

**LiNEAR**

# KROMA

*Random Access Analyser  
User Manual*





## Section i INTRODUCTION

### i.1 Identification Data

This document is the user manual of the instrument named KROMA.

KROMA is a random access automatic analyser.

This document must be considered part of the KROMA 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-10751-01-B
- Document revision: B
- Revision date: Sept 10, 2009
- Software version: 1.x
- Date of software version: Sept 10, 2009

#### i.1.2 Instrument

- KROMA: p/n 10750-xx-A  
(xx=version)

#### i.1.3 Producer

- **LINEAR CHEMICALS, SL**

Joaquim Costa, 18, 2<sup>a</sup> planta. 08390 Montgat – Barcelona (SPAIN).

T. (+34) 93 469 49 90. F (+34) 93 469 34 35

Sant Antoni M<sup>a</sup> Claret, 8 bis. 08390 Montgat – Barcelona (SPAIN)

[www.linear.es](http://www.linear.es) e-mail: [info@linear.es](mailto:info@linear.es)



## i.2 Copyright

The content of this document, the pictures, the tables and the graphics included, is intellectual property of LINEAR CHEMICALS, SL Unauthorized copies, total or partial, could cause legal actions in order to preserve owner's interests.

## i.3 End User Licence Agreement (EULA) for KROMA Software

This End-User License Agreement ("EULA") is a legal agreement between the User (either an individual or a single entity) and the manufacturer LINEAR CHEMICALS SL (LINEAR ). This EULA states the terms and conditions upon which LINEAR offers to license the Software defined below together with all related documentation and accompanying items including, but not limited to, the executable programs, drivers, libraries and data files associated with such programs, collectively known as the "Software".

LINEAR CHEMICALS, reserves itself the right to modify this EULA at any time and without notice.

### Definitions

"Software" and "Program" and "Product" shall be taken as referring to any version of KROMA program files and to any and all copies, updates, modifications, OEM KROMA based systems, functionally-equivalent derivatives, or any parts or portions thereof.

"You" or "User" or "End-User" shall be taken as referring to the individual using the Software.

"Entity" shall be taken as referring to the organization or group associated with or employing the User, and for which the User is utilizing the Program to provide scheduling. The Entity shall also be bound by the terms and conditions of this EULA as agreed to by the User.

### Copyright

All title and copyrights in and to the Software (including but not limited to any images, photographs, animations, text, and "applets" incorporated into the SOFTWARE PRODUCT), the accompanying printed materials, and any copies of the Software are owned by LINEAR CHEMICALS, SL or its suppliers. The Software is protected by copyright laws and international treaty provisions. Therefore, you must treat the Software like any other copyrighted material.

### Limitations on Reverse Engineering, Decompilation, and Disassembly

The Software may not be modified, reverse-engineered, or de-compiled in any manner through current or future available technologies.



### Permission for KROMA Installation and Use

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

### Termination

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 KROMA instrument complies the following directive:

- Directive IVD 98/79/EC - In-Vitro Diagnostic Medical Devices

## i.5 Patents

Not applicable.

## i.6 Purpose of This Document

This document is the user manual of the automatic “random access” analyser KROMA. 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.7 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 KROMA system to be read, in case of necessity, during daily laboratory activity.**



## i.8 List of Contents

<b>Section i INTRODUCTION .....</b>	<b>2</b>
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 KROMA Software .....	3
i.4 International and European Prescriptions.....	4
i.5 Patents.....	4
i.6 Purpose of This Document .....	4
i.7 Use of Manual.....	4
i.8 List of Contents .....	6
i.9 List of Figures .....	14
<b>Section 1 SAFETY .....</b>	<b>17</b>
1. Safety Prescriptions.....	17
1.1. General Instructions .....	17
1.2. Labelling .....	19
1.3. Safety Precautions .....	23
1.3.1. Installation .....	23
1.3.2. Operations .....	23
1.3.3. Maintenance.....	24
1.3.4. Transport and Storage .....	24
1.4. Risks During Use.....	25
1.4.1. Risks for the Operators.....	25
1.4.2. Safety Information for the Operators.....	25
1.4.3. Information on Liquids and Infected Parts.....	25
1.4.3.1. Treatment .....	26
1.4.3.2. Waste Materials .....	26
1.5. Advices for a Correct Use .....	27
<b>Section 2 ICONS .....</b>	<b>28</b>
2. Icons.....	28
<b>Section 3 INSTALLATION.....</b>	<b>30</b>
3. Description of the Instrument.....	30
3.1. Supplied Parts .....	31
3.1.1. List of the Supplied Parts .....	31
3.1.2. List of Optional Parts .....	31
3.2. Installation Requirements .....	33
3.2.1. Mechanical Constrains.....	33
3.2.2. Environment Constrains .....	33
3.2.3. Software .....	33
3.3. Storing the Instrument.....	34
3.4. Unpacking .....	34



---

3.4.1.	Packing Characteristics .....	34
3.4.2.	Inspection for Damages Caused by the Transportation .....	34
3.4.3.	Unpacking KROMA.....	35
3.5.	Instrument Installation.....	37
3.5.1.	Main Steps to Follow During Instrument Installation .....	37
3.5.2.	Electrical Connections and Stabilizer.....	38
3.5.3.	External Fuses.....	39
3.5.4.	Fittings and Consumables .....	39
3.5.4.1.	Liquid Solutions for KROMA.....	40
3.5.4.2.	Liquid Tanks .....	41
3.6.	Software and Firmware Installation .....	43
3.6.1.	Requirements and Recommendations.....	43
3.7.	4-channel ISE module (option) .....	44
3.7.1.	ISE Module Installation.....	45
3.7.1.1.	Connections .....	45
3.7.1.2.	Fittings and Tubing .....	46
3.7.2.	ISE module Solutions and Consumables .....	46
<b>Section 4</b>	<b>THEORY OF OPERATION.....</b>	<b>48</b>
4.	The Instrument .....	48
4.1.	Generals .....	48
4.1.1.	PC and Management Software.....	51
4.1.2.	Barcode Reader (Option) .....	52
4.1.3.	Refrigeration Unit for Reagents (Option) .....	53
4.2.	Operating Principles .....	54
4.2.1.	Operating Principle in Clinical Chemistry .....	54
4.2.1.1.	Lambert-Beer Law.....	56
4.2.1.2.	Types of Reactions .....	58
4.2.1.3.	End-Point Methods.....	58
4.2.1.4.	Kinetic Methods .....	60
4.2.1.5.	Calibration in Clinical Chemistry .....	63
4.2.1.6.	Calibration Curve .....	63
4.2.2.	Operating Principle in Turbidimetry .....	65
4.2.3.	Method Timings and Result Calculations.....	66
4.3.	The ISE Module.....	89
4.3.1.	Generals .....	89
4.3.2.	ISE Module (option), Operating Principles .....	90
4.3.3.	Electrodes .....	91
4.3.4.	Fluid Management .....	92
4.4.	Bibliography .....	94
<b>Section 5</b>	<b>FUNCTIONS.....</b>	<b>95</b>
5.	Functions .....	95
5.1.	Purpose of the Instrument .....	95
5.2.	Instruments Functions.....	95
5.3.	Functions.....	98



---

5.3.1.	Loading Trays.....	98
5.3.1.1.	Sample Tray.....	100
5.3.1.2.	Reagent Tray .....	100
5.3.2.	Sample and Reagent Dispensing Assembly - ARM .....	101
5.3.2.1.	Sampling Probe Sub-assembly.....	102
5.3.2.2.	Diluter.....	103
5.3.2.3.	Electrovalve .....	104
5.3.2.4.	Pump for Probe Washing .....	104
5.3.3.	Probe Washing Sink .....	105
5.3.4.	Incubation and Reading Assembly and Washing Station .....	105
5.3.4.1.	Incubation and Reading Assembly .....	106
5.3.4.2.	Optical Group .....	107
5.3.4.3.	Washing Station and Pumps .....	108
5.3.5.	Barcode Reader (option) .....	110
5.3.6.	Electronics.....	110
5.3.7.	Power Supply Units.....	111
5.3.8.	KROMA Software and User Interface .....	114
5.3.8.1.	Management Software Structure .....	114
5.3.8.2.	Introduction to Main Menu .....	115
5.3.8.3.	Introduction to Work List Menu .....	115
5.3.8.4.	Introduction to Status Menu.....	116
5.3.8.5.	Introduction to Results Menu.....	116
5.3.8.6.	Introduction to Chemistry Menu.....	116
5.3.8.7.	Introduction to Memory Files Menu .....	117
5.3.8.8.	Introduction to System Config Menu .....	117
5.3.8.9.	ISE module Config Menu .....	117
5.3.9.	ISE module (option) .....	118
5.3.10.	L.I.S. Interface (option) .....	118
<b>Section 6</b>	<b>PERFORMANCES AND LIMIT OF USE.....</b>	<b>119</b>
6.	Generalities.....	119
6.1.	General principles .....	119
6.2.	Performances.....	119
6.2.1.	Photometer and optical group .....	120
6.2.2.	Dispensing Assembly .....	120
6.2.3.	Washing Station .....	120
6.2.4.	Carry-over .....	120
6.2.5.	Instrument Throughput .....	120
6.3.	Calculations .....	120
<b>Section 7</b>	<b>OPERATING PROCEDURES AND MENUS.....</b>	<b>122</b>
7.	Overview.....	122
7.1.	Management Software Description .....	122
7.1.1.	Main Menu.....	124
7.1.2.	Work List Menu.....	125
7.1.2.1.	Patient Private Data Window.....	133



7.1.2.2. Work List Display Window .....	135
7.1.3. Reagents Menu, During Work List programming .....	137
7.1.4. Work List Summary Menu .....	140
7.1.5. Status Menu .....	143
7.1.6. Methods Menu .....	151
7.1.6.1. Dilutions by Sample Submenu .....	170
7.1.6.2. Dispensable Volumes .....	172
7.1.6.3. Reading and Incubation Times .....	173
7.1.6.4. Calibration Curve .....	174
7.1.7. Formula Builder Menu .....	175
7.1.8. View Restriction Menu.....	177
7.1.9. Reagents Menu.....	180
7.1.10. Profiles Menu.....	183
7.1.11. Standards Menu .....	185
7.1.12. Quality Control Menu .....	190
7.1.12.1. QC and Levy-Jennings Graph.....	193
7.1.13. Results by Patient Menu .....	195
7.1.13.1. Kinetics and Fixed-Time Methods OD graph.....	199
7.1.13.2. Results and Methods Exported Files .....	200
7.1.14. Repetitions Menu .....	203
7.1.15. Results by Method Menu .....	205
7.1.16. Q.C./Std Results Menu.....	208
7.1.17. Memory Files Menu .....	211
7.1.17.1. Patient Results Auto-exporting for Back Up .....	214
7.1.17.2. Report Window.....	215
7.1.18. Std/Q.C. Archive Menu.....	217
7.1.18.1. QC Results Exported Files .....	220
7.1.18.2. QC results Auto-exporting for Back Up.....	222
7.1.19. System Config Menu .....	223
7.1.19.1. Action Logs Auto-exporting for Back Up.....	227
7.1.20. Users Menu .....	228
7.1.21. ISE Module Menu.....	230
7.1.21.1. ISE Calibration Auto-exporting for Back Up .....	233
7.1.22. Show Alerts Window and Actions.....	234
7.1.23. Extra Procedures Pull-down Menu.....	236
7.2. Preparation for Operation .....	238
7.2.1. Safety Rules.....	238
7.2.1.1. Knowledge Level Required .....	238
7.2.2. Samples Handling .....	238
7.2.2.1. Samples .....	238
7.2.2.2. Sample Pre-treatment.....	239
7.2.2.3. Sample Storage.....	239
7.2.2.4. Sample Identification by Bar-code.....	239
7.2.2.5. Sample Tube Minimum Volume.....	240



7.2.2.6. Dead Volume .....	240
7.2.3. Reagents and Consumables .....	240
7.2.3.1. Use .....	241
7.2.3.2. Storage .....	241
7.2.3.3. Reagent identification .....	241
7.2.4. Tooling and Fittings .....	242
7.3. ISE Module Configuration and Use (if included as option) .....	243
7.3.1. Methods Menu, ISE module Methods settings .....	245
7.3.2. Reagents Menu, Configuration of ISE module Solutions .....	245
7.3.3. Work List Menu, Electrolytes Programming .....	246
7.3.4. Working Session, Status Menu .....	247
7.3.5. Working Session Results and Warning on Results .....	248
7.3.6. Troubleshooting Low Slope, Noise and Drift Error or Other ISE module Issues .....	250
7.3.7. ISE Electrodes Calibration .....	252
7.3.8. ISE Module, Working with Controls .....	253
7.3.9. ISE Module, Memory Files - Database .....	253
7.3.10. ISE Module, Shutdown Procedure .....	253
7.4. Procedures .....	255
7.4.1. Operating Flow Chart .....	255
7.4.2. Instrument Set-up and Power-On .....	256
7.4.3. Login, Main Menu Access and Auto-diagnosis .....	257
7.4.4. Warming Up Procedure .....	258
7.4.5. Working Session Programming and Run .....	260
7.4.5.1. Manual Work List Programming and Run .....	261
7.4.5.2. Automatic Work List Programming with L.I.S. Connection .....	266
7.4.5.3. Notes on Standards and Control .....	270
7.4.6. Set Reagents on Board During WL Programming .....	271
7.4.7. Running a Work List .....	273
7.4.8. Working Session .....	274
7.4.8.1. Pausing a Working Session .....	275
7.4.8.2. Adding STAT Samples During a Run .....	276
7.4.8.3. Adding One or More Samples During a Run .....	277
7.4.9. Working Session Results .....	278
7.4.9.1. Filing a Concluded Patient .....	278
7.4.9.2. Deleting Some Analyses' Results .....	279
7.4.9.3. Deleting a Sample and its Analyses' Result .....	279
7.4.9.4. Repetition of One or More Analysis .....	280
7.4.9.5. Printing Results .....	280
7.4.9.6. Calculation of Statistic Parameters .....	281
7.4.10. Methods Control System .....	282
7.4.10.1. Reagent Panel: Manual Configuration .....	282
7.4.10.2. Automatic Panel Configuration .....	283
7.4.10.3. Reagents Barcode Scanning .....	283



7.4.10.4. Reagent Lot Number Modification .....	284
7.4.10.5. Programming Profiles.....	284
7.4.10.6. Deleting Profiles.....	285
7.4.11. Working with Standards and Controls .....	286
7.4.11.1. Mono-standard Methods .....	286
7.4.11.2. Multi-standard Methods.....	287
7.4.11.3. Entering Values for Controls (QC) .....	288
7.4.11.4. Viewing Levy-Jennings Graphs and Printing QC Values .....	289
7.4.12. Memory Files - Database .....	291
7.4.12.1. Searching and Handling Patient Results .....	291
7.4.12.2. Searching and Handling QC Results.....	293
7.4.13. Shutdown Procedure.....	295
<b>Section 8 MAINTENANCE.....</b>	<b>296</b>
8. Generalities.....	296
8.1. General Rules.....	296
8.1.1. Competences .....	296
8.1.2. Cleaning.....	296
8.1.3. Disinfection .....	297
8.1.3.1. Instrument Disinfection .....	297
8.1.3.2. Metallic Sampling Probe Disinfection .....	297
8.1.3.3. Waste Tubing Disinfection.....	298
8.1.3.4. Charge Tubing Disinfection.....	298
8.1.3.5. Washing Station Needles Disinfection .....	298
8.1.3.6. Waste Tank Disinfection .....	298
8.1.3.7. Systemic Solution and Cleaner Solution Tanks Cleaning.....	298
8.2. Safety Precautions .....	299
8.3. Periodic Maintenance Plan.....	300
8.3.1. Daily Maintenance Scheduling.....	300
8.3.2. Weekly Maintenance Scheduling.....	300
8.3.3. Two Months Maintenance Scheduling .....	301
8.3.4. Six Months Maintenance Scheduling .....	302
8.3.5. One Year Maintenance Scheduling .....	302
8.3.6. Other Maintenance Needs.....	302
8.3.7. Maintenance Charts .....	303
8.4. ISE Module Maintenance Scheduling.....	306
8.4.1. Scheduling for LOW Volume Users .....	306
8.4.1.1. Daily Maintenance Scheduling .....	306
8.4.1.2. One Months Maintenance Scheduling .....	306
8.4.1.3. Six Months Maintenance Scheduling .....	307
8.4.1.4. One Year Maintenance Scheduling.....	307
8.4.2. Scheduling for HIGH Volume Users.....	308
8.4.2.1. Daily Maintenance Scheduling .....	308
8.4.2.2. One Months Maintenance Scheduling .....	308
8.4.2.3. Six Months Maintenance Scheduling .....	308



---

8.4.2.4.	At 3,000 samples Maintenance Scheduling .....	309
8.4.2.5.	At 10,000 samples Maintenance Scheduling .....	309
8.4.2.6.	One Year Maintenance Scheduling.....	309
8.5.	Maintenance Procedures.....	310
8.5.1.	Generalities.....	310
8.5.2.	Reading Cuvettes Replacement.....	310
8.5.2.1.	Single Cuvette Replacement .....	311
8.5.3.	Peristaltic Pump Heads Replacement.....	312
8.5.4.	Photometer Lamp Replacement.....	314
8.5.5.	Sampling Probe Replacement .....	315
8.6.	ISE Module Maintenance Procedures .....	317
8.6.1.	Reagent Pack Replacement.....	317
8.6.2.	Electrodes Replacement.....	319
8.6.3.	Electrodes Storage .....	320
<b>Section 9</b>	<b>PROBLEM SOLVING .....</b>	<b>322</b>
9.	Introduction .....	322
9.1.	Generalities .....	322
9.2.	Auto-diagnosis System .....	322
9.3.	Main Failures and Corrective Actions.....	323
9.4.	Instrument Status Messages.....	328
9.4.1.	Error Messages, Warnings and Troubleshooting.....	328
9.4.2.	Competences .....	338
<b>Section 10</b>	<b>TECHNICAL SPECIFICATIONS .....</b>	<b>339</b>
10.	Generalities .....	339
10.1.	Instrument Technical Specifications .....	339
10.1.1.	Sample Tray .....	339
10.1.2.	Barcode Sample Identification (Option) .....	339
10.1.3.	Barcode reader (Option).....	339
10.1.4.	Reagent Tray.....	339
10.1.5.	Barcode Reagent Identification (Option) .....	340
10.1.6.	Smart Card Reader (Option) .....	340
10.1.7.	Sampling System .....	340
10.1.8.	Incubation and Reading Cuvette Tray .....	341
10.1.9.	Optical Group .....	341
10.1.10.	Washing Station.....	342
10.1.11.	ISE Module (option).....	342
10.1.12.	Control Electronics .....	343
10.1.13.	Productivity .....	343
10.1.14.	Liquid Consumption and Waste Autonomy .....	343
10.2.	Control System Technical Specifications.....	343
10.3.	Mechanical Calibrations, Trimmings and Tunings.....	344
10.4.	Power Supply Requirements .....	344
10.5.	Operating Environment Requirements .....	344
10.6.	Storage Environment Requirements.....	344



---

10.7.	Dimensions and Weight.....	344
10.8.	Emissions.....	345
10.9.	Electromagnetic Compatibility.....	345
10.10.	Electrical Consumptions (with options) .....	345
<b>Section 11</b>	<b>ADDITIONAL INFORMATION.....</b>	<b>346</b>
11.	Generalities.....	346
11.1.	Quick Start Guide .....	346
11.2.	Warranty Limitations.....	346
11.3.	List of Spare Parts and Consumables .....	348
11.4.	Information for Orders.....	350
11.5.	System Expansions .....	350
11.6.	Service.....	350
11.6.1.	Training Courses .....	350
11.6.2.	Firmware and Software Upgrades .....	350
11.7.	Forms.....	351
11.7.1.	Training Course Evaluation .....	351
11.7.2.	Customer's Satisfaction Questionnaire .....	353
<b>Section 12</b>	<b>GLOSSARY .....</b>	<b>355</b>
12.	Glossary .....	355
12.1.	List of Acronym and Abbreviations .....	355
12.2.	List of Terms .....	356



## i.9 List of Figures

<b>Figure 1:</b> Instrument Label .....	<b> Error! Marcador no definido.</b>
<b>Figure 2:</b> Electrical Risk Label .....	19
<b>Figure 3:</b> Electrical Risk Icons .....	19
<b>Figure 4:</b> Laser Light Risk Label .....	20
<b>Figure 5:</b> Laser risk Icon .....	20
<b>Figure 6:</b> Moving Part Risk Label .....	20
<b>Figure 7:</b> Potentially Infected Area Label .....	21
<b>Figure 8:</b> Biological Risk Icon .....	21
<b>Figure 9:</b> Generic Risk Icon .....	21
<b>Figure 10:</b> Potentially Infected Tank Label .....	22
<b>Figure 11:</b> CE Mark .....	28
<b>Figure 12:</b> Generic Danger Icon .....	28
<b>Figure 13:</b> Electrical Danger Icon .....	28
<b>Figure 14:</b> Laser Light Danger Icon .....	29
<b>Figure 15:</b> Biological Danger Icon .....	29
<b>Figure 16:</b> KROMA .....	<b> Error! Marcador no definido.</b>
<b>Figure 17:</b> Power Block and Main Line Protection Fuses .....	39
<b>Figure 18:</b> Charging and Waste Tanks .....	41
<b>Figure 19:</b> Charging/Waste Tanks Connections .....	42
<b>Figure 20:</b> ISE Module, location into the instrument (behind the front panel) .....	44
<b>Figure 21:</b> ISE Module, Reagent Pack connection .....	45
<b>Figure 22:</b> KROMA Working Area .....	48
<b>Figure 23:</b> Barcode Reader (option) .....	52
<b>Figure 24:</b> Refrigeration Unit – ON/OFF Switch .....	53
<b>Figure 25:</b> Photometer, Functional Drawing .....	55
<b>Figure 26:</b> Generic End-Point Method .....	59
<b>Figure 27:</b> End Point Method .....	60
<b>Figure 28:</b> Kinetic Method .....	61
<b>Figure 29:</b> Calibration Curve .....	64
<b>Figure 30:</b> KROMA, working area .....	89
<b>Figure 31:</b> ISE Module, functional diagram .....	90
<b>Figure 32:</b> KROMA, Working Area .....	98
<b>Figure 33:</b> Sample and Reagent Tray .....	99
<b>Figure 34:</b> ON/OFF Switches .....	100
<b>Figure 35:</b> Dispensing Assembly .....	101
<b>Figure 36:</b> ARM Diluter Pump .....	101
<b>Figure 37:</b> Electrovalve and Diluter .....	102
<b>Figure 38:</b> Diluter and Electrovalve .....	103
<b>Figure 39:</b> Probe Washing Pump .....	104
<b>Figure 40:</b> Washing Sink .....	105
<b>Figure 41:</b> Incubation and Reading Assembly and Washing Station .....	106



<b>Figure 42:</b> Optical Group – Measurement Circuit.....	107
<b>Figure 43:</b> Washing Station.....	108
<b>Figure 44:</b> Washing Station Scheme .....	108
<b>Figure 45:</b> Washing Station Dispensing Pumps .....	109
<b>Figure 46:</b> Washing Station Aspiration Pumps.....	109
<b>Figure 47:</b> Main Switch Block .....	111
<b>Figure 48:</b> Rear Panel.....	112
<b>Figure 49:</b> Internal Fuses .....	112
<b>Figure 50:</b> User Interface .....	115
<b>Figure 51:</b> Software, SW Functional Drawing .....	123
<b>Figure 52:</b> Main Menu.....	124
<b>Figure 53:</b> Work List Menu .....	126
<b>Figure 54:</b> Patient Private Data Window .....	133
<b>Figure 55:</b> Work List Display Window.....	135
<b>Figure 56:</b> Reagents Menu during WL programming .....	137
<b>Figure 57:</b> Work List Summary Menu .....	140
<b>Figure 58:</b> Starting session with alerts .....	142
<b>Figure 59:</b> Status Menu - WL in run .....	143
<b>Figure 60:</b> Menu Status – System temporary in Pause during a run .....	144
<b>Figure 61:</b> Menu Status – Reagent text summary window.....	144
<b>Figure 62:</b> Menu Status – Loading the Idle Status .....	148
<b>Figure 63:</b> Methods Menu .....	151
<b>Figure 64:</b> Calibration Curve .....	174
<b>Figure 65:</b> Formula Builder.....	175
<b>Figure 66:</b> Restriction Menu .....	177
<b>Figure 67:</b> Reagents Menu .....	180
<b>Figure 68:</b> Profiles Menu.....	183
<b>Figure 69:</b> Standards Menu – Mono-standard example .....	185
<b>Figure 70:</b> Standards Menu – Multi-standard example .....	186
<b>Figure 71:</b> Quality Control Menu .....	190
<b>Figure 72:</b> Levy-Jennings Graph .....	193
<b>Figure 73:</b> Results by Patient Menu .....	195
<b>Figure 74:</b> Kinetics/Fixed Time graph.....	199
<b>Figure 75:</b> Repetitions Menu .....	203
<b>Figure 76:</b> Results by Method Menu .....	205
<b>Figure 77:</b> Selection and Statistics Calculation .....	205
<b>Figure 78:</b> Q.C./Std Results Menu.....	208
<b>Figure 79:</b> Memory Files Menu .....	211
<b>Figure 80:</b> Report Window.....	215
<b>Figure 81:</b> Std/Q.C. Archive Menu.....	217
<b>Figure 82:</b> System Config Menu .....	223
<b>Figure 83:</b> Users Menu .....	228
<b>Figure 84:</b> ISE module Menu .....	230
<b>Figure 85:</b> Show Alerts Window .....	234



---

<b>Figure 86:</b> Extra Procedure Pull-down Menu .....	236
<b>Figure 87:</b> Primary Tubes – Barcode labelling .....	239
<b>Figure 88:</b> 50ml Reagent Bottle – Barcode Labelling .....	242
<b>Figure 89:</b> 20ml Reagent Bottle – Barcode Labelling .....	242
<b>Figure 90:</b> Operating Flow Chart .....	255
<b>Figure 91:</b> Power-On Switches.....	256
<b>Figure 92:</b> Software – Login Password .....	257
<b>Figure 93:</b> Software, Start-Up Main Page.....	258
<b>Figure 94:</b> Software, Work List Menu .....	260
<b>Figure 95:</b> Software, Patient Private Data Window.....	262
<b>Figure 96:</b> Software, Display Work List .....	263
<b>Figure 97:</b> Software, Work List programming.....	268
<b>Figure 98:</b> Software, Reagent Menu .....	271
<b>Figure 99:</b> Software, Work List Summary Menu .....	273
<b>Figure 100:</b> Software, Status Menu .....	274
<b>Figure 101:</b> Software, Result by Patient Menu .....	278
<b>Figure 102:</b> Software, Reagent Menu .....	282
<b>Figure 103:</b> Software, Quality Control Menu .....	289
<b>Figure 104:</b> Software, Memory Files, Patients Archive Menu .....	291
<b>Figure 105:</b> Software, Std/Q.C. Archive Menu.....	293
<b>Figure 106:</b> Cuvette Replacement.....	311
<b>Figure 107:</b> Peristaltic Pump Heads Placement.....	312
<b>Figure 108:</b> Pumps and Loads Connection to Power Boards (back-view) .....	313
<b>Figure 109:</b> Photometer Lamp Replacement.....	314
<b>Figure 110:</b> Sampling Probe Replacement .....	315
<b>Figure 111:</b> ISE Module, Outline .....	317
<b>Figure 112:</b> ISE Module, Reagent Pack replacement.....	318



## 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 LINEAR SL, been damaged, altered, repaired or modified in any manner, due to negligence or other reasons, by persons not author LiNEAR to represent LINEAR SL, even if they have sold/worked on the product. LINEAR SL is not liable for any Warranty obligations should any modifications (on hardware and software) or repairs have been made to the product without LINEAR SL'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 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.

### Electrical Hazard

The following label is placed on the instrument.

- a) one of the following label is placed on the instrument on the removable back panel; it informs 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: 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 : 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 advLiNEAR the qualified technician about the laser source characteristics.



*Laser Light Risk Label*

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



*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 probe and washing station.



*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.



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 near the washing sink pump just behind the front panel, one on the washing station cover and one on the sampling ARM. The label informs the user of the possible contamination from infected liquids or probe.



Biological Risk Icon

### Generic Hazard

One of this icon is placed on the front of the instrument. It informs the user of the potential risk associated with removing the protection and with residual 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.



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.



*Potentially Infected Tank Label*



## 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 from 100Vac to 240Vac with frequency range from 47Hz to 63Hz.

**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 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. 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 **to avoid 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 remove protection defence during the run without reasons; its opening is controlled by the software managing the instrument (follow proper procedures).
- Follow 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 LINEAR or by its representative.

In order to get the best performances and to fully use the instrument, the producer advises 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,...) 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 probe.
- All needles and the tip of the washing station.
- Waste tank and waste tubing.
- Cuvettes tray.
- Washing sink for the sampling probe.

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 off 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 dispose off 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 KROMA. **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 (1kVA capacity)** to overcome supply gaps (it assures more than 1 hour autonomy). Short supply gaps can cause wrong results not traceable by the operator nor by the instrument itself.
- 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.



CE Mark

- **Safety Icons**

#### Warning of Moving Parts

This icon is placed on the sampling probe protection defence of the instrument and on the protection of the washing station of the reading cuvettes. It informs the user of the potential risk caused by moving mechanic parts when the protection defence is opened or the washing station protection is removed.



Generic Danger Icon

#### Electrical Risk Danger

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



Electrical Danger Icon

**Laser Light Danger**

This symbol (icon), placed near the sample and 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 (barcode fixed on the sampling ARM and rotating with it).

*Laser Light Danger Icon***Contamination by Infected Liquids**

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

*Biological Danger Icon*



## Section 3 INSTALLATION

### 3. Description of the Instrument

KROMA 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.

KROMA is available in bench-top version.



**Figure 4:** KROMA

The KROMA User Software application is installed on an external PC, provided with LCD monitor, mouse and keyboard; it allows the complete control of the instrument.

The instrument working area is limited by a plastic protection defence avoiding contact of the operator with moving parts. This area includes samples, reagents and the sampling ARM; the reaction cuvettes tray is covered by a carter. Cuvette tray temperature is constantly maintained at 37°C. Reagents can be refrigerated at about 12°C (option). On the instrument left side are placed two switches, one for the electronic control of the instrument (green colour) and the other for the cooling (red colour). The ON/OFF status of the cooler 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), bounded to the sampling ARM, allows the positive identification of reagent bottles and of sample tubes, when barcodes are used and enabled.

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 supplied together with the instrument.

#### 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:

Item	Code	Conf./Pack
External PC with mother board box	P3140000095	1 pcs
CD with SW licence	n.a.	1 pcs
CD with drivers	n.a.	1 pcs
Power cord for PC	S0200000082	1 pcs
Monitor	S0200000049	1 pcs
Power cord for monitor	S0200000082	1 pcs
Serial cable for monitor	n.a.	1 pcs
Keyboard with mouse	n.a.	1 pcs
USB cable for printer	n.a.	1 pcs
Printer	n.a.	1 pcs
Operation program software	n.a.	1 CD
Serial cable	P3140000022	1 pcs
Waste tank 25 lt	P3140000104	1 pcs
Charge tank 20 lt for systemic sol.	P3140000027	1 pcs
Cleaner sol. tank 5 lt	P3140000023	1 pcs
Systemic solution 6x50 ml	P3140000087	1 kit
Multiclean solution 2 lt	P3140000114	2 kit
Rinse solution (Cvt) 6x50 ml	P3140000113	1 kit
Rinse solution (Prb) 6x50 ml	P3140000115	1 kit
Cuvette's extraction tool	P3140000077	1 pcs
Instrument Power cord	S0200000082	1 pcs
Kit tubes for waste tank (25 lt) red	P3140000081	1 pcs
Kit tubes for charge tank (20 lt) systemic sol. Green	P3140000082	1 pcs
Kit tubes for cleaner sol. tank (5 lt) blue	P3140000083	1 pcs
Serum cups 3 ml	P3140000001	1,000 pcs
Tank adapter (Funnel)	S0200000217	1 pcs
Reagent bottle 20 ml	P3140000020	30 pcs
Reagent bottle 50 ml	P3140000019	50 pcs
Caps for reagent bottle	P3140000079	80 pcs
Reading cuvettes	P3140000002	5 pcs
User manual	MNU-10751-01-A	1 pcs
Quick start guide	GRS-10751-01-A	1 pcs
Conformity declaration	PP. 04/05	1 pcs

#### 3.1.2. List of Optional Parts

The following items are considered as option and can be supplied "on request" with the system:



- Bar code reader.
- Reagent refrigeration (cooler).
- Personal Computer, including: CPU, LCD monitor, keyboard, mouse and A4 printer.
- ISEModule.



## 3.2. Installation Requirements

To achieve a correct installation of the system 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 can be assured.

### 3.2.1. Mechanical Constrains

KROMA must be exclusively used indoor and not outdoor.

KROMA must be installed on a horizontal flat surface not subject to vibrations (i.e.: centrifuges,...). The workbench (min. 120cm long and 80 cm deep) must be stable to avoid unwanted oscillations and auto-vibrations, indeed it must accept 70kg minimum on its surface.

### 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 ISE fall to 65% at 32°C.

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.

In order to give easy operations around the bench-top version, the user must provide enough space for the LCD monitor, the keyboard and the mouse and an underlying flat plane for the management PC.

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

### 3.2.3. Software

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



### 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 as described in section 10.

#### 3.4.1. Packing Characteristics

The instrument KROMA is generally sent closed in a 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 packed separately from instrument and together with the KROMA accessories in another 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 KROMA

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.

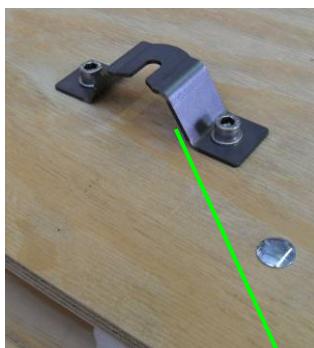




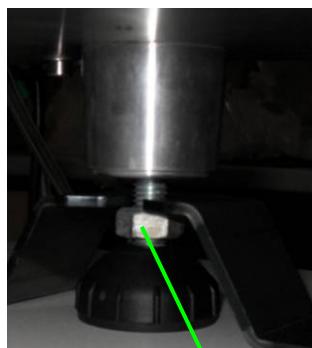
4. Carefully lift up and remove the side walls of the box.



5. Take out the protective film from the instrument (if any).
6. Loosen up the nut locking any instrument feet on each of the four clamps fixed on the wooden base by using one open-end wrench ch=17 (metric); then shift sideways the instrument out of the clamps.



CLAMP

NUT ON  
INSTRUMENT'S FOOT

7. Lift instrument up and place it on the working bench.
8. Place monitor, keyboard and mouse of the PC on the workbench and the CPU close to the instrument.
9. Control that all parts listed in the packing list are there.
10. 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 box in case you want to store or to move the instrument.**



### 3.5. Instrument Installation

KROMA 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 CHEMICALS, SL

When installing the instrument apply the procedure specified in the following paragraphs. Detailed instructions on safety have been given in Section 2.

#### 3.5.1. Main Steps to Follow During Instrument Installation

After having unpacked the KROMA Instrument and prepared the work bench follow the steps below; some of them have been detailed in the following paragraphs:

1. Place the instrument on the work bench.
2. Remove protections.
3. Unpack the Personal Computer and its accessories; check and eventually **set the PC Power Supply voltage selector** to be compliant to the main line specification (110Vac or 220Vac).
4. Place the LCD monitor, the keyboard and the mouse of the PC on the workbench and the CPU close to the instrument.



5. Connect the PC parts: CPU, monitor, keyboard, mouse and printer.
6. Connect the PC to the KROMA instrument through the RS-232 serial cable.



Serial Cable

7. 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 KROMA instrument.



8. 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 KROMA instrument.
9. Empty the Waste tank, the 25-litres red one, and connect it to the KROMA instrument.
10. Install both the PC and the KROMA Instrument to the main line through a 1kVA UPS; check the ground connections and use the power cord supplied with the instrument (it has been tested at factory).

Functional task	Type of connection
Serial Link Instrument/PC (not crossed)	RS-232, SUBD-9pin standard connectors
Instrument power supply	3-poles IEC Socket 2-poles+ground Schuko Plug



Power Cord

11. Power on the KROMA instrument.
12. Power on the Personal Computer and wait for the Operating System running.
13. Run the KROMA software: 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, overall performance of the KROMA System are 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: KROMA cannot manage temporary power supply gaps. Consequently it is strongly recommended to install an UPS, able to supply 1.0kVA, 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 first the power cord.



**Figure 5:** Power Block and Main Line Protection Fuses

### 3.5.4. Fittings and Consumables

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

The instrument must be connected to the three provided 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 cuvettes in optical plastic (Bionex®); 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).

List of disposable materials is given in paragraph 11.4 “List of Spare Parts and Consumables”.



### 3.5.4.1. Liquid Solutions for KROMA

KROMA 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**  
*(for Cuvette Extra-washing):* filled into 50ml reagent bottle type 1.
- **Rinse solution EW Prb**  
*(for Probe Extra-washing):* filled into 20ml reagent bottle type 2.

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 CHEMICALS, SL

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 2 litres or 5 litres containers. It is ready to be used and it must be poured into the apposite 5 litres tank (Blue connections).

The Cleaner Solution must be purchased by LINEAR CHEMICALS, SL The kit contains sodium hydroxide at 3.7%, it's corrosive, and causes burnings. Use the solution for diagnostic only on KROMA System. 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 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

The KROMA needs the charge/waste tanks close to it; it is then possible to put them under the workbench on left side.



20lt Systemic Solution  
Tank



5 lt Cleaner Solution  
Tank



25lt Waste  
Tank

**Figure 6:** Charging and Waste Tanks

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

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

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

Tanks wiring	Instrument
<b>20lt Systemic solution tank</b> , <b>green</b> floating fitting	➔ to be plugged into left panel fitting, ( <b>Systemic</b> )
<b>5lt Cleaner tank</b> , <b>blue</b> floating fitting	➔ to be plugged into centre panel fitting, ( <b>Cleaner</b> )
<b>25lt Waste tank</b> , <b>red</b> floating fitting	➔ to be plugged into right panel fitting, ( <b>Waste</b> )



**Figure 7:** Charging/Waste Tanks Connections

In the floor-standing version, tanks are accessible by opening the right door. 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 hydraulic joint;
- **Green** colour: for Systemic solution tank, electric connector and hydraulic joint;
- **Blue** colour: for Cleaner solution tank, electric connector and hydraulic joint.



### 3.6. Software and Firmware Installation

The KROMA 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 last revision of the LINEAR CHEMICALS, SL document code RPT-10654-00-x, "KROMA firmware and software upgrade procedure & Software first installation procedure".

#### 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 other LiNEAR stated, further software updates for KROMA must be installed by LINEAR CHEMICALS, SL authorized personnel only or by local distributors to assure a correct operation of the system.



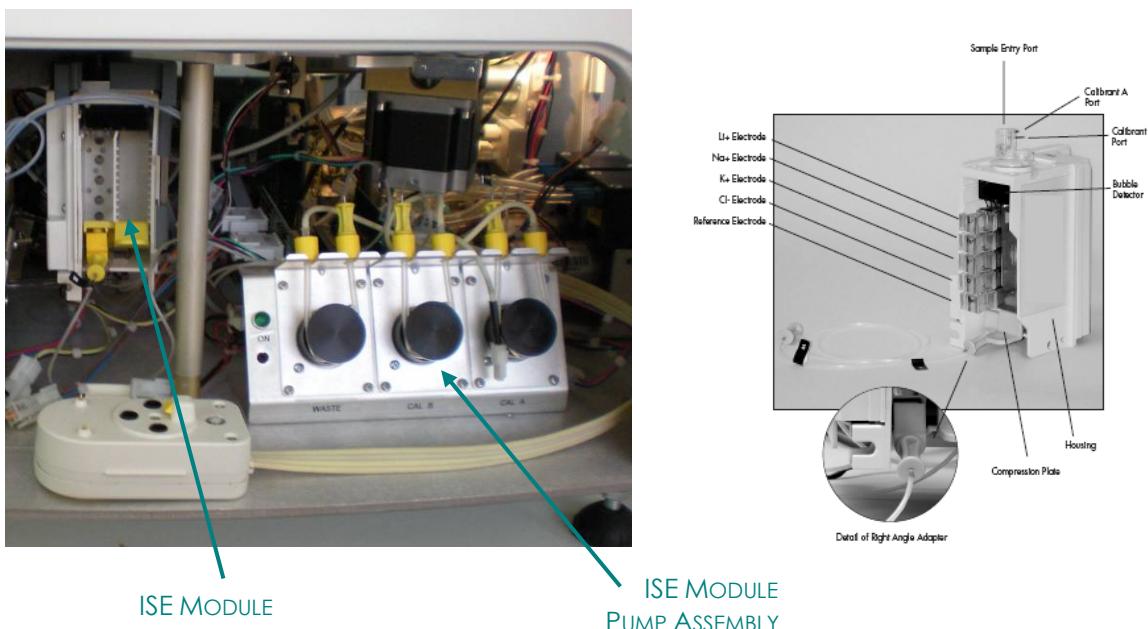
### 3.7. 4-channel ISE Module (option)

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 ( $\text{Li}^+$ ,  $\text{Na}^+$ ,  $\text{K}^+$ , and  $\text{Cl}^-$ ), 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);
- the ISE Module reagent pack connector;
- ISE Module hydraulic tubing and fittings.



**Figure 8:** ISE Module, location into the instrument (behind the front panel)

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



Electrodes, Reagent pack (Cal A + Cal B + Waste), Cleaning Solution and Urine Diluent are not included in the standard shipping; they are consumables to be order apart.

### 3.7.1. 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, he can enable or disable it by software (ISE Module Config menu).

#### 3.7.1.1. Connections

The instrument doesn't require the user to carry out any electrical connections. The Producer has already installed at factory also the flat cable connecting the ISE Module Controller with pumps and electronics.

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



**Figure 9:** 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.**



### 3.7.1.2. Fittings and Tubing

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

### 3.7.2. 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**. It is contained into the Reagent Pack together with Calibrant B and Waste.
- **Calibrant B.** It is used in two-point and single-point calibrations **for urine sample analysis**. It is contained into the Reagent Pack together with Calibrant A and Waste.

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 in the proper position of 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 daily 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 advise. Contains ammonium bifluoride.**



3. **Urine Diluent.** Urine samples are diluted to perform urine measurement: 1 part urine sample to 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 in the proper position of 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

KROMA 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 KROMA 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 150test/hour (or up to 250test/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 test sequence 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 too.

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

The instrument can be used for *in vitro* diagnostic (IVD) analysis of serum, plasma, urines and CSF.



**Figure 10:** KROMA Working Area

The instrument automatically performs the following base operations:

- sampling, dispensing and on-line volume control of the reagents;
- sampling and dispensing of the samples;
- 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.

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 20 positions for bottles of 50ml/20ml without the need of any special adapter or support. Reagent positions can also be assigned to additional bottles used: for probe and cuvette extra-washing solutions, for sample diluent (50ml vial containing distilled water or physiologic solution) or for ISE Module cleaning solution and urine diluent.

A two-reagent method needs 2 positions of the tray; at the same time a three-reagents method needs 3.

The reagent assembly can be equipped with an integrated **cooler** (option on request) that allows the preservation of the reagents on board.

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

KROMA can memorize a minimum of 1,000 different methods. Each method can use up to three different reagents. For each sample it is possible to program up to 60 different methods (parameters); the system will automatically manage the worklist on the base of only 20 methods on-line.

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

The sample tray includes 9 positions that can be indifferently assigned to samples, standards/calibrators and quality controls.

**Primary tubes** with diameter ranging from **12mm to 13mm** and height ranging from **75mm to 85mm** or “Hitachi® like” **3ml sample cups** with 12mm diameter can be used in the 9 positions provided for samples without the use of any adapter.

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 arm and dispensed in the cuvette for incubation and reading. It is possible to dispense from a minimum of 180µl up to 500µl total reagent volume for R1, R2 and R3. Provided the sum of reagent volumes to be greater or equal to 180µl, each of the reagents can be sampled anyway from 1µl to 500µl, with 1µl 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 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 $\mu$ l up to 320 $\mu$ l, with 1 $\mu$ l minimum increment.

The total volume of sample and reagents, dispensed for each reading cuvette, **must** be included between 200 $\mu$ l and 500 $\mu$ l: the **typical reaction volume is between 220 $\mu$ l and 250 $\mu$ l**; in order to preserve a much longer life to the cuvettes it is suggested **not to overcome 300 $\mu$ l total reaction volume**. The arm provides a heating element devoted also to the warming up of the reagents; the probe is washed, internally and externally, after every sampling cycle.

The incubation and the reading are performed in the cuvette tray that contains 80 cuvettes in optic plastics (Bionex®). Each of the 80 cuvettes 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 to the constant temperature of 37°C to allow the incubation and the correct interpretation of the results of reading. **The maximum incubation and reading time is 720sec.**

The duration of a machine cycle is fixed; in every cycle the machine performs the following readings: the readings related to the methods, the reading of the cuvette that has been washed (auto-zero value updating) and a reading of a reagent blank (just one cycle before dispensing the sample).

The optical group is composed by a photometer with a 10-positions filter tray: interferential filters are 8, the wavelengths are included within 340nm and 700nm; one position is devoted to the auto-zero resetting of the off-set. One more position is free for one additional and optional wavelength. The light source is constituted by a 12V/20W halogen lamp. The standard version provides the following wavelengths:

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

It is possible to customize the wavelengths on request.

For every sample the following method types can be selected: **End-point, Bi-chromatic End-point, Kinetics, Fixed Time (two-points kinetics), Differential two-reagents, Differential Sample Blank**. The system can work in reaction **sample starting** mode or in reaction **substrate starting** mode.

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

The instrument, for results out of range, performs on request the sample dilution and the repetition of the tests.



As already mentioned KROMA 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.

Though an apposite selection check in the method, it is possible to enable the subtraction of the value of the reagent blank from the final result.

Results of analyses are displayed as soon as they conclude.

The instrument provides up to 9 positions for standard and calibrators and allows the calibration curves generation from 2 to 8 points with automatic dilution of the standard.

Quality Control serum for "abnormal low", "normal" and "abnormal high" can be used and placed in any position of the sample tray. The presentation of the measurements is on a 3 level Levy-Jennings graph where the last 50 verifications are visualized.

The manual generation of the Work Lists is extremely simplified and it is possible to add samples at any moment. The graphical user interface of the software 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.

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

The KROMA 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 KROMA Software is based on the operating system 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: 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  $\geq 0,3\text{mm}$ . 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 11:** 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**"; 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.

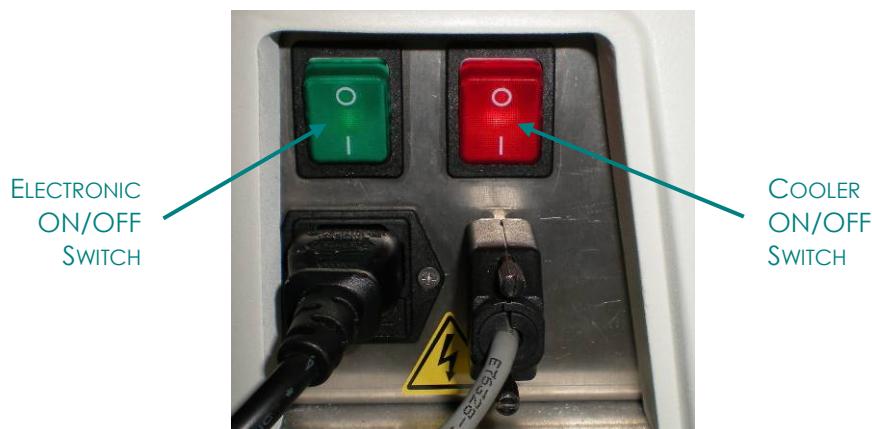
In this way it is possible to create a "free of human errors" correspondence between the Work List and sample tray positions (with L.I.S. connection option).

#### 4.1.3. Refrigeration Unit for Reagents (Option)

The instrument can contain an internal cooler unity for the refrigeration of the reagent bottles, to preserves them at constant temperature of about  $12^{\circ}\text{C} \pm 2^{\circ}\text{C}$  (anyway not lower than  $14^{\circ}\text{C}$  below the ambient temperature).

The cooler includes a Peltier-cells circuit controlled by temperature sensors.

The command for turning ON/OFF the cooler unit is separate and independent from that dedicated to the power ON/OFF of the electronics; in this way it is possible to turn ON or OFF the refrigeration unity independently from the rest of the instrument.



**Figure 12:** Refrigeration Unit – ON/OFF Switch



## 4.2. Operating Principles

KROMA 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 Hematology 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 tests of Clinical Chemistry, currently used with KROMA instrument, 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

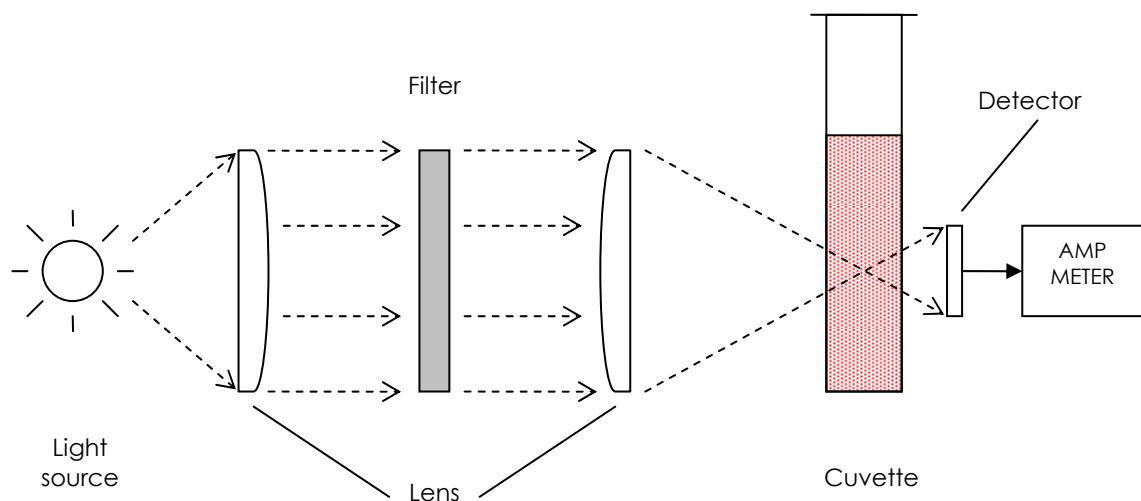
- Cholesterol
- HDL Cholesterol
- LDL Cholesterol
- Triglycerides



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 800nm (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 13:** 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.

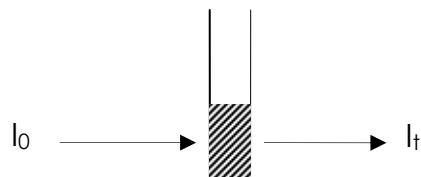
The light source is generally an incandescent halogen lamp.

#### 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 trough 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 ( $\infty$ ). 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];
- $\epsilon$  = molar extinction coefficient, or extinction of a solution containing 1mole/lit and examined along 1cm thickness at the considered wavelength.

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

$$A = \epsilon$$

that means: constant  $\epsilon$  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  $\epsilon$  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 by 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:

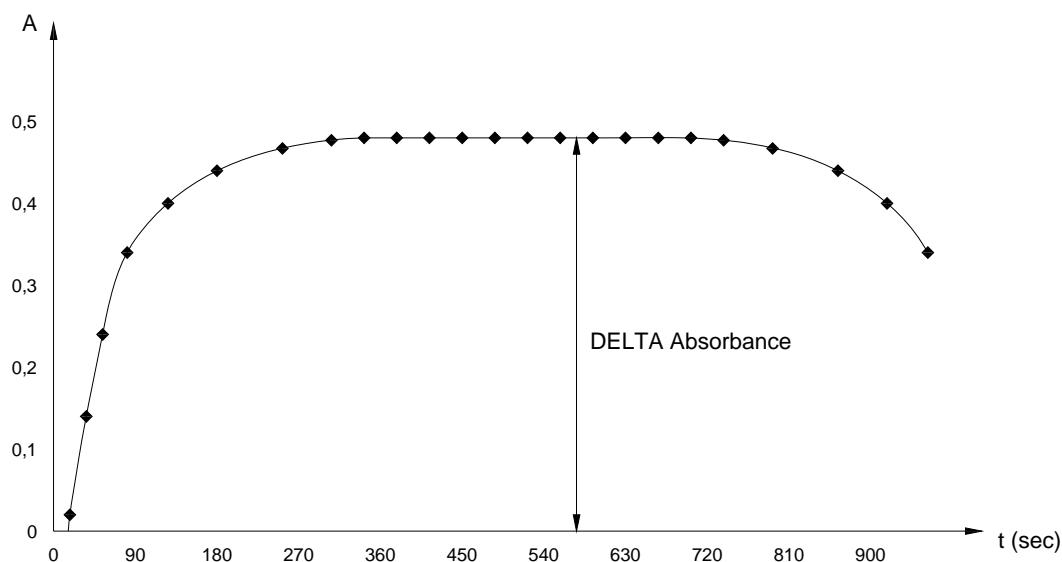
- END-POINT, or final point method,
- KINETIC, or multiple points method.

#### 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  $\Delta t$ , 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 14:** 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.

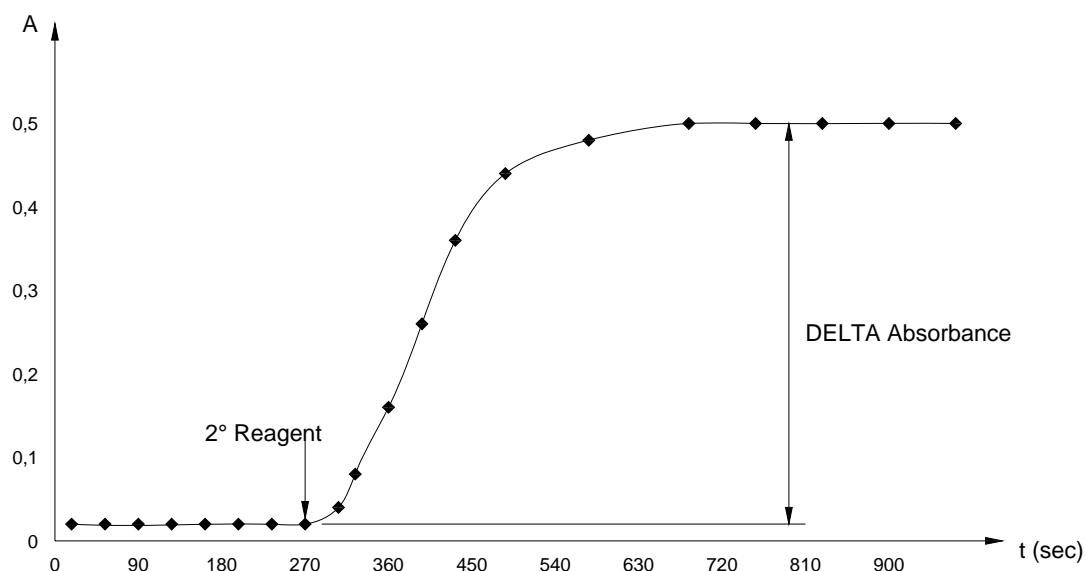
**Example:**

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 15:** 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*.

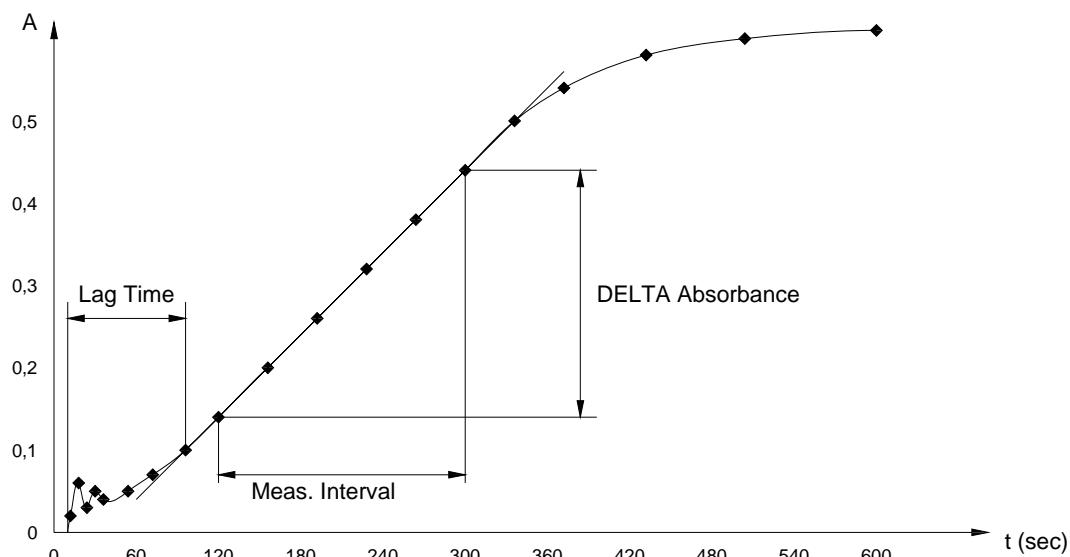


Figure 16: Kinetic Method

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:

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

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

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

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:

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

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 ( $\Delta A$ ) 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),

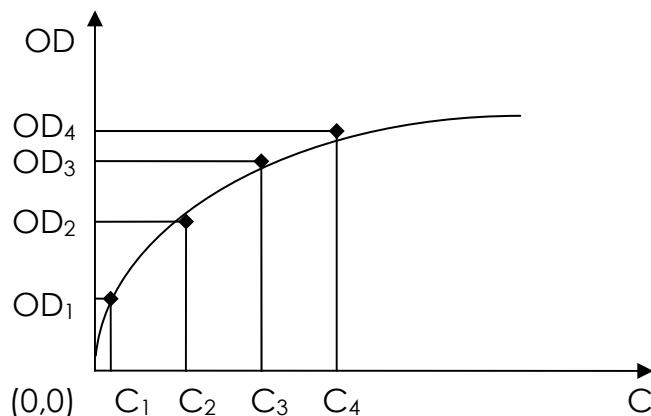


- when one measurement is taken out at a wavelength that is not that required by the method of a given reaction (i.e.: not enough wavelength filters).

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 absorbance 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 17:** 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, piece LiNEAR, 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, like LiNEAR 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 KROMA 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 KROMA have been listed below:

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



#### 4.2.3. Method Timings and Result Calculations

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

Note that any operation during analysis routines is regulated by machine cycles. One machine cycle includes one or more of the following activities: reagent aspiration and dispensing, sample aspiration and dispensing, probe 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 several single reading, 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:

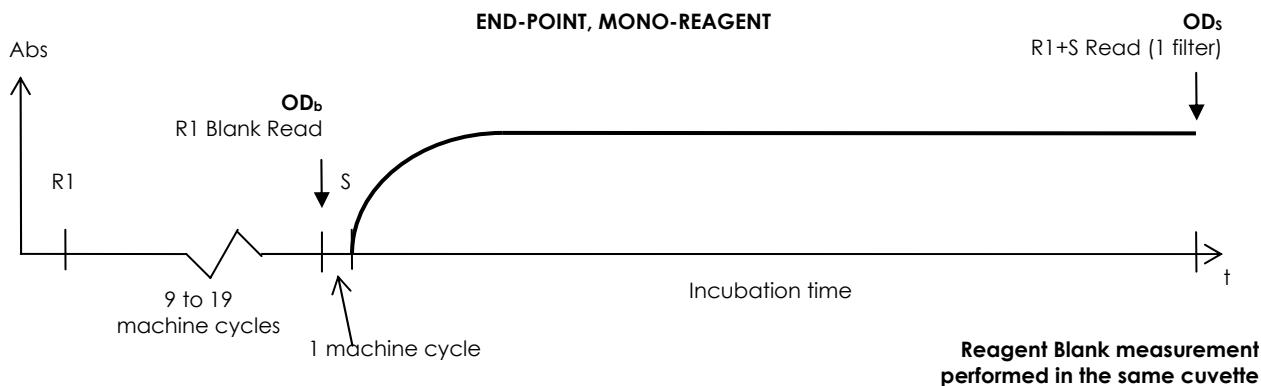
- R1** : **Reagent 1** dispensing.
- R2** : **Reagent 2** dispensing.
- R3** : **Reagent 3** dispensing.
- S** : **Sample** dispensing.
- d** : **optical path** = 0,6cm, inner distance between the two side walls orthogonal to the optical light-path, into the cuvette containing the reaction.
- Res** : **result** (or Concentration **C**)
- V<sub>m</sub>** : **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  $\lambda$ .



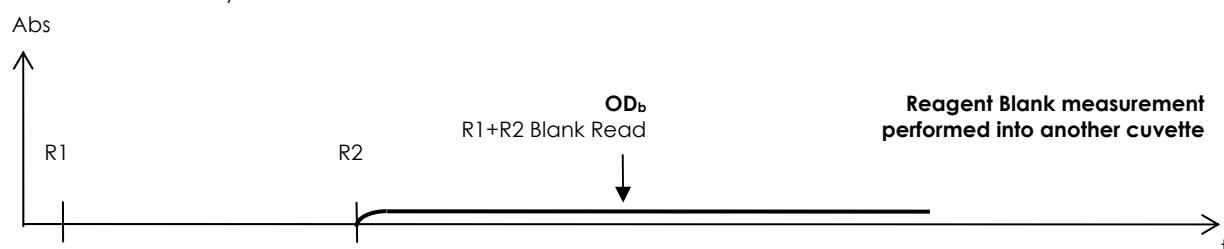
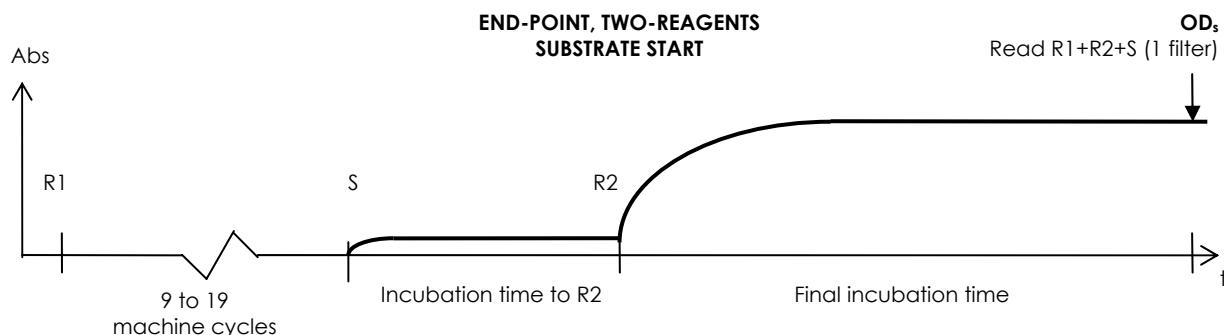
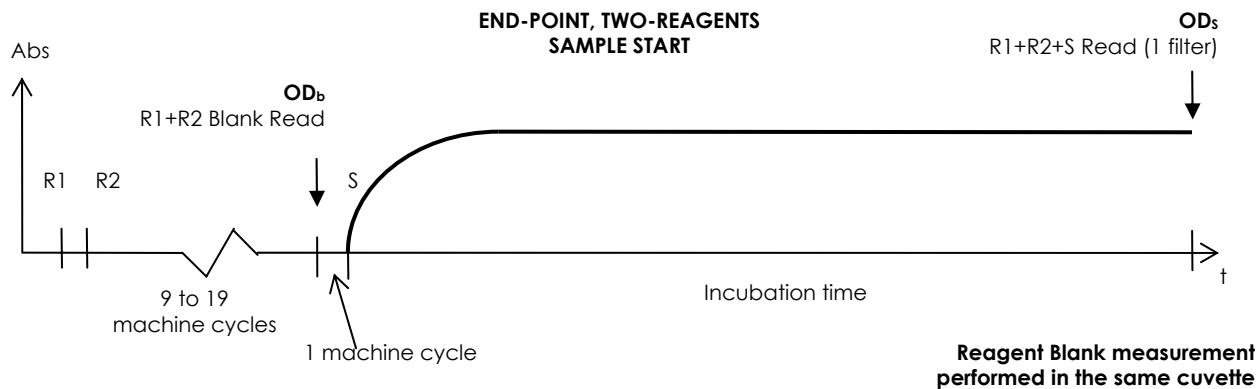
- V<sub>o</sub>** : **transparent value** – average value of the light passing the cuvette containing the *Systemic washing solution* measured at the end of the cuvette washing cycle at the wavelength  $\lambda$ .
- V<sub>os</sub>** : **Off-set vale** – average value of the residual light passing the cuvette containing the *Systemic washing solution* measured in “dark” conditions when the light source is not enabled.
- OD** : **Optical Density** measured (Absorbance-Abs)
- OD<sub>b</sub>** : **Optical Density** measured on the cuvette containing the reagent only (reagent blank).
- OD<sub>bc</sub>** : **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<sub>s</sub>** : **Concentration** of the sample.
- OD<sub>s</sub>** : **Optical density** measured on the cuvette containing the reaction with the sample.
- C<sub>st</sub>** : **Concentration** of the standard (or calibrator).
- OD<sub>st</sub>** : **Optical density** measured on the cuvette containing the reaction with the standard or calibrator.
- F** : **Factor**.
- V<sub>s</sub>** : **Volume** of the Sample.
- V<sub>R1</sub>** : **Volume** of the Reagent 1.
- V<sub>R2</sub>** : **Volume** of the Reagent 2.
- V<sub>R3</sub>** : **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  $\lambda$ .



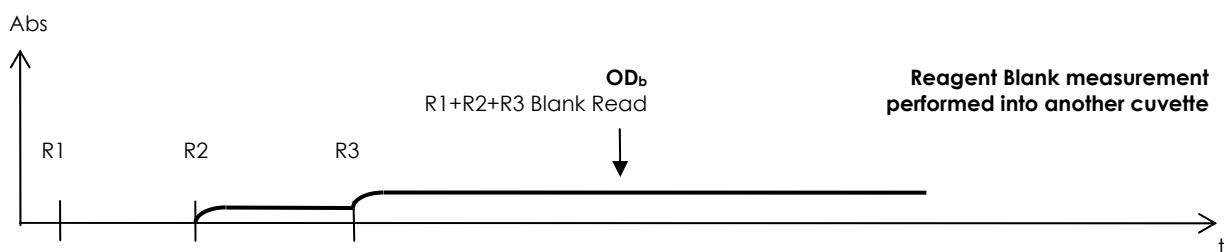
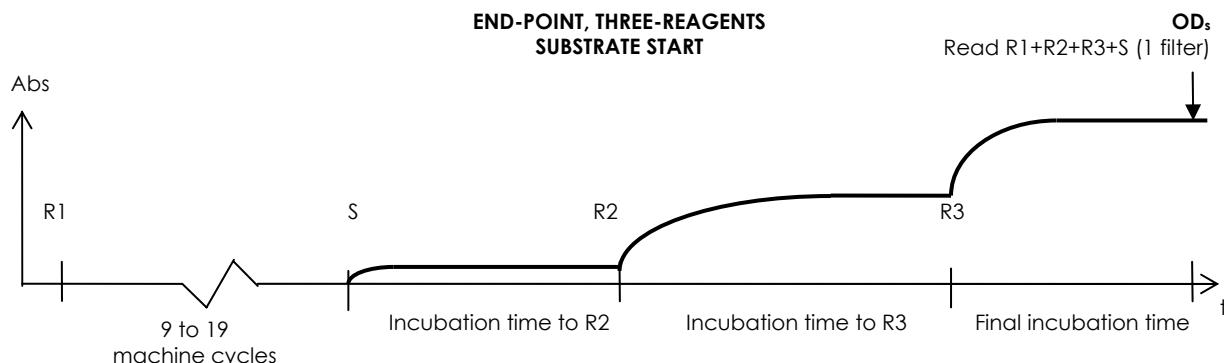
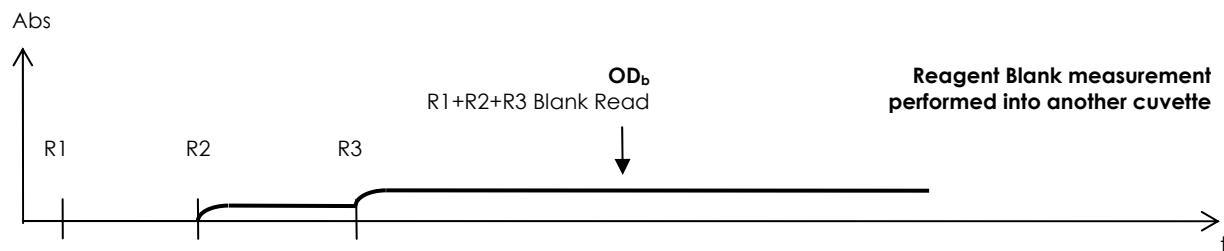
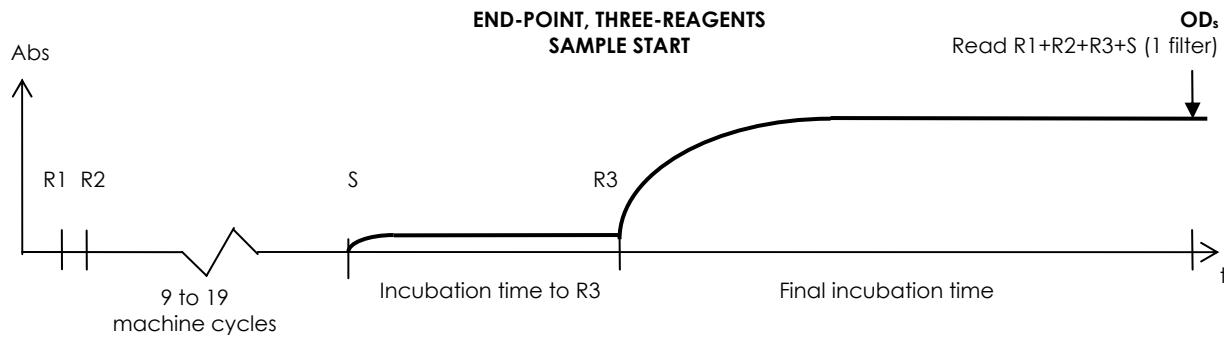
Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u>  $ResEP = (OD_S \cdot F)$  calculation of Factor F:  $F = \frac{C_{st}}{OD_{st}}$  OD <sub>st</sub> measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u>  $OD_{bc} = OD_b \cdot \left( \frac{V_{R1}}{V_{R1} + V_S} \right)$  $ResEPb = [(OD_S - OD_{bc}) \cdot F]$  calculation of Factor F:  $F = \frac{C_{st}}{(OD_{st} - OD_{bc})}$  OD <sub>st</sub> 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 <sub>bc</sub> ) is taken into account.



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



Calculation without Blank Value	Calculation with Blank Value
<p><u>Multi-Standard Concentration Result:</u></p> <p><math>ResEP = Intpol(OD_S)</math></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><math>ResEPB = Intpol(OD_S - OD_{bc})</math></p> <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (<math>OD_{bc}</math>) is taken into account.</p>





Calculation without Blank Value	Calculation with Blank Value
<p><u>Single-Standard Concentration Result:</u></p> <p><b>ResEP = (OD<sub>S</sub> · F)</b></p> <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{OD_{st}}$ <p>OD<sub>st</sub> measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> $OD_{bc} = OD_b \cdot \left( \frac{V_{R1} + V_{R2} + V_{R3}}{V_{R1} + V_{R2} + V_{R3} + V_s} \right)$ <p><b>ResEPb = [(OD<sub>S</sub> – OD<sub>bc</sub>) · F]</b></p> <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{(OD_{st} - OD_{bc})}$ <p>OD<sub>st</sub> measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> <p><b>ResEP = Intpol(OD<sub>S</sub>)</b></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><b>ResEPB = Intpol(OD<sub>S</sub> – OD<sub>bc</sub>)</b></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<sub>bc</sub>) is taken into account.</p>

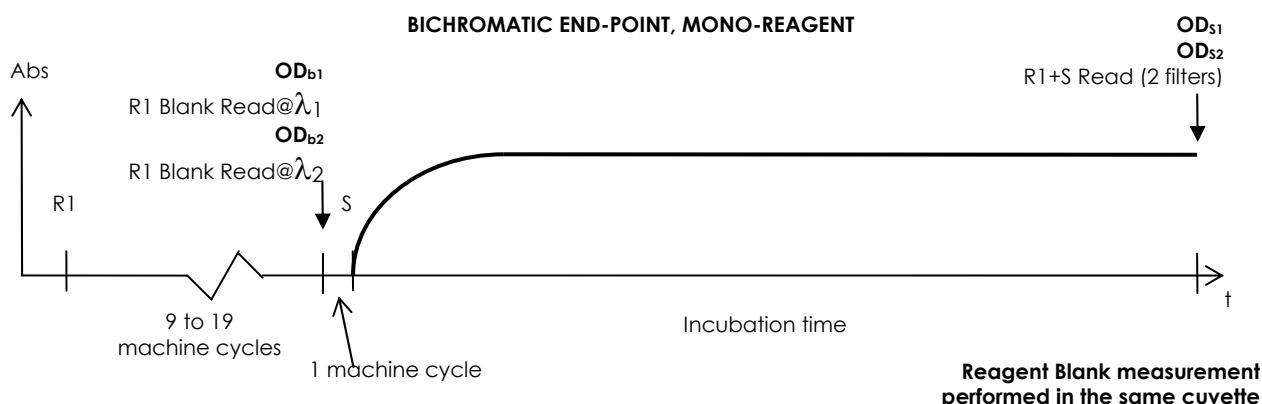


### Bichromatic ENDPOINT Method

The result is related to the difference between the 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  $\lambda_1$  and  $\lambda_2$ .

**OD<sub>\_1</sub>** : **measured value** – V<sub>m</sub> at wavelength  $\lambda_1$

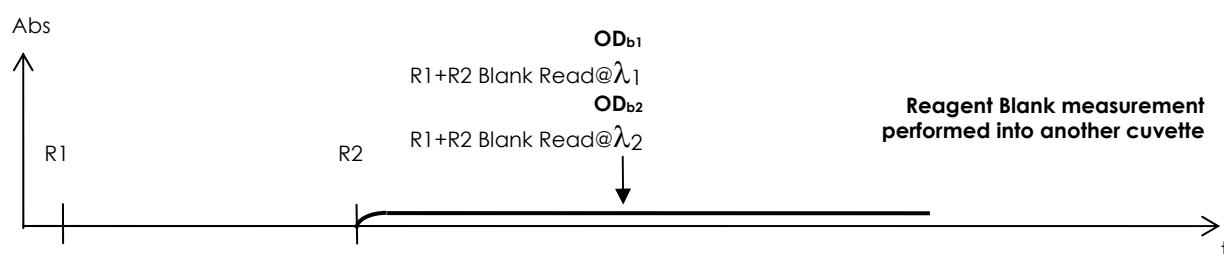
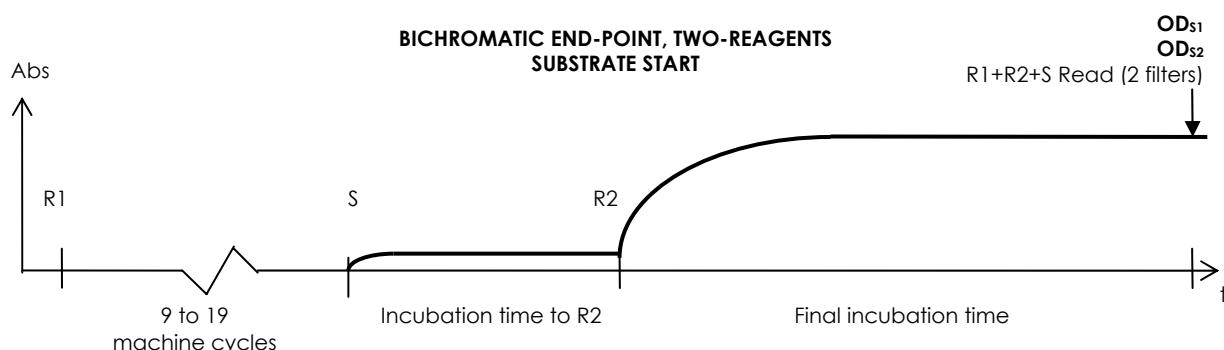
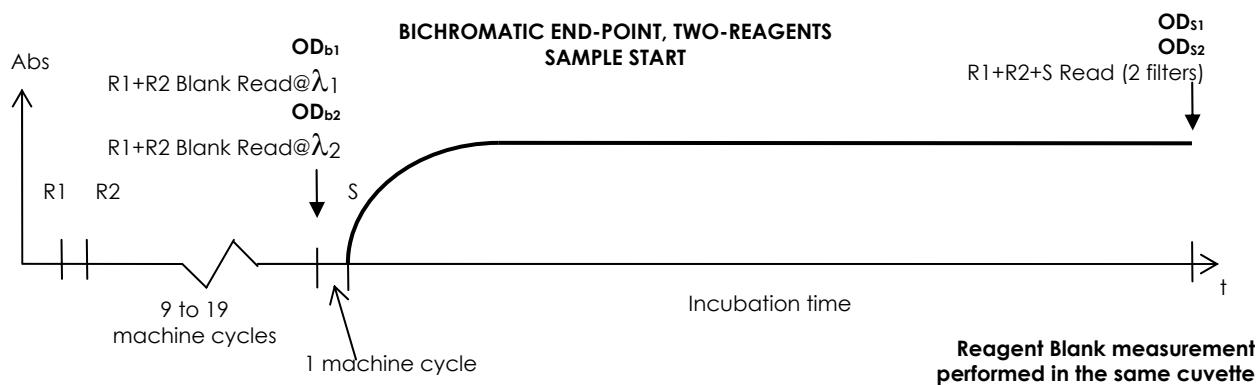
**OD<sub>\_2</sub>** : **measured value** – V<sub>m</sub> at wavelength  $\lambda_2$



Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u> $\Delta OD_S = (OD_{s2} - OD_{s1})$ $ResBE = [\Delta OD_S \cdot F]$ calculation of Factor F: $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ OD <sub>stx</sub> measured with the standard in place of the sample	<u>Single-Standard Concentration Result:</u> $\Delta OD_{bc} = (OD_{b2} - OD_{b1}) \cdot \left( \frac{V_{R1}}{V_{R1} + V_S} \right)$ $\Delta OD_S = (OD_{s2} - OD_{s1})$ $ResBEb = [(\Delta OD_S - \Delta OD_{bc}) \cdot F]$ calculation of Factor F: $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_{bc})}$ OD <sub>st</sub> measured with the standard in place of the sample

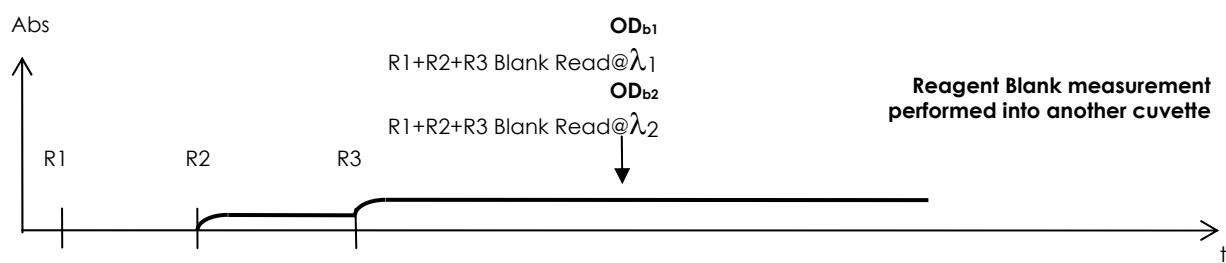
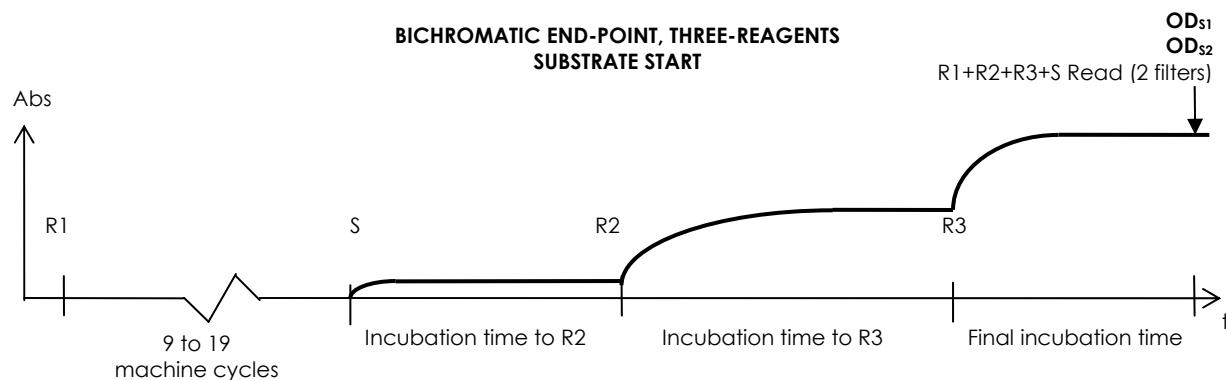
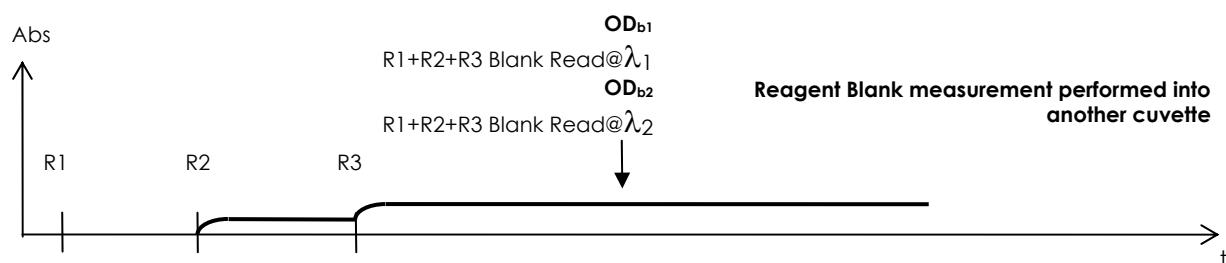
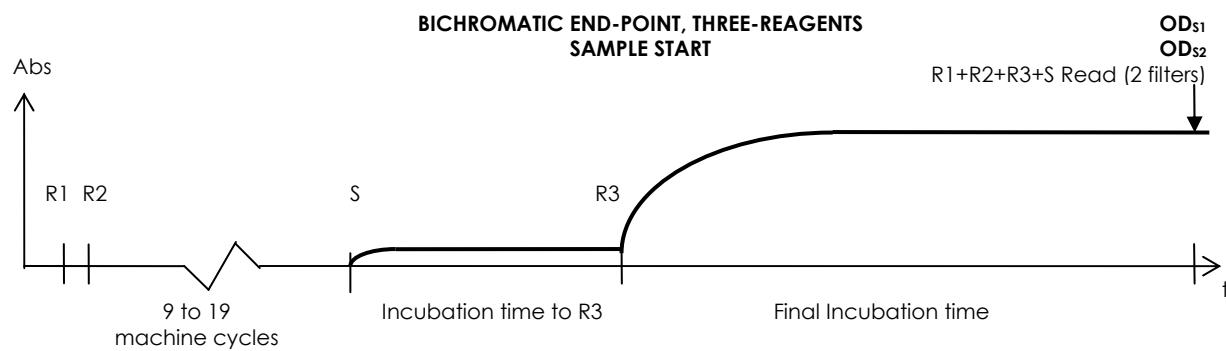


Calculation without Blank Value	Calculation with Blank Value
<p><u>Multi-Standard Concentration Result:</u></p> <p><math>ResBE = \text{Intpol}(\Delta OD_s)</math></p> <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C.</p>	<p><u>Multi-Standard Concentration Result:</u></p> <p><math>ResBEb = \text{Intpol}(\Delta OD_s - \Delta OD_{bc})</math></p> <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (<math>OD_{bc}</math>) is taken into account.</p>





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





Calculation without Blank Value	Calculation with Blank Value
<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_S = (OD_{S2} - OD_{S1})$ <p><b>ResBE = <math>[\Delta OD_S \cdot F]</math></b></p> <p>calculation of Factor <b>F</b>:</p> $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ <p><math>OD_{stx}</math> measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_{bc} = (OD_{b2} - OD_{b1}) \cdot \left( \frac{V_{R1} + V_{R2} + V_{R3}}{V_{R1} + V_{R2} + V_{R3} + V_S} \right)$ $\Delta OD_S = (OD_{S2} - OD_{S1})$ <p><b>ResBEb = <math>[(\Delta OD_S - \Delta OD_{bc}) \cdot F]</math></b></p> <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_{bc})}$ <p><math>OD_{st}</math> measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> <p><b>ResBE = Intpol(<math>\Delta OD_S</math>)</b></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><b>ResBEb = Intpol(<math>\Delta OD_S - \Delta OD_{bc}</math>)</b></p> <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (<math>OD_{bc}</math>) is taken into account.</p>

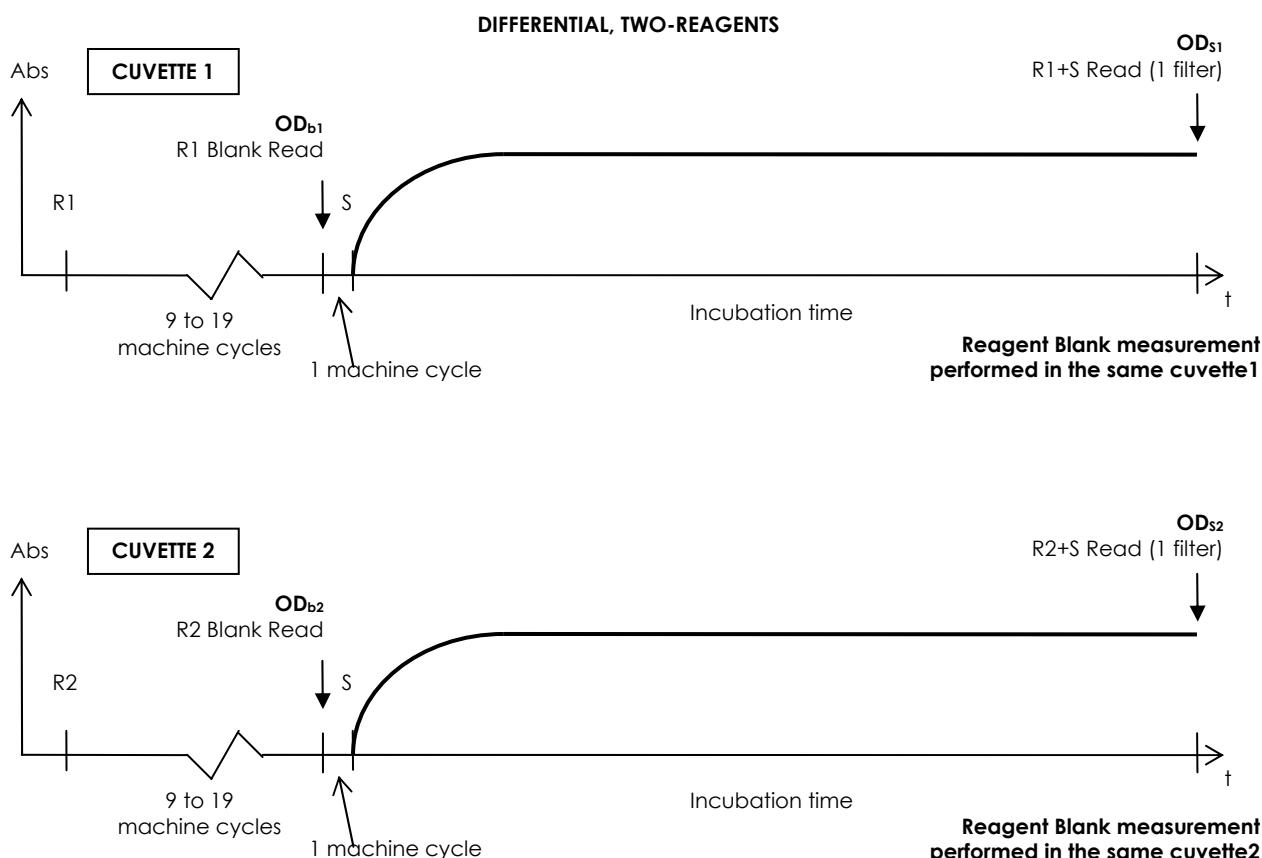
**Differential ENDPOINT – TWO REAGENT Method**

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  $\lambda$  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  $\lambda$  into another *different* cuvette, at the end of the same incubation time t.

**OD<sub>1</sub>** : **measured value** – Sample + R1 in cuvette #1

**OD<sub>2</sub>** : **measured value** – Sample + R2 in cuvette #2





Calculation without Blank Value	Calculation with Blank Value
<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_S = (OD_{S2} - OD_{S1})$ <p><b>ResDD = [ΔOD<sub>S</sub> · F]</b></p> <p>calculation of Factor <b>F</b>:</p> $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ <p>OD<sub>stx</sub> measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_{S1} = OD_{S1} - \left( OD_{b1} \cdot \frac{V_{R1}}{V_{R1} + V_S} \right)$ $\Delta OD_{S2} = OD_{S2} - \left( OD_{b2} \cdot \frac{V_{R2}}{V_{R2} + V_S} \right)$ <p><b>ResDDb = [(ΔOD<sub>S2</sub> - ΔOD<sub>S1</sub>) · F]</b></p> <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{(\Delta OD_{st2} - \Delta OD_{st1})}$ <p>OD<sub>st</sub> measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> <p><b>ResDD = Intpol(ΔOD<sub>S</sub>)</b></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><b>ResDDb = Intpol(ΔOD<sub>S2</sub> - ΔOD<sub>S1</sub>)</b></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) is taken into account.</p>

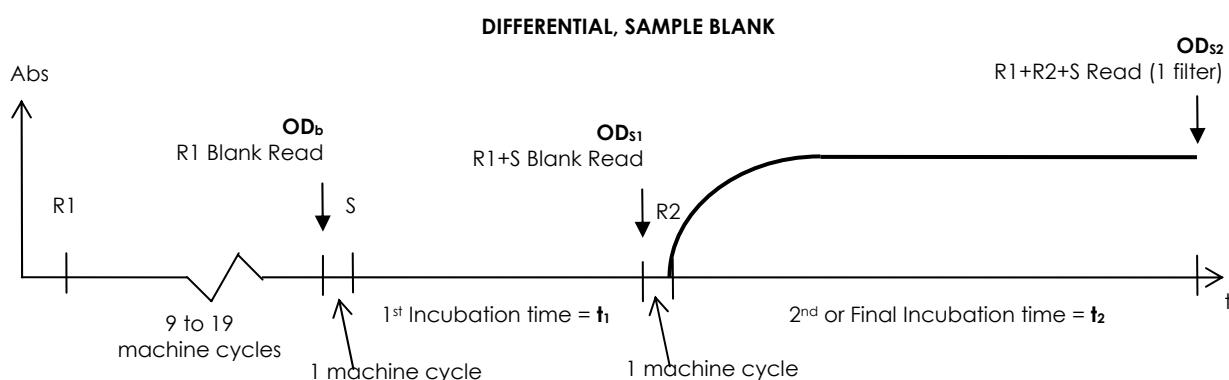
**Differential ENDPOINT – SAMPLE BLANK Method**

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

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

**OD<sub>1</sub>** : **measured value** – Sample + R1 after incubation time  $t_1$  (sample blank)

**OD<sub>2</sub>** : **measured value** – Sample + R1 + R2 after incubation time  $t_2$



Calculation without Blank Value	Calculation with Blank Value
<u>Single-Standard Concentration Result:</u>	<u>Not Applicable</u>
$K = \left( \frac{V_{R1} + V_S}{V_{R1} + V_{R2} + V_S} \right)$ $\Delta OD_S = [OD_{S2} - (OD_{S1} \cdot K)]$ $ResDS = \Delta OD_S \cdot F$	
calculation of Factor <b>F</b> :	
$F = \frac{C_{st}}{[OD_{st2} - (OD_{st1} \cdot K)]}$ <p>OD<sub>stx</sub> measured with the standard in place of the sample</p>	



Calculation without Blank Value	Calculation with Blank Value
<p><u>Multi-Standard Concentration Result:</u></p> <p><math>ResDD = Intpol(\Delta OD_s)</math></p> <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C.</p>	<p><u>Not Applicable</u></p>

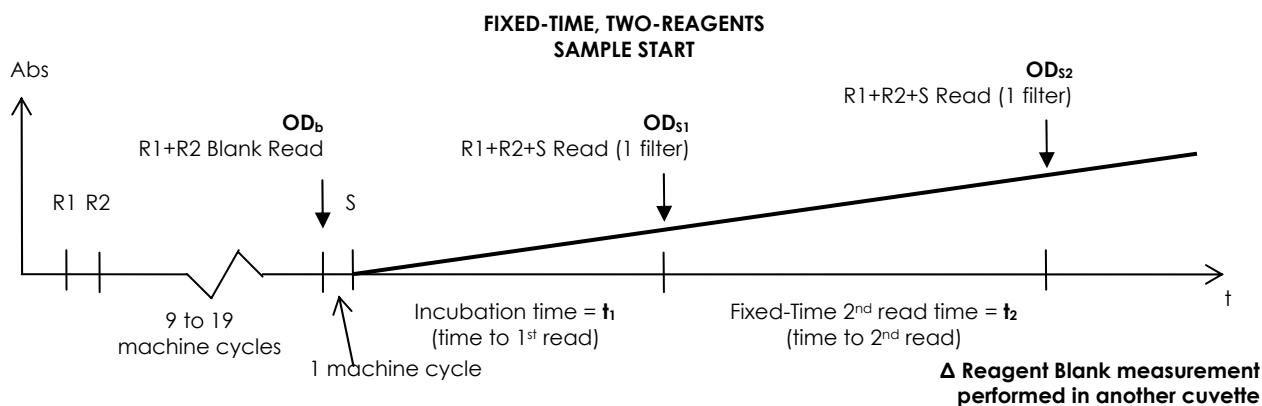
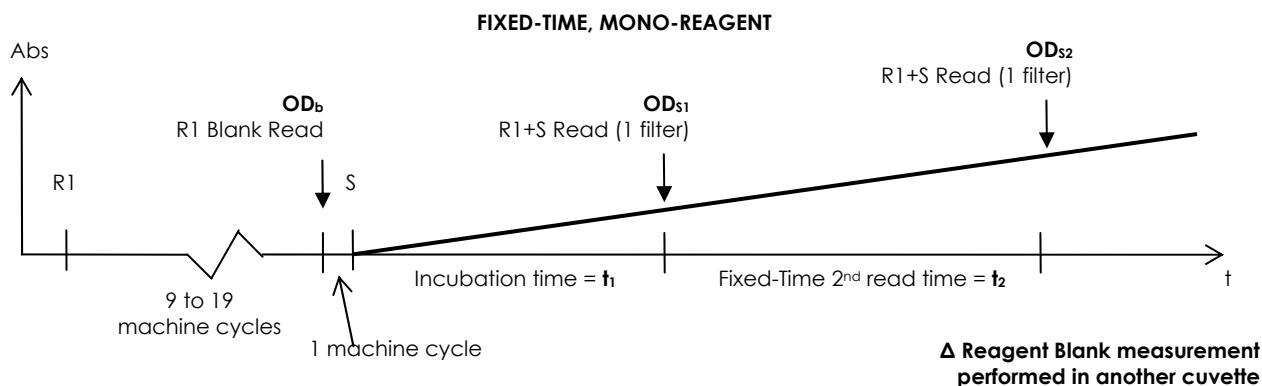
**FIXED TIME Method**

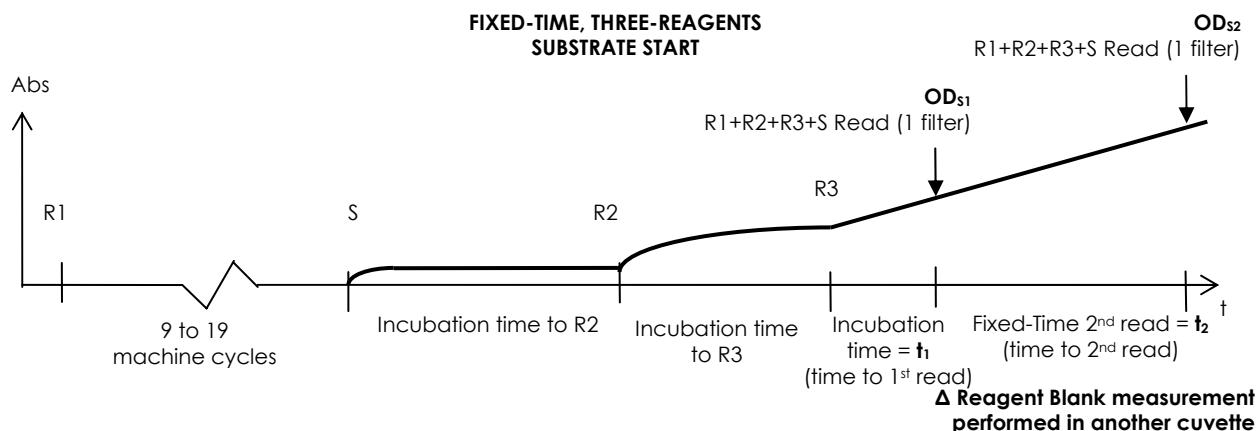
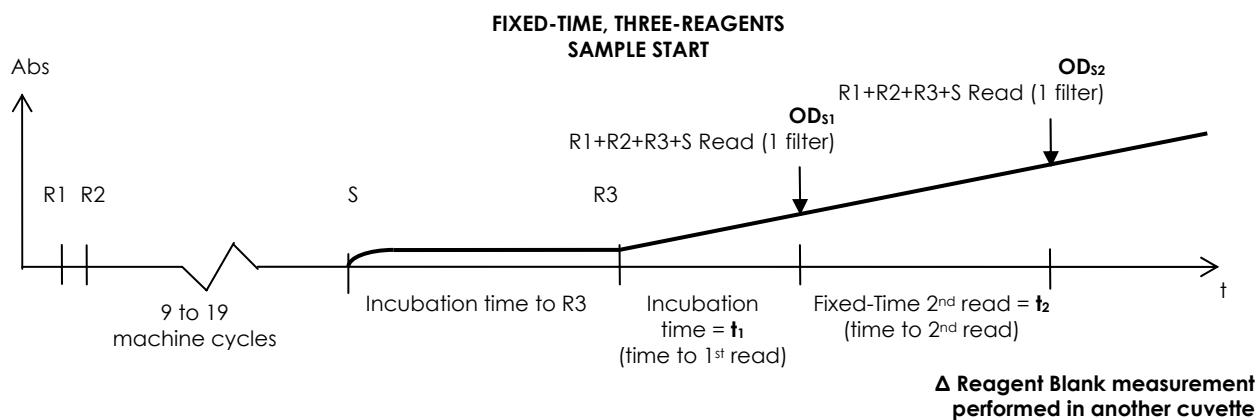
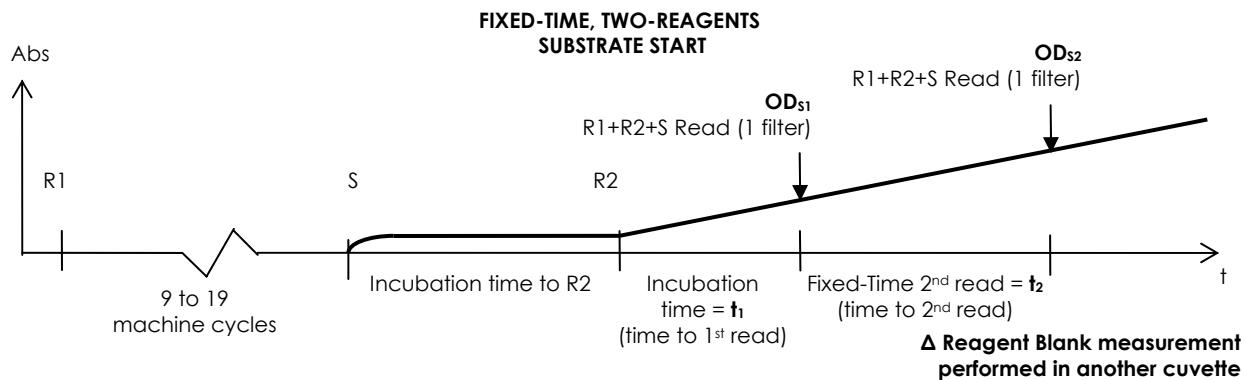
The result is related to the difference between the two absorbencies taken on the **same** cuvette at two different time instants:

- the absorbance of the sample mixed with the reagent R1 (or with R1+R2 or with R1+R2+R3) at a fixed wavelength  $\lambda$ , 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  $\lambda$ , measured after a fixed reading time  $t_2$  (starting after 1<sup>st</sup> measurement reading).

**OD<sub>s1</sub>** : **measured value** – Reaction after incubation time  $t_1$

**OD<sub>s2</sub>** : **measured value** – Reaction after fixed 2<sup>nd</sup> read time  $t_2$





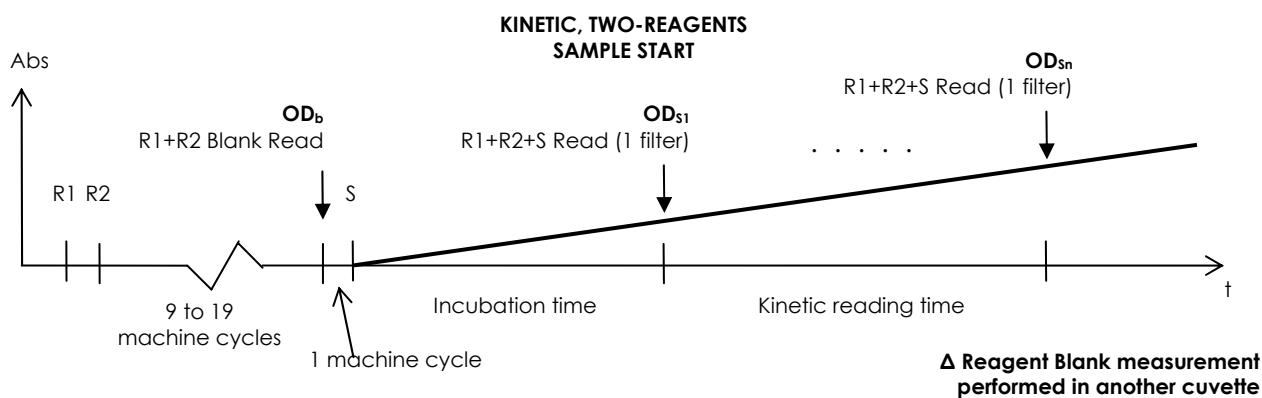
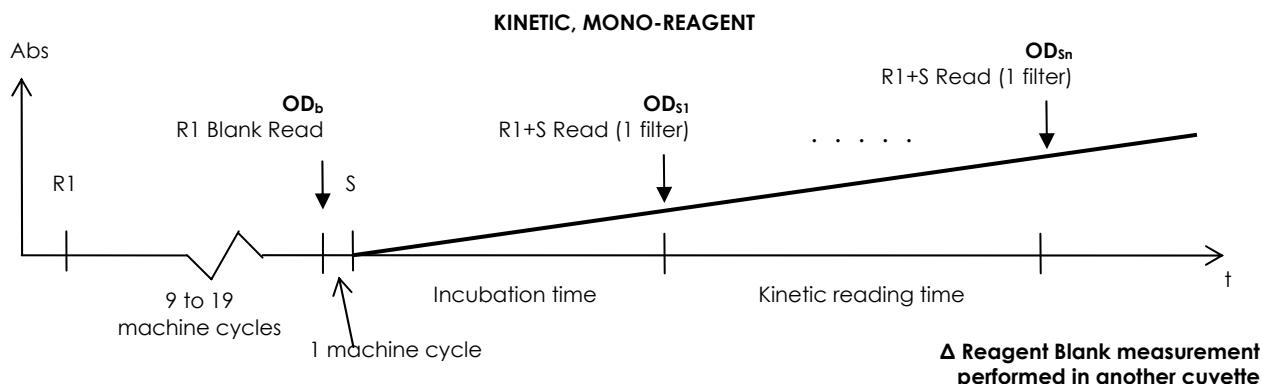


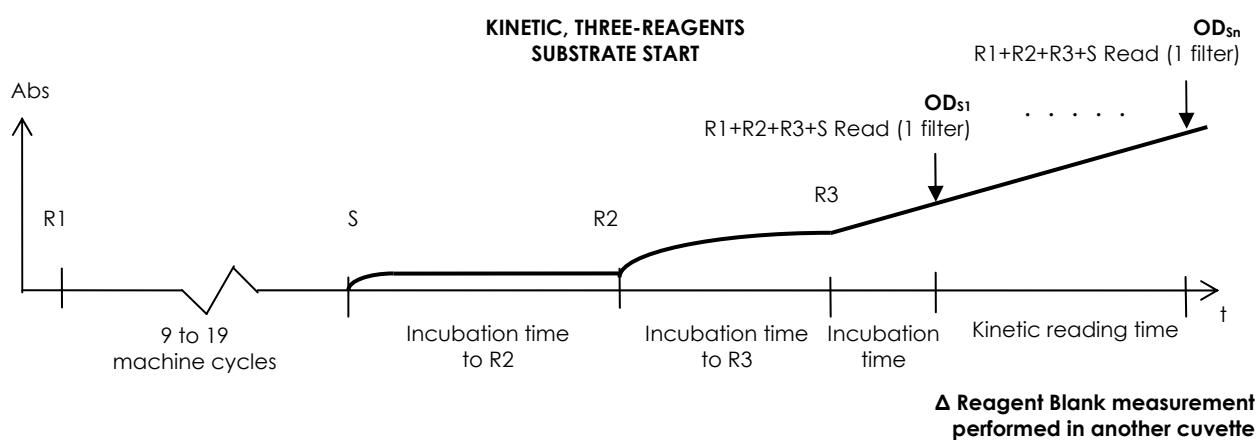
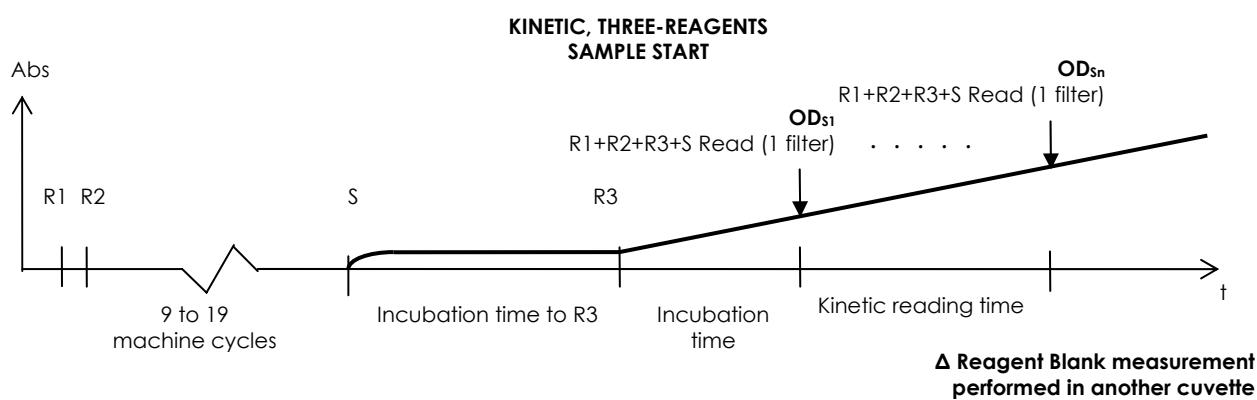
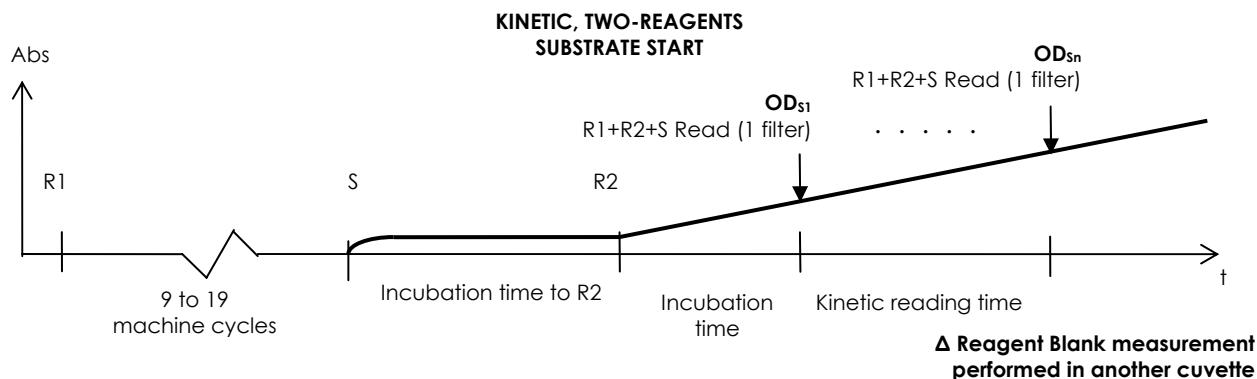
Calculation without Blank Value	Calculation with Blank Value
<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_S = (OD_{S2} - OD_{S1})$ <p><b>ResFT = <math>(\Delta OD_S) \cdot F</math></b></p> <p>calculation of Factor <b>F</b>:</p> $\Delta OD_{st} = (OD_{st2} - OD_{st1})$ $F = \frac{C_{st}}{(\Delta OD_{st})}$ <p><math>OD_{stx}</math> measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> $\Delta OD_b = OD_{b2} - OD_{b1}$ $\Delta OD_S = OD_{S2} - OD_{S1}$ $ResDDb = [(\Delta OD_S - \Delta OD_b) \cdot F]$ <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{(\Delta OD_{st} - \Delta OD_b)}$ <p><math>OD_{st}</math> measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> <p><b>ResDD = Intpol(<math>\Delta OD_S</math>)</b></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><b>ResDDb = Intpol(<math>\Delta OD_S - \Delta OD_b</math>)</b></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) is taken into account.</p>

**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  $\lambda$ . The measurement is taken  $n$  times ( $n=3\div9$ ) during the “reading time” interval  $\Delta T$ .

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
<p><u>Single-Standard Concentration Result:</u></p> <p>Calculation of the slope, intercept and FIT (squared correlation coefficient) over the OD<sub>x</sub>/time array of the <b>n</b> measured values</p> $ResKT = (slope_s) \cdot F \cdot 60$ <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{(slope_{st}) \cdot 60}$ <p>OD<sub>st</sub> measured with the standard in place of the sample</p>	<p><u>Single-Standard Concentration Result:</u></p> <p>Calculation of the slope, intercept and FIT (squared correlation coefficient) over the OD<sub>x</sub>/time array of the <b>n</b> measured values for sample and reagent blank</p> $ResKTB = [(slope_s) - (slope_b)] \cdot F \cdot 60$ <p>calculation of Factor <b>F</b>:</p> $F = \frac{C_{st}}{[slope_{st} - slope_b] \cdot F \cdot 60}$ <p>OD<sub>st</sub> measured with the standard in place of the sample</p>
<p><u>Multi-Standard Concentration Result:</u></p> $ResKT = Intpol(slope_s) \cdot 60$ <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> $ResKTB = Intpol (slope_s - slope_b) \cdot 60$ <p>Interpolation with the Calibration Curve determined on the “n” values read for the “n” standard solution at different C. The reagent blank (OD<sub>bc</sub>) is taken into account.</p>



## 4.3. The ISE Module

KROMA system can include the option **ISE Module** used as a component of the chemistry analyzer itself. It measures lithium, sodium, potassium, and chloride concentration and transmits the results of the measurements carried out on serum, plasma and urine to the analyzer for integration into the test results report.

### 4.3.1. Generals

The ISE Module includes ion-selective electrodes and three peristaltic pumps to be mounted within KROMA chemistry analyzer. The ISE Module measures the concentration of Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, and Cl<sup>-</sup> in serum, plasma and diluted urine. An integrated sample entry port is positioned on top of the ISE Module in correspondence of the aperture near the 9<sup>th</sup> sample tube position.



**Figure 18:** KROMA, working area

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

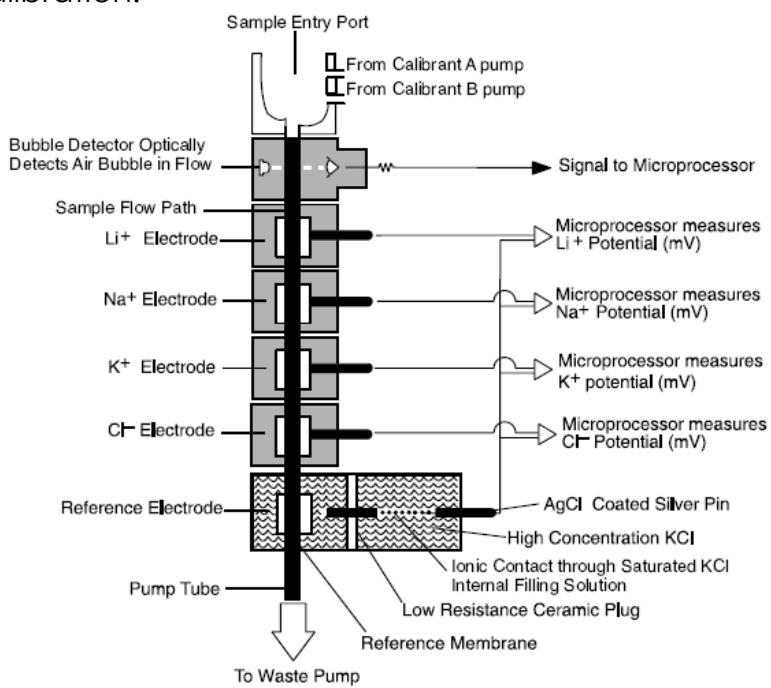
The ISE Module houses snap-in, snap-out electrodes which connect directly to an electronic board within the ISE Module.

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 deposited by the KROMA 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 19:** 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 KROMA reagent tray, aspirated, and deposited into the sample entry port by the instrument ARM.

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

#### 4.3.2. ISE module (option), 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 previously. 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<sup>+</sup>, Na<sup>+</sup> and K<sup>+</sup> and 45mV/decade for Cl<sup>-</sup>.

Acceptable slope limits are:

Slope	(mV/decade)
Na <sup>+</sup>	52–64
Cl <sup>-</sup>	40–55
Li <sup>+</sup>	47–64
K <sup>+</sup>	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<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, or Cl<sup>-</sup>).

### 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 (it takes about 2 minutes) at the end of the working day before instrument shuts down.**

- A pump calibration is automatically performed by the instrument during 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.
- When more than 50 samples are 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.

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**.

#### 4.3.4. Fluid Management

When measuring **serum or plasma** samples, the instrument inhales 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) and dispenses it into the clean dilution cup aside the proper sample tube. The instrument then inhales 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



sampling 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 consumptions and reagent pack data.



#### 4.4. Bibliography

- Carl A. Burtis and Edward R. Ashwood (1999) - *Tietz Textbook of Clinical Chemistry* (3<sup>rd</sup> Edition) – Saunders
- Tietz N. (1976) – *Fundamentals of clinical chemistry* - Saunders
- Colton T. (1974) – *Statistics in medicine* - Little, Brown and Company
- Brinkley M. (1992) - *A brief survey of methods for preparing conjugates with dyes, haptens and cross-linking reagents* - Bioconjugate Chem. **3**, 2-13.
- Diamandis E.P. and Christopoulos T.K. (1991) - *The biotin-(strep)avidin system: Principles and applications in biotechnology* - Clin. Chem. **37**(5), 625-636.
- Harlow E. and Lane D. eds. (1988) - *Antibodies: A Laboratory Manual* - Cold Spring Harbor Laboratory - Cold Spring Harbor, NY.
- Wilchek M. and Bayer E.A. (1988) - *The avidin-biotin complex in bioanalytical applications* - Anal. Biochem. **174**, 1-32.
- Youden W.J. (1960) – *The sample, the procedure and the laboratory* - Anal. Chem. 32.23A.
- Filippo Pasquinelli - *Diagnostica e Tecniche di Laboratorio: Vol.1 – Chimica Clinica* - Ed. Rosini Firenze
- Levy S., Jennings E.R. – *The use of control chart in the clinical laboratory* - Am. J. Clin. Pathol. 20.1059.1950
- J.O. Westgard, P.L. Barry, M.R. Hunt, T. Groth - *A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry* - Clin. Chem. 27:493-501, 1981
- Luigi Spandrio (2001) - *Principi e Tecniche di Chimica Clinica* – Ed. Piccin Nuova Libraria S.p.A. Padova



## Section 5 FUNCTIONS

### 5. Functions

#### 5.1. Purpose of the Instrument

KROMA is an automatic analyser for in-vitro diagnosis (IVD) of clinical chemistry and turbidimetry tests to be used in laboratories and similar diagnostic facilities. KROMA 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

KROMA is a System that 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 probe 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 programming.
- 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).

KROMA system can operate as “open system” or “closed system” depending on the particular customer’s agreement.



KROMA shows the main hardware and software characteristics that are listed in the following tables:

### 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 assures the best accuracy and reproducibility.
- Minimization of probe carry-over through an on-line special washing procedure of the sampling probe.
- Minimization of cuvette carry-over and contamination through an on-line special washing procedure and test restriction constrains.
- Reagent pre-heating during sampling.
- Capacitive liquid sensor able to detect the level of samples and reagents.
- Shock sensor able to detect obstacles during the way down of the sampling arm.
- 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 distributed intelligence electronic; its modularity allows fast and pointed servicing.
- Easy loading by smart-card of the information related to the reagents used from the instrument (option).
- Four electrodes ISE module with auto calibration and bubble detector (option).
- Minimization of the human risk factor.

### Software

- Application based on MS Windows XP® Operative System.
- Easy to use User Interface.
- 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 downloading.
- Reduction of risks due to human errors.
- Reagent incompatibilities and cross-contaminations management (through restrictions).



## 5.3. Functions

The KROMA instrument includes the following functional sub-assemblies:

- Loading trays, one for patient samples calibrators, standards and controls and for Reagents (within working area).
- Sampling ARM assembly (within working area).
- Sampling probe washing sink (within working area).
- Incubation and optical reading assembly and washing station (within working area).
- Barcode reader (internal, on the ARM - option).
- Command and control electronics (internal).
- Power supply (internal).
- Management software and user interface (on external management PC).
- ISE module (internal - optional).
- L.I.S. interface (option).



**Figure 20:** KROMA, Working Area

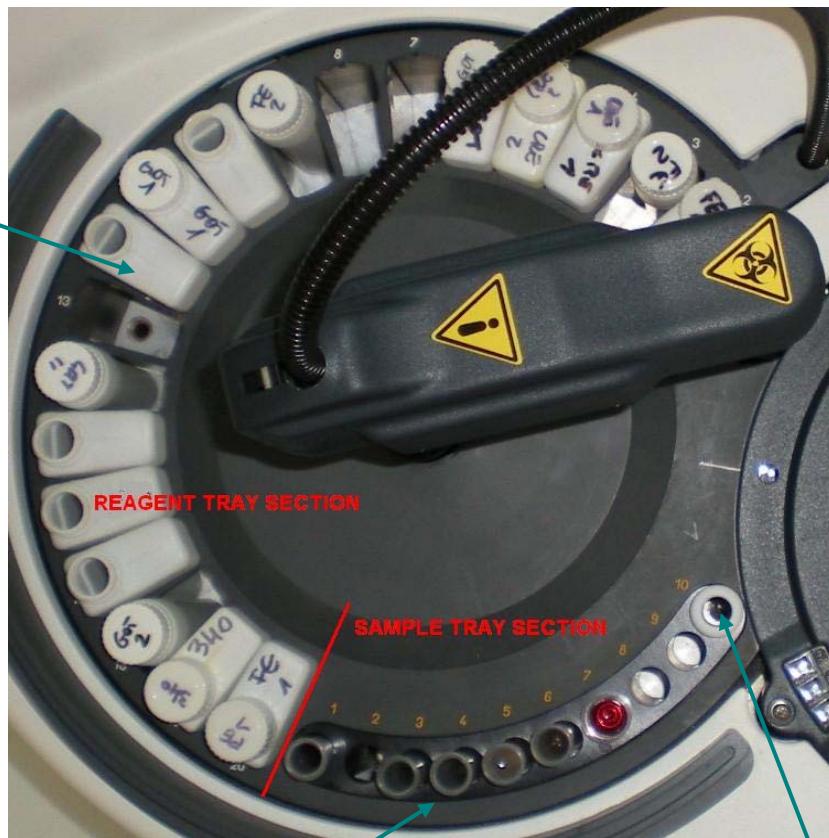
### 5.3.1. Loading Trays

The loading trays include:

- Sample tray section - 9 positions.
- Reagent tray section - 20 positions - and reagent cooler (refrigeration as option).



REAGENT TRAY  
20 Positions for  
50ml or 20ml Reagent  
Bottles,  
including Diluent and  
Washing Solutions



SAMPLE TRAY  
9 Positions for Samples,  
Standard and Controls



Sample Positions for:  
• 12/13mm diam. Sample Tubes  
• 3ml Sample Cups without any Adapter

**Figure 21:** Sample and Reagent Tray



### 5.3.1.1. Sample Tray

This tray is located on left side of the working area. It includes 9 numbered positions to place samples; **STAT** samples can be placed anywhere. All positions can be used for primary tubes whose height ranges from 75mm up to 85mm and diameter from 12mm up to 13mm. It is possible to use 3ml sample cups (diameter 12mm – purchasing code P3140000001) without the need of any adapter. Any position can be indifferently assigned: to patient sample, to Standard or Calibrator, to Controls. All numbered positions are identified by pantographic numbers, increasing in counter-clock wise direction.

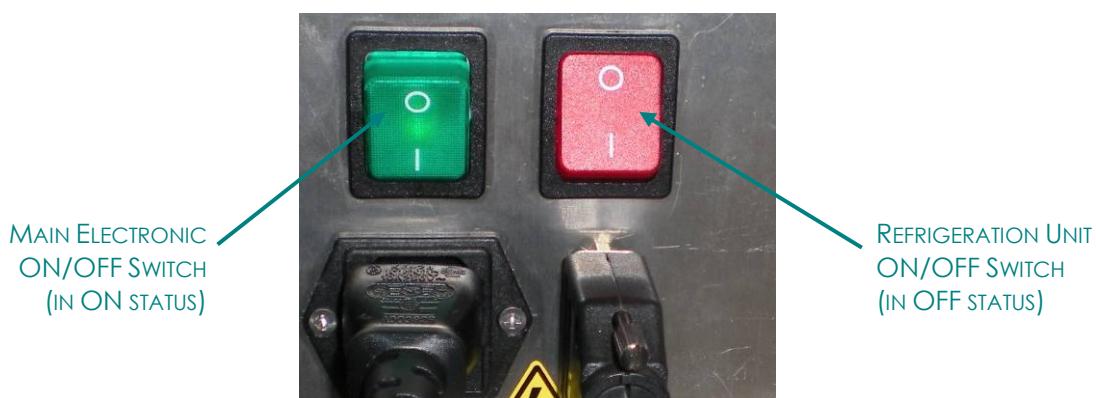
### 5.3.1.2. Reagent Tray

This tray is positioned on left side of the working area. It includes **20** numbered positions; all of them are refrigerated. There can be placed **50ml** reagent bottles or **20ml** reagent bottles without the need of any support.

Any of them can be assigned to the diluent (distilled water, physiologic solution or similar) or to other solutions (washing solutions or ISE Module solutions). 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 20 different mono-reagent methods or any combination of mono-, two- and three-reagent parameters can be placed on the tray.



**Figure 22:** ON/OFF Switches

The cooler (option) preserves all reagent bottles at constant temperature of about  $13^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ; the refrigeration temperature assures a decrease in temperature of at least  $14^{\circ}\text{C}$  below the ambient temperature. Cooling is achieved by using a double Peltier cells system. Through a specific switch placed in the left side of the instrument (red colour) it is possible to turn ON/OFF only the cooler without affecting the general electronic ON/OFF status.



### 5.3.2. Sample and Reagent Dispensing Assembly - ARM

This assembly is used for aspiration and dispensation of samples and reagents; it is composed by the following main parts:

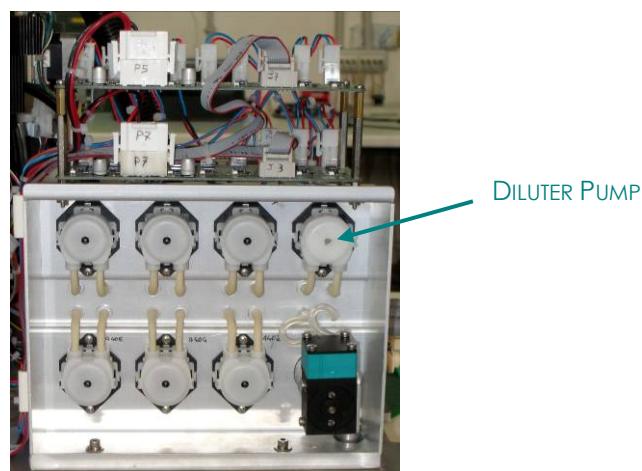
- Sampling probe sub-assembly (including: capacitive liquid level detector, vertical obstacle sensor and pre-heater coil).
- Diluter.
- Electrovalve.
- Remote probe washing pump (or Diluter Pump).

This assembly draws the liquid from the sample tray (samples, standards, calibrators or controls) or from the reagent tray (reagents, diluent or washing solutions) and dispenses it in the incubation cuvette.

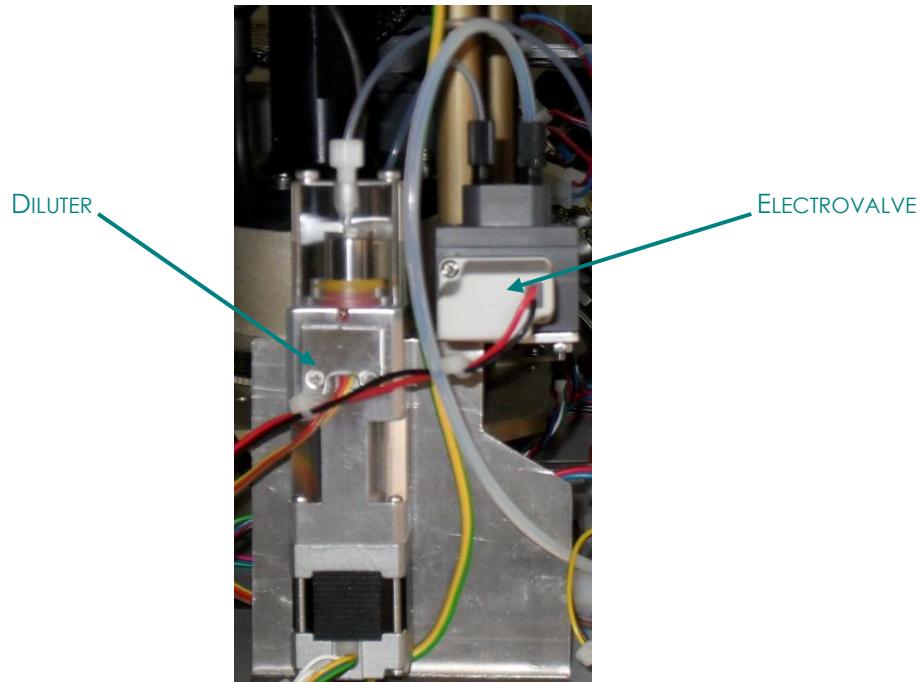
After each dispensing operation, within the same machine cycle, the instrument automatically performs a washing cycle of the probe in the apposite well (Washing Sink) before the next aspiration.



**Figure 23:** Dispensing Assembly



**Figure 24:** ARM Diluter Pump



**Figure 25:** Electrovalve and Diluter

### 5.3.2.1. Sampling Probe Sub-assembly

This sub-assembly (part of the sampling arm) is composed by the probe itself, by the liquid level sensor, by the obstacle sensor and by the heater coil.

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 effective 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.

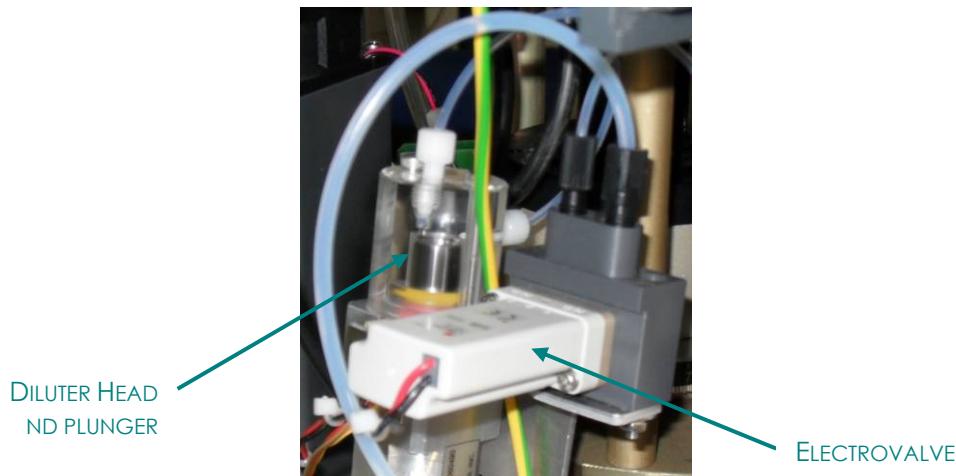
Hence the probe sub-assembly, beyond the probe itself, includes:

- One capacitive liquid detector, that limits the depth of penetration into the liquid (and consequently the contamination) and allows the correct volume monitoring; this sensor has been potted 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;
- One heater coil, providing a pre-heating of the fluids to easily reach the incubation temperature in the reading cuvettes and to help probe cleaning during rinsing.



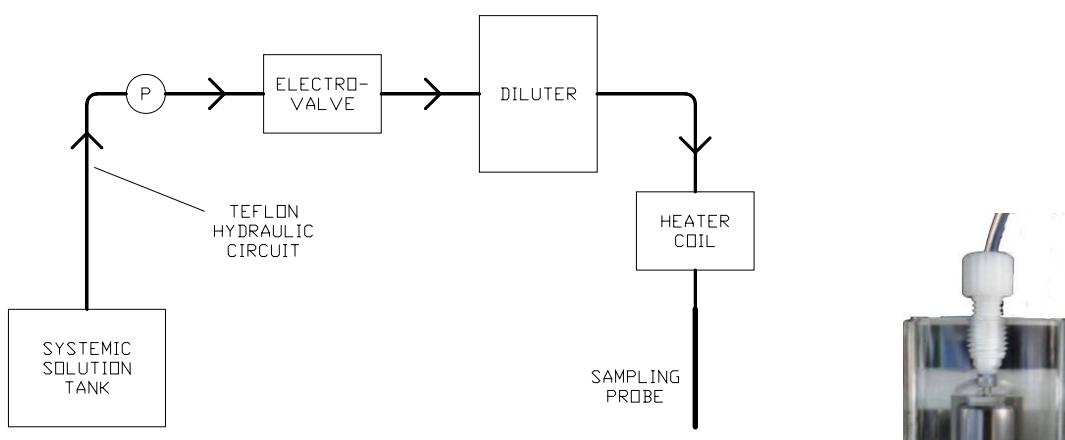
### 5.3.2.2. Diluter

The instrument is equipped with one diluter that provides aspiration and dispensing of the correct volume for: samples, reagents, standard, calibrators, controls, diluents and washing solutions, assuring great precision also for very small volumes.



**Figure 26:** Diluter and Electrovalve

The 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 500 $\mu$ l minimum.
- High sampling resolution.
- Minimized dead volume.
- High dimensional accuracy plunger.
- Long life plunger seal.





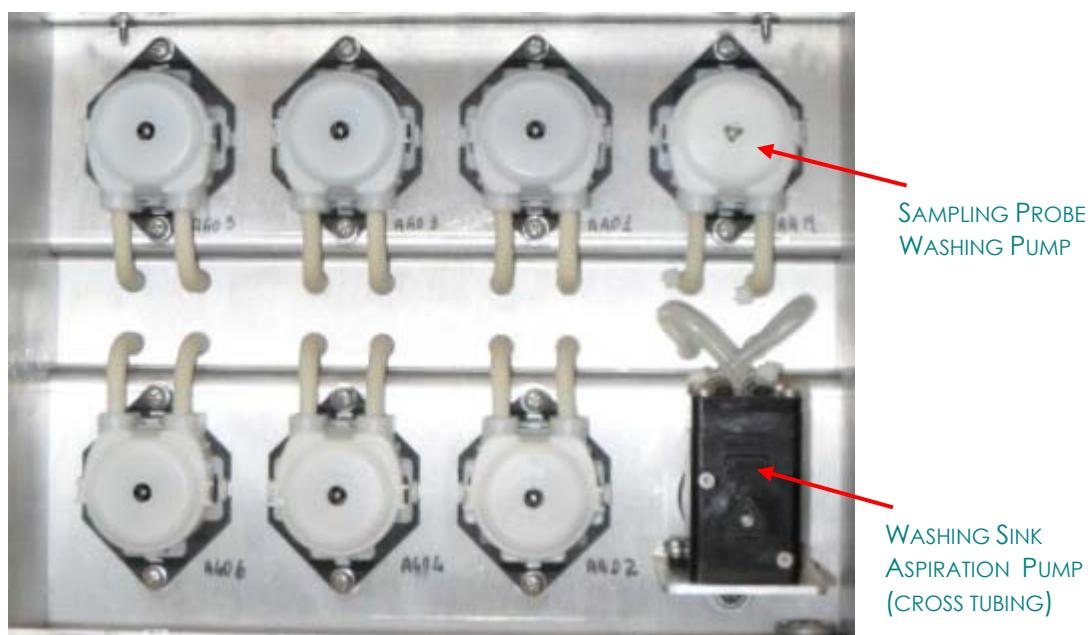
During sampling, the electrovalve closes the way out to systemic solution circuit; when washing, the electrovalve opens to the systemic solution circuit and the washing peristaltic pump starts pumping.

### 5.3.2.3. Electrovalve

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

### 5.3.2.4. Pump for Probe Washing

The diluter pump is used to move the systemic solution into the probe and its hydraulic circuits whose inner surface must be washed. Pumps have been placed on a support just behind the right side panel of the instrument in order to facilitate periodic maintenance operations and integrity monitoring to the service personnel.



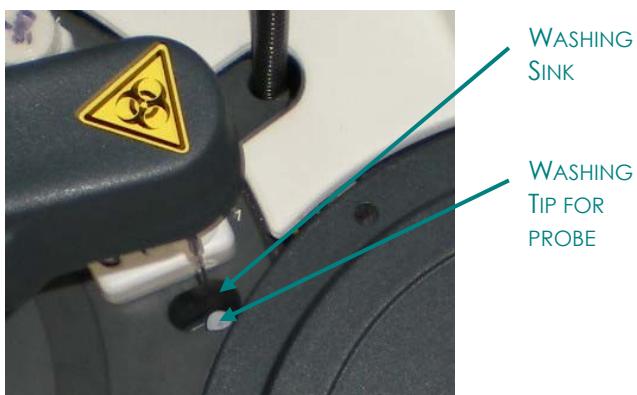
**Figure 27:** Probe Washing Pump

Following each dispensing cycle, the instrument performs a probe washing cycle by enabling the electrovalve and the washing pump. Washing cycles have been tuned at factory to reduce cross-contamination and avoid sample and reagent carry-over.



### 5.3.3. Probe Washing Sink

The washing sink is a well located in centre of the working area, between the reagent and sample wheels and the reading cuvette tray. After dispensing, the probe is rinsed into the white tip, within the washing sink, in order to wash the inner and outer surfaces.



**Figure 28:** Washing Sink

To discharge the washing sink, the system automatically starts an aspiration pump to empty the well once after any 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 reading of cuvette Absorbance.
- Optical group.
- Cuvette washing station.

The ARM assembly provides to dispense the reaction solutions into the cuvette for incubation and reading according to the parameters defining any method. Each cuvette, at the end of its incubation time, is positioned in front of the optical group; in this way the photometer can read the colour developed by the reaction. After the reading and according to the scheduling of the management system, the washing station provides to discharge the products of the reaction and the washing of the cuvette itself for reusing.



**Figure 29:** Incubation and Reading Assembly and Washing Station

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 will be then crossed by the optical path. The reading group provides the selection of the wave-length, by moving the filter tray 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 used to contain solutions to be incubated and read.

When requested during the machine cycle, the cuvette tray rotates for placing the right cuvettes under the sampling probe.

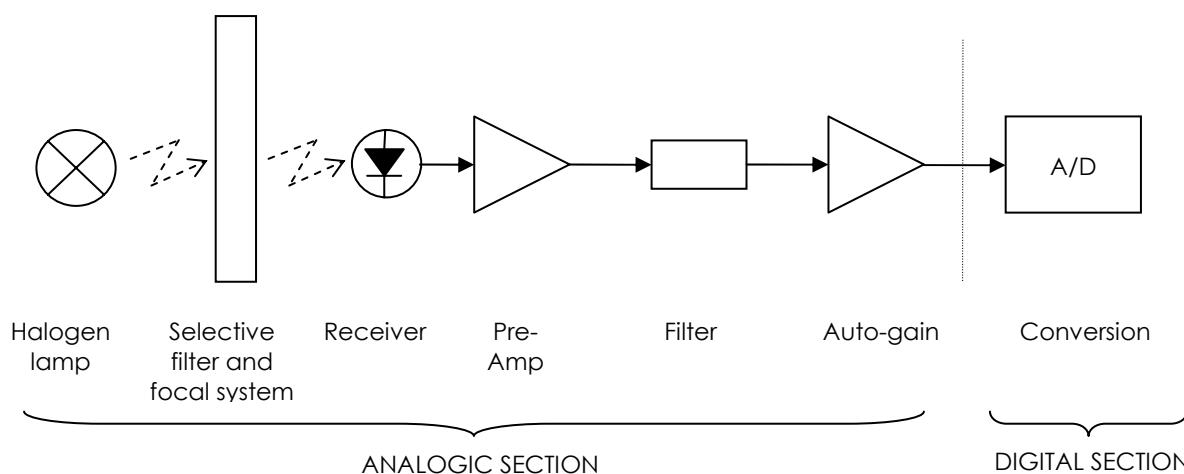
At the end of any single incubation time, during which the system continues the sampling in other cuvettes, the particular cuvette to be read is moved in front of the optical group. After reading the cuvette is discharged from liquids, washed and dried by the washing station. After being washed, the cuvette is optically checked in order to verify its good transparency and to update 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, skips and doesn't use it until it tries to wash it again. If, after three more washing cycles, the cuvette is still dirty, the system will ask for replacing it with a new one by marking it in red colour.



This assembly is kept at constant temperature in order to maintain at  $37,0^{\circ}\text{C} \pm 0,2^{\circ}\text{C}$  the temperature of the solutions in the cuvettes (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 schematic. 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 boundary conditions change.



**Figure 30:** 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:

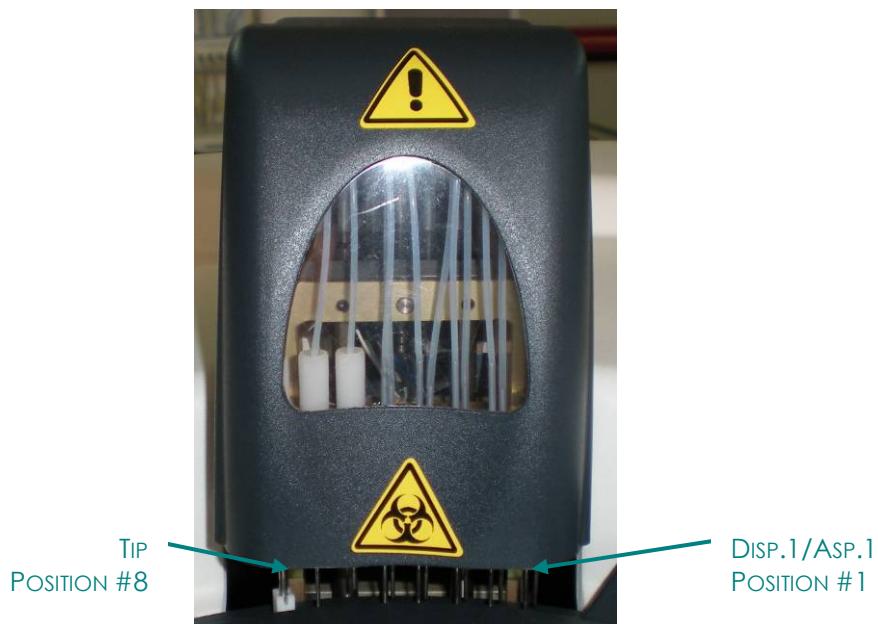
- 340nm
- 405nm
- 492nm
- 505nm
- 546nm
- 578nm
- 630nm
- 700nm.

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



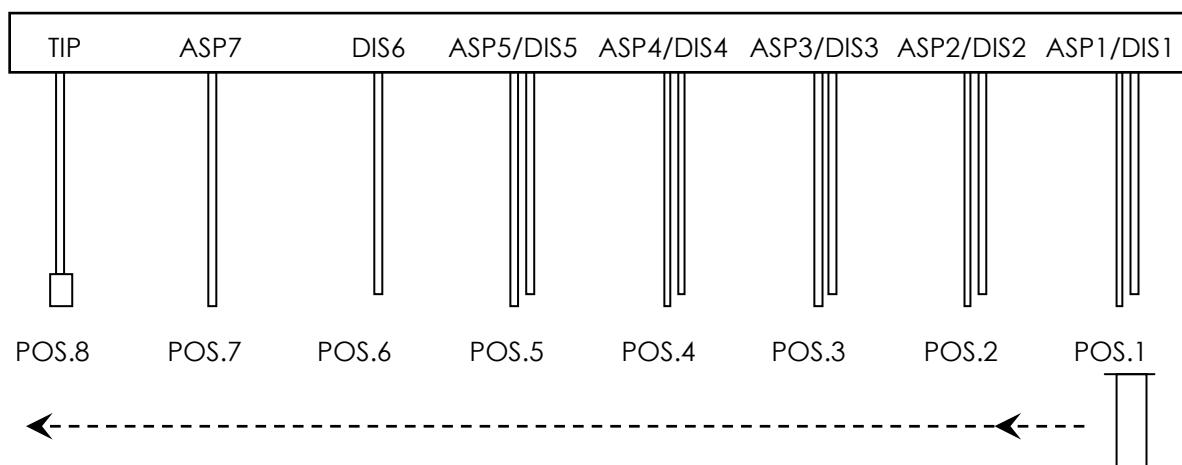
### 5.3.4.3. Washing Station and Pumps

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).



**Figure 31:** Washing Station

The washing station architecture has been shown in the following picture:



**Figure 32:** Washing Station Scheme

The washing station includes:

- 6 peristaltic pumps, for the washing solution dispensing (all peristaltic pumps are placed behind the front panel of the instrument);



- 2 diaphragm pumps, for aspiration and drying of the cuvettes (the diaphragm pumps are placed behind the back panel of the instrument).

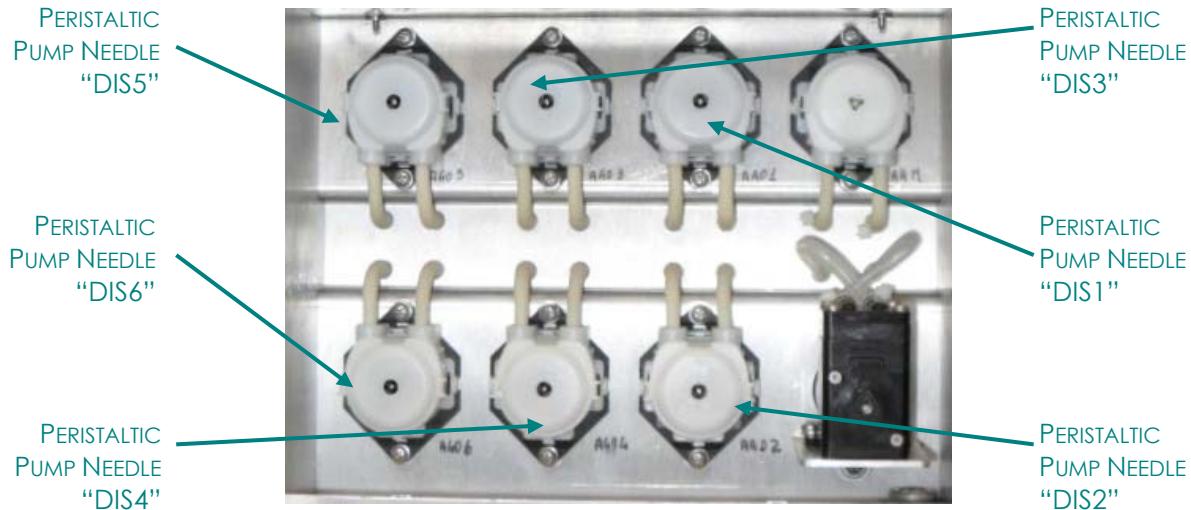


Figure 33: Washing Station Dispensing Pumps

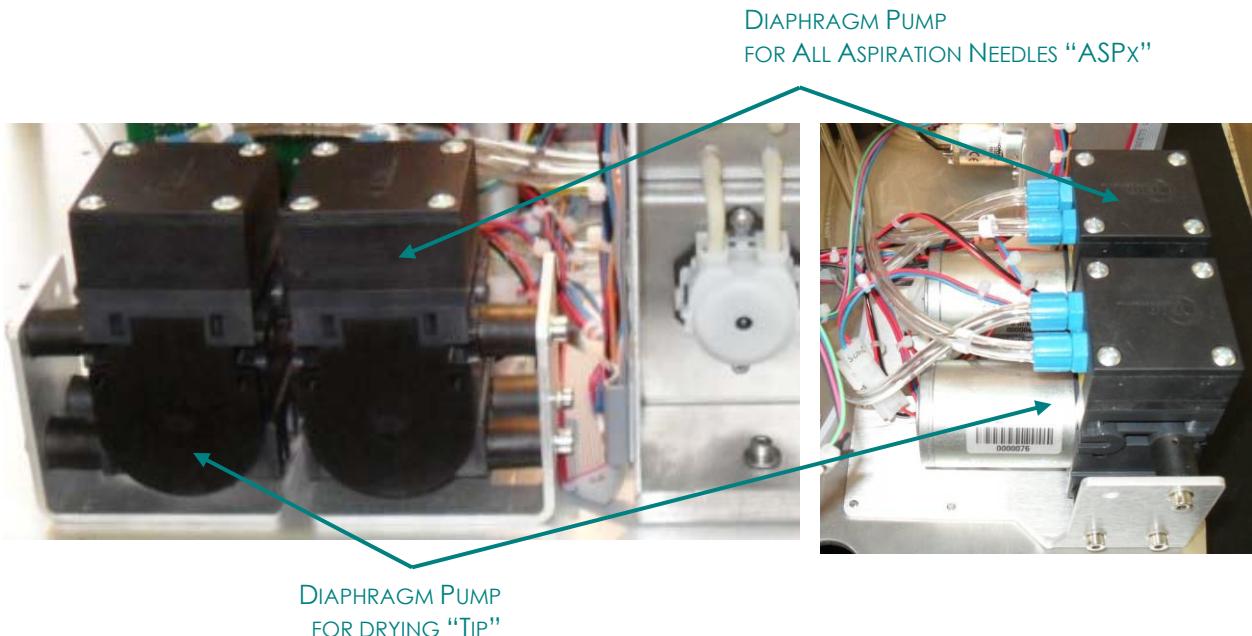


Figure 34: Washing Station Aspiration Pumps

Each of the 6 peristaltic pumps is directly connected to only one dispensation needle (short ones) of the washing station. One of the two diaphragm pumps is connected in parallel to the 6 **aspirating needles** (long ones), the second one 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 any every 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 discharged and then washed twice with Cleaner Solution; it comes out half-full;
- Positions 2÷4 (couple of needles): the cuvette is discharged and then washed twice with Systemic Solution; it comes out half-full;
- Position 5 (couple of needles): the cuvette is discharged and then washed once with Systemic Solution; it comes out empty;
- Position 6 (single needle): the cuvette is filled with Systemic Solution and then controlled optically (transparent or zero-value updating);
- Position 7 (single needle): the cuvette has been emptied out;
- Position 8 (tip): the cuvette has been dried from liquid residuals.

Dedicated washing and/or reading cuvette cycles are automatically run by the system at start-up and shutdown 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.

Cuvette whose absorbance is out of the allowed range are automatically “marked” by the system and not used in subsequent sampling cycles. When the “marked” cuvette reaches once more the washing station, it is washed and read again; this up to the reaching of the acceptable value and anyway within three times. In case this would not be possible the instrument invites the user to replace it by colouring it 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.

### 5.3.5. Barcode Reader (option)

KROMA can be equipped on request with a barcode reader integrated into the instrument and fixed to the sampling ARM assembly. 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. All 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.

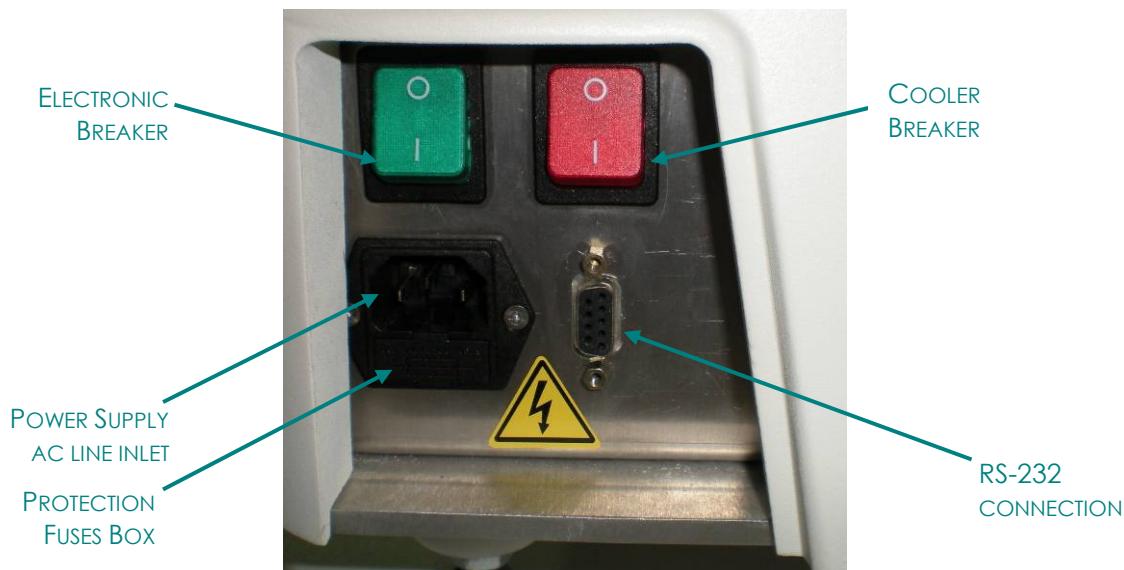
The digital control circuit, the data acquisition and signal conditioning circuits have been shielded and placed far away by the power circuits. Thus electrical switching Noise influence has been minimized.

### 5.3.7. Power Supply Units

The instrument includes a **filtered universal 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 to 240Vac**, whose frequency ranges from **47Hz to 63Hz** without voltage selections required (except that for PC).

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

- The main breakers (electronic and cooler).
- Two line protection fuses.
- One line filter and one suppressor.
- The supply cable inlet.
- The RS-232 serial connector (DB-9 F).



**Figure 35:** 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.**

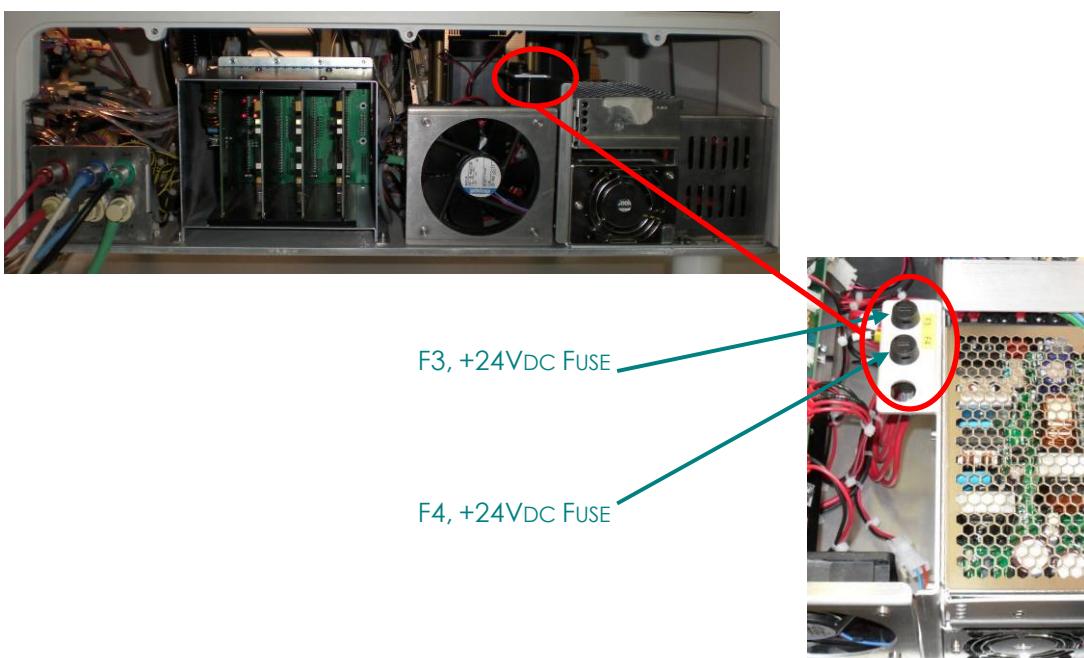
The internal low voltage +24Vdc supply lines are protected by two fuses placed inside of the instrument, on a support behind the right side panel and next the power supply box.



**Figure 36:** Rear Panel

The fuse bracket includes 2 fuses:

- Fuse F3: size 5mmX20mm, rating 8A/250Vac, T-Type (delayed).
- Fuse F4: size 5mmX20mm, rating 8A/250Vac, T-Type (delayed).



**Figure 37:** Internal Fuses



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

The refrigeration unit (option), is fed with a dedicated +12Vdc power supply protected against over-current.

**WARNING**

**When replacing or controlling 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. KROMA Software and User Interface

KROMA 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) in serial connection with the instrument KROMA. 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.

Within any menu, currently displayed on the monitor, the operator is informed by the system when any functional alarm rises up; the system activates the acoustic buzzer (beeper) and a window that explain the problem and the resolution of it.

A proximity sensor controls if the upper instrument sampling probe protection defence is closed; in case it's open during the run, the sampling arm, 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 protection defence open.

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

#### **WARNING**

**The producer recommends not running on the PC any other software different from the KROMA 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

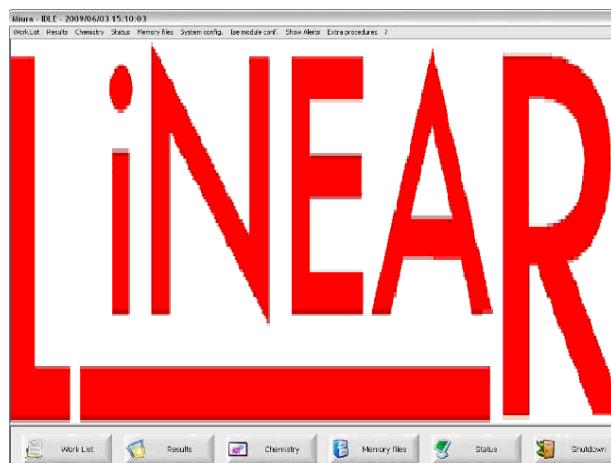
The KROMA management software is organized in two main modules following a Client/Server architecture.

At lower level, the KROMA Server 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 Client represents the User Interface, the User interacts with it. Client and Server exchange data, information and commands through a TCP/IP protocol.

All results are stored in the PC HD 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 (option).

**Figure 38:** User Interface

The following paragraphs briefly describe the main menus and summarize the most important functions of the KROMA 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 seven 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 cover before running the system.

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 and/or reagent 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 working session execution the PC visualizes:

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

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

- To run auto-zero cycles (includes tubing refilling and probe/cuvettes washing) through the *StartUp* command.
- To run rinsing cycles for the sampling probe (includes arm reset), through the *Smp ARM Rinsing* command.
- To run the optical group gain calibration cycles (includes cuvette washing and auto-zero procedures), through the *Gain Calibration Cycle* command.
- To run cuvette extra-washing procedure with a special solution, through the *Extra wash* command.
- To request a single cuvette in the middle of the front aperture for replacing it, through the *Move cvt tray* command.
- To hibernate and to wake-up the system.

#### 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.

In a separate sub-menu it is possible to display results of standard (calibration) and controls (QC). Another sub-menu is for the manual managing of 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 curve and to check their values (when required) and factors.

### 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 different keys (like name, date, ...). It is also possible to export the result of the research into special text files. That's valid for patients as for standards and 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.

### 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)

KROMA 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 (option)

KROMA 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

This section describes the modes and measurement conditions of the instrument performances; calculation methods are statistic or of indirect type.

#### 6.1. General principles

In the following paragraphs 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:** is cuvette contamination during tests; 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 obtained (normalization to 60min).

The tests, briefly described in apposite company documents.

#### 6.2. Performances

The performances considered for evaluation are those necessary to check the correct functions and parameters:

- Photometer and optical group;
- Dispensing assembly;
- Cuvette washing station;
- Carry-over minimizing;
- Instrument throughput (machine cycle time check).



### 6.2.1. Photometer and optical group

The test is carried out by evaluating precision and accuracy obtained over the values of a series of readings of the same liquid solution.

### 6.2.2. Dispensing Assembly

The test is carried out by evaluating precision and accuracy obtained over the values of a series of readings of the same liquid solution dispensed by the instrument, and comparing them with the readings obtained by manually dispensing the same quantities.

### 6.2.3. Washing Station

This test checks the cuvette washing by evaluating, on a zero-concentration solution, the quantity of a high concentration reaction residual left.

### 6.2.4. Carry-over

This test is used to check the contamination among various reaction solutions. It is performed evaluating the contamination among a solution a high concentration solution and other zero-concentration solutions.

### 6.2.5. Instrument Throughput

This test is used to verify that the number of tests (belonging on the same method) carried out by the instrument in a fixed time complies the specifications.

The measurement is performed measuring the break time between the first and the last result issued (or by counting how many results can be obtained in an hour starting from the first available). It is expressed in test/hour.

## 6.3. Calculations

The following formulas can be applied to the OD (Absorbance A) test results to get the required values.

Calculation of the average value:

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

where:

- $OD_m$  = average value
- $OD_i$  = measured value



- $n$  = number of determinations.

If "n" determinations of the same sample have been carried out, all values are distributed all around its average value called "the most probable value". Clearly, more the more determinations the more the value is statically reliable.

Calculation of the standard deviation:

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

Where:

- $SD$  = standard deviation,
- $OD_m$  = average value,
- $OD_i$  = measured value,
- $n$  = number of determinations.

This is the parameter that considers the distribution of the determinations all around the average value: a system is defined precise when a small dispersion from the average value is obtained. Hence, to evaluate the quality of the system, the distribution of the determinations around the average value must be considered.

Calculation of the coefficient of variation (index of precision):

$$CV = \frac{SD}{OD_m} \cdot 100$$

Where:

- $CV$  = coefficient of variation (in %),
- $SD$  = standard deviation,
- $OD_m$  = average value.

This parameter evaluates the precision of the data obtained; it gives in percentage the measure of the result dispersion around the average value (low values stand for higher precisions and vice-versa).

Calculation for accuracy (index of accuracy):

$$ACC = \frac{|OD_m - OD_r|}{OD_m} \cdot 100$$

where:

- $ACC$  = accuracy
- $OD_m$  = average value
- $OD_r$  = reference value.

This parameter evaluates the data accuracy; it gives the percentage gap to the real value (low values stand for higher accuracies and vice-versa).



## 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 management system through the detailed explanation of all menus;
- setting-up and preliminary operations;
- description of the operating procedures;
- additional functionalities.

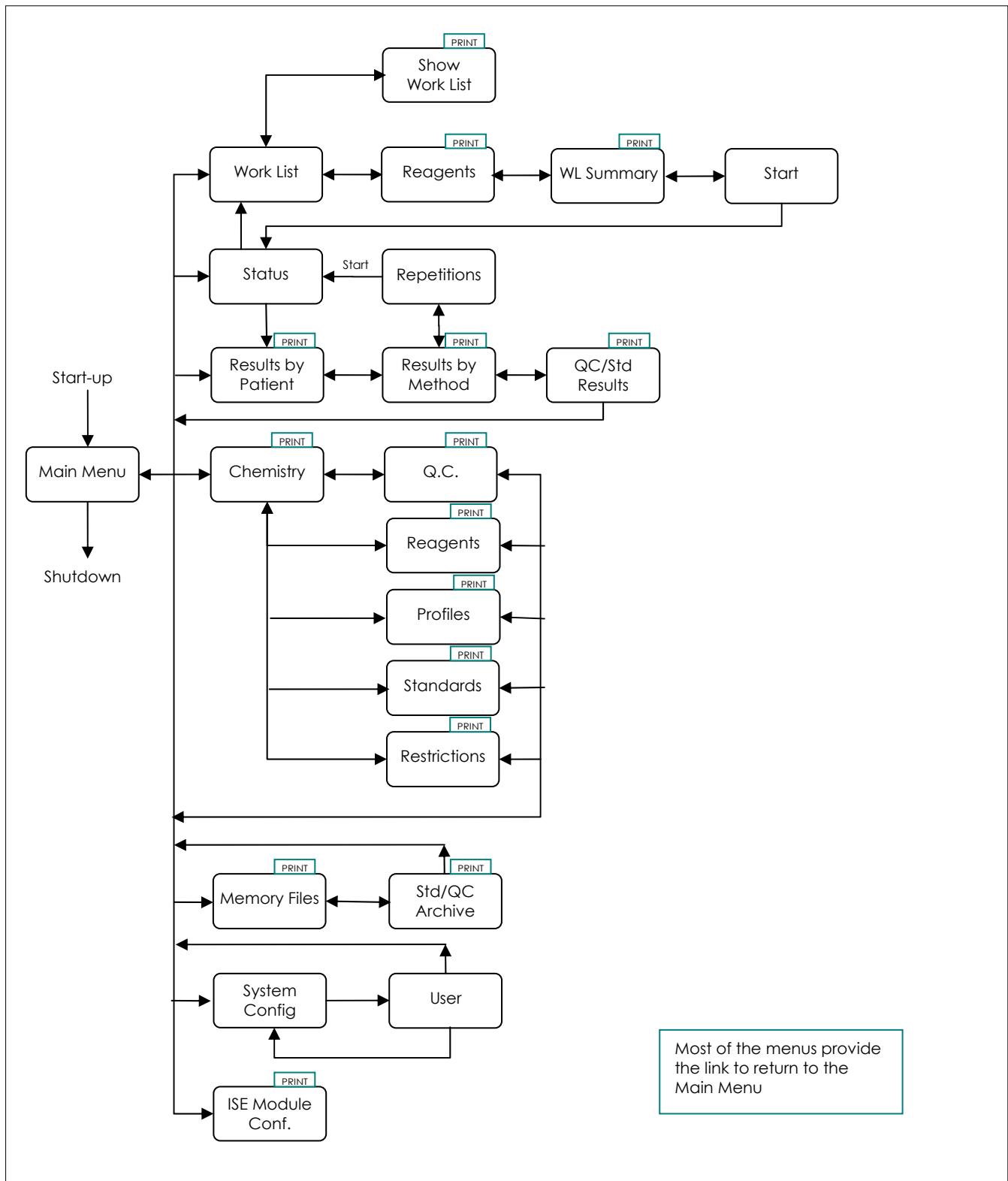
#### 7.1. Management Software Description

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

A password allows the operator to login at one of three levels of operation; only the authorized personnel can change it.

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.

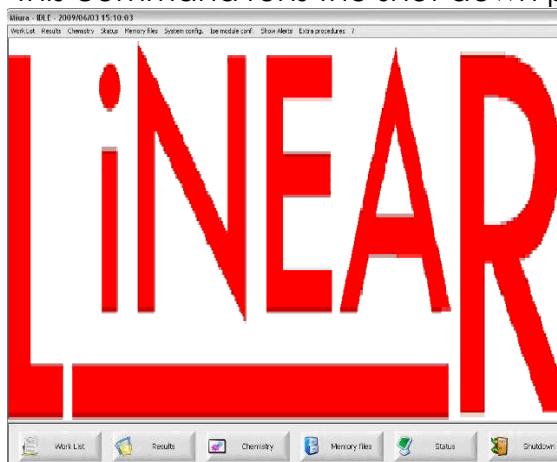
**Figure 39:** Software, SW Functional Drawing



### 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 and 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 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 in stand-by where it allows some more auxiliary functions.
- Shutdown, this command runs the shut down procedure.



**Figure 40:** 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.

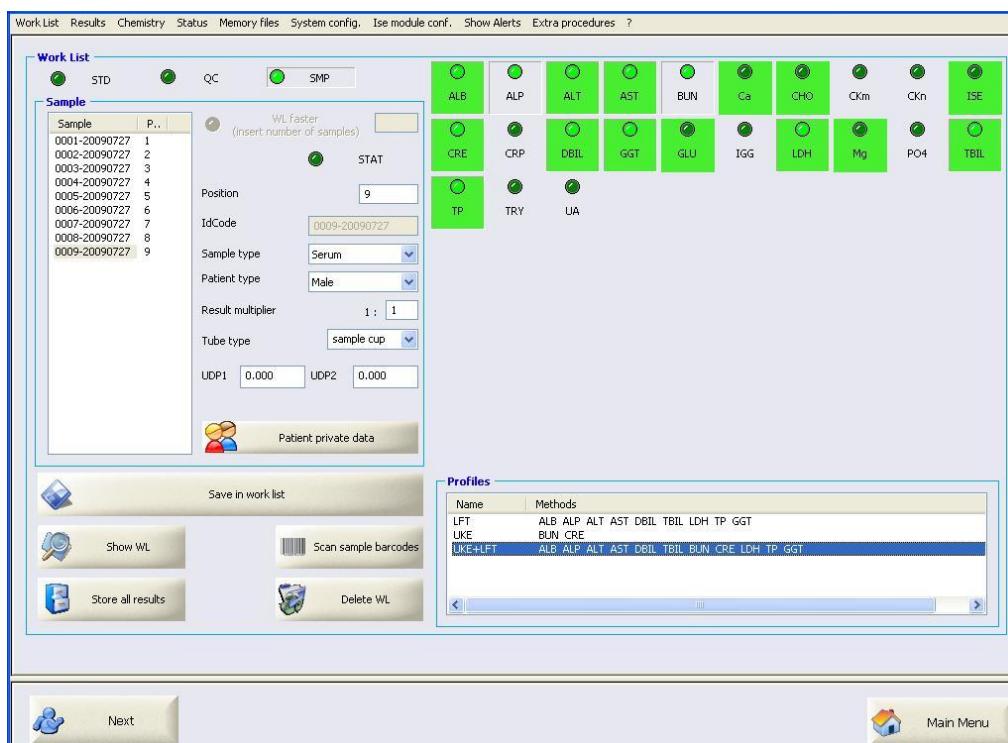
The operative fields and the operational commands included have the following meaning:



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"><li>• reset of alarms;</li><li>• probe rinsing and arm reset;</li><li>• cuvette extra-wash cycles;</li><li>• optical gain calibration cycles (includes wavelength gain equalization, and cuvette auto-zeroing and washing);</li><li>• start-up procedure, including: tubing refilling, cuvette washing and auto-zeroing;</li><li>• replacing of cuvette;</li><li>• visualization of reagent tray configuration and of cuvette status;</li><li>• system hibernation and wake-up.</li></ul> 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"><li>• the real time analysis progress for each sample in work list;</li><li>• the real time status for each reagent used in work list;</li><li>• the real time status for each cuvette;</li><li>• the status of each process step, in a special status window;</li><li>• the operating status of the instrument.</li></ul>
Shutdown:  Shutdown	This command quits the system by running the shutting down procedure. This procedure gives the operator the chance to run a final washing of all cuvettes before exit ( <b>the manufacturer suggests to run always the washing procedure</b> ). It also allows the change of user by asking for a different login.

### 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 41:** Work List Menu

This menu shows the actual Work List constantly on the left, while methods have been listed into one panel on the right. The panel can contain a maximum of 60 available methods. Methods can be already on board in assigned positions, then they are green back-lighted or not. Any of them can be chosen and programmed in the Work List.

Any programmed sample is added in the sample window. 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.

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 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 samples whose results have not yet been validated and archived.

Patients whose results must be stored in the archive lie in that list and they will be removed only upon storing; 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 stored in memory 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:

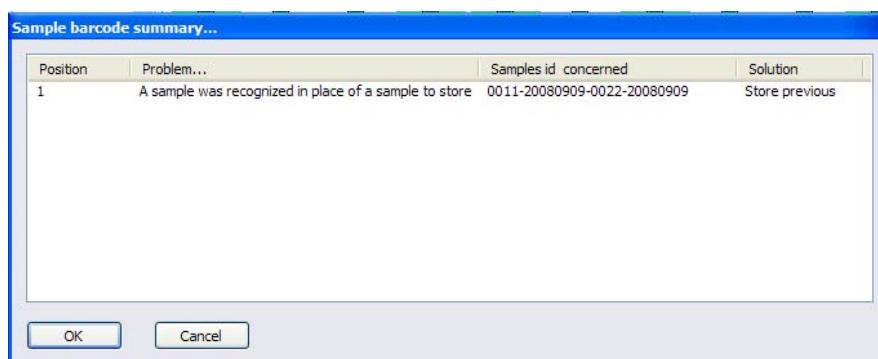
Field/Command	Function
SMP:	this flag must be activated when a sample must be programmed in the Work List; in this case the system shows in the right panel the list of the methods set as visible.
QC:	this flag must be activated when a standard/calibrator must be programmed in the Work List; in this case the system shows in the right panel the list of the methods that can be calibrated because a standard has been set.
STD:	this flag must be activated when a control must be programmed in the Work List; in this case the system shows in the right panel the list of the methods whose control/s values have been set.
Sample window:	this window shows all samples (patients, standards/calibrators and controls) 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).
WL faster (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 in the range from 1 to 9.
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 as 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 in the range from 1 to 9. The software automatically shows the first free position in the sample tray. Samples not assigned to a position on the tray have number "0".
IdCode:	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, <b>the system automatically assigns a code</b> whose format is the following: <ul style="list-style-type: none"><li>• xxxx,      it is the progressive number within the day;</li><li>• -,           dash</li><li>• yyyy,      it is the current year;</li><li>• mm,        it is the current month;</li><li>• dd,        it is the current day.</li></ul>



Field/Command	Function
	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 <b>L.I.S.</b> , this field is automatically filled by the software with the <b>IdCodes</b> given by the host system and correspondent to the sample <b>bar-code</b> .
	Duplication of Sample ID codes in the same solar day is checked controlled and permitted only on operator request.
Sample type:	this pull down menu allows the selection of the type of sample; the following choices are allowed: <ul style="list-style-type: none"><li>• Serum;</li><li>• Urine;</li><li>• CSF;</li><li>• Plasma.</li></ul>
Patient type:	this pull down menu allows the selection of the patient type; the following choices are allowed: <ul style="list-style-type: none"><li>• Male;</li><li>• Female;</li><li>• Paediatric.</li></ul>
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"><li>• Sample tube;</li><li>• Sample Cup, when using 3ml sample cup.</li></ul> The system automatically gives as default what it has been selected in the System Config. Menu: "Default sample tube type" field; the operator can anyway change any particular tube type in case that sample has different one from default. In this way it is possible to use mixed type of tubes in the sample tray and within the same run.
UDP1:	this field allows the user to 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 the formula itself.
UDP2:	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 the formula itself.
Patient Private Data:	this command opens a window whose fields can be filled with the personal and administrative patient data.
Save in Work List:	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



Field/Command	Function
Scan sample barcode:	<p>previous menu.</p> <p>with this command the system runs the scanning of the sample barcodes labelling the tubes in the tray. The ARM turns one or more times to allow 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.</p> <p>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.</p> <p>When some problems are 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.</p> <p>The message window has been represented below; possible problems are the following:</p> <ul style="list-style-type: none"><li>- Case of a sample that have been processed but not yet validated and archived: in its position the reader has detected a <b>new sample</b>; the system stores the old sample results and it accepts the new sample to be processed in its position.</li><li>- Case of a sample that have been processed but not yet validated and archived: its position has been detected as <b>free</b> (or anyway the barcode is <b>not readable</b>); the system stores the old sample results and it sets the position as free.</li><li>- Case of a sample that have been partially processed and the system <b>doesn't find it</b> 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).</li><li>- Case of sample whose <b>barcode is not readable</b>: the system considers the position as free.</li><li>- Case of barcode error: the system only alerts the operator.</li></ul>



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.

In case of unreadable barcodes the operator can anyway manually modify the WL data.

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

Store all results:

This command runs the automatic storing in archive of all the results obtained for samples, standards/calibrators and controls of the previous run. Consequently, those positions on the sample tray will be cleared and made available for new WL programming.

Delete WL:

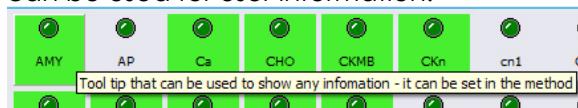
This command deletes any current Work List currently under programming. Samples in process or concluded will not be deleted.

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 the methods menu (in 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 **controls** this means that only



## Field/Command

## Function

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:



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 ( $n>1$ ) 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



Field/Command	Function
Main Menu:	tray positions. 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 a Windows-style dialog box titled "Patient private data". Inside, there are several input fields and buttons. The fields contain the following data:

Last name	Mario	First name	Rossi
Date of birth	1980/03/27	Age	27
Address	Via dei Fiori, 987 - 00100 Roma - Italy		
Email	m.rossi@provider.ff		
Phone	+4599987654321		
Bed	47	Dpt.	2
Clinic	KS78H	Request date	02/12/2007
Doctor	Bianchi		
Notes	Nationality: Italian		

At the bottom are two buttons: "Save" with a floppy disk icon and "Back" with a left arrow icon.

**Figure 42:** Patient Private Data Window

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

Field/Command	Function
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.
Birth date:	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"><li>• yyyy → year, 4 digits</li><li>• mm → month, 2 digits</li><li>• dd → day, 2 digits.</li></ul>
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).



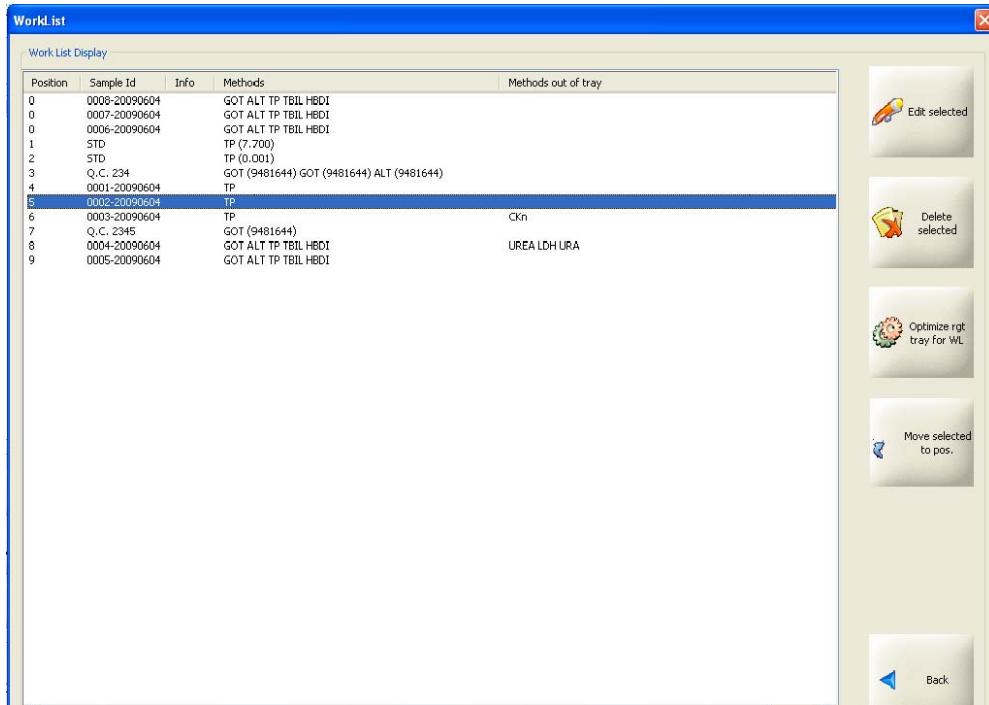
Field/Command	Function
Department:	this alphanumeric field allows the operator to introduce the department.
Clinic:	this alphanumeric field allows the operator to introduce the clinic ID.
Request date:	this alphanumeric field allows the operator to introduce the date of the analysis request. Format of the field: yyyy/mm/dd, where <ul style="list-style-type: none"><li>• yyyy → year, 4 digits</li><li>• mm → month, 2 digits</li><li>• dd → day, 2 digits.</li></ul>
Doctor:	this alphanumeric field allows the operator to introduce the ID of the doctor.
Note:	this alphanumeric field allows the operator to introduce eventual remarks.
<b>Commands</b>	
Save:	this command saves the patient data.
Back:	this command allows the operator to go back to the Work List menu without to save any modification.

The compilation of the fields above is not 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.



### 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 43:** Work List Display Window

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

Field/Command	Function
<b>Work List Display Window</b>	
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.
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 <b>not</b> present on the reagent tray and must be placed.
<b>Commands</b>	
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.
Delete selected:	if a sample has been selected with the left mouse button, this command

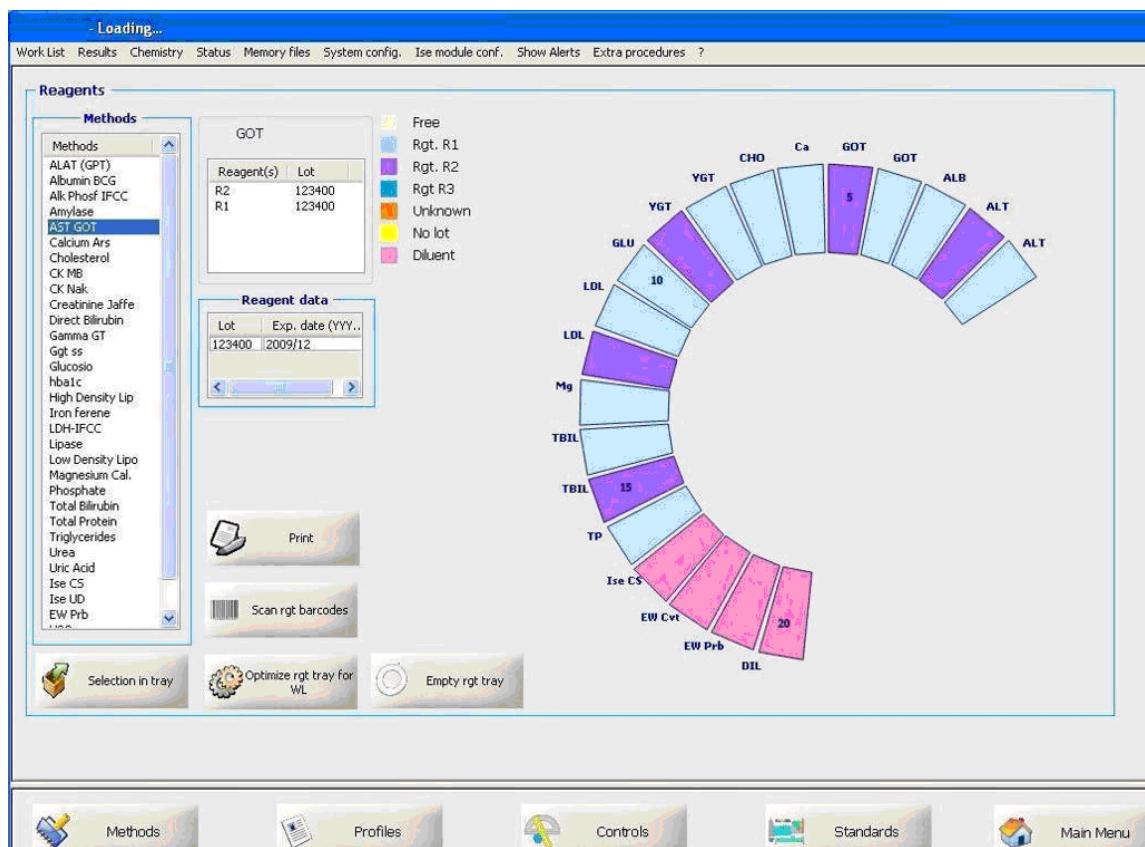


Field/Command	Function
	allows the operator to delete it. It is also possible to multiple-select more samples, following the typical Windows® mode, and to delete all of them at the same time: <ul style="list-style-type: none"><li>• Selecting a range of samples:</li></ul>
	click with the left mouse button 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.
	<ul style="list-style-type: none"><li>• 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.</li></ul>
Optimize rgt tray for WL:	this command optimizes the reagent tray configuration in order to satisfy the Work List parameter needs: it will include in the tray positions only needed reagents clearing what is not needed.
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.
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* from the menu *Work List* or the command *Reagents* from 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 44:** 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 any single reagent from its position on the tray, the operator has to click, drag and 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 visible. The operator can select with the left mouse button one of the methods to display in the window Reagents the associated reagents to place on-board.												
Reagents window:	when the operator selects one method in Methods, 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"><li>• For mono-reagents methods only R1 is visualized.</li><li>• For bi-reagents methods R1 and R2 are visualized.</li><li>• For three-reagents methods R1, R2 and R3 are visualized.</li></ul> 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 lot number.												
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.												
Print:	through this command the operator can send a print-out of all reagents and their positions placed on the reagent tray.												
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><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												



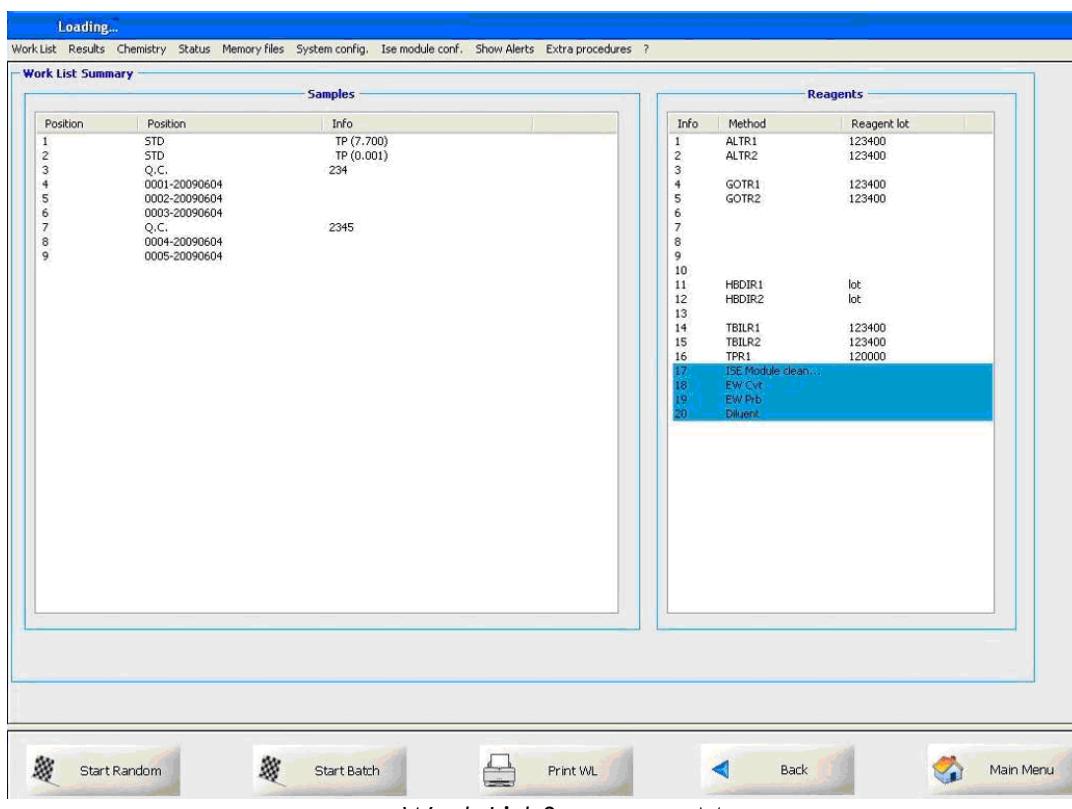
Field/Command	Function
	been read and understood but the method is not included in memory); <ul style="list-style-type: none"><li>• Yellow: No lot position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot number, that has to match with that provided on the reagent bottles);</li><li>• 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).</li></ul>
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, <b>previously selected</b> , in the reagent window. The multiple selection of more samples is possible following the typical Windows® mode: <ul style="list-style-type: none"><li>• 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 ==&gt; the range is then selected.</li><li>• 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.</li></ul> 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 poitions.
<b>Commands</b>	
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 controls to be processed.



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

Field/Command	Function
<b>Samples Window</b>	
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).
<b>Reagents Window</b>	
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.



Field/Command	Function
Reagent lot:	this column, not editable, shows the reagent lot code (the word "lot" is shown in case code is missing).
<b>Commands</b>	
Start Random:	this command allows the operator to start the working session in <b>Random mode</b> . 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 <b>Batch mode</b> . 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.



- Loading...

Work List Results Chemistry Status Memory files System config... Ise module conf... Show Alerts Extra procedures ?

Work List Summary

Samples Reagents

Position	Sample Id	Info
1	0021-20090618	
2	0022-20090618	
3	0023-20090618	
4	0024-20090618	
5	0025-20090618	
6	0026-20090618	
7	0027-20090618	
8	0019-20090618	
9	0020-20090618	

Scheduling WL errors

Met...	Problem...	Action
GLU	Few tests available in smart card. Not all patient can be scheduled.	Skipped in scheduling
HDLC	No reagent in the tray	Skipped in scheduling
HDLC	Few tests available in smart card. Not all patient can be scheduled.	Skipped in scheduling

Start Cancel

Start Random Start Batch Print WL Back Main Menu

Starting session with alerts



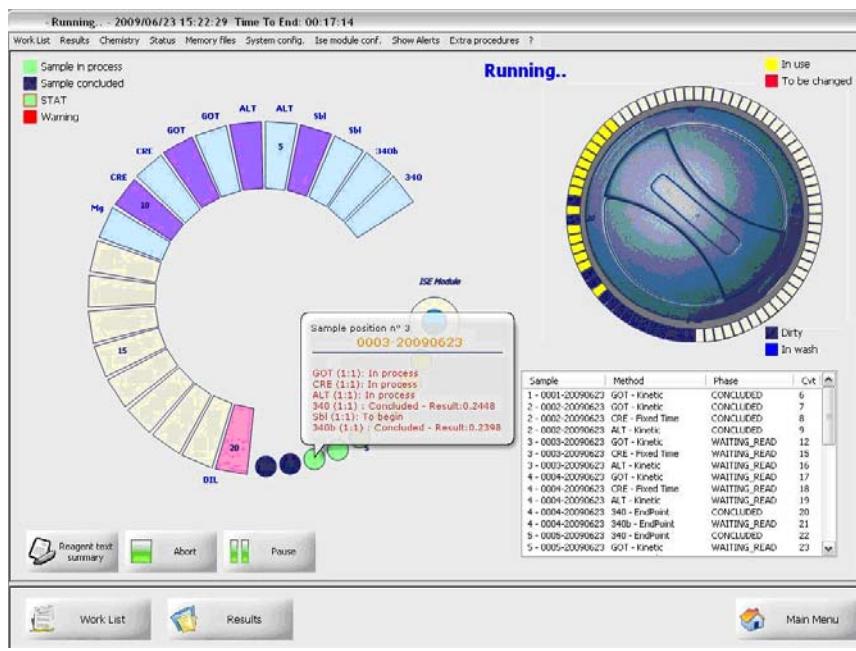
### 7.1.5. Status Menu

The Status menu shows the operator the actual instrument status under operating conditions. Basically this menu can show 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.

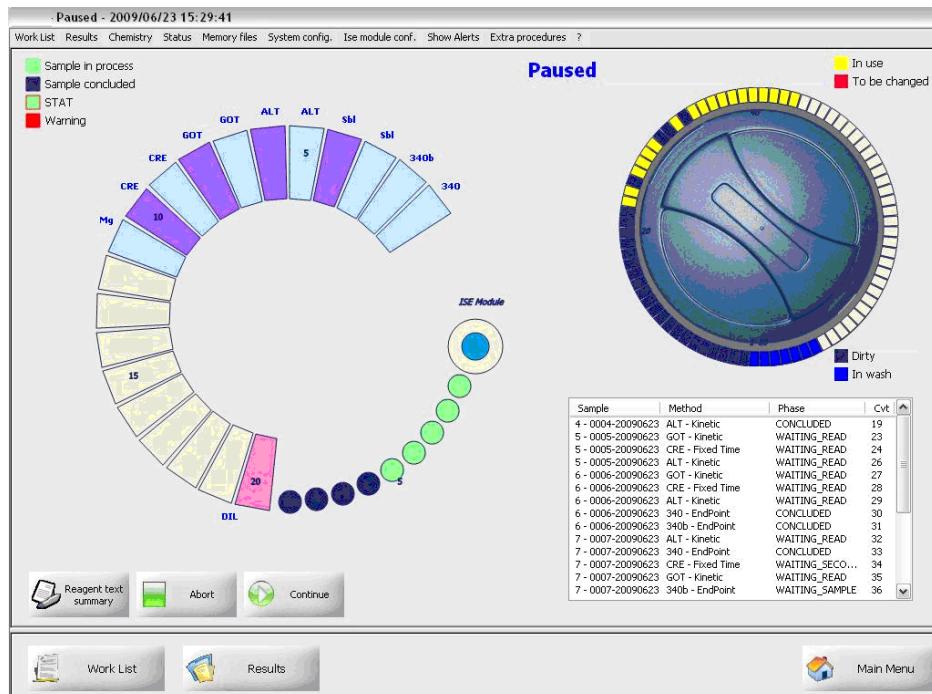
#### STATUS – For system in running

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

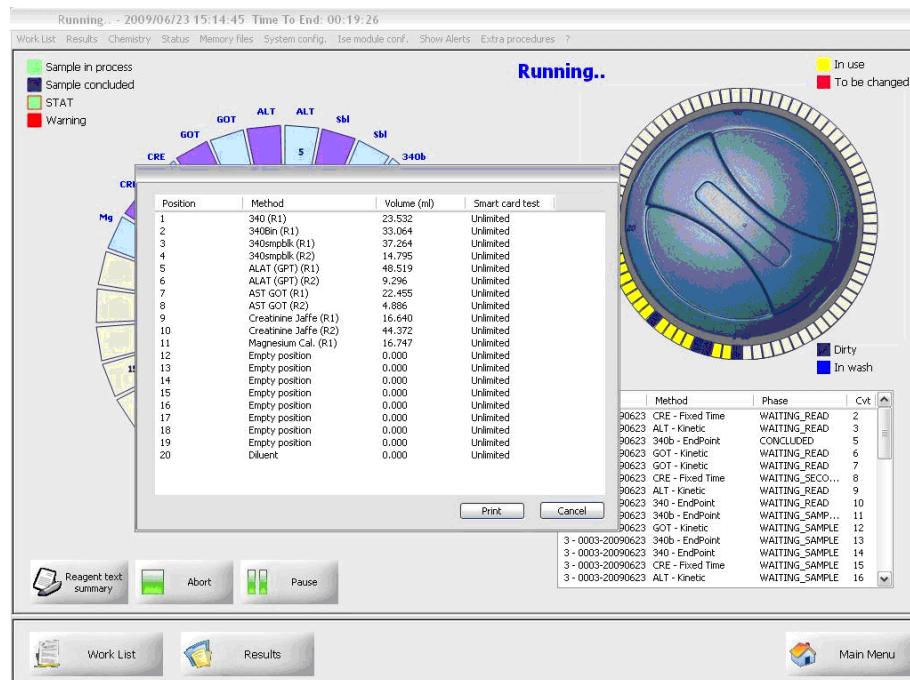
- the actual status of the instrument (running, in pause, in alarm, in warning, etc.);
- the status of any single analysis (sample, control and standard) that is under process and then not yet concluded; each position of the sample tray shows, in run-time, the progress through the use of different colours depending on the state of the analyses;
- the configuration of the reagent tray and the status of the reagent bottles or methods (residual volume or number of tests, 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.



Status Menu - WL in run



Menu Status – System temporary in Pause during a run



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



Field/Command	Function
Yellow position:	Work List.
Green position:	it identifies a sample included in the Work List but not yet processed.
Dark blue position:	it identifies a sample in processing phase.
Any-colour position with red border:	it identifies a sample completely processed whose results can be stored in archive.
Red position:	it identifies a sample included in the Work List as "urgent" ( <b>STAT</b> ).  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"><li>• to definitely abort the residual analyses and to conclude the sample (<b>Abort</b>),</li><li>• to refill the empty tube with more sample and to perform the rest of the analyses (<b>Retry</b>),</li><li>• to exit, leaving the sample as it is postponing the decision (<b>Exit</b> - the system doesn't consider the run of analysis as finished until the operator decision whether to abort or to continue).</li></ul> In case it is chosen to refill the sample, the operator needs: <ul style="list-style-type: none"><li>• to click with the left mouse button the button <i>Pause</i> on the monitor, </li><li>• to wait the arrest of both sampling arm phases,</li><li>• to open the protection defence,</li><li>• to refill the sample,</li><li>• to close the protection defence,</li><li>• to click with the left mouse button the button <i>Continue</i> on the monitor. </li></ul>

**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"><li>• Diluent - distilled water or physiological solution (this solution is used for any dilutions),</li><li>• EWP – Extra Washing Probe solution (this solution is used for probe extra-washing in case of restrictions between methods),</li><li>• EWC – Extra Washing Cuvette solution (any position, this solution is used for cuvette extra-washing in case of restrictions between methods or cuvette extra-washing cycles),</li><li>• ISE CS – ISE Module Cleaning solution (any position, this solution is used</li></ul> |



Field/Command	Function
Red position:	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), 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"><li>the reagent marked in red is <b>finished</b>; 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"><li>to definitely abort all the remaining analyses (<b>Abort</b>);</li><li>to replace the reagent bottle with a new one (<b>Retry</b>);</li><li>to go out leaving the reagent as it is and to postpone the decision (<b>Exit</b> - the system doesn't consider the run of analysis as finished until the operator decision whether to abort or to retry).</li></ul></li><li>the measurement of the <b>control</b>, 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"><li>to abort all the analyses related to the method (<b>Abort</b>);</li><li>to repeat the measurement on the control (<b>Retry</b>);</li><li>to ignore the result of the control and to perform however the analyses related to the method (<b>Ignore</b>);</li><li>to go out leaving the reagent as it is and to postpone the decision (<b>Exit</b> - the system doesn't consider the run of analysis as finished until the operator decision whether to abort, to retry or to ignore).</li></ul></li></ul>
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 test left).
<b>Cuvette tray</b>	
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.
<b>Scheduling window</b>	
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).
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.

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

## Notes:

- 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.
- 2- Operations are **not** necessarily listed following a sequential descending or ascending time ordering.

**ISE module icon**

It is present **only** in case the ISE Module is included and configured in the system. It shows the actual ISE Module status.  
When outer area colour is "**white**", the ISE Module doesn't show any problem during operation. It is working correctly.  
In case the outer area colour is "**red**" then the ISE Module is in alarm and it needs intervention by the operator.

**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 needs to place the instrument in Pause** in case he needs:

- to replace a reagent which is over;
- to replace, add or refill a sample;
- to add a STAT;
- to control the working area.

**The operator must open the protection defence 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.

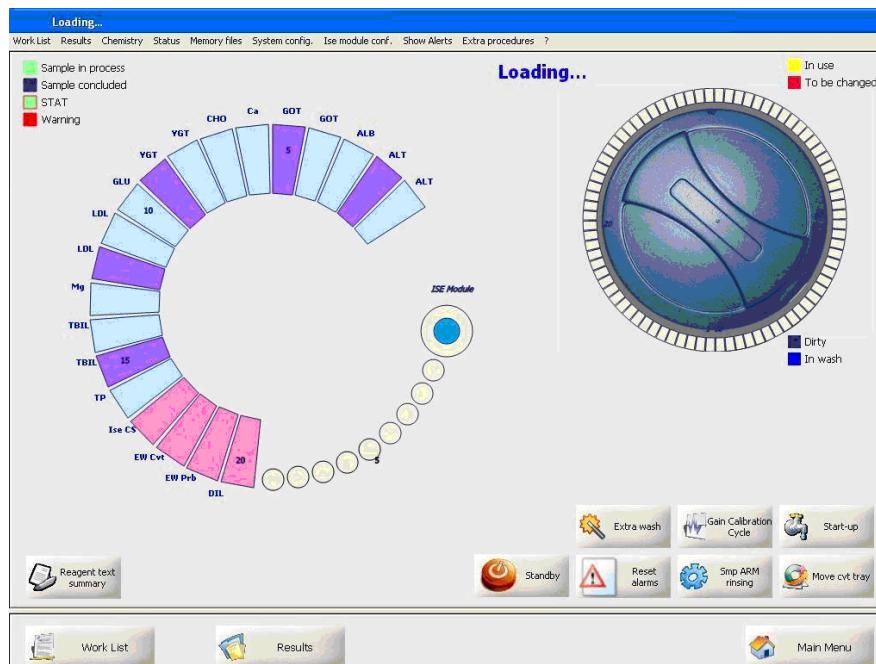


The operator can control the progress of the analysis for each sample in the tool-tip that opens when clicking with the left mouse button on any sample.

### 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 the sampling probe;
- run a complete cuvette extra-washing cycle using the dedicated cuvette extra-wash solution on the reagent tray;
- run a wavelength optical gain calibration cycle (it includes 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 in the centre of the aperture provided on the cover in front of the instrument a cuvette to replace;
- query the system to show the residual volume for each reagent;
- place the system in “stand by” (hibernation) or wake it up.



**Figure 45:** Menu Status – Loading the Idle Status

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

Field/Command	Function
<b>Sample tray positions</b>	
As per Running status, previously described.	
<b>Reagent tray positions</b>	



Field/Command	Function
As per Running status, previously described.	
<b>Cuvette tray</b>	As per Running status, previously described.
<b>ISE module icon</b>	As per Running status, previously described.
<b>Commands</b>	
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).
ARM rinsing:	this command allows the operator to run the rinsing of the sampling probe and the reset of the ARM.
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 and anyway once a week depending on the volume of analysis performed by the lab. Once a day for >1,000test/day runners.
Gain Calibration Cycle:	this command allows the operator to refill tubing, to wash all cuvettes, to 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).
Start-up:	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 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.
Standby/Wake up:	the command " <b>standby</b> " allows the operator to manually place the system in the "hibernate status". In this status the lamp, motors and heaters will be disabled in order to save power and prolong lamp life. When the system is in hibernation, this button turns to the green " <b>wake up</b> " label.



Standby



Wake up

The system **resumes** the operative Idle status in two cases:

- manually, when the operator clicks on the "wake up" command;
- automatically at a given time, if programmed in the System config. menu.

In both cases the system will enter the warming up status or not with the same rules and with the same behaviour described for the "warming up" cycles at the system start up: warming up performance and duration are just the same as for power up.

Moreover, the system can be programmed for automatic hibernation after a given time from initial Idle status (program this feature in System config. Menu); wake up modes and conditions are the same described above.



Field/Command	Function
Work List:	
Results:	
Main Menu:	

**WARNING**

**During hibernation never shut down the software as the system needs anyway to be controlled and managed.**

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*.



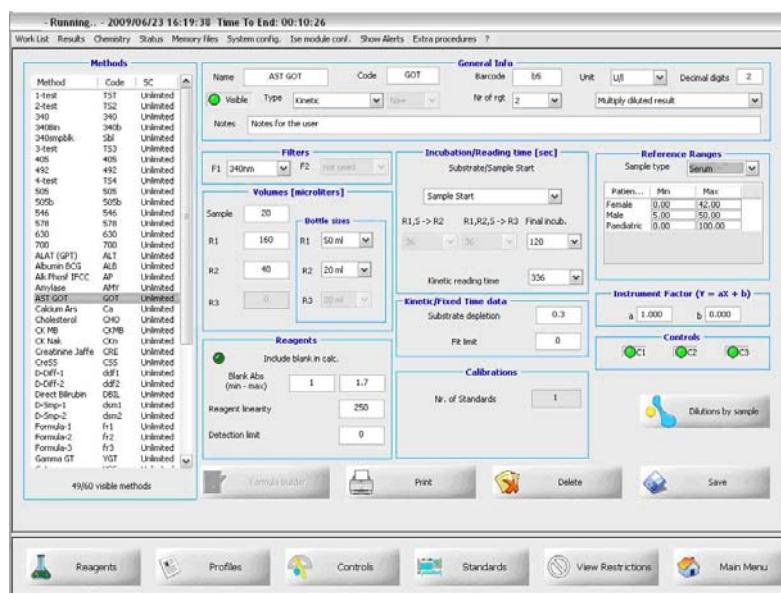
## 7.1.6. Methods Menu

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 others already used. Any method can be modified by changing fields and parameters when the method is not included in a work list to be run or whose results must be archived. 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 probe cross-contaminations. This is useful wherever it should exist a significant method incompatibility.



**Figure 46:** 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
<b>Methods section</b>	
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”.
<b>General Info section</b>	
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.
	<b>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.</b>
Barcode:	this field allows the operator to enter the two-digit code that will identifies the method as part of the barcode printed on the bottle label (if used). This two-digit code must be arranged after agreement with the producer.
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"><li>• Kinetic</li><li>• Fixed Time (Two points kinetic)</li><li>• Differential – Sample Blank</li><li>• Differential – Two reagents</li><li>• Bichromatic End-point</li></ul>



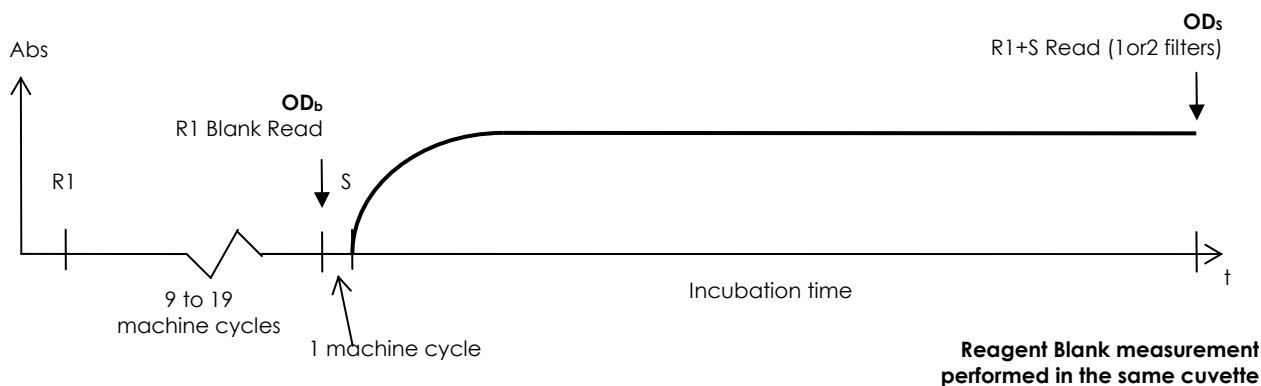
Field/Command	Function
	<ul style="list-style-type: none"><li>• End-Point</li><li>• Formula (for calculated parameters . i.e. creatinine clearance)</li><li>• ISE module electrolytes (Na+, K+, Li+ and Cl-). If ISE module has been selected, the LINEAR selection pull down menu will be enabled.</li></ul>
Units:	this pull down menu allows the user to select the <b>unit of measurement</b> to be used for the results of the analyses related to that method. The following units are available: <ul style="list-style-type: none"><li>• Abs</li><li>• UI/ml</li><li>• µmol/l</li><li>• mg/l</li><li>• g/l</li><li>• %</li><li>• U/l</li><li>• mEq/l</li><li>• mmol/l</li><li>• µg/dl</li><li>• mg/dl</li><li>• g/dl</li><li>• none</li></ul> Unit of Measurement changes do not affect results.
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/to show the method in 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.
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, 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 diluted sample by dilution ratio set during worklist programming: <ul style="list-style-type: none"><li>• Multiply diluted results: the obtained result is multiplied by the sample dilution ratio set in the method, section "dilutions by sample";</li><li>• Not multiply diluted results: the obtained result is NOT multiplied by the sample dilution ratio.</li></ul>
ISE electrolytes selection:	this pull down menu allows the operator to select the desired electrolytes. The following ISE methods are available: <ul style="list-style-type: none"><li>• Na+</li><li>• K+</li><li>• Li+</li><li>• Cl-</li></ul>
Note:	this field allows the user to introduce some text comments or notes to be



Field/Command	Function
<b>Filters section</b>	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.
F1:	this pull down menu allows the user to select the wavelength used by this method for the photometric reading (or for the first photometric reading in case of <i>Bichromatic</i> method).
F2:	this pull down menu, active only for <i>Bichromatic</i> endpoint methods, allows the user to select the wavelength used by this method for the second photometric reading in case of <i>Bichromatic</i> method. The instrument calculates: (F2result – F1result).
<b>Volumes [microlitres] section</b>	
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).
<b>Bottle sizes sub-section</b>	
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 → FOR FOLLOWING DIFFERENT CASES:**  
**Incubation/Reading Time [sec] section → valid in case of END-POINT or BICHROMATIC mono-reagent**



**Substrate/Sample Start:** this field is disabled in case of mono-reagent.

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

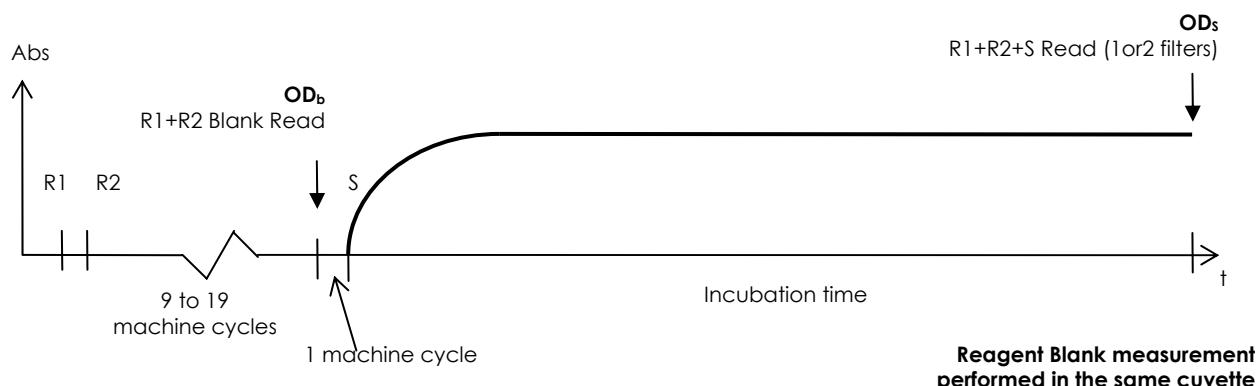
**R1,R2,S->R3:** this field is disabled in this case.

**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 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

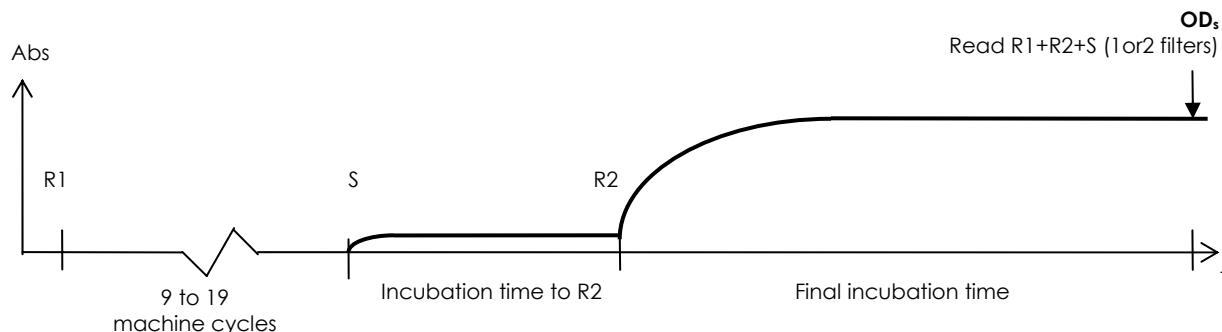
(R1 + R2 + sample).

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 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:**

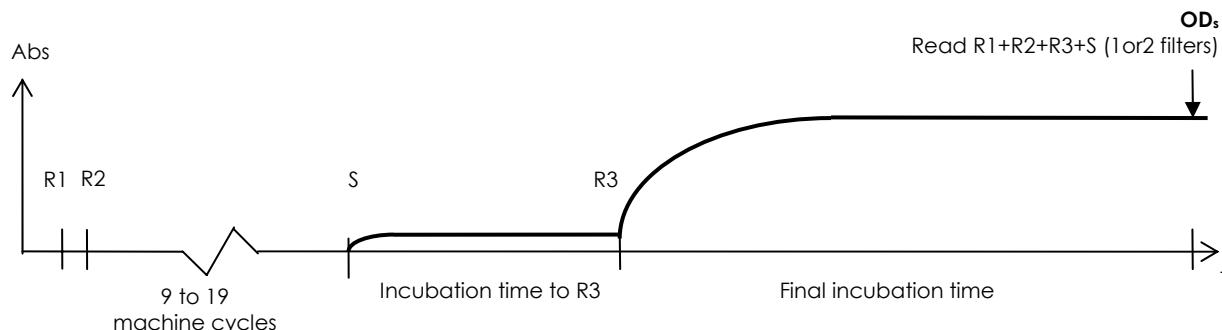
**Final incub.:**

this field 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 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:

R1,R2,S->R3:

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)

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.

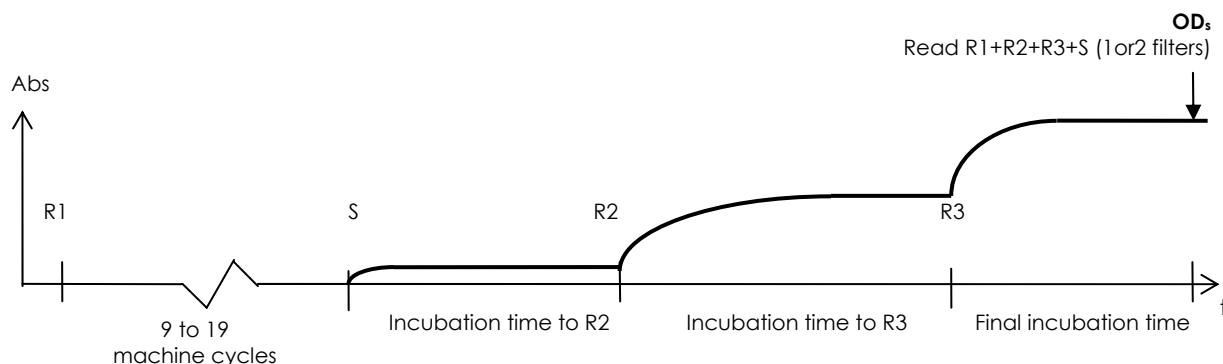
Final incub.:

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.

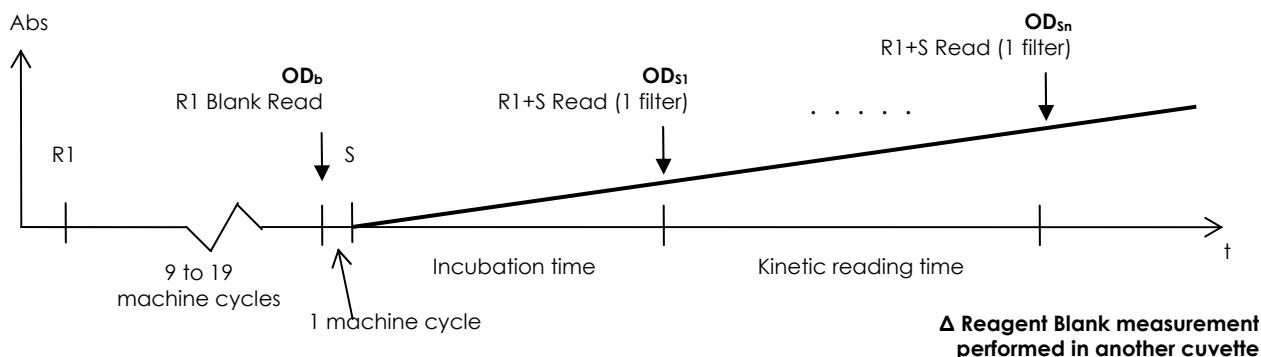
Final incub.:

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).

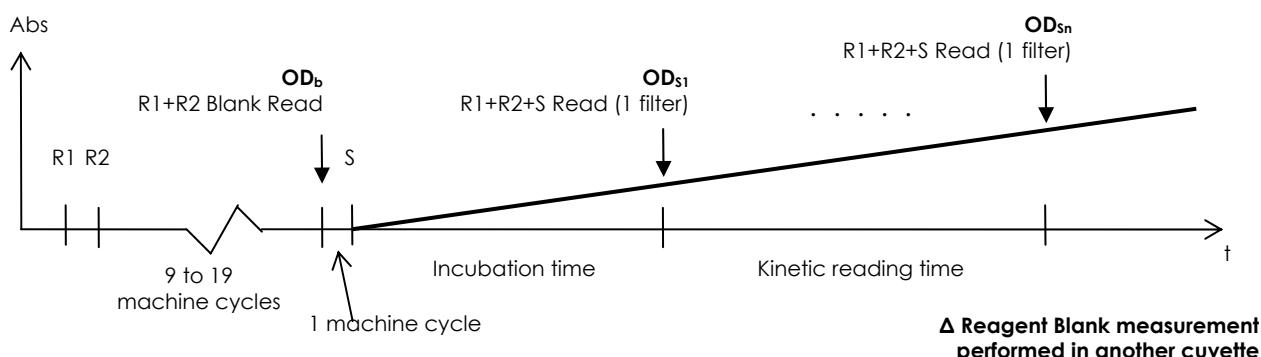
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**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:

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.

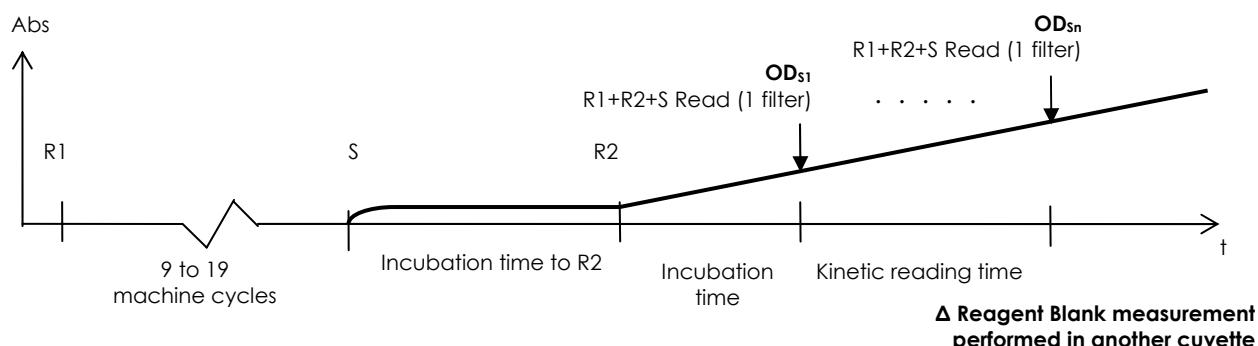
Kinetic reading time:

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 + 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.

Kinetic reading time:

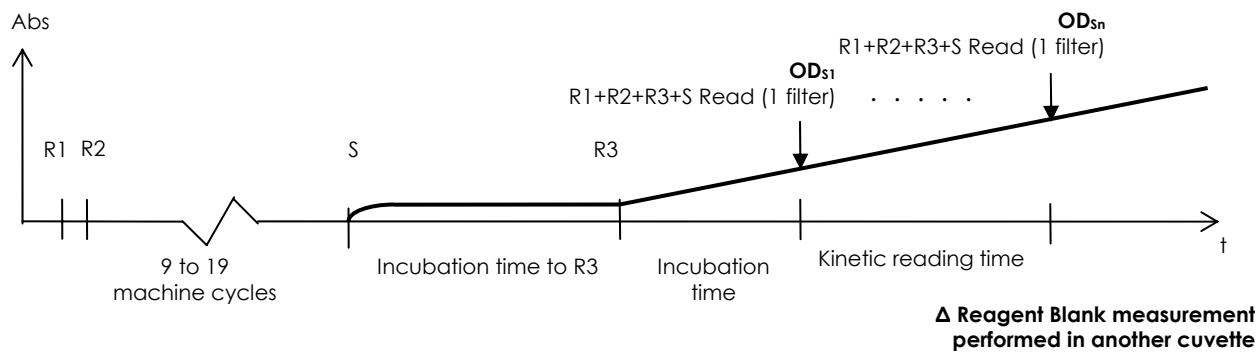
this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

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 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.

**Kinetic reading time:**

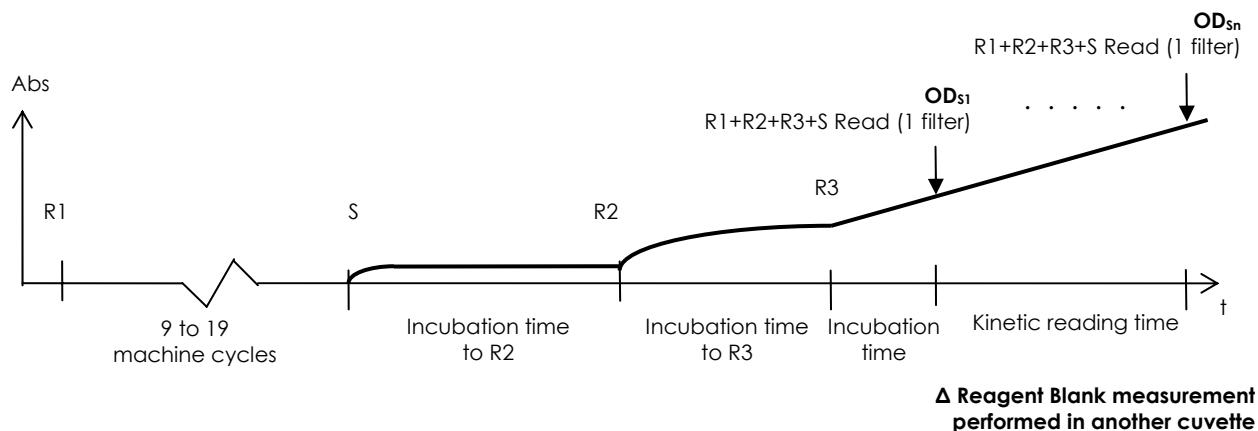
this field allows the user to enter the time (in seconds) during which the instrument performs the readings on the solution in cuvette.

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 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

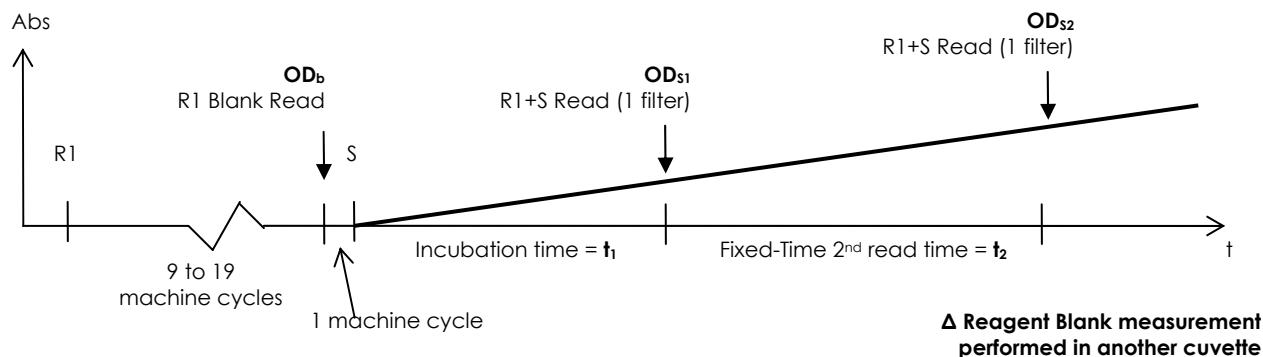
(R1 + R2 + sample + R3).

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.

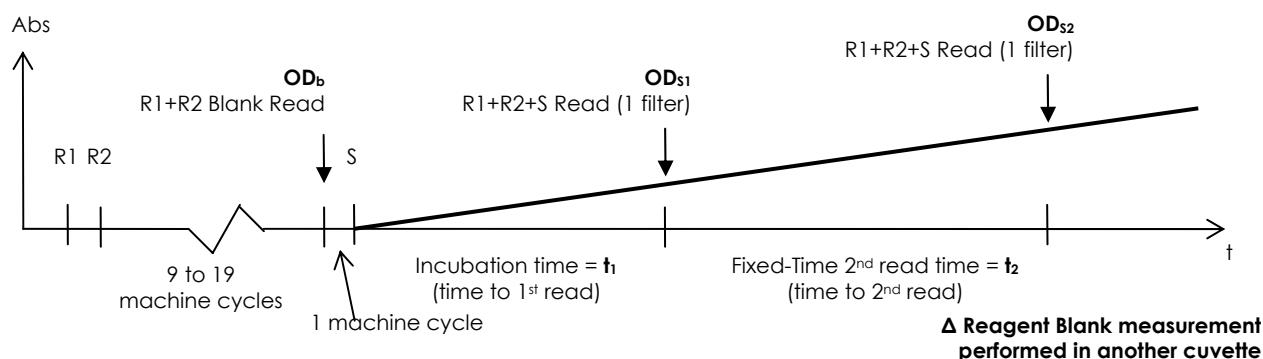
Final incub.: this field allows the user to enter the incubation time (in seconds) of the solution in cuvette

(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).

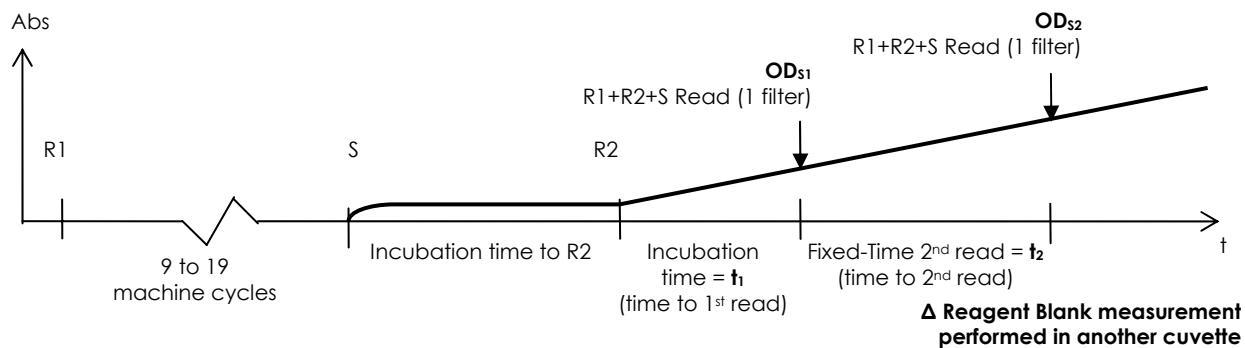


It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**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.

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 + sample + R2).

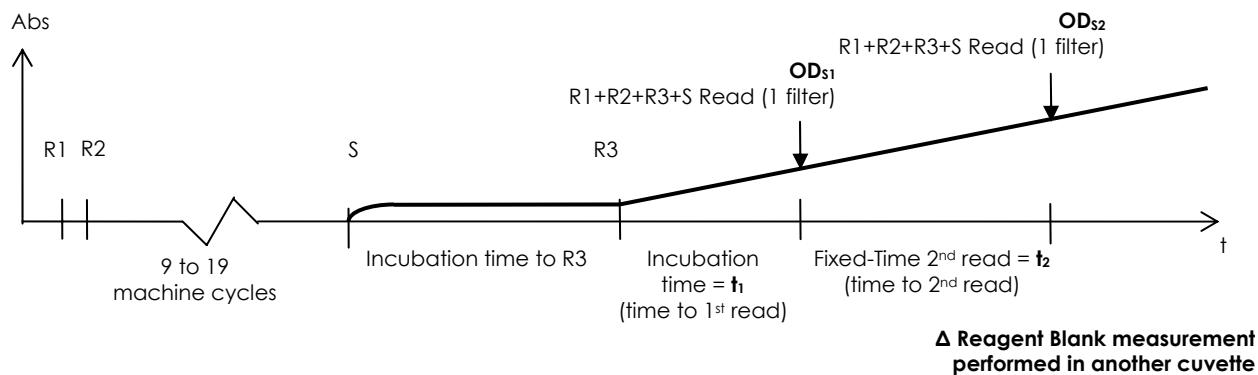
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**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).

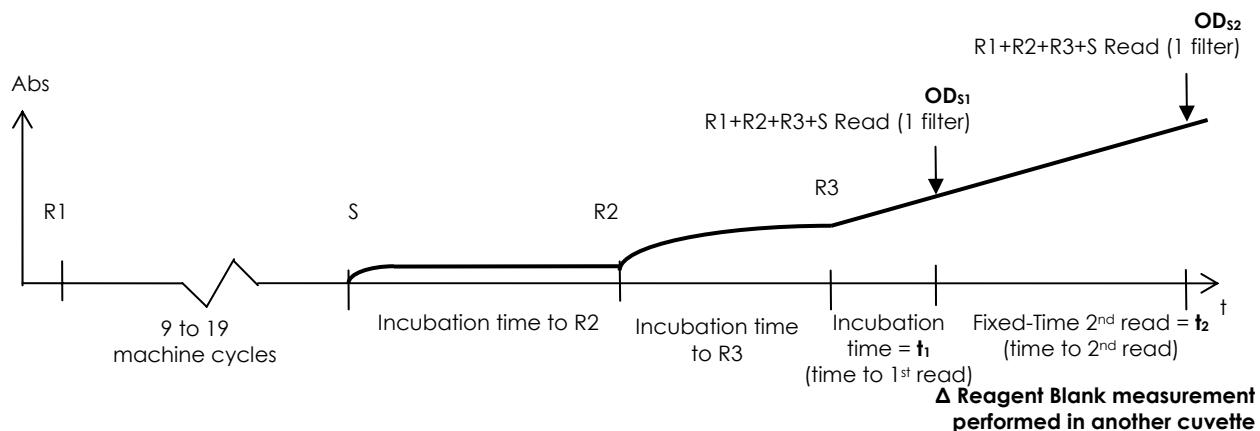
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**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).

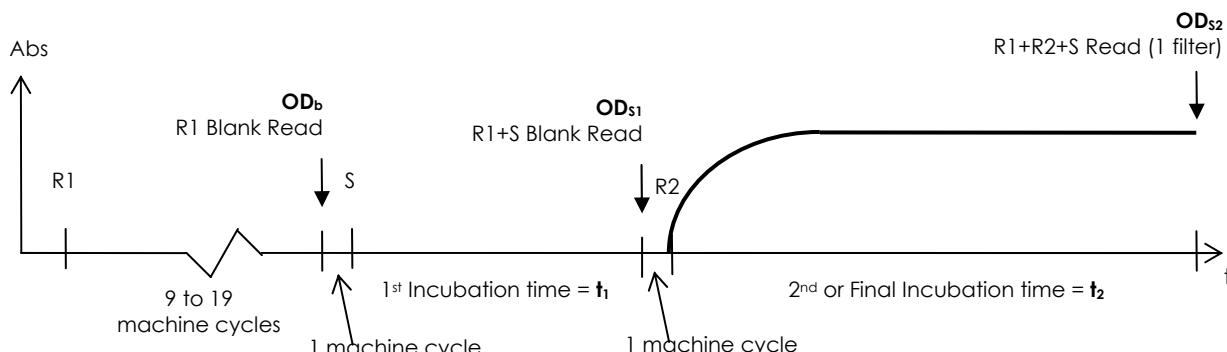
It is the time elapsing from the dispensing of the sample to the reading of the reaction. A pull down menu gives the opportunity to choose one of the following selections (in terms of seconds): 36, 60, 96, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660 and 720.

**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**



**Substrate/Sample Start:** this field is disabled in this case.

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

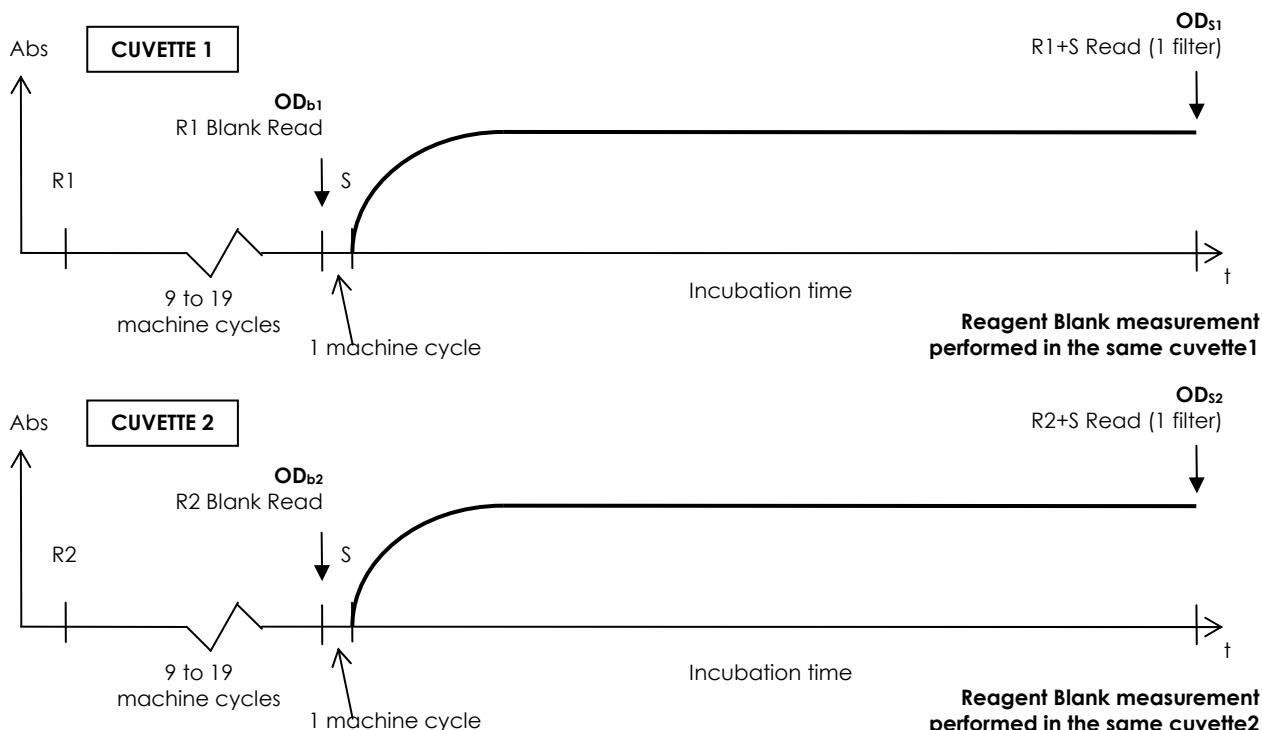
**R1,R2,S->R3:** this field is disabled in this case.

**First 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 FIRST reading of the solution "R1 + 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 + sample) + R2].

It is the time elapsing from the dispensing of the reagent R2 to the second reading of the solution "(R1 + 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: U.DDDDDDD (6 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: U.DDDDDDD with values included in the range 0 to 1. The absolute "best fit" is obviously identified by 1.000000.

**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).

**Calibration section**

- Nmb. of standards: this field, not editable, highlights the number of standards used for the calibration of the method. If the value is = 1 (mono-standard), the method needs one only standard, if the number is  $2 \leq n \leq 8$  (multi-standard), the method needs to generate a calibration curve over "*n*" points. In this case it is possible to display the calibration curve (only when already existing in memory).
- Calib. Curve: this command, active for "*n*"  $\geq 1$  (multi-standard), gives the user the opportunity to display the calibration curve (only when already existing in memory).
- Curve type: this pull down menu, active for "*n*"  $\geq 2$  (multi-standard), allows the user to select the algorithm to be used for the calibration curve generation; each selection becomes active after saving the method. Calibration curves actually included are: linear regression, Cubic spline, Piecewise linear and Logit/Log 4 Parameters.

**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 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.



- C2: 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.
- C3: 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.

**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).
- 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 selected method after modifications and automatic control of the congruence of volume data and incubation/reading times that have been set.
- 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.



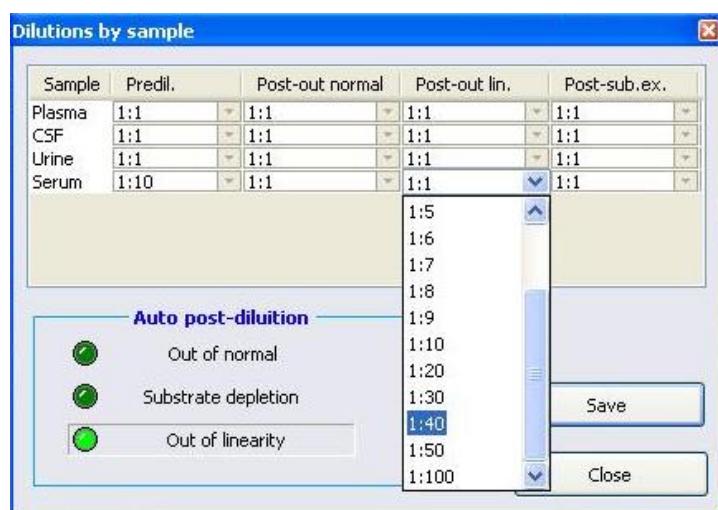
### 7.1.6.1. Dilutions by Sample Submenu

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 provided are: Plasma, CSF, Urine and Serum.

The dilution can be made just before the analysis (*pre-dilution*) or consequently to a 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, 1:20, 1:30, 1:40, 1:50 and 1:100.

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

Field/Command	Function
<b>Sample dilution table</b>	
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</i> detected



Field/Command	Function
<b>Selections</b>	(exhaustion of the substrate). If 1:1, the system will not consider that post-dilution.
Out of normal:	this selection allows the operator to enable the auto post-dilution in case the result has been detected "out of normal". 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.
<b>Commands</b>	
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 $\mu$ l and 500 $\mu$ l: the typical suggested reaction volume is anyway from 200 $\mu$ l to 260 $\mu$ l; in order to preserve cuvettes longer life, it is suggested not to overcome 300 $\mu$ l of total reaction volume.

With reference to **reagents**, it is possible to dispense from a minimum of 180 $\mu$ l up to 450 $\mu$ l reagent volume of R1, R2 and R3 in total. Provided the sum of reagent volumes greater or equal to 180 $\mu$ l, each of the reagents can be sampled anyway from 1 $\mu$ l to 450 $\mu$ l, with 1 $\mu$ 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 $\mu$ l up to 300 $\mu$ l, with 1 $\mu$ l minimum increment. The system performs the automatic mixing of the sample with the reagent into the cuvette.

The **suggested** values (in  $\mu$ 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		
Fixed Time	Sum of Reagent Volumes (R1 or R1 + R2 or R1 + R2 + R3) 200 $\mu$ l÷250 $\mu$ l	Total of Volumes (Reagents + Sample) 200 $\mu$ l÷260 $\mu$ l
Bichromatic		
End Point		
Differential - 2 Reagents	R1 and R2 200 $\mu$ l÷250 $\mu$ l	R1 + Sample and R2 + Sample 200 $\mu$ l÷260 $\mu$ l
Differential - Sample Blank	R1 + Sample 200 $\mu$ l÷250 $\mu$ l	R1 + Sample + R2 200 $\mu$ l÷260 $\mu$ 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: <b>SAMPLE STARTING</b> 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 Blank	36-720			36-720			720
Differential 2-Reagents				36-720			720

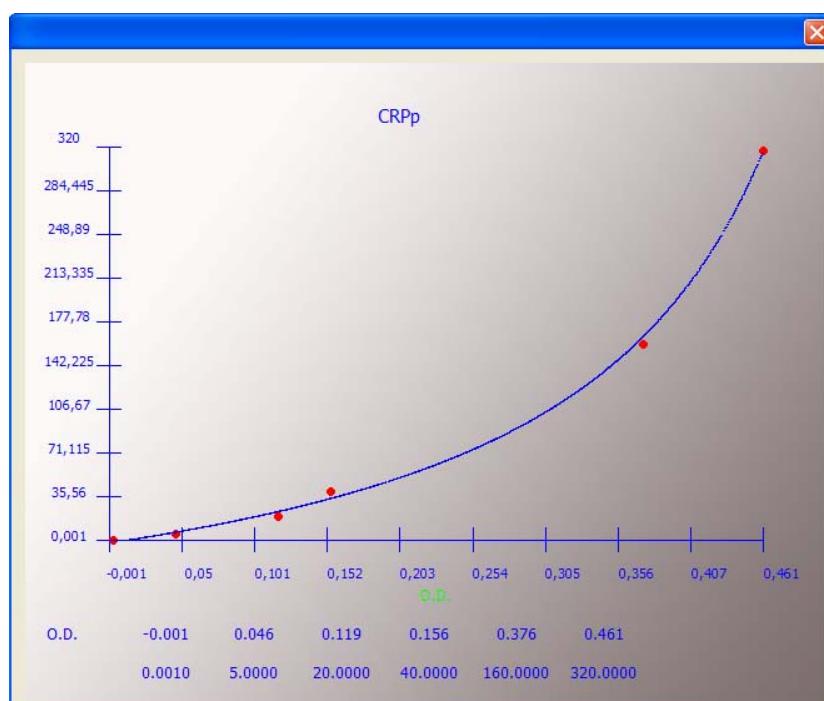
Type: <b>SUBSTRATE STARTING</b> Methods	1st incub.	Incub. to R2: R1,S=>R2	Incub. to R3: R1,R2,S =>R3	Final Incub.	Fixed Time 2nd read	Kinetic Reading Time	MAX Total Method Time
End Point 2-Reag. (Monochr./Bichrom.)		36-720		36-720			720
End Point 3Reag. (Monochr./Bichrom.)		36-720	36-720	36-720			720
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. 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, Concentration vs. OD values. This graph is related to the concentrations, that have been set in the menu *Standards* (when already existing in memory), and to the measured 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 and Logit/Log 4Parameters.

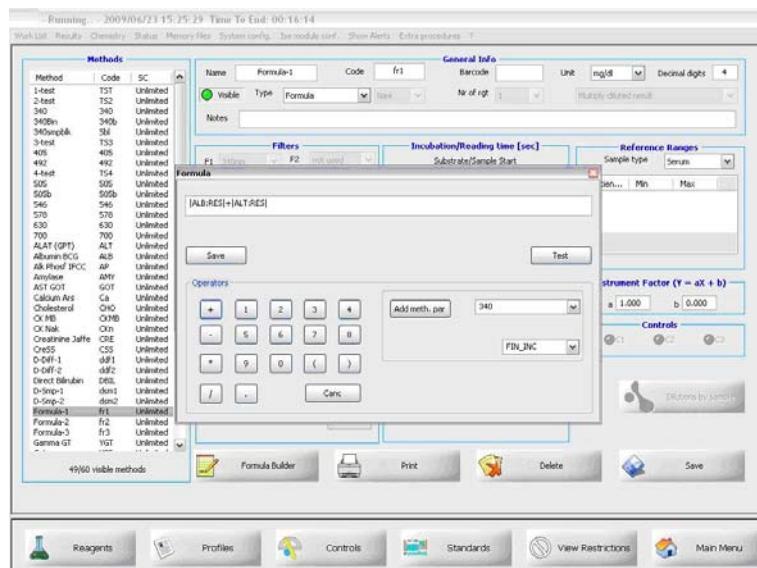


**Figure 47:** Calibration Curve



### 7.1.7. Formula Builder Menu

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 48:** 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 command:	this command allows the operator to save new formula editing or modifications.
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"><li>• FIN_INC, that is the final incubation time (in Conc.)</li><li>• RES, that is the result of the test</li><li>• RGT_O.D., that is the reagent blank O.D. result (in Abs)</li><li>• SMP_O.D., that is the final O.D. result (in Abs)</li><li>• U.D.P.1 that a custom value 1 specific of each patient</li></ul>



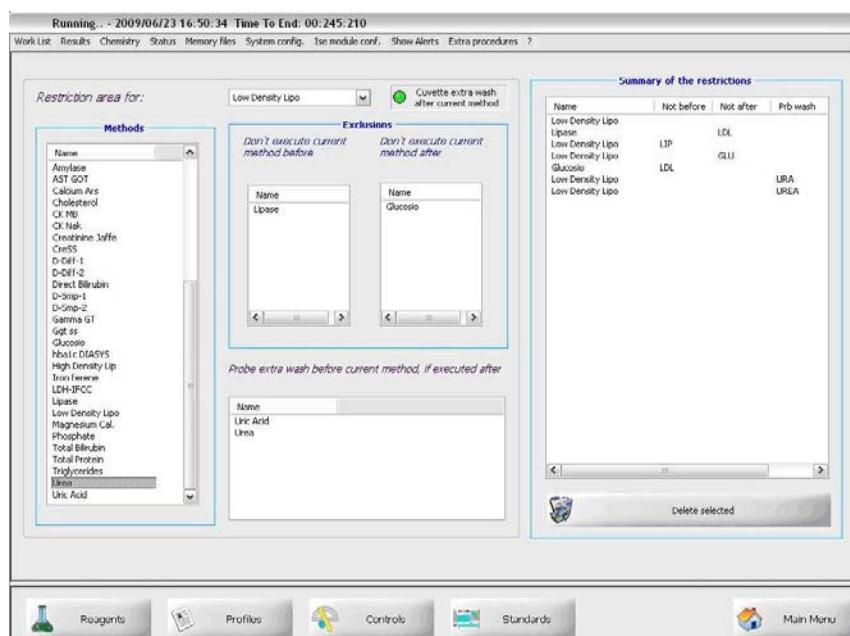
Field/Command	Function
	<ul style="list-style-type: none"><li>• U.D.P.2 that a custom value 2 specific of each patient</li><li>• VOL_R1, that is the reagent R1 volume in <math>\mu\text{l}</math></li><li>• VOL_R2, that is the reagent R2 volume in <math>\mu\text{l}</math></li><li>• VOL_R3, that is the reagent R3 volume in <math>\mu\text{l}</math></li><li>• VOL_SMP, that is the sample volume in <math>\mu\text{l}</math>.</li></ul>
Add meth. par:	this command allows the operator to add the selected parameter method into the formula.



### 7.1.8. 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 not to give too many constrains to the software and to maintain a good efficiency, the operator must use restrictions only where and when really necessary, without overdoing.**



**Figure 49:** 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 probe 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, LDL will never be executed **just one test before** Lipase and it also will never be executed **just one test after** Glucose.

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 after Uric Acid and Urea.

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:

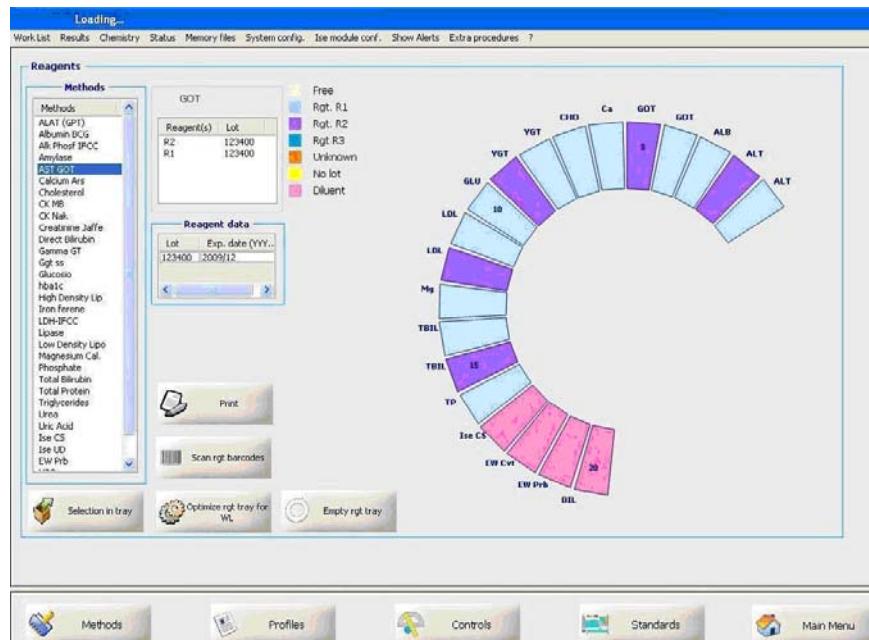
Field/Command	Function
Restriction area for:	a pull-down menu allows the operator to choose the method whose restriction must apply to. Just click and select one of the list of all method previously set as visible.
Methods window:	this column, not editable, includes all methods stored in the system and 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: “Don’t 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: “Don’t 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.
Summary of the restrictions:	this window lists all methods for which have been set restrictions.
<b>Commands</b>	
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.
Main Menu:	this command allows the operator to go back to the Main Menu.



### 7.1.9. 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 50:** Reagents Menu

The right side of this menu shows the configuration of the on-board reagents for each panel; 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 any single reagent from its position on the tray, the operator has to click, drag and 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 Reagents 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"><li>• For mono-reagents methods only R1 is visualized.</li><li>• For bi-reagents methods R1 and R2 are visualized.</li><li>• For three-reagents methods R1, R2 and R3 are visualized.</li></ul> 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.														
Print:	through this command the operator can send a print-out of all reagents and their positions placed on the reagent tray.														
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><tr><td>• Orange:</td><td>Unknown position used by an unknown reagent (its barcode has been read and understood but the method is not included in memory);</td></tr><tr><td>• Yellow:</td><td>No lot position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot</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 been read and understood but the method is not included in memory);	• Yellow:	No lot position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot
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 been read and understood but the method is not included in memory);														
• Yellow:	No lot position used by a known reagent whose lot number is missing (the operator must then introduce the proper lot														



Field/Command	Function
	number, that has to match with that provided on the reagent bottles); <ul style="list-style-type: none"><li>• Pink:</li></ul>
Selection in tray:	Diluent, or solution for processing 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). 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, <b>previously selected</b> , in the reagent window. The multiple selection of more samples is possible following the typical Windows® mode: <ul style="list-style-type: none"><li>• Selecting a range of samples:</li></ul>
Optimize rgt tray for WL:	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. <ul style="list-style-type: none"><li>• 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.</li></ul> 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.
Empty rgt tray:	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.
<b>Commands</b>	
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.



### 7.1.10. 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.

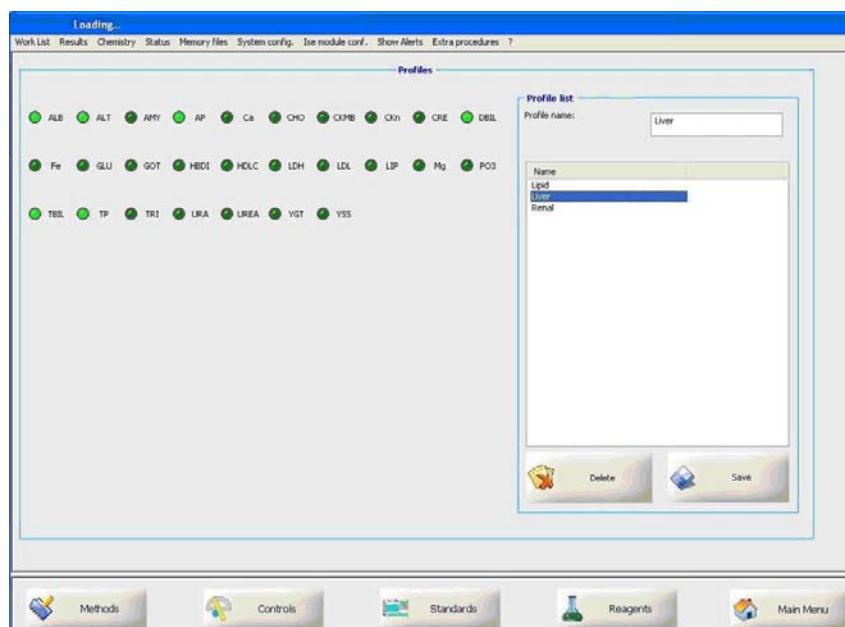


Figure 51: Profiles Menu

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.
<b>Profile List section</b>	
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.
Save:	this command allows the operator to save a profile that has been created or modified.
Methods:	this command allows the operator to enter the Methods menu.



Field/Command	Function
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.



### 7.1.11. 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 the special fields included in this menu it is possible to load the values of the standard or the factors for each method, and to assign the bottle positions on the sample tray and the number of repetitions (if one or three – for triplicate). Standards and calibrators can be placed in any position within the sample tray section.

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: the purpose is the Calibration Curve generation. Dilutions of the standard can be automatically performed by the instrument; the operator can use kits of pre-diluted ready-to-use standards without enabling, in this case, the instrument to auto-dilution.

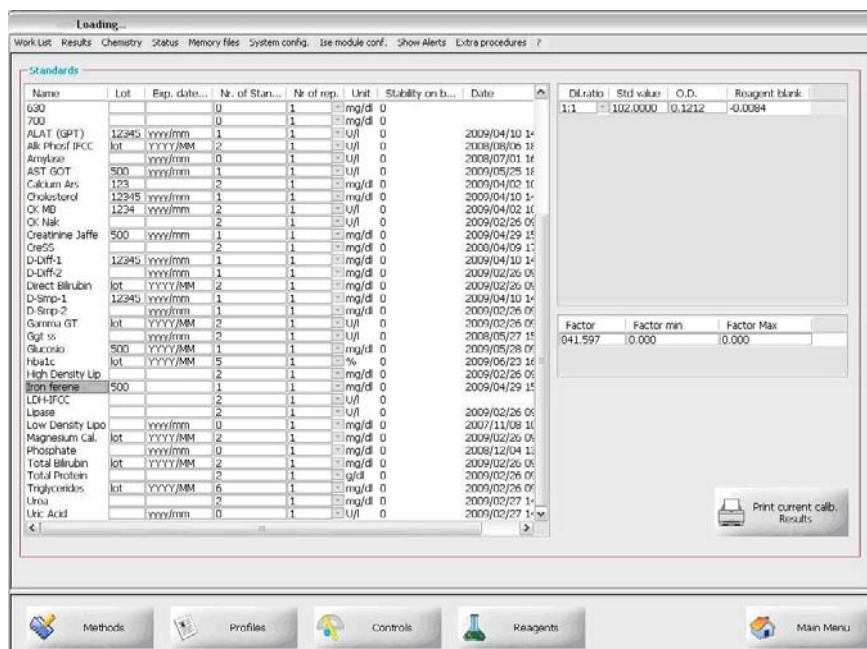


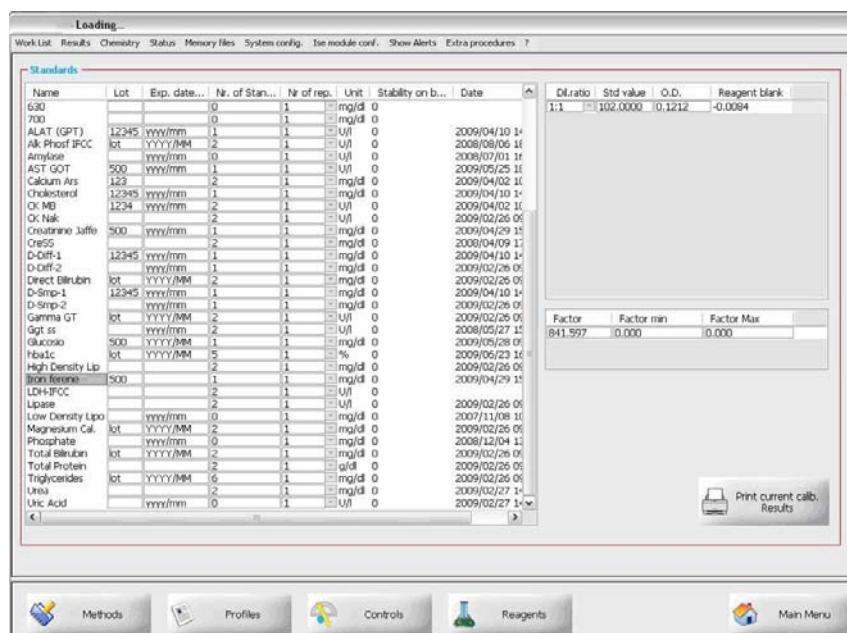
Figure 52: Standards Menu – Mono-standard example

The operator can anyway choose if to perform the calibration of the method or to assign it a fixed Factor; in case the operator runs the standardization of some methods, the previous factor in memory will be however overwritten by the new measured value (the program gives evidence of standardization date and time). For the calculation of the factor the operator must previously introduce 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 it has been assigned a standard or a factor to each of the method to be used. The system let the operator choose if performing the standard just once (choose "1") or if repeating it two more times - triplicate (choose "3"); in the latter case, the value is given as the average of the two nearest values.

**Note:** when the operator is setting calibration curves he has to write standard values, and then dilution ratios, 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).



**Figure 53:** 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 1 and 8. Mono-standard=1. Calibration curves allowed from 2 to 8 points.
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.
Stability on board:	this numeric field allows the user to set the number of days of calibration



Field/Command	Function
	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 or has been modified.
<b>Standard value section</b>	
This section 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.	
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, 1:20, 1:30, 1:40, 1:50, and 1:100.  In case of Master Curves or pre-diluted standards, that doesn't need 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.
	<b>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 @ zero concentration).</b>
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"><li>• the operator <b>must</b> always introduce the value of the concentrated standard (1:1);</li><li>• the values of the other diluted standards are automatically calculated and introduced by the system when the operator introduces the dilution ratio;</li><li>• 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 isn't 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.</li><li>• 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).</li></ul> <b>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</b>



Field/Command	Function
O.D.:	<b>top (i.e.: concentrated) to the lowest on the bottom (i.e.: saline @ zero concentration).</b> 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).
<b>Factor value section</b>	
This section is active only in case of Nr. of Standards $n \geq 2$ , multi-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: <ul style="list-style-type: none"><li>• 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).</li><li>• when needed, the value of the standard must be introduced <b>with its proper sign</b> (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.</li></ul>
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). Together with the Factor min it states the acceptable factor normal 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 <b>left equal to 0</b> , the control on the range is skipped and then <b>disabled</b> .
<b>Commands</b>	
Print Current Calib.	This command allows the operator to print all current calibrations and factors.
Results:	this command allows the operator to enter the Methods menu.
Methods:	this command allows the operator to enter the Profiles menu.
Profiles:	this command allows the operator to enter the Quality Control menu.
Controls:	



Field/Command	Function
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.

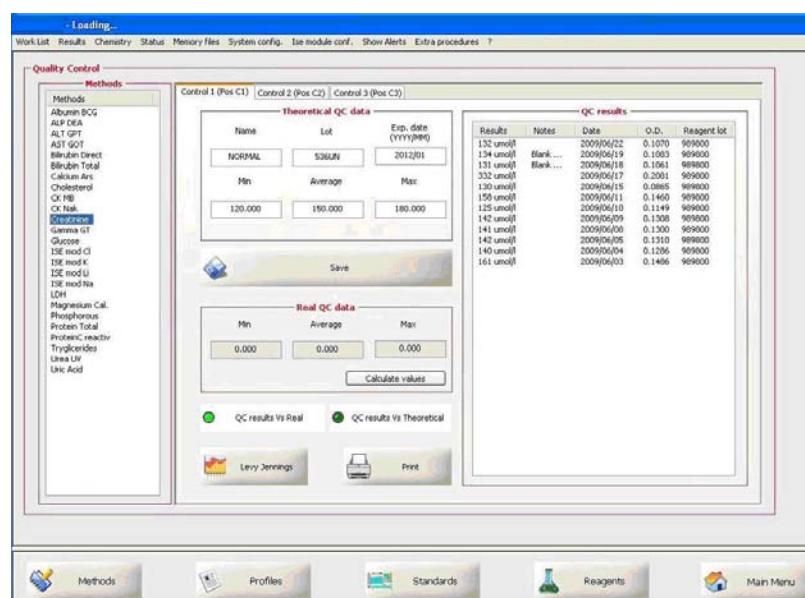


### 7.1.12. Quality Control Menu

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 controls depending on his needs (i.e.: Abnormal low, normal, abnormal high).



**Figure 54:** 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 more 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.

A side window titled "Real QC data" displays statistical values: Min (41.161), Average (43.544), and Max (45.374). Below these are "Calculate values" and "Print" buttons. At the bottom, there are radio buttons for "QC results Vs Real" and "QC results Vs Theoretical".

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



Field/Command	Function
<b>Methods section</b>	
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.
<b>Control 1 (Pos C1) section</b>	
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. <b>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.</b>
Exp. date (YYYY/MM):	this alphanumeric field allows the operator to introduce the expiring date of the control. The format of this field is <b>YYYY/MM</b> where, <ul style="list-style-type: none"><li>• YYYY is the year (i.e.: 2007)</li><li>• MM is the month (i.e.: 03 for March)</li></ul>
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). <b>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.</b>
Theor.:	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). <b>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.</b>
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). <b>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.</b>
Real 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 as the -3 <sup>rd</sup> standard deviation over all of the QC results). <b>The calculation is performed by activating the command Calculate values.</b> <b>The system can perform meaningful calculations only when the QC results are ≥2.</b>
Average:	this numeric field is automatically filled by the system and shows the operator the <i>average</i> value for the control (calculated as the mean over all of the QC results). <b>The calculation is performed by activating the command Calculate values.</b> <b>The system can perform meaningful calculations only when the QC results are ≥2.</b>
Max:	this numeric field is automatically filled by the system and shows the



Field/Command	Function
Calculate values:	operator the <i>maximum</i> value for the control (calculated as the +3 <sup>rd</sup> standard deviation over all of the QC results). <b>The calculation is performed by activating the command Calculate values.</b> <b>The system can perform meaningful calculations only when the QC results are ≥2.</b>
Selections	
QC Results vs. theoretical:	this command allows calculation of Min, Average and Max values over all of the QC results shown into the side window. When activated the system shows the values.
QC Results vs. real:	this selection allows the operator to display in the Levy-Jennings graph the values given in the technical sheet of the QC serum used: <ul style="list-style-type: none"><li>• min (-3<sup>rd</sup> SD),</li><li>• theoretical,</li><li>• max (+3<sup>rd</sup> SD).</li></ul>
Commands	
Save:	this command allows to save the QC values entered by the operator and deduced from the technical sheet following the QC serum kit.
Print:	this command allows the operator to print all of the QC results in Controls History. The program asks the operator if to include or not the Levy-Jennings graph. Depending on the selection QC Results vs. theoretical or QC Results vs. real, the graph will show theoretical values or calculated values as min (-3 <sup>rd</sup> SD), theoretical and max (+3 <sup>rd</sup> SD).
View Levy Jen. Graph:	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. Depending on the selection QC Results vs. theoretical or QC Results vs. real, the graph will show theoretical values or calculated values as min (-3 <sup>rd</sup> SD), theoretical and max (+3 <sup>rd</sup> SD).
<b>Control 2 (Pos C2) section</b>	as per Control 1 (Pos C1) section but for C2 control data.
<b>Control 3 (Pos C3) section</b>	as per Control 1 (Pos C1) section but for C3 control data.
<b>QC Results section</b>	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



Field/Command	Function
OD:	QC sera. 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.
<b>Other commands</b>	
Methods:	this command allows the operator to enter the <i>Methods</i> menu.
Profiles:	this command allows the operator to enter the <i>Profiles</i> menu.
Standards:	this command allows the operator to enter the <i>Standard</i> menu.
Reagents:	this command allows the operator to enter the <i>Reagents</i> menu.
Main Menu:	this command allows the operator to go back to the <i>Main Menu</i> .

### 7.1.12.1. QC and Levy-Jennings Graph

For each of the three quality controls 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.

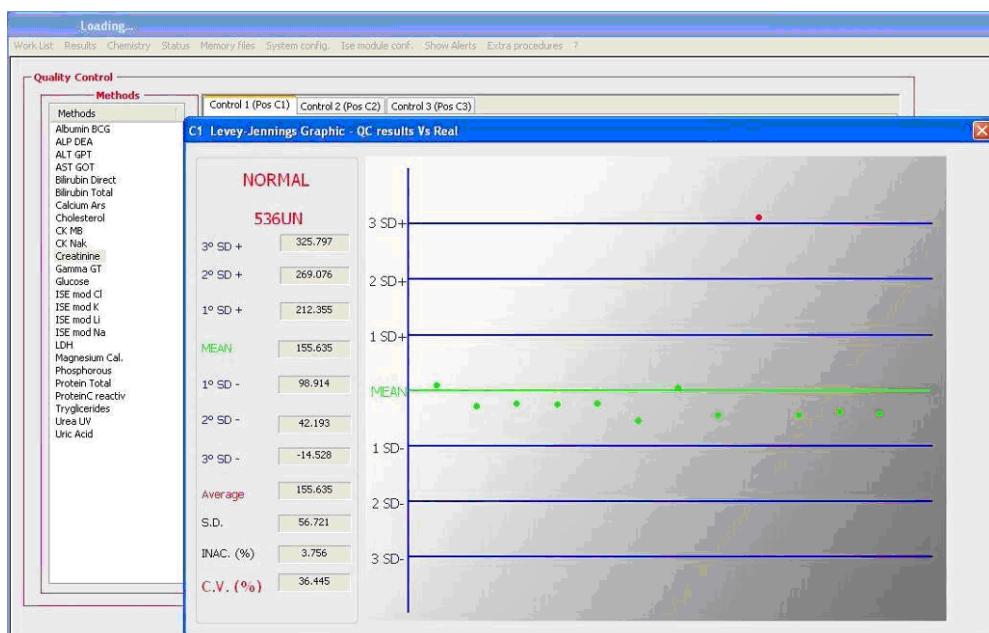


Figure 55: Levy-Jennings Graph

In 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 last 50 values (one for each day) 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 show respectively “theoretical values” or “calculated values” for min (-3rd SD), theoretical and max (+3rd SD) straight lines.



	<b>QC Results vs. theoretical</b>	<b>QC Results vs. real</b>
<b>min (-3<sup>rd</sup> SD)</b>		
<b>average (mean)</b>	deduced from technical sheet for QC serum	calculated over QC serum measurement results
<b>max (+3<sup>rd</sup> SD)</b>		

The other values ( $\pm 1\text{SD}$  and  $\pm 2\text{SD}$ ) are resulting from calculation.

When the result of a control falls within the 3<sup>rd</sup> standard deviation ( $\pm 3\text{SD}$ ) from the mean value, 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 3<sup>rd</sup> standard deviation ( $\pm 3\text{SD}$ ) 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 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 2<sup>nd</sup> standard deviation ( $\pm 2\text{SD}$ ) 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).**



### 7.1.13. 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 of the methods run for each sample (patient). Displayed results are related to the Work List in progress or to the last one performed if not yet stored.

In this menu, by the pull down menu, the operator can choose the patient whose results have to be displayed; the operator, after verification and 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 an existing method, all related Patient results running that particular method must be archived (stored in memory) and also related Standard and QC.**

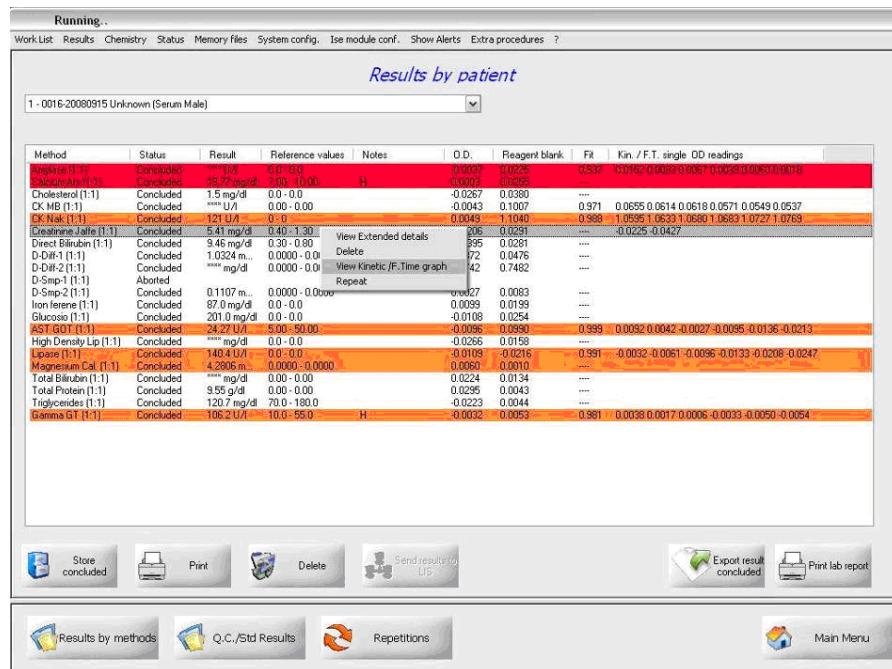


Figure 56: Results by Patient Menu

**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, 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
<b>Patient/Sample field</b>	
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.
<b>Results window</b>	
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.
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"><li>• concluded, test has been concluded;</li><li>• in process, test is in progress;</li><li>• to begin, test has to begin (repetitions);</li><li>• aborted, test has been aborted;</li><li>• in error, system in error – the results is not reliable;</li><li>• to repeat, test has been chosen to be repeated.</li></ul>
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 values:	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.
Notes:	this column, not editable, shows eventual notes remarked by the system (i.e.: out of normal, out of linearity, out of calibration). 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 <b>higher than normal range</b> it shows the capital letter "H", in case of result <b>lower than normal range</b> it shows the capital letter "L".
OD:	this column, not editable, shows the final raw value measured and expressed in absorbance (OD). This field is not printed on the report.
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. This field is not printed on the report.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated on the linear regression for kinetic methods.
Kin. / F.T. single OD readings:	This column, not editable, shows each single OD value read for Kinetics (during the reading time) or for Fixed Time methods (first and second values).
<b>Commands performed through the right mouse button on the selected test method</b>	
View Extended details:	it is useful to display information about results out of normal. Select with the left mouse button one analysis that has been highlighted in orange or

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

View kinetics/F.Time graph:

red, then click on the selection with the right mouse button and click *View Extended details* on the pop-up menu: important information about the results, if any, will be displayed.

Delete:

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 click *View graph* on the pop-up menu: the single ODs are shown in graphic mode.

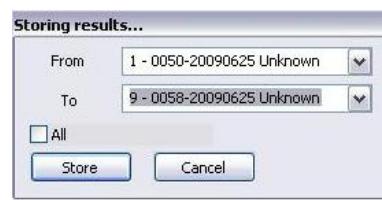
Repeat:

select one or more analyses to delete with the left mouse button, then click on the selection with the right mouse button and click *Delete* on the pop-up menu: the selection is then cut.

**Commands**

Store concluded:

this command opens a special window that allows the operator to archive a range of patients, whose analyses have been concluded, in the archive.



Print:

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 system has been enabled to the L.I.S. connection (Laboratory Information System), this command opens a special window that allows the operator to select a range of patients whose results will be send to the host computer.

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.

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**



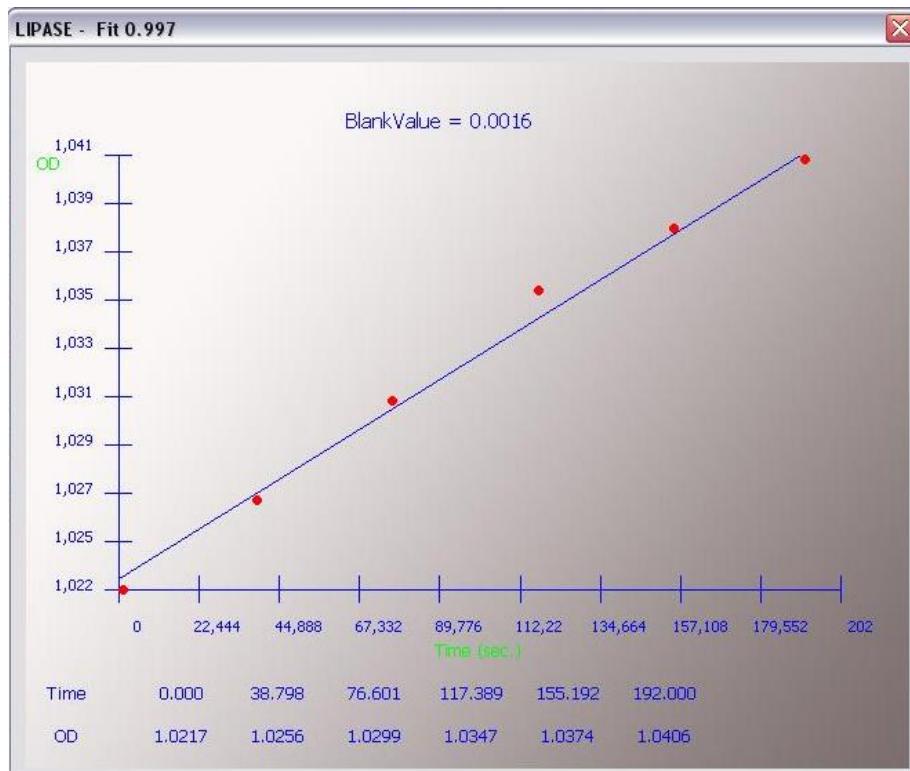
results for treating data on his own under his responsibility (it can be used in case of L.I.S. connection is missing).

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.



### 7.1.13.1. Kinetics and Fixed-Time Methods OD graph

This graph can be displayed by the pop-up menu (View graph) that can be enabled by selecting an analysis in Result for Patient menu (w/mouse right click).



**Figure 57:** Kinetics/Fixed 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 has been visualized.



### 7.1.13.2. 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 KROMA managing PC has been connected into a LAN.

In case that the KROMA PC has been included into a LAN, the “ExportedResults” folder can be “shared” in network in order to allow an host computer to download and treat the file itself.

The exported files are \*.csv type.

#### KROMA program root folder

**ProgramRoot = %ROOT% \Program Files\KROMA**

#### 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.

Location of the file:

**%ProgramRoot% \ExportedResults**

File name:

**exp\_YYYY\_MM\_DD\_hh\_mm.csv**  
(i.e.: exp\_2006\_10\_17\_17\_23.csv)

where:

- YYYY = year
- MM = month
- DD = day
- hh = hour
- mm = minute.

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
-------------------	--------------	-----------------	------------------------	----------------	--------------	--------	---------------------	-------------------------	-------------------------	------

\* 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 Method Export 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.**

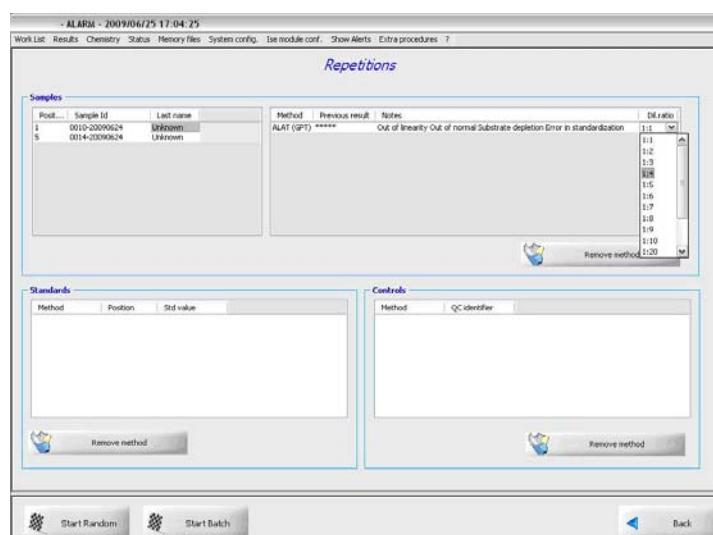


### 7.1.14. Repetitions Menu

The operator can enter the *Repetitions* menu by selecting the command *Repetitions* in the *Results for Patient* menu. This menu allows the management of the sample, standard or controls to be repeated by running them within the Work List in progress, if any, or in the next one to be run.

Samples will be repeated as soon as possible after the command Start, standards and controls will be scheduled and repeated at the end of the run (in a new one). In this menu the operator can also delete analyses or samples that have 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 58:** Repetitions Menu

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

Field/Command	Function
<b>Samples section - Patient window</b>	
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.
<b>Samples section - Method window</b>	
Method:	this column, not editable, shows the analyses to repeat.
Previous result:	this column, not editable, shows the analyses of the previous obtained result.
Notes:	this column, not editable, shows eventual notes on the previous analysis session.
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, 1:20, 1:30, 1:40, 1:50, 1:100.



Field/Command	Function
	<b>The ratio 1:n is intended as 1 part of “n” parts. Thus, the ratio 1:1 doesn’t provide any dilution.</b>
<b>Std/QC section - Standards/calibrators window</b>	
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.
<b>Std/QC section - Controls window</b>	
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).
<b>Commands</b>	
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 Random 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 Status Menu 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 Batch 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 Status Menu 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 Results by Patient.



### 7.1.15. 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. 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.

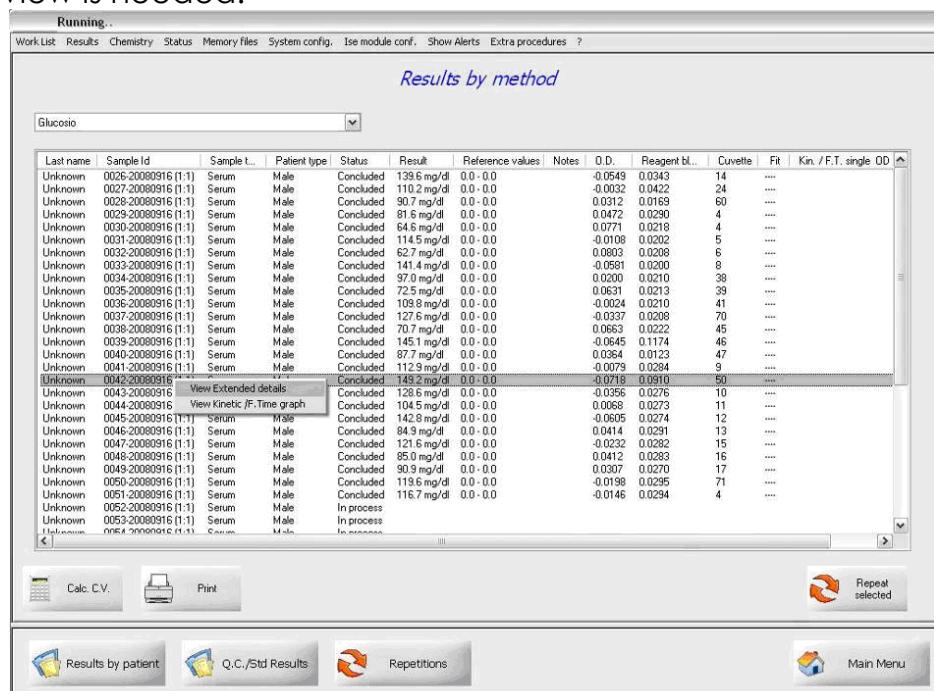


Figure 59: Results by Method Menu

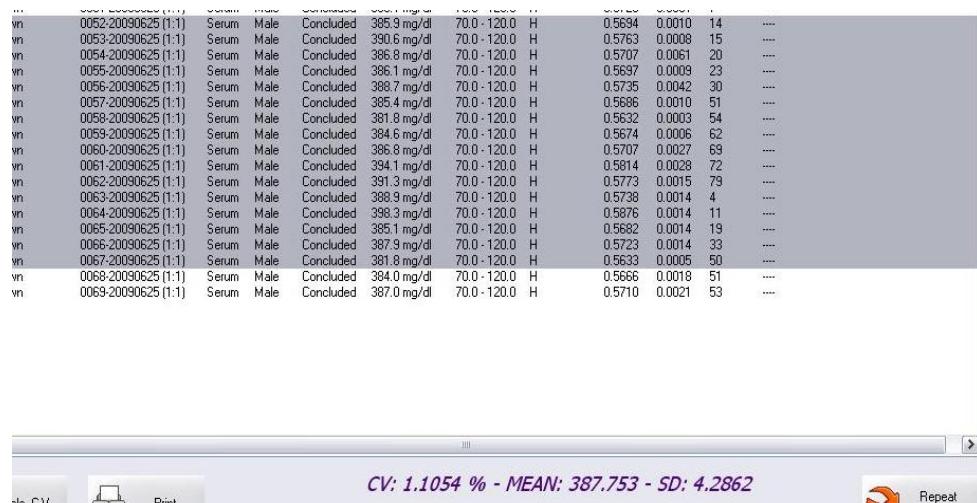


Figure 60: Selection and Statistics Calculation



In this menu the operator can:

- select one of all test methods whose results have to be displayed;
- select one single test in order to view more details or to display the graph (valid for kinetics and fixed time);
- calculate, only for the selected samples, 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
<b>Method field</b> Pull down menu:	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.
<b>Results windows</b> Last name: Sample id:	this column, not editable, shows the last name of each patient. 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 or CSF).
Patient type:	this field, not editable, shows the patient type (if male, female or paediatric).
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"><li>• concluded, method whose analysis has been concluded;</li><li>• in process, method whose analysis is in progress;</li><li>• to begin, methods whose analysis has to begin (repetitions);</li><li>• aborted, method whose analysis has been aborted;</li><li>• in error, system in error – the results is not reliable;</li><li>• to repeat, method whose analysis has been chosen to be repeated.</li></ul>
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.
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.
Notes:	this column, not editable, shows eventual notes and abnormalities detected by the system (i.e.: out of normal, out of linearity).



Field/Command	Function
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 value measured in terms of absorbance (OD). This value is measured by the instrument on any single reading cuvette with reagent.
Cuvette:	this column, not editable, shows the cuvette number where the analysis has been incubated and read.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated for the kinetic methods.
Kin. / F.T. single OD Readings:	This column, not editable, shows each single OD value of Kinetics / Fixed Time readings.
<b>Commands performed through the right mouse button on the selected test method</b>	
View Extended details:	it is useful to display information about results out of normal. Select with the left mouse button one analysis that has been highlighted in orange or red, then click on the selection with the right mouse button and click View Extended details on the pop-up menu: important 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 click View graph on the pop-up menu: the single ODs are shown in graphic mode.
<b>Commands</b>	
Calc. C.V.:	when activated, this command allows the system to calculate, over all of the previously <b>selected</b> analyses, the following statistic parameter: <ul style="list-style-type: none"><li>• Coefficient of Variation (CV);</li><li>• Mean;</li><li>• Standard Deviation (SD).</li></ul>
Print:	this command allows the operator to print the results for the selected method.
Repeat selected:	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.
Results by patient:	this command allows the operator to go back to the Results by patient 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.
Main Menu:	this command allows the operator to go back to the Main Menu.
Note: the selection of more results can be executed with the typical Windows® mode:	
<ul style="list-style-type: none"><li>• 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.</li><li>• 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.</li></ul>	



### 7.1.16. 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 the controls 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:

- store in archive (Memory files menu) the obtained control results;
- print into a compact laboratory report results of standards and controls actually displayed.

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

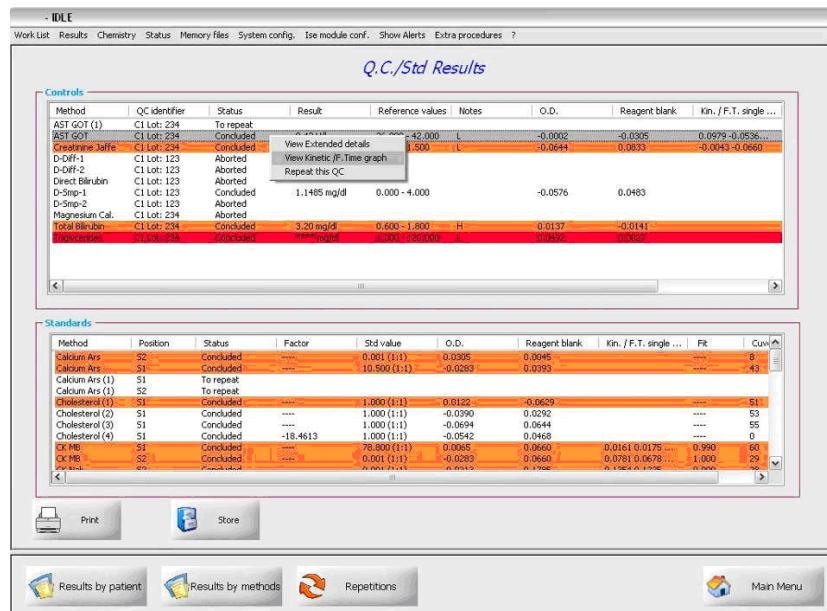


Figure 61: Q.C./Std Results Menu

**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, LiNEAR ity, 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	



Field/Command	Function
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"><li>• concluded, test has been concluded;</li><li>• in process, test is in progress;</li><li>• to begin, test has to begin (repetitions);</li><li>• aborted, test has been aborted;</li><li>• in error, system in error – the results is not reliable;</li><li>• to repeat, test has been chosen to be repeated (at the end of the run).</li></ul>
Result:	this column, not editable, shows the final result and unit of measurement for each control completed.
Reference values:	this column, not editable, shows the lower and the higher limits of the range set for that control.
Notes:	this column, not editable, shows eventual notes remarked by the system as: H=high result – above range, L=low result – below range.
O.D.:	this column, not editable, shows the final value measured in terms of absorbance (OD).
Reagent blank:	this column, not editable, shows the reagent blank value in terms of absorbance (OD).
Kin. / F.T. single OD Readings:	This column, not editable, shows each single OD value of Kinetics / Fixed Time readings.
Fit:	this column, not editable, shows the value of the fit (squared correlation factor) calculated for the kinetic methods.
Cuvette:	this column, not editable, shows the cuvette number where the specific reaction has been incubated and read.
<b>Standards section</b>	
Method:	this column, not editable, shows the method whose standard is related to.
Position:	this column, not editable, shows the position of the standard on the sample tray.
Status:	this column, not editable, shows the progress of any single standard. The following conditions are possible: <ul style="list-style-type: none"><li>• concluded, test has been concluded;</li><li>• in process, test is in progress;</li><li>• to begin, test has to begin (repetitions);</li><li>• aborted, test has been aborted;</li><li>• in error, system in error – the results is not reliable;</li><li>• to repeat, test has been chosen to be repeated (at the end of the run).</li></ul>
Factor:	this column, not editable, shows the factor related to each standard.
Std value:	this column, not editable, shows the value given to 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 measured value in terms of absorbance (OD).
Kin. / F.T. single OD Readings:	This column, not editable, shows each single OD value of Kinetics / Fixed Time readings.
Cuvette:	this column, not editable, shows the cuvette number where the analysis has been incubated and read.

**Commands performed through the right mouse button on the selected test method**



Field/Command	Function
View Extended details:	it is useful to display information about results out of normal. Select with the left mouse button one test that has been highlighted in orange or red, then click on the selection with the right mouse button and click <i>View Extended details</i> on the pop-up menu: important 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 test with the left mouse button, then click on the selection with the right mouse button and click <i>View graph</i> on the pop-up menu: the single ODs are shown in graphic mode.
Repeat the QC: or Repeat the standard:	select one or more tests to delete with the left mouse button, then click on the selection with the right mouse button and click <i>Repeat</i> on the pop-up menu: the selected analyses are then moved to the <i>Repetitions</i> menu. In that menu the operator can re-run that analysis in the actual working session and with different dilutions.
Commands	
Print:	this command allows the printing of a compact laboratory report with all results displayed.
Store:	this command allows the operator to store in archive (Memory Files menu) the displayed QC 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.
Main Menu:	this command allows the operator to go back to the <i>Main Menu</i> .



### 7.1.17. 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:

- *surname*,
- *patient id code*,
- *date*,
- *method*
- *calibration unique id number*;

any combination of that given keys is possible for creating any research criterion.

**Search panel**

Last name	Name	Sample Id	Method	Result	Reference values	Cal. Unique id	O.D.	Reagent blank	Notes
Unknown	Unknown	000-20080505	Albumin BCG (1:1)	4.45 g/dl	0.000 - 0.000	400	1.4489	0.1804	Out of nor
Unknown	Unknown	0002-20080505	Albumin BCG (1:1)	4.52 g/dl	0.000 - 0.000	400	1.4715	0.2117	Out of nor
Unknown	Unknown	0003-20080505	Albumin BCG (1:1)	4.55 g/dl	0.000 - 0.000	400	1.4815	0.1932	Out of nor
Unknown	Unknown	0004-20080505	Albumin BCG (1:1)	4.65 g/dl	0.000 - 0.000	400	1.5149	0.1914	Out of nor
Unknown	Unknown	0005-20080505	Albumin BCG (1:1)	4.47 g/dl	0.000 - 0.000	400	1.4548	0.2099	Out of nor
Unknown	Unknown	0001-20080505	ALP DEA (1:1)	169.03 U/l	80.000 - 160.000	364	0.0615	0.5032	Out of nor
Unknown	Unknown	0002-20080505	ALP DEA (1:1)	175.26 U/l	80.000 - 160.000	364	0.0628	0.5032	Out of nor
Unknown	Unknown	0003-20080505	ALP DEA (1:1)	177.56 U/l	80.000 - 160.000	364	0.0628	0.4981	Out of nor
Unknown	Unknown	0004-20080505	ALP DEA (1:1)	180.51 U/l	80.000 - 160.000	364	0.0657	0.6082	Blank out
Unknown	Unknown	0005-20080505	ALP DEA (1:1)	165.35 U/l	80.000 - 160.000	364	0.0601	0.4927	Out of nor
Unknown	Unknown	0001-20080505	AST GOT (1:1)	41.35 U/l	5.000 - 50.000	366	-0.0237	1.3382	
Unknown	Unknown	0002-20080505	AST GOT (1:1)	43.24 U/l	5.000 - 50.000	366	-0.0248	1.3465	
Unknown	Unknown	0003-20080505	AST GOT (1:1)	42.49 U/l	5.000 - 50.000	366	-0.0243	1.3536	
Unknown	Unknown	0004-20080505	AST GOT (1:1)	43.14 U/l	5.000 - 50.000	366	-0.0247	1.3567	
Unknown	Unknown	0005-20080505	AST GOT (1:1)	44.00 U/l	5.000 - 50.000	366	-0.0241	1.3567	
Unknown	Unknown	0001-20080505	Calcium Arts (1:1)	10.27 mg/dl	7.000 - 10.000	396	0.3780	0.8149	Out of nor
Unknown	Unknown	0002-20080505	Calcium Arts (1:1)	9.37 mg/dl	7.000 - 10.000	396	0.3452	0.8303	Error in sta
Unknown	Unknown	0003-20080505	Calcium Arts (1:1)	9.49 mg/dl	7.000 - 10.000	396	0.3497	0.8000	Error in sta
Unknown	Unknown	0004-20080505	Calcium Arts (1:1)	9.36 mg/dl	7.000 - 10.000	396	0.3448	0.7604	Error in sta
Unknown	Unknown	0005-20080505	Calcium Arts (1:1)	9.37 mg/dl	7.000 - 10.000	396	0.3451	0.8236	Error in sta
Unknown	Unknown	0001-20080505	Cholesterol (1:1)	114.00...	0.000 - 0.000	399	0.2824	0.0739	Blank out
Unknown	Unknown	0002-20080505	Cholesterol (1:1)	110.52...	0.000 - 0.000	399	0.2742	0.0722	Blank out
Unknown	Unknown	0003-20080505	Cholesterol (1:1)	110.52...	0.000 - 0.000	399	0.2931	0.0588	Out of nor
Unknown	Unknown	0004-20080505	Cholesterol (1:1)	119.85...	0.000 - 0.000	399	0.2974	0.0669	Out of nor
Unknown	Unknown	0005-20080505	Cholesterol (1:1)	116.51...	0.000 - 0.000	399	0.2891	0.0667	Out of nor
Unknown	Unknown	0001-20080505	Creatinine (1:1)	1.33 mg/dl	0.400 - 1.300	398	0.0673	0.2001	Blank out
Unknown	Unknown	0002-20080505	Creatinine (1:1)	1.21 mg/dl	0.400 - 1.300	398	0.0616	0.2097	Blank out
Unknown	Unknown	0003-20080505	Creatinine (1:1)	1.17 mg/dl	0.400 - 1.300	398	0.0598	0.1923	
Unknown	Unknown	0004-20080505	Creatinine (1:1)	1.16 mg/dl	0.400 - 1.300	398	0.0601	0.1942	
Unknown	Unknown	0005-20080505	Creatinine (1:1)	1.18 mg/dl	0.400 - 1.300	398	0.0592	0.1938	
Unknown	Unknown	0001-20080505	Gamma GT (1:1)	39.69 U/l	10.000 - 55.000	298	0.0343	1.0254	Blank out
Unknown	Unknown	0002-20080505	Gamma GT (1:1)	39.69 U/l	10.000 - 55.000	298	0.0337	1.0254	Blank out
Unknown	Unknown	0003-20080505	Gamma GT (1:1)	39.69 U/l	10.000 - 55.000	298	0.0337	1.0254	Blank out
Unknown	Unknown	0004-20080505	Gamma GT (1:1)	39.69 U/l	10.000 - 55.000	298	0.0337	1.0254	Blank out
Unknown	Unknown	0005-20080505	Gamma GT (1:1)	39.69 U/l	10.000 - 55.000	298	0.0337	1.0254	Blank out

**Operational commands**

Search, Export, Print, Delete, Delete selected, Show details.

**Navigation**

Std / Q.C. Archive, Main Menu.

**Figure 62: Memory Files Menu**

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

#### Field/Command

#### Function

##### Search Panel section

- Surname:** this field allows the operator to introduce the patient last name to search in archive. The system considers the content of this field only if the searching option "by surname" has been flagged.
- Id code:** this field allows the operator to introduce the patient idcode to search in archive. The system considers the content of this field only if the searching option "by idcode" has been flagged.
- Method:** this field allows the operator to introduce the analysis method to search in



Field/Command	Function
Cal. Unique id:	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.
Date (yyyy mm dd) from:	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.
Date (yyyy mm dd) to:	this field allows the operator to select the analysis range starting date to search in archive. The system considers the content of this field only if the searching option "by date" has been flagged.
By surname:	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 the searching option "by date" has been flagged.
By idcode	this selection allows the operator to search a patient "by last name" key. It can be selected together with other keys.
By date:	this selection allows the operator to search a patient the "by idcode" key. It can be selected together with other keys.
By method:	this selection allows the operator to search a patient "by date" key. It can be selected together with other keys.
By cal. Unique id:	this selection allows the operator to search a patient "by method name" key. It can be selected together with other keys.
<b>Research results window</b>	<b>Research results window</b>
Last name:	this column, not editable, shows the surname of the patients found by the searching process.
Name:	this column, not editable, shows the name 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 values:	this column, not editable, shows the lower and the higher limits of the normal result range set in the Methods Menu.
Cal. Unique 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).
Notes:	this column, not editable, shows the notes related to the side analysis result.
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**

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

**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 *Delete* on the pop-up menu: that particular test will be deleted.

**Show 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. Through this window the operator can modify any patient personal data or print the report of the results. Select with the left mouse button one test, then click on the selection with the right mouse button and click *Show details* on the pop-up menu.

**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:** 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.

**Show 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. 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.

**Note:** the selection of more results can be executed with the typical Windows® mode:

- 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.



### 7.1.17.1. 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**; for each sample an average of 10 analyses is carried out, hence the database will 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.csv**

(i.e.: result\_2006\_10\_17.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:*

<b>idArchive</b>	<b>idPatient</b>	<b>Barcode</b>	<b>Method name</b>	<b>results</b>	<b>Minimum Reference Value</b>	<b>Maximum Reference Value</b>	<b>Date</b>

*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.



### 7.1.17.2. 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.

The screenshot shows the 'Report' window with the following sections:

- Patient private data:** Fields for Last name (Mario), Name (Rossi), Date of birth (1915/02/29), Address (Via dei Firoi, 1297 - Bologna), Bed (23), Clinic (W34F), Dpt. (Gen.), Request date (2008/01/12), Doctor (Bianchi), Email (email@provider.xx), Phone (+390012335678987), and Notes (None). Buttons for Save and Print are also present.
- Analysis results table:** A grid showing Sample Id, Methods, Result, Reference values, and Notes for various tests. The data is as follows:

Sample Id	Methods	Result	Reference values	Notes
0002-20080505	AST GOT (1:1)	43.24 U/l	5.000 - 50.000	
0002-20080505	Creatinine (1:1)	1.21 mg/dl	0.400 - 1.300	Blank out of range
0002-20080505	Cholesterol (1:1)	110.52 mg/dl	0.000 - 0.000	Blank out of range Out of ...
0002-20080505	Calcium Ars (1:1)	9.37 mg/dl	7.000 - 10.000	Error in standardization
0002-20080505	ALP DEA (1:1)	175.43 U/l	80.000 - 160.000	Out of normal
0002-20080505	Albumin BCG (1:1)	4.52 g/dl	0.000 - 0.000	Out of normal
0002-20080505	Gamm GT (1:1)	39.06 U/l	10.000 - 55.000	Blank out of range
0002-20080505	Triglycerides (1:1)	133.18 mg/dl	70.000 - 180.000	
0002-20080505	Protein Total (1:1)	6.92 g/dl	0.000 - 0.000	Out of normal
0002-20080505	Phosphorous (1:1)	4.26 mg/dl	0.000 - 0.000	Out of normal
0002-20080505	Glucose (1:1)	101.18 mg/dl	70.000 - 120.000	
0002-20080505	Urea UV (1:1)	43.03 mg/dl	12.000 - 45.000	
0002-20080505	Uric Acid (1:1)	4.37 mg/dl	0.000 - 0.000	Out of normal
0002-20080505	Iron ferene (1:1)	104.93 mg/dl	0.000 - 0.000	Out of normal

Figure 63: Report Window

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

Field/Command	Function
<b>Patient private data section</b>	
Last name:	this alphanumeric field shows the surname of the patient and allows the operator to modify it.
Name:	this alphanumeric field shows the name of the patient and allows the operator to modify it.
Date of birth (YYYY/MM/DD):	this alphanumeric field shows the patient date of birth and allows the operator to modify it. The format of the field is: yyyy/mm/dd where, <ul style="list-style-type: none"><li>• yyyy → year, 4 digits;</li><li>• mm → month, 2 digits;</li><li>• dd → day, 2 digits.</li></ul>
Address:	this alphanumeric field shows the address of the patient and allows the operator to modify it.
Bed:	this alphanumeric field shows the bed number of the patient and allows the operator to modify it.
Clinic:	this alphanumeric field shows the clinic number of the patient and allows the operator to modify it.



Field/Command	Function
Dpt:	this alphanumeric field shows the department of the patient and allows the operator to modify it.
Request date (YYYY/MM/DD):	this alphanumeric field shows the date of the analysis request for the patient and allows the operator to modify it. The format of the field is: yyyy/mm/dd where, <ul style="list-style-type: none"><li>• yyyy → year, 4 digits;</li><li>• mm → month, 2 digits;</li><li>• dd → day, 2 digits.</li></ul>
Doctor:	this alphanumeric field shows ID of the doctor and allows the operator to modify it.
E-mail:	this alphanumeric field shows the e-mail address of the patient and allows the operator to modify it.
Phone:	this alphanumeric field shows the telephone number of the patient and allows the operator to modify it.
Notes:	this alphanumeric field shows eventual remarks and allows the operator to modify it.
<b>Test results window</b>	
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 values:	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.
<b>Commands</b>	
Save:	this command allows the operator to save modifications of the patient data.
Print:	this command allows the operator to print the patient analysis report.



### 7.1.18. 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: method, lot number, date and calibration unique id; any combination of the keys is possible for creating a research criterion.

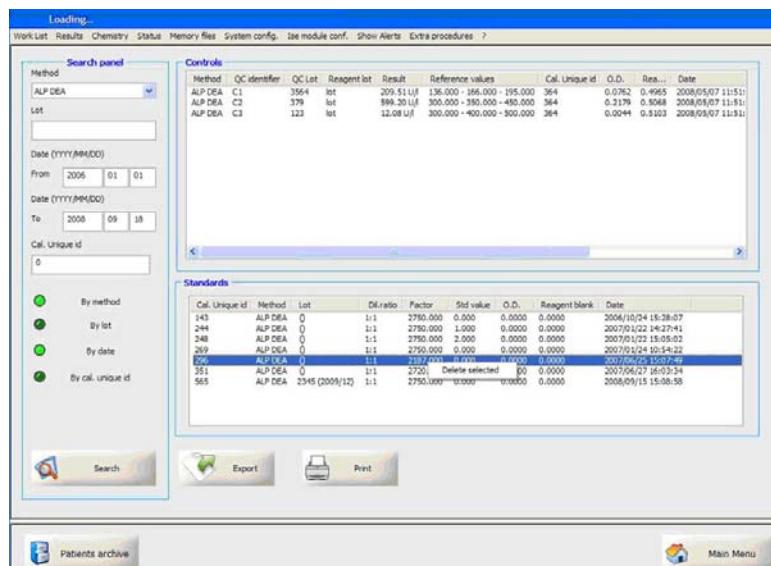


Figure 64: Std/Q.C. Archive Menu

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

Field/Command	Function
<b>Search Panel window</b>	
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.
Lot:	this field allows the operator to introduce the lot number of the standard/controls have to be searched in the archive. The system considers the content of this field only if the option search "by lot" is flagged.
Date (yyyy mm dd) from:	this field allows the operator to select the test range starting date to search in archive. The system considers the content of this field only if the searching option "by date" has been flagged.
Date (yyyy mm dd) to:	this field allows the operator to select the test range ending date to search in archive. The system considers the content of this field only if the



Field/Command	Function
Cal. Unique id:	searching option "by date" has been flagged. 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.
By method:	this selection allows the operator to search standard/controls "by method". It can be selected together with other keys.
By lot:	this selection allows the operator to search standard/controls "by lot". It can be selected together with other keys.
By date:	this selection allows the operator to search "by date". It can be selected together with other keys.
By cal. Unique id:	this selection allows the operator to search a patient "by Cal. Unique id". It can be selected together with other keys.
<b>Controls window</b>	
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.
Reference values:	this column, not editable, show the lower and the higher limits of the normal range of the control.
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.
Notes:	this column, not editable, shows the notes related to the control's analysis result.
<b>Standards window</b>	
Cal. Unique 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.
<b>Commands</b>	
Search:	this command allows the operator to start the research of standards and controls based on the chosen criteria.



Field/Command	Function
Export:	this command allows the user to export the searched QC and standards into a file. See " <b>QC Results Exported File</b> " paragraph of this manual for format and location of exported file.
Print:	This command allows user to print all result in a compact format report.
Patients Archive:	this command allows the operator to enter the Patient Archive menu.
Main Menu:	this command allows the operator to go back to the Main Menu.

**Note: the “Export all” 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 and under his responsibility.**

**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.**



### 7.1.18.1. QC Results Exported Files

The command *Export QC* in Std/QC Archive menu gives the operator the possibility to export the results of controls into files. They include the result of the research carried out in the Std/QC Archive menu.

This file is exported into a special folder ("exported results") for user handling; it can be copied on a media or accessed by a host computer when, in example, the KROMA managing PC has been connected into a LAN.

In case that the KROMA PC has been included 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.

#### KROMA program root folder

**ProgramRoot = %ROOT% \Program Files\KROMA**

#### Location and Format of the QC exported file

This file includes the results searched and displayed in the Std/QC Archive.

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 file:*

**%ProgramRoot% \ExportedResults**

*File name:*

**expQC\_YYYY\_MM\_DD\_hh\_mm.csv**  
(i.e.: expQC\_2006\_10\_17\_55\_43.csv)

*where:*

- YYYY = year
- MM = month
- DD = day
- hh = hour
- mm = minute.

*File Structure Format:*

Record delimiter character: **ascii code 10 (Line Feed)**

Record Field delimiter: **ascii code 59 (';')**

*Record fields:*

Method Internal Index *	Method Acronym	QC Identifier	QC lot	Reagent lot	Result	Unit of Measurement	Minimum Reference Value	Theoretical Reference Value	Maximum Reference Value	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.
- 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.



### 7.1.18.2. QC results Auto-exporting for Back Up

The system stores in memory up to 8,000 records; when reaching the 8,000<sup>th</sup> 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 file is a “.csv” type (Comma Separated Value) available to the user; the name given to the file has the following format: *ResultQCDaily\_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.

*Location of the file:*

**%ProgramRoot% \Export**

*File name:*

**ResultQCDaily\_yyyy\_mm\_dd.csv**

(i.e.: ResultQCDaily\_2006\_10\_17.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:*

<b>idMethod</b>	<b>Acronym</b>	<b>QCIdentifier</b>	<b>Lot</b>	<b>results</b>	<b>UM</b>	<b>Min</b>	<b>Mean</b>	<b>Max</b>	<b>Date</b>
-----------------	----------------	---------------------	------------	----------------	-----------	------------	-------------	------------	-------------

*Fields meaning:*

- idMethod: 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).
- Acronym: acronym given to the analysis method.
- QC Identifier: identify if control C1, C2 or C3.
- Lot: lot number of the QC serum.
- Result: result of the control.
- UM: unit of measurement of the result.
- Min: minimum normal value of the control.
- Mean: theoretical value of the control.
- Max: 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.

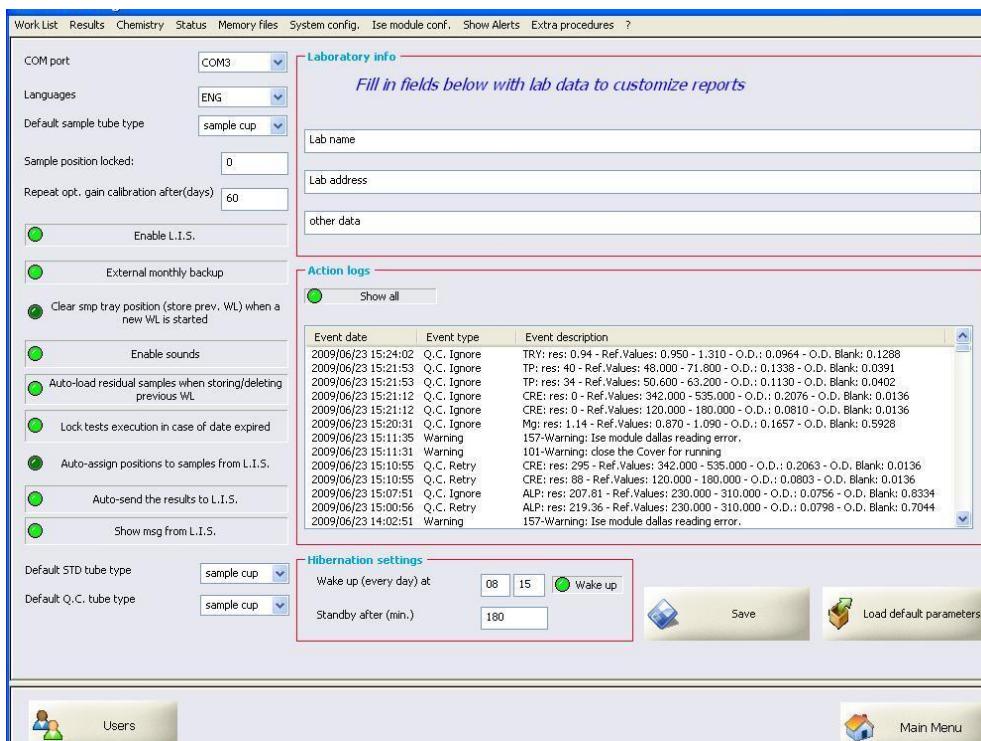


### 7.1.19. System Config Menu

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, etc.

#### **WARNING**

**Never use sample cups different from those suggested by the producer.  
It could cause sampling probe crashes and/or false samplings.**



**Figure 65:** System Config Menu

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

Field/Command	Function
<b>Selections</b>	
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 <b>Save</b> ; any modification will be operating at the next software start-up, so close and restart the complete 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 <b>Save</b> ; any modification will be active immediately even if full



Field/Command	Function
Default sample tube type:	activation will be operating at the next start up. 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"><li>• sample tube</li><li>• 3ml sample cups.</li></ul> Any modification must be saved and it will be active with the next Start running.
Sample position locked:	this field allows the operator to block and lock the sample tray on the position (normally 1) introduced <b>only for service purposes</b> . That means: the instrument, during sampling operations in the run, doesn't consider the real position of each sample given during Work List programming, but it will draw 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. <b>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.</b>
	<b>WARNING</b> <b>Instrument must operate in normal condition only with this field set to "0".</b>
Repeat opt. gain calibration every (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 days are counted starting from 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.
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.
External monthly back-up:	if this selection is active, every month the user software interface will ask the operator for the back up of the database into a special encrypt file. In case the operator chooses for the automatic back up procedure, he will be asked to decide the path.
Free 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 Start command only if it has been started by the Idle 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	if this selection is active, the system doesn't enable the operator to run



Field/Command	Function
case of date expired:	tests whose reagent, standard/calibrators or control expiry date have been exceeded; they are <b>locked and cannot be run</b> . 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.
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). <b>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.</b>
Show msg from L.I.S.:	if this selection is active, the system automatically will <b>display</b> the message "New samples received from L.I.S." <b>anytime</b> 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.
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"><li>• sample tube;</li><li>• 3ml sample cups.</li></ul> 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"><li>• sample tube;</li><li>• 3ml sample cups.</li></ul> Any modification must be saved and it will be active with the next Start running.
<b>Laboratory Information window</b>	
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



Field/Command	Function
	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.
<b>Hibernation settings</b>	
Wake up (every day) at:	this field allows the operator to set the <b>hour</b> and the <b>minute</b> for the automatic <b>system wake up</b> from a previous hibernate status. The wake up can take place either if the hibernation status was entered manually (on operator command from Status menu) or if it was entered automatically (see the following command). The automatic wake up is enabled by selecting the command Wake up (see the following). <b>Note: the wake up requires the system running during hibernation that means: never exit the software when system is in hibernation.</b>
Standby after (min):	this field enables the automatic stand by of the system after a given time from entering the Idle status. If this field is left equal to "0" (zero) minutes, then the automatic stand by feature is <b>disabled</b> . By entering in this field <b>the number of minutes</b> included in the range between 1 minute and 720 minutes (12 hours) the stand by feature is enabled and the system will enter the hibernation mode after that given time is expired. That time counting starts from when the Idle status is entered; any action of the operator on the mouse and/or on the keyboard retriggers the time counter to zero. The hibernation status includes the following actions: lamp shut down, motor disabling, incubation heater disabling. The hibernation can be stopped and the Idle status resumed just on operator manual command (see Status menu) or after the automatic wake up feature has been set and enabled. Of course the Idle status will be entered after the warming up time that follows the same rules as for a system start up: <ul style="list-style-type: none"><li>• Hibernation time for less than 2 minutes: No Warming Up</li><li>• Hibernation time for more than 2 minutes and less than 120 minutes: only 20 minutes lamp warming up time</li><li>• Hibernation time for more than 120 minutes: complete warming up including cuvette washing and auto-zeroing.</li></ul> <b>Note: during hibernation never exit the software.</b>
Wake up:	this command allows the operator to enable the automatic system wake up feature. When this command is selected the system perform the auto wake up following the rules given above. If not selected, the system will not perform any auto wake up.
<b>Commands</b>	
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.
Users:	This command allows the operator to enter the Users menu.
Main:	this command allows the operator to go back to the Main Menu.



### 7.1.19.1. Action Logs Auto-exporting for Back Up

The system stores in memory and keeps on-line up to 5,000 main events; when reaching the 10,000<sup>th</sup>, the program removes the oldest 2,000 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.

*Location of the file:*

**%ProgramRoot% \Export**

*File name:*

**ExpLogs\_yyyy\_mm\_dd.csv**

(i.e.: ExpLogs\_2006\_10\_17.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:*

<b>idEvent</b>	<b>EventType</b>	<b>EventTime</b>	<b>EventDescription</b>
----------------	------------------	------------------	-------------------------

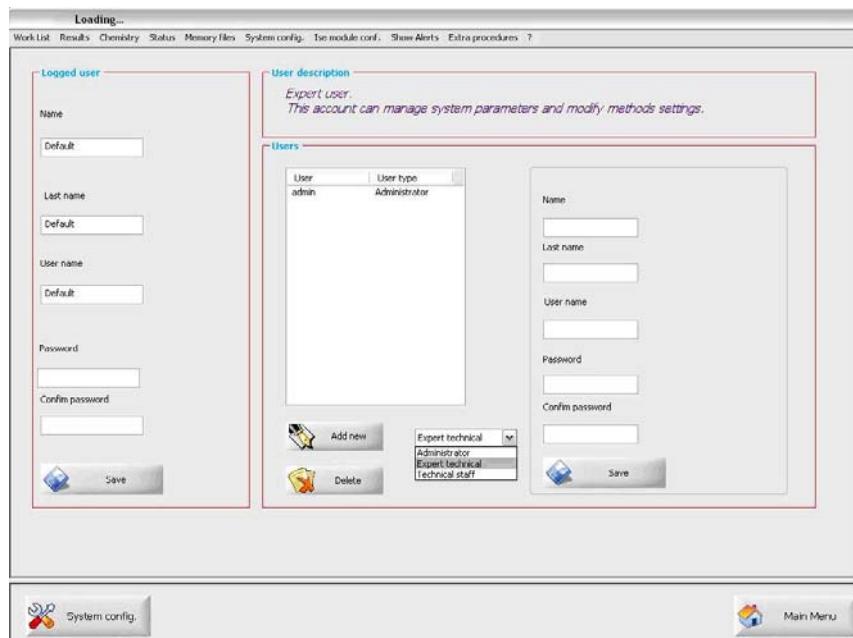
*Fields meaning:*

- 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.



### 7.1.20. 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.



**Figure 66:** Users Menu

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

Field/Command	Function
<b>Logged User section</b>	
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.
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.
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.
<b>All Users section</b>	
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.



Field/Command	Function
Users type column:	this window, not editable, shows the level of login for the side user.
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.
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.
<b>Commands</b>	
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 side 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.
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, which 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 ...).  |



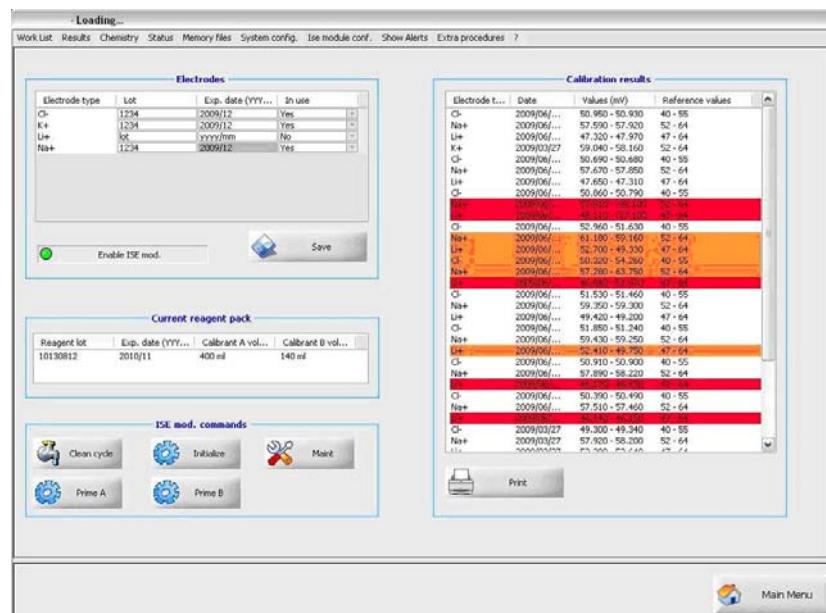
### 7.1.21. ISE Module Menu

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. The operator can enter the ISE Module menu by selecting the command ISE Module 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 67:** ISE Module Menu

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

Field/Command	Function
<b>Electrodes section</b>	
<b>Electrode table list</b>	
<b>Electrode type:</b>	this field lists the electrodes included in the ISE Module: Na+, K+, Li+ and Cl-.
<b>Lot:</b>	this field allows the user to introduce Lot number referred to the electrodes aside. Any modification must be saved by clicking the command Save.
<b>Exp. date (YYYY/MM):</b>	this field allows the user to introduce the expiration date of the electrodes. Any modification must be saved by clicking the command



Field/Command	Function
In use:	Save. this field allows the user to set any single electrode as <b>enabled</b> or <b>disabled</b> . The system will not consider disabled electrodes that can be replaced with dummy ones (called “ <b>spacers</b> ”) and of course their meaningless results. That means that also calibration results and patient results associated with disabled electrodes will be ignored.
Commands	
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.
<b>Current reagent pack section</b>	
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.
<b>Calibration results section</b>	
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 then 1.5mV.	
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.
<b>ISE Module commands</b>	
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.



Field/Command	Function
Initialize:	this command allows the operator to reply the <b>initialization cycle</b> of the ISE Module once more. It is just the same that has 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 <b>before to change electrodes</b> . It must be activated before to replace one or more electrodes. It suspends 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.
<b>Other commands</b>	
Print:	this command allows the operator to print the list of the calibration results displayed in the Calibration result window.
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.

Location of the file:

**%ProgramRoot% \Export**

File name:

**expisecal\_yyyy\_mm\_dd.csv**  
(i.e.: expLiNEARcal\_2006\_10\_17.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:

<b>idisecal</b>	<b>idMeth</b>	<b>CalRES1</b>	<b>CalRES2</b>	<b>Date</b>
-----------------	---------------	----------------	----------------	-------------

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. 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.

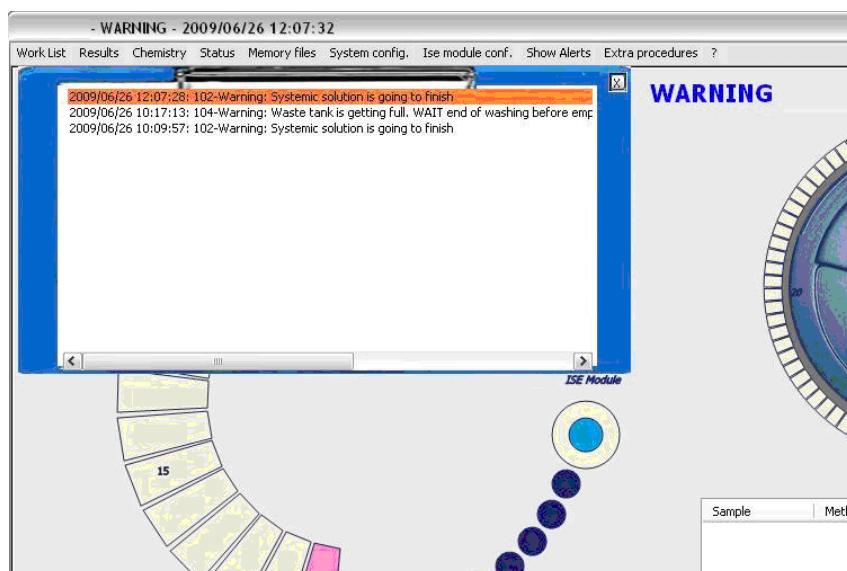


Figure 68: Show Alerts Window

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

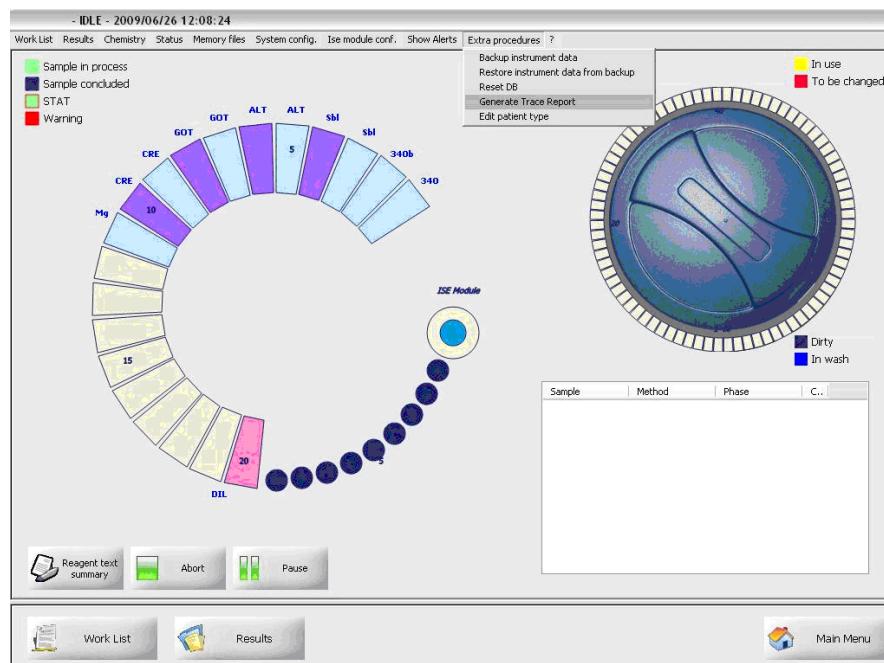


some reagents are finished, the operator must decide if to abort the related analyses into that run or if to refill the bottles and continue the run itself). Refer to the troubleshooting section of this manual for correct interpretation.



### 7.1.23. Extra Procedures Pull-down Menu

This pull-down menu can be open, from any menu, by selecting the command **Extra Procedures** located in the upper menu-bar only.



**Figure 69:** 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 system 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 day

of 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 because the use of this command clears also results that have been concluded but not stored. So, use it after memorization of the 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 stored into the folder C:\Program Files\KROMA\TraceReports.



## 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 dispensation.

**NOTE: The information over samples provided by this manual has a general meaning. An attentive reading of the reagent kit product instructions 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

KROMA can be used for an automatic In-Vitro analysis of the following samples types:

- serum,
- plasma,
- urine,
- CSF,



and other biological fluids resulting by the sample treatment (read the section on the documentation complementing the Reagent Kit).

### 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. KROMA pre-dilutes each Sample if requested during Work List compilation.

### 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

KROMA can adopt a barcode reader (option) for positive sample identification and their relation to the Work-List.

SAMPLE TUBES

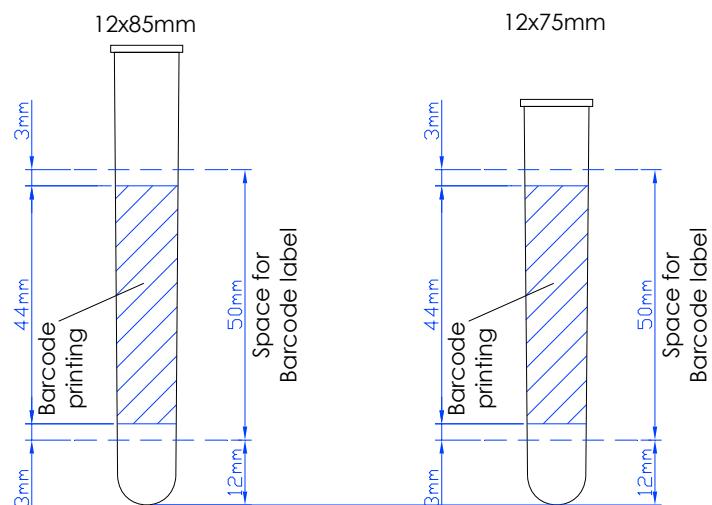


Figure 70: Primary Tubes – Barcode labelling



When the barcode reader is used, the label (50mm high) must be stick on the primary tubes (diameter=12÷13mm, height=75÷85mm), 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,  
height = 75÷85mm.

**Note: Pay attention in not using primary tubes higher than 85mm as sampling probe can be damaged; in order to extract primary tubes easily after use, don't use them if shorter than 75mm.**

The sample tray includes 50 primary sample positions plus 6 positions for paediatric samples can be contained in small paediatric cups that can be supplied on request. These cups are the same used as: dilution cups for sample dilution, for standard/calibrators and for controls.

#### WARNING

**The use of sample tubes that do not meet the conditions required could give some problems in sample aspiration/dispensation and then can 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	Code	Dead Volume
Primary tube diam. 12mm	-----	≤120µl
3ml sample cups	P3140000001	≤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.

Both 50ml and 20ml bottles can be used without the need of any support or adapter.



**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

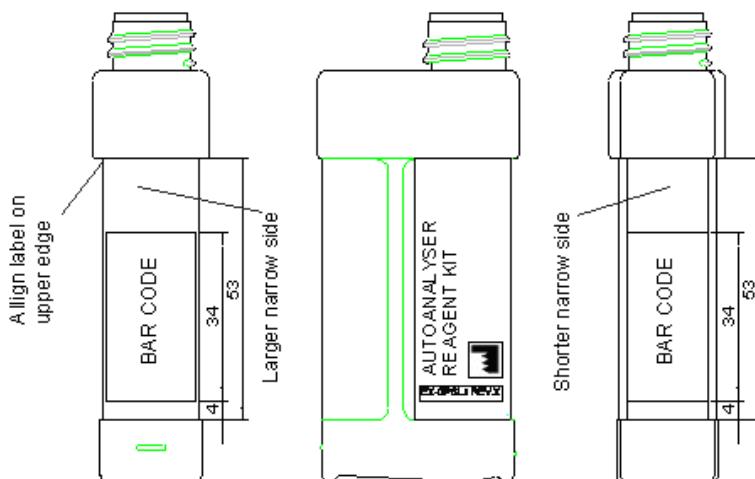
In order to store reagents and consumables properly, the user must follow the instruction provided by the product documentation following the kits.

**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

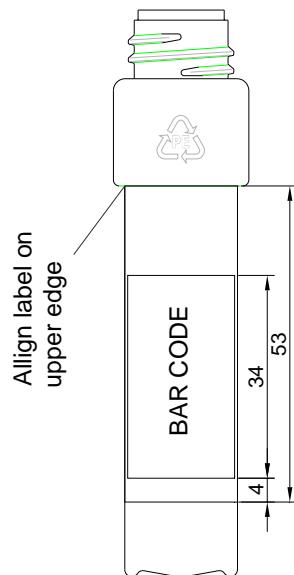
KROMA can adopt a barcode reader (option) for the reagent identification and their association with the reagent tray position and the Work List.

When the barcode reader is used, the label must be stick on the bottles (50ml and 20ml type) so that the printed barcode is respecting the following pictures.





**Figure 71:** 50ml Reagent Bottle – Barcode Labelling



**Figure 72:** 20ml Reagent Bottle – Barcode Labelling

The barcode type must be: **code 128 type-B**.



#### 7.2.4. Tooling and Fittings

A list and description of the KROMA tooling and fittings is provided by Section 3 of this manual.



### 7.3. ISE module Configuration and Use (if included as option)

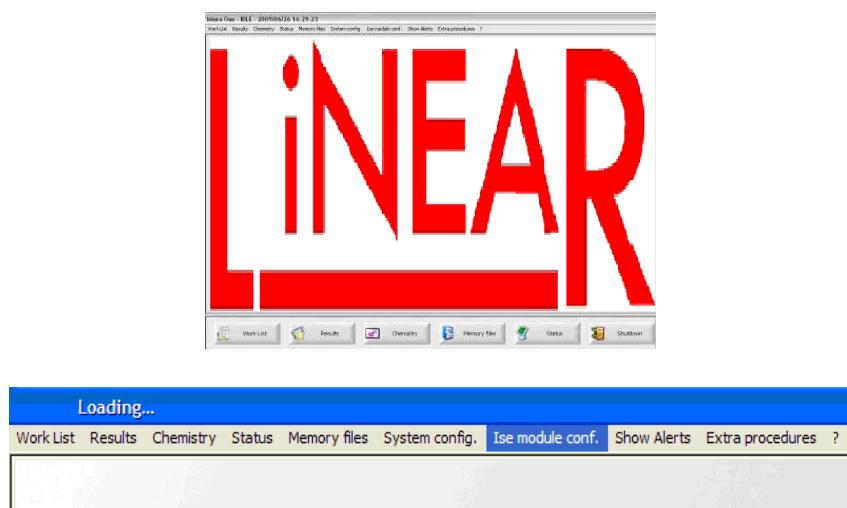
When the ISE module is included as option in the instrument, it must be powered on and configured as “enabled” in the user software interface before to use it for electrolyte analysis. This must be done once and the configuration will last until the next change.

A green internal lamp shows that the ISE module is powered on; it must be lighting ON when instrument is in electronic ON status.

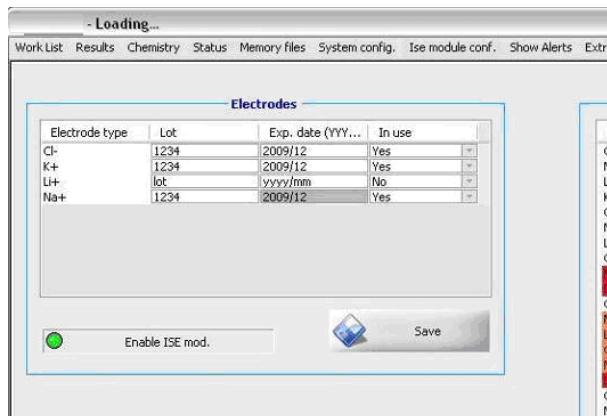
When the user plans not to use the ISE module for more than one week, he can disable it by software and extract and save the electrodes. The following procedure must be followed when the User needs to enable or disable the ISE module by software.

#### **Enable the ISE module:**

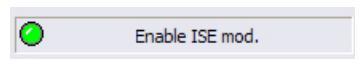
1. Switch ON the instrument.
2. Run the KROMA software and wait for the Warming Up
3. From the KROMA user interface software enter the ISE module configuration menu by clicking “ISE module config” on the upper Menu bar.



The *ISE module config* menu allows the operator to enable or disable the ISE module in the system



4. Check *Enable LINEAR mod.*



5. Click on *Save* button



6. Click on *Initialize* button to start ISE module.



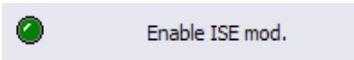
Initialization includes automatic priming of Calibrant A, priming of Calibrant B, Bubble check, Pump Calibration Cycle and ISE Calibration cycle. Results of ISE Calibration are stored in the ISE Calibration history table (left side) and, when not in range, it's automatically repeated until it's valid (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



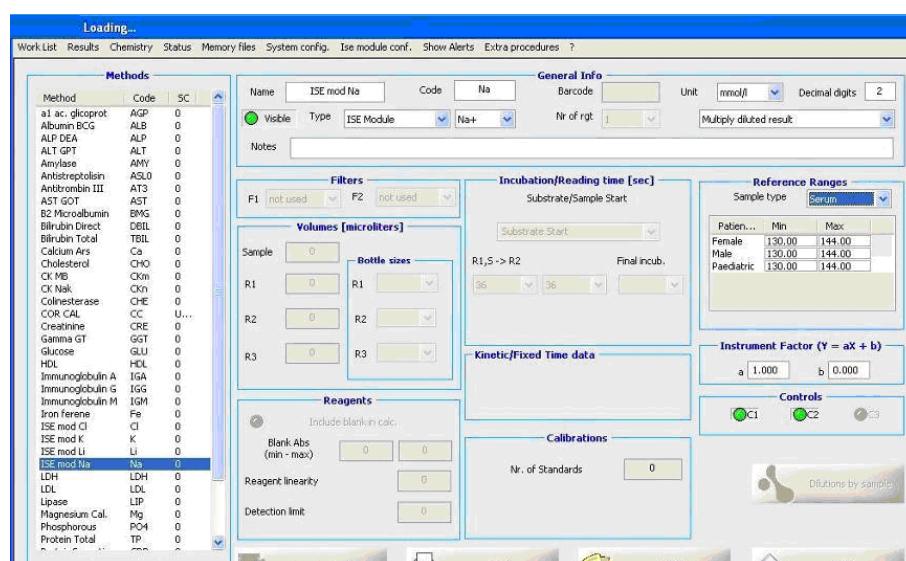
From this moment at any further system power on the ISE module will be disabled.



### 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 included in the work list.

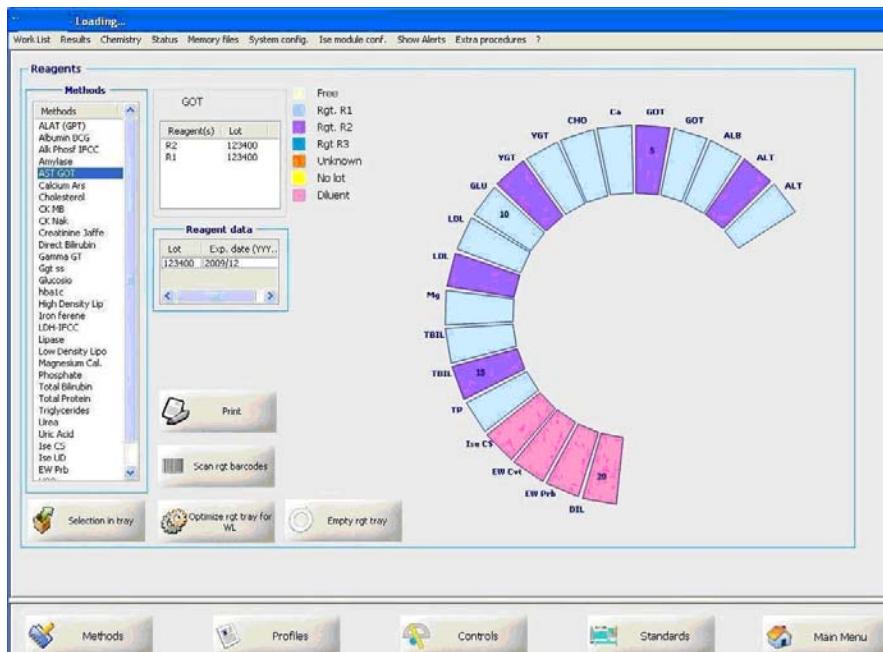
If not included in the list the user must set them. For each ISE module method, the type field in the General Info section must show “**ISE module**” and it must be selected the **kind of electrode** (if Na+, K+, Li+ or Cl-). Also, appropriate **Results Normal Values** have to be introduced and **Controls** must be chosen.



### 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 (if some urine analyses have been requested) within the “Reagent” menu.

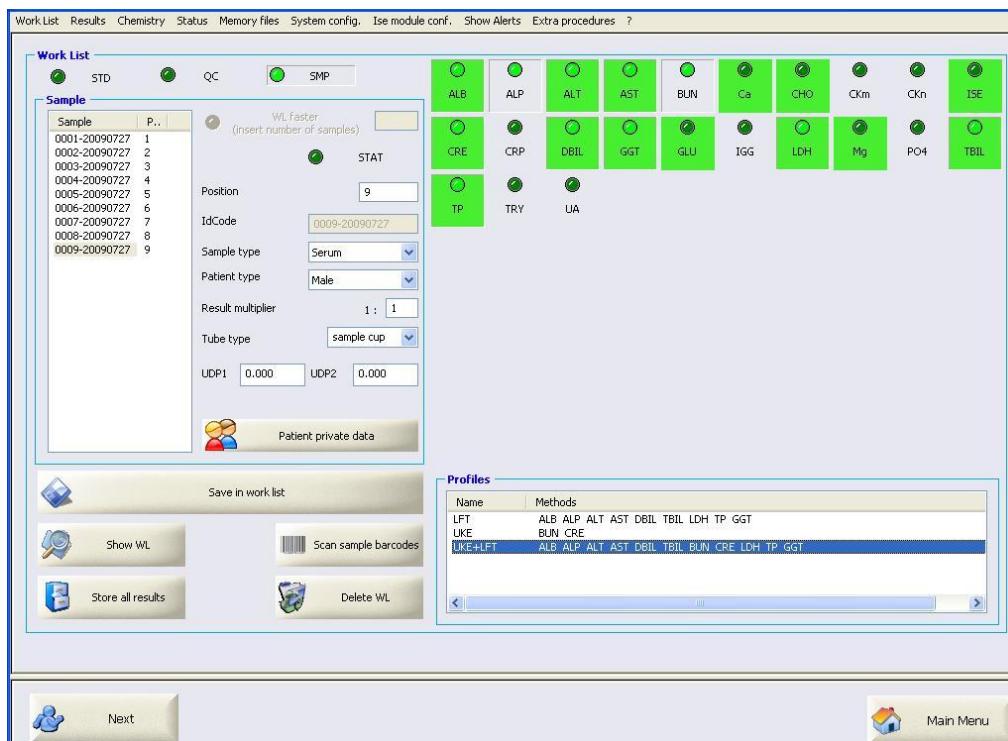
This can be achieved by placing ISE **CS** (ISE Cleaning Solution) and ISE **UD** (ISE Urine Diluent) in the reagent tray like for other methods (click and drag with mouse); remember that the cleaning solution and the urine diluent must be previously poured into 20ml reagent bottle. Of course this includes 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 of 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

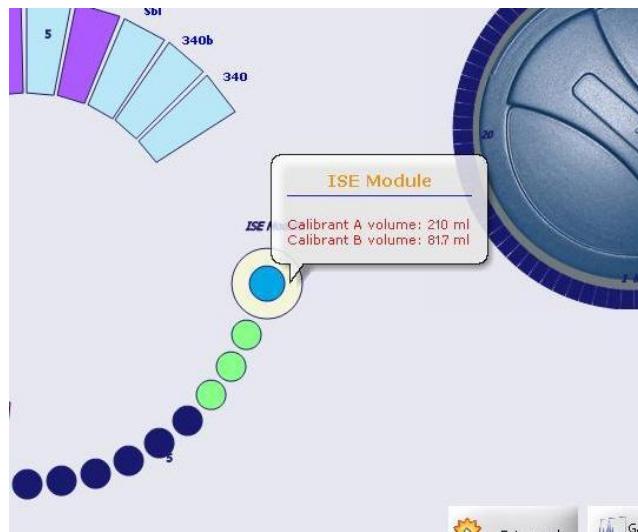
If the User has selected **urine**, the system automatically dilutes 1:10 the sample and works on it without any intervention or further possibility for the operator.

#### 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 center 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	Kin. / F.T. single OD readings
Urea UV (1:1)	Concluded	96.76 mg/dl	12.00 - 45.00	H	-0.2556	1.6616	---	1.4797 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	0.1324	---	0.3258 0.3563
Glucose (1:1)	Concluded	220.62 m...	70.00 - 120.00	H	0.7248	0.0205	---	
AST GOT (1:1)	Concluded	99.11 U/l	5.00 - 50.00	H	-0.0589	1.3324	1.000	1.3071 1.2148 1.1110
ALT GPT (1:1)	Concluded	94.12 U/l	5.00 - 50.00	H	-0.0539	1.3514	1.000	1.3415 1.2479 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	149.89 m...	0.00 - 0.00	H	—	—	—	
Uric Acid (1:1)	Concluded	7.71 mg/dl	0.00 - 0.00	H	0.1309	0.0493	---	

View Extended details  
 Delete  
 Repeat  
 View Kinetic /F.Time graph

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 ISE module config menu, if the problem persists contact service. See also next Troubleshooting paragraph. Repeat analysis.
ISE Mv Out	mV reading out of admissible range (for Cal B or Sample).	Re-initialize the ISE module from the ISE module config 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: 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 Troubleshooting paragraph.
ISE Mv noise	mV noise out of admissible range (for Cal B or Sample).	Repeat analysis.
ISE Mv noise	mV noise out of admissible range (for Cal A during calibration or in Sample mode or for Cal B in Urine mode).	Initialize the ISE module from the ISE module config menu. If the problem persists: 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 Troubleshooting paragraph.



Warning	Description	Action
ISE Cal A Drift	Cal A drift in Sample or Slope drift in calibration.	Repeat analysis. Re-initialize the ISE module from the <i>ISE module config</i> menu, wait 20 minutes if electrodes are new and repeat initialization. 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.
ISE out of slope	Result Out of Slope or Out of Machine range.	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 (if the OFF time was greater than 2 minutes). During Warming Up the instrument automatically initializes the ISE module; initialization cycle includes the following steps:

1. Priming Calibrant A;
2. Priming Calibrant B;
3. Bubble detector check and calibration;
4. Pump calibration;
5. ISE calibration.

If one of these activities fails, the system automatically retries it for 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 module 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 (*Print* button).



Calibration results			
Electrode t...	Date	Values (mV)	Reference values
Cl-	2009/06/...	50.950 - 50.930	40 - 55
Na+	2009/06/...	57.590 - 57.920	52 - 64
Li+	2009/06/...	47.320 - 47.970	47 - 64
K+	2009/03/27	59.040 - 58.160	52 - 64
Cl-	2009/06/...	50.690 - 50.680	40 - 55
Na+	2009/06/...	57.670 - 57.850	52 - 64
Li+	2009/06/...	47.650 - 47.310	47 - 64
Cl-	2009/06/...	50.860 - 50.790	40 - 55
Li+	2009/06/...	47.110 - 47.100	47 - 64
Cl-	2009/06/...	52.960 - 51.630	40 - 55
Na+	2009/06/...	61.180 - 59.160	52 - 64
Li+	2009/06/...	52.700 - 49.330	47 - 64
Cl-	2009/06/...	50.320 - 54.260	40 - 55
Na+	2009/06/...	57.280 - 63.750	52 - 64
Li+	2009/06/...	52.410 - 49.750	47 - 64
Cl-	2009/06/...	51.530 - 51.460	40 - 55
Na+	2009/06/...	59.350 - 59.300	52 - 64
Li+	2009/06/...	49.420 - 49.200	47 - 64
Cl-	2009/06/...	51.850 - 51.240	40 - 55
Na+	2009/06/...	59.430 - 59.250	52 - 64
Li+	2009/06/...	52.410 - 49.750	47 - 64
Cl-	2009/06/...	50.910 - 50.900	40 - 55
Na+	2009/06/...	57.890 - 58.220	52 - 64
Li+	2009/06/...	46.170 - 46.070	47 - 64
Cl-	2009/06/...	50.390 - 50.490	40 - 55
Na+	2009/06/...	57.510 - 57.460	52 - 64
Li+	2009/06/...	46.190 - 46.150	47 - 64
Cl-	2009/03/27	49.300 - 49.340	40 - 55
Na+	2009/03/27	57.920 - 58.200	52 - 64
Li+	2009/03/27	45.200 - 52.140	47 - 64

For each electrode both values (in mV) are shown.

Results will be back-lighted in **orange** in case the repeatability is out of the limit.

Results will be back-lighted in **red** in case values are out of the reference range.

### 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 KROMA 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 shut down procedure.

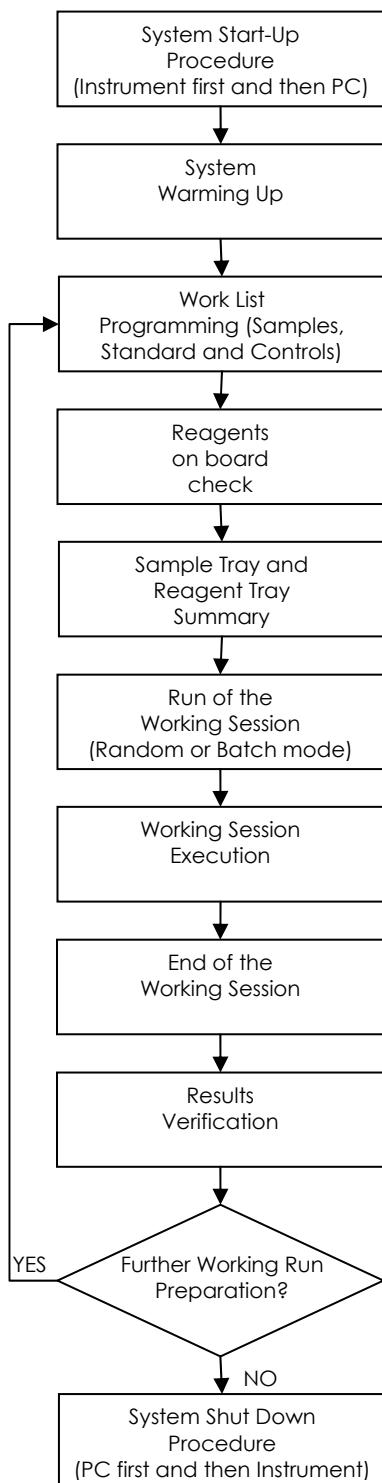
**WARNING**

The Manufacturer recommends the operator never switch off the *Personal Computer* during the shut down procedure as database can corrupt.



## 7.4. Procedures

### 7.4.1. Operating Flow Chart



**Figure 73:** 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

Two switches are placed on the left side 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.

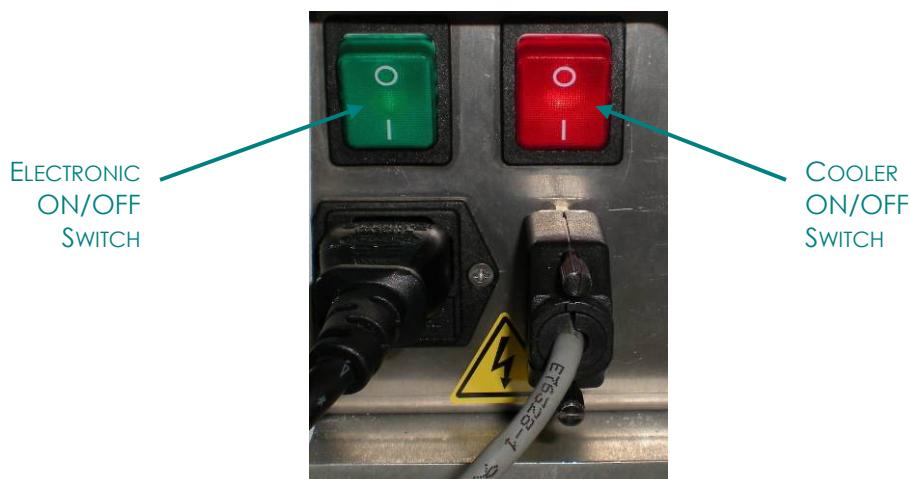


Figure 74: Power-On Switches

**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 following 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 (Multiclean @ 4% NaOH).
4. Turn on the system following the sequence below:
  - a. the Green switch (for electronic),
  - b. if wished, the Blue switch (for refrigeration).
5. Power ON the control PC and wait for the operating system loading.
6. Run the KROMA User Software Interface.



### 7.4.3. Login, Main Menu Access and Auto-diagnosis

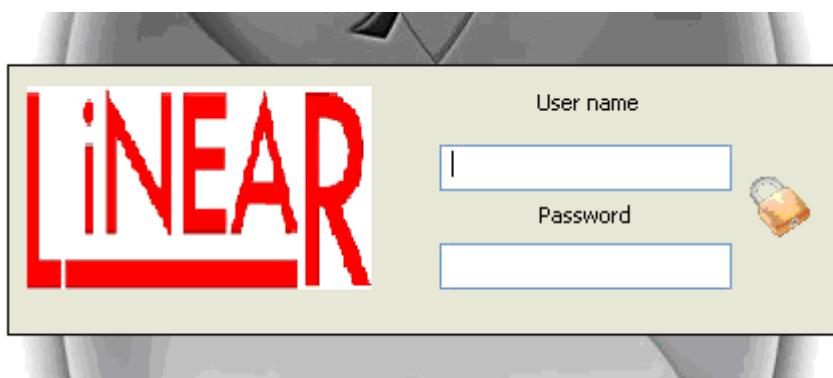
As soon as the software starts up, the instrument goes into motors reset and then it checks all main functions. The software also asks the user to login in order to gain access at the required operating level:

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**”.

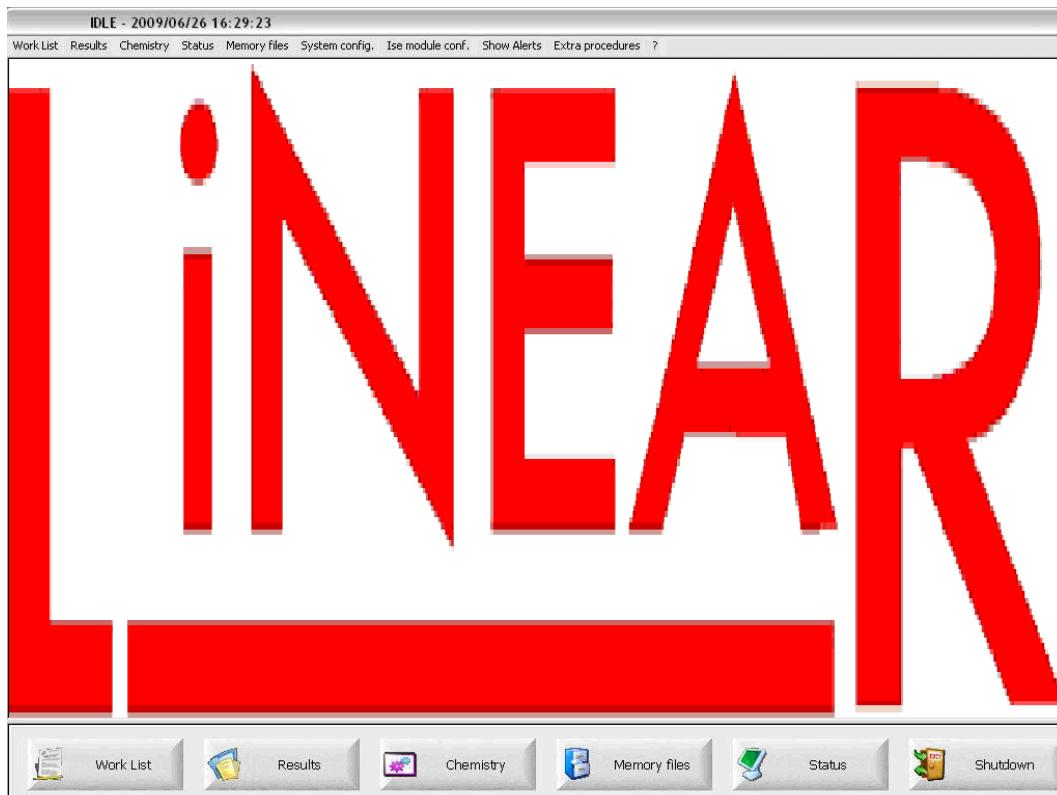
the user at Administrator Level can change these data at any. The access is denied until the correct password is entered. As mentioned before, three password levels are provided. Any account must be set or modified in the System config. → User Menu:

- Administrator level, this kind of user can fully operate on the instrument.
- Expert Technician 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.
- Technician level, this kind of user can operate on the instrument without modifying anything (i.e.: methods, accounts, etc.).



**Figure 75:** Software – Login 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.



**Figure 76:** Software, Start-Up Main Page

#### 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 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 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 and auto-check;
- start, control and regulation of the cuvette incubation heater;
- start of the sampling arm heater coils;
- 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 associated to the any sample. All of the analyses that have been programmed for samples, standard/calibrators, and controls constitute the working session and they'll be run at the *START* command.

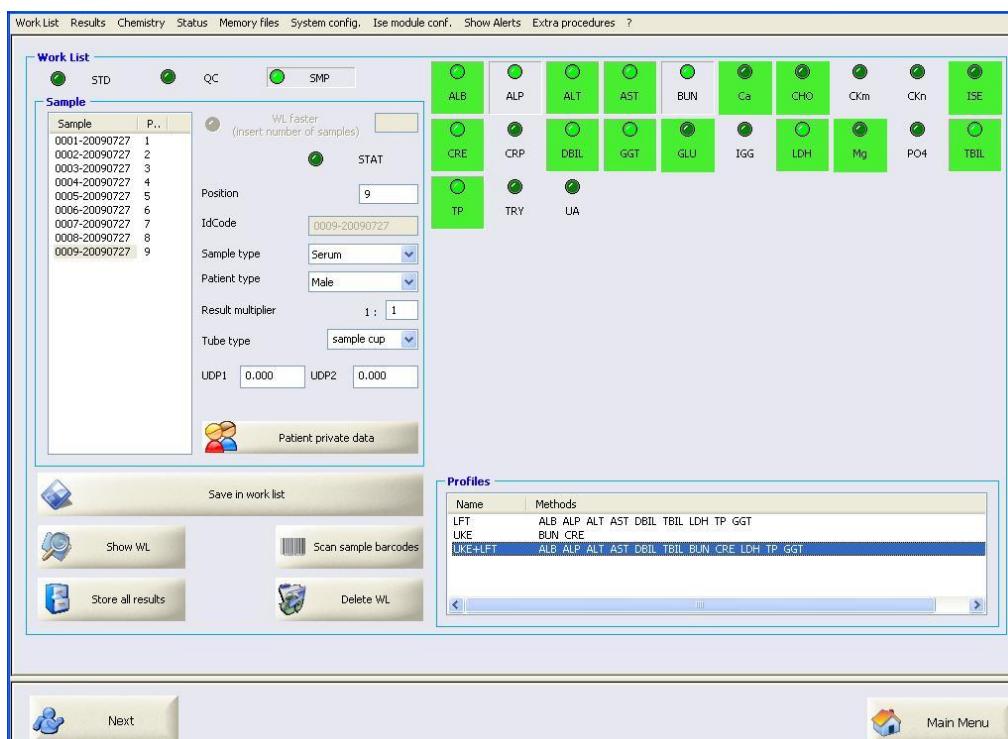


Figure 77: Software, Work List Menu

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.

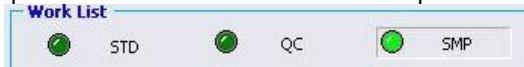
On the other hand, when the L.I.S. connection has been established, the patient list (list of sample IdCodes) and associated analyses will be uploaded from the host remote Personal Computer to the KROMA system that assigns them positions on the tray with the help of the bar-code reader.



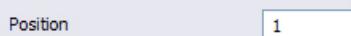
#### 7.4.5.1. Manual Work List Programming and Run

Standard procedure for manual Work List programming and run in case that no samples are hanging waiting for position assignment:

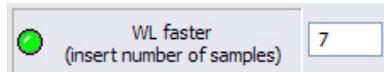
1. Select the “SMP” option in order to enter the patient Work List.



2. Enter the desired sample position (on the sample tray) in the Position field or accept the one proposed (the first lower free position is always automatically displayed).



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	P...
0001-20090727	1
0002-20090727	2
0003-20090727	3
0004-20090727	4
0005-20090727	5
0006-20090727	6
0007-20090727	7
0008-20090727	8
0009-20090727	9

WL faster  
(insert number of samples)

STAT

Position

IdCode

Sample type

Patient type

Result multiplier

Tube type

UDP1  UDP2

Patient private data

3. Enter the sample identification code *IdCode*; 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	Diam. 12

5. Select Patient type, from the pull down menu.

Sample type	Serum
Patient type	Male
Result multiplier	Male
Tube type	Diam. 12

6. Select Patient Private Data and enter data in the fields of the displayed window (if desired).

**Patient private data**

Last name	Mario	First name	Rossi
Date of birth	1980/03/27	Age	27
Address	Via dei Fiori, 987 - 00100 Roma - Italy		
Email	m.rossi@provider.ff		
Phone	+4599987654321		
Bed	47	Dpt.	2
Clinic	KS78H	Request date	02/12/2007
Doctor	Bianchi		
Notes	Nationality: Italian		

Save      Back

**Figure 78:** 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.

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.

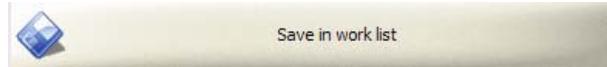
Position	STAT
IdCode	0013-20090625
Sample type	Plasma
Patient type	Male
Result multiplier	1 : 1
Tube type	Diam. 12



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 work list* to save the sample/s together with the programmed analyses in the current Work List that is under creation.



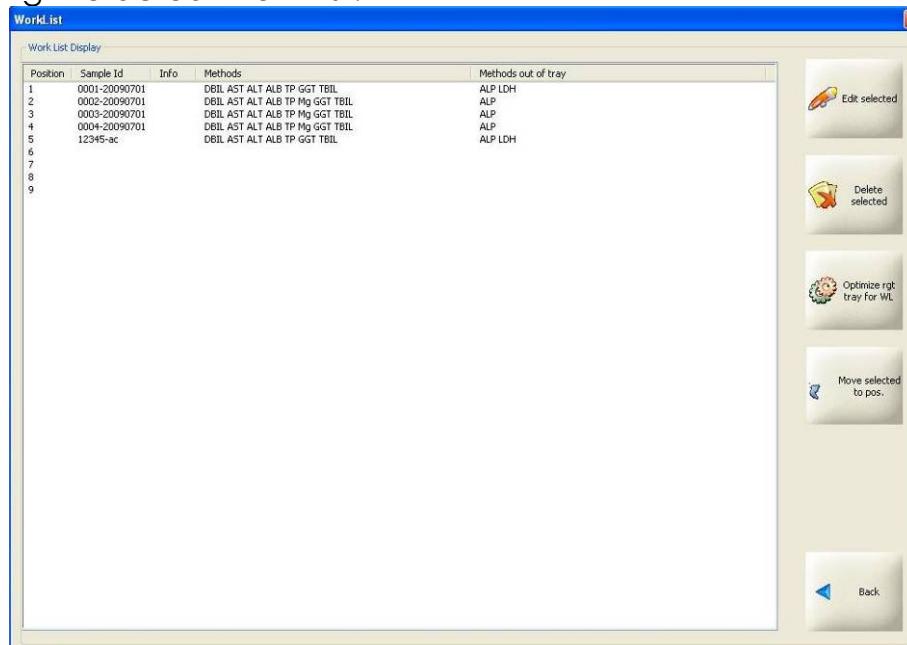
When a sample has been saved in the Work List, the program automatically shows the User, in the *Position* field, the first available position on the sample tray.

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 79:** 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, carry on 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.*



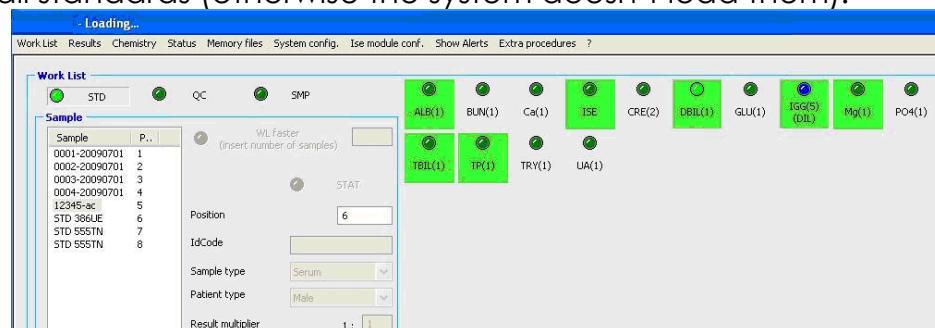
To go back to the Work List, select the command Back.

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



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).

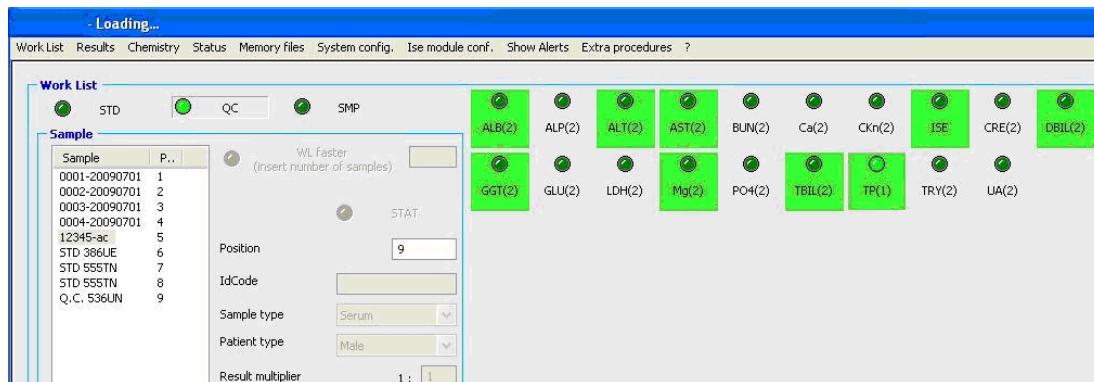


After selection, click on “Save in work list” to include the standard in the working session. The number between brackets stands for the number of standards to be performed.

14. In case that also controls must be run, select the “QC”

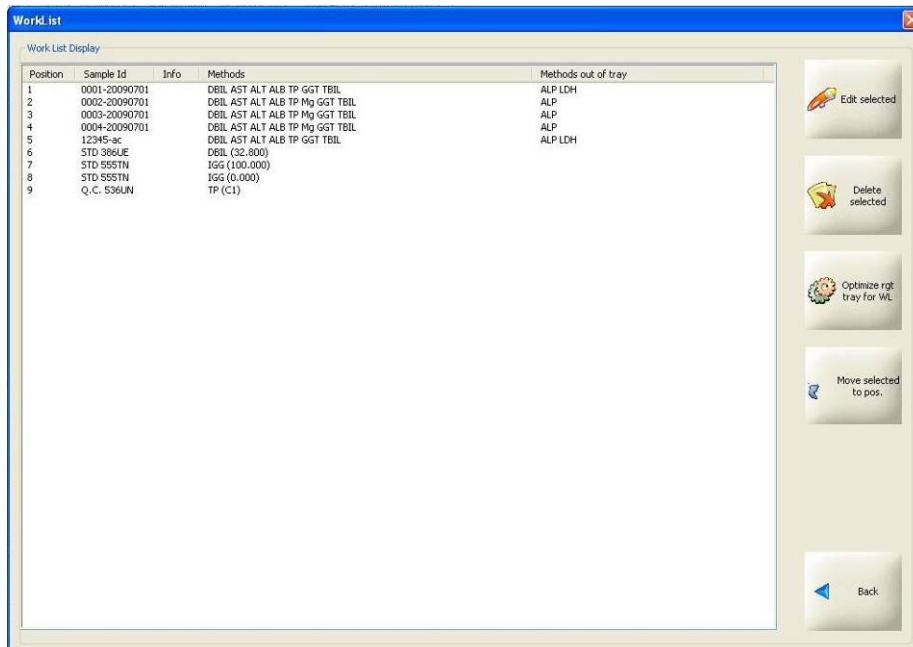


15. Then proceed with the selection of the method/s to be controlled and assigning a new position to each of them. Remember that controls with same lot number have the same sample position on the tray.

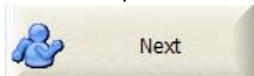


After selection click on “Save in work list” to include the controls in the working session.

16. If the Show WL command is again selected, the program displays the actual Work List:



When finish, select the command Next to proceed with the next page about Reagent tray configuration control,



In case the KROMA 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

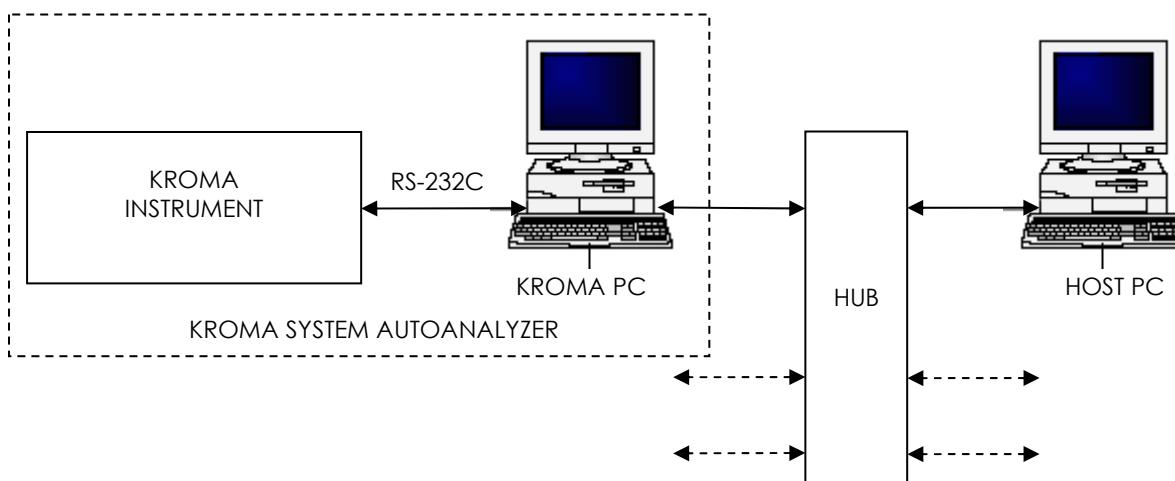
When the L.I.S. connection has been enabled and it is operative, the host remote workstation in the laboratory can set a link with the KROMA system for data exchange.

The link is based on an ASTM-like protocol described in the document cod. MNT-10910-01-x (see last revision) addressed to 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 KROMA 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 KROMA 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 KROMA 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.

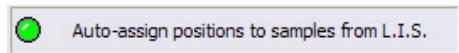




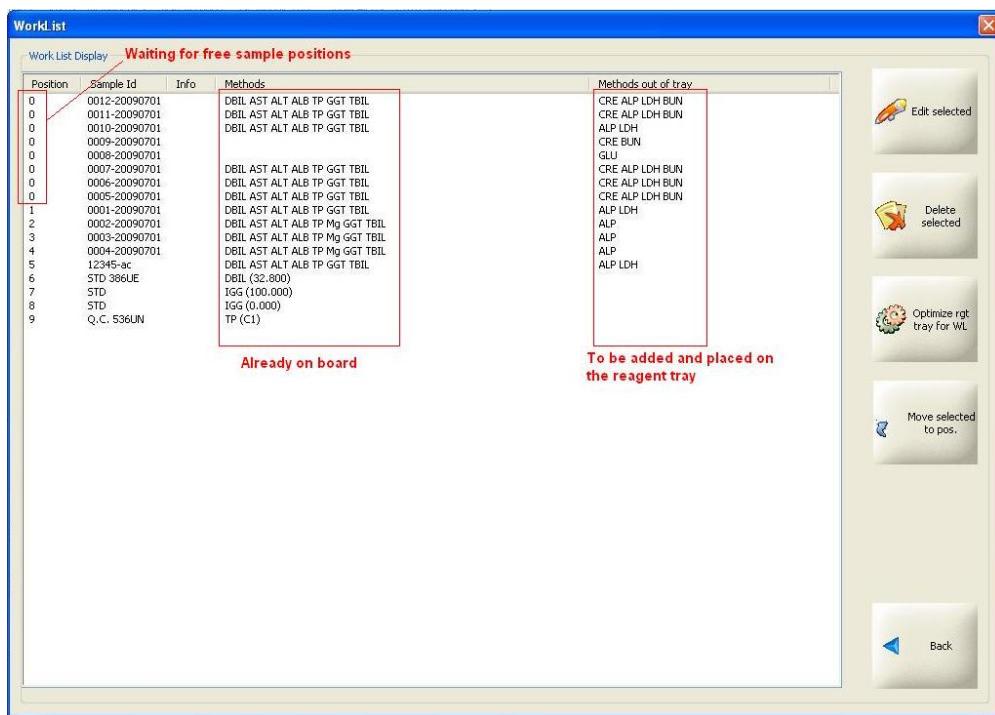
When the KROMA system receives new data from the host computer, it displays the following message on the monitor:



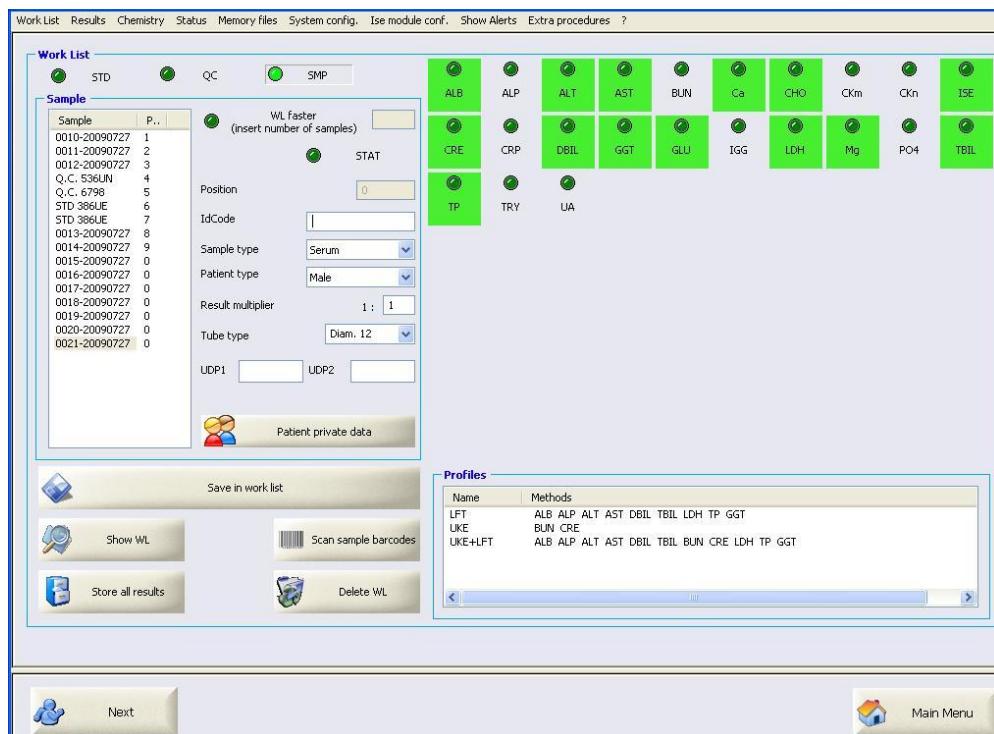
The operator, in order to run a new WL or to add those new samples to a WL in running, has to click on OK and must enter the Work List menu.  
All samples received from L.I.S. will be added into the sample window on the left side of this menu. Upon receipt, if the following selection in the System config. 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.



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 80:** 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.

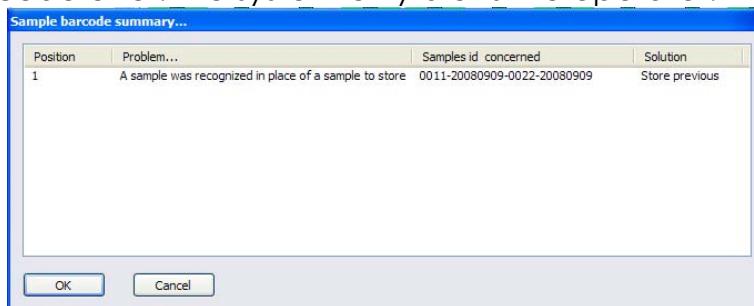
By running the command *Scan sample barcode* the tray turns one or more times to allow the reader to scan barcodes attached on the tubes and adds the samples in the Work List. Recognized samples will be associated to their physical position on the sample tray. In case of Work List downloaded from L.I.S. 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 moment manually modifies 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 can be run one shot or in triplicate.

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.

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.

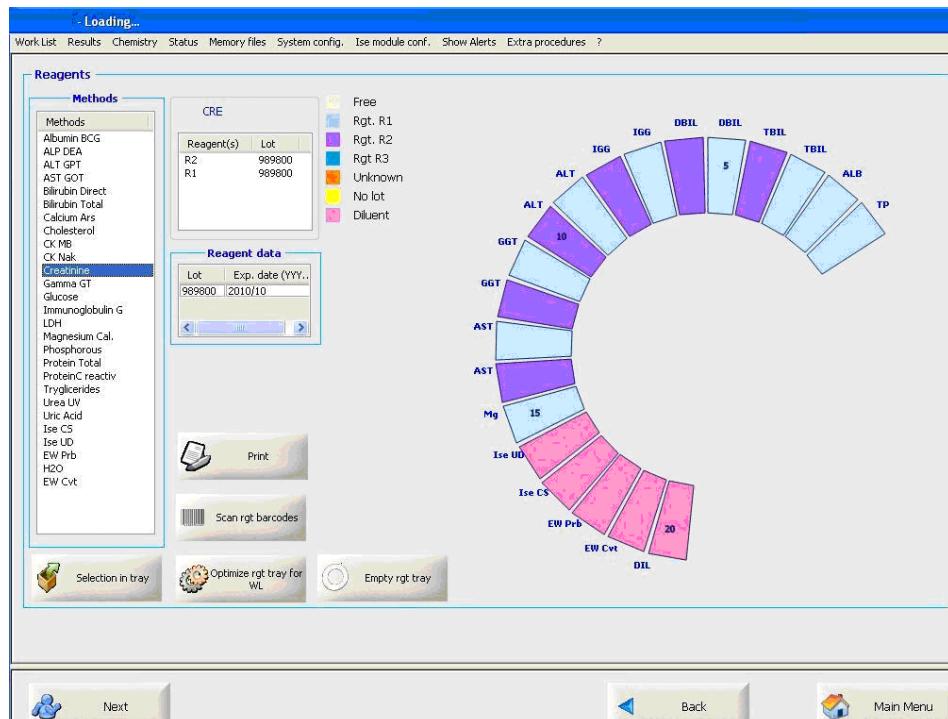
**Note: The system can anyway process standards and controls in the current work list even if they have been scheduled after the first Start command. Standards and Controls can then be added and launched in the current run.**

**Note: It is possible to run Work list with only Standards and/or Controls programmed.**



## 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 81:** Software, Reagent Menu

1. If necessary, reset all the tray positions by clicking on the button *Empty rgt tray*:

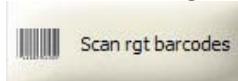


2. In the Methods window, click with the mouse on the method to be introduced in the tray.
3. In the Reagents window, click the mouse on the Reagent (R1, R2, etc.) and drag it to a position on the tray. The position is automatically allocated and saved in the configuration.
4. Enter the reagent lot and expiry date.
5. Place in the same manner the other reagents of the same method (if any).
6. Repeat the operations 3 to 6 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.

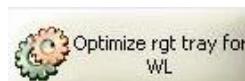




In case that reagents have been provided with proper bar-coding and the KROMA includes the reader, the operator can simply place the reagent bottles on the reagent tray positions and then by clicking the button:



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 actual work list 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 can be anyway used when needed).

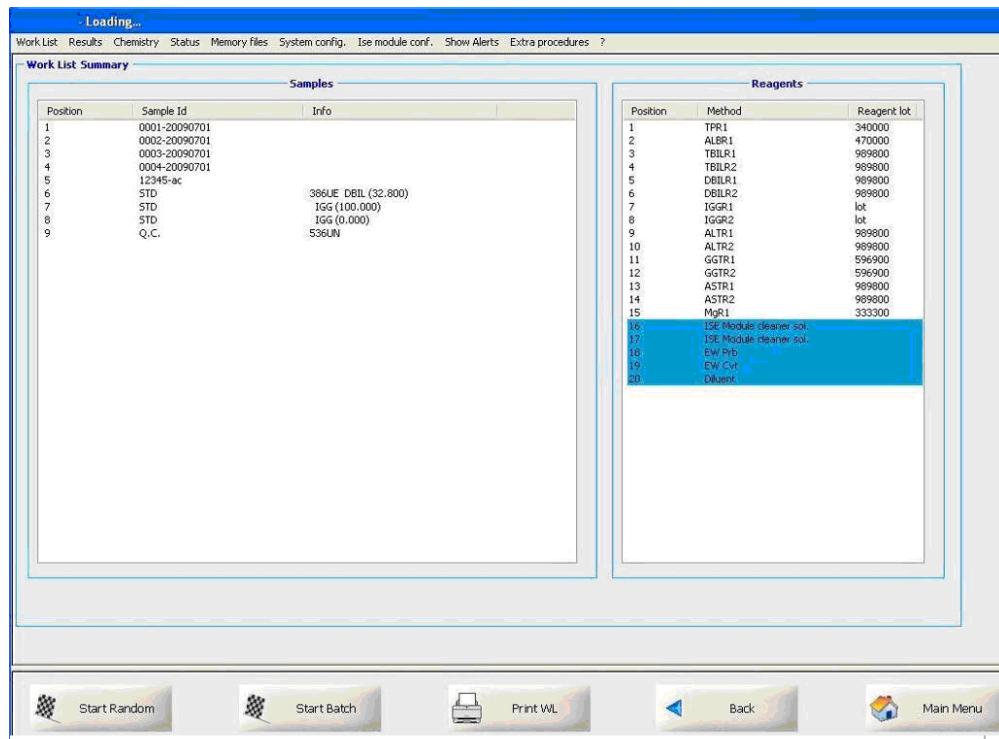
More reagents, previously selected in the method window, can be automatically moved in the tray by clicking on the button





### 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 82:** 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.



### 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.

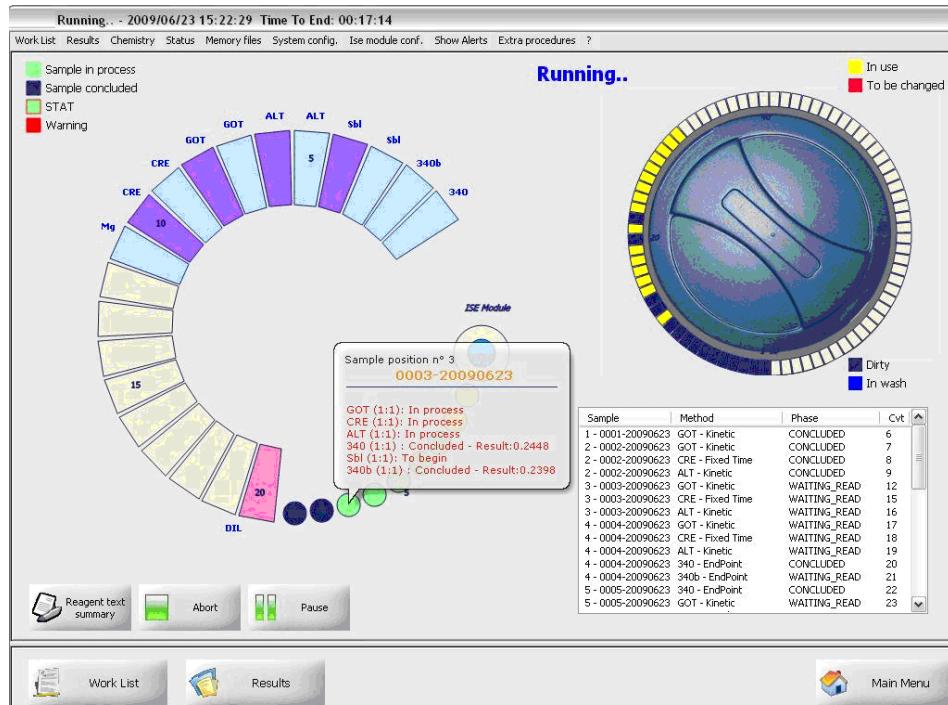


Figure 83: Software, Status Menu

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.

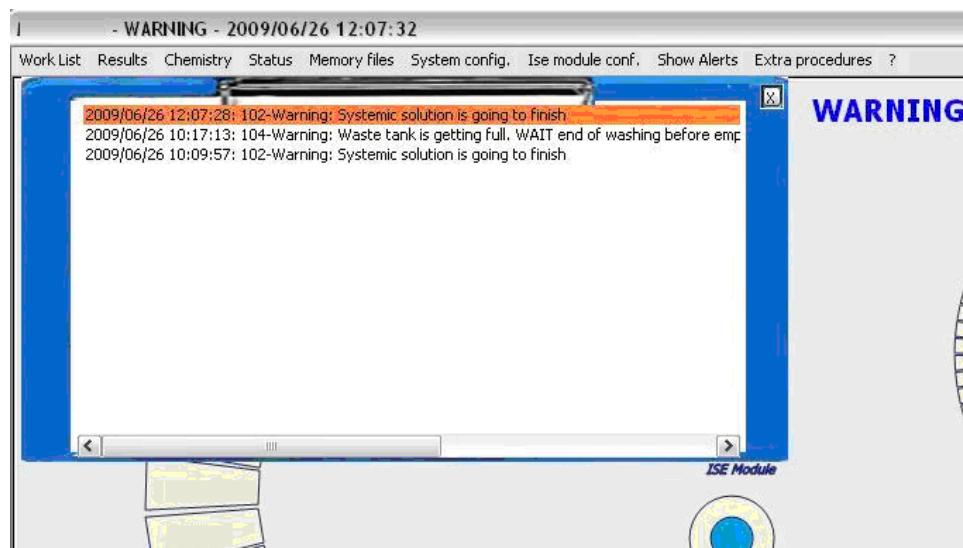
Actions allowed in other menus:

- 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 than 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 overcome.



#### 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 Sampling Arm to complete the phase and to stop above the Washing Sink.
3. Open the protection defence and do the needed operations.
4. Close the protection defence.
5. Select the command **Continue** to start again the working session.





### 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:

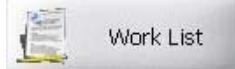
1. Check if the needed number of free positions are available on the sample tray;
2. If free positions are missing, open the *Results for patient* menu, validate the results of completed Samples and archive them.  
**Note: whenever possible, the user should leave some positions on the sample tray free for STAT urgency.**
3. Select the Command *Pause* to pause the Instrument.



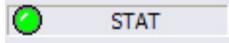
4. Wait Sampling Arm to complete their working phase and to stop above the Washing Sink.
5. Open the protection defence and introduce the STATs (urgent sample).
6. Close the protection defence.
7. Select the command *Continue* to start again the working session.



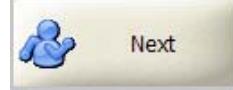
8. Select the command *Work List* to program the STAT.



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 then 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 protection defence, take the completed samples out and replace them with the new samples.
6. Close the protection defence.
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

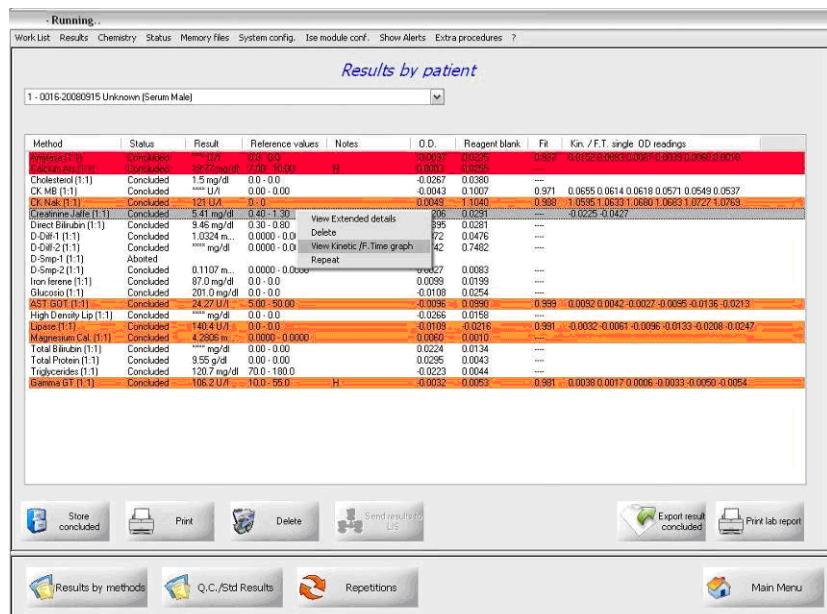
The Results menu allows the operator to handle and display all results obtained in the last working session or in the current run (for analyses concluded).

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.**

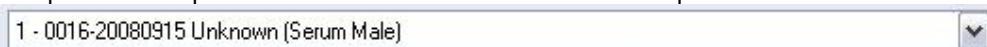


**Figure 84:** Software, Result by Patient Menu

### 7.4.9.1. Filing a Concluded Patient

When all the analyses on a sample have been concluded, the patient data and results can be filed. The procedure is described below:

1. In the patients' pull down menu select the sample to be focused.



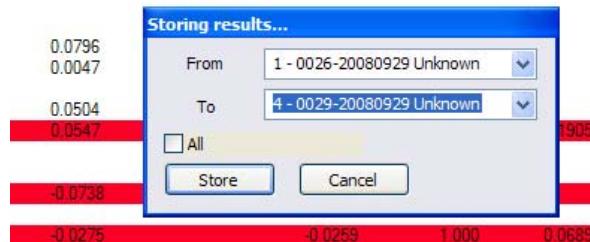
2. Control the displayed results in order to validate them.
3. Select the command *Store selected patient*.



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 completed can be moved to the archive.

#### 7.4.9.2. Deleting Some Analyses' Results

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				0.0000
Calcium Ars (1:1)	Concluded			H	0.0208
Cholesterol (1:1)	Concluded				0.0093
CK MB (1:1)	Concluded				-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.



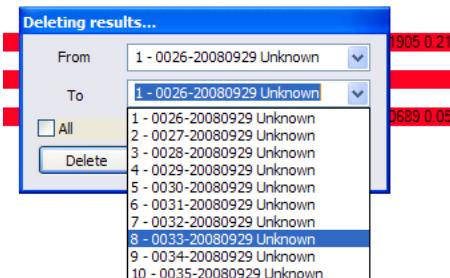
2. Select the command Delete.



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

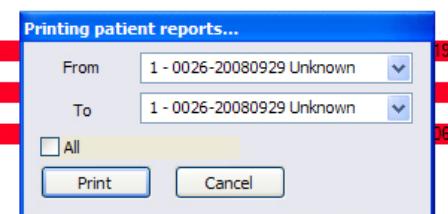
The user can print Result reports for each Patient.

The procedure is described below:

1. From the *Result by Patient* menu select the command *Print*.



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*;



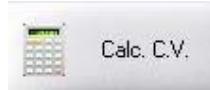
4. In the window that opens on the command above, choose the first and the last patient to be printed in the compact report then click on the command *Print*.

#### 7.4.9.6. Calculation of Statistic Parameters

The user can run the automatic calculation of the statistic parameters on a set of equal analysis, 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. Methods 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.

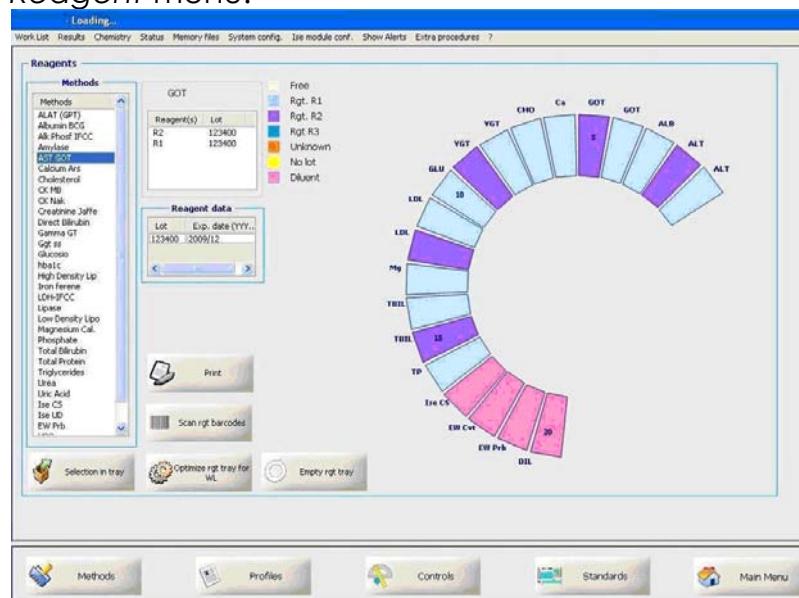
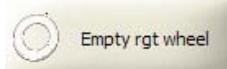


Figure 85: Software, Reagent Menu

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.



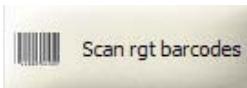
Remember to place on the reagent tray also the following solutions:

- 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 is included in the system, it is enabled and urine must be processed).

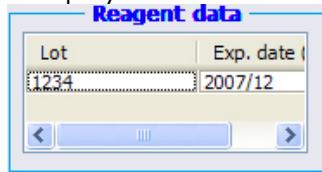
#### 7.4.10.2. Automatic Panel Configuration

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 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.

More 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);



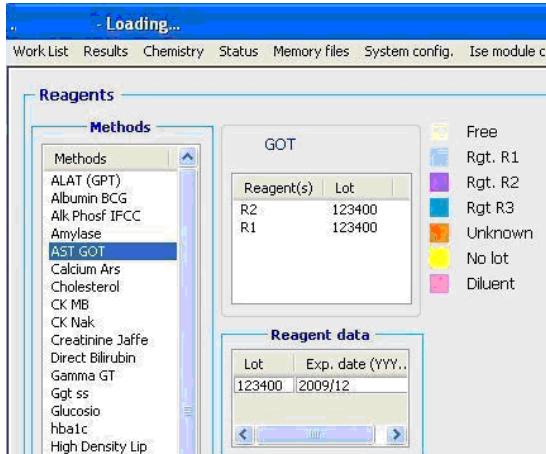
- The reagents, whose barcode has been read but not found in the saved list, are displayed as *Unknown (orange)*; a reagent can be manually given a position at a later time, following the procedure described in the paragraph above.
- The reagents without any barcode or those, whose barcode has not been read, are assimilated to free positions; a reagent can be manually given a position at a later time, following the procedure described in the paragraph above.
- The reagents whose lot number has not been assigned are displayed in **yellow**.
- 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).



Profile list

Profile name: Test #2

Name
Test #1
Test #2

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 paragraph describes how to set standards/calibrators and Controls data.

Name	Lot	Exp. d...	Nr. of Stan...	Nr of rep.	Unit	Stability on b...	Date	Dilution	Std value	O.D.	Reagent blank
630			0	1	mg/dl	0		1:1	12.5000	1.4866	0.6956
700			0	1	mg/dl	0		1:1	0.7100	1.2473	0.6944
ALAT (GPT)	12345	yyyy/mm	1	1	U/l	0	2009/04/10 14:	1:1	5.5120	1.0276	0.0000
Alk Phos IFCC	lot	YYYY/MM	2	1	U/l	0	2008/08/06 18:3	1:1	2.2300	0.6977	0.6964
Amylase		yyyy/mm	0	1	U/l	0	2008/07/01 16:	1:1	0.0010	0.4667	0.6628
AST GOT	500	yyyy/mm	1	1	U/l	0	2009/05/26 09:				
Calcium Ars	123	2	1	1	mg/dl	0	2009/04/02 10:				
Cholesterol	12345	mmm/mm	1	1	mg/dl	0	2009/04/10 14:				
CK MB	1234	yyyy/mm	2	1	U/l	0	2009/04/02 10:				
OK Nak		mmm/mm	2	1	U/l	0	2009/02/26 09:				
Creatinine Jaffe	500	www/mm	1	1	mg/dl	0	2009/04/29 15:				
CreSS		2	1	1	mg/dl	0	2008/04/09 17:				
D-Diff-1	12345	www/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Diff-2		www/mm	1	1	mg/dl	0	2009/02/26 09:				
Direct Bilirubin	lot	YYYY/MM	2	1	mg/dl	0	2009/02/26 09:				
D-Smp-1	12345	www/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Smp-2		www/mm	1	1	mg/dl	0	2009/02/26 09:				
Gamma GT	lot	YYYY/MM	2	1	U/l	0	2009/02/26 09:				
Ggt ss		www/mm	2	1	U/l	0	2008/12/04 13:				
Glucosio	500	YYYY/MM	2	1	U/l	0	2009/05/27 15:				
Total Protein	123	2	1	1	g/d	0	2009/02/26 09:				
Magnesium Cal.	12345	www/mm	2	1	mg/dl	0	2009/02/26 09:				
Phosphate	12345	www/mm	0	1	mg/dl	0	2008/12/04 13:				
Total Bilirubin	lot	YYYY/MM	2	1	mg/dl	0	2009/02/26 09:				
High Density ...		2	1	1	g/d	0	2009/02/26 09:				
Triglycerides	lot	YYYY/MM	0	1	mg/dl	0	2009/02/26 09:				
Urea		www/mm	2	1	mg/dl	0	2009/02/27 14:				
Urinc Acid		www/mm	0	1	U/l	0	2009/02/27 14:				

Print current calib. Results

Methods   
 Profiles   
 Controls   
 Reagents   
 Main Menu

#### 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. d...	Nr. of Stan...	Nr of rep.	Unit	Stability on b...	Date	Dil.ratio	Std value	O.D.	Reagent blank
630			0	1	mg/dl	0		1:1	114.0000	0.5561	0.0827
700			0	1	mg/dl	0					
ALAT (GPT)	12345	yyyy/mm	1	1	U/l	0	2009/04/10 14:				
Alk Phos IFCC	lot	YYYY/MM	2	1	U/l	0	2008/08/06 18:3				
Amylase		yyyy/mm	0	1	U/l	0	2008/07/01 16:				
AST GOT	500	yyyy/mm	1	1	U/l	0	2009/05/25 18:				
Calcium Ars	123	2	1	1	mg/dl	0	2009/04/02 10:				
Cholesterol	12345	mmm/mm	1	1	mg/dl	0	2009/04/10 14:				
CK MB	1234	yyyy/mm	2	1	U/l	0	2009/04/02 10:				
OK Nak		mmm/mm	2	1	U/l	0	2009/02/26 09:				
Creatinine Jaffe	500	www/mm	1	1	mg/dl	0	2009/04/29 15:				
CreSS		2	1	1	mg/dl	0	2008/04/09 17:				
D-Diff-1	12345	www/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Diff-2		www/mm	1	1	mg/dl	0	2009/02/26 09:				
Direct Bilirubin	lot	YYYY/MM	2	1	mg/dl	0	2009/02/26 09:				
D-Smp-1	12345	www/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Smp-2		www/mm	1	1	mg/dl	0	2009/02/26 09:				
Gamma GT	lot	YYYY/MM	2	1	U/l	0	2009/02/26 09:				
Ggt ss		www/mm	2	1	U/l	0	2008/12/04 13:				
hba1c DIASYS	500	YYYY/MM	5	1	%	0	2009/05/28 16:				
High Density ...		2	1	1	mg/dl	0	2009/02/26 09:				
Iron ferene	500	1	1	1	mg/dl	0	2009/04/29 15:				

Factor Factor min Factor Max

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 monostandard.



5. In the field Nr. of Repetition select 1 (one shot) or 3 (for triplicate – it repeats the standard 3 times taking the mean of the two nearest results).
6. In the field Stability on board 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. d...	Nr. of Stan...	Nr of rep.	Unit	Stability on b...	Date	Dil.ratio	Std value	O.D.	Reagent blank
630			0	1	mg/dl	0		1:1	12.5000	1.4866	0.6956
700			0	1	mg/dl	0		1:1	8.7100	1.2473	0.6944
ALAT (GPT)	12345	yyyy/mm	1	1	U/l	0	2009/04/10 14:	1:1	5.5120	1.0276	0.0000
Alk Phos IFCC	lot	YYYY/MM	2	1	U/l	0	2008/08/06 18:	1:1	2.2300	0.6977	0.6964
Amylase		yyyy/mm	0	1	U/l	0	2009/07/01 16:	1:1	0.0010	0.4657	0.6628
AST GOT	500	yyyy/mm	1	1	U/l	0	2009/05/25 18:				
Calcium Ars	123		2	1	mg/dl	0	2009/04/02 10:				
Cholesterol	12345	yyyy/mm	1	1	mg/dl	0	2009/04/10 14:				
CK MB	1234	yyyy/mm	2	1	U/l	0	2009/04/02 10:				
CK Nak			2	1	U/l	0	2009/02/26 09:				
Creatinine Jaff	500	yyyy/mm	1	1	mg/dl	0	2009/04/29 15:				
CreSS			2	1	mg/dl	0	2008/04/09 17:				
D-Diff-1	12345	yyyy/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Diff-2			1	1	mg/dl	0	2009/02/26 09:				
Direct Bilirubin	lot	YYYY/MM	2	1	mg/dl	0	2009/02/26 09:				
D-Smp-1	12345	yyyy/mm	1	1	mg/dl	0	2009/04/10 14:				
D-Smp-2			1	1	mg/dl	0	2009/02/26 09:				
Gamma GT	lot	YYYY/MM	2	1	U/l	0	2009/02/26 09:				
Ggt ss		yyyy/mm	2	1	U/l	0	2008/05/27 15:				
Glucosio	500	YYYY/MM	1	1	mg/dl	0	2009/05/28 09:				
hba1c DIASYS	lot	YYYY/MM	5	1	%	0	2009/06/23 16:				
High Density ...		mm	2	1	mg/dl	0	2009/02/26 09:				
Iron ferano	iron		1	1	mg/dl	0	2009/04/29 15:				

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 multistandard. 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 *Stability on board* 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 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.

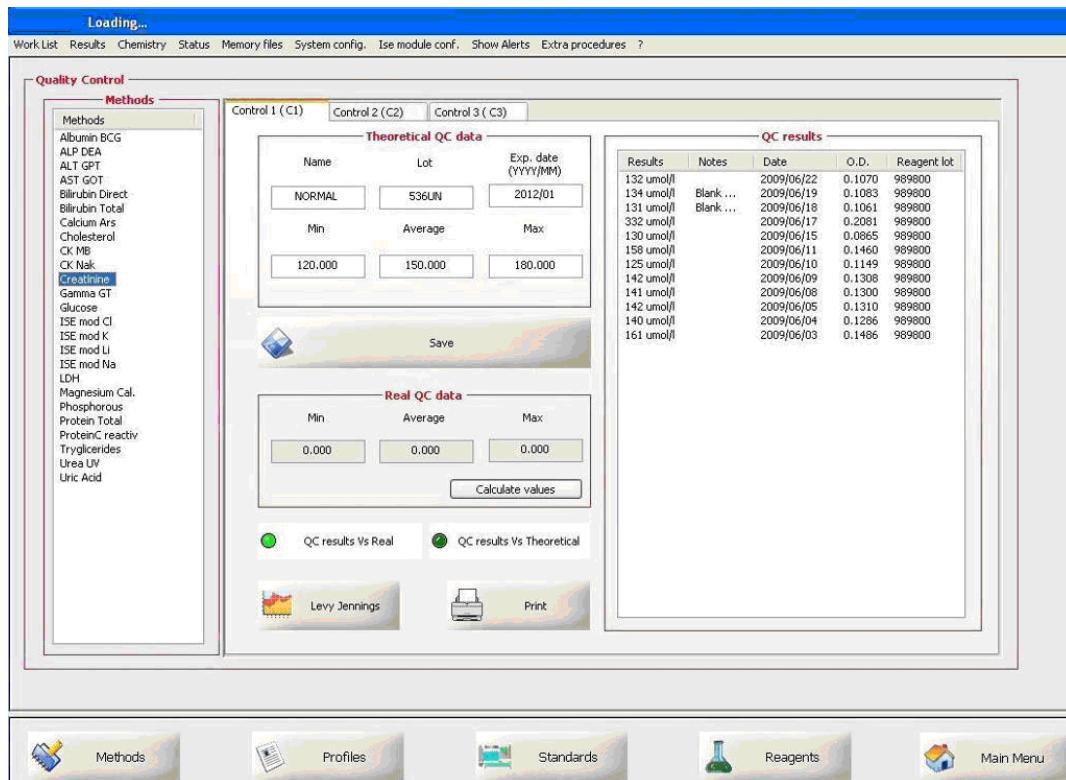
Once standards have been measured, the system updates automatically the following fields:

- O.D., with the measured absorbance value;
- Reagent Blank, with the reagent blank value measured a run before the standard dispensation.

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.

#### 7.4.11.3. Entering Values for Controls (QC)

The following procedure allows the operator to enter values and parameters for QC sera:



**Figure 86:** 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.



- Click on command Calculate values to compute and to show the Real QC data calculated 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.

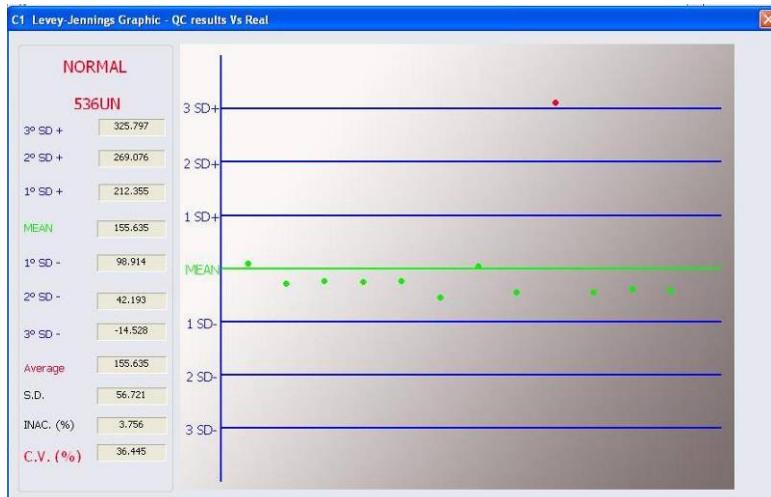
- In order to show Levy-Jennings graph, select Real or Theoretical

QC results Vs Real       QC results Vs Theoretical

click on the command



to get

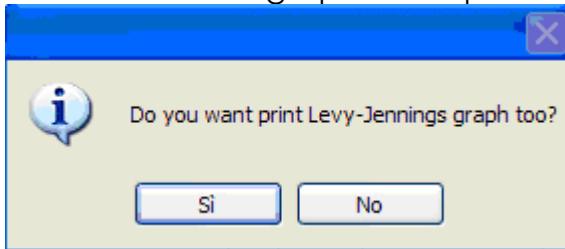


showing Controls results over Real or Theoretical QC data.

- To print the data reported in the QC Results window, click on the command Print

Print

and choose if to include or not the graph in the print.



The printed out report data contents depends on the previous selection: Real or Theoretical.



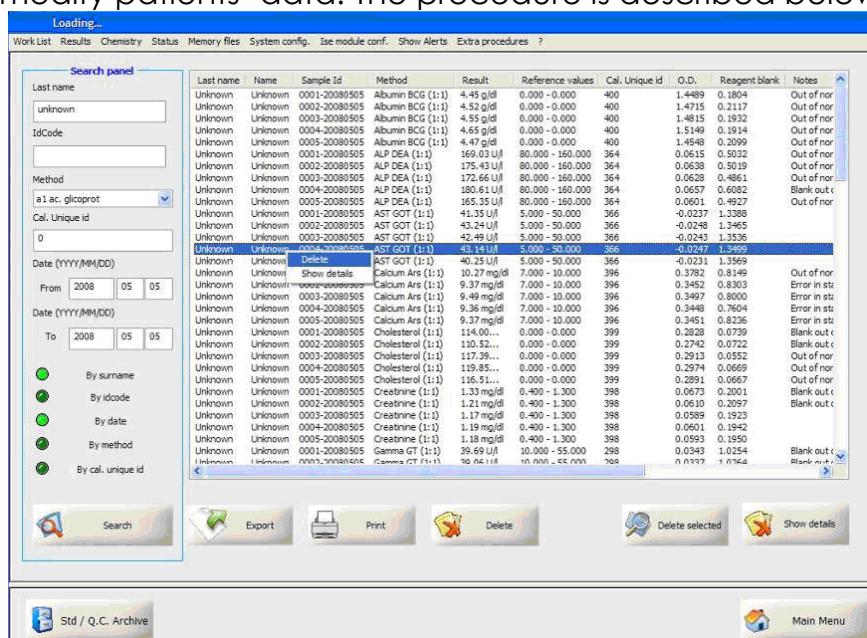
## 7.4.12. Memory Files - Database

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 87:** Software, Memory Files, Patients Archive Menu

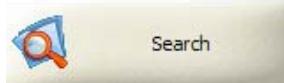
1. In the field *Last Name* it is possible to enter the patient's surname, if surname is needed as research key (in case no name have been used, you can type the word "unknown" to show all samples whose name never has been assigned).
2. In the field *IdCode* it is possible to enter the sample Id code, if sample identification code is needed as research key.
3. In the field *Method* it is possible to enter the test to search for, if test name is needed as research key.
4. In the field *Cal. Unique id* it is possible to enter the calibrator unique identification number given by the system, if it is needed as research key.
5. 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.



6. Choose then one of the searching criteria (keys); any combination of them is valid and the system considers all keys in logic "and" to refine the research:



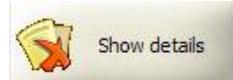
7. Click the command **Search**; the search results will be displayed in the right side window when the search has been completed (a note above the Command Search will advise about the number of results found).



8. To open a patient report, right click with the mouse on the result and then select the command **Show details** from the pop up menu.

Unknown	Unknown	0003-20080505	AST GOT (1:1)	42.49 U/l	5.000 - 50.000	366
Unknown	Unknown	0004-20080505	AST GOT (1:1)	43.14 U/l	5.000 - 50.000	366
Unknown	Unknown	Delete	AST GOT (1:1)	40.25 U/l	5.000 - 50.000	366
Unknown	Unknown	Show details	Calcium Ars (1:1)	10.27 mg/dl	7.000 - 10.000	396
Unknown	Unknown	0002-20080505	Calcium Ars (1:1)	9.37 mg/dl	7.000 - 10.000	396
Unknown	Unknown	0003-20080505	Calcium Ars (1:1)	9.49 mg/dl	7.000 - 10.000	396
Unknown	Unknown	0004-20080505	Calcium Ars (1:1)	9.36 mg/dl	7.000 - 10.000	396

or click the **Show detail** button:



9. In case some data modifications are needed in the **Report** window, make them and then select the command **Save data** or select the command **Print** results to print the results report, or close the **Report** window to exit.

The Report window displays patient information and laboratory results. The patient data includes: Last name (Rossi), Name (Giacomo), Date of birth (1900/02/29), Address (Via delle Pigne, 453/a - Roma), Bed (3456), Clinic (o/987x), Dpt. (Med. Gen.), Request date (2007/12/28), Doctor (Bianco), Email (n.cogn@provid.it), Phone (+3906123456789), Notes (None), Save button, and Print button. Below the patient data is a table of laboratory results:

Sample Id	Methods	Result	Reference values	Notes
0051-20080925	Creatinine Jaffe (1:1)	1.94 mg/dl	0.400 - 1.300	Blank out of range Out of normal
0051-20080925	Cholesterol (1:1)	4.2 mg/dl	0.000 - 0.000	
0051-20080925	Calcium Ars (1:1)	3.33 mg/dl	7.000 - 10.000	Blank out of range Out of normal
0051-20080925	Gamma GT (1:1)	72.4 U/l	10.000 - 55.000	Blank out of range Out of normal
0051-20080925	Magnesium Cal. (1:1)	0.6691 mg/dl	0.000 - 0.000	Blank out of range
0051-20080925	Total Bilirubin (1:1)	3.18 mg/dl	0.000 - 0.000	
0051-20080925	CK Nak (1:1)	234 U/l	0.000 - 0.000	Blank out of range Out of best fit
0051-20080925	CK MB (1:1)	36.83 U/l	0.000 - 0.000	Blank out of range
0051-20080925	Amylase (1:1)	0.0 U/l	0.000 - 0.000	
0051-20080925	Glucosio (1:1)	426.6 mg/dl	0.000 - 0.000	
0051-20080925	Lipase (1:1)	0.0 U/l	0.000 - 0.000	Out of linearity
0051-20080925	D-Snp-1 (1:1)	0.1189 mg/dl	0.000 - 0.000	Blank out of range Out of normal Substrate depleted
0051-20080925	D-Diff-2 (1:1)	0.3363 mg/dl	0.000 - 0.000	

10. 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:

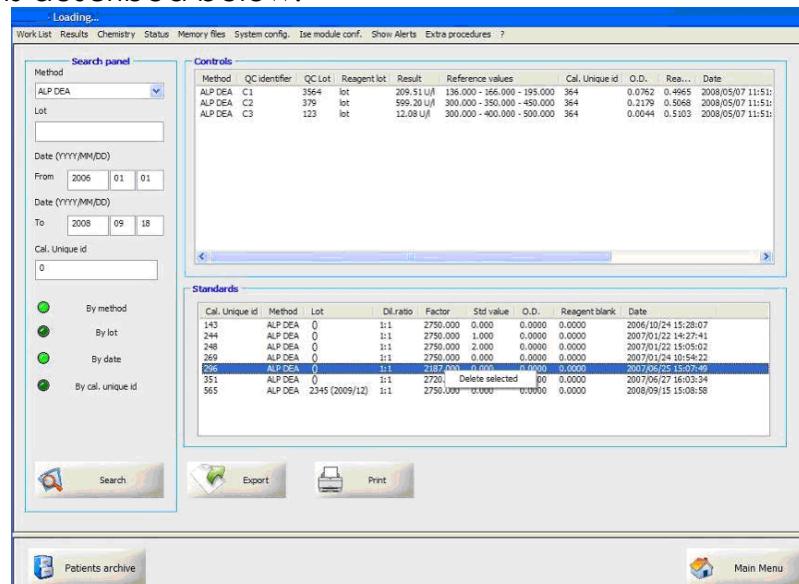
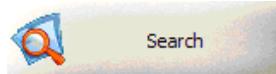


Figure 88: Software, Std/Q.C. Archive Menu

1. In the field *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 *Lot* it is possible to enter the lot number, if needed as search key.
3. 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.
4. In the field *Cal. Unique 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 of the 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.

Calcium Arsenazo 1:1	24.127	10.400	0.43
Calcium Arsenazo 1:1	24.127	10.400	0.00
Calcium Arsenazo 1:1	23.273	10.400	0.44
Choles Delete selected	517.245	147.000	0.28
POTASSIO SGM 1:1	8.534	5.000	0.58
POTASSIO SGM 1:1	8.534	5.000	0.00



### 7.4.13. Shutdown Procedure

The **Shutdown** command starts the automatic system shutdown. The program gives the operator the default option for the final cuvette washing to be used only in case the system is restarted within few minutes (i.e.: during servicing). As the procedure completes, the KROMA 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 strongly suggests to run a Cleaner cycle before shutting down the system (it will take only some minutes).

#### **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 shut down procedure as database can corrupt.**

**Never switch off the instrument before to shut down the software.**



## Section 8 MAINTENANCE

### 8. Generalities

This section provides the user recommendations for a proper maintenance of the instrument KROMA.

**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 KROMA proper operation and given performances only for systems that are kept under constant maintenance as per the scheduling given in the following paragraphs.**

### 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 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 8.2 in this section (“Safety precautions”) 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 Probe 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 form eventual deposits or residuals.

#### **WARNING**

**The above procedure 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 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 out on KROMA 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 LINEAR has been included in the system as option) is exposed in paragraph 8.4.

#### 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. In case of ISE module on board run a cleaning cycle.
2. On automatic instrument shut down procedure never disable the final washing.
3. Remove and disinfect any fluid leakage in the working area.
4. Remove all reagents from the reagent tray and clean the upper carousel in case of fluid leakage; disinfect any potentially contaminated part.
5. 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.
6. 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. It is very important that every five days, at the end of the working day, the operator runs the automatic **cuvette Extra wash cycle** from the Status menu, in



order to deeply clean reading cuvettes; remember to place an keep on board the EW Cvt solution (Extra Wash Cuvette solution). In case of big test runners with **high test volumes** (>1,500test/day), this procedure must be repeated every day.

2. Remove all reagents from the reagent tray and clean the bottom of the tray in case of fluid leakages or condensation; disinfect any potentially contaminated part.
3. Clean the outside surface of the metallic Sampling Probe with an ethanol solution at 70%.
4. Make sure that sample Probe is fixed in the proper positions and that it's undamaged.

### 8.3.3. 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 dynamic.
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. Gently oil the outer surface 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.





### 8.3.4. Six Months Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to carry on the following steps for the semi-annual maintenance.

1. Replace **all Reading Cuvettes** between 6 and 12 months according to the user working volume of tests.
2. Clean and disinfect metallic Sampling Probe.
3. Replace the washing station white tip.

### 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).
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.

### 8.3.6. Other Maintenance Needs

The following steps can be required in case of breakdown or damage (they must be carried out by Authorized Technical Personnel only, with the exception of single cuvette replacing).

#### **When needed:**

1. Replace the vacuum pump (or check and clean internal valves) of the washing station aspiration needles if not aspirating.
2. Replace the vacuum pump (or check and clean 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 clogged 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 or in case of fluid leakage.
7. Replace diluters if out of order or damaged (durability longer than 4,000,000 full strokes if operated with the **systemic solution** suggested by the manufacturer).
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.



KROMA	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
Systemic Solution refill																																
Cleaner Solution refill																																
Waste emptying																																
Tank Tygon® Tubing check																																
Final Washing cycle																																
Working area disinfection																																
Reagent Tray disinfection																																
Sample Tray disinfection																																
Cuvette Extra Washing Cycle																																
Operator initials																																



KROMA		MAINTENANCE CHART		Month: Year:		1-YEAR MAINTENANCE		Date	
WEEKLY MAINT.		Date	Date	Date	Date	6-MONTHS MAINTENANCE	Date	Date	
Reagent Tray cleaning						Gain calibration		Cuvettes replacing	
Probe cleaning						Tygon® Tubing washing		Sampling Probe Cleaning	
Probe checking						Systemic Tank cleaning		Washing Station white tip	
Reagent Tray cleaning						Cleaner Tank cleaning		Operator initials	
						Waste Tank cleaning		Washing Sink cleaning	
						ARM shaft oiling		Instrument verification	
						Operator initials		Operator initials	
OTHER MAINT.		Type of intervention		Date		Date		Date	
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 instrument KROMA (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

The scheduled periodic operations to carry out on ISE module for low volume users (processing **less than 100 samples/day**) have been listed in the following paragraph; 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. After instrument Warming Up check the ISE Calibration values in the *ISE module conf* menu. If not in range run again ISE Initialization.
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 Months 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 components for the semi-annual maintenance.

1. Li<sup>+</sup> Electrode.
2. Na<sup>+</sup> Electrode.
3. K<sup>+</sup> Electrode.
4. Cl<sup>-</sup> 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

The scheduled periodic operations to carry out on ISE module for high volume users (processing **greater than 100 samples/day**) have been listed in the following paragraph; 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. After instrument Warming Up check the ISE Calibration values in the *ISE module conf* menu. If not in range run again ISE Initialization.
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.**

#### 8.4.2.2. One Months 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 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 components after 3,000 samples.

1. Li<sup>+</sup> Electrode.

#### 8.4.2.5. At 10,000 samples Maintenance Scheduling

The user MUST ask the Authorized Technical Personnel to replace the following components after 10,000 samples.

1. Na<sup>+</sup> Electrode.
2. K<sup>+</sup> Electrode.
3. Cl<sup>-</sup> 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 Section 11, paragraph "List of Spare Parts and Consumables".

### 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 P3140000002 (or P3140000103 – reading plate with cuvettes).**

**Do not reuse cuvettes that have been previously dismissed even if washed, it affects results.**

Replace the cuvette following the instructions below:

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 set a *Start up* cycle in 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): take 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 update the zero values of all the reading cuvettes.



**Figure 89:** Cuvette Replacement

### 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 *Start up* from the *Status* menu, so that the machine updates the zero values of all the reading cuvettes.



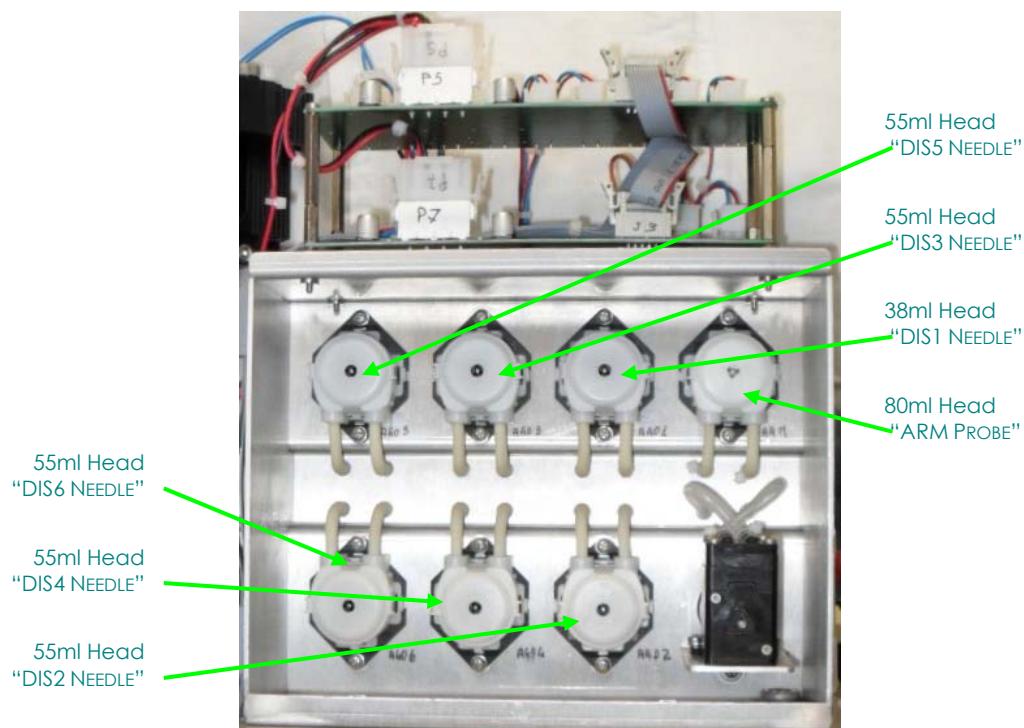
### 8.5.3. Peristaltic Pump Heads Replacement

Replace peristaltic pump heads only with instrument powered 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 right side panel of the instrument.
2. Unplug the peristaltic pump tubing from the Pump Assembly nipples after sliding the tubing lock washer.

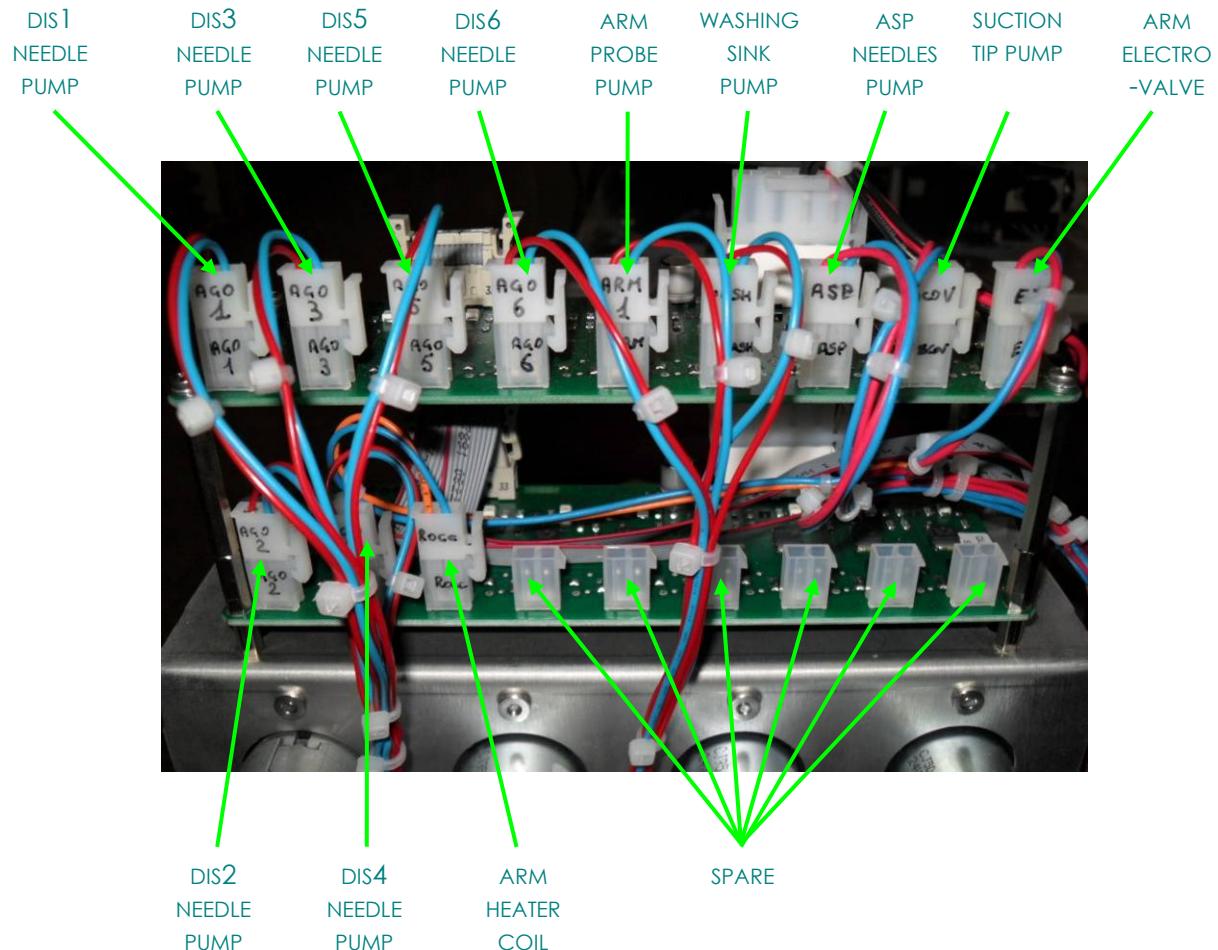


**Figure 90: Peristaltic Pump Heads Placement**

3. Release retention head clips and slip the head off from its motor shaft.
4. Clean the motor shafts with a dry cloth.
5. Plug the new heads on its motor shafts.
6. Plug the peristaltic pump tubing in the proper nipples.
7. Close the instrument right side panel.
8. Switch the instrument on, start the software and wait the end of the warm up.
9. 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:



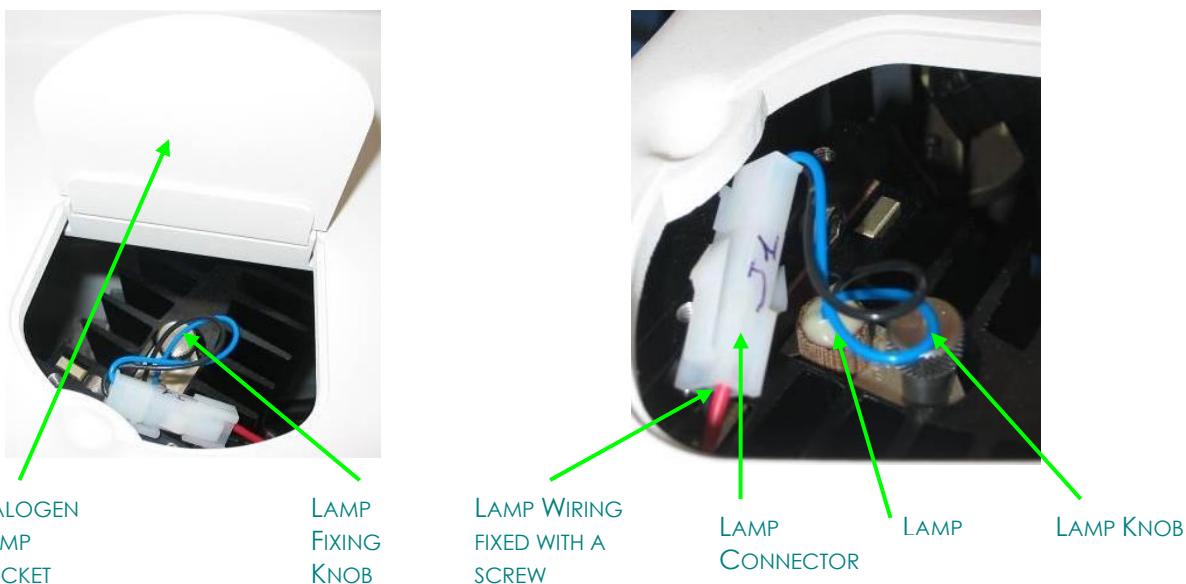
**Figure 91:** Pumps and Loads Connection to Power Boards (back-view)



### 8.5.4. Photometer Lamp Replacement

Replace the Photometer 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 (provided by the Manufacturer with code P3140000105) includes the fixing support but not the knob: save it.

Don't remove the lamp from its metallic support: the lamp height has been calibrated at factory and the fixed on that support.



**Figure 92:** 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 warm up.
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**

**Do not touch the new lamp bulb with your fingers: grease and damp could affect its lasting performance.**

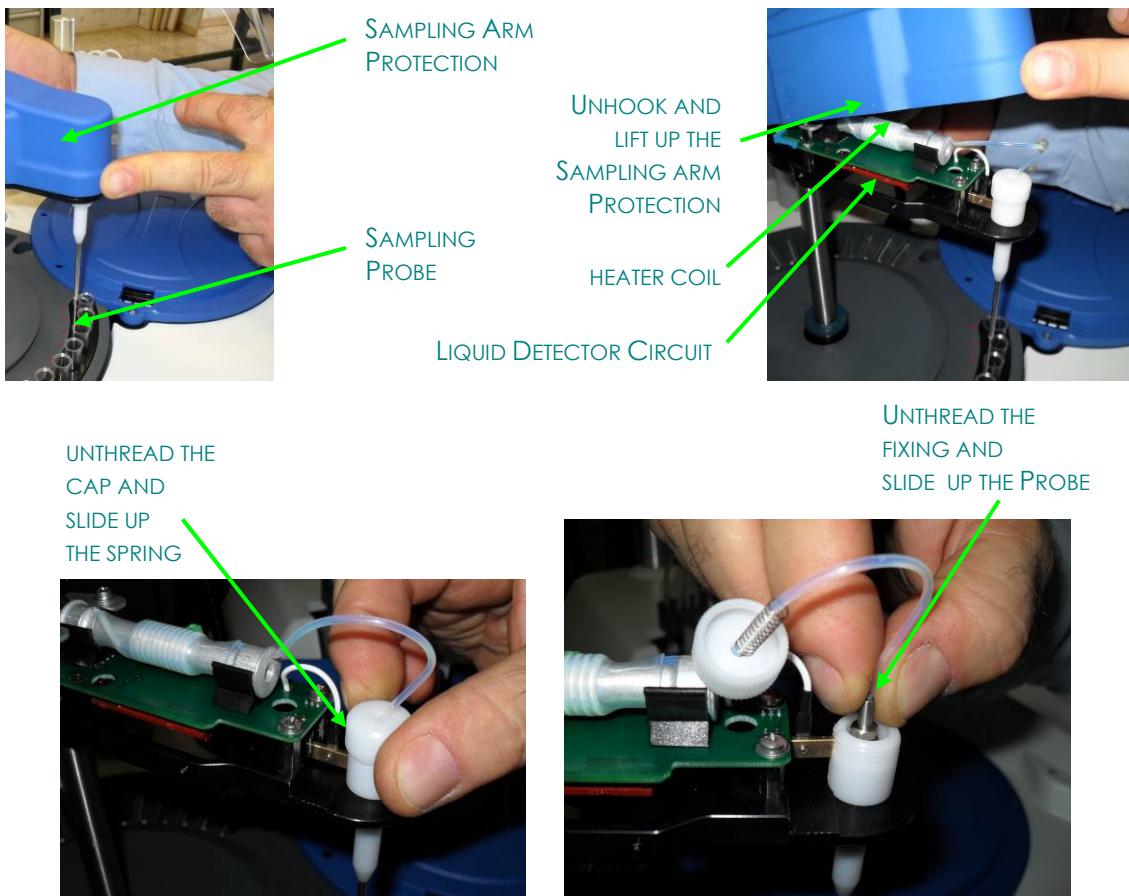


### 8.5.5. Sampling Probe Replacement

Replace the sampling probe with instrument in OFF.

Make sure that the new probe (provided by the Manufacturer with code: P3140000016) 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 93:** 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).

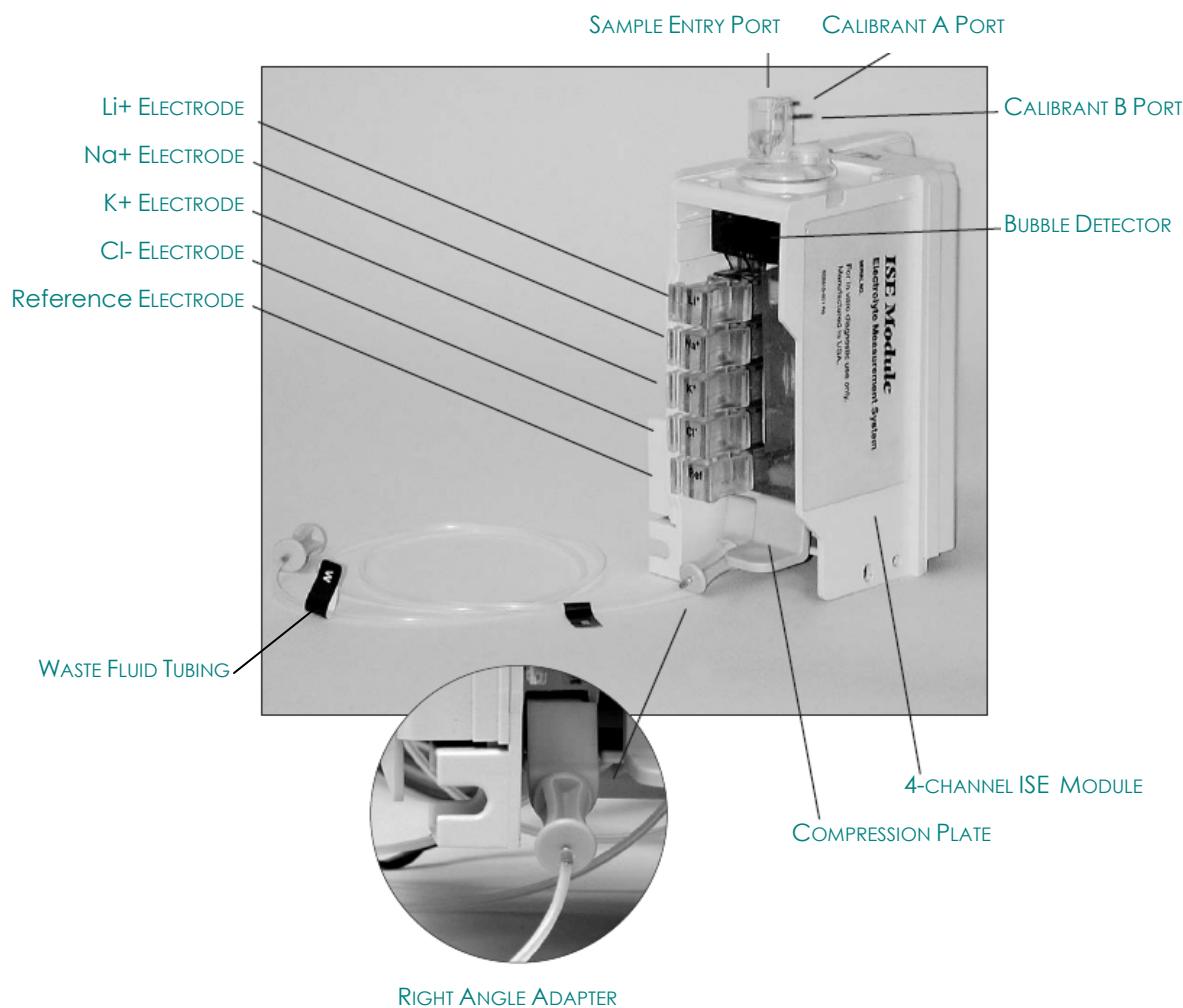


- Slide the fixing along the tubing and screw it paying attention that the probe is not blocked.
- Slide the spring and the cap along the tubing and screw the cap; make sure that probe can move freely in its seat in opposition to the retention spring without to get blocked.
- Fasten the arm cover in its original position by slightly stretching it.
- Switch the instrument on, run the software and wait the end of the warm up.
- Run three Arm Rinsing 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 KROMA system (option).



**Figure 94:** 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:

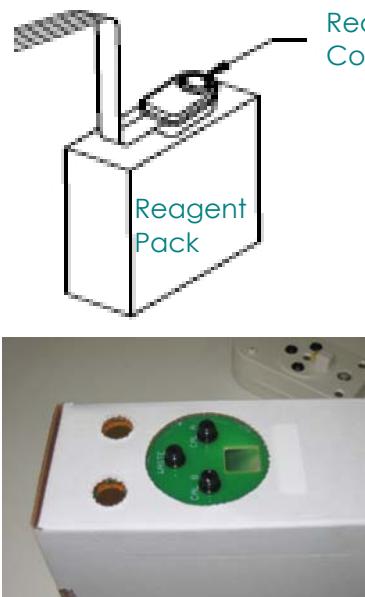
1. Consider the ISE module Reagent Pack containing Calibrat A, Calibrat B and Waste;
2. Press the yellow button of the Reagent Pack Connector and disconnect it from the pack;



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

**Figure 95:** ISE module, Reagent Pack replacement

### WARNING

**Biohazard Waste:** used reagent pack contain waste material and they must be always considered potentially infected. Dispose off according to local laws and rules.



### 8.6.2. Electrodes Replacement

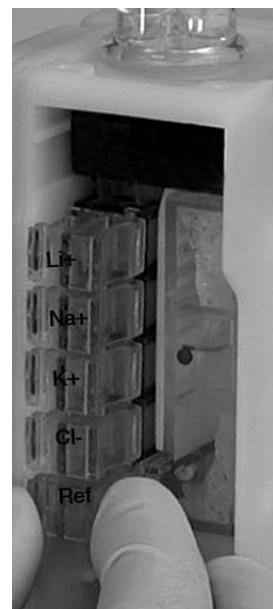
When electrodes maintenance period has expired they must be replaced with new ones. Replace Electrodes only with system powered OFF.

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 off 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 storage**);
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 *Do 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<sup>+</sup>** and **Cl<sup>-</sup>** 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<sup>+</sup>** and **Li<sup>+</sup>** electrodes until fluid fills the lumen;
11. Cover both ends of the lumen (both sides of the K<sup>+</sup> and Li<sup>+</sup> electrodes) with tape to hold the Calibrant in place;
12. Insert the K<sup>+</sup> and Li<sup>+</sup> 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<sup>+</sup> and Li<sup>+</sup> 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 (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 performance 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 position sensors (including diluter);
- correct positioning of the cuvettes tray;
- incubation temperature;
- ambient operating electronics temperature;
- vertical sampling arm “crash”;
- washing station operation;
- barcode reader operation;
- ISE module status (if included and enabled).

The system also displays warning windows in case of alarm or functional notices (empty loading tanks, full waste tank, 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;
- in case of alarm.

The system PC enables acoustic sounds in case of 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 KROMA and a brief description of the possible corrective actions:

Problem	Possible Cause	Corrective Action
THE INSTRUMENT DOESN'T START AND DOESN'T RESET AT POWER UP:	1. Protection defence open:	Close the Defence protection of the instrument.
THE INSTRUMENT DOESN'T RESETS OR DOESN'T 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 3 minutes; then power it on again. If not enough, power off the system (PC and instrument) for 3 minutes and power it on once more. If the problem persists contact service.
	3. Hardware malfunctioning:	Contact service.
EXTERNAL PRINTER NOT WORKING	1. Absence of link:	Verify the connection between instrument and external PC and the correct installation of the printer driver in the PC.
SAMPLING PROBE FAILURE DURING ASPIRATION AND DISPENSATION	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 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.



Problem	Possible Cause	Corrective Action
	2. Diluter head:  3. Diluter electrovalve not working:  4. Systemic and/or Cleaner solution external charge tubing is empty, liquid doesn't flow:  5. Teflon® tubing of the diluter head is empty:  6. Sampling Probe occluded:	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.  Verify that during sampling, the Electrovalve switches ON and OFF. If not, contact the service.  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.  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.  Verify that the probe isn't occluded and it is internally clean. Clean it first with several washings ( <i>Arm rinsing</i> ) then use disinfection procedure for probe. If damaged change it. The systemic solution must be clean and without floating particles; verify and clean the tank internal filter.
SAMPLING PROBE DOES NOT WASH, MISSING OF WASHING SOLUTION FLOW	1. Diluter electrovalve not working:  2. Teflon® tubing between Electrovalve and Diluter damaged:  3. Hydraulic circuits empty (most common cause when arm doesn't wash):	Verify that during sampling, the Electrovalve switches ON/OFF. If not contact the service.  Verify that the Teflon® tubing fittings between Electrovalve and Diluter Head are correctly fastened, undamaged and that tubing is not bended or obstructed. If damaged change it.  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.



Problem	Possible Cause	Corrective Action
	4. Pump worn away or not working:  5. Sampling probe occluded:	Verify the Pump motor: it must turn during washing. If not moving, change it.  Verify that the probe isn't occluded and it is internally clean. Clean it first with several ARM washings then use disinfection procedure for probe. 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 probe occluded:  2. Diluter Head:  3. Arm Heater Coil tubing not connected or damaged or shows many air bubbles inside:  4. Dirty cuvettes:  5. Photometer lamp:  6. Externally wet cuvettes:	Verify that the probe is not occluded and that it is internally clean. Clean it first with several ARM washings then use disinfection procedure for probe. If damaged change it. The Systemic solution must be clean and without floating particles; verify and clean the tank internal filter.  Verify the Diluter Head, if it contains floating particles or big air bubbles clean it with several probe washings.  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.  Run a Start up cycle, take out the cuvette and control that their narrow walls are clean inside and outside; dirty cuvettes must be replaced. Run an Extra wash cycle with EW Cvt solution.  Verify the photometer lamp is on and stable, if not replace it. Most of times this is noticed by bad kinetic results.  Switch the instrument off, take out all cuvettes, in case they are



Problem	Possible Cause	Corrective Action
		wet carefully dry them with a clean soft cloth. Then wait about 1 hour and then replace all cuvette back; run a <i>Calibration</i> 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 <i>Calibration</i> 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 service.
POOR CUVETTE WASHING, THE CUVETTES ARE DIRTY INSIDE.	1. Peristaltic Pumps worn away or not working:	Verify the Peristaltic Pump heads: if worn, change them. Verify the Peristaltic Pump motor: they must turn during washing. If not moving, change them.
	2. Washing Station dispensing tubing:	Verify that the aspiration Teflon® tubing, placed under the Washing Station protecting Cap, are undamaged and without



Problem	Possible Cause	Corrective Action
		leakages. If damaged, replace them or contact the service.
	3. Washing Station dispensing needles:	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 LINEAR 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 Protection defence 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 protection defence open. Close the protection defence to restart and continue the working session.
102	Warning: Systemic solution	Systemic solution is ending.	Sampling is arrested. Reactions



Code	Message	Cause	Action
	is going to finish.		actually in incubation are anyway carried out also with cover open and concluded. After readings, cuvettes are washed and the system waits for tank refilling. Refill the Systemic solution tank by unfastening the tank cap and keeping the float sensor in the empty position (down): 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. Reactions actually in incubation are anyway carried out also with cover open and concluded. After readings, cuvettes are washed and the system waits for tank refilling. Refill the Cleaner solution tank by unfastening the tank cap and keeping the float sensor in the empty position (down): the system then restarts the sampling run. Do not disconnect tubing during run.
104	Warning: Waste tank is getting full.	Waste tank is almost full.	Sampling is arrested. Reactions actually in incubation are anyway carried out also with cover open and concluded. After readings cuvettes, are washed and the system waits for tank refilling. Empty the tank or replace with an empty one AFTER the end of the washing phase and keeping the float sensor in the full position (up): the system then restarts the sampling run. Do not disconnect tubing during cuvette washing or running.
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



Code	Message	Cause	Action
			<p>Pause and wait that ARM stops, open the protection defence and replace the bottle; close the protection defence and click on Continue, then click on Retry.</p>
106	Warning: Some samples are empty. In the Status menu click on red reagents.	Some samples are finished. A sample (or standards or controls) that is finished is marked in RED on the Status menu.	<p><b>In case of Sample:</b> Click on the RED sample and follow the instructions on the screen. Press Retry after refilling the sample; press Abort to skip the hanging analyses; press Exit to exit the window without any decision and change. To refill the sample: click on Pause and wait that ARM stops, open the cover and refill the tube; close the protection defence and click on Continue, then click on Retry.</p> <p><b>In case of Standard:</b> Click on the RED standard and follow the instructions on the screen. Press Retry after replacing Standard; press Abort to skip standardization, controls and analyses related to that standard; press Ignore to skip standard and to use old Factor in memory for computing results (for control and analyses); press Exit to exit the window without any decision and change. To refill the standard: click on Pause and wait that ARM stops, open the protection defence and refill the cup; close the protection defence and click on Continue, then click on Retry.</p> <p><b>In case of Control:</b> Click on the RED control and follow the instructions on the screen. Press Retry after replacing Control; press Abort to skip controls and related analyses; press Ignore to skip control and to process anyway the related analysis; press Exit to exit the window without any decision and change.</p>



Code	Message	Cause	Action
			To refill the control: click on Pause and wait that ARM stops, open the protection defence and refill the cup; close the protection defence 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 restart the System.	The sampling probe of the ARM crashed against an obstacle during its way down.	Remove any obstacle on the probe way down, i.e.: sample caps, etc. Press the button Continue in the



Code	Message	Cause	Action
			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 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 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 ARM doesn't rise and descend 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 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 ARM diluter fails during motions.	Verify the absence of obstacles or particles into the Diluter transparent head; press the button <i>Continue</i> in the Status menu to retry, the system should



Code	Message	Cause	Action
			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 <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, contact service.
128	Warning: Incubation temperature out of range.	Incubation temperature out of limits.	Verify that the instrument is ON and communicating with PC. 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 <i>Clean WL</i> from the <i>Status</i> menu and repeat the procedure. If the problem persists contact service.



Code	Message	Cause	Action
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 contact service.
142	Warning: unknown method loaded by smart card.  It can be activated only for instrument operating under smart-card.	A method not included in the list has been loaded by smart card and its memorization in the database failed.	Contact service.
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, store results and 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 <i>ISE module conf</i> menu. Do it more times if required. Change Reagent pack and initialize ISE module from <i>ISE module conf</i> menu. If the problem persists contact service.
147	Warning: ISE module	Some air is in the Calibrant B	Reinitialize ISE module from <i>ISE module conf</i> menu.



Code	Message	Cause	Action
	purge B error. In Status page click on ISE icon.	tubing or the Calibrant B is finished.	module conf menu. Do it more times if required. Change Reagent pack and initialize ISE module from <i>ISE module conf</i> 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 <i>ISE module conf</i> menu. Do it more times if required. If the problem persists contact service.
149	Warning: ISE module bubble cal error. In Status page click on ISE icon.	Air in fluids or fluid leakage 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 <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



Code	Message	Cause	Action
			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). 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 are 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	No flow in the path or fibrine is	Check for electrodes properly



Code	Message	Cause	Action
	flow. In Status page click on ISE icon.	plugging the electrode flow-path.	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 ISE module conf menu (command Clean cycle). 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. 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. KROMA 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 Retry to repeat Control; press Abort to skip controls and analyses related to that control; press Ignore to ignore control result and to run anyway analyses; press Exit to exit the window without any decision and change.
162	Warning: KROMA 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



Code	Message	Cause	Action
			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.
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.
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 KROMA technical specifications and environmental requirements.

#### 10.1. Instrument Technical Specifications

##### 10.1.1. Sample Tray

- Tube positions (for routine and STAT samples, standards/calibrators and controls): 9
- Tube types to be used:  $\varnothing=12\text{mm}\div13\text{mm}$   
 $H=75\text{mm}\div85\text{mm}$
- Sample cups (cups cod. P3140000001): 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:  $\geq0,3\text{mm}$
- 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): 20



• Mono-reagent positions:	19 max
• Reserved position for diluent:	1
• Reagent bottle type 1:	50ml
• Reagent bottle type 2:	20ml
• Refrigeration temperature: (Option)	14°C below T <sub>amb</sub> , limited @ +12°C ± 2°C

### 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: 0,3mm

### 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

• Number of sampling arms:	1
• Number of Diluters (Micro Metering Pump):	1
• Diluter resolution:	0,119µl/pls
• Diluter accuracy (all stroke):	0.1% max
• Max diluter volume (including air gaps and protection):	520µl
• Sampling volume (increment= 1µl) for sample:	1µl÷300µl
• Sampling volume (increment= 1µl) for reagent:	1÷450µl
• Liquid level detector:	capacitive
• Obstacle sensor:	opto-coupler
• Heater Coil (for liquid pre-heating):	yes
• Multi-reagent mixing:	yes, on R2 and R3 electrovalve
• Separation from washing solution:	Automatic or on-request
• Test repetition:	internal and
• Probe washing:	



external

### 10.1.8. Incubation and Reading Cuvette Tray

- Reading system: direct reading optical group
- Number of incubation and reading cuvettes: 80, auto-wash
- Type of cuvettes: Bionex® optical plastics
- Reaction volume in cuvette: 200÷500µl
- Typical reaction volume in cuvette: 220÷260µl
- Optical path (Bionex® cuvette): 6mm
- Incubation temperature (preset): 37°C ± 0,2°C
- Incubation time: controlled programmable @ max 720sec
- Reading time (Kinetics and Fixed Time methods): programmable @ max 336sec.
- Cuvettes washing and drying: automatic washing station

### 10.1.9. Optical Group

- Optic system: direct reading photometer
- Wavelengths: interf. filters
- Number of reading channels: 1
- Reading method: horizontal
- Light source (long life halogen lamp: 2000 hours) 12V/20W
- Detector: Si Photodiode
- Measurement range (conversion to 10mm): 0÷3Abs
- Photometer resolution: 0.0001Abs
- Automatic gain: yes
- Automatic auto-zero: yes, on-line
- Automatic gain calibration: yes
- Automatic off-set calibration: yes
- Wavelength range (filter tray - 8 position + 1 off-set + 1 spare): 340÷700nm

#### 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 positions:	8
• Dispensing/Aspirating couple of needles:	5
• Dispensing needles:	1
• Aspirating needles:	1
• Drying tip:	1
• Cleaner solution dispensing:	Position 1
• Systemic solution dispensing:	Positions: 2÷6

### 10.1.11. ISE module (option)

• Test type on serum, plasma and diluted urine (less electrodes possibility by using proper 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
• 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
- 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 150 test/h
- Number of mono-reagent tests in run with ISE module: up to 250 test/h

### 10.1.14. Liquid Consumption and Waste Autonomy

- Systemic solution average consumption (@ max throughput): <1.50 lt/h
- Cleaner solution average consumption (@ max throughput): <0.20 lt/h
- Average waste volume (@300 test per hour): ≈1.60 lt/h
- Average machine autonomy @ max throughput (Start-up and shutdown procedures included): ≈12 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
- User Interface: Windows® XP



- LIS (optional)

based  
on request

**Patients Filing:**

- File dimensions:

Up to 150,000  
records

**QC results Filing:**

- File dimensions:

Up to 8,000  
records

### 10.3. Mechanical Calibrations, Trimmings and Tunings

During daily working the instrument doesn't require any mechanical calibration, trimming or tuning performed by the operator. All mechanical calibrations have been carried out at factory. In case a further calibration is required, it must be performed by Authorized Personnel.

### 10.4. Power Supply Requirements

- Supply line voltage (without selection):
- Supply line voltage selector:
- Supply line frequency:
- System Line UPS – 1kVA

100÷240Vac  
not needed  
47÷63Hz  
Requested,  
for instrument  
and PC

### 10.5. Operating Environment Requirements

- Temperature:
- Humidity (without condensation):
- Max altitude:

+18°C÷+32°C  
20%÷80% RH  
2000m

**Distance from close walls/objects:**

- Lateral gap
- Gap from the back

≥150mm  
≥160mm

### 10.6. Storage Environment Requirements

- Temperature:
- Humidity (without condensation):
- Max altitude:

+5°C÷+45°C  
5%÷95% RH  
9000m

### 10.7. Dimensions and Weight

**Dimensions:**



- Bench top instrument version: H= 610mm
  - Clear space required at the sides of the instrument: W= 830mm
  - Clear space required at the back of the instrument: D= 640mm
  - 150mm
  - 150mm
- Weight:**
- Bench top instrument weight (without fluids): ≈40kg

## 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: 450VA
- Operating typical power: 300VA typ
- Power factor ( $\cos\phi$ ): 0,93 typ



## Section 11 ADDITIONAL INFORMATION

### 11. Generalities

This section contains some additional information about the KROMA instrument.

#### 11.1. Quick Start Guide

The handbook "KROMA – Quick Start Guide", last version, contains a brief summary of the KROMA instructions for use and notices.

#### 11.2. Warranty Limitations

LINEAR SL 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, LINEAR SL will repair or replace at factory, any defective product, on condition that the Client promptly communicates the defect to LINEAR SL.

This warranty applies exclusively to new products which have never been used and which have not, after shipment by LINEAR SL, been damaged, altered, repaired or modified in any manner, due to negligence or other reasons, by persons not authorised to represent LINEAR SL, even if they have sold/worked on the product. LINEAR SL is not liable for any Warranty obligations should any modifications or repairs have been made to the product without LINEAR SL'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 LINEAR SL, 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. LINEAR SL does not provide any other guarantees, explicit or implicit, regarding the product, except for the present Warranty. Without limitation to the above general information, LINEAR SL 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 LINEAR SL as regards the warranty.

LINEAR SL is not liable for damages, expenses or damage to the client or third parties due to accidental causes. LINEAR SL 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;
- Any consumable item;
- Reading cuvettes;
- Charging and waste tanks and fittings;
- Diluter;
- Hydraulic circuits;
- Any peristaltic pump heads.
- ISE module Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup> 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.



### 11.3. List of Spare Parts and Consumables

SPARE PARTS			
Item	Code	P/N	Kit
STEP MOTOR DRIVE - 2X1.5A - VER.02	P3140000060	10002-02-A	1 pcs
STEP MOTOR DRIVE - 2X1.5A - VER.05		10002-05-A	1 pcs
STEP MOTOR DRIVE - 2X1.5A - VER.06		10002-06-A	1 pcs
PWR DRIVER MODULE - 9X1A - VER.00	P3140000049	10006-00-C	1 pcs
PHOTODIODE MODULE - VER.00	P3140000048	10011-00-B	1 pcs
MAIN CONTROLLER VER.01	P3140000028	10012-01-C	1 pcs
ARM1 CONTROLLER	P3140000029	10012-02-C	1 pcs
R&W CONTROLLER	P3140000031	10012-04-C	1 pcs
CNT POWER SUPPLY - VER.01	P3140000033	10028-01-A	1 pcs
LHP POWER BOARD		10762-00-A	1 pcs
0.5ML DILUTOR ASSEMBLY	P3140000063	10036-00-A	1 pcs
1.17NB1.8 MOTOR ASSY	P3140000044	10040-00-A	1 pcs
0.48NB1.8 MOTOR ASSY	P3140000042	10041-00-A	1 pcs
1.17NB0.9 MOTOR ASSY	P3140000045	10042-00-A	1 pcs
INCUBATION HEATER STRIP	P3140000047	10043-00-A	1 pcs
OPTO SENSOR VER.00	P3140000035	10045-00-A	1 pcs
OPTO SENSOR VER.03		10045-03-A	1 pcs
LM35 TEMP SENSOR VER01	P3140000038	10050-01-A	1 pcs
LM35 TEMP SENSOR VER02	P3140000039	10050-02-A	1 pcs
2-WAY EV ASSY		10051-00-B	1 pcs
0.20NB1.8 MOTOR ASSY	P3140000046	10055-00-A	1 pcs
BUZZER ASSY	P3140000053	10058-00-A	1 pcs
SR10_30 PUMP ASSY VER.01	P3140000051	10060-01-A	1 pcs
ZRP ASPIRATION PUMP VER.00 (FOR ASPIRAT. NEEDLES)		10938-00-A	1 pcs
ZRP ASPIRATION PUMP VER.01 (FOR TIP)		10938-01-A	1 pcs
RS232 FS9F CABLE ASSY	P3140000084	10062-00-A	1 pcs
24V FAN ASSY	P3140000066	10110-00-A	1 pcs
12V 60x60 FAN ASSY		10112-00-A	1 pcs
CABLAGGIO PHOTODIODE	P3140000011	10148-00-A	1 pcs
CABLAGGIO BARCODE		10155-00-A	1 pcs
OPP ARM MODULE REV.C	P3140000040	10205-00-C	1 pcs
PCB COIL HEATER	P3140000041	10209-00-A	1 pcs
WASHING STATION HEAD	P3140000074	10211-00-A	1 pcs
0.43NB1.8 MOTOR ASSY	P3140000043	10252-00-A	1 pcs
LIQUID 1 TANK REV.B		10405-00-B	1 pcs
LIQUID 2 TANK REV.B		10406-00-B	1 pcs
WASTE TANK REV.B		10407-00-B	1 pcs
ASPIRATION NEEDLE FOR WASHING STATION (SINGLE)	P3140000005	DMC-20077	1 pcs
DISPENSING NEEDLE FOR WASHING STATION (SINGLE)	P3140000006	DMC-20078	1 pcs
DRYING TIP FOR WASHING STATION NEEDLE (SINGLE)	P3140000097	DMC-20169	1 pcs
DRYING TIP + NEEDLE FOR WASHING STATION (SINGLE)	P3140000050	N.A.	1 pcs
KIT OF ASPIRATION + DISPENSING NEEDLE FOR WASHING STATION (PAIR)	P3140000098	DMC-20261	1 kit
FITTING DIAM. 2,3mm	P3140000024	N.A.	10 pcs
FITTING DIAM. 3mm	P3140000026	N.A.	10 pcs
NUT (BIGGER) 20281-00-A	P3140000089	N.A.	10 pcs



NUT (SMALLER) 23-08-010A	P3140000090	N.A.	10 pcs
FERULE 1/8 YELLOW, P-300	P3140000106	N.A.	20 pcs
FERULE 1/8 BLUE, P-200	P3140000107	N.A.	20 pcs
CABLAGGIO M100 SWITCHES		10774-00-A	1 pcs
CABLAGGIO M100 FILTER		10775-00-A	1 pcs
CABLAGGIO M100 DC OUTPUT		10776-00-A	1 pcs
CABLAGGIO M100 POWER		10777-00-A	1 pcs
CABLAGGIO M100 FLAT		10778-00-A	1 pcs
CABLAGGIO M100 SENSORS		10779-00-A	1 pcs
CABLAGGIO M100 ARM		10781-00-A	1 pcs
CABLAGGIO LHP POWER		10940-00-A	1 pcs
KROMA 100 CONTROLLER MOTHER BOARD		10803-00-B	1 pcs
500ul DILUTER		10911-00-A	1 pcs
MICROSWITCH SENSOR		10943-00-A	1 pcs
38ML SR10_30 PUMP ASSY	S3141000534	10638-00-A	1 pcs
80ML SR10_30 PUMP ASSY	S0200000107	10946-00-A	1 pcs
APN20 PUMP ASSY	S3141000575	10947-00-A	1 pcs

**ACCESSORIES AND CONSUMABLES**

Item	Code	P/N	Kit
HALOGEN LAMP 12 V 20 W	P3140000105	10749-00-A	1 pcs
KIT OF FUSES	P3140000075	N.A.	1 kit
KIT OF TUBES (El-Valve & washing station)	P3140000076	N.A.	1 kit
KIT OF TUBES FOR CLEANER SOLUTION TANK (5 lt - blue)	P3140000083	10648-00-B	1 pcs
KIT OF TUBES FOR SYSTEMIC SOLUTION TANK (20lt - green)	P3140000082	10647-00-B	1 pcs
KIT OF TUBES FOR WASTE TANK (25lt - red)	P3140000081	10649-00-B	1 pcs
MULTICLEAN SOLUTION 6x2 lt	P3140000112	N.A.	6x2 lt
PC SERIAL CABLE	P3140000022	N.A.	1 pcs
PRIMARY TUBES FOR SAMPLES	P3140000100	N.A.	1000 pcs
READING CUVETTES	P3140000093	N.A.	200 pcs
READING TRAY WITH 80 CUVETTE	P3140000103	N.A.	1 kit
REAGENT BOTTLE R1 WITH CAP - 50 ml	P3140000019	N.A.	50 pcs
REAGENT BOTTLE R2 WITH CAP - 20 ml	P3140000086	N.A.	50 pcs
RINSE SOLUTION (Ew Cvt) 6x50 ml	P3140000113	N.A.	6x50 ml
RINSE SOLUTION (Ew Prb) 6x20 ml	P3140000115	N.A.	6x20 ml
SAMPLE CUPS 3 ml	P3140000001	N.A.	1000 pcs
SAMPLING PROBE	P3140000016	N.A.	1 pcs
SYSTEMIC SOLUTION 6x50 ml	P3140000087	N.A.	6x50 ml
TOOL FOR SINGLE CUVETTE EXTRACTION	P3140000077	N.A.	1 pcs
ISE Module Cl- Electrode	S3141000286	5203	1pcs
ISE Module K+ Electrode	S3141000285	5202	1pcs
ISE Module Li+ Eletrode	S3141000287	5205	1pcs
ISE Module NA+ Electrode	S3141000284	5201	1pcs
ISE Module Cleaning Solution 90 ml	S3141000292	5421	1pcs
ISE Module Fluid Tubing kit	S3141000294	5611	1kit
ISE Module Pump Tubing kit	S3141000293	5610	1kit
ISE Module Reagent Pack (Cal A, Cal B, Waste)	S3141000290	5420	1pcs
ISE Module Reference Electrode	S3141000288	5204	1pcs



ISE Module Spacer Electrode	S3141000289	5206	1pcs
ISE Module Tubing Adapter	S3141000295	5612	1kit
ISE Module Urine Diluent 125 ml	S3141000351		1pcs
ISE Module Urine Diluent 500 ml	S3141000291	5408	1pcs

## 11.4. Information for Orders

Please contact our LINEAR SL offices or the local sales distributor.

## 11.5. System Expansions

Refer to paragraph 3.1.2 “List of Optional Parts” for KROMA instrument additional options.

## 11.6. Service

Service is provided by LINEAR CHEMICALS, SL or by Authorized Personnel belonging on local distributors.

### 11.6.1. Training Courses

All the training courses are organized by LINEAR CHEMICALS, SL and take place in the LINEAR CHEMICALS, SL offices in MONTGAT - SPAIN or they are scheduled by the local distributor.

### 11.6.2. Firmware and Software Upgrades

When needed and applicable, any software and firmware upgrade must be performed by Authorized Personnel only with a special procedure from the Management PC.



## 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 return it to the following address:

#### LINEAR SL –

Joaquim Costa, 18, 2<sup>a</sup> planta. 08390 Montgat – Barcelona (SPAIN).  
T. (+34) 93 469 49 90. F (+34) 93 469 34 35  
[www.linear.es](http://www.linear.es) e-mail: [info@linear.es](mailto:info@linear.es)



# Training Course Evaluation Form

## KROMA 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 return it to the following address:

**LINEAR SL –**

Joaquim Costa, 18, 2<sup>a</sup> planta. 08390 Montgat – Barcelona (SPAIN).  
T. (+34) 93 469 49 90. F (+34) 93 469 34 35  
[www.linear.es](http://www.linear.es)      e-mail: [info@linear.es](mailto:info@linear.es)



# Customer's Satisfaction Questionnaire

## KROMA 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 break-down 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 determining the results by interpolation.
Calibrator	Sample that contains an analite 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.