ZellECHEM®
PRO

USER MANUAL

ZellECHEM Pro User manual version: V.01.06.25

Preface

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The manual describes the analyzer system ZELLECHEM PRO and the new software version V1.09. Please call SSQLLP if you need advice or you have any questions.

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1. Safety Precautions and Potential Hazards

1.1. General

Before you start installing and working with the analyzer, you should read the safety precautions andregulations shown in this chapter. Safety comes first!
The analyzer was designed and manufactured according to modern standards and with regard to international safety regulations. All possible risks that were known at the time of manufacturing were taken into account and either eliminated or reduced. Nevertheless, some sources of danger cannot be eliminated. Please note the following guidelines.
When operating the analyzer all national or international guidelines and regulations must be observed, as in the normal lab routine. Power supply accessories (cables/plugs) must be installed in such a way that sourcesof danger (overheating of cables, short circuit due to incorrect fuse ratings, loose cables etc.) are eliminated. The user should be aware, that if the analyzer is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. The analyzer is supplied without anti-virus software.
It is the user's facility management's responsibility to ensure that all personnel who operate or maintain the equipment are trained in its operation and safe use. It is the user's facility management's responsibility to assure safety inspections are complete. Contact your local SSQ LLPservice personnel or authorized SSQ LLP service personnel for required safety guidance.
It is the user's facility management's responsibility to ensure that all personnel who operate or maintain the equipment are trained in its operation and safe use. It is the user's facility management's responsibility to assure safety inspections are complete. Contact your local SSQ LLP service personnel or authorized SSQ LLP service personnel for required safety guidance

1.1.1. Basic assumptions for risk analysis

The following assumptions are the basis for the risk analysis. It is assumed that:

- The Samples were adequately derived, prepared, handled, and labeled before being loaded into the device.
- Reagents and calibrators were adequately stored, prepared, handled, and labeled before being loaded into the device.
- Adequate quality control procedures are observed by laboratory personnel to check the performance ofthe analyzing system by adequate use of control material.
- Laboratory personnel involved in operation and handling of the device are adequately trained.
- Laboratory personnel involved in operation and handling of the device are aware of the risks involved in handling material of human origin (biological hazards) and that correct procedures are followed to prevent infection.
- Service personnel involved in preventive and corrective maintenance of the device are adequately trained.
- Service personnel who maintain the device know the risks of biological hazards and follow the correct precautions.
- Preventive maintenance is performed in accordance with the instructions provided by the User Manual and the Service Manual.
- Original replacement parts are used in maintenance of the device.
- Original disposables are used in operation of the device.
- Reagents and methods are validated before actual samples are measured.
- Service personnel must follow the instructions to install and check the device.
- Limit checks are correctly implemented and used in the test parameter settings. (absorbance, reagent blank absorbance, control, calibrator, etc.).
- A rotor blank run is performed once every day before measurements are performed.
- Test results obtained from the instrument are carefully examined by an expert before any further measures are taken based on the analytical results.

1.1.2 Operator qualification

The analyzer should only be used by qualified and trained personnel, who have taken part in a specialoperator training course on the instrument.
For clinical tests, the instrument should be used under the management of a doctor or clinical inspector.

1.1.3 Service technician qualification

To install, maintain and repair the instrument, a service technician has to be trained on the instrument by the manufacturer or their representative. A service technician is also expected to be familiar with the normal operation of the instrument as described in the operator manual and the special operations as described in the Service manual.

1.2. Description of symbols

1.2.1 Symbols on the instrument

WARNING
Attention, consult instructions for use. This symbol appears on several parts of the analyzer and the specific meaning of each of these symbols is described below.

WARNING
Hot surface. This label is attached on or close to parts of the instrument that get hot when the instrument is switched on. Make sure to keep fingers and other body parts clear of the hot surface.

WARNING
Pinch point. Fingers and other body parts can be pinched where this label shows. Make sure tokeep fingers and other body parts clear of the pinch point.

BIOHAZARD
The contents of the container marked with this symbol are a biological hazard and are potentially infectious. This symbol is shown on waste bottles.

ATTENTION
This symbol means that at the end of life, the analyzer must be separately collected in accordanceto the European Directive 2002/96/EC.

1.2.2 Symbols in the manual

WARNING
Failure to follow information contained in warning messages could lead to serious personal injury and/or damage to the analyzer.

ATTENTION
Failure to follow information contained in the attention messages could lead to damage to theanalyzer.

Note
Notes contain additional information corresponding to the text.

1.3 Hazards

1.3.1 Electrical hazards

WARNING

To prevent the risk of electrical shock and/or damage to the instrument, operators should not open the covers of live parts (electrical) of the instrument. Only authorized personnel, e.g. service technicians, may open the instrument to perform maintenance or repairs.

Touching the live parts when the power is on may cause severe injury.

1.3.2 Mechanical hazards

WARNING

DO NOT put your fingers/hands into the pathway of any part while the analyzer is in operation.DO NOT attempt mechanical repair unless the instrument is not in operation or OFF.

1.3.3 Lamp

WARNING

During operation, the photometric lamp becomes extremely hot. DO NOT look directly into the lightpath of the lamp when it is on.

DO NOT touch the lamp when it is on!

If the lamp needs to be changed, wait until the lamp has cooled down. For details refer to 10.2 Replace and adjust the lamp in this manual.

1.3.4 Chemical hazards

The operator is responsible for taking all necessary precautions against hazards associated with the use of clinical laboratory chemicals. Specific recommendations for each reagent used with the analyzer are normally found on the manufacturer's package inserts or on product information sheets for each chemical. Wipe up any reagent spillage on the instrument immediately.

Additional precautions:

Consult the reagent manufacturer for information on the concentrations of heavy metals and other toxic constituents in each reagent.

Avoid direct body-contact with reagents and cleaning solutions. Direct body-contact may result in irritation or damage to your skin. Refer to the manufacturer's reagent kit box and package inserts, or product information sheets for specific instructions.

1.3.5 Biohazard

BIOHAZARD

Patient samples, controls, calibrators and liquid waste are potentially infectious. The handling of patient samples, control sera and liquid waste must be performed according to national and international laboratory safety regulations.

Patient samples, controls, calibrators and liquid waste should be considered potentially infectious and capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV) and other blood borne pathogens. The handling of these substances must be performed in accordance with established laboratory safety regulations in order to minimize risk to laboratory staff. This includes wearing of gloves, splash protection, etc. Contact of skin and mucous membranes must be avoided. This also applies to all components of the instrument that are exposed to these substances. If any specimen is spilled on the instrument, wipe it up immediately and clean the contaminated surface with a disinfectant.

In various countries there are regulations on the disposal of waste. Refer to local sources for additionalinformation on correct waste disposal.

1.3.6 Operational requirements

WARNING
Do not place the analyzer against a wall. There must be access available at all times to the rear access panels of the analyzer. Make sure the power switch available and there is free circulation of ventilation air.

To reduce the risk of shock due to hazardous voltage. Customer must provide a properly grounded outlet (an earth ground) for installation as described in the installation requirements section of this manual.

Never place any device emitting strong electronic magnetic fields (EMFs) near the ZELLECHEM PRO (ONLY USE INDOORS).

1.3.7 Packing, Handling and storage requirement

ATTENTION
It has been recommended to maintain an environment with temperatures between 10 °C and 40 °C. during transport and storage of the analyzer.

PACKING, STORAGE AND HANDLING:

Markings and labels are legible, durable and tamper resistant. It must be wrapped with stretch roll, bubbleroll and thermocol / sponge sheet to avoid a dent or damage to Touch screen and any utility connection. And last should be packed in corrugated box. The corrugated box must have signs “UPSIDE” “FRAGILE”.

Do not use following material for packaging:

Foil, Cellophane, PVC, Polyester, Polyamide (nylon), Impervious Polypropylene film.

Handling for ZELLECHEM PRO:

At the customer’s place product can be easily handled as device is very low weight which can be lift by hand very easily and move one place to another.

1.4 Pre-Installation

The analyzer, cooling unit and other devices, parts and accessories are shipped in transport boxes and have to be unpacked and installed by a qualified service technician from the manufacturer or his designated representative. If these instructions are not observed, the manufacturer does not assume responsibility for the occurring damage or improper operation of the analyzer. The customer is responsible for providing the necessary facilities as described in detail in 2.2.2 Installation. Only use manufacturer supplied power supply cord. If an inadequate rating power cord used, then the manufacturer does not assume responsibility for occurring damage or improper operation of the analyzer.

1.4.1. External connections

WARNING

Only instruments that meet the relevant safety requirements may be connected to the analyzer.

1.4.2. Maintenance

ATTENTION

For continued protection against risk of Electric only use fuses of the specified type and current ratings.

For maintenance and repair procedures (e.g. photometer lamp) follow the instructions given by service personnel or specified in the manual.
Do not use unsuitable tools for repairs (e.g. screwdrivers which are not insulated for work performed at electrical components).
During operation and maintenance of the instrument, proceed according to the instructions and do not touchany parts of the instrument other than those specified.
Avoid touching any mechanical parts while the instrument is operating. This may cause operation to stop or damage the instrument.
Only original spare parts should be used in the maintenance of this analyzer.
Only original disposables and accessories should be used in the operation of this analyzer.
Never leave a reagent/sample mixture in the flow cell for longer than necessary. Always clean the flow cell after a batch of measurements and keep the flow cell filled with distilled water when not in use.

1.4.3 Instrument unused for a long time

If the instrument is not to be used for a long period of time, before you switch ON the analyzer, contact SSQLLP Technical Support for further information.

1.5 Use of materials with the analyzer

1.5.1 Specimens

This analyzer is designed for measurements of analytes in samples of serum, plasma and urine. Patient samples should be prepared and handled in accordance with the instructions from the reagent manufacturer.Refer to the reagent kit insert for detailed instructions.

ATTENTION

Make sure that the sample/reagent mixture does not contain any blood clots, dust or other insoluble contaminants. If insoluble contaminants are contained in the sample, correct measuring values maynot be obtained.

1.5.2 Reagents and calibrators

The Analyzer manufacturer does not recommend the use of specific reagents or calibrators in combinations with thisanalyzer. Several reagent manufacturers have application sheets available for a large variety of clinical chemistry tests. Therefore, contact your local reagent supplier for the application sheets required.

ATTENTION

Treat all reagents according the manufacturer's recommendations. Refer to the reagent kit box and package inserts, or product information sheets for specific instructions.

Disclaimer

The manufacturer assumes no responsibility for erroneous test results caused by reagentkits, calibrators and/or test parameters that are not provided by the manufacturer.

1.5.3 1.5.3 Controls

The manufacturer recommends the use of quality control solutions with known values for each test in accordance with international regulations and guidelines. Results obtained should fall within the limits definedby the day-to-day variability of the system as determined in the user laboratory. If the results fall outside the laboratory's established limits, refer to the troubleshooting information in this manual or contact your agent.

1.5.4 1.5.4 Analytical results

The analytical results do not only depend upon correct operation of the analyzer but also on a variety of external influences beyond the control of the manufacturer. Therefore, the test results obtained with this instrument must be carefully examined by a clinical inspector or doctor, before any diagnostic or therapeuticmeasures are taken based on the analytical results.

WARNING

An incorrectly measured result may lead to an error in diagnosis, thereby posing a danger to thepatient.

2. Introduction

2.1 The system

2.1.1 Intended use

The analyzer is a semi-automatic chemistry analyzer, to be used in combination with certain reagents for in vitro diagnostic measurement of analytes in samples of serum, plasma, urine and aqueous standard solutions. The analyzer is designed as an ´open´ system. Most clinical chemistry tests that require a photometric measurement can be adapted for the system. The analyzer is intended for use in clinical chemistry laboratories where the workload is of low quantity. The analyzer must be operated by qualified and trained personnel.

Disclaimer

Depending on the specific characteristics of the involved reagent kit, the results obtained from a clinical chemistry system may vary. The test parameters for each test (and each reagent supplier), need to be developed and validated by appropriate methods [for exampleusing ECCLS[1] or NCCLS[2] or CDSCO guidelines] before the system is used for actual measurements ofpatient samples. The manufacturer is not responsible for erroneous test results caused by reagent kits, calibration and controls and incorrect test parameters.

1 ECCLS = European Committee for Clinical Laboratory Standard
2 NCCLS = National Committee for Clinical Laboratory Standards (USA)
3 CDSCO=Central Drugs Standard Control Organization.

2.1.2 System presentation

The instrument is small and compact and consists of an analyzer, a logic controller unit with an integrated screen and a printer.
The analyzer is for bench top use to save space in the laboratory. User defined tests are entered via touch screen display.
The software provides calibration and control measurements, results statistics and reports. A total of 80 tests can be programmed. Data transmission is via the serial port on the instrument.

2.2 Shipping and Installation

2.2.1 Unpacking

The box should be inspected for damage and contents. In case of any damage or missing parts, please informyour supplier. The box contains the following parts:

	Item
	The Analyzer
	Accessory kit

The accessory kit contains the following parts:

	Item
	Aspiration Tube
	Lamp
	Paper roll
	Waste Bottle and waste silicon tube
	Warranty card
	Power Plug (12 VDC adapter)
	Operational Manual / QC Report

2.2.2 Installation

1. Remove all Packing of the instrument.
2. Place the instrument on a level surface.

Note
The surface must be clean, free from obstructions, vibration and direct sunlight.

3. Make sure the analyzer has a space of 10 cm at the rear for a free flow of air.
4. Check power supply specification at customer's site.
5. Connect all cables and plugs (e.g. Power plug) when the analyzer is in place.
6. Connect the waste tubing to a waste collection facility or sink.
7. Install the printer paper (see section 10.1.1).
8. Make sure to remove all accessories before discarding the packaging.
9. Customer must provide a properly grounded outlet (an earth ground) for installation.

2.2.3 Warranty

If the analyzer has a defect or malfunction, please inform your distributor immediately. Your distributor will inform you about all guaranteed conditions.

3. Theory

3.1 General Information

Parameters are measured as spectral absorbance A (λ) relative to a zero-adjustment on water [A (λ) = 0].The zero-adjustment takes place automatically at the start of each test series. The relationship between concentration and change in spectral absorbance determines the concentration.
The following measurement methods are available.

- Absorbance
- Kinetic, with or without reagent blank, with or without linearity check, with or without sample blank.
- Monochromatic endpoint, with or without reagent blank, with or without sample blank.
- Bichromatic endpoint, with or without bichromatic reagent blank, with or without bichromatic sample blank
- Two point, with or without reagent blank, with or without sample blank.
- Non-linear calibration method (Curve fittings)

In the following sub-chapters a detailed explanation, including the equations for each method is given.

3.1.1 Absorbance

The absorbance is calculated according to Lambert-Beers law:

$$A = \varepsilon \times d \times c = -\log T = 2 - \log T\%$$

3.1.2 Principle of Kinetic tests

The kinetic method is usually used for enzyme activity tests. The reaction is monitored during the time programmed at intervals of 0.5 seconds. The measurements are checked for linearity. If the non-linearity is greater than the programmed limit, and the delta absorbance per minute (δAbs/min) is greater than 15 milli absorbance per minute (mAbs/min), the analyzer issues a warning message.
The calculation of Kinetic methods is as follows:

$$c\ (U|L) = \quad \delta Abs/min \times \left(\frac{V_{total} \times 1000}{\varepsilon \times d \times V_{sample}} \right)$$

* Note that the second part of the formula corresponds to the enzymatic factor (F). This factor can be found inthe package insert of the test.

The non-linearity is calculated as follows:

$$NonLin = \frac{\delta Abs/min_{(1)} - \delta Abs/min_{(2)}}{\delta Abs/min} \times 100\%$$

3.1.3 Principle of Endpoint tests

Reactions that reach an endpoint are measured using the endpoint function. The reaction is normallycompleted before the sample/reagent mixture is aspirated and so before measurement. An endpointmeasurement is performed in 2 seconds on the analyzer. Different calculations are available.

Standard endpoint

$$c = \frac{Abs_{sample}}{Abs_{std}} \quad c_{std}$$

To calculate the sample concentration, c , the factor F is calculated as follows:

$$F = \frac{c_{std}}{Abs_{std}}$$

The sample concentration is calculated as follows:

$$c = Abs \times F$$

Endpoint with reagent blank

$$c = \frac{Abs_{sample} - Abs_{reag.}}{Abs_{std} - Abs_{reag.}} c_{std}$$

$$F = \frac{c_{std}}{Abs_{std} - Abs_{reag.}}$$

$$c_{sample} = \left(Abs_{sample} - Abs_{reag.}\right) \times F$$

Endpoint with reagent blank and sample blank

$$c = \frac{\left(Abs_{sample} - Abs_{reag.}\right) - \left(Abs_{sample} - Abs_{reag.blk}\right)}{\left(Abs_{std} - Abs_{reag.}\right) - \left(Abs_{std.blk} - Abs_{reag.blk}\right)} c_{std}$$

$$F = \frac{c_{std}}{\left(Abs_{std} - Abs_{reag.}\right) - \left(Abs_{std.blk} - Abs_{reag.blk}\right)}$$

$$c_{sample} = \left(\left(Abs_{sample} - Abs_{reag.}\right) - \left(Abs_{sample.blk} - Abs_{reag.blk}\right)\right) \times F$$

Abbreviation	Explanation
reag	The reagent blank with an active reagent.
reag.blk	The reagent blank with an inactive reagent.
sample.blk	The sample blank for a sample.
std.blk	The sample blank for the standard.

Bichromatic endpoint

$$c = \frac{\left(Abs_{sample\lambda1} - Abs_{sample\lambda2}\right)}{\left(Abs_{std\lambda1} - Abs_{std\lambda2}\right)} c_{std}$$

The factor calculation and the formula for bichromatic endpoints with reagent blank or sample blank areidentical to the standard endpoint method.

3.1.4 Principle of two point tests

$$c = \frac{\left(Abs_{sample,t1} - Abs_{sample,t0}\right)}{\left(Abs_{std\ ,t1} - Abs_{std,t0}\right)} c_{std}$$

The factor calculation and the formula for two point test with reagent blank or sample blank are identical

to the standard endpoint method.

3.1.5 Curve fitting algorithms

The curve of best fit for non-linear tests creates the best fit from a series of calibrator measurements. This paragraph describes the theoretical background for the available methods. The procedure to obtain the measurements is given in section 6.2.2 The Standards values.

4-point Logit-Log curve

The 4-point Logit-Log (4PLL) curve matches the following equation:

$$A = A_0 + \frac{K}{1 + e^{-a-b \ln C}}$$

A is the absorbance (typically dAbs/min), *C* is the concentration. The factors A_0, *K*, *a* and *b* are determined with a Non-Linear Least Squares (NLLS) curve fit method.

NLLS curve fitting

Non-Linear Least Squares (NLLS) curve fitting is performed using the Levenberg-Marquardt method. Beforethis method is applied, the following checks are performed:

1 All concentrations must be monotonically increasing
2 All absorbance values must be either monotonically increasing or monotonically decreasing

The Levenberg-Marquardt method is an iterative approach that modifies the factors for a curve until one of the following criteria is met:

1 Chi-square is below 1 x 10^{-6}
2 Chi-square changes less than 0.0001 in three successive iterations (in this case the NLLS curve fitting isin a valley and only slowly iterates toward a better result)

The approach fails if more than 100 iterations are performed without meeting either of the above criteria.

Calculation of concentration from absorbance

The following steps are performed to determine a concentration from a measured absorbance:
A_{cal0}, A_{cal1}, ..., A_{caln} are absorbances of calibrators 0, 1, ..., n.
C_{cal0}, C_{cal1}, ..., C_{caln} are concentrations of calibrators 0, 1, ..., n.
$A_{measured}$ is the measured absorbance.
C_{calc} is the calculated concentration.

1 Check the validity of measured absorbance ($A_{measured}$):
   - for increasing curves:
     if $A_{measured}$ < 0.99 x A_{cal0} then set RL flagif
     $A_{measured}$ > 1.01 x A_{caln} then set RH flag
   - for decreasing curves:
     if $A_{measured}$ < 0.99 x A_{cal0} then set RH flagif
     $A_{measured}$ > 1.01 x A_{caln} then set RL flag
2 If either the RL or RH flag is set, the calculation of the concentration is aborted.
3 For 4PLL the concentration is calculated using:

$$C_{calc} = e^{\left(\frac{-In\left(-1-\frac{K}{A_0-A_{measured}}\right)a}{b}\right)}$$

4 If the calculation did not yield a result, the absorbance is checked against the absorbances of the curve:

Note
The absorbance of the second calibrator is used. This check is performed because the curve fit is

sometimes non-continuous and starts above the first calibrator (for increasing curves). For Logit- Log curves this typically occurs when $A_0 > A_{cal0}$. In this case the result is clipped to the value of the first calibrator (typically 0).

- for increasing curves:
  if $A_{measured} < A_{cal1}$ then $C_{calc} = C_{cal0}$
  if $A_{measured} > A_{cal1}$ then set RH flag
- for decreasing curves:
  if $A_{measured} < A_{cal1}$ then set RH flag if
  $A_{measured} > A_{cal1}$ then $C_{calc} = C_{caln}$

5 The calculated concentration is checked for feasibility: If
$C_{calc} < -99999$ then set RL flag
If $C_{calc} > 999999$ then set RH flag

Cubic spline calculation

The cubic spline fitting algorithm determines if a logarithmic axis yields a better fit. It maps the absorbanceand concentration values to an *x* and *y* axis using logarithmic relations.

The value on the *x* axis is derived from the absorbance using any of the following possible relations:

1 $x = A$
2 $x = \ln(-A - g_x)$
3 $x = \ln(A - g_x)$

The concentration is derived from the value on the *y* axis, using any of the following possible relations:

1 $C = f \bullet y$
2 $C = f\,(-e^y - g_y)$
3 $C = f\,(e^y + g_y)$

The factors f, g_x and g_y are determined by the curve fitting algorithm. The relation between *x* and *y* is given by the following formula:

$y_k\,(x) = a_k x^3 + b_k x^2 + c_k x + d_k$

In this formula, the factors a_k, b_k, c_k and d_k are determined using the cubic spline fitting algorithm. Which factors must be used depends on the measured values. The following must hold:

$x_k < x_{measured} < x_{k+l}$

The value for x is then determined by:

$x = x_{measured} - x_k$

Linear

Multipoint linear calibration is carried out by solve for slope and intercept by using the method of linear regression and least squares. Calculations to solve for slope and intercept are automatically performed by theinstrument. The mathematical theory exceeds the scope of this manual, but can be found in every standard mathematical textbook.

$C_m = Intercept + Slope * A_m$

C_m is the calculated concentration, A_m is the measured absorbance, *Intercept* and *Slope* are calculated by the analyzer.

4. System description

4.1 Parts of the system

4.1.1 The cover

The cover protects the measurement unit.

ATTENTION
Do not remove the cover when the analyzer is on.
If you touch parts while the instrument is on you can cause personal injury and cause damage tothe analyzer.

4.1.2 The sipper unit

The sipper unit is located at the front of the analyzer. The sipper unit encloses the sipper tube used for aspirating samples, reagents and cleaning solutions. The sipper button starts the aspiration process.

To aspirate a fluid do as follows:

1. Place the bottle with the liquid under the sipper tube.
2. Make sure the tube is deep enough in the liquid to aspirate the necessary fluid. A minimum of 450 µl of liquid is necessary to ensure proper measurement or cleaning.
3. Push the sipper button to start the aspiration.

4.1.3 The measurement unit

The measurement unit that measures the sample mixture is under the Main cover. It consists of an optical system, photometer lamp, and light filters.

4.1.4 The pump

The pump is located at the back. It transports fluids from the sipper unit to the measurement unit and to the waste tube.

4.1.5 The printer

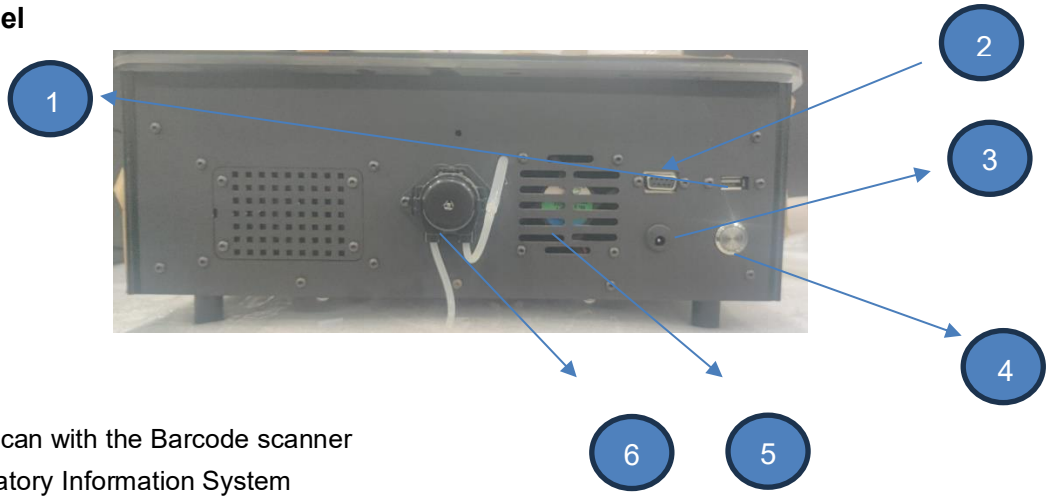
The inbuilt printer is provided in Main unit. It uses a thermal paper roll.

4.1.6 The screen

The color touch screen displays the software commands and results.

4.2 Technical Information

4.2.1 Rear panel



1 USB – To scan with the Barcode scanner
2 LIS - Laboratory Information System
3 Power Supply- Connect power supply to run analyzer.
4 Power Button- To on and off the Analyzer.
5 Fan - This will keep the air circulation inside the analyzer.
6 Peristaltic pump- Suction and discharge of the Reagent

4.2.2 Technical data

Dimensions and weight	
Width x Depth x Height	40 x 33 x 15 cm
Weight	4.0 kg
Power requirements	
Operating Supply voltage	12 VDC tolerance ± 5%
Input Voltage range	100 ~ 240 VAC
Supply frequency	50Hz ± 3 Hz
Power consumption	Max. 80 watt
Installation category II	In accordance to IEC 664
Mains cable	Suitable for non-polarized 220 V outlets.
Environmental conditions	
Ambient temperature	15 °C - 35 °C
Maximum relative humidity	80% at temperature up to 30 °C, decreasing linear to 65% at 35 °C.
Altitude	max. 2000 m
Pollution degree	2 (in accordance with IEC 664)
Approvals	CDSCO, USFDA registered
Sound level	(Min) 41 dB – (Max) 44 dB

5. Start the system for the first time

5.1 Start the analyzer

5.1.1 Pre-start checks

Do the following checks before you start the analyzer.

WARNING

Read the safety warnings and cautions and potential hazards listed in chapter 1, before youoperate the analyzer. Follow all local safety regulations.

1. Make sure that the power cable is connected to the power supply and to the analyzer.
2. Make sure that the waste tube from the analyzer leads to a suitable waste container.a
   Empty the waste container if necessary.
   b Do not contaminate yourself, the analyzer or the environment with bio-hazardous material.
   c Make sure the waste container is no more than half a meter above or one meter below the level of theanalyzer.
3. Printer is provided inbuilt with the analyzer. Make sure the printer paper is enough for the printing of results.
   a Lift the cover of printer.
   b Check the paper. Replace if necessary.
   C Keep some paper out and close the cover.
4. Prepare the following solutions to clean the flow cell:

   Touch and Hold the Wash Button to clean the Flow Cell.
   - detergent solution (distilled water containing 5% non-foaming detergent)
   - 98% Methanol solution
   - distilled water
5. Prepare the calibrators and controls required according to the manufacturer ‘s instructions.
6. Prepare the reagents and samples required according to the manufacturer’s instructions and to the regulations of the laboratory.

ATTENTION

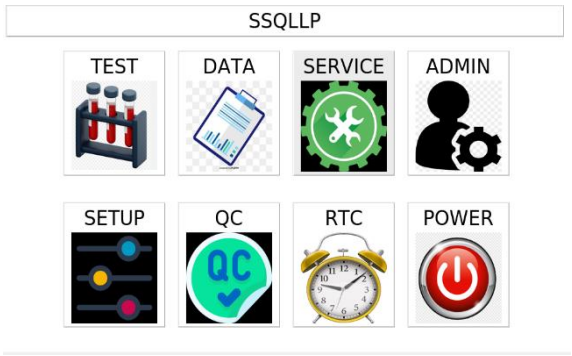
Samples and reagents must not contain fibrin, dust, or any other insoluble contaminants. Insoluble contaminants lead to incorrect measurements and may endanger the patient.

5.1.2 Set the analyzer on

ATTENTION
It is advised to let the analyzer warm up for half an hour after you set the analyzer to on. The analyzer must be at operating temperature to give correct measurements.
You can use this warm-up time to clean the flow cell.

1. Make sure all pre-start checks are complete.
2. Set the analyzer to ON. The power Switch is on the back panel of the analyzer.

3. Wait for the analyzer to initialize, do a system reset and a maintenance check. The Below screen showswith the all functions.



5.1.3 Flow cell Cleaning

Note
Allow 12 minutes for the analyzer to flush the flow cell. 10 Minutes for the detergent flush and 2 minutes for the distilled water flush.

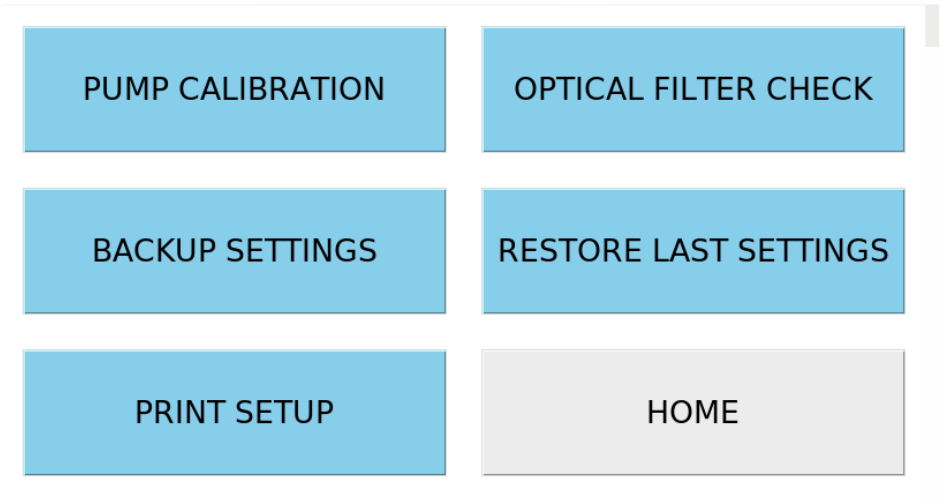
- Fill a bottle with 5% detergent solution.
- Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 45 ml of liquid is necessary to make sure proper cleaning.
- Place the bottle with the liquid under the sipper tube.
- Go to test screen and select the any one test.
- Fill a bottle with distilled water.
- Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 10 ml of liquid is necessary to make sure proper cleaning.
- Place the bottle with the liquid under the sipper tube.
- Keep the bottle against the sipper press wash button up to 60 sec else 10 ml once complete press wash button again to make turn off washing process.

5.2 Start the system service menu

Note
This chapter describes the actions necessary to start the analyzer for the first time. Pre- programmed tests are present on the system depending on the distributor. If you need to program tests refer to chapter 6.

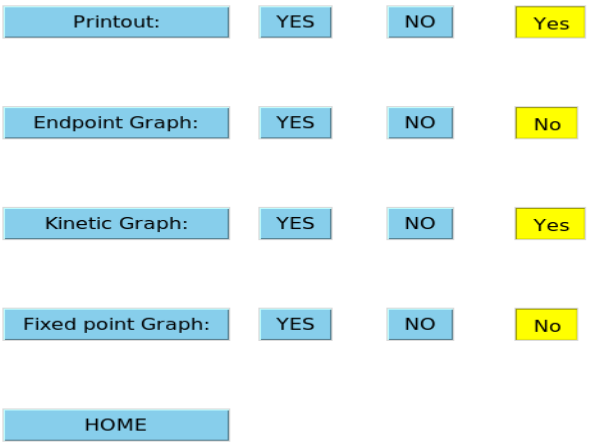
When you start the analyzer for the first time, it is necessary to program the system parameters to make sure the analyzer works correctly. Do as follows.

1. Select Service from home screen.
2. You will see a screen like below.
3. You can check pump calibration, print setup and optical filter from here.

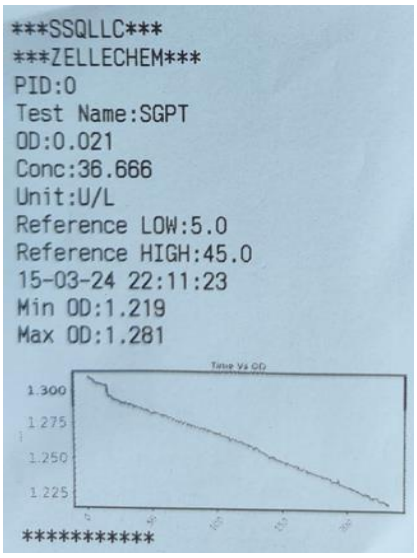


5.2.1 Set the General parameters/Printer setup

1. Touch Print setup and you can see below screen.
2. If you want to print in the printer, select yes beside the printout button.
3. If you want to print a graph of any method from kinetic, Fixed point, End point in the printer, Select yes button.



- **Routine Printout Format:**



Here in print out format

"SSQLLC" will represent end user institution or laboratory as per entered at powerscreen

"ZELLECHEM" will represent analyzer model name

"Patient ID" will represent PID which was enter respectively

"Test Name" will represent which test was you run

"OD" will represent optical Density

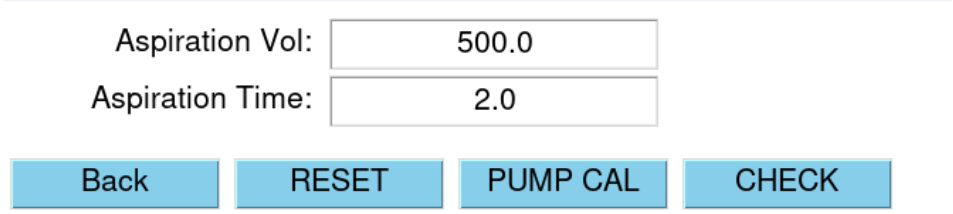
"UNIT" Which shows that the Result is in units.

"Min OD" will represent Minimum optical Density

"Max OD" will represent maximum optical Density

5.2.2 Pump calibration

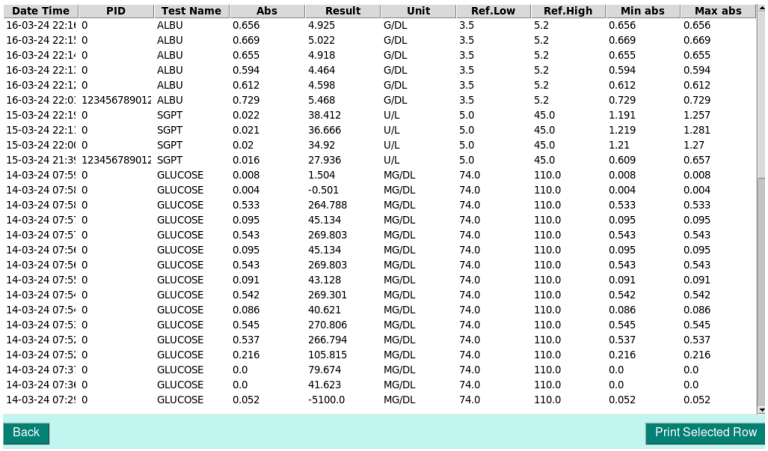
1. Go to the pump calibration and the screen below will appear.



2. Enter aspiration volume and prepare the same volume of water to aspirate.
3. Now press the pump calibration button until the aspiration volume finishes.
4. Aspiration time automatically SAVE .
5. If you want to check again, press the reset button and follow same method.

5.3 DATA

- After press the Data button it will show below screen.



Date Time	PID	Test Name	Abs	Result	Unit	Ref.Low	Ref.High	Min abs	Max abs
16-03-24 22:1	0	ALBU	0.656	4.925	G/DL	3.5	5.2	0.656	0.656
16-03-24 22:1	0	ALBU	0.669	5.022	G/DL	3.5	5.2	0.669	0.669
16-03-24 22:1	0	ALBU	0.655	4.918	G/DL	3.5	5.2	0.655	0.655
16-03-24 22:1	0	ALBU	0.594	4.464	G/DL	3.5	5.2	0.594	0.594
16-03-24 22:1	0	ALBU	0.612	4.598	G/DL	3.5	5.2	0.612	0.612
16-03-24 22:0	123456789012	ALBU	0.729	5.468	G/DL	3.5	5.2	0.729	0.729
15-03-24 22:1	0	SGPT	0.022	38.412	U/L	5.0	45.0	1.191	1.257
15-03-24 22:1	0	SGPT	0.021	36.666	U/L	5.0	45.0	1.219	1.281
15-03-24 22:0	0	SGPT	0.02	34.92	U/L	5.0	45.0	1.21	1.27
15-03-24 21:3	123456789012	SGPT	0.016	27.936	U/L	5.0	45.0	0.609	0.657
14-03-24 07:5	0	GLUCOSE	0.008	1.504	MG/DL	74.0	110.0	0.008	0.008
14-03-24 07:5	0	GLUCOSE	0.004	-0.501	MG/DL	74.0	110.0	0.004	0.004
14-03-24 07:5	0	GLUCOSE	0.533	264.788	MG/DL	74.0	110.0	0.533	0.533
14-03-24 07:5	0	GLUCOSE	0.095	45.134	MG/DL	74.0	110.0	0.095	0.095
14-03-24 07:5	0	GLUCOSE	0.543	269.803	MG/DL	74.0	110.0	0.543	0.543
14-03-24 07:5	0	GLUCOSE	0.095	45.134	MG/DL	74.0	110.0	0.095	0.095
14-03-24 07:5	0	GLUCOSE	0.543	269.803	MG/DL	74.0	110.0	0.543	0.543
14-03-24 07:5	0	GLUCOSE	0.091	43.128	MG/DL	74.0	110.0	0.091	0.091
14-03-24 07:5	0	GLUCOSE	0.542	269.301	MG/DL	74.0	110.0	0.542	0.542
14-03-24 07:5	0	GLUCOSE	0.086	40.621	MG/DL	74.0	110.0	0.086	0.086
14-03-24 07:5	0	GLUCOSE	0.545	270.806	MG/DL	74.0	110.0	0.545	0.545
14-03-24 07:5	0	GLUCOSE	0.537	266.794	MG/DL	74.0	110.0	0.537	0.537
14-03-24 07:5	0	GLUCOSE	0.216	105.815	MG/DL	74.0	110.0	0.216	0.216
14-03-24 07:3	0	GLUCOSE	0.0	79.674	MG/DL	74.0	110.0	0.0	0.0
14-03-24 07:3	0	GLUCOSE	0.0	41.623	MG/DL	74.0	110.0	0.0	0.0
14-03-24 07:2	0	GLUCOSE	0.052	-5100.0	MG/DL	74.0	110.0	0.052	0.052

Back | Print Selected Row

- In this screen, the customer can show the Result of the old Test.
- Total of 9999 Results can be stored in the analyzer.
- If you want a print of an old report, you can take print of the old report by touching that report and press the

Print Selected Row Button.

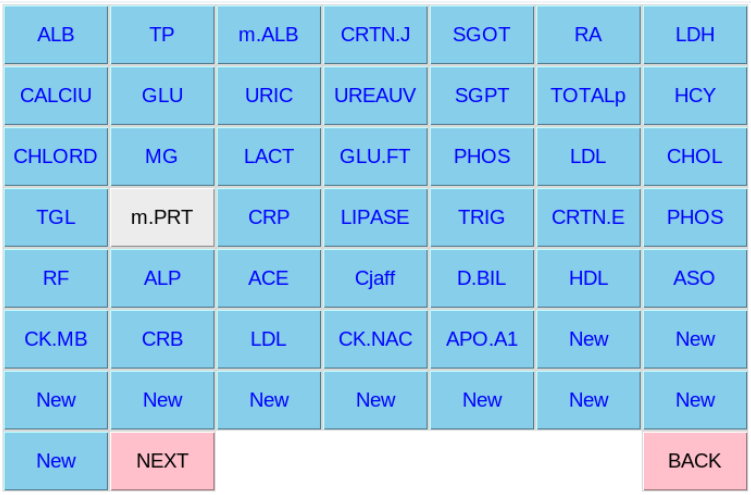
5.4 RTC

- For the change date and time, press the RTC Button.
- Then Keypad will open in which you have to enter date and Time as per show in Below Format.
  - **MM/DD/YYYYHR:MIN:SEC**
- For example , 1st February 2025 , 5:30 PM can be mentioned as 02/01/202517:30:00
- After you enter date and time you have to restart the machine.

6. Program Test Setup and calibrators

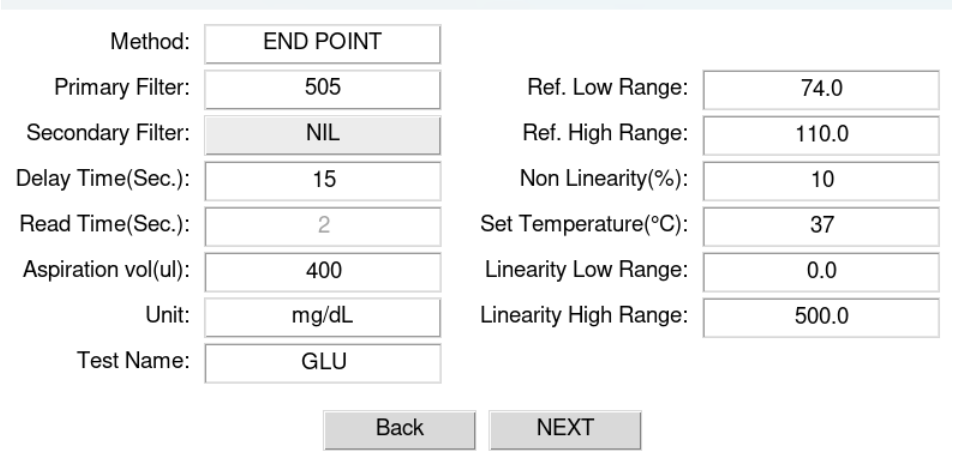
6.1 Program Setup

By tapping on “SETUP” on the home page will open this screen. Here, there Is list of program tests can be set. Go to reagent set up below screen will appear.

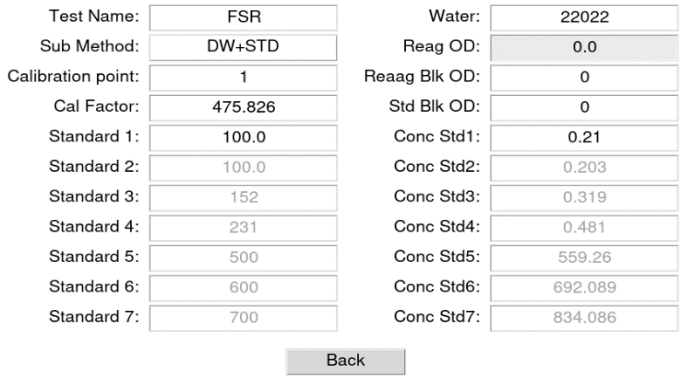


1 Each program name can be set separately with alphanumeric digit.

2 By tapping on any program name will open the below screen



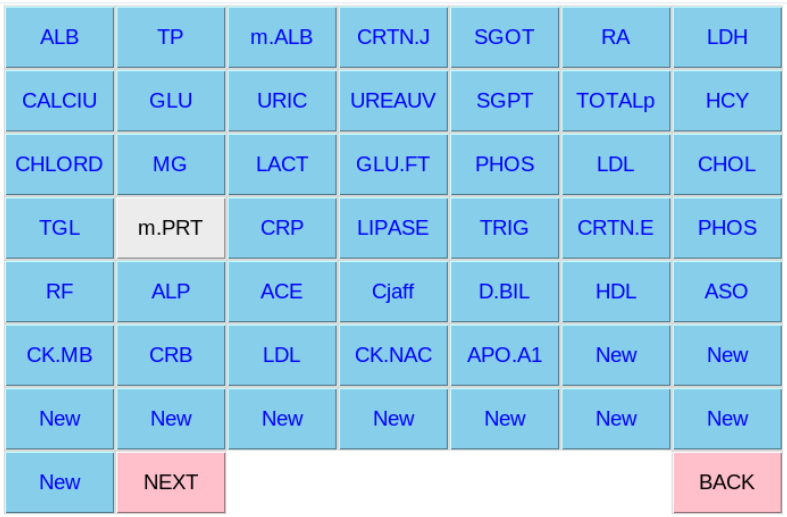
3 Enter all details as per reagent criteria suggested by reagent supplier and press Next button.



4. Enter all details as per Reagent criteria suggested by reagent supplier.

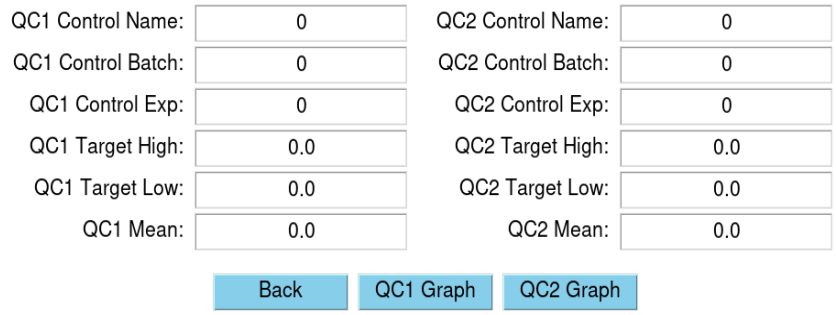
6.2 Q.C setting

Each program has individual calibration setting and Touch QC button below screen will pop up.



Touch any one test, Bellow screen will appear.

Enter all details as per reagent or control or standard criteria suggested by reagent or control or standard supplier.



Enter all details as per reagent or control or standard criteria suggested by reagent or control or standard supplier.

7. Performing tests

7.1 Introduction

7.1.1 Solutions

Water
Is distilled water used to measure initial absorbance.

Sample blanks
The sample blank is made up from distilled water and the patient sample. The sample blank is used to measure the background color of the sample. Follow the reagent manufacturer's instructions as indicated inthe package inserts for the reagents.

Reagent blanks
The reagent blank is made by adding the reagent to distilled water. The reagent blank is used to measure the background color of the reagent without the patient's sample.

Reagent
The reagent is used to measure thebackground color of the reagent without the patient's sample.

Standards/calibrator
The calibrator is made by adding the reagent to the calibrator sample. The calibrator is used to calibrate the analyzer for a certain test. Follow the reagent manufacturer's instructions as indicated in the package insertsfor the reagents.

Control
The control is made up from reagent and the control sample. The control is used to make sure the analyzer isin operating limits. Follow the reagent manufacturer's instructions as indicated in the package inserts for the reagents.

7.2 Test selection

The method of each test differs depending on the test selected. The measurements that follow can be programmed for all tests, but are not always necessary. This chapter describes all measurements that are available. A sample blank, a reagent blank, calibrators and controls are not always required, however the water blank measurement always must be done. Refer to the different tests in this chapter for the procedurefor each measurement.
The following measurements can be required:

- Sample blank
- Reagent blank
- Calibrator
- Control

Note:

The water blank is always necessary and must not be missed.

7.2.1 Preconditions

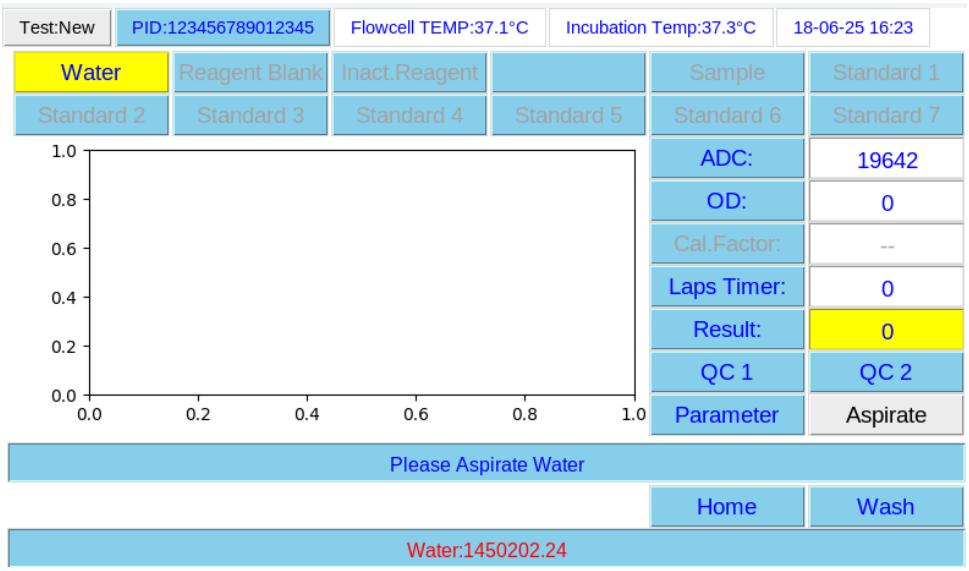
The following conditions must be made before you start any test.

- All Tests, controls and calibrators must be programmed.
- The flow cell must be clean
- All samples, reagents and blanks must be prepared

7.2.2 Start the test and do water blank

Water blank

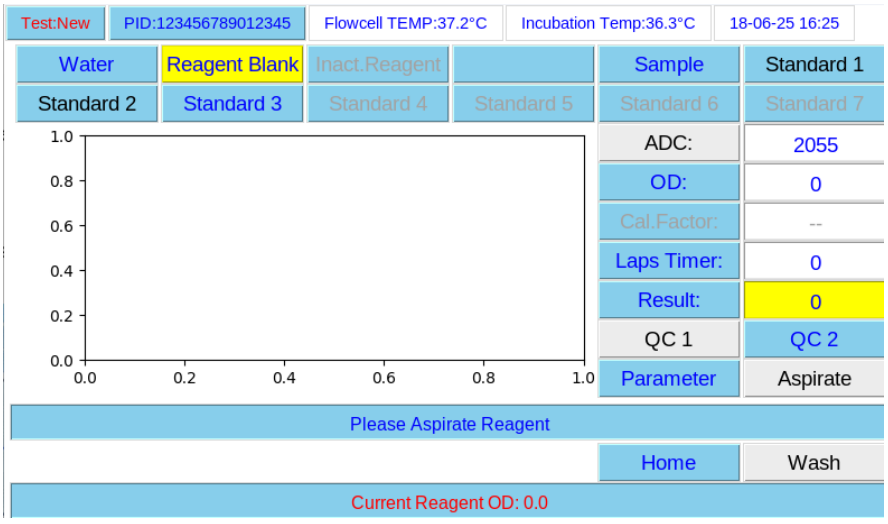
Every test requires a water blank measurement. The following screen shows.



1. Press “Water” button.
2. Fill a bottle with distilled water.
3. Place the bottle with the liquid under the sipper tube.
4. Press the bottle against the sipper button to start aspiration.
5. Data will process and result show just beside the result button.
   Analyzer will make the transport volume to make a break between solutions.

7.2.3 Reagent blank

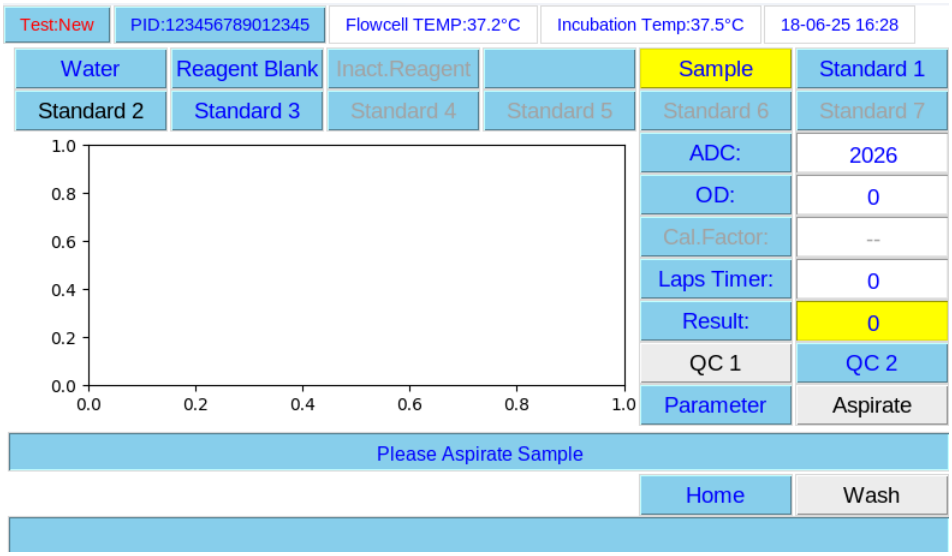
If a Reagent blank is necessary the following screen shows. Do as follows.



1. Press “Reagent blk” button.
2. Place the bottle with the Reagent blank under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
4. Data will process and result store just below Reagent blk button.

7.2.4 Reagent

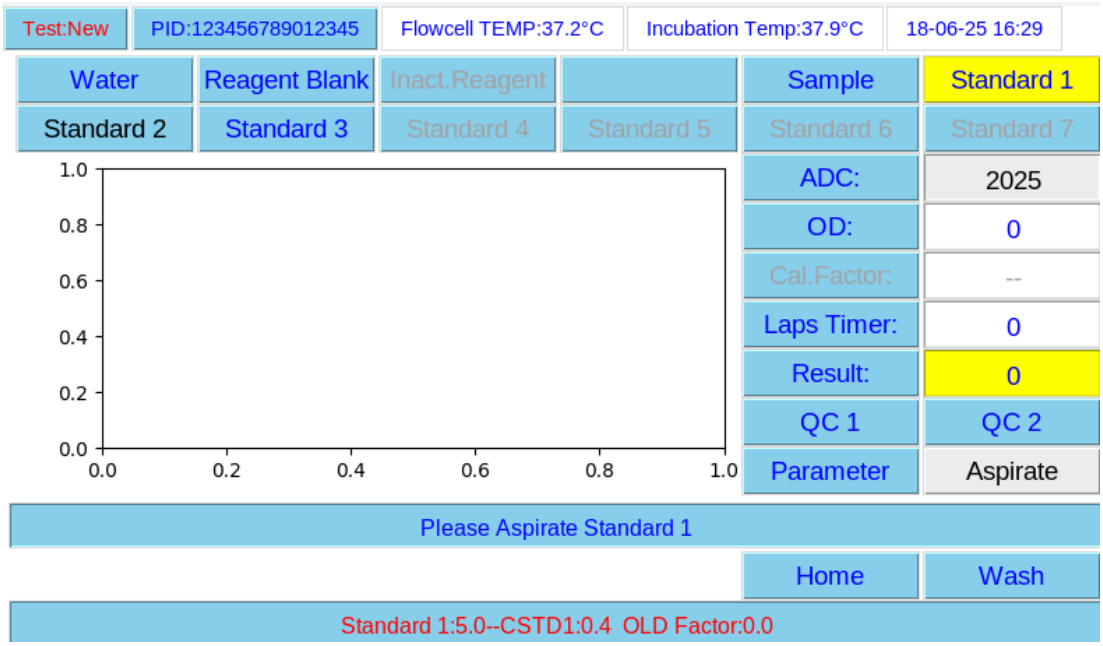
If a Reagent is necessary the following screen shows. Do as follows.



1. Press “Standard” button.
2. Place the bottle with the Reagent under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
4. Data will process and result store just below Reagent button.

7.2.5 Sample Blank

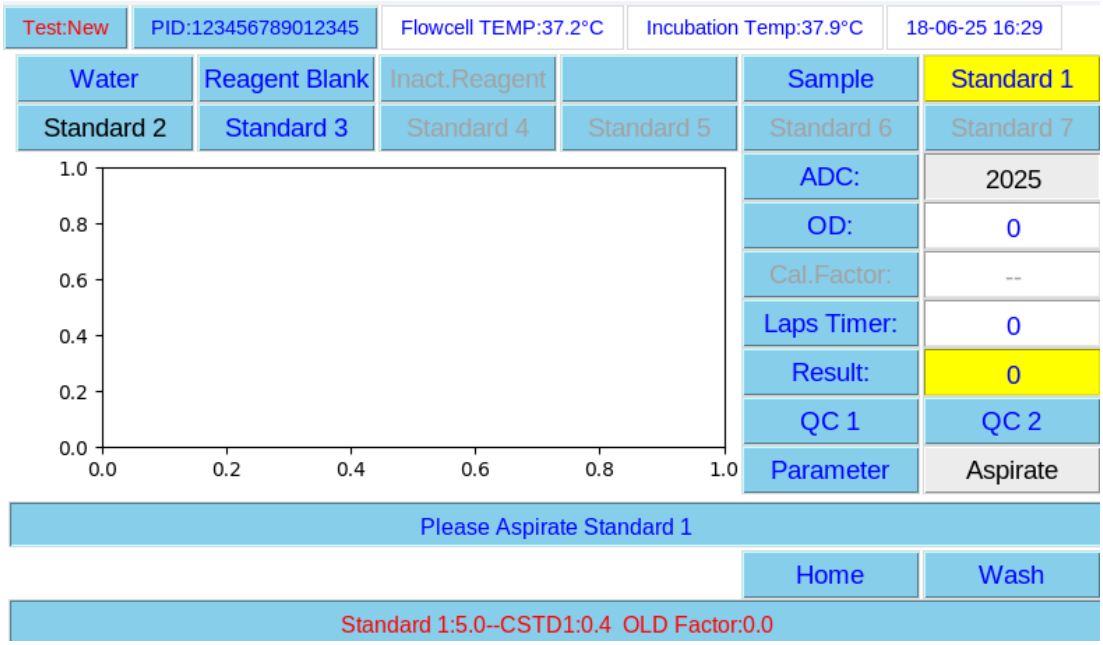
If a standard blk is necessary the following screen shows. Do as follows.



1. Press “Standard” button.
2. Place the bottle with the standard blank under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
4. Data will process and result show just besides Result.

7.2.6 Standard

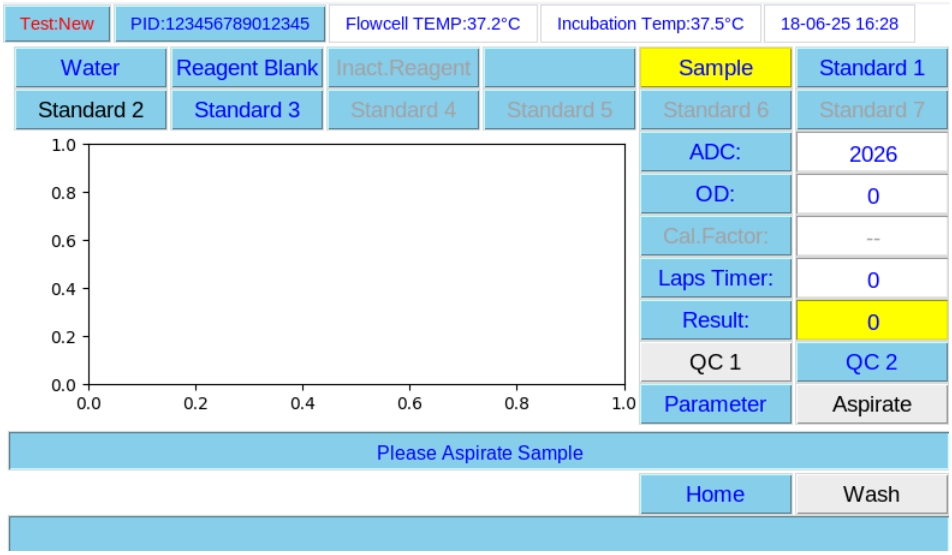
If a standard is necessary the following screen shows. Do as follows.



1. Press “Standard” button.
2. Place the bottle with the standard under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
4. Data will process and result store just below standard button.
   The same system must be followed if more than one standards are set in setup depend on reagent manufacturer.

7.2.7 Sample

If a Sample is necessary, the following screen shows. Do as follows.



1. Press “Sample” button.
2. Place the bottle with the sample under the sipper tube.
3. Press the bottle against the sipper button to start aspiration.
4. Data will process and result store just beside result.

8. Quality control

8.1 QC information

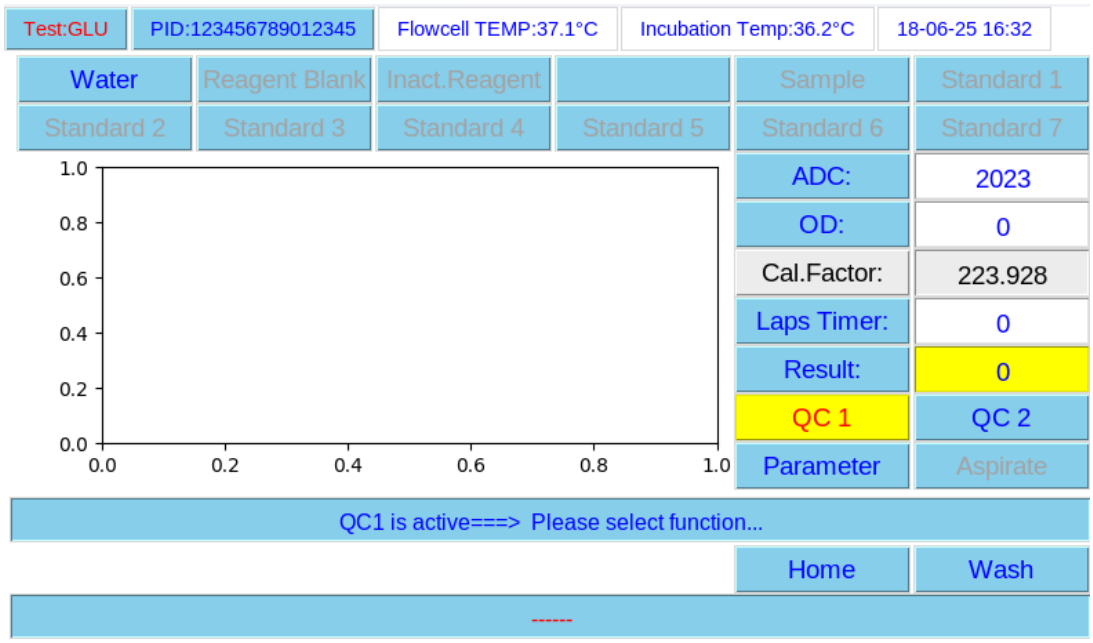
8.1.1 General

Statistical information about the controls is given in the Quality Control menu. Two controls can be defined for each test that is programmed.

The analyzer stores the last 30 results in the form of a Levey-Jennings plot together with all the statistical information. When you add one more result, the oldest will be deleted and the statistics be re-calculated. The statistical information can be shown by test or by control. To show by control, select the control first; toshow by test, select test first. The procedure here is to shown by test, but the logic for each test is the same.

8.1.2 QC sample

If you want to run QC then go to test and select the test which you want to run. Below screen will appear.

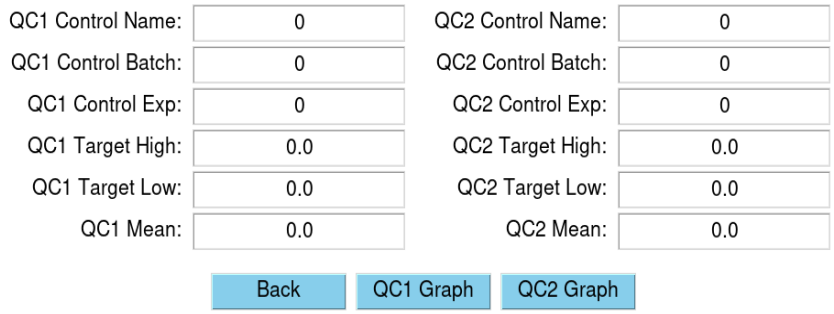


By selection QC1 Control or QC2 Control respected result will be stored accordingly.

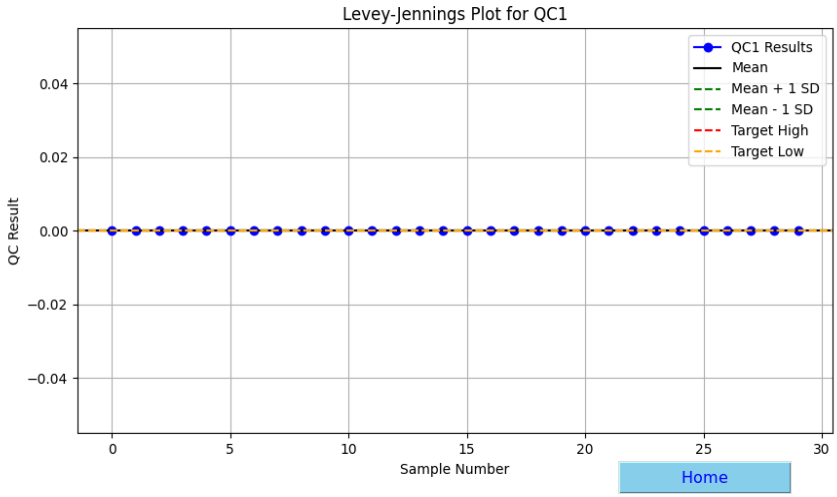
1 Press “QC 1” or “QC 2” button.
2 Place the bottle with the sample under the sipper tube.
3 Press the bottle against the sipper button to start aspiration.
4 Data will process and result will show beside the Result.

8.1.3 QC graph

Go to the home screen and press QC set up where all details can be set as per below screen followed by program selection



Press QC1 Graph or QC2 Graph and respected screen will appear as below



Here you can check the graph of last 30 tests.

9. Maintenance

9.1 Daily maintenance

The keep the analyzer accurate and free from micro-biological contamination of the flow path and flow cell, the daily maintenance must be adhered to. The daily maintenance schedule has two cleaning procedures; half daily and end of day maintenance. The half daily maintenance must be carried out every four hours. Theend of day must be carried before the analyzer is shut down. If the analyzer has not had the end of day maintenance procedure, when the analyzer is started next time, the end of day maintenance procedure will start. The half daily maintenance and the end of day maintenance are in addition to the Change of test maintenance.

Disconnection of main power cord for maintenance, first touch the power button which show on the screen as per show in the fig. turn off the device by switch which provided at the back side and later on switch off the mains power line, now main cord plug removes from the main power socket for its safe operation. When the ZELLECHEM PRO needs to be relocated, please contact SSQ LLP or your local authorized agents.

9.2 End of day maintenance

The end of day maintenance should be made before the analyzer is shut down. Do as follows.

Note
Allow 12 minutes for the analyzer to flush the flow cell. 10 Minutes for the detergent flush and 2 minutes for the distilled water flush.

- Fill a bottle with 5% detergent solution.
- Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 45 ml of liquid is necessary to make sure proper cleaning.
- Place the bottle with the liquid under the sipper tube.

- Go to system set up and then flow cell washing.
- Keep the bottle against the sipper press start washing button on screen.
- Fill a bottle with distilled water.
- Make sure the bottle is deep enough to aspirate the necessary fluid. A minimum of 10 ml of liquid is necessary to make sure proper cleaning.
- Place the bottle with the liquid under the sipper tube.
- Keep the bottle against the sipper press start wash button on screen.

10. Replacements

10.1 Replace the paper roll

Make sure the paper roll has enough paper at the beginning of the day. To replace the paper roll, do as follows:

1. Remove the Black cover from printer.
2. Remove the empty roll from the paper holder.
3. Insert the new paper roll.
4. Keep some paper outside the printer and close the black cover of the printer.
5. Gently pull the paper through the printer head.

10.2 Replace the lamp

If the lamp has a defect or the absorbance readings are incorrect in the first instance contact your service technician or dealer. To replace the lamp do as follows:

WARNING
Do not touch the lamp for five minutes after the lamp is turned off.The lamp is very hot.

1. Remove the cover from the analyzer.
2. Wait five minutes for the lamp to cool.
3. Remove the lamp from the socket.
4. Fix the new lamp into the socket with care until the lamp is fully in.

ATTENTION
Do no touch the new lamp with bare fingers. Salt from your fingers will reduce the life of the lamp.Wear surgical gloves when handling the new lamp.

11. Compliance and Reference standard

11.1 Device safety compliance

The ZELLECHEM PRO complies with following standard.

- IEC 61010-1:2010, AMD1:2016 (Edition 3.1) Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010 2-010: 2019 (Fourth Edition) Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.

11.2 Electromagnetic compatibility (EMC) compliance

The ZELLECHEM PRO complies with following EMC standard.

- IEC 61326-1: 2020 (Third edition Electrical equipment for measurement, control and laboratory use, medical device - EMC requirements - Part 1: General requirements.

12. Troubleshooting

12.1 General

The analyzer is error tolerant with proven accuracy and precision. This chapter describes the causes and possible solutions to errors and faults.
Indications of problems are noticeable by high or low, erratic, or unexpected results. Obvious errors are indicated by flags in the results screens. Hardware errors are indicated by error messages, software errors are indicated by warning messages.

WARNING
Problems that are not described in this chapter or cannot be solved by the use of this chapter should be referred to your service technician. You must not alter the system without consulting theservice technician.

The problems that occur are attributable to two main causes:
- Sample and reagent problems
- Analyzer problems

12.2 Sample and reagent problems

To prevent errors due to samples and reagents check the following:
Samples
- Check that the sample is not too hemolytic, icteric or lipemic.
- Check that the sample material is fresh and treated according to the requirements of the manufacturer ofthe reagents, as listed on the package insert of the test.

Reagents, calibrators and controls
- Check the reagent expiry date.
- Check the reagent dilution ratio.
- Check that the water is de-ionized or distilled and free from impurities.
- Check the storage requirements, frozen or cooled.
- Check the settings in the QUALITY CONTROL menu; target values, high and low limits of the control.
- Check the settings in the TEST PARAMETER menu; reference and absorbance limits of the specific test.
- Check the manufacturers required volume for each reagent, calibrator and control.
- Check the correct pipette is used to prepare the solution.

12.2.1 Analyzer problems

To prevent errors due to the analyzer, check the following:
- Check the connections of the power supply unit.
- Check external connections to external printer.
- Check all tube connections.

12.3 Problems, causes and solutions

This sub-chapter describes problems and possible causes and solutions. The problem, cause, solution, is divided into error Messages and physical conditions.

12.3.1 Error messages

Error messages normally indicate a hardware problem and are number coded with a short explanation. Switchthe analyzer off for 10 seconds and switch back on again. Check to see if this solved the problem. If not contact your service technician.

Error code	Cause	Solution
Temp. Achieving	The flow cell has not reached the correct temperature.	Wait for a few minutes for Achieving Temp. Even if Temperature Dose not come,switch the analyzer off and reset the analyzer. If the problem is still present, contact you service technician.
	Check the Temp. set point	Enter the set point.
Aspiration Or Filter Error	No light or insufficient light.	Check lamp and lamp adjustment.
	No water in the flowcell or polluted flowcell.	Check flowcell. Flush the flowcell.
	Filter Wheel not Rotating	No filter or defect filter. Check the filter wheel. Contact your service technician.
Non-Linearity Detected	Vibration Inside the flow cell	Check the Analyzer is Besides of the centrifuge machine
	Pipetting error	Recheck the sample.

12.3.2 Physical problems

The following are problems due to physical conditions.

Problem	Cause	Solution
No sample aspiration. The analyzer does not aspirate, the pump works normally.	Insufficient cleaning or a polluted sample is used.	Check all tubes and flowcell for obstruction. Contact you service technician.
Insufficient sample aspiration.	The fluid system leaks. Air is aspirated instead of fluid. Unstable display readings is an indication.	Check all tubes and flowcell.
	The waste bottle is too high or too low relative to the analyzer.	Place the bottle no more than 0.5 m above or below the analyzer.
No result. The message "Measurement under range" shows.	The blank test is not made correctly.	Repeat the blank test procedure. Check the flow cell. Check the test parameters.

Problem	Cause	Solution
Drop out of measurements.	Air bubbles in the flow cell as a result of pollution in the system.	Do the end of day maintenance procedure. Flush through with methanol.
	Air bubbles in the flowcell due to leakage of the fluid system.	Check all tube connections of the fluid system especially those before the flow cell.
	Air bubbles in the flowcell due to the sample/reagent mixture is too cold. An increase of the vacuum inside the fluid system. Spontaneous formation of bubbles.	Add 0.1% neutral detergent to the reagent.
Poor reproducibility. Measurement results are not reproducible. Variation between measurements is too high.	Leakage of the sipper tube.	Check the connection of the sipper tube.
	Programmed sipper volume is too high.	Check the sipper volume.
	Air bubbles in the flow cell.	Do the end of day maintenance procedure. Flush through with methanol. Check the tube connections.
	The reagents are not stable. Pollution in the reagents.	Use fresh reagents.
Results too low. The values of the controls are too low.	Kinetic test. The delay before the kinetic test is too short.	Check the delay time in the test parameters.
	Measurements temperature is too low.	Contact you service technician.
Results too high.	The product of (factor x ΔAbs) is too great. R-Flag may also show.	Check the factor. Make sure calibration is correct. Check standard values in the test parameters.
	The absorbance value of the reagent/sample mixture is out of linear range. R-Flag may also show.	Use fresh reagent or dilute the sample.