

# HumaStar 100/200

| User Manual



CE

Cat No. 16890/1

**HUMAN**

Diagnostics Worldwide



## **REVISION LIST OF THE MANUAL**

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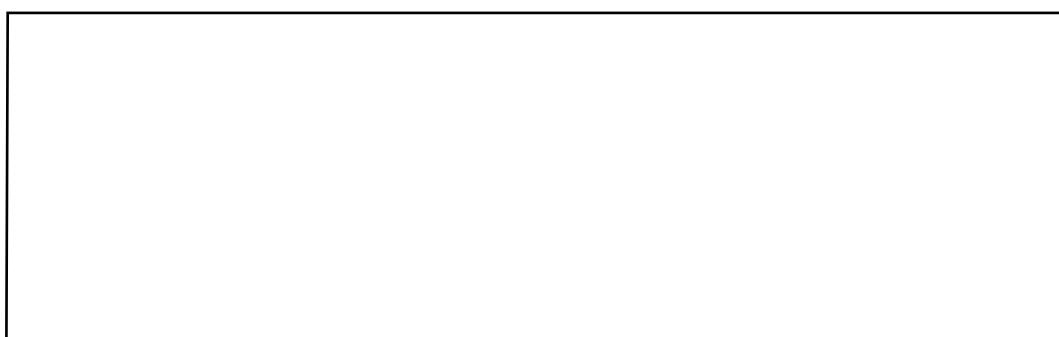
## **SYSTEM VERSION**

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## **SERVICE AND SUPPORT**





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## 1 SAFETY INSTRUCTIONS

### 1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully.

In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the appropriate operating procedures. Please contact your HUMAN authorised local Technical Service in the event of instrument failure or other difficulties with the instrument.

### 1.2 User warranty

HUMAN warrants that instruments sold by one of its authorized 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. 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

The instrument must be used for its intended purpose (see below). It must be operated in perfect technical conditions, by qualified personnel, in such working conditions and maintained as described in this manual. This manual contains instructions for qualified professional operators.



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Recommendation of good laboratory practice and local regulations (e.g. RiliBÄK, CAPGuidelines, CLIA) must be followed. The user must validate and document the performance of the analyzer. Daily quality control using suitable control material of different concentration levels is mandatory.

Quality control is to be repeated whenever the conditions of the measurement have changed (new calibrator, new reagent, service of the instrument, etc.) 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. The HumaStar 100/200 analyzers are automatic random-access clinical chemistry analyzers specially designed and developed to perform clinical chemistry tests for in vitro diagnostic use.

#### **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 flat, stationary working surface, that is free of vibrations. Do not operate in area with excessive dust.

Operate at temperature and at a humidity level in accordance with the specifications listed in this manual. Do not operate this instrument with covers and panels removed.

Use only 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. The 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 environments that are potentially explosive or at risk of fire. Prior to cleaning and/or performing maintenance on 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.

Relevant international safety regulations have been taken into consideration and risks have been reduced in the design and manufacture of the analyzers. However, many sources of danger are outside the operating parameters of any instrument but are inherent to the conditions of operation and to the testing process itself.

The safety precautions are organized under the following headings:

- Electrical
- Biohazard
- Health
- Labels
- Waste
- Disinfection
- Damage or malfunction

### 1.5 Electrical hazard

The initial and most immediate dangers in instrument operations are those caused by contact with electrical system. This may be the result of instrument failures, incorrect procedures or by the incautious behaviour of the operator. Risks of this nature may involve extreme danger to laboratory personnel and in addition may cause severe damage to private or public objects and equipment. Proper outlet connections are absolutely mandatory.

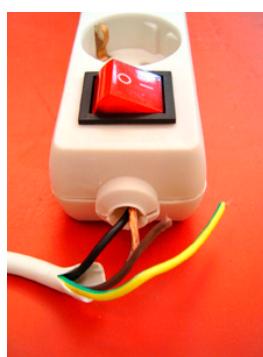


FIGURE 1

Improper use of extension cords increases the risk of electrical overload.

**FIGURE 2**

Install a surge suppressor to avoid any loss of data.

**FIGURE 3**

- It is mandatory to connect the power cable of both computer and instrument directly to electrical outlets that are properly grounded to reduce, in so far as it is possible, the risk of electrocution.
- If extensions cords are required they may be used only upon the advice of an electrician capable of specifying the hardware required to avoid an overload of the connections.
- When liquid is released inside the analyzer by improper operation, it is very dangerous to continue using the instrument. If this occurs, unplug the power cable to avoid electrical shock and contact technical assistance. By removing the cabinet, laboratory personnel risk contact with dangerous high voltage parts.
- Never insert objects in the openings of the cabinet of your computer or instrument. Such action is extremely dangerous and can cause shorting out of interior components including the possibility of fire or even fatal electrical shock.

- Install a surge suppressor and an uninterruptible power supply (UPS). This will help to shield your computer from sudden, transient increases and decreases in electrical power.
- Be sure that power connections of the analyzer are not connected to the same circuit of all important equipment or facilities (such as surgical equipment, respirators or critical refrigeration) to ensure the continuous operation in case of a failure of the analyzer.
- Before cleaning the instrument with liquid products, remember to disconnect the power cables from the electrical outlet.
- Nothing should rest or be placed on the power cables. They should be arranged in such a way as to avoid laboratory paths of circulation where they can be walked on or fallen over.
- Fuses according to the electrical specifications provided must always be used. Never short circuit fuse-holders or substitute a material with the fuse replacements provided.

## 1.6 Biohazard

Analytical instruments for in vitro diagnostic application 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. The instrument is labelled with the "BIOHAZARD" warning label shown below.



FIGURE 4  
Biological hazard symbol

Risks of this nature involve the use in any form of any of the liquids inherent in the clinical testing process, whether they be samples, reagents, calibrators or controls (e.g. calibrators and controls may be prepared from human serum and therefore should be considered as potentially hazardous as the samples to be tested) or liquid waste. When dealing with these liquids in any capacity, follow

the instructions of manufacturer, HUMAN distributor, supplying agency or other for exact procedures regarding handling, manipulating of any kind, mixing or disposal.

#### **1.6.1 Precautions following liquid contact**

- To ensure complete safety, contact with any liquid during laboratory work should be considered suspect and potentially dangerous for personal health and any areas exposed should be flushed immediately with water and be disinfected.
- Regardless of type, all samples should be immediately considered infectious, and upon contact users should quickly wash the exposed areas with soap and water, and quickly receive treatment according to laboratory standards. A doctor or an appropriate medical facility should be contacted as soon as possible.

### 1.6.2 Laboratory work habits

- Never touch samples mixtures and waste liquids with bare hands. Disposable plastic gloves should be worn at all times during laboratory work.
- In addition to that, to avoid a higher risk of infection owing to cuts, abrasions and other skins lesions, protect properly any wound with suitable care.
- Never pipette by mouth when transferring liquids. Use only appropriate disposable pipettes or pipette tips to avoid contamination.
- Wear safety glasses, surgical mask and lab coat (or other protective clothing) at all times during testing or other potentially hazardous tasks.
- Use different containers to prepare and store all liquids and label each one to avoid unwanted mixing.
- Never mix different liquids together if not required by specific procedure. For example a mix of acid and alkaline detergents may produce hazardous toxic gas.
- Never wash or reuse disposable material (e.g. tubes, cups, pipettes). Any potentially infected object must be disposed following the local law procedures and never used again for any purpose.
- Wear safety gloves and wear a laboratory coat at all times.
- Use disposable pipettes.
- Use safety glasses and a protective mask for critical works.



FIGURE 5

FIGURE 6

## 1.7 Health

### 1.7.1 Lamp

To replace the halogen lamp, switch-off the power and wait at least 5 minutes for the lamp to cool down. If you touch the lamp before it is cool you may get badly burned. Direct light from the halogen lamp may result in damage to the eyes. While the analyzer is turned on avoid looking directly into the lamp or the beam.

### 1.7.2 Moving parts

Do not touch the moving parts of the analyzer while the analyzer is operating (e.g. sample arm and reaction rotor). Do not insert fingers or your hand in an opening. Make sure to not pinch your fingers when closing the lid of the instrument. Hold the lid with two hands. Only hold the lid by the front handle. Only operate the instrument when the cover is closed. Never open the cover while the instrument is running.

### 1.7.3 Cleaning solutions and reagents

Any contact with cleaning solution can be extremely dangerous. In case of accidental contact with either skin or eyes or other mucous membranes, rinse with large amounts of water and seek medical attention.

Some reagents are strong acids or alkalis. Exercise great care so that reagents do not come into contact with any part of the body or clothing. Rinse areas that come in contact with reagents immediately with clear water. If a reagent comes into contact with your eyes, rinse with clear water for at least 15 minutes and immediately consult a doctor.

Always read the Material Safety Data Sheets (MSDS) and other relevant product documentation that are provided for reagents and solutions.

## 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.

### Electrical

**WARNING - Electrical risk:** This label is placed on the right side of each analyzer adjacent to the power switch to alert the operator of the presence of high electrical voltage.



FIGURE 7

### High temperatures

**WARNING - Lamp:** This label may be placed on the panel covering the lamp housing to alert the user of the high temperatures possible with the halogen lamp.



FIGURE 8

### Biohazard

**WARNING - Infectious area:** This label is placed conspicuously on the upper front of the analyzer cover to alert user of the risk of contamination when using any biological materials (serum, plasma, urine, controls, calibrators).

**WARNING - Waste tank:** This label is placed on the external waste tank to alert the user of the risk of contamination from the liquid contained.

**WARNING - Waste connections:** This label is placed on the left side of the analyzer near the waste connections to alert the user of the risk of contamination from liquids within.



FIGURE 9

### **Corrosive, acids, alkalis**

Further labels for corrosive substances, acids or alkalis may be placed on the respective products.

**WARNING - Corrosive:** This label is placed on cleaning solutions that have ingredients in sufficient concentrations to be classified as corrosive.

**FIGURE 10**



### **General warning**

This label is placed as a general warning of all dangers that are related to the instrument (e.g. moving parts, pinching fingers).

**FIGURE 11**



## **1.9 Waste - 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 dismounted from electric/electronic parts and disposed off in accordance with applicable local regulations. The waste liquids are classified as CER 180103 according to CEE directives 91/156/CEE, 91/689/CEE, 94/62/CEE.

### **1.10 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 authorized 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.

### **1.11 Damage or malfunction**

If the instrument shows any external damage or any malfunctioning during operation, immediately disconnect the power cord and contact your HUMAN distributor for technical assistance. Under no circumstance should technical interventions be performed by any other than approved engineers and qualified specialists.



## 2 ANALYZER DESCRIPTION

### 2.1 The analyzer

Intended Purpose: "HumaStar 100/200 is an automated analyzer for the photo-optical determination of levels or activity of various clinical chemistry parameters and electrolytes in human serum, plasma, urine, or whole blood. In combination with HUMAN's clinical chemistry reagents, it may be used as an aid to diagnosis, for screening, or monitoring, depending on the used reagents, of a range of medical conditions. For laboratory professional use only." Methods for Human Reagents are preinstalled and validated.

However this does not relieve the user from validating each method for himself in his own environment and for his patient population. Especially the reference ranges (Pathological Ranges) are not preset for HUMAN methods. They must be evaluated and entered locally.

The analyzer automatically performs reagent and sample pipetting, incubations, photometric measurements and calculations. Programming and operating the analyzer is simple and made easy by the intuitive user interface software (HI software). The software, which is supplied with the analyzer, has to be installed on a PC connected to the instrument via USB.

The HI software is used as interface between the analyzer and the operator. It allows the operator to program tests, organize results, perform and analyze quality controls, check the status of the analyzer and much more. The low level control of the analyzer is implemented on the integrated electronics. The analyzer can perform tests with one, two or three reagents, monochromatic or bichromatic, end-point, differential, fixed time and kinetic mode. Calibration can be made using a factor or using calibrators. Multi-calibrators can be programmed and interpolated as linear or non linear functions.

All results are permanently stored and are traceable to the method. Quality control results can be examined as a list or in a chart format. Features of the instrument includes reagent cooling, automatic washing of the reaction cuvettes, and a sample barcode reader. Samples can be placed on the instrument using primary tubes or sample cups. Different sample trays allow the use of different sizes of sample tubes and cups.

## 2.2 Reagents

### 2.2.1 Reagent trays

The instrument has a removable reagent tray with 29 positions for reagents and 1 for diluent. Each position can be used for small (20ml) or large (50ml) bottles. Independent refrigeration permits reagents to be cooled on-board when the analyzer is switched off. Anyway it is recommended to close reagents and keep them in the refrigerator if not needed for a longer period. Multiple assortments of reagents can be prepared in advance of testing using additional trays. Multiple assortments of reagents can be prepared in advance of testing using additional trays. See also chapter 4.

The reagent tray consists of a recessed semicircular compartment adjacent to the rotating sample arm. The bottom of the compartment is lined with a continuous refrigerated plate. When in position the tray permits bottles to rest directly on the plate. Refrigeration is provided by three 30W Peltier cells mounted directly under and in contact with the plate. A heatsink and fans located below cool the lower heated surfaces of the Peltier cells.

### 2.2.2 Diluents

Position 30 ("DIL") on the reagent tray is reserved for the diluent. This position cannot be used for any other reagent or solution. Most Human methods use physiological (0.9%) NaCl solution as diluent. Refer to the leaflet of the reagent to know which diluent is suitable for your method. Diluent is necessary to finish start-up procedure.

**Note:** You may also order Diluent (cat. no. 16663/10) for the analyzer, in case physiological (0.9%) NaCl solution is not available locally.

**Do not use NaCl-solution as diluent for methods that are influenced by either sodium or chloride.**

### 2.2.3 Special Wash Solution

Special Wash Solution (also called „Cleaning“ in Hi software) is a mix of de-ionized water (max. 10 µS) and sodium hydroxide (NaOH). The final concentration of NaOH in the tank must be 60 mmol/l (equal to approximately 0.24% NaOH).

The easiest way is to order the Special Wash Solution from Human:

Please check the leaflet of Special Wash Solution (cat.no. 18974) for the dilution and preparation to be used on the analyzer.

Cat. no. 18974 contains 30 ml of NaOH (2 mol/l) in each bottle.

! Note: Special Wash Solutions  
are classified as dangerous goods.

Read the leaflet and the material safety datasheets of the solutions carefully. NaOH in the concentrations above is considered corrosive and has to be handled with care.

#### Extra wash

There are two types of wash solutions that can be used for the "Extra wash" option. The solutions are ready to use in reagent bottles.

Cat.No.	Name	Content
18973	Cuvette Clean	4x100ml
18974	Special Wash Solution	12x3ml



#### Post injection

For the "Post injection" option, Cuvette Clean (Cat.No. 18973) must be used.

! Note: Most HUMAN turbidimetry methods are programmed with the "Post injection" option and require Cuvette Clean for execution.

Cat.No.	Name	Content
18973	Cuvette Clean	4x100ml

#### **2.2.4 Placing solutions and diluents on the sample tray**

Instead of placing (wash) solutions and special diluents on the reagent tray, you can also place solutions or diluents on the sample tray. The purpose of this feature is to save positions on the reagent tray. Solutions and diluents on the sample tray can be used and accessed by methods. Position 60 of the sample tray is reserved for this purpose. If you do not require this feature and want to use all 60 positions on the tray for samples, it can be deactivated by your service engineer.

#### **2.2.5 Reagent cooling**

All reagent positions of the instrument are cooled by peltier elements. If you want to completely turn off the analyzer and/ or the reagent cooling (e.g. during night or weekend), close all reagent bottles and store the complete reagent trays in a refrigerator.

You must not remove the bottles one by one, it is very convenient to put the complete reagent trays into a refrigerator.

### **2.3 Sample quality**

The analyzer does not automatically detect lipaemic, icteric or hemolytic samples. Limits for interference with reagents are listed in the reagent leaflets. Users are required to check the sample quality visually before placing them on the analyzer.

### **2.4 Random access**

The working process of HumaStar 100 and 200 analyzers is completely optimized for random access operations. Tests are executed in the scheduled order with a test completed and a result produced every cycle. This is achieved by fixing machine-cycles for each instrument type, and each type may differ.

HumaStar 100, has a standard 36-second cycle it can perform two operations. which allows a rate for both single or double reagent tests of 100 tests per hour. (For double dispensation with incubation time 1 equal to 180 sec.) Thus the maximum time for the longest test (Incubation 1 + Incubation 2 + Readings) is 22 machine cycles for a total of 792 seconds or, with HumaStar 100, slightly more than 13 minutes per test. Laboratories are free to organize their work schedule, per sample, per method or per job.

HumaStar 200 has a standard 18-second machine cycle, but can only perform one operation per cycle. Maximum incubation times are however equal to HumaStar 100.

#### Test priority

Within the scheduled testing order described above, the three test levels are given the following priorities:

- **First level:** Reagent blanks and calibrations.
- **Second level:** Samples defined urgent (see chapter 6.3.1 for details).
- **Third level:** Normal tests and QC's.

## 2.5 Multiple readings

The instrument can take a reading at every machine-cycle for every test. Up to 20 readings can be taken for every test (usually a feature found only in large analyzers). This number of readings allows that the reaction curve can then be inspected visually and rejected if unsatisfactory.

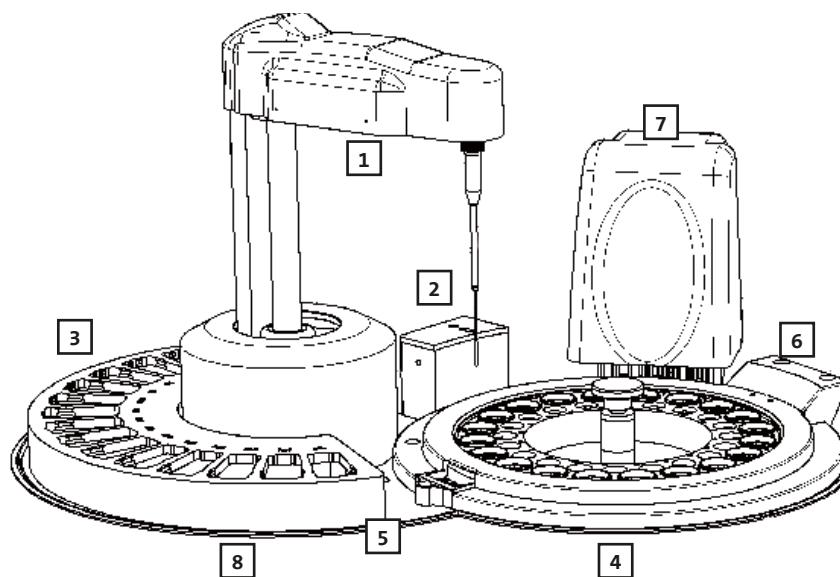
By default the instrument is configured to perform readings at every machine cycle. To slightly increase the throughput, readings can also be taken only during machine cycles which are necessary for the calculation of the results.

### 2.5.1 Part identification

#### Analyzer

FIGURE 12

- 1 Pipetting arms and needles (with shock sensors).  
Arm 1= left. Arm 2 = right.
- 2 Needle wash stations
- 3 Reagent trays
- 4 Sample tray
- 5 Cuvette rotor
- 6 Optical group
- 7 Cuvette wash station
- 8 Sample barcode

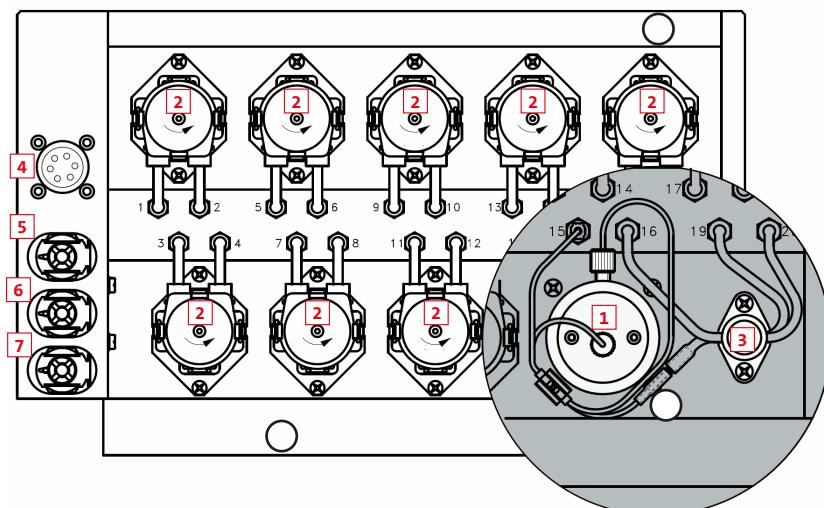


#### Hydraulic panel

The hydraulic panel is accessible by removing the cover panel on the left side of the instrument where are located the tank connections.

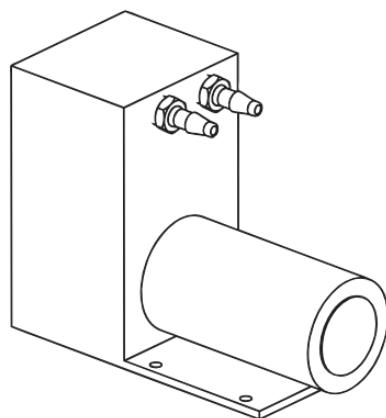
FIGURE 13

- 1 Diluter syringes
- 2 Peristaltic pumps
- 3 Pinch valves
- 4 Tank level sensors connector
- 5 Water rapid connection
- 6 Cleaning solution rapid connection
- 7 Waste rapid connection



### Mechanical functions

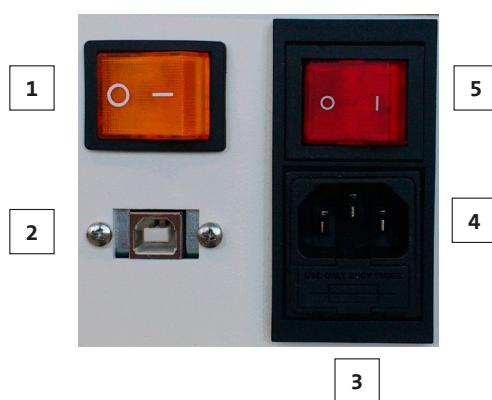
The principal mechanical movements are powered by stepper motors which are activated when the analyzer is switched on and remain on until power-off or stand-by. The liquid movements are controlled by eight/six peristaltic pumps and two vacuum pumps powered by direct current motors and activated when required.



**FIGURE 14**

The number of pumps differs from HumaStar 100 to HumaStar 200

### Connection panel



**FIGURE 15**

- 1 Switch for reagent refrigeration
- 2 USB port
- 3 Fuse compartment
- 4 Power cord fitting
- 5 Main power switch

**!** Note: You must never open the cover while the instrument is running! Movements are only stopped by the cover switch after some delay. The risk of moving parts is not completely prevented.

### Cover switch

As a safety precaution the analyzer is equipped with a cover detection switch. When the cover is open or not properly closed, movements of the sampling are suspended. The software will monitor if the cover is open or not. Internal functions (e.g. test readings and cuvette wash) continue as programmed.

## 2.6 Specifications

### 2.6.1 General

TABLE 1

Item	Specification
Analyzer type	Benchtop
Throughput approx.	HumaStar 100: 100 tests/hour* for single- and double-shot methods
	HumaStar 200: Up to 200 tests/hour* for single-shot methods
	Approx. 120-130 tests/hour* for a typical panel of 3 single- and 4 double-shot methods.
	* Valid if double-shot methods run with standard in- cubation time between 1st and 2nd pipetting of 180 seconds and no special cleaning or “post reaction injection” option and no incompatibility is selected. Maximum incubation + reading time: 792 seconds
Dimension instrument	69x76x52cm (WxDxH)
Space required for routine use	Min. 150x90x100cm (WxDxH)
Weight instrument	51kg
Operat. environm.	Operating temperature instrument: 16°-30°C Variation during testing must not exceed +/-2°C Maximum operating temperature for automatic check of reagent and calibration stability: 25°C (see chapter 2.2.5) Relative humidity: Up to 80% non-condensation Pressure: Up to 2000m of altitude

Power supply	220 - 240 and 110-120 Vac 50 / 60 Hz, single phase with ground Independent on-off switch for refrigerated reagent plate Independent on-off switch for refrigerated reagent plate Fuse compartment/ fuses: T2A/250V, 5x20mm Used for 230 and 110 VAC Power consumption: less than 200 VA (external PC excluded) Ground resistance: less than 0.1 Ohm Leakage current: less than 2.5mA The use of an online UPS is mandatory. Instrument and computer must be grounded.
External computer	Instrument is controlled by external computer Connection of external computer via USB port
Computer: Recommended	19 inch touchscreen, 1280 x 1024 resolution, 6 USB ports, Core i3, 4GB RAM SSD (Solid-State-Drive) memory (min. 64 GB)* No Atom CPU or use dedicated graphic GPU 6 USB ports (instrument, mouse, keyboard, printer, touch screen) LAN port for LIS host communication External printer, A4
Instrument control	Instrument continues operation independent from external PC (low level control computer implemented in instrument electronics) Real-time multitasking microprocessor based control Easy access to the electronics
Adjustments	Mechanical adjustments by service engineer through software (teaching) Optical adjustments automatic by software
Working mode	Random access, STAT (urgent), continuous access (using pause function)
Start-up	The start-up procedure is run daily: self-test, reader offset of optics, wash and check of all cuvettes Duration: Approximately 45 minutes.
Errors and warnings	Logging of warnings and errors
User languages**	English French Spanish
Different access levels	User, Administrator, Service Password protection

\*Software can react slow when using a HDD for data storage. Therefore SDD is highly recommended.

\*\*Additional languages can be translated by distributor

### 2.6.2 Reagents

TABLE 2

Item	Specification
Reagent types	Substrates, Enzymatic, Turbidimetric, Latex-enhanced turbidimetric
Reagent tray	removable rack, aluminium base and upper part made of plastic
Number of reagent bottles on board	30 bottles total
Reagent refrigeration	Approx. 9°C below room temperature (measured at the bottom of the reagent bottle)
Reagents	50 or 20ml bottles or sample tubes/cups with adapter (Cat. No. 16890/15)
Placing bottles	Continuous loading After clicking <b>Pause</b> , loading of new bottles is possible as soon as 2 <sup>nd</sup> pipetting of an ongoing test is finished. Ongoing test is lost, if cover is opened anyways.
Drain	Drain for condensation water in reagent tray. Instrument must be slightly tilted. Outflow underneath instrument with possibility to connect tube.

### 2.6.3 Reaction and liquid system

Item	Specification
Cuvette rotor	80 washable BIONEX™ cuvettes Up to 30 000 tests per rotor Optical path 6mm
Reaction volume	210 - 350µl
Temperature control	100W heating resistance, temperature sensor, safety thermostat Reaction cells: 38°C +/-0.2°C *. Reagent at approx. 37°C. Heat transfer by air *after stabilization of temperature
Hydraulic system	8 (HumaStar 200) or 6 (HumaStar 100) self-priming peristaltic pumps with replaceable neoprene cassette 2 Vacuum pumps 2 Pinch valves Manifold
Cuv. wash station	8 step washing sequence for each cuvette Needles: - 6 dispensing + aspiration, 1 aspiration, 1 cleaning (HumaStar 200) - 4 dispensing + aspiration, 1 aspiration, 1 cleaning (HumaStar 100) (8 step washing sequence for each cuvette)
Water consumption	100: Less than 1 l/h 200: Less than 2 l/h 8ml/test *
	* for standard washing procedure (no. 1) of cuvettes and needle. Start-up, maintenance and shut-down not included.
Water quality	De-ionized or distilled Minimum <10µS Filtered
Water tanks	Systemic solution, 20l Cleaning solution, 2l Waste, 20l (biohazard) All tanks are equipped with level switches and safety connectors
Waste transport	Pump for transport out of the instrument

TABLE 3

#### 2.6.4 Pipetting system

TABLE 4

Item	Specification
Pipettor	One pipettor. Used for sample and reagent.
Needle washing	Sampling needle washed internally and externally after every operation Washing intensity parameter included in method setting
Level sensing	Capacity measurement
Collision sensors	Vertical direction
Sample pipetting	Range 2 - 300µl
Reagent pipetting	Range 5 - 350µl
Mixer(sample,reagents)	Mixing by sample needle upon dispensation
Pipetting precision	< 1 CV% for 16µl (within run); < 1.5 CV% for 8µl (within run)

#### 2.6.5 Samples

FIGURE 16

Item	Specification
Loading	Continuous sample programming in user software Programming of new samples during ongoing measurement Continuous loading After clicking <b>Pause</b> , physical loading of new samples is possible after pipetting 2 of an ongoing test is finished. Ongoing test is lost, if cover is opened before. STAT function
Sampling arm	1 Sampling arm, 1 sampling needle, 110mm needle stroke
Samples tray	Included in standard delivery (Cat.No.16890/10): Removable tray, 60 numbered positions*: (Primary) tubes of 12-12.5mm, max. 100mm length, 5-7 ml; 10mm cups of 0.5-1.5ml, (cups require a metal adapter for level detection, Cat.No. 16890/12) Optional accessory (Cat.No. 16890/11): Removable tray, 20+20 numbered positions*: 20 (primary) tubes of 12-16mm, max. 100mm length; 20 cups (2ml type, Hitachi compatible)
	*By default 1 position is reserved for diluents and wash solutions. See chapter 2.2.4.

Diluter syringe	Long life plunger Syringe capacity: 368µl Syringe resolution: 0.07µl Automatic dilution process (pre- and post-dilution) In-needle dilution if allowed by method's sample volumes Automatic pre-dilution in a reaction cuvette, up to 1:100 Automatic sample dilution (dilution ratio calculated by the instrument) of abnormal levels, excessive substrate consumption and/ or lack of linearity. Automatic pre-dilution for calibrators (up to 8Stds.), controls and samples to fit any method requirement.
Sample Barcode	Internal sample barcode reader Positive identification of samples, controls, standards Label position min. 60mm above lower end of the tube.
Barcode types	1D Codabar Code 128 Code 39 2 of 5 Codes UPC/EAN ISBT 128
Sample statistics	Mean, CV%, SD
Automatic request	Calibrators added automatically to worklist if need (calibration stability)
Dead volume	Typically: 13x75mm tubes: 200µl 16x100mm tubes: 400µl 1ml cups: 100µl 2ml cups: 100-150µl

## 2.6.6 Measurement

FIGURE 17

Item	Specification
Photoamplifier	Photoelectric detector Signal amplifier Response range: 340nm to 900nm Low electronic noise
Optical group	Lamp, filter disk, cuvettes, detector, amplifier, 2 focusing lenses, optical glass. Direct reading reaction cuvettes, 6mm optical path During the run, periodical measurement of lamp emission at all the wavelengths and compensation for drift Optical group completely closed, protection against dust and humidity. Interference filters size of aperture: 10mm external diameter including metal sleeve. Optical diameter 8mm
Wavelengths	10-position filter disk: 8 positions provided with interference filters of 340, 405, 505, 546, 578, 600, 650, 700nm wavelengths 1 free position and 1 solid position for dark reading
Wavelength accuracy	+/-2nm on peak wavelength
Half Bandwidth	10nm
Band pass	+/-5nm
Measurement	Monochromatic reading Bichromatic reading
Photometer precision	Δ Abs 0.02 Abs (within run); CV < 1% at 1 Abs (within run); CV < 3% at 0.05 Abs (within run)
Photometer linearity	0.25 to 2.5 Abs
Lamp	1 halogen lamp (6V, 10W) with extended UV emission Lamp can be changed by end-user
Lamp life	Automatic lamp saving mode: Voltage reduction, fast reactivation
Adjustment	Gain is adjusted automatically by the instrument It is not necessary to adjust offset in the field
Earliest reading time after sample adding	<3 sec after end of mixing
Cuvette blank	Individual blank taken and used for every cuvette Separate blank for each wavelength
Cuvette check	Automatic cuvette check and by-pass of dirty cuvettes (Startup, washing, measurement)
Time to first result (from standby)	<10 min

Timing information	Time until all tests are finished
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### 2.6.7 Methods

Item	Specification
Method types	Endpoint Kinetic Fixed time Bichromatic end-point Bichromatic kinetic Self-blank ( $OD2=R1+R2$ or $R1+S$ , $OD1=R1+R2+S$ ) Differential endpoint Differential endpoint with sample blank Calculated tests
Test methods	60 active methods on instrument
Reaction time	Maximum 756 sec. (from 1 <sup>st</sup> to last cycle)
Cycle steps	Add R1, add (R1a+R1b), read reagent blank, add sample, mix, read sample blank, incubate, read, add R2, mix
Units	One unit used for results and reports. A second unit is used for the calibrators and controls management
Method version	Version number is set for methods to assure traceability
Date of last change	“Date of last change” is updated automatically for methods to assure traceability
Method Notes	Method notes allow additional information to the user
Multiple reagents	Up to 3 reagents

TABLE 5

### 2.6.8 Calibration

TABLE 6

Item	Specification
Calibration	Free standard/ control positions on sample tray Monitoring of calibration and controls. Missing calibration and control are indicated to the user.
Calibration database	All calibrations (including expired calibrations) are saved in a database and can be viewed
Calibration curve	<b>Linear</b> Factor Linear regression Average (repetition of standards) <b>Non-linear</b> Cubic Spline Polylinear Multiparameters (logit-log) Four parameters ((logit-log)) Five parameters (sigmoidal) <b>Up to 8 standards</b> Calibration curve can be displayed and printed
Detection of outlier	Automatic detection of outliers in the calibration curve  Outliers can be repeated without repeating the complete calibration
Repetition of standard	Each measured standard can be repeated individually
Reagent blank	Can be selected to be included in calibration curve calculation (optional reagent blank subtraction) Validity time can be defined Reagent blank is used for integrity check of the reagent

### 2.6.9 Service and maintenance

Item	Specification
Maintenance	Software controlled routine maintenance program
Maintenance by service engineer	Once per year (with typical throughput of <650 tests/day)
Firmware update	Firmware can be updated by service engineer

TABLE 7

! Note: Software version 1.2 and higher requires at least firmware version 1.36 or higher

### 2.6.10 Data handling

Item	Specification
Result database	All results are stored in a permanent database Search function in database
Traceability of results	Method and calibration details are linked to the result
HOST/ LIS	Ethernet LAN (samples, work list, results) Standard ASTM protocol Bi-directional polling mode on LAN
Reports printing	By patient, single test, complete sample, work sheet, method and QC's, calibration curves, kinetics, continuous printing (automatic printing of sample report when his tests are finished) Automatic sample reports upon test completion if requested Cumulated patient report (sort by method or by date)
Update of methods	Intelligent and comfortable update Update procedure detects method with new date which is available and updates this method upon confirmation
Quality control	Three-level controls per test Calibrator/ control LOT monitoring, exclusion of failing results from graphic and statistics is possible Levey-Jennings plots Westgard multi rules (5 rules)

TABLE 8

## 2.7 Installation

### 2.7.1 Site

Prepare a location for your analyzer based on maximum laboratory efficiency and adequate work space. Keep in mind the patterns of work and staff circulation to ensure a trouble-free lab operation. See also chapter 1 *Safety instructions*. An example of an ideal bench-top work surface.

FIGURE 18



- The laboratory bench for the analyzer has to be a level surface of solid construction. This is to avoid vibration, malfunction and twisting of the cover.
- Instrument feet have to be at equal distance and stand on a level surface.
- A space of 15cm on both sides and behind the instrument is the minimum requirement to allow adequate ventilation. Ventilation is essential for the cooling of the analyzer's components. Reagent cooling, calibration, blank stability) can only function properly, if adequate ventilation is allowed.
- An additional work area on one or both sides of the instrument will contribute greatly to the work efficiency of laboratory personnel during operation.
- If sufficient space is available a surface 90-100cm deep by 170-200cm in working width will allow a generous surface for the analyzer and the necessities of work (e.g. tubes, reagents, samples, calibrators, controls, pipettes, user manuals). 110cm in free height are necessary to conveniently open the lid of the analyzer.

### 2.7.2 Environment

- The location of the analyzer should be dust-free, away from drafts, heat sources and direct sunlight.
- Satisfactory operation of the analyzer may be conducted with temperature ranges from 16°C to 30°C and with a variation during the testing process not to exceed ±2°C. Temperatures outside this range may cause erroneous operation.
- Air conditioning may be required to ensure result quality if temperatures exceed limits.
- Relative humidity should not fall below 10% or rise above 80% with no condensation.
- Ensure that the electromagnetic standards are met. Refer to European directive on electromagnetic compatibility.

### 2.7.3 Storage

If for any reason the instrument has been subjected to prolonged storage or is moved to a new location, a revision and installation by a specialized engineer is required before proceeding with operation.

### 2.7.4 Shipment

- The shipment of the analyzer generally is the responsibility of the HUMAN distributor and delivery is often made in person by an agent of the HUMAN distributor.
- If the shipment arrives by private or commercial carrier, immediately inspect the condition and if there is any damage to either container report it immediately to both transporter and HUMAN distributor.
- Check if the shock and/ or tilt indicators have been activated during the shipment.
- If the damage is extensive, it may be best to refuse the shipment to avoid any doubt in the attribution of responsibilities.

**!** Note: It is always advisable to keep the wooden container in case you need to return the analyzer for adjustment or repairs.

## 2.8 Unpacking

The analyzer arrives in a wooden container. The top of the container is secured with screws. The box is built with nails which should never be removed, only the screws should be removed. If you are not sure on what to do, it is best to wait for the arrival of a representative of the HUMAN HUMAN distributor to remove the analyzer from the container.

In order to open the box:

1. Unscrew with the help of a normal Philips screwdriver the screws that are present on the superior part of the box.
2. Lift the top cover and check for any damage that may have been caused during the transportation. In case of damage please contact your local HUMAN distributor.
3. Unscrew with the help of a normal Philips screwdriver the screws that are present on the inferior part of the box.
4. Lift the external wooden walls.
5. With the help of a wrench remove the metal supports that hold together the instrument and the wooden platform.
6. Move the instrument from the wooden platform to the work surface where it will be installed.

### Upon arrival

The application of safety procedures should begin at the installation stage. Although it may be overlooked, this initial phase can also involve risks, that should be taken into consideration, some more serious than others.

- Care should be taken during the unpacking of the shipment, particularly when using tools and sharp instruments that may cause injuries.
- One person should never try to move the analyzer alone. A move properly requires at least two people, both from the point of view of the people doing the work and for the safety of the instrument. Move the instrument by holding on to the metal frame underneath the instrument.

- Plug the computer and the instrument power cables into properly grounded electrical outlets to help prevent electrical shock. Proper grounding is not only important for the security of the user, but it is also important for the quality of the measurement signal. Improper grounding can cause interfering signals in the photometer. The quality of the measurement, especially the precision, can be deteriorated. **10 Ohms resistance between the outlet and the ground** can be regarded as a guideline, but need to be confirmed by a capable local electrician.
- All instruments should be connected directly to a suitable electrical outlet. Extension cords may be used only with the advice of an electrician capable of specifying the hardware required to avoid an overload of the connections.
- Install a surge suppressor and an uninterruptible power supply (UPS). This will help to shield your analyzer and computer from sudden, transient increases and decreases in electrical power.
- After installation or moving of the instrument, it needs to be checked and readjusted by a trained engineer. The performance of the instrument can deteriorate if it is not well adjusted.

## 2.9 Installation

The installation of the instrument must always be performed by a trained engineer. Recommendations of the Human Service Manual (Cat.No. 16890/2) must be followed.

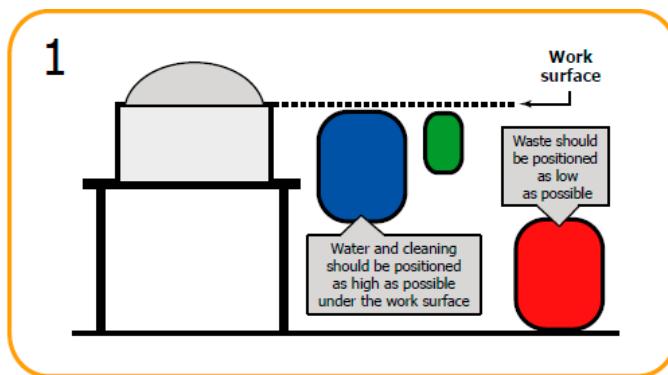


FIGURE 19

**!** Note: Hydraulic tubes have easy-to use snap-on connectors, each with a special valve to prevent liquid loss when disconnecting the tubes. Ensure that the metal tab of each connector is released and ready to be snapped in place to ensure a safe attachment.

1. Place the three tanks below the work surface as described in the picture.
2. Position connecting tubes as straight as possible to avoid the creation of air bubbles.
3. Insert and rotate the BLACK connector to secure the three liquid level sensors.
4. Connect the three tanks to the corresponding hydraulic tube connections on the analyzer.
5. Hydraulic connections are colour coded as follows:

Blue	Water tank (20l)
Green	Cleaning solution tank (2l)
Red	Waste tank (20l)

6. PC connections
  - Connect the USB mouse to a PC port
  - Connect the USB touch-screen (optional) to a PC port
  - Connect the USB keyboard to a PC port
  - Connect the monitor to PC
  - Connect a power cord to the monitor and to the power outlet
  - Connect a power cord to the PC and to the power outlet
7. Connect a USB cord to the PC port and to the analyzer port.
8. Connect a power cord to the instrument and to the power outlet.
9. Install the Hi user software and the default HUMAN settings. The installation of the Hi user software and the installation of the default HUMAN settings are described in a separate document that is provided together with the software and the settings (Cat.No. 16890/24 or 16895/24).
10. After the installation or moving of the instrument, the engineer must perform a check and calibration of all mechanical components (e.g. pipetting arm, wash station, sample tray, reaction tray). Mechanical adjustments can be altered when the instrument is moved or shipped. The misadjustment can reduce the performance of the instrument and lead to errors.
11. After installation, maintenance or prolonged non-operation, a “prime hydraulic system” must be performed before the usual start-up.

## 2.10 Moving

Follow this procedure, if you want to move the analyzer to another location in the lab. At least two persons are required for moving the analyzer. Lift the instrument slowly holding the metal base and in such a way that the cover remains in the closed position.

Before moving the analyzer follow these steps:

1. Disconnect power cord and USB connection.
2. Disconnect the four tanks tubing and the level sensors. Be sure to avoid contact with potentially infectious liquid waste when disconnecting tubes.
3. Fix the sampling arm in the uppermost position using the foam protection tube provided with the shipment.
4. Ensure that the cover is correctly closed.

After moving the analyzer follow these steps:

1. Reconnect the USB and the power cord
2. Reconnect the tank tubes and the level sensors
3. Execute a "Prime hydraulic system" from the maintenance panel.

## 2.11 User software

The user software (HI software) requires to have the latest version of Microsoft™ .NET framework installed on the computer. You can run the software with Windows™ 10. Both, 32- or 64-bit operating systems are compatible. It is possible to run two instances of the HI software on one computer, thus operating two analyzers with only one computer. Interface response can be slower if the computer is not sufficiently powerful. A SSD drive will further improve the speed of the software and is highly recommended.

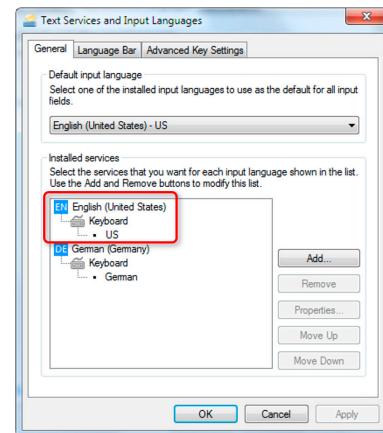
! Note: After moving the analyzer it is recommended to execute a complete mechanical calibration in order to ensure the quality of results. Ask your local HUMAN distributor for a complete mechanical calibration of the machine.

### 2.11.1 English (USA) keyboard and language drivers

If you are using a non-English version of Windows, you need to install the English (USA) keyboard and language drivers in Windows. The HI software requires these drivers for operation (e.g. using the external barcode scanner). For checking if the required drivers are installed, proceed as described below.

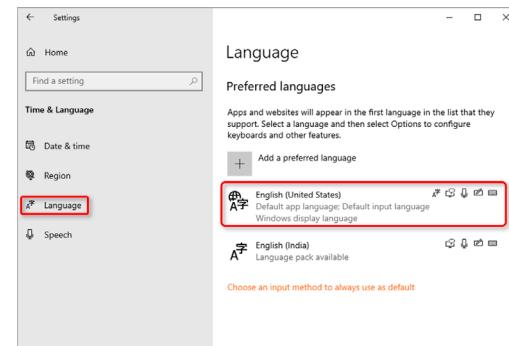
Windows 7: Control Panel > Change keyboards or other input methods > Keyboards and Languages > Change keyboards...

**FIGURE 20**



Windows 10: Search for “language”

**FIGURE 21**



Detailed instructions of how to install the English (USA) keyboard and language are included in the general software installation instructions.

## 2.12 Condensate water in reagent tray

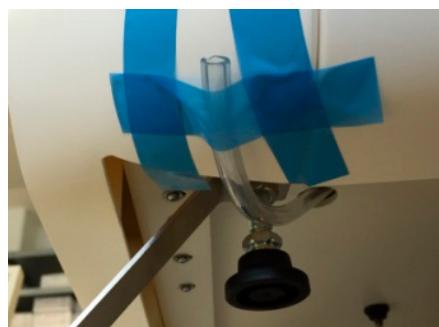
Condensate water will accumulate in the cooled reagent tray. Especially in humid environments. There are three options how to remove the condensate water from the reagent tray.

- In dry environments it is sufficient to dry the reagent tray during daily maintenance using a cloth.
- In humid environments, it is possible to remove a small plug inside the reagent tray (see Figure 22). The condensate water can flow into the small hole in will be let to an outlet underneath the instrument (see Figure Figure 22 and Figure Figure 23).
- In very humid environments, the outlet underneath the instrument should be connected to a waste tank.

Ask your local service engineer to prepare the instrument in a way that is suitable for your environment.



**FIGURE 22**  
Condensate water drain



**FIGURE 23**  
Condensate water outlet

## 2.13 Standard delivery

The standard analyzer delivery consists of a set of items that are listed in chapter 2.13.1. There are several accessories and consumables that are INCLUDED in this standard delivery (see chapter 2.13.2). Other accessories and consumables are NOT included, but might be necessary for the operation of the analyzer (see chapter 2.13.3).

### 2.13.1 Scope of supply and accessories

The instrument (Cat.No. 16890I/16895I) is delivered in a wooden container with internal foam for collision protection and a shock and tilt indicator attached to the outside of the box. Edges of the container are enforced with additional wooden boards. The accessories are delivered with the instrument in a separate carton box (Cat.No. 16890AI/16895AI). Further accessories (UPS, power adapter, safety socket) are also delivered in separate boxes.

TABLE 9  
Complete Set (Cat.No.  
16890/16895)

Qty.	Description	Cat.No.	Comment
1	HumaStar 100/200	16890I/16895I	See contents below
1	UPS 800VA/ 230V	18961	
1	HumaStar 16890/16895	16890AI/	
1	Accessories Kit	16895AI	See contents below
1	Adapter EU to USA	18967	
1	Adapter EU to UK	18968	
1	Power safety socket (EU)	18969	

TABLE 10  
Content of HumaStar 100/200  
(Cat.No. 16890AI/16895) -  
Analyzer wooden box

### 2.13.2 Items included in Cat.Nos. 16890I/16895I and 16890AI/16895AI

The items listed in the set (Cat.No. 16930) contain the following components:

Qty.	Description	Cat.No.	Comment
1	HumaStar 100/200	16890AI/16895	Analyzer
1	Sample tray 60 positions	16890/10	Mounted inside the instrument

Wash Additive (Cat. No. 18971) and Special Wash Solution (Cat. No. 18974, or another NaOH solution, see chapter 5.3.2.2) are necessary for the use of the instrument. Cuvette Clean (Cat. No. 18973) is necessary for HUMAN turbidimetric tests (see chapter 4.4.3.5). They are not contained in the standard delivery and have to be ordered separately.

Qty.	Description	Cat.No.	Comment
1	User manual	16890/1 or 16895/1	
1	Sample cups 1ml adapter (for sample tray 60 positions)	16890/12	
1	Removable reagent bottle tray (30 pos.)	16890/13	
1	Software and Settings USBCard	16890/24 or 16895/24	Labelled with versions
1	Reaction cuvettes starter kit with pliers (20 pcs.)	16890/40	
1	Sample tubes 12mm, 5 ml (50 pcs.)	16890/42	
1	Sample cups 1 ml (for sample tray 60 positions, 50 pcs.)	16890/43	16890/43 is a starter pack. With Cat. No. 16890/31 this sample cups can be ordered in a quantity of 1000 pcs.
1	Fuses kit	16890/50	T2A/250V, 5x20mm. Used for 230 and 110 VAC
1	Halogen lamp	16890/51	Spare lamp
1	Waste tank 20l (low contamination)	16890/55	
1	Water tank 20l	16890/56	
1	Cleaning solution tank 2l	16890/57	
1	Tanks tubing group	16930/58	
1	Power cord	16890/146	Standard VDE removable power cord
1	USB cable 3m	16890/231	

**TABLE 11**

Content of HumaStar  
100/200 Accessories Kit  
(Cat.No. 16890AI/16895AI)  
- 16890AI/16895AI box

### 2.13.3 Additional accessories and consumables (not included)

Accessories and consumables that might be necessary, but are NOT included in the standard delivery. Items marked with \* are necessary for operation. Other items might only be necessary according to the reagents you run. Read the reagent leaflets to know which diluents and wash solutions are required for each Human reagent.

Description	Cat.No.	Comment
* Wash Additive 4x25ml	18971	Standard wash solution. Necessary for operation! See chapter 14.2.2.
* Special Wash Solution 12x30ml	18974	Contains NaOH. Dangerous good regulations apply! Necessary for operation! See chapters 14.2.3 and 14.2.2.
Cuvette Clean 4x100ml	18973	Necessary for turbidimetric tests. See chapters 2.2.3 and 14.2.3.

**TABLE 12**

Additional accessories and  
consumables (NOT included in  
standard delivery)

Sample tray 60 positions	16890/11	Installed on instrument.
Reagent bottle 20ml (30pcs.)	16890/34	
Reagent bottle 50ml (30pcs.)	16890/35	
Sample tubes 12x85mm, 5ml (1000 pcs.)	16890/30	
Sample cups 1ml (1000 pcs.)	16890/31	For sample tray 60 positions 16890/10
* Personal Computer	18992P	Can be purchased locally or from HUMAN
* TFT Screen	17901M	Can be purchased locally or from HUMAN
LCD Touchscreen Monitor	18991MT	Can be purchased locally or from HUMAN
(*) Laser Printer	18993L	Can be purchased locally or from HUMAN
Reaction Cuvettes (200 pcs.)	16890/33	80 cuvettes are sufficient for ap- proximately up to 30.000 tests. 80+20 cuvettes are contained in the standard delivery.

## 2.14 Size and weight of packaging

Size, weight and storage/transportation conditions of Cat.No. 16890I/16895I and 16890AI/16895AI:

TABLE 13  
Packaging

Cat.No.	Description	Size (WxDxH)	Gross weight	Storage/ transp.
16890/	HumaStar	92 x 86 x 79	90kg (integrated	0-50°C, 10-85% rel.
16895	100/200	cm + 58 x 38 x 58 cm	pallet)	humidity (noncon- densing)
16890AI/	Accessories	58x38x50 cm,	8kg	0-50°C, 10-85% rel.
16895AI	Kit			humidity (noncon- densing)

### 3 ROUTINE UTILISATION

#### 3.1 Switch on/ log-in/ start-up

Follow this procedure to switch on the analyzer and start the user software.

1. Switch on the analyzer (5) and the reagent cooling (1). Instrument warm-up will begin (see also chapter 3.6.5).

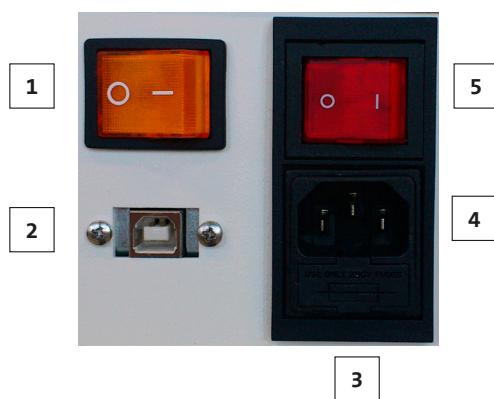


FIGURE 24

- 1 Switch for reagent refrigeration
- 2 USB port for external computer
- 3 Fuse compartment
- 4 Power cord fitting
- 5 Main power switch

2. Switch on the PC and the (touch screen) monitor.
3. Click on the “Hi” icon on your desktop.
4. Click on the “hi” icon in the systray tool to start the software.

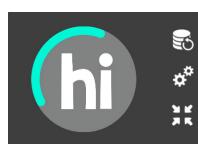


FIGURE 25

5. Enter the appropriate name and password and press OK.

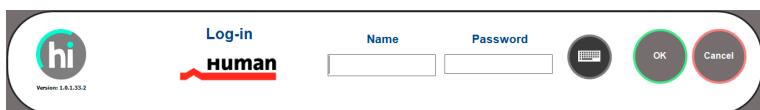
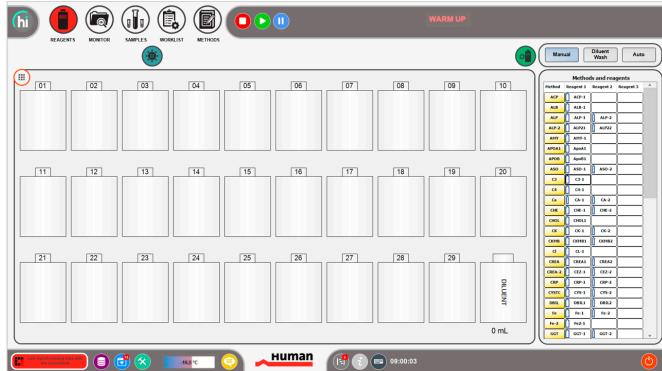


FIGURE 26

6. Upon entry and confirmation of the appropriate name and password the REAGENTS tab will appear (see also chapter 4). The remaining temperature offset of the reaction cuvettes is displayed in the command bar (see picture below). Once the synchronization has finished and the final temperature has been reached, the display will disappear.

FIGURE 27



### 3.2 Start-up

**!** Note: Diluent must be placed in reagent tray position "DIL" before you run the start-up.

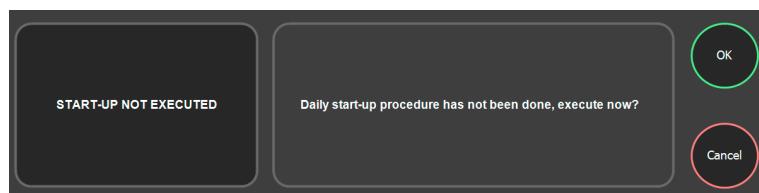
#### 3.2.1 Run start-up every 24 hours

The daily start-up is necessary to assure the analyzer's performance and precision and to avoid damage caused by malfunctioning pumps. During start-up the following operations are executed:

1. Self-test
2. Prime of the hydraulic system
3. Check of the pumps
4. Calibration of the optical group (lamp emission, autozero, offset)
5. Wash of all reaction cuvettes
6. Recording of reference readings taken at all wavelengths for each cuvette when filled with water (cuvette water blank)

If start-up has not been executed within the previous 24 hours, the DAILY START-UP message box will appear.

FIGURE 28



Click **OK** to execute this procedure. Then, upon completion of warm-up, a prime of the hydraulic system, a wash cycle and optical calibration will be executed. This procedure can take up to 45 minutes. After successful completion of start-up, test execution can begin. See chapter 3.7.1 to schedule an automatic start-up of the instrument before you arrive in the laboratory.

### 3.2.2 Start-up in the evening

If it is more suitable for the laboratory workflow, you can perform the start-up in the evening, followed by a prime of the hydraulic system in the morning when you start your daily work routine. When the first run in the morning is started from the STOPPED status, the instrument will perform a short prime anyhow. This prime is usually sufficient to eliminate bubbles in the hydraulic system.

### 3.2.3 Continuous operation

If the instrument is used continuously (also during the night), a Quick start-up is sufficient to be run on a daily basis. Just in that case, it is not required to perform the complete start-up every 24 hours. Small bubbles will be anyhow removed by the continuous operation and large bubbles do not have sufficient time to accumulate.

### 3.2.4 Start-up with empty hydraulic system

If the system was not fully filled with liquid, you must perform a prime of the hydraulic system before the execution of the start-up. This is the case, if the liquid tanks were empty, if they were disconnected, or if tubes were empty. You might get error messages during start-up, if this recommendation is not followed. The same applies, if the instrument has not been used for a longer period.

## 3.3 Autozero

“Autozero” is a procedure performed automatically by the instrument or manually by the service engineer.

For example it is performed:

- During start-up
- Periodically (every 30 min. if no test is executed) when the instrument is in “RUN” status.
- When the instrument was in “STOPPED” status and the user clicks RUN to start a new measurement (see chapter 3.6.5).

The “autozero” value is the calibration of the photometer at 100% transmission of the light. 100% transmission is equivalent to zero absorbance (“Abs.” or “OD”). The “Dark” value is the calibration of the photometer at 0% transmission.

### 3.4 Notifications



Some of the icons in the software are shown with a small red square in the top right corner. This “notification” has the same meaning as notifications on some of your mobile phone apps (e.g. unread e-mail messages). You can find the notifications on the bottom line of the main screen and also elsewhere in the software. The number designates the number of unread notifications related to that item (e.g. unfinished maintenance tasks or new log entries).

FIGURE 29



### 3.5 Touch screen keyboard

Routine functions of the software can be used with a touch screen monitor. A touch screen “Keyboard” is accessible where required.

1. Click in the textbox that you want to edit.
2. Click on the **Keyboard** button.
3. Type your desired text by clicking the keyboard buttons.

FIGURE 30



### 3.6 Main screen

The design and configuration of the command structure is controlled by a hierarchy of easily identified icons moving from the primary functions on the “Main screen” to secondary commands for individual tab functions.

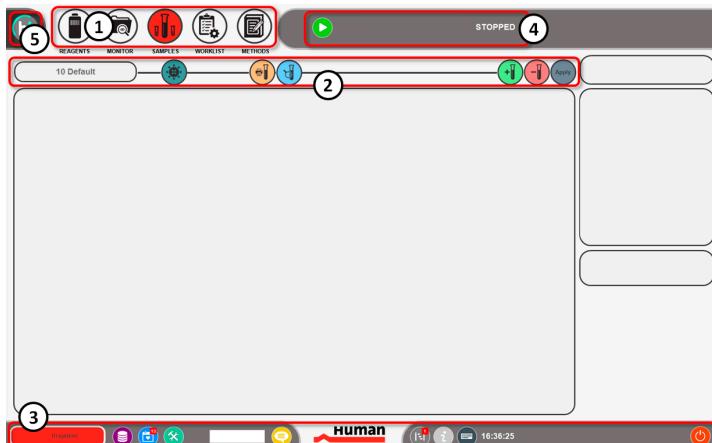


FIGURE 31

#### (1) Primary tabs (see chapter 3.6.2)

On the upper side of the screen you can find five icons (primary tabs) related to the primary functions of the software.

- REAGENTS
- MONITOR
- SAMPLES
- WORKLIST
- METHODS

#### (2) Secondary commands (see chapter 3.6.3)

Below the Primary tabs you can find the Secondary commands.

Secondary commands are specific for each Primary tab.

#### (3) Command bar (see chapter 3.6.6)

On the bottom of the screen you can find the command bar. The Commands bar allow access to additional functions, as for example the Quality Control, the LOT management (target values of controls and calibrators), the Maintenance work form and shut-down procedures. If the connection between PC and analyzer is not established, a warning will be displayed on the command bar.

#### (4) Principal controls (see chapter 3.6.5)

On the top on the right side there are the “Principal controls” (start, stop, pause) and the current “State” of the analyzer is displayed.

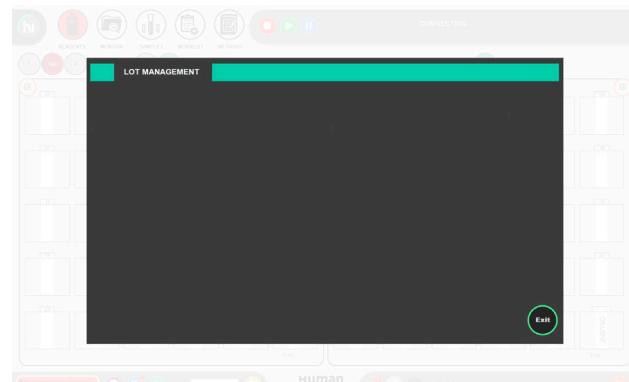
#### (5) Activity manager

In the top left corner, there is the “Activity manager” that shows the last activities (e.g. Start-up) that were done by the instrument.

### 3.6.1 Work forms

Some functions are shown in separate “Work forms” (windows). Work forms can cover the whole screen or overlay only parts of it. In the following picture you can see such a Work form that overlays part of the screen:

FIGURE 32

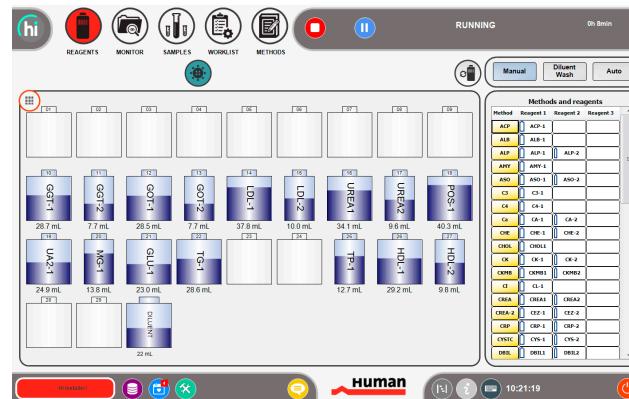


### 3.6.2 Primary tabs

Here is an overview of the five primary tabs:

#### REAGENTS

FIGURE 33



In this section you can:

- Assign and adjust bottle positions.
- Manage multiple reagent trays.
- Place and manage reagents, wash solutions and diluents.
- Check volumes of reagents.

## MONITOR

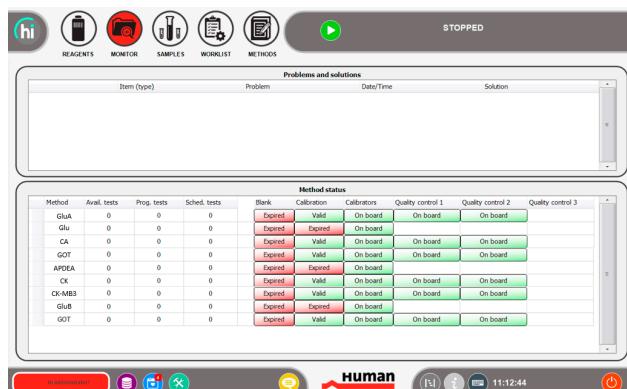


FIGURE 34

In this section you can:

- Check and monitor the status of all reagents on-board.
- Check if the instrument is ready to run patient samples.
- Identify and manage problems.
- Provide solutions for identified problems.
- Review method status (calibration, QC, etc.).

## SAMPLES



FIGURE 35

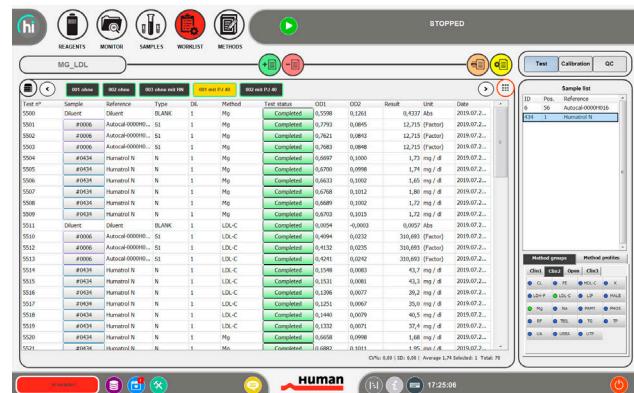
In this section you can:

- Save and file a sample list for reuse (without related tests).
- Retrieve and load a sample list from a saved file (without related tests).
- Clear displayed sample list (with related tests).
- Add/Remove a sample.
- Apply modified data to select a sample in the list.
- Display work form for sample report.
- Display work form for sample inspection.

- Display work form showing tray positions for samples, calibrators and controls.

## WORKLIST

**FIGURE 36**

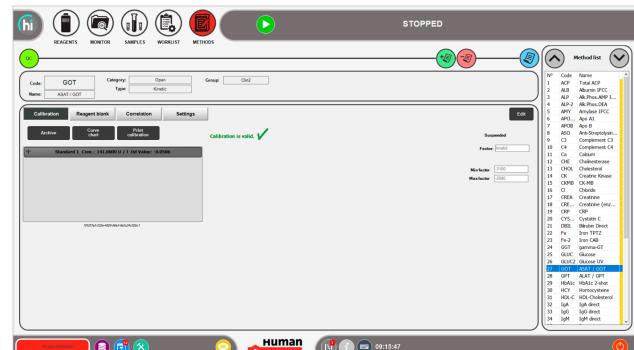


In this section you can:

- Create and manage test lists.
- Organize tests in worksheets and worklists.
- Run, inspect and rerun tests.
- Run calibration and QC.

## METHODS

**FIGURE 37**



In this section you can:

- Set and monitor calibrations.
- Check and manage methods.
- Check reagent blanks.
- Assign quality controls (QC).
- Access QC results.

### 3.6.3 Secondary commands

The secondary commands are different for each primary tab. They are individual functions that are required for the work to be done on the individual tabs. Click each of the primary functions to gain access to its secondary commands.

#### REAGENTS tab

 Click on REAGENTS tab to access its secondary commands.

The following secondary commands are available on this tab:

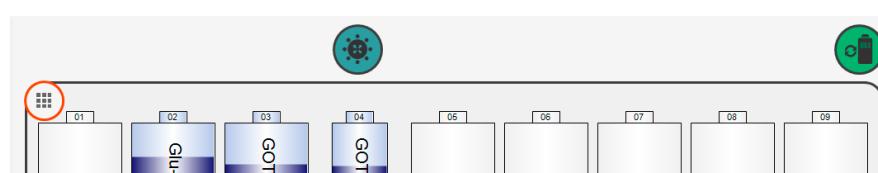
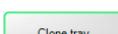
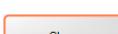


FIGURE 38

 Click on the ACTION button to access commands.

 Select Retrieve and load a reagent bottle tray from saved file.

 Clone tray Save assigned positions and file reagent bottle tray for reuse.

 Clear Clear displayed bottle positions.

 Place and manage wash solutions or diluents on sample tray.

 Click on the ACTION button to access commands.

### MONITOR tab

 Click on **MONITOR** tab to access this tab.  
There are no secondary commands on this tab (see chapter 5 for details).

### SAMPLES tab

 Click on **SAMPLES** tab to access its secondary commands.  
The following secondary commands are available on this tab:

FIGURE 39



 Open sample tray selection window.

 Display work form showing tray positions for samples, calibrators, controls and cleaning solutions.

 Display and print **sample report**.

 Display work form for **sample inspection**.

 Add/ Remove a sample/ calibrator/ control.

 Apply modified data to selected sample.

**WORKLIST tab**

 Click on **WORKLIST** tab to access its secondary commands.  
The following secondary commands are available on this tab:

**FIGURE 40**

 Access to Worklist Selection.

 Create a new worksheet.

 Remove selected worksheet.

 Run all tests of the worksheet.

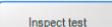
 Print a report of the selected worksheet ("Worksheet report").

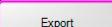
 Click on the action button to access commands.

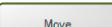
 Recalculate test(s) using the current calibration and blank.

 Remove test(s) from worksheet.

 Run selected test(s) of the worksheet.

 Show TEST INSPECTION work form for the selected test.

 Export test(s) and reaction curves as CSV-file (import in Excel).

 Move test(s) to another worksheet.

### METHODS tab

 Click on **METHODS** tab to access its secondary commands.

The following secondary commands are available on this tab:

FIGURE 41



 Access the work form to assign quality controls to each method, and to check QC results.

 Add a new method. **Note: Only for Administrator access level or above in combination with a license for open channels.**

 Delete selected method.

 Access the work form to check the working parameters of the analysis (method).

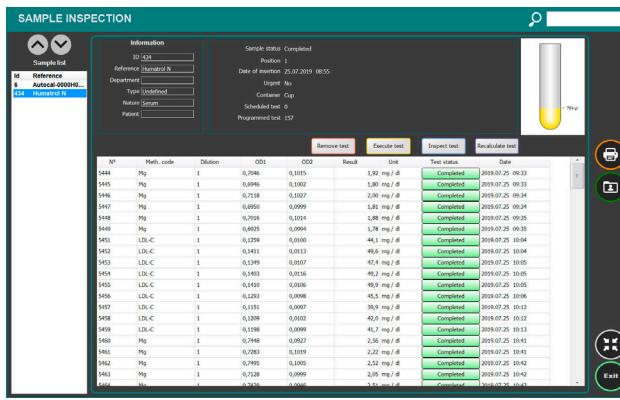
Before continuing, users are urged to experiment with the main page command structure. Using the graphics on these pages as a guide, access each of the mentioned tabs several times.

Run through the secondary commands at random. A bit of practice early on will ensure a more complete understanding of how to operate this instrument and illustrate just how user friendly it is.

### 3.6.4 Work forms

Work forms (windows) are provided for specific functions where access to more detailed information is required. Some **examples** are shown below. Details for each work form are explained in the corresponding chapters.

 **Sample inspection** (see chapter 6.4) - on **SAMPLES** tab.

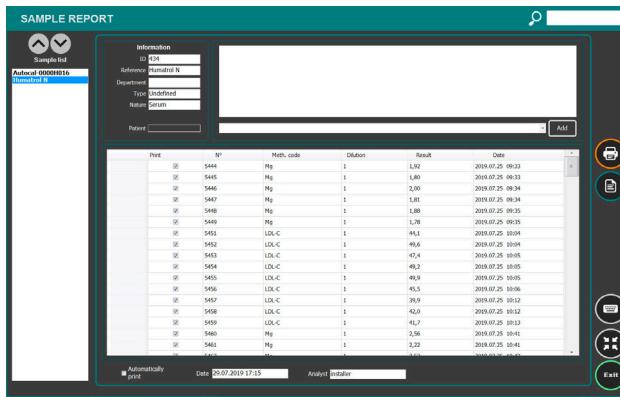


The screenshot shows a table of test results for sample ID E3H. The columns are labeled: N°, Meth. code, Dilution, OSL, Result, Date, and Test status. The results are as follows:

N°	Meth. code	Dilution	OSL	Result	Date	Test status
5444	Mg	1	0,9946	0,0103	1,97 mg / d	Completed 2019/07/25 09:33
5445	Mg	1	0,9946	0,0102	1,98 mg / d	Completed 2019/07/25 09:33
5446	Mg	1	0,7118	0,0102	2,00 mg / d	Completed 2019/07/25 09:34
5447	Mg	1	0,6959	0,0099	1,95 mg / d	Completed 2019/07/25 09:34
5448	Mg	1	0,5118	0,0104	1,98 mg / d	Completed 2019/07/25 09:35
5449	Mg	1	0,6925	0,0094	1,78 mg / d	Completed 2019/07/25 09:35
5451	LDL-C	1	0,239	0,0100	44,1 mg / d	Completed 2019/07/25 10:04
5452	LDL-C	1	0,1411	0,0113	49,6 mg / d	Completed 2019/07/25 10:04
5453	LDL-C	1	0,1407	0,0107	47,1 mg / d	Completed 2019/07/25 10:05
5454	LDL-C	1	0,1410	0,0116	46,9 mg / d	Completed 2019/07/25 10:05
5455	LDL-C	1	0,1410	0,0106	49,7 mg / d	Completed 2019/07/25 10:05
5456	LDL-C	1	0,2392	0,0098	45,5 mg / d	Completed 2019/07/25 10:06
5457	LDL-C	1	0,1511	0,0097	36,3 mg / d	Completed 2019/07/25 10:12
5458	LDL-C	1	0,1309	0,0107	42,9 mg / d	Completed 2019/07/25 10:12
5459	LDL-C	1	0,1309	0,0098	42,9 mg / d	Completed 2019/07/25 10:13
5460	Mg	1	0,9448	0,0092	2,56 mg / d	Completed 2019/07/25 10:41
5461	Mg	1	0,7983	0,0109	2,27 mg / d	Completed 2019/07/25 10:41
5462	Mg	1	0,7495	0,0105	2,21 mg / d	Completed 2019/07/25 10:42
5463	Mg	1	0,7128	0,0099	2,05 mg / d	Completed 2019/07/25 10:42
5464	Mg	1	0,7128	0,0098	2,03 mg / d	Completed 2019/07/25 10:42

FIGURE 42

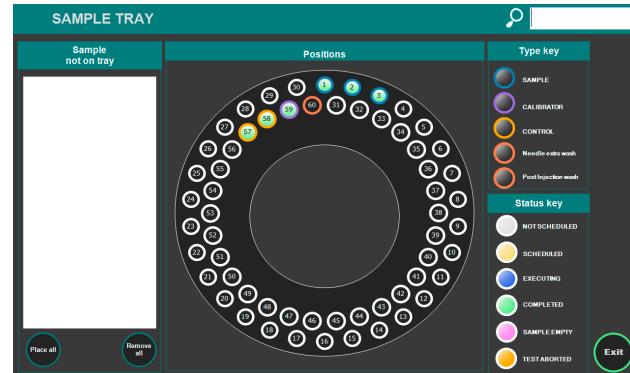
 **Sample report** (see chapter 6.5) - on **SAMPLES** tab.



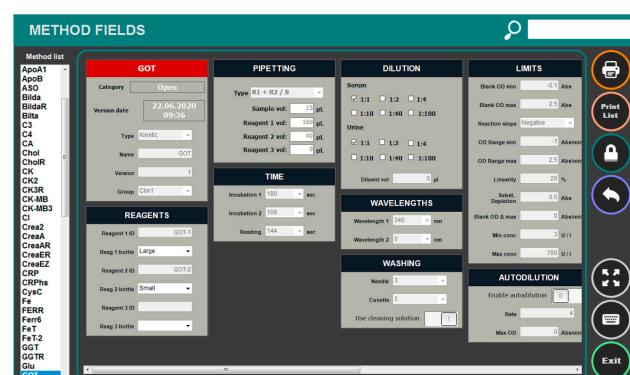
The screenshot shows a table of test results for sample ID E3H. The columns are labeled: N°, Meth. code, Dilution, OSL, Result, Date, and Test status. The results are as follows:

N°	Meth. code	Dilution	OSL	Result	Date	Test status
5444	Mg	1	1,92	1,86	2019/07/25 09:33	Completed
5445	Mg	1	1,80	2,00	2019/07/25 09:33	Completed
5446	Mg	1	2,00	1,95	2019/07/25 09:34	Completed
5447	Mg	1	1,81	1,86	2019/07/25 09:34	Completed
5448	Mg	1	1,86	1,86	2019/07/25 09:35	Completed
5449	Mg	1	1,78	1,86	2019/07/25 09:35	Completed
5451	LDL-C	1	44,1	49,6	2019/07/25 10:04	Completed
5452	LDL-C	1	49,6	49,6	2019/07/25 10:04	Completed
5453	LDL-C	1	47,4	49,2	2019/07/25 10:05	Completed
5454	LDL-C	1	49,2	48,2	2019/07/25 10:05	Completed
5455	LDL-C	1	48,9	48,9	2019/07/25 10:05	Completed
5456	LDL-C	1	45,5	39,9	2019/07/25 10:06	Completed
5457	LDL-C	1	39,9	42,0	2019/07/25 10:12	Completed
5458	LDL-C	1	42,0	41,7	2019/07/25 10:12	Completed
5459	LDL-C	1	41,7	3,56	2019/07/25 10:41	Completed
5460	Mg	1	3,56	2,22	2019/07/25 10:41	Completed
5461	Mg	1	2,22	3,13	2019/07/25 10:42	Completed

FIGURE 43


**Sample tray (see chapter 6.6) - on SAMPLES tab.**
**FIGURE 44**

Inspect test

**Test inspection (see chapter 7.6) - on WORKLIST tab.**
**FIGURE 45**
**Method fields (see chapter 8.4) - on METHODS tab.**
**FIGURE 46**

### 3.6.5 State of the analyzer and principal controls



FIGURE 47

The state of the analyzer can be monitored or controlled using the icons in the upper right corner of the main page. Icons for additional services and information can be found in the Command bar at the bottom of the main page (see chapter 3.6.6).

#### Principal controls - stop, run, pause



- Click **RUN** to start the scheduled tests.
- Click **PAUSE** while the instrument is “Running” to load new samples or reagents.
- Click **STOP** to abort all pipettings and put the instrument in the STOPPED state.

#### State of the analyzer

##### WARM-UP

Approximately 20 to 30 minutes of warm-up time are required for the cuvettes before testing is possible (warm-up status bar shown in lower left panel). When warm-up has finished the analyzer automatically reaches the STOPPED state.

**!** Note: During your daily routine you (especially if the analyzer should be ready to measure emergency samples at any time), it is recommended to not stop the analyzer and leave it in IDLE state. Leaving the analyzer in IDLE allows to be ready to process new samples without delay. Starting a test from STOPPED state will take approx. 9 minutes (short prime of hydraulic system and Autozero procedure are executed).

#### **STOP REQUESTED/ STOPPED**

The user may request the machine to stop. Normally within one machine cycle (less than a minute) the machine goes into the STOPPED state. In this state the analyzer is completely stopped. There are no mechanical movements. Testing temperature is maintained.

#### **START-UP**

Upon start-up the analyzer begins by executing a prime of the hydraulic system, a wash cycle and the optical calibration of the reaction cuvettes.

#### **CHECKING LEVELS**

Indicates that reagent volumes are being checked after a request while in STOPPED state.

#### **RUNNING**

The analyzer is running. The sampling arm is in motion. Tests, problems, volumes are constantly monitored. Do not open the analyzer's cover, because you might get hurt by moving parts!

#### **IDLE**

The analyzer is running, but has no work to process. When in this state an automatic optical calibration is processed every hour.

#### **IDLE WASH**

The analyzer is running, but has no tests to execute, some cuvettes are dirty and the analyzer starts washing them.

#### **COVER OPEN**

If the cover is opened during the running state, the analyzer will suspend the sampling of new tests. Dispensations will be skipped until the cover is closed and all tests requiring a second dispensation will be aborted. (Tests requiring no further dispensation will continue).

#### **PAUSE REQUESTED/ PAUSED**

A pause may be requested at any time (PAUSE REQUESTED) and reached (PAUSED) when the current sampling runs have been completed. The instrument cover can then be opened to permit the user to perform on-board functions. (Reagents and samples on board can be removed or added. During this time the reading process of ongoing tests continues.)

**PROBLEM**

Indicates that the analyzer has stopped and testing cannot continue without user (or technical) intervention.

**WASHING**

The analyzer has finished the routine work and starts washing the reaction cuvettes.

**SHUT-DOWN**

The analyzer begins closing procedures by executing the necessary wash cycles. When these are completed the instrument can be switched off.

**CONNECTING...**

The software is trying to connect to the analyzer. TIME (e.g. 9 min.) Time until the scheduled tests of the worklist are finished. Left and right arm are indicated separately. Note: The time does not include the preparation time (see Note under “STOP REQUESTED / STOPPED”).

**3.6.6 Command bar**

Several functions can be accessed through the “Command bar” that is on the bottom of the main screen.

**FIGURE 48**

Login status and synchronization status.

Data modules (chapter 12)

Maintenance (chapter 14)

Additional tools (chapter 13)

Admin functions (chapter 15)

Log viewer (chapter 16)

Instrument information (see below)

Power button (chapter 3.7)



### Connection status

The connection between the analyzer and the PC is indicated by three different triangular symbols that appear on the command bar.

or no symbol shown: Connected  
PC connection is established correctly

: Connecting  
PC is trying to connect

: Not connected  
Problem(s) detected

Click on the triangular symbol to reconnect if possible.

Some reasons for not being connected:

1. Analyzer not turned on
2. Analyzer not connected to PC
3. Wrong communication port selected
4. Connecting cable damaged
5. PC communication port in use

If the PC and the analyzer are “Not connected” for any reason (see chapter 3.6.8) the “Communication error” box shown below will be displayed. Check the communication cable and click **Retry**.

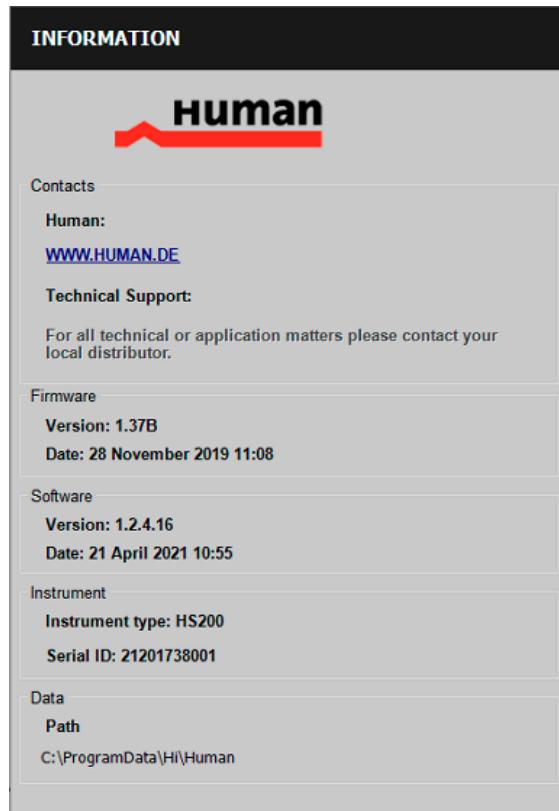
FIGURE 49



If the problem persists, the error may also be caused by the erroneous configuration of the serial communication port. In this case select the appropriate port from the provided list and click **Retry**.

**Instrument information**

 Click on the **Instrument information** button to access this function.

**FIGURE 50**

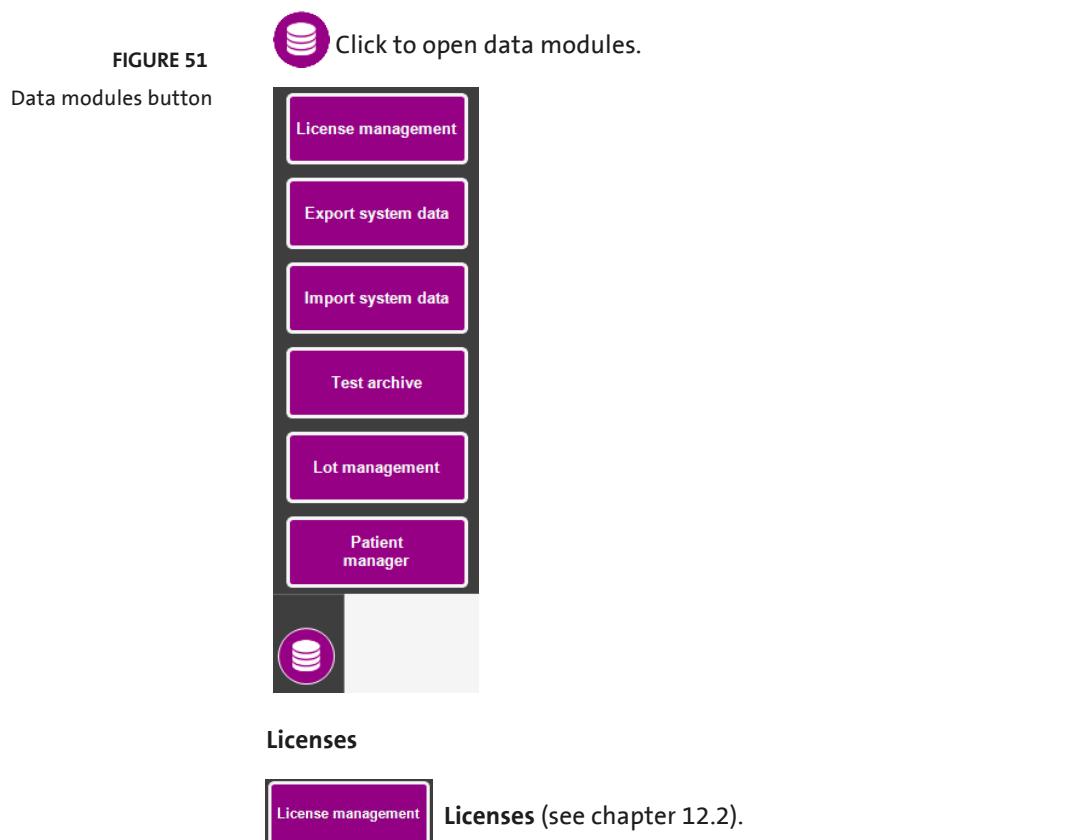
Instrument information

The following information is provided:

- Firmware version and date
- Software version and date
- Instrument type (HS200=HumaStar 200) and serial number
- Path of the data folder. The data folder contains all the data of the analyzer (methods, settings, results, archives, languages, log-files etc.). See chapter 17 to create a backup of this folder.

### 3.6.7 Data modules

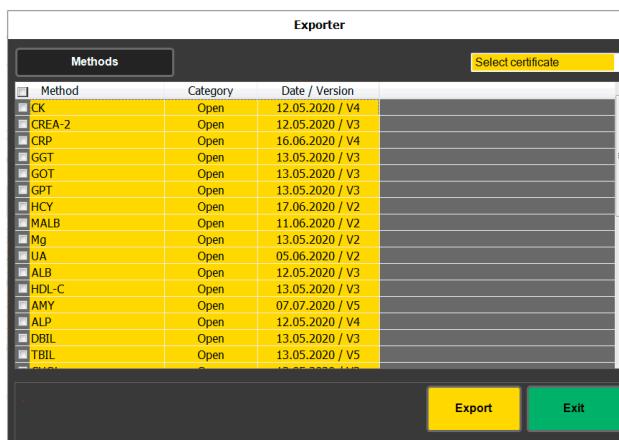
Data modules are provided for data management features. By clicking the indicated icon in the Command bar you can access the modules. Some examples are shown below. Details for each data module are explained in chapter 12.



## Export system data

**Export system data**

**Export system data** (e.g. export methods to be used on another instrument, see chapter 12.3).



**FIGURE 53**

## Import system data

**Import system data**

**Import system data** (e.g. import methods, see chapter 12.4).

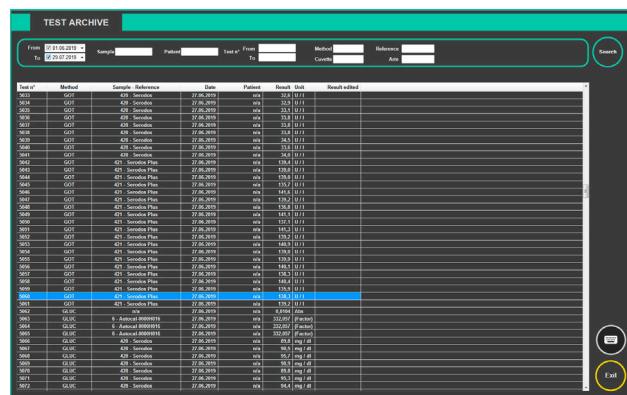


**FIGURE 54**

Test archive

Test archive

**Test archive** (search and check old test results, see chapter 12.5).

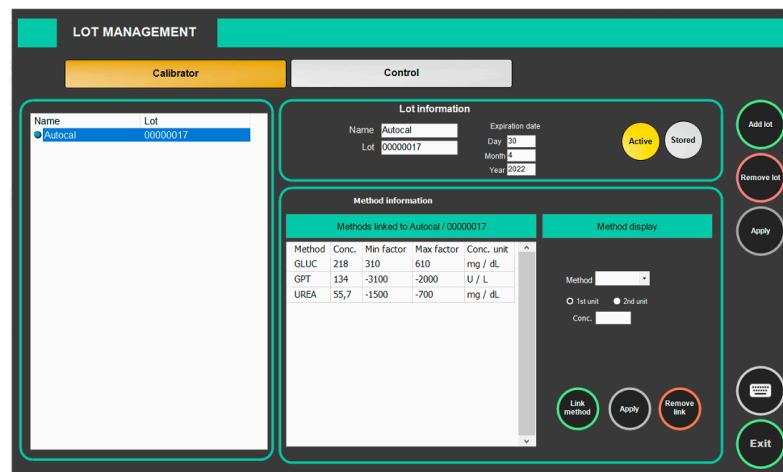


**FIGURE 55**

## Lot management

## Lot management

**Lot management** (e.g. enter target values for calibrators and controls, see chapter 12.6).



**FIGURE 56**

## Patient manager

**Patient manager**

**Patient management (search and check patient test result history, see chapter 7).**

The screenshot shows a 'PATIENT MANAGEMENT' interface. On the left, there's a sidebar with 'Information' containing details like 'Name: Sigi Schneider', 'Family Name: Schneider', and 'Address: 5th Avenue'. The main area has a table with columns 'Name', 'Family Name', and 'Date of birth'. It lists three patients: Sigi Schneider (alias), Herbert Schneider, and Dora Schmitz. To the right are buttons for 'Add patient', 'Edit patient', 'Complete patient list', 'Detailed search', 'Patient test list', and 'OK'.

FIGURE 57

## 3.6.8 Maintenance

Click to open MAINTENANCE work form. See chapter 14 for details.



FIGURE 58

The MAINTENANCE PROCEDURES work form allows the execution of all maintenance procedures. The procedures of the “Routine maintenance” must be performed on a daily, weekly or monthly basis.

MAINTENANCE PROCEDURES				
Daily	Status	Last execution date	Estimated time left	Details
Start-Up		Expired	07.36.06.06.17	1 day(s)
Quick Start-Up		Expired	07.36.06.06.17	1 day(s)
Shutdown		Expired	14.22.06.06.17	1 day(s)
Weekly	Status	Last execution date	Estimated time left	Details
Replace water tank		Valid	09.25.06.06.17	1 day(s)
Replace cleaning tank		Valid	07.57.06.06.17	1 day(s)
Replace waste tank		Valid	07.57.06.06.17	1 day(s)
Replace special waste tank		Valid	07.57.06.06.17	1 day(s)
Monthly	Status	Last execution date	Estimated time left	Details
Special current wash		Valid	07.57.24.05.17	14 day(s)
Special nozzle wash		Valid	13.37.18.05.17	20 day(s)
Pump Test		Valid	12.03.18.05.17	20 day(s)

FIGURE 59

## Notifications

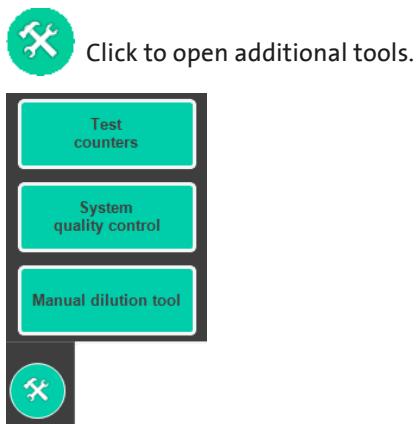
Notification flags will indicate if maintenance procedures need to be performed.



### 3.6.9 Additional tools - quality control

The “Additional tools” mainly allow access to the **System Quality Control** work form (see chapter 13.3).

**FIGURE 60**



Other “Additional tools” allow...

- Cumulative listing of the number of tests executed for each method
- System quality control: Check quality control statistics, Westgard rules and Levey-Jennings graphics for all methods.
- Manual dilution tool for preparing a sample pre-dilution to be added to the test mix as a supplement to normally scheduled dilutions.

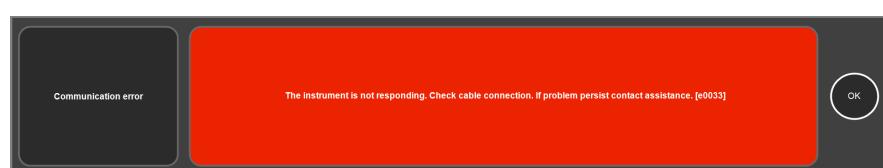
### 3.6.10 Message boxes

Message boxes can be displayed above the normal window to notify the user, give information or request confirmation.

#### Colour code of message boxes

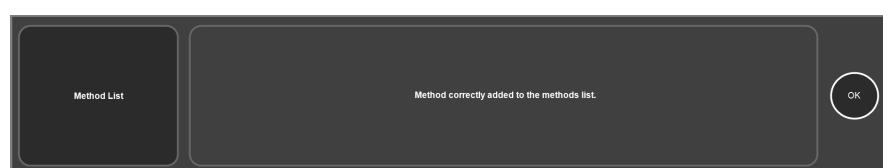
1. Error/ problem: Red

**FIGURE 61**



2. Confirmation required: Grey

**FIGURE 62**



3. Warning (possible data loss): Yellow

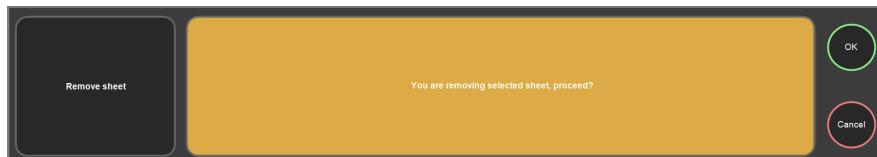


FIGURE 63

4. Calibrator information: Purple

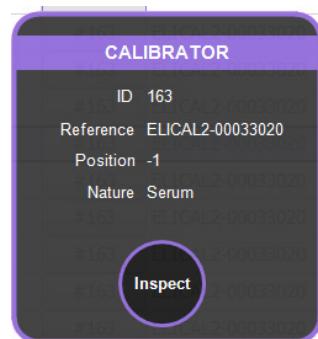


FIGURE 64

5. Control information: Orange



FIGURE 65

6. Sample information: Blue

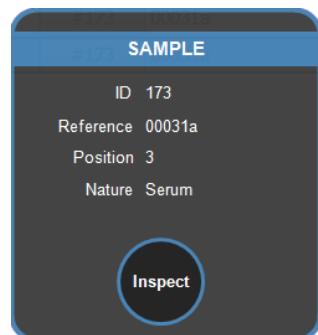
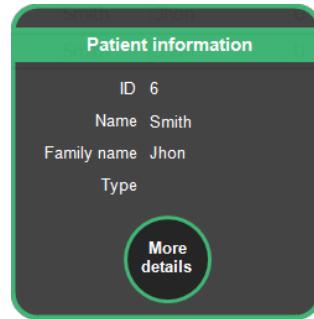


FIGURE 66

## 7. Patient information: Green

**FIGURE 67**



### 3.6.11 Quick access

“Quick access” allows to jump from one screen to another by just one simple click. To “quick access” (from MONITOR tab or SAMPLE tab) relevant information and working functions, click on any colour coded item under “Problem and solution” or “Method status”.

**FIGURE 68**



The three part diagram above shows one example of how “quick access” can simplify required operational tasks. When either “Missing” or “Expired” is selected (“Calibration” column in “Method status”) the message box “ADD CALIBRATION TESTS” is displayed and following an “OK-click” the entire list of tests required for calibration is automatically added to the “Worksheet panel”. You have now added all tests for the calibration of a method with only two clicks.

The colour coded buttons below show examples of “quick access” functions:

**FIGURE 69**

Solutions to problems	Additional information	Error detection	Resources missing
Provide a new bottle of GLU-1	Valid	Expired	Not on board
Empty the waste tank and access the panel for confirmation	Completed	Test aborted	Reag. 1 empty
Technical assistance required	Executing	Predilution error	Sample empty
	Result unusable	Reag. blank error	Diluent empty

### 3.7 Shut-down/ switch off

#### Getting there

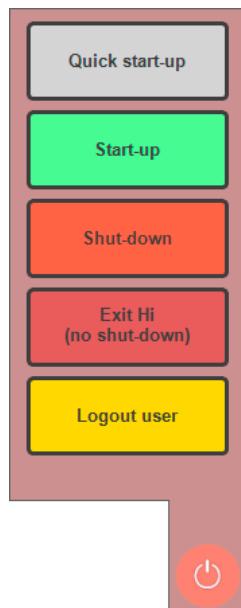
 Click **Power button** to show commands.



FIGURE 70

#### Functions

The following commands are available:



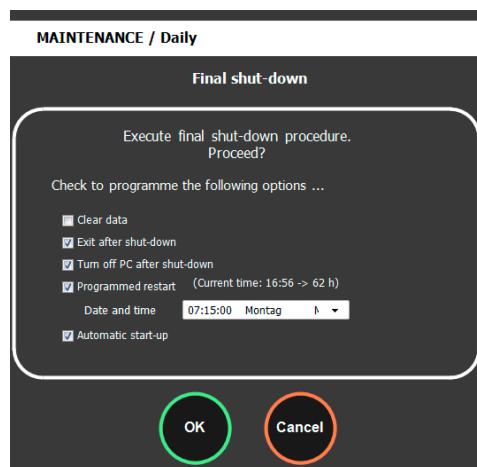
1. **Quick start-up**  
The “Quick start-up” is the same as the normal “Start-up”, but without filling of the hydraulic system and performing the pump test.
2. **Start-up**  
Perform complete “Start-up”.
3. **Shut-down**  
Perform “Shut-down” of the instrument.
4. **Exit Hi (no shut-down)**  
Exits the Hi software, but does not perform the instrument shut-down. Use this command, if the testing is to be resumed shortly, a final wash of the reaction cuvettes is not required at this time.
5. **Logout user**  
Logout the current user and login as a different user.

#### 3.7.1 Step by step: Shut-down the instrument

At the end of each working day you must perform a “Shut-down” before switching off the instrument. The Shut-down procedure is required to initiate the cleaning of the reaction cuvettes that have not been cleaned before. If this procedure is neglected any test residue remaining may damage the cuvette walls. This will reduce testing accuracy and possibly require earlier replacement of cuvettes. Follow these steps to perform the “Shut-down”:

1.  To begin **closing** procedures, first click the **Power button** to access the options required.
2.  To continue closing procedures, select the **Shut-down** option to access the final shut-down procedure.

FIGURE 71



3. Select the required Shut-down options/ automatic actions to be performed after shutdown:
  - **Clear data:** Close all open worksheets and samples.
  - **Exit after shut-down:** Exit software automatically after shut-down has finished.
  - **Turn off PC after shut-down**
  - **Programmed restart:** Set a date and time for the automatic wake-up of the instrument (e.g. next morning).
  - **Automatic start-up:** After automatic wake-up of the instrument. An automatic start-up will be performed. This option is very useful to save time in the morning. If automatic wake-up and start-up have been programmed, they are completed before the lab personnel will arrive in the laboratory and the instrument is immediately ready for use.
4. Close all reagent bottles using the lids that are provided with each bottle.

**!** Note: The diluent in position “DIL” on the reagent tray is required for  
the Start-up. Leave this bottle open, if automatic Start-up has been pro-  
grammed.

5. Switch off the PC and the monitor.
6. Switch off the analyzer

**!** Note: If “Programmed restart” has been checked during “Shut-down”, do  
not turn off the main power switch (2) and the instrument will hibernate  
(“sleeping mode”) until the selected “Date and time”.

7. Do not switch off the reagent cooling (1) if the reagents remain on the ana-  
lyzer!

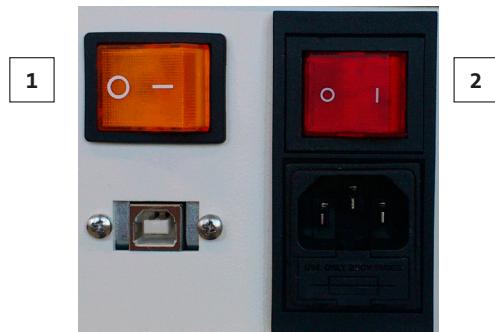


FIGURE 72



## 4 REAGENTS TAB



FIGURE 73

### 4.1 Overview

In this chapter, the **REAGENTS** tab and its functions will be explained in detail. On the **REAGENTS** tab you can load reagents, wash solutions and diluents on the analyzer. You can also check the volume for each bottle.

### 4.2 Functions

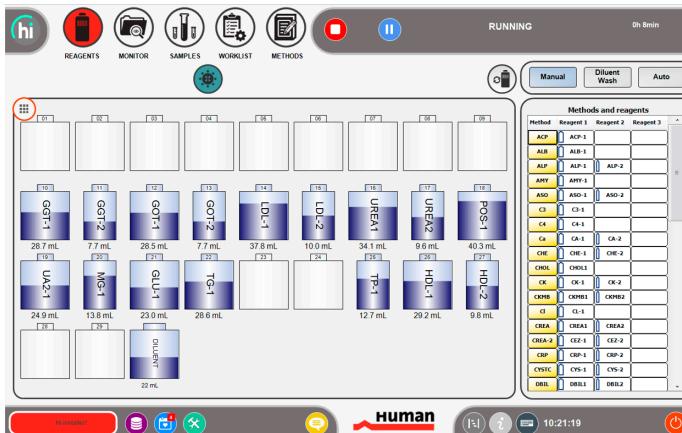


FIGURE 74

In this section you can:

- Assign and adjust bottle positions.
- Manage multiple reagent trays.
- Place and manage reagents, wash solutions and diluents.
- Check volumes of reagents.

Place and manage wash solutions and diluents on the sample tray.

 Check liquid levels when the analyzer is STOPPED (see chapter 4.3 for details)

 Opens functions to manage and switch between multiple reagent trays:

Select

Select and load a reagent bottle panel/ tray from saved file

Clone tray

Save the active reagent bottle panel for reuse

Clear

Clear displayed bottle positions

### 4.3 Checking liquid levels

The checking of liquid levels of reagents, wash solutions and diluents is possible while the analyzer is STOPPED and while the analyzer is RUNNING. Checking of liquid levels is important to see if there are sufficient reagents, wash solutions and diluents on-board.

The checking of the liquid level is also used to detect eventual mispositioning of reagents. While checking the liquid level, the content is compared to the inventory of used and new reagents. A warning message is shown, if an inconsistency is detected.

#### 4.3.1 Step by step: Checking liquid levels while STOPPED

When the analyzer is STOPPED proceed in the following way to check the liquid level of bottles on-board:

1.  Click on any bottle position in the panel to be checked. The position will be highlighted in yellow.
2.  Then click **Check levels** to check the selected liquid levels.

If no bottle selection is made, and **Check levels** is requested, the liquid levels of all reagents, wash solutions and diluents currently on-board will be measured.

#### 4.3.2 Step by step: Checking liquid levels while RUNNING

While the analyzer is RUNNING reagent liquid levels of tests being executed are constantly monitored. Click any bottle position in the panel at any time to request a liquid level check of that specific bottle. The bottle is shown in yellow to indicate that it will be checked.

**!** Note: When the instrument detects a bottle of reagent that has been newly placed on the reagent tray (one found previously insufficient), all of the tests that were stopped for the lack of that specific reagent will be automatically rescheduled.

#### 4.3.3 Colour code of liquid levels

The illustration below shows an enlarged version of how the actual liquid levels of reagents on-board appear in the **Bottle positions** panel. Reagent bottles are displayed with number of tests instead of volumes (See chapter 4.4 for details).

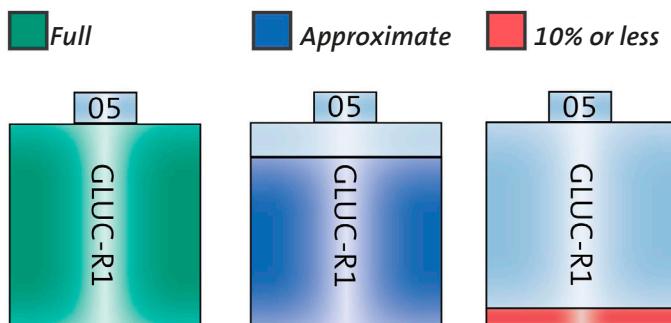
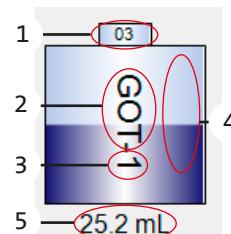


FIGURE 75

#### 4.4 Reagent information

For each bottle shown on the reagents panel, the following information is available:

FIGURE 76



1. Position on the reagent tray (red if shock sensor has detected a lid on the bottle or has hit an obstacle)
2. Method Code
3. Reagent component (R1: Reagent 1, R2: Reagent 2)
4. Filling volume of the bottle (colour code and graphic illustration of the filling volume)
5. Volume of reagent.

#### 4.5 Colour code of method/ reagent status

The status of a method and the reagent is indicated by a colour code on the REAGENT tab, in the bottle information window and on the MONITOR tab.

FIGURE 77

Method	Available tests	Programmed tests	Scheduled tests	Stock	Calibration	Calibrators	Quality control 1	Quality control 2	Quality control 3
DBIL	135	3	0	Valid	Missing	On board			
GLUC	99	0	0	Valid	Invalid	On board			
GPT	45	4	0	Valid	Programmed	On board	On board	On board	
TBL		3	0	Programmed	Missing	On board			
UNDA		0	0	Desired	Expired	On board			

	Green or no colour:	Can be used - Status is OK
	Yellow:	Warning - Close to expiring *
	Red:	Cannot be used - Expired

\* The pre-warning time can be defined by the laboratory administrator. See chapter 15.3 for details.

The following items are monitored and shown with a different colour according to their status:

- Expiry date
- Calibration stability
- Blank stability



## 5 MONITOR TAB



FIGURE 78

### 5.1 Overview

In this chapter the **MONITOR** tab will be explained in detail. The **MONITOR** tab allows constant monitoring of the status of all critical items that may interrupt the normal testing process. “General problems” are indicated in the upper part of the screen. A full waste tank or an empty wash tank might be problems that are indicated here.

On the bottom of the screen the status of calibrations, blanks and quality control is monitored for each method. (Only those methods are shown for which tests are in the worklist or reagents are loaded on the tray.) Once a problem is identified, a solution may be provided by using the “quick access” function (see also chapter 3.6.11). Use the **MONITOR** tab to check if the analyzer is ready to measure patient samples without further interruptions.

### 5.2 Functions

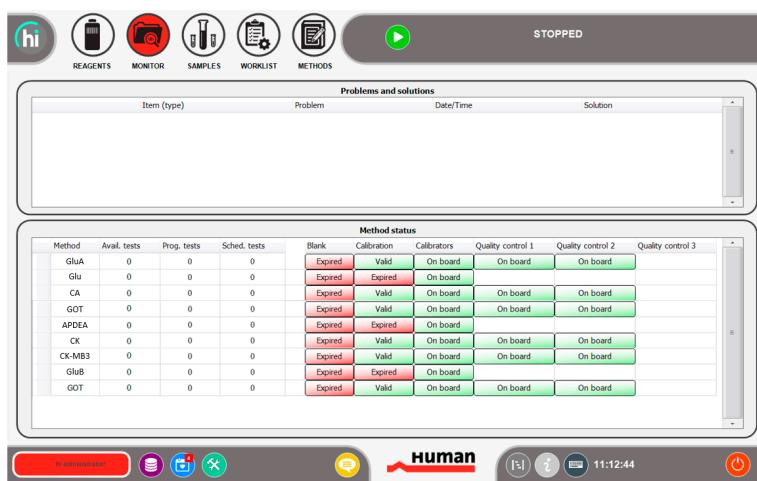


FIGURE 79

## 1. Problems and solutions

Identifies problems concerning the instrument and indicates possible solutions for the user.

- **Item (type):** Type of the item
- **Problem:** Description of the problem encountered
- **Date/ Time:** Timestamp of the event
- **Solution:** Proposed solution

## 2. Method status

Provides information for each method that is programmed on the analyzer. Indicates scheduled and available tests, the status of reagent blank, calibration, calibrators and quality control.

If the status is shown in green, then you are ready to go. If the status of any method or item is shown in red, then there is some operation that needs to be done before you start to measure patient samples. See chapter 5.2.1 for details.

### 5.2.1 Method status and quick access

See chapter 3.6.11 for a general explanation of “Quick Access”. You can click on any status button to quick access a possible solution. If a calibration is expired and you click on the red status button “Expired”, all necessary calibrations and blanks will be automatically added to the worklist.

**BLANK/ CALIBRATION**

These two columns display information about the current status of the reagent blank and the calibration executed for this method.

Missing	Has never been executed
Expired	No longer valid <sup>1</sup>
Valid	Has been executed and is still valid
Invalid	Unusable (Reagent BLANK / Calibration)
Programmed	Programmed in the worklist
Scheduled	Included in the worklist

**CALIBRATORS/ QUALITY CONTROL<sup>2</sup>**

These four columns display information about the presence of calibrators and controls on the sample tray.

On board	Specified and present
Expired	Specified but no longer valid
Not on board	Specified but not present
Method error	Not specified in method

<sup>1</sup>Possible drift in chemical characteristics of reagent

<sup>2</sup>Users may elect to apply quality controls at any time to monitor the accuracy of ongoing analyses

## 5.2.2 Summary

**FIGURE 80**

The figure shows two tables from the software interface. The top table is titled 'Problems and solutions' and lists four items with their types, problems, dates, and solutions:

Item (type)	Problem	Date	Solution
GLU-1 (reagent)	Empty	3/16/2009 4:21:26	Provide a new bottle of GLU-1
Waste (weekly maintenance)	Tank full	3/16/2009 4:21:26	Empty the waste tank and access the panel for confirmation
Wash station (instrument)	Mechanical error	3/16/2009 4:21:26	Technical assistance required
GLUP (method)	Incorrect field value	3/16/2009 4:21:26	Administrator assistance required

Arrows point from the table columns to the corresponding labels: 'Type of problem' points to the first column, 'Nature of problem' to the second, 'Date and time since problem was detected' to the third, and 'Solutions provided with analyzer or designated by administrator' to the fourth. A circled asterisk (\*) is located at the bottom right of the table.

The bottom table is titled 'Method status' and shows the status of three methods (CK, Fe, LDH-P) across various parameters:

Method	Avail. tests	Prog. tests	Sched. tests	Blank	Method status				
					Calibration	Calibrators	Quality control 1	Quality control 2	Quality control 3
CK	Bottle missing	1	0	Programmed	Expired	On board	On board	On board	On board
Fe	Bottle missing	0	0	Expired	Expired	On board	On board	On board	On board
LDH-P	Bottle missing	0	0	Expired	Programmed	On board			

Annotations below the table explain the data: 'Tests programmed' points to the 'Prog. tests' column, 'Tests scheduled' points to the 'Sched. tests' column, and 'Recorded status of blank, calibration, calibrators and quality controls' points to the 'Method status' columns. A note says 'Click for "Rapid access" to related sections'.

## 5.2.3 Prewarning time

When a status is valid Valid, but the background is displayed in yellow, this means that the validity of this status is about to expire. This feature can be configured by the administrator in the settings menu (see chapter 15.3.5).

## 6 SAMPLES TAB



FIGURE 81

### 6.1 Overview

In this chapter the SAMPLES tab will be explained in detail. Use the SAMPLES tab to load/ unload samples, calibrators and controls on the sample tray. Furthermore you can also print sample reports in this tab.

### 6.2 Functions

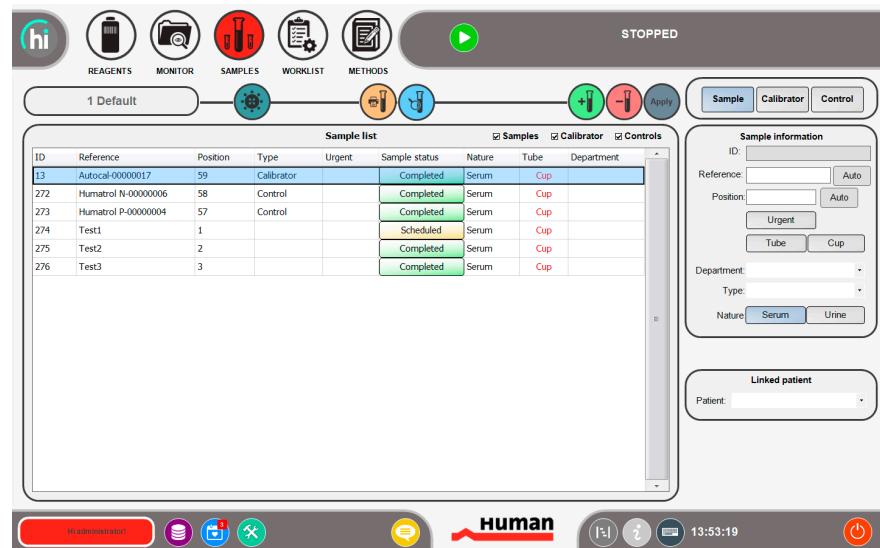


FIGURE 82

Access to Sample Tray Selection (see chapter 6.7)

- Display work form showing tray positions for samples, calibrators and controls
- Add/ Remove a sample/ calibrator/ control
- Display work form for sample report
- Display work form for sample inspection

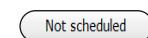
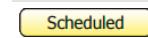
 Apply modified data to selected sample

Samples Calibrator Controls

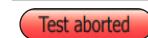
The “Sample list” shows all samples, calibrators and controls that are currently loaded on the tray. Use the checkboxes to filter the “Sample list”.

### 6.2.1 Sample status - quick access

#### ROUTINE

	One or more tests of that sample are waiting for confirmation
	All tests of that sample have been scheduled
	One or more tests of that sample are being executed
	All tests of that sample have been completed and are correct

#### SAMPLE ERRORS

	Sample remaining is insufficient for testing
	One or more tests of the sample have been aborted

Click on any of the Sample status buttons to get further information.  
See chapter 3.6.11 for more information on Quick access.

## 6.3 Sample list management

This chapter explains how to place samples, calibrators and controls on the sample tray. You will also learn how to modify samples that are already placed and how to remove samples from the tray.

### 6.3.1 Step by step: Place a sample/ calibrator/ control to the tray

1. Click on a category on the right side of the screen (Sample, Calibrator, Control)



2. Enter **Sample information** (see list below).
3. After data fields are complete, click **Plus** to add the new sample.
4. Repeat steps 1 to 3 until all samples required for the current worklist have been entered and added to the sample list.

### 6.3.2 Sample information

#### ID (sample, calibrator, control)

Barcode ID of a sample, calibrator or control. This information is read automatically by the barcode scanner and cannot be edited by the user.

#### Reference (sample only)

Enter any reference (number or characters) for the identification of a sample.  
Click **Auto** to assign a consecutive number automatically.

#### Reference (calibrator, control)

Select any calibrator or control that you have created under “Lot management” (see chapter 12.6).

#### Position (sample, calibrator, control)

Click **Auto** for next available position. You can also enter a specific position using the keyboard. Note: Do not modify the position of samples, calibrators or controls that have been detected by the barcode scanner.)

#### Urgent (sample, calibrator, control)

To identify samples or controls of an urgent nature (STAT). (Calibrators are always urgent and are auto-tagged as such.) Urgent samples or controls will be processed before other samples and controls.

#### Tube/ cup (sample, calibrator, control)

Identify sample container to be used.

**Department (sample only)**

You can organise your samples by the department/customer that has sent the sample. Select from the list that is provided. The Administrator can add more departments/ customers to the list.

**Type (sample only)**

Sample type (male, female, etc.). Select from the list that is provided. All sample types that have been assigned as “Pathological ranges” (reference ranges) in the methods can be selected. The Administrator can add more “Pathological Ranges” to the list if needed.

**!** Note: HUMAN methods for reagents do not contain pathological ranges by default, because they might be different from one patient population to another. See chapter 10.3. The Administrator can define pathological ranges for all HUMAN methods.

**Nature (sample only)**

Select serum or urine.

**Linked patient (sample only)**

Establish links between patients and samples for analyzer archives. After the result of a test is available, it is saved and linked to the selected patient in the patient archive. In the patient archive it is possible to search for old results or to track the change of results over time of individual patients. See chapter 12.7 for details.

### 6.3.3 Step by step: Create a new patient:

1. Click **New...** to enter a new patient.

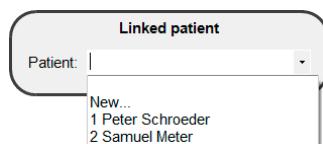


FIGURE 83

2. Enter patient information.

A screenshot of a "NEW PATIENT" form. It includes fields for "Name" (with a keyboard icon), "Family name", "Type" (with a dropdown arrow), and three buttons: "Keyboard", "New patient" (highlighted with a green circle), and "Cancel".

FIGURE 84

3. Click **New patient** to save the entries.

### 6.3.4 Step by step: Link a sample to an existing patient:

1. Click on patient name or start typing the name/ ID to enter **PATIENT SEARCH**.

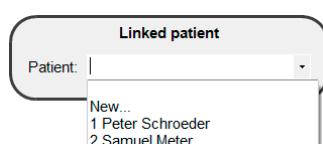


FIGURE 85

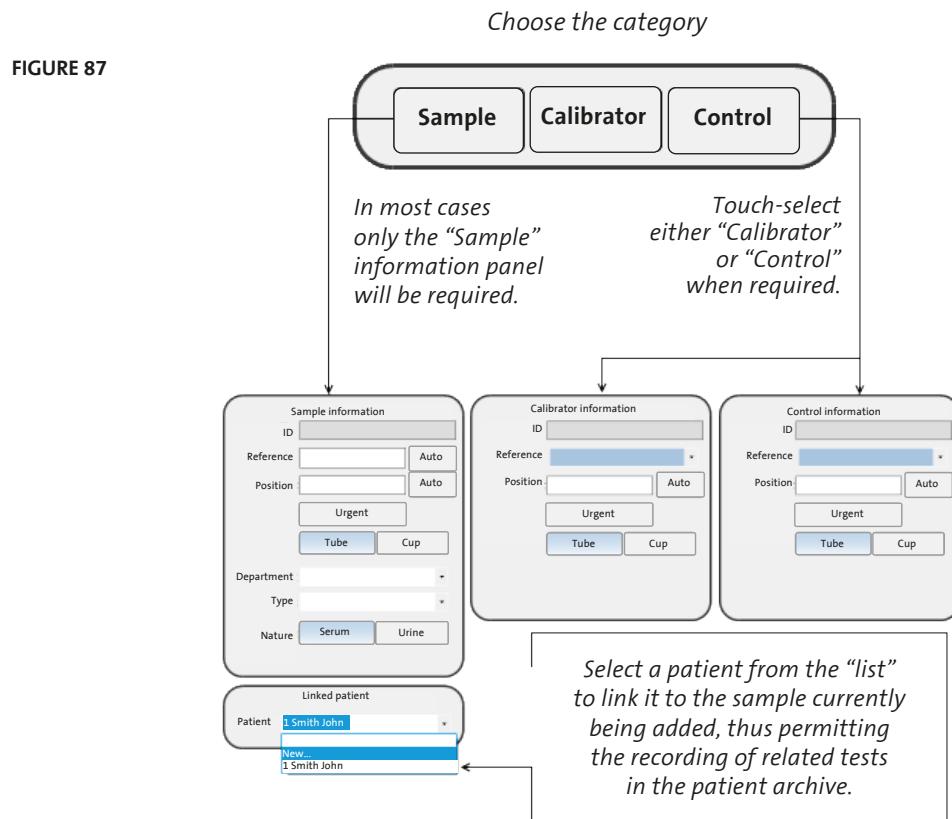
2. If you start typing the name or ID, the **PATIENT SEARCH** work form will open automatically.

A screenshot of a "PATIENT SEARCH" form. It displays search results for "Peter Schroeder" and "Samuel Meter". Below the results is a search bar with the letter "s" and two buttons: "Select" and "New patient".

FIGURE 86

3. Click **Select** to link the sample to this patient.

### 6.3.5 Overview of commands



### 6.3.6 Step by step: Delete existing sample

1. Select a sample/ calibrator/ control from the **Sample list**.
2. Click the **Remove** icon to delete the sample/ calibrator/ control from the sample list.

### 6.3.7 Step by step: Modify an incorrect entry of an existing sample

1. Select a sample/ calibrator/ control from the **Sample list**.
2. Make the necessary changes.
3. Click **Apply** to apply the changes.

## 6.4 SAMPLE INSPECTION work form

The **SAMPLE INSPECTION** work form shows an overview of sample information. A graphic display shows the remaining sample volume. All results for the selected sample listed in a table.

### 6.4.1 Getting there

 To access the information for a sample, select that line in the sample list and click the **Inspect** icon to open the **SAMPLE INSPECTION** work form.

### 6.4.2 Functions

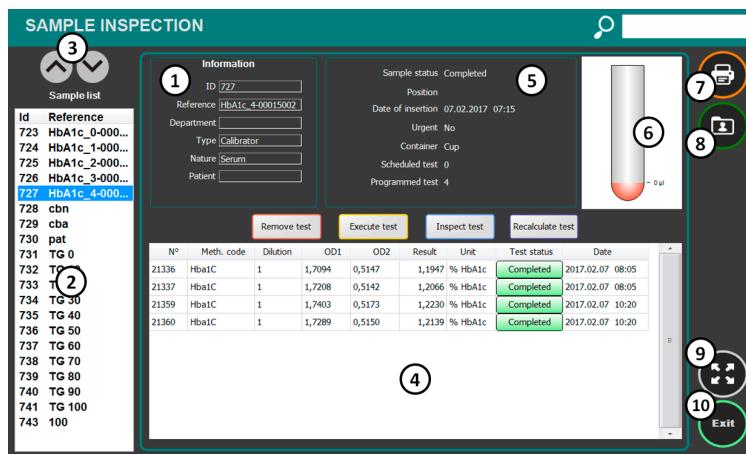
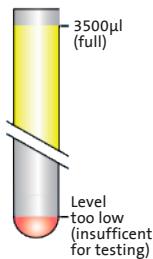


FIGURE 88

1. Basic information about the selected sample is shown under **Information**.
2. Subsequent list of other samples can be accessed here without returning to the **SAMPLES** tab.
3. Click for next sample or previous sample.
4. Table of all test results for the selected sample. Tests are listed with information on test no., method code, dilution, ODs, result, status and date.
5. Additional information for the selected sample (e.g. position, urgent)

6. Graphic showing the actual sample volume.

**FIGURE 89**



7. Access **SAMPLE REPORT** (see chapter 6.5)
8. Access **Patient Management** (see chapter 12.7)
9. Maximize or minimize work form
10. Exit **SAMPLE INSPECTION** work form

## 6.5 SAMPLE REPORT work form

Use this work form to print a sample report. The sample report contains all (or selected) test results of a given sample.

### 6.5.1 Getting there

- On the **SAMPLES** tab select any sample and click the **Print** button.
- On the **SAMPLE INSPECTION** work form click the **Print** button.

### 6.5.2 Functions

**FIGURE 90**

The screenshot shows the 'SAMPLE REPORT' work form. The interface includes:

- Information Panel:** Shows Sample ID (724), Reference (HbA1c\_1-0001500), Department (Calibrator), Type (Calibrator), Nature (Serum), and Patient (empty). Buttons include Print (6), Save (7), and OK (12).
- Comment Area:** A text field for 'Type comment here' with a placeholder '(13)'.
- Result Table:** A grid showing test results for HbA1c. Columns include Print, Nº, Meth. code, Dilution, Result, and Date. Rows are numbered (4) through (10). Data example: Row (4) has Nº 21330, Meth. code HbA1C, Dilution 1, Result 0,1238, Date 2017/02/07 08:00.
- Buttons at the bottom:** Automatically print (9), Date (10) set to 14/02/2017 14:28, Analyst (11) set to blank, and OK (12).

1. Basic information about the selected sample is shown under **Information**.
2. Subsequent selections of other samples can be accessed here without returning to the **SAMPLES** tab
3. Next sample, previous sample
4. Checked tests will be included in the report. If you want to exclude some tests from the report, you need to uncheck them.
5. All test results that are completed for the selected sample. Tests are listed with information on test no., method code, dilution, result and date.
6. Print sample report
7. Preview the report (or save it as PDF, Excel or Word file)
8. Minimize or maximize
9. Check to automatically print report when all tests for that sample are completed
10. Date and time
11. Name of analyst (user)
12. Exit **SAMPLE REPORT** work form
13. Add a comment to the sample report. You can enter any comment using the keyboard or you can select from a list of predefined comments. The Administrator can modify the list of predefined comments (see chapter 15.3.7).

## 6.6 SAMPLE TRAY work form

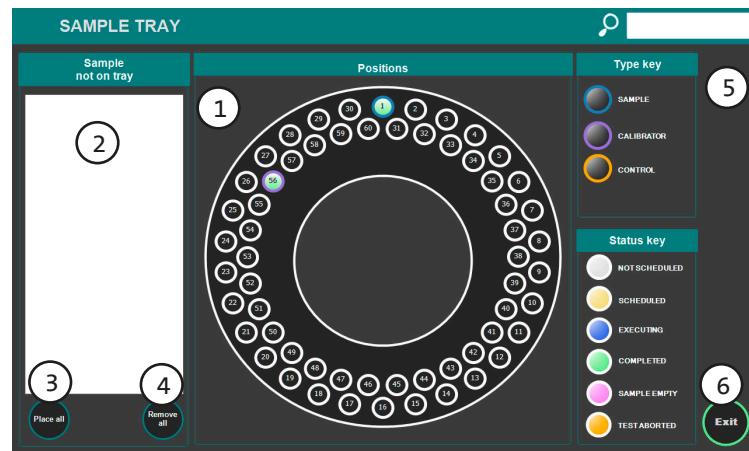
In this work form you can remove or place samples. You can also monitor type, location and status of samples displayed. This work form shows the positions assigned to urgencies, samples, calibrators and controls, with the colour coded status of each.

### 6.6.1 Getting there

 On the **SAMPLES** tab click on the **Sample tray** button.

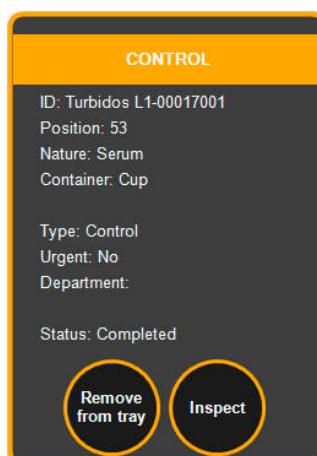
### 6.6.2 Functions

FIGURE 91



1. Select any tray position to display colour coded information panels:

FIGURE 92



There are commands to remove a sample or display the **SAMPLE INSPECTION** work form.

2. List of samples with no assigned tray positions; Select any item and then click on a tray position to place that item.
3. Auto placement of all samples listed to any empty tray positions
4. Remove all samples from the tray
5. Colour coded keys permit identification of the position of samples/ urgencies/ calibrators/ controls, and the status (see chapter 6.2.1 for description of colour code) of each in the testing process.

Code examples:

-  SAMPLE (blue ring)
- +  
 COMPLETED (green centre)
- =  
 SAMPLE COMPLETED (blue and green)

#### 6. Exit SAMPLE TRAY work form

##### “Type key” and “Status key”

- The outer ring of the items indicates the type (“Type key”): Sample, Calibrator, Control
- The inner colour of the item indicates the status (“Status key”): Not scheduled, Scheduled, Executing, Completed, Sample empty, Test aborted
- The number indicates the position on the tray.



FIGURE 93

! Note: Click any key to display the message boxes showing relevant information (like Reference, Position and Nature).



FIGURE 94

## 6.7 Sample tray selection

On the HumaStar analyzer you can work with more than one sample tray. This function can be useful if the analyzer is running and you want to place new samples on a second sample tray. After the analyzer has finished the run, you can just replace the complete sample tray instead of placing the samples one by one.

(Note: You must order a second sample tray from Human, because only one tray is delivered with the analyzer.) The Sample Tray Selection button is used to load or switch between different sample trays. You can also delete unnecessary sample trays.

### 6.7.1 Getting there

Click on the **Sample Tray Selection** button to access the **Sample Tray Selection** work form.

2 Default

### 6.7.2 Functions

FIGURE 95

SAMPLE TRAY SELECTION			
Tray	ID	Notes	
1	1	Default	
Select	3	Sample Tray Nr. 2	Delete

Close
Add

The sample tray that is currently positioned on the analyzer will be indicated by the number “1” in the column “Tray” referring the physical assigned tray.

- Click **Select** to position that row’s tray on the analyzer and activate it.
- Click **Delete** to delete the tray from the database.
- Click **Add**, type a name and then click **Insert** to add a new tray in the list (but it won’t be positioned on a physical one yet).
- Click **Close** to go back without performing any change.

## 7 WORKLIST TAB



FIGURE 96

### 7.1 Overview

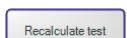
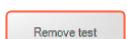
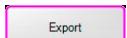
In this chapter the **WORKLIST** tab will be explained in detail. On the **WORKLIST** tab you can do the following operations:

- Select tests that you want to run for a given sample and add them to the worklist or worksheet.
- Add calibrations and controls to the worklist or worksheet.
- Start the run to process tests.
- See the status of ongoing tests.
- See results for completed tests.
- Print a “Worksheet”.

### 7.2 Functions

Test n°	Reference	Type	Ok.	Method	Test status	Result	Date
29834	Amy med	N	1	Amy	Completed	0,0186	0,0016
29835	Amy high	N	1	Amy	Completed	0,1253	0,0017
29836	Amy high	N	1	Amy	Completed	0,1392	0,0004
29837	LDL low	N	1	LDL	Completed	0,1340	0,0223
29838	LDL low	N	1	LDL	Completed	0,1374	0,0116
29839	LDL med	N	1	LDL	Completed	0,2295	0,0371
29840	LDL med	N	1	LDL	Completed	0,2298	0,0163
29841	LDL high	N	1	LDL	Completed	0,3021	0,0236
29842	LDL high	N	1	LDL	Result unusable	0,0354	0,0553
29843	CK low	N	1	CKL	Completed	0,0083	0,0000
29844	CK low	N	1	CKL	Completed	0,0076	0,0000
29845	CK med	N	1	CKL	Completed	0,0164	0,0000
29846	CK med	N	1	CKL	Completed	0,0184	0,0000
29847	CK high	N	1	CKL	Completed	0,0588	0,0000
29848	CK high	N	1	CKL	Completed	0,0570	0,0000
29849	CK low	N	1	CKDL	Completed	0,0100	0,0000
29850	CK low	N	1	CKDL	Completed	0,0098	0,0000
29851	CK med	N	1	CKDL	Completed	0,0117	0,0000
29852	CK med	N	1	CKDL	Completed	0,0155	0,0000
29853	CK high	N	1	CKDL	Completed	0,0635	0,0002
29854	CK high	N	1	CKDL	Completed	0,0647	0,0002

FIGURE 97

-  Worklist selection (see chapter 7.7.3)
-  Create a new worksheet
  -  Remove the selected worksheet
  -  Print a report of the selected worksheet ("Worksheet report")
  -  Schedule/ run all tests of the selected worksheet
  -  ACTION button - Performs an operation on the selected test(s). Click on the button to access commands:
    -  Recalculate test(s) using the current calibration and blank.
    -  Remove test(s) from worksheet
    -  Run selected test(s) of the worksheet
    -  Show TEST INSPECTION work form for the selected test
    -  Export test(s) and reaction curves as CSV-file (import in Excel)
    -  Move test(s) to another worksheet.
  -  STACK - Toggles between two different views of the worksheets.
  -  STOP, START and PAUSE a run. See also chapter 3.6.5.
  -  Test status - Click to access the "TEST INSPECTION" work form for this test (see chapter 7.6).

### 7.3 Worklists and worksheets

All tests are organized in “Worklists” and “Worksheets”. The active worklist is indicated in the secondary command bar.

October

One worklist can contain multiple worksheets. Worksheets are “pages” of tests. All worksheets of the active worklist are shown underneath the secondary command bar.

Monday Tuesday Wednesday Thursday Friday

For testing convenience the worklist can be broken down to create individual worksheets of tests for specific user purposes (e.g. all calibrations, all controls, all glucose, all samples of a specific department, all test of the same sample, all tests that are run by one user). You can use the worklists and worksheets to organize your samples and your daily work. You can process and run different worksheets at the same time.

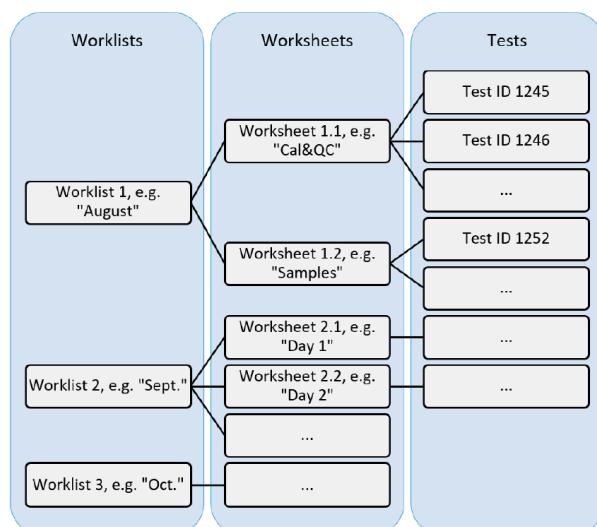
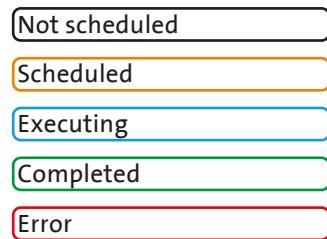


FIGURE 98

### 7.3.1 Colour code of worksheets

The status of worksheets is colour coded by coloured frames. The active/ selected worksheet is filled with yellow colour.



## 7.4 Run a test, calibration or QC

### 7.4.1 Step by step: Adding a test, calibration, QC to a worksheet

#### Sample test

1. Choose category “Test”.
2. Select any sample from the “Sample list”.
3. Select test method(s) or profiles that you want to run (see chapter 7.4.3).

#### Calibration and blank

1. Choose category “Calibration”.
2. Select either “Standard” (calibration) or “Reagent blank”.
3. Select test method(s) or profiles that you want to process (see chapter 7.4.3).

#### QC

1. Choose category “QC”.
2. Select from “QC1”, “QC2” and “QC3”.
3. Select test method(s) that you want to process (see chapter 7.4.3).

#### 7.4.2 Overview of command structure

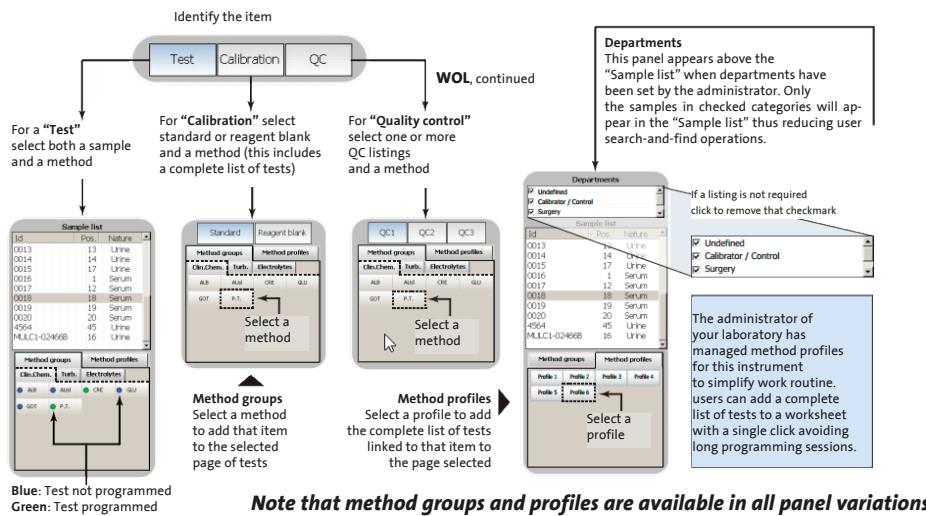


FIGURE 100

#### 7.4.3 Method selection

Methods are organized in different groups. Multiple methods can be selected with one click by setting up "Method profiles".

The administrator can create new groups and profiles. He can also assign methods to groups and profiles. See chapters 15.3.6 and 15.3.8.

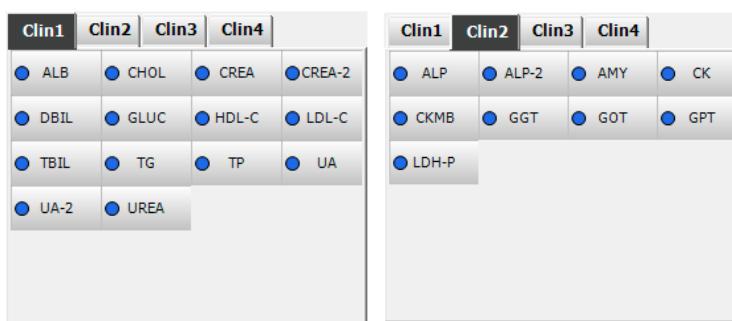


FIGURE 101

 (QC and Calibration only) Methods with bright background can be selected for scheduling a QC or calibration.



1. (QC and Calibration only) Methods with bright background can be selected for scheduling a QC or calibration.
2. (QC and Calibration only) Methods with dark background CANNOT be selected, because no QC or Standard has been assigned in *Lot management* (see chapter 12.6).

 (QC and Calibration only) Methods with dark background CANNOT be selected, because no QC or Standard has been assigned in “*Lot management*” (see chapter 12.6).

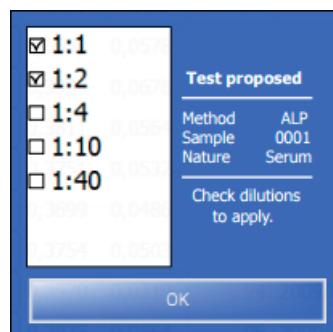
 (Test and Calibration only) Methods with a green mark have been selected.

 (Test and Calibration only) Methods with a blue mark have NOT been selected.

#### 7.4.4 Dilutions

If more than one dilution is available for the selected method selected, a box will be shown for the selection of the dilution rate.

FIGURE 102



**Note:** If the status of a test is “Result unusable”, it may be possible that the sample is too concentrated. When this is the case the test should be repeated with an appropriate dilution rate based on the previous result.

Rates that are checked will be inserted in the current worksheet.

In the **METHOD FIELDS** the administrator can define automatic dilutions for high results. See chapter 9.3.6.

## 7.5 Check and print completed results

### 7.5.1 Automatic check of result limits

The software automatically checks the result's validity according to certain "limits" that are set in the **METHOD FIELDS**. For HUMAN Reagents all limits are pre-defined, except the Pathological Ranges.

Pathological Ranges must be set by the Administrator. If a limit is exceeded the result is shown in red together with the limit that is exceeded. For example the result of 266.08 is (L)ower than the limit of 300.

Result	
266,08 < L (300)	

FIGURE 103

Test status	OD1	OD2	Result	Unit
Completed	-0,0230	1,5784	-0,0230	Abs
Completed	1,4611	1,5085	-0,0244	Abs
Completed	1,4527	1,4983	-0,0226	Abs
Completed	0,8590	1,3498	-0,4678	Abs
Completed	0,8673	1,3482	-0,4579	Abs
● Completed	1,1823	1,6586	149,35 > H	μmol / l

FIGURE 104

Click on a test result to show the limits of that test (e.g. pathological ranges).

Test status	OD1	OD2	Result	Unit	Date
Completed	-0,0230	1,5784	-0,0230	Abs	2018.11.2...
Completed	1,4611	1,5085	-0,0244	Abs	2018.11.2...
Completed	1,4527	1,4983	-0,0226	Abs	2018.11.2...
Completed	0,8590	1,3498	-0,4678	Abs	2018.11.2...
Completed	0,8673	1,3482	-0,4579	Abs	2018.11.2...
● Completed	1,1823	1,	Min 19,10	Reference (μmol / l) 25,55	Max 32,00

FIGURE 105

### 7.5.2 Test status, details, errors and flags

In the “Test status” column of the worksheet table all tests are indicated with a status. You can click on any of the status buttons to get more information and to access the **TEST INSPECTION** work form for this test (see chapter 7.6).

FIGURE 106



#### ROUTINE

##### Not scheduled

Test programmed/ Waiting for scheduling

##### Completed

Test result finished correctly and usable

##### Scheduled

Test scheduled/ Waiting for execution

##### Executing

Test in process

##### Result edited

Test result edited by user

##### ● Results unusable

Test result unusable. A red dot indicates that the result is flagged. Click to get more details.

##### ● Completed

Test result finished. A red dot indicates that the result is flagged (e.g. Westgard rules violated). Click to get more details.

## INSTRUMENT ERRORS

### Predilution error

Predilution failed. An error occurred during the preparation of the predilution. The test is not able to locate the prediluted sample.

### Mechanical error

Mechanical problem. One of the mechanical movements has lost some steps of the motor. Test has been aborted. Repeat the test. If the error happens frequently, call technical assistance.

### Test aborted

Test aborted. The STOP button has been clicked by the user while the test is executed.

### Method error (95)

The test has been executed with a method that has a filter with an incorrect autozero. Troubleshooting: Execute lamp auto-adjustment and execute start-up.

### Method error (99)

Method Error. The method that is uploaded on the instrument has an error. Go to the METHODS tab and click the **Method error** message to get details. (“99” is a placeholder and not an actual error code.)

### Optical error

Reading failed. The OD of the reading is too high (too dark). Check reagents (possible mix-up). Repeat test with dilution. If all/many tests have an Optical error, check the lamp.

### Shock error

Shock Error. E.g. needle has hit an obstacle. Check the correct position of the sample/cup/tube/bottle. Check for lid on bottle. If it happens frequently without an obvious reason, call assistance to perform a mechanical adjustment.

### Error (99)

Error 99. Unexpected error. Report the error to technical assistance (example of an error code).

### Communication error

Communication Error. See solution 1 in chapter 18.

### AD overflow

Lamp energy is too high. Probably the lamp is close to the end of the lifetime. Perform start-up. Calibrate and/or change lamp. Call assistance if this does not help.

### Tube ref. error

Tube ref. error. There is a problem with the cuvette/water blank of this cuvette. Repeat Quick Start-up. Adjust/calibrate lamp.

## RESOURCE ERRORS

**Reag. 1 missing**

Not assigned on reagent panel.

**Reag. 2 missing**

Not assigned on reagent panel.

**Reag. 1B missing**

Not assigned on reagent panel.

**Diluent missing**

Dilution not assigned.

**Post Inj missing**

Post Injection solution not assigned.

**Cuv.Ext.Wash missing**

Cuvette ExtraWash solution not assigned.

**Needle Ext.Wash missing**

Needle ExtraWash solution not assigned.

**Reag. closed 1 missing**

The reagent has not been placed/assigned on the reagent tray.

**Reag. closed 2 missing**

The reagent has not been placed/assigned on the reagent tray.

**Reag. closed 3 missing**

The reagent has not been placed/assigned on the reagent tray.

**Reag. blank error**

If this error shows up for the measurement of the blank itself, there are two possibilities:

- The OD of the blank measurement is below the “Blank OD min”, which defined in the method settings.
- The OD of the blank measurement is above the “Blank OD max”, which defined in the method settings.

If this error shows up for the measurement of a sample:

- The reagent blank of this test has expired. You have to schedule the measurement of a new reagent blank.

**ReagentXExpired**

Can be Reagent1Expired, Reagent2Expired, or Reagent3Expired. This error appears if the test is scheduled after the expiration of the bottle. The problem is that the reagent can't be scheduled if the bottle is expired.

**Level failed**

Repetition of the liquid level sense of the sample is not consistent. Check for bubbles. Position of the needle/ tube may not be good. If problem persists, call assistance.

**Reag. 1 empty**

Reagent assigned insufficient

**Reag. 2 empty**

Reagent assigned insufficient

**Reag. 1B empty**

Reagent assigned insufficient

**Diluent empty**

Diluent provided insufficient

**Sample N empty**

Sample provided insufficient

**Post.Inj. empty**

Post Injection solution insufficient

**Cuv.Ext.Wash empty**

Cuvette ExtraWash solution insufficient

**Needle Ext.Wash empty**

Needle ExtraWash solution insufficient

! Note: See chapter 18 for more  
details on error messages and  
troubleshooting.

## 7.6 TEST INSPECTION work form

### 7.6.1 Overview

This work form provides detailed information about a test. It includes a graphic of test readings (reaction curve) and result issues (flags, warnings, etc.).

You can also trace the test result to the calibration, the method, and the LOT of standard that have been used to calculate the result.

**Inspect test** To inspect the result of a test on a worksheet select that test line and click **Inspect test** to display the work form. You can also click on the “Test status” to Quick Access the work form.

FIGURE 107



1. Sample: Information about the sample of the selected test. Click on the magnifying glass button to show details.
2. Result and further details of the result calculation basis. Click on the turning arrows button to recalculate the result with the current calibration and blank.

Within 24 hours from test execution, if either calibration or blank were faulty, and thus were adjusted, it is possible to request a new result calculation with the latest calibration and blank.

OD1 is the main reading/reaction of the test.

OD2 is the secondary/reference reading (e.g. water/cuvette blank, reagent blank, sample blank, 2nd wavelength,...). See chapter 11 for details on OD1 and OD2.

For the reagent blank of a kinetic test, the OD2 is the first reading point in Abs (not Abs/min).

OD1 of endpoint and endpoint self-blank: The indicated readings are raw values. The values are shown without subtraction of the water blank of the cuvettes.

OD1 and OD2 of kinetic, fixed time, bichromatic: The values that are shown already include the water blank of the cuvette.

3. **Result issues:** Error messages and flags related to this test will be displayed here.
4. **Date:** Date and time of the test execution.
5. **Status:** Status of the test, e.g. “Completed”, “Result unusable”.
6. **Method:** Details of the method that was used for the execution and calculation of this test. Click on the arrow button to show details.
7. **Calibration:** Details of the calibrator, the calibrator LOT and the calibration that was used for the calculation of the result. Click on the arrow button to show details.
8. **Type of the sample** (N: normal sample; S: standard; QC: control; BLANK: Reagent blank)
9. **Resources:** Number of the reaction cuvette and pipetting arm that was used for this test.

**10. Resource LOTs**

11. **Reaction curve:** The y-axis is showing the absorbance and the x-axis is showing the time in seconds.  
Red section: Incubation time 1  
Yellow section: Incubation time 2  
Green section: Reading time (these measurements are actually used for result calculation)  
Orange section: Time after the reading is finished  
The reading point that is selected on the left side is highlighted with a grey, vertical line. For bichromatic tests both wavelengths are shown in the graphic as blue and red line. The incubation 1, incubation 2, reading times are shown as colored background.
12. **Optical readings:** Endpoint and endpoint self-blank: The indicated readings are raw values. The values are shown without subtraction of the water blank of the cuvettes. Kinetic, fixed time, bichromatic: The values that are shown already include the water blank of the cuvette.
13. **Test list:** List of all active worksheets and the tests that are in those worksheets.
14. **Up/down:** Select next test or previous test in the worksheet.
15. **Search function:** You can use this function to search or filter for a Test Id. Enter part of an Id or the complete Id of a test. The tests that are listed in the "Test list" are filtered according to the input in this field. Click on the "+" to expand any worksheet and select any of the filtered tests.
16. **Print:** Print a test report.
17. **Rerun:** Rerun (schedule again) this test.
18. **Virtual keyboard:** You can use this virtual keyboard for the search function (15.), if you have a touch screen.
19. **Maximize or minimize:** Expand the window to full screen or reduce to a smaller window.
20. **Exit:** Exit the "TEST INSPECTION" form

**7.6.2 Reaction curve**

Readings are taken during every machine cycles. It is very helpful for troubleshooting to see all readings taken every machine cycle for each test during the entire testing process.

**Full reaction curve and throughput**

The administrator can deactivate the reading during every machine cycle. In that case only readings that are necessary for the calculation of the results will be executed. This will result in a slightly (<10%) higher throughput. See chapter 15.3.6 for changing the setting.



FIGURE 108

The reaction curve is divided in different sections (see chapter 10):

- Red: Incubation time 1
- Yellow: Incubation time 2
- Green: Reading time

Experienced operators familiar with the trends normally associated with the reaction curves may be in a position to judge the validity of tests executed on specific samples. This can provide a valuable asset which is particularly effective when testing samples with specific pathological characteristics (see anomaly highlighted in red circle of the chart).

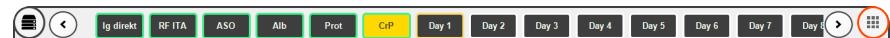
## 7.7 Advanced functions

### 7.7.1 Stack button

 STACK - Toggles between two different views of the worksheets.

1. Use the sliders on the left and right to browse through stacked worksheet tabs.

FIGURE 109



2. Hide the slider and see all worksheets.

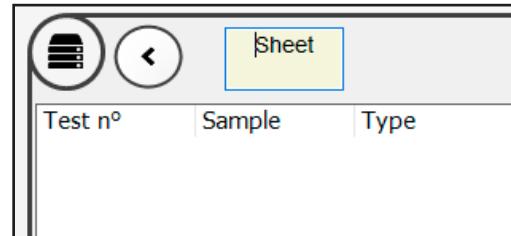
FIGURE 110



### 7.7.2 Rename worksheet

1. Click and hold a Worksheet button to edit the name of this worksheet.
2. Click **Enter** to apply changes.

FIGURE 111



### 7.7.3 Worklist selection

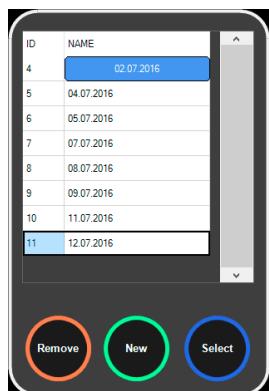
Getting there

FIGURE 112



The **WORKLIST SELECTION** work panel can be opened by clicking on the name of the active Worklist.

## Overview



In the work panel you can see all worklists that have been saved. The selected/ active worklist is the one with the blue rectangle and centred text.

FIGURE 113

## Functions

The following functions are available:

-  Use to add/ save the current worklist as a **new** worklist in the database. Changes made to the active worklist and the worksheets are saved automatically.

1. The insertion form will be shown.



FIGURE 114

2. Type the new name and then click “Insert”.

-  Remove/ delete the selected worklist.
-  Load/ activate the selected worklist.

**Note:** Even if you delete a worklist or worksheet, test results are still accessible through the “Test archive” function (see chapter 12.5).

#### 7.7.4 Action button

Click on any test to select this test and then click on the **ACTION** button to execute one of the functions explained hereafter. You can also select multiple tests by one of the following means:

- Click on any test, hold the mouse button pressed and move it up or down.
- Click on any test, then hold down the **Shift** key on your keyboard and click on any other test (all tests between the first and the second click are selected).
- Hold the **Ctrl** key on your keyboard and click on any number of individual tests.

#### Functions

FIGURE 115

Test n°	Sample	Type	Dil.	Method	Test status	OD1	OD2	Result	Unit	Date
2845	Diluent	BLANK	1	UREAUV	Completed	-0,0897	1,7581	-0,0897	mg/dl	2016/07/12 09:03
2846	Diluent	BLANK	1	CREAT	Completed	-0,1002	0,2448	-0,1002	mg/dl	2016/07/12 09:02
2847	Diluent	BLANK	1	TBILI	Completed	0,0377	0,4515	-0,4138	mg/dl	2016/07/12 09:07
2848	Diluent	BLANK	1	ALK	Completed	-0,0842	1,0783	-0,0842	U/L	2016/07/12 09:15
2849	Diluent	BLANK	1	SGPT	Completed	-0,2379	2,2540	-0,2379	U/L	2016/07/12 09:05

The following operations are possible:

**Recalculate test** Within 24 hours from test execution, if either calibration or blank were faulty, it is possible to recalculate test(s) from the raw absorbances using the current calibration and blank.

**Remove test** Remove test(s) from worksheet.

**Execute test** Schedule test(s) to be processed during next run (click the **Start** button to actually start the run). Depending on the “Test status” different operations are done:

- “Not scheduled” tests will be scheduled and executed.
- “Completed” tests will be copied (replicated). Copies will be inserted in the worksheet (possibly diluted) and executed.
- Tests with “Error” will be run again.

**Inspect test** Show TEST INSPECTION work form for the selected test (see chapter 7.6).

**Export** Export the selected tests and reaction curves as CSV-file for import in Excel (Function not accessible for regular user).

**Move** Move test(s) to another worksheet. Confirm the destination and click **OK** to finalize the procedure.

### 7.7.5 How to repeat a „Completed“ test

1. Select the test(s) to be repeated.

Test n°	Sample	Reference	Type	Dil.	Method	Test status	OD1	OD2	Result	Unit	Date
1502	#0120	Turbidos L1-00018001	N	1	CRP	Completed	0,1954	0,1367	7,2	mg / l	2018.12.07 12:13
1503	#0120	Turbidos L1-00018001	N	1	CRP	Completed	0,1962	0,1374	7,2	mg / l	2018.12.07 12:13
1504	#0120	Turbidos L1-00018001	N	1	CRP	Completed	0,1958	0,1368	7,3	mg / l	2018.12.07 12:14
1505	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6387	0,2810	61,9	mg / l	2018.12.07 12:14
1506	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6377	0,2860	60,7	mg / l	2018.12.07 12:17
1507	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6400	0,2801	62,3	mg / l	2018.12.07 12:18
1508	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6468	0,2834	63,0	mg / l	2018.12.07 12:18
1509	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6562	0,2835	64,8	mg / l	2018.12.07 12:18
1510	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6517	0,2764	65,3	mg / l	2018.12.07 12:19
1511	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6284	0,2679	62,5	mg / l	2018.12.07 12:19
1512	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6415	0,2747	63,7	mg / l	2018.12.07 12:20
1513	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6432	0,2798	63,0	mg / l	2018.12.07 12:25
1514	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6465	0,2806	63,5	mg / l	2018.12.07 12:26
1515	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6491	0,2748	65,1	mg / l	2018.12.07 12:26
1516	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6647	0,2967	63,9	mg / l	2018.12.07 12:26
1517	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6477	0,2949	61,0	mg / l	2018.12.07 12:27
1518	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6494	0,2836	63,5	mg / l	2018.12.07 12:27
1519	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6434	0,2839	62,3	mg / l	2018.12.07 12:28
1520	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6644	0,2901	65,1	mg / l	2018.12.07 12:31
1521	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6529	0,2834	64,2	mg / l	2018.12.07 12:31
1522	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6687	0,3027	63,5	mg / l	2018.12.07 12:31
1523	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6470	0,2866	62,4	mg / l	2018.12.07 12:32

CV%: 0,00 | SD: 0,00 | Average 63,90 Selected: 1 Total: 56

FIGURE 116

2. Click on the **ACTION** button and then **Execute test**.

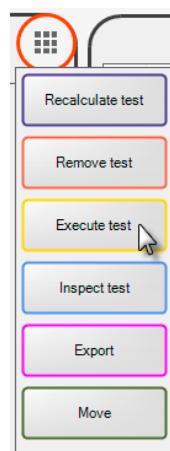
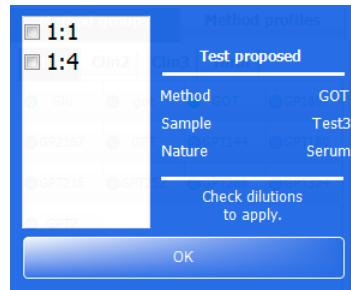


FIGURE 117

3. If dilutions are defined for this method (see chapter 10.4.16), you can select the dilution rate and then click OK. If no dilutions are defined in the method, this step is skipped.

**FIGURE 118**

4. The test is added at the end of the worksheet.

**FIGURE 119**

Test n°	Sample	Reference	Type	Dil.	Method	Test status	OD1	OD2	Result	Unit	Date
1505	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6387	0,2810	61,9	mg / l	2018.12.07 12:14
1506	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6377	0,2860	60,7	mg / l	2018.12.07 12:17
1507	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6400	0,2801	62,3	mg / l	2018.12.07 12:18
1508	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6468	0,2834	63,0	mg / l	2018.12.07 12:18
1509	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6562	0,2835	64,8	mg / l	2018.12.07 12:18
1510	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6517	0,2764	65,3	mg / l	2018.12.07 12:19
1511	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6284	0,2679	62,5	mg / l	2018.12.07 12:19
1512	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6415	0,2747	63,7	mg / l	2018.12.07 12:20
1513	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6432	0,2798	63,0	mg / l	2018.12.07 12:25
1514	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6465	0,2806	63,5	mg / l	2018.12.07 12:26
1515	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6491	0,2748	65,1	mg / l	2018.12.07 12:26
1516	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6647	0,2967	63,9	mg / l	2018.12.07 12:26
1517	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6477	0,2949	61,0	mg / l	2018.12.07 12:27
1518	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6494	0,2836	63,5	mg / l	2018.12.07 12:27
1519	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6434	0,2839	62,3	mg / l	2018.12.07 12:28
1520	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6644	0,2901	65,1	mg / l	2018.12.07 12:31
1521	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6529	0,2834	64,2	mg / l	2018.12.07 12:31
1522	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6687	0,3027	63,5	mg / l	2018.12.07 12:31
1523	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6470	0,2866	62,4	mg / l	2018.12.07 12:32
1524	#0121	Turbidos L2-00018001	N	1	CRP	Completed	0,6481	0,2838	63,2	mg / l	2018.12.07 12:32
2085	#0121	Turbidos L2-00018001	N	1	DBIL	Scheduling...			n/a	mg / dl	

Selected: 1 Total: 49

## 7.8 Worksheet management

To create a new worksheet of tests click the **Plus** button to show the **NEW SHEET** window.

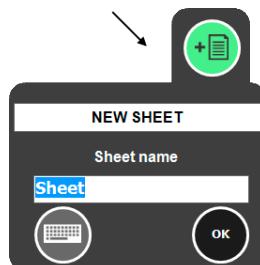


FIGURE 120

Type in a name or other designation suitable to identify the new worksheet and then click **OK**.

- To remove a worksheet of tests select that sheet and click **Minus**.
- ⌚ To schedule a complete worksheet of tests select that sheet and click on the **Execute** button (click the **Start** button to actually start the run). The tests will be executed in the order top to bottom (see below for other options). If you want to execute only selected tests, use the **Action** button (see chapter 7.7.4).
- 🖨️ To print a **Worksheet report** select that sheet and click on **Print**. You can choose from two printing options: "Print complete worksheet" or "Print only selected tests".

### 7.8.1 Worksheet table

FIGURE 121

Test n°	Sample	Type	Dil.	Method	Test status	OD1	OD2	Result	Unit	Date
2845	Diluent	BLA (4)	1	UREAUV	Completed	-0,0897	1,7581	-0,0897	mg/dl	2016/07/12 09:03
2846	Diluent	BLANK	1	CREAT	Completed	-0,1002	0,2448	-0,1002	mg/dl	2016/07/12 09:02
2847	Diluent	BLANK	1	TBILI	Completed	0,0377	0,4515	-0,4138	mg/dl	2016/07/12 09:07
2848	Diluent	BLANK	1	ALK	Completed	-0,0842	1,0783	-0,0842	U/L	2016/07/12 09:15
2849	Diluent	BLANK	1	SGPT	Completed	-0,2379	2,2540	-0,2379	U/L	2016/07/12 09:05
2850	Diluent	BLANK	1	ALB	Completed	0,2536	0,4219	-0,1683	g/dl	2016/07/12 09:07
2851	Diluent	BLANK	1	TP	Completed	0,0902	0,3203	-0,2301	g/dl	2016/07/12 09:07
2852	Diluent	BLANK	1	SGOT	(2) Completed	-0,1775	1,9793	-0,1775	U/L	2016/07/12 09:05
2853	Diluent	BLANK	1	CHOL	Completed	0,0596	0,2898	-0,2302	mg/dl	2016/07/12 09:07
2854	Diluent (1)	BLANK	1	TRIG	Completed	0,0862	0,5012	-0,4150	mg/dl	2016/07/12 09:08
2855	QUANTINO... QC	1	UREAUV	Result unusable		-0,2609	0,0000	n/a	mg/dl	2016/07/12 09:18
2856	QUANTINO... QC	1	CREAT	Result unusable		0,6205	0,8077	n/a	mg/dl	2016/07/12 09:17

1. Click any **Sample** to display the message boxes showing relevant information (like Reference, Position and Nature). (If the “Sample” column is not shown in your table, ask your Administrator to activate it in the Settings).
2. Click to open **Test Inspection** (see chapter 7.6).
3. Click to toggle the slider.
4. Type can be: BLANK, S1 to S8 (standard), D1 to D3 (automatic dilutions), QC1 to QC3 (quality control), N (normal test).

FIGURE 122



### 7.8.2 Worksheet columns, order of worksheet

To change the order of the tests in your worksheet, click on any of the columns’ titles (e.g. click on **Method** to sort by method). This function is similar to the Microsoft Windows Explorer.

Test n°	Sample	Reference	Type	Dil.	Method	Test status	OD1	OD2	Result	Date
27474	Diluent		BLANK	1	IgA	Completed	0,0342	0,0213	0,0129	2016.11.23 10:28

FIGURE 123

If the complete worksheet is scheduled at once, tests will be processed top to bottom. You can use the order function to define if tests are processed in the order by methods (batch), by sample or by test no.

! Note: Blanks and calibrators  
! are always processed before  
normal samples.

The administrator can define, which columns (e.g. Reference, Name, Type, OD1, OD2, Result, Unit, ...) are shown in the worksheet table. See chapter 15.3.9.

### 7.8.3 Test result editing

Double click on a result to edit it.

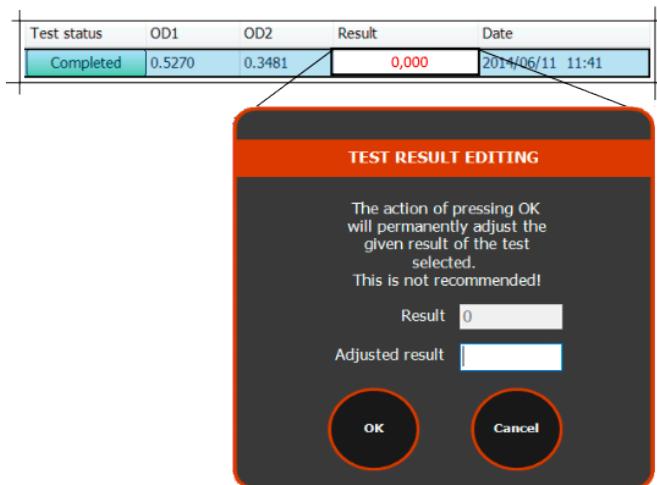


FIGURE 124

When required, HI software permits test results to be edited (only if authorized by the laboratory administrator).

Test results which have been edited are labelled with an "E" in the sample reports to permit the patient to understand that the result has been edited manually and has not been executed and calculated on the analyzer.

! Note: Please note that in some countries it may be illegal to edit test results. Generally this is not good laboratory practice and the operator takes full responsibility for any possible consequence of editing test results.

**FIGURE 125**

Analysis:						
Method Name	Result	Unit	Evaluation	Min	Max	
Cholesterol	4.9	mmol/l	High	0	0	
Calcium	2.13	mmol/l	High	0	0	
ASAT / GOT	0.0368 > H (0.03)	U/ml	High	10	30	
ALAT / GPT	33.3	U/l	High	0	0	E

In the worksheet and in the test archive the result is shown with the status “Result edited”:

Result edited

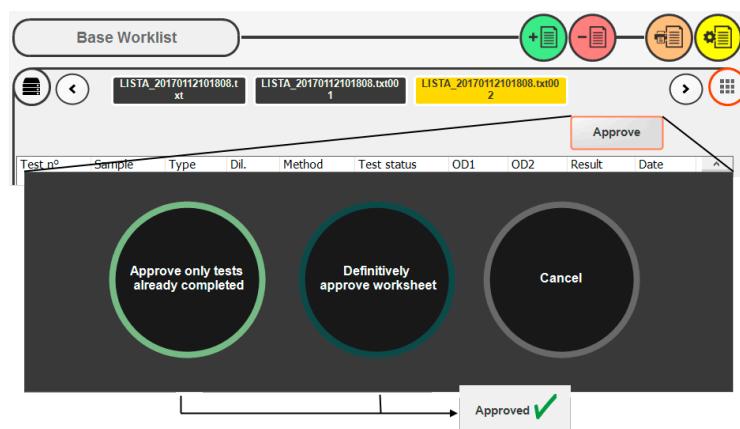
#### Administrator function

Editing of results can be enabled or disabled by the administrator in the instrument's settings (see chapter 15.3.6).

#### 7.8.4 LIS management system

If software for the management of the laboratory (LIS - Laboratory Information System) has been set-up to work together with the instrument, it is possible to receive worksheet data from the central computer. When this happens a message box requesting confirmation will be displayed. Upon “OK”, LIS information will be transferred to a normal worksheet and will then be executed.

After one or more tests have been finished, it is possible to “Approve only the tests already completed”. The approved tests will be immediately transferred to the central computer. Alternatively it is possible to “Definitely approve the worksheet”. All tests belonging to this sheet will be transferred automatically to the central computer once they are completed.

**FIGURE 126**

## 8 METHODS TAB



FIGURE 127

### 8.1 Overview

In this chapter the functions of the METHODS tab will be explained in detail. Calibration and reagent blanks are basic and critical for testing (e.g. readings and calculations, interpolations, testing processes, timings, volumes). Be careful when changing them.

On the METHODS tab you can...

- Check and manage **calibrations** for all methods.
- Check the **history of calibrations** and **blanks** for all methods.
- Check and manage **quality control (QC)** for all methods.
- Create and manage new **methods on instruments with a license for open channels**.
- Manage **reference ranges and units** for all methods.

#### 8.1.1 Main elements and controls

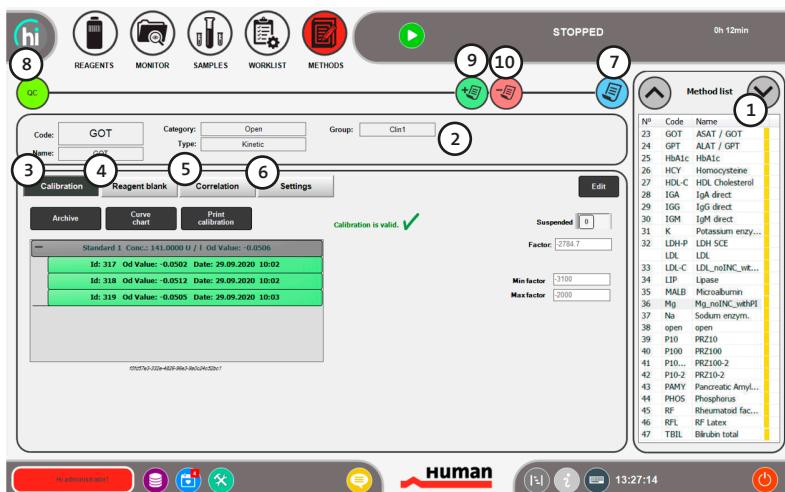


FIGURE 128

**1. Method list**

Click on any method to select it. All information and functions that are shown on the left side of the screen refer to the method that you have selected. A total of up to 60 methods may be included in the list at any given time.

**2. Designations**

Information about the selected method.

**3. Calibration**

Information about the actual and old calibrations of the selected method (see chapter 8.1.2).

**4. Reagent blank**

Information about the actual and old reagent blanks of the selected method.

**5. Correlation**

Information used to adjust results with correlation models (offset and slope). See chapter 8.4.

**6. Settings**

Settings for the calibration and the reagent blank of the selected method.

**7. Method fields**

Access the “METHOD FIELDS” work form to check the working parameters of the selected method (see chapter 11).

**8. Quality control**

Access the “QUALITY CONTROL” work module to assign controls to each method and to check QC results/ status (see chapter 13.3).

**9. ADD method**

Click **Add** to create a new method (administrator access level on instruments with a license for open channels only).

**10. DELETE method**

Click **Delete** to remove the selected method (administrator access level only).

### 8.1.2 Four tabs: Calibration, correlation, reagent blank, settings

Calibrations are the means by which the instrument transforms ODs (optical density values) into interpretable results (concentrations). It can be a linear function (factor) or it can be a non-linear function described by multiple points (standards). To ensure accurate results it is mandatory to execute a calibration of the method each time it is requested by the system.

The calibration section is structured in four tabs:



#### Calibration

On this tab it is possible to access the actual calibrations executed on the machine including old instances ("Archive").

#### Reagent blank

On this tab it is possible to access the actual reagent blanks executed on the machine including old instances.

#### Correlation

On this tab it is possible to define a correlation formula of the results (offset and slope).

#### Settings

On this tab is possible to edit or view the configuration settings used to execute the calibration for the selected method.

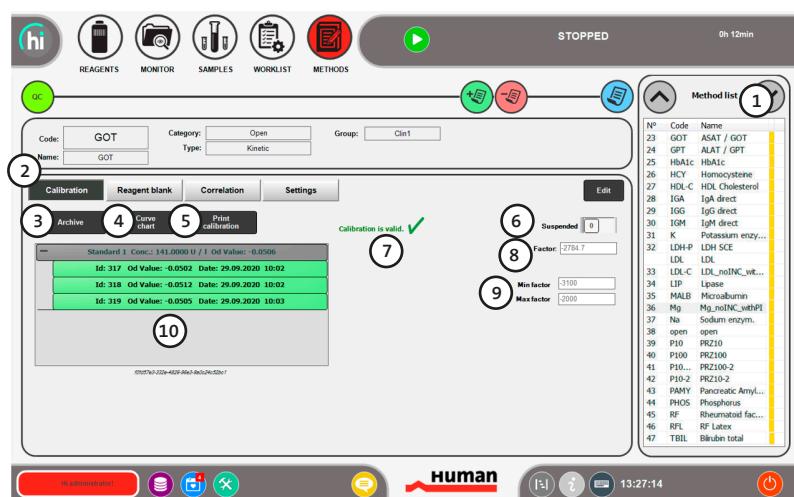
## 8.2 Calibration



Click on **Calibration** to access this menu.

### Functions

**FIGURE 129**



1. **Method list:** Select a method in the “Method list”
2. **Calibration:** Click on the **Calibration** tab to access this screen.
3. **Archive:** History of all calibrations executed for the selected method.
4. **Curve chart:** Graphic of the calibration points (including repetition points).
5. **Print calibration:** Print an overview of the current calibration.
6. **Suspended ON/OFF:** Manual suspend (deactivate) the current calibration.
7. **Calibration is ...:** The status of the calibration of the selected method.
8. **Factor:** The latest factor used to calculate the test result from the detected ODs. Only methods with one or two standards use factors. For more standards the interpolation is used.
9. **Factor (Min/ Max):** Acceptance range of the factor (when applicable)
10. **Calibration tree:** All measured standards (and repetitions) that are used in the current calibration.

### 8.2.1 Calibration status

The status of a calibration is clearly indicated on the top right corner of the calibration tree.

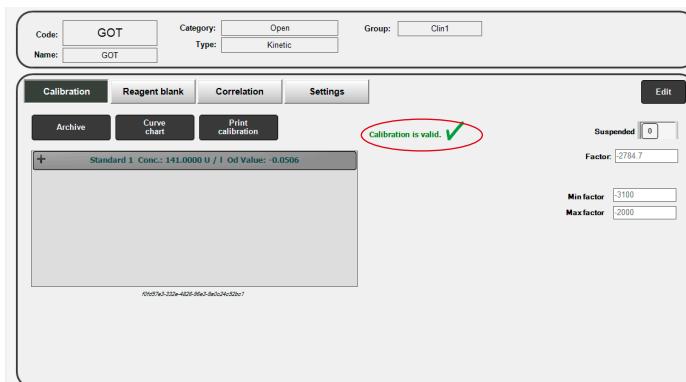


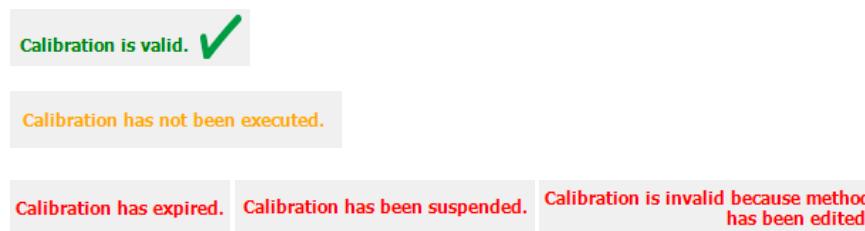
FIGURE 130

#### Possible status

Calibrations can have different statuses:

- Calibration is valid.
- Calibration has not been executed.
- Calibration has expired.
- Calibration has invalid results.
- Calibration has been suspended.
- Calibration is invalid because method has been edited.
- Calibration points are missing.
- Calibration is not usable.
- Calibration is non monotonic.

Example of colours that are used to indicate the status:



### Automatic monitoring of calibration

The software automatically monitors the status of all calibrations. If the calibration of a method is no longer valid the user will be alerted both in the **MONITOR** tab (see chapter 5) and in the test creation process in the **WORKLIST** tab (see chapter 7). In this case it will be necessary to measure a new calibration before other tests are executed for this method.

#### 8.2.2 Calibration tree

The calibration tree shows each single standard with information regarding concentration and OD. The standards are colour coded according the “Calibration status”.

FIGURE 131

<b>+</b>	Standard 1 Conc: 0,000 OD: 0,042
<b>+</b>	Standard 2 Conc: 32,000 OD: 0,128
<b>+</b>	Standard 3 Conc: 63,000 OD: 0,352
<b>+</b>	Standard 4 Conc: 100,000 OD: 0,722
<b>+</b>	Standard 5 Conc: 143,000 OD: 1,218

#### Expand the calibration tree

Click on any standard to expand it and see all the repetition points (replicates) of this standard. Each repetition point is indicated with its execution date and OD value.

FIGURE 132

<b>+</b>	Standard 1 Conc: 0,000 OD: 0,042
<b>-</b>	Standard 2 Conc: 32,000 OD: 0,128
	ID: 863 OD:{0:0,128} Date: 07.02.2017 10:14
	ID: 864 OD:{0:0,128} Date: 07.02.2017 10:15
<b>+</b>	Standard 3 Conc: 63,000 OD: 0,352
<b>+</b>	Standard 4 Conc: 100,000 OD: 0,722
<b>+</b>	Standard 5 Conc: 143,000 OD: 1,218

**Modify calibration points and automatic outlier detection**

By selecting a single repetition point it is possible to deactivate/reactivate, edit or repeat this point.

	Standard 1 Conc: 0,000 OD: 0,042
	Standard 2 Conc: 32,000 OD: 0,128
	ID: 863 OD:{0:0,128} Date: 07.02.2017 10:14
	ID: 864 OD:{0:0,128} Date: 07.02.2017 10:15
	Standard 3 Conc: 63,000 OD: 0,352
	Standard 4 Conc: 100,000 OD: 0,722
	Standard 5 Conc: 143,000 OD: 1,218



FIGURE 133

1. Right click on any repetition point to access the action panel.

**2. Deactivate/ activate**

Click on the red button is to deactivate/reactivate this single repetition point. Once deactivated, the calibration point will be ignored during the calculation process. If enabled in the Settings and the Method Fields of this method, outliers are automatically detected and deactivated.

**3. Edit**

The blue button permits to manually edit the result of the repetition point.

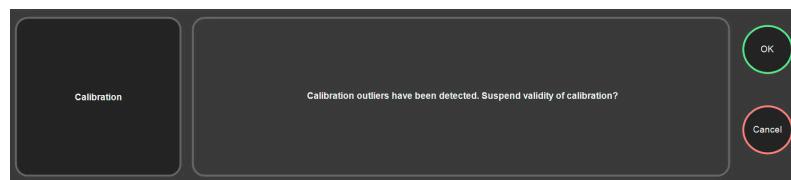
**4. Repeat**

Click on the green button to repeat the single calibration point and execute it in the worklist. Once finished the old result will be replaced by the new result and the calibration will be recalculated.

### 8.2.3 Outlier detection

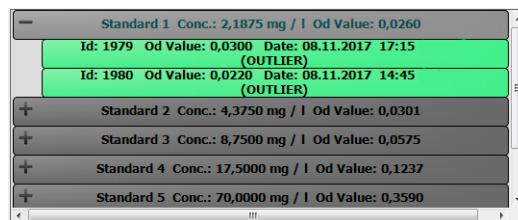
The software has a function to automatically detect outliers in multi-point calibration curves. This will help to automatically evaluate the quality of the calibration curve. If an outlier is detected, the following error message will be shown. Accepting the error message with OK will suspend the validity of the calibration.

FIGURE 134



In the calibration tree, outliers are marked with “(OUTLIER)”.

FIGURE 135



The function is not available for polylinear calibration curves and for methods with only one or two standards (also if multiple replicates of these standards are programmed).

### Administrator functions

The outlier detection can be globally activated or deactivated in the Settings (see chapter 15.3.8). For each individual method the outlier detection must be activated and a threshold (in percentage) must be set in the Method Fields (open methods only). See chapter 9.3.14.

#### 8.2.4 Factor

The factor is calculated for single and double standard calibrations (linear calibration curve). It represents the conversion factor between the OD and the concentration of the parameter. For methods with zero-standard calibrations the factor is set to a certain value (Fix-Factor).

FIGURE 136

A screenshot of a software interface showing calibration factor settings. At the top, it says "Factor: -2981,4". Below that are two input fields: "Min Factor: -3100" and "Max Factor: -2000".

#### Factor limits

“Min” and “Max Factor” limits are set to assure a valid calibration. If the calculated factor is out of range, there might be a problem. Carefully check the standard measurement, the standard itself, the reagent, the method, the instrument, and repeat the measurement of the standard.

#### Open methods

The factor for zero-standard (Fix-Factor) methods can be set by the “Installer” access level. In the METHOD FIELDS a “Min Factor” and a “Max Factor” can be set by the “Installer” access level..

#### 8.2.5 Archive

Archive

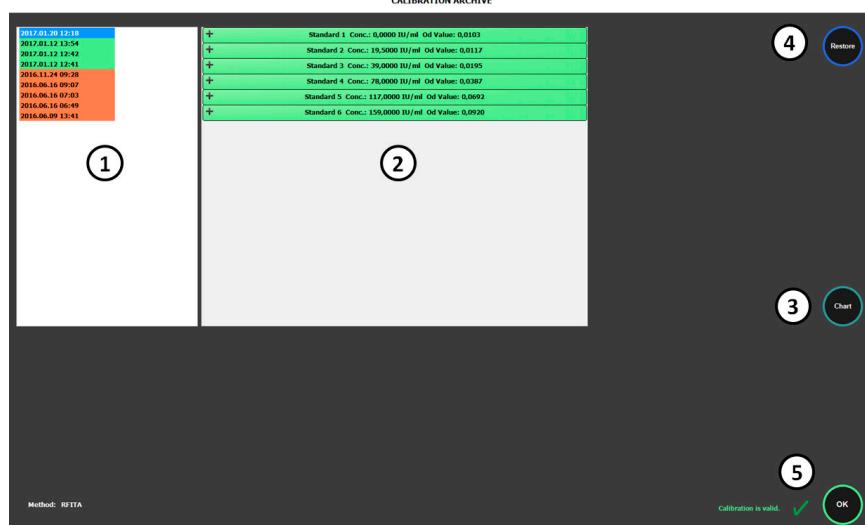
Click on “Archive” to access the “CALIBRATION ARCHIVE”.

#### Overview

In the CALIBRATION ARCHIVE it is possible to either view or restore an old calibration. Viewing and comparing old calibrations can help to judge the quality of the current calibration. Restoring an old calibration allows the user to go back to the old calibration, if the new calibration has failed and it cannot be repeated.

## Functions

FIGURE 137



### 1. List of calibrations

All calibrations for the selected method are listed on the left side of the “CALIBRATION ARCHIVE” work form. They are listed with the date and time of the execution. Click on any calibration to select it. A colour code indicates the status of the calibration:

- Green: Valid calibration of the current method
- Red: Invalid/expired calibration
- Blue: Selected calibration

### 2. Calibration tree

On the right side of the screen you can see the calibration tree for the selected calibration. Click on any calibration point to expand it and see the repetitions.

### 3. Chart

View chart of the reaction curve

### 4. Restore

Restores the selected calibration. Note that old calibrations that are expired continue to be expired even when restored. In this case you cannot run new tests with this calibration but only recalculate old tests that have been executed when the calibration was still valid.

### 5. OK

Close window

### 8.2.6 Curve chart

Curve chart

Click on “Curve chart” to access the “CURVE CHART”.

#### Overview

Show a curve chart of the calibration standards (including repetition points). If activated in the METHOD FIELDS (see chapter 9), outliers are automatically detected and indicated in the chart.

#### Functions

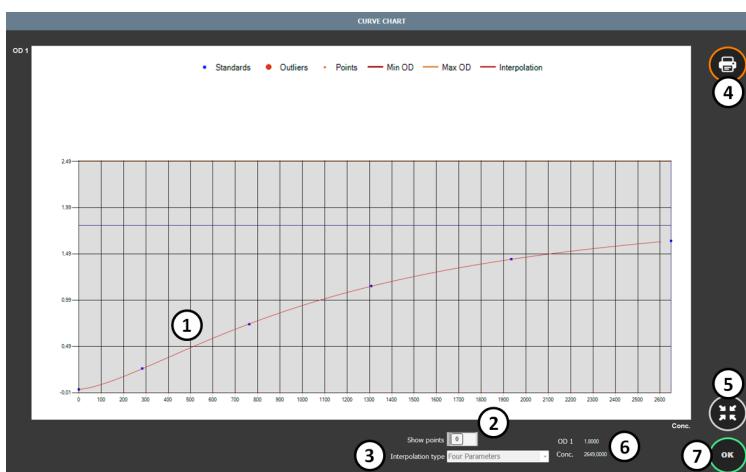


FIGURE 138

##### 1. Chart

Chart of the calibration curve, calibration points, repetition points and detected outliers.

##### 2. Show points

Activate to plot all single repetition points on the chart.

##### 3. Interpolation type

(Only for calibrations with more than two standards) Interpolation type that is used to calculate the calibration curve (e.g. Cubic Spline, Polylinear)

##### 4. Print

Execute a printout of the current calibration curve.

##### 5. Expand

Click to expand or reduce the window.

##### 6. OD 1 and Conc.

OD 1 and concentration of the current position of the cursor in the chart.

##### 7. OK

Close window

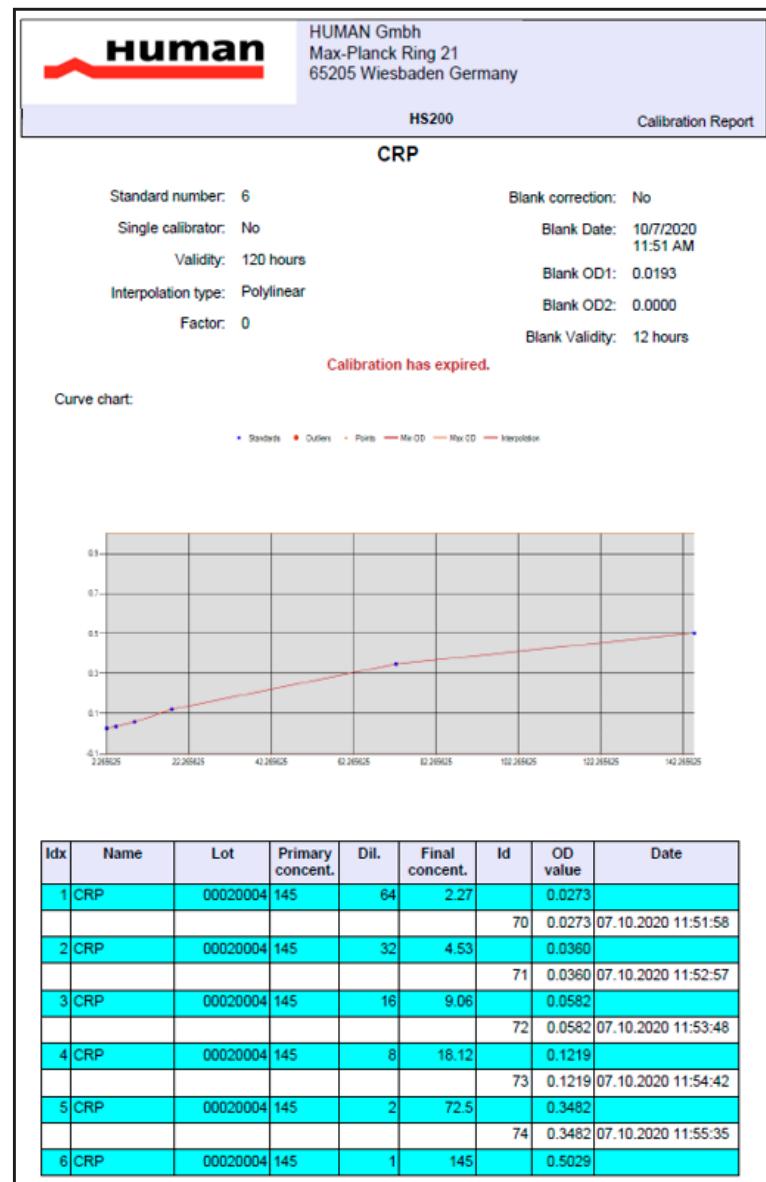
### 8.2.7 Print calibration

**Print calibration**

Print a report showing the current calibration status and chart.

Print a report showing the current calibration status and chart.

FIGURE 139



### 8.3 Reagent blank

Click on “Reagent blank” to access this menu.



#### 8.3.1 Overview

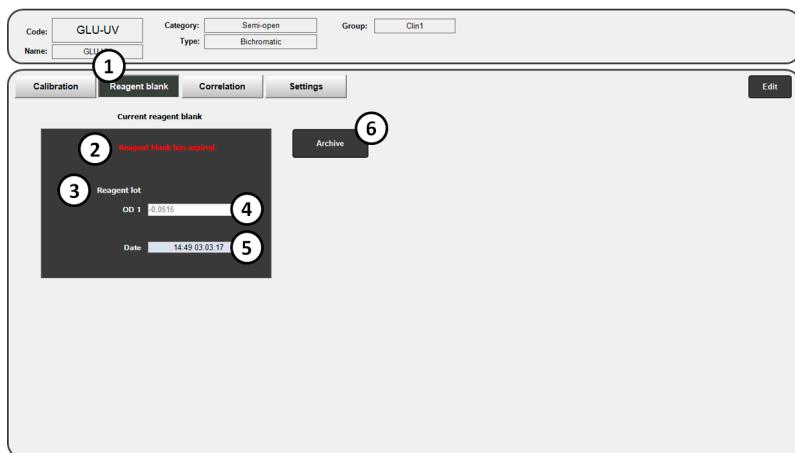
Reagent blanks are used to subtract the colour of the reagent itself from the calculation of the result. As reagents can change with time, the reagent blank is only valid for a limited time. The validity of the reagent blank is automatically monitored by the software. The user will be notified when a new reagent blank needs to be measured.

Reagent blank limits in the METHOD FIELD assure that the reagent is in good condition before being used.

The stability of the reagent blank is shown in the “Settings” menu. In this menu you can check the value and the status of current reagent blank. You can also check and restore old reagent blanks from the archive. Chapter 11 explains how the reagent blank is included in the result calculation.

## Functions

FIGURE 140



### 1. Reagent blank

Click to access this menu.

### 2. Status

Status of the current reagent blank.

### 3. Reagent lot

N/A

### 4. OD1

OD values currently used to calculate the reagent blank expressed in absorbances (abs).

### 5. Date

Date and time of the execution of the current blank.

### 6. Archive

Click to access the “REAGENT BLANK ARCHIVE” work form.

### 8.3.2 Archive

**Archive** Click on “Archive” to access this menu.

#### Overview

In the REAGENT BLANK ARCHIVE it is possible to either view or restore old reagent blanks. Viewing and comparing old blanks can help to judge the quality of the current blank. The window is similar to the CALIBRATION ARCHIVE (see chapter 8.2.5).

## Functions

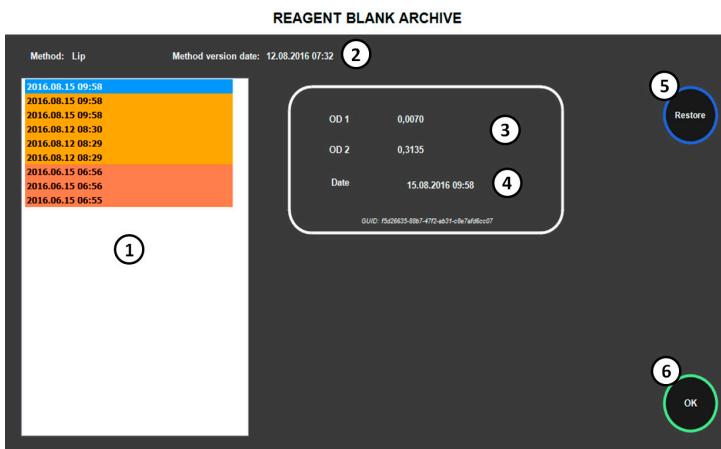


FIGURE 141

### 1. List of blanks

All blanks for the selected method are listed on the left side of the “REAGENT BLANK ARCHIVE” work form. They are listed with the date and time of the execution. Click on any blank to select it. A colour code indicates the status of the blank:

- Green: Valid blank of the current method
- Red: Invalid/expired blank
- Blue: Selected blank

### 2. Method version date

Date of the last modification of the method.

### 3. OD1, OD2

Optical density of the blank.

### 4. Date

Date and time of the execution of the blank.

### 5. Restore

Restores the selected blank. Note that old blanks that are expired continue to be expired even when restored.

### 6. OK

Close window.

## 8.4 Correlation

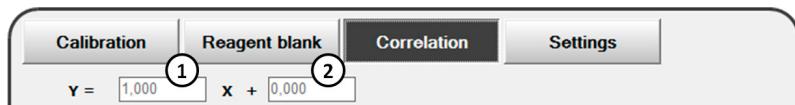


Click on “Correlation” to access this menu.

### 8.4.1 Overview

This function is used to align the results found on this instrument with results obtained from other instruments of reference. HUMAN reagents have been validated **without** “Correlation” ( $Y=1.000X+0.000$ ). By activating the correlation, the HUMAN validation data becomes invalid. Using the “Correlation” is under the responsibility of the laboratory. A statistical method comparison study must be performed to obtain reliable correlation values. Most laboratories must NOT use correlation.

### 8.4.2 Functions



#### 1. Slope

Every result that is calculated for this method will be multiplied by the factor (slope) in the first field.

#### 2. Offset

The entry in the second field will be added (offset) to every result that is calculated for this method. (Positive and negative values can be entered).

**Administrator:** You must use the access level administrator to perform these operations.

#### 8.4.3 Procedure

1. **Edit** Click “Edit” to unlock the correlation settings.
2. Enter slope and offset.
3. **OK** Click “OK” to lock the correlation settings again.

### 8.5 Settings



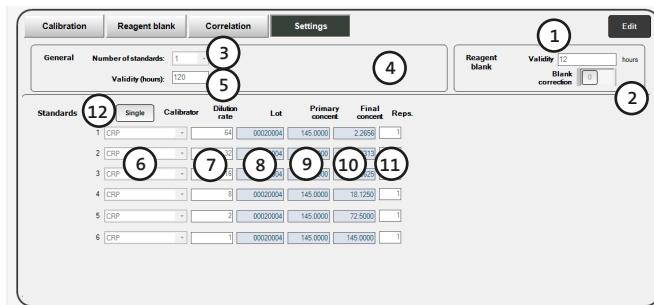
Click on “Settings” to access this menu.

#### 8.5.1 Overview

- Check and manage settings for the calibration of the selected method.
- Number of standards.
- Calibration and reagent blank stability (validity).
- Select calibrator that is used for the method.
- Dilution of calibrators
- Repetition (replicates) of calibrators
- Interpolation type (e.g. Polylinear, Cubic Spline)

### 8.5.2 Functions

FIGURE 142



**1. Validity**

Stability of the reagent blank in hours.

**2. Blank correction**

The reagent blank is used in result calculation if checked.

**3. Number of standards**

Number of standards that are used for the calibration.

**4. Interpolation type**

Interpolation type that is used for calculation of calibration curve (Cubic Spline, Polylinear, etc.). See chapter 8.6.

**5. Validity**

Stability of the calibration in hours.

**6. Calibrator**

Selection of the calibrator that is used for the calibration (e.g. Autocal) or "BLANK". See chapter 8.2 for details on using BLANK as the first calibration point.

**7. Dilution rate**

Dilution rate that is applied to the calibrator (e.g. 1:1, 1:2, 1:4, 1:8) The "Final concentration" must be increasing from top to bottom. The highest dilution rate must be on top.

**8. Lot**

Active LOT that is currently in use for the selected calibrator.

**9. Primary concentration**

Primary concentration of the calibrator of the active LOT.

**10. Final concentration**

Final concentration (incl. dilution) used for the standard.

Final concentration = Primary concentration <?> Dilution rate.

**11. Replicates**

Replicates (repetitions) of points to be executed for each standard.

**12. Single**

Click on "Single" and the calibrator in position 1 will be repeated for all positions.

### 8.5.3 Procedure - Change settings

**Administrator:** You must use the access level administrator to perform these operations. The administrator can change all Settings for open methods. The validated core of protected methods can not be changed, but lab specific settings (e.g. units) can still be adjusted.

1.  Click on “Edit” to enable editing of the Settings.
2. Change the settings according to the requirements of the method.
3.  Upon completion click **OK**.

## 8.6 Interpolation types

Calibration is the mean by which ODs are transformed into results. It can be a linear function or it can be a non-linear function described by multiple points.

### 8.6.1 Linear functions

Interpolation type: “Linear regression”

#### WITHOUT REPETITIONS

- Single standard (linear function)

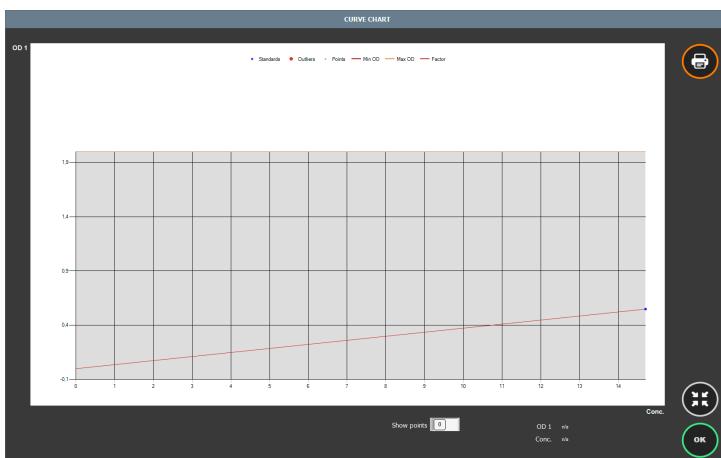
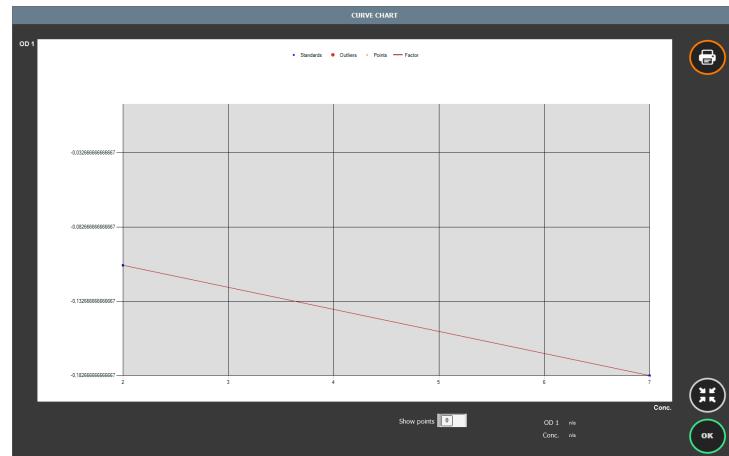


FIGURE 143

- Single standard with blank subtraction (linear with blank offset)
- Two standards

FIGURE 144



#### WITH REPETITIONS

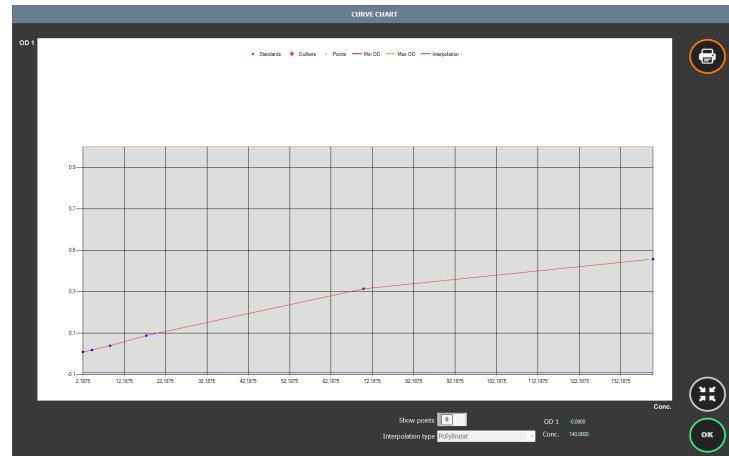
- Multiple standard average (linear function)
- Multiple standard average with blank subtraction (linear with blank offset)
- Multiple standards linear regression

#### 8.6.2 Non-linear functions

##### - Polylinear

Interpolation (curve passes exactly through each calibration point). Cannot accept two calibration points with the same concentration. Also called "Point-to-point" curve.

FIGURE 145



- **Cubic Spline**

Interpolation (curve passes exactly through each calibration point). Cannot accept two calibration points with the same concentration.

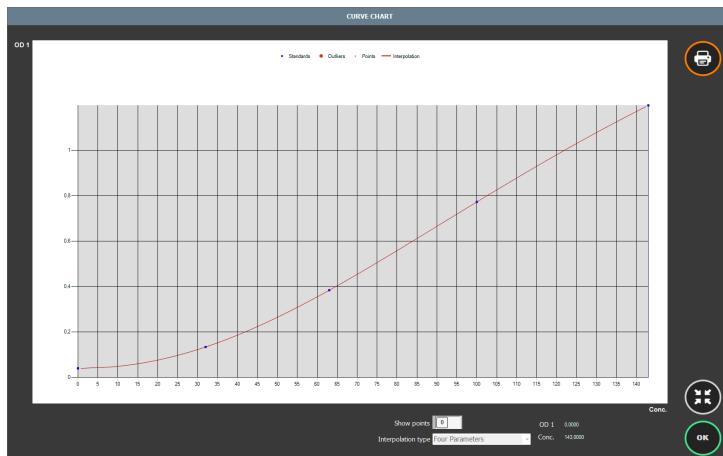
- **Multiparameters**

Convergence or best-fit function, that does not necessarily pass exactly through all calibration points. Logit-log function.

- **Four Parameters**

Convergence or best-fit function, that does not necessarily pass exactly through all calibration points. Sigmoid/logistic curve that is commonly used to represent growth processes. The curve is symmetrical, the change from the initial value and the change towards the final value occur at roughly the same rate.

$$f(x) = \frac{a_0 - a_1}{1 + (x/a_2)^{a_3}} + a_1$$



**FIGURE 146**

- **Five Parameters**

Convergence or best-fit function, that does not necessarily pass exactly through all calibration points. Logistic curve. The curve is similar to the Four parameters, but it has an additional asymmetry parameter.

$$f(x) = \frac{a_0 - a_1}{(1 + (x/a_2)^{a_3})^{a_4}} + a_1$$

**FIGURE 147**

### 8.6.3 Single or multiple calibrator(s)

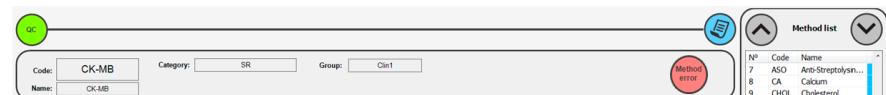
Multiple points of calibration with different concentrations must be sorted by *increasing order* of final concentration. This can be obtained in two ways:

- Employing several different calibrators sorted by *increasing order of concentration*;
- Employing a single calibrator for different calibration points, setting a *decreasing dilution rate*.

In the first calibration row it is possible to place a BLANK.

## 8.7 Method errors

Whenever a method error occurs, a special red icon appears just below the blue “Method Fields” icon:

**FIGURE 148**

### 8.7.1 Procedure

 Clicking on the red “Method error” icon opens a popup window showing details about the error.



FIGURE 149

### 8.7.2 List of possible errors

- **Invalid filter**  
A filter with the wavelength inserted is not mounted on the instrument. This error should never appear, if it happens there could have been loss of data.
- **Invalid calibration of method filters**  
The optical calibration at “Start-up” has failed.
- **Pipetting not allowed**  
There is a volume error that prevents the pipetting from happening.
- **Diluent (specific) bottle missing in reagent plate**  
A diluent bottle (specific for the method) is missing from reagent plate.
- **Diluent (specific) empty**  
A diluent bottle (specific for the method) is empty.
- **Post injection bottle missing in reagent plate**  
A post injection bottle is missing from reagent plate.



FIGURE 150

- **Post injection solution empty**  
A post injection solution bottle is empty.
- **Cuvettes Extra Wash solution bottle missing in reagent plate**  
The bottle with the solution for Cuvette Extra-Wash is missing from reagent plate.
- **Cuvettes Extra Wash solution empty**  
The bottle with the solution used for Cuvette Extra Wash is empty.
- **Needle Extra Wash solution bottle missing in reagent plate**  
The bottle with the solution for Needle Extra Wash is missing from reagent plate.
- **Needle Extra Wash solution empty**  
The bottle with the solution used for Needle Extra Wash is empty.

## 8.8 Adding new methods

**Only for instruments with a license for open channels.**

**Administrator:** You must use the acces level administrator to perform these operations.

**!** Note: The total number of methods is usually limited to 60.

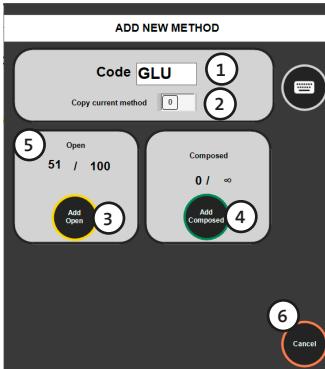
The administrator can create a limited number of open methods based on the respective license for open channels. These methods can be edited and are under the sole responsibility of the laboratory. The administrator can also create an unlimited number of composed methods.

### 8.8.1 Procedure

 Click Add to create a new method.

### 8.8.2 Functions

FIGURE 151



1. **Code:** Enter the method code (e.g. GLU, CREA) associated with the new method.
2. **Copy current method:** If toggled, copies the current selected method properties.
3. **ADD OPEN:** Adds a new open method.
4. **ADD COMPOSED:** Adds a new composed method. See chapter 9.4.
5. Number of used and available channels.
6. **CANCEL:** Exit without adding any method.

## 9 METHOD FIELDS

### 9.1 Overview

The working parameters set in the METHOD FIELDS work form for each method define how this method is processed by the analyzer. Depending on the method type (composed, protected or open) different parameter fields are visible or can be edited by the administrator. Some of the method fields may be only visible to the administrator. The validated core of protected methods can not be changed, but lab specific settings (e.g. units) can still be made.

This screenshot shows the 'METHOD FIELDS' work form for a 'GOT' method. The form is divided into several sections:

- Method list:** A sidebar listing various test codes such as ALB, ALP, ALP-2, AMY, CS, CHOL, CK, CKMB, CREA, CREA-2, CRP, DBIL, F, F-2, GGT, GLUC, GOT, GPT, HbA1c, HCY, HDL-C, K+, LDH-P, LDL-C, MMGB, Mg, Na-e, PHOS, TBIL, TO, TP, UA, UA-2, UREA.
- GOT Section:**
  - Category:** Open
  - Version date:** 13.05.2020 (0537)
  - Type:** Kinetic
  - Name:** GOT / GOT
  - Version:** 3
  - Group:** Clin2
- PIPETTING:** Settings for sample and reagent volumes.
- DILUTION:** Serum dilution ratios (1:1, 1:2, 1:4, 1:10, 1:40, 1:100).
- LIMITS:** Blank OD min (-0.1 Abs), Blank OD max (2.5 Abs), Reaction slope (negative), OD Range min (-1 Absorbance), OD Range max (2.5 Absorbance), Linearity (20 %), Scale Description (0.5 Abs), Blank OD A max (0 Absorbance), Min conc (3 U/l), Max conc (700 U/l).
- TIME:** Incubation times (180, 108, 144 sec).
- WAVELENGTHS:** Wavelengths 1 (340 nm) and 2 (0 nm).
- WASHING:** Settings for needle and cuvette.
- AUTODILUTION:** Enable autodilution, Rate, Max OD.

FIGURE 152

This screenshot shows the 'INCOMPATIBILITY' work form. It includes:

- NOTES:** Notes section containing RIF 12211, 12011, 12021, 12031; R1=BBF, R2=SBB; Calibrator: AUTOCAL (REF 13160).
- CALIBRATOR FACTOR LIMITS:** Min factor (-100), Max factor (-2000).
- OUTLIERS:** Max. curve deviation (0 %).
- UNITS:** Units 1 (U/l), Units 2, Units 3, Decimal digits (0), Target molecule.
- PATHOLOGICAL RANGES:** A table for defining pathological ranges with columns for Min..., Sample type, Maxima..., Add, Remove, and Edit buttons.

FIGURE 153

## 9.2 Getting there

 To access the work form select any method from the “Method list” on the **METHODS** tab and click this button.

## 9.3 Open methods

**Administrator:** You must use the access level administrator to perform these operations (Only for instruments with a license for open channels). The administrator can create and edit a limited number of open methods. All fields of the open method can be edited by the administrator.

The method fields shown in this chapter can be edited to specify the working parameters for each type of analysis to be made. All data entered will define exact procedures for each test. For questions regarding programming parameters of the reaction consult your reagent leaflet (volumes, incubation time, wavelengths. etc.).

All method fields are organized in groups (e.g. “Time”, “Pipetting”, etc.). All groups are divided in three categories:

- |   |  |
|---|--|
| <ol style="list-style-type: none"><li>1. Designations</li><li>2. Process parameters<ul style="list-style-type: none"><li>• Pipetting</li><li>• Time</li><li>• Wavelengths</li><li>• Washing</li><li>• Incompatibility</li></ul></li></ol> | <ol style="list-style-type: none"><li>3. Result parameters<ul style="list-style-type: none"><li>• Limits</li><li>• Autodilution</li><li>• Dilutions</li><li>• Pathological ranges</li><li>• Result units</li></ul></li></ol> |
|---|--|

### 9.3.1 Method fields overview



FIGURE 154

#### 1. Method list

Fast switching between different methods

#### 2. Designations

Section which is named according to the method code (e.g. "GLU"). It contains basic information about the selected methods.

#### 3. Reagents

Reagent bottle definition and selection of reagent bottle size.

#### 4. Pipetting

Liquid volumes pipetted

#### 5. Time

The time scheduled for the test reaction (e.g. between sampling and reading)

#### 6. Dilution

Code for diluent and dilutions used for testing. Serum and urine rates.

#### 7. Wavelengths

Each method requires specific wavelength(s) for the reading(s) to be performed

#### 8. Washing

Code for wash solutions. Programmed intensity of washings required for each test sequence.

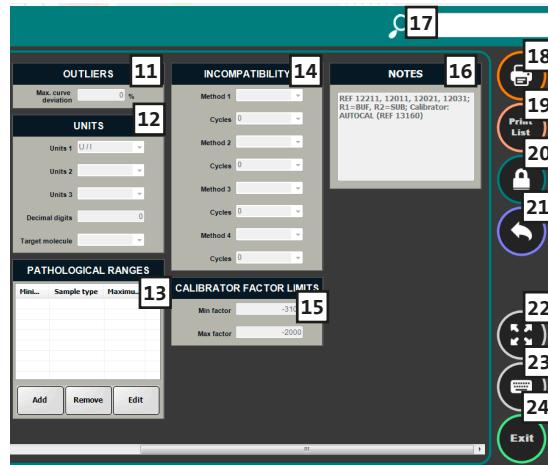
#### 9. Limits

Working limits for results validity (e.g. measuring range).

#### 10. Autodilution

Dilution rate used in the event of automatic test repetition.

FIGURE 155



11. **Outliers:** Criteria for the automatic detection of calibration outliers.
12. **Units:** Choose appropriate measurement units for reports and input of calibrators and controls.
13. **Pathological Ranges:** Min/ Max values for various sample types (reference ranges).
14. **Incompatibility:** Methods that must be separated to avoid chemical incompatibility. Number of cycles that are skipped in the work queue to avoid contamination owing to incompatible reagents.
15. **Calibrator Factor Limits:** Acceptance criteria for the linear calibrations.
16. **Notes:** Free text field. Used for important information and recommendations to the user.
17. **Search function:** Enter any string to filter method fields
18. **Print:** Print selected method.
19. **Print list:** Print overview of all methods.
20. **Lock/ unlock:** Lock to secure data. Unlock to edit fields.
21. **Undo:** Undo changes.
22. **Expand/ minimize:** Expand the form to full screen or minimize the form.
23. **Keyboard:** Virtual keyboard.
24. **Exit:** Close the Method Fields window.

FIGURE 156



### 9.3.2 Process parameters

“Process parameters” are functions that control the instrument during testing:

1. Pipetting
2. Time
3. Wavelengths
4. Washing
5. Incompatibility

! Note: Any changes to these parameters must be synchronized with the analyzer. This process is handled automatically immediately upon closing the Method Fields form.

### 9.3.3 Result parameters

“Result parameters” are functions that control result calculations, limit definition and other automatic features of the analyzer.

1. **Limits:** Work limit values for result validity.
2. **Autodilution:** Settings for automatic dilution rates.
3. **Dilutions:** Serum and urine dilution rates available.
4. **Pathological ranges:** Pathological values for various sample types.
5. **Units:** Result units (measurements or designations) for the analysis being performed.

! Note: Synchronization of analyzer and PC is not required following changes to these parameters.

### 9.3.4 Designations and reading types

GLUC	
Category	Open
Version date	13.05.2020 08:36
Type	Bichromatic
Name	Glucose
Version	2
Group	Clin1

FIGURE 157

#### 1. Code

Reference for identification of the method (AMY, GLU, GOT, CRE...). This cannot be changed for an existing method. Delete or copy to create a method with another code.

#### 2. Category

Open

#### 3. Version date

Timestamp of the last change of this method.

#### 4. Type

Reading type (Endpoint, Kinetic, etc.). See chapter 9.3.5.

5. **Name**

Full name of the method (Amylase, Glucose, Creatinine, etc.)

6. **Version**

Version of the method. Numeric values only (1, 2, etc.). Increment version whenever you make a change to the method.

7. **Group**

Methods grouped for testing (order by type, frequency, alphabetical etc.)

Method groups will be used in the **WORKLIST** tab (see chapter 7.4.3).

### 9.3.5 Reading types

- **Endpoint**

Measures the OD of the reaction at the end of the incubation time. The reference is the cuvette blank OD recorded during the start-up.

- **Endpoint self-blank**

For reactions with two dispensations. Measures the OD of the reaction at the end of the incubation time. The reference is the OD of the cuvette after the 1st dispensation (depending on what has been dispensed, either a reagent blank or a sample blank).

- **Bichromatic endpoint**

Measures the OD of the reaction at the first wavelength. The reference is the OD of the reaction at the 2nd wavelength.

- **Differential endpoint**

Executes two endpoint tests: 1st (Reagent 1 + Sample); 2nd (Reagent 2 + Sample). Measures the OD of the 1st reaction minus OD of the 2nd reaction. Used for sample blank with single reagent methods.

- **Differential endpoint (sample blank)**

Executes two endpoint tests: 1st (Reagent 1 + Reagent 2 + Sample); 2nd (Reagent 1 + Sample only, used as the sample reference). Measures the OD of the first reaction minus the OD of the reference reaction.

- **Fixed time**

For reactions having a curvilinear variation of the OD. Measures the OD difference between the end and the beginning of the reading time.

- **Kinetic**

For reactions where the OD varies linearly. Measures the OD variation rate of the reaction (absorbances per minute). Monochromatic and bichromatic kinetics are possible.

**!** Note: For complete descriptions of all "Method types" provided with this analyzer see chapter 11.2.

### 9.3.6 Reagents

This group is used to define the name and the size of the reagent bottles that are used for each specific method.

### 9.3.7 Pipetting

Volumes are managed in two separate columns, one for the 1<sup>st</sup> pipetting and one for the 2<sup>nd</sup>.

Type	R1 + R2 / S
Sample vol:	15 $\mu\text{L}$
Reagent 1 vol:	160 $\mu\text{L}$
Reagent 2 vol:	40 $\mu\text{L}$
Reagent 3 vol:	0 $\mu\text{L}$

FIGURE 158

#### Sample vol: Range 2 to 200 $\mu\text{l}$

SMP volume can be set in the 1<sup>st</sup> or the 2<sup>nd</sup> pipetting, but not in both. Together the SMP and R2 volumes can only be set in the 2<sup>nd</sup> pipetting.

#### Reagent 1 vol: Range 0 to 300 $\mu\text{l}$

Reagent R1 volume can be dispensed only in the 1<sup>st</sup> pipetting.

#### Reagent 2 vol: Range 0 to 300 $\mu\text{l}$

Reagent R2 volume can be set in the 1<sup>st</sup> or the 2<sup>nd</sup> pipetting, but not in both.

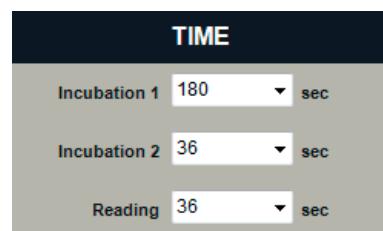
#### Reagent 3 vol: Range 0 to 300 $\mu\text{l}$

Reagent R3 volume can be set in the 1<sup>st</sup> or the 2<sup>nd</sup> pipetting, but not in both.

### 9.3.8 Time

The incubation and reading times scheduled for the test reaction (i.e. between sampling and reading.) For each method it is necessary to define the number of seconds for the incubation of the reaction mix in the cuvette (1<sup>st</sup> and 2<sup>nd</sup> in case of a 2<sup>nd</sup> pipetting) and for the duration of the reading process.

FIGURE 159



#### Incubation 1: Range 0 to 600 seconds

For methods that use only the 1<sup>st</sup> pipetting: Incubation 1 is the time between pipetting and the beginning of the reading. It is also the time necessary for the reaction stabilization (e.g. secondary reactions, thermal stabilization). For methods that use both pipetting: Incubation 1 is the fixed time between the 1<sup>st</sup> and the 2<sup>nd</sup> pipetting. In that case Incubation 1 can be set to 180 or 360 seconds. 180 seconds is the standard time. Note that the throughput of the analyzer will be slower when you use 360 seconds.

**Incubation 2: Range 0 to 600 seconds**

For methods that use both pipetting: Incubation 2 is the time that elapses between the 2<sup>nd</sup> pipetting and the beginning of the reading. It is also the time necessary for secondary reactions and thermal stabilization. For methods using only the 1<sup>st</sup>: Time is automatically set to zero.

**Reading: Range 0 to 600 seconds**

The reading time is the time during which the readings are employed for the calculations. The instrument executes one reading of the reaction OD every machine cycle.

**Restrictions of the incubation times****Fixed Incubation 1 for double dispensation methods**

The Incubation 1 time between dispensations (two pipettings) has a fixed duration (5 machine cycles which is 180 seconds), which is the approximate time needed to bring the liquids to the required reaction temperature. The length of Incubation 1 time for a single dispensation method is variable. Also the Incubation 2 time for double dispensation methods is variable and can be specified according to the selection provided in the method fields.

**Total reaction time**

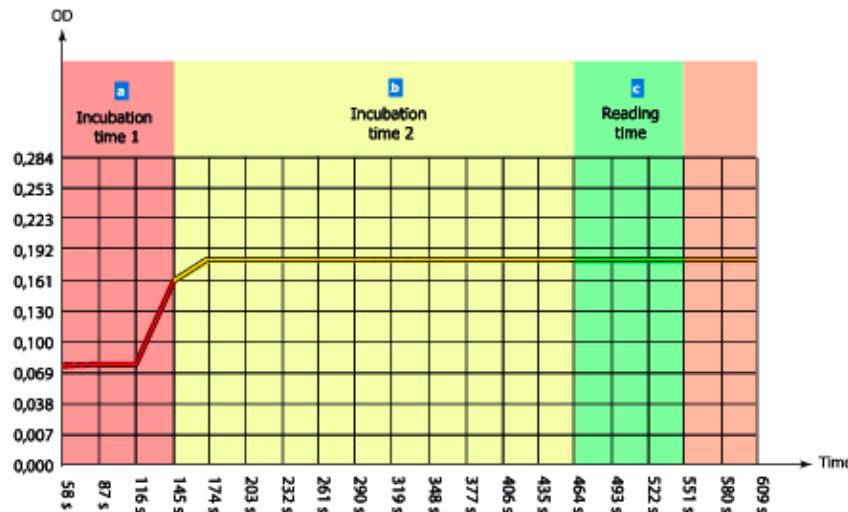
The analyzers total reaction time for Incubation 1 + Incubation 2 + Reading cannot exceed 612 seconds (36 seconds x 17 cycles) and each of these must be a multiple of the instrument machine cycle-time provided.

For ENDPOINT SELF BLANK methods, the readings collected during the 3 cycles before the second pipetting are used to calculate the reference OD2 of the reaction. For DIFFERENTIAL ENDPOINT methods two separate tests are executed in two adjacent cuvettes. The first test is R1 + SMP, the second test is R2 + SMP using only the 1<sup>st</sup> pipetting (for these two tests only the first incubation time is used).

A graphic representation of the readings taken during a test reaction:

FIGURE 160

**!** Note: OD values can continue to be taken following “Reading time” up to the maximum time programmed (shown in orange). These are not processed in the result calculation. This option can be activated by your service engineer.



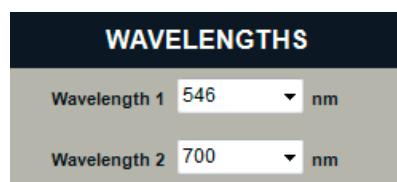
### 9.3.9 Wavelengths

Each method requires specific wavelength(s) for the reading(s) to be performed. It is possible to select a wavelength from the list of the filters installed on board (the standard available filters on board are listed below):

340nm	578nm
405nm	600nm
505nm	650nm
546nm	700nm

A method employing a filter that is not included in those installed on board, cannot be executed. In which case an error will be shown in the programmed worklist.

FIGURE 161



**Wavelength 1: Range 340 to 900 nm**

Select appropriate wavelength which is required for the test.

**Wavelength 2: Range 340 to 900 nm**

Bichromatic methods require a second wavelength selection.

### Differential methods

Differential methods use the first wavelength for the first test and the second wavelength for the second test. If a second wavelength is not set, the first will be used for both test.

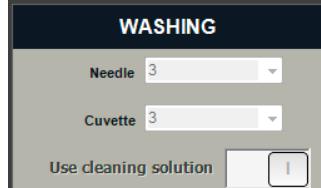
### Bichromatic methods

Bichromatic methods require both wavelengths because they execute the reading as the difference between the reaction OD for the first wavelength and the reference OD for the second wavelength.

#### 9.3.10 Washing

For each individual method it is possible to define the wash procedure and the wash intensity for the cuvettes and the pipetting needle. The purpose is twofold: to optimize water consumption and to avoid reagent and sample carry-over between tests.

FIGURE 162



#### Needle: Range 1 to 8

(9-10 are not used, they are open to future implementations)

Set needle wash intensity/time (1-4 increasing intensity).

5-8 are equivalent to 1-4, but an additional mixing step of reagents and samples is added after the pipetting.

1. Basic time
2. +33% time
3. +67% time
4. +100% time
5. Equivalent to 1 + extra mixing after pipetting
6. Equivalent to 2 + extra mixing after pipetting
7. Equivalent to 3 + extra mixing after pipetting
8. Equivalent to 4 + extra mixing after pipetting

**Cuvette: Range 1 to 4****(5-10 are not used, they are open to future implementations)**

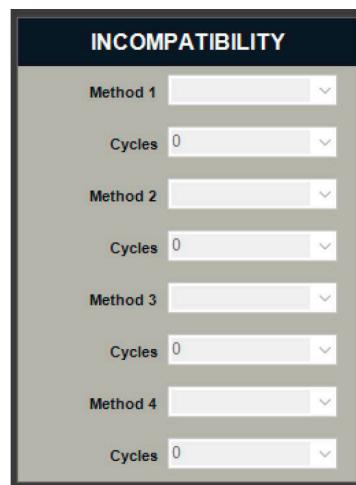
Set cuvette wash intensity/volume (1-4 increasing volume)

1. Basic volume (400 µl)
2. +20% volume
3. +40% volume
4. +60% volume

**9.3.11 Incompatibility**

Methods used in the testing process may be separated to avoid chemical incompatibilities or carry-over.

FIGURE 163



**!** Note: Both the sampling needle and reaction cuvettes are monitored.

Owing to chemical incompatibility certain methods may not be used immediately before another in the testing process. Four conflicting conditions can be designated for any method listed. Administrators may specify the number of cycles (from 1 to 6) that must be skipped to avoid a result that is contaminated and thus unusable (e.g tests using methods incompatible with those of the test just executed will be removed and reinserted after the designated number of cycles).

### 9.3.12 Pathological ranges (reference ranges)

A list of sample types may be set by the administrator (e.g. male, female). In the test reports, if a result is lower than the minimum normal value “<L” is indicated. If a result is higher than the maximum normal value “>H” is indicated. Minimum and maximum normal reference values are expressed in primary units. There is an unlimited number of different sample types that can be created.

**FIGURE 164**

## Add, remove and edit Pathological Ranges

1. To add a new “Sample type” click **Add**, select from the “list” of previously added types (or enter a new name of a sample type for specific use). Enter the maximum and minimum range, then click **OK**.

Add pathological value

Sample type	<input type="text"/>
Minimum	<input type="text"/>
Maximum	<input type="text"/>

**Add**    **Cancel**

**FIGURE 165**

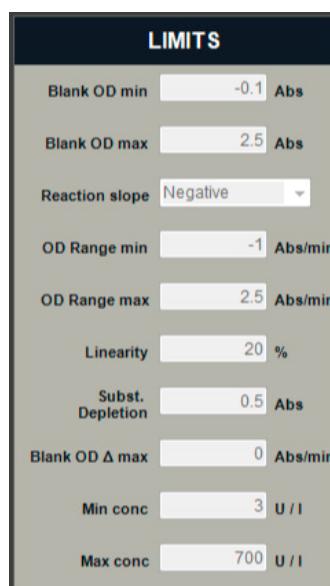
2. To remove a type, select a line item and click **Remove**.
  3. To modify a type, select a line item, click **Edit**, change the information and click **OK**.

### 9.3.13 Limits

Work limit values for results validity. Limits can be set to automatically check if a result is likely to be valid.

**!** Note: OD values are not negative. However the result of subtracting two OD values may be negative (e.g. bichromatic or differential, decreasing kinetic or fixed time).

FIGURE 166



#### Blank OD

##### Blank OD min: Range

**-9.999 to +9.999 Abs or Abs/min**

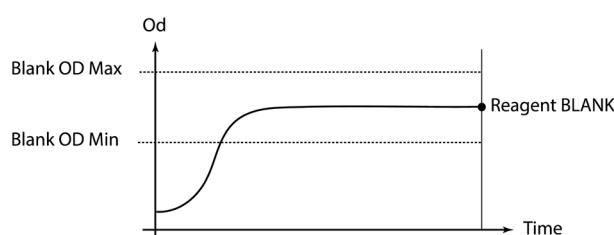
Absolute minimum OD value of the reagent blank reaction that is used to check whether the reagent absorbance is within the range set by the manufacturer.

##### Blank OD max: Range

**-9.999 to +9.999 Abs or Abs/min**

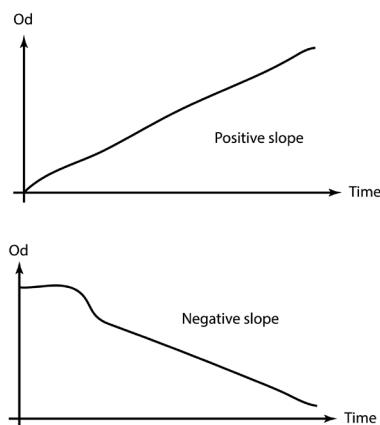
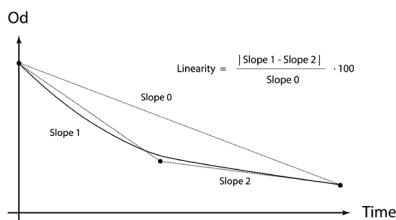
Absolute maximum OD value of the reagent blank reaction that is used to check the reagent performance.

FIGURE 167



**Reaction slope****Reaction slope:****Positive, Negative or n/a**

Checks the trend of the reaction. A slope error is generated if the slope has a trend opposed to the one defined. The “n/a” value disables the slope check.

**FIGURE 168****Linearity****FIGURE 169****OD range****OD range min:**

**Range -9.999 to +9.999**

**Abs or Abs/min**

Lower limit of the allowable OD value of the reaction. Below this limit the warning  
“Detection limit” is displayed.

**OD range max:**

**Range -9.999 to +9.999**

**Abs or Abs/min**

Upper limit of the allowable OD value of the reaction. Over this limit the warning  
“Result not available” is displayed. *In this case, the repetition of the test will allow the sample to be diluted with the rate defined in the autodilution field.*

! Note: the absolute value of the “OD range min” must be lower than the absolute value of the “OD range max” (e.g. OD min is -1 and OD max is -2).

### **Details on the evaluation of OD min/max limits:**

The evaluation of the limits depends on the preset slope.

#### Slope not defined “n/a”:

If the slope is not set, the OD of the test is compared to OD min and OD max limits. The OD is equal to OD1-OD2. If the OD is not in the range of OD min to OD max, an error (“Od Max error” or “Od Min error”) is given. The OD as well as ODmin and ODmax can be positive or negative.

#### Slope set to positive or negative:

If the slope is set negative, the absolute (positive) value of the OD is checked against the limits.

#### Unit of the ODs:

The OD values, including ODmin and ODmax for kinetic methods are in Abs/min. For all other methods the values are in Abs.

#### Example for a slope set to “negative” for a kinetic method:

OD1 = - 0.6174 Abs/min

OD2=0,0000 Abs/min

OD = |OD1-OD2| = |-0.6174 - 0.0000| = 0.6174 Abs/min

OD min = 0 Abs/min

OD max = 0.5 Abs/min

Check if ODmin<OD<ODmax fails, because 0.6174 Abs/min is above 0.5 Abs/min. An error is given.

### **Concentration min/max**

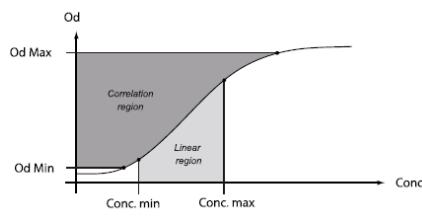
#### **Conc. min:**

Lower limit of the allowable concentration value of the test.

#### **Conc. max:**

Upper limit of the allowable concentration value of the test.

*If either a lower or an upper concentration limit is reached the warning “Concentration error” is displayed.*

**Note: Concentration vs. OD limits****Concentration vs. OD limits**

**Concentration limits** are more flexible than OD limits but they can be applied only if a valid calibration is applicable.

**OD limits** can be applied to all reactions, calibrations included, and are not subordinate to the existence of a calibration.

**Detection limits**

When a detection problem is present, results are not reliable in a specific region (see chart). It is then possible to identify the problem by setting up two different lower limits (Od Min and Conc. Min.). When the reaction saturates, the concentration cannot be processed in a specific region (see chart). It is then possible to identify the problem by setting up two different upper limits (Od Max and Conc. Max).

ODs resulting above the validity region of the calculation method (e.g. linear region), can be monitored using the upper concentration limit. The upper OD limit can be higher than the upper concentration limit. It typically defines the OD value above which there is no accurate correlation with the concentration.

### 9.3.14 Outliers

Maximum deviation in percentage of a single standard from the calculated calibration curve. If a single standard is outside this range, it is automatically detected as an outlier. See chapters 15.3.8 and 8.2.3 for more information.

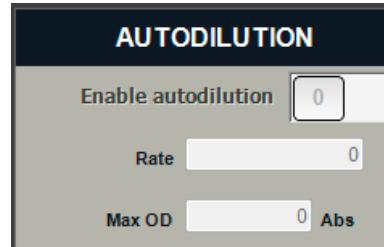
FIGURE 170



### 9.3.15 Autodilution

The automatic setting of a dilution rate in the event of a test repeat (i.e. single sample / single test). Autodilution is enabled by a non-zero value of the maximum OD. In this case, when a test exceeds the maximum OD (negative or positive), the instrument automatically schedules a repetition of the same test with the dilution factor given by the Rate value.

FIGURE 171



The instrument will also execute automatically diluted tests if one of these test errors is encountered:

- Optical error ( $OD > 3.2$  Abs)
- Linearity error
- Substrate depletion error

When needed, a second repetition is channelled using a multiplied dilution rate.

**On/Off:** Toggle to activate autodilution

**Rate: Range 1 to 100**

Dilution rate applied to a test for an automatic repetition. E.g. If rate is set to 2, an automatic dilution 1:2 is performed. If the test error persists, a second automatic dilution 1:4 is performed. Further dilution steps are performed if required (1:8, 1:16 etc.). Setting the rate to 5 will do 1:5, 1:25, 1:100 dilutions (1:100 being the maximum possible dilution).

**Max OD: Range -9.999 to +9.999 Abs (Abs/min for kinetics)**

Where the OD of a test has a value beyond the maximum OD, the instrument repeats automatically the test with the dilution set in the “Rate” field. Negative ODs are possible. For example setting Max OD=-0.5 will execute an autodilution if the OD is below -0.5 .

### 9.3.16 Dilution

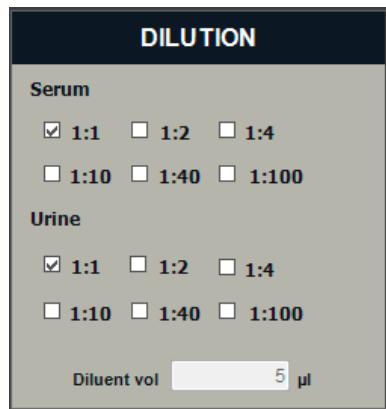


FIGURE 172

**Diluent vol**

Volume of diluent that is always pipetted together with the sample. Activated if set to a non-zero value. The volume is fixed and independent from any additional dilution rate that is applied. The diluent is always aspirated first, then the sample is aspirated.

Sample and diluent are dispensed in the reaction cuvette at the same time. Consequently the sample is “flushed” out by the diluent which follows. If you use small sample volumes in the method, this function is useful to avoid that any sample remains inside the pipetting needle.

### Serum and Urine

Dilution rates are available for serum and urine.

**Serum:** Dilutions allowed for serum samples

**Urine:** Dilutions allowed for urine samples

Checked dilutions will be proposed during worksheet creation (see chapter 7.4.4). If a list has only one dilution checked, this will be used. If two or more dilutions are checked, these will be displayed in a selection box during worksheet creation.

### Selection box for dilution when creating a worksheet or scheduling a test.

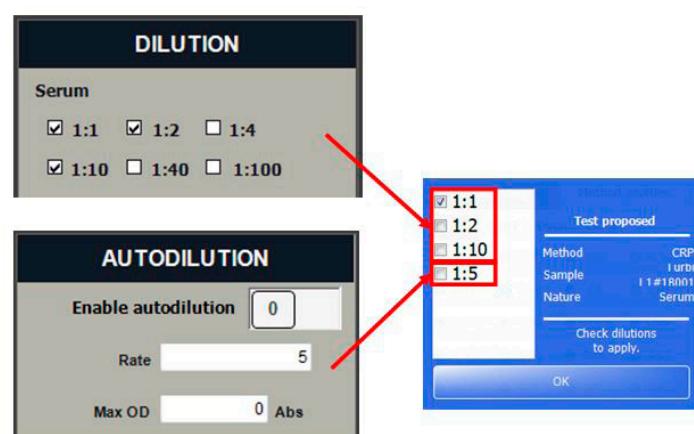
When a new test is created you can choose between the defined/checked rates in the method DILUTION field.

FIGURE 173



When a test is repeated, you can also choose the rate that is defined in the AUTODILUTION field.

FIGURE 174



### Dilution modes

Dilutions are automatically handled by this analyzer. There are two dilution modes. The analyzer chooses which mode to use depending on the sample volume defined in the method.

#### In-needle dilution

Used for small volume direct dilutions. Substitutes a portion of the sample volume with diluent during the dispensation. The maximum in-needle dilution that can be done is the ratio of the sample volume (in  $\mu\text{l}$ ) to the minimum sample volume ( $2\mu\text{l}$ ). If the test requires a dilution greater than the maximum volume possible using in-needle dilution, the analyzer will execute the required pre-dilution of the sample in a reaction cuvette.

#### Sample pre-dilution in a reaction cuvette

Used for dilutions requiring larger liquid volumes. This is automatically used and handled by the analyzer. Individual sample pre-dilutions are executed once and employed for all tests requiring that particular dilution.

*Sample in 1<sup>st</sup> pipetting.* During the run, but before executing a test needing a specific pre-dilution, the analyzer prepares a sample pre-dilution in the current reaction cuvette and then, in the next cycle, uses this diluted sample for the test reaction.

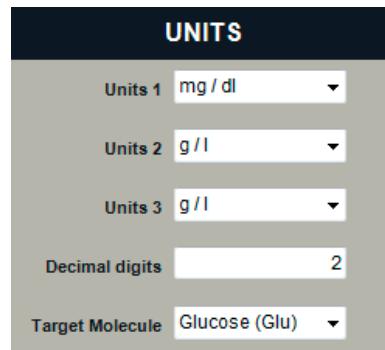
*Sample in 2<sup>nd</sup> pipetting.* First, the analyzer prepares a sample pre-dilution in the current reaction cuvette. Then, in the next cycle, it pipettes the reagents in the next cuvette as normal. Finally, the pre-diluted sample is dispensed during the 2<sup>nd</sup> pipetting.

! Note: Priority is always given to the in-needle dilution.

### 9.3.17 Result units

Selection of the appropriate measurement units or designations for this method/parameter.

FIGURE 175



Units of measure are selectable from these drop-down menus. When switching to a new unit, conversion between different units (e.g. results in worksheet) will be done automatically, if a meaningful conversion possible. Units in the table are grouped by dimensional analysis.

#### Units 1 (Default units)

Default units will be employed if Units 2 or 3 are empty.

#### Units 2 (optional)

Secondary units employed in “Lots management” to directly load LOT information from data sheets.

#### Units 3 (optional)

Units employed for results and reports.

#### Decimal digits: Range 0 to 4

Number of digits employed in result reports.

### Target molecule (optional)

If a molecule is involved, it can be indicated in order to use its molar mass to convert between Mass/Volume and Substance/Volume (i.e. allows conversion between mass and moles using Molar Mass). Conversion between Normality and Substance/Volume is possible considering a valence of fixed value 1.

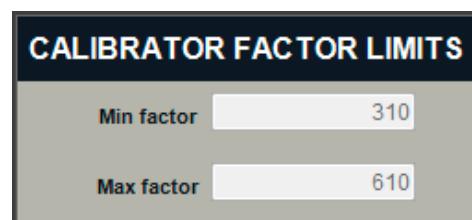
### Units provided by default

abs	absorbance	
ng/ml	nanograms/millilitre	
µg/ml	micrograms/millilitre	
µg/dl	micrograms/decilitre	
mg/dl	milligrams/decilitre	<i>Mass</i>
g/dl	grams/decilitre	<i>Volume</i>
µg/l	micrograms/litre	
mg/l	milligrams/litre	
g/l	grams/litre	
nmol/l	nanomole/litre	
mmol/l	millimole/litre	<i>Substance</i>
µmol/l	micromole/litre	<i>Volume</i>
mval/l	millival/litre	
meq/l	milliequivalent/litre	<i>Normality</i>
µkat/l	microkatal/litre	
µmol/l s	micromole/litre*second	<i>Substance</i>
U/ml	Enzyme Unit/millilitre	<i>VolumeTime</i>
U/l	Enzyme Unit/litre	
IU/ml	IntlUnit/millilitre	
IU/l	IntlUnit/litre	<i>IntlUnit</i>
kIU/l	KiloIntlUnit/litre	<i>Volume</i>
mmol/mol	IFCC	Glycated
%	NGSP	Haemoglobin

! Note: Changing Units 3 will automatically convert old results in the worksheets and reports. Changing Units 1 will not automatically convert pathological ranges and concentration limits in the method. You need to check and adjust them.

### 9.3.18 Calibrator factor limits

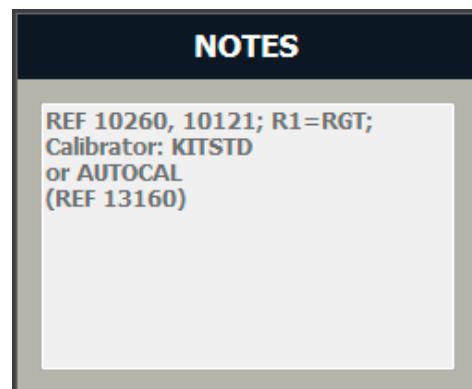
FIGURE 176



Acceptance criteria for the linear calibrations.

### 9.3.19 Notes

FIGURE 177



Free text field. Used for important information and recommendations to the user.

## 9.4 Composed methods

Composed methods are defined by a mathematical expression (formula) containing the results of several tests as variables (e.g. BIND = BT - BD). Scheduling a composed test will start the execution of the base tests. When these tests are completed, the analyzer calculates the result of the composed test using the formula and replaces the base test codes with their results.



FIGURE 178

### 9.4.1 Procedure

1. Create a new composed method (see chapter 8.8).
2. Click on **Edit** to enable editing of the Settings.
3. Enter the formula in the field.
4. Upon completion click **OK**.

### 9.4.2 Formula

Composed methods are defined by a mathematical expression (formula) containing the results of several tests as variables. (E.g. you can create a method called "BIND" and write as formula "BILT-BILD" to calculate the Indirect Bilirubin from the Total Bilirubin and the Direct Bilirubin. BILT and BILD need to be the Code of any existing method).

You can use mathematical expression like "+", "-", "\*", or "/" in the formula. As decimal separator you have to use the standard separator defined in the language of your operating system (either "." or ",").



## 10 INSTRUMENT CYCLE

The instrument cycle is composed of two pipetting operations. An operation can dispense a single liquid or two at the same time (see table below for combinations available).

**1<sup>st</sup> pipetting:** When dispensed the execution of a test begins.

**2<sup>nd</sup> pipetting:** Dispensed when a test has completed the first incubation.

When required diluent is collected and dispensed with the sample in the same pipetting. After the first dispensation, two machine cycles are skipped before the reading process starts as previously described. The following pipetting sequences can be selected in the method (for open instruments only):

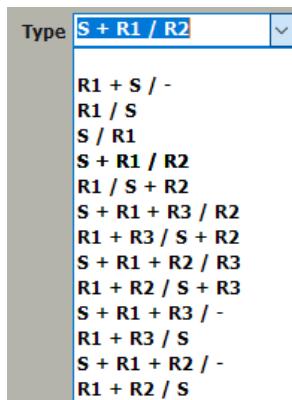


FIGURE 179

1 <sup>st</sup> pipetting	2 <sup>nd</sup> pipetting	Dispensation
R1 + S	-	R1 and sample together
R1	S	R1, then sample
S	R1	Sample, then R1
S + R1	R2	Sample and R1, then R2
R1	S + R2	R1, then sample and R2
S* + R1 + R3	R2	Sample*, R1 and R3, then R2
R1 + R3	S + R2	R1 and R3, then sample and R2
S* + R1 + R2	R3	Sample*, R1 and R2, then R3
R1 + R2	S + R3	R1 and R2, then sample and R3
S* + R1 + R3	-	Sample*, R1 and R3 together
R1 + R3	S	R1 and R3, then sample
S* + R1 + R2	-	Sample*, R1 and R2 together
R1 + R2	S	R1 and R2, then sample

### Total reaction volume

The total **reaction volume** (SMP + R1 + R2 + Diluent) which is typically 220 $\mu$ l, but must be at least 210 $\mu$ l and must not exceed 310 $\mu$ l to avoid soiling the upper part of the reaction cuvette.

#### **Incubation time**

For every test the 2<sup>nd</sup> pipetting is executed with a fixed incubation delay (**Incubation 1**) following the 1<sup>st</sup> pipetting which is typically set at 5 machine cycles (180 seconds). To comply with tests requiring a longer compulsory reaction during Incubation 1, it is possible to double this time (360 seconds). Instrument throughput will be lower in that case.

#### **Differential endpoint**

For both types of differential endpoint methods two separate tests are executed in different tubes.

For **DIFFERENTIAL ENDPOINT** methods the first test is R1 + SMP, the second is R2 + SMP and both use only the 1<sup>st</sup> pipetting.

For **DIFFERENTIAL ENDPOINT SAMPLE BLANK** methods the first test is R1 + SMP using only the 1<sup>st</sup> pipetting, while the second is R1 + SMP + R2 where both pipettings are used.

#### **Sample blank**

The sample blank can be performed also in a single tube with **SELF-BLANK ENDPOINT** methods that have R1 + SMP in the 1<sup>st</sup> pipetting and R2 in the 2<sup>nd</sup> pipetting; the sample blank reading, just before the 2<sup>nd</sup> pipetting, is then subtracted from the endpoint reading.

### **10.1 Pipetting schemes**

In the following diagrams you can see the different pipetting and reading schemes that are possible. For Endpoint all three possible combination (1 reagent and 1 pipetting; 1 reagent and 2 pipettings; 2 reagents and 2 pipettions) are shown in three different diagrams. For all other types they are summarized in one diagram.

Pipettions are orange lines on top of the time axis, readings are red lines on the bottom of the time axis.

**Explanation of abbreviations:**

R1	Reagent 1
R2	Reagent 2
S	Sample
Inc1	Incubation time 1
Inc2	Incubation time 2 (multiple of reading cycle of 36s)
Read	Reading time (multiple of reading cycle of 36s)
OD1	Optical density 1
OD2	Optical density 2
$\lambda_1$	1 <sup>st</sup> wavelength
$\lambda_2$	2 <sup>nd</sup> wavelength
Factor	Factor (linear) or interpolation (non-linear)

a) Endpoint, 1 reagent, 1 pipetting

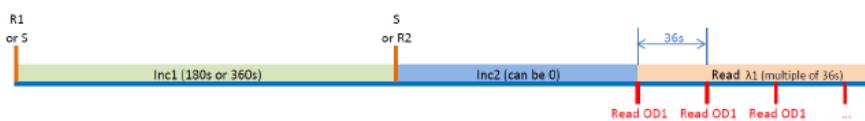


$$\text{Result} = (\text{OD1}-\text{OD2}) * \text{Factor}$$

OD2=cuvette with water at  $\lambda_1$

OD1=average of all Read OD1

b) Endpoint, 1 reagent, 2 pipettings

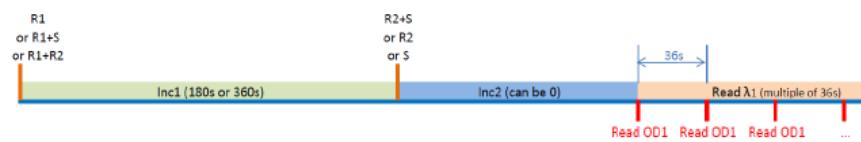


$$\text{Result} = (\text{OD1}-\text{OD2}) * \text{Factor}$$

OD2=cuvette with water at  $\lambda_1$

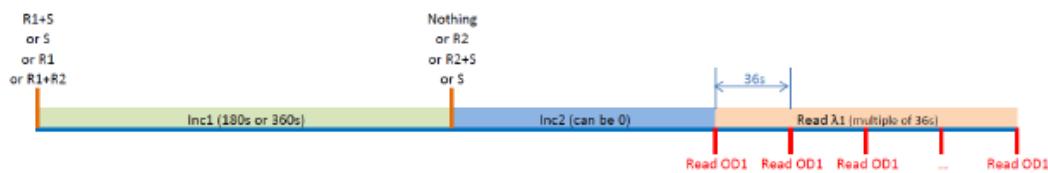
OD1=average of all Read OD1

c) Endpoint, 2 reagents, 2 pipettings



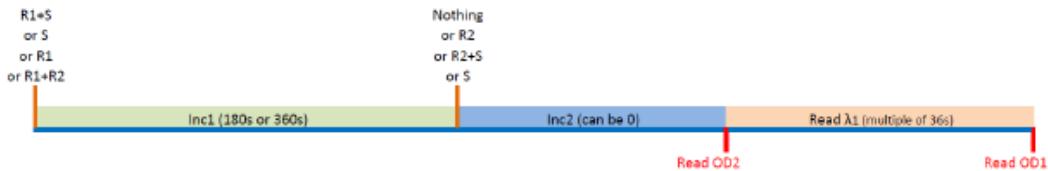
Result=(OD1-OD2)\*Factor  
 OD2=cuvette with water at  $\lambda$ 1  
 OD1=average of all Read OD1

d) Kinetic, 1 or 2 reagents, 1 or 2 pipettions



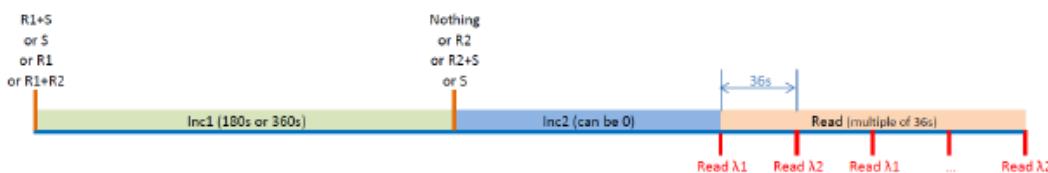
Result=OD1\*Factor  
 OD1=linear regression of all Read OD1

e) Fixed time, 1 or 2 reagents, 1 or 2 pipettions



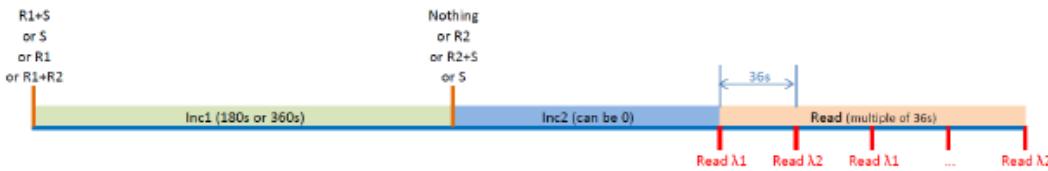
Result=(OD1-OD2)\*Factor

f) Bichromatic Endpoint, 1 or 2 reagents, 1 or 2 pipettions



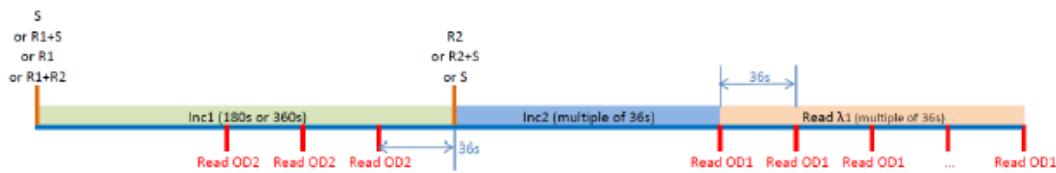
Result=(OD1-OD2)\*Factor  
 OD2=average of all Read λ2  
 OD1=average of all Read λ1

g) Bichromatic Kinetic

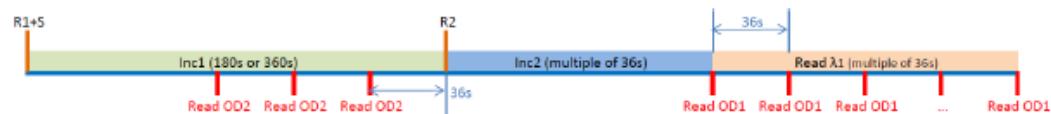


Result=(OD1-OD2)\*Factor  
 OD2=linear regression of all Read  $\lambda_2$   
 OD1=linear regression of all Read  $\lambda_1$

h) Endpoint Self-blank, 1 or 2 reagents, 2 pipettings

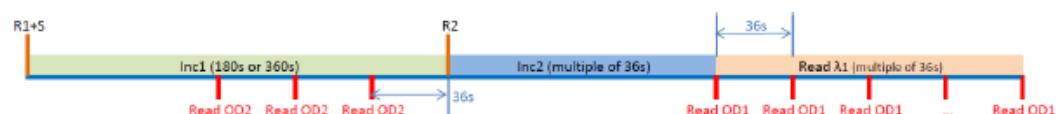


Result=(OD1-OD2)\*Factor  
 OD2=average of all Read OD2 (OD2 is corrected for volume)  
 OD1=average of all Read OD1  
 i) Endpoint Self-blank (used as sample blank), 2 reagents, 2 pipettings



Result=(OD1-OD2)\*Factor  
 OD2=average of all Read OD2 (OD2 is corrected for volume)  
 OD1=average of all Read OD1

j) Endpoint Self-blank (used as reagent blank), 1 or 2 reagents, 2 pipettings



Result=(OD1-OD2)\*Factor  
 OD2=average of all Read OD2 (OD2 is corrected for volume)  
 OD1=average of all Read OD1



## 11 RESULT CALCULATION

This chapter describes how the software calculates the result (concentration) from the actual OD that is measured by the instrument. The calibration transforms the OD of a test into a result. The result is calculated as a function of the OD. The OD is read and calculated according the Method Type.

### 11.1 Calibration

The calibration is defined by:

- A set of calibration points (1 to 8) with a known concentration; Calibration points must all be different and monotonic in interpolation-type calculations (poly-linear and cubic spline); they can also be multiple coincident in regression-type calculations (linear regression and four parameters exponential regression).
- The optical density of every calibration point, measured with specific calibration tests;
- The calculation type mathematical function, defined around this set of calibration points (“Interpolation type”).

#### 11.1.1 Zero, single, two or multiple standards

- For Zero, single or two standard methods the result is calculated on the factor.
- For multiple standard methods the result is calculated with an interpolation function (linear regression, polylinear cubic spline, four parameter).
- In cases of sample dilution the result is multiplied by the ratio of dilution to obtain the original concentration of the sample.

Depending on the number of defined standards, the result is calculated in the following ways:

**Zero standards (fixed factor)**

Result = OD • Factor

**One standard (calculated factor)**

$$\text{Factor} = \frac{\text{Standard concentration}}{\text{Standard OD}}$$

Result = OD • Factor

**Two standards (calculated factor)**

$$\text{Factor} = \frac{\text{Standard 2 concentration} - \text{Standard 1 concentration}}{\text{Standard 2 OD} - \text{Standard 1 OD}}$$

Result = Factor(OD - Standard 1 OD) + Standard 1 concentration

**Multiple standards**

The result is evaluated with an interpolation or with a regression function.

**Interpolation types**

The following types of interpolation are provided:

- Linear regression;
- Polylinear
- Cubic Spline interpolation
- Multiparamters
- Four Parameters
- Five Parameters

A visual comparison of the interpolation types provided is possible. See chapter 8.6 for details.

## 11.2 Method types

- Endpoint
- Endpoint self-blank
- Bichromatic endpoint
- Differential endpoint
- Differential endpoint sample blank
- Kinetic
- Fixed time

### Reading procedures

- **Endpoint, Endpoint self-blank, Kinetic, Fixed time** procedures all employ a single set of 20 readings collected at the defined wavelength, one reading per cycle.
- **Bichromatic** procedures employ a double set of 10 readings each collected using the first wavelength during odd cycles and the second wavelength during even cycles.
- **Differential** procedures, which require double reactions, employ two different reactions in two different cuvettes and two full sets of 20 readings each.

### Calculation of the Optical Density (OD)

OPTICAL DENSITY	Op = Optical path (0.6 cm for all calculations); Va = Average value of measurements during reading time; Vo = Dark reference reading; Vx = Water reference reading.
-----------------	--

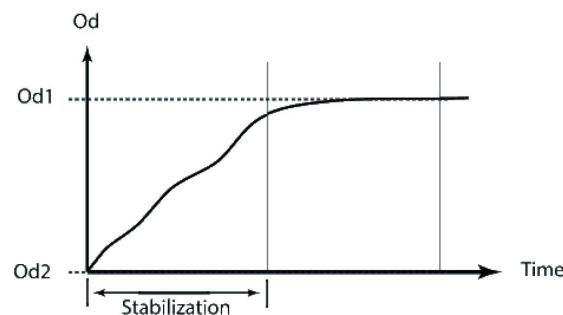
$$Od = - \frac{1}{Op} \cdot \left[ \log_{10} \left( \frac{Va-Vo}{Vx-Vo} \right) \right]$$

OD values are expressed in absorbances. All values are normalized to an optical path of 10mm.

Up to 20 readings are processed to obtain two synthetic values, the reaction optical density (OD1) and the reference optical density (OD2). Of the reading procedures, only kinetic does not use the reference OD2. The method types differ only in the way OD1 and OD2 are extracted. When a test is executed but the calibration is missing or faulty, the message "Result unusable" is displayed. When a new calibration is available the operator can recalculate the results.

### 11.2.1 Endpoint

FIGURE 180



**A single reading which reaches a constant optical density at the end of the reaction**

The reaction OD1 is the average of the measured readings taken, at the specified wavelength, after the end of the stabilization.

The reference OD2 is the OD of the reaction cell filled with water, taken at the selected wavelength during start-up.

The optical density of the endpoint test is the difference between the reaction OD1 and the reference OD2.

**Calculations used for endpoint to obtain the test result from the optical density obtained**

For single-standard methods: Result =  $(\text{Od1} - \text{Od2}) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation  $(\text{Od1} - \text{Od2})$

### 11.2.2 Endpoint self-blank

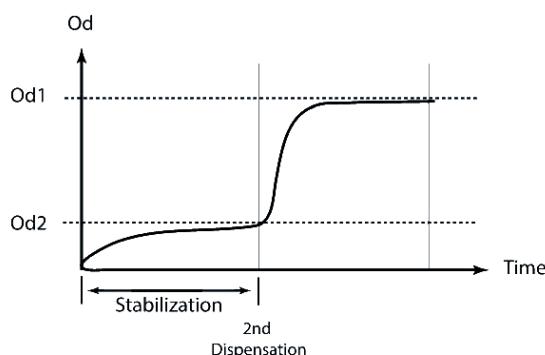


FIGURE 181

**A single reading which reaches a constant optical density at the end of the reaction**

Any reaction based on two pipettings with the volume of the first dispensation higher than 210 $\mu$ l can be set as Endpoint self-blank.

#### Commonly used

Sample blank configuration which dispenses R1 + SMP in the first pipetting and R2 in the second.

#### Other

Endpoint Reagent Blank configuration which dispenses R1 or R1 + R2 in 1st pipetting and SMP in the 2<sup>nd</sup> pipetting.

The reaction OD1 is the average of the measured readings taken, at the specified wavelength, after the end of the incubations.

The reference OD2 is the reading of the reaction before adding the second dispensation. OD2 is corrected to compensate the dilution effect of the volume addition during the second dispensation.

**Calculations used for endpoint self-blank to obtain the test result from the optical density obtained**

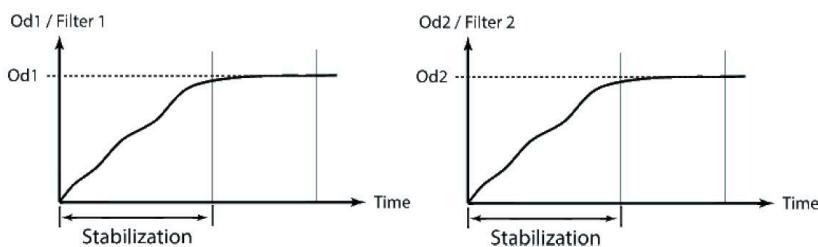
For single-standard methods: Result =  $(\text{Od1} - \text{Od2}) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation ( $\text{Od1} - \text{Od2}$ )

### 11.2.3 Bichromatic endpoint

FIGURE 182

FIGURE 183



**Employs two readings each using a different filter which reach constant optical densities at the end of the reactions**

The reaction OD1 is the average of the measured readings taken, at the specified first wavelength, after the end of the incubations.

The reference OD2 is the average of the measured readings taken, at the specified second wavelength, after the end of the incubations.

The optical density of the bi-chromatic test is the difference between the reaction OD1 and the reference OD2.

Bichromatic tests should have an even number of readings.

**Calculations used for bichromatic endpoint to obtain the test result from the optical density obtained**

For single-standard methods: Result =  $(\text{Od}1 - \text{Od}2) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation  $(\text{Od}1 - \text{Od}2)$

#### 11.2.4 Differential endpoint

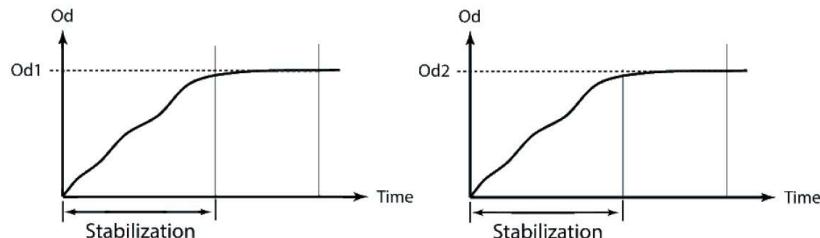


FIGURE 184

FIGURE 185

**Reaches a constant optical density at the end of each reaction (two independent reactions).**

The differential test is executed performing two different reactions in two different reaction tubes, the first with R1 + SMP, the second with R2 + SMP.

The reaction OD1 is the average of the measured readings taken, at the specified wavelength, after the end of the incubations of the first test (R1).

The reaction OD2 is the average of the measured readings taken, at the specified wavelength, after the end of the incubations of the second test (R2).

The optical density of the differential test is the difference between the reaction OD1 and the reference OD2.

**Calculations used for endpoint to obtain the test result from the optical density obtained**

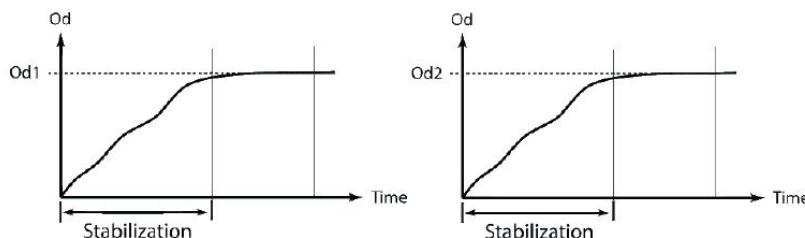
For single-standard methods: Result =  $(\text{Od}1 - \text{Od}2) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation  $(\text{Od}1 - \text{Od}2)$

### 11.2.5 Differential endpoint (sample blank)

FIGURE 186

FIGURE 187



**Reaches a constant optical density at the end of each reaction (one with and one without second reagent).**

**It is used for sample colour subtraction.**

The differential sample blank test is executed performing two different reactions in two different reaction tubes. The first with R1 + R2 + SMP, the second with only R1 + SMP. In the second test the volume of R1 is the same volume of R1 + R2 of the first test. The reaction OD1 is the average of measured readings taken, at the specified wavelength, after the end of the incubations of the first test (R1 + R2).

The reference OD2 is the average of the measured readings taken, at the specified wavelength, after the end of the incubations of the first test (R1). The optical density of the differential sample blank test is the difference between the reaction OD1 and the reference OD2.

**Calculations used for endpoint to obtain the test result from the optical density obtained**

For single-standard methods: Result =  $(\text{Od}1 - \text{Od}2) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation ( $\text{Od}1 - \text{Od}2$ )

### 11.2.6 Fixed time

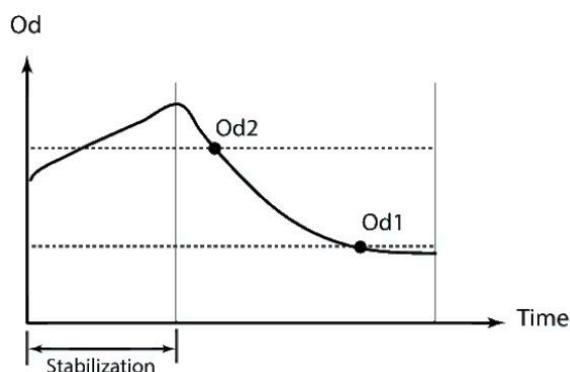


FIGURE 188

The OD is the difference between measurements taken at the beginning and the end of the time period.

The reference OD2 is the value taken at the specified first wavelength, after the end of the incubations, at the beginning of the reading time.

The reaction OD1 is the value taken at the specified first wavelength, at the end of the reading time.

The optical density of the fixed time test is the difference between the reaction OD1 and the reference OD2.

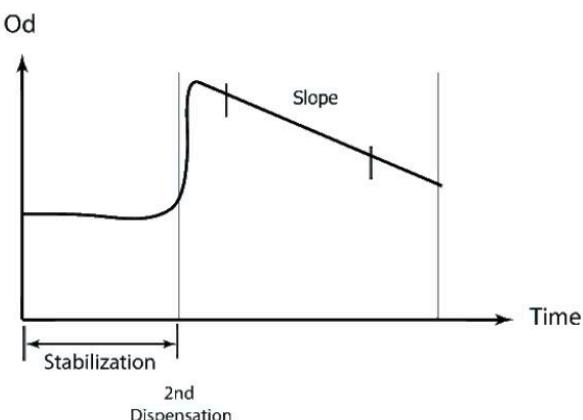
**Calculations used for endpoint to obtain the test result from the optical density obtained**

For single-standard methods: Result =  $(\text{Od1} - \text{Od2}) \cdot \text{Factor}$

For multi-standard methods: Result = Interpolation  $(\text{Od1} - \text{Od2})$

### 11.2.7 Kinetic

FIGURE 189



The reaction OD1 is the rate of change of the reaction, after the incubation, during the reading time, expressed in Absorbances per minute.

The optical density of the kinetic test is the reaction OD1. The reference OD2 is not used.

For more information on substrate depletion and reaction slope see chapter 9.3.13.

Kinetic can also be bichromatic reactions.

**Calculations used for endpoint to obtain the test result from the optical density obtained**

For single-standard methods: Result = Slope • Factor

For multi-standard methods: Result = Interpolation (Slope)

**!** Note: A reagent blank test is automatically inserted in the worklist when the blank correction of the method used is required but has expired or has never been executed.

### 11.3 Reagent blank

For all readings requiring reagent blank corrections, the result is calculated by subtracting the blank value from the optical density obtained.

$OD = OD \text{ calculated for sample} - OD \text{ calculated for reagent blank}$

## 12 DATA MODULES

In this chapter, the Data Modules will be explained in detail.

- Click the **DATA MODULES** button to access.



### 12.1 Overview

The following Data Modules are available:

- **Licenses**

If a special license is needed to run the software, you can activate the license here. This feature is usually not required for most users.

License management

Export system data

Import system data

Test archive

Lot management

Patient manager

- **Import system data**

E.g. import of new methods.

- **Export system data**

E.g. export of methods that you want to import on another instrument.

- **Test archive**

Database of all patient test results. Search by Date, Sample, Patient or Method.

- **Lot management**

Database of all patients with history of their results.

- **Lot management**

All functions dealing with the management of calibrator and control LOTs (e.g. entering target values for calibrators and controls).



## 12.2 Licenses

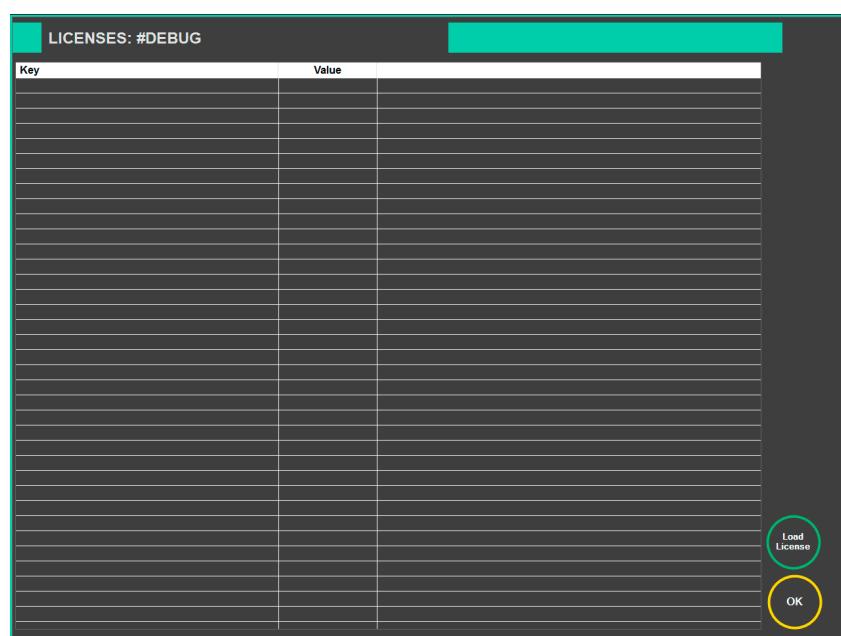
## Getting there

**License management** Click this button to access the work window.

## Overview

Here you can manage all the licenses. Licenses might be needed for special software features. If necessary, HUMAN will provide license files. If you have not received any license file, you can ignore this function. License files defining the amount of protected and open channels.

FIGURE 190



### **12.2.1 Step by step: Load a license**

1.  Click on this button to load a new license.
  2. Select the file and click OK.

## 12.3 Export system data

## Getting there

Click this button to access the work window.

## Overview

You can use this Data Module to export methods that you want to import on another instrument.

**FIGURE 191**

### 12.3.1 Step by step: Exporting methods

1. Select the methods to be exported.
2. Click **Export** and select a destination folder in order to create a data export file.

## 12.4 Import system data - Import methods

### Getting there

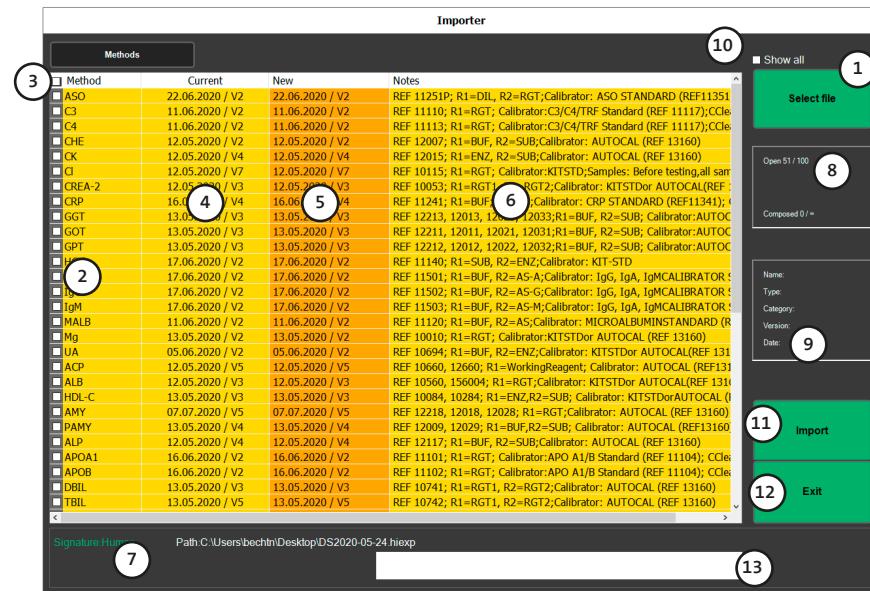
 Click this button to access the work window.

### Overview

You can use this Data Module to import data that was previously exported from another instrument or that you have received from HUMAN or your HUMAN distributor (e.g. update of methods).

### 12.4.1 Functions

FIGURE 192



### 1. Select file

Click to open a new data file.

### 2. Method

Method Code

Click on the checkbox to select this method for import.

### 3. Select all

Click on the checkbox in the title bar to select all methods.

### 4. Current

Date and Version of the current method on the analyzer. "n/a" means that this method is not available on the analyzer.

### 5. New

Date and Version of the method in the data file.

Methods that are identical on the analyzer and in the data file are shown in blue. Methods that are different on the analyzer and in the data file are shown in orange.

<input type="checkbox"/> Method	Current	New
<input type="checkbox"/> ASO	22.06.2020 / V2	22.06.2020 / V2
<input type="checkbox"/> C3	11.06.2020 / V2	11.06.2020 / V2
<input type="checkbox"/> C4	11.06.2020 / V2	11.06.2020 / V2
<input type="checkbox"/> CHE	12.05.2020 / V2	12.05.2020 / V2
<input type="checkbox"/> CK	12.05.2020 / V4	12.05.2020 / V4
<input type="checkbox"/> CI	12.05.2020 / V7	12.05.2020 / V7
<input type="checkbox"/> CREA-2	12.05.2020 / V3	12.05.2020 / V3
<input type="checkbox"/> CRP	16.06.2020 / V4	16.06.2020 / V4
<input type="checkbox"/> GGT	13.05.2020 / V3	13.05.2020 / V3
<input type="checkbox"/> GOT	13.05.2020 / V3	13.05.2020 / V3
<input type="checkbox"/> GPT	13.05.2020 / V3	13.05.2020 / V3
<input type="checkbox"/> HCY	17.06.2020 / V2	17.06.2020 / V2
<input type="checkbox"/> IgA	17.06.2020 / V2	17.06.2020 / V2
<input type="checkbox"/> IgG	17.06.2020 / V2	17.06.2020 / V2
<input type="checkbox"/> IgM	17.06.2020 / V2	17.06.2020 / V2
<input type="checkbox"/> MALB	11.06.2020 / V2	11.06.2020 / V2
<input type="checkbox"/> Mg	13.05.2020 / V2	13.05.2020 / V2
<input type="checkbox"/> UA	05.06.2020 / V2	05.06.2020 / V2
<input type="checkbox"/> ACP	12.05.2020 / V5	12.05.2020 / V5
<input type="checkbox"/> ALB	12.05.2020 / V3	12.05.2020 / V3
<input type="checkbox"/> HDL-C	13.05.2020 / V3	13.05.2020 / V3
<input type="checkbox"/> AMY	07.07.2020 / V5	07.07.2020 / V5
<input type="checkbox"/> PAMY	13.05.2020 / V4	13.05.2020 / V4
<input type="checkbox"/> ALP	12.05.2020 / V4	12.05.2020 / V4
<input type="checkbox"/> APOA1	16.06.2020 / V2	16.06.2020 / V2
<input type="checkbox"/> APOB	16.06.2020 / V2	16.06.2020 / V2
<input type="checkbox"/> DBIL	13.05.2020 / V3	13.05.2020 / V3
<input type="checkbox"/> TBIL	13.05.2020 / V5	13.05.2020 / V5

FIGURE 193

### 6. Notes

Notes of the method in the data file.

### 7. Sign

HUMAN methods will be signed. Non-HUMAN methods are not signed.

### 8. Channels

Number of methods that are currently installed on the analyzer.

### 9. Method information

Highlight one method to see details about this method.

## 10. Show all

By default only methods that are different between the analyzer and the data file are shown in the table. Check “Show All” to see all methods that are in the data file.

## 11. Import

Import the selected methods.

## 12. Exit

Exit this work form.

## 13. Status Bar

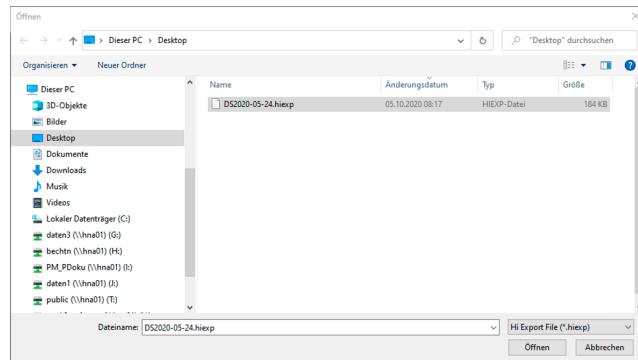
Will show the status of import/export.

### 12.4.2 Step by step: Importing methods

Follow these steps to import new or updated methods:

1.  Click **Select File**.
2. Choose the data file that you have received.

**FIGURE 194**



**!** Note: If you try to import more open methods than there are open channels on the instrument, you will get an error message.

3. The software automatically compares the “New” methods to the “Current” methods that are installed on the instrument. If a “New” and a “Current” method are the same, they are not shown in the table. Only methods that are different are shown by default. The software compares version and date of the method to identify a “different” method.
4.  (Check the “Show All” option to show all methods from the data file.)
5. Select the methods that you want to import.
6.  Click **Import** to import the selected methods.
7. The software will show the following message upon completion of the import:  Package has been correctly loaded.

Package has been correctly loaded.

## 12.5 Test archive

### Getting there

**Test archive**

Click this button to access the work window.

### Overview

The Test Archive allows the user to search and filter for executed tests by Date, Sample ID, Patient ID, Test no., Method Code, Reference, Cuvette or Arm (left/right). All patient, calibrator and control test results are in the archive.

TEST ARCHIVE						
Test n°	Method	Sample / Reference	Date	Patient	Result	Unit
469	GOT	11 - HUMATROL N	15.05.2020	n/a	37.46	U/l
470	GOT	11 - HUMATROL N	15.05.2020	n/a	30.31	U/l
471	GOT	11 - HUMATROL N	15.05.2020	n/a	29.13	U/l
472	GOT	11 - HUMATROL N	15.05.2020	n/a	31.49	U/l
473	GOT	11 - HUMATROL N	15.05.2020	n/a	29.72	U/l
474	GOT	11 - HUMATROL N	15.05.2020	n/a	30.55	U/l
475	GOT	11 - HUMATROL N	15.05.2020	n/a	29.72	U/l
476	GOT	11 - HUMATROL N	15.05.2020	n/a	30.61	U/l
477	GOT	11 - HUMATROL N	15.05.2020	n/a	31.19	U/l
478	GOT	11 - HUMATROL N	15.05.2020	n/a	31.19	U/l
479	GOT	11 - HUMATROL N	15.05.2020	n/a	30.20	U/l
480	GOT	11 - HUMATROL N	15.05.2020	n/a	27.96	U/l
481	GOT	11 - HUMATROL N	15.05.2020	n/a	29.72	U/l
482	GOT	11 - HUMATROL N	15.05.2020	n/a	30.02	U/l
483	GOT	11 - HUMATROL N	15.05.2020	n/a	29.43	U/l
484	GOT	11 - HUMATROL N	15.05.2020	n/a	31.19	U/l
485	GLUC	12 - SERODIOS	15.05.2020	n/a	37.67	U/l
486	GLUC	12 - SERODIOS	15.05.2020	n/a	35.61	U/l
487	GLUC	12 - SERODIOS	15.05.2020	n/a	36.20	U/l
488	GLUC	12 - SERODIOS	15.05.2020	n/a	37.96	U/l
489	GLUC	12 - SERODIOS	15.05.2020	n/a	36.76	U/l
490	GLUC	12 - SERODIOS	15.05.2020	n/a	35.26	U/l
491	GLUC	12 - SERODIOS	15.05.2020	n/a	34.43	U/l
492	GLUC	12 - SERODIOS	15.05.2020	n/a	37.67	U/l
493	GLUC	12 - SERODIOS	15.05.2020	n/a	36.20	U/l
494	GLUC	12 - SERODIOS	15.05.2020	n/a	35.81	U/l
495	GLUC	12 - SERODIOS	15.05.2020	n/a	33.24	U/l
496	GLUC	12 - SERODIOS	15.05.2020	n/a	37.08	U/l
497	GLUC	12 - SERODIOS	15.05.2020	n/a	37.37	U/l
498	GLUC	12 - SERODIOS	15.05.2020	n/a	36.79	U/l
499	GLUC	12 - SERODIOS	15.05.2020	n/a	36.20	U/l
500	GLUC	12 - SERODIOS	15.05.2020	n/a	37.96	U/l
501	GLUC	12 - SERODIOS	15.05.2020	n/a	33.55	U/l

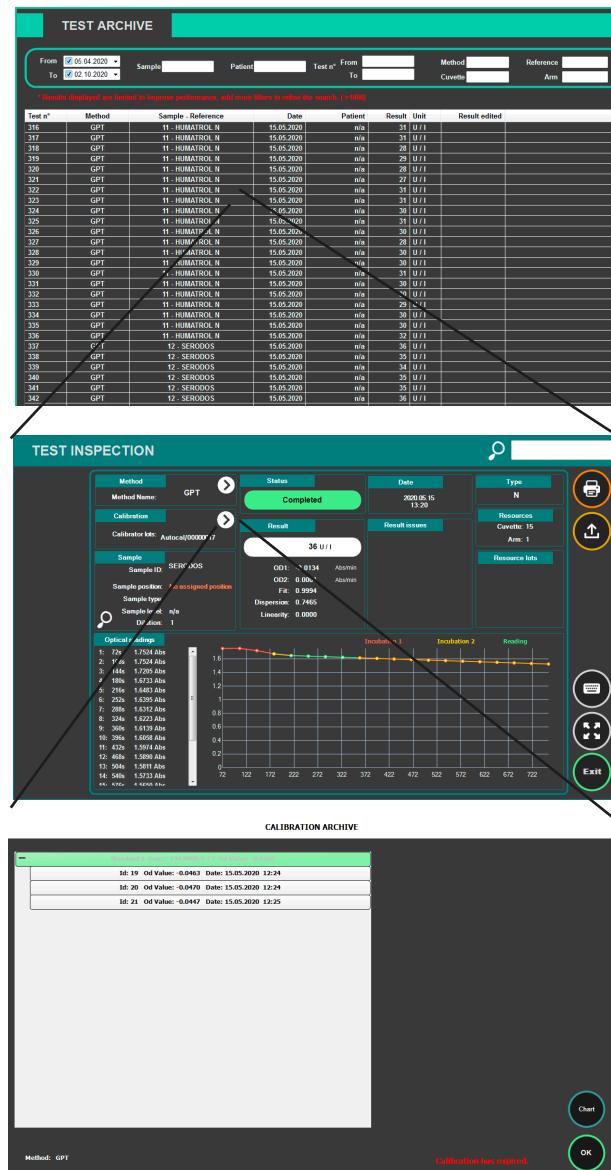
FIGURE 195

### 12.5.1 Step by step: Searching for results

1. Set filters according to your needs.
2. Click “Search” to show filtered results in the table. The search function will also find partial strings. For example you can search for the Method Code “CK” and the results will be shown for “CK” and “CK-MB”.
3. Double click on any result to see the TEST INSPECTION work form for this test (see chapter 7.6).

**Note: Maximum 1000 results**  
**! are shown in the table at the same time. Further restrict your search to show the test results you are looking for.**

FIGURE 196



## 12.6 Lot management

### 12.6.1 Overview

#### Getting there

Lot management

Click this button to access the work window.

#### Description

The **LOT MANAGEMENT** data module is very important for your daily routine. You use this Data Module to enter target values for calibrators and controls.

To simplify the information loading and monitoring process, this module has been designed to manage the calibrator and control LOTS in a single database.

In the **LOT MANAGEMENT** data module you can:

- Add new LOTS of calibrators and controls
- Add target values
- Inspect the target values of calibrators and controls

#### Tabs

The **LOT MANAGEMENT** is organized in two tabs:

- Calibrator
- Control



FIGURE 197

Click on **Calibrator** or **Control** to access the tab.

### 12.6.2 Calibrator tab

#### Getting there

Select **Calibrator** to enter the LOT MANAGEMENT of calibrators.

#### Functions

**FIGURE 198**



#### 1. Tabs

Select tab.

#### 2. Lot information

Enter Name, LOT, Expiry date of the Calibrator

#### 3. List

List of all Calibrators, Controls

#### 4. Method information

List of methods that are currently linked to the selected Calibrator

#### 5. Method display

Linking a method to a Calibrator and entering target values.

Each LOT can be linked to as many methods as required. Once a LOT/method linkage has been established it never needs to be recorded again. Unused LOTs can be deactivated. Only one LOT of each calibrator can be active at a time.

### Step by step: Adding a new calibrator

1. Enter “Name” (e.g. “Autocal”), “Lot” (e.g. “003”) and Expiration date.

Lot information

Name:

Lot:  Expiration date: Month:  Year:

Active  Stored

FIGURE 199

2.  Click “Add lot”

**!** Note: If you have just opened the Calibrator tab, the input fields are empty. If you have already selected another calibrator from the list, just enter the new values into the appropriate fields. After clicking “Add lot”, the new information will be saved. Don’t worry, the data of the old calibrator will not be deleted.

### Step by step: Remove/ delete a LOT

1. Select a calibrator from the list on the left side of the screen.

Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Autocal	00000017
BioRad1	00066321
BioRad2	00066322
BioRad3	00066323
C3/C4/TRF	00000000
CKMB	00015001
CRP	00000000
CRP	00000057
Cyst C 2	00000000
Cyst C1	00000000
Cyst C3	00000000
Cyst C4	00000000
Cyst C5	00000000
Fer15	00000000
Ferr125	00000000
Ferr250	00000000

FIGURE 200

2.  Click “Remove lot”

### Step by step: Change a name, LOT or expiration date

1. Select a calibrator from the list on the left side of the screen.

**FIGURE 201**

Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Autocal	00000017
BioRad1	00066321
BioRad2	00066322
BioRad3	00066323
C3/C4/TRF	00000000
CKMB	00015001
CRP	00000000
CRP	00000057
Cyst C 2	00000000
Cyst C 1	00000000
Cyst C 3	00000000
Cyst C 4	00000000
Cyst C 5	00000000
Fer15	00000000

2. Do the required changes (Name, Lot, Expiration date)

3. Click “Apply” (on the right side of the screen!)

### Step by step: Entering target values

1. Select a calibrator from the list on the left side of the screen.

**FIGURE 202**

Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Autocal	00000017
BioRad1	00066321
BioRad2	00066322
BioRad3	00066323
C3/C4/TRF	00000000
CKMB	00015001
CRP	00000000
CRP	00000057
Cyst C 2	00000000
Cyst C 1	00000000
Cyst C 3	00000000
Cyst C 4	00000000
Cyst C 5	00000000
Fer15	00000000

2. Select a method from the drop-down menu.



3. Select if you want to use the 1st or the 2nd unit for the target values.



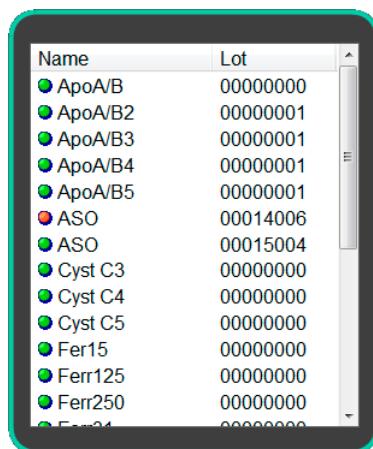
4. Enter the target value as "Conc."

5.  Click "Link method".

6. Continue from step 2. for every method that you want to link to the calibrator.

#### Step by step: Remove link between calibrator and method

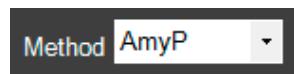
1. Select a calibrator from the list on the left side of the screen.



Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Cyst C3	00000000
Cyst C4	00000000
Cyst C5	00000000
Fer15	00000000
Ferr125	00000000
Ferr250	00000000
Fer-24	00000000

FIGURE 203

2. Select a method from the drop-down menu.

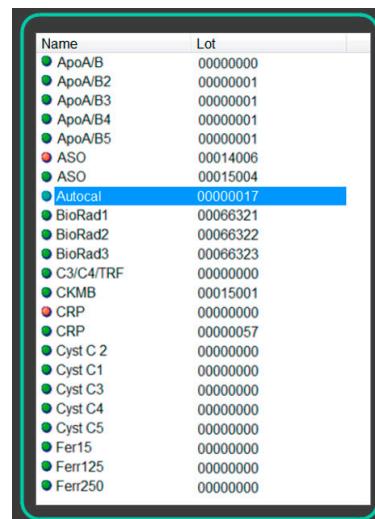


3.  Click "Remove link"

### Step by step: Change a target value

1. Select a calibrator from the list on the left side of the screen.

FIGURE 204



Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Autocal	00000017
BioRad1	00066321
BioRad2	00066322
BioRad3	00066323
C3/C4/TRF	00000000
CKMB	00015001
CRP	00000000
CRP	00000057
Cyst C 2	00000000
Cyst C 1	00000000
Cyst C 3	00000000
Cyst C 4	00000000
Cyst C 5	00000000
Fer15	00000000
Ferr125	00000000
Ferr250	00000000

2. Select a method from the drop-down menu.



3. Select if you want to use the 1<sup>st</sup> or the 2<sup>nd</sup> unit for the target values.



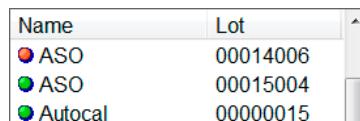
4. Enter the new target value as "Conc."

5. Click **Apply** (underneath the "Conc." field!)

### Step by step: Activating or storing a LOT

Calibrator LOTs must be activated to use them. Unused LOTs can be stored (deactivated). Active LOTs are indicated in green, stored LOTs are indicated in red. Only one LOT of each calibrator can be active at the same time.

FIGURE 205



Name	Lot
ASO	00014006
ASO	00015004
Autocal	00000015

1. Select a calibrator from the list on the left side of the screen.

Name	Lot
ApoA/B	00000000
ApoA/B2	00000001
ApoA/B3	00000001
ApoA/B4	00000001
ApoA/B5	00000001
ASO	00014006
ASO	00015004
Autocal	00000017
BioRad1	00066321
BioRad2	00066322
BioRad3	00066323
C3/C4/TRF	00000000
CKMB	00015001
CRP	00000000
CRP	00000057
Cyst C 2	00000000
Cyst C1	00000000
Cyst C3	00000000
Cyst C4	00000000
Cyst C5	00000000
Fer15	00000000
Ferr125	00000000
Ferr250	00000000

FIGURE 206

2. Click on **Active** to activate the LOT or click on **Stored** to store the LOT.

### 12.6.3 Control tab

#### Getting there

Select **Control** to enter the Lot management of controls.

#### Functions

Method information	
Methods linked to Humatrol N / 00000006	
Method	Conc. Min conc. Max conc. Conc. unit
APDEA	122 92 153
GOT	33,4 25,7 41,1 U / l
GLU	108 90,7 125 mg / dl
TP	8,7 7,81 9,73
CreaA	1,0 0,8 1,26
GLU-UV	104 87,4 121
Mg	1,86 1,56 2,16
Mg2id	1,86 1,56 2,16

FIGURE 207

Handling of Controls is the same as for Calibrators.

**!** Note: The minimum to maximum concentration range is interpreted by the software as the target concentration +/- 2 SD (standard deviations).

There are only two differences:

- Instead of a target concentration only, you have to enter a target concentration and a minimum concentration (lower acceptance range of the control). The maximum concentration (upper acceptance range of the control) is calculated automatically.

Conc.	29
Min conc.	22
Max conc.	36

-  By clicking on the QC button you can go directly to the QUALITY CONTROL work panel.

## 12.7 Patient management

Getting there



Click this button to access the work window.

### Overview

This module is a database of patients and test results linked to those patients. It provides information and procedures for the management of patients and their test results (e.g. list of patients, patient searches, tests organized by date or analysis, show patient history, print reports). If you are not using an LIS, you can use this database locally on the instrument's computer.

### 12.7.1 Functions

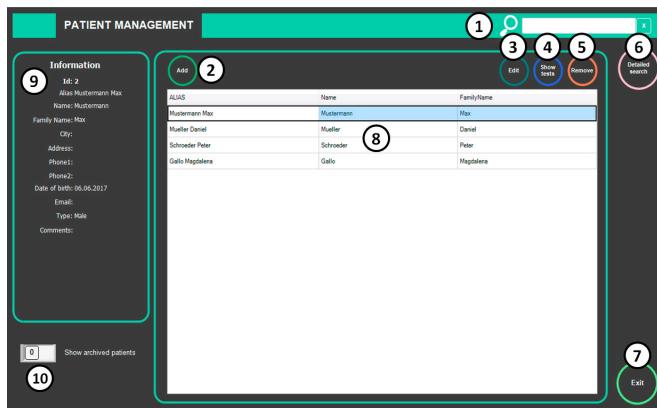


FIGURE 208

1. Enter “**Search string**” to filter the patient list (e.g. Name, Family name, Type, ID) and to search for patients in archive
2. “**Add**” a new patient to the list
3. “**Edit**” selected patient
4. Show “**PATIENT TEST LIST**” with all test results that are linked to the selected patient
5. **Remove** patient to the archive (see also “**Show archived patients**”)
6. Access “**Detailed search**” to identify patients by entering multiple search criteria
7. **Exit** “**PATIENT MANAGEMENT**” module
8. **Patient list**
9. Detailed information for the selected patient
10. Check “**Show archived patients**” to also include patients from the archive in search/list. (Archived patients are old patients that have been “removed”, but its information is still available for traceability purposes).

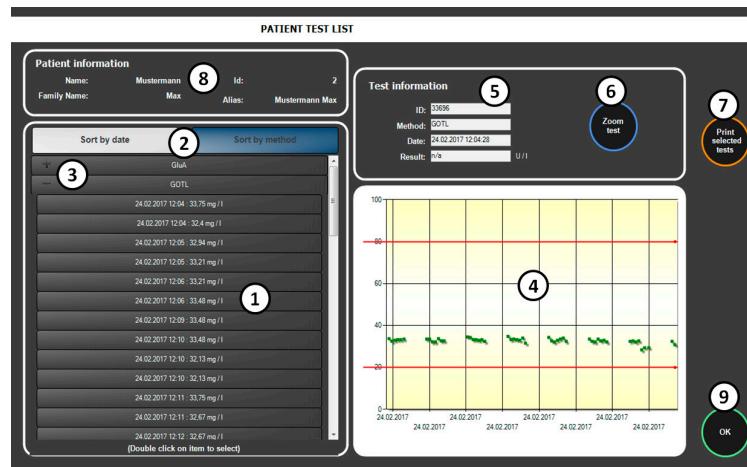
## 12.7.2 Patient test list

### Getting there

 Click to access the work form “PATIENT TEST LIST”.

### Functions

FIGURE 209



1. **Test list** showing all tests that are linked to the patient.
2. Selection of how the “Test list” is sorted: “Sort by date” of execution or “Sort by method”
3. Click on “+” to **expand** the list or click “-” to reduce the list. Double click any test to **select/unselect** it. Selected tests are highlighted in another colour.

FIGURE 210

+	CA
-	Mg
	30.11.2016 07:09 : 1.888034724
	30.11.2016 07:10 : 2.013274896
	30.11.2016 14:26 : 2.045930648
	30.11.2016 14:27 : 2.514584876
	01.12.2016 06:57 : 2.083056548
	01.12.2016 07:04 : 2.037030352
	01.12.2016 14:31 : 2.201833828
	01.12.2016 14:31 : 1.991004156
	02.12.2016 09:52 : 2.320611108
	02.12.2016 09:53 : 2.319126292
	05.12.2016 08:30 : 1.784629832
	05.12.2016 08:35 : 1.890043468

4. **Graphic** showing the evolution of test results over time. Select “**Sort by method**” and then the method name in the list to plot the graphic. Reference ranges (pathological ranges) are shown as red lines.
5. “**Test information**” Partial information about the selected test (ID, Method, Date, Result).
6. For detailed information about the selected test click on “**Zoom test**” to access the “Test information” work form (see chapter 7.6 for details).
7. Click “**Print selected tests**” to print a report of the tests previously selected tests in the list.
8. **Patient** information.
9. Click to **exit** this work form.



## 13 ADDITIONAL TOOLS

### 13.1 Overview

In this chapter, the Additional Tools will be explained in detail.

#### 13.1.1 Getting there

 Click on the Additional Tools button in the command bar.

#### 13.1.2 Functions

- Cumulative listing of the number of tests executed for each method (see chapter 11).
- QC results and statistics of single methods; Performance report of the entire system (see chapter 12.6).
- Manual dilution

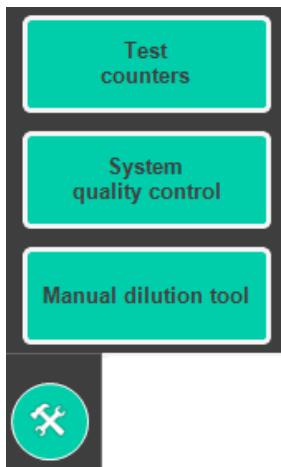


FIGURE 211

## 13.2 Test count

### 13.2.1 Getting there



Click on “Test counters” to access this module.

### 13.2.2 Description

This special management feature provides a continually updated record of all testing activities executed including liquid quantities of reagents that have been used. Select this module to review the number of tests recorder or print a report of current listings.

### 13.2.3 Functions

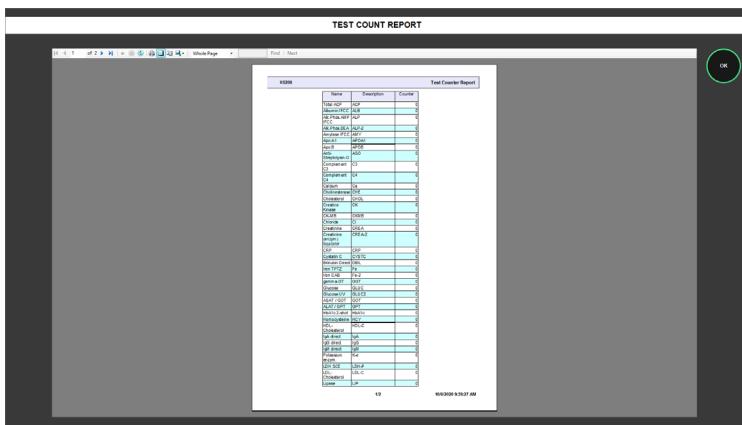
FIGURE 212

The screenshot shows a software interface titled "TEST COUNT". At the top, there are two tabs: "Current worklist" (selected) and "Historical". Below the tabs is a table with the following columns: N°, Method, Analysis, Test executed, R1 used (ml), R2 used (ml), and R1 + R2 used (ml). The table contains 41 rows of data. Three numbered callouts point to specific elements: 1 points to a "Print" icon, 2 points to the "Historical" tab, and 3 points to an "OK" button at the bottom right.

N°	Method	Analysis	Test executed	R1 used (ml)	R2 used (ml)	R1 + R2 used (ml)
1	ACP	Add Phosphatase total	34	7	0	7
2	ALB	Albumin	93	22	0	22
3	ALP	Alk.Phos.IFC	7	1	0	1
4	ALP-2	Alk.Phos.opt	78	12	3	16
5	AMY	alpha Amylase	160	32	0	32
6	ASO	Anti-Streptolysin-O	81	16	4	20
9	CA	Calcium	31	3	3	6
10	CHE	Cholinesterase	35	7	1	8
11	CHOL	Cholesterol	14	3	0	3
12	CK	CK-NAC	285	50	7	57
13	CK-MB	CK-MB	80	14	2	16
15	CREA	Creatinine Jaffe	32	6	2	8
16	CREA-2	Creatinine enzym.	93	20	7	26
17	CRP	C-reactive protein	377	75	19	94
19	DBIL	Bilirubin direct	191	38	10	48
21	GGT	gamma-GT	300	54	14	68
22	GLUC	Glucose	329	82	0	82
23	GOT	ASAT / GOT	271	43	11	54
24	GPT	ALAT / GPT	5	1	0	1
25	HbA1c	HbA1c	22	4	1	5
26	HCY	Homocysteine	25	5	0	6
39	P10	PRZ10	149	40	0	40
40	P100	PRZ100	-1	0	0	0
41	P100-2	PRZ100-2	32	10	0	10

- Number of tests counted per method and volumes for each reagent

## **2. Print a report of tests counted**



**FIGURE 213**

3. **OK** to Exit “TEST COUNT” module
  4. Select “**Current worklist**” to display test count of the active worklist only.  
Select “**Historical**” to display complete test count of the instrument.

### 13.3 Quality Control

### 13.3.1 Getting there

The **QUALITY CONTROL** module can be accessed in three ways:

-  It can be accessed from the “METHODS tab” using the “QC” button (see chapter 8 for details).

It can also be accessed through the “Lot management”

### 13.3.2 Description

This module has been designed to control the quality of the system by monitoring the QC results of methods and extracting information regarding the accuracy and precision of the instrument. Daily execution and checking of different control levels for each method is mandatory.

- Assign controls to methods (up to three controls per method)
- Provide a Levey-Jennings graphic of all QC results executed over time
- Determine accuracy and precision level of the instrument and the methods
- Activate/deactivate Westgard rules
- Print a report of quality controls

### 13.3.3 Functions

**FIGURE 214**



1. **“Reference” values** for mean and CV% taken from control LOT data (see chapter 12.6 for entering target values). Mean=Target value. CV%=(Standard deviation)/Mean.
2. **“Calculated” values** for mean and CV% using all items checked in test results list (see item 3).
3. List of **tests executed** in the selected period (see item 4) for the selected method and control. Any items that remain unchecked will be excluded from the values calculated and also from the graphic chart. If more than one QC test has been executed per day, only the final test will be checked.
4. **Levey-Jennings graphic** of QC results with dated reference lines. It is possible to select the period of control evaluation using the “From” and “To” date selections.

5. Select a “Control” for this method. Up to three different controls (control levels) can be used.
6. **List of methods**
7. **Print report** of the selected quality control for the selected method.
8. **Westgard rules**  
Activate any of the Westgard rules to be applied to the controls. If Westgard rules are activated, QC results are automatically monitored according to those rules. If any rule is violated, this rule will be highlighted here in red.
9. Select date range
10. Quick access to “Lot management”
11. **Exit “QUALITY CONTROL” module**

#### **13.3.4 Step by step: Checking the accuracy and precision of a method**

1. Enter target values for all controls that you want to use (see chapter 12.6.3).
2. According to your schedule, measure all controls on a daily basis. See chapters 6 and 7 to learn how to measure controls.
3. Access the “Quality Control” module
4. Select up to three controls from the drop-down menus (see item (5) of the Functions).
5. Click on the button on the left of any of the three controls.
6. Check the calculated values (see item (2) and the Levey-Jennings graphic).

#### **13.3.5 Westgard rules**

Westgard rules are based on statistical methods. They are used to automatically analyze QC data. Westgard rules are used to define specific performance limits and can be used to detect both random and systematic errors. Control ranges (see chapter 12.6.3) are interpreted as target concentration +/- 2 SD (standard deviations).

If any rule is violated, this rule will be highlighted in red in the Quality Control work form. Test and calibration results of a method will be flagged with “Westgard rule error”, if any active rule is violated for this method.

Test status if Westgard rules have been violated:  .

In the description below “s” means “standard deviations”.

#### **1<sub>3</sub>s**

A QC is rejected when a single control measurement exceeds the target plus 3s or the target minus 3s limits.

#### **2<sub>2</sub>s**

A QC is rejected when 2 consecutive control measurements exceed the same target plus 2s or the same target minus 2s limit.

#### **R<sub>4</sub>s**

A QC is rejected when 1 control measurement in a group exceeds the target plus 2s and another control measurement exceeds the target minus 2s.

#### **4<sub>1</sub>s**

A QC is rejected when 4 consecutive control measurements exceed the same target plus 1s or the same target minus 1s limit.

#### **10x**

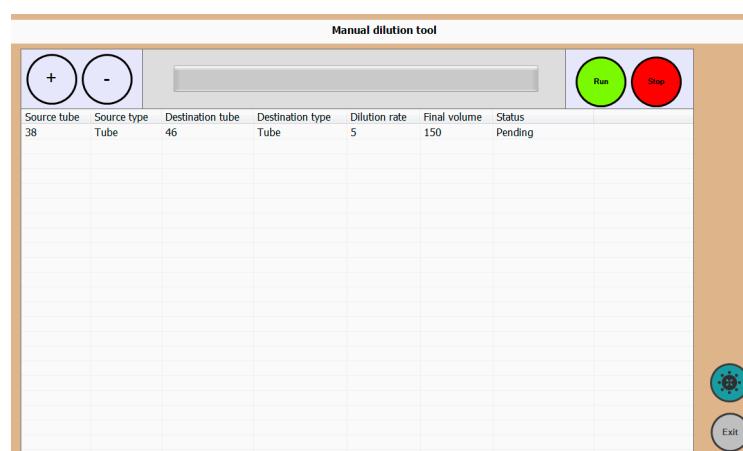
A QC is rejected when 10 consecutive control measurements fall on one side of the target.

### **13.4 Manual dilution tool**

#### **13.4.1 Overview**

This tool has been designed especially to permit the user to save time during the preparation of pre-diluted samples when required.

**FIGURE 215**



### 13.4.2 Step by step

1. Click + to create the new dilution item to be inserted in the grid.



2. Enter the information required for each dilution item...

Source tube	<input type="text"/>
Source type	<input type="text"/>
Destination tube	<input type="text"/>
Destination type	<input type="text"/>
Final volume	<input type="text"/> (100-2000)
Dilution rate	<input type="text"/> (1-100)
Status	
<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

FIGURE 216

**Source tube:** Tube position of the concentrated liquid

**Source type:** Type of tube where concentrated liquid is located

**Destination tube:** Position of the empty tube where dilution is to be performed

**Destination type:** Type of tube where dilution is to be performed

**Final volume (100-2000):** Final volume of diluted solution required

**Dilution rate (1-100):** Rate of dilution that should be applied during the dilution process

**Status:** During run the status of the dilution item will be shown, it should not be entered.

3. Click the **OK** button to confirm your entries.
4. Select one or more dilution items in the grid and press - to remove them.
5. Once all dilution items required has been created, click the **Run** button to initiate the procedure.



6. At any time during the dilution procedure it is possible to "STOP" the process by clicking the red button
7. Access the "Sample tray" form (see chapter 6.6).





## 14 MAINTENANCE

### 14.1 Overview

The MAINTENANCE PROCEDURES work form allows the execution of all maintenance procedures.

#### Getting there

 Click to open MAINTENANCE PROCEDURES work form.



Use the buttons “Routine” and “Special” to switch between the two pages:

 **10** Click to access Routine maintenance procedures.

 **3** Click to access Special maintenance procedures.

#### Functions

FIGURE 217

MAINTENANCE PROCEDURES				
	Status	Last execution date	Estimated time left	Details
Daily				
Start Up	✗ Expired	07:36 06.06.17	1 day(s)	
Quick Start Up	✗ Expired	07:36 06.06.17	1 day(s)	
Shut-down	✗ Expired	14:22 06.06.17	1 day(s)	
Weekly				
Replace water tank	✓ Valid	09:25 06.06.17	1 day(s)	
Replace cleaning tank	✓ Valid	07:57 06.06.17	1 day(s)	
Replace waste tank	✓ Valid	07:57 06.06.17	1 day(s)	
Replace special waste tank	✓ Valid	07:57 06.06.17	1 day(s)	
Monthly				
Special cuvette wash	✓ Valid	07:57 24.05.17	14 day(s)	
Special needle wash	✓ Valid	12:27 18.05.17	20 day(s)	
Pump Test	✓ Valid	12:03 18.05.17	20 day(s)	

1. **Status**  
Status of each Maintenance procedure (“Valid” or “Expired”)
2. **Last execution date**  
Last date and time when this Maintenance procedure has been executed.
3. **Estimated time left**  
Time until next execution of this Maintenance procedure must be executed.
4. **Routine**  
Click to show the “Routine” Maintenance procedures (Daily, Weekly, Monthly).
5. **Special**  
Click to show the “Special” Maintenance procedures (Halogen lamp, Peristaltic pumps, Reaction cuvettes, Hydraulic system).
6. **Maintenance procedures**  
Click on either Maintenance procedure to get more details or execute this procedure.
7. **OK**  
Click **OK** to exit the “Maintenance Procedures” panel.

## 14.2 Routine

The procedures of the “Routine maintenance” must be performed on a daily, weekly or monthly basis. Maintenance procedures might have to be executed more frequently according to your use of the instrument. E.g. Special cuvette wash is required more frequently if you are measuring many turbidimetric tests.

### 14.2.1 Daily maintenance

These procedures must be executed each day:

1. **Start-up.** Mandatory every day (every 24h) to ensure that the calibration of the optical group is renewed. An automatic start-up can be programmed to be performed by the instrument before the user arrives in the lab. If it is more suitable for the laboratory workflow, the start-up can also be performed in the evening, followed by a prime hydraulic system in the morning.
2. **Quick Start-up.** In alternative to the basic start-up, this Quick Start-up is faster, but it skips the filling of the hydraulic system and the pump test. Only recommended in exceptional cases.

3. **Shut-down.** Required to initiate the cleaning of the reaction cuvettes before switching off the analyzer. All tests must be finished before initiating the Shut-down. Mandatory every day before switching off the analyzer.
4. **Cleaning** the instrument. Use a cloth and 70-96% ethanol as disinfectant. Do not let the instrument soak with disinfectant for a long time. See also Safety Instructions in chapter 1. Clean and dry the condensate water from the reagent tray.
5. **Cleaning the pipetting needles.** Use a cloth and 70-96% ethanol as disinfectant to carefully clean the needles from the outside. Cleaning should be done in the morning before the daily start-up. If you are using the programmed start-up in the morning, you can also clean the needle in the evening after finishing your routine. Cleaning the needle is important, because a dirty needle can falsify results or lead to increased carry-over.

#### 14.2.2 Weekly maintenance

Three procedures must be done at least once a week.

1. Replace water tank (20l) BLUE
2. Replace cleaning solution tank (2l) GREEN
3. Replace waste tank (20l) RED

Common resources should be monitored and refilled/emptied as required to prevent premature stopping of scheduled work. Liquid levels sensors will notify the user, if wash tanks are empty or waste tanks are full.

#### Step by step: Replace wash tanks

1. Stop the analyzer and go to the MAINTENANCE PROCEDURES work form.
2. Click “Replace tank: Water tank” or “Replace tank: Cleaning solution tank”.  
The following window will appear.

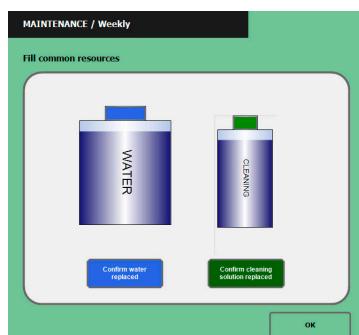


FIGURE 218

3. Empty and clean the respective tank.
4. Refill the tank with the appropriate mix of water and cleaning solution (see table below).
5. Reconnect the tank.
6. Click “Confirm water replaced” or “Confirm cleaning solution replaced”.
7. Continue to replace other tanks.
8. Prime the hydraulic system (see chapter 14.3.6).

**Preparation of solution for Water tank (20l) BLUE**

This tank must be filled with “Systemic Solution” (also called “Water” in Hi software), which is a mix of de-ionized, filtered water (max. 10µS) and Wash Additive (Cat.No. 18971). Please check the leaflet of Wash Additive for the dilution and preparation of the Systemic Solution.

Tank	Cat.No.	Name	Concentration
Water tank (20l) BLUE	18971	Wash Additive	According to leaflet

**Preparation of solution for Cleaning solution tank (2l) GREEN**

This tank must be filled with diluted “Special Wash Solution” (also called “Cleaning” in Hi software), which is a mix of de-ionized, filtered water (max. 10µS) and sodium hydroxide (NaOH) (Cat. no. 18974). The final concentration of NaOH in the tank must be 60mmol/l (equal to approximately 0.24% NaOH).

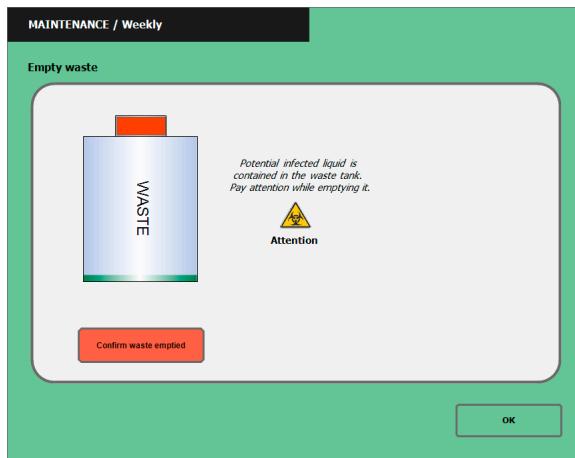
Please check the leaflet of Special Wash Solution (Cat.No. 18974) for the dilution and preparation to be used on the analyzer. Cat.No. 18974 contains 30 ml of NaOH (2mol/l) in each bottle. Read the leaflet and the material safety data sheet of the solution carefully. NaOH in the concentrations above is considered corrosive and has to be handled with care.



Tank	Cat.No.	Name	Concentration
Clean. sol. tank (2l) GREEN	18974	Special Wash Sol.	60 mmol/l NaOH

**Step by step: Replace waste tanks**

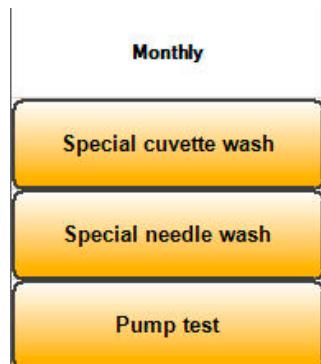
1. Stop the analyzer and go to the MAINTENANCE PROCEDURES work form.
2. Click “Replace tank: Waste tank”. The following window will appear.

**FIGURE 219**

3. Empty the respective tank.
4. Reconnect the tank.
5. Click “Confirm waste emptied”
6. Click “OK”.
7. Continue to replace other tanks.

**14.2.3 Monthly maintenance**

Three procedures should be executed at least monthly to avoid a shift of tests results or deterioration of critical parts.

**FIGURE 220**

- 1. Special cuvette wash**

Special wash procedure of the reaction cuvettes that uses concentrated wash solutions that are placed on the reagent tray.

- 2. Special needle wash**

Special wash procedure of the pipetting needle that uses concentrated wash solutions that are placed on the reagent tray.

- 3. Pump test**

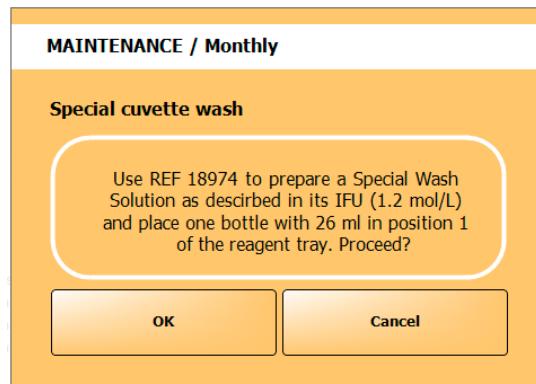
This function performs a precise measurement of liquid volumes and rates of flow for the wash function of the sampling needle, and for the cuvette wash station functions of dispensation and aspiration. It is recommended to perform the test on a monthly basis or if test results are not satisfactory.

Procedures 1. and 2. should also be executed whenever your reaction cuvettes or your pipetting needle is dirty. Depending on the parameters that are run on the instrument, reaction cuvettes tend to get dirty faster. Carefully observe the reaction cuvettes when you run turbidimetric test on the instrument.

#### **Step by step: Special cuvette wash**

1. Stop the analyzer
2. Place at least 26ml of **Special Wash Solution** (Cat.No. 18974) diluted according to its leaflet in position 1 of the reagent tray.
3. Click "Special cuvette wash". The following window will appear.

FIGURE 221



4. Click "OK" to start the procedure.

### Special Wash Solution

Special Wash Solution (cat. no. 18974) contains 30ml of NaOH 2mol/l in each bottle. Read the leaflet and the material safety data sheet of the solution carefully. NaOH in the concentrations above is considered corrosive and has to be handled with care. The solution is not ready-to-use in reagent bottles and need to be diluted according to its leaflet!



Cat.No.	Content	Name
18974	12 x 30 ml	Special Wash Solution

### Step by step: Special needle wash

1. Stop the analyzer
2. Place at least 4ml of Special Wash Solution (Cat.No. 18974) diluted according to its leaflet in position 1 of the reagent tray.
3. Click "Special needle wash". The following window will appear.

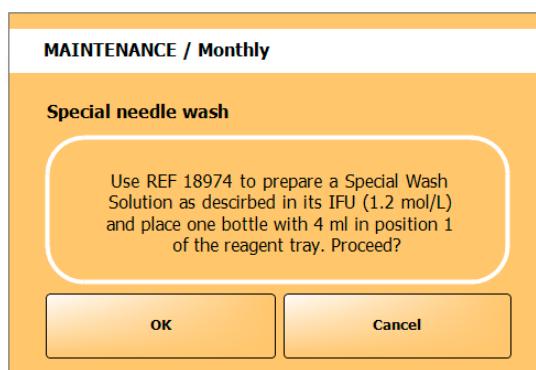


FIGURE 222

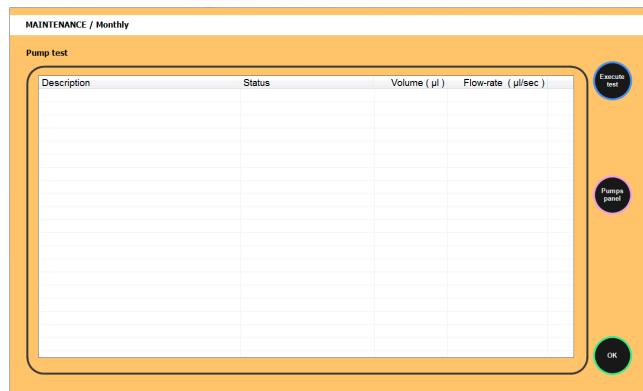
**Note:** See notes for Special Wash Solution above. The same Special Wash Solution that is used for "Special cuvette wash" (see above) is also used for "Special needle wash".

4. Click "OK" to start the procedure.

### Step by step: Testing pumps

1. Stop the analyzer
2. Place a tube with minimum 5ml of water in position 1 of the sample tray.
3. Click **Execute test**.

FIGURE 223



4. After finishing the pump test the software will indicate a “Status” for each pump:
  - “Warning” (the capacity of the pump is outside the range of validity)
  - “Replace” (see chapter 14.3.4 for replacement)
  - “OK” (the pump is functioning properly)

FIGURE 224

MAINTENANCE / Monthly

Pump test

Description	Status	Volume (µl)	Flow-rate (µl/sec.)
Wash station dispensing pump 1	OK	371	742
Wash station dispensing pump 2	OK	339	678
Wash station dispensing pump 3	OK	365	731
Wash station dispensing pump 4	OK	359	718
Wash station dispensing pump 5	Warning	380	760
Wash station dispensing pump 6	Warning	361	902
Wash station vacuum pump	Replace	2011	2011
Needle wash well dispensing pump	OK	516	516
Needle wash well aspirating pump	OK	938	938

5. The status of the pumps in the “Pumps panel” (see chapter 14.3.4) is updated after you have run the pump tests.

### 14.3 Special

These procedures should be executed whenever required. These procedures should also be used to monitor the remaining lifetime of certain parts.



FIGURE 225

- 1 Halogen lamp
- 2 Peristaltic pumps
- 3 Reaction cuvettes
- 4 Prime or empty the hydraulic system (wash solution / special wash solution / diluter syringe).

#### 14.3.1 Halogen lamp



FIGURE 226

##### 1. Filter status

- Filter number
- Wavelength provided by the filter
- mVolts detected on the optical amplifier with the specific filter
- Efficiency of the filter in % that indicates the decay of the filter life. The initial value (100%) has been set during production of the instrument. Efficiency values are tested during the Autozero (see chapter 3.4) calibration. The indicated efficiency of the filters also includes the status of the lamp. Call assistance, if one of the filters is more than 20% different from

the other filters. If there is a progressive decay of multiple filters, this is due to the lamp.

- Filter evaluation automatically provided for easy understanding of the user. Invalid if below 1000mV. “Dif” means that the reading of the filter is unstable.
- 2. Expected/average (remaining) lamp life in % and life counter in hours.
- 3. Replace lamp button. Use to reset the lamp life counter to zero.
- 4. Execute auto-calibration button. Use to calibrate the optical group after replacement of the lamp.
- 5. Offset value of the photodetector. This information is used only for technical support purposes. Optimal range for “Current” is 50.0mV to 100.0mV, values should not be close to or even below 0mV. The value is sensitive to the environment temperature.

#### 14.3.2 Lamp

When should I replace a lamp?

- When the lamp is broken.
- When the results are not stable.
- When start-up or autozero test (automatic calibration of optical group) has failed. The software will show an error message in that case.

**Note:** It is always recommended to order a second lamp to keep in your laboratory in case of lamp failure. Lamp life is not an exact science and will depend on a very big number of variables which make it almost impossible to predict the exact life of a lamp.

The lamp does not need to be replaced when the “expected lamp life” percentage is at 0%. The “expected lamp life” is a statistical value (approx. 1000h) that indicates when you should expect the lamp to fail. If the “expected lamp life” is lower than 5% you should have a spare lamp ready on stock.

#### Step by step: Replacing the lamp

The halogen lamp can be replaced by a capable and trained user in the laboratory.

**Attention:** Be sure that the analyzer is turned off, that the power supply cable is disconnected and the lamp has cooled for at least 5 minutes.



1. Remove the panel in the back of the instrument covering the lamp housing.
2. Unplug the wire connecting the lamp to the analyzer. Release the thumbscrew and remove the entire lamp fitting. Completely remove the thumbscrew from the “old” lamp fitting and attach it to the “new” replacement.
3. Insert the “new” halogen lamp fitting in the lamp housing,
4. Firmly tighten the thumbscrew and plug in the lamp wire.
5. Reconnect the power supply cable.
6. Turn on the instrument and log-in.
7. Access the “Maintenance” panel.
8. Select the “Special” section and access the “Halogen Lamp” panel
9. Click **Replace lamp**.
10. Click **Execute lamp auto-calibration** to adjust and improve the lamp performance.
11. Click **OK** and return to the main page, wait for the auto-calibration procedure to finish.

#### 14.3.3 Filters

When should I replace the filters?

- When one of the filter is evaluated as “Invalid”.

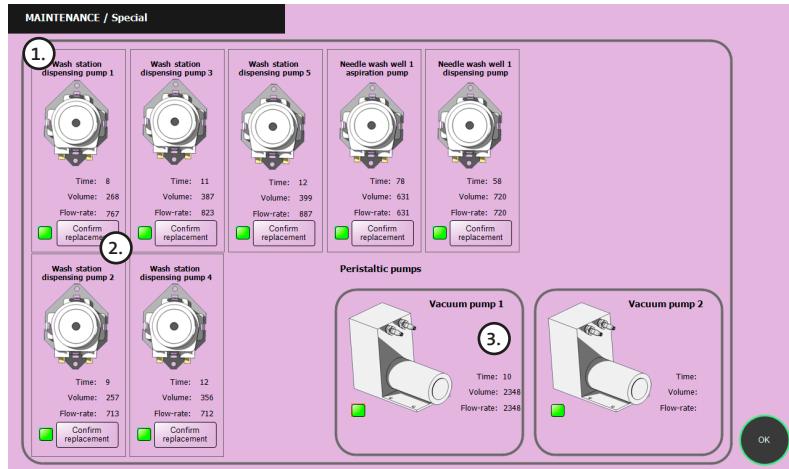
#### Replacing a filter

The replacement of the filters must be performed by technical personnel that has been correctly trained. Please contact your local HUMAN distributor for assistance.

**Note:** Each filter is independent and can be replaced individually. If a filter is marked as invalid, all methods that are performed using that method will be temporarily suspended. All the other methods will be performed normally.

#### 14.3.4 Peristaltic pumps

FIGURE 227



1. Peristaltic pumps panel (there are 10 panels, one for each peristaltic pump).
  - Time [hours]: Effective usage time of the pump (sum of all small movements of the pump)
  - Volume [ $\mu$ l]: Volume that is pumped during one activation cycle. The value shown here is a running average of the last pump tests and the start-up. For “Wash station dispensing pumps” 1 and 2 it should be around 300 $\mu$ l (minimum 200 $\mu$ l). For “Wash station dispensing pumps” 3 to 6 it should be around 400 $\mu$ l (minimum 200 $\mu$ l). The green indicator becomes red, if the minimum volume is not reached during pump test or start-up.
  - Flow-rate [ $\mu$ l/sec]: Normalized volume per 1 second. The value shown here is a running average of the last pump tests and the start-up. The “Needle wash well aspiration/dispensing pumps” should have a flow-rate of around 633 $\mu$ l/sec (minimum 500 $\mu$ l/sec). The green indicator becomes red, if the minimum flowrate is not reached during pump test (see chapter 14.2.3) or start-up.
2. Confirm replacement button. Click this button to reset the counter (time) and record the replacement.
3. Vacuum pumps panel (there are 2 panels, one for each vacuum pump). The maximum flow-rate is 2700 $\mu$ l/sec, the actual flow should be as high as possible. The green indicator becomes red, if the vacuum pump was not able to completely empty the cuvettes during the last pump test or start-up.

**When should I replace a peristaltic pump?**

- When the green indicator located next to the “Confirm replacement button” becomes red.



- When one of the pumps start making anomalous noise.

**Step by step: Replacing a peristaltic pump**

**Attention:** When replacing the needle wash well aspiration pump handle with care to avoid possible biological contamination.



1. Click **STOP** (top right main page) and wait for the “STOPPED” status to appear. **Attention:** Ensure that the analyzer is completely stopped before continuing with this operation.
2. Manually remove the cover left-side panel covering the hydraulic group.
3. Identify the pump head to be replaced. Disconnect the tubes of that pump.
4. Press the lateral release clips and remove the pump head. Align a new pump head with the axis of the motor and insert until it “clicks” into place.
5. Reconnect the tubes with the nipples.
6. Following each pump change click **Confirm replacement** in the software.
7. Click **OK** to return to the maintenance overview.
8. Select “**Routine**” page.
9. Execute a “Pump test” to verify the capacity and the correct work of the pump just installed.

**!** Note: During the monthly pump test, the user may be notified that a malfunction has occurred that may involve the replacement of a pump.

**!** Note: It is always recommended to order one or more spare pump heads and to keep them in your laboratory.

**!** Note: During the monthly pump test, the user may be notified that a malfunction has occurred that may involve the replacement of a pump.

### When should I replace the vacuum pump?

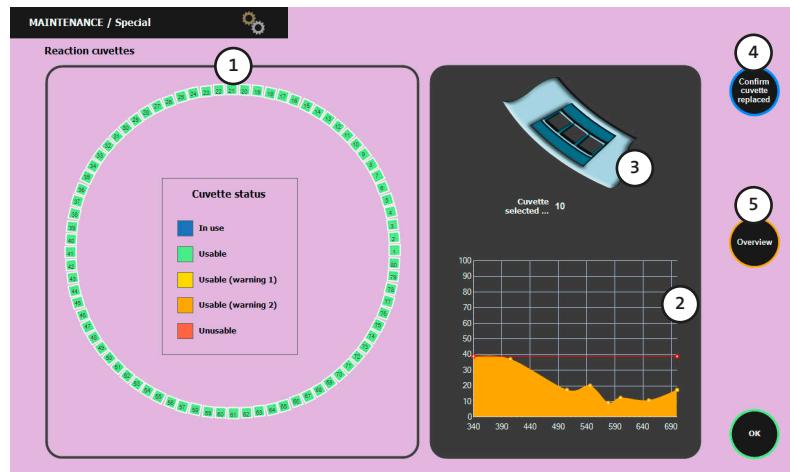
- When the green indicator becomes red.

#### Procedure:

The replacement of the vacuum pumps should be performed by technical personnel that has been correctly trained. Please contact your local HUMAN distributor for assistance.

#### 14.3.5 Reaction cuvettes

FIGURE 228



1. Cuvette rotor representation. Click on the single cuvette to select it. Each colour represent a specific state:

Blue	Cuvette is being use and no information about its current status is available
Green	Cuvette is good and is available for the machine to use
Yellow	Cuvette is good, but has received a first level of warning
Orange	Cuvette is good, but has received a second level of warning
Red	Cuvette is not usable and has been excluded by the system

2. Chart showing the absorbance at each available wavelength of the selected cuvette

Orange	Chart of the absorbances at each wavelength during the last start-up
Blue line	Absorbance at 340nm that was taken during the last reading
Red line	Baseline at 100 mAbs. This threshold should ideally not be exceeded

3. Currently selected cuvette number
4. Confirm cuvette replacement button
5. Cuvettes overview button

**When should I replace a cuvette?**

- When the cuvette has been excluded by the system (red).
- Optical reading results are not satisfactory.

**!** Note: It is always recommended to have spare cuvettes ready in your laboratory.

**Procedure:**

**!** Note: Before proceeding with the replacement of the cuvettes it is recommended to try with the execution of a cuvette special wash procedure.

1. Click **STOP** (top right main page) and wait for the “STOPPED” status to appear. **Attention:** Ensure that the analyzer is completely stopped before continuing with this operation.
2. Click on any “Unusable” cuvette.

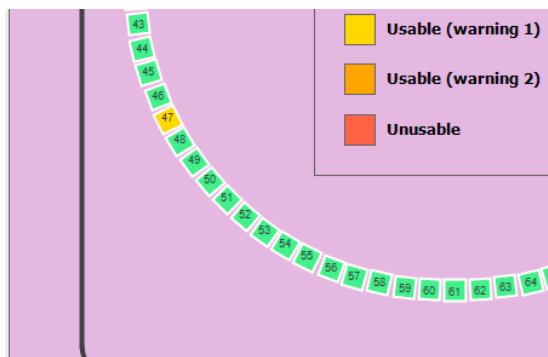


FIGURE 229

3. This cuvette will be positioned at the opening for removal and replacement.



FIGURE 230

4. Use the tweezers that are supplied with the instrument to manually remove the “old” cuvette.

FIGURE 231



**Attention:** The kinked arm of the tweezers should grab the cuvette from the lateral side and be inserted underneath the edge of the cuvette.

FIGURE 232

FIGURE 233



5. Then insert the “new” cuvette. Hold the cuvette with the tweezers as explained above.

FIGURE 234



**Attention:** Never touch the lower part of the cuvette with your fingers or any tool, especially not the areas where the light is passing through!

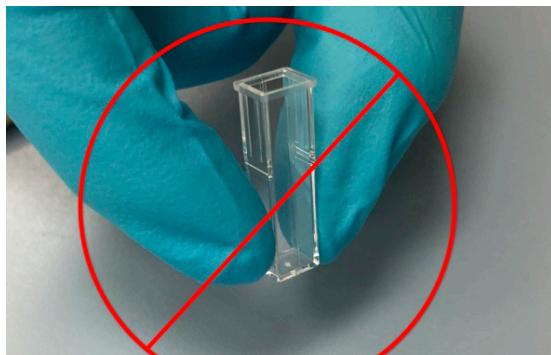


FIGURE 235

6. Push the cuvette down until it “clicks” into place.

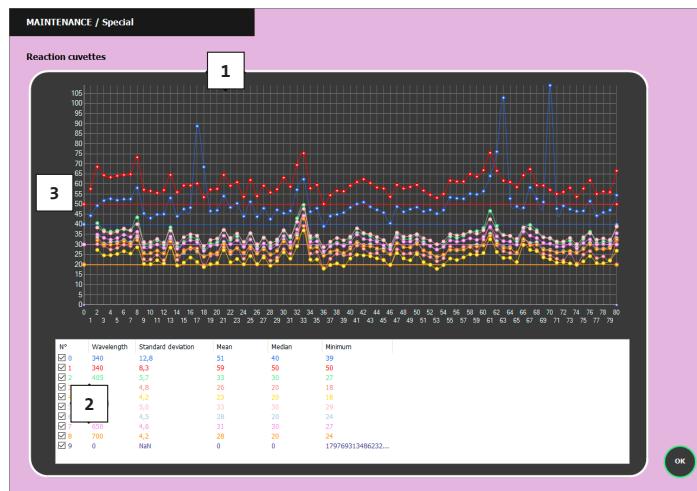


FIGURE 236

7. Upon completion click **Confirm cuvette changed**.
8. Repeat steps 2 – 7 for any other cuvette that needs to be replaced.
9. Perform a Quick start-up to measure the new cuvette blanks.

## Cuvettes overview

**FIGURE 237**



**Note:** A cuvette should always have optical values that are similar to the other cuvettes. If one or more cuvettes are visibly different from the others it is recommendable to replace that single cuvette.

The cuvettes overview is a useful tool that permits to easily compare the cuvettes between them.

1. Complete chart with all the wavelengths of all the cuvettes.
2. Select the checkbox of the wavelength that should be displayed on the chart
3. Table info
  - Wavelength
  - Standard deviation
  - Mean
  - Median
  - Minimum

#### 14.3.6 Hydraulic System

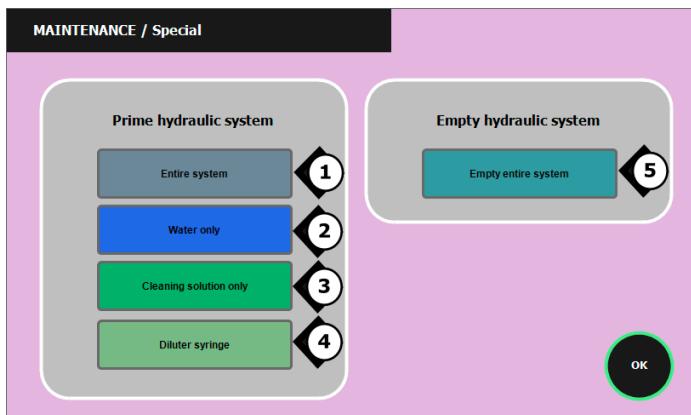


FIGURE 238

1. **Entire system:** Fill the entire hydraulic system completely. Normally executed when bubbles are present in the system. Duration of this procedure is approximately 20 minutes.
2. **Water only:** Fill the only the segment of the hydraulic system that is connected with the water tank. Normally executed after replacing the water tank.
3. **Cleaning solution only:** Fill the only the segment of the hydraulic system that is connected with the cleaning solution tank. Normally executed after replacing the cleaning solution tank.
4. **Diluter syringe:** Execute a special fill that has been designed to remove the bubbles from the diluter.
5. **Empty entire system:** Unload of all liquids presents inside the hydraulic system of the machine. Normally used for moving/storing the machine or if the machine is not being used for a long period of time.

## 14.4 Notifications

If maintenance steps have not been executed, this will be indicated to the user. The following example shows notifications when the start-up has not been executed.

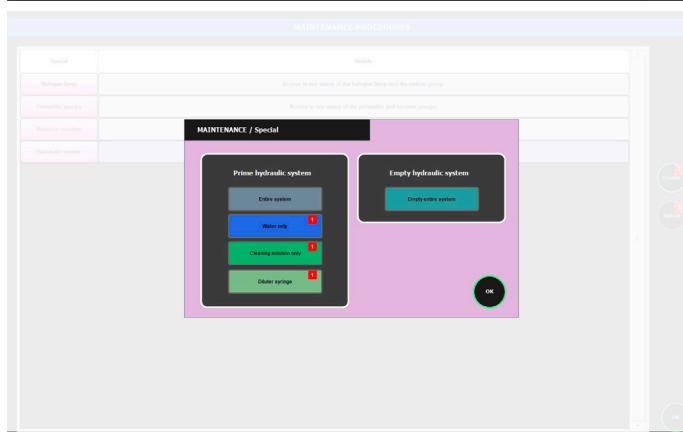
FIGURE 239

MAINTENANCE PROCEDURES				
Date	Status	Last execution date	Estimated time left	Details
Start up	<span style="color: red;">X</span> Expired	08:40 21.07.19		
Quick start up	<span style="color: red;">X</span> Expired	08:40 21.07.19		
Start down	<span style="color: red;">X</span> Expired	08:40 21.07.19		
<b>Weekly</b>				
Replace tank. Waste tank	<span style="color: red;">X</span> Expired	07:14 21.07.19		
Replace tank. Cleaning sol...	<span style="color: red;">X</span> Expired	07:14 21.07.19		
Replace tank. Waste tank	<span style="color: red;">X</span> Expired	07:14 21.07.19		
Replace tank. Special was...	<span style="color: red;">X</span> Expired	07:14 21.07.19		
<b>Weekly</b>				
Special nozzle wash	<span style="color: green;">✓</span> Valid	19:00 20.07.19	21 day(s)	
Special nozzle wash	<span style="color: green;">✓</span> Valid	09:00 23.07.19	14 day(s)	
Pump test	<span style="color: green;">✓</span> Valid	19:37 23.07.19	14 day(s)	

FIGURE 240

MAINTENANCE PROCEDURES	
Special	Details
Halogen lamp	Access to see status of the halogen lamp and the optical group.
Pneumatic pump	Access to see status of the pneumatic and vacuum pump.
Reaction nozzles	Access to see status of the reaction nozzles and noz.
Hydraulic system	Hydraulic priming operation is required. Access to see more details. Operator active is required (2).

FIGURE 241



## 15 ADMIN FUNCTIONS

### 15.1 Overview

**Administrator:** You must be access level administrator to perform these operations.

Certain operations concerning instrument functions are reserved for the administrator. Effective use of the procedures provided here govern the visual appearance of the software and the working parameters of the laboratory.

#### Getting there

To access administrative functions, click the yellow icon in the command bar.



#### Sections

Three sections are available in the ADMIN FUNCTION:

- Accounts
- Settings
- Statistics



FIGURE 242



### Accounts

Managing multiple user accounts with different access levels. Allocating instrument access only to authorized persons will improve laboratory security levels and reinforce the responsibilities of all operators.



### Settings

Adjusting the configuration and working parameters of the software (language, logo, profiles, method groups, etc.) will ensure greater efficiency throughout all operational procedures.



### Statistics

Statistics (CV, standard deviation, mean) and graphics for each sample (sorted by method). Monitoring the statistics that result from the ongoing testing process will permit greater levels of accuracy in laboratory operations.

## 15.2 ACCOUNTS

### Overview

There are multiple access levels for the system (User, Administrator, Service etc.). For each access level you can create multiple users with individual name and password. Access levels allow to restrict the use of some functions to authorized persons. For laboratory convenience it is recommended that one account be created for each operator.

“User” accounts are normally assigned to regular laboratory operators and permit only routine level work. By setting up multiple users the activities of all users are traceable to the operator that has performed the task (e.g. execution of tests, maintenance procedures). Certain functions that are described in this manual are only available for the Administrator.

## Functions

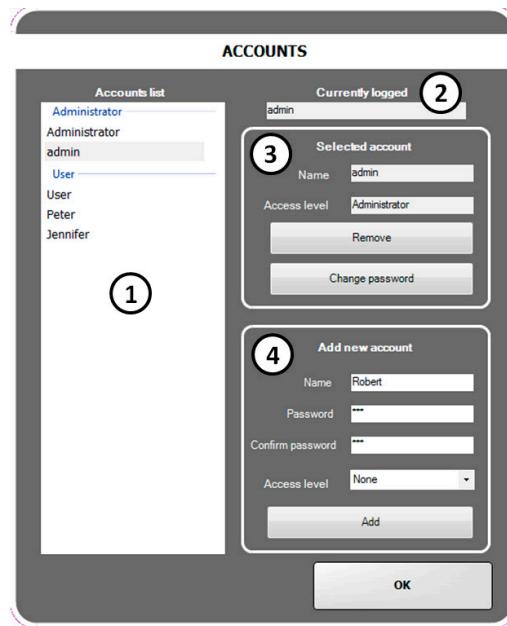


FIGURE 243

- 1. Accounts list:**  
Accounts are listed by the order of the access level.
- 2. Currently logged:**  
Account currently logged in.
- 3. Select account:**  
Delete account(s). Edit password(s).
- 4. Add new account:**  
Create new account(s).

**Note:** It is important that the administrator grants access to the instrument only to those who have been briefed in its use.

### 15.2.1 Step by step: Add new account

To add personnel to the “Accounts list”...

1. Enter “Name”
2. Enter “Password”
3. Confirm password by re-entering it into “Confirm password”
4. Select “Access level” (User, Administrator)
5. Click **Add**

FIGURE 244

The dialog box is titled "Add new account". It contains four input fields: "Name" (with value "usr1"), "Password" (redacted), "Confirm password" (redacted), and "Access level" (set to "User"). Below the fields is a large "Add" button.

### 15.2.2 Step by step: Delete account

To delete a user from the “Accounts list”...

1. Select the user in the “Accounts list”
2. Click **Remove** and confirm the change by clicking **OK**.

FIGURE 245

The dialog box is titled "Selected account". It contains two input fields: "Name" and "Access level". Below these fields are two buttons: "Remove" and "Change password".

### 15.2.3 Step by step: Change password

To change the password of a user...

1. Select the user in the “Accounts list”
2. Click **Change password**
3. Enter “New password” and “Confirm password”
4. Click **OK**

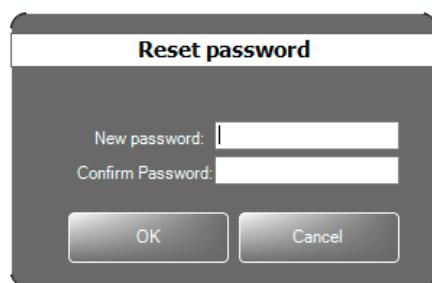


FIGURE 246

## 15.3 Settings

### 15.3.1 Overview

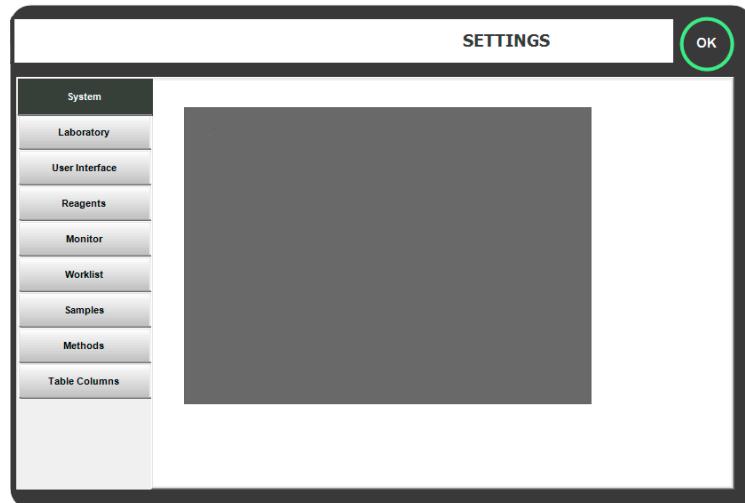
The following pages outline in detail the functions to be performed in settings. Configuration of the analyzer is one of the most important administrative tasks. A system that has been adjusted based on laboratory work requirements adds to the greater efficiency of the entire programme of work. Properly adjusted settings will also help users/ operators perform their work with greater ease and accuracy.

#### Getting there

 Click the **SETTINGS** icon to open the SETTINGS form.

Use the side panel on the left to navigate to different sections of the “SETTINGS”:

FIGURE 247



Click **OK** after completion to store the adjusted settings .

#### How to use Move, Remove and Add

Some sections (Departments, Report comments, Method groups, Method profiles) contain lists that you can edit by using the following commands:

FIGURE 248



- Click **Move-up** to skip a space and re-insert item selected above.
- Click **Move-down** to skip a space and re-insert item selected below.
- Click **Remove** to delete item selected.
- To list a new item insert the name in the text box below the list and click **Add**.

### 15.3.2 System

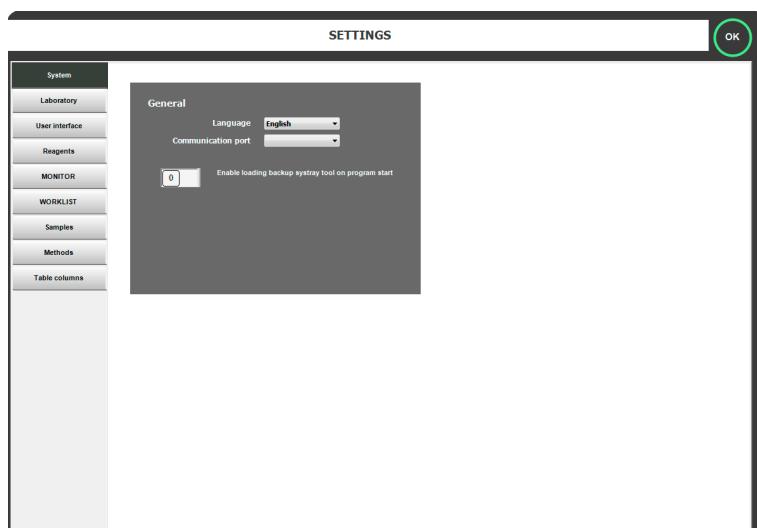


FIGURE 249

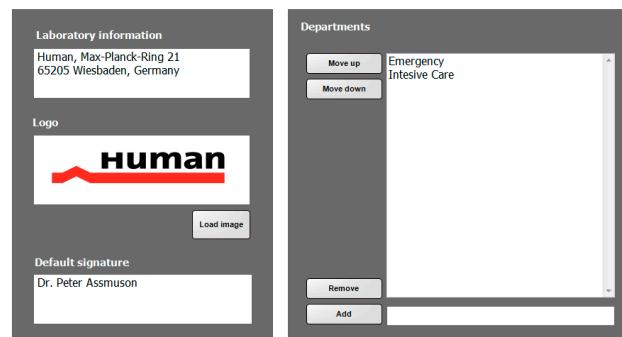
Use drop-down menus and toggles to edit values.

#### General

- **Language**  
Select the language to be used
- **Communication port**  
Change the configuration of the communication port used for linking PC and analyzer
- **Toggle**  
Automatic loading of Systray Tool on program start (see chapter 17 for details).

### 15.3.3 Laboratory

**FIGURE 250**



Write relevant info in the provided text-boxes.

#### Laboratory Information

Insert a “Laboratory Information” as desired (name, address, telephone, fax, email) to be used in printouts.

#### Logo

Insert a laboratory logo for printout reports (maximum size 300x100 pixels).

#### Default signature

Insert a default signature which appears on reports.

#### Departments

Create departments to organize specific sample groups. You can filter and order samples and worklists according to departments. This increases work efficiency to meet laboratory needs (see Worklist tab).

### 15.3.4 User interface

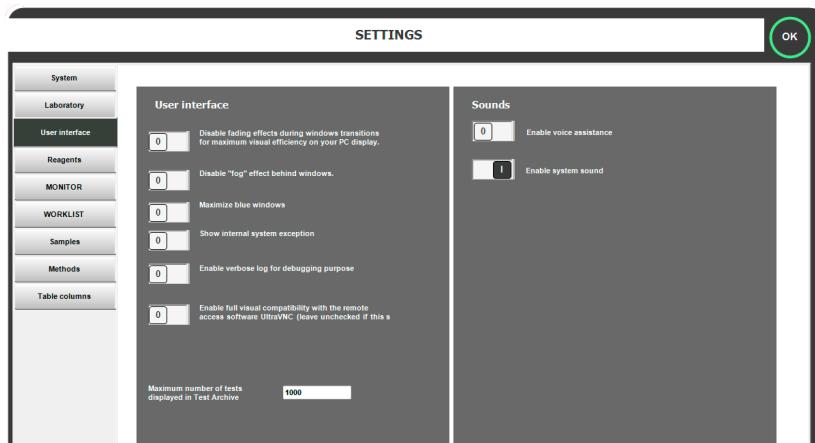


FIGURE 251

Use toggles to edit values.

#### User interface

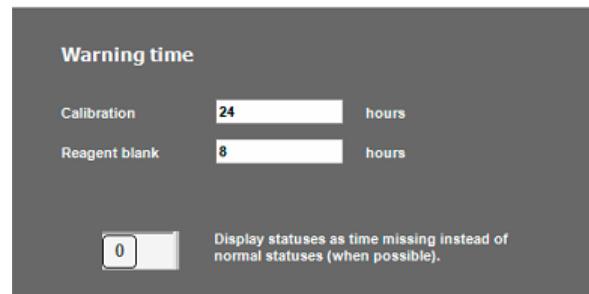
- Enable/ disable visual effects provided with the software
- Enable/ disable reporting and logging of specific errors

#### Sounds

- Enable/ disable voice assistant
- Enable/ disable system sounds

### 15.3.5 Monitor

FIGURE 252



A warning time can be set for the calibration stability and the reagent blank stability. If enabled, this feature will warn the user when any of the mentioned items is about to expire.



**Green or no colour:** Status is OK



**Yellow:** Close to expiring



**Red:** Expired

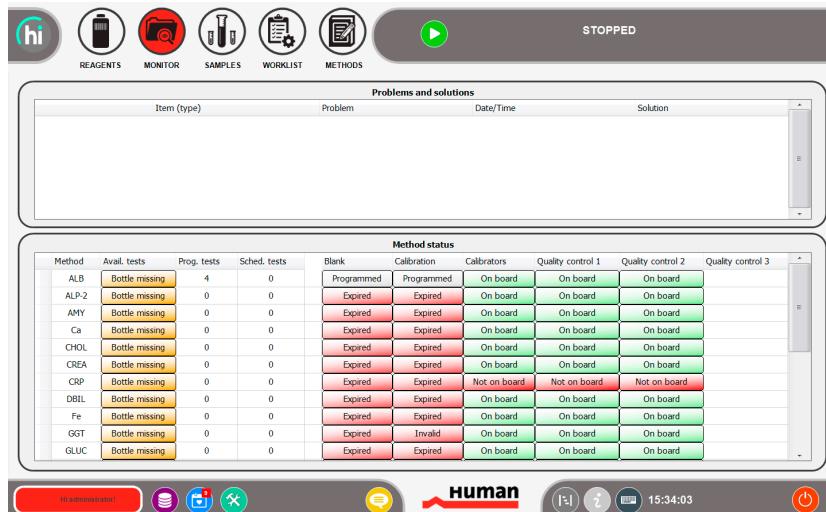


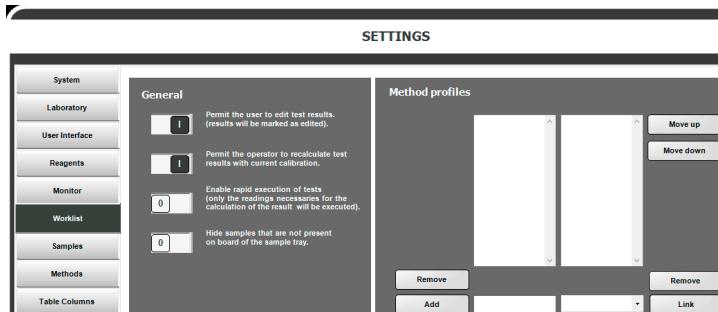
FIGURE 253

One example of how to use this function:

The warning times can be set to the length of one shift in the laboratory. In this way the user can check the status at the beginning of his shift. If any field is indicated in yellow, during his shift there will be an intervention necessary. In that case the user might decide to run e.g. a new calibration already at the beginning of the shift. In that way he is prepared for eventual emergency samples that might arrive during his shift.

### 15.3.6 Worklist

FIGURE 254



Use toggles and Move/ Remove/ Add control to manage settings

#### General

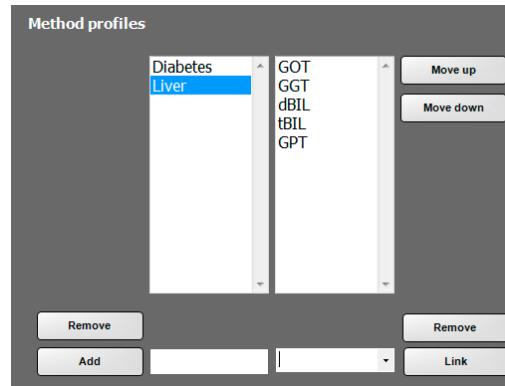
- Allow/ prohibit user access level to edit test results
- Allow/ prohibit user access level to recalculate test results
- Enable/ disable rapid execution
 

If enabled, only readings necessary for the calculation of the result will be executed. If disabled, readings will be taken during the complete reaction and the full reaction curve will be available. The instrument has a slightly lower throughput, if enabled.
- Enable/ disable hiding samples

#### Method Profiles

- Create necessary profiles to be used in the “Method profiles” panel (see chapter 7). By selecting a method profile on the WORKLIST tab, the complete list of tests in that profile is added to the worksheet. The sequence of tests is respected.

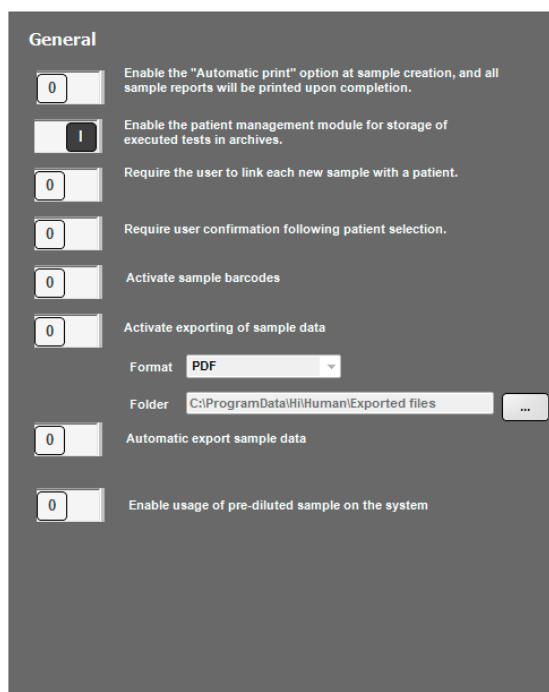
FIGURE 255



**!** Note: “Move”, “Remove” and  
“Add” functions are described  
in chapter 15.3.1.

**Step by step: Create a new profile**

1. Enter the name of the profile.
2. Click **Add**.
3. Click on the newly created profile to select it.
4. Select any test from the drop-down menu.
5. Click **Link** to link this test to the profile.
6. Repeat steps 4 and 5 to link more tests.

**15.3.7 Samples****FIGURE 256**

Use toggles to manage settings.

### General

- Enable the “Automatical print“ option at sample creation, and all sample reports will be printed upon completion.
  - By activating this option, the checkmark “Automatically print” in the SAMPLE REPORT form (see chapter 15.3.2) will be activated by default. This means that a Sample Report will be printed for each sample once all tests of this sample are finished.
- Enable the patient management module for storage of executed tests in archives.
  - If disabled, certain functions of the software are not shown: “Linked patient” (see chapter 6.3.1), “Patient management” button (see chapter 12.7), columns “Name” and “Family name” in worklists or sample lists
- Require the user to link each new sample with a patient.
  - Samples can only be added, if they are linked to a patient in the patient management module. If the patient management module should be used in the laboratory, this option helps to prevent that the user forgets to link a sample to a patient.
- Require user confirmation following patient selection.
  - Full patient information is shown after the selection of the patient. Information must be confirmed by the user before the patient is linked to the sample. This should avoid mix-up of two patients with the same name.

FIGURE 257

Patient

Alias:	Igor Volosatov
Name:	Igor
Family Name:	Volosatov
Address:	Hauptstraße 17
City:	80809 München
Date of birth:	06.02.1990
Phone1:	
Phone2:	
Email:	
Type:	

Comments  
Patient of Dr. Andres

Confirm   Barcode   Cancel

- Activate sample barcodes
  - Enable or disable the barcode scan button on the SAMPLES tab.

- Activating exporting of sample data
  - Enable to have an additional button on the SAMPLE REPORT form. The “Export” button allows sending the results in a single file (Excel, Word, PDF, JPG, CSV, etc.) into a defined folder by just clicking one button. The folder can be defined in the Settings. This function can be used to report results to a computer (e.g. doctor’s computer) on the network, even if no LIS is available.

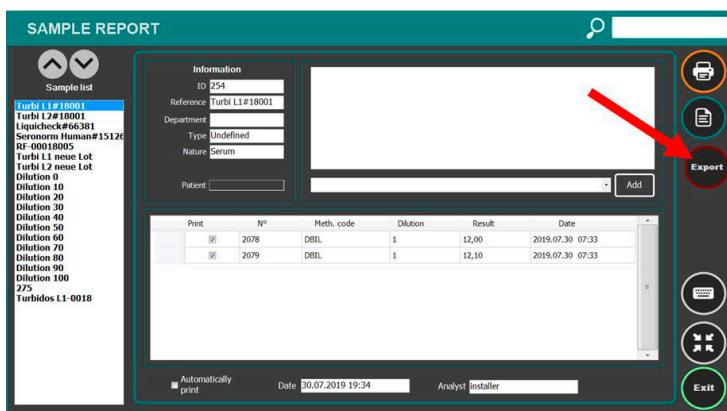


FIGURE 258

- Automatic export sample data
  - Export of SAMPLE REPORTS (as described above) is done automatically when all results for the sample are available.

#### Sample report comments

- Create listings of prearranged comments to save time when preparing sample reports (see SAMPLE REPORT)

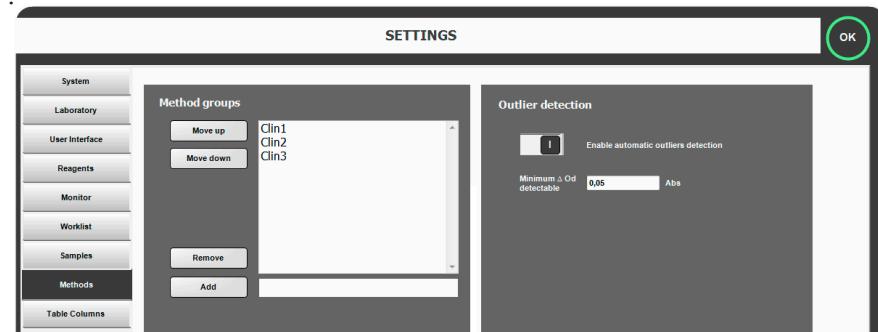


FIGURE 259

Use Move/Remove/Add control to manage settings.

### 15.3.8 Methods

FIGURE 260



Use toggles and Move/Remove/Add control to manage settings

#### Method groups

- Create method groups to provide combinations suitable for maximum testing efficiency. You can order all methods by arranging them in different groups.
- All methods must be added to a “Method group” in order to use them (see chapter 11 for details).
- Groups are listed under “Method groups” in the WORKLIST tab and under “Group” in the “Designations” panel of the method fields.

FIGURE 261  
FIGURE 262

Clin1	Clin2	Clin3	Clin4
ALB	CHOL	CREA	CREA-2
DBIL	GLUC	HDL-C	LDL-C
TBIL	TG	TP	UA
UA-2	UREA		

- HUMAN methods are by default arranged in the following groups: “Clin1”, “Clin2”, “Clin3”, “Clin4”.
- You can also move HUMAN methods to other groups, if required.

- For example you can create your own groups for frequently used methods or by grouping all methods according to their indication.
- Make sure that the number of methods in one group is limited to 24. If you assign more than 24 methods, they will not be shown on the WORKLIST tab.

### Outlier detection

See also chapters 8.2.3 and 9.3.14.

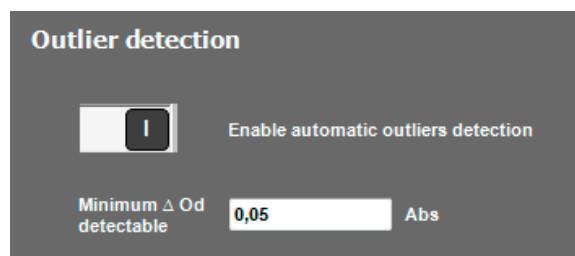


FIGURE 263

- Enable automatic outliers detection: Globally activate or deactivate the outlier detection for all methods.
- Minimum delta Od detectable: Minimum delta of the absolute absorbance between a standard and the calibration curve to be detected as outlier. Standards that are within the minimum delta range are NOT detected as outliers. This absolute threshold must be set avoid false detection of outliers. E.g. A standard is measured with 0.0015 Abs and the calibration curve is at 0.0017 Abs. The relative difference is 17%, which would detected as outlier (Max. curve deviation set to 5% in method fields). However the absolute difference is only 0.0002 Abs, which is acceptable.

### 15.3.9 Table columns

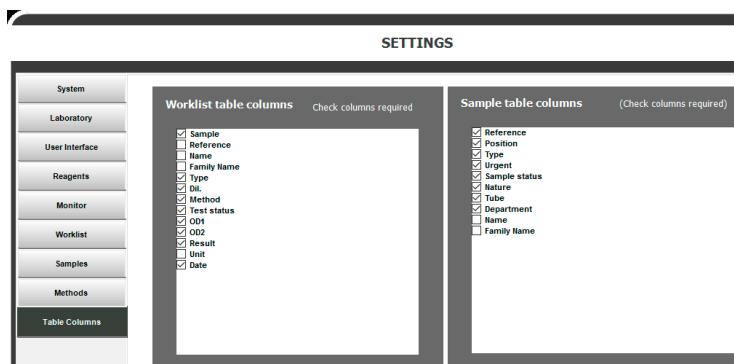


FIGURE 264

Use checkboxes to select items.

These settings allow you to choose which information is shown in the tables of the WORKLIST tab and the SAMPLE tab.

FIGURE 265



Use the settings to select the columns that are shown in the table.

#### Worklist table columns

- Check the item representing any column (Type, ID...) to insert it in each tab of worksheet panel. Leave unchecked if the column is not needed (see chapter 7 WORKLIST tab).

#### Sample table columns

- Check the item representing any column (Type, ID...) to insert it in the sample list. Leave unchecked if the column is not needed (see chapter 6 SAMPLES tab).

## 15.4 Statistics

### 15.4.1 Overview

The STATISTICS work module is a valuable tool that can determine the accuracy of the instrument by showing statistical calculations on test results. The following pages outline in detail the functions to be performed in statistics. For each sample on the instrument, you can see calculated statistics and a graphic for each parameter.

#### Getting there

 Click the STATISTICS icon to open the STATISTICS work form.

### 15.4.2 Functions

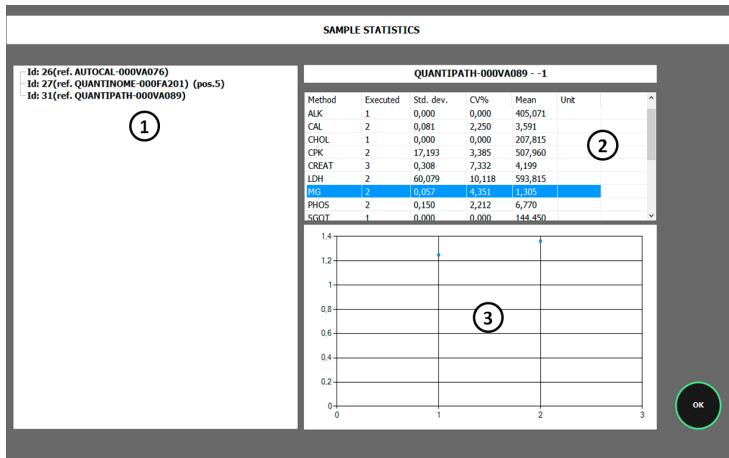


FIGURE 266

1. Select any sample that is currently on the instrument.
2. List of all tests that have been executed for the selected sample.  
For each method additional information is included (i.e. number of test executed, standard deviation, CV%, mean, units). Select any method to show the graphic.
3. Graphic chart representing the trend of test results.  
If you want to see the history of patient tests results, use the PATIENT MANAGEMENT module (see chapter 12.7).



## 16 LOG VIEWER

### 16.1 Overview

The Log Viewer is a useful tool to visualize the log events, such as error messages, warnings or tasks that have been finished.

#### Getting there

 Click to access to “Log Viewer”



### 16.2 Functions



FIGURE 267

1. You can search by Type, User or Date.
2. Log entries
3. Select any log entry and click “Show” to see the details of the selected log entry.

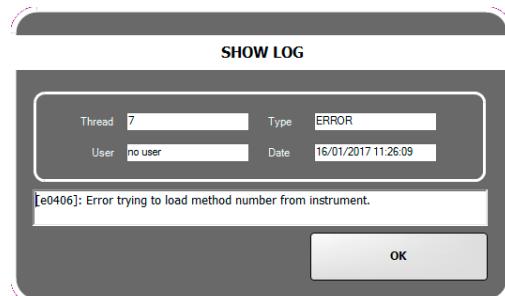


FIGURE 268



## 17 SYSTRAY TOOL

### 17.1 Overview

The Systray Tool is a useful tool to automatically create or schedule backups of the entire data folder. With this tool it is also possible to restore previously created backups.

- !** Note: All backups are automatically compressed in a zip format in order to  
● minimize the required space on the PC.

### 17.2 Getting there

In the notification area of the Windows™ task bar (systray) double-click the “Hi” icon in order to open the Systray Tool.

- !** Note: If the Systray Tool does not show in the systray, the administrator has  
● not activated it in the settings of the analyzer (see chapter 15.3).



Customized configuration possible.  
See chapter 15.3.

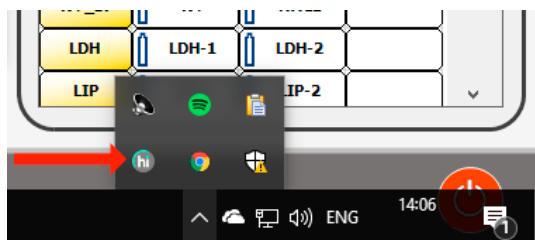
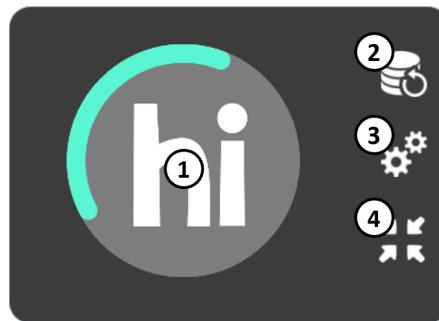


FIGURE 269

### 17.3 Functions

The Systray Tool provides four buttons.

FIGURE 270



1. Click to launch the HI software
2. Backups
3. Settings
4. Minimize the Systray Tool window

#### 17.3.1 Backups

There are four buttons in the backups section.

FIGURE 271



##### Backup

The Backup button will manually create a **full backup** (zip-file) of the complete data folder.

The full backup is intended for internal usage in the laboratory.

It is possible to restore a full backup on YOUR analyzer in case the database is corrupted or content in the database has been deleted.

For data protection purposes, it is NOT possible to restore this backup on ANOTHER analyzer.

The backup will be saved in the following directory:

*C:\ProgramData\Hi\SysTray\Backups\*

The backup file is named:

*Human YYYYMMDDHHMMSS.zip*

YYYY: Year

MM: Month

DD: Day

HH: Time (hours)

MM: Time (minutes)

SS: Time (seconds)

### Restore

You can use this function to restore a backup that was made on YOUR analyzer using the “Backup” function.

### Schedule Backup

The Schedule backup button will permit to access the backup planner.

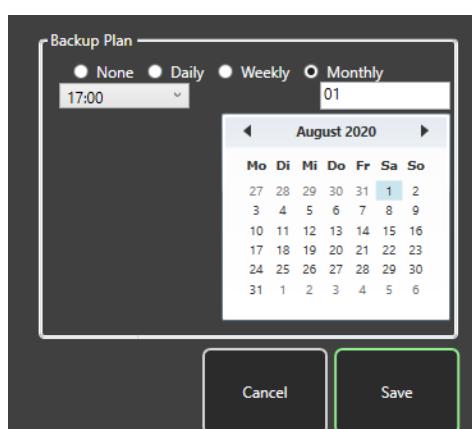


FIGURE 272

! Note: The automatic backups will be created only if the Systray Tool is running. In order to automatically start the Systray Tool when the Hi software is started. Closing the Hi software does not automatically close the Systray Tool, too. To close the Systray Tool right-click on the Hi systray icon.

It is possible to define three types of automatic backups: Daily, weekly or monthly.

- Daily backup will allow to define the time when the backup will be created.
- Weekly backup will allow to define the time and the day of the week when the backup will be created.
- Monthly backup will allow to define the time and the day of the month when the backup will be created.

### Create service backup

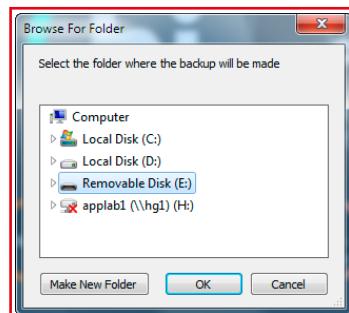
Use this function, if a “backup” is requested for trouble shooting by your service engineer or application specialist. It is highly recommended to always include a service backup when you are asking for help or claim a problem.

For privacy and data protection purposes, this backup (zip-file) does not contain any personal patient information (e.g. name, date of birth, address,...). Information that is required for trouble shooting (test results, reaction curves, test no., etc.) is contained in the database.

When you click the “Create service backup” button, the software will ask where you want to save the service backup (e.g. on a USB-stick).

**FIGURE 273**

**Note:** Whenever you report a problem to your service engineer or application specialist, it is highly recommended to include this service backup in the inquiry you are sending. This will help to investigate your problem and you will receive a solution for the issue much faster.



The backup file is named:

*Human YYYYMMDDHHMMSS.zip*

### 17.3.2 Settings

Three different settings can be made in this work window.

**FIGURE 274**



**Hi software folder**

Location of the Hi software itself.

By default it is set to *C:\Program Files (x86)\Hi\V1\_2\Hi.exe*

**Runtime data folder**

Location where all of your data is stored (database).

By default it is set to *C:\ProgramData\Hi\Human*

**Import from folder**

If you have an old data folder from software version < 1.0.1.x, you can use this function to migrate your data to the current software database structure.



## 18 TROUBLE SHOOTING

### 18.1 Software error codes

Occasionally, while operating the instrument, it is possible that a message box is displayed. If the message is an error (red colour) the message is most of the time ended with a software code.

ID	Software Code	Problem description	Solution number
1	e0001	You are not connected to an instrument! The program will be closed now.	1
2	e0002	Unable to read firmware version from instrument.	1
3	e0003	Connect the instrument before proceeding.	1
4	e0006	Problem uploading methods.	2
5	e0008	An error occurred while saving the settings.	3
6	e0017	Startup procedure has been interrupted, it is recommended to repeat the procedure.	4
7	e0018	Needle Rinse procedure has been interrupted, it is recommended to repeat the procedure.	4
8	e0019	Empty Tubes procedure has been interrupted, it is recommended to repeat the procedure.	4
9	e0020	Prime Hydraulics procedure has been interrupted, it is recommended to repeat the procedure.	4
10	e0021	Wash Cuvettes procedure has been interrupted, it is recommended to repeat the procedure.	4
11	e0022	Shut-down procedure has been interrupted, it is recommended to repeat the procedure.	4
12	e0023	Only the first XX methods have been loaded on the instrument, please check the number of methods and try again.	5
13	e0025	The maximum number of methods has been reached.	5

14	e0026	The current method already exists in the method list.	6
15	e0033	The instrument is not responding. Check cable connection. If problem persist contact assistance.	1
16	e0036	Non-volatile RAM error	22
17	e0037	Lamp out-of-work	11
18	e0038	No clean reaction tubes	8
19	e0039	Reaction high temperature error	18
20	e0040	Error on sampling needle	21
21	e0041	Error On Wash Station	21
22	e0042	Error On Needle Rotation	21
23	e0043	Error On Sample Plate	21
24	e0044	Error On Reaction Rotor	21
25	e0045	Error On Diluter Syringe	21
26	e0046	Error On Filter Wheel	21
27	e0047	Reaction low temperature error	13
28	e0048	Barcode reader not ready	22
29	e0049	Well wash disp. pump error	14
30	e0050	Well wash asp. pump error	15
31	e0051	Vacuum pump 1 error	12
32	e0052	Vacuum pump 2 error	12
33	e0053	Wash disp. 1 pump error	16
34	e0054	Wash disp. 2 pump error	16
35	e0055	Wash disp. 3 pump error	16
36	e0056	Wash disp. 4 pump error	16
37	e0057	Wash disp. 5 pump error	16
38	e0058	Wash disp. 6 pump error	16
39	e0059	Special waste tank full (yellow)	9
40	e0060	Waste tank full (red)	9
41	e0061	Water tank empty	9
42	e0062	Wash tank empty	9
43	e0063	Sample tube empty in predilutions	17
44	e0064	Diluent bottle empty in predilutions	17
45	e0065	Needle shock error	10
48	e0068	Firmware error	0
49	e0069	Reading A/D Overflow	11
50	e0070	Reading A/D time-out	22
51	e0071	Invalid autozero	11
52	e0072	Reaction rotor dirty	8
53	e0073	Wash station down error	21

55	e0075	Error in outer plate offset calibration	19
56	e0076	Low liquid level in sample tube 1	17
57	e0077	Special wash bottle missing in reagent position 1	20
58	e0078	Needle shock detector is stuck	7
100	e0253	SN Level sensor fail	
101	e0254	Power board 1 error	
102	e0255	Power board 2 error	
103	e0256	Power board 3 error	
104	e0257	Power board 4 error	
105	e0258	Error on sampling needle 2	
106	e0259	Error on needle rotation 2	
107	e0260	Error on diluter syringe 2	
108	e0261	SN needle 2 shock error	
109	e0262	SN needle 2 shock sensor fail (closed when needle up)	
110	e0263	SN needle 2 level sensor fail	
111	e0264	Well 1 wash disp. pump error	
112	e0265	Well 1 wash asp. pump error	
113	e0266	Unknown error	0

Solution number	Description	Referenced documents
0	<p>Unexpected problem copy data folder from instrument</p> <ul style="list-style-type: none"> <li>- Contact your HUMAN distributor and forward data folder.</li> </ul>	Service manual
1	<p>Possible problem with communication:</p> <ul style="list-style-type: none"> <li>- Check if power is ON</li> <li>- Check if instrument moves sample plate 3 times when turning on to verify instrument is working.</li> <li>- Verify USB cable</li> <li>- Verify USB port</li> <li>- Swap with another available USB port If not working contact technical service</li> </ul>	Service manual

	A problem with one of the method fields:
2	<ul style="list-style-type: none"> <li>- Check that firmware and software version are compatible.</li> <li>- Check method fields</li> <li>- Check connection</li> <li>- If not working contact technical service and restart software.</li> </ul>
3	Possible problem with PC: <ul style="list-style-type: none"> <li>- Restart PC</li> <li>- Re-install software</li> <li>- Change PC.</li> </ul>
4	Procedure has been interrupted <ul style="list-style-type: none"> <li>- Check if operator did not click STOP button</li> <li>- Check the presence of all resources required by procedure</li> <li>- Check cover is correctly closed</li> <li>- Check object obstructing arm movement</li> <li>- Repeat same procedure that has been interrupted</li> </ul>
5	The maximum number of methods has been reached or exceeded <ul style="list-style-type: none"> <li>- Remove one or more methods not currently in use</li> <li>- Restart the software</li> </ul>
6	<ul style="list-style-type: none"> <li>- Change method code</li> <li>- Try to add method again</li> <li>- Check that needle is not bent.</li> </ul>
7	<ul style="list-style-type: none"> <li>- Check that needle correctly moves up and down into guide</li> <li>- If not working contact technical service</li> </ul>
8	Execute shut-down procedure <ul style="list-style-type: none"> <li>- Execute "Cuvette special wash" procedure from Maintenance panel</li> <li>- Replace dirty cuvettes and execute start-up</li> </ul>

Service  
manual

- 
- |    |   |                |
|----|---|----------------|
| 9  | <ul style="list-style-type: none"><li>- Check that floats connector is correctly inserted</li><li>- Check that floats are correctly inserted into tanks</li><li>- Check tanks liquid levels (empty or re-fill if required)</li><li>- Execute correct procedure from Maintenance panel</li></ul> |                |
| 10 | <ul style="list-style-type: none"><li>- Check for presence of caps on reagent bottles</li><li>- Check for object obstructing normal arm/needle movement</li><li>- If not working see solution 7</li></ul>   | Go to 7        |
| 11 | <ul style="list-style-type: none"><li>- Run lamp auto calibration and run the instrument</li><li>- Eventually replace halogen lamp and repeat step 1</li><li>- Contact technical service</li></ul>  | Service manual |
| 12 | <ul style="list-style-type: none"><li>- Check that waste tank connector is correctly inserted and if the waste tube is not bended.</li><li>- If not working contact technical service</li></ul>   | Service manual |
| 13 | <ul style="list-style-type: none"><li>- Check if room temperature is not lower than 15°C</li><li>- If not working see solution 22</li></ul>   | Go to 22       |
| 14 | <ul style="list-style-type: none"><li>- See solution 9</li><li>- Check that the needle is not clogged</li><li>- Execute fill tubes</li></ul>  | Go to 9        |
| 15 | <ul style="list-style-type: none"><li>- Check that the wash well is drain is not clogged</li><li>- See solution 12</li></ul>  | Go to 12       |
| 16 | <ul style="list-style-type: none"><li>- Check wash station needles are not clogged</li><li>- If not working see solution 9</li><li>- Execute pump test and check pump state, replace cartridge if required</li></ul>  | Go to 9        |
| 17 | <ul style="list-style-type: none"><li>- Check that samples tubes have been correctly placed on board.</li><li>- Check if room temperature is not higher than 30°C</li></ul>   | Go to 22       |
| 18 | <ul style="list-style-type: none"><li>- If not working see solution 22</li><li>- Run lamp auto-calibration</li></ul>  | Go to 22       |
| 19 | <ul style="list-style-type: none"><li>- Replace lamp</li><li>- Run start-up procedure</li></ul>   |                |

- 
- |    |   |
|----|---|
| 20 | - Check that the reagent bottle has been correctly placed   |
|    | - Check that the minimum level in the bottle is present in the bottle                             |
| 21 | - If problem does not persist, notify technical assistance and continue with work                 |
| 22 | - Turn off and on the instrument<br>- Restart Software<br>- If problem persist contact assistance |
- 

## 18.2 Result flags, results issues and error messages

A red dot next to the “Result unusable” or “Completed” button in the worksheet indicates that this result is flagged. Click on the button to open the Test Inspection work form and get further information about the flag in the “Result issues” section. Especially the “Result unusable” error message in the worksheet can have different/multiple causes.

Type of result problems: There are two types of flags that can be issued by the system: errors and issues. Errors are severe problems that do not allow the instrument to give a result (result unusable). Issues (“Warnings”) are minor problems that have been detected during the process that should be evaluated by the laboratory operator in order to define if the result provided by the instrument is usable or should be discarded.

<b>Message</b>	<b>Calibrator lot error</b>
<b>Type</b>	Error
<b>Description</b>	This flag is issued when one or more calibrators for the method calibration have either not been defined correctly or have expired.  - Check that the calibrators have correctly been linked to the method - Check the whether the calibrator being used has expired
<b>Troubleshooting</b>	
Internal code error	CalibrationLotError
<b>Message</b>	<b>Calibration error</b>
<b>Type</b>	Error

Description	This flag is issued when the calibration used for the calculation of the result is not valid.
Troubleshooting	- Execute again the calibration of the method
Internal code error	CalibrationError
Message	<b>Calibration Od error</b>
Type	Error
Description	<p>This flag is issued in the following conditions:</p> <ul style="list-style-type: none"> <li>- When the method calibration has only one standard and the OD is equal to zero</li> <li>- When the method calibration has two standards and the ODs of both standards are equal to zero</li> <li>- When the method has no standards (factor), and the factor is equal to zero</li> </ul>
Troubleshooting	<ul style="list-style-type: none"> <li>- If the method has standards, execute the calibration of the method used checking that the calibrators have been put in the right positions of the sample tray.</li> <li>- If the method has no standards, change the method factor</li> </ul>
Internal code error	CalibrationOdError
Message	<b>Calibration standard error</b>
Type	Error
Description	<p>This flag is issued in the following conditions:</p> <ul style="list-style-type: none"> <li>- When the method calibration has only one standard and the standard concentration is equal to zero</li> <li>- When the method calibration has two standards and both standard calibrations are equal to zero.</li> <li>- If the current active calibration has a number of standard different from the one defined in the settings (caused by the editing of the calibration settings)</li> <li>- If the calibration has not been executed</li> <li>- When the method has no standards (factor), and the factor is equal to zero</li> </ul>
Troubleshooting	<ul style="list-style-type: none"> <li>- Check the concentrations of the calibration standards for the selected method</li> <li>- Execute again the calibration of the method</li> <li>- If the method has no standards, change the method factor</li> </ul>
Internal code error	CalibrationStandardError
Message	<b>Concentration error</b>
Type	Warning

Description	The concentration (result) is higher than the maximum concentration limit set in the method. The result is provided as ">xx".
Troubleshooting	<ul style="list-style-type: none"> <li>- Check if the calibration/factor is correct</li> <li>- Re-execute the test with a higher dilution rate</li> <li>- Check with your system specialist if the concentration limit has been correctly set.</li> </ul>
Internal code error	ConcentrationError
Translation string	CONC_ERR
Message	<b>Sensibility error</b>
Type	Warning
Description	The concentration (result) is lower than the minimum concentration limit set in the method.
Troubleshooting	<ul style="list-style-type: none"> <li>- Check if the calibration/factor is correct</li> <li>- Re-execute the test to see if any problem occurred during the reaction.</li> <li>- Check with your system specialist if the concentration limit has been correctly set.</li> </ul>
Internal code error	SensibilityError
Message	<b>Fit error</b>
Type	Warning
Description	The readings of a kinetic test are not enough aligned. The fit value is below 0.98
Troubleshooting	<ul style="list-style-type: none"> <li>- If the concentration in the sample is very low, the warning can be ignored</li> <li>- Else there can be several causes (electrical noise, bubbles in the hydraulics, mixing problems, etc)</li> <li>- If the problem persists, contact the technical service.</li> </ul>
Internal code error	FitError
Message	<b>Linearity error</b>
Type	Warning
Description	The linearity is the percent variation between the first half of the slope and the second half. If the linearity value is higher than the threshold defined in the method, the warning is issued. This means that the slope is decelerating because the substrate is depleted.
Troubleshooting	The sample is too concentrated. Repeat the test using at least a 1:4 dilution.
Internal code error	LinearityError

<b>Message</b>	<b>Od Max error</b>
<b>Type</b>	The OD of the test has exceeded the maximum limit set in the method.
<b>Description</b>	<ul style="list-style-type: none"> <li>- If the test is a BLANK the limit is "Blank OD Max"</li> <li>- If the test is a normal test the limit is "OD Range Max", inverted if the "Reaction slope" is negative</li> <li>- If the test is a BLANK, change the reagent bottles present on board of the specific method with fresh bottles and repeat the test.</li> </ul>
<b>Troubleshooting</b>	<ul style="list-style-type: none"> <li>- If the test is a normal test, repeat the test (possibly with a higher dilution rate)</li> <li>- Check with your system specialist if the OD limit has been correctly set.</li> </ul>
<b>Internal code error</b>	OdMAxError
<b>Message</b>	<b>Od Min error</b>
<b>Type</b>	The OD of the test is lower than the minimum limit set in the method.
<b>Description</b>	<ul style="list-style-type: none"> <li>- If the test is a BLANK the limit is "Blank OD Min"</li> <li>- If the test is a normal test the limit is "OD Range Min", inverted if the "Reaction slope" is negative</li> <li>- If the test is a BLANK, change the reagent bottles present on board of the specific method with fresh bottles and repeat the test.</li> </ul>
<b>Troubleshooting</b>	<ul style="list-style-type: none"> <li>- If the test is a normal test, repeat the test to see if any problem occurred during the reaction.</li> <li>- Check with your system specialist if the OD limit has been correctly set.</li> </ul>
<b>Internal code error</b>	OdMinError
<b>Message</b>	<b>Slope error</b>
<b>Type</b>	Error
<b>Description</b>	The OD of the reaction varied in the direction opposite to that specified in the method.
<b>Troubleshooting</b>	<ul style="list-style-type: none"> <li>- If the concentration is very low and the reaction is almost flat, you can ignore it</li> <li>- Else there is probably a problem in the reagents. Check if all the reagents have been correctly placed on board and that they have been handled correctly.</li> </ul>
<b>Internal code error</b>	SlopeError
<b>Message</b>	<b>Substrate limit error</b>
<b>Type</b>	Error

Description	The OD of the reaction of a kinetic test at the first usable reading is too different from the correspondent blank reading (too low for decreasing reactions or too high for increasing reactions). This means that the substrate is depleted and the reaction is not usable.
Troubleshooting	The sample is too concentrated. Repeat the test using at least a 1:4 dilution.
Internal code error	SubstrateLimitError
Message	<b>Sample level not coherent</b>
Type	
Description	The sample level detected is not coherent with the theoretical sample level calculated from last measurement.
Troubleshooting	<ul style="list-style-type: none"> <li>- Repeat the test</li> <li>- Check if on the surface of the sample bubbles are present</li> <li>- Check if the sample cup/tube is correctly inserted</li> <li>- Clean the sampling needle</li> </ul>
Internal code error	SampleLevelIncoherent
Message	<b>Westgard rule error</b>
Type	Issue/Error
Description	The flag is issued by the system when the QC of the method executed is currently not respecting the Westgard rules ( <a href="http://www.westgard.com">www.westgard.com</a> ).
Troubleshooting	<ul style="list-style-type: none"> <li>- Repeat QC</li> <li>- Change reagent LOTS</li> <li>- Execute a method standard calibration</li> <li>- Deactivate westgard rules for specific method</li> </ul>
Internal code error	WestGardError







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