URIT

URIT-8210/
URIT-8211/URIT-8216

Automatic Chemistry Analyzer

OPERATION MANUAL

URIT Medical Electronic Co., Ltd.

CATALOGUE

Copyright and Declaration

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Thank you very much for your purchase of the URIT Automatic Chemistry Analyzer.

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All instructions must be followed strictly during operation. In no event should URIT be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions described in this manual.

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If a malfunction occurred under normal use because of the material and workmanship, URIT will provide one year's warranty service from the date of installation to this instrument which sold by URIT and agents. The using period of this instrument is 10 years.

Once the following situations occurred, URIT assumes no liability to the safety, reliability and operation condition of the instrument, and all agreed right of free service is deem to be waived permanently and unconditionally.

- Instrument under improper use or not by maintenance or has been damaged.
- Using the reagents and accessories not supplied or approval by URIT.
- Instrument damage caused by false operation or negligence because of user or others operates the instrument not comply with this manual.
- Replace accessories not specified by URIT, maintaining, repairing by a personnel who does not authorized by URIT.
- Components are discounted, drawing and readjusted not approved by URIT.

NOTE

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PREFACE

The document is the operating manual for URIT Automatic Chemistry Analyzer. It describes the structure, operation, maintenance and troubleshooting concerning the instrument in details. Users should read carefully the manual and get special training before operating to guarantee instrument precision, normal operation and personal safety.

The document is not used for any other use except for reference. Please see the instrument for the actual appearance.

Furthermore, please refer to the wooden case label for the date of production.

The service life of instrument is 10 years.

1. Safety symbol

Following are the safety symbols which used together with character in the manual.

Marking	Meaning
 **Warning**	Operator should operate under the manual otherwise serious injury maybe caused or even lost life. Serious injury involving go blind, trauma, burn (excess temperature), electric shock, cataclasis, toxication and other sequela.
 **Caution**	System damage or incorrect result may cause if not comply with the manual to operate.
 **Note**	Following the manual to avoid personal injury, physics damage and a series of adverse impact on test results. Also point out source of infection. Personal injury involving mild burns, electric shock or drug allergy. Physical damage involves damage to building, animal and pet.
 **Biohazard**	Biohazard means the biological factor may be caused hazard to the environment and organism.

2. Sign illustration

The following pictorial markings are marked on instrument to remind user safety. Please check the marking regularly and keep clean. Please contact URIT to change if the marking is fuzzy or break off.

	Caution. Refer to the accompanying document		Be careful electric shock
	Caution. Hot surface		Biohazard
	Protective earthing		Power on
	Power off		In vitro diagnostic Medical device
	Environmental Protection lifetime		Keep away from heat and radioactive source
	Serial Number		Manufacturer
	Recovery		May cause personal injury
	Date of manufacture		Period of Validity
	Refer to operating manual		Upward
	Keep away from rain		No turning over
	Fragile, Handle with care		Limit of stacking layer
	Laser radiation(for barcode function)		

SAFETY GUIDELINES

Please read the following safety cautions. Any violation will cause personal injury or damage of instrument.

CAUTION

If the operator does not in accordance with the guidance when operate the instrument, the protective measures will likely failure**.**

Prevent Breakage and Flammability

Please comply with the following precaution to prevent breakage.

CAUTION

1) Installation should be complied with installed instruction of the manual.
2) If relocation is necessary, contact your local distributor or URIT firstly.

Prevent Electric Shock

Please comply with the following precaution for preventing electric shock.

CAUTION

1) Users other than the servicing personal authorized by our company must not open the rear cover and left or right cover when turn on the power.
2) If a spill occurs or liquid gets into the instrument, please contact URIT. Neglecting the liquid may cause electric shock.

Prevent Personnel Injury

Please comply with the following precautions for preventing injury.

CAUTION

1) While the instrument in motion, DO NOT touches the moving parts, such as aspirating probe, stirrer and washing station of reaction tray, etc.
2) DO NOT put your finger or hand into the open part of instrument.

Eyes Protection

Please comply with the following precaution for eyes protection.

CAUTION

1) DO NOT directly look at the light emitting from the lamp source when the instrument is in motion.
2) Turn off the power and wait for at least 15 minutes until the light source is cooling before replacing light source to prevent scald.

Precision and Accuracy of Data

Please attention the following matters for getting the accurate data.

CAUTION

1) DO NOT open the top cover, reaction tray cover and reagent/sample tray cover when the instrument is under analyzing condition.
2) Please check the accuracy of instrument by quality-control before using.
3) Please comply with the manual to maintain, check and replace the assembly unit.
4) Please comply with the corresponding explanation to handle the reagent, quality-control materials and reference materials.
5) Please handle the sample according to the requirements of manual.

Chemical and Biological Safety

Please comply with the following matters for chemical and biological prevention.

Biological Hazard

If chemical adheres to the human body, contagion may occur. DO NOT touch the sample, mixed solution and waste solution directly. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

CAUTION

Some reagents are strong acid or alkaline. Please use them carefully avoiding direct contact. If the reagent spill to the human body immediately washes it off with water and soap. If the reagent splashes into eyes accidentally, wash it off with water and consult an oculist.

Preventive warning of electromagnetic compatibility

Declaration

The instrument has been passed EMC test of Bay Area Compliance Laboratories Corp.

It is suggest evaluating the electromagnetic environment before using the instrument.

CAUTION

When use the instrument in the dry environment, especially in the environment where placed some artificial materials (synthetic fabrics, carpets, etc.), may cause damaged electrostatic discharge and resulted a wrong conclusion.

It is forbidden to use the instrument near by the strong radiation source, otherwise will interfere use.

Handle Waste Solution

Please comply with the following matters when handle the waste solution in order to avoid personal injury and protect environment.

Biological Hazard

1) Some substances contained in QC solution, standard solution and waste solution are regulated by discharge standards and pollution control regulations, waste must be disposed according to the relevant environmental protection regulations.

2) Be sure to put on protective gloves, clothes, or even goggles if necessary when dispose waste solution.

System Dispose Hazards

Please comply with the following matters to dispose of the waste analyzer.

CAUTION

Materials of the analyzer are subject to contamination regulations. Dispose of the waste analyzer in accordance with your local or national rules.

Fire and Explosion Hazards

Observe the following instructions to prevent fire and explosion.

CAUTION

Alcohol is flammable substance. Please exercise caution while using alcohol.

Using Precaution

Please read the following using precaution carefully when operate the instrument. Any violation will affect the precision and accuracy.

Systematic Usage

CAUTION

1) Automatic Chemistry Analyzer is intended use for medical institution and laboratory to analyze some specific chemical composition of human body fluid. If the instrument to be used beyond this scope, consult URIT firstly.
2) Please consider together with the clinical symptom or other analyzing result when make the clinical judgment.

Operator

CAUTION

The instrument is operated only by technicians, doctors and laboratory personnel who trained by URIT.

Operational Environment

CAUTION

1) Please install the instrument according to the specified installed instruction in the manual. Otherwise, the results may not reliable even may cause system damage.
2) Please contact URIT if system state is changed.

Caution on Electromagnetic Wave Interference

CAUTION

1) Keep the instrument away from strong noise source and electromagnetic wave. Turn off mobile phones and transmitter-receiver when operating the instrument since the electromagnetic wave may cause an adverse effect on instrument.
2) Do not use other medical instrument around the system that may generate electromagnetic wave interfere with their operations.

Indication for System Use

CAUTION

1) The operator must training before operating the instrument. Please follow the instruction of manual to operate. Improper operation may cause personal injury, system damage and improper result.

2) Please make a calibration and quality-control test before use the system for the first time to ensure it can be used normally.

3) A quality-control test must be done when use the system. Otherwise, the reliability of the result could not be guaranteed.

4) Do not open the sample/reagent cover while in the analyzing process.

5) The communication joint of analytical part is set to connect with the communication joint of operational part. Please use the cables of URIT for connecting.

6) The operation part is an external computer which is installed the specified operational software. The computer should be for the instrument exclusive use. DO NOT run any other software when it is connected with the instrument. Inappropriate manner may result in computer virus infection

7) DO NOT touch the keyboard, indicator and mouse when your hands is wet, also includes the chemistry.

System Maintenance

CAUTION

1) Maintaining according to the instruction. Incorrect maintenance may lead to wrong result even caused system damage and personal injury.

2) Dust may be there after long-time placement. Cleaning the surface by soft cloth or little soap solution if necessary. Never use organic solvent such as alcohol. Wipe the surface after cleaning.

3) Please turn off all the power supply and pull up the plug before cleaning. Take measures to prevent water into the system, otherwise, will cause system damage or personal injury.

4) Calibration analyses must be done when changed the light source, optical system, sample needle, reagent needle, stirrer and any other major component.

5) Please turn off the power and wait the light is cooled down to avoid scald.

Setup of Parameters

NOTE

To define such parameters as sample volume, reagent volume and wavelength, follow the instructions in this manual and the instruction of reagents.

Precaution for Handling Samples

CAUTION

1) Sample must not contain insoluble substances such as fibrin and dust. Coagulation and impurity may block the aspirating probe thus causing bad effect on tests. Medicine, anticoagulant, preservative exist in sample may influence test result, hemolytic, icterus and chyle also will cause incorrect result. Suggest do background test.
2) Store the sample correctly. Sample structure will change and even caused incorrect result in wrong storage.
3) DO NOT expose samples in the air for a long time because they may be contaminated or boiled off and thus erroneous test result may occur.
4) Certain sample cannot be analyzed please contact reagent supplier for details.
5) Certain sample need to be preprocessed please contact reagent supplier or distributor.
6) Consult manual for sample volume when do the test.
7) Be sure the sample is located on right position to avoid inaccurate results.

Handling Reagents, Calibration and Control

CAUTION

1) Proper reagent, calibration solution and control solution are needed for analyses.
2) Please choose correct reagent. Consult the manufacturer or distributor if uncertain about the usage of reagent
3) For storage, handling and usage of reagent, standard solution and control serum, refer to the Instruction for Use provided by their manufacturers. Improper storage may not guarantee the accuracy of test result even though they are not expired.
4) Be sure to perform calibration when replacing reagent. Otherwise, inexact test result may occur.
5) Cross-contamination among reagents may influence test results. Contact your reagent supplier for details.

Data Back Up

CAUTION

Please backup the analysis data and measurement parameters regularly.

Contraindication

Note

The instrument is not applicable.

Other Cautions

CAUTION

1) DO NOT touch the keyboard, indicator and mouse when your hands is wet, also includes the chemistry.

2) Check samples for contamination (dust, or fibrinogen) and air bubble before analyses.

3) For replacements of major parts, such as light source lamp, aspirating probe, reaction cuvette, etc., please contact URIT.

4) For settings of sample volume, reagent volume, wavelength, standard values, etc., please refer to the instruction in reagent kit as well as this operating manual. Checking the quality of distilled water and detergent, check calibration results, control results, and sample results after analyses. Make sure there is no air bubble in the flow paths.

CHAPTER 1 INSTRUMENT INTRODUCTION

1.1 Brief introduction

Automatic chemistry analyzer is a clinical chemistry instrument with the characteristics of open, full-automatic, discrete/optional, STAT priority and controlled by computer. It is intended for use in conjunction with reagents to measure quantitatively certain chemical items in serum, urine and cerebrospinal fluid. Please read the operating manual carefully before using since it is a high sophisticated instrument.

Work Unit consists of optical unit, mechanical operation unit, liquid path control unit, hardware circuit unit and operating unit.

1) Optical unit consists of 90 cuvettes, long lifetime halogen light and rear light-splitting optical system.
2) The mechanical unit consists of sample and reagent processing system, which driven by constant current motor to ensure stable motion. The sample system includes sample tray, sample arm, sample injector and washing pool; the reagent system includes reagent tray, reagent arm, reagent injector and washing pool. The instrument also includes a unique stirring arm and eight-step washing system.
3) The liquid path control unit consists of vacuum pump, solenoid valve, rinse system and pipeline system, etc. Using positive and negative pressure control system, precisely to control the pressure to ensure the stability of liquid path.
4) The hardware circuit unit consists of power board, main board, terminal board, barcode board and ISE board, etc.
5) The operating unit is an external computer, the allocations are as follows:
   CPU: dual core frequency, 2.4 GHz or above; or multicore CPU.
   Memory: 2GB or above, 4GB is recommended.
   Hard disk: 120G or above, 500G is recommended.
   Resolution: 1024*768 or above, 1440*900 is recommended.
   and there are serial port, net mouth and CD-ROM drive（or USB port)
   The application software should be setup under the Windows 7, Windows XP is also could be used (professional SP3).

The instrument is easy to operate. The layout of the screen menu is reasonable, name is simple. Such as testing parameter setup, patient's information input, quality-control, reagent, data query, standard, running test and hardware parameter. After setting, put the sample and reagent to the instrument and begin to analyzing. Print out the result by the external printer at last.

1.2 Intended use

The instrument is applied for professional, in vitro use in hospitals, clinics and laboratories.

Caution

Some samples may not be analyzed according to the tested parameter and reagent. For the case of these samples, please contact reagent manufacturer or distributor.

1.3 Main structure

1.3.1 Front view

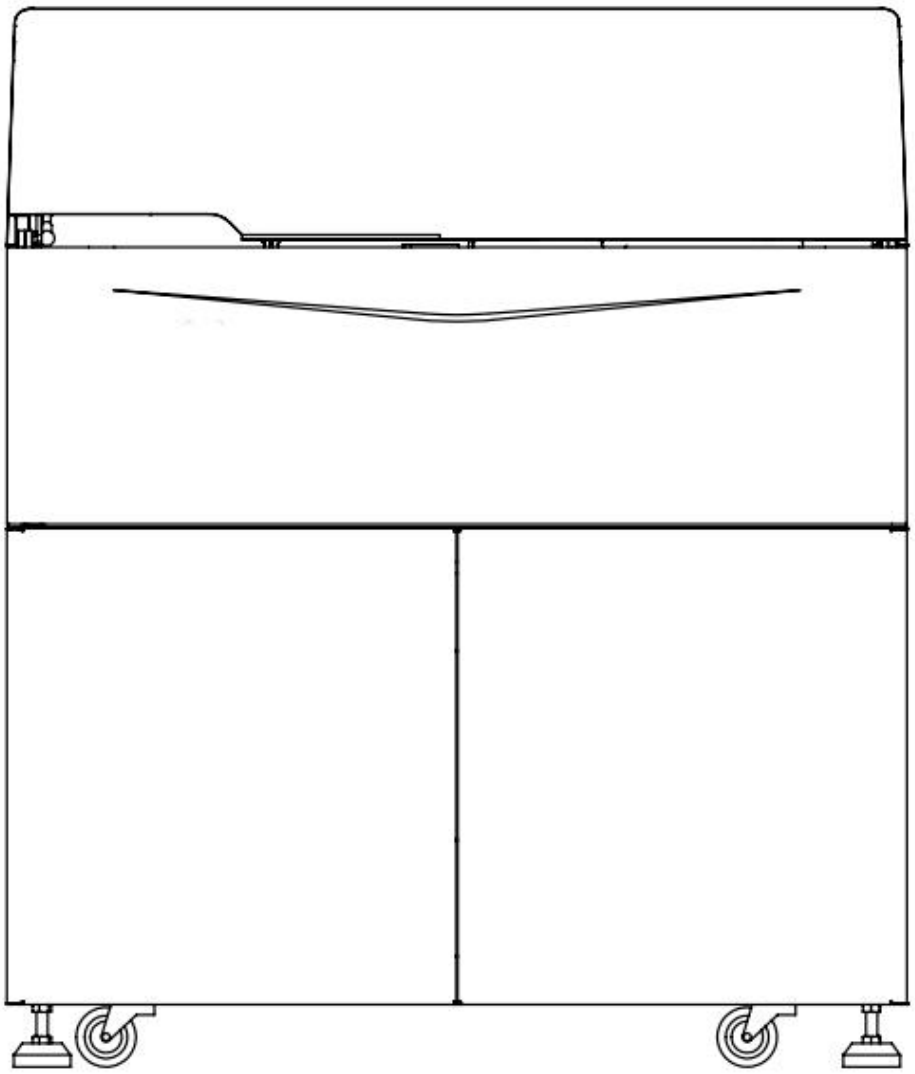


Figure 1.3.1 Front view of Analysis Unit (URIT-8210/URIT-8211/URIT-8216)

1.3.2 Rear view

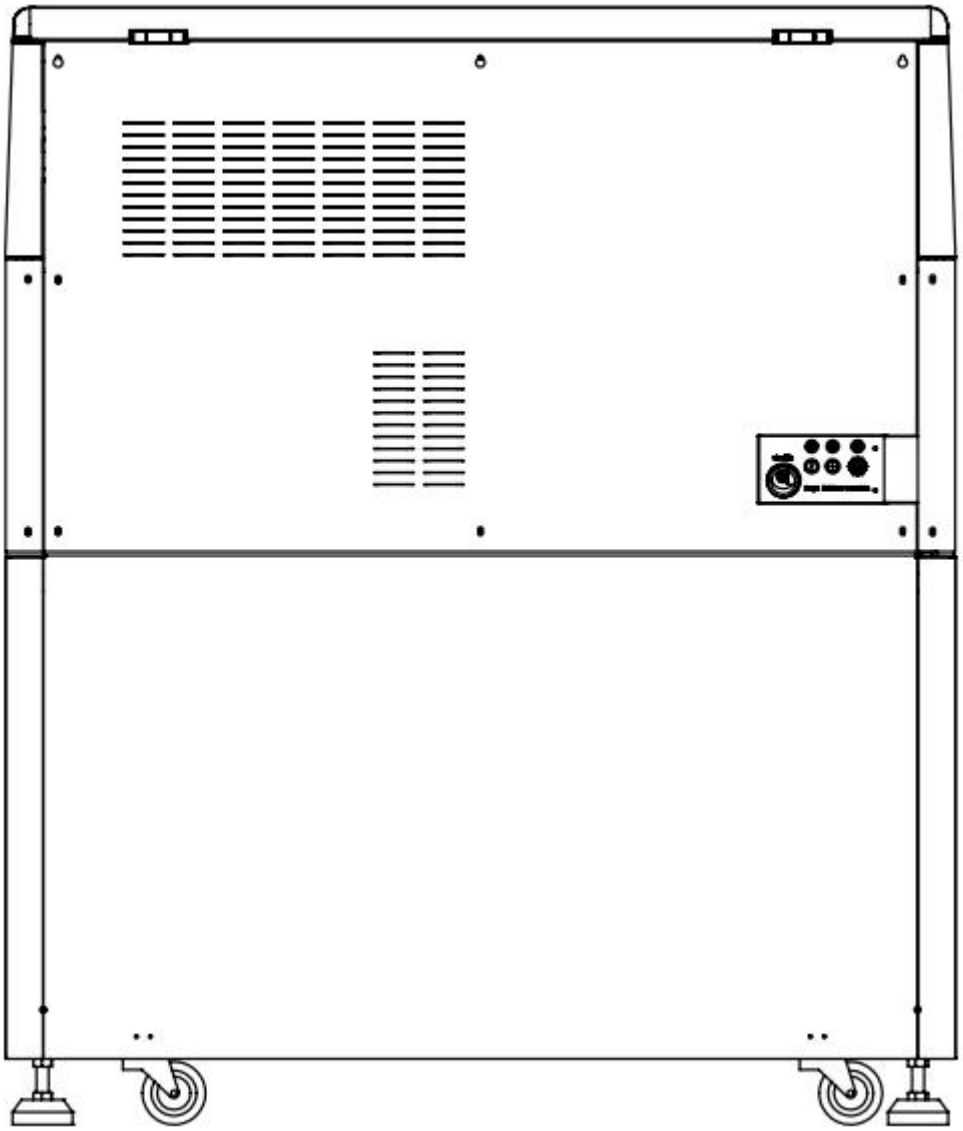


Figure 1.3.2 Rear View of Analytical Unit (URIT-8210/URIT-8211/URIT-8216)

1.4 Instrument function

1) System: Full-automatic, discrete/optional, STAT priority, with reset function.
2) Stand-by: 24 hours stand-by, auto-sleep and one key start-up function.
3) Rinse: Rinsing the inside and outside of aspirating probe with constant-temperature distilled water, and spring type clean the stirrer; washing station of eight-pin-ten-step rinse the cuvettes with detergent, and provides independent path detergent system, separate rinse available among items.
4) Sample probe: With liquid level sensing, volume tracking function, auto-protective function to prevent from collision. The function of probe-clog detected is optional.
5) Reagent probe: With liquid level sensing, volume tracking function, auto-protective function to prevent from collision. The preheating function is optional.
6) Alarm: Alarm automatically when reagent, sample, distilled water or detergent is shortage and waste solution is overfull; skip the unqualified cuvette automatically; when the absorbance is out of range, the system will alarm.
7) Backup reagent position: Three reagent positions available for the same item. When the first alarm to lack of reagent occurs, aspirating probe will turn to the second reagent position to aspirate reagent automatically, and the second alarm occurs, aspirating probe will turn to the third reagent position to aspirate reagent.
8) Reagent capacity expansion: It's provides the function that a reagent position can be set to test several items.
9) Sample capacity expansion: Calibration or QC position can be opened as regular sample position; and in the same way, regular sample position can be opened as calibration or QC position.
10) Test method: End point, rate assay(kinetic method), 2-point end point, 2-point rate assay (2-point kinetic method), dual-wavelength, blank method(reagent blank, sample blank and water blank), immune turbidimetry, double reagent, electrode, colorimetric method , sample appearance inspection (serum index, such as jaundice, hemolysis and lipid turbidity, etc.) , nonlinear detection, etc.
11) Calibration method: At least linearity (single point, two points, multi points) and non-linearity calibration. Multiple calibration formula including Logit-Log4P, Logit-Log5P, exponential function, spline, exponential 5P, parabola, Wei Bull, K factor method, etc.
12) Calibration system: Selecting best test point according to reaction curve, not need to calibrate for second time; Calibration time is selectable and result is calculated automatically. Tracking calibration function, the change of K value is presented on a drawing. 8 calibrations in different

concentration can be used for each item.

13) QC rule: At least including westgard and levey-Jennings QC rules.
14) QC method: Real-time QC, within-day QC, between-days QC.
15) QC processing function: Predefine different controls. More than 4 controls can be tested simultaneously and QC could be inserted randomly in the course of testing. QC diagram could be stored, displayed and printed.
16) Colorimetric method: Colorimetric in reaction cup directly, and single-hole detection.
17) Monitor: Monitoring cuvette online, display whole reaction process in real time, skip and mark the unqualified cuvette automatically.
18) Pre-diluents/Retest: The software could identify the sample which substrate is use up and linearity is over range, for these samples, system could select pre-diluents test and retest manually or automatically. The diluents time could be programmed. Max dilute multiple is up to 250.
19) Data reset: Reselect measure point against abnormal sample (Substrate use up, over range of linearity) and recount without retest.
20) Enzyme linear verification and expanding function: Automatic verifies and searches the enzyme linear reaction interval, and then obtains real results.
21) User mode: Hospital mode, blood station mode, physical examination center mode etc.
22) Item sequence: Item print and measuring sequence could be programmed.
23) Patient result and data storage: store and backup automatically and permanently in infinite quantity.
24) Software management: Multilevel authority management to guarantee the security of information.
25) Network: Data exchange between LIS and HIS automatically.
26) Barcode reader: The instrument supports the barcode scanning function. Supporting coda bar, interleaved 2of 5, code128, code39, code93, UPC/EAN and any other barcode rules.
27) Printing function: Various printing format, support Chinese/English printing. User could edit the format of report.
28) Light source: Long-life halogen lamp, auto-sleep, cooling by wind.
29) Barcode Scanning: The instrument supports the barcode scanning function.
30) LIS/HIS: Support HL7 Protocol.
31) ISE: Support ISE Module.

1.5 Technical parameter

1) Test speed: 330T/H(constant speed,pure chemical), 575T/H(with ISE, Li^+, K^+, Na^+, Cl^-)
2) Sample tray: 71 sample positions(expandable), which consist of routine sample positions, standard positions, quality control positions, probe washing position and STAT position; Various samples can be put together, sample cups, neonate ultramicro quantity cup, primitive tube and plastic tube is appropriate for those positions.
3) Reagent tray: 60 reagent positions (expandable), two specification bottles are available.
4) Cuvette: Holds 90 UV hardish cuvettes.
5) Optical system: high-resolution filter and halogen light, the characteristic of optical system is full-close, static, array and after-spectral. There are 10 wavelength for choosing (340nm, 405nm, 450nm, 492nm, 510nm, 546nm, 578nm, 630nm, 700nm, 800nm). And there are two blank position alternatives to choose.
6) Absorbance range: -0.5~6.0, distinguish ability 0.0001.
7) Reagent refrigeration: Refrigerate temperature is 2℃ to 8℃.
8) Sample Volume per test: 2μL to 35μL, variable in 0.05μL.
9) Reagent Volume per test: 10μL to 300μL, variable in 0. 5μL.
10) Reaction Volume: 150μL to 900μL.
11) Reaction cup optical path: 7mm.
12) Light Source: 12V/20W.
13) Temperature Control: air bath mode to keep constant temperature in 37℃±0.3℃.
14) Item storage: up to 1200.
15) Max reaction time: 14min.
16) Water consumption: ≦8L/H.
17) Structure: one reagent probe, one sample probe, one stirrer, one reaction tray , one reagent and sample tray.

1.6 Main structure

The analyzer is mainly consisting of analytical unit, computer and printer. The computer and printer are optional accessories.

User can buy the computer and printer by himself.

The analyzer is mainly used for analyze sample, measure the clinical chemical component in all kinds of samples and generate the result data. The analyzer is mainly composed of the following units:

1) Reaction system
2) Sample processing system

3) Reagent processing system
4) Stirring system
5) Automatic cleaning mechanism
6) Liquid path system
7) Photoelectric detection system

Computer winch has install the automatic biochemical analyzer operating software, is mainly used for complete the test application, biochemical test, reaction process monitoring, calculate the results, as well as the data input, storage and query, etc.

The printer is used for print the test results and other data. The analyzer support ink-jet printer, laser printer and needle printer. The printer is not the standard allocation, please contact us if you need or buy by yourself.

The accessory kit of analyzer is contains the related accessories such as reaction cup, reagent bottles and liquid pipe, etc.

1.6.1 Reaction system

Reaction system is made up of reaction tray and cuvettes. It is mainly used for loading cuvette, and provides appropriate and constant working environment for reaction solution of sample and reagent; at the same time, according to the program control sequence to transfer the cuvette to the specified photoelectric data acquisition position to detect the signal for absorbance measurement. Cuvette colorimetric directly, single hole detection.

Warning

Covering the reaction tray cover when instrument is running. Please wait for stop if you need to remove the cover.

1) Reaction tray

Reaction tray adopts the disc type physical design, contains 90 cuvettes. Reaction tray is doing circular motion in constant speed during the test; please add the sample, reagent or stirring when it is in static state. It is mainly used for loading reaction cups, and then transferring them to photoelectric data acquisition position to measure the absorbance of reaction solution.

The reaction ray is air bath type and temperature fluctuation is ±0.3℃.

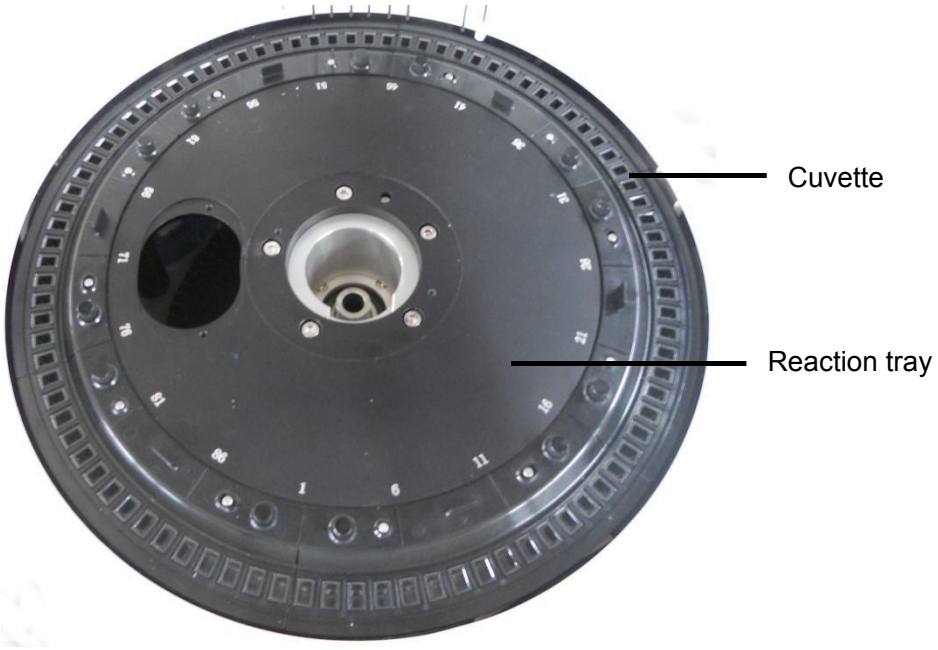


Figure 1.6.1 Reaction tray

2) Cuvettes

Cuvette is the place for sample and reagent undergoes chemical reaction. It is made of hard material with good light-admitting quality (quartz cup is optional). The volume of reaction solution is 150μL to 900μL. After each test, the cuvette will be cleaned and dried automatically and used for next time.

1.6.2 Sample processing system

Sample processing system is mainly used for loading samples, and then transfers each sample to the sample absorbing position for absorb the sample, and inject it to reaction cup where reacts with reagent, at last measure the absorbance of reaction solution by optical detecting system.

The sample processing system includes sample tray, sample and reagent adding mechanism, aspirating probe cleaning system and sample injection pump.

1) Sample tray

Warning

If it is needs to open the sample tray cover or adding sample, please make sure the instrument is under standby mode or power off status, otherwise may damage the instrument or cause personal injury.

Sample tray and reagent tray are located in the same tray, sample tray is outside, and inside is the reagent tray. Sample tray is mainly used for loading sample cups (tubes) which contain sample, standard solution or quality control solution, and then transfer them to sample aspirating position, and then wait for sample probe aspirates sample.

- Routine sample position: From 1 to 55
- Emergency position: From E1 to E4

- Calibration position: From S1 to S8
- QC position: From C1 to C4

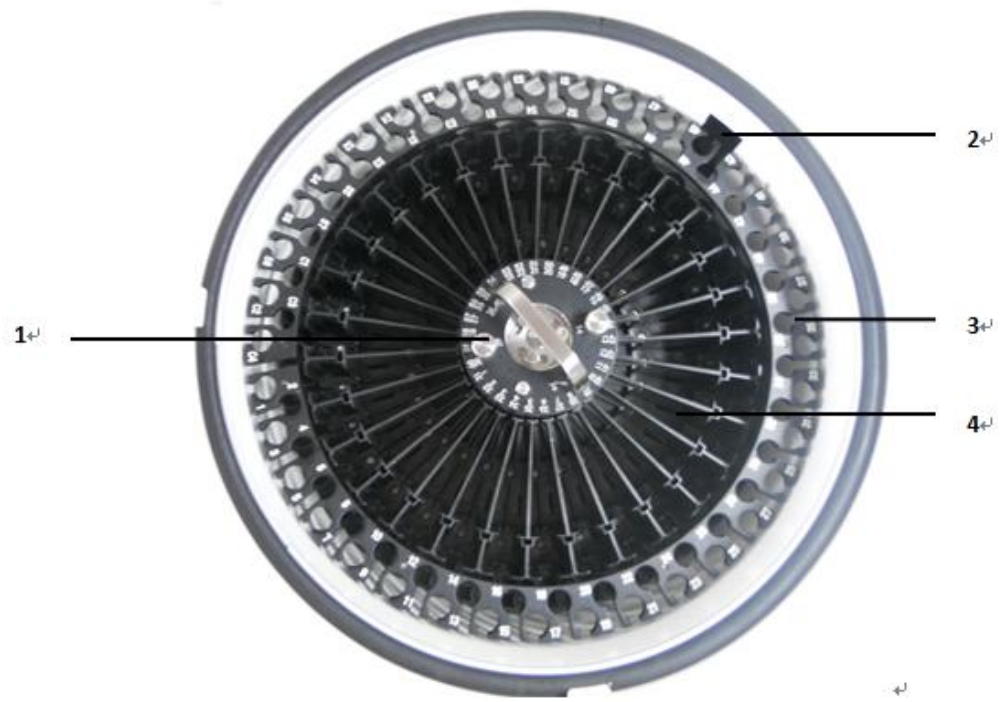


Figure 1.6.2-1 Reagent/sample tray

1- Set screw of reagent/sample tray 3-Sample tray

2- Scanning window of reagent/sample tray 4-reagent tray

Users can put the diluted sample in any routine sample position; It is allows setting 20 virtual sample tray at most, and only one is default. It can edit 1340 samples at the same time once. The sample tray supports to locate newborn ultra-micro sample cup, original blood collection tube, plastic tube, etc.

2）Reagent/sample adding mechanism

Reagent/sample adding mechanism is used for aspirating quantitative volume of sample and adds to cuvette. Reagent/sample adding mechanism is composed of aspirating probe, probe rocker arm, probe driven shaft, syringe and corresponding flow path, as shown in figure 1.6.2-2.

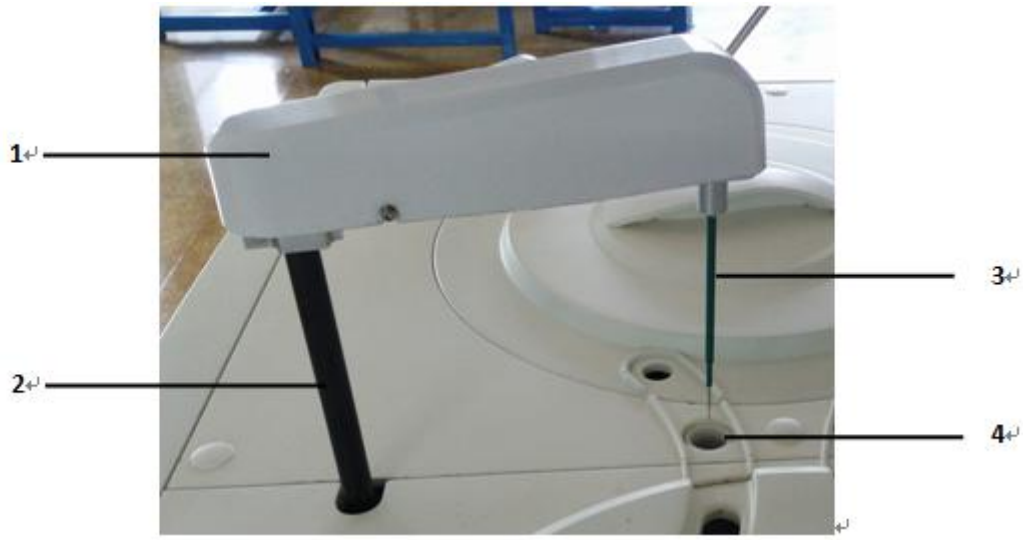


Figure 1.6.2-2 Reagent/sample adding mechanism

1- Rocker arm 3- sample probe

2- Driven shaft 4-cleaning pool

Probe is mainly realize the basic function of aspirating certain volume of sample and then inject to the reaction cup, and the volume range is 2μL to 35μL, increasing by 0.05μL. The sample probe also has the following functions:

a) Firstly, the aspirating mechanism has level detecting and volume tracking function. The probe could detect the liquid level automatically and drop to aspirate sample.

b) Secondly, the aspirating mechanism has anti-collision function. The anti-collision system will start when the probe strike obstacles to prevent probe from damage.

Warning

Do not put hand or any other parts on the way where the probe is moving to, otherwise will cause personal injury and instrument damage.

3）Probe cleaning system

The inside of probe is cleaned by high-pressure water in one-way; and outside is cleaned by distilled water in spraying method.

1.6.3 Reagent processing system

The reagent processing system is used for loading reagent bottles and transfer the position to aspirating reagent, then inject to cuvettes. The optical detecting system will analyze the item parameter in the solution of cuvette. The reagent processing system includes reagent tray, reagent/sample aspirating mechanism, probe cleaning system and syringe pump.

1) Reagent tray

Warning

Please turn off the instrument if its need to open the cover of reagent tray or add reagent. Otherwise will cause personal injury or instrument damage.

Reaction tray adopts the disc type physical design, is mainly used for loading reagent bottles, and then transfers each reagent bottle to the reagent aspirating position, wait for reagent probe to aspirate the reagent.

Reaction tray provides 60 reagent positions; two specifications reagent bottle can be placed. Reaction tray is integrated, including outer ring and inner ring, and provides 30 reagent positions in each lap, No. 60 is diluent position, and No.30 is detergent position.

The reagent tray with 24 hours non-stop refrigeration function, and the temperature keep in the range of 2℃ to 8℃, make sure the reagent in reagent bottle is always stored in low temperature environment, guarantee the stability of reagent nature, reduce volatility.

Note

The power supply of reagent refrigeration system is separate from the analyze part, so in the case of main power is turned on, refrigeration system will always in working state.

2）Reagent adding mechanism

Reagent/sample adding mechanism has the function of absorb certain amount of reagent from the regent bottle, and then inject it to the cuvette.

Figure 1.6.3 reagent adding mechanism

1- Rocker arm 3- reagent probe

2- Driven shaft 4-cleaning pool

The probe also has the following functions:

a) Liquid level sensing and volume tracking: probe can automatically detect the liquid level inside the reagent bottle, and according to absorb volume to determine the descending depth to realize the volume tracking function.

b) Collision protection function: When probe contacts the obstacle, the anti-collision system will be automatically started to prevent from collision, so as to protect the reagent probe from damage.

3）Reagent probe cleaning system

The inside of probe is cleaned by high-pressure water in one-way; and outside is cleaned by distilled water in spraying method.

1.6.4 Stirring system

Stirring mechanism is used for stir the mixed solution in reaction cup after inject R2.

Stirring mechanism is mainly composed of stirrer, rocker arm and the drive shaft, as shown in figure 1.6.4.

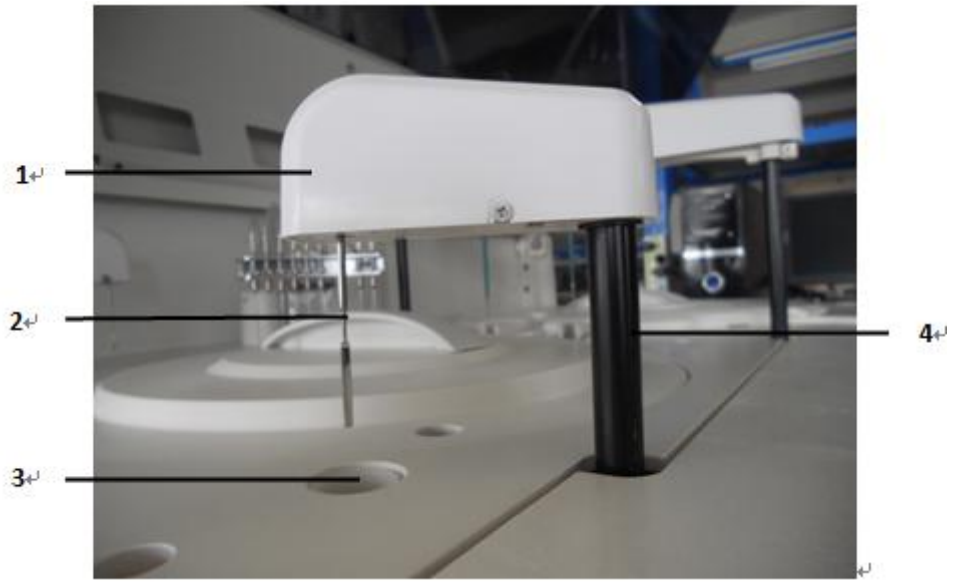


Figure 1.6.4 stirring mechanism

1- Rocker arm 3-stirrer washing pool

2- Rabble 4- driven shaft of stirrer

The hydrophobic material of the surface of stirrer can prevent the reaction solution was carried by stirrer, and its work mode is rotation type.

The cleaning system is spring type to rinse the stirrer from top to bottom.

1.6.5 Automatic cleaning mechanism

The automatic cleaning is also called eight-step automatic cleaning, which will draw off the solution

after test over and inject distilled water to clean the cuvette, and then draw off again after cleaning. The clean procedure is according to the setting order. The cleaning mechanism also has the anti-collision function to ensure the cleaning mechanism stop to work after collide obstacle so that to prevent leakage. The cleaning mechanism as shown in figure 1.6.5:

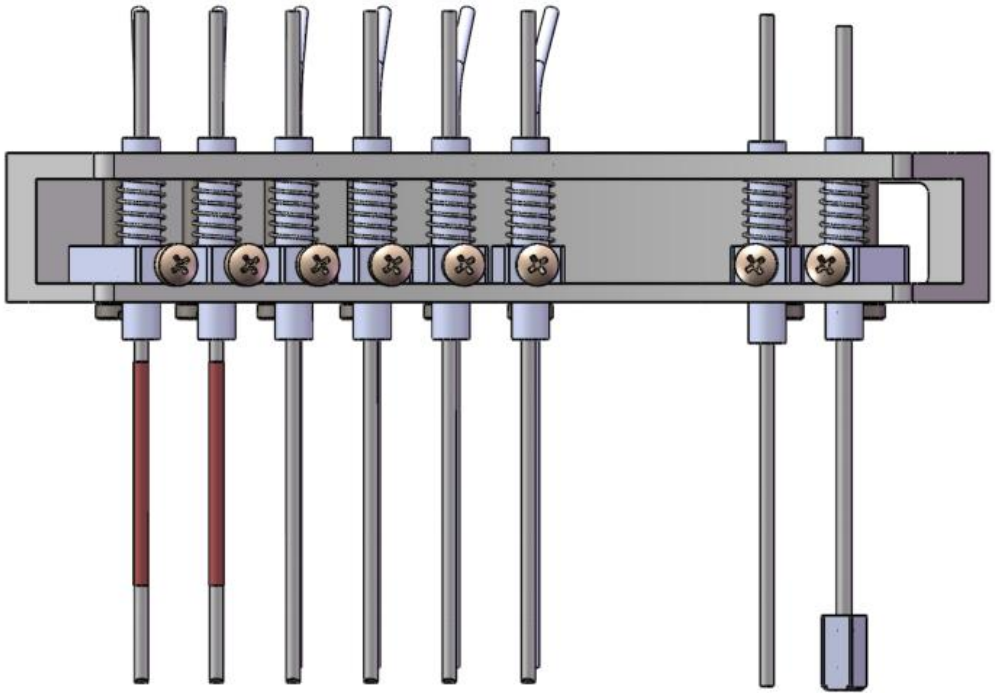


Figure 1.6.5 Cleaning mechanism

Table 1-1 Function of cleaning probes

No.	Probe	Function	No.	Probe	Function
1	First group-short probe	Injecting detergent	5	Fifth group-short probe	Injecting distilled water
	First group-long probe	Draw off high concentration waste solution		Fifth group-long probe	Draw off low concentration waste solution
2	Second group-short probe	Injecting distilled water	6	sixth group-short probe	Injecting distilled water
	Second group-long probe	Draw off high concentration waste solution		sixth group-long probe	Draw off low concentration waste solution
3	Third group-short probe	Injecting distilled water	7	Seventh group	Draw off low concentration waste solution
	Third group-long probe	Draw off low concentration waste solution	8	Eighth group	Block –sip up distilled water
4	Forth group-short probe	Injecting distilled water			

	Forth group-long probe	Draw off low concentration waste solution			

The automatic cleaning mechanism cleans the cuvette in eight-steps cleaning way by detergent and distilled water, to ensure the cuvettes are clean and dry and prevent cross contamination. The eight-steps cleaning way is explained as follows:

The First step: The first group probes draw off the high-concentration waste solution from cuvettes, and then inject detergent to clean the cuvettes.

The Second step: The second group probes draw off high-concentration solution from cuvettes, and then inject distilled water to clean cuvettes.

The third step to sixth step: The third group to six group probe is used for drawing off the waste solution, and then injects distilled water to clean cuvettes repeat.

The seventh and eighth step: to drain cuvettes dry.

1.6.6 Liquid path system

The liquid path system of the instrument is located on the left in the inner of instrument. The liquid path system mainly consists of vacuum pump, solenoid valves, proportioner, cleaning system and pipe system. A vacuum positive and negative pressure system is used to control the pressure to ensure the stability of liquid path system. The function of liquid path system is to control the liquid and gas by using various pump or valves, so that to achieve the cleaning function to clean cuvettes, probes and stirrer.

1.6.7 Photoelectric detecting system

The photoelectric system is full-closed, static, concave holographic aberration-reduced grating, rear light-splitting optical system. It is one of the core parts of instrument. The performance of photoelectric detection system directly affects the accuracy and precision of the instrument. The function of photoelectric detection system is generating and splitting light source, receiving light signal and completing conversion.

The light source is generated from halogen lamp which can generate continuous and stable spectrum. The spectrum will through the lens' group and be focused. At last, spectrum goes through cuvette and lens to enter the photoelectric detection system. The photoelectric detection system consists of optical system and signal detection system. The function of photoelectric detection system is detected intensity of light which through the solution in cuvettes. Then convert the optical

signal to electric signal, and to detect the change of electric signal to reflect the change of the intensity of light.

The performance of photoelectric detection system as follows:

- wavelengths: Include 340nm, 405nm, 450nm, 492nm, 510nm, 546nm, 578nm, 630nm, 700nm, and 800nm, and there are two vacancy positions for option.
- Wavelength accuracy:±1nm.
- Linear range: -0.5 to 6.0.
- Resolution ratio: 0.0001.
- Light source: Halogen lamp, 12V/20W.

1.7 Optional modules

The optional module is not the standard allocation when the instrument is delivery. Customers accord to the needs to select the optional module. The instrument supports three optional modules as follows:

a) ISE module
b) Sample barcode scanning system
c) Reagent barcode scanning system

1.7.1 ISE module

ISE is the abbreviation of Ion-Selective Electrode. ISE module consists of selective electrode (includes Na^+ ion, K^+ ion and CL^- ion), reference electrode, injection and test passageway, syringe and waste solution emission components. The ISE module is mainly used for testing the concentration of Na^+ ion, K^+ ion and CL^- ion which included in serum, plasma and diluted urine. The working principle is the method of indirect ion-selective electrode.

1.7.2 Sample barcode scanning system

The sample barcode scanning system is located on the right of sample tray. Only the sample position of outer track supports the scanning function but inner track does not. The sample barcode scanning system consists of three parts as follows:

a) Sample barcode scanner
b) Barcode label
c) Hardware and software which controls barcode scanning

The scanning system will scan the barcode of the sample tube automatically when the sample tube is placed on the sample tray, and then the sample information is displayed on the screen.

Table 1-2 Parameter and requirements of sample barcode

Item	Description
Support barcode system	Codabar,Code128,Code39,UPC/EAN,Code93 and interleaved 2 of 5
Precision of barcode	0.2mm to 0.5mm
Barcode digit	3 to 27
format and content of barcode	Setup by user
width of maximum barcode label	55mm
height of minimum barcode	10mm
Gradient of maximum barcode	±5°
Printing quality	Not less than C level（ANSI MH10.8M）
Width to narrow ratio	2.5 to 3.0:1
Printing paper	Coated paper or paper surface polishing. Since the normal paper can use for printing, but the quality is not guaranteed. So it is not recommended to use normal paper.
Barcode character	The significant character will be printed, and it is recommended to use number 0 to 9 and capital letter A to Z.

1.7.3 Reagent barcode scanning system

The reagent barcode scanning system is located on the right of reagent tray, which mainly consists of three components as follows:

a) Reagent barcode scanner
b) Barcode label
c) Hardware and software which controls barcode scanning

The scanning system will scan the barcode of the reagent bottle automatically when the bottle is placed on the reagent tray, and then the reagent information is displayed on the screen.

1.8 Operational software

The operational part is a computer which is installed automatic chemistry software. The computer controls the operation of analyzer and display analysis result. The operational software includes administration procedure and test procedure. The administration procedure is used for editing parameter, applying test; and test procedure is used for calibration, QC and routine sample test. The operational software should be installed on a computer which is applying with the allocation to

ensure the analyzer in normal motion state.

Note

Computer is a part of analyzing system. User can buy according to the needs. Please refer to chapter 1.1 for detail allocation of computer.

1.8.1 Main interface

The main interface is shown as figure 1.8.1.

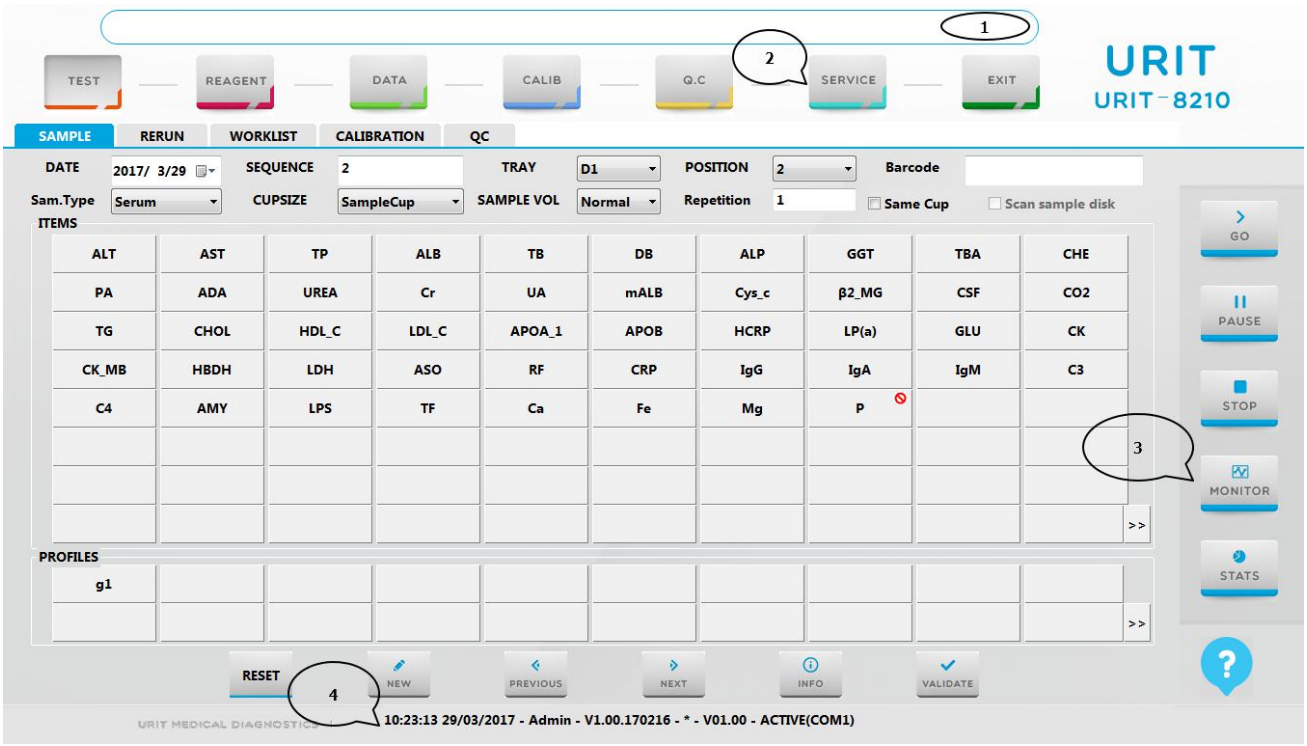


Figure 1.8.1 Main interface

1. Warning information prompt box:

The prompt information will be shown in the box if there are any abnormal. Click relative picture and know more about warning information.

2. Module button

There are six module buttons on the main interface. They are test, reagent, data, calibration, QC and service. Click the corresponding button to operate.

3. Buttons of test operation

1) **GO**: when there are test items in the test list, clicks GO button to begin test.

2) **PAUSE**: click the button to stop test if you need; and click the button again to begin the test if it could continue.

3) **STOP**: click the button to stop test.

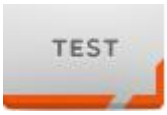
4) **MONITOR**: click the button to enter to monitoring interface.

5) **STAT**: click the button if it is needs to do an emergent test.

4. Login prompt: there are four parts, system time, user, version and system status.

1.8.2 Function of module button

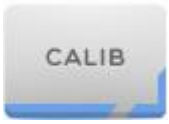
The module buttons include six as follows:



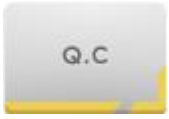
: There are five interfaces could be opened. They are sample, retest, work list, calibration and QC. It is used for the test of routine item, calibration item, QC item, retest and patient's information registration.

: click the button to set reagent position, type, lot number, valid time, etc. It's also could scan the reagent and sample barcode, and check the reagent allowance.

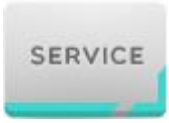
: There are three main selections in the data interface. They are result, historical and financial. The test result and reaction curve could be check in the interface. And the financial interface could be set, test time and reagent volume and cost could be statistics.



: There are four interfaces, calibration solution setup, calibration factor list, calibration history and multiple standard value setups. It is used for setup parameter of calibration solution, check calibration result and curve, and setup historical interface; Furthermore, it can check the historical calibration parameter information. The multiple standard interface is used for check the information and curve of multi point item.



: includes QC solution setup, QC result and QC diagram analysis interfaces. It is mainly used for setup parameter of QC solution, to check QC result and curve; and QC diagram analysis interface is used for check and compare the QC information.

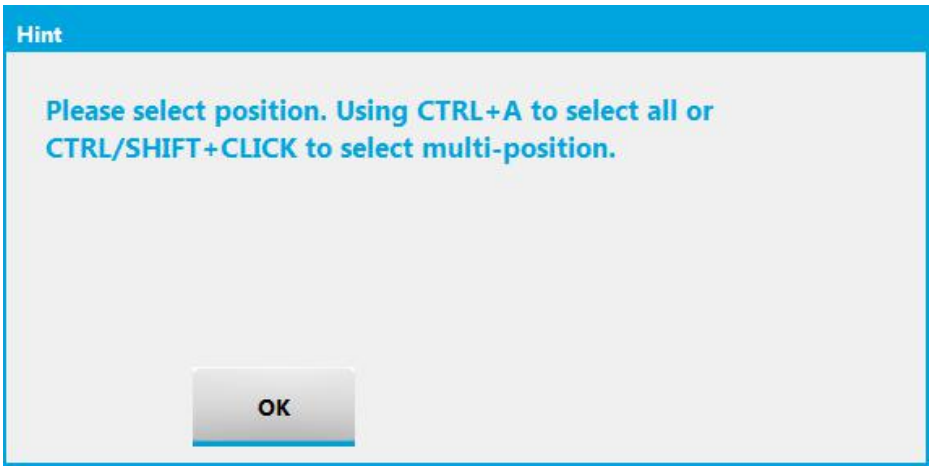


: includes parameters, customization, maintenance, register and login/out interfaces. Click parameter icon to setup parameter of routine item, manual item, combined item, calculated item and print consequence. Customization interface is mainly used for setup system parameter, and maintenance interface is used for doing maintaining operations.

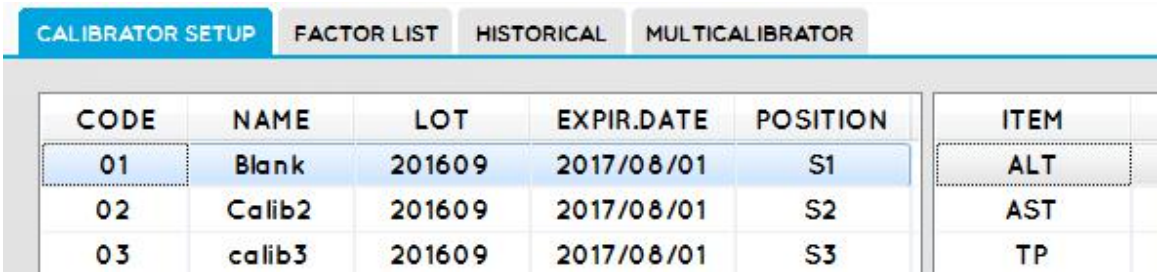
: include log off and exit software.

1.8.3 Elements of common interface

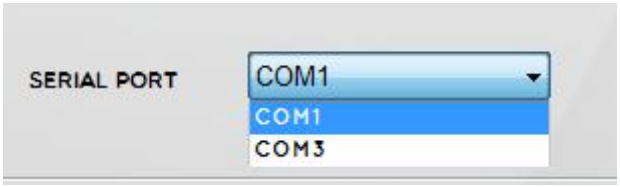
1. Dialogue box: it is a common interface to complete a human-computer interaction. Such as follows:



2. Tab: click a tab to changing-over the shown contents. Such as follows:

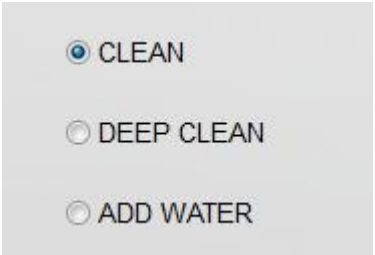


3. Drop down list: click the arrow tip on the right of drop down list and select you need. Such as follows:



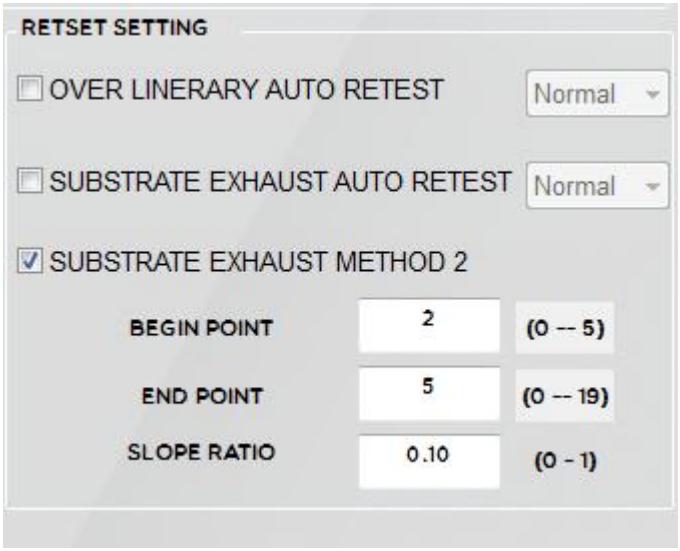
4. Buttons: the function of button is to open a dialogue box or execute a function which has been definition. Click a button to do corresponding operation. Such as follows:

5. Radio button: Only one item could be select in a group, which called as radio button. Such as follows:

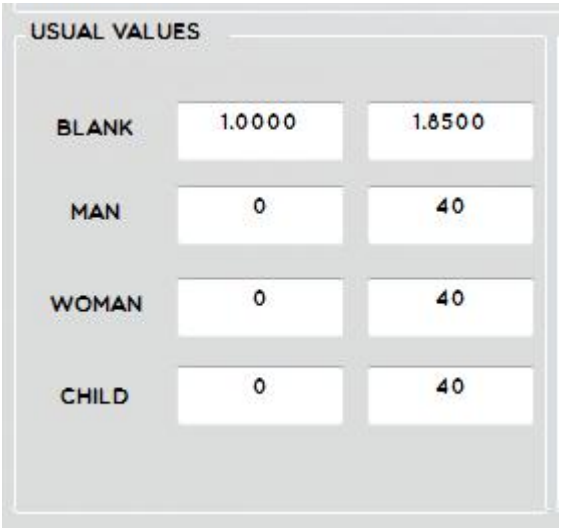


6. Check box: It can select one or more item in a group button, which called as check box. Such as

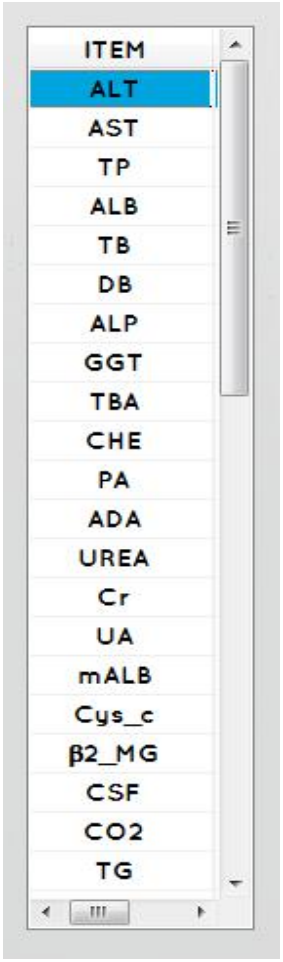
follows:



7. Editable box: It accepts and displays the character which is input by users. Such as follows:



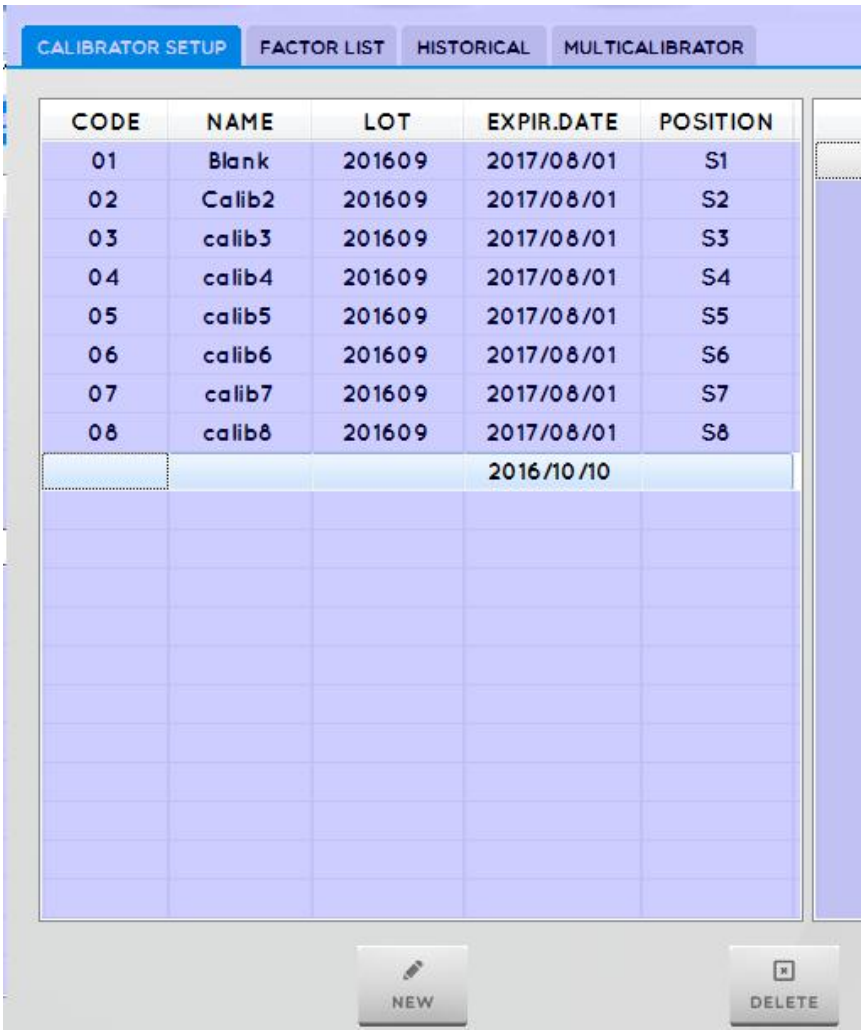
8. Scroll bar: if the contents displayed exceed size, the scroll bar will occur. Such as follows:



9. Table: it is allowed to edit the table. When the table is in editable state, the color is translucent. Such as follow:

CODE	NAME	LOT	EXPIR.DATE	POSITION
01	Blank	201609	2017/08/01	S1
02	Calib2	201609	2017/08/01	S2
03	calib3	201609	2017/08/01	S3
04	calib4	201609	2017/08/01	S4
05	calib5	201609	2017/08/01	S5
06	calib6	201609	2017/08/01	S6
07	calib7	201609	2017/08/01	S7
08	calib8	201609	2017/08/01	S8

And if it is needs to build a new line, click focus in the table and then click **New** button. Such as follows:


CALIBRATOR SETUP
FACTOR LIST
HISTORICAL
MULTICALIBRATOR
CODE
NAME
LOT
EXPIR.DATE
POSITION
01
Blank
201609
2017/08/01
S1
02
Calib2
201609
2017/08/01
S2
03
calib3
201609
2017/08/01
S3
04
calib4
201609
2017/08/01
S4
05
calib5
201609
2017/08/01
S5
06
calib6
201609
2017/08/01
S6
07
calib7
201609
2017/08/01
S7
08
calib8
201609
2017/08/01
S8
2016/10/10
NEW
DELETE

CHAPTER 2 INSTALLATION

CAUTION

Only the technicians of URIT can install the instrument.

Only the URIT technicians can install the instrument, users shall make preparation for satisfying the installation requirements in accordance with this manual. If relocation is necessary, please contact your local distributor or URIT.

2.1 Instrument inspection

Please check the carton according to the following procedures:

1) Carefully unpack the package and take out the Automatic Chemistry Analyzer and the accessories.
2) Inspect the instrument and accessories for quantity and visible signs of damage according to the accompanying Packing List.
3) Contact distributor or manufacturer immediately if there is any loss or damage.

2.2 Installation requirement

NOTE

The instrument is high sophisticated thus proper installation is very important to its performance. User should ensure the environment and electrical condition is complying with the recommended conditions as follows.

2.2.1 Installment environment

1) Indoor use only
2) Keep away from direct sunlight
3) Dust free
4) Installed on horizontal ground
5) Ground load capacity: 500kg
6) Atmosphere Pressure: 79kPa to 106kPa
7) No corrosive and flammable substance indoor
8) Room temperature: keep in the range of 15℃ to 30℃
9) Relative Humility:40% to 85%
   If the temperature and humidity exceed ranges, the accuracy of result cannot be ensured.
10) Good ventilation does not face air conditioner.
11) No obvious vibration.
12) Keep away from electromagnetic field and electricity interruption.
13) The instrument should be near to the power.

14) Time requirements: when move the instrument from outdoor to indoor, standby the instrument for 8 hours before turning on if the temperature range exceed 10℃ to avoid condensation.

2.2.2 Power requirements

The following power must be prepared; switchboard should be located within 10m.

1) Power

AC 230V, 50/60Hz, 850VA

2) Grounding

Adapt to local power needs, using three-pin power plug

3) Plug board

A 20A output plug board with more than three 5A sockets. Heavy-duty devices should not share the plug board with the instrument, such as refrigerator, air conditioner etc.

4) 3 core power cable cat is using; the type of wire and plug is depended on voltage.

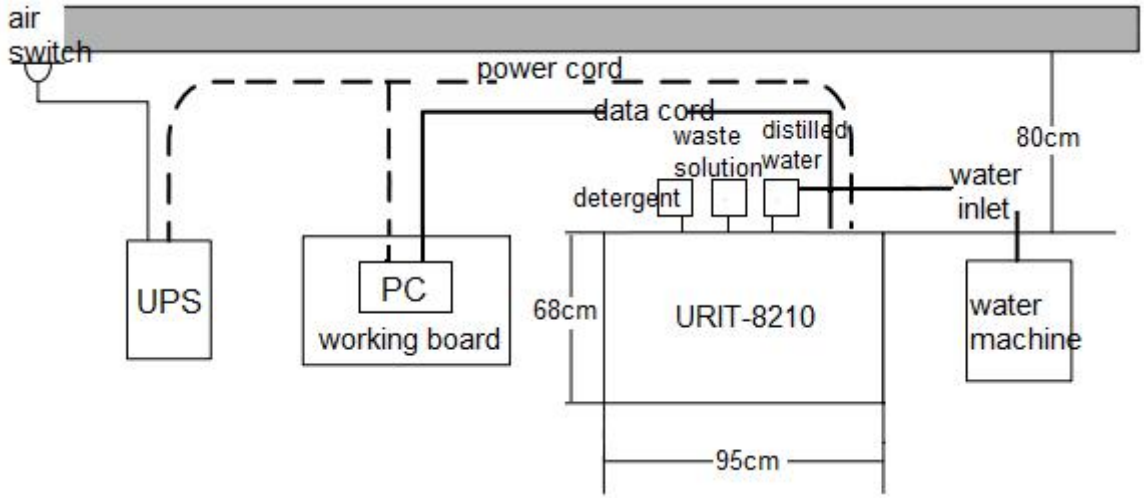
Warning

Make sure the instrument is grounded properly. Poor grounding may cause bad effects on test result and even damage to the instrument.

User should prepare a uninterrupted power supply which power is 3000W or above to avoid interruption and fluctuation from other power to prevent instrument damage.

2.2.3 Location requirements

The instrument installation layout is below. Surrounding distance is the recommended maintenance space.



Instrument Dimension: 95cm×68cm×111cm (L×W×H)

Dimension of Operating Board (Only for reference): 70cm×50cm×80cm (L×W×H)

2.3 Instrument connection

Caution

Please connect the instrument under the instruction of URIT service engineer or the personnel authorized by URIT.

After the instrument was installed, it is needs to connect the power line, communication line, flow path tubes to run properly.

2.3.1 Connect the power line and communication line

1) Take out the power line, one end insert into the power interface of instrument, the other end connected to the power.
2) Using the communication line which provided by URIT for connection. One end connects to the COM serial port of computer; the other end connects to the RS232 serial port of instrument. And please tighten by the screws.

Caution

When connect the communication line, please turn off the instrument power first.

2.3.2 Connect the liquid path

Biological Hazard

1) Do not touch the solution when dispose the waste solution and to see a doctor if the waste solution splash to eyes.
2) Disposing the waste solution according to the local regulations..

Please correctly connect the liquid path tubes after the instrument connection has been completed.

2.3.2.1 Connect the distilled water bucket

1) Filled the bucket with distilled water;
2) Take out the distilled water tube from the accessory kit, one end connected to the distilled water interface of the instrument, the other end connected to distilled water bucket;
3) Take out the BNC wire from the accessory kit, one end connected to the distilled water BNC interface of the instrument, the other end connected to the BNC interface of the distilled water bucket.

2.3.2.2 Connect the waste solution bucket

1) Take out the waste solution tube（big size）from the accessory kit, one end connected to the waste solution interface of the instrument, the other end insert into the waste solution bucket;
2) Take out the waste solution tube（small size）from the accessory kit, one end connected to the

waste solution interface of the instrument, the other end connect to waste solution bucket.

3) Take out the BNC wire from the accessory kit, one piece connected the waste solution BNC interface of the instrument and bucket; another piece connected the BNC interface of the waste solution BNC interface of bucket.

NOTE

1) After complete the connection of liquid path tubes, please do not start the instrument until filled the distilled water.
2) The outlet of waste solution tube（big size）should below the instrument water outlet.

2.3.2.3 Connect the detergent bucket

1) Filled the bucket with detergent;
2) Take out the detergent tube from the accessory kit, one end connected to the detergent interface of the instrument, the other end connected to detergent bucket;
3) Take out the BNC wire from the accessory kit, one end connected to the detergent BNC interface of the instrument, the other end connected to the BNC interface of the detergent bucket.

2.3.3 Connect the printer

1) Confirm the computer of operation department has installed the printer driver;
2) Connect the printer to analyzer by right data cable;
3) Place printing paper.

Note

Please install the printer type which supported by computer operating system.

CHAPTER 3 DETAILED FUNCTION DESCRIPTION of SYSTEM

System includes six main buttons; they are test, reagent, data, calibration, QC and service.

3.1 Detailed description of module function

3.1.1 Software registration (Do the following steps after software installation)

1. Click **Service** icon.
2. Click **Register** icon, and the register interface will display. (The interface will display when it is the first time to login)

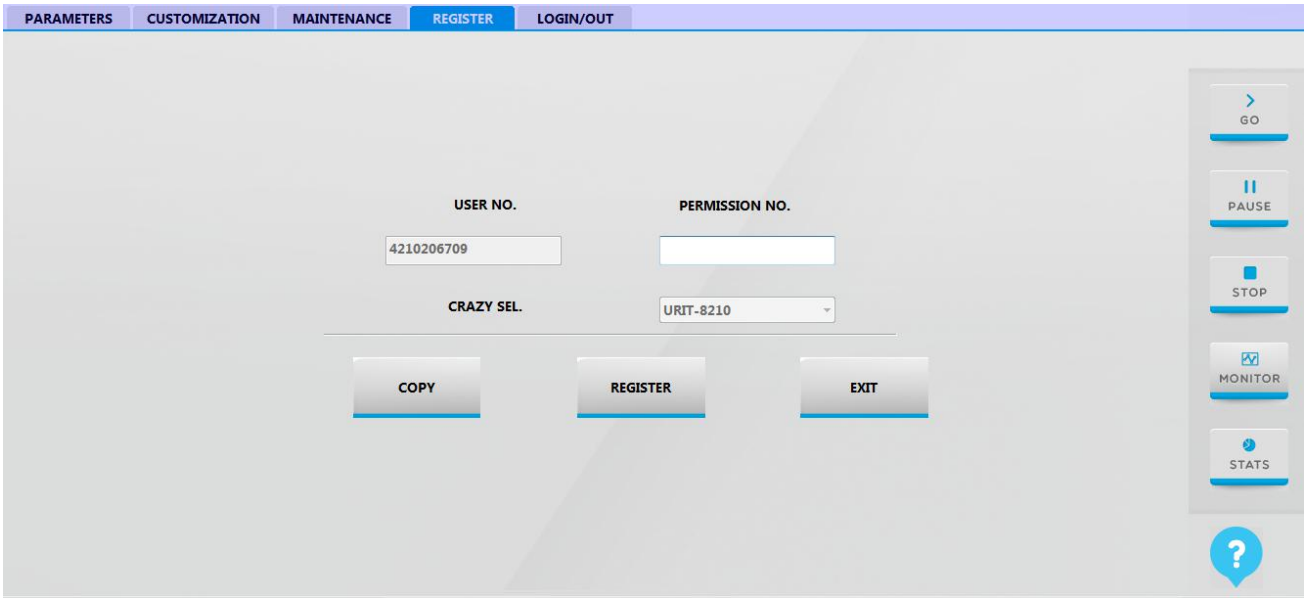


Figure 3.1.1 Registration interface

3. Provide the user No. to the software agency to get permission No.
4. Input the permission No. and click register.

3.1.2 Login

1. Click **Service** icon.
2. Click **Logout** icon, the login interface will display.
3. Input the name and password, then click login.

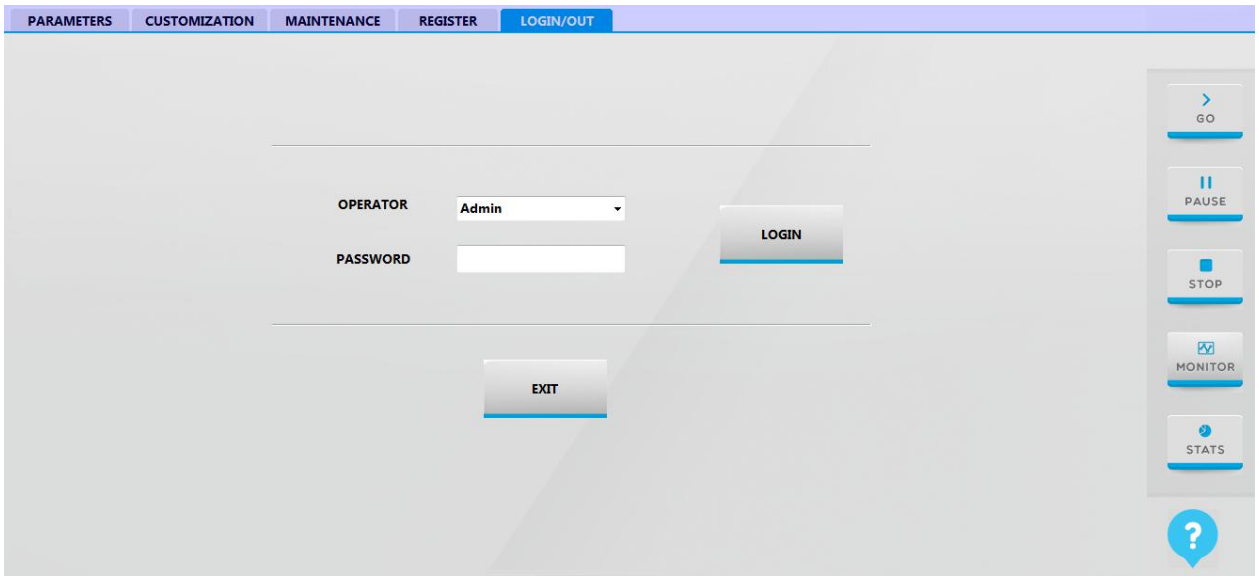


Figure3.1.2 Login interface

4. Click logout to exit system.

3.1.3 Parameter setup

Parameter setup includes routine item setup, manual item setup, combined item setup, calculated item setup and item display and print consequence setup.

1) Click **Service** icon.

2) Click **Parameter** to enter the interface.

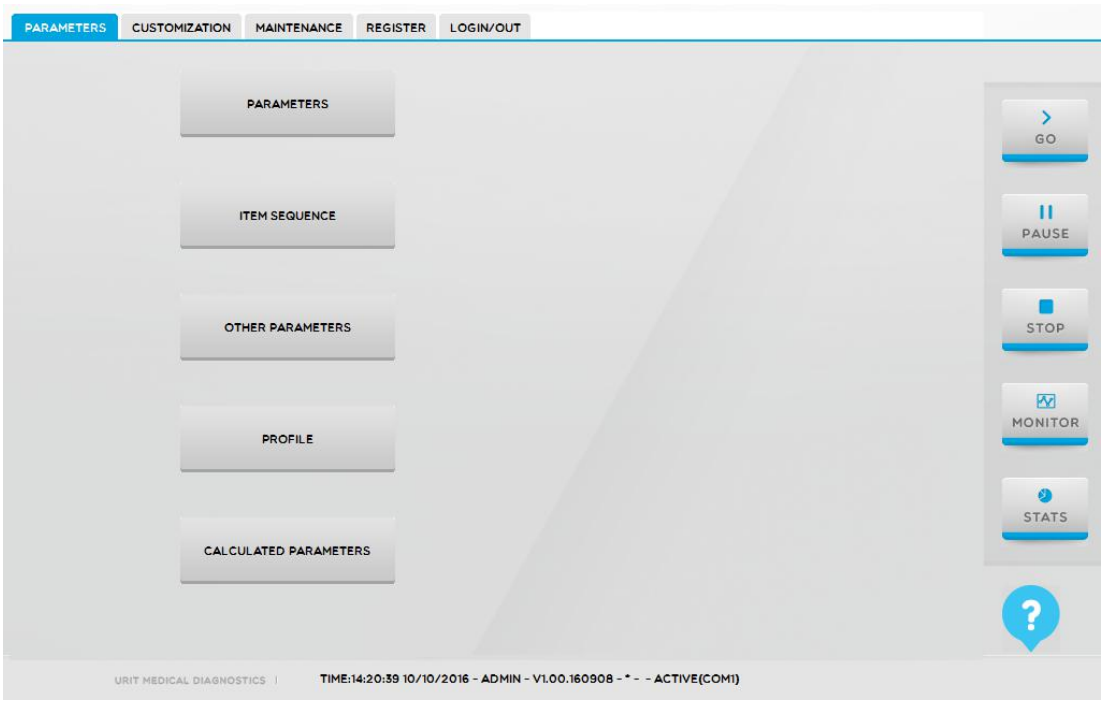


Figure 3.1.3 Parameter setup

3.1.3.1 Routine item setup

Click **Parameter** icon and dialogue box will pop up. User can click **OK** to enter the interface and not

need to input password.

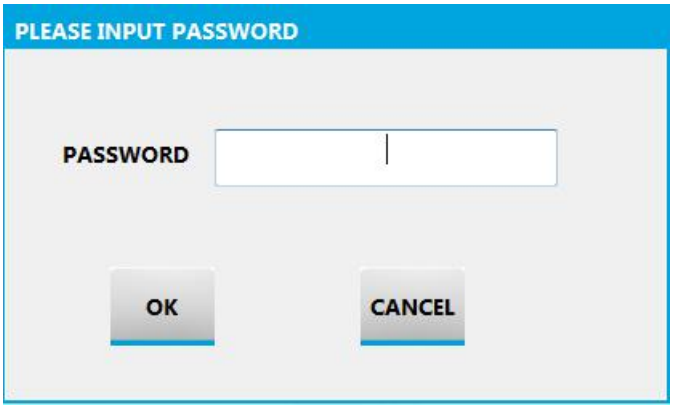


Figure 3.1.3.1-1 Password test interface

NOTE

1) The parameter of routine item is default to close, and user only can modify some basic parameter. Please contact URIT if you need to modify or add new item parameter.
2) This chapter is for reagent open state.

There are two interfaces for setup routine item parameter.

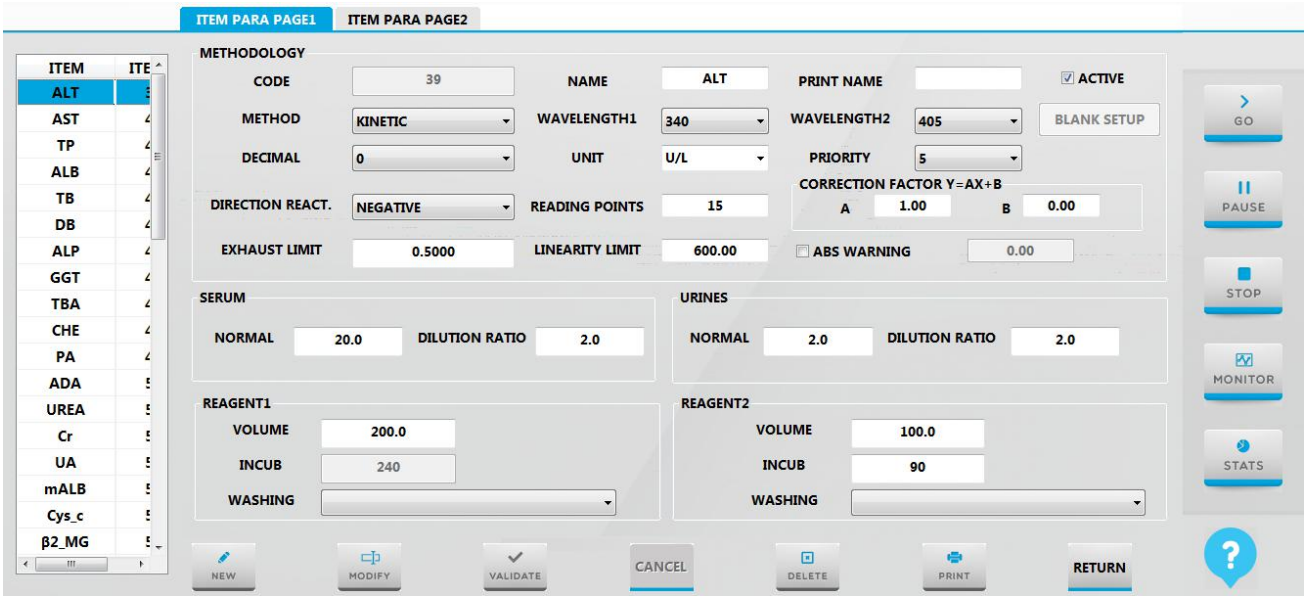


Figure 3.1.3.1-2 Item parameter page 1

1) Item list: the list displays all the routine item of the system.

Basic operation:

1) Click any one cell: cancel a routine item which is selected before, then select an item in the cell, the interface will display the information of this routine item.
2) Select a cell and press **[SHIFT]** key, then select another cell: to select a cell, then press **[SHIFT]** key, and click another cell, the cells all between the before one and another one will be selected. And the information of these items will display.
3) Select a cell and press **[control]** key, then select another cell: the item will not be cancel which

selected before press **[control]** key, and the another cell will be selected. The information of the two items will display.

Note: The basic operations of the table are as the above, and not introduce more if there is no any other operation.

2) Item parameter page 1

The meaning of the parameters displays in this interface is as follow:

1) Code

Code consists of number and not allow repeat, a new code is one big than the max code.

2) Name

Not allow repeat and not need to case-insensitive and allow inputting number, letters and underline.

3) Printing name

The name of item when printing, it's could explain further.

4) Active

Only to click the table, the selected item can be displayed in the interface and can be test.

5) Method

It is the method to analyze result. The methods include endpoint, kinetic, 2-point endpoint and 2-point kinetic. Please refer to chapter 5.2 for the detail introduction of these methods.

6) Wavelength 1

The wavelength 1 is the main wavelength, which is used for test the absorbance of reaction product according to the absorb characteristics of the product.

7) Wavelength 2

Wavelength 2 is the sub wavelength, which is used for eliminate the interference from other object to main wavelength. Such as flicker of light source, drift and cuvette scratch. The selection of sub wavelength is the same as main. When choose the wavelength, please attention the sub one should not the same as main one, if the sub one is NONE, the analyze method is single-wavelength method.

8) Blank setup

There are two ways to setup blank reading point; they are normal modes and advanced mode. The normal mode is the permanent point, and for advanced mode, it is need to confirm the original point and end point accord to the reaction curve of immune reagents project. The advanced mode only can use under end-point method. Please refer to chapter 7.1 for more information about blank setup.

9) Unit

The unit of item result. The following table lists some common use unit of item results.

Table 3-1 Unit of item result

No.	Unit	English name
1	%	Percent

2	g/dL	Grams per deciliter
3	g/L	Grams per liter
4	IU/mL	International units per milliliter
5	mg/dL	Milligrams per deciliter
6	mg/L	Milligrams per liter
7	mmol/L	Millimoles per liter
8	U/L	Units per liter
9	Umol/L	Micromoles per liter

10) Decimal place:

To select the test result should keep how many places of decimal, can be set up 0~4 decimal places.

11) Correction factor:

It is used for item standard factor correction. Correction factors including slope and intercept, when the QC test result of an item appears overall small amount deviation, the correction factors are the compensation factors for system to do compensation calculating. After test, the system will automatically use the correction factors according to the following formula for correcting test result:

$y = ax + b$.

x is the test result before correction;

y is the test result after correction;

a is the correction slope;

b is the correction intercept.

12) Reaction direction:

Absorbance is increase or decrease during the reaction process. Reaction direction can only be set under the test method of rate method, including positive reaction and side reaction.

Positive reaction: Absorbance is increasing with the extension of time.

Side reaction: Absorbance is decreasing with the extension of time.

13) Substrate exhaustion:

Substrate exhaustion is only effect on rate method.

Substrate exhaustion does not means the substrate in reaction solution has been used up, because the enzymatic reaction is reversible, even if the reaction is achieve a balance, but according to different equilibrium constants, there will have different proportions of substrate to retain in the reaction solution. That is to say, when test the initial speed in enzymic catalytic reaction, the substrate is in a state of excess. For the specific introduction, please refer to chapter **7.2 substrate exhaustion**.

14) Test priority:

When measuring multiple items of the same sample, the system will first test the item with high

priority. Options includes: PRI_1 to PRI_36 and the priority level is gradually reduced. PRI_1 has the highest priority will be first tested. So like that, PRI_36 has the lowest priority will be last tested.

15) Measuring point:

The point is read continuously during the absorbance test after incubation.

16) Linear range of reagent

The linear range is range between the result and degree of reaction (the degree of reaction means the absorbance of reaction solution and absorbance change rate), which indicate the measurable range. The linear range is setup by users according to reagent instruction, system will mark the result which is exceed the linear range automatically and definite it as non-linear.

17) Absorbance alarm

To setup absorbance range, and system will alarm automatically when the absorbance value exceed the range. The absorbance range is -4.0 to 5.0.

18) Sample volume

The sample volume includes serum, blood plasma and urine.

Volume: it is the volume which is needed to add to cuvette during a test.

Pre-diluted times: it is the times diluted in a sample test.

19) Reagent volume:

Reagent volume is the volume which is needed to add to cuvette during a test. It is includes R1 volume and R2 volume. Please accord to reagent instruction to setup reagent volume.

20) Incubation time:

It is the time begins with mixture of reagent and sample to the end of reaction in the end point test. And it is the time from choosing the first absorbance point until to choose the second point in the two point test. It is need to setup two reagents incubation time in the dual-reagent test. Please accord to reagent instruction or laboratory file to setup.

21) Cleaning before or after the test:

For serious pollution item test, you should use detergent to rinse the sample probe and reagent probe before or after the test. For reagent 1, rinse after test; for reagent 2, rinse before or after test, or rinse before and after test.

3) Item parameter page 2

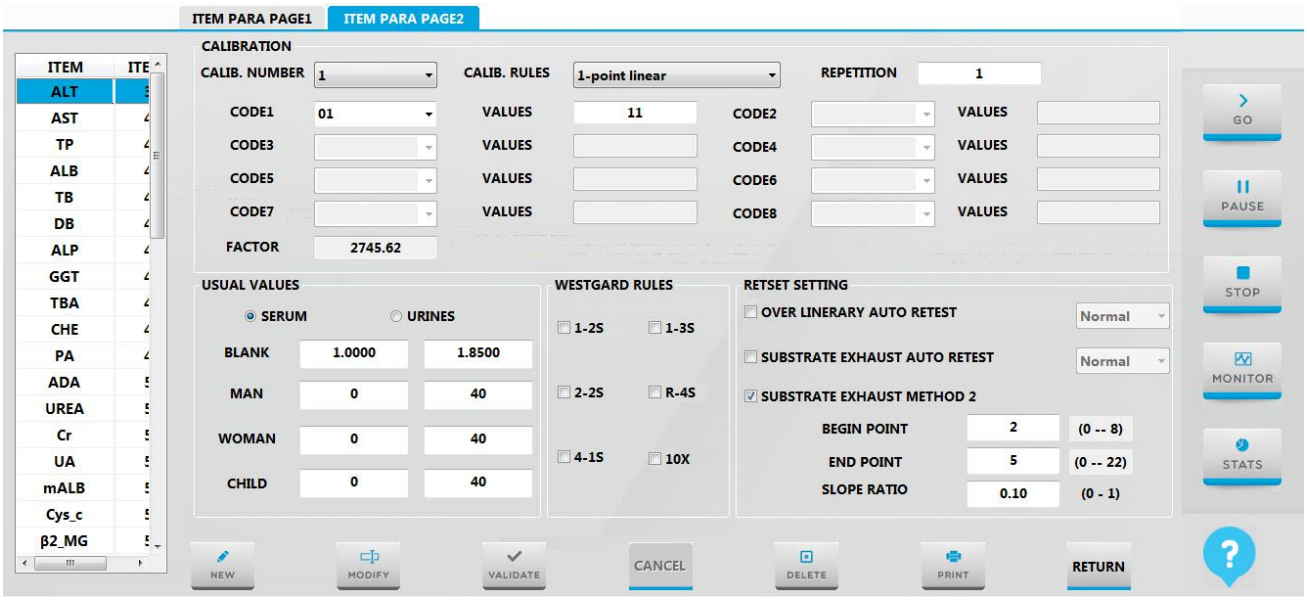


Figure 3.1.3.1-3 Item parameter page 2

The interface displays the calibration, normal value information of routine item. The definition of each parameter is as follows:

1) Standard quantity: it is to set quantity of standard.

One item can set 8 calibration solutions at most.

The number of calibration solution should correspond with calibration method. Such as follows:

Table 4-3 Calibration method and standard quantity

Calibration method	Standard number
Single point linear	N=1
Two point linear	N=2
Multiple point linear	3≤N≤8
Parabola	N=3
Broken line	3≤N≤8
Logistic-Log 4P	4≤N≤8
Logistic-Log 5P	5≤N≤8
Exponential 5P	5≤N≤8
Spline	3≤N≤8
Weibull	3≤N≤8

2) Calibration rules

The calibration rules include single-point linear, multi-point linear, two-point linear, broken line, Spline, Logistic-Log 4P and Logistic-Log 5P, etc. Please refer to 5.5 for details.

3) Repeat times

It is the time of calibration solution test.

4) Calibration solution

It is the number of calibration solution, and corresponds with the interface displayed.

5) Calibration value

It is the concentration value of calibration solution.

6) Standard factor

Standard factor is the K value too; system will modify the standard factor after test. And user could input the factor manually accord to the reagent instruction. The item is not need to calibrate if input the standard factor; otherwise it is must to calibrate.

NOTE

The setup of standard factor is only for single-point test, and not suitable for other calibration method.

7) Normal value

It is the value of each item of different age range and sex. Reference range is the concentration range of normal sample, includes serum and urine. If the result exceeds range, that means the patient is not in good health status. Or if the result out of range, system will mark with character H when exceed highest, and mark L when exceed lowest. This phenomenon includes cuvette blank, women and children.

8) QC rules

QC rules include 1-2DS, 1-3DS, 2-2DS, 1-4DS, 4-1DS and 10X, etc. Please refer to chapter 5.6 for more details.

9) Retest setup

Superlinear auto retest:

When the result exceeds linear range, system will prompt whether need to retest or not.

Select the check box and the item will be retest which linear range is exceeded.

Substrate depletion retest:

When substrate depletion is occurred, system will prompt whether need to retest or not.

Select the check box and the item will be retest which occurs substrate depletion.

NOTE

It's must to retest if the substrate depletion is occurred.

The other way to judge substrate depletion: the way is only apply to rate method, please refer to chapter 7.2.3 for more information.

4) Basic buttons

[New] button: in non-editable mode, click **New** button, the item number, item name and print name will be clear up, in which the value of item number is one more than the routine item. Enter to editable mode, to input basic information of the new routine item.

[Modify] button: click **Modify** button to modify the basic information of current routine item.

[Delete] button: in non-editable mode, click **Delete** button, the current routine item will be delete. The interface of routine item will renovate after deleting successfully.

[Print] button: select the routine item in the list (select one or more), click **Print** button, the consequence of the selected item will be printed.

[Validate] button: click the button in editable mode, the basic information of routine item will be save, and mode return to non-editable. (The interface will renovate of the routine item)

[**Cancel**] button: click the button in editable mode, and the current editable content will be cancel and return to non-editable mode.

3.1.3.1.1 Add a new routine item

1) Click **New** button and add a new blank box.
2) Input the basic parameter of new item.
3) Click **Validate** icon to save the current information.

3.1.3.1.2 Modify routine item

1) Select arbitrary item to enter the interface.
2) Click **Modify** button to enter editable mode.
3) Modify the parameter according the needs.
4) Click **Validate** button to save the current information.

3.1.3.1.3 Delete routine item

1) Take out the reagent of the item which will be deleting.
2) Select the item which is needed to delete in the list.
3) Click **Delete** button to delete the selected item.

3.1.3.2 Instruction of item sequence interface

In the item sequence interface, the sequence of all items can be setup. Click **item sequence** in the service interface.

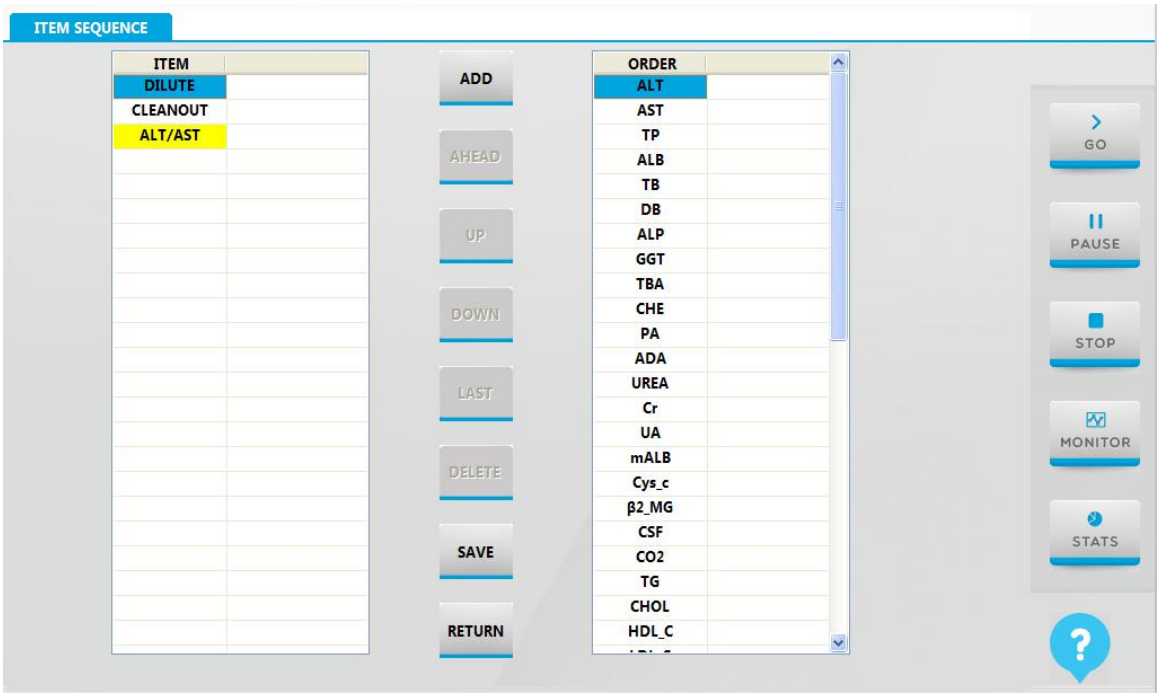


Figure 3.1.3.2 Item sequence interface

1) **Item list:** all the items will display in the list.

2) **Basic buttons:**

[ADD]: select an arbitrary item and click **Add**, the item will be added to sequence list and seated at last. (It cannot be added if the item has existed.)

[Ahead]: select an item and click **Ahead** button, the sequence of this item will one ahead in the sequence list.

[Up]: select an item in the list, click **Up** button, the sequence of this item will step one ahead in the item list.

[Down]: select an item in the list, click **Down** button, the sequence of this item will step one back in the list.

[Last]: select an item in the sequence list, click **Last** button, the sequence of this item will back to last.

[Delete]: select an item in the list, click **Delete** button, the item will be deleting.

[Save]: click the button, the sequence will be saved and the interface will be renovated.

[Return]: click the button to return to the forward menu.

3.1.3.3 Instruction of other parameter interface

Other parameter interface is mainly for setup information of manual item.

Manual item is the item could not be test by analyzer directly, but the result of manual item will be printed together with other item. Or use our analyzer to print the result which analyze by other instrument.

Click **Other parameters** to enter the interface.

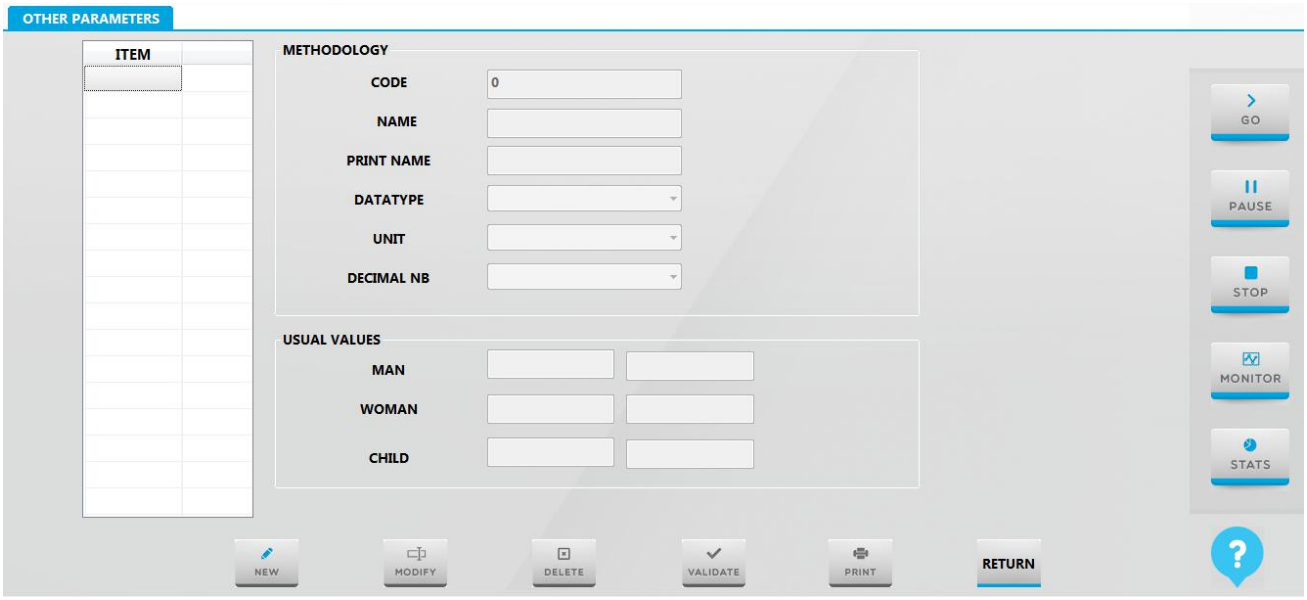


Figure 3.1.3.3 Manual item setup interface

1) Manual item list: the list displays all manual items.
2) Basic information of manual item: its displays the basic information of manual item. The basic information are as follows:
   a) Code: the code of manual item and created automatically and not allow repeating, the code number range is 90000 to 99999.
   b) Name: the name of manual item and not allow repeating.
   c) Print name: the name displays when printing.
   d) Data type: include value type and character type. The unit, decimal place, normal low value and normal high value could be selected in value type; and in character type, the result is input as character, such as +,-, negative and positive.
   e) Unit: it is the unit of manual item.
   f) Decimal place: it is the decimal place of manual item, from 0 to 5.
   g) Normal value: it is used for
3) Basic button

[New] button: click the button in non-editable mode, all data will clear up, and enter to editable mode to add new manual item. (The code should in the range of 90000 to 99999).

[Modify] button: click the button to enter editable mode, and modify the information of current manual item.

[Delete] button: click the button to delete the current manual item in non-editable mode. (The interface will renovate after delete successfully)

[Print] button: select an item in the list (it is allow to select one or more) and click **Print** button, all the sequence of the selected item will be printing.

[Validate] button: click the button in editable mode to save or cancel save the information of current

manual item, then return to non-editable mode. (the interface will be renovate after renew successfully)

[Return]: click the button to return to forward menu.

3.1.3.3.1 Add new manual item

1) Click **New** button to add a new blank box.
2) Input code, name and print name of manual item.
3) Select data type, if you select value type, please input unit, decimal place, normal low value and normal high value too.
4) Click **Validate** to complete setup.

3.1.3.3.2 Modify manual item

1) Select manual item in the list which is need to modify.
2) Click **Modify** button.
3) Modify the information.
4) Click **Validate** button to complete setup.

3.1.3.3.3 Delete manual item

1) To select manual item in the list.
2) Click **Delete** button to delete the item.

3.1.3.4 Instruction of profile item setup

To combine relative items together, the combined items with clear clinical significance. Such as liver function, renal function, etc. And it is also convenient for user to apply test rapidly.

Combined item is consisting of chemical items, but not include calculated items and ISE items. Only the user with special authority can setup, modify and delete the combined item.

Click Profile in service interface to enter combined item interface as follows:

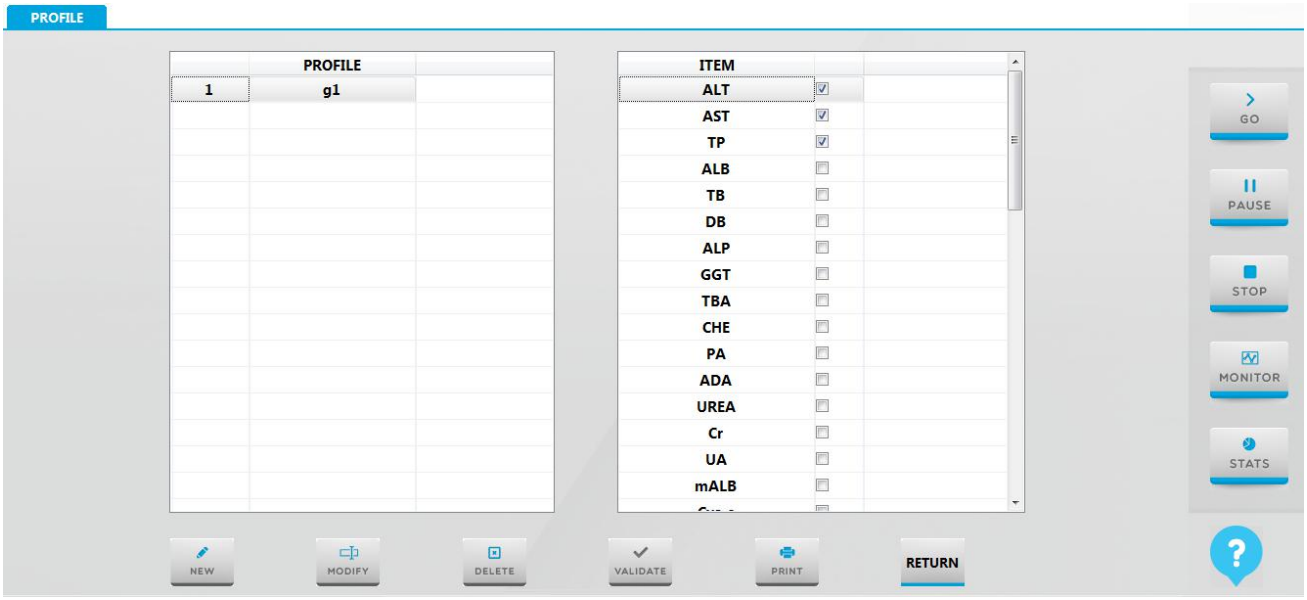


Figure 3.1.3.4 Combined item setup interface

1. Combined item list: its display all combined items.
2. Combined item information list: its display the information of relative combined item.

   Basic operation:

   a) In editable mode, select arbitrary item and click check box: [click/unclick] the item.

   b) In editable mode, select some items, click arbitrary check box: [click/unclick] all the items.
3. Basic buttons:

[New] button: click the button to reset all data of combined item in editable mode, and add new combined item.

[Modify] button: click the button to modify the name and other information of current combined item.

[Delete] button: click the button to delete the selected combined item in non-editable mode.

[Print] button: select one or more combined item and click Print, the sequence of all items which is selected will be printing.

[Validate]: click the button to save or cancel save the information of current combined item and return to non-editable mode. (The interface will be renovate after renew successfully)

[Return]: click the button to return to forward menu.

3.1.3.4.1 Add new combined item

1) Click **New** button and add a new blank box.
2) Input name of combined item.
3) Select the items which are need to combine.
4) Click **Validate** and complete combined.

3.1.3.4.2 Modify combined item

1) Select the combined item which is needed to modify.
2) Click **Modify** to enter editable mode.
3) Re-select items which are needed to combine.
4) Click **Validate** button to complete modify.

3.1.3.4.3 Delete combined item

1) Select combined item which is need to delete.
2) Click **Delete** to delete the combined item.

3.1.3.5 Instruction of calculated item interface

Calculated item is the item which calculated from different items and with clinical significance, such as A/G, ALT/AST, etc. It is an indirect test item.

Calculated item is combined with item, calculated symbol and calculated relationship, which combined to a special calculated formula. Only the user who with special authority can setup, modify and delete calculated item.

Calculated item is not test, and not need to calibration and QC test. The result of calculated item is calculated by formula and item result.

Click **calculated item** in service interface to enter as follows:

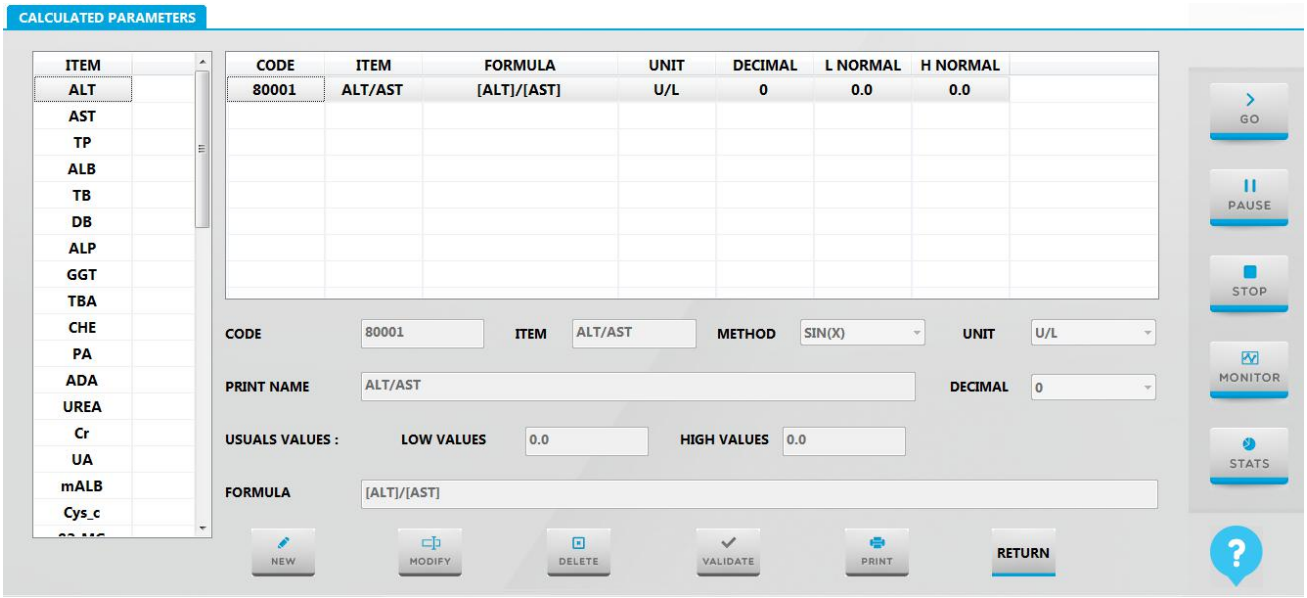


Figure 3.1.3.5 Interface of calculated item

1. Calculated item list: to display all calculated items.
2. Basic information of calculated items: to display basic information of calculated items and

formula.

1) Code: the code of calculated item, created automatically and not allow repeating, the code range is from 80000 to 89999.
2) Item: name of calculated item.
3) Formula: used for calculated item.
4) Unit: unit of calculated item.
5) Print name: name displays when printing to explain the calculated item further.
6) Decimal place: decimal place of result, from o to 4.
7) Normal use value:
    a) Normal low value: it is used for calculated the minimum value of calculated item in the range.
    b) Normal high value: it is used for calculated the maximum value of calculated item in the range.
8) Formula: it is used for calculated result. Select arbitrary item in the list, the editable box will display the item.

3. Normal item list: to display all normal items.
4. Basic buttons:

[New] button: click the button to reset information of calculated item in non-editable mode, and enter to editable mode to add new calculated item.

[Modify] button: click the button to modify the basic information of calculated item and formula.

[Delete] button: click the button to delete the selected calculated item. (The interface will renovate after deleting successfully)

[Print] button: select one or more calculated items and click **Print** button, the sequence of all selected item will be printing.

[Validate] button: click the button to save or cancel the basic information of current calculated item. (The interface will renovate after validate successfully)

[Return]: click the button to return to forward menu.

3.1.3.5.1 Add calculated item

1) Click **New** to add a new blank box.
2) Input basic information of calculated item.
3) Click **Validate** button to complete.

3.1.3.5.2 Modify calculated item

1) Select item which is need to modify
2) Click **Modify** and enter to editable mode.

3) Input basic information of calculated item.
4) Click **Validate** button to complete modify.

3.1.3.5.3 Delete the calculated item

1) Select an item in the list which is needed to delete.
2) Click Delete button to delete.

3.1.4 Customization

It is mainly includes users, general settings, print format, print order, dictionary, communication settings and Lis settings.

Click Service button and then click Customization button to enter the interface as follows:

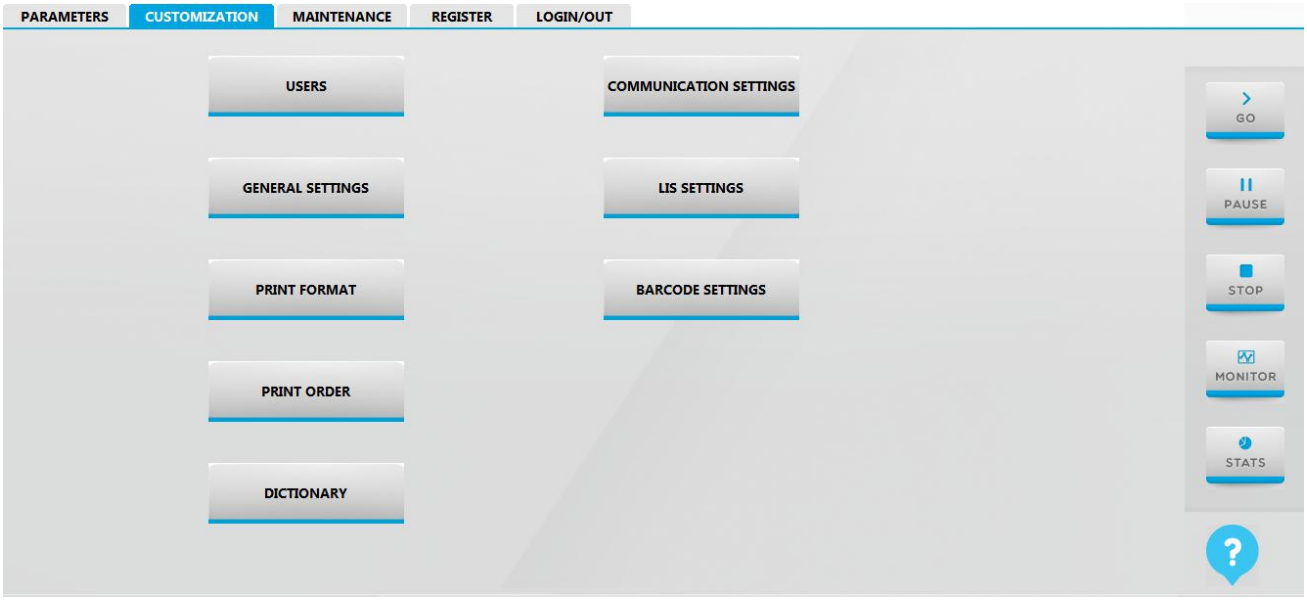


Figure 3.1.4 Customization interface

3.1.4.1 Instruction of user interface

The user interface is mainly used for setup user's information.

Click User button in Customization interface to enter.

There are four tabs in the interface; they are user setup, user group setup, department setup and doctor setup.

3.1.4.1.1 User setup

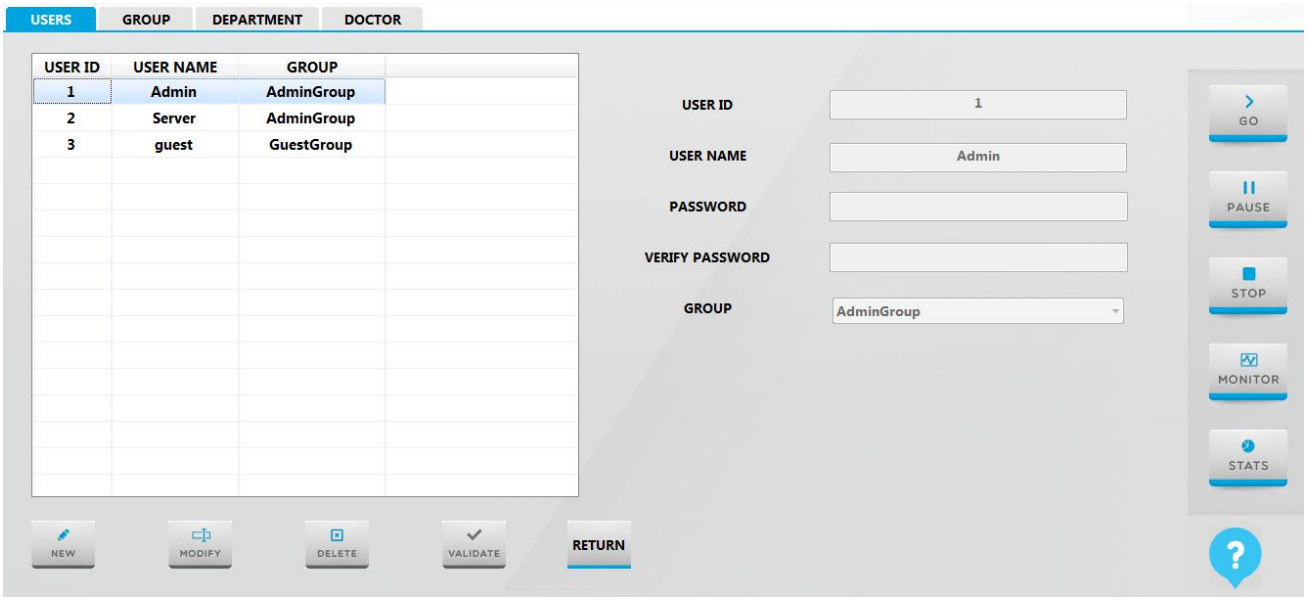


Figure 3.1.4.1.1 User setup interface

1. User management list: to display all users.
2. User's basic information: to display correspond information. It is includes user ID, user name, password, verify password and group.
3. Basic buttons:

   [New] button: click the button to reset user's information and add new user.

   [Modify] button: click the button to enter editable mode, and modify the user's information.

   [Delete] button: click the button to delete the current user. (The interface will be renovate after delete successfully)

   [Validate] button: click the button to save or cancel save the information of user and return to non-editable mode. (The interface will renovate after renew successfully)

   [Return]: click the button to return to forward menu.

3.1.4.1.2 User group setup

User group setup interface is mainly used for setup authority of user group. To click the options in the right side of list, this is the authority of user group.

Click Group button to enter the interface as follows:

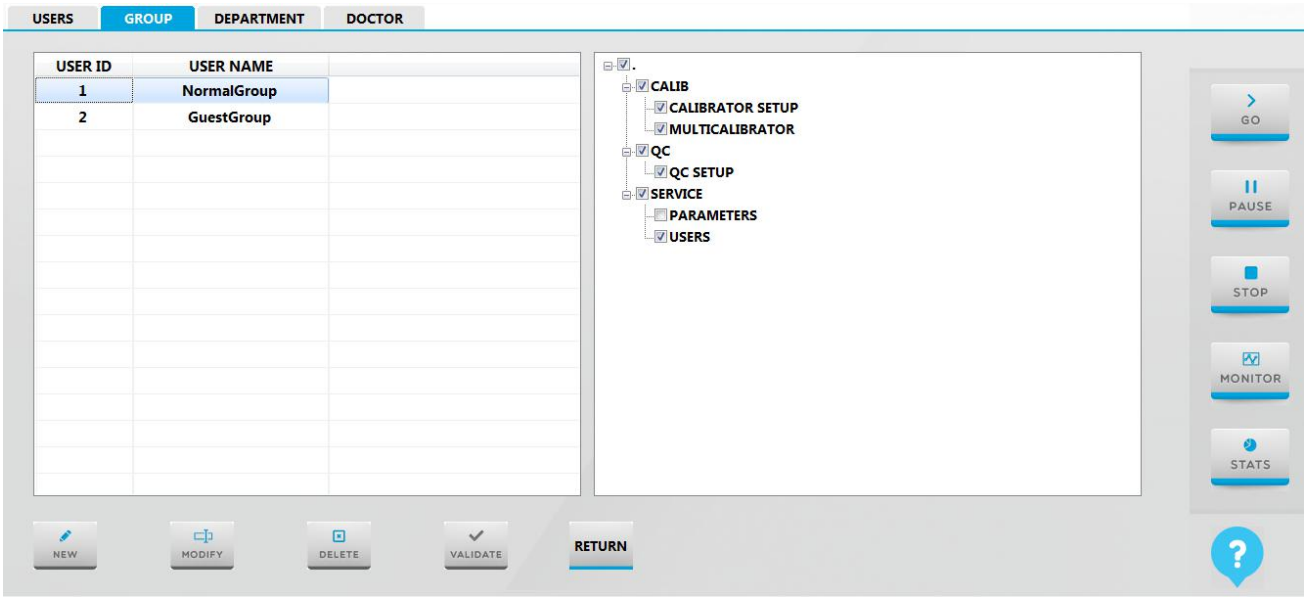


Figure 3.1.4.1.2 Setup interface of user group

1. User management list: to display all user groups.
2. Authority information of user: to display the authority information of user.
3. Basic buttons:

   [New] button: click the button to reset authority of user group and add a new user group.

   [Modify] button: click the button to enter editable mode, modify the information and authority of user group.

   [Delete] button: click the button to delete the selected user group. (The user group cannot be deleted if the user group is in use.)

   [Validate] button: click the button to save or cancel save the information and authority of user group.

   [Return]: Click the button to return to forward menu.

3.1.4.1.3 Department setup

Department interface is used for setup department information. Click **Department** button to enter the interface as follows:

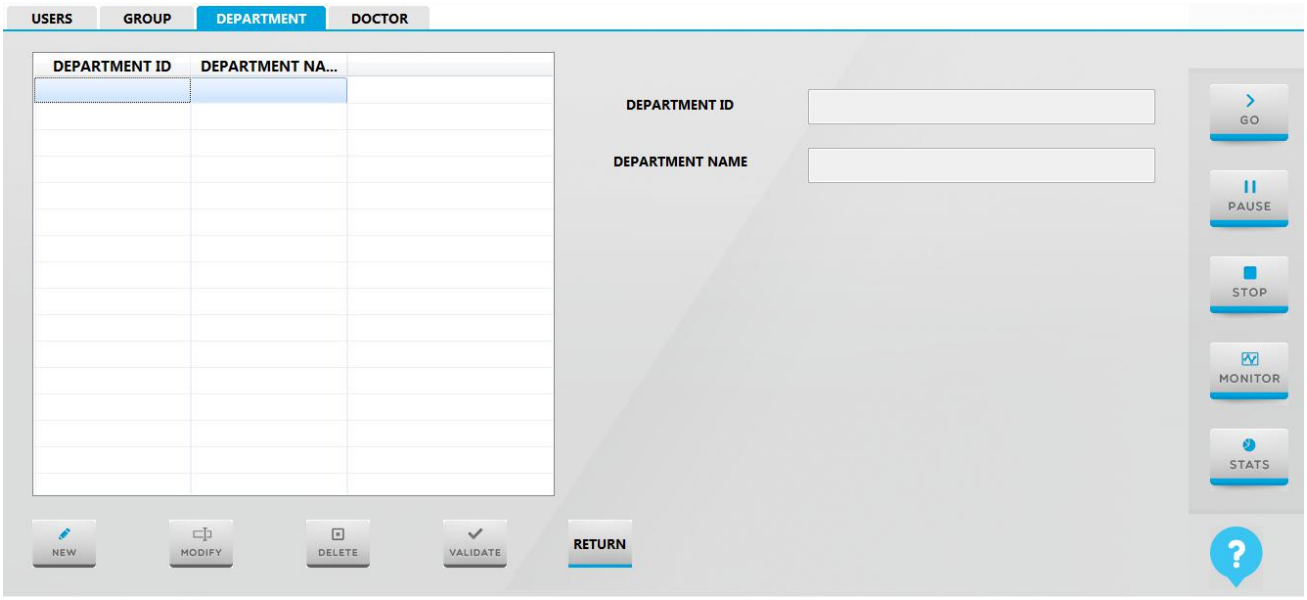


Figure 3.1.4.1.3 Department setup interface

1. Department list: display all department information.
2. Department information: display the corresponding department information. Includes department ID and department name.
3. Basic buttons:

   [New] button: click the button to reset department information and enter to editable mode, and add new department information.

   [Modify] button: click the button to enter editable mode, and modify the selected department information.

   [Delete] button: click the button and delete the selected department information. (It cannot be deleted if the department is in use; and the interface will renovate if the information is delete successfully)

   [Validate] button: click the button to save or cancel save the editable department information and return to non-editable mode. (The interface will be renovate if renew successfully)

   [Return]: click the button to return to forward menu.

   Click **Department** button to enter the department setup interface.

3.1.4.1.4 Doctor setup

Doctor setup is used for setup doctor information.
Click **Doctor** button to enter the interface as follows:

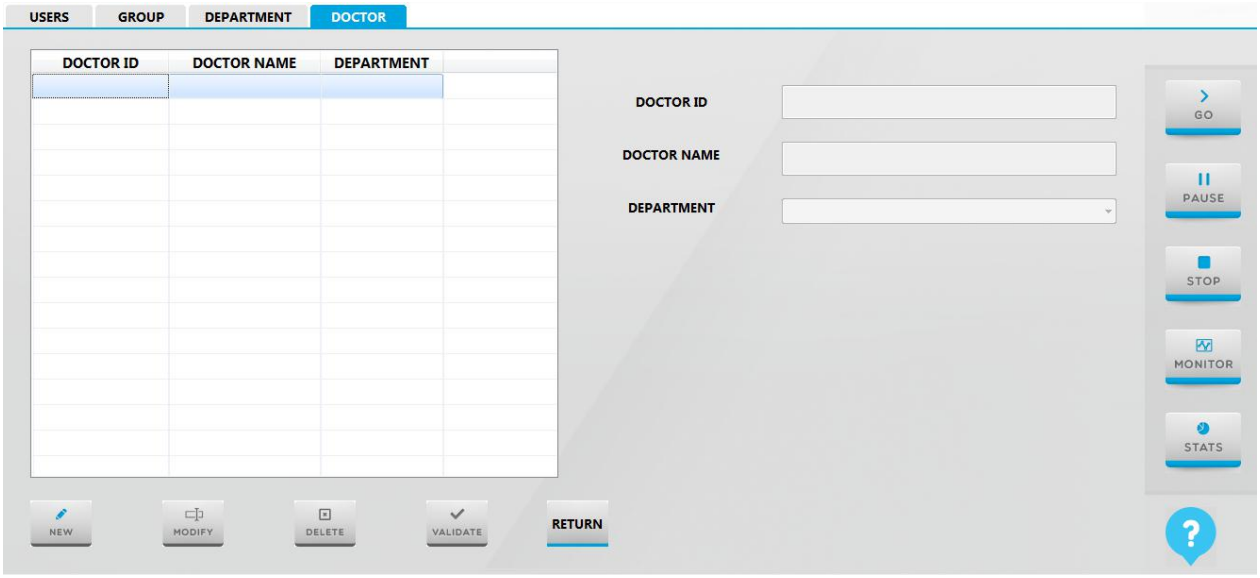


Figure 3.1.4.1.4 Doctor Setup interface

1. Doctor list: to display all doctor information.
2. Doctor information: to display the information of corresponding doctor.
3. Basic buttons:

   [New] buttons: click the button to reset doctor's information and enter to editable mode to add new doctor's information.

   [Modify] button: click the button to enter editable mode to modify doctor's information.

   [Delete] button: click the button to delete the information of doctor. (The interface will renovate if delete successfully)

   [Validate] button: click the button to save or cancel save the doctor's information. (The interface will renovate if validate successfully)

   [Return]: click the button to return to forward menu.

3.1.4.2 Instruction of general setting

General setting interface is used for setting general parameter of system.
Click **General setting** button to enter the interface as follows:

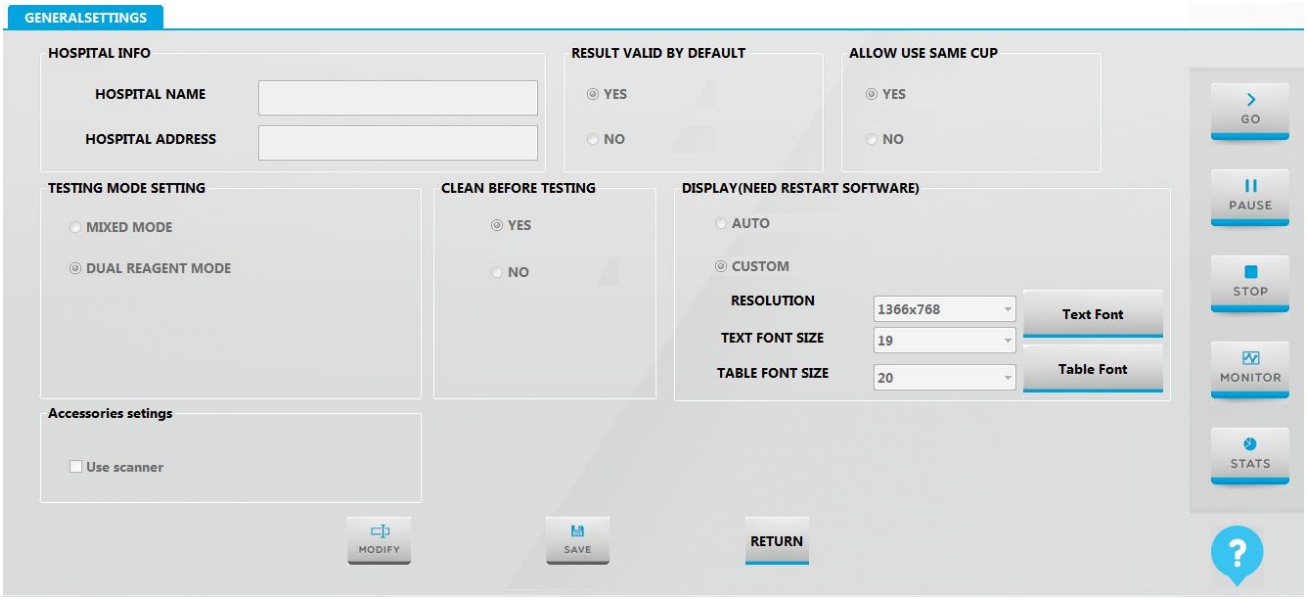


Figure 3.1.4.2 General setting interface

1. General information: to display general parameter information of system includes basic information of hospital (hospital name and hospital address), default process mode for result (effective or not effective), test mode setting (mixed mode and double reagent mode), rinse setting before test (rinse or not rinse), and automatically print (yes or no).
2. Basic buttons:

   [Modify] button: click the button to enter editable mode, and modify the general parameter of system.

   [Save] button: click the button to save the current system parameter, then return to non-editable mode.

   [Return]: click the button to return to forward menu.

3.1.4.3 Instruction of print format

The print format interface consists of print format 1 interface and print format 2 interface.

3.1.4.3.1 Print format 1

Print format 1 interface is used for setup report form and format. Please refer to chapter 7.4 for more information about custom print setting.
Click Print format to enter the interface as follows:

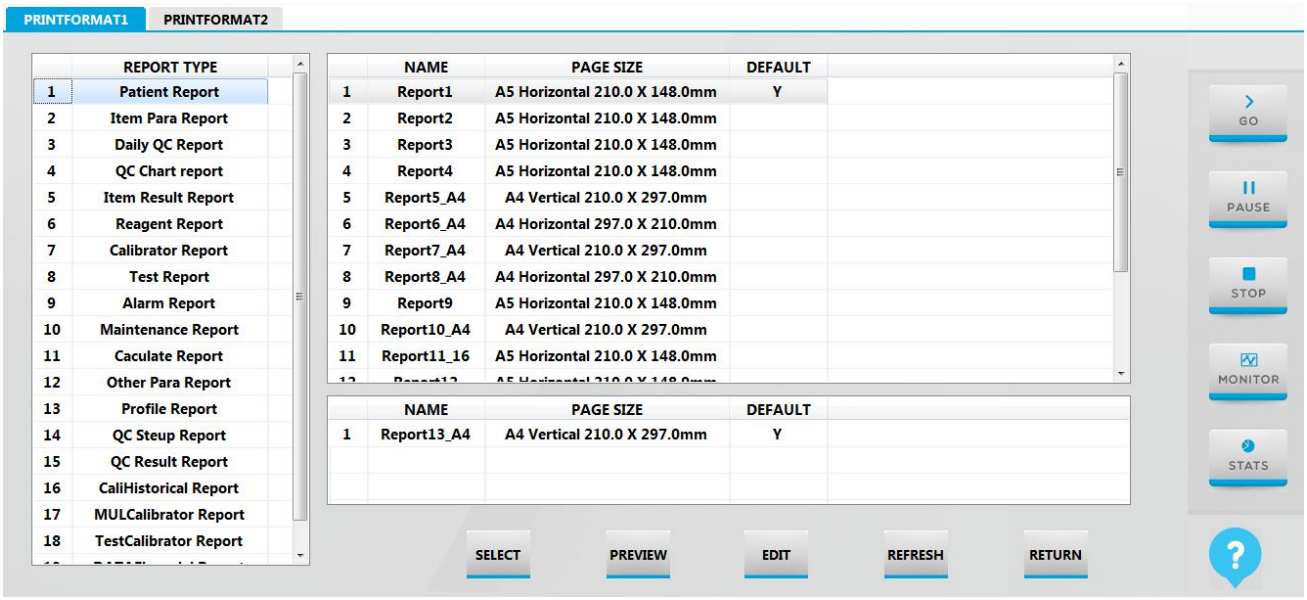


Figure 3.1.4.3.1 Interface of print format 1

1. Report type list: to display all report types, includes patient's report, item parameter report, daily QC report, QC chart report and item result report.
2. Report information list: to display all the information of the selected report type, the information includes report name, paper size and default specification.
3. Backup print report information list: to display the backup print report information, includes report name, paper size and default specifications.
4. Basic buttons:

   [Select] button: to select arbitrary report and click the button, the report type is selected as the default print report.

   [Review] button: to select arbitrary report and click the button, to review the report template before printing.

   [Edit] button: to select arbitrary report and click the button, to edit the format of report template.

   [Refresh] button: click the button to refresh the report information.

   [Return]: click the button to return to forward menu.

3.1.4.3.2 Print format 2

The interface of print format 2 is used for setup the name of number filed of varies report.
Click Print format 2 to enter the interface as follows:

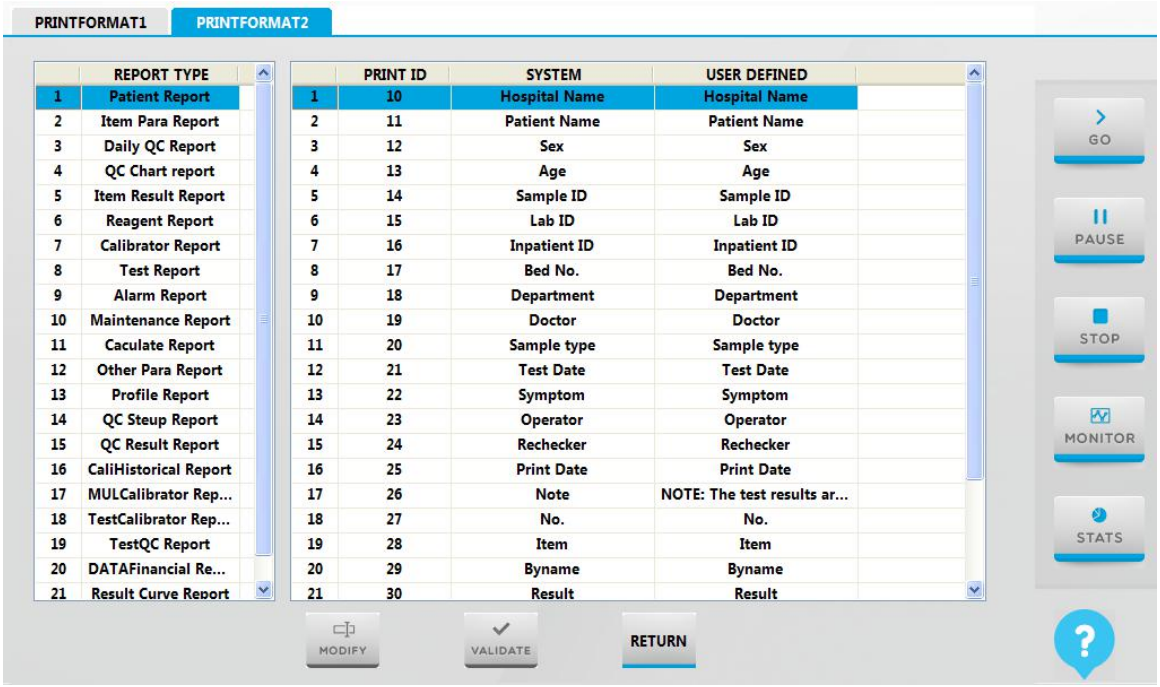


Figure 3.1.4.3.2 print format 2

1. Report type list: to display all report types.
2. Report field list: to display all field information of the selected report type, includes the information of print ID, system default and user defined.
3. Basic buttons:

   [Modify] button: to select arbitrary field and click the button to modify the name of the selected field.

   [Validate] button: click the button to save the name then return to non-editable mode.

   [Return]: click the button to return to forward menu.

3.1.4.4 Instruction of dictionary interface

The dictionary interface is mainly used for setup general data list.
Click **Dictionary** to enter the interface as follows:

Figure 3.1.4.4 Dictionary interface

1. Dictionary type list: to display information of all dictionary type includes dictionary code and dictionary name.

2. Dictionary data list: to display all information of dictionary data, such as content code, content and content description.

3. Basic buttons:

   [New] button: click the button to enter editable mode, and add field information in dictionary data list.

   [Modify] button: to select arbitrary field information and click the button to modify the information.

   [Delete] button: to select arbitrary field in dictionary data list and click the button to delete the selected field information. (The interface will renovate if delete successfully)

   [Validate] button: click the button to save the information of field name and return to non-editable mode. (The interface will renovate if validate successfully)

   [Return]: click the button to return to forward menu.

3.1.4.5 Instruction of communication setting

Communication setting is used for setting port which connects system and instrument.
Click **Communication setting** button to enter the interface as follows:

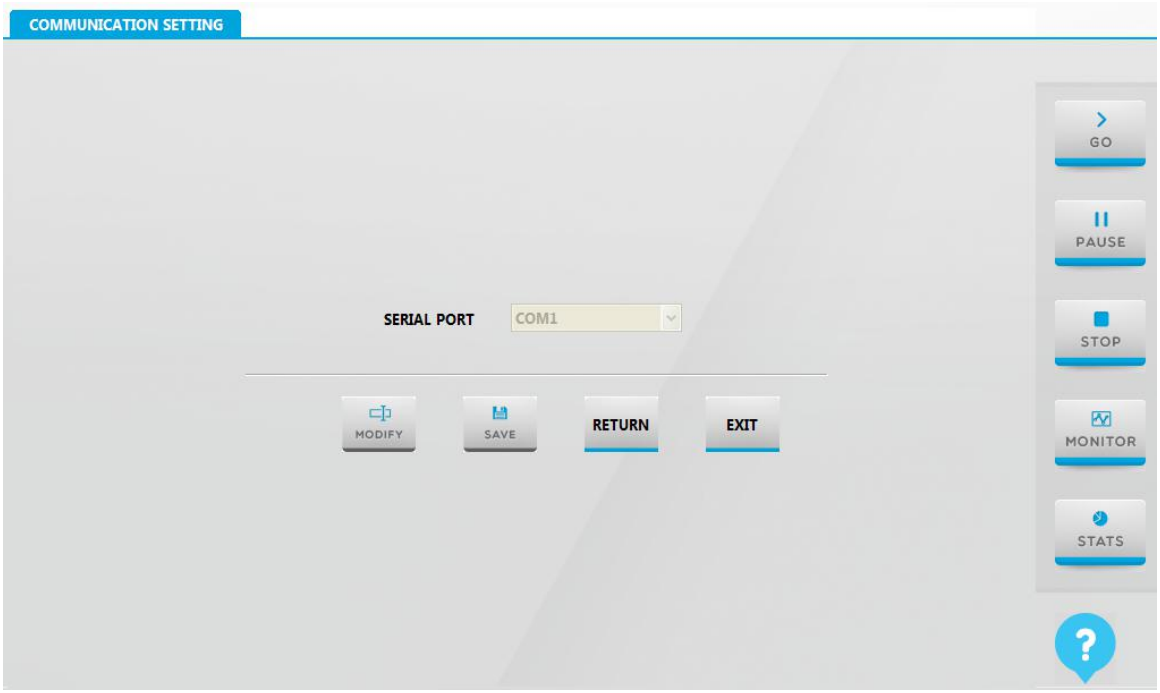


Figure 3.1.4.5 communication setting interface

1. Port information: for selection and display the port name which is using now.
2. Basic buttons:

[Modify] button: click the button to enter editable mode and modify the port information.

[Save] button: click the button to save the port information.

[Return]: click the button to return to forward menu.

[Exit] button: click the button to exit system.

3.1.4.6 LIS setting

To click Lis setting button to enter the interface in customization interface. The connecting parameter and transfer mode could be set in this interface. For more information, please refer to chapter 7.4.

3.1.5 Maintenance interface

This interface includes seven sub-interfaces; they are probe and stirrer cleaning, cuvette rinsing, cuvette signal, signal detection, mechanism adjustment, self-test control and temperature control.

1. Click Service button.
2. Click Maintenance button to enter the interface.

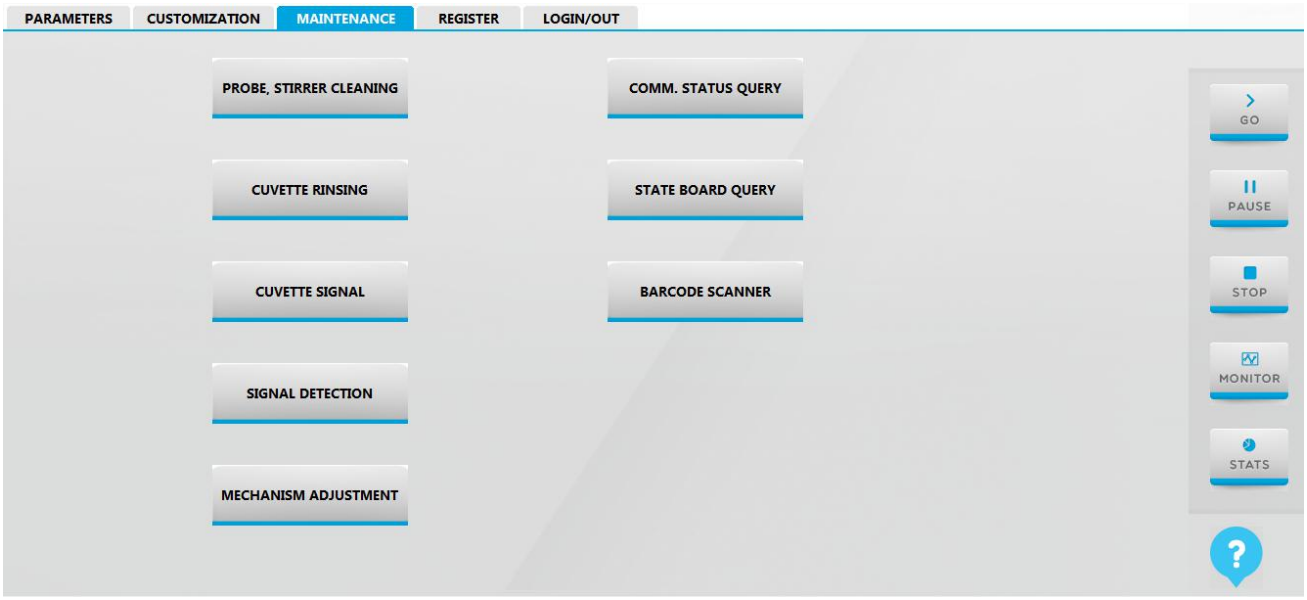


Figure 3.1.5 Maintenance interface

3.2 Instruction of applying module

3.2.1 Instruction of sample interface

1. Click Test button.
2. Click Sample button to enter the interface and it is the default interface.

This interface is used for editing the test list.

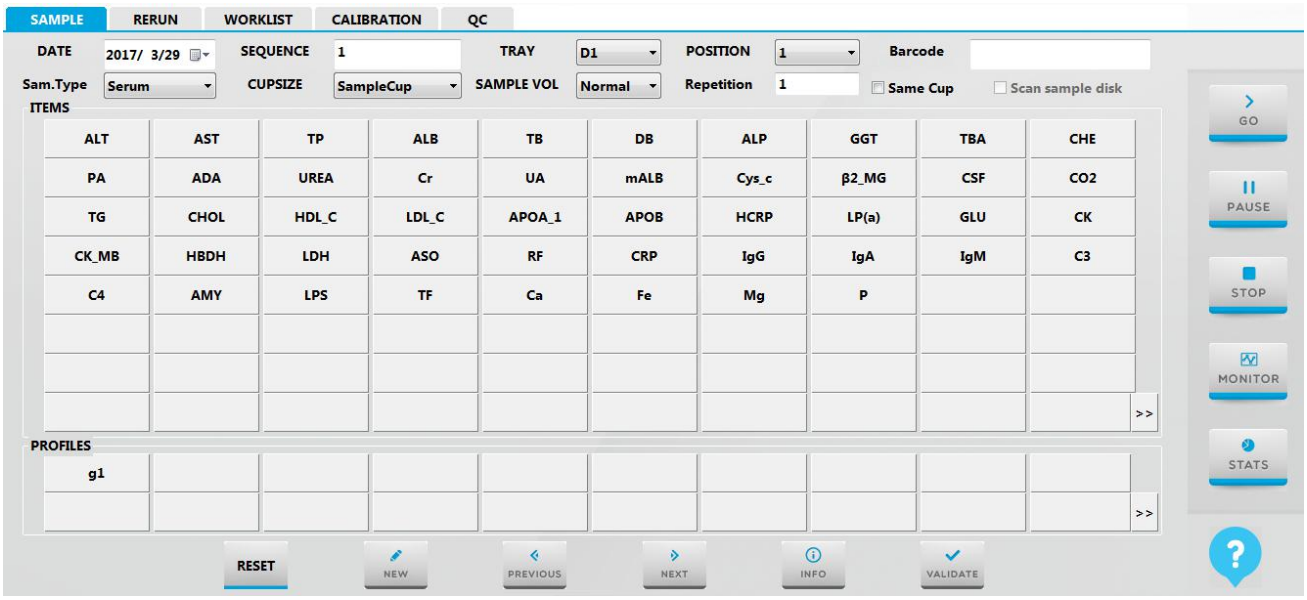


Figure 3.2.1-1 applying interface of routine sample

1) Basic information of sample:

The basic information includes date, sample ID, dummy sample tray, sample position, barcode, sample type, sample specification, sample volume, repetition and same cuvette.

Definition of some information:

[Repetition]: to test for more times for one sample.

[Same cuvette]: this selection only available for repetition; if not click the selection, the number is recursion according to **[Sample position]**, and occupy the sample position accord to **[repetition]** and default the several samples will locate on the position and create correspond list; if click the selection, it is default the sample will be test for several times and create correspond list accord to **[repetition].**

2) Item information of sample:

: If the button color is blue, it has been selected.

: If a green circle display on the right up position, that means the item has been test and created result.

: if a not perfect red circle display on the right up position, that means the item has been apply test and not create result.

: If a stop mark display, that means this item has not used or not calibrate or not setting or calibrate failure. Its cause the item cannot be used. And click the item to know more about reasons.

Basic operation:

Right click arbitrary item: if the test list is blank, the item list will display, and the selected item will be set in correspond buttons.

Click arbitrary item: select/cancel the item.

3) Information of combined item: to provide normal use combined item.

4) Basic buttons:

[LIS] button: click the button to download the sample information for LIS server.

[Reset] button: click the button to put the sample ID to the last test ID.

[New] button: built a new sample, click to build a new sample.

[Previous]: click the button to display the forward sample information.

[Next]: click the button to display the next sample information.

[Infor]: click the button to display the information of patient and add or delete the information.

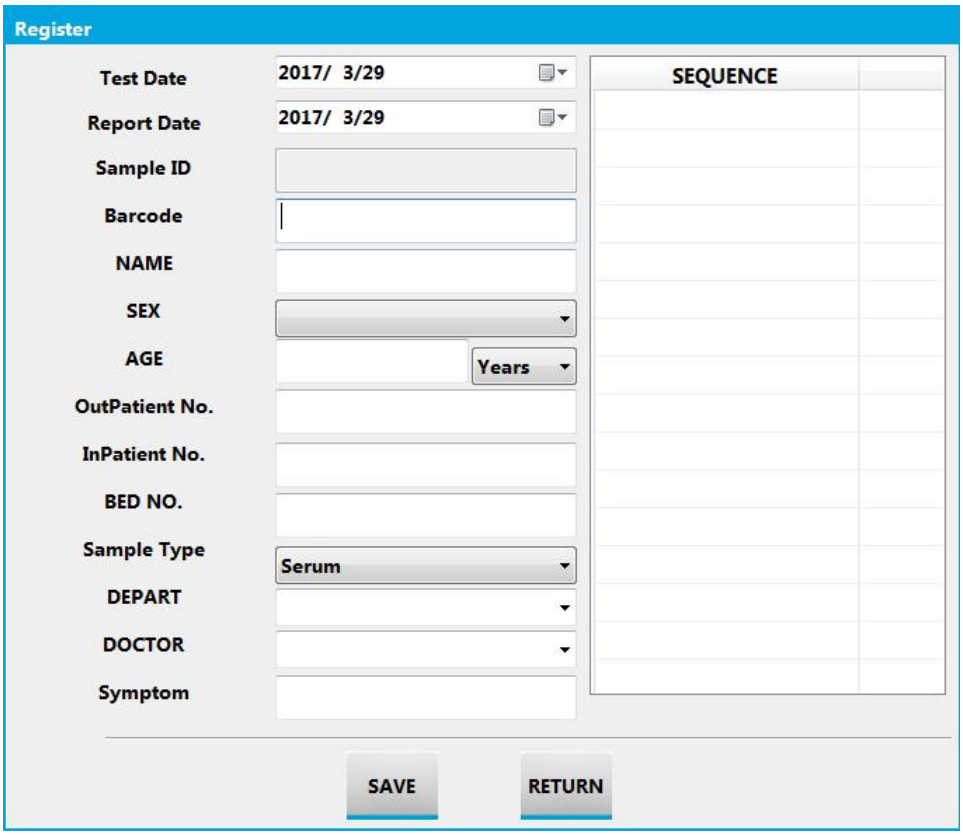


Figure 3.2.1-2 Interface of patient's information

3.2.2 Instruction of calibration interface

The interface is used for setting calibration items.

Click Test button.

Click Calibration button to enter the interface as follows:

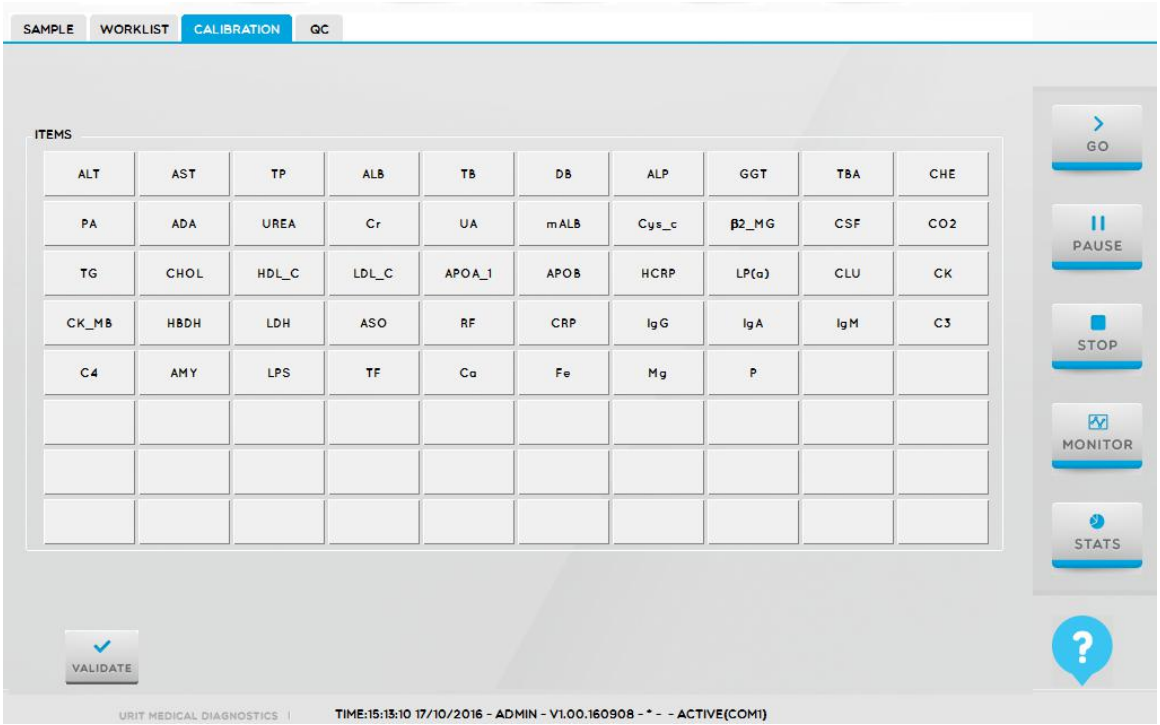


Figure 3.2.2 calibration interface

1. Information of calibration item: to provide items to calibration.
2. Basic buttons:

[Validate]: click the button to add the item to test list after confirm the item information.

3.2.3 QC interface instruction

This interface is used for setup QC item.

1. Click **Test** button.
2. Click **QC** button to enter the interface as follows:

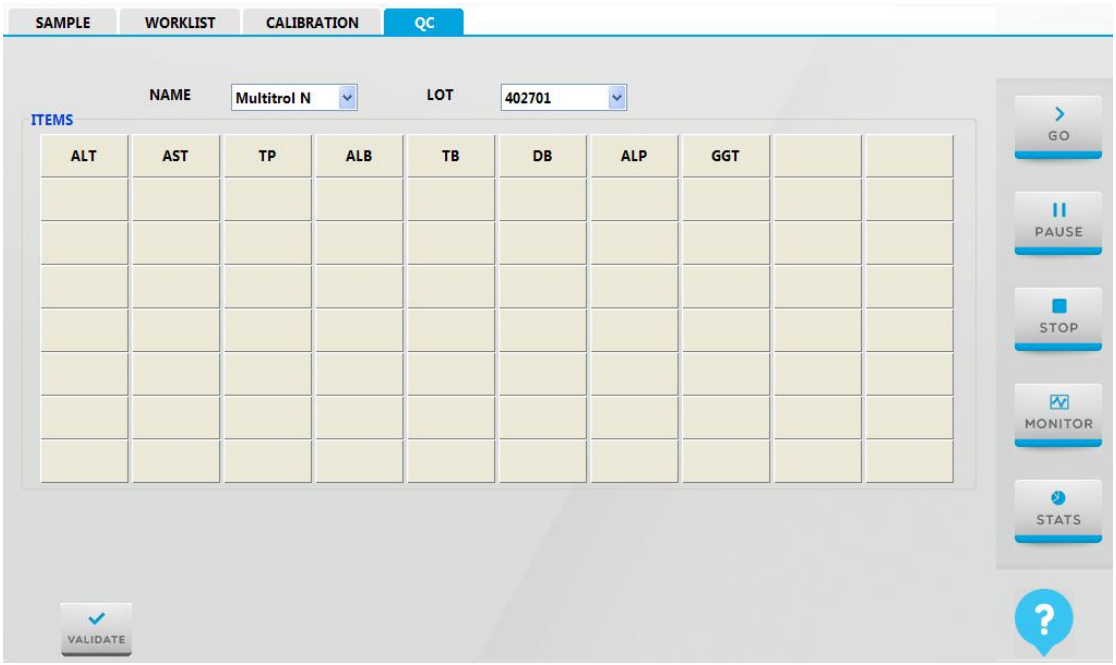


Figure 3.2.3 QC interface

1) QC lot: to provide name and lot information of QC item.
2) QC item information: to provide item for QC test.
3) Basic button:

[Validate]: click the button to add the item to the list after confirming the information.

3.3 Instruction of reagent interface

The reagent interface is for setup reagent information.
Click Reagent button to enter the interface as follows:

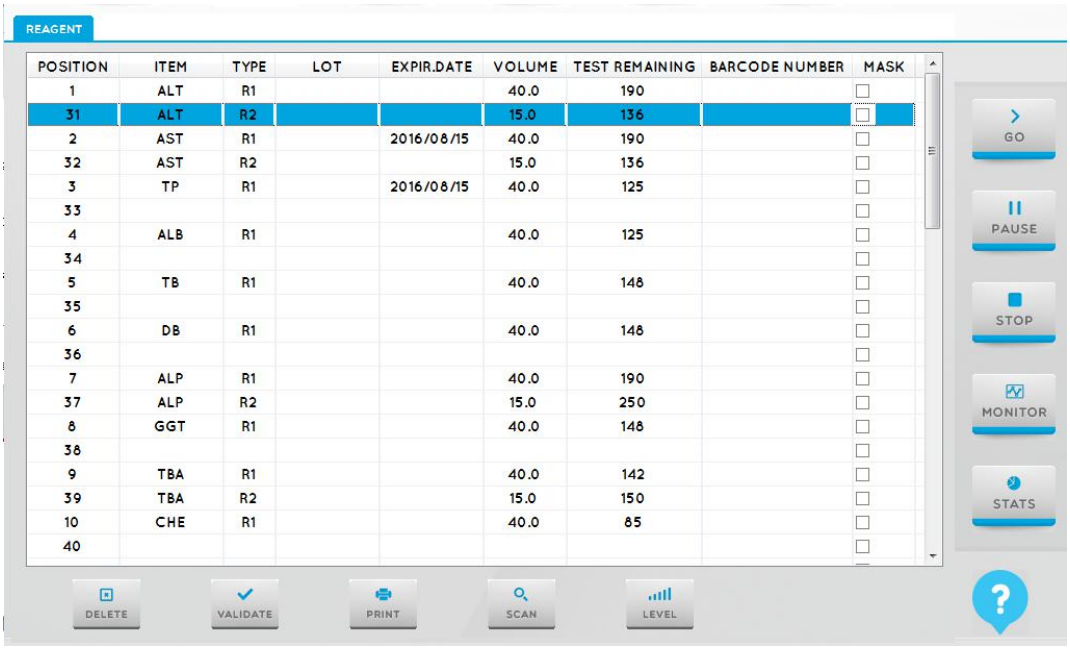


Figure 3.3 Reagent interface

Note: to double click arbitrary reagent position, and modify the item, type, lot, expiry date and barcode of the reagent.

1) Information list of reagent tray: The reagent position, item, type, lot, expiry date, reagent allowance, test times, barcode and mask information is display in the interface.

[Mask]: if the button is selected, that means the reagent allowance is zero, and the reagent cannot be used, the color is shown as red.

2) Basic buttons:

[Delete]: select arbitrary reagent and click the button to clean up the information this reagent.

[Validate]: click the button to save the reagent information in editable mode and return to non-editable mode.

[Print]: click the button to print out the information of reagent tray.

[Scan]: click the button to scan the barcode of one or more reagent position which is selected, and the qualified barcode will display in the correspond reagent.

[Level]: to select one or more reagent position, click the button, the system will detect the reagent allowance, and display in correspond reagent position.

3.4 Instruction of data interface

The interface includes three sub-interfaces, they are result, historical record and financial.

3.4.1 Result interface

The interface is used for query and confirms the test result information.
Click **Data** icon.

Click **Result** button to enter the interface.

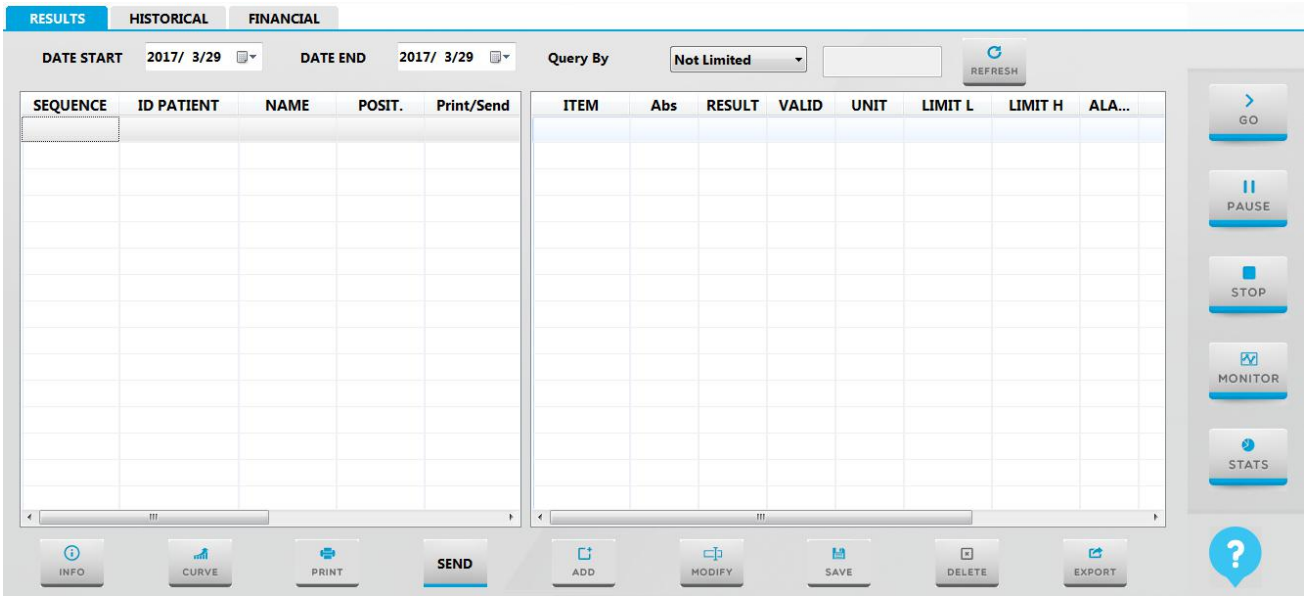


Figure 3.4.1-1 result interface

1) Result screening conditions: the time range and query condition can be combined to screen.

To input the time range, click Refresh button to query the test information which confirm with the test time.

Basic operation:

To fill in time range and select the query condition, then click Refresh button, the information in the range can be query. The query conditions are as follows:

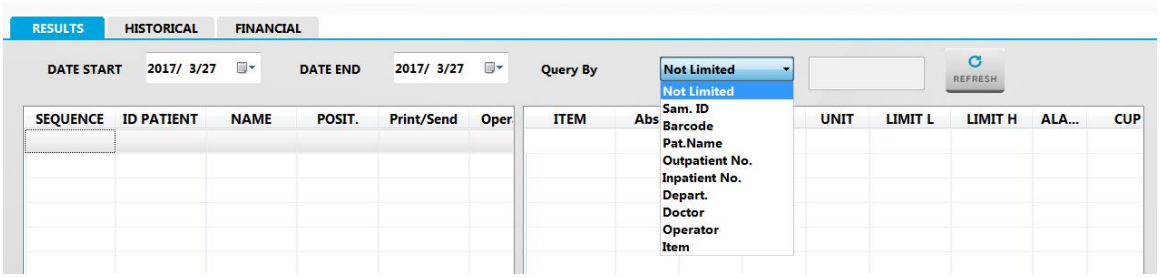


Figure 3.4.1-2 Query conditions

2) Sample information list:

The sample test information is display accord to ID group; the list information includes sample ID, barcode, dummy sample tray, sample position, sample cuvette specifications and patient's name.

Basic operation:

Right click the arbitrary position of the top of column and a list menu is pop up:

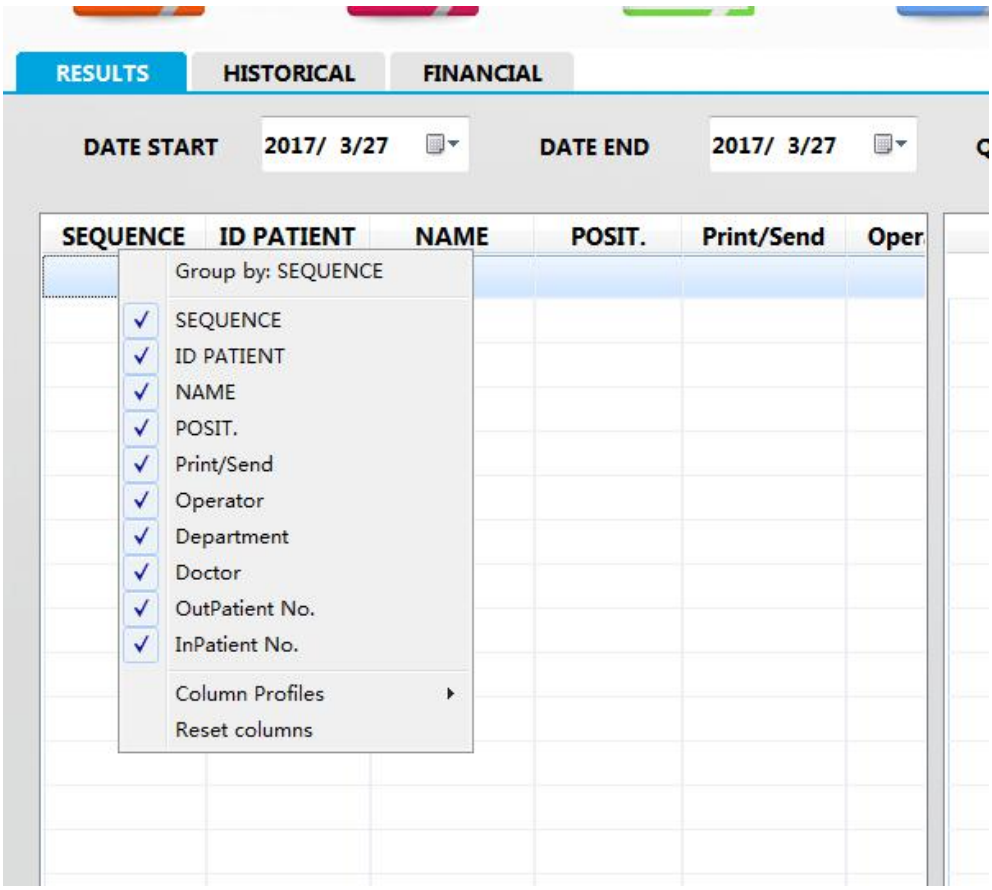


Figure 3.4.1-2 list setup menu

- To display by group accord to the position which the mouse stand on.
- Cancel group display.
- Display/ hide some information of column.
- Reset the table format.

(All the table allocate the setup menu, and we do not do more description)

3) Item information list:

To display the result information of the selected item, includes item, result, validate, unit, normal low value, normal high value, alarm.

[Validate]: click the selection means this result is apply and not click means it is not apply.

4) Basic button:

[Curve]: To select arbitrary result and click the button, it will turn to result curve interface and the curve of the result will display.

[Print]: To select arbitrary result and click the button, to print the result.

[Add]: To click the button to add item information in the current item list.

[Modify]: select an ID, and click modify button in non-editing modes to modify the test result.

[Send]: To select arbitrary item and click the button to send to LIS sever.

[Export]: click the button to export the information in the sample list and item list to the file.

3.4.2 Instruction of historical record interface

The interface is used for query the historical result.

1. Click Data button.
2. Click Historical button to enter the interface as follows:

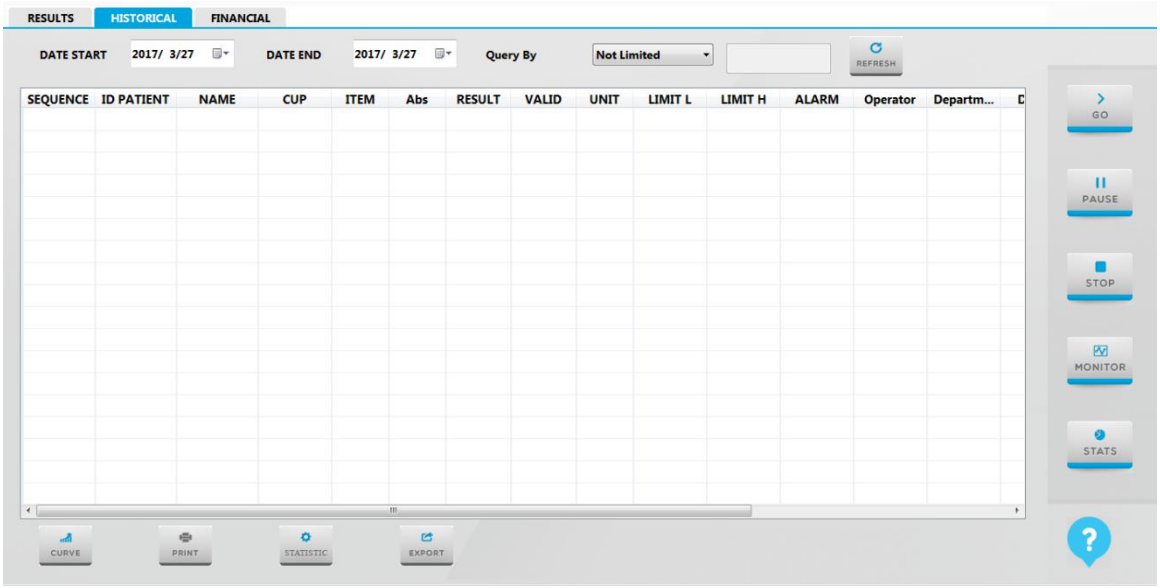


Figure 3.4.2-1 Historical record interface

1) Result screening condition:

The time range and query condition can be combined to screen.

Basic operation: fill in time range, select the query condition, click refresh the test information could be query. The query conditions are as follows:

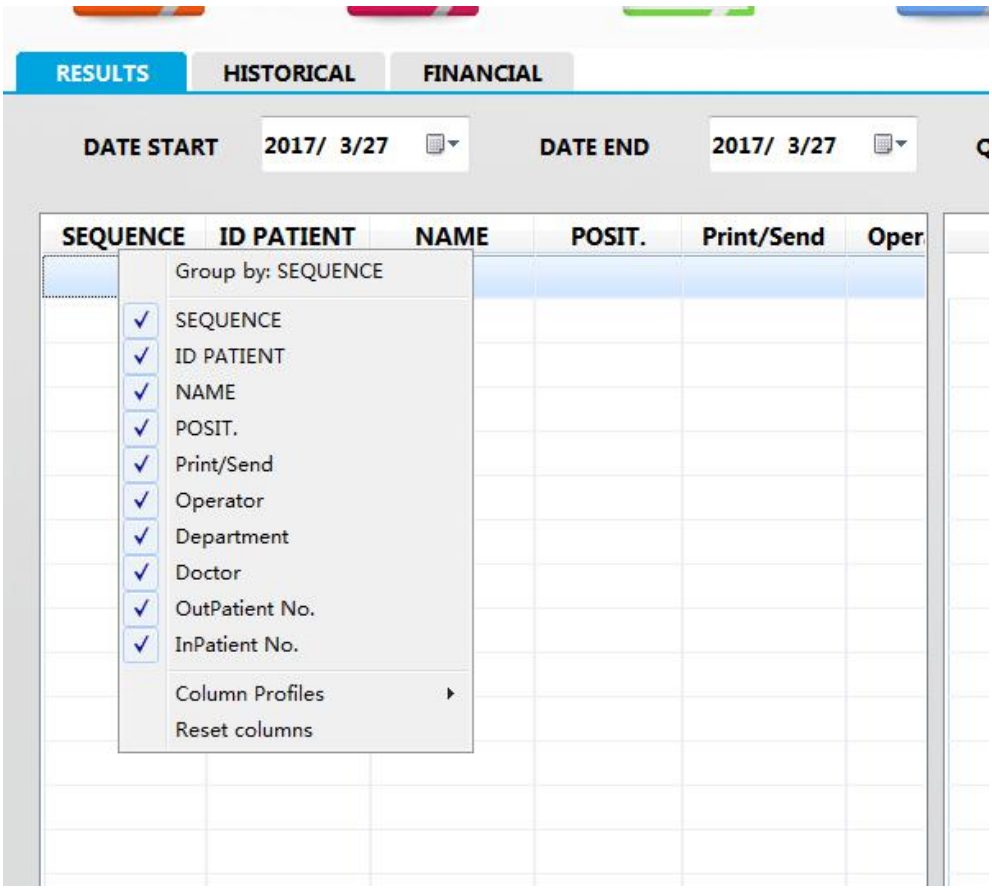


Figure 3.4.2-2 Query conditions

2) Item information list: to display the item information , includes sample ID, barcode, cuvette No., patient's name, item, result, validate, unit, normal low value, normal high value and alarm.

3) Basic button:

[Curve]: select arbitrary result, click the button to enter result curve interface, the curve of the result will display.

[Print]: to select arbitrary item and click the button to print all result.

[Statistic]: click the button to pop up a statistic table and which display the statistic conditions of the result.

[Export]: click the button to export the information to the file.

3.4.3 Instruction of financial interface

The interface is used for setup and statistic the test times of each item, the consuming reagent volume, cost and profit.

1. Click Data button.
2. Click **Financial** button to enter the interface as follows:

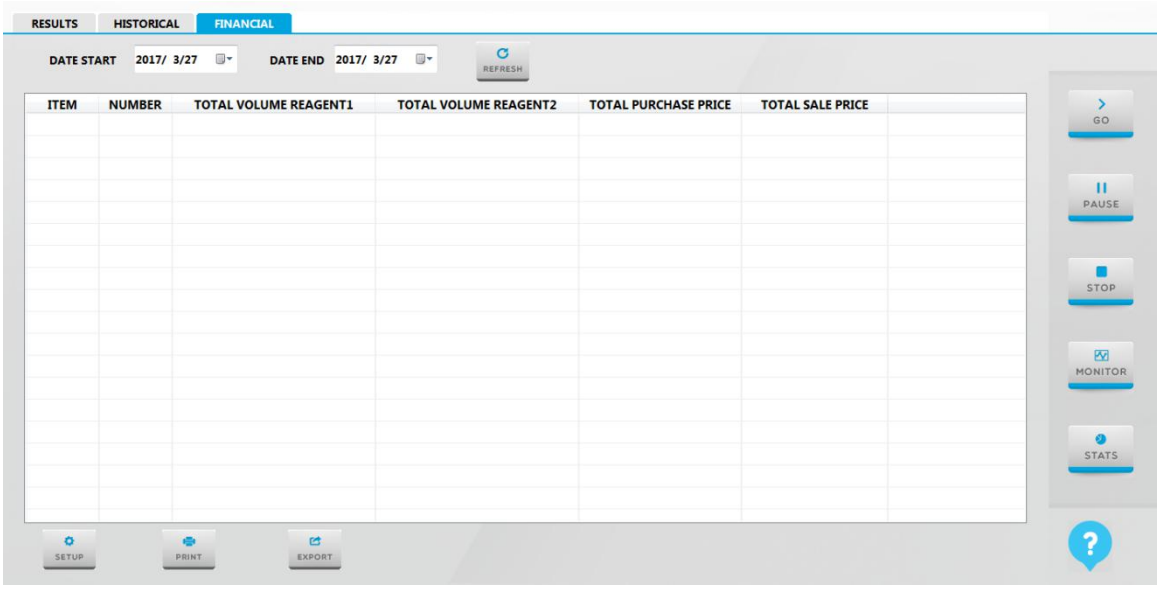


Figure 3.4.3-1 financial interface

1) Result screening conditions:

The statistic time range is the screening condition.

Basic operation: click Refresh after confirming and query the test information which comply with the range.

2) Item list:

To display the list, includes item, test times, total consuming of reagent1, total consuming of reagent 2, total cost and sale price.

3) Basic buttons:

[Setup]: click the button, a price setup interface will pop up; you can setup the cost and sale price of each item.

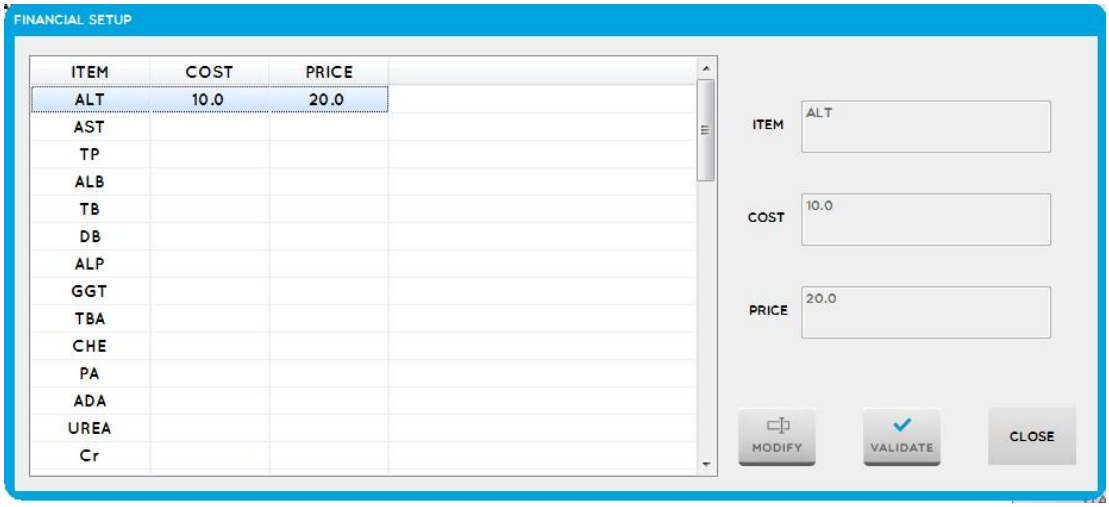


Figure 3.4.3-2 price setup interface

[Print]: click the button to print all result.

[Export]: click the button to export the information to the file.

3.5 Instruction of calibration interface

The calibration interface includes four sub-interface, they are calibrator setup, factor list, historical and multi-calibrator.

3.5.1 Instruction of calibrator setup interface

The interface is used for setup calibrator parameter.

1. Click Calibration button.
2. Click Calibrator setup to enter the interface as follows:

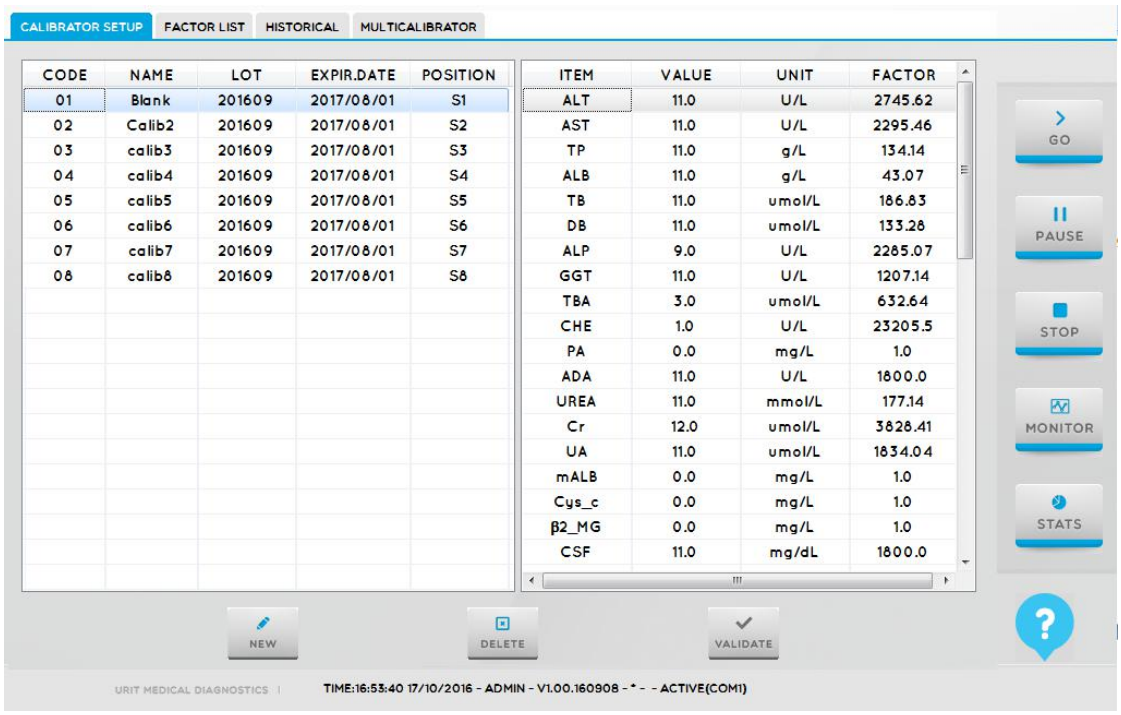


Figure 3.5.1 Calibrator setup

Note: double click the column and enter to editable mode, click left of mouse or move by click left/right on the keyboard to let the point stay on the cell. The cell is in dashed frame, press F2 or click to enter to editable mode. Click Enter to end the editable operation and go to edit the next cell.

1) Information list of calibrator: to display the calibrator No., calibrator name, lot, validity date and calibrator position.
2) Information list of calibration item: to display information of each item which includes calibration item, concentration, unit and calibration factor.
3) Basic buttons:

[New]: when the point stay on the list of calibrator, click the button to enter editable mode, to add new Information of calibrator; when the point stay on the list of calibration item, click the button to enter editable mode, to add new item parameter information.

[Delete]: to select arbitrary calibrator information in the information list, click the button to delete the information of the calibrator and its parameter information; when select arbitrary calibration item and click the button, the parameter information of the item will be delete.

[Validate]: click the button to save the information and return to non-editable mode.

3.5.1.1 New-built calibrator

1. Click **New** to add a new blank item frame.
2. Input the number of calibrator, name, lot, validity and position.
3. Click **Validate** to complete.

3.5.1.2 Modify calibrator

1. Select a calibrator in the information list.
2. Double click the row of the selected calibrator and enter to editable mode.
3. Newly input the calibrator information.
4. Click **Validate** to complete.

3.5.1.3 Delete calibrator

1. Select a calibrator in information list which is aim to delete.
2. Click Delete button.

3.5.2 Instruction of factor interface

This interface is used for checking the calibration parameter information of each item.

1. Click **Calibration** button.
2. Select **Factor list** to enter the interface.

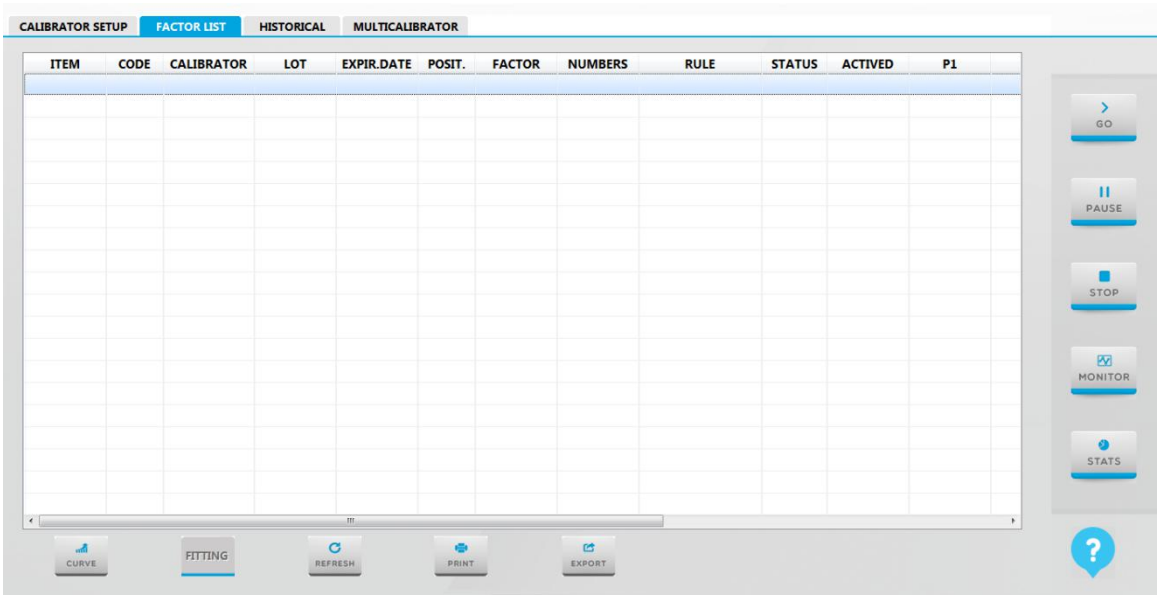


Figure 3.5.2 Factor list interface

1) Calibration parameter list: the list includes the information of calibration item, number, name, lot, expiry date, position and factor.
2) Basic buttons:

[Curve]: to select arbitrary item and click the button to enter to curve interface, the curve of the result of the item will display.

[Fitting]: single-linear item, the secondary button could not be select; to select multi-point calibrate item and click the button, it will skip to curve interface. The curve of the result is displayed in the interface.

[Print]: click the button to print the calibration parameter information of all calibration items in the list.

[Export]: click the button to export the calibration parameter information to the file.

[Refresh]: click the button to refresh the parameter information.

3.5.3 Historical interface

The interface is used for check and setup the historical calibration parameter information of each item.

1. Click **calibration** button.
2. Click **Historical** to enter the interface as follows:

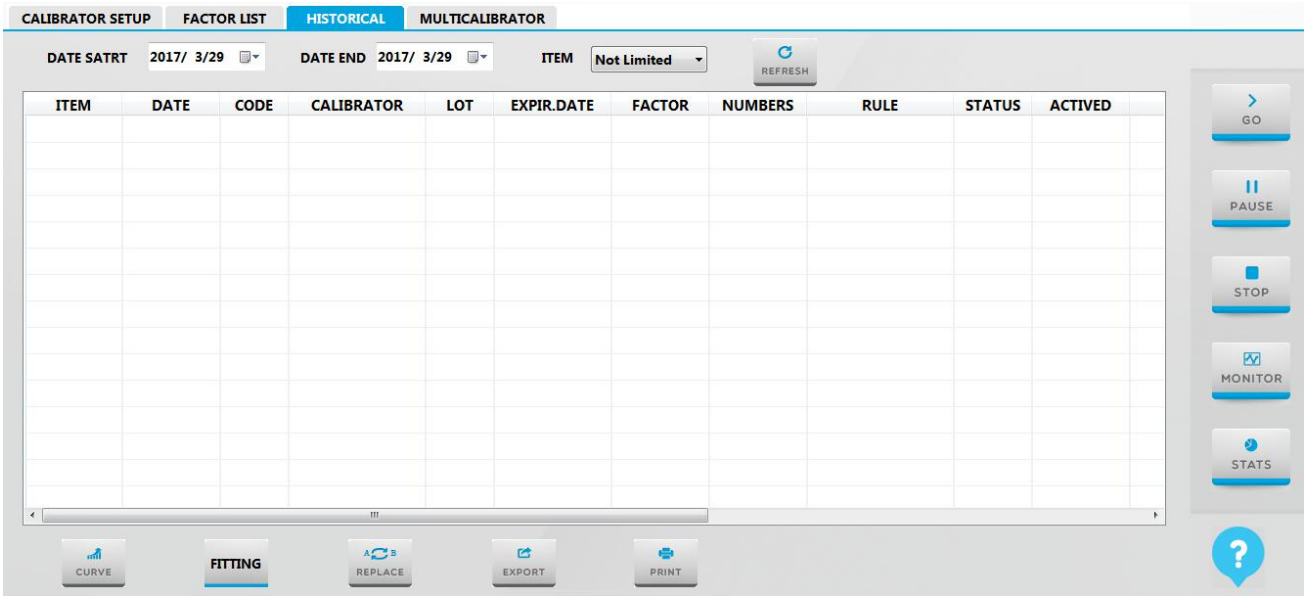


Figure 3.5.3 Historical interface

1) Result screening conditions:

The screening conditions include time range of calibration and calibration items.

2) Calibration result list:

To display the calibration information according to calibration time group, the information includes calibration time, calibration number, calibrator name, lot, expired time, factor, etc.

Basic buttons:

[Fitting]: single-linear item, the secondary button could not select; select multi-points item then click the button, the calibration curve could be fitting.

[Replace]: To select arbitrary calibration information and click the button, the current calibration

information is setup as the applied calibration parameter. (After click the button, a [Password check] interface will pop up, the password is admin.)

[Print]: click the button to print all calibration information of the current calibration items.

[Export]: click the button to export all calibration information of the items to the file.

3.5.4 Instruction of multi-calibrator interface

The interface is used for check item information and curve.

1. Click **Calibration** button.
2. Click **Multi-calibrator** button to enter the interface as follows:

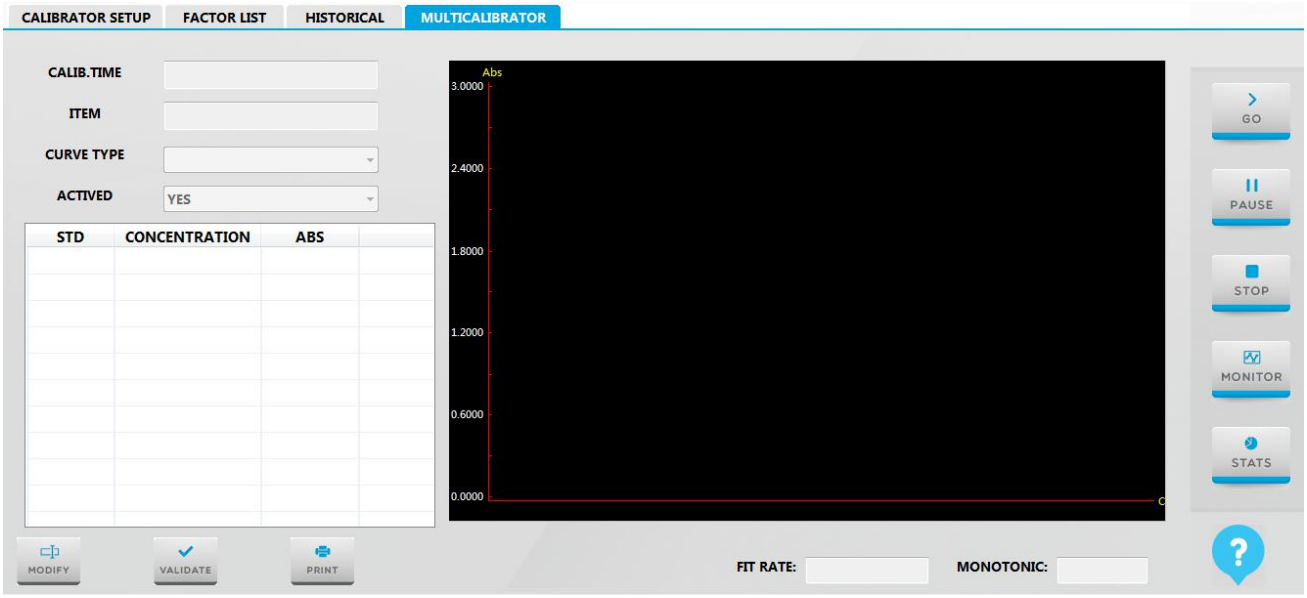


Figure 3.5.4 multi-calibrator interface

1) Item screening conditions:

The screening conditions include calibration items and curve type.

Basic operation: to select a calibration item, and then select the curve type, the result information will display in the result list. And correspond curve is displayed on the calibration diagram.

2) Calibration result list:

The result list includes calibration standard consequence, calibrator concentration and absorbance.

3) Calibration curve: This is displayed according to the item result information and curve type.

4) Fitting rate: to display the fitting rate of curve.

5) Basic buttons:

[Print]: click the button to print all information of calibration item and corresponding curve.

[Export]: click the button to export the result to the file.

3.6 Instruction of QC interface

The interface includes QC setup, QC result and QC chart.

3.6.1 QC setup interface

The interface is used for setup parameter of QC solution. It is allow applying QC test only the QC parameter is setup correctly, such as QC lot, target value and SD value. And it is allow setup QC when the system is free and the user with the authority.

1. Click **QC** button.
2. Select **QC setup** to enter the interface and it is a default interface.

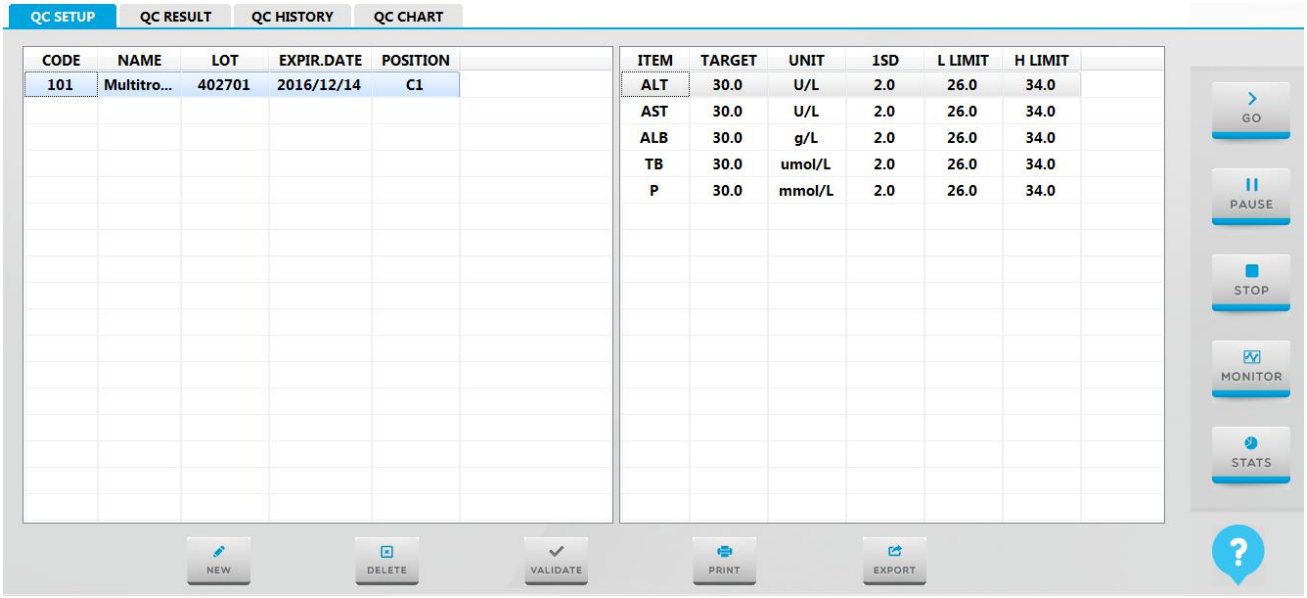


Figure 3.6.1 QC setup interface

NOTE: when the point stand on the QC information list, double click the cell and enter to editable mode, then modify the QC information; when the point stand on QC parameter list, double click the cell to enter editable mode, then modify the parameter information of QC item.

1) Information list of QC:

The list displays the QC information, which includes QC number, QC name, QC lot, expired date and QC position.

Basic operation: to modify all information in the list in editable mode.

2) Parameter list of QC item:

Select a QC, the information of QC corresponding with each item will display, include QC item, target value, unit, standard deviation, normal low value and normal high value.

Basic buttons:

[New]: when the point stand on the QC information list, click the button to enter editable mode, add new QC information; when the point stand on the QC parameter list, click the button to enter editable mode, to add new QC parameter information.

[Delete]: to select arbitrary QC, click the button to delete all QC information and corresponding item parameter information; to select arbitrary QC item in the item parameter list, click the button to delete

the item parameter information.

[Validate]: click the button to save the content and return to non-editable mode.

[Print]: click the button to print all item parameter information in the parameter list.

[Export]: click the button to export the QC information and corresponding item parameter to the file.

3.6.1.1 Add new QC

1. Click **New** button to add a new blank frame.
2. Input QC number, name, lot, expired date and reagent position.
   - The QC lot number is not allowing repeat.
   - The lot number is consisting of character and numbers.
3. Click **Validate** to complete.

3.6.1.2 Modify QC

1. Select the QC in the QC information list which is needs to modify.
2. Double click the column of the selected QC, the information can be editable.
3. Reenter the QC information.
4. Click **Validate** to complete modification.

3.6.1.3 Delete QC

1. Select a QC in the QC information list.
2. Click **Delete** button to delete.

3.6.2 QC result interface

The interface is used for check QC test result.

1. Click QC button.
2. Click QC result button to enter the interface as follows:

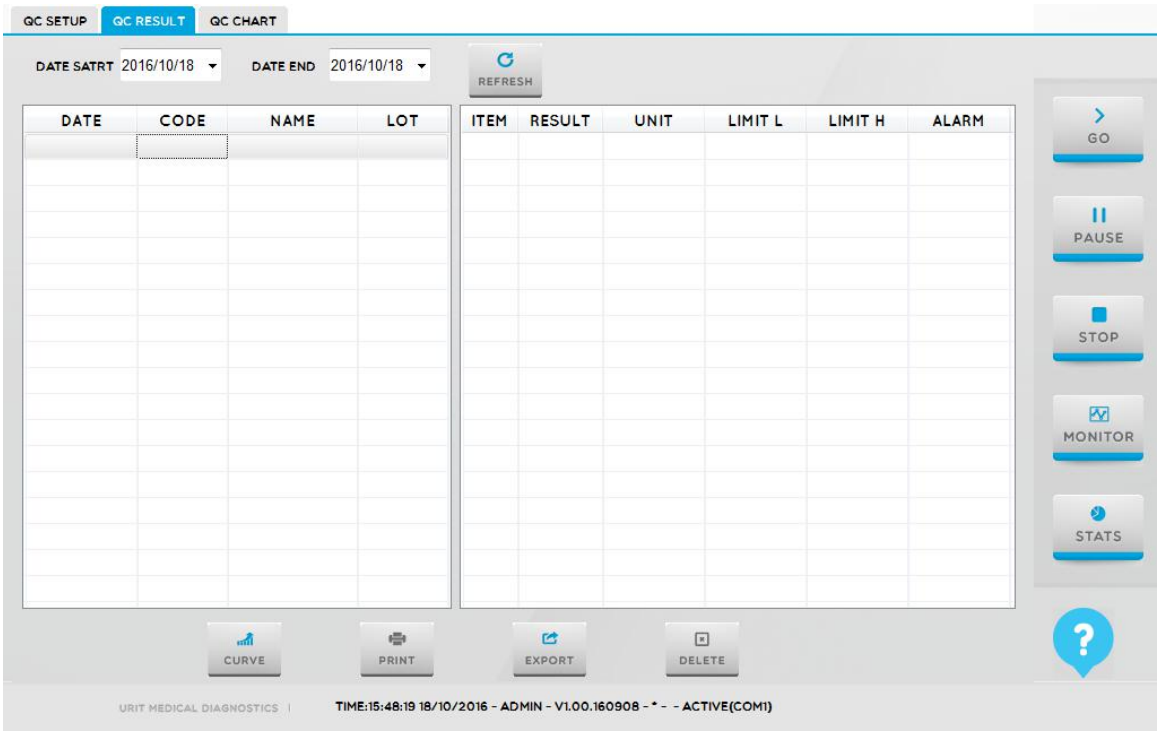


Figure3.6.2-1 QC result interface

1) QC result screening conditions: the test time range is the screening conditions.
2) QC test information list: the information includes QC test time, QC number, QC name and lot number.
3) QC item information list: the information includes QC item, QC result, unit, normal low value, normal high value and prompt.
4) Basic buttons:

[Curve]: to select arbitrary QC item result, click the button to enter result curve interface to check the curve of the selected item.

[Print]: click the button to print all information in the test information list and item information list.

[Export]: click the button to export all information in the test information list and item information list.

[Delete]: to select an arbitrary QC item result, click the button to delete the item result information.

3.6.3 QC chart interface

The interface is used for check and analysis QC chart.

1. Click **QC** button.
2. Click **QC chart** button to enter the interface as follows:

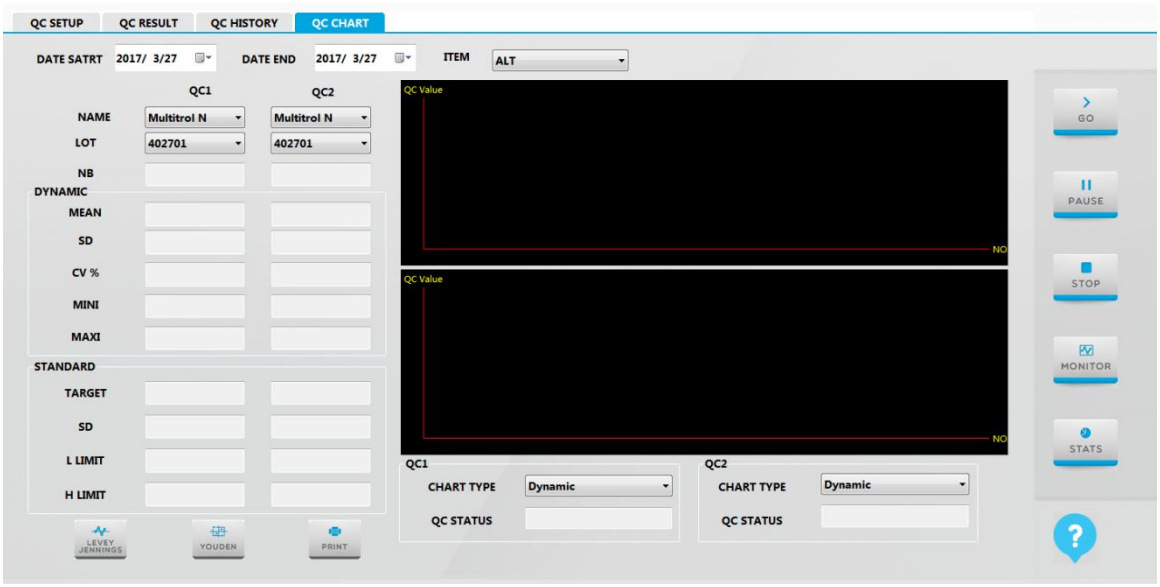


Figure3.6.3-1 QC chart analyze interface

1. QC result screening conditions: the conditions include time range and QC item.
2. QC comparative information: to select the name and corresponding lot according to the QC item, then the result of this lot will display. It can analyze two different results which QC and lot are different. The QC chart will be describing accord to result.
3. QC chart

To describe the QC chart according to the result which analyze by QC comparative information.

4. Basic buttons:

[LEVERY JENNINGS]: click the button, the result will be described as the LEVERY JENNINGS QC chart.

[YOUDEN]: click the button, the result will be described as the YOUDEN QC chart.

[Print]: click the button to print out QC result and QC chart.

3.7 Instruction of alarm interface

This module includes alarm and alarm records interface.

3.7.1 Instruction of alarm interface

This interface is used for check the current alarm information.

1. Click the alarm frame on the top.

2. Click Alarm button to enter the interface as follows:

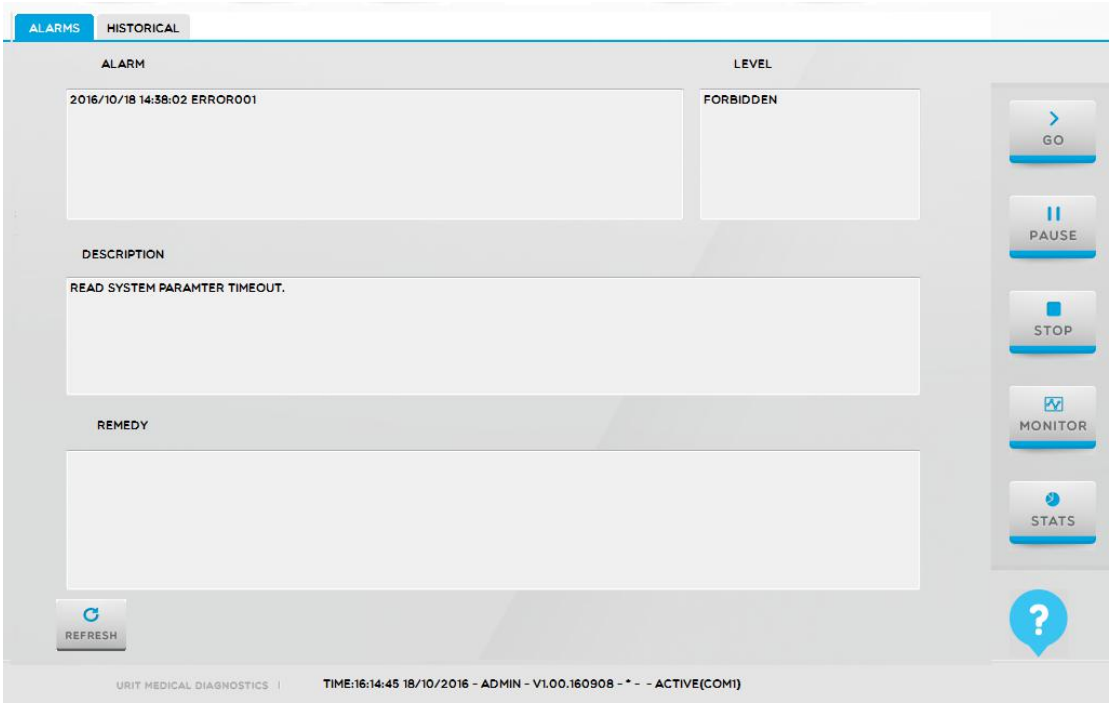


Figure 3.7.1 alarm interface

1) Detail alarm information: alarm number, alarm level, alarm description and remedy.

2) Basic button:

[Refresh]: click the button to clean up the current alarm information.

3.7.2 Instruction of alarm record interface

This interface is used for check historical alarm information.

1. Click the alarm frame on the top.

2. Click Historical to enter the interface as follows:

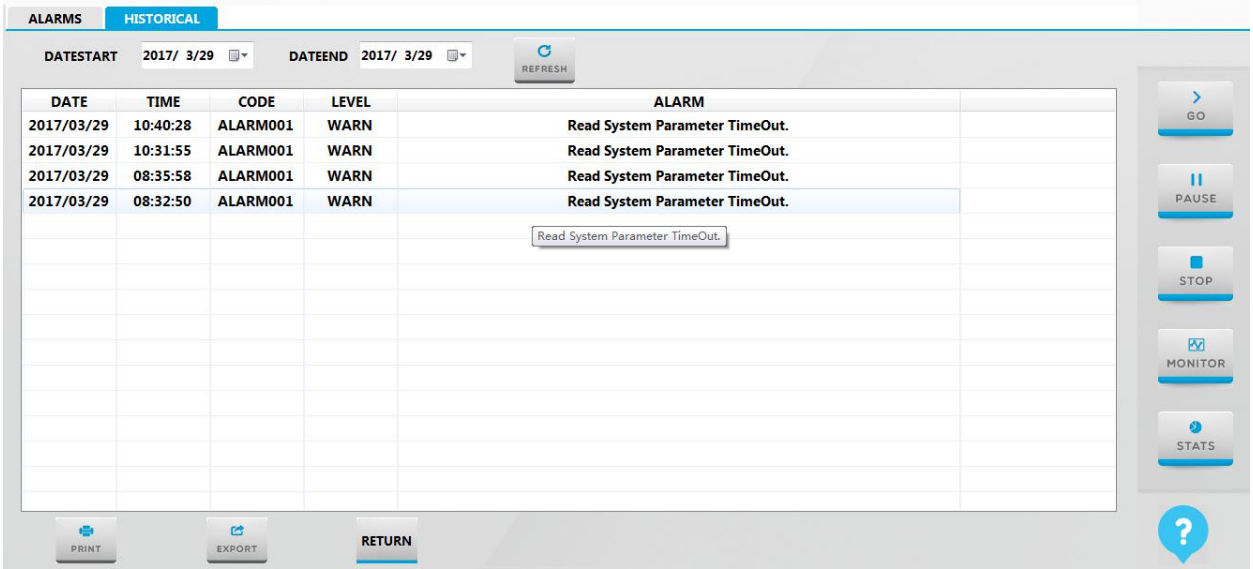


Figure 3.7.2 Historical interface

1. Alarm screening conditions: the time range is the screening conditions.
2. Detail alarm information: alarm date, alarm time, alarm number, alarm level and alarm content.
3. Basic buttons:

[Print]: click the button to print out all alarm information.
[Export]: click the button to export all alarm information to the file.
[Return]:click the button to return to the forward menu.

CHAPTER 4 BASIC OPERATION

Following show the basic operation procedures of instrument. Suggesting perform standard analyses every day after start-up and do control analyses.

4.1 Operation procedures

Table 4-1 Operation procedures

Operation procedures	Description	Related chapter
1. Check before powering on	Check sample probe/stirrer, distilled water bucket, waster solution bucket ,detergent bucket and power supply	**4.2**
2.Power on	Power on, start the operating system, confirm the instrument and reagents status	**4.3**
3. Preparation before test	Biochemical reagent and detergent preparation	**4.4**
4. Calibration test	Calibration solution preparation, Calibration test application, start calibration test	**4.5**
5. QC test	Control solution preparation, QC test application, start QC test	**4.6**
6. Routine sample test	Sample preparation, routine sample test application, start sample test	**4.7**
7. Emergency sample test	Emergency sample test application, Start emergency sample test	**4.8**
8.Special test	Sample complementing test, modify sample test, sample retest and diluted sample test	**4.9**
9. Test status and stop	Check reagent tray/sample tray/reaction tray status, Pause/exit/emergency exit operations	**4.10**
10. Daily maintenance	Maintenance operations, such as empty the waste solution	**4.11**
11.Power off	Power off, 24 hours standby and power off operation	**4.12**

4.2 Check before powering on

Please check the following matters before powering on, to ensure the normal work of the system after start.

1. Check the power supply

1) Check the power supply to confirm it has the ability to provide correct voltage.
2) Check whether the UPS switch is in **ON** status.
3) Check whether the analyzer host, computer and print are well connected.

2. Check the printer

Check whether the printer paper is enough and properly installed.

3. Check the sample adding system

Sample probe, reagent probe and stirrer are easy to get dirty or damaged, so before starting up, please look for any dirt or bending.

1) Check sample probe, reagent probe and stirrer are whether stained with water or dirt, whether bend or clogged.
2) Check each rinse tanks are whether stained with dirt or clogged.

If sample probe, reagent probe and stirrer are stained with dirt, please refer to chapter 9.4.1.

If sample probe and reagent probe are clogged, please refer chapter 9.6.2 for unclogging.

If sample probe, reagent probe and stirrer are bending, please contact URIT for replacing.

If rinse tanks are stained with dirt or clogged, please refer chapter 9.4.2 to operate.

4. Check the detergent and the diluent solution

The instrument could not continue testing when the detergent is inadequate, so please make sure the detergent is enough.

1) Check whether the detergent in sample tray and reagent tray are enough. If not, please timely adding or replacing.
2) Check whether the diluent solution in reagent tray is enough. If not, please timely adding.
3) Open the front door of the analyzer host, and then check whether the detergent in detergent bottle is enough. If not, please timely adding or replacing.

For the specific operation, please refer to chapter 9.3.2.

Warning

1) In order to ensure the cleaning effect and instrument performance, please use the detergent specified by URIT, otherwise may cause the instrument damage.
2) When adding detergent into detergent bucket, do not over the marked the highest line.

Biological Hazard

DO NOT touch the detergent. If it adheres to hands or clothes, wash it off with water immediately. If it splashes into eyes, wash it off with water immediately and consult a doctor.

5. Check the distilled water bucket and the waste solution bucket

The instrument could not continue testing when the distilled water is inadequate or waste solution bucket is overfill, so please check the following maters before power on.

1) Check whether the distilled water is enough. If not, please timely adding.
2) Check whether the waster solution is too much. If yes, please empty the waste solution bucket.
3) Check whether the flow path tubes are bending or leakage.

Note

In order to ensure the accuracy of test results, avoid flow path clogged, please use the water machine to make water.

Biological Hazard

1) When check the connection of waster solution, be sure to put on protective gloves, clothes, or even goggles if necessary.
2) DO NOT touch the waste solution. If it adheres to hands or clothes, wash it off with water immediately. If it splashes into eyes, wash it off with water immediately and consult a doctor. Please comply with the medical waste management regulations to handle the waste solution.

4.3 Start up

4.3.1 Power on

After the instrument is properly connected to a power outlet, you should according to the following order to turn on the instrument.

1) Turn on the instrument power switch (In the right side of instrument)
2) Turn on the instrument test switch (In the right side of instrument)

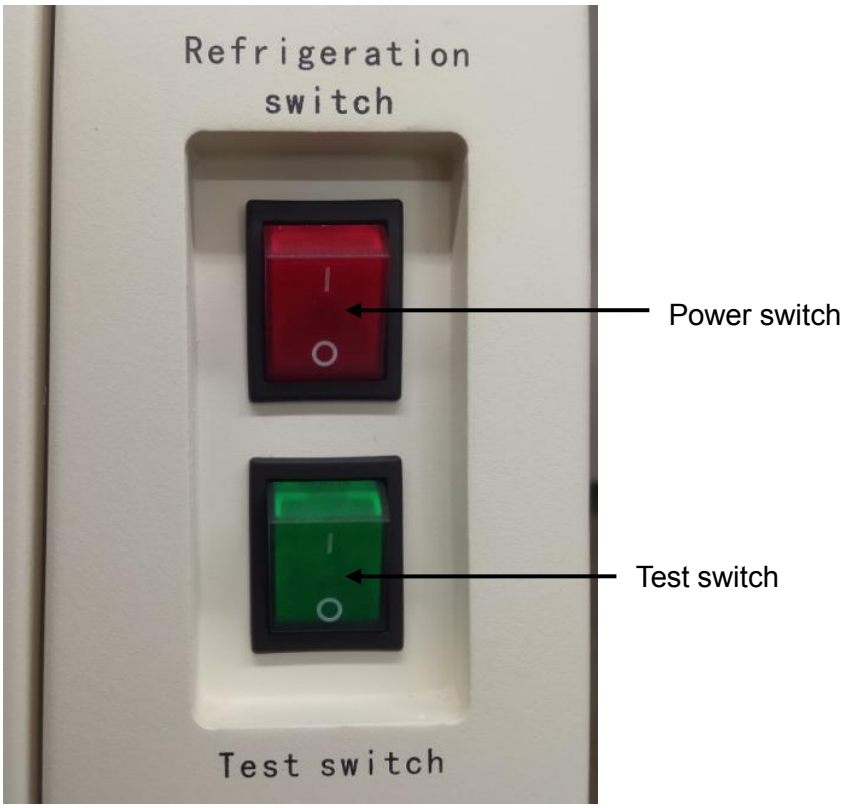


Figure 4.3.1 Switch

Remind

For power switch and test switch, switch up is on-state, **I** is on, **O** is off.

Note

The power switch and test switch is mutual independence. The cold storage function is turn on when the power switch is on; turn on the test switch to begin test.

3) Turn on the display monitor of computer of the operation unit;
4) Turn on the computer of operation unit;
5) Turn on the printer.

4.3.2 Start the operating software

1) After login the Windows operating system, then double-click the biochemical management software desktop icon; or select **Start** Program to start the biochemical management software. Wait until pop up the login dialog, as shown in the figure below:

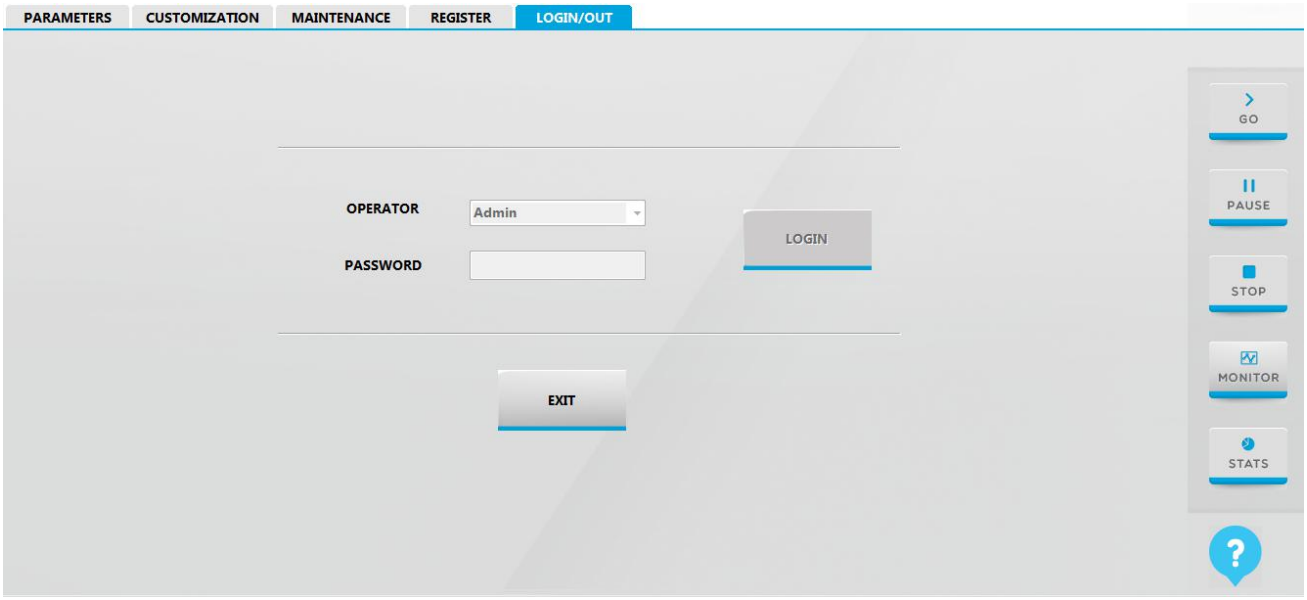


Figure 4.3.2-1 Login interface

2) Input the registered doctor's name and the corresponding password to enter system to operate analyzer.

3) Enter the system and a dialogue box will pop up, click **Execute**, system will clean the probe, stirrer and cuvette automatically.

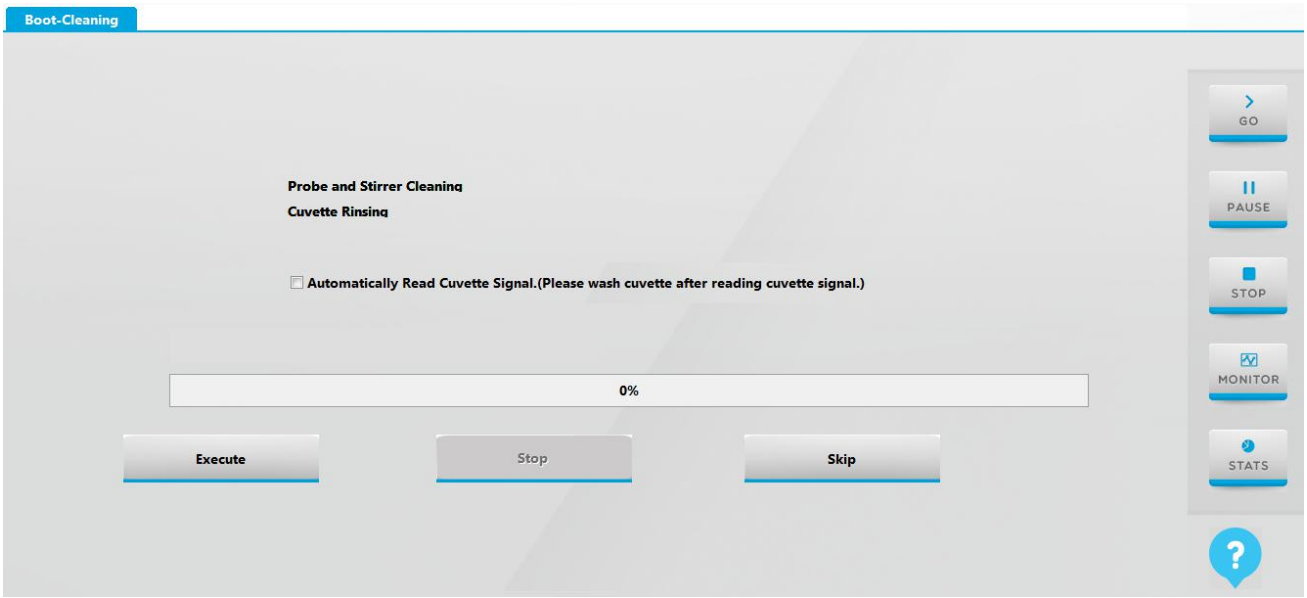


Figure 4.3.2-2 Maintenance interface after power on

Note

It is make sure the cover of detergent of No.30 position has been cover well before click execute. Otherwise will cause probe collision.

4) Switch user: user could click **Execute** to exit system, than use different user name to login.

Note

User authority management is applied to limit certain function for low permission user, which is benefit for user to manage the software reasonably. There are three user groups, user, administrator and guest.

Note

Instrument with the function of 24 hours stand-by, auto sleep and one-key setup.

Caution

In order to ensure accurate test results, please preheat 30 minutes after turn on the instrument, and then start testing operation, to ensure that the light source and temperature control are stable.

4.3.3 Confirm the instrument status

After start, please check various states of instrument if necessary, such as: check the temperature of reagent tray and reaction tray, and the status of detergent, distilled water and waste solution. Make sure they are all right. If not, please refer to chapter **9 Care and Maintenance** and chapter **11 Alarm and troubleshooting** to operate.

1) Check whether the analyzer host sends alarm sound;

◆ If yes, that's means the instrument has something wrong. Continue to the next step;

◆ If not, the instrument status still needs to be confirmed. Continue to the next step.

2) Click menu bar **Instrument maintenance→Instrument status query**, this interface will display instrument status and marked the abnormal status.

4.4 Pre-test preparation

4.4.1 Prepare the biochemical reagent

After confirm the instrument status, please prepare the measurement using reagent.

Biological Hazard

1) Be careful not to spill out reagent. If reagent is spilled, wipe the area by dry fabric immediately.
2) When replace the reagent, be sure to put on protective gloves, clothes, or even goggles if necessary. If it adheres to hands or clothes, wash it off with water immediately. If it splashes into eyes, wash it off with water immediately and consult a doctor.

1) Be sure to use the certified reagents. Read through the reagent instructions and set up parameters properly before analyses. For biochemical item parameter setup, please refer to chapter **3.1.3.1 Normal item parameter setting**.
2) If reagent is insufficient, replace it with a whole new bottle. Place the reagent bottle in the specified position according to the preset reagent parameters. Please according to the following operations to place the regent:

◆ Click **Reagent** icon in main menu, and then select the **Standard** option;

◆ Check the remaining volume and reagent position, the user should according to the item and position in this interface to place the corresponding reagent.

3) Reagent should be stored at temperature of 2℃ to 8℃. Long-time exposure in the air may deteriorate the reagents.

Note

1) In order to avoid firing pin phenomenon, please correctly place the reagent bottle.
2) Air bubbles are not permitted in the reagent bottle.
3) Please make sure the instrument is in standby mode or turned off when open or closed the cap of reagent bottle in reagent tray.

4.4.2 Prepare the detergent

Detergent is used for clean the reaction cup, reagent probe and sample probe. So when detergent is insufficient, the system will pop up alert information, in order to not affect the test result, please add detergent timely.

Dilute detergent proportionally, and then add into the detergent bottles, sample cup (tube) which on the position for detergent of sample tray and reagent bottle which on the position for detergent of reagent tray.

Warning

1) Don't mistake the original detergent, such as acid detergent and alkaline detergent, when they mixed, it will produce poisonous gas.
2) When using concentrated detergent, please dilute detergent properly first.
3) Be careful not to spill out original detergent. If original detergent is spilled, wipe the area by dry fabric immediately. Otherwise it will produce poisonous gas and damage the instrument.
4) When adding detergent into detergent bucket, do not over the marked the highest line.

Biological Hazard

DO NOT touch the detergent when open the original detergent bucket. If it adheres to hands or clothes, wash it off with water immediately. If it splashes into eyes, wash it off with water immediately and consult a doctor.

4.4.3 Confirm the reagent status

It is necessary to check the reagent whether put on the right position or not, and whether the reagent allowance is enough for the daily test.

1) Click **Reagent** button to enter the interface.
2) Select the reagent information of the item.
3) Click **Scan** button to check the reagent allowance.

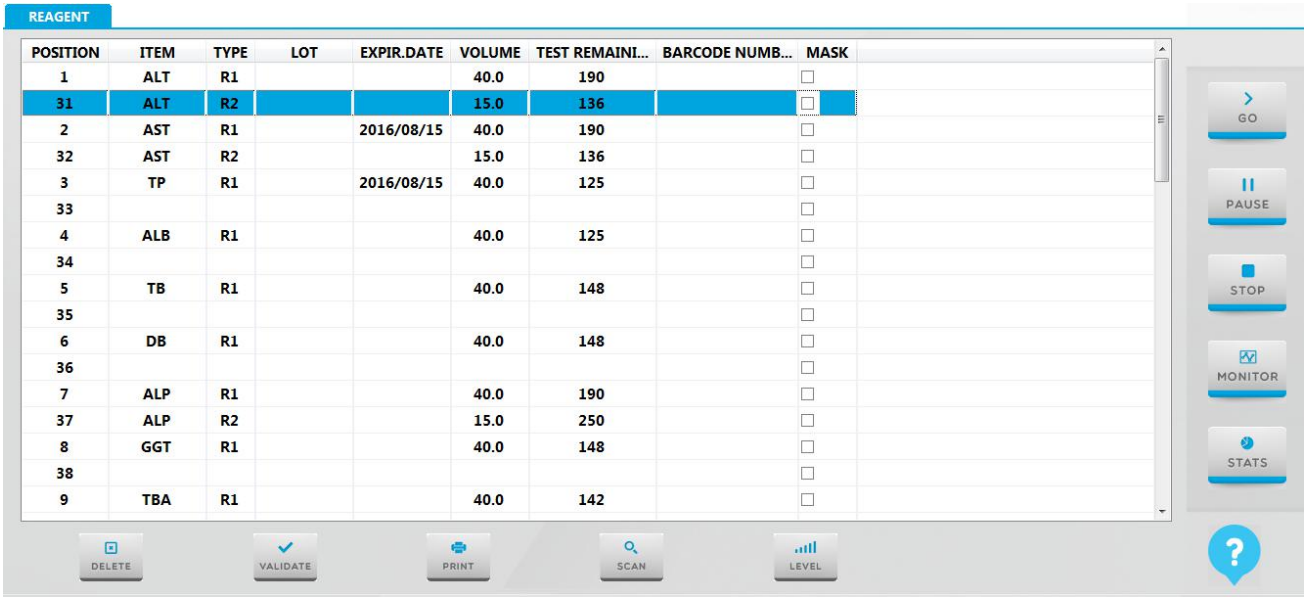


Figure 4.4.3 Reagent interface

4.5 Calibration test

Test the absorbance change rate of the known concentration calibration solution, and then according to the computational relationship between concentration and change rate (Calibration method), to calculate the coefficient of the computational relationship (Calibration coefficient), and then determine the specific operation expression between concentration and change rate. So the routine sample can be tested according to the specific operation expression and the absorbance change rate.

It is suggested to perform calibration every six months or under the following situations:

- When initially installing and running the instrument.
- Added a new item.
- When changing reagent batch number or type, unless specified by the lab that the change will not influence the precision.
- After replacing the major components, such as lamp, sampling mechanism, probe, or cuvette etc.
- After performing a preventive maintenance on the instrument.
- When control result shows abnormal offset, tendency, or falls out of the acceptable range and it cannot be corrected by routine tests.

4.5.1 Prepare the calibration solution

According to the calibration specification and related laboratory requirements to prepare the calibration solution, and then add proper volume of calibration solution into sample cup and place the cup in the standard position to do the calibration operation.

Biological Hazard

Incorrect use of calibration solution can cause infection, do not let your hands contact with the calibration solution. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the calibration solution splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

Caution

Do not use the expired calibration solution, otherwise may lead to inaccurate measurements.

4.5.2 Application for the calibration test

After prepare the calibration solution, please according to the steps below to apply for calibration test. Before apply for biochemical item calibration test, please make sure that the concentration and position of calibration solution have been set up correctly, details please refer to chapter 3.5 instruction of calibration interface.

1) Click **Test** button;
2) Click **Calibration** button to enter the interface.

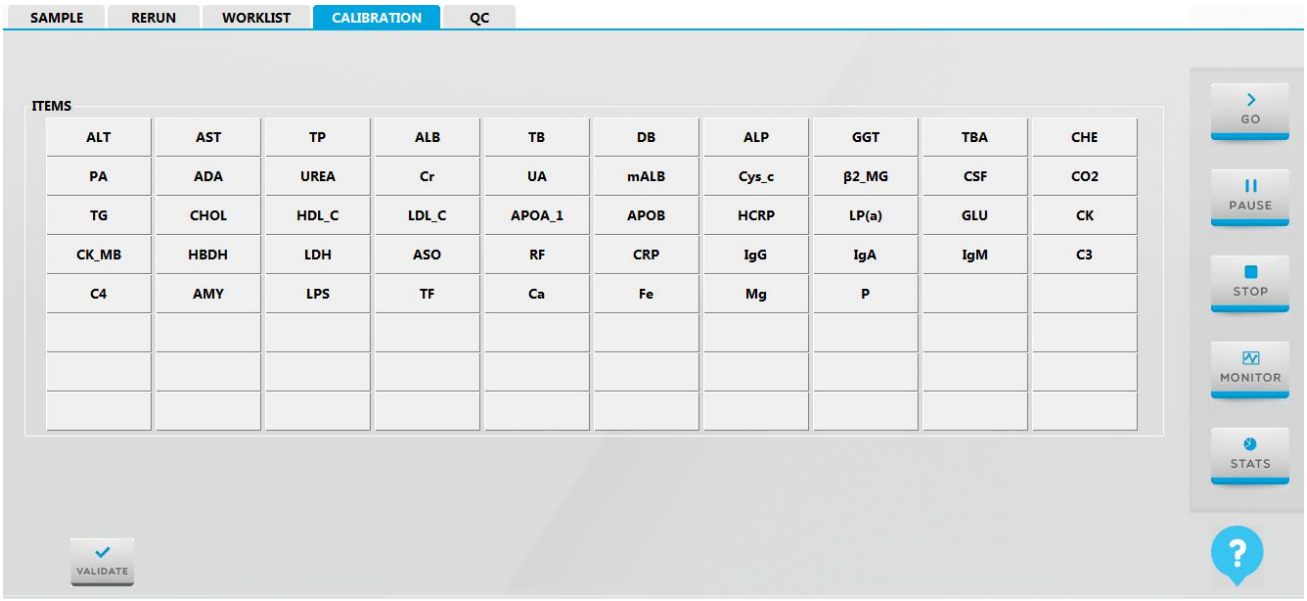


Figure 4.5.2 Calibration application interface

3) Select the item you need to calibrate, and then click **Validate** button to add it into the right side test item list, and also you can see the position information of calibration item in this interface.

4.5.3 Start the calibration test

After calibration test application and correct place the calibration solution in sample tray, now you can starting the calibration test.

1) Click **GO** button to enter the test interface;
2) Click **TEST** button in test interface to start the calibration test.

Caution Note

Before test, please make sure the calibration solution has been correctly selected and placed.

4.6 QC test

Every time after perform a calibration test, replace reagent lot number, perform maintenance and troubleshooting operations, please perform a QC test to make sure that the instrument performance is stable.

QC test might need multiple quality control samples. In order to determine whether the instrument test performance is stable, after establish the standard curves, please run the QC test for every test items in everyday, quality control tests including test the control solution in high and low concentration each three times when before test, under testing and after test.

Note

QC test results must within the allowed error range before test the actual sample.

4.6.1 Prepare the control solution

According to the control solution specification and related laboratory requirements to prepare the control solution, and then add proper volume of control solution into sample cup and place the cup in the QC position to do the QC operation.

Biological Hazard

Incorrect use of control solution can cause infection, do not let your hands contact with the control solution. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the control solution splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

Caution

Do not use the expired control solution, otherwise may lead to inaccurate measurements.

4.6.2 Application for the QC test

Before apply for biochemical item QC test, please make sure you have complete the parameter setting, such as target value and SD value. Details please refer to chapter 3.6 instruction of QC setting.

1) In menu, click **Test** button;
2) Click **QC** button to enter the interface;

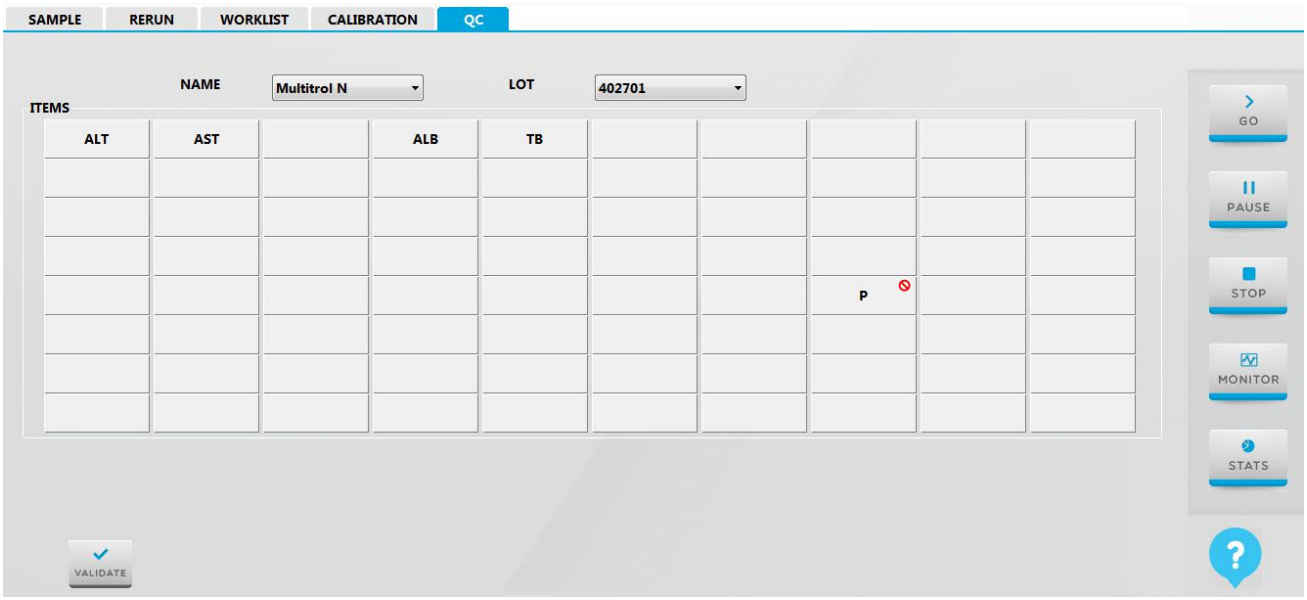


Figure 4.6.2 QC test interface

3) Select the QC sample position from the lower right corner drop-down list;
4) Click **Validate** button to add it into QC item test list.

4.6.3 Start the QC test

After QC test application and correct place the control solution in sample tray, now you can starting the QC test.

1) Click **Go** button to enter the test interface;
2) Click **TEST** button in test interface to start the QC test.

Note

Before test, please make sure the control solution has been correctly selected and placed.

4.7 Routine sample test

If QC test results are indicate the system is under controllable range, then you can start test patient's sample.

This section describes how to apply routine sample tests. You can apply for single biochemical item test and profile item test. Before test, please make sure that the test items' parameters have been set up correctly, including: test method, test wavelength, sample volume and reagent volume, etc., details please refer to chapter 3.1.3.1 Instruction of routine item interface.

4.7.1 Manual apply sample test

4.7.1.1 Prepare the sample

Add the sample into the specific sample cup, or directly use the test tube which meets the requirement of instrument specification. In test interface, select the corresponding sample position to perform the sample test.

Note

Before add the sample, please observe sample appearance and shape, such as jaundice, hemolysis, chylemia , etc.

Caution

Do not use the expired sample, otherwise may lead to inaccurate measurements.

Biological Hazard

Incorrect use of sample can cause infection, do not let your hands contact with the sample. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

4.7.1.2 Application for the routine sample test

When analyzing a normal patient's sample, it is needs accord to the test application form's information to do the sample test setting and patient information registration.

1) Click Test button in main menu to enter the interface, then select the biochemical items and apply for routine sample test in this interface;

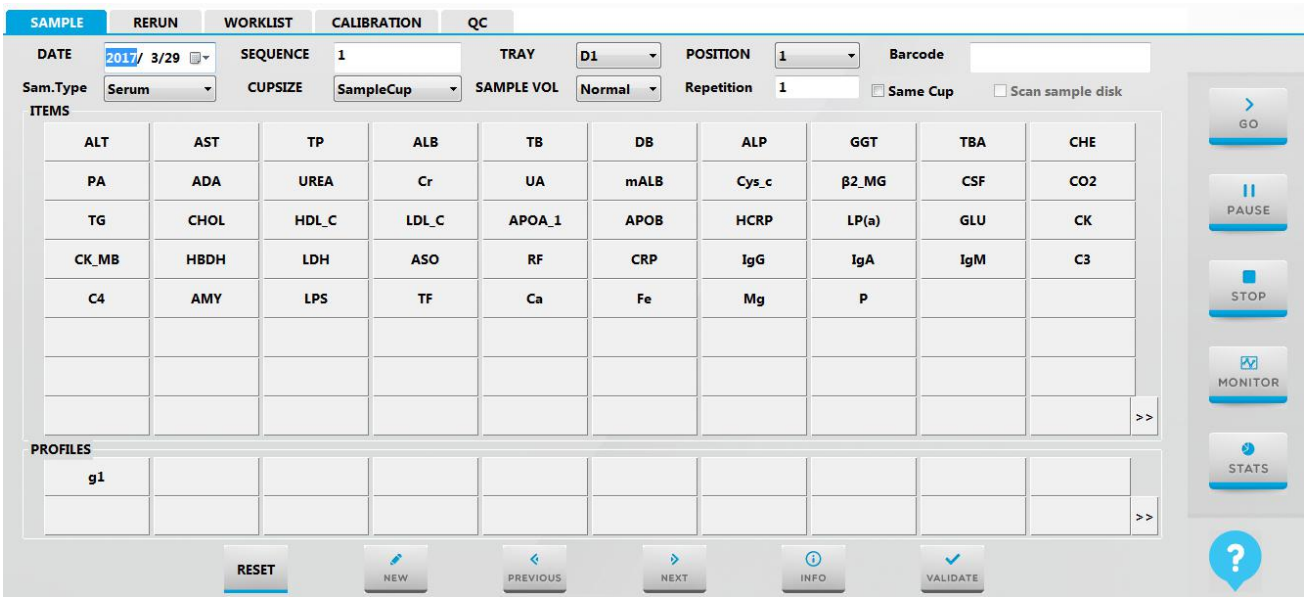


Figure 4.7.1.2 Routine item test application interface

2) Select the date as the default date of test.
3) Input the sample ID in【**Sam. ID**】;

   The default sample ID is 1. Sample ID could be added automatically by system, and also entered manually. You cannot use the same sample ID for two different samples, otherwise the former test results will be covered by the later one.
4) Select the virtual sample tray from【**Dummy tray**】pull-down list;

   Sample supports virtual sample tray setting, sample tray allows set 20 virtual sample tray maximum.
5) To select the position which sample will be put in **[position]** pull-down list.

   System default No.1 position is the first position and user also can choose by himself.
6) Input patient number in **[Barcode]** frame.
7) To select sample type in **[Sample type]** frame.
8) Select the size of cuvette from【**Cup size**】pull-down list, options include sample cup, test tube, test tube 1, the default is sample cup.
9) Select sample volume in **[sample volume]** frame; include original volume and diluent volume.
10) Input the repeat time of sample test. One is default.

    Please input the times if you need to apply a batch of routine test. Click **Same cup**, so the test use the same cup, if not, use different cups.
11) Click **Validate** button to add the item or combined item into the list;

    The color of item is blue which has been selected, and click again to cancel selected.

    If the item cannot be selected, that means calibrate failure or not setup reagent position or reagent allowance is zero.

Note

Please be sure to place the sample correctly in the applied sample position.

Remind

In order to improve the efficiency, the patient basic information such as name, gender, can edit in the testing process.

4.7.1.3 Start the sample analysis

After apply routine sample test and locate sample well, it can start test.

1. Click **Work-list** to check the information, dummy tray D1 is default to display. If several dummy trays have been used, click the button on the right bottom to switch.

   |< to display the list of D1 dummy tray.

   < to display the list of next dummy tray.

   > to display the list of forward dummy tray.

   >| to display the list of D20 dummy tray.

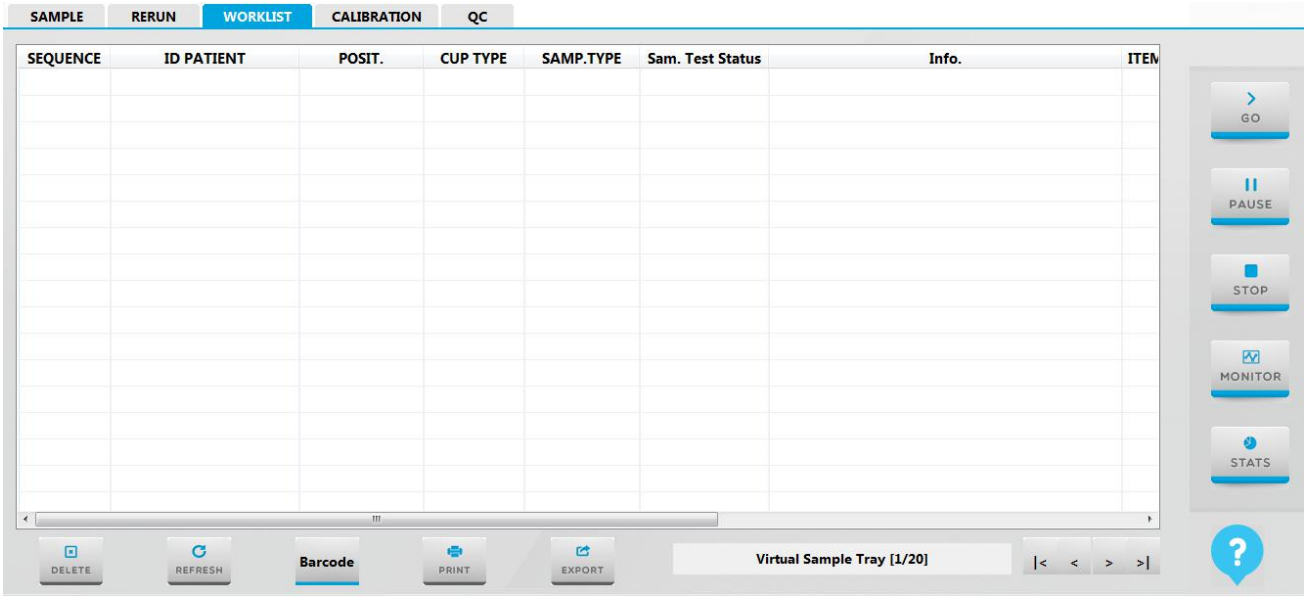


Figure 4.7.1.3 Sample applying list

2. Click 

icon and enter the test system.

3. Click **Test** icon in test interface.

Note

Please confirm the sample has been located on correct position, then click Test icon.

4.7.2 Apply sample test by use sample barcode scanning with two-way LIS system

Note

1) This chapter is only apply for matching sample barcode module, is it useless if you not install barcode scanner.
2) The automatic sample applying function only achieve when the two-way LIS system is connected, the sample test list will be download from LIS server.

4.7.2.1 Prepare sample

Add the sample to the tube which specification is appropriate. The tube sticks barcode, please refer to chapter 1.7.2 for more information about the parameter of barcode. After adding, put the tube to the sample tray and pay attention the barcode should aim the barcode scanning window.

Barcode printing requirements:

1. It recommends using the paper which size is 30mm*50mm to print or the size is near to.

2. It recommends using barcode which precision is 0.25mm that means the width of pinstripe of barcode is 0.25mm.

3. The margin between barcode and paper should more than 5mm, such as follows:

Figure 4.7.2.1-1

Barcode sticking requirements:

1. The barcode should stick well, and the gradient not allow exceeding±5°.

2. For the length of 100mm tube, the barcode should stick on the middle of tube, the distance from top or bottom to barcode is 20mm. See figure 4.7.2.1-2.

3. For the length of 75mm tube, the barcode should stick near to top, the distance from bottom to barcode should more than 20mm. See figure 4.7.2.1-2.

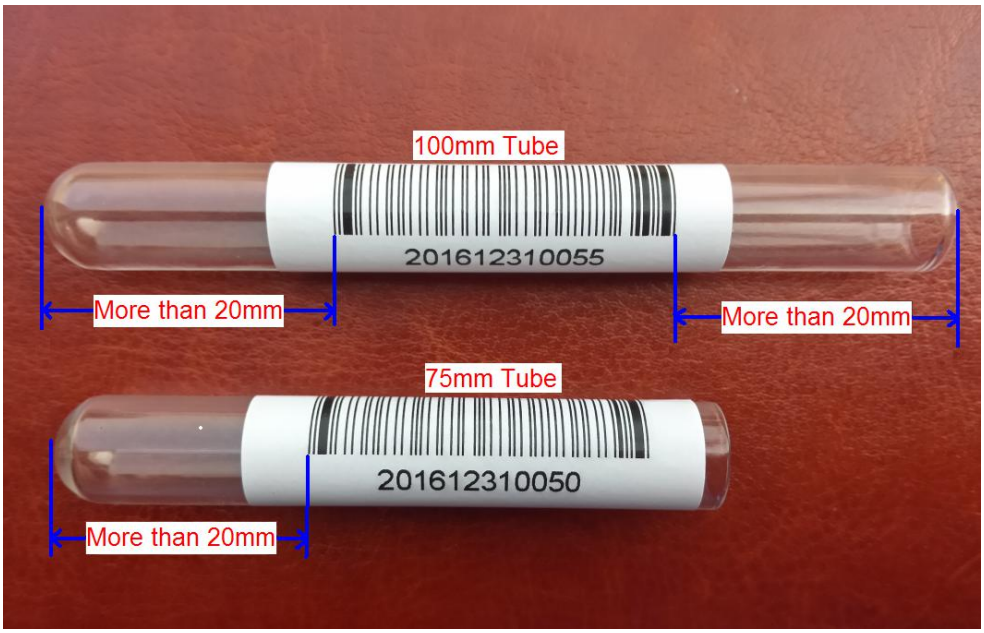


Figure 4.7.2.1-2

Note

Please make sure the centrifugal effect of serum is well if use the blood tube to test, to avoid fibrin block the probes.

Note

Do not stick water or dirt on the barcode, otherwise it cannot be identified.

Note

Please observe the sample appearance and form before test. Such as hemolysis, jaundice, and chylemia.

Note

Do not use the sample which is expired, or the result will not correct.

Biochemical hazard

Incorrect use of sample can cause infection, do not let your hands contact with the sample. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

4.7.2.2 Sample application

1) Click 

icon to enter the routine sample applying interface.

2) Click **Scan sample disk** when the LIS system has been connected.

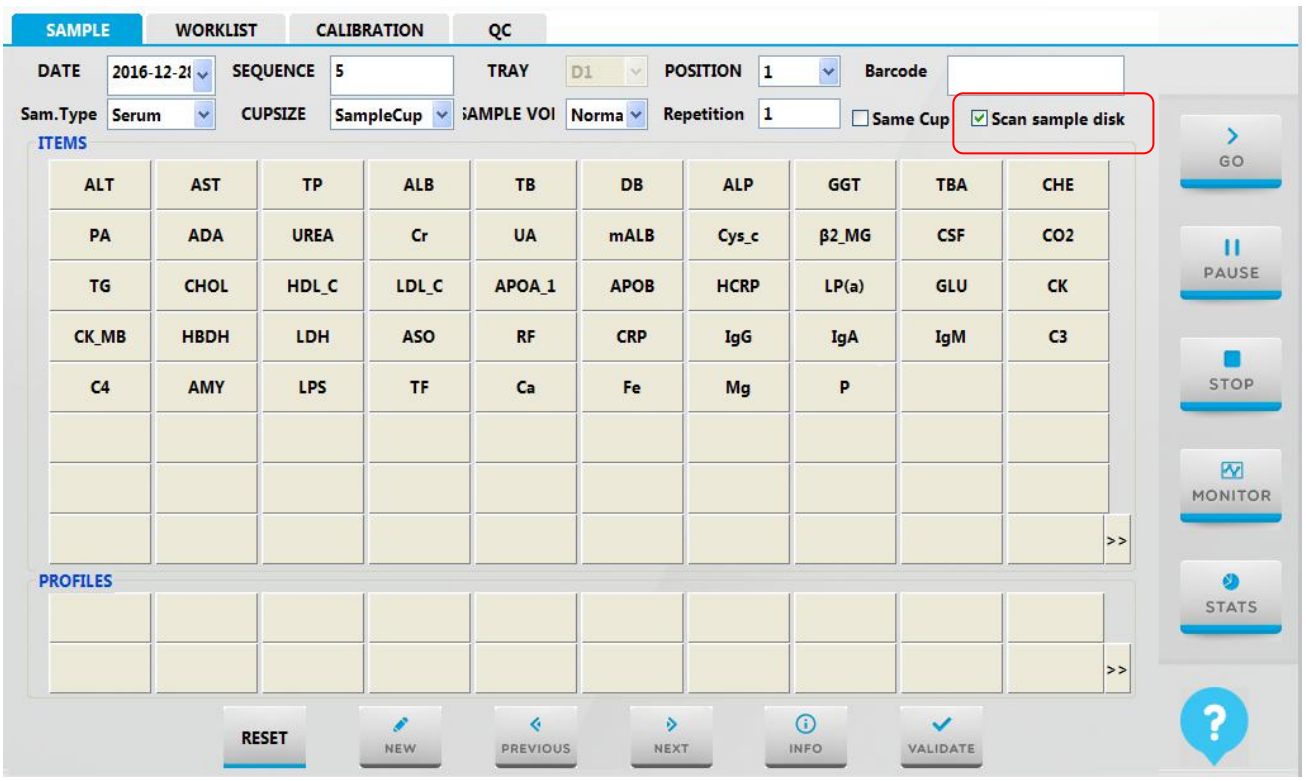


Figure 4.7.2.2 sample barcode apply sample test

4.7.2.3 Start sample analyzing

1) Click 

icon.

2) Instrument will scan the sample and get test list from LIS server. When the barcode is matching with test list, the test is start.

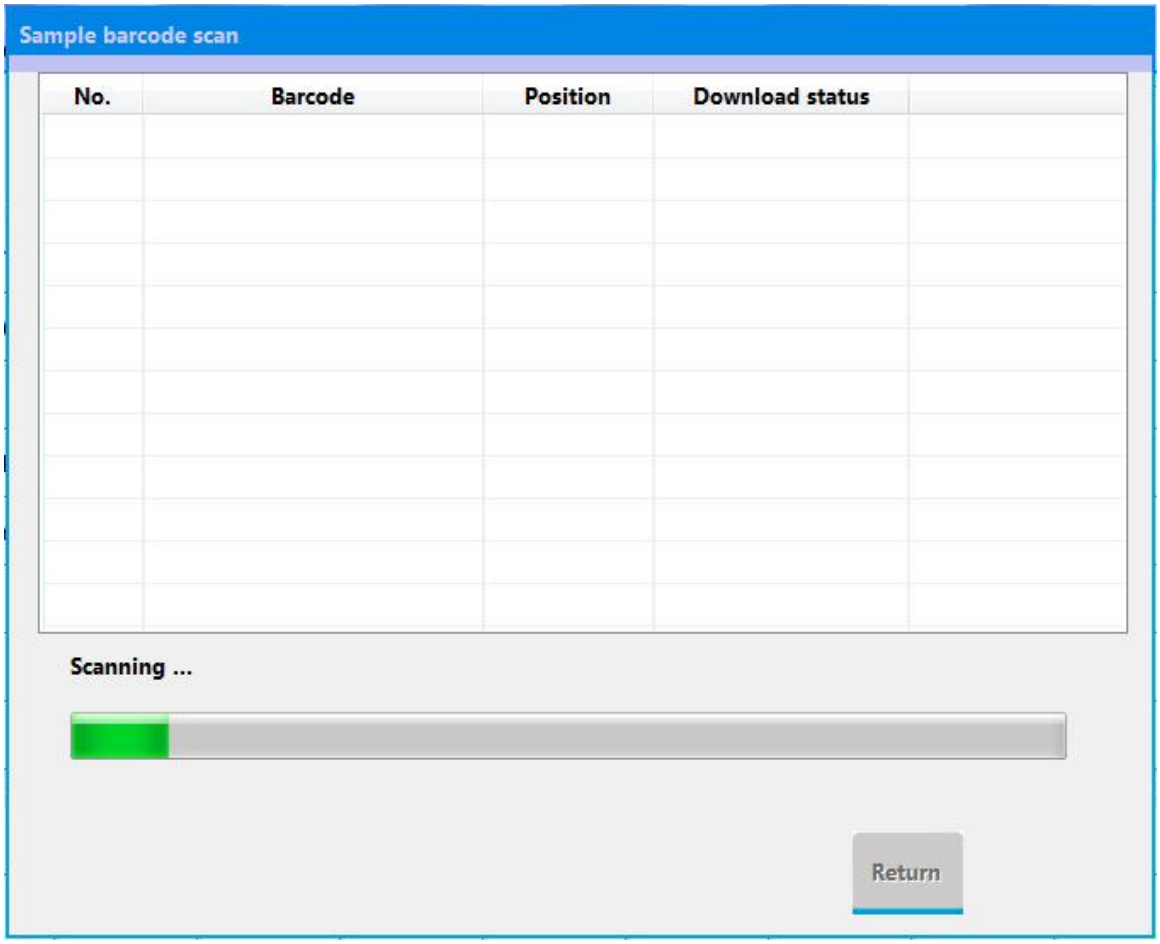


Figure 4.7.2.3 sample barcode scan

Note

To make sure the sample scanning discrimination is correct:

1) Be sure the scanning window is clear and no dust, to wipe by paper if there is dirt or dust.
2) To make sure the barcode on tube is clear and no dirt.

3) When one of the sample barcode is not scanning, do the following steps:

a) Click 

icon and return to management software, click

icon, the status bar will appears countdown.

b) Click 

icon to enter routine sample applying interface.

c) Input barcode in barcode frame, and select the position in drop-down list and press **Enter** key, the software will get test list from LIS server.

Note

If the position which scan by barcode is collides with manual selecting one, the software will prompt, the two samples will not test, and it is need to check the sample position.

d) When the countdown is over, sample tray will stop adding sample; now put the sample to the setting position.

e) Click 

icon, if the sample tray barcode scanning is click, instrument will scan sample tray to confirm whether the sample position is change or not.

4.7.2.4 Send result to LIS sever

First method: send automatically, click **result send in real time** in LIS setting interface, when all the result of a sample is calculated, system will send the results to LIS server.

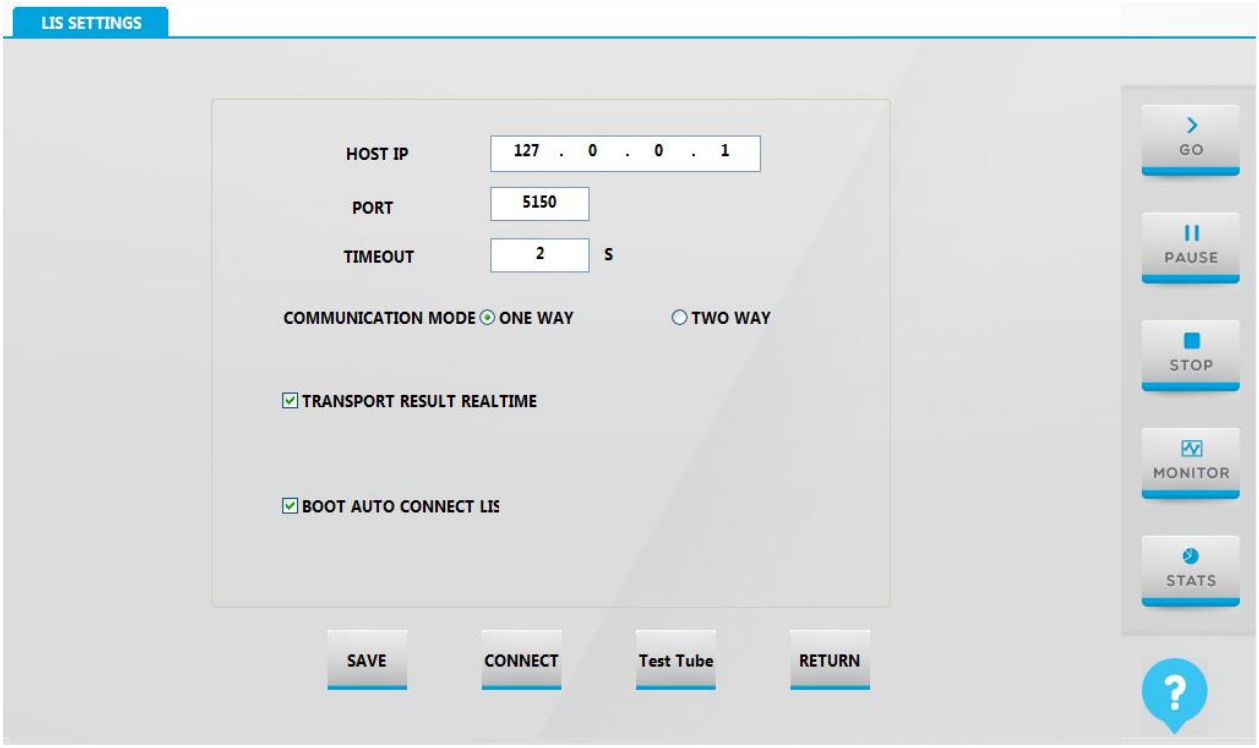
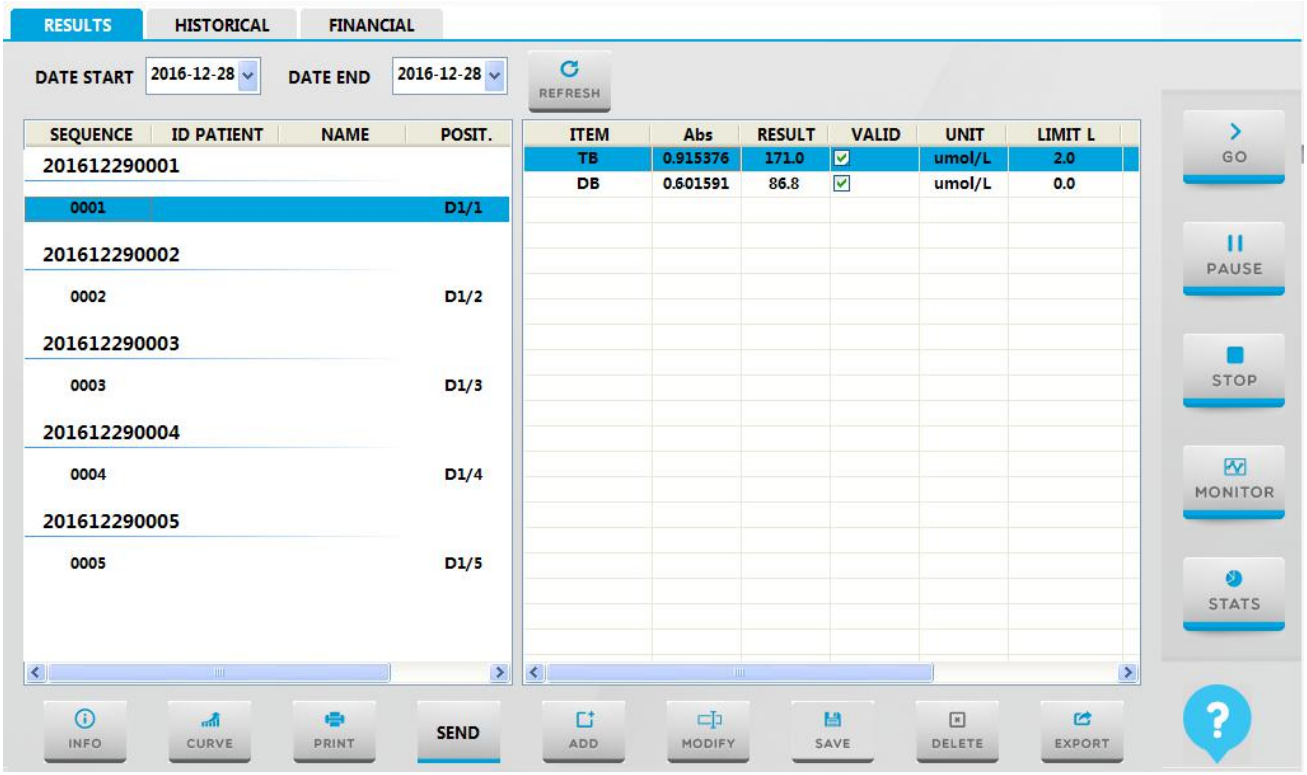


Figure 4.7.2.4-1 Transport result in real time setup

Second method: send automatically, do not click **result send in real time**, select a sample ID which has been examined, click **Send** icon to send the data to LIS server.



Figures 4.7.2.4-2 manually send result

4.8 Emergency sample test

In an emergency situation, emergency sample test is prior to routine sample test.

Biological Hazard

Incorrect use of patient sample can cause infection, do not let your hands contact with the patient sample. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

4.8.1 Application for the emergency sample test

Emergency sample application is suitable for the single emergency sample application, this product does not provide batch emergency samples application.

1) Click 

button in test system, as shown in figure 4.8.1.

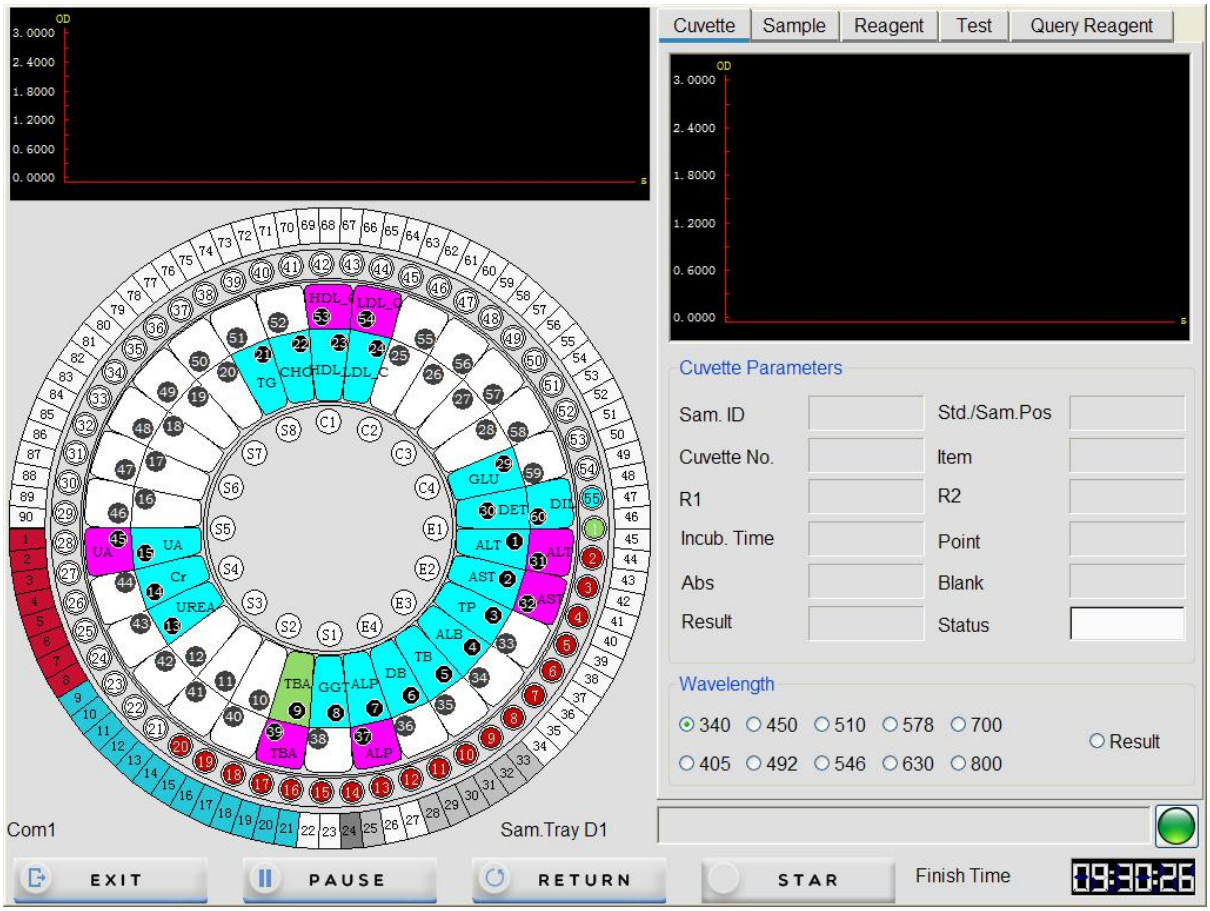


Figure 4.8.1 Test interface

Main functional buttons:

[Exit]: click the button to exit test system.

[Pause]: click the button to enter pause status when the system completes the current operation.

[Return]: click the button to return to the management procedure.

[Start]: click the button to start test.

Biological Hazard

Sample adding probe is direct contact with the patient sample, so it is potentially infectious. Please place the emergency sample after the instrument operation is stopped, in order to avoid your hand scratched by sample adding probe.

2) Click 

button, the status bar will appears countdown.

3) Click 

icon to enter the routine sample applying interface.

4) To apply STAT sample test according to chapter 4.7.

5) When is countdown is over, sample tray will stop to add sample, put the sample to STAT position, the position is from E1 to E4.

NOTE

Be sure the STAT sample is put on STAT position.

6) Put the adding sample in the position. The STAT positions are from E1 to E4.

4.8.2 Start the emergency sample test

1) Click **STAT** button to enter the test system;
2) To click **Continue** to test STAT sample priority;

4.9 Special sample test

Except for routine sample test, during testing process usually requires sample or item complementing, dilute sample or retest the abnormal sample.

4.9.1 Sample Complementing Test

Biological Hazard

Incorrect use of sample can cause infection, do not let your hands contact with the sample. Be sure to put on protective gloves, clothes, or even goggles if necessary. If the sample splashes to the skin accidentally, please treat immediately according to the working standards and consult a doctor.

Caution

Do not use the expired sample, otherwise may lead to inaccurate measurements.

Sample complementing test operations are the same as routine sample test.

1) Click 

button in test system;

And then the system will enter suspended state after complete the current sample adding operation.

2) Click 

button in test system, the countdown bar will appear as follow;

3) Click Apply icon to enter routine sample application interface.
4) Please refer chapter **4.7** for the routine sample test to complete the new sample complementing;
5) When the countdown is over, sample tray will stop adding sample, put the sample to the sample tray;

Biological Hazard

Sample adding probe is direct contact with the patient sample, so it is potentially infectious. Please place the sample after the instrument operation is stopped, in order to avoid your hand scratched by sample adding probe.

6) Click 

button in routine sample application interface to continue the sample test;

4.9.2 Re-test the sample

After complete the sample test, the system allows retest the sample automatically or manually. But only allows retest the item which has been tested. Manually retest can be operated in test data interface; automatic retest can be set according to exceeding linear range or substrate exhaustion.

Warning

The results of retest item will cover the original test results.

4.9.2.1 Manually retest the sample

After test, if you find any abnormal test results in test data interface, and then this sample can be manually retested

1) Click **Test** icon.

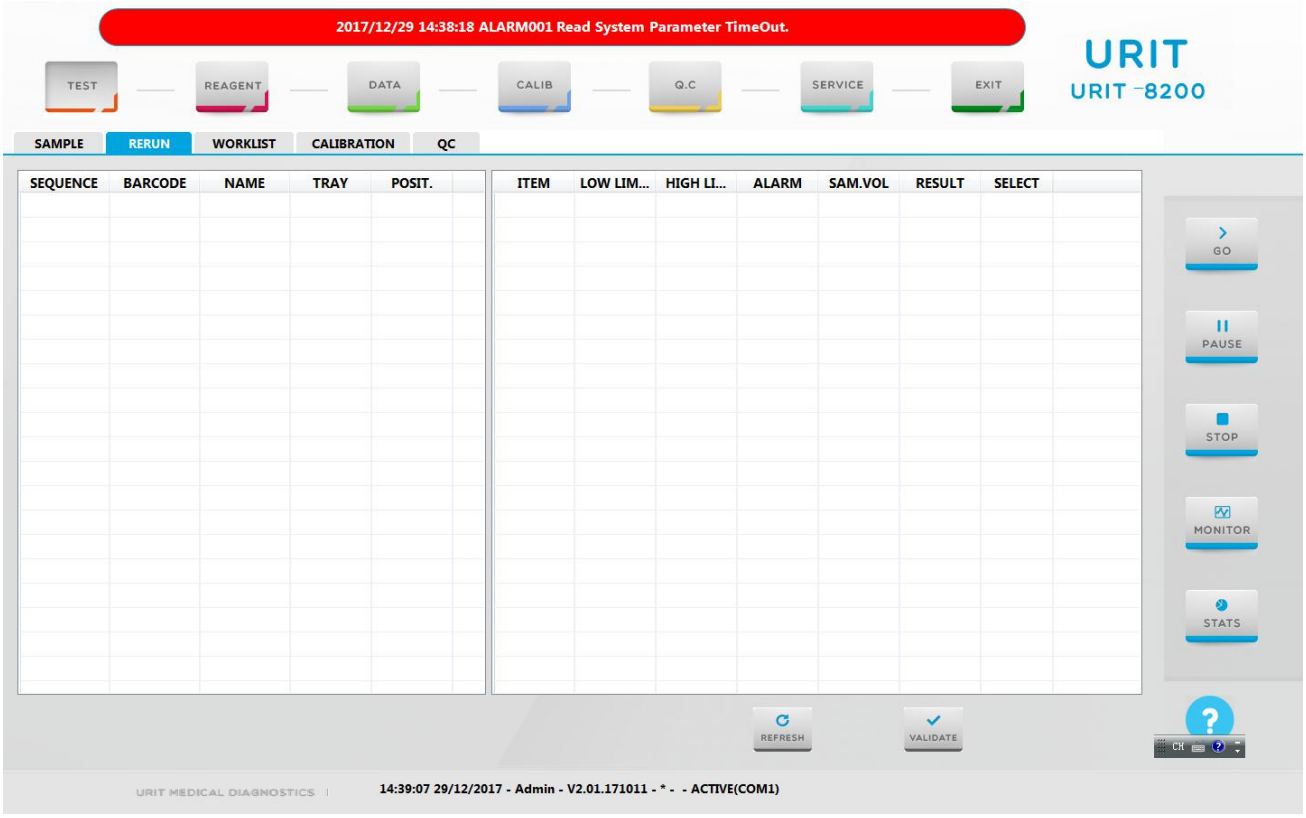


Figure 4.9.2.1 Retest manually

2) Select application list icon to check the sample test list, and select the ID which is need to retest.
3) The item of the ID will display.
4) Select the item which needs to retest and click the **Validate** button to add the item to the list.

4.9.2.2 Automatic retest after exceeding linear range

Through normal item parameter setting interface to set the automatic retest condition: exceeding linear range. After the sample test, the system will judge the test results and when the results are

exceeding linear range, and then the system will automatic retest this item. .

1) In main interface, click **Service** button;
2) Select **Parameter** option to enter the interface;
3) Select the item which exceeding linear range to setup from the left side item list;
4) Click **Modify** to enter editable mode.
5) Input linear limit in **[LINERITY LIMIT]** frame.

Figure 4.9.2.2-1 Item parameter setup interface

6) Click **Over linear auto test frame**.

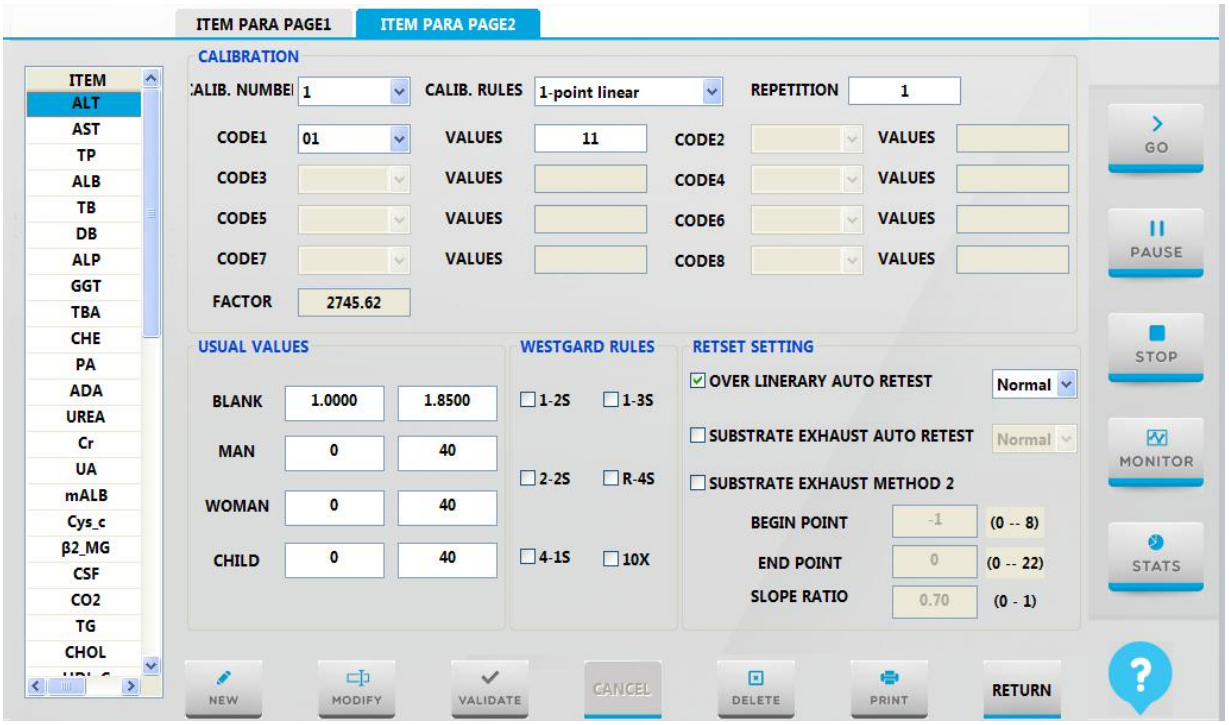


Figure 4.9.2.2-2 Item parameter setup interface

7) Click **Validate** to save setup. In future test, system will auto retest if the item occurs substrate exhaustion.

4.9.2.3 Automatic retest when substrate exhaustion

In rate method, the user can through the parameter item interface to set the substrate exhaustion judgment method and automatic retest when substrate exhaustion. After the sample test, the system will judge the test results and when the results appear substrate exhaustion, and then the system will automatic retest this item.

Note

Substrate exhaustion setting is only effect on rate method.

---

1) In main interface, click the **Service** icon;
2) Select **Parameter** option to enter the interface;
3) Select the item which needs to automatic retest when substrate exhaustion from the left side item list;
4) Click **Modify** to enter editable mode;
5) Click **Substrate exhaust auto retest** frame.
6) To setup the judge methods of substrate exhaustion, please refer to chapter 7.2.
7) Click Validate to save. And in future test, system will auto retest when the substrate is exhaust.

4.9.3 Sample dilution test

Due to differences of the patient's condition, for some samples, the test results of individual items are relatively high, so you can manually or automatic dilute the sample to certain degree, or for certain item, dilute the sample to certain degree, and then start test. After the sample testing is completed, if discover some results are exceeding the reference range or identify abnormal, then you can through the manually retest method to dilute the sample and retest it.

1) Click **Service** button;
2) Click **Parameter** button to enter the interface;
3) Select the item which is needed to pre-dilute in the left list.
4) Input dilutes times in the **[Dilution ratio]** frame. The ration range is 2 to 250.
5) Click **Validate** to complete setup.

4.10 Test status and stop

During the test process, the user can through the test system to check the situation in the process of reaction.

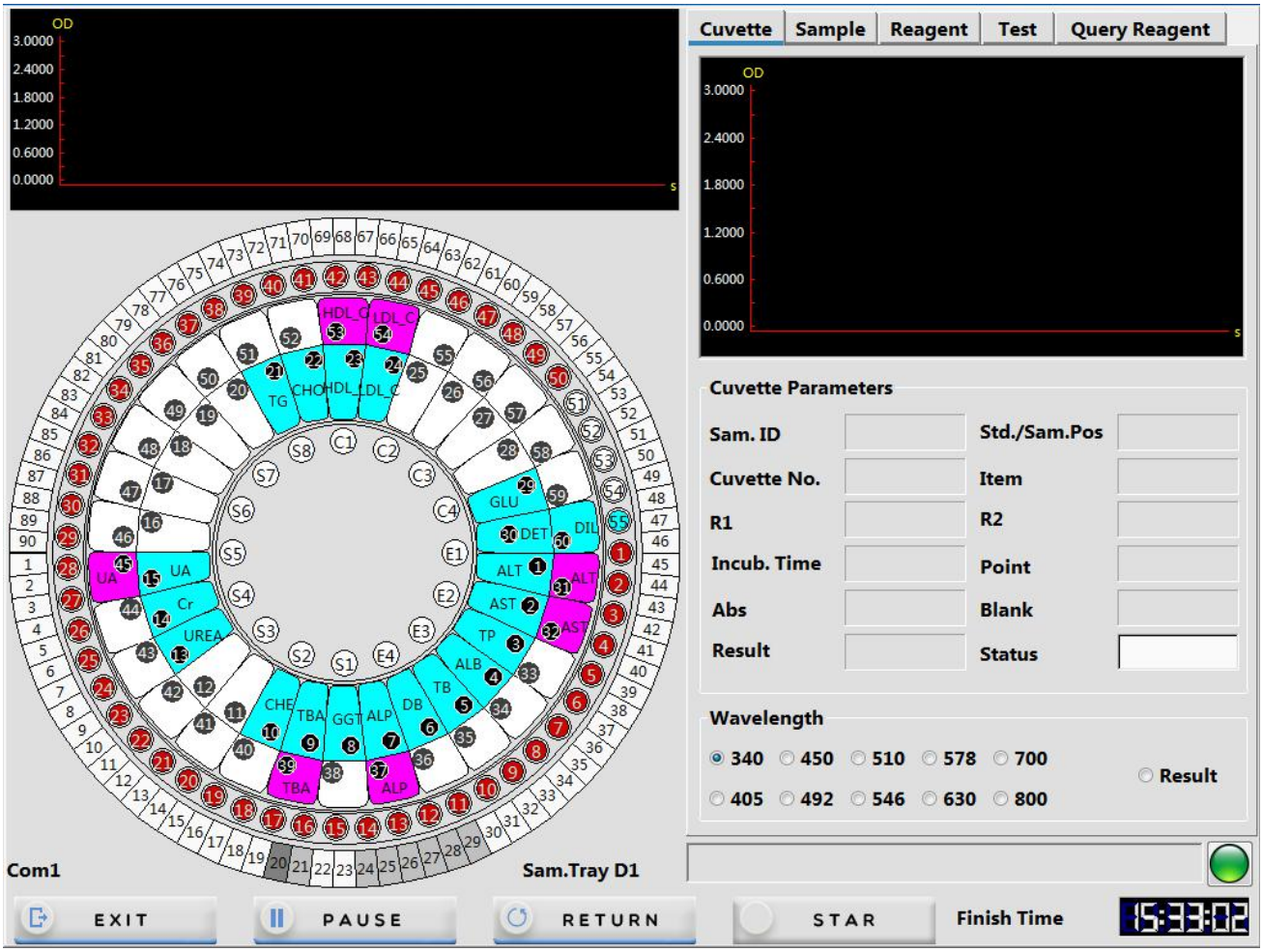


Figure 4.10 Test interface

Color identification of reaction tray is as follows.

Color	Meaning
Green	Adding reagent R1
Red	Adding sample
Light red	Adding reagent R2
Blue	Test has been completed

4.10.1 Check the test status

1) Click the **Cuvette** option which in the right side of test system to check the reaction cup, you can see the reaction cup's reagent information in this interface, including test items, incubation time, test points, absorbance and test results, etc.

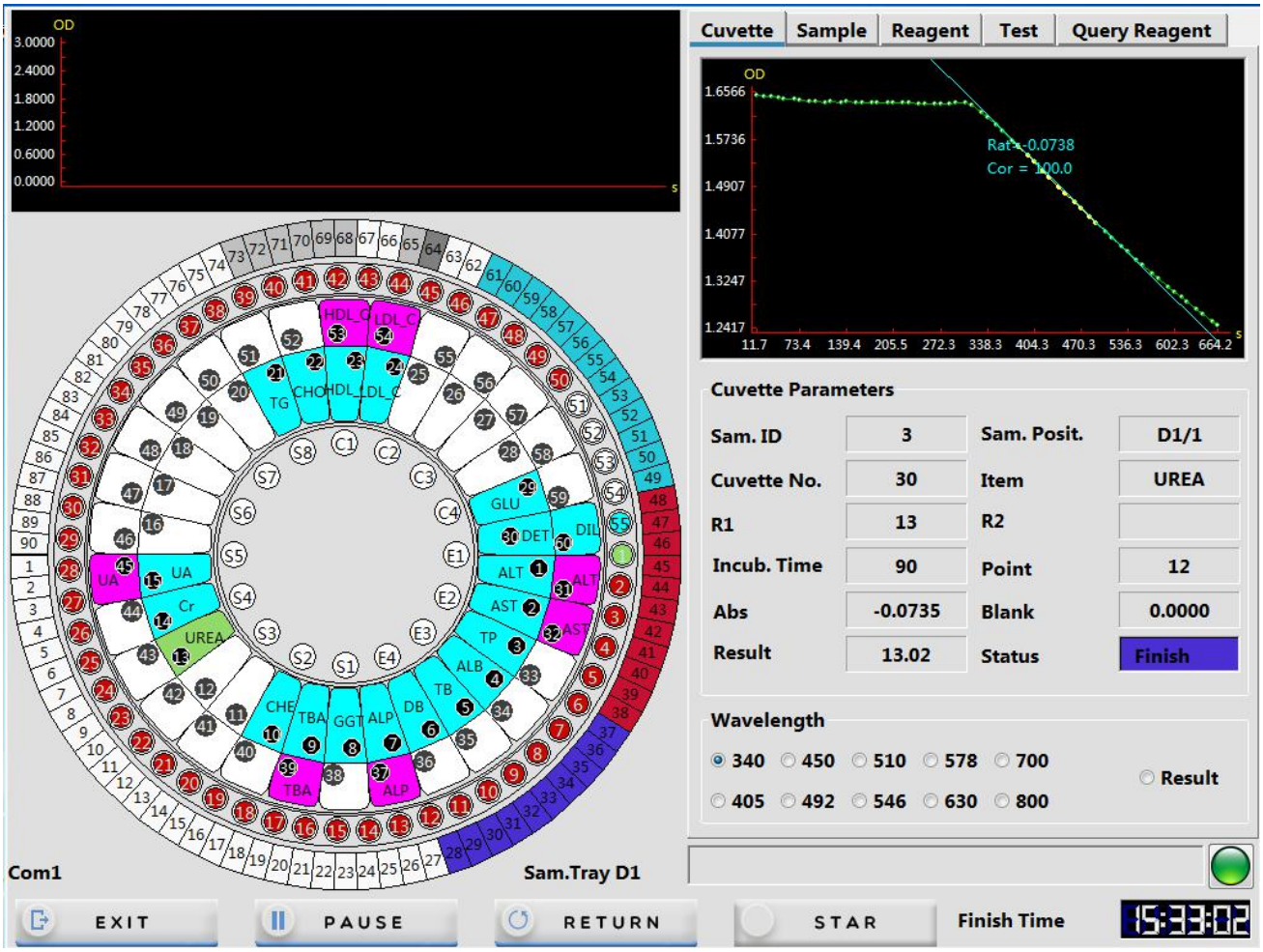


Figure 4.10.1-1 Reaction cup state interface

2) Click the **Sample** option which in the right side of test system, and then select the sample ID which you want to check, you can see all the reagent information under that sample ID.

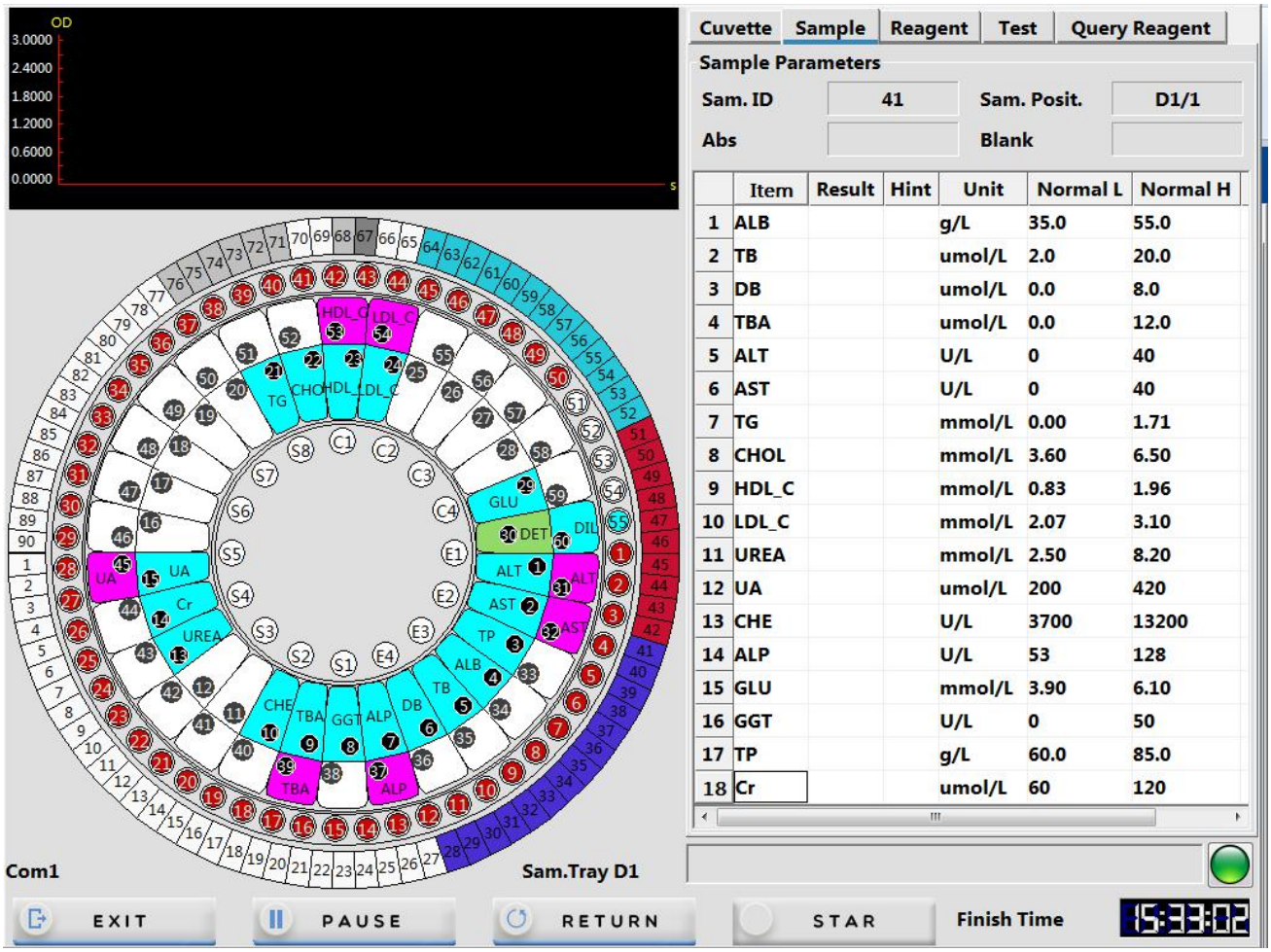


Figure 4.10.1-2 Sample information interface

3) Click the **Reagent** option which in the right side of test system, and then select the item which you want to check, and then you can see all the test results and normal high and low value under that reagent.

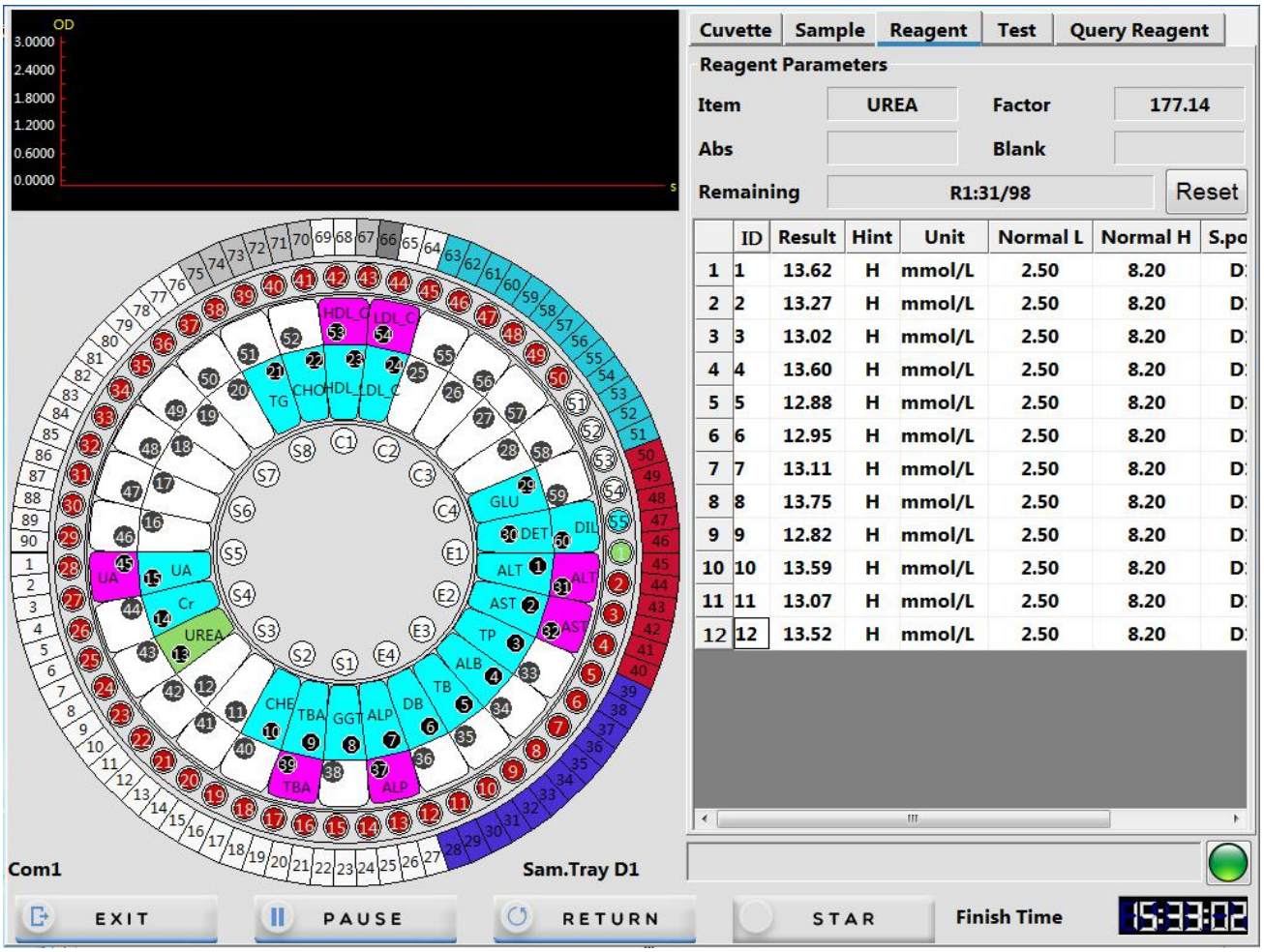


Figure 4.10.1-3 Reagent information interface

4) Click the **Test** option which in the right side of test system, to check the applied test list, and then you can see test results of each test item and their normal high and low value.

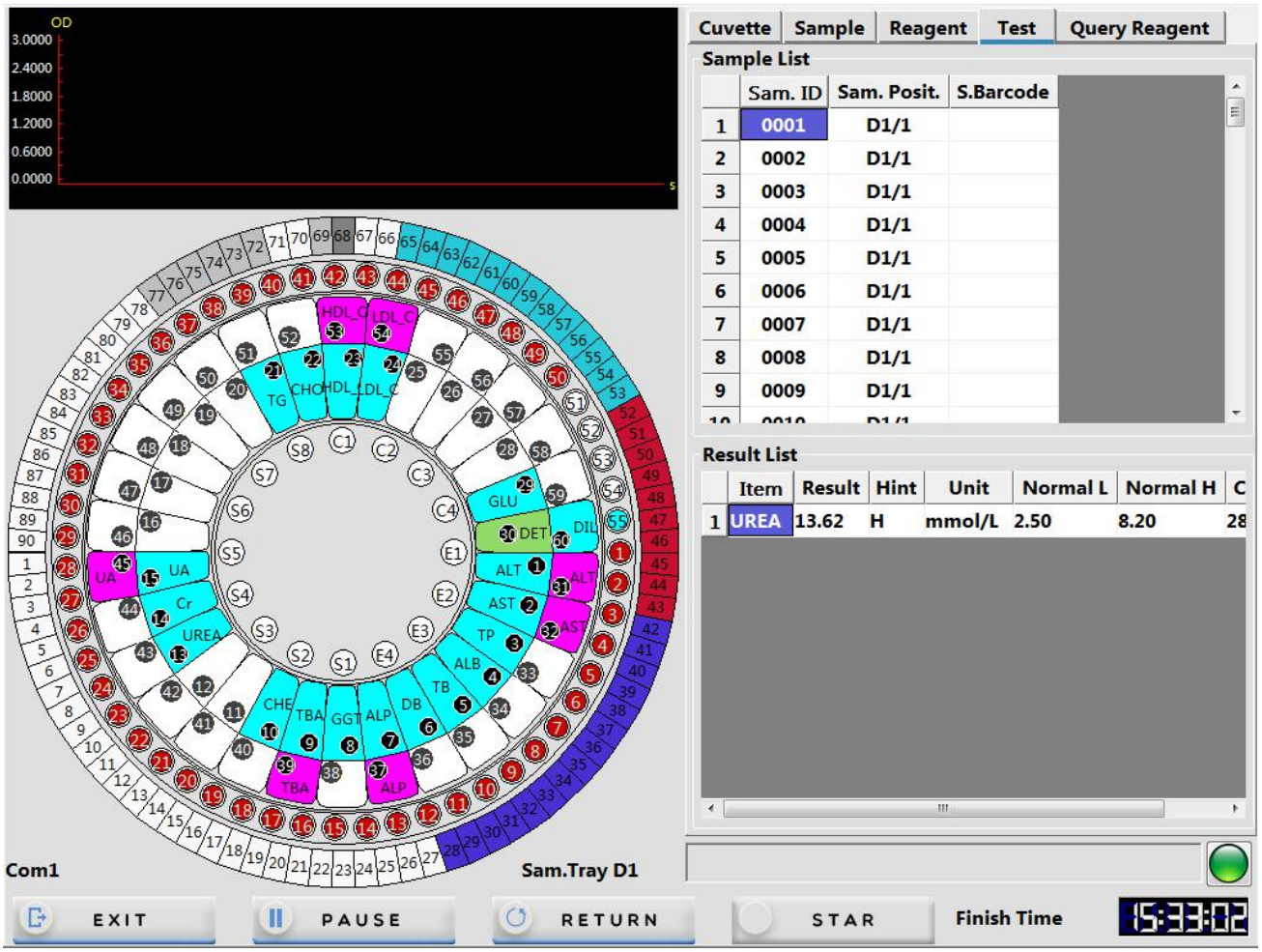


Figure 4.10.1-4 Test item information interface

5) Click the **Query Reagent** option which in the right side of test system, to check the reagent position, remaining volume and measurable number. If the remaining volume is insufficient will be displayed in red.

6) Click  button which in the right side of alarm column to enter the instrument status surveillance.

◆ Button displays green, indicates everything is normal.

◆ Button flashes yellow, indicates instrument or test is abnormal. Please click the button to check the alarm information.

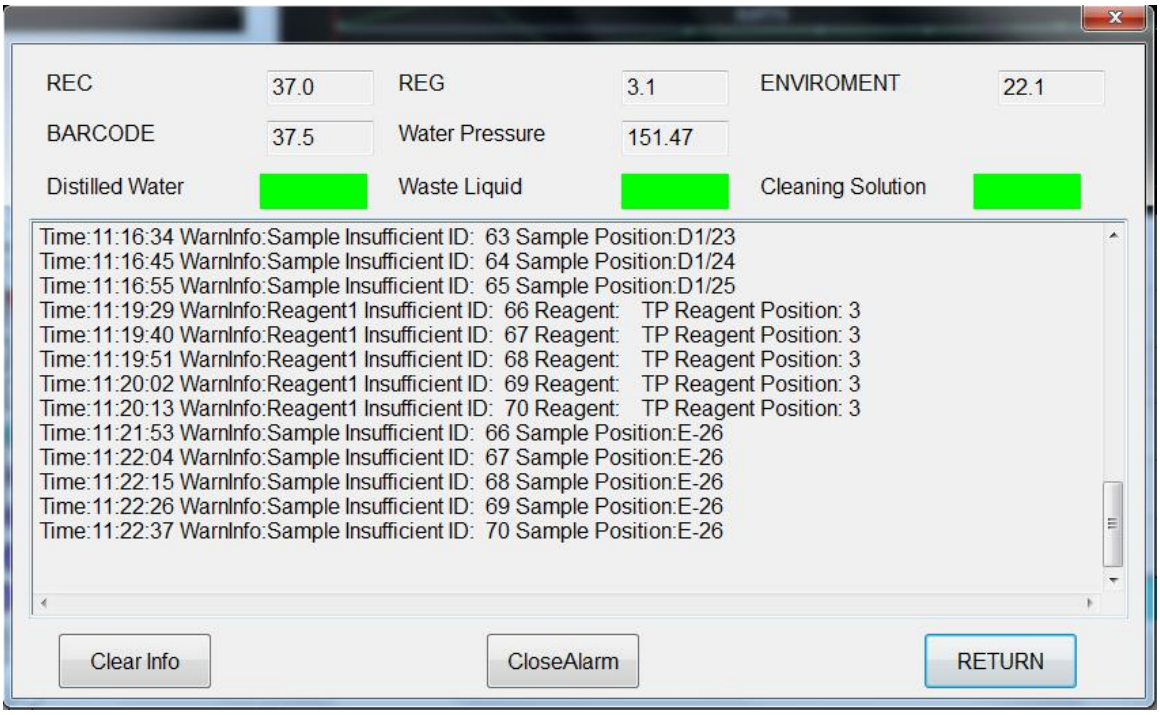


Figure 4.10.1-5 Alarm information display interface

The main function keys:

【**Clear Info**】:Click this button to clear the current alarm information.

【**Close Alarm**】:Click this button to close the alarm sound.

【**RETURN**】:Return to test system interface.

4.10.2 Pause operation

During the test, if appear the situations of reagent, detergent or distilled water is insufficient, or waste solution is too much, please click **Pause** button in test system, and then perform the related operations after the system stop adding sample. After that, click **Continue** button to continue to test.

4.10.3 Exit

After all the samples have been tested, please click **Exit** button in the test system to exit, test data will be saved automatically.

4.10.4 Emergency exit

After perform emergency exit operation during the test, the instrument will terminate all test action, and cancel all sample application, so please perform with cautious. Unless special circumstances, such as instrument malfunction, URIT do not recommend using this function. If necessary, you can perform the emergency exit operation no matter what status the instrument is.

Click the **Emergency exit** button which in the left bottom of test system, and then click **Confirm** in the pop up dialog box. And then the system will cancel all the unfinished sample tests.

Note

If you perform emergency exit operation, for the samples which have complete the test, the system will automatically save the test results.

4.11 Routine maintenance

After complete all the tests, please according to chapter 9.3 to do the instrument maintenance.

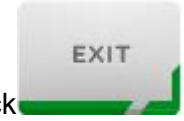
Daily maintenance items including:

1) Check distilled water bucket;
2) Check waste solution bucket;
3) Check detergent bucket;
4) Check reagent/sample injection pump;
5) Check/Rinse sample adding probe and stirrer;
6) Check print/printing paper.

4.12 Power off

After complete all the tests, please perform end operations for the biochemical analyzer, start the instrument cleaning function, exit system and shut off the power. At the same time after power off, you still need to do the related maintenance operations, in order to convenient for next use.

4.12.1 Power off

1) Confirm the system is in standby mode;
2) Click 

icon. A dialogue box will pop up, and click **Execute** to clean the probe, stirrer and cuvette, the distilled water will be injected to cuvette to soak.

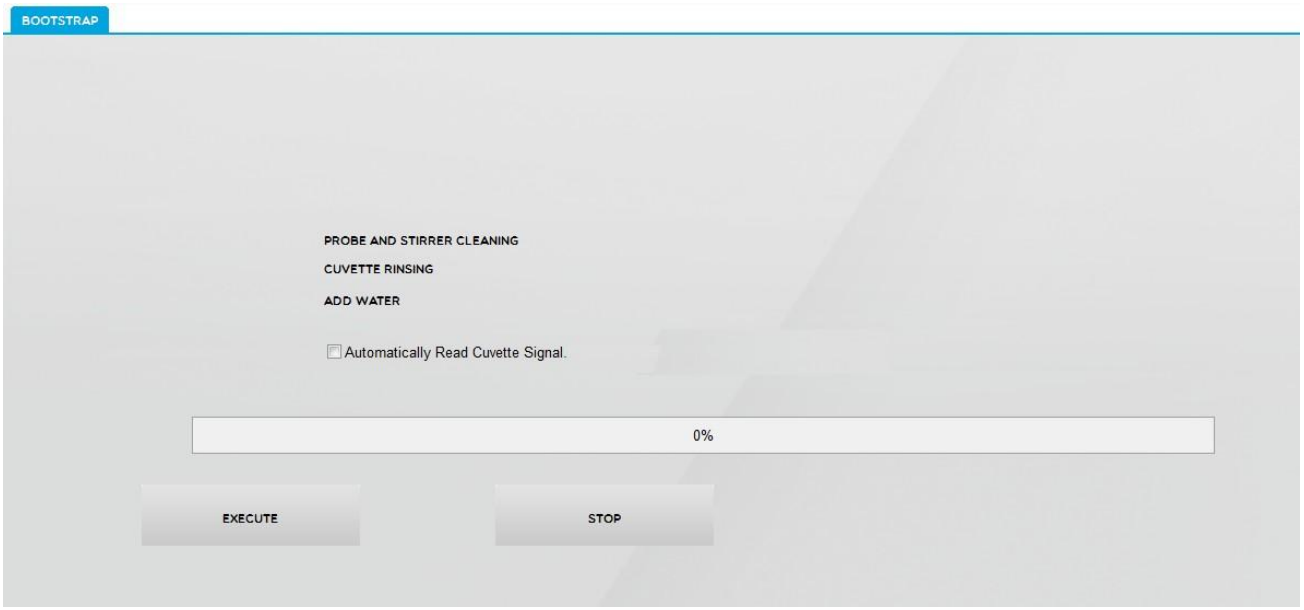


Figure 4.12.1 Power off maintenance

3) Turn off the power supply in the following order:

   a) Printer power supply

   b) Computer power supply

   c) Instrument test power supply (The right side of the instrument)

   d) Instrument main power supply (The right side of the instrument)

Note

1) The power supply of reagent refrigeration system is separate from the instrument test power supply, so in the case of main power is turned on, refrigeration system will always in working state. If you need to turn off cold system, turn off main power.

2) If you don't use the instrument for a long time, please close the switchboard switch.

4.12.2 24 hours standby

If you need to keep the instrument in 24 hours standby mode, please do not turn off the main power supply when perform the shutdown operation (Please refer to chapter **4.12.1 Power off**), which keeps the reagent tray refrigeration function. And then turn on the instrument test power supply when you need to run the system.

4.12.3 Operation after Power off

Biological Hazard

1) Some substances contained in reagent, QC solution, standard solution, detergent and waste solution are regulated by discharge standards and pollution control regulations, waste must be disposed according to the relevant environmental protection regulations, and consult relevant reagent manufacturers or distributors.

2) Be sure to put on protective gloves, clothes, or even goggles if necessary when dispose waste solution.

1) In reagent tray, cover the reagent bottle cap.

Note

If you turn off the instrument main power supply, then the reagent tray refrigeration function will lose efficacy, then reagents must be stored in refrigerator.

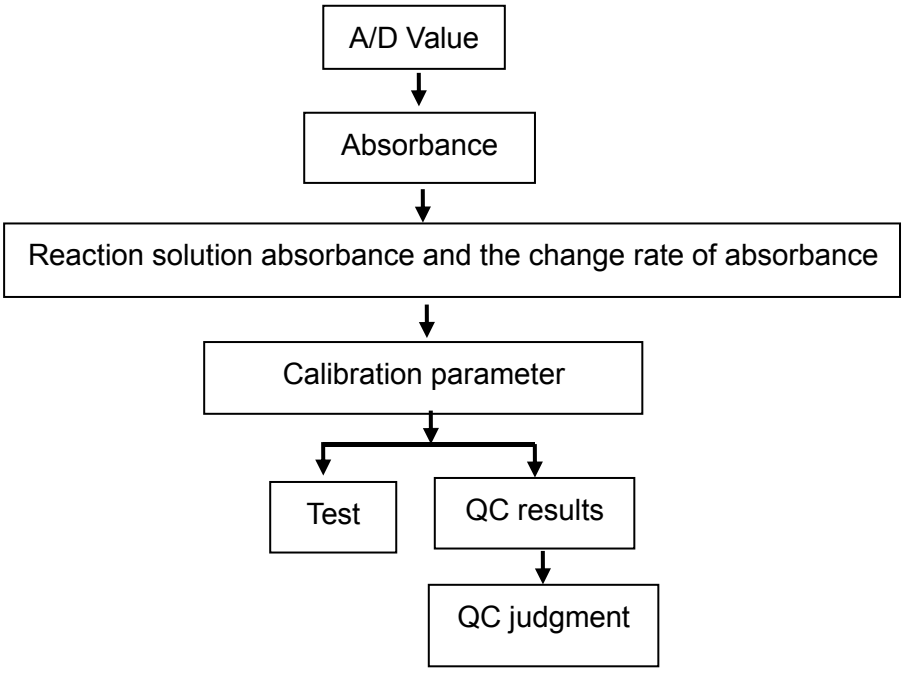
2) Remove the calibration solution, control solution and sample from the sample tray.

3) Check the analyzer host bench whether there is a stain. If so, please wipe it clean with a clean soft cloth.

4) Check waste solution bucket. If the waste solution is too much, please empty the waste solution bucket.

CHAPTER 5 OPERATING PRINICPLE

This product is a fully automatic, discrete, surname–elect style clinical biochemical analyzer, fully controlled by computer. With the aid of all kinds of calculation method and measuring principles, it can quickly finish various tests. System data analyzing and calculating process is shown in the following figures:



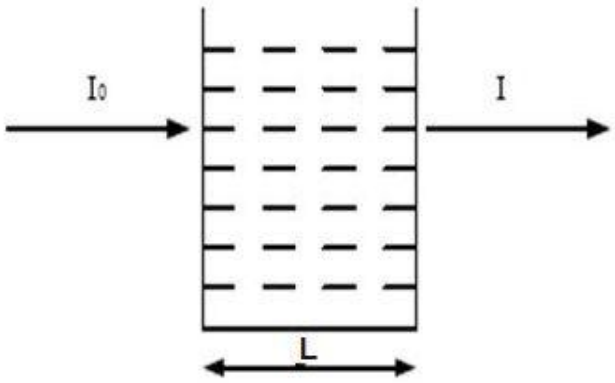
The system through photoelectric conversion, signal amplification and A/D conversion to test the intensity of light firstly, and then according to the intensity of the light to calculate the reaction solution absorbance and the change rate of absorbance, and according to the change rate of absorbance to calculate the calibration parameters. Finally, according to QC test to calculate the QC results, and determines whether the system is stable, and then according to the calibration parameters to calculate the sample test results

5.1 Principle

The definition of absorbance:

When a bunch of collimated monochromatic light which intensity is I_0 get through the cuvette(which the concentration of absorptiometic matter is C and optical path is L), as shown in the figure below, some of the photons are absorbed, light intensity I_0 is attenuate to I, then the absorbance of this solution A is equal to:

$$A = -\lg \frac{I}{I_0}$$



I_0 ---Input intensity.

I ---Output light intensity.

$\frac{I}{I_0}$ ---Light transmittance.

Lambert's Beer Law:

$$A = \varepsilon CL$$

The following formula can be deduced:

$$-\lg \frac{I}{I_0} = \varepsilon CL$$

Among them:

C: The concentration of solution.

L: The optical path of cuvette（Unit: cm）.

ε: Light absorption coefficient.

Molar absorption coefficient: The recommended term for the absorbance for a molar concentration of a substance with a path length of l cm determined at a specific wavelength.

Specific absorptivity: Absorbance (of light) per unit path length (usually the centimeter) and per unit of mass concentration.

Measure I, I_0, and L, and then calculate the concentration C according to the formula above.

5.2 Test methods

Automatic biochemical analyzer is based on Lambert's Beer Law to analyze and calculate, the basic calculation methods including:

1) Endpoint method (One point endpoint method)

2) 2-point endpoint method (Double reagent endpoint method)

3) Two point-speed method (fixed-time method)

4) Rate method（Kinetic method）

5.2.1 Endpoint method

Endpoint method: Reaction reaches equilibrium after a period of reaction, because the equilibrium constant of reaction is very big, then all the substrate (sample) can be thought transform into product, and the absorbance of reaction solution is not increase (or decrease) any more, and the increase (or decrease) of absorbance level is directly proportional to the concentration of the test sample. This kind of method is often called end point method, and to be more precise should become "balanced" method, which is the most ideal type of analysis.

End point method is insensitive to small change of reaction conditions (such as enzyme amount, PH, temperature, etc.), as long as this change will not affect the reaction reaches equilibrium within a certain amount of time.

Computing method:

Endpoint method (single reagent) reaction curve as shown in the figure below:

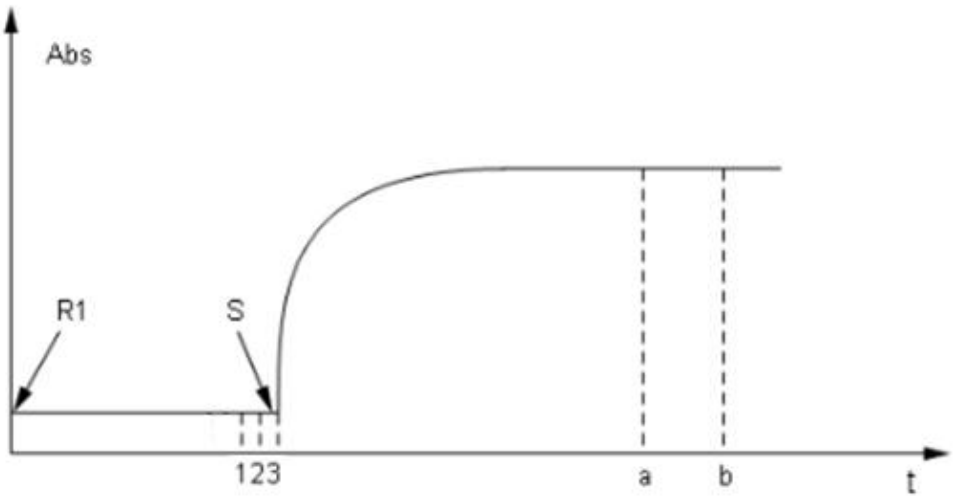


Figure 5.2.1 Single reagent endpoint method reaction curve

R1: Adding the first reagent

S: Adding sample

A: Absorbance test start point

B: Absorbance test end point

1 to 3: Blank absorbance test point for reagent 1

The system will record the absorbance change since add R1, until the end of the longest reaction time.

- Reagent parameter setting:

  S to a: Incubating time of the first reagent

  a to b: Test points

- Result calculation:

$$C = (A_1 - \lambda A_0) \times K$$

  C: The concentration of reactant

  K: Calculation factor

  A_1: The average absorbance from a to b

  A_0: The average absorbance of 1~3 before add S, that is the R1 blank

  Λ: Volume correction factor

- The calculation of volume correction factor

  Volume correction factor includes λ1, calculation method as follow:

$$\lambda 1 = \frac{VR1}{VR1 + VS}$$

  VR1: Volume for the first reagent

  VS: Volume for the actual added sample

Caution

Above reagent blank absorbance test point is defaulted by the system, for immune reagent item, it can be set according to the need.

5.2.2 2-Point endpoint method

Selecting the first absorbance (Aa) before reaction, and selecting the second one (Ab) when the reaction is balanced or has completed, the difference between two absorbances are used for calculating result.

Formula: CU=(Ab－Aa×λ)×K

K: Absorbance coefficient (standard factor)

Computing method:

2-point Endpoint Method is mainly used for double reagent endpoint method calculation, and the computing method of sample blank and volume correction factor have been added, the basic principle is the same as the endpoint method, the reaction curve is shown in figure 5.2.2:

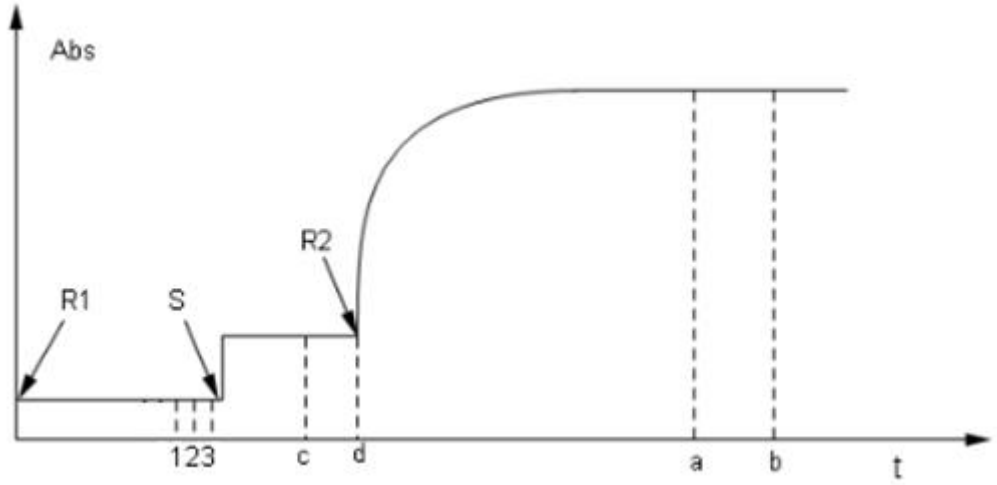


Figure 5.2.2 Double reagent 2-point endpoint method reaction curve

R1: Adding the first reagent

S: Adding sample

R2: Adding the second reagent

A: Absorbance test start point

B: Absorbance test end point

c to d: Special blank test start point, usually take five test points, if the set time is not enough for 5 test points, then the system will automatically select blank test points according to time.

1 to 3: Blank absorbance test point for reagent 1

The system will record the absorbance change since add R1, until the end of the longest reaction time.

- Reagent parameter setting:

  S to R2: Incubating time of the first reagent

  R2 to a: Incubating time of the second reagent

  a to b: Test points

- Result calculation:

$$C = [(A_2 - A_0) - (A_1 - A_0) \times \lambda_1] \times K$$

C: The concentration of reactant

K: Calculation factor

K_1: Volume correction factor

A_1: The average absorbance from c to d, and that is the sample blank

A_2: The average absorbance from a to b

A_0: Reaction cup water blank, the instrument will real-time read the reaction cup water blank

$$\lambda_1 = \frac{VR1 + VS}{VR1 + VS + VR2}$$

VR1: Volume for the first reagent

VS: Volume for the actual added sample

VR2: Volume for the second reagent

5.2.3 Two point-speed method (fixed-time method)

Two point-speed methods is also known as primary kinetic method and fixed time method, is another form of dynamic method. In a certain reaction time, reaction rate is directly proportional to the substrate concentration in first power, that is: v=k[S]. Due to the substrate is consuming constantly, so the reaction rate is constantly decreasing, so the absorbance change is more and more small. This kind of reaction will take a very long time to reach equilibrium, so theoretically you can monitor it at any time, but due to the complexity of serum components, reaction is complex in the start point, so please wait until the reaction into stable reaction period.

C=（Ab—Aa）/（b - a）×C

Computing method:

Two point-speed method reaction curve as shown in the figure below:

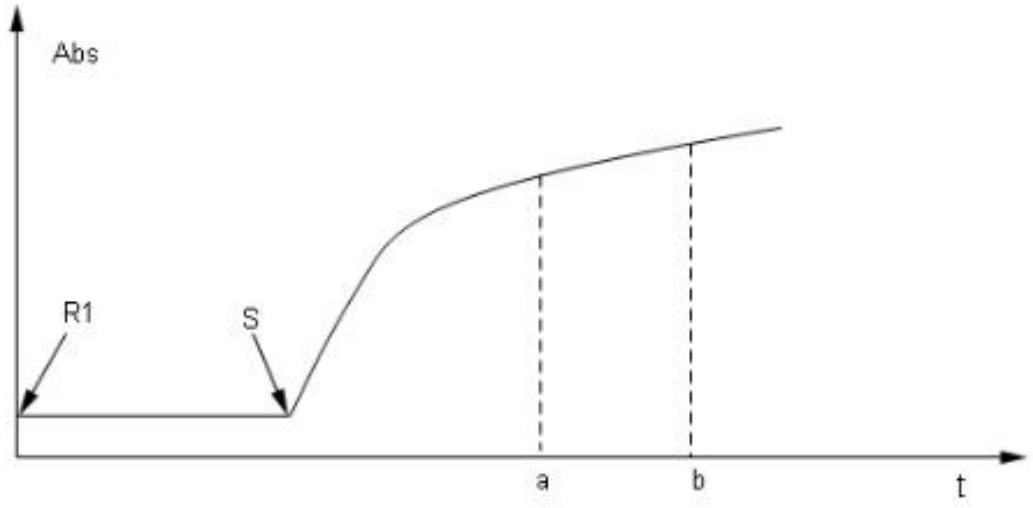


Figure 5.2.3 Two point-speed method reaction curve（single reagent and forward reaction）

R1: Adding the first reagent

S: Adding sample

A: Absorbance test start point

B: Absorbance test end point

The system will record the absorbance change since add R1, until the end of the longest reaction time.

- Reagent parameter setting:

  S to a: Incubating time of the first reagent

  a to b: Test points (time)

- Result calculation:

$$C = \left(\frac{A_b - A_a}{t_b - t_a} \right) \times K$$

C: The concentration of reactant

K: Calculation factor

A_a: The absorbance in a point

A_b: The absorbance in b point

t_a: Time to a point

t_b: Time to b point

Note

Double reagent calculation is the same as the single reagent.

5.2.4 Rate method (kinetic method)

Rate method is also called the zero order dynamics method, reaction rate is directly proportional to the substrate concentration in zero power, so that is nothing to do with the substrate concentration. In the process of the reaction, reactant can produce a product in constant speed, and cause the absorbance of test solution evenly decrease or increase under a certain wavelength, and the decrease or increase speed is directly proportional to the activity or concentration of the analyze.

Rate method is also known as the continuous monitoring method, it is mainly used for the determination of enzyme activity. Enzymes are a kind of special protein which produced by living organisms and have catalytic effect in vivo and in vitro, and almost all of the metabolic reactions in vivo are enzyme catalysis. Enzyme catalytic efficiency is very high and very unstable. The concentration change of enzyme in the human body can reflect a lot of diseases. At the same time, enzyme content is very low, so in addition to the immunological method, it cannot be tested directly, and you can only measure the material changes within a certain time in the process of catalytic reaction, namely enzymatic reaction rate, or enzyme activity. And you can through measuring the concentration decrease of substrate or the concentration increase of product, to track the process of substrate conversion into product in enzymatic reaction. Enzymatic reaction process can be divided into several periods. Delay period: Early stage of the chemical reaction, the change of substrate and product are not obvious, this period lasts few seconds to minutes; zero order reaction period: The period which the change of substrate and product and time are in a straight line, and the product is produced in constant speed; first order reaction period: The period which the reaction rate is continue decreasing.

$$C=\Delta A\times F=\Delta A\times Vt/Vs\times 1000/\varepsilon$$

C: Concentration of enzyme activity, the unit is the U/L

F: Conversion factor

E: Mmol extinction coefficient

Vt: Total reaction volume

Vs: Sample volume

ΔA: Change of absorbance per minute

Computing method:

Rate method reaction curve as shown in the figure below:

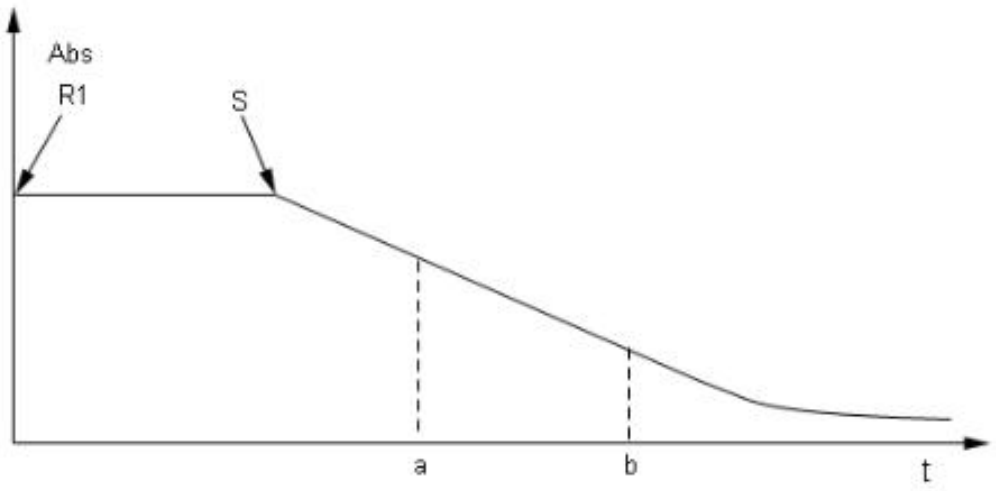


Figure 5.2.4 Rate method reaction curve（single reagent and negative reaction）

R1: Adding the first reagent

S: Adding sample

a: Absorbance test start point

b: Absorbance test end point

The system will record the absorbance change since add R1, until the end of the longest reaction time.

- Reagent parameter setting:

  S to a: Incubating time of the first reagent

  a to b: Test points (time)

- Result calculation

$$C = \Delta A_{ab} / \min \times K$$

C: The concentration of reactant

K: Calculation factor

$\Delta A_{ab} / \min$: The absorbance change rate from c to d

Note

Double reagent calculation is the same as the single reagent.

5.3 Calibration

Test the absorbance change rate of the known concentration calibration solution, and then according to the computational relationship between concentration and change rate (Calibration method), to calculate the coefficient of the computational relationship (Calibration coefficient), and then determine the specific operation expression between concentration and change rate. So the routine sample can be tested according to the specific operation expression and the absorbance change rate.

5.3.1 Introduction

Calibrate the test items by calibration reference materials, this is the necessary condition to provide accuracy and reliability measurement data for clinical. Calibration is under specified conditions to test the control solution, and then compare the test results with control solution reference range. The test items which tested by clinical biochemical analyzer must calibrate by calibration reference materials.

Calibration process: Through a certain concentration calibration substance, and using the product of chemical reaction to determine the light absorption of reaction solution for specific wavelength, and then change the absorbance variation to concentration value. Usually is according to the relationship between absorbance value and concentration (Calibration method), to determine the calculation formula or to draw the standard curve.

Calibration method is mainly divided into two categories: linear calibration and nonlinear calibration. The linear calibration is divided into two kinds, one kind is completely linear, the other is piecewise linear.

1) Completely linear calibration method: $A = C \times K + b$,including: Single point linear calibration method (also called factor method), two points linear calibration method (also called linear method) and multi-points linear calibration method (3 points and above) (also called linear regression method)

2) Piece-wise linear calibration method: $A = \begin{cases} C \times K1 - \\ C \times K2 \\ C \times K3 \\ \cdots\cdots \end{cases}$. Polygon method belongs to the

piece-wise calibration method.

3) Nonlinear calibration method: Parabola, Logistic-Log 4P, Logistic-Log 5P, Exponential 5P, Spline, etc.

Introductions:

1) Endpoint method, 2-point endpoint method, two point-speed method and rate method can be corresponding to above calibration method.

2) In the calibration formula:

A: Absorbance

C: The concentration of calibration solution

K、b: Calibration parameter

Calibration solution is the standard solution, which the concentration has been accurate measured.

5.3.2 Liner calibration

1) Single point linear calibration method

Calibration formula: $A = C \times K$

Calibration parameter: K, $K = \frac{A\ Mark}{C\ Mark}$

Calibration curve as shown in figure 5.3.2-1:

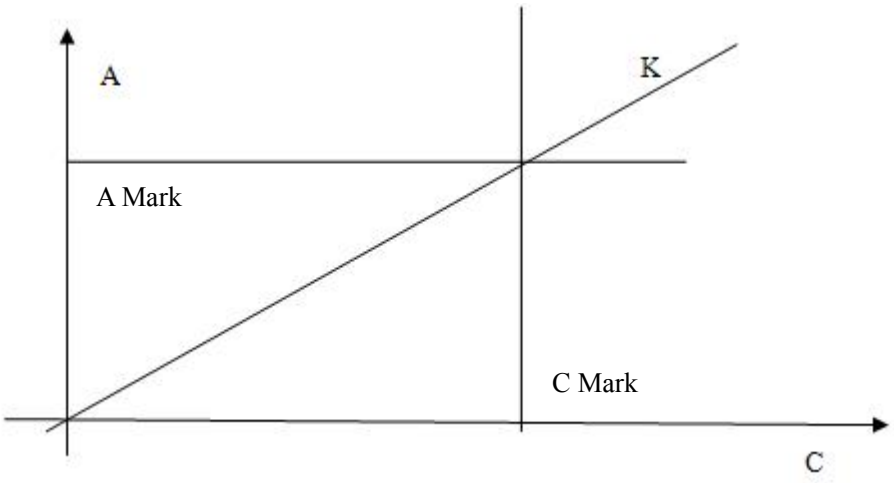


Figure 5.3.2-1 Single point linear calibration

Single point linear calibration only needs to provide a standard substance. Most enzymology items can directly input factor (input value F=1/K) instead of calibration.

Concentration calculation: $C = \frac{A}{K}$ or $C = A \times F$

K: Calibration parameter; F: Input factor number.

2) Two points linear calibration method

Calibration formula: $A = C \times K + b$

Calibration parameter: K and b

Among them, $K = \frac{A2 - A1}{C2 - C1}$, $b = A1 - (\frac{A2 - A1}{C2 - C1}) \times C1$

Calibration curve as shown in figure 5.3.2-2:

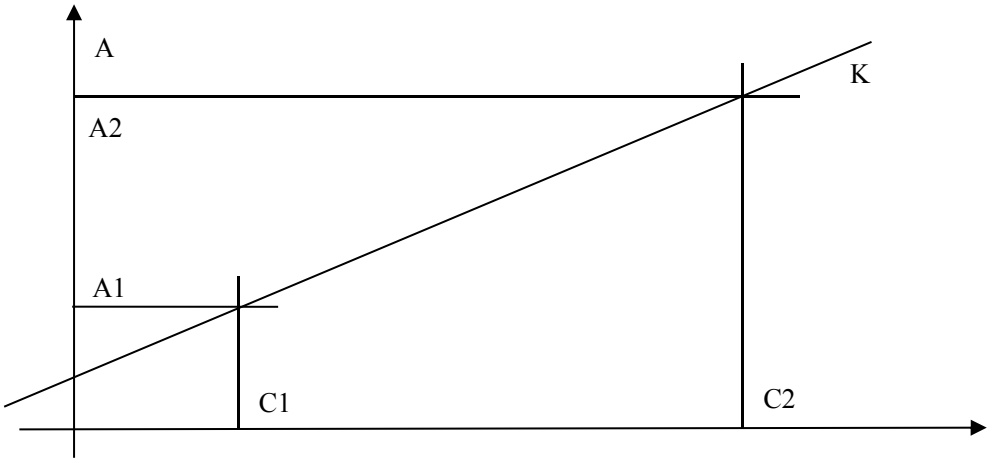


Figure 5.3.2-2 Two point's linear calibration

Two points linear calibration needs to provide two standard substances.

C1: The concentration of calibration solution 1;

C2: The concentration of calibration solution 2;

A1: The absorbance of calibration solution 1;

A2: The absorbance of calibration solution 2.

Concentration calculation: $C = \frac{A - b}{K}$, K and b are calibration parameters.

3) Multipoint points linear calibration method

Calibration formula: $C = K \times A + b$

Calibration parameter: K and b

Multipoint point's linear calibration needs to provide n (n ≥3) standard substances.

Ci: The concentration of calibration solution i;

Ai: The absorbance of calibration solution i.

Using the linear least square method to solve K and b:

$$K = \frac{\sum_{i=1}^{n} C_i A_i - (\sum_{i=1}^{n} C_i)(\sum_{i=1}^{n} A_i)/n}{\sum_{i=1}^{n} C_i^{\,2} - (\sum_{i=1}^{n} C_i)^2/n}$$

$$b = (\sum_{i=1}^{n} A_i)/n - \left[\frac{\sum_{i=1}^{n} C_i R_i - (\sum_{i=1}^{n} C_i)(\sum_{i=1}^{n} A_i)/n}{\sum_{i=1}^{n} C_i^{\,2} - (\sum_{i=1}^{n} C_i)^2/n}\right](\sum_{i=1}^{n} C_i)/n$$

4) Polygon method

Calibration formula: $C_x = K_n \times (A_x - A_n) + C_n$

Among them, 3≦n≦8

Calibration curve as shown in figure 5.3.2-3:

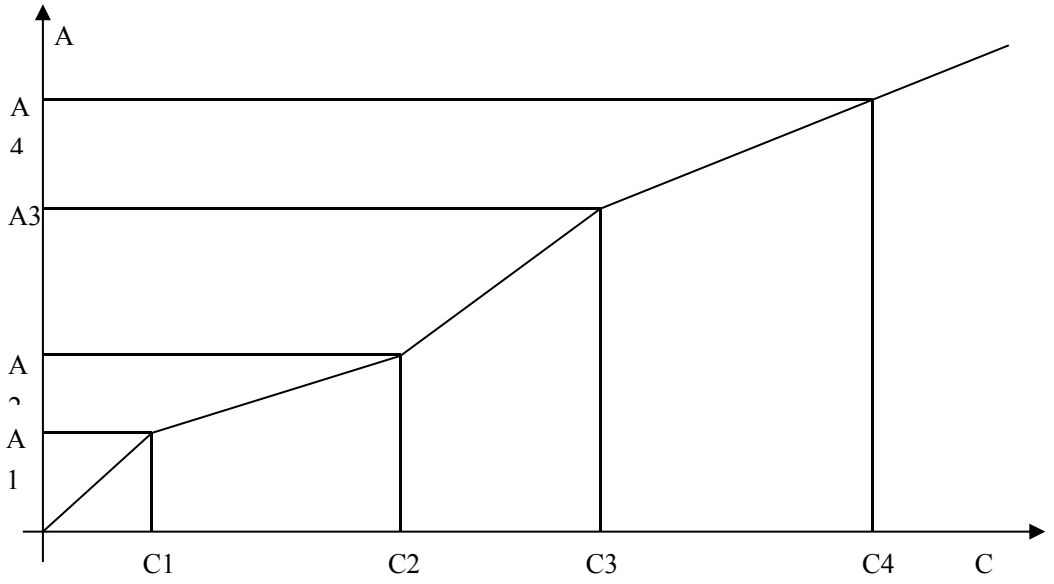


Figure 5.3.2-3 Polygon method

Polygon method needs to provide n（n ≥3） standard substances, on $C_i \le C_x \le C_{i=1}$ interval, using two points calibration method to calculate Ki and bi.

Concentration calculation: First according to Ax determine the interval of Cx, and then according to $C_x = \frac{A_x - b}{K_x}$ to calculate.

5.3.3 Nonlinear calibration

1) Porabola

Calibration formula: $A = aC_2 + bC + c$

Calibration parameter: a, b and c

Porabola method needs to provide at least three standard substances, to solve the ternary system of linear equations.

Calibration curve as shown in figure 5.3.3-1:

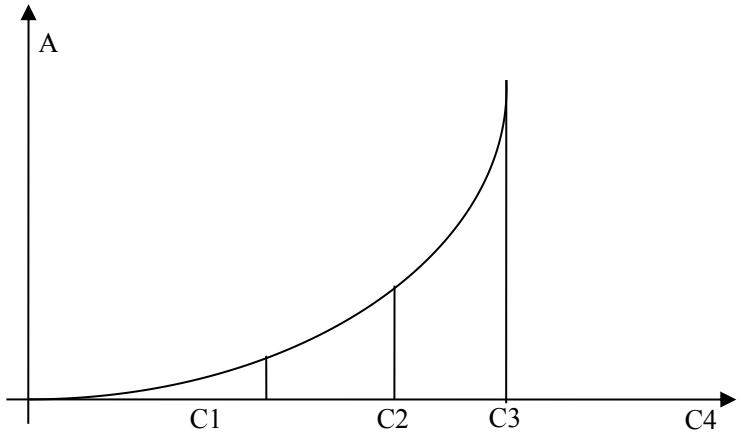


Figure 5.3.3-1 Parabola

Concentration calculation: $C = \frac{-b \pm \sqrt{b^2 - 4ac}}{2a}$

2) Logistic-Log 4P

Calibration formula: $A = A_0 + K \frac{1}{1 + \exp[-(a + b \ln C)]}$

Calibration parameter: A_0, a, b and c

A_0: The absorbance of calibration solution which concentration is zero

(If the user does not provide zero concentration standard substance, then the A_0 is 0. This method requires at least four different concentrations of standard substances, using a third-party library levmar for fitting to solve.)

Calibration curve as shown in figure 5.3.3-2:

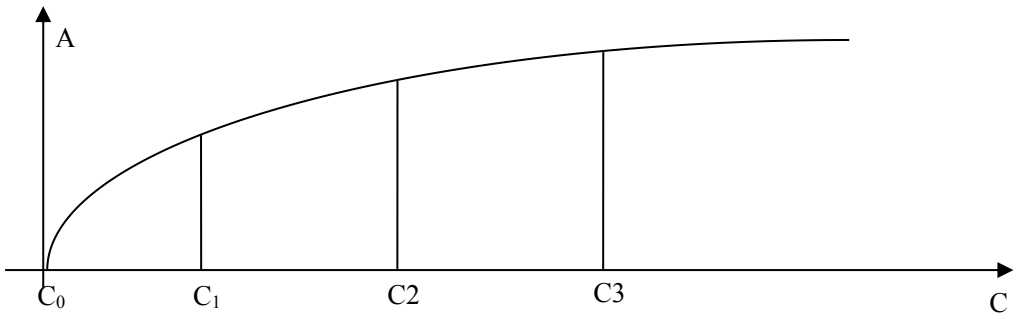


Figure 5.3.3-2 Logistic-Log 4P

Concentration calculation: $C = \exp(\frac{-a - \ln(\frac{K}{A + A_0})}{b})$

3) Logistic-Log 5P

Calibration formula: $A = A_0 + K\frac{1}{1 + \exp[-(a + b\ln C + cC)]}$

Calibration parameter: A_0, K, a, b, c and d.

A_0: The absorbance of calibration solution which concentration is zero

(If the user does not provide zero concentration standard substance, then the A_0 is 0. This method requires at least five different concentrations of standard substances, using a third-party library levmar for fitting to solve.)

Concentration calculation: Using the dichotomy, the accuracy is one over one thousand.

4) Exponential 5P

Calibration formula: $A = A_0 + K \times \exp[a\ln C + b(\ln C)^2 + c(\ln C)^3]$

Calibration parameter: A_0, K, a, b, c and d.

A_0: The absorbance of calibration solution which concentration is zero

(If the user does not provide zero concentration standard substance, then the A_0 is 0. This method requires at least five different concentrations of standard substances, using a third-party library levmar for fitting to solve.)

Calibration curve as shown in figure 5.3.3-3:

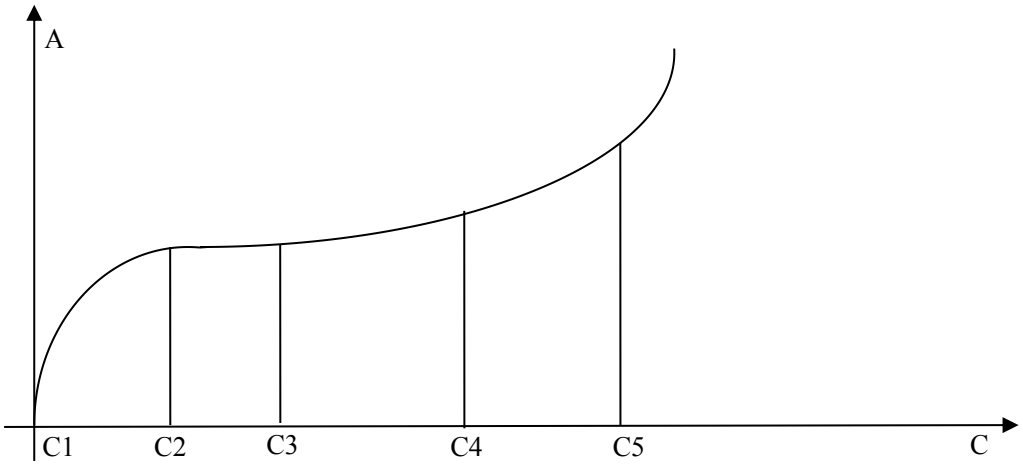


Figure 5.3.3-3 Exponential 5P

Concentration calculation: Using the dichotomy, the accuracy is one over one thousand.

5) Spline

Calibration formula: $C - C_i = A_{0i} + ai \times (C - C_i) + bi \times (C - C_i)^2 + ci \times (C - C_i)^3 - A$

Calibration parameter: There are 4i parameters, A0i, ai, bi, and ci.

This method requires 2 to 6 different concentrations of standard substances, using a third-party library levmar for curve fitting to solve. Because it is piecewise fitting, the fitting degree is the highest in all of the nonlinear calibration.

Concentration calculation: Using the dichotomy to calculate

5.4 Quality control judgment method

5.4.1 Introduction

System uses Levery Jennings and Westgard quality control method to judge the QC results for all the test items. Since each test item may set to use one or more than one control solution, therefore, the system uses different rules to judge different conditions.

5.4.2 Levey-jennings method

This method belongs to the first generation quality control method; the specific rules are as follows:

1-2S rule: Any quality control result exceeding mean value ±2SD, judged to be out of control.

1-3S rule: Any quality control result exceeding mean value ±3SD, judged to be out of control.

5.4.3Westgard method

The ±2SD and ±3SD control methods of Levey-Jennings have obvious differences between error detection sensitivity and out of control error recognition specificity, but Westgard method is combine them skillfully, and introduce other quality control rules to form multiple rules control method. Purpose is to improve the efficiency of control, both the error detection has good sensitivity, and the recognition of out of control error has good specificity.

- In multiple rules control method, Westgard suggests use two control solution, high concentration and low concentration, to form a control range.（You can also just use one control solution, but there are a lot of limitations）
- Draw seven parallel lines on the quality control chart: Mean value, mean value+1S, mean value -1S, mean value +2S, mean value -2S, mean value +3S and mean value -3S, convenient for observation.
- In Westgard method, the 1-2S is only as the warning rule, not the out of control rule. Make full use of it has good sensitivity on error detection, but also limits its weakness on error specificity is poor.

It only points out the possible problems, but still needs through a series of sequence checking, and then judging by other rules.

- After selection, the 1-3S, 2-2S, R-4S, 4-1S and 10X rules are listed as out of control rules, so it will both sensitive to random errors and system error. So the multiple rules control method is greatly improving the control efficiency.

As shown in the following table:

Quality control rules	Interpretation of the results
1-2S	Warning
1-3S	Random error
2-2S	System error
R-4S	Random error
4-1S	System error
10x	System error

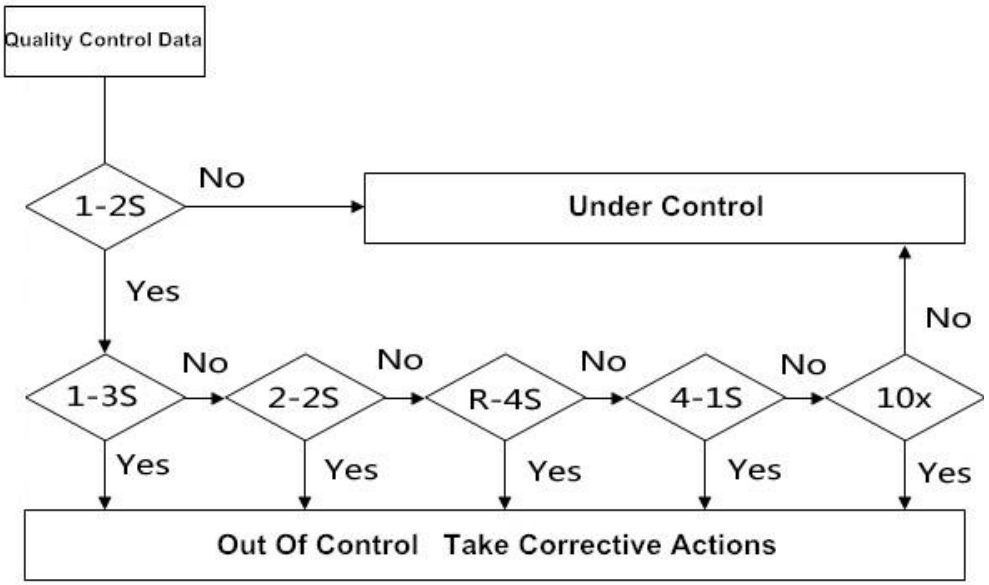


Figure 5.4.3-1 Westgard multiple rules control method

1) 1-2S rule

Because the 1-2S is only as the warning rule, not the out of control rule. If the test results of this batch are both within the range of mean value±2S, then it indicates the test results of this batch are both under control. If there has one QC result exceeding the range of mean value ±2S(Do not include the results just on the mean v2-2alue±2S line), then it indicates the test results of this batch may have problems, need to check, but is only a warning, not out of control. And then please according to the quality control method to check whether there are the following out of control performances.

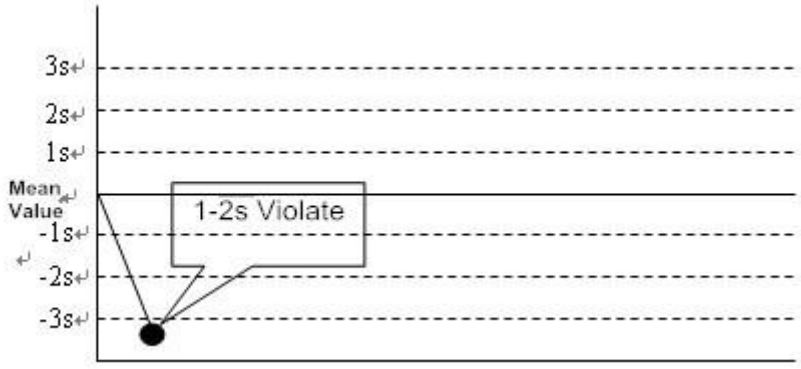


Figure 5.4.3-2 1-2s Quality control rule

2) 1-3S rule

If there has one QC result not only exceeding the range of mean value±2SD, but also exceeding the range of mean value±3SD, judged to be out of control, it belongs to the random error.

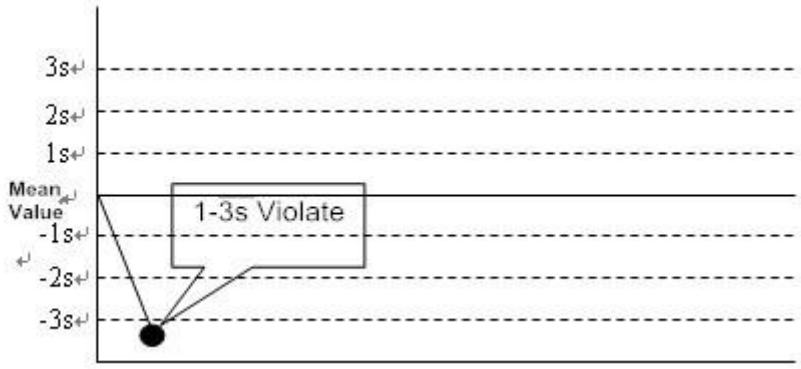


Figure 5.4.3-3 1-3s Quality control rule

3) 2-2S rule

2-2S rule:

a) The test results of two control solution from the same batch are exceeding the control range of mean value±2SD.

b) Or the test results of same control solution from two continuous batches are both exceeding the control range of mean value±2SD, judged to be out of control, it belongs to the system error.

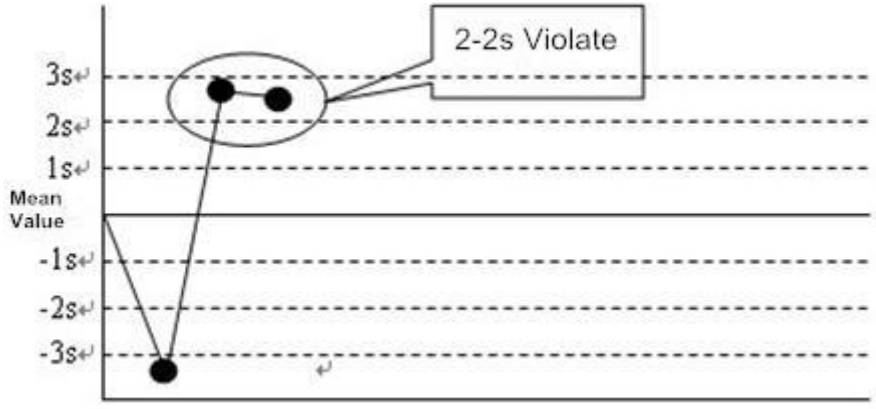


Figure 5.4.3-4 2-2s Quality control rule

4) R-4S rule

The test results of two control solution from the same batch are exceeding the control range of 4SD, one is exceeding mean value+2SD, the other is exceeding mean value-2SD, judged to be out of control, and it belongs to the random error.

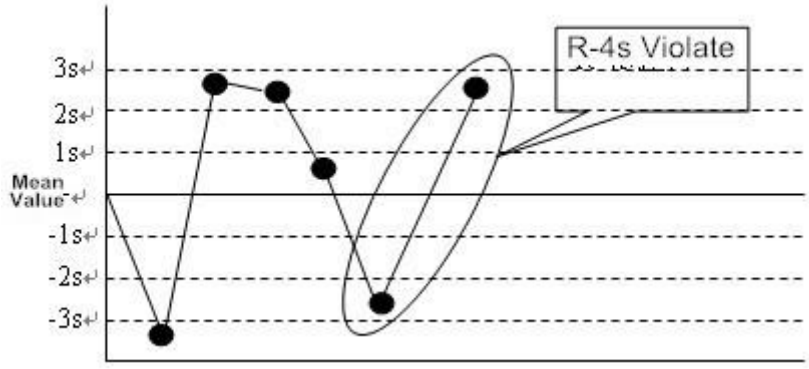


Figure 5.4.3-5 R-4s Quality control rule

5) 4-1S rule

4-1S:

a) Including this warning QC result, the three previous QC results of this control solution and this QC result are both exceeding the control range of mean value±1SD.

b) Including this warning QC result, the previous QC result of this control solution is exceeding the control range of mean value±1SD, and the two QC results of another control solution are both exceeding the control range of mean value±1SD.

Judged to be out of control and it belongs to the system error.

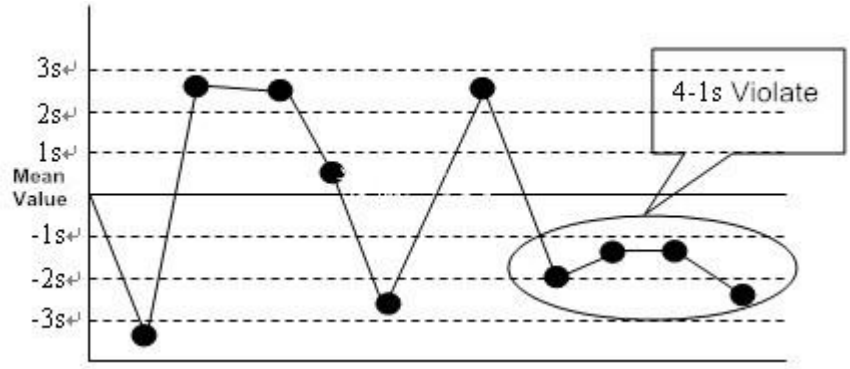


Figure 5.4.3-6 4-1s Quality control rule

6) 10X rule

10 consecutive QC results are fall in the same side of the mean value (higher or lower than the mean value, for the size of the deviation does not require), judged to be out of control, and it belongs to the system error.

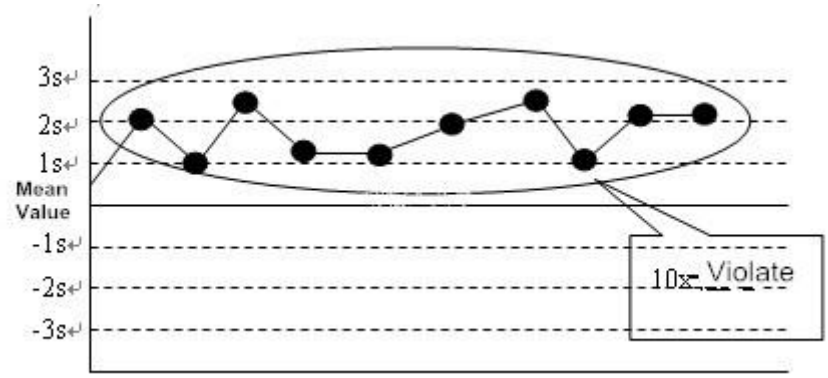


Figure 5.4.3-7 10x Quality control rule

5.4.4 Quality control judgment precautions

When quality control results appear the above situation, please pay attention to the following matters:

1) 1-2S is warning rules, not out of control rules. When test result is exceeding the control range of mean value±2SD, you do not need to retest it immediately, please check whether it really out of control.

2) Even it really out of control, please do not delete the QC results which are exceeding the control range of mean value ±2SD, because after all these points are deleted, the results range will become small, and then the S of next month quality control chart will become small too; and then the quality control range will become unreal, increase the difficulty of control.

3) So when appears 1-2S, please first check whether it really out of control. And when it really out of control, retest the control solution, and check out of control reason, and then please retest the patient sample after correct the error.

CHAPTER 6 DATA PROCESSING

This chapter is mainly introduces how to view, edit and print various test data and reaction curve.

6.1 Check the calibration result

You can check the biochemical item's calibration parameters and calibration formula, and all the calibration parameters and results within a period of time through the calibration result interface. You can also check the item's calibration curve and test curve, and edit and recalculate the calibration parameters.

6.1.1 Check the calibration curve

The minimum concentration and the maximum concentration of calibration solution was divided into several parts by the calibration curve, and then draw a curve according to the absorbance of each parts, reflects the algorithm relationship between concentration and absorbance. For the linear calibration test, calibration curve is a straight line; and for nonlinear calibration test, calibration curve is a curve.

1) In main menu, click **Calibration** icon;

2) Click **Multi calibrator** button.

3) Select the item which needs to check the calibration curve from the left side item list;

4) In drop down list to select the calibration curve type;

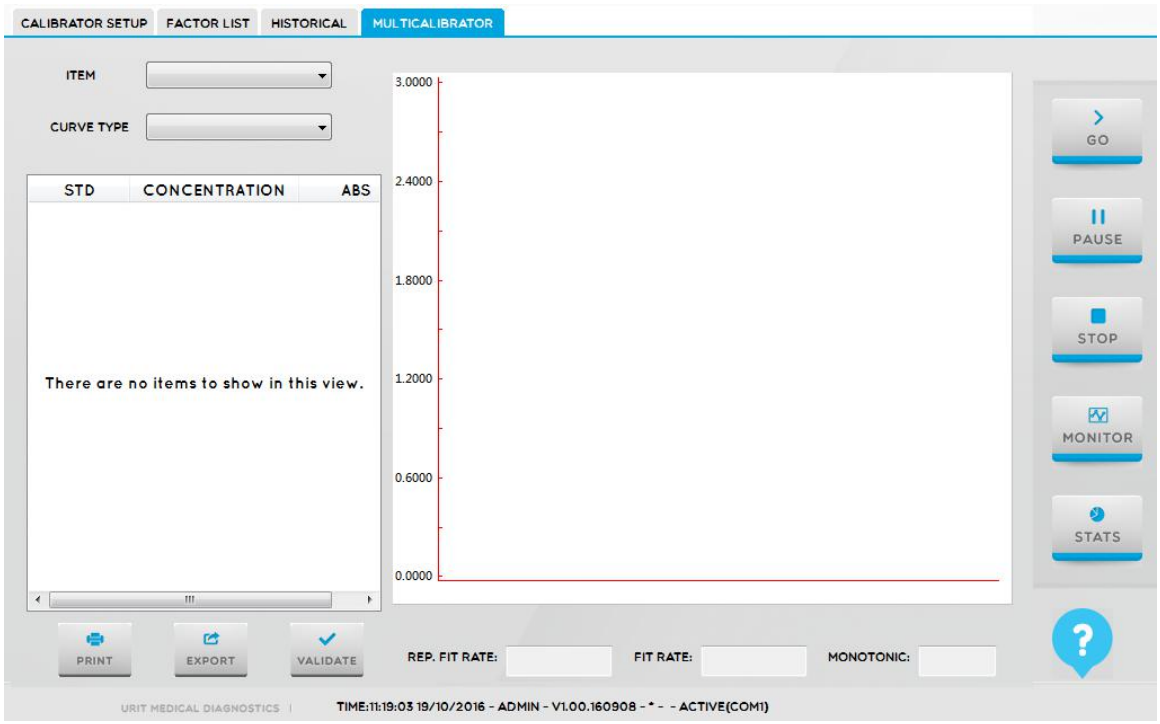


Figure 6.1.1 Check calibration curve interface

6.1.2 Check the reaction curve

Reaction curve: Draw a curve according to the absorbance of reaction solution (which mixed by calibration solution and reagent) in each point from entire test cycle, it reflects the absorbance relationship between dominant wavelength and complementary wavelength.

How to check the reaction curve:

1) In main menu, click **Calibration** button;

2) Click Factor list to enter the interface;

3) Select an item which you need to check the curve;

4) Click **Curve** to enter the interface.

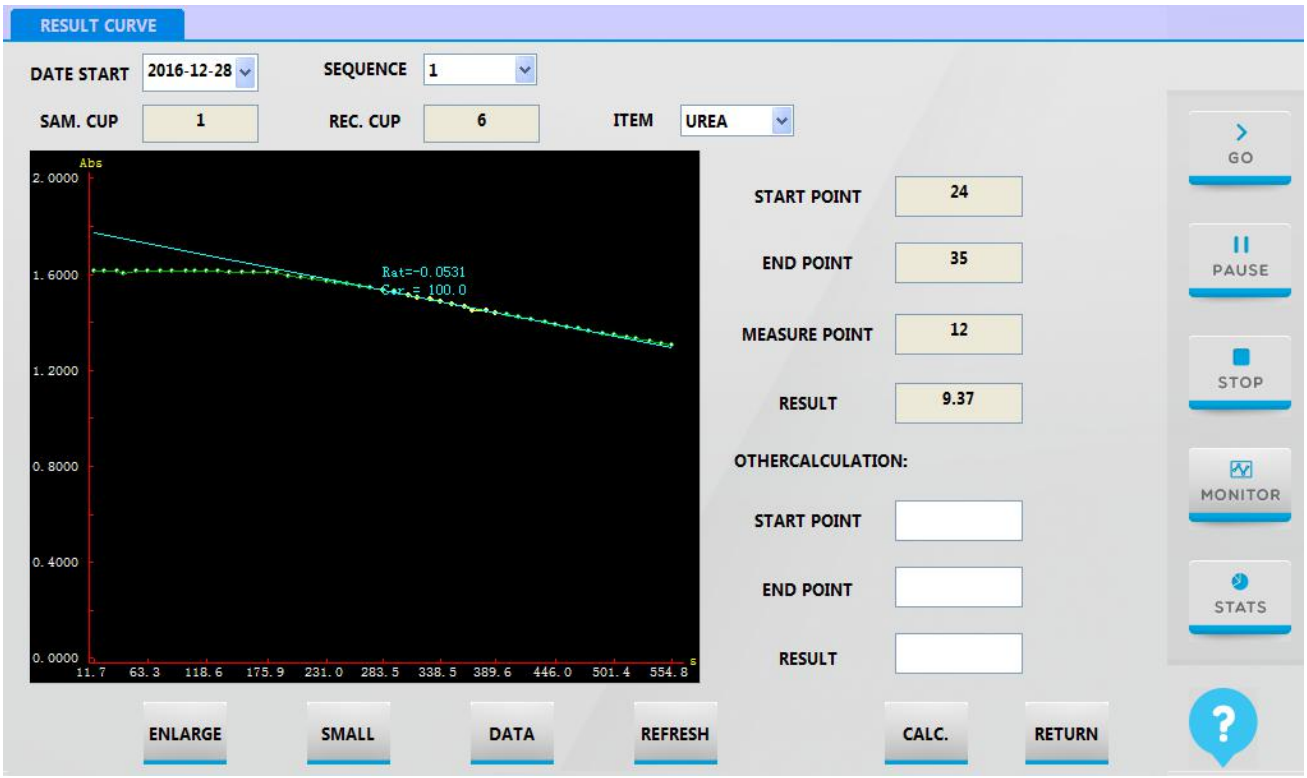


Figure 6.1.2 Test curve display interface

【**Enlarge**】: Magnify the precision of the y coordinate.

【**Small**】: Reduce the precision of the y coordinate.

【**Calculate**】:According to the user sets start point and end point to recalculate the test curve.

6.2 Check the QC result

After the QC tests, quality control test results and the quality control chart can be viewed in QC data interface. Please accord to chapter **5.6 Quality control judgment method** to judge the QC results.

6.2.1 Check the QC Curve

1) In menu bar, click **QC** button;

2) Click **QC chart** to enter the interface.

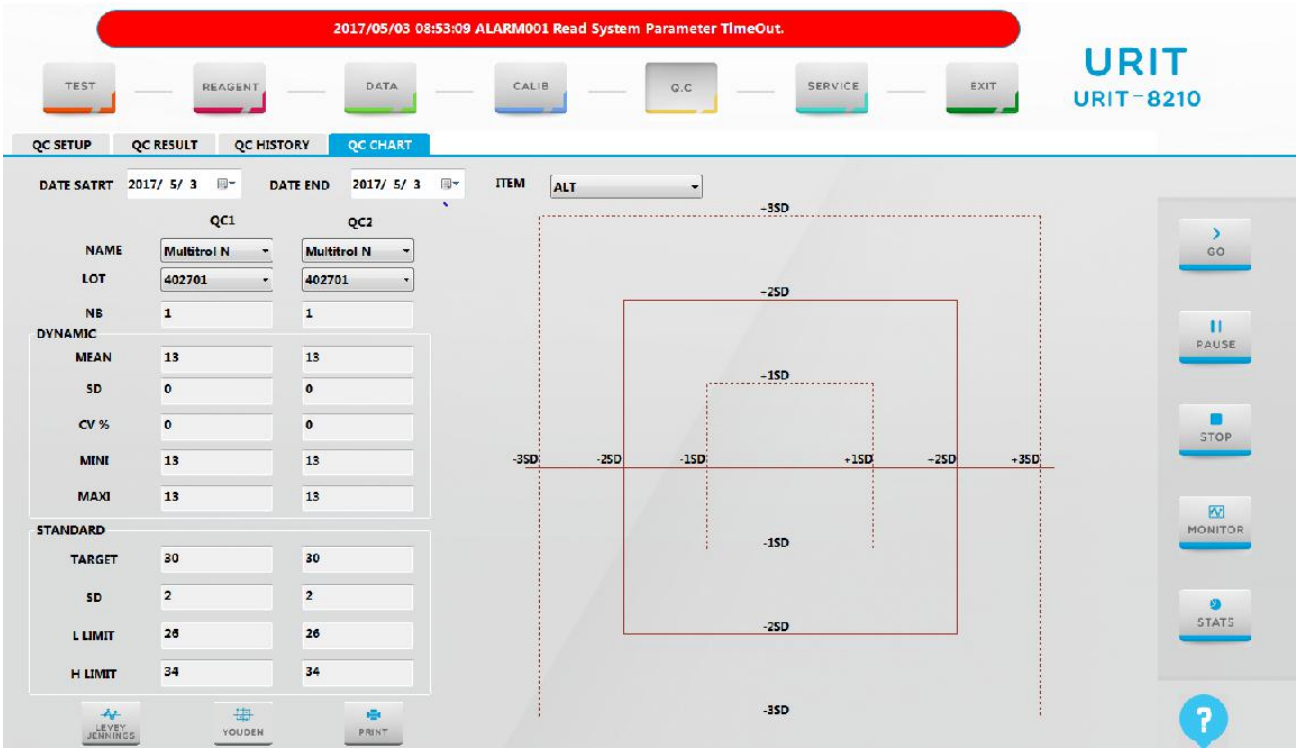


Figure 6.2.1 QC chart analysis interface

3) Select the begin and end date to check the QC chart in a period. The day of the date is default.

4) To select a item to check its chart at “item” tablet.

5) Select the corresponding QC name and lot NO. of the item to check the chart.

6.2.2 Check reaction curve

1) Click QC icon in the menu.

2) Select QC result to enter the interface.

3) Select an item to check its reaction curve.

4) Click Curve to enter the interface to check.

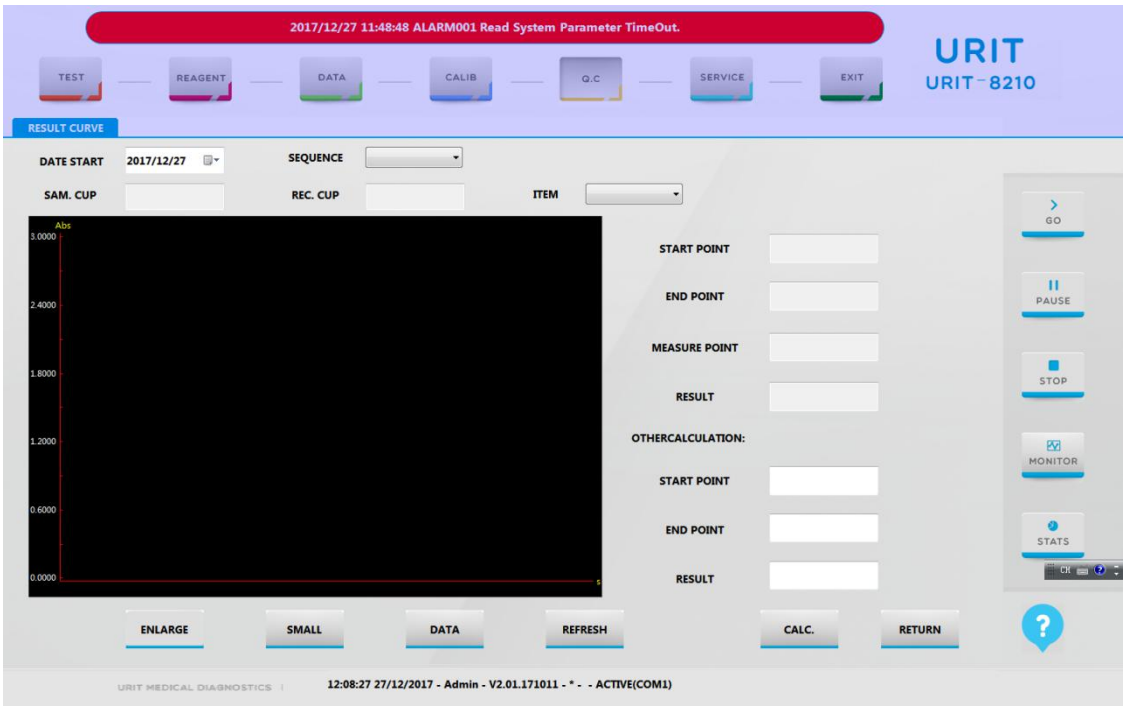


Figure 6.2.2 QC curve interface

[enlarge]: enlarge the accuracy of Y-axis.

[small]:reduce the accuracy of Y-axis.

[calc]:re-calculate the curve according to the initial and ending point which setup by users.

6.3 View and handle the sample result

After the analysis, you can through registration interface to view and handle the test results of routine sample and emergency sample. Sample registration interface displays sample test results and provides the function of edit the patient information or results.

6.3.1 Patient information registration

You need to input the patient information during or after the sample test, including: sample ID, patient name, gender, age, Patient No, hospital number, sample type, inspection department, clinician and clinical impression, in order to output the complete inspection report. There are two ways for patient information registration, one is registers the information in the process of test, the other is registers the information after finish the test. In a massive sample testing, registers the patient information in the process of test will help you improve the working efficiency.

You can view and edit the sample information, no matter what status the system is in.

1) Return to main interface;

◆ Registers the information in the process of test: Click **return to management process** button in test system.

◆ Registers the information after finish the test: Click **Exit** button in test system.

2) Click **Test** icon to enter interface;

3) Click Information to enter patient's information registration interface.

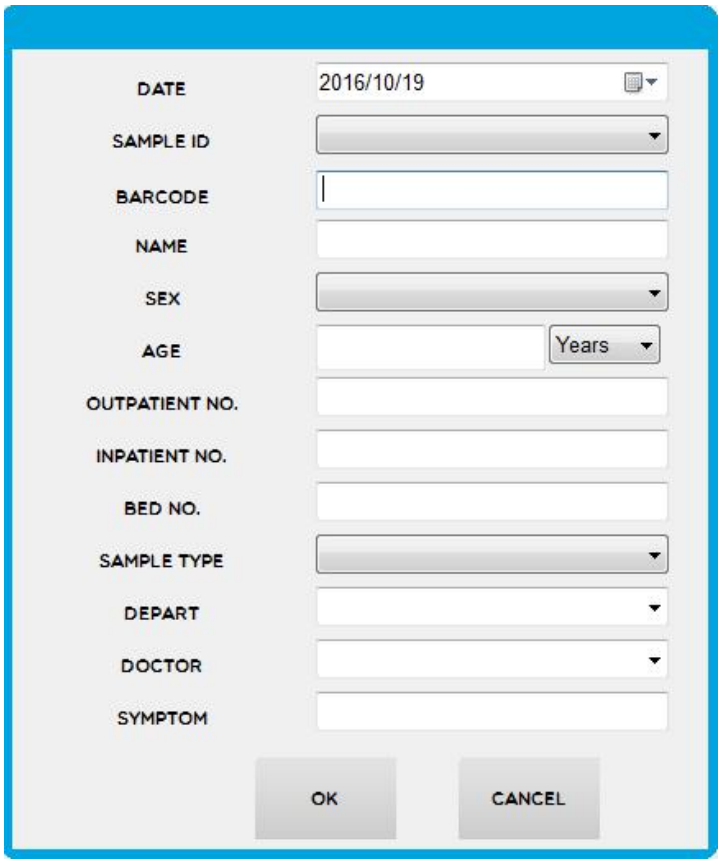


Figure 6.3.1 Patient's information registration interface

4) Input the patient name in【**Name**】;

5) Input the age of the patient in the first box of【**Age**】, and then select the unit of age from the second box; Age units including: years, months, days, hours and minutes, the default is years.

6) Select the patient's clinician from the【**Doctor**】pull-down list; User can accord need to edit clinician. For specific operation, please refer to chapter 3.1.4.1.4.

7) Select the inspection department from the【**Department**】pull-down list; The user can accord need to increase the inspection department. For specific operation, please refer to chapter 3.1.4.1.3.

8) Select the patient's gender from the【**Sex**】pull-down list; Options include: man, woman and child. The default is man.

9) Input the patient's status in the **[Symptom].**

10) To select the sampling date in **[Date].**

11) Click **OK** to complete information edition. To click **Previous** or **Next** button to complete the forward or next patient's information registration.

6.3.2 Check the reaction curve

Sample result's reaction curve: Draw a curve according to the absorbance of reaction solution (which mixed by sample and reagent) in each point from entire test cycle, it reflects the absorbance relationship between dominant wavelength and complementary wavelength.

1. The lab can use the **reaction curve** to check the test data's test curve, and then through check the test curve to analyze the test data.

1) Click menu bar **Data** to enter the interface;

2) The interface is default to display the intraday result, display by sample ID group. To select a sample ID which you need to check, the ID will display in the right list.

3) To select an item which you need to check the curve.

4) Click **Curve** to enter the interface.

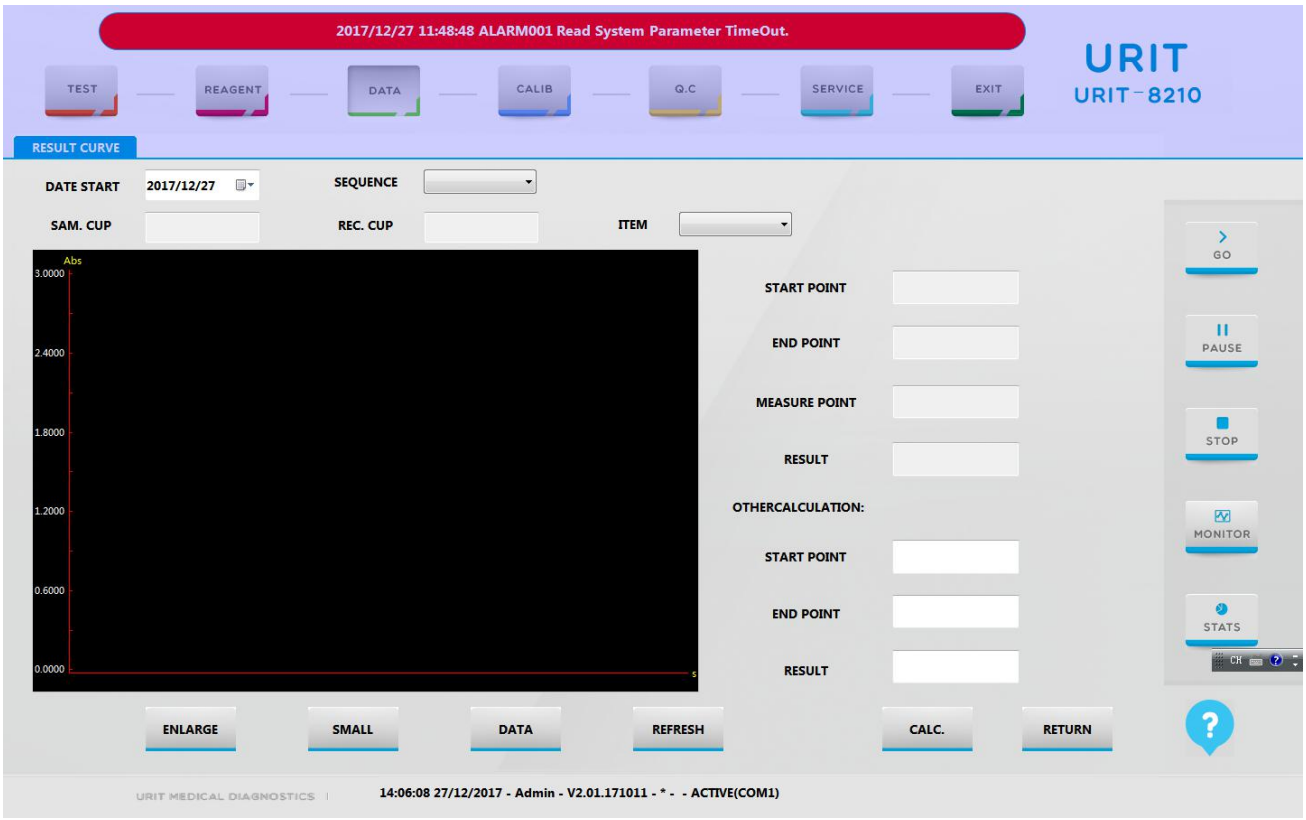


Figure 6.3.2 Sample curve display interface

【**Enlarge**】: Magnify the precision of the y coordinate.

【**Small**】: Reduce the precision of the y coordinate.

【**Calculate**】:According to the user sets start point and end point to recalculate the test curve.

4. Historical result curve

1) Click **Data** button.

2) Click **Historical** button to enter the interface.

3) Select an item which you need to check the curve.

4) Click **Curve** to enter the interface to check.

6.4 Print test result

All kinds of test results and the data can be printed out by the default printer and specified print template. You can set the printer type, default printer and hospital name shown on the report, and also you can set the print order of test items.

6.4.1 Print QC result

6.4.1.1 Print QC result

1) Click QC button and QC result to enter the interface as follows:

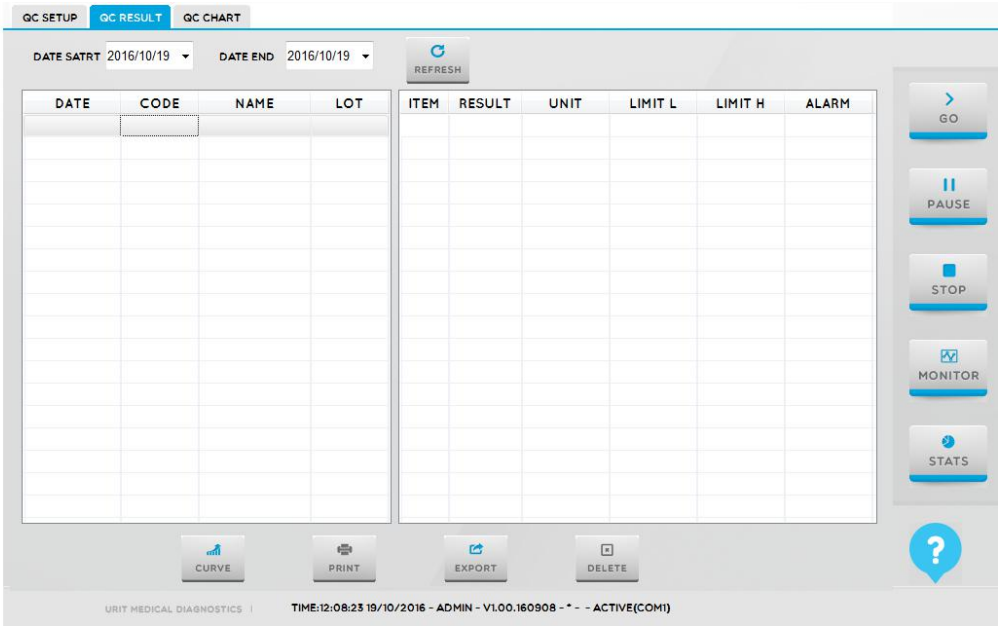


Figure 6.4.1.1 QC result interface

2) To select the begin date and end date in the list to print.

3) Click **Print** is OK.

6.4.1.2 Print QC chart

1) Click QC and QC chart to enter the interface as follows:

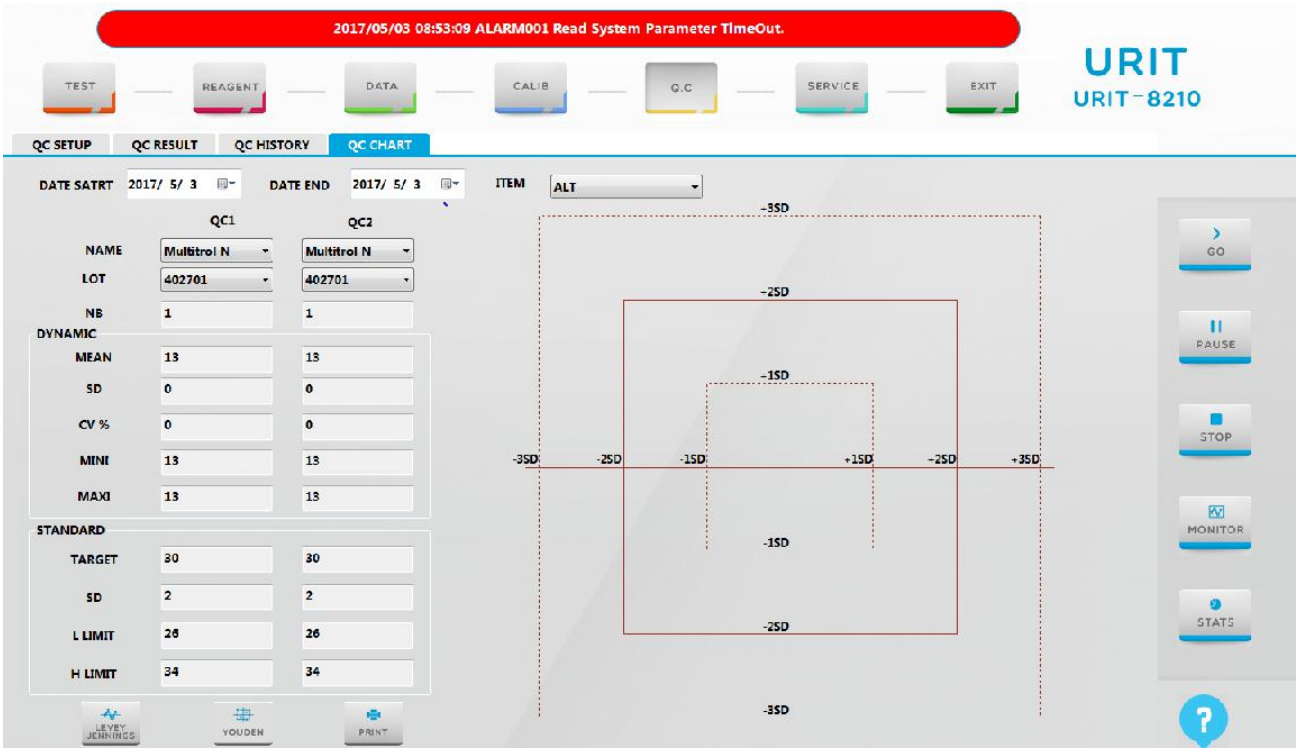


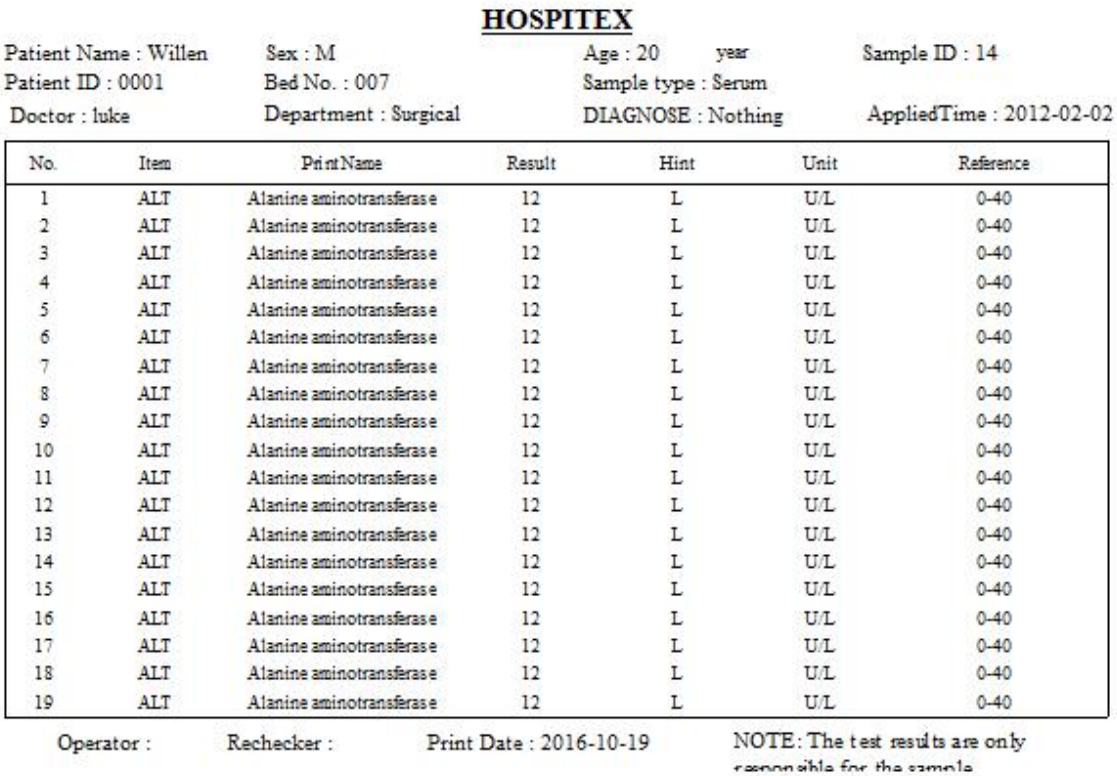
Figure 6.4.1.2 QC chart interface

2) To select the test date of the item which you need to print in the list.
3) To select the item which you need to print.
4) Select the corresponding name and lot number of the item.
5) Click **Print** button.
6) To select a printer, this has been installed well to print.

6.4.2 Print sample report

1) Click **Data** then **Results** button to enter the interface.
2) To select a sample ID which you need to print.
3) Click **Print** button, system will print by default printer and print template.

The report templates are as follows:



HOSPITEX

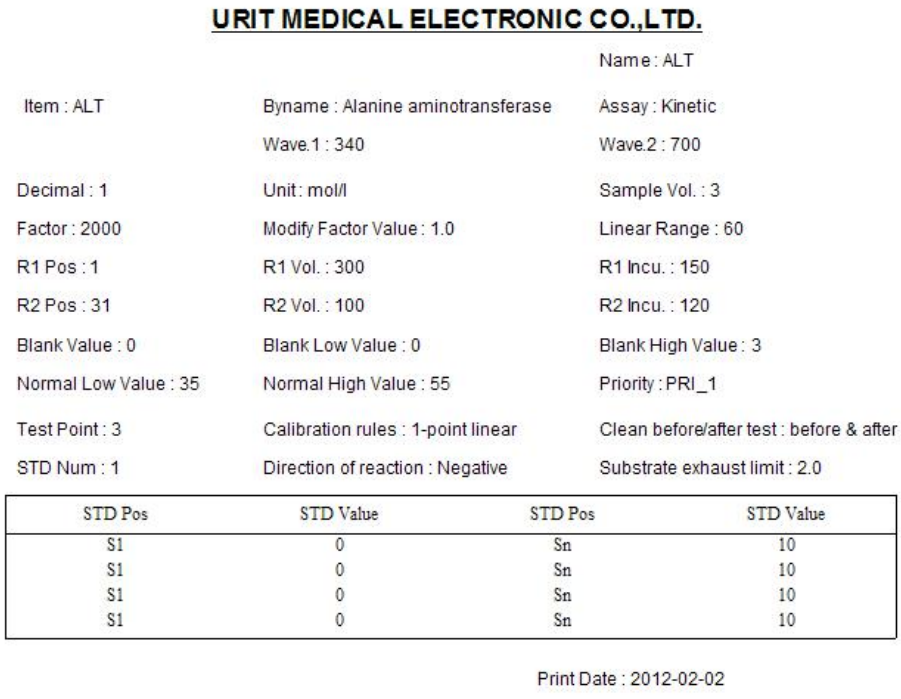
Patient Name : Willen Sex : M Age : 20 year Sample ID : 14
Patient ID : 0001 Bed No. : 007 Sample type : Serum
Doctor : luke Department : Surgical DIAGNOSE : Nothing AppliedTime : 2012-02-02

No.	Item	PrintName	Result	Hint	Unit	Reference
1	ALT	Alanine aminotransferase	12	L	U/L	0-40
2	ALT	Alanine aminotransferase	12	L	U/L	0-40
3	ALT	Alanine aminotransferase	12	L	U/L	0-40
4	ALT	Alanine aminotransferase	12	L	U/L	0-40
5	ALT	Alanine aminotransferase	12	L	U/L	0-40
6	ALT	Alanine aminotransferase	12	L	U/L	0-40
7	ALT	Alanine aminotransferase	12	L	U/L	0-40
8	ALT	Alanine aminotransferase	12	L	U/L	0-40
9	ALT	Alanine aminotransferase	12	L	U/L	0-40
10	ALT	Alanine aminotransferase	12	L	U/L	0-40
11	ALT	Alanine aminotransferase	12	L	U/L	0-40
12	ALT	Alanine aminotransferase	12	L	U/L	0-40
13	ALT	Alanine aminotransferase	12	L	U/L	0-40
14	ALT	Alanine aminotransferase	12	L	U/L	0-40
15	ALT	Alanine aminotransferase	12	L	U/L	0-40
16	ALT	Alanine aminotransferase	12	L	U/L	0-40
17	ALT	Alanine aminotransferase	12	L	U/L	0-40
18	ALT	Alanine aminotransferase	12	L	U/L	0-40
19	ALT	Alanine aminotransferase	12	L	U/L	0-40

Operator : Rechecker : Print Date : 2016-10-19 NOTE: The test results are only responsible for the sample

Figure 6.4.2-1 Patient report default print template interface

Other default print templates are as below:



URIT MEDICAL ELECTRONIC CO.,LTD.

Name : ALT

Item : ALT Byname : Alanine aminotransferase Assay : Kinetic
Wave.1 : 340 Wave.2 : 700
Decimal : 1 Unit : mol/l Sample Vol. : 3
Factor : 2000 Modify Factor Value : 1.0 Linear Range : 60
R1 Pos : 1 R1 Vol. : 300 R1 Incu. : 150
R2 Pos : 31 R2 Vol. : 100 R2 Incu. : 120
Blank Value : 0 Blank Low Value : 0 Blank High Value : 3
Normal Low Value : 35 Normal High Value : 55 Priority : PRI_1
Test Point : 3 Calibration rules : 1-point linear Clean before/after test : before & after
STD Num : 1 Direction of reaction : Negative Substrate exhaust limit : 2.0

STD Pos	STD Value	STD Pos	STD Value
S1	0	Sn	10
S1	0	Sn	10
S1	0	Sn	10
S1	0	Sn	10

Print Date : 2012-02-02

Figure 6.4.2-2 Item parameter report default print template

Daily QC Report

QCLot : 123 Test Date : 2012-05-04 Print Date : 2012-05-04

No.	Item	Byname	Result	Target Value	SD
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8
1	ALT	Alanine aminotransferase	12	3	0.8

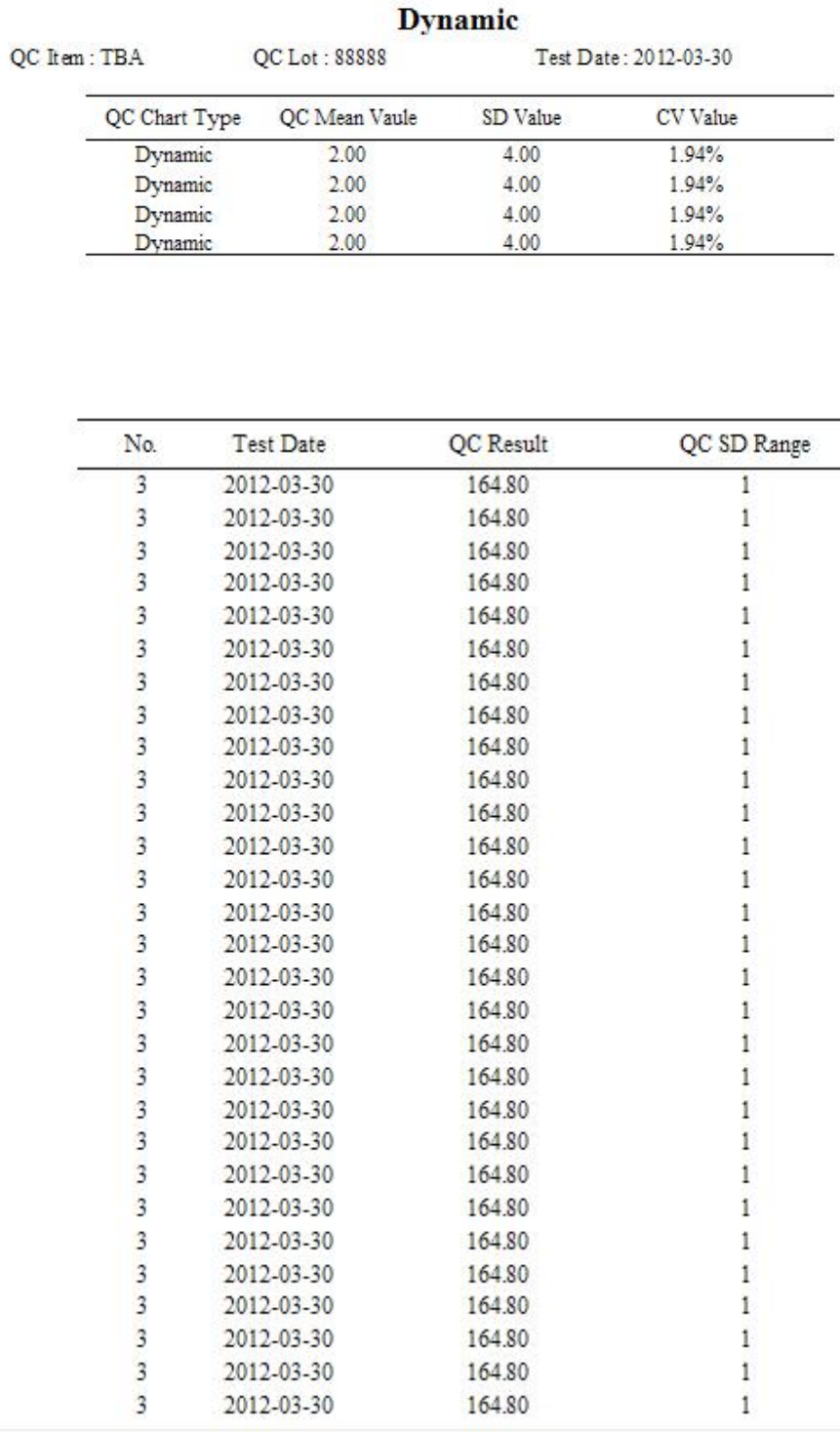
Figure 6.4.2-3 Within-day QC report default print template

URIT MEDICAL ELECTRONIC

Item : ALT Test Date : 2012-05-04 Print Date : 2012-05-04

No.	Sam. ID	Result	Hint	Unit	Normal L	Normal H
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60
1	007	12	L	mol/l	20	60

Figure 6.4.2-4 Item result report default print template



Dynamic

QC Item : TBA QC Lot : 88888 Test Date : 2012-03-30

QC Chart Type	QC Mean Vaule	SD Value	CV Value
Dynamic	2.00	4.00	1.94%
Dynamic	2.00	4.00	1.94%
Dynamic	2.00	4.00	1.94%
Dynamic	2.00	4.00	1.94%

No.	Test Date	QC Result	QC SD Range
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1
3	2012-03-30	164.80	1

Figure 6.4.2-5 Between-days QC report default print template

CHAPTER 7 ADVANCED SETTINGS

In the process of biochemical test, the user sometimes needs to do some special settings. This chapter is mainly to introduce the user to set blank, substrate exhaustion judgment method, custom print and LIS.

7.1 Blank setting

Note

Blank setting is only effective in the endpoint method.

7.1.1 Introduction

In testing, for some special reagent, user needs according to its features to do the related blank setting. For example: in immune reagent's emulsion method item, there is a unique blank interference in emulsion method reagent, and it cannot be eliminated by 2-point endpoint method. Takes H-CRP item as an example, the item uses double reagent, after the first reagent mixed with sample, it still the same like common reagent, but after adding the second reagent, it will produce a absorbance jump, and then gradually reaction. And this sudden jump is due to the latex components in the second reagent, so the smooth curve which behind that is the real reaction, so you should select the stable range to calculate the results, as shown in figure below:

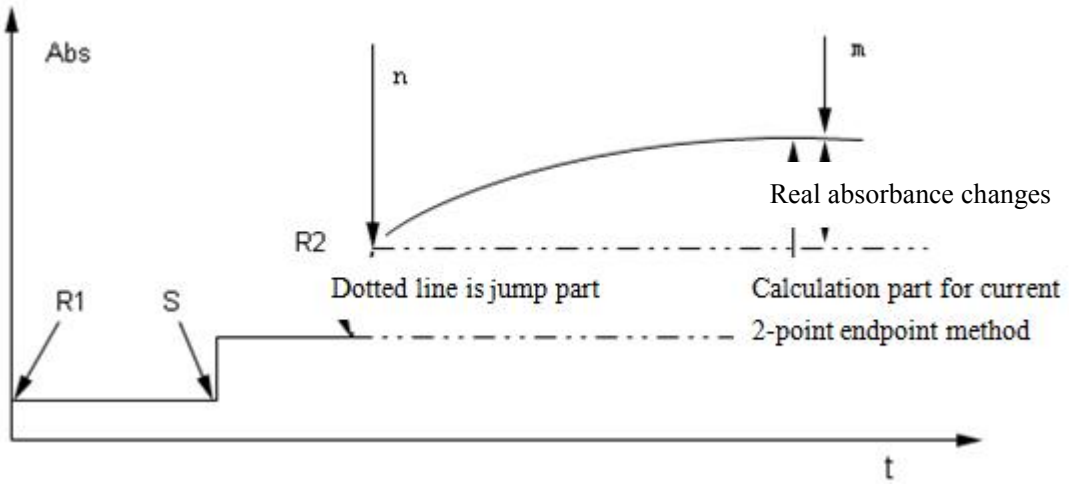


Figure 7.1.1 Immune item reaction curve

7.1.2 Blank setting

Software blank setting provides blank calculation start point (n) setting and blank calculation end point (m) setting, to avoid the jump part, so that the calculation results more close to the real value.

Because different reagent or item may cause different jump position, so the software provides different setting selections, as shown in figure below:

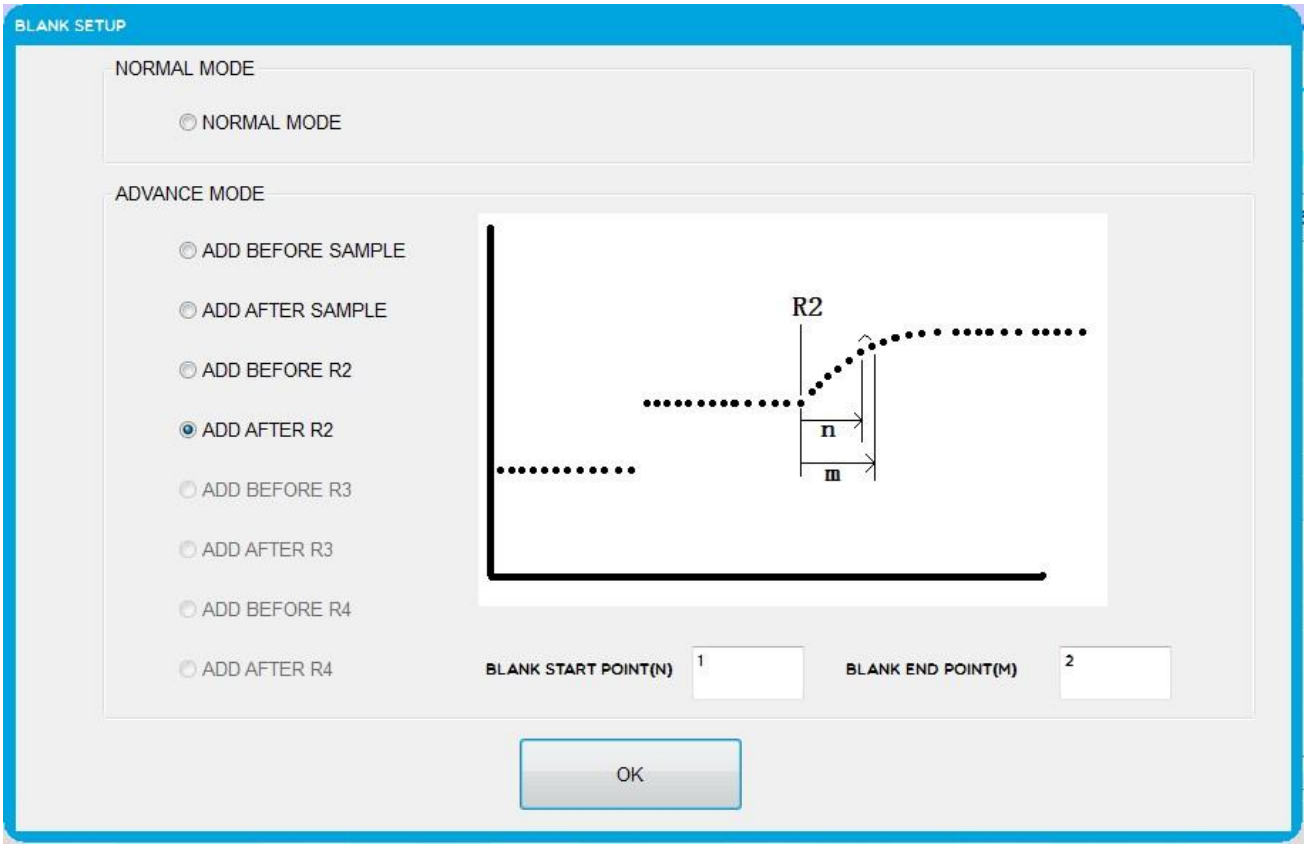


Figure 7.1.2-1 Blank setting selection

Advanced mode setting requires you according to the corresponding immune reagent item's reaction curve to set the blank start point and blank end point, thus avoid the blank jump part for effective calculation.

Generally, there are four settings in advanced mode (only discuss single reagent or double reagent), takes adding sample point and adding R2 point as nodes, as shown in figure 7.1.2-2, blank selection range is divided into A, B and C three parts.

Single reagent item is open blank 1 and blank 2 settings.

Double reagent item is open blank 1, blank 2, blank 3 and blank 4 settings

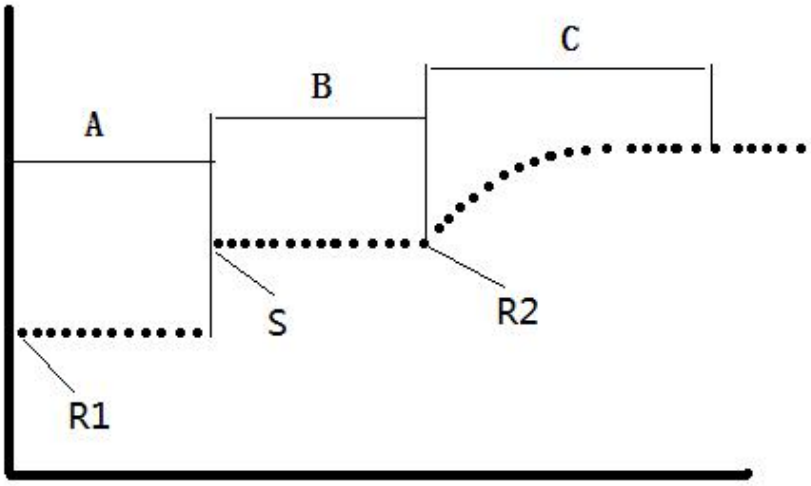


Figure 7.1.2-2 Blank setting selection range

Takes double reagent item as an example, the specific method is as follows:

1) The first blank setting, takes sample(S) as node, selects **Before adding sample** as blank interval, as shown in figure 7.1.2-3, S is the adding sample point, the blank absorbance is the average absorbance from n point to the m point.

Note

1) The interval of n and m should between the interval of R1 and S.
2) Point m should be greater than or equal to point n.

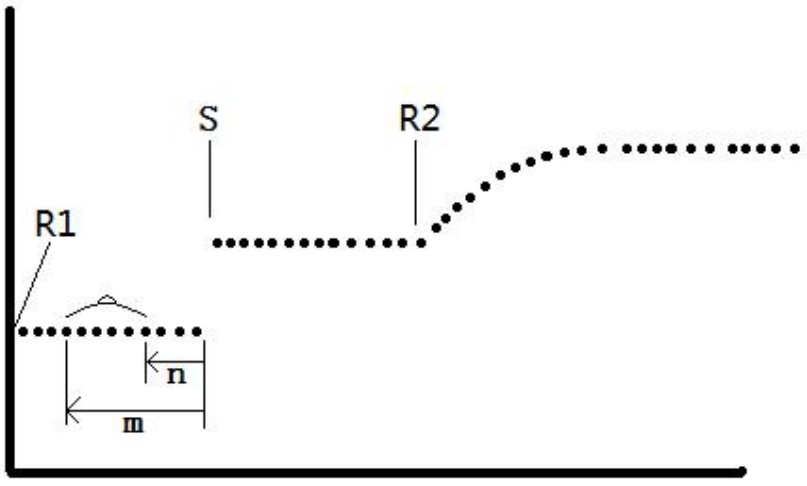


Figure 7.1.2-3 Before adding sample

2) The second blank setting, takes sample(S) as node, selects **After adding sample** as blank interval, as shown in figure 7.1.2-4, S is the adding sample point, the blank absorbance is the average absorbance from n point to the m point.

Note

1) Point m should be greater than point n.

2) M time's period should be less than the first reagent's incubation time.

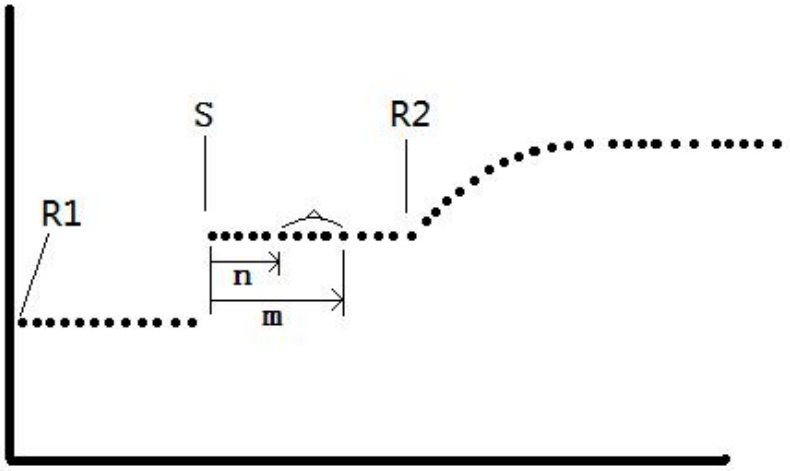


Figure 7.1.2-4 After adding sample

3) The third blank setting, takes adding the second reagent(R2) as the node, selects **Before adding the second reagent** as blank interval, as shown in figure 7.1.2-5, R2 is the adding the second reagent point, the blank absorbance is the average absorbance from n point to the m point.

Note

1) Point m should be greater than point n.

2) M times period should be less than the second reagent's incubation time.

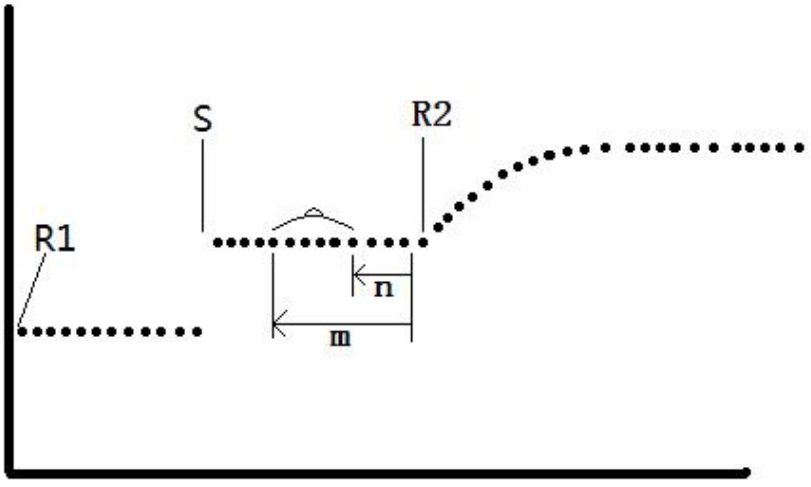


Figure 7.1.2-5 Before adding the second reagent

4) The fourth blank setting, takes adding the second reagent(R2) as the node, selects **After adding the second reagent** as blank interval, as shown in figure 7.1.2-6, R2 is the adding the second reagent point, the blank absorbance is the average absorbance from n point to the m point.

Note

1) Point m should be greater than point n.
2) M times period should be less than the second reagent's incubation time.

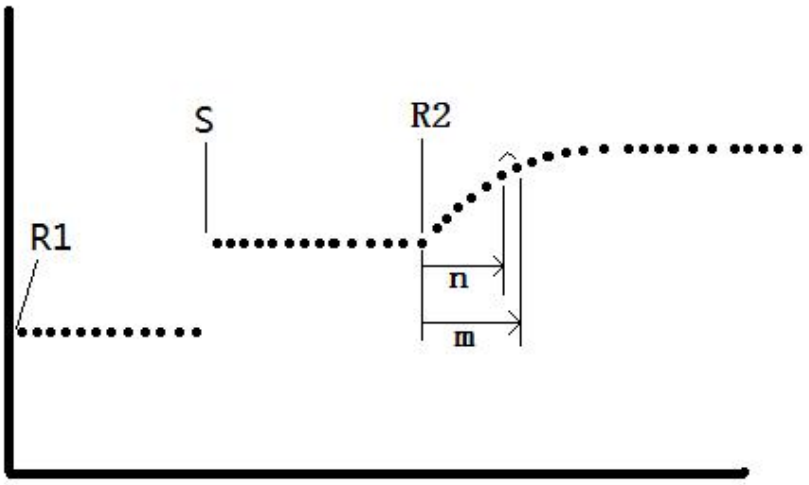


Figure 7.1.2-6 Before adding the second reagent

7.2 Substrate exhaustion judgment method

7.2.1 Introduction

Note

Substrate exhaustion judgment is only effect on rate method.

In rate method test, some high concentration (active) sample will make substrate exhaustion, make the reaction is no longer level 0 or level 1, if the instrument does not have the substrate exhaustion judgment function or set the identification parameters incorrectly, will lead to incorrect results. So in order to correctly reflect the determination results, it is necessary to set the substrate exhaustion limit (a specific absorbance), this absorbance is the critical point of linear area and nonlinear area or level 1 reaction area and multistage reaction area.

When uses continuous monitoring method to test the enzyme activity, during the monitoring periods, if absorbance increase or decrease more than the substrate exhaustion limit, then the sample enzyme activity is very high, the substrate will be exhausted, so the absorbance will deviate from the linear, make the determination results is unreliable.

This analyzer provides two kinds of substrate exhaustion judgment method, and figure 7.2.1 shows the substrate exhaustion situation in single reagent and negative reaction.

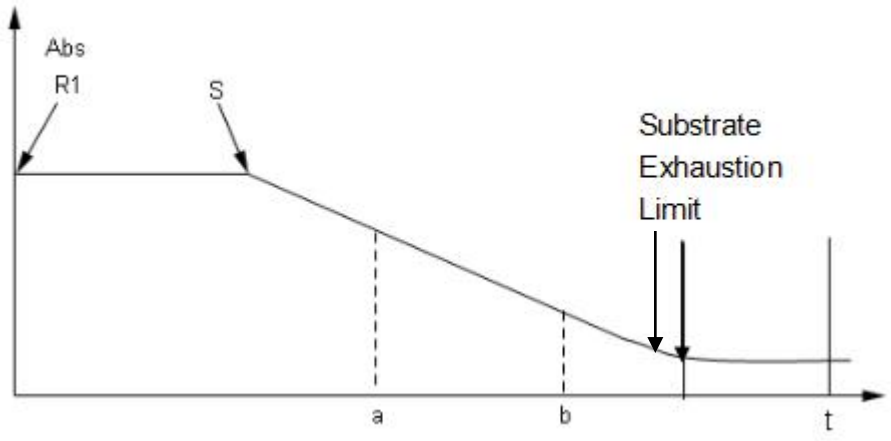
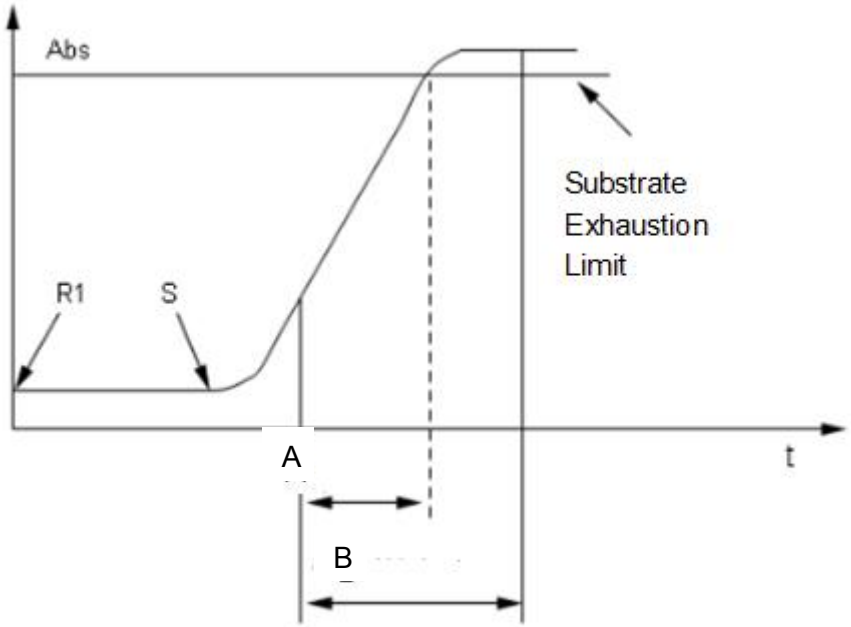


Figure 7.2.1 Substrate exhaustion（Single reagent, negative reaction）

7.2.2 Substrate exhaustion judgment method 1（absorbance limit）

Relevant experiments are used to determine the absorbance value of substrate exhaustion, set the limit, the average of last three points in positive reaction absorbance reading area is greater than the absorbance value of **substrate exhaustion limit**, negative reaction is less than this value, then judged as substrate exhaustion. Figure 7.2.2-1 is the first substrate exhaustion judgment setting area.

Figure 7.2.2-1 The first substrate exhaustion judgment setting area



A: linear range B: points reading area

Figure 7.2.2-2 Substrate exhaustion（Single reagent, forward reaction）

7.2.3 Substrate exhaustion judgment method 2（Slope ratio）

Substrate exhaustion judgment method 2: Judgment based on reaction curve slope (absorbance change rate), and set the related settings in reagent parameter setting interface.

Figure 7.2.3-1 The second substrate exhaustion judgment setting area

Meaning for each parameters:

1) Main slope（Main points reading area）

Test points: Normal points reading area's slope (absorbance change rate) which set up by reagent parameters.

2) Deputy slope（Deputy points reading area）

In the second substrate exhaustion method, set the points reading area's slope (absorbance change rate).

3) Start point

Deputy slope as the reading point start point, in single reagent, start counting point after adding the sample; in double reagent, start counting point after adding the second reagent, and then start point

cannot greater than the main slope's start reading point.

4) End point

Deputy slope reading point end point, and the reading point of end point should be less then the last point of main slop.

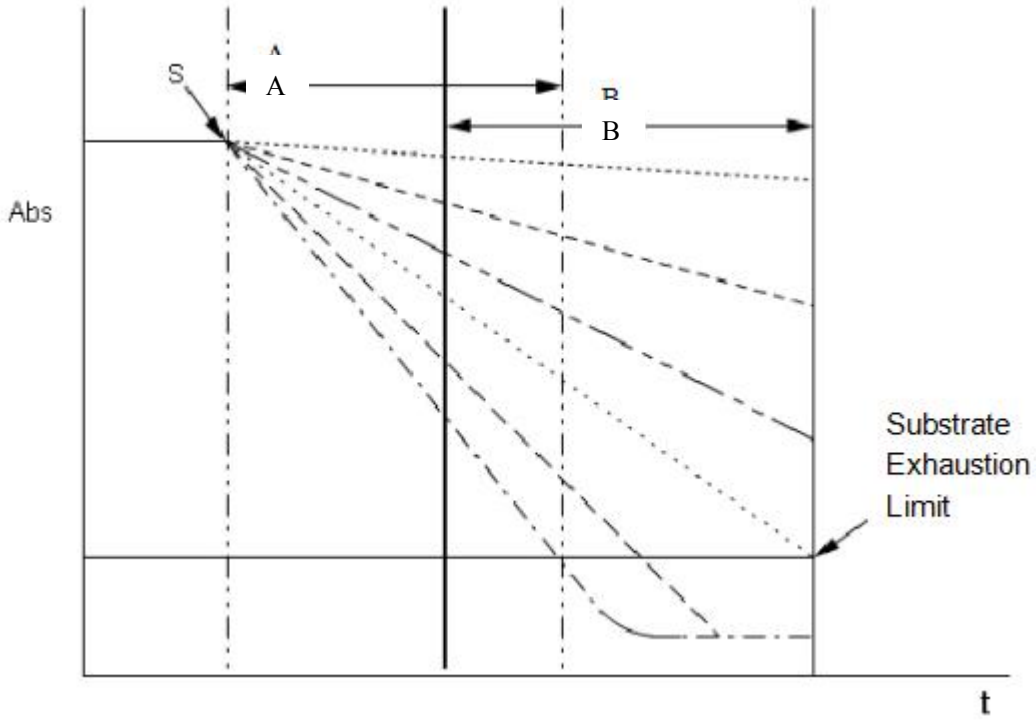
5) Slope ratio

Slope ratio: Main slope/deputy slope. When the value of the slope ratio is less than the setting value, then it will be judged as substrate exhaustion, this method can be used in conjunction with the first method 1, or only use the first method.

When it judged as substrate exhaustion, no matter is triggered by the first method or the second method, as long as you check the second judgment method, the system will automatically take the deputy slope (absorbance change rate) as the calculation slope, and then the sample result is: deputy slope × K.

Note

Deputy slope's start point is restricted by main slope's start point, so the start point cannot be greater than the main slope's start point, and the end point is also cannot be greater than the main slope's end point.



A: Deputy points reading area B: Main points reading area

Figure 7.2.3-2 The second substrate exhaustion judgment method（Single reagent, negative reaction）

Note

Double reagent judgment method is the same as the above method.

7.3 LIS setting

7.3.1 Introduction

LIS (Laboratory Information System) is an external host, through the fixed interface connected to the analyzer, used for download the sample application information, and receive the sample test results from the analyzer. The LIS system support the function of test data from multiple biochemical analyzers uploaded to the same server, to realize data share.

Before using the LIS to download the sample application information and realize data transmission, you need to set up the LIS communication parameters and results transmission method.

Before using LIS function, please make sure the system has equipped with the LIS. If not, please contact URIT or local distributor.

7.3.2 LIS communication parameter setting

Before using the LIS, you need to set up the LIS communication parameters, such as: server IP, port, communication mode and other parameters.

1) Click **Service,** then **Lis setting**, to enter the LIS connection setting interface, as shown in figure 7.3.2;

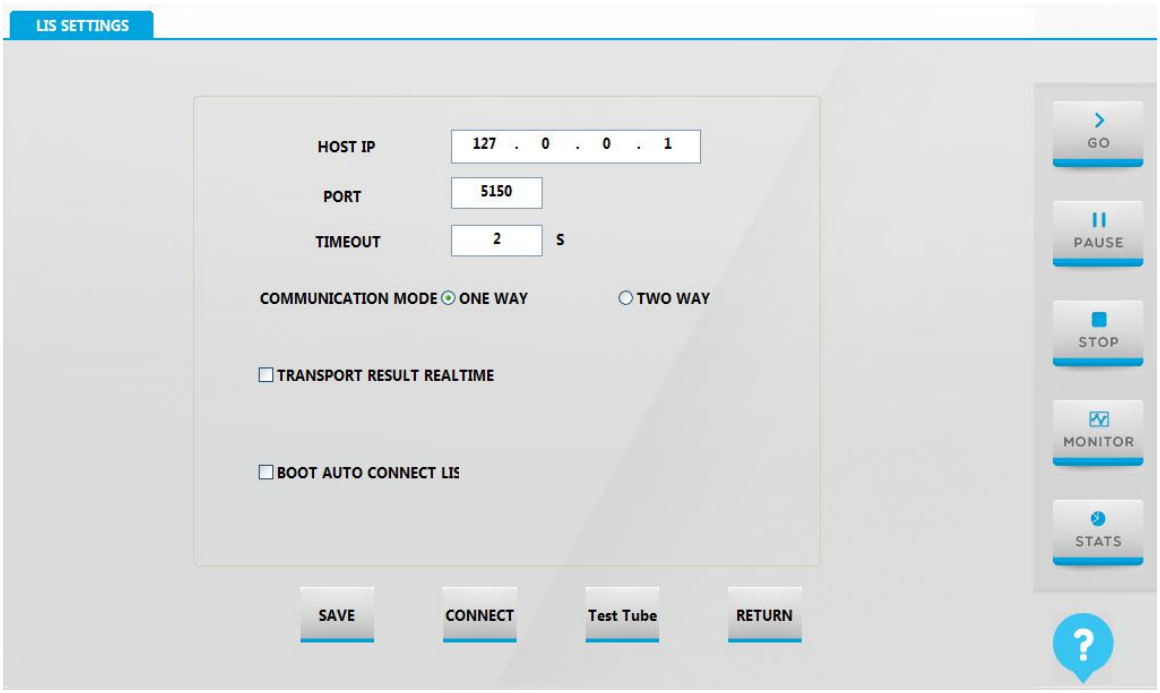


Figure 7.3.2 LIS setting

2) Set the following parameters;

3) Click **SAVE** button to save the current setting;

4) Click **Connect** to connect the analyzer and LIS host;

The meaning of main parameters:

1) IP address

Input the IP address of LIS host. Through the network to connect the LIS host to the analyzer and the connection is based on TCP/IP protocol.

2) Port

Input the LIS host communications port, that is the LIS server monitoring port number.

3) Communication Mode

Set the communication mode between the analyzer and LIS host, options include: **One way** and **Two way**.

One way transmission: The biochemistry analyzer can only send the test results, sample information and QC information to the LIS server, but cannot get sample application information from the LIS server.

Two way transmission: The biochemistry analyzer can not only send the test results, sample information and QC information to the LIS server, but also can get sample application information

from the LIS server; and at the same time, the LIS server can also send the sample application information to the analyzer's LIS module.

4) Send Result Real-time

If the user selects this check box, after the end of each test and obtain test results, the system will automatically send the test results to the LIS.

5) Get sample info real-time

If the user selects this check box, the analyzer will get sample application information from the LIS server in real time. This setting is only used for two-way transmission mode.

6) Auto Connect

If the user selects this check box, when start the software system, it will automatic connect to the LIS server.

7) Connect timeout

Set the analyzer and the LIS server connection timeout limit, the unit is in seconds.

When the analyzer is download the sample application from the LIS, or trying to connect or send results to the LIS, if the connection time is beyond the set timeout limit, then the system will gives alarm and prompt connection fails.

8) Same sample barcode

When the barcode of download sample is already exists, please select the required operation in the drop-down menu. The system provides the following options:

- Added: Added a new sample ID for the same sample barcode;
- Skip: Do not handle the existing same sample barcode's sample information;
- Cover: Use the current sample to cover the existing sample (including the sample information, test results, etc.).

7.3.3 Send test result to LIS

After the connection is successful, click Data then Result to send the sample information to Lis server.

1) Click Data button and select result to enter the interface.

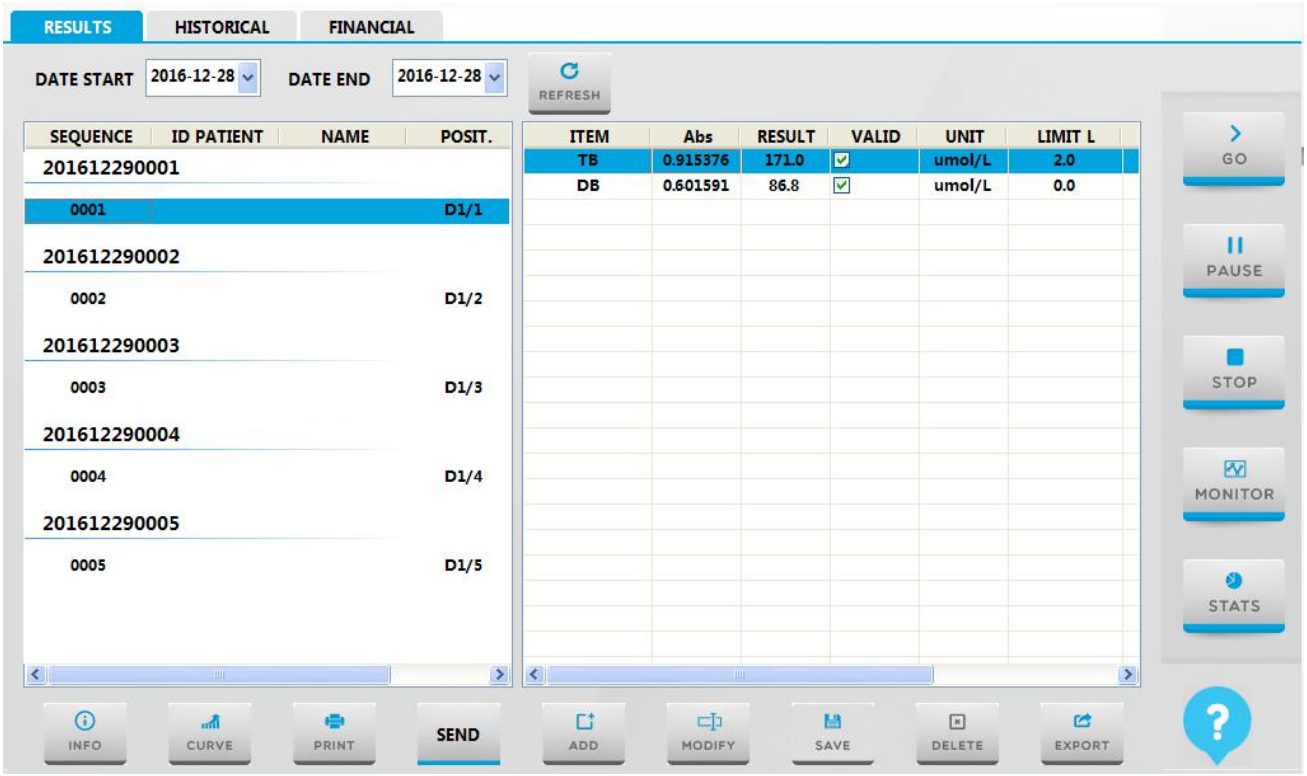


Figure 7.3.3 Send test result to LIS

2) To select the sample ID which is need to send to Lis server.

3) Click **Send** button.

7.3.4 Download the sample application information

After Lis connecting successfully, you could download the sample information from Lis server.

1) Click **Test** then **Sample** button to enter the interface.

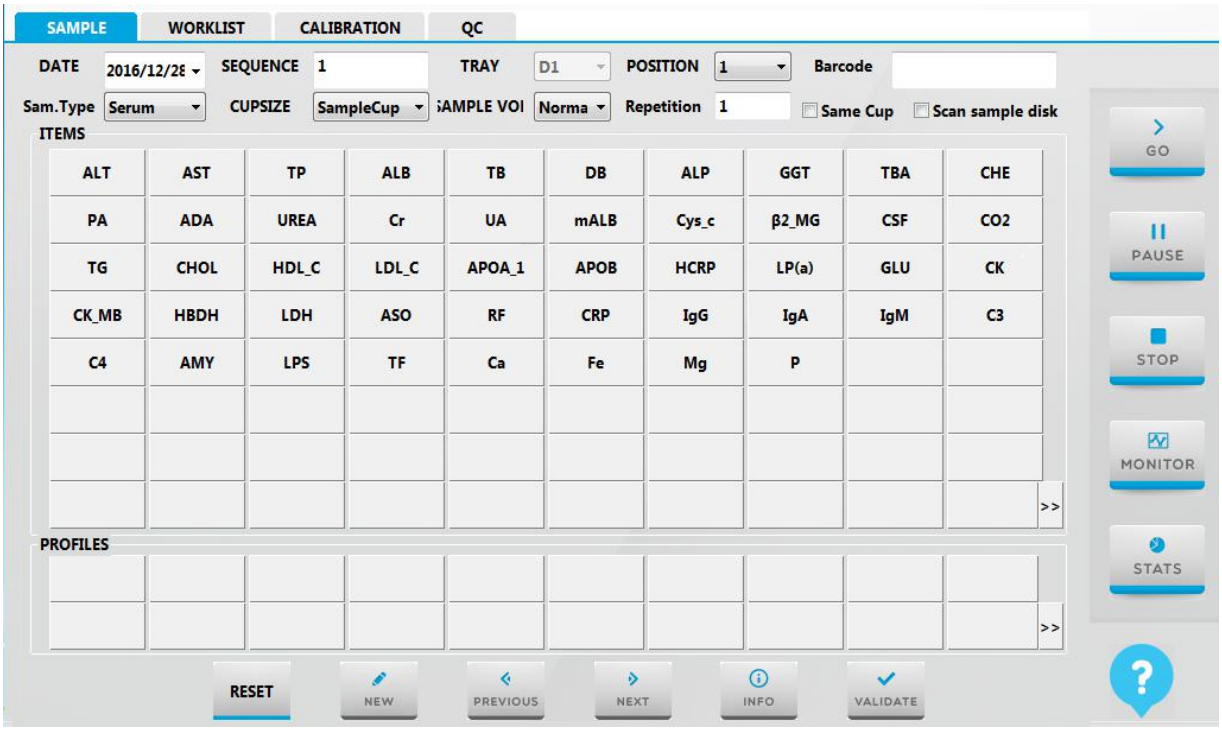


Figure 7.3.4-1 sample application interface

2) Click **Lis** button to download the sample information from Lis server.

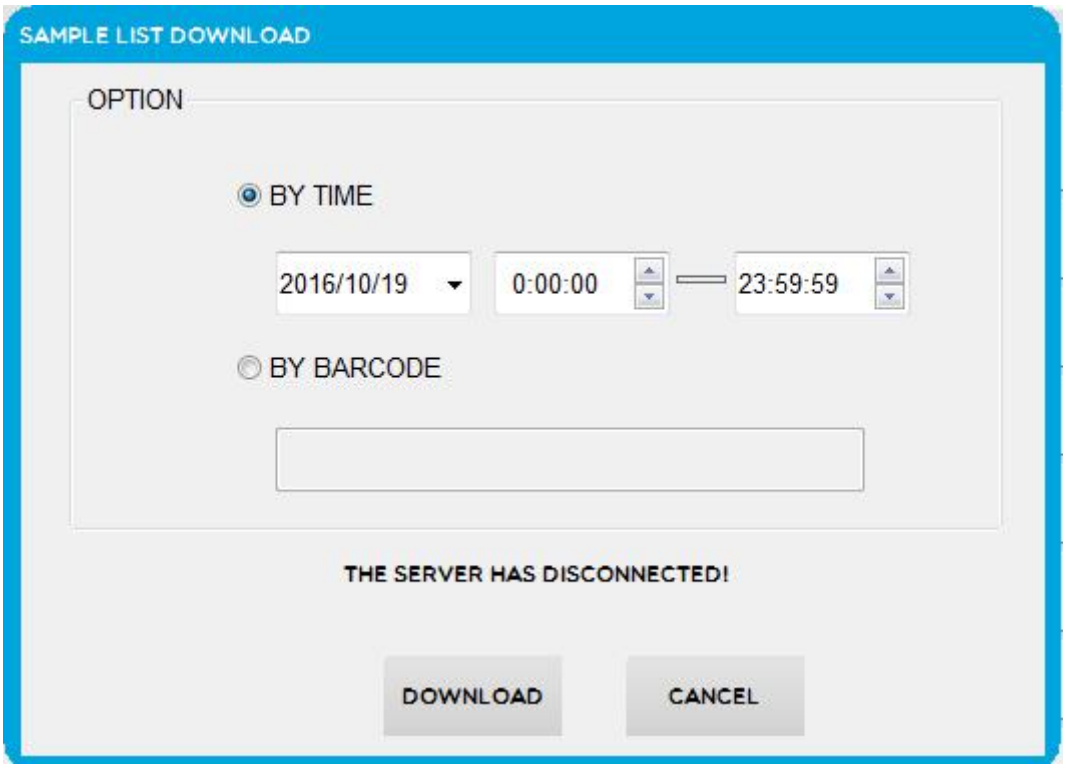


Figure 7.3.4-2 Download the sample application information

You can download the information by time or by barcode.

7.4 Custom print setting

7.4.1 Introduction

All kinds of test results and the data can be printed out by the default printer and specified print template. You can set the printer type, default printer and hospital name shown on the report, and also you can set the print order of test items.

System provides custom print setting, allows the user to adjust the report print template. Before set custom print setting, please make sure that the current biochemical analyzer system has this function.

7.4.2 Print setup 1

In menu bar, click **Service→Customization→Print format** to enter the print setting interface. Print setting interface is divided into two sub-interfaces, one is print format 1, the other is print format 2, as shown in figure 7.4.2-1.

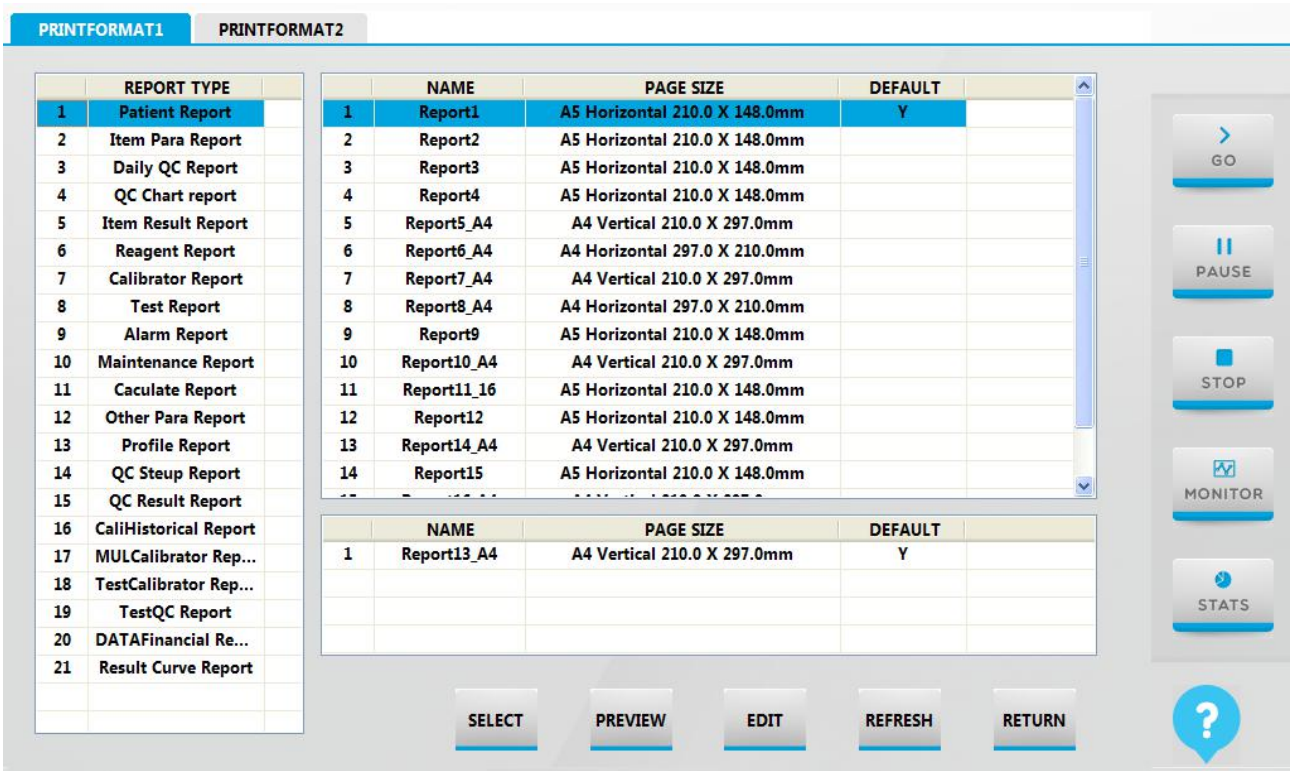


Figure 7.4.2-1 print format 1

The templates in current system are mainly include patient report, item parameter report, daily QC report, days QC report and item result report, each category has different conventional print template and purpose.

- Patient report: Used for print the patient sample test results, and this report category is using most frequently.
- Item parameter report: Used for print the test item related parameters, convenient for user to understand this item's parameter setting.
- Daily QC report: Used for print the within-day quality control chart.
- Days QC report: Used for print the between-days quality control chart.
- Item result report: According to item to print the test results.

Main keys:

【**Select**】: Click this button, the system will set the selected template to default template, and marked in **Y**.

【**Preview**】: Click this button to preview the selected template.

【**Edit**】: Click this button to edit the selected template.

[Refresh]: click the button to refresh the information list.

[Return]: click the button to return to the forward menu.

Users can edit the template by the following steps:

1) Select the report type from the left side of the template management interface;

2) Select the template which needs to edit from the conventional print template list;

3) Click **Edit** button to enter the template editing interface;

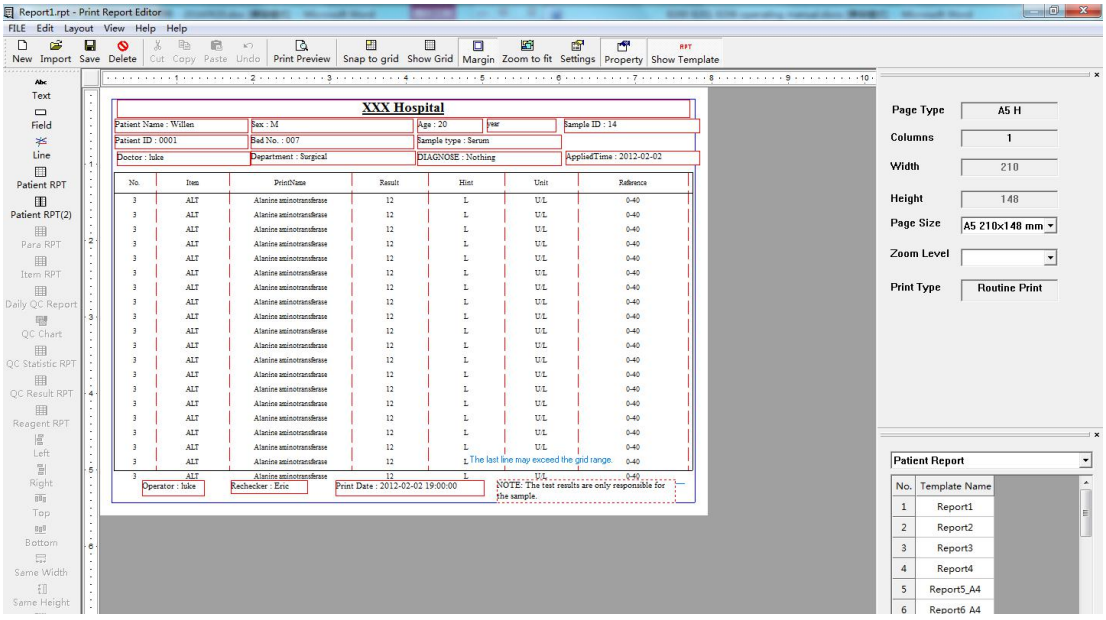


Figure 7.4.2-2 Edit test template interface

4) According to the needs to edit and adjust the template;

5) Click **File→Save**, to save the edited template.

7.4.3 Print format 2

Print template's each item corresponding to a print ID, system program through the print ID to identify the print content. Print ID dictionary setting interface is mainly used for set the tag name for the corresponding print ID.

Click **Print format 2** to enter the interface as shown in figure 7.4.3.

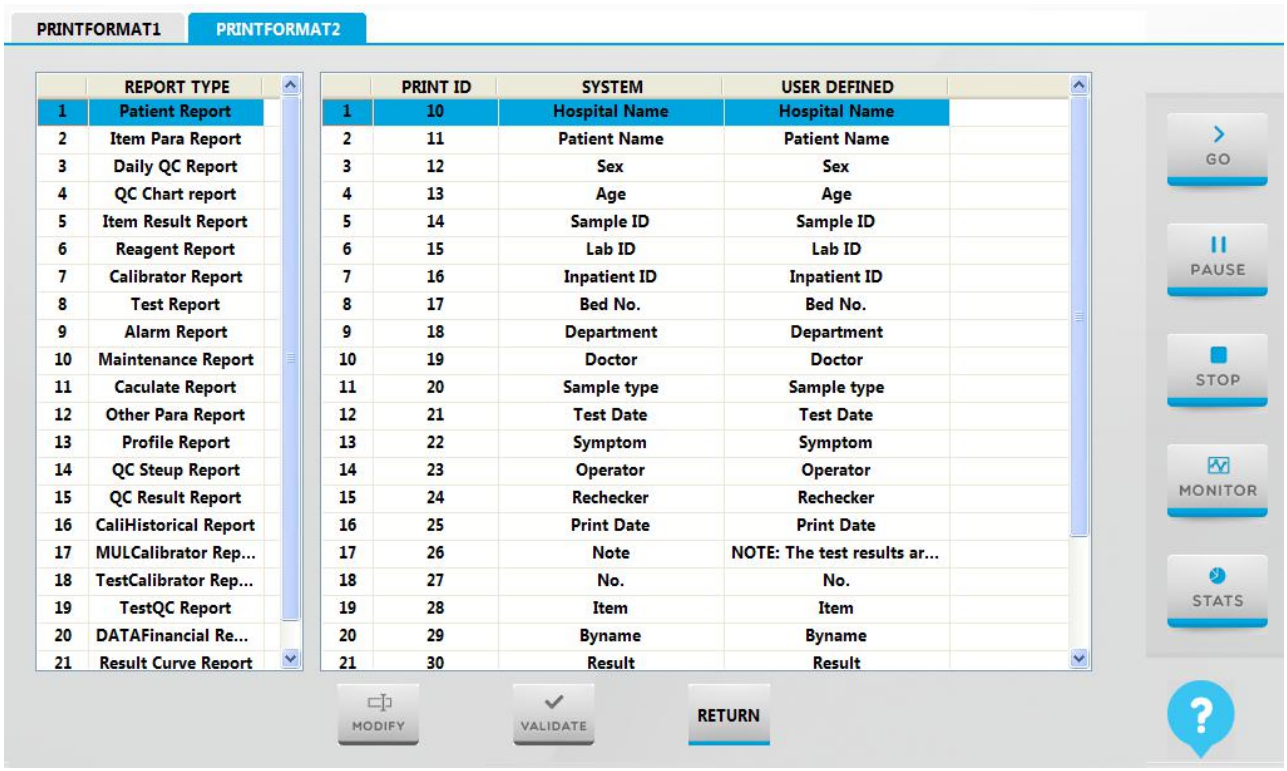


Figure 7.4.3 Print format 2

Users can set the print ID display tag name by the following steps:

1) Select report type from the report type list;

2) Select the tag name which needs to edit from the print ID list;

3) Modify the tag name in the right side box;

4) Click **Save** button to save the current setting.

CHAPTER 8 QC ANALYSES AND CALIBRATION

8.1 General information

The reliability of test result is determined by two aspects: One is the precision, which means test results are stable in repeatability. Precision can be guaranteed by establishing perfect room quality control system; the other one is accuracy, which means test results close to target value. Accuracy can be guaranteed by proper method and calibration. It is, therefore, necessary to select certified control sample and calibration solution, and use them strictly according to their instructions.

8.2 Quality control

8.2.1 Type of quality control materials

1) Freeze-dry control, liquid control and mixed control serum, classified according to physical property.
2) Fixed value and non-fixed value control sample, classified according to the presence and absence of fixed value. Different inspection body can choose more than one quality control as quality control.
3) Inspection institutions should be according to their own situation to choose one or more than one quality control materials as their indoor quality control materials.

8.2.2 Use and storage

1) Use control sample following the Instructions for Use provided by control supplier.
2) Make sure the quality of control solution redissolved from freeze-dry control sample is stable.
3) Make sure the dilution ratio is accurate and consistent each time redissovling freeze-dry control sample.
4) DO NOT shake control sample fiercely when redissovling freeze-dry control sample.
5) Store control sample according to requirement. DO NOT use expired product.
6) Perform QC analyses under the same operating conditions as that of sample analyses.

8.2.3 Setup of target value, SD and control Limit

QC target value and control limit are usually provided by the control samples supplier, also, you can determine them through the following methods:

1) Setup of interim target value (mean value) and SD

   Perform QC analyses at least 20 times with a new batch of control sample. Calculate the mean value and standard deviation from the obtained QC data.

2) Setup of regular target value (mean value) and SD

   Obtain the accumulated mean value of original 20 QC data as the target value while the accumulated mean value of 3~5 month QC data as the standard deviation.

3) Setup of control limit

Control limit is the multiplier of standard deviation. Control limit of analytical item is determined according to different QC rules.

8.3 Calibration

Calibration solution contains the known quantity object, which is used for calibrating the value of this method; the calibration solution is concerned with the method, reagent and instrument. The function of calibration solution is to reduce or eliminate systematic error caused by instrument and reagent. It should be better to use human serum matrix to reduce matrix effect.

It is suggested to perform calibration every six months or under the following situations:

- When initially installing and running the instrument.
- When changing reagent batch number or type, unless specified by the lab that the change will not influence the precision.
- After replacing the major components, such as lamp, sampling mechanism, probe, or cuvette etc.
- After performing a preventive maintenance on the instrument.
- When control result shows abnormal offset, tendency, or falls out of the acceptable range and it cannot be corrected by routine tests.

8.4 Reasons of random error

Below are the possible reasons of random error.

1) Inaccurate dispensing volume (sample, reagent)

   Aspirating mechanism is leakage; air bubbles in flow path; contaminated probe; deflective injection of reagent, etc.

2) Optical system failure

   Lamp is faulty.

3) Metamorphic Reagent

   Metamorphic Reagent

4) Adverse quality-control samples

   Use of wrong control sample;

5) Inadequate wash

   Stirrer wash is inadequate.

6) Adverse mixture

   The depth of stirrer to cuvette is excursion; stirrer mechanism faulty.

8.5 Reason of systematic error

1) Inaccurate standard

   The dissolvent of standard solution is inappropriate.

2) Metamorphic reagent

   The reagent is metamorphic, and the batch number is various.

3) Temperature

   The temperature control is inappropriate.

8.6 How to deal with out-of-control

According to the following procedures to deal with the Out-of-Control situations:

1) Fill in Out-of-Control report and report to your lab supervisor.

2) Simply and quickly review the operating procedure to find out the possible reasons.

3) If no evident error is found, move to the following steps for further checkup.

- Retest the out-of-control item by using the same bottle of control sample. Strictly obey the operation flow to check if the out-of-control is due to operation incorrectly or random error. If retest result falls outside the acceptable range, proceed to the next step.
- Retest the out-of-control item by using a new bottle of control sample (same lot). If retest result is in control, the previous bottle of control sample may be to blame. If retest result still falls outside the allowable range, proceed to the next step.
- Retest the out-of-control item by using a new lot of control sample. If retest result is in control, the previous lot of control sample may be deteriorated. Then check the expiration date and storage condition. If retest result still falls outside the allowable range, proceed to the next step.
- Perform instrument maintenance; retest the out-of-control item. Check the instrument state; check whether the light source is changed or not; and whether the cuvette need to wash or replaced. Furthermore, replacing reagent. If the retest result still falls outside range, proceed to the next step.
- Re-calibration and retest out-of-control item. Perform calibration by using new calibrating solution. Proceed to the next step if the result still falls outside range.
- Obtain technical help. If you cannot get the in-control result after performing the above five steps, contact reagent manufacturer or URIT to get more technical support.

CHAPTER 9 MAINTENANCE

To ensure the reliable performance and sound working state and lifetime, please operate the instrument and do regular maintenance strictly obeying the requirements in this operating manual. It is important for users to master the knowledge in this chapter and the further study will make the instrument in the best operating condition and best performance.

The system provides the instrument maintenance instructions, through the maintenance instructions to perform basic maintenance operations. Please record the time and content for each maintenance for later viewing.

For the problems which cannot be solved or covered in this chapter, please contact URIT.

Warning

1) Please strictly follow this manual to operate, otherwise may cause the instrument damage or personal injury.

2) Please perform the instrument maintenance after trained and authorized by URIT, otherwise the commitment terms which in the contract are no longer valid.

3) Do not spray the liquid such as water, reagent and detergent on the system's mechanical or electrical parts.

4) For safety reason, please turn off the test power supply and main power supply before maintenance.

Biological Hazard

During the maintenance, be sure to put on protective gloves, clothes, or even goggles if necessary when dispose waste solution.

9.1 Maintenance supplies and tools

In maintenance, you may use the following tools and strengthen detergent.

- **Tools**

1) A set of M3 internal hexagonal wrench

2) Straight screwdriver (middle size)

3) Needle detector

4) Clean beaker

5) tweezers

6) Clean gauze

7) Clean cotton swab

8) Brush (used when cleaning bucket)

9) 5ml injector

- **Detergent**

1) Alkaline detergent (concentrated detergent)

2) Sodium hypochlorite solution which concentration is 10% to 30%

3) Absolute alcohol

4) Distilled water

Note

1) When using concentrated detergent, please dilute detergent properly first.

2) Do not mix the acid detergent with alkaline detergent, when they mixed, it will produce poisonous gas.

3) Please use the detergent specified by URIT, otherwise may not be able to obtain accurate analysis results.

9.2 Maintenance orders

The maintenance orders include probe and stirrer cleaning, cuvette rinsing, cuvette signal, A/D value, self-test control, temperature query and barcode.

9.2.1 Probe and Stirrer Cleaning

Clean the sample adding probe and stirring stick to avoid the reaction solution remains in the flow path, specific operations are as follows:

1) Click Service button;

2) Click Maintenance button;

3) Click Probe and stirrer cleaning to enter the interface as follows:

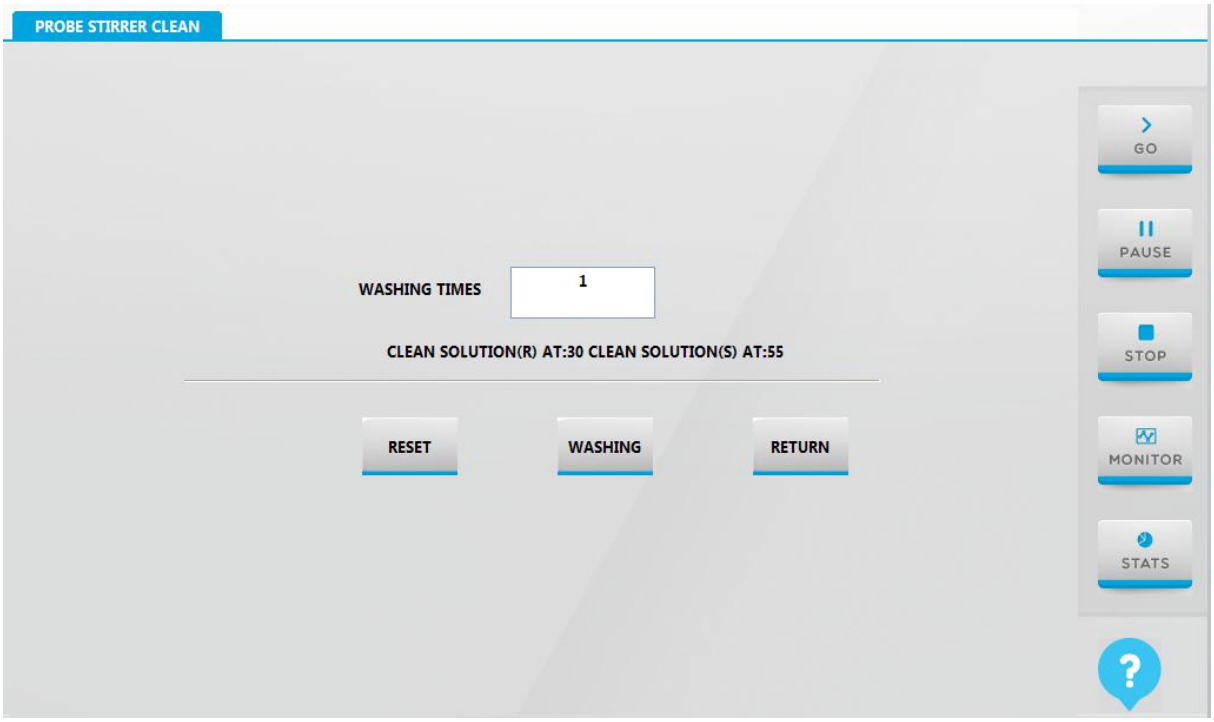


Figure 9.2.1 Probe and Stirrer cleaning interface

4) Input the number of you want to clean in the **Wash times**, the default is 1 time, maximum up to five times;

5) Click **WASHING** button, and then the system start to clean the sample adding probe and stirrer.

The main function keys:

【WASH】: Clean the sample adding probe and stirrer.

【RESET】: Perform the reset operation.

【RETURN】:click the button to return to the forward menu.

Note

1) In order to keep the sample adding probe and stirrer clean, please at least perform five times rinse operation a day when starting up.

2) Before perform rinse operation, please make sure the No.30 position of reagent tray have enough detergent.

9.2.2 Cuvette cleaning

Clean the cuvette to avoid the reaction solution remains in the reaction cup, specific operations are as follows:

1) Click Service button;

2) Click Maintenance button;

3) Click Cuvette Rinsing button to enter the interface as follows:

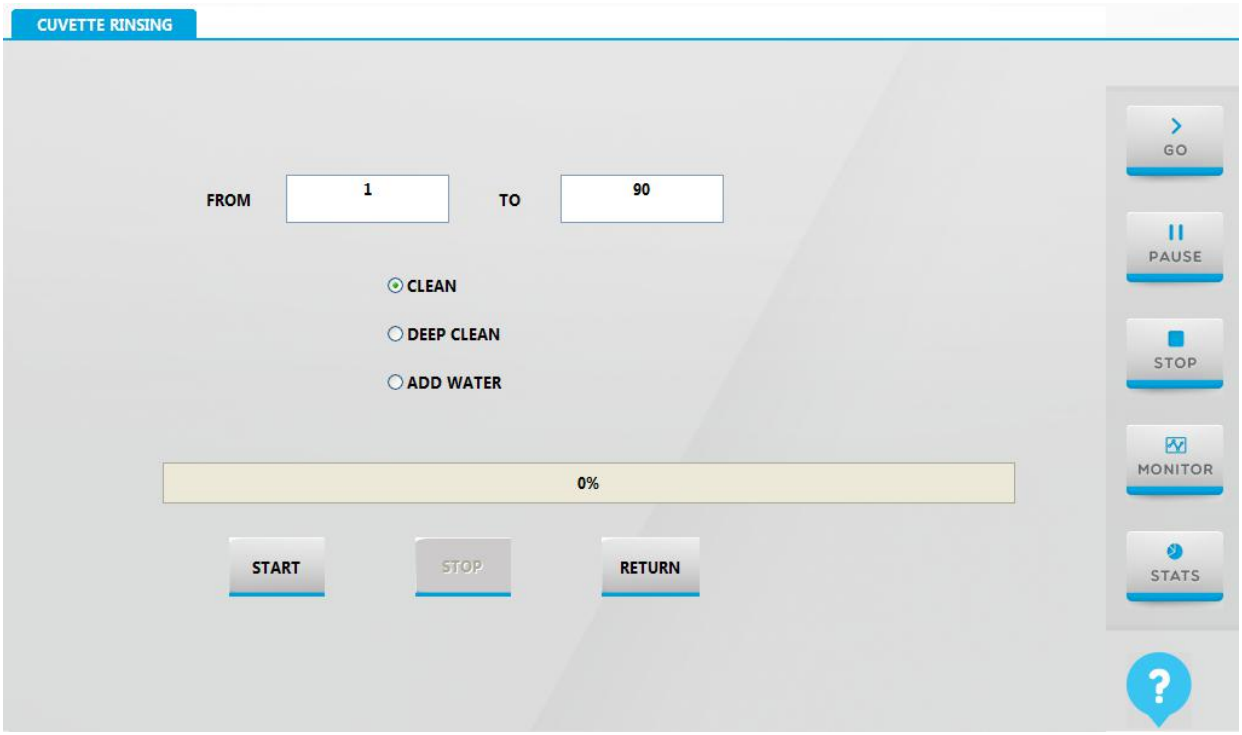


Figure 9.2.2 Cuvette rinsing interface

4) If you want to clean all the reaction cups, please select from 1 to 90 and then click the **WASH** button. If you want to selective clean the reaction cups, please input the reaction cup number which you want to clean, and then click the **WASH** button.

The main function keys:

【Clean】: All the reaction cups filled with distilled water.

【Deep Clean】: Clean all the reaction cups with detergent.

【Add water】: fill the cuvette with distilled water full.

【Start】: click the button to start to clean.

【STOP】: Stop the current cleaning action.

【RETURN】:click the button to return to the forward menu.

Note

1) In order to keep the reaction cup clean, please at least perform 1 time rinse operation for all the reaction cups a day when power on and power off.
2) In order to keep the reaction cup clean, please at least perform 1 time deep cleaning operation weekly.

9.2.3 Cuvette signal reading (Cuvette blank）

Reaction cup after long time use, the inner surface will remain with substances such as protein or debris which cannot be cleaned, it will affect the light transmittance of reaction cup; or if there are scratches or cracks in the reaction cup inner wall or outer wall, and it also can affect the transmittance or uniformity of reaction cup, so as to affect the accuracy and stability of the absorbance test results. So you need to check the reaction cup's working condition. You can check all the reaction cup state and wavelength signal value through **Cuvette signal reading**. Specific operations are as follows:

1) Click **Service** button;

2) Click **Maintenance** button;

3) Click **Cuvette signal** button to enter the interface as follows:

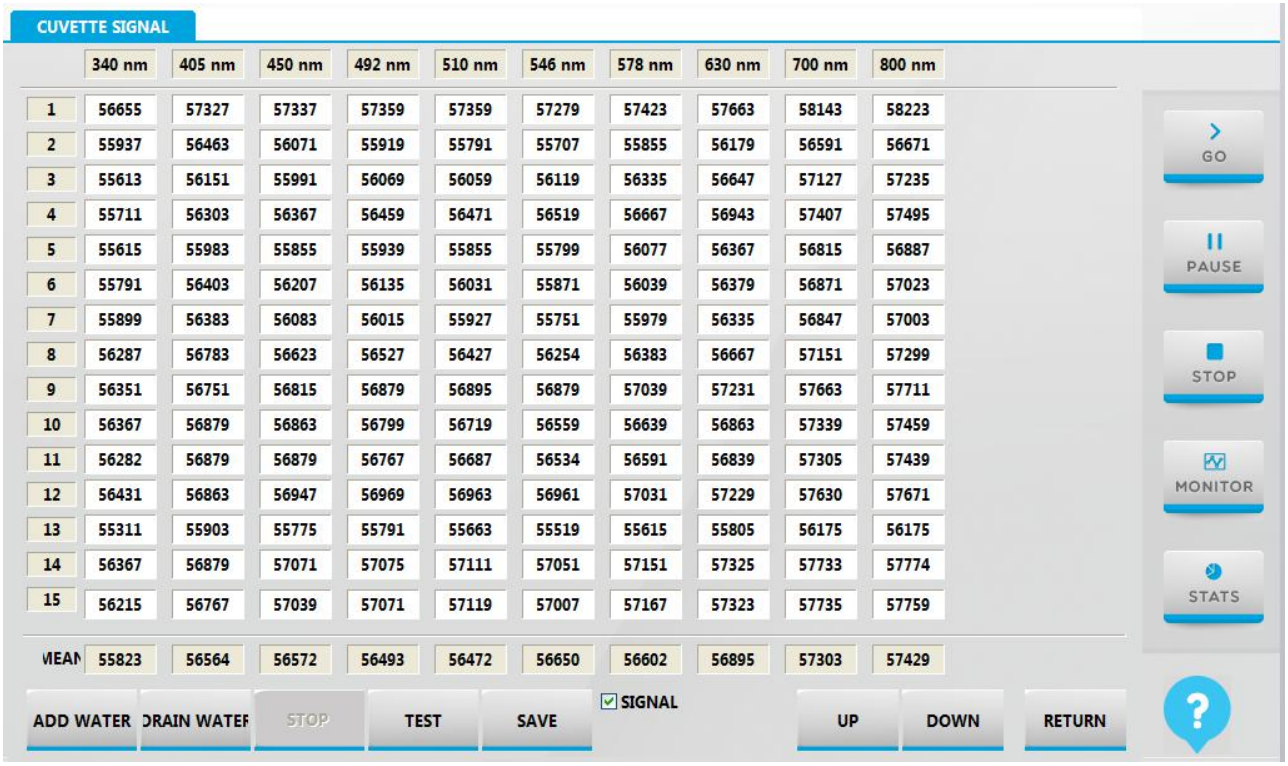


Figure 9.2.3 Cuvette signal reading interface

4) Click **Add Water** button, to inject the water into the reaction cup;

5) After water injection is completed, please click **Test** button;

6) Check the AD value in the list;

Through the left or right arrow to scroll the list, to check all the reaction cup AD value. All the listed AD value should be within the range of 30000 to 65535 (instrument has been used for a period of time), if

not beyond this range any more, please contact URIT;

7) Click **SAVE** button, to save the read AD value;

8) Click **Drain Water** button to empty the reaction cup, then the reaction cup signal is read.

: Through check this button to switch the absorbance and the A/D signal.

9.2.4 A/D signal reading

A/D signal reading is used for determine whether the reaction cup with besmirch, whether the attenuation of light source is below the threshold value, the reaction cup clean degree and the radiation intensity of the illuminant light are directly affect the absorbance stability of the instrument. Specific operations are as follows:

1) Click **Service** button;

2) Click **Maintenance** button;

3) Click **Signal detection** button to enter the interface.

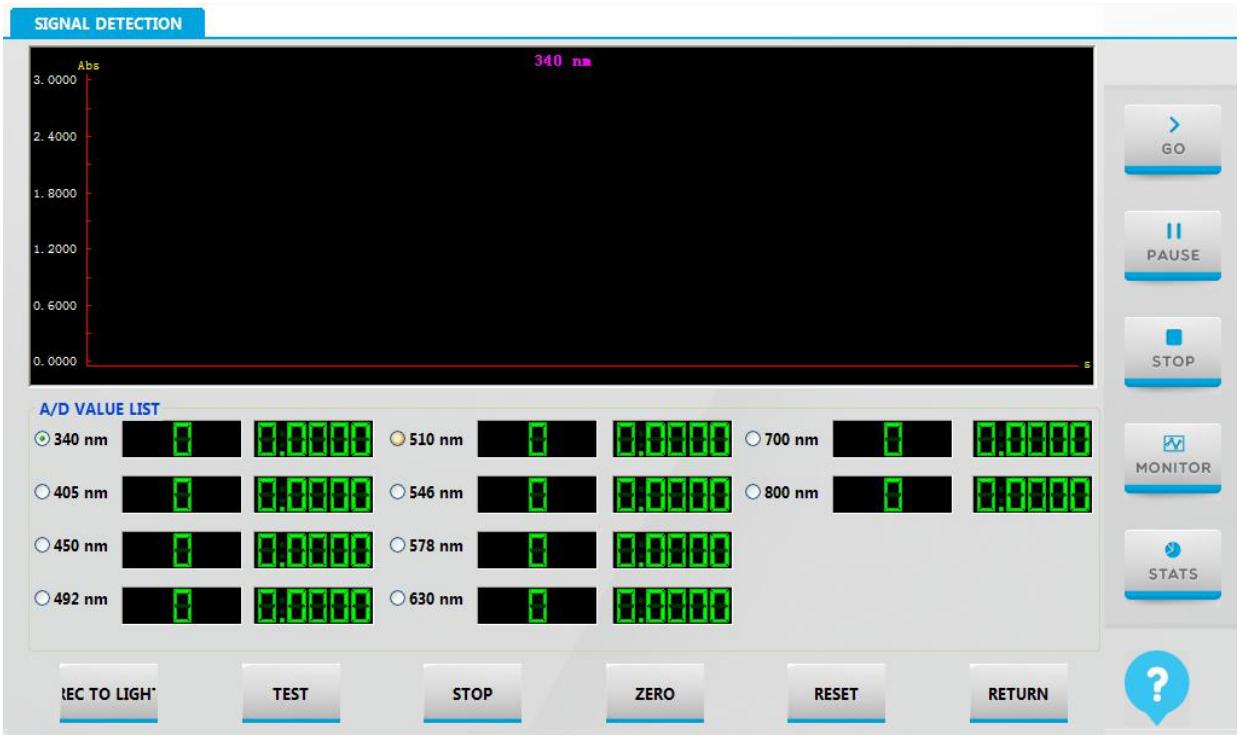


Figure 9.2.4 A/D signal reading interface

4) The instrument will automatically read the AD value.

The main function keys:

【**TEST**】: Click the button, system begin to read A/D value.

[STOP]: click the button, the system stop to read.

【**ZERO**】: Absorbance returns to zero.

【**RESET**】: Re-clock.

【**RETURN**】: click the button to return to the forward menu.

9.2.5 Self-test control

Self-test control is mainly to check the instrument status is normal or not. Specific operations are as follows:

1) Click **Service** button;

2) Click **Maintenance** button;

3) Click **self-test control** to enter the interface:

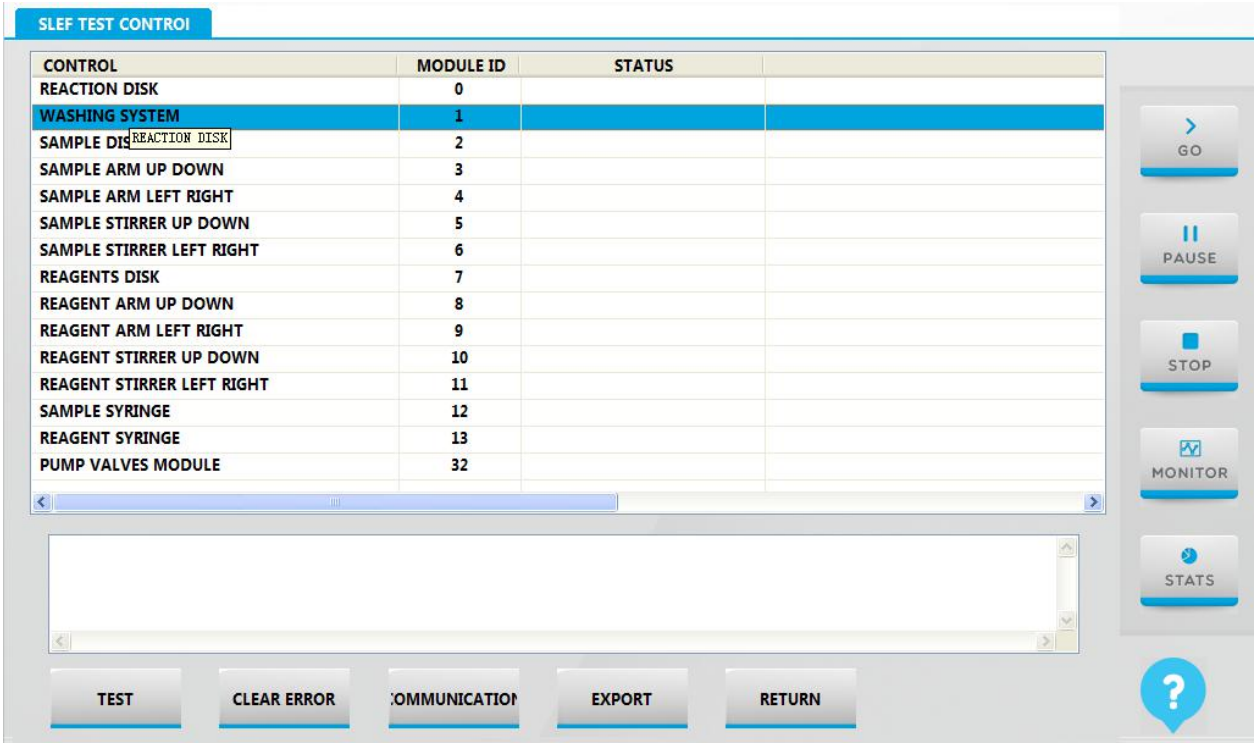


Figure 9.2.5 self-test control interface

4) Click **Test** button to start the test;

The main function keys:

[TEST]: Click **TEST** button to start the test;

[Communication]: check the communication is normal or not.

[Clear Error]: If the instrument has malfunctioned (such as firing pin, command receiving anomaly, communication failure, etc.), the instrument will record the error status, and through the error flag to prohibit instrument continues to execute the command. When the error flag is cleared, the instrument can continue to execute the command.

[Export]: export the status information to the file.

【**RETURN**】: click the button to return to the forward menu.

Note

When there is a problem, please check the instrument status to find the reason.

9.2.6 Temperature check

The temperature query interface display the temperature of regent tray, reaction tray, environment and barcode gun. If the temperature exceed, the color will turn red.

1) Click Temperature control button in maintenance interface of service interface:

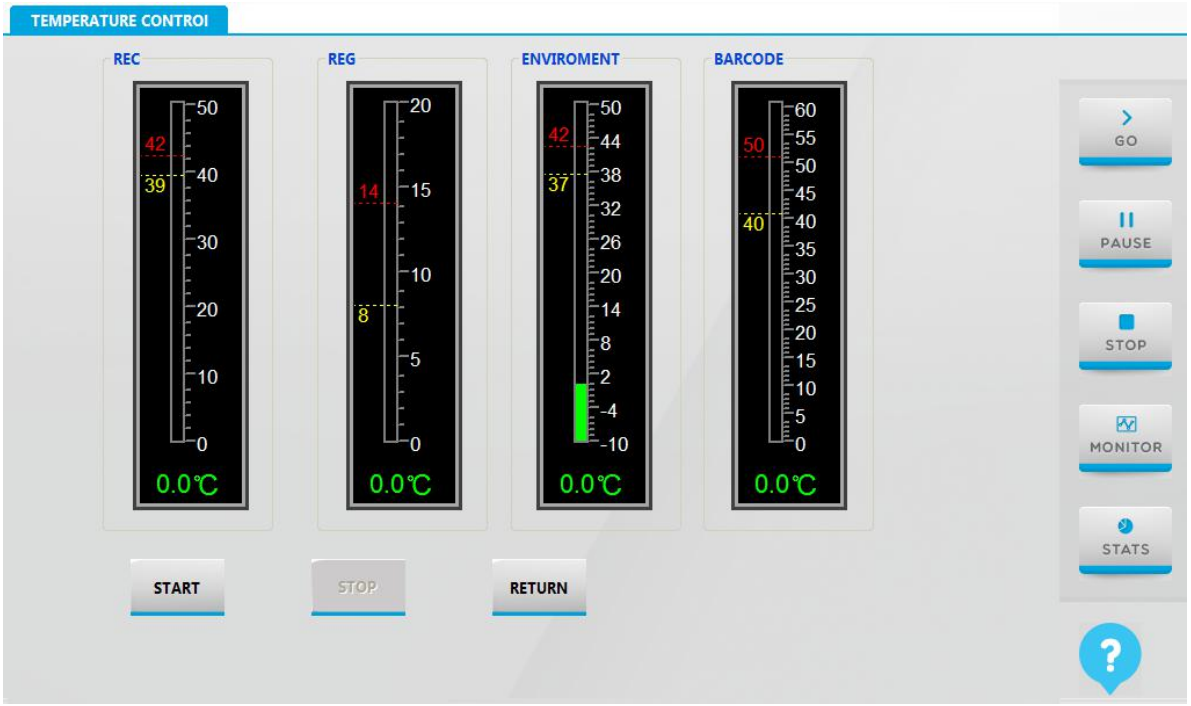


Figure 9.2.6-1 Temperature check interface

2) Click Start button, system will read the temperature automatically.

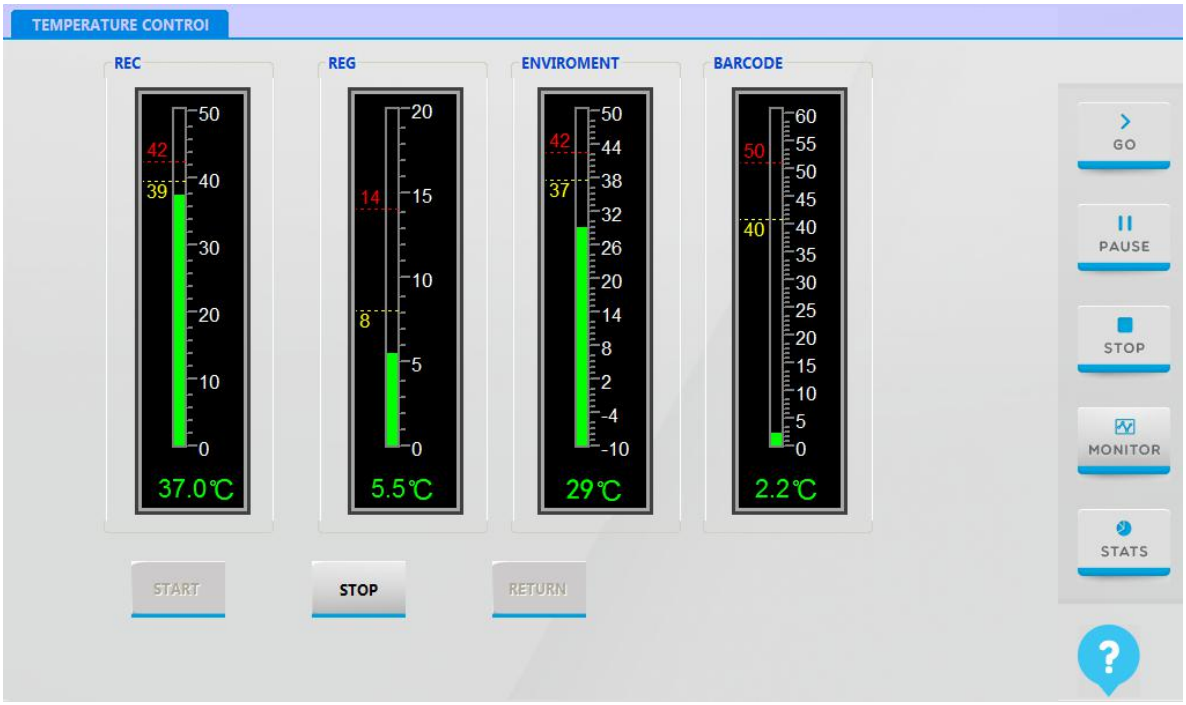


Figure 9.2.6-2 reading temperature

9.3 Daily maintenance

Daily maintenance shall be performed at the end of a day or before you start test, mainly for check the distilled water bucket, waste solution bucket, detergent bottle, syringe, sample probe, reagent probe, stirrer and printer.

9.3.1 Check the distilled water bucket

Lack of distilled water or distilled water bucket connection abnormal, can lead to water supply shortage or leaking, and result in the test cannot be continuous.

1) Check the distilled water allowance;

If the distilled water is not enough, turn off the test switch and screw off the cover, add enough distilled water.

Figure 9.3.1-1 cover of distilled water bucket

2) Check whether the pipes insert well or not, or leakage. If yes, do the following steps:

a) Pull out the pipe and check whether damaged or not.

Figure 9.3.1-2 pull out distilled water pipe

b) Cut off the damaged part, or insert the pipe well and check whether leakage or not.

Caution Note

The BNC interface of distilled water bucket, detergent bucket and waste solution bucket should be connected to the BNC interface of the instrument correctly. If you make the wrong connection, then the instrument will not be able to send normal alarm.

9.3.2 Check the detergent bucket

Note

Please use the detergent manufactured by URIT.

1) Check the allowance of detergent; if not enough, do the following steps:
   a) Turn off the test switch and screw off cover.

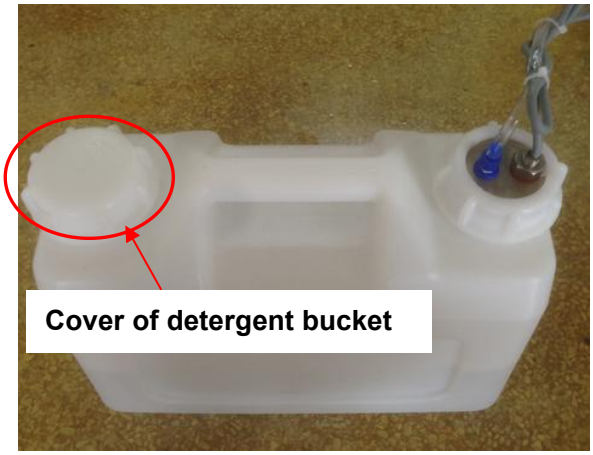


Figure 9.3.2-1 cover of detergent bucket

   b) Make up the concentrated alkaline detergent with distilled in proportion, then pour to detergent bucket.
   c) Screw on cover.
2) Check the pipe whether leakage or not. If yes, do the following steps:
   a) Turn off test power, screw off connector of detergent pipe.

Figure 9.3.2-2 screw off detergent pipe

   b) Pull out the pipe from blue connector, and then cut off damaged part.
   c) If there are no damaged phenomenon, pull in pipe and check whether leakage or not.

9.3.3 Check the waste solution bucket

Waste solution bucket connection abnormal, or not timely empty the waste solution bucket, it will cause waste solution overflow, so as to cause environmental pollution and cross contamination, even damage the instrument. Therefore, regularly check the waste solution bucket and its connection are very necessary.

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when dispose waste solution.

2) Waste solution must be disposed according to the relevant environmental protection regulations, please consult the relevant reagent manufacturer or distributor.

---

1) Confirm the test power supply has been turned off;

2) Screw off BNC cover, take out BNC components;

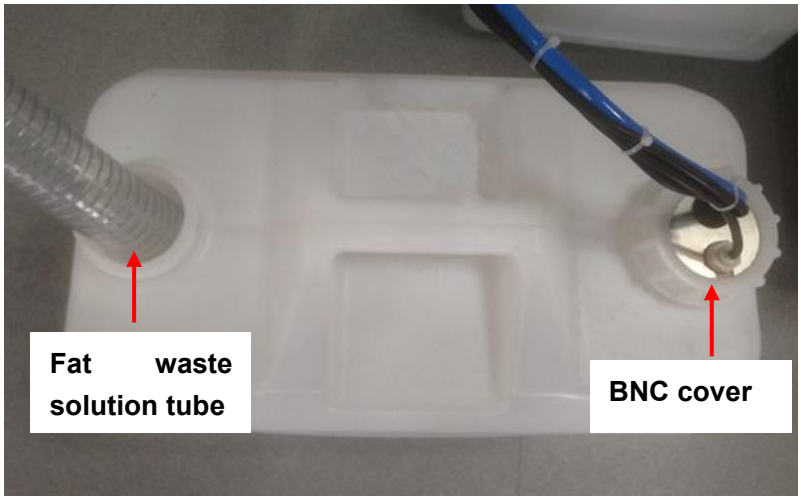


Figure 9.3.3-1 Waste solution bucket diagram

Figure 9.3.3-2 Screws off BNC cover **Figure 9.3.3-3 Take out BNC components**

3) Pull out fat waste solution pipe;

Figure 9.3.3-4 take out fat pipe

4) Empty the waste solution bucket into the hospital specified waste solution processing pool;

5) Connect the waste solution tubes; screw on cover and insert the pipe well.

9.3.4 Check the Detergent and dilution in sample and reagent tray

Detergent or dilution insufficient will result in the test cannot be continuous. Please check the detergent remaining volume every day before start testing, if the detergent is insufficient, should be added in time.

1) Confirm the test power supply has been turned off;

2) Check the remaining volume of No.30 detergent position: If not enough, add to enough.

3) check the remaining volume of N0.60 dilution position, if not enough, add to enough.

9.3.5 Check/Clean the Sample Adding Probe, Stirrer

If sample probe, reagent probe or stirrer is abnormal, then the instrument will not be able to correct analysis. So before test, check the outer wall of sample adding probe and stirrer for any stains and crystallization, and check whether the sample adding probe and stirrer are clogged or bended.

（1）normal state （2）abnormal state （3）abnormal state

Figure 9.3.5 Reagent probe/sample probe's normal and abnormal flow direction

If there are any stains and crystallization, please refer to 9.4.1 to clean.

In figure 1, the flow is vertical discharge from the point of probe, belongs to the normal state; In figure 2 and figure 3, the flow appears spraying phenomenon, that's means the sample adding probe is clogged, please refer to **9.6.2** to unclog.

If the sample adding probe and stirrer are clogged or bend, please contact URIT for replacement..

9.3.6 Check the Printer/Printing Paper

Please check whether the printer is work properly, and the printing paper is enough or not.

9.4 Weekly Maintenance

In order to keep the instrument best working state and safe to use, please weekly perform the following maintenance.

9.4.1 Clean the probe and stirrer

Caution

1) Please operate with cautious, in order to avoid your hand scratched by sample adding probe.

2) Ethyl alcohol has flammability, when using, need to be very careful.

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.
2) The used gauze must be disposed according to the relevant environmental protection regulations.

The inner side of sample adding probe and the outward of needle tip are easy to contaminate, not only easy to adhere serum, reagent, water, etc., but also easy to cause the clogging, so it need to regularly checking and properly cleaning.

1) Turn off the test power supply;
2) Gently upward pull the sample adding probe rocker arm to the highest point, and then through rotate the rocker arm to move the sample adding probe to the easy operation position;
3) Use the tweezers to pick up the gauze which dip in the anhydrous alcohol, and then wipe the surface of probe from top to bottom, until the probe surface is clean and no sticky dirty.

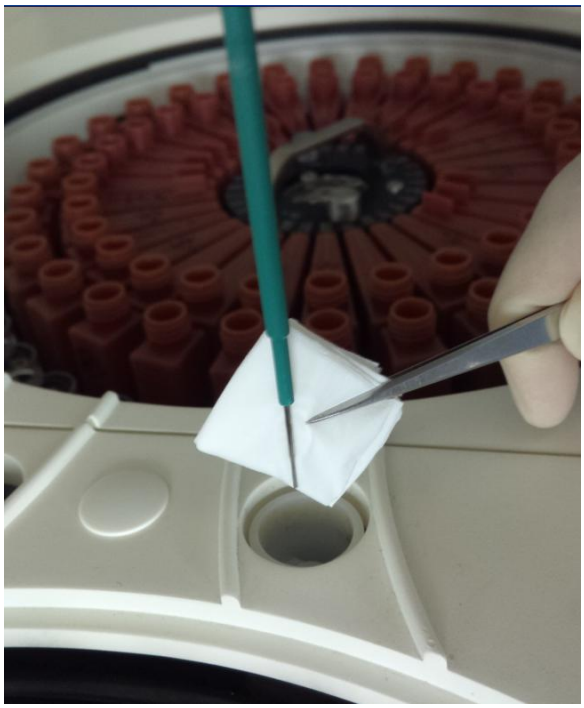


Figure 9.4.1-1 clean probe

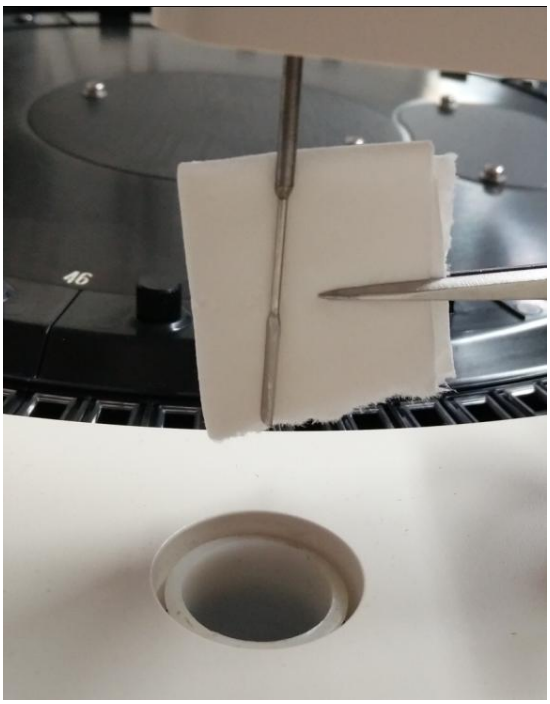


figure 9.4.1-2 clean stirrer

Caution

1) When cleaning, do not use the tweezers to direct contact with the sample adding probe, prevent it scratches the sample adding probe; please avoid overexertion to prevent reagent probe deformation.
2) After you complete the sample adding probe surface cleaning operation, please rotate it to the top of rinse tank.

4) Turn on the test power source;

5) Start software and click probe clean button;

6) Input the clean time as 3 times, click **Washing**, system will reset the probe and stirrer and clean by detergent automatically.

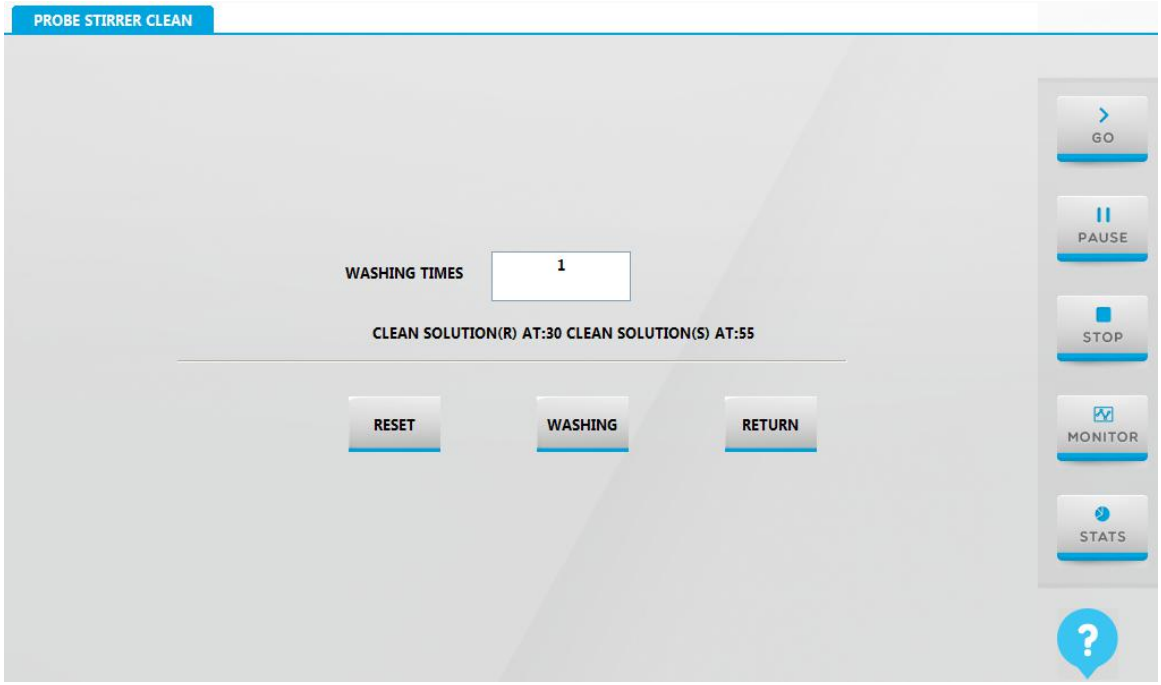


Figure9.4.1-3 probe and stirrer clean

9.4.2 Clean washing pool

After long-time use, there is dust or waste or germ accumulates in washing pool, so that lead pipe clog. It is suggesting cleaning the pool weekly to make sure clean and unblocked.

Caution

Please operate with cautious, in order to avoid your hand scratched by sample adding probe.

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

2) The used gauze must be disposed according to the relevant environmental protection regulations.

1) Turn off test power.
2) Pull up the probe and stirrer to the top point; turn the rocker to a place where easy to operate.
3) Inject 50ml chloros solution which concentration is 10% to 30% or alcohol, soak for 5 minutes.

Note

Please wash clean by distilled water after soak for a while. And make sure there are no chloros and alcohol.

4) Inject 100ml distilled water to each pool to wash clean.
5) Use a cotton bud with alcohol to clean the surface and around until there are no stains.

Note

Please attention not leaves the cotton or other object in the pool to avoid block.

Figure 9.4.2-1 clean washing pool

6) Turn on test power.
7) Start software and click Probe cleaning.
8) Input washing time as 3 times and click Washing, system will reset the probe and stirrer and clean by detergent automatically.

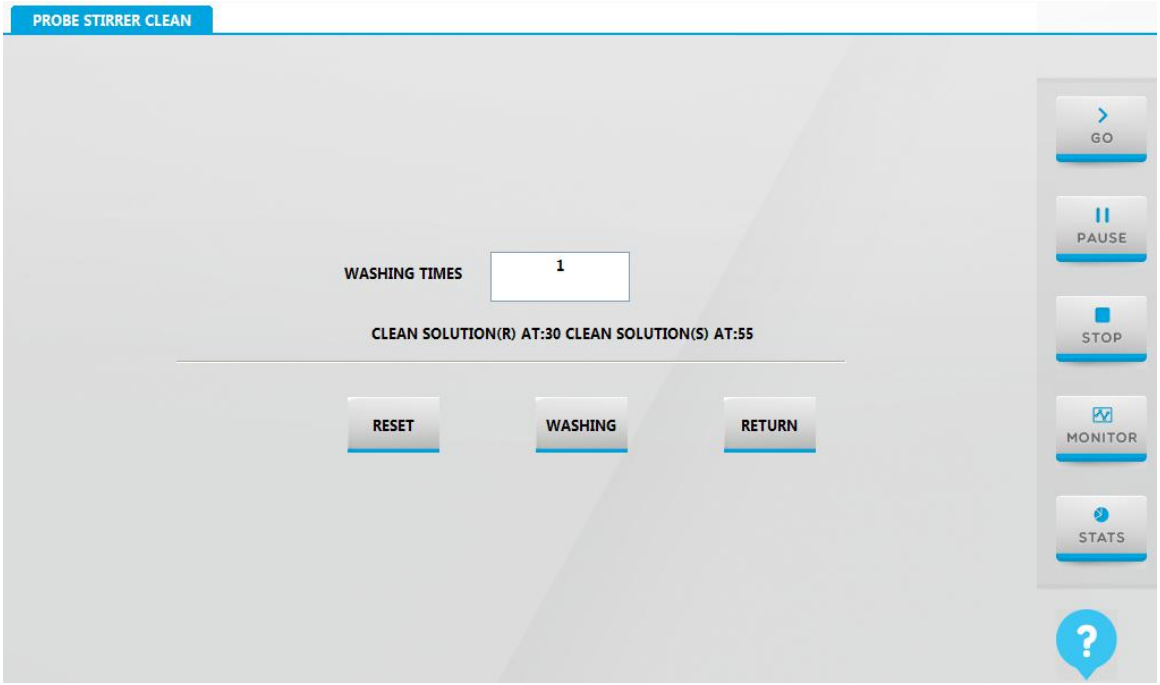


Figure 9.4.2-2 probe and stirrer cleaning

9.4.3 Clean the washing Mechanism

Caution

1) Please operate with cautious, in order to avoid your hand scratched by the needle tip.

2) When cleaning, do not use the tweezers to direct contact with the cleaning hand probe, prevent it scratches the cleaning hand; please avoid overexertion to prevent cleaning hand probe deformation.

3) During the cleaning operation, the distilled water should not flow into the cuvette; otherwise it will contaminate the cuvette.

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

2) The used gauze must be disposed according to the relevant environmental protection regulations.

In order to avoid the waste solution deposition on the cleaning mechanism and cause cross contamination, please weekly clean the automatic cleaning mechanism.

1) Turn off the test power supply;

2) Use the tweezers to pick up the gauze which dip in the distilled water, and then wipe the surface

of probe from top to bottom, until the probe surface is clean and no sticky dirty. As shown in figure:

Figure 9.4.3 clean washing mechanism

9.4.4 Clean reagent tray/sample tray

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.
2) The used gauze must be disposed according to the relevant environmental protection regulations.

1) Turn off test power, open the cover of sample and reagent tray.
2) Use the gauze with alcohol to clean the surface of tray until there are no stains.

Figure 9.4.4 clean sample and reagent tray

3) Use gauze with distilled water to clean the surface of tray until there is no alcohol mark.

4) Put on the cover of trays.

9.4.5 Clean the reaction tray

Biological Hazard

Be sure not to use the gauze which with alcohol or detergent to clean the reaction tray otherwise will corrode the tray. User should undertake the lose if violate the regulation.

Note

Do not let the distilled water stain in gauze flow into cuvette to avoid pollution.

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

2) The used gauze must be disposed according to the relevant environmental protection regulations.

1. Turn off test power.
2. Use a tweezers to take gauze which with distilled water to clean the surface of reaction tray until there is no stains.

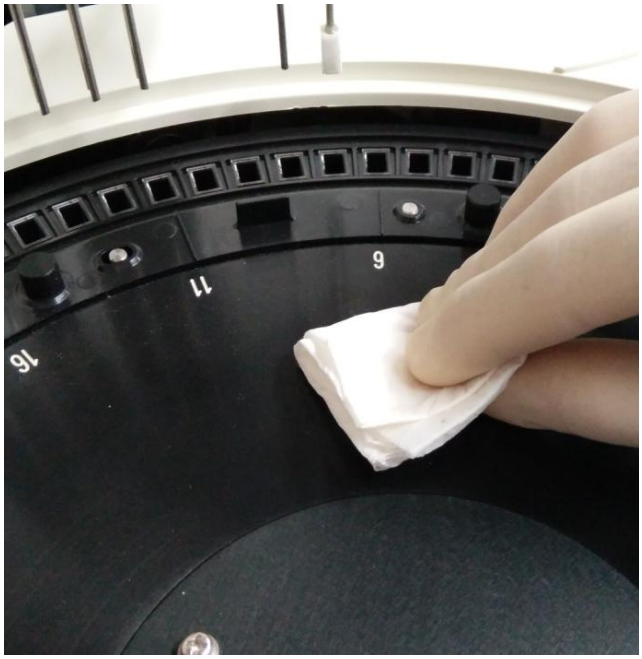


Figure 9.4.5 clean the reaction tray

9.4.6 Clean the Instrument Panel

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

2) The used gauze must be disposed according to the relevant environmental protection regulations.

Caution

During the cleaning operation, the distilled water should not flow into the panel gap.

1) Turn off the test power supply;

2) Use the gauze which dips in the distilled water to wipe the instrument panel and the cover of the reaction tray, the sample tray and the reagent tray, until the surface are clean and no stain.

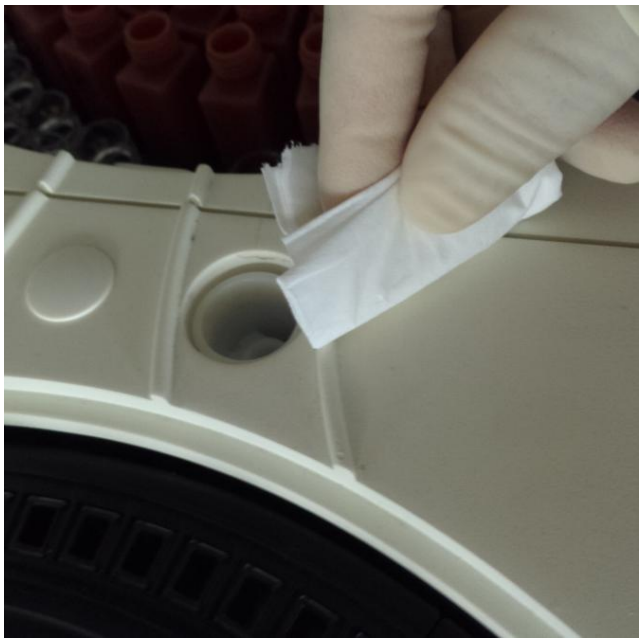


Figure 9.4.6 clean panel

9.4.7 Strengthen Clean the Cuvette

In order to clean the reaction cup deposition stains, and prolong the service life of reaction cup, so you need to weekly perform the reaction cup strengthen cleaning.

1) Make sure the detergent bucket has enough detergent;

2) Click **Cuvette rinse** to enter the interface.

3) Select **deep clean** to start the deep cleaning.

4) To soak the cuvette for a while, and click **clean** to clean all cuvette, avoid abnormal after long-time soak with detergent.

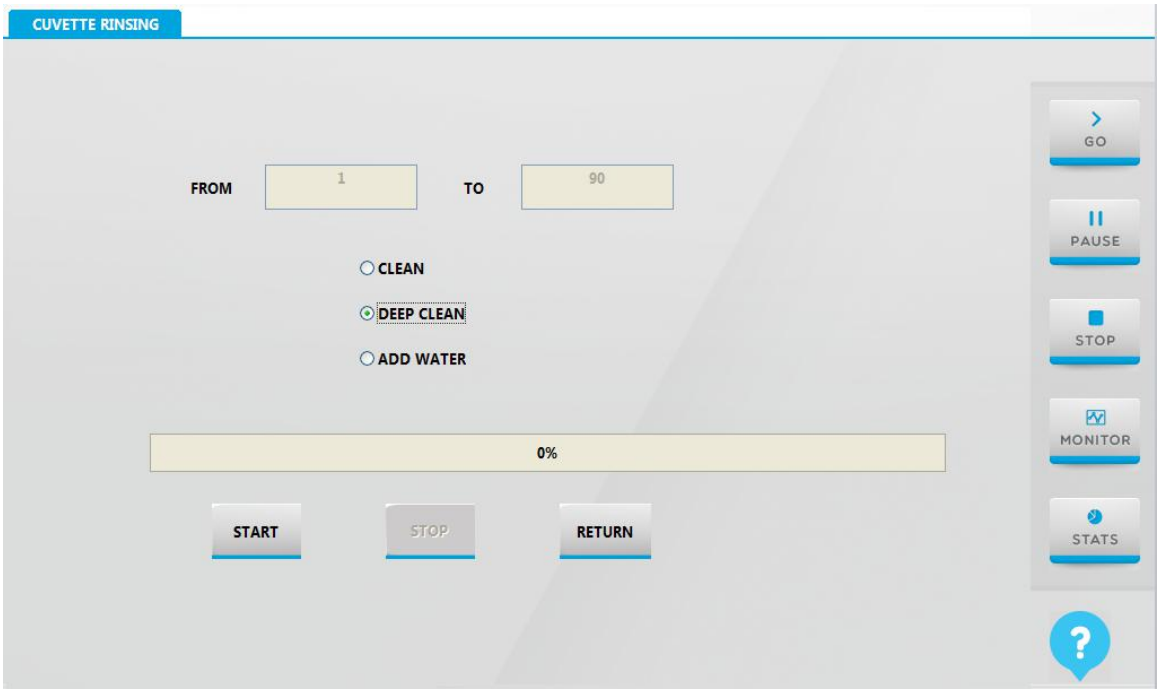


Figure 9.4.7 Cuvette clean

9.4.8 Check the A/D value

Cuvette after long time use, the inner surface will remain with substances such as protein or debris which cannot be cleaned, it will affect the light transmittance of cuvette; or if there are scratches or cracks in the cuvette inner wall or outer wall, and it also can affect the transmittance or uniformity of cuvette, so as to affect the accuracy and stability of the absorbance test results. So you need to check the working condition of cuvette.

1) Turn on the instrument test power supply, and then enter the system software;

2) In main menu, click **service** then **cuvette signal** to enter interface;

3) Click **Add Water** button.

4) After injecting water, click **Test**.

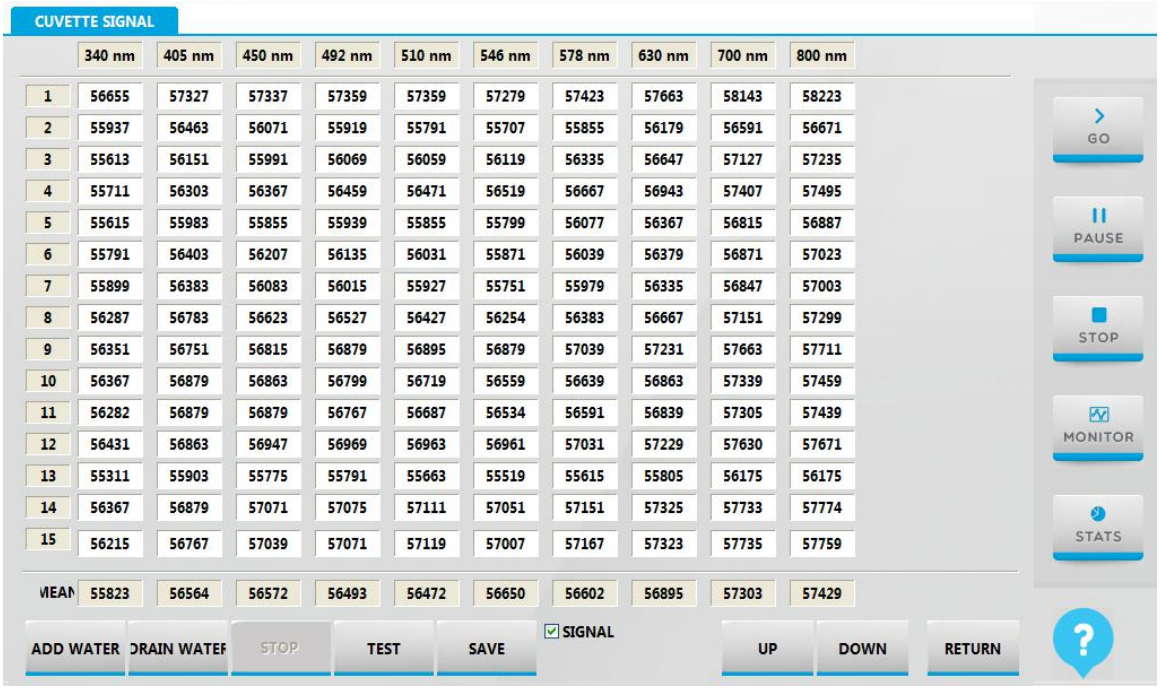


Figure 9.4.8 Cuvette signal reading interface

5) To check whether all A/D value in the range of 30000 to 60000, only the instrument has been use for a period; to click up or down to turn page.

   If not, please check or change the cuvette according to chapter 9.6.1.

   If yes, click Save to save the cuvette blank value.

6) Click **Drain Water** button to empty the cuvette.

9.5 Monthly Maintenance

In order to keep the instrument best working state and safe to use, please monthly perform the following maintenance.

9.5.1 Clean the Distilled Water Bucket

1) Turn off the instrument test power supply;

2) Screw off the BNC cover and cover of distilled water bucket;

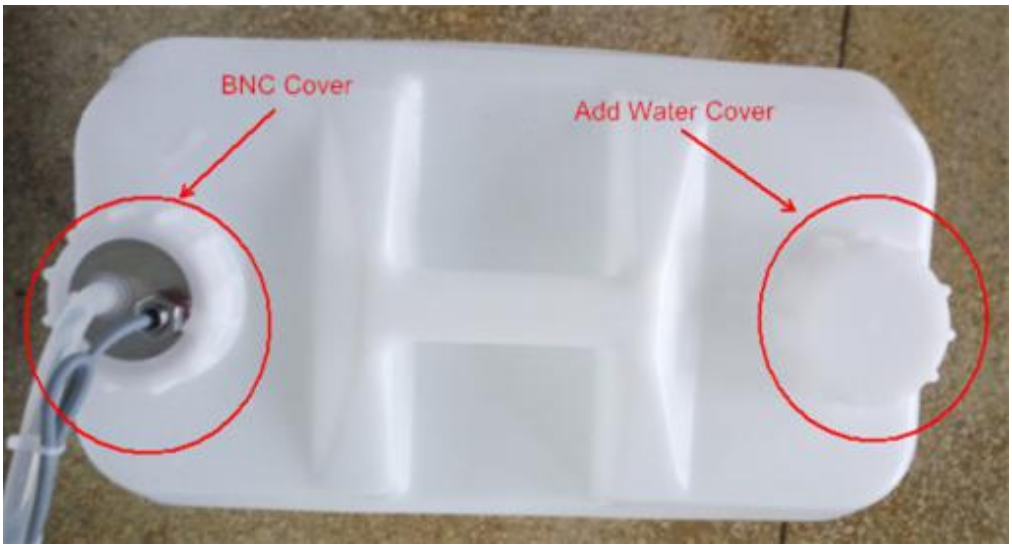


Figure 9.5.1-1 distilled water bucket

3) Take out BNC component.

Figure 9.5.1-2 BNC component

Note

1. Be careful not to damage the liquid level sensing components when take out the BNC components.
2. Put the BNC component on a clean desk after cleaning.

4) Pour out the remain distilled water;

5) Clean the inner of distilled water bucket, use a brush if necessary.

6) Use clean gauze to clean the surface and cover of distilled water bucket.

7) Put the BNC component into bucket and screw on cover.

9.5.2 Clean the Detergent Bucket

1) Confirm the test power supply has been turned off;

2) Counterclockwise to unscrew the detergent cover;

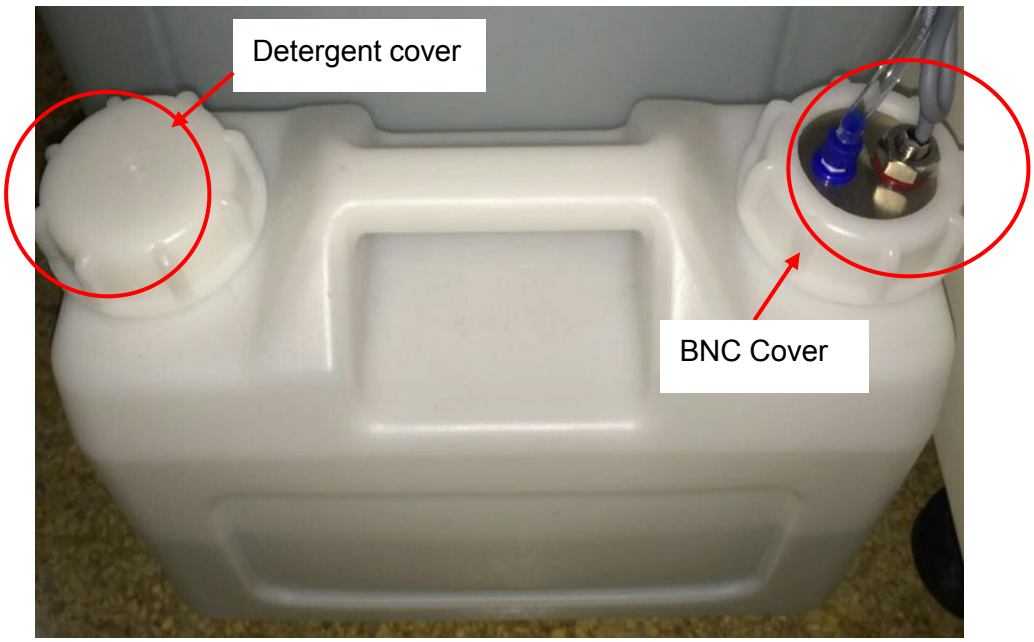


Figure 9.5.2-1 detergent bucket

3) Screw off BNC cover and take out BNC component;

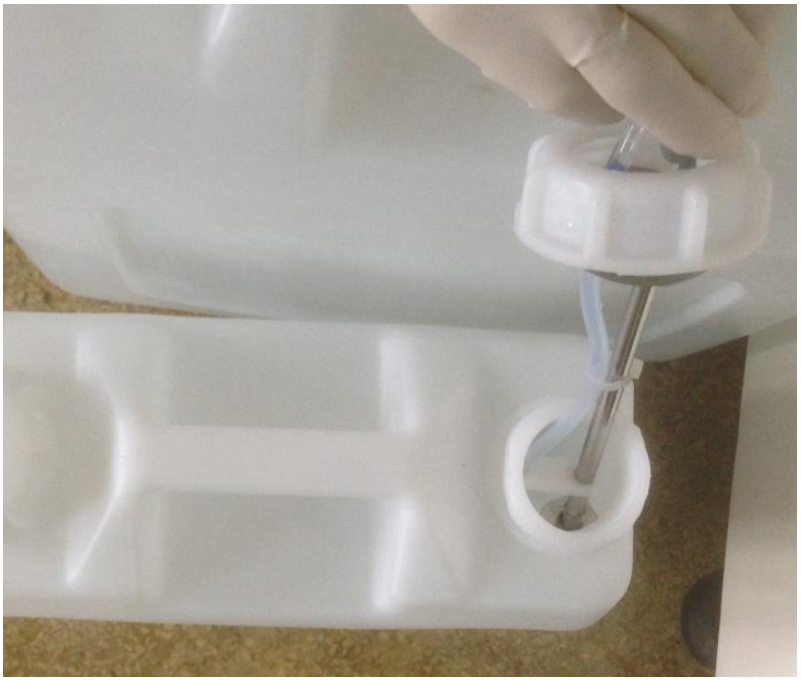


Figure 9.5.2-2 BNC component

4) Pour out the rest of detergent.

5) To clean the inner of detergent bucket, to use a brush if necessary.

Note

Be careful not to scratch the liquid level sensor, pipe and filter when use a brush to clean.

Note

If you a clean brushes to clean the inner wall of the bucket, be careful not to scratch the liquid level sensor, drainage pipe and the filter.

6) Use clean gauze to wipe the surface and cover of detergent bucket.

7) Screw on cover, put in BNC component to the bucket, then tighten the BNC cover.

9.5.3 Clean the Waste Solution Bucket

Biological Hazard

1) Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.
2) Waste solution must be disposed according to the relevant environmental protection regulations, please consult with the related reagent manufacturer or distributor.
3) The used gauze must be disposed according to the relevant environmental protection regulations.

1) Turn off the instrument test power supply;

2) Take out the BNC cover and take out the BNC and the thin pipe components;

3) Pull out the waste solution tube(big size);

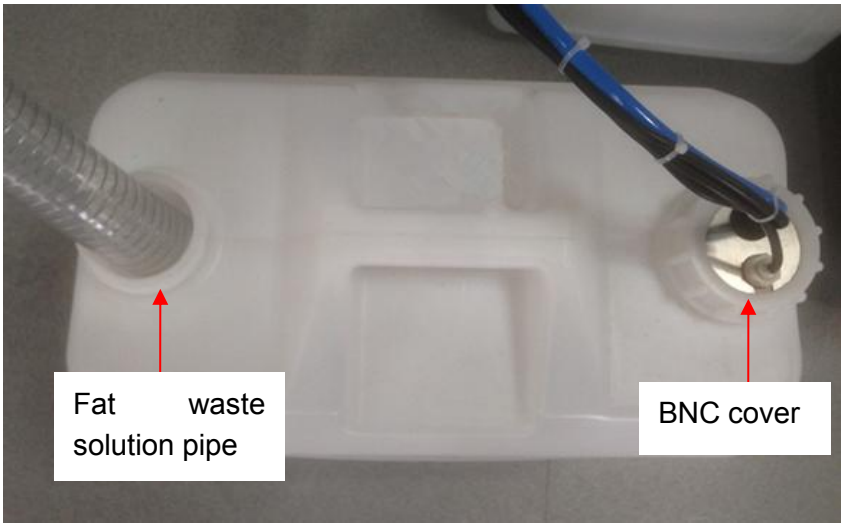


Figure 9.5.3-1 waste solution bucket

Figure 9.5.3-2 take out BNC component

4) Take out fat waste solution pipe;

5) Pour the waste solution to the appointed waste handling pool.

6) To clean bucket by distilled water, use a brush if necessary.

7) Use clean gauze to wipe the surface and cover of waste solution bucket.

8) Insert fat waste solution pipe well.

9) Put in BNC components and screw tighten the cover.

9.5.4 Clean the driven shaft of sample adding probe

Please regularly clean the driven shaft of sample adding probe to reduce the actuating shaft moving noise and wear, to ensure the service life.

1) Turn off the instrument test power supply;

2) Gently upward pull the sample adding probe arm to the highest point;

3) Use clean gauze to wipe the driven shaft of sample adding probe

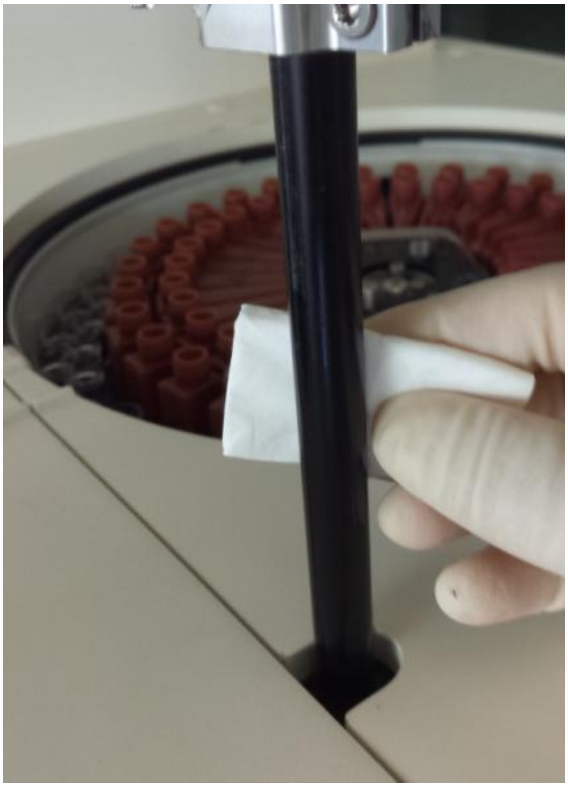


Figure 9.5.4 clean driven shaft

Note

Do not use alcohol or other corrosive detergent to clean the driven shaft, otherwise may cause the driven shaft carton phenomenon. Please use the special lubricants to maintain the drive shaft.

9.5.5 Clean the stirrer driven shaft

Please regularly clean the stirrer actuating shaft to reduce the actuating shaft moving noise and wear, to ensure the service life.

1) Turn off the instrument test power supply;

2) Gently pull the stirrer arm to the highest point;

3) Use clean gauze to wipe the stirrer actuating shaft.

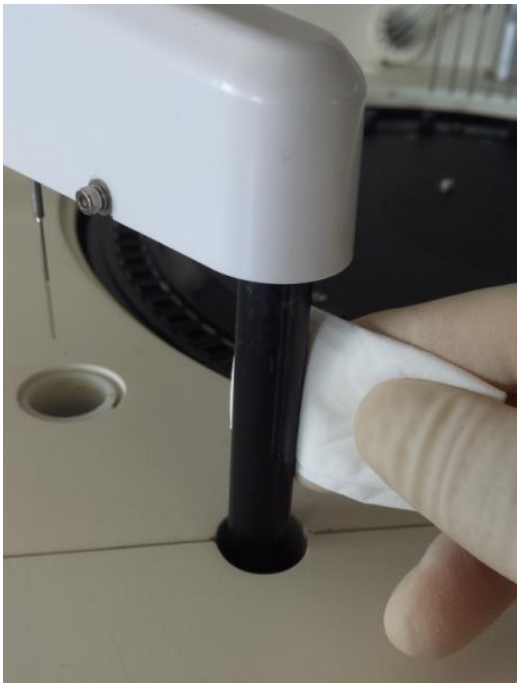


Figure 9.5.5 clean driven shaft of stirrer

Note

Do not use alcohol or other corrosive detergent to clean the drive shaft, otherwise may cause the drive shaft carton phenomenon. Please use the special lubricants to maintain the drive shaft.

9.5.6 Clean the washing mechanism

1) Click **Service** then **Cuvette clean button**;

2) Check the cuvette cleaning process, make sure the needle tip of group 1 probe to group 6 probe are parallel and level, the needle tip of group 7 and the lower end surface of group 8 (block) are parallel and level;

3) Check the cleaning syringe needle and block for any stain, crack, etc., please clean or replace it if necessary.

Note

Do not use alcohol to clean the cleaning probe, because the cuvette will damaged by the alcohol, use the detergent supplied by URIT to clean.

9.6 Special maintenance

This section introduces some long-term use and delicate parts replacement method.

9.6.1 Replace cuvette

When the cuvette is contaminated by serum or debris, or appears scratches or broken, it will affect the accuracy of test absorbance. So it is necessary to check the cuvette, replace the cuvette if found abnormally.

Warning

1) When install the reaction cup, be careful not to scratch it. Do not touch middle-lower part of the reaction cup's light through surface, otherwise it will cause the absorbance data is not accurate.
2) When operating, be sure to use no fiber and powder gloves, in order to make sure not contaminate the light through surface of reaction cup.

Biological Hazard

Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

Caution

Please use the accessories recommended by URIT, otherwise can lead to system performance degradation.

NOTE

1) To use a tweezers to remove the cuvette.
2) If there is a large number of cuvette need to maintain, please contact your local distributor or URIT.

1) Click **Service** then **cuvette signal** and **execute** button to enter the signal reading interface;
2) Click **Add water** then **Test** to read the cuvette blank value.

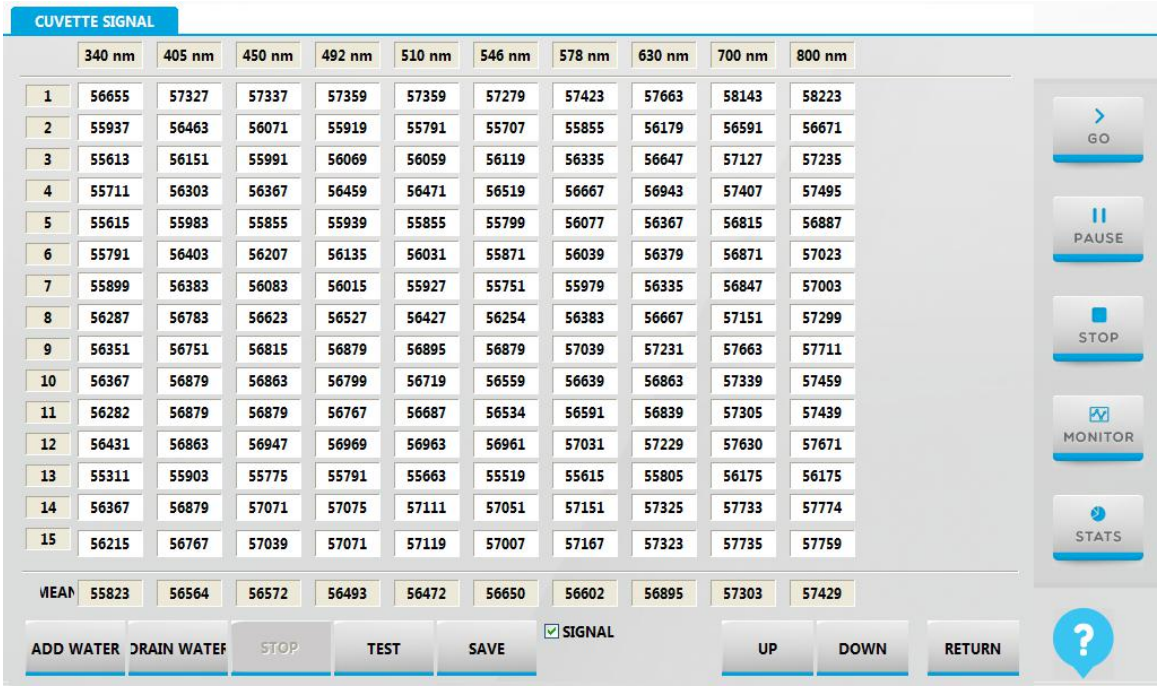


Figure 9.6.1-1 cuvette signal reading

3) To check whether all signal in the range of 30000 to 60000, the range only for the instrument used for a period. Click up and down to turn page.

4) If all signal in the range, click save then return.

5) Click **Service** then **cuvette clean** and **drain** button to drain out water in the cuvette.

6) Click Test again if there any abnormal and make sure the following questions:

a) If the value less than or near to 30000, please replace a set of cuvettes or lamp.

b) If the A/D value of one column is small, to screen the cuvette number and check if there are any abnormal.

- If there are no abnormal in cuvette, maybe there are air bubbles in cuvette when read the value, please add water again and read the cuvette blank.
- If there are obvious stains in cuvette, use distilled water to clean, or soak for 10 minutes by detergent before clean if necessary.

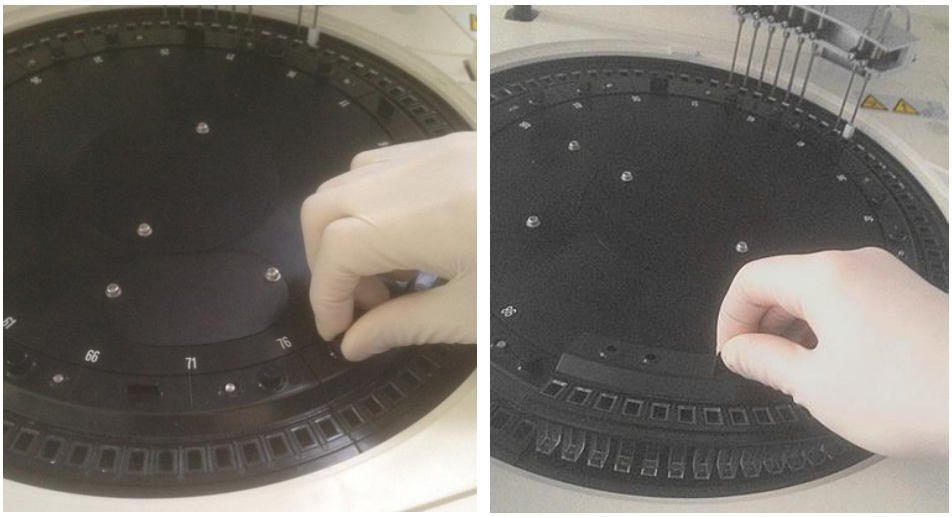


Figure 9.6.1-2 takes out cuvette

- If the value still not good or cuvette is split up, please contact distributor or URIT to replace it.

9.6.2 Unclog or replace Probe

Warning

Please operate with cautious, in order to avoid your hand scratched by sample adding probe.

Biological Hazard

Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

In order to avoid probe clog, please make sure the centrifugal effect. If the test result is too low or near to zero, check the probe.

1) Check whether there are any fault in instrument, such as lamp is out or leakage or probe not down to the sample cup, etc.
2) If there are no fault, check whether there are fibrin on the sample cup or test tube, and check the water flow when clean probe, if the water not flow out or flow not smooth, that because the probe clog.

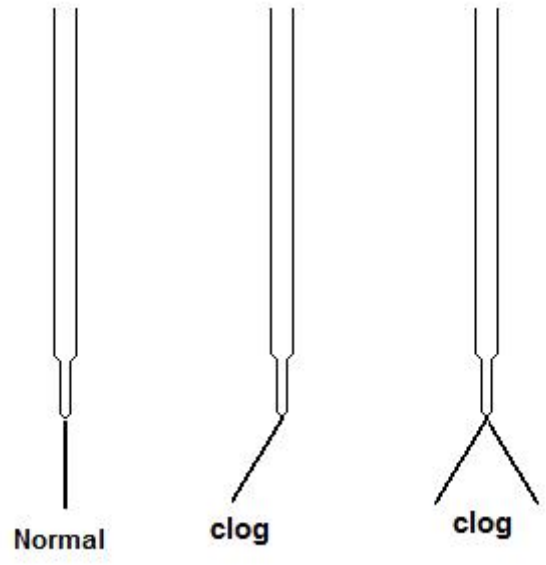


Figure 9.6.2-1 probe clog diagram

If the probe is clog, do the following steps:

1) Turn off test power.
2) Check the position of probe in washing pool and remember it.
3) Take the probe arm to the top point and convenient to operate.
4) Screw out two screws on the cover of probe, upward take the cover.

Figure 9.6.2-2 take out cover of probe

5) One hand take the probe, the other hand take the pipe smoothly, and screw off the fixed leg. Be careful not to lose the spring, and take the plug of probe line, take it from down to up.

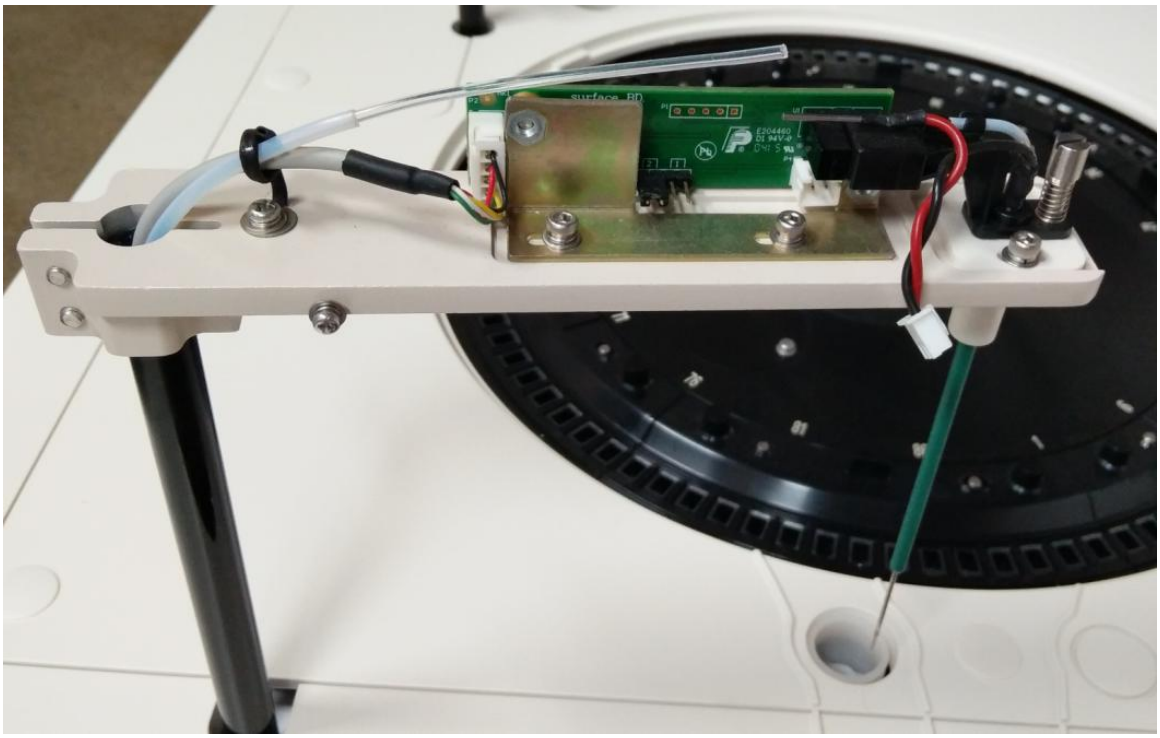


Figure 9.6.2-3 takes out probe

Warning

Do not lose the fixed leg and spring when take out the probe.

6) Use a needle machine to unclog the probe.

Warning

Do not scratch the inner of probe when use the needle machine to unclog the probe.

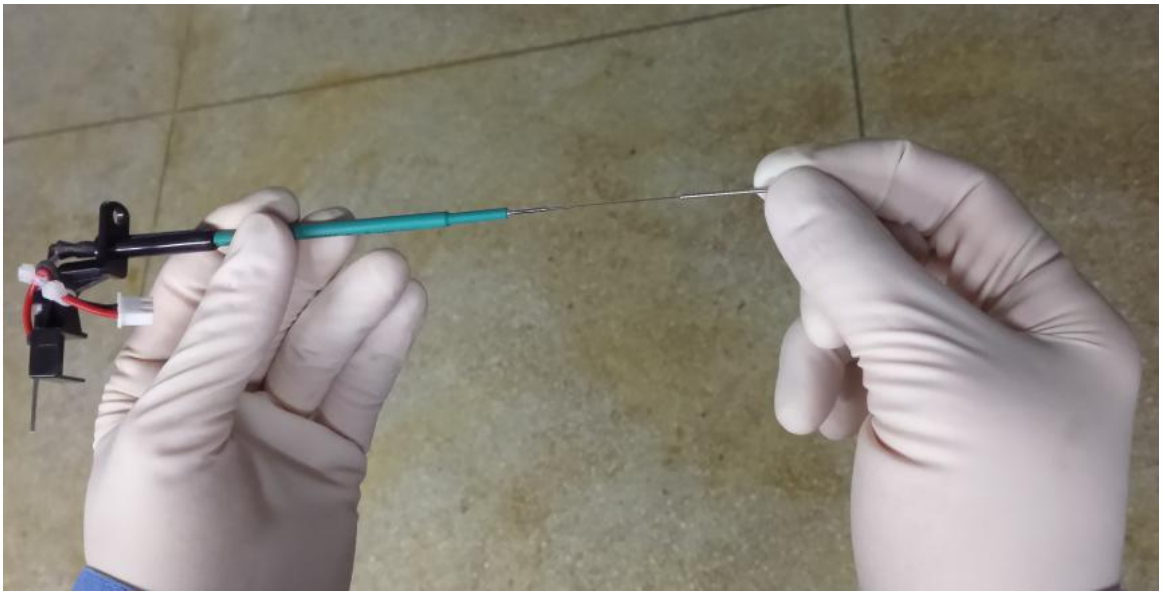


Figure 9.6.2-4 unclog probe

7) To use an injector to inject water to the probe, clean the inner until stains is pour out. If the probe still clog or scratch, please contact URIT to replace it.

Figure 9.6.2-5 unclog the probe

Note

Only the URIT or authorized person can replace the probe.

8) Put the probe to the install hole from up to down, and tighten with fixed leg and spring, insert the plug of probe.

9) One hand softly take the connector of probe, the other hand take the Teflon pipe, insert probe to the pipe.

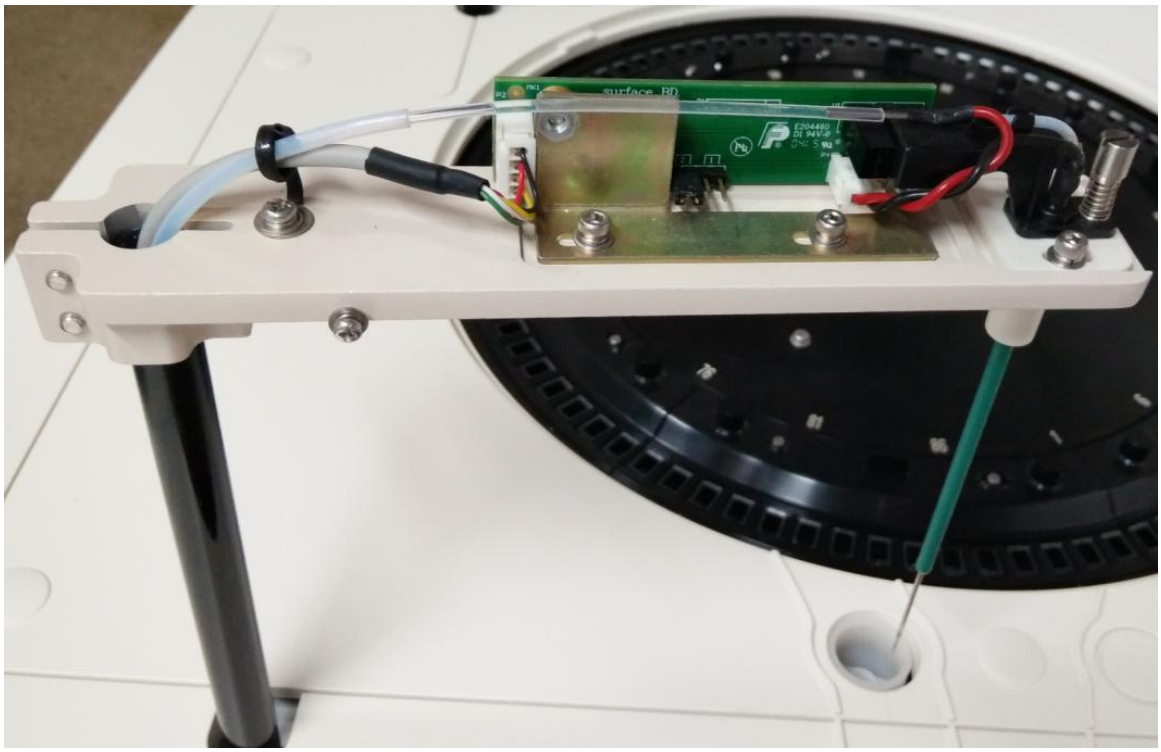


Figure 9.6.2-6 install probe

Note

1) The pipe should insert well, otherwise will cause leakage so that to damage the electric board.
2) If there is damage on the pipe, cut off a little if necessary.
3) Attention the spring cannot take the probe, otherwise will cause the an-collision function failure. The cover should be tightening to make sure the gap sealing.

10) Take the probe softly and cover well, screw tightly two screws.
11) Turn on test power.
12) Start software, click Service then probe, stirrer clean and execute button, click reset at last.
13) To check the probe position to the washing pool, the position should the same as step 2. If the position deviation is too big, please contact URIT.

9.6.3 to unclog/replace reagent probe

Warning

Please operate with cautious, in order to avoid your hand scratched by sample adding probe.

Biological Hazard

Be sure to put on protective gloves, clothes, or even goggles if necessary when operating.

The reagent probe will not clog in normal. If it is clog, please do the following steps:

1) Turn off test power.
2) To check the reagent probe position and remember it.
3) Pull up the probe to the top point.
4) Screw off the two fixed screws and take out the cover of probe.

Figure 9.6.3-1 take out the reagent probe cover

5) One hand takes the connector softly, and turns around the other connector until it is take off. Then pull out the plug to take out the reagent probe from down to up.

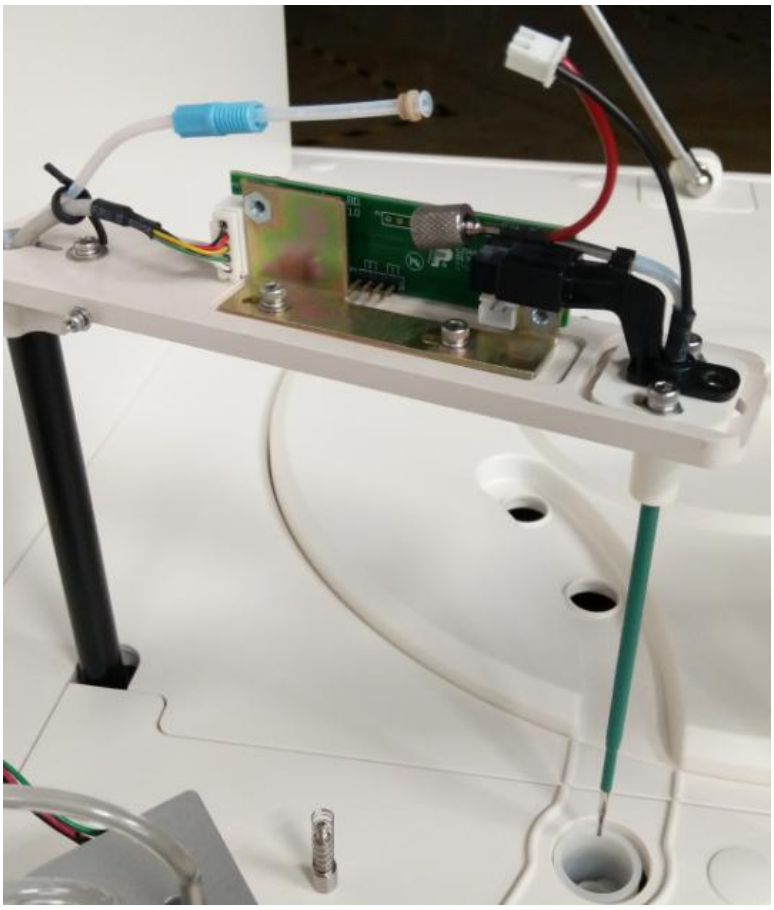


Figure 9.6.3-2 takes off reagent probe

Warning

Do not lose the fixed leg and spring when take out the probe.

6) Unclog the probe until it is clog.

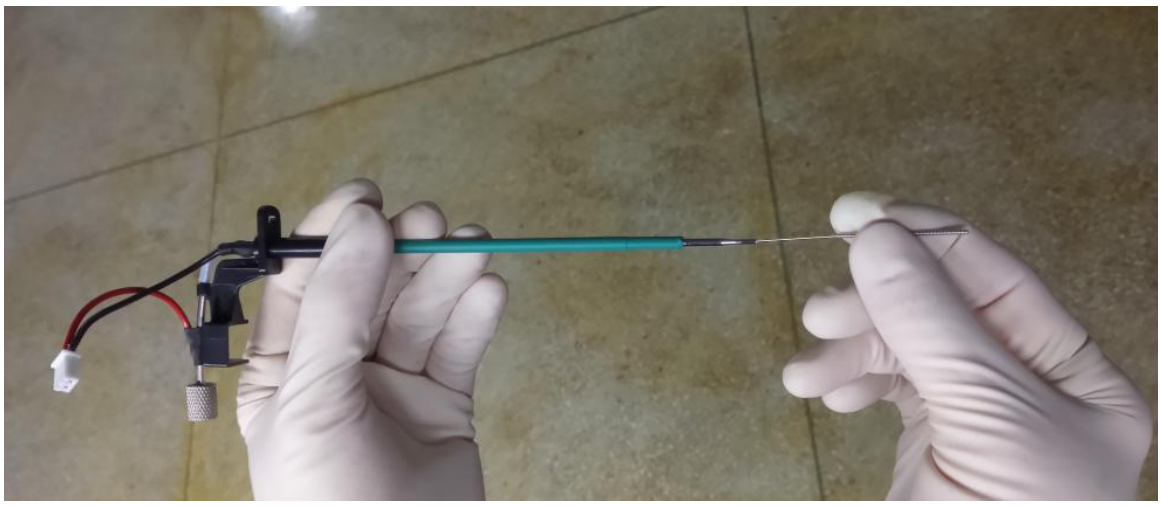


Figure 9.6.3-3 unclog reagent probe

Warning

Do not scratch the inner of probe when use the needle machine to unclog the probe.

7) To use an injector to inject water to the probe, clean the inner until stains is pour out. If the probe

still clog or scratch, please contact URIT to replace it.

Figure 9.6.3-4 unclog the reagent probe

Note

Only the URIT or authorized person can replace the probe.

8) Put the probe to the install hole from up to down, and tighten with fixed leg and spring, insert the plug of probe.

9) One hand softly take the connector of probe, the other hand take the Teflon pipe, insert probe to the pipe.

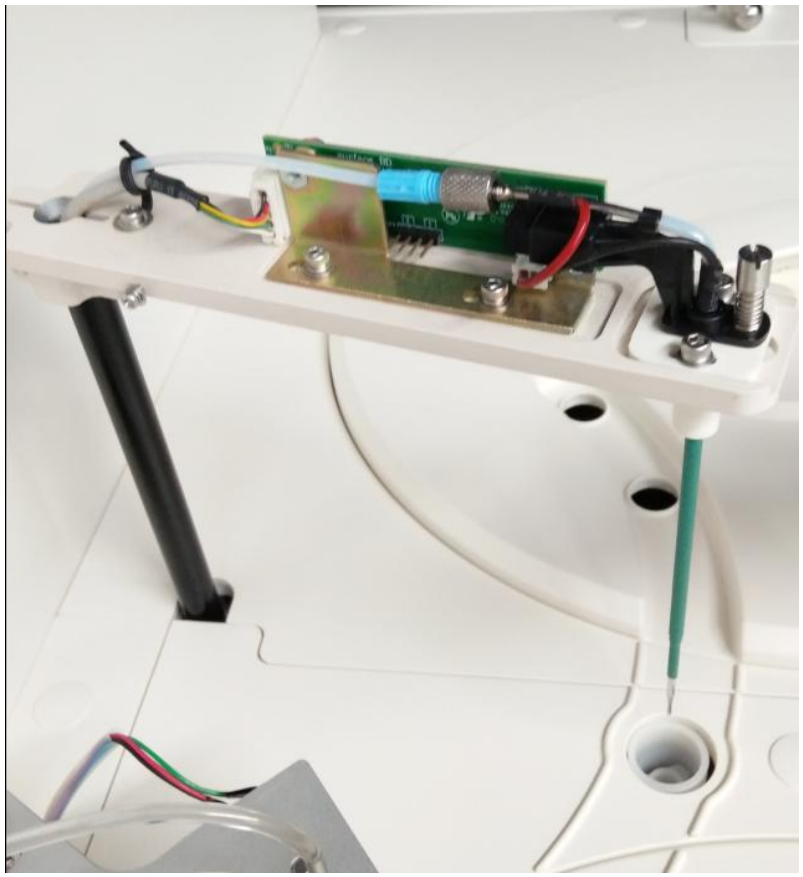


Figure 9.6.3-5 install reagent probe

Note

1) The pipe should insert well, otherwise will cause leakage so that to damage the electric board.
2) If there is damage on the pipe, cut off a little if necessary.
3) Attention the spring cannot take the probe, otherwise will cause the an-collision function failure. The cover should be tightening to make sure the gap sealing.

10) Take the probe softly and cover well, screw tightly two screws.
11) Turn on test power.
12) Start software, click Service then probe, stirrer clean and execute button, click reset at last. To check the probe position to the washing pool, the position should the same as step 2. If the position deviation is too big, please contact URIT

9.6.4 Replace the light source lamp

The light source lamp's filament position has a great impact on the optical performance of the instrument optical path, if the light source lamp damaged or exceed the rated life (2000 hours), then

the light source lamp must be replaced.

Warning

1) Light source lamp can only be replaced by URIT authorized personnel, if you need to replace the light source lamp, please contact URIT.
2) Before replace the optical system's light source lamp, please disconnect the analyzer host main power, and wait at least 15 minutes until the light source to cool. Before the light source cooling, please do not touch, it may cause burns.

9.7 Preventive Maintenance

Check the instrument periodically to ensure the stability of instrument. We suggest doing preventive maintenance for the instrument. That includes the following maintenance.

1) Daily and periodical check the instrument.

2) Maintain or replace the components periodically which are long-term use and easy to damage.

3) Be sure the store is enough, such as detergent, distilled water, etc.

4) Improve the operating condition. Such as the temperature, humidity, water quality, powder and air, etc.

9.8 Maintenance for long-term shutdown

If the instrument is plan to not used exceed two days (not include two days) or plan to use after shut down for a long time, do the following steps before power on.

1) Empty the distill water bucket, waste solution bucket and detergent bucket and clean them. And drain off the water in the pipe. According to your needs to determine whether drain off the anti-freeze fluid or not.
2) Clean the distilled water bucket and detergent bucket before using the instrument. Inject the fresh distill water and detergent to the bucket.
3) Click **Service** to clean the pipe and cuvette two times at least.

CHAPTER 10 STORAGE AND TRANSPORTATION

10.1 Storage

The wrapped instrument should be stored at a ventilated room, with temperature range from -40℃ to 55℃, ambient humidity not exceeding 95%, atmospheric pressure is 75kPa to 106kPa. DO NOT store the instrument along with any poison or corrosive.

The instrument stored for over one year may fall short of the precision of measurement. Therefore, it is suggested to perform mechanical calibration and alignment procedure when using the instrument.

Note

Please contact URIT to perform calibration for mechanism of the instrument.

10.2 Transportation

After the analyzer put into packing container, you may choose any way to transport it, but it cannot be inverted, and during the transportation should be moisture proof, sun block and anti-collision. Do not ship the analyzer with any poison or corrosive.

Note

The instrument can be transport when the packing is good. The transport temperature range from -40℃ to 55℃, ambient humidity not exceeding 95%, atmospheric pressure is 75kPa to 106kPa.

CHAPTER 11 WARNING AND FAULT TREATMENT

This chapter relates the methods to find and exclude faults of instrument. If the faults still exist after following the instructions in this chapter or you need more and detailed information, please contact URIT.

This chapter lists the common faults of instrument, along with treatment. When the instrument is broken down, user can find out the cause of faults based on the warning information sent by instrument, and then operate according to the fault treatment list.

11.1 Fault treatment

Fault treatment is mainly used to help users to find and exclude fault of instrument. And it offers the method about how to get technical support and help from URIT in time. The skills of treatment are accumulated from the in-depth knowledge about the instrument and the experience in the using process.

User should read through this operating manual and be familiar with the normal operation and preventive maintenance of analyzer.

In general, there are three steps to treat faults:

1) Confirming fault

2) Classifying fault

3) Eliminating fault

Step 1: Confirming fault

Users should not only confirm the fault, but also clearly know what the normal status should be when the fault is eliminated.

Step 2: Classifying fault

Faults can be categorized into three types.

- Fault relating to hardware.
- Fault relating to software.
- Test fault relating to sample analysis.

The fault relates to hardware or software can only be maintained by URIT or qualified engineer

authorized by URIT. Test fault relates to sample analysis can be eliminated under the instruction of engineer of URIT.

Step 3: Eliminating fault

The maintenance engineer authorized by URIT takes proper measures to eliminate the fault.

If users are able to eliminate the fault by themselves or under the directions of maintenance engineer, it will save a lot of time.

11.2 Obtaining Technical Help

When the instrument is broken down, please contact URIT if you need technical support. But you should provide the following detailed and clear description about the fault and related information:

1) The instrument model;
2) The serial number of instrument;
3) The detailed and clear description of fault symptom and operating condition (such as the operating interface and status, etc.);
4) The data and report relating to the fault.

This chapter lists the common fault of instrument, along with treatment. When the instrument is broken down, user can find out the cause of fault based on the warning information.

11.3 Common fault treatment

The troubleshooting table below presents the various problems and malfunctions that may occur during operation. If the problem cannot be solved through the recommended methods, contact URIT please.

NOTE

For replacing parts of the instrument, refer to Appendix A.

Table 11.3 Troubleshooting

SN	PHENOMENON	POSSIBLE CAUSE	Treatment
1	Instrument is not active when power is on.	1) Incorrect connection with power cord. 2) No electricity with power receptacle. 3) The safety fuse is fusing 4) Improper COM interface is selected. 5) Communication cable error.	1) Connect power cord correctly. 2) Check if the power receptacle is in good condition. 3) Replace fuse(8A) 4) Confirm select the correct connector at [service→ customization → communication setup] 5) Make sure the RS232 communication cable is connected to PC correctly.
2	Cuvette blank error	Cuvette dirty or damage Light source aging	1) Select [Service → Maintenance → Cuvette rinse], Check if reaction cuvettes are dirty or damage. Replace them if necessary 2) Replace light source.
3	Lamp is dark	1) Bad contact of lamp holder. 2) Lamp is burned out.	1) Check or replace the lamp holder 2) Replace the lamp. 3) If the problem persists, contact your local distributor or URIT.
4	Water or detergent does not come out through the probe washing pool or stirrer washing pool	1) Flow path tube is leaky. 2) Flow path tube is clogged. 3) Water or detergent is used up.	1) Reconnect the tube or replace it. 2) Unclog the tube. 3) Replenish water or detergent.

5	Inaccurate aspirated volume of reagent or sample.	1) Air leaks in the flow paths. 2) Air bubbles are formed in meter regulator. 3) Probe is clogged. 4) Magnetic valve problem	1) Check flow path tubes. Reconnect or replace tubes if necessary. 2) Reconnect meter regulator. Eject air bubbles. 3) Unclog or replace probe. 4) Check magnetic valve and replace it if necessary.
6	Adding or draining water is abnormal	1) Flow path tube is leaky. 2) Flow path tube is clogged. 3) Vacuum pump error.	1) Reconnect the tube or replace it. 2) Unclog the tube. 3) Check the vacuum pump and replace it if necessary.
7	A certain movable part is out of control	Light coupling is short circuited or broken.	Check the wire of light coupling or replace the light coupling.
8	Liquid level sensor is out of order	1) Liquid level sensor board is defective. 2) Bad contact with liquid level sensor board. 3) Liquid level sensor power cord is damage.	1) Check the liquid level sensor board and replace it if necessary. 2) Reconnect the liquid level sensor board. 3) Replace the liquid level sensor power cord.
9	Inaccurate test result or poor repeatability.	1) Cuvette is dirty or breakage. 2) Inaccurate aspirated volume of reagent or sample. 3) Lamp is deteriorated. 4) Parameters of analytical item are set improperly. 5) Ground wire is absent with power supply.	1) Select Service → maintenance → cuvette signal to check whether cuvette is dirty. Clean or replace the cuvette. 2) Check sample injector and tube whether leakage existed. 3) Replace the lamp. 4) Set the parameter follows the operation manual. Make sure the instrument is well grounded by means of the ground pole.

		6) Reagent problem.	5) Check if the reagent is certified. Perform recalibration.
10	Stirrer does not work.	1) Stirrer motor is broken. 2) Bad contact of stirrer circuit. 3) Stirrer power cord is damage.	1) Replace the stirrer motor. 2) Reinstall the stirrer motor. 3) Replace the stirrer power cord.
11	Abnormal motor movement	1) Communication error. 2) Mechanical parts are loose or stuck. 3) Light coupling joint of motor is loose. 4) 4) Light coupling is defective.	1) Turn the instrument off, slowly rotate the sample adding probe and sample tray, check whether the rotation is all right. 2) Open the instrument; enter service → maintenance → mechanism adjustment to adjust parameter. (Only accessible to professional person authorized by URIT). 3) Check the light coupling and replace it if necessary.
12	Water leaks from nozzles of cuvette cleaner.	1) Flow path tube is leaky. 2) Magnetic valve problem. 3) Vacuum pump problem.	1) Check the flow path tube. Reconnect or replace the tube if necessary. 2) Check the magnetic valve and replace it if necessary. 3) Check the vacuum pump and replace it if necessary.
13	Water drops adhere to the tip of probe.	1) Flow path tube is leaky. 2) Magnetic valve problem. 3) 3) The exterior of probe is dirty or scathed.	1) Check the flow path tube. Reconnect or replace the tube if necessary. 2) Check the magnetic valve and replace it if necessary. 3) Check the exterior of probe. Clean

			or replace the probe if necessary.
14	Reagent tray cannot be cooled.	The cooling system is failed or cooling temperature is not low enough.	1) Check if the reagent tray is sealed completely. 2) Check if the heat dissipation device works normally. 3) Check if the refrigerants are used up. 4) Check if the circulation system of the cooling device works normally. 5) Replace the peltier.
15	Instrument alarm sound	1) Waste full 2) Inadequate distilled water 3) Inadequate detergent	1) Empty the waste solution barrel 2) Add distilled water 3) add detergent
16	Probe and stirrer collision	1) Instrument parameters are set improperly. 2) Human carelessness, such as reagent bottle lid is not opened, operator does not proper operation. 3) Put foreign objects on the operation panel. 4) Motor problem. 5) Light coupling error. 6) Mechanism or belt is loose.	1) Enter service → maintenance → mechanism adjustment to adjust parameter. (Only accessible to professional person authorized by URIT). 2) Read through the Operating Manual and avoid human mistake. 3) Do not put foreign objects on the operation panel. 4) Check if the motor is installed and works properly. 5) Check the light coupling and replace it if necessary. 6) Lock screw or readjust the degree of tightness for belt.

11.4 Test result data alarm

Data alarm: Mark the abnormal test results and its possible cause. And then for you make the further judge according to the mark information. Data alarm is not necessarily malfunction, but it will affect the test results. Therefore, we need to pay special attention to. Detailed result mark shown in the following table:

Table 11-4 Test result data alarm

Mark	Description	Possible cause	Solution
Lack of R1	Alarm item's first reagent is insufficient	Alarm item's first reagent is insufficient which cannot perform the normal test	Please timely replenish the first reagent, and then retest this alarm item
Exceed linear range	Alarm item's result is beyond the scope of reagent linear	When alarm item's result is beyond the scope of reagent linear, then the test result is abnormal value	Perform the pre-dilution test for this item again
R1 position interference	The alarm item's first reagent sampling abnormal, unable to normal adding sample	The alarm item's first reagent sampling has been interfered, unable to normal adding sample	1) Check to make sure that the first reagent bottle is in the same level as other reagent bottles; 2) Check whether the first reagent sample adding probe is too sensitive, check whether the current environment humidity is too big; 3) Retest the alarm item.
Lack of sample	Alarm item's sample volume is insufficient	Alarm item	Please timely replenish the sample, and then retest this alarm item
S position interference	Alarm item's sample volume is insufficient	Alarm item's sample volume is insufficient which cannot perform the normal test	Please timely replenish the sample, and then retest this alarm item
Lack of R2	Alarm item's second	Alarm item's second reagent is insufficient	Please timely replenish the second reagent, and then retest

	reagent is insufficient	which cannot perform the normal test	this alarm item
R2 position interference	The alarm item's first reagent sampling abnormal, unable to normal adding sample	The alarm item's first reagent sampling has been interfered, unable to normal adding sample	1) Check to make sure that the first reagent bottle is in the same level as other reagent bottles; 2) Check whether the first reagent sample adding probe is too sensitive, check whether the current environment humidity is too big; 3) Retest the alarm item.
substrate exhaustion	Alarm item appears substrate exhaustion during the test	Alarm item's reaction substrates are almost run out, absorbance increase or decrease exceed the absorbance change range, which makes the monitoring period's absorbance deviate from the linear, makes the determination results become unreliable, for more information, please refer to chapter 7.2.1	Perform the pre-dilution test for this item again
Lack of dilution	Diluent is insufficient which affect the pre-dilution operation	Diluent has not been timely replenished	Please timely replenish the diluent
Time out	Alarm item test was not completed before cleaning	Alarm item measurement point is too long or incubation time is too long, not to reach the monitoring period or monitoring period is not over yet before cleaning, cause	1) Adjust the incubation time to advance the monitoring period 2) Adjust the measurement point to make the monitoring period become shorter.

		the software still calculating	
dilution position interference	Abnormal dilution sample absorption cannot perform normal pre-dilution.	Alarm item cannot perform the normal dilution sampling.	1) Check to make sure that diluent bottle is in the same level as other reagent bottles; 2) Check whether the first reagent sample adding probe is too sensitive, check whether the current environment humidity is too big; 3) Retest the alarm item.
Exceed calibration range	Alarm item's result is beyond the scope of calibration value	For nonlinear calibration item, if the results beyond the scope of calibration value which cannot be guaranteed. (calibration problem), so the alarm is given	1) Trust this results; 2) According to the situation analysis whether the sample item needs to do pre-dilution test.
Exceed factor range	Only appeared in the calibration test results, and the result is beyond the scope of a given factor, the calibration factor may be abnormal.	One point calibration item needs to set the calibration factor range, in order to avoid test results abnormal which caused by abnormal factor	1) Re-calibration; 2) Check to see if the calibration solution has been expired or invalid.

APPENDIX A REPLACEABLE COMPONENTS

SN	Name	Remark
1	Fuse	T6.3AL 250V
2	Reaction Cuvette	Replacing the cuvettes every 6 months or by needs
3	lamp	Replace it after use for 2000hours or system prompt to replace.
4	Sample cup	Single use
5	Reagent bottle	Original matching reagent, give up the bottle after use up
6	Distilled water filter	Replace every 6 months
7	Head of filter	Replace every 1 year
8	One-way valve	Replace every 2 years
9	Pipes of whole instrument	Replace every 3 years
10	Gear of reaction tray	Replace every 3 years
11	Timing belt	Replace every 5 years
12	Probes	Sample probe, reagent probe; replacing when it is damaged or bend
13	Step Motor	Replacing after 8000 hours' use
14	fan	Replace after 20,000 hours' use, clean the dust every 3 months
15	Pump of waste solution	The lifetime of pump is 8000 hours Replace period of diaphragm and seal components is 1000 hours.
16	Detergent injecting pump	The lifetime of motor is 2500 hours Replace period of diaphragm and seal components is 1000 hours
17	Solenoid Valve	Replacing when it is failure
Main Replaceable Optional Accessories		
18	K electrode（optional）	
19	Li electrode（optional）	
20	Na electrode（optional）	
21	Cl electrode（optional）	
22	Reference electrode（optional）	
23	Isolation electrode（optional）	

NOTE

Please use the components provided by URIT for instrument maintenance and replacement. And the components should be replaced by service personnel who are authorized by URIT.URIT will not be responsible for any consequences resulting from using components or accessories not specified by URIT.

NOTE

The above list is just for reference. URIT possesses the right of final explanation about the specific replaceable components.

APPENDIX B ACCESSORIES LIST

No.	Name	Quantity	Remark
1	Protective tube	4	T6.3AL 250V,Replacing when it is failure
2	Power line	1	Replacing when it is failure
3	Network line	1	3m, Replacing when it is failure
4	Reagent bottle	80	30 × 20mL and 30 × 40ml, Replacing when it is failure
5	Reagent bottle cap	80	Replacing when it is failure
6	Sample cup	800	Replacing when it is failure
7	Distilled water bucket component	1	20L, distilled water bucket which need to regularly maintain, and replacing when it need, please refer chapter 9.3.1 to replace and maintain.
8	Waste solution bucket component	1	20L, waste solution bucket which need to regularly maintain, and replacing when it need, please refer chapter 9.3.3 to replace and maintain.
9	Detergent bucket component	1	5L, detergent bucket which need to regularly maintain, and replacing when it need, please refer chapter 9.3.2 to replace and maintain.
10	Distilled water tube	1	2m（silicone tube 6.4×9.6）with female connector, which need to use the specified distilled water tube to replace when it need.
11	Waste solution tube	2	2m（silicone tube 6.4×9.6）with female connector, which need to use the specified waste solution tube to replace when it need.
12	Water draining tube	2	0.8m, which need to use the specified water draining tube to replace when it need.
13	Detergent tube	/	2m（ND100-65 6.4×9.6）, which need to use the specified detergent tube to replace when it need.
14	Clamp	2	Replacing when it is failure
15	Socket head wrench	4	φ1.5, φ2, φ2.5, φ3 and φ4 one each, replacing when it is failure
16	Screw driver	2	No.3 and No.4 one each, replacing when it is failure
17	Needle detector	1	Replacing when it is failure
18	Color mark pen	1	Replacing when it is failure
19	Socket	1	Replacing when it is failure

20	Sample probe	1	Sample probe which need to regularly maintain, and replacing when it is damaged or bend, please refer chapter 9.6.2 to replace and maintain.
21	Reagent probe	1	Reagent probe which need to regularly maintain, and replacing when it is damaged or bend, please refer chapter 9.6.3 to replace and maintain.
22	stirrer	1	Replace when it is bend of damage
23	Reaction tray cover	1	Replacing when it is failure
24	Reagent sample tray cover	1	Replacing when it is failure
25	Computer	1	Optional
26	Printer	1	Optional

Appendix C Biochemical test items list

The biochemical test items are as follows for reference.

No.	Type	Item	Name
1	Liver function	ALT	Alanine aminotransferase
2		AST	Aspartate amino transferase
3		TP	Total protein
4		ALB	albumin
5		TB	Total Bilirubin
6		DB	Bilirubin direct
7		ALP	Alkaline phosphaatase
8		GGT	Glutamyltransferase
9		TBA	Total bile acid
10		CHE	Cholinesterase
11		PA	Prealbumin,
12		ADA	Adenosine deaminase
13	Renal Function	UREA	Urea
14		CRE	Creatinine
15		UA	Uric Acid
16		β2-MG	β 2-microglobulin
17		MALB	Micro albumin
18		Cys-c	Cystatin c
19		CO2	Carbon dioxide
20		CSF/UTP	Cerebro-Spinal Fluid Total urine protein
21	Lipids and lipoproteins	TG	Triglyceride
22		CHOL	Cholesterin
23		HDL_C	High-density cholesterol
24		LDL_C	Low-density cholesterol
25		APOA_1	Serum apolipoprotein A1
26		APOB	Serum apolipoprotein B
27		HCRP	Hypersensitive C-reactive protein
28		Lp(a)	Lipoprotein(a)
29	sugar	Glu	Glucose
30	Myocardial enzyme	CK	Creatine Kinase
31		CK_MB	Creatine kinase-MB isoenzyme
32		HBDH	Hydroxybutyrate dehydrogenase
33		LDH	Lactate dehydrogenase

34		LDH1	Lactate dehydrogenase isoenzyme 1
35	Rheumatism	ASO	Anti-Streptolysin O
36		RF	Rheumatoid factor
37		CRP	C-reactive protein
38	Immunoglobulin and complement	IgG	Immunoglobulin G
39		IgA	Immunoglobulin A
40		IgM	Immunoglobulin M
41		C3	Complement component 3
42		C4	Complement component 4
43	Pancreatic	AMY	Amylase
44		LPS	Lipase
45		PAMY	Pancreatic amylase
46	Ionic	Fe	Ferrum
47		Ca	Calcium
48		Mg	Magnesium
49		P	Phosphor
50	Special protein	TF	Transferrin