

# HumaStar 600

| User Manual



Cat No. 16660/001

**Human**

Diagnostics Worldwide



## REVISION LIST OF THE MANUAL

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## SYSTEM VERSION

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## SERVICE UND SUPPORT

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## 1 SAFETY INSTRUCTIONS

### 1.1 Introduction

This manual is considered as a part of the instrument; it has to be at the operator's hand as well as at the maintenance operator's availability. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid instrument damage or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the suitable operating procedures. In case of breakdowns or any troubles with the instrument, apply to the local Technical Service.

### 1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, diskettes, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

HUMAN shall be relieved of any obligation under this warranty, unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.

This warranty does not apply to damages incurred in shipment of goods. Any damage so incurred shall be reported to the freight carrier for settlement or claim.

### 1.3 Intended Use of the Instrument IVD

The instrument is intended for in vitro diagnostic application by professional users. It has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the GENERAL SAFETY WARNINGS. This manual contains instructions for professional qualified operators. The external PC must not be used for purposes other than those designated in this manual. The analyzer is designated for indoor use only. Recommendation provided in the leaflet for all reagents and consumables have to be observed.

### 1.4 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual. Place the product so that it has proper ventilation.

The instrument should be installed on a stationary flat working surface, free from vibrations.

Do not operate in area with excessive dust.

Work at room temperature and humidity, according to the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.

Only use the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument, use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in potentially explosive environment or at risk of fire.

Prior to cleaning and/or maintaining the instrument, switch off the instrument and remove the power cord.

For cleaning use only materials specified in this manual, otherwise parts may become damaged. It is recommended always to wear protective apparel and eye protection while using this instrument. Respective warning symbols, if appearing in this manual, should be carefully considered.

### **1.5 Disposal Management Concept**

The currently valid local regulations governing disposal must be observed. It is in the responsibility of the user to arrange proper disposal of the individual components.

All parts which may comprise potentially infectious materials have to be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal have to be carefully observed.

The instruments and electronic accessories (without batteries, power packs etc.) must be disposed off according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power source have to be dismantled from electric/electronic parts and disposed off in accordance with applicable local regulations.

### **1.6 Instrument Disinfection**

Analytical instruments for in vitro diagnostic involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

Before doing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination should be performed by authorised well-trained personnel only, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre, or from authority's interventions.

### 1.7 Biohazard warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples, calibrators and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

For safety reasons, we have labeled instruments with the „BIOHAZARD“ warning label below.

**FIGURE 1**  
Biological Hazard Symbol



### 1.8 Additional Labels

The labels used on Human products are among those specified by the international Organisation for Standardization (ISO).

They are placed at critical points on each instrument as a warning of the risks involved.

While operating any of our instruments take note of these and observe the precautions described.



Warning Electrical Risk - This label indicates the operator of the presence of high electrical voltage.



Warning Danger: This label indicates a potential hazard which, if not avoided, can result in injury to an operator and/or serious property damage. Please read the manual for instructions before opening.

## 2 INTRODUCTION

The HumaStar 600 is a reliable in vitro diagnostic chemistry analyzer for automatic testing of routine clinical chemistry tests and electrolytes.

Being real random access, this HumaStar 600 is the ideal solution for medium to large size labs, with a throughput of more than 600 photometric tests/hour (720 tests/hour with ISE).

Continuous process can be achieved as samples sectors can be loaded quickly and simply allowing nonstop operation. Sectors can hold primary tubes and small sample cups.

Refrigerated reagent tray can hold up to 48 different containers ranging from 20 to 70ml depending on configuration.

The optional ISE unit gets electrochemical measurement of Na<sup>+</sup>, K<sup>+</sup> and Cl<sup>-</sup> electrolytes with automatic urine sample dilution. The instrument is controlled by a PC workstation that has graphical -user friendly- interface software. The software provides total control over the analyzing process and gives easy access to advanced statistical functions and reports. Versatile method setup comprises end point, fixed point, kinetics, ISE, coagulation, calculated and externals.

Optional features include:

- Flexible pre- and post washing for each test to prevent carryover.
- Auto rerun with automatic dilution of samples which are out of linear range.
- Automatically duplicate for result confirmation
- Extra volume dispensing of water or reagent to improve accuracy.
- Reagent integrity check for safe operation.
- Automatic predilution for calibrators, controls, blanks and samples to fit any method insert.
- Curve and linear calibration with unlimited number of standards for highest accuracy.
- Onboard sample and reagent bar code reading assure positive identification.
- Capacity sensor monitors sample and reagent volumes.
- Instant mixing during dispense gives precise initial reaction time.
- Automatic acceptance of calibrators, control and samples increase the walk away time.
- Current activity monitor screen indicates to the operator when the routine will be finished
- Clot detector
- Low water consumption.



### 3 SYSTEM DESCRIPTION

#### 3.1 Unpacking

Remove all the parts from their package.

When unpacking the instrument, please make sure that the following items are contained in the packing. In case of damage or missing item, please contact the supplier immediately.

| Quantity | Description                                   | REF       |
|----------|---|-----------|
| 1        | Software CD                                   | 16661     |
| 2        | Reaction cuvettes (box of 1200)               | 16661/1   |
| 2        | Drying block kit                              | 16661/11  |
| 1        | Reagent recipients with cap (x 30) vol. 70 ml | 16661/2   |
| 1        | Reagent recipients with cap (x 30) vol. 25 ml | 16661/3   |
| 2        | Peristaltic Pump tubing kit x 3               | 16661/4   |
| 2        | Sample tubes 13 mm. kit x 100                 | 16661/5   |
| 1        | Halogen lamp 12V 20W                          | 16661/7   |
| 5        | Sample Rack                                   | 16661/15  |
| 1        | Serial Cable                                  | 16661/16  |
| 1        | User Manual                                   | 16660/001 |

TABLE 1

#### 3.2 Installation

##### 3.2.1 INSTALLATION REQUIREMENTS

Carefully read the safety instructions included in this manual.

Install the instrument on a hard floor with a resistance of at least 50 kg/cm<sup>2</sup>; use, if possible, ceramic or stone floor.

Avoid carpets or very soft rubber.

Mains should be close to the instrument (less than two meters) and must fulfill local regulations.

Free access to main switch is required. A distance of 50 cm from the left side of instrument to nearest table or wall is advisable. Right side must have a free space of at least 30 cm for ventilation purposes.

Space must be empty over instrument to 2.10 m. Avoid using shelves, walls or screens above instrument.

Instrument is mounted on wheels and can be moved towards the front for servicing and cleaning purposes. Allow free space of about two times the instrument depth.

**!** Instrument is Installation Category II. Instrument requires protective ground connection. Verify ground connection before installing the instrument.

**!** User must be warned about the use of instrument under abnormal grounding conditions. It is advisable not to complete installation under poor ground conditions.

**!** Preparation of System Wash Solution IFU of Wash Add Ref 18971.

### 3.2.2 ELECTRICAL CONNECTIONS

Plug in the mains cord to a socket with ground connection. The power requirements for the HumaStar 600 are as follows: **100~240 VAC, 50/60 Hz, 1400 VA** maximum.

Maximum voltage between ground and neutral lead: 0.5 volts.

There is a J9 serial port type RS232C connector in the rear part of the instrument. Connect the HumaStar 600 to the computer serial port using the provided cable. Tighten retaining screws.

### 3.2.3 HYDRAULICS

The waste deposit collects the drainage of the probe washing stations and occasional waste from the dispensing stations and cuvette washers. Place the emptied bottle in the correct location and orientation (see Figure 23).

Pay attention that the funnel is inside the bottle neck. The waste bottle has a capacity of 20 L and the wash solution bottle of 10 L. To prepare the system wash solution, purified water should be used with less than 2  $\mu\text{S}/\text{cm}$  and less than 100 CFU/mL to avoid contamination of the system with ions and bacteria. Described specification fall in CLSI Type 2 water category.

Level metering is made by means of a load cell system (scale) for wash solution- and waste bottle. Warning messages will appear before the system wash solution is empty and the waste bottle full.

Put the pump tubing of the washing pumps in place. Take out the plastic protection tube (typically yellow) from the probe arm's vertical shaft before operating. The system is ready to use. Flush the system at least 3 times in order to ensure that all bubbles have been removed from the tubing and syringe.



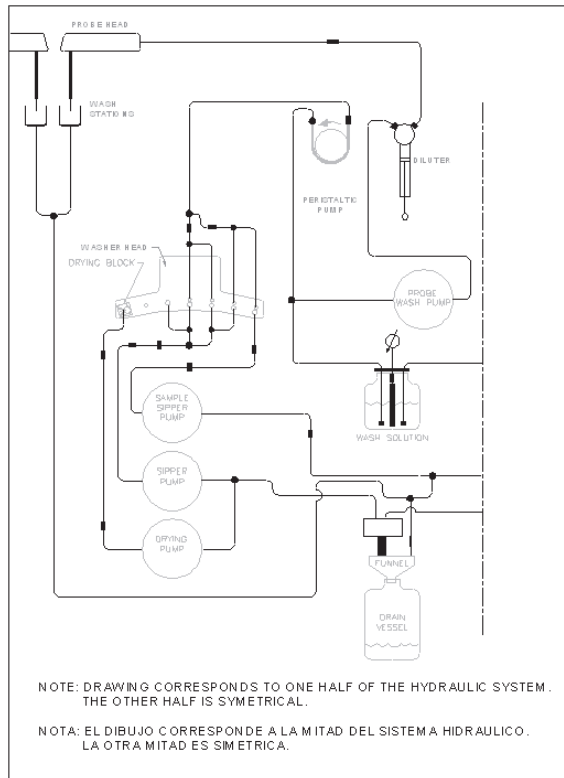


FIGURE 2

### 3.2.4 HANDLING OF BIOLOGICAL FLUIDS

Before connecting wash and drain lines, be sure to remember and understand regulations and cautions about potentially dangerous biological fluids.

Keep in mind the following considerations:

1. Due to the presence of biological fluids, some instrument areas are potentially dangerous. They are warned with the symbol see Figure 1.

Dispensing tips, reaction cuvettes and drain fluid bottle are the most endangered areas.

**!** Never dispose potentially dangerous fluids on public drain system.

Refer to chapter 1.5.

1. Sample handling, drain fluid disposal and reaction cuvettes replacement must be done with safety disposable gloves manufactured according local regulations for biological fluids handling.
2. Drain fluid must be neutralized. The addition of 0,5 % Sodium Hypochlorite is suggested.
3. Verify and use local regulations on discarding pathological fluids.
4. If instrument is to be translated to other location or stored for a long period, perform at least 5 purge cycles, remove cleaning solution bottle and repeat purge cycles until drain lines are empty. Neutralize and dispose drain fluid.

### 3.2.5 COMPUTER SETUP

Follow the instruction set of the computer's manufacturer to connect and operate the computer system.

The minimum requirements for the computer are:

TABLE 2

|                           |  |
|---------------------------|--|
| <b>Processor</b>          | Intel Core i3 or higher  |
| <b>Memory</b>             | 4 Gb Ram   |
| <b>Video board</b>        | Graphics Enging GeForce 8400 or equivalent   |
| <b>Monitor</b>            | 17" (VIS 15.7")  |
| <b>Display resolution</b> | 1024x768 (vertical refresh > 70 Hz)  |
| <b>Colour quality</b>     | 16 bits  |
| <b>Hard drive</b>         | 500 Gb SATA 3 7200 rpm or better   |
| <b>CD-Drive</b>           | CD-RW or DVD-RW or DVD-R   |
| <b>USB port</b>           | 2.0 or higher  |
| <b>Keyboard</b>           | 105-key Performance keyboard   |
| <b>Pointing device</b>    | USB mouse  |
| <b>Soundcard</b>          | Integrated 16 bit (optional)   |
| <b>Speakers</b>           | (optional)   |
| <b>Network adapter</b>    | Ethernet 10/100 Mbits  |
| <b>Serial Port</b>        | RS-232 serial port<br>Additional serial port for LIS connection, (USB to RS232 adapter – optional) |
| <b>Operating system</b>   | Win 7 (32 and 64 bit), Win 10 (64 bit)   |
| <b>Compatible printer</b> | Any Windows™ compatible printer maybe installed.   |

The computer should be used only for the operation of the instrument. Any other programmes beside the instrument software may cause instument malfunction and /or breakdown.

#### The visual effects to best performance.

Change the setting of the operating system. Under properties → Advanced options → visual effects select "Adjust for best performance".

**Setting of the Anti Virus Software**

We recommend the use of Anti Virus Software on the Personal Computer of the HumaStar 600. The HumaStar 600 “Rayo” directory has to be excluded from the scanning process. Please refer to the documentation of the Anti Virus Software **Don’t use the predefined MS Windows folders.**

**3.2.6 PARAMETERS**



There are few parameters for software and instrument use accessible to operator. They are located in:

**3.2.6.1 Software**

Includes pages for communications, LIS and bar code reader.

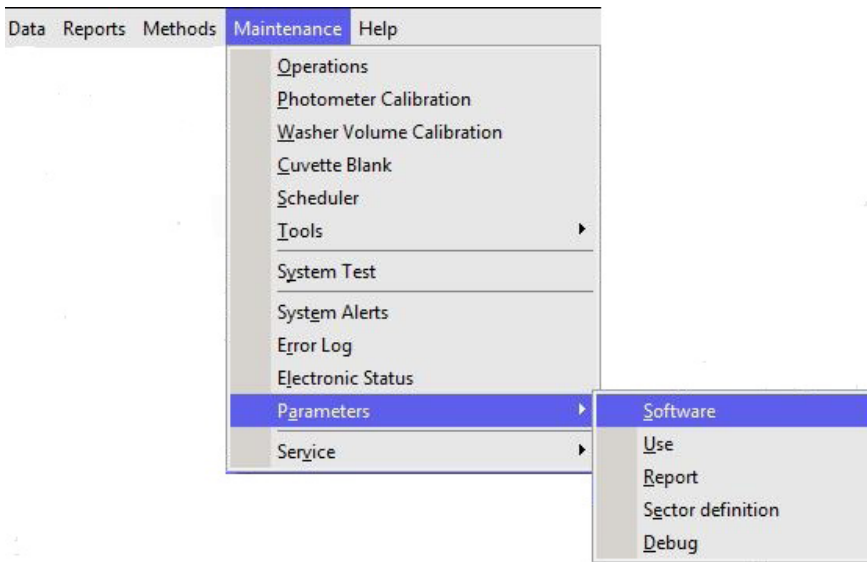


FIGURE 3

## General

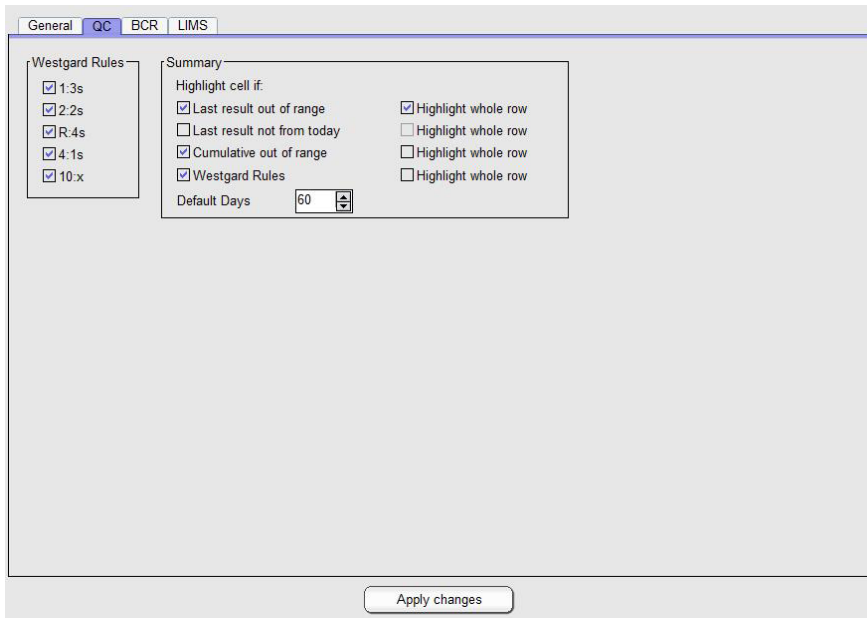
FIGURE 4

1. Communications: Select serial port according to your computer setting and specification. If setting is wrong, the HumaStar 600 temporarily checks for other port; but if no ports are free, program might not work properly.
2. Language: Select among languages already set in the translator. Changes will come into effect when program is closed and re-opened.
3. Historic: Defines size in days and numbers that calibrators, controls and samples will stay in "upper" memory. Controls and samples above these days will be stored at the cumulative historic files and can be recalled.
4. Random access: Two options are provided: batch and full random access.
5. Coagulation: (Service only - not in use):
6. Online printing: Enables printing; selector of printout of pending acceptance samples and printout of manually accepted results.
7. Automatic: Selection of active warnings and software behavior on a number of different routine analysis. ISE processing check can be enabled by default with a parameter. The DI empty warning can stop dilutions if checked and issue warning, but continue (with warning) if not checked.
8. Automatic acceptance: Sample results can be automatically accepted when they are within the reference range, after an automatic repeat and/or when a calibration is reused.
9. Patient window: Selection of display
10. Sample Default Type: Defines which sample type will be used as default on the sample requisition screen.

11. Reagent integrity check: run the reagent integrity check at each start of samples or only once a day.
12. Clot behavior: Enables the use of clot detection and offers additional options in analyzer behavior in case that a clot is detected. Options: only flag - a flag is added to the result, invalidate - the result will be deleted. The function to aspirate the same sample again, can be enabled or disabled. Refer also to section 4.1.1.

Press **Apply Changes** in order to save the changes.

## QC



The screenshot shows a software window with tabs for General, QC, BCR, and LIMS. The QC tab is active. On the left, under 'Westgard Rules', there are five checked options: 1.3s, 2.2s, R-4s, 4-1s, and 10.x. In the center, under 'Summary', there are two columns of options. The first column has 'Last result out of range' (checked), 'Last result not from today' (unchecked), 'Cumulative out of range' (checked), and 'Westgard Rules' (checked). Below these is a 'Default Days' field with the value 60. The second column has four 'Highlight whole row' options, all of which are unchecked. At the bottom center of the window is an 'Apply changes' button.

FIGURE 5

1. Westgard Rules: options to select rules which should be evaluated at Levey Jenning Plots at the "QC Done" window.
2. Summary: Option to select QC results which should be highlighted at the "QC Statistics" window.

Press **Apply Changes** in order to save the changes.

## BCR

FIGURE 6

The screenshot shows the BCR configuration window with the following settings:

- Samples
- Reagents
- Sector

**Reagent configuration:**

| Method / Solution | BCR code position | Reagent number position |
|-------------------|-------------------|-------------------------|
| From: 1           | From: 1           | From: 4                 |
| Length: 3         | Length: 3         | Length: 1               |

**Bottle type:**

|           |
|-----------|
| From: 5   |
| Length: 1 |

Bottle id position

|           |
|-----------|
| From: 1   |
| Length: 0 |

Expiration

Format: mmyy

From position: 6

**Sample configuration:**

Id position

|           |
|-----------|
| From: 1   |
| Length: 0 |

**Reagent no read behaviour:**

Ask each time

Ask at the end

**Lot Number:**

Mix lots

Apply changes

1. BCR: Barcode reading can be activated for sectors, samples and reagents by checking the corresponding box. When sectors are provided with bar code identification, it is not necessary to define a number for sector loading.
2. Reagent configuration: Select setting according to your requirements. This selector defines options for Method, bottle type, expiration date format and starting position. In case of closed parameters, values are predefined and no intervention is necessary.
3. Sample configuration: If Id position is not selected, all barcode digits are read.
4. Reagent no read behaviour: If reagent barcode is activated two options are available for barcode reading error messages. The message can show up each time an error occurs or at the end of the reagent barcode reading.
5. Lot Number: To use multiple lots for the same reagent select the box "Mix lots".

Press **Apply Changes** in order to save the changes.

LIMS

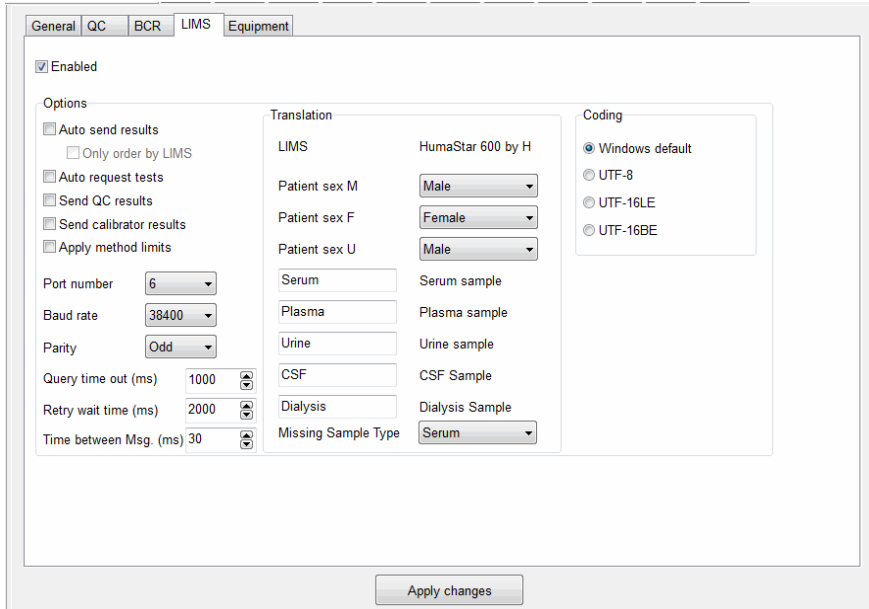


FIGURE 7

1. Enabled: Select to activated and set informations for the communication with host computer.
2. Options: Select parameters according to specifications of your LIMS provider.

3.2.6.2 Use

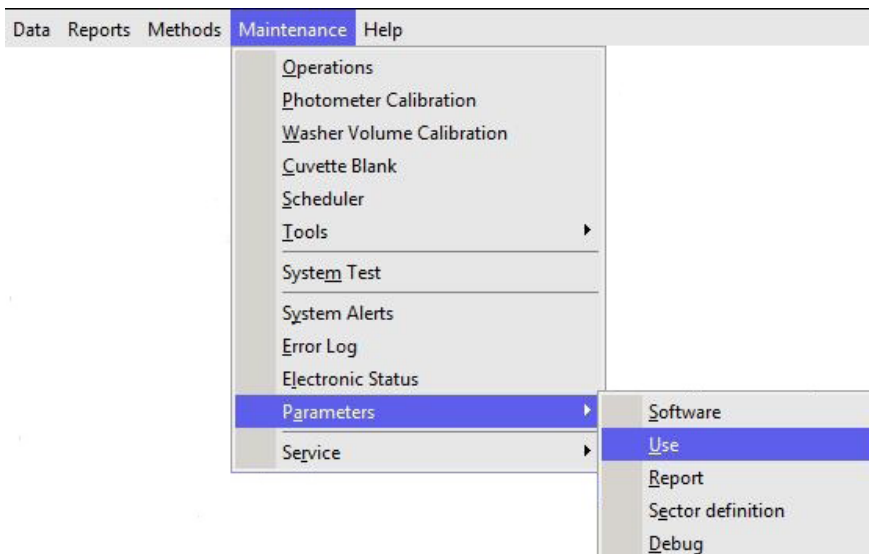


FIGURE 8

Use parameters are split in several sections: Cuvette absorbance limits, ISE and definitions of sample vials.

FIGURE 9

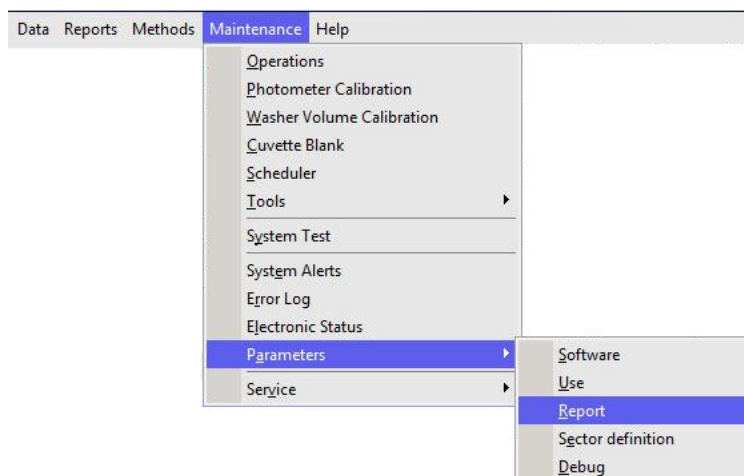
The screenshot shows a configuration window with three main sections:

- Cuvette blank:**
  - Low limit (Abs): 0,0900 (with a 0,000 target and a refresh icon)
  - High limit (Abs): 0,1700 (with a 0,000 target and a refresh icon)
  - Tolerance: 0,0200 (with a 0,000 target and a refresh icon)
- Sample vials:**
  - Primary area (mm2 x10): 500 (with a 0 target and a refresh icon)
  - Secondary area (mm2 x10): 500 (with a 0 target and a refresh icon)
- ISE:**
  - Serum pre wash: [Red X] [Change]
  - Urine pre wash: [Red X] [Change]
  - Others pre wash: [Red X] [Change]
  - Prime: [Red X] [Change]

1. Cuvette blank: Upper- and lower limits for the cuvette check (air) can be set. The tolerance value indicates the allowed absorbance variation of the first reading after cuvette change and the actual reading.
2. Sample vials: Two different sample diameters vials can be defined. This feature is useful to define pediatric vials. Volume calculations require careful section measurement for each defined vial.
3. ISE: Sample prewash can be enabled or disabled. For details, refer to ISE User Manual REF 16663/1.

### 3.2.6.3 Report

FIGURE 10





This section allows sorting how methods are ordered in report and printout. Keys **Up** and **Down** allow moving methods to different positions in the final printout. If not enabled, sorting will take place alphabetically. Press **Apply Changes** in order to save the changes.

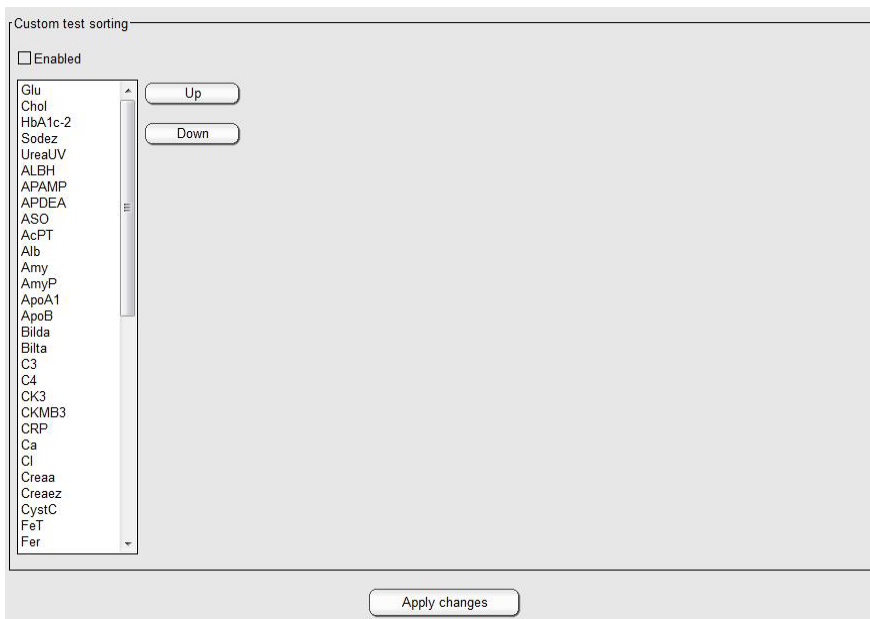


FIGURE 11

**3.2.6.4 Sector definition**

In this section user defines the number of sectors that are available on the analyzer.

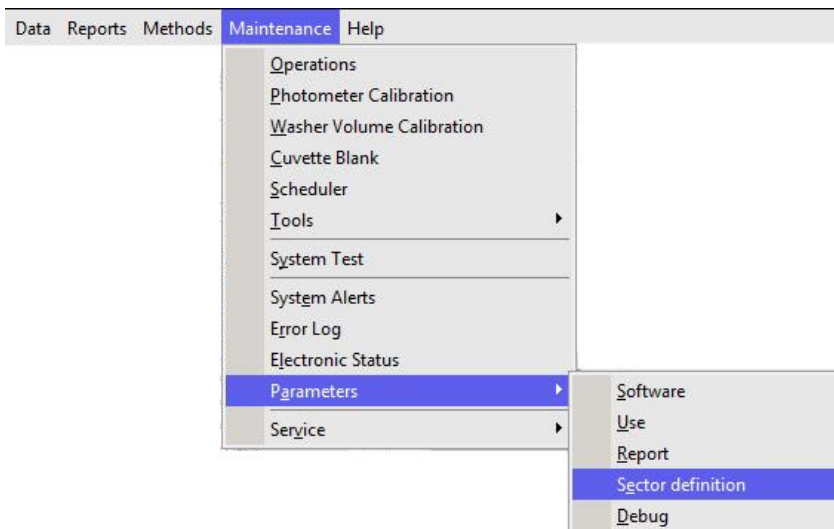
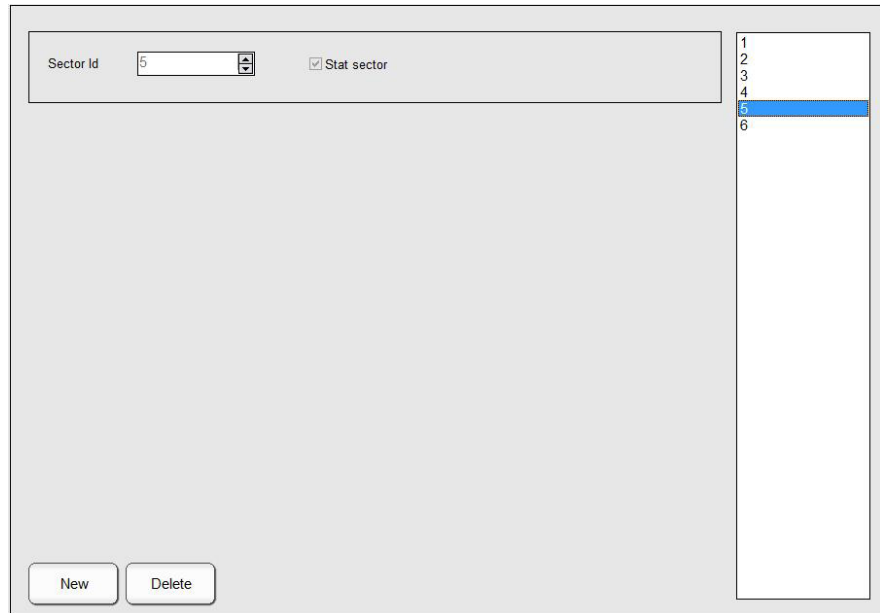


FIGURE 12

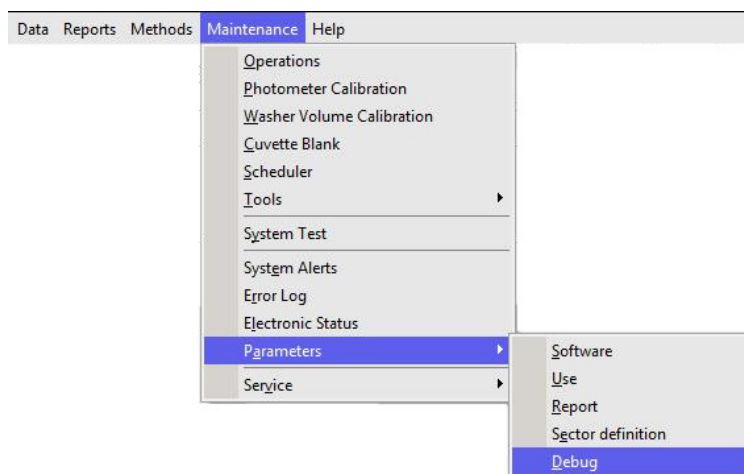
FIGURE 13



Up to 99 sample tray sectors can be programmed and up to five can be on board at the same time.

On the right side of the screen all programmed sectors are displayed. Press **New** to add another sector. To define it as a STAT, tick the box “STAT sector” and press **Ok**. All samples placed on a STAT sector will be processed with priority.

### 3.2.6.5 Debug



In this section hardware and hardware check functions can be activated or deactivated.

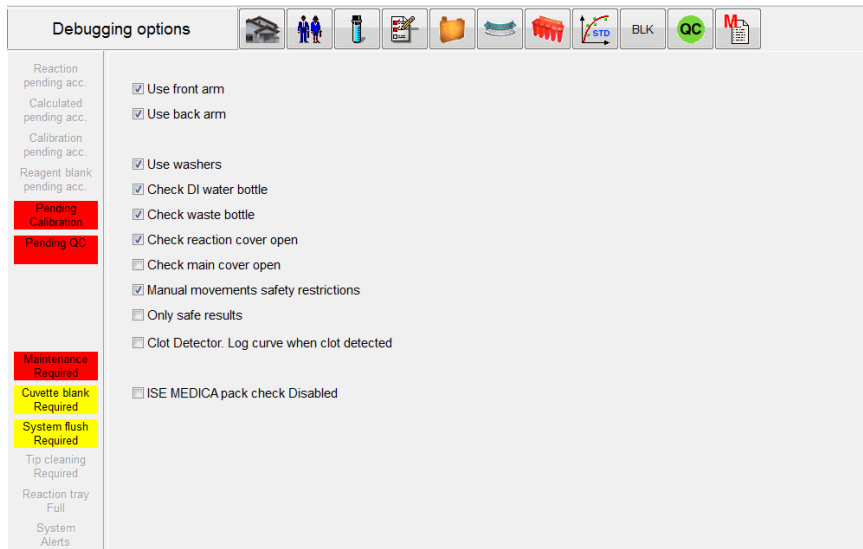


FIGURE 14

To minimize down time following parts can be temporary deactivated: front- or back arm and washer. In case the system is connected to a water supply and drain system the sensors for DI water and waste should be deactivated. During routine use the reaction cover check should be activated. If the function “Only safe results” is enabled, test with following flag: “wrong direction”, “initial absorbance limit”, “high consumption”, “correlation coefficient < 0.8” and “unstable ion” can not be accepted.

### 3.2.7 TOOLS



#### 3.2.7.1 Translator

Translator operates on the language selected in Software parameters.

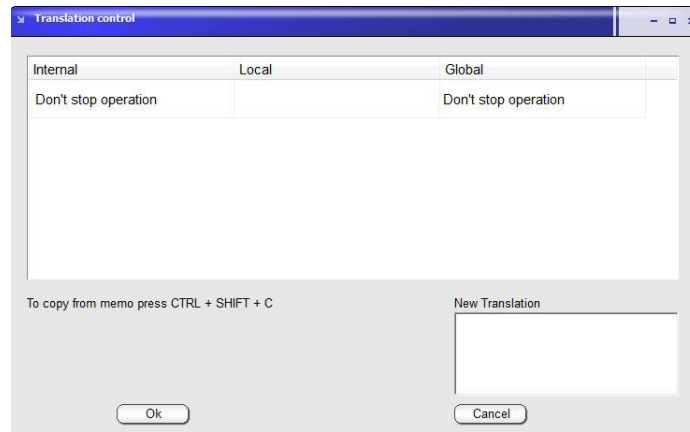
There are two basic ways of translating: translation control and dictionary.

##### Translation Control

To translate by translation control, place mouse pointer on the screen and phrase whose translation must be modified; press keys **Shift + Control + C**. The following screen will open:

**!** Always end any modification  
by pressing the  
**CTRL + SHIFT + C** keys.

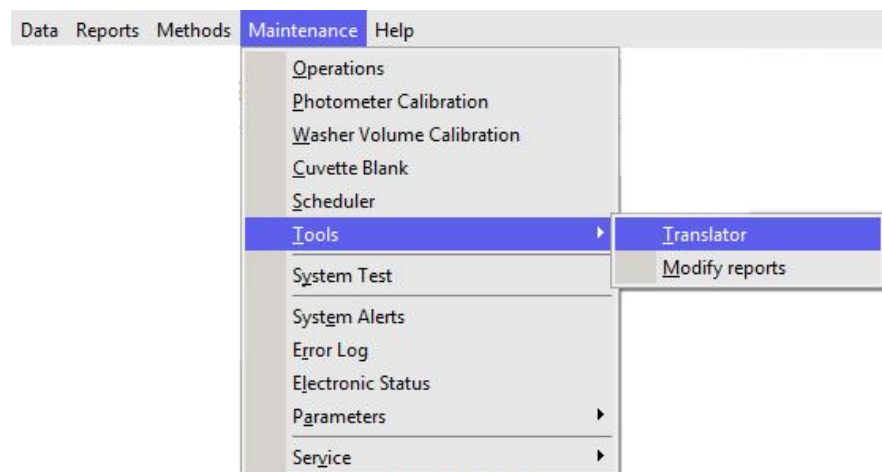
FIGURE 15



Left column is the Instrument Internal Language (mostly English); second and third column are the present translation, if any. A new “Local” translation will modify only the screen the Translation control window has been opened. All modifications done in “Global” will effect all entries in the software. Modifications take effect only when program is restarted. When a given translation is empty, system will use Internal language, no matter which language is selected.

Translation with Dictionary:

FIGURE 16



Translation can be done using the dictionary tool.

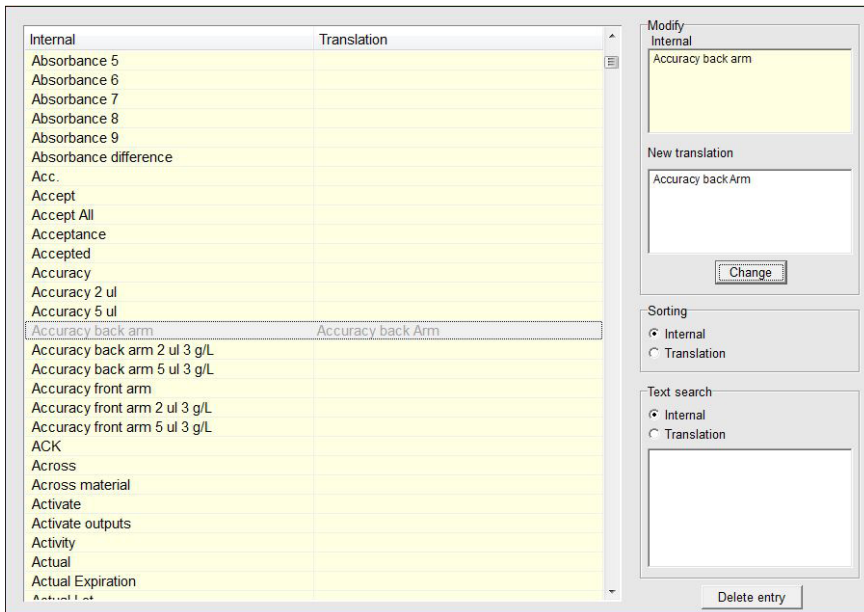


FIGURE 17

When any entry is selected, upper window shows internal text and lower window, the translation, if present. Sorting can be performed by internal or by translation. There is also a built-in search tool. Entries can be deleted by pressing the corresponding button.

### 3.2.7.2 Modify reports

Customized report can be modified in

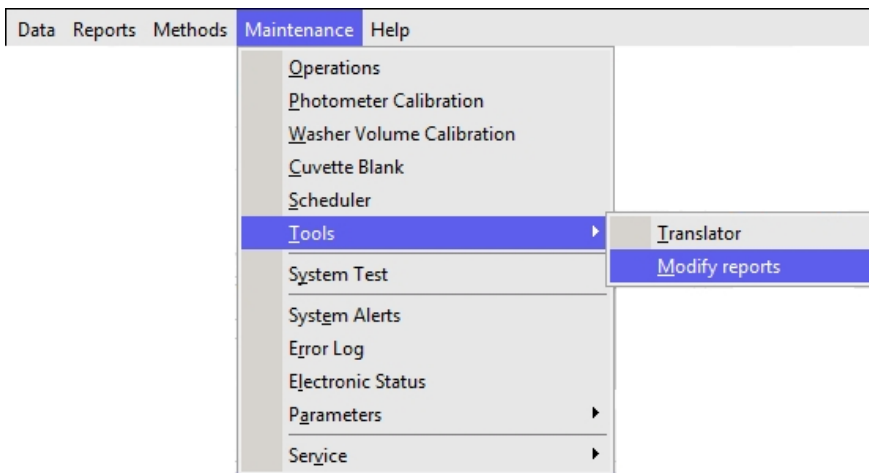
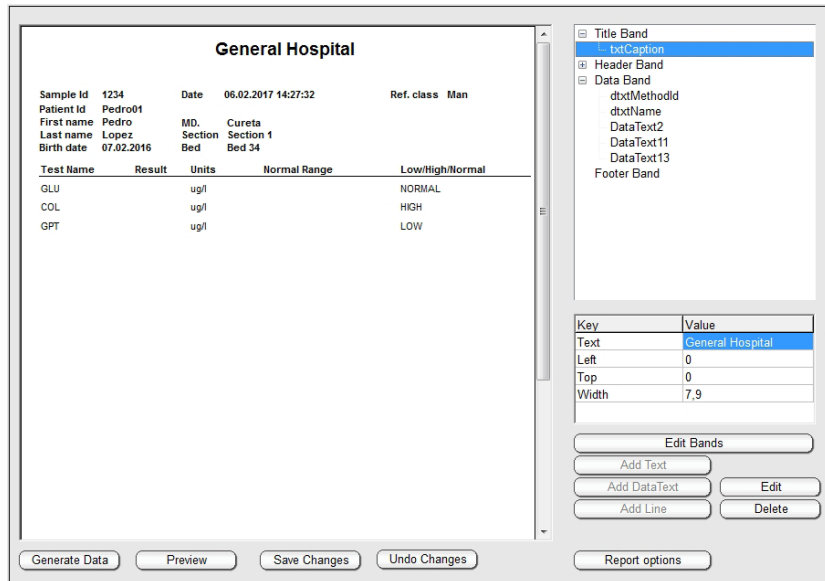


FIGURE 18

At top right there are four bands (title,header, data and footer) which split the report in four separate sections:

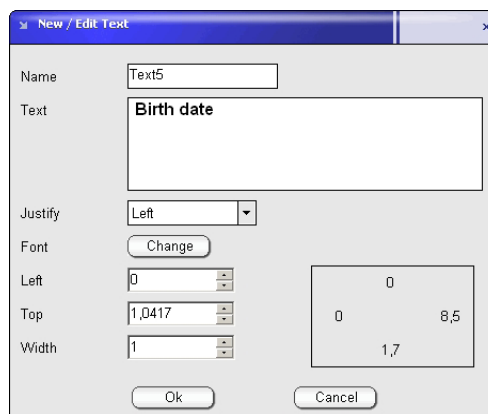
FIGURE 19



To enable or disable a band use the function “Edit Bands”.

By clicking on the + button next to each band a variable number of additional text captions will appear. It is possible to add, edit or delete text, data text or lines for each band. Following screen will be open when the “Add” or “Edit” button is pushed. Text, position, size, font can be modified in this screen.

FIGURE 20



There are two types of fields: **DataText** are the Results written by instrument once a value is printed. They can be moved, eliminated, changed font, etc. but its text is out of operator’s control. There also Report variables that can be added

at this time. They include page numbering date and time in different possible formats.

In the New/Edit Data Text, the Change button allows selecting the desired field to be shown. The **Texts** are the true headers corresponding to the Data texts and can be fully modified by pressing **Change** button:

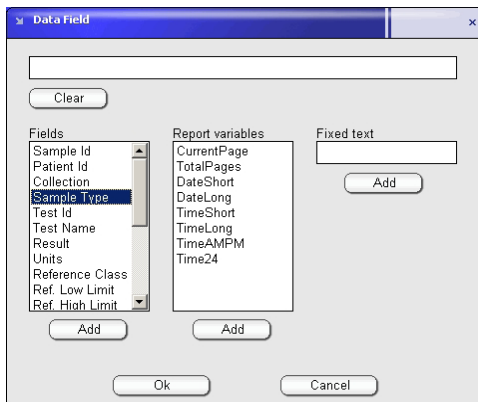


FIGURE 21

As an example, the following report format is included in software. User can experiment on adding, removing and modifying printed fields.

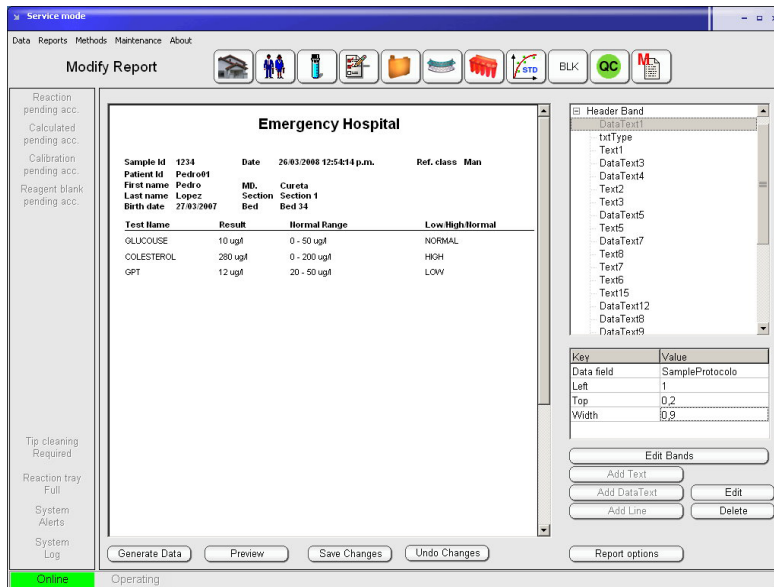


FIGURE 22

### 3.3 Parts of the Instrument

#### 3.3.1 FRONT VIEW

**FIGURE 23**  
Front View

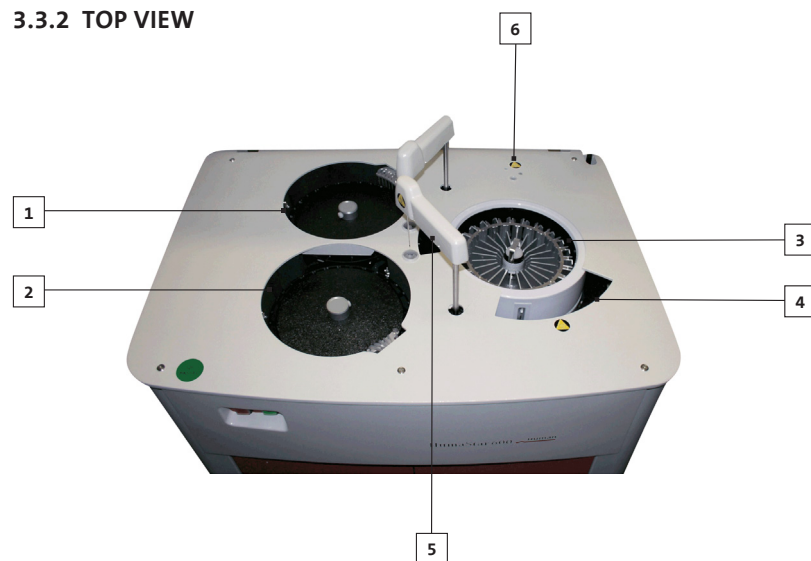
- 1 On/Off switch
- 2 Cooling switch
- 3 Waste tank
- 4 Washing pumps
- 5 Front/Back dilutor
- 6 System Wash Container



#### 3.3.2 TOP VIEW

**FIGURE 24**  
Top view

- 1 Back reaction tray
- 2 Front reaction tray
- 3 Reagent tray
- 4 Sample sectors
- 5 Front/back pipettors
- 6 ISE unit





### 3.3.3 LEFT SIDE

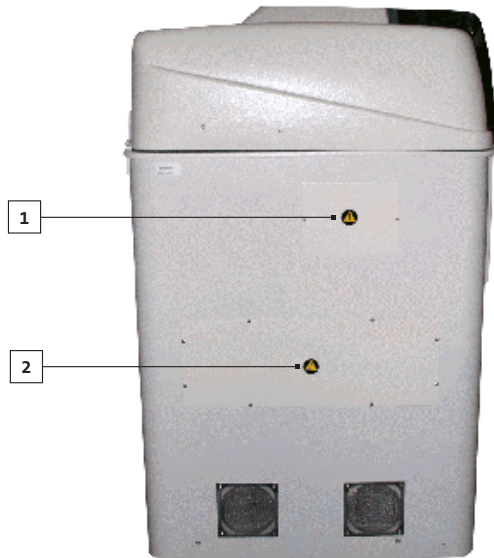


FIGURE 25

- 1 Service door for lamp
- 2 Electronics

### 3.3.4 SAMPLES AND SAMPLE SECTORS

Samples are loaded in a 19 positions sample sector. Continuous processing is possible by the use of different bar-coded sample sectors, which the user can insert or remove from sample tray during analysis. After loading the sector, samples are immediately identified by direct barcode reading together with sample sector type recognition. Five segments can be present simultaneously in the sample tray, while up to 99 external (out of tray) sectors can be handled by the system. STAT samples can be loaded in special high priority sectors to be processed. Standard sector holds 19 bar-coded primary tubes or 19 non bar-coded cups and primary tubes. Special sector for 16 mm external diameter tubes is available upon request.

Sectors can hold:

- micro cup: 0.5 ml
- standard cup: 1.5 ml
- primary tube: 5 ml (13 x 75 mm)  
7 ml (13 x 100 mm)  
10 ml (16 x 100 mm)



FIGURE 26

Standard 19 positions  
bar-coded sector

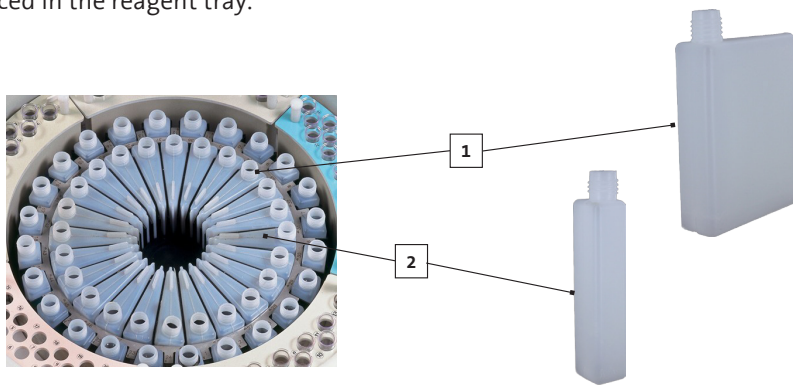
### 3.3.5 REAGENTS

This HumaStar 600 has a cooled reagent tray where 25ml and 70ml containers can be placed. The reagent tray includes integrated barcode reader for 24 inner and 24 outer positions. Sample Diluent as well as cleaning solutions are also placed in the reagent tray.

**FIGURE 27**

Reagent tray and different containers positions

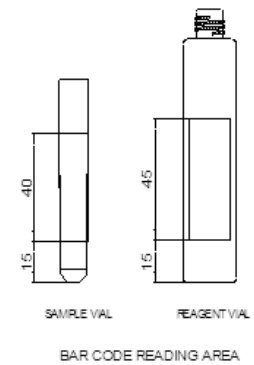
- 1 Inner position
- 2 Outer position



### 3.3.6 BARCODES

Maximum length for samples and reagents barcodes, length is up to 20 alphanumeric characters. For details on labeling position, see figure (Data expressed in mm).

Available codes for both sample barcodes or reagent barcodes, are Code 128 (NCCLS recommended), UPC/EAN, Code 39, PARAF, Tri-Optic, 2 of 5 Codes, Codabar, Code 93, Code 11, MSI Plessey and Telepen.



### 3.3.7 CUVETTES

Samples and reagents are dispensed into a multiple cuvette strip. Each strip has 5 cuvettes. Reaction trays hold 16 cuvettes strips each, having the system a total of 160 cuvettes.

**FIGURE 28**

Cuvettes strips



### 3.4 Software functions overview

The software offers complete functionality to control the instrument and monitor the overall operation which includes: samples and patients management, control reagents, program tests, calibration of methods, perform QC tasks, reactions follow up, statistic on results, among others.

#### 3.4.1 LEVELS OF ACCESS

System has different levels of access depending of the type of user:

- Normal user
- Power user
- Supervisor
- Service

Select in main menu:

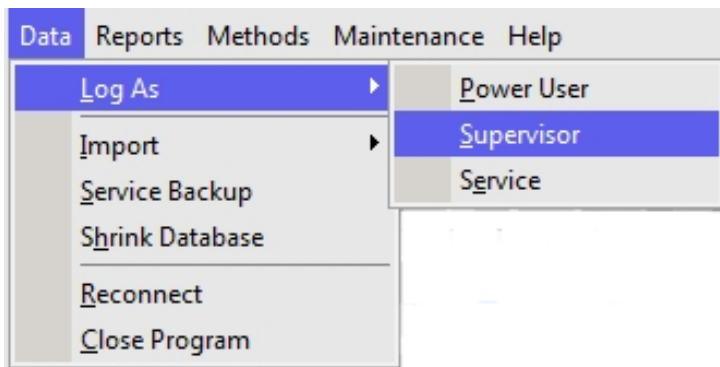


FIGURE 29

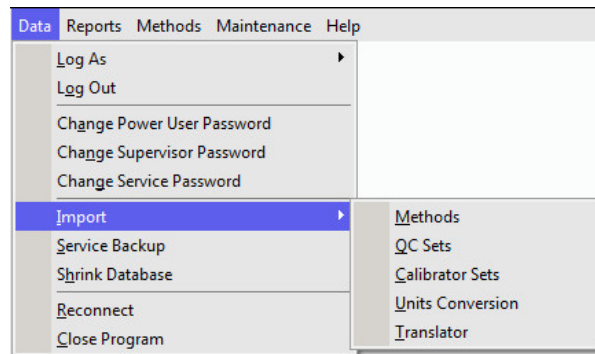
Select Power User, Supervisor or Service and introduce corresponding Password.

Normal User is the default operator, which can only operate the system. Power User can define control sets and calibration sets. Several actions described in the present manual will be available to Supervisor only. They will be indicated with the symbol:



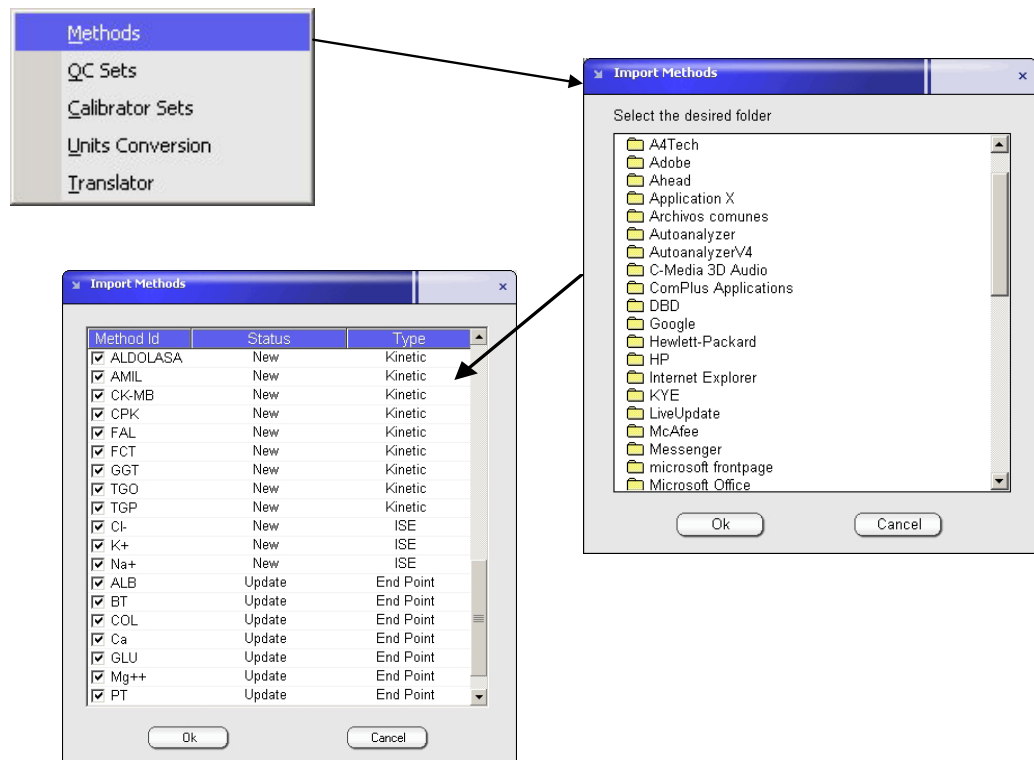
### 3.4.2 DATA MENU

FIGURE 30



Import: Methods, QC Sets, Calibration Sets, Units Conversions and Translator information can be imported.

FIGURE 31



Service Backup: creates a instrument image for service puposes.  
Reconnect: restarts the instrument hardware operation.

3.4.3 MAIN SCREEN

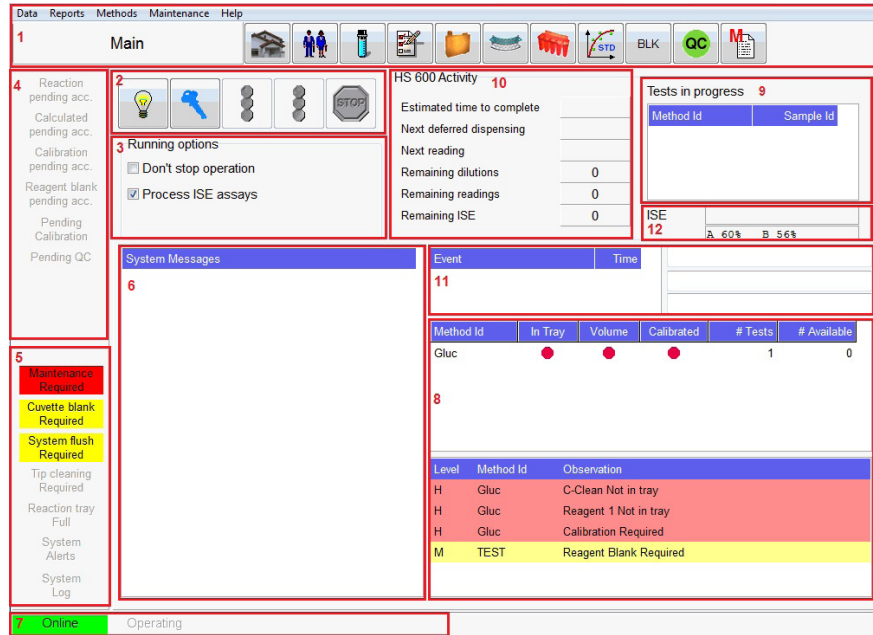


FIGURE 32

Main Screen






- 1 Menu & Quick keys
- 2 Control bar
- 3 Running options
- 4 Operator request
- 5 System information
- 6 System messages
- 7 Transmission and operating status
- 8 Calibration and reagent status
- 9 Tests in progress
- 10 Current activities
- 11 Eventlog
- 12 ISE eventlog

Main screen combines the information required for instrument operation, allowing user to check for instrument status and intervention (when required) at a glance.

1. **Quick keys menu** provide direct access to the major program functions.





|  |   |
|--|---|
|  | <b>Main</b><br>review the information about current run.  |
|  | <b>Patients</b><br>set demographic data and relevant information.                               |
|  | <b>Samples</b><br>define and order chemistry, ISE, coagulation and calculated tests.            |
|  | <b>Tests</b><br>review pending reactions and analysis results.                                  |
|  | <b>Reagent tray</b><br>graphically insert or remove reagents in tray.                           |
|  | <b>Sample tray</b><br>load new samples and graphically insert or remove sample sectors in tray. |

TABLE 3

|   |  |
|---|--|
|  | <b>Reactions</b><br>graphically review cuvette usage and change cuvettes.                      |
|  | <b>Calibrations</b><br>request or browse pending acceptance, historic and in use calibrations. |
|  | <b>Blanks</b><br>definition, review and acceptance of reagent blanks.                          |
|  | <b>Quality Control</b><br>request or browse QC and handle statistical functions.               |
|  | <b>Methods</b><br>browse and edit definitions of methods.                                      |

2. **Control bar** gives control over mayor automatic routine operation.

TABLE 4

|   |   |
|---|---|
|  | <b>Initialize</b><br>initialize all instrument units to home positions.                                     |
|  | <b>Start</b><br>begin the routine operation.  |
|  | <b>Stop</b><br>stop the routine operation.  |
|  | <b>Suspend and restart dilutions.</b><br>Allows to momentarily stopping dilutions for sample and STAT load. |

3. **Running options** can be selected by operator according requirements which depend on the moment and opportunity.

**Non-stop operation:** when this option is selected, the automatic cycle does not finish and after sample process instrument is in stand-by condition. This option is recommended when additional samples for processing are expected soon. For daily work end, deselect the option.

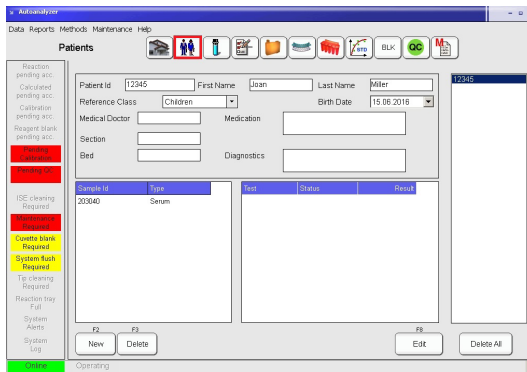
**Process ISE assays:** disable if ISE samples are not expected for the day. This option will not be shown if ISE module is not enabled.

**Process Coagulation assays:** disable if coagulation samples are not expected for the day. This option will not be shown, if coagulation assays are not enabled.

4. **Operation request bar** provides actions requested from instrument to complete some operation such as confirmation of calibrations, confirmation on sample results outside reference class limits, etc.
5. **System information** indicates the status of the system such as maintenance tasks, system alerts and system logs.
6. **System messages** registers most relevant notes and warnings the instrument operation can generate such as running out of sample and reagent or qc results out of range.
7. **Transmission and operating status** displays communication condition between the computer and the instrument (Connecting, Online or Offline and Operating) phase of operation (pre automatic, automatic and post automatic) and LIS communication status.
8. **Calibration and reagent status** shows required reagent volumes to accomplish the processing of the on-tray samples as well as reagent availability. With right click in mouse, options about operations are shown. In addition Information on missing or expired reagents or calibrations are included.
9. **Test in progress** provide the list of pending tests.
10. **Current activity and summary** contain relevant information about the estimated time to complete the analysis, in progress, tests, next dispensing / reading operation and remaining readings and dispenses as well as approximate time of completion. The ISE status is displayed including reagent pack content.
11. **Eventlog** views the current operation status and the details (initialization, warming up, photometer calibration, cuvette check, cuvette blank, clot calibration, cuvette washing, tip cleaning, system flush, intensive cuvette cleaning and intensive washer cleaning).
12. **ISE eventlog** views the current operation status of ISE (calibration, cleaning and sample analysis) and the content of the reagent pack in percentage.

### 3.4.4 QUICK KEY MENUS

FIGURE 33



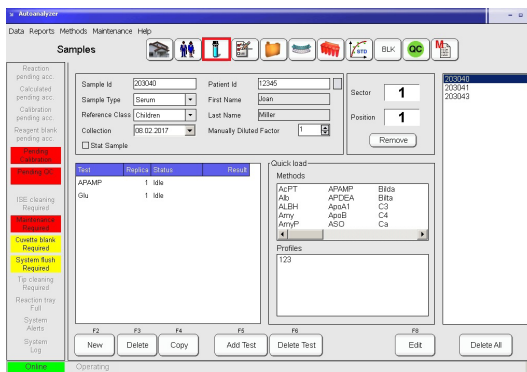
#### Patients Menu:

Data such as patient name, sample type, MD, diagnostic can be included. Also, the assignment of samples to each patient is performed.

For calculated methods, if more than one sample is involved, all must be assigned to the patient.

The patients window can also be accessed directly from samples window.

FIGURE 34



#### Samples Menu:

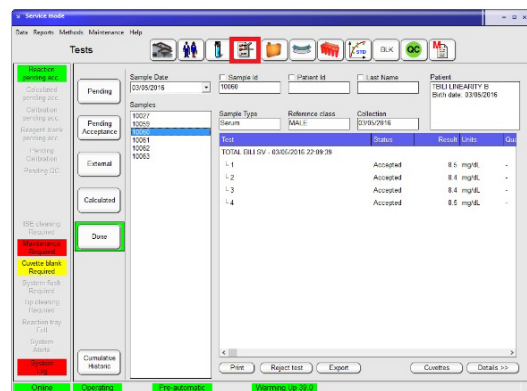
Data from samples are added to this identification screen: Id, type, collection date.

Also, tests and number of replicates are incorporated.

This load can be performed method by method or with the aid quick load and Profile screens.

Patients can be defined with button located to the left of Patient Id.

FIGURE 35



#### Tests Menu:

In this menu flagged and calculated results can be validated and/or repeated.

Test results can be printed or exported.

Data storage of sample is unlimited.

External results can be imported, to complete reports and calculated methods.



**Reagent Tray Menu:**

From main menu it is possible to access the reagent tray programming to place or remove reagent or solutions.

The second reagent of a given double reagent method will be marked with a dot. Slide mouse over a reagent on the tray to obtain details on the right panel regarding reagent usage, available volume and pending reactions.

Alternative views on reagents and calibration status are available. Click apply to place vials in the tray.

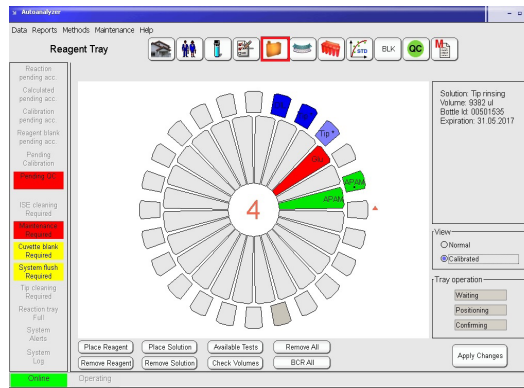


FIGURE 36

**Sample Tray Menu:**

A sample tray consists of five sectors 19 samples each.

User can prepare and load additional sectors while instrument is operating. Primary tubes (light edging) and secondary cups (bold edging) are available. Indication of colors: green - patient, orange - calibrator and purple - QC. Position strikethrough - no test requisition.

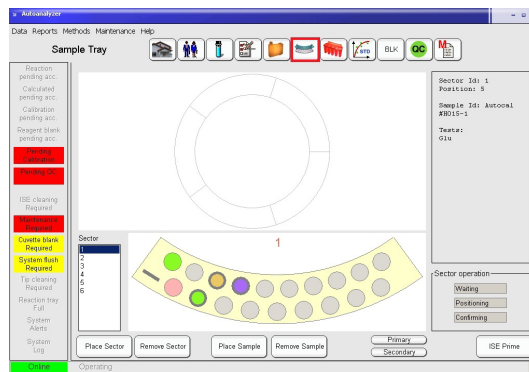


FIGURE 37

**Reaction Tray Menu:**

Two buttons may be used to force a manual wash of the cuvettes or assert the replacement with new ones.

When this operation is performed motors are disengaged for easier operation and reconnected when done.

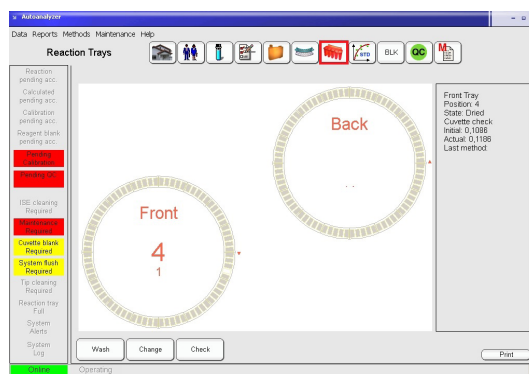
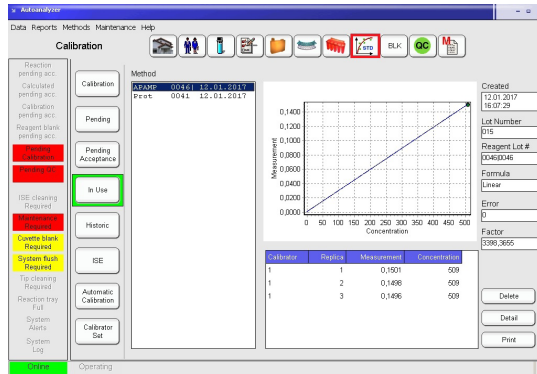


FIGURE 38

FIGURE 39

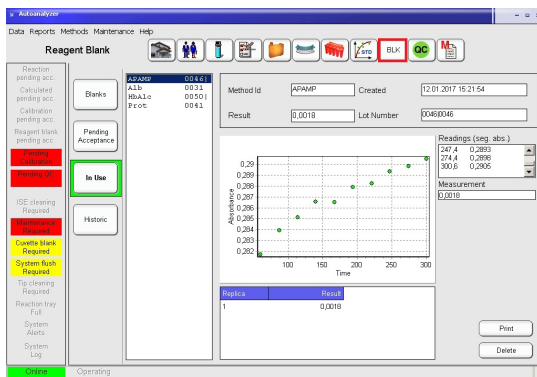
**Calibration Menu:**

Calibrations (single and multi-point) can be defined, performed and requested in this menu.

A calibration set is a group of data defining tests, standard solutions and concentrations, allowing any combination of multi-point and multi-calibrators.

Once defined, user can confirm pending acceptance and browse in use or historic calibrations.

FIGURE 40

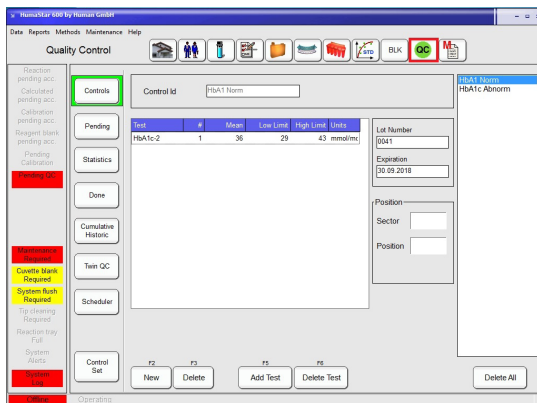
**Reagent Blank Menu:**

Reagent blanks can be programmed in this menu.

If they are within the automatic set up limits, they can be viewed and validated.

Historical results can be viewed and assessed in order to help reagent performance troubleshooting.

FIGURE 41



**Quality Control Menu:** QC material can be defined, performed, requested and validated in this menu.

Levy-Jennings plot and Westgard multi-rules are integrated to facilitate QC analysis.

Twin QC is designed to relate high and low controls and get an accurate statistical picture.

Scheduler is designed to program controls at pre-set dates.

**Method Definition Menu:**  
 New methods for the open channels can be set up by the supervisor. For the closed channels the limits and reference classes can be set.

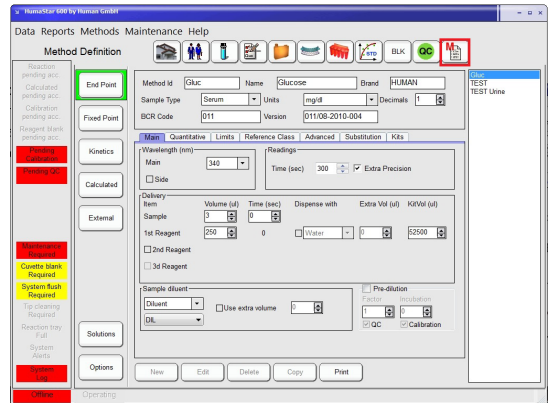


FIGURE 42



## 4 GET READY FOR OPERATION

Complete all the steps pointed out in the preceding chapter before continuing. After verifying correct voltage settings, connect instrument and computer to mains. The suggested startup sequence is:

Turn on instrument by pressing the red button on the front (see Figure 23).

Turn printer on.

Turn monitor on.

Turn computer on.

Turn reagent cooling system on by pressing green button lateral on the front panel.

Once operating system is ready, activate the desktop's program icon to open the HumaStar 600 program.

Accept the startup offered by the program, wait until operation finishes and checks there are no visible warning messages on the screen. Otherwise, refer to the troubleshooting chapter in this manual (see chapter 9 "Troubleshooting").

**!** Do not change the computer date or time during operation. The current operation will be aborted and all in-progress reactions will be lost.

### 4.1 Automatic operation

Load of method definitions, samples, analysis, profiles, etc. will be described in detail in the next chapters. Here, the automatic measuring procedure will outlined.

Once samples and reagents are loaded, main window will show pending analysis, present and required reagents, and any other flagged condition. If one or more samples are not listed, verify that samples are already positioned in sample tray and have been assigned.

**!** Pending samples are shown when samples are loaded on tray and tray is already positioned in instrument.



Press the startup (key) button.

The system conditions will be tested (system wash solution, Diluent, clot detector, drain, pump tubing, syringes and blocks cycles). If any failure is detected, a warning will be issued at this time. Additional warning messages will be issued if maintenance procedures have not been performed, if reagent blanks and calibrations are not valid and reagent volumes are too low or missing.

There are three cycles (shown in the transmission and operating status):

- Pre-automatic
- Automatic
- Post-automatic

Indication of operation in progress is shown in the screen in green color.

**Pre-automatic** cycle includes initialization, warming up and cuvette testing. System stops if more than 15 cuvettes are dirty in any tray and a warning is issued.

No new sample entries are allowed in this period. A warning is issued if cooling system is off or defective.

**Automatic cycle** includes reagent testing, integrity check, test analysis and calculations. Also printouts can be generated in this period.

**Post-automatic** includes cuvette washing, probe cleaning and conditioning and remaining printout.

If “Non Stop operation” has been selected, instrument remains idle until new samples are introduced or the check box gets deselected.

#### **4.1.1 CLOT DETECTOR**

System counts with two clot detectors, one in each probe. They operate based on a differential pressure principle.

Clot detector is installed in

***Maintenance > Service > Parameters > Instrumentals > Others***

Detectors automatically calibrated when automatic cycle starts. Several working conditions can be adjusted. They are defined in section 3.2.6.1:

***Maintenance > Parameters > General***

and modified with Supervisor privileges.

Operation of clot detectors can be enabled or disabled; if clot is detected, then sample can be repeated or not.

The clot condition will be posted in the details of the sample result.

If sample is discarded, it will continue as in process and a message will be shown in the window of messages in main menu. Clot detector version is posted in the ErrorsLog.txt file.

## 5 ROUTINE TASKS

### 5.1 Reagents

#### 5.1.1 REAGENT TRAY



To inspect the onboard reagents press the **Reagent Tray** Menu button. The reagents tray window is displayed showing a graphical representation of the actual distribution of reagents in the tray.

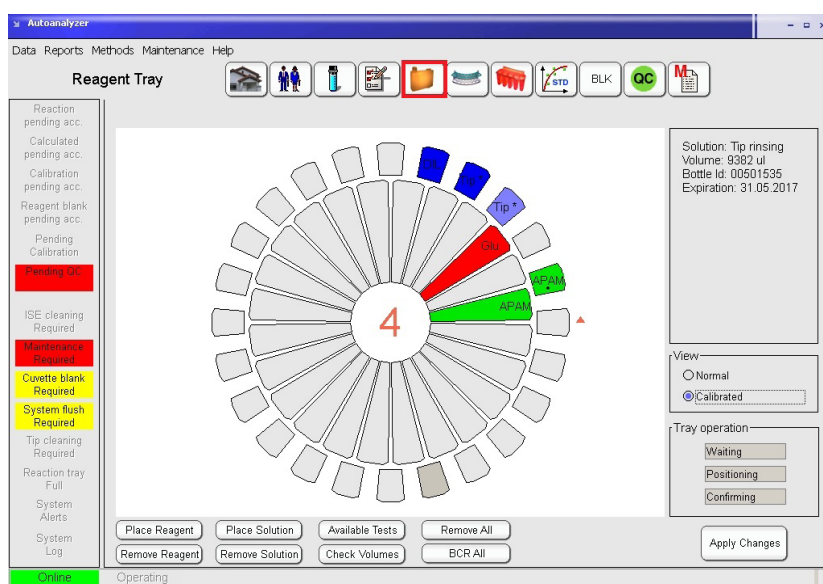


FIGURE 43

**!** After the placing or removing reagents as described below, user should press **Apply Changes** to start the positioning sequence for reagent placement/removal.

To up date the view, read the barcode labels or assign the reagents manually.

Each bottle shows the first four letters of its method name. When two or more method names start with the same four letters an asterisk (\*) is shown for both. One dot under the name indicates second reagent (R2), 2 points a third reagent (3).

Detailed information of each reagent bottle is displayed in the right panel just pointing with the mouse to the desired position. A reagent can belong to one or more methods. Information includes:

- Method name
- Reagent number
- Lot number
- Bottle number
- Expiration date
- Available test number
- Available volume
- Pending tests
- Date reagent was placed onboard
- Expired date

It can be defined more than one vial for each method.


If the first bottle is empty, the system will automatically switch to the next bottle. The + in the right field indicates the second bottle. Multiple lots of the same reagent can also be placed simultaneously on the reagent tray and separately calibrated.

The colors used for positions allow to easily distinguish as follows:

TABLE 5

|                   |   |
|-------------------|---|
| <b>Green</b>      | Reagent in position and in use (programmed samples)                           |
| <b>Red</b>        | Reagent not calibrated (only shown if "Calibrated" on the "View" is selected) |
| <b>Blue</b>       | Tip cleaning solutions, diluents and C-Clean                                  |
| <b>Yellow</b>     | Reagent not in use  |
| <b>Light Gray</b> | Free position   |
| <b>Dark Gray</b>  | Reagent not in use or removed   |

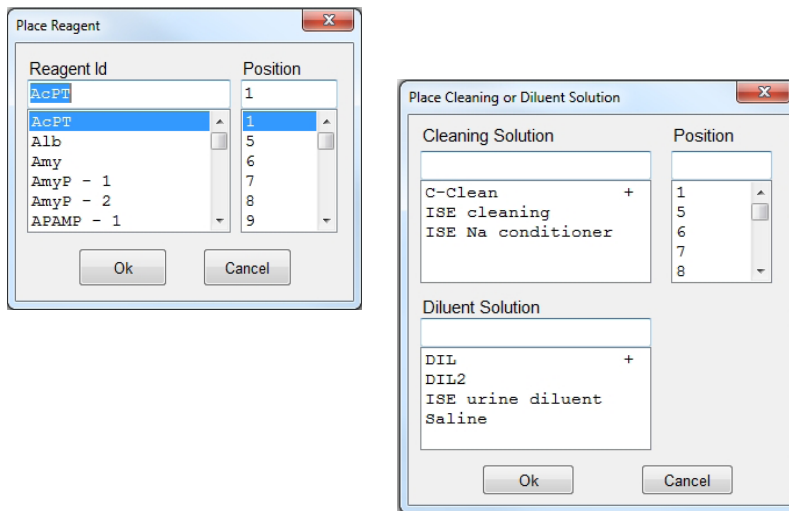
### 5.1.2 LOADING BARCODED REAGENTS, DILUENT AND CLEANING SOLUTIONS

 Barcoded reagents, diluent and cleaning solutions can be randomly placed into the reagent tray and will be checked and identified by pressing **BCR All** button. To load barcoded reagents on a single position right click a suitable position and pick **Change & BCR check**. A question mark symbol will be issued at the specified position. Place the reagent on this position and press **Apply Changes** to start the positioning sequence for reagent loading into the tray and barcode reading. When a reagent is not included in the table of methods in use but its code detected as located in the tray, it is automatically included in the methods in use. If a reagent barcode label cannot be read a window will open and the barcode can be insert manually.



### 5.1.3 LOADING NON BARCODED REAGENTS AND SOLUTIONS

To define a reagent into the tray, press **Place Reagent**, then from the window select the reagent and desired position and press **Ok** or press **Cancel** or **Esc** key to abort. Defined reagent position will exhibit dark gray color.



! After the placing or removing reagents as described below, press **Apply Changes** to start the positioning sequence for vial placement/removal.

FIGURE 44

To define a diluent or cleaning solution into the tray press **Place Solution** and proceed as above.

It is also possible to click on a position in the reagent tray display, right click and pick **Place Reagent**, **Place Diluent Solution**, **Place Cleaning Solution** options. Select the desired reagent or solution and press **Ok** when done or **Cancel** to abort.

Press **Apply Changes** and the reagent tray turn the selected position to the bottle insert/remove area. Message will be: **Put CREA-1 in position 2.**

Open the cover, insert the reagent or solution bottle and close the cover. Then press **Ok** to confirm the operation. If more than one reagent is loaded, several messages will be shown in sequence.

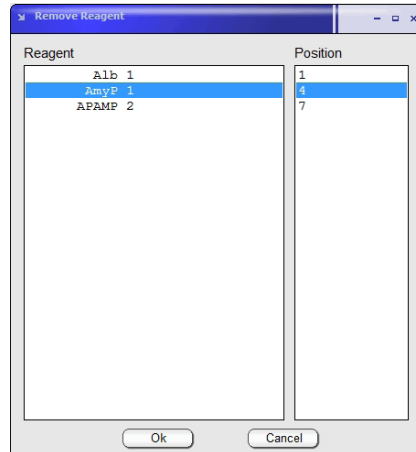
! If **Apply Changes** is not pressed, selected positions will remain in dark gray color and cannot be used.

### 5.1.4 REMOVING REAGENTS AND SOLUTIONS

To remove reagent/s from the tray, press **Remove Reagent**, select one or more reagent/s or desired positions. Press **Ok** when done or **Cancel** to abort.

FIGURE 45

! Before starting automatic procedure, volumes can be tested. Press **Check Volumes** button for this operation.



To remove a diluent or cleaning solution from the tray press **Remove Solution**, select or type in the desired solution and proceed as above.

To select more than one item from the list, press and hold **Ctrl** key while selecting the new item. To select a range of items, select the first item, then press and hold **Shift** key while selecting the last item. Alternatively for extended selection use the mouse by click and drag.

☞ Alternatively, to remove a reagent or solution from a particular position in the tray, right click the desired position and pick **Remove** option.

⌚ Press **Apply Changes** and the Reagent tray drive the selected position/s to the bottle insert/remove area. Following window appears:

FIGURE 46



☞ Open the cover, take out the reagent or solution bottles and close the cover. Press **Ok** button to confirm the operation.

Same procedure must be followed for removing diluents and solutions.

### 5.1.5 REFILLING REAGENT BOTTLES (ONLY FOR OPEN CHANNELS)

When pressing right button over a given reagent, menu will include a Refill option. Once the **Apply Changes** button is pressed, tray will move in the desired reagent position.

Several reagent vials can be refilled with this procedure: when **Apply Changes** is pressed tray will sequentially position in all the defined refilling reagents. The dilution restart is automatic.

### 5.1.6 METHOD ASSIGNMENT TO TRAYS

Methods can be assigned for processing either in the front or back reaction tray. Only those methods defined as Methods in Use can be assigned to a tray. Default assignment is to the front tray if not otherwise specified at the application protocol of the method.

For tray assignment, follow:

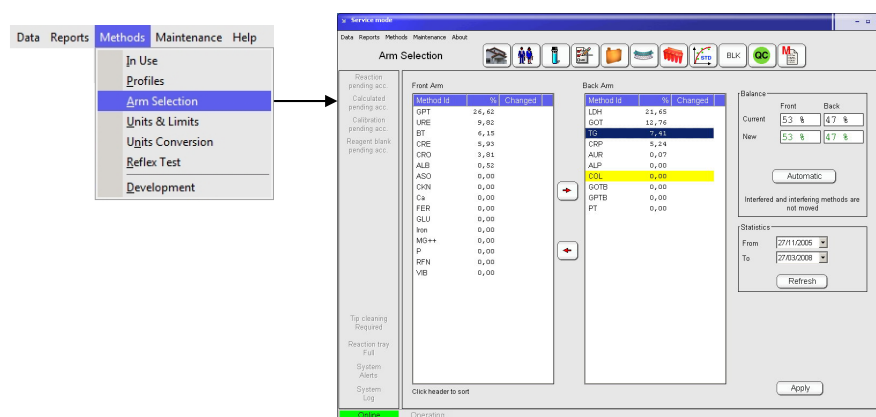


FIGURE 47

There is a unique feature consisting an automatic reassignment of methods to the trays, according historic statistics and with the criterion of minimum total analysis time. Automatic reassignment does not include interfering or interfered methods. Interfered methods are posted in red color and consecutive use is avoided either at the arm or cuvette sequence level. To apply it, first **Refresh** the desired period for statistical analysis and then press the **Automatic** button. Moved methods will be indicated with an X. Press **Apply** to save the changes.

## 5.2 Samples

Samples can be loaded directly or associated to patients. Tests and calculated methods (which including a chemistry measurement) are assigned to samples

and not directly to patients. External methods and calculated methods are always assigned to patients.

### 5.2.1 WORKING WITH PATIENTS



To create or work with patients press the **Patient** Menu button.

FIGURE 48

1. Patient Information are shown at the Patient report. All fields are automatically confirmed and only the Patient Id is mandatory. Patient Id cannot be modified, only option is to delete the entry.
2. Display of all defined patients.
3. Display of all samples defined for the patient Id shown above.
4. Display of all tests defined for the patient Id shown above.

### 5.2.2 DEFINING SAMPLE DATA AND TESTS



To define new samples or request tests for a given sample, press the **Samples** Menu button.

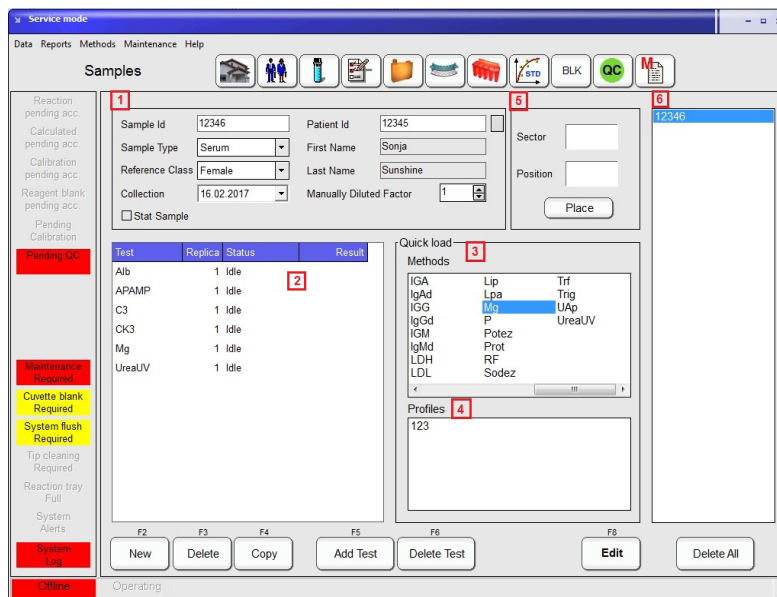



FIGURE 49

In this menu it is possible to add, edit, delete and copy samples and corresponding tests.

1. Sample Information including Id, type, reference class, collection date, priority (STAT), Patient Id (can be predefined in the patient menu or generated directly using the the button next to the patient Id field) and the manual dilution factor.
2. Programmed tests for the sample Id shown above.
3. Quick load to add tests.
4. Predefined profiles to add multiple tests. To define a profile see section 5.9.1.
5. Samples can be placed immediately on a sector.
6. Display of all programmed samples.

 To edit information for an already defined sample, select the sample from the list on the right and press **Edit** button, add or change information and then press **Browse** (depending on the mode the function of the F8 button is Edit or Browse) to switch to navigation mode.

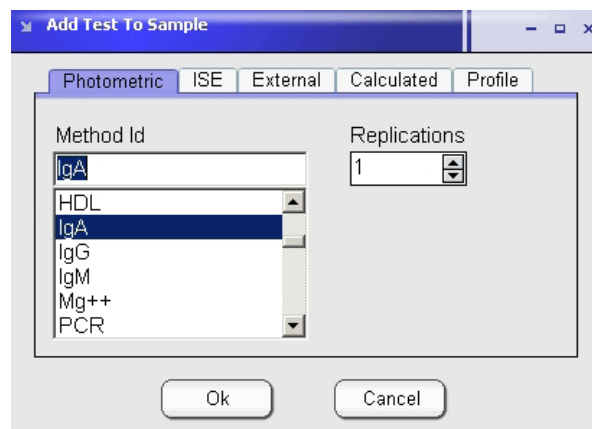
Press **New** button to define a new sample. Sample ID number will be counted up automatically, but can also be changed manually. To generate a patient di-

rectly from this side, press the button located right of the patient Id. Input all necessary information and then press **Browse** to switch to the navigation mode.

To request new tests for a sample, first select the sample from the list on the right window and then either:

Press **Add Test** to choose a single test from the window (shown below).

FIGURE 50



Alternatively, double click on the desired methods or profiles, in **Quick load** panel or **Profiles** panel.

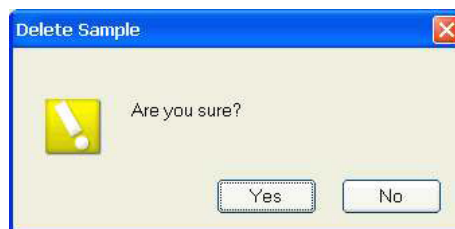
When replicates of the same sample are required, use the **Add Test** button or press method ID several times in the Quick load window.

Without requiring its introduction in a STAT sector, any sample can be defined as STAT at all times by checking **Stat Sample**. This will enhance its priority over other samples. To place samples directly in a sector, select the sample number and press **Place**. A new window opens, select the sector and position number and press **Ok** to save or **Cancel** to abort.

### 5.2.3 REMOVING A SAMPLE

To remove a sample from the list press **Delete** :


FIGURE 51



Then press **Yes** to confirm or **No** to abort.

**Delete All** button will remove all samples from the window on the right side.

#### 5.2.4 REMOVING TESTS

 To remove tests from a sample, first select the sample from the list on the right window and then press **Delete Test**. Select tests to remove from the list.

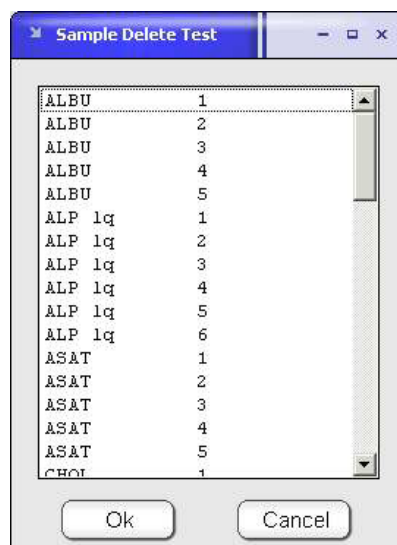


FIGURE 52

Press **Ok** when done or **Cancel** to abort.

#### 5.2.5 COPY DATA

New samples can be generated by copying data from another sample. Press **Copy** button and a window will open for selection of number of replicates. New ID numbers will be correlative to the original one. If alphabetic characters are present in the ID, new digits are added.

## 5.2.6 LOADING SAMPLES

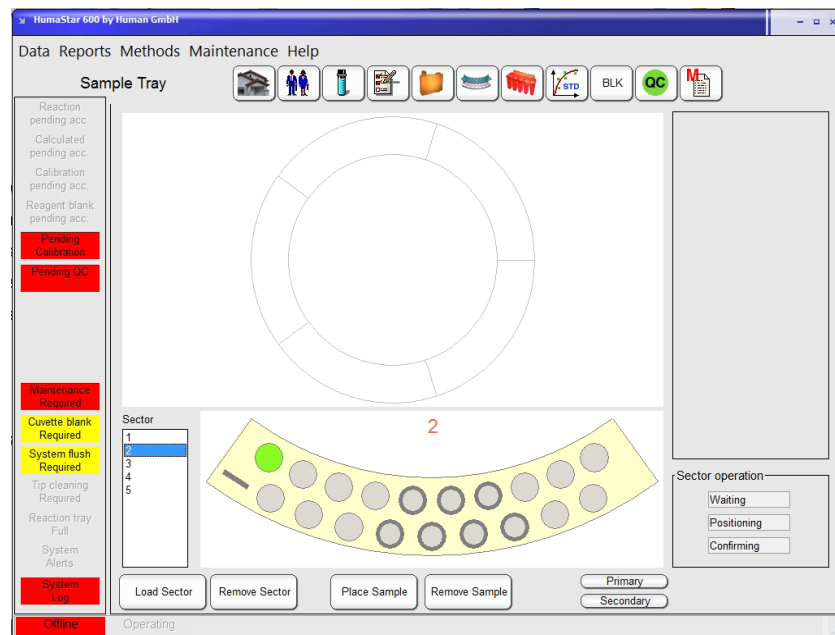


To manage samples and sample sectors press the **Sample Tray** button.

FIGURE 53

! Use **Secondary** to set a given sector for use with cups vials, press **Primary** to return to primary vial mode or press right mouse button on a given position.

! Use **Data > Log as supervisor** and then **Maintenance > Parameters > Use** to set the secondary sample vial section before using this option.



☞ To review a sample sector content, just point the mouse over the desired sector on the tray. The complete list of samples will be displayed on the right panel.

☞ To review a sector which is not placed in the tray, select the sector number on the left side. The selected sector will be displayed in the lower panel. Point the mouse over the desired position and all sample/test information will be displayed on the right panel.

Data are also available for printout in

**Reports > Input Tray**

### 5.2.6.1 Loading barcoded samples

Be sure that barcode reading is enabled. Access for enabling is in

**Maintenance > Parameters > Software** (Supervisor only)






Once a sector is loaded, codes are read for all samples, if samples are not present, reader will reach code located on the rear of sector. Its reading is equivalent to “sample is not present”.


When Sample ID is recognized, vial position will match defined sample. If sample ID was not defined in advance, new sample entry is created with recognized ID but user will have to complete data.

If one or more codes are not read by the barcode, samples still can be measured; a window will open containing the detected non coded samples and operator can accept or reject them.

#### 5.2.6.2 Loading non barcoded samples, calibrators and controls


 To place a sample, calibrator or control in a sector, first click in a sector ID from the list of sectors and then press **Place Sample**. Chose from *Samples, Calibrators* or *Controls* tab, and select the desired sample and sector position. Press **Place** to confirm selection, and then repeat the operation or press **Exit** to return. Press **Place All** to fill all the free positions in sector with available samples in a sequential order.


#### 5.2.7 REMOVING A SAMPLE


 To remove samples from a sector, first click on a sector ID from the list of sectors and then press **Remove Sample**. Select the sample IDs or sector positions to remove. Press **Ok** when done or **Cancel** to abort.


To select more than one item from the list, press and hold **Ctrl** key while selecting the new item. To select a range of items, select the first item, then press and hold **Shift** key while selecting the last item. Alternatively, to extend the selection use the mouse to click and drag.


#### 5.2.8 PLACING A SECTOR ON THE TRAY


 To place a sector on the tray, first click on a sector ID from the sectors list, then press **Load Sector**.

 The sample tray drives the first available sector position to the sample sector insertion/removal area.

 Remove the old sector if any, place the new one.


 **Note that non barcoded samples have to be assigned to a sector position before inserted to a sample tray.**


 **To allow samples to be added or removed the sector must be out of the tray. No samples can be added to or removed from an on-tray sector.**


 **When sectors are coded for BCR reading, it is not necessary to declare the sector number, user will be prompted to put any sector in the first available position. If sector is not coded user must specify any non-used sector position.**

When done press **Ok** button to confirm the operation. Don't press Ok before you have physically placed the sector in the sample tray. Right after the Ok click, the tray will start to move.

### 5.2.9 REMOVING A SECTOR

 To remove a sector from the tray, first click on the sector ID from the list of sectors or click on an on-tray sector, and then press **Remove Sector** .

 The sample tray drives the selected sector position to the sample sector insertion/removal area.

 Remove the sector.

When done press **Ok** button to confirm the operation.

### 5.2.10 LOADING A STAT

A STAT sample placed on a STAT sector or STAT position has priority over all other samples. For sector definition, select

**Data > Log as supervisor** and then **Maintenance > Parameters > Sector definition**

Define a new sector with a number and assign the STAT condition. Be sure that number is not already defined in the column to the right. If so, first delete definition and then re-enter new definition, including STAT condition. To give a sample a STAT priority on a routine sector, select the **Stat Sample** option in the Sample menu.

**5.2.11 REPORTS**

From the menu bar, select **Reports**.

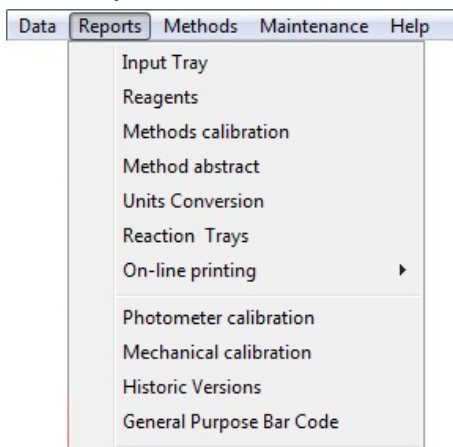


FIGURE 54

**Following reports can be generated:**

|                                 |   |
|---------------------------------|---|
| <b>Input Tray</b>               | Data of samples introduced by operator or through LIS.  |
| <b>Reagents</b>                 | Reagents and solutions already present in tray. Only those used by the programmed samples are shown.                                      |
| <b>Method calibration</b>       | The lot number (only when barcoded reagents are used), the status of active calibrations and the calibration formula used are shown.      |
| <b>Method abstract</b>          | All methods are listed classified by type. Data include ID, name and version.   |
| <b>Unit Conversion</b>          | All defined unit conversions are displayed.   |
| <b>Reaction Trays</b>           | Cuvette status for all cuvettes in both trays. Data include condition, initial and actual air blank.                                      |
| <b>Online printing</b>          | When laser or inkjet printers are used, samples are printed once batch is ready. This option allows printing even if batch is incomplete. |
| <b>Photometer calibration</b>   | Data from the last performed photometer calibration.  |
| <b>Mechanical Calibration</b>   | Values of the last mechanical calibration for trays, arm, washers, etc.   |
| <b>Historic versions</b>        | History of the method versions loaded on the system. See section 6.1.   |
| <b>General Purpose Bar Code</b> | One page of general purpose barcodes will be displayed and can be printed.  |
| <b>Usage</b>                    | Report of used reagents, run tests or used bottles can be calculated for a defined periode can be displayed, printed or exported.         |

TABLE 6

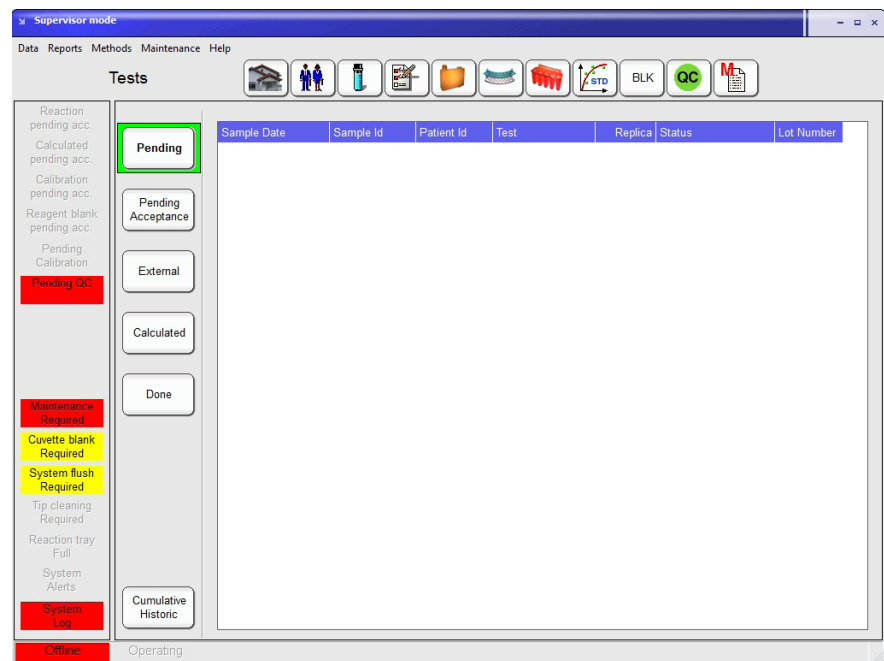
In all options, the **Report Preview** window is open. To print, press the corresponding icon or select **File > Print**.

### 5.3 Test results



To inspect sample results press the **Test** Menu button.


FIGURE 55



In the Tests Menu following options are available:

| TABLE 7 | Option                     | Description  |
|---------|----------------------------|--|
|         | <b>Pending</b>             | All non-processed and in-process tests are shown.  |
|         | <b>Pending Acceptance</b>  | Results can be accepted, rejected or a rerun can be triggered (normal or diluted).   |
|         | <b>External</b>            | Values from another source, usually required for a calculated test, can be insert.   |
|         | <b>Calculated</b>          | Calculated results can be checked and confirmed.   |
|         | <b>Done</b>                | Results can be reviewed sorted by last name, sample Id or patient Id. Using the Print button results and patient reports can be printed (refer to section 5.3.3). Press Export and results will be exported to a csv file which can be imported to excel. To see the detail information of a result (raw data) select a result and press Detail. |
|         | <b>Cumulative Historic</b> | Results can be stored permanently in folders named with year and month. The button Cuvettes is for Service use only.   |


### 5.3.1 ACCEPTANCE OF RESULTS

 To confirm the result for a given test open the **Pending Acceptance** Menu, then select the desired sample test from the list and then press **Accept**. Press **Reject** to reject the test result. To reprocess the reaction just press **Rerun** or **Diluted Replicate** if additional dilution could be useful for confirmation of result. A dilution factor can be introduced.

### 5.3.2 REFLEX TESTS

Reflex tests are those automatically launched when a given test is out of determined limits. Condition for the reflex test launch can be relative to fixed values or to a reference class.

### 5.3.3 PRINTOUT OF RESULTS

 Results can be printed in different ways and operator has full control on the display of the results. This is a post run operation and is not related to the online printing controlled by

*Maintenance > Parameter > Software.*

Press the **Print** button from Test Menu Done screen and following submenu opens:

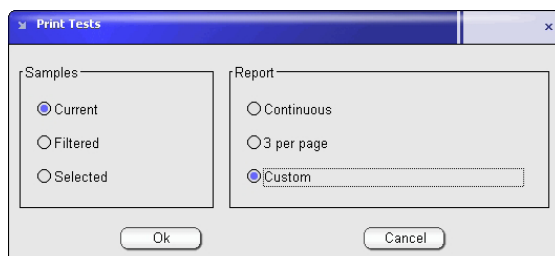



FIGURE 56

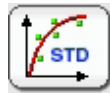
 Printing can be performed on all samples, some filtered or selected. Selection can be made by pressing **Ctrl** Key while pointer is pressed on selected samples. A range is selected by pressing mouse on the first and then pressing **Shift** key and pointing to the last one of the desired ranges.

There are three types of reports: Continuous - samples are printed out one after the other; 3 per page - according a fixed report format; Custom - according report made by use of the Report Format Generator, refer to section 3.2.7.2 Modify reports.

### 5.3.4 CUVETTE

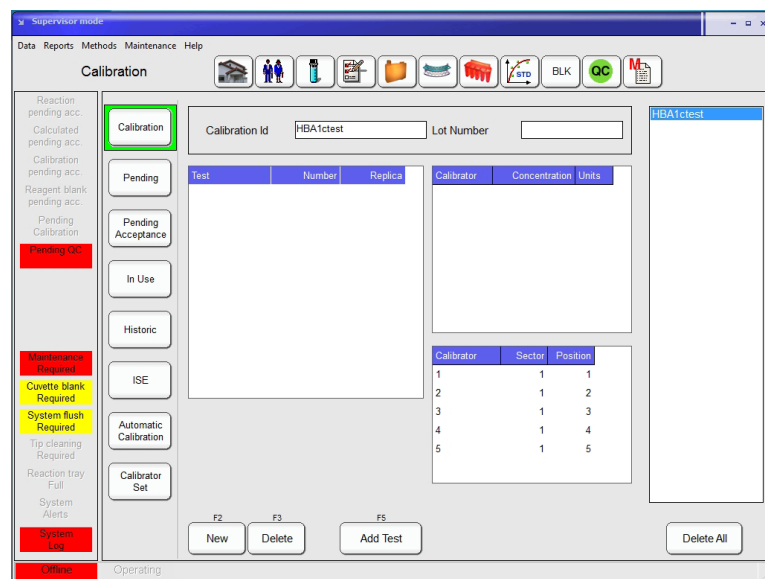
Report use for service engineers only.

## 5.4 Calibration



To enter a new calibration or define a calibrator set, press **Calibration** Menu button.

FIGURE 57



In the Calibration Menu following options are available:

TABLE 8

|                              |   |
|------------------------------|---|
| <b>Calibration</b>           | New calibrations can be requested or requested calibrations can be deleted.   |
| <b>Pending</b>               | All non-processed and in-process calibrations are shown.  |
| <b>Pending Acceptance</b>    | In case the manual acceptance is programmed and/or the reaction is flagged the calibration has to be manually accepted. Use the reject function to rerun the calibration and Detail to see the reaction measurements.   |
| <b>In Use</b>                | Actual calibrations can be reviewed, deleted or printed   |
| <b>Historic</b>              | Former calibrations can be reviewed or reactivated for the actual use. The calibration is shown in the In Use screen with a warning and the results should be flagged (function "Check Re-used Calibration" in <b>Maintenance&gt;Parameters&gt;Software&gt;General</b> has to be enabled). WARNING this function must be cautiously used, never mix calibrations and actual reagent lots. |
| <b>ISE</b>                   | Actual and historic ISE calibrations can be reviewed.   |
| <b>Automatic calibration</b> | Calibrator Lot numbers can be defined for the use in the next automatic calibration, this can be in advance.  |
| <b>Calibrator Set</b>        | Single and Multipoint calibrators can be set up, modified or deleted.   |

### 5.4.1 CALIBRATOR SETS



Calibrators for single or mutipoint calibrations are defined for methods. This calibrators can contain a single- or multiple methods. Following information are included in the sets: calibrator set Id, Lot number, number of vials, tests, mean values and automatic dilution if necessary. Once the calibrator sets are created it is easy to request calibrations in routine. Only Supervisor and Power user can define a new calibrator set.

#### 5.4.1.1 Defining a calibrator set

Open the **Calibration** Menu and select on the left side the **Calibrator Set** Submenu.

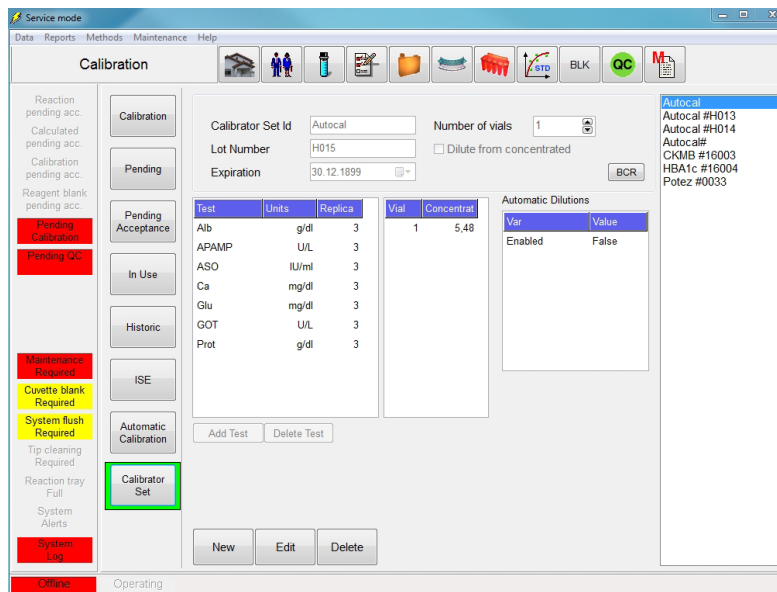



FIGURE 58

 To edit the definition of an already defined calibrator set, first select the calibrator set from the list on the right and then press **Edit**.

To enter or define a new calibrator set, press **New**. Assign a calibrator Set Id and the corresponding lot number of the calibrator. In case of a multipoint calibration insert the number of vials, default it is on 1 for a single point calibration. To add a new test to the calibrator set press **Add Test**.

FIGURE 59

The screenshot shows the 'Add Test to Calibrator' dialog box. It features a 'Method Id' list on the left with 'Alb' selected. Below this is a table with two columns: 'Vial' and 'Concentration', containing one row with values '1' and '5,5'. To the right of the table is the 'Automatic Dilutions' section, which includes an 'Enabled' checkbox, a 'Dilutions #' field set to '3', a 'Serial factor' field set to '2,000', and two more checkboxes: 'Include blank' and 'Include 1:1'. Below this is the 'Vial' section, which contains a table with columns 'Number' and 'Concentration', and a unit field 'g/dl'. The table has one row with values '1', '5,500', and 'g/dl'. An 'Add' button is located below this table. At the bottom right of the dialog, there is a 'Replicas' field set to '3'. 'Ok' and 'Cancel' buttons are positioned at the bottom center of the dialog.


Select the method from the list or type in the method Id. Select the calibrator vial number, concentration and the number of replicates and press **Add**. It is recommended to use at least 2 replicates for each calibration point.

Press **Ok** when done or **Cancel** to abort. For a multi calibrator repeat this steps for each test/method.

To remove a method from the calibrator set, select the test and press **Delete Test**. Once no further modifications are required for the calibrator set, press **Ok** to finish or **Cancel** to abort.

Once tests are loaded in the grid, concentration values can be edited at all times.

#### 5.4.1.2 Removing a calibrator set

 To remove a calibrator set from the list, select the calibrator set from the list on the right and press **Delete**. Press **Yes** to confirm or **No** to abort.

#### 5.4.1.3 Automatic Dilutions

It is possible to dilute a single calibrator for a multi point calibration. When **Add Test** is pressed, the following screen will show up:



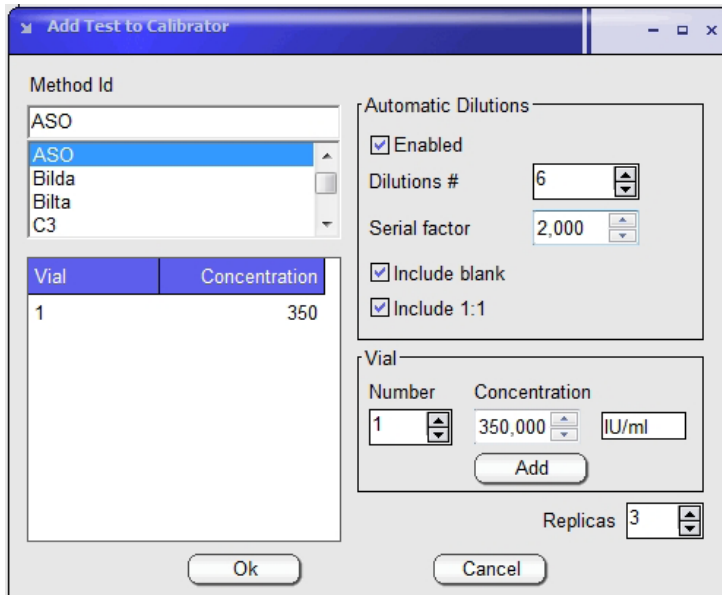


FIGURE 60

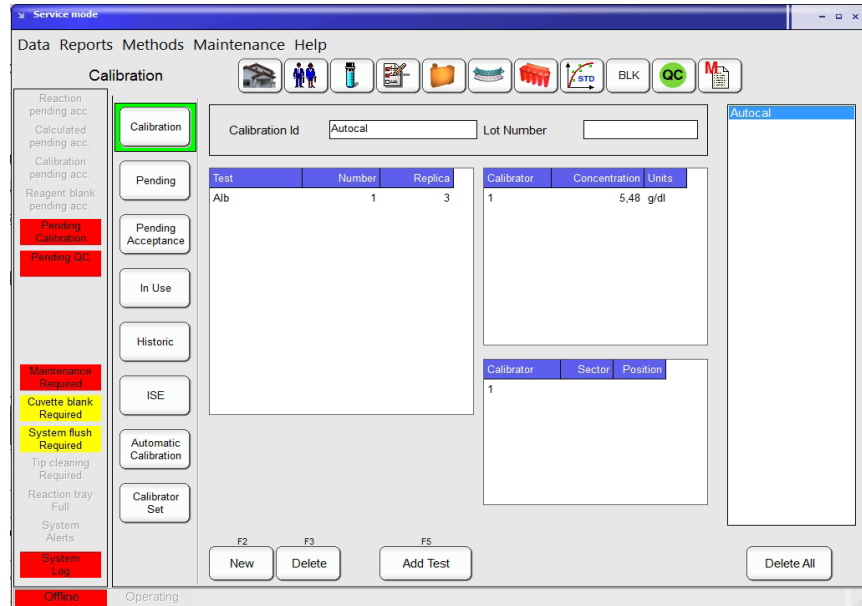
The window for automatic **Dilutions** will show the number of points that integrate the curve. The **Serial factor** indicates the dilution factor: a factor of 2 will define the concentration as 1/2, 1/4, 1/8, etc.; a factor of 3 will define concentrations as 1/3; 1/9; 1/27; etc. The set optionally can include the mother solution (1:1) and the blank. If included, they are within the defined number (i.e. Dilution # of 6 it is 1:1, 1:2, 1:4, 1:8, 1:16 and blank). The concentration of mother solution is defined in the **Vial** sector. A minimum of 2 standards and a maximum of 10 standards are accepted.

**!** The instrument will automatically adjust the number of times this procedure is repeated for completing all requested calibrators and replicates.

#### 5.4.2 REQUESTING A CALIBRATION

Open the **Calibration** Menu and select on the left side the **Calibration** Submenu.

FIGURE 61




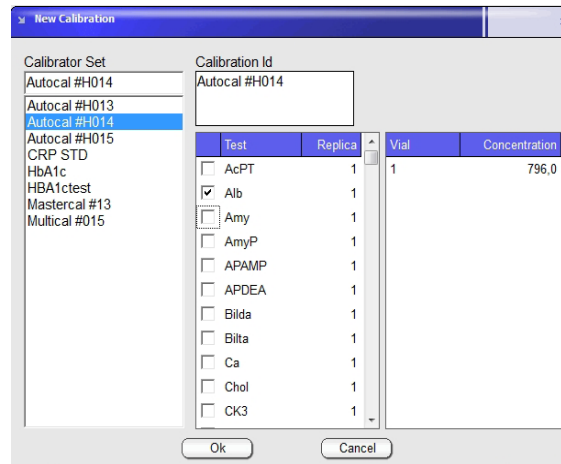
 To request a new calibration based on a calibrator set, press **New**.

FIGURE 62



Select or type in the desired calibrator set. Edit the calibration ID if necessary and check at least one test you want the calibration to take into account.

Press **Ok** when done or **Cancel** to abort.

To request at a later time another method from the calibrator set, select the calibration from the list on the right and press **Add Test**. Check one or more tests you want to add. Define the number of replicates. They can be equal or different for different tests. Press **Ok** when done or **Cancel** to abort.

### 5.4.3 ORDERING A CALIBRATION

To load the calibrator’s cups on the instrument sample tray refer to section 5.2.6.

### 5.4.4 CALIBRATION ACCEPTANCE

Open the **Calibration** Menu and select on the left side the **Pending Acceptance** Submenu. Following window will be displayed:

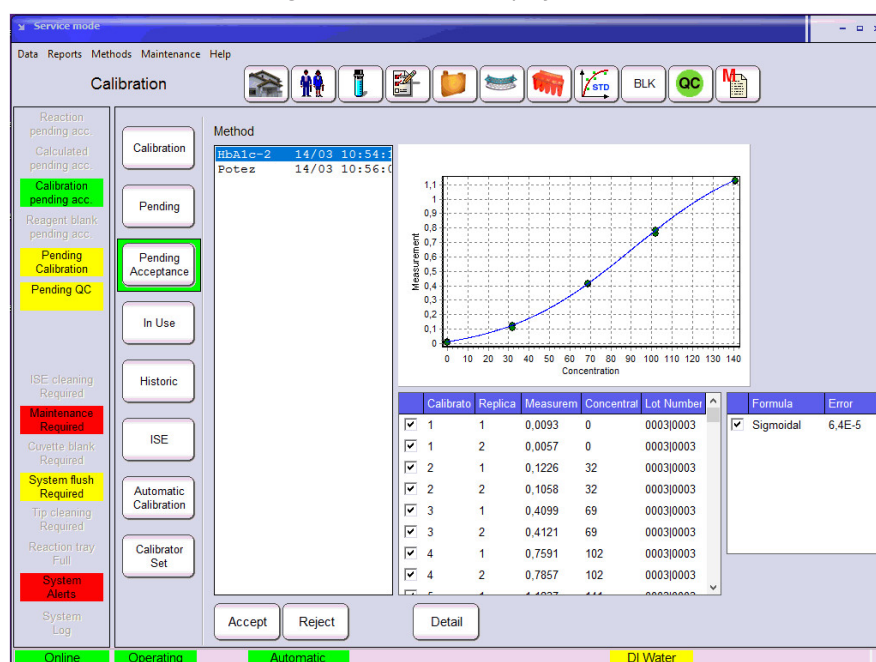


FIGURE 63

To confirm a calibration test result, select the desired method and the calibration curve including replicates will be displayed.

Before acceptance of a calibration individual replicates can be disabled. Unselect the box in front of a replicate which should be excluded from the calibration curve calculation.

Column to the right of each function will show the least squares adjusting value. Select function with minimum value unless some special feature is required. Experiment deselecting one or more standards and observe recalculated values. Press **Accept** once the calibration curve and values are as desired. In this case, at least one value for each vial must be selected.

Press **Reject** to mark the calibration as unusable.

#### 5.4.4.1 Flagged results

Press **Detail** to expand the detailed area for the selected reaction. This panel points out active flags. Results may be flagged if validity limits, duplica-

tion limits or reference class limits and so on are exceeded. Both low and high limits can be set independently (see chapter 6.2.4 for details).

#### 5.4.4.2 Calculations

For the calibration curve calculation following formulas are available:

TABLE 9

|                    |  |
|--------------------|--|
| <b>Linear</b>      | $Abs = Ax + B$   |
| <b>Multilinear</b> | $Cx = C1s + (C2s - C1s) * (Sx - S1s) / (S2s - S1s)$<br>linear interpolation between consecutive standards            |
| <b>Spline</b>      | $C = a * A^3 + b * A^2 + c * A + d$<br>where consecutive 3d degree polynomials joining consecutive data              |
| <b>Sigmoid</b>     | $Abs = L + ((H - L) / (1 + \exp(-(Conc - a) / b)))$<br>where H, L, a and b are automatic adjusting parameters        |
| <b>Logit4</b>      | $Abs = R + (K / (1 + \exp(-(a + b * \ln(Conc))))))$<br>where K, a, b are automatic adjusting parameters              |
| <b>Logit5</b>      | $Abs = R + (K / (1 + \exp(-(a + b * \ln(Conc) + c * Conc))))$<br>where K, a, b, c are automatic adjusting parameters |

Calibration fit parameter is shown in all cases.

If curve is forced to pass through zero, functions logit 4 and logit 5 will diverge because of the logarithm function and will not be shown.

Logit5 requires a minimum of 5 standards; logit4 requires a minimum of 4 standards; sigmoid and multi linear functions require a minimum of 3 standards.

#### 5.4.5 AUTOMATIC CALIBRATION



It is possible to define for each method, which Calibrator Set will be used in the next calibration, once the present one is expired, deleted or a lot number changed. This set can also be “Run in advance” and be ready several hours before the present calibration expires. Open the **Calibration Menu** and select on the left side the **Automatic Calibration** Submenu.

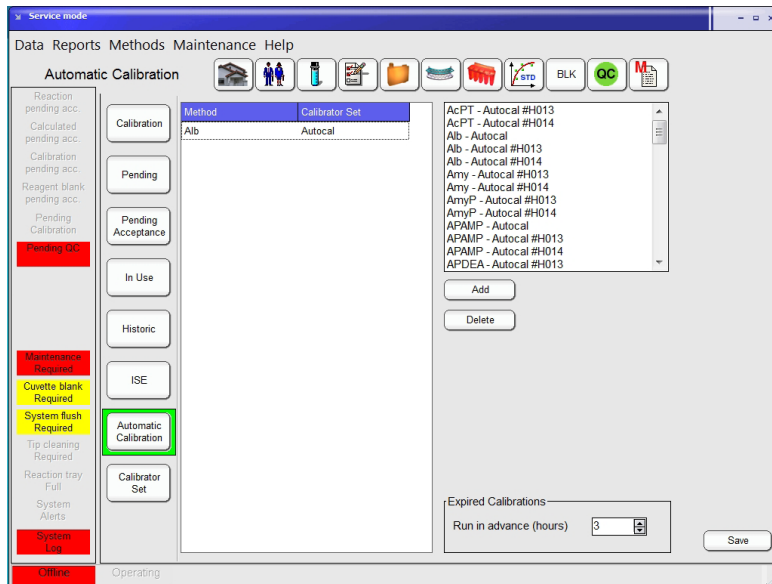


FIGURE 64

Select from the right window the desired Method-Calibration Set combination and press the **Add** button. With the corresponding button the Run in advance interval is also fixed. This interval is checked every 15 minutes when the system is running, it is in the “don’t stop” mode or during start operation.

## 5.5 Reagent Blank



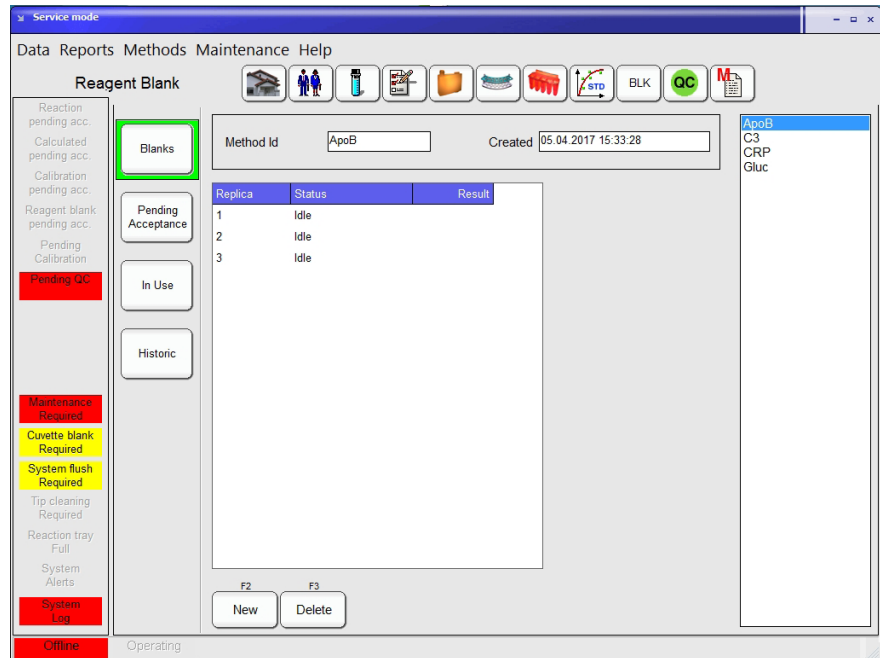
Reagent Blank can be measured in the automatic procedure or directly from the **Reagent Blank** Menu.

When the automatic measurement starts, blanks are requested for the following reasons:

1. No reagent blank available
2. It expired
3. Reagent was removed, refilled or changed
4. A new reagent lot was introduced

In that case, a window opens with the list of required blanks. User can include the number of required replicates.

FIGURE 65



In the **Reagent Blank** Menu following options are available:

- |                           |   |
|---------------------------|---|
| <b>Blanks</b>             | New reagent blank can be requested or requested reagent blanks can be deleted.  |
| <b>Pending Acceptance</b> | In case the manual acceptance is programmed and/or the reaction is flagged the reagent blank has to be manually accepted. When replicates are taken, they can be accepted or reject individually. The final result is the average of all accepted values. Use the reject function to rerun the reagent blank. |
| <b>In Use</b>             | Actual reagent blanks can be reviewed, deleted or printed.  |
| <b>Historic</b>           | Former reagent blanks can be reviewed or printed.   |

To request a reagent blank press the **New** button in the **Blanks** Submenu.

FIGURE 66

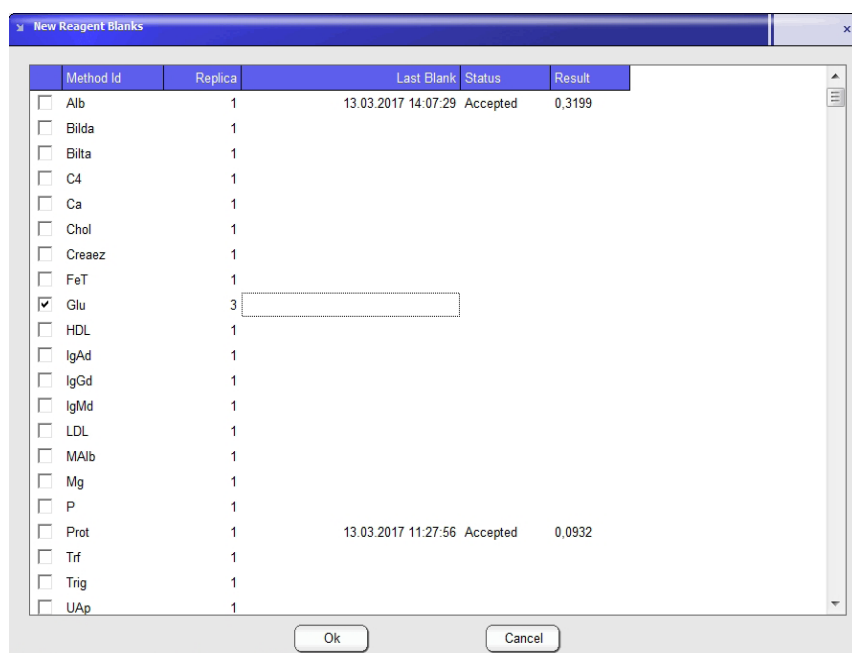


Table shows last measured absorbance and its date. By checking and adding the number of replicates, blanks can be measured.

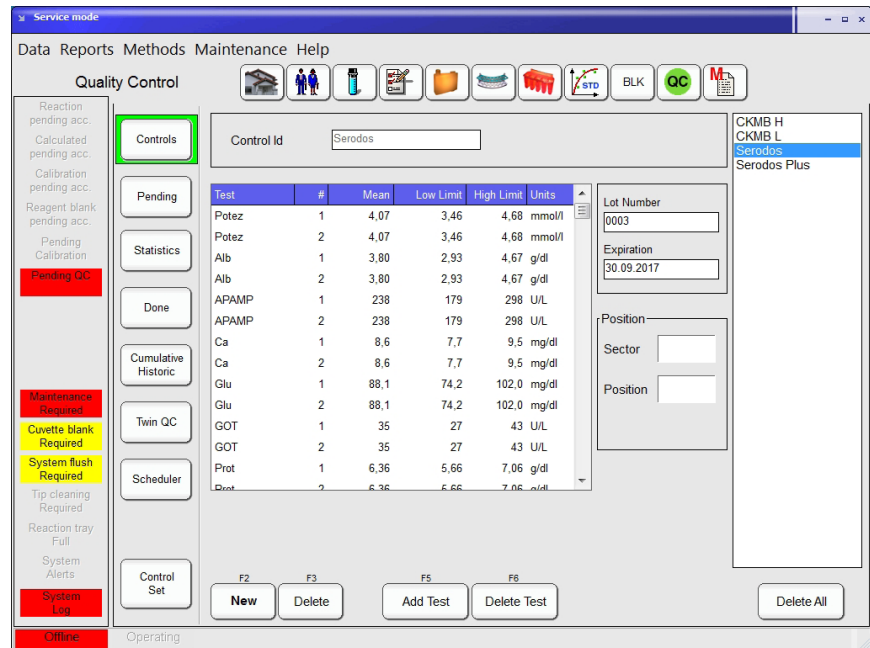
### 5.6 Quality control

Quality control system is based on the use of Control Sets. A control set is a vial of a given brand and lot containing all the desired analytes with their respective admissible ranges. Control sets from different brands and levels can be defined. Once the Control Set is defined, it is daily used by defining a Control and selecting from the set the desired analytes and number of replicates. New Control Sets must be defined when a new lot is available and new admissible ranges are defined.



To add, edit or request a quality control, press the **Quality Control** Menu button.

FIGURE 67



In the Quality Control Menu following options are available:

|                            |   |
|----------------------------|---|
| <b>Controls</b>            | New control for specific tests can be requested or requested controls/tests can be deleted.   |
| <b>Pending</b>             | All non-processed and in-process controls are shown.  |
| <b>Statistics</b>          | A statistic of QC samples of a special period can be displayed or printed.  |
| <b>Done</b>                | Controls measured in a specific time frame can be displayed. Tests can be deleted (only out of the statistics), a rerun can be requested, statistics can be displayed and the results can be printed or exported. |
| <b>Cumulative Historic</b> | Archived QC results can be reviewed.  |
| <b>Twin QC</b>             | Quality control results will be displayed in a Youden Plot.   |
| <b>Scheduler</b>           | QC actions can be programmed in advance for the complete week.  |
| <b>Control Set</b>         | Single and Multi controls can be set up, modified or deleted.   |



5.6.1 CREATING A CONTROL SET



Open the **Quality Control** Menu and select on the left side the **Control Set** Submenu.

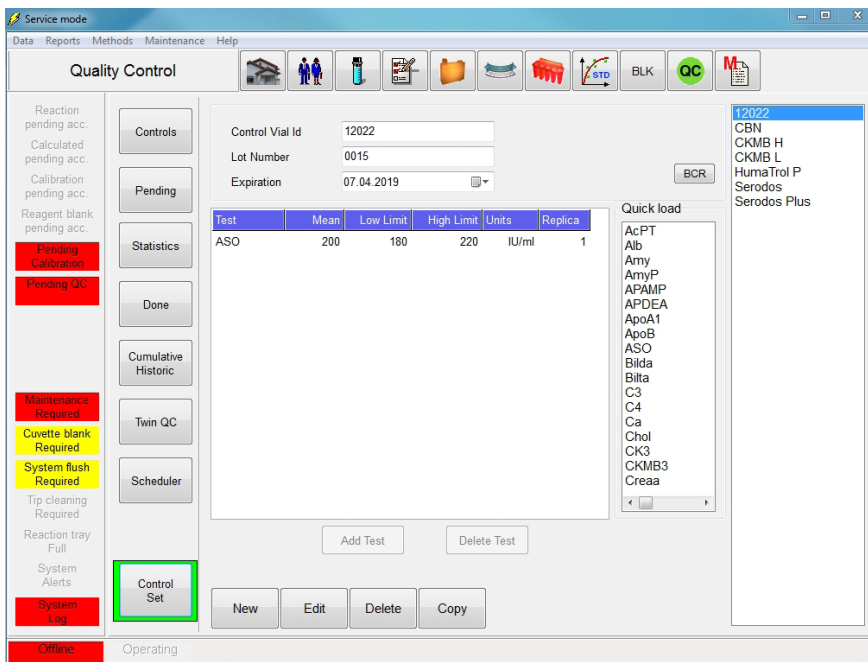


FIGURE 68

To define a new control set, press **New** .

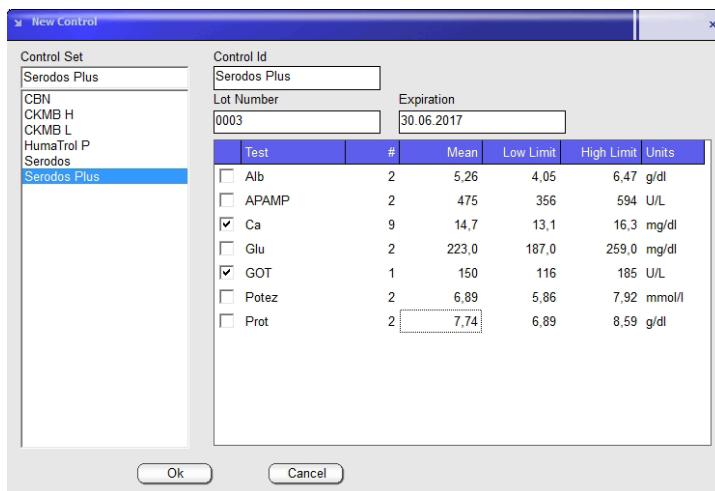


FIGURE 69

Define control set id, introduce lot number and expiration date for traceability purposes and filtering options.


To edit the definition of a already defined control set and select the control set from the list on the right and then press **Edit** .

To add a new test to the control set press **Add Test** and select or type in the method ID. Then type in the concentration range for that method and press **Ok** to add the test or **Cancel** to abort. To remove a method from the control set, press **Delete Test** .

Define the number of default **Replicas** for each test within each control set. This number will be used every time the control set is used or scheduled. Repeat this operation for each required test on the profile. Then press **Ok** to finish or **Cancel** to abort.

Alternatively, double click on the Quick load list to add tests in the control set and type the values in the corresponding fields. Mean values are calculated automatically.

Once tests are loaded in the grid, concentration limits can be edited at all times.

 To remove a control set from the list, first select the control profile from the list on the right and then press **Delete** . Press **Yes** to confirm or **No** to abort. **Delete All** button will remove all control sets.

5.6.2 REQUESTING A CONTROL

Open the **Quality Control** Menu and select on the left side the Submenu **Controls**.

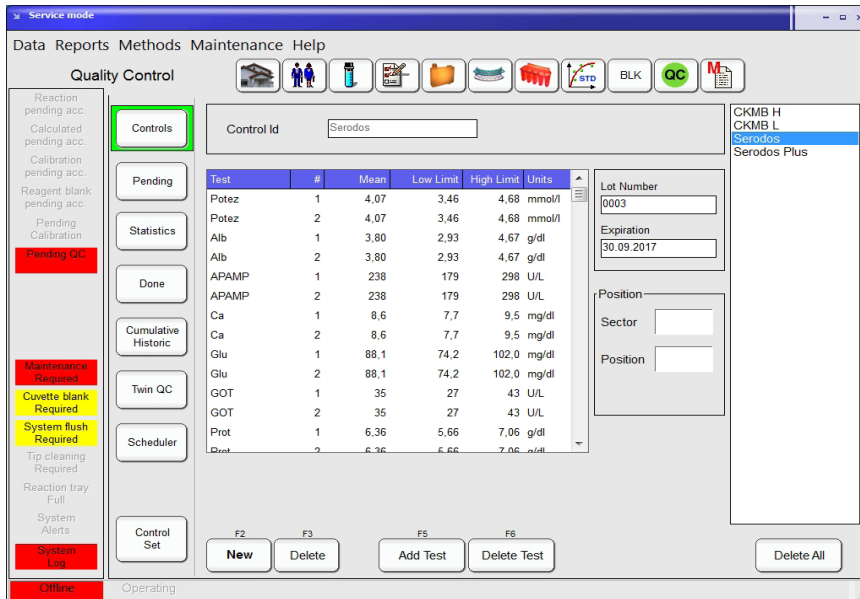


FIGURE 70

To request a control based on a control set press **New**.

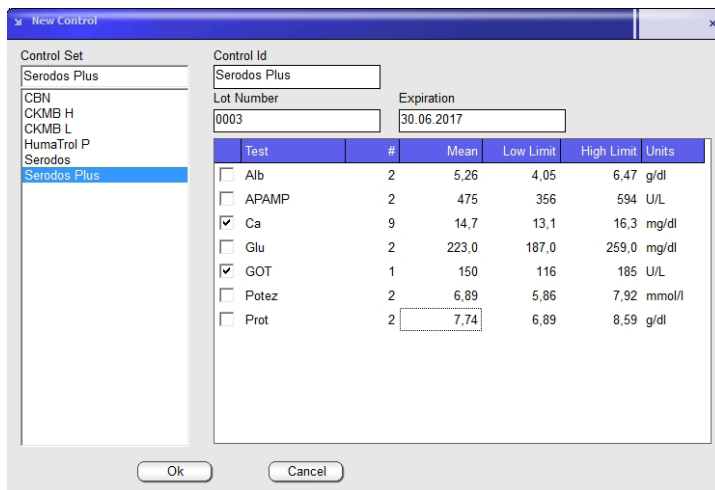


FIGURE 71

Select the desired control set in the list on the left side. Tick at least one box in front of a test name to select them and enter the number of replicates. Replicates can be set individually per test with a maximum value of 10. Push the blue box above in order to select or deselect all tests. Control Id is automatically gen-

erated by using the Control Set Name. This Id can be modified at the moment of generation but not at a later time.

New tests included in the Control Set can be added later using the Control sub-menu: Select the control from the list on the right and press **Add Test** . Check one or more tests that you want to add. Press **Ok** when done or **Cancel** to abort.

To remove a test from the control press **Delete Test**. Select one or more tests from the list. Press **Ok** to confirm or **Cancel** to abort.

### 5.6.3 PROCESSING A CONTROL

Once the control has been requested, load it in a vial and place in the instrument as indicated in 5.2.6.

If the barcode reading procedure is performed and a control set is recognized, it will be associated with any pending action already defined in the scheduler. If not programmed in scheduler, no action will be taken on the control.

Use the **Pending** Submenu tests to review non-processed (idle) or in-progress control tests.

User must consider that test results may stay idle if the system operation runs out of reagent or control sample.

Use the **Cumulative Historic** Submenu to review data already stored in previous runs. They will be organized in directories, where results of each month are automatically stored.

### 5.6.4 PROCESSED CONTROLS

To display processed Controls, open the **Quality Control** Menu and select on the left side the Submenu **Done**.

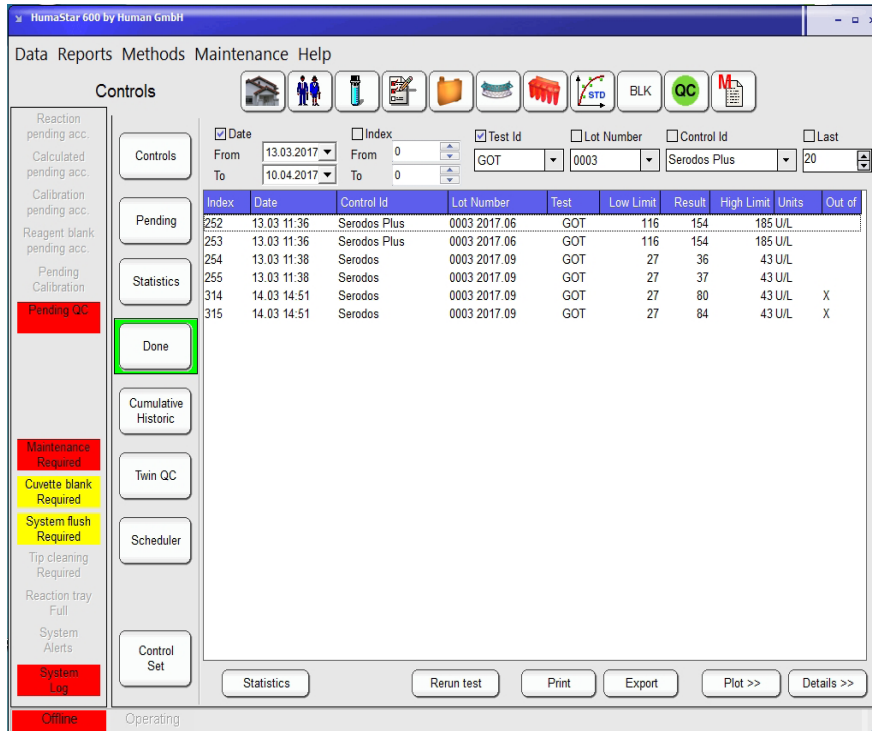


FIGURE 72

In the upper section following filter options are available to display the desired data:

Date (From - To)

Index (From - To)

Test Id

Lot Number

Control Id

Last (number of displayed results)

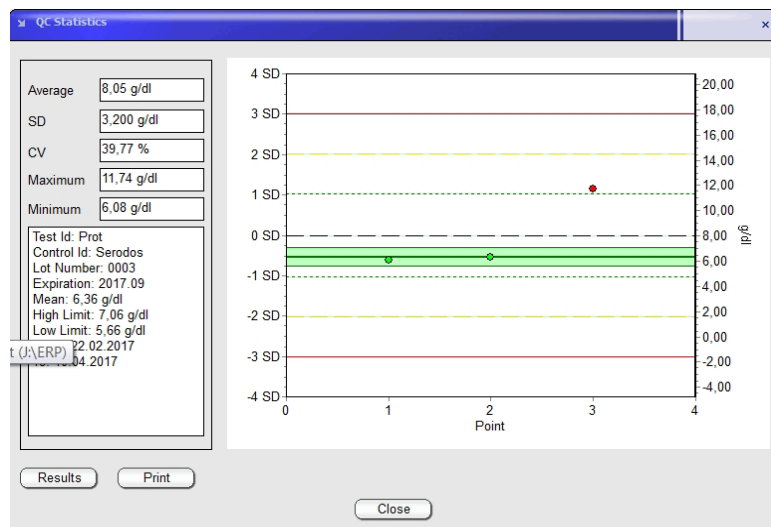
Date selectors show calendar for simple selection. All results are indexed and index is shown at the beginning of each column. Selectors can be used separately or together. Selectors act as logical AND which allows refining the selection. The results are displayed including the low and high limits and they are marked in the last column by an X when they are out of range.

Select a result and press the **Details >>** button to show extended information. The raw data curve is displayed including the information about dilution factor, reagent- and calibrator lot numbers. Press the **<< Plot** button to display the results in a graph.

Select a single result and press **Rerun test** to repeat the measurement. Press the **Print** button to print the displayed results or **Export** to export the displayed results into a csv file.

Press the **Statistics** button to display a Levy-Jennings graph with relevant statistical data and the Westgard rules violations, as shown below.

FIGURE 73



To print the displayed data, press the **Print** button. Before the print will be displayed an opportunity to enter comments is given.

To exclude results from the statistics press the **Results** button. Press **Close** to get back to the main window.

To view additional statistic press the **Statistics** Submenu button on the left side.

FIGURE 74

The HumaStar 600 software interface shows the Statistics submenu selected. The data table below displays the following information:

| Test  | Control      | Lot Num | Units   | Mean  | Assigned Values | Range | Low  | High | Last  | Time           | Mean  | Cumulative    | CV    | SD   | WR |
|-------|--------------|---------|---------|-------|-----------------|-------|------|------|-------|----------------|-------|---------------|-------|------|----|
| Ca    | HumaTrol P   | 0004    | mg/dl   | 0,0   | 0,0 - 0,0       | 0,0   | 0,0  | 0,0  | 16,0  | Mi 22.02 10:23 | 8,2   | 10,8 - 14,0   | 1,44% | 0,20 | -  |
| Ca    | Serodos      | 0003    | mg/dl   | 8,6   | 7,7 - 9,5       | 0,3   | 0,3  | 0,3  | 6,3   | Mi 22.02 10:20 | 8,2   | 8,1 - 8,7     | 1,59% | 0,13 | -  |
| GOT   | HumaTrol P   | 0004    | U/L     | 0     | 0 - 0           | 0     | 0    | 0    | 0,0   | Mi 22.02 10:24 | 1,5   | 1,5 - 1,5     | 1,20% | 1,9  | -  |
| GOT   | Serodos      | 0003    | U/L     | 35    | 27 - 43         | 3     | 3    | 3    | 35    | Mi 22.02 10:22 | 34    | 33 - 37       | 2,78% | 1,0  | X  |
| GOT   | Serodos Plus | 0003    | U/L     | 150   | 116 - 185       | 14    | 14   | 14   | 145   | Do 16.02 14:28 | 143   | 140 - 145     | 1,34% | 1,9  | -  |
| Glu   | HumaTrol P   | 0004    | mg/dl   | 0,0   | 0,0 - 0,0       | 0,0   | 0,0  | 0,0  | 220,0 | Mi 22.02 10:27 | 220,0 | 219,0 - 220,0 | 0,97% | 2,18 | X  |
| Glu   | Serodos      | 0003    | mg/dl   | 88,1  | 74,2 - 102,0    | 9,0   | 9,0  | 9,0  | 96,0  | Mi 22.02 14:41 | 91,8  | 88,3 - 97,9   | 2,75% | 2,52 | X  |
| Glu   | Serodos Plus | 0003    | mg/dl   | 223,0 | 187,0 - 259,0   | 23,0  | 23,0 | 23,0 | 230,5 | Do 16.02 14:31 | 230,3 | 226,3 - 235,0 | 1,16% | 2,66 | -  |
| HbA1c | CBA          | 0041    | mol/mol | 104   | 90 - 118        | 10    | 10   | 10   | 109   | Do 16.02 15:16 | 108   | 106 - 110     | 1,44% | 1,5  | -  |
| HbA1c | CBN          | 0041    | mol/mol | 36    | 29 - 43         | 3     | 3    | 3    | 31    | Do 16.02 15:14 | 31    | 31 - 31       | 0,00% | 0,0  | -  |

The results of the day will be displayed including the Westgard rules violation, the assigned- and cumulative values. CV and SD are calculated if multiple measurements are available.

Press **Detail** to display the single measurements. To exclude a results form the statistics, select a result in the table on the left side, press **Exclude** and insert a reason. The point will be removed from the graph and the calculation on the main screen will be recalculated. The result is not deleted it can be included again. To get back to the main screen, press **Details** again.

The red color indicates that the results are out of the assigned range or out of WR (Westgardrules), green they are inside the assigned range. Additionally, supervisor can define which Westgard Rule will be applicable to this window from **Maintenance > Parameters > Software > QC tab**.

### 5.7 Twin QC

Twin QC operates on quality controls already performed and its purpose is relating high and low controls and getting Youden plots and correlated Levy-Jennings plots.

Youden Plot is a bi-dimensional plot where correlated data for two-level systems or normal/abnormal data, taken in the same run are represented.

To display Twin QC , open the **Quality Control** Menu and select on the left side the Submenu **Twin QC**.

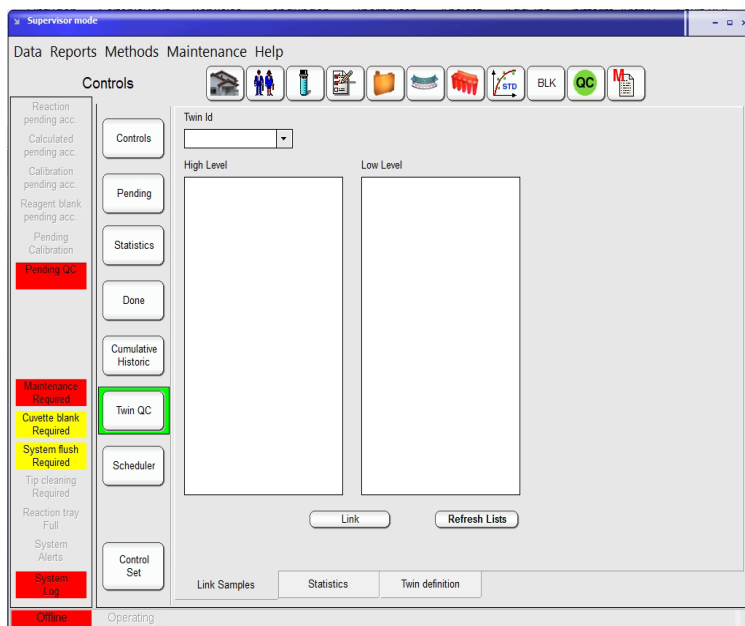


FIGURE 75

For operation, proceed as follows:

1. Define a Twin set. Press the **Twin definition** tab:
  - Define a name which defines a given set of controls.
  - Select the prefix for the high and low (or normal/abnormal) levels. It is important that they must coincide with the Control Vial Id (given in the Control Set).

FIGURE 76

2. Link the samples. Press the **Link Samples** tab:
  - Select the Twin Id.
  - Press the **Refresh Lists** button to display all controls which correspond to high and low level.
  - Select for each level a control and press **Link**.

FIGURE 77

**!** Coupled quality control is a useful tool if both controls of each pair are taken in similar conditions. Observe index number, date, time and lot number and verify that data were taken in close conditions.



3. To display the linked Twin QC press **Statistics** tab.

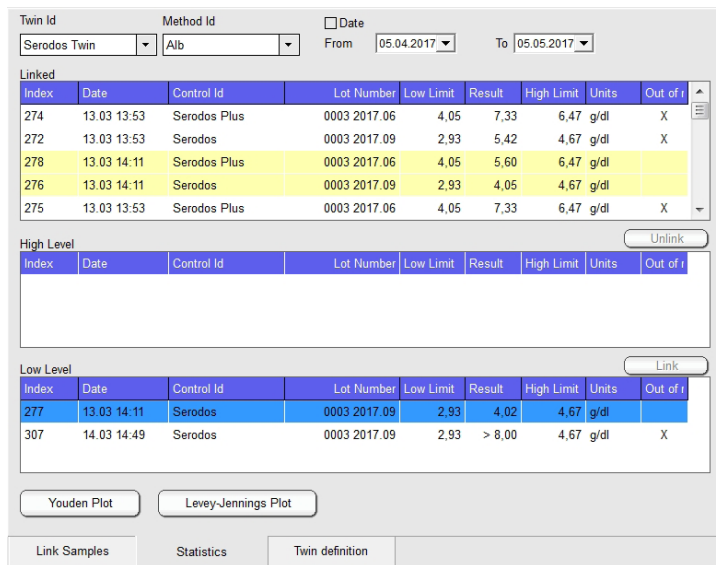


FIGURE 78

- Linked entries will appear in the upper (Linked) window. For identification purposes entries will be shown in alternate colors yellow and white. Every entry can be unlinked by selecting one of both components and pressing the **Unlink** button.
- Select the desired method, and the initial and final date for the study.
- Press the **Youden Plot** button to display the plot.

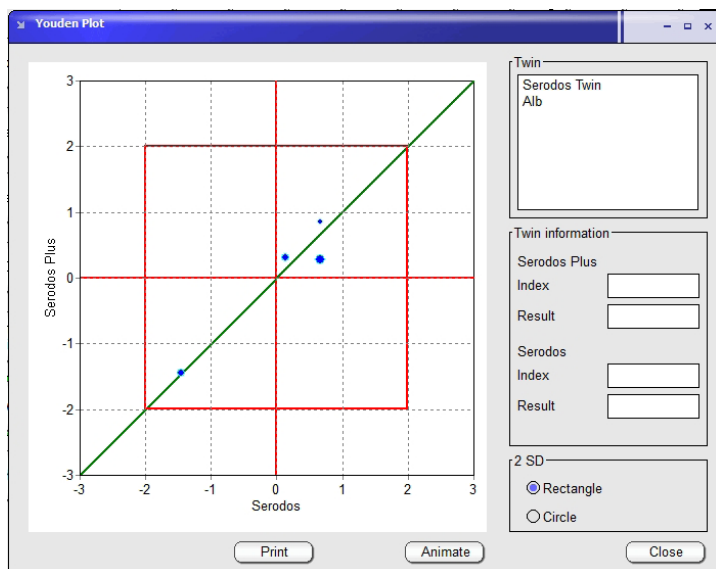
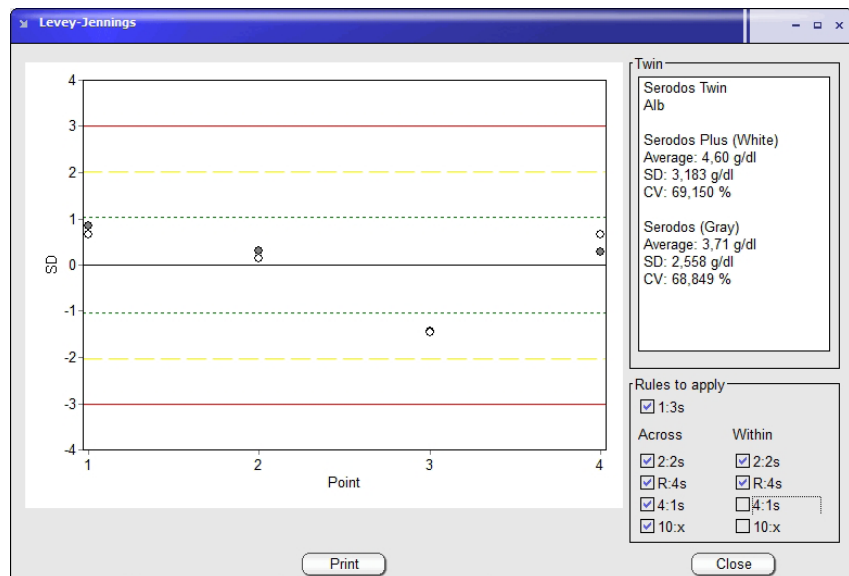


FIGURE 79

- This statistical technique involves both normal and abnormal controls and graphically helps to differentiate between systematic and random errors. The square represents  $\pm 3$  standard deviations for both controls. Red circle represents  $SQR(SD1^2 + SD2^2) = 2$ . The two median lines (vertical and horizontal axis) represent zero error normal and abnormal controls, respectively. The intersection of both median lines is called the Manhattan Median. The diagonal through the Manhattan Median is the ideal location, high correlation position for the pairs. Points near the line but outside the 2SD circle indicate a systematic error. Points that lie far from the 45-degree reference line indicate a random error.
- Press the **Levey-Jennings Plot** button and following graph will be displayed:

FIGURE 80



### 5.7.1 QC SCHEDULER

To display and program the QC Scheduler, open the **Quality Control** Menu and select on the left side the Submenu **Scheduler**.

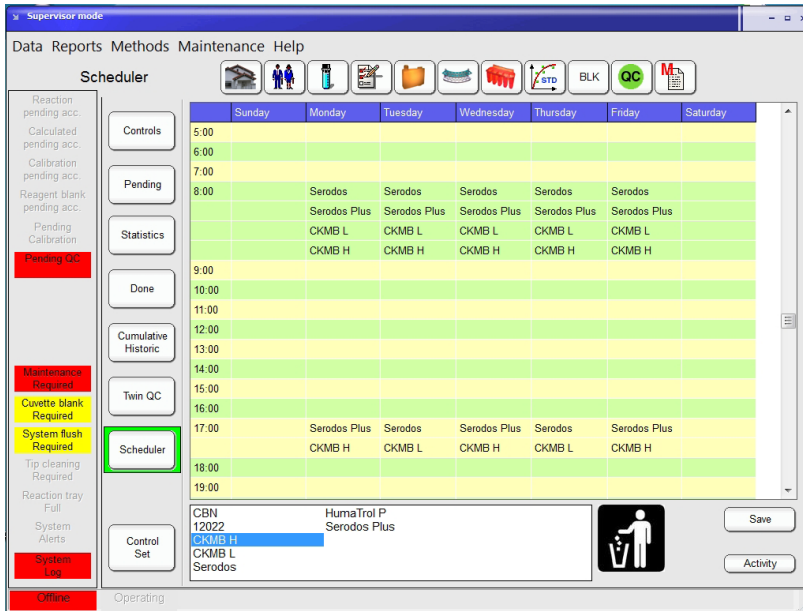


FIGURE 81

QC scheduler allows programming in advance all the QC actions on a weekly basis.

The defined controls are shown in the lower part of the screen. They must be dragged and dropped in the desired hour and day and then saved by pressing the **Save** button. They are immediately in the Pending QC status shown in red in the left side of the screen. They can be removed by dragging and dropping on the trash symbol.

They remain as pending until they are in the list of programmed samples and all the included reactions are processed. The Activity shows the next programmed action on each control, but they are due immediately after programming. If only some test are pending, warning flag will be in yellow color.

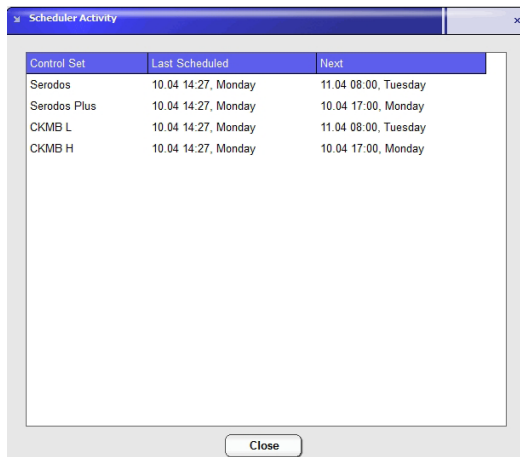


FIGURE 82

## 5.8 Working with LIS

The use of information management systems is widespread in hospitals and health centres where data must be collected from different kinds of instruments. The LIS (or LIMS) capability provides a reliable way for information interchange through ASTM E1381 and E1394 standards.

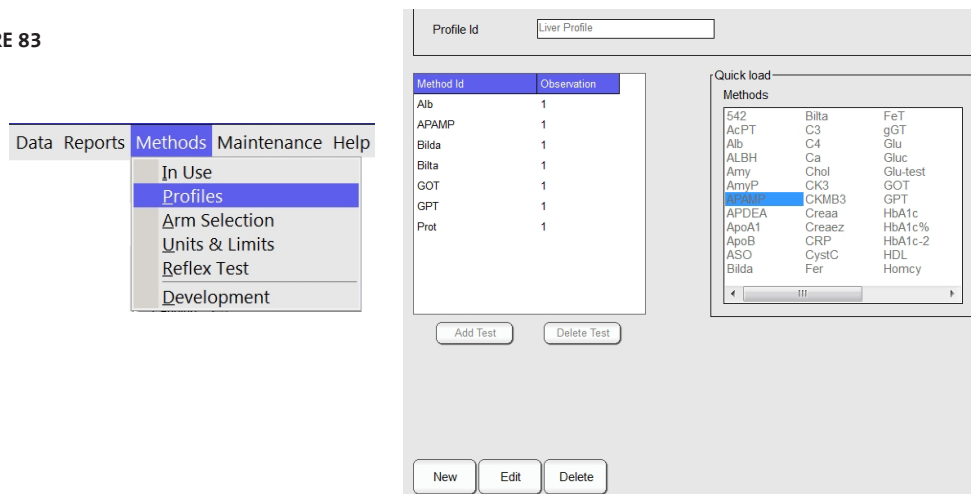
Refer to the LIS integration guide for more information.

## 5.9 Definition and use of sample profiles

Sample profiles are useful for ordering predefined patterns of tests.

### 5.9.1 DEFINING A SAMPLE PROFILE

FIGURE 83



To define a new sample profile, press **New**.

Enter a Profile Id and use the Quick load to add test by double click the test name. Tests can also be added or deleted using the **Add Test** or **Delete Test** button.

To edit a existing profile, select the name from the list on the right side and press **Edit**. Tests can be added or deleted as described above.

Repeat this operation for each required test on the profile. Then press **Ok** to finish or **Cancel** to abort.

#### 5.9.1.1 Removing a sample profile

To remove a sample profile from the list, first select the sample profile from the list on the right and then press **Delete**. Press **Yes** to confirm or **No** to abort.

## 6 DEFINITION OF METHODS



### For open channels only!

There are four major types of methods or procedures in clinical chemistry analysis results. Photometric methods control the way the reactions take place. Their definitions include the volumes of reagent and sample, the times when the absorbance measurements shall be taken by the photometer and the calculations to obtain the final result. ISE methods define the ion selective electrode measurements only. Calculated and external methods are used to compute a new result with the results of other methods and/or externally added values.

### 6.1 Method Types and Calculations



To work with methods press the **Method Definition** Menu button.

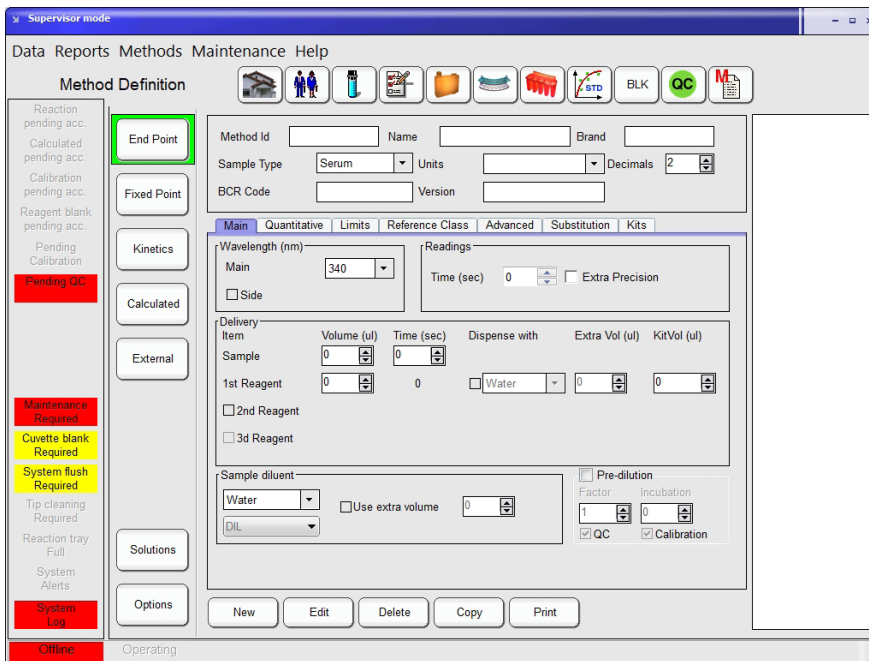


FIGURE 84

### 6.1.1 ENDPOINT

#### 6.1.1.1 Single point end point

##### Readings

A single absorbance reading ( $A_1$ ) is taken at specified time after reagent addition. Other absorbance reading ( $Ae_1$ ) may be taken immediately after the first reading for extra precision.

##### Measurement

$$M = A_1 - B.$$

where B is the measurement of the reagent blank if required, otherwise set to 0. The reagent blank determination is analogous to sample reaction.

If extra precision is required, measurement is computed as the average of the first and extra precision readings as

$$M = ((A_1 + Ae_1) / 2) - B$$

##### Limitations

Reagent times for R2/R3 (if any) shall be 0.

#### 6.1.1.2 Two point end point

##### Readings

The first absorbance reading ( $A_1$ ) is taken just before last reagent addition. The second absorbance reading ( $A_2$ ) is taken at specified time after last reagent addition.

##### Measurement

The measurement is calculated as

$$M = (A_2 - F \cdot A_1) - B$$

Where F is a **Volume Factor Correction** given by

$$F = (V_1 + V_s) / (V_1 + V_2 + V_s)$$

With  $V_1$ : first reagent volume

$V_2$ : second reagent volume

$V_s$ : sample volume

If no correction is applied, formula becomes

$$M = (A_2 - A_1) - B.$$

where B is the measurement of the reagent blank if required, otherwise set to 0.

The reagent blank determination is analogous to sample reaction.

If extra precision is required, readings are computed as the average of the first and extra precision readings as

$$M = ((A_2 + Ae_2) / 2 - (A_1 + Ae_1) / 2) - B.$$

#### Limitations

Reagent times for R2/R3 shall be greater than 0.

#### Extra precision

Other absorbance readings ( $Ae_1$  and  $Ae_2$ ) may be taken immediately after each reading.

### 6.1.2 FIXED POINT

#### Readings

The first and second absorbance readings ( $A_1$  and  $A_2$ ) are taken at specified times ( $NT_1$  and  $NT_2$ ) after last reagent addition. Real reading times in seconds since last reagent addition are observed ( $RT_1$  and  $RT_2$ ).

#### Measurement

The measurement is calculated as

$$M = ((A_2 - A_1) \cdot (NT_2 - NT_1) / (RT_2 - RT_1)) - B.$$

where B is the measurement of the reagent blank if required, otherwise set to 0.

The reagent blank determination is analogous to sample reaction.

If extra precision is required, absorbance readings are interpolated from  $Ae_i$  at  $RTe_i$  and  $A_i$  at  $RT_i$  as

$$Al_i = Ae_i + (A_i - Ae_i) / (RT_i - RTe_i) \cdot (NT_i - RTe_i)$$

and measurement is calculated as

$$M = (Al_2 - Al_1) - B.$$

#### Extra precision

Absorbance readings ( $Ae_1$  and  $Ae_2$ ) are taken 6 seconds before  $NT_1$  and  $NT_2$ . Real reading times since last reagent addition are observed ( $RTe_1$  and  $RTe_2$ ).

### 6.1.3 KINETICS

#### Readings

Absorbance readings ( $A_{c1}$  and  $A_{c2}$ ) for rate evaluation (consumption) are taken at specified times ( $NT_{c1}$  and  $NT_{c2}$ , with values of 30 and 45 s) after last reagent addition. Real reading times in seconds since last reagent addition are observed ( $RT_{c1}$  and  $RT_{c2}$ ).

Absorbance readings ( $A_1$  to  $A_n$ ) are taken at specified times ( $NT_1$  to  $NT_n$ , equally time spaced) after last reagent addition. Real reading times in seconds since last reagent addition are observed ( $RT_1$  to  $RT_n$ ). The number of readings is  $n = 10$  in normal conditions.

Once the 10 readings are taken, the linear correlation coefficient is estimated; also, correlation is estimated but excluding all 10 points, one by one. System will select the condition of best correlation, excluding the worst point, if necessary.

#### Measurement

Consumption evaluation is calculated per 1 minute as

$$C = (A_{c2} - A_{c1}) / (RT_{c2} - RT_{c1}) \cdot (60 \text{ s}).$$

The measurement is calculated as

$$M = b(A_i, RT_i) \cdot (60 \text{ s}) - B$$

where B is the measurement of the reagent blank if required, otherwise set to 0.

The reagent blank determination is analogous to sample reaction.

With  $i$  from 1 to  $n$ , where  $b(y,x)$  function returns the slope of the linear correlation of absorbance against time pairs of values as shown in the following equation:

$$b = \frac{n \sum xy - (\sum x)(\sum y)}{n \sum x^2 - (\sum x)^2}$$

where  $x$  is the represents the time and  $y$  the absorbance.

## 6.2 Method parameters

Several sections can be accessed in the method definition window.

### 6.2.1 COMMON PARAMETERS

The common parameters are available for following methods: Endpoint, Fixed Point, Kinetics, Calculated and External.

FIGURE 85

|             |                                    |         |                      |          |                                |
|-------------|------------------------------------|---------|----------------------|----------|--------------------------------|
| Method Id   | <input type="text"/>               | Name    | <input type="text"/> | Brand    | <input type="text"/>           |
| Sample Type | <input type="text" value="Serum"/> | Units   | <input type="text"/> | Decimals | <input type="text" value="2"/> |
| BCR Code    | <input type="text"/>               | Version | <input type="text"/> |          |                                |



| Item        | Input   | Comments   |
|-------------|---|--|
| Method Id   | Letters (A to Z, a to z), numbers (0 to 9) and hyphen signs (- and _) | It is unique; first 4 characters are used for the identification in the reagent tray screen      |
| Name        | Letters (A to Z, a to z), numbers (0 to 9) and hyphen signs (- and _) | Used in reports  |
| Brand       | Letters (A to Z, a to z), numbers (0 to 9) and hyphen signs (- and _) | Manufacturer; not available for Calculated and External methods                                  |
| Sample Type | Serum, Plasma, Urine, CSF, Dialysis and Whole Blood                   | Sample material used for the method; not available for Calculated and External methods           |
| Units       | Predifined in the scroll down menu                                    | More can be added in the Options menu  |
| Decimals    | 0 to 6  | Decimal positions used for results   |
| BCR Code    | Letters (A to Z, a to z), numbers (0 to 9) and hyphen signs (- and _) | Identifies reagent as defined by manufacturer; not available for Calculated and External methods |
| Vesion      | Letters (A to Z, a to z), numbers (0 to 9) and hyphen signs (- and _) | Allows to keep control of the release version of the method                                      |

TABLE 10

### 6.2.2 MAIN PAGE

These general parameters are applicable for all photometric/colorimetric reactions. Others are specific to the reaction type.

The screenshot shows a software window with several tabs: Main, Quantitative, Limits, Reference Class, Advanced, Substitution, and Kits. The 'Main' tab is active. The interface is divided into several sections:

- Wavelength (nm):** Includes 'Main' and 'Side' dropdown menus, both set to 340.
- Readings:** Includes 'Incubation (sec)' and 'Reaction Time (sec)' spinners, both set to 0, and an 'Extra Precision' checkbox.
- Delivery:** A table for reagent delivery:
 

| Item  | Volume (ul) | Time (sec) | Dispense with                  | Extra Vol (ul) | KitVol (ul) |
|---|-------------|------------|--------------------------------|----------------|-------------|
| Sample  | 0           | 0          |                                |                |             |
| 1st Reagent                                     | 0           | 0          | <input type="checkbox"/> Water | 0              | 0           |
| <input checked="" type="checkbox"/> 2nd Reagent | 0           | 0          | <input type="checkbox"/> Water | 0              | 0           |
| <input checked="" type="checkbox"/> 3d Reagent  | 0           | 0          | <input type="checkbox"/> Water | 0              | 0           |
- Sample diluent:** Includes a dropdown menu set to 'Water', a 'Use extra volume' checkbox, and a spinner set to 0.
- Pre-dilution:** Includes a 'Pre-dilution' checkbox, 'Factor' and 'Incubation' spinners (set to 1 and 0), and 'QC' and 'Calibration' checkboxes.

FIGURE 86

TABLE 11

| Item                    | Input  | Comments  |
|-------------------------|--|---|
| <b>Wavelength (nm)</b>  |  | Mono- or bichromatic measurement; 12 WL (340 - 800 nm)  |
| Main                    | Select from drop down menu                       | Choose a WL from the installed filters  |
| Side                    | Check and select from drop down menu or No Check | Check to enable a second WL and choose a WL from the installed filters  |
| <b>Readings</b>         |  |   |
| Incubation (sec)        | 1 to 1500  | Only for Fixed Point and Kinetics; time between the last dispensing and the first reading   |
| (Reaction) Time (sec)   | 1 to 1500  | Reading time is counted after the addition of the last fluid  |
| Extra Precision         | Check / No Check                                 | Endpoint (two consecutive readings are averaged; Fixed Point each value is the linear interpolation of two readings, one before and one after the specified time) |
| <b>Delivery</b>         |  |   |
| Volume (µl)             |  | Max volume per pipetting 470 µl;<br>Min/Max reaction volume 180/650 µl  |
| Sample                  | 2 to 100 µl                                      | Set in increments of 1 µl   |
| 1 <sup>st</sup> Reagent | 5 to 500 µl                                      | Set in increments of 1 µl   |
| 2 <sup>nd</sup> Reagent | Check or No Check;<br>5 to 500 µl                | Check the box to use a second reagent; Set in increments of 1 µl  |
| 3 <sup>rd</sup> Reagent | Check or No Check;<br>5 to 500 µl                | Check the box to use a third reagent; Set in increments of 1 µl   |
| Time (sec)              | 1 to 1500  | R1 is dispensed at time 0; S, R2 or R3 can be set variable by insert a different time   |
| Dispense with           | Check / No Check                                 | Check and the drop down menu will be available  |
|                         | Water / Extra Reagent                            | Water will be added to the reaction/ extra reagent will be discarded  |
| Extra volume (µl)       |  | Max total per dispensing 470 µl   |
| Kit Vol (µl)            |  | Reagent volume in the bottle (excluding the dead volume)  |
| <b>Sample diluent</b>   |  |   |
| First drop-down         | Water/Diluent/Reagent                            | Select from the drop-down   |
| Second drop - down      | Select from the drop-down                        | According to the above decision, different diluents (defined in Solutions menu) and the reagents of this test are available                                       |
| Use extra volume        | Check / No Check                                 | Check and the defined extra volume of the sample diluent will be used and after dispensing discarded  |

|                    |                  |   |
|--------------------|------------------|---|
| <b>Predilution</b> | Check / No Check | Check to enable the sample predilution function   |
| Factor             | 1 to 100         | Dilution will be done in an extra cuvette; dilution volume 300 µl (factor 10 -> 30 µl sample + 270 µl sample diluent) |
| QC                 | Check / No Check | Check and QC samples will be pre diluted  |
| Calibration        | Check / No Check | Check and Calibration samples will be prediluted  |

### 6.2.2.1 Specific data

#### End point

**Readings.** Measuring time starting when last reagent was added if more than one or when sample was added if only one reagent is present. When **Extra Precision** is used (recommended), two consecutive readings are averaged.

#### Fixed Point

**Readings. Incubation** is the time interval between addition of last reagent and the first reading. **Reaction time** is the time interval between two readings. When **Extra Precision** is used (recommended), each value is the linear interpolation of two readings, one before and one after the specified time.

#### Kinetics

**Readings. Incubation** is the time interval between addition of last reagent and the first reading. **Reaction time** is the time interval in which 10 readings are performed. These 10 readings define the slope for the concentration calculation (in some cases, only 9 points are considered; see section 6.1.3).

### 6.2.3 QUANTITATIVE

Calibration, reagent blank and reaction specific parameters are set up in the Quantitative tab.

FIGURE 87

TABLE 12

| Item                      | Input                            | Comments  |
|---------------------------|----------------------------------|---|
| <b>Method Correlation</b> |                                  |   |
| Slope                     | -999999 to 999999                | The concentration value (X) will be corrected with the equation $Y=AX + B$<br>Slope = A   |
| Offset                    | -999999 to 999999                | Offset = B  |
| <b>Direction</b>          |                                  |   |
| Direction                 | Ascending or Decreasing          | Reaction direction according the method<br>Select from drop down menü   |
| Direction Check           | Check / No Check                 | Direction will be checked and result will be flagged if direction is wrong and the result has to be manually accepted   |
| <b>Calibration type</b>   |                                  |   |
| Curve / Linear            | Check / No Check                 | Check if one or more calibrators should be used   |
| Validity time (days)      | Check / No Check;<br>1 to 999999 | Check and insert the number of days, if the calibration stability should be checked; after the number of days or if a new reagent lot is on board, the calibration curve expires and a new calibration will be requested. |
| Fixed                     | Check / No Check; 1 to 20        | Check and insert the number of points used in the calibration; If this option is not selected, the user can define a calibrator set with any number of points.  |

|                                 |  |  |
|---------------------------------|--|--|
| Mandatory formula               | None, Linear, MultLinear, Sigmoidea, Logit4, Logit5 or Spline. | Select from dop down menu if a special formula should be used; if none is used the formula can be manually modified in the Calibration>Pending Acceptance window |
| Factor                          | -999999 to 999999  | Insert the factor  |
| Use from this method            | Check / No Check   | Check if the calibration curve from different method should be used and select the method from the drop down menu  |
| <b>Reagent blank</b>            |  |  |
| Enabled                         | Check / No Check   | Check if a reagent blank should be used in the calculation of the result   |
| Sample replacement with Diluent | Diluent/Reagent<br>Drop down menu                              | Select which solution should be used<br>All diluents defined in Method Definition > Solutions are available  |
| Reagent                         | Drop down menu   | All reagents defined in the Main tab are available   |
| Validity time                   | 1,3,6 or 12 hours;<br>1 to 120 days                            | New reagent blank will be requested if the defined time expires or a reagent lot or bottle number is modified  |
| Default replicates              | 1 to 10  |  |
| Automatically performed         | Check / No Check   | Check if the reagent blank should be performed automatically   |

#### 6.2.4 LIMITS

Checks and automatic acceptance ranges are set up in the Limits tab.

FIGURE 88

TABLE 13

| Item   | Input                               | Comments   |
|--|-------------------------------------|--|
| <b>Concentration validity limit</b>            |                                     | Linearity range check  |
| Low  | -999999 to 999999                   | Insert the low linearity limit according the method IFU  |
|  | Not rerun, Rerun, More Sample       | Select from drop down menu; result can be flagged, repeated as original run or repeated with more sample volume  |
| High   | -999999 to 999999                   | Insert the high linearity limit according the method IFU   |
|  | Not rerun, Predilution, Less Sample | Select from drop down menu; results can be flagged, repeated with a predilution (the predilution factor is established automatically (taking in account low and high limit and calculates the dilution factor for the measured absorbance to get readings in the middle) or repeated with less sample volume |
| <b>Integrity check absorbance limit</b>        |                                     | Reagent integrity (quality) check; only reagent will be dispensed into a cuvette and measured each morning   |
| Low limit                                      | -999999 to 999999                   | Insert a low absorbance limit  |
| High limit                                     | -999999 to 999999                   | Insert a low absorbance limit  |
| <b>Concentration duplication limit</b>         |                                     | Result verification check; normal repetition can be triggered according to each laboratory need  |
| Low limit                                      | -999999 to 999999                   | Insert a low absorbance limit  |
| High limit                                     | -999999 to 999999                   | Insert a low absorbance limit  |
| <b>Reagent blank automatic acceptance</b>      |                                     | If automatic acceptance is enabled, reagent blank results within the specified limits will not appear on the Pending Acceptance window of blanks, they show up directly in the In Use window of blanks   |
| Low limit                                      | -999999 to 999999                   | Insert a low absorbance limit  |
| High limit                                     | -999999 to 999999                   | Insert a high absorbance limit   |
| <b>Calibration factor automatic acceptance</b> |                                     | If automatic acceptance is enabled, calibration factors within the specified limits will not appear on the Pending Acceptance window of calibration, they show up directly in the In Use window of calibrations  |
| Low limit                                      | -999999 to 999999                   | Insert a low factor limit  |
| High limit                                     | -999999 to 999999                   | Insert a high factor limit   |
| Change in %                                    | Check / No Check; -999999 to 999999 | Check if the deviation from the previous valid (in use) calibration should be checked and insert the allowable percentage  |

|                                      |                                    |   |
|--------------------------------------|------------------------------------|---|
| <b>Correlation coefficient limit</b> | Only for Kinetics; Linearity Check |   |
| Low limit                            | -999999 to 999999; drop down menu  | Insert a limit and select if a rerun should be triggered or not |

**6.2.5 REFERENCE CLASSES**

Reference classes define the normal limits or reference values for the various types of samples: men, women, children, etc.

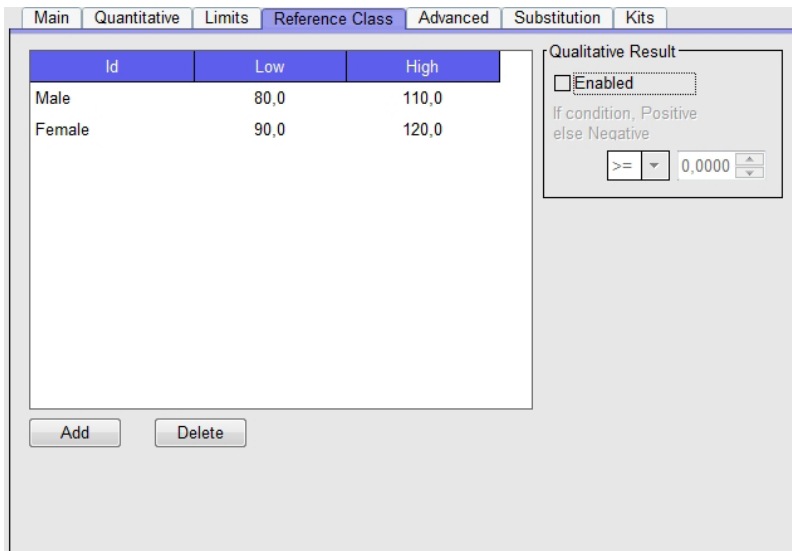


FIGURE 89

Reference classes can be added to the method definition using particular low and high limits. Reference classes are used for analysis flagging and reports. The reference classes are introduced in the **Options** (see section 6.4). To introduce an already defined reference class in the method, press the **Add** button and following window will displayed:

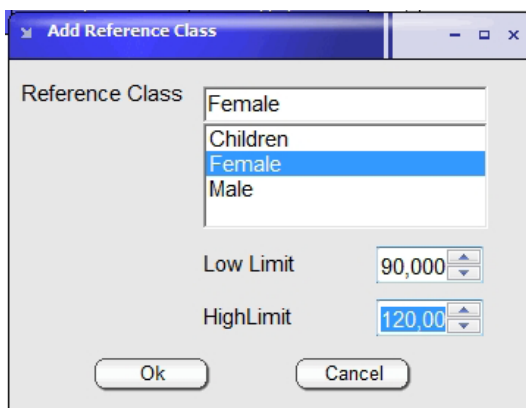


FIGURE 90

Select the reference class and insert the Low and High Limit. Press **Ok** to confirm or **Cancel** to abort.

To Delete a reference classe, select the line in the table and press **Delete**.

**Qualitative Result** can be evaluated using the option on the right side of the screen.

Check the box and the results can be reported as positive or negative instead of a numerical value.

Insert the function ( $>=$ ,  $>$ ,  $<$  or  $<=$ ) and the value for the decision between positive and negative.

### 6.2.6 ADVANCED FEATURES

Advanced features include procedures to avoid contamination, shaking behaviour and on board stability.

FIGURE 91

TABLE 14

| Item          | Input                            | Comments   |
|---------------|----------------------------------|--|
| Tip post wash | Check / No Check                 | Check to enable always an extra probe wash after dispensing to the cuvette |
| Water         | Check / No Check                 | Check to use water for the extra wash                                      |
| Solution      | Check / No Check, drop down menu | Check and select the solution which should be used for the extra post wash |



|                              |                                  |   |
|------------------------------|----------------------------------|---|
| <b>Tip pre wash</b>          | Check / No Check                 | Check to enable an extra probe wash before aspirating the reagent   |
| Water                        | Check / No Check                 | Check to use water for the extra wash   |
| Solution                     | Check / No Check, drop down menu | Check and select the solution which should be used for the extra wash   |
| Reagent                      | Check / No Check, drop down menu | Check and select the reagent which should be used for the extra wash  |
| When                         | Always / After interf. methods   | Usage always or only when a defined interfering method was used before the method   |
| <b>Cuvette post wash</b>     | Check / No Check                 | Check to enable the addition of a solution to the reaction cuvette before washing   |
| Solution                     | Drop down menu                   | Select the solution to be used  |
| Vol (µl)                     | 0 to 50                          | Insert the volume to be used  |
| Time (sec)                   | 0 to 60                          | Insert the time the added solution should be incubated together with the reaction liquid  |
| <b>After sample tip wash</b> | Check / No Check                 | Check to enable an external tip wash after aspiration of the sample (to improve the linearity in methods with very low absorbances)   |
| <b>Interfering methods</b>   |                                  | Add or delete methods which interfere the existing method   |
| <b>Sample Acceptance</b>     | Manual/Automatic                 | Manual to send all results to the Pending Acceptance tab in the Tests Menu; automatic to send all results without flag to the Done tab in the Tests Menu (flagged results will all the time be show up in the Pending Acceptance) |
| <b>Arm selection</b>         |                                  | Select the arm which should be used (important to take contamination avoidance and speed in consideration)  |
| Front                        | Check / No Check                 | Check if the front arm should be used   |
| Back                         | Check / No Check                 | Check if the back arm should be used  |
| Shake                        | Off / Normal / x2 / x3 / x4      | Adjust the shaking during the tip cleaning, intermediate wash, reaction cuvette and pre dilution mixing. Normal (centrifugal) mixing duration is 500 msec   |
| <b>Viscouse reagent</b>      | Check / No Check                 | Check if the reagent has a sticky consistency and the dilutor speed will be slowed down   |
| <b>On board stability</b>    |                                  |   |
| Time                         | 1,3,6 or 12 hours; 1 to 120 days | Select the on board stability given by the manufacturer   |
| Keep using                   | Check / No Check                 | Check to enable the reagent longer than the on board stability (a warning will be issued)   |

### 6.2.7 CONSUMPTION

This section applies to kinetic methods only.

FIGURE 92

| Item                            | Input             | Comments   |
|---------------------------------|-------------------|--|
| <b>Consumption check</b>        | Check / No Check  | Check to enable substrate depletion check; reaction curve will be checked for a excessive initial substrate consumption  |
| Limit (Abs/min)                 | -999999 to 999999 | Given by the manufacturer (approx. Abs/min of the linearity limit at the point of interest)  |
| First and second point          | Check / No Check  | Check and evaluation is performed between the two first reading points   |
| Time and first point            | Check / No Check  | Check and the evaluation is performed before the reading is started  |
| Time before first (sec)         | 0 to ...          | Define the time when the check should take place (recommendation: incubation < 60 sec set to 15; incubation > 60 sec set to 30)  |
| <b>Behaviour</b>                |                   |  |
| Conservative                    | Check / No Check  | Check and during the reading time the system perform 10 readings   |
| Adaptative                      | Check / No Check  | Check and the system will automatically increase the total reaction time and the interval between the readings if the consumption rate is low to optimize precision and decrease the total reading interval if the consumption rate is high to preserve linearity; recommended |
| <b>Initial absorbance limit</b> | -999999 to 999999 | Insert the OD limit; if absorbance is below limit in a decreasing reaction or above limit in increasing reaction the sample will be prediluted   |
| Dilution factor                 | 1 to 120          | Insert a dilution factor   |

**6.2.8 REAGENT SUBSTITUTION**

Two or more methods can share the same reagent. Or a defined diluent can be used as a reagent.

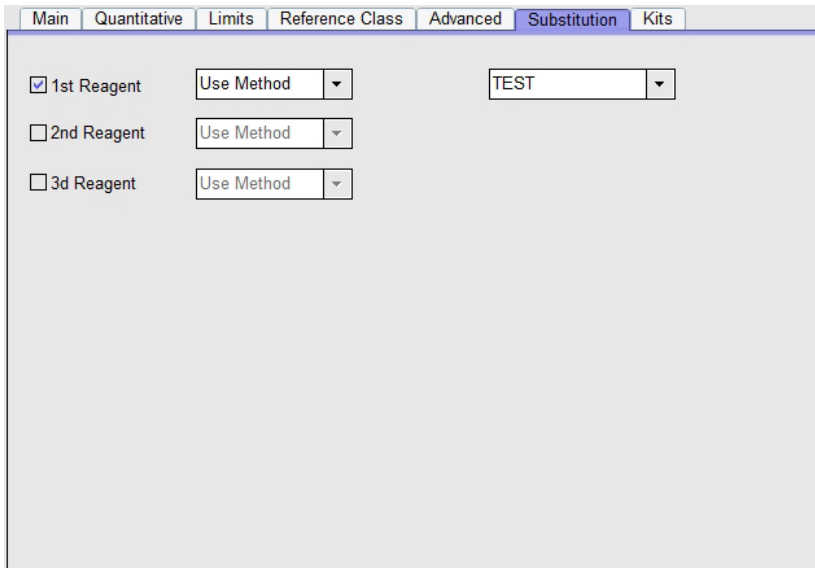


FIGURE 93

| Item                          | Input            | Comments  |
|-------------------------------|------------------|---|
| <b>1<sup>st</sup> Reagent</b> | Check / No Check | Check to apply a reagent or diluent for reagent 1                               |
|                               | drop down menu   | Choose "Use Method" for a reagent of a different method or a predefined diluent |
|                               | drop down menu   | If "Use Method" is chosen, select the method (this method belongs to R2 and R3) |
| <b>2<sup>nd</sup> Reagent</b> | Check / No Ceck  | Check to apply a reagent or diluent for reagent 2                               |
|                               | drop down menu   | Choose "Use Method" for a reagent of a different method or a predefined diluent |
| <b>3<sup>rd</sup> Reagent</b> | Check / No Check | Check to apply a reagent or diluent for reagent 3                               |
|                               | drop down menu   | Choose "Use Method" for a reagent of a different method or a predefined diluent |

TABLE 16

## 6.2.9 KITS

### Kits

For barcoded reagents different kit sizes can be used.

FIGURE 94

|   | BCR Code | On board Stab. | R1 KitVol (ul) |
|---|----------|----------------|----------------|
| Kit 1                                     | 033      | 120 Days       | 32100          |
| <input checked="" type="checkbox"/> Kit 2 | 603      | 120 Days       | 1200           |
| <input type="checkbox"/> Kit 3            |          |                |                |

The information of the first kit are automatically insert from the Main and Advanced tab. If a second Kit size should be used insert the BCR code, the on board stability and the Kit Volume in  $\mu\text{l}$ .

### 6.3 Solutions

To set up Solutions press the **Method Definition** Menu button and select the Submenu **Solution**.

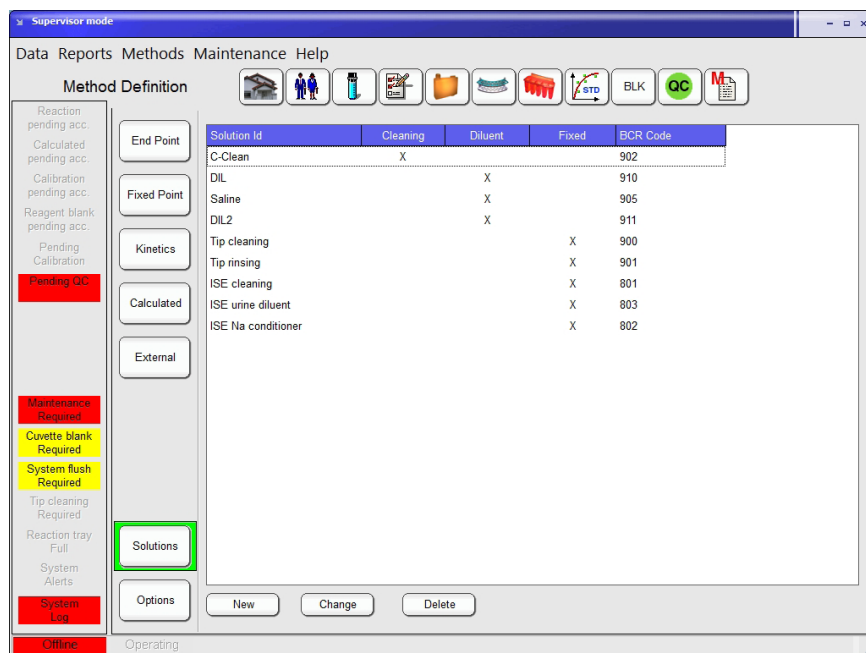


FIGURE 95

Two categories of solutions are available:

**Fixed in the system** Solutions which are fixed in the system and can not be modified

| Solution  | Ref      | BCR Code | Usage   |
|-----------|----------|----------|---|
| Tip Clean | 16663/25 | 900      | Clean the probe after “Start” and before going to “Standby” |
| Tip Rinse | 16663/25 | 901      | Rinse the probe after Tip Clean                             |

ISE solutions described in the ISE User Guide

TABLE 17

**User defined** Generic and specific dilutents required in some methods

| Solution         | Ref      | BCR Code | Usage   |
|------------------|----------|----------|---|
| Diluent (DIL)    | 16663/10 | 910      | Diluent: pre- and post dilution of serum samples; reagent blank                                     |
| Diluent 2 (DIL2) | 16663/11 | 911      | Diluent: pre- and post dilution of urin samples   |
| Cuvette Clean    | 16663/20 | 902      | Cleaning: tip pre- and post wash; cuvette post wash; maintenance (refer to chapter 8.2.2 and 6.2.6) |

TABLE 18

To add more solutions or dilutents press the **New** button.

FIGURE 96

The 'Solutions' dialog box is shown with the following details:

- Title:** Solutions
- Id:** DIL2
- BCR code:** 911
- Type:**
  - Cleaning
  - Diluent
- Buttons:** Ok, Cancel

Insert a ID and a BCR code (if barcoded), Select the Type and press **Ok** to confirm or **Cancel** to abort.

Once the solution is set up only BCR code is possible to change.

To delete a solution, select the solution in the table and press **Delete**.

## 6.4 Options

To add or delete Reference Classes or Measurement Units press the **Method Definition** Menu button and select Submenu **Options**.

FIGURE 97

The 'Supervisor mode' interface shows the following components:

- Menu:** Data, Reports, Methods, Maintenance, Help
- Method Definition:**
  - End Point
  - Fixed Point
  - Kinetics
  - Calculated
  - External
  - Solutions
  - Options** (highlighted)
- Reference Classes:**
  - Baby
  - Children
  - Female
  - Male
  - Buttons: Add, Delete
  - Default: [ ]
- Measurement Units:**
  - %
  - µg/dl
  - µg/l
  - µkat/l
  - µmol/l
  - µmol/l.s
  - Abs
  - g/dl
  - g/l
  - IU/ml
  - mg/dl
  - mg/l
  - mmol/l
  - mmol/mol Hb
  - mval/l
  - ng/ml
  - U/L
  - Buttons: Add, Delete
- Status Bar:** Offline, Operating

Following options are available:

**Reference classes** Defined reference classes are displayed; to add a new press **Add** and type in the name and press **Ok** to confirm or **Cancel** to abort; to delete select the line and press **Delete** .  
If a reference class is used in a method it is not possible to delete them. One can be set to default.

**Measurement Units** Defined measurement units are displayed, to add a new measurement unit, press **Add** and type in the unit and press **Ok** to confirm or **Cancel** to abort; to delete select the line and press **Delete** .

## 6.5 Calculated methods

To add, modify, delete or print a calculated test press the **Method Definition** Menu button and select the Submenu **Calculated**.

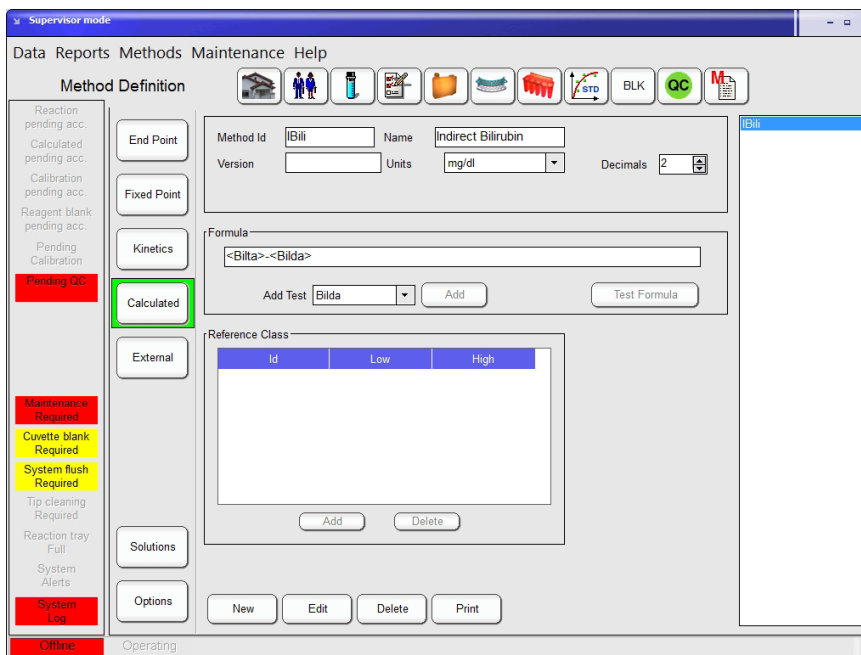


FIGURE 98

Press **New** to add a new calculated test. Method ID, name, units, decimals, version name are introduced as in any other method.

Create a formula using methods combined with common mathematical operators (+, -, \*, /, (), and so on) and if available external methods.

To insert a method select the name on the drop down menu below and press **Add**. The method name will be inserted at the point the cursor is placed in the formula. Press **Test Formula** to check the formula's consistency.

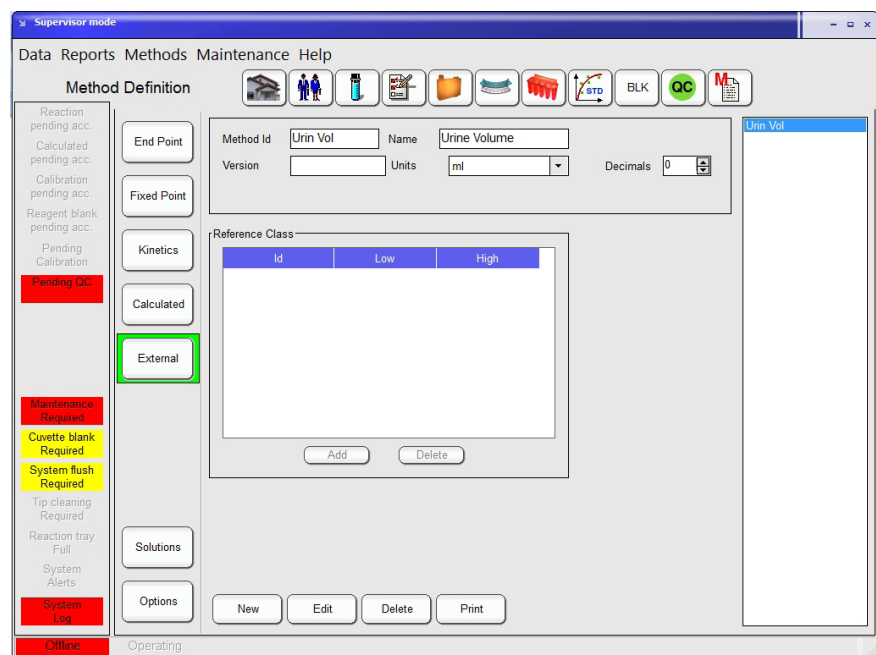
External methods can be used in formula if previously stored in memory.

Methods may correspond to different samples if samples are assigned to the same patient. To add a reference class to the calculated formula, press **Add** and select the class and insert the low and high limit. Press **Ok** to confirm or **Cancel** to abort.

## 6.6 External Methods

To add, modify, delete or print an external method press the **Method Definition** Menu button and select the Submenu **External**.

FIGURE 99



External methods are printed out together with those calculated by the instrument.

They are useful for the introduction of constants in the calculated methods. Such constants are, for instance "Creatinine clearance", "24-hour volume", etc. Method ID, name, units, decimals, external names are introduced as usual.

To add a reference class to the external method, press **Add** and select the class and insert the low and high limit. Press **Ok** to confirm or **Cancel** to abort.



### 6.7 Units and Limits

Units and limits can be modified from the menu of methods without direct access to a given method in particular. This feature is used to set lab specific limits or checks to closed methods.

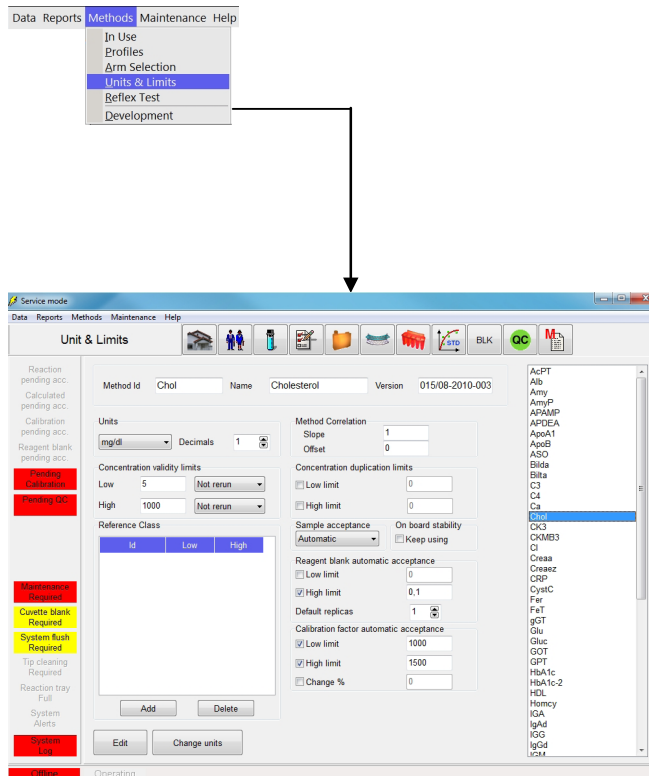


FIGURE 100

In brief, the method ID and measuring units can be modified. Method correlation, concentration duplication limits and reagent blank and calibration automatic acceptance limits can be set. Reference classes can be modified, deleted or added. Additionally sample acceptance can be assigned as manual or automatic and on board stability can be extended by checking the Keep Using button.

### 6.8 Development of a Method

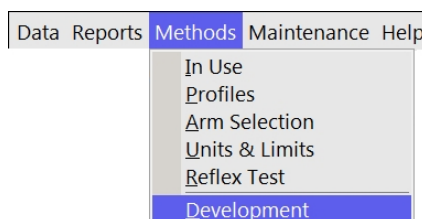
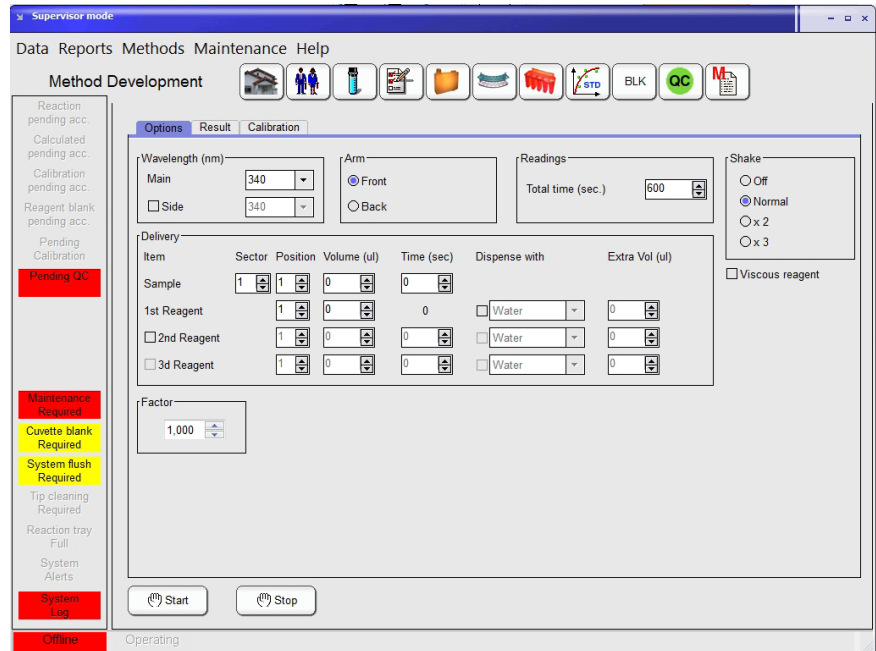


FIGURE 101

FIGURE 102



The option gives access to review in real time any reaction. This method does not run with others as part of the automatic cycle. It is used alone, sample by sample and its purpose is to study slope, end point, optimum range, incubation period, etc. of individual reactions.

In **Options**, basic method parameters are defined: wavelengths, number of reagents, volumes, total measuring time. In Calibration page, analysis type is defined and fit formula calculated. In Results, measurements can be viewed graphically and Time 1 and Time 2 can be adjusted in order to focus on required time interval. This function is mostly used for research and development projects as well as method optimization.

**7 ISE MODULE CAT.-NO. 16663-03**

See HumaStar 600 ISE MODULE User Manual, 16663/1.



### 8 MAINTENANCE

A regular maintenance is necessary, to keep the system in good operating condition. The scheduler will help to manage the daily, weekly and monthly maintenance. From time to time it's also necessary to do some maintenance on demand i.e. Cuvette change.

A recommended summary of tasks for daily, weekly and monthly maintenance is presented in the table below:

| Frequency        | Task                               |
|------------------|------------------------------------|
| <b>Daily</b>     | Inspection and Cleaning of Probes  |
|                  | Check and Replace System Solutions |
|                  | Empty Waste Bottle                 |
|                  | Hydraulic Testing - System Flush   |
| <b>Weekly</b>    | Intensive Cuvette Cleaning         |
|                  | Cuvette Water Blank                |
|                  | Service Backup                     |
| <b>Monthly</b>   | Photometer Calibration             |
|                  | Washer Volume Calibration          |
|                  | Clean System Bottles               |
|                  | Intensive Washer Cleaning          |
| <b>On Demand</b> | Cuvette Change                     |
|                  | Lamp Replacement                   |
|                  | Pump Tube Replacement              |

FIGURE 103

#### 8.1 Scheduler

Maintenance Scheduler can be accessed either from the warnings bar (if a warning is yellow or red, click on it) on the system information field at the main window or from main menu:

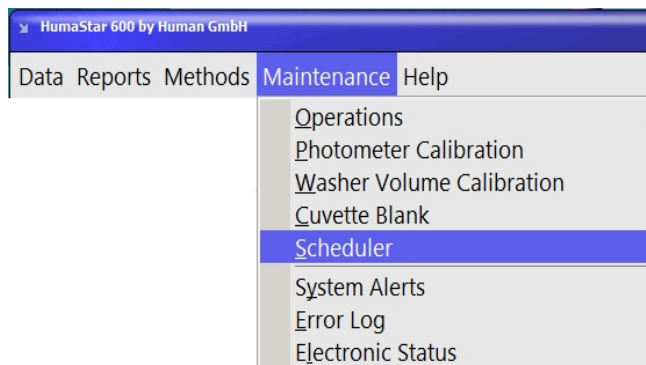


FIGURE 104

The scheduler window is further divided into two tabs which are the **Status** and **Schedule**. Both windows are analytically presented at next sections. Red color indicates that one or more of the scheduled tasks has not been completed.

### 8.1.1 SCHEDULE

To schedule the alerts for the maintenance tasks a number of parameters which involve daily lab routine operation are edited in this screen in order to set the preferred times for maintenance tasks.

FIGURE 105

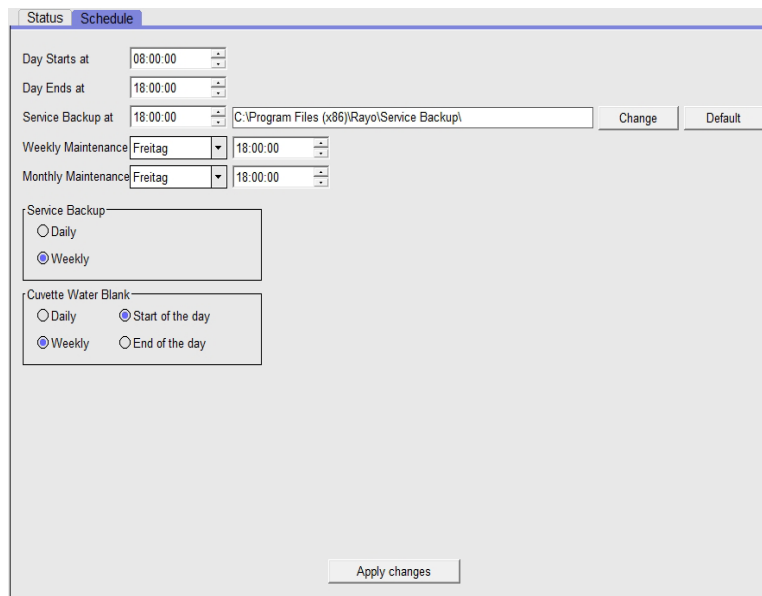


TABLE 19

| Item                | Input            | Comments   |
|---------------------|------------------|--|
| Day start at        | 0 to 24 o'clock  | Set the time of routine start  |
| Day Ends at         | 0 to 24 o'clock  | Set the time of routine stops  |
| Service Backup at   | 0 to 24 o'clock  | Set the time when the Backup should take place                                 |
| Change              |                  | Select the folder to store the service back up (recommended to an external MD) |
| Default             |                  | Press to use the default folder  |
| Weekly Maintenance  | Monday to Sunday | Select the day the weekly maintenance should take place                        |
|                     | 0 to 24 o'clock  | Set the time when the weekly maintenance should take place                     |
| Monthly Maintenance | Monday to Sunday | Select the day the monthly maintenance should take place                       |
|                     | 0 to 24 o'clock  | Set the time when the alert should take place                                  |

**Service Backup**

|        |                  |                           |
|--------|------------------|---------------------------|
| Daily  | Check / No Check | Check for a daily backup  |
| Weekly | Check / No Check | Check for a weekly backup |

**Cuvette Water Blank**

|                  |                  |  |
|------------------|------------------|--|
| Daily            | Check / No Check | Check for a daily cuvette water blank                            |
| Weekly           | Check / No Check | Check for a weekly cuvette water blank                           |
| Start of the day | Check / No Check | Check, if the maintenance should be done on the start of the day |
| End of the day   | Check / No Check | Check, if the maintenance should be done on the end of the day   |

Press **Apply changes** to save the modifications.

**8.1.2 STATUS**

A list of maintenance tasks is presented in this window with the dates and times that were last executed as well as the times that are next scheduled for. The activities are mainly separated into Daily, Weekly, Monthly and On Demand maintenance routines and can be performed directly from this screen by pressing the corresponding Perform button which will either initialize the task directly or will transfer to the corresponding screen of the software.

If the "Next scheduled" time is reached an alert will be shown on the main screen in the system information field. Additional details for some of the tasks can be found in separate sections of the maintenance chapter.

FIGURE 106

|                            | Last execution      | Next scheduled      |         |
|----------------------------|---------------------|---------------------|---------|
| System Flush               | Never               | Tomorrow 08:00      | Perform |
| Intensive Cuvette Cleaning | Do 06.04.2017 10:50 | Today 18:00         | Perform |
| Service Backup             | Never               | Today 18:00         | Perform |
| Cuvette Water Blank        | Never               | Fr 12.05.2017 08:00 | Perform |
| Change Solutions           | Do 06.04.2017 10:50 | Today 18:00         | Perform |
| Clean Needle               | Do 06.04.2017 10:50 | Today 18:00         | Perform |
| Photometer Calibration     | Do 06.04.2017 10:50 | Today 18:00         | Perform |
| Washer Volume Calibration  | Do 06.04.2017 10:50 | Today 18:00         | Perform |
| Clean System Bottles       | Do 06.04.2017 10:50 | Today 18:00         | Perform |

## 8.2 Daily Maintenance

Recommended operations should be performed at the start of every run or on demand.

### 8.2.1 INSPECTION AND CLEANING OF PROBES

The probes are a delicate part of the instrument. Precision of results is essentially dependent on how well the probes are maintained. Probe tip must be kept clean.

1. Inspect if the probes are not bent or damaged. If a probe is defective contact your technical support.
2. Inspect the probes for debris and clean them if contaminated.
3. Open the Maintenance scheduler status screen and press **Perform** behind the Clean needle function.
4. Gently remove protein deposits or solids from tip with a cotton swab soaked in 70% Alcohol. Dry with lint-free tissue.
5. Press **Ok** when done. The scheduler will be updated automatically.
6. After Cleaning the probes, flush the system.

### 8.2.2 CHECK AND REPLACE SYSTEM SOLUTIONS

System wash solution and cleaning solutions are necessary to run the system. Provide all solutions to avoid interruption during the run.

**System Wash Solution:** The system washes the probes between sample aspirations, requiring approximately 4 mL of wash solution for each performed test in case of single reagent tests. The washing solution is pumped up from its reservoir and is disposed into the waste reservoir, both reservoirs have electronic level sensors. If volume is not sufficient, a message will warn after initialization.



The **Tip clean** and **Tip rinse** solutions are needed to clean and rinse the probes after measurement, before the system stops and should be replaced (if not used up) all three months.

The **Cuvette Clean** is used during run for tip pre/post wash- and cuvette post wash and should be replaced (if not used up) all three months.

The **Diluent** is used for sample/calibrator pre- and post dilution and for blank measurements and should be replaced (if not used up) once a month.

1. Check the system wash solution behind the front door, if necessary prepare new, for details refer to the IFU of Wash Add Ref 18971. After replacement flush the system. Don't top up to avoid contamination and bacterial grow.
2. Check the Tip Clean and - Rinse (Ref 16663/25) in the reagent tray, replace if necessary.
3. Check the Cuvette Clean (Ref. 16663/20) in the reagent tray, replace if necessary.
4. Check the Diluent (Ref. 16663/10) in the reagent tray, replace if necessary.

### 8.2.3 EMPTY WASTE BOTTLE

The waste bottle is placed on a scale and if the bottle is full, the system will show an alarm. Open the front door, empty the waste bottle and put it back into the system.

### 8.2.4 HYDRAULIC TESTING – SYSTEM FLUSH

System flush is required at least once per day and can be set to be automatically performed during analyzer start up at the beginning of the day. In case that analyzer has stayed operational and has not been switched off then the system flush warning will come up at the specified time. Air gaps and bubbles should be flushed, if present, particularly after the filling operation of system bottles or after cleaning the probes.

1. Open the Maintenance scheduler status screen and press **Perform** behind the **System Flush** function.
2. During process look for:
  - Presence of bubbles or air gaps in system
  - Leakage in peristaltic pump
  - Constant and uniform flow from probe tip
  - No droplets hanging on probe tip
  - In case new bubbles generate in the process, Refer to chapter 9 "Troubleshooting".
3. The scheduler will be updated automatically.

## 8.3 Weekly Maintenance

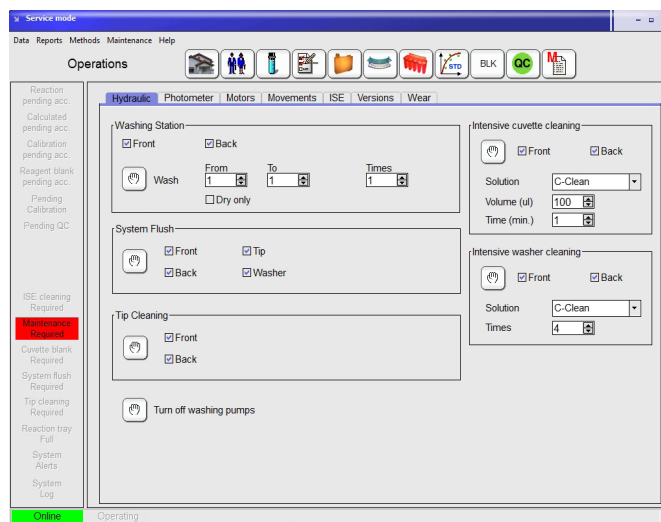
Proceed to the daily maintenance routine.


### 8.3.1 INTENSIVE CUVETTE CLEANING

Intensive cuvette cleaning should be done at least weekly. In case of an intense contamination of the cuvettes (i.e. high usage of Latex reagents) it may be necessary to clean the cuvettes more often. The system checks the cuvettes before each run and if cuvettes get's unusable in a short time, it is a sign to clean them more often. Place neat Cuvette Clean Solution (Ref 16663/20) on the reagent tray. Approximately 25 min are needed to clean all cuvettes.

1. Open the Maintenance scheduler status screen and press **Perform** behind the **Intensive Cuvette Cleaning** function.

FIGURE 107



2. Check the box for Front and Back on the “Intensive cuvette cleaning” section.
3. Select the C-Clean as solution to use.
4. Select the volume to 300 µl of C-Clean to be dispensed to the cuvettes.
5. Set the time to 1 min (increase the time by an intense contamination).
6. Check if enough C-Clean is placed on the reagent tray (160 x the volume set above).
7. Press  to start the cleaning.
8. After the cuvette cleaning finished the scheduler will be updated automatically. It is mandatory to perform a Cuvette Water Blank after the cleaning.

### 8.3.2 CUVETTE WATER BLANK

Cuvette water blank should be done weekly and after each intensive cuvette cleaning.

Washers are dispensing system wash in all cuvettes and photometer records the background measurement of each cuvette at all 12 filters. The process takes place into two parts; at first system wash is dispensed to the first 40 cuvettes, absorbances are read, cuvettes are then dried and then the other half of the cuvette tray is filled and read. Process takes approximately 15 min and if acceptance criteria are fulfilled, cuvettes are considered clean.

1. Open the Maintenance scheduler status screen and press **Perform** behind the Cuvette Water Blank function.

| Tray  | #  | F.01   | F.02   | F.03   | F.04   | F.05   | F.06   | F.07   | F.08   | F.09   | F.10   | F.11   | F.12   |
|-------|----|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Front | 1  | 0.0686 | 0.0525 | 0.0509 | 0.0494 | 0.0491 | 0.0492 | 0.0482 | 0.0478 | 0.0485 | 0.0481 | 0.0481 | 0.0571 |
| Front | 2  | 0.0661 | 0.0504 | 0.0486 | 0.0478 | 0.0476 | 0.0474 | 0.0466 | 0.0465 | 0.0471 | 0.0465 | 0.0465 | 0.0560 |
| Front | 3  | 0.0663 | 0.0509 | 0.0492 | 0.0481 | 0.0480 | 0.0478 | 0.0471 | 0.0469 | 0.0476 | 0.0472 | 0.0471 | 0.0570 |
| Front | 4  | 0.0659 | 0.0499 | 0.0486 | 0.0474 | 0.0477 | 0.0472 | 0.0464 | 0.0460 | 0.0469 | 0.0460 | 0.0468 | 0.0562 |
| Front | 5  | 0.0674 | 0.0506 | 0.0488 | 0.0476 | 0.0479 | 0.0476 | 0.0470 | 0.0473 | 0.0476 | 0.0476 | 0.0471 | 0.0575 |
| Front | 6  | 0.0660 | 0.0502 | 0.0487 | 0.0481 | 0.0469 | 0.0472 | 0.0464 | 0.0461 | 0.0471 | 0.0464 | 0.0468 | 0.0561 |
| Front | 7  | 0.0664 | 0.0507 | 0.0490 | 0.0476 | 0.0475 | 0.0475 | 0.0466 | 0.0463 | 0.0471 | 0.0468 | 0.0467 | 0.0563 |
| Front | 8  | 0.0671 | 0.0509 | 0.0492 | 0.0488 | 0.0487 | 0.0481 | 0.0475 | 0.0473 | 0.0482 | 0.0474 | 0.0478 | 0.0572 |
| Front | 9  | 0.0672 | 0.0511 | 0.0492 | 0.0489 | 0.0485 | 0.0484 | 0.0476 | 0.0472 | 0.0480 | 0.0475 | 0.0480 | 0.0574 |
| Front | 10 | 0.0675 | 0.0514 | 0.0497 | 0.0485 | 0.0482 | 0.0477 | 0.0472 | 0.0468 | 0.0473 | 0.0467 | 0.0469 | 0.0566 |
| Front | 11 | 0.0687 | 0.0524 | 0.0509 | 0.0493 | 0.0494 | 0.0493 | 0.0481 | 0.0480 | 0.0485 | 0.0484 | 0.0483 | 0.0577 |
| Front | 12 | 0.0678 | 0.0527 | 0.0502 | 0.0497 | 0.0489 | 0.0486 | 0.0480 | 0.0481 | 0.0488 | 0.0486 | 0.0483 | 0.0587 |
| Front | 13 | 0.0674 | 0.0518 | 0.0498 | 0.0486 | 0.0487 | 0.0484 | 0.0474 | 0.0474 | 0.0476 | 0.0475 | 0.0474 | 0.0573 |
| Front | 14 | 0.0657 | 0.0499 | 0.0484 | 0.0467 | 0.0473 | 0.0470 | 0.0465 | 0.0464 | 0.0471 | 0.0461 | 0.0466 | 0.0559 |
| Front | 15 | 0.0674 | 0.0505 | 0.0490 | 0.0477 | 0.0481 | 0.0477 | 0.0471 | 0.0470 | 0.0478 | 0.0473 | 0.0477 | 0.0572 |
| Front | 16 | 0.0671 | 0.0512 | 0.0494 | 0.0481 | 0.0479 | 0.0477 | 0.0469 | 0.0467 | 0.0473 | 0.0474 | 0.0473 | 0.0567 |
| Front | 17 | 0.0653 | 0.0498 | 0.0482 | 0.0469 | 0.0473 | 0.0470 | 0.0462 | 0.0462 | 0.0469 | 0.0462 | 0.0469 | 0.0555 |
| Front | 18 | 0.0660 | 0.0503 | 0.0481 | 0.0477 | 0.0474 | 0.0471 | 0.0465 | 0.0465 | 0.0477 | 0.0470 | 0.0475 | 0.0568 |
| Front | 19 | 0.0672 | 0.0511 | 0.0495 | 0.0485 | 0.0488 | 0.0476 | 0.0476 | 0.0469 | 0.0478 | 0.0475 | 0.0476 | 0.0577 |
| Front | 20 | 0.0722 | 0.0556 | 0.0540 | 0.0527 | 0.0522 | 0.0513 | 0.0506 | 0.0505 | 0.0509 | 0.0501 | 0.0505 | 0.0597 |
| Front | 21 | 0.0664 | 0.0502 | 0.0482 | 0.0473 | 0.0475 | 0.0471 | 0.0463 | 0.0465 | 0.0471 | 0.0465 | 0.0468 | 0.0563 |
| Front | 22 | 0.0673 | 0.0512 | 0.0495 | 0.0489 | 0.0478 | 0.0478 | 0.0467 | 0.0465 | 0.0470 | 0.0477 | 0.0465 | 0.0568 |
| Front | 23 | 0.0685 | 0.0521 | 0.0506 | 0.0486 | 0.0486 | 0.0485 | 0.0474 | 0.0466 | 0.0474 | 0.0469 | 0.0470 | 0.0568 |
| Front | 24 | 0.0701 | 0.0535 | 0.0512 | 0.0496 | 0.0494 | 0.0494 | 0.0482 | 0.0487 | 0.0487 | 0.0483 | 0.0476 | 0.0578 |
| Front | 25 | 0.0676 | 0.0517 | 0.0502 | 0.0493 | 0.0488 | 0.0488 | 0.0480 | 0.0479 | 0.0484 | 0.0480 | 0.0483 | 0.0581 |

FIGURE 108

2. The cuvette water blank starts automatically.
3. After the cuvette water blank finished the scheduler will be updated automatically. The actual and the previous results are displayed on the screen.

### 8.3.3 SERVICE BACKUP

Perform the backup at least once per week to save all necessary information needed to reinstall the system and retrieve data in an emergency.

Save the Backup on an external memory device. Duration can vary from a few seconds up to a couple of minutes, depending on the size of the database.

1. Open the Maintenance scheduler status screen and press **Perform** behind the Service Backup function.
2. The Backup starts automatically and a pop up window appears when it finished.
3. Press **Ok** and the scheduler will be updated.

## **8.4 Monthly Maintenance**

Proceed to the weekly maintenance routine.

### **8.4.1 PHOTOMETER CALIBRATION**

This calibration will determine the optimum reading position in the middle of each cuvette.

Please perform this maintenance directly after intensive cuvette clean and cuvette water blank to ensure the cuvettes in Pos 1 are clean. The calibration will take approximately 10 minutes.

1. Open the Maintenance scheduler status screen and press **Perform** behind the Photometer Calibration function and a pop up window will appear. If the cuvette is clean, a new placement is not necessary.
2. Press **Ok** and the calibration will start automatically.
3. When finished refer to the summarize tab and following window will be displayed:

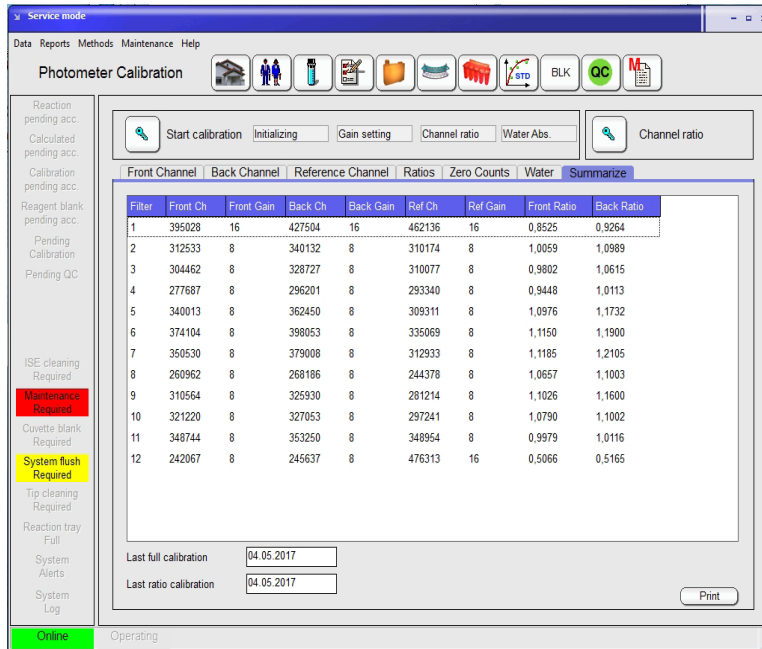


FIGURE 109

Check following values:

Front and Back Gain  $\leq 8$

Ref Gain  $\leq 16$

4. If the gains are over the limit, refer to chapter 9 “Troubleshooting”.

### 8.4.2 WASHER VOLUME CALIBRATION

The washer volume should be between 500 and 700  $\mu\text{l}$ . The calibration will take approximately 3 minutes. The screen will show the pump steps settings and new pump steps required for system delivery in all four wash steps.

1. Perform a System Flush (refer to 8.2.4).
2. Open the Maintenance scheduler status screen and press **Perform** behind the Washer Calibration function.
3. The Calibration will start automatically and a pop up window will appear when it finished.
4. Press **Ok** to get the screen, displayed below:

FIGURE 110



5. If the new values are around 650 press **Save new values** to save them.

### 8.4.3 CLEAN SYSTEM BOTTLES

The system wash- and waste bottles need to be cleaned manually once per month. This is not controlled by analyzer software. Build of dirt and potential biological contamination within the containers could seriously influence performance of the analyzer. To clean the bottles follow the below instructions.

1. Open the Maintenance scheduler status screen and press **Perform** behind the Clean System Bottles function.
2. Take out and empty the system wash bottle.
3. Clean with dilute hypochlorite (1 %) and rinse several times with water and at the end with deionized water.
4. Refill with wash solution (for more information read the IFU of Wash Add Ref 18971).
5. Take out and empty the waste bottle.
6. Clean with dilute hypochlorite (1 %) and rinse once with water.
7. Press **Ok** when finished, the scheduler will be updated.
8. Flush the System.

### 8.4.4 INTENSIVE WASHER CLEANING

To provide a good cuvette cleaning the wash station should be cleaned at least monthly using the instructions below. The procedure will take approximately 5 min. To open the Operation menu select:

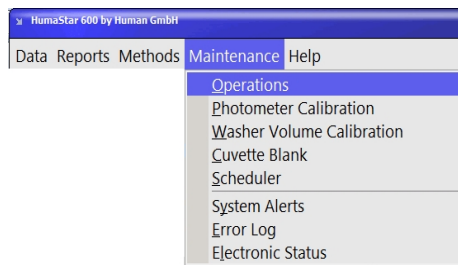


FIGURE 111

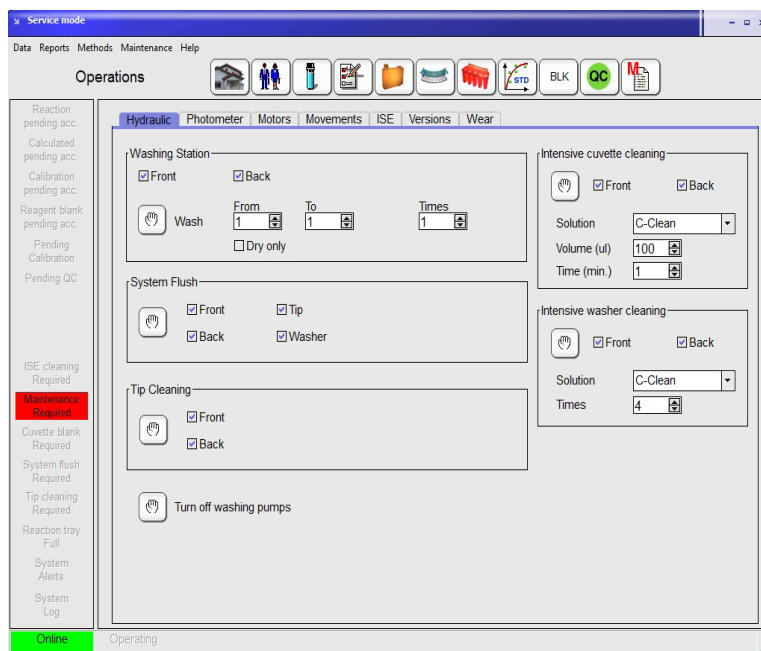



FIGURE 112

1. Check the box for Front and Back in the “Intensive washer cleaning” section.
2. Select the C-Clean for the Solution to use.
3. Check if C-Clean (Ref 16663/20) is placed on the reagent tray.
4. Press  to start the washer cleaning. At the end of the cleaning the system starts a normal wash and drying cycle to clean the used cuvettes. The scheduler will be updated automatically.

At the end of the cleaning the system starts a normal wash and drying cycle to clean the used cuvettes. The scheduler will be updated automatically.

## 8.5 Maintenance on Demand

The tasks below should be performed when instrument indicates the need of corrective action, or when operation anomalies are encountered.

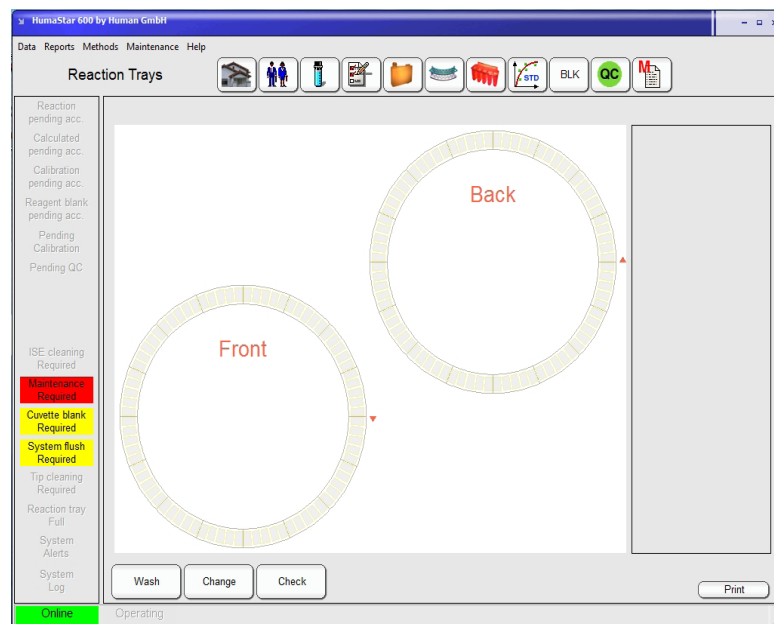
### 8.5.1 CUVETTE CHANGE

Before starting every automatic cycle, the instrument will check the cuvette status. When following circumstances occur the system stops and the cuvettes have to be changed:

- A. When more than 15 cuvettes are out of the absorbance limit (given by the manufacturer)
- B. When the usage value of 25.000 is reached (Maintenance>Operations>Wear)

**All cuvettes should be changed at the same time.** To change cuvettes open the **Reaction Tray Menu**.

FIGURE 113



1. Press **Change** and a following pop up window will be displayed: “Check the Front- and Back Tray box and press **Ok** .”
2. Remove the red and black covers from the front- and back reaction tray.
3. The reaction tray can be turned with the hand to remove all cuvettes.
4. Place new cuvettes and replace the black and the red cover.
5. When finished press **Ok** .
6. The cuvette water blank will be automatically started, when the temperature in the reaction try is reached. The number in the counter table (Wear) will be reset to Zero.



### 8.5.2 LAMP REPLACEMENT

When required, lamp replacement can be easily performed by user following these instructions:

1. Turn off and unplug instrument from Main Plug and wait 10 min in order to let the lamp cool down.
2. Remove lamp cover from left side of instrument, lamp will be visible.
3. Press lever on lamp socket to remove burnout lamp.
4. Insert new lamp in place securely. There is only one possible position due to different size of connecting pins.
5. Lamp is pre-focused, does not require other handling.
6. Reinstall cover, tighten screws.
7. Wait approximately 20 minutes and then start a cuvette water blank.

**!** Do not touch lamp bulb with bare hands, only with gloves. If touched accidentally, clean with lint-free cloth or tissue paper and alcohol.

### 8.5.3 PUMP TUBE REPLACEMENT

The pump tubing has a useful life given by a pre-fixed number of work cycles. When that number is surpassed, instrument will show a message for tubing replacement. At the earliest opportunity the replacement must be done (it is not necessary to stop the system during work).

1. Pull fittings up and out of bracket.
2. Pull tube out of its lodging rotating by hand the pump rotor if necessary.
3. Insert new tube on the fittings.
4. Install in inverse order.
5. Turn slowly rotor by hand until tubing is properly lodged.
6. Reset the cycle counter on the Wear screen (see below).
7. Proceed at least 3 system flushes.

## 8.6 Counters

Some of the parts in the system needs to be tracked how often they are used. The display about the actual numbers will be find in:

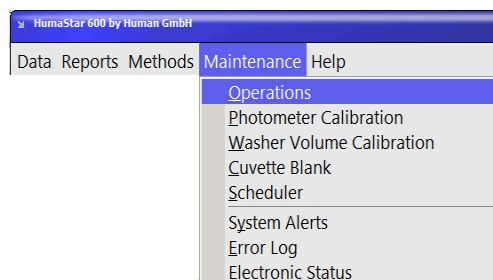


FIGURE 114

Open the **Wear** tab:

FIGURE 115

|                                | Actual | Limit     | Last reset date |       |
|--------------------------------|--------|-----------|-----------------|-------|
| <b>Front</b>                   |        |           |                 |       |
| Syringe cycles                 | 1.701  | 100.000   | 23.02.2016      | Reset |
| Diluter valve cycles           | 3.342  | 1.000.000 | 23.02.2016      | Reset |
| Dryer block cycles             | 5.267  | 500.000   |                 | Reset |
| Dryer pumps cycles             | 5.267  | 250.000   |                 | Reset |
| Peristaltic pump tubing cycles | 4.536  | 50.000    | 23.02.2016      | Reset |
| Peristaltic pump rotor cycles  | 4.536  | 500.000   |                 | Reset |
| Cuvette dilutions              | 0      | 25.000    | 04.05.2017      |       |
| <b>Back</b>                    |        |           |                 |       |
| Syringe cycles                 | 1.709  | 100.000   | 23.02.2016      | Reset |
| Diluter valve cycles           | 3.343  | 1.000.000 | 23.02.2016      | Reset |
| Dryer block cycles             | 4.881  | 500.000   |                 | Reset |
| Dryer pumps cycles             | 4.881  | 250.000   |                 | Reset |
| Peristaltic pump tubing cycles | 4.640  | 50.000    | 23.02.2016      | Reset |
| Peristaltic pump rotor cycles  | 4.640  | 500.000   |                 | Reset |
| Cuvette dilutions              | 0      | 25.000    | 04.05.2017      |       |
| ISE number of samples          | 0      | 10.000    |                 | Reset |
| Lubrication                    | 70     | 250.000   | 25.04.2017      | Reset |

Table includes actual readings, limits and latest replacement dates.

When a limit is reached, the system issues a warning. The maintenance should be done as soon as possible, but there is no need to interrupt routine work. When a replacement is done, the reset button should be pressed to reset the actual number to zero.

Check regularly this table and be sure to have spares for all elements.

## 9 TROUBLESHOOTING

Instrument related problems can be classified into three groups:

1. Operation malfunctions with visual, acoustic or printed warnings.
2. Visible faults or problems.
3. Measurement inconsistencies (for example: GOT method with high dispersion).

### 9.1 Messages and Warnings

Self-explanatory messages are not included in the present listing.

| Message                               | Cause                                      | Action                                 | TABLE 20 |
|---------------------------------------|--|--|----------|
| Change reaction cuvettes.             | All 160 cuvettes are dirty.                | Replace reaction cuvettes.             |          |
| Front / Back syringe exceeded.        | Preset limit is surpassed.                 | Replace at the earliest opportunity.   |          |
| Front / Back pump turns exceeded      | Preset limit is surpassed.                 | Replace at the earliest opportunity.   |          |
| There is no enough cleaning solution. | Cleaning or rinsing solutions are missing. | Replace required System Wash Solution. |          |

### 9.2 Visible faults

#### 9.2.1 GENERAL FAULTS

| Symptom                             | Corrective Action   | TABLE 21 |
|-------------------------------------|---|----------|
| Drops on probe tip after dispensing | Verify hydraulic system in accordance to user's manual.<br>Clean probe tip by submerging in Solution 1 for 5 minutes. |          |
| Drops on tip after wash cycle.      | Verify hydraulic system for leaks or obstructions.  |          |
| Abnormal noises.                    | Defective fans.<br>Moving parts blocked or frozen.<br>Contact Technical Support.                                      |          |

|   |  |
|---|--|
| Temperature in reaction tray is too high. (Do not be concerned about arm probe temperature) | Room temperature too high, (should always be at least 4°C lower than selected working temperature).<br>Example: For 37°C incubation temperature, Room temperature should not exceed 33°C.<br>If Room temperature is within limits, and problem persists, call Technical Support. |
| Temperature in reaction tray is too low. (Do not be concerned about arm probe temperature)  | Room temperature excessively low. Verify instrument operating range, and adequate the room temperature.<br>If room temperature is within specified range and problem persists, call Technical Support.   |

### 9.2.2 MEASUREMENT INCONSISTENCIES

Consider storage and handling of reagents, standards and controls:

1. Verify expiration date, storage temperatures on and off analyzer.
2. Check that reagent was not frozen. Check color changes, sediments, turbidity, no foam.
3. Check for mixed reagents from different lots or re-use of reagent bottles.

#### All methods

1. Verify cuvettes for dirt or scratching.
2. Verify there are no bubbles or droplet.
3. Verify there are no obstructions on probe, check for non constant or regular flow.
4. Recalibrate photometer.

#### Colorimetrics with high dispersion

1. Replace sample by a standard and verify dispersion.
2. Perform hydraulic verification.
3. Check for sample centrifugation, increase time and speed.
4. Perform energy, noise photometric stability and dilution tests.

#### Colorimetrics with proper dispersion but values too high or low

1. Verify standard, compare calculated factor with stored (historic) factors, and recalibrate method. If problem persists, replace standard and/or reagent.
2. Clean probe and check for cross contamination by changing the order of dispensing ("Time priority for reagents" parameter). Check proper probe washing/clean probe.

3. Check for exceeded method linear range; compare method definition with reagent specification.
4. Verify sample volume is not excessive.
5. Perform stray light verification, high range and low range linearity test, and dilution test.

**Kinetics with high dispersion or low linearity**

1. Verify if incubation time is too short or heaters are not working properly.
2. Verify for abnormally high initial absorbance for decreasing kinetics (problems with reagent preparation) or too low on increasing kinetics. Replace reagents and compare results.
3. Check lamp for stability.
4. Use new cuvettes and test again, check cuvettes for dirt or scratching.
5. Perform noise and photometric stability tests, clean filters.
6. For some kinetics: verify if sample volume is too low.
7. For some kinetics: verify centrifugation (increase time and speed).

**Kinetics with normal values too high**

1. Perform energy, noise and photometric stability.
2. Perform temperature verification.
3. Some kinetics: incorrect factor for selected temperature and volume.
4. Replace lamp, clean filters.

**Kinetics with normal and pathological values too high**

1. Verify incubation time and temperature. Perform temperature test.
2. Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

**Kinetics with normal and pathological values too low**

1. Check for short incubation time or low temperature.
2. Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

**Kinetics with values too low or too high on the whole range**

Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

**Two point kinetics (high dispersion)**

1. Verify if standard absorbance is too low (verify data provided by standard manufacturer).
2. Verify initial consumption is too high (verify data provided reagent manufacturer).
3. Perform energy tests.
4. Verify reagent handling and storage.
5. Check method parameter for reagent, low sample volume or too short interval times.
6. Check time table for dispersion on first measurement.

**Two point kinetics (high dispersion)**

Verify factor, standard and method for reagent.

**Repetition or dilution (colorimetric or non linear kinetics)**

1. Verify if sample volume is too high, check reagent linear limit.
2. Replace reagent and compare.

**Repetition or dilution (two point kinetics)**

This is not actually an error; it is because volume / absorbance change relationship is not linear, and so it is necessary to dilute standard and compare.

**Reactions (general comparison between reactions)**

1. Control quality of water.
2. Verify proper usage of solutions (System Wash Solution, rinse solution, etc).
3. Use uric acid to check water quality.
4. Verify for frosted cuvettes (presence of salts).
5. Verify scratching or old reactions residues (not enough washing).
6. Perform instrument validation tests.

**“Standard absorbance error” message**

1. Check/replace standard.
2. Replace standard by a known concentration sample.
3. Decrease parameter “minimal standard absorbance”.

**“Doubtful” flagged reaction**

This message appears when concentration after dilution is lower than measured before dilution; it could be due a bubble, dirty probe or problem in reagent.

## 10 APPENDIX

### 10.1 Technical Specification

|                       |   |
|-----------------------|---|
| <b>Throughput</b>     | Up to 600 test/hr with 1 shot assays; Typical 450 tests/hr with 2 shot assays; plus 120 test/hr ISE (optional).   |
| <b>Analysis Modes</b> | <p>End point with sample or reagent blank.</p> <p>Factor or standard.</p> <p>Priority selection by sample (profile) or by reagent (batch).</p> <p>Calibration curve with any number of standards. Automatic curve fit, multipoint, logit 4/5, etc.</p> <p>Turbidimetry.</p> <p>Fast and two-point kinetics (zero and first order).</p> <p>Routine, batch, STAT procedures, profiles.</p> <p>Enzymes. Drugs.</p> <p>Automatic sample dilution on abnormal levels, excessive substrate consumption and/ or lack of linearity. Automated reflex testing.</p> <p>Full quality control: Levy-Jennings and Twin plots, Westgard rules.</p> <p>Import/export data, methods and historic files.</p> <p>Automatic backup procedure.</p> <p>Test selection, automatic calibration, calibration curve multipoint calibration, polygonal.</p> <p>Sample blank compensation, calculated tests, Quality control, auto re-run, record of calibration, data storage (historic results).</p> <p>Automatic pre-dilution and post-dilution (ratio 1:2 to 1:100)</p> <p>Stat: Highest priority in operation.</p> <p>Continuous sample load.</p> <p>Decontaminating post wash.</p> |
| <b>Samples</b>        | <p>Sample volume: 2 to 100 <math>\mu\text{L}</math>/test (in increments of 1.0 <math>\mu\text{L}</math>).</p> <p>Sample Tray: 95 (5 racks x 19 positions) ID bar code equipped positions for routine, stat and control samples and standard solutions.</p> <p>Primary tube (length up to 100 mm), Pediatric vial</p>  |

TABLE 22

|                                    |  |                                    |                   |                                 |                    |            |                   |
|------------------------------------|--|------------------------------------|-------------------|---------------------------------|--------------------|------------|-------------------|
| <b>Reagents</b>                    | <p>Maximum number of simultaneous tests: 24 double to 48 single reagent tests + 3 with optional ISE unit.</p> <p>1 to 3 reagents, 5 to 500 µL/test each (in increments of 1 µL), final total solution volume 180 to 500 µL/test</p> <p>Reagent bottles capacities: 25 and 70.</p> <p>Reagent cooling compartment: 48 cooled positions. Multiple vials per test.</p> <p>Reagent temperature 9°C+/-2°C for room temperature between 15 and 30°C.</p> |                                    |                   |                                 |                    |            |                   |
| <b>Reaction</b>                    | <p>Water consumption: 5 L / hour.</p> <p>Warm air incubator: 37°C.</p> <p>Reaction cuvette: re-usable plastic 6 mm light path with 6-stage washing</p> <p>Reaction time: 0 to 10 min.</p> <p>Reaction temperature: 37°C ± 0.1°C.</p> <p>Stirring: After dispensing each reagent.</p>   |                                    |                   |                                 |                    |            |                   |
| <b>Optics</b>                      | <p>Double beam</p> <p>Photometric Range: -0.1 to 3.6 A.</p> <p>Measuring wavelength: 340 to 800 nm (selectable among 12 wavelengths). Photometry: Single or Double-wavelength simultaneous reading.</p>  |                                    |                   |                                 |                    |            |                   |
| <b>ISE Unit</b>                    | <p>Na<sup>+</sup>, K<sup>+</sup> and Cl<sup>-</sup> measurements.</p> <p>Samples: serum or urine.</p>  |                                    |                   |                                 |                    |            |                   |
| <b>Data Management</b>             | <p>Windows™ based Software.</p> <p>Interface LIS: bi-directional RC 232 C, according to ASTM 1394 requirements.</p>  |                                    |                   |                                 |                    |            |                   |
| <b>Printout</b>                    | <p>Customer's optimized (Analysis result, work list, list of samples, Quality Control, Calibration curves, etc.)</p>   |                                    |                   |                                 |                    |            |                   |
| <b>Environmental conditions</b>    | <p>Transportation and storage: 10 to 40°C, humidity 30 to 90%, pressure 600 to 1050 hPa.</p> <p>Use: 15 to 30 °C, humidity 40 to 80%, pressure 600 to 1050 hPa.</p>  |                                    |                   |                                 |                    |            |                   |
| <b>Power Requirements</b>          | 110/220V, 50/60 Hz, 1,4 kVA  |                                    |                   |                                 |                    |            |                   |
| <b>Dimensions (WxDxH):</b>         | <table border="0"> <tr> <td>Instrument without any components:</td> <td>100 x 74 x 113 cm</td> </tr> <tr> <td>Space required for routine use:</td> <td>162 x 128 x 160 cm</td> </tr> <tr> <td>Packaging:</td> <td>135 x 86 x 135 cm</td> </tr> </table>  | Instrument without any components: | 100 x 74 x 113 cm | Space required for routine use: | 162 x 128 x 160 cm | Packaging: | 135 x 86 x 135 cm |
| Instrument without any components: | 100 x 74 x 113 cm  |                                    |                   |                                 |                    |            |                   |
| Space required for routine use:    | 162 x 128 x 160 cm   |                                    |                   |                                 |                    |            |                   |
| Packaging:                         | 135 x 86 x 135 cm  |                                    |                   |                                 |                    |            |                   |
| <b>Weight:</b>                     | Gross: 250 kg, Net: 180 kg.  |                                    |                   |                                 |                    |            |                   |









HUMAN

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The logo graphic consists of a horizontal red bar with a white, stylized 'H' shape cutout in the center, positioned to the left of the word 'Human'.

**Human**