Note: the program can connect a method to a barcode read in the tray only if the barcode number has been saved in the database. This means that the program will identify only those reagents previously saved in the Methods Menu.

The following rules are valid:

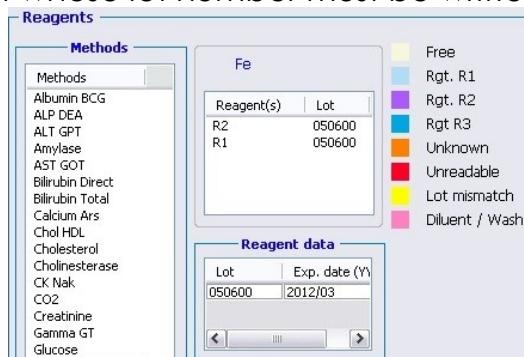
- Only the reagents saved in Methods as “visible” are loaded in configuration and displayed in a colour corresponding to the reagent type (R1, R2 or R3);
- The reagents, whose barcode has been read but not found in the saved list, are displayed as **Unknown (orange)**; a reagent can be manually given a position at a later time, following the procedure described in the paragraph above.
- The reagents without any barcode or those whose barcode has not been read, are displayed as **Unreadable (red)**.
- The reagents whose lot number has not been assigned are displayed in **yellow**.
- Free positions are left as **white**.
- The diluent must have a barcode, and its position is the last one on the reagent tray section (more bottles can be anyway added).

7.4.10.4. Reagent Lot Number Modification

The production Lot number can be entered or deleted by the operator for each of the reagents.

The procedure to introduce a lot number is the following:

1. Select the reagent whose lot number must be written.



2. Double click the field lot and enter the Lot number.

To modify a lot follow the instructions below:

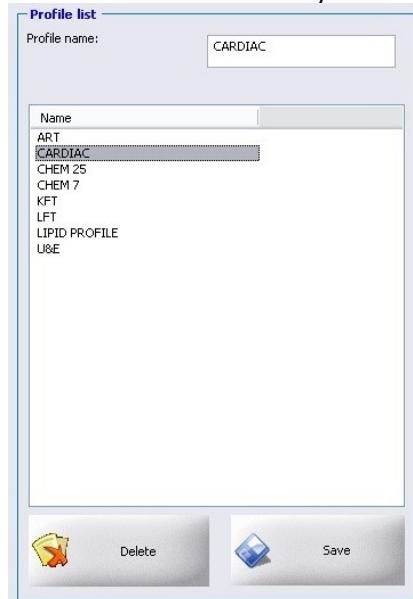
1. Select the Reagent whose lot must be modified;
2. Double click the field lot to be modified and enter the new lot number and the expiration date.

7.4.10.5. Programming Profiles

The following procedure allows the Profile programming:



1. Enter the *Profiles* menu.
2. In the *Profile Name* field enter a name for the profile to create (or select the name of an existing profile to be modified).



3. Select the methods to be included in the profile.



4. Select Save to save the profile with the name chosen (it will be visible in the Work List menu).



7.4.10.6. Deleting Profiles

The following procedure allows the profile deletion:

1. Enter the *Profiles* menu.
2. In the *Profile Name* select the profile to delete.
3. Click on *Delete* to delete the selected profile.





7.4.11. Working with Standards and Controls

The following paragraphs describes how to set standards/calibrators and Controls data.

Name	Lot	Exp. date...	No. of St...	No. of rep.	Unit	Calibration...	Date	Use...	Dil.ratio	Std val...	Backfit	OD	Reac
Albumin	06111...	2013/01	1	3	g/dl	21	2011/12/2...			25.000	25.000	-0.200	1.243
Alkaline Phos	06111...	2013/01	1	3	U/l	0	2012/01/1...			0.000	0.000	-0.017	1.231
ALT	06111...	2013/01	1	3	U/l	0	2012/01/1...						
Amylase	06111...	2013/01	1	3	U/l	0	2012/01/1...						
AST	06111...	2013/01	1	3	U/l	0	2012/01/1...						
AST2	06111...	2013/01	0	3	U/l	0	2012/01/1...						
BUN	06111...	2013/01	1	3	mg/dl	14	2012/01/1...						
BUN2	06111...	2013/01	1	1	mg/dl	0	2012/01/1...						
Calcaum	06111...	2013/01	1	3	mg/dl	28	2012/01/1...						
Cholesterol	06111...	2013/01	1	3	mg/dl	28	2011/12/2...						
Co2	N200301	2012/01	2	3	mmol/l	7	2012/01/...						
Co2 WITH BLK	N200301	2012/01	2	3	mmol/l	0	2012/01/...						
CPK	06111...	2013/01	1	3	U/l	0	2012/01/...						
CPK	1234	2012/12	4	1	ug/dl	0	2012/02/0...						
Creatinine	06111...	2013/01	1	3	mg/dl	5	2012/01/...						
Creatinine2	06111...	2013/01	1	1	mg/dl	0	2012/01/...						
dicromate 2...	lot	YYYY/MM	0	3	Abs	0	2012/01/2...						
Direct Bilirubin	Eon Do...	2013/01	1	3	mg/dl	21	2012/01/...						
Fix Time (blk)	lot	YYYY/MM	0	1	mg/dl	0	2012/01/...						
Fix Time (no)	lot	YYYY/MM	0	1	mg/dl	0	2012/01/...						
fixed time test	06111...	2013/01	1	3	g/dl	0	2012/01/...						
GGT	06111...	2013/01	1	3	U/l	0	2012/01/...						
GGT2	06111...	2013/01	0	3	U/l	0	2012/01/...						
Glucose	06111...	2013/01	1	3	mg/dl	28	2012/01/...						
HDL Cholesterol	Eon HD.../yyyy/mm	1	3	mg/dl	7	2011/12/2...							
Iron	Eon Iro.../yyyy/mm	1	3	ug/dl	28	2011/12/...							
LDH	06111...	2013/01	1	3	U/l	0	2012/01/...						
LDL Cholesterol	Eon LD.../yyyy/mm	1	3	mg/dl	21	2011/12/...							
Magnesium	06111...	2013/01	1	3	mg/dl	21	2011/12/...						
Phosphate, I...	06111...	2013/01	1	3	mg/dl	28	2011/12/...						
Total Bilirubin	06111...	2013/01	1	3	mg/dl	7	2012/01/...						
Total Protein	06111...	2013/01	1	3	g/dl	21	2012/01/...						
Triglycerides	06111...	2013/01	1	3	mg/dl	28	2011/12/...						
Uric Acid	06111...	2013/01	1	3	mg/dl	21	2011/12/...						

7.4.11.1. Mono-standard Methods

The following procedure allows the operator to include set standard values and/or factor for mono-standard methods:

1. In the Standards menu select the method in the left window.



Name	Lot	Exp. date...	No. of St...	No. of rep.	Unit	Calibrat...	Date
Albumin	06111C00	2013/01	1	3	g/dl	21	2011/12/21
Allkaline Phos	06111C00	2013/01	1	3	U/l	0	2012/01/12
ALT	06111C00	2013/01	1	3	U/l	0	2012/01/12
Amylase	06111C00	2013/01	1	3	U/l	0	2012/01/12
AST	06111C00	2013/01	1	3	U/l	0	2012/01/16
AST2	06111C00	2013/01	0	3	U/l	0	2012/01/17
BUN	06111C00	2013/01	1	3	mg/dl	14	2012/01/12
BUN2	06111C00	2013/01	1	1	mg/dl	0	2012/01/16
Calcium	06111C00	2013/01	1	3	mg/dl	28	2012/01/10
Cholesterol	06111C00	2013/01	1	3	mg/dl	28	2011/12/20
CO2	N300301	2012/01	2	3	mmol/l	7	2012/01/20
CO2 WITH BLK	N300301	2012/01	2	3	mmol/l	0	2012/01/20
CPK	06111C00	2013/01	1	3	U/l	0	2012/01/12
CRP	1234	2012/12	4	1	ug/dl	0	2012/02/07
Creatinine	06111C00	2013/01	1	3	mg/dl	5	2012/01/23
Creatinine2	06111C00	2013/01	1	1	mg/dl	0	2012/01/16
dichromate 2...	lot	YYYY/MM	0	3	Abs	0	2012/01/23
Direct Bilirubin	Eon Bilirub Cal	2013/01	1	3	mg/dl	21	2012/01/16
Fix Time (blk)	lot	YYYY/MM	0	1	mg/dl	0	2012/01/11
Fix Time (no...)	lot	YYYY/MM	0	1	mg/dl	0	2012/01/11
fixed time test	06111C00	2013/01	1	3	g/dl	0	2012/01/10
GGT	06111C00	2013/01	1	3	U/l	0	2012/01/12
GGT2	06111C00	2013/01	0	3	U/l	0	2012/01/16
Glucose	06111C00	2013/01	1	3	mg/dl	28	2012/01/18
HDL Cholesterol	Eon HDL Cal	YYYY/MM	1	3	mg/dl	7	2011/12/20
Iron	Eon Iron Cal	YYYY/MM	1	3	ug/dl	28	2011/12/20
LDH	06111C00	2013/01	1	3	U/l	0	2012/01/12
LDL Cholesterol	Eon LDL Cal	YYYY/MM	1	3	mg/dl	21	2011/12/20
Magnesium	06111C00	2013/01	1	3	mg/dl	21	2011/12/20
Phosphate, I...	06111C00	2013/01	1	3	mg/dl	28	2011/12/20
Total Bilirubin	06111C00	2013/01	1	3	mg/dl	7	2012/01/16
Total Protein	06111C00	2013/01	1	3	g/dl	21	2012/01/10
Triglycerides	06111C00	2013/01	1	3	mg/dl	28	2011/12/20

2. Just after selection, the right section of the display shows data: dilution ratio, standard value and factor related to the selected method.
3. In the fields *Lot* and *Expiry date* enter the lot number and the date of expiration of the standard to be used. That information is given by the producer in the Standards or Calibrator kit.
4. In the field *Nr. of Standard* enter 1 (one) for mono-standard.
5. In the field *Nr. of Repetition* select 1 (one shot) or 3 (for triplicate – it repeats the standard 3 times taking the main of the two nearest results – it excludes the farthest).
6. In the field *Calibration stability* set the number of days for duration of the calibration on the system.
7. Leave the dilution ratio to 1:1 and in the *Std value* enter the value of the standard. If method standardization is not required this field can be left equal to 0 (in this case the factor value must be entered). The reference values are provided by the producer in the Standards or Calibrator technical sheets.
8. In the field *Factor* enter the value of the factor in case the standardization is not required. If method standardization is required this field can be left equal to 0 (in this case the program will automatically update the value). The Factor is kept in memory until the next manual or automatic modification.
9. Set values for *Factor min* and for *Factor max* in case a control over factor admissible range is wished.

Once the standard has been measured, the system overwrites automatically the following fields:

- O.D., with the measured absorbance value.



- Reagent Blank, with the reagent blank value measured a machine cycle before the standard dispensation.
- Date, with the date and time of the last standardization.
- Factor, with the calculated factor value.

7.4.11.2. Multi-standard Methods

The following procedure allows the operator to include a method in the multi-standard method list and to set standard values and/or master curves.

1. In the Standards menu select the method in the left window.

Name	Lot	Exp. date...	No. of St...	No. of rep.	Unit	Calib...	Date
Albumin	06111C00	2013/01	1	3	g/dl	21	2011/12/21 11:
Alkaline Phos	06111C00	2013/01	1	3	U/l	0	2012/01/12 12:
ALT	06111C00	2013/01	1	3	U/l	0	2012/01/12 12:
Amylase	06111C00	2013/01	1	3	U/l	0	2012/01/12 12:
AST	06111C00	2013/01	1	3	U/l	0	2012/01/16 14:
AST2	06111C00	2013/01	0	3	U/l	0	2012/01/17 12:
BUN	06111C00	2013/01	1	3	mg/dl	14	2012/01/12 12:
BUN2	06111C00	2013/01	1	1	mg/dl	0	2012/01/16 15:
Calcium	06111C00	2013/01	1	3	mg/dl	28	2012/01/10 12:
Cholesterol	06111C00	2013/01	1	3	mg/dl	28	2011/12/20 16:
CO2	N300301	2012/01	2	3	mmol/l	7	2012/01/20 15:
CO2 WITH BLK	N300301	2012/01	2	3	mmol/l	0	2012/01/20 15:
CPK	06111C00	2013/01	1	3	U/l	0	2012/01/12 12:
CPR	1234	2012/12	4	1	ug/dl	0	2012/02/07 16:
Creatinine	06111C00	2013/01	1	3	mg/dl	5	2012/01/23 13:
Creatinine2	06111C00	2013/01	1	1	mg/dl	0	2012/01/16 15:
dichromate 2...	lot	YYYY/MM	0	3	Abs	0	2012/01/23 14:
Direct Bilirubin	Eon Bilb Cal	2013/01	1	3	mg/dl	21	2012/01/16 14:
Fix Time (blk)	lot	YYYY/MM	0	1	mg/dl	0	2012/01/11 16:
Fix Time (no..	lot	YYYY/MM	0	1	mg/dl	0	2012/01/11 16:
fixed time test	06111C00	2013/01	1	3	g/dl	0	2012/01/10 14:
GGT	06111C00	2013/01	1	3	U/l	0	2012/01/12 14:
GGT2	06111C00	2013/01	0	3	U/l	0	2012/01/11 14:
Glucose	06111C00	2013/01	1	3	mg/dl	28	2012/01/18 14:
HDL Cholesterol	Eon HDL Cal	yyyy/mm	1	3	mg/dl	7	2011/12/20 16:
Iron	Eon Iron Cal	yyyy/mm	1	3	ug/dl	28	2011/12/20 16:
LDH	06111C00	2013/01	1	3	U/l	0	2012/01/12 14:
LDL Cholesterol	Eon LDL Cal	yyyy/mm	1	3	mg/dl	21	2011/12/20 16:
Magnesium	06111C00	2013/01	1	3	mg/dl	21	2011/12/20 16:
Phosphate, I...	06111C00	2013/01	1	3	mg/dl	28	2011/12/20 16:
Total Bilirubin	06111C00	2013/01	1	3	mg/dl	7	2012/01/16 15:
Total Protein	06111C00	2013/01	1	3	g/dl	21	2012/01/10 12:
Triglycerides	06111C00	2013/01	1	3	mg/dl	28	2011/12/20 16:

2. Just after selection, the right section of the display shows data: dilution ratios, standard value and factor related to the selected method.
3. In the fields *Lot* and *Expiry date* enter the lot number and the date of expiration of the standard to be used. That information is given by the producer in the Standards or Calibrator kit.
4. In the field *Nr. of Standard* enter the number of points for a Calibration Curve for the multi-standard. The number must be included between 2 and 8 points.
5. In the field *Nr. of Repetition* select 1 (one shot) or 3 (for triplicate – it repeats any point of the curve 3 times taking the main of the two nearest results for each).
6. In the field *Calibration stability* set the number of days for duration of the calibration on the system.
7. In the field *Std value* field of the most top row enter the value of the concentrated standard. When setting calibration curves the operator has always to write standard values, and then dilution ratios (if different from 1:1),



in decreasing order by descending (from top to down): that means, the greatest value on the top (i.e.: concentrated) to the lowest on the bottom (i.e.: saline @ zero concentration).

8. In the *Dil ratio* field enter the wished dilution ratio. The program updates automatically the diluted standard value when different from 1:1 with relation to the 1:1 highest value.
9. In the following rows, repeat steps above for all the lower dilution values required for the calibration curve construction.
10. When the last point to be set is the zero concentration (i.e.: saline) leave its dilution ratio = 1:1.

Before running the Work List the user must place the concentrated standards (1:1), in the correct positions of the sample tray.

In case the automatic dilution is not needed and pre-diluted standards are used, the user must place all pre-diluted standards in the correct positions of the sample tray.

Once standards have been measured, the system updates automatically the following fields:

- O.D., with the measured absorbance value;
- Reagent Blank, with the reagent blank value measured a run before the standard dispensation
- Backfit values
- Curve equation parameters.

In order to set a master curve, that doesn't need any standardization, the user must enter also the OD values for the different concentrations (see specific reagent kit inserts).

7.4.11.3. Entering Values for Controls (QC)

The following procedure allows the operator to enter values and parameters for QC sera:

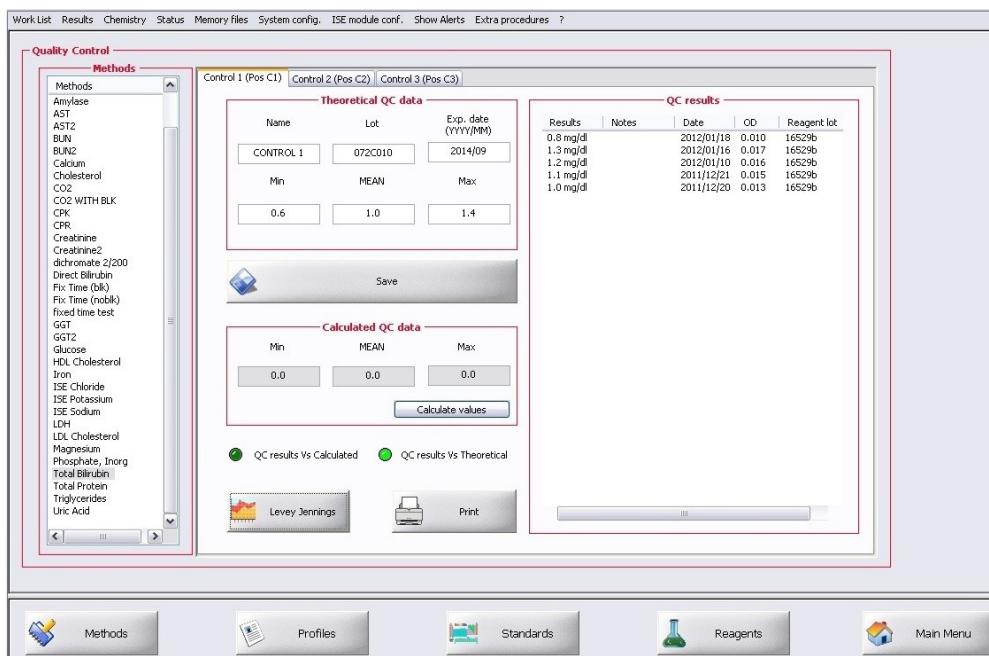


Figure 115: Software, Quality Control Menu

1. In the Q.C. menu, select the method whose control values and data have to be filled.
2. Select Control 1 tab, or Control 2 tab or Control 3 tab.
3. Enter or modify the following data: name, lot number, exp. date, minimum value, theoretical value and maximum value (lot number must be always present).
4. Select the command Save to save the data just entered.



5. Repeat the steps above for the other tabs if required.

The minimum, theoretical and maximum values are reported in the technical documentation of the Control (QC) serum.

7.4.11.4. Viewing Levy-Jennings Graphs and Printing QC Values

The following procedure allows the operator to view Levy-Jennings graph of a QC series of values:

1. In the Q.C. menu, select the method whose control values and data have to be filled.
2. Select Control 1 tab, or Control 2 tab or Control 3 tab.
3. Click on command Calculate values to compute and to show the Calculated QC data over QC results; fields min, average and max will be filled if more than two QC results are available.

**Calculate values**

These fields are different from the ones above because they do not show the theoretical values given on the technical sheet but just the values calculated over the QC results of the instrument; such values give the feeling of the system trend.

4. In order to show Levy-Jennings graph, select Calculated or Theoretical



QC results Vs Calculated



QC results Vs Theoretical

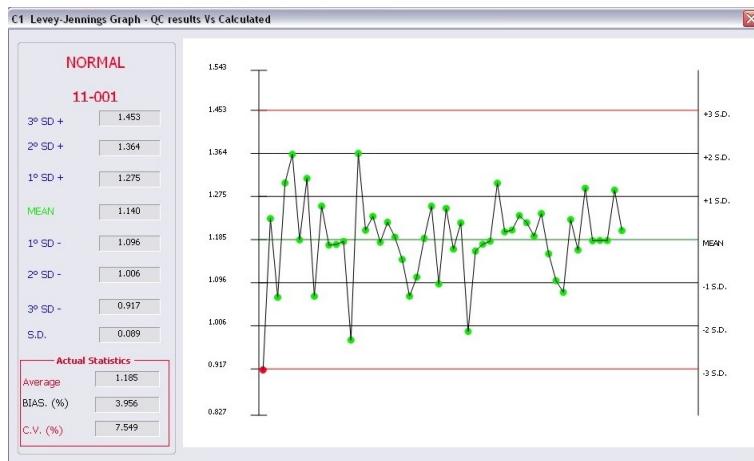
click on the command



to get the following pic



showing Controls results vs. Calculated or



showing Control results vs. Calculated QC data (for monitoring of system trend).



5. To print the data reported in the QC Results window, click on the command Print



and choose if to include or not the graph in the print.



The printed out report data contents depends on the previous selection: Calculated or Theoretical.



7.4.12. Memory Files - Database

The Memory files menu allows the operator to handle and to display all results previously filed for samples, standards and controls.

The user can run a result research in the database by entering any combination of the searching keys.

7.4.12.1. Searching and Handling Patient Results

The User can run a patient search (by last name, date, IDcode or combination) in the database, in order to display, check and print the patient's analysis results or modify patients' data. The procedure is described below:

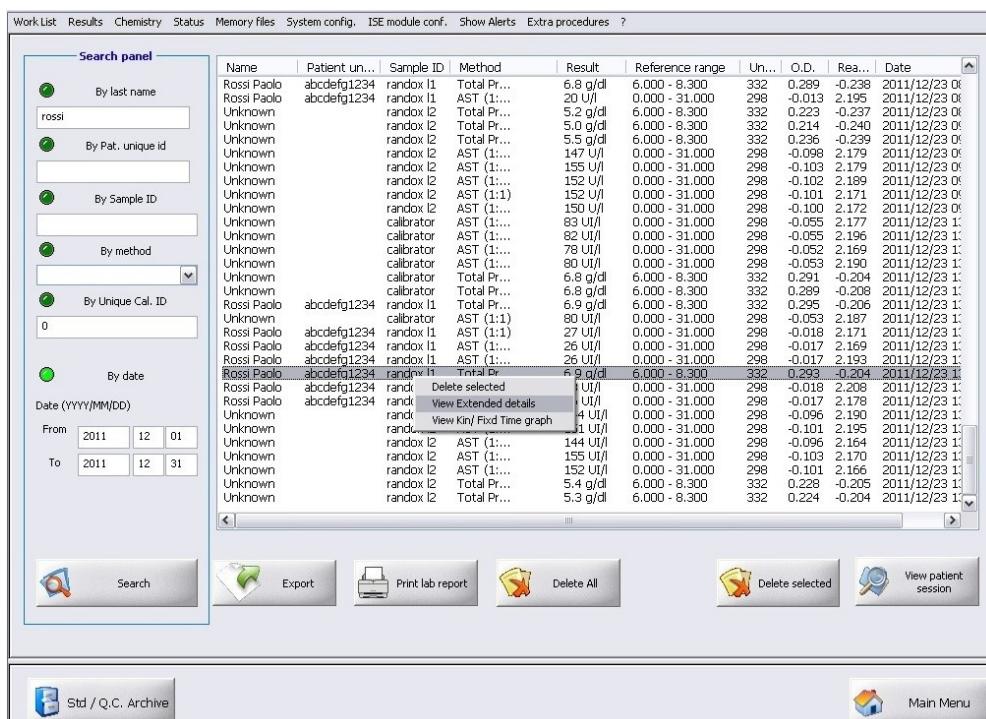


Figure 116: Software, Memory Files, Patients Archive Menu

1. In the field *By last name* it is possible to enter the patient's surname, if surname is needed as research key (in case no name have been used, you can type the word "unknown" to show all samples whose name never has been assigned).
2. In the field *By Pat. Unique id* it is possible to enter the patient's id number, if it is needed as research key.
3. In the field *By Sample ID* it is possible to enter the sample Id code, if sample identification code is needed as research key.



4. In the field *By method* it is possible to enter the test to search for, if test name is needed as research key.
5. In the field *By Unique Cal. ID* it is possible to enter the calibrator unique identification number given by the system, if it is needed as research key.
6. In the field *Date from / to* it is possible to enter the starting date and ending date of the period in which to search for results, if needed as search key.
7. Enable the searching criteria (keys) by lighting the green lamp aside; any combination of them is valid and the system considers all keys in logic "and" to refine the research:

Search panel

- By last name
rossi
- By Pat. unique id
- By Sample ID
- By method
- By Unique Cal. ID
0
- By date
Date (YYYY/MM/DD)
From: 2011 12 01
To: 2011 12 31

8. Click the command **Search**; the search results will be displayed in the right side window when the search has been completed (a note above the Command Search will advise about the number of results found).



9. To view details, right click with the mouse on the result and then select the command **View extended details** from the pop up menu.

Rossi Paolo	abcdefg1234	random	AS1 (1:...	26 UI/l
Rossi Paolo	abcdefg1234	random	Total Pr	6.9 g/dl
Rossi Paolo	abcdefg1234	random	Delete selected	UI/l
Rossi Paolo	abcdefg1234	random	View Extended details	UI/l
Unknown	random	random	View Kin/ Fixd Time graph	4 UI/l
Unknown	random	random		1 UI/l

or click the **View patient session** button to see patient private data:



10. In case some data modifications are needed in the patient Report window, make them and then select the command **Save** or select the command **Print patient report** to print the results report, or close the Report window to exit.



The screenshot shows the 'Report' window with two main sections: 'Patient private data' and 'Daily session'.

Patient private data:

- Patient unique id: abcdefg1234
- Last name: Rossi, Name: Paolo, Date of birth: 1950/02/27, Address: Via del Fiore, 1
- Bed: 23, Clinic: drt/6, Dpt.: Ren01, Request date: 2012/12/18, Doctor: RED, Age: 61
- Email: none, Phone: Notes: [empty]

Daily session:

- Sample comments: [empty]
- Table of results:

Sample ID	Methods	Result	Reference range	Notes
randox II	Total Protein (1:1)	7,0 g/dl	6,00 - 8,300	
randox II	AST (1:1) - Rep 1	21 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 2	18 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 3	22 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 4	21 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 5	18 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 6	18 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 7	20 U/l	0,000 - 31,000	
randox II	AST (1:1)	20 U/l	0,000 - 31,000	
randox II	AST (1:1) - Rep 9	20 U/l	0,000 - 31,000	
randox II	Total Protein (1...	6,9 g/dl	6,000 - 8,300	
randox II	Total Protein (1...	6,9 g/dl	6,000 - 8,300	
randox II	Total Protein (1...	6,9 g/dl	6,000 - 8,300	

11. Click the command **Look up** to search for other samples processed with the same *Patient unique id* number, if desired to search for other analyses performed on the same patient (same id number) in the past.
12. The other commands in the menu allow the operator to delete selections or all searched results, to print a laboratory compact report or to export results.

7.4.12.2. Searching and Handling QC Results

The User can run a search (by last method, QC lot number, date or Id) in the database, in order to display, verify and print the control and standard results, by entering any combination of the searching keys. The procedure is described below:

The screenshot shows the 'Controls' and 'Standards' search interface.

Controls:

- Method: CO2
- Search panel:
 - By method: CO2
 - By lot: [empty]
 - By date: From 2011/11/07, To 2011/12/31
 - By Unique Cal. ID: 0
- Table of results:

Method	Q.C.	QC Lot	Reagent lot	Result	Theoretical r...	Unique Cal. ID	O.D.	R...	Date
CO2	C1	07202010	lot	15 mmol/l	11,000...	336	...	1...	20...
CO2	C2	072C120	lot	27 mmol/l	20,000...	336	...	1...	20...
CO2	C2	072C120	lot	27 mmol/l	20,000...	336	...	1...	20...
CO2	C1	07202010	lot	18 mmol/l	11,000...	336	...	1...	20...

Standards:

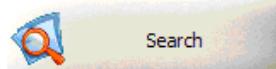
- Table of results:

Uni...	Meth...	Lot	Dil...	Fa...	Std v...	O.D.	Reag...	Date	Backfit	Cal. Curve
328	CO2	06111c00 (yyyy/mm)	1:1	---	26.000	-0.218	1.219	2011/12/21 10:39:33	0.000	
328	CO2	06111c00 (yyyy/mm)	1:1	---	26.000	-0.054	1.237	2011/12/21 10:39:33	0.000	
329	CO2	06111c00 (yyyy/mm)	1:1	---	27.500	-0.218	0.000	2011/12/21 10:39:45	27.500	y = -0.006
329	CO2	06111c00 (yyyy/mm)	1:1	---	0.000	-0.054	1.229	2011/12/21 10:39:45	-0.000	y = -0.006
336	CO2	06111c00 (yyyy/mm)	1:1	---	27.500	-0.205	Delete selected	21 11:17:09	27.500	y = -0.006
336	CO2	06111c00 (yyyy/mm)	1:1	---	0.000	-0.028	1.311	2011/12/21 11:17:09	0.000	y = -0.006
- Buttons: Export, Print

**Figure 117:** Software, Std/Q.C. Archive Menu

1. In the field *By method* it is possible to enter the test to search for standard/control, if test name is needed as research key.
2. In the field *By lot* it is possible to enter the lot number, if needed as search key.
3. In the field *By date from / to* it is possible to enter the starting date and ending date of the period in which to search for results, if needed as search key.
4. In the field *By Unique Cal. ID* it is possible to enter the calibrator unique identification number given by the system, if it is needed as research key.
5. Choose one or more search criteria (keys) below:

6. Click the command *Search*; the search results will be displayed in the right side windows when the search has been completed; the upper window list QC results, the lower window lists Standard results.



7. The command *Print* allows the User to print a laboratory compact report; the command *Export* allows the User to export results.
8. By selecting a result and clicking with the right mouse button is possible to delete results.

329	CO2	06111c00 (yyyy/mm)	1:1	---	27.500	-0.218	0.000	2011/12/21 10:39:45	27.500	y = -0.0
329	CO2	06111c00 (yyyy/mm)	1:1	---	0.000	-0.054	1.337	2011/12/21 10:39:45	-0.000	y = -0.0
336	CO2	06111c00 (yyyy/mm)	1:1	---	27.500	-0.205	Delete selected	21 11:17:09	27.500	y = -0.0
336	CO2	06111c00 (yyyy/mm)	1:1	---	0.000	-0.028	1.311	2011/12/21 11:17:09	0.000	y = -0.0



7.4.13. Shutdown Procedure

The *Shutdown* command starts the automatic system shutdown including final Extra Washing cycle.

The final cuvette extra washing can be disabled only in case the system is restarted within few minutes (i.e.: during servicing).

As the procedure completes, the software exits and the Operating System can be closed. The instrument can then be powered down.



In case the instrument includes the ISE Module, the producer suggests to run a Cleaner cycle before shutting down the system (it will take only some minutes). By enabling the *Shutdown the PC* selection, the system powers down the PC when closing.

It's possible to exit the current user and entering a new one without restarting the software by the command *Change user*.

WARNING

The Manufacturer recommends the user to enable cuvette washing during shut down at the end of any working day in order to preserve performances and to extend cuvette life.

WARNING

The Manufacturer recommends never switch off the instrument before completing the software shut down procedure.

The Manufacturer recommends never switch off the personal computer during the shutdown procedure as database can corrupt.

Never switch off the instrument before the software shutdown.



Section 8 MAINTENANCE

8. Generalities

This section provides the user recommendations for a proper maintenance of the instrument.

NOTE: the producer reminds the user that the periodic visual inspection of the instrument is the first and easier way to guarantee the best performance of the instrument itself.

WARNING

An improper maintenance could affect the system performance.

The producer assures the system proper operation and given performances only for systems that are kept under constant maintenance as prescribed by the periodic maintenance program.

8.1. General Rules

General instructions for a periodic maintenance:

- Make sure that the instrument working area is clean and kept clear.
- Any fluid leakage in the working area must be immediately rinsed and dried.
- The instrument must be constantly inspected to ensure a good system performance.
- Waste of disposals must observe the safety norms and the local law.
- If any part of the system breaks down, it must be immediately repaired or replaced by Authorized Technical Personnel.
- Read carefully the information on infected fluids provided in this manual (see Section 1).

8.1.1. Competences

If a system breakdown occurs, the reparation must be immediately performed by Authorized Technical Personnel only.

The periodic maintenance procedures previously described must be performed by the User together with the distributor's Authorized Technical Personnel.

8.1.2. Cleaning

The reagent tray, the sample tray and the working area must be cleaned constantly with a soft cloth that doesn't leave any residues by the user.



8.1.3. Disinfection

This paragraph contains the information and instructions for a proper disinfection of the instrument carried out by the user.

WARNING

Read carefully Section 1 (“Safety”) and paragraph “Safety precautions” of this Section before performing the instrument maintenance.

- During maintenance of the instrument a complete protection must be worn: gown with long sleeves (ending with elastic bands), shock-resistant rubber gloves and protective glasses.
- Prepare two sodium hypochlorite solutions (commercial hypochlorite): one at 1%, the other at 0.5%. The commercial hypochlorite has generally a 5,25% concentration, in which case prepare the solutions as follows:
Solution A (about 1%): 200ml hypochlorite and 800ml deionised water.
Solution B (about 0.5%): 100ml hypochlorite and 900ml deionised water.

WARNING

The procedure recommended in this section does not ensure that all the virus and micro-organisms are inactive and the instrument is sterilized, although it minimizes any risk.

8.1.3.1. Instrument Disinfection

Follow the procedure below:

1. wet all the parts presenting contaminate fluid deposits with cotton wool soaked in Solution A;
2. remove the deposits and wet the rest of the surface with the same solution. This must be kept wet for at least 15 minutes in order to be fairly disinfected;
3. remove then the hypochlorite with cotton wool soaked in deionised water.

WARNING

Do not soak the metallic parts (probe, washing station needles) longer than 20 minutes as the solution can have a corrosive effect.

8.1.3.2. Metallic Sampling Probes Disinfection

Dip at least 3cm of each metallic sampling probe in a basin containing Solution A for 15 minutes at least, and then rinse them carefully in deionised water.

At the end, run two ARM rinsing cycles from the Status menu for probe refilling and washing.



8.1.3.3. Waste Tubing Disinfection

Dump the waste tubing in a container for contaminated materials and replace it with new tubing; otherwise, if the tubing is not damaged, unplug the side fittings and soak everything in Solution A for 20 minutes, then rinse it with distilled water.

8.1.3.4. Charge Tubing Disinfection

Wash the Tygon® tubing from external tanks of the instrument; this will prevent tubing and valve to be obstructed by eventual salt crystals:

1. Disconnect from systemic solution and cleaner solution tanks the Tygon® charging tubing;
2. Wash the inner and outer tubing with sodium Hypochlorite Solution A.
3. Rinse them with distilled water.
4. Let the Tygon® tubing drying out.
5. Put all tubing back in the proper tanks (systemic and cleaner solution tanks must be full) and run a Start-up cycle from the Status menu for tubing refilling, system washing and auto-zeroing.

8.1.3.5. Washing Station Needles Disinfection

Clean the metallic needles with cotton wool soaked in Solution A and then clean them carefully with deionised water. Power on the instrument and run a Start-up cycle from the Status menu for tubing refilling and needle washing.

8.1.3.6. Waste Tank Disinfection

Completely empty the tank in a container for contaminated materials. Fill the tank with Solution A and let it soak for about 20 minutes, and then rinse it carefully in deionised water.

8.1.3.7. Systemic Solution and Cleaner Solution Tanks Cleaning

Empty tanks in a proper container completely. Fill tanks with bi-distilled water and shake them, then empty in a proper container; repeat this procedure several times in order to clean it from eventual deposits or residuals.

WARNING



The above procedures does not ensure that all the virus and micro-organism are inactive and the machine is sterilized, although it reduces only the risk at a minimum level.

8.2. Safety Precautions

Any maintenance operation left to the user must be carried out with the instrument switched OFF and with the power supply cable disconnect from the socket.

WARNING

Read carefully Section 1 ("Safety") before the instrument maintenance.



8.3. Periodic Maintenance Plan

The following paragraphs show the scheduling for the periodic maintenance operations to carry on the system; read carefully all instructions.

Note: missing of Maintenance Scheduling by end user invalidates product warranty terms and conditions.

Periodic Maintenance Plan for ISE Module (valid if ISE Module has been included in the system as option) is exposed in paragraph “ISE Module Maintenance Scheduling” in this Section.

8.3.1. Daily Maintenance Scheduling

The user MUST follow instructions described below for the daily maintenance.

At the beginning of the day

1. Check the volume of the Systemic Solution tank and refill it before run.
2. Check the volume of the Cleaner Solution tank and refill it before run.
3. Check the volume of the Waste tank and empty it before run.
4. Check the Tygon® tubing to/from external tanks in order to detect and eliminate occlusions or eventual defects.

WARNING

Waste is potentially infectious and can be hazardous to health. It must be disposed according to national and international instructions for the safe disposal of Bio-hazardous waste.

At the end of the day

1. It is very important that at the end of **each working day**, the operator runs the **daily cuvette Extra wash cycle** or from the Status menu or as part of the automatic **shutdown procedure**; this in order to deeply clean reading cuvettes. Remember to place an keep permanently on board the EW Cvt solution vial (Extra Wash Cuvette bottle).
2. Clean the outside surface of the metallic Sampling Probe with an ethanol solution at 70%.
3. In case of ISE Module on board run an ISE cleaning cycle.
4. On automatic instrument shut down procedure **never** disable the final washing.
5. Remove and disinfect any fluid leakage in the working area.
6. Check for condensation on the bottom of the reagent tray: if too much, take out bottles and sop it up with a dry clean cloth or with the help of a pipette – in case of high liquid level check the condensation draining circuit.



7. Remove all samples from the sample tray and clean the upper carousel in case of fluid leakage; disinfect any potentially contaminated part.

8.3.2. Weekly Maintenance Scheduling

The user MUST follow instructions described below for the weekly maintenance.

1. Remove all reagents from the reagent tray and clean the bottom of the tray in case of fluid leakages; disinfect any potentially contaminated part.
2. Clean the internal surface of the probe washing sink (well) with an ethanol solution at 70%.
3. Make sure that sample Probe is fixed in the proper positions and that it's undamaged.

8.3.3. 20,000 tests Maintenance Scheduling

When the number of tests run on the system since the “last **cuvette** replacement” approaches 20,000, the software alerts the operator with a message on the screen: it's time to replace cuvettes that must be changed with new ones. The new “Cvt status menu” includes the following fields and commands:

1. “Cvt total counting” field: it gives the total number of tests that have been run on the system **since its installation** or software upgrade, whose date is shown in the field aside.
2. “Cvt partial counting” field: it gives the number of tests that have been run on the system **since the last cuvette replacement**, whose date is shown in the field aside.
3. “Cvt changed” button: it resets the partial counter. It must be pressed just after having replaced the cuvettes. This action is logged into the event logger. It also runs a “Gain calibration cycle”.
4. “Move cvt tray” button: it moves the cuvette tray at the cuvette number desired (for single cuvette replacement).

Cvt status	
Cvt total counting (begun at)	
103689	2011/04/21
Cvt partial counting (begun at)	
5189	2012/03/14
Cvt changed	
Move cvt tray	

The cuvette replacement procedure is given below:

1. With the system in Idle, remove the cuvette tray cover.
2. Remove the cuvette support (the black plastic one holding the reaction cuvettes).
3. Replace it with one with new cuvette rotor and fix it back.
4. Assemble the cuvette cover.
5. Enter the “Cvt status menu” and **press the “Cvt changed” button**: the system resets the partial test counter and automatically runs a *Gain calibration cycle* to adjust the filters gain and to perform the new autozero.



This procedure must be performed any time cuvettes will be replaced in order to reset the test counter and to fix the appropriate filter gains.

Note: replace cuvettes only with original ones distributed by the Producer.

8.3.4. Two Months Maintenance Scheduling

The user **must** follow the instructions described below for the twice-monthly maintenance.

1. Run a *Gain Calibration Cycle* from the Status menu in order to equalize, reset and check optical filter gains and to optimize measurement performances.
2. Wash the Tygon® tubing to/from external tanks of the instrument; this will prevent tubing and valves to be obstructed by salt crystals.
3. Clean Systemic solution tank.
4. Clean Cleaner solution tank.
5. Clean Waste tank.
6. Clean and disinfect metallic Sampling Probe, washing station needles and tip.
7. Gently oil the outer surface of the ARM's shaft with some Vaseline grease (see picture below). Use a dust-free cloth slightly soaked with some Vaseline grease in order to spread it all along the outer surface of the steel upper arm shaft; this will resolutely help the continuous up and down shaft sliding.



8.3.5. One Year Maintenance Scheduling

The user **must** ask the Authorized Technical Personnel to carry on the following steps for the **annual maintenance plan**.

1. Replace all peristaltic pump heads (about 450,000 machine working cycles in 1 year).



2. Replace photometer halogen lamp for optimized performances (2,000 hours or 1 year max) and then run a Gain Calibration cycle.
3. Replace the sampling probe for optimized performances (replace earlier if damaged).
4. Replace tanks tubing with new ones for best operation.
5. Clean and disinfect the instrument probe washing sink to remove soils.
6. Verify instrument operation and check positions coordinates.
7. Replace the washing station white tip on the eighth position.

8.3.6. Other Maintenance Needs

The following items can be required in case of breakdown or damage (service carried out by Authorized Technical Personnel only with the exception of cuvettes).

When needed:

1. Replace the vacuum pump (or check internal valves) of the washing station aspiration needles if not aspirating.
2. Replace the vacuum pump (or check internal valves) of the washing station tip if not aspirating.
3. Replace complete peristaltic pumps in case of motor breakdown.
4. Replace any dispensing washing station needle if clotted or damaged.
5. Replace sampling probe aspiration tubing (heater coil) if damaged or in case of fluid leakage.
6. Replace washing station head tubing (Teflon® and Tygon®) if damaged, bended or squeezed and in case of fluid leakage evidence.
7. Replace diluter if out of order or damaged (long durability if operated with the **systemic solution** suggested by the manufacturer – 5,000,000 full strokes minimum).
8. Replace single reading cuvette when requested by the software.

In case the instrument is not used for long period provide to slip off the peristaltic pump heads from the shaft to avoid internal tubing walls sticking. Cover the instrument and take the power cord off from the power inlet.

8.3.7. Maintenance Charts

In order to trace instrument history, in the following two pages are annexed the monthly maintenance charts to be copied for use.



MAINTENANCE CHART																																			
		Month: Year:		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31					



MAINTENANCE CHART		Month: Year:		DAILY MAINTENANCE		1-YEAR MAINTENANCE		Date		2-MONTHS MAINTENANCE		Date		Date		Date		System:		
Systemic Solution refill	Cleaner Solution refill	Waste emptying	Tank Tygon® Tubing check	Daily Extra-Washing cycle	Working area disinfection	Sampling Probe Disinfection	WS White Tip replacing	Operator initials	Operator initials	Gain calibration	Tygon® Tubing washing	Systemic Tank cleaning	Cleaner Tank cleaning	Waste Tank cleaning	ARM shaft oiling	Instrument verification	Date	Date	Month: Year:	Month: Year:
Peristaltic Pump Heads replacing	Photometer Lamp replacing	Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Peristaltic Pump Heads replacing	Photometer Lamp replacing	Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Date	Date	Month: Year:	Month: Year:
Photometer Lamp replacing	Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Photometer Lamp replacing	Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Date	Date	Month: Year:	Month: Year:
Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Sampling Probe replacing	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Date	Date	Month: Year:	Month: Year:
Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Tanks Tubing replacing	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Date	Date	Month: Year:	Month: Year:
Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Washing Sink cleaning	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Date	Date	Month: Year:	Month: Year:
Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Instrument verification	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Date	Date	Month: Year:	Month: Year:
WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	WS White Tip replacing	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Operator initials	Date	Date	Month: Year:	Month: Year:
Operator initials	Date	Date	Date	Date	Date	Date	Date	Date	Date	Operator initials	Date	Date	Date	Date	Date	Date	Date	Date	Month: Year:	Month: Year:



System:						
WEEKLY MAINT.	Date					
Reagent Tray cleaning						
Washing Sink cleaning						
Probe checking						
				Cuvette Rotor Replacing (if any)		
OTHER MAINT.	Type of intervention					
					Operator initials	



8.4. ISE Module Maintenance Scheduling

This section provides the user recommendations for a proper maintenance of the ISE Module when integrated into the system (option).

NOTE: the producer reminds again the user that the periodic visual inspection of the devise is the first and easier way to guarantee the best performance of the device itself.

The ISE Module requires very little operator maintenance. The only daily maintenance required is to run the cleaning solution after the last sample of the day; the system automatically run it after 50 patient samples, whichever is first. Clean the sample inlet port once per month. All other parts and expendables are replacement items (see schedule in the following). Use only Producer approved components to avoid warranty terms decay.

8.4.1. Scheduling for LOW Volume Users

In the following paragraphs are scheduled the periodic operations to carry out on ISE Module for low volume users (processing of **less than 100 samples/day**); read carefully all instructions.

8.4.1.1. Daily Maintenance Scheduling

The user MUST follow the instructions described below for the daily maintenance.

At the beginning of the day

1. Check ISE Calibration values in the *ISE module conf* menu after system warming up. If values are not in range run ISE calibration again.
2. Check pump tubing integrity.
3. Check for the red ball indicator floating in the internal reference electrode solution. If it no longer floats replace electrode.

At the end of the day

1. Run a Cleaning Cycle from the *ISE module conf* menu before instrument shut down (make sure that the *ISE Cs* cleaning solution bottle is on board).
2. Remove and disinfect any fluid leakage around the sample entry port in the working area.
3. Check for fluid leaks around tubing fittings and below the ISE Module itself.

WARNING

Liquid waste can be potentially infectious and can be hazardous to health. It must be disposed according to national and international instructions for the safe disposal of Bio-hazardous waste.



8.4.1.2. One Month Maintenance Scheduling

The user MUST follow the following instructions for the monthly maintenance.

1. Clean ISE module upper sample inlet port using a cotton swab and distilled water and paying attention not to leave any residues.

8.4.1.3. Six Months Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following electrodes and components for the **semi-annual** maintenance.

1. Li⁺ Electrode.
2. Na⁺ Electrode.
3. K⁺ Electrode.
4. Cl⁻ Electrode.
5. Reference Electrode.
6. Pump tubing (on ISE Module peristaltic pumps).

8.4.1.4. One Year Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following components for the annual maintenance.

1. Fluidic tubing.



8.4.2. Scheduling for HIGH Volume Users

In the following paragraphs are scheduled the periodic operations to carry out on ISE Module for low volume users (processing **greater than 100 samples/day**); read carefully all instructions.

8.4.2.1. Daily Maintenance Scheduling

The user MUST follow the instructions described below for the daily maintenance.

At the beginning of the day

1. Check ISE Calibration values in the ISE module conf menu after system warming up. If values are not in range run ISE calibration again.
2. Check pump tubing integrity.
3. Check for the red ball indicator floating in the internal reference electrode solution. If it no longer floats replace electrode.
4. If the instrument hasn't been powered down overnight, provide an ISE initialization (includes calibrations). Initialization is normally included in the instrument warming up cycle.

At the end of the day

1. Run a Cleaning Cycle from the ISE module conf menu before instrument shut down.
2. Remove and disinfect any fluid leakage around the sample entry port in the working area.
3. Check for fluid leaks around tubing fittings and below the ISE Module itself.

WARNING

Liquid waste can be potentially infectious and can be hazardous to health. It must be disposed according to national and international instructions for the safe disposal of Bio-hazardous waste.

8.4.2.2. One Month Maintenance Scheduling

The user MUST follow the following instructions for the monthly maintenance.

1. Clean ISE module upper sample inlet port using a cotton swab and distilled water and paying attention not to leave any residues.



8.4.2.3. Six Months Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following electrodes and components for the semi-annual maintenance.

1. Pump tubing.

8.4.2.4. At 3,000 samples Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following electrode after 3,000 samples.

1. Li⁺ Electrode.

8.4.2.5. At 10,000 samples Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following electrodes after 10,000 samples.

1. Na⁺ Electrode.
2. K⁺ Electrode.
3. Cl⁻ Electrode.
4. Reference Electrode.

8.4.2.6. One Year Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following components for the annual maintenance:

1. Fluidic tubing.



8.5. Maintenance Procedures

8.5.1. Generalities

Refer to the following paragraphs for the ordinary and extraordinary maintenance operations including replacing of parts. To get the correct part code refer to the actual Producer Spare Parts and Consumables List – ask the Manufacturer for the last version.

8.5.2. Reading Cuvettes Replacement

In order to replace all reading cuvettes the instrument must be ON and the User Interface software is running. Make sure that the new cuvettes are clean and not scratched on the narrower walls (the ones crossed by the measurement optical path).

NOTE: cuvettes replacement requires complete body protection, gown with long sleeves (ending with elastic bands), shock-resistant rubber gloves and protective glasses.

NOTE: replace cuvettes only with original ones provided by the Manufacturer with code.

Never reuse cuvettes that have been previously dismissed even if washed, it affects results.

Replace the cuvette following the instructions below, one by one:

1. Open the Status menu.
2. Make sure that cuvettes to be replaced have been left empty by the instrument at the end of the working session, otherwise run a Start up cycle from the Status menu.
3. Select Move cvt tray and enter the cuvette number = 2.
4. Under the cuvette tray cover, top front aperture, there are 3 cuvettes (1 to 3): extract them out by using the appropriate extraction tool.
5. Repeat steps described in 3-4 (step by 3 cuvettes at time) until all the cuvettes have been taken away.
6. Select Move cvt tray and enter the cuvette number = 2.
7. Under the protection top front aperture, there are 3 empty cuvette places (1 to 3): place a new cuvette in each place (leave it falling down in the seat and then press until triggering the click that ensures the cuvette is fixed in the tray).
8. Repeat steps described in 6-7 (step by 3 cuvettes at time) until all cuvettes have been replaced.



9. Start a Gain Calibration Cycle from the Status menu. The cycle includes an auto-zero cycle that allows the instrument to wash all cuvettes, to level the different wavelength gains and to update / reset the zero values of all the reading cuvettes.

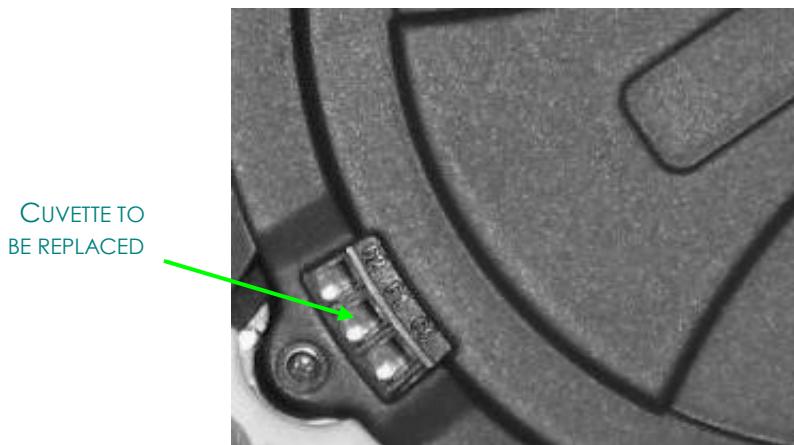


Figure 118: Cuvette Replacement

Alternatively it is possible to replace the whole cuvette rotor by unfastening the cuvette cover and removing the black plastic cuvette support.

8.5.2.1. Single Cuvette Replacement

Replace a single Cuvette if required by the software, if it is damaged or deteriorated.

1. Make sure that the Cuvette to be replaced has been empty by the instrument at the end of the working session.
2. In the Status menu select Move cvt tray and enter the number of the cuvette to be replaced. Within the protection cover top front aperture, the cuvette to be replaced has been moved: take it out, using the appropriate extraction tool, and replace it with a new one (leave it falling down in the seat and then press until triggering the click that ensures the cuvette is fixed in the tray).
3. Run a Gain Calibration Cycle from the Status menu. The cycle includes an auto-zero cycle that allows the instrument to wash all cuvettes, to level the different wavelength gains and to update / reset the zero values of all the reading cuvettes.



8.5.3. Peristaltic Pump Heads Replacement

Replace peristaltic pump heads only with instrument in power down.

NOTE: for the peristaltic pump head replacement wear complete protection, with long sleeves (ending with elastic bands), shock-resistant rubber gloves and protective glasses. Replace peristaltic pump heads only with original parts provided by the Manufacturer.

Replace the peristaltic pump heads following the instructions below:

1. Open the front pump panel of the instrument.
2. Unplug the peristaltic pump tubing from the Pump Assembly nipples.

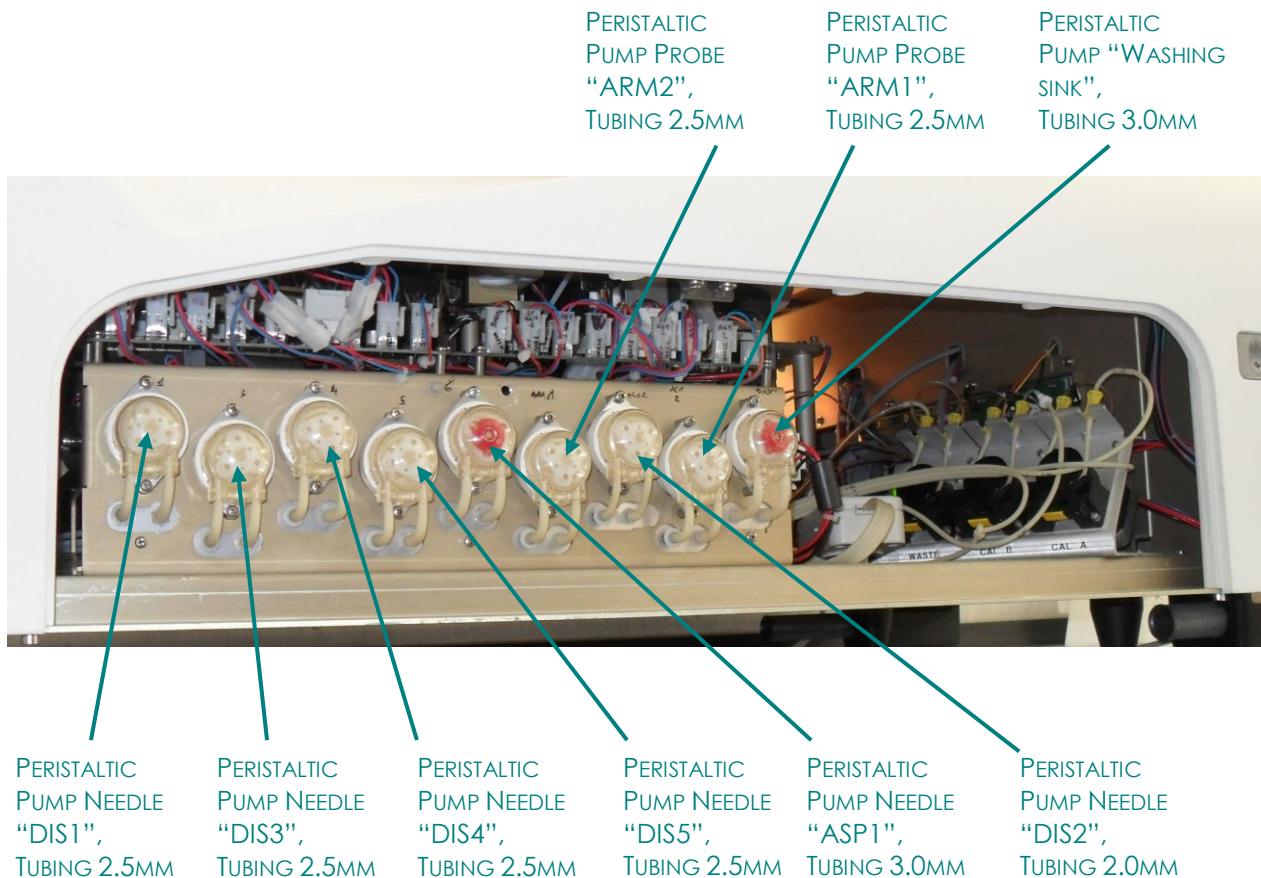


Figure 119: Peristaltic Pump Heads Placement

3. Turn about 30° CCW the pump head and slip the head off from its motor shaft.
4. Plug the new heads on its motor shafts (same angle) and turn 30° back CW until the "click".
5. Plug the peristaltic pump tubing in the proper nipples.
6. Close the instrument front panel.



7. Switch the instrument on, start the software and wait the end of the warm up.
8. Run a *Start up* cycle from the *Status* menu to wash cuvettes and to update their auto-zero values.

Refer to the pictures below for pumps and load connections to the PWR Driver Board connectors:

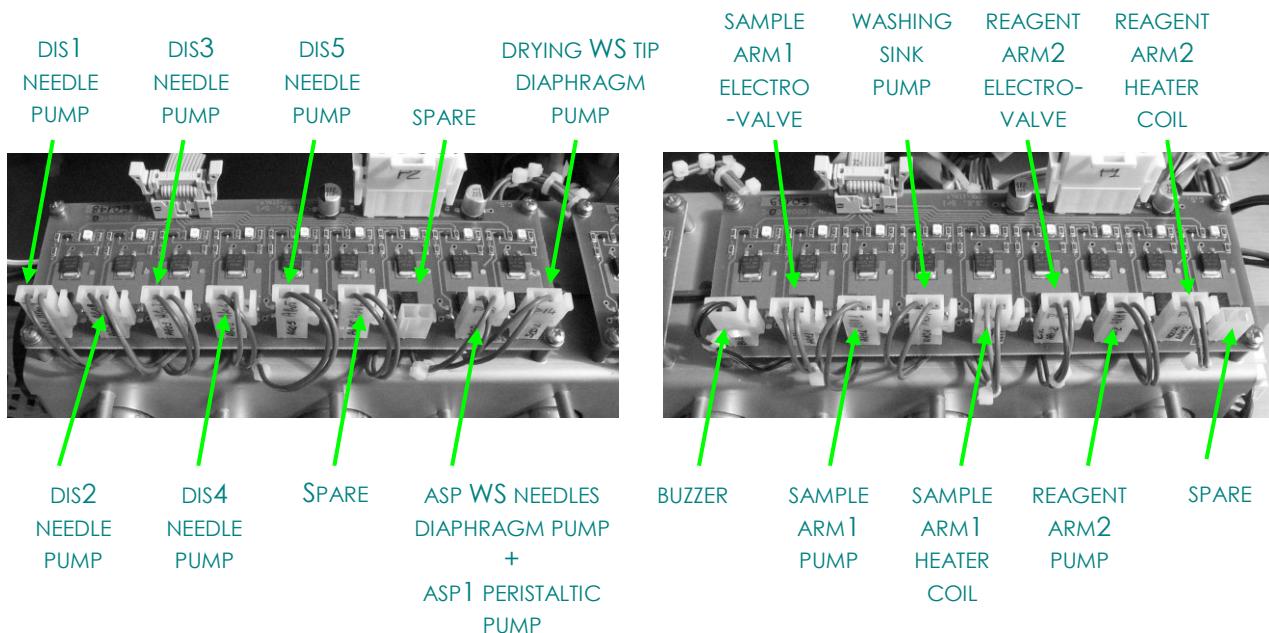


Figure 120: Pumps/Loads Connections to the PWR Driver Boards



8.5.4. Photometer Lamp Replacement

Replace the Photometer halogen lamp with the instrument in power off; wait at least 5 minutes from the shutdown to allow the bulb to cool down and to avoid oneself burns. The new halogen lamp +12V/20W includes the fixing support but not the knob: save it.

WARNING

Halogen lamps operate at extremely high temperatures that can cause serious physical injuries and property damage.

Never touch the lamp when it is on, or soon after it has been turned off, as it is hot and may cause serious burns.

Do not look directly at the operating lamp for any period of time; this may cause serious eye injury.

Don't remove the lamp from its metallic support: the lamp height has been calibrated at factory and the fixed on that support.



Figure 121: Photometer Lamp Replacement

To replace the photometer lamp follow the instructions below (ref. to the pictures):

1. Open the wicket protecting the lamp assembly.
2. Unplug the lamp connector from the main wiring (pay attention do not let it slide inside the machine).
3. Unfasten the lamp knob.
4. Take out the lamp with its support.
5. Place a new lamp, with its support, in the slot and tight the fastening knob.
6. Plug the connector back to the fixed wiring.



7. Switch the instrument on, start the software and wait the end of the warming up (around 20 minutes).
8. Start a *Gain Calibration Cycle* from the *Status* menu. It includes the auto-zero cycle that allows the instrument to level the different wavelength gains and update the zero values of all the reading Cuvettes.

WARNING

Lamps are very fragile. Do not drop, crush, bend or shake them. Vibration or impact will cause filament breakage and short lamp life.

Do not touch the Halogen bulb surface with your bare hands. Oils from skin can lead to breakage or shorten the life of the lamp. Use clean gloves or lint-free cloth for installation and removal.



8.5.5. Sampling Probes Replacement

Replace the sampling probe with instrument in OFF. Use only probes supplied by the manufacturer. In case of Double ARM system sampling probes for both arms are the same.

Make sure that the new probe does not present any imperfection.

NOTE: for the sampling probe replacement a complete protection must be worn, with long sleeves (ending with elastic bands), shock-resistant rubber gloves and protective glasses.

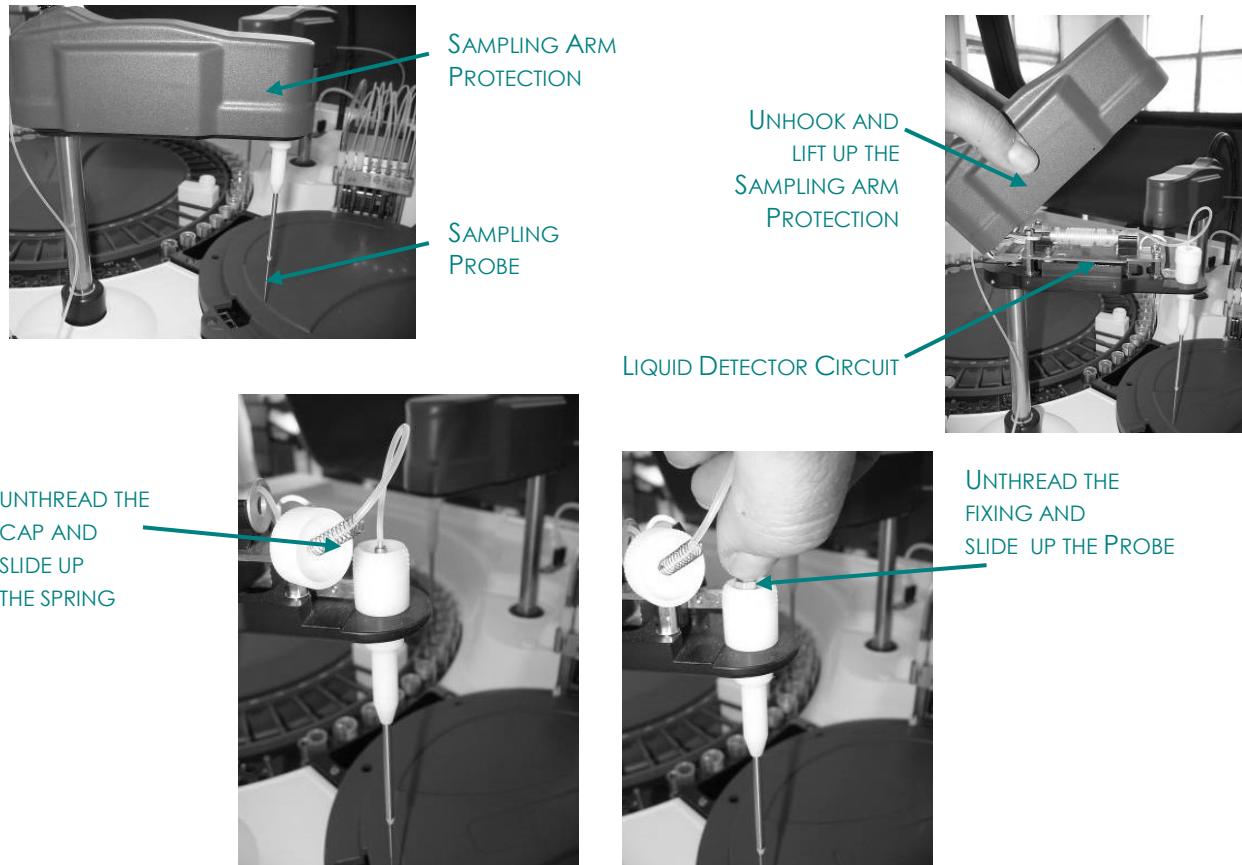


Figure 122: Sampling Probe Replacement

To replace the probe follow the instructions below (ref. to the pictures):

- Unfasten the arm protection cover by slightly stretching it, and slide it backwards to lift it.
- Unscrew the cap and slide it, together with the spring, along the teflon tubing.
- Unscrew the probe fixing and slide it along the pipe.
- Take the old probe out of the teflon tubing (do not bend the tubing), put it in a container for contaminated materials, and replace it with a new one.



- Place the new probe top end into the teflon tubing (do not bend the tubing and use latex gloves).
- Slide the fixing along the tubing and screw it paying attention that the probe is not blocked.
- Slide the spring and the cap along the tubing and screw the cap; make sure that probe can move freely in its seat in opposition to the retention spring without to get blocked.
- Fasten the arm cover in its original position by slightly stretching it.
- Switch the instrument on, run the software and wait the end of the warm up.
- Run three times the *Arm Rinsing* (one for each ARM) commands from the *Status* menu. The cycle includes probe washing and refill of the probe hydraulic tubing.



8.6. ISE Module Maintenance Procedures

Refer to the following paragraphs for details about the main maintenance procedures over the ISE Module when integrated in the system (option).

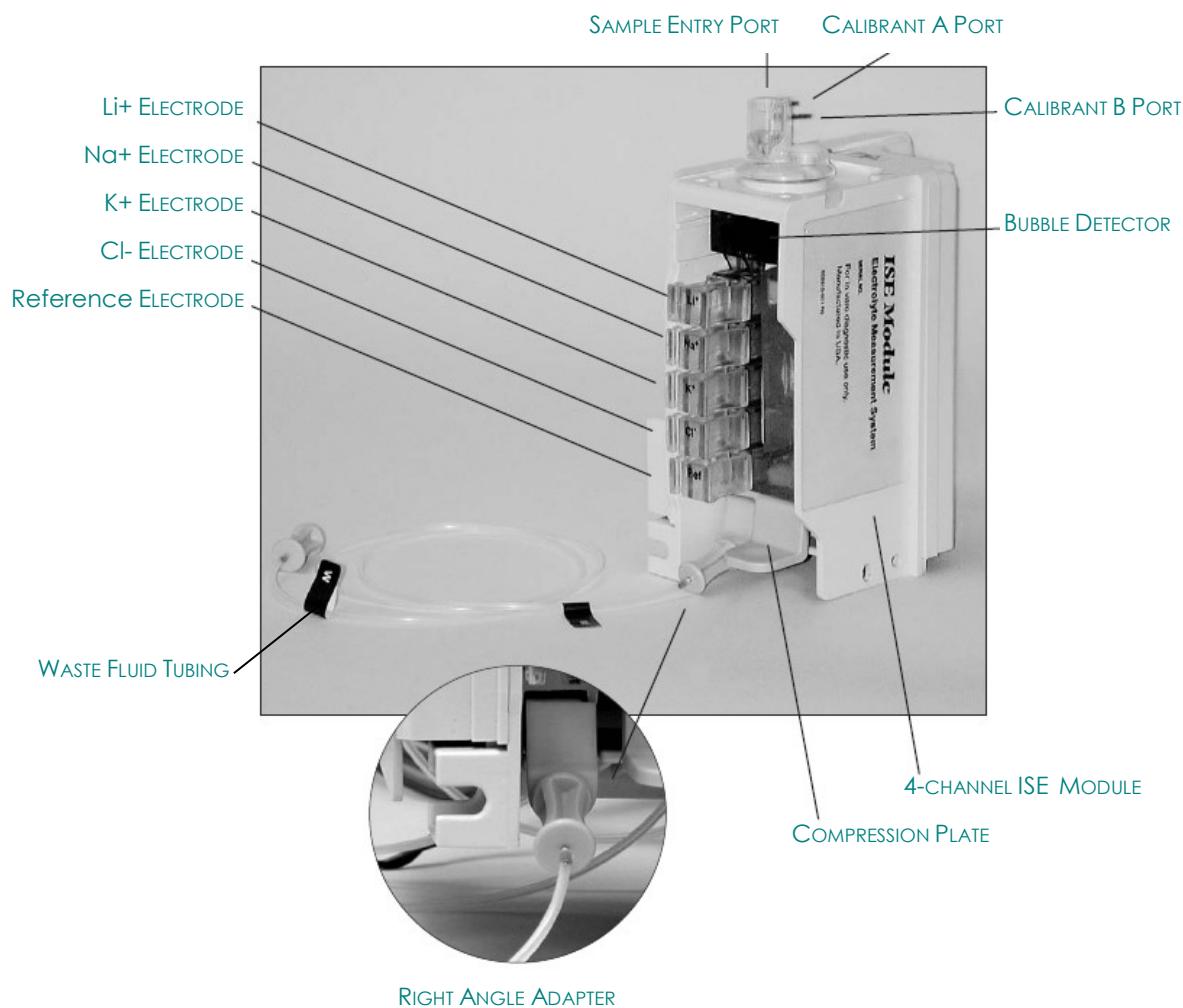


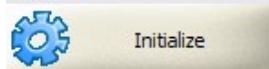
Figure 123: ISE Module, Outline

8.6.1. Reagent Pack Replacement

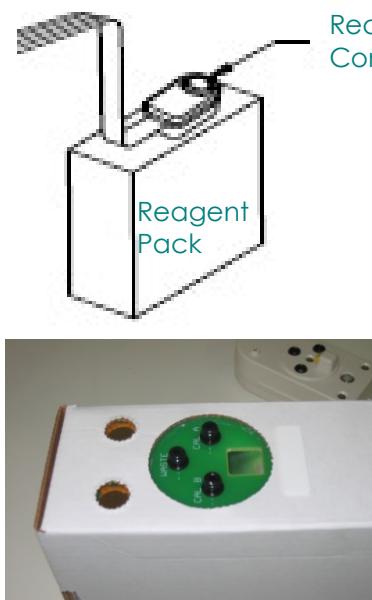
When exhausted, Reagent Pack must be changed with a new one. Replace Reagent Pack with system in *Idle* status.
Follow the procedure below:



1. Consider the ISE Module Reagent Pack containing Calibrant A and Calibrant B (and Waste in case the output has not been connected to the system waste tank);
2. Press the yellow button of the Reagent Pack Connector and disconnect it from the pack;
3. Connect the Reagent Pack Connector on the new pack and be sure that it's stable on it;
4. From the *ISE module conf* menu run the *Initialize* command



5. Place the Reagent Pack back in its place paying attention not to bend or occlude tubing, close the front panel and start working.



Reagent Pack Connector

OD_{b1λ.1}**Figure 124:** ISE Module, Reagent Pack replacement**WARNING**

Biohazard Waste: used reagent packs contain waste material and they must be always considered potentially infected. Dispose off according to local laws and rules.



8.6.2. Electrodes Replacement

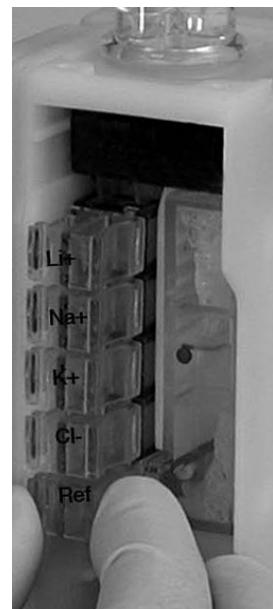
When electrodes maintenance period has expired they must be replaced with new ones. Replace Electrodes only with system powered OFF.

Follow the procedure below:

1. From the *ISE module conf* menu run the command *Maint* to purge the ISE Module path; 
2. Shut down the system (software and instrument);
3. Open the front panel of the instrument and carefully extract the Reagent Pack;
4. Depress the compression plate and remove all electrodes from the ISE Module (start with the upper one);
5. Dispose of the electrodes to be replaced according to local rules (**they can be infected**);
6. Remove new electrodes from sealed bag;
7. Remove the yellow flag from Reference electrode and if necessary soak the reference electrode in warm water until the lumen of the electrode has been cleared of salt build-up (**do not throw away the yellow flag with its flow path line – it can be used in case of ISE Module electrode storing**);
8. Install the new electrodes in the ISE Module (starting from the bottom – Reference electrode);
9. Power Up the system;
10. If the system doesn't go into the Warming Up, run the *Initialize* command from the *ISE module conf* menu (being the electrode new, it could drift) otherwise jump to the next step; 
11. Wait for 15 minutes then run again the *Initialize* command (time required for new electrode re-hydrating).

WARNING

Used electrodes must be always considered potentially infected.



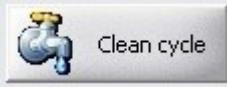


8.6.3. Electrodes Storage

In a day or two with the power off, the user might notice that it may take some time for the electrodes to regain stability. The longer this period, the more acute the problem will occur. The original silicone pump tubes may start crimping after a couple of weeks depending on the ambient temperature. The solutions in the various lines may dry out and form blockages or restrictions.

If the laboratory plans to store the instrument or to leave it OFF for long time (more than one week), the following steps should be performed:

ISE Module de-activation

1. From the *ISE module conf* menu run the command *Clean cycle* to clean the ISE Module path; 
2. From the *ISE module conf* menu run the command *Maint* to purge (and empty) the ISE Module path; 
3. Shut down the system (software and instrument);
4. Open the front panel of the instrument;
5. Remove the Reagent Pack from the reagent connector and discard;
6. Depress the compression plate and remove all electrodes from the ISE Module (start with the upper one), including the Reference electrode;
7. Place **Na⁺** and **Cl⁻** electrodes into their individual sealed bags;
8. Reinsert the Reference Electrode flow path line with yellow flag, if available, and then put into its individual sealed bag;
9. Aspirate a small volume of Calibrant A from the top port of the Reagent Pack into a syringe fitted with a blunt needle;
10. Inject sufficient Calibrant A into the lumen of the **K⁺** and **Li⁺** electrodes until fluid fills the lumen;
11. Cover both ends of the lumen (both sides of the K⁺ and Li⁺ electrodes) with tape to hold the Calibrant in place;
12. Insert the K⁺ and Li⁺ electrodes into their sealed bags.

Note: for all electrodes, make sure that they are wiped dry prior to storing in sealed bags.

WARNING

Used electrodes must be always considered potentially infected.

ISE Module re-activation

(operate with system instrument down)

1. Remove all electrodes from sealed bag;
2. Remove tape from K⁺ and Li⁺ electrodes;



3. If necessary soak the reference electrode in warm water until the lumen of the electrode has been cleared of salt build-up (**do not throw away the yellow flag with its flow path line – it can be used in case of ISE Module storage**);
4. Remove the yellow flag from Reference electrode and if necessary soak the reference electrode in warm water until the lumen of the electrode has been cleared of salt build-up (**do not throw away the yellow flag with its flow path line – it can be used in case of ISE Module storage**);
5. Install electrodes in the ISE Module (starting from the bottom – Reference electrode);
6. Connect the Reagent Pack to the ISE Module reagent connector;
7. Power Up the system;
8. If the system doesn't perform Warming Up, from the *ISE module conf* menu run the *Initialize* command (being the electrode new, it could drift) otherwise jump to the next step;

Wait for 15 minutes then run again the *Initialize* command (time required for new electrode re-hydrating).





Section 9 PROBLEM SOLVING

9. Introduction

This section provides the user with the rules for effective corrective actions.

9.1. Generalities

Corrective actions allow the user to solve ordinary problems through easy maintenance operations.

WARNING

Read carefully Section 1 –“Safety” before any maintenance operation and refer to Section 8 if necessary.

Before any maintenance operation make sure that:

- The working area is clean and free from leakages and rubbles.
- Fluid leakages must be immediately rinsed and dried.
- All the information about infected fluids (see Section 1) must be read.
- In case of fault or breakdown of any part of the system, the reparation must be immediately performed by Authorized Technical Personnel to assure instrument performance and results reliability.

9.2. Auto-diagnosis System

When the instrument is turned on, the firmware operates a system self-diagnosis and provides the hardware reset as soon as the software starts up.

Warning messages alert the user in case of failures.

Moreover, during instrument operation the system checks “on line” the main assemblies and reports any functional anomaly.

From a hardware point of view the following assemblies and functions are controlled:

- serial link communication between the external PC and the instrument;
- electronic controller boards, and their intra-communication;
- motors, motions and home positioning (including diluters);
- correct positioning of the cuvettes tray;
- incubation temperature;
- vertical sampling arms “crash”;
- washing station motion;
- barcode reader self-check;
- ISE Module status (when included and enabled).



The system also displays warning windows in case of alarm or functional notices (empty loading tanks, full waste tank, cover open, etc.)

The instrument activates an acoustic beeper in the following events:

- at the end of the warming up;
- at the end of an analysis run;
- at the end of significant phases or operations (i.e.: start-up cycle and gain calibration cycle)
- in case of alarms.

The PC alerts with short acoustic sounds (if enabled and in case of multimedia display) upon one of the following events:

- Test result concluded,
- Sample list received from L.I.S.,
- System alarm status,
- System warning status,
- User software start,
- User software shutdown.

9.3. Main Failures and Corrective Actions

This paragraph provides a list of problems that could be encountered on the system and a brief description of the possible corrective actions:

Problem	Possible Cause	Corrective Action
THE INSTRUMENT DOESN'T START AND RESET AT POWER UP:	1. Cover open:	Close the Cover of the instrument.
THE INSTRUMENT DOESN'T RESETS OR CORRECTLY WARMS UP WHEN POWERED ON	1. Serial link failure:	Verify that the serial cable connecting the instrument and the PC is correctly fastened on both sides.
	2. Power On problem:	Switch the instrument off and keep it off for 2 minutes; then power it on again. If not enough, power off the system (PC and instrument) for 2 minutes and power it on once more. If the problem persists contact service.
EXTERNAL PRINTER NOT WORKING	3. Hardware malfunctioning:	Contact service.
REAGENT AND/OR SAMPLE PROBES FAILURES DURING ASPIRATION AND	1. Arm Heater Coil tubing not connected or damaged:	Verify that the tubing of the Heater Coil is correctly plugged on the sampling probe without



Problem	Possible Cause	Corrective Action
DISPENSATION		<p>any leakage. Verify that the fittings on the Diluter Head are fastened and without fluid leakages. If the tubing or the fittings are damaged, replace them with new ones.</p>
	2. Diluter head:	<p>Verify that the Diluter Head doesn't leak out and that, during sampling, the white Diluter Plunger moves up and down. In case of damage contact the service.</p>
	3. 3-way diluter electrovalve not working:	<p>Verify that during sampling, the Electrovalve switches ON and OFF. If not, contact the service.</p>
	4. Systemic and/or Cleaner solution external charge tubing is empty, liquid doesn't flow:	<p>Verify that system solution tank isn't empty and that the Tygon® tubing is undamaged and <u>not bended</u> or obstructed and that the filter dips into the liquid. If damaged change it.</p>
	5. Teflon® tubing of the diluter head is empty:	<p>Verify that the Heater Coil Teflon® tubing is undamaged and not bended or obstructed. If damaged change it. Verify that the Teflon® tubing between Electrovalve and Diluter Head is undamaged and not bended or obstructed. If damaged change it.</p>
	6. Sampling Probes occluded:	<p>Verify that the probe isn't occluded and it is internally clean. Clean it first with several washings (<i>Refill sample/reagent arm</i>) then use disinfection procedure for probes. If damaged change it. The systemic solution must be clean and without floating particles; verify and clean the tank internal filter.</p>
REAGENT AND/OR SAMPLE PROBES DO NOT WASH, MISSING OF WASHING SOLUTION FLOW	1. 3-way diluter electrovalve not working:	<p>Verify that during sampling, the Electrovalve switches ON/OFF. If not contact the service.</p>
	2. Teflon® tubing between 3-way Electrovalve and Diluter damaged:	<p>Verify that the Teflon® tubing fittings between Electrovalve and Diluter Head are correctly fastened, undamaged and that</p>



Problem	Possible Cause	Corrective Action
		tubing is not bended or obstructed. If damaged change it.
	3. Hydraulic circuits empty (most common cause when both arms don't wash):	Verify that systemic solution tank isn't empty and that the Tygon® tubing is undamaged and not bended or obstructed and that the filter dips into the liquid. If damaged change it.
	4. Pumps worn away or not working:	Verify the Pump motors: they must turn during washing. If not moving, change them.
	5. Sampling probe occluded:	Verify that the probe isn't occluded and it is internally clean. Clean it first with several ARM washings then use disinfection procedure for probes. If damaged change it. The systemic solution must be clean and without floating particles; verify and clean the tank internal filter.
TEST RESULTS NOT RELIABLE NOR REPEATABLE:	1. Sampling probes occluded:	Verify that the probes aren't occluded and that they are internally clean. Clean it first with several ARMs washings then use disinfection procedure for probes. If damaged change it. The Systemic solution must be clean and without floating particles; verify and clean the tank internal filter.
	2. Diluter Head:	Verify the Diluter Head, if it contains floating particles or big air bubbles clean it with several probe washings.
	3. Arm Heater Coil tubing not connected or damaged or shows many air bubbles inside:	Verify that the tubing of the Heater Coil is correctly plugged on the sampling probe without any leakage. Verify that the fittings on the acrylic Diluter Head are correctly fastened. Verify if probe tubing or fittings are undamaged, otherwise change them with new ones.
	4. Dirty cuvettes:	Run a Start up cycle, take out the cuvette and control that their



Problem	Possible Cause	Corrective Action
		narrow walls are clean inside and outside; dirty cuvettes must be replaced. Run an Extra wash cycle with EW Cvt solution.
	5. Photometer lamp:	Verify the photometer lamp is on and stable, if not replace it.
	6. Externally wet cuvettes:	Switch the instrument off, take out all cuvettes, in case they are wet carefully dry them with a clean soft cloth. Then wait about 1 hour and then replace all cuvette back; run a Calibration cycle. In case the problem persist contact the service.
	7. Decayed Reagent:	Verify that the reagent used for the method, whose results are out of control, is not expired.
	8. Wrong or decayed control:	Verify that the control used for the method, whose results are out of control, is not expired and it's the correct one.
	9. Contamination:	Verify that the solution in cuvette is not contaminated by external agents.
	10. Damaged Filter:	Run a Calibration cycle and, in case of filter alarm, contact the service.
POOR CUVETTE WASHING, THE CUVETTES ARE WET INSIDE.	1. Waste tubing:	Verify that the external Waste tubing is not bended or obstructed and well fastened to its side fittings.
	2. Aspiration tubing of the Washing Station:	Verify that the aspiration Teflon® and Tygon® tubing, placed under the Washing Station protecting Cap, are undamaged and without leakages. If damaged replace them or contact the service.
	3. Aspiration Pumps:	Verify that both Aspiration Pumps works during washing. If not, contact the service.
	4. Drying Tip:	Verify that the Washing Station drying tip is undamaged. If damaged, contact the service.
	5. Washing Station aspiration needles:	Verify that the longest needles of the Washing Station are clean and not damaged nor occluded. If not, contact the



Problem	Possible Cause	Corrective Action
POOR CUVETTE WASHING, THE CUVETTES ARE DIRTY INSIDE.	1. Peristaltic Pumps worn away or not working: 2. Washing Station dispensing tubing: 3. Washing Station dispensing needles:	Verify the Peristaltic Pump heads: if worn, change them. Verify the Peristaltic Pump motor: they must turn during washing. If not moving, change them. Verify that the aspiration Teflon® tubing, placed under the Washing Station protecting Cap, are undamaged and without leakages. If damaged, replace them or contact the service. Verify that the shortest needles of the Washing Station are clean and not damaged nor occluded. If not, contact the service.
THE SAMPLING PROBE WASHING SINK DOESN'T GET EMPTY DURING WORKING SESSIONS	1. Emptying Pump worn or not working:	Verify the Pump motor: it must turn during washing. If not moving, change it.
THE SOFTWARE DOESN'T START WHEN RUN AFTER POWER UP:	1. Database and its back-up could be corrupted or missing:	Call for service and substitution of database with the latest valid back up copy. PAY ATTENTION DURING SYSTEM SHUT DOWN: follow always the correct procedure and do not switch the PC off manually before the procedure is completed.



9.4. Instrument Status Messages

The Status menu of the User Interface software constantly shows the performance status of the instrument during operation.

The system shows the message window only when alarm or warning conditions occur.

Message	Meaning
LOADING	The system is loading information and data; instrument and PC are exchanging messages.
WARMING UP	The system is performing the warming up procedure.
IDLE	The system is ready to operate and waiting for commands.
READING AND WASHING	The system is in start-up procedure, refilling tubing, auto-zeroing and washing cuvettes.
CALIBRATING	The system is in optical gain calibration cycle.
SCHEDULING	The Work List has been started, the system is scheduling the analysis in order to proceed with the run.
RUNNING	The system is running a working session which is not yet concluded.
ABORTING	A working session has been interrupted and the system is reading and washing all cuvettes (auto-zero cycle).
IN ALARM	The system is in alarm status: a message window is at the same time shown; an action is required to proceed.
IN WARNING	The system is in warning status: a message window is at the same time shown; an action or decision can be asked to the operator.
EXTRA WASHING	The system is performing the extra-washing of all reading cuvettes using the EW Cvt solution placed on the reagent tray.

9.4.1. Error Messages, Warnings and Troubleshooting

Any warning or alarm during normal operation is shown in the alert window.

In case it is included in the system, ISE Module warnings are considered as a warning for the system (in fact it doesn't stop the instrument like normal alarms). In that case the ISE icon on Status menu becomes red and the operator is asked to click on it to decide what to do.

This paragraph provides a list of the error codes, its displayed linked messages, and the actions required in case of any problem occurring during the instrument working:

Code	Message	Cause	Action
101	Warning: Close the cover for running.	The cover of the instrument has been open during run.	Sampling is arrested. Reading of reactions actually in incubation will be continued up to the end, also with cover open. Close the cover to restart and continue the working session.
102	Warning: Systemic solution is going to finish.	Systemic solution is ending.	Sampling is arrested. Reading of reactions actually in incubation



Code	Message	Cause	Action
			will be continued up to the end. After a time out, the system washes readings cuvettes and waits for tank refilling. Refill the Systemic solution tank: the system then restarts the sampling run. Do not disconnect tubing during run.
103	Warning: Cleaner solution is going to finish.	Cleaner solution is ending.	Sampling is arrested. Reading of reactions actually in incubation will be continued up to the end. After a time out, the system washes readings cuvettes and waits for tank refilling. Refill the Cleaner solution tank: the system then restarts the sampling run. Do not disconnect tubing during run.
104	Warning: Waste tank is getting full. WAIT end of washing before emptying.	Waste tank is almost full.	Sampling is arrested. Reading of reactions actually in incubation will be continued up to the end. After a time out, the system washes readings cuvettes and waits for tank empty. Empty the tank or replace with an empty one just AFTER the end of the washing phase: the system then restarts the sampling run. Do not disconnect tubing during cuvette washing or run.
105	Warning: Some reagents are empty. In the Status menu click on red reagents.	Some reagents, used in the Work List, are finished. A reagent that is finished is marked in RED on the Status menu.	Click on the RED reagent and follow the instructions on the screen. Press <i>Retry</i> after replacing the bottle; press <i>Abort</i> to skip that type of analysis; press <i>Exit</i> to exit the window without any decision and change. To change the bottle: click on <i>Pause</i> and wait that ARMs stop, open the cover and replace the bottle; close the cover and click on <i>Continue</i> , then click on <i>Retry</i> .
106	Warning: Some samples are empty. In the Status menu click on red reagents.	Some sample are finished. A sample that is finished is marked in RED on the Status menu.	Click on the RED sample and follow the instructions on the screen. Press <i>Retry</i> after refilling the sample; press <i>Abort</i> to skip the hanging analyses; press <i>Exit</i>



Code	Message	Cause	Action
			to exit the window without any decision and change. To refill the sample: click on Pause and wait that ARMs stop, open the cover and refill the tube; close the cover and click on Continue, then click on Retry.
107	Alarm: Refill Systemic solution tank and in Status menu press Continue button.	Systemic solution is over; the system is blocked.	Refill the tank and then press the button Continue in the Status menu.
108	Alarm: Refill Cleaner solution tank and in Status menu press Continue button.	Cleaner solution is over; the system is blocked.	Refill the tank and then press the button Continue in the Status menu.
109	Alarm: Empty Waste tank and in Status menu press Continue button.	Waste is full; the system is blocked.	Empty the tank and then press the button Continue in the Status menu after replacing it.
110	Alarm: Internal hardware communication error. In run press Continue button else restart the System.	Hardware error.	Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected check if the instrument is ON. Shutdown the program, the PC and the instrument and then restart the system. If the problem persists, contact service.
111	Alarm: Washing station not working. In run press Continue button else restart the System.	The Washing Station isn't properly working, it didn't enter cuvettes.	Verify the absence of obstacles under the washing station needles. Verify calibration. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. If the problem persists contact service.
112	Alarm: Cuvette tray encoder not working. In run press Continue button else restart the System.	The cuvette tray motion fails positioning.	Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. If the problem persists contact service.
113	Alarm: Sample ARM is crashing. In run press Continue button else	The Sample ARM crashed against an obstacle during its way down.	Remove any obstacle on the probes way down, i.e.: sample caps, etc.



Code	Message	Cause	Action
	restart the System.		Press the button <i>Continue</i> in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. If the problem persists check if the probe is entering the correct positions (tips of washing sinks, cuvettes, ...) and contact service.
114	Alarm: Reagent ARM is crashing. In run press Continue button else restart the System.	The Reagent ARM crashed against an obstacle during the descend.	Remove any obstacle on the probes way down, i.e.: reagent bottle caps, etc. Press the button <i>Continue</i> in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. If the problem persists check if the probe is entering the correct positions (tips of washing sinks, cuvettes, ...) and contact service.
115	Alarm: Serial communication error. Check the cable.	Error due to serial link hardware failure between the external PC and the instrument.	Shutdown the program, the PC and the instrument and verify that the serial cable is fastened on both ends and that is undamaged otherwise change it. Restart the system. If the problem persists, contact service.
117	Alarm: Problem on filter: xxx.	Filter xxx could be damaged.	In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. Run a <i>Calibration</i> cycle. If the problem persists, don't run methods using that wavelength and contact service.
118	Alarm: X-Sample ARM motion not properly working. In run press Continue button else restart the System.	The Sample ARM doesn't rotate correctly.	Verify the absence of obstacles on the working area. Press the button <i>Continue</i> in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart



Code	Message	Cause	Action
			the system. If the problem persists contact service.
119	Alarm: Y-Sample ARM motion not properly working. In run press Continue button else restart the System.	The Sample ARM doesn't rise and descend correctly.	Verify the absence of obstacles on the working area. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
120	Alarm: Diluter Sample ARM motion not properly working. In run press Continue button else restart the System.	The sample ARM diluter fails during motions.	Verify the absence of obstacles or particles into the Diluter transparent head; press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
121	Alarm: X-Reagent ARM motion not properly working. In run press Continue button else restart the System.	The Reagent ARM doesn't rotate correctly.	Verify the absence of obstacles on the working area. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
122	Alarm: Y-Reagent ARM motion not properly working. In run press Continue button else restart the System.	The Reagent ARM doesn't rise and descend correctly.	Verify the absence of obstacles on the working area. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
123	Alarm: Diluter Reagent ARM motion not properly working. In run press Continue button else restart the System.	The reagent ARM diluter fails during motions.	Verify the absence of obstacles or particles into the Diluter transparent head; press the button Continue in the Status menu to retry, the system should recover. In case the alarm is



Code	Message	Cause	Action
			again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
124	Alarm: Reagent tray motion not properly working. In run press Continue button else restart the System.	The reagent tray fails during motions.	Verify the absence of obstacles on its working area and the free movement of the tray. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
125	Alarm: Sample tray motion not properly working. In run press Continue button else restart the System.	The sample tray fails during motions.	Verify the absence of obstacles on its working area and the free movement of the tray. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service.
126	Alarm: Washing station motion not properly working. In run press Continue button else restart the System.	The Washing Station is not properly working, the motion has problems.	Verify the absence of obstacles under the needles. Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. If the problem persists, contact service.
127	Warning: Hardware over temperature. Shutdown the system and control ambient temperature.	The temperature of electronics environment is too high.	Shutdown the program, the PC and the instrument and verify that the operating ambient temperature is within specification. If not, do not operate the instrument. If it's within the range, wait for 30 minutes and restart the system. If the problem persists contact service.
128	Warning: Incubation temperature out of range.	Incubation temperature out of limits.	Verify that the instrument is ON and communicating with PC.



Code	Message	Cause	Action
			Verify that the operating ambient temperature is within specification. If not, do not operate the instrument. If it's within the range, shutdown the program, the PC and the instrument and restart the system after 10 minutes. If the problem persists contact service.
129	Warning: Bar-code reader out of order.	Barcode communication out of order.	Shutdown the program, the PC and the instrument and restart the system. If the problem persists contact service. The instrument can anyway operate without barcode identification.
130	Warning: Check Photometer lamp.	Photometer lamp doesn't work properly.	Check that the lamp is on and stable. Shutdown the program, the PC and the instrument and restart the system. If the problem persists change the lamp and run a calibration cycle.
131	Alarm: Client-Server TCP/IP error. Restart the system.	PC internal software error.	Shutdown and restart the system. If the problem persists contact service.
132	Problem during WL scheduling process. Try again.	Error during Work List scheduling.	At the end of the actual working session, select Clean WL form the Status menu and repeat the procedure. If the problem persists contact service.
133	Communication error. Command cannot be send to server. Try again.	Temporary Client/Server error.	Retry after some seconds.
134	Database error. Restart the system.	Internal database error.	At the end of the actual working session shutdown and restart the system. If the problem persists contact service.
136	Problem during the filing process. Not all patient data registered.	Error during filing of patients in archive.	None, results are lost. If the problem persists contact service.
137	Alarm: Filter motor not properly working. In run press Continue button else restart the System.	The filter tray fails during motion.	Press Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and restart the system. If the problem persists



Code	Message	Cause	Action
			contact service.
138	Warning: Cooler liquid low level. Call service for refilling.	The liquid of the reagent cooling circuit reached the low level.	Liquid must be refilled by service. Instrument can anyway operate with reduced performances for reagent refrigeration. Contact service.
139	Warning: some standards are empty. In the Status menu click on red standards.	Some standards used in Work List are finished. A standard that is finished is marked in RED in the Status menu.	Click on the RED standard and follow the instructions on the screen. Press <i>Retry</i> after replacing Standard; press <i>Abort</i> to skip standardization, controls and analyses related to that standard; press <i>Ignore</i> to skip standard and to use old Factor in memory for computing results (for control and analyses); press <i>Exit</i> to exit the window without any decision and change. To refill the standard: click on <i>Pause</i> and wait that ARMs stop, open the cover and refill the cup; close the cover and click on <i>Continue</i> , then click on <i>Retry</i> .
140	Warning: some controls are empty. In the Status menu click on red controls.	Some controls used in Work List are finished. A control that is finished is marked in RED in the Status menu.	Click on the RED control and follow the instructions on the screen. Press <i>Retry</i> after replacing Control; press <i>Abort</i> to skip controls and related analyses; press <i>Ignore</i> to skip control and to process anyway the related analysis; press <i>Exit</i> to exit the window without any decision and change. To refill the standard: click on <i>Pause</i> and wait that ARMs stop, open the cover and refill the cup; close the cover and click on <i>Continue</i> , then click on <i>Retry</i> .
141	Warning: some dilution cups are empty. In the Status menu click on red cups.	Some diluted samples are finished. A diluted sample that is finished is marked in RED in the Status menu.	Click on the RED sample dilution cup and follow the instructions on the screen. Press <i>Retry</i> to let the instrument automatically refilling the cup with dilution; press <i>Abort</i> to skip dilutions and hanging related analyses; press <i>Exit</i> to exit the window without any decision and change.
142	Warning: unknown method loaded by smart	A method not included in the list has been loaded by smart	Contact service.



Code	Message	Cause	Action
	card. It can be activated only for instrument operating under smart-card.	card and its memorization in the database failed.	
143	Warning: it is not possible remove selected method. Store or run all the analysis on this method before delete it.	The operator tried to delete a method in the while it is running.	Wait for the end of the run, save results, then delete the method.
144	Alarm: critical internal error. Please try to restart the system.	The software or part of it could be missing or corrupted.	Try to restart the system. If not working, contact the service.
145	Warning: Ise module communication lost. In Status page click on Ise icon.	The ISE Module doesn't respond. It could be OFF or its wiring isn't properly fixed or it's damaged.	Check if the ISE module is in ON condition. Check that wiring is properly fixed on the back of the ISE Module and on the mother-board. If the problem persists contact service.
146	Warning: Ise module purge A error. In Status page click on Ise icon.	Some air is in the Calibrant A tubing or the Calibrant A is finished.	Reinitialize ISE Module from ISE module conf menu. Do it more times if required. Change Reagent pack and initialize ISE Module from ISE module conf menu. If the problem persists contact service.
147	Warning: Ise module purge B error. In Status page click on Ise icon.	Some air is in the Calibrant B tubing or the Calibrant B is finished.	Reinitialize ISE Module from ISE module conf menu. Do it more times if required. Change Reagent pack and initialize ISE Module from ISE module conf menu. If the problem persists contact service.
148	Warning: Ise module pump cal error. In Status page click on Ise icon.	Calibration of pump motors failed. Air in fluids or hardware failure.	Check for liquid leakages in the ISE Module and check that tubing are free. Check for electrodes properly seated. Re-initialize ISE Module from ISE module conf menu. Do it more times if required. If the problem persists contact service.
149	Warning: Ise module bubble cal error. In Status	Air in fluids or fluid leakage or hardware failure.	Check for liquid leakages in the ISE Module and check that



Code	Message	Cause	Action
	page click on Ise icon.		tubing are free. Check for electrodes properly seated. Re-initialize ISE Module from <i>ISE module conf</i> menu. Do it more times if required. If the problem persists contact service.
150	Warning: Ise module air in urine. In Status page click on Ise icon.	Air detected into urine sample or pump tubing obstructed.	Check the sample it must be free of bubbles. Repeat the sample. Check for liquid leakages in the ISE Module and check that tubing are free. Check for electrodes properly seated. Re-initialize ISE Module from <i>ISE module conf</i> menu. If the problem persists contact service.
151	Warning: Ise module calibration error. In Status page click on Ise icon.	ISE Calibration was not successful. Values out of range or difference between the two consecutive calibrations out of range.	Repeat calibration by re-initializing ISE Module from <i>ISE module conf</i> menu. Do it more times if needed. Check for electrodes properly seated. If the problem persists contact service.
152	Warning: Ise module air in cal A. In Status page click on Ise icon.	Calibrant A is segmented with air or fibrine is plugging the electrode flow-path.	Check for electrodes properly seated and compressed. Check compression plate, spring and seal. Remove and reassemble electrodes (verify that electrodes and o-rings are properly installed). Run a cleaning procedure from <i>ISE module conf</i> menu (command <i>Clean cycle</i>). Re-initialize ISE Module from <i>ISE module conf</i> menu. If the problem persists contact service.
153	Warning: Ise module air in cal B. In Status page click on Ise icon.	Calibrant B is segmented with air or fibrine is plugging the electrode flow-path.	Check for electrodes properly seated and compressed. Check compression plate, spring and seal. Remove and reassemble electrodes (verify that electrodes and o-rings are properly installed).



Code	Message	Cause	Action
			Run a cleaning procedure from <i>ISE module conf</i> menu (command <i>Clean cycle</i>). Re-initialize ISE Module from <i>ISE module conf</i> menu. If the problem persists contact service.
154	Warning: Ise module air in cleaner. In Status page click on Ise icon.	Cleaning solution is segmented with air or fibrine is plugging the electrode flow-path.	Check the cleaning bottle it must be free of bubbles. Check for electrodes properly seated and compressed. Check compression plate, spring and seal. Remove and reassemble electrodes (verify that electrodes and o-rings are properly installed). Run a cleaning procedure from <i>ISE module conf</i> menu (command <i>Clean cycle</i>). If the problem persists contact service.
155	Warning: Ise module air in segment. In Status page click on Ise icon.	Air in segment.	Check samples to be free of bubbles. Check for liquid leakages in the ISE Module and check that tubing is free. Check for electrodes properly seated and the o-ring are in place. Re-initialize ISE Module from <i>ISE module conf</i> menu. If the problem persists contact service.
156	Warning: Ise module no flow. In Status page click on Ise icon.	No flow in the path or fibrine is plugging the electrode flow-path.	Check for electrodes properly seated and compressed. Check compression plate, spring and seal. Remove and reassemble electrodes (verify that electrodes and o-rings are properly installed). Run a cleaning procedure from <i>ISE module conf</i> menu (command <i>Clean cycle</i>). If the problem persists contact service.
157	Warning: Ise module dallas reading error. In Status page click on Ise icon.	Reagent Pack chip damaged or reagent pack connector not properly plugged.	Check Reagent Pack connection properly installed and fixed to the reagent connector.



Code	Message	Cause	Action
			Change the Reagent Pack. If the problem persists also with other packs contact service.
158	Warning: Ise module dallas writing error. In Status page click on Ise icon.	Reagent Pack chip damaged or reagent pack connector not properly plugged.	Check Reagent Pack connection properly installed and fixed to the reagent connector. Change the Reagent Pack. If the problem persists also with other packs contact service.
159	Alarm: Internal memory error.	System memory data not congruent.	Restart the system. If the problem persists contact service.
160	Warning: L.I.S. module client error. Please restart the application.	Error on the L.I.S. interface.	Restart the system. If the problem persists contact service.
161	Warning: some controls are out of range. Please verify in status menu.	Some controls set in Work List are out of range.	Click on the RED control and follow the instructions on the screen. Press <i>Retry</i> to repeat Control; press <i>Abort</i> to skip controls and analyses related to that control; press <i>Ignore</i> to ignore control result and to run anyway analyses; press <i>Exit</i> to exit the window without any decision and change.
162	Warning: LIS Server not active or not enabled.	LIS interface not answering.	Restart the system. If the problem persists contact service.
163	Alarm: the version of the firmware is wrong.	The firmware version programmed on controller boards is not updated.	Contact service.
164	Alarm: Fatal error from firmware. Call for service	Firmware internal error: missing of congruency.	Restart the system (instrument + PC). If the problem persists contact service.
165	Alarm: barcode not properly working. Call for service.	Barcode reader not working.	Restart the system (instrument + PC). If the problem persists contact service.
166	Alarm: flash memory corrupted. Call for service.	Error during parameters loading or down loading.	Restart the system (instrument + PC). If the problem persists contact service.
167	Alarm: communication lost with MASTER controller. In run press "Continue" button, else restart the system.	Main Controller board not properly working.	Restart the system (instrument + PC). If the problem persists contact service.



Code	Message	Cause	Action
168	Alarm: communication lost with ARM 1 controller. In run press "Continue" button, else restart the system.	ARM1 Controller board not properly working.	Restart the system (instrument + PC). If the problem persists contact service.
169	Alarm: communication lost with ARM 2 controller. In run press "Continue" button, else restart the system.	ARM2 Controller board not properly working.	Restart the system (instrument + PC). If the problem persists contact service.
170	Alarm: communication lost with R&W controller. In run press "Continue" button, else restart the system.	R&W Controller board not properly working.	Restart the system (instrument + PC). If the problem persists contact service.
171	Alarm: Cuvette tray motion not properly working. In run press Continue button, else restart the system.	The cuvette tray motion fails during motion.	Press the button Continue in the Status menu to retry, the system should recover. In case the alarm is again detected, shutdown the program, the PC and the instrument and then restart the system. Verify if some obstacles is into cuvette tray to stop the rotation. If the problem persists contact service.

9.4.2. Competences

In case of system breakdown, the fault must be repaired by Authorized Personnel only.

The maintenance procedures described in this section have to be carried out by the user, if not otherwise stated in the "Action" fields.



Section 10 TECHNICAL SPECIFICATIONS

10. Generalities

This section contains the technical specifications and environmental requirements of the system in its different configurations.

10.1. Instrument Technical Specifications

10.1.1. Sample Tray

a) Configuration at **59-sample** positions

- Tube positions (for any routine and STAT samples, standards/calibrators and controls): 59
- Tubes used (without adapter): $\varnothing=12\text{mm}\div16\text{mm}$
- Sample cups (cups cod. P3140000001 – to be used with adapter cod. P3140000018 **only**): $H=75\text{mm}\div100\text{mm}$
- Sample cups (cups cod. P3140000001 – **no** adapter required): 3ml, $\varnothing=12\text{mm}$

b) Configuration at **79-sample** positions

- Tube positions (for any routine and STAT samples, standards/calibrators and controls): 79
- Tubes used (without adapter): $\varnothing=12\text{mm}\div13\text{mm}$
- Sample cups (cups cod. P3140000001 – **no** adapter required): $H=75\text{mm}\div100\text{mm}$
- Sample cups (cups cod. P3140000001 – **no** adapter required): 3ml, $\varnothing=12\text{mm}$

10.1.2. Barcode Sample Identification (Option)

Barcode positive sample identification (only on tubes)

Barcode available Codes

- Code 128 type B
- Code UPCA/UPCE
- Code 39
- Code EAN 8/13
- Code 2/5 Interleaved
- Code 93
- Codabar

Codes features:

- module: $\geq0,25\text{mm}$
- code width: $\leq34\text{mm}$



10.1.3. Barcode reader (Option)

- Laser wavelength: $\lambda=650\text{nm}$
- Scan: 600/sec
- Resolution: 0,15÷0,5mm
- In conformity with EN 60825-1 (2001/11), resp. 21 CFR 1040.10

10.1.4. Reagent Tray

- Total positions (for bottle Type 1 or type 2): 49
- Mono-reagent positions: 48 max
- Reserved position for diluent: 1
- Reagent bottle type 1: 50ml
- Reagent bottle type 2: 20ml
- Refrigeration temperature: 14°C below T_{amb} , limited @ +12°C ± 2°C
- Other solutions on board: EW Cvt for cuvette extra-washing, EW Prb for probe extra-washing

10.1.5. Barcode Reagent Identification (Option)

Barcode positive reagent identification

Code:

- Code used: 128 type B
- Number of characters: 9

Code features:

- Thin bar module: 0,25mm

10.1.6. Smart Card Reader (Option)

PC Smart Card reader

- Link to external PC: USB
- Interface: USB 2.0
- Support, protected memory smart card: 1024bytes
- Data format: encrypted

Possibility to close the system with reagent management.



10.1.7. Sampling System

a) Single ARM configuration:

- Number of sampling arms: 1
- Number of Diluters (Micro Metering Pump): 1
- Diluter resolution: 0,1925µl/pls
- Diluter accuracy: < 1%
- Diluter precision: < 1%, dispensing 2% of total volume
- Max diluter volume (including air gaps and protection): 500µl
- Sampling volume (increment= 1µl) for sample: 1-300µl
- Sampling volume (increment= 1µl) for reagent: 1-450µl
- Liquid level detector: capacitive
- Obstacle sensor: opto-coupler
- Separation from washing solution: electrovalve
- Probe washing: internal and external
- Multi-reagent mixing: yes, on R2 and R3
- Sample/Reagent mixing: yes
- Test repetition: Automatic or on-request
- Sample pre-dilution: Yes, parameters into applications
- Sample repetition with post-dilution: Yes, automatic and on-request; parameters into applications

a) Double ARMs configuration:

- Number of sampling arms: 2
- Number of Diluters (Micro Metering Pump): 2
- Diluters resolution: 0,1925µl/pls
- Diluters accuracy: < 1%
- Diluters precision: < 1%, dispensing 2% of total volume
- Max diluters volume (including air gaps and protection): 500µl
- Sampling volume (increment= 1µl) for sample: 1-300µl
- Sampling volume (increment= 1µl) for reagent: 1-450µl
- Liquid level detector: capacitive
- Obstacle sensor: opto-coupler



• Separation from washing solution:	electrovalve
• Probe washing:	internal and external
• Multi-reagent mixing:	yes, on R2 and R3
• Sample/Reagent mixing:	yes
• Test repetition:	Automatic or on-request
• Sample pre-dilution:	Yes, parameters into applications
• Sample repetition with post-dilution:	Yes, automatic and on-request; parameters into applications

10.1.8. Incubation and Reading Cuvette Tray

• Reading system:	direct reading
• Number of incubation and reading cuvettes:	optical group
• Type of cuvettes:	80, auto-wash
• Possible reaction volume in cuvette:	Bionex® optical plastics
• Typical reaction volume in cuvette:	200-500µl
• Max recommended volume in cuvette:	220-260µl
• Optical path (Bionex® cuvette):	300µl
• Incubation temperature (preset):	6mm
• Incubation time:	37°C ± 0,2°C
• Reading time (Kinetics and Fixed Time methods):	controlled
• Cuvettes washing and drying:	programmable @ max 720sec

10.1.9. Optical Group

• Optic system:	direct reading
• Wavelengths:	photometer
• Number of reading channels:	interf. filters
• Reading method:	1
• Light source (long life halogen lamp: 2000 hours)	horizontal
	12V/20W



- Detector: Si Photodiode
- Measurement range (conversion to 10mm): 0÷3Abs
- Photometer resolution: 0.0001Abs
- Automatic wavelength gain: yes
- Automatic cuvette auto-zero: yes, on-line
- Automatic gain calibration: yes
- Automatic off-set calibration: yes
- Wavelength range (Standard filters - 8 position + 1 off-set + 1 spare): 340-700nm
- Wavelength range, possibility to read up to 800nm by additional filters

Standard interferential filters:

- Filter 1 340nm
- Filter 2 405nm
- Filter 3 492nm
- Filter 4 505nm
- Filter 5 546nm
- Filter 6 578nm
- Filter 7 630nm
- Filter 8 700nm
- Spare position: 1
- Off-set position: 1

10.1.10. Washing Station

- Total on-line washing and drying steps: 8
- Dispensing/Aspirating couple of needles: 5
- Additional aspirating needles: 1
- Drying tip: 1
- Cleaner solution dispensing: Position 2
- Systemic solution dispensing: Positions: 1 and 3-6

10.1.11. ISE Module (option)

- Test type on serum, plasma and diluted urine (not used electrodes can be replaced by proper dummy spacers): Na+, K+, Li+, Cl-
- Serum sample volume required: 100µl typ.
(tot. 70-200µl)
- Urine sample volume required: 2x100µl typ.
(tot. 140-200µl)
- Analysis time: 35sec typ.



- Number of calibrants (ISE Module): 2 (Cal.A e Cal.B)
- Reagent pack including: Cal.A, Cal.B (and Waste)
- Other reagents needed on reagent tray: ISE cleaning solution, Urine diluent
- Max number of electrodes (ISE Module): 4 + reference
- Bubbles detector (ISE Module): yes
- ISE Module test ranges:

Whole blood, serum, plasma

Analyte	Units	Test range limits	Resolution of results
Li+	mmol/l	0.20-3.50	0.01
Na+	mmol/l	100.0-200.0	0.1
K+	mmol/l	1.00-8.00	0.01
Cl-	mmol/l	50.0-150.0	0.1

Urine

Analyte	Units	Test range limits	Resolution of results
Na+	mmol/l	10-500	1
K+	mmol/l	5-200	1
Cl-	mmol/l	15-400	1

10.1.12. Control Electronics

- Structure: modular, real-time
- Number of microcontrollers: 3, multi-processor
- PCB assembly Technology: SMT
- Communication Bus: double, for data and synchro

10.1.13. Productivity

- Number of methods that can be run simultaneously (multi-reagent tests reduce the throughput): 19 max
- Number of mono-reagent tests in run without ISE module: up to 120test/h
- Number of mono-reagent tests in run with ISE module: up to 180test/h

10.1.14. Liquid, Consumption and Waste Autonomy

- Water quality for Systemic and Cleaner solutions, bi-distilled - conductivity: <1.5 µS/cm
- Systemic solution average consumption (@ max throughput): <2.30 lt/h



- Cleaner solution average consumption (@ max throughput): <0.15 lt/h
- Average waste volume (@300 test per hour): ≈2.5 lt/h
- Average machine autonomy @ max throughput (Start-up and shutdown procedures included): ≈7 hours

10.2. Control System Technical Specifications

External control PC

- Intel Pentium IV 2.8GHz Hyper Threading tech. or Intel Dual Core 2.8GHz minimum
- RAM: 512 MByte
- Hard Disk: ≥ 40GByte
- CD Rom: 1
- Colour screen 15"/17", resolution 1024x768: 1
- Key-board: 1
- Mouse: 1
- Serial COM port RS-232: 1
- USB ports: 2 x USB 2.0
- Ethernet: 1
- Parallel ports: 1
- Printer: ink-jet A4

Software:

- Operating system: Windows® XP or Windows® 7
- User Interface: Windows® XP based
- L.I.S. (optional) ASTM based protocol

Patient Results Filing:

- Dimensions (on line – before autoexporting for back up): dynamic, between 100,000 and 150,000 records

Standard/QC results Filing:

- Dimensions (on line – before autoexporting for back up): Last twelve months results

10.3. Mechanical Calibrations, Trimmings and Tunings

During daily working the instrument doesn't require any mechanical calibration, any trimming or any tuning performed by the operator. All mechanical calibrations have been carried out at factory or during service.



In case a further calibration is required, it must be performed by Authorized Personnel.

10.4. Power Supply Requirements

- | | |
|---|--|
| • Supply line voltage for instrument (without selection): | 100÷240Vac |
| • Supply line voltage for PC (with selection): | 100÷240Vac |
| • Supply line frequency: | 50÷60Hz |
| • System Line UPS – 1kW | Requested,
for instrument
and PC |

10.5. Operating Environment Requirements

- | | |
|---|-------------|
| • Temperature: | +18°C÷+32°C |
| • Humidity (without condensation): | 20%÷80% RH |
| • Max altitude: | 2000m |
| Distance from close walls/objects: | |
| • Lateral gap | ≥150mm |
| • Gap from the back | ≥160mm |

10.6. Storage Environment Requirements

- | | |
|------------------------------------|------------|
| • Temperature: | +5°C÷+45°C |
| • Humidity (without condensation): | 5%÷95% RH |
| • Max altitude: | 9000m |

10.7. Dimensions and Weight

Dimensions:

- | | |
|--------------------------------------|--|
| • Bench top instrument version: | H= 585mm
cover closed
H= 980mm
cover open
W= 1140mm
D= 750mm
H= 1260mm
cover closed
H= 1655mm
cover open
W= 1320mm
D= 770mm |
| • Floor standing instrument version: | |



- Clear space required at the sides of the instrument: 150mm
- Clear space required at the back of the instrument: 160mm

Weight:

- Bench top instrument weight (without fluids): ≈80kg
- Floor standing instrument weight (without fluids): ≈160kg

10.8. Emissions

Average emission level respects international normative.
There isn't any gas emission, implosion or explosion risk.

10.9. Electromagnetic Compatibility

The instrument has been produced in conformity with EN61326-1 normative.

10.10. Electrical Consumptions (with options)

- Max power: 650VA
- Operating typical power: 350VA typ
- Power factor ($\cos\phi$): 0,93 typ



Section 11 ADDITIONAL INFORMATION

11. Generalities

This section contains some additional information about the instrument.

11.1. Quick Start Guide

The handbook "Quick Start Guide", last version, contains a brief summary of the instructions for use and notices.

11.2. Warranty Limitations

The Producer guarantees all products manufactured by itself, hereinafter "Product" or "Products", under normal conditions of use, against materials and manufacturing defects, for a period of TWO YEARS (if not otherwise stated) starting from date of shipping from Manufacturer to the Client (hereinafter the "Warranty Period"). During the Warranty Period, the Producer will repair or replace at factory, any defective product, on condition that the Client promptly communicates the defect to the Producer.

This warranty applies exclusively to new products which have never been used and which have not, after shipment by the Producer, been damaged, altered, repaired or modified in any manner, due to negligence or other reasons, by persons not authorised to represent the Producer, even if they have sold/worked on the product. The Producer is not liable for any Warranty obligations should any modifications or repairs have been made to the product without the Producer's express written consent.

This Warranty applies to products which replace defective products and to repaired products, for the duration of the original Warranty Period only. Unless agreed in writing by the Producer, the Warranty period cannot be extended as a result of defects or repairs. Transfer of the ownership of the product by the Client to a third party does not extend the warranty period, which remains bound by the above conditions.

The above warranty is exclusive and replaces any other guarantees. The Producer does not provide any other guarantees, explicit or implicit, regarding the product, except for the present Warranty. Without limitation to the above general information, the Producer does not guarantee the commercial value of the product nor its suitability for any particular purpose. No affirmations or interpretations not expressly contained in this document are binding on the Producer as regards the warranty.



The Producer is not liable for damages, expenses or damage to the client or third parties due to accidental causes. The Producer is bound to repair or replace the product under the circumstances specified in this document.

This Warranty does not affect any statutory rights.

The **Warranty does not apply** to the parts listed below:

- Sampling probe;
- Washing station needles and tip;
- Photometer lamp;
- Serial cable;
- Consumable items;
- Reading cuvettes;
- Charging and waste tanks and fittings;
- Hydraulic circuits;
- Any peristaltic pump heads.
- ISE Module Li⁺, Na⁺, K⁺, Cl⁻ and reference electrodes;
- ISE Module spacer electrodes;
- ISE Module Fluid Tubing;
- ISE Module Pump Tubing;
- ISE Module Sample inlet port (4-channel sample cup kit);
- ISE Module Reagent Pack;

One year Warranty applies to the parts listed below:

- Peristaltic Pump DC Motors;
- Diaphragm Pumps and fittings;
- Vacuum Pumps and fittings;
- ISE Module Reagent Pack connector;
- Diluter.



11.3. List of Spare Parts and Consumables

Ask the Producer sales office in order to get the last Spare Parts List including Consumables.

11.4. Information for Orders

Please contact the Producer offices or the local sales distributor.

11.5. System Expansions

Refer to paragraph "List of Optional Parts" (Section 3) for the instrument and for additional options.

11.6. Service

Service is provided by LiNEAR or by Authorized Personnel belonging on local distributors.

11.6.1. Training Courses

All the training courses are organized by LiNEAR and take place in the LiNEAR offices in Rome - Italy or they are scheduled by the local distributor.

11.6.2. Firmware and Software Upgrades

Software and firmware upgrades must be run by service Authorized Personnel only by following the standard procedure learnt at the training sessions.



11.7. Forms

11.7.1. Training Course Evaluation

The form in the next page regards the Training Course satisfaction; you are kindly requested to fill this anonymous questionnaire and to mail it back to:

LINEAR
info@linear.es



Training Course Evaluation Form

System: _____
Activities Evaluation

Specific Performance	Importance	Satisfaction/Mark
1. Instrument Overview	A B C	1 2 3 4 5
2. Software Overview	A B C	1 2 3 4 5
3. Application Overview	A B C	1 2 3 4 5
4. Instrument Operation	A B C	1 2 3 4 5
5. Evaluation of Results	A B C	1 2 3 4 5
6. Maintenance	A B C	1 2 3 4 5
7. Troubleshooting	A B C	1 2 3 4 5

Legend:

Importance Level:

A - Very important

B - Important

C - Not so important

Satisfaction Level:

1 - Very unsatisfied

2 - Unsatisfied

3 - Satisfied

4 - Very satisfied

5 - Extremely satisfied

Missing features to be implemented, other comments or suggestions:



11.7.2. Customer's Satisfaction Questionnaire

The form in the next page regards the Customer's satisfaction; you are kindly requested to fill this anonymous questionnaire and to mail it back to:

LINEAR
info@linear.es



Customer's Satisfaction Questionnaire

System: _____
General Information

Clinical chemistry	<100	<input type="checkbox"/>	100÷1000	<input type="checkbox"/>	>1000	<input type="checkbox"/>
Nr. Tests/day						
Turbidimetry	<100	<input type="checkbox"/>	100÷500	<input type="checkbox"/>	>500	<input type="checkbox"/>
Nr. of Tests/day						

General Opinion on Instrument's Performances

Specific Performance	Importance	Satisfaction/Mark
1. Sampling assembly	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
2. Cooling plate	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
3. Readings and results	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
4. Sampling needle washing	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
5. Cuvettes washing	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
6. Throughput	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
7. Software: User Interface	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Legend:

- Importance Level:
A - Very important
B - Important
C - Not so important
- Satisfaction Level:
1 - Very unsatisfied
2 - Unsatisfied
3 - Satisfied
4 - Very satisfied
5 - Extremely satisfied

Comments or suggestions:





Section 12 GLOSSARY

12. Glossary

This section describes the list of acronyms and abbreviations and the list of terms used in this document.

12.1. List of Acronym and Abbreviations

A	Ampere
AD	Applicable Document
Abs	Absorbance
AC/DC	AC/DC Power Supply
ASTM	American Society for Testing Material
CC	Clinical Chemistry
CSF	Cerebral Spinal Fluid
CV	Coefficient of Variation
FW	Firmware
GLP	Good Laboratory Practice
HW	Hardware
IVD	In-Vitro Diagnostic
LCD	Liquid Crystal Display
LIS	Laboratory information system
N.A.	Not Applicable
OD	Optical Density
OFF	Shutdown condition
ON	Start-up condition
P	Power
PC	Personal Computer
Q.C.	Quality Control
SD	Standard Deviation
SW	Software
T	Transmittance
TBC	To be Confirmed
TBD	To be Defined
TBV	To be Verified
V	Volt
VA	Volt-Ampere
Vac	Alternate Voltage
Vdc	Continuous Voltage
W	Watt



WL Work List

12.2. List of Terms

Sampling probe	It is used to intake and to dispense liquids: reagents, dilutors, calibrators, standards and samples.
Absorbance	It is correlated to colour intensity of a liquid. The light that crosses a dark liquid it is “absorbed”.
Auto-diagnosis	Automatic instrument search of the cause of a breakdown or malfunctioning.
Barcode	Information codified in a barcode format.
Blank	Value corresponding to none reaction (only reagent).
Calibration Curve	Curve made using a series of calibrators at different concentrations that allow to determine the results by interpolation.
Calibrator	Sample that contains an analyte known concentration.
Controls	Sample that contains an analyte known concentration: low activity, normal activity and high activity. Controls are used to verify if the system is reliable.
Database	A file used to store data.
Default	Standard value or document.
Halogen lamp	Lamp used to generate light during the reading phase.
Interferential Filters	Calibrated filters used to filter the colorimetric reactions generated by chemical reactions.
Login	It allows the user to enter the System.
Logoff	It allows the user to exit the System.
Maintenance	Series of operations to execute daily, weekly or periodically to assure a good functioning of the instrument.
Optical Sensor (detector)	Electronics necessary to the photometer to convert the light in electrical signal.
Password	Sequence of alphanumeric characters requested to enter the User Interface.
Peristaltic pump	Pump to aspire the waste liquids or to dispense the washing liquids.
Photometric Reading System	System composed by a light source, interferential filters and detector. It is used to measure the colour intensity of the liquid in the cuvettes at the end of the reaction.



Ray	Light path.
Shutdown	Safety shutdown procedure.
Smart-Card	Card given with the reagents containing the specific information of the reagent lot.
Stepping motor	Special motors used for move assemblies.
Waste Tank	Tank where waste liquids are collected.
Work List	List of tests to carry out for each patient; data necessary for the system to carry out a correct working session.