LiNEAR

KROMA iT

Random Access Analyzer

Quick Start Guide

i.1 INTRODUCTION

i.2 Identification Data

This document is the Quick Start Guide of the instrument named KROMA.
KROMA is a random access automatic analyser and this document gives a brief and quick description of the instrument and of the main operational procedures.
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

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- Document revision: A
- Revision date: July 9, 2009
- Software version: 1.0.0.3
- Date of software version: July 8, 2009

i.1.2 Instrument

- KROMA: 1800050
- KROMA iT: 3800050

i.1.3 Producer

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i.3 Copyright

i.4 Use of This Document

This handbook is a quick guide to give the user an easy approach to the instrument KROMA. The user can easily find the main procedures for operating the instrument.

Note: the producer recommends anyway the user to read carefully all sections of the KROMA User 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.

Note: This document cannot in any case replace the KROMA User Manual that remains the reference document for a correct use of the instrument.

This document must be preserved and kept close to the KROMA to be read, in case of necessity, during daily laboratory activity.

i.5 List of Contents

Section 1 GENERALITIES

1. Safety Prescriptions and Precautions

The user must strictly observe all prescriptions given in Section 1 of the KROMA - User Manual, last version.
The instrument does not constitute an electrocution hazard if installed without modification, and if connected to an electrical power supply having the requested characteristics. The instrument, that must be always and permanently grounded, is provided with a three conductor sheated cable to be connected to single-phase sockets from 100Vac to 240Vac with frequency range from 47Hz to 63Hz.
Install the instrument and the PC under a 1kVA - UPS.

1.1. Installation and Maintenance

The installation, the check and the calibration must be made by qualified authorized technicians on buyer's request.
The user must respect the installation and maintenance specifications given in the KROMA - User manual, last version.

1.2. Advices for a Correct Use

The user must observe the recommendations given in the KROMA - User manual, last version.

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 OPERATING PROCEDURES

2. Overview

This Section gives the operator a list of the main procedure to operate the instrument.

2.1. 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 200µl and 500µl: the ***typical suggested reaction volume is anyway from 200µl to 260µl***; in order to preserve cuvettes longer life, it is suggested **not to overcome 300µl of total reaction volume**.
With reference to **reagents**, it is possible to dispense from a minimum of 180µl up to 450µl *reagent volume* of R1, R2 and R3 in total. Provided the sum of reagent volumes greater or equal to 180µl, each of the reagents can be sampled anyway from 1µl to 450µl, with 1µl 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 1µl up to 300µl, with 1µl minimum increment. The system performs the automatic mixing of the sample with the reagent into the cuvette.

The **suggested** values (in **µl**) to be programmed in the methods are included in the ranges shown in the following table:

Method type	**Suggested Volumes** (Sample/Substrate Starting)	
Kinetic	Sum of Reagent Volumes (R1 or R1 + R2 or R1 + R2 + R3) 200µl÷250µl	Total of Volumes (Reagents + Sample) 200µl÷260µl
Fixed Time		
Bichromatic		
End Point		
Differential - 2 Reagents	R1 and R2 200µl÷250µl	R1 + Sample and R2 + Sample 200µl÷260µl
Differential - Sample Blank	R1 + Sample 200µl÷250µl	R1 + Sample + R2 200µl÷260µl

2.2. Reading and Incubation Times

With reference to the incubation and reading times the following table is valid for the different typologies of test methods and gives the admissible ranges:

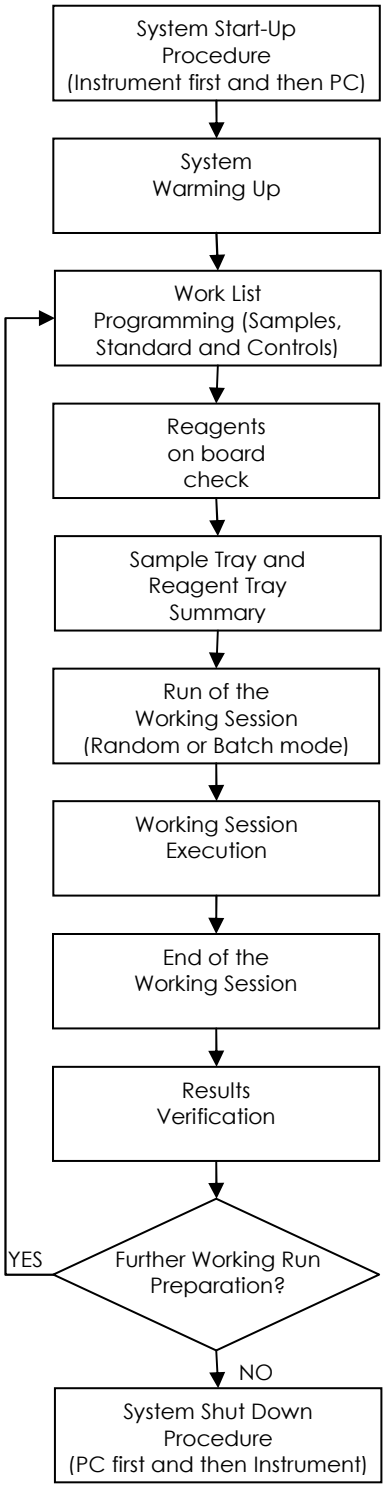
Type: SAMPLE STARTING Methods	1st incub.	Incub. to R2: R1,S=>R2	Incub. to R3: R1,R2,S =>R3	Final Incub.	Fixed Time 2nd read	Kinetic Reading Time	MAX Total Method Time
End Point 1-Reag. (Monochr./Bichrom.)				36-720			**720**
End Point 2-Reag. (Monochr./Bichrom.)				36-720			**720**
End Point 3Reag. (Monochr./Bichrom.)			36-720	36-720			**720**
Fixed Time 1-Reag.				36-720	48-336		**720**
Fixed Time 2-Reag.				36-720	48-336		**720**
Fixed Time 3-Reag.			36-720	36-720	48-336		**720**
Kinetic 1-Reag.				36-720		48-336	**720**
Kinetic 2-Reag.				36-720		48-336	**720**
Kinetic 3-Reag.			36-720	36-720		48-336	**720**
Differential Sample Blank	36-720			36-720			**720**
Differential 2-Reagents				36-720			**720**

Type: SUBSTRATE STARTING Methods	1st incub.	Incub. to R2: R1,S=>R2	Incub. to R3: R1,R2,S =>R3	Final Incub.	Fixed Time 2nd read	Kinetic Reading Time	MAX Total Method Time
End Point 2-Reag. (Monochr./Bichrom.)		36-720		36-720			**720**
End Point 3Reag. (Monochr./Bichrom.)		36-720	36-720	36-720			**720**
Fixed Time 2-Reag.		36-720		36-720	48-336		**720**
Fixed Time 3-Reag.		36-720	36-720	36-720	48-336		**720**
Kinetic 2-Reag.		36-720		36-720		48-336	**720**
Kinetic 3-Reag.		36-720	36-720	36-720		48-336	**720**

Note: The *maximum total method time* is intended as the sum of the incubation times and of the reading time (if any), and it cannot overcome 720sec in order to avoid degradation in throughput performance.

2.3. Procedures

2.3.1. Operating Flow Chart



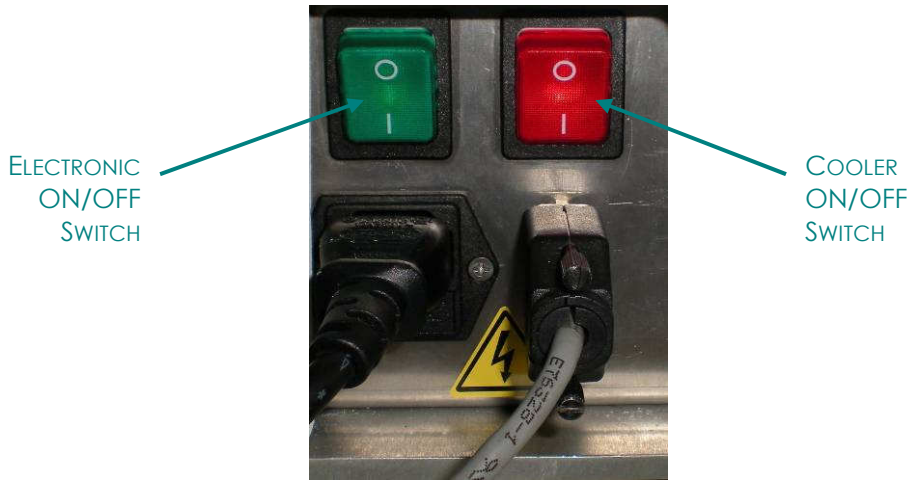
The operator, through the user interface, has the possibility to program and to execute Work Lists that include tests for each patient, standards, calibrators and quality controls. The details on the use of the user interface are traced in the following paragraphs.
The previous figure shows the operating flow chart.

2.3.2. 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.



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.

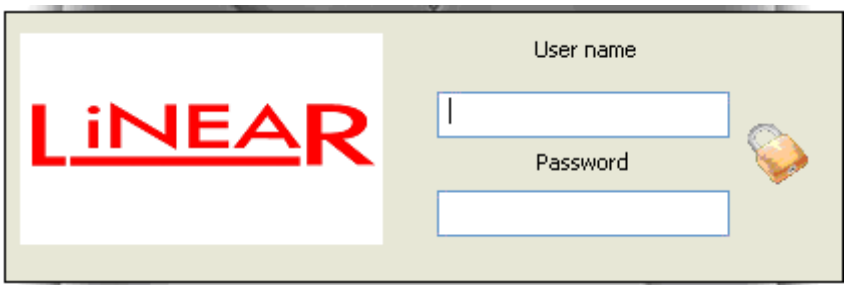
2.3.3. Login, Main Menu Access and Auto-diagnosis

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):

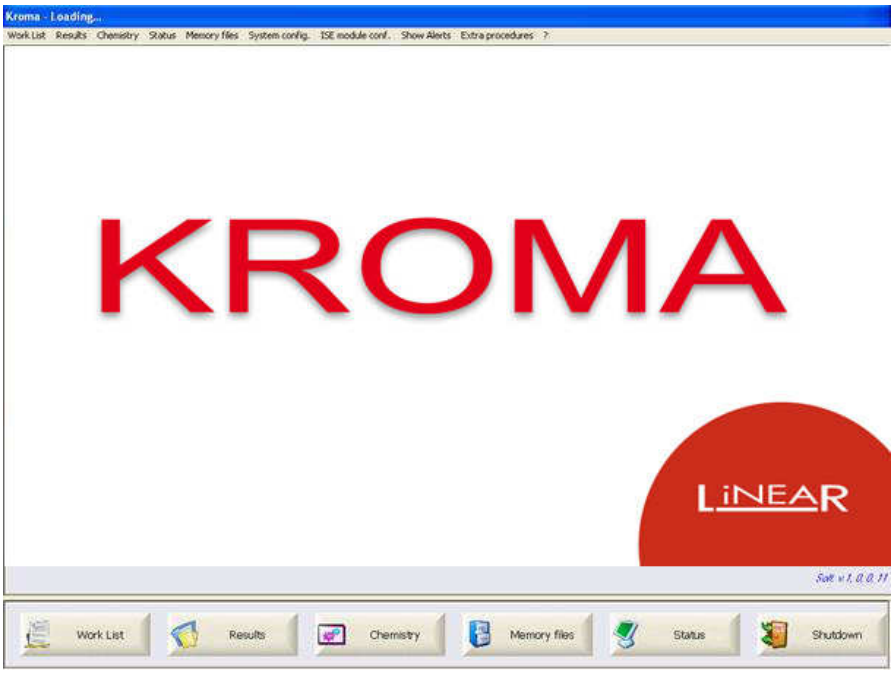
- the default user name is "**admin**"
- the default password is "**12345678**".

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.).



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.



2.3.4. Warming Up Procedure

During the start up, the system automatically measures and verifies the time from the last shut down:

1. 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.
2. 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).
3. in case this OFF time is **below 2 minutes**, the system ignores any warming up procedure and enters directly the Idle status ready to start.

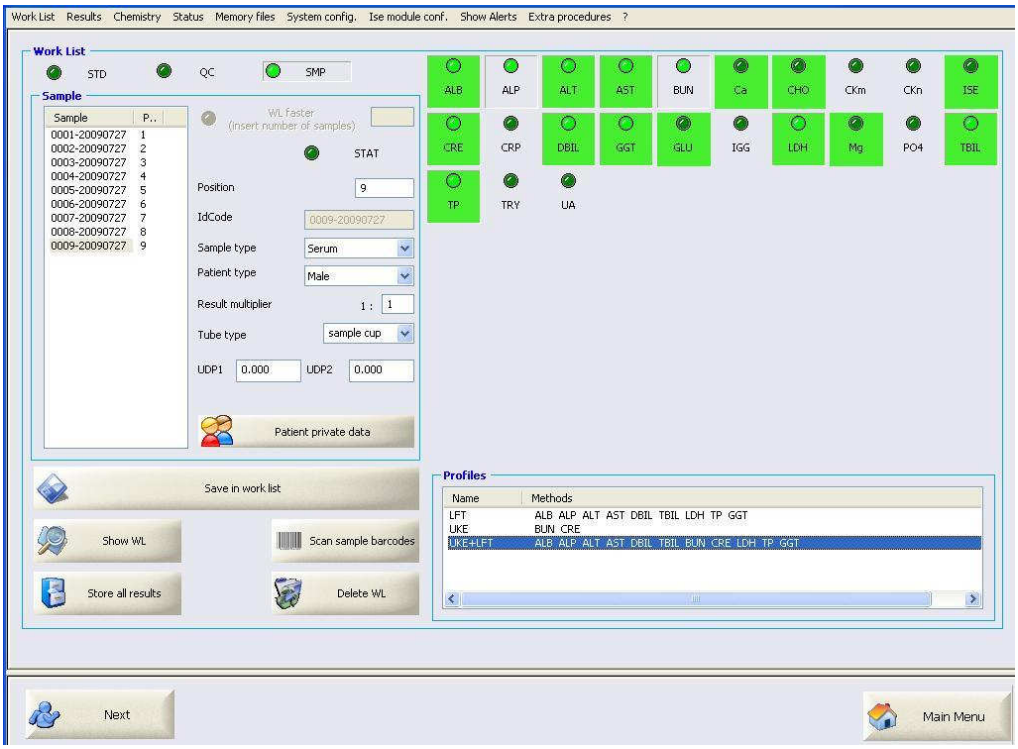
The full Warming Up auto-procedure takes about 30 minutes; in this phase the system carries out the following operations:

- 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.

2.3.5. 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 constitutes the working session and they'll be run at the *START* command.



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.

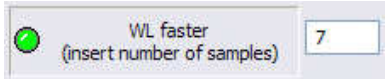
2.3.5.1. Manual Work List Programming and Run

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

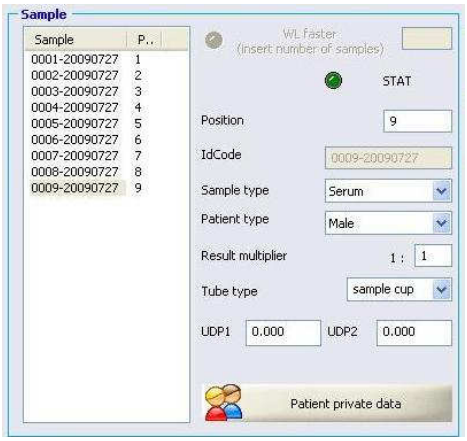
1. Select the "SMP" option in order to enter the patient Work List.

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:



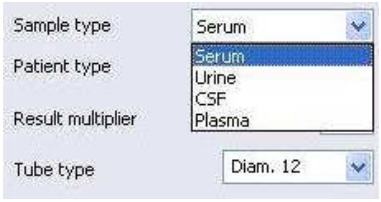
in this case introduce the number of the samples to be programmed. Those samples will be automatically assigned to the first free positions on the sample tray. If desired, single positions can be moved by selecting a sample and giving it a new position number:



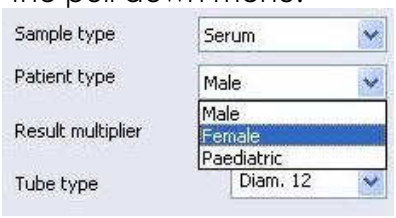
3. Enter the sample identification code *IdCode*; in case the user does not enter a sample ID, the program gives it a code automatically.
   Code format:

   "xxxx-yyyymmdd"

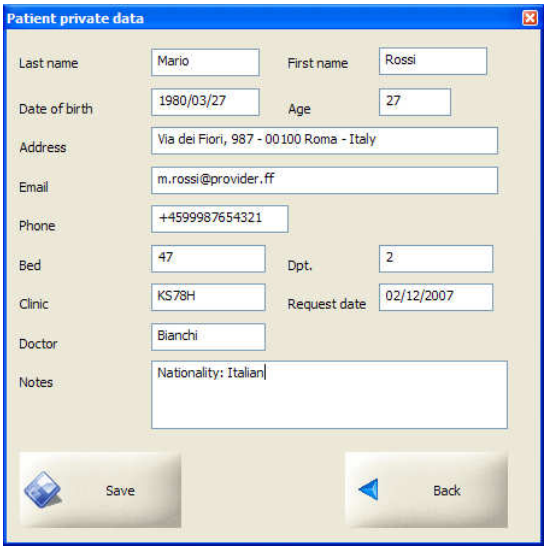
   where
   xxxx=progressive number of the day,
   yyyy=year,
   mm=month,
   dd=day.
   Once given and saved, this IdCode number cannot be modified anymore: can be deleted but not changed.
4. Select the *Sample type*, from the pull down menu.



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

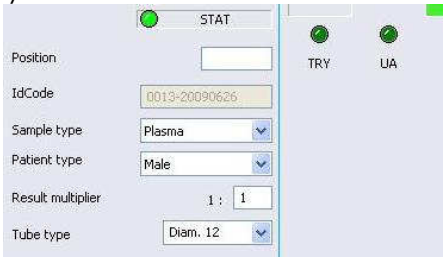


6. Select *Patient Private Data* and enter data in the fields of the displayed window (if desired).



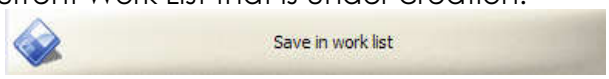
This data can be entered before or during the working session or, at the end of the session from the archive menu, after the results have been saved in the *Memory files*. In the latter case any the single sample can be recalled.

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.



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*.

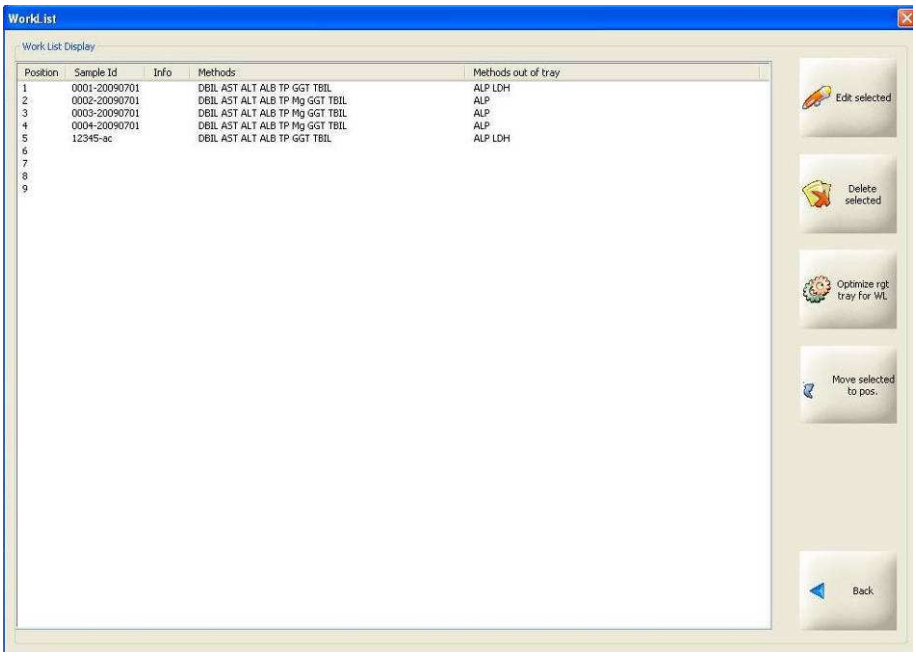
9. Select *Save in work list* to save the sample/s together with the programmed analyses in the current Work List that is under creation.



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:



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.*

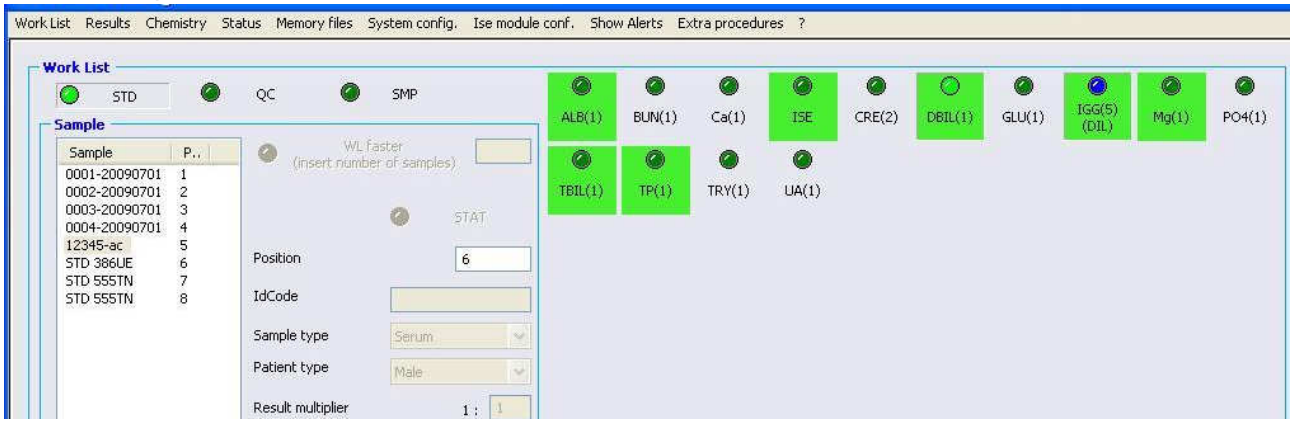
To go back to the Work List, select the command *Back*.

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.

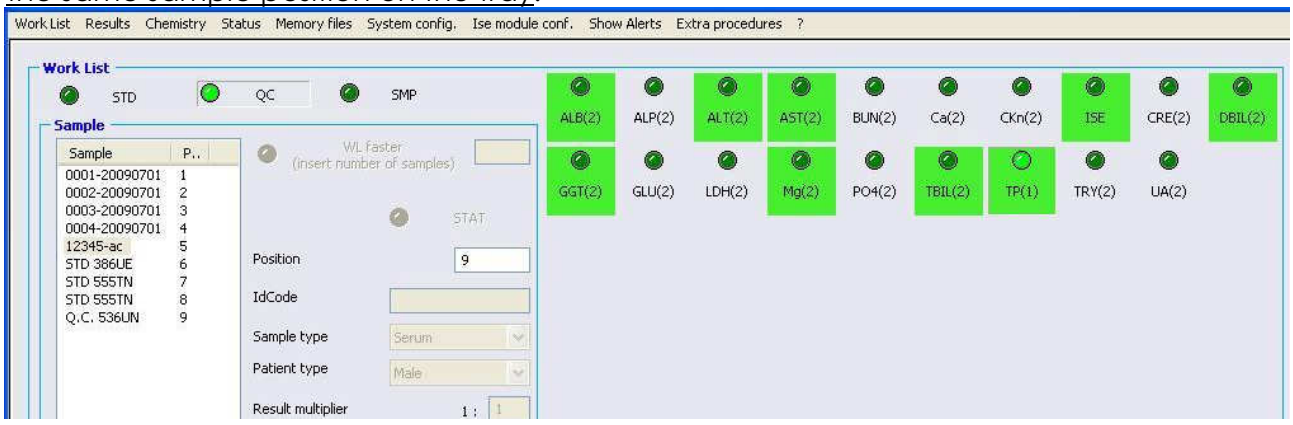
Remember that standard/calibrators with same *lot number* and the same *dilution ratio* (case of standard ready-to-use not to be diluted) have the same sample position on the tray. In case the standard dilution must be performed automatically by the instrument, click twice on the method until you get 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.

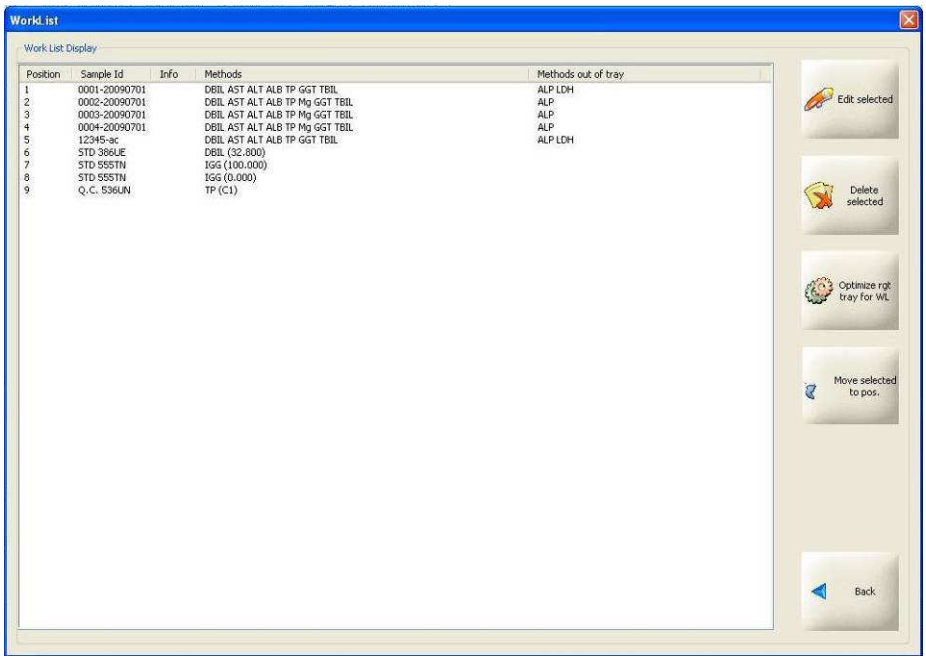
14. In case that also controls must be run, select the "QC"

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:

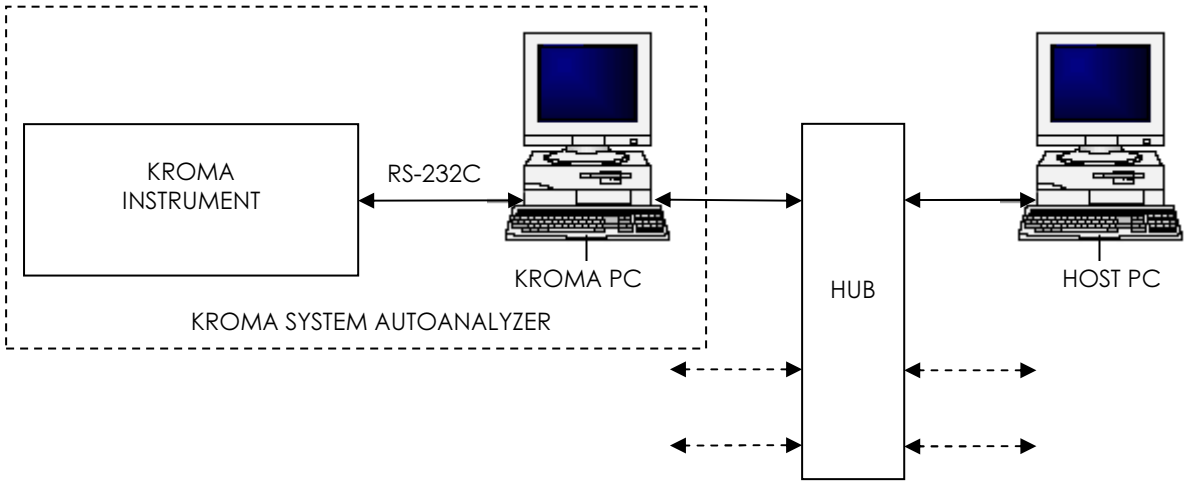


When finish, select the command *Next* to proceed with the next page about Reagent tray configuration control,

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.

2.3.5.2. Automatic Work List Programming with L.I.S. Connection

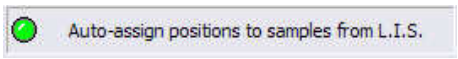
When the L.I.S. connection has been enabled and it is operative, the host remote workstation in the laboratory can set a link with the KROMA system for data exchange.
The link is based on an ASTM-like protocol described in the document cod. MNT-10910-01-x (see last revision) addressed to technical personnel 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.



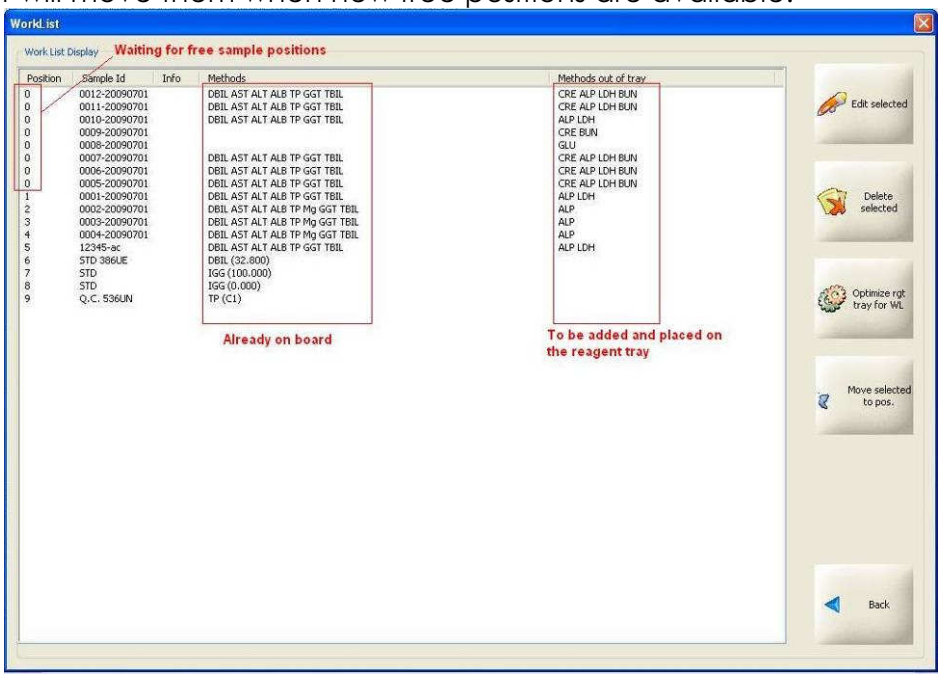
When the KROMA system receives new data from the host computer, it displays the following message on the monitor:

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.

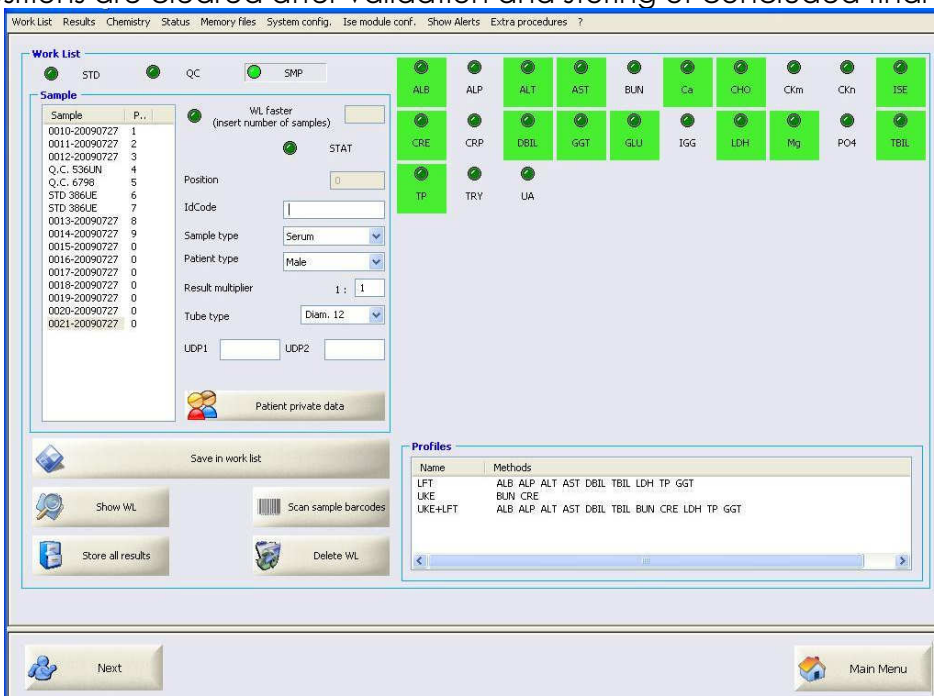
All samples received from L.I.S. will be added into the sample window on the left side of this menu. Upon receipt, if the following selection in the *System config.* menu has been checked



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.

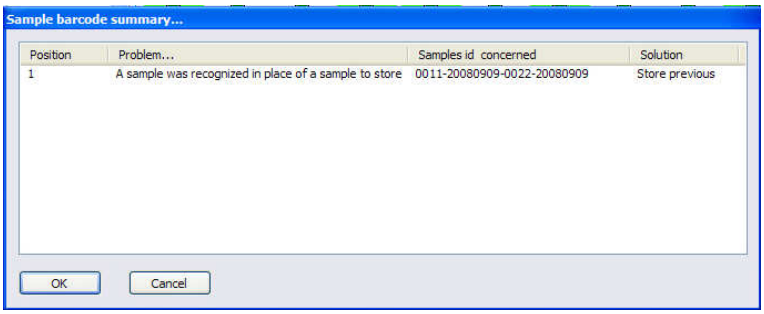


The operator will *Start* samples after having placed them on the sample tray.
New free positions are cleared after validation and storing of concluded final results.



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 modify WL data.

2.3.5.3. Notes on Standards and Control

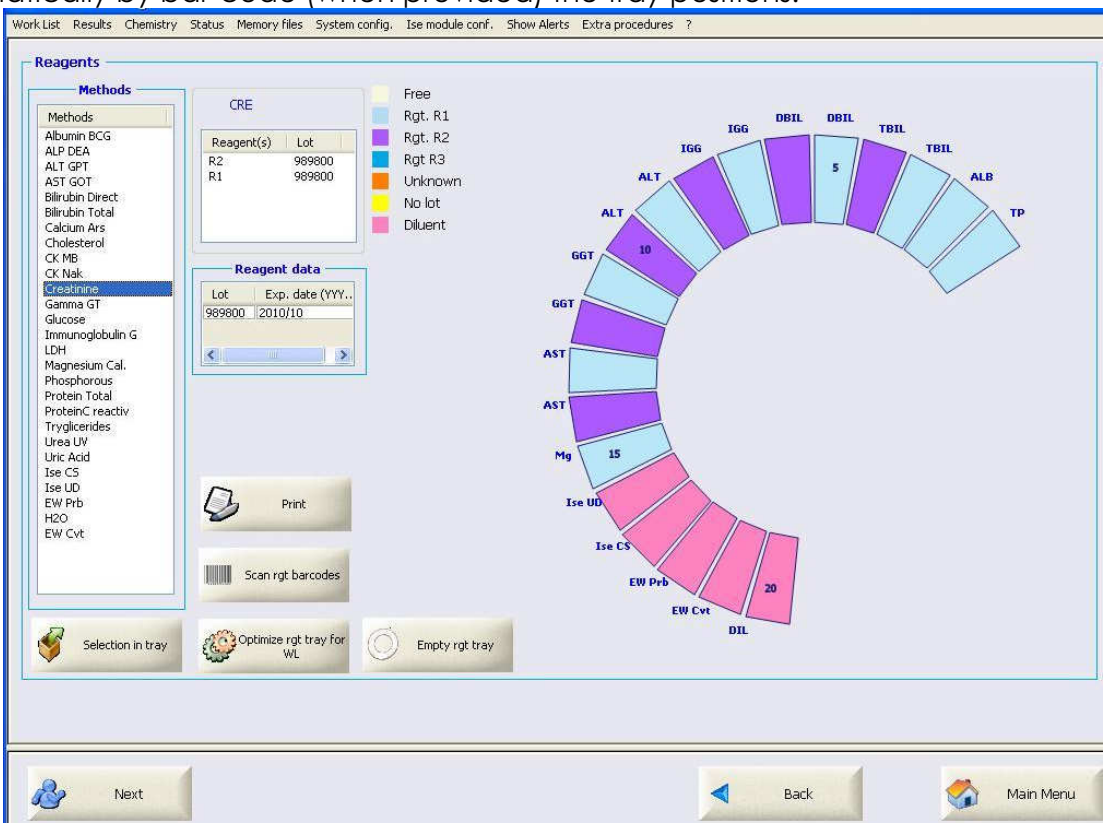
The factor (F) or the calibration curve used for calculation of the final result is saved in the system for a proper result interpretation. The F factor can be the result of a standardization/calibration or it can be previously and manually set by the user. At the end of any standardization, the system 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.

2.3.6. Set Reagents on Board During WL Programming

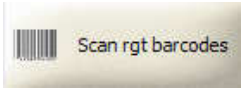
In the *Reagent* menu, the user can set reagents on board configuring manually or automatically by bar-code (when provided) the tray positions.



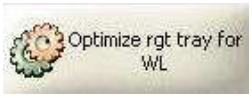
1. If necessary, reset all the tray positions by clicking on the button *Empty rgt tray*:

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:



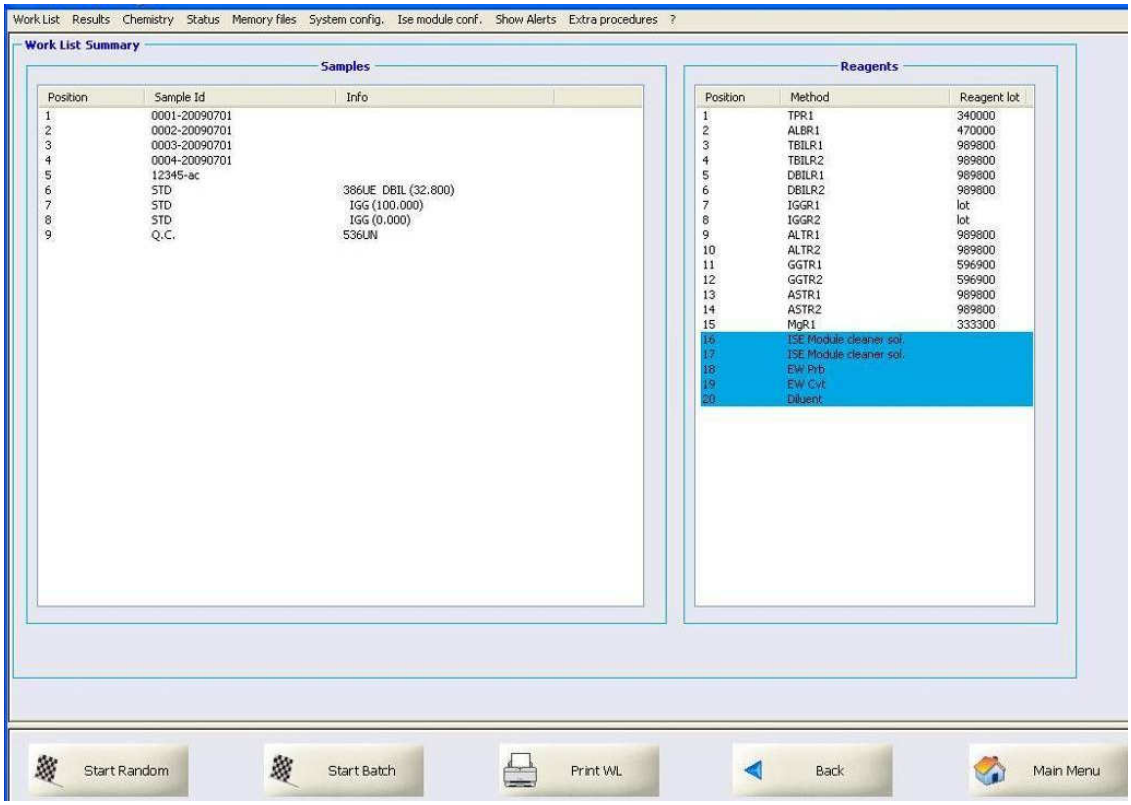
the system will auto-configure the reagent tray positions on the screen.
If the bar-codes are missing, the system can optimize the reagent tray by clicking the button:



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

2.3.7. 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.

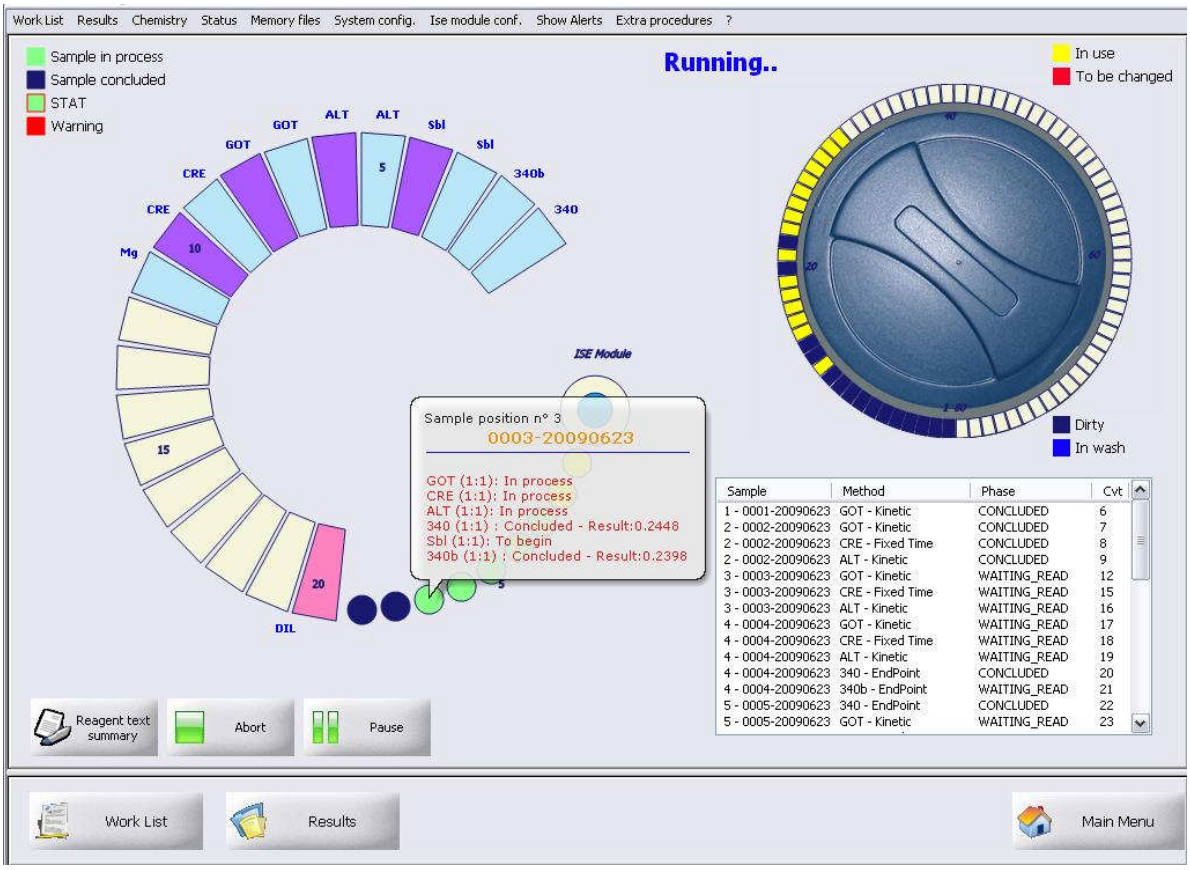


1. In the *Samples* window check the congruence of sample tray positions for Sample, Standard and Controls and of values for eventual Calibration Curves.
2. In the *Reagents* window check the congruence with the tray of the reagent positions.
3. Select the command *Start Random* to run the working session 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.

2.3.8. 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.



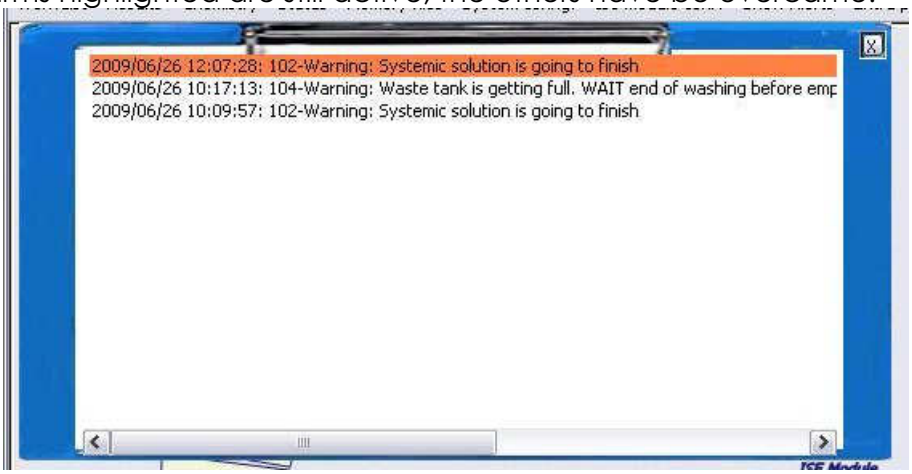
The user can perform congruent operative actions or enter other menus in the software while the working session is in progress.
Operative actions allowed in this Menu:

- 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 fron of any menu. Warnings are highlighted in orange, alarms in red. Warnings/alarms highlighted are still active, the others have be overcame.



2.3.8.1. 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.

2.3.8.2. Adding STAT Samples During a Run

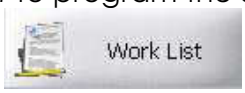
The user can add urgent samples (STAT) at any time. The STAT sample can be placed in a free position of the sample tray (save and discharge concluded samples if more free positions are requested).
The procedure is the following:

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.

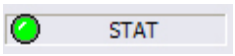
3. Select the Command *Pause* to pause the Instrument.

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.

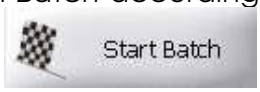


9. Program the analyses for the STAT and activate the priority selection *STAT*.



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.

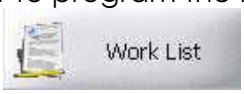
2.3.8.3. Adding One or More Samples During a Run

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.

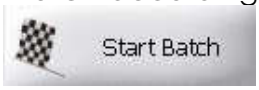
4. Wait for the sampling Arm to complete the phase and stop above Washing Sink.
5. Open the protection defence, take the completed samples out and replace them with the new samples.
6. Close the protection defence.
7. Select the command *Continue* to start again the working session.

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.



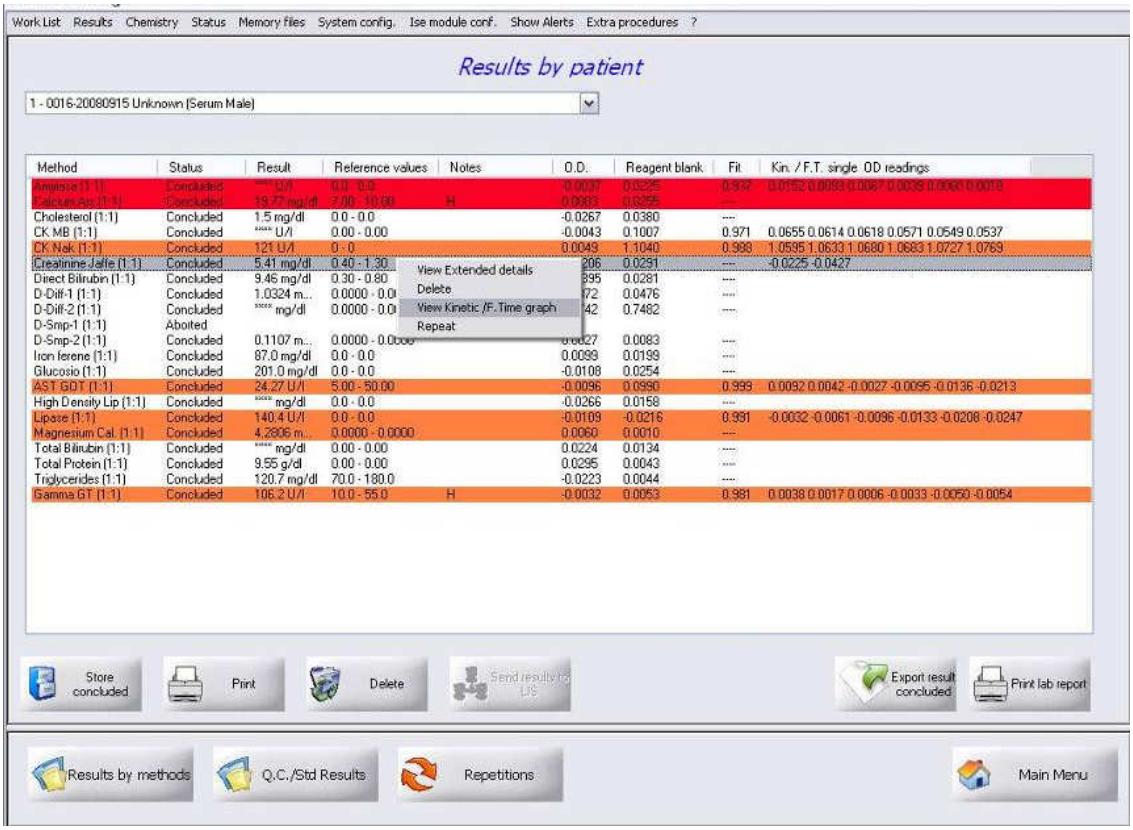
The system will process the new samples as soon as possible after completing the previous ones.

2.3.9. 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.



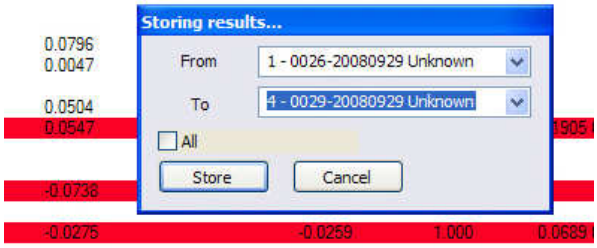
2.3.9.1. Filing a Concluded Patient

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).



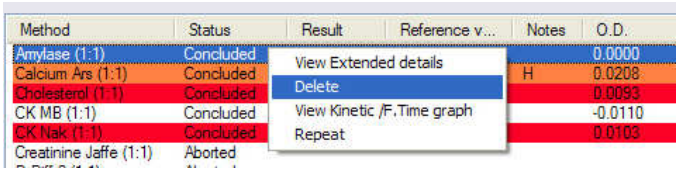
Note: only patients whose analyses have been completed can be moved to the archive.

2.3.9.2. 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*.



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.

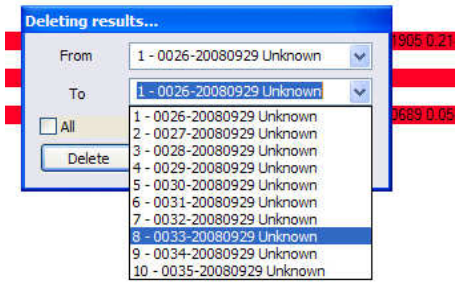
2.3.9.3. Deleting a Sample and its Analyses' Result

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.

2.3.9.4. 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).

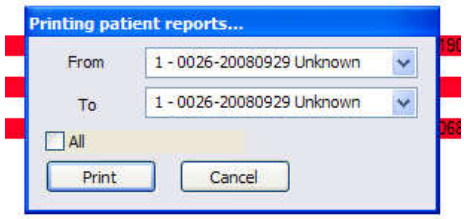
Note: The repetition can be run for concluded tests only.

2.3.9.5. Printing Results

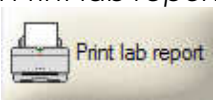
The user can print Result reports for each Patient.
The procedure is described below:

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*.

2.3.9.6. 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.

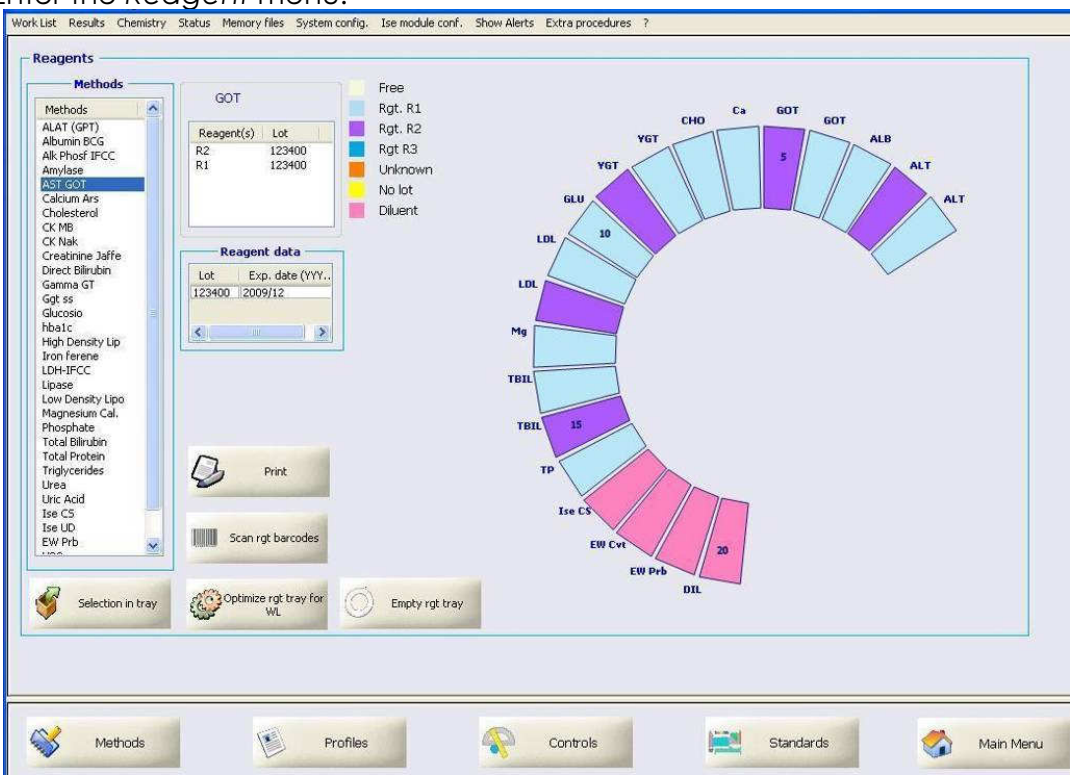
2.3.10. Methods Control System

Using the Chemistry Menu and all its sub-menus, the user can handle reagent, standard and controls' data.

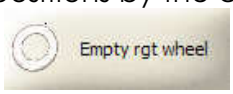
2.3.10.1. Reagent Panel: Manual Configuration

The following procedure allows the manual creation of a panel concerning a reagent tray configuration:

1. Enter the *Reagent* menu.



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:

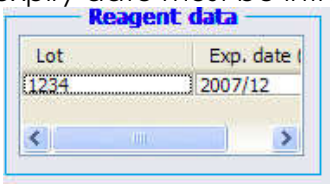
- EW Cvt: extra wash solution for cuvettes (used for cuvettes extra washing or in case of method restrictions to prevent interferences);
- EW Prb: extra wash solution for sampling probe (used for probe extra washing in case of method restrictions to prevent interferences);

2.3.10.2. 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).

2.3.10.3. 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:

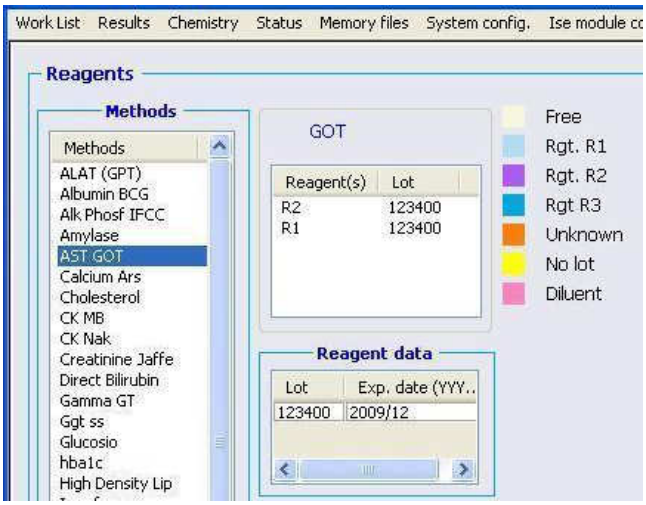
- Only the reagents saved in *Methods* as "visible" are loaded in configuration and displayed in a colour corresponding to the reagent type (R1, R2 or R3);
- The reagents, whose barcode has been read but not found in the saved list, are displayed as *Unknown* (**orange**); a reagent can be manually given 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).

2.3.10.4. 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.

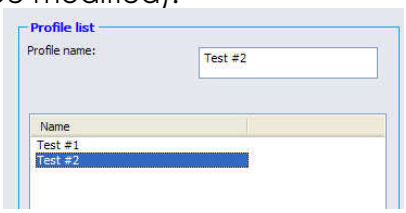
To modify a lot follow the instructions below:

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.

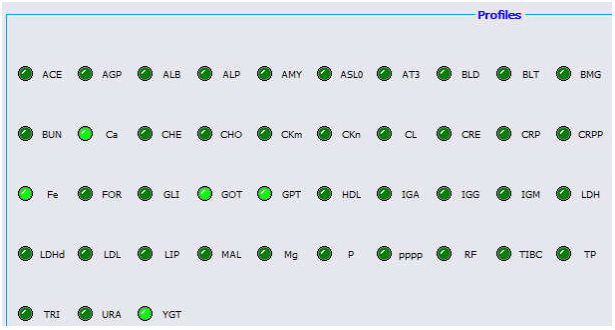
2.3.10.5. Programming Profiles

The following procedure allows the Profile programming:

1. Enter the *Profiles* menu.
2. In the *Profile Name* field enter a name for the profile to create (or select the name of an existing profile to be modified).



3. Select the methods to be included in the profile.

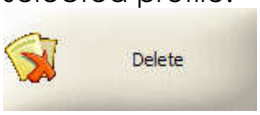


4. Select *Save* to save the profile with the name chosen (it will be visible in the Work List menu).

2.3.10.6. Deleting Profiles

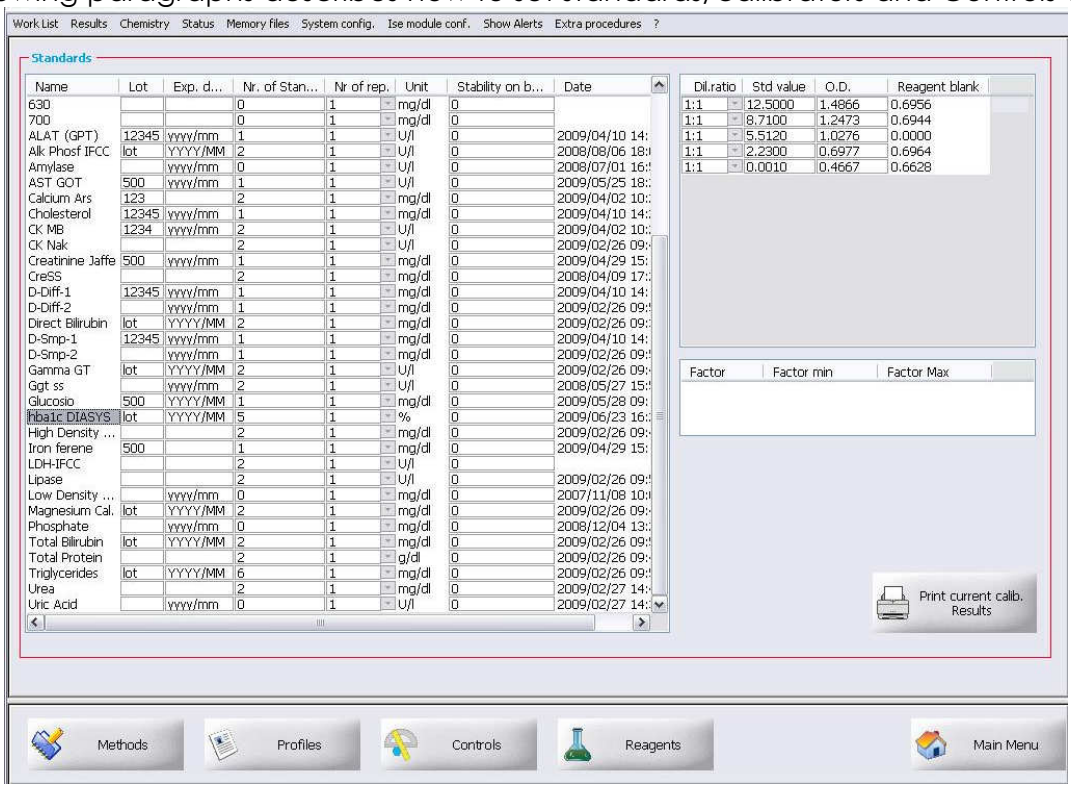
The following procedure allows the profile deletion:

1. Enter the *Profiles* menu.
2. In the *Profile Name* select the profile to delete.
3. Click on *Delete* to delete the selected profile.



2.3.11. Working with Standards and Controls

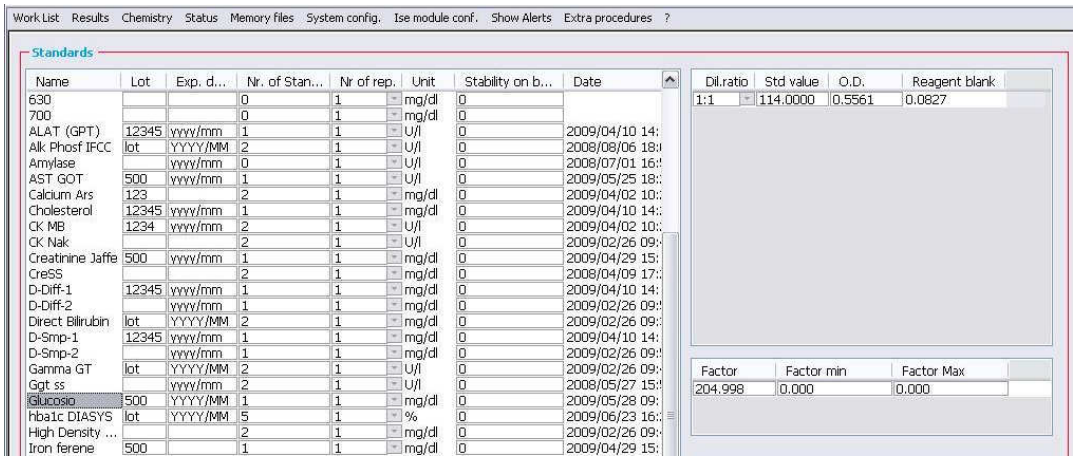
The following paragraphs describes how to set standards/calibrators and Controls data.



2.3.11.1. 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.



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 main 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.

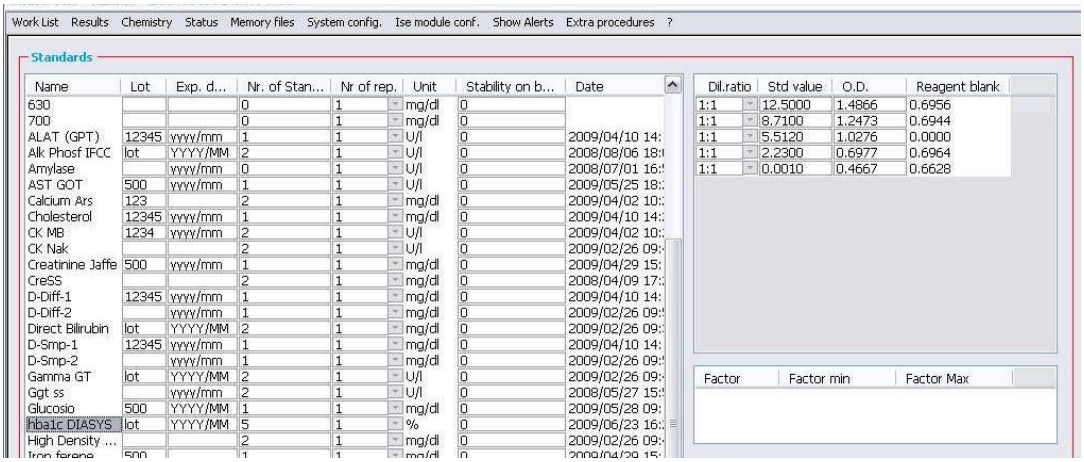
Once the standard has been measured, the system overwrites automatically the following fields:

- *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.

2.3.11.2. 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.



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.

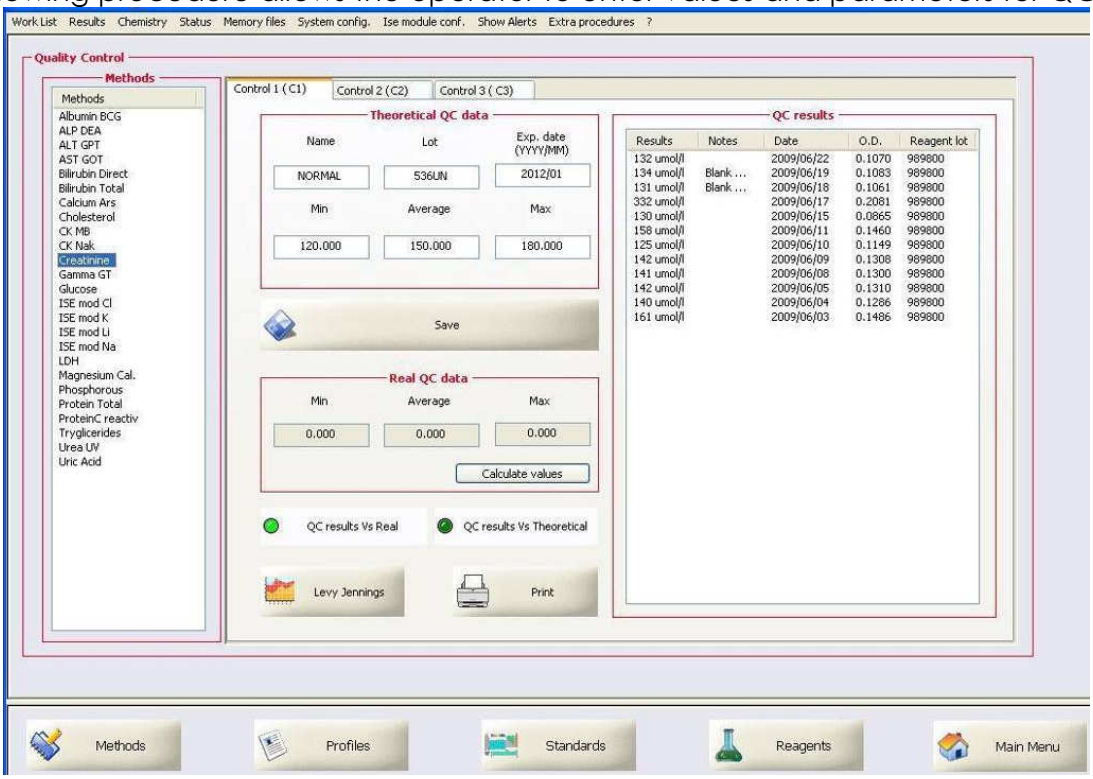
Before running the Work List the user must place the concentrated standards (1:1), in the correct positions of the sample tray.
In case the automatic dilution is not needed and pre-diluted standards are used, the user must place all pre-diluted standards in the correct positions of the sample tray.
Once 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.

2.3.11.3. Entering Values for Controls (QC)

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



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.

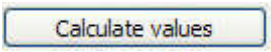
5. Repeat the steps above for the other tabs if required.

The minimum, theoretical and maximum values are reported in the technical documentation of the Control (QC) serum.

2.3.11.4. Viewing Levy-Jennings Graphs and Printing QC Values

The following procedure allows the operator to view Levy-Jennings graph of a QC series of values:

1. In the Q.C. menu, select the method whose control values and data have to be filled.
2. Select Control 1 tab, or Control 2 tab or Control 3 tab.
3. Click on command *Calculate values* to compute and to show the Real QC data calculated over QC results; fields *min*, *average* and *max* will be filled if more then two QC results are available.

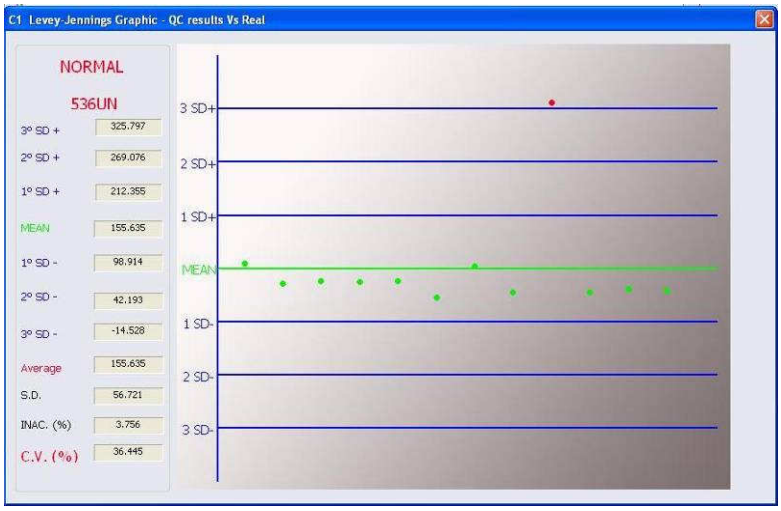


These fields are different from the ones above because they do not show the theoretical values given on the technical sheet but just the values calculated over the QC results of the instrument; such values give the feeling of the system trend.

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

click on the command

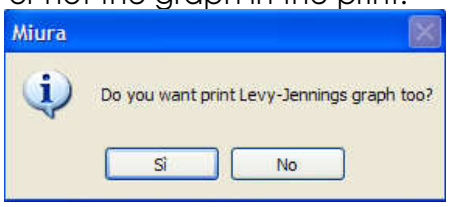
to get



showing Controls results over Real or Theoretical QC data.

5. To print the data reported in the QC *Results* window, click on the command *Print*

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



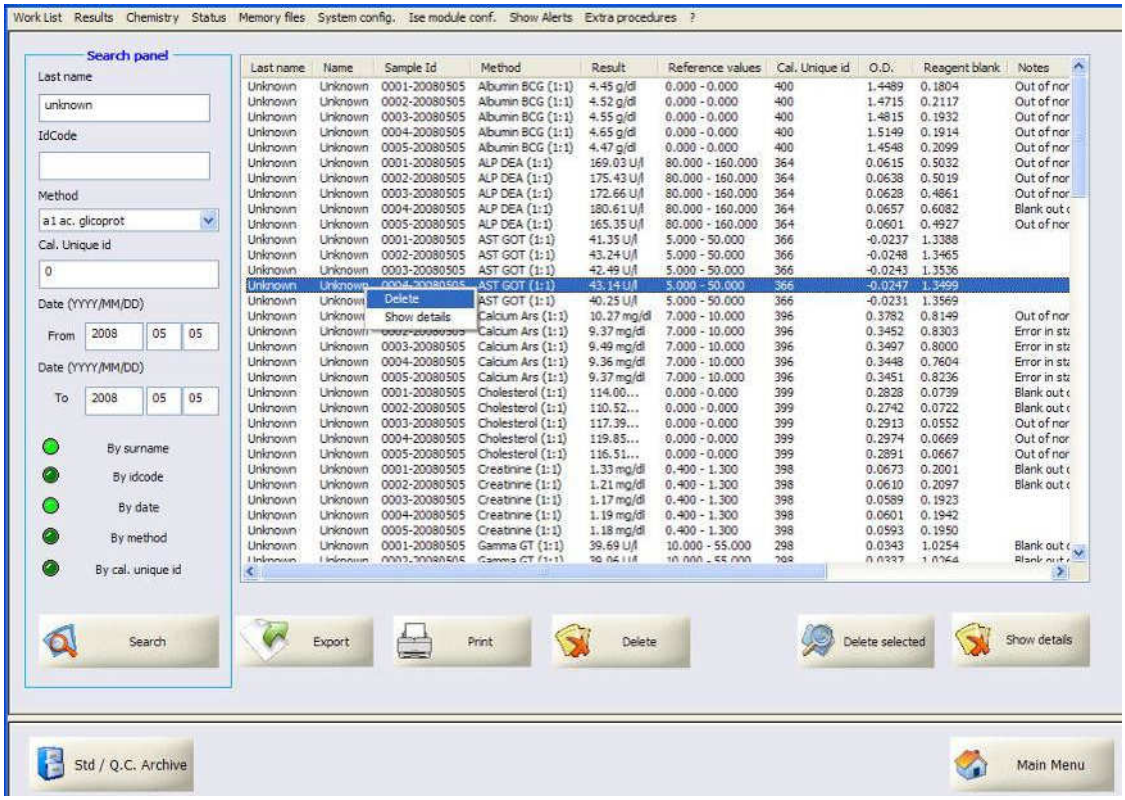
The printed out report data contents depends on the previous selection: Real or Theoretical.

2.3.12. 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.

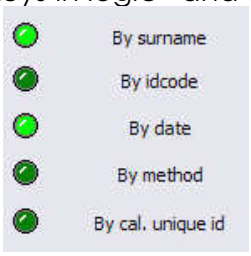
2.3.12.1. Searching and Handling Patient Results

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:

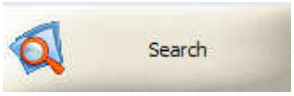


1. In the field *Last Name* it is possible to enter the patient's surname, if surname is needed as research key (in case no name have been used, you can type the word "unknown" to show all samples whose name never has been assigned.
2. In the field *IdCode* it is possible to enter the sample Id code, 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.

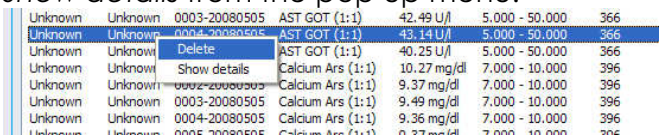
6. Choose then one of the searching criteria (keys); any combination of them is valid and the system considers all keys in logic "and" to refine the research:



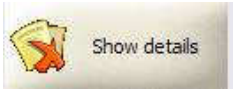
7. Click the command *Search*; the search results will be displayed in the right side window when the search has been completed (a note above the Command *Search* will advise about the number of results found).



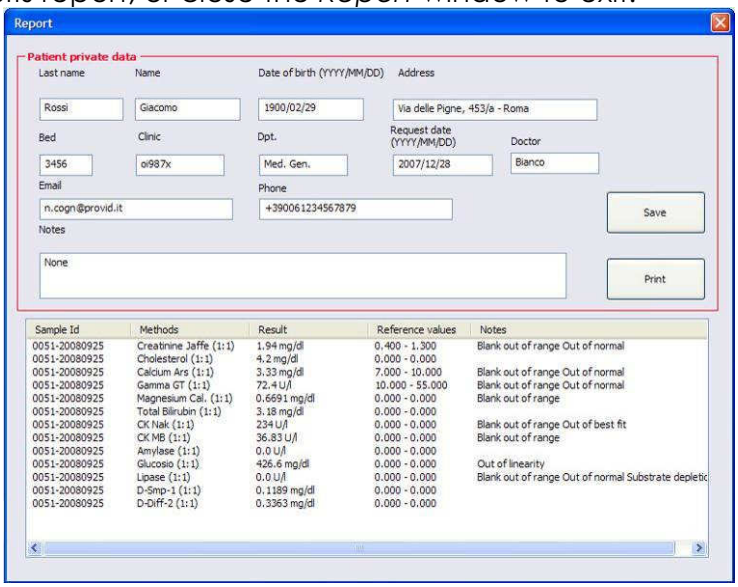
8. To open a patient report, right click with the mouse on the result and then select the command *Show details* from the pop up menu.



or click the *Show detail* button:



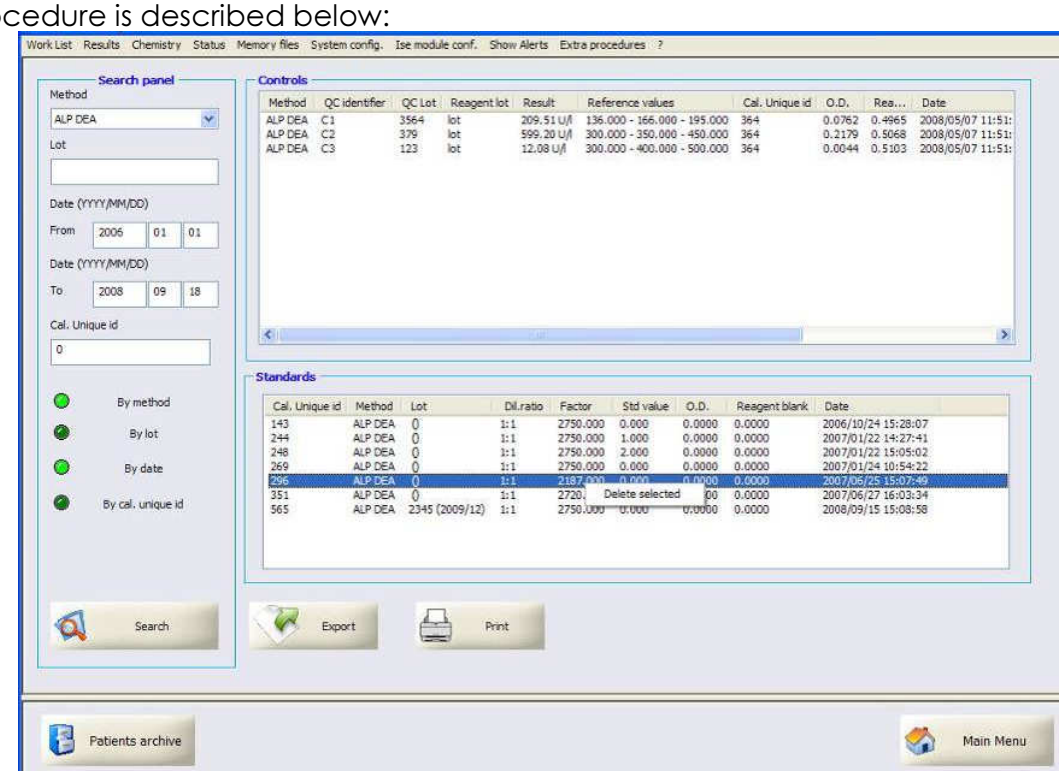
9. In case some data modifications are needed in the *Report* window, make them and then select the command *Save data* or select the command *Print results* to print the results report, or close the *Report* window to exit.



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.

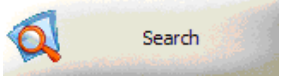
2.3.12.2. Searching and Handling QC Results

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:



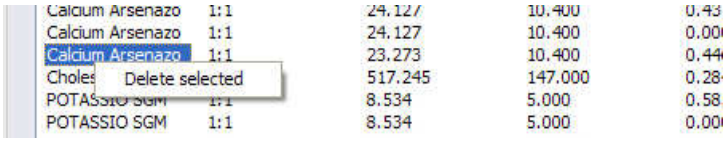
1. In the field *Method* it is possible to enter the test to search for standard/control, if test name is needed as research key.
2. In the field *Lot* it is possible to enter the lot number, if needed as search key.
3. In the field *Date from / to* it is possible to enter the starting date and ending 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.



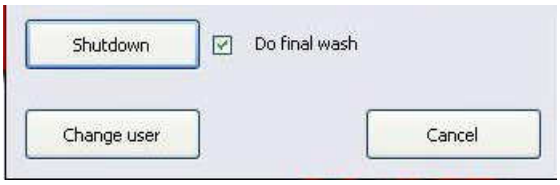
7. The command *Print* allows the User to print a laboratory compact report; the command *Export* allows the User to export results.

8. By selecting a result and clicking with the right mouse button is possible to delete results.



2.3.13. 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.



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.